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DESCRIPTION WO2019080995A1

[0001]

13 TITLE

[0002]

17 BREAST PUMP

[0003]

21 TECHNICAL FIELD

[0004]

25 The present invention relates to a breast pump for pumping out human breast milk as well as a breast cap, a milk collection container and a method for operating a breast pump.

[0005]

30 STATE OF THE ART Devices for pumping out human breast milk are well known.

31 Basically there are two different types: the first are operated manually, i.e. the negative pressure required for pumping out is generated by manually operating the vacuum pump.

33 In the second types, the vacuum pump is electrically operated.

34 These vacuum pumps are connected to a breast shield either directly or via a vacuum line.

35 The breast shield has an interior to accommodate the mother's breast or her nipple. The negative pressure is transferred to the interior via a first line, the pumped milk flows via a second line into a milk collection container.

[0006]

41 WO 2016/014494 AI and WO 2016/014469 AI describe a compact breast pump in which pumped milk is transported into a milk collection container under positive pressure.

43 For this purpose, for example, a milk pipe is cyclically squeezed. WO 201 1/035447 AI discloses a breast pump in which the vacuum line simultaneously forms the milk line. The pumping chamber, in which the negative pressure is generated, fills with milk during pumping, so that the pumping system changes from a pneumatic system to a hydraulic system and the milk that has already been pumped out becomes the working fluid. So that the pump chamber can fill with milk, a valve is arranged at the outlet of the pump chamber, which leads to the milk collecting container. This valve only opens at a certain pressure within the pump chamber, i.e. when the pump chamber is sufficiently filled with milk.

[0007]

54 This combined pneumatic and hydraulic pump has several advantages.

55 The system has no or almost no dead volume. The pumping unit can be minimized because once the system has been filled with milk, only a low pumping power is required to pump out more milk. In particular, batteries with a lower capacity can be used than with pneumatic vacuum pumps. The vacuum pump can therefore be made more cost-effective and smaller. The breast pump is particularly suitable for so-called “hands-free” applications in which the breast pump is worn on the body and no hands are needed to hold the breast shield. Due to the minimized dead volume, the applied pressure is also easier to control. This means that individually optimized pumping parameters can be selected for each mother.

[0008]

66 A breast pump is also described in WO 2013/049944 A2, which changes from a pneumatic to a hydraulic pump system.

68 There is a pressure sensor in the pump chamber, which includes a flag attached to a flexible membrane.

[0009]

73 PRESENTATION OF THE INVENTION

[0010]

77 It is therefore an object of the invention to optimize the breast pump mentioned above.

[0011]

81 This task is solved by a breast pump according to claims 1, 8, 35, 36, 39 and 42, a milk collection container according to claim 41, a breast shield according to claim 43 and a method with the features of claim 44.

[0012]

87 In a preferred embodiment, the breast pump according to the invention for pumping out human breast milk has a housing with a drive unit, a pump chamber with a flexible pump membrane driven by the drive unit to generate a vacuum and a breast shield with an interior for receiving a mother's breast.

91 The interior can be subjected to a cyclically changing negative pressure by means of the pump chamber, with a milk channel leading from the interior through a first inlet opening into the pump chamber, with pumped milk flowing from the interior of the breast shield through the milk channel into the pump chamber, and with the pump chamber having an outlet opening , through which the pumped milk flows from the pump chamber into a milk collecting container.

96 A multi-part hygiene module is present, the hygiene module having a first part with a flow opening for connection to the interior, a valve body with at least one valve and a second part with a rigid shell to form the pump chamber, the valve body between the first and second parts is arranged and wherein the hygiene module as a whole can be sealingly and releasably connected to the housing of the breast pump.

[0013]

104 This hygiene module has a compact design.

105 It is easy to assemble and disassemble, making it easy to clean the relevant parts of the breast pump.

107 The use of a valve body in the hygiene module makes manufacturing, assembly and cleaning even easier.

[0014]

112 The rigid shell preferably has a milk path which extends from the pump chamber into a milk collecting container and which runs at least over a partial area perpendicular to a drive axis of the pump membrane.

115 The milk path preferably runs in a plane perpendicular to the drive axis, the milk path in this plane extending over at least half of the height of the pump chamber, preferably over the entire height of the pump chamber.

118 The course of this milk path makes it possible to at least partially, preferably completely fill the pumping chamber with pumped milk, so that during pumping there is a change from a pneumatic pumping system to a mixed or even completely hydraulic pumping system.

[0015]

124 Preferably, the valve body has at least one flow valve and one ventilation valve.

125 Preferably, the valve body is formed in one piece from a flexible material. This makes manufacturing, assembly and cleaning easier.

[0016]

130 Preferably the first part is a component of the breast shield.

131 This means that the breast pump can be made compact and the hygiene module can be easily attached to the breast pump without the breast shield also having to be installed.

[0017]

136 The breast shield preferably has a flange for a detachable connection to the housing.

[0018]

140 The connection to the housing can be established in a particularly simple manner if it is positive and non-positive, preferably a bayonet lock.

142 In a further preferred embodiment, the breast pump according to the invention for pumping out human breast milk has a breast shield with an interior for receiving a mother's breast and a pump chamber, the interior being able to be subjected to a cyclically changing negative pressure by means of the pump chamber.

146 A milk channel leads from the interior through a first inlet opening into the pump chamber, through which pumped milk flows from the interior of the breast shield into the pump chamber. The pump chamber has an outlet opening through which the pumped milk flows from the pump chamber into a milk collecting container. When the breast pump is in the vertical position of use, the outlet opening is arranged in an upper region of the pumping chamber and/or above the inlet opening, at least at the beginning of a pumping process.

[0019]

155 This means that the pump chamber can be almost completely filled with milk and the system can be converted from a pneumatic to a hydraulic or mixed pneumatic/hydraulic system within a very short time.

158 The same drive power for the pumping means, e.g. B. the pump membrane, leads to a greater pump performance, i.e. to a higher negative pressure in the pump chamber and thus in the interior of the breast shield. Batteries with a lower capacity can be used. This reduces manufacturing costs, increases the overall service life of the pump and minimizes the size of the drive unit.

[0020]

166 The milk channel preferably forms a vacuum channel for applying the cyclically changing negative pressure to the interior of the breast shield.

168 This means that the vacuum is first applied via the same line or channel and the milk is then sucked out. The same line or channel is used for both working fluids, i.e. Air and milk, used.

[0021]

173 Depending on the embodiment, the pump is a piston pump, a diaphragm pump or another type of vacuum pump.

175 Preferably, however, the pump chamber has a rigid first shell and a flexible pump membrane, wherein the pump membrane lies sealingly against the first shell and wherein the pump membrane is driven and by its movement relative to the first shell a negative pressure can be generated in the pump chamber. A flexible media separation membrane is preferably arranged between the rigid shell and the flexible pump membrane, so that the pump membrane is protected from contact with pumped milk. Milk and air that are present in the breast shield only reach the media separation membrane. The pump membrane and the other parts of the breast pump are therefore protected from contamination.

[0022]

186 The media separation membrane can be easily separated from the pump membrane.

187 It is preferably part of the hygiene module already mentioned. The media separation membrane can preferably be separated from the remaining parts of the hygiene module and thus cleaned in a simple manner. The remaining parts of the hygiene module can also be separated from one another as necessary so that they can be cleaned and then put back together in a simple manner and preferably without tools and used again.

[0023]

195 The first shell preferably has an outlet channel which extends from the outlet opening of the pump chamber to an outlet, the outlet channel extending at least over a partial area in a direction perpendicular to the direction of movement of the pump membrane.

198 It preferably runs in a plane perpendicular to this direction of movement, with the channel preferably extending over at least half the height of the pump chamber, preferably over the entire pump chamber.

[0024]

204 In other embodiments, the channel is partially or completely designed as a closed channel.

205 Preferably, however, the pump membrane or, if present, the media separation membrane

closes the outlet channel of the rigid first shell to form a channel that is closed except for the release opening and the outlet.

[0025]

211 The trough preferably extends adjacent to the pump chamber and not within it.

[0026]

215 In a preferred embodiment, the breast shield has a first passage opening, which forms part of the milk canal, the passage opening being arranged in an upper region of the interior when the breast shield is in the position of use, at least at the beginning of the pumping process, so that the interior below the first passage opening with pumped milk Milk can be filled.

[0027]

222 This allows the breast shield to be partially or completely filled with milk at the start of the pumping process.

224 This massively shortens the time until switching to the hydraulic pump system.

225 Usually, the interior of the breast shield is filled first and then the pump chamber before the milk reaches the milk collection container for the first time.

[0028]

230 Preferably, the milk channel can be closed by means of a first valve in order to remove the pumped milk from the pumping chamber at the end of the pumping process.

232 This valve is preferably the same valve that opens and closes automatically when the milk is pumped out.

234 It is now permanently closed for emptying. Depending on the embodiment, the closure takes place manually or automatically, e.g. B. using the electronic control of the breast pump. If a valve is arranged subsequently, the first valve can always be open during the pumping process.

[0029]

241 Preferably, there is an emptying channel between the interior of the breast shield and the pump chamber, which runs separately from the milk canal, the emptying channel being closable by means of a second valve.

244 The emptying channel is closed during the pumping process and is open at the end of the pumping process. Depending on the embodiment, this is also done manually or automatically. The second valve preferably functions in the same or similar way as the first valve. It is preferably designed identically. It opens and closes during the pumping process when

emptying the breast shield in the same way as the first valve when pumping breast milk from the mother's breast. If a valve is arranged subsequently, the second valve can always be open during the emptying process.

[0030]

254 Preferably there is also a ventilation valve for ventilating the interior of the breast shield.

255 This is also preferably always closed during the pumping process and is opened manually or automatically to make emptying the breast shield easier.

[0031]

260 Preferably, the ventilation valve can be closed together with the second valve and can be opened together with it.

[0032]

265 In a preferred embodiment, a third valve is present which maintains a basic negative pressure when the cyclically changing negative pressure in the interior of the breast shield increases.

267 The pressure in the interior of the breast shield is therefore below atmospheric pressure throughout the entire pumping process and preferably also during emptying.

269 This reduces the strain on the nipple and has a positive effect on the flow of milk from the mother's breast.

[0033]

274 There is preferably a fourth valve in the milk channel, which opens and closes in accordance with the negative pressure applied.

276 This fourth valve is arranged downstream of the first valve in the direction of pumping out the milk. However, the fourth valve can also be formed by the first valve, as already described above. However, if it is downstream, it can be designed, for example, as a flutter valve in the valve body.

[0034]

283 Preferably, there is a fifth valve in the emptying channel, which opens and closes in accordance with the negative pressure applied.

285 This fifth valve is arranged downstream of the second valve in the direction of emptying the milk. The fifth valve can be formed by the second valve as described above. If it is downstream, it can be, for example, a flutter valve in the valve body.

[0035]

291 Preferably at least one part, preferably all of the valves mentioned are arranged in a common valve body.

293 This makes manufacturing easier and minimizes costs.

[0036]

297 The valve body is preferably designed in one piece and flexible.

298 It is preferably made of silicone.

[0037]

302 The breast pump preferably has a pump housing with a drive for the pump membrane, the rigid first shell being detachably connected to the pump housing.

304 This makes assembly easier, even after cleaning by the mother.

[0038]

308 Preferably, the first rigid shell is part of a multi-part module which can be connected together to the pump housing, the module further having at least the valves mentioned.

310 This module is preferably the hygiene module mentioned above.

[0039]

314 Preferably, the first rigid shell is part of an adapter part, with the valve body being held in a receptacle of the adapter part.

316 This makes assembly easier and, in particular, enables a modular structure and the use of a hygiene module.

[0040]

321 Preferably, the module further comprises a manual actuation means for simultaneously actuating the first and second valves.

323 Manually operating the two valves is a cost-effective and reliable solution. Preferably, the adapter part and the actuating part cannot be detached from one another in a non-destructive manner. This ensures that the module is always put together correctly and can only be used together with all elements. Preferably, the breast pump has a pump housing, wherein the breast shield can be releasably attached to the pump housing and by attaching the breast shield to the pump housing, parts which lie between the breast shield and the pump housing are sealingly connected to one another, so that a tight connection between the pump chamber and the interior of the breast shield arises. The breast shield is easy to hold by hand, making it easier to assemble the pump. Since the remaining parts also fit tightly due to the attachment of

the breast shield to the pump housing, the breast pump is ready for use with a single movement, namely the attachment of the breast shield to the pump housing.

334 The individual parts can be removed just as easily for cleaning. Preferably the breast shield and the valve body are part of the module.

[0041]

339 The breast pump preferably has a pump housing to which the breast shield can be releasably attached, the breast pump further having a milk collecting container which can be attached to the pump housing by means of a snap lock.

342 Fastening the milk collection container using a snap lock is unconventional. Twist locks are usually used. Thanks to the snap closure, the container can be designed differently and, in particular, can be attached and removed more quickly.

[0042]

348 The milk collecting container preferably has a base body and a lid, the lid being at least partially air-permeable and liquid-impermeable.

350 This lid thus forms a valve which is used for ventilation, but which also allows the container to be turned upside down without loss of liquid. The lid preferably has an air-permeable and liquid-impermeable membrane. Preferably, the lid is clamped between the milk collection container and the pump and can be positioned using spacer pins. In addition, the lid is preferably provided with a one-way valve, which leads from the pump chamber into the milk collecting container.

[0043]

359 In a preferred embodiment, the breast pump for pumping out human breast milk has a breast shield with an interior for receiving a mother's breast and a pump chamber, wherein the interior can be subjected to a cyclically changing negative pressure by means of the pump chamber.

362 A milk channel leads from the interior through a first inlet opening into the pump chamber, through which pumped milk flows from the interior of the breast shield into the pump chamber. The pump chamber has an outlet opening through which the pumped milk flows from the pump chamber into a milk collecting container. An emptying channel is present between the interior of the breast shield and the pumping chamber, which runs separately from the milk canal, the emptying channel being closable by means of a valve, the emptying channel being closed during the pumping process and being open at the end of the pumping process. This makes it easy to remove milk from the breast shield at the end of the pumping process. The emptying channel is preferably subjected to a negative pressure by means of the pump chamber in order to actively pump out the milk and force it into the milk collecting container.

[0044]

375 In a preferred embodiment, the breast pump for pumping out human breast milk has a breast shield with an interior for receiving a mother's breast and a pump chamber, wherein the interior can be subjected to a cyclically changing negative pressure by means of the pump chamber.

378 A milk channel leads from the interior through a first inlet opening into the pump chamber, through which pumped milk flows from the interior of the breast shield into the pump chamber. The pump chamber has an outlet opening through which the pumped milk flows from the pump chamber into a milk collecting container. The breast pump has a pump housing, a pump membrane and a module, the module having at least one rigid shell to form the pump chamber and the breast shield. The module can be attached as a unit to the pump housing, creating a tight connection between the pump chamber and the interior of the breast shield and the pump membrane being held sealingly between the module and the pump housing. This makes it easier for the mother to clean the relevant parts of the breast pump and to assemble it after such cleaning.

[0045]

391 The module preferably also has a valve body which is arranged between the breast shield and the rigid shell.

393 The valve body and the corresponding areas of the first and second parts, which preferably have sealing seats for the valves of the valve body, form a common valve unit, also called a valve construct.

[0046]

399 Preferably, the module further has a manual actuation means for actuating at least one valve of the valve construct.

[0047]

404 In a preferred embodiment, the breast pump for pumping out human breast milk has a breast shield for receiving a mother's breast, a pump housing and a milk collecting container, the pump housing being detachably connectable to the breast shield on the one hand and detachably connected to the milk collecting container on the other hand.

408 The milk collection container can be attached to the pump housing using a snap lock.

[0048]

412 This breast pump preferably has a pump chamber and a milk channel through which pumped milk flows from an interior of the breast shield into the pump chamber, the pump chamber having an outlet which is connected to the milk collecting container and through which the pumped milk flows into the milk collecting container.

[0049]

419 In a preferred embodiment, there is a milk collecting container according to the invention for connection to a pump housing of a breast pump for pumping out human breast milk, the milk collecting container having a lid which faces the pump housing and which is permeable to air and impermeable to liquids at least in one area.

[0050]

426 In a preferred embodiment, the breast pump for pumping out human breast milk has a breast shield for receiving a mother's breast and a pump housing, the breast shield being detachably connectable to the pump housing.

429 The breast shield can be connected to the pump housing using a bayonet lock.

430 In a preferred embodiment, a breast shield according to the invention is present, which is used to attach to a pump housing of a breast pump.

432 The breast shield has an interior for receiving the mother's breast and a connector for attachment to the pump housing, the connector being provided with a bayonet lock.

[0051]

437 In a preferred variant of a method according to the invention for operating a breast pump for pumping out human breast milk, the breast pump has a breast shield with an interior for receiving a mother's breast and a pump chamber, the interior being subjected to a cyclically changing negative pressure by means of the pump chamber.

441 In a first pumping phase, the interior is subjected to the cyclically changing negative pressure in order to pump milk from the mother's breast, the interior being filled with pumped milk without any pumped milk flowing out of the interior.

444 In a second pumping phase, pumped milk flows from the interior into the pumping chamber and the pumping chamber is filled with pumped milk. In a third pumping phase, the pumped milk flows from the pump chamber into a milk collecting container, with the interior and the pump chamber remaining filled with pumped milk. The change from the second pumping phase to the third pumping phase occurs when a level of the pumped milk reaches an outlet opening which leads from the pumping chamber to the milk collecting container, whereby milk flows through the outlet opening from the pumping chamber into the milk collecting container.

[0052]

454 Thanks to this process, the pumping system switches relatively quickly from a pneumatic to a hydraulic or predominantly hydraulic pumping system.

456 This means that smaller drives and less powerful motors can be used.

[0053]

460 Preferably, the first pumping phase is a completely or predominantly pneumatic pumping phase and the second pumping phase is a completely or predominantly hydraulic pumping phase.

[0054]

465 In a preferred variant of the method, the interior space is almost completely filled in the first pumping phase.

467 In a preferred variant, the interior and/or the pumping chamber are almost completely filled with pumped milk in the second and/or third pumping phase.

[0055]

472 Preferably, the change from the first pumping phase to the second pumping phase takes place in that a filling level of the pumped milk reaches a first through-opening, which leads from the interior to the pumping chamber, whereby milk flows through the first through-opening from the interior into the pumping chamber.

[0056]

479 In the third pumping phase, the pumped milk preferably flows through the first through opening into the pump chamber and through the outlet opening into the milk collecting container.

[0057]

484 Preferably, in a fourth pumping phase, the interior is emptied and the milk that has already been pumped out is guided from the interior to the milk collecting container through a second through opening.

[0058]

490 Preferably, the first through opening can be closed with a first valve and the second through opening can be closed with a second valve, the second through opening being always closed during the first to third pumping phases.

493 Preferably, the first through opening is always closed during the fourth pumping phase.

[0059]

497 Preferably, the second through opening leads from the interior into the pump chamber and is in fluid communication with the outlet opening via the pump chamber.

[0060]

502 Preferably, a base negative pressure is maintained during at least part of the pumping phases, preferably during the first, second and third pumping phases.

504 Preferably, a third valve is present, which first opens and then closes when the pressure of the cyclically changing negative pressure increases towards atmospheric pressure, thereby maintaining the basic negative pressure.

507 Further embodiments and variants of the method are specified in the dependent claims.

[0061]

511 The individual elements listed in the claims can also be combined to form other combinations without having to adopt all the features of the claims.

513 In particular, individual elements can also be used in purely pneumatic breast pumps, especially in pneumatic membrane breast pumps.

[0062]

518 BRIEF DESCRIPTION OF THE DRAWINGS

[0063]

522 Preferred embodiments of the invention are described below with reference to the drawings, which serve only for explanation and are not to be interpreted in a restrictive manner.

524 Shown in the drawings:

[0064]

528 Figure 1 is a perspective view of a breast pump according to the invention,

[0065]

532 Figure 2 is an exploded view of the breast pump according to Figure 1 in a perspective view;

[0066]

536 Figure 3 is an exploded view of the breast pump according to Figure 1 in a further perspective view; Figure 4 shows a partial section through the breast pump according to Figure 1 in a first perspective view;

[0067]

542 Figure 5 shows a partial section through the breast pump according to Figure 1 in a second perspective view;

[0068]

547 Figure 6 shows a longitudinal section through a hygiene module, attached to a

[0069]

551 Carrier module of the breast pump according to Figure 1 in an exploded view; Figure 7 is a perspective view of the assembled hygiene module according to Figure 6;

[0070]

556 Figure 8a is a perspective view of a breast shield of the breast pump according to

[0071]

560 Figure 1;

[0072]

564 Figure 8b shows a partial section through the breast shield according to Figure 8a;

[0073]

568 Figure 9a is a perspective view through a valve body of the breast pump according to Figure 1;

[0074]

572 Figure 9b shows a partial section through the valve body according to Figure 9a;

[0075]

576 Figure 9c shows a longitudinal section through the valve body according to Figure 9a;

[0076]

580 Figure 9d is a view of the valve body according to Figure 9a;

[0077]

584 Figure 10a is a perspective view of an adjusting ring of the breast pump according to

[0078]
588 Figure 1;

[0079]
592 Figure 10b is a view of the adjusting ring according to Figure 10a;

[0080]
596 Figure I Ia is a perspective view of an adapter part of the breast pump according to

[0081]
600 Figure 1 from a first page;

[0082]
604 Figure 1Ib shows a partial section through the adapter part according to Figure I1a;

[0083]
608 Figure 11c is a perspective view of the adapter part according to Figure I1a from a second side;

[0084]
612 Figure 12a is a perspective view of a media separation membrane

[0085]
616 Breast pump according to Figure 1 from a first side;

[0086]
620 Figure 12b is a perspective view of the media separation membrane according to Figure

[0087]
624 12a from a second page;

[0088]

628 Figure 12c shows a longitudinal section through the media separation membrane according to Figure 12a; Figure 13a is a perspective view of a pump membrane of the breast pump according to Figure 1 from a first side;

[0089]

634 Figure 13b is a perspective view of the pump membrane according to Figure 13a from a second side; Figure 13c shows a longitudinal section through the pump membrane according to Figure 13a;

[0090]

640 Figure 14 is a perspective view of a carrier module of the breast pump according to Figure 1;

[0091]

644 Figure 15 is a perspective view of an upper frame part

[0092]

648 Milk collection container of the breast pump according to Figure 1;

[0093]

652 Figure 16 shows a longitudinal section through the upper frame part according to Figure 15 with a

[0094]

657 container valve;

[0095]

661 Figure 17 is a perspective view of a vessel in the milk collection container of the breast pump according to Figure 1; Figure 18 shows a schematic representation of the pump system according to the invention

[0096]

667 applying negative pressure;

[0097]

671 Figure 19a shows the pump system shown schematically according to Figure 1 in the

[0098]

675 Activation of the mother's breast in a first lifting position;

[0099]

679 Figure 19b shows the pump system according to Figure 19a in a second lifting position;

[0100]

683 Figure 19c is a graphical representation of the pressure within a breast shield

[0101]

687 Change from the first lifting position to the second lifting position according to Figures 19a and 19b; Figure 20a shows the pump system according to Figure 19a at the beginning of the milk flow from the

[0102]

693 chest in a first lifting position;

[0103]

697 Figure 20b shows the pump system according to Figure 20a in a second lifting position;

[0104]

701 Figure 20c is a graphical representation of the pressure within a breast shield

[0105]

705 Change from the first lifting position to the second lifting position according to Figures 20a and 20b;

[0106]

710 Figure 21a shows the pump system according to Figure 19a during the continuous

[0107]

714 milk flow from the breast in a first lifting position; Figure 21b shows the pump system according to Figure 21a in a second lifting position;

[0108]

719 Figure 21c is a graphical representation of the pressure within a breast shield

[0109]

723 Change from the first lifting position to the second lifting position according to

[0110]

727 Figures 21a and 21b;

[0111]

731 Figure 22a shows the pump system according to Figure 19a when the milk flow ends in a first stroke position;

[0112]

736 Figure 22b shows the pump system according to Figure 22a in a second lifting position;

[0113]

740 Figure 22c is a graphical representation of the pressure within a breast shield

[0114]

744 Change from the first lifting position to the second lifting position according to

[0115]

748 Figures 22a and 22b;

[0116]

752 Figure 23a shows the pump system according to Figure 19a when emptying in a first

[0117]

756 lifting position;

[0118]

760 Figure 23b shows the pump system according to Figure 23a in a second lifting position and Figure 23c shows a graphic representation of the pressure within a breast shield

[0119]

765 Change from the first lifting position to the second lifting position according to

[0120]

769 Figures 23a and 23b.

[0121]

773 DESCRIPTION OF PREFERRED EMBODIMENTS

[0122]

777 A preferred embodiment of the breast pump according to the invention is shown in FIGS. 1 to 17.

[0123]

782 The overview of the individual components

[0124]

786 As can be seen in Figure 1, the breast pump has a compact structure.

787 It has a pump housing 8 with a breast shield 2 attached to it and a milk collecting container 9 also attached to the pump housing 8.

789 A motor with a force transmission element, for example a spindle, is arranged in the pump housing 8.

791 The pump housing 8 also contains at least one electronic control for controlling the motor, actuation switch 86 for actuating the pump and an energy storage device.

793 Figures 2 and 3 show an exploded view of this breast pump.

794 It includes the mentioned breast shield 2 for receiving the mother's breast, a valve body 3 made of a flexible material, in particular silicone, an adapter part 4, a two-part adjusting ring 5, a media separation membrane 6, a pump membrane 7, a carrier module 8 ', which is part of the pump housing 8 as well as the already mentioned milk collection container 9.

[0125]

801 The milk collection container

[0126]

805 The milk collecting container 9 can preferably be latched onto the underside of the pump housing 8, preferably it can be releasably attached in a pivoting manner.

807 Corresponding latching elements 901, 902 can be seen in FIG. 17.

808 The pump housing 8 has matching latching elements, but not shown here.

[0127]

812 The milk collecting container 9 has a vessel 90 with an interior 900 for receiving the pumped milk (see Figure 17).

814 This vessel 90 is open at the top and can be closed with a lid.

815 The lid includes a rigid lower frame member 91, a rigid, semi-rigid or flexible cover 92 and a rigid upper frame member 93.

817 The lower frame part 91 corresponds to the shape of the circumference of the opening of the vessel 90 and lies sealingly on it.

819 The rigid upper frame part 93 clamps the cover between the lower and upper frame parts 91, 93.

821 Preferably, the two frame parts 91, 93 are glued together, welded or cannot be separated from one another in a non-destructive manner.

823 The cover 92 is a film or other membrane-like part which is permeable to air but impermeable to liquids.

825 Air can therefore escape from the vessel 90, but no liquid can escape.

[0128]

829 The upper frame part 93 preferably also corresponds in shape to the shape of the vessel 90, in particular its frame 930 corresponds to the shape of the lower frame part 91.

831 It is shown in detail in Figures 15 and 16.

832 In the frame 930 there are 92 struts 931 to reinforce and protect the cover.

833 A handle 933 makes lifting the lid easier.

834 Spacer pins 934, which are arranged on the frame 930 and protrude beyond it, ensure a distance from the pump housing 8 when the milk collecting container 9 is mounted, so that air

can escape from the container interior 900 into the environment.

837 A valve receptacle 932 is formed on the upper frame part 93 and forms the only liquid access into the interior of the vessel 90.

[0129]

842 A container valve 94, which is designed as a one-way valve, is arranged in this valve receptacle 932.

844 This means that when the lid is closed, liquid can only get into the milk collecting container 9, but not out.

846 The container valve 94 is preferably a duckbill valve as shown here.

[0130]

850 The hygiene module

[0131]

854 A hygiene module according to the invention is shown in Figures 6 and 7.

855 It includes at least the connector 23 of the chest tube 2, the valve body 3, the adapter part 4 and the adjusting ring 5.

857 As shown here, it can also include a flexible media separation membrane 6.

858 If the breast shield is made in one piece, it is part of the hygiene module as a whole.

859 The parts mentioned can, as shown in Figures 6 and 7, be put together to form a common assembly and releasably fastened together in the carrier module 8 '.

861 For this purpose, the connector 23 of the breast shield 2 can preferably be fastened in a positive and non-positive manner in corresponding receptacles, here two opposite side arms 80, of the carrier module 8 '.

864 The connection is preferably made via a bayonet lock, as shown here.

865 The connector 23 has a corresponding flange 22, the side arms 80 of the carrier module 8' have corresponding receptacles for the flange and the other elements of the bayonet lock.

[0132]

870 Thanks to the attachment of the breast shield to the carrier module 8 'and thus to the pump housing 8, the parts in between, i.e. the valve body 3, the adapter part 4 and the media separation membrane 6 of the hygiene module as well as the pump membrane 7, are also tightly connected to one another.

[0133]

877 The adjusting ring 5 is preferably not detachably attached to the adapter part 4 in a non-

destructive manner, and can be pivoted relative to the adapter part 4 about the longitudinal central axis of the hygiene module.

880 The individual parts of the device and their interaction are described below.

[0134]

884 The breast shield

[0135]

888 The breast shield 2 is shown in Figures 8a and 8b.

889 It is used to hold the mother's breast.

890 It has a funnel 20 for resting on the mother's breast and an interior 200, which can be subjected to a cyclically changing negative pressure and in which the mother's breast or at least the nipple is received.

893 The breast shield is preferably made in one piece and preferably from a rigid or semi-rigid plastic.

895 However, it can also be made in several parts.

896 It can also be used with a soft liner, e.g.

897 B. with a breast shield insert made of soft silicone.

898 The funnel 20 is followed by a connector 23 with an at least partially circumferential flange 22, which forms part of the bayonet lock mentioned.

900 The interior 200 merges into a through opening 21 on the side of the nozzle 23 facing away from the chest, which forms a channel running in the central longitudinal axis.

902 On the connector 23, on the side of the flange 22 facing away from the chest, there is a recess on two diametrically opposite sides.

[0136]

907 A first outlet opening 24 and an angular first flow opening 25 are present in the first recess.

908 The first outlet opening 24 leads from the interior 200 to the outside of the nozzle 23, more precisely into the first recess.

910 The first flow opening 25 leads from this first recess in a preferably rectangular channel to the free end face of the nozzle 23 facing away from the chest.

912 On the circumference of the nozzle 23 there is a ventilation opening 26 next to the first outlet opening 24, but outside the first recess.

914 This leads from the interior 200 to the outside.

[0137]

918 On the diametrically opposite side of the nozzle 23 there is an analogous second recess with a second outlet opening 27 and a second passage opening 28, which are designed in the same

way as the first openings.

921 Furthermore, a second ventilation opening 29 is also present outside the second recess and next to the second outlet opening 27.

923 This second ventilation opening 29 actually has no function but is closed when the device is used as intended.

925 However, so that the breast shield 2 can also be mounted on the carrier module 8 'in a position rotated by 180 °, all openings are arranged symmetrically.

[0138]

930 The valve body

[0139]

934 Figures 9a to 9d show the valve body 3.

935 The valve body 3 is made of a flexible material, preferably silicone.

936 It is preferably formed in one piece.

937 It has a hollow cylindrical base body 30 with a rear wall 31.

938 There is a through opening 32 centrally in the rear wall.

939 On the side facing away from the chest, the rear wall 31 has a groove 312 which runs annularly around the through opening 32 and forms a sealing surface 310 on the opposite side near the chest.

942 The circumferential edge of the through opening 32 is provided with a circumferential sealing lip 311 on the side facing away from the chest (see Figures 9b and 9c).

944 The area of the rear wall 31 within the circumferential sealing surface 310 thus forms a valve, which, as explained further below, serves as a base vacuum valve.

[0140]

949 The base body 30 has a radially projecting positioning lug 33 on the side facing the chest.

950 A first knob 34 and a ventilation knob 35 are present on the jacket of the base body 3.

951 There is a second knob 36 diametrically opposite.

952 The three knobs protrude radially outwards.

953 The first knob 34 and the second knob 36 are solid, i.e. not hollow.

954 The ventilation knob 35 has a through opening from the interior of the base body 30 to the outside.

[0141]

959 In the annular area of the rear wall 31 between the sealing surface 310 and the jacket of the base body 30, diametrically opposed valve flaps are also present.

961 A first of these valve flaps is provided with the reference number 37, and a second of these

valve flaps is provided with the reference number 38.
963 They are preferably located on the same diagonal as the first and second knobs 34, 36.

[0142]
967 The adjusting ring

[0143]
971 Figures 10a and 10b show the adjusting ring 5.
972 It is preferably stiff and preferably made of plastic.
973 The adjusting ring 5 preferably consists of two parts.
974 A first part 50 has the shape of a half ring and is provided with a first plug part 51 at both free ends.
976 The second part 52 also has the shape of a half ring and is provided with a second plug part 53 at each of its free ends.
978 The first and two parts 50, 52 form a common ring and the two pairs of plug parts 51, 53 are provided with latching elements 54 in order to preferably be permanently connected to one another.
981 On the inner circumference of the ring there is a partially circumferential stop 55 which projects radially inwards and which prevents the adjusting ring 5 from being removed again after assembly on the adapter part 4.
984 A first and a second pressing element 56, 57 are formed on the inner wall of the adjusting ring.
985 These are preferably elevations projecting radially inwards, which merge via an inclined surface, also called a ramp, into a surface running parallel to the inner surface of the ring.
987 An actuating lever 58 which projects towards the outside is formed on the first part 50.

[0144]
991 The adapter part

[0145]
995 Figures I1a to 11c show the adapter part 4.
996 It preferably consists of a rigid material, preferably plastic.
997 It has a hollow cylindrical base body 40 with a substantially closed, flange-like wall 41 on the pump side.
999 The base body 40 has a first window 400 and a diametrically opposite second window 401 in its jacket.
1001 On the end face of the base body 40 near the breast cap there is a positioning aid 402, which forms the counterpart to the positioning base 33 of the valve body 3 and which, together with the positioning nose 33, serves to position the valve body 3 in a rotation-proof manner.

[0146]

1007 The pump-side wall 40 extends in a direction, which is referred to here as downward, into a channel wall 410.

1009 The pump-side wall also has a raised central wall part 42, which projects into the area near the breast shield.

1011 On the opposite side of the wall part 42, i.e. facing the pump housing, a concave surface is formed, which forms the already mentioned rigid shell and is part of the pump chamber 47.

[0147]

1016 A first through opening 43 and a second through opening 44 are present in the pump-side wall 41 between the raised wall part 42 and the jacket of the base body 40.

1018 The two through openings 43, 44 are diametrically opposed to one another.

1019 In this example they are circular.

1020 In the edge area of the raised wall part 42, but already on its elevation, a first backwash opening 45 and a second backwash opening 46 are present.

1022 These are preferably elongated.

1023 These openings all lead into the pump chamber 47.

[0148]

1027 As can be seen in Figure 11c, the concave shell of the pump chamber 47 is surrounded by a circumferential flat edge, which serves as a sealing surface.

1029 A channel 48 runs in this edge, which preferably begins at an uppermost point of the pump chamber 47 and is in fluid-communicating connection with it via an outlet opening 480.

1031 The channel 48 runs along the circumference of the pump chamber 47, here in a part circle, downwards to an outlet 49.

1033 The outlet 49 is located in the channel wall 410.

[0149]

1037 The media separation membrane

[0150]

1041 The media separation membrane 6 is shown in FIGS. 12a to 12c.

1042 It is designed to be flexible, is preferably made in one piece and is preferably made of silicone.

1043 It has a membrane surface 60, which is preferably provided in a known manner with at least one annular groove.

1045 A central region 61 of the membrane surface is preferably raised and faces the adapter part 4.

1046 The edge of the membrane surface 60 is designed as a sealing surface 62 and lies sealingly against the edge of the adapter part 4, whereby the pump chamber 47 is formed.

1048 A channel 63 runs within the sealing surface 62 along the circumference of the media separation membrane 6 and forms the sealing closure of the channel 48 of the adapter part 4.

1051 A recess 64 in the lower region of the media separation membrane 6 facing the pump housing serves as a free space for a pressure sensor, which is described below.

[0151]

1056 The media separation membrane 6 preferably has, as shown in the figures, stiffeners in the form of ribs, which ensure the functionality of the media separation membrane.

1058 This means that the ribs ensure that the membrane moves in the desired manner and still always fits tightly against its neighboring parts.

1060 The pump membrane

[0152]

1064 The pump membrane 7 is shown in FIGS. 13a to 13c.

1065 It also has a membrane surface 70 and a central area 71.

1066 In contrast to the full-surface media separation membrane 6, the central region 71 of the pump membrane 7 is provided with a through opening 72, the edge region of which preferably has a reinforcement 73, here in the form of ribs.

1069 There is again a circumferential sealing surface 74 which, in the assembled state of the device, rests sealingly on the corresponding surface of the carrier module 8 '.

1071 Outside the sealing surface 74 there are side wings 77. When assembled, the side wings 77, together with the circumferential flat sealing surface 74 (FIG. 13b), form a tight barrier against liquids acting from the outside and thus protect the electronics.

[0153]

1077 The lower area of the pump membrane 7, which is still located within the closed circumferential sealing surface 74, is designed as a pressure sensor.

1079 The pressure sensor comprises a sensor surface 75 in the form of a membrane, which is connected to the membrane surface 70 via a connecting web, and a flag 76, which projects vertically from the sensor surface in the direction of the pump housing. This type of pressure sensor is described in WO 2013/049944 AI.

[0154]

1086 As can be seen in the figures, the media separation membrane 6 and the pump membrane 7 have similar shapes, in particular with regard to their movable areas to generate the negative

pressure.

1089 The carrier module

[0155]

1093 The carrier module 8' is shown in Figure 14.

1094 It is held in an outer housing of the pump housing. The outer housing is visible in Figure 1. Preferably, the carrier module 8' is screwed into this outer housing. The corresponding fastening holes are provided with the reference number 84. The carrier module can be made in one piece from plastic. However, it can also be made in several parts and/or from a different material. The carrier module 8 'has two protruding side arms 10 with a bayonet lock for receiving the breast shield 2. The side arms are arranged laterally on a spindle holder 82. The spindle receptacle 82 has a through opening and a circumferential edge 85, which forms the counterpart to the sealing surface 74 of the pump membrane 7. On the spindle holder 82, a motor holder 81 is formed in the form of a shell. The motor holder 81 serves to hold an electric motor, which is connected to a spindle 83 (see Figure 4).

[0156]

1107 How the assembled assembly works

[0157]

1111 Based on Figure 6 you can see how the individual openings and valves interact.

1112 The valve body 3 can be inserted into the hollow cylindrical base body 40 of the adapter part 4 in a rotational position.

1114 The adjusting ring 5 is already permanently connected to the adapter part 4, with the first pressing element 56 protruding inwards through the first window 400 and the second pressing element 57 protruding inwards through the second window 401. The first knob 34 of the valve body 3 is located below the first window 400 and the second knob 36 is above the first window 401. The valve flaps 37, 38 of the valve body 3 are each located above the first and second through openings 43, 44 of the adapter part. The sealing lip 31 1 lies sealingly on the raised wall part 42, with the first and second backwash openings being arranged in a tight annular area between the groove 312 and the sealing lip 31 1.

[0158]

1125 If the breast shield 2 is now inserted, the first knob 34 lies above the first outlet opening 24 and the ventilation knob 35 lies above the first ventilation opening 26.

1127 The second knob 36 lies above the second outlet opening 27. The second ventilation opening 29 is covered by the jacket of the valve body 4 and is therefore closed.

[0159]

1132 If the breast shield 2 is now connected to the carrier module 8 ', the individual connections between the channels and openings described are created and sealed from the outside.

[0160]

1137 In Figures 4 and 5 the breast pump according to the invention is shown in the assembled state.

1139 As can be clearly seen, this system has virtually no dead space.

1140 In Figure 4 the spindle 83 can be seen, which drives the pump membrane 7. The media separation membrane 6 has a shape which hugs the pump membrane 7, so that both membranes 6, 7 move together and no losses occur here either. The pump housing 8, more precisely the carrier module 8', has a rear wall 85, against which the pump membrane 7 lies sealingly when the hygiene module is attached to the carrier module 8'. This can be clearly seen in Figures 4 and 5. The adjusting ring 5 is pivotally arranged within the side arms 80, with the actuating lever 58 also serving as a display element. It moves along a display 87, which is attached to the pump housing 8 and which thus provides the user with information about the position of individual valves and thus indicates the operating status of the pump. This means that it is displayed whether the pump is ready for pumping or is in the emptying state. This is explained below. By turning the adjusting ring 5, individual valves can be opened and closed manually.

1152 More specifically, the first outlet opening 24 can be opened and closed manually together with the first flow opening 25 as an alternative to the second outlet opening 27 together with the second flow opening 28. The first ventilation opening 26 is opened and closed together with the second outlet opening 27 and the second flow opening 28. The second ventilation opening 29 always remains closed due to its position within the valve body 3.

[0161]

1160 If the breast shield 2 is positioned relative to the valve body 3 in such a way that the second openings are at the position of the first openings, the second ventilation opening is of course opened and closed instead of the first.

[0162]

1166 In a first position, which is selected at the beginning of the pumping process and throughout the entire pumping process, the second knob 36 of the valve body 3 is pressed down by the second pressing element 57 of the adjusting ring and lies on the recess and thus the second outlet opening 27 and the second Flow opening 28 of the breast shield 2.

1170 In addition, the ventilation knob 35 is pressed onto the first ventilation opening 26 by the first pressing element 56 and closes it.

1172 The first knob 34 of the valve body 3, on the other hand, is released, so that the first outlet opening 24 and the first flow opening 25 form a fluid-communicating channel from the interior 200 of the breast shield into the base body 30 of the valve body 3. This is best seen in Figures 2, 3 and 6. In a second position, the adjusting ring 5 is rotated. The first pressing element 56 releases the ventilation knob 35 and thus the first ventilation opening 26, but presses the first knob 34 onto the recess and thus closes the first outlet opening 24 and the first flow opening 25. The second pressing element 57 also releases the second knob 36, so that the second outlet opening 27 and the second flow opening 28 now form an open, continuous channel from the interior 200 of the breast shield 2 into the valve body 3. The second outlet opening 27 and the second flow opening 28 form an emptying channel, which will be described in more detail below. The mutual opening and closing preferably takes place at the same time.

1184 However, it is also possible to arrange the pressing elements offset so that all openings are closed in an intermediate state.

[0163]

1189 Pumping breast milk and emptying process

[0164]

1193 So that milk can be pumped out of the mother's breast, the actuating lever 58 and thus the adjusting ring 5 are brought into the first position mentioned.

1195 By means of the drive, the pump membrane 7 is moved back and forth together with the media separation membrane 6 to the adapter part 4, so that a negative pressure is created in the pump chamber 47 and in the interior 200 of the breast shield 2.

1198 The vacuum line from the pump chamber 47 into the interior space 200 of the breast shield 2 is formed by the first through opening 43 in the adapter part 4, the opening in the valve body 3 covered by the first valve flap 37 and the channel formed by the first flow opening 25 and the first outlet opening 24 in the breast shield. The base vacuum valve, formed, among other things, by the sealing lip 31 1 of the valve body 3, enables a base negative pressure to be maintained in the interior 200 of the breast shield 2 when the pump stroke runs towards atmospheric pressure. The basic vacuum valve opens towards atmospheric pressure during the pump stroke and only closes when a predetermined minimum pressure in the interior 200 is reached. The mode of operation is explained in more detail below using a diagram. The air flows back into the breast shield 2 via the first and second backwash openings 45, 46 of the adapter part 4, the through opening 32 of the valve body 3 and the through opening 21 of the breast shield 2.

[0165]

1213 By applying this vacuum to the mother's breast, it is stimulated and milk flows from the breast

into the interior 200 of the breast shield 2.

1215 The interior 200 fills until the milk level reaches the first outlet opening 24. The breast shield 2 is preferably held in such a way that this first outlet opening 24 is located in an upper region of the breast shield 2.

[0166]

1221 The pumped milk then flows through the channel, formed by the first outlet opening 24 and the first passage opening 25, and through the opening covered by the first valve flap 37 into the adapter part 4, where it passes through the first through opening 43 into the pump chamber 47.

[0167]

1228 The pump chamber 47 also fills with milk until the outlet opening 480 located at the top is reached.

1230 The milk then flows through the channel, formed by the channel 48 of the adapter part 4 and the channel 63 or the cover of the media separation membrane 6, through the outlet 49 out of the hygiene module and through the container valve 94 into the milk collecting container 9.

[0168]

1236 If the pump stroke creates a negative pressure towards atmospheric pressure, the base vacuum valve opens first and allows a partial backflow of the air or milk in the interior 200.

1238 This partial backflow occurs through the first and second backwash openings 45, 46, the open base vacuum valve, the through opening 32 and the through opening 21.

1240 The valve closes at a certain vacuum value in the interior so that the pressure cannot rise further towards atmospheric pressure.

[0169]

1245 When the mother wants to stop pumping out the milk or when no more milk flows from the breast, she pivots the adjusting ring 5 into the second position.

1247 The previously used vacuum and milk channel is closed by closing the first outlet opening 24 and the first passage opening 25. However, the second outlet opening 27, the second passage opening 28 and the first ventilation opening 26 open. This changeover can take place while the pump is running, i.e. with the pump membrane 7 still being driven. The pump can also be switched off and then put back into operation. Since the pump now continues to suck, the milk that is still in the interior 200 of the breast shield 2 and has already been pumped out of the mother's breast is passed through the second release opening 27, the second passage opening 28, the opening of the valve body 3 covered by the second valve flap 37 and the second Through opening 44 of the adapter part 4 is pumped into the pump

chamber 47. From there it is displaced from the pump chamber 47 towards the outlet opening 480 by the movement of the pump membrane 7 and the media separation membrane 6. It therefore also flows through the channel 48 and the outlet 49 into the milk collecting container 9.

1260 In this way, both the interior 200 of the breast shield 2 and the pump chamber 47 can be almost completely emptied. The device can also be placed in an inclined position in order to empty all of the milk from the system into the milk collecting container 9.

[0170]

1266 It should be noted that at the beginning of the pumping process, the breast pump is preferably held in such a way that the first outlet opening 24 of the breast shield and the outlet opening 480 of the pumping chamber 47 are located in an upper region of the respective cavity.

1269 This allows air to escape from the system and the two hollow chambers are filled with milk relatively quickly. This enables a change as quickly as possible from a purely pneumatic pump system with air as the working fluid to a purely or predominantly hydraulic pump system in which milk forms the working fluid or at least forms a large proportion of the working fluid. However, it is not absolutely necessary that the openings are arranged in this way at the beginning of the pumping process. Changing from one pump system to the other simply takes a long time and/or cannot be completed completely.

[0171]

1279 As soon as the milk has partially flooded the interior 200 and the pump chamber 47, preferably up to the openings mentioned, the breast pump can be moved into any position.

1281 This applies not only to the breast shield 2 and the pump chamber 47, but in particular also to the milk collecting container 9. Thanks to the container valve 94 designed as a check valve and thanks to the liquid-impermeable cover 92, the milk collecting container 9 can even be turned upside down without affecting the operation of the breast pump.

[0172]

1288 In preferred embodiments, the breast shield and also the adjusting ring are illuminated so that the mother can carry out a visual check while pumping at night.

[0173]

1293 The breast pump described above is merely an exemplary embodiment in which the principle according to the invention can be implemented and the method according to the invention can be applied.

1296 Figures 18 to 23c therefore show again schematically what the core of the ideas according to the invention lies.

[0174]

1301 Basic principle

[0175]

1305 The breast shield 2 with the interior 200 is shown schematically in FIG.

1306 The breast shield 2 is placed sealingly on a mother's breast, the nipple W protrudes into the interior 200.

1308 The interior 200 is connected to a pump chamber 47 via an outlet opening 16.

1309 An additional emptying opening 19 also leads from the interior 200 to the pump chamber 47. The outlet opening 16 is provided with a pump valve 12, the emptying opening with a drain valve 14. A base vacuum valve 13 closes a third opening 17 between the vacuum chamber 47 and the interior 200 of the breast shield 2. A ventilation opening 15, which can be closed with a ventilation valve 11, also leads from the interior 200 of the breast shield 2 to the outside.

[0176]

1318 The volume of the pump chamber 47 can be changed by means of a pump means 10, for example a pump membrane or a piston.

1320 The pumping means 10 is driven, for example by means of a spindle 100.

[0177]

1324 An outlet opening 480 leads from the pump chamber 47 into a milk collecting container 9.

1325 The inlet into the milk collecting container 9 is preferably provided with a check valve, here called container valve 94. The milk collecting container 9 is ventilated; an inlet 95 with an inlet valve 96 is preferably present for this purpose.

[0178]

1331 The comparison with the exemplary embodiment described in detail above shows that the ventilation opening 15 and the ventilation valve 11 correspond to the first ventilation opening 26, the ventilation knob 35 and the first pressing element 56.

[0179]

1337 The outlet opening 16 and the base vacuum valve 12 of the schematic representation correspond to the first outlet opening 24, the first flow opening 25, the first knob 34, the first pressing element 56 and the first valve flap 37 of the specific exemplary embodiment.

[0180]

1343 The emptying opening 19 and the emptying valve 14 of the schematic representation correspond to the second outlet opening 27, the second flow opening 28, the second knob 36, the second pressing element 57 and the second valve flap 38 of the specific exemplary embodiment.

[0181]

1350 The base vacuum valve 13 and the third opening 17 of the schematic representation correspond to the sealing lip 311, the first and second backwash openings 45, 46 and the through opening 32 in the valve body 3 of the specific exemplary embodiment.

[0182]

1356 The container valve 94 in the schematic representation corresponds to the container valve in the specific exemplary embodiment.

[0183]

1361 The inlet 95 and the inlet valve 96 of the schematic representation are formed in the specific exemplary embodiment described above by the air-permeable and liquid-impermeable cover, i.e. by a correspondingly selected cover film.

[0184]

1367 These valves can also be implemented in other ways.

1368 The valve openings can also be accommodated in an additional module part, which is detachably connected to the breast shield.

1370 In addition, the outlet opening 16 and/or the emptying opening 19 can be designed as a channel which runs in a line, in particular a flexible line.

1372 Depending on the design of this line, the pump chamber can be arranged at a distance from the breast shield and, depending on the embodiment, also at a distance from a valve module.

1374 The valves can preferably be accommodated in a module which is arranged between the pump chamber and the breast shield funnel.

1376 If the pump chamber is arranged at a distance from the breast shield, the valve module can be arranged adjacent to the pump chamber or adjacent to the breast shield or can be a component of the breast shield.

[0185]

1382 The following explains how it works:

[0186]

1386 In the illustration according to Figure 18, the pump is not yet switched on.

1387 The valves are closed except for the inlet valve 96 of the milk collecting container 9.

1388 Atmospheric pressure prevails in all areas, i.e. p=0.

[0187]

1392 In the illustration according to Figures 19a to 19c, the pumping process begins and the mother's breast is stimulated by the negative pressure applied.

1394 The pump valve 12 can open and close.

1395 In the specific exemplary embodiment, the first outlet opening 24 and the first flow opening 25 are released and the first valve flap 37 opens and closes the valve.

1397 The drain valve 14 is tightly closed. In the specific exemplary embodiment, this is done by bringing the adjusting ring 5 into the corresponding position and tightly closing the second outlet opening 27 and the second flow opening 28. Likewise, the ventilation valve 11 remains tightly closed. In the specific exemplary embodiment, this is achieved by the first knob 34 closing the first ventilation opening 26 by means of the adjusting ring 5. The pumping means 10, preferably a pump membrane or a piston, is pulled outwards in order to generate a negative pressure in the pump chamber 47 (here e.g. B. - 150 mmHg). The pump valve 12 opens and the negative pressure is transferred into the interior 200 of the breast shield 2, or Air flows from this interior into the pump chamber 47. There is also a negative pressure in the interior, ideally the same pressure of -150 mmHg, for example. The pressure curve in the line space 200 is shown in Figure 19c. The pressure according to reference number a) corresponds to the pressure in the interior 200 according to FIG. 19a.

1409 The container valve 94 remains closed. The pressure in the milk collecting container 9 is still atmospheric pressure, i.e. p=0. If the pumping means 10 is now pushed back and the volume of the pumping chamber 47 is reduced, the pumping valve 12 closes and the pressure in the pumping chamber 47 increases to atmospheric pressure p-0. The pressure in the interior 200 also increases due to the base vacuum valve 13 now being opened. However, since the base vacuum valve 13 closes at a certain negative pressure, a base vacuum is maintained in the interior 200. This is, for example, -20 mmHg. This situation is shown in Figure 19b and the pressure curve is labeled b) in Figure 19c. Comparing Figures 19a and 19b also shows how the nipple W expands and contracts again in the interior 200.

[0188]

1421 In Figures 20a to 20c the flow of milk from the mother's breast has begun.

1422 The milk is given the reference symbol M in the figures. The interior 200 of the breast shield 2 fills with pumped milk. A lake of milk is created below the pump valve 12. Thanks to the milk

now available, the pump power increases while the drive power remains the same, for example to -170 mmHg in the pump chamber 47 and the interior 200. As before, the pump valve 12 and the base vacuum valve 13 open and close with each pump stroke, with the emptying valve 14 and the ventilation valve 11 remaining closed. Figure 20a shows the situation at maximum negative pressure (absolute value), which is also marked with a) in Figure 20c. Figure 20b shows the situation while maintaining the basic negative pressure in the interior 200 and atmospheric pressure in the pump chamber 47, which is marked with b) in Figure 20c. As soon as the interior 200 has filled with milk M up to the outlet openings 16, milk M flows through the pump valve 12 into the vacuum chamber 47. The pumped milk M now also fills the vacuum chamber 47 until its level reaches the outlet opening 480 to the milk collecting container 9.

1435 Now the container valve 94 opens, preferably due to the pressure of the accumulated milk M, and milk M flows into the milk collecting container 9.

[0189]

1440 Figures 21a to 21c show the situation in which, optimally, there is no longer any air in the system and the original pneumatic system has completely changed to a hydraulic system.

1442 In practice, a mixed system is often present, with the pumped milk preferably filling a significant portion of the volumes and thus forming the main working fluid. As already explained with reference to Figures 19a to 19c, the pump valve 12 and the base vacuum valve 13 open and close in accordance with the pump stroke, so that a negative pressure is generated in the interior 200 and a basic negative pressure can be maintained. The pressure in the vacuum chamber 47 changes, for example, between -250 mmHg and 0 mmHg, the pressure in the interior between -250 mmHg and -20 mmHg. The pressure in the milk collecting container 9 remains at atmospheric pressure, i.e. at 0 mmHg.

[0190]

1453 Figures 22a to 22c show the situation when milk no longer flows from the breast.

1454 The system initially continues to pump, and the pump pressure is no longer sufficient to open the container valve 94 to the milk collecting container 9. This is the point in time at which the pump valve 12 is completely closed and the emptying valve 14 is activated so that it can now open and close automatically. In the specific exemplary embodiment, the adjusting ring 5 is adjusted manually for this purpose. However, other ways of activating or deactivating these two valves are possible. For example, they can be controlled with appropriate electronics.

[0191]

1463 In Figures 23a to 23c, the pump valve 12 is now firmly closed and the emptying channel and the emptying valve 14 are opened.

1465 The pumping means 10 continues to move and continues to generate a pressure in the

pumping chamber 47 that varies from a maximum negative pressure to atmospheric pressure. In accordance with this movement, the emptying valve 14 also opens and closes, like the pump valve 12 before, and thus pumps the milk M from the interior 200 into the pump chamber 47. From there it is conveyed into the milk collecting container 9, preferably first by means of negative pressure and then by means of displacement by the pumping means 10. In this pumping situation, the emptying valve 14 is preferably located at a low point on the breast shield, preferably relatively far down. The sinking lake of milk in the interior can be clearly seen in Figures 23a and 23b. Figures 23a and 23b again show the two extreme situations of a pump stroke. The pressure curve is shown in Figure 23c. The pressure curve in the interior 200 is relatively unspecific. The pump will therefore continue to be operated during emptying. If there is still milk in the vacuum chamber 47 at the end, it can easily be directed into the milk collecting container 9 by tilting or turning the pump upside down.

[0192]

1481 The breast pump according to the invention and the method according to the invention thus enable the use of pumped milk in a hydraulic pump system, whereby the drive of the pump can be minimized.

[0193]

1487 REFERENCE SYMBOL LIST

[0194]

1491 32 Through opening pump means 33 positioning nose

[0195]

1495 Spindle 34 first stud

[0196]

1499 Ventilation valve 35 ventilation knob

[0197]

1503 Pump valve 36 second knob

[0198]

1507 Basic vacuum valve 37 first valve flap

[0199]

1511 Drain valve 38 second valve flap ventilation opening

[0200]

1515 Outlet opening 4 adapter part

[0201]

1519 third opening 40 base body

[0202]

1523 Drain opening 400 first window

[0203]

1527 401 second window

[0204]

1531 Breast shield 402 positioning aid

[0205]

1535 Funnel 41 pump-side wall interior 410 channel wall

[0206]

1539 Through opening 42 raised wall part flange 43 first through opening nozzle 44 second through opening first outlet opening 45 first backwash opening first flow opening 46 second backwash opening first ventilation opening 47 pump chamber

[0207]

1545 second outlet opening 48 gutter

[0208]

1549 second flow opening 480 outlet opening second ventilation opening 49 outlet valve body 5

adjusting ring

[0209]
1554 Basic body 50 first part

[0210]
1558 Rear wall 51 first connector part

[0211]
1562 Sealing surface 52 second part

[0212]
1566 Sealing lip 53 second plug part groove 54 latching element stop 83 spindle

[0213]
1570 first pressing element 84 mounting holes second pressing element 85 edge

[0214]
1574 Operating lever 86 operating switch

[0215]
1578 87 Advertisement

[0216]
1582 Media separation membrane

[0217]
1586 Membrane surface

[0218]
1590 Central area 9 milk collection container sealing surface 90 vessel

[0219]

1594 Gutter 900 interior

[0220]

1598 Recess 901 first latching element^{''}

[0221]

1602 902 second latching element pump membrane 91 lower frame part membrane surface 92 cover

[0222]

1607 Central area 93 upper frame part passage opening 930 frame

[0223]

1611 Reinforcement 931 struts

[0224]

1615 Sealing surface 932 Valve holder Sensor surface 933 Handle

[0225]

1619 Flag 934 spacer pins

[0226]

1623 Side wing 94 container valve

[0227]

1627 95 inlet

[0228]

1631 Pump housing 96 inlet valve

[0229]

1635 Carrier module

[0230]

1639 Side arm W nipple

[0231]

1643 Motor mount M milk

[0232]

1647 Spindle mount

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(54) **Title:** BREAST PUMP

(54) **Bezeichnung:** BRUSTPUMPE

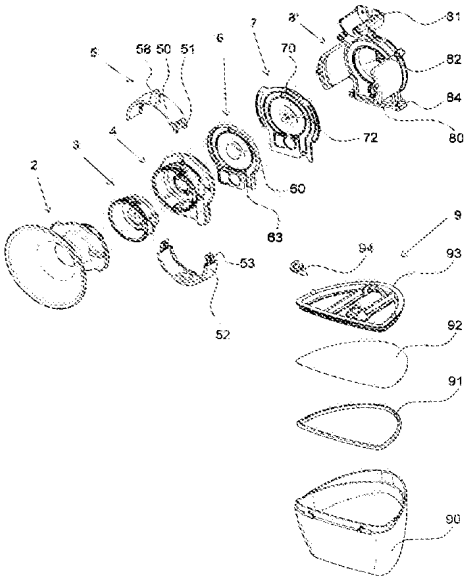

FIG. 2

(57) **Abstract:** A breast pump for expressing human breast milk has a housing (8), a pumping chamber (47) with a driven pump membrane (7) for generating a vacuum, and also has a breastshield (2) with an interior (200) in which to position a breast. Expressed milk flows from the interior (200), through a milk channel, into the pumping chamber (47), which has an outlet opening (480) through which expressed milk flows from the pumping chamber (47) into a milk-collecting container (9). The breast pump has a multi-part hygiene module (2, 3, 4, 5) having a first part (2) with a throughflow opening (24, 25) for connection to the interior (200), having a valve body (3) with at least one valve (34, 37), and having a second part (4) with a rigid shell for forming the pumping chamber (47). The valve body (3) is arranged between the first and second parts (2, 4) and the hygiene module (2, 3, 4, 5) can be connected, as a whole, to the housing (8) of the breast pump in a sealing and releasable manner.

(57) **Zusammenfassung:** Eine Brustpumpe zum Abpumpen von menschlicher Muttermilch weist ein Gehäuse (8), eine Pumpkammer (47) mit einer angetriebenen Pumpmembran (7) zur Erzeugung eines Vakuums und eine Brusthaube (2) mit einem Innenraum (200) zur Aufnahme einer Mutterbrust auf. Abgepumpte Milch fliesst vom Innenraum (200) durch einen Milchkanal in die Pumpkammer (47), welche eine Auslassöffnung (480) aufweist, durch die abgepumpte Milch von der Pumpkammer (47) in einen Milchsammelbehälter (9) fliesst. Die Brustpumpe weist ein mehrteiliges Hygienemodul (2, 3, 4, 5) auf mit einem ersten Teil (2) mit einer Durchflussöffnung (24, 25) zur Verbindung mit dem Innenraum (200), einem Ventilkörper (3) mit mindestens einem Ventil (34, 37) und einem zweiten Teil (4) mit einer steifen Schale zur Bildung der Pumpkammer (47). Der Ventilkörper (3) ist zwischen dem ersten und zweiten Teil (2, 4) angeordnet und das Hygienemodul (2, 3, 4, 5) ist als Ganzes mit dem Gehäuse (8) der Brustpumpe dichtend und lösbar verbindbar.

[Fortsetzung auf der nächsten Seite]

DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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— *mit internationalem Recherchenbericht (Artikel 21 Absatz 3)*

TITEL

BRUSTPUMPE

TECHNISCHES GEBIET

Die vorliegende Erfindung betrifft eine Brustpumpe zum Abpumpen von menschlicher Muttermilch sowie eine Brusthaube, einen Milchsammelbehälter und ein Verfahren zum Betreiben einer Brustpumpe.

STAND DER TECHNIK

Vorrichtungen zum Abpumpen von menschlicher Muttermilch sind hinlänglich bekannt. Grundsätzlich gibt es zwei verschiedene Typen: die ersten werden manuell bedient, d.h. der für das Abpumpen notwendige Unterdruck wird durch manuelle Betätigung der Vakuumpumpe erzeugt. Bei den zweiten Typen ist die Vakuumpumpe elektrisch betrieben.

Diese Vakuumpumpen sind entweder direkt oder über eine Vakuumleitung mit einer Brusthaube verbunden. Die Brusthaube weist einen Innenraum zur Aufnahme der Mutterbrust bzw. deren Brustwarze auf. Der Unterdruck wird über eine erste Leitung in den Innenraum übertragen, die abgepumpte Milch fliesst über eine zweite Leitung in einen Milchsammelbehälter.

WO 2016/014494 A1 und WO 2016/014469 A1 beschreiben eine kompakte Brustpumpe, bei welcher abgepumpte Milch unter positivem Druck in einen Milchsammelbehälter transportiert wird. Hierfür wird beispielsweise eine Milchleitung zyklisch gequetscht.

WO 2011/035447 A1 offenbart eine Brustpumpe, bei welcher die Vakuumleitung gleichzeitig die Milchleitung bildet. Die Pumpkammer, in welcher der Unterdruck erzeugt wird, füllt sich während des Abpumpens mit Milch, so dass das Pumpsystem von einem pneumatischen System in ein hydraulisches System wechselt und die bereits abgepumpte

Milch zum Arbeitsfluid wird. Damit sich die Pumpkammer mit Milch füllen kann, ist am Ausgang der Pumpkammer, welcher zum Milchsammelbehälter führt, ein Ventil angeordnet. Dieses Ventil öffnet sich erst bei einem bestimmten Druck innerhalb der Pumpkammer, d.h. wenn die Pumpkammer ausreichend mit Milch gefüllt ist.

Diese kombinierte pneumatische und hydraulische Pumpe weist mehrere Vorteile auf. Das System weist kein oder fast kein Totvolumen auf. Das Pumpaggregat kann minimiert werden, da nach Füllung des Systems mit Milch nur mehr eine geringe Pumpleistung notwendig ist, um weitere Milch abzupumpen. Insbesondere lassen sich Batterien mit geringerer Kapazität verwenden als bei pneumatischen Vakuumpumpen. Die Vakuumpumpe lässt sich somit kostengünstiger und kleiner ausbilden. Die Brustpumpe eignet sich insbesondere für sogenannte „hands-free" Anwendungen, bei welchen die Brustpumpe am Körper getragen und keine Hände zum Festhalten der Brusthaube benötigt werden. Aufgrund des minimierten Totvolumens lässt sich zudem der angelegte Druck leichter kontrollieren. Dadurch lassen sich für jede Mutter individuell optimierte Pumpparameter wählen.

In WO 2013/049944 A2 ist ebenfalls eine Brustpumpe beschrieben, welche von einem pneumatischen in ein hydraulisches Pumpsystem wechselt. In der Pumpkammer ist ein Drucksensor vorhanden, welcher eine an einer flexiblen Membran angebrachte Fahne umfasst.

DARSTELLUNG DER ERFINDUNG

Es ist deshalb eine Aufgabe der Erfindung, die oben genannte Brustpumpe zu optimieren.

Diese Aufgabe löst eine Brustpumpe gemäss den Ansprüchen 1, 8, 35, 36, 39 und 42, ein Milchsammelbehälter gemäss Anspruch 41, eine Brusthaube gemäss Anspruch 43 sowie ein Verfahren mit den Merkmalen des Anspruchs 44.

In einer bevorzugten Ausführungsform weist die erfindungsgemässe Brustpumpe zum Abpumpen von menschlicher Muttermilch ein Gehäuse mit einer Antriebseinheit, eine

Pumpkammer mit einer von der Antriebseinheit angetriebenen flexiblen Pumpmembran zur Erzeugung eines Vakuums und eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust auf. Der Innenraum ist mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagbar, wobei ein Milchkanal vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer führt, wobei abgepumpte Milch vom Innenraum der Brusthaube durch den Milchkanal in die Pumpkammer fliesst, und wobei die Pumpkammer eine Auslassöffnung aufweist, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst. Ein mehrteiliges Hygienemodul ist vorhanden, wobei das Hygienemodul einen ersten Teil mit einer Durchflussöffnung zur Verbindung mit dem Innenraum, einen Ventilkörper mit mindestens einem Ventil und einen zweiten Teil mit einer steifen Schale zur Bildung der Pumpkammer aufweist, wobei der Ventilkörper zwischen dem ersten und zweiten Teil angeordnet ist und wobei das Hygienemodul als Ganzes mit dem Gehäuse der Brustpumpe dichtend und lösbar verbindbar ist.

Dieses Hygienemodul ist kompakt aufgebaut. Es lässt sich einfach montieren und auseinander nehmen, so dass sich die relevanten Teile der Brustpumpe einfach reinigen lassen. Die Verwendung eines Ventilkörpers im Hygienemodul erleichtert die Herstellung, den Zusammenbau und die Reinigung zusätzlich.

Vorzugsweise weist die steife Schale einen Milchpfad auf, welcher von der Pumpkammer in einen Milchsammelbehälter führt und welcher mindestens über einen Teilbereich senkrecht zu einer Antriebsachse der Pumpmembran verläuft. Vorzugsweise verläuft der Milchpfad in einer Ebene senkrecht zur Antriebsachse, wobei sich der Milchpfad in dieser Ebene über mindestens die Hälfte der Höhe der Pumpkammer, vorzugsweise über die gesamte Höhe der Pumpkammer erstreckt. Der Verlauf dieses Milchpfades ermöglicht es, die Pumpkammer mit abgepumpter Milch mindestens teilweise, vorzugsweise vollständig zu füllen, so dass während des Abpumpens von einem pneumatischen Pumpsystem auf ein gemischtes oder sogar vollständig hydraulisch funktionierendes Pumpsystem gewechselt wird.

Vorzugsweise weist der Ventilkörper mindestens ein Durchflussventil und ein Belüftungsventil auf. Vorzugsweise ist der Ventilkörper einstückig aus einem flexiblen

Material gebildet. Dies erleichtert sowohl die Herstellung, wie auch den Zusammenbau und die Reinigung.

Vorzugsweise ist der erste Teil ein Bestandteil der Brusthaube. Dadurch lässt sich die Brustpumpe kompakt ausbilden und das Hygienemodul lässt sich auf einfache Art und Weise an der Brustpumpe befestigen, ohne dass zusätzlich noch die Brusthaube montiert werden muss.

Vorzugsweise weist die Brusthaube einen Flansch zur lösbaren Verbindung mit dem Gehäuse auf.

Die Verbindung mit dem Gehäuse lässt sich auf besonders einfache Art und Weise herstellen, wenn sie form- und kraftschlüssig, vorzugsweise ein Bajonettverschluss, ist.

In einer weiteren bevorzugten Ausführungsform weist die erfindungsgemässe Brustpumpe zum Abpumpen von menschlicher Muttermilch eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer auf, wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagbar ist. Ein Milchkanal führt vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer, durch welchen abgepumpte Milch vom Innenraum der Brusthaube in die Pumpkammer fliesst. Die Pumpkammer weist eine Auslassöffnung auf, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst. Die Auslassöffnung ist in vertikaler Gebrauchslage der Brustpumpe mindestens zu Beginn eines Abpumpvorgangs in einem oberen Bereich der Pumpkammer und/oder oberhalb der Einlassöffnung angeordnet.

Dadurch lässt sich die Pumpkammer annähernd vollständig mit Milch füllen und das System kann innerhalb kürzester Zeit von einem pneumatischen in ein hydraulisches oder gemischt pneumatisch/hydraulisches System übergeführt werden. Dieselbe Antriebsleistung für die Pumpmittel, z.B. der Pumpmembran, führt zu einer grösseren Pumpleistung, d.h. zu einem betragsmässig höheren Unterdruck in der Pumpkammer und somit im Innenraum der Brusthaube. Es lassen sich Batterien mit geringerer Kapazität verwenden. Dies vermindert die Herstellungskosten, erhöht die Lebensdauer der Pumpe

insgesamt und minimiert die Grösse der Antriebseinheit.

Vorzugsweise bildet der Milchkanal einen Vakuumkanal zur Beaufschlagung des Innenraums der Brusthaube mit dem sich zyklisch ändernden Unterdruck. D.h. es wird über dieselbe Leitung bzw. über denselben Kanal zuerst das Vakuum angelegt und anschliessend die Milch abgesaugt. Dieselbe Leitung bzw. derselbe Kanal wird für beide Arbeitsfluide, d.h. Luft und Milch, verwendet.

Je nach Ausführungsform ist die Pumpe eine Kolbenpumpe, eine Membranpumpe oder eine andere Art Vakuumpumpe. Vorzugsweise weist die Pumpkammer jedoch eine steife erste Schale und eine flexible Pumpmembran auf, wobei die Pumpmembran dichtend an der ersten Schale anliegt und wobei die Pumpmembran angetrieben ist und durch deren Bewegung relativ zur ersten Schale ein Unterdruck in der Pumpkammer erzeugbar ist.

Vorzugsweise ist zwischen der steifen Schale und der flexiblen Pumpmembran eine flexible Medientrennmembran angeordnet, so dass die Pumpmembran vor einem Kontakt mit abgepumpter Milch geschützt ist. Milch und Luft, welche in der Brusthaube vorliegen, gelangen nur bis zur Medientrennmembran. Die Pumpmembran und die übrigen Teile der Brustpumpe sind somit vor einer Kontamination geschützt.

Die Medientrennmembran lässt sich auf einfache Art und Weise von der Pumpmembran trennen. Sie ist vorzugsweise Teil des bereits erwähnten Hygienemoduls. Die Medientrennmembran lässt sich vorzugsweise von den übrigen Teilen des Hygienemoduls trennen und so auf einfache Art und Weise reinigen. Auch die übrigen Teile des Hygienemoduls lassen sich soweit notwendig voneinander trennen, so dass sie gereinigt und anschliessend auf einfache Art und Weise und vorzugsweise ohne Werkzeuge wieder zusammen gesetzt und erneut verwendet werden können.

Vorzugsweise weist die erste Schale eine Auslassrinne auf, welche sich von der Auslassöffnung der Pumpkammer zu einem Ausgang erstreckt, wobei die Auslassrinne mindestens über einen Teilbereich in einer Richtung senkrecht zur Bewegungsrichtung der Pumpmembran verläuft. Vorzugsweise verläuft sie in einer Ebene senkrecht zu dieser Bewegungsrichtung, wobei sich die Rinne vorzugsweise über mindestens die Hälfte der

Höhe der Pumpkammer, vorzugsweise über die gesamte Pumpkammer erstreckt.

In anderen Ausführungsformen ist die Rinne teilweise oder ganz als geschlossener Kanal ausgebildet. Vorzugsweise verschliesst jedoch die Pumpmembran, oder, falls vorhanden, die Medientrennmembran die Auslassrinne der steifen ersten Schale zu einem bis auf die Auslössöffnung und den Ausgang geschlossenen Kanal.

Die Rinne erstreckt sich vorzugsweise neben der Pumpkammer und nicht innerhalb derselben.

In einer bevorzugten Ausführungsform weist die Brusthaube eine erste Durchlassöffnung auf, welche Teil des Milchkanals bildet, wobei die Durchlassöffnung in Gebrauchslage der Brusthaube mindestens zu Beginn des Abpumpvorgangs in einem oberen Bereich des Innenraums angeordnet ist, so dass der Innenraum unterhalb der ersten Durchlassöffnung mit abgepumpter Milch befüllbar ist.

Dadurch lässt sich die Brusthaube zu Beginn des Abpumpvorgangs mit Milch teilweise oder ganz füllen. Dies verkürzt die Zeit bis zum Wechsel auf das hydraulische Pumpsystem nochmals massiv. Üblicherweise wird zuerst der Innenraum der Brusthaube gefüllt und anschliessend die Pumpkammer, bevor die Milch erstmals in den Milchsammelbehälter gelangt.

Vorzugsweise ist der Milchkanal mittels eines ersten Ventils verschliessbar, um am Ende des Abpumpvorgangs die abgepumpte Milch aus der Pumpkammer zu entfernen. Dieses Ventil ist vorzugsweise dasselbe Ventil, welches sich beim Abpumpen der Milch selbsttätig öffnet und schliesst. Für die Entleerung wird es nun permanent geschlossen. Die Schliessung erfolgt je nach Ausführungsform manuell oder automatisch, z.B. mittels der elektronischen Steuerung der Brustpumpe. Ist nachfolgend ein Ventil angeordnet, so kann das erste Ventil während des Abpumpvorgangs auch stets geöffnet sein.

Vorzugsweise ist ein Entleerungskanal zwischen dem Innenraum der Brusthaube und der Pumpkammer vorhanden, welcher getrennt vom Milchkanal verläuft, wobei der Entleerungskanal mittels eines zweiten Ventils verschliessbar ist. Der Entleerungskanal ist

während des Abpumpvorgangs geschlossen und ist am Ende des Abpumpvorgangs geöffnet. Auch dies erfolgt je nach Ausführungsform manuell oder automatisch. Das zweite Ventil funktioniert vorzugsweise gleich oder ähnlich wie das erste Ventil. Es ist vorzugsweise identisch ausgebildet. Es öffnet und schliesst sich während des Pumpvorgangs beim Entleeren der Brusthaube gleich wie das erste Ventil während des Abpumpens der Muttermilch aus der Mutterbrust. Ist nachfolgend ein Ventil angeordnet, so kann das zweite Ventil während des Entleerungsvorgangs auch stets geöffnet sein.

Vorzugsweise ist zudem ein Belüftungsventil zur Belüftung des Innenraums der Brusthaube vorhanden. Dieses ist ebenfalls vorzugsweise während des Abpumpvorgangs stets geschlossen und wird manuell oder automatisch geöffnet, um das Entleeren der Brusthaube zu erleichtern.

Vorzugsweise ist das Belüftungsventil gemeinsam mit dem zweiten Ventil verschliessbar und es lässt sich gemeinsam mit diesem öffnen.

In einer bevorzugten Ausführungsform ist ein drittes Ventil vorhanden, welches bei Druckanstieg des sich zyklisch ändernden Unterdrucks im Innenraum der Brusthaube einen Basisunterdruck beibehält. Der Druck im Innenraum der Brusthaube liegt somit während des gesamten Abpumpvorgangs und vorzugsweise auch während der Entleerung unter dem Atmosphärendruck. Dies vermindert die Belastung der Brustwarze und wirkt sich positiv auf den Milchfluss aus der Mutterbrust aus.

Vorzugsweise ist im Milchkanal ein viertes Ventil vorhanden, welches sich nach Massgabe des angelegten Unterdrucks öffnet und schliesst. Dieses vierte Ventil ist in Abpumprichtung der Milch dem ersten Ventil nachfolgend angeordnet. Das vierte Ventil kann jedoch auch, wie oben bereits beschrieben, durch das erste Ventil gebildet sein. Ist es jedoch nachgeordnet, kann es beispielsweise als Flatterventil im Ventilkörper ausgebildet sein.

Vorzugsweise ist im Entleerungskanal ein fünftes Ventil vorhanden ist, welches sich nach Massgabe des angelegten Unterdrucks öffnet und schliesst. Diese fünfte Ventil ist in Entleerungsrichtung der Milch dem zweiten Ventil nachfolgend angeordnet. Das fünfte

Ventil kann wie oben beschrieben durch das zweite Ventil gebildet sein. Ist es nachgeordnet, kann es beispielsweise ein Flatterventil im Ventilkörper sein.

Vorzugsweise ist mindestens ein Teil, vorzugsweise sind alle der genannten Ventile in einem gemeinsamen Ventilkörper angeordnet. Dies erleichtert die Herstellung und minimiert die Kosten.

Vorzugsweise ist der Ventilkörper einstückig und flexibel ausgebildet. Vorzugsweise besteht er aus Silikon.

Vorzugsweise weist die Brustpumpe ein Pumpengehäuse mit einem Antrieb für die Pumpmembran auf, wobei die steife erste Schale lösbar mit dem Pumpengehäuse verbunden ist. Dies erleichtert den Zusammenbau, auch nach einer Reinigung durch die Mutter.

Vorzugsweise ist die erste steife Schale Bestandteil eines mehrteiligen Moduls, welches gemeinsam mit dem Pumpengehäuse verbindbar ist, wobei das Modul des Weiteren mindestens die genannten Ventile aufweist. Dieses Modul ist vorzugsweise das oben genannte Hygienemodul.

Vorzugsweise ist die erste steife Schale Bestandteil eines Adapterteils, wobei der Ventilkörper in einer Aufnahme des Adapterteils gehalten ist. Dies erleichtert die Montage und ermöglicht insbesondere einen modulartigen Aufbau sowie die Verwendung eines Hygienemoduls.

Vorzugsweise umfasst das Modul ferner ein manuelles Betätigungsmittel zum zeitgleichen Betätigen des ersten und zweiten Ventils. Die manuelle Betätigung der zwei Ventile ist eine kostengünstige und betriebssichere Lösung.

Vorzugsweise sind das Adapterteil und das Betätigungsteil nicht zerstörungsfrei voneinander lösbar. Dadurch ist sichergestellt, dass das Modul stets korrekt zusammengestellt und nur mit sämtlichen Elementen gemeinsam verwendet werden kann.

Vorzugsweise weist die Brustpumpe ein Pumpengehäuse auf, wobei die Brusthaube lösbar am Pumpengehäuse befestigbar ist und wobei durch die Befestigung der Brusthaube am Pumpengehäuse Teile, welche zwischen Brusthaube und Pumpengehäuse liegen, dichtend miteinander verbunden werden, so dass eine dichte Verbindung zwischen Pumpkammer und Innenraum der Brusthaube entsteht. Die Brusthaube lässt sich einfach mit der Hand halten, was den Zusammenbau der Pumpe erleichtert. Da die übrigen Teile durch die Befestigung der Brusthaube am Pumpengehäuse ebenfalls dicht anliegen, ist die Brustpumpe somit mit einem einzigen Handgriff, nämlich der Befestigung der Brusthaube am Pumpengehäuse, einsatzbereit. Ebenso einfach lassen sich die einzelnen Teile entfernen, um gereinigt zu werden. Vorzugsweise sind die Brusthaube und der Ventilkörper Teil des Moduls.

Vorzugsweise weist die Brustpumpe ein Pumpengehäuse auf, an welchem die Brusthaube lösbar befestigbar ist, wobei die Brustpumpe ferner einen Milchsammelbehälter aufweist, welcher am Pumpengehäuse mittels eines Schnappverschlusses befestigbar ist. Die Befestigung des Milchsammelbehälters mittels eines Schnappverschlusses ist unkonventionell. Üblicherweise werden Drehverschlüsse verwendet. Dank des Schnappverschlusses lässt sich der Behälter anders ausbilden und insbesondere schneller befestigen und entfernen.

Vorzugsweise weist der Milchsammelbehälter einen Grundkörper und einen Deckel auf, wobei der Deckel mindestens teilweise luftdurchlässig und flüssigkeitsundurchlässig ausgebildet ist. Dieser Deckel bildet somit ein Ventil, welches der Belüftung dient, welches aber auch ermöglicht, dass der Behälter ohne Flüssigkeitsverlust auf den Kopf gestellt werden kann. Vorzugsweise weist der Deckel eine luftdurchlässige und flüssigkeitsundurchlässige Membran auf. Vorzugsweise ist der Deckel zwischen dem Milchsammelbehälter und der Pumpe eingeklemmt und mittels Distanzstiften positionierbar.

Zudem ist der Deckel vorzugsweise mit einem Einwegventil versehen, welches von der Pumpkammer in den Milchsammelbehälter führt.

In einer bevorzugten Ausführungsform weist die Brustpumpe zum Abpumpen von

menschlicher Muttermilch eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer auf, wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagbar ist. Ein Milchkanal führt vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer, durch welchen abgepumpte Milch vom Innenraum der Brusthaube in die Pumpkammer fliesst. Die Pumpkammer weist eine Auslassöffnung auf, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst. Ein Entleerungskanal ist zwischen dem Innenraum der Brusthaube und der Pumpkammer vorhanden, welcher getrennt vom Milchkanal verläuft, wobei der Entleerungskanal mittels eines Ventils verschliessbar ist, wobei der Entleerungskanal während des Abpumpvorgangs geschlossen ist und am Ende des Abpumpvorgangs geöffnet ist. Dadurch lässt sich Milch am Ende des Abpumpvorgangs auf einfache Art und Weise aus der Brusthaube entfernen. Der Entleerungskanal wird vorzugsweise mittels der Pumpkammer mit einem Unterdruck beaufschlagt, um die Milch aktiv abzupumpen und in den Milchsammelbehälter zu drängen.

In einer bevorzugten Ausführungsform weist die Brustpumpe zum Abpumpen von menschlicher Muttermilch eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer auf, wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagbar ist. Ein Milchkanal führt vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer, durch welchen abgepumpte Milch vom Innenraum der Brusthaube in die Pumpkammer fliesst. Die Pumpkammer weist eine Auslassöffnung auf, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst. Die Brustpumpe weist ein Pumpengehäuse, eine Pumpmembran und ein Modul auf, wobei das Modul mindestens eine steife Schale zur Bildung der Pumpkammer und die Brusthaube aufweist. Das Modul ist als Einheit am Pumpengehäuse befestigbar, wobei eine dichte Verbindung zwischen der Pumpkammer und dem Innenraum der Brusthaube geschaffen wird und wobei die Pumpmembran zwischen dem Modul und dem Pumpengehäuse dichtend gehalten ist. Dies erleichtert die Reinigung der relevanten Teile der Brustpumpe durch die Mutter und den Zusammenbau nach einer derartigen Reinigung.

Vorzugsweise weist das Modul ferner einen Ventilkörper auf, welcher zwischen

Brusthaube und steifer Schale angeordnet ist. Der Ventilkörper sowie die entsprechenden Bereiche des ersten und zweiten Teils, welche vorzugsweise Dichtsitze für die Ventile des Ventilkörpers aufweisen, bilden eine gemeinsame Ventileinheit, auch Ventilkonstrukt genannt.

Vorzugsweise weist das Modul ferner ein manuelles Betätigungsmittel zur Betätigung mindestens eines Ventils des Ventilkonstrukts auf.

In einer bevorzugten Ausführungsform weist die Brustpumpe zum Abpumpen von menschlicher Muttermilch eine Brusthaube zur Aufnahme einer Mutterbrust, ein Pumpengehäuse sowie einen Milchsammelbehälter auf, wobei das Pumpengehäuse einerseits lösbar mit der Brusthaube und andererseits lösbar mit dem Milchsammelbehälter verbindbar ist. Der Milchsammelbehälter ist mittels eines Schnappverschlusses am Pumpengehäuse befestigbar.

Vorzugsweise weist diese Brustpumpe eine Pumpkammer und einen Milchkanal auf, durch welchen abgepumpte Milch von einem Innenraum der Brusthaube in die Pumpkammer fliesst, wobei die Pumpkammer einen Ausgang aufweist, welcher mit dem Milchsammelbehälter verbunden ist und durch welchen die abgepumpte Milch in den Milchsammelbehälter fliesst.

In einer bevorzugten Ausführungsform ist ein erfindungsgemässer Milchsammelbehälter zur Verbindung mit einem Pumpengehäuse einer Brustpumpe zum Abpumpen von menschlicher Muttermilch, vorhanden, wobei der Milchsammelbehälter einen Deckel aufweist, der dem Pumpengehäuse zugewandt ist und der mindestens in einem Bereich luftdurchlässig und flüssigkeitsundurchlässig ist.

In einer bevorzugten Ausführungsform weist die Brustpumpe zum Abpumpen von menschlicher Muttermilch eine Brusthaube zur Aufnahme einer Mutterbrust und ein Pumpengehäuse auf, wobei die Brusthaube lösbar mit dem Pumpengehäuse verbindbar ist. Die Brusthaube ist mittels eines Bajonettverschlusses mit dem Pumpengehäuse verbindbar.

In einer bevorzugten Ausführungsform ist eine erfindungsgemässe Brusthaube vorhanden, welche zur Befestigung an einem Pumpengehäuse einer Brustpumpe dient. Die Brusthaube weist einen Innenraum zur Aufnahme der Mutterbrust und einen Stutzen zur Befestigung am Pumpengehäuse auf, wobei der Stutzen mit einem Bajonettverschluss versehen ist.

In einer bevorzugten Variante eines erfindungsgemässen Verfahren zum Betätigen einer Brustpumpe zum Abpumpen von menschlicher Muttermilch weist die Brustpumpe eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer auf, wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagt wird. In einer ersten Pumpphase wird der Innenraum mit dem sich zyklisch ändernden Unterdruck beaufschlagt, um Milch aus der Mutterbrust abzupumpen, wobei der Innenraum mit abgepumpter Milch gefüllt wird, ohne dass abgepumpte Milch aus dem Innenraum hinausfliesst. In einer zweiten Pumpphase fliesst abgepumpte Milch aus dem Innenraum in die Pumpkammer und die Pumpkammer wird mit abgepumpter Milch gefüllt. In einer dritten Pumpphase fliesst die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter, wobei der Innenraum und die Pumpkammer mit abgepumpter Milch gefüllt bleiben. Der Wechsel von der zweiten Pumpphase zur dritten Pumpphase erfolgt, indem ein Füllstand der abgepumpten Milch eine Auslassöffnung erreicht, welche von der Pumpkammer zum Milchsammelbehälter führt, wodurch Milch durch die Auslassöffnung von der Pumpkammer in den Milchsammelbehälter fliesst.

Dank dieses Verfahrens stellt das Pumpsystem relativ schnell von einem pneumatischen auf ein hydraulisches oder vorwiegend hydraulisches Pumpsystem um. Dadurch lassen sich kleinere Antriebe und leistungsschwächere Motoren verwenden.

Vorzugsweise ist die erste Pumpphase eine vollständig oder vorwiegend pneumatische Pumpphase und die zweite Pumpphase eine vollständig oder vorwiegende hydraulische Pumpphase.

In einer bevorzugten Variante des Verfahrens wird der Innenraum in der ersten Pumpphase annähernd vollständig gefüllt. In einer bevorzugten Variante werden der Innenraum und/oder die Pumpkammer in der zweiten und/oder dritten Pumpphase annähernd

vollständig mit abgepumpter Milch gefüllt.

Vorzugsweise erfolgt der Wechsel von der ersten Pumpphase zur zweiten Pumpphase, indem ein Füllstand der abgepumpten Milch eine erste Durchgangsöffnung erreicht, welche vom Innenraum zur Pumpkammer führt, wodurch Milch durch die erste Durchgangsöffnung vom Innenraum in die Pumpkammer fliesst.

Vorzugsweise fliesst in der dritten Pumpphase die abgepumpte Milch durch die erste Durchgangsöffnung in die Pumpkammer und durch die Auslassöffnung in den Milchsammelbehälter.

Vorzugsweise wird in einer vierten Pumpphase der Innenraum entleert und die darin befindliche, bereits abgepumpte Milch wird durch eine zweite Durchgangsöffnung aus dem Innenraum zum Milchsammelbehälter geführt.

Vorzugsweise ist die erste Durchgangsöffnung mit einem ersten Ventil verschliessbar und die zweite Durchgangsöffnung mit einem zweiten Ventil verschliessbar, wobei die zweite Durchgangsöffnung während der ersten bis dritten Pumpphase stets geschlossen ist.

Vorzugsweise ist die erste Durchgangsöffnung während der vierten Pumpphase stets geschlossen.

Vorzugweise führt die zweite Durchgangsöffnung vom Innenraum in die Pumpkammer und steht über die Pumpkammer in fluidkommunizierender Verbindung mit der Auslassöffnung.

Vorzugsweise wird während mindestens einem Teil der Pumpphasen, vorzugsweise während der ersten, zweiten und dritten Pumpphase ein Basisunterdruck beibehalten.

Vorzugsweise ist ein drittes Ventil vorhanden, welches bei Druckanstieg des sich zyklisch ändernden Unterdrucks in Richtung Atmosphärendruck zuerst öffnet und dann schliesst und dadurch den Basisunterdruck beibehält.

Weitere Ausführungsformen und Varianten des Verfahrens sind in den abhängigen Ansprüchen angegeben.

Die einzelnen in den Ansprüchen aufgeführten Elemente lassen sich auch zu anderen Kombinationen zusammenfügen, ohne dass sämtliche Merkmale der Ansprüche übernommen werden müssen. Insbesondere lassen sich einzelne Elemente auch in reinen pneumatischen Brustpumpen verwenden, insbesondere in pneumatischen Membran-Brustpumpen.

KURZE BESCHREIBUNG DER ZEICHNUNGEN

Bevorzugte Ausführungsformen der Erfindung werden im Folgenden anhand der Zeichnungen beschrieben, die lediglich zur Erläuterung dienen und nicht einschränkend auszulegen sind. In den Zeichnungen zeigen:

Figur 1 eine perspektivische Darstellung einer erfindungsgemässen Brustpumpe,

Figur 2 eine Explosionsdarstellung der Brustpumpe gemäss Figur 1 in einer perspektivischen Ansicht;

Figur 3 eine Explosionsdarstellung der Brustpumpe gemäss Figur 1 in einer weiteren perspektivischen Ansicht;

Figur 4 einen Teilschnitt durch die Brustpumpe gemäss Figur 1 in einer ersten perspektivischen Ansicht;

Figur 5 einen Teilschnitt durch die Brustpumpe gemäss Figur 1 in einer zweiten perspektivischen Ansicht;

Figur 6 einen Längsschnitt durch ein Hygienemodul, befestigt an einem Trägermodul der Brustpumpe gemäss Figur 1 in Explosionsdarstellung;

Figur 7 eine perspektivische Darstellung des zusammengesetzten Hygienemodul gemäss Figur 6;

Figur 8a eine perspektivische Darstellung einer Brusthaube der Brustpumpe gemäss Figur 1;

Figur 8b einen Teilschnitt durch die Brusthaube gemäss Figur 8a;

Figur 9a eine perspektivische Darstellung durch einen Ventilkörper der Brustpumpe gemäss Figur 1;

Figur 9b einen Teilschnitt durch den Ventilkörper gemäss Figur 9a;

Figur 9c einen Längsschnitt durch den Ventilkörper gemäss Figur 9a;

Figur 9d eine Ansicht des Ventilkörpers gemäss Figur 9a;

Figur 10a eine perspektivische Darstellung eines Stellrings der Brustpumpe gemäss Figur 1;

Figur 10b eine Ansicht des Stellrings gemäss Figur 10a;

Figur 11a eine perspektivische Darstellung eines Adapterteils der Brustpumpe gemäss Figur 1 von einer ersten Seite;

Figur 11b einen Teilschnitt durch das Adapterteil gemäss Figur 11a;

Figur 11c eine perspektivische Darstellung des Adapterteils gemäss Figur 11a von einer zweiten Seite;

Figur 12a eine perspektivische Darstellung einer Medientrennmembran der Brustpumpe gemäss Figur 1 von einer ersten Seite;

Figur 12b eine perspektivische Darstellung der Medientrennmembran gemäss Figur 12a von einer zweiten Seite;

Figur 12c einen Längsschnitt durch die Medientrennmembran gemäss Figur 12a;

Figur 13a eine perspektivische Darstellung einer Pumpmembran der Brustpumpe gemäss Figur 1 von einer ersten Seite;

Figur 13b eine perspektivische Darstellung der Pumpmembran gemäss Figur 13a von einer zweiten Seite;

Figur 13c einen Längsschnitt durch die Pumpmembran gemäss Figur 13a;

Figur 14 eine perspektivische Darstellung eines Trägermoduls der Brustpumpe gemäss Figur 1;

Figur 15 eine perspektivische Darstellung eines oberen Rahmenteils eines Milchsammelbehälters der Brustpumpe gemäss Figur 1;

Figur 16 einen Längsschnitt durch das obere Rahmenteil gemäss Figur 15 mit einem Behälterventil;

Figur 17 eine perspektivische Darstellung eines Gefässes des Milchsammelbehälters der Brustpumpe gemäss Figur 1;

Figur 18 eine schematische Darstellung des erfindungsgemässen Pumpsystems vor Anlegen eines Unterdrucks;

Figur 19a das schematisch dargestellte Pumpsystem gemäss Figur 1 bei der Aktivierung der Mutterbrust in einer ersten Hubposition;

Figur 19b das Pumpsystem gemäss Figur 19a in einer zweiten Hubposition;

Figur 19c eine grafische Darstellung des Drucks innerhalb einer Brusthaube beim Wechsel von der ersten Hubposition in die zweite Hubposition gemäss den Figuren 19a und 19b;

Figur 20a das Pumpsystem gemäss Figur 19a zu Beginn des Milchflusses aus der Brust in einer ersten Hubposition;

Figur 20b das Pumpsystem gemäss Figur 20a in einer zweiten Hubposition;

Figur 20c eine grafische Darstellung des Drucks innerhalb einer Brusthaube beim Wechsel von der ersten Hubposition in die zweite Hubposition gemäss den Figuren 20a und 20b;

Figur 21a das Pumpsystem gemäss Figur 19a während des kontinuierlichen Milchflusses aus der Brust in einer ersten Hubposition;

Figur 21b das Pumpsystem gemäss Figur 21a in einer zweiten Hubposition;

Figur 21c eine grafische Darstellung des Drucks innerhalb einer Brusthaube beim Wechsel von der ersten Hubposition in die zweite Hubposition gemäss den Figuren 21a und 21b;

Figur 22a das Pumpsystem gemäss Figur 19a bei Beendigung des Milchflusses in einer ersten Hubposition;

Figur 22b das Pumpsystem gemäss Figur 22a in einer zweiten Hubposition;

Figur 22c eine grafische Darstellung des Drucks innerhalb einer Brusthaube beim Wechsel von der ersten Hubposition in die zweite Hubposition gemäss den Figuren 22a und 22b;

Figur 23a das Pumpsystem gemäss Figur 19a beim Entleeren in einer ersten Hubposition;

Figur 23b das Pumpsystem gemäss Figur 23a in einer zweiten Hubposition und

Figur 23c eine grafische Darstellung des Drucks innerhalb einer Brusthaube beim Wechsel von der ersten Hubposition in die zweite Hubposition gemäss den Figuren 23a und 23b.

BESCHREIBUNG BEVORZUGTER AUSFÜHRUNGSFORMEN

In den Figuren 1 bis 17 ist ein bevorzugtes Ausführungsbeispiel der erfindungsgemässen Brustpumpe dargestellt.

Die Zusammenschau der einzelnen Bauteile

Wie in Figur 1 erkennbar ist, ist die Brustpumpe kompakt aufgebaut. Sie weist ein Pumpengehäuse 8 mit einer daran befestigten Brusthaube 2 und einem ebenfalls am Pumpengehäuse 8 befestigten Milchsammelbehälter 9 auf. Im Pumpengehäuse 8 ist ein Motor mit einem Kraftübertragungselement, beispielsweise eine Spindel, angeordnet. Im Pumpengehäuse 8 sind ferner mindestens eine elektronische Steuerung zur Steuerung des Motors, Betätigungsschalter 86 zur Betätigung der Pumpe und ein Energiespeicher vorhanden.

Die Figuren 2 und 3 zeigen eine Explosionsdarstellung dieser Brustpumpe. Sie umfasst die erwähnte Brusthaube 2 zur Aufnahme der Mutterbrust, einen Ventilkörper 3 aus einem flexiblen Material, insbesondere Silikon, ein Adapterteil 4, einen zweiteiligen Stellring 5, eine Medientrennmembran 6, eine Pumpmembran 7, ein Trägermodul 8', welches Teil des Pumpengehäuses 8 ist sowie den bereits erwähnten Milchsammelbehälter 9.

Der Milchsammelbehälter

Der Milchsammelbehälter 9 ist vorzugsweise auf der Unterseite des Pumpengehäuses 8 an dieses einklinkbar, vorzugsweise lässt es einschwenkbar lösbar befestigen. Entsprechende Einrastelement 901, 902 sind in Figur 17 erkennbar. Das Pumpengehäuse 8 weist dazu passende, jedoch hier nicht dargestellte Einrastelemente auf.

Der Milchsammelbehälter 9 weist ein Gefäss 90 mit einem Innenraum 900 zur Aufnahme der abgepumpten Milch auf (siehe Figur 17). Dieses Gefäss 90 ist oben offen ausgebildet und mit einem Deckel verschliessbar. Der Deckel umfasst ein steifes unteres Rahmenteil 91, eine steife, halbsteife oder flexible Abdeckung 92 und ein steifes oberes Rahmenteil 93. Das untere Rahmenteil 91 entspricht der Form des Umfangs der Öffnung des Gefässes 90 und liegt dichtend auf diesem auf. Das steife obere Rahmenteil 93 klemmt die Abdeckung zwischen unterem und oberen Rahmenteil 91, 93 ein. Vorzugsweise sind die zwei Rahmenteile 91, 93 miteinander verleimt, verschweisst oder auf andere Art und Weise nicht zerstörungsfrei voneinander lösbar. Die Abdeckung 92 ist eine Folie oder ein anderes membranähnliches Teil, welche luftdurchlässig aber flüssigkeitsundurchlässig ist. Somit kann Luft aus dem Gefäss 90 entweichen, jedoch keine Flüssigkeit austreten.

Das obere Rahmenteil 93 entspricht vorzugsweise ebenfalls in seiner Form der Form des Gefässes 90, insbesondere entspricht sein Rahmen 930 der Form des unteren Rahmenteils 91. Es ist in den Figuren 15 und 16 detailliert dargestellt. Im Rahmen 930 sind zur Verstärkung und als Schutz der Abdeckung 92 Streben 931 vorhanden. Ein Griff 933 erleichtert das Anheben des Deckels. Distanzstifte 934, welche auf dem Rahmen 930 angeordnet sind und diesen überragen, gewährleisten bei montiertem Milchsammelbehälter 9 einen Abstand zum Pumpengehäuse 8, so dass Luft aus dem Behälterinnenraum 900 in die Umgebung entweichen kann. Eine Ventilaufnahme 932 ist am oberen Rahmenteil 93

angeformt und bildet den einzigen Flüssigkeitszugang in den Innenraum des Gefässes 90.

In dieser Ventilaufnahme 932 ist ein Behälterventil 94 angeordnet, welches als Einwegventil ausgebildet ist. Somit kann bei geschlossenem Deckel Flüssigkeit nur in den Milchsammelbehälter 9 hinein gelangen, nicht jedoch hinaus. Das Behälterventil 94 ist vorzugsweise, wie hier dargestellt, ein Entenschnabelventil.

Das Hygienemodul

In den Figuren 6 und 7 ist ein erfindungsgemässes Hygienemodul dargestellt. Es umfasst mindestens den Stutzen 23 der Brusthabe 2, den Ventilkörper 3, das Adapterteil 4 sowie den Stellring 5. Es kann zudem, wie hier dargestellt ist, auch eine flexible Medientrennmembran 6 umfassen. Ist die Brusthaube einstückig ausgeführt, so ist sie gesamthaft Teil des Hygienemoduls.

Die genannten Teile lassen sich, wie in den Figuren 6 und 7 dargestellt, zu einer gemeinsamen Baugruppe zusammenfügen und gemeinsam im Trägermodul 8‘ lösbar befestigen. Hierfür ist der Stutzen 23 der Brusthaube 2 vorzugsweise form- und kraftschlüssig in entsprechende Aufnahmen, hier zwei einander gegenüberliegende Seitenarme 80, des Trägermoduls 8‘ befestigbar. Vorzugsweise erfolgt die Verbindung über einen Bajonettverschluss, wie hier dargestellt ist. Der Stutzen 23 weist einen entsprechenden Flansch 22 auf, die Seitenarme 80 des Trägermoduls 8‘ entsprechende Aufnahmen für den Flansch und die übrigen Elemente des Bajonettverschlusses.

Dank der Befestigung der Brusthaube am Trägermodul 8‘ und somit am Pumpengehäuse 8 sind auch die dazwischenliegenden Teile, d.h. der Ventilkörper 3, das Adapterteil 4 und die Medientrennmembran 6 des Hygienemoduls sowie die Pumpmembran 7 miteinander dicht verbunden.

Der Stellring 5 ist vorzugsweise nicht zerstörungsfrei lösbar auf dem Adapterteil 4 befestigt, wobei er relativ zu diesem um die Längsmittelachse des Hygienemoduls schwenkbar ist.

Im Folgenden werden die einzelnen Teile der Vorrichtung und deren Zusammenwirken beschrieben.

Die Brusthaube

In den Figuren 8a und 8b ist die Brusthaube 2 dargestellt. Sie dient zur Aufnahme der Mutterbrust. Sie weist einen Trichter 20 zur Auflage auf die Mutterbrust und einen Innenraum 200 auf, welcher mit einem sich zyklisch ändernden Unterdruck beaufschlagbar ist und in welchem die Mutterbrust oder zumindest die Brustwarze aufgenommen wird.

Die Brusthaube ist vorzugsweise einstückig und vorzugsweise aus einem steifen oder halbsteifen Kunststoff gefertigt. Sie kann jedoch auch mehrteilig ausgeführt sein. Sie kann zudem mit einem weichen Liner verwendet werden, z.B. mit einem Brusthaubeneinsatz aus einem weichen Silikon.

Der Trichter 20 folgt ein Stutzen 23 mit einem mindestens teilweise umlaufenden Flansch 22, welcher einen Teil des genannten Bajonettverschlusses bildet. Der Innenraum 200 geht auf der brustabgewandten Seite des Stutzens 23 in eine Durchgangsöffnung 21 über, welche einen in der Mittellängsachse verlaufenden Kanal bildet. Am Stutzen 23, auf der brustabgewandten Seite des Flansches 22 ist, ist auf zwei diametral gegenüberliegenden Seiten je eine Vertiefung vorhanden.

In der ersten Vertiefung ist eine erste Auslassöffnung 24 sowie eine winkelförmige erste Durchflussöffnung 25 vorhanden. Die erste Auslassöffnung 24 führt vom Innenraum 200 zur Aussenseite des Stutzens 23, genauer in die erste Vertiefung. Die erste Durchflussöffnung 25 führt von dieser ersten Vertiefung in einem vorzugsweise rechtwinkligen Kanal zur brustabgewandten freien Stirnfläche des Stutzens 23. Auf dem Umfang des Stutzens 23 ist neben der ersten Auslassöffnung 24, aber jedoch ausserhalb der ersten Vertiefung, eine Belüftungsöffnung 26 vorhanden. Diese führt vom Innenraum 200 nach aussen.

Auf der diametral gegenüberliegenden Seite des Stutzens 23 ist eine analoge zweite Vertiefung mit einer zweiten Auslassöffnung 27 und einer zweiten Durchlassöffnung 28 vorhanden, welche gleich ausgebildet sind wie die ersten Öffnungen. Des Weiteren ist

ebenfalls ausserhalb der zweiten Vertiefung und neben der zweiten Auslassöffnung 27 eine zweite Belüftungsöffnung 29 vorhanden. Diese zweite Lüftungsöffnung 29 hat eigentlich keine Funktion sondern ist bei bestimmungsgemässen Gebrauch der Vorrichtung verschlossen. Damit die Brusthaube 2 jedoch in um 180° gedrehter Position ebenfalls am Trägermodul 8' montiert werden kann, sind alle Öffnungen symmetrisch angeordnet.

Der Ventilkörper

Die Figuren 9a bis 9d zeigen den Ventilkörper 3. Der Ventilkörper 3 ist aus einem flexiblen Material, vorzugsweise aus Silikon, gefertigt. Er ist vorzugsweise einstückig ausgebildet. Er weist einen hohlzylinderförmigen Grundkörper 30 mit einer Rückwand 31 auf. In der Rückwand befindet sich zentral eine Durchgangsöffnung 32. Die Rückwand 31 weist auf der brustabgewandten Seite eine die Durchgangsöffnung 32 ringförmig umlaufende Rille 312 auf, welche auf der gegenüberliegenden, brustnahen Seite eine Dichtfläche 310 bildet. Der umlaufende Rand der Durchgangsöffnung 32 ist auf der brustabgewandten Seite mit einer umlaufenden Dichtlippe 311 versehen (siehe Figuren 9b und 9c). Der Bereich der Rückwand 31 innerhalb der umlaufenden Dichtfläche 310 bildet somit ein Ventil, welches wie weiter unten erläutert ist, als Basisvakuum-Ventil dient.

Der Grundkörper 30 weist auf der brustzugewandten Seite eine radial abstehende Positioniernase 33 auf. Am Mantel des Grundkörpers 3 ist eine erste Noppe 34 sowie eine Belüftungsnoppe 35 vorhanden. Diametral gegenüberliegend befindet sich eine zweite Noppe 36. Die drei Noppen stehen radial nach aussen vor. Die erste Noppe 34 und die zweite Noppe 36 sind massiv, d.h. nicht hohl, ausgebildet. Die Belüftungsnoppe 35 weist eine Durchgangsöffnung vom Innenraum des Grundkörpers 30 nach aussen auf.

Im Ringbereich der Rückwand 31 zwischen Dichtungsfläche 310 und Mantel des Grundkörpers 30 sind einander ebenfalls diametral gegenüber liegende Ventilklappen vorhanden. Eine erste dieser Ventilklappen ist mit dem Bezugszeichen 37 versehen, eine zweite dieser Ventilklappen mit dem Bezugszeichen 38. Sie befinden sich vorzugsweise auf derselben Diagonalen wie die erste und der zweite Noppe 34, 36.

Der Stellring

Die Figuren 10a und 10b zeigen den Stellring 5. Er ist vorzugsweise steif und

vorzugsweise aus Kunststoff ausgebildet. Der Stellring 5 besteht vorzugsweise aus zwei Teilen. Ein erstes Teil 50 weist die Form eines halben Ringes auf und ist an beiden freien Enden mit einem ersten Steckerteil 51 versehen. Der zweite Teil 52 weist ebenfalls die Form eines halben Ringes auf und ist an seinen freien Enden mit je einem zweiten Steckerteil 53 versehen. Der erste und zwei Teil 50, 52 bilden einen gemeinsamen Ring und die zwei Steckerteil-Paare 51, 53 sind mit Einrastelementen 54 versehen, um sich vorzugsweise unlösbar miteinander zu verbinden. Am inneren Umfang des Rings ist ein teilweise umlaufender, nach innen radial vorstehender Anschlag 55 vorhanden, welcher nach erfolgter Montage auf dem Adapterteil 4 ein erneutes Entfernen des Stellrings 5 verhindert. An der innere Wandung des Stellrings ist ein erstes und ein zweites Anpresselement 56, 57 angeformt. Diese sind vorzugsweise radial nach innen vorstehende Erhöhungen, welche über eine Schrägfläche, auch Rampe genannt, in einen parallel zur Ringinnenfläche verlaufende Fläche übergehen. Am ersten Teil 50 ist ein nach assen vorstehender Betätigungshebel 58 angeformt.

Das Adapterteil

Die Figuren 11a bis 11c zeigen das Adapterteil 4. Es besteht vorzugsweise aus einem steifen Material, vorzugsweise aus Kunststoff. Es weist einen hohlzylinderförmigen Grundkörper 40 mit einer im Wesentlichen geschlossenen, flanschartigen pumpenseitigen Wand 41 auf. Der Grundkörper 40 weist in seinem Mantel ein erstes Fenster 400 und ein diametral gegenüberliegendes zweites Fenster 401 auf. An der brusthaubennahen Stirnfläche des Grundkörpers 40 ist eine Positionierhilfe 402 vorhanden, welche das Gegenstück zur Positioniernase 33 des Ventilkörpers 3 bildet und welche gemeinsam mit der Positioniernase 33 der drehsicheren Positionierung des Ventilkörpers 3 dient.

Die pumpenseitige Wand 40 verlängert sich in einer Richtung, welche hier als unten bezeichnet wird, in eine Kanalwand 410. Die pumpenseitige Wand weist ferner einen erhöhten zentralen Wandteil 42 auf, welcher in den brusthaubennahen Bereich ragt. Auf der gegenüberliegenden Seite des Wandteils 42, also dem Pumpengehäuse zugewandt, ist somit eine konkave Fläche ausgebildet, welche die bereits genannte steife Schale bildet und einen Teil der Pumpkammer 47 ist.

Zwischen dem erhöhten Wandteil 42 und Mantel des Grundkörpers 40 ist in der

pumpenseitigen Wand 41 eine erste Durchgangsöffnung 43 und eine zweite Durchgangsöffnung 44 vorhanden. Die zwei Durchgangsöffnungen 43, 44 liegen einander diametral gegenüber. Sie sind in diesem Beispiel kreisförmig ausgebildet. Im Randbereich des erhöhten Wandteils 42, jedoch bereits auf seiner Erhöhung, sind eine erste Rückspülöffnung 45 und eine zweite Rückspülöffnung 46 vorhanden. Diese sind vorzugsweise länglich ausgebildet. Diese Öffnungen führen alle in die Pumpkammer 47.

Wie in Figur 11c zu erkennen ist, ist die konkave Schale der Pumpkammer 47 von einem umlaufenden planen Rand umgeben, welche als Dichtfläche dient. In diesem Rand verläuft eine Rinne 48, welcher vorzugsweise an einem obersten Punkt der Pumpkammer 47 beginnt und mit dieser über eine Auslassöffnung 480 in fluidkommunizierender Verbindung steht. Der Kanal 48 verläuft entlang des Umfangs der Pumpkammer 47, hier teilkreisförmig, nach unten zu einem Auslass 49 hin. Der Auslass 49 befindet sich in der Kanalwand 410.

Die Medientrennmembran

In den Figuren 12a bis 12c ist die Medientrennmembran 6 dargestellt. Sie ist flexibel ausgebildet, ist vorzugsweise einstückig und vorzugsweise aus Silikon gefertigt. Sie weist eine Membranfläche 60 auf, welche vorzugsweise in bekannter Weise mit mindestens einer ringförmigen Rille versehen ist. Ein Zentralbereich 61 der Membranfläche ist vorzugsweise erhöht ausgebildet und dem Adapterteil 4 zugewandt. Der Rand der Membranfläche 60 ist als Dichtfläche 62 ausgebildet und liegt dichtend am Rand des Adapterteils 4 an, wodurch die Pumpkammer 47 gebildet wird. Eine Rinne 63 verläuft innerhalb der Dichtfläche 62 entlang des Umfangs der Medientrennmembran 6 und bildet den dichtenden Verschluss der Rinne 48 des Adapterteils 4. Eine dem Pumpengehäuse zugewandte Vertiefung 64 im unteren Bereich der Medientrennmembran 6 dient als Freiraum für einen Drucksensor, welcher nachfolgend noch beschrieben ist.

Die Medientrennmembran 6 weist vorzugsweise, wie in den Figuren dargestellt ist, Versteifungen in Form von Rippen auf, welche die Funktionsweise der Medientrennmembran sicherstellen. D.h. die Rippen gewährleisten, dass sich die Membran in gewünschter Art und Weise bewegt und trotzdem stets dichtend an ihren benachbarten Teilen anliegt.

Die Pumpmembran

In den Figuren 13a bis 13c ist die Pumpmembran 7 dargestellt. Auch sie weist eine Membranfläche 70 sowie einen Zentralbereich 71 auf. Im Gegensatz zur vollflächigen Medientrennmembran 6 ist der Zentralbereich 71 der Pumpmembran 7 mit einer Durchgangsöffnung72 versehen, deren Randbereich vorzugsweise eine Verstärkung 73, hier in Form von Rippen, aufweist. Es ist wiederum eine umlaufende Dichtfläche 74 vorhanden, welche im zusammengesetzten Zustand der Vorrichtung dichtend auf der entsprechenden Fläche des Trägermoduls 8' anliegt. Ausserhalb der Dichtfläche 74 befinden sich Seitenflügel 77. Die Seitenflügel 77 bilden zusammen mit der umlaufenden planen Dichtfläche 74 (Figur 13b) im zusammengebauten Zustand eine dichte Barriere gegenüber von aussen einwirkenden Flüssigkeiten und schützen somit die Elektronik.

Der untere Bereich der Pumpmembran 7, welcher sich jedoch noch innerhalb der geschlossenen umlaufenden Dichtfläche 74 befindet, ist als Drucksensor ausgebildet. Der Drucksensor umfasst eine Sensorfläche 75 in Form einer Membran, welche über einen Verbindungssteg mit der Membranfläche 70 verbunden ist, und einer Fahne 76, welche der Sensorfläche senkrecht in Richtung Pumpengehäuse vorsteht. Diese Art Drucksensor ist in WO 2013/049944 A1 beschrieben.

Wie in den Figuren erkennbar ist, weisen die Medientrennmembran 6 und die Pumpmembran 7 ähnliche Formen auf, insbesondere bezüglich ihrer zur Erzeugung des Unterdrucks bewegbaren Bereiche.

Das Trägermodul

Das Trägermodul 8' ist in Figur 14 dargestellt. Es ist in einem Aussengehäuse des Pumpengehäuses gehalten. Das Aussengehäuse ist in Figur 1 sichtbar. Vorzugsweise ist das Trägermodul 8' in diesem Aussengehäuse verschraubt. Die entsprechenden Befestigungslöcher sind mit dem Bezugszeichen 84 versehen. Das Trägermodul lässt sich einstückig aus Kunststoff herstellen. Es kann jedoch auch mehrteilig und/oder aus einem anderen Material gefertigt sein. Das Trägermodul 8' weist zwei vorstehende Seitenarme 10 mit einem Bajonettverschluss zur Aufnahme der Brusthaube 2 auf. Die Seitenarme sind seitlich an einer Spindelaufnahme 82 angeordnet. Die Spindelaufnahme 82 weist ein

Durchgangsöffnung auf sowie einen umlaufenden Rand 85, welcher das Gegenstück zur Dichtfläche 74 der Pumpmembran 7 bildet. Auf der Spindelaufnahme 82 ist eine Motoraufnahme 81 in Form einer Schale ausgebildet. Die Motoraufnahme 81 dient der Halterung eines Elektromotors, welcher mit einer Spindel 83 (siehe Figur 4) verbunden ist.

Wirkungsweise der zusammengesetzten Baugruppe

Anhand der Figur 6 lässt sich erkennen, wie die einzelnen Öffnungen und Ventile zusammenwirken.

Der Ventilkörper 3 lässt sich in den hohlzylindrischen Grundkörper 40 des Adapterteils 4 drehpositioniert einführen. Der Stellring 5 ist dabei bereits unlösbar mit dem Adapterteil 4 verbunden, wobei das erste Anpresselement 56 durch das erste Fenster 400 nach innen ragt und das zweite Anpresselement 57 durch das zweite Fenster 401 nach innen ragt. Die erste Noppe 34 des Ventilkörpers 3 befindet sich dabei unterhalb des ersten Fensters 400 und die zweite Noppe 36 oberhalb des ersten Fensters 401. Die Ventilklappen 37, 38 des Ventilkörpers 3 befinden sich jeweils über der ersten bzw. der zweiten Durchgangsöffnung 43, 44 des Adapterteils. Die Dichtlippe 311 liegt dichtend auf dem erhöhten Wandteil 42 auf, wobei die erste und zweite Rückspülöffnung in einem dichten Ringbereich zwischen Rille 312 und Dichtlippe 311 angeordnet sind.

Wird nun die Brusthaube 2 eingesetzt, so liegt die erste Noppe 34 über der ersten Auslassöffnung 24 und die Belüftungsnoppe 35 liegt über der ersten Belüftungsöffnung 26. Die zweite Noppe 36 liegt über der zweiten Auslassöffnung 27. Die zweite Belüftungsöffnung 29 ist vom Mantel des Ventilkörpers 4 überdeckt und somit verschlossen.

Wird nun die Brusthaube 2 mit dem Trägermodul 8‘ verbunden, so werden die einzelnen Verbindungen zwischen den beschriebenen Kanälen und Öffnungen erstellt und gegenüber aussen gedichtet.

In den Figuren 4 und 5 ist die erfindungsgemässe Brustpumpe im zusammen gesetzten Zustand dargestellt. Wie gut erkennbar ist, weist dieses System praktisch keinen Totraum auf.

In Figur 4 ist die Spindel 83 erkennbar, welche die Pumpmembran 7 antreibt. Die Medientrennmembran 6 hat eine Form, welche sich der Pumpmembran 7 anschmiegt, so dass sich beide Membrane 6, 7 gemeinsam bewegen und auch hier keine Verluste auftreten. Das Pumpengehäuse 8, genauer das Trägermodul 8' weist eine Rückwand 85 auf, an welcher die Pumpmembran 7 dichtend anliegt, wenn das Hygienemodul am Trägermodul 8' befestigt ist. Dies ist in den Figuren 4 und 5 gut erkennbar. Der Stellring 5 ist schwenkbar innerhalb der Seitenarme 80 angeordnet, wobei der Betätigungshebel 58 auch als Anzeigeelement dient. Er bewegt sich entlang einer Anzeige 87, welche am Pumpengehäuse 8 angebracht ist und welche dem Benutzer somit Auskunft über die Stellung einzelner Ventile gibt und somit den Betriebszustand der Pumpe gibt. D.h. es wird angezeigt, ob die Pumpe betriebsbereit zum Abpumpen ist oder sich im Entleerungszustand befindet. Dies wird nachfolgend erläutert.

Durch Drehen des Stellrings 5 lassen sich einzelne Ventile manuell öffnen und schliessen. Genauer lassen sich die erste Auslassöffnung 24 gemeinsam mit der ersten Durchflussöffnung 25 alternativ zur zweiten Auslassöffnung 27 gemeinsam mit der zweiten Durchflussöffnung 28 manuell öffnen und schliessen. Die erste Belüftungsöffnung 26 wird gemeinsam mit der zweiten Auslassöffnung 27 und der zweiten Durchflussöffnung 28 geöffnet und geschlossen. Die zweite Belüftungsöffnung 29 bleibt aufgrund ihrer Position innerhalb des Ventilkörpers 3 stets geschlossen.

Ist die Brusthaube 2 derart relativ zum Ventilkörper 3 positioniert, dass die zweiten Öffnungen an der Position der ersten Öffnungen liegen, wird selbstverständlich die zweite anstelle der ersten Belüftungsöffnung geöffnet und geschlossen.

In einer ersten Stellung, die zu Beginn des Abpumpvorgangs und während des gesamten Abpumpvorgangs gewählt ist, wird die zweite Noppe 36 des Ventilkörpers 3 durch das zweite Anpresselement 57 des Stellrings nach unten gedrückt und liegt auf der Vertiefung und somit der zweiten Auslassöffnung 27 und der zweiten Durchflussöffnung 28 der Brusthaube 2 auf. Zudem wird die Belüftungsnoppe 35 durch das erste Anpresselement 56 auf die erste Belüftungsöffnung 26 gedrückt und verschliesst diese. Die erste Noppe 34 des Ventilkörpers 3 ist hingegen freigeben, so dass die erste Auslassöffnung 24 und die erste

Durchflussöffnung 25 einen fluidkommunizierenden Kanal vom Innenraum 200 der Brusthaube in den Grundkörper 30 des Ventilkörpers 3 bilden. Dies ist am besten in den Figuren 2, 3 und 6 erkennbar.

In einer zweiten Stellung wird der Stellring 5 gedreht. Das erste Anpresselement 56 gibt die Belüftungsnoppe 35 und somit die erste Belüftungsöffnung 26 frei, presst hingegen die erste Noppe 34 auf die Vertiefung und verschliesst somit die erste Auslassöffnung 24 und die erste Durchflussöffnung 25. Das zweite Anpresselement 57 gibt zudem die zweite Noppe 36 frei, so dass nun die zweite Auslassöffnung 27 und die zweite Durchflussöffnung 28 einen offenen, durchgehenden Kanal vom Innenraum 200 der Brusthaube 2 in den Ventilkörper 3 bilden. Die zweite Auslassöffnung 27 und die zweite Durchflussöffnung 28 bilden einen Entleerungskanal, welcher weiter unten noch genauer beschrieben wird.

Das gegenseitige Öffnen und Schliessen erfolgt vorzugsweise gleichzeitig. Es ist jedoch auch möglich, die Anpresselemente so versetzt anzuordnen, dass in einem Zwischenzustand alle Öffnungen verschlossen sind.

Abpumpen der Muttermilch und Entleerungsvorgang

Damit Milch von der Mutterbrust abgepumpt werden kann, wird der Betätigungshebel 58 und somit der Stellring 5 in die erwähnte erste Stellung gebracht. Mittels des Antriebs wird die Pumpmembran 7 gemeinsam mit der Medientrennmembran 6 zum Adapterteil 4 hin und zurückbewegt, so dass in der Pumpkammer 47 und im Innenraum 200 der Brusthaube 2 ein Unterdruck entsteht. Die Vakuumleitung von der Pumpkammer 47 in den Innentraum 200 der Brusthaube 2 ist dabei gebildet durch die erste Durchgangsöffnung 43 im Adapterteil 4, die Öffnung im Ventilkörper 3 bedeckt durch die erste Ventilklappe 37 sowie den Kanal gebildet durch die erste Durchflussöffnung 25 und die erste Auslassöffnung 24 in der Brusthaube.

Das Basisvakuumventil, unter anderem gebildet durch die Dichtlippe 311 des Ventilkörpers 3, ermöglicht die Erhaltung eines Basisunterdrucks im Innenraum 200 der Brusthaube 2, wenn der Pumphub in Richtung Atmosphärendruck verläuft. Das Basisvakuumventil öffnet sich beim Pumphub in Richtung Atmosphärendruck und

schliesst erst bei Erreichen eines vorgegebenen Minimaldrucks im Innenraum 200. Die Wirkungsweise wird weiter unten anhand eines Schemas nochmals genauer erläutert. Der Rückfluss der Luft in die Brusthaube 2 erfolgt über die erste und zweite Rückspülöffnung 45, 46, des Adapterteils 4, die Durchgangsöffnung 32 des Ventilkörpers 3 und die Durchgangsöffnung 21 der Brusthaube 2.

Durch Anlegen dieses Vakuums an die Mutterbrust wird diese stimuliert und Milch fliesst aus der Brust in den Innenraum 200 der Brusthaube 2. Der Innenraum 200 füllt sich, bis der Füllstand der Milch die erste Auslassöffnung 24 erreicht. Die Brusthaube 2 wird dabei vorzugsweise so gehalten, dass sich diese erste Auslassöffnung 24 in einem oberen Bereich der Brusthaube 2 befindet.

Die abgepumpte Milch fliesst dann durch den Kanal, gebildet durch die erste Auslassöffnung 24 und die erste Durchlassöffnung 25, und durch die von der ersten Ventilklappe 37 bedeckten Öffnung in das Adapterteil 4, wo sie durch die erste Durchgangsöffnung 43 in die Pumpammer 47 gelangt.

Die Pumpkammer 47 füllt sich ebenfalls mit Milch, bis die oben angeordnete Auslassöffnung 480 erreicht ist. Die Milch fliesst anschliessend durch den Kanal, gebildet durch die Rinne 48 des Adapterteils 4 und der Rinne 63 bzw. der Abdeckung der Medientrennmembran 6 durch den Auslass 49 aus dem Hygienemodul heraus und durch das Behälterventil 94 in den Milchsammelbehälter 9.

Wenn der Pumphub jeweils von Erzeugung eines Unterdrucks in Richtung Atmosphärendruck, so öffnet sich zuerst das Basisvakuum-Ventil und ermöglicht einen Teilrückfluss der Luft bzw. der Milch Innenraum 200. Dieser Teilrückfluss erfolgt durch die erste und zweite Rückspülöffnung 45, 46, das offene Basisvakuumventil, die Durchgangsöffnung 32 und die Durchgangsöffnung 21. Das Ventil schliesst sich bei einem bestimmten Vakuumwert im Innenraum, so dass der Druck nicht weiter Richtung Atmosphärendruck ansteigen kann.

Wenn die Mutter das Abpumpen der Milch beenden will bzw. wenn keine Milch mehr aus der Brust fliesst, so schwenkt sie den Stellring 5 in die zweite Stellung. Der bisher benützte

Vakuum- und Milchkanal wird verschlossen, indem die erste Auslassöffnung 24 und die erste Durchlassöffnung 25 verschlossen werden. Dabei öffnen sich jedoch die zweite Auslassöffnung 27, die zweite Durchlassöffnung 28 und die erste Belüftungsöffnung 26. Diese Umstellung kann bei laufender Pumpe, d.h. bei nach wie vor angetriebener Pumpmembran 7, erfolgen. Die Pumpe kann hierfür auch abgestellt und anschliessend wieder in Betrieb genommen werden. Da die Pumpe nun weiter saugt, wird die sich noch im Innenraum 200 der Brusthaube 2 befindliche, bereits aus der Mutterbrust abgepumpte Milch durch die zweite Auslössöffnung 27, die zweite Durchlassöffnung 28, die durch die zweite Ventilklappe 37 verdeckte Öffnung des Ventilkörpers 3 und die zweite Durchgangsöffnung 44 des Adapterteils 4 in die Pumpkammer 47 gepumpt. Von dort wird sie durch die Bewegung der Pumpmembran 7 und der Medientrennmembran 6 aus der Pumpkammer 47 in Richtung Auslassöffnung 480 verdrängt. Sie fliesst somit ebenfalls durch die Rinne 48 und den Auslass 49 in den Milchsammelbehälter 9. Auf diese Weise lassen sich sowohl der Innenraum 200 der Brusthaube 2 wie auch die Pumpkammer 47 annähernd vollständig entleeren. Die Vorrichtung lässt sich zudem in eine Schräglage bringen, um die gesamte Milch aus dem System in den Milchsammelbehälter 9 zu entleeren.

Zu beachten ist, dass zu Beginn des Abpumpvorgangs die Brustpumpe vorzugsweise so gehalten wird, dass sich die erste Auslassöffnung 24 der Brusthaube und die Auslassöffnung 480 der Pumpkammer 47 in einem oberen Bereich des jeweiligen Hohlraums befinden. Dadurch kann Luft aus dem System entweichen und die zwei Hohlkammern werden relativ schnell mit Milch gefüllt. Dies ermöglicht ein möglichst rasches Wechseln von einem rein pneumatischen Pumpsystem mit Luft als Arbeitsfluid in ein reines oder mehrheitliches hydraulisches Pumpsystem, in welchem Milch das Arbeitsfluid bildet oder zumindest einen grossen Anteil des Arbeitsfluids bildet. Es ist jedoch nicht zwingend notwendig, dass die Öffnungen zu Beginn des Abpumpvorgangs derart angeordnet sind. Der Wechsel von einem Pumpsystem in das andere benötigt einfach längere Zeit und/oder kann nicht vollständig vollzogen werden.

Sobald die Milch den Innenraum 200 und die Pumpkammer 47 teilweise geflutet hat, vorzugsweise bis zu den genannten Öffnungen, kann die Brustpumpe in eine beliebige Position gebracht werden. Dies gilt nicht nur für die Brusthaube 2 und die Pumpkammer

47, sondern insbesondere auch für den Milchsammelbehälter 9. Dank des als Rückschlagventil ausgebildeten Behälterventils 94 und dank der flüssigkeitsundurchlässigen Abdeckung 92 kann der Milchsammelbehälter 9 sogar auf den Kopf gestellt werden, ohne den Betrieb der Brustpumpe zu beeinträchtigen.

In bevorzugten Ausführungsformen ist die Brusthaube und auch der Stellring beleuchtet, damit die Mutter auch in der Nacht während des Abpumpens eine Sichtkontrolle durchführen kann.

Die oben beschriebene Brustpumpe ist lediglich ein Ausführungsbeispiel, in welcher das erfindungsgemässe Prinzip umgesetzt und das erfindungsgemässe Verfahren angewendet werden kann. In den Figuren 18 bis 23c ist deshalb nochmals schematisch dargestellt, worin der Kern der erfindungsgemässen Ideen liegt.

Grundprinzip

In Figur 1 ist schematisch die Brusthaube 2 mit dem Innenraum 200 dargestellt. Die Brusthaube 2 ist dichtend auf eine Mutterbrust angelegt, die Brustwarze W ragt den Innenraum 200 hinein. Der Innenraum 200 ist über eine Auslassöffnung 16 mit einer Pumpkammer 47 verbunden. Eine zusätzliche Entleerungsöffnung19 führt ebenfalls vom Innenraum 200 zur Pumpkammer 47. Die Auslassöffnung 16 ist mit einem Pumpventil 12 versehen, die Entleerungsöffnung mit einem Entleerungsventil 14. Ein Basisvakuumventil 13 schliesst eine dritte Öffnung 17 zwischen Vakuumkammer 47 und Innenraum 200 der Brusthaube 2. Eine mit einem Belüftungsventil 11 verschliessbare Belüftungsöffnung 15 führt zudem vom Innenraum 200 der Brusthaube 2 nach aussen.

Das Volumen der Pumpkammer 47 ist mittels eines Pumpmittels 10, beispielsweise einer Pumpmembran oder einem Kolben, veränderbar. Das Pumpmittel 10 ist angetrieben, beispielsweise mittels einer Spindel 100.

Von der Pumpkammer 47 führt eine Auslassöffnung 480 in einen Milchsammelbehälter 9. Der Einlass in den Milchsammelbehälter 9 ist vorzugsweise mit einem Rückschlagventil, hier Behälterventil 94 genannt, versehen. Der Milchsammelbehälter 9 ist belüftet,

vorzugsweise ist hierfür ein Einlass 95 mit einem Einlassventil 96 vorhanden.

Der Vergleich mit dem oben ausführlich beschriebenen Ausführungsbeispiel zeigt, dass die Belüftungsöffnung 15 und das Belüftungsventil 11 der ersten Belüftungsöffnung 26, der Belüftungsnoppe 35 und dem ersten Anpresselement 56 entsprechen.

Die Auslassöffnung 16 und das Basisvakuumventil 12 der schematischen Darstellung entsprechen der ersten Auslassöffnung 24, der ersten Durchflussöffnung 25, der erste Noppe 34, dem ersten Anpresselement 56 sowie der ersten Ventilklappe 37 des konkreten Ausführungsbeispiels.

Die Entleerungsöffnung 19 und das Entleerungsventil 14 der schematischen Darstellung entsprechen der zweiten Auslassöffnung 27, der zweiten Durchflussöffnung 28, der zweiten Noppe 36, dem zweiten Anpresselement 57 sowie der zweiten Ventilklappe 38 des konkreten Ausführungsbeispiels.

Die Basisvakuumventil 13 sowie die dritte Öffnung 17 der schematischen Darstellung entsprechen der Dichtlippe 311, der ersten und zweiten Rückspülöffnung 45, 46 sowie der Durchgangsöffnung 32 im Ventilkörper 3 des konkreten Ausführungsbeispiels.

Das Behälterventil 94 der schematischen Darstellung entspricht dem Behälterventil des konkreten Ausführungsbeispiels.

Der Einlass 95 und das Einlassventil 96 der schematischen Darstellung sind in dem oben beschriebenen konkreten Ausführungsbeispiel durch die luftdurchlässige und flüssigkeitsundurchlässige Abdeckung, d.h. durch eine entsprechend gewählte Abdeckfolie, gebildet.

Diese Ventile lassen sich auch auf andere Art und Weise verwirklichen. Die Ventilöffnungen können auch in einem zusätzlichen Modulteil untergebracht sein, welches mit der Brusthaube lösbar verbunden ist. Zudem können die Auslassöffnung 16 und/oder die Entleerungsöffnung 19 als Kanal ausgebildet sein, welcher in einer Leitung, insbesondere einer flexiblen Leitung verläuft. Je nach Ausbildung dieser Leitung kann die

Pumpkammer beabstandet zur Brusthaube und je nach Ausführungsform auch beabstandet zu einem Ventilmodul angeordnet sein. Die Ventile lassen sich vorzugsweise in einem Modul unterbringen, welches zwischen Pumpkammer und Brusthaubentrichter angeordnet ist. Ist die Pumpkammer beabstandet zur Brusthaube angeordnet, so kann das Ventilmodul benachbart zur Pumpkammer oder benachbart zur Brusthaube angeordnet sein bzw. ein Bestandteil der Brusthaube sein.

Im Folgenden wird die Funktionsweise erläutert:

In der Darstellung gemäss Figur 18 ist die Pumpe noch nicht eingeschaltet. Die Ventile sind bis auf das Einlassventil 96 des Milchsammelbehälters 9 geschlossen. In allen Bereichen herrscht Atmosphärendruck, d.h. p=0.

In der Darstellung gemäss den Figuren 19a bis 19c beginnt der Pumpvorgang und die Mutterbrust wird durch den angelegten Unterdruck stimuliert. Das Pumpventil 12 kann sich öffnen und schliessen. Im konkreten Ausführungsbeispiel ist hierfür die erste Auslassöffnung 24 und die erste Durchflussöffnung 25 freigegeben und die erste Ventilklappe 37 öffnet und schliesst das Ventil. Das Entleerungsventil 14 ist fest verschlossen. Im konkreten Ausführungsbeispiel erfolgt dies, indem der Stellring 5 in die entsprechende Position gebracht wird und die zweite Auslassöffnung 27 und die zweite Durchflussöffnung 28 fest verschliesst. Ebenso bleibt das Belüftungsventil 11 fest verschlossen. Im konkreten Ausführungsbeispiel wird dies erreicht, indem mittels des Stellrings 5 die erste Noppe 34 die erste Belüftungsöffnung 26 verschliesst.

Das Pumpmittel 10, vorzugsweise eine Pumpmembran oder ein Kolben, wird nach aussen gezogen, um einen Unterdruck in der Pumpkammer 47 zu erzeugen (hier z.B. -150 mmHg). Das Pumpventil 12 öffnet sich und der Unterdruck wird in den Innenraum 200 der Brusthaube 2 übertragen, bzw. Luft strömt aus diesem Innenraum in die Pumpkammer 47. Auch im Innenraum herrscht somit ein Unterdruck, optimalerweise derselbe Druck von beispielsweise -150 mmHg. Der Druckverlauf im Innenraum 200 ist in Figur 19c dargestellt. Der Druck gemäss Bezugszeichen a) entspricht dem Druck im Innenraum 200 gemäss Figur 19a. Das Behälterventil 94 bleibt geschlossen. Der Druck im Milchsammelbehälter 9 beträgt nach wie vor Atmosphärendruck, d.h. p=0.

Wird das Pumpmittel 10 nun zurückgeschoben und die Pumpkammer 47 im Volumen verkleinert, so schliesst sich das Pumpventil 12 und der Druck in der Pumpkammer 47 erhöht sich bis zum Atmosphärendruck p=0. Der Druck im Innenraum 200 steigt aufgrund des nun geöffneten Basisvakuumventils 13 ebenfalls an. Da sich das Basisvakuumventil 13 jedoch bei einem bestimmten Unterdruck schliesst, wird ein Basisvakuum im Innenraum 200 beibehalten. Dieser liegt beispielsweise bei -20 mmHg. Diese Situation ist in Figur 19b gezeigt und der Druckverlauf in Figur 19c mit b) bezeichnet.

Durch Vergleich der Figuren 19a und 19b zeigt sich auch, wie sich die Brustwarze W im Innenraum 200 dehnt und wieder zusammenzieht.

In den Figuren 20a bis 20c hat der Milchfluss aus der Mutterbrust begonnen. Die Milch ist in den Figuren mit dem Bezugszeichen M versehen. Der Innenraum 200 der Brusthaube 2 füllt sich mit abgepumpter Milch. Es entsteht ein Milchsee unterhalb des Pumpventils 12. Dank der nun vorhandenen Milch erhöht sich die Pumpleistung bei gleichbleibender Antriebsleistung, beispielsweise auf -170 mmHg in der Pumpkammer 47 und dem Innenraum 200. Nach wie vor öffnet und schliessen sich bei jedem Pumphub das Pumpventil 12 und das Basisvakuumventil 13, wobei das Entleerungsventil 14 und das Belüftungsventil 11 geschlossen bleiben. Figur 20a zeigt die Situation bei maximalem Unterdruck (absoluter Wert), welcher auch mit a) in Figur 20c gekennzeichnet ist. Figur 20b zeigt die Situation bei Beibehaltung des Basisunterdrucks im Innenraum 200 und Atmosphärendruck in der Pumpkammer 47, was in Figur 20c mit b) gekennzeichnet ist.

Sobald sich der Innenraum 200 mit Milch M bis zur Auslassöffnungen 16 gefüllt hat, fliesst Milch M durch das Pumpventil 12 in die Vakuumkammer 47. Die abgepumpte Milch M füllt nun auch die Vakuumkammer 47 bis ihr Füllstand die Auslassöffnung 480 zum Milchsammelbehälter 9 erreicht. Nun öffnet sich das Behälterventil 94, vorzugsweise auf Grund des Drucks der angesammelten Milch M und Milch M fliesst in den Milchsammelbehälter 9.

Die Figuren 21a bis 21c zeigen die Situation, in welcher sich optimalerweise keine Luft mehr im System befindet und das ursprüngliche pneumatische System vollständig auf ein

hydraulisches System gewechselt hat. In der Praxis ist oft ein gemischtes System vorhanden, wobei die abgepumpte Milch vorzugsweise einen wesentlichen Teil der Volumina füllt und somit das Hauptarbeitsfluid bildet.

Wie bereits anhand der Figuren 19a bis 19c erläutert, öffnen und schliessen sich das Pumpventil 12 und das Basisvakuumventil 13 nach Massgabe des Pumphubs, so dass ein Unterdruck im Innenraum 200 erzeugt und eine Basisunterdruck beibehalten werden kann. Der Druck in der Vakuumkammer 47 wechselt dabei beispielsweise zwischen -250 mmHg und 0 mmHg, der Druck im Innenraum zwischen -250 mmHg und -20 mmHg. Der Druck im Milchsammelbehälter 9 bleibt bei Atmosphärendruck, also bei 0 mmHg.

In den Figuren 22a bis 22c ist die Situation dargestellt, wenn keine Milch mehr aus der Brust fliesst. Das System pumpt zuerst noch weiter, wobei der Pumpdruck nicht mehr ausreicht, um das Behälterventil 94 zum Milchsammelbehälter 9 zu öffnen. Dies ist der Zeitpunkt, an welchem das Pumpventil 12 vollständig geschlossen und dafür das Entleerungsventil 14 aktiviert wird, so dass sich dieses nun selbsttätig öffnen und schliessen lässt. Im konkreten Ausführungsbeispiel wird hierfür der Stellring 5 manuell verstellt. Andere Arten, diese zwei Ventile zu aktivieren bzw. deaktivieren sind jedoch möglich. Beispielsweise lassen sie sich mit einer entsprechenden Elektronik steuern.

In den Figuren 23a bis 23c ist nun das Pumpventil 12 fest verschlossen und dafür der Entleerungskanal und das Entleerungsventil 14 geöffnet. Das Pumpmittel 10 bewegt sich weiter und erzeugt nach wie vom in der Pumpkammer 47 einen sich von einem maximalen Unterdruck zur Atmosphärendruck wechselnden Druck. Nach Massgabe dieser Bewegung öffnet und schliesst sich, wie vorher das Pumpventil 12, auch das Entleerungsventil 14 und pumpt somit die Milch M aus dem Innenraum 200 in die Pumpkammer 47. Von dort wird sie in den Milchsammelbehälter 9 gefördert, vorzugsweise zuerst mittels Unterdruck und anschliessend mittels Verdrängung durch das Pumpmittel 10. Das Entleerungsventil 14 befindet sich in dieser Pumpsituation vorzugsweise an einer tiefen Stelle der Brusthaube, vorzugsweise relativ weit unten. Der sinkende Milchsee im Innenraum ist in den Figuren 23a und 23b gut erkennbar. Die Figuren 23a und 23b zeigen wiederum die zwei Extremsituationen eines Pumphubs. Der Druckverlauf ist in Figur 23c dargestellt. Der Druckverlauf im Innenraum 200 ist relativ unspezifisch.

Die Pumpe wird somit während des Entleerens weiterhin betätigt. Sollte sich zum Schluss noch Milch in der Vakuumkammer 47 befinden, lässt sie sich durch Kippen oder „auf den Kopf stellen“ der Pumpe einfach in den Milchsammelbehälter 9 leiten.

Die erfindungsgemässe Brustpumpe und das erfindungsgemässe Verfahren ermöglichen somit die Verwendung von abgepumpter Milch in einem hydraulischen Pumpsystem, wodurch der Antrieb der Pumpe minimiert werden kann.

BEZUGSZEICHENLISTE

10	Pumpmittel
100	Spindel
11	Belüftungsventil
12	Pumpventil
13	Basisvakuumventil
14	Entleerungsventil
15	Belüftungsöffnung
16	Auslassöffnung
17	dritte Öffnung
19	Entleerungsöffnung
2	Brusthaube
20	Trichter
200	Innenraum
21	Durchgangsöffnung
22	Flansch
23	Stutzen
24	erste Auslassöffnung
25	erste Durchflussöffnung
26	erste Belüftungsöffnung
27	zweite Auslassöffnung
28	zweite Durchflussöffnung
29	zweite Belüftungsöffnung
3	Ventilkörper
30	Grundkörper
31	Rückwand
310	Dichtungsfläche
311	Dichtlippe
312	Rille
32	Durchgangsöffnung
33	Positioniernase
34	erste Noppe
35	Belüftungsnoppe
36	zweite Noppe
37	erste Ventilklappe
38	zweite Ventilklappe
4	Adapterteil
40	Grundkörper
400	erstes Fenster
401	zweites Fenster
402	Positionierhilfe
41	pumpenseitige Wand
410	Kanalwand
42	erhöhter Wandteil
43	erste Durchgangsöffnung
44	zweite Durchgangsöffnung
45	erste Rückspülöffnung
46	zweite Rückspülöffnung
47	Pumpkammer
48	Rinne
480	Auslassöffnung
49	Auslass
5	Stellring
50	erster Teil
51	erstes Steckerteil
52	zweiter Teil
53	zweites Steckerteil
54	Einrastelement

55	Anschlag
56	erstes Anpresselement
57	zweites Anpresselement
58	Betätigungshebel
6	Medientrennmembran
60	Membranfläche
61	Zentralbereich
62	Dichtfläche
63	Rinne
64	Vertiefung
7	Pumpmembran
70	Membranfläche
71	Zentralbereich
72	Durchgangsöffnung
73	Verstärkung
74	Dichtfläche
75	Sensorfläche
76	Fahne
77	Seitenflügel
8	Pumpengehäuse
8‘	Trägermodul
80	Seitenarm
81	Motoraufnahme
82	Spindelaufnahme
83	Spindel
84	Befestigungslöcher
85	Rand
86	Betätigungsschalter
87	Anzeige
9	Milchsammelbehälter
90	Gefäss
900	Innenraum
901	erstes Einrastelement¨
902	zweites Einrastelement
91	unterer Rahmenteil
92	Abdeckung
93	oberer Rahmenteil
930	Rahmen
931	Streben
932	Ventilaufnahme
933	Griff
934	Distanzstifte
94	Behälterventil
95	Einlass
96	Einlassventil
W	Brustwarze
M	Milch

PATENTANSPRÜCHE

1. **Brustpumpe** zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe ein Gehäuse mit einer Antriebseinheit, eine Pumpkammer mit einer von der Antriebseinheit angetriebenen flexiblen Pumpmembran zur Erzeugung eines Vakuums und eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust aufweist,
   wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagbar ist,
   wobei ein Milchkanal vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer führt, wobei abgepumpte Milch vom Innenraum der Brusthaube durch den Milchkanal in die Pumpkammer fliesst, und wobei die Pumpkammer eine Auslassöffnung aufweist, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst,
   dadurch gekennzeichnet,
   dass ein mehrteiliges Hygienemodul vorhanden ist, wobei das Hygienemodul einen ersten Teil mit einer Durchflussöffnung zur Verbindung mit dem Innenraum, einen Ventilkörper mit mindestens einem Ventil und einen zweiten Teil mit einer steifen Schale zur Bildung der Pumpkammer aufweist, wobei der Ventilkörper zwischen dem ersten und zweiten Teil angeordnet ist und wobei das Hygienemodul als Ganzes mit dem Gehäuse der Brustpumpe dichtend und lösbar verbindbar ist.

2. Brustpumpe nach Anspruch 1, die steife Schale einen Milchpfad aufweist, welcher von der Pumpkammer in einen Milchsammelbehälter führt und welcher mindestens über einen Teilbereich senkrecht zu einer Antriebsachse der Pumpmembran verläuft.

3. Brustpumpe nach einem der Ansprüche 1 oder 2, wobei der Ventilkörper mindestens ein Durchflussventil und ein Belüftungsventil aufweist.

4. Brustpumpe nach einem der Ansprüche 1 bis 3, wobei der Ventilkörper einstückig aus einem flexiblen Material gebildet ist.

5. Brustpumpe nach einem der Ansprüche 1 bis 4, wobei der erste Teil Bestandteil der Brusthaube ist.

6. Brustpumpe nach einem der Ansprüche 1 bis 5, die Brusthaube einen Flansch zur lösbaren Verbindung mit dem Gehäuse aufweist.

7. Brustpumpe nach Anspruch 6, wobei die Verbindung form- und kraftschlüssig, vorzugsweise ein Bajonettverschluss, ist.

8. **Brustpumpe** zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer aufweist, wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagbar ist, wobei ein Milchkanal vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer führt, durch welchen abgepumpte Milch vom Innenraum der Brusthaube in die Pumpkammer fliesst, und wobei die Pumpkammer eine Auslassöffnung aufweist, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst, dadurch gekennzeichnet, dass die Auslassöffnung in vertikaler Gebrauchslage der Brustpumpe mindestens zu Beginn eines Abpumpvorgangs in einem oberen Bereich der Pumpkammer und/oder oberhalb der Einlassöffnung angeordnet ist.

9. Brustpumpe nach Anspruch 1, wobei der Milchkanal einen Vakuumkanal zur Beaufschlagung des Innenraums der Brusthaube mit dem sich zyklisch ändernden Unterdruck bildet.

10. Brustpumpe nach einem der Ansprüche 8 oder 9, wobei die Pumpkammer eine steife erste Schale und eine flexible Pumpmembran aufweist, wobei die Pumpmembran dichtend an der ersten Schale anliegt und wobei die Pumpmembran angetrieben ist und durch deren Bewegung relativ zur ersten Schale ein Unterdruck in der Pumpkammer erzeugbar ist.

11. Brustpumpe nach Anspruch 10, wobei zwischen der steifen Schale und der flexiblen Pumpmembran eine flexible Medientrennmembran angeordnet ist, so dass die

Pumpmembran vor einem Kontakt mit abgepumpter Milch geschützt ist.

12. Brustpumpe nach einem der Ansprüche 10 oder 11, wobei die erste Schale eine Auslassrinne aufweist, welche sich von der Auslassöffnung der Pumpkammer zu einem Ausgang erstreckt, wobei die Auslassrinne sich mindestens über einen Teilbereich in einer Richtung senkrecht zur Bewegungsrichtung der Pumpmembran verläuft.

13. Brustpumpe nach einem der Ansprüche 11 oder 12, wobei die Pumpmembran, oder, falls vorhanden, die Medientrennmembran die Auslassrinne der steifen ersten Schale zu einem bis auf die Auslössöffnung und den Ausgang geschlossenen Kanal verschliesst.

14. Brustpumpe nach einem der Ansprüche 1 bis 13, wobei die Brusthaube eine erste Durchlassöffnung aufweist, welche Teil des Milchkanals bildet, wobei die Durchlassöffnung in Gebrauchslage der Brusthaube mindestens zu Beginn des Abpumpvorgangs in einem oberen Bereich des Innenraums angeordnet ist, so dass der Innenraum unterhalb der ersten Durchlassöffnung mit abgepumpter Milch befüllbar ist.

15. Brustpumpe nach einem der Ansprüche 1 bis 14, wobei der Milchkanal mittels eines ersten Ventils verschliessbar ist, um am Ende des Abpumpvorgangs die abgepumpte Milch aus der Pumpkammer zu entfernen.

16. Brustpumpe nach einem der Ansprüche 1 bis 15, wobei ein Entleerungskanal zwischen dem Innenraum der Brusthaube und der Pumpkammer vorhanden ist, welcher getrennt vom Milchkanal verläuft, und wobei der Entleerungskanal mittels eines zweiten Ventils verschliessbar ist, wobei der Entleerungskanal während des Abpumpvorgangs geschlossen ist und am Ende des Abpumpvorgangs geöffnet ist.

17. Brustpumpe nach einem der Ansprüche 1 bis 16, wobei ein Belüftungsventil zur Belüftung des Innenraums der Brusthaube vorhanden ist.

18. Brustpumpe nach den Ansprüchen 16 und 17, wobei das Belüftungsventil gemeinsam mit dem zweiten Ventil verschliessbar ist und sich gemeinsam mit diesem öffnen lässt.

19. Brustpumpe nach einem der Ansprüche 1 bis 18, wobei ein drittes Ventil vorhanden ist, welches bei Druckanstieg des zyklisch sich ändernden Unterdrucks im Innenraum der Brusthaube einen Basisunterdruck beibehält.

20. Brustpumpe nach einem der Ansprüche 1 bis 19, wobei im Milchkanal ein viertes Ventil vorhanden ist, welches sich nach Massgabe des angelegten Unterdrucks öffnet und schliesst.

21. Brustpumpe nach einem der Ansprüche 1 bis 20, wobei im Entleerungskanal ein fünftes Ventil vorhanden ist, welches sich nach Massgabe des angelegten Unterdrucks öffnet und schliesst.

22. Brustpumpe nach einem der Ansprüche 1 bis 21, wobei mindestens ein Teil, vorzugsweise alle, der genannten Ventile in einem gemeinsamen Ventilkörper angeordnet sind.

23. Brustpumpe nach Anspruch 22, wobei der Ventilkörper einstückig und flexibel ausgebildet ist.

24. Brustpumpe nach einem der Ansprüche 10 bis 23, sofern rückbezogen auf Anspruch 10, wobei die Brustpumpe ein Pumpengehäuse mit einem Antrieb für die Pumpmembran aufweist und wobei die steife erste Schale lösbar mit dem Pumpengehäuse verbunden ist.

25. Brustpumpe nach Anspruch 24, wobei die erste steife Schale Bestandteil eines mehrteiligen Moduls ist, welches gemeinsam mit dem Pumpengehäuse verbindbar ist, wobei das Modul des Weiteren mindestens die genannten Ventile aufweist.

26. Brustpumpe nach den Ansprüchen 23 und 25, wobei die erste steife Schale

Bestandteil eines Adapterteils ist und wobei der Ventilkörper in einer Aufnahme des Adapterteils gehalten ist.

27. Brustpumpe nach Anspruch 26, wobei das Modul ferner ein manuelles Betätigungsmittel umfasst zum zeitgleichen Betätigen des ersten und zweiten Ventils.

28. Brustpumpe nach Anspruch 27, wobei das Adapterteil und das Betätigungsteil nicht zerstörungsfrei voneinander lösbar sind.

29. Brustpumpe nach einem der Ansprüche 1 bis 28, wobei die Brustpumpe ein Pumpengehäuse aufweist, wobei die Brusthaube lösbar am Pumpengehäuse befestigbar ist und wobei durch die Befestigung der Brusthaube am Pumpengehäuse Teile, welche zwischen Brusthaube und Pumpengehäuse liegen, dichtend miteinander verbunden werden, so dass eine dichte Verbindung zwischen Pumpkammer und Innenraum der Brusthaube entsteht.

30. Brustpumpe nach den Ansprüchen 25 und Anspruch 29, wobei die Brusthaube und der Ventilkörper Teil des Moduls sind.

31. Brustpumpe nach einem der Ansprüche 1 bis 30, wobei die Brustpumpe ein Pumpengehäuse aufweist, an welchem die Brusthaube lösbar befestigbar ist, und wobei die Brustpumpe ferner einen Milchsammelbehälter aufweist, welcher am Pumpengehäuse mittels eines Schnappverschlusses befestigbar ist.

32. Brustpumpe nach Anspruch 31, wobei der Milchsammelbehälter einen Grundkörper und einen Deckel aufweist, wobei der Deckel mindestens teilweise luftdurchlässig und flüssigkeitsundurchlässig ausgebildet ist.

33. Brustpumpe nach Anspruch 32, wobei der Deckel eine luftdurchlässige und flüssigkeitsundurchlässige Membran aufweist.

34. Brustpumpe nach einem der Ansprüche 31 bis 33, wobei der Deckel mit einem

Einwegventil versehen ist.

35. **Brustpumpe** zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer aufweist, wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagbar ist, wobei ein Milchkanal vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer führt, durch welchen abgepumpte Milch vom Innenraum der Brusthaube in die Pumpkammer fliesst, und wobei die Pumpkammer eine Auslassöffnung aufweist, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst, dadurch gekennzeichnet, dass ein Entleerungskanal zwischen dem Innenraum der Brusthaube und der Pumpkammer vorhanden ist, welcher getrennt vom Milchkanal verläuft, und wobei der Entleerungskanal mittels eines Ventils verschliessbar ist, wobei der Entleerungskanal während des Abpumpvorgangs geschlossen ist und am Ende des Abpumpvorgangs geöffnet ist. .

36. **Brustpumpe** zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer aufweist, wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagbar ist, wobei ein Milchkanal vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer führt, durch welchen abgepumpte Milch vom Innenraum der Brusthaube in die Pumpkammer fliesst, und wobei die Pumpkammer eine Auslassöffnung aufweist, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst, dadurch gekennzeichnet, dass die Brustpumpe ein Pumpengehäuse, eine Pumpmembran und ein Modul aufweist, wobei das Modul mindestens eine steife Schale zur Bildung der Pumpkammer und die Brusthaube aufweist, wobei das Modul als Einheit am Pumpengehäuse befestigbar ist, wobei eine dichte Verbindung zwischen der Pumpkammer und dem Innenraum der Brusthaube geschaffen wird und wobei die Pumpmembran zwischen dem Modul und dem Pumpengehäuse dichtend gehalten ist.

37. Brustpumpe nach Anspruch 36, wobei das Modul ferner einen Ventilkörper aufweist,

welcher zwischen Brusthaube und steifer Schale angeordnet ist.

38. Brustpumpe gemäss Anspruch 37, wobei das Modul ferner ein manuelles Betätigungsmittel zur Betätigung mindestens eines Ventils des Ventilkörpers aufweist.

39. **Brustpumpe** zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube zur Aufnahme einer Mutterbrust, ein Pumpengehäuse sowie einen Milchsammelbehälter aufweist, wobei das Pumpengehäuse einerseits lösbar mit der Brusthaube und andererseits lösbar mit dem Milchsammelbehälter verbindbar ist, dadurch gekennzeichnet, dass der Milchsammelbehälter mittels eines Schnappverschlusses am Pumpengehäuse befestigbar ist.

40. Brustpumpe nach Anspruch 39, wobei sie eine Pumpkammer und einen Milchkanal aufweist, durch welchen abgepumpte Milch von einem Innenraum der Brusthaube in die Pumpkammer fliesst, und wobei die Pumpkammer einen Ausgang aufweist, welcher mit dem Milchsammelbehälter verbunden ist und durch welchen die abgepumpte Milch in den Milchsammelbehälter fliesst.

41. **Milchsammelbehälter** zur Verbindung mit einem Pumpengehäuse einer Brustpumpe zum Abpumpen von menschlicher Muttermilch, dadurch gekennzeichnet, dass der Milchsammelbehälter einen Deckel aufweist, der dem Pumpengehäuse zugewandt ist und der mindestens in einem Bereich luftdurchlässig und flüssigkeitsundurchlässig ist.

42. **Brustpumpe** zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube zur Aufnahme einer Mutterbrust und ein Pumpengehäuse aufweist, wobei die Brusthaube lösbar mit dem Pumpengehäuse verbindbar ist, dadurch gekennzeichnet, dass die Brusthaube mittels eines Bajonettverschlusses mit dem Pumpengehäuse verbindbar ist.

43. **Brusthaube** zur Befestigung an einem Pumpengehäuse einer Brustpumpe gemäss Anspruch 42, wobei die Brusthaube einen Innenraum zur Aufnahme der Mutterbrust

und einen Stutzen zur Befestigung am Pumpengehäuse aufweist, dadurch gekennzeichnet, dass der Stutzen mit einem Bajonettverschluss versehen ist.

44. **Verfahren** zum Betätigen einer Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer aufweist, wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagt wird,
wobei in einer ersten Pumpphase der Innenraum mit dem sich zyklisch ändernden Unterdruck beaufschlagt wird, um Milch aus der Mutterbrust abzupumpen, wobei der Innenraum mit abgepumpter Milch gefüllt wird, ohne dass abgepumpte Milch aus dem Innenraum hinausfliesst,
wobei in einer zweiten Pumpphase abgepumpte Milch aus dem Innenraum in die Pumpkammer fliesst und die Pumpkammer mit abgepumpter Milch gefüllt wird und
wobei in einer dritten Pumpphase die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst, wobei der Innenraum und die Pumpkammer mit abgepumpter Milch gefüllt bleiben,
wobei der Wechsel von der zweiten Pumpphase zur dritten Pumpphase erfolgt, indem ein Füllstand der abgepumpten Milch eine Auslassöffnung erreicht, welche von der Pumpkammer zum Milchsammelbehälter führt, wodurch Milch durch die Auslassöffnung von der Pumpkammer in den Milchsammelbehälter fliesst.

45. Verfahren nach Anspruch 44, wobei die Brustpumpe während des Abpumpens von einem pneumatischen Pumpsystem auf ein hydraulisches Pumpsystem wechselt, wobei die erste Pumpphase eine pneumatische Pumpphase ist und die zweite Pumpphase eine hydraulische Pumpphase ist.

46. Verfahren nach einem der Ansprüche 44 oder 45, wobei der Innenraum in der ersten Pumpphase annähernd vollständig gefüllt wird.

47. Verfahren nach einem der Ansprüche 44 bis 46, wobei der Innenraum und/oder die Pumpkammer in der zweiten und/oder dritten Pumpphase annähernd vollständig mit abgepumpter Milch gefüllt sind.

48. Verfahren nach der Ansprüche 44 bis 47, wobei der Wechsel von der ersten Pumpphase zur zweiten Pumpphase erfolgt, indem ein Füllstand der abgepumpten Milch eine erste Durchgangsöffnung erreicht, welche vom Innenraum zur Pumpkammer führt, wodurch Milch durch die erste Durchgangsöffnung vom Innenraum in die Pumpkammer fliesst.

49. Verfahren nach Anspruch 48, wobei in der dritten Pumpphase die abgepumpte Milch durch die erste Durchgangsöffnung in die Pumpkammer fliesst und durch die Auslassöffnung in den Milchsammelbehälter fliesst.

50. Verfahren nach einem der Ansprüche 44 bis 49, wobei in einer vierten Pumpphase der Innenraum entleert wird und die darin befindliche, bereits abgepumpte Milch durch eine zweite Durchgangsöffnung aus dem Innenraum zum Milchsammelbehälter geführt wird.

51. Verfahren nach den Ansprüchen 48 und 50, wobei die erste Durchgangsöffnung mit einem ersten Ventil verschliessbar ist und wobei die zweite Durchgangsöffnung mit einem zweiten Ventil verschliessbar ist, wobei die zweite Durchgangsöffnung während der ersten bis dritten Pumpphase stets geschlossen ist.

52. Verfahren nach Anspruch 51, wobei die erste Durchgangsöffnung während der vierten Pumpphase stets geschlossen ist.

53. Verfahren nach Anspruch 52, wobei die zweite Durchgangsöffnung vom Innenraum in die Pumpkammer führt und über die Pumpkammer in fluidkommunizierender Verbindung mit der Auslassöffnung steht.

54. Verfahren nach einem der Ansprüche 44 bis 53, wobei während mindestens einem Teil der Pumpphasen, vorzugsweise während der ersten, zweiten und dritten Pumpphase ein Basisunterdruck beibehalten wird.

55. Verfahren nach Anspruch 54, wobei ein drittes Ventil vorhanden ist, welches bei

Druckanstieg des zyklisch sich ändernden Unterdrucks in Richtung Atmosphärendruck zuerst öffnet und dann schliesst und dadurch den Basisunterdruck beibehält.

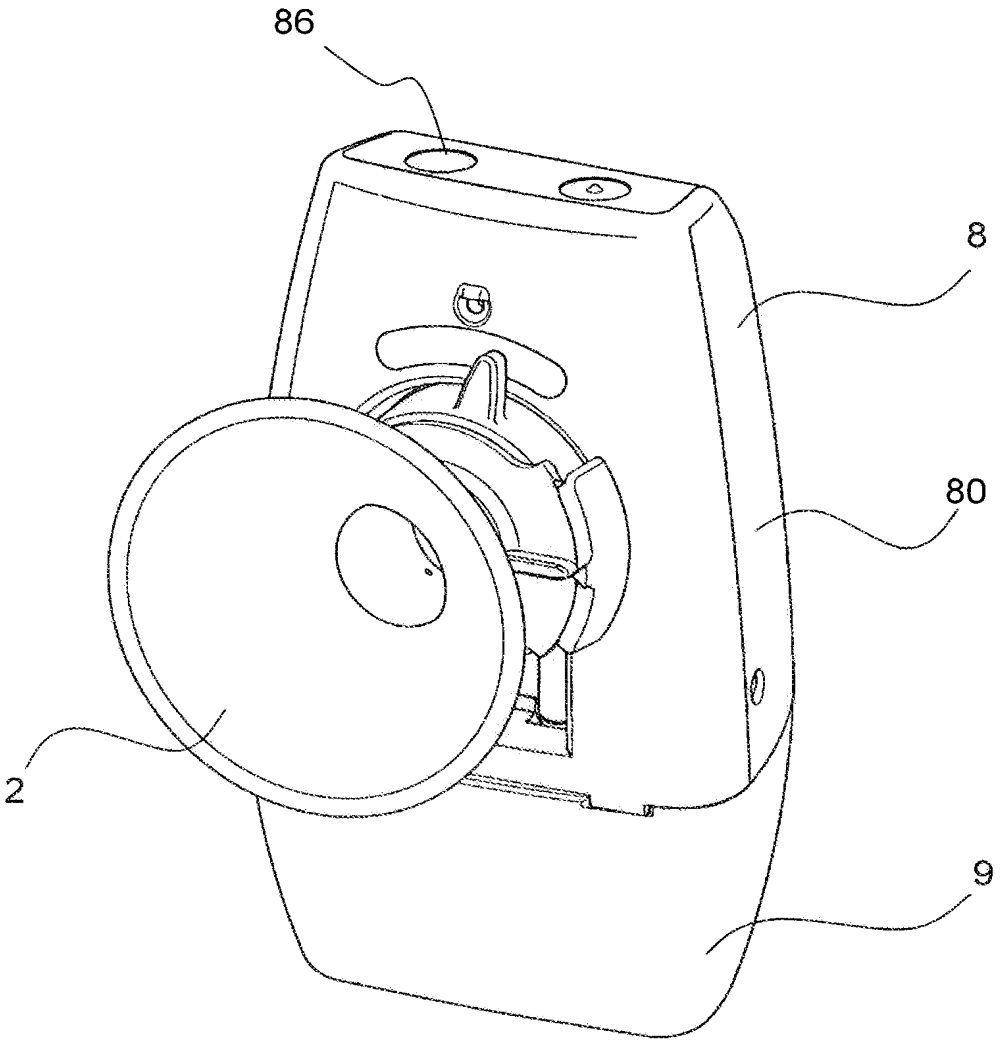

FIG. 1

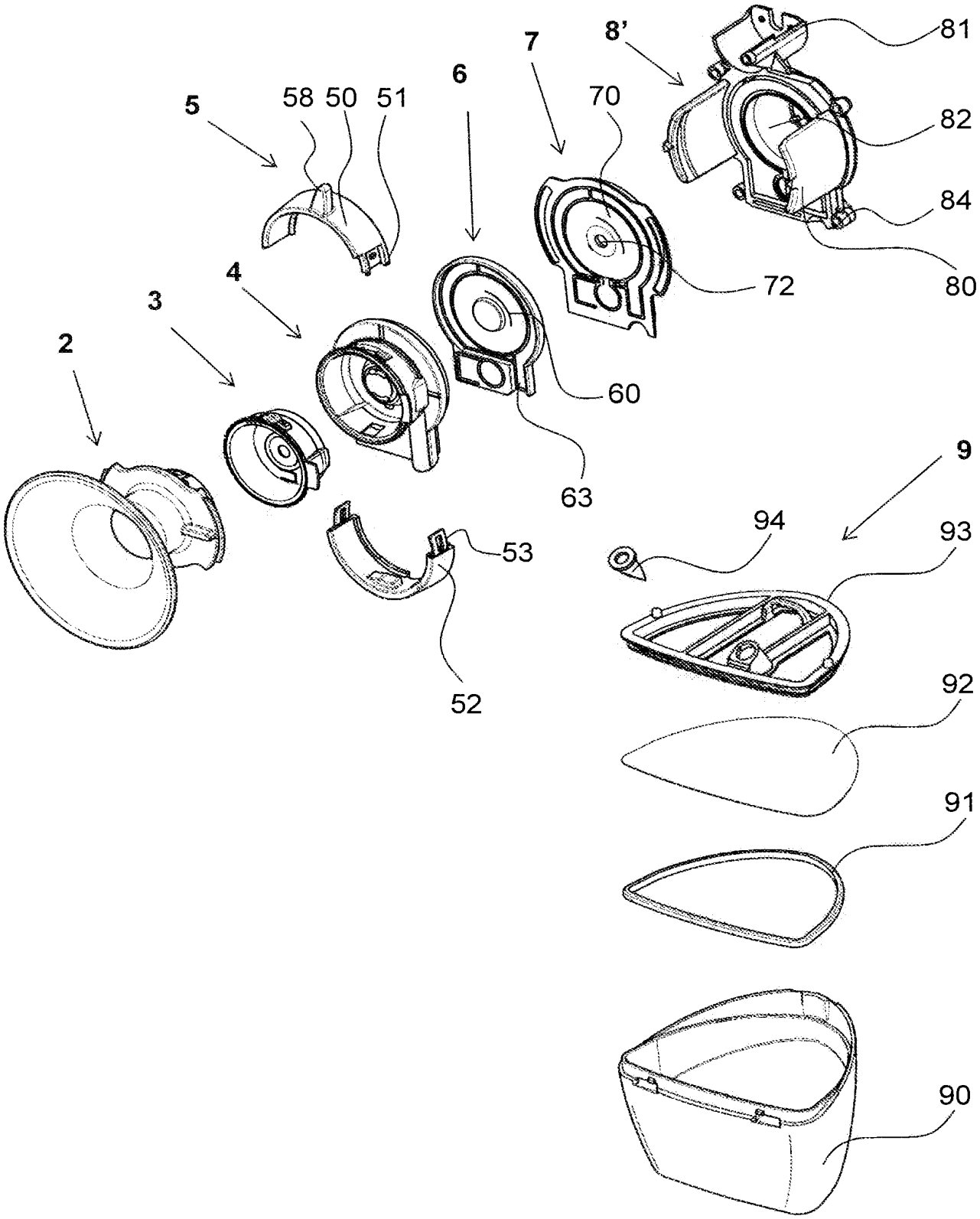

FIG. 2

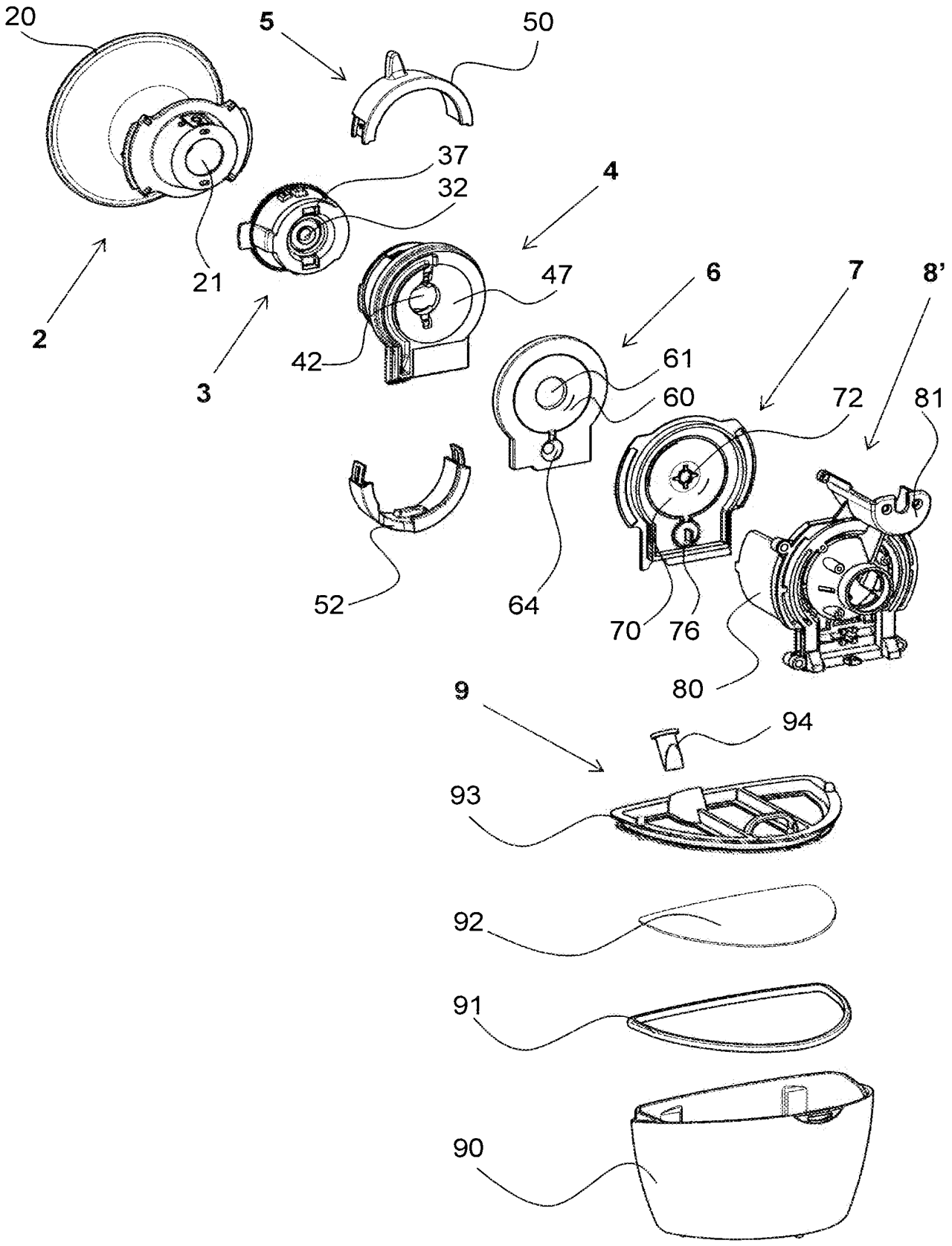
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FIG. 3

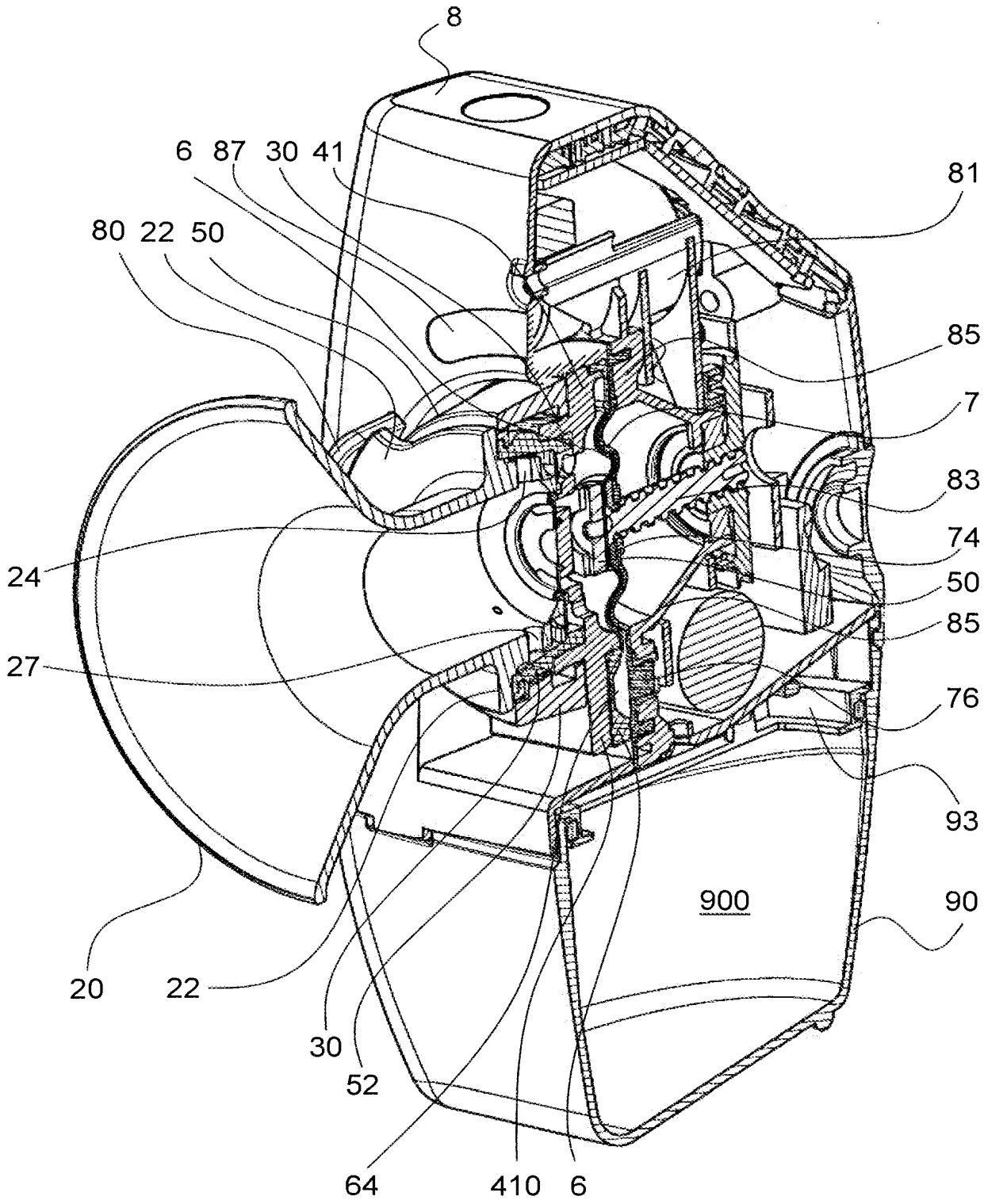
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FIG. 4

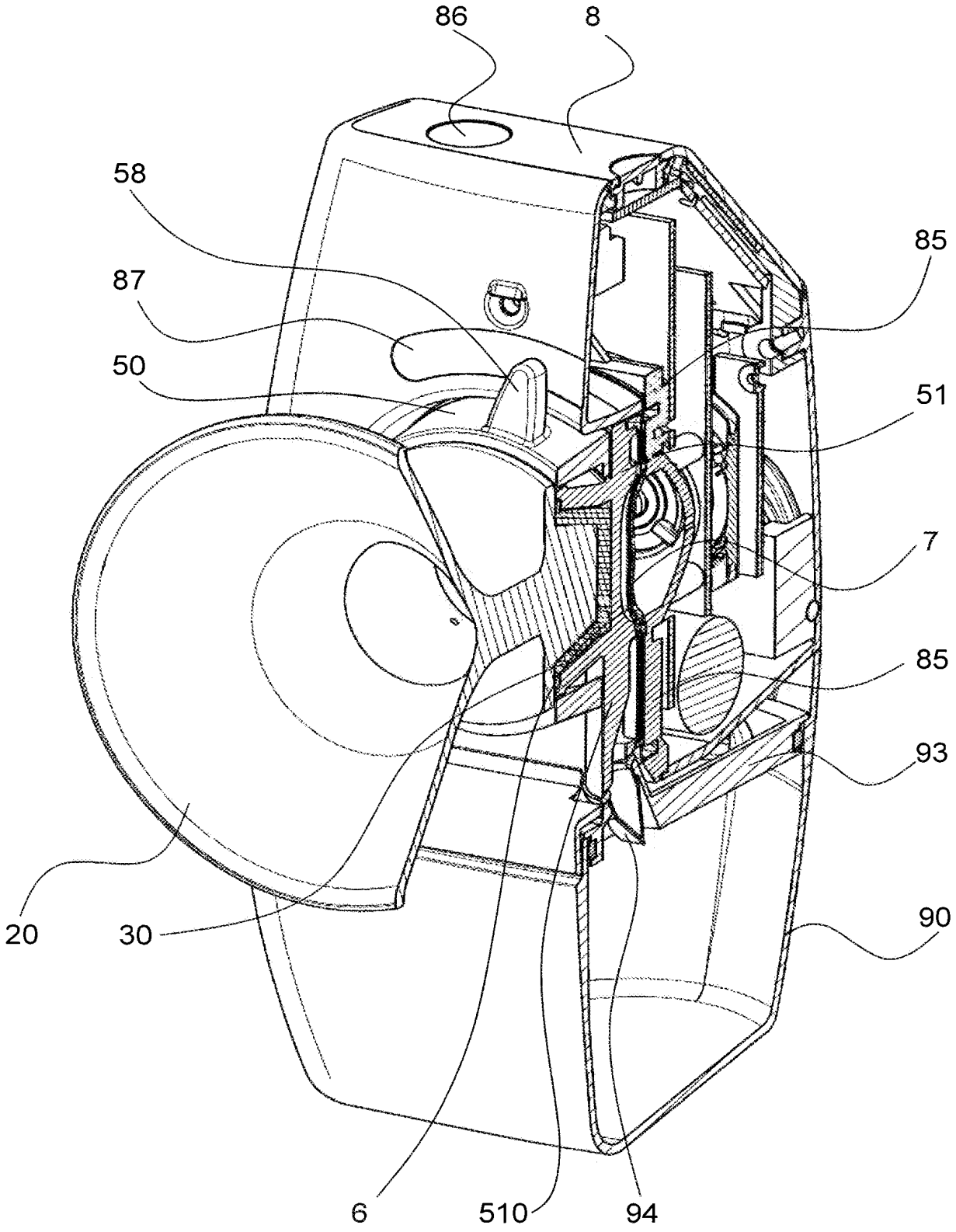

FIG. 5

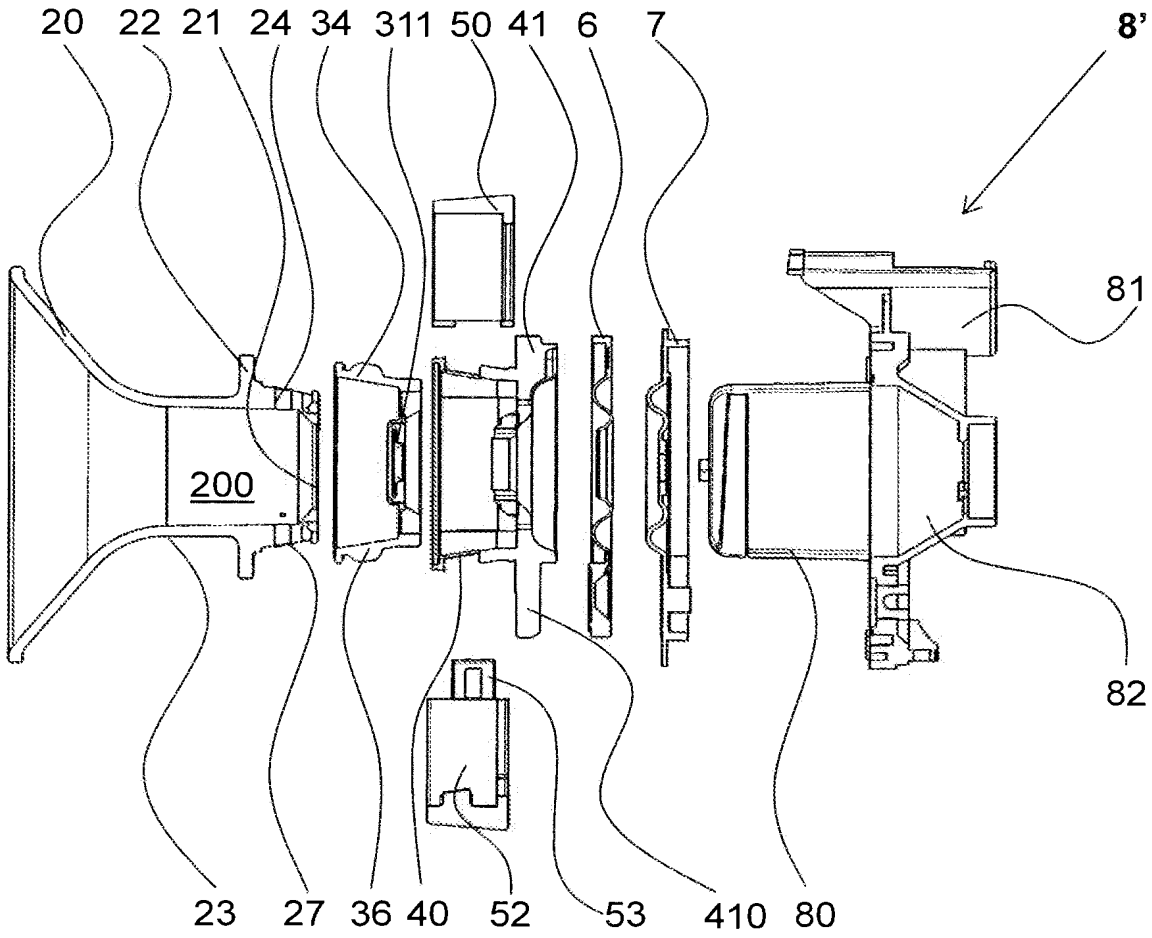
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FIG. 6

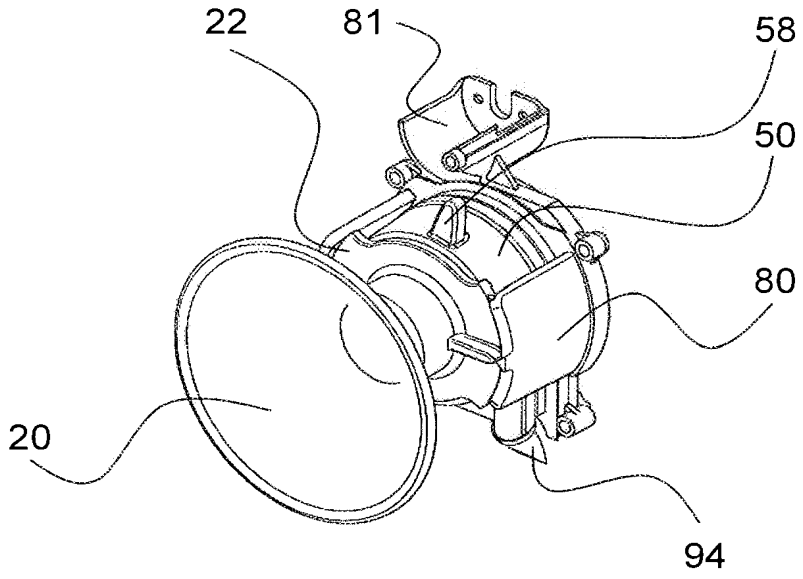
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FIG. 7

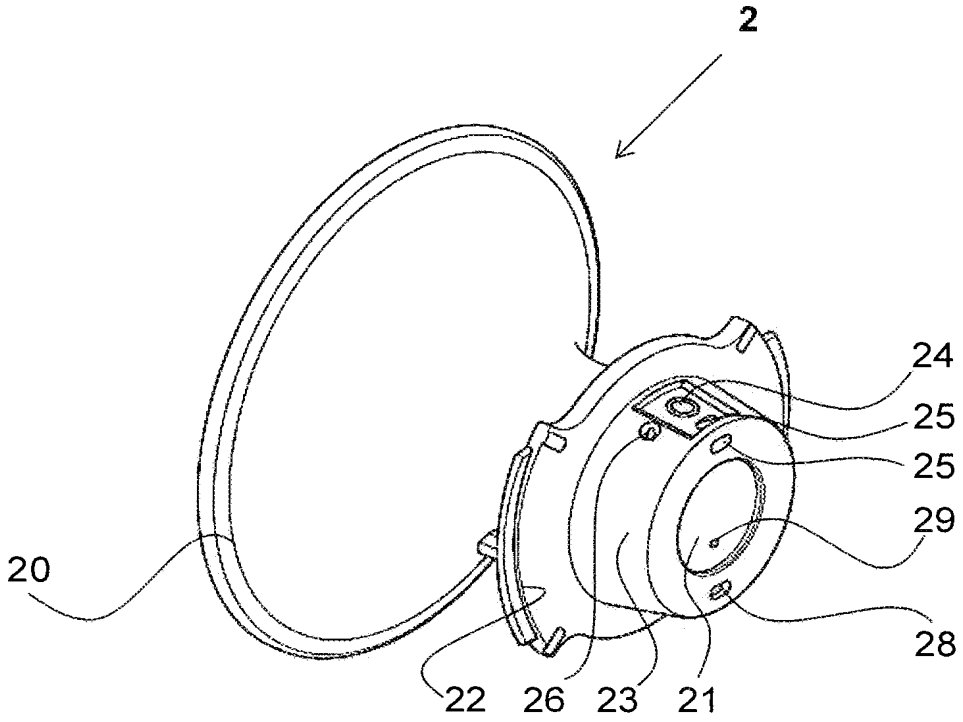

FIG. 8a

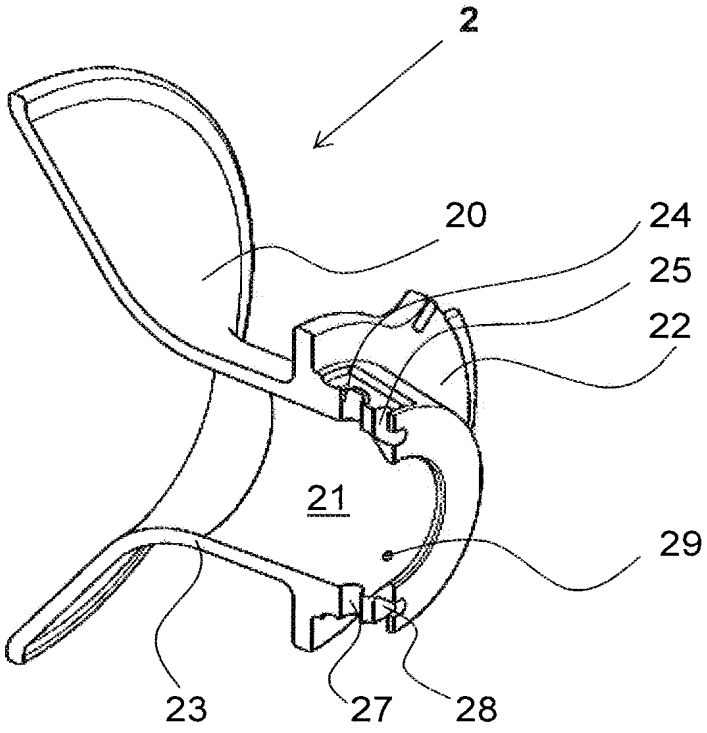

FIG. 8b

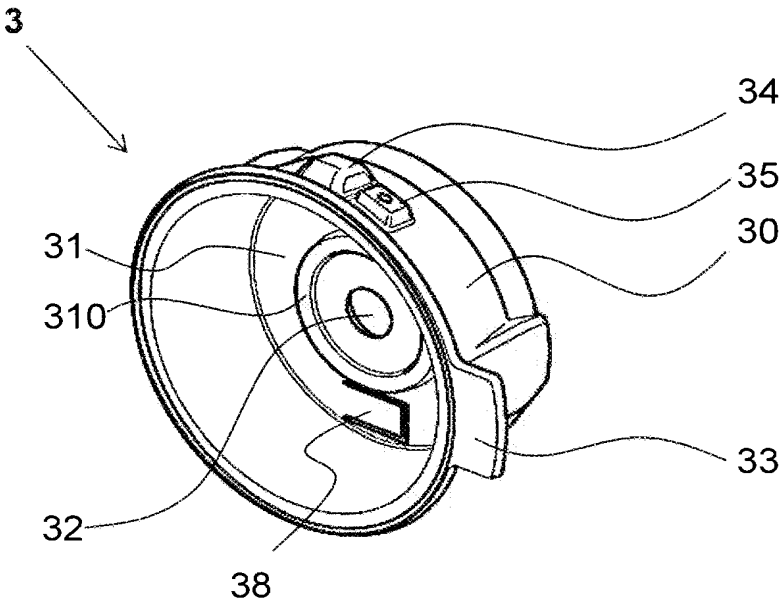

FIG. 9a

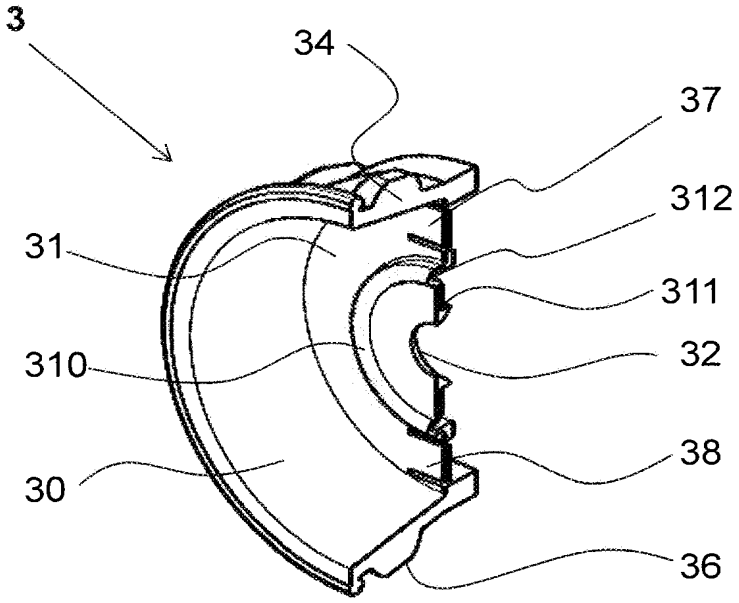

FIG. 9b

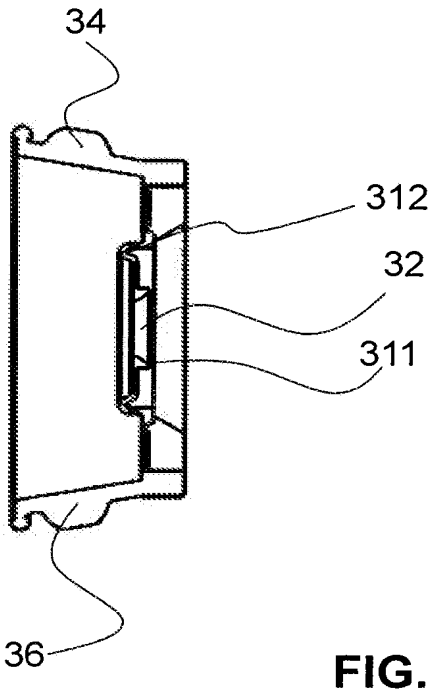

FIG. 9c

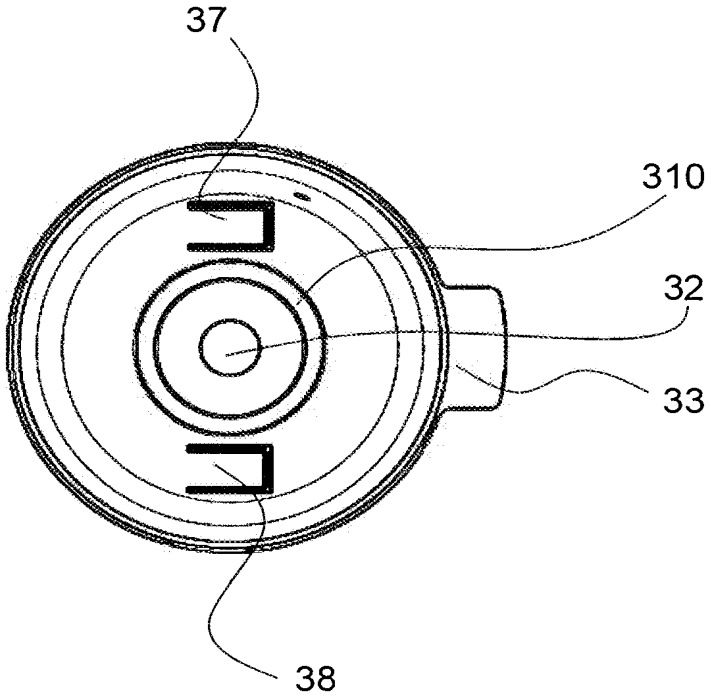

FIG. 9d

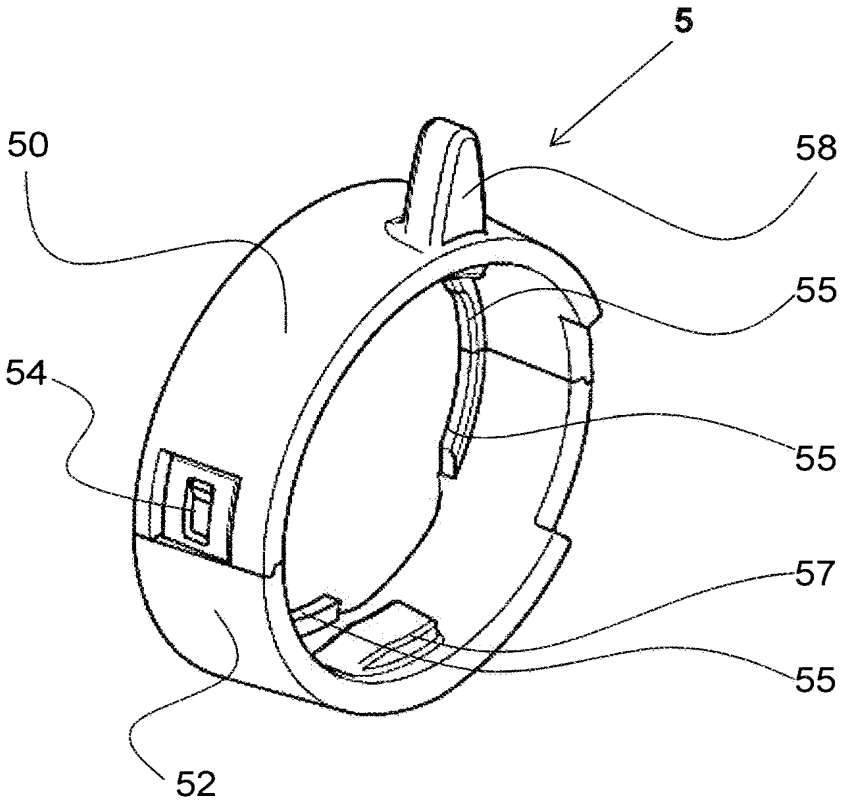

FIG. 10a

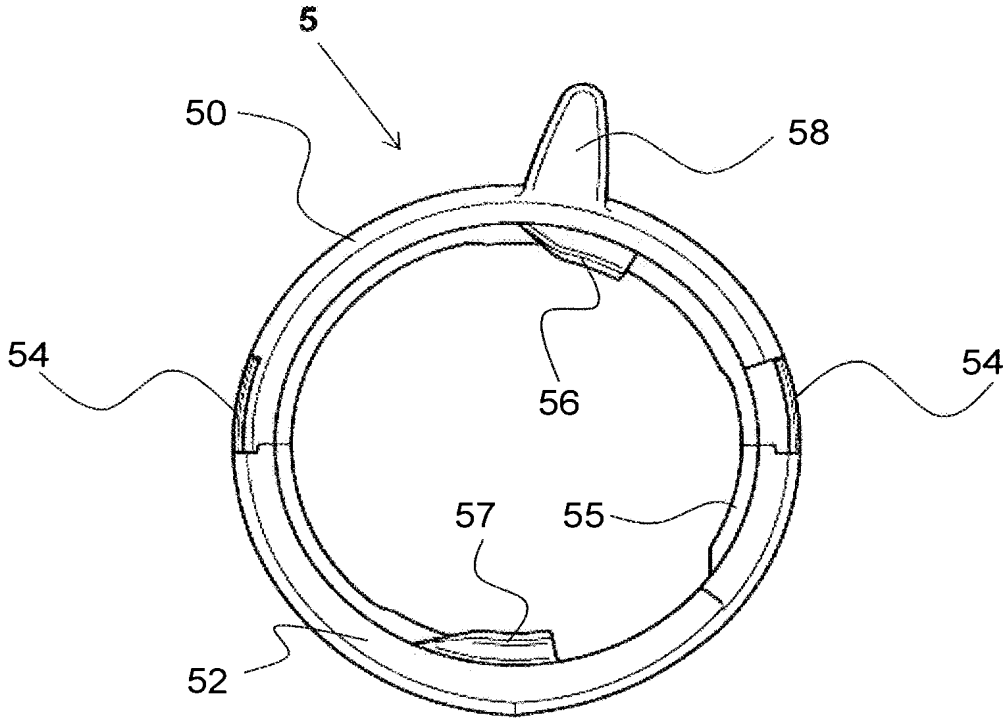

FIG. 10b

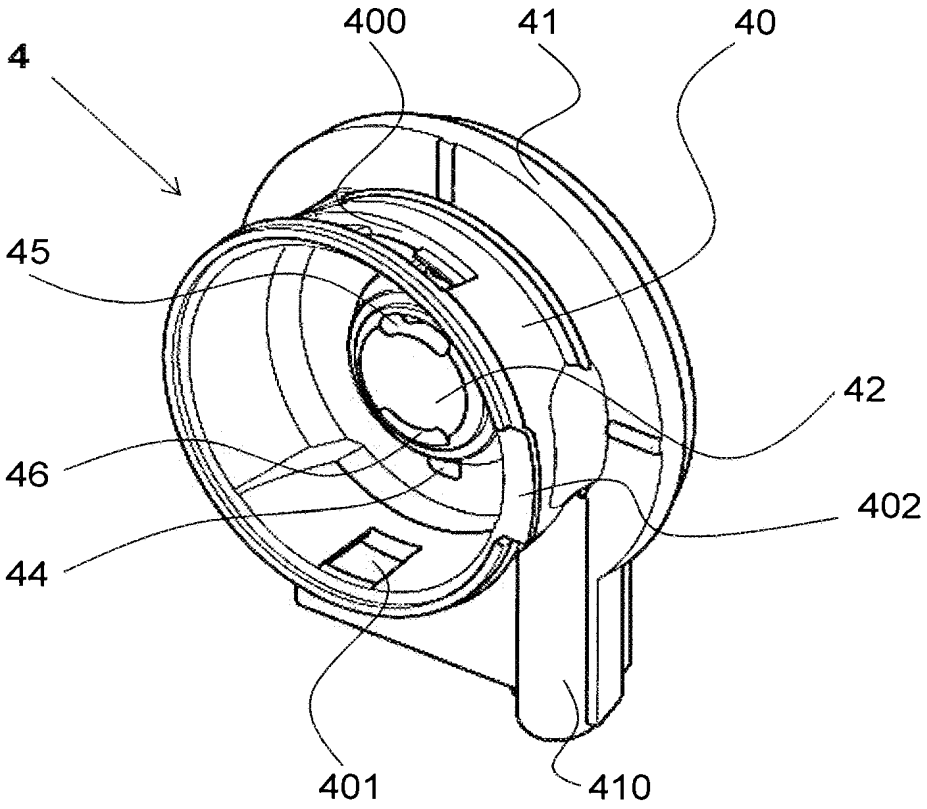

FIG. 11a

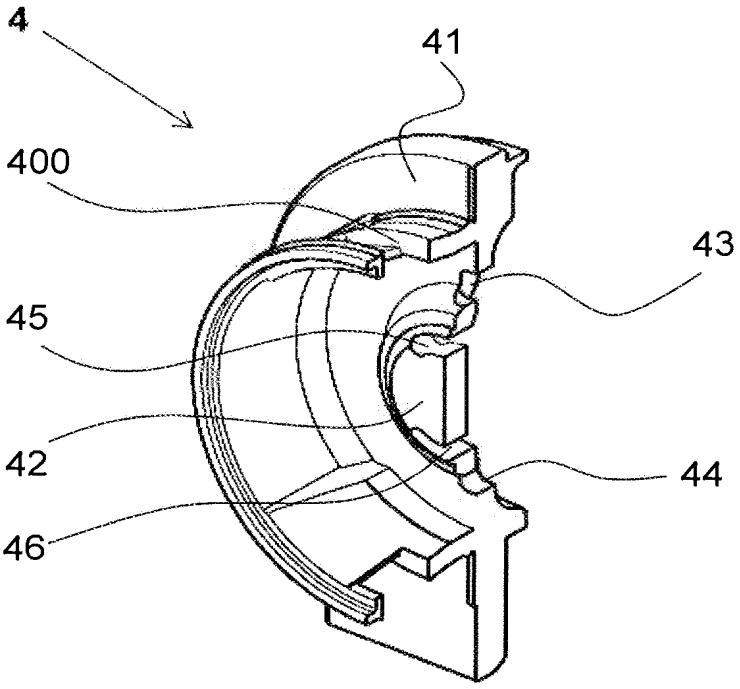

FIG. 11b

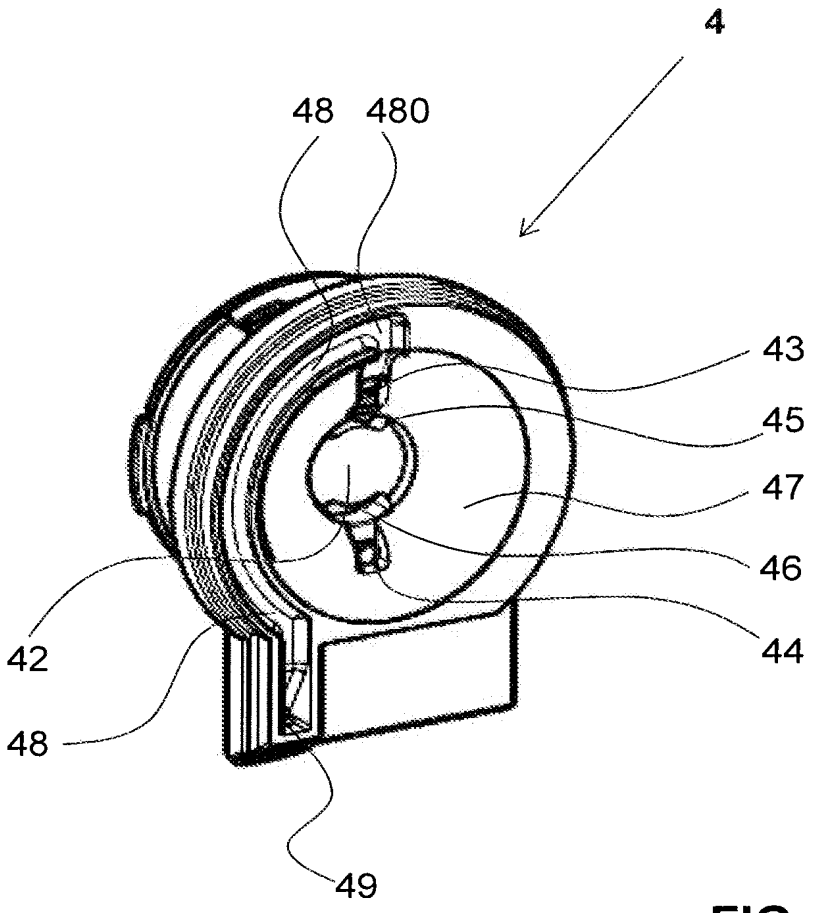

FIG. 11c

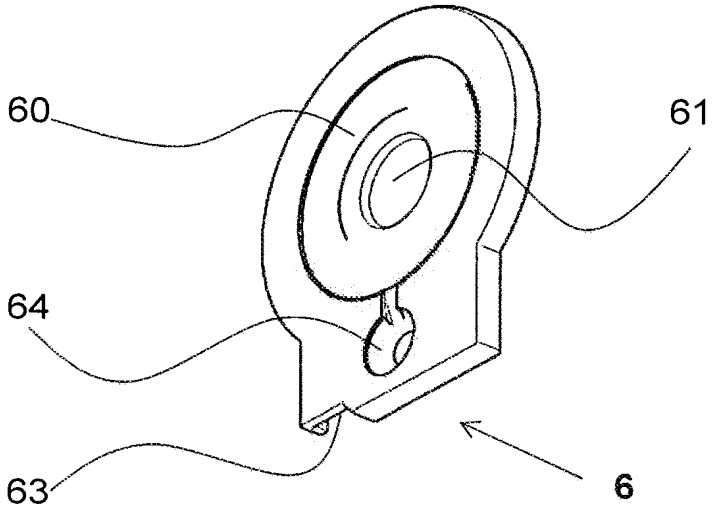

FIG. 12a

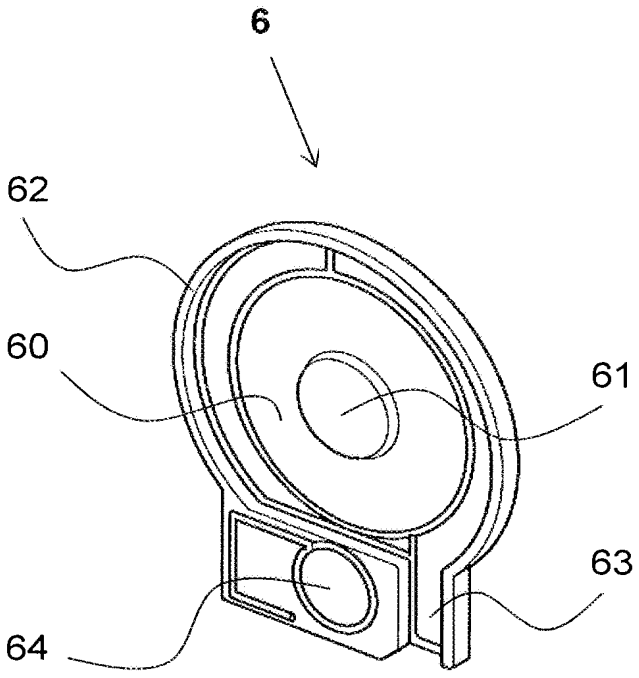

FIG. 12b

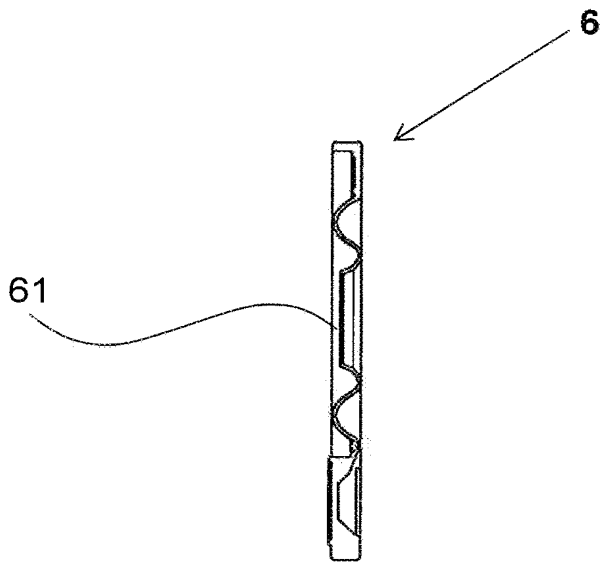

FIG. 12c

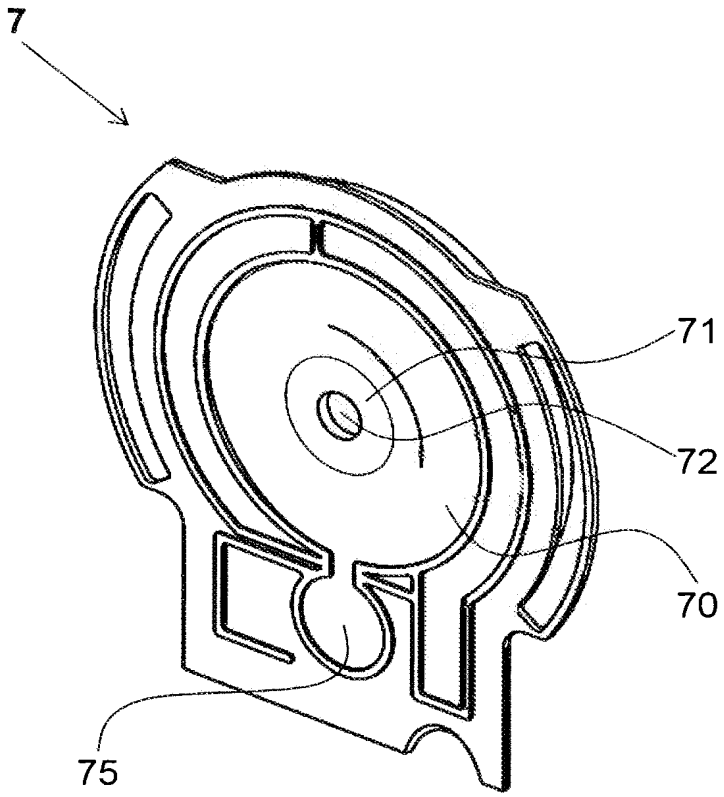

FIG. 13a

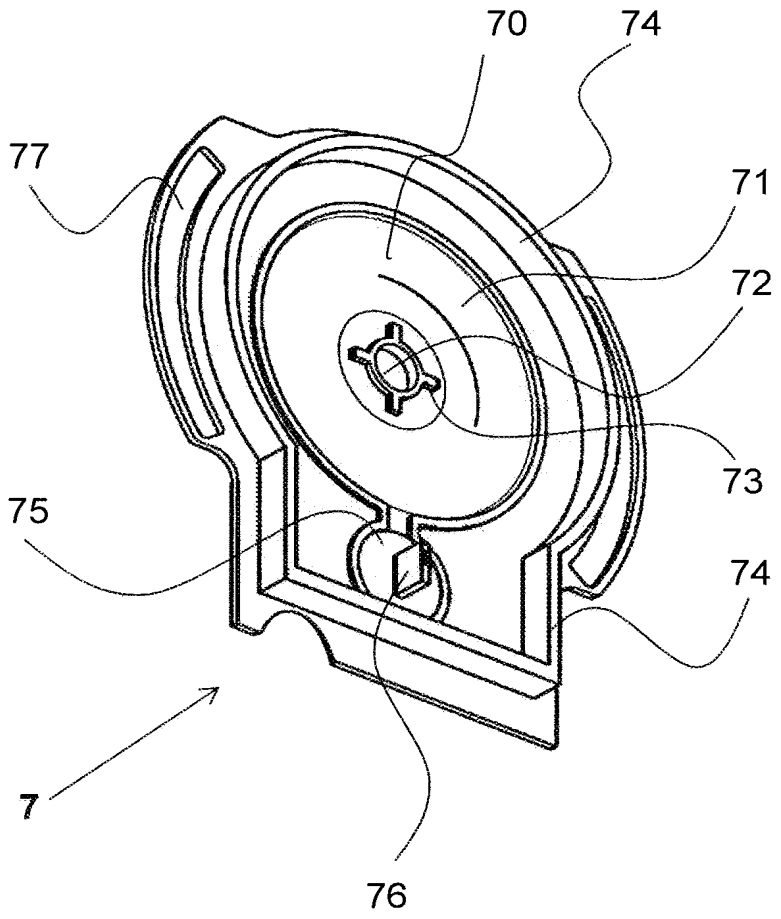

FIG. 13b

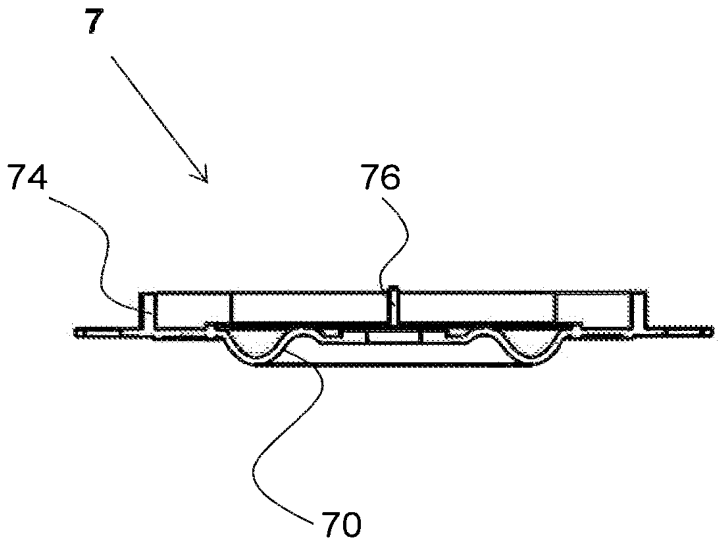

FIG. 13c

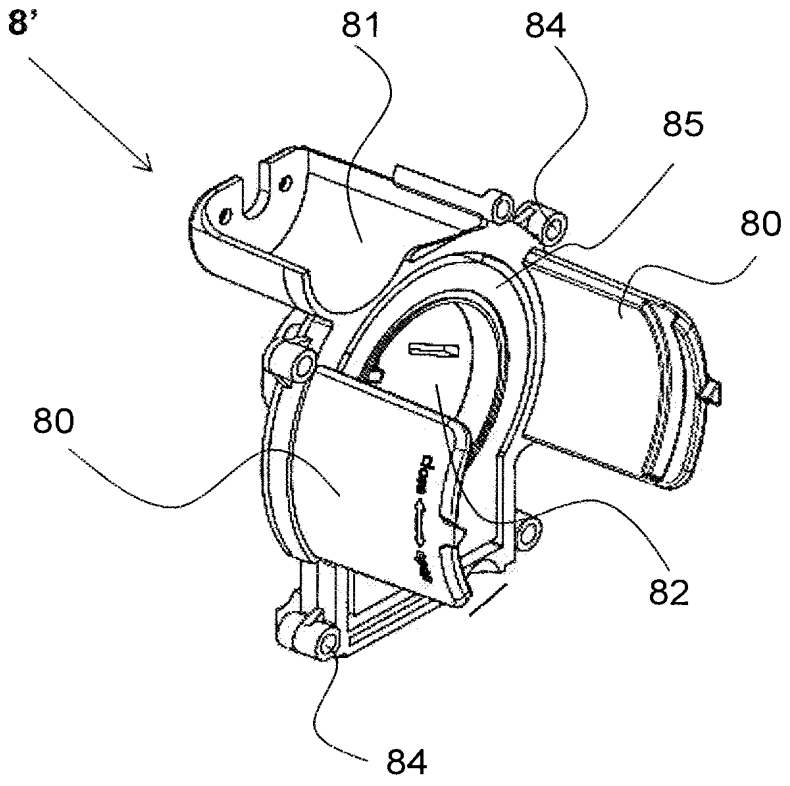

FIG. 14

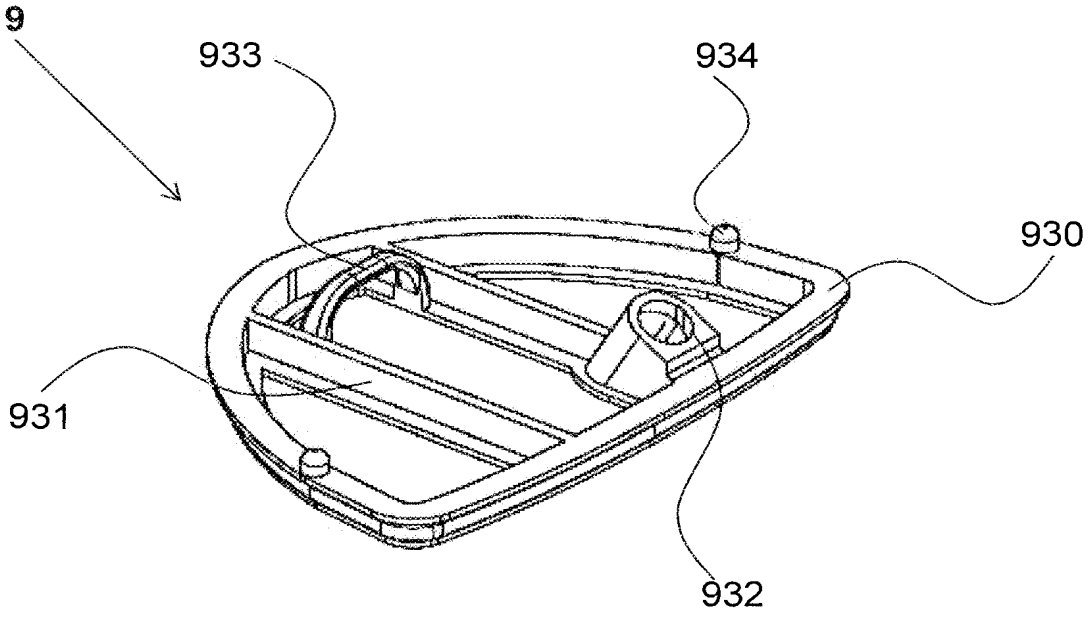

FIG. 15

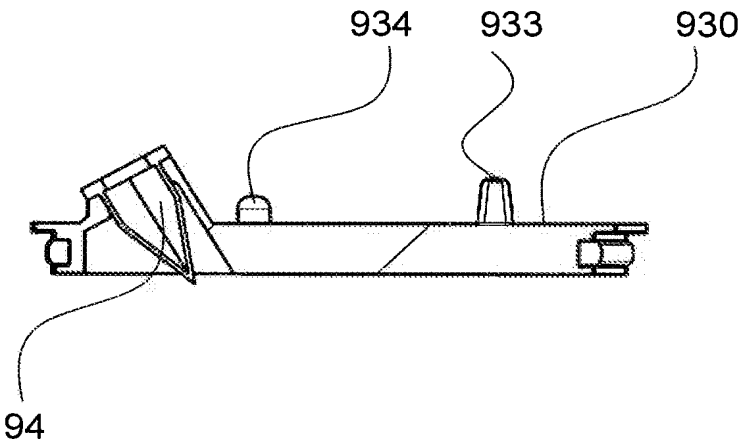

FIG. 16

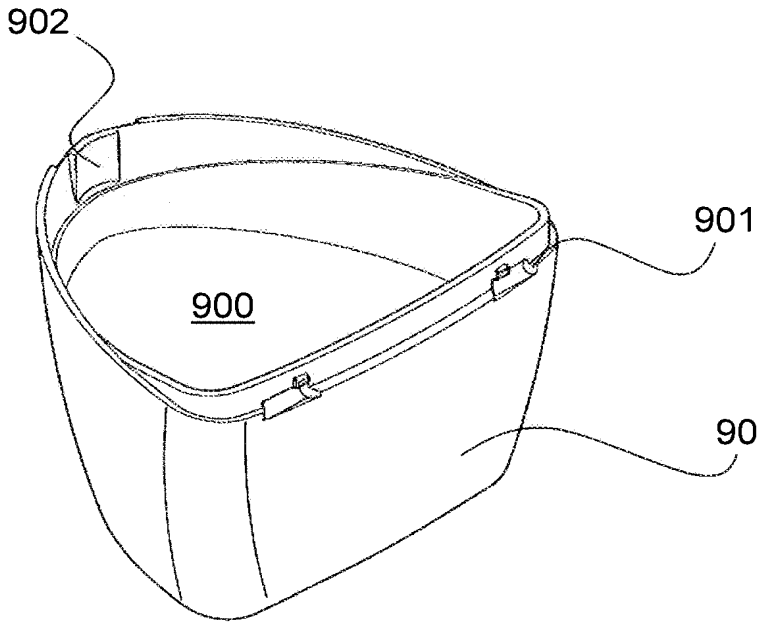

FIG. 17

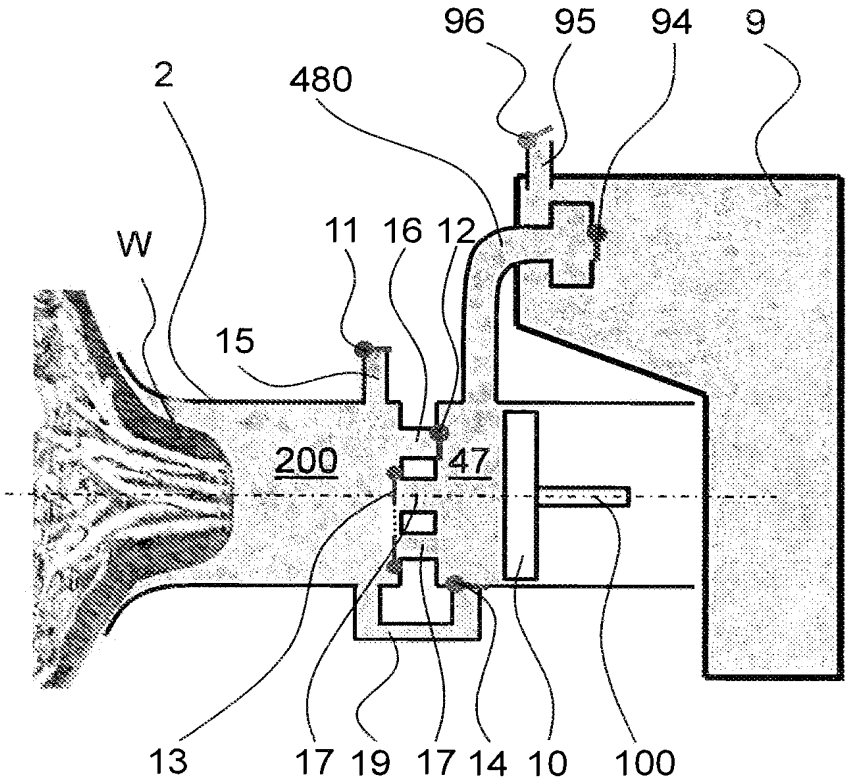

FIG. 18

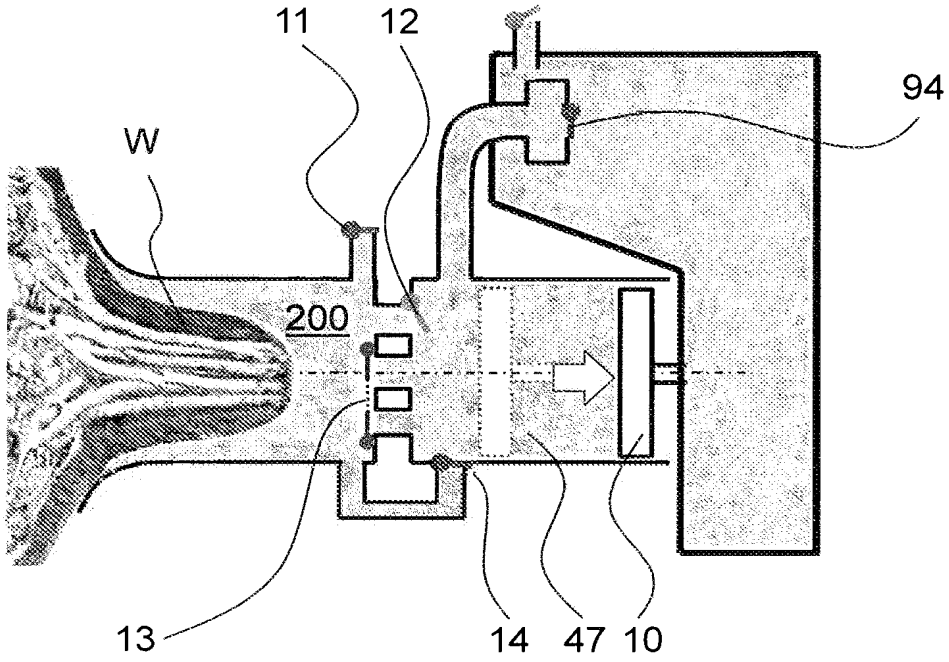

FIG. 19a

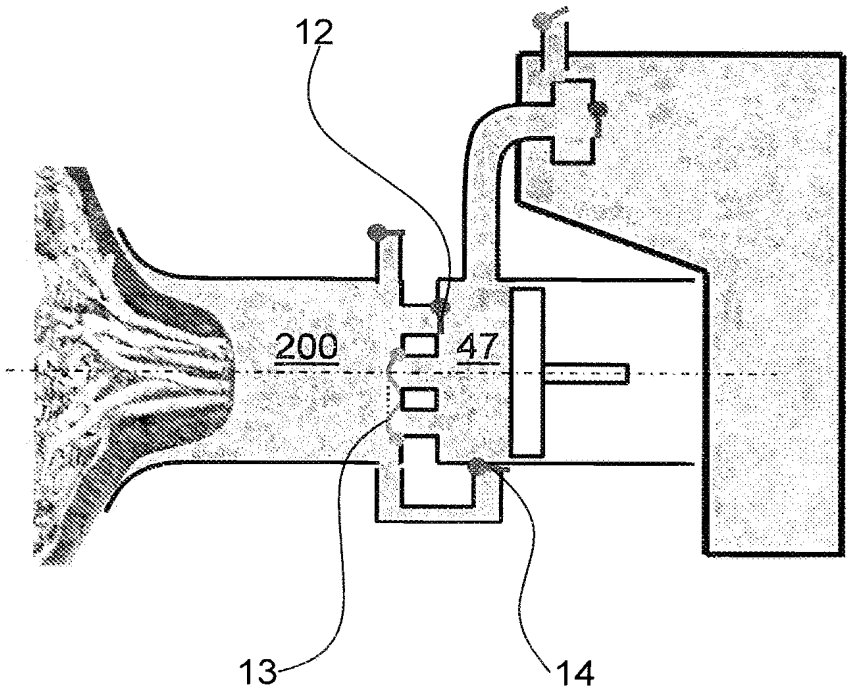

FIG. 19b

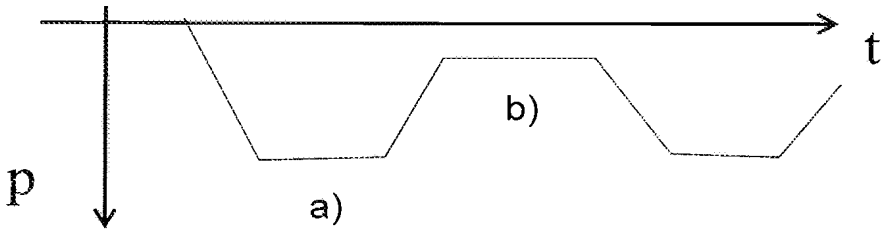

FIG. 19c

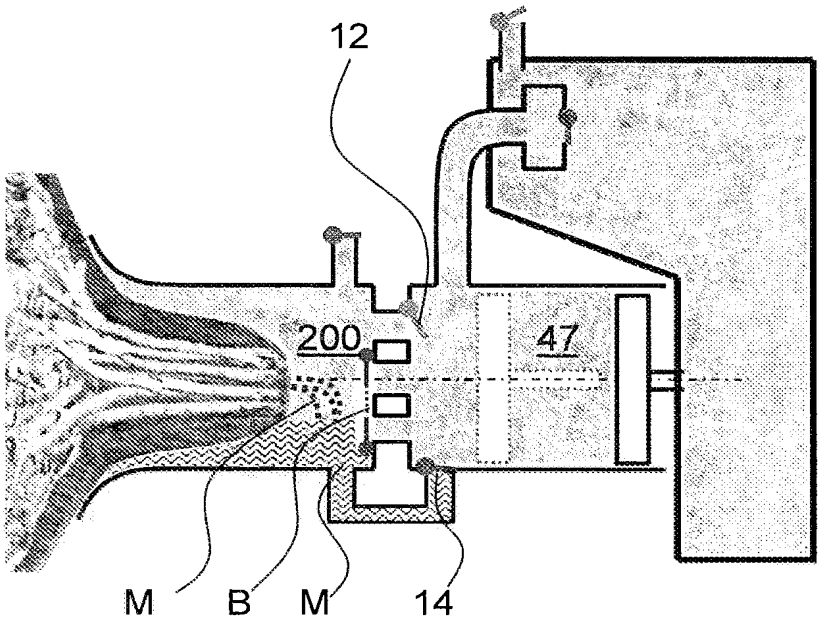

FIG. 20a

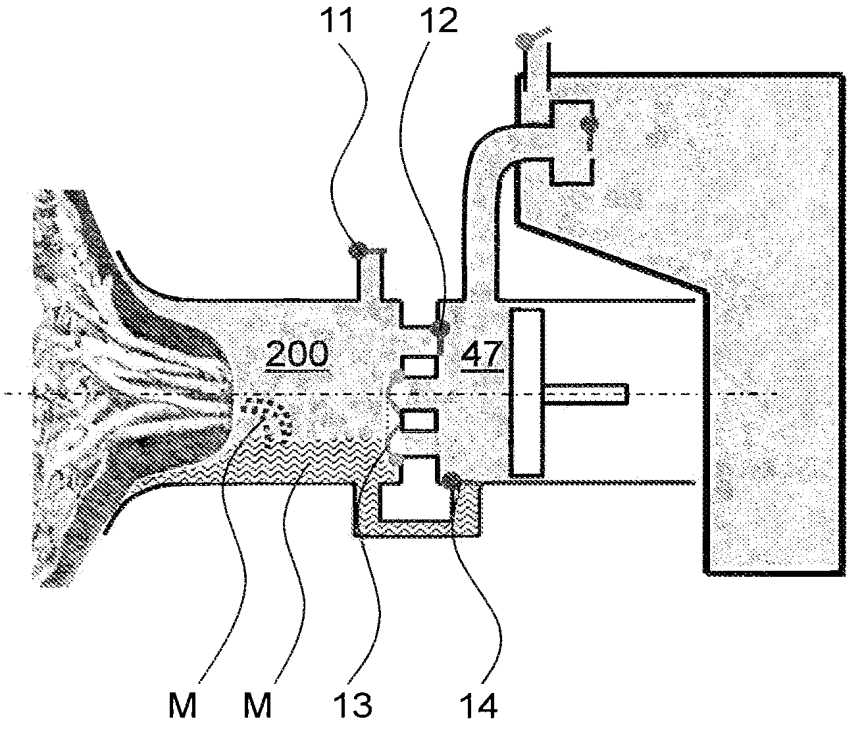

FIG. 20b

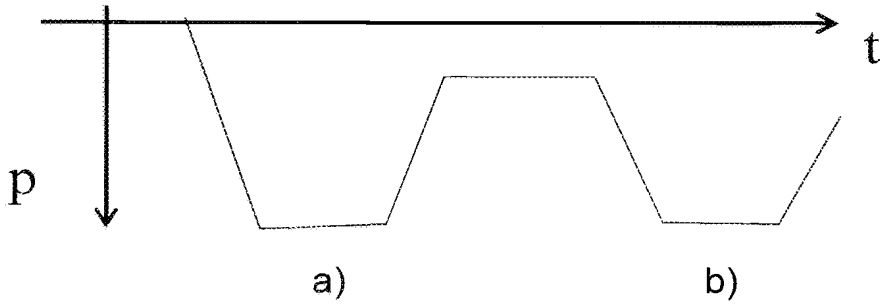

FIG. 20c

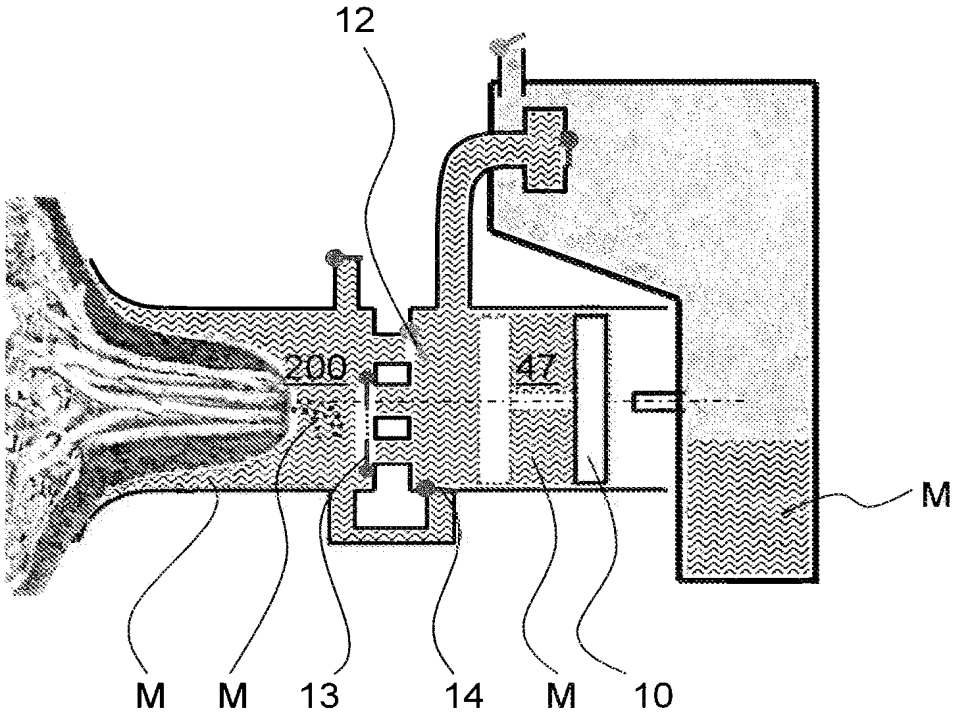

FIG. 21a

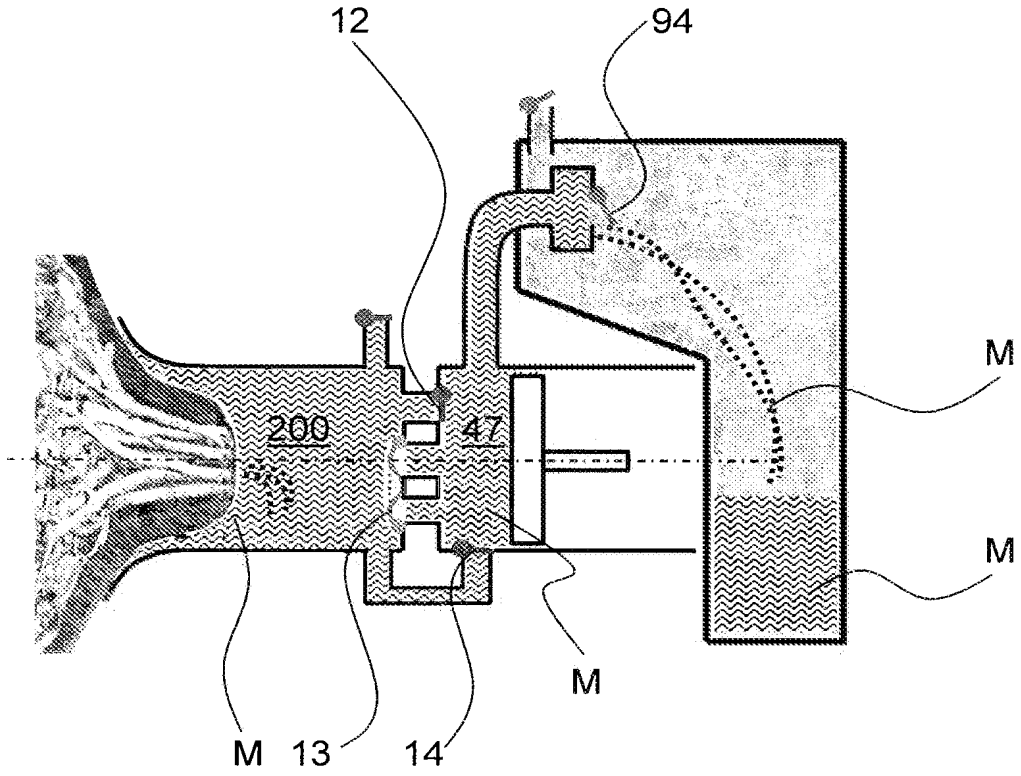

FIG. 21b

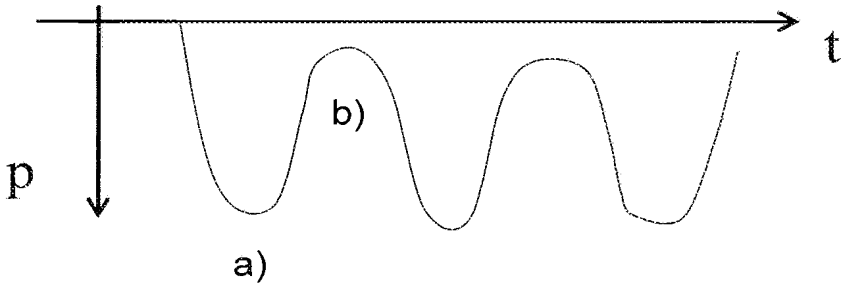

FIG. 21c

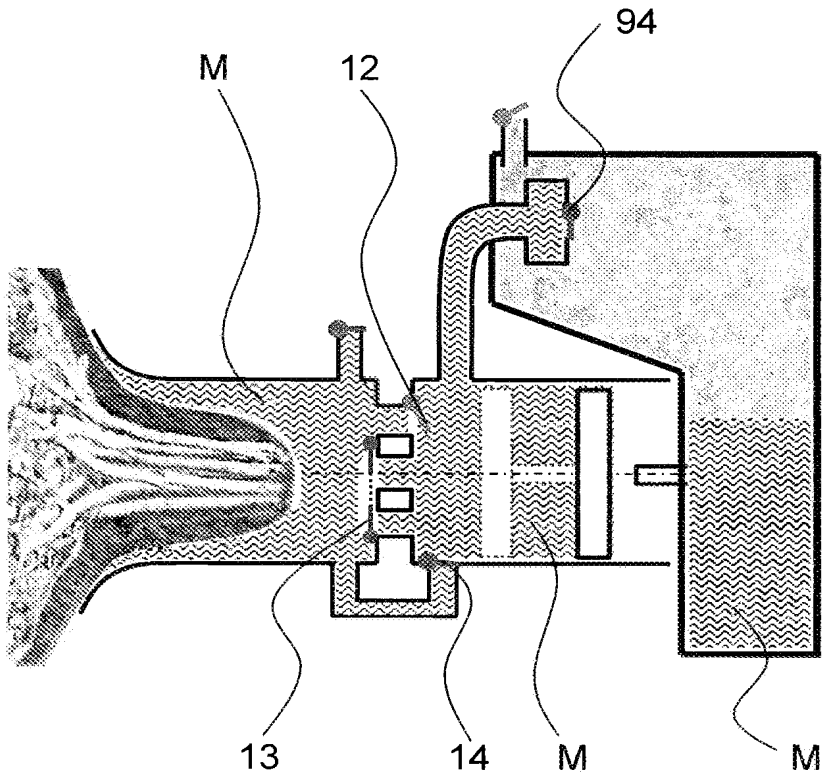

FIG. 22a

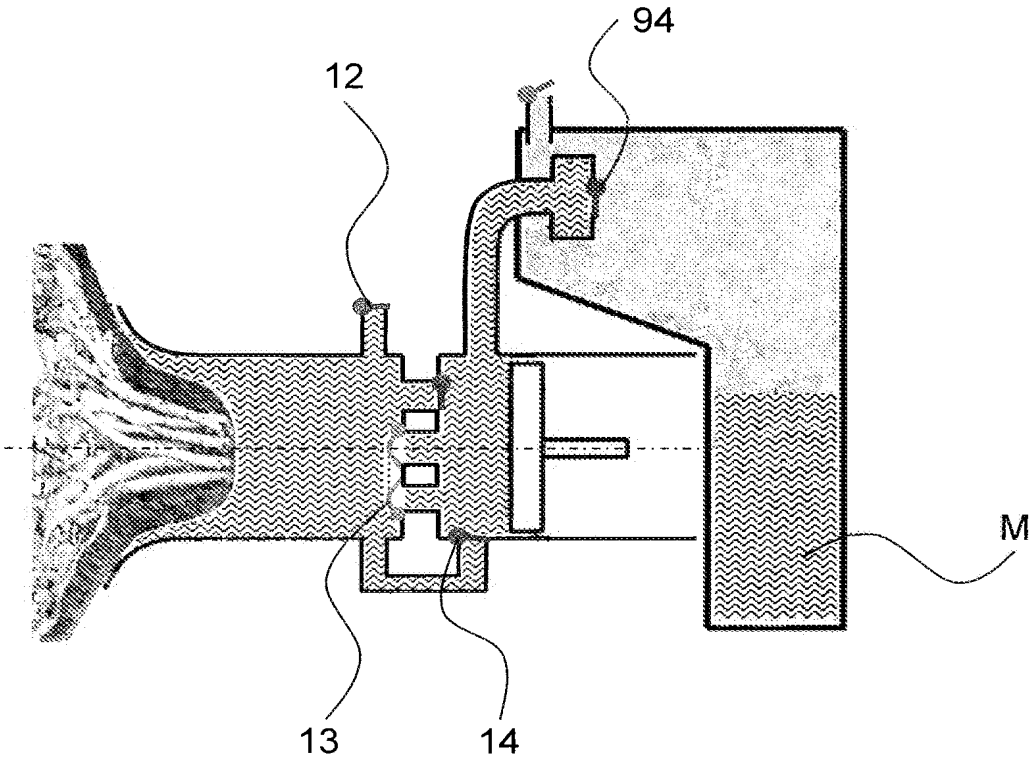

FIG. 22b

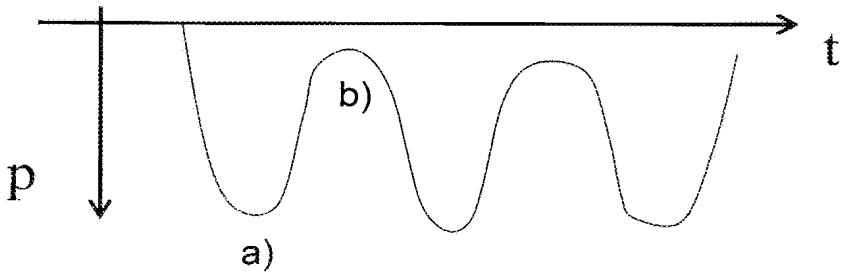

FIG. 22c

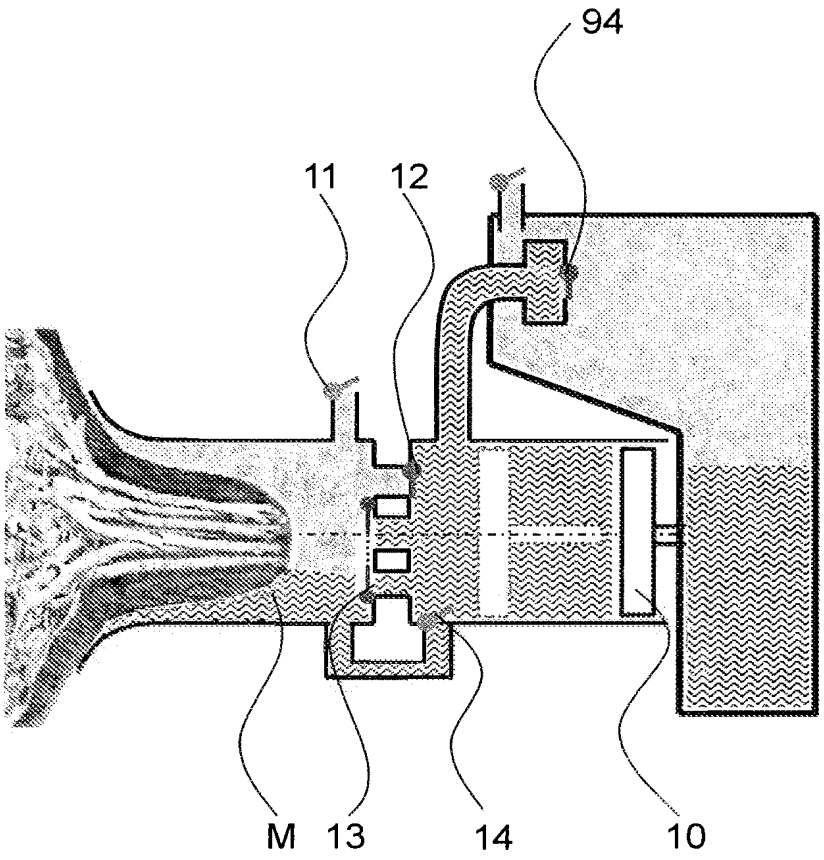

FIG. 23a

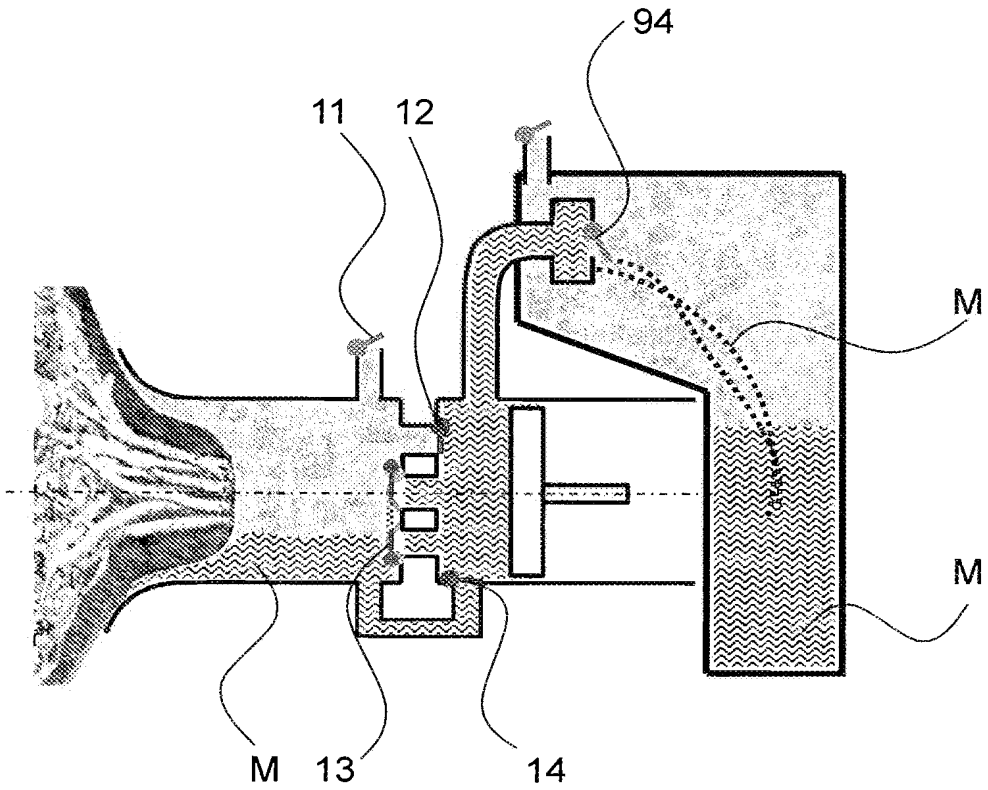

FIG. 23b

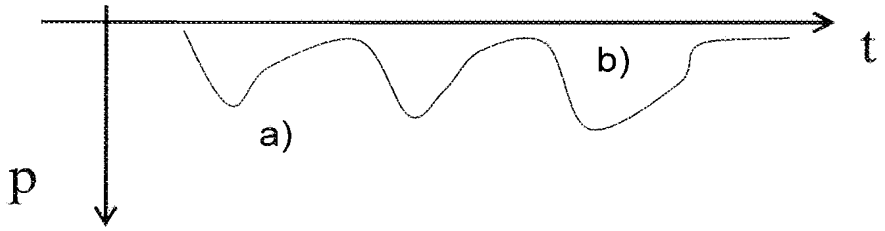

FIG. 23c

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/077141

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/06
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2011/035447 A1 (MEDELA HOLDING AG [CH]; WEBER BEDA [CH]; FURRER ETIENNE [CH]; SCHLIENG) 31 March 2011 (2011-03-31) cited in the application page 12, line 4 - page 13, line 28 page 18, line 12 - page 19, line 18 figures 1-4,12-14 -----	1,44
X	US 2012/071820 A1 (LUZBETAK MARK A [US] ET AL) 22 March 2012 (2012-03-22) page 3, paragraph 47 - page 5, paragraph 64 figures 1A-9 ----- -/--	1,2,4,5, 9,10,12, 22-26, 29,30

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 July 2018	20/07/2018

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Kempeneers, Johanna

2

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2016/131677 A1 (MEDELA HOLDING AG [CH]) 25 August 2016 (2016-08-25) page 8, line 30 - page 12, line 11 figures 1-13	1,2,4,5, 9,10,12, 22-26, 29,30

X	WO 2016/014494 A1 (EXPLORAMED NC7 LLC [US]) 28 January 2016 (2016-01-28) cited in the application	8,15,19, 20,29,30
A	page 25, paragraph 205 - page 29, paragraph 213 page 36, paragraph 227 - page 37, paragraph 227 page 38, paragraph 229 page 58, paragraph 270 - page 60, paragraph 273 page 63, paragraph 279 - page 64, paragraph 279 claim 1 figures 1-4,7A-7C,11A,11B,20,21A,21B,23,31A,31B,32 A-32C,36	44

X	WO 2016/014469 A1 (EXPLORAMED NC7 LLC [US]) 28 January 2016 (2016-01-28) cited in the application	8,14, 17-19, 29,30
A	page 16, paragraph 135 - page 18, paragraph 138 page 20, paragraph 145 - page 21, paragraph 145 page 22, paragraph 148 - page 23, paragraph 148 page 25, paragraph 153 - page 27, paragraph 156 page 28, paragraph 159 - page 30, paragraph 161 page 33, paragraph 167 figures 1,3,5A-5C,52C,53A-53E,58A-58E,59A-59G	44

A	EP 3 058 967 A1 (MEDELA HOLDING AG [CH]) 24 August 2016 (2016-08-24) page 5, paragraph 38 page 6, paragraph 49 - paragraph 59 figures 1,2,11a-11c,12,13a,13b,14a,14b,15,16	8,44

2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2017/077141

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
1-30, 44-55

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

The International Searching Authority has found that this international application contains multiple inventions:

1. Claims 1-7, 9 (in full); 10-30 (in part)

A breast pump for pumping human breast milk, the breast pump having a housing with an actuating unit, a pump chamber with a flexible pump membrane actuated by the actuating unit to produce a vacuum, and a breast shield with an interior for receiving a human breast; wherein a milk duct leads from the interior to the pump chamber via a first inlet opening, and wherein the pump chamber has an outlet opening via which the pumped milk flows from the pump chamber into a milk collection container; wherein a multi-component hygiene module is provided, the hygiene module having a first component with a flow opening for connection to the interior, a valve body with at least one valve, and a second component with a rigid shell forming the pump chamber; wherein the valve body is positioned between the first and second components, and wherein the hygiene module is sealingly and detachably connectable as a whole unit to the housing of the breast pump.

2. Claims 8, 44-55 (in full); 10-30 (in part)

A breast pump for pumping human breast milk, the breast pump having a breast shield with an interior for receiving a human breast, and a pump chamber; wherein a milk duct leads from the interior to the pump chamber via a first inlet opening, and wherein the pump chamber has an outlet opening via which the pumped milk flows from the pump chamber into a milk collection container; wherein with the breast pump in a vertical working position the outlet opening, at least at the start of a pumping operation, is positioned in an upper part of the pump chamber and/or above the inlet opening; a method for operating a breast pump to pump human breast milk, the breast pump having a breast shield with an interior for receiving a human breast, and a pump chamber; wherein in a first pumping phase a cyclically varying negative pressure is applied to the interior by way of the pump chamber so as to pump milk from the human breast, the interior being filled with pumped milk without the pumped milk flowing out of the interior; wherein in a second pumping phase pumped milk flows from the interior into the pump chamber and the pump chamber is filled with pumped milk; and wherein in a third pumping phase the pumped milk flows from the pump chamber into a milk collection container, the interior and the pump chamber remaining filled with pumped milk; wherein the changeover from the second pumping phase to the third pumping phase takes place when a fill level of the pumped milk reaches an outlet opening that leads from the pump chamber to the milk collection container, allowing milk to flow from the pump chamber into the milk collection container via the outlet opening.

3. Claim 35

A breast pump for pumping human breast milk, the breast pump having a breast shield with an interior for receiving a human breast and a pump chamber; wherein a milk duct leads from the interior to the pump chamber via a first inlet opening, and wherein the pump chamber has an outlet opening via which the pumped milk flows from the pump chamber into a milk collection container; wherein between the interior of the breast shield and the pump chamber an emptying duct is provided which runs separately from the milk duct, and wherein the emptying duct can be closed by a valve, the emptying duct being closed during the pumping operation and opened at the end of the pumping operation.

.../...

4. Claims 36-38

A breast pump for pumping human breast milk, the breast pump having a breast shield with an interior for receiving a human breast, and a pump chamber; wherein a milk duct leads from the interior to the pump chamber via a first inlet opening, and wherein the pump chamber has an outlet opening via which the pumped milk flows from the pump chamber into a milk collection container; wherein the breast pump has a pump housing, a pump membrane and a module; wherein the module has at least one rigid shell forming the pump chamber and the breast shield; wherein the module can be attached to the pump housing as a unit, an airtight connection being created between the pump chamber and the interior of the breast shield, and the pump membrane being sealingly held between the module and the pump housing.

5. Claims 31-34, 39, 40

A breast pump for pumping human breast milk, the breast pump having a breast shield with an interior for receiving a human breast, a pump chamber, and a milk collection container; wherein the pump housing is detachably connectable to both the breast shield and the milk collection container, the milk collection container being attachable to the pump housing by means of a spring latch.

6. Claim 41

A milk collection container for connecting to a pump housing of a breast pump for pumping human breast milk, the milk collection container having a lid that faces the pump housing and is air-permeable and liquid-impermeable in at least one region.

7. Claims 42, 43

A breast pump for pumping human breast milk, the breast pump having a breast shield for receiving a human breast, and a pump chamber; wherein the breast shield is detachably connectable to the pump housing; wherein the breast shield can be connected to the pump housing by means of a bayonet fastener; a breast shield for attachment to a pump housing of a breast pump according to claim 42; wherein the breast shield has an interior for receiving the human breast and a connection piece for attachment to the pump housing, the connection piece being provided with a bayonet fastener.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2017/077141

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2017/077141

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INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/EP2017/077141

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
INV. A61M1/06
ADD.

Nach der Internationalen Patentklassifikation (IPC) oder nach der nationalen Klassifikation und der IPC

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
A61M

Recherchierte, aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
EPO-Internal, WPI Data

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	WO 2011/035447 A1 (MEDELA HOLDING AG [CH]; WEBER BEDA [CH]; FURRER ETIENNE [CH]; SCHLIENG) 31. März 2011 (2011-03-31) in der Anmeldung erwähnt Seite 12, Zeile 4 - Seite 13, Zeile 28 Seite 18, Zeile 12 - Seite 19, Zeile 18 Abbildungen 1-4,12-14 -----	1,44
X	US 2012/071820 A1 (LUZBETAK MARK A [US] ET AL) 22. März 2012 (2012-03-22) Seite 3, Absatz 47 - Seite 5, Absatz 64 Abbildungen 1A-9 ----- -/--	1,2,4,5, 9,10,12, 22-26, 29,30

[X] Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen [X] Siehe Anhang Patentfamilie

* Besondere Kategorien von angegebenen Veröffentlichungen :
"A" Veröffentlichung, die den allgemeinen Stand der Technik definiert, aber nicht als besonders bedeutsam anzusehen ist
"E" frühere Anmeldung oder Patent, die bzw. das jedoch erst am oder nach dem internationalen Anmeldedatum veröffentlicht worden ist
"L" Veröffentlichung, die geeignet ist, einen Prioritätsanspruch zweifelhaft erscheinen zu lassen, oder durch die das Veröffentlichungsdatum einer anderen im Recherchenbericht genannten Veröffentlichung belegt werden soll oder die aus einem anderen besonderen Grund angegeben ist (wie ausgeführt)
"O" Veröffentlichung, die sich auf eine mündliche Offenbarung, eine Benutzung, eine Ausstellung oder andere Maßnahmen bezieht
"P" Veröffentlichung, die vor dem internationalen Anmeldedatum, aber nach dem beanspruchten Prioritätsdatum veröffentlicht worden ist
"T" Spätere Veröffentlichung, die nach dem internationalen Anmeldedatum oder dem Prioritätsdatum veröffentlicht worden ist und mit der Anmeldung nicht kollidiert, sondern nur zum Verständnis des der Erfindung zugrundeliegenden Prinzips oder der ihr zugrundeliegenden Theorie angegeben ist
"X" Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann allein aufgrund dieser Veröffentlichung nicht als neu oder auf erfinderischer Tätigkeit beruhend betrachtet werden
"Y" Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann nicht als auf erfinderischer Tätigkeit beruhend betrachtet werden, wenn die Veröffentlichung mit einer oder mehreren Veröffentlichungen dieser Kategorie in Verbindung gebracht wird und diese Verbindung für einen Fachmann naheliegend ist
"&" Veröffentlichung, die Mitglied derselben Patentfamilie ist

Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
12. Juli 2018	20/07/2018

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Kempeneers, Johanna

2

C. (Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	WO 2016/131677 A1 (MEDELA HOLDING AG [CH]) 25. August 2016 (2016-08-25) Seite 8, Zeile 30 - Seite 12, Zeile 11 Abbildungen 1-13	1,2,4,5, 9,10,12, 22-26, 29,30

X	WO 2016/014494 A1 (EXPLORAMED NC7 LLC [US]) 28. Januar 2016 (2016-01-28) in der Anmeldung erwähnt	8,15,19, 20,29,30
A	Seite 25, Absatz 205 - Seite 29, Absatz 213 Seite 36, Absatz 227 - Seite 37, Absatz 227 Seite 38, Absatz 229 Seite 58, Absatz 270 - Seite 60, Absatz 273 Seite 63, Absatz 279 - Seite 64, Absatz 279 Anspruch 1 Abbildungen 1-4,7A-7C,11A,11B,20,21A,21B,23,31A,31B,32 A-32C,36	44

X	WO 2016/014469 A1 (EXPLORAMED NC7 LLC [US]) 28. Januar 2016 (2016-01-28) in der Anmeldung erwähnt	8,14, 17-19, 29,30
A	Seite 16, Absatz 135 - Seite 18, Absatz 138 Seite 20, Absatz 145 - Seite 21, Absatz 145 Seite 22, Absatz 148 - Seite 23, Absatz 148 Seite 25, Absatz 153 - Seite 27, Absatz 156 Seite 28, Absatz 159 - Seite 30, Absatz 161 Seite 33, Absatz 167 Abbildungen 1,3,5A-5C,52C,53A-53E,58A-58E,59A-59G	44

A	EP 3 058 967 A1 (MEDELA HOLDING AG [CH]) 24. August 2016 (2016-08-24) Seite 5, Absatz 38 Seite 6, Absatz 49 - Absatz 59 Abbildungen 1,2,11a-11c,12,13a,13b,14a,14b,15,16	8,44

2

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/EP2017/077141

Feld Nr. II Bemerkungen zu den Ansprüchen, die sich als nicht recherchierbar erwiesen haben (Fortsetzung von Punkt 2 auf Blatt 1)

Gemäß Artikel 17(2)a) wurde aus folgenden Gründen für bestimmte Ansprüche kein internationaler Recherchenbericht erstellt:

1. ☐ Ansprüche Nr.
weil sie sich auf Gegenstände beziehen, zu deren Recherche diese Behörde nicht verpflichtet ist, nämlich

2. ☐ Ansprüche Nr.
weil sie sich auf Teile der internationalen Anmeldung beziehen, die den vorgeschriebenen Anforderungen so wenig entsprechen, dass eine sinnvolle internationale Recherche nicht durchgeführt werden kann, nämlich

3. ☐ Ansprüche Nr.
weil es sich dabei um abhängige Ansprüche handelt, die nicht entsprechend Satz 2 und 3 der Regel 6.4 a) abgefasst sind.

Feld Nr. III Bemerkungen bei mangelnder Einheitlichkeit der Erfindung (Fortsetzung von Punkt 3 auf Blatt 1)

Diese Internationale Recherchenbehörde hat festgestellt, dass diese internationale Anmeldung mehrere Erfindungen enthält:

siehe Zusatzblatt

1. ☐ Da der Anmelder alle erforderlichen zusätzlichen Recherchengebühren rechtzeitig entrichtet hat, erstreckt sich dieser internationale Recherchenbericht auf alle recherchierbaren Ansprüche.

2. ☐ Da für alle recherchierbaren Ansprüche die Recherche ohne einen Arbeitsaufwand durchgeführt werden konnte, der zusätzliche Recherchengebühr gerechtfertigt hätte, hat die Behörde nicht zur Zahlung solcher Gebühren aufgefordert.

3. ☒ Da der Anmelder nur einige der erforderlichen zusätzlichen Recherchengebühren rechtzeitig entrichtet hat, erstreckt sich dieser internationale Recherchenbericht nur auf die Ansprüche, für die Gebühren entrichtet worden sind, nämlich auf die Ansprüche Nr.
1-30, 44-55

4. ☐ Der Anmelder hat die erforderlichen zusätzlichen Recherchengebühren nicht rechtzeitig entrichtet. Dieser internationale Recherchenbericht beschränkt sich daher auf die in den Ansprüchen zuerst erwähnte Erfindung; diese ist in folgenden Ansprüchen erfasst:

Bemerkungen hinsichtlich eines Widerspruchs

☐ Der Anmelder hat die zusätzlichen Recherchengebühren unter Widerspruch entrichtet und die gegebenenfalls erforderliche Widerspruchsgebühr gezahlt.

☐ Die zusätzlichen Recherchengebühren wurden vom Anmelder unter Widerspruch gezahlt, jedoch wurde die entsprechende Widerspruchsgebühr nicht innerhalb der in der Aufforderung angegebenen Frist entrichtet.

☒ Die Zahlung der zusätzlichen Recherchengebühren erfolgte ohne Widerspruch.

WEITERE ANGABEN **PCT/ISA/** 210

Die internationale Recherchenbehörde hat festgestellt, dass diese internationale Anmeldung mehrere (Gruppen von) Erfindungen enthält, nämlich:

1. Ansprüche: 1-7, 9(vollständig); 10-30(teilweise)

Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe ein Gehäuse mit einer Antriebseinheit, eine Pumpkammer mit einer von der Antriebseinheit angetriebenen flexiblen Pumpmembran zur Erzeugung eines Vakuums und eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust aufweist, wobei ein Milchkanal vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer führt, und wobei die Pumpkammer eine Auslassöffnung aufweist, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst, wobei ein mehrteiliges Hygienemodul vorhanden ist, wobei das Hygienemodul einen ersten Teil mit einer Durchflussöffnung zur Verbindung mit dem Innenraum, einen Ventilkörper mit mindestens einem Ventil und einen zweiten Teil mit einer steifen Schale zur Bildung der Pumpkammer aufweist, wobei der Ventilkörper zwischen dem ersten und zweiten Teil angeordnet ist und wobei das Hygienemodul als Ganzes mit dem Gehäuse der Brustpumpe dichtend und lösbar verbindbar ist.

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2. Ansprüche: 8, 44-55(vollständig); 10-30(teilweise)

Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer aufweist, wobei ein Milchkanal vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer führt, und wobei die Pumpkammer eine Auslassöffnung aufweist, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst, wobei die Auslassöffnung in vertikaler Gebrauchslage der Brustpumpe mindestens zu Beginn eines Abpumpvorgangs in einem oberen Bereich der Pumpkammer und/oder oberhalb der Einlassöffnung angeordnet ist; Verfahren zum Betätigen einer Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer aufweist, wobei der Innenraum mittels der Pumpkammer mit einem sich zyklisch ändernden Unterdruck beaufschlagt wird,wobei in einer ersten Pumpphase der Innenraum mit dem sich zyklisch ändernden Unterdruck beaufschlagt wird, um Milch aus der Mutterbrust abzupumpen, wobei der Innenraum mit abgepumpter Milch gefüllt wird, ohne dass abgepumpte Milch aus dem Innenraum hinausfliesst, wobei in einer zweiten Pumpphase abgepumpte Milch aus dem Innenraum in die Pumpkammer fliesst und die Pumpkammer mit abgepumpter Milch gefüllt wird und wobei in einer dritten Pumpphase die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst, wobei der Innenraum und die Pumpkammer mit abgepumpter Milch gefüllt

WEITERE ANGABEN PCT/ISA/ 210

bleiben,wobei der Wechsel von der zweiten Pumpphase zur dritten Pumpphase erfolgt, indem ein Füllstand der abgepumpten Milch eine Auslassöffnung erreicht, welche von der Pumpkammer zum Milchsammelbehälter führt, wodurch Milch durch die Auslassöffnung von der Pumpkammer in den Milchsammelbehälter fliesst.

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3. Anspruch: 35

Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer aufweist, wobei ein Milchkanal vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer führt, und wobei die Pumpkammer eine Auslassöffnung aufweist, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst, wobei ein Entleerungskanal zwischen dem Innenraum der Brusthaube und der Pumpkammer vorhanden ist, welcher getrennt vom Milchkanal verläuft, und wobei der Entleerungskanal mittels eines Ventils verschliessbar ist, wobei der Entleerungskanal während des Abpumpvorgangs geschlossen ist und am Ende des Abpumpvorgangs geöffnet ist..

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4. Ansprüche: 36-38

Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube mit einem Innenraum zur Aufnahme einer Mutterbrust und eine Pumpkammer aufweist, wobei ein Milchkanal vom Innenraum durch eine erste Einlassöffnung in die Pumpkammer führt, und wobei die Pumpkammer eine Auslassöffnung aufweist, durch welche die abgepumpte Milch von der Pumpkammer in einen Milchsammelbehälter fliesst, wobei die Brustpumpe ein Pumpengehäuse, eine Pumpmembran und ein Modul aufweist, wobei das Modul mindestens eine steife Schale zur Bildung der Pumpkammer und die Brusthaube aufweist, wobei das Modul als Einheit am Pumpengehäuse befestigbar ist, wobei eine dichte Verbindung zwischen der Pumpkammer und dem Innenraum der Brusthaube geschaffen wird und wobei die Pumpmembran zwischen dem Modul und dem Pumpengehäuse dichtend gehalten ist.

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5. Ansprüche: 31-34, 39, 40

Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube zur Aufnahme einer Mutterbrust, ein Pumpengehäuse sowie einen Milchsammelbehälter aufweist, wobei das Pumpengehäuse einerseits lösbar mit der Brusthaube und andererseits lösbar mit dem Milchsammelbehälter verbindbar ist, wobei der Milchsammelbehälter mittels eines Schnappverschlusses am

WEITERE ANGABEN PCT/ISA/ 210

Pumpengehäuse befestigbar ist.
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6. Anspruch: 41

Milchsammelbehälter zur Verbindung mit einem Pumpengehäuse einer Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei der Milchsammelbehälter einen Deckel aufweist, der dem Pumpengehäuse zugewandt ist und der mindestens in einem Bereich luftdurchlässig und flüssigkeitsundurchlässig ist.
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7. Ansprüche: 42, 43

Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brustpumpe eine Brusthaube zur Aufnahme einer Mutterbrust und ein Pumpengehäuse aufweist, wobei die Brusthaube lösbar mit dem Pumpengehäuse verbindbar ist, wobei die Brusthaube mittels eines Bajonettverschlusses mit dem Pumpengehäuse verbindbar ist; Brusthaube zur Befestigung an einem Pumpengehäuse einer Brustpumpe gemäss Anspruch 42, wobei die Brusthaube einen Innenraum zur Aufnahme der Mutterbrust und einen Stutzen zur Befestigung am Pumpengehäuse aufweist, wobei der Stutzen mit einem Bajonettverschluss versehen ist.

INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

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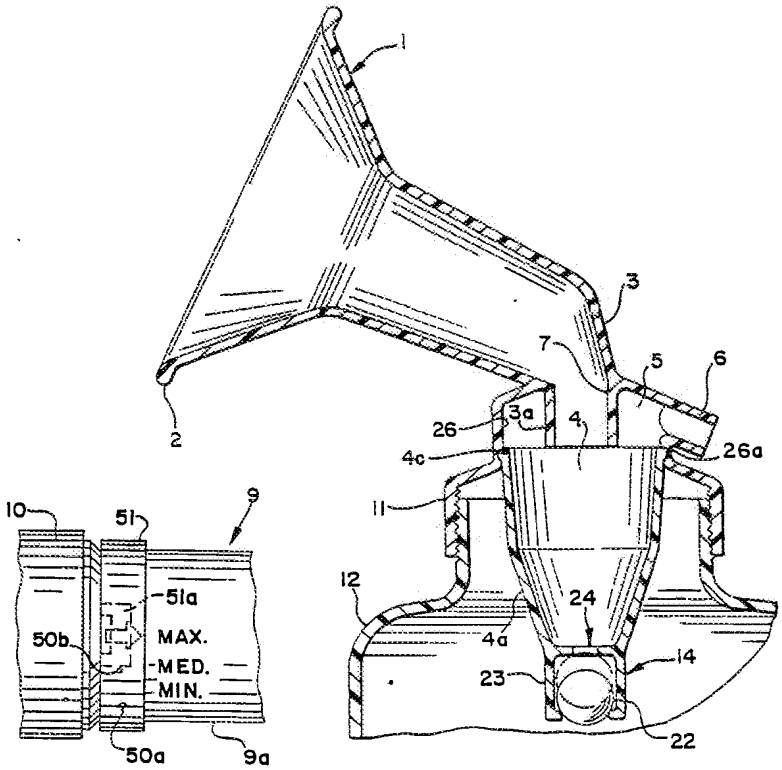
(57) Abstract

A breastpump is provided with a valve mechanism (14) that closes a collection chamber (4) when a vacuum is applied to a hood member (1) and opens the collection chamber when the vacuum is removed. The valve mechanism (14) is removably attached to the collection chamber for ready cleaning. A baffle (7) in the hood member (1) protects the vacuum line from milk flow. One embodiment of the invention has a connecting sleeve (10) for connecting either a manually driven pneumatic pump (9) or a motor driven pneumatic pump to the hood body to create an intermittent vacuum. A connector (56) is further provided for use with a pair of breastpumps operated simultaneously by a motor driven pneumatic pump. An adjustment piece (36) for decreasing the cross-sectional area of a funnel-shaped hood member (1) is also disclosed for use of the breastpumps with smaller breasts. One type of manually driven piston pump (9) useful with the invention has apertures (50a, 50b) formed through the pump cylinder wall that are selectively opened and closed for adjustment of the piston pump vacuum.



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BREASTPUMP

This is a continuation-in-part application of U.S. Patent Application Serial No. 874,879 filed June 6, 1986, which is a continuation of Serial No. 612,602 filed May 21, 1984 (now abandoned), which is a continuation-in-part of Serial No. 296,081 filed August 25, 1981 (now abandoned).

FIELD OF THE INVENTION

The present invention generally relates to breastmilk pumps, and more particularly relates to a new and improved: valving mechanism for a breastmilk pump; a suction hood for a breastmilk pump; a manually adjustable pump-vacuum control mechanism for a manual pump; and an adaptor for pumping milk from two breasts simultaneously.

BACKGROUND OF THE INVENTION

Breastmilk pumps are well known, and are generally comprised of a hood that fits over the breast, a vacuum pump connected to the hood for generating an intermittent vacuum within the hood, and a receptacle for the expressed milk. Manually driven vaccum pumps as well as those that are driven by a motor are ordinarily used. The vacuum pumps of these devices,

as a rule, intermittently generate a vacuum or negative pressure within the hood, with the hood encompassing the nipple and a substantial amount of the breast. The intermittent suction action of the pump serves to pull on the breast and thereby extract milk in an action reminiscent of suckling. The milk so extracted typically flows from the hood into a collection container for storage and later use.

Apart from the purely hygienic requirements for such equipment, there also exist technical problems which are at least insufficiently solved with regard to prior art devices. One such significant failing of nearly all of the prior art devices is that the milk expressed often reaches the vacuum line or even the pump. In order to eliminate such a serious problem, many prior devices contain so-called safety volumes between the hood and the pump. Such a solution of the problem is expensive and usually cannot provide effective protection of the vacuum line and pump from milk. Also, varying degrees of vacuum can be generated as the milk receptacle fills, which must then be compensated for.

Another important consideration in the design of a breastpump is the vacuum created by the pump and its effect upon the breast. While it is the ultimate desire to design a breastpump that perfectly duplicates a baby's nursing action, this is extremely difficult to achieve. However, there are several important characteristics that a breastpump, properly designed, can simulate. Three things about the vacuum and its application to the breast are considered very important. These are: (a) how much vacuum does a pump create on the breast; (b) how long is that vacuum applied to the breast; and (c) can the vacuum be regulated within safe, natural limits to suit the mother's comfort with proper expression of milk?

First, a vacuum that is much greater than that "vacuum" created by a suckling baby is not only unnatural, it can also cause pain and injury to the breast. Second, just as too much vacuum can hurt the breast, too long an application of vacuum is also unnatural, and may create discomfort and injury. Third, uncontrollable vacuum -- either vacuum in excess of safe, natural limits or vacuum that cannot be fine-tuned for a woman's comfort -- makes a breastpump less effective or even useless.

In utilizing breastpumps, whether they are of a motor driven or manually driven type, it has been found that the wide variety in the size of breasts also gives rise to problems if a single breastpump is to be given universal application. This is particularly true in regard to smaller breasts, since the hoods used by most breastpumps are designed to handle a medium or larger-size breast. For example, the small breast can be sucked into a standard size hood to an extent that, if not necessarily painful, is at least rather uncomfortable. In general, the funnel of such a suction hood should abut the breast at a distance from the nipple that is as large as possible, which condition demands a funnel for the hood which is also as large as possible. While it has become obvious that the provision of different suction hoods having various funnel diameters solves such a problem, it does so in an unsatisfactory way, since providing a product line of different size hoods is expensive from a marketing and manufacturing standpoint.

SUMMARY OF THE INVENTION

One of the principal objects of the present invention is to provide a breastpump that has an improved structure including a simple but effective valv-

ing mechanism which prevents breastmilk from entering the vacuum line or suction pump.

A particularly noteworthy advantage of the valving mechanism of the present invention is that a relatively constant negative pressure or vacuum can be applied to the breastpump, since no variable volumes, (i.e., in the receiving container), are present in this device. This allows the employment of smaller pumps, since the volume of the vacuum or negative pressure which is necessary for intermittent operation can be considerably smaller in comparison to other known solutions. It is also not necessary to create a vacuum to compensate for the volume of the receiving container due to the presence of the valve of the present invention.

Another object of the present invention is to provide a breastpump that has a readily adjustable vacuum in a manually driven (non-motor) application.

Yet another object of the present invention is to provide a new and improved construction of a suction hood for a breastpump, which suction hood is relatively simple in construction and design, economical to manufacture, extremely reliable in operation, not readily subject to breakdown or malfunction, and requires a minimum of maintenance and servicing yet is effective in expressing breastmilk without fouling the equipment.

Still another object of the present invention is to provide a breastpump assembly which collects milk from both breasts simultaneously.

To these ends, which will become more readily apparent in regard to the detailed description of various embodiments of the invention which follows, the present invention comprises a hood body or member to which a collecting or catch chamber is connected. At the outlet

of the collecting chamber there is provided a valve which closes a passage leading from the collecting chamber to a receiving container. When a vacuum or negative pressure is applied to the hood from a suction device, which may be manually operated or motor driven, the valve closes the collecting chamber outlet to the receiving chamber, but opens the outlet on the return cycle of the pump to force the milk expressed from the collecting chamber into the receiving container.

The valve used is extremely effective, simple in construction, and is easily cleaned. In one embodiment the valving mechanism comprises a ball valve. In a second and presently preferred construction, the valving mechanism comprises a reciprocating disk. In this latter construction, the valving mechanism is part of an adaptor that is removably attached to an extension of the hood that forms part of the collecting chamber, so that the valve can be readily removed for cleaning.

It will be noted that due to the provision of the collecting or catch chamber with a valve, milk can be pumped to a receiving container in the form of a plastic bag, since the vacuum or negative pressure no longer affects the receiving container. Moreover, an overflow can be avoided, since the valve opens promptly and the expressed milk quickly flows into the receiving container.

A baffle arrangement is further used in conjunction with the valve mechanism to prevent milk from passing into the vacuum line or from reaching the vacuum pump.

The present invention also provides a breast-pump that, in a manual mode (i.e., using a piston pump that is hand operated), applies a governed vacuum to express milk from the breast. With an electric motor driven pneumatic pump, its maximum vacuum and timing are governed by the machine and remains relatively

constant. With hand-driven piston pumps, too much vacuum could be applied to the breast and for an undesirably long interval, depending on the speed and length of stroke with which the woman is operating the piston pump. The present invention provides for a vacuum release within the piston cylinder that automatically releases the vacuum as soon as the maximum desired vacuum is reached at the end of a predetermined stroke.

The present invention also provides for the adjustment of the vacuum level in the hand-driven piston pump application of the invention. This is accomplished in a preferred form of the invention through the use of a rotatable ring on the piston cylinder that selectively opens and closes apertures in the cylinder to adjust the flow of air into the cylinder during an evacuation stroke of the piston, and thereby adjust the amount of vacuum generated. The vacuum control is readily manipulated for easy adjustment of the vacuum generated.

The problem of the small breast that does not fit the "standardized" construction of the hood is solved in the present invention by providing an improved construction for the suction hood which includes at least one adjusting piece having a shape similar to that of the general funnel structure of the main funnel of the hood, and which is insertable into the main hood funnel to reduce the latter's cross-sectional area. In particular, a preferred funnel-shaped adjusting piece has a generating angle for the outer surface of the adjusting piece funnel which corresponds to the generating angle of the inner surface of the main funnel of the hood, with the inner surface of the adjusting piece having a larger generating angle than that of the inner surface of the main funnel. The adjusting piece effectively reduces the diameter of the main funnel at the base of the main funnel so that the hood can be conveniently used by women with smaller breasts.

Yet another object of the present invention is accomplished in the use of a device that enables a single motor driven pneumatic pump to express milk from two breasts simultaneously. The device comprises a y-shaped tubular connector that permits use of two of the foregoing breastpumps at the same time.

The foregoing objects and advantages of the present invention will be further understood upon consideration of the following detailed description of the invention taken in conjunction with the accompanying drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a partial vertical sectional view of a first embodiment of a breastpump made in accordance with the present invention in which a ball valve is used;

FIG. 2 is a view similar to that of FIG. 1 showing another embodiment of a breastpump made in accordance with the present invention using a manually driven suction pump mechanism, and employing a disk valve mechanism, and shows as well the use of an adaptor for small breasts;

FIG. 2A is a view similar to that of FIG. 2 showing yet another embodiment of a breastpump made in accordance with the present invention;

FIG. 2B is an enlarged sectional view of a modified connector for use with a motor driven pump;

FIGS. 3 through 5 show a vacuum adjustment mechanism for use with the manually driven suction pump of the device of FIG. 2A; and

FIG. 6 shows a connector for a double-pump application for use in collecting milk from two breasts simultaneously.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

Turning now to FIG. 1, a first embodiment of a breastpump made in accordance with the teachings of the present invention is shown. This arrangement comprises a hood body or hood member 1 having two ends. The first end 2 has a substantially wide cross-section (diameter), and is funnel shaped. During operation of this device, funnel end 2 is placed over the breast of the user. A second end 3 of the hood member constitutes a generally cylindrical extension of the funnel, and has a cross-section substantially narrower than the cross-section of the end 2. The second end 3 communicates with a collecting or catch chamber 4 and with a vacuum passage 5 via a short tubular extension 3a.

The vacuum passage 5 also communicates with a vacuum line 6, which in this embodiment is shown as a short stem which is connected with a flexible tube (not shown) that extends to a vacuum or suction pump, such as an electric motor driven pneumatic pump.

The collecting chamber 4 is arranged substantially immediately after the extension 3a of the hood. Separating means in the form of a depending separation wall 7 (which here is the rear wall of the extension 3a) forms a baffle between the end of the hood extension 3a and the collecting chamber 4, and the vacuum line 6. It will be noted that the bottom of the separation wall 7 is below the level of the top end of the vacuum line 6. Milk expressed into the hood member 1 is thus blocked by the separation wall 7 from thereby entering into the vacuum line 6.

At the lower portion of the collecting chamber 4 is a valve mechanism 14. In this embodiment, this valve mechanism 14 is a ball-type valve having a ball 22 captured within a cage 23 formed in the bottom of a

cup-like receptacle 4a that defines the majority of the collecting chamber 4. The top of the ball valve cage 23 has an upper opening 24 which is opened and closed by action of the ball 22. Opening 24 constitutes the outlet for the collecting chamber 4. In operation, the application of a suction or negative pressure to the hood member 1 and collecting chamber 4 by the suction pump connected to the vacuum line 6 causes the ball 22 to be drawn upwardly (as shown in FIG. 1) to close the upper opening 24. Milk expressed through the suction action will thus collect in the collecting chamber 4. Release of the negative pressure will thereupon cause the ball 22 to drop free of the opening 24 allowing the milk to flow around the ball through the ball valve cage 23 and into a container or receptacle 12.

The collecting receptacle 4a is of a size to allow a typical volume of milk expressed in a single stroke to collect without overflowing, with the action of the ball valve being sufficiently quick to release the milk from the collecting chamber 4 into the container 12 for the next stroke. Milk thus does not substantially collect in the collecting chamber 4 between strokes.

It will be further noted that the collecting chamber receptacle 4a is received in an enlarged portion 26 at the tail-end of the hood member 1. A snap-fit is made using a bead 4c formed around the top edge of the collection chamber receptacle 4a that is received in annular recess 26a. The snap-fit permits easy removal of the collection chamber receptacle 4a and valve mechanism 14 for cleaning, as well as for cleaning of the hood member 1. Also, connecting means in the form of a collar 11 is provided for connection of the hood member 1 and the collecting chamber 4 with the container 12, as through the screw-threaded attachment of the collar 11 to the neck of the container 12.

A second possible embodiment of the invention is shown in FIG. 2, and employs a valving mechanism that is different from that of the preceding embodiment, but operates on the same general principle. This valving mechanism shown in FIG. 2 is not presently preferred, with the valving mechanism of FIG. 2A being considered much more advantageous. It will further be understood that like numbers denominate the same general structure or element in all of the various embodiments shown in the FIGS.

In FIG. 2, the suction or vacuum pump is specifically shown as a manually driven piston pump 9 having a pump cylinder 9a and a piston 9b which reciprocates within the cylinder 9a under action of a piston rod 9e. The pump cylinder 9a is connected to the hood member 1 by means of a connecting means or connecting sleeve 10 which forms part of the hood member 1. Connecting sleeve 10 is internally screw threaded to match with the screw threads formed on the outer part of an end of the piston cylinder 9a. Forward end 9d of the piston cylinder butts against a shoulder formed around the interior of the connecting sleeve 10 in a substantially air-tight fit. An aperture 9c is formed in the wall of the piston cylinder 9a at a point which corresponds to what is presently considered to be the maximum desired vacuum pressure to be reached on an average stroke of the manually driven piston pump. Once the head of the piston 9b passes beyond this aperture 9c in its downward (vacuum-inducing) stroke, the vacuum produced is automatically released. The piston cylinder has a displacement (volume at full outward stroke) of about 40 cc at the point of vacuum release.

The valve 14 in the embodiment of FIG. 2 is of a disk-type valve composed of a tubular housing 15, a perforated plate 16 that extends across the diameter of the housing 15, a disk 17, a guiding member 18 and a stop member 19. The disk 17 is adapted to travel along the guide 18 between a closed and an open position of the valve 14.

The valve 14 includes an upper chamber 20 which forms part of the collecting chamber 4, and collects milk when the valve 14 is in a closed position (with the disk 17 in facial engagement with the bottom of the perforated plate 16, thereby closing the openings 16' of the perforated plate). The tubular housing 15 of valve 14 is removably attached to the hood member 1 by means of a suitable releasable closure attaching means 21. In this embodiment of the invention, this attaching means is accomplished through a threaded engagement with the hood extension 3a.

During the operation of the embodiment of FIG. 2, the hood member 1 is held against the breast of the user with the main funnel body or portion 31 surrounding the nipple and adjacent breast. An intermittent vacuum is created by operation of the pump 9. The vacuum created in the collecting chamber 4 causes the disk 17 to be lifted to an upper position which sealingly closes apertures 16' of the perforated plate 16.

Due to the sealing engagement between an inside portion of the main funnel body 31 of the hood member 1 and the breast during the application of the vacuum, the milk is sucked from the breast of the user. The force of gravity causes the milk to be accumulated in the collecting chamber 4, particularly in the upper portion 20 of the valve housing 15. As soon as the negative pressure is discontinued, the disk 17 drops into its lower position and the milk which has been collected in the collecting chamber 4 thereby flows downwardly into the container 12.

Separation wall 7 combines with a rear wall 8 of the hood member extension 3a to form a baffle to prevent milk from reaching the vacuum line 6. This baffle forms a more restricted vacuum passage 5 than that of FIG. 1 for better protection of the vacuum line 6.

Yet another embodiment of the invention is depicted in FIG. 2A. This embodiment differs from that of FIG. 2 only in respect of the valve 14 and an insert or adjusting piece 36 which is inserted into the main funnel body 31. This adjustment piece 36 will be discussed in further detail hereafter.

The valve mechanism 14 of FIG. 2A also uses a disk-member 17' as the valve member, but does away with a guiding member such as that illustrated at 18 of FIG. 2. Instead, disk 17' is captured within a tubular shaped valve housing 15' that has an upper portion 15a and a lower portion 15b. Lower portion 15b has a slightly smaller interior diameter than that of the upper portion 15a. A small gap 15c is formed between the upper and lower portions 15a, 15b within which the disk 17' is captured and vertically reciprocates. Ribs 15d connect the top and the bottom portions 15a, 15b. Nibs 17a formed on the disk 17' extend beyond the inboard edge of the top portion 15a to further locate the disk member 17' within the gap 15c. These nibs 17a abut against the bottom edge of the upper housing portion 15a when the housing 15' is removed from the hood member 1.

When the vacuum pump 9 is operated with the embodiment of FIG. 2A, the disk 17' is caused to move upwardly under vacuum where it contacts and seats against the bottom edge or lip of an extended length 3b of tubular extension 3a, thus closing the upper portion 20 of the housing 15' and thereby closing the collecting chamber 4. When the vacuum is released, the disk 17' drops from the foregoing seat and rests upon stand-off bosses 15f formed on the top of the lower housing portion 15b.

This allows the milk collected in the upper housing portion 20 and collecting chamber 4 to flow downwardly into the container 12.

As in the embodiment of FIG. 2, the valve 14 of this embodiment is also releasably attached to the end of the hood member 1. That attachment takes the form of a split-collar arrangement for the upper housing portion 15a, as shown by the slot 15e formed in the upper portion 15a. The internal diameter of the upper portion 15a is slightly smaller than the outside diameter of the lengthened portion 3b of extension 3a of the hood end. The slotted portion 15a can thus be releasably wedged on the lengthened portion 3b.

An adjusting piece 36 is shown in both FIGS. 2 and 2A comprising a funnel-shaped section 37 that is made integral with a cylindrical portion 38 that forms an extension of the funnel section 37. The extension portion 38 abuts against the inner surface of a similar cylindrical portion 32 that forms an extension of the main funnel 31 of the hood member 1 through the use of wing-shaped rib or distance pieces 39, 40. The adjusting piece 36 reduces the diameter of the base of main funnel 31 for use of the breastpump with smaller breasts.

The generating angle of the outer surface of the funnel 37 of the adjusting piece 36 corresponds to the generating angle of the inner surface of the main funnel 31. The generating angle of the inner surface of the adjusting piece funnel 37 is slightly larger, however, and thus decreases the operative cross-section of the main funnel 31. The adjusting piece 36 thus reduces the opening into the extension 32 of the hood member 1. This enables the main funnel 31 to still abut a significant amount of the breast along a large distance from the nipple without a smaller breast being sucked into the extension 38 of the adjusting piece 36.

It will also be noted that the funnel 37 of the adjusting piece 36 terminates in a sharp edge 37a to lie ridgelessly on the inner surface of the main funnel 31. This sharp edge 37a provides a good seal between the adjusting piece funnel 37 and the main funnel 31. This in turn provides a correct seal between the breast and the main funnel 31, the result of which is that no significant amount of air will be sucked by the breastpump during use. This sharp-edge engagement between the adjusting piece funnel 37 and the main funnel 31 also provides a smooth surface within the hood member 1 that prevents irritation of the breast during use of the breastpump.

Extension 38 of the adjusting piece 36 is long enough to accommodate the full length of the compressed nipple therein without the nipple extending significantly beyond an inner end 38a of the adjusting piece. The suction force upon the breast nipple causes the nipple areola to extend radially, with the nipple desirably pressed on the inner surface of the adjusting piece 36 but not beyond the inner end 38a of the extension 38. As shown in FIG. 2, the adjusting piece extension 38 is approximately half as long as the extension 32 of the main funnel 31. Adjusting piece 36 has a slightly longer extension 38 in the embodiment of FIG. 2A.

The present invention also provides for adjustment of the amount of vacuum generated during manual pumping. This feature of the invention is illustrated in FIG. 2A and particularly in FIGS. 3 through 5, which show a modification made to the type of hand-operated piston pump 9 of FIG. 2.

A pair of spaced apart apertures in the form of pin holes 50a and 50b are formed through the pump cylinder 9a adjacent the end 9d of the piston cylinder.

The pin holes 50a, 50b each have a diameter of about .6 mm. A ring 51 carried on the piston cylinder 9a overlies the cylinder holes 50a, 50b. An interior chamber or channel 50a is formed on the inside of the ring 51. This interior channel 51a is sufficiently long to allow both of the holes 50a, 50b to fit within the channel 51a simultaneously (FIG. 5). The channel 51a has openings 51b at either end that are open to atmosphere. The ring 51 is preferably made out of a flexible or semi-flexible rubber-like material that grips the outside of the pump cylinder 9a and enables a good seal to be maintained between the ring and the piston cylinder.

The ring 51 is designed to be rotated on the piston cylinder to positions indicated as "Maximum", "Medium" and "Minimum" vacuum, as illustrated in the FIGS. 3 through 5. Maximum vacuum (FIG. 3) has neither hole 50a or 50b within the area of the channel 51a. The holes 50a, 50b are covered by the ring 51 and no air enters the piston cylinder 9a therethrough.

Medium vacuum is established by rotating the ring 51 so that hole 50b is within the channel 51a. Air can thus enter through the channel openings 51b into the channel 51a and through the hole 50b into the pump cylinder 9a to thereby modify the vacuum (FIG. 4).

Minimum vacuum is established by rotating the ring 51 so that both of the holes 50a, 50b are located within the channel 51a (FIG. 5). The amount of vacuum or pull on the breast generated by the manual pump 9 can thus be readily adjusted by the user as circumstances warrant.

Yet another feature of the invention is illustrated in FIG. 6 for operating two breastpumps simultaneously. This is possible when using an electric motor driven pneumatic pump. Two of the breastpumps illustrated in any of FIGS. 1, 2, or 2A could be used in this application. FIG. 6 illustrates

a device to be used when expressing milk from both breasts simultaneously that is particularly adapted for use with the breastpumps of FIGS. 2 and 2A, however. This device comprises a Y-shaped connector formed from a flexible base hose or tube 53 and flexible extension hoses or tubes 54 and 55, the latter tubes forming the arms of the Y. A Y-shaped hollow connector piece 56 includes a plurality of attachment stems that the respective tubes 53 through 55 fit over.

One end of the base tube 53 is connected via a hollow connector piece 57 to the output of a suitable motor driven pneumatic pump 58. Ends of the extension tubes 54, 55 fit over nipples 59 formed on a screw-threaded adapter 60. The nipples 59 have an internal opening 59a which extends into a tubular portion 61 of the adapter 60. Adapters 60 are specifically designed for use in the embodiments of FIGS. 2 and 2A, and are screw threaded to the sleeve 10 in place of the manually driven pump 9. The embodiments of the breastpump depicted in these two FIGS. can thus be used with a motor driven vacuum pump as well as with a manually driven piston pump.

FIG. 2B illustrates another adaptation for the breast pump of this invention which enables hook-up to a pneumatic pump (such as pump 58). A tubular connector 62 has an end sized to snuggly fit, in an interference fit, within a widened opening 5a to the vacuum channel 5, which is provided with an elbow-type bend to this end. A flange 62a around the middle of the connector 62 serves as a stop within the elbow, and also forms a stop for a tube 63 which is connected to the other end of the connector 62. The tube is connected at its opposite end to a motor driven pump. No adapter, such as adapter 60, is thus necessary with this embodiment using the connector 62.

Thus, while the invention has been described with reference to certain present embodiments, those skilled in this art will recognize modifications of structure, arrangement, composition and the like that can be made to the present invention, yet still fall within the scope of the invention as hereafter claimed.

What is claimed is:

1. A breastpump comprising:

a hood body for placement over a breast, said hood body having a main funnel-shaped portion within which the breast is received and a tubular extension extending downstream from said main funnel portion;

means for connecting said tubular extension of said hood body with a vacuum line to periodically withdraw air from said hood body in a manner that draws the breast into said main funnel portion and thereby expresses milk from the breast into said tubular extension;

a wall formed interiorally of said tubular extension separating said vacuum line connecting means from the breastmilk flow, said wall depending from an upper interior side wall of said tubular extension with said vacuum line connecting means having a connection with said tubular extension above the bottom of said wall, said wall forming a baffle preventing milk from entering said vacuum line;

a catch chamber for expressed milk connected with said tubular extension, said catch chamber being located downstream from said tubular extension and having an inlet and an outlet;

a valve mechanism located at said catch chamber outlet, said valve mechanism having a valve member which closes said catch chamber outlet when a vacuum is applied to said hood body and opens said catch chamber outlet when said vacuum is removed;

means for removably attaching said valve mechanism to said hood body adjacent said catch chamber such that said hood mechanism can be readily removed for cleaning; and

a container communicating with said catch chamber and valve mechanism to receive and hold milk released through said catch chamber outlet.

2. The breastpump of claim 1 wherein the valve mechanism comprises a tubular valve housing having a circumferential slot formed therethrough dividing said housing into an upper portion and a lower portion, said upper and lower housing portions being joined together by connecting means which does not substantially obstruct said slot, a solid disk-shaped valve member sized larger than said collecting chamber outlet and adapted to seat against a lip defining said outlet when a vacuum is applied to said hood body to thereby close said outlet, said valve member being captured for movement within said circumferential slot.

3. The breastpump of claim 2 wherein said disk-shaped valve member has radially extended nibs which engage an edge formed on the bottom of said upper valve housing portion when said valve mechanism is not attached to said hood body, with ribs extended between said upper and lower valve housing portions forming said valve housing portion connecting means, said ribs preventing lateral movement of said disk-shaped valve member out of said circumferential slot, and stand-off bosses formed on said lower housing portion on which said disk-shaped valve member rests in the absence of vacuum.

4. The breastpump of claim 3 wherein said upper valve housing portion is in the form of a split collar, said split collar having a longitudinally extending slot formed therein along part of its length, said upper valve housing portion being removably attached to said collecting chamber by pressing said split collar onto a

tubular portion of said catch chamber, said split collar having an interior diameter slightly smaller than the outside diameter of said catch chamber tubular portion so that said split collar is stretched radially outwardly by said catch chamber tubular portion and thereby wedged in placed thereon.

5. The breastpump of claim 4 wherein said valve housing circumferential slot is located immediately below said outlet lip when said valve mechanism is attached to said collecting chamber, said disk-shaped valve member seating against said outlet lip which lip is formed on the end of said catch chamber tubular portion.

6. The breastpump of claim 1 wherein said valve mechanism comprises a ball valve in a cage which is located at the downstream end of a cup-shaped receptacle, said receptacle having an upper circular edge with a circumferential bead formed about said circular edge, said bead being received in an annular groove formed about the interior of said hood in the area of said collecting chamber with said valve mechanism snap-fitting to said hood body.

7. The breastpump of claim 1 wherein said valve member comprises a tubular valve housing having a perforated plate extending across the interior of said tubular housing, and a disk-shaped valve member movable on a pin that is connected to said perforated plate to close said perforations when a vacuum is applied to said hood body.

8. A breastpump comprising:

a hood body for placement over a breast, said hood body having a main funnel-shaped portion within which the breast is received and a tubular extension extending downstream from said main funnel portion;

a connecting sleeve formed with said tubular extension for connecting said tubular extension with a vacuum line to periodically withdraw air from said hood body in a manner that draws the breast into the funnel portion and thereby expresses milk from the breast into said tubular extension, said connecting sleeve having means formed thereon for connection with a manually driven pneumatic pump as well as a motor driven pneumatic pump;

a wall formed interiorally of said tubular extension separating said vacuum line connecting means from the milk flow, said wall forming a baffle preventing milk from entering said vacuum line;

a catch chamber for expressed milk connected with said tubular extension, said catch chamber being located downstream from said tubular extension and having an inlet and an outlet;

a valve mechanism located at said catch chamber outlet, said valve mechanism having a valve member which closes said catch chamber outlet when a vacuum is applied to said hood body and opens said catch chamber outlet once the vacuum is removed; and

a receiving container communicating with said catch chamber and valve mechanism to receive and hold milk released through said catch chamber outlet.

9. The breastpump of claim 8 wherein said connecting sleeve is screw-threaded for engagement with a screw-threaded end of a manually driven single piston

pneumatic pump and for engagement with a screw-threaded adapter for a motor-driven pneumatic pump, said motorized pump adapter comprising a threaded member engageable with said connecting sleeve and having a bore extended through said threaded member with an exterior connector for said bore to which a hose from said motor driven pneumatic pump can be connected, said motorized pump adapter and said manually driven pneumatic pump being usable interchangeably with said breastpump.

10. The breastpump of claim 9 wherein a pair of said motorized pump adapters are provided for use with a pair of breastpumps, said adapters each being connected by a length of hose to a Y-shaped tubular connector, a third length of hose connecting said tubular connector to the output end of a motor driven pneumatic pump.

11. The breastpump of claim 9 wherein a pair of said motorized pump adapters are provided for use with a pair of breastpumps, said adapters being connected to the ends of a Y-shaped length of hose with a third end of said hose being connected with the output end of a motor driven pneumatic pump.

12. The breastpump of claim 1 further including an adjusting piece insertable into said main funnel portion to reduce the interior cross-sectional area of the base of said main funnel portion adjacent said main funnel tubular extension, said funnel-shaped adjusting piece having a funnel portion and a cylindrical extension that is insertable into said main funnel tubular extension, said extension of said adjusting piece being sufficiently long to receive a nipple therein without said nipple extending beyond the downstream end of said

adjusting piece extension, distance pieces formed on said extension of said adjusting piece spacing and locating said adjusting piece extension relative to said main funnel tubular extension, a generating angle of an outer surface of said adjusting piece funnel portion corresponding to a generating angle of an inner surface of said main funnel portion, an inner surface of said adjusting piece funnel having a larger generating angle than the generating angle of the outer surface thereof, with a sharp edge being formed about the upstream end of said adjusting piece funnel which sharp edge lies ridgelessly on said inner surface of said main funnel portion.

13. The breastpump of claim 8 further including an adjusting piece insertable into said main funnel portion to reduce the interior cross-sectional area of the base of said main funnel portion adjacent said main funnel tubular extension, said adjusting piece having a funnel portion and an extension that is insertable into said tubular main funnel extension, said extension of said adjusting piece being sufficiently long to receive a nipple therein without said nipple extending beyond the downstream end of said adjusting piece extension, distance pieces formed on said extension of said adjusting piece spacing and locating said adjusting piece extension relative to said main funnel tubular extension, a generating angle of an outer surface of said adjusting piece funnel portion corresponding to a generating angle of an inner surface of said main funnel portion, an inner surface of said adjusting piece funnel having a larger generating angle than the generating angle of the outer surface thereof, with a sharp edge being formed about the upstream end of said adjusting

piece funnel which sharp edge lies ridgelessly on said inner surface of said main funnel portion.

14. The breastpump of claim 8 wherein said breastpump includes a manually driven piston pump engageable with said connecting sleeve, said piston pump comprising a piston head mounted for reciprocal movement within a piston chamber under action of a hand-driven piston rod, said piston cylinder having at least one aperture formed therein communicating with said piston chamber, and means for opening and closing said aperture to adjust the amount of vacuum generated in said piston chamber when said piston pump is operated.

15. The breastpump of claim 8 wherein said breastpump includes a manually driven piston pump engageable with said connecting sleeve, said piston pump comprising a piston head mounted for reciprocal movement within a piston cylinder under action of a hand-driven piston rod, said piston cylinder having at least two apertures formed therein communicating with said piston chamber, a ring mounted to rotate on the exterior of said piston cylinder, said ring having an interior channel formed therein which communicates with atmosphere and which is rotated with said ring to selectively uncover said apertures to thereby adjust the amount of vacuum generated in said piston chamber when said piston pump is operated.

16. The breastpump of claim 15 wherein neither aperture is exposed within said ring channel for maximum vacuum, two apertures are exposed within said ring channel for a minimum vacuum, and one aperture is

exposed within said ring channel for an intermediate vacuum between said maximum and minimum vacuums.

17. A breastpump comprising:

a hood body for placement over a breast, said hood body having a main funnel-shaped portion within which the breast is received and a tubular extension extending downstream from said main funnel portion;

a manually driven piston pump engaged with said tubular extension along a vacuum line for generating an intermittent vacuum in said hood body, said piston pump comprising a piston head mounted for reciprocal movement within a piston cylinder under action of a hand-driven piston rod, said piston cylinder having at least one aperture formed therein communicating with said piston chamber, and means for opening and closing said aperture to adjust the amount of vacuum generated in said piston chamber when said piston pump is operated;

a baffle formed interiorally of said tubular extension separating said vacuum line from breastmilk flow, said baffle preventing milk from entering said vacuum line;

a catch chamber for expressed milk connected with said tubular extension, said catch chamber being located downstream from said tubular extension and having an inlet and an outlet;

a valve mechanism located at said outlet end of said catch chamber, said valve mechanism having a valve member which closes said catch chamber outlet when a vacuum is applied to said hood body and opens said catch chamber outlet once the vacuum is removed; and

a receiving container communicating with said catch chamber and valve mechanism to receive and hold milk released through said catch chamber outlet.

18. The breastpump of claim 17 wherein said piston cylinder has at least two apertures formed therein communicating with said piston chamber, a ring mounted to rotate on the exterior of said piston cylinder exterior, said ring having an interior channel formed therein which communicates with atmosphere and which is rotated with said ring to selectively uncover said apertures to thereby adjust the amount of vacuum generated in said piston chamber when said piston pump is operated.

19. A manually driven piston pump with an adjustable piston chamber pressure, comprising:

a piston head mounted for reciprocal movement within a piston cylinder under action of a hand-driven piston rod, said piston cylinder having at least one aperture formed therein communicating with said piston chamber, and means for opening and closing said aperture to adjust the amount of vacuum generated in said piston chamber when said piston pump is operated.

20. The piston pump of claim 19 wherein said piston cylinder has at least two apertures formed therein communicating with said piston chamber, a ring mounted to rotate on said piston cylinder exterior, said ring having an interior channel formed therein which communicates with atmosphere and which is rotated with said ring to selectively uncover said apertures to thereby adjust the amount of vacuum generated in said piston chamber when said piston pump is operated.

21. A suction hood for an apparatus for removing mother's milk comprising:

a main body having the shape of a funnel within which the breast is received;

an adjusting piece also having the shape of a funnel, said adjusting piece being insertable into said main body funnel to alter at least a portion of the cross-sectional area of said main funnel body at the base of said funnel adjacent a substantially cylindrical extension of said main funnel body, said funnel-shaped adjusting piece having a cylindrical extension insertable into said cylindrical extension of said main funnel body, said cylindrical extension of said adjusting piece being sufficiently long to receive a nipple therein without said nipple extending beyond the downstream end of said adjusting piece extension, distance pieces formed on said extension of said adjusting piece spacing and locating said adjusting piece extension relative to said tubular extension of said main funnel body, a generating angle of an outer surface of said adjusting piece funnel corresponding to a generating angle of the inner surface of said main funnel body, an inner surface of said adjusting piece funnel having a larger generating angle than the generating angle of the outer surface thereof, with a sharp edge being formed about the upstream edge of said adjusting piece funnel which sharp edge lies ridgelessly on said inner surface of said main funnel body.

22. A breastpump comprising:

a hood body for placement over a breast, said hood body having a main funnel-shaped portion within which the breast is received and a tubular extension extended downstream from said main funnel portion;

a connecting sleeve formed with said tubular extension of said main funnel for connecting said tubular extension with a vacuum line to periodically withdraw air from said hood body in a manner that draws the breast into said hood body and thereby expresses milk from the breast into said main funnel tubular extension, said connecting sleeve having screw-threads for engagement with a screw-threaded end of a manually driven single piston pneumatic pump and for engagement with an adapter for a motor driven pneumatic pump, said motorized pump adapter comprising a screw-threaded member engageable with said connecting sleeve with a bore extending through said threaded member and an exterior connector for said bore to which a hose from said motor-driven pneumatic pump can be connected, said motorized pump adapter and said manually driven pump being useable interchangeably with said breastpump;

said manually driven piston pump comprising a piston head mounted for reciprocal movement within a piston cylinder under action of a hand-drive piston rod, said piston cylinder having at least two apertures formed therein communicating with said piston chamber, a ring mounted to rotate on said piston cylinder exterior, said ring having an interior channel formed therein which communicates with atmosphere and which is rotated with said ring to selectively uncover said apertures to thereby adjust the amount of vacuum generated in said piston chamber when said piston pump is operated;

a wall formed interiorally of said tubular extension separating said connecting sleeve and thereby the vacuum line from milk flow, said wall depending from an upper interior side wall of said main funnel tubular extension with said vacuum line connecting sleeve communicating with said tubular extension above

the bottom of said wall, said wall forming a baffle preventing milk from entering said vacuum line;

a catch chamber for expressed milk connected with said main funnel tubular extension, said catch chamber being located downstream from said main funnel tubular extension and having an inlet end and an outlet;

a valve mechanism located at said catch chamber outlet, said valve mechanism comprising a tubular valve housing has a circumferential slot formed therethrough dividing said housing into an upper and a lower portion, said upper and lower portions being joined together by ribs extending between said upper and lower valve housing portions which ribs to not substantially obstruct said slot, a solid disk-shaped valve member sized larger than said collecting chamber outlet and adapted to seat against a lip defining said outlet when a vacuum is applied to said hood body to thereby close said outlet, said valve member being captured for movement within said circumferential slot with said ribs preventing lateral movement of said disk-shaped valve member out of said circumferential slot, stand-off bosses being formed on said lower housing portion on which said disk-shaped valve member rests in the absence of vacuum, said disk-shaped valve member having radially extending nibs which engage an edge formed on the bottom of said upper valve housing portion when said valve mechanism is not attached to said hood body, said upper valve housing portion being in the form of a split-collar have a longitudinally extending slot formed therein along part of its length, said upper valve housing portion being removably attached to said collecting chamber by pressing said split-collar onto a tubular portion of said catch chamber, said split-collar having an interior diameter slightly smaller than the outside diameter of said catch chamber tubular portion so that

said split-collar is stretched radially outwardly by said catch chamber tubular portion and thereby wedged in place thereon, said valve housing circumferential slot being located immediately below said outlet lip when said valve mechanism is attached to said collecting chamber to enable said disk-shaped valve member to seat against said catch chamber outlet lip;

a container communicating with said catch chamber and valve mechanism to receive and hold milk released through said catch chamber outlet; and

an adjusting piece insertable into said main funnel portion to reduce the interior cross-sectional area of the base of said main funnel portion adjacent said tubular main funnel extension, said adjusting piece having a funnel portion and a cylindrical extension of said adjusting piece funnel portion that is insertable into said main funnel tubular extension, said adjusting piece extension being sufficiently long to receive a nipple therein without said nipple extending beyond the downstream end of said adjusting piece extension, distance pieces formed on said adjusting piece extension spacing and locating said adjusting piece extension relative to said main funnel tubular extension, a generating angle of an outer surface of said adjusting piece funnel portion corresponding to a generating angle of an inner surface of said main funnel portion, an inner surface of said adjusting piece funnel portion having a larger generating angle than the generating angle of the outer surface thereof, with a sharp edge being formed about the upstream end of said adjusting piece funnel which sharp edge lies ridgelessly on said inner surface of said main funnel portion.

FIG_1

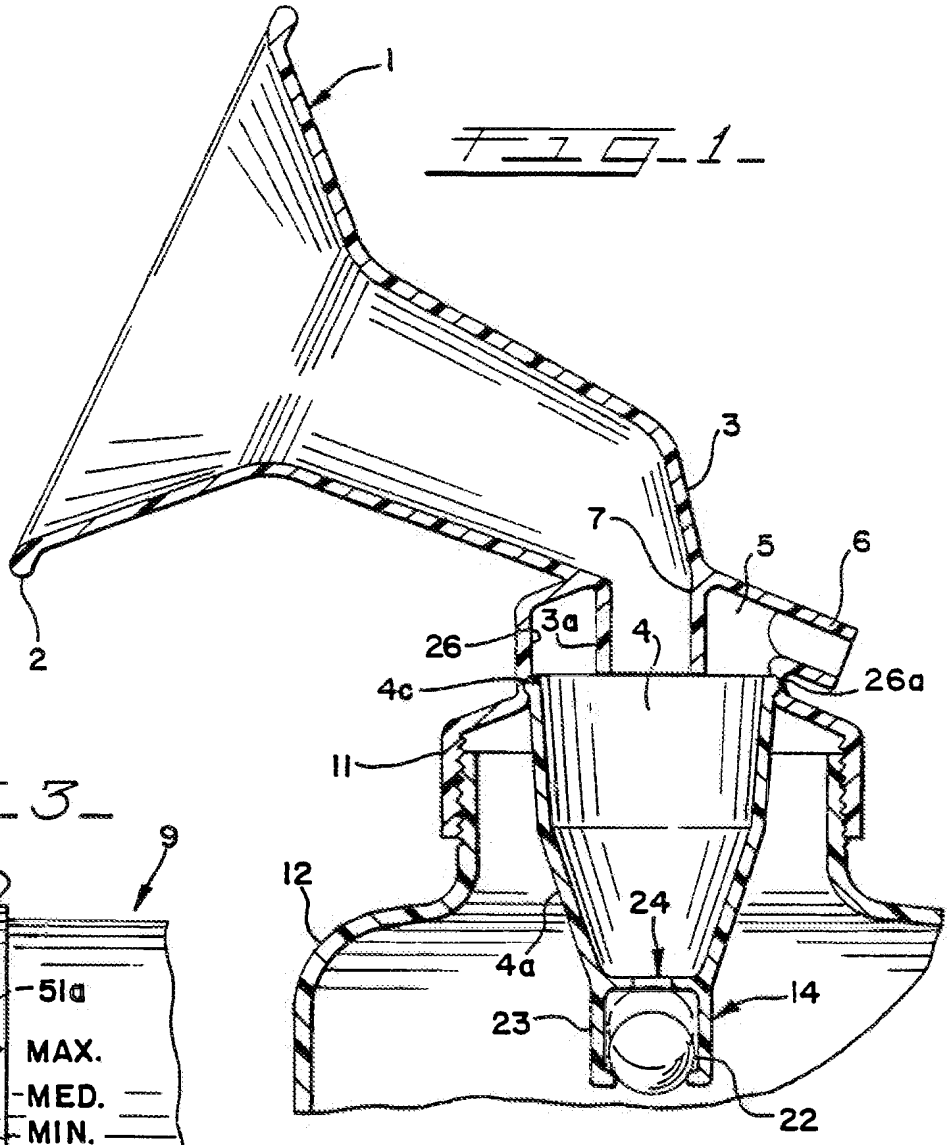


FIG_3

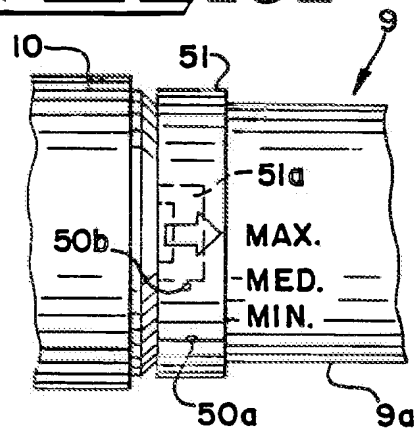


FIG_4

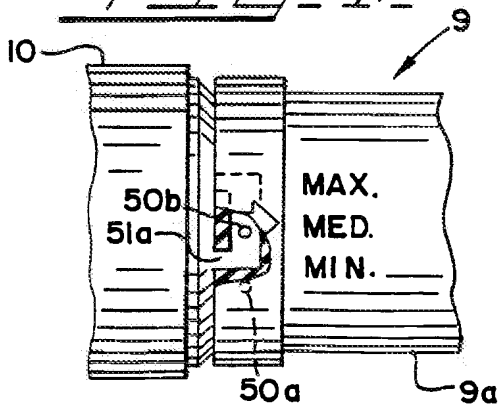


FIG_5

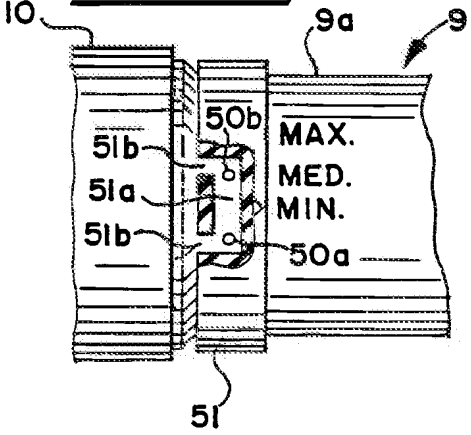
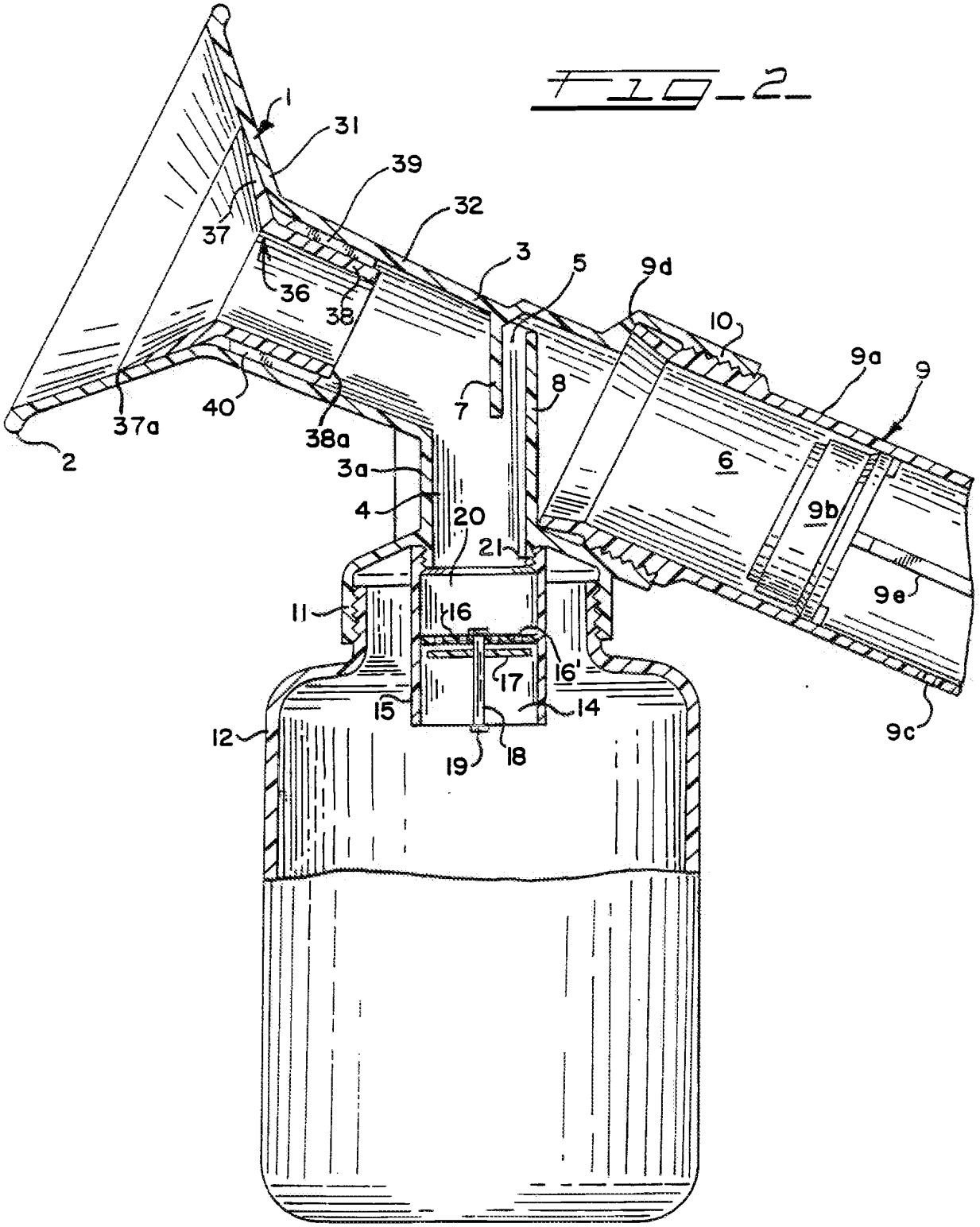


FIG_2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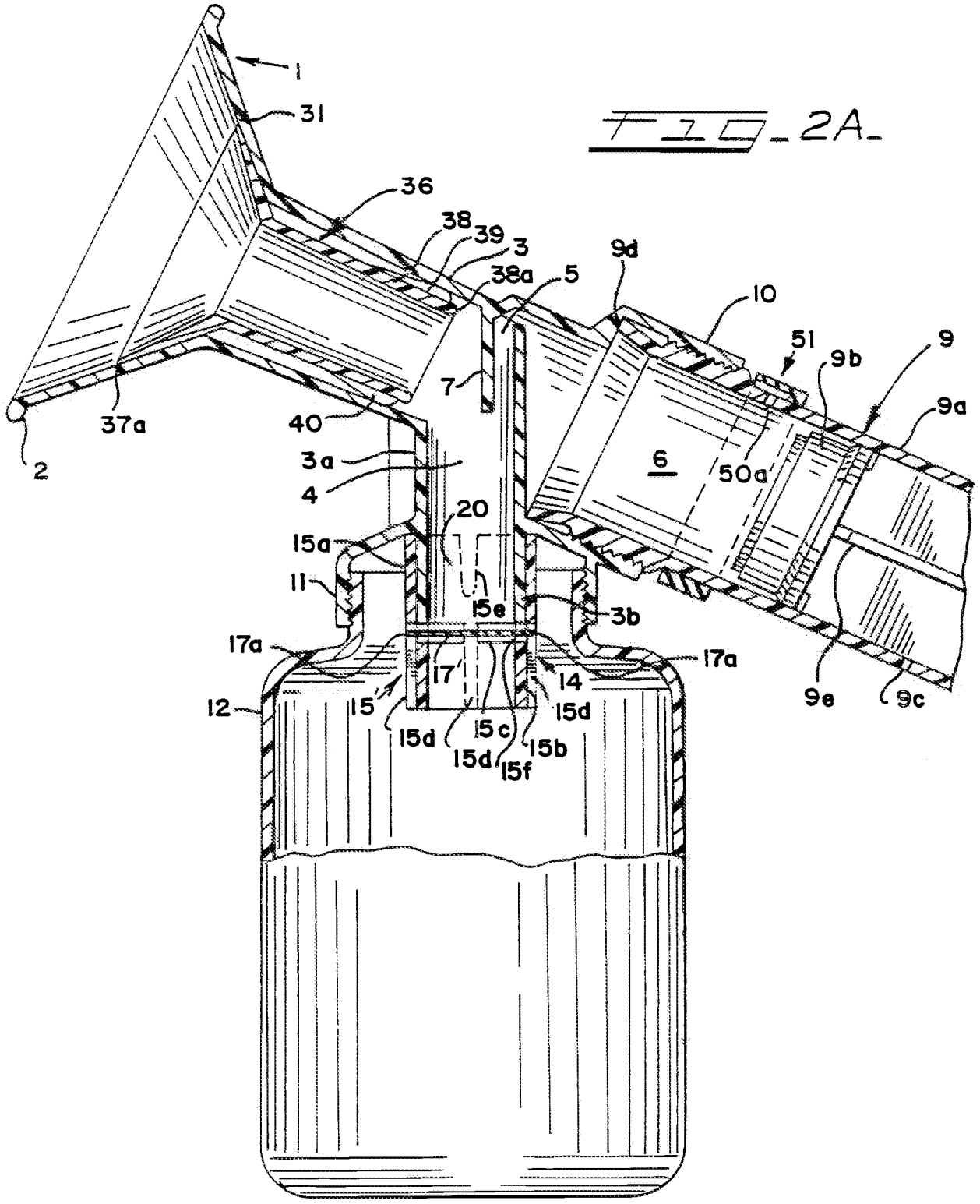
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15a
11
15e
3b
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15d
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9e
9c

FIG_2A_

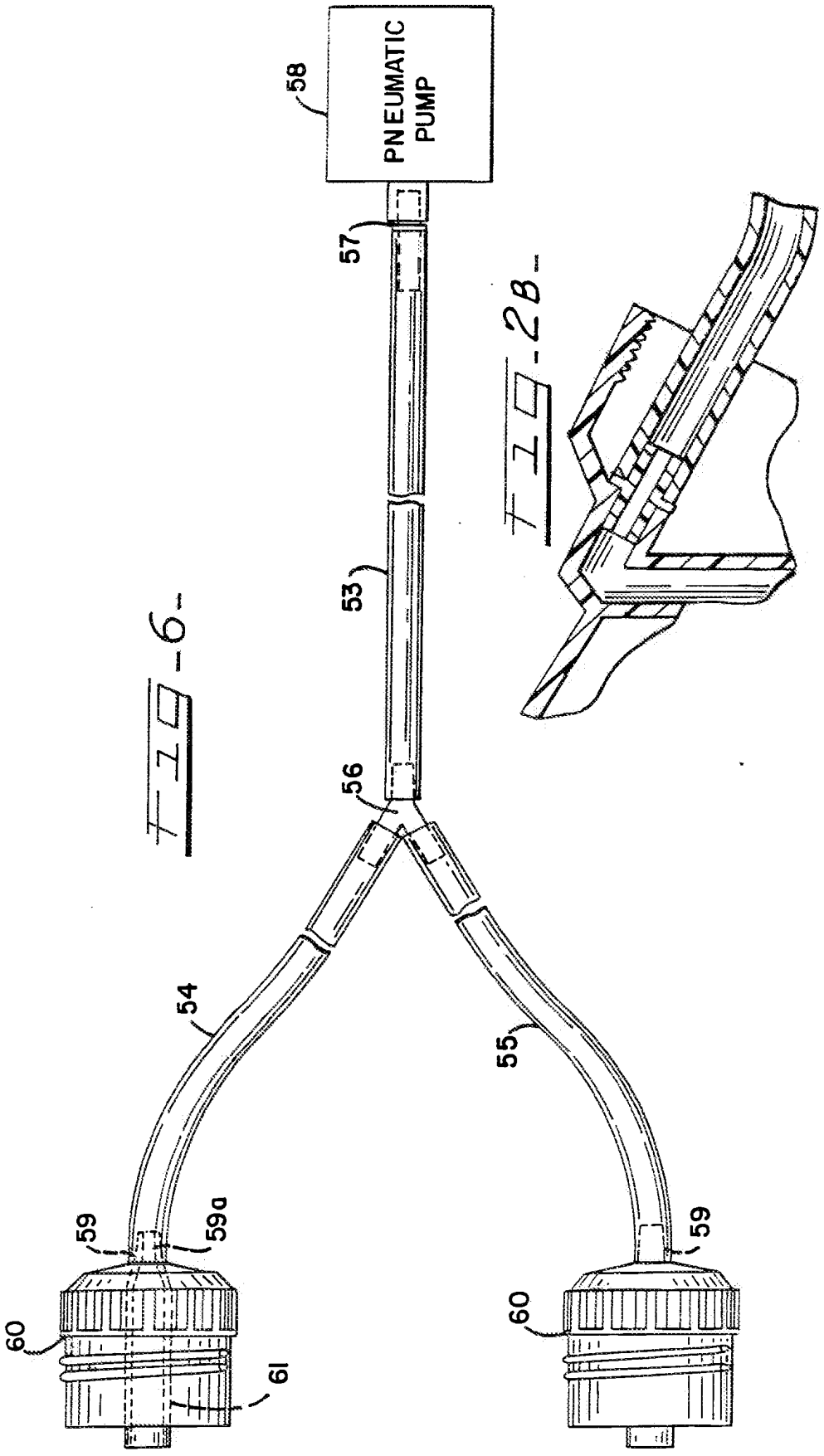

FIG-6-

FIG-2B-

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US88/01784

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (4): A61M/1/06
U.S.CL : 604/74,346

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S.	137/533,19 604/74-76,118,119,323,335,346 119/14.32,14.33,14.53

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	G.B., 762,701 (KUPFER) 05 December 1956, see fig. 1 and page 2, lines 40-50	1,6,8
Y	It., 407,293 (PUIATTI) 27 September 1944, see the entire document	1,6,8
Y	U.S.,A, 1,184,293 (ZERATSKY) 23 May 1916, see fig. 1, elements G and G'	1,6,8
Y	U.S.,A, 1,596,520 (ESKHOLME) 17 August, 1926 see fig. 2,	6

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
05 August 1988	12 SEP 1988
International Searching Authority	**Signature of Authorized Officer**
ISA/US	J.L. Kruter

Form PCT/ISA/210 (second sheet) (Rev.11-87)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers . because they relate to subject matter [12] not required to be searched by this Authority, namely:

2. ☐ Claim numbers , because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

3. ☐ Claim numbers_____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

The separate and distinct species of
a. fig. 1 claims 1,6,8
b. fig. 2 claims 1, 7-9,12,13,21
c. fig. 2,4 claims 1-5,8,9,12,13,21
d. fig. 3,4,5 claims 1-5,8,9,12-20,22
e. fig. 6 claims 6,11

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
1,6,8

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: CHIARO TECHNOLOGY LIMITED	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, COURTNEY B
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Supplemental Information Disclosure Statement

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

Listed on accompanying IDS Forms PTO/SB/08a or its equivalent and PTO/SB/08b or its equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Applicant has listed dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) and is being filed within three months of the date of filing of a national application other than a continued prosecution application (CPA), OR within three months of the date of entry of the national stage as

set forth in 37 C.F.R. § 1.491 in an international application, OR before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

Copies of documents **FP1-FP9** and **NPL1-NPL13** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2)(ii), no copies of the U.S. patents and patent application publications cited on the attached IDS Forms are submitted.

It is expected that the examiner will review the prosecution and cited art in the parent Application No. 16/009,547, filed June 15, 2018 in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

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(54) Title: BREAST PUMP SYSTEM AND METHODS

(57) Abstract: Systems and methods for pumping milk from a breast, wherein the milk is expressed from the breast under suction and milk is expulsed from the pumping mechanism to a collection container under positive pressure.

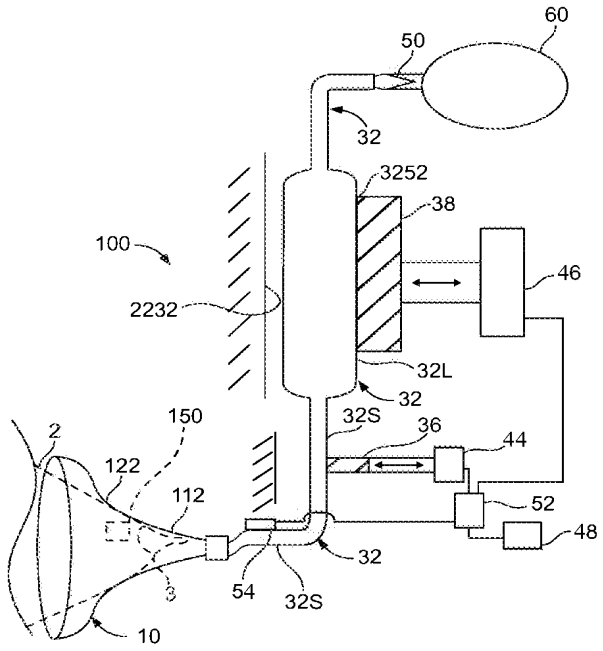

FIG. 20

WO 2016/014494 A1

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BREAST PUMP SYSTEM AND METHODS

FIELD OF THE DISCLOSURE

[0001] The present disclosure generally relates to portable, energy efficient breast pump systems and methods for collecting milk from a breast of a nursing mother.

BACKGROUND OF THE DISCLOSURE

[0002] As more women become aware that breastfeeding is the best source of nutrition for a baby, and also offers health benefits to the nursing mother, the need is increasing for breast pump solutions that are user-friendly, quiet, discrete and versatile for use by a nursing mother in various situations. This is particularly true for the working mother, who is away from the home for eight to ten hours or more and needs to pump breast milk in order to have it available for her baby, but it is also a requirement for many other situations where the mother is away from the privacy of the home for an extended period, such as during shopping, going out to dinner or other activities.

[0003] Although a variety of breast pumps are available, most are awkward and cumbersome, requiring many parts and assemblies and being difficult to transport. Hand pump varieties that are manually driven are onerous to use and can be painful to use. Some powered breast pumps require an AC power source to plug into during use. Some systems are battery driven, but draw down the battery power fairly rapidly as the motorized pump continuously operates to maintain suction during the milk extraction process. Many of the breast pumps available are clearly visible to an observer when the mother is using it, and many also expose the breast of the mother during use.

[0004] There is a continuing need for a small, portable, self-powered, energy efficient, wearable breast pump system that is easy to use and is discrete by not exposing the breast of the user and being invisible or nearly unnoticeable when worn.

[0005] To ensure that the nursing baby is receiving adequate nutrition, it is useful to monitor the baby's intake. It would be desirable to provide a breast pump system that easily and accurately monitors the volume of milk pumped by the system, to make it convenient for the nursing mother to know how much milk has been extracted by breast pumping. It would also be desirable to track milk volume pumped per session,

so that the volume of milk contained in any particular milk collection container can be readily known.

[0006] Many existing breast pump systems can cause considerable discomfort to the user over time. One cause of such discomfort is chafing of the nipple against the nipple flange/housing as the nipple stretches and contracts during the pumping session. There is a continuing need for a breast pump system that is more comfortable to the user, even over repeated pumping sessions.

SUMMARY OF THE DISCLOSURE

[0007] Briefly and in general terms, the present disclosure is directed toward breast pump systems or methods. The system includes breast contacting structure and a storage container, and structure that delivers milk from a breast to the storage container. The method involves pumping milk from a breast and delivering the pumped milk into the storage container.

[0008] According to one aspect of the present disclosure, a system for pumping milk from a breast includes one or more of: a skin contact member configured to form a seal with the breast; a conduit in fluid communication with and connected to the skin contact member; a driving mechanism configured to establish a vacuum profile within the conduit; an external shell; and a milk collection container; wherein the external shell comprises a compartment facing a distal end of the external shell, the external shell further comprising a proximal end surface facing away from the proximal end; wherein the skin contact member, the conduit and the driving mechanism are received in the compartment of the external shell; wherein the milk collection container is positionable over the distal end surface of the shell; and wherein the system is shaped and configured to be contoured to the breast of a user.

[0009] In various of the disclosed embodiments, the system defines a natural breast profile. The natural breast profile is contemplated to fit comfortably and conveniently into a bra of a user and to present a natural look. As such, the profile is characterized by having a non-circular base. Moreover, like natural breasts, the profile of the device or system is contemplated to define one or more asymmetric curves and off-center inertial centers.

[0010] In at least one embodiment, the skin contact member, the conduit, the driving mechanism, the external shell and the milk collection container are all contained within a cup of a brassiere.

[0011] In at least one embodiment, the system is battery powered, the system comprising a battery, wherein the battery is received in the compartment of the external shell.

[0012] In at least one embodiment, the proximal surface of the external shell is shaped and configured to be contoured to the breast of a user and to thus provide a more natural appearance when under clothing worn by the user.

[0013] In at least one embodiment, the proximal surface of the external shell comprises a polygonal, flat, irregular or discontinuously curved shape dissimilar to the curvature of the breast; and the milk collection container is configured to interface with the proximal surface and to be shaped and configured to be contoured to the breast of a user and to thus provide a more natural appearance when under the clothing of the user.

[0014] In at least one embodiment, the proximal surface comprises flat surfaces that form an angular external surface.

[0015] In at least one embodiment, the proximal surface comprises a flat central portion and convex portions extending radially from the flat central portion.

[0016] In at least one embodiment, the milk collection container is configured and dimensioned to have variable volume when filled, so as to conform to the proximal surface of the external shell as the milk collection container is being filled with milk, while providing a convex shape externally, so as to mimic a natural shape of the breast.

[0017] In at least one embodiment, the milk collection container is pre-shaped to follow contours of the proximal surface of the external shell and to providing a convex shape externally, so as to mimic a natural shape of the breast.

[0018] In at least one embodiment, the milk collection container comprises a rigid distal surface that mates with contours of the proximal surface of the external shell, and a flexible proximal surface that moves as milk enters the milk collection container, to provide a convex shape that mimics a natural shape of the breast.

[0019] In at least one embodiment, the milk collection container comprises a flexible distal surface that changes shape to mate with contours of the proximal surface of the

external shell as milk enters the milk collection container, the milk collection container further comprising a rigid proximal surface that provides a convex shape that mimics a natural shape of the breast.

[0020] In at least one embodiment, the milk collection container comprises a rigid distal surface pre-shaped to mate with contours of the proximal surface of the external shell as milk enters the milk collection container.

[0021] In at least one embodiment, the milk collection container comprises at least one structural element configured to restrict an amount of expansion of the milk collection container or provide shape to the milk collection container even when empty.

[0022] In at least one embodiment, the at least one structural element is selected from the group consisting of baffles, heat seals, struts and restrictions.

[0023] In at least one embodiment, the milk collection container comprises a unique identifier configured to be read by a computer processor and that uniquely distinguished the milk collection container from all other milk collection containers.

[0024] In at least one embodiment, the unique identifier comprises a sensor.

[0025] In at least one embodiment, the sensor comprises a passive sensor.

[0026] In at least one embodiment, the system further includes a controller positioned within the external shell and configured to control operations of the driving mechanism.

[0027] In at least one embodiment, the milk collection container comprises a unique identifier configured to be read by at least one of the controller and an external computer processor and that uniquely distinguished the milk collection container from all other milk collection containers.

[0028] In at least one embodiment, the unique identifier comprises a sensor.

[0029] In at least one embodiment, the sensor comprises a passive sensor.

[0030] In at least one embodiment, the sensor is selected from the group consisting of: RFID device, NFC device, Wi-Fi device, BLUETOOTH device and BLUETOOTH Low Energy (BTLE) device.

[0031] In at least one embodiment, the sensor is selected from the group consisting of: RFID devices and NFC devices.

[0032] In at least one embodiment, the milk collection container comprises a one-way valve that permits milk inflow into the milk collection container but prevents milk backflow from the milk collection container to the conduit.

[0033] In at least one embodiment, the conduit is integral with the milk collection container.

[0034] In at least one embodiment, the system further includes a contour element; wherein the contour element extends distally from a distal perimeter of the external shell and proximally extends over a distal portion of the external shell to provide a contoured extension of the external shell that provides a visually more appealing appearance that more closely mimics a natural appearance of the breast supported by a bra.

[0035] In at least one embodiment, the contour element tapers distally to form a smooth transition with the breast when the system is mounted on the breast.

[0036] In at least one embodiment, the contour element is removably attached to the external shell using at least one of snaps, hook-and-loop type fasteners, buttons, magnets adhesive, or friction fit.

[0037] In at least one embodiment, the contour element comprises a lateral portion that extends distally from the distal perimeter by a first length, and a medial portion that extends distally from the distal perimeter by a second length, wherein the first length is greater than the second length.

[0038] In at least one embodiment, the contour element is formed of lightweight material comprising at least one of foam, plastic or fabric.

[0039] In at least one embodiment, the contour element is formed of a single thin layer of plastic or fabric.

[0040] In at least one embodiment, the external shell comprises a key and the contour element comprises a mating key; wherein the mating key mates with the key when the contour element is mounted on the external shell and ensures that the contour element is positioned relative to the external shell consistently so that orientation of the contour element relative to the external shell upon successive mountings does not vary rotationally, superiorly, inferiorly, laterally or medially.

[0041] In at least one embodiment, the contour element is adjustable to accommodate different breast sizes.

[0042] In at least one embodiment, the contour element comprises a first edge and a second edge, wherein the first edge overlaps the second edge and can be adjusted to reduce, increase or maintain a circumference of a distal perimeter of the contour element.

[0043] In at least one embodiment, the overlap of the first edge relative to the second edge can be adjusted to reduce, increase or maintain a circumference of a proximal perimeter of the contour element.

[0044] In at least one embodiment, the contour element comprises a material that facilitates cutting a portion of a distal perimeter thereof for tailoring a fit of the contour element to the breast.

[0045] In at least one embodiment, the contour element comprises predetermined markings to assist in adjusting the contour element to various predetermined sizes.

[0046] In at least one embodiment, the external shell comprises at least one key and the contour element comprises multiple mating keys that mate with each the at least one key, respectively, to allow adjustment of a size of the contour element.

[0047] In at least one embodiment, the contour element is made of a resilient material that conforms to a shape of an object that the contour element is compressed against.

[0048] In at least one embodiment, the contour element is substantially flat-shaped in an unbiased configuration.

[0049] In at least one embodiment, the contour element is attachable to a proximal end portion of the external shell.

[0050] In at least one embodiment, the contour element, when supported by a bra, contours to the external shell and the bra.

[0051] In at least one embodiment, the system further includes a valve in the conduit adjacent the skin contact member, wherein the valve is configured to open in a first direction when vacuum is generated in the conduit, to close when positive pressure up to a predetermined positive pressure is applied to the valve, and to open in a second direction when positive pressure exceeding the predetermined positive pressure is applied to the valve.

[0052] According to another aspect of the present disclosure, a system for pumping milk from a breast includes one or more of: an external shell including a compartment facing a distal end of the external shell, the external shell further comprising a proximal end surface facing away from the proximal end; the external shell carrying a self-contained power source and a pump mechanism; a skin contact member supported by the external shell; an outlet for expelling breast milk received from the breast interfaced with the skin contact member; and a milk collection container in fluid communication with the outlet and positioned against the distal end surface of the external shell; wherein the system is shaped and configured to be contoured to the breast of a user.

[0053] In at least one embodiment, the system is contained within a cup of a brassiere.

[0054] In at least one embodiment, the skin contact member, the external shell and the milk collection container are sized and configured to be supported between the breast and a breast cup of a bra while the system is actively pumping milk from the breast and expelling the milk through the outlet and into the milk collection container.

[0055] According to another aspect of the present disclosure, a milk collection container for use with a breast pump system includes one or more of: a preformed surface shaped to mimic the natural appearance of a breast; and a flexible surface opposing the preformed convex surface, the flexible surface being configured to expand as milk enters the milk collection container.

[0056] In at least one embodiment, the milk collection container is mounted to an external surface of an external shell of a milk pump, wherein upon milk entering the milk collection container, the flexible surface moves outwardly and conforms to a conformation of the external shell.

[0057] In at least one embodiment, the milk collection container comprises at least one structural element configured to restrict an amount of expansion of the milk collection container or provide shape to the milk collection container even when empty.

[0058] In at least one embodiment, the at least one structural element is selected from the group consisting of baffles, heat seals, struts and restrictions.

[0059] According to another aspect of the present disclosure, a system for pumping milk from a breast includes one or more of: a skin contact member configured to form

a seal with the breast; a conduit in fluid communication with and connected to the skin contact member; a driving mechanism configured to establish a vacuum profile within the conduit by cyclically compressing and allowing decompression of a portion of the conduit; and an external shell containing the conduit and the driving mechanism and supporting the skin contact member.

[0060] In at least one embodiment, the system further includes a milk collection container, wherein the milk collection container is in fluid communication with the conduit.

[0061] In at least one embodiment, the milk collection container is positionable over the distal end surface of the shell; and the system is shaped and configured to be contoured to the breast of a user.

[0062] In at least one embodiment, the skin contact member includes: a breast contact portion configured and dimensioned to fit over a form a seal with a portion of the breast; and a nipple receiving portion extending from the breast contact portion.

[0063] In at least one embodiment, the nipple receiving portion comprises a non-tapering portion attached to the breast contact portion, and a tapering portion extending from the non-tapering portion, the tapering portion configured and dimensioned to receive the nipple of the breast.

[0064] In at least one embodiment, the non-tapering portion is cylindrical and the tapering portion is conical.

[0065] In at least one embodiment, the non-tapering portion is ovular or elliptical in cross section.

[0066] In at least one embodiment, the tapering portion is ovular or elliptical in cross section.

[0067] In at least one embodiment, both the non-tapering and the tapering portions are ovular or elliptical in cross section.

[0068] In at least one embodiment, the breast contact portion comprises a first central longitudinal axis and the nipple receiving portion comprises a second central longitudinal axis; and the first and second central longitudinal axes are collinear.

[0069] In at least one embodiment, the breast contact portion comprises a first central longitudinal axis and the nipple receiving portion comprises a second central longitudinal axis; and the first and second central longitudinal axes are parallel.

[0070] In at least one embodiment, the breast contact portion comprises a first central longitudinal axis and the nipple receiving portion comprises a second central longitudinal axis; and the first and second central longitudinal axes intersect.

[0071] In at least one embodiment, a top part of the nipple receiving portion is configured to contact an upper surface of the nipple and a bottom part of the nipple receiving portion is configured to contact a lower surface of the nipple; wherein the top part is formed a material having a first hardness and the bottom part is formed of a material having a second hardness; and wherein the first hardness is greater than the second hardness.

[0072] In at least one embodiment, the breast contact portion comprises at least one region on an inner surface thereof, the at least one region configured to contact the breast and provide friction thereagainst that is greater than friction provided by a remainder of the inner surface of the breast contact portion.

[0073] In at least one embodiment, the system further includes a resilient flap extending radially inwardly from a portion of the breast contact member; wherein when the breast is inserted into the breast contact member, the breast folds down the flap against an inner wall of the breast contact member; and wherein when the breast is removed from the breast contact member, the flap resiliently returns to an unbiased position and extends radially inwardly, thereby retaining milk within the breast contact member that would otherwise have spilled out of the breast contact member.

[0074] In at least one embodiment, the flap comprises a tacky or roughened surface configured to increase friction against the breast when contacting the breast.

[0075] In at least one embodiment, the system further includes a sensor mounted in or on the skin contact member or the conduit; and a controller configured to control operation of the driving mechanism and to receive signals from the sensor.

[0076] In at least one embodiment, the system further includes a first sensor mounted in or on the skin contact member or the conduit, wherein a thickness of the skin contact member or conduit at a location of mounting the first sensor comprises a first

thickness; and a second sensor mounted in or on the skin contact member or the conduit, wherein a thickness of the skin contact member or conduit at a location of mounting the second sensor comprises a second thickness; wherein the second thickness is greater than the first thickness.

[0077] In at least one embodiment, the system further includes one or more of: a controller configured to control operation of the driving mechanism; and a switch in electrical communication with the controller, the switch extending into the skin contact member or the conduit at a distance from an inner wall of the skin contact member or the conduit predetermined as a distance by which the inner wall deflects when a predetermined vacuum pressure has been attained; wherein, upon attaining the predetermined vacuum pressure, the switch is activated by contact with the inner wall and sends a signal to the controller.

[0078] In at least one embodiment, the switch extends into the nipple receiving portion of the skin contact member.

[0079] According to another aspect of the present disclosure, a method of operating a system for pumping milk includes one or more of: providing the system comprising a skin contact member configured to form a seal with the breast, a conduit in fluid communication with and connected to the skin contact member; a driving mechanism including a compression member configured to compress and allow decompression of the conduit in response to inward and outward movements of the compression member, a sensor, and a controller configured to control operation of the driving mechanism; sealing the skin contact member to the breast; operating the driving mechanism to generate predetermined pressure cycles within the conduit; monitoring by the controller of at least one of position and speed of movement of the compression member relative to the conduit; measuring or calculating pressure within the conduit; maintaining or modifying motion of the compression member as needed, based upon feedback from the calculated pressure and at least one of position and speed of movement of the compression member, to ensure that the predetermined pressure cycles continue to be generated.

[0080] In at least one embodiment, the predetermined pressure cycles comprise extraction mode pressure cycles, the method further including: manually adjusting a maximum suction pressure to modify the predetermined pressure cycles.

[0081] In at least one embodiment, the predetermined pressure cycles comprise extraction mode pressure cycles, the method further including: purging milk from the conduit when the controller identifies that the compression member has reached a location that is a predetermined percentage of a predetermined outward motion limit of the compression member relative to the conduit.

[0082] In at least one embodiment, the purging includes: controlling the compression member by the controller to drive the compression member to a predetermined inward motion limit of the compression member thereby driving milk out of a portion of the conduit compressed by the compression member.

[0083] In at least one embodiment, the method further includes controlling the compression member to carry out the compression mode cycles after performing the purging.

[0084] In at least one embodiment, the predetermined pressure cycles comprise extraction mode pressure cycles, and the controller increases a stroke distance of the compression member relative to an amount of milk entering the conduit, to maintain predetermined pressures during the extraction mode pressure cycles.

[0085] In at least one embodiment, the predetermined pressure cycles comprise latch mode cycles, wherein upon determination that milk has entered the conduit or after a predetermined period of time, the controller operates the compression member to achieve predetermined extraction mode pressure cycles, wherein the predetermined extraction mode cycles differ from the predetermined latch mode cycles by at least one of maximum suction level or cycle frequency.

[0086] In at least one embodiment, the predetermined pressure cycles comprise extraction mode pressure cycles, and the method further includes: monitoring, by the controller, pressure waves within at least one of the conduit and the skin contact member; monitoring, by the controller, at least one of position and speed of the compression member relative to pressure levels monitored by the monitoring pressure waves; and changing at least one of speed, stroke length and position of the

compression member when a predetermined amount of change in the monitored pressure versus monitored position or speed of the compression member is identified, so as to maintain execution of the predetermined pressure cycles.

[0087] In at least one embodiment, the controller monitors positions of the compression member; and wherein, upon detecting that the compression member has reached a location that is a predetermined percentage of a predetermined outward motion limit of the compression member relative to the conduit, the controller controls the compression member to purge milk from the conduit.

[0088] According to another aspect of the present disclosure, a system for pumping milk includes one or more of: a skin contact member configured to form a seal with a breast; a conduit in fluid communication with and connected to the skin contact member; a driving mechanism including a compression member configured to compress and allow decompression of the conduit in response to inward and outward movements of the compression member; a sensor; and a controller configured to control operation of the driving mechanism; wherein upon sealing the skin contact member to the breast, the controller operates the driving mechanism to generate predetermined pressure cycles within the conduit, monitors at least one of position and speed of movement of the compression member relative to the conduit, measures or calculates pressure within the conduit based upon signals received from the sensor, and maintains or modifies motion of the compression member as needed, based upon feedback from the calculated pressure and at least one of position and speed of movement of the compression member, to ensure that the predetermined pressure cycles continue to be generated.

[0089] In at least one embodiment, the predetermined pressure cycles comprise extraction mode pressure cycles, and the system is configured to allow manual adjustment of a maximum suction pressure to modify the predetermined pressure cycles.

[0090] In at least one embodiment, the predetermined pressure cycles comprise extraction mode pressure cycles, and the controller operates the driving mechanism to purge milk from the conduit when the controller identifies that the compression

member has reached a location that is a predetermined percentage of a predetermined outward motion limit of the compression member relative to the conduit.

[0091] In at least one embodiment, the purging includes controlling the compression member by the controller to drive the compression member to a predetermined inward motion limit of the compression member thereby driving milk out of a portion of the conduit compressed by the compression member.

[0092] In at least one embodiment, the controller is further configured to control the compression member to carry out the compression mode cycles after performing the purging.

[0093] In at least one embodiment, the predetermined pressure cycles comprise extraction mode pressure cycles, and the controller increases a stroke distance of the compression member relative to an amount of milk entering the conduit, to maintain predetermined pressures during the extraction mode pressure cycles.

[0094] In at least one embodiment, the predetermined pressure cycles comprise latch mode cycles and, upon determination that milk has entered the conduit or after a predetermined period of time, the controller operates the compression member to achieve predetermined extraction mode pressure cycles, wherein the predetermined extraction mode cycles differ from the predetermined latch mode cycles by at least one of maximum suction level or cycle frequency.

[0095] In at least one embodiment, the predetermined pressure cycles comprise extraction mode pressure cycles, and the controller is further configured to: monitor pressure waves within at least one of the conduit and the skin contact member; monitor at least one of position and speed of the compression member relative to pressure levels monitored by the monitoring pressure waves; and change at least one of speed, stroke length and position of the compression member when a predetermined amount of change in the monitored pressure versus monitored position or speed of the compression member is identified, so as to maintain execution of the predetermined pressure cycles.

[0096] In at least one embodiment, the controller monitors positions of the compression member and, upon detecting that the compression member has reached a location that is a predetermined percentage of a predetermined outward motion limit of

the compression member relative to the conduit, the controller controls the compression member to purge milk from the conduit.

[0097] According to another aspect of the present disclosure, a method of purging milk from a milk pumping system after completion of a milk extraction process includes one or more of: providing the system comprising a skin contact member configured to form a seal with the breast, a conduit in fluid communication with and connected to the skin contact member; and a driving mechanism including a compression member configured to compress and allow decompression of the conduit for pumping milk from a breast during the milk extraction process, wherein the skin contact member is sealed to the breast during the milk extraction process; upon completion of the milk extraction process, reversing a direction the driving mechanism to operate in an opposite direction to a direction of the driving mechanism executed to perform the milk extraction process, to decrease suction within the conduit; breaking the seal of the skin contact member with the breast; and reversing the direction of the driving mechanism again, after breaking the seal, to the direction of the driving mechanism executed to perform the milk extraction process, thereby driving milk from the conduit.

[0098] In at least one embodiment, upon breaking the seal, the reversing the direction of the driving mechanism again is initiated manually by an operator.

[0099] In at least one embodiment, the system detects when the seal is broken and automatically reverses the direction of the driving mechanism upon the detection when the seal is broken.

[00100] In at least one embodiment, the method further includes ending the driving milk from the conduit by ceasing operation of the driving mechanism.

[00101] In at least one embodiment, the ending is initiated manually by an operator.

[00102] In at least one embodiment, the system initiates the ending automatically at a predetermined time after the reversing the direction of the driving mechanism again is initiated.

[00103] In at least one embodiment, the system initiates the ending automatically, by measuring a compliance of the conduit and initiating the ending when the compliance reaches a predetermined compliance value.

[00104] In at least one embodiment, the reversing a direction of the driving mechanism to decrease suction within the conduit comprises decreasing the suction to greater than -20mmHg.

[00105] In at least one embodiment, the reversing a direction of the driving mechanism to decrease suction within the conduit comprises decreasing the suction and establishing a slight positive pressure.

[00106] In at least one embodiment, the reversing a direction of the driving mechanism to decrease suction within the conduit comprises decreasing the suction to about 0mmHg.

[00107] In at least one embodiment, the reversing a direction of the driving mechanism to decrease suction within the conduit, comprises establishing a pressure in the conduit to a value in the range of from about -20mmHG to about -50mmHg.

[00108] According to another aspect of the present disclosure, a system for pumping milk includes one or more of: a pair of breast pumps, each breast pump comprising: a skin contact member configured to form a seal with a breast; a conduit in fluid communication with and connected to the skin contact member; a driving mechanism configured to establish a vacuum profile within the conduit; a controller configured to control operation of the driving mechanism; and means for indicating whether the breast pump is attached to a left breast or a right breast, when both of the breast pumps are attached to the left and right breasts.

[00109] In at least one embodiment, each driving mechanism comprises a compression member configured to compress and allow decompression of the conduit in response to inward and outward movements of the compression member.

[00110] In at least one embodiment, the means for indicating is configured to receive a signal by one of the breast pumps from the other of the breast pumps to establish relative locations of the breast pumps.

[00111] In at least one embodiment, each breast pump further comprises a magnetic coil, wherein a signal sent to one of the magnetic coils by the controller associated with the magnetic coil in one of the breast pumps induces a signal in the magnetic coil of the other of the breast pumps, the signal being interpretable by the controllers to identify relative positioning of the breast pumps.

[00112] According to another aspect of the present disclosure, a system for pumping milk includes one or more of: a skin contact member configured to form a seal with a breast; a conduit in fluid communication with and connected to the skin contact member; a driving mechanism configured to establish a vacuum in the conduit; and means for indicating an amount of wear of at least one of the skin contact member and the conduit.

[00113] In at least one embodiment, the means for indicating comprises a time-based indicator.

[00114] In at least one embodiment, the time-based indicator comprises a marking that fades or appears over time.

[00115] In at least one embodiment, the time-based indicator comprises a clocking mechanism that provides at least one of a visual or audible indication at the end of a predetermined time period.

[00116] In at least one embodiment, the time-based indicator comprises an indicator provided with a plurality of LCD bars that darken upon pressing and holding a reset button and the bars lighten sequentially over predetermined time periods.

[00117] In at least one embodiment, the means for indicating an amount of wear comprises a wear indicator configured such that at least one of a color change or marking appears or fades to indicate wear.

[00118] In at least one embodiment, the system further includes a computer processor, wherein the means for indicating an amount of wear comprises the computer processor configured to track cumulative time of use of at least one of the skin contact member and the conduit.

[00119] In at least one embodiment, the means for indicating amount of wear comprises a processor; wherein the processor is configured to: track a position of the driving mechanism relative to the conduit; correlate pressure changes in the conduit relative to the position of the driving mechanism when the conduit is first used; continue to correlate the pressure changes relative to the position during continued uses of the conduit; compare correlation values from the continued correlations with correlation values from the correlations when the conduit is first used; and indicate an amount of wear of the conduit based on the comparison of correlation values.

[00120] In at least one embodiment, the processor is included in the breast pump system.

[00121] In at least one embodiment, the processor is in an external computer, external to the breast pump system.

[00122] In at least one embodiment, the time-based indicator comprises a processor configured to track usage time of at least one of the skin contact member and the conduit.

[00123] In at least one embodiment, at least one of the skin contact member and the conduit is provided with a passive sensor, and the processor is configured to track the passive sensor during use of the system.

[00124] According to another aspect of the present disclosure, a method of operating a system for pumping milk includes one or more of: providing the system comprising a skin contact member configured to form a seal with the breast, a conduit in fluid communication with and connected to the skin contact member; a driving mechanism including a compression member configured to compress and allow decompression of the conduit in response to inward and outward movements of the compression member, a sensor, a controller configured to control operation of the driving mechanism and to receive signals from the sensor, and a milk collection container in fluid communication with the conduit; sealing the skin contact member to the breast; operating the driving mechanism to extract milk from the breast and pumping the milk into the milk collection container; and calculating a volume of milk pumped into the milk collection container, based on dimensions of the conduit and positions of the compression member.

[00125] In at least one embodiment, the calculating a volume of milk pumped comprises: calculating a total volume pumped based on the dimensions of the conduit and the positions of the compression member; calculating the volume of milk pumped as a percentage of the total volume, based on a compliance assessment of the conduit performed by comparing pressure changes of the conduit to positions of the compression member.

[00126] In at least one embodiment, the system further includes a one-way valve interconnecting the conduit and the milk collection container, and the method further

includes: monitoring the one-way valve to determine when milk begins to flow into the milk collection container and stops flowing into the milk collection container; wherein the calculating a volume of milk pumped into the milk collection container, is based on dimensions of the conduit and positions of the compression member over a time period during which milk is flowing into the milk collection container.

[00127] According to another aspect of the present disclosure, a nipple shield includes one or more of: a central region configured to cover a nipple of a breast and having a first thickness; an attachment portion surrounding the central region, the attachment region being configured to attach to the breast and having a second thickness; wherein the second thickness is greater than the first thickness; and wherein the central region comprises one or more openings to allow milk to pass therethrough.

[00128] In at least one embodiment, the first thickness is a thickness in the range of about 0.2mm to about 1mm and the second thickness is a thickness in the range of about 2mm to about 5mm.

[00129] In at least one embodiment, the first thickness is about 0.25mm.

[00130] These and other features of the disclosure will become apparent to those persons skilled in the art upon reading the details of the systems and methods as more fully described below.

BRIEF DESCRIPTION OF THE DRAWINGS

[00131] Fig. 1 shows a side view of a breast pump system (without milk collection container) according to an embodiment of the present disclosure.

[00132] Fig. 2 shows a distal, perspective view of the system of Fig. 1, with the outer shell having been removed/made transparent to show components otherwise covered by the outer shell.

[00133] Fig. 3 shows a view as in Fig. 2, but with the skin contact member removed to illustrate more details of the pumping region.

[00134] Fig. 4 illustrates components of a system according to an embodiment of the present disclosure.

[00135] Fig. 5 is a partial view of the system of Figs. 2-3 showing a compression member and driver in more detail.

[00136] Fig. 6 is a partial view of the system of Figs. 2-3 showing another compression member and driver in more detail.

[00137] Figs. 7A-7C schematically illustrate one exemplary operation mode of the compression members according to an embodiment of the present disclosure.

[00138] Fig. 8 illustrates a side view of a skin contact member according to an embodiment of the present disclosure.

[00139] Fig. 9 illustrates a side view of a prior art breast flange.

[00140] Fig. 10A is a sectional view of structure shown in Fig. 8.

[00141] Fig. 10B is a sectional view of an alternative embodiment of a nipple receiving portion according to an embodiment of the present disclosure.

[00142] Fig. 11A is a longitudinal sectional view of structure shown in Fig. 11B.

[00143] Fig. 11B is a distal end view of a skin contact member according to another embodiment of the present disclosure.

[00144] Fig. 12A is a side, cross-sectional view of a skin contact member according to an embodiment of the present disclosure.

[00145] Fig. 12B is a transverse, cross-sectional view of the skin contact member of Fig. 12A taken from the bottom of the system, showing the skin contact member and tube with the outer shell.

[00146] Fig. 12C is a proximal end view of the skin contact member of Fig. 12A showing a tube connected thereto.

[00147] Fig. 13 is a schematic representation showing components defining the total system volume according to an embodiment of the present disclosure.

[00148] Fig. 14 shows a compression member compressing a tubing portion, according to an embodiment of the present disclosure.

[00149] Fig. 15 is a chart illustrating relationships between tubing volume, tubing deflection and load on the compression member, according to an embodiment of the present disclosure.

[00150] Fig. 16 illustrates compression of a tubing portion by a compression member, according to an embodiment of the present disclosure.

[00151] Fig. 17 shows the power consumption data for a system according to an embodiment of the present disclosure.

[00152] Fig. 18 is an end view of an external shell of a system according to an embodiment of the present disclosure.

[00153] Fig. 19 shows characteristics of systems using various tubing dimensions, according to various embodiments of the present disclosure.

[00154] Fig. 20 is a schematic representation of working components of a system according to an embodiment of the present disclosure.

[00155] Figs. 21A-21B show a proximal perspective view and a side view, respectively, of a skin contact member according to an embodiment of the present disclosure.

[00156] Fig. 21C is a cross-sectional view of Fig. 21C taken along line 21C-21C in Fig. 21A.

[00157] Fig. 21D shows a strain gauge mounted on or in a skin contact member according to an embodiment of the present disclosure.

[00158] Fig. 21E shows a cross-sectional illustration of a nipple receiving portion in which a first non-contact sensor has been attached to a relatively thinner wall of the nipple receiving portion and a second non-contact sensor has been attached to a relatively thicker wall of the nipple receiving portion.

[00159] Fig. 22 shows an indicator mounted on the inside of a breast contact member so that it can be readily viewed by a user prior to mounting the system to the breast, according to an embodiment of the present disclosure.

[00160] Fig. 23 illustrates another location in which an indicator may be placed, according to an embodiment of the present disclosure.

[00161] Fig. 24 illustrates an example of a reusable, time-based indicator that may be employed, according to an embodiment of the present disclosure.

[00162] Fig. 25 illustrates tracking of a skin contact member and/or tubing by a controller of the system and/or an external computer, according to an embodiment of the present disclosure.

[00163] Fig. 26 shows a wear indictor located on a tubing portion, according to an embodiment of the present disclosure.

[00164] Fig. 27 illustrates a wear indicator on a skin contact member, according to an embodiment of the present disclosure.

[00165] Fig. 28 illustrates an example of an arrangement for tracking a compression

member position, according to an embodiment of the present disclosure.

[00166] Figs. 29A-29B illustrate one or more tacky regions provided to facilitate restriction of the breast, according to an embodiment of the present disclosure.

[00167] Figs. 30A-30B illustrate differences between a skin contact member having a relatively larger internal angle and skin contact member having a relatively smaller internal angle, respectively.

[00168] Fig. 30C illustrates a portion of the areola at the juncture with the nipple that needs ample room to expand for optimal extraction of milk.

[00169] Figs. 31A-31B schematically illustrate breast pump systems according to alternative embodiments of the present disclosure.

[00170] Figs. 32A-32B illustrate a milk collection container for use in a system according to another embodiment of the present disclosure.

[00171] Fig. 32C illustrates a milk collection container that is formed so that the distal surface of the container, when filled with milk has a shape that matches the proximal surface contour of the external shell of the system, according to an embodiment of the present disclosure.

[00172] Fig. 33 shows a milk container having baffles that internally connect to the internal walls of portions of the container, according to an embodiment of the present disclosure.

[00173] Fig. 34 illustrates a milk collection container that includes a passive sensor, according to an embodiment of the present disclosure.

[00174] Fig. 35 illustrates a milk collection container wherein the connector contains a one-way valve, according to an embodiment of the present disclosure.

[00175] Fig. 36 illustrates a milk collection container according to another embodiment of the present disclosure.

[00176] Fig. 37 illustrates a milk container provided with an easily identifiable marking, according to an embodiment of the present disclosure.

[00177] Fig. 38 illustrates events that may be carried out to perform a purge according to an embodiment of the present disclosure.

[00178] Figs. 39A-39B illustrate various arrangements that may be provided to the system to help prevent loss of milk out of the system upon detachment of the system

from the breast, according to embodiments of the present disclosure.

[00179] Figs. 40A-40B illustrate two different cross-sectional views of a contour element provided with a breast pump system according to an embodiment of the present disclosure.

[00180] Figs. 41A-41B illustrate a single thin layer of plastic or fabric used as a contour element, according to an embodiment of the present disclosure.

[00181] Fig. 42 illustrates a contour element fitted on an external shell in which the external shell is provided with a key that ensures that the contour element is properly oriented on the external shell each time the two components are mated, according to an embodiment of the present disclosure.

[00182] Fig. 43 illustrates a contour element in which a first edge of the contour element overlaps a second edge, and can be adjusted to reduce, increase or maintain the circumference of the distal perimeter, while at the same time reducing, increasing or maintaining the proximal perimeter, according to an embodiment of the present disclosure.

[00183] Fig. 44 illustrates a contour element provided with predetermined markings that may be provided to assist the user in adjusting the contour element to better contour to the breast that it is to be used on, according to an embodiment of the present disclosure.

[00184] Fig. 45A illustrates an external shell provided with two keys, according to an embodiment of the present disclosure.

[00185] Fig. 45B illustrates a contour element provided with mating keys that are configured to mate with the keys of the external shell of Fig. 45A.

[00186] Figs. 46A-46B illustrate a contour element according to another embodiment of the present disclosure.

[00187] Fig. 47 illustrates events that may be carried out by a system during an extraction mode of pumping milk from a breast, according to an embodiment of the present disclosure.

[00188] Fig. 48 illustrates a nipple shield according to an embodiment of the present disclosure.

[00189] Fig. 49 schematically illustrates apparatus used to perform testing on a light body vinylpolysiloxane breast flange.

[00190] Fig. 50 illustrates results from the testing apparatus used in the testing described with regard to Fig. 49.

[00191] Fig. 51 schematically illustrates modified apparatus used to test the dynamic force-pressure relationship of a system, according to an embodiment of the present disclosure.

[00192] Figs. 52-53 illustrate results from the testing apparatus used in the testing described with regard to Fig. 51.

[00193] Fig. 54 schematically illustrates apparatus used to test the relationship between the position of a target location of a nipple receiving portion and vacuum level within the nipple receiving portion, according to an embodiment of the present disclosure.

[00194] Fig. 55 schematically illustrates apparatus used to test the relationship between the position of a target location of a nipple receiving portion and vacuum level within the nipple receiving portion, according to an embodiment of the present disclosure.

DETAILED DESCRIPTION OF THE DISCLOSURE

[00195] Before the present systems and methods are described, it is to be understood that this disclosure is not limited to particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present disclosure will be limited only by the appended claims.

[00196] Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limits of that range is also specifically disclosed. Each smaller range between any stated value or intervening value in a stated range and any other stated or intervening value in that stated range is encompassed within the disclosure. The upper and lower limits of these smaller ranges may independently be included or excluded in the range, and each range where either, neither or both limits are included in the smaller ranges is also encompassed within the disclosure, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the disclosure.

[00197] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure belongs. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present disclosure, the preferred methods and materials are now described. All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited.

[00198] It must be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a sensor" includes a plurality of such sensors and reference to "the pump" includes reference to one or more pumps and equivalents thereof known to those skilled in the art, and so forth.

[00199] The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. The dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

Definitions

[00200] The term “dead space” as used herein refers to volume within the system that is not directly acted upon by the pump of the system. Dead space is calculated by the total volume minus the active pump volume. The total volume is the volume in the skin contact member 10 and tubing 32, from the nipple receiving portion 112 to the one-way valve 50, when the system 100 has been attached and sealed to a breast 2, such that the total volume is the space in the nipple receiving portion 112 not occupied by the nipple 3/areola 4, and the remaining volume from there to the one-way valve 50. The active pumping volume is the volume displaced by the compression member (e.g., compression member 38)when the compression member is moved from one limit of a full stroke to the other limit. The nipple will also move with a changing pressure; the total system volume change is the combination of these two (plus any minor system compliance).The dead space is the non-pumping volume of the system.

[00201] “Let down mode”, as used herein, refers to a mode where the vacuum profile is characterized by higher frequency and shallower (smaller) magnitude changes in

vacuum level. Let down mode may also be referred to as "non-nutritive suction mode" or "non-nutritive mode".

[00202] "Extraction mode", as used herein, refers to a mode where the vacuum profile is characterized by lower frequency and deeper magnitude changes in vacuum, relative to "let down mode" (non-nutritive mode). Extraction mode may also be referred to as "nutritive suction mode" or "nutritive mode".

[00203] "Purging" refers to an act of transferring milk from the active pumping region of the pump tube into the collection chamber or bag.

[00204] "Latch suction" or "latch vacuum" refers to a minimum vacuum level established when the pump is attached to the breast. This is set at the lowest level of vacuum, a pressure which is below atmospheric pressure, which is effective to attach the system to the breast.

Detailed Description

[00205] Fig. 1 is a side view of a breast pump system 100 (without milk collection container) according to an embodiment of the present disclosure. The outer shell 34 of system 100 is shaped and configured to be contoured to the breast of a user and to thus provide a more natural appearance when under the clothing of the user. As can be appreciated from the figures, the system can define a natural breast profile. The natural breast profile is contemplated to fit comfortably and conveniently into a bra of a user and to present a natural look. As such, the profile is characterized by having a non-circular base unlike that embodied in a generally dome-shaped configuration. Extending from the base are curved surfaces having asymmetric patterns. Moreover, like natural breasts, the profile of the device or system is contemplated to define one or more asymmetric curves and off-center inertial centers. Various natural breast shapes can be provided to choose from to the tastes and needs of a user. Fig. 2 is a distal, perspective view of the system 100 of Fig. 1, with the outer shell 34 having been removed/made transparent to show components otherwise covered by the outer shell 34. System 100 includes a skin contact member 10 (such as the breast flange shown in Fig. 2, or member having a different shape, but configured to seal to the breast of a wearer and provide fluid communication with the pump) a

pumping region 30 and a conduit 32. Fig. 3 shows a view as in Fig. 2, but with the skin contact member 10 removed to illustrate more details of the pumping region 30.

[00206] Fig. 4 illustrates components of a system 100 according to an embodiment of the present disclosure. Conduit 32 includes a large conduit portion 32L that is relatively larger in cross-sectional inside area than the cross-sectional inside area of small conduit portion 32S. Although both portions 32S and 32L are shown as tubular portions being circular in cross-section, the present disclosure is not limited to such, as one or both portions could be shaped otherwise. For example, the conduit region 32L in the embodiment of Fig. 3 is not cylindrical, but is formed as a pump chamber having a substantially oval face 32F and walls that extend substantially perpendicular thereto. Further details of this embodiment of conduit region 32L can be found in US Provisional Application Nos. 62/052,476 filed 09/19/2014 and 62/053,095 filed 09/10/2014, both of which are hereby incorporated herein, in their entireties, by reference thereto. The conduit region 32S2, which joins one way valve 50 and large conduit region 32L in fluid communication, may be, but is not necessarily of the same dimensions as small conduit region 32S. Like regions 32S and 32L, region 32S2 may be cylindrical and circular in cross section, but need not be. When tubular, the cross-sections may be oval square, other polyhedral shape, non-symmetrical, or non-geometric shape.

[00207] In the embodiment of Figs. 2-3, latching, pumping and extraction forces are established by two compression members 36, 38 which are actively driven by drivers 44 and 46 respectively. Although more than two compression members could be used and one or more than two drivers could be used, the currently preferred embodiment uses two compression members respectively driven by two drivers as shown. Fig. 5 is a partial view of the system 100 of Figs. 2-3 showing compression member 36 and driver 44 in more detail. Fig. 6 is a partial view of the system 100 of Figs. 2-3 showing compression member 38 and driver 46 in more detail.

[00208] Figs. 7A-7C schematically illustrate one exemplary operation mode of the compression members 36, 38 according to an embodiment of the present disclosure. In Fig. 7A, tubing portions 32S and 32L are closed off, or substantially closed off by compression members 36 and 38, respectively. Upon powering up the system 100 the

compression member 36 opens as illustrated in Fig. 7B and the compression member 38 begins to withdraw away from anvil surface 2232 which gradually increases the suction level within tubing 32. When a predetermined maximum suction level is achieved (as confirmed by pressure readings taken from a pressure sensor, described below), the compression member 38 ceases its travel in the current direction, and either maintains that position for a predetermined period of time (or moves slightly in the same direction to compensate for decreasing suction as milk enters the system) when the operating mode of the system 100 has a predetermined time to maintain maximum suction, or reverses direction and compresses the tube 32L until the latch suction level is achieved. If the maximum suction level has not yet been achieved by the time that the compression member is fully retracted away from the anvil surface 2232 on the first stroke, then the compression member 36 again compresses the tube 32S to seal off the current vacuum level in the environment of the breast, and the compression member 38 fully compresses the tube portion 32L to squeeze more air out of the system (out through one-way valve 50). Then the compression member 36 reopens to fully open tube portion 32S and compression member carries out another stroke, again moving away from the anvil surface 2232 to generate a greater suction level. This cycling continues until the maximum suction level is achieved. It is noted that it is possible in some cases to achieve the maximum suction level on the first stroke, whereas in other cases, multiple strokes may be required.

[00209] Fig. 7B shows the tubing portion 32S fully open as the compression member 36 is released and compression member 38 is moving away from anvil surface 2232 to increase suction within the tubing 32. Upon achieving the maximum suction, the system may be designed and programmed so that the compression member 38 does not travel to its fullest possible extent in either direction to achieve the maximum and latch suction levels, so as to allow some reserve suction and pressure producing capability. When the maximum suction level has been achieved, and the pumping profile is programmed to return to latch pressure, the compression member 38 advances toward the anvil surface 2232, compressing tubing portion 32L, thereby raising the pressure in the tubing 32. Upon achievement of the latch suction pressure, compression member 36 closes off the tubing 32S again to ensure that the latch pressure is maintained

against the breast, so that sufficient suction is maintained. At this stage, the compression member 38 again begins moving away from the anvil surface 2232 to increase the suction level back to maximum suction, and compression member 36 opens (moves away from anvil surface 2230) to allow tube 32S to open and the breast 2 to be exposed to the maximum suction. Alternatively, the system may be programmed so that the compression member 38 cycles between maximum and latch suction levels without the compression member 36 closing during a point in each cycle, with the compression member 36 closing when the latch pressure is exceeded.

[00210] Upon selection of a milk extraction mode, the compression member 36 and compression member 38 function in the same manners as in the latch mode, but in a manner that follows an extraction waveform determined by the selected extraction mode. During the compression stroke of compression member 38, compression member 36 closes when the latch pressure/suction level is achieved. Continued compression by the compression member 38 (Fig. 7C) increases the pressure in the tubing 32 downstream of the compression member 36 to establish a positive pressure to drive the contents (milk) of tube portion 32L out of the tube portion 32L through smaller tubing portion 32S2 downstream of 32L and out through one-way valve 50. The positive pressure attained is sufficient to open the one-way valve for delivery of the milk out of the tubing 32 and into a milk collection container. In one embodiment, the positive pressure is in the range of 20mm Hg to 40mm Hg, typically about 25mm Hg. Upon reversing the motion of compression member 38, compression member 36 opens when the suction level returns to the latch suction level and compression member 38 continues to open to increase the suction level to the maximum suction level.

[00211] Prior art breast pump systems typically cycle between 0 mmHg (or close to 0) and peak vacuum, which is typically up to 250mmHg vacuum. The flanges of the prior art systems (i.e., the component that contacts and seals to the breast) typically have a shaped, distal portion and a large cylinder section to accommodate the nipple of the breast as it is drawn forward into the cylinder by the application of vacuum. During pumping with these prior art pump systems, the nipple cycles back and forth significantly matching the cycling of vacuum from 0 to peak set vacuum. This motion

is typically at least 1cm of motion (nipple extends and contracts by at least 1 cm) and can be significantly greater. Studies have shown that the nipple motion resulting from a nursing baby is not very large, e.g., on the order of about 4-5mm of motion total (Elad paper, other Hartman group papers).

[00212] The present disclosure establishes a latch vacuum to cause the skin contact member/breast flange 10 to seal to the breast. The latch vacuum established by the system is currently about 60mmHg, but can be any value in a range of from about 20 mmHg to about 80 mmHg. Once the system 100 has been latched to the breast via skin contact member 10, the system then cycles between the latch vacuum and a target (also referred to as "peak" or "maximum") suction level. Due to the fact that the system 100 does not cycle down to 0 mmHg, but maintains suction applied to the breast, with the minimum end of the suction cycle being the latch suction level (e.g., about 60mm Hg), the nipple does not contract as much as it would with use of a prior art breast pump system. It has been observed that the nipple draws into the skin attachment member 10 with the initial latch achievement in an analogous fashion as the formation of a teat during breastfeeding. Once the vacuum cycles between the latch and target vacuum levels, there is significantly less motion of the nipple back and forth with the vacuum changes, as compared to what occurs with use of prior art systems.. The nipple motion (distance between fully extended and fully retracted) during use of the present system is typically less than about 2mm, and in some cases less than about 1mm.

[00213] This greatly reduced motion of the nipple during cycling results from establishment of the latch at latch vacuum level, and then limiting the range of vacuum swing between latch vacuum (suction) and peak vacuum (suction). Typically the difference in vacuum between latch vacuum and peak vacuum is less than 200 mmHg, more typically less than 150 mmHg. In one example, the latch vacuum was 50 mmHg and the peak vacuum was 200 mmHg, resulting in a vacuum difference of 150 mmHg.

[00214] Limiting the nipple motion as described with use of the present system offers several benefits to the user. One benefit is that there is less friction on the side of the nipple against the flange wall, thereby greatly reducing the risk of irritation, skin damage, pain, swelling, etc. As a result, the present system is significantly more comfortable to use by a nursing mother, and this benefit is increasingly noticeable over

repeated uses. By maintaining at least a latch suction level at all times, the present system provides a more secure and persistent seal to the breast and significantly reduces the potential for leaks of air and/or milk. Because the nipple moves significantly less, this provides a more "natural" feel to the user that more closely simulates the feel of a nursing baby. Because the nipple travels less, this allows for the skin attachment member/flange 10 to be designed as a lower profile component, as its length can be shorter since it does not need to accommodate the greater length in nipple movement experienced by prior art systems. This allows the overall amount of protrusion of the system 100 from the breast to less than that in the prior art, as the overall length of the system is reduced by the reduction in length of the skin contact member/flange 10. Thus, the distance from the tip of nipple to exposed end of the housing the system is reduced.

[00215] Fig. 8 illustrates a side view of a skin contact member 10 according to an embodiment of the present disclosure. As shown, the breast contact portion 122 is symmetrical about the nipple receiving portion 112, although, alternatively, the nipple receiving portion 112 could be offset in a manner as described herein. The overall length 110 of the skin contact member 10 in this embodiment is about 63.75mm. Fig. 9 illustrates a longitudinal sectional view of a prior art breast flange 210. The overall length 212 of flange 210 is about 60.6mm. The skin contact member 10 is designed to reduce the internal volume of the nipple receiving portion 112 relative to the internal volume of the nipple receiving portion 214 of the prior art device, which is enabled by the significantly reduced amount of motion experienced by the nipple 3 during a milk extraction process using a system 100 including skin contact member 10, according to the present disclosure. The nipple receiving portion 112 of the skin contact member 10 is contoured to more closely match the natural shape of the nipple, thereby eliminating or significantly reducing dead space that exists around the nipple in prior art systems. In the example shown, the nipple receiving portion 112 is cylindrical in the portion 112A adjoining the breast contact portion 122, and then tapers conically in the portion 112B that extends from portion 112A to the connector 134. This design allows for receiving a portion of the areola 4 into the nipple receiving portion 112A while also limiting dead space by providing the conical portion 112B. The diameters of all cross-

sections of the nipple receiving portion 112 are large enough to allow nipple dilation. The inside diameter of the conically tapering portion 112B tapers from an inside diameter equal to the inside diameter of the cylindrical portion, down to a smaller inside diameter. As noted, the length of the nipple receiving portion 112 is significantly less than that of the prior art. In the example shown in Fig. 8, the length 114 of the nipple receiving portion 112 is about 23mm , as compared to the length 216 of 36.9mm (may be in the range of about 350mm to about 500mm) of the prior art nipple receiving portion 214.. Length 112 may vary within a range of about 22mm to about 29mm. The length 114 of the nipple receiving portion 112 is sufficient to allow engorgement of the nipple 3 under vacuum, without the distal tip of the nipple 3 contacting the proximal end of the nipple receiving portion 112.

[00216] Experimentation with the present system 100 has shown that the majority of women's nipples extend into the nipple receiving portion 112 with a length of about 1.6cm under latch suction of about 50mmHg (-50mmHg pressure). The extra length provided by the nipple receiving portion 112 (beyond the length of the nipple under latch vacuum is provided to allow for a small amount of extension of the nipple under target vacuum, typically about 1-2mm under maximum suction of about 150mmHg, and to allow for a small amount of additional forward motion the nipple may experience as the pump primes. Accordingly, there is provided at least about 2mm, up to about 6mm of space in the nipple receiving portion that extends lengthwise proximally of the tip of the nipple 3 when it is under latch pressure.

[00217] The diameter 116 of the nipple entrance to the nipple receiving portion 112 is large enough to accommodate the majority of nipple sizes so that the nipple is not constricted from some engorgement while under vacuum. The nipple 3 expands in diameter by a large amount at the base (the region that joins the areola 4) than it does at the tip, which allows the nipple receiving portion 112B to be made conical-shaped, as shown. The diameter 116 of the entrance opening of the nipple receiving portion 112, in the embodiment of Fig. 8 is about 24mm, but may be in a range of about 22mm to about 29mm. The inside diameter 118 at the proximal end of the nipple receiving portion 112B is about 13.16mm in Fig. 8, but can be in the range of about 9mm to about 20mm. In contrast, the inside diameter 218 of portion 214 of flange 210 is about

23.5mm over the entire length of the portion 214.

[00218] A portion of the areola 4 may also be drawn into the nipple receiving portion 112, so that it is alternately compressed and at least partially relieved of compression by the pumping system 100 to simulate the way a baby naturally feeds. However, the skin contact member 10 is configured to restrict the areola 4 from completely entering the nipple receiving portion 112 and to restrict portions of the breast 2 other than the nipple 3 and areola 4 from entering the nipple receiving portion 112. This prevents the tip of the nipple 3 from contacting the proximal end of the nipple receiving portion 112, even under maximum vacuum.

[00219] In any of the embodiments of skin contact member 10 disclosed herein, the top part of the nipple receiving portion 112 may be formed of a relatively harder and/or stiffer material and the bottom part of the nipple receiving portion 112 may be formed of a relatively softer and/or more flexible material to better simulate a nursing baby during use, as the baby's tongue, which contacts the bottom of the nipple 3 is softer and more flexible than the baby's palate, which contacts the top of the nipple 3 during nursing.

[00220] To facilitate restriction of the breast 2, the breast contact portion 122 may be provided with one or more tacky regions 360, see Figs. 29A-29B. Although shown as continuous ring about the interior surface of breast contact portion 122 in Figs. 29A-29B, tacky region 360 may span one or more portions of this circumference and can be provided as one or a plurality of segments. The tacky region(s) provide more friction with the breast 2 than does the remainder of the skin contact member 10, thereby providing resistance to the portions of the breast 2 that contact it, preventing it from being drawn in toward nipple receiving portion 112. The tacky region 160 may be formed by a different material than the remainder of the skin contact member 10, and/or may be a coating or roughened area to provide the increase in friction. For example, the tacky region may be silicone, with the remainder of the skin contact member being formed of polyethylene, or one of the other materials described herein for using in making the skin contact member. By preventing these portions of the breast from sliding into the nipple receiving portion 112, this reduces incidences of pain from compression of too much breast tissue, and provides sufficient space in the

nipple receiving portion 112 for the nipple 3 to naturally engorge for milk volume expression.

[00221] The internal angle 120 of the breast contact portion 122 of the skin contact member 10 is designed for use with the present system 100 and to maximize comfort of the user. The internal angle may also facilitate the ability to restrict portions of the breast 2 from moving forward too much into the nipple receiving portion 112. In the embodiment of Fig. 8, the internal angle 120 is about 112°, which is wider than the internal angle of prior art flanges. For example, the angle 218 of the breast contact portion 220 of the prior art flange 210 is ninety degrees. The wider angle 120 helps to prevent the breast tissue from being funneled into the nipple receiving portion 112, so that less breast tissue is received in the nipple receiving portion 112, making use of the present skin contact member 10 more comfortable than flanges of the prior art and providing space for nipple engorgement. By providing the wider angle 120, this also allows the overall system to be effectively shortened and allows the system to lie flatter against the breast to improve both comfort and appearance. In the embodiment of Fig. 8, the length 124 of the breast contact portion 122 is 15mm, but may be in the range of from about 12mm to about 19mm. In contrast, the length 222 of breast contact portion 220 is 25.8mm, which causes a system using flange 210 to extend further out from the breast than would a system using the skin contact member 10.

[00222] Figs. 30A-30B illustrate differences between skin contact members 122A having a relatively larger internal angle 122A and skin contact member 122B having a relatively smaller internal angle 122B. The smaller angle 122B provides the ability to interact with relatively more breast tissue on more variations in breast sizes and shapes. The breast contact portion of 122A of the skin contact member shown in Fig. 30A has an internal angle 120A that is larger than the internal angle 120B of breast contact member 122B shown in Fig. 30B. As a result, when these skin contact members 10 are mounted to the breast 2, the initial contact of the breast tissue to the breast contact member 122A at 362A is lower on (or further into) the breast contact portion 122A than where the breast tissue initially contacts breast contact member 122B at 362B. The higher (or further out) initial contact location 362B of the breast 2 on the breast contact portion 122B provides more contact surface (compare length 364B to 364A) of

the breast 2 on the breast contact portion 122, which better controls the tissue movement in the nipple receiving portion 112 and creates more tension on the teat as it forms, due to the increase surface contact area available. The teat starts to form sooner and the increased tension on the breast aids in holding back breast tissue 2 and the distal portion of the areola 4 from being sucked into the nipple receiving portion 112. A larger length 366B and area for the areola 4 and nipple 3 to form a teat are provided by the smaller angle 120B, relative to the length 366A and area of the embodiment in Fig. 30A, as length 366B is greater than length 366A by an amount sufficient to make the internal volume of the skin contact member over the length 366B greater than the internal volume of the skin contact member over the length 366A. With the larger angle 122A of the embodiment in Fig. 30A, the areola contacts the sides of the breast contact portion 122A upon initial contact of the breast 2 with portion 122A, so that there is no room for the areola 4 to expand. For optimal results, there needs to be a lengthening and widening of the areola 4 during milk extraction, as this is what occurs when a baby suckles. The space provided between the areola 4 and the opening to the nipple receiving portion 112 upon initial contact of the breast 2 to breast contact portion 122, allows the areola 4 to lengthen and expand (widen) as the nipple 3 is drawn into the nipple receiving portion 112. Fig. 30C illustrates the portion 4P of the areola 4 at the juncture with nipple 3 that needs ample room to expand for optimal extraction of milk, as this portion includes milk ducts that will not expel milk as efficiently, or at all, if they are not allowed to expand. The skin contact members 10 of the present disclosure are preferably configured to allow up to about 0.25 inches (about 0.5cm) length of the areola 4 to be drawn into the nipple receiving portion 112, and to prevent additional portions of the areola from entering the nipple receiving portion 112.

[00223] The thickness of the material forming the breast contact portion 122 and nipple receiving portion 112 in the embodiment of Fig. 8B is about 1.5mm, but the thickness may be in the range of from about 1mm to about 4mm. Alternatively, the thicknesses of the breast contact portion 122 and the nipple receiving portion 112 may be different from one another. The breast contact portion 122 and nipple receiving portion 112, as well as the tubing connector 134 can be made of silicone or other compliant,

biocompatible material, such as, but not limited to polyurethane and/or polyether block amides (PEBAX) to provide a soft interface with the breast and also provide a seal around the areola and nipple of the breast The inner housing 126 of the breast contact portion 122 can be rigid, semi-rigid or compliant. Likewise, the nipple receiving portion 112 can be rigid, semi-rigid or compliant. Part of the breast contact portion 122 that adjoins and serves as an entrance to the nipple receiving portion 112, is configured to be in contact with at least the perimeter portions of the areola 4 and can be made of a less lubricious material (relative to the lubricity of the nipple receiving portion 112) to provide more frictional resistance on at least the perimeter of the areola to help prevent it from being drawn into the nipple receiving portion 112, and to provide tension on the breast tissue away from the nipple 3 and areola 4, to control the amount of areola 4 that is allowed into the nipple receiving portion 112. Since the present system 100 significantly reduces movement of the nipple 3 during pumping, the surface that provides more friction and tension reduces the risks of chafing or blistering of tissue that would be experienced in a currently available nipple flange, as they experience considerably more nipple 3 movement during pumping. The nipple receiving portion 112 and inner housing 126 can be made of different materials and/or hardnesses and/or rigidity. For example, the inner housing 126 can be rigid and the nipple receiving portion 112 can be compliant, or any other combination of materials, hardnesses and rigidities could be provided. Preferably the breast contact portion 122 and nipple receiving portion 112 are compliant and made from silicone, although other materials and combinations of materials could be used, including, but not limited to or polyethylene terephthalate (PET), polyurethanes, polyethylene, high density polyethylene (HDPE), low density polyethylene (LDPE), polyamides, polyethylene terephthalate (PET) and/or PEBAX. For the embodiments where there is compliance, the nipple receiving portion 112 may be capable of iteratively opening and closing during extraction of milk from the breast using system 100, thereby simulating a feeding cycle similar to the sequence of the tongue against the nipple when a baby is suckling.

[00224] In the embodiment of Fig. 8, the nipple receiving portion 112 includes portion 112A which is cylindrical and portion 112B, which is cone-shaped, with the internal

angle 130 of cone-shaped portion 112B being about 60 degrees. The internal angle of the cone may be in the range of from about 55 degrees to about 65 degrees.

[00225] Both the cylindrical portion 112A and the cone-shaped portion 112B are circular in cross-section, as exemplified by the cross-section illustration of Fig. 10A, which is taken along line 10A-10A in Fig. 8. Alternatively, one or both of portions 112A, 112B may be ovular or elliptical in cross-section, as illustrated by 112A', 112B' in Fig. 10B. This ovular or elliptical cross-section more closely resembles the shape of a suckling baby's mouth and will therefore provide a pressure/force contour to the nipple that is more similar to the suckling of the baby.

[00226] Further alternatively, the skin contact member 10 may have an adjustable opening 132 to the nipple receiving portion 112 and also the flange angle 120 may be adjustable, so that both the breast contact portion 122 and opening can be sized to optimize the fit against the areola and reception of the nipple. In at least one embodiment, inserts are provided on the inside of the breast contact portion 122. Additionally or alternatively, inserts can be provided on the back of the breast contact portion 122 In any of these arrangements, inserts change the angle of breast contact portion 122 relative to the breast 2 as it is mounted on the breast. Still further, an insert can be provided to make the opening smaller. Different combinations of flange angle 120 and opening 132 diameter may be required for different sizes and shapes of breasts. For example, a relatively smaller opening 132 and relatively smaller angle 120 may be required for a breast that is relatively more elastic than average, while a relatively larger angle 120 and relatively larger opening 132 may be better for a breast that is more taut than average. Further alternatively, a series of skin contact members 10 may be provided to provide a range in angle 120 and opening 132 variations. The wall thickness 128 may also be varied to accommodate changes in the angle 120 of the breast contact portion 122.

[00227] Portion 134 is the tubing connector that is used to connect the skin contact member 10 in fluid communication with the tubing 32. The diameter 136 of the opening 138 that provides the fluid communication with the tube 32 is about 25mm in Fig. 8, but may be in the range of from about 20mm to about 28mm. The length 142 of portion 134 is about 23.8mm in Fig. 8, but may be in the range of from about 20mm to

about 28mm.

[00228] Fig. 11A is a longitudinal sectional view taken along line 11A-11A in Fig. 11B and Fig. 11B is a distal end view of a skin contact member 10 according to another embodiment of the present disclosure. In this embodiment, the nipple receiving portion 112 is not centered with respect to the breast contact portion 122, in contrast to the embodiment of Fig. 8 where the breast contact portion 122 is concentric with nipple receiving portion 112. Instead, in this embodiment, the central axis 146 of the nipple receiving portion 112 is positioned below the central axis 148 of the breast contact portion 122, when the skin contact portion is placed in the orientation in which it is used for attachment to the breast, see Fig. 11B. In this embodiment, the opening 132 to the nipple receiving portion 112 is slightly larger in diameter than that of the embodiment of Fig. 8, (25mm vs. 23mm) to accommodate users with slightly larger nipples. The opening diameter 219 of the prior art flange 210 shown in Fig. 9 can be in the range of about 21mm to about 32mm. Of course, the offset embodiments of the present disclosure could also use the smaller opening 132 size. Likewise, the embodiment of Fig. 8 could be provided with the larger opening 132 size. In this offset embodiment, the angle 120A of the breast contact portion 122 that is above the nipple receiving portion 112, relative to the central axis 150 of the breast contact portion 122 (and the central axis 164 of the nipple receiving portion 112 when the central axes 150 and 164 are parallel, as in the embodiment of Fig. 11A) is flatter than the angle 120B of the breast contact portion 122 that is below the nipple receiving portion 112, relative to the central axes 150 and 164, see Fig. 11A. In other embodiments, central axis 150 is not parallel with central axis 164. In the example shown in Fig. 11A, angle 120A is about 69 degrees and angle 120B is about 52 degrees. However, angle 120A may be any angle in the range of from about 32 degrees to about 85 degrees and angle 120B may be any angle in the range of from about 32 degrees to about 85 degrees. This configuration provides a better fit to the natural curvature of the breast to which the breast contact portion 122 is contacted, relative to a design where both angles 120A and 120B are equal. To maintain the plane of the perimeter around the distal opening 152 of the breast contact portion 122 substantially normal to the central axis 150 as shown in Fig. 11A, the distance 154 from the top of the opening 132 to the top of the

perimeter of distal opening 152 is greater than the distance 156 from the bottom of the opening 132 to the bottom of the perimeter of distal opening 152, due to the difference in angles 120A and 120B. In the example shown in Fig. 11A, distance 154 is about 36.32mm, but may be any value in the range of from about 15mm to about 62mm; and distance 156 is about 21.3mm, but may be any value in the range of from about 10mm to about 58mm. The outside diameter 158 of the breast contact portion 122 at the distal opening (see Fig. 11B) is about 82.3mm, but may be any value in the range of from about 60mm to about 150mm. The distance 160 from the top of the perimeter of the distal opening 152 to the central axis 164 of the nipple receiving portion is about 49.8mm in the embodiment of Fig. 11A, but may be any value in the range of from about 30mm to about 60mm. The distance 162 from the bottom of the perimeter of the distal opening 152 to the central axis 164 of the nipple receiving portion in the embodiment of Fig. 11A is about 33mm but may be any value in the range of from about 25mm to about 40mm. In contrast, the flange 210 of Fig. 9 is symmetrical, with the distance 254 from the top of the perimeter of the distal opening to the central axis of the flange 210 being 28.2mm and the distance 256 from the bottom of the perimeter of the distal opening to the central axis of the flange 210 being 28.2mm.

[00229] Multiple holes or ports 140 are provided at the interface of the nipple receiving portion 112 with the tubing connector 134 to allow the breast milk drawn from the nipple 3 to enter the tubing 32 connected to the tubing connector 134 and in fluid communication with holes/ports 140. These holes/ports 140 allow milk to be delivered into the tubing connector 134 and tubing 32, and also prevent the nipple 3 from being drawn into the tubing connector 134 and tubing 32.

[00230] Fig. 12A is a side, cross-sectional view of the skin contact member 10 and tube 32 with the outer shell 34. Fig. 12B is a transverse, cross-sectional view from the bottom of the system 100 showing the skin contact member 10 and tube 32 with the outer shell 34. Although tube 32 is shown schematically as a single sized tube for simplicity, the large portion 32L in this embodiment has an inside diameter larger than the inside diameter of smaller tube portions 32S. Fig. 12C is a proximal end view of the skin contact member 10 showing tube 32 connected thereto. In one embodiment, the inside diameter of the tube 32L is about 3/8". In another embodiment, the inside

diameter of the tube 32L is about 7/16". In another embodiment, the inside diameter of the tube 32L is about ½". In another embodiment, the inside diameter of tube portion 32L is about 5/16". In one embodiment, the inside diameter of tube portions 32S and 32S2 is about ¼". In another embodiment, the inside diameter of tube portions 32S and 32S2 is about 3/32". In another embodiment, the inside diameter of tube portions 32S and 32S2 is about 1/8".

[00231] In one embodiment, the total system volume is about 24.0 cc. The total volume is calculated as the space in the nipple receiving portion 112 (that is not occupied by the nipple 3) and tube portions 32S, 32L and 32S2 up to the one-way valve 50, see the schematic representation in Fig. 13. Other embodiments may have a significantly less total system volume, in the range of about 4cc to about 24cc, preferably in the range of about 4.5cc to about 12cc, more preferably in the range of about 5cc to about 8cc or about 8cc to about 10cc. In the embodiment with total system volume of about 24.0 cc, the active pump volume, i.e., the volume displacement achievable by compressing tube portion 32L from fully uncompressed to the limit of compression by compression member 38 is about 3.4 cc. The compression member 38 in this embodiment has a compression member length 38L (with length defined as shown in Fig. 14, 38L) of about 2.5". When there is only air in the tubing 32 of the system 100, pressure swing by moving the compression member 38 inwardly against the tubing portion 32L and outwardly away from the tubing portion is limited, due to the compressibility of the air. In this embodiment, with the system under vacuum of -60 mmHg, a full stroke of the compression member (from compressed to fully uncompressed tube portion 32L) increases the vacuum to -160 mmHg. The ratio of pumping volume to total system volume is important with regard to power and size of the pumping system. In this embodiment, the tube portion 32L was made of silicone (Dow Corning SILASTIC®) having a .375' inside diameter and a wall thickness of .094", with a hardness of 50 Shore A. Using the 2.5" long compression member, the force applied to the tube portion 32L under full compression was 19.6lbf.

[00232] In a preferred embodiment, it is preferred to avoid both completely compressing the tube portion 32L and well as allowing full rebound of the tubing portion 32L. Near full compression, a sharp increase in compression force is required

(see Fig. 15, #302), which is not efficient for the small amount of additional pressure change obtained thereby, given the significant increase in motor power and energy consumption that it would require. Near full rebound of the tubing portion, the resulting pressure changes are less efficient, given the amount of energy expended by the driver 46 to withdraw the compression member 38 fully, see Fig. 15, #305 During let down mode operation of the system 100, the system 100 operates to effect let down of the milk in the breast 2, prior to extraction, with a maximum suction target of up to 120mmHg (typically, about 100mmHg (-100mmHg pressure)) to establish let down. The goal of letdown mode (or non-nutritive suction mode) is to stimulate the breast 2 to express milk. The relatively shallow (small vacuum change range) and relatively fast frequency of the pumping during this phase are meant to mimic the initial suckling action of a child at the breast. In this mode, the first 10% of the tubing compression (Fig. 15, #305) is less productive. This is because during let down phase, the suction pressure is not allowed to exceed the maximum let down suction of 110mmHg or 120mmHg, or whatever the maximum let down suction is set at, so the compression member 38 does not cycle to the range of the first 10% of the tubing compression. Therefore, as the compression member 38 is drawn in a direction away from the tube portion 32L, the system 100 is designed to reach -100mmHg (a suction pressure of 100mmHg) (or -120mmHg, or whatever the maximum let down suction is designed to be), by the time that the compression member 38 has reached a position in which tube 32L is 90% uncompressed, see 307. Further movement of the compression member 38 away from the tube portion 32L from 90% to 100% compressed (see region 305) is less helpful to generate additional vacuum as the tube portion 32L functions like a weak spring during this portion of expansion. The chart in Fig.15 tracks the rebound pressure generation by the tube portion 32L after compression to a specific level. For example, 100% compression of tube portion 32L followed by sealing the tube and letting it rebound would generate >300mmHg. A small deflection generating 10mmHg is not 'useful' for pumping purposes of the system 100. 200mmHg vacuum is established when the tubing 32L is about 25% compressed and then released, see 309. The compression member 38 needs only to actuate within the ranges of vacuum generation that are useful for the pumping purposes of the system 100. Actuating the

compression member 38 to compress the tube portion 32L near 100% is inefficient due to the compression load ramping up. Also, actuating the compression member 38 paddle near 0% compression of the tubing portion 32L is only useful for controlling low vacuum peaks. As the tubing portion 32L rebounds it reaches its capacity for vacuum draw and further withdrawal of the compression member 38 away from the tubing portion 32L only causes the paddle to lose contact with the tubing portion 32L.

[00233] During let down (non-nutritive) mode the system 100 can be configured to operate between -60mmHg and -100mmHg in one example. In this example, the compression member 38 can compress the tubing portion 32L nearly fully (e.g., about 97%) and then be moved away from the tubing portion 32L to generate vacuum. The maximum latch suction pressure of -100mmHg will be reached with a small amount of rebound of the tubing portion 32L and the compression member 38 can be cycled relative to the tubing portion 32L between -100mmHg and -60mmHg in a narrow range or band near full compression of the tube portion 32L. As milk flows, that narrow band shifts (volume in -> paddle lifting) until 100 is generated around 10% (90% rebound) at which point the tube portion 32L will be purged by fully compressing it (up to or near 100% compressed) to drive out the contents and thereby regain more capacity for pumping with relatively less compression of the tube portion 32L again. In another embodiment, compression member 38 operates in a range to compress tube portion 32L from about 10% compressed up to about 97% compressed. Additionally, the compression member 38 can move to a position where tube 32L is 0% compressed to allow for installation, changing, etc. of the tubing 32. Typically during purging, the vacuum level is reduced to minimum vacuum (e.g., about -60mmHg) and the compression member 36 is used to close off (seal) tubing portion 32 to maintain 60mmHg vacuum against the breast 2. Then the compression member 38 fully compresses the tubing portion 32L to purge the contents of tubing portion 32L.

[00234] The contact surface of the compression member 38 can be shaped to improve pumping efficiency and reduce power requirements of the system 100. Fig. 16 shows an end view of compression member 38 during compression of tubing portion 32L. The contact surface 38S of compression member 38 is convex in the direction transverse to the longitudinal axis of the compression member 38, such as by radiusing,

for example, to avoid unproductive crushing of the side walls of the tube portion 32L. This minimizes the peak load on the driver 46. It can be seen in Fig. 16 that the central portion of the tube 32L is completely closed as the inner walls contact one another, while the portions near the sides of the annulus do not completely close off.

[00235] For the embodiment having the total system volume of 24.0 cc, 19.6 lbs. pumping force was provided by the driver 46 and compression member 38. The estimated mechanism capacity was 44 lb. "Mechanism capacity" refers to the maximum compression force that could be applied to the tubing portion 32L by the driver 46 and compression member 38, and is a factor of voltage, driver 46 stall torque, and other characteristics of the drive train, such as gear reduction, etc. The system used a servo motor as the driver 46 connected to the compression member 38 with a 0.188" lever arm 304 (see Fig. 14), to provide a 246:1 gear ratio and 5.9 ft-lb. torque with a 500 mA current draw. The maximum desired speed of this pump system is 90 cycles/min (CPM), with full compression travel limited to about 65CPM. When the compression travel (stroke) is reduced, such as when in letdown mode, the speed can be increased. The pump system has a 'dry' 100 mmHg swing (i.e., change in vacuum is about 100mmHg from one end of a full stroke to the other when there is no fluid in the tubing 32), so the full travel stroke may not be required in letdown mode, as the vacuum swing is less than 100mmHg, e.g., about 60mmHg latch suction to about 100mmHg maximum suction. The force requirements of the pumping system can be greatly reduced by reducing the dead space in the total system volume, which in turn then requires less pumping volume per cycle/stroke. By reducing the gear ratio, this can increase the actuation of the compression member to make it quicker and more responsive to pressure changes.

[00236] The driver 44 and compression member 36 were configured to apply about 1.0 lbf to the tube having 3/8" inside diameter, to fully close (pinch) it off. Driver 44 included an HS-85MG servo motor having dimensions of .51" x 1.14" x 1.2", a 3.0 in-lb. stall torque and .238" lever arm to provide about 12.8 lbf capacity.

[00237] Fig. 17 shows the power consumption data for the system described above having 24.0 cc total system volume, .375" inside diameter tube 32, and 2.5" compression member 38 described above. The drivers 44, 46 were powered by four

alkaline "C" sized batteries which provided a voltage 330 of about 6V. The currents were measured using a multimeter in series with the battery connection to the drivers. The system was set to drive the compression member 38 over the full stroke relative to the tube portion 32L during operation. A single 15 minute pumping session required about 110 mAh of power, see 336. An estimate for a day's worth of pumping was set as four sessions, resulting in the power requirement for a full day 338 to be about 440 mAh. The average current 332 was calculated to be about 440 mA and the maximum current 334 capability was about 0.83A.

[00238] In one embodiment, the external shell 34 that contains the other components of the breast pump system (except for the milk collection container which is mountable over the external shell 34) is configured to have about an 11 cm (4.3") diameter 340 (see Fig. 18) and a length 342 (see Fig. 1) of about 4.1 cm (1.6"), although the diameter 340 may be any value within the range of from about 10 cm to about 14 cm and the length 342 may be a value within the range of from about 3.5 cm to about 6 cm. An external shell 34 having a diameter 340 of about 11 cm and length 342 of about 4.1 cm provides a housing volume for the components of about 151.2 cc. Assuming dead volume in the nipple receiving portion 112 to be about 1.8 cc and a 1 cm length of tubing 32 provided for compression by compression member 36 with the nipple receiving portion 112 off center of the breast contact portion 122 by about 1.5 cm, Fig. 19 shows characteristics of systems 100 using various tubing dimensions. These characteristics were measured using tubing 32 that was uniform throughout and thus did not have a smaller tubing portion 32S and larger tubing portion 32L, but the principle still holds for using tubing 32 having both small 32S and large 32L portions. It can be seen that reducing the dead volumes 350 and 352, the pumping efficiency 354 (pumping volume divided by total system volume 352 + 356) increases. This allows a reduction in the length 38L of compression member 38, resulting in relatively lower pump power and energy consumption requirements.

[00239] The system 100 is responsive to pressure changes within the tubing 32 caused by entry of milk into the tubing 32. Fig. 20 is a schematic representation of working components of the system 100 according to an embodiment of the present disclosure. The compression elements 36 and 38 are driven by dedicated compression drivers 44,

46. Alternatively, compression elements 36 and 38 could be driven by a single compression driver, controlled by controller 52 to drive each of the compression elements 36, 38 in the manner desired. As shown, the compression elements 36, 38 comprise pistons, but alternative features could be used to accomplish the same function, such as lever arms, screw drives, clamps, cams, pincers, rollers, magnets, electro-magnets, linear drives, solenoids, gears, stepper motors, or other features, respectively. Further characteristics of alternative embodiments of compression members and compression surfaces thereof can be found in U.S. Provisional Application Serial Nos. 62/027,685, filed 07/22/2014; 62/050,810, filed 09/16/2014; 62/052,476, filed 09/19/2014; and 62/053,095, filed 09/19/2014; each of which is incorporated herein, in its entirety, by reference thereto.

[00240] Each compression element 36, 38 is operatively connected to a driver 44, 46, respectively, for independent, but coordinated driving and retraction of the compression elements 36, 38. When electrically-powered drivers are used, a battery 48 is electrically connected to the drivers 44, 46, as well as the controller 52 and pressure sensor 54, and supplies the power necessary to operate the drivers 44, 46 to drive the compression and retraction of the compression elements 36, 38.

[00241] A sensor 54 is used to provide feedback to the controller 52 for controlling the pumping cycles to achieve and/or maintain desired vacuum levels. Sensor 54 is preferred to be a pressure sensor but could also be a flow, temperature, proximity, motion sensor or other sensor capable of providing information usable to monitor the safety or function of the pump mechanism of system 100. As shown, sensor 54 is a non-contact sensor 54, meaning that it is not in fluid communication with the milk or vacuum space of the system 100. Preferably sensor 54 is located nearby where the tip of the nipple 3 of the breast 2 is located to determine actual pressure being exposed to the breast 2/nipple 3, but other sensors 54 may be located within the system 100, for example, near where the one-way valve 50 is located, and can be used to monitor other features such as container 60 contents or expulsion pressure or flow rate. More generally, sensor 54 can be located anywhere in the system between the breast 2 and the one-way valve 50 into the collection container 60. Sensor 54 can be located either on the breast side of the compression member 36 or the other side of the compression

member 36. When located on the breast side (i.e., upstream of the compression member 36), the sensor always provides the pressure experienced by the breast 2 and can thus be used to monitor and determine the pressure environment of the breast 2 even when the compression member 36 has sealed off the tubing portion 32S. If the sensor 54 is on the other side of the compression member 36 (i.e., downstream of the compression member 36), sensor 54 can always provide pressure at the breast 2 except when the compression member 36 has sealed off the tubing portion 32S. Thus, a sensor 54 can be placed anywhere in communication with tube 32 and be used to monitor and control the system via sensor readings feedback to the controller 52. With at least one sensor 54 present, by monitoring either flow or pressure directly or indirectly and also taking into account the cycles and actual positions of the compression elements 36, 38 over time, it is possible to derive/calculate approximately the volume of milk produced during a pumping session as well as understand the flow-rate at any particular time in a pumping session. The accuracy of this measurement is greatest when there is no leak of air around the breast 2 and also when there is negligible air within the tube 32, after elimination by a few cycles of the pumping mechanism.

[00242] A one-way valve 50 such as a duckbill valve or other type of one-way valve is provided at the end of tube 32 where it enters the milk collection/storage container 60 (or, alternatively, can be connected in fluid communication with the storage container by another tube. Valve 50 prevents back flow of milk into the tube 32, as well as preventing air from entering the proximal end of the tube 32 and thereby maintains the suction (vacuum) level in the tube 32. Valve 50 can further be designed to open in the reverse direction, for safety purposes, if a predetermined maximum vacuum level is exceed in tubing 32, such as greater than 250 mm Hg vacuum (-250mm Hg pressure), for example. In at least one embodiment, the pressure at which the valve 50 opens to allow flow into the milk collection container 60 is about 25mm Hg. In an alternative embodiment, a pressure relief valve 150 can optionally be provided in the system 100, such as in the skin contact member 10, or other location along tubing 32. The pressure relief valve 150 can be configured to release at vacuums greater than a predetermined amount, (e.g., vacuums greater than 250mm Hg (pressures less than -250mm Hg), or

some other predetermined maximum vacuum level). The one-way valve 50 can be configured and designed such that it allows fluid to flow through it when the pressure in tubing 32 is positive, e.g., about 25mm Hg, or some other predesigned "crack pressure". The action of the compression elements cycles between increasing vacuum when the compression elements move in a direction away from tube 32 and decreasing when the compression elements compress the tube 32, but typically should not increase the vacuum to greater than the predetermined maximum vacuum. As the compression elements 36, 38 compress the tube 32, the pressure in the system 100 goes up and reaches the minimum suction level (e.g., latch suction level, such as -60mmHg, -30mm Hg, or some other predetermined latch suction level), at which time the compression member (pinch valve) 36 seals off portion 32S thereby maintaining the minimum suction (latch suction) against the breast 2. Continued compression of portion 32L by compression member 38 continues to increase the pressure downstream of compression member 36, until the crack pressure is reached (e.g., 25mm Hg or some other predetermined, positive crack pressure), that opens the one-way valve 50. The compression elements 36, 38 continue compressing tube 32, pumping fluid (milk) through the one-way valve 50 and into the collection container 60 until the compression element 38 reaches an end point in travel (typically before "bottoming out" against the anvil 2232). The end point in travel of the compression element 38 against portion 32L may be predetermined, or may be calculated on the fly by the controller 52 using feedback from pressure sensor 54 and feedback from the driver of the compression element 38, from which the controller 52 can calculate the relative position of the compression element 38 over the course of its travel. The compression member 36 remains closed throughout this process, as it is used to seal off the tube 32 the entire time that the compression element 38 is pumping milk out of the region 42 and into the collection container 60). As the compression elements 36, 38 reverse direction and pull away from the tube 32, they start the cycle again.

[00243] As milk enters the system, the suction level decreases (pressure increases). The feedback provided by pressure monitoring via pressure sensor 54 provides input to a feedback loop that adjusts the position of the compression member 38 to maintain the desired vacuum (pressure) within the tubing 32 by compensating for the changes in

pressure that occur to changing amounts of milk in the tubing 32. For example, for a relatively larger amount of milk in the tubing, this will require a relatively shorter stroke of the compression member 38 toward anvil surface 2232 to achieve the latch pressure. This modification can be addressed by either slowing the movements of the compression member 38 to achieve the same timing cycle for pumping, or increasing the cycle frequency due to the less time taken for the shorter strokes of the compression member 38.

[00244] A contact pressure sensor 54 is shown in Fig. 4, wherein the pressure sensor 54 contacts the vacuum space (and, potentially, the milk) in the system 100. In this embodiment, a T-connector 370 is connected to the proximal end of the nipple receiving portion 112, so that both tube 32S and a tube 32P can be joined in fluid communication with the interior of the nipple receiving portion 112. In this way, pressure sensor 54 is placed in line, in fluid communication with the tube 32 and nipple receiving portion 112, and can measure pressure directly, as a result.

[00245] Alternatively, or additionally, one or more non-contact pressure sensors can be employed in the system 100. In the embodiment of Fig. 20, non-contact pressure sensor is located external of the tubing portion 32S. Various different types of non-contact pressure sensors can be used, such as optical sensors, magnetic sensors, linear variable differential transformer (LVDT) sensors, or the like. Further details about non-contact pressure sensors that may be employed in the present disclosure can be found in U.S. Provisional Application Serial Nos. 62/053,095 and 62/027,685.

[00246] Figs. 21A-21B show a proximal perspective view and a side view, respectively, of skin contact member 10 according to an embodiment of the present disclosure, with four different potential locations for placement of a non-contact sensor 54. At location 350A, a thicker wall is provided relative to the thickness of the nipple receiving portion 112 . In this example, the thickness of location 350A was 4.12mm and the thickness of the nipple receiving portion 112 was 2.38mm. At location 350B, a thinner wall is provided relative to the thickness of the nipple receiving portion 112. In this example, the thickness of location 350B was 1mm and the thickness of the nipple receiving portion 112 was 2.38mm. At location 350C, the thickness was the same as the rest of the nipple receiving portion, but protruding outwardly therefrom, see the cross-

sectional view of Fig. 21C taken along line 21C-21C in Fig. 21A. The thickness at location 350D is the same as the thickness of the nipple receiving portion; in this example, 2.38mm. It has been found that all locations 350A-350D will displace relative to vacuum changes within the system according to a linear relationship (although by different scaling factors, which can be determined empirically), see Example 1 below. Accordingly, a non-contact sensor 54 can be employed at any of locations 350A-350D to measure displacement changes in those locations. Pressure change measurements can then be calculated from the displacement change measurements, due to the linear relationship that exists between force applied to the locations 350A-350D and pressure within the system that causes the force. More generally, pressure changes in the system 100 can be measured by measuring opposition forces of any pre-loaded fluid contacting wall of the system 100.

[00247] Force versus displacement of a portion of the skin contact member 10, such as a portion of the nipple receiving member 112 also exhibits a linear relationship. Thus, displacement of a portion of the skin contact member 10 can be measured and pressure change can be calculated therefrom. Further, strain measurement can be used to calculate pressure changes. Therefore, attachment of a strain gauge 54 (see Fig. 21D) to skin contact member 10, typically on a region of nipple receiving member 112, can be used to measure strain changes in that region, which measurements can be used to calculate pressure changes within the nipple receiving member 112.

[00248] Use of a system 100 provided with a non-contact pressure sensor 54 would include loading the skin contact member 10 onto the main body/pump housing 34 (unless it has already been pre-loaded) and then turning on the pump power. As the pump system 100 goes through a power up routine, the controller 52 reads the force applied by the pressure sensor 54, position of the sensor 54 relative to the potentiometer when a displacement sensor 54 is used, or strain on the strain gauge when a strain gauge is used as the pressure sensor 54. This is the preload force applied by the sensor 54 to the wall of the nipple receiving portion 112 or tube 32, or position, or strain measured by the strain gauge, before the skin contact member 10 has been applied to the breast 2, so it is a state in which the pressure in tube 32 is atmospheric pressure. The controller 52 then calibrates the system such that the preload force or

position or measured strain equates to atmospheric pressure. Based upon a look-up table or a best fit equation, the controller 52 can now convert any changes in force, position or strain read by the pressure sensor 54 against the wall of the nipple receiving portion 112 or tube 32 to pressure readings in the system 100 during operation of the breast pump system 100 upon attachment to the breast 2.

[00249] Optionally, the system 100 may be provided with two or more non-contact sensors 54 for determining pressure within the system 100. For example, by placing sensors 54 on different regions of the nipple receiving portion 112 that have different wall thicknesses, the linearity of the pressure changes measured by the sensors 54 on the different wall thicknesses will occur within different ranges of pressure (vacuum). Fig. 21E shows a cross-sectional illustration of nipple receiving portion 112 in which a first non-contact sensor 54 (see 54A) has been attached to a relatively thinner wall of the nipple receiving portion 112 and a second non-contact sensor 54 (see 54B) has been attached to a relatively thicker wall of the nipple receiving portion 112. The sensor 54B provides data for pressure change calculations at a higher range of vacuum pressures (lower pressures) than that provided by the sensor 54A. The vacuum ranges in which the sensors 54A, 54B provide accurate data (linear relationship) can be designed to overlap, so that the effective range of linearity and thus the range for accurately measuring changes in vacuum pressure can be extended. Furthermore, when the vacuum pressure measured is in the overlap region, where reliable data is provided by both sensors 54A and 54B, this can be used as a check on the accuracy of each of the sensors 54A, 54B, and/or used for calibration purposes. The present disclosure is not limited to the use of one or two sensors 54, as more than two sensors 54 may be applied in this manner, with or without overlapping pressure measurement ranges, preferably with overlap. Fig. 21F illustrates a pressure sensor 55 that may be employed to trigger or indicate when a predetermined vacuum pressure has been attained within the system. Pressure sensor 55 may be a switch that is in electrical communication with the controller 52. Pressure sensor 55 extends into the nipple receiving portion 112 (or, alternatively, tubing 32) at a predetermined distance from an inner wall of the nipple receiving portion 112/tubing 32 that has been calculated or empirically determined to be the distance that the inner wall deflects when the

predetermined vacuum pressure has been attained in the nipple receiving portion 112/tubing 32. Accordingly, when the inner wall contacts the sensor 55 (as indicated by the dashed line in Fig. 21F), sensor 55 sends a signal to the controller 52 and the controller interprets the signal to indicate that the predetermined vacuum level has been reached. This type of sensor 55 could be used, for example, to indicate when maximum vacuum has been achieved. Alternatively, or additionally, sensor 55 could be provided to act as a safety mechanism, wherein the controller 52 would shut down the system if a signal is received from the sensor 55, as this would indicate that an abnormally high level of vacuum has been reached. For example, the system may be shut down if 350mmHg vacuum is reached, or some other predetermined level of vacuum that is considered to be too much vacuum for safe operation.

[00250] To account for the possibility of degradation of pump tubing 32 and/or the skin contact member 10 over time the system can optionally be provided with an indicator that will alert the user when it is time to replace the skin contact member 10 and/or tubing 32. Fig. 22 shows an indicator 352 mounted on the inside of breast contact member 352 so that it can be readily viewed by a user prior to mounting the system 100 to the breast 2. Indicator 352 can measure a predetermined time/lifespan to change tube 32 and/or skin contact member 10 via a time based indicator, such as markings that fade or appear over time, other clocking mechanism that provides a visual and/or audible indication at the end of the measured time. In the event that the skin contact member 10 and/or tubing degrades over time, such as resulting from fatigue and/or oxidation, washing, etc., indicator 352 can track an average expected lifetime of the skin contact member 10 and/or tubing 32, and present a visible and/or audible indication to the user when it is time to replace the current skin contact member 10 and/or tubing with a new component. Average expected lifetimes of these components can be determined experimentally through testing, so that the average expected lifetime can be empirically calculated and programmed into the indicator. Changes in properties (e.g., elasticity, stiffness, etc.) of the tubing 32 and/or skin contact member 10 could result in inaccurate pressure readings, insufficient sealing of the skin contact member 10 to the breast 10 causing air and/or milk leakage, reduced pumping performance etc. Indicator 352 may be a time-based indicator, such as markings that

fade or appear over time.

[00251] Fig. 23 illustrates another location in which indicator may be placed, in this case on the external shell 34 of the system 100. If the situation is that the time to replacement of the skin contact member 10 is different from the time to replacement of the tubing 32, and in which the embodiment has a skin contact member 10 that is configured to be separable from the tubing (some embodiments provide the skin contact member 10 and tubing 32 as an integral unit), then two indicators 352 may be provided, one set for a time to replacement of the skin contact member 10 and the other set to the time to replacement of the tubing.

[00252] Indicator 352 may be disposable, such as the type used on the skin contact member 10 as shown in Fig. 22 or on tubing 32, or may be reusable, where appropriate, such as those mounted on the external shell 34 as shown in Fig. 23 (although indicators 352 on shell 34 could also be made disposable and be removable from and replaceable on shell 34). Fig. 24 illustrates one example of a reusable, time-based indicator 352 that may be employed. In this embodiment, indicator 352 is provided with a plurality of LCD bars 354 that darken upon pressing and holding the reset button 356. Once the bars have darkened, a timer that is initiated, the timer having been programmed for the time to replacement of the skin contact member 10 and/or tubing 32. As shown in Fig. 24, the indicator has four bars 354, although more or fewer could be provided. For the four-bar embodiment, when one-quarter of the time to replacement has elapsed after the resetting of the bars, the top bar becomes clear, or lightens, so that only three bars remain visibly dark. Each bar sequentially lightens or clarifies after each successive passing of a quarter of the time to replacement, until all bars are clear when the time period expires. Thus, this type of indicator not only indicates when the full time to replacement has elapsed, but can also provide the user with an indication of approximately how much time is remaining until replacement is required, i.e., three dark bars indicates that ¾ of the use time still remains prior to the need to replace, etc.

[00253] Alternatively, or additionally, other types of indicators 352 may be provided, including, but not limited to: indicators that change with friction, interaction with moving parts, or the like. For example, a wear indicator 352 can be located anywhere on tubing 32, such as in a location where compression member 38 contacts tube 32L,

where compression member 36 contacts tube 32S, or in another location such as where tubing 32 snaps into the pump housing/region 30. Fig. 26 shows a wear indictor located on tubing portion 32L. Wear indicator 352 may be placed anywhere on tubing 32 where wear is likely to occur. Wear, such as through friction resulting from interaction between tubing 32 and another component (compression member 36 or 38, pump housing 30, etc.) wears away a color of the indicator 352 as the wear occurs. Thus, when the color disappears or changes color, this indicates that it is time to change the tubing 32.

[00254] Likewise, a wear indicator 352 may be used on a component of skin contact member 10 in a location where it contacts the pump housing 30 when it is snapped into position. Fig. 27 illustrates a wear indicator 352 on skin contact member 10. Wear occurs as the skin contact member is attached to, and removed from the pump housing. Color change may be used to indicate when it is time to change the skin contact member, in a way that is described above.

[00255] Further alternatively, or additionally, the system 100 may detect tubing 32 wear. Controller 52 can track the position of the compression member 38 relative to tubing 32. Fig. 28 illustrates one example of an arrangement for tracking compression member 38 position, although the present disclosure is not limited to this arrangement, as alternative arrangements may be provided. In the embodiment of Fig. 28, driver 46 includes a motor 46M, a gear box 46G and an encoder 46E mounted to opposite ends of motor 46M. As motor 46M rotates, encoder 46E, which is fixed relative to the rotating motor shaft, rotates with the motor. An optical monitor 1146, such as an infrared laser or the like is beamed against the encoder 46E, such as the rotating blades of the encoder 46E cross the optical beam emitted by the optical monitor 1146 as the motor rotates. As the blades cross the beam, the beam is reflected back to a sensor 1148. By counting the reflections, the sensor 1148 and controller 52 can calculate the position of the motor 46M from a start position, and thus the position of the compression member 38 that it is driving, relative to a reference or starting position of the compression member 38. A similar arrangement can be provided for the driver 44 of compression member 36.

[00256] Thus controller 52 can keep track of the position of motor 46 and the position

of compression member 38 relative to the tubing 32L. Since the controller 52 also tracks the pressure within tubing 32 via sensor 54 (e.g., as illustrated in Fig. 20), the controller 52 can correlate pressure changes developed in tubing 32 relative to position (and/or optionally, speed) of compression member 38. This correlation can be calculated when tubing 32 is new, i.e., upon initial use. Correlation calculations can be continually performed by controller 52 over subsequent uses of the system, and compared to the correlation values from the first use. The correlation comparisons will show a trend over the lifetime of the tubing 32 with subsequent uses. As the tubing 32 begins to wear out, less pressure change may be produced by the same change in position/speed of compression member 38 compared to when the tubing was new. This difference in pressure change can be tracked, and, when a predetermined amount of difference occurs, the controller 52 can send a warning to display 165 and/or external computer 470, that it is time to change the tubing 32. Also, by tracking the trend in usage of the system 100 over time and the rate of change of difference in pressure change resulting therefrom, the controller can estimate and predict when the time to change the tubing 32 will occur, and thus can send a warning to display 165 and/or external computer 470 at a predetermined time before the tubing 32 will need to be changed. For example, such a warning could be sent one week, one month, or some other predetermined time before it is actually time to change the tubing 32.

[00257] Further alternatively or additionally, usage of the skin contact member 10 and/or tubing 32 can be tracked by controller 52 and/or external computer 470 using a passive sensor 358 (see Fig. 25) via RFID or NFC, for example. One or more sensors 358, each provided with a unique identifier (ID) can be attached to or embedded into skin contact member 10 and or tubing 32. With each use of the system, this/these unique ID('s) can be identified by the controller 52 and/or external computer 470 to know that the skin contact member 10 and/or tubing 32 has been used, and the number of uses can thus be tracked, and/or times or use and/or cycle counts (number of cycles during use that the compression members 38 and/or 3 have executed). By tracking this data, the controller 52 and/or external computer can then indicate when it is time to change/replace the skin contact member 10 and/or tubing.

[00258] Further alternatively or additionally, the usage of the skin contact member 10

and/or tubing 32 can be tracked, such as by using radio-frequency identification (RFID) or near field communication (NFC) tracking. This tracking can be carried out, for example, by embedding a passive sensor/chip 358 configured to RFID or NFC tracking into one or both of the skin contact member 10 and tubing 32, see Fig. 25. The one or more chips 358 can be identified by the controller 52 of the pumping system 100 (by hard wire and/or wirelessly, preferably wirelessly) by an external computer 470, which may be, but is not limited to: a smartphone, a tablet computer, a laptop computer, a notebook computer or a server. The controller 52 and/or external computer 470 communicates with the passive sensor(s)/chip(s) 358 which indicate(s) when the system is in use. By tracking the times of use and/or number of uses, or even pump cycle counts, the controller 52, or external computer can alert the user when it is time to change the skin contact member 10 and/or tube 32. Alerts may be audible and or visual, such as a beep or voice message emitted from the external computer 470 via speaker 472 and/or a visual alert such as text and/or graphics displayed on display 478, or by the controller 52, via optional display 165 and/or optional speaker 168. The tracking provided by the passive sensors 358 provide the ability to assign a unique identifier to each component that a sensor 358 is attached to or embedded in. Thus, the controller 52 and/or external computer 470 can readily distinguish between each skin contact member 10 and tube 32 used.

[00259] This same technology can be provided with the milk collection containers 60, so that tracking of extraction date and time, volume extracted, etc. can be recorded and stored with regard to each milk collection container used with the system 100 to extract milk. Thus, the system 100 can register individual milk collection containers 60, so that the user can readily identify when milk in each container 60 was collected, the volume in each container 60, etc. The breast pump system can record the volume of milk in any given container 60 during a pumping session. The data recorded can be sent to an external computer 470 and/or over the Internet, either automatically or manually.

[00260] There are multiple ways to link data to a particular milk collection container 60. Containers 60 may be provided with easily identifiable marking 60M (see Fig. 37), such as alphanumeric markings (letters, numbers) of other markings that are readily

identifiable and distinguishable from one another. Additionally or alternatively, marking 60M on each container 60 can include a barcode, QR code, RFID, NFC, other magnetic or electromagnetic identifier, or the like pre-printed on the container 60. When initiating a milk pumping session using system 100 with milk collection container 60 mounted thereto, or at the end of the session or anytime in between, the user can scan the mark with a scanner on an external computer 470 (smartphone or the like), or scan using the system 100 itself in embodiments where controller 52 is provided with a scanner 101 on the system 100 as illustrated in Fig. 1, or manually input the identifier of the mark 60M if no barcode is used, and thus link the particular milk collection container with the mark 60M in the database on the external computer. At the end of the milk extraction system, when data is exported to the external computer 470 and/or Internet/cloud-based database, the data, such as volume, extraction date and time, etc. are exported along with the identifier of the mark 60M so the data is linked and stored relative to the identifier for that particular milk collection container 60.

[00261] The mark 60M when in range of the controller 52 and/or external computer 470 may automatically activate the system 100 for a pumping session, or activate an activatable feature of the system, such as a power switch that can be operated by the user to initiate a pumping session. If a container 60 contains a mark 60M that is not recognizable by the controller 52 and or external computer 470, or contains no mark 60M at all, then the system 100 may be configured so as to be prevented from operating for a milk extraction session, as no unique ID has been recognized in this instance. By ensuring that a milk collection container 60 used has a recognizable, unique ID, this can provided additional assurances for safety, sterility and quality of the milk collection container 60 used. The presence of the unique identifier 60M allows the system 100 to track when the milk collection container 60 enters into proximity with the system 100 for use in an extraction session, when it leaves the proximity at the end of the session, as well as other data already described, such as volume of milk extracted, date and time of extraction, length of extraction session, etc. These information capabilities can be useful for managing personal use and consumption by the user's baby, as well as for milk donation services, where milk extracted from one

mother may be donated to a milk bank, or to a baby having a different mother. With regard to milk donation services, a collection bank can scan the milk collection container 60 into the bank database using the same unique identifier provided by the mark 60M and confirm that this is a container 60 that is qualified for the program. In embodiments where container 60 includes the one-way valve 50, this provides further assurance that no milk has been removed from the container 60 prior to it arriving at the milk collection bank.

[00262] The controller 52 and/or external computer 470 may be provided with memory storing a database of registered unique ID's which can be regularly updated by communication with a central database through a network (either wirelessly or by wire) such as the Internet. Alternatively, controller 52 and/or external computer may connect with the central database, such as by WiFi or other wireless connection to the Internet, or even by Ethernet connection.

[00263] As already noted milk collection container 60 may be provided with a passive sensor 358, such as an RFID or NFC chip (see also Fig. 34), which may either be attached thereto or embedded therein, which can be used to link the milk collection container 60 to all data recorded in regard to it..

[00264] As an alternative to pre-marked collection containers 60, a user could manually mark the containers 60 with unique identifiers and manually enter these identifiers into the external computer. Alternatively, the manual marks could be scanned into the external computer.

[00265] The system 100 can calculate the volume of milk pumped into milk collection container 60. By knowing the dimensions of the tubing 32 downstream of the compression member 36 when compression member 36 has sealed off tubing portion 32S, the overall volume capacity of the system 100 downstream of compression member 36 can be calculated. Tracking of the position of the compression member 38 relative to the tube 32 (such as by knowing the driver 46 position at all times, for example), dictates the volume change in the tubing 32. As the pumping process is carried out, pumping/purging of milk into the milk collection container occurs when the compression member 36 has closed off the small tube portion 32S at the location of compression. When the compression member 36 has closed off tube portion 32S, the

change in position of compression member 38 that occurs to carry out the purge of milk from the tubing 32 and into the milk collection container 60 can be used to calculate the change in volume of the tubing 32 downstream of the compression member 36, which equates with volume of milk that is pushed into the milk collection container 60 bag through the one way valve 50.

[00266] Optionally, an estimation of the percentage of milk and air in the system tubing 32 can be calculated based on a compliance assessment of the tubing 32, such as at tubing portion 32L. The more air in the tubing relative to milk, the more the tube portion 32L will move for a given force thereagainst by compression member 38L or a given pressure change. This relationship can be mapped, for example, to provide a look up table to identify the percentage of air and percentage of milk in the tube 32 before purging. Then, knowing the volume that has been purged by knowing the travel of the compression member 38 during the purge, the volume of milk and the volume of air can be calculated.

[00267] Further optionally, the opening of the valve 50 can be monitored or the movement of fluid past the valve 50 can be monitored. By knowing the crack pressure of the valve 50 and knowing the pressure within the tubing 32, this can identify when a purge actually pushes through (i.e., when pressure in tube 32 reaches the crack pressure). This can increase the accuracy of the calculated purge volume by beginning the volume calculation at the position of the compression member at the time that the crack pressure is reached.

[00268] In addition to calculating the volume of milk purged with each purge cycle, the system (via controller 52) can sum the volumes from all purge cycles to calculate the total volume pushed into the milk collection container 60 during a milk extraction session. This volume can be stored with a unique identifier provided to the milk container so that the system 100 keeps a record of how much milk is stored in each milk collection container 60. This information can also be time stamped so that the user will know the time and date that milk was collected, regarding each milk collection container. Additional statistics can be calculated, including, but not limited to: average volume per extraction session, total volume extracted for any given day, average milk extraction volume per day, etc. Any and all of this data can be exported

to an external computer, either manually, or it may be automatically uploaded to the computer 470 when the computer 470 is within range of the system 100 for wireless communication, or when the computer 470 is connected to the system by wire. Further optionally, any or all of this data can be either manually or automatically uploaded to a cloud service over the Internet, either wirelessly or by wire.

[00269] When calculating milk volume pumped from the system 100, there is a need to distinguish between any air pumped by the system versus milk pumped from the system, as well as pumping mixtures of milk and air. When initiating a milk pumping/extraction session, there is air in the tubing 32 this initial volume of air needs to be pumped into the milk collection container 60 to prime the pumping system 100. Distinction between pumping air versus pumping milk can be recognized by correlating pressure changes with the amount of movement of compression member 38 needed to establish the pressure changes. For example, when air is in the tubing, a greater change in position, or more overall travel of the compression member 38 is need to establish the same pressure change than that needed when the tubing 32 is filled with milk. Thus, relatively more motion of the compression member with relatively less pressure change indicates air in the tubing 32. This difference in pressure may also be detected when the compression member 36 is open (i.e., not closing off tube portion 32S) and compression member 38 is retracting and this increasing the vacuum pressure.

[00270] Figs. 31A-31B schematically illustrate breast pump systems 100, according to alternative embodiments of the present disclosure, in which the external shell 34 of the system does not need to be continuously curved, but, instead can have another shape, such as geometrical (all or a portion of which is non-curved) or even irregular or some other custom shape designed to conserve space. In the embodiment of Fig. 31A, shell 34 has substantially flat surfaces that form an angular external surface. These surfaces can more closely contour the internal components of the system than that provided by a continuously convex external shell 34., and thereby eliminate spaces that are devoid of components in a system with a continuously convex external shell 34. In the embodiment of Fig. 32B, external shell has a flat central portion, similar to the embodiment of Fig. 31A, but has convex portions extending radially from the flat

central portion. It is noted that these are two non-limiting shapes provided, as the shape of external shell can take on almost any shape that is well suited to receiving the internal components of the system 100, while eliminating as much void space as possible. Milk collection container 60 is mountable over the external shell 34. The milk collection container 60 can be formed so as to have variable volume when filled, so as to conform to the external surface of the external shell, while providing a convex shape externally, so as to mimic the shape of the breast 2. As shown in Fig. 31A, the peripheral portions of the container 60 are thinner when filled than the central portion of the container 60 when filled. In Fig. 31B, the container is pre-shaped to follow the contours of the external shell 34 when filled, including bulbous portions 34B that conform to the concave portions of the external shell 34. These solutions provide for a more compact overall system, while at the same time maintaining the appearance of the system 100 when worn to resemble that of the natural breast. The external surface 60E of the milk collection bag 60 can be formed so as to maintain a continuously convex appearance even when the milk collection bag is empty. The milk collection bag 60 may have a rigid inner surface that mates with the contours of the external shell 34 and a soft, flexible external surface that inflates/moves as milk enters the bag 60, while maintaining a convex/naturally appearing breast shape. Alternatively, the exterior surface of the milk collection bag 60 may be rigid to maintain breast/convex shape and the inner surface may be soft and flexible to match the contours of the external shell 34, as the bag 60 expands while it fills up with milk. Another option is for both surfaces to be rigid and yet allow some motion as the space/bladder in between fills with milk, allowing the surfaces to move apart as needed to accommodate the volume of milk received.

[00271] Figs. 32A-32B illustrate a milk collection container 60 for use in system 100 according to another embodiment of the present disclosure. In this embodiment, container 60 has a preformed convex surface 60C that is shaped to mimic the natural appearance of the breast 2. Surface 60c may be pre-formed such as by molding or the like, and maintains the convex shape shown, even when the container is empty, as well as when it contains milk. When mounted on the system housing 34 the convex shape 30 provides the appearance of a natural breast, with or without containment by a bra.

The opposite surface 60F of the container 60 is flexible and may even contain wrinkles or folds 60W when container 60 is empty. As the container 60 fills with milk, the container 60 expands by moving the flexible surface outwardly. During the outward movement of the flexible surface 60W, the flexibility of this surface allows it to conform to the shape of the system housing/external shell 34 to maximize conservation of space of the entire system 100. Fig. 32A illustrates in dashed lines the shape of the flexible surface 60W when is moved to contour to the external shell 34 of the embodiment of Fig. 31A. Fig. 32B illustrates in dashed lines the shape of the flexible surface 60W when is moved to contour to the external shell 34 of the embodiment of Fig. 31B.

[00272] In addition or alternative to the flexible surface provided 60F provided with a pre-shaped surface 60C, milk collection container may be further be provided with one or more structural elements, 76, such as baffles, heat seals, struts or other restrictions that restrict the amount of expansion of flexible surface 60F relative to contoured surface 60C and or provide shape to the collection container 60 even when empty. Fig. 33 shows container 60 having baffles 76 that internally connect to the internal walls of portions 60F, 60C to limit the amount of expansion in the areas where the baffles 76 are located, relative to the amount of expansion that the remaining areas can experience. Baffles 76 can be provided in any pattern desired so as to customize the expanded contours of the flexible surface 60F to conform to a particular contour of an external shell 34.

[00273] Fig. 32C illustrates a milk collection container 60 that is formed so that the distal surface 60D of the container, when filled with milk has a shape that matches the proximal surface contour of the external shell 34. The proximal surface 60C may be flexible or pre-formed with the convex shape that mimics the appearance of the breast 2.

[00274] Even in embodiments of the breast pump system 100 wherein the external shell is convex, the milk collection container 60 used therewith with have varying levels of thickness from top to bottom and side to side when milk is collected into the container 60 while mounted on the system. Accordingly the container 60 can be pre-shaped or preconfigured to take on a shape having varying thicknesses between the rear and front

walls when containing milk.

[00275] Fig. 34 illustrates a milk collection container 60 that includes a passive sensor 358 that can be either attached to or embedded in the container 60. Sensor 358 may be an RFID or NFC device, or the like that contains a unique identifier (ID) is created in a manner that is recognizable to controller 52 and/or external computer 470. The controller 52 and/or external computer are provided with a reading application that can wirelessly read the unique ID when the container 60 that includes the sensor 358 having the unique ID is brought into close proximity with the controller 52, such as by mounting the collection container 60 to the external shell 34. Once read, this unique ID is then referenced by the controller 52 and/or external computer 470 into a database application that contains detailed information as to what the sensor 358 is attached to. Upon confirming the specific collection container that the sensor 358 is attached to/embedded in, the system 100 can then track usages of that specific container, including, but no limited to: volume of milk collected, date and time of collection, duration of extraction session, etc. Optionally, if a collection container 60 does not include a sensor 358 with a unique ID that is recognizable to the system 100, then the system will not operate with that collection container.

[00276] Fig. 35 illustrates a milk collection container 60 wherein the connector 62 contains one-way valve 50, according to an embodiment of the present disclosure. With this embodiment, the external shell 34 or tubing 32 would not be provided with the one-way valve 50, but would be provided with a mating connector to connect to connector 62 containing the one-way valve. Whether one-way valve 50 is provided with the connector 62/collection container 60 or provided at the end of tubing 32, the mating connector for connecting to connector 62 can otherwise be the same. Examples of mating connector arrangements can be found, for example in Provisional Application Serial no. 62/027,685. Other examples of connector types that can be used for connector 62 and mating connector include, but are not limited to: bayonet-type, threaded connectors, compression fittings, flared fittings, etc.

[00277] Fig. 36 illustrates a milk collection container 60 according to another embodiment of the present disclosure. In this embodiment, tubing 32 is made integral with the milk collection container 60 and one-way valve 50 as shown. The open end of

tubing 32 is provided with a connector 62 configured to mate with connector 134 of skin contact member 10.

[00278] When a user has completed the pumping phase of extracting milk from a breast 2, it is useful and efficient to purge as much milk that remains in the tubing 32 from the tubing 32 and into the milk collection container 60. Fig. 38 illustrates events that may be carried out to perform a purge according to an embodiment of the present disclosure. At event 3802 the system 100 ends the pumping cycle having been carried out during the extraction phase. Ending of the extraction phase can be performed upon elapse of a predetermined extraction phase time, calculation of a predetermined amount of milk having been pumped, manual cessation of the extraction phase by the operator, or some other predetermined value having been achieved after performing the extraction. At event 3804 the direction of the pumping stroke of compression member 38 is reversed and the compression member 38 is run in the reverse direction to decrease suction within the tubing 32 and optionally create a small positive pressure within the tubing 32 to facilitate removal of the system 100 from the breast 2. Alternatively, the suction may be decreased to a level where a slight suction remains so that the user still pulls the system 100 of the breast 2 to detach it. Preferably the vacuum is reduced to 0mmHg, or a slightly positive pressure to automatically detach the system 100 from the breast 2. The end pressure value where the pressure reduction by reverse pumping is ceased can be in the range of about -20mmHG (weak vacuum) to a positive 50mmHg (e.g., the crack pressure of the valve 50). The compression member 36 does not close off the tubing portion 32S during this process, rather, tubing portion 32S remains open. Initiation of this reverse pumping may occur automatically after executing event 3802 or, alternatively, may be initiated by the user actuating a purge actuator on the optional control panel 166 provided on the system 100 (see Fig. 23). This process continues until the seal of the system 100 to the breast 2 is broken, which is detected by the controller 52 via sensor 54 at event 3806. Once exposure of the tubing 32 to atmospheric pressure is detected at event 3806, the stroke direction of pumping is again reversed thereby pumping the milk in tubing 32 under positive pressure and driving the milk from the tubing 32 into the container 60 at event 3808. At event 3810 the purge process ends. Event 3810 can occur at some predetermined

time after initiation of event 3808, or can be initiated by measuring the compliance of tubing portion 32L and executing event 3808 when the compliance of tubing portion 32L indicates that the contents in tubing portion 32L have a least a predetermined percentage of air therein (such as 90% 95%, 97% or some other predetermined percentage). If by chance, the system 100 accidentally or otherwise becomes resealed to the breast 2 during purge pumping, the system 100 can automatically shut down as it senses vacuum pressure being regenerated in the vicinity of the breast 2/skin contact member 10.

[00279] Figs. 39A-39B illustrate various arrangements that may be provided to the system 100 to help prevent loss of milk out of the system upon detachment of the system 100 from the breast 2. These arrangements can be provided in embodiments that are configured to execute a purge operation in a manner described with regard to Fig. 38 above, but can also be provided in systems 100 that used different purge techniques other than that described with regard to Fig. 38.

[00280] A weak valve 390, such as a flap valve of the like can be provided in small tube portion 32S, near where it connects to the skin contact member 10, as illustrated in Figs. 39A-39B. Valve 390 is very flexible so that it opens in a first direction (upwardly as shown in Figs. 39A-39B) when vacuum is generated in tubing 32. A very small amount of vacuum (much less than latch vacuum, for example about 5-15mmHg) is sufficient to open the valve 390 in the upward direction, see 390A. The valve 390 is sufficiently stiff to remain closed under a positive pressure equal to the hydrostatic pressure generated when the tubing 32 is completely filled with milk. A positive pressure that is generated which is above this hydrostatic pressure by a predetermined amount (e.g., 5-15mmHg positive pressure greater than the positive pressure generated by a full column of milk) forces the valve 390 open in the opposite direction, see 390B (i.e., downwardly, as illustrated in Figs. 39A-39B). With this arrangement, the breast pump system 100 can be unsealed and detached from the breast 2 after extracting milk therefrom and the milk remaining in the tubing 32 will be prevented from escaping out of the skin contact member 10 by the closed valve 390. The system 100 can then be run in a forward stroke motion to generate positive pressure using compression member 38 to drive the milk from the tubing 32 and into the milk collection container

60.

[00281] Additionally or alternatively, a valve or flap may be provided to extend radially inwardly from the bottom portion of the breast contact member 122 as shown in Fig. 39A. When the breast 2 is inserted into the breast contact member 122 for carrying out an extraction session, the breast 2 folds down the flap/valve 522 against the inner wall of the breast contact member 122, see 522-2, When the breast 2 is removed from the breast contact member 122, the flap/valve 522 resiliently returns to is its unbiased position (see 522-1), where it extends radially inwardly and thereby retains milk within the breast contact member 122 that would otherwise have spilled out of the system. By tipping the breast contact member 122 up, the user can cause the milk in the breast contact member 122 to flow into the nipple receiving portion 112 under gravity, where it can be pumped into and through the tubing 32 to be purged into the milk collection container. Further alternatively, flap 522 may be provided with a tacky surface that contacts the breast 2 so as to assist in providing tension to the breast 2 to control the amount of breast tissue that enters the nipple receiving portion 112, similar to the function of the tacky regions 360 described above. Further optionally or additionally, the stiffness or strength of the valve/flap 522 can be such that the breast contact member 10 has to be pressed against the breast 2 to deflect the valve/flap 522, which thereby establishes tension. Still further, flap 522 can be provide at both top and bottom locations of the breast contact member 122 (rather than just at the bottom as shown in Fig. 39A), or at other locations intermediate the top and bottom, or could be formed continuously around the entire perimeter of the breast contact member 122.

[00282] Figs. 40A-40B illustrate two different cross-sectional views of a contour element 410 provided with a breast pump system 100. Contour element 410 extends distally from the distal perimeter 34D of the external shell 34 and proximally extends over the distal portion of external shell 34 to provide a contoured extension of the external shell that provides a visually more appealing appearance the more closely mimics the natural appearance of a breast 2 supported by a bra. The contour element 410 tapers distally to form a smoother transition with the breast 2 when the system 100 is mounted on the breast 2, thereby making the system 100 less visible or noticeable when worn by a user. The contour member 410 can be configured to snap around the

circumference of the main body 34 of system 100 or form a friction fit therewith, for example.

[00283] Fig. 40A shows a cross-sectional view illustrating the upper and lower portions of the contour element 410. Fig. 40B shows that contour element on the left and right sides of the external shell 34. The embodiment shown in Fig. 40B is for the right breast. A contour element for the left breast would be a mirror image of that shown in Fig. 40B, as, in both cases, the contour element 410 has a lateral portion 410A that extends further distally from perimeter 34D than the distance that medial portion 410B extends distally from the perimeter 34D. The lateral portions of the systems 100 are contoured more by the contour element 410 then are the medial portions, as the medial portions are where the cleavage of the breasts is formed, so deviation from the natural appearance is less visible on the medial sides. Further, the medial extensions are less as there is less space to extend into. Additionally, the contour element 410 may extend over a portion of the proximal end portion of the external shell 34 to provide additional "flatness" to the proximal end of the system 100 to make it appear more like a natural breast 2 as opposed to a more pointy "ice cream scoop" shape, Although the sections of component 410 in Figs. 40A-40B are illustrated as solid material in Figs. 40A-40B, such as being made of foam, plastic, or other lightweight material, they could alternatively be made hollow, or even made of one layer of material to provide the same contouring shapes. Thus a single thin layer of plastic or fabric could be alternatively used, for example as illustrated in Figs. 41A-41B. The material of the contour element 410 may be resilient so that if it is depressed or distorted, it will naturally spring back to a contour that appears natural.

[00284] Attachment members 412 such as snaps, hook-and-loop type fasteners, buttons, magnets or other attachment members may be provided on one, or preferably more than on locations of the external shell 34 and internal surface(s) of the contour element 410 to ensure securement of the contour element 410 relative to the external shell, and to ensure that the proper orientation of the contour element 410 relative to the external shell 34 is achieved each time they are connected, so as to provide the desired appearance,

[00285] Fig. 42 illustrates an embodiment of a contour element 410 fitted on an external

shell 34 in which the external shell 34 is provided with a key 34K that ensures that the contour element 410 is properly oriented on the external shell 34 each time the two components are mated. The contour element 410 has a mating key 410K that mates with key 34K and ensures that the contour element 410 position relative to the external shell 34 does not rotationally vary nor does it vary superiorly, inferiorly, laterally or medially, but rather is positioned substantially exactly the same relative to the external shell 34 each time it is mounted thereover. As shown, the key 34K extends from the surrounding surface of the external shell 34K and the mating key 410K is an opening in the contour element 410 that mates to the mating key 34K. Alternatively key 34K could be formed as a depression in the external shell 34 and mating key 410K could be a ridge extending inwardly (or a solid shape extending inwardly) from the surrounding inner surface of the contour element 410 and shaped to mate with key 34K. It is further noted that the shapes of the key 34K and mating key 410 are not limited to those shown, but could be any shape that ensures that the contour element 410 can be mounted to the external shell 34 in one orientation and position. Further, the key 34K and mating key 410K do not need to be centrally located, but could be at any location on the external shell 34 (and corresponding location of contour element 410). Also, multiple keys 34K and mating keys 410K could be provided at multiple locations.

[00286] The contour element can be adjustable, so that it can be adjusted for a best fit relative to the breast 2, and so that it can be fitted to different sizes and shapes of breasts 2 and still provided a more natural appearance in each case. Fig. 43 illustrates an embodiment of contour element in which a first edge 414 of the contour element 410 overlaps a second edge 416, and can be adjusted to reduce, increase or maintain the circumference of the distal perimeter 410D, while at the same time reducing, increasing or maintaining the proximal perimeter 410P. After adjustment, the first edge 414 can be fixed to the underlying surface of the contour element 410 that it overlies, such as by use of hook-and-loop type fasteners, snaps, adhesive, or the like. The contour element can be further tailored for a better fit, if needed, but cutting away all or a portion of the distal perimeter 410D to a length desired, so as to adjust the length by which the contour element 410 extends from the distal perimeter 34D on the top, bottom and sides of the device. All of these distances can be tailored to be as

needed.

[00287] Fig. 44 illustrates an embodiment of contouring element 410 provided with predetermined markings that may be provided to assist the user in adjusting the contouring element 410 to better contour to the breast 2 that it is to be used on. For example, markings 418, 420, 422 and 424 can be provided as suggested starting locations for placement of the edge 414 overlapping edge 416 and placed at the appropriate marking for D cup, C cup, B cup and A cup sizing, respectively. Markings 426, 428 and 430 are suggested locations to cut away the distal edge 410D to fit 36", 34'" and 32" breasts 2, respectively.

[00288] Fig. 45A illustrates an embodiment in which external shell 334 is provided with two keys 34K1 and 34K2. The contour element of Fig. 45B is provided with mating keys 410K1A and 410K2 that are configured to mate with keys 34K1 and 34K2, respectively, when the contour element 410 is in a first sizing configuration. Additional mating keys 410K1B and 410K1C are provided to mate with key 34K1 when the contouring element 410 is adjusted in a manner described above to better contour with smaller size breasts 2. Although two additional mating keys 410K1 and 410K2 are shown, more or fewer can be provided where more or less adjustability is needed. Likewise, additional mating keys could be provided for 410K2, in addition to, or alternative to the provision of multiple mating keys 410K1.

[00289] Figs. 46A-46B illustrate a contour element 410 according to another embodiment of the present disclosure. In this embodiment, contour element 410 is made of an easily compressible material such as a light, resilient foam that readily conforms to the shapes of objects that it is compressed against. In the embodiment shown, the contour element 410 is a substantially straight plate-shaped element that tapers at its ends, but other shapes could be employed. The center portion of the contour element 410 can be attached to the external shell 34 as shown in Fig. 46A, using any of the connectors, adhesives or the like described previously. When the system 100 is supported by a bra 440 as shown in Fig. 46B, the contour element 410 contours to the external shell 34 of the system, and also contours to the bra 440, thereby providing a natural breast shaped appearance. Further alternatively, the contour element 410 of Fig. 46A could be made thinner and would not be required to

contour to the external shell 34, as the bra 440 provides a contouring shape.

[00290] The system 100 can be configured to distinguish whether it has been attached to the left breast 2 or the right breast 2 of the user. This can be useful for tracking milk volume output per breast, per session, total daily volume per breast, etc. When using two of the pump systems, the tracking of data for each breast can still be maintained accurately, even when one of the pump systems 100 is attached to the left breast during a current pumping session after having been attached to the right breast during a previous pumping session. In one embodiment, the pumping systems 100 can establish current location (i.e., left or right breast) by receiving a signal from the other pumping system having been attached to the other breast 2. This established relative left-right locations of the two pumping systems 100, so that each system 100 can accurately record as to whether milk is being extracted from the right breast 2 or left breast 2. This identification is automatic, without any user input required and it also relieves the burden on the user to otherwise keep track of which pump system 100 is placed on each breast and to maintain this order with each successive pumping session.

[00291] An orientation signal, such as by Wi-Fi, BLUETOOTH, BLUETOOTH Low Energy (BTLE), RFID, NFC or the like may be used to automatically determine which pump 100 is on which breast 2. One or more magnetic coils 450 may optionally be provided in each pump system 100 (e.g., see Fig. 23) such that the relative positions of the pump systems 100 can be determined to each other by the signal, akin to the way that surgical tracking is performed with coil magnetic sensors. By placing magnetic coils on the left and right sides of the pump systems 100, and running a small current through the coil 450 in one of the pump systems 100, the current induces a signal in the coil 450 in the other pump system 100. The signal strength is low and is only induced when the breast pump systems are close together, such as when mounted on adjacent breasts 2. This signal can be used to determine the relative locations of the pump systems 100, i.e., which system 100 is mounted on the left breast 2 and which system 100 is mounted on the right breast 2.

[00292] The system 100 can calculate the pressure during operation in any of the manners described above. The suction (pressure) level can be varied as desired, and by continuously or repeatedly measuring/calculating pressure, the feedback provided by

sensor(s) 54 to controller 52 provides a control loop that can be used to adjust the compression member 38 position and/or speed to vary the suction pressure to a level desired, or maintain a desired suction pressure. Thus, controller 52 can control the positions and speeds of compression members 36, 38 to achieve any vacuum pressure pumping profile desired, and provide automatic, real time adjustments to maintain a desired vacuum pressure within the system.

[00293] The controller 52 tracks the position of the compression member 38 relative to the tubing 32L, such as by keeping track of the driver 46 position or shaft position (interconnecting linkage between driver 46 and compression member 38), and calculates (or looks up) pressure based upon data received from sensor 54. Thus, changes in position and/or speed of the compression member 38 by controller 52 can be controlled by resulting changes in pressure calculated or looked up, relative to the pressure sought to be achieved. Controller 52 can control compression member 36 in a similar manner, but control of member 36 is more focused on position control, as the compression member 36 needs to fully close off tube portion 32S when maintaining latch suction against the breast 2/nipple3. However, the closing off is timed and performed at the determined latch pressure, which is known from the data received from sensor 54.

[00294] During extraction, the compression member 38 cycles between latch suction and maximum suction to extract milk from the breast 2. The suction level of the maximum suction can optionally be adjusted to the comfort of the user, anywhere between latch suction pressure to a maximally allowed suction pressure, such as -250mmHg or some other predetermined maximally allowed suction pressure. As the tubing 32 receives more and more milk volume, the compression member moves farther and farther in the direction away from tube portion 32L to achieve/maintain maximum suction. As the compression member 38 begins to near its position limit away from the tube portion 32L (near the fully uncompressed state of tube portion 32L), the controller 52, knowing the position of the compression member 38 at all times, controls the driver 46 to purge the milk currently held in the large tube portion 32L, by driving the compression member 38 to its opposite position limit (where it compresses the large tube portion 32L the most). This reestablishes, or resets the

compression member, so that it again can establish the maximum suction level without nearing its position limit. This process is repeated each time the compression member 38 comes within a predetermined distance from its position limit.

[00295] Fig. 47 illustrates events that may be carried out by the system 100 during an extraction mode of pumping milk from a breast. At event 4702, after latch and let down of milk have been achieved, the system begins operating in extraction mode. In extraction mode, the system cycles between latch suction (e.g., about 55mmHg, or a value preselected from the range of about 25mmHg to about 80mmHg suction) and maximum suction (e.g., about 150mmHg, or a value preselected from the range of about 130mmHg to about 200mmHg suction). The pumping cycle may be a regular, continuous cycle, or may be pre-programmed to provide some irregularity, such as occasional pauses in pumping action to simulate when a breastfeeding baby pauses to take a break before resuming suckling. The cycle speed of the pumping action is predetermined in the embodiment, such as 60 cycles per minute, or some other predetermined rate. Optionally, the operator may be able to set or adjust the cycle speed to be used when initiating the extraction mode and/or at any time during operation in extraction mode. The controller 52 monitors the pressure waves within the system 100 at event 4704 and the motion of the compression member 38. If there has been no expression of milk, the pressure wave profile and the motion of the compression member 38 are fairly consistent, with little or no changes in end points of the travel of the compression member. As milk enters the system, the controller will need to move the compression member further to achieve the same target maximum vacuum level and this change in the pressure versus compression member 38 position relationship is identified by the controller as an indicator that milk has entered the tubing 32. When substantially no change in the pressure versus compression member 38 position has occurred, pumping continues with the current pumping cycle parameters as to speed and movement of the compression member 38. When the pressure versus compression member 38 position changes, such as due to milk entering the system, the controller 52 at event 4704 identifies the change in the relationship between compression member 38 position and vacuum pressure achieved, via feedback from sensor 54 and monitoring of the motor, gear train and/or compression

member positions, and adjusts the speed, travel range and/or position of compression member 38 at event 4708 in an effort to maintain the desired pressure profile, cycling between latch vacuum and maximum vacuum levels. If no pressure/position relationship change (within a predetermined minimal range) is sensed at 4704, then the system continues pumping with the current cycle control parameters at event 4706.

[00296] At event 4710 the controller checks to determine whether the outward position limit of the compression member 38 has been reached during the attempt to maintain the system operating according to the predetermined pressure profile. If the position limit has been reached, then the controller 52 at event 4712 controls the system to perform a purge procedure by reducing the pressure to latch pressure; sealing off tubing portion 32S by compressing it with compression member 36, and operating driver 46 to drive the compression member 38 inwardly against the tube portion 32L to the other position limit to purge the milk from the tube portion 32L and then processing proceeds to event 4714. If the position limit has not been reached at event 4710 then processing proceeds directly to event 4714. At event 4714 the pressure is again checked to see if predetermined pressure parameters have been achieved. If the pressure profile has been returned to target (the predetermined pressure profile) then the controller checks to see whether processing should continue at event 4716. Optionally, event 4716 can be omitted and the extraction mode can be ended manually by the operator. Even when event 4716 is adopted, the user can manually stop the extraction mode at any time by actuating a manual switch on control panel 166. Extraction mode pumping may automatically end after a predetermined time period, or when some other event has been achieved. For example, flow of milk can be calculated based upon the pressure change calculations made by the controller, and total volume of milk extracted can also be calculated. Accordingly, extraction mode pumping can be ended after a predetermined volume of milk has been pumped, for example, or when the controller 52 estimates that the milk flow has diminished below a predetermined flow rate for a determined amount of time. Further alternatively, the system 100 can be automatically shut down after the controller 52 determines that a predetermined time period (e.g., one minute or some other predetermined time period) has elapsed during which there has been zero flow of milk. Further alternatively, the

system can be automatically shut down after the controller 52 has determined that a combination of events have occurred, e.g., after five minutes if flow is at zero for at least one minute, or some other predetermined combined logic.

[00297] If extraction mode is to continue at event 4716, the processing proceeds to event 4704. If extraction mode is to end, then the process ends at event 4718. If the predetermined pressure profile has not been achieved at event 4714, the processing proceeds to event 4708.

[00298] A build supply mode can be programmed into the system that can be used by the user to help increase milk production. Using characteristics of the system 100, when in build supply mode, with a milk extraction volume goal having been set, the system 100 will conduct the pumping session including the extraction mode as usual, but once the historical volume has been achieved, the system 100 will continue pumping with pumping characteristics that simulate a hungry, growing baby such as increasing the maximum suction and holding that level for slightly longer during a pumping cycle to simulate a baby trying to draw more milk out of the breast 2, before shutting down.

[00299] In another embodiment, the predetermined pumping cycle speed of the system 100 in extraction mode can automatically increase according to the age of the user's baby. It has been found that the sucking frequency of a newborn infant is slower than that of the same baby at six months old, for example. By tracking the age of the user's baby, the controller 52 can automatically scale the increase of the predetermined pumping cycle speed to the age of the user's baby. Thus, for example, when using the system 100 when the user's baby is a newborn, the cycle speed might be 60 CPM (cycles per minute), and might be 65 CPM when the baby is two months old, and might be 70 CPM when the baby is six months old. These numbers are only exemplary and the disclosure is not to be limited to them, as the more general concept of automatically increasing the predetermined cycling frequency based on age of the baby is what is disclosed.

[00300] If the total volume of the tubing 32 and skin contact member 10 (minus the volume occupied by the breast 2 and nipple 3) is represented as T and the volume that is displaceable by compression member is represented as P, then P should be greater

than 16.2% of T for purposes of this disclosure, i.e., P/T>.162

[00301] Fig. 48 illustrates a nipple shield 480 according to an embodiment of the present disclosure. Nipple shield 480 can be attached to the breast 2 as shown in Fig.48 (such as by suction, reattachable adhesive, etc.) to cover the nipple 3 when the mother is breastfeeding her baby. One of more openings 482 are provided in the tip region of the nipple shield 480 to allow the baby to draw milk through the nipple shield 480. The tip portion 484 that overlies the nipple 3 and at least part of the areola 4 is made much thinner than the attachment portion 486 that surrounds the tip portion 484. For example, the nipple shield 480 may be made of a single material, such as silicone, or other biocompatible elastomer with similar elasticity properties, with the tip section being about 0.25mm in thickness (or in the range of about 0.1 mm to about 1mm), while the attachment portion 486 may have a thickness in the range of about 2mm to about 5mm. This provides the attachment portion 486 with more structural support and a better retention ability on the breast 2, while the thinner tip portion 484 can easily expand, thereby providing minimal resistance to the engorgement of the nipple 3 and areola 4, so as not to restrict the milk flow from the breast.

EXAMPLES

[00302] The following examples are put forth so as to provide those of ordinary skill in the art with a complete disclosure and description of how to make and use the present disclosure, and are not intended to limit the scope of what the inventors regard as their disclosure nor are they intended to represent that the experiments below are all or the only experiments performed. Efforts have been made to ensure accuracy with respect to numbers used (e.g. amounts, forces, pressure, etc.) but some experimental errors and deviations should be accounted for.

EXAMPLE 1

[00303] Testing was done on a light body vinylpolysiloxane breast flange (Danville Star VPS #80011-01 (manufactured by Danville Materials in Ramon, CA), to determine the relationship between force applied to the nipple receiving portion 494 and pressure (vacuum) within the nipple receiving portion 494. The nipple receiving portion 494

was immobilized by a support 496 and a predetermined force was applied by a load cell 490 (see Fig. 49 to the nipple receiving portion 494 opposite the supported side of the nipple receiving portion 494. A stopper 498 was used to allow establishment of a vacuum within the nipple receiving portion 494 and a tube 502 was used to connect syringe 504 and pressure gauge 506 in fluid communication with the interior space of the nipple receiving portion 494. Various runs were made with different preload forces applied to the nipple receiving portion 494 by load cell 490, ranging from 1.5N to 4N, which corresponded to preload displacements (at atmospheric pressure) of the wall of the nipple receiving portion ranging from -1.41mm to -11.60 mm, see Fig. 50. The pressure changes in the nipple receiving portion 494 generated by withdrawing the plunger of syringe 504 were measured by pressure gauge 506 and recorded and plotted relative to the forces on the nipple receiving portion measured by the load cell 490.

[00304] Fig. 50 shows the plotted results, with the recorded data points interconnected by best fit lines to show that the data shows a substantially linear relationship between pressure (vacuum) 510 within the nipple receiving portion 494 and force 512 measure on the external surface of the nipple receiving portion 494. As the vacuum increased (pressure decreased), the force exerted by the nipple receiving portion on the load cell sensor 490 decreased according to a linear force-pressure relationship.

EXAMPLE 2

[00305] The arrangement of Example 1 was modified to test the dynamic force-pressure relationship of the system. An oscilloscope 508 (see Fig. 51) was electrically connected to receive output pressure reading and force readings from pressure gauge 506 and load cell/sensor 490 respectively. Like Example 1, preload displacements at atmospheric pressure were varied for different runs of the test, ranging from -11.60mm to -1.41mm. For each run, the vacuum was cycled between high vacuum to low vacuum three times. For each run, the force exerted by the nipple receiving portion on the sensor of load cell 490 was observed to decrease as the vacuum increased, according to a substantially linear force-pressure relationship. Fig. 52 shows a plot of vacuum 512 and force 514 plotted as voltage received by the oscilloscope 508 versus time, for the run with the preload displacement of -11.60mm. It can be observed that

the force 514 decreases linearly proportionally to the increase in vacuum 512 and vice versa. The same can be observed in Fig. 53, which plots vacuum 512 and force 514 as voltage received by the oscilloscope 508 versus time, for the run with the preload displacement of -1.41mm. Similar results were observed for additional runs having initial displacements of -10.47mm, -8.50mm. -7.47mm, -6.22mm, -5.65mm, -3.54mm, -4.69mm and -2.44mm, respectively. I

EXAMPLE 3

[00306] The arrangement of Example 1 was modified to test the relationship between the position of a target location of the nipple receiving portion 494 and vacuum level within the nipple receiving portion 494, see Fig. 54. In this Example, the load cell 490 of Example 1 was replaced by a marker block 516 preloaded against the nipple receiving portion 494 with a spring 518 at atmospheric pressure. Upon pulling a vacuum in the system by withdrawing the plunger of the syringe 504, the marker block 516 moves with the wall of the nipple receiving portion 494 as it flexed inwardly due to the reduction in pressure.

EXAMPLE 4

[00307] The arrangement of Example 1 was modified to test the relationship between the position of a target location of the nipple receiving portion 494 and vacuum level within the nipple receiving portion 494, see Fig. 55. In this Example, the load cell 490 of Example 1 was replaced by a first and second marker block 522, 524, connected by arms to a potentiometer 520, with the first marker block 522 being fixed to a stationary reference location and the second marker block 524 being fixed to the nipple receiving portion 494 and thus movable directly with movements of the nipple receiving portion. The second marker 524 was preloaded against the nipple receiving portion 494 at atmospheric pressure. Upon pulling a vacuum in the system by withdrawing the plunger of the syringe 504, the marker block 524 moves with the wall of the nipple receiving portion 494, relative to the fixed marker block 522, as the nipple receiving portion 494 is flexed inwardly due to the reduction in pressure. The movement of marker 524 angularly moves the arm 526 relative to arm 528 and this angular

movement was registered by the potentiometer and sent to oscilloscope 508. The change in angle 530 was measured by the potentiometer, and the linear change in the distance 532 between the position of marker 524 and marker 522, can be calculated by a difference in the original distance 532 and the distance corresponding to the angle calculated from the angle change measured, relative to the original angle.

[00308] While the present disclosure has been described with reference to the specific embodiments thereof, it should be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the disclosure. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process step or steps, to the objective, spirit and scope of the present disclosure. All such modifications are intended to be within the scope of the present disclosure.

CLAIMS:

That which is claimed is:

1. An automated method of pumping milk from a breast, the method comprising:

providing a breast pump system including breast contacting structure and a collection container;

forming a seal between the breast pump system and the breast; and

pumping milk expressed from the breast to the collection container;

wherein the milk is pumped upwards from the breast and routed to the collection container.

2. The method of any preceding claim, further comprising maintaining at least a latch suction on the breast throughout a pumping cycle.

3. The method of any preceding claim, further comprising a tube in communication with the breast contacting structure, wherein the tube is substantially directed upwards so that milk extracted from a breast flows upwardly upon exiting the nipple.

4. The method of any preceding claim, wherein the suction applied to the breast for expression of the milk comprises a first suction level, and wherein, during expulsing, a second suction level is maintained against the breast, the second suction level being lower than the first suction level.

5. The method of any preceding claim, wherein the collection container is formed to maintain a continuously convex appearance even when the collection container is empty.

6. The method of any preceding claim, further comprising limiting nipple motion to reduce risk of irritation.

7. The method of any preceding claim, wherein the system includes a nipple receiving portion, wherein the nipple receiving portion is configured to restrict an areola from completely entering the nipple receiving portion.

8. The method of any preceding claim, wherein the system includes a nipple receiving portion, wherein the nipple receiving portion includes a non-tapering portion attached to a breast contact portion, and a tapering portion extending from the non-tapering portion, the tapering portion configured and dimensioned to receive the nipple of the breast.

9. The method of any preceding claim, wherein the system includes a breast contact portion having a first central longitudinal axis and a nipple receiving portion having a second central longitudinal axis, wherein the first and second central longitudinal axes intersect.

10. The method of any preceding claim, further comprising providing a controller, the controller remotely controlling operational settings of the breast pump system.

11. An automated system for controlling pumping cycles to pump milk from a breast, the system comprising:

a breast contacting structure configured and dimensioned to form a seal with the breast;

a collection container for storing the milk pumped from the breast; and

a tube in fluid communication with the collection container, the tube extending upwardly;

wherein milk extracted from the breast flows upwardly from the nipple.

12. The system of any previous claim, wherein the milk is pumped through the tube against gravity.

13. The system of any previous claim, wherein at least a latch suction is maintained throughout a pumping cycle.

14. The system of any previous claim, further comprising a controller configured to control operational settings of the system.

15. The system of any previous claim, wherein the suction applied to the breast for expression of the milk comprises a first suction level, and wherein, during expulsing, a second suction level is maintained against the breast, the second suction level being lower than the first suction level.

16. The system of any preceding claim, further comprising a nipple receiving portion including a non-tapering portion attached to the breast contacting structure, and a tapering portion extending from the non-tapering portion, the tapering portion configured and dimensioned to receive the nipple of the breast.

17. The system of any preceding claim, wherein the non-tapering portion is cylindrical and the tapering portion is conical.

18. The system of any preceding claim, wherein the non-tapering portion is ovular or elliptical in cross section.

19. The system of any preceding claim, wherein the tapering portion is ovular or elliptical in cross section.

20. The system of any preceding claim, further comprising structure limiting nipple motion to reduce risk of irritation, wherein nipple motion is under 1mm.

.

21. The system of any preceding claim, further comprising structure limiting nipple motion to reduce risk of irritation, wherein nipple motion is less than about 2mm.

.

22. The system of any preceding claim, further comprising a controller, the controller controlling sensing pumping function and modifying pumping to reach target waveforms in response to changes in one or more of flow, gravity, and movements and positions of the user.

23. The system of any preceding claim, wherein the nipple receiving portion is configured to contact an upper surface of a nipple and a bottom part of the nipple receiving portion is configured to contact a lower surface of the nipple, wherein the top part is formed of a material having a first hardness and the bottom part is formed of a material having a second hardness, the fist hardness being greater than the second hardness.

24. The system of any preceding claim, wherein the routing the extracted milk upwardly facilitates removal of air from the collected milk.

25. The system of any preceding claim, further comprising structure limiting nipple motion to reduce risk of irritation, wherein nipple motion is from under 1mm to less than about 2mm.

26. The system of any preceding claim, further comprising a nipple receiving portion, wherein the nipple receiving portion is configured to restrict an areola from completely entering the nipple receiving portion.

27. The system of any preceding claim, further comprising a resilient flap extending radially inwardly from a breast contact structure, wherein when the breast is inserted into the breast contact structure, the breast folds down the flap and the flap returns to an unbiased position and extends radially inwardly, thereby retaining milk within the breast contact structure.

28. The system of any preceding claim, further comprising a compression member functioning to facilitate pumping of milk, and a controller monitoring pressure feedback information and at least one of position and speed of movement of the compression member to ensure that predetermined pressure cycles continue to be generated.

29. The system of any preceding claim, further comprising a compression member configured to facilitate pumping of milk, predetermined pressure cycles including extraction mode pressure cycles, and a controller that increases stroke distance of the compression member relative to an amount of milk being extracted to maintain predetermined pressures during an extraction mode pressure cycle.

30. The system of any preceding claim, further comprising a time based indicator indicating passage of time.

31. The system of any preceding claim, further comprising a nipple shield.

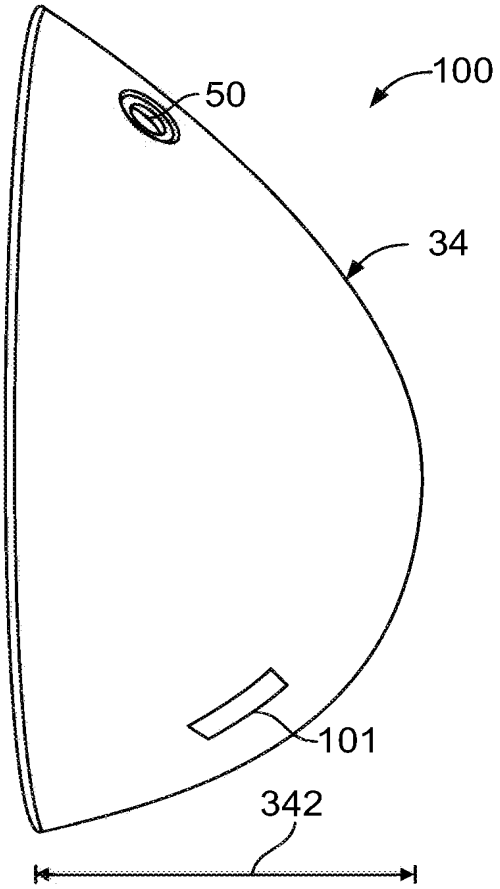


FIG. 1

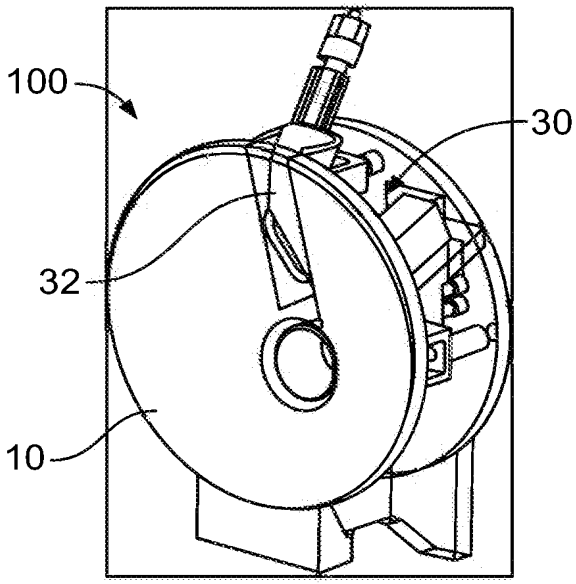


FIG. 2

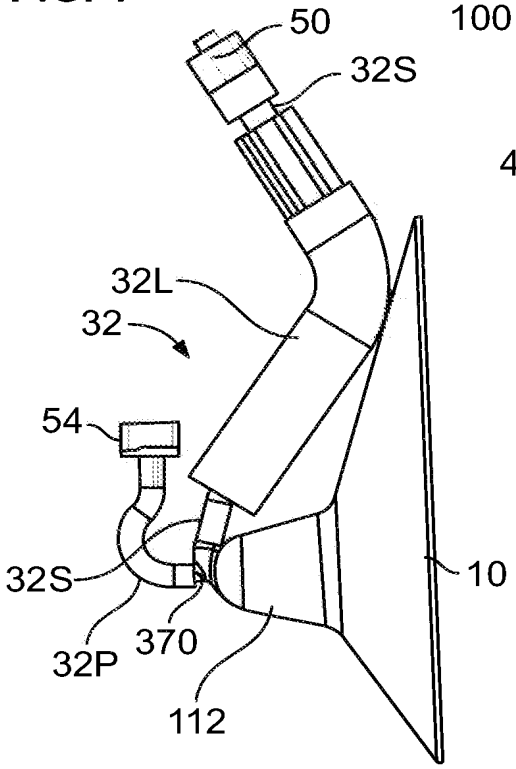


FIG. 4

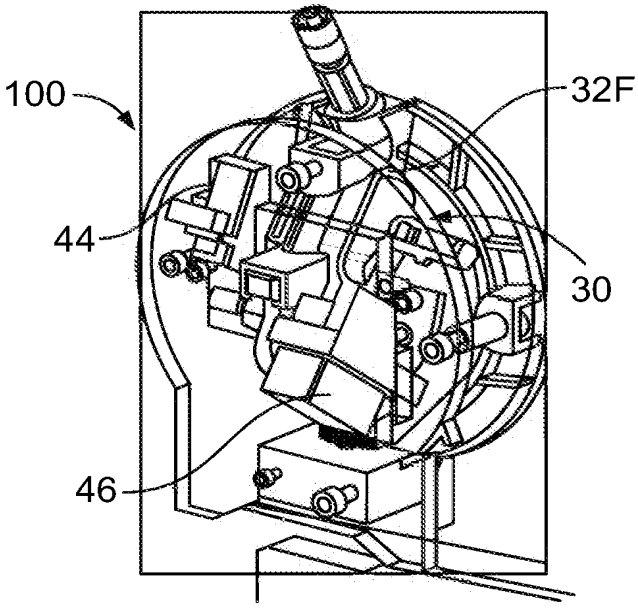


FIG. 3

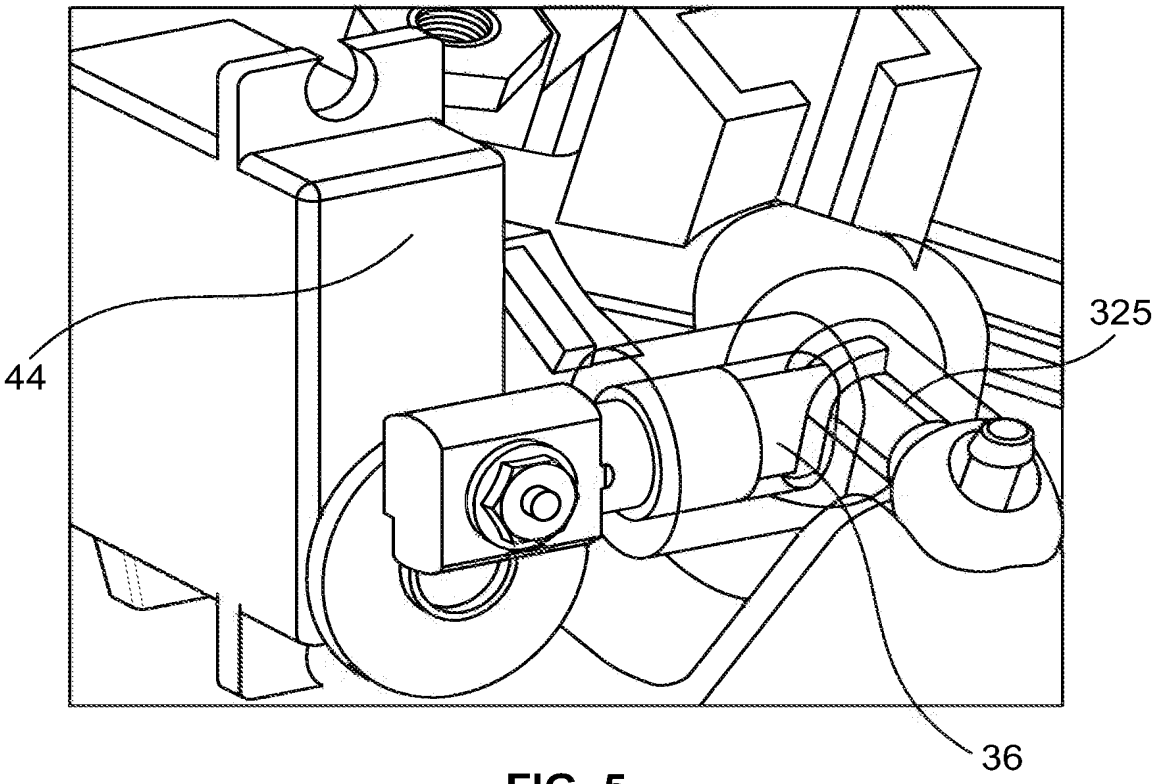


FIG. 5

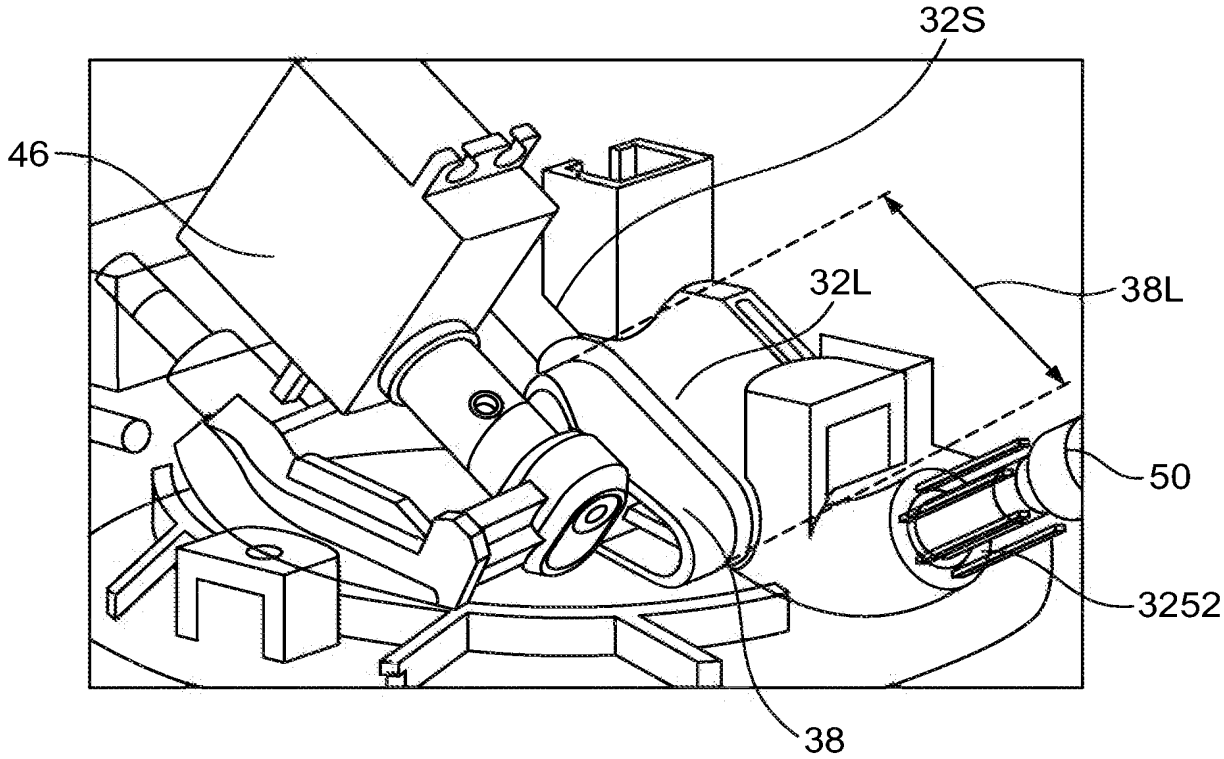


FIG. 6

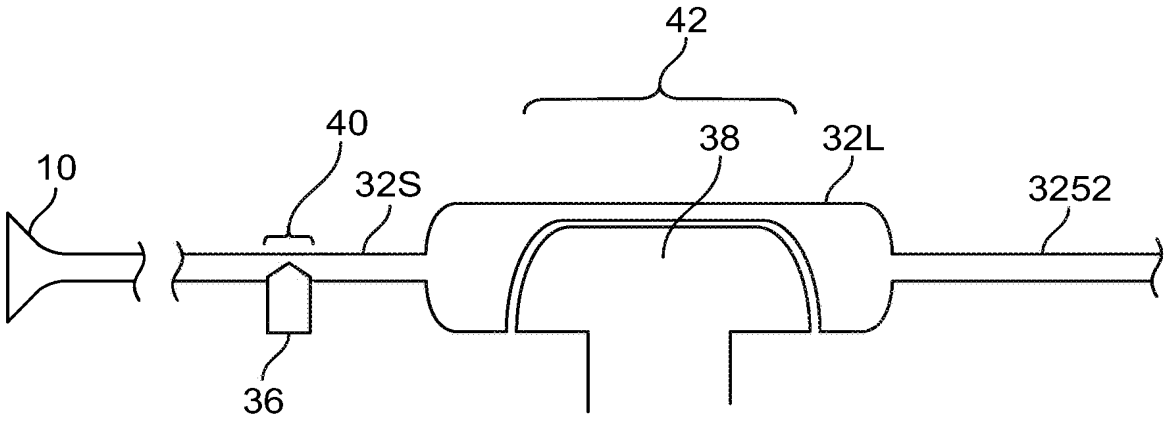


FIG. 7A

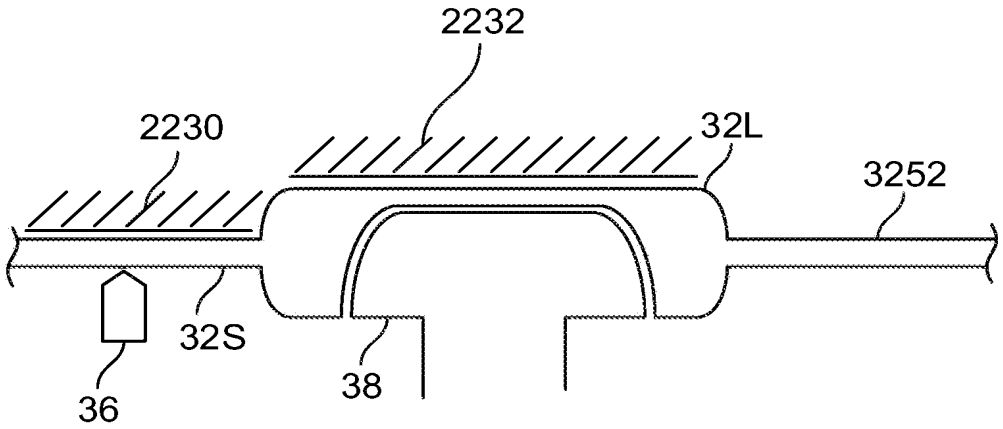


FIG. 7B

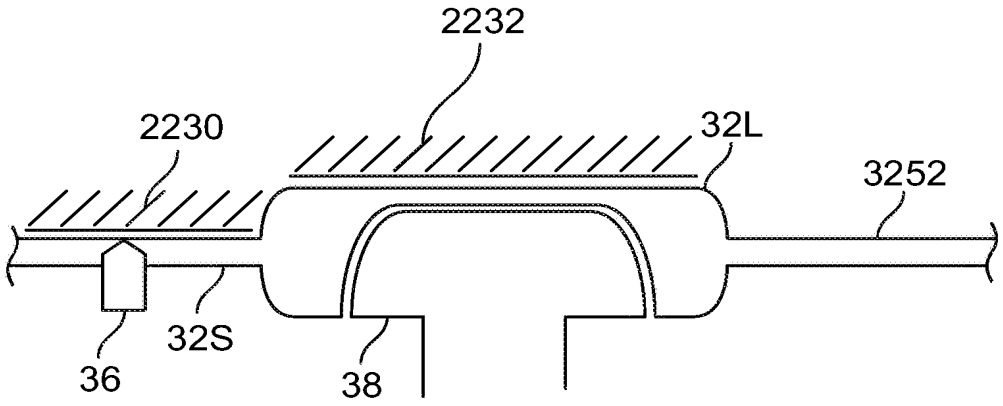


FIG. 7C

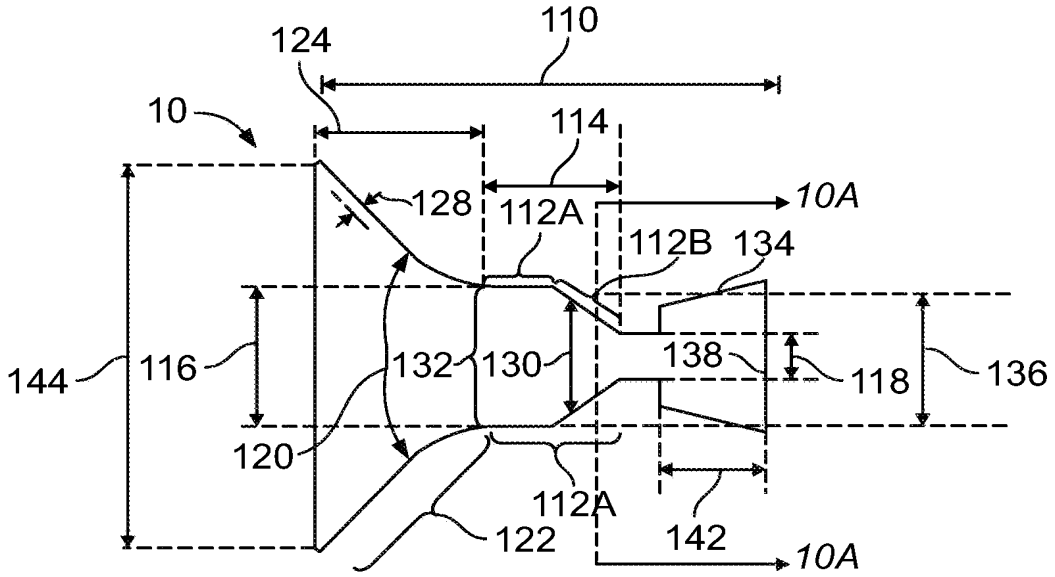


FIG. 8

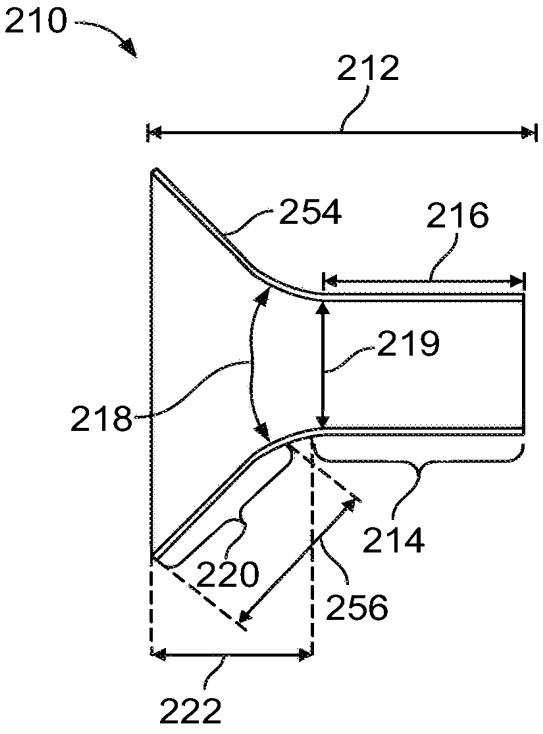


FIG. 9
PRIOR ART

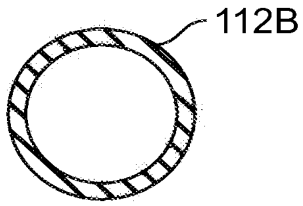


FIG. 10A

FIG. 10B

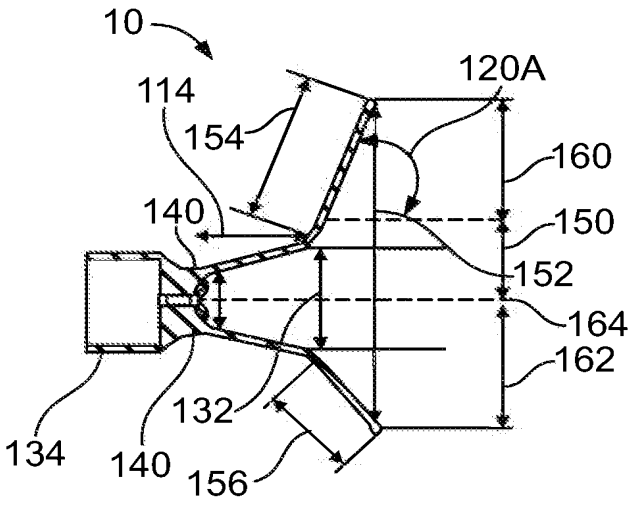


FIG. 11A

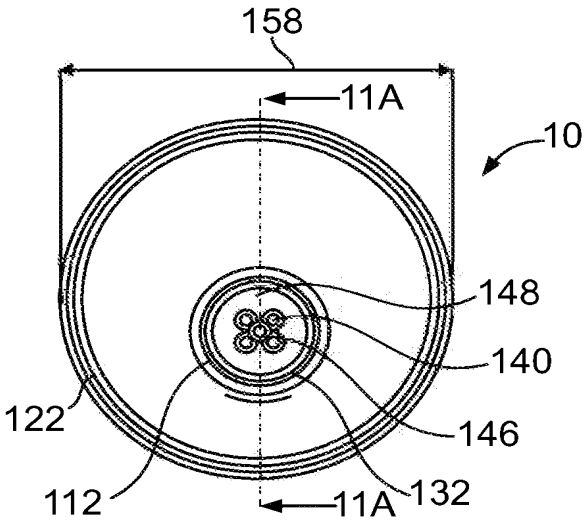


FIG. 11B

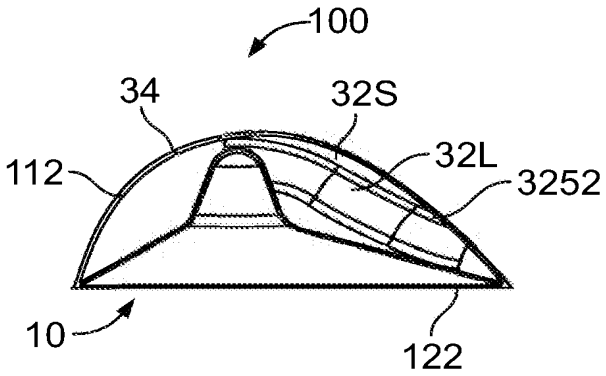


FIG. 12A

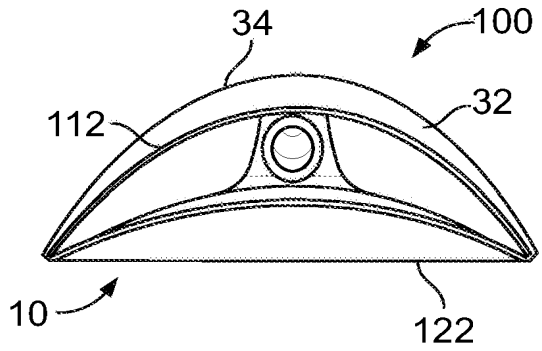


FIG. 12B

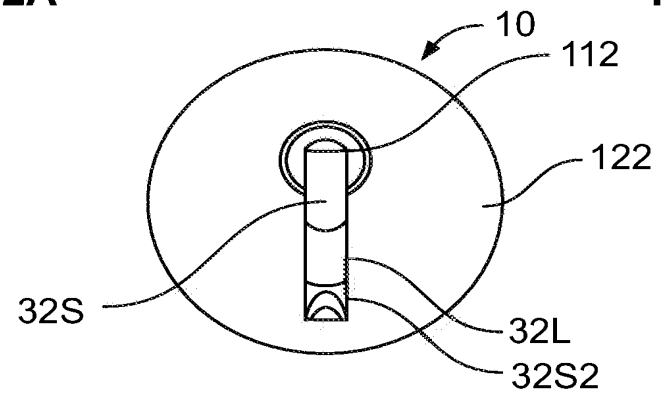


FIG. 12C

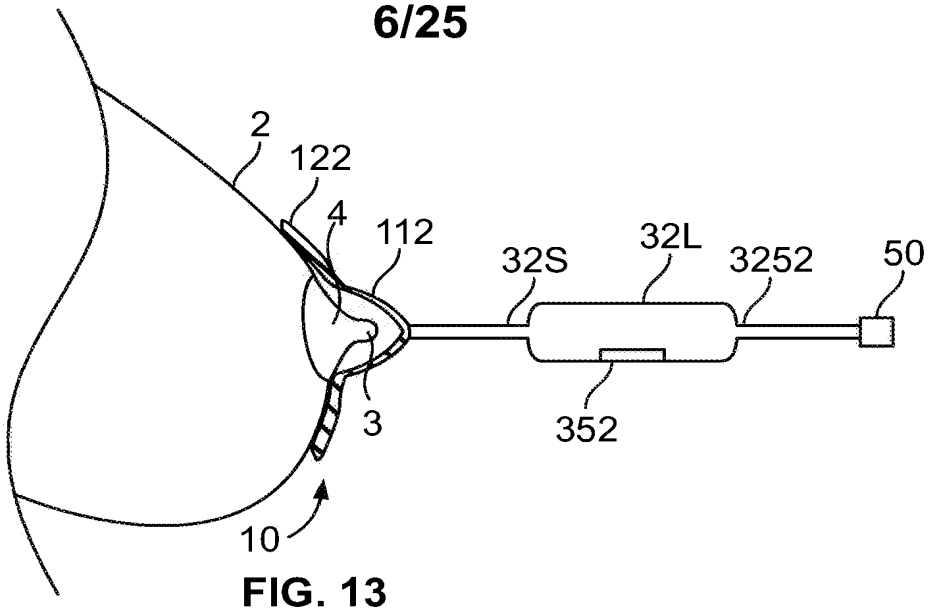


FIG. 13

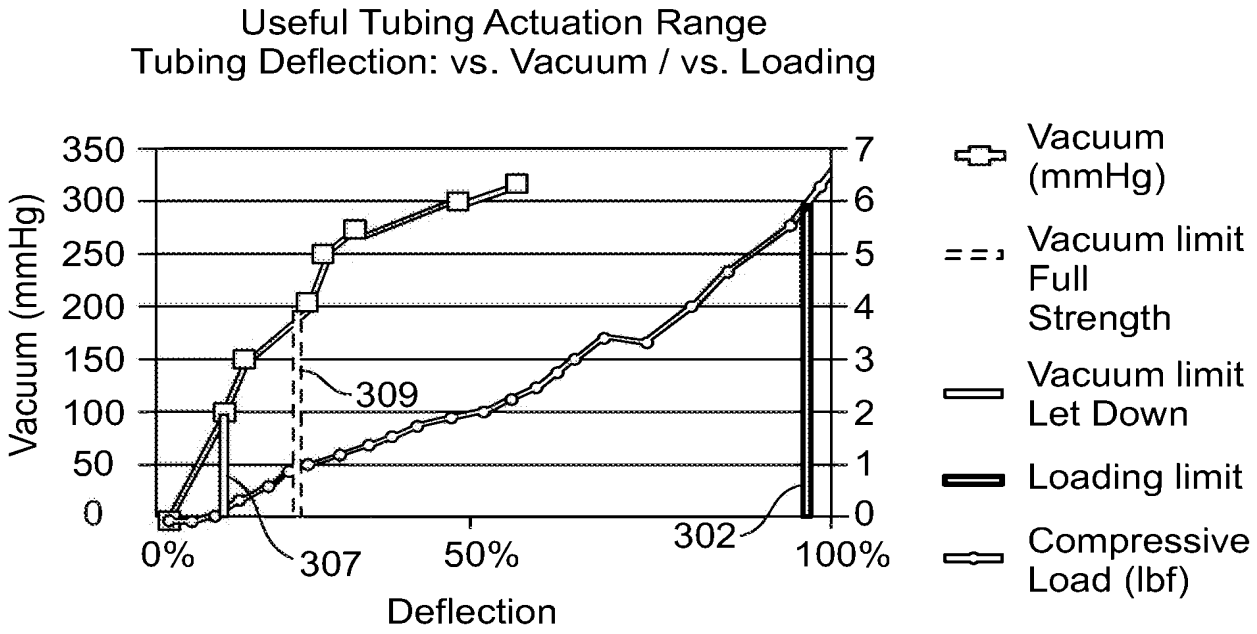


FIG. 15

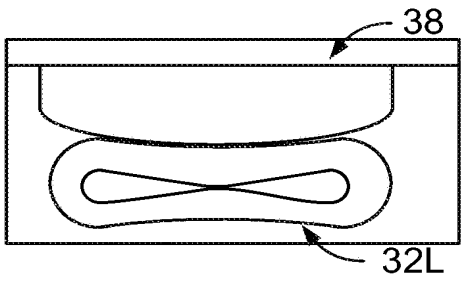


FIG. 16

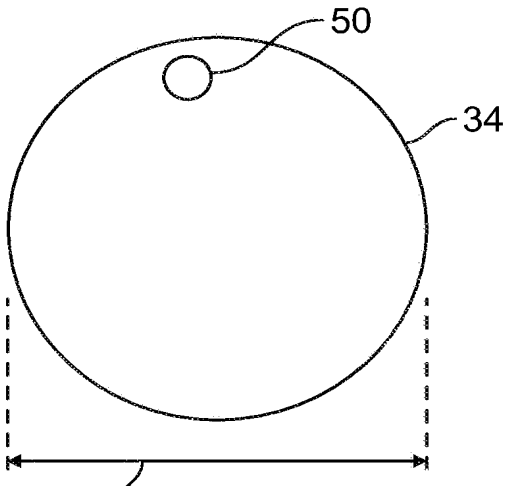


FIG. 18

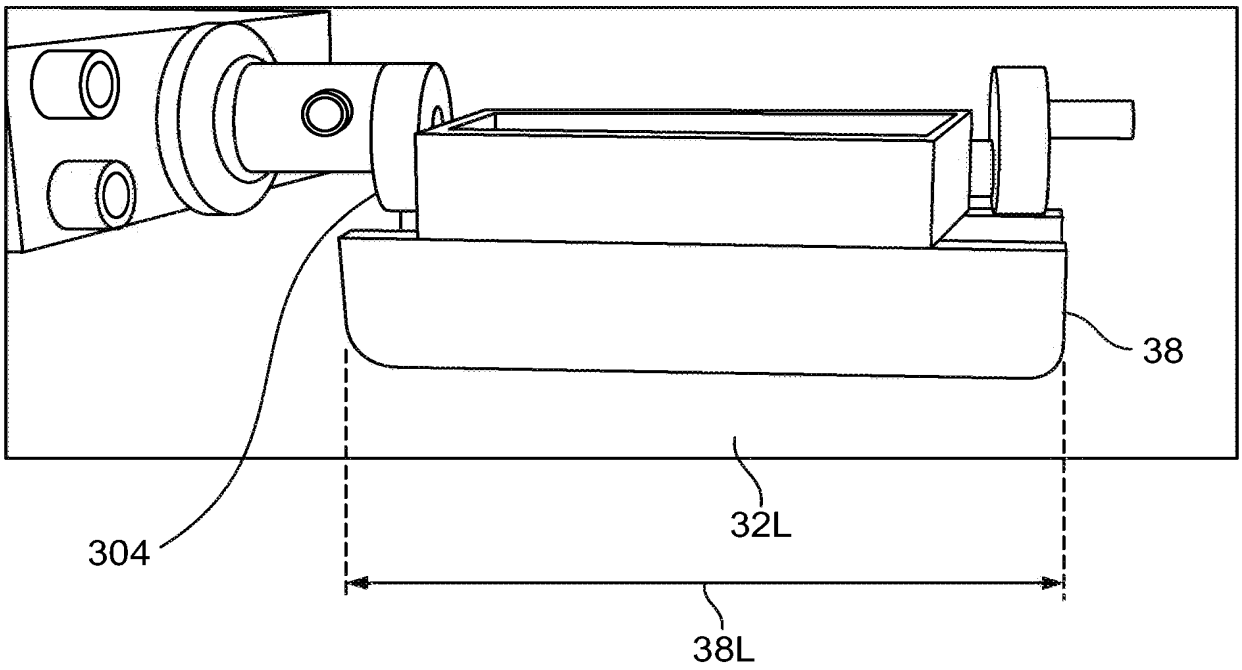


FIG. 14

Run Time	minutes	hours	sessions
Single Session	15	0.250	1
Full Day	60	1.000	4

	Voltage (V)	MAX Current (A)	Average Current (mA)	Required capacity-single session (mAh)	Required Capacity-full day (mAh)
Alkaline - C(x4)	6	0.83	440	110	440
	330	334	332	336	338

FIG. 17

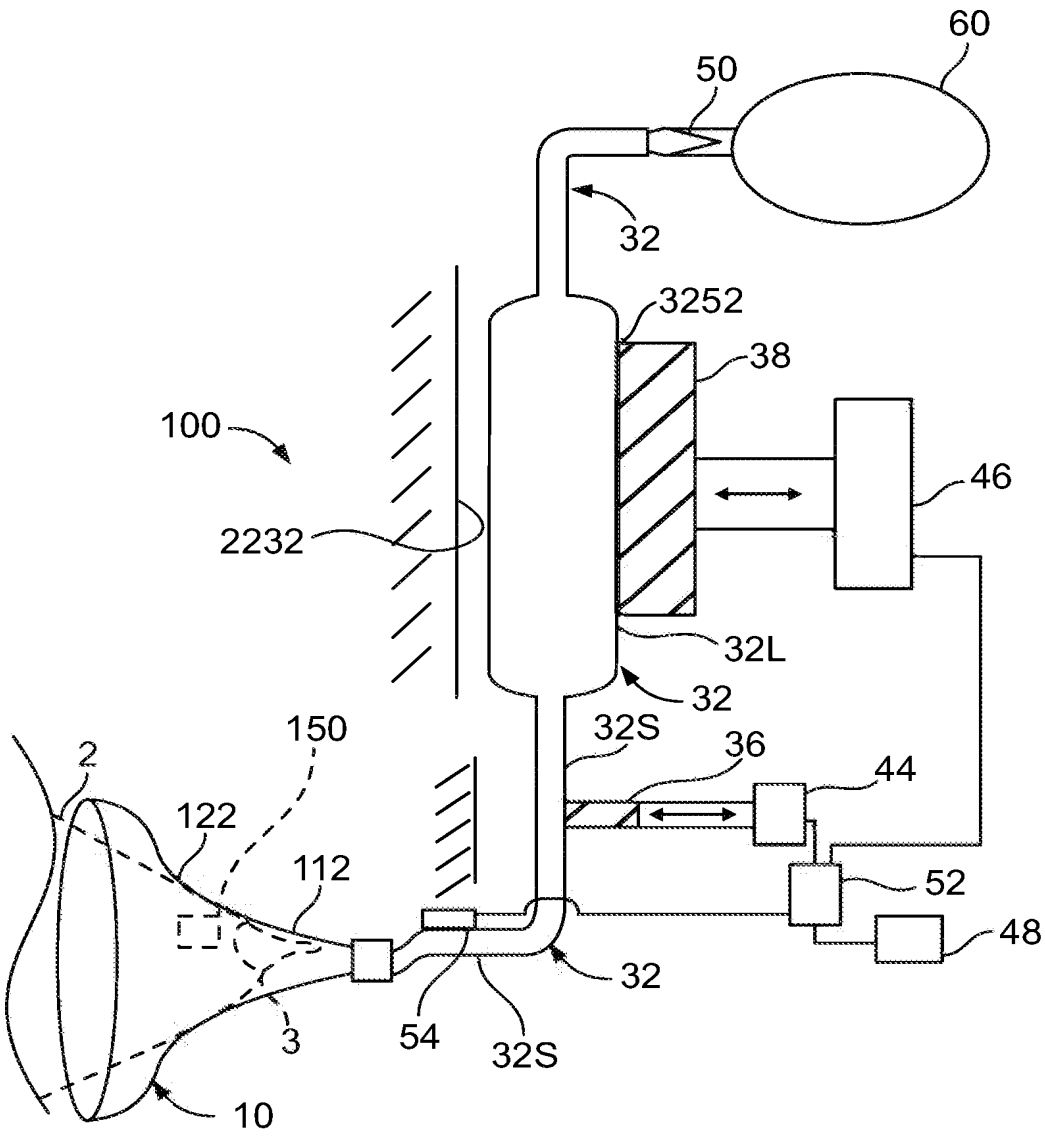
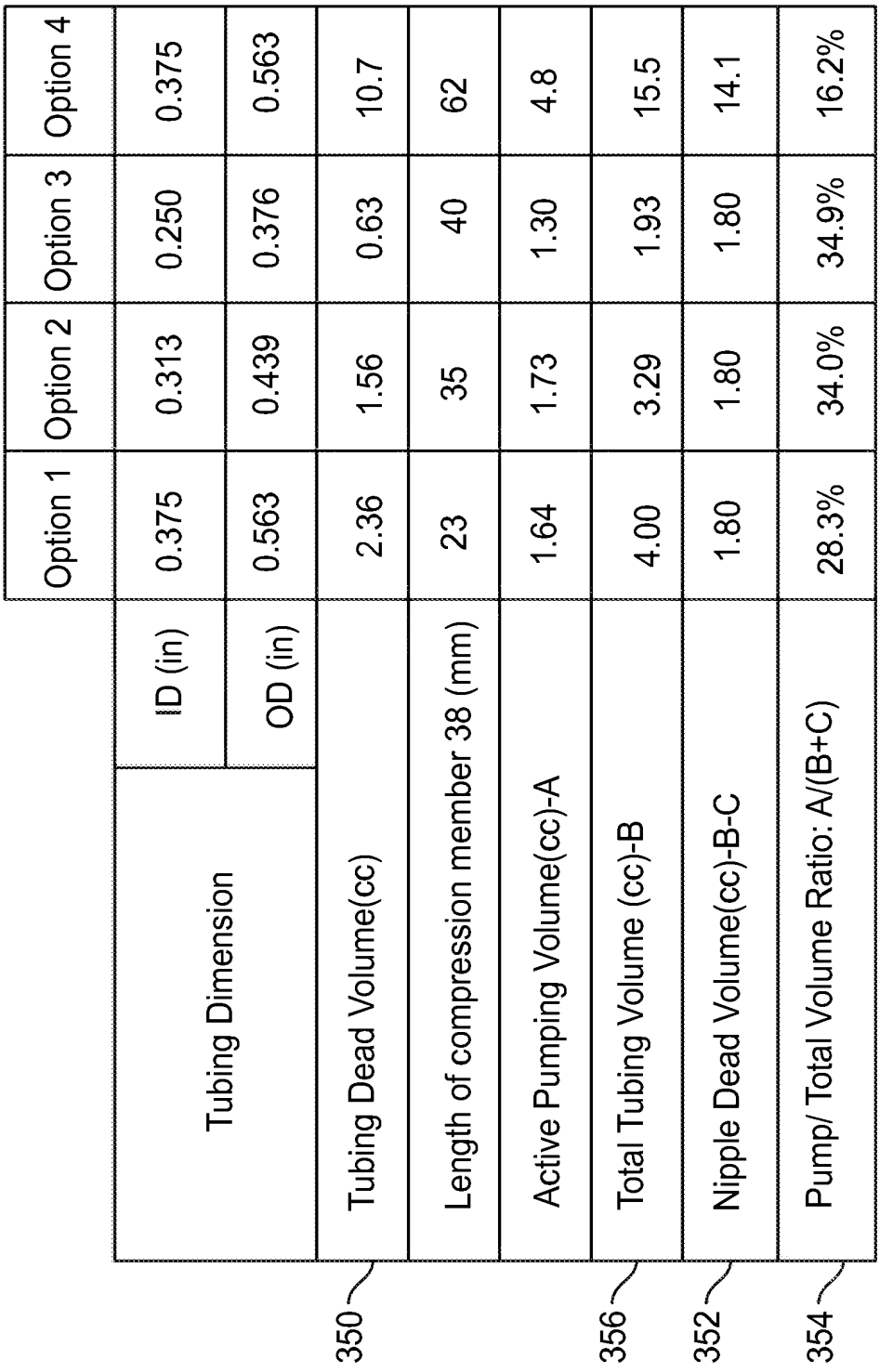

60
50
32
3252
38
100
46
2232
32L
32
150
32S
36
44
2
122
112
52
48
32
3
54
32S
10

FIG. 20



		Option 1	Option 2	Option 3	Option 4
Tubing Dimension	ID (in)	0.375	0.313	0.250	0.375
	OD (in)	0.563	0.439	0.376	0.563
Tubing Dead Volume(cc)		2.36	1.56	0.63	10.7
Length of compression member 38 (mm)		23	35	40	62
Active Pumping Volume(cc)-A		1.64	1.73	1.30	4.8
Total Tubing Volume (cc)-B		4.00	3.29	1.93	15.5
Nipple Dead Volume(cc)-B-C		1.80	1.80	1.80	14.1
Pump/ Total Volume Ratio: A/(B+C)		28.3%	34.0%	34.9%	16.2%

350 356 352 354

FIG. 19

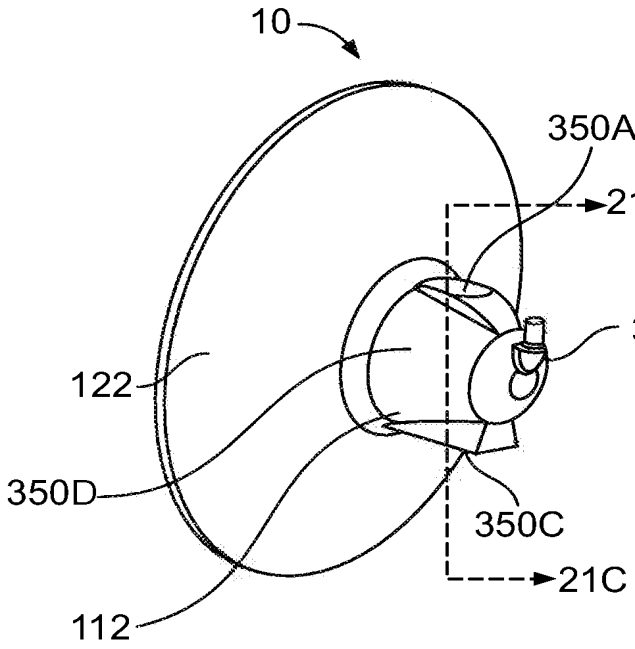


FIG. 21A

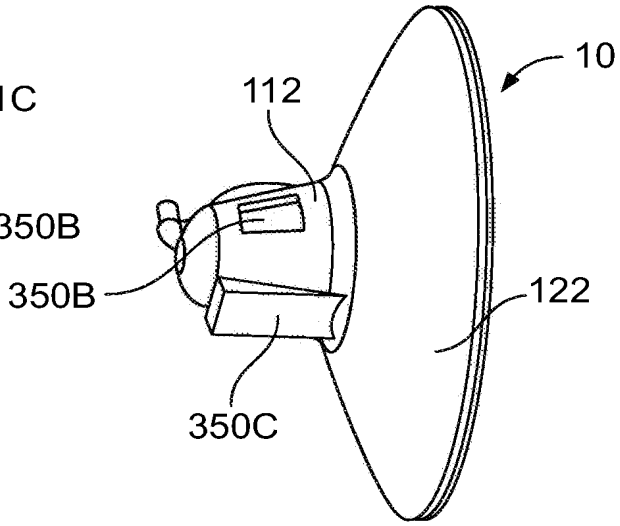


FIG. 21B

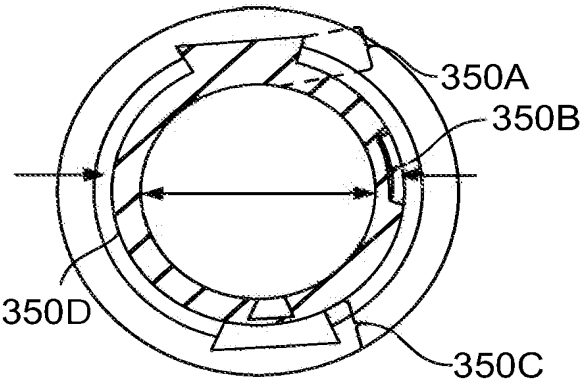


FIG. 21C

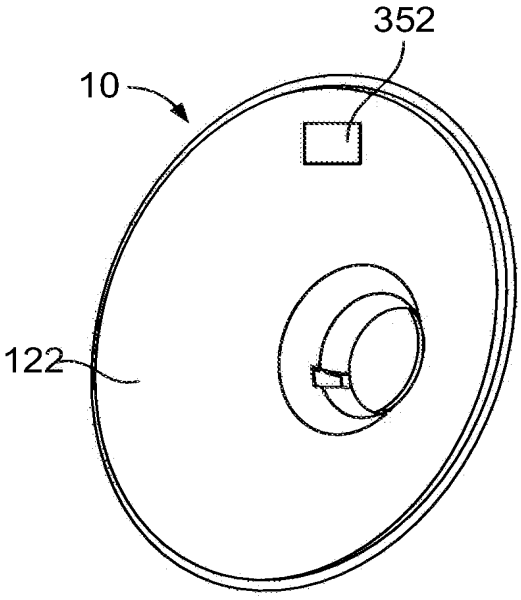


FIG. 22

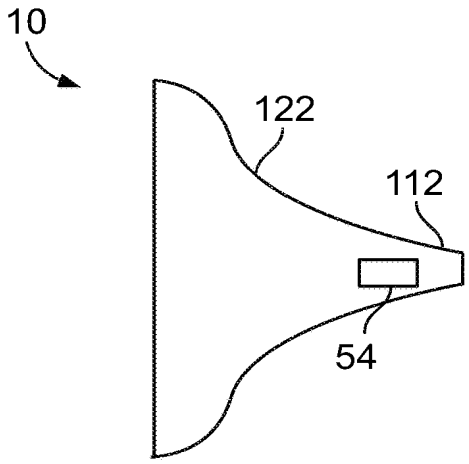


FIG.21D

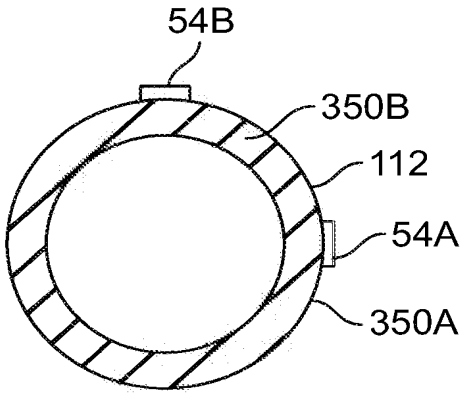


FIG.21E

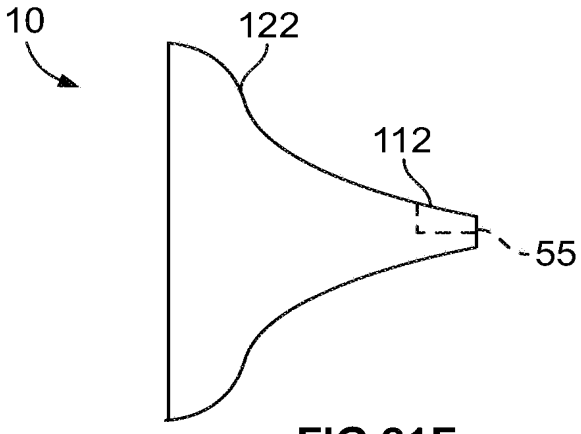


FIG.21F

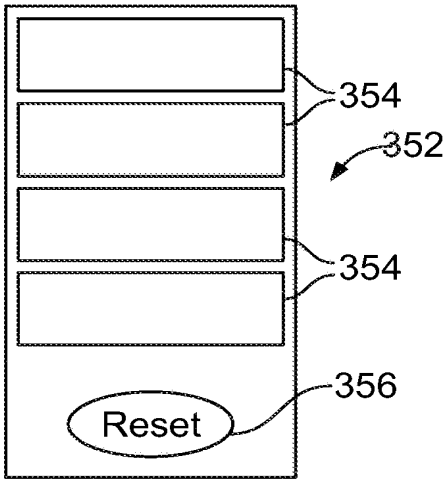


FIG. 24

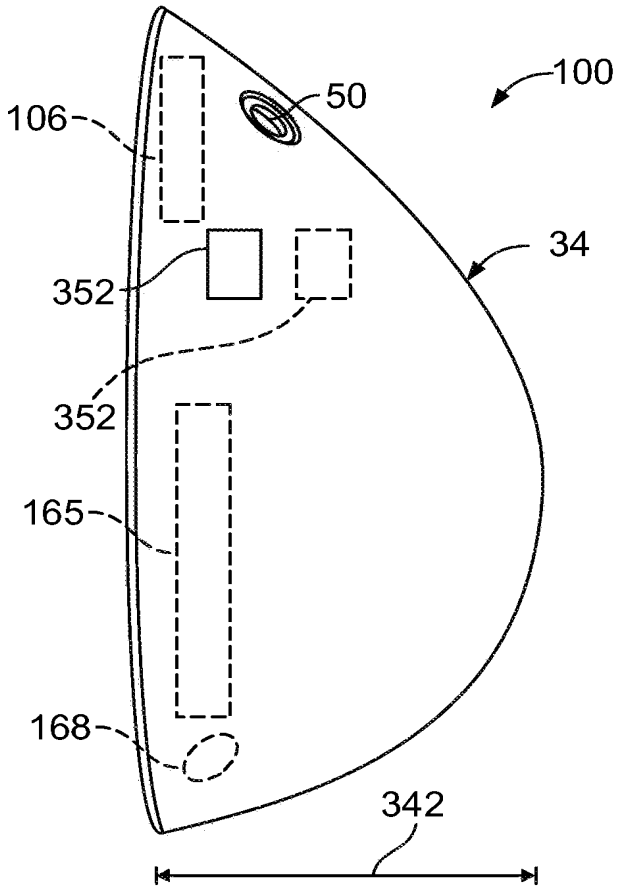


FIG. 23

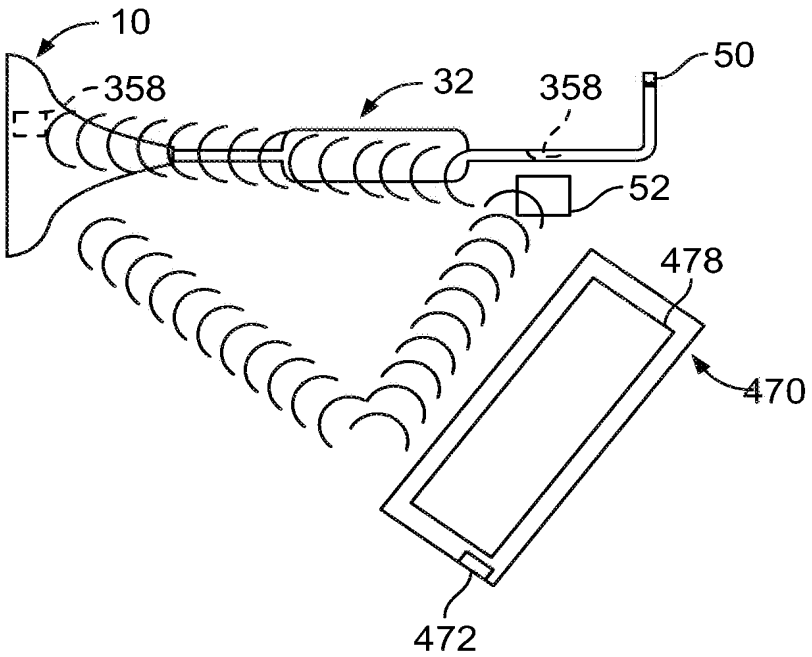


FIG. 25

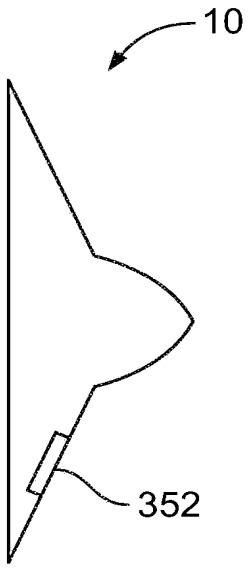


FIG. 27

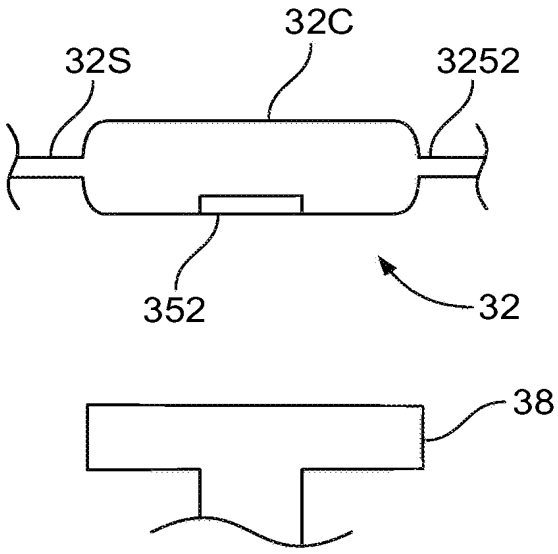


FIG. 26

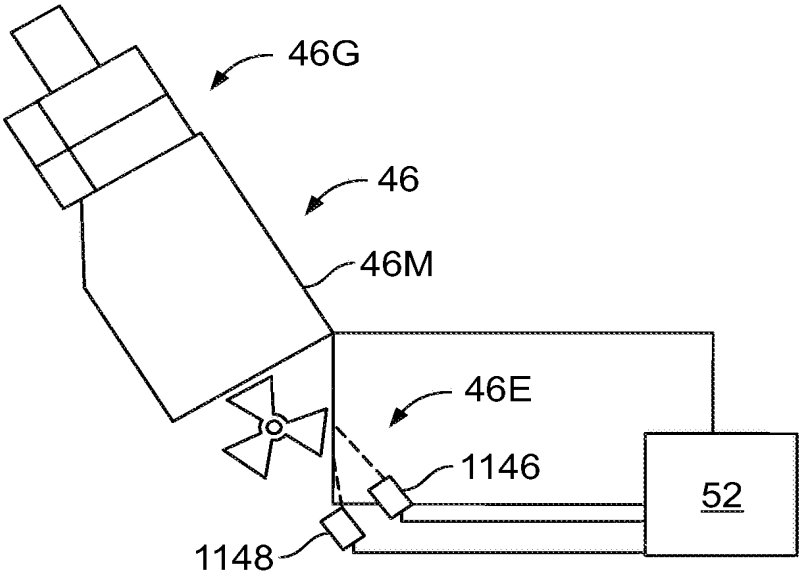


FIG. 28

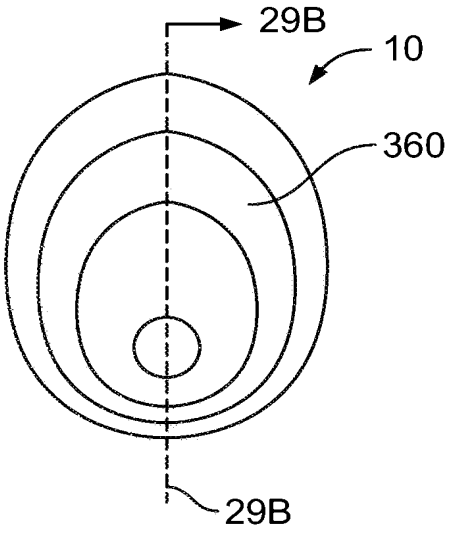


FIG. 29A

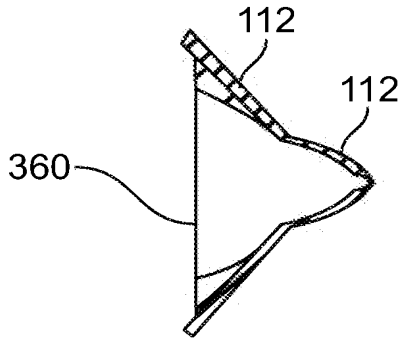


FIG. 29B

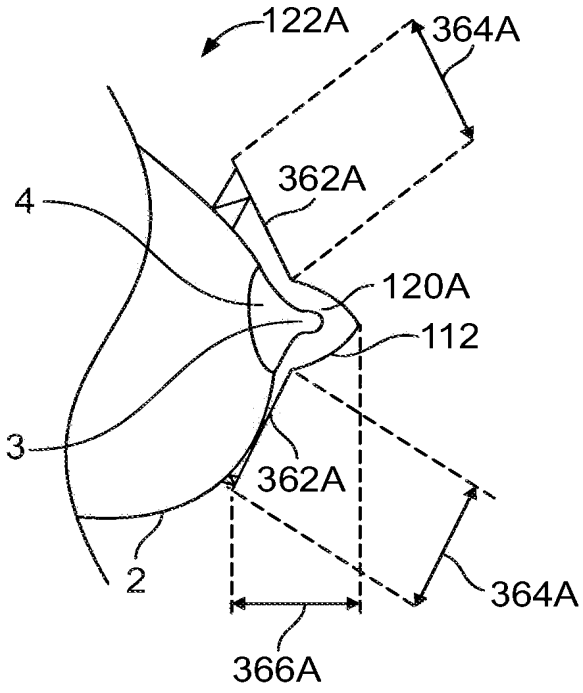


FIG. 30A

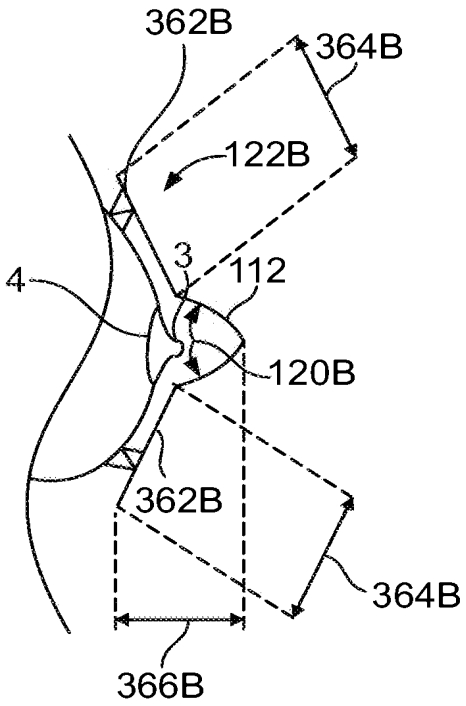


FIG. 30B

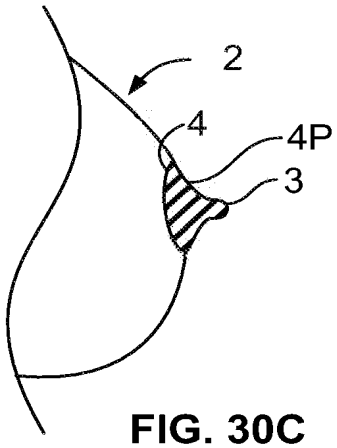


FIG. 30C

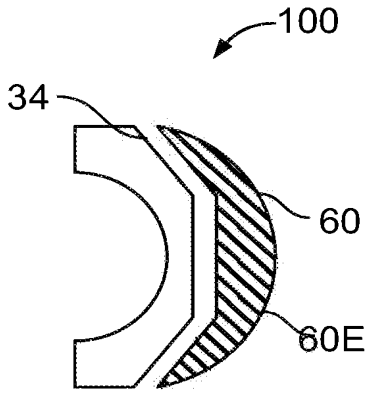


FIG. 31A

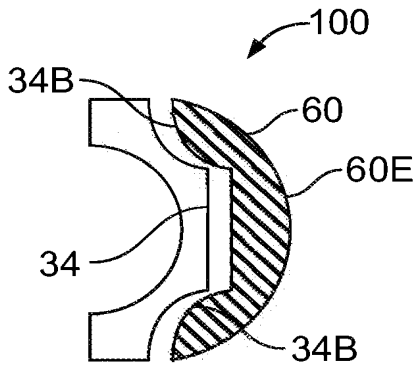


FIG. 31B

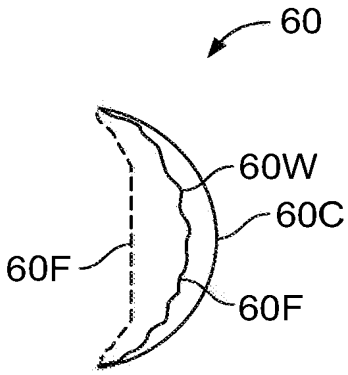


FIG. 32A

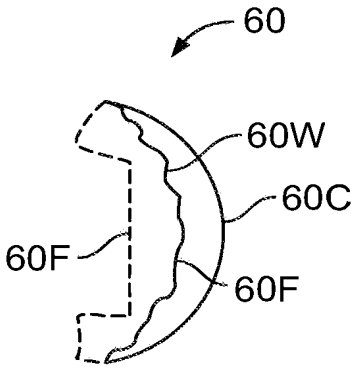


FIG. 32B

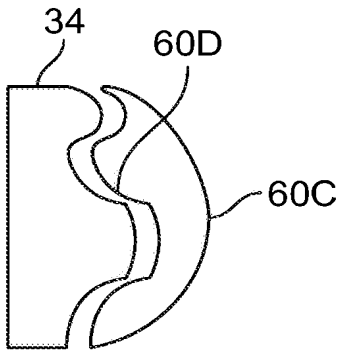


FIG. 32C

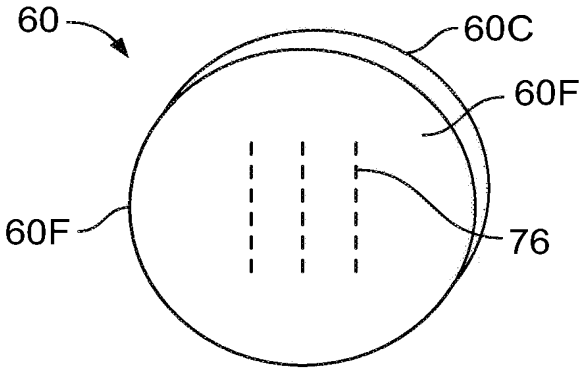


FIG. 33

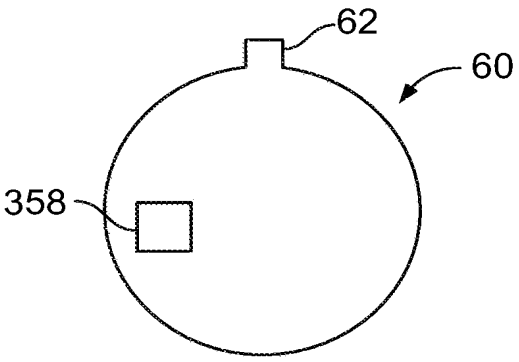


FIG. 34

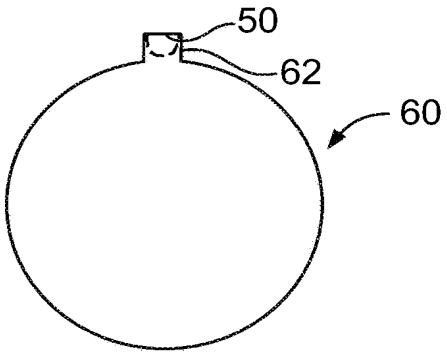


FIG. 35

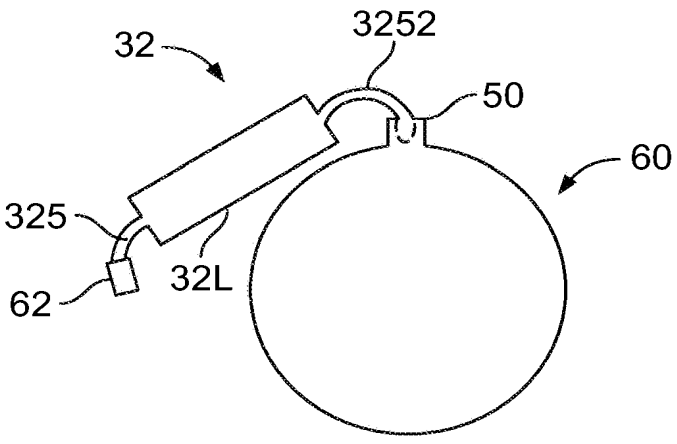


FIG. 36

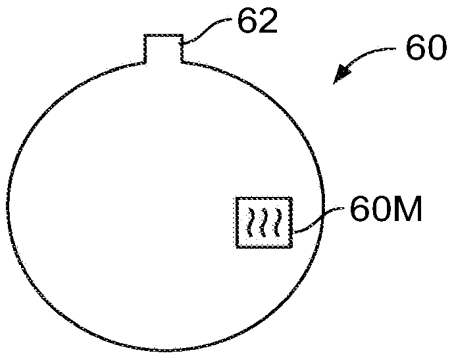


FIG. 37

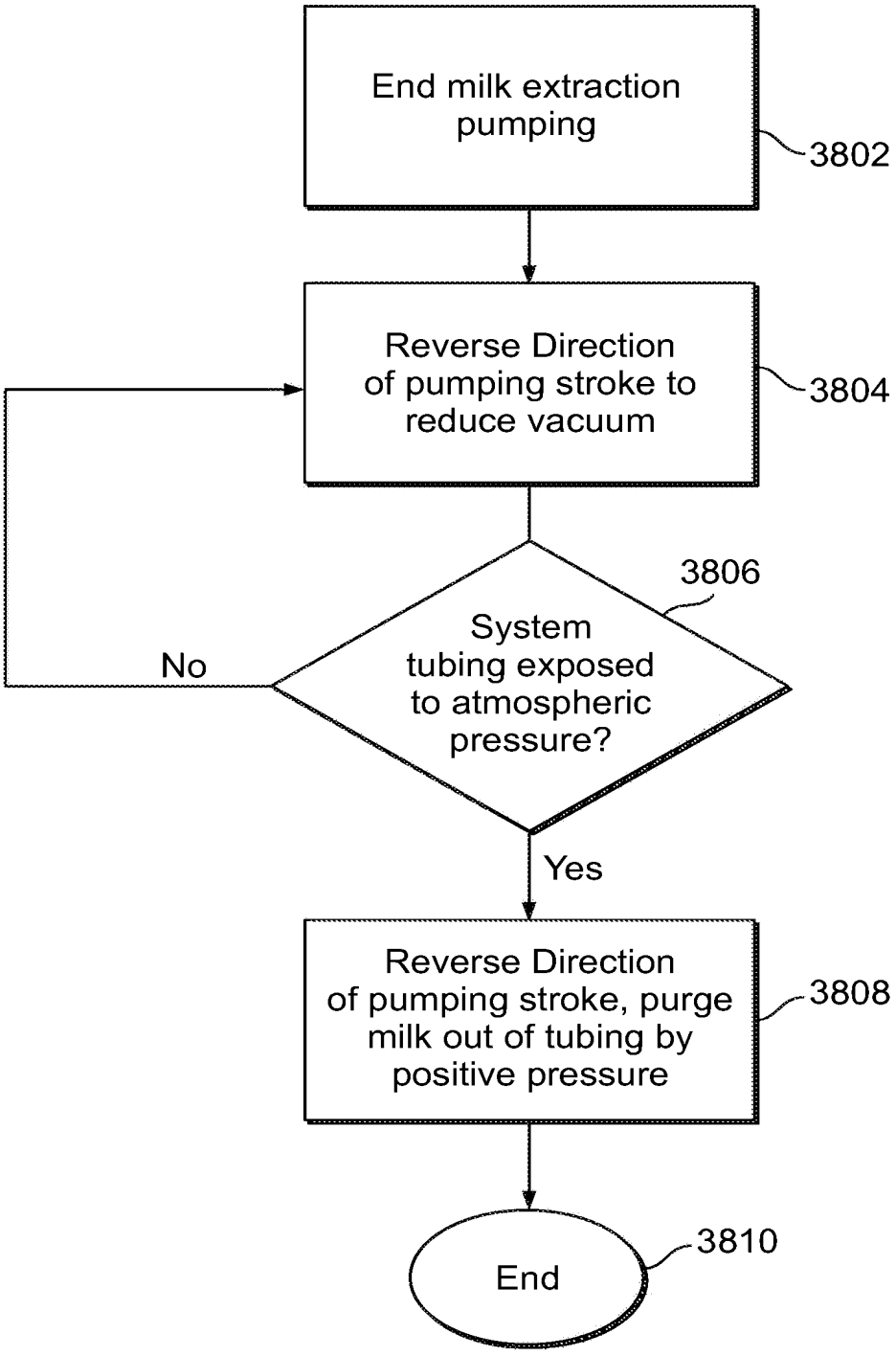

End milk extraction pumping
3802
Reverse Direction of pumping stroke to reduce vacuum
3804
3806
System tubing exposed to atmospheric pressure?
No
Yes
Reverse Direction of pumping stroke, purge milk out of tubing by positive pressure
3808
End
3810

FIG. 47

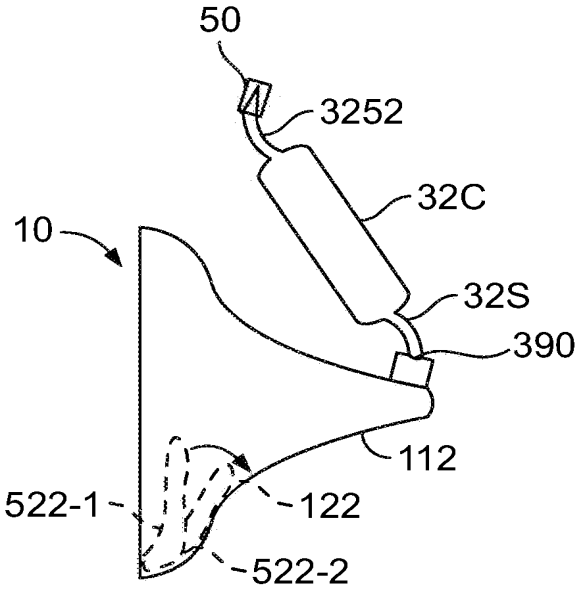


FIG. 39A

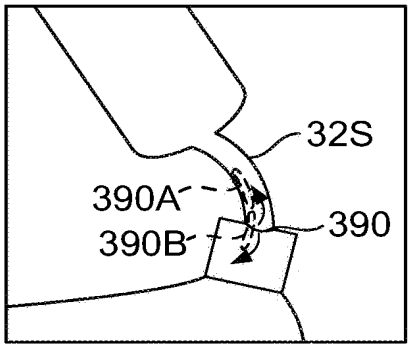


FIG. 39B

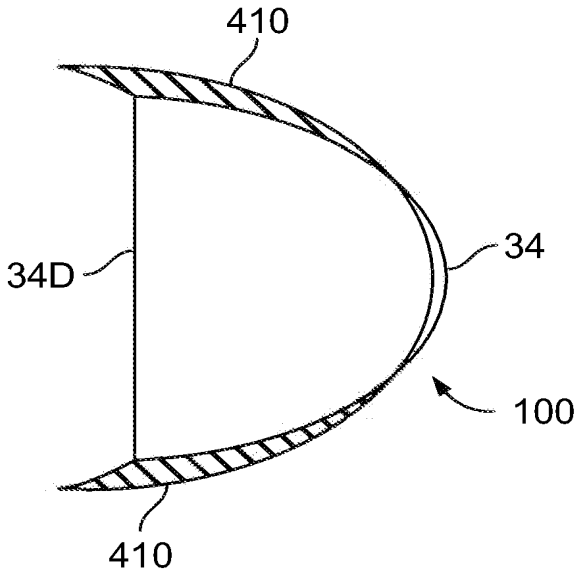


FIG. 40A

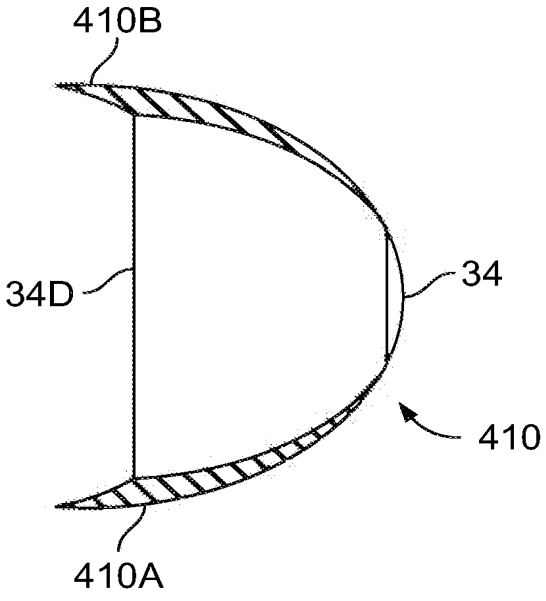


FIG. 41A

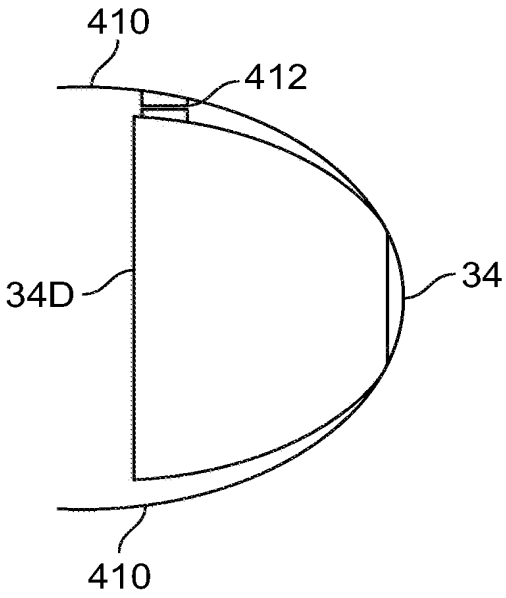


FIG. 41A

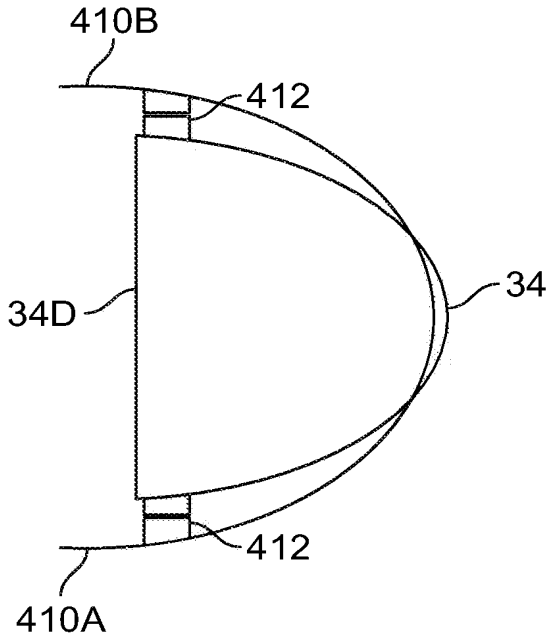


FIG. 41B

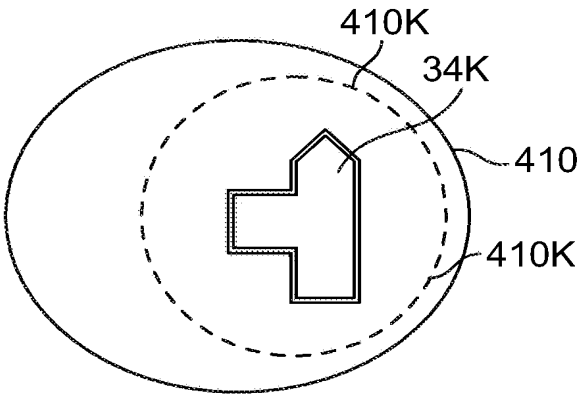


FIG. 42

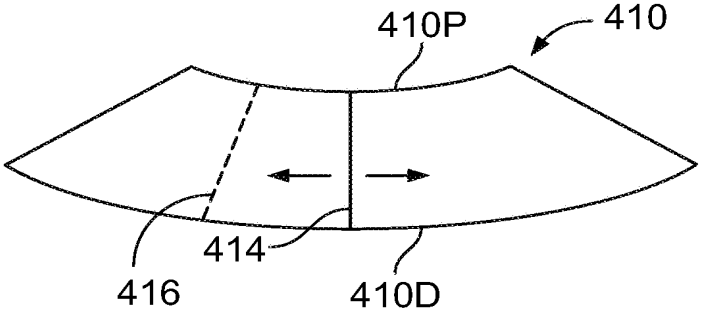


FIG. 43

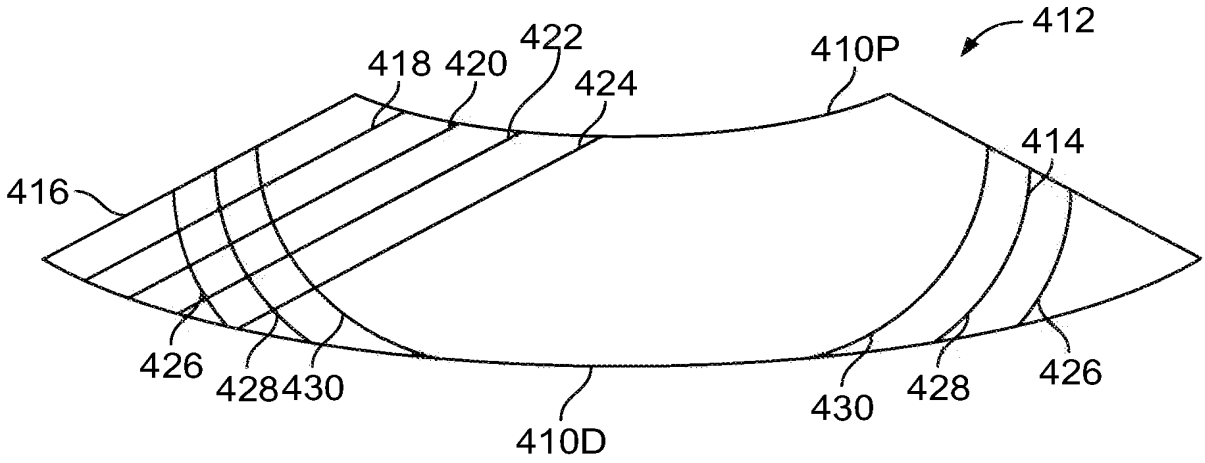


FIG. 44

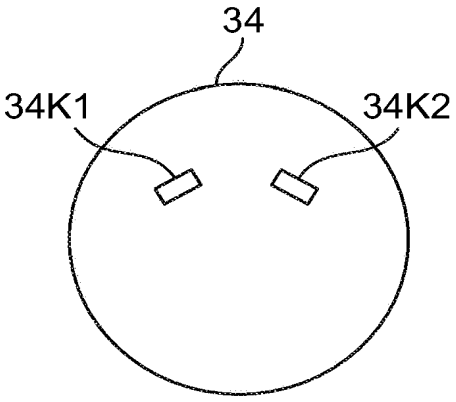


FIG. 45A

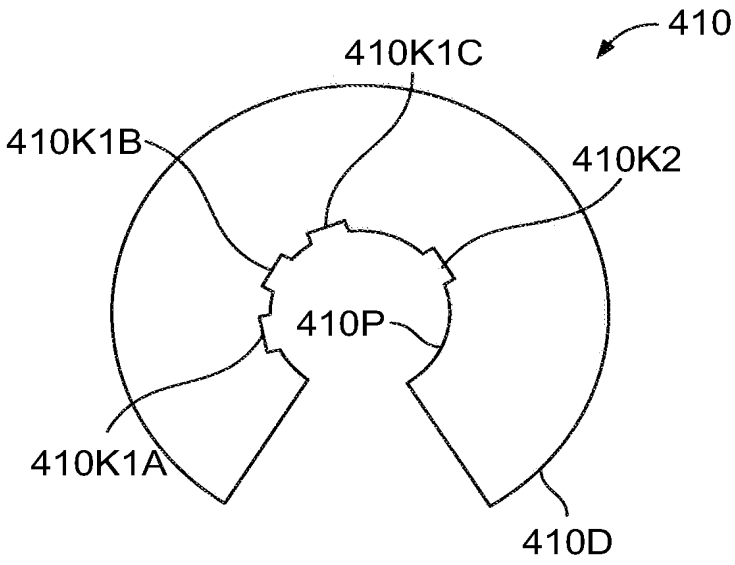


FIG. 45B

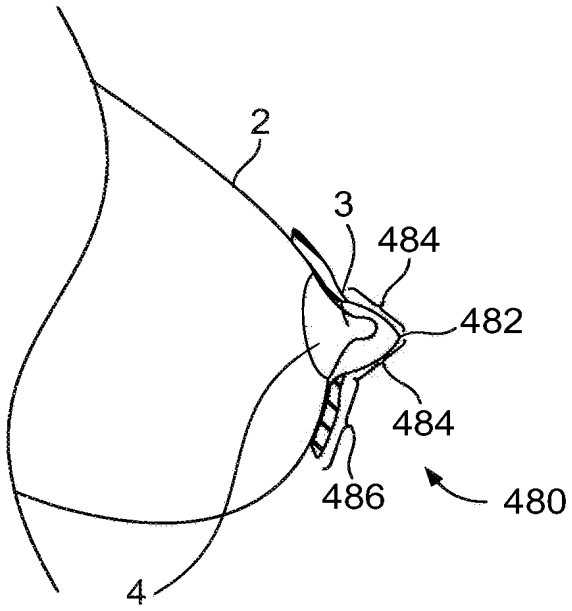


FIG. 48

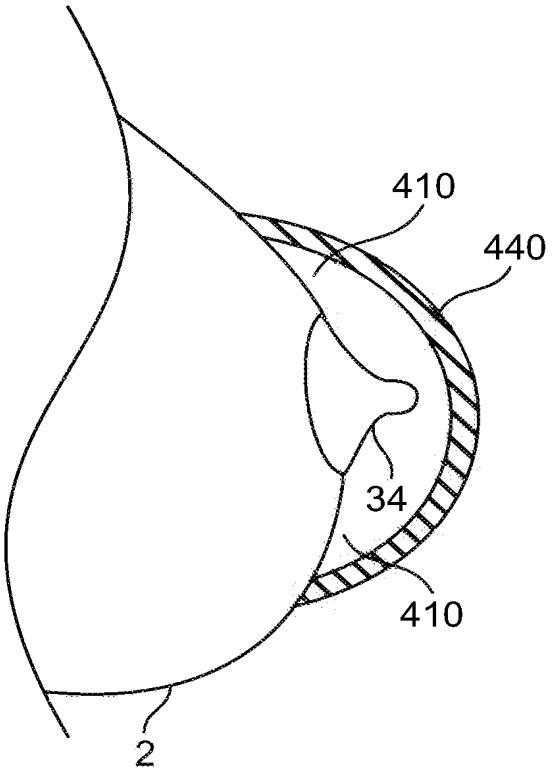


FIG. 46B

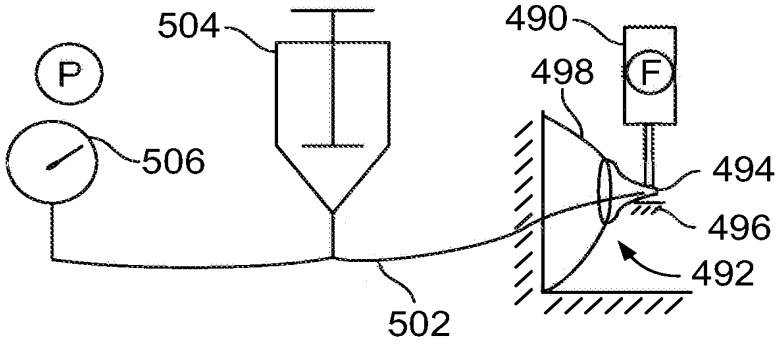


FIG. 49

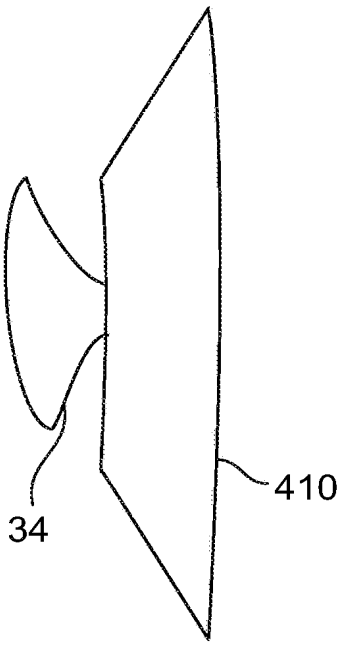


FIG. 46A

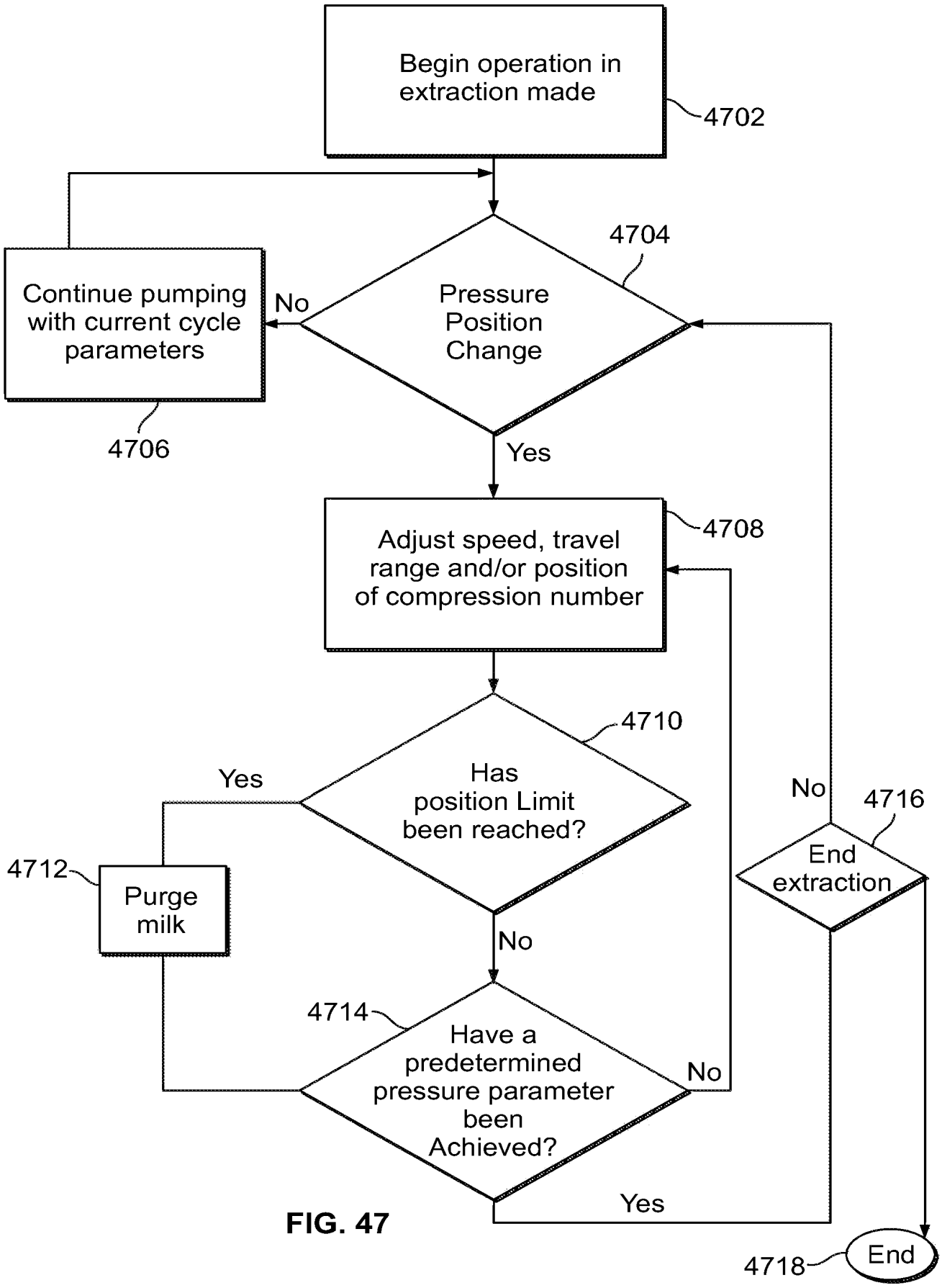

Begin operation in extraction made
4702
4704
Pressure Position Change
No
Continue pumping with current cycle parameters
4706
Yes
Adjust speed, travel range and/or position of compression number
4708
4710
Has position Limit been reached?
Yes
4712
Purge milk
No
4714
Have a predetermined pressure parameter been Achieved?
No
Yes
No
4716
End extraction
4718
End

FIG. 47

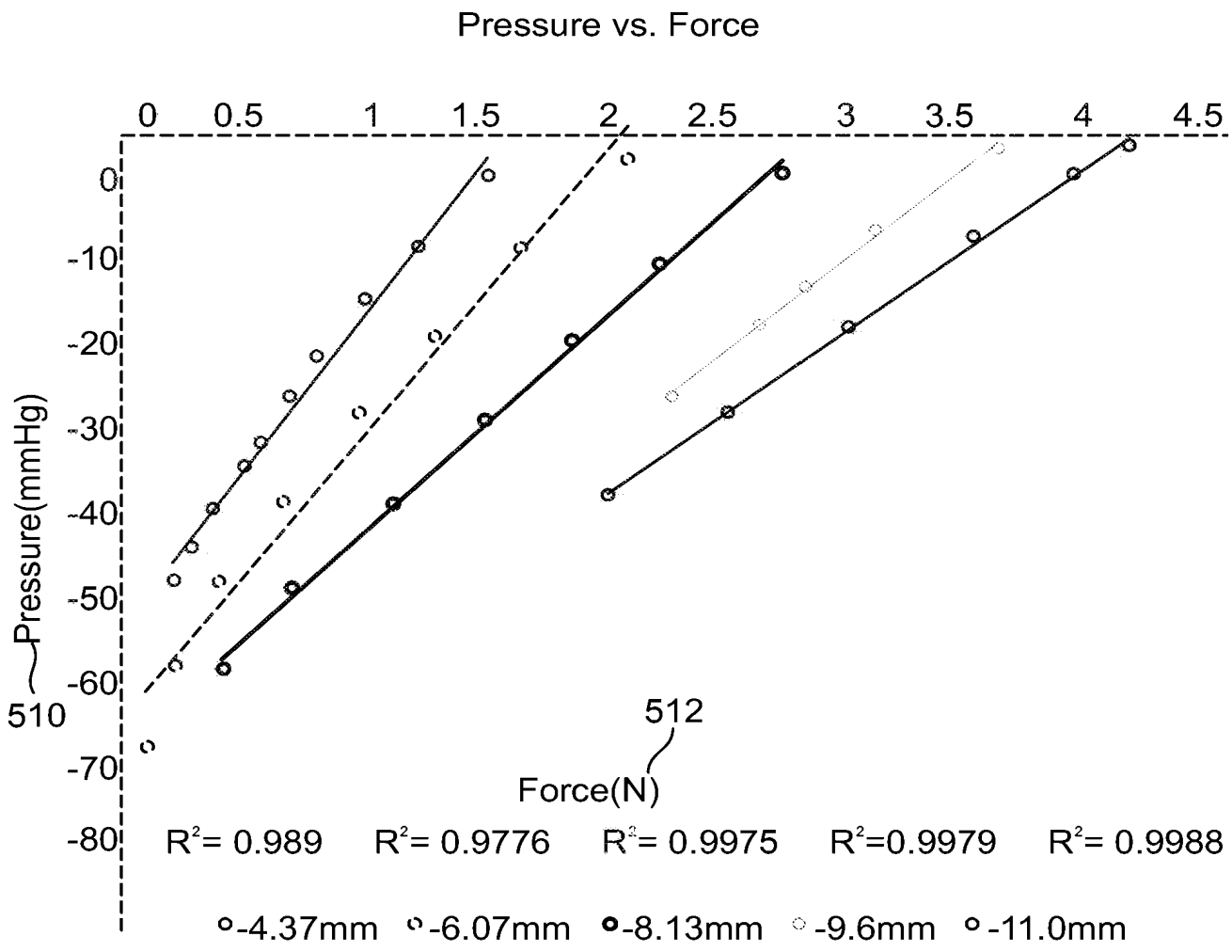

Pressure vs. Force
0 0.5 1 1.5 2 2.5 3 3.5 4 4.5
0
-10
-20
-30
-40
-50
-60
-70
-80
Pressure(mmHg)
510
512
Force(N)
R²= 0.989
R²= 0.9776
R²= 0.9975
R²=0.9979
R²= 0.9988
-4.37mm
-6.07mm
-8.13mm
-9.6mm
-11.0mm

FIG. 50

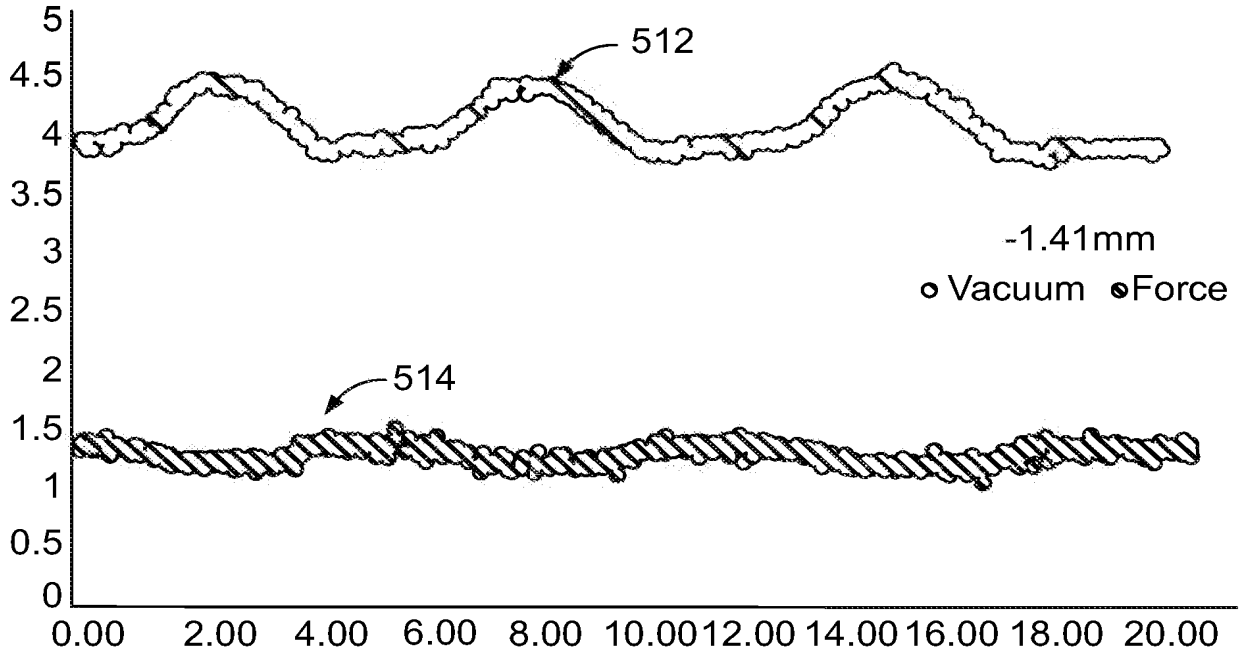

5
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
512
514
-1.41mm
Vacuum
Force
0.00 2.00 4.00 6.00 8.00 10.00 12.00 14.00 16.00 18.00 20.00

FIG. 53

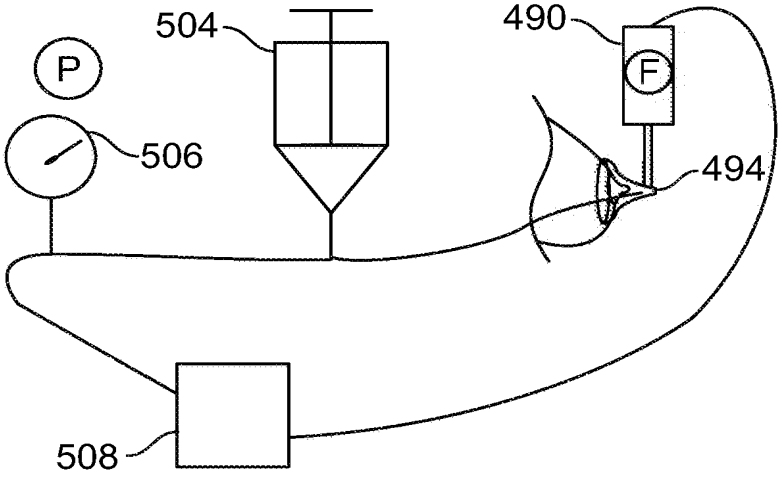

504
490
P
F
506
494
508

FIG. 51

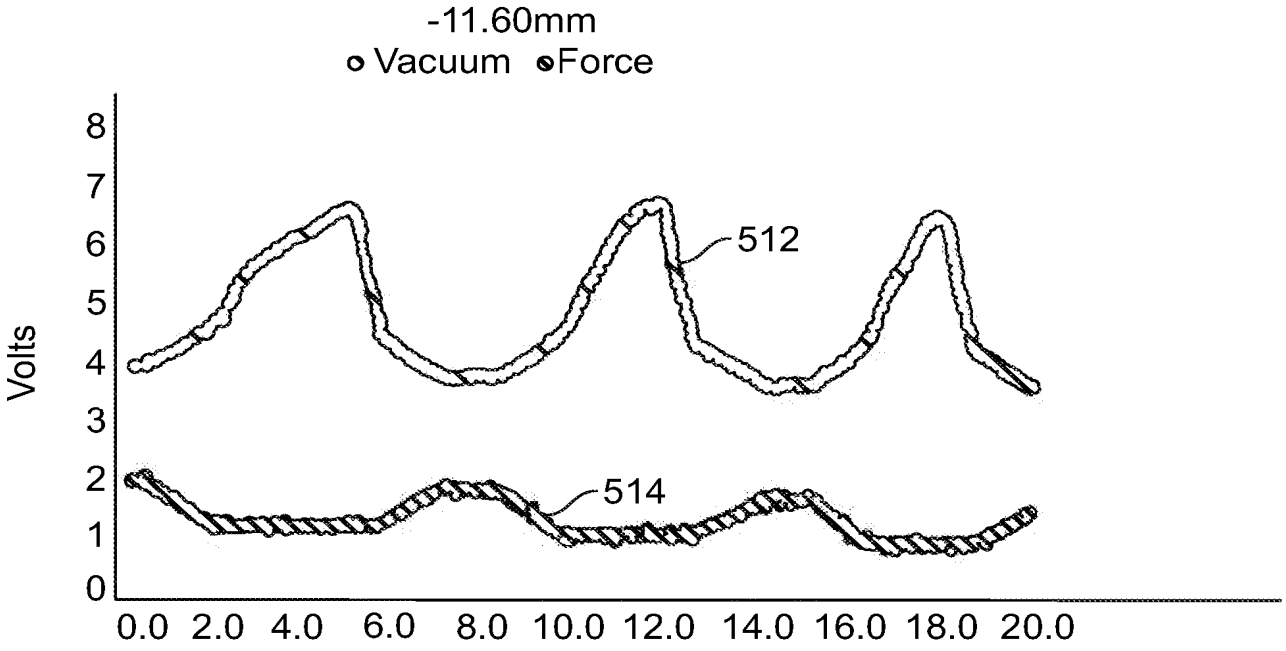

-11.60mm
Vacuum
Force
Volts
8
7
6
5
4
3
2
1
0
512
514
0.0 2.0 4.0 6.0 8.0 10.0 12.0 14.0 16.0 18.0 20.0

FIG. 52

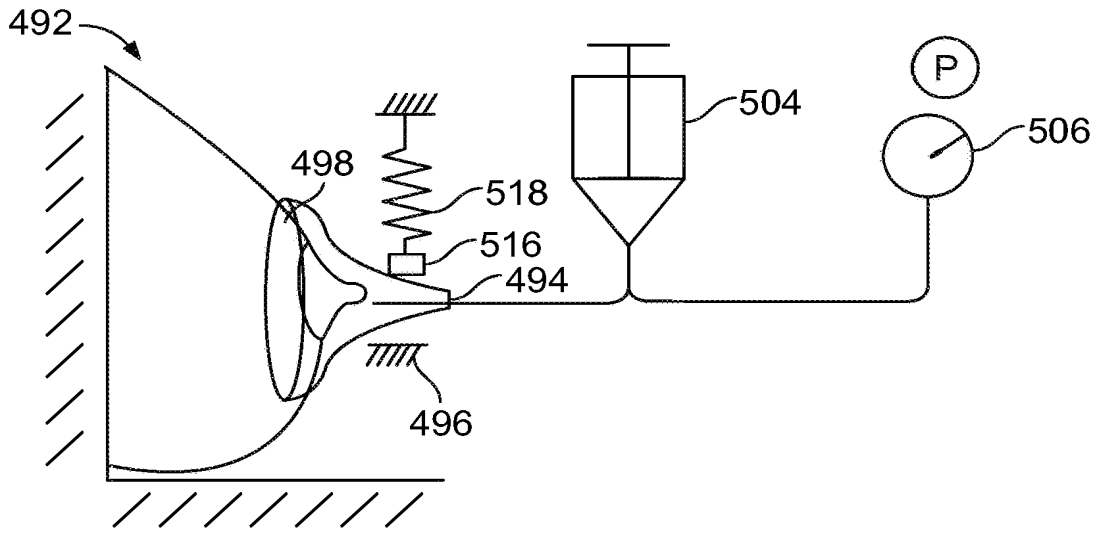

492
498
518
516
494
496
504
P
506

FIG. 54

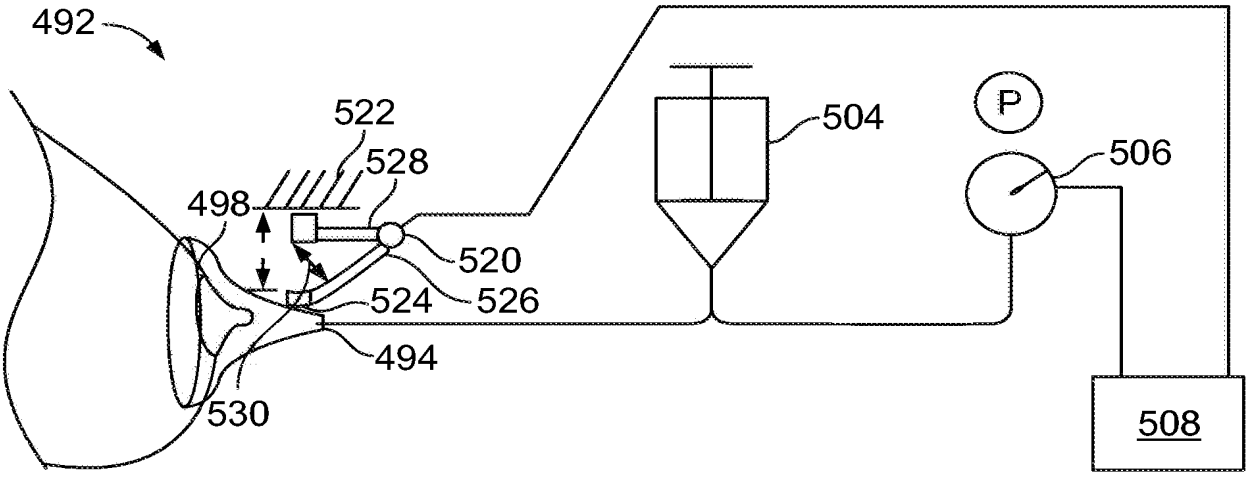

492
522
528
498
520
524
526
494
530
504
P
506
508

FIG. 55

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 2015/041285

A. CLASSIFICATION OF SUBJECT MATTER

A61M 1/06 *(2006.01)*

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M 1/06

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Espacenet, USPTO, CIPO, PatSearch, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6840918 B1 (THE FIRST YEARS INC.) 11.01.2005, col. 3 lines 8-31, 49-54, claims 1, 12, 19, fig. 1-3	1-3, 11-13
A	CN 201692384 U (HONGJI LIAO) 05.01.2011	1-3, 11-13
A	US 5810772 A (ANTON NIEDERBERGER) 22.09.1998	1-3, 11-13

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 September 2015 (24.09.2015)	01 October 2015 (01.10.2015)

Name and mailing address of the ISA/RU:	Authorized officer
Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37	E. Nosova Telephone No. (495) 531-64-81

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 2015/041285

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 4-10, 14-31
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**04/17/2024 05:03:54 PM Z ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	65131167	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 25

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2024-04-17-Transmittal-Form-sIDS-4944-0120006.pdf	1	Miscellaneous Incoming Letter	166 KB
2024-04-17-sIDS-Pleading-4944-0120006.pdf	2	Letter specifying the conditions for filing under 37 CFR 1.97	99 KB
2024-04-17-sIDS-SB08-4944-0120006.pdf	4	Information Disclosure Statement (IDS) Form (SB08)	170 KB
Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.			
FOR_1_CN2452494Y.pdf	15	Foreign Reference	535 KB

FOR_2_EP3299043A1.pdf	25	Foreign Reference	282 KB
FOR_3_WO9000413A1.pdf	38	Foreign Reference	805 KB
FOR_4_WO02102437A2.pdf	61	Foreign Reference	1298 KB
FOR_5_WO2008137678A1.pdf	52	Foreign Reference	842 KB
FOR_6_WO2016014494A1.pdf	110	Foreign Reference	1380 KB
FOR_7_WO2017139437A1.pdf	77	Foreign Reference	1621 KB
FOR_8_WO2018054758A1.pdf	25	Foreign Reference	313 KB
FOR_9_WO2019080995A1.pdf	129	Foreign Reference	2315 KB
NPL_1_Rule 71-3-Amended-Cl.pdf	4	Non Patent Literature	23 KB
NPL_2_AAP.pdf	5	Non Patent Literature	75 KB
NPL_3_Courage.pdf	17	Non Patent Literature	350 KB
NPL_4_GB201709566.2-Priority-document1.pdf	44	Non Patent Literature	1144 KB
NPL_5_GB201709564.7-Priority-document2.pdf	24	Non Patent Literature	287 KB
NPL_6_GB201709561.3-Priority-document3.pdf	24	Non Patent Literature	476 KB
NPL_7_GB201809036.5-Priority-document4.pdf	169	Non Patent Literature	2876 KB

NPL_8_Illinois-Nursing-Mothers-Act.pdf	2	Non Patent Literature	45 KB
NPL_9_Silicone-Rubber-Complete-Guide.pdf	4	Non Patent Literature	130 KB
NPL_10_Rule71-3-Reply.pdf	1	Non Patent Literature	15 KB
NPL_11_British-Columbia.pdf	2	Non Patent Literature	29 KB
NPL_12_How-to-choose.pdf	8	Non Patent Literature	425 KB
NPL_13_Wyatt.pdf	6	Non Patent Literature	97 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2024-04-17-Transmittal-Form-sIDS-4944-0120006.pdf	5A7585C535166FA515819BDA7C3451F31BA729C91D8D6F8AF20CB08DDF43D2534B7CCB05B1E9F526F7839C9D0252C89BA1FA9A9CDEC282F5AC2D8F04FFCBBCA7
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FOR_2_EP3299043A1.pdf	C99586E31A5E3E532EEE39AE8547829B99B65392F7A1617902DAA70F69FEB2DB9C091BAC50AF6BE2A68BBE6228575B86C07B7A98301BBFE00AAFE05F9210A677

FOR_3_WO9000413A1.pdf	88BFA504C57FB57563F031FE434AEB161AA7803971339A87A08D66569D51CF9A09B15D20D241B32404C8C1BF8D2108713E122120341209B30050B8A018AA3A56
FOR_4_WO02102437A2.pdf	CE2825089841355E044013CCA2F84FD3E053A4C2896307137F8714295E1D7D2D3007BDC817983C42ACE46B9581D162753A4CEC0A445DE88B24EFBCBED302B8C8
FOR_5_WO2008137678A1.pdf	F797128173E3B3AADB6101EDB6A07BED6F0BB8E8860116B0C8BCE9BFC18BFA8137B061BCF959A3361BD4CA2B428634A86616680BCEB395541C1AD52D89B65D8D
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DESCRIPTION EP3299043A1

10 TECHNICAL FIELD

[0001]

14 The present invention relates to a breast shield unit of a breast pump for pumping out human breast milk and a valve head of such a breast shield unit.

16 STATE OF THE ART

[0002]

20 To pump human breast milk, a breast shield is placed on the mother's breast, which is connected to a vacuum pump in order to apply a cyclically varying negative pressure to the breast. The pumped milk passes through a milk duct from the breast shield into a milk collection container. In order to keep the dead volume as small as possible when pumping, a milk channel from the breast shield to the milk collecting container is usually provided with a check valve, which opens to allow the pumped milk to enter the milk collecting container. This check valve is preferably arranged on an adapter which connects the breast shield to the milk collection container and usually also the breast shield to the vacuum pump or to a vacuum hose leading to the vacuum pump. The check valve can be arranged on a valve head, which is permanently or detachably connected to the adapter, also called a coupling part.

[0003]

33 Such a device is known, for example, from WO 2014/161099 A1.

34 The breast shield unit described there has a flow sensor which detects the change in a valve flap of the check valve, so that conclusions can be drawn about the flow of milk from the breast shield into the milk collection container.

[0004]

US 2016/0082166 A1 discloses an adapter with a sensor for detecting milk production, the sensor communicating via a wireless connection with a mobile data receiver or with the breast pump.

[0005]

WO 2006/003655 A1 shows a nipple shield which is placed on the mother's breast while breastfeeding a baby.

This nipple shield is equipped with a sensor that measures the volume of milk emerging from the milk.

[0006]

WO 2009/081313 A1 discloses a breast shield with at least one sensor for optimizing and personalizing the pumping process.

[0007]

These breast shield units are relatively complex and therefore cost-intensive to construct.

Since the breast shields and milk collection containers can or may often only be used once or a few times, they should be able to be manufactured as cost-effectively as possible and/or they should be easy to clean.

PRESENTATION OF THE INVENTION

[0008]

It is therefore an object of the invention to create a breast shield unit that is as cost-effective as possible, but which still allows the amount of milk pumped out to be recorded.

[0009]

This task is solved by a breast shield unit and a valve head with the features of patent claim 1 or 15.

[0010]

The breast shield unit according to the invention of a breast pump for pumping out human breast milk has a breast shield for resting on a mother's breast, a milk collection container for receiving pumped breast milk, an adapter for connecting the breast shield to the milk collection container and a valve head.

80 A milk channel extends from the breast shield through the adapter and through the valve head into the milk collection container.

82 The valve head has a valve which closes and opens the milk channel during pumping, with a fill level sensor being arranged in the valve head to measure a fill level of the milk collecting container.

[0011]

88 Since the fill level sensor is arranged in the valve head, the breast shield, the adapter and the milk collection container can be designed cost-effectively.

90 In particular, standard parts can be used.

91 It is also advantageous that the valve head can be designed in such a way that it can be used as an accessory in existing breast shield units. This makes it unnecessary to redesign known breast shield units.

[0012]

97 The milk collecting container is preferably designed to be rigid or semi-rigid.

98 It is preferably a milk bottle, which can be closed airtight with a lid after removing the valve head, the adapter and the breast shield. Preferably, the same bottle can be used together with a teat to be attached during use as a feeding bottle for administering breast milk to an infant.

[0013]

104 By measuring the level in the milk collection container, an exact measure of the breast milk actually available is obtained.

106 The measurement is preferably carried out during pumping. The fill level information is preferably updated promptly during pumping.

[0014]

111 The measurement data can be forwarded to an evaluation unit and/or a controller and/or a display of the breast pump as raw data or as data that has already been evaluated using an electronic unit integrated in the valve head.

114 In a simple embodiment, the breast pump simply displays this data. In other embodiments, the data is used additionally or alternatively for current or later control of the pump, e.g. B. to automatically switch from a stimulation to an expression mode or vice versa. In further embodiments, the data is used alternatively or in addition to automatically changing the pumping parameters or the patterns of the vacuum curves, whereby this is also carried out for the current and/or for a later pumping process, depending on the embodiment.

[0015]

123 The raw data and/or the evaluated data can also be sent to other recipients, for example to a smart device such as a smartphone or to another personal device belonging to the mother.

125 This makes it easier for her to record the level, even if she cannot see the milk collection container. In addition, the data can be transferred directly to the Internet, for example to a cloud, so that it is also available to third parties.

[0016]

131 Thanks to the level measurement, the volume of milk pumped out can be determined.

132 By deriving the volume signal, the milk flow can also be detected.

[0017]

136 Preferably, the fill level sensor is a distance sensor for measuring a distance from a surface of the pumped breast milk located in the milk collection container, i.e. the pool of milk located in the container.

139 In this way, the filling level can be measured in a simple manner, without the container itself having to be equipped with a filling level sensor and without having to contact the milk using mechanical means.

[0018]

145 A transit time sensor, also called a TOF sensor (time of flight sensor), is particularly suitable as a fill level sensor.

147 It has been shown that such TOF sensors are suitable for measuring the level of milk, although they are unsuitable for measuring the level of water, for example.

[0019]

152 The distance sensor, in particular the TOF sensor, allows a distance measurement from the sensor to the filling level within the milk collection container.

154 If the geometry of the milk collection container is known, preferably if the position angle of the milk collection container in three-dimensional space is also known, the fill level and thus the milk volume can be calculated.

[0020]

160 If a TOF sensor is used, an optical connection from the sensor to the opposite bottom of the milk collection container is necessary.

162 Preferably, the TOF sensor is positioned so that it is located on a longitudinal central axis of the milk collection container. This longitudinal central axis preferably forms an axis of rotational

symmetry of the milk collecting container.

[0021]

168 In a simple embodiment, only the fill level sensor is arranged in the valve head, which measures the fill level of the milk in the container as a parameter.

170 However, there is preferably at least one additional sensor in the valve head, preferably two or more additional sensors for measuring further parameters.

[0022]

175 Such an additional sensor is, for example, a flow sensor that measures the flow through the valve.

177 This flow sensor is, for example, an optical sensor which detects a deflection of a valve flap of the valve. The sensor is preferably a light barrier which detects the position of the valve flap. For this purpose, a protruding wing is preferably arranged on the valve flap, which penetrates the light path of the light barrier. Such a flow sensor is disclosed, for example, in WO 2014/161099.

[0023]

185 This additional measurement of the flow enables the level measurement to be corrected by the level sensor, especially when there are only small volumes of milk in the milk collection container.

188 This flow sensor can also be used during movements of the milk collection container to correct or completely replace the measurements of the fill level sensor, which is inaccurate during this period. Furthermore, this flow sensor can be used as a control device that determines whether the valve has opened at all or how often and/or when it opens. This information can be used to control the level sensor. For example, there is no need to measure the level if the valve has not opened and therefore no new milk has entered the milk collection container.

[0024]

197 Alternatively or additionally, a position sensor is preferably present as a further sensor, which detects the position of the milk collecting container in three-dimensional space and thus its tilt position in three-dimensional space.

200 An acceleration sensor is particularly suitable as a position sensor. The data from the position sensor are preferably used to compensate for the signals from the fill level sensor when the milk collecting container is tilted. The position sensor is preferably additionally used to determine whether the milk collecting container 5 is actually in a position to ensure a meaningful level measurement.

[0025]

208 The fill level sensor and at least the position sensor, preferably also all other sensors, are preferably arranged in a fixed position relative to one another in the valve head.

[0026]

213 The signals, also called raw data, from the fill level sensor and, if present, from the at least one further sensor, are preferably forwarded directly to external units, such as, for example, to an evaluation and control unit of the breast pump or to another external evaluation unit.

[0027]

219 However, an electronic unit for processing the signals from the fill level sensor is preferably arranged in the valve head.

221 This internal electronic unit preferably also processes the signals from at least one further sensor, if present.

[0028]

226 Preferably, the electronic unit is designed to exchange data with at least one of the following units: breast pump, information technology-equipped “smart device” such as a smartphone; external data processing unit such as personal computers; Cloud; Internet, Internet access unit.

[0029]

233 For easy use of the valve head, it is preferably designed to be wireless to the outside and plugless in terms of electronic plugs.

235 This also makes cleaning easier and allows the valve head to be reused multiple times.

[0030]

239 In one embodiment, the valve head is an integral part of the adapter.

240 In this case, the entire adapter can be designed as a valve head, i.e. the further sensors can be arranged distributed over the adapter and do not have to be located adjacent to the connection to the milk collecting container.

[0031]

246 In another embodiment, the valve head can be detachably connected to the adapter and/or the milk collection container.

248 This embodiment is particularly suitable as a retrofit kit.

[0032]

252 Preferably, the fill level sensor and, if present, the at least one further sensor and, if also present, the electronic unit are protected against the ingress of liquid.

254 The valve head is preferably dishwasher-safe.

[0033]

258 Further embodiments are specified in the dependent claims.

259 BRIEF DESCRIPTION OF THE DRAWINGS

[0034]

263 A preferred embodiment of the invention is described below with reference to the drawings, which serve only for explanation and are not to be interpreted in a restrictive manner.

265 Shown in the drawings:

266 Figure 1

267 a schematic representation of a breast shield unit according to the invention when placed on a mother's breast and

269 Figure 2

270 a schematic representation of the breast shield unit according to Figure 1 in communication with external units.

272 DESCRIPTION OF PREFERRED EMBODIMENTS

[0035]

276 A breast shield unit according to the invention is shown in Figure 1.

277 It has a breast shield 1 for receiving a mother's breast B, in particular the nipple.

278 The breast shield 1 is firmly or preferably detachably connected to an adapter 2, also called a coupling part.

280 The adapter 2 can be connected directly to a manual or electric motor-operated breast pump.

281 As shown here, it is preferably connected to the breast pump via a vacuum line 3, in particular via a silicone hose.

283 The breast pump is shown in Figure 2 and provided with the reference number 30 there.

[0036]

287 The adapter has an interior 20, which forms part of a milk channel from the breast shield 1 to a milk collecting container 5.

289 The milk collecting container 5 is releasably attached to a connecting piece 21 of the adapter 2.

[0037]

293 A valve head 4 is fixedly or detachably arranged on the adapter 2, the valve head 4 preferably being fixed in position relative to the adapter 2.

295 For example, the valve head 4 is formed in one piece with the adapter 2 or can be connected to it via a plug or screw connection.

[0038]

300 The adapter 2 and the valve head 4 are preferably made of a rigid plastic.

301 The milk collecting container 5 is preferably designed to be rigid or semi-rigid.

302 The milk collecting container 5 is also preferably made of plastic.

303 It can be transparent, semi-transparent or opaque.

[0039]

307 The valve head 4 preferably projects into the milk collecting container 5.

308 The valve head 4 has a check valve.

309 In this exemplary embodiment, the valve has a valve flap 40 articulated on one side.

310 The reference number 40 'designates the valve flap in the open position, the reference number 40 in the closed position.

[0040]

315 The path of the pumped milk is shown in Figure 1 by individual milk drops.

316 The milk emerging from the mother's breast B is designated by the reference symbol a, the milk flowing into the valve head 4, which usually falls, is designated by b, the milk collecting in front of the closed valve flap 40 is designated by c and the milk that finally reaches the milk collecting container 5 is designated by d.

320 The milk lake in the milk collecting container 5, i.e. the milk that has already been collected, is provided with the reference number e.

322 Depending on the embodiment, the valve flap 40 opens due to the prevailing pressure conditions during each suction cycle or only when enough milk c has accumulated in front of the flap to open it.

325 Other ways of opening the valve are also possible.

[0041]

329 In the area of the valve flap 40 there is preferably a flow sensor 8, here an optical sensor designed as a light barrier.

331 In the schematic representation according to Figure 1, it appears to be floating within the milk

collecting container 5.

333 However, it is also attached to the valve head 4.

[0042]

337 The flow sensor 8 measures the opening angle of the valve flap 40.

338 The detection area of the flow sensor 8, i.e. the light path, is provided with the reference number 80 in Figure 1.

340 The opening angle of the valve flap 40 is approximately proportional to the amount of milk "flowing out" d.

342 In order to optimize the measurement accuracy, the opening angle of the valve flap 40 is preferably scanned with at least 30 measurements/sec.

344 As mentioned at the beginning, this measurement signal is used to correct the measurement of the fill level sensor described below, especially for small fill heights.

346 This sensor can also be used to determine whether and when the valve flap 40 has opened.

[0043]

350 A fill level sensor 6 is arranged in an electronics area 42 of the valve head 4 that is separate from the milk channel.

352 The electronics area 42 is preferably designed as a closed chamber.

353 The separation from the rest of the valve head can take place, for example, via a partition 41.

354 If this is designed at an angle, it also facilitates the flow of milk to the valve flap 40.

[0044]

358 The fill level sensor 6 has a detection area 60, which is directed towards the opposite bottom of the milk collecting container 5.

360 The fill level sensor 6 is therefore preferably arranged on the lower end face of the valve head 4.

362 The fill level sensor 6 is preferably located on the longitudinal central axis of the milk collecting container 5, which preferably simultaneously forms the rotational symmetry axis R of the milk collecting container 5.

365 The fill level sensor 6 is preferably a distance sensor, preferably an optical distance sensor and even more preferably a TOF sensor (time of flight sensor).

[0045]

370 The TOF sensor measures a distance from the sensor surface to the milk surface.

371 This distance is converted into volume by a microcontroller of an electronic unit 9, taking into account the bottle geometry.

373 The radiation and thus the detection area 60 of the TOF sensor is usually conical or collimated.

[0046]

377 A position sensor 7, here a motion sensor, is preferably also arranged in the electronics area 42.

379 This position sensor 7 measures the movement or tilting position of the valve head 4 and thus of the milk collecting container 5 connected to it via the adapter 2.

381 The signals or data are delivered to the above-mentioned electronic unit 9, in particular the same microcontroller.

383 They serve to compensate for the signals from the fill level sensor 6 when the milk collecting container 5 is tilted and thus increase the accuracy of the measurement.

385 The tilt position is designated in Figure 1 with a double arrow and the reference symbol P.

[0047]

389 The level sensor 6 and the position sensor 7 are arranged in a fixed position relative to one another; i.e. if one sensor gets into a tilted position and/or is moved, the same applies to the other sensor.

392 The same preferably also applies to the flow sensor 8.

393 The milk collecting container 5 is also arranged in a fixed position relative to the fill level sensor 6 and, if present, to the position sensor 7.

395 This is done via the corresponding connection with the adapter 2 and the corresponding connection between the adapter 2 and the valve head 4.

[0048]

400 The above-mentioned electronics unit 9 is preferably also arranged in the electronics area 42 of the valve head 4.

402 It preferably has an energy supply integrated in the valve head 4, in particular an energy storage device.

404 Preferably no cables or plug connections lead to the outside.

405 The data transfer from the electronics unit 9 to the outside and, if available, also from the outside to the electronics unit 9, preferably takes place wirelessly.

407 The energy transmission is preferably also carried out wirelessly.

408 The electronics area 42 is preferably sealed off from the outside in a liquid-tight manner.

[0049]

412 2 shows various communication paths 90 of the breast shield unit according to the invention with external information storage and/or information processing units.

414 The measured values provide the mother, lactation consultants or other experts with information about the amount of milk pumped.

416 Since the mother cannot necessarily see the milk collection container 5 while pumping, it is possible for her to have this fill level displayed on a display of the breast pump 30, on a smart device SD, such as her smartphone or tablet, or on another suitable device .

419 In addition, this data can be made available to the Internet via an Internet access unit I without any further action on the part of the mother.

421 For example, they can be stored in a suitable cloud C or transmitted to another unit OD, such as a personal computer.

423 These measured fill level curves can be used to optimize pumping parameters or measurement algorithms at the same time or later.

425 Pumping parameters include, for example, vacuum level and pumping frequency, duration of a stimulation program (let-down) of the pump before an automatic or manual switch to the expressive, i.e. normal pumping process, and the like.

[0050]

431 The breast shield unit according to the invention and the valve head according to the invention enable filling level measurement without structural changes to the breast shield and milk collection container.

434 They also enable data exchange with external information storage and/or information processing units.

436 REFERENCE SYMBOL LIST

1

440 breast shield

441 9

442 Electronics unit

2

446 adapter

447 90

448 Way of communication

449 20

450 inner space

451 21

452 Connection piece

453 b

454 mother's breast

3

458 Vacuum line
459 a
460 milk emerging from the mother's breast
461 30
462 breast pump
463 b
464 Milk falling into the valve head

4
468 Valve head
469 c
470 Milk collecting in the valve head
471 40
472 valve flap
473 40'
474 Valve flap in open position
475 d
476 emerging from the valve head
477 41
478 partition wall
479 milk
480 42
481 Electronics area
482 e
483 Milk collected in the milk collection container

5
487 Milk collection container
488 P
489 Rotating position of the milk collection container in the room

6
493 Level sensor
494 60
495 Detection range of the level sensor
496 I
497 Internet access unit
498 SD
499 Smart device

7

503 Position sensor

504 C

505 Cloud

506 O.D

507 Other units

8

511 Flow sensor

512 80

513 Flow sensor detection range

514 R

515 Axis of rotation

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(54) BRUSTHAUBENEINHEIT

(57) Eine Brusthaubeneinheit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch weist eine Brusthaube (1) zur Auflage an eine Mutterbrust, einen Milchsammelbehälter (5) zur Aufnahme von abgepumpter Muttermilch, einen Adapter (2) zur Verbindung der Brusthaube (1) mit dem Milchsammelbehälter (5) sowie einen Ventilkopf (4) auf. Ein Milchkanal erstreckt sich von der Brusthaube (1) durch den Adapter (2) und den Ventilkopf (4) in den Milchsammelbehälter (5). Der Ventilkopf (4) weist ein Ventil (40) auf, welches den Milchkanal während des Abpumpens schliesst und öffnet, wobei im Ventilkopf (4) ein Füllstandsensor (6) angeordnet ist zur Messung eines Füllstandes des Milchsammelbehälters (5). Die erfindungsgemässe Brusthaubeneinheit ermöglicht eine Füllstandmessung ohne bauliche Veränderung der Brusthaube und Milchsammelbehälter. Sie ermöglicht zudem einen Datenaustausch mit externen Informationsspeicher- und/oder Informationsverarbeitungseinheiten.

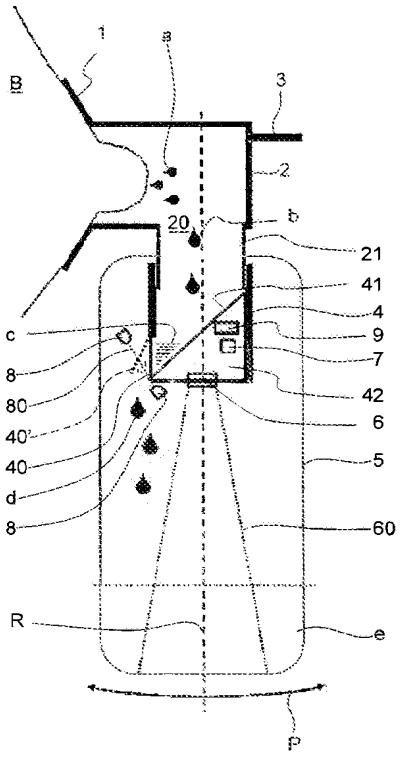

FIG. 1

EP 3 299 043 A1

Beschreibung

TECHNISCHES GEBIET

[0001] Die vorliegende Erfindung betrifft eine Brusthaubeneinheit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch sowie einen Ventilkopf einer derartigen Brusthaubeneinheit.

STAND DER TECHNIK

[0002] Zum Abpumpen von menschlicher Muttermilch wird auf die Mutterbrust eine Brusthaube aufgesetzt, welche mit einer Vakuumpumpe verbunden ist, um die Brust mit einem zyklisch variierenden Unterdruck zu beaufschlagen. Die abgepumpte Milch gelangt durch einen Milchkanal von der Brusthaube in einen Milchsammelbehälter. Um das Totvolumen beim Abpumpen möglichst klein zu halten, ist ein Milchkanal von der Brusthaube zum Milchsammelbehälter üblicherweise mit einem Rückschlagventil versehen, welches sich für den Einlass der abgepumpten Milch in den Milchsammelbehälter öffnet. Dieses Rückschlagventil ist vorzugsweise an einem Adapter angeordnet, welcher die Brusthaube mit dem Milchsammelbehälter und üblicherweise auch die Brusthaube mit der Vakuumpumpe oder mit einem zur Vakuumpumpe führenden Vakuumschlauch verbindet. Das Rückschlagventil kann auf einem Ventilkopf angeordnet sein, welcher fest oder lösbar mit dem Adapter, auch Kopplungsteil genannt, verbunden ist.

[0003] Eine derartige Vorrichtung ist beispielsweise aus WO 2014/161099 A1 bekannt. Die dort beschriebene Brusthaubeneinheit weist einen Durchflusssensor auf, welcher die Veränderung einer Ventilklappe des Rückschlagventils detektiert, so dass Rückschlüsse auf den Durchfluss der Milch von der Brusthaube in den Milchsammelbehälter gezogen werden können.

[0004] US 2016/0082166 A1 offenbart einen Adapter mit einem Sensor zur Detektion der Milchproduktion, wobei der Sensor über eine drahtlose Verbindung mit einem mobilen Datenempfänger oder mit der Milchpumpe kommuniziert.

[0005] WO 2006/003655 A1 zeigt ein Brusthütchen, welches während dem Stillen eines Babys auf die Mutterbrust aufgesetzt wird. Dieses Brusthütchen ist mit einem Sensor versehen, welches das aus der Milch austretende Milchvolumen misst.

[0006] WO 2009/081313 A1 offenbart eine Brusthaube mit mindestens einem Sensor zur Optimierung und Personalisierung des Pumpvorgangs.

[0007] Diese Brusthaubeneinheiten sind relativ aufwändig und deshalb kostenintensiv aufgebaut. Da die Brusthauben und Milchsammelbehälter oft jedoch nur einmal oder wenige Male verwendet werden können oder dürfen, sollten sie möglichst kostensparend gefertigt werden können und/oder sie sollten einfach zu reinigen sein.

DARSTELLUNG DER ERFINDUNG

[0008] Es ist deshalb eine Aufgabe der Erfindung, eine möglichst kostengünstige Brusthaubeneinheit zu schaffen, welche aber dennoch eine Erfassung der abgepumpten Milchmenge erlaubt.

[0009] Diese Aufgabe lösen eine Brusthaubeneinheit sowie ein Ventilkopf mit den Merkmalen des Patentanspruchs 1 bzw. 15.

[0010] Die erfindungsgemässe Brusthaubeneinheit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch weist eine Brusthaube zur Auflage an eine Mutterbrust, einen Milchsammelbehälter zur Aufnahme von abgepumpter Muttermilch, einen Adapter zur Verbindung der Brusthaube mit dem Milchsammelbehälter sowie einen Ventilkopf auf. Ein Milchkanal erstreckt sich von der Brusthaube durch den Adapter und durch den Ventilkopf in den Milchsammelbehälter. Der Ventilkopf weist ein Ventil auf, welches den Milchkanal während des Abpumpens schliesst und öffnet, wobei im Ventilkopf ein Füllstandsensor angeordnet ist zur Messung eines Füllstandes des Milchsammelbehälters.

[0011] Da der Füllstandsensor im Ventilkopf angeordnet ist, lassen sich die Brusthaube, der Adapter und der Milchsammelbehälter kostengünstig ausbilden. Es lassen sich insbesondere Standardteile verwenden. Vorteilhaft ist ferner, dass sich der Ventilkopf so ausbilden lässt, dass er in bereits vorhandenen Brusthaubeneinheiten als Zubehörteil verwendet werden kann. Ein Redesign bekannter Brusthaubeneinheiten erübrigt sich dadurch.

[0012] Vorzugsweise ist der Milchsammelbehälter steif oder halbsteif ausgebildet. Vorzugsweise ist er eine Milchflasche, welche nach dem Entfernen des Ventilkopfes, des Adapters und der Brusthaube mit einem Deckel luftdicht verschliessbar ist. Vorzugsweise lässt sich dieselbe Flasche gemeinsam mit einem im Gebrauch aufzusetzenden Sauger als Saugflasche zur Verabreichung der Muttermilch an einen Säugling verwenden.

[0013] Durch die Messung des Füllstandes im Milchsammelbehälter wird ein genaues Mass über die tatsächlich zur Verfügung stehende Muttermilch erhalten. Die Messung wird vorzugsweise während des Abpumpens durchgeführt. Die Angabe zum Füllstand wird vorzugsweise während des Abpumpens zeitnah aktualisiert.

[0014] Die Messdaten lassen sich als Rohdaten oder als mittels einer im Ventilkopf integrierten Elektronikeinheit bereits ausgewertete Daten an eine Auswerteeinheit und/oder eine Steuerung und/oder eine Anzeige der Brustpumpe

weiterleiten. In einer einfachen Ausführungsform zeigt die Brustpumpe diese Daten lediglich an. In anderen Ausführungsformen werden die Daten zusätzlich oder alternativ zur aktuellen oder späteren Steuerung der Pumpe verwendet, z.B. um automatisch von einem Stimulations- in einen Expressionsmodus oder umgekehrt zu schalten. In weiteren Ausführungsformen werden die Daten alternativ oder zusätzlich zur automatischen Veränderung der Pumpparameter oder der Muster der Vakuumkurven verwendet, wobei auch dies je nach Ausführungsform für den aktuellen und/oder für einen späteren Pumpvorgang durchgeführt wird.

[0015] Die Rohdaten und/oder die ausgewerteten Daten lassen sich auch an andere Empfänger senden, beispielsweise an ein Smart Device wie einem Smartphone oder an ein anderes persönliches Gerät der Mutter. Dies erleichtert ihr die Erfassung der Füllstandmenge, auch wenn sie den Milchsammelbehälter nicht sehen kann. Zudem lassen sich die Daten direkt dem Internet, beispielsweise einer Cloud, zuführen, um auch Dritten zur Verfügung zu stehen.

[0016] Dank der Messung der Füllstandmenge lässt sich das abgepumpte Milchvolumen bestimmen. Durch Ableitung des Volumensignals lässt sich auch der Milchfluss detektieren.

[0017] Vorzugsweise ist der Füllstandsensor ein Distanzsensor zur Messung einer Distanz von einer Oberfläche der im Milchsammelbehälter befindlichen abgepumpten Muttermilch, d.h. des im Behälter befindlichen Milchsees. Auf diese Weise lässt sich der Füllstand auf einfache Weise messen, ohne dass der Behälter selber mit einem Füllstandsensor versehen werden muss und ohne dass die Milch mit mechanischen Mitteln kontaktiert werden muss.

[0018] Als Füllstandsensor eignet sich insbesondere ein Laufzeitverfahren-Sensor, auch TOF Sensor genannt (Time of flight Sensor). Es hat sich gezeigt, dass sich derartige TOF Sensoren zur Füllstandmessung von Milch eignen, obwohl sie beispielsweise für eine Füllstandmessung von Wasser ungeeignet sind.

[0019] Der Distanzsensor, insbesondere der TOF Sensor, erlaubt eine Distanzmessung vom Sensor bis zur Füllstandhöhe innerhalb des Milchsammelbehälters. Sofern die Geometrie des Milchsammelbehälters bekannt ist, vorzugsweise wenn zusätzlich der Lagewinkel des Milchsammelbehälters im dreidimensionalen Raum bekannt ist, lässt sich damit der Füllstand und somit das Milchvolumen berechnen.

[0020] Wird ein TOF Sensor verwendet, so ist eine optische Verbindung vom Sensor zum gegenüberliegenden Boden des Milchsammelbehälters notwendig. Vorzugsweise ist der TOF Sensor so positioniert, dass er sich auf einer Längsmittelachse des Milchsammelbehälters befindet. Vorzugsweise bildet diese Längsmittelachse eine Rotationssymmetrieachse des Milchsammelbehälters.

[0021] In einer einfachen Ausführungsform ist im Ventilkopf lediglich der Füllstandsensor angeordnet, welcher als Parameter den Füllstand der Milch im Behälter misst. Vorzugsweise ist im Ventilkopf jedoch mindestens ein zusätzlicher Sensor, vorzugsweise sind zwei oder mehrere zusätzliche Sensoren zum Messen von weiteren Parametern vorhanden.

[0022] Ein derartiger zusätzlicher Sensor ist beispielweise ein Durchflusssensor, welcher den Durchfluss durch das Ventil misst. Dieser Durchflusssensor ist beispielsweise ein optischer Sensor, welcher eine Auslenkung einer Ventilklappe des Ventils detektiert. Vorzugsweise ist der Sensor eine Lichtschranke, welche die Position der Ventilklappe detektiert. Vorzugsweise ist auf der Ventilklappe hierfür ein vorstehender Flügel angeordnet, welcher den Lichtpfad der Lichtschranke durchdringt. Ein derartiger Durchflusssensor ist beispielsweise in WO 2014/161099 offenbart.

[0023] Diese zusätzliche Messung des Durchflusses ermöglicht eine Korrektur der Füllstandmessung durch den Füllstandsensor insbesondere wenn sich erst kleine Milchvolumen im Milchsammelbehälter befinden. Auch lässt sich dieser Durchflusssensor während Bewegungen des Milchsammelbehälters verwenden, um die Messungen des während dieses Zeitraums ungenauen Füllstandsensors zu korrigieren oder ganz zu ersetzen. Des Weiteren lässt sich dieser Durchflusssensor als Kontrollmittel einsetzen, welches feststellt, ob sich das Ventil überhaupt geöffnet hat bzw. wie oft und/oder wann es sich öffnet. Diese Angaben lassen sich zur Steuerung des Füllstandsensors verwenden. Beispielsweise erübrigt sich eine Füllstandmessung, wenn sich das Ventil nicht geöffnet hat und somit keine neue Milch in den Milchsammelbehälter gelangt ist.

[0024] Alternativ oder zusätzlich ist als weiterer Sensor vorzugsweise ein Positionssensor vorhanden, welcher die Lage des Milchsammelbehälters im dreidimensionalen Raum und somit seine Kipplage im dreidimensionalen Raum detektiert. Als Positionssensor eignet sich insbesondere ein Beschleunigungssensor. Die Daten des Positionssensors werden vorzugsweise verwendet, um die Signale des Füllstandsensors in Kipplagen des Milchsammelbehälters zu kompensieren. Der Positionssensor wird vorzugsweise zusätzlich dazu verwendet, um festzustellen, ob der Milchsammelbehälter 5 überhaupt in einer Position ist, um eine sinnvolle Füllstandmessung zu gewährleisten.

[0025] Der Füllstandsensor und mindestens der Positionssensor, vorzugsweise auch alle anderen weiteren Sensoren, sind vorzugsweise zueinander lagefixiert im Ventilkopf angeordnet.

[0026] Die Signale, auch Rohdaten genannt, des Füllstandsensors und falls vorhanden, des mindestens einen weiteren Sensors, werden vorzugsweise direkt an externe Einheiten weitergeleitet, wie beispielsweise an eine Auswerte- und Steuereinheit der Brustpumpe oder an eine andere externe Auswerteeinheit.

[0027] Vorzugsweise ist jedoch im Ventilkopf eine Elektronikeinheit zur Verarbeitung der Signale des Füllstandsensors angeordnet. Vorzugsweise verarbeitet diese interne Elektronikeinheit auch die Signale des mindestens einen weiteren Sensors, falls vorhanden.

[0028] Vorzugsweise ist die Elektronikeinheit zum Datenaustausch mit mindestens einer der folgenden Einheiten

ausgebildet: Brustpumpe, informationstechnisch aufgerüstetes "Smart Device" wie Smartphone; externe Datenverarbeitungseinheit wie Personal Computer; Cloud; Internet, Internetzugangseinheit.

[0029] Zur einfachen Verwendung des Ventilkopfes ist dieser vorzugsweise nach aussen kabellos und bezüglich elektronischen Steckern steckerlos ausgebildet. Dies erleichtert zudem die Reinigung und ermöglicht eine mehrfache Wiederverwendung des Ventilkopfes.

[0030] In einer Ausführungsform ist der Ventilkopf ein integraler Bestandteil des Adapters. In diesem Fall kann der gesamte Adapter als Ventilkopf ausgebildet sein, d.h. die weiteren Sensoren können über den Adapter verteilt angeordnet sein und müssen sich nicht benachbart zum Anschluss an den Milchsammelbehälter befinden.

[0031] In einer anderen Ausführungsform ist der Ventilkopf lösbar mit dem Adapter und/oder dem Milchsammelbehälter verbindbar. Diese Ausführungsform eignet sich insbesondere als Nachrüstset.

[0032] Vorzugsweise sind der Füllstandsensor und falls vorhanden der mindestens eine weitere Sensor sowie falls ebenfalls vorhanden die Elektronikeinheit gegen Eindringen von Flüssigkeit geschützt. Vorzugsweise ist der Ventilkopf spülmaschinenfest ausgebildet.

[0033] Weitere Ausführungsformen sind in den abhängigen Ansprüchen angegeben.

KURZE BESCHREIBUNG DER ZEICHNUNGEN

[0034] Eine bevorzugte Ausführungsform der Erfindung ist im Folgenden anhand der Zeichnungen beschrieben, die lediglich zur Erläuterung dienen und nicht einschränkend auszulegen sind. In den Zeichnungen zeigen:

Figur 1 eine schematische Darstellung einer erfindungsgemässen Brusthaubeneinheit bei Anlage auf einer Mutterbrust und

Figur 2 eine schematische Darstellung der Brusthaubeneinheit gemäss Figur 1 in Kommunikation mit externen Einheiten.

BESCHREIBUNG BEVORZUGTER AUSFÜHRUNGSFORMEN

[0035] In Figur 1 ist eine erfindungsgemässe Brusthaubeneinheit dargestellt. Sie weist eine Brusthaube 1 zur Aufnahme einer Mutterbrust B, insbesondere der Brustwarze, auf. Die Brusthaube 1 ist fest oder vorzugsweise lösbar mit einem Adapter 2, auch Kopplungsteil genannt, verbunden. Der Adapter 2 kann direkt mit einer manuell oder elektromotorisch betriebenen Brustpumpe verbunden sein. Vorzugsweise ist er, wie hier dargestellt, über eine Vakuumleitung 3, insbesondere über einen Silikonschlauch, mit der Brustpumpe verbunden. Die Brustpumpe ist in Figur 2 dargestellt und dort mit dem Bezugszeichen 30 versehen.

[0036] Der Adapter weist einen Innenraum 20 auf, welcher einen Teil eines Milchkanals von der Brusthaube 1 zu einem Milchsammelbehälter 5 bildet. Der Milchsammelbehälter 5 ist an einem Anschlussstutzen 21 des Adapters 2 lösbar befestigt.

[0037] Am Adapter 2 ist ein Ventilkopf 4 fest oder lösbar angeordnet, wobei der Ventilkopf 4 vorzugsweise lagefixiert zum Adapter 2 ist. Beispielsweise ist der Ventilkopf 4 gemeinsam einstückig mit dem Adapter 2 ausgebildet oder über eine Steck- oder Schraubverbindung mit ihm verbindbar.

[0038] Der Adapter 2 und der Ventilkopf 4 sind vorzugsweise aus einem steifen Kunststoff gefertigt. Der Milchsammelbehälter 5 ist vorzugsweise steif oder halbsteif ausgebildet. Vorzugsweise besteht auch der Milchsammelbehälter 5 aus Kunststoff. Er kann durchsichtig, halbdurchsichtig oder opak ausgebildet sein.

[0039] Der Ventilkopf 4 ragt vorzugsweise in den Milchsammelbehälter 5 hinein. Der Ventilkopf 4 weist ein Rückschlagventil auf. In diesem Ausführungsbeispiel weist das Ventil eine einseitig angelenkte Ventilklappe 40 auf. Das Bezugszeichen 40' bezeichnet die Ventilklappe in geöffneter Stellung, das Bezugszeichen 40 in geschlossener Position.

[0040] Der Weg der abgepumpten Milch ist in Figur 1 durch einzelne Milchtropfen dargestellt. Die aus der Mutterbrust B austretende Milch ist mit dem Bezugszeichen a bezeichnet, die in den Ventilkopf 4 fliessende, üblicherweise fallende Milch mit b, die sich vor der geschlossenen Ventilklappe 40 sammelnde Milch mit c und die schliesslich in den Milchsammelbehälter 5 gelangende Milch mit d. Der Milchsee im Milchsammelbehälter 5, also die bereits gesammelte Milch, ist mit dem Bezugszeichen e versehen. Je nach Ausführungsform öffnet die Ventilklappe 40 aufgrund der herrschenden Druckverhältnisse bei jedem Saugzyklus oder erst, wenn sich genügend Milch c vor der Klappe angesammelt hat, um diese zu öffnen. Andere Arten, das Ventil zu öffnen, sind auch möglich.

[0041] Im Bereich der Ventilklappe 40 ist vorzugsweise ein Durchflusssensor 8, hier ein als Lichtschranke ausgebildeter optischer Sensor vorhanden. In der schematischen Darstellung gemäss Figur 1 erscheint er innerhalb des Milchsammelbehälters 5 zu schweben. Er ist jedoch ebenfalls am Ventilkopf 4 befestigt.

[0042] Der Durchflusssensor 8 misst den Öffnungswinkel der Ventilklappe 40. Der Erfassungsbereich des Durchflusssensors 8, d.h. der Lichtpfad, ist in Figur 1 mit dem Bezugszeichen 80 versehen. Der Öffnungswinkel der Ventilklappe

40 ist in etwa proportional zur "abfliessenden" Milchmenge d. Um die Messgenauigkeit zu optimieren, wird der Öffnungswinkel der Ventilklappe 40 vorzugsweise mit mindestens 30 Messungen/sec abgetastet. Dieses Messsignal wird, wie eingangs erwähnt, zur Korrektur der Messung des nachfolgend beschriebenen Füllstandsensors verwendet, insbesondere bei kleinen Füllhöhen. Zudem lässt sich mittels dieses Sensors feststellen, ob und wann sich die Ventilklappe 40 geöffnet hat.

[0043] In einem von vom Milchkanal getrennten Elektronikbereich 42 des Ventilkopfes **4** ist ein Füllstandsensor 6 angeordnet. Der Elektronikbereich 42 ist vorzugsweise als geschlossene Kammer ausgebildet. Die Trennung vom restlichen Ventilkopf kann beispielsweise über eine Trennwand 41 erfolgen. Ist diese schräg ausgebildet, erleichtert sie zudem den Milchfluss zur Ventilklappe 40.

[0044] Der Füllstandsensor 6 weist einen Erfassungsbereich 60 auf, welcher zum gegenüberliegenden Boden des Milchsammelbehälters 5 hin gerichtet ist. Der Füllstandsensor 6 ist deshalb vorzugsweise an der unteren Stirnfläche des Ventilkopfes 4 angeordnet. Bevorzugterweise befindet sich der Füllstandsensor 6 auf der Längsmittelachse des Milchsammelbehälters 5, welche vorzugsweise gleichzeitig die Rotationssymmetrieachse R des Milchsammelbehälters 5 bildet. Der Füllstandsensor 6 ist vorzugsweise ein Distanzsensor, bevorzugt ein optischer Distanzsensor und noch bevorzugter ein TOF Sensor (Time of flight Sensor).

[0045] Der TOF Sensor misst eine Distanz von der Sensoroberfläche bis zur Milchoberfläche. Diese Distanz wird, unter Einbezug der Flaschengeometrie, von einem Mikrokontroller einer Elektronikeinheit 9 in Volumen umgerechnet. Die Abstrahlung und somit der Erfassungsbereich 60 des TOF Sensors ist üblicherweise konisch oder kollimiert.

[0046] Im Elektronikbereich 42 ist vorzugsweise zudem ein Positionssensor **7**, hier ein Bewegungssensor, angeordnet. Dieser Positionssensor **7** misst die Bewegung oder Kipplage des Ventilkopfes **4** und somit des mit diesem über den Adapter 2 verbundenen Milchsammelbehälters 5. Die Signale oder Daten werden an die oben genannte Elektronikeinheit 9, insbesondere demselben Mikrokontroller, geliefert. Sie dienen der Kompensation der Signale des Füllstandsensors 6 bei Kipplagen des Milchsammelbehälters 5 und erhöhen somit die Genauigkeit der Messung. Die Kipplage ist in Figur 1 mit einem Doppelpfeil und dem Bezugszeichen P bezeichnet.

[0047] Der Füllstandsensor 6 sowie der Positionssensor **7** sind zueinander lagefixiert angeordnet; d.h. gerät der eine Sensor in eine Kipplage und/oder wird er bewegt, so gilt gleiches für den anderen Sensor. Vorzugsweise gilt gleiches auch für den Durchflusssensor 8. Der Milchsammelbehälter 5 ist ebenfalls lagefixiert zum Füllstandsensor 6 und, falls vorhanden, zum Positionssensor **7** angeordnet. Dies erfolgt über die entsprechende Verbindung mit dem Adapter 2 und der entsprechenden Verbindung zwischen Adapter 2 und Ventilkopf 4.

[0048] Die oben genannte Elektronikeinheit 9 ist vorzugsweise ebenfalls im Elektronikbereich 42 des Ventilkopfes 4 angeordnet. Vorzugsweise verfügt sie über eine im Ventilkopf 4 integrierte Energieversorgung, insbesondere einen Energiespeicher. Vorzugsweise führen keine Kabel oder Steckverbindungen nach aussen. Der Datentransfer von der Elektronikeinheit 9 nach aussen und falls vorhanden, auch von aussen zur Elektronikeinheit 9, findet vorzugsweise drahtlos statt. Die Energieübertragung erfolgt vorzugsweise ebenfalls drahtlos. Der Elektronikbereich 42 ist vorzugsweise flüssigkeitsdicht nach aussen abgeschottet.

[0049] In Figur 2 sind verschiedene Kommunikationswege 90 der erfindungsgemässen Brusthaubeneinheit mit externen Informationsspeicher- und/oder Informationsverarbeitungs-Einheiten dargestellt. Die Messwerte geben der Mutter, Stillberaterinnen oder anderen Experten Auskunft über die abgepumpte Milchmenge. Da die Mutter den Milchsammelbehälter 5 während des Abpumpens nicht unbedingt sehen kann, wird es ihr ermöglicht, diese Füllstandmenge auf einem Display der Brustpumpe 30, auf einem Smart Device SD, wie beispielsweise ihr Smartphone oder ihr Tablet, oder auf einem anderen geeigneten Gerät anzeigen lassen. Zudem können diese Daten ohne weiteres Zutun der Mutter über eine Internetzugangseinheit I dem Internet zur Verfügung gestellt werden. Sie können beispielsweise in eine dafür geeignete Cloud C gespeichert werden oder einer anderen Einheit OD, wie zum Beispiel einem Personal Computer, übermittelt werden. Diese gemessenen Füllstandmengenverläufe lassen sich zur zeitgleichen oder späteren Optimierung von Abpumpparametern oder Messalgorithmen einsetzen. Abpumpparameter sind beispielsweise Vakuumhöhe und Pumpfrequenz, Dauer eines Stimulationsprogramms (let-down) der Pumpe vor einem automatischen oder manuellen Wechsel auf den expressiven, d.h. normalen Abpumpvorgang und ähnliches.

[0050] Die erfindungsgemässe Brusthaubeneinheit und der erfindungsgemässe Ventilkopf ermöglichen eine Füllstandmessung ohne bauliche Veränderung der Brusthaube und Milchsammelbehälter. Sie ermöglichen zudem einen Datenaustausch mit externen Informationsspeicher- und/oder Informationsverarbeitungseinheiten.

BEZUGSZEICHENLISTE

1	Brusthaube		
		9	Elektronikeinheit
2	Adapter	90	Kommunikationsweg
20	Innenraum		
21	Anschlussstutzen	B	Mutterbrust

(fortgesetzt)

3	Vakuumleitung	a	aus der Mutterbrust austretende Milch
30	Brustpumpe		
		b	in den Ventilkopf fallende Milch
4	Ventilkopf	c	im Ventilkopf sich sammelnde Milch
40	Ventilklappe		
40'	Ventilklappe in geöffneter Stellung	d	aus dem Ventilkopf austretende
41	Trennwand		Milch
42	Elektronikbereich	e	im Milchsammelbehälter gesammelte Milch
5	Milchsammelbehälter		
		P	Drehposition des Milchsammelbehälters im Raum
6	Füllstandsensor		
60	Erfassungsbereich des Füllstandsensors		
		I	Internetzugangseinheit
		SD	Smart Device
7	Positionssensor	C	Cloud
		OD	Andere Einheiten
8	Durchflusssensor		
80	Erfassungsbereich des Durchflusssensors	R	Rotationsachse

Patentansprüche

1. Brusthaubeneinheit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brusthaubeneinheit eine Brusthaube (1) zur Auflage an eine Mutterbrust, einen Milchsammelbehälter (5) zur Aufnahme von abgepumpter Muttermilch, einen Adapter (2) zur Verbindung der Brusthaube (1) mit dem Milchsammelbehälter (5) sowie einen Ventilkopf (4) aufweist, wobei sich ein Milchkanal von der Brusthaube (1) durch den Adapter (2) und den Ventilkopf (4) in den Milchsammelbehälter (5) erstreckt und wobei der Ventilkopf (4) ein Ventil (40) aufweist, welches den Milchkanal während des Abpumpens schliesst und öffnet, **dadurch gekennzeichnet, dass** im Ventilkopf (4) ein Füllstandsensor (6) angeordnet ist zur Messung eines Füllstandes des Milchsammelbehälters (5).

2. Brusthaubeneinheit nach Anspruch 1, wobei der Füllstandsensor (6) ein Distanzsensor zur Messung einer Distanz von einer Oberfläche der im Milchsammelbehälter (5) befindlichen abgepumpten Muttermilch, vorzugsweise ein Laufzeitverfahen-Sensor (Time of flight Sensor), ist.

3. Brusthaubeneinheit nach einem der Ansprüche 1 bis 2, wobei im Ventilkopf (4) mindestens ein weiterer Sensor (7, 8) angeordnet ist.

4. Brusthaubeneinheit nach Anspruch 3, wobei einer des mindestens einen weiteren Sensors ein Durchflusssensor (8) ist, welcher den Durchfluss durch das Ventil (40) misst.

5. Brusthaubeneinheit nach Anspruch 4, wobei der Durchflusssensor (8) ein optischer Sensor ist, welcher eine Auslenkung einer Ventilklappe (40) des Ventils detektiert.

6. Brusthaubeneinheit nach einem der Ansprüche 1 bis 5, wobei einer des mindestens einen weiteren Sensors ein Positionssensor (7) ist, welcher die Position des Milchsammelbehälters (7) im dreidimensionalen Raum und somit seine Schräglage im dreidimensionalen Raum detektiert.

7. Brusthaubeneinheit nach Anspruch 6, wobei der Positionssensor (7) ein Beschleunigungssensor ist.

8. Brusthaubeneinheit nach einem der Ansprüche 6 oder 7, wobei der Füllstandsensor (6) und der Positionssensor (7) zueinander lagefixiert im Ventilkopf (4) angeordnet sind.

9. Brusthaubeneinheit nach einem der Ansprüche 1 bis 8, wobei im Ventilkopf (4) eine Elektronikeinheit (9) zur Ver-

arbeitung von Signalen des Füllstandsensors (6) angeordnet ist.

10. Brusthaubeneinheit nach Anspruch 9 und mindestens einem der Ansprüche 4 bis 8, wobei die Elektronikeinheit (9) zur Verarbeitung von Signalen des mindestens einen weiteren Sensors (7, 8) ausgebildet ist.

11. Brusthaubeneinheit nach einem der Ansprüche 9 oder 10, wobei die Elektronikeinheit (9) zum Datenaustausch (91, 92, 93, 94, 95, 96, 97) mit mindestens einer der folgenden Einheiten ausgebildet ist: Brustpumpe (30), informationstechnisch aufgerüstetes "Smart Device" (SD) wie Smartphone, externe Datenverarbeitungseinheit wie Computer (OD), Cloud (C), Internet, Internetzugangseinheit (I).

12. Brusthaubeneinheit nach einem der Ansprüche 1 bis 11, wobei der Ventilkopf (4) nach aussen kabellos und bezüglich elektronischen Steckern steckerlos ausgebildet ist.

13. Brusthaubeneinheit nach einem der Ansprüche 1 bis 12, wobei der Ventilkopf (4) integraler Bestandteil des Adapters (2) ist.

14. Brusthaubeneinheit nach einem der Ansprüche 1 bis 13, wobei der Ventilkopf (4) lösbar mit dem Adapter (2) und/oder dem Milchsammelbehälter (5) verbindbar ist.

15. Ventilkopf einer Brusthaubeneinheit nach einem der Ansprüche 1 bis 14, wobei der Ventilkopf (4) ein Ventil (40) aufweist, welches den Milchkanal während des Abpumpens schliesst und öffnet, und wobei im Ventilkopf ein Füllstandsensor (6) angeordnet ist zur Messung eines Füllstandes des Milchsammelbehälters (5).

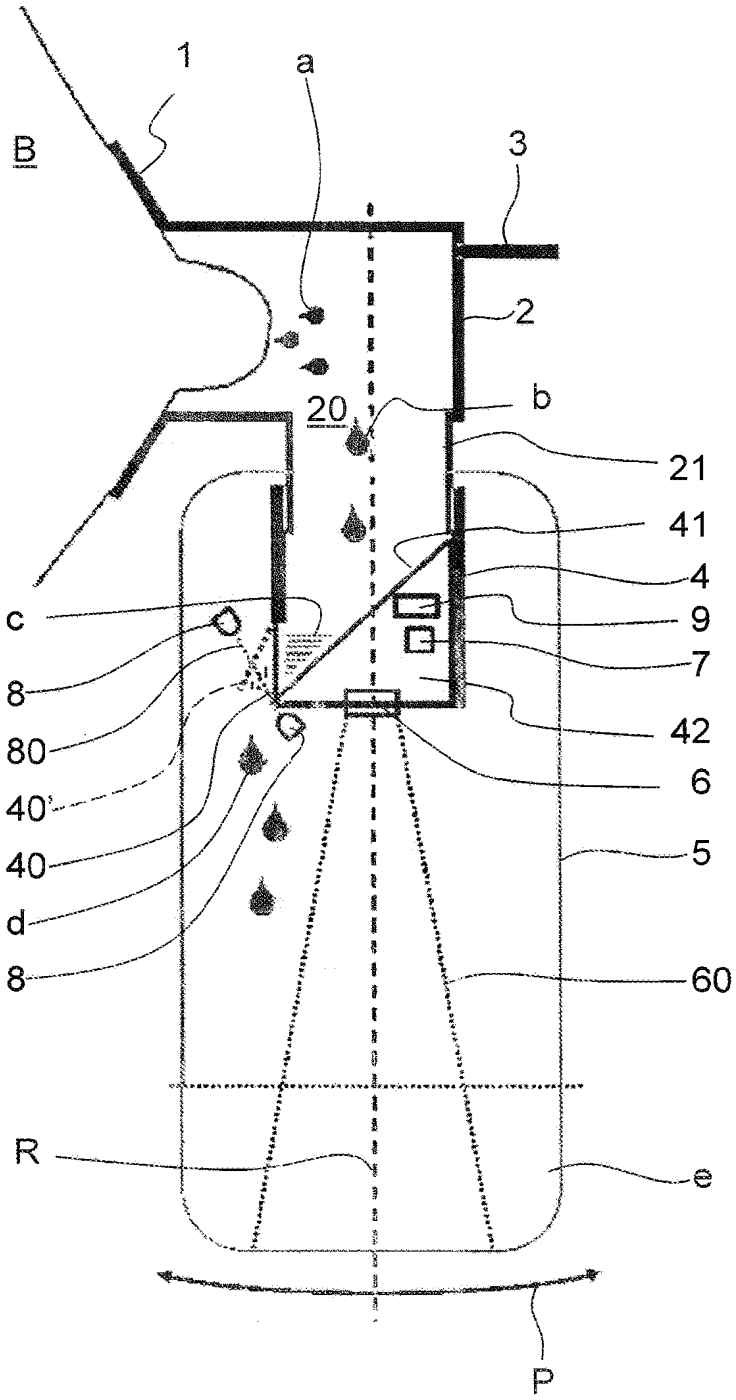

FIG. 1

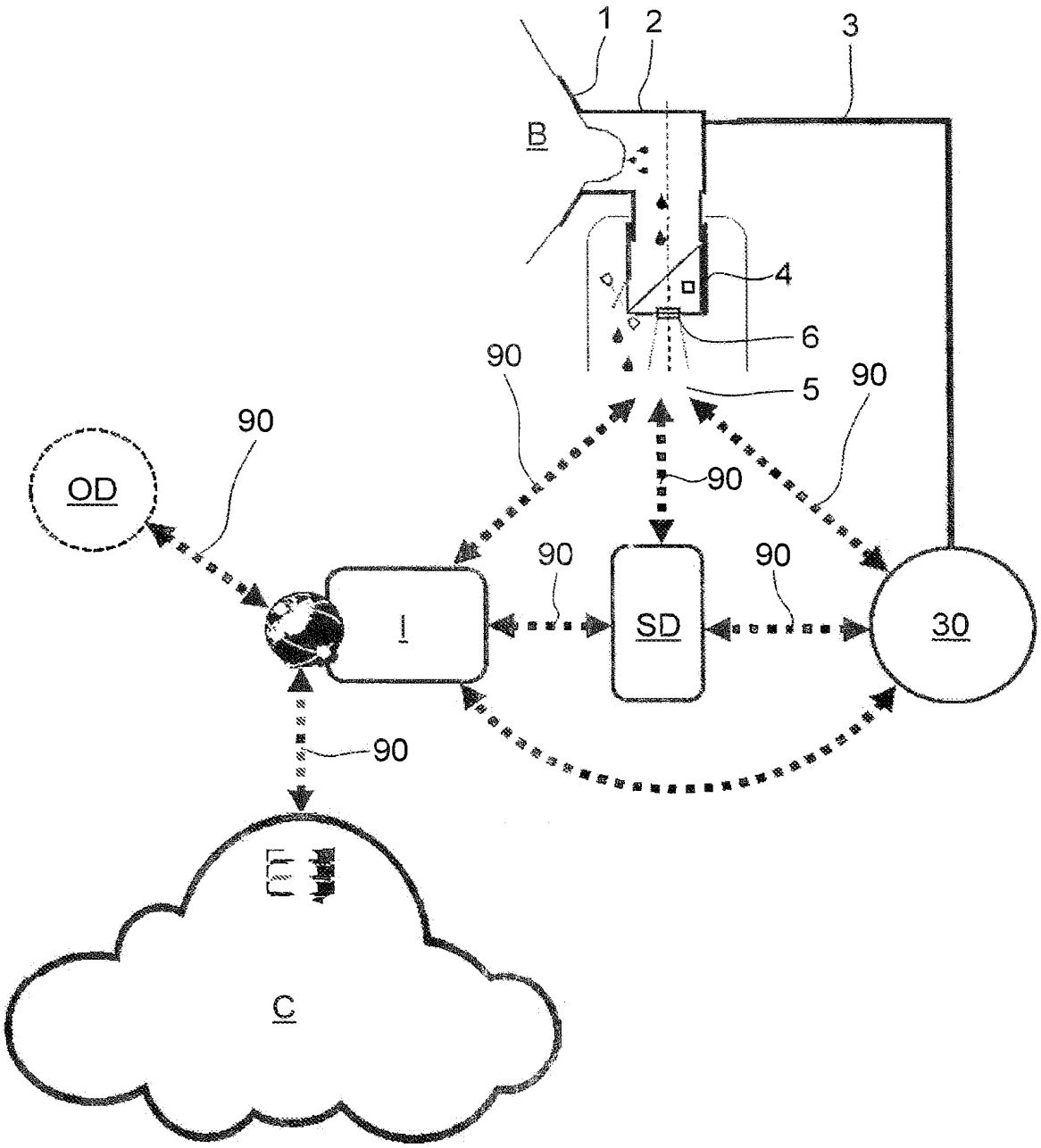

FIG. 2

Europäisches Patentamt
European Patent Office
Office européen des brevets

EUROPÄISCHER RECHERCHENBERICHT

Nummer der Anmeldung
EP 16 19 0122

EINSCHLÄGIGE DOKUMENTE

Kategorie	Kennzeichnung des Dokuments mit Angabe, soweit erforderlich, der maßgeblichen Teile	Betrifft Anspruch	KLASSIFIKATION DER ANMELDUNG (IPC)
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Der vorliegende Recherchenbericht wurde für alle Patentansprüche erstellt

Recherchenort	Abschlußdatum der Recherche	Prüfer
Den Haag	8. März 2017	Schlaug, Martin

KATEGORIE DER GENANNTEN DOKUMENTE

X : von besonderer Bedeutung allein betrachtet
Y : von besonderer Bedeutung in Verbindung mit einer anderen Veröffentlichung derselben Kategorie
A : technologischer Hintergrund
O : nichtschriftliche Offenbarung
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T : der Erfindung zugrunde liegende Theorien oder Grundsätze
E : älteres Patentdokument, das jedoch erst am oder nach dem Anmeldedatum veröffentlicht worden ist
D : in der Anmeldung angeführtes Dokument
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& : Mitglied der gleichen Patentfamilie, übereinstimmendes Dokument

EPO FORM 1503 03.82 (P04C03)

ANHANG ZUM EUROPÄISCHEN RECHERCHENBERICHT ÜBER DIE EUROPÄISCHE PATENTANMELDUNG NR. EP 16 19 0122

In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten europäischen Recherchenbericht angeführten Patentdokumente angegeben.
Die Angaben über die Familienmitglieder entsprechen dem Stand der Datei des Europäischen Patentamts am
Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

08-03-2017

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Für nähere Einzelheiten zu diesem Anhang : siehe Amtsblatt des Europäischen Patentamts, Nr.12/82

IN DER BESCHREIBUNG AUFGEFÜHRTE DOKUMENTE

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In der Beschreibung aufgeführte Patentdokumente

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Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 4

Complete if Known	
Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 2 of 4

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Application Number	17/181,057
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
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Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
	NPL1	Amended Claims in Response to Rule 71(3) (clean) regarding European Patent Application No. 18741597.1 to Positec Power Tools (Suzhou) Co. Ltd; dated February 20, 2024; 4 pages.	
	NPL2	Breastfeeding and the Use of Human Milk, American Academy of Pediatrics, Pediatrics, Vol. 100, No. 6, December 6, 1997; pp. 1035-1039.	
	NPL3	Courage, Katherine, "The Sucky History of the Breast Pump," Innovation, Smithsonian Magazine, September 12, 2022; 17 pages. Available at: https://www.smithsonianmag.com/innovation/sucky-history-of-the-breast-pump-180980653/	
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Sheet 3 of 4

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
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Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 4 of 4

Complete if Known	
Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Yangbeini Wang #800,005/	Date (YYYY-MM-DD)	2024-04-17
Name/Print	Yangbeini Wang	Registration Number	800,005

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

22122310.1

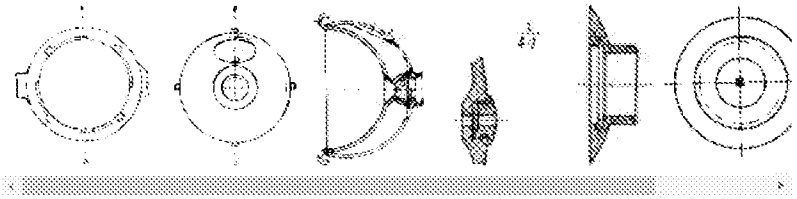
Patents CN2452494Y

Brassiere, combining/separation type multi-function mamma-care latex receiving apparatus

Abstract

The utility model relates to a special milk collection device for lactation women. The external shape of the utility model forms a brassiere shape. A body is optionally combined and detached with a frame. The body is a hollow hemisphere structure. The component parts of the body is respectively a milk loading device, an elastic rubber sheet, an air valve, a connecting cover, a rubber nipple, a nipple cover, etc., from interior to exterior. The utility model fundamentally solves the problem that the breasts of antepartum women have galactozemia (galactorrhea named as the traditional Chinese medicine) and milk expansion. The utility model has the advantages of portability, and milk collection and milk suction at any time, and also has many functions of beneficial milk secretion, recovery of breast shape, etc.

Images (7)



CN2452494Y

Claims

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Other languages: Chinese

Inventor: [redacted]

Current Assignee : Individual

Worldwide applications

2000 CN

Application CN 00214870 events

2000-05-23	Application filed by Individual
2000-05-23	Priority to CN 00214870
2001-10-10	Application granted
2001-10-10	Publication of CN2452494Y
2010-05-23	Anticipated expiration
Status	Expired - Fee Related

Info: Cited by (4), Legal events, Similar documents, Priority and Related Applications

External links: Espacenet, Global Dossier, Discuss

Claims (6)

Hide Dependent

1. medicated bra, the multi-functional mamma-care latex receiving apparatus of combining/separation type have an elastic sheet rubber and an air valve in body, it is characterized in that: body is common medicated bra shape; Body is connected and composed by milk receptacle, elastic sheet rubber, air valve, linking lid, pacify, milk skull and circular frame; Be connected lid and use with milk receptacle and milk skull and be threaded, elastic sheet rubber glue is attached on the milk receptacle, and air valve is embedded in the elastic sheet rubber, and the pacify lower end is pressed to be attached to and is connected in the lid, and that milk receptacle and circular frame use block is protruding, draw-in groove is connected.

2. the milk device that connects according to claim 1, it is characterized in that: the milk receptacle medial and lateral are semi-spherical shape, form central space, Porose in the middle of the medial wall, what link to each other with the hole is horn-like body and semicylinder, is identical shaped hole in it; The semicylinder front end is arranged with some apertures, and end has external screw thread; The circular periphery of milk receptacle is distributed with arc boss, with the groove in the corresponding circular frame; Milk receptacle is inboard with soft cloth or sponge.

3. the milk device that connects according to claim 1 is characterized in that: linking is covered the inboard and is a plane, scribbles one deck rubber around the plane, there is a screw centre, outside the screw and in the arc lateral wall space is arranged, a circular hole is arranged in the middle of the lateral wall, circular hole is outer for having externally threaded cylinder.

4. the milk device that connects according to claim 1 is characterized in that: the hatch frame of pacify is, the nipple crown center is out one or multi-channel osculum (cut rubber fill) by cutter.

5. the milk device that connects according to claim 1 is characterized in that: milk skull inwall is porose, and female thread is arranged in the hole, and the sealing of hole primary coat one deck is with rubber or fill up a sheet rubber

6. the milk device that connects according to claim 1 is characterized in that: milk receptacle and circular frame adopt and can close, from connected mode.

Description

Medicated bra, the multi-functional mamma-care latex receiving apparatus of combining/separation type

This utility model relates to a kind of milk device that connects, and what particularly relate to women breast-feeding their children connects the milk utensil.

" galactozemia " phenomenon of women breast-feeding their children (" Chinese medicine " claims " galactorrhea " again), it is not bright so far that it produces reason, The treatment aspect, Western medicine does not have specially good effect, and the middle medication phase is long; This phenomenon is seriously perplexing women's orthobiosis for a long time.To this, people do not have the fixed milk utensil that connects at all: things such as the bibulous paper of the usefulness that has, cloth,

sponge connect milk, and what have connects milk with vessel such as feeding bottle, teacups.Take above measure, though can solve " galactozemia " for the moment, inconvenience is arranged: connect milk with things such as paper, cloth, sponges, it is too little to connect the milk amount, can cause outer, garment to be soaked; Connect milk with vessel such as bottle, cups, should not be away from home or public situation.If be on duty, sleep, connect milk under the situation such as travelling, usually can be hard to guard against, make us in a dilemma.

As for the milk that expands, people's breast pump commonly used is handled now, and breast pump has alleviated many miseries really, but it should not public situation use, and can not in time suck or the like in sleep, has produced many unnecessary troubles.

The multiple undesirable condition that connects milk in processing, occurs in the problem that the sucks process at prior art, I have succeeded in developing medicated bra, the multi-functional mamma-care latex receiving apparatus of combining/separation type, not only fundamentally alleviated " galactozemia ", that the milk that expands is brought is painful and overcome all drawbacks of the prior art, and possesses multiple new beneficial functions.Its function is specific as follows:

(1) this utility model be a kind of women breast-feeding their children's of being specifically designed to breast " galactozemia ", the milk that expands connect the milk utensil.

(2) use of the present utility model is very convenient, and use next to the shin is fit to use under the situations such as sleep, work, travelling.

(3) connect milk in time, thoroughly.

(4) help the making full use of of secretion, nursing and milk of breast milk.

(5) suck rapidly, in time.

(6) protection breast, make breast comfortable.

(7) be of value to breast health, make its natural relaxation, can impel breast normal recovery and the prevention mastoptosis.

(8) give the aesthetic feeling of breast enlargement.

The purpose of this utility model is in order to scheme realization down.

The outward appearance of medicated bra, the multi-functional mamma-care latex receiving apparatus of combining/separation type and typical circular medicated bra are approximate, and main body is the front end breast, and appendage is for connecting circular frame and two elastic frenulums of main body.The combining of main body and framework adopted the bayonet socket mode that is rotatably connected, can make main body with people's liberty in conjunction with separate, thereby reach purpose easy to use.

Connecing milk device main body outwards is made up of six parts such as milk receptacle, elastic sheet rubber, air valve, linking lid, pacify, milk skulls successively from the lining.Wherein, milk receptacle, milk skull are threaded with the use that is connected lid, and elastic sheet rubber glue is attached on the milk receptacle, and air valve is embedded in the elastic sheet rubber, and the pacify lower end is pressed to be attached to and is connected in the lid.

Milk receptacle is close to breast, and inside and outside sidewall is hemispherical design, forms intermediate space, spills or the milk of sucking-off in order to Sheng.In the middle of its medial wall a hole is arranged, so that nipple reaches in the milk receptacle, what the hole linked to each other therewith is to be horn-like cylinder, and what bulk phase connected therewith is semicylinder.Horn-like body is the hole identical with profile with semicylinder inside.Evenly distributed on the semicylinder front end arcwall have some apertures, so that milk flows at the bottom of the device, end has external screw thread.One round and elastic sheet rubber is arranged at the top, lateral wall of milk receptacle, and the shell fragment middle and lower part has a circular air valve again, and this structure is in order to suck.Four semicircle boss that join with circular frame of the circular periphery uniform distribution of milk receptacle are with the groove in the corresponding circular frame.The milk receptacle inboard is close to breast portion and is stained with one deck sponge or soft cloth, guarantees to use comfortable.

Be connected lid in order to be connected milk receptacle and nipple and milk skull.Its inboard is a plane, and the plane periphery scribbles one deck rubber in order to sealing, in the middle of the plane screw is arranged, and links to each other with the double-screw bolt of milk receptacle.Screw outwards has a space and circular hole, is the ground of staying in of nipple, and the circular hole outer periphery is used for connecting the milk skull for having externally threaded cylinder.

Nipple is common pacify commonly used, and opening is cut together by cutter or several forms.

The milk skull design for cylinder, in have screw to match with being connected the double-screw bolt that covers, fill up a caulking gum thin slice bottom it.

Above-mentioned except that individual explanations, all the other materials are all plastics.

Owing to adopt such scheme, the utility model has following advantage:

What at first, originally connect the milk device and be a kind of women breast-feeding their children of being specifically designed to " galactozemia " or " galactorrhea " (" Chinese medicine " claims) connects the milk utensil.Its appearance will be filled a hole in the market.It compared with prior art have connect milk in time, convenient, advantage such as amount is big, connect the trouble of milk before fundamentally having eliminated, use it, no matter when and where " galactozemia " can not influence orthobiosis of people.

Secondly, originally connect the milk device and help making full use of of breast feeding and milk.Use and originally connect the milk device, when the baby need suck the breast, can take away rapidly and connect the milk device, in time feed; Do not have enough to eat as the baby, the also available milk that connects in the milk device is directly fed, and does not need to pour in other nursing devices again, uses very convenient.

The 3rd, use originally to connect the milk device and be of value to udder health, can hold up and protect breast, make its natural relaxation, thereby improve blood circulation, the promotion galactopoiesis; For the wean rear udder attachment intact recovery and prevent that the mastoptosis is useful especially.

The 4th, originally connect the use next to the shin of milk device, change the use inconvenience of existing breast pump, any occasion is even can to suck, and makes breast have plentiful aesthetic feeling.

Below in conjunction with drawings and Examples, this utility model is further specified.

Figure 1 shows that the front view (elastic frenulum partly omits) that originally connects the milk device.

Figure 2 shows that the single milk device circular frame front view that connects, A-A is a slice location.

Fig. 3 is the single full sectional view that connects milk device circular frame.

Fig. 4 is the single front view that connects milk device main body, and B-B is a slice location.

Fig. 5 is the single full sectional view (air valve slightly) that connects milk device main body.

Fig. 6 is the complete section front view (air valve slightly) of milk receptacle.

Fig. 7 is the full sectional view (I is the labelling of partial enlarged drawing among Fig. 6) of air valve.

Fig. 8 is for being connected the complete section front view of lid.

Fig. 9 is the hatch frame sketch map of nipple.

Figure 10 is the complete section front view of milk skull.

Originally connect the size of milk device according to women breast-feeding their children's breast, design different model, with milk receptacle medial wall semi-round ball radius (being the radius of breast) is the size of its specification of representative, this radius increases then partly increases such as milk receptacle lateral wall, the cross section that is connected lid, the diameter of circular frame, guarantees that again breast is comfortable when containing the increase of milk amount.

Be suitable for radius be 60mm breast to connect the milk device be embodiment, be described below:

This connects the mutual alignment of milk device each component part and assembly relation as shown in Figure 1, wherein: 1, elastic frenulum; 2, circular frame; 3, milk receptacle; 4, elastic sheet rubber; 5, air valve; 6, be connected lid; 7, pacify; 8, milk skull.

Be auxiliary with each accompanying drawing below, construction features, size and performance, the material etc. of each part that originally connects the milk device are described.

1, elastic frenulum (Fig. 1)

Connect human body and the usefulness that connects the milk device.

Elastic frenulum is wide to be 30mm, length overall is about 400mm (can design several specifications according to different chest measurements), the left side elastic webbing is connected the left side frame left side, the right side elastic webbing is connected right side frame the right, can stick with glue or modes such as framework Bao Qi are connected, the other end of left and right side elastic frenulum has hook for the usefulness of binding mutually.There are the long 35mm of being, wide elastic frenulum to link to each other in the middle of the framework of the left and right sides for 30mm (deciding) according to two colpus distance.

Material is general elasticity strap.

2, circular frame (Fig. 2, Fig. 3)

Its effect be make connect milk device main body can close by people's liberty, from, reach purpose easy to use.

Framework inner edge diameter is 120mm, and the outside diameter is 144mm, the symmetrical center line of bayonet socket and framework vertical axis angle at 45. the long 10mm of bayonet socket, wide 9mm, the thick 2mm that is of the inside and outside edge of bayonet socket, the thick 8mm of framework.It is the arc groove of 4mm (draw-in groove) that four sections radiuses are arranged in the framework, be evenly distributed in the framework, its bayonet socket and groove all with boss (the blocking protruding) fit of milk receptacle periphery.

3, milk receptacle (Fig. 6)

Spill or the milk of sucking-off in order to Sheng.

Its inside and outside sidewall is all hemisphere, and the lateral wall diameter is 130mm, and the medial wall radius is 60mm, wall thickness 2mm.The same axis of inside and outside sidewall, the center of circle be at a distance of 20mm, the center of circle, lateral wall partially outside.It is that the opening of 50mm matches with being connected to cover that there is diameter in the milk receptacle outside.It is the elastic sheet rubber of 50mm that there is a diameter at 10mm place, opening top, the air valve that has an elastomeric material to make on it.In the middle of the milk receptacle medial wall hole, diameter being arranged is 30mm, and what link to each other with the hole is tubaeform cylinder, and the centre is a flared hole, wall thickness 2mm, and " loudspeaker " arc is 40mm, " loudspeaker " internal orifice diameter is 15mm.What link to each other with internal orifice is semicylinder, and diameter is 30mm, in the post hole of same shape, wall thickness 2mm are arranged.Semicylinder, front end is evenly distributed, and some diameters are arranged is the aperture of 1-4mm, flows into usefulness at the bottom of the device for milk; It is the external screw thread of 30mm that end has nominal diameter, the high 4mm of this cylinder.It is the boss (blocking protruding) of bayonet socket and draw-in groove in the suitable circular frame of 8mm, long 8mm, thick 2mm that the milk receptacle periphery has diameter.Comfortable for guaranteeing to use, the inner surface of milk receptacle (promptly with the breast contact site) is covered with one deck soft cloth or sponge, clad can from distance inboard aperture 20mm to outward flange.

Except that individual indicating, other material is plastics.

4, elastic sheet rubber (Fig. 4)

In order to negative pressure in the supercharge, suck to finish.

10mm place above the opening of milk receptacle lateral wall, it is the elastic sheet rubber of 50mm that diameter of section is arranged, and the centre is thin (thick is 2mm), and firmly periphery is saturating cumulative thick, and the thick 3mm of edge is to increase elasticity.

Material is the strong rubber of elasticity.

5, air valve (Fig. 7)

Connect gas in the milk device in order to discharge, with negative pressure in the supercharge.

Air valve is positioned at the middle and lower part of elastic sheet rubber, is made up of base, rubber closure, rubber tissue.One diameter is arranged at the base bottom is the hole of 2mm, hole depth 2mm, the cylinder space of Kong Shangwei diameter 8mm, dark 2.5mm; To be fit to rubber closure.This space opening diameter is 6mm.Rubber closure bottom surface diameter is 8mm, and bottom edge has the wide arc boss of 2mm, in order to push down rubber tissue one side.The rubber closure upper end is that diameter is the arc boss of 10mm, and there is the dark 1mm of a groove middle and upper part, with suitable base openings, and can seal.Rubber closure is 2mm by a diameter, and is long for running through in the circular columns hole of 4.5mm.Rubber tissue is diameter 7mm, the thin slice of thick 0.5mm, and pad is in the rubber closure bottom.

Material is a rubber.

6, be connected lid (Fig. 8)

In order to connect milk receptacle, pacify and milk skull.

Linking is covered the inboard and is a plane, and diameter is 57mm, with the outer side-to-side anastomosis of the outer hole wall of milk receptacle.Scribble the rubber of one deck of wide 3mm in order to sealing at the plane periphery.This planar thick 2mm, there is a screw centre, and nominal diameter is 30mm, adapts with screw thread in the milk receptacle.Between screw and the arc lateral wall (radius is 55mm) is a space, is used for installing pacify.Outside wall thickness 2mm, it is the circular hole of 23mm that there is a diameter centre, is the cylinder that has external screw thread (nominal diameter is 28mm) outside the hole, the high 8mm of tube, thick 2mm.

Material is plastics.

7, pacify (Fig. 9)

Make the usefulness of feeding infant.

Pacify for general requirements.The nipple crown center is out together by cutter or is intersected several (cutting till the rubber) osculum of long 2mm.This opening is changed circular open in the past, and benefit is only just to go out milk when the baby sucks.

8, milk skull (Figure 10)

In order to the protection nipple.

The milk skull is a cylinder, and height is 9mm, and diameter is 30mm.Cylinder one side is porose, hole depth 8mm, and it is the female thread of 28mm that nominal diameter is arranged in the hole, is connected lid in order to connect.Be primed with one deck rubber in the hole or fill up a sheet rubber, in order to sealing.

Material is plastics.

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Publication number	Priority date	Publication date	Assignee	Title
CN100367888C *	2005-01-05	2008-02-13	朱允元	Air sac squeezing type massaging and breast milk squeezing brassiere
CN101155606B *	2005-04-07	2010-09-01	美德乐控股公司	Valve, especially for a breast cup set
CN105434178A *	2016-01-10	2016-03-30	陈文婷	Nipple stickers and bra with nipple stickers
CN106535814A *	2014-04-29	2017-03-22	赛林股份有限公司	Protective hood for a surgical operation field
Family To Family Citations				

* Cited by examiner, † Cited by third party, ‡ Family to family citation

Similar Documents

Publication	Publication Date	Title
US11273240B2	2022-03-15	Milk suction and collection device
US20090062731A1	2009-03-05	Breast Pump
CN2452494Y	2001-10-10	Brassiere, combining/separation type multi-function mamma-care latex receiving apparatus
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Priority And Related Applications

Priority Applications (1)

Application	Priority date	Filing date	Title
CN 00214870	2000-05-23	2000-05-23	Brassiere, combining/separation type multi-function mamma-care latex receiving apparatus

Applications Claiming Priority (1)

Application	Filing date	Title
CN 00214870	2000-05-23	Brassiere, combining/separation type multi-function mamma-care latex receiving apparatus

Legal Events

Date	Code	Title	Description
2001-10-10	C14	Grant of patent or utility model	
2001-10-10	GR01	Patent grant	
2005-07-13	C19	Lapse of patent right due to non-payment of the annual fee	
2005-07-13	CF01	Termination of patent right due to non-payment of annual fee	

[19]中华人民共和国国家知识产权局

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[12]实用新型专利说明书

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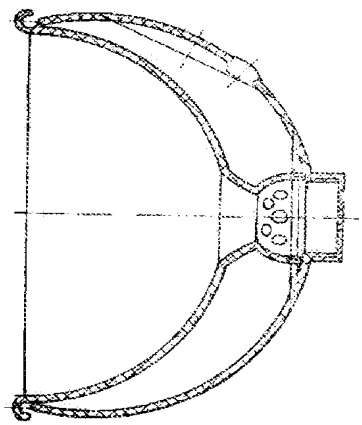
[54]实用新型名称 乳罩、合离式多功能健乳接奶器

[57]摘要

一种专门用于哺乳期妇女的接奶器具，它的外观呈乳罩形状，主体与框架 可随意合、离；主体为中空半球体结构，其构成部分由里至外依次为：盛奶器、弹性橡胶片、气阀、衔接盖、橡皮奶头、奶头盖等。它从根本上解决了产前妇 女的乳房“漏乳”（《中医学》又称“乳汁自出”）、胀奶所带来的困扰，具有 随身携带，随时接奶、吸奶的特点，还具备了有益于乳汁分泌及乳房形体的恢 复等诸多功能。



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权　利　要　求　书

1. 乳罩、合离式多功能健乳接奶器，在器体中有一弹性橡胶片和一气阀，其特征是：器体呈普通乳罩形状；器体由盛奶器、弹性橡胶片、气阀、衔接盖、橡皮奶头、奶头盖及圆形框架连接构成；衔接盖与盛奶器及奶头盖使用螺纹连接，弹性橡胶片胶附在盛奶器上，气阀镶嵌在弹性橡胶片中，橡皮奶头下端压附在衔接盖中，盛奶器与圆形框架使用卡凸、卡槽连接。

2. 根据权利要求1所述的接奶器，其特征是：盛奶器内、外侧呈半球形状，形成中部空间；内侧壁中间有孔，与孔相连的是喇叭状体和半圆柱体，其内为相同形状的孔；半圆柱体前端排列有若干小孔，末端带有外螺纹；盛奶器的圆形周边分布有弧形凸台，以对应圆形框架中的凹槽；盛奶器内侧附有软布或海绵。

3. 根据权利要求1所述的接奶器，其特征是：衔接盖内侧呈一平面，平面周围涂有一层橡胶，中间有一螺孔，螺孔外与弧形外侧壁内有一空间，外侧壁中间有一圆孔，圆孔外为带有外螺纹的圆筒。

4. 根据权利要求1所述的接奶器，其特征是：橡皮奶头的开口结构是，奶头顶部中间被刀切一道或多道小口(切透橡皮为止)。

5. 根据权利要求1所述的接奶器，其特征是：奶头盖内壁有孔，孔内有内螺纹，孔底涂一层密封用橡胶或垫一橡胶片。

6. 根据权利要求1所述的接奶器，其特征是：盛奶器与圆形框架采用可合、离的连接方式。

乳罩、合离式多功能健乳接奶器

本实用新型涉及一种接奶器，特别是涉及哺乳期妇女的接奶器具。

哺乳期妇女的“漏乳”现象(《中医学》又称“乳汁自出”)，其产生原因至今未明；治疗方面，西药无特效，中药疗期过长；此现象长期严重困扰着妇女的正常生活。对此，人们根本没有固定的接奶器具：有的用吸水性强的纸、布、海绵等物接奶，有的用奶瓶、茶杯等器皿接奶。采取以上措施，虽能解决一时“漏乳”，却有诸多不便：用纸、布、海绵等物接奶，接奶量太小，会导致外部衣物浸湿；用瓶、杯等器皿接奶，不宜出门在外或公众场合。如果在上班、睡眠、旅行等情况下接奶，常常会防不胜防，令人狼狈不堪。

至于胀奶，现在人们常用吸奶器处理，吸奶器的确减轻了不少痛苦，但其不宜公众场合使用，也不能在睡眠中及时吸奶等等，产生了不少不必要的麻烦。

针对现有技术在处理接奶、吸奶问题过程中出现的多种不良状况，我研制成功了乳罩、合离式多功能健乳接奶器，不但从根本上减轻了“漏乳”、胀奶所带来的痛苦和克服了现有技术中的种种弊端，而且具备多种新的有益功能。其功能具体如下：

㈠本实用新型系一种专门用于哺乳期妇女乳房“漏乳”、胀奶的接奶器具。

㈡本实用新型的使用十分方便，贴身使用，适合睡眠、工作、旅行等情况下使用。

㈢接奶及时、彻底。

㈣有利于母乳的分泌、喂养及乳汁的充分利用。

㈤吸奶迅速、及时。

㈥保护乳房、使乳房舒适。

㈦有益于乳房的健康、使其自然放松，可促使乳房的正常恢复并预防乳房下垂。

㈧给人以乳房丰满之美感。

本实用新型的目的是用以下方案实现的。

乳罩、合离式多功能健乳接奶器的外观与普通圆形乳罩近似，主体为前端乳房状物，附属部分为连接主体的圆形框架及两条弹性系带。主体与框架的结合采用卡口旋转连接方式，可使主体随人的意志自由结合与分离，从而达到使

用方便的目的。

接奶器主体从里向外依次由盛奶器、弹性橡胶片、气阀、衔接盖、橡皮奶头、奶头盖等六部分组成。其中，盛奶器、奶头盖与衔接盖的使用螺纹连接，弹性橡胶片胶附在盛奶器上，气阀镶嵌在弹性橡胶片中，橡皮奶头下端压附在衔接盖中。

盛奶器紧贴乳房，内、外侧壁均为半球形设计，形成中间空间，用以盛漏出或吸出的乳汁。其内侧壁中间有一孔，以使乳头伸到盛奶器内，与此孔相连的是呈喇叭状柱体，与此体相连的是半圆柱体。喇叭状体与半圆柱体内部为与外形相同的孔。半圆柱体前端弧形壁上均匀排列有若干小孔，以使乳汁流入器底，末端带有外螺纹。盛奶器的外侧壁上部有一圆形弹性橡胶片，弹片中下部又有一圆形气阀，此结构用以吸奶。盛奶器的圆形周边均匀分布四个与圆形框架相接的半圆形凸台，以对应圆形框架中的凹槽。盛奶器内侧紧贴乳房部位粘附有一层海绵或软布，确保使用舒适。

衔接盖用以衔接盛奶器与奶头及奶头盖。其内侧呈一平面，平面周边涂有一层橡胶用以密封，平面中间有一螺孔，与盛奶器的螺柱相连。螺孔向外有一空间与圆孔，是奶头的栖身之地，圆孔外侧周围为带有外螺纹的圆筒，用来连接奶头盖。

奶头为普通常用橡皮奶头，开口由刀切一道或数道而成。

奶头盖为圆柱体设计，内有螺孔与衔接盖的螺柱相吻合，其底部垫一密封橡胶薄片。

上述除个别说明外，其余材料皆为塑料。

由于采用上述方案，本实用新型具有以下优点：

首先，本接奶器是一种专门用于哺乳期妇女“漏乳”或“乳汁自出”（《中医学》称）的接奶器具。它的出现，将填补市场空白。它与现有技术相比具有接奶及时、方便、量大等优点，从根本上消除了以前接奶的麻烦，使用它，无论何时何地“漏乳”，都不会影响人的正常生活。

其次，本接奶器有利于母乳喂养及乳汁的充分利用。使用本接奶器，当婴儿需要吃奶时，可迅速拿掉接奶器，及时喂养；如婴儿吃不饱，还可用接奶器内的乳汁直接喂养，不需再倒入其他喂奶器内，使用十分方便。

第三，使用本接奶器有益于乳房健康，能托起并保护乳房，使其自然放松，从而改善血液循环，促进乳汁分泌；对于断奶后乳房的完好恢复及防止乳房下垂特别有益。

第四，本接奶器贴身使用，一改现有吸奶器的使用不便，任何场合匀可进行吸奶，而且使乳房具有丰满之美感。

下面结合附图和实施例，对本实用新型进一步说明。

图1所示为本接奶器的主视图(弹性系带部分省略)。

图2所示为单个接奶器圆形框架主视图，A--A为剖切位置。

图3为单个接奶器圆形框架的全剖视图。

图4为单个接奶器主体的主视图，B--B为剖切位置。

图5为单个接奶器主体的全剖视图(气阀略)。

图6为盛奶器的全剖主视图(气阀略)。

图7为气阀的全剖视图(I 为图6中局部放大图的标记)。

图8为衔接盖的全剖主视图。

图9为奶头的开口结构示意图。

图10为奶头盖的全剖主视图。

本接奶器根据哺乳期妇女乳房的大小，设计出不同型号，以盛奶器内侧壁半圆球半径(即乳房的半径)为代表其规格的尺寸，此半径增大则盛奶器外侧壁、衔接盖的截面、圆形框架的直径等部分增大，在盛奶量增大的同时又确保乳房舒适。

以适用半径是60mm的乳房的接奶器为实施例，描述如下：

此接奶器各组成零件的相互位置和装配关系如图1所示，其中：1、弹性系带；2、圆形框架；3、盛奶器；4、弹性橡胶片；5、气阀；6、衔接盖；7、橡皮奶头；8、奶头盖。

下面以各附图为辅，说明本接奶器的各零件的结构特点、尺寸大小及性能、材料等。

1、弹性系带(图1)

作连接人体与接奶器之用。

弹性系带宽为30mm，总长约为400mm(可依据不同胸围设计几种规格)， 左侧弹性带连接在左侧框架左边，右侧弹性带连接在右侧框架右边，可用胶粘或把框架包起等方式连接，左、右侧弹性系带的另一端有挂钩供相互连结之用。左右框架中间有长为35mm、宽为30mm(据两乳间距而定)的弹性系带相连。

材料为一般弹性布带。

2、圆形框架(图2、图3)

其作用是使接奶器主体可按人的意志自由合、离，达到使用方便的目的。

框架内边直径为120mm，外边直径为144mm，卡口的对称中心线与框架垂直轴线成45°角，卡口长10mm，宽9mm，卡口内、外缘厚均为2mm，框架厚8mm 。框架内有四段半径为4mm的弧形凹槽(卡槽)，均匀分布在框架中， 其卡口与凹槽皆与盛奶器周边的凸台(卡凸)相适合。

3、盛奶器(图6)

用以盛漏出或吸出的乳汁。

其内、外侧壁皆为半球体，外侧壁直径为130mm，内侧壁半径为60mm， 壁厚2mm。内、外侧壁同一轴线，圆心相距20mm，外侧壁圆心偏外。 盛奶器外侧有直径为50mm的开口与衔接盖相吻合。开口上方10mm处有一直径为50mm的弹性橡胶片，其上有一橡胶材料制成的气阀。 盛奶器内侧壁中间有一孔， 直径为30mm，与孔相连的是喇叭形柱体，中间为喇叭形孔，壁厚2mm， “喇叭”弧为40mm，“喇叭”内口直径为15mm。与内口相连的是半圆柱体，直径为30mm，内有同样形状的柱孔，壁厚2mm。半圆柱体，前端均匀排列有若干直径为1-- 4mm的小孔，供乳汁流入器底之用；末端有公称直径为30mm 的外螺纹， 此柱体高4mm。盛奶器周边有直径为8mm、长8mm、厚2mm的适合圆形框架中卡口与卡槽的凸台(卡凸)。为确保使用舒适，盛奶器的内侧表面(即与乳房接触部位)覆上一层软布或海绵，覆面从距内侧孔20mm处至外边缘。

除个别注明外，其它材料为塑料。

4、弹性橡胶片(图4)

用以增加器内负压，以完成吸奶。

在盛奶器外侧壁开口上方10mm处，有截面直径为50mm的弹性橡胶片，中间较薄(厚为2mm)，往周边逐渐增厚，边缘处厚3mm，以增加弹性。

材料为弹性强的橡胶。

5、气阀(图7)

用以排出接奶器内气体，以增加器内负压。

气阀位于弹性橡胶片的中下部，由底座、橡皮塞、橡皮片组成。底座底部有一直径为2mm的孔，孔深2mm，孔上为直径8mm、深2.5mm的柱体空间；以适合橡皮塞。此空间开口直径为6mm。橡皮塞底面直径为8mm，底面边缘有2mm 宽的弧形凸台，用以压住橡皮片一侧。橡皮塞上端是直径为10mm的弧形凸台，中上部有一凹槽深1mm，以适合底座开口，并能密封。橡皮塞被一直径为2mm，长为4.5mm的圆形柱孔贯穿。橡皮片为直径7mm，厚0.5mm的薄片，垫在橡皮塞底部。

材料为橡胶。

6、衔接盖(图8)

用以连接盛奶器，橡皮奶头及奶头盖。

衔接盖内侧呈一平面，直径为57mm，与盛奶器外孔壁外侧吻合。在平面周边涂有宽3mm的一层用以密封的橡胶。此平面厚2mm，中间有一螺孔，公称直径为30mm，与盛奶器中螺纹相适应。螺孔与弧形外侧壁(半径为65mm)之间为一空间，用来安装橡皮奶头。外侧壁厚2mm，中间有一直径为23mm的圆孔，孔外为带有外螺纹(公称直径为28mm)的圆筒，筒高8mm，厚2mm。

材料为塑料。

7、橡皮奶头(图9)

作喂养婴儿之用。

为一般规格的橡皮奶头。奶头顶部中间被刀切一道或交叉数道(切透橡皮为止)，长2mm的小口。此开口一改以往圆形开口，好处是只有在婴儿吮吸时才出奶。

8、奶头盖(图10)

用以保护奶头。

奶头盖为圆柱体，高为9mm，直径为30mm。柱体一侧有孔，孔深8mm，孔内有公称直径为28mm的内螺纹，用以连接衔接盖。在孔底涂有一层橡胶或垫一橡胶片，用以密封。

材料为塑料。

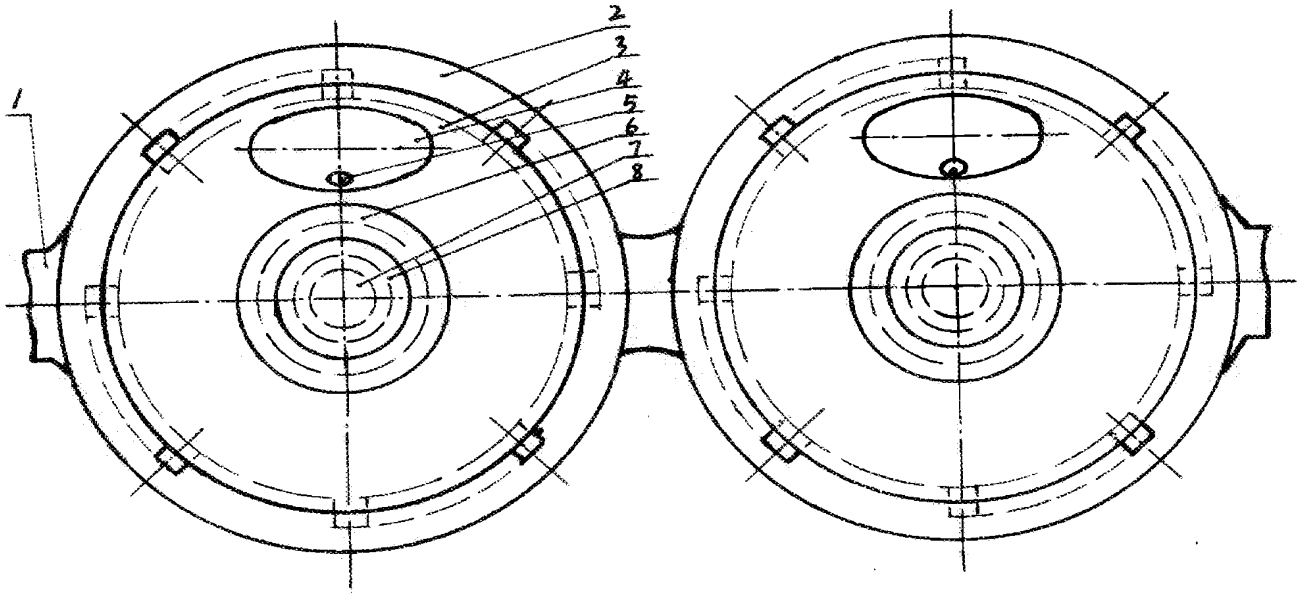

图 1

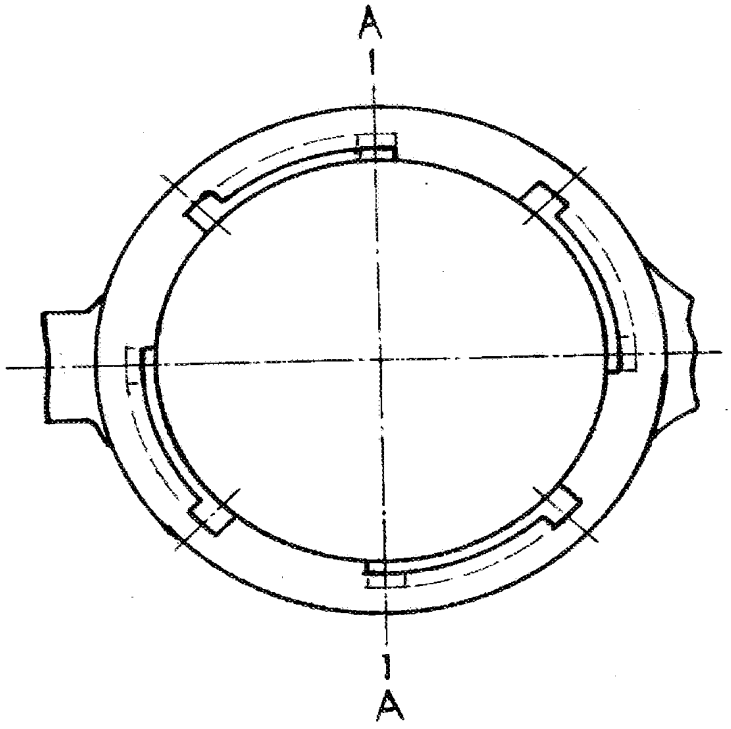

图 2

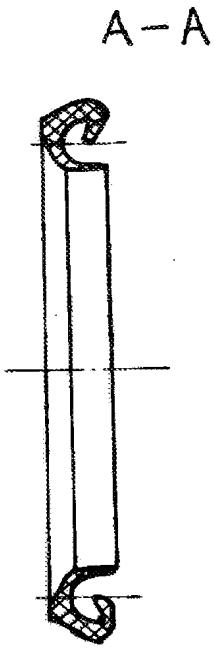

图 3

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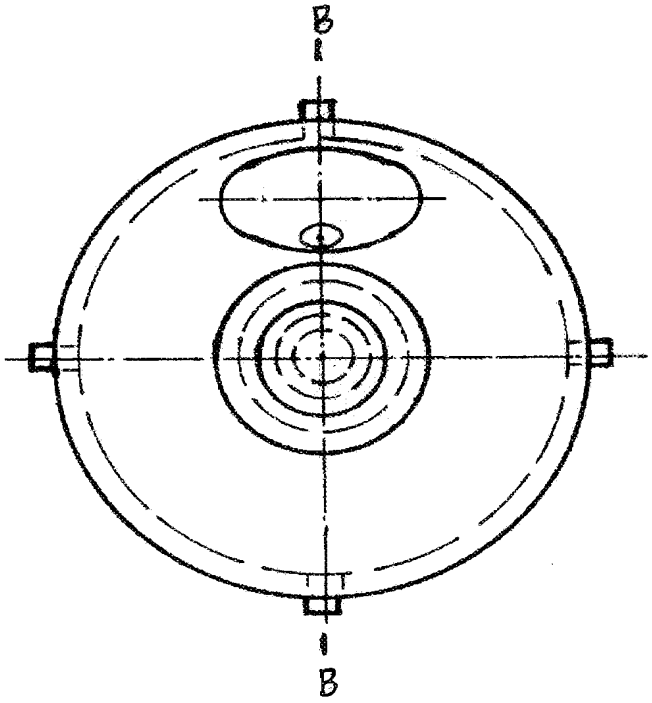
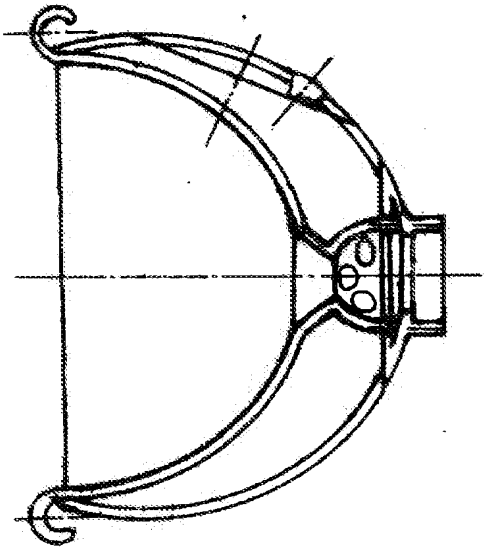


图 4



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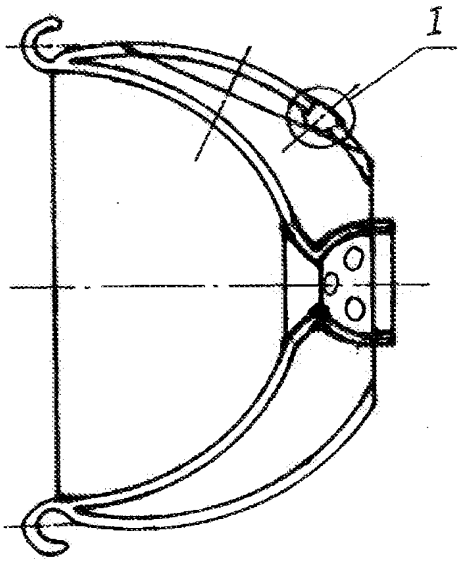

图 6

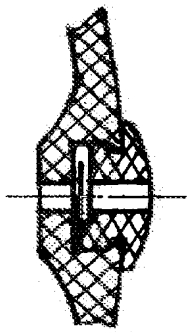

图 7

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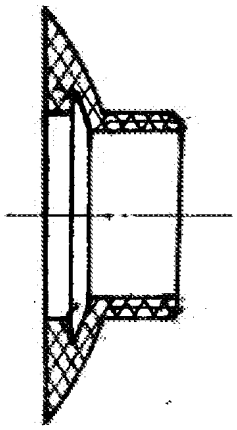

图 8

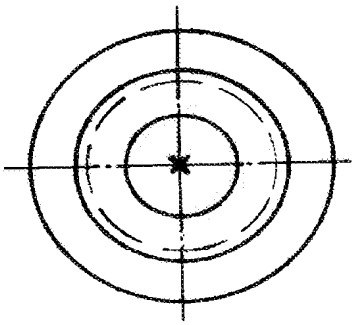

图 9

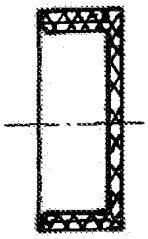

图 10

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[Continued on next page]

(54) Title: BREAST PUMP ASSEMBLY AND METHODS

(57) Abstract: Systems and methods for pumping milk from a breast, wherein the milk is expressed from the breast under suction and milk is expulsed from the pumping mechanism to a collection container under positive pressure.

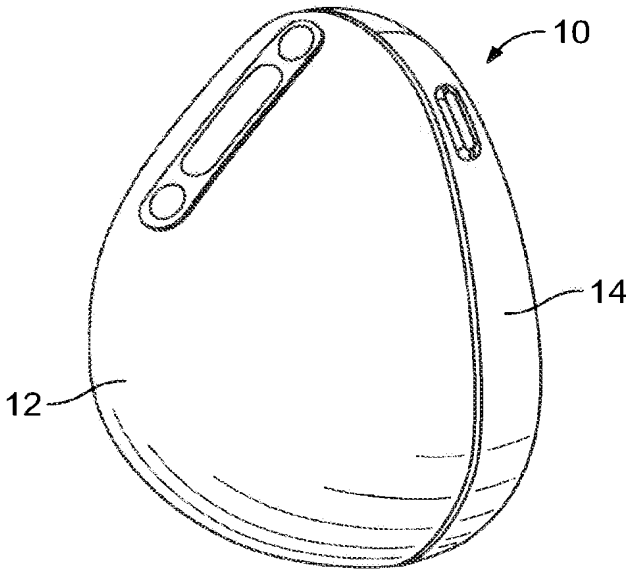

FIG. 1A

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BREAST PUMP ASSEMBLY AND METHODS

FIELD OF THE DISCLOSURE

[0001] The present disclosure generally relates to portable breast pump systems and methods for collecting milk from a breast of a nursing mother.

BACKGROUND OF THE DISCLOSURE

[0002] As more women become aware that breastfeeding is the best source of nutrition for a baby, and also offers health benefits to the nursing mother, the need is increasing for breast pump solutions that are user-friendly, quiet, discrete and versatile for use by a nursing mother in various situations. This is particularly true for the working mother, who is away from the home for eight to ten hours or more and needs to pump breast milk in order to have it available for her baby, but it is also a requirement for many other situations where the mother is away from the privacy of the home for an extended period, such as during shopping, going out to dinner or other activities.

[0003] Although a variety of breast pumps are available, a number are awkward and cumbersome, requiring many parts and assemblies and being difficult to transport. Hand pump varieties that are manually driven are onerous to use and can be inconvenient to use. Some powered breast pumps require an AC power source to plug into during use. Some systems are battery driven, but draw down the battery power fairly rapidly as the motorized pump continuously operates to maintain suction during the milk extraction process. Many of the breast pumps available are clearly visible to an observer when the mother is using it, and many also expose the breast of the mother during use.

[0004] There is a continuing need for a small, portable, self-powered, energy efficient, wearable breast pump system that is easy to use, that mimics natural nursing, and is discrete by not exposing the breast of the user and nearly unnoticeable when worn.

[0005] To ensure that the nursing baby is receiving adequate nutrition, it is useful to monitor the baby's intake. It would be desirable to provide a breast pump system that easily and accurately monitors the volume of milk pumped by the system, to make it convenient for the nursing mother to know how much milk has been extracted by

breast pumping. It would also be desirable to track milk volume pumped per session, so that the volume of milk contained in any particular milk collection container can be readily known.

[0006] There is a continuing need for a breast pump system that is effective and convenient to use. The present disclosure addresses these and other needs.

SUMMARY OF THE DISCLOSURE

[0007] Briefly and in general terms, the present disclosure is directed toward breast pump systems or methods. The system includes breast contacting structure and a collection or storage container or assembly, and structure that delivers milk from a breast to the collection assembly. The method involves pumping milk from a breast and delivering the pumped milk into the collection assembly or storage container. In one particular aspect, the breast pump system responds in real time to optimize pumping action for a particular user during a particular pumping session.

[0008] According to one aspect of the present disclosure, a system for pumping milk from a breast includes one or more of: a skin contact member or flange configured to form a seal with the breast; a conduit in fluid communication with and connected to the skin contact member; a driving mechanism configured to establish a vacuum profile within the conduit; an external shell; a milk collection container; and a non-transitory computer readable medium having stored thereon instructions executable by a computing device to cause the computing devices to perform functions associated with and directed by the instructions; wherein the external shell comprises a compartment; wherein the skin contact member, the conduit and the driving mechanism are received in the compartment of the external shell; wherein the milk collection container is positionable within the shell; and wherein the system is shaped and configured to be contoured to the breast of a user.

[0009] In one or more embodiments, the system can include one or more of structure configured to address fluid ingress, pinch protection structure, a flex-tube structured to accomplish efficient and predictable pumping of fluid and the creation of desirable pressure profiles, and cooperating structure for fluid collection secure attachment and removal.

[0010] In various embodiments, the storage container can be specifically configured to prevent kinking and for durability and handling. The storage container can be designed to hold, accept or retain milk or other fluids. A flow feature can be incorporated into the storage container in the form of a scallop structure, valves and materials can be chosen to facilitate removing air or gases, tabs and wings can be provided for handling, and structure adapted for the removal of milk from a collection assembly.

[0011] In various of the disclosed embodiments, the system defines a breast profile. The natural breast profile is contemplated to fit comfortably and conveniently into a bra of a user and to present a natural look. As such, the profile is characterized by having a non-circular base. Moreover, like natural breasts, the profile of the device or system is contemplated to define one or more asymmetric curves and off-center inertial centers. In one aspect, the system defines a breast enhancement system for enlarging the appearance of the user's breast.

[0012] In at least one embodiment, the system functions by operating a control system that tracks internal pressure of the system against a known waveform. In this regard, the waveform can be a vacuum waveform indicative of pressures applied to a breast, and can define a sine wave fluctuating between about 60mmHg of vacuum to a vacuum from about 120mmHg to about 250mmHg, or other desirable or useful waveform.

[0013] In one or more embodiments, the system includes a controller that accomplishes real time pressure control inside the system.

[0014] In one or more embodiments, the system includes a controller providing automated compliance sensing and response.

[0015] In one or more embodiments, the system includes a non-contact pressure sensing arrangement that does not touch the skin or the milk inside the tube while accurately determining internal pressure of the tube.

[0016] In one or more embodiments, the system includes one or more controllers that automatically detects one or more of letdown, overfill and flow.

[0017] In one or more embodiments, the system is disabled when the flange is not placed in an operating position.

[0018] In one or more embodiments, the system can be adapted to visualize a user's data and trends as it relates to volume (from each breast and total), and number of

sessions on several dimensions (per day, per week and per month). Data and analytics can also be provided on pumping session.

[0019] In at least one embodiment, the flange or skin contact member, the conduit, the driving mechanism, the external shell and the milk collection container are all contained within a cup of a brassiere. In other embodiments, the container need not be contained within the housing, and the pump need not be in a cup of a brassiere, but can be unsupported or supported by itself or by other clothing or a nursing tank top or a band surrounding the user's body.

[0020] In at least one embodiment, the system is battery powered, the system comprising a battery, wherein the battery is received in the compartment of the external shell.

[0021] In at least one embodiment, the milk collection container comprises a one-way valve that permits milk inflow into the milk collection container but prevents milk backflow from the milk collection container to the conduit. In one embodiment, the collection container or container assembly includes an extra part, valve or fitment that is attached thereto and facilitates creating a seal with the container to establish a closed system. In one embodiment, the milk container can include a one-way valve that cannot be removed without destroying milk container or valve function. The valve can assume a myriad of shapes and kinds including an umbrella valve, a duckbill valve, a ball valve or other valve. Moreover, in one or more embodiments, the container can be flexible or rigid, or disposable or reusable.

[0022] According to another aspect of the present disclosure, a system for pumping milk from a breast includes one or more of: a flange or skin contact member configured to form a seal with the breast; a conduit in fluid communication with and connected to the skin contact member; a driving mechanism configured to establish a vacuum profile within the conduit by cyclically compressing and allowing decompression of a portion of the conduit; and an external shell containing the conduit and the driving mechanism and supporting the skin contact member.

[0023] In at least one embodiment, the system further includes a milk collection container, wherein the milk collection container is in fluid communication with the conduit.

[0024] In at least one embodiment, the skin contact member includes: a breast contact portion configured and dimensioned to fit over and form a seal with a portion of the breast; and a nipple receiving portion extending from the breast contact portion.

[0025] According to another aspect of the present disclosure, a method of operating a system for pumping milk includes one or more of: providing the system comprising a skin contact member configured to form a seal with the breast, a conduit in fluid communication with and connected to the skin contact member; a driving mechanism including a compression member configured to compress and allow decompression of the conduit in response to inward and outward movements of the compression member, a sensor, and a controller configured to control operation of the driving mechanism; sealing the skin contact member to the breast; operating the driving mechanism to generate predetermined pressure cycles within the conduit; monitoring by the controller of at least one of position and speed of movement of the compression member relative to the conduit; measuring or calculating pressure within the conduit; maintaining or modifying motion of the compression member as needed, based upon feedback from the calculated pressure and at least one of force, position and speed of movement of the compression member, to ensure that the predetermined pressure cycles continue to be generated.

[0026] In at least one embodiment, the predetermined pressure cycles comprise extraction pressure cycles, and the controller increases a stroke distance of the compression member relative to an amount of milk entering the conduit, to maintain predetermined pressures during the extraction pressure cycles.

[0027] In at least one embodiment, the predetermined pressure cycles comprise latch cycles, wherein upon determination that milk has entered the conduit or after a predetermined period of time, the controller operates the compression member to achieve predetermined extraction pressure cycles, wherein the predetermined extraction cycles differ from the predetermined latch cycles by at least one of maximum suction level, cycle frequency or waveform shape. Moreover, in one or more embodiments, the system includes structure or functions to recognize when a user is done pumping, or includes structure or functions such that when there is a loss of vacuum recognition which allows the user to easily end a pumping session by simply

pausing and pulling the device off of the breast. Additionally, in one or more embodiments, the system can include an auto-purge function or an accelerometer functioning as gesture recognition so that the device can interpret what the user is attempting to accomplish.

[0028] According to another aspect of the present disclosure, a system for pumping milk includes one or more of: a flange or skin contact member configured to form a seal with a breast; a conduit in fluid communication with and connected to the skin contact member; a driving mechanism including a compression member configured to compress and allow decompression of the conduit in response to inward and outward movements of the compression member; a sensor; and a controller configured to control operation of the driving mechanism; wherein upon sealing the skin contact member to the breast, the controller operates the driving mechanism to generate predetermined pressure cycles within the conduit, monitors at least one of position and speed of movement of the compression member relative to the conduit, measures or calculates pressure within the conduit based upon signals received from the sensor, and maintains or modifies motion of the compression member as needed, based upon feedback from the calculated pressure and at least one of force, position and speed of movement of the compression member, to ensure that the predetermined pressure cycles continue to be generated.

[0029] These and other features of the disclosure will become apparent to those persons skilled in the art upon reading the details of the systems and methods as more fully described below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0030] Fig. 1A shows a perspective view of a breast pump system according to an embodiment of the present disclosure.

[0031] Fig. 1B is a rear view, depicting the flange of the pump system of Fig. 1A.

[0032] Fig. 2 shows a front view of the system of Fig. 1 with the shell removed.

[0033] Fig. 3 depicts a back view of the system of Fig. 1 with the flange removed..

[0034] Fig. 4 is a cross-sectional side view of the system of Fig. 1.

[0035] Fig. 5 is an inside view of the system of Fig. 1, depicting the flex conduit of the pump assembly.

[0036] Fig. 6A is an exploded view of the system of Fig. 1, depicting mechanical components of the system.

[0037] Figs. 6B-D depict views of an alternative approach to housing structure.

[0038] Figs. 6E-G depict views of yet another alternative approach to housing structure.

[0039] Fig. 6H is a perspective view, depicting a first approach to a system including a removable battery structure.

[0040] Fig. 6I is a perspective view, depicting a second approach to a system including a removable battery structure.

[0041] Fig. 6J is a perspective view, depicting a third approach to a system including a removable battery structure.

[0042] Fig. 7A is a schematic representation, depicting operational components of the system.

[0043] Fig. 7B is a graphical representation, depicting motor position and vacuum versus time.

[0044] Fig. 7C is a graphical representation, depicting motor position versus volume.

[0045] Fig. 8 is a top view, depicting one embodiment of a storage collection assembly of the present disclosure.

[0046] Fig. 9 is an enlarged view, depicting a neck and valve of the storage collection assembly of Fig. 8.

[0047] Fig. 10 is an enlarged view, depicting a valve assembly of the storage collection assembly.

[0048] Fig. 11A is a perspective view, depicting a storage collection assembly connected to the system.

[0049] Fig. 11B is a perspective view, depicting a first step in installing a collection assembly.

[0050] Fig. 11C is a perspective view, depicting a second step in installing a collection assembly.

[0051] Fig. 11D is a top view, depicting a third installation step.

[0052] Fig. 11E shows yet another collection assembly installation step.

[0053] Fig. 12 is a cross-sectional view, depicting a portion of the system.

[0054] Fig. 13 is a perspective view, depicting a door assembly of the system.

[0055] Fig. 14 is a cross-sectional view, depicting details of the door assembly.

[0056] Fig. 15 shows details of the door assembly.

[0057] Fig. 16 is an enlarged view, depicting structure of a pinch protection assembly.

[0058] Fig. 17 is an enlarged view, depicting other structure of a pinch protection assembly.

[0059] Fig. 18 is a perspective view, depicting a flex circuit of the system.

[0060] Fig. 19 is a top view, depicting a user interface assembly.

[0061] Fig. 20 is a bottom view, depicting further details of the user interface assembly.

[0062] Fig. 21 shows power access support structure of the system.

[0063] Figs. 22-28 depict various aspects of a remote user interface system.

[0064] Figs. 29-41 depict various further aspects of a remote user interface system.

DETAILED DESCRIPTION OF THE DISCLOSURE

[0065] Before the present systems and methods are described, it is to be understood that this disclosure is not limited to particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present disclosure will be limited only by the appended claims.

[0066] Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limits of that range is also specifically disclosed. Each smaller range between any stated value or intervening value in a stated range and any other stated or intervening value in that stated range is encompassed within the disclosure. The upper and lower limits of these smaller ranges may independently be included or excluded in the range, and each range where either, neither or both limits are included in the smaller ranges is also encompassed within the disclosure, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the disclosure.

[0067] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure belongs. Although any methods and materials similar or equivalent to those

described herein can be used in the practice or testing of the present disclosure, the preferred methods and materials are now described. All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited.

[0068] It must be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a sensor" includes a plurality of such sensors and reference to "the pump" includes reference to one or more pumps and equivalents thereof known to those skilled in the art, and so forth.

[0069] The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. The dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

[0070] Various details of the present system can be found in PCT Application Nos. PCT/US15/41257, PCT/US15/41271, PCT/US15/41277, and PCT/US15/41285 each filed 07/21/2015, and PCT/US15/50340 filed 09/16/2015, each of which are hereby incorporated herein, in their entireties, by reference thereto.

[0071] Figs. 1A-B are perspective and back views of a breast pump system 10 according to an embodiment of the present disclosure. The breast pump system 10 can include one or more of the below introduced or described features or functions, or a combination thereof. The housing or outer shell 12 of system 10 can be shaped and configured to be contoured to the breast of a user and to thus provide a more natural appearance when under the clothing of the user. As can be appreciated from the figures, the system can define a natural breast profile. The natural breast profile is contemplated to fit comfortably and conveniently into a bra of a user and to present a natural look. As such, the profile is characterized by having a non-circular base unlike that embodied in a generally dome-shaped configuration. Extending from the base are curved surfaces having asymmetric patterns. Moreover, like natural breasts, the profile of the device or system is contemplated to define one or more asymmetric curves and off-center inertial centers. Various natural breast shapes can be provided to choose from to the tastes and needs of a user. An opposite side of the pump system 10 is

configured with a flange 14 which is sized and shaped to engage a breast of a user. The flange 14 is contoured to comfortably fit against a wide range of user's bodies and to provide structure for sealingly engaging with breast tissue. In one particular embodiment, the flange 14 can form generally rigid structure, and alternatively or additionally unlike a standard flange can lack sharp edges or a lip portion against which breast tissue might be engaged during use. In this regard, the flange includes surfaces that extend outwardly from a nipple receiving portion of the flange to engage breast tissue, thus providing extra surface area for comfortably contacting tissue. Various approaches are contemplated to the flange with respect to a user's nipple. One approach involves aligning a horizontal line formed within the flange structure a bit higher than center with the rationale that the perspective of the mother is from above. This perspective allows the user to better align the breast with the horizontal line to better center the nipple in the actual center of a nipple receiving portion of the flange, thus offsetting any tendency to aim/line up low associated with centered lines because the user's perspective is from above the line and also because the device is pivoted into place in certain instances.

[0072] Fig. 2 is a front view of the system 10 of Fig. 1, with the housing or outer shell 12 having been removed and made transparent to show components otherwise covered by the housing 12. In particular, with the housing 12 removed, various electronic components can be identified. The system controller is embodied in a circuit board 15 that is in communication with a flex-circuit 16, each cooperating to connect to and control various electro-mechanical components of the system 10. A control panel 17 is in electronic communication with the controller via the flex-circuit 16 and provides the user with the ability to power the system on and off as well as to alter functioning. One or more motors 44, 46 are further provided and controlled electronically by the system to effect manipulation of actuators (described below) operating on a conduit or flex-tube 32 (See Figs. 4 and 5). A battery 48 is included to provide a rechargeable power source and is configured to be plugged into a power source for charging. Further, there is provided a load cell assembly 54 that is configured to provide a pressure sensing function as described below. It is contemplated that at least in one embodiment, the conduit or flex-tube 32 is oriented to run from inferior to superior relative to the nipple

of a breast when the user is upright.

[0073] Fig. 3 shows an opposite side of the system 10 with the flange 14 removed to illustrate more details of the pumping function. The conduit or flex-tube 32 (See Figs. 4-6) includes generally spherically shaped connectors 33 that are sized and shaped to be removably received in recesses 34 formed in a pump chassis 35. The connectors 33 are designed to automatically engage with moving motor paddles without the user being aware or having to make adjustments, or assemble parts. The pump chassis 35 functions to support the electronic and electro-mechanical structures of the system 10 (See also Fig. 2). It also provides spacing for a pinching actuator 36 that is configured to be advanced and retracted toward and away from the conduit or flex-tube 32 as described further below. Other pumping action is accomplished through the engagement of the conduit or flex-tube 32 with recesses 34 by a compression and expansion member 38 (See Fig. 7A). Embossed engraving is further provided within a well formed in the chassis 35, the engraving providing product and other information relevant to the breast pump. In this way, certain adhesive labels need not be applied to the breast pump structure.

[0074] In general, real-time pressure control can be managed by a controller of the system 10. The controller tracks pressure and moves a pump motor either in or out to influence the pressure in the direction of its choosing. By way of oscillating motion of the motor, the pump can be configured to pull on the connectors 33 of the conduit or flex-tube 32 structure to increase its volume. If there is vacuum in the system 10 that vacuum can be increased as the volume of the tube increases. Pushing in the tube decreases its volume. This in turn causes the vacuum level to decrease in the tube, and can cause a relative positive pressure if vacuum decreases enough. The pump controller applies these principles, sensing the current pressure and then nudging a compression member or paddle of the motor assembly in a direction required to generate a pressure target. By doing this repeatedly in real time, the system can create a controlled vacuum waveform that matches waveforms desired to be applied to a user's nipple.

[0075] The pump can slowly pull the compression member or paddle out until it hits a pre-determined target. Should the paddle be moved to the end of its range without

being able to generate a desired vacuum, the system will be purged to generate more vacuum potential. The purge functions to push material out of the system to create a strong vacuum potential. It accomplishes this by first closing a pinch on the conduit or flex-tube or closing off the flex-tube with a flap, dam, etc., then evacuating the flex-tube, for example, by pushing closed the paddle, which forces volume out of the flex-tube and any fluid or air that was inside that volume is also ejected through the one-way valve and into the collection receptacle. When the paddle retracts again, it can then generate much higher vacuum as contents of the tube had been previously purged. Once a higher vacuum can be generated, the system can open the pinch valve so that the desired vacuum profile can be applied to a breast and desired pressure waveform can be produced.

[0076] When the system is filled with air, it is very compliant such that a large change in motor positioning makes only a small change in vacuum. When the system is filled with fluid on the other hand, a small change in motor positioning makes a big change in vacuum. In one particular approach, an encoder including a plurality of spaced magnets is associated with the motor. The magnets can be placed along a periphery of a generally disc shaped encoder with the magnets oriented parallel to the axis of rotation of the encoder. One or more hall effect sensors can be configured on or surface mounted to the circuit board 15 and positioned to read the motion and position of the magnets. In this way, the position of the motor can be determined and monitored. Thus, a challenge can be to configure the system so that it is stable when the system is responsive, and effective when it is not as responsive. One contemplated approach is to tune the controller for a relatively rigid system and to input unit-less quantities that move the motor in required directions where the amplitude of which is modified depending on the output of the system. Accordingly, a cascade controller can be created to grow an input wave if system output is smaller than desired to hit pressure targets and can be shrunk if the system output is larger than required. This can be accomplished in real time by observing output verses input. In this way, the controller can be continuously adjusting target waveforms. Top half and bottom half waveforms can have independent control which facilitates centering waveforms in an effective manner, and results in a system that is both very accurate and quick to adjust.

[0077] The system can further be provided with automated letdown detection. The pump can sense when it is full of fluid and responds accordingly by switching between pumping and letdown when fluid has begun to flow. In one approach an algorithm incorporated into the system can operate to look at the ratio of maximum and minimum of a target wave in the pump and compare that against the output of the pump. The result is a unit-less but very reliable sensing of system compliance. This can be tuned to trigger an internal event when the compliance crosses some known values that represent when the system is full of fluid. Any other measurement of compliance can be used in an equivalent way.

[0078] In another approach to letdown detection, it is noted that pushing a tube of air does not generate the same forces as pushing a tube of fluid. Tracking the force generated during a purge can also give a strong indication of when the system is full of fluid. An event can be generated to track this such that when the force of a purge crosses some known threshold the system can be said to be full of fluid rather than air. This approach may involve less tracking of data and less tuning that is subject to change with pump design or breast tissue. In yet another approach, letdown detection can be based upon tracking flow. That is, when flow begins, letdown must have occurred and when a small volume of flow has been collected the system can switch to pumping. Further, letdown can be tracked by looking at the relative rate of change of vacuum measured to motor position. Note that this relative rate of change is a measurement of compliance. As this ratio goes up in magnitude, it can be concluded that the system is filling with fluid.

[0079] Fig. 4 illustrates a cross-section of components of a system 10 according to an embodiment of the present disclosure. Flex-tube or conduit 32 (isolated in Fig. 5) includes a large conduit portion 32L that is relatively larger in cross-sectional inside area than the cross-sectional inside area of small conduit portion 32S. The large conduit portion 32L terminates with an opening sized for cleaning and is generally sized to accept a small finger tip. Although both portions 32S and 32L are shown as tubular portions, the present disclosure is not limited to such, as one or both portions could be shaped otherwise. When tubular, the cross-sections may be oval, square, other polyhedral shape, non-symmetrical, or non-geometric shape. Further, the flex-tube 32

can include an enlarged bulbous portion 32B configured near a terminal end of the large conduit portion 32L that is provided to help accommodate system hysteresis.

[0080] Figure 6A depicts an exploded view of structural and mechanical components of the system 10. Configured between the housing 12 and flange 14 is the chassis 35. Notably, the chassis can be configured to snap into engagement with the housing 12. Moreover, in a preferred embodiment, the chassis 35 supports directly or indirectly all of the pump components. In particular, a PCB controller mount 62 is supported by the chassis 35 and is configured to be connected to and support the circuit board 15 (See also Fig. 2). A battery bracket 64 is also supported by the chassis 35 and is sized and shaped to receive a rechargeable battery 48 assembly that powers the system 10. A cover jack 65 is further included to provide access to the battery assembly and for accepting a power cord connector (not shown). Motor mounting 66 and motor receiver structure 67 is also supported by the chassis 35 and are configured to receive and support the system motor which is powered by the battery and which functions to move actuators operating on the conduit or flex-tube 32. Also supported by the chassis 35 are an actuator bracket 69, and a load cell bracket 70 and load cell receiver 71. Moreover, user interface panel can include a button membrane 72 and a button membrane housing 73 each supported on the housing 12 and placed in engagement with the flex-circuit 16 that provides the user with system control.

[0081] In order to connect the conduit or flex-tube assembly 32 to the system 10, there are provided a flex-tube ring 80 and a flex-tube collar 82. The flex-tube collar 82 is sized and shaped to be received into slots 84 on the flange. A fluid container fitment 86 (shown in isolation from the container) is sized and shaped to be received into the flex-tube collar 82. A door assembly 90 is attached to the flange 14 and configured to swing open and closed to both provide access to an interior of the system 10 as well as to support a robust connection between the fitment 86 and flex-tube collar 82. Accordingly, it is contemplated that in at least one embodiment, the collection or container assembly is supported and maintained in attachment by friction around a shaft of the conduit to the collection or container assembly, and partially by the door assembly 90 which can enclose and hold the collection or container assembly in place. In alternative embodiments, the breast pump assembly can omit a door assembly

entirely. Thus, the flange itself can include structure for retaining the container assembly in place. Moreover, the door assembly or other structure that replaces the door assembly can be transparent so that a direct view to the container assembly is provided.

[0082] In alternative embodiments, the housing 14 is defined by an irregular shape that includes contours that track or mimic the internal components and structure of the pump system. In one particular approach as shown in Figs. 6B-D, an outer surface of the housing 14 is characterized by an irregular shaped indentation 91, providing the outer surface with an irregular shape. Various differently shaped indentations 91 can be employed (See also Figs. 6E-G). Various configurations of a separate breast cup skin or interface structure 98 is sized and shaped to fit over the housing 14 and indentation 91 to form a desired shape such as the breast shape depicted in the figures. It is noted that the breast pump system can work with or without the breast cup skin or interface structure. Alignment and attachment structure or holes can be further provided to facilitate the mating of the interface structure 91 with the housing 14 and the interface structure can assume a myriad of colors, textures and durometer to enhance or change tackiness, softness for security and outer feel in the bra. Various other breast and other shaped can also be provided.

[0083] In yet further combined or separate embodiments (See Figs. 6H-J), the housing 14 can be adapted or configured to additionally or alternatively accommodate a replaceable battery. Here, the housing 14 includes various other shaped indentations 91 sized and shaped to accommodate the battery. In this approach, the battery includes its own attachable housing 99 that mates with the housing 14 indentation 91, the housing 14 covering other pumping structures. In one approach, mating features include flat, right-angled structures, and alignment and attachment holes and structures are further provided.

[0084] As shown schematically in Fig. 7, latching, pumping and extraction forces can be established by two compression members 36, 38 that are actively driven by motor drivers 44 and 46 respectively. Although more than two compression members could be used and one or more than two drivers could be used, the currently preferred embodiment uses two compression members respectively driven by two drivers as

shown. A system controller or system software and/or firmware controls the action of the drivers in real time, responsive to pre-determined latching and production targets or schemes as detected by the pressure sensor or load cell assembly. The firmware can be written so that such targets can be approached at various speeds, sometimes relatively quickly and other times more slowly or gently to thereby provide multiple stimulation and expression levels. Thus, for example, latch can be achieved taking alternatively more gradual or quicker approaches, and there can be controls determining the level at which latch is achieved. Various levels of suction can be present during expression as well. Tubing portions 32S and 32L can be closed off, or substantially closed off by compression members 36 and 38, respectively. Moreover, such active pumping members can be configured to engage upon a tubing channel generally perpendicularly to the net flow of fluid or milk within the channel. Also, a pinch region of the tubing channel can be configured to open through passive recoil located next to a compression region of the tubing channel which opens through an assistive active support. Upon powering up the system 10 the compression member 36 opens and the compression member 38 begins to withdraw away and through its connection to structure such as the ball connector of the conduit or flex-tube 32 thereby gradually increases the suction level within tubing 32. When a predetermined maximum suction level is achieved (as confirmed by pressure readings taken from a pressure sensor, described below), the compression member 38 ceases its travel in the current direction, and either maintains that position for a predetermined period of time (or moves slightly in the same direction to compensate for decreasing suction as milk enters the system) when the operating mode of the system 10 has a predetermined time to maintain maximum suction, or reverses direction and compresses the tube 32L until the latch suction level is achieved. If the maximum suction level has not yet been achieved by the time that the compression member can be fully retracted away on the first stroke, then the compression member 36 again compresses the tube 32S to seal off the current vacuum level in the environment of the breast, and the compression member 38 fully compresses the tube portion 32L to squeeze more air out of the system. Then the compression member 36 reopens to fully open tube portion 32S and compression member carries out another stroke, again moving away to generate a greater suction

level. This cycling continues until the maximum suction level is achieved. It is noted that it is possible in some cases to achieve the maximum suction level on the first stroke, whereas in other cases, multiple strokes may be required.

[0085] Upon achieving the maximum suction, the system may be designed and programmed so that the compression member 38 does not travel to its fullest possible extent in either direction to achieve the maximum and latch suction levels, so as to allow some reserve suction and pressure producing capability. When the maximum suction level has been achieved, and the pumping profile can return to latch vacuum, the compression member 38 advances compressing tubing portion 32L, thereby raising the vacuum in the tubing 32. Upon achievement of the latch suction vacuum, compression member 36 closes off the tubing 32S again to ensure that the latch vacuum is maintained against the breast, so that sufficient suction is maintained. At this stage, the compression member 38 again begins moving away to increase the suction level back to maximum suction, and compression member 36 opens to allow tube 32S to open and the breast 2 to be exposed to the maximum suction. Alternatively, the system may be programmed so that the compression member 38 cycles between maximum and latch suction levels without the compression member 36 closing during a point in each cycle, with the compression member 36 closing when the latch vacuum is exceeded.

[0086] Upon commencing milk extraction, the compression member 36 and compression member 38 can function in the same manner as in latching, but in a manner that follows an extraction waveform determined by the selected extraction pumping determined in real time by system controls which are responsive to the load cell assembly or pressure sensing assembly. At this stage, any sounds created by the pumping action of the system are decreased as milk or fluid flows through the pump mechanism. During the compression stroke of compression member 38, compression member 36 closes when the latch pressure/suction level is achieved. Continued compression by the compression member 38 increases the pressure in the tubing 32 downstream of the compression member 36 to establish a positive pressure to drive the contents (milk) of tube portion 32L out of the tube portion 32L through smaller tubing portion 32S2 downstream of 32L and out through a one-way valve. The positive

pressure attained is sufficient to open the one-way valve for delivery of the milk out of the tubing 32 and into a milk collection container. In one embodiment, the positive pressure is in the range of 20mm Hg to 40mm Hg, typically about 25mm Hg. Upon reversing the motion of compression member 38, compression member 36 opens when the suction level returns to the latch suction level and compression member 38 continues to open to increase the suction level to the maximum suction level.

[0087] The present disclosure can establish a latch vacuum to cause the flange or skin contact member/breast 14 to seal to the breast. The latch vacuum established by the system is currently about 60mmHg, but can be any value in a range of from about 20 mmHg to about 100 mmHg. Once the system 10 has been latched to the breast via skin contact member 14, the system then cycles between the latch vacuum and a target (also referred to as "peak" or "maximum") suction level. Due to the fact that the system 10 does not cycle down to 0 mmHg, but maintains suction applied to the breast, with the minimum end of the suction cycle being the latch suction level (e.g., about 60mm Hg), the nipple does not contract as much as it would with use of a prior art breast pump system. It has been observed that the nipple draws into the skin attachment member 10 with the initial latch achievement in an analogous fashion as the formation of a teat during breastfeeding. Once the vacuum cycles between the latch and target vacuum levels, there is significantly less motion of the nipple back and forth with the vacuum changes, as compared to what occurs with use of prior art systems. The nipple motion (distance between fully extended and fully retracted) during use of the present system is typically less than about 2mm, and in some cases less than about 1mm. Accordingly, the system provides latching that is not only more like natural nursing, but the reduced nipple motion is also more like natural nursing as evidenced by scientific literature. In one particular approach, the system can employ ultrasound to observe nipple motion during pumping to ensure that desired nipple motion is achieved.

[0088] This greatly reduced motion of the nipple during cycling results from establishment of the latch at latch vacuum level, and then limiting the range of vacuum swing between latch vacuum (suction) and peak vacuum (suction). Typically the difference in vacuum between latch vacuum and peak vacuum is less than 200 mmHg,

more typically less than 150 mmHg. In one example, the latch vacuum was 50 mmHg and the peak vacuum was 200 mmHg, resulting in a vacuum difference of 150 mmHg.

[0089] Limiting the nipple motion as described with use of the present system offers several benefits to the user. One benefit is that there is less friction on the side of the nipple against the flange wall, thereby greatly reducing the risk of irritation, skin damage, pain, swelling, etc. As a result, the present system is significantly more comfortable to use by a nursing mother, and this benefit is increasingly noticeable over repeated uses. By maintaining at least a latch suction level at all times, the present system provides a more secure and persistent seal to the breast and significantly reduces the potential for leaks of air and/or milk. Because the nipple moves significantly less, this provides a more "natural" feel to the user that more closely simulates the feel of a nursing baby. Because the nipple travels less, this allows for the skin attachment member/flange 14 to be designed as a lower profile component, as its length can be shorter since it does not need to accommodate the greater length in nipple movement experienced by prior art systems. This allows the overall amount of protrusion of the system 10 from the breast to less than that in the prior art, as the overall length of the system is reduced by the reduction in length of the skin contact member/flange 14. Thus, the distance from the tip of nipple to exposed end of the housing the system is reduced.

[0090] The breast contact portion can be symmetrical about the nipple receiving portion although, alternatively, the nipple receiving portion could be offset. The skin contact member 14 is designed to reduce the internal volume of the nipple receiving portion, which is enabled by the significantly reduced amount of motion experienced by the nipple during a milk extraction process using a system 10 including skin contact member 14, according to the present disclosure. The nipple receiving portion of the skin contact member 14 is contoured to more closely match the natural shape of the nipple, thereby eliminating or significantly reducing dead space that exists around the nipple in prior art systems. The nipple receiving portion can be cylindrical in the portion adjoining the breast contact portion, and then can taper conically. This design allows for receiving a portion of the areola into the nipple receiving portion while also limiting dead space. The diameters of all cross-sections of the nipple receiving portion

are contemplated to be large enough to allow nipple dilation. The length of the nipple receiving portion can be about 23mm and the length may vary within a range of about 22mm to about 29mm. The length of the nipple receiving portion is sufficient to allow engorgement of the nipple under vacuum, without the distal tip of the nipple contacting the proximal end of the nipple receiving portion. In an alternative approach, the nipple receiving portion can be sized and/or shaped to mimic the anatomy of a child that is nursing. In this regard, rather than being generally cylindrical, the nipple receiving portion define more of a natural mouth shape or a generally rectangular sleeve with rounded corners and curved surfaces. The teat of the breast is thus formed into a more natural nursing shape by the natural shaped nipple receiving portion.

[0091] The internal contour 120 of the flange 14 is designed for use with the present system 10 and to maximize comfort of the user. The internal angles and generally flat portions also facilitate the ability to restrict portions of the breast from moving forward too much into the nipple receiving portion. The wider angle helps to prevent the breast tissue from being funneled into the nipple receiving portion, so that less breast tissue is received in the nipple receiving portion, making use of the flange 14 more comfortable than flanges of the prior art and providing space for nipple engorgement. By providing the wider angles, this also allows the overall system to be effectively shortened and allows the system to lie flatter against the breast to improve both comfort and appearance.

[0092] In one embodiment, the total system volume is about 24.0 cc. The total volume is calculated as the space in the nipple receiving portion (that is not occupied by the nipple) and tube portions 32S, 32L and 32S2 up to the milk collection or container assembly. In the embodiment with total system volume of about 24.0 cc, the active pump volume, i.e., the volume displacement achievable by compressing tube portion 32L from fully uncompressed to the limit of compression by compression member 38 is about 3.4 cc. When there is only air in the tubing 32 of the system 10, pressure swing by moving the compression member 38 inwardly against the tubing portion 32L and outwardly away from the tubing portion is limited, due to the compressibility of the air. In this embodiment, with the system under vacuum of -60 mmHg, a full stroke of the compression member (from compressed to fully uncompressed tube portion 32L)

increases the vacuum to -160 mmHg. The ratio of pumping volume to total system volume can be important with regard to power and size of the pumping system. In this embodiment, the tube portion 32L was made of silicone. It has been recognized that reduced motion of the compression members when pumping allows for more quiet action of the pump motor, and a more quiet system overall. Further, the present system employs the milk expressed as the medium for system hydraulics, and this medium is in direct contact with the user's breast against which a vacuum is drawn. Thus, the system can employ air suction against the breast for initial latching and pumping and then converts to utilize expressed breast milk for pumping action or power.

[0093] During let down operation, the system 10 operates to effect let down of the milk in the breast, prior to extraction, with a maximum suction target of up to 120mmHg (typically, about 100mmHg (-100mmHg pressure)) to establish let down. The goal of letdown (or non-nutritive suction) is to stimulate the breast to express milk. The relatively shallow (small vacuum change range) and relatively fast frequency of the pumping during this phase are meant to mimic the initial suckling action of a child at the breast. This is because during let down phase, the suction pressure is not allowed to exceed the maximum let down suction of 110mmHg or 120mmHg, or whatever the maximum let down suction is set at. Therefore, as the compression member 38 is drawn in a direction away from the tube portion 32L, the system 10 is designed to reach -100mmHg (a suction pressure of 100mmHg) (or -120mmHg, or whatever the maximum let down suction is designed to be), by the time that the compression member 38 has reached a position in which tube 32L is mostly uncompressed.

[0094] During let down (non-nutritive) the system software and/or firmware communicates instructions to system motors based upon readings taken and communicated from the pressure sensing assembly so that the system is configured to operate between -60mmHg and -100mmHg in one example. In this example, the compression member 38 can compress the tubing portion 32L nearly fully and then be moved away from the tubing portion 32L to generate vacuum. The maximum latch suction pressure of -100mmHg will be reached with a small amount of rebound of the tubing portion 32L and the compression member 38 can be cycled relative to the tubing

portion 32L between -100mmHg and -60mmHg in a narrow range or band near full compression of the tube portion 32L. As milk flows, that narrow band shifts at which point the tube portion 32L will be purged by fully compressing it to drive out the contents and thereby regain more capacity for pumping with relatively less compression of the tube portion 32L again.

[0095] The system 10 is responsive to pressure changes within the tubing 32 caused by entry of milk into the tubing 32. Referring again to Fig. 7, the compression elements 36 and 38 are operatively connected to a driver 44, 46, respectively, for independent, but coordinated driving and retraction of the compression elements 36, 38. When electrically-powered drivers are used, a battery 48 is electrically connected to the drivers 44, 46, as well as the controller 52 and pressure sensor 54, and supplies the power necessary to operate the drivers 44, 46 to drive the compression and retraction of the compression elements 36, 38.

[0096] The sensor 54 is used to provide feedback to the controller 52 for controlling the pumping cycles to achieve and/or maintain desired vacuum levels. Sensor 54 is preferred to be a load cell sensor providing data utilized to calculate system pressure, but could also be a pressure, flow, temperature, proximity, motion sensor or other sensor capable of providing information usable to monitor the safety or function of the pump mechanism of system 10. As shown, sensor 54 is a non-contact sensor 54, meaning that it is not in fluid communication with the milk or vacuum space of the system 10.

[0097] As described above, the conduit or flex-tube 32 is placed in operative connection with a motor. An opposite side of the flex-tube 32 is equipped with the sensor 54 that takes the form of a load cell. The positioning of the motor is tracked and the force on the tube 34 is assessed to determine internal vacuum. By employing machine learning or supervised learning regression techniques, the system 10 can be trained to interpret the motor positioning and tubing strain (as well as motor speed or pump settings), while compensating for noise and hysteresis, to arrive at a pressure/vacuum level. More specifically, a neural net system or any mathematical regression of the data can be incorporated into system firmware so that sensor input can be translated to pressure/vacuum levels. In this regard, the system 10 can include

or communicate with a non-transitory computer readable medium having stored thereon instructions executable by a computing device of the system or external to the system to cause the computing devices to perform functions associated with and directed by the firmware.

[0098] To train the neural net, large amount of data is generated, both from an accurate vacuum reading as well as strain gauge readings. All of the data is sent to software so that post processing can be conducted. It has been determined that data taken during normal pump flow lends itself best to training the system 10. For example, data can be gathered when flow is at 2-3 ml/min, and when system pumping is slow at each pressure target. This approach ensures that the motor moves along its entire travel cycle relatively evenly and noise associated with high flow is not introduced into calculations. Highly controlled settings are also used to generate data so that unbiased data is generated. Further, system accuracy can be increased when using specifically generated neural nets for specific ranges of pressures. A special code is employed to isolate data from different pumping limits in training data, and uses only that data to generate a neural net that is used later when pumping to the same limits.

[0099] Turning now to Figs. 8-10, one embodiment of a collection or container assembly 60 is shown. In one particular embodiment, the collection or container assembly 60 can be formed from two 2.5-3.0 mil sheets of material that can be band welded or otherwise joined together along a perimeter 92 of the assembly, and can be sized to retain up to 4.5 ounces, or alternatively 8 ounces of fluid. In particular, the collection or container assembly 60 can be pre-formed to optimize or maximize the space inside the pump system and flange. For shipping, the collection or container assembly can be pulled closed with a vacuum to make it flat or thin for packaging or handling. A body of the collection or container assembly is generally bladder shaped and includes a generally asymmetrical oval central opening 93 created by an interior band seal. In one particular approach, the body can additionally include gussets to provide more volume. A pair of wings 94 extend into the central opening 93 and are provided for handling and facilitating positioning of the collection or container assembly 60 within a pump system 10. A narrow neck portion 95 is centrally positioned and extends longitudinally away from the central opening 93. The neck

portion 95 includes a tab portion 96 that provides structure for grasping and removal, and can further include one or more cut-outs or tear-able elements 97 provided for aiding in tearing the container 90. Further scoring is also contemplated to help in the tearing of the bag assembly 90. Also, in alternative embodiments, the collection or container assembly 90 can be re-sealable, re-usable, include larger or smaller openings or include spout structure for pouring contents. A spout can also be attached to the fitment or valve of the collection assembly to facilitate pouring. Such a spout could further include structure which temporarily or permanently defeats the valve or fitment. The valve of the collection or container assembly can also be re-usable with a second or subsequent collection or container assembly, and therefore is removable from the container assembly.

[00100] Moreover, in one particular embodiment, the collection or container assembly 90 can be made from polyethylene and can be bisphenol A free, as well as food grade material. It should be freezable without tearing and withstand approximately 0-80 degree Celsius temperatures. Additionally, tensile strength can be from 2300-2900 psi and tear strength from 440-600 psi, with a water vapor transmission rate max of about 0.5g/100in^2/24hrs and an oxygen transfer rate of about 150cc/100in^2/24hrs. In alternate embodiments, the material of the collection or container assembly can be Gore-tex or Tyvek, for example. Such alternative materials can permit out-gasing. Accordingly, a non-closed or un-sealed system is also contemplated. In this specific regard, other vents or approaches to venting the system can be incorporated into one or more embodiments. Thus, self-venting of the container assembly or active venting while using the pump system or after use can be accommodated. In one approach, a pressure valve can be incorporated into the system and configured to activate after some system pressure is reached, and further the valve can be designed to act as a fluid barrier, only allowing air and not fluid to escape.

[00101] It is contemplated that the system is configured to pump into a sealed collection or container assembly 60, or one that incudes an integral valve or an otherwise airtight collection or container assembly 60, or combinations thereof. In this specific regard, the system can alternatively or additionally be closed and never vented to the atmosphere, and/or the system suction is only reduced through the flow of milk

into the system. Thus, in at least one approach, milk or fluid that is pumped through the system is never exposed to new outside air from the environment once it enters the collection or container assembly. Accordingly, the orientation of the pump system or person has virtually no impact on the functioning of the system (i.e., no spills). The collection or container assembly can include a rigid or flexible sealing component, such as a ring or gasket into which the pump or container valve is pushed or twisted and sealed. The collection or container assembly can also include an opening or hole or structure that is pierced such that the container assembly seals about the member that goes into it. Moreover, there are contemplated a range of disposable and durable combinations of container 101 and valve fitment 102 arrangements such that one or both of the container bag 101 and fitment 102 are disposable or reusable. Additionally, the container can configured to be inside or outside of the pump housing.

[00102] The fitment 102 can embody a valve such as an umbrella valve assembly 103 or other type of one-way valve connected in fluid communication with the storage container 101. The fitment can also assume a myriad of alternative embodiments, and can additionally or alternatively be formed integral with the container. For example, in one contemplated approach, the fitment and/or the valve can be formed as part of the container rather than define a separate component attached to the container. As shown in Figs 8-10, however, the tail 104 of the umbrella valve 103 can be employed to defeat the valve when desired such as to remove gases, by turning it and engaging the tail against the valve body. Additionally, the valve includes a generally cylindrical portion having a diameter of approximately .585 inches extending from a flat base 104 having a width of approximately .875 inches. It is the flat base portion 104 that is captured and sealed between the two sheets of bag container material and includes a tail 106. The tail 106 functions to ensure flow through the neck portion of the container assembly 60 particularly when it is placed into the pump assembly (See Fig. 11A), and has a narrow, elongated shape that permits flow thereabout. That is, the tail 106 maintains flow through the neck even when the neck is folded as the container assembly is attached to the breast pump body. Valve 103 prevents back flow of milk into the flex-tube 32, and facilitates maintaining the suction (vacuum) level in the flex-tube 32. In other embodiments, other features can

be provided or built into a valve to allow for depression or otherwise overcome the valve to vent air. Such approaches can involve a protrusion that is attached or associated with the valve so that as the protrusion is pushed toward the collection or container assembly, an edge of the valve is translated to thereby break the valve internal seal. Moreover, a nub can be attached to valve structure and configured inside the container assembly. Tugging on the nub through a layer of the container assembly thus results in freeing an edge of the valve and breaking the valve seal.

[00103] In at least one embodiment, the pressure at which the valve 103 opens to allow flow into the milk collection container 60 is about 25mm Hg. The valve 103 can be configured and designed such that it allows fluid to flow through it when the pressure in conduit or flex tubing 32 is positive, e.g., about 25mm Hg, or some other predesigned "crack pressure". The action of the compression elements cycles between increasing vacuum when the compression elements move in a direction away from flex-tube 32 and decreasing when the compression elements compress the flex-tube 32, but typically should not increase the vacuum to greater than the predetermined maximum vacuum. As the compression elements 36, 38 compress the flex-tube 32, the pressure in the system 10 goes up and reaches the minimum suction level (e.g., latch suction level, such as -60mmHg, -30mm Hg, or some other predetermined latch suction level), at which time the compression member (pinch valve) 36 seals off portion 32S thereby maintaining the minimum suction (latch suction) against the breast. Continued compression of portion 32L by compression member 38 continues to increase the pressure downstream of compression member 36, until the crack pressure is reached (e.g., 25mm Hg or some other predetermined, positive crack pressure), that opens the valve 103. The compression elements 36, 38 continue compressing flex-tube 32, pumping fluid (milk) through the valve 103 and into the collection container assembly 60 until the compression element 38 reaches an end point in travel. The end point in travel of the compression element 38 against portion 32L may be predetermined, or may be calculated in real time by the controller 52 using feedback from pressure sensor 54 and feedback from the driver of the compression element 38, from which the controller 52 can calculate the relative position of the compression element 38 over the course of its travel. The compression member 36 remains closed throughout this

process, as it is used to seal off the tube 32 the entire time that the compression element 38 is pumping milk out into the collection container assembly 60. As the compression elements 36, 38 reverse direction and pull away from the flex-tube 32, they start the cycle again.

[00104] As milk enters the system, the suction level decreases (pressure increases). The feedback provided by pressure monitoring via pressure sensor 54 provides input to a feedback loop that adjusts the position of the compression member 38 to maintain the desired vacuum (pressure) within the conduit or flex tubing 32 by compensating for the changes in pressure that occur to changing amounts of milk in the flex tubing 32. For example, for a relatively larger amount of milk in the tubing, this will require a relatively shorter stroke of the compression member 38 to achieve the latch pressure. This modification can be addressed by either slowing the movements of the compression member 38 to achieve the same timing cycle for pumping, or increasing the cycle frequency due to the less time taken for the shorter strokes of the compression member 38.

[00105] Use of a system 10 provided with a non-contact pressure sensor 54 would include loading the collection or container assembly 60 into the system 10 (See Figs. 11A-E). In a first step (Fig. 11B), the flange 14 is removed from engagement with the remainder of the system 10. Attached to the flange is the conduit or flex-tube 32. The central opening 93 is placed over a central projection of the flange 14 and the flex-tube 32. Next, the user can pinch the wings 94 under the flex-tube 32 (Fig. 11C) followed by tucking the collection or container assembly 60 into the flange 14. The fitment 102 is placed within the collar 82 of the flex-tube 32 (See Figs. 11A and 11E). In certain embodiments, the collection or container assembly 60 can have useful labels, icons or notifications. For example, milk droplet icons can be printed on the collection or container assembly 60 in increasing size to indicate the degree to which the container is filled, and a "this side up" message can be included to aid the user in properly installing collection or container assembly 60. Also, the container assembly 60 includes a number of surfaces away from storage areas where printing or handwriting can be placed. For example, the wings 94 can be used as a writing or printing surface as can the pull tab 96. Similar labeling or messages (for example, a

"thanks mom" message) can be included on the collar 84 or other portion of the flex-tube 32 to aid in properly orienting the flex-tube with respect to the flange 14. It is to be recognized that the collection or container assembly can be placed in alternative locations as well. For example, the collection or container assembly can be configured around the nipple of the breast. In this regard, the container assembly itself can form the desired flange or breast contacting structure into its core construction. In one specific approach, the container assembly can also include more surface area facing the breast superior to the nipple than inferior thereto.

[00106] It is contemplated that the door assembly 90 be employed to both provide a continuous contour of the flange 14 for engaging a user's breast as well as to support the engagement of the collection or container assembly 60 with the system 10. Thus, the door assembly 90 can be configured to pivot with respect to the flange 14, and employed to close the system 10 as it is snapped over and closes the pump. With this approach, the fitment 102 and container bag 101 are securely sandwiched between the collar 82 of the conduit or flex-tube 32 and the door assembly 90, with a cylindrical portion of the fitment 102 received within the collar 82. The collar 82 can also provide rigidity to the flex-tube 32 so that it can be loaded into the flange 14 as well as to provide an annular back-up when the fitment 102 is inserted. Ribs or o-rings can be provided on an interior surface of the flex-tube to facilitate sealing with the fitment 102 and can have a radius of approximately .64mm. In one embodiment, the interior diameter of the flex-tube between the ribs can be approximately 14.6 +/- .17mm, while the outer diameter of the fitment 102 can be on the order of 14.8 +/-.17mm so that an interference fit results, with a force of around 1-2.5lbs.

[00107] As best seen in Figs. 12 and 13, the door assembly 90 further includes a pair of spaced and curved guiding arms 105. The arms 105 are contoured to guide the door assembly 90 as it closes over and about a pair of curved railings 107. In this way, as the door assembly 90 rotates toward the conduit or flex-tube 32, a latch 109 of the door assembly 90 first clears and then seats beyond and behind the railings 107 to thereby provide a robust engagement with the flange 14 and bag assembly 60 when it is loaded in the system 10 (See also Fig. 11). As best seen in Figs. 8 and 9, the fitment 102 includes a scalloped portion 110 which functions to facilitate this robust

engagement and provide relief of undue stresses being placed upon the bag assembly when securely mounted within the system by resisting kinking. The door assembly can further include one or more ribs 111 (Fig. 15) that engage and provide directed support to the fitment 102.

[00108] Turning now to Figs. 16-18, there is shown an approach to protecting against pinching by moveable parts of the pump system 10. One or more magnets 118 can be attached to the flange 14. A corresponding sensor 119 (such as a hall effect sensor) can be attached to the flex circuit 16 that is mounted to a mounting bracket 120 (See also Fig. 3). The system 10 can be configured to only permit the motor to be activated when the sensor detects the magnet 118. In this way, the pumping action of the system and in particular, the compression members will not move until the flange 14 is attached properly to the housing 12, consequently avoiding any pinching or engagement of such components with the user. In other approaches, mechanical or electronic switches or RFID technology, or optical sensor or sonar technology can be incorporated into the system to provide the desired safeguards, such that the system will not operate unless all components of the system (i.e., flange, tubing and storage) are fully connected.

[00109] In another approach, the system 10 can include firmware that operates to track system pressure on a load cell. Here, the motor paddle can be arranged and controlled by firmware so that it is moved outwardly .5mm or some defined distance and pressure on the load cell is observed to see if the conduit or flex-tube is properly installed. Where the pressure observed is not as expected, such as if there is no pressure, the motors will not be permitted to move inward for pumping. Using a similar technique, proper collection container install can be tested. After the motor extends, the pinch can seal the flex-tube. Once the motor comes back out, a vacuum will only be measured if the bag is properly installed, sealing air from filling the tube on the container side.

[00110] It has also been recognized that fluid ingress protection may be necessary for the pump system. Thus, it is contemplated that various gaskets can be configured within the structure of the system. One particular location for a gasket is the interface between the chassis and housing, and accordingly, a specially designed gasket is

configured about a perimeter of the chassis along a section which is intended to engage the housing. In this regard, a .3mm interference fit is contemplated between the gasket and the housing. Also, gaskets can be configured about moving receiver structure such as that of the load cell and motor to help prevent fluid ingress.

[00111] Once the flange or skin contact member 14 is placed onto the main body/pump housing 34 then pump power can be engaged. Referring now to Figs. 19-20, there is shown an enlarged view of the user interface panel which as stated above includes a button membrane 72 and a button membrane housing 73 each supported on the housing 12 and placed in engagement with the flex-circuit that provides the user with system control. Here, the membrane 72 acts as a light pipe. Light emission, intensity and button deflection forces are configured for convenient and effective interaction by the user. Accordingly, pressing the power button 130 functions to start the pump system 10 through its interaction with a switch 131 configured on the flex circuit 16 (See Fig. 18). It is noted that other switches 132 can further be provided on the flex circuit which line up with other contemplated system control buttons included on the flex membrane 72. Should the system 10 require external power or the battery charged, access to supporting electronics is gained through the cover jack 65 that is configured in the shell 12 (Fig. 21).

[00112] As the pump system 10 goes through a power up routine, the controller 52 reads force on the load cell when a load cell is used as the pressure sensor 54. This is the load measured by the load cell, before the skin contact member 14 has been applied to the breast, so in one approach it is a state in which the pressure in the conduit or flex-tube 32 is atmospheric pressure. The controller 52 then calibrates the system such that the preload force or position or measured load or strain equates to atmospheric pressure. Based upon a neural network or computer learning, load or strain detected at the flex-tube 32 can be converted to pressure readings in the system 10 during operation of the breast pump system 10 upon attachment to the breast.

[00113] The system 10 can calculate the volume of milk pumped into system or alternatively the volume collected in the milk collection container assembly 60. By knowing the dimensions of the conduit or flex tubing 32 downstream of the compression member 36 when compression member 36 has sealed off tubing portion

32S, the overall volume capacity of the system 10 downstream of compression member 36 can be calculated. With reference again to Fig. 7, tracking of the position of the compression member 38 relative to the tube 32 (such as by knowing the driver 46 position at all times, for example), dictates the volume change in the tubing 32. As the pumping process is carried out, pumping/purging of milk into the milk collection container occurs when the compression member 36 has closed off the small tube portion 32S at the location of compression. When the compression member 36 has closed off tube portion 32S, the change in position of compression member 38 that occurs to carry out the purge of milk from the flex tubing 32 and into the milk collection container 60 is used to calculate the change in volume of the tubing 32 downstream of the compression member 36, which equates with volume of milk that is pushed into the milk collection container 60 bag.

[00114] In particular, under one algorithm, as flow enters the system 10, it is recognized that the motor must move further and further out to generate latch vacuum. Tracking this movement and the rate of position change of compression or paddle members as they generate latch vacuum is one way of measuring flow. The slope of a line that is associated with tracking paddle locations for latch vacuum, for example, is directly proportional to flow. After a tuning step to correlate this relationship, calculating flow from the slope of this line can be readily accomplished.

[00115] Using another approach, the number of purges can be tracked when the system is full for the purpose of measuring flow. As stated, it can be determined when the system 10 is purging fluid versus purging air since the forces are much higher for purging fluid than purging air. Thus, counting the number of purges that contain fluid, and knowing the volume that is purged for each purge leads to a calculation of flow without requiring significant system tuning or calibration, and avoiding confusing a slow air leak with flow. Leaks can also be detected by employing an algorithm involving closing the pinch compression member, followed by closing the pump compression or paddle member, and then pulling the pump compression member outwardly to create a vacuum. By then holding the pump compression member in this position and verifying the vacuum is maintained, it can be determined if there is a leak in the system 10.

[00116] In addition to calculating the volume of milk purged with each purge cycle, the system (via controller 52) can sum the volumes from all purge cycles to calculate the total volume entering the pump or alternatively pushed into the milk collection container 60 during a milk extraction session. This volume can be stored with a unique identifier provided to the milk container so that the system 10 keeps a record of how much milk is stored in each milk collection container 60. This information can also be time stamped so that the user will know the time and date that milk was collected, regarding each milk collection container. Additional statistics can be calculated, including, but not limited to: average volume per extraction session, total volume extracted for any given day, average milk extraction volume per day, etc. Any and all of this data can be exported to an external computer, either manually, or it may be automatically uploaded to the computer when the computer is within range of the system 10 for wireless communication, or when the computer is connected to the system by wire. Further optionally, any or all of this data can be either manually or automatically uploaded to a cloud service over the Internet, either wirelessly or by wire.

[00117] In one preferred approach, volume that is extracted from a breast is calculated by building a map of motor location versus volume at a specific vacuum such as -60mmHg, since the same is a reliable and predictably repeatable vacuum level. To build this relationship, various known rates of flow are created within the breast pump, and motor locations at -60mmHg are identified and stored as data. A script is then employed to extract such data to build this motor versus volume scale. In particular, as shown in Fig. 7B line M represents motor location versus time and line V represents vacuum versus time. This data is entered into the script to arrive at a graph of volume over time. The script looks at indications of times of purge and tosses out data except a first clean start and finish of a cycle between purges represented by the spike S in Fig. 7B. An adjustment is made for time such that relative time for the data selected replaces absolute time. The script also functions to filter out data that is too far above or below -60mmHg. Relative time is then turned into volume in that motor location becomes volume difference over a relative time span. This data can be plotted as a line (See Fig. 7C), the area under which represents volume. The output of the script

represented as a line having a particular slope is expressed as numbers and as a 6th order equation representing the line. This 6th order equation is incorporated into the code base and is employed during real time to convert measured motor locations during pumping at approximately -60mmHg into volume. Calculus is thus ultimately employed to arrive at this volume calculation in that motor location versus volume is integrated between two points to determine differences in volume. At certain levels of flow there can be an adjustment factor multiplied by volumes calculated when comparing calculated flows with real world experimentation, in particular to accommodate for flows shortly before and after purging, for example, or for flow above 15ml/minute. Additionally based upon empirical observations, when the pump is filled with air, a mathematical constant is incorporated into the volume calculations. A determination that the pump is filled with air can be made by observing how hard the motor has to work, and knowing that the motor has to work harder to create vacuum changes when the system is filled with air as opposed to when the system is fluid filled.

[00118] When calculating milk volume pumped from the system 10, as stated, there is a need to distinguish between any air pumped by the system versus milk pumped from the system, as well as pumping mixtures of milk and air. When initiating a milk pumping/extraction session, there is air in the tubing 32 this initial volume of air needs to be pumped into the milk collection container 60 to prime the pumping system 10. Again, distinction between pumping air versus pumping milk can be recognized by correlating pressure changes with the amount of movement of compression member 38 needed to establish the pressure changes. For example, when air is in the tubing, a greater change in position, or more overall travel of the compression member 38 is needed to establish the same pressure change than that needed when the tubing 32 is filled with milk. Thus, relatively more motion of the compression member with relatively less pressure change indicates air in the tubing 32. This difference in pressure may also be detected when the compression member 36 is open (i.e., not closing off tube portion 32S) and compression member 38 is retracting and this increasing the vacuum pressure.

[00119] When a user has completed the pumping phase of extracting milk from a breast, it is useful and efficient to purge as much milk that remains in the tubing 32 from the

tubing 32 and into the milk collection container 60. Ending of the extraction phase can be performed upon elapse of a predetermined extraction phase time, calculation of a predetermined amount of milk having been pumped, manual cessation of the extraction phase by the operator, or some other predetermined value having been achieved after performing the extraction. The direction of the pumping stroke of compression member 38 is reversed and the compression member 38 is run in the reverse direction to decrease suction within the tubing 32 and optionally create a small positive pressure within the tubing 32 to facilitate removal of the system 10 from the breast. Alternatively, the suction may be decreased to a level where a slight suction remains so that the user still pulls the system 10 of the breast to detach it. Preferably the vacuum is reduced to 0mmHg, or a slightly positive pressure to automatically detach the system 10 from the breast. The end pressure value where the pressure reduction by reverse pumping is ceased can be in the range of about -20mmHG (weak vacuum) to a positive 50mmHg (e.g., the crack pressure of the valve to the container). The compression member 36 does not close off the tubing portion 32S during this process, rather, tubing portion 32S remains open. Initiation of this reverse pumping may occur automatically or, alternatively, may be initiated by the user. This process continues until the seal of the system 10 to the breast is broken, which is detected by the controller via sensor 54. Once exposure of the tubing 32 to atmospheric pressure is detected, the stroke direction of pumping is again reversed thereby pumping the milk in tubing 32 under positive pressure and driving the milk from the tubing 32 into the container 60. If by chance, the system 10 accidentally or otherwise becomes resealed to the breast during purge pumping, the system 10 can automatically shut down as it senses vacuum pressure being regenerated in the vicinity of the flange or breast/skin contact member 14.

[00120] The system 10 can be configured to distinguish whether it has been attached to the left breast or the right breast of the user. This can be useful for tracking milk volume output per breast, per session, total daily volume per breast, etc. When using two of the pump systems, the tracking of data for each breast can still be maintained accurately, even when one of the pump systems 10 is attached to the left breast during a current pumping session after having been attached to the right breast during a previous pumping session. In one embodiment, the pumping systems 10 can establish

current location (i.e., left or right breast) by receiving a signal from the other pumping system having been attached to the other breast. This established relative left-right locations of the two pumping systems 10, so that each system 10 can accurately record as to whether milk is being extracted from the right breast or left breast. This identification is automatic, without any user input required and it also relieves the burden on the user to otherwise keep track of which pump system 10 is placed on each breast and to maintain this order with each successive pumping session. Left and right pump labeling is also contemplated such as by placing markings on the system housing or cover jack, for example, near the power connector.

[00121] Various approaches to assessing milk volume can be included in the pump system. Certain approaches are describe in co-pending International Application No. PCT/US15/50340, the entirety of contents of which are incorporated herein by reference. A further approach to assessing expressed milk volume involves placing one or more disposable data collection devices on the mom or child. One specific approach involves creating a boundary on the skin of a breast and employing a fiducial to conveniently measure the change in size of the boundary. This change in size is then correlated to milk production to arrive at a volume of milk expressed or pumped. A crib or bassinet can also include sensors and communication hardware that communicate with the pump system so both assess and management milk consumption and needs, and baby health.

[00122] The system 10 can calculate the pressure during operation in any of the manners described above. The suction (pressure) level can be varied as desired, and by continuously or repeatedly measuring/calculating pressure, the feedback provided by sensor(s) 54 to controller 52 provides a control loop that can be used to adjust the compression member 38 position and/or speed to vary the suction pressure to a level desired, or maintain a desired suction pressure in real time. Thus, controller 52 can control the positions and speeds of compression members 36, 38 to achieve any vacuum pressure pumping profile desired, and provide automatic, real time adjustments to maintain a desired vacuum pressure within the system. Also contemplated is responding in real time to maintain flow. This can accomplished independent or in conjunction with monitoring and regulating pressure in real time.

[00123] The controller 52 tracks the position of the compression member 38 relative to the tubing 32L, such as by keeping track of the driver 46 position or shaft position (interconnecting linkage between driver 46 and compression member 38), and calculates (or looks up) pressure based upon data received from sensor 54. The system controller or firmware is programmed with or retains information relating values detected by system sensors with driver positions and speed and system pressure. Thus, changes in position and/or speed of the compression member 38 by controller 52 can be controlled by resulting changes in pressure calculated or looked up, relative to the pressure sought to be achieved. As stated above, by using machine learning or supervised learning regression techniques, the system 10 can be trained to interpret the motor positioning and tubing strain (as well as motor speed or pump settings), while compensating for noise and hysteresis, to arrive at a pressure/vacuum level. More specifically, a neural net system or other mathematical regression can be incorporated into system firmware so that sensor input can be translated to pressure/vacuum levels. Controller 52 can thus control compression member 36 in a similar manner, but control of member 36 is more focused on position control, as the compression member 36 needs to fully close off tube portion 32S when maintaining latch suction against the breast/nipple. However, the closing off is timed and performed at the determined latch pressure, which is known from the data received from sensor 54.

[00124] Turning now to Figs. 22-28, various aspects of remote control and data collection approaches are presented. In at least one contemplated embodiment, the system 10 can be configured to communicate with a server, a remote computer, smartphone or other device such as through signal, such as by Wi-Fi, BLUETOOTH, BLUETOOTH Low Energy (BTLE), RFID, NFC or the like. In particular, one or more chips can be incorporated into the controller of the pumping system 10 (by hard wire and/or wirelessly, preferably wirelessly) and configured to be in communication with an external computer. The controller and/or external computer communicates with the sensor(s)/chip(s) which indicate(s) when the system is in use, and can track usage. By tracking the times of use and/or number of uses, or even pump cycle counts, for example, the controller, or external computer can alert the user when it is time to change components or to report on usage aspects. In this way, information such as the

tracking of extraction date and time, volume extracted, etc. can be recorded and stored with regard to each milk collection container used with the system 10 to extract milk. Thus, the system 10 can register individual milk collection containers, so that the user can readily identify when milk in each container was collected, the volume in each container, etc. The breast pump system can record the volume of milk in any given container during a pumping session. The data recorded can be sent to an external computer and/or over the Internet, either automatically or manually. Thus, user data and trends can be collected, stored and analyzed as they relate to volume (from each breast and in total), as can be the number of sessions on several dimensions (per day, week or month). Data and analytics can thus be provided to a user concerning pumping sessions.

[00125] In one particular approach, at least the session start time, the session end time and total volume of milk extracted from the breast can be stored and tracked. Sessions can be defined as the commencement of latch and can continue up to and through pauses of up to 5 minutes, for example. Thus, a pause of over 5 minutes can be defined as the end of the previous session. A language protocol is generated so that there is a two-way communication between an external device or program and the breast pump. That is, both the pump and external device can create and understand and are responsive to specific messages. Further, live data and historical data can be treated differently, and their data streams maintained separately. Live updates are generated and stored at the pump and are available by the external device to retrieve (for example, up or down button activations or volume updates). Accordingly, such live data can be reflected on and update the screen of the external device. Historical data is stored inside the pump in a stream and the pump can communicate with this stream to extract or act upon the same. An internal pump memory such as a disc within a chip or other internal flash stores, communicates with the pump so that session data is written to an internal history log. At the end of a session, for example, the pump will write the session data to its internal history log and the external device will ask if there is any data and if the pump indicates that there is, then the external device will download this historical data to update its non-live view screens. The external device can also make this same query after an extended time and then download multiple session data, and

the query also can be made during a session. In one particular embodiment, as much as 600 sessions of data can be stored.

[00126] In one or more embodiments, the system can additionally or further include structure configured to accomplish or functionality operating as an Active Pause Mode, that allows the system to maintain latch vacuum, while remaining (especially under no/low flow) virtually silent. Such a system stays much quieter than pump mode, but ensures the system does not fall off the breast. It can be employed by the user mom when she needs to interact with others and does not want them to hear the pump, or for some other reason where she might not be ready to remove the device but does not want active pumping either.

[00127] The remote user interface 140 on an external device can take a myriad of forms. The pump system can also be personalized such as by giving one or more pumps a name (Fig. 22). A user profile can be created for a child and linked to a child's birthdate (Fig. 23). Other details such as tracking the child's age when use of the system commenced can be gathered so that analytics pertinent to the child's age can be generated. In this way, pump performance can be tracked to the growth of the child. Reminders can be entered into the system (Figs. 24) so that the user can focus on matters other than breast pumping. Notifications can be keyed to time or volume of milk pumped while both of such criteria as well as battery life can be tracked and reflected on the remote computer (Figs. 25-28). Easily understood and convenient graphics are contemplated for expressing status such as curved hemispherical strips 150 reflecting volumes pumped for each pump system, the same information also being shown in numerical form 152. Timing countdowns as well as information from one or more previous sessions can also be graphically displayed for effectively communicating with a user. The ability to remotely begin a new session can also be made available to the user.

[00128] The remote user interface 140, whether provided as an App, on a cell phone, computer or other computing device, can also include specific user control functionality, and various related easy to understand displays (See Figs. 29-41). As shown in Fig. 29, in one or more approaches, the amount of milk pumped is tracked by day, and an option is provided to the user to set a session tracker by day. The amounts

pumped are also tracked by breast. A user can set one or more of time and volume of pumping by breast for one or more pumping sessions. For example (Figs. 30-31), a volume target can be set by the user by various increments such as .1 ounces. This setting can be set and saved, or canceled. As shown in Fig. 32, the user can then control whether to pump with one or both breasts, and then the system starts tracking pumped volume (see Fig. 33). As pumping progresses (Fig. 34), easily readable curved bars reflect the amount of volume being pumped by each breast, the bars becoming thicker as more volume is pumped. The user can adjust suction levels for one or both of the pumps attached to a breast (Figs. 35-36) to coordinate pumping or to otherwise pump as desired. After reflecting the changes in suction level, the user can return the system to tracking volumes pumped by breast (Fig. 37), and an indication of volume remaining to be pumped is also provided. Once the pumping target is met, such as a target volume (Fig. 38), the user interface will indicate that the session has been completed. Thereafter, an updated set tracker is presented, with an ability to set further pumping schedules (Fig. 39). The user can then select an option to depict a summary of pumping or a history of pumping (see Figs. 40 and 41). The data provided by the user interface can include bar graphs and numerical data showing pumping by day and by breast and session times and number of session. Additionally, circles can be sized to represent relative amounts of pumping by date, and color coated by breast.

[00129] The pump system can also include a power management system that functions to save power. In one aspect, the pump system can be characterized as having multiple modules or threads, each running separate programs. Each thread, such as fifteen to twenty different threads, is designed to operate in a manner to save power. That is, each thread is controlled so that it seeks and finds its own maximum, minimum required power mode.

[00130] The pump system can be further configured so that the power management system includes a power hierarchy including various different levels at which the threads seek to achieve maximum, minimum required power. In one approach, the levels can include one or more of hibernate, standby, standby with LED's and active. Hibernate can be characterized as a deep sleep state and standby can be defined at a level where the system is running the computer chip and running calculations but not

external components are being run. Standby with LED's can mean just that the LED's are engaged and active can mean that external components like the motors and sensors are working. The power system can thus function so that a query is sent to each thread asking for the thread's current state and it's minimum required mode. The power system then cycles through each thread and sets the power level at the maximum, minimum power level required so that each thread can properly operate.

[00131] In still yet further embodiments and approaches, the pump system can alternatively or additionally include built-in or computer or App based functionality to de-stress the user's life, empower the user to better take care of the nursing baby's health, maximize the user's mobility and freedom, and support all that is involved in becoming or being a parent. In these regards, pump system structure and functionality can include one or more of keying on pain points, physical conditions, sleep, pain relief, and post partum issues, tracking sleep, sensing and tracking baby vitals and movement, focusing on connected health with the mom as the caregiver, and/or providing education, guidance or instruction on movement and ways to carry a baby, fertility, post baby needs, health of the mom, ultrasound and fertility. The pump system can additionally include App integration with smart bottles, smart scales or the like to facilitate managing overall baby health and nutrition. App updates can additionally be provided about stimulation and letdown, and timing of pumping based upon such information, such as suggestion to begin pumping. System structure and functionality can also involve updating pumping profiles based upon baby age and needs, developing pumping functionality which enhance milk production, enhance efficiency or comfort or better mimic baby. Data can be stored in the cloud for analysis, and additional functionality can be provided to modify speeds and alternated between and among customized modes and profiles. Additional or a myriad of sizes of flanges and bag or container assemblies can be provided to the user as can nighttime pump functionality or programming including automated sessions with starts and stops.

[00132] Inventory management is further functionality that is provided as part of the structure of the pump system. In connection with the same, container assemblies can include structure that is scannable or which otherwise communicates with the inventory management system (eg., via bar codes, RFID chips). Further, operative

communication structure can be provided so that the user can transmit data with and between a baby-center platform that stores data thus facilitating an avenue for the effective management of the baby's nutrition, and links can be made to automatically communicate with milk banks and donation centers. Additionally, a caregiver data share system can be included within the functionality and structure of the pump system. Texting is added to other forms and avenues for communicating such important and useful information.

[00133] While the present disclosure has been described with reference to the specific embodiments thereof, it should be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the disclosure. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process step or steps, to the objective, spirit and scope of the present disclosure. All such modifications are intended to be within the scope of the present disclosure.

CLAIMS:

That which is claimed is:

1. A wearable system to pump fluid from a breast, the system comprising:

a skin contacting structure configured and dimensioned to form a seal with the breast; and

a conduit in fluid communication with the skin contacting structure;

wherein fluid extracted from the breast flows into a sealed collection assembly, or sealed collection assembly having an integral valve system or an airtight collection assembly for storing the fluid pumped from the breast.

2. The system of claim 1, wherein the wearable system pumps fluid through the conduit against gravity.

3. The system of any previous claim, wherein the wearable system maintains at least a latch suction throughout a pumping cycle.

4. The system of any previous claim, further comprising a controller configured to control operational settings of the wearable system.

5. The system of any previous claim, the collection assembly further having a fitment sized to be received within the conduit.

6. The system of any preceding claim, further comprising a controller configured to adjust pumping in real time.

7. The system of any preceding claim, further comprising a flange and door configured in the flange, wherein the door engages the collection assembly and maintains an engagement between the collection assembly and the conduit.

8. The system of any preceding claim, wherein the conduit includes spherical connectors, one spherical connector being placed into engagement with a compression member configured to facilitate pumping of fluid through the conduit.

9. The system of any preceding claim, wherein the conduit includes a bulged portion configured to accommodate system hysteresis.

10. The system of any preceding claim, further comprising a flange, a chassis and a housing, wherein the flange, chassis and housing snap together.

11. The system of any preceding claim, further comprising structure for impeding fluid ingress into the wearable system.

12. The system of any preceding claim, further comprising a controller, the controller controlling a pumping function and modifying pumping to reach targets in real time.

13. The system of any preceding claim, further comprising further comprising a flange, a chassis and a housing, wherein the chassis supports internal components of the wearable system.

14. The system of any preceding claim, further comprising structure configured to provide pinch protection.

15. The system of any preceding claim, further comprising a sensor configured to sense whether the system is properly assembled and a controller adapted to prohibit pumping until the sensor detects that the system is properly assembled.

16. The system of any preceding claim, wherein the collection assembly is placed within an interior of the system.

17. The system of any preceding claim, wherein the collection assembly includes an umbrella valve.

18. The system of any preceding claim, wherein the collection assembly is formed from two sheets bonded together.

19. The system of any preceding claim, wherein the collection assembly includes a central opening and a pair of wings extending into the central opening.

20. The system of any preceding claim, further comprising a computer configured to remotely control the system, the computer configured to collect, store and analyze user data and trends as related to volume from each breast and in total, and the number of sessions on several dimensions such as per day, week or month.

21. The system of any preceding claim, wherein the collection assembly includes a fitment that is integral with the collection assembly.

22. The system of any preceding claim, wherein the collection assembly includes a fitment that is attached to the collection assembly.

23. The system of any preceding claim, wherein removing the fitment from the collection assembly destroys the collection assembly or fitment.

24. The system of any preceding claim, wherein the collection assembly is disposable.

25. The system of any preceding claim, wherein the collection assembly is reusable.

26. The system of any preceding claim, wherein the system is sealed.

27. The system of any preceding claim, wherein the system pumps milk.

28. The system of any preceding claim, wherein a valve can be reattached to a second or subsequent collection assembly.

29. The system of any preceding claim, wherein the system is not closed.

30. The system of any preceding claim, further comprising a flange configured to engage breast tissue, wherein the flange includes a generally rigid flat section.

31. The system of any preceding claim, wherein the container assembly is positioned around a nipple of a breast.

32. The system of any preceding claim, wherein the breast contacting structure is incorporated into the collection assembly.

33. The system of any preceding claim, wherein the container assembly includes more surface area superior to a nipple of a breast than inferior thereto.

34. The system of any preceding claim, wherein the tube is configured to run inferior to superior relative to a nipple of the breast when the user is upright.

35. The system of any preceding claim, wherein a tube channel of the conduit includes a section that opens through passive recoil configured next to a section that opens through an assistive support.

36. The system of any preceding claim, wherein the collection assembly is at least partially supported and maintained in attachment to the system by friction with the conduit, and partially by a door assembly that encloses and holds the collection assembly in place.

37. The system of any preceding claim, wherein the collection assembly includes a one-way valve allowing fluid ingress but preventing backflow.

38. The system of any preceding claim, wherein the collection assembly includes a tear-able element to allow removal of fluid.

39. The system of any preceding claim, further comprising a safety mechanism configured to prohibit system functioning unless the system is completely assembled for use.

40. The system of any preceding claim, wherein an air-tight passageway is provided from a nipple source to the collection assembly.

41. The system of any preceding claim, wherein the system is never vented to the atmosphere.

42. The system of any preceding claim, wherein suction in the system is reduced only through the flow of fluid therethrough.

43. The system of any preceding claim, wherein any sounds generated by the system are reduced by fluid flow through the system.

44. The system of any preceding claim, wherein orientation of the system has no effect on functioning on the system.

45. The system of any preceding claim, wherein the system defines a breast enhancement system for enlarging the appearance of the user's breast, the system defining a natural breast profile.

46. A method of power management for a breast pump system having a plurality of modules each running individual programs, comprising:

providing a power hierarchy including a plurality of levels;

controlling the modules so that each module seeks and finds its maximum, minimum required power level;

generating a query asking for a current state and a minimum required mode for each module; and

cycling through each module and setting a power level for each module at its maximum, minimum power level required so that each modul can properly operate.

47. The method of claim 45, wherein the power levels include one or more of a hibernate level, a standby level, a standby with LED level and an active level.

48. A container assembly for a breast pump system, comprising;

a body, the body including a neck and a central opening;

a neck portion extending from the body; and

a fitment configured in the neck portion, the fitment including a tail sized and shaped to maintain the neck portion in an open position when the neck is bent.

49. The container assembly of claim 48, further comprising wings, the wings defining structure for manipulating the container assembly.

50. The container assembly of claim 48, the fitment further including a one-way valve.

51. The container assembly of claim 48, further comprising a tab extending from the neck portion.

52. The container assembly of claim 48, further comprising a tear-able section configured into the neck portion.

53. The container assembly of claim 48, wherein the tail has a narrow and elongated shape so that fluid can flow around the tail.

54. A method for calculating volumes extracted from a breast by a breast pump, comprising:

tracking and storing motor location versus time;

tracking and storing vacuum versus time; and

determining a relationship between motor location and volume of milk extracted from a breast by the breast pump.

55. The method of claim 54, comprising mapping motor location versus volume at a specific vacuum.

56. The method of claim 55, wherein the specific vacuum level is -60mmHg.

57. The method of claim 54, further comprising generating known rates of flow within the breast pump at a known specific vacuum within the breast pump and identifying motor location.

58. The method of claim 54, further comprising observing indications of purging of the breast pump and eliminating data other than that associated with a clean start and a clean finish between purges.

59. The method of claim 54, further comprising adjusting for relative time to calculate volume.

60. The method of claim 54, further comprising filtering out data associated with vacuum levels other than a range about a target specific vacuum level.

61. The method of claim 54, further comprising adjusting volume calculations for flows above a pre-determined level.

62. The method of claim 54, further comprising incorporating a mathematical constant into volume calculations to take into account when air is in the breast pump.

63. A method of handling data associated with a breast pump system, comprising;

generating and storing live data from operating the breast pump system;

generating and storing historical data from operating the breast pump system; and

maintain live data streams separate from historical data streams.

64. The method of claim 63, wherein historical data is stored in the breast pump system.

65. The method of claim 63, wherein live data is employed to update a device external to the breast pump system.

66. The method of claim 63, further comprising updating an external device with historical data.

67. The method of claim 63, further comprising storing session data, wherein a session is defined as commencing upon achieving latch and ending when latch ceases or there is a pause in pumping for over five minutes.

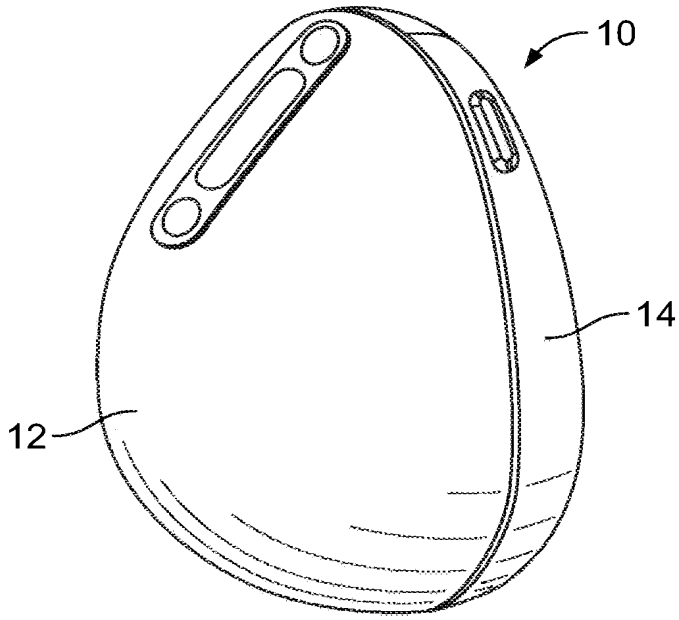

FIG. 1A

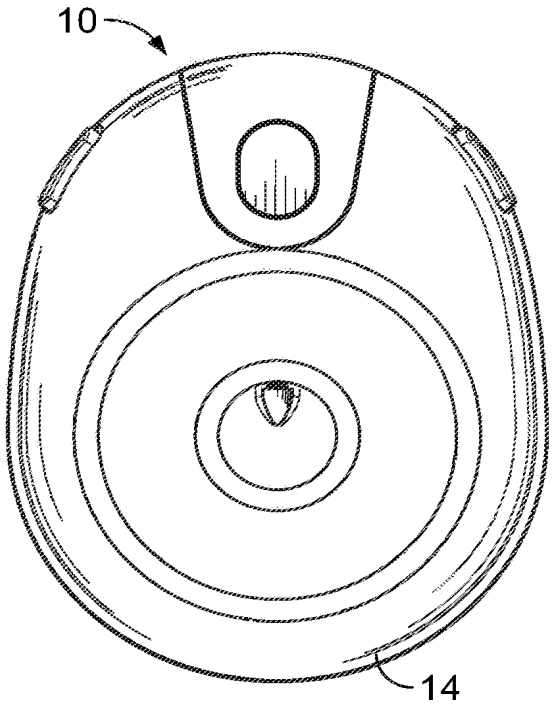

FIG. 1B

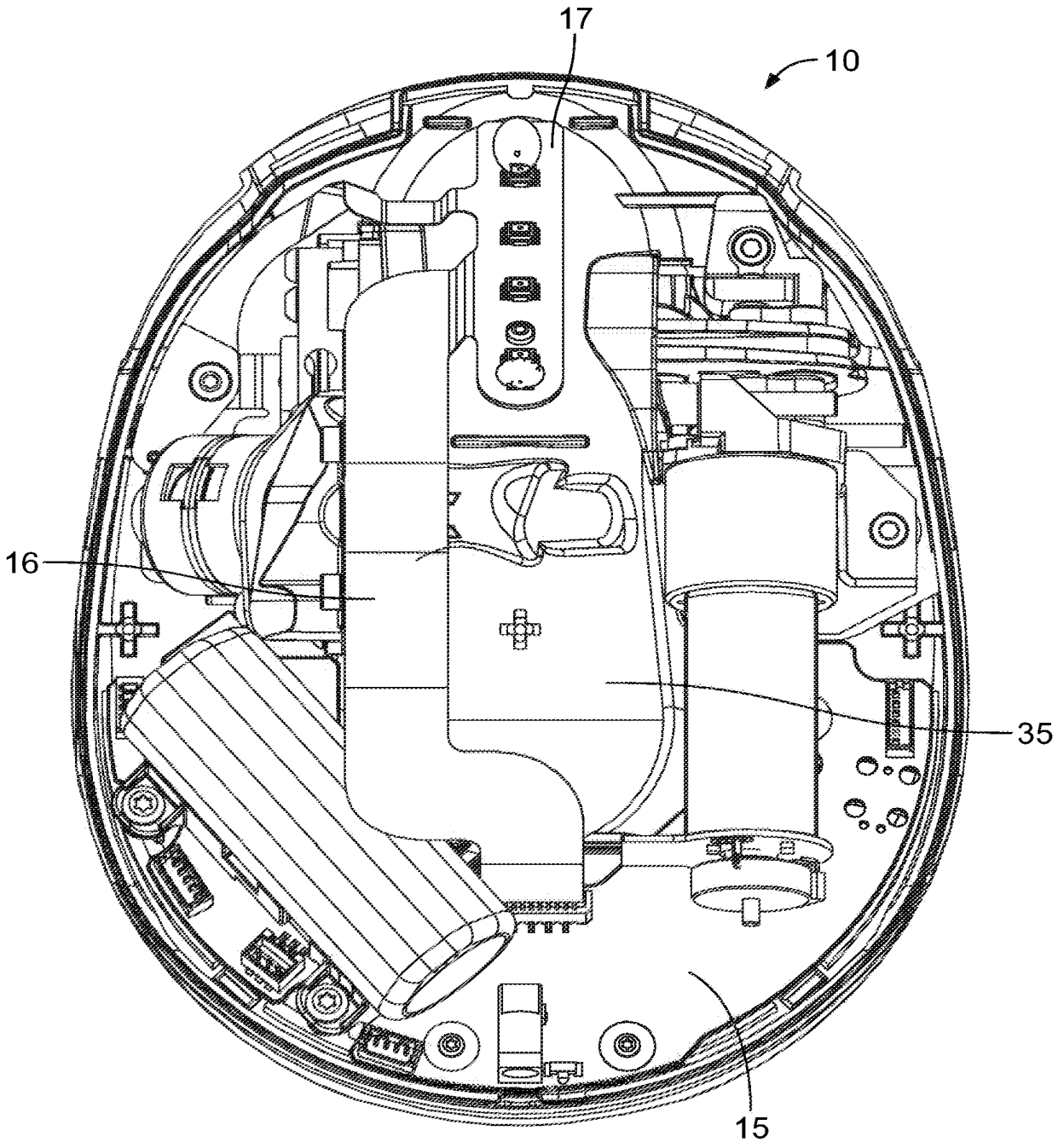

FIG. 2

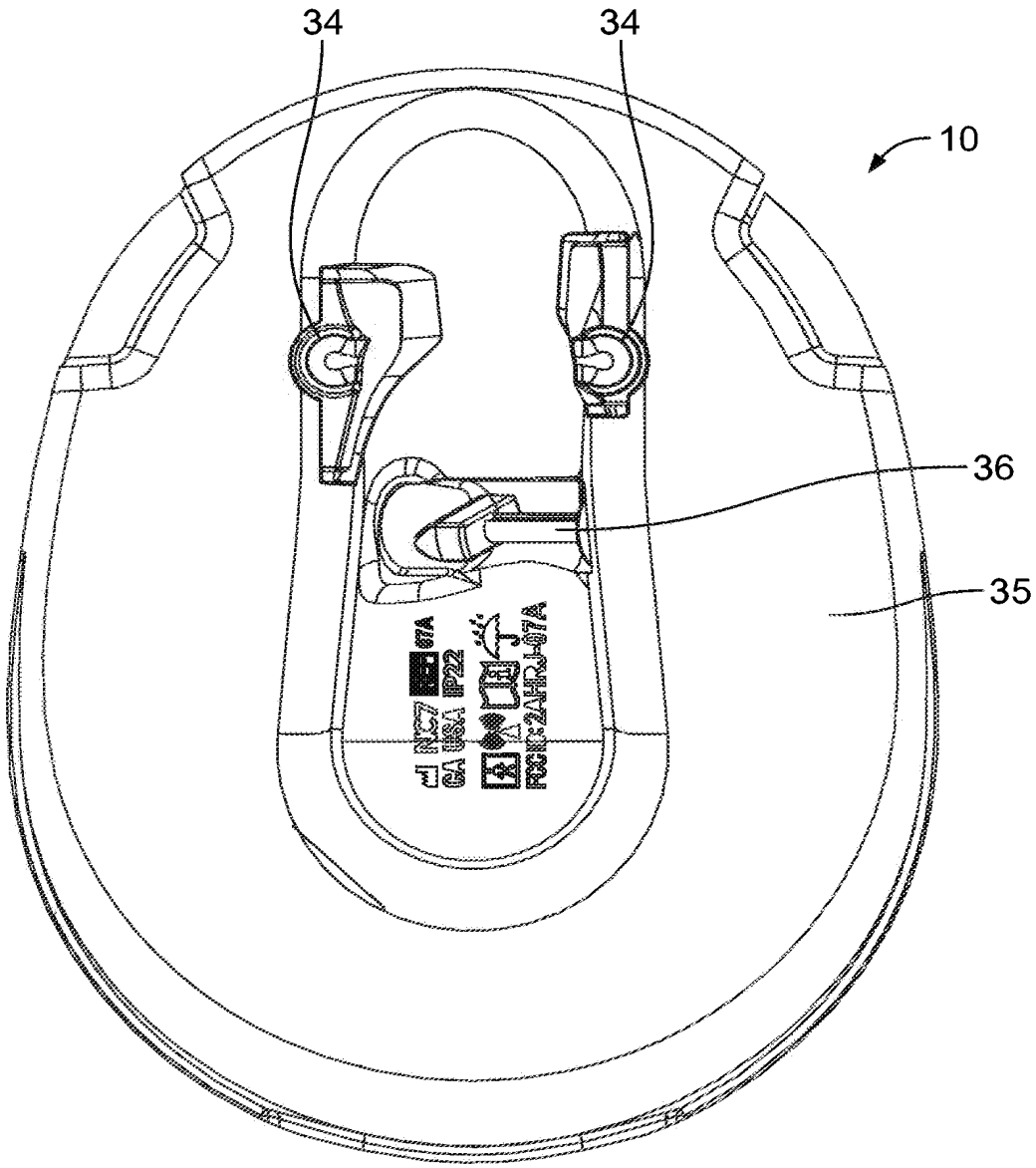

FIG. 3

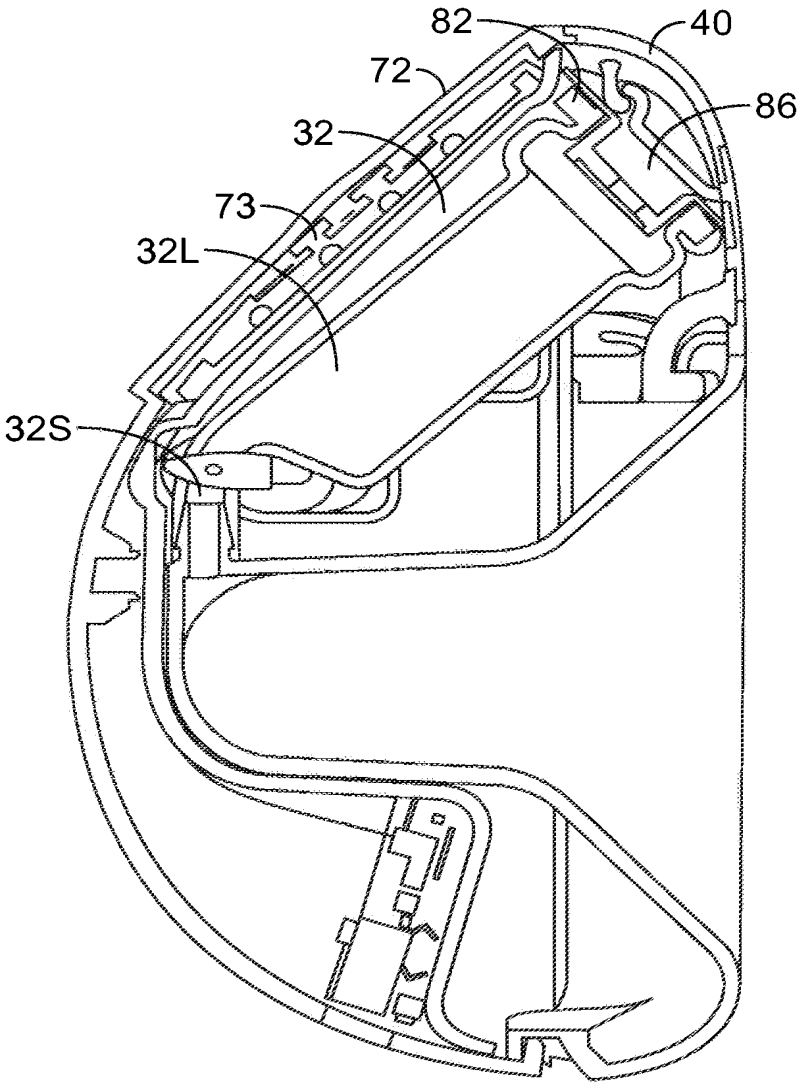

FIG. 4

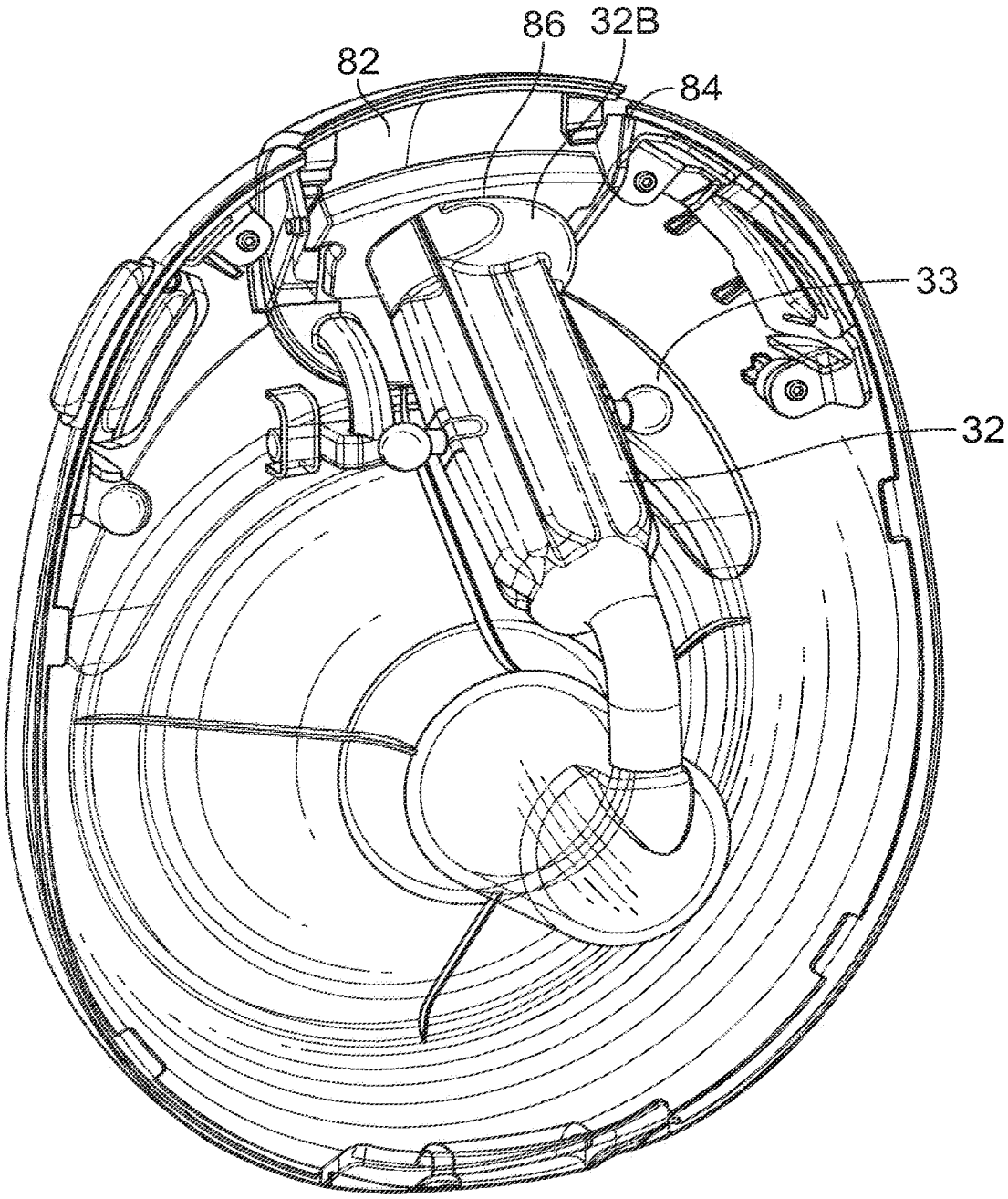

FIG. 5

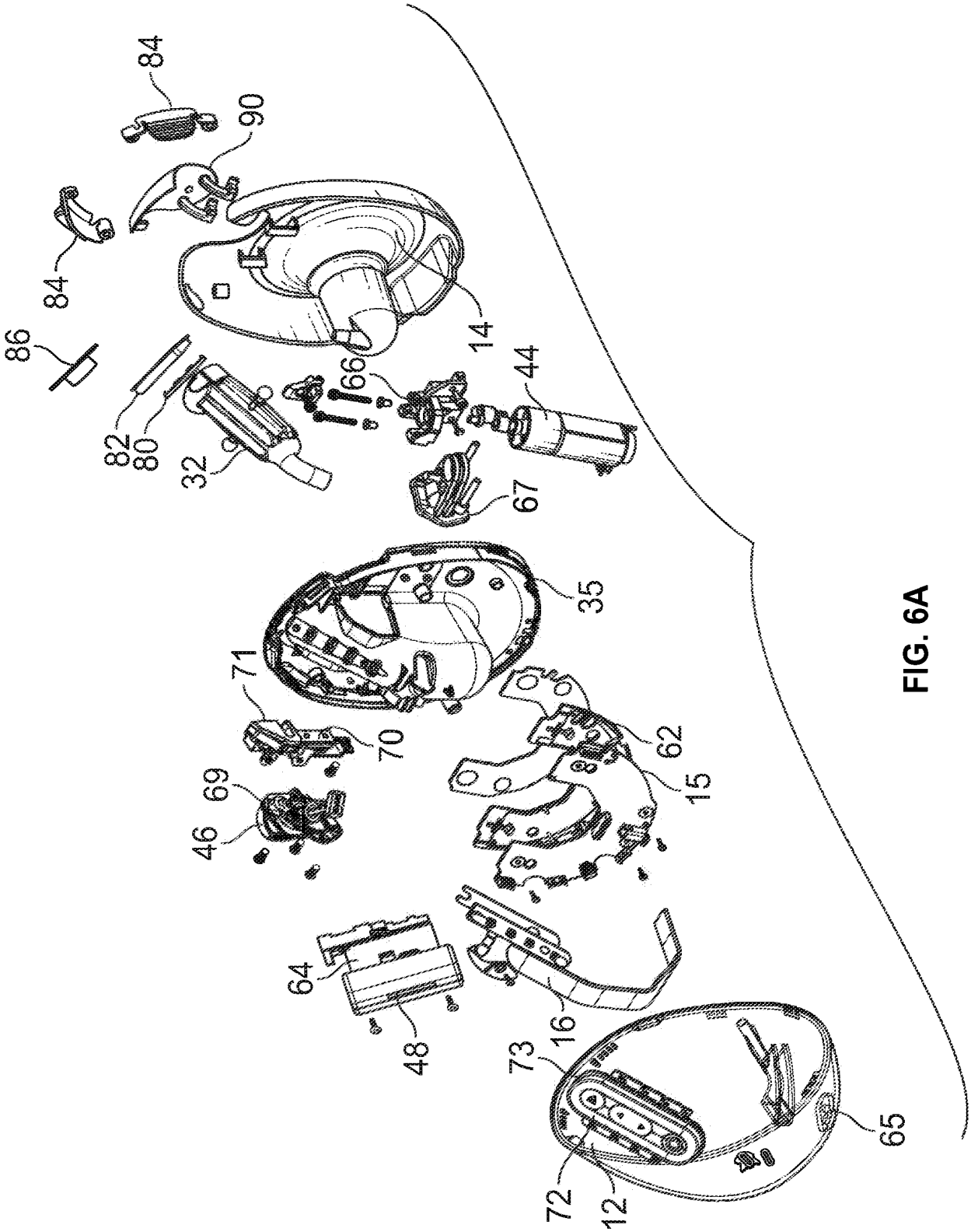
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FIG. 6A

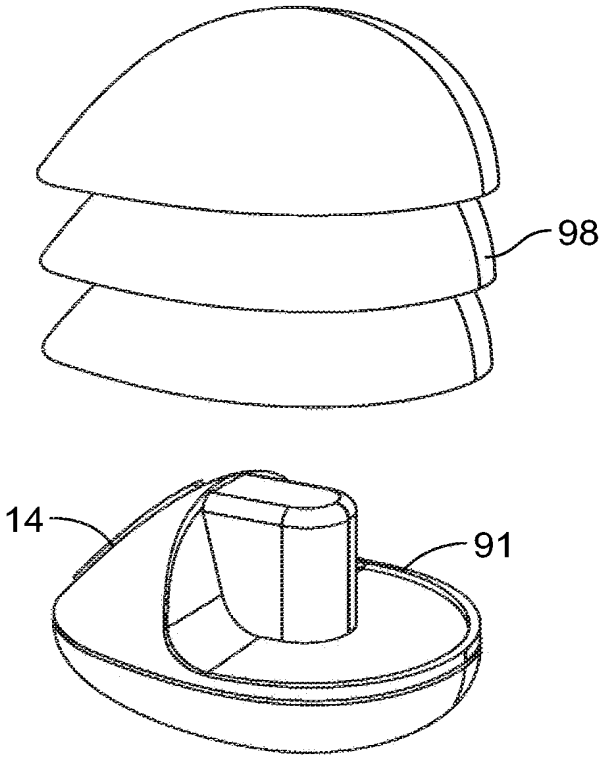


FIG. 6B

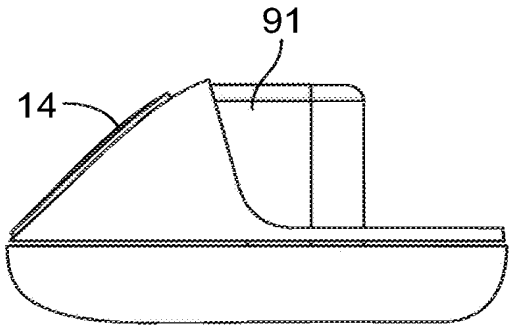


FIG. 6C

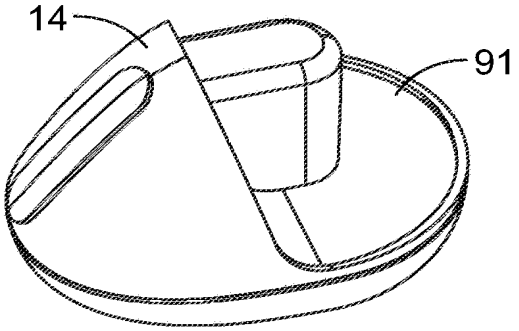


FIG. 6D

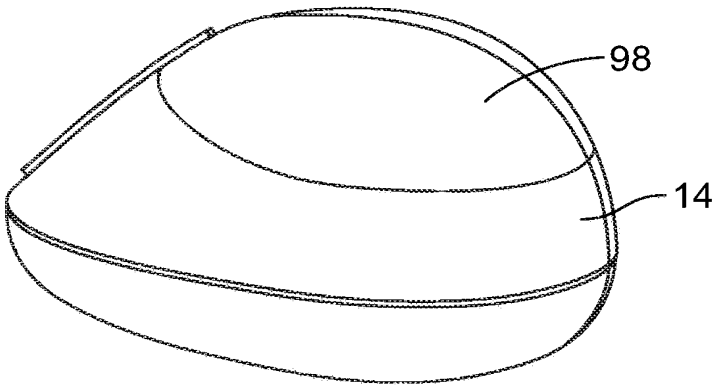
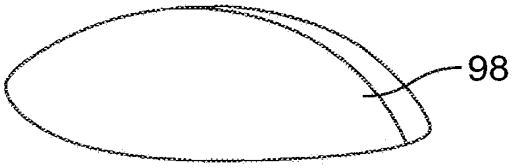


FIG. 6E



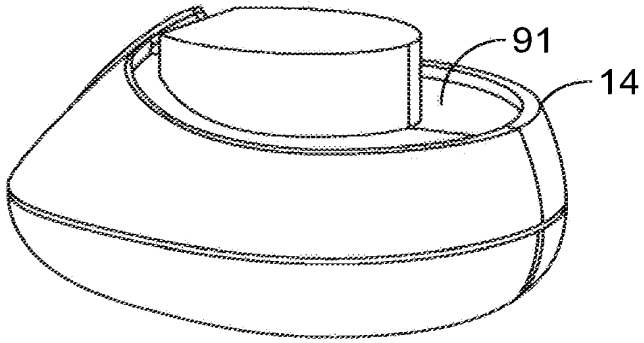


FIG. 6F

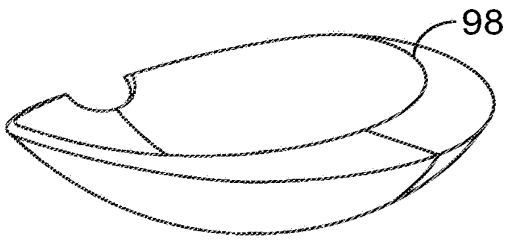


FIG. 6G

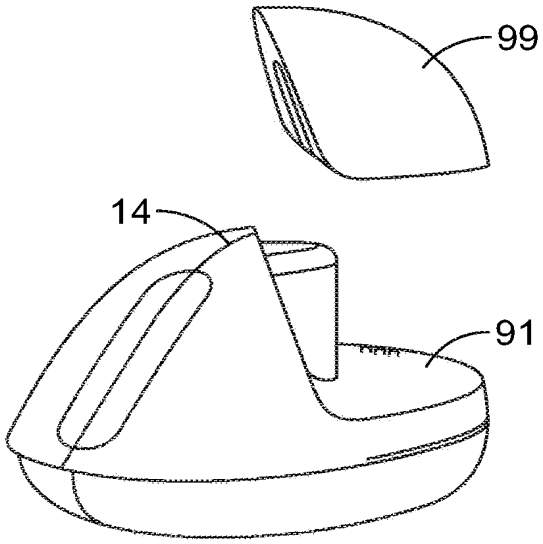


FIG. 6H

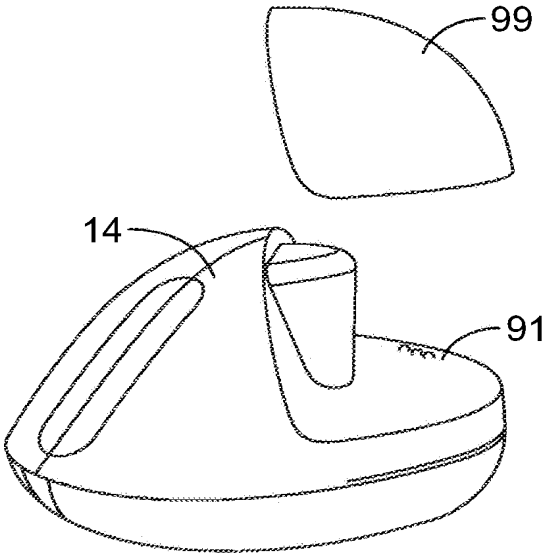


FIG. 6I

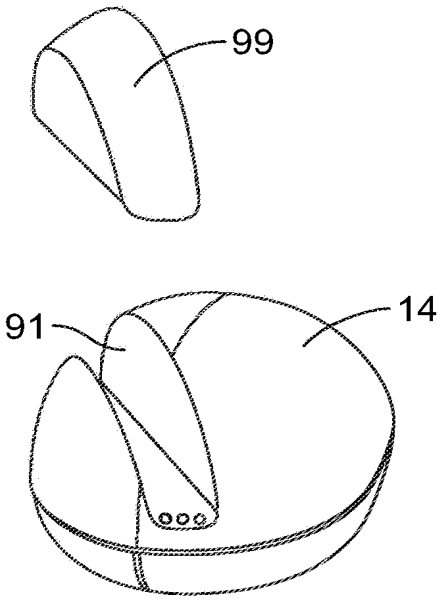


FIG. 6J

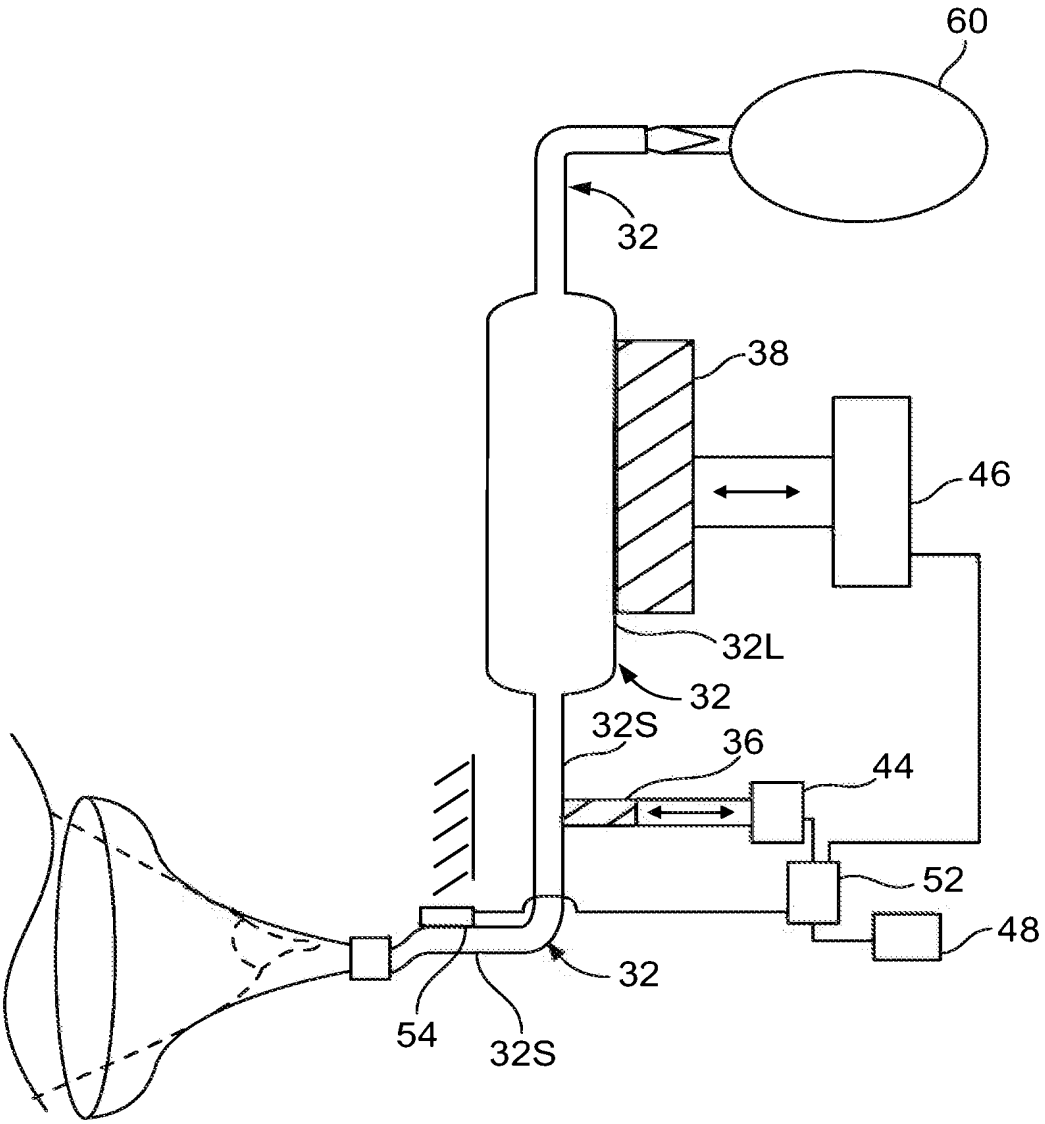


FIG. 7A

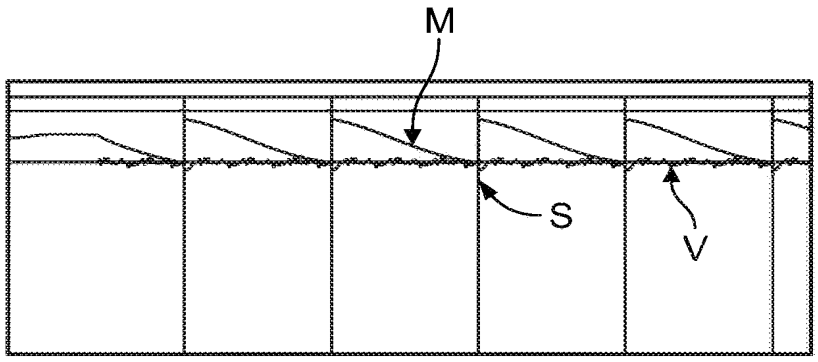


FIG. 7B

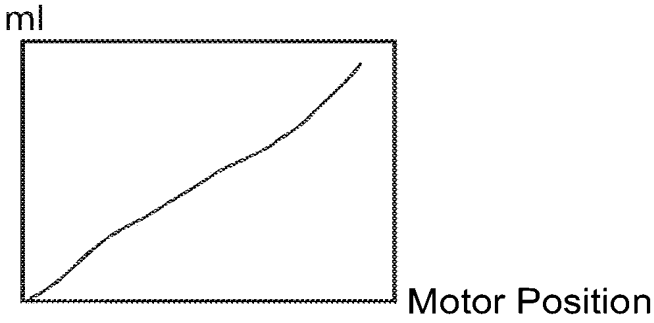


FIG. 7C

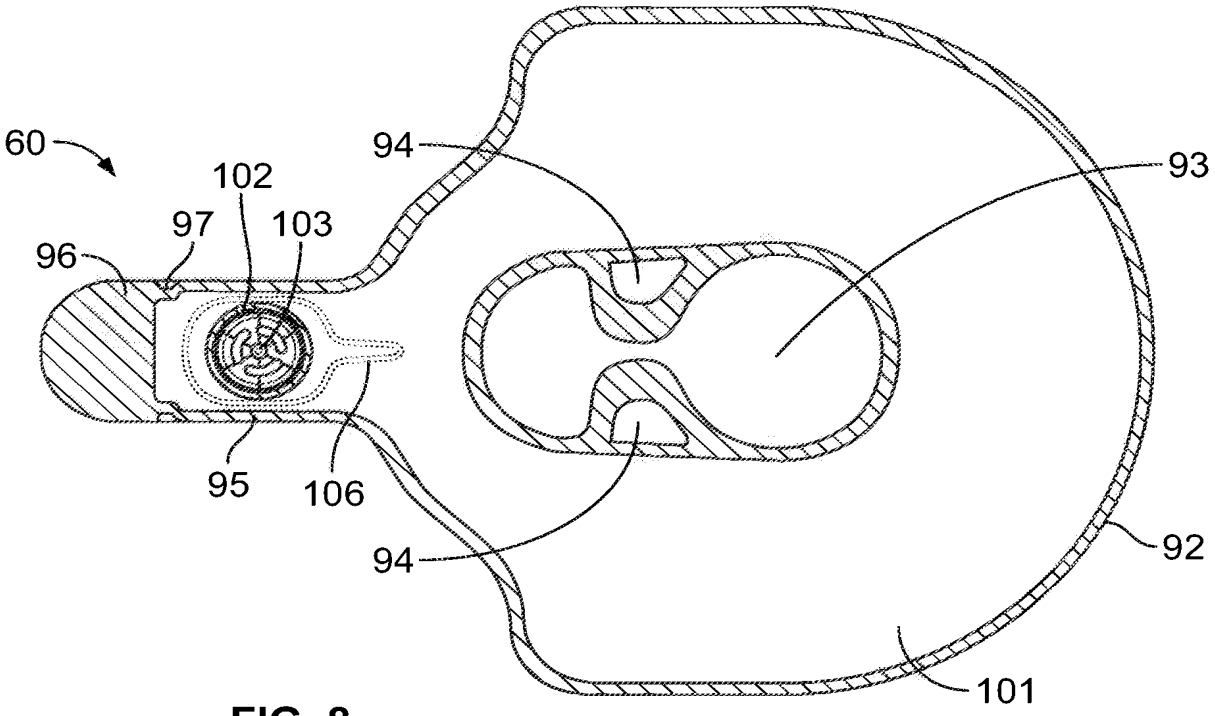


FIG. 8

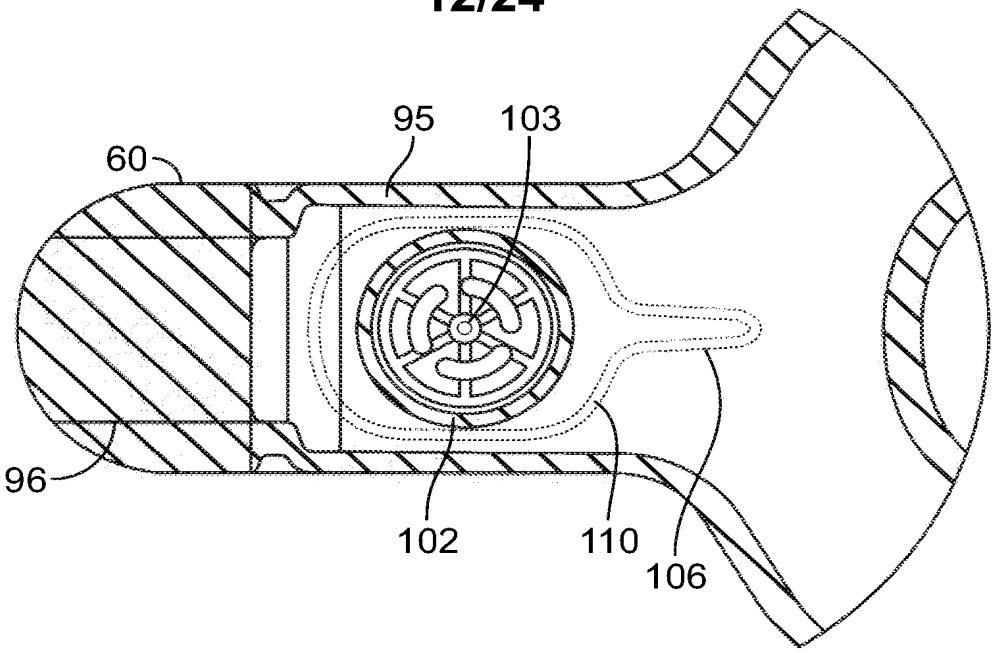


FIG. 9

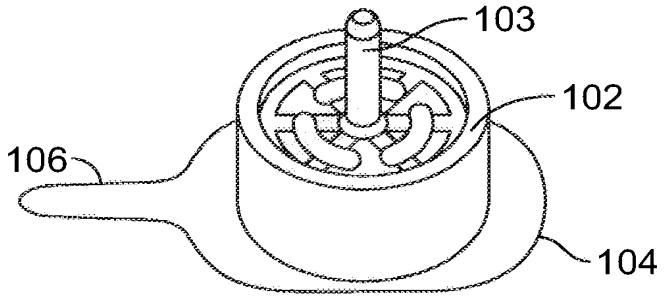


FIG. 10

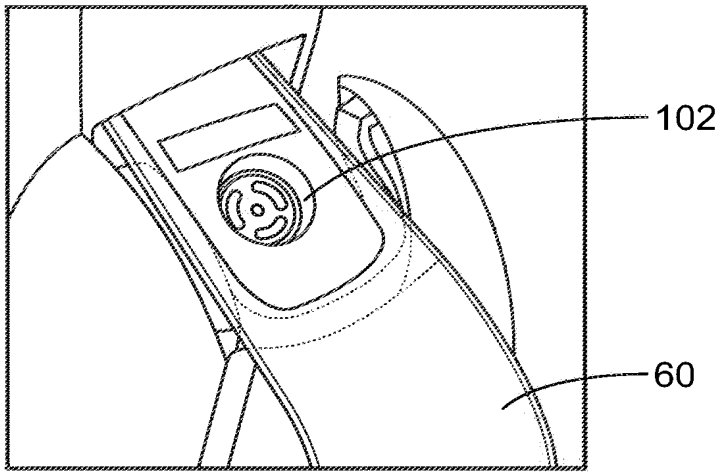


FIG. 11A

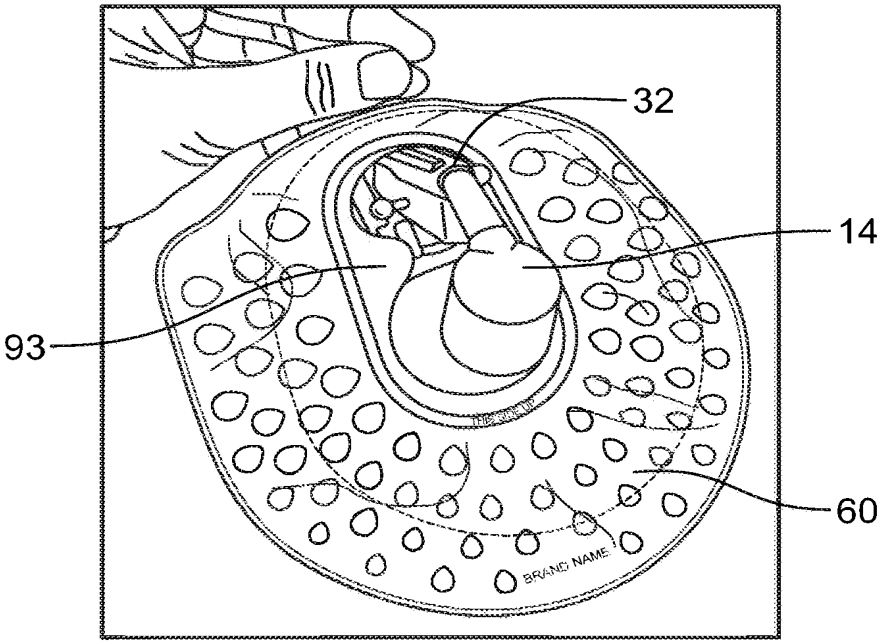


FIG. 11B

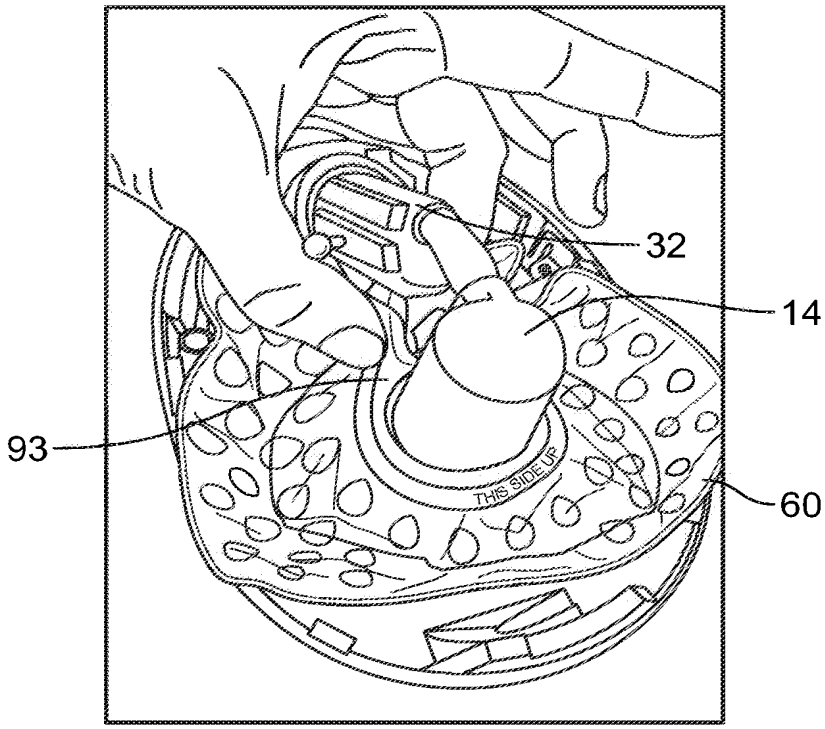


FIG. 11C

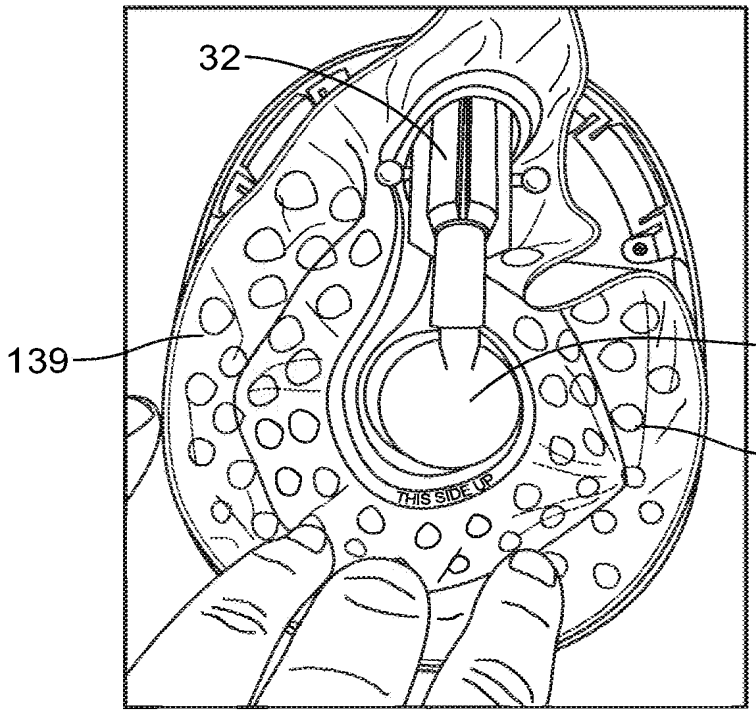


FIG. 11D

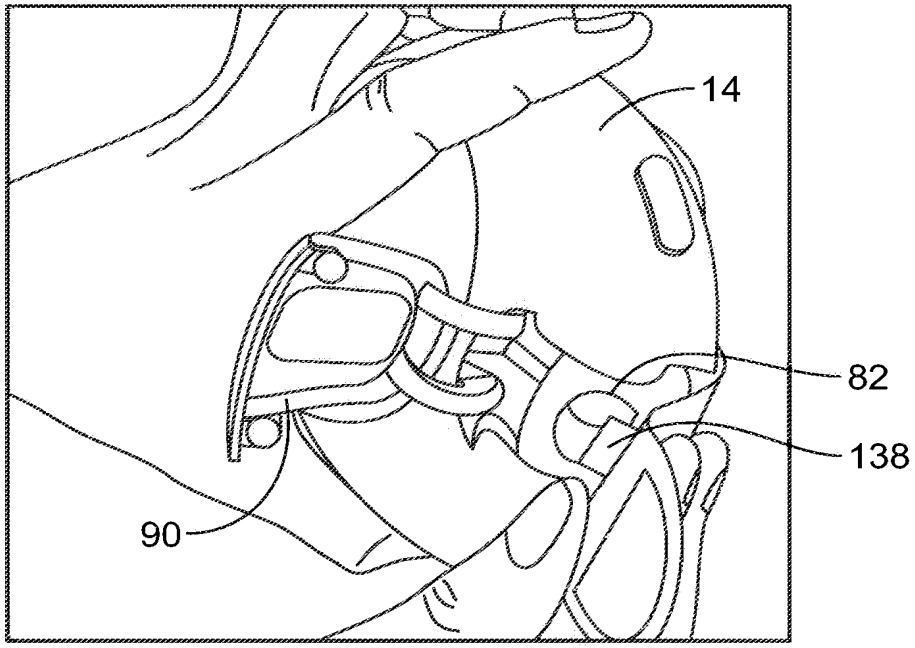


FIG. 11E

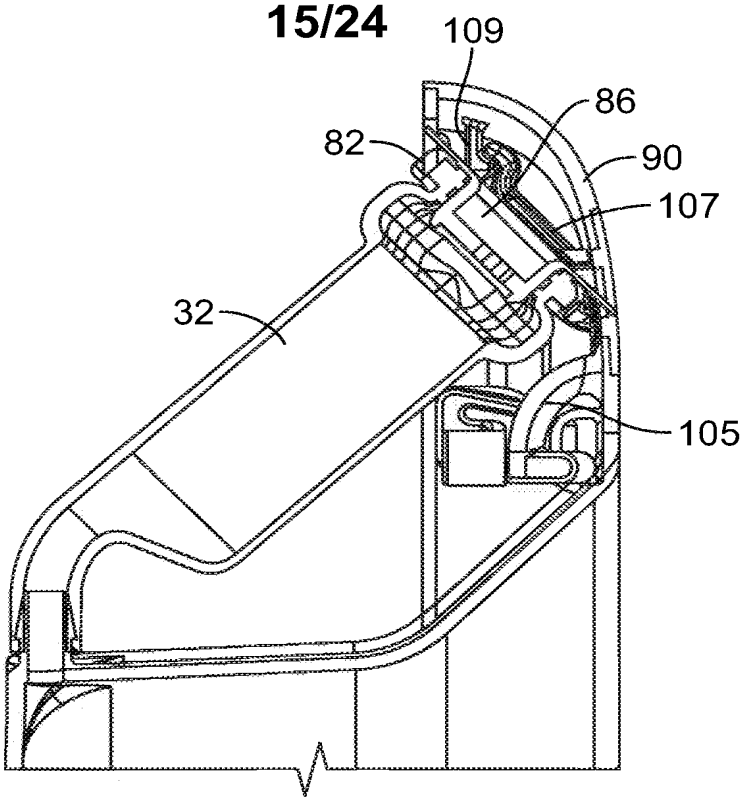


FIG. 12

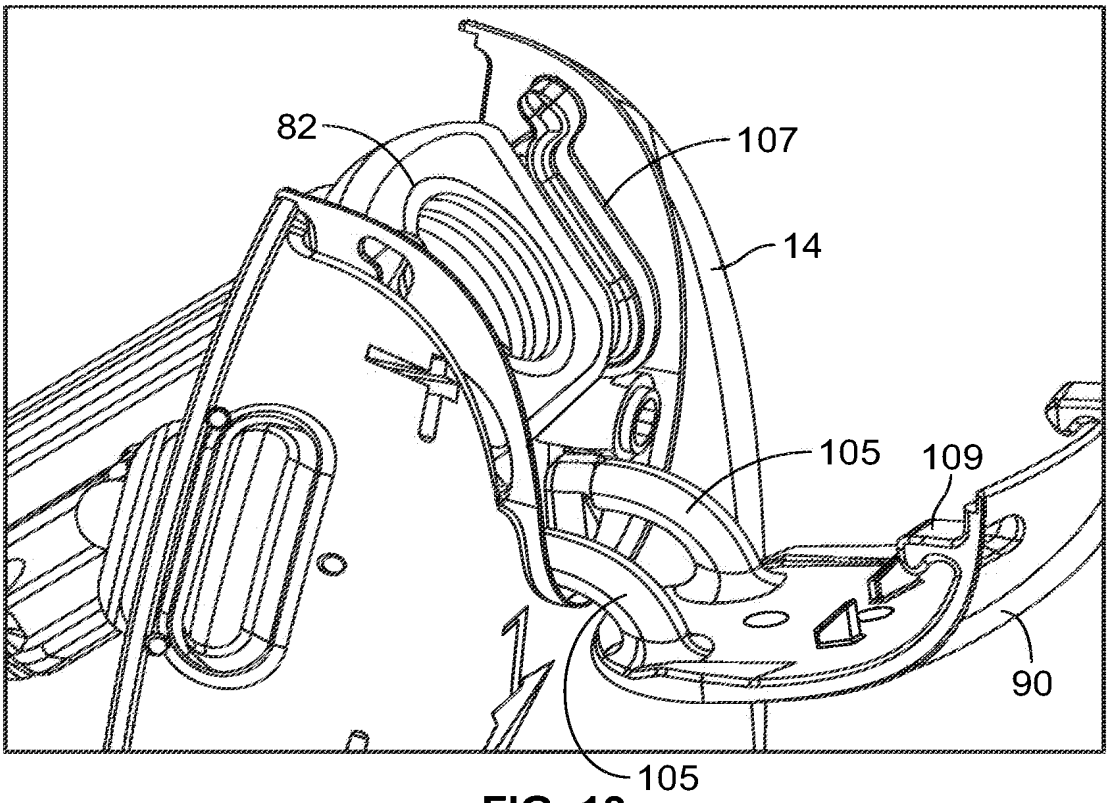


FIG. 13

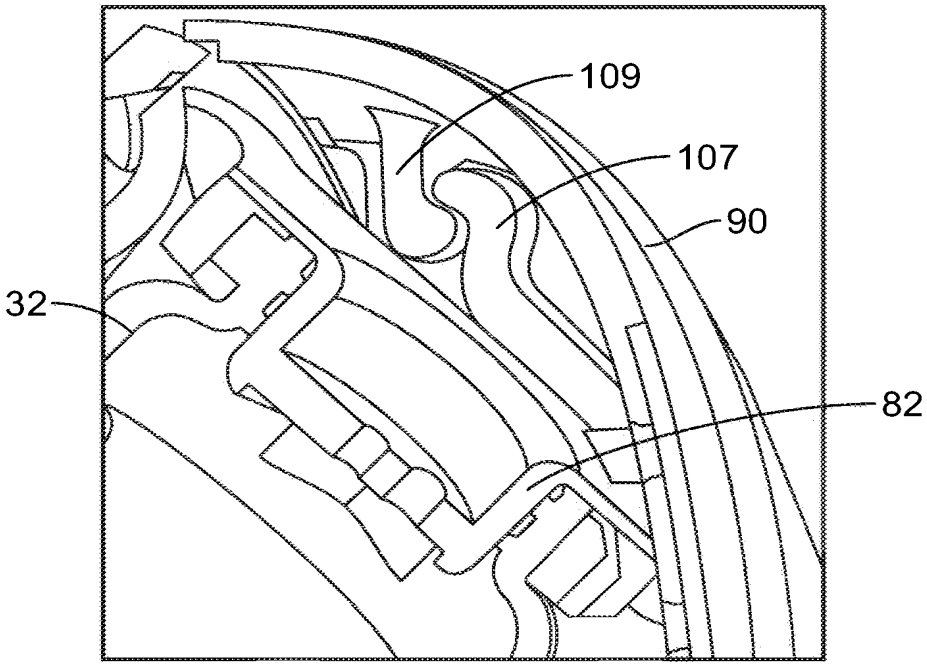


FIG. 14

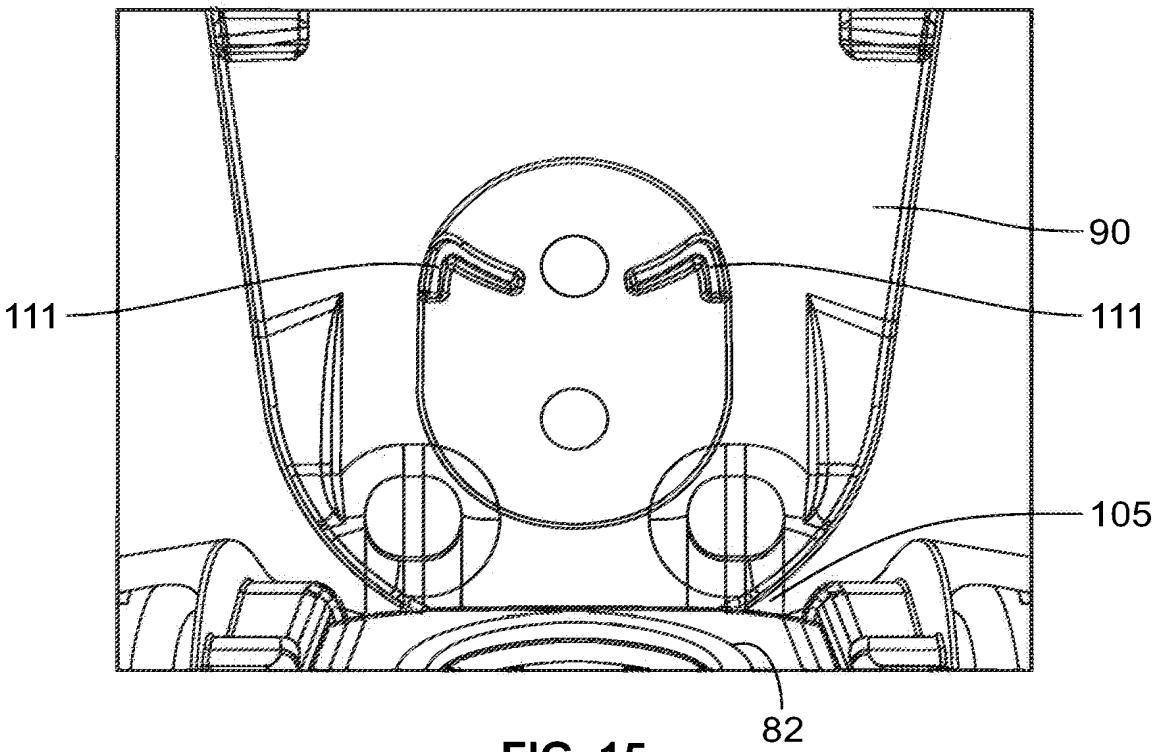


FIG. 15

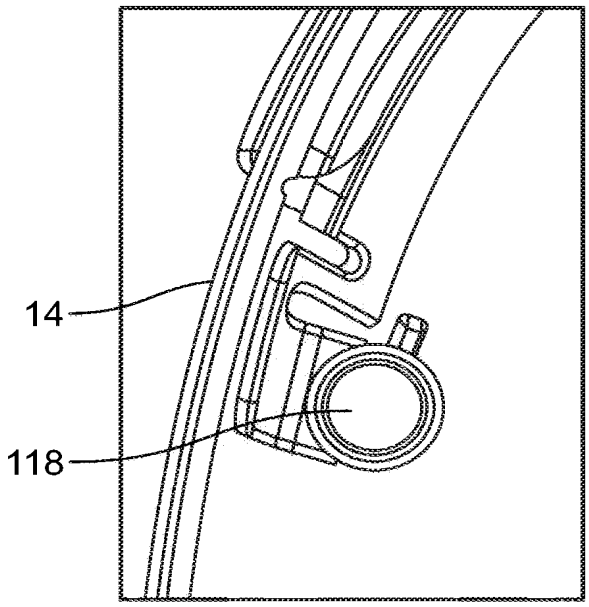


FIG. 16

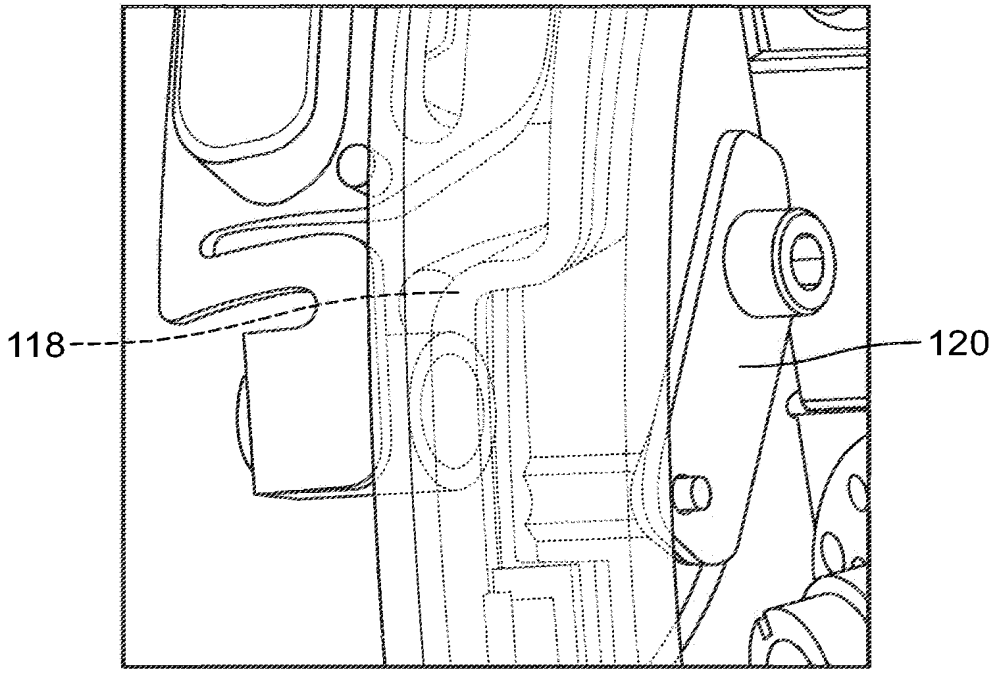


FIG. 17

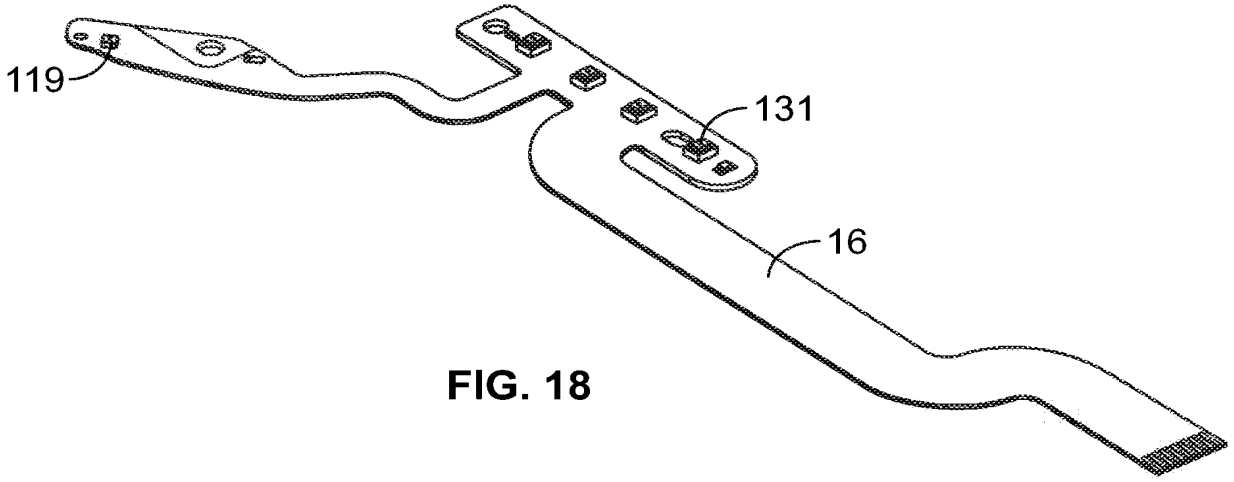


FIG. 18

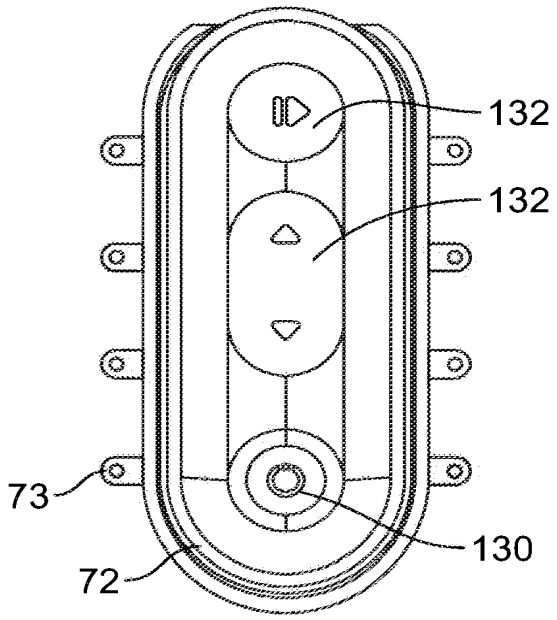


FIG. 19

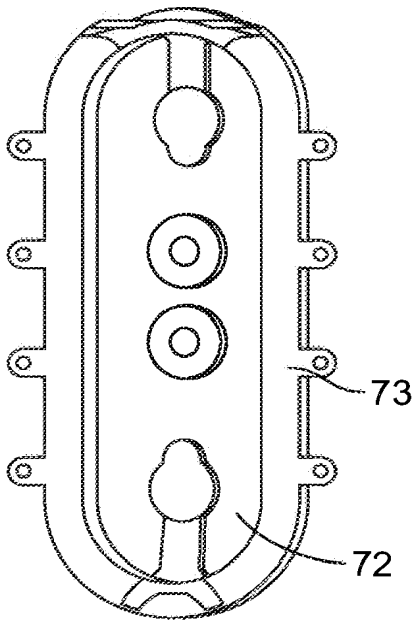


FIG. 20

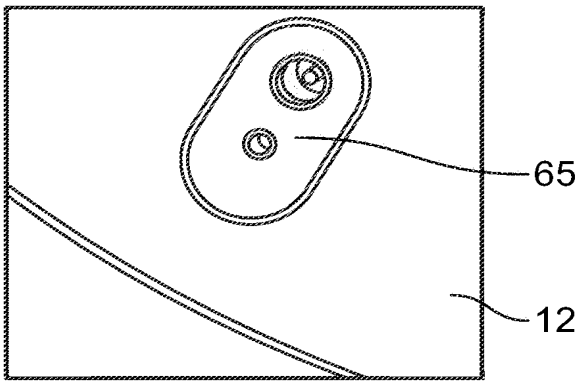


FIG. 21

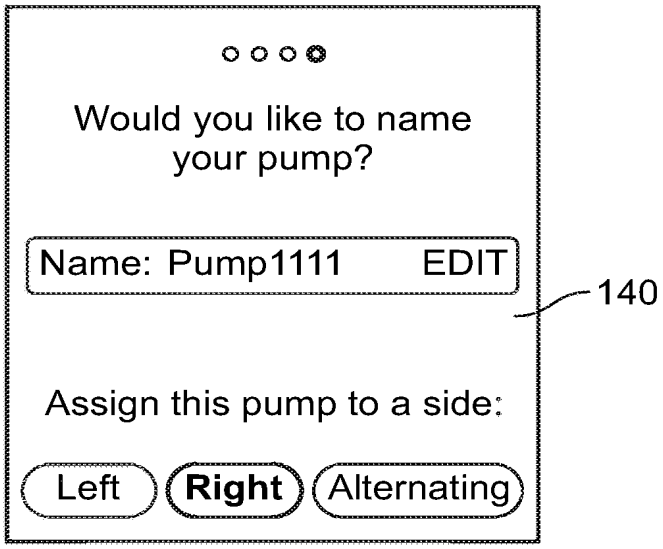

Would you like to name your pump?
Name: Pump1111 EDIT
140
Assign this pump to a side:
Left
Right
Alternating

FIG. 22

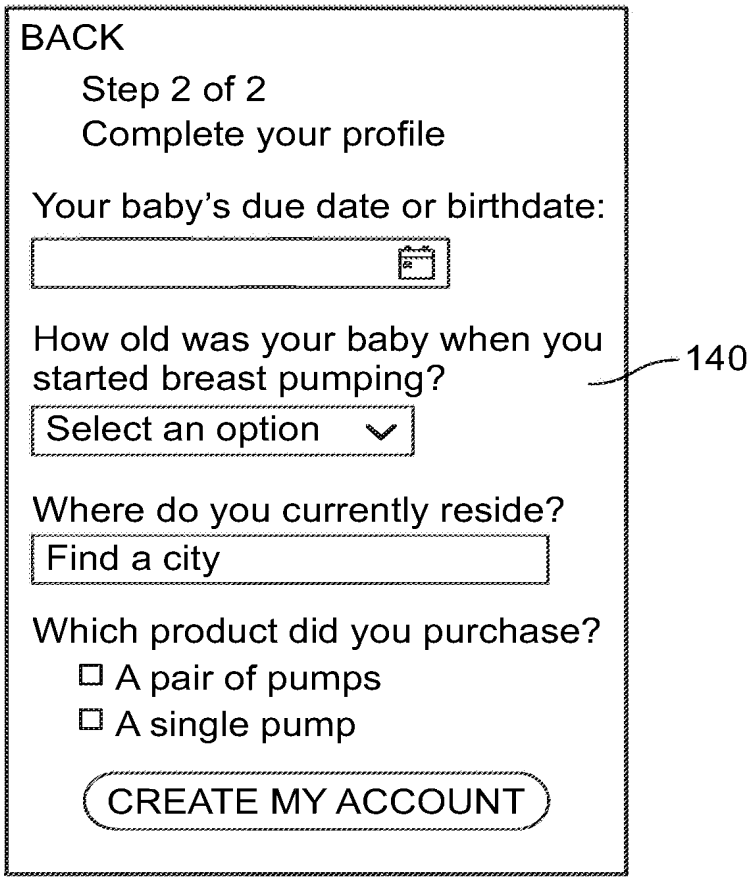

BACK
Step 2 of 2
Complete your profile
Your baby's due date or birthdate:
How old was your baby when you started breast pumping?
140
Select an option
Where do you currently reside?
Find a city
Which product did you purchase?
A pair of pumps
A single pump
CREATE MY ACCOUNT

FIG. 23

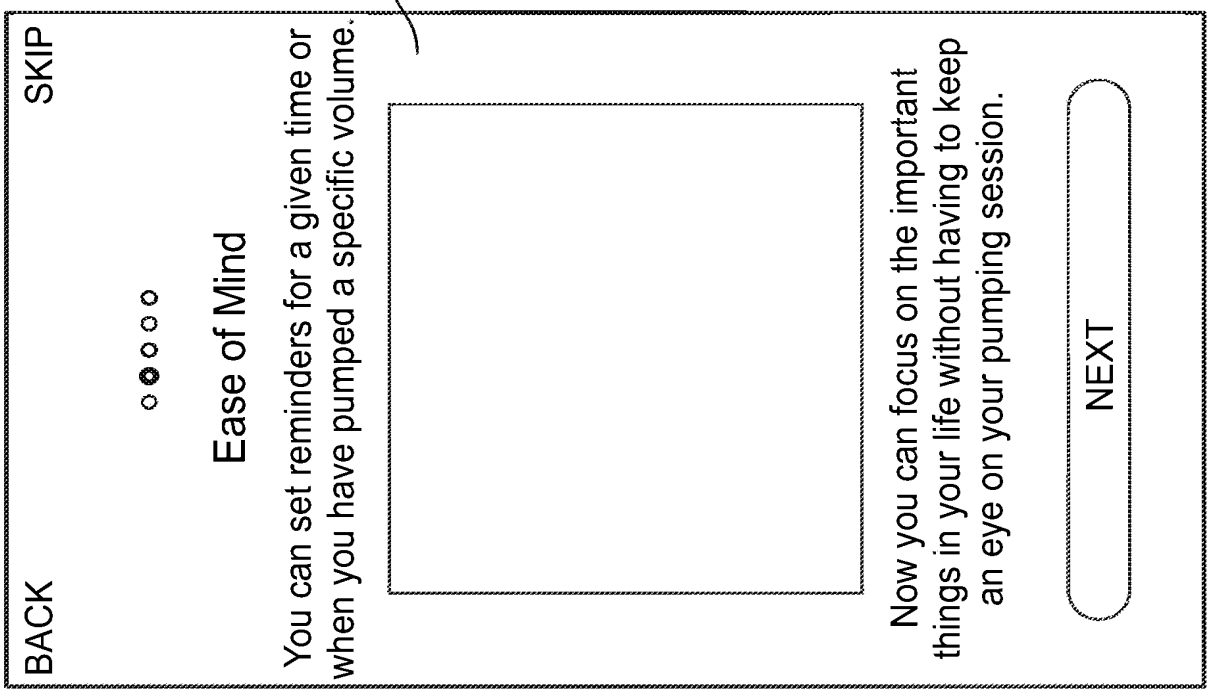

BACK
SKIP
Ease of Mind
You can set reminders for a given time or when you have pumped a specific volume.
140
Now you can focus on the important things in your life without having to keep an eye on your pumping session.
NEXT

FIG. 24

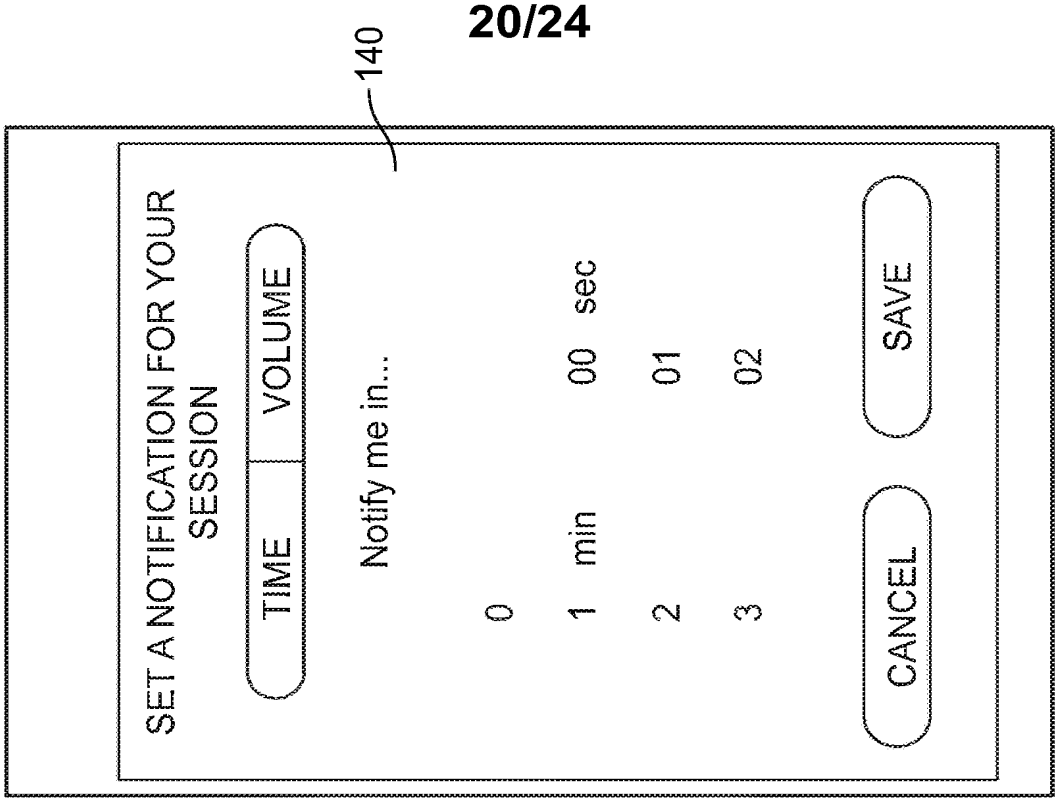

SET A NOTIFICATION FOR YOUR SESSION
TIME
VOLUME
140
Notify me in...
0
1 min
2
3
00 sec
01
02
CANCEL
SAVE

FIG. 25

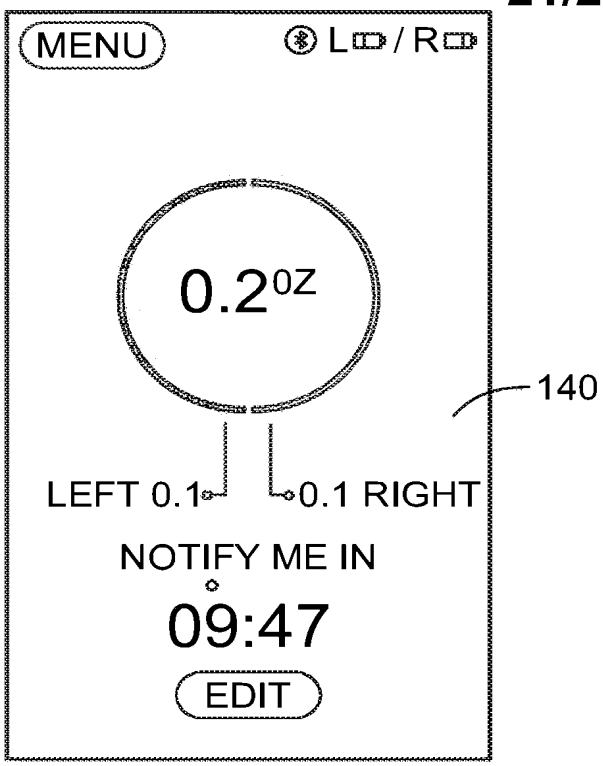


FIG. 26

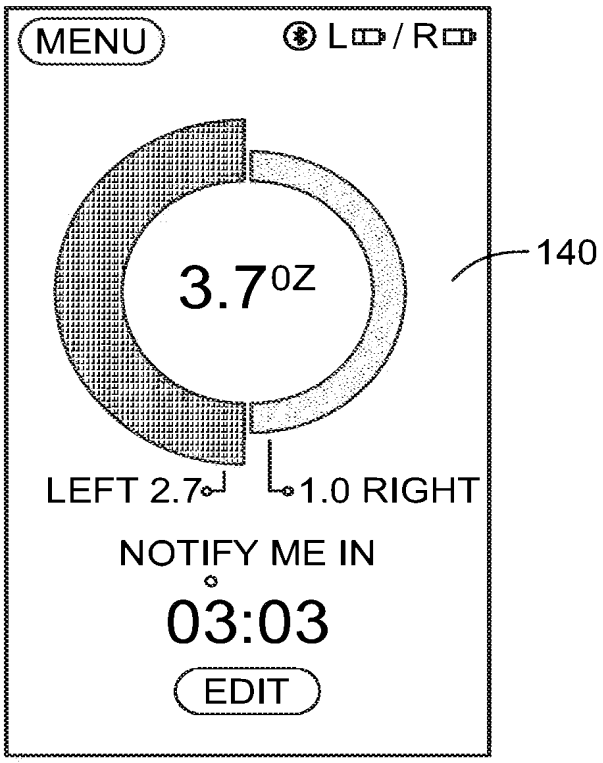


FIG. 27

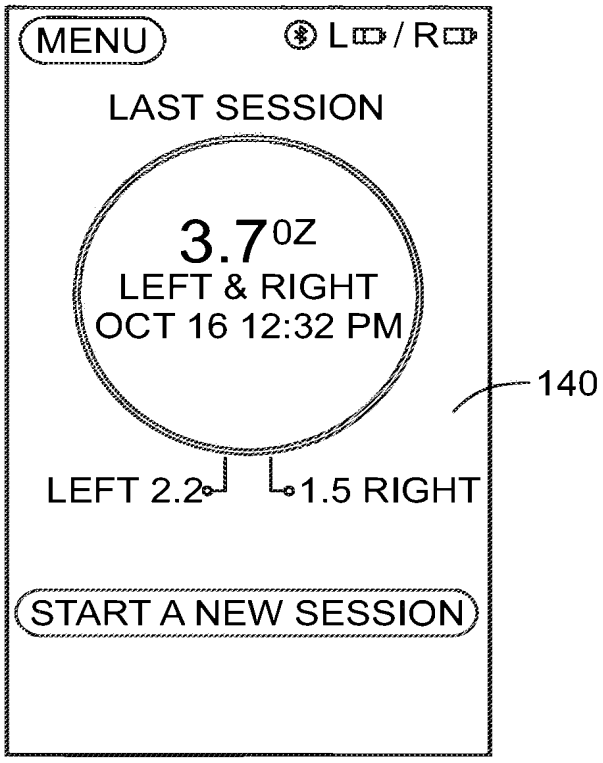


FIG. 28

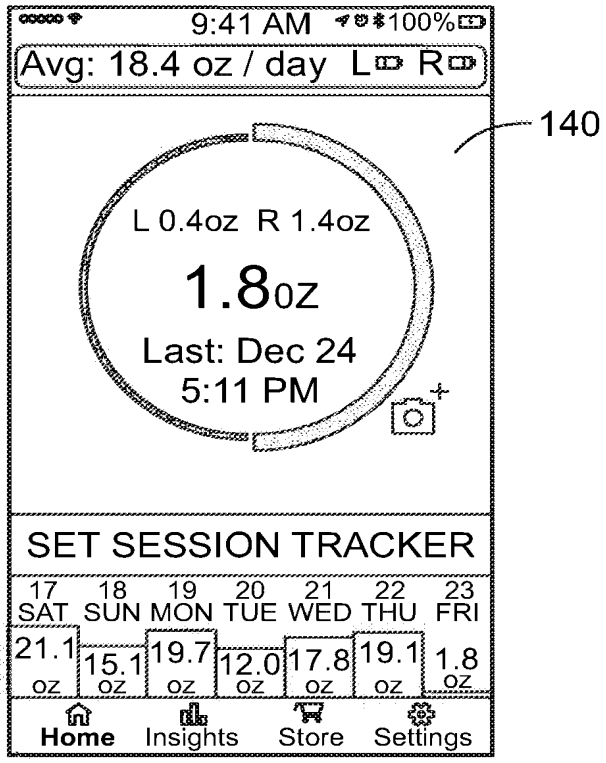


FIG. 29

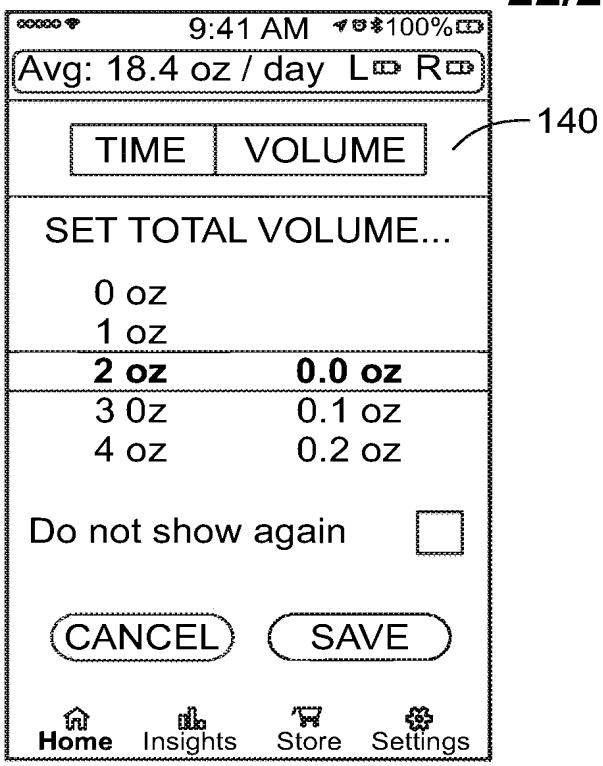


FIG. 30

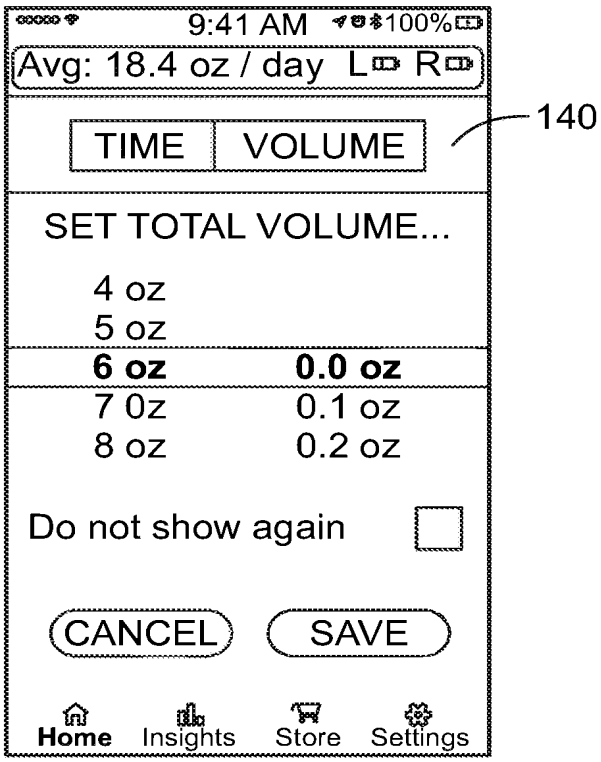


FIG. 31

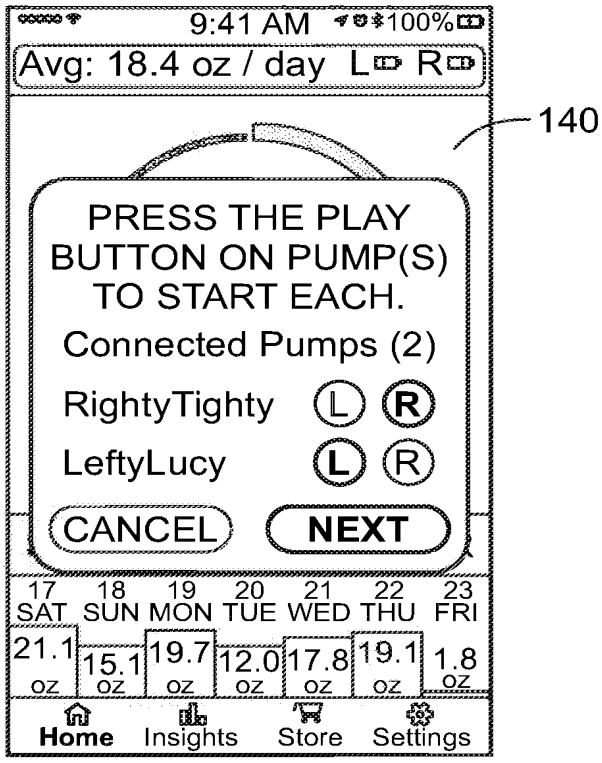


FIG. 32

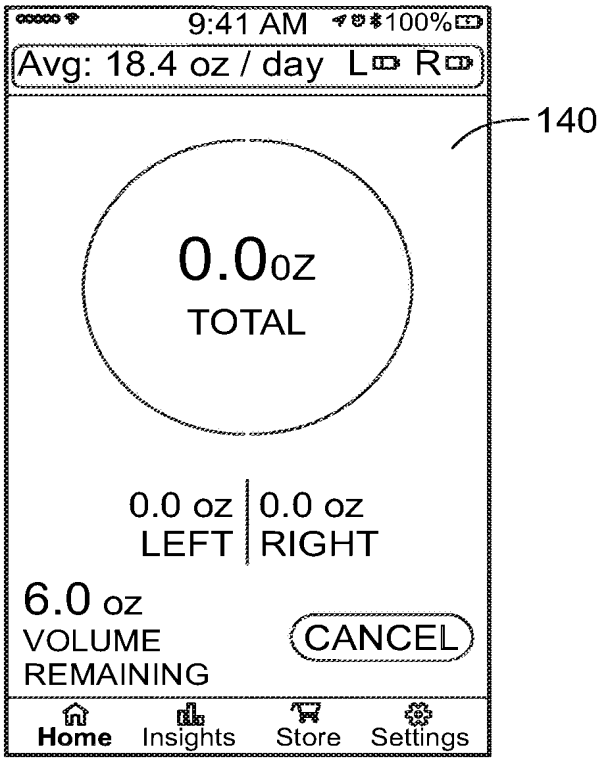


FIG. 33

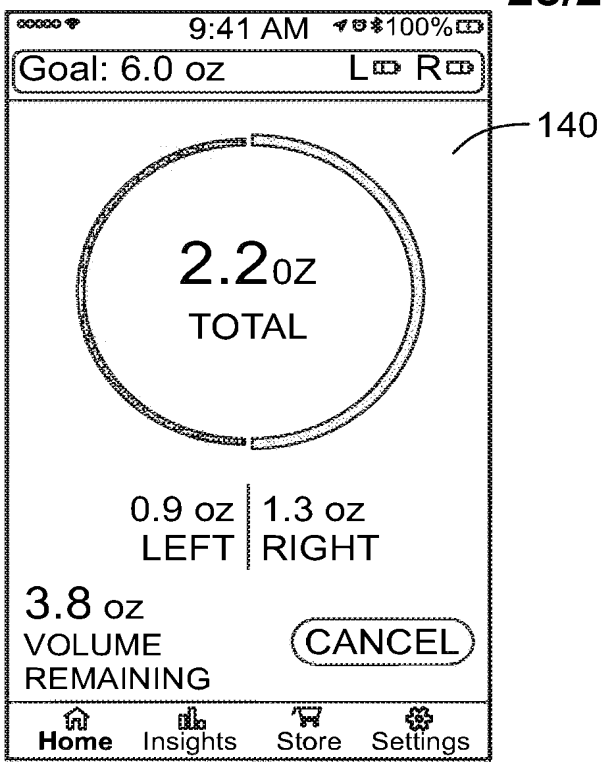


FIG. 34

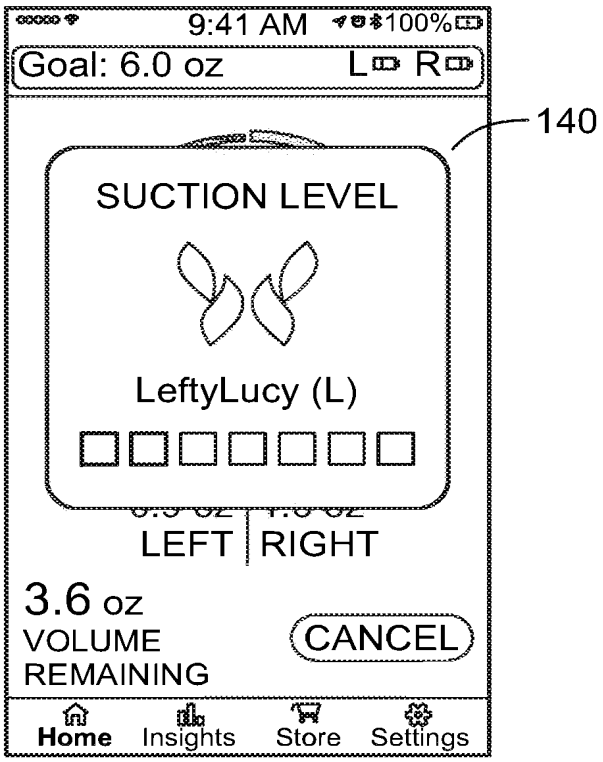


FIG. 35

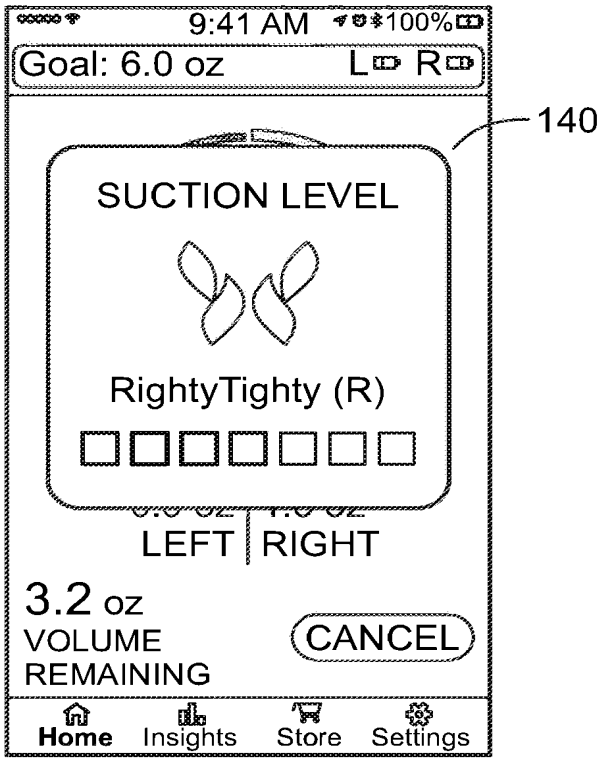


FIG. 36

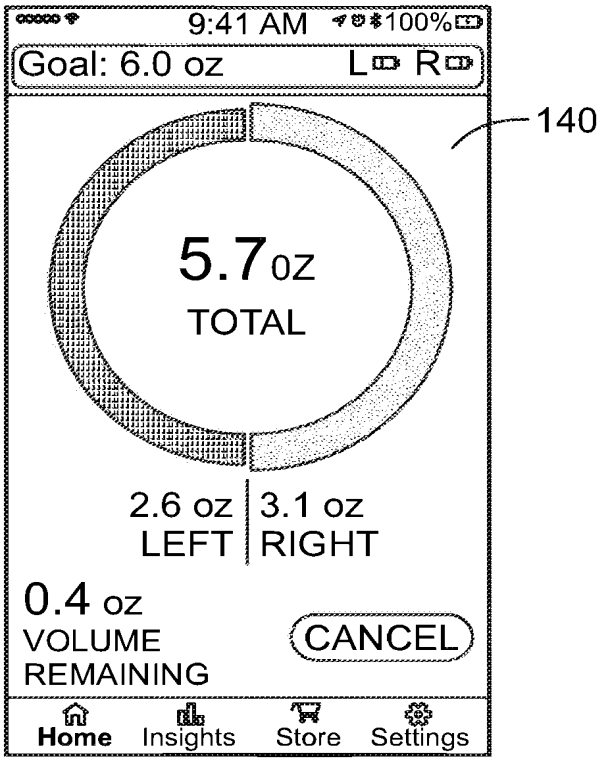


FIG. 37

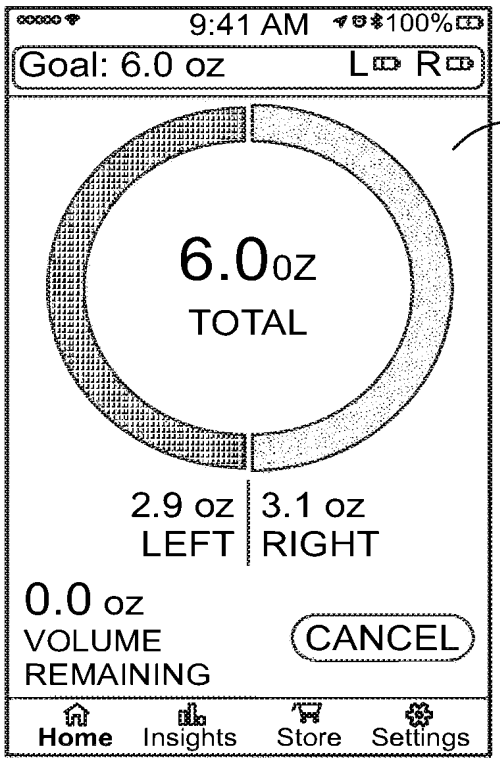


FIG. 38

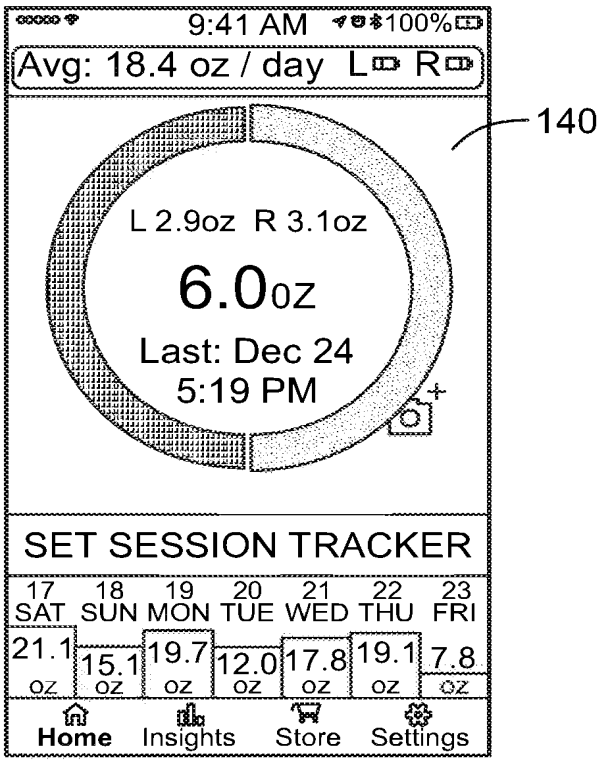


FIG. 39

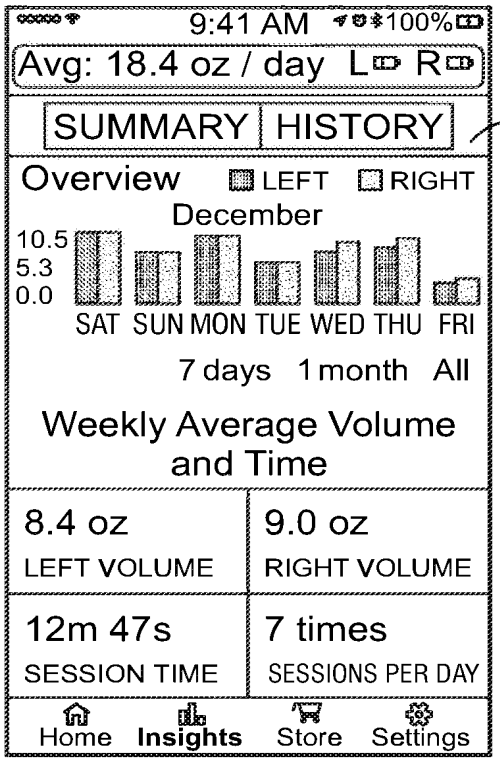


FIG. 40

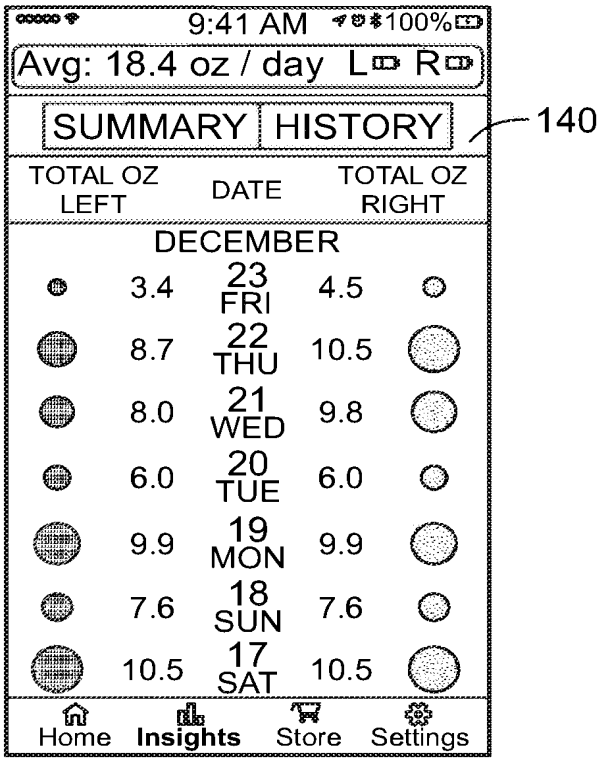


FIG. 41

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 2017/017112

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 4-45
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 2017/017112

A. CLASSIFICATION OF SUBJECT MATTER

A61M1/06 *(2006.01)*

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M 1/00, 1/06, A61H 7/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatSearch, DWPI, ESP@CENET, Google, WIPO, USPTO

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2014205436 A3 (DS LABS INC) 24.12.2014, abstract, paragraphs [0072]-[0073], [0075]-[0076], [0089], [0091]-[0095], [0100], [0106]-[0109], figs 1, 10A-C, 11A-B, 12A-B, 13, 14A-B, 17A-C, 23A-D, 24-25	1-3, 46-53
X	WO 2016014488 A1 (EXPLORAMED NC7 LLC) 28.01.2016, claims 9,19, [0011], [00154], [00156], [00184], [00188], [00190], [00195], [00199], [00220], fig.41	54-57, 59, 61
Y		58, 60, 62
X	US 2014378895 A1 (CLINICARE LTD) 25.12.2014, abstract, paragraphs [0040]-[0045], [0052], [0054]-[0056], figs. 1, 2	63-67
Y	WO 2016014494 A1 (EXPLORAMED NC7 LLC) 28.01.2016, paragraphs [0081]-[0083], [00268]	58
Y	US 2015148709 A1 (MILKOTECH SYSTEMS LTD) 28.05.2015, paragraphs [0040]-[0044], [0051]	60, 62

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 May 2017 (30.05.2017)	08 June 2017 (08.06.2017)
Name and mailing address of the ISA/RU: Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37	Authorized officer E.Nosova Telephone No. (8-495) 531-65-15

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 2017/017112

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	Freemie Collection Cups, A Hands-free, Concealable Single or Double Breast Pump Collection System, User Manual , 17.03.2015, pp. 1-20 Retrieved from <www.freemie.com>	1-3, 46-53
A	US 8357116 B2 (MEDELA HOLDING AG) 22.01.2013	48-53

Form PCT/ISA/210 (continuation of second sheet) (January 2015)

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(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
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PCT

(10) International Publication Number
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(51) International Patent Classification:
A61M 1/06 (2006.01)

(21) International Application Number:
PCT/US2008/062422

(22) International Filing Date: 2 May 2008 (02.05.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/915,937 4 May 2007 (04.05.2007) US

(71) Applicant *(for all designated States except US)*: **WHISPER WEAR, INC.** [US/US]; 2161 Mewmarket Parkway, Suite 214, Marietta, GA 30067 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **MYERS, Kenneth, E.** [GE/GE]; Whisper Wear, Inc., 2161 Newmarket Parkway, Suite 214, Marietta, GA 30067 (GE).

(74) Agent: **MEHRMAN, Michael, J.**; Mehrman Law Office, P.C., 5605 Glenridge Drive, Suite 795, Atlanta, GA 30342 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:
— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
..... *of inventorship (Rule 4.17(iv))*

Published:
..... *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(54) Title: HANDS-FREE BREAST PUMP WITH BALANCED RECIPROCATING DRIVE

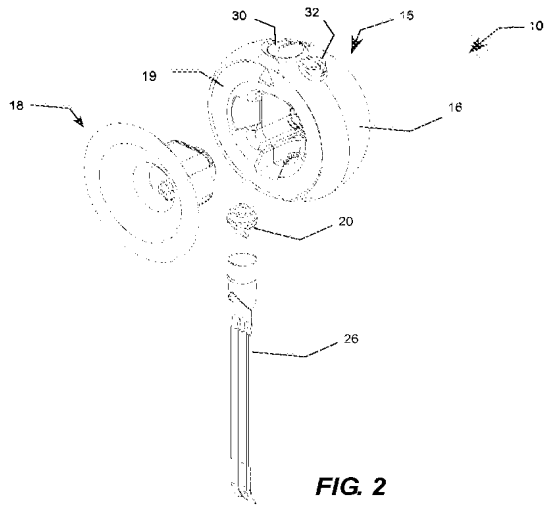

FIG. 2

(57) Abstract: A hands-free breast pump that includes a balanced push-pull reciprocating drive system that applies pumping force to a vacuum chamber formed by a breast interface cup during inward and outward pump strokes. The breast pump includes a breast cup that has a resilient bellows structure that partially collapses the volume of the vacuum chamber during the inward stroke and recovers the volume of the vacuum chamber during the outward stroke. The pump mechanism includes a cam drive system that translates rotary electric motor power into reciprocating linear action of an actuator arm that drives the bellows structure. The bellows structure acts like a spring that charges (resists the pump force) during the inward stroke and discharges (assists the pump force) during the outward stroke, and the shape of the cam track is designed to produce a desired operating profile for the pump.

WO 2008/137678 A1

Hands-Free Breast Pump with Balanced Reciprocating Drive

REFERENCE TO RELATED APPLICATION

This application claims priority to United States Provisional Patent Application Serial No. 60/915,937 filed May 4, 2007 entitled "Hands-Free Breast Pump with Balanced Reciprocating Drive," which is incorporated herein by reference.

TECHNICAL FIELD

The present invention is generally related to breast pumps that cause nursing mothers to express breast milk and, more particularly, to a hands-free breast pump with a balanced push-pull vacuum generation system that applies pumping force to a bellows structure of a vacuum chamber formed by a breast interface cup during inward and outward pump strokes.

BACKGROUND OF THE INVENTION

The first hands-free breast pump including a self-contained pump mechanism and power source configured to be held in place between a nursing mother's breast and bra is described in U.S. Patent No. 7,223,255 entitled "System For a Portable, Hands-Free Breast Pump and Method of Using the Same," which is incorporated herein by reference. The hands-free breast pump described in this patent, which will be referred to as the Gen-1 design, has been a successful commercial product. The present patent is directed to a second generation breast pump, which is referred to as the Gen-2 design, that includes significant improvements over the initial Gen-1 design.

More specifically, the Gen-1 design operates by applying force generated by a motor during the inward stroke of a pump mechanism to a movable part (referred to as a bellows structure) of a vacuum chamber located at the end of the breast cup (also referred to as breast interface flange). The force applied by the pump mechanism to the bellows structure of the vacuum chamber causes the bellows structure to partially collapse, thereby reducing the volume of the vacuum chamber to create positive pressure that forces any expelled milk located in the breast cup through a one-way valve and into a collection bag. Upon the release of the inward stroke of the pump

mechanism, the bellows structure of the Gen-1 design is configured to resiliently recover its shape during an outward stroke to restore the original volume of the vacuum chamber, thereby increasing the volume of the vacuum chamber to create negative pressure within the vacuum chamber. The one-way valve vents the vacuum chamber during the inward stroke and seals the vacuum chamber during the outward stroke to create a milking action. That is, the outward stroke of the pump applies suction to the breast and the inward stroke forces the expressed milk through the one-way valve and into a collection bag.

As described above, the Gen-1 design utilizes an unbalanced pump mechanism that applies force to the vacuum chamber only during the inward stroke, whereas the resiliency of the bellows structure of the breast cup creates the suction during the outward stroke. Therefore, the pump mechanism is required to compress the bellows structure of the breast cup during the inward stroke, much like compression of a spring, sufficiently to allow the resiliency of the breast cup to generate the negative pressure that creates the suction action. Like a compressed spring, the bellows structure of the breast cup resiliently recovers its shape upon the release of the compression force to create the suction action without assistance from the pump motor, which applies force only during the inward stroke. While this type of pump mechanism is highly functional, it requires application of a significant force to the breast cup during the inward stroke, which tends to urge the breast cup out of its seat within the breast pump housing. Unless properly constrained, the force can be sufficient to cause the breast cup to pop out of its seat in the pump housing, which can cause the pump to malfunction. Although the breast cup can be restrained within its seat in the housing using a suitable device, such as tabs, detent mechanisms or a support ring, these features add complexity and cost to the pump.

Perhaps more importantly, the additional breast cup restraining features make the pump more difficult to assemble with the breast cup properly seated within the pump housing. Inevitably, a certain number of users are unable to assemble the pump correctly. Unfortunately, the pump looks and sounds like it is working properly even when the breast cup is not seated properly, and the user can find it difficult to detect that the breast cup is not seated properly. This gives some users who experience this

problem the misimpression that the pump is assembled correctly and yet performs poorly, when the real problem is that the breast cup is not properly seated in the pump housing. Apparent pump malfunction due to improper breast cup seating has, therefore, been a recurring problem with the Gen-1 design.

The unbalanced nature of the Gen-1 pump design (i.e., the application of motor force only during the inward stroke) also requires a relatively powerful pump motor to compress the bellows structure of the breast cup on the inward stroke against an amount of natural resiliency of the silicon that is sufficient to generate the desired suction within the breast cup on the outward stroke. Pumping against this amount of spring force on the inward stoke, without the assistance of the motor on the outward stroke, is inefficient because the motor is used in an unbalanced manner in that high force is applied from the motor on the inward stroke, whereas no force is applied by the motor on the outward stroke. This unbalanced pump design requires higher power, reduces the cycle rate, taxes the motor, and stresses the internal gear train components to a higher degree than could be obtained from a more balanced design. Accordingly, there remains a need for more effective, efficient and user friendly hands-free breast pump designs.

SUMMARY OF THE INVENTION

The present invention meets the needs described above in a second generation hands-free breast pump, referred to as the Gen-2 design, that includes a balanced push-pull vacuum generation system that applies pumping force to a bellows structure of a vacuum chamber formed by a breast interface cup during the inward and outward pump strokes. More specifically, the breast pump includes a breast cup that has a resilient bellows structure that partially collapses the volume of the vacuum chamber during the inward stroke and recovers the volume of the vacuum chamber during the outward stroke. The pump mechanism, which includes a cam drive system that translates rotary electric motor power into reciprocating linear action of an actuator arm that drives the bellows structure, applies force to the bellows structure during the inward pump stroke causing a reduction in the volume of the vacuum chamber and during the outward pump stroke causing an expansion of the volume of the vacuum chamber. The

bellows structure acts like a spring that charges (resists the pump force) during the inward stroke and discharges (assists the pump force) during the outward stroke, and the shape of the cam track is designed to produce a desired operating profile for the pump. In addition, the shape of the cam track is carefully designed and fine tuned to produce a desired operating profile for the pump to mitigate motor current spikes, undue gear stress and reduce noise while producing a desired suck-release profile for the pump.

The use of a balanced drive system that applies force to the bellows structure of the breast cup during both the inward and outward pump strokes reduces the resiliency required of the bellows structure of the breast cup from that of the Gen-1 design, resulting in a more effective, efficient and user friendly hands-free breast pump design. For example, the Gen-2 pump running on a single AA battery achieves comparable suction levels at a comparable cycle rate when compared to the Gen-1 design running on two AA batteries. In addition, the reduced pumping force of the Gen-2 design allows this embodiment to achieve improved performance with a motor operating at significantly lower RMP and a significantly smaller gear ratio, which reduces the required number of gear meshes and allows for larger, more robust gears. These design improvements result in a lower cost, better performing, quieter and more robust breast pump that is easier to manufacture, easier to assemble, and has significantly fewer parts in the pump drive train. The Gen-2 pump also incorporates a number of other important design improvements, as described in more detail below. These additional features and advantages of the Gen-2 pump will become apparent to the skilled artisan upon examination of the following drawings and detailed description. It is intended that all such additional features and advantages be included within the scope of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross sectional side view of a hand-free breast pump held in its operative position between the breast of a nursing woman and the cup of a bra worn by the woman while the pump is actively pumping breast milk into a collection bag supported by the breast pump and bra.

FIG. 2 is a an exploded perspective view showing the major components of the hand-free breast pump and accessories including the breast pump, the breast cup, the one-way valve, and the milk transport stem.

FIG. 3 is a perspective view of an assembled hands-free breast pump with the breast cup installed in its operative position.

FIG. 4 is a perspective view of an assembled hands-free breast pump of FIG. 3 with the breast cup removed.

FIG. 5 is a perspective view of a breast cup for a hands-free breast pump prior to engagement with the actuator arm of the breast pump.

FIG. 6 is a perspective view of the breast cup of FIG. 5 after engagement with the actuator arm of the breast pump.

FIG. 7 is a perspective view of the breast cup showing the opening for receiving the one-way valve.

FIG. 8 is a side view of the breast cup.

FIG. 9A is a cut-away side view of the breast cup showing the flange top in the outward position.

FIG. 9B is a cut-away side view of the breast cup showing the flange top in the inward position.

FIG. 10 is a first perspective view of the internal configuration of the breast pump.

FIG. 11 is a second perspective view of the internal configuration of the breast pump.

FIG. 12 is an assembled perspective view of the drive train of the breast pump.

FIG. 13 is a first exploded perspective view of the drive train of the breast pump.

FIG. 14 is a second exploded perspective view of the drive train of the breast pump.

Fig. 15 is an end view of the breast cup.

Fig. 16 is a bottom view of the breast cup.

FIG. 17 is a perspective view of the breast cup with the flange top in the outward position.

FIG. 18 is a perspective view of the breast cup with the flange top in the inward position.

FIG. 19 is a perspective view of the breast pump with an installed breast cup showing the actuator arm and flange top in the outward position.

FIG. 20 is a perspective view of the breast pump with an installed breast cup showing the actuator arm and flange top in the inward position.

FIG. 21 is a perspective view of the breast pump with the valve, stem and collection bag assembled in their operative positions.

FIG. 22 is another perspective view of the breast pump with the valve, stem and collection bag assembled in their operative positions.

FIG. 23 is a disassembled perspective view of the breast pump showing the major components and accessories.

FIG. 24 is a front view of the drive cam of the breast pump.

FIG. 25 is a perspective view of the drive cam of the breast pump.

FIG. 26 is an illustrative operating curve for a breast pump with a duty cycle of approximately one-half.

FIG. 27 is an illustrative operating curve for a breast pump with a duty cycle of approximately two-thirds.

FIG. 28 is an assembled perspective view of a modified drive train for the breast pump that includes a belt drive.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

The present invention may be embodied in a hands-free breast pump with a balanced push-pull mechanical actuator and cam drive system that applies pumping force to a bellows structure of a breast interface cup during inward and outward pump strokes. As the Gen-1 design applied no motor force to the bellows structure on the outward pump stroke, configuring the Gen-2 pump to apply any amount of motor force to the bellows structure during both the inward (push) and outward (pull) strokes achieves some level of balance in the drive system and therefore improves the balance over the Gen-1 design. Significant attention has been paid to this design feature in the Gen-2 pump, which achieves a relatively high level of balance, for example where the force applied by the pump during the inward stroke is within eighty percent (80%) of the force applied during the outward stroke. In the particular embodiment shown in the

figures and described below, the Gen-2 pump is well optimized to achieve even higher levels of balance, for example where the force applied by the pump during the inward stroke is within ninety percent (90%) or more of the force applied during the outward stroke during the normal operating mode. This high level of balance is achieved through careful design of the resilient bellows structure of the breast cup and the cam drive system of the breast pump that translates rotary electric motor power into reciprocating linear action of the actuator arm to efficiently develop a desired pump operating profile. The bellows structure acts like a spring that charges (resists the pump force) during the inward stroke and discharges (assists the pump force) during the outward stroke, and the shape of the cam track is carefully designed and fine tuned to produce a desired operating profile for the pump.

In the Gen-2 breast pump, the primary components of the milk collection system include a silicone breast cup with a collapsible bellows structure at the end of the nipple tunnel (also called the vacuum chamber) which serves to displace air and produce a vacuum within the breast cup. The vacuum chamber is vented by a silicone one-way valve that opens during the inward (positive pressure) pump stroke to allow air and milk to be exhausted from the nipple tunnel, and then closes during the outward (negative pressure) pump stroke to seal the nipple tunnel and allow vacuum to be created within the nipple tunnel. The milk expressed from the breast is expelled from the breast cup through the one-way valve, along a wave-shaped splint or open straw (also called a stem), and into a freezer grade, polyethylene or similar milk collection bag. The breast pump is held between the user's breast and the cup of her bra (also called a brassier), the stem and neck of the collection bag pass between the user's chest and the bottom edge of the bra, and the retention area (pouch portion) of the collection bag is supported below the bra. The flexible, wave-shaped splint or open straw that inserts into the neck of the milk collection bag allows a simple snap connection to the breast pump housing, while also serving as a splint to keep an open path in the neck of the milk collection bag for the milk to travel under the taut band of the user's bra and into the retention area of the milk collection bag.

The Gen-2 pump mechanism includes a rotary electric motor that moves an actuator arm through a reciprocating linear motion. The actuator arm interfaces with a

barb connected to a disc, which is connected to the flange top at the end of the nipple tunnel of the breast cup. The nipple tunnel forms a vacuum chamber when the breast cup forms an air-tight seal with the user's breast. The linear reciprocating motion of the actuator arm moves a bellows structure at or near the end of the nipple tunnel reciprocally through an inward stroke and an outward stroke. The inward stroke partially collapses the volume of the vacuum chamber and the outward stroke restores the volume in a repeating cycle to alternately create and release suction within the nipple tunnel.

The Gen-2 pump includes a self-contained pump unit and power source enclosed within a dome shaped housing that receives and supports the removable breast cup. The housing compactly contains the pump motor, the drive train, and a power source, such as one or more batteries, and the associated electrical and mechanical features of the pump. In the embodiment described in detail below, for example, the pump achieves acceptable performance using a single AA battery as the power source. The pump housing with a received breast cup fits discreetly between the user's breast and a breast cup of a normal brassiere. It should also be appreciated that the motorized drive train could be replaced by a manually operated drive mechanism. In addition, the battery could be replaced by a connector to an external power source, such as an electrical plug connected to a DC power source (such as an automotive power supply) or an AC power converter configured to plug into a conventional AC power outlet.

Balanced operation of the motor and drive train, which results in motor force applied to the vacuum chamber during the inward and the outward strokes during the normal use mode, represents a key improvement of the Gen-2 design over the Gen-1 design. In fact, the Gen-2 pump achieves a high level of balance in the motor and drive train operation, resulting in a substantially similar amount of motor force applied to the vacuum chamber during the inward and the outward strokes. This highly balanced motor and drive train operation reduces the maximum force required from the motor and drive train, which allows the Gen-2 pump to use a lower-RPM motor and a lower gear ratio while achieving higher pump cycling rates, lower power consumption, and longer battery life.

Another Gen-2 improvement is found in the design of the bellows structure that creates the suction within the breast cup. The Gen-2 bellows structure has a substantially reduced surface area translating at the end of nipple tunnel, presenting reduced resistance to the inward stroke and a more efficient movement of the resilient silicon. The reduced resistance of the bellows structure, which allows for the reduction in pump force applied to the bellows structure, also improves the vacuum retention of the breast cup by significantly reducing vacuum lost due to collapse and flexure of the nipple tunnel portion of the breast cup area near the bellows structure. The breast interface portion of the breast cup has also been improved to include an extended funnel-shaped section, which extends further up the breast surface to contact a larger portion of the breast to more evenly distribute the pressure between the breast cup and the breast. This avoids pressure points on the breast that could otherwise result from tight or unevenly fitting brassieres that tend to press the breast pump firmly against the breast. The improved pressure distribution allows less compression of milk ducts, thereby improving milk flow from the breast and into the pump.

The Gen-2 breast cup includes additional improvements, including side walls of the nipple tunnel that are sufficiently thick to be rigid enough to retain its shape (i.e., avoid partial collapse of the nipple tunnel and resulting vacuum loss) under the highest vacuum applied by the pump mechanism without a supplemental rigid support ring. The breast cup retention features, including the retention rib and detent mechanisms retaining the breast cup within the pump housing, have been relocated to be proximate to the bellows structure at the extreme rear of breast cup (i.e., near the flange top or end of the nipple tunnel) to counter the pump force applied during the inward stroke that tends to urge the breast cup out of its seat in the housing. Locating the breast cup support features adjacent to the bellows structure also helps to provides shape retention assistance in that area of the breast cup.

The barb shaped breast cup retention rib on the rear flange perimeter also allows easy insertion by the user while offering good retention in the housing while in use. Side barbs on the outer walls of the nipple tunnel function as detent mechanisms that provide tactile and audible feedback letting user know when breast cup has been fully inserted into the pump housing. The rounded shape of the ends of these barbs

facilitates removal of the breast cup from the housing and prolongs the life of the breast cup. Recessed seating of the one-way valve provides a helpful visual cue to the user when the valve is fully seated and aids in valve retention in the breast cup when the cup is inserted and removed from housing.

On the interior of the nipple tunnel, the length of the vacuum chamber has been increased to reduce the chance of end of the user's nipple "bottoming out" or contacting the flange top at the end of the nipple tunnel attached to the movable bellows structure during the inward pump stroke. The thick and rigid side walls of the nipple tunnel prevent the tunnel from collapsing and pinching the user's nipple under the vacuum created during the outward stroke. The bottom surface of the nipple tunnel on the interior of the nipple tunnel is angled downward toward the outlet to prevent milk from pooling in the end of the nipple tunnel, which could otherwise lead to spills or waste. The bottom surface of the nipple tunnel also includes a distinct trough or milk flow channel leading to a larger, more funnel shaped outlet in the bottom of the nipple tunnel to aid in effective flow of milk out of the nipple tunnel area and into the outlet for efficient transport into the milk collection bag. In addition, a lofted "dam" of material is located between the outlet and the front of the nipple tunnel where the breast cup interfaces with the user's breast to minimize the chance that milk could flow back out of the nipple tunnel and onto the user's clothing.

The push-pull vacuum generation action of the Gen-2 design actively creates consistent vacuum levels by forcing a repeatable level of nipple tunnel volume expansion and contraction. The barb at the end of the nipple tunnel, which allows the actuator arm to both push and pull on the flange top, is shaped to facilitate both engagement with, and disengagement from, the detent opening in the actuator arm without special user intervention. The breast cup mold includes slots that allow sufficient silicon to flow into the disc retention area of the breast cup to create a strong connecting layer of material holding the disc in place to produce a durable breast cup. The one-way valve has a larger opening that allows milk to flow more freely and evacuate the nipple tunnel of the breast cup more efficiently.

In the Gen-2 pump, an electro-mechanical movement replaces the electronically controlled drive of the Gen-1 design, yet still allows for adjustment of both vacuum level

and cycle rate. The cam drive system of the Gen-2 pump reduces the complexity and cost of the pump. In addition, the cam drive system allows the reciprocating, push-pull linear action of the actuator arm with a force distribution curve that can be controlled by carefully designing the shape of the cam track to maximize efficiency and reduce gear and motor stress. The net benefit is a higher pump cycling rate with a lower speed, quieter motor. The smaller gear ratio allows the Gen-2 pump to utilize a smaller number of larger, more robust and quieter gears. The reduction in total gear ratio requirement provided by the Gen-2 cam drive system allows for larger gears with more tooth surface contact. In addition to higher strength and reliability, these larger toothed gears can be fabricated in softer materials which, combined with the additional surface contact and lower operating speed, serves to significantly quiet the drive train operation.

The Gen-2 pump also includes an interference-based vacuum adjustment mechanism. Specifically, two parallel, partially co-planar sliding panels (i.e., the cam follower and the actuator arm) are joined by a coil spring that is preloaded to effectively lock the two panels together during normal, maximum vacuum operation. However, when the linear motion of the actuator arm panel is impeded by the shaft of the vacuum adjust mechanism, the actuator arm panel no longer translates inward with the movement of the cam follower panel. Instead, the cam follower panel continues to move according to its relationship with the cam path of the cam gear. The difference in translation of the two panels is absorbed by the compression of the spring linkage of the two panels. Under expected normal use, the user will operate the pump at full vacuum and no interference by the vacuum adjustment mechanism, and therefore no additional, forced compression of the linking spring. Thus, the normal use is the most efficient operating mode. The spring linkage between the cam follower and the actuator arm also produces the benefit of allowing the motor and gear train to continue to cycle without becoming jammed in the event that the motion of the actuator arm is impeded, for example when the actuator arm is blocked by an external object or manually held in place.

Turning now to the figures, in which like element numerals refer to like elements throughout the several figures, a particular embodiment of the Gen-2 breast pump is shown in the figures and described in the accompanying text. The Gen-2 breast pump

leverages the successful technology from the original Gen-1 pump design and significantly improves upon performance, ease of use, manufacturability and reliability. The intended use of the Gen-2 pump as supported between the user's breast and the cup of a normal brassier and the overall approach to milk collection remains largely unchanged from the Gen-1 design, whereas the Gen-2 pump mechanism and breast cup have been substantially redesigned to achieve a number of major improvements.

FIG. 1 is a cross sectional side view of a hand-free Gen-2 breast pump **10** held in its operative position between the breast **12** of a nursing woman and the cup **14** of a brassier worn by the woman while the pump is actively pumping breast milk from the woman's breast. The breast pump **10** includes a dome-shaped outer housing **16** that faces the inner surface of the brassier cup **14** and an inner housing **19** that receives the breast cup **18**, which interfaces with the woman's breast **12**. The breast cup **18** includes a nipple tunnel that forms a vacuum chamber **22** between the breast cup and the woman's breast, which is vented through an opening or outlet **24** through the bottom of the breast cup. The outer housing **16** can include a transparent window (e.g., the removable cover plate **65** shown in FIG. 23) to allow the user to see the position and condition of the nipple after the breast pump has been placed in its operative position against the breast. This allows the user to adjust the position of the pump against the breast to center the nipple in the nipple tunnel, and also allows the user to observe the nipple during pumping, which can be helpful, for example, to maintain awareness of milk letdown, milk flow and nipple inversion.

During its inward stroke, the pump mechanism (shown best in Figs. 12-14) pushes on an integrated (molded-in) disk located at the end of the vacuum chamber (also called the flange top) to cause a bellows structure (shown best in Figs. 9A-B, 17 and 18) located at or near the end of the vacuum chamber to partially collapse (move inward) and thereby reduce the volume of the vacuum chamber to create positive pressure within the vacuum chamber. During its outward stroke, the pump mechanism pulls on the barb attached to the disk at the top of the vacuum chamber causing the bellows structure to recover its original shape (move outward) to restore the original volume of the vacuum chamber, thereby increasing the volume of the vacuum chamber to create negative pressure within the vacuum chamber. A one-way valve **20** vents the

vacuum chamber during the inward stroke and seals the vacuum chamber during the outward stroke to create a milking action. The expressed milk is forced through the outlet **24**, through the one-way valve **20**, along the exterior surface of the wave-shaped stem **26**, and into a collection bag **28** that is supported by the breast pump and the elastic, wire or other structure at the bottom edge of the brassier.

FIG. 2 is an exploded perspective view showing the major components of the hand-free breast pump **10** including the pump enclosure **15** that contains the pump mechanism and power source, the breast cup **18**, the one-way valve **20** and the stem **26**. The pump enclosure **15** includes a dome-shaped outer housing **16** and an inner housing **19** configured to receive the breast cup **18**. The breast pump **10** also includes a sliding power control switch **30** and a vacuum control knob **32**. In this particular embodiment, the power control switch **30**, which affects the cycling rate of the pump, includes three settings, fast, slow and off. The vacuum control knob **32** may be turned through a rotation range that is slightly less than a full rotation to adjust the vacuum level by adjusting the pump stroke length.

FIG. 3 is a perspective view of an assembled hands-free breast pump **10** with the breast cup **18** installed in its operative position. FIG. 4 is a perspective view of the breast pump with the breast cup removed. These views also show the power switch control knob **30** and the vacuum control knob **32**. Although this embodiment includes a three-position power switch, the cycle rate adjustment mechanism may include a larger number of available rate settings, such as a slider, dial or multi-position selection switch that allows the user to control the cycle rate of the pump. Cycle rate adjustment is typically accomplished by adjusting the voltage applied to the pump motor, for example through a resistive voltage divider or voltage-limiting diodes. The vacuum adjustment knob **32** allows the user to adjust the strength of the vacuum or suction generated by the pump. Vacuum adjustment is typically accomplished by adjusting the stroke length of the pump actuator arm, in this embodiment through an eccentric cam surface on a shaft connected to the vacuum adjustment knob **32**. The eccentric cam of the vacuum adjustment mechanism selectively blocks and thereby adjusts the stroke length of the pump actuator arm.

FIG. 5 is a perspective view of the breast cup **18** prior to engagement with the actuator arm **34** of the breast pump. The breast cup **18** includes a flange top **36** at the end of a nipple tunnel **46** that includes an over-molded disk having an attached barb **38** that engages with a keyhole or teardrop shaped detent opening **40** in the actuator arm **34**. FIG. 6 shows the breast cup **18** with the barb **38** engaged in the detent opening **40**. The barb **38** and detent opening **40** are configured such that the barb securely engages with the detent opening when the breast cup is received within the breast pump, and the barb releases from the detent opening when the beast cup is removed from the breast pump. The breast cup **18** also includes a bellows structure **42**, which is shown in FIG. 5 in its outward position. The bellows structure **42** is also shown in the outward position in Figs. 6, 8, 9A, 16, 17 and 19. During the inward stroke of the pump mechanism, the actuator arm **34** pushes the flange top **36** to its inward position, which causes the bellows structure **42** to reduce the volume of the vacuum chamber formed by the nipple tunnel and thereby create positive pressure within the vacuum chamber. The bellows structure **42** is shown in the inward position in Figs. 9B, 18 and 20. During the outward stroke, the actuator arm **34** pulls the flange top **36** back into its outward position, which causes the bellows structure to increase the volume of the vacuum chamber and thereby create negative pressure or suction within the vacuum chamber. The resiliency of the bellows structure **42** resists the inward stroke and assists in the outward stroke, aiding in the balanced operation of the pump. In normal use mode, with the breast cup producing vacuum, the outward force of the natural resiliency of the bellows structure largely offsets the inward force of vacuum created within the breast cup, resulting in balance in the pump operation.

The vacuum chamber of the breast cup **18** is formed by the nipple tunnel **46** having side walls that are sufficiently thick to prevent the side walls from collapsing from the high vacuum generated during the reciprocal action of the bellows structure **42**. That is, the nipple tunnel **46** is sufficiently rigid to support the reciprocal action of the bellows structure **42** without further support from a support ring or other structure within the pump housing. This is a significant improvement over the Gen-1 breast cup design, which requires a separate support ring for additional support.

The breast cup **18** also includes a funnel shaped breast interface section **48**, which spreads the breast contact surface and the associated compressive force (pressure) over a significantly larger portion of the breast and breast cup. The breast cup also includes an outer flange area **50**, that together with the interface section, form an air-tight seal with the woman's breast. Spreading out the breast contact surface area reduces the possibility of undesired restriction of milk flow due to compression of milk ducts in the breast. The breast cup **18** is held within the pump housing with a catch rib **53** located toward the end of the exterior wall of the nipple tunnel proximate to the bellows structure **42**. A pair of detent tabs located on the exterior wall of the nipple tunnel "click into place" to provide the user with tangible, audible feedback indicating that the breast cup is fully inserted into the housing. One detent tab **52a** is shown in Fig. 5 and an opposing detent tab is located on the opposite side of the nipple tunnel **46**. Both detent tabs **52a** and **52b** are shown in FIGS. 15 and 16.

FIG. 7 is a perspective view of the breast cup **18** showing the nipple tunnel **46**, breast interface section **48**, outer flange area **50**, and the outlet **24** that receives the one-way valve. FIG. 8 is a side view of the breast cup **18**. FIG. 9A is a cut-away side view of the breast cup **18** showing the flange top **36** in the outward position. FIG. 9B is a similar view showing the breast cup **18** with the flange top **36** in the inward position. During the inward pump stroke, the actuator arm of the breast pump pushes the flange top **36** from the outward position shown in FIG. 9A to the inward position shown in FIG. 9B, which creates positive pressure inside the vacuum chamber formed by the breast cup and the user's breast. During the inward stroke, the one-way valve located in the outlet **24** vents the positive pressure, which expels milk from the breast cup through the outlet. During the outward pump stroke, the actuator arm of the breast pump pulls the flange top **36** from the inward position shown in FIG. 9B to the outward position shown in FIG. 9A, which creates negative pressure (suction) inside the vacuum chamber. During the outward stroke, the one-way valve located in the outlet **24** seals the outlet, which causes the negative pressure (suction) to be sustained within the vacuum chamber to create a milking action promoting the expression of milk from the user's breast. As noted previously, the bellows structure **42** resiliently resists the inward stroke and assists the outward stroke such that, when the breast cup is operating in its normal

mode cyclically creating and sustaining suction during the outward stroke and expelling milk through the outlet vented by the one-way valve during the inward stroke, the amount of force applied by the pump mechanism to the flange top **36** is substantially the same during the inward and outward pump strokes.

FIGS. 10 and 11 are perspective views of the internal configuration of the breast pump **10**. These views show the outer housing **16**, the power switch control knob **30**, and the vacuum adjustment knob **32** located on the exterior of the pump. On the interior of the housing, the breast pump includes a pump mechanism **50** powered by a power source **52**, in this embodiment a single AA battery. The pump mechanism **50** includes a motor **54** and a drive train **56**, which are shown more clearly in the assembled view of FIG. 12 and the exploded views of FIGS. 13 and 14. The drive train **56**, which translates the rotary motion of the motor **54** to reciprocating linear motion of the actuator arm **34**, is supported by a motor plate **60** that is attached to the pump housing by a number of shock absorbing bushings for noise reduction. The motor plate **60** supports the motor and includes gear supports **62**, **64** and **66** along with slide channels or slots **68** and **70** for receiving the cam follower **72** and actuator arm **34**, respectively. The motor **54** drives a pinion gear **80**, which engages a drive gear **82** supported by the first gear support **62**, which engages a translation gear **84** supported by the second gear support **64**, which engages a cam gear **86** supported by the third gear support **66**.

The face of the cam gear **86** contains a cam track **90** (shown in FIGS. 24 and 25) that engages a cam follower pin **92** on the cam follower **72** to translate rotary motion of the cam gear into linear motion of the cam follower. The cam follower **72** engages the actuator arm **34** by way of a coil spring **94**, which is sufficiently rigid to support the force required to drive the actuator arm when the actuator arm is unconstrained. The cam follower **72** includes a boss **73** that interfaces with the spring **94**, which is captured within a spring channel **95** (shown in FIG. 14) of the actuator arm **34**. The coil spring **94** compresses to allow the cam follower **72** to move through its range of motion when movement of the actuator arm **34** is constrained. In particular, movement of the actuator arm **34** may be selectively constrained by the cam shaft **96** (shown in FIG. 13) driven by the vacuum adjustment knob **32**, which controls the stroke of the actuator

arm. The cam shaft **96** has an eccentric cam surface (or may contain multiple flat contact surfaces of varying radius relative to the center of the cam shaft) that blocks a variable amount of the available travel of the actuator arm **34** as the vacuum adjustment knob **32** is rotated.

In addition to providing vacuum adjustment, placement of the coil spring **94** in the drive train linkage between the actuator arm **34** and the cam follower **72** allows the cam follower to continue to reciprocate through its full path of motion even when the actuator arm **34** is manually blocked by another obstruction, for example when the actuator arm is jammed or held down by a person's hand. The coil spring **94** therefore provides stress relief to the drive train and motor, which cannot be manually jammed by blocking the actuator arm. This is a beneficial design feature that avoids potential damage to the pump from jamming the actuator arm, such as stalling and a potential over-current condition that could cause overheating of the motor, stripping of the gears, breaking of the gear supports, bending or breaking of the motor plate, and so forth. The coil spring **94** may also be selected to limit the maximum vacuum that the pump can generate, for example to a maximum limit of 250 mm Hg, which provides a beneficial safeguard against over stressing the mother's breast during pump operation.

Fig. 15 is an end view of the breast cup **18** and Fig. 16 is a bottom view of the breast cup showing the bellows structure **42**, the nipple tunnel **46**, the breast interface section **48**, the outer flange area **50**, the detent tabs **52a-b**, the outlet **24** that receives the one-way valve, the flange top **36**, and the barb **38**. FIG. 17 is a perspective view of the breast cup **18** with the flange top **36** and barb **38** in the outward position. This view also shows the one-way valve **20** in its operative position in the outlet **24**. FIG. 18 is a perspective view of the breast cup **18** with the flange top **36** in the inward position. FIG. 19 is a perspective view of the breast pump **10** with the breast cup **18** installed showing the actuator arm **34** and flange top **36** in the outward position. FIG. 20 is a perspective view of the breast pump **10** with the breast cup **18** installed showing the actuator arm **34** and flange top **36** in the inward position.

FIG. 21 is a perspective view of the breast pump **10** with the valve **20**, stem **26** and collection bag **28** assembled in their operative positions. The collection bag includes an elongated neck **27** that receives the stem **26**. The stem as received within

the neck of the collection bag extends into an opening in the pump enclosure, where the neck of the collection bag is captured in place between the top portion of the stem and the pump enclosure. The enclosure holds the top portion of the stem against the outlet of the breast cup to provide a leak-free milk transfer path from the outlet **24** of the breast cup to the container portion of the collection bag. As shown in FIG. 1, the stem **26** as received within the elongated neck of the collection bag passes between the bottom of the brassier and the user's chest, such that the container portion or pouch of the collection bag is suspended below and supported by the brassier. The wave shape across the transverse dimension of the stem **26** allows the milk to be transported along the exterior of the stem past the bottom of the brassier even though the stem and the neck of the collection bag are captured between the bottom of the brassier and the user's chest sufficiently firmly to support the container portion of the milk collection bag below the brassier without the aid of hands or other support devices. The collection bag **28** also includes seams **29** that extend from the neck **27** into the container portion of the bag. These seams prevent the collection bag from spilling milk when the collection bag holding milk is laid on its side with the stem **26** removed from the bag. This milk collection system has proven to be very successful in the Gen-1 design, and has therefore been retained in the Gen-2 design with some helpful improvements.

FIG. 22 is another perspective view of the breast pump **10** with the valve **20**, stem **26** and collection bag **28** assembled in their operative positions. In FIGS. 21 and 22, the removable cover plate **65** (shown in FIG. 23) that attaches to the outer housing **16** is transparent or removed to reveal the top of the breast cup **18** and its interface with the actuator arm **34**. The cover plate **65** may be transparent to allow the user to view the inside of the pump in the area of engagement between the actuator arm and the breast cup when the cover plate is installed. Because the silicon breast cup is also substantially transparent, the user can observe the condition of the nipple and milk flow through the cover plate or window **65**, which may also be removable to provide physical access to the area of engagement between the actuator arm and the breast cup. This helps the user observe and adjust the interface between the barb **38** and the detent opening **40** in the actuator arm **34**, if necessary, to ensure that the actuator arm is properly engaged with the breast cup. The inner housing **19** of the breast pump may

include an additional transparent window on the top of the breast pump enclosure adjacent to the power switch and vacuum control knob allowing the user to view the interface between her breast and the nipple channel of the breast cup from above to aid in proper placement of the breast pump on the breast. If desired, the entire breast pump enclosure may be manufactured from a transparent material to maximize visibility of the internal pump components and to aid in proper placement of the breast pump on the breast.

FIG. 23 is a perspective view of a particular embodiment of the breast pump **10** disassembled showing with the major components and accessories. The accessories of the breast pump include the breast cup **18**, the one-way valve **20**, the stem **26** and the collection bag **28**. The components of the drive train include the motor plate **60**, the pinion gear **80**, which attaches to the drive shaft of the motor **54**, the drive gear **82**, the translation gear **84**, and the cam gear **86**. The gear posts of the motor plate **60** may be cast in the material of the motor plate or they may be inserts, such as stainless steel pins. The cam gear **86** drives the cam follower **72** by way of the cam follower pin **92** (shown in FIGS. 13 and 14), which rides in the cam slot **90** (shown on FIGS. 24 and 25). In this embodiment, the cam follower pin **92** is covered by a sleeve **112**, which may be made from NYLON® impregnated with TEFLON® or another suitable material to provide a self-lubricating surface, to reduce friction between the cam slot and the cam follower pin and extend the life of the cam gear. The cam follower **72** is coupled to the actuator arm **34** by way of the coil spring **94**. The hood **33** covers the actuator arm **34** for sound proofing and sealing out liquid or other contaminants. The motor plate **60** is mounted to the pump enclosure by bushings **25** for noise reduction.

The adjustment components of the breast cup include the vacuum control knob **32**, which drives the eccentric cam shaft **96**. The cam shaft selectively blocks a portion of the stroke of the actuator arm **34** to provide vacuum adjustment, while the coil spring **94** in the linkage between the actuator arm and the cam follower **72** allows the cam follower to move through its full range of motion regardless of the whether a portion of the stroke of the actuator arm is blocked by the cam shaft. A water-tight gasket **110** seals the interface between the vacuum control knob **32** and the housing of the breast pump. The power control knob **30** operates a three-position power control switch **116**,

which is secured to the housing by screws **112**. A water-tight gasket **114** seals the interface between the power control knob **30** and the housing of the breast pump.

The electrical components of the breast cup include the motor **54**, the battery **52**, and the wiring **118** for electrically connecting the motor the to the battery by way of the switch **116**. The battery is electrically connected by way of a spring-type battery terminal **97** that fits into a socket in the pump housing and a leaf-type battery terminal **21** that is supported by a c-channel **120** that fits into a socket in the housing.

The components of the breast pump housing include the inner housing **19** that receives the breast cup **18**, the dome-shaped outer housing **16** that faces the inner surface of the breast cup of the user's brassier, and the removable battery cover **23**. The outer housing **16** includes a removable (and transparent, if desired) cover plate or window **65**. The inner housing **19** may also include a transparent window at the top of the housing below the vacuum control knob **32** and power control knob **30**.

FIG. 24 is a front view and FIG. 25 is a perspective view of the cam gear **86** of the breast pump showing the cam track **90**, which has a rounded carotid shape to produce the desired pump operating curve. As noted previously, the shape of the cam track **90** can be precisely selected to produce an operating curve with desired characteristics including a desired suck-release ratio or duty cycle. FIG. 26 is an illustrative operating curve **100** for a breast pump with a duty cycle of approximately one-half, and FIG. 27 is an illustrative operating curve **102** for a breast pump with a duty cycle of approximately two-thirds. The operating curve **100** has a suck-release ratio of approximately 1:1 (i.e. suck time = x, release time = x), whereas the operating curve **102** has a suck-release ratio of approximately 2:1 (i.e. suck time = 2y, release time = y), as indicated in the figures. Referring to FIGS. 24 and 25, the shape of the operating curve **100**, **102** is controlled by the shape of the cam track **90** and can be adjusted by changing the shape of the cam track within the operating capability of the motor and gear train. The dynamic properties of the gear train and the bellows structure of the breast cup also affect the performance of the breast pump.

Referring to FIGS. 26 and 27 with further reference to the breast cup shown in FIGS. 8, 9A-B and 15-18 and the shape of the cam track shown in FIGS. 24 and 25, the performance of the breast pump is generally optimized by designing the breast cup with

a high degree of balance in the drive train so that the bellows structure **42** of the breast cup **18** requires about the same amount of force during the inward stroke as during the outward stroke during normal operating conditions. Up to 250 mm Hg of negative pressure is generated on the outward stroke (when the one-way valve is closed) while only a small level of positive pressure is required on the inward stroke (when the one-way valve is open) to evacuate the expressed milk through the one-way valve and into the collection bag. On the other hand, the silicon of the bellows structure resists the inward stroke and assists in the outward stroke as the bellows resiliently returns to its original shape. That is, the bellows structure acts like a spring that is charged during the inward stroke and discharged during the outward stroke. Given this configuration, the performance of the breast pump is generally optimized when the bellows structure requires about the same maximum amount of force during the inward stroke as during the outward stroke under normal operating conditions, which results in minimum peak power consumption and a relatively steady current profile for the motor.

Although precise power optimization is not required for the pump to operate acceptably, taking the pumping dynamics into account allows the engineer to select among the available design parameters to obtain an efficient pump design that meets the basic design criteria of the breast pump. The design objectives include a maximum suction close to but not more than 250 mm Hg, and maximum suction in the range of 210 to 240 mm Hg is expected to produce acceptable results. An operating profile with a duty cycle of about two-thirds is considered to be desirable because this profile is generally consistent with the measured suck-release profile of a live nursing baby, and operating profiles with duty cycles in the one-half to two-thirds range are expected to produce acceptable results. The pump should operate at about 60 cycles per second to be roughly consistent with a nursing baby, and cycle rates in the range of 45 to 65 cycles are expected to produce acceptable results. Experience with the Gen-2 design confirm that the embodiments described in this application meet these design criteria and perform acceptably on live nursing adult women.

More specifically, these design objectives can be achieved using the breast cup profile shown in FIGS. 8, 9A-B and 15-18 manufactured from 50 durometer silicon, the shape of the cam track shown in FIGS. 25 and 26 producing a linear stroke of the

actuator arm in the range of approximately 7.5-8.5 mm, and a motor driven by a single 1.5 Volt AA battery. For this particular embodiment of the breast pump, the motor may be rated for 2.4 Volts DC and 7,700 rpm (e.g., Mabuchi FF-180SH motor). The operating speed of the motor is a function of the load applied to the motor and can be further controlled by adjusting the applied voltage through the range of about 1.0 to 1.5 Volts, for example through the use of a resistive voltage divider or voltage limiting diodes. Vacuum adjustment can be controlled with a cam shaft that selectively blocks and thereby controls the stroke of the actuator arm in the range of about 6 to 8 mm. The coil spring in the drive train between the cam follower and the actuator arm should be selected to limit the suction that can be developed by the breast cup to be no greater than about 250 mm Hg.

The operating noise of the pump can be mitigated by using a relatively soft material, such as a 50 durometer urethane, for the drive gear. As shown in FIG. 28, the mesh between the pinion gear and the drive gear may also be replaced by a belt drive if further noise mitigation is desired. The other gears may also be 50 durometer urethane, or they may be manufactured from NYLON® or another suitable material. Manufacturing the gears from a self lubricating material, such as NYLON® impregnated with TEFLON® is also desirable. The gear teeth should be shaped to minimize chatter in the drive train, as shown in the applicable figures, and the gears can be machine cut, injection molded, or manufactured with another suitable process. The housing can be made of any material suitable for injection molding the desired shape exhibiting acceptable strength and durability, such as LEXAN®.

The motor plate may be manufactured from a similar material, such as LEXAN®, and the gear support posts may be cast as part of the motor plate or they may be metal inserts, such as stainless steel pins. The bushings at the attachment points between the motor plate and the housing can be made of rubber or a synthetic material such as NEOPRENE® or any other material suitable for this purpose. It is important that the motor plate be sufficiently rigid to prevent bending in a manner that constricts the slide channels or slots where the cam follower and actuator arm slide, as this could result in binding. To prevent binding, the slide channels may be reinforced with metal inserts, such as stainless steel, to provide increased rigidity. The actuator arm and cam

follower may be ULTEM®, NYLON® or another suitable material, and a self lubricating material, such as NYLON impregnated with TEFLON®, is also desirable for these components. The pin of the cam follower may be cast as part of the cam follower. The cam follower pin may be covered by a sleeve made from a suitable material, such as stainless steel, or the may be a metal insert, such as a stainless steel pin. The cam follower pin may carry a sleeve made of NYLON impregnated with TEFLON® or similar material to reduce friction between the cam follower pin and the cam slot of the cam gear during normal operation of the pump.

FIG. 28 shows an assembled perspective view of a modified drive train **104** for the breast pump that includes a belt drive **106** between the motor-driven gear and the main drive gear. The belt drive further mitigated noise produced by the drive train.

In view of the foregoing, it will be appreciated that present invention provides significant improvements in breast pumps. It should be understood that the foregoing relates only to the exemplary embodiments of the present invention, and that numerous changes may be made therein without departing from the spirit and scope of the invention as defined by the following claims.

CLAIMS

1. A breast pump comprising:

a housing supporting a pump mechanism operative for reciprocal movement through an inward pump stroke and an outward pump stroke;

a breast cup configured to be supported by the housing in engagement with the pump mechanism comprising an interface section configured to form an air-tight seal with an adult human breast received against the interface section;

the breast cup and the breast creating a vacuum chamber configured to reduce in volume when compressed during the inward pump stroke and to increase in volume when expanded during the outward pump stroke;

the breast cup further comprising an outlet for expelling breast milk expressed from the breast;

a one-way valve operative to vent the vacuum chamber to allow the milk to pass through the outlet when the vacuum chamber is compressed during the inward pump stroke to create positive pressure within the vacuum chamber, the one-way valve further operative for sealing the vacuum chamber when the vacuum chamber is expanded during the outward pump stroke to create negative pressure within the vacuum chamber, thereby creating a milking action for causing milk to be expressed from the breast; and

wherein the pump mechanism comprises a balanced drive system configured to apply force to compress the vacuum chamber during the inward pump stroke and to apply force to expand the vacuum chamber during the outward pump stroke.

2. The breast pump of claim 1, wherein the housing and breast cup are sized and configured to be supported between the adult human breast and a breast cup of a brassier while the breast pump is actively pumping milk from the breast and expelling the milk through the outlet.

3. A breast pump of claim 2, wherein the housing and breast cup are sized and configured to be supported by the brassier without the aid of hands or other support devices.

4. The breast pump of claim 3, wherein the housing is configured to receive an electric battery for delivering electric power to the pump mechanism.

5. The breast pump of claim 4, wherein the housing is configured to receive an electric power cord for delivering electric power to the pump mechanism.

6. The breast pump of claim 1, wherein the vacuum chamber comprises a resilient bellows structure that resists the force applied by the pump mechanism during the inward stroke and assists the force applied by the pump mechanism during the outward.

7. The breast pump of claim 6, wherein the force applied by the pump mechanism in normal operation during the inward stroke is within eighty percent of the force applied by the pump mechanism during the outward stroke.

8. The breast pump of claim 1, wherein the one way valve is removably received within the outlet of the breast cup.

9. The breast pump of claim 1, wherein the breast cup is removably received within the housing.

10. The breast pump of claim 1, further comprising a motor and cam gear for translating rotary motion of the motor to linear reciprocating motion of an actuator arm that removably engages with the breast cup, pushes a bellows structure to compress the vacuum chamber during the inward pump stroke and pulls the bellows structure to expand the vacuum chamber during the outward pump stroke.

11. The breast pump of claim 10, further comprising a vacuum adjustment mechanism operative to selectively block a portion of the motion of the actuator arm to adjust the length of the inward and outward pump strokes to adjust the amount of negative pressure generated by the vacuum chamber.

12. The breast pump of claim 11, further comprising a spring linkage in a drive train between the cam gear and the actuator arm permitting the vacuum adjustment mechanism to selectively block a portion of the motion of the actuator arm without blocking rotation of the cam gear.

13. The breast pump of claim 12, wherein the vacuum adjustment mechanism comprises a cam shaft having an eccentric cam surface that selectively blocks a varying amount of the motion of the actuator arm in response to rotation of the cam shaft.

14. The breast pump of claim 1, wherein the housing comprises a transparent window facilitating viewing a nipple of a user's breast when the breast is received against the interface section of the breast cup.

15. The breast pump of claim 1, further comprising a milk collection container for collection milk expelled from the breast cup.

16. The breast pump of claim 15, wherein the milk collection container comprises a milk collection bag comprising an elongated neck and a container portion in fluid communication with the neck.

17. The breast pump of claim 16, further comprising a milk conduit having a coupling end in fluid communication with the outlet of the breast cup and a stem section received within the elongated neck of the collection bag, wherein the brassier supports the housing, the breast interface flange, the milk conduit, and the milk collection bag without the aid of hands or other support devices.

18. The breast pump of claim 17, wherein the milk conduit received within the elongated neck of the collection bag is configured to pass between a lower edge of the brassier and the body of a user wearing the brassier.

19. The breast pump of claim 18, wherein the stem section of the milk conduit defines an elongated dimension and a narrow dimension, and the stem section defines an open wave shape across the narrow dimension.

20. The breast pump of claim 16, wherein the container portion of the milk collection bag comprises first and second side panels and the milk collection bag comprises one or more seams sealing the first and second side panels together within part of the container portion of the milk collection bag to prevent milk contained within the container portion from leaking through the elongated neck when the milk collection bag is laid down horizontally on the first or second side panel without the milk conduit received within the elongated neck.

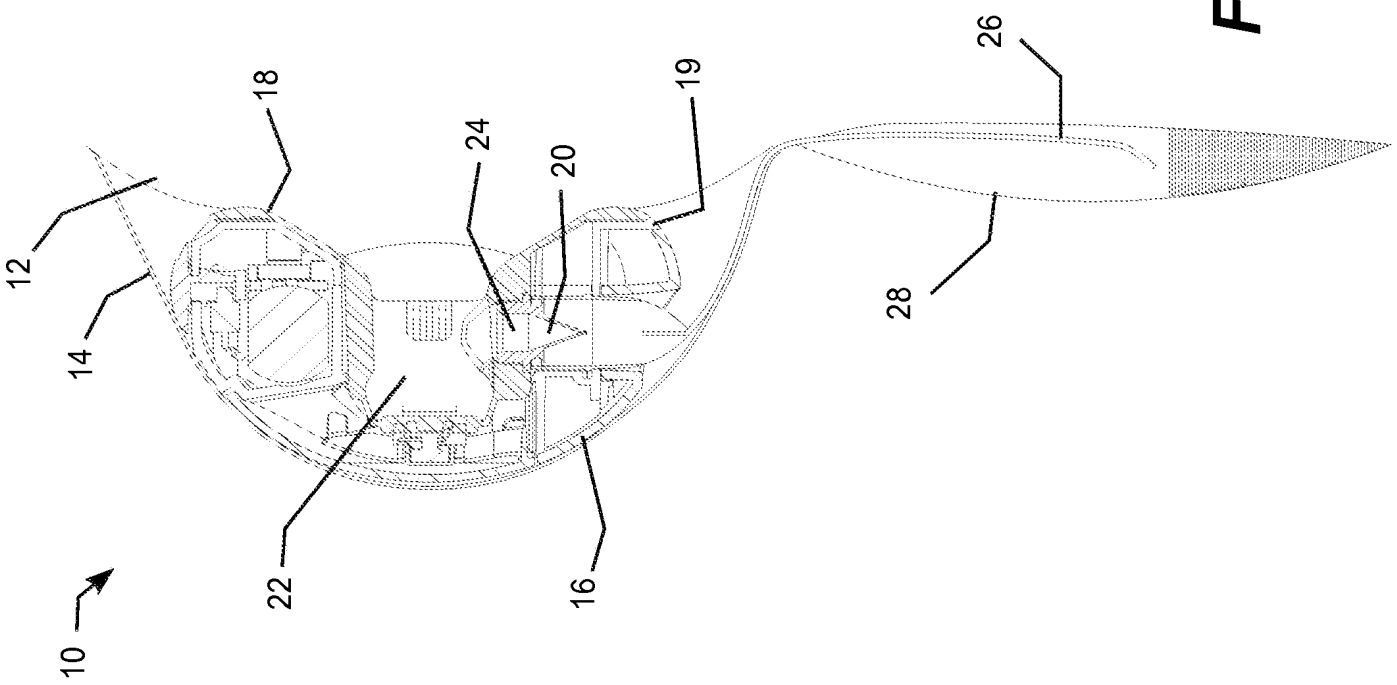

FIG. 1

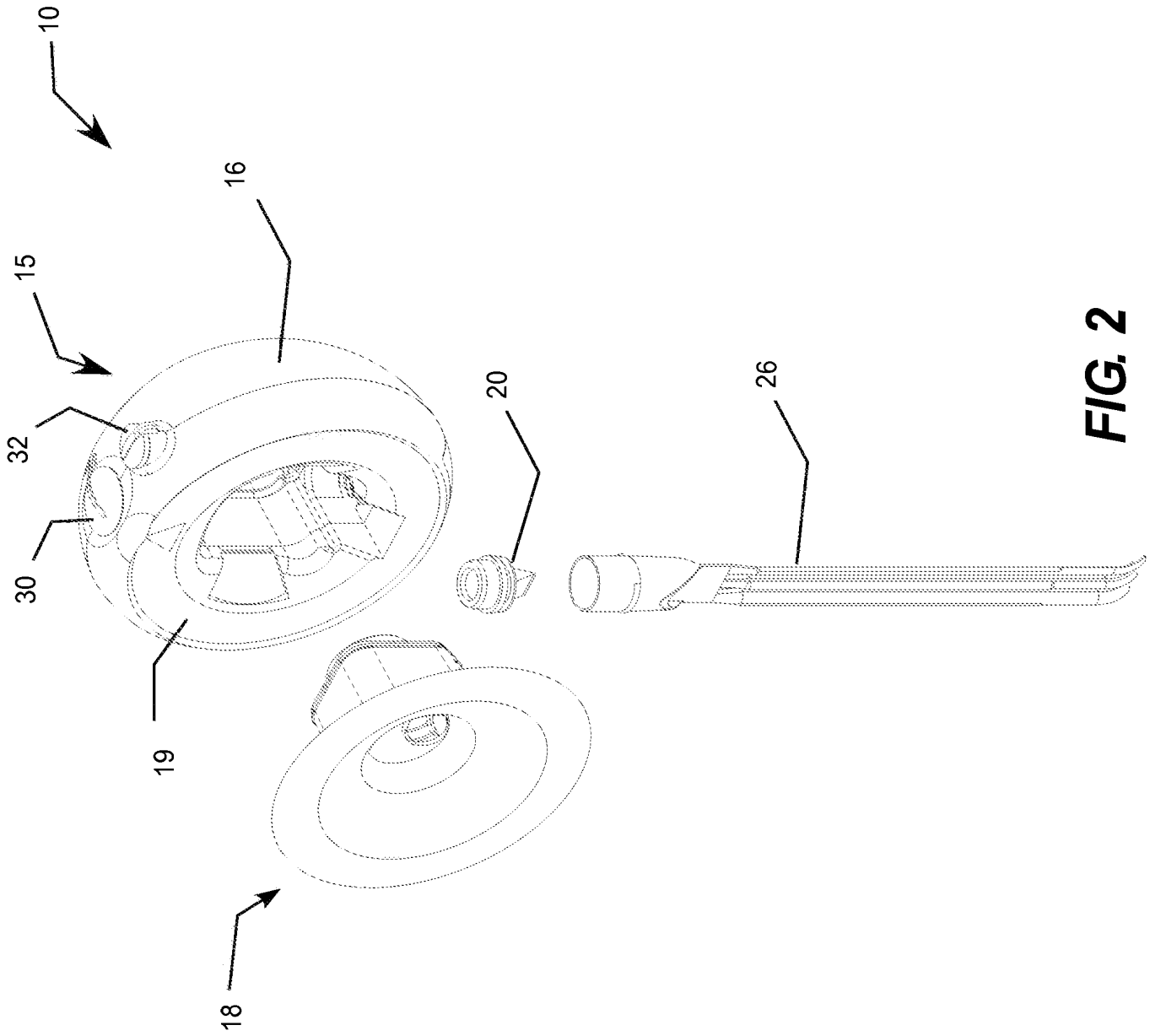

FIG. 2

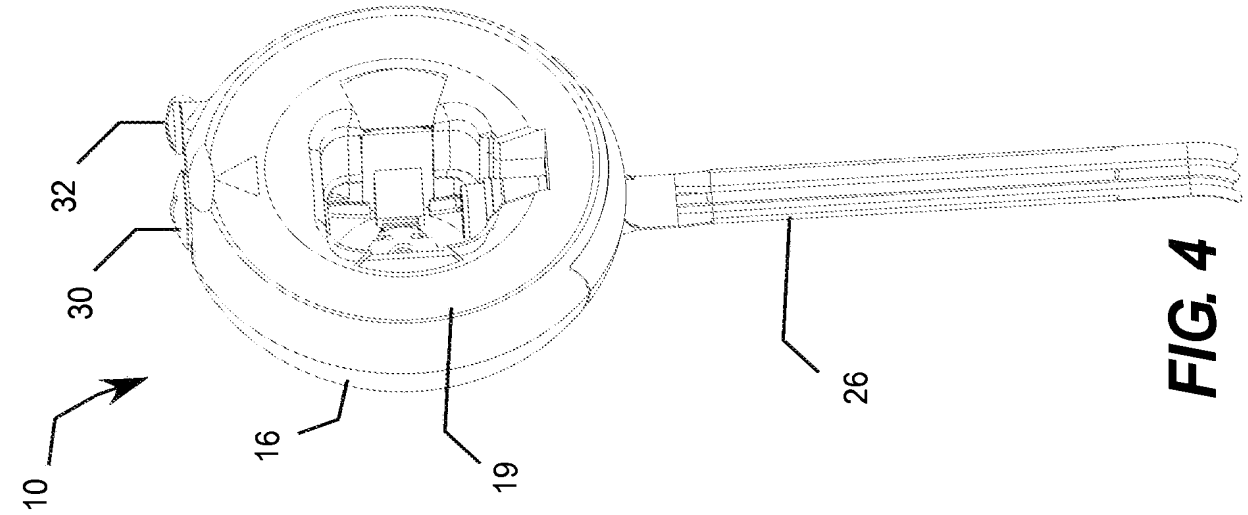

FIG. 4

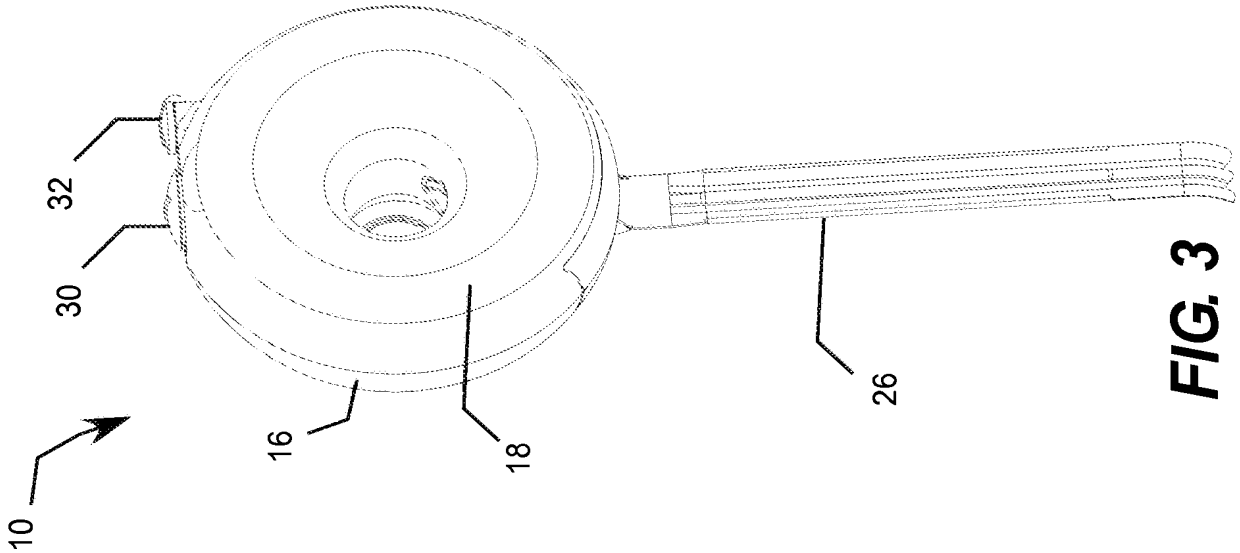

FIG. 3

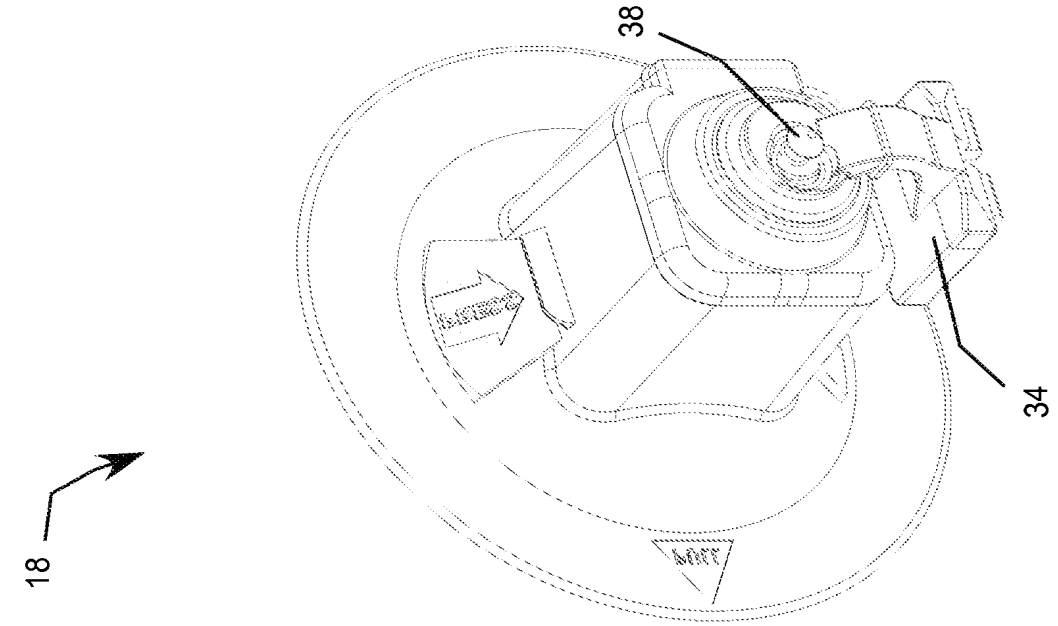

FIG. 6

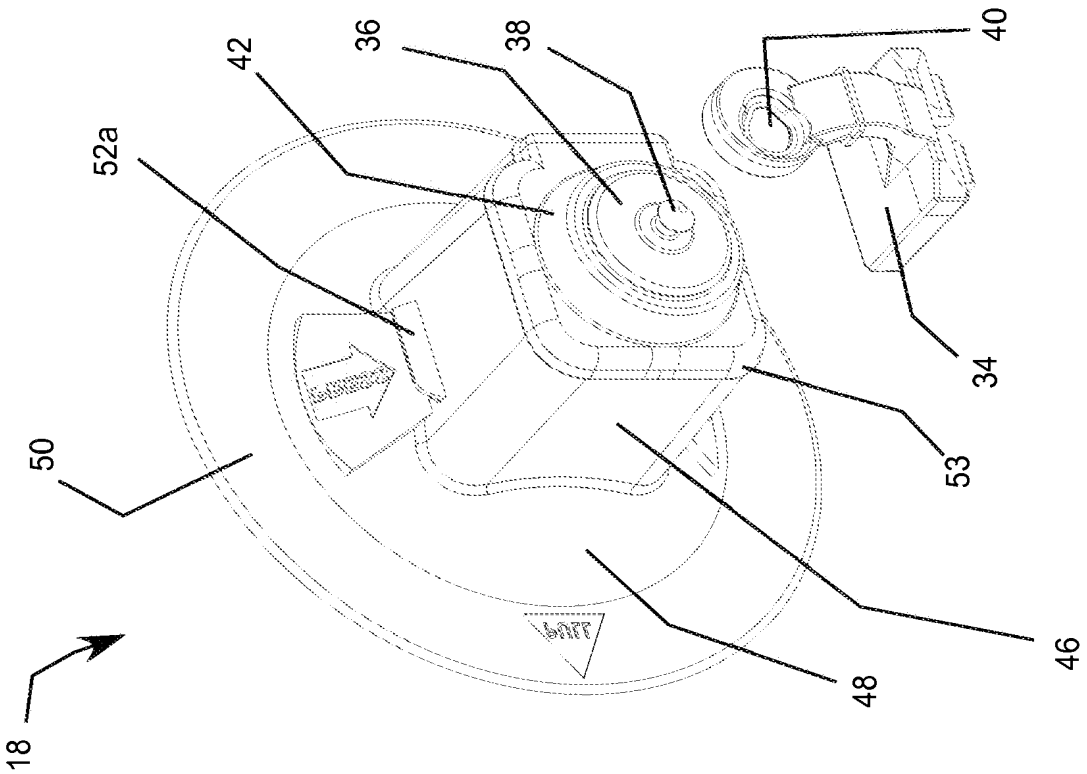

FIG. 5

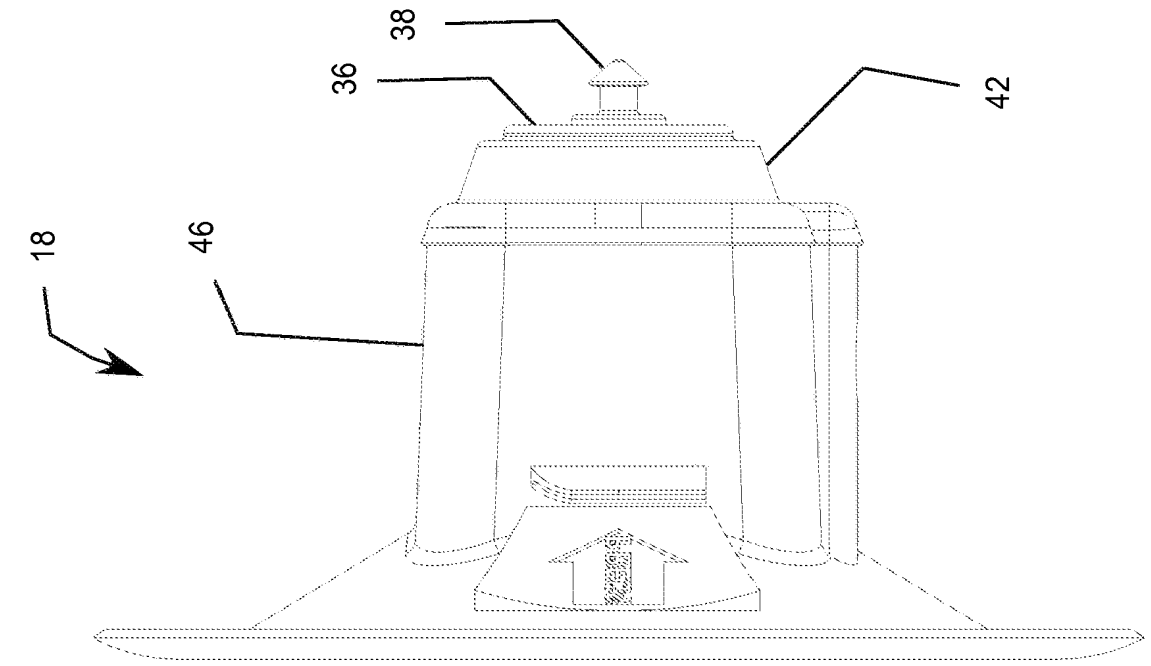

FIG. 8

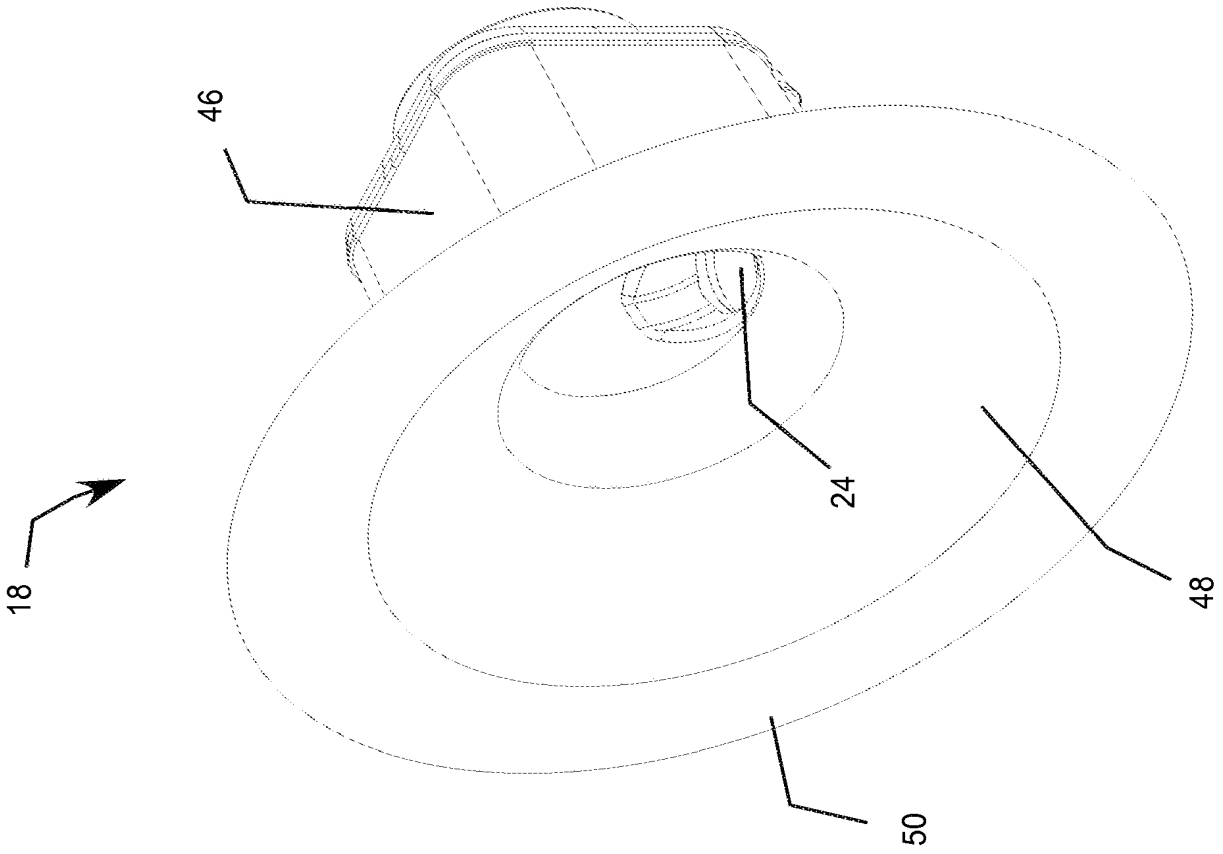

FIG. 7

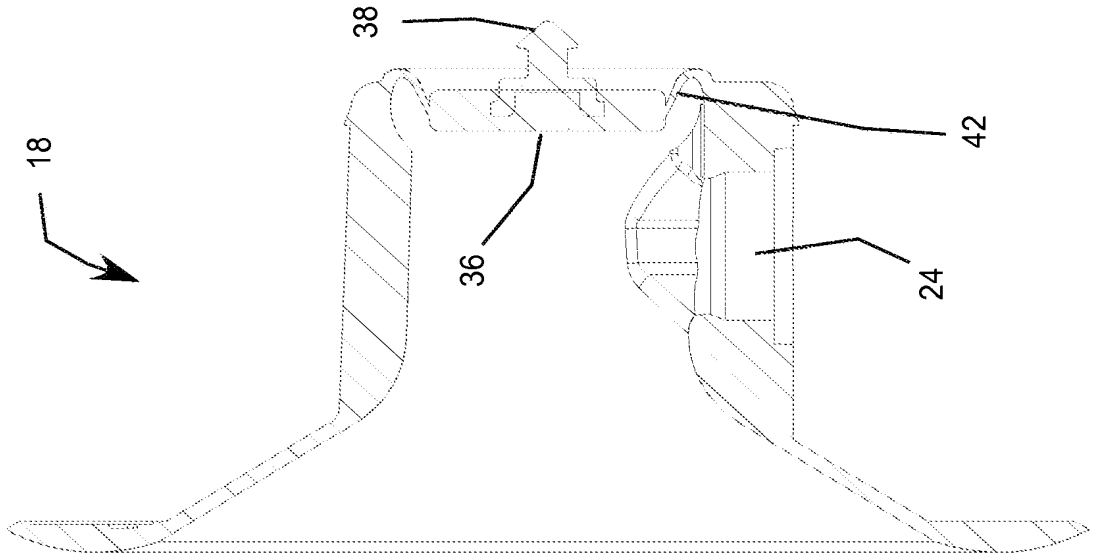

FIG. 9B

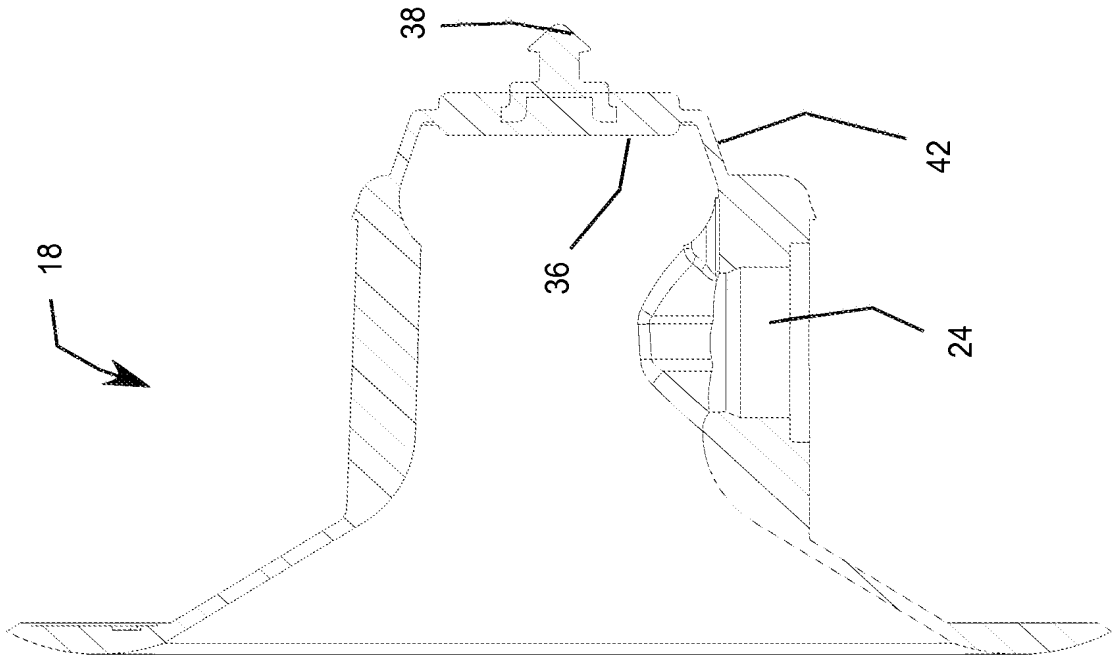

FIG. 9A

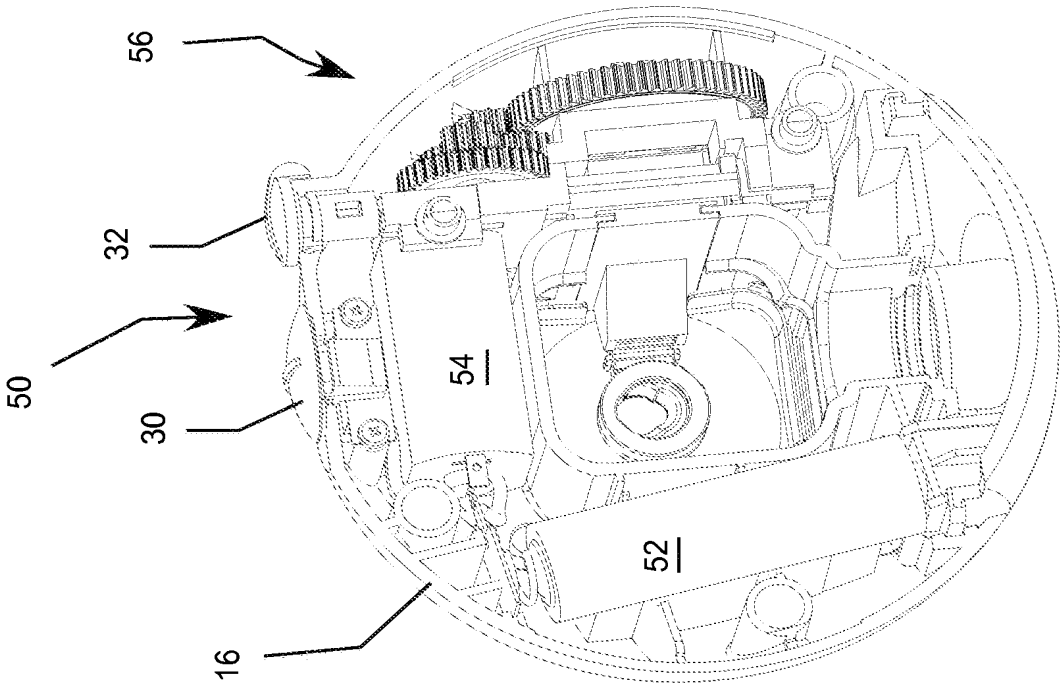

FIG. 11

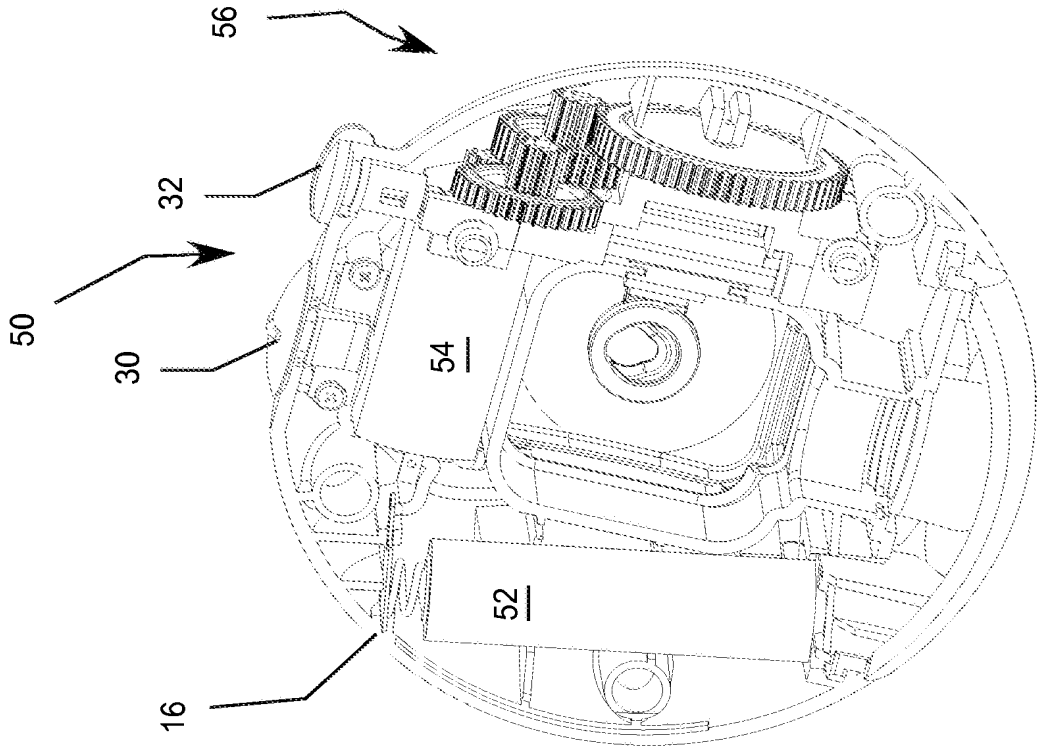

FIG. 10

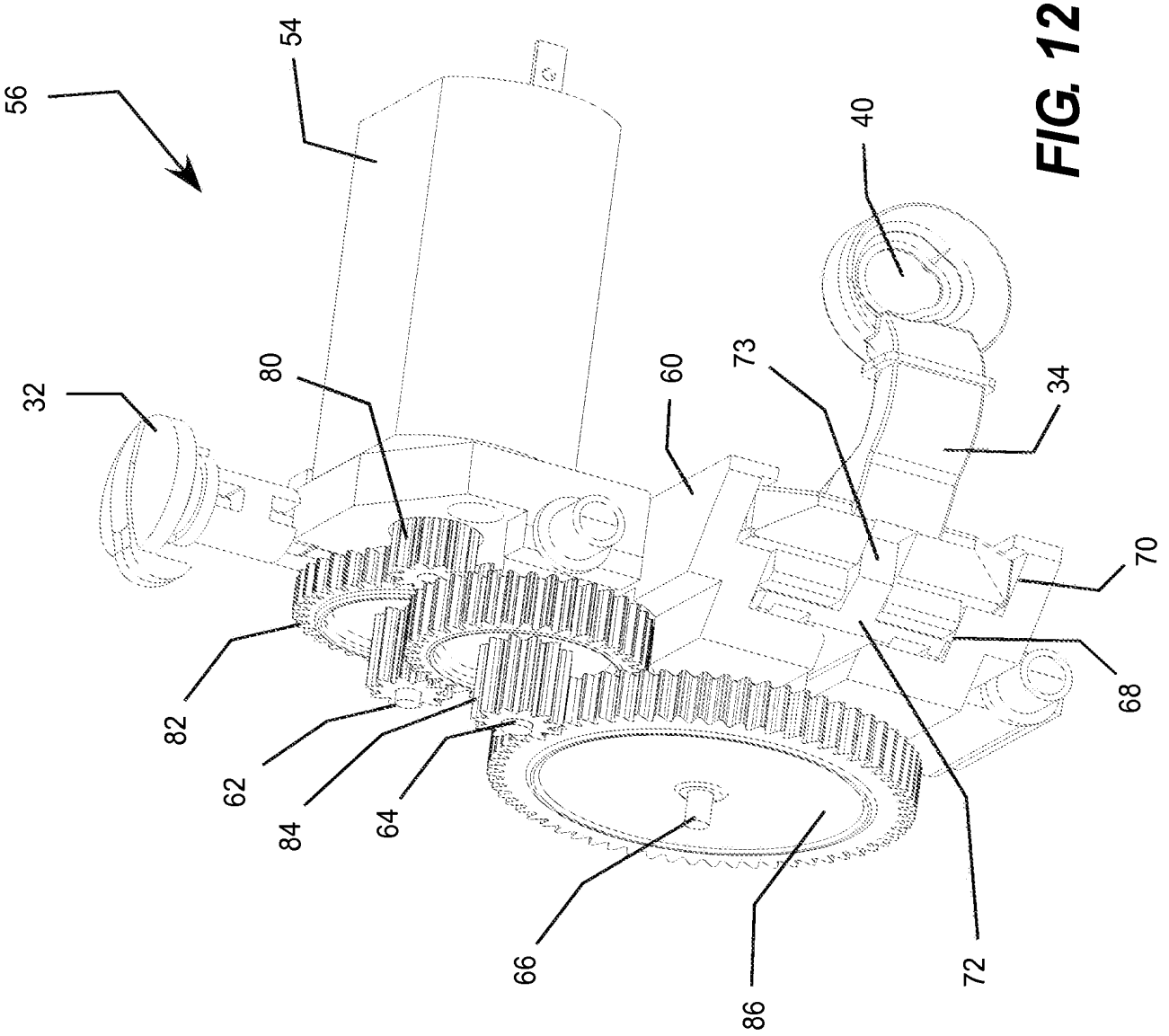

FIG. 12

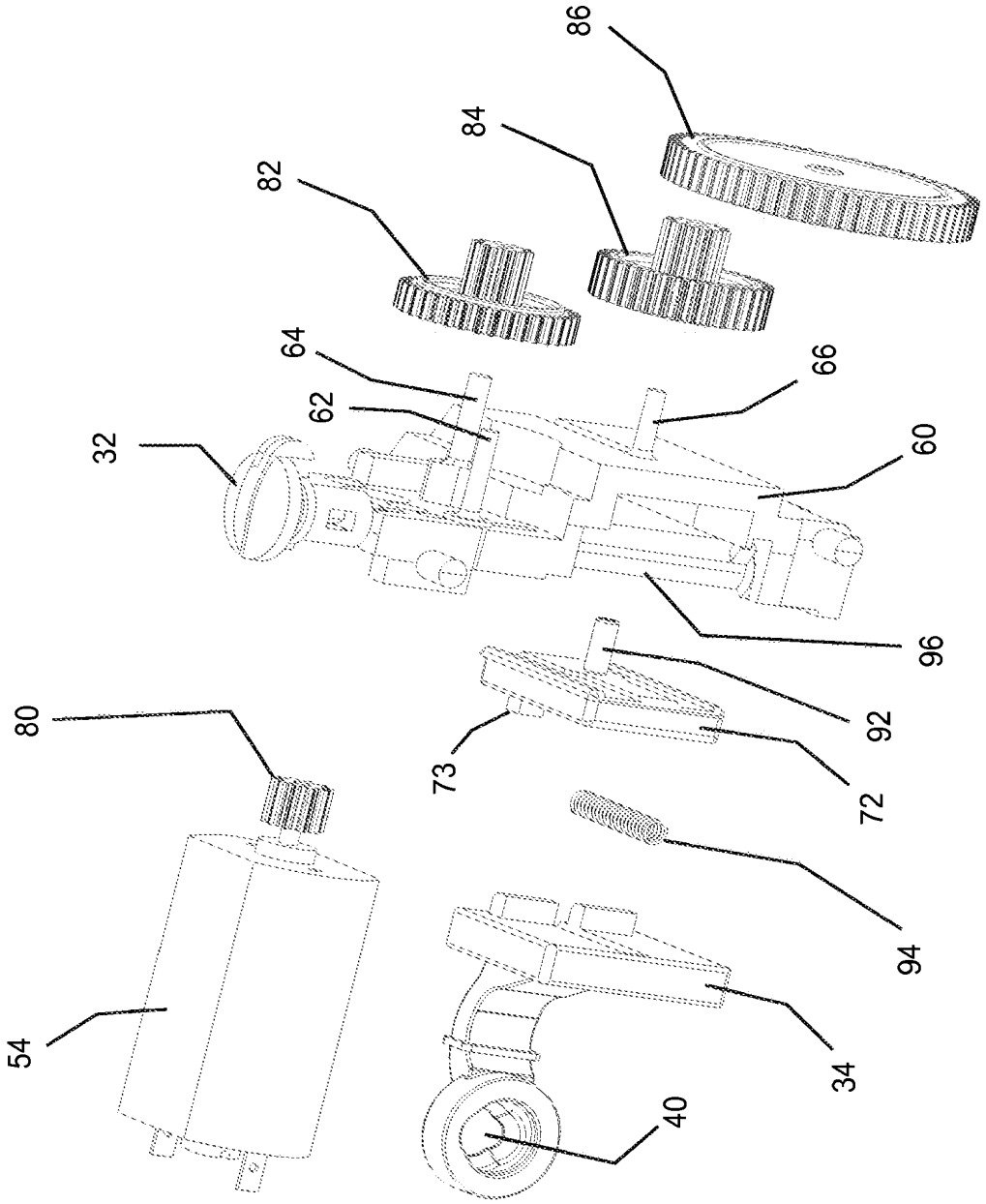

FIG. 13

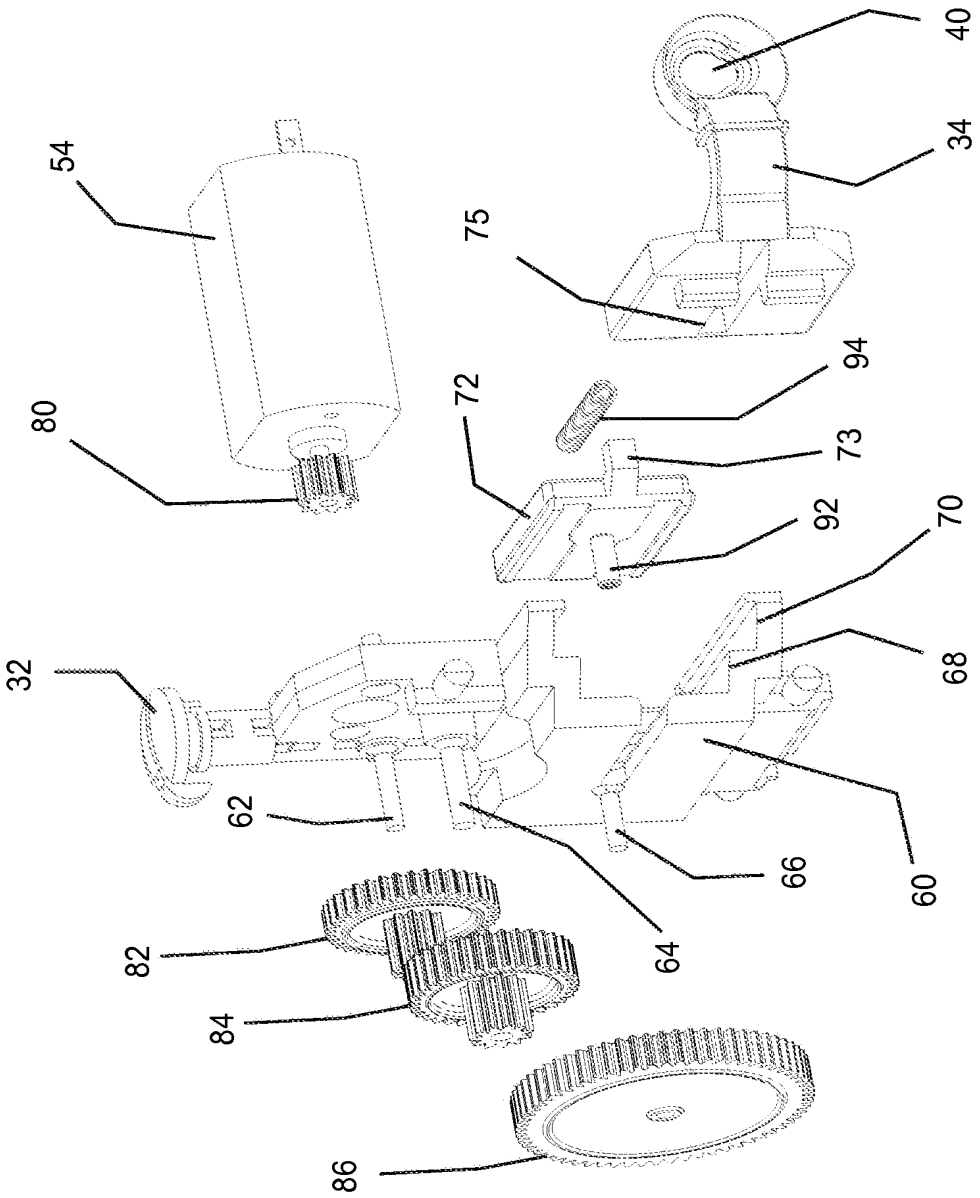

FIG. 14

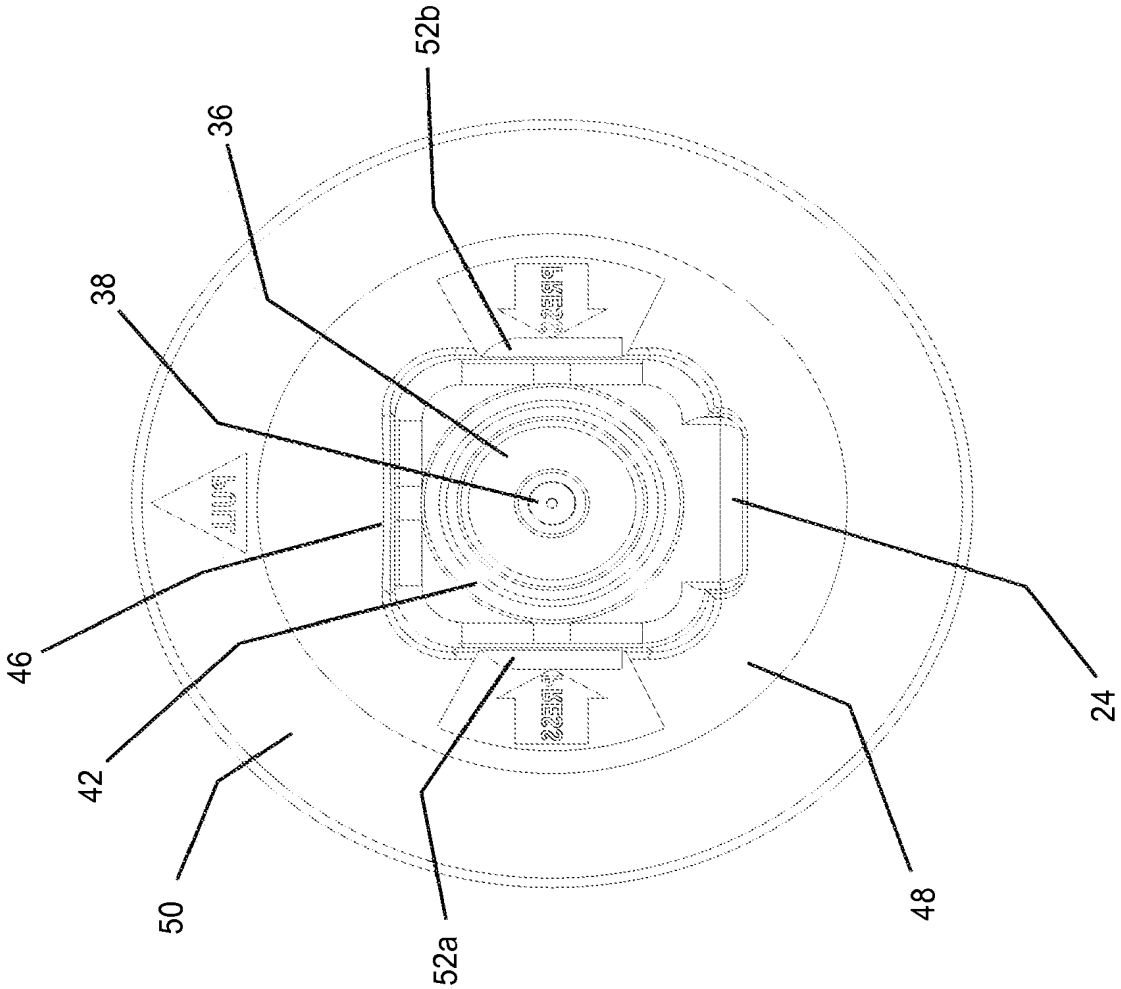

FIG. 15

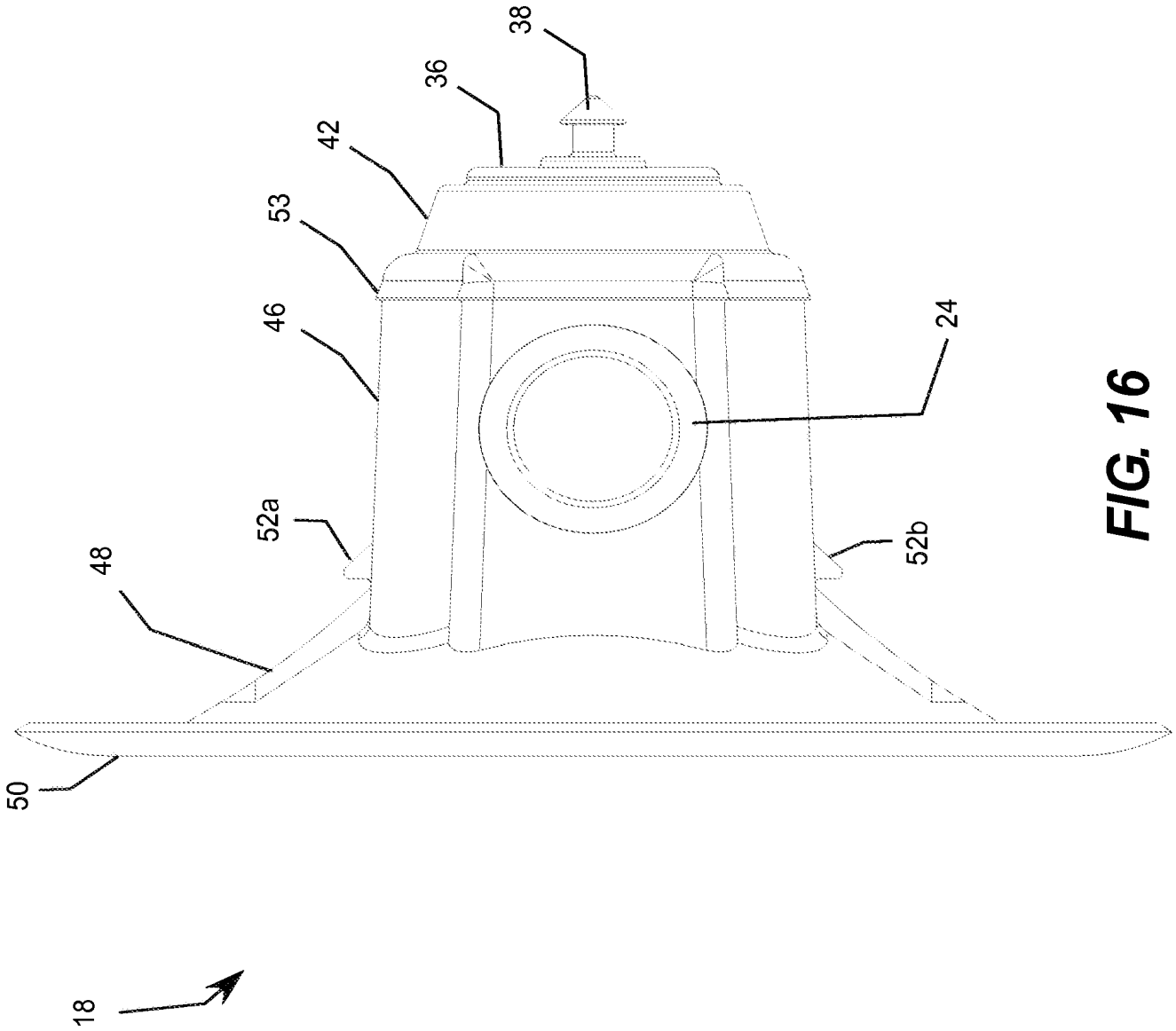

FIG. 16

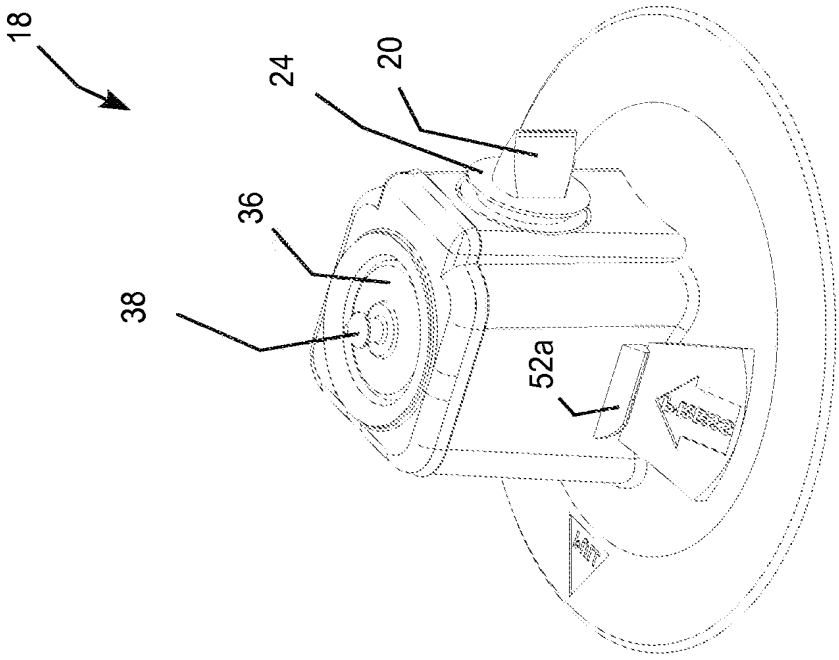

FIG. 18

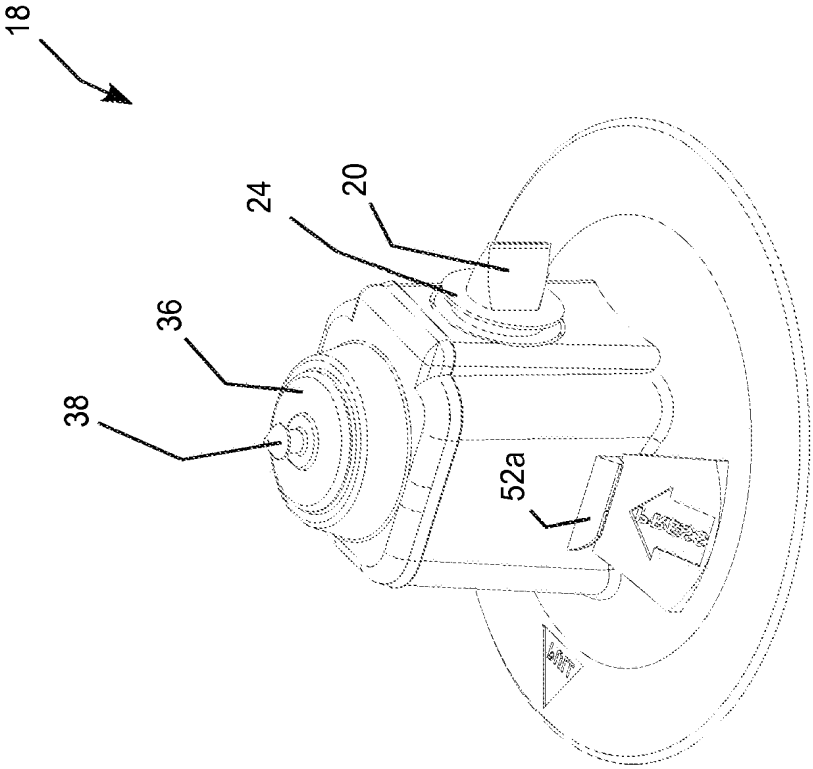

FIG. 17

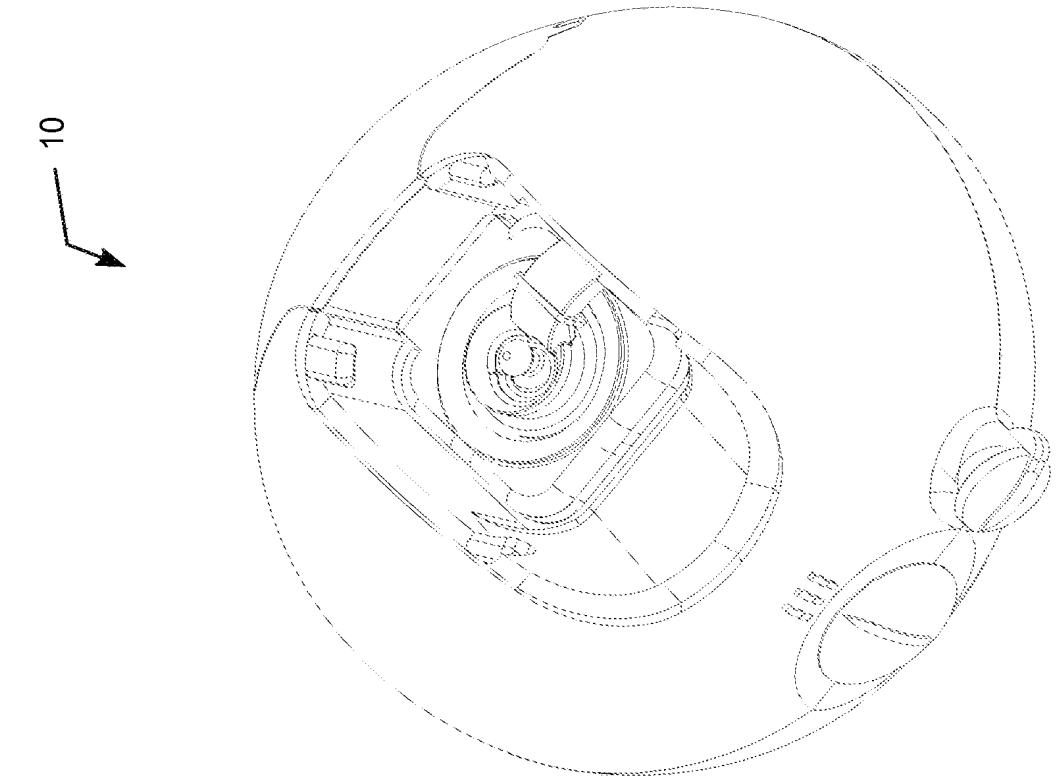

FIG. 20

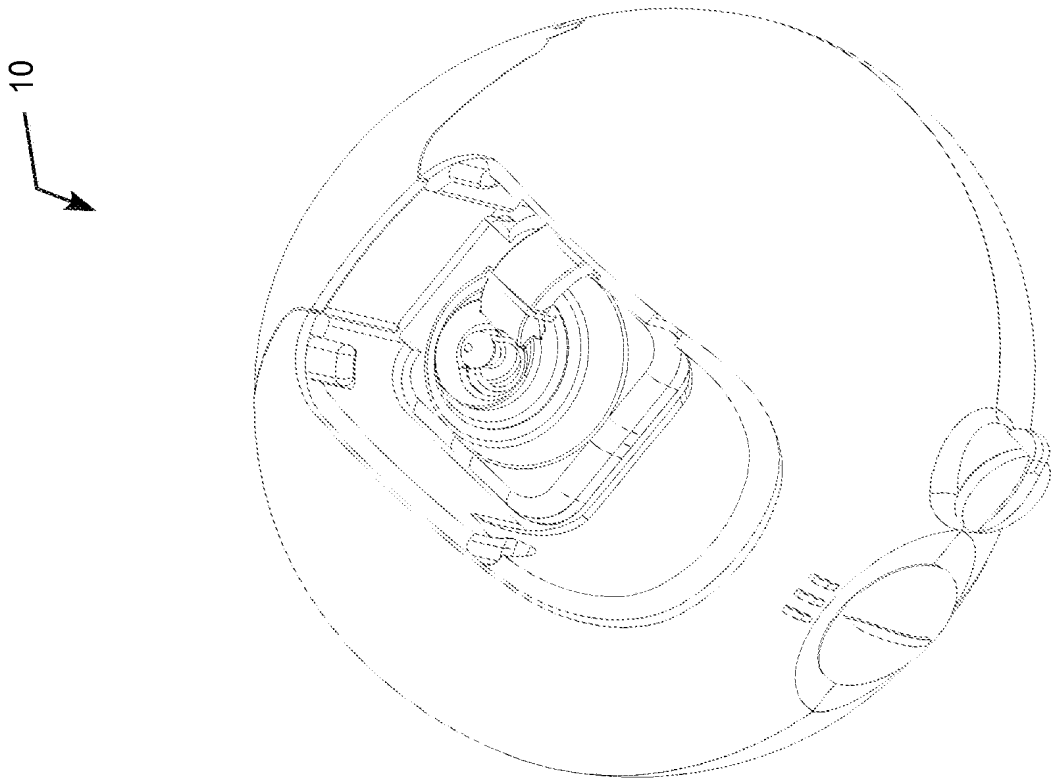

FIG. 19

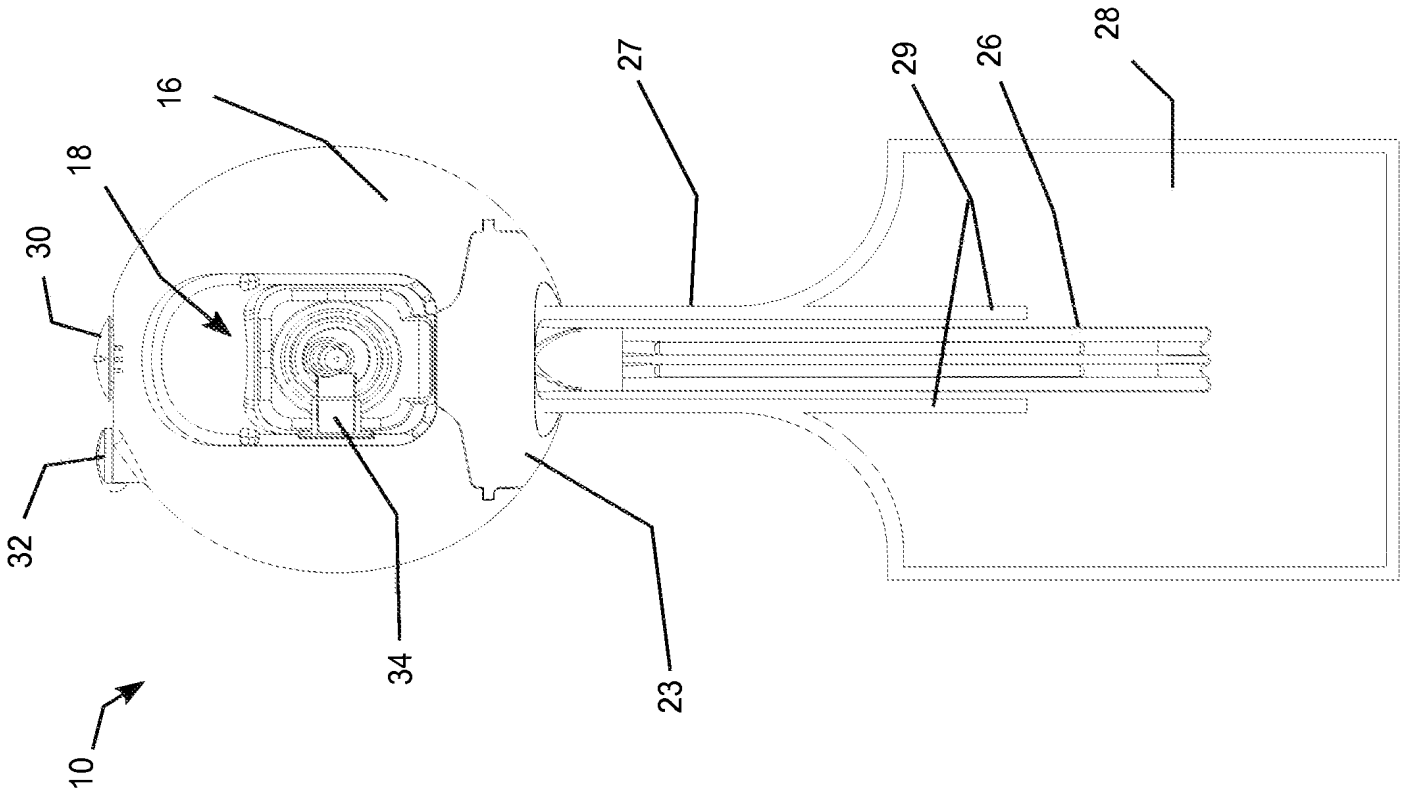

FIG. 21

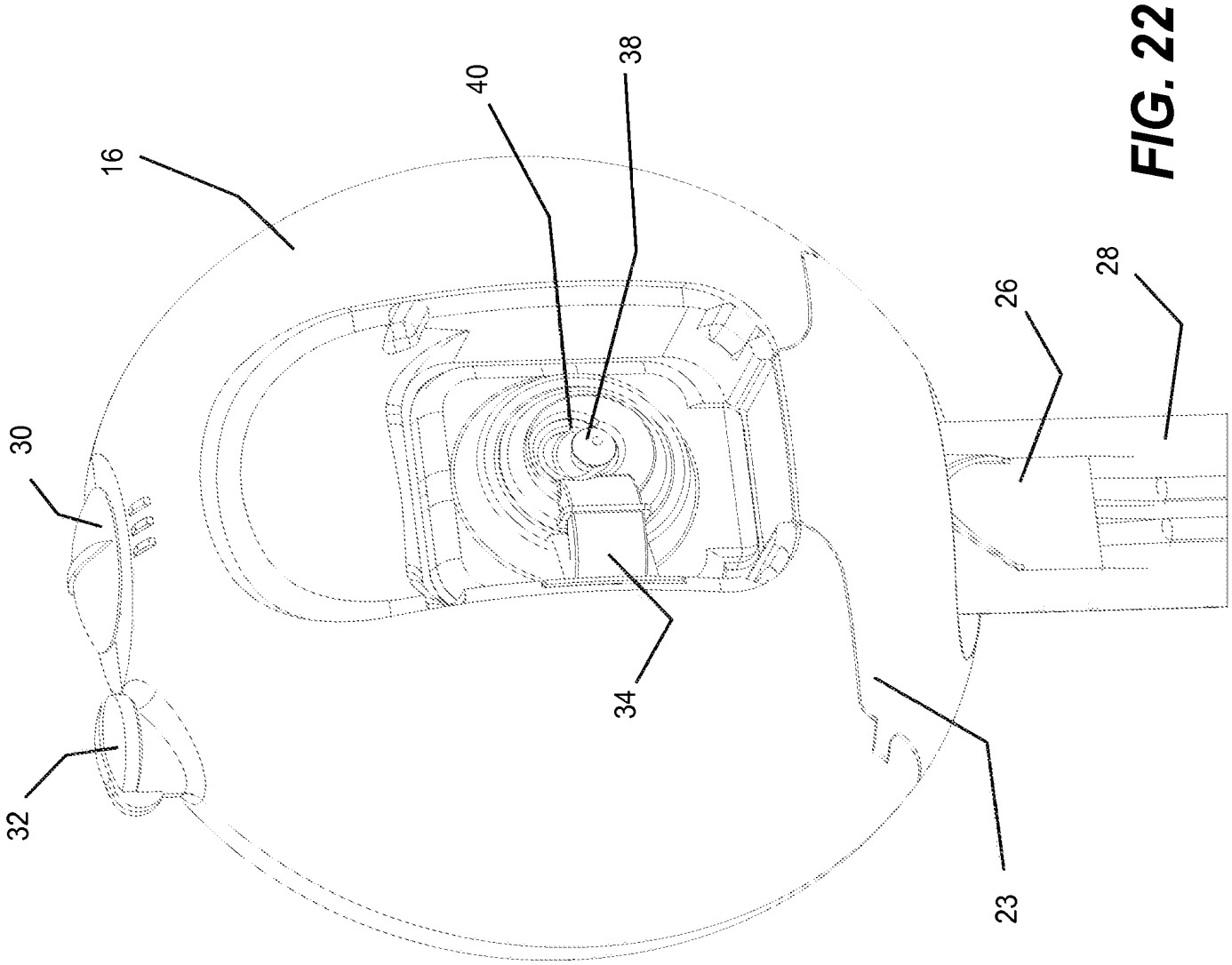

FIG. 22

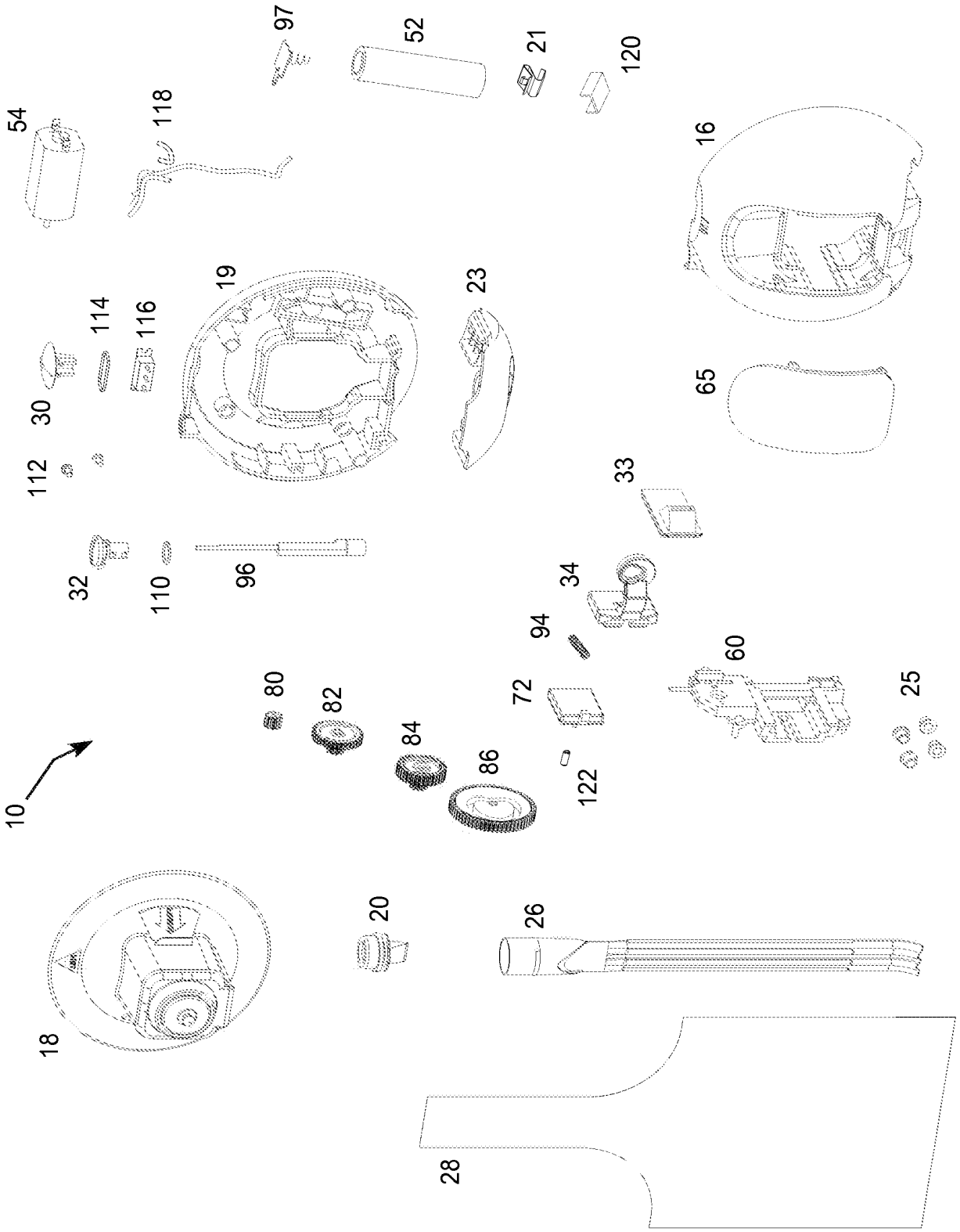
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FIG. 23

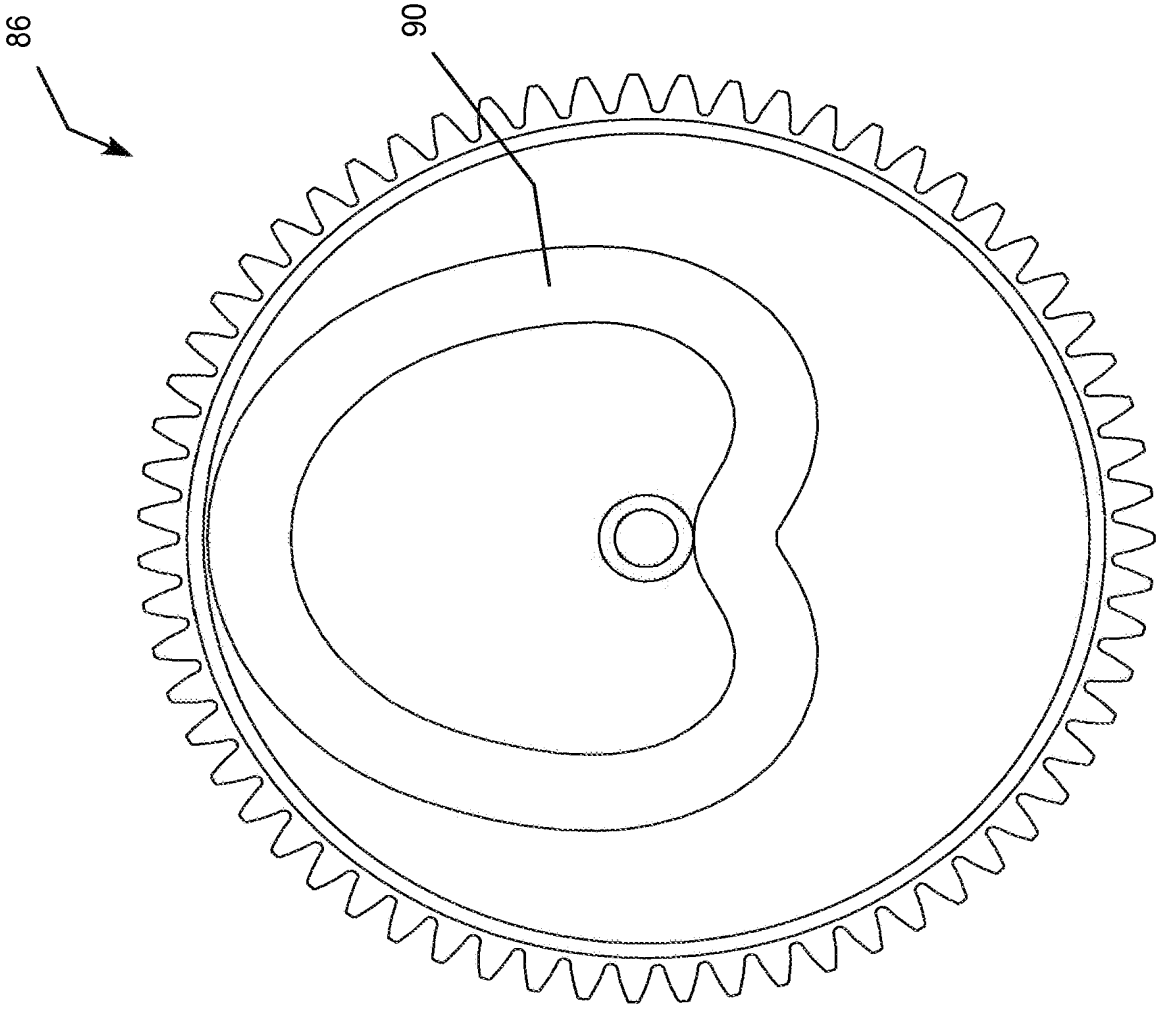

FIG. 24

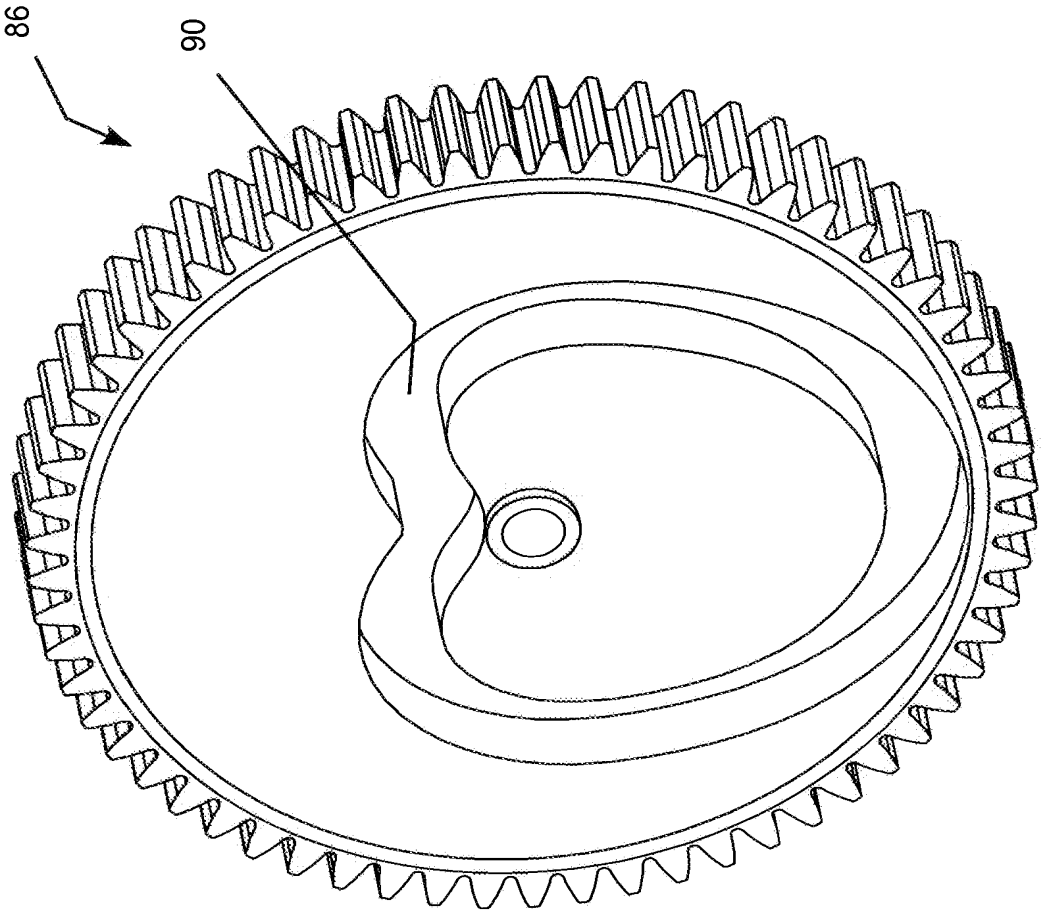

FIG. 25

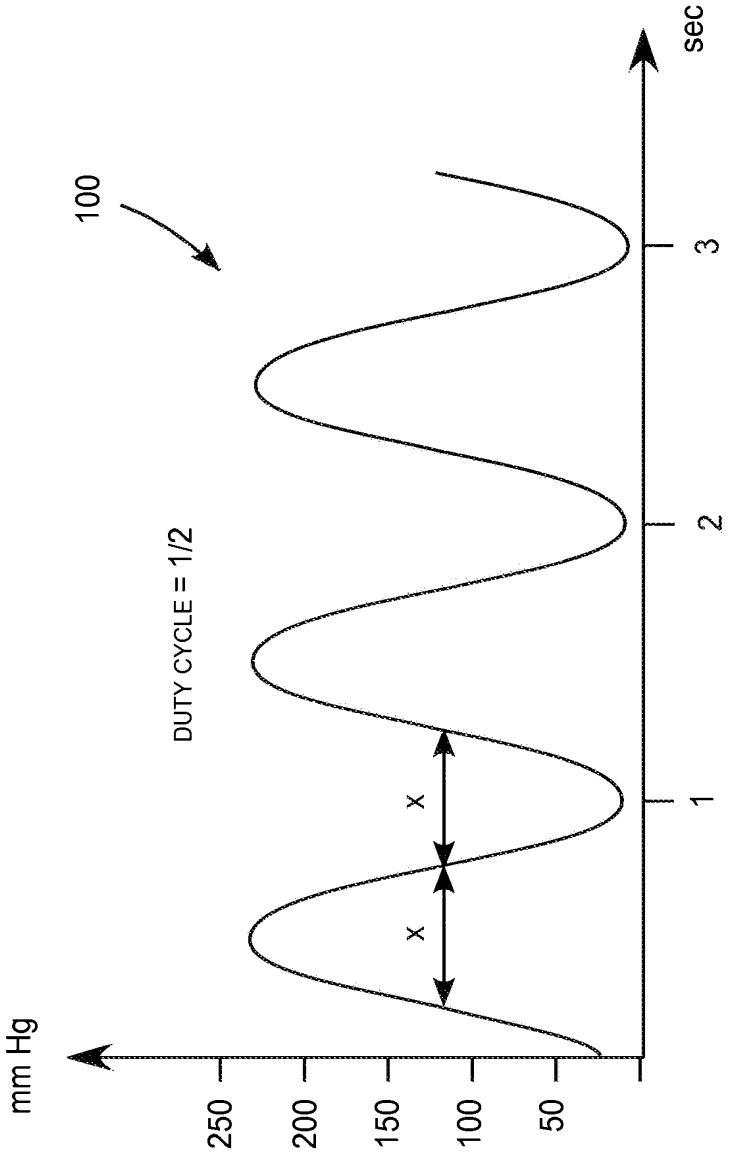

FIG. 26

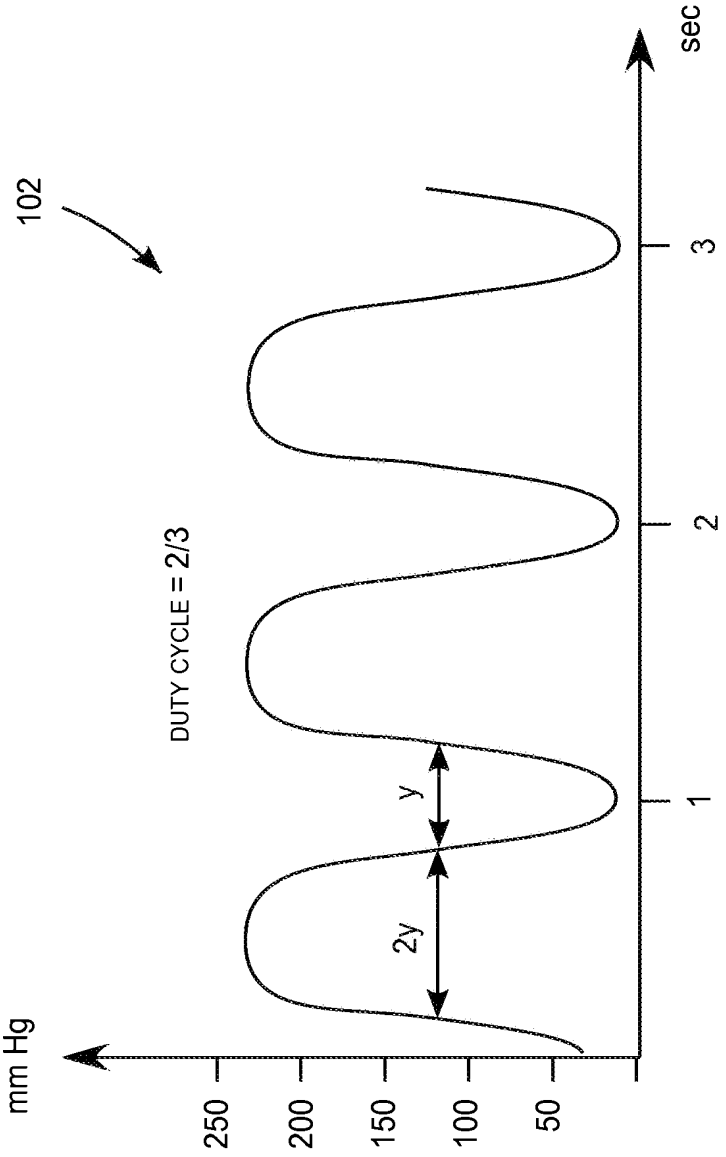

FIG. 27

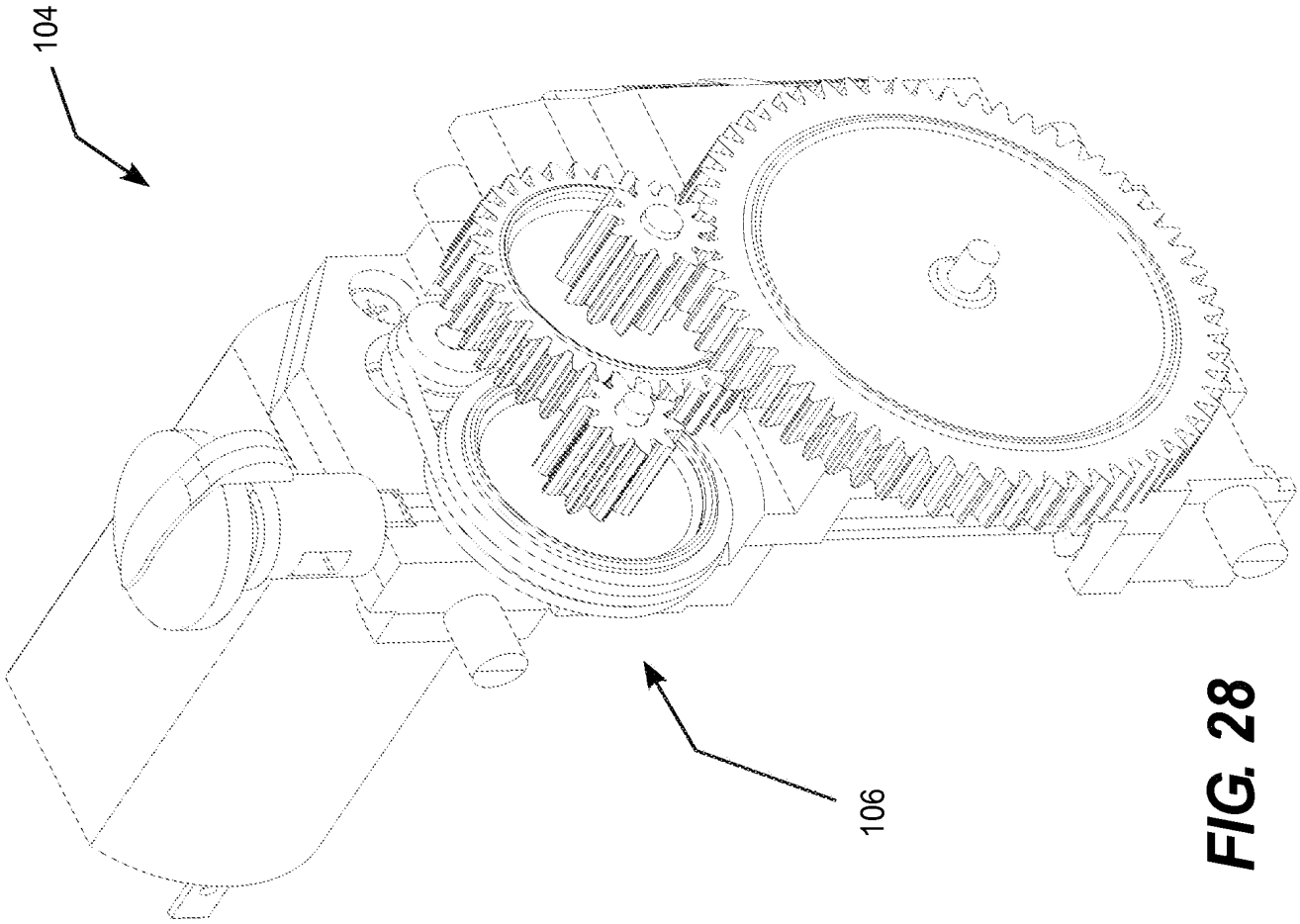

FIG. 28

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/062422

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2002/193731 A1 (MYERS KENNETH E [US] ET AL) 19 December 2002 (2002-12-19) cited in the application paragraph [0062]; figures 6,11a,20a	1
A	US 2004/127845 A1 (RENZ CHARLES J [US] ET AL) 1 July 2004 (2004-07-01) paragraph [0129]; figure 12	1
A	US 4 857 051 A (LARSSON KARL O A H [CH]) 15 August 1989 (1989-08-15) column 5, line 44 - column 6, line 34; figure 2	1

[ ] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 August 2008	04/09/2008

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European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Lakkis, Angeliki

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002193731 A1	19-12-2002	NONE	
US 2004127845 A1	01-07-2004	NONE	
US 4857051 A	15-08-1989	NONE	

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WO 02/102437 A2

(54) Title: SYSTEM FOR A PORTABLE HANDS-FREE BREAST PUMP AND METHOD OF USING THE SAME

(57) Abstract: A portable, hands-free and user friendly breast pump for facilitating breast-feeding, incorporates a dome-shaped housing having a servomotor mechanism; a hat-shaped flange having a chamber portion, a brim portion and an outlet, the chamber portion being formed so as to be placed over a nipple on a breast so as to define a chamber between the flange and the breast, and the brim portion being formed to surround the nipple and thereby form a suction seal therebetween; and a one-way venting element formed to operatively communicate with the chamber so as to vent pumped milk from the chamber via the outlet. The housing, the flange and the venting element are connected into an integral device held against the breast and underneath clothing so as to keep the integral device hidden. Breast milk is collected via a plastic collection bag that connects directly with the pump underneath clothing such that the milk is isolated from any contaminants in the air and may be easily stored immediately after being collected.

SYSTEM FOR A PORTABLE HANDS-FREE BREAST PUMP AND METHOD OF USING THE SAME

BACKGROUND OF THE INVENTION

Field of the Invention

[1] The invention generally relates to a portable, hands-free, and visually friendly breast pump system and method for collecting milk from a breast of a nursing mother which may be hidden from view when in use. In particular, the invention may be hidden underneath the clothing of a nursing mother, which provides privacy and avoids any attention and the awkwardness experienced by the nursing mother using existing breast pumps.

Description of the Related Art

[2] Breastfeeding is the best source of nutrition for a baby, and it also offers health benefits to the nursing mother. Often, the nursing mother needs to use a breast pump to collect milk. A variety of breast pumps are available. The basic types of breast pumps include manual (hand operated) pumps and electric pumps. The electric pumps may be battery and/or AC powered. Further, the electric pumps may be self-cycling or require some manual user control. U.S. Pat. No. 6,213,840 combines a manual hand pump with a breast pump support bra which supports the weight of the breast. While most hand pumps are inexpensive and portable, they are typically uncomfortable, inefficient, and difficult to clean.

[3] Some electric pumps are not battery-operated such that the nursing mother has to be near a power outlet. Other electric pumps, such as the diaphragm pump disclosed in U.S. Pat. Nos. 6,257,847 and 6,090,065, are assembled from many parts (hoses, gaskets, valves, etc.) which are difficult to clean, wash and carry. Figure 27 illustrates such a prior art system from the '065 patent having many parts which makes it cumbersome and difficult to use. In particular, in such a traditional breast pump, the milk has to pass through a plurality of components, such as a funnel P20, a cylindrical guiding means P22, a cap assembly P30, a reservoir P40, an inlet P62 connected to the suction assembly, etc., just to get to a container.

[4] The website at http://www.epinions.com/kifm-Health-Nursing_and_Feeding-Breast_Pumps-All/tk_~PR001.1.5 lists many commercially available breast pumps. Most of the electric breast pumps, such as Hollister's Purely Yours™ Kit, are

cumbersome and noisy, and thus very stressful for the nursing mother to use. In addition, while the nursing mother is using these breast pumps to collect milk, she cannot take care of the baby or do anything else.

[5] Even more, these pumps share the disadvantage that the mother's breast is exposed during use (lack of privacy) and that their motors are noisy. The breast pump vest described in U.S. Pat. No. 5,571,084, although covering most of the breast, is heavy and inconvenient to wear.

[6] Currently, there are no portable and user-friendly breast pumps capable of achieving private, quiet, easy, efficient, and effective breast-feeding.

SUMMARY OF THE INVENTION

[7] It is a purpose of this invention to provide a portable and hands-free breast pump system that facilitates hands-free, private, quiet, easy, efficient, and effective breast-pumping.

[8] It is another purpose of this invention to allow a nursing mother to collect milk via a breast pump hidden from view beneath clothing.

[9] It is another purpose of this invention to allow a nursing mother to collect milk via a breast pump while nursing a baby or doing something else at the same time.

[10] It is another purpose of this invention to provide a breast pump that has very few parts, and is easy to assemble and clean.

[11] It is another purpose of this invention to provide a breast pump that is cost-effective and easy to transport.

[12] It is another purpose of this invention to provide a breast pump with a vacuum chamber which also functions as a part of the vacuum mechanism.

[13] It is still another purpose of this invention to reduce the contamination of the milk during the processing, such as collection and storage, by a breast pump system.

[14] It is still another purpose of this invention to accurately emulate the suckling action of a baby when breast-feeding so as to facilitate the numerous benefits of breast-feeding to the mother and to the baby.

BRIEF DESCRIPTION OF THE DRAWINGS

[15] The foregoing and additional features and characteristics of the present invention will become more apparent from the following detailed description considered with reference to the accompanying drawings in which like reference numerals designate like elements and wherein:

Figure 1A is a perspective view showing the front side of the breast pump according to a preferred embodiment of the invention; and Figure 1B is a perspective view showing the rear side of the breast pump according to the first embodiment of the invention.

Figure 2 is a rear view of a top housing cover of the breast pump according to the first embodiment of the invention shown in Figure 1.

Figure 3 is side view showing the breast pump according to a second embodiment of the invention.

Figure 4 shows the details of the slide button according to the second embodiment of the invention.

Figure 5 is an exploded view showing the breast pump of the first embodiment of the invention.

Figure 6 is an exploded view showing the breast pump of the second embodiment in conjunction with a one-way valve and a splint.

Figure 7 is an enlarged inset view of a positive connect pin of the breast pump according to the second embodiment of the present invention.

Figure 8A shows an adapter for connecting a positive contacting pin to an external power supply of the invention, while Figure 8B shows an example of a tethered drive configuration of the present invention.

Figure 9 is an enlarged inset view showing the connection between the external power supply of Figure 8A and a positive contacting pin.

Figures 10A and 10B show cross-sectional views of different embodiments of the flange of the invention.

Figures 11A-C show a rear-piston lever-arm system of the breast pump according to the second embodiment that communicates with the servomotor mechanism so as to move linearly.

Figure 12 shows a second embodiment of a rear-piston lever-arm system in conjunction with a servomotor mechanism of the breast pump according to the first embodiment.

Figure 13 show a third embodiment of the rear-piston lever-arm system in conjunction with another embodiment of the servomotor mechanism according to the invention.

Figure 14 is an exploded view showing the servomotor mechanism illustrated in Figure 13.

Figure 15 shows a second embodiment of the linear movement mechanism according to the present invention.

Figure 16 shows a third embodiment of the linear movement mechanism according to the present invention.

Figure 17 shows a one-way valve for use with the breast pump of the invention.

Figure 18A shows a splint for use with the breast pump of the invention, while Figure 18B shows an outer sleeve according to the present invention.

Figures 19A and 19B show a collection bag for use with the breast pump of the invention.

Figures 20A and 20B show cross-sectional views of the pump along with splint and the bag bent to conform with the contour of the user's breast and body.

Figures 21A-C depict the actual suckling profiles of a seven-month-old baby boy.

Figures 22A and 22 B depict the suckling profiles of the present invention.

Figure 23 depict the suckling profiles of a conventional, mass-retail double pump set.

Figures 24A and 24B depict the suckling profiles of a conventional high-end double pump set.

Figures 25A and 25B depict the suckling profiles of a conventional battery powered portable pump.

Figure 26 shows a carrying case for a breast pump system according to the present invention.

Figure 27 is an exploded view showing the breast pump of the prior art (U.S. Pat. No. 6,090,065).

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[16] With reference to the figures, like reference characters will be used to indicate like elements throughout the several embodiments and views thereof. In particular, referring to Figures 1A and 1B, the breast pump 10 of the invention is embodied as a volume-displacement-type pump. Figure 1A is a perspective view of a preferred embodiment of the present invention showing the front side of the breast pump 10 with a dome-shaped housing shell 12. The housing shell 12 gives a natural appearance of the shape of a breast when the pump 10 is concealed underneath the user's clothing. Figure 1B is a perspective view showing the rear side of the breast pump 10.

[17] The pumping action generated by the breast pump 10 depends upon a cycle rate and a vacuum level which are controlled via an adjusting means 14. In one implementation, a user may use one finger to slide button 16 in an axial direction along the groove 18 so as to adjust the vacuum level (or range). Figure 2 depicts the open top housing cover 12a of breast pump showing the rear side of the slide button 16 shown in Figure 1.

[18] In a second embodiment shown in Figure 3, the slide button 16 is configured to slide in a circumferential direction along the groove 18 so as to adjust the pumping action to continuously vary the vacuum level. A push button 20 is used to control the cycling rate by incrementally increasing the rate with each push of the button 20 up to the fastest cycling rate designed into the pump. A further push of the button 20 then rolls the increment back to the slowest cycling rate for a continuous loop operation. Figure 4 depicts that the slide button 16 is connected to an electrical contacting base

21 with an arm 16a so as to slide the electrical contacting base 21 and vary the vacuum level.

[19] Referring to Figure 5, each breast pump 10 includes a housing shell 12, a central deck 22 with a servomotor mechanism 24 integrated therewith, and a straw-hat shaped breast "flange" 30 having a flange top 35. The servomotor mechanism 24 is a servomotor mechanism powered by at least one power source 26, such as two AA batteries. The central deck 22 includes a pump seat 28 for receiving the servomotor mechanism 24, two battery seats 32, 32' for receiving the batteries 26, and a tunnel 34 extending toward the housing shell 12 for guiding and receiving a piston cylinder 25 of a rear-piston lever-arm system 100 (See Figures 11A - 11C). A central deck cover 22' is used to fixedly encase the servomotor mechanism 24 and the two batteries 26 in the central deck 22.

[20] A second embodiment of the breast pump 10 as shown in Figure 6 is designed for a breast larger than that to which the first embodiment shown in Figure 5 is applied. Therefore, the central deck 22 of this second embodiment of the breast pump has a larger space that allows the two batteries 26 to be positioned parallel to one another. In addition, the central deck 22 of the second embodiment incorporates other parts for other parts, such as motor cover 40, rather than the fewer integral pieces as in the first embodiment.

[21] Specifically, the breast pump 10 of the second embodiment includes the housing shell 12, the cycling rate button 20, the vacuum level slide button 16, the central deck 22, the flange 30, the servomotor mechanism 24, and the batteries 26. In addition, the second embodiment includes a flange support 36 placed between the flange top 35 and the piston cylinder 25, a servomotor cover 40, a battery cover 38, a printed circuit assembly("PCA")/microprocessor 90, a PCA compartment 41, a DC power jack pin 42 (positive), a DC power jack tab 43 (negative), a battery contact 52, and a pair of screws 49 (Figure 6).

[22] The first embodiment of the breast pump uses traditional positive and negative contact plates with springs for receiving each battery. In the second embodiment of the breast pump, one positive contact pin 42 (Figure 7 inset view) is used instead. Both of these configurations would be known in the art for purposes of connecting to batteries held in small compartments.

[23] The second embodiment of the breast pump (Figure 6) has an additional flange support 36 designed to protect against any overshooting of the strokes towards the

flange top 35. The flange support 36 is fixed in place with the control deck 22, such as via a rotating lock mechanism, and then fitted around the exterior of the vacuum chamber 60 so as to have an interference fit at least around the base of the flange 30 (i.e., the 'bellows' area of the flange which creates the air displacement). The flange support 36 is an individual part of the unit assembly designed to be attached onto the flange 30. The flange support 36 not only holds the flange 30 in place during the pumping action (prevents over-pressure on the flange top 35) but also supports the vacuum chamber 60 from collapsing.

[24] Unlike most other breast pumps which have their pump mechanisms situated outside of their breast interface elements or even at a remote distance from the breast interface element, the servomotor mechanism 24 of the invention is integrated inside the pump 10. The servomotor mechanism 24 is designed to be lightweight (for example, 0.4 oz. making each entire pump 10 weigh only 2.4 oz. without batteries or 4.2 oz. with batteries) such that it sits directly inside the pump 10 and is supported by the housing without any additional components. The pump 10 in turn is exclusively supported by the bra and the negative pressure created between the breast and the flange 30 by the servomotor mechanism 24 and the lever arm system 100. In variations of the present invention, the servomotor mechanism 24 may be substituted with an external driving mechanism, such as an electrical motor or a tethered manual pumping device, to provide the negative pressure for pumping. The implementations of such substitute devices would have those devices modularized such that they could be substituted for one another and be easy to replace.

[25] In a third embodiment of the breast pump, power for the external servomotor mechanism 24 is located outside the housing. As shown in Figure 8A, an adapter 46 is used to connect a positive contacting pin to the external power supply 26 via a wire 26a. Figure 9 shows an inset view of how the adapter 46 is attached to the positive contacting pin 44. This embodiment has the advantage of a longer-lasting power supply that can be used, for example, in an institutional setting (i.e., a hospital) or even a home setting where a more limited range of mobility is acceptable or even desired.

[26] Alternatively, as shown in Figure 8B, the servomotor mechanism 24 may be replaced by a servomechanism 24' that may be just a mechanical or pneumatic linkage 101 connected to the lever arm 21 for implementing the pumping action of the vacuum chamber 60. The linkage 101 is connected to a remote control 103 that acts as the user's control for pumping via a linkage element 103. For example, in a

mechanical implementation, the linkage element 103 is a wire in a sleeve similar to that used in bicycle handbrake controls, while the control 103 is a hand- or foot-pedal that the user manipulates to move the lever arm 21 in the pump 10. Alternatively, in a pneumatic implementation, the linkage element 103 is a flexible pipe that feeds air or fluid into the linkage 101. The control 102 is also a hand- or foot-pedal that controls the flow of control air/fluid to the linkage 101 to then operate the pumping motion of the lever arm 21. The specific details for implementing either of the above-discussed alternative embodiments would be within the knowledge of those skilled in the art.

[27] Various components of the system are formed from resiliently plastic or other resin-type materials to accomplish various purposes. For example, in order that the splint 110 be flexible so as to conform with the shape of the user's breast, and so that the overall structure of the pump 10 is lightweight, including but not limited to the housing shell 12, the housing cover 12a, the lever arm 21 and the central deck 22, these various parts are formed from plastic. Other components in the system would be formed from materials appropriate to their function as would be understood by those skilled in the art. Other materials for the various components may also be used as would be known in the art so long as the selection of such materials is not inconsistent with the structure, operation and purpose of each such component and of the present invention as a whole.

[28] In the general operation and use of the present invention, as shown in Figures 20B, the pump 10 contacts the breast only with the breast flange 30, and the dome-shaped housing shell 12 does not contact the breast. A vacuum chamber 60 is defined between the breast flange 30 and the breast, and is completely isolated from the working components of the breast pump 10; the servomotor mechanism 24 is only in contact with the exterior surface of the breast flange 30. This allows the vacuum chamber 60 to be maintained at a negative air pressure while keeping the breast milk from contacting any other parts of the breast pump 10. The invention significantly reduces the number of parts that can come in contact with the milk so as to make the system easy to clean and sanitary. Further, the invention eliminates the potential of the milk co-mingling with any room air contaminants.

[29] The breast flange 30 is made from silicone or other soft elastic material for interfacing directly with a breast and situated on the breast with an inlet hole 50 (See Figures 5, 10A and 10B). The inlet hole 50 is designed for seating a nipple and areola in a vacuum chamber 60 which is defined between the breast pump 10 and the breast. The soft breast flange 30 allows the wearer to pump milk quickly and painlessly by

mimicking the baby's suckling movements when the servomotor mechanism 24 moves the flange 30, thereby triggering the female body's natural reaction to produce milk.

[30] A health benefit for the user or mother derived from the invention is that, as the nerves in the nipple and areola are stimulated by the action of the invention, the pituitary gland receives a signal to release prolactin and oxytocin into mother's blood stream. Prolactin relaxes the mother and stimulates the alveoli to produce more milk. Oxytocin causes the alveoli to contract and squeezes milk into the ducts. In contrast, the traditional hard funnel breast pumps (See Figure 27) simply pull the nipple into the rigid shaft to obtain milk. The hard shaft of the funnel is rigid and unyielding so that the suction concentrates on the nipple and creates a stinging sensation.

[31] Varying thicknesses in the silicone flange 30 helps the breast pump 10 to attach to the breast and be compressed towards the nipple by the rear-piston lever-arm system 100 shown in Figures 6, 11A-11C and 13. Pumping sessions become faster by using the soft flange 30 since the milk is being removed in a more natural way than with a traditional hard funnel. As such, the milk is also better extracted from the breast to avoid any decrease of milk production due to the remaining breast milk in the breast. The milk residuals reduce hormone stimulation for milking.

[32] As shown in Figure 10A, the flange 30 includes an outlet 62 through which the milk drawn from the breast flows out of the flange 30. As will be discussed further herein, the milk is then directed away from the breast pump 10 and stored. In a variation of the flange 30, as shown in Figure 10B, the outlet 62 is funnel-shaped so as to direct the milk flow out of the flange 30 and prevent the milk from flowing back towards the breast.

[33] In at least one of the embodiments of the invention, the nipple is well seated at the back of the breast pump 10 (inside the chamber 60), where only air is directly in contact with the nipple. When the nipple is placed inside the flange 30, the nipple rests within the vacuum chamber 60 with the surface of the surrounding area of the breast in contact with the surface of the flange 30. Air compression and suction is then controllably generated to occur by virtue of the cap-shaped piston cylinder 25 being cyclically pushed toward the breast so as to physically push on the top 35 of the flange 30 (see Figure 11A), and then released. The top 35 is formed with a relatively thin and soft side wall which has an accordion-style, contour-shape with alternating convex and concave edges formed on its surface for transferring and converting the contact pressure from the cap-shaped piston cylinder 25 to air compression and

suction on the nipple. In order to strengthen the top 35 and to help in uniformly compressing the vacuum chamber 60, the top 35 may be formed with a circular, reinforcing plate 35a fixedly imbedded therein. The reinforcing plate 35a is formed with a dome-shaped alignment stub or nipple 35b on a top center portion of the plate that aligns with the alignment dome 25b of the piston cylinder 25 so as to center the vacuum chamber 60 within the piston cylinder 25. This centered alignment is especially important in keeping the vacuum chamber 60 from floating or misaligning within the piston cylinder 25 during the pumping operation.

[34] In a first embodiment of the rear-piston lever-arm system 100, as shown in the exploded view of Figure 11A, the top of the piston cylinder 25 is shaped like a yo-yo or a doughnut without a hole. The lever arm 21 has a protrusion 21a on the top that contacts with the alignment dome 25b of the piston cylinder 25. The lever arm 21 is a projecting handle used to adjust or operate the piston cylinder 25. In particular, the-rear piston lever-arm system 100 mechanically communicates with the servomotor mechanism 24 so as to be activated by the mechanism and thereby pivotally move the lever arm 21 which then linearly moves the piston cylinder 25 along a line generally parallel with the centerline of the pump 10. Such a linear movement is depicted, wherein the start or "upstroke" position of the piston cylinder's linear movement is shown in Figure 11B.

[35] Figure 11C shows the lever arm 21 pivoted forward thereby linearly pushing the piston cylinder toward the flange 30 in a "downstroke" motion. The lever arm 21 pushes the protrusion 21a against the alignment dome 25b of the piston cylinder 25 to move the piston cylinder 25 toward the nipple. As mentioned, the nipple is insulated by the vacuum chamber 60 of the flange 30 from direct contact with other components such as the piston cylinder 25. The motion of the piston cylinder 25 is controlled by the level arm 21 which sets the default position of the piston cylinder 25 within the tunnel 34 such that the piston cylinder 25 rests away from the breast when the pump is not in action. During operation, in the "upstroke" motion, the lever arm 21 pivots back thereby releasing the piston cylinder 25 and the top 35 of the flange 30. The movement of the piston cylinder 25 is rather short, delicate and efficient in comparison with the pumping action of other breast pumps.

[36] The servomotor mechanism 24 activates the rear-piston lever-arm system 100 embodied in the lever arm 21 and the piston cylinder 25 to create the "downstroke" action inward (toward the breast). This downstroke action displaces the air in the flange 30 which exits via a one-way valve 140 (See Figure 17) that is inserted into the

outlet 62, thereby releasing the vacuum and actively stimulating the breast for further expression of milk. In addition, milk expressed by the breast flows out also through the one-way valve 140 and into a collection bag 300 (as will be explained further herein). The "upstroke" action not only moves the lever arm 21 and the piston cylinder 25 back into their start positions, but also generates the vacuum pressure against the breast. The upstroke and downstroke action of the system 100 alternatingly generates and releases the volume displacement vacuum in the chamber 60, and in particular in the flange 30. Among the features of this construction, the "upstroke" passively maintains or creates the vacuum via the vacuum chamber 60 of the flange 30 elastically returning to its normal state, and not by any energy expended by the servomotor mechanism 24. However, in other embodiments, the protrusion 21a may be linked to piston cylinder 25 and the top 35 so as to actively generate both the "upstroke" and "downstroke" motions of the vacuum chamber 60.

[37] In order to further simulate the suckling motion of an infant, the preferred suckling time to releasing time is , for example, approximately 3:1 in a cycle of a second. Namely, the suckling stage takes 3/4 second, and the releasing stage takes 1/4 second for each cycle. However, other cycling ratios may be used based on individual user preferences or breastfeeding requirements. The combination of the servomotor mechanism 24, the lever arm 21 and the piston cylinder 25 provides precision control of the air compression inside the chamber 60 which allows the precise controlling of the cycle rate and the vacuum level.

[38] In a second embodiment of the rear-piston lever-arm system 100, as shown in Figure 12, the lever arm 21 is formed to surround the side wall of the cylinder piston 25 and connect to the piston via a protrusion 25c formed on the side wall. When the lever arm 21 pivots, it rotatively pushes on the protrusion 25c (rather than push on the top 35 of the piston cylinder 25) thereby linearly moving the cylinder piston 25. Otherwise, the operation and effects of this second embodiment are the same as those of the first embodiment.

[39] As shown throughout the drawings, the present invention includes various embodiments for the servomotor mechanism 24. Figures 11A-C depict using a first embodiment of servomotor mechanism 24, while Figures 5 and 12 illustrate a second embodiment of the servomotor mechanism 24 that is used with the rear piston 25 and the modified lever arm 21. Figures 6 and 13 shows a third (preferred) embodiment of the servomotor mechanism 24 applied to a third variation of the lever arm 21.

[40] Figure 14 illustrates an exploded view of the third embodiment of the servomotor mechanism 24 so as to provide an example of the internal structure for a servomotor mechanism that would be applicable to the present invention. That embodiment is implemented via a structure that includes a potentiometer 201, an output gear 202, cluster gears 203-206, a DC motor 207, an arm 208, a motor housing 209, a screw 210, a rotary pot contact 211, a power contact 212, a gear train motor shaft 213, a front cover 214, a rear cover 215, and a pinion gear 216. Essentially, a servomotor mechanism for the present invention is implemented via mechanical or electromechanical system that pivotally moves a lever arm that then linearly moves a piston (in this case, a cylindrical piston 25) that then creates the pumping motion in the flange 30. The electric motor structure of the third embodiment (even of the first and second embodiments) as described above is one such system. Otherwise, given this disclosure of the invention, one of skill in the art should be able to devise other structures for a servomotor mechanism that would serve the purposes of the present invention and within the scope and intent of the claims.

[41] Figures 15 and 16 illustrate other systems for providing the above-mentioned linear movements for the cylindrical piston 25, and thus the pumping operation of the flange 30. For example, Figure 15 shows a lead screw mechanism with a rotary motor. The motor 240 oscillates at a cycle rate set by the user, and the vacuum level is controlled either by the user also, or by a microprocessor 90 (See Figure 6) according to a predetermined stroke/suckling profile. The rotation of a lead screw 250 pushes a plunger 260 so as to push the top 35 of the flange 30 toward the breast. The reverse rotation of the motor 240 rotates the lead screw 250 away from the breast so as to move the plunger 260 away from the breast. This allows the flange 30 to return to its natural state so as to create a negative pressure in the vacuum chamber 60.

[42] In Figure 16, the lead screw 250 is substituted with a rack and pinion 270, wherein the motor 240 again oscillates at a cycle rate set by the user, and the vacuum level is controlled either by the user also, or by a microprocessor 90 (See Figure 6) according to a predetermined stroke/suckling profile. The linear movement of the rack and pinion 270 pushes the plunger 260 pushing the top 35 of the flange 30 toward the breast. The reverse rotation of the motor 240 linearly moves the rack and pinion 270 away from the breast so as to move the plunger 260 away from the breast. Again, this allows the flange 30 to return to its natural state and create a negative pressure in the vacuum chamber 60.

[43] The one-way valve 140 shown in Figure 17 is used in conjunction with the outlet 62 of the flange 30. The valve is generally implemented as a one-piece element that is inserted into the outlet 62. Alternatively, the one-way valve may be constructed as an integral part of the flange 30. Its main function is to help maintain the vacuum in the chamber 60 during operation and to help draw the expressed milk away from the chamber 60 in the flange 30 so as to flow to a collection bag 300. However, other embodiments as those of skill in the art would understand may be accomplished used to implement the one-way valve 140.

[44] The splint 110 shown in Figure 18A guides the milk from the pump to a collection bag 300. The splint 110 has a cup 115 and a wave-form portion 117. The cup 115 and the wave-form portion 117 of the splint 110 are inserted into the neck of the collection bag 300, extending downward to ensure the neck walls do not collapse due to the pressure from the bra at the point where the collection bag exits at the bottom edge of the bra (as will be discussed further hereinbelow). The cup 115 is formed to pressure fit into the outlet 70 of the housing shell 12 when inserted using an upward sliding force. The cup 115 is intended to have at least a liquid-tight fit within the outlet 70 while guiding the milk out of in the chamber 60. Preferably, the cup 115 has an air-tight fit when positioned in the outlet 70. Such a pressure fit is intended to hold the bag 300 tightly to the cup 115 so as to avoid any milk spillage and any air contaminants therebetween. At the bottom of the cup 115, there are holes 116 through which the milk is intended to flow out of the cup 115 and onto the wave-form portion 117 of the splint 110. In a preferred embodiment, the cup 115 has an extruded rim which will contact the outer edge of the neck of a collection bag 300 so as to further seal the neck. The splint may be formed integrally with the bag by incorporating the extruded tube in the construction of the collection bags. In such a case, a hot-pressed tear-off line is set between the end of the splint and the end of the bag neck.

[45] Also, in another variation as shown in Figure 18B, an outer sleeve 111 is used to surround the neck 310 of the bag 300. The outer sleeve serves to protect the neck of the bag 300 as it extends from the pump to the body 305 of the bag 300. In this implementation, the neck 310 of the bag connects directly to the one-way valve 140 with the sleeve 111 surrounding the connection. In one form, the outer sleeve 111 is C-shaped in cross-section and also formed of a resiliently plastic material, which allows the sleeve to have some flexibility. Other cross-sectional shapes or configurations as would be understood by one of skill in the art to perform the same function as the C-shaped sleeve may be used.

[46] When viewed along its longitudinal axis, the wave-form portion 117 has a substantially sinusoidal contour, wherein the peaks and valleys of the sinusoidal contour form channels along which the milk flows downward to the collection bag 300. The use of the wave form portion 117 enjoys several benefits over using a conventional tube form. First, it avoids any obstruction caused by air bubbles stuck in a tube. Second, a splint having a wave-form portion is more easily bent than a tube so as to conform with the contour of the breast and the bra to in order to reach the collection bag or a bottle. Third, the wave-form portion is easier to clean and keep sanitized than a tube. Plastic tubing needs to be cleaned each use. If washed, it has to be hung to allow it to drain and dry thoroughly. In contrast, the wave-form splint dries out more easily than a tube form. Lastly, a wave-form structure confronts less air resistance than a tube when it is inserted into either a regular container or the collection bag 300. As will be discussed further hereinbelow, the sub-assembly of the one-way valve 140 and the splint 110 provides further support for the vacuum chamber 60 so as to prevent it from collapsing.

[47] As shown in Figures 19A and 19B, the collection bag 300 is made of plastic and substantially deflated so as to be maintained in a substantially vacuum state for receiving the splint 110 and the milk. In one embodiment, the collection bag 300 is made by hot-pressing two thin plastic sheets to form a square bag body 305 with sealed edges 301, 301', 302, 303, 303' and a neck 310 with sealed edges 311 and 311'. Meanwhile, each perforation line 312 is punched with holes for easily separating the bags with a slight force. At the same time, graduations are printed on the surface of one plastic sheet to indicate ounces or milliliters. The sequentially hot-pressed bags are rolled into one roll to reduce storage space and make them easy to transport. Alternatively, the bags may be made using other conventional methods for fabricating plastic bags known in the art. Also, the bags may be formed into other shapes or with additional features (i.e., resealable tops, adhesive surfaces) or using other different materials that have the same manufacturing, sanitary and liquid-proof characteristics.

[48] The sealed edges 311 and 311' of the neck extend into the bag body 305 so that the splint 110, including the cup 115, can be fully inserted inside the neck 310 to completely seal the splint inside the collection bag 300 thereby avoiding any milk spillage outside of the collection bag 300 during use. After the collection bag 300 is filled, a user can remove the splint 110 and roll the neck 310 so as to seal the bag. Further, adhesive tape or an adhesive surface formed on the neck 310 or the body 305 may be used to fixedly secure the rolled neck to the body of the bag.

[49] In another embodiment, an additional pair of sealed edges 306, 306' in a V-shape are hot-pressed next to the neck 310 to provide additional pressure on the neck after the neck has been pressed from the top-down to expel any residual milk in the neck of the bag. In addition, the sealed edges 311, 311' include lower extensions that promote the sealing of the neck 310 when the neck is pressed, so as to function as a simple, one-way valve to prevent milk spillage after the neck is press-sealed. The neck of the collection bag with the sealed edges in a V-shape effectively becomes spill-proof after being pressed shut. This structure of the bag 300 solves the common problem encountered by mothers that use conventional plastic collection bags when they pump for breast milk. The plastic collection bags of the prior art have not been able to provide any effective means for sealing closed so as to allow the mother to put down the bags without spilling.

[50] In a further embodiment of the invention, an additional tear notch 304 is hot-pressed at a corner of the bag so that a user may tear off the bag at the line to release the milk into another container to feed a baby. Additional tear notches are hot-pressed at the neck of the bag so that a user may alter the length of the neck by tearing off the bag at any one of the notches.

[51] In a preferred implementation, each bag 300 is a freezer grade bag made of FDA rated plastic and intended only for single use so as to keep the milk from contamination caused by any residuals of old milk and eliminate laborious cleaning. The preferred dimensions of the bag body are 4.25 inches by 3 inches, and the dimension of the neck is 5.0 inches in length. The capacity of each bag is 4-8 ounces, which is the average production amount for a nursing mother. However, other dimensions may be used as one of skill in the art would understand.

[52] Like breastfeeding, pumping is a learned skill. Most mothers are able to express only a few drops of milk when they first try a breast pump. Sometimes if mothers don't see milk immediately after beginning pumping, they start to pump harder or increase the suction with the mistaken idea that more pressure will "pull" the milk out. Doing this can cause discomfort and anxiety and actually discourage the let-down response. The invention is simple and easy to use so that the mother will intuitively become efficient at pumping without much practice and knowledge of how the breast works. In addition, many working mothers have no option but to pump in their offices or in a restroom. The privacy of using a conventional breast pump and the effect of the ambient air on the safety of the breast milk are at issue.

[53] As generally illustrated in Figures 20A and 20B, a user just inserts a one-way valve 140 (if made as a separate component) into the hole in the flange 30 as a cap on the splint/bag. Otherwise, if the valve 140 is manufactured to be an integral part of the flange 30, then the user just then proceeds with inserting the "splint" 110 (the wave-shape guiding means) into neck 310 of a disposable collection bag 300. The splint 110 serves to keep the neck 310 of the bag fluid-passable as it passes underneath the bottom edge of the bra. The sub-assembly is inserted into the outlet 70 of the housing 12 at the bottom of the flange 30 and the breast pump 10. With the sub-assembly in place, the cup 115 of the splint 110 fixedly connects to the outlet of the one-way valve 140.

[54] There is no need for the mother to undress herself in order to use the breast pump of the invention. In contrast, all the prior art requires a user to undress herself so as to use the pump.

[55] After inserting the splint 110 into the housing shell 12, the user can insert the entire pump 10 with the sub-assembly of the splint 110 and collection bag 300 underneath her clothing and against the her breast. The inlet hole 50 is positioned over the breast so as to cover and surround the nipple and thereby catch the expressed breast milk. Alternatively, the user can insert the pump 10 underneath the clothing first, then insert the sub-assembly of the splint 110 and the collection bag 300.

[56] In at least one embodiment, the insertion of the sub-assembly may be designed to act as an activation switch for the operation of the pump 10. Alternatively, either the slide button 16 or the push button 20 may be used as the activation switch, or a combination of the slide button 16 or the push button 20 in conjunction with the insertion of the sub-assembly. In an even further embodiment, the servomotor mechanism 24 may be activated by an initial movement of the switch 16 resulting from the insertion of the sub-assembly.

[57] When a collection bag is filled or when the user is finished using the pump 10, the splint 110 along with the bag 300 is removed from the pump 10, but with the one-way valve 140 left in place to keep the outlet 70 plugged thereby prevent any milk from dripping out of the outlet 70. Upon removal of the sub-assembly, in one embodiment, contact between the sub-assembly and a switch of the servomotor mechanism 24 is severed which turns off the pump 10. As mentioned, the vacuum chamber 60 is air-tight and isolated from outside air turbulence. Such a design not only maintains the privacy of the user but keeps the pump from contacting any outside air contaminants.

[58] With respect to the adjusting means 14 (See Figure1A, 1B and 3), the pumping rate is controlled via a microprocessor 90 which reads the user inputs from the switch slide button 16 and the push button 20 for the vacuum level and the cycling rate, respectively, so as to power the servomotor mechanism 24 accordingly. The servomotor mechanism 24 in turn activates the rear-piston lever-arm system 100 to create a stroke action toward and away from the breast in accordance with the desired settings. When the appropriate time has passed, the microprocessor 90 will reverse the motor system to allow the flange 30 to return to its natural state. As noted above, the stroke action is programmed to mimic the natural suck-hold-release-relax cycling of a nursing baby according to the age of the baby. The present invention applies mimicking the baby's suckling movements to trigger a nursing mother's natural reaction to produce milk. The pumping rate in the present invention may be controlled and/or programmed to mimic both the nutritive and non-nutritive suckling actions of the a baby, which have distinctly different cycling characteristics.

[59] According to a controlled study of a seven-month-old baby boy, the suck-hold-release-relax cycle starts with a series of non-nutritive sucks at low vacuum levels with a high suckling rate as the suckling pulses depicted in Figure 21A. The non-nutritive suckling rate typically is higher than nutritive suckling; in this example, the non-nutritive suckling exceeded 100 cycles/min while nutritive suckling was 30 - 60 cycles/min. The peak vacuum level of each suck increases until reaching a threshold for milk expression (the first and second nutritive sucks) then holds longer on the threshold (152 mmHg, in this case) than non-nutritive sucks with no plateau but mere a peak. The plateaus exhibit distinct flatness to hold the threshold vacuum level of each cycle. The holding period (in the plateau) is about 2-3 times of the relax period (drop from the plateau).

[60] Figure 21B shows a second example illustrating a steady-state post-ejection reflex action. Essentially, the baby has achieved a rhythm in suckling. Figure 21C illustrates the threshold vacuum level decreasing with the cycle rate increasing. In this example, the baby is finishing feeding and/or tiring. Overall, the study reveals that the holding and releasing timing of a baby suckling is not symmetrical. Depending on the baby, there may be rapid transitions between holding and releasing periods. In the present invention, the microprocessor 90 is programmed to mimic the natural suck-hold-release-relax cycling of a nursing baby along the lines of the results of the study.

[61] The microprocessor 90 may be programmed to suggest or control the vacuum level and the cycle rate. In one preferred embodiment, the microprocessor 90 is programmed with artificial intelligence so as to mimic the natural suck-hold-release-relax cycling of a nursing baby as discussed. Each stroke of the breast pump of the present invention has a definite holding period, which is about 2 - 3 times the relaxation period. As depicted in Figures 22A and 22B, the cycle profile is designed to be consistent regardless of the maximum vacuum level or the cycle rate settings.

[62] In particular, the suction level starts at a minimum at the beginning for a new nursing mother, and then some quick, short pulses at the start of the pumping to especially stimulate and imitate more closely the way a baby initiates breastfeeding. Once the milk is flowing freely, long steadier strokes are initiated so as to be effective and less tiring. Since each woman has a different comfort level, the level may then be gradually increased to what is comfortable for her. The pumping mechanism supports a cycle rate up to 80 cycles per minute, which is higher than most of the other portable breast pumps (25-60 cycles/minute). However, the preferred cycle rates range from 35-60 cycles per minute which balances the efficiency and the comfort of the user. The most preferred cycle rate (45 cycles/minute) takes less than one-quarter second to fully vacuum the chamber 60 and incurs minimum noise.

[63] This stroke action creates a vacuum on the order of 200 mmHg in the flange 30 while the one-way valve 140 seals off the opening. As shown in Figures 22A and 22B, when the maximum vacuum level is set at 136 mmHg, the matching cycle rate is 39 cycles/min. when the maximum vacuum level is set at 204 mmHg, the matching cycle rate is 36 cycles/min. Vacuum control circuitry is provided for allowing manual adjustment of the level of vacuum generated by the electric pump means. This is accomplished by controlling the stroke length of the servomotor mechanism. In another embodiment of the invention, some residual vacuum is programmed in the stroke profile.

[64] In another variation of the invention, a flow sensor may be connected with the adjusting means 14 to monitor the suckling results of the stroke actions.

[65] In contrast, the commercially available products simply operate under mathematics profiles rather than a natural baby suckling profile as the present invention. For example, the characteristics of one inexpensive, mass-produced double pump set allows manual control as well as residual vacuum as shown in Figure 23. However, it operates with excessive tissue stress due to its slow vacuum rise profile. In addition, it operates terribly inefficient at 7 cycles/minute, which takes 8 seconds to

reach the full vacuum level of 220 mmHg. Other conventional high-end double pump sets operate according to the profiles such as those shown in Figures 24A and 24B which are within appropriate vacuum levels (180-200 mmHg) at an appropriate cycle rate range of 47-53 cycles/ min. Nevertheless, such systems have no holding periods, but instead release their vacuums immediately upon reaching full vacuum. One popular battery powered portable pump as shown in Figures 25A and 25B operates with appropriate holding periods (1-1.4 seconds) and releasing periods (0.9 second), but dragging along a slowly increasing profile from vacuum levels 100 to 270 mmHg at inefficient cycle rate range of 27-29 cycles/ min. Such a profile yields long periods of stress on the breast to reach a excessively high vacuum level of 270 mmHg.

[66] Studies and experience have shown that young breastfed babies usually need to nurse every 2-3 hours, and that it is best to pump on the same schedule. The more the breasts are stimulated, the more milk is produced. A good time for many mothers to pump is about one hour after the baby's first morning feeding. Most women tend to have more milk earlier in the day. The length of time spent pumping varies with each woman and with each day. When pumping one side at a time, alternating breasts several times during expression is more stimulating and can result in a higher volume of milk. Pumping at one side of the breast and nursing on the other side has the advantage of using the body's natural response to let down the milk for the baby.

[67] The microprocessor 90 of the present invention may be programmed to suggest or control the timing for pumping. For example, using two pumps 10 simultaneously can cut the total pumping time in half. Double pumping may also result in better stimulation of prolactin due to its sense of balance provided to a nursing mother. In a double pump arrangement, the adjusting mechanism 14 of each pump may be linked by hardwire connection or by wireless link to coordinate or synchronize their strokes via the microprocessor 90.

[68] A commercial implementation of the portable breast pump system of the invention as shown would include two breast pumps 10, a pair of valves 140 and splints 110, and a roll of collection bags. All of those components would be stored in a soft sided black shoulder bag 400 (Figure 26) having two storage compartments, the upper compartment 403 includes a working surface for storage of the pumps on its breast pump holders 409, 409', the accessories, and complete instructions; and the lower compartment 405 includes heat-insulating side walls and at least one cooling element 407. The cooling element 407 is formed with concave seats for receiving collection bottles or bags. The closeness of the walls hold the collection bags next to

the cooling element surfaces. The portable breast pump system of the invention would weigh only about 2 lbs., rather than the 8 - 10 lbs. of other commercially available portable breast pump system, or even then 25-40 lbs. of those used in hospitals. The cooler is available from Rubbermaid® (Blue ICE Model No. 1056). The shoulder bag 400 may be manufactured by companies such as California Innovation® with synthetic fabric surfaces which are easy to wipe clean. The aggregate weight of the cooler and the shoulder bag is approximately 2.5 lbs.

[69] Parts of the pump such as the collection bags 300 are sterilized to FDA's hygienic standard for rubber articles before the first use, while other parts that come into contact with the mother's skin or the milk will need to be sterilized before first use. After initial use, only the flange 30, the valve 140 and the splint 110 need to be washed in warm, soapy water, rinsed with hot water and drained on a clean towel. However, periodic boiling for sterilization may be desirable, depending on the individual needs of the baby.

[70] In summary, the breast pump of the present invention provides several unique features. As noted above, various parts of the system are made of plastic materials so as to be lightweight, easy to clean/maintain and easily conform with the contour of the user's breast (Figures 20A and 20B). Working moms can thus easily pump their milk and save it for the babysitter or daycare. The breast pump of the invention has very few parts so as to be easily assembled and cleaned. The overall system of the present invention also results in a breast pump smaller than commercially available breast pumps such as Hollister's Purely Yours™ Kit, i.e. about 1/4 size of other portable (the shoulder bag actually is 70% smaller) and Medela's Pump in Style system.

[71] The principles, preferred embodiments and modes of operation of the present invention have been described in the foregoing specification. However, the invention which is intended to be protected is not limited to the particular embodiments disclosed. The embodiments described herein are illustrative rather than restrictive. Variations and changes may be made by others, and equivalents employed, without departing from the spirit of the present invention. Accordingly, it is expressly intended that all such variations, changes and equivalents which fall within the spirit and scope of the present invention as defined in the claims, be embraced thereby.

WHAT IS CLAIMED IS:

1. A portable, hands-free and visually friendly breast pump for facilitating breast-pumping, comprising:

a dome-shaped housing having a servomotor mechanism;

a hat-shaped flange having a chamber portion, a brim portion and an outlet, the chamber portion being formed so as to be placed over a nipple on a breast so as to define a chamber between the flange and the breast, and the brim portion being formed to surround the nipple and thereby form a suction seal therebetween; and

a one-way venting element formed to operatively communicate with the chamber so as to vent pumped milk from the chamber via the outlet, wherein

the servomotor mechanism is operatively connected to the chamber portion of the flange so as to induce a pumping motion onto the chamber portion and create vacuum in the chamber to thereby pump milk from the breast, the chamber being sealed via the vacuum except at the outlet, and

the housing, the flange and the venting element are connected into an integral device held against the breast and underneath clothing so as to keep the integral device hidden.

2. A portable, hands-free and visually friendly breast pump according to claim 1, further comprising a guiding means operatively connected to the one-way venting element for guiding the pumped milk into a container.

3. A portable, hands-free and visually friendly breast pump according to claim 1, wherein the outlet of the flange has the funnel shape.

4. A portable, hands-free and visually friendly breast pump according to claim 1, further comprising a flange support for preventing overshooting of strokes towards the flange, said flange support is fixed in place by fitting snuggly around a base of the flange.

5. A portable, hands-free and visually friendly breast pump according to claim 1, wherein the hat-shaped flange is integrally formed from an elastic material.

6. A portable, hands-free and visually friendly breast pump according to claim 1, wherein the dome-shaped housing further includes therein a portable power supply.

7. A portable, hands-free and visually friendly breast pump according to claim 1, wherein the servomotor mechanism of the housing flange is operatively connected to the chamber portion of the flange so as to impart an alternating stroking action onto the chamber portion, whereby the chamber portion generates an air displacement and vacuum alternating motion that mimics suckling movement of a baby.

8. A portable, hands-free and visually friendly breast pump according to claim 1, wherein the guide means includes a flexible guide element that extends from the integral device to a container and that is flexibly positionable so as to operatively connect the integral device to the container whereby the integral device, the guide element and the container are maintained against the breast and under the clothes.

9. A portable, hands-free and visually friendly breast pump system according to claim 8, wherein the guide element includes an elongated, flexible splint having a wave-form shape in a transverse direction of the splint.

10. A portable, hands-free and visually friendly breast pump system according to claim 9, wherein the guide means further include a cup head to be connected to the outlet, said cup head is connected with the wave-form splint with at least one hole at the bottom of the cup head for the milk to leak through to the wave-form splint.

11. A portable, hands-free and visually friendly breast pump system according to claim 10, wherein the cup fits snugly into the outlet under an upward sliding force so as to be air-tight while guiding the milk out of in the chamber.

12. A portable, hands-free and visually friendly breast pump system according to claim 2, wherein the container is a collection bag.

13. A portable, hands-free and visually friendly breast pump system according to claim 12, wherein the collection bag is formed from a thin, synthetic, leak-proof material.

14. A portable, hands-free and visually friendly breast pump system according to claim 12, wherein the container is a collection bag having a neck for snugly receiving the guiding means so as to allow leakproof flow of milk via the guiding means into the bag while maintaining operative contact with the guiding means.

15. A portable, hands-free and visually friendly breast pump system according to claim 14, wherein the neck of the collection bag has two sealed edges in a V-shape to make the neck spell-proof after being pressed.

16. A portable, hands-free and visually friendly breast pump system according to claim 11, wherein the container is a collection bag having a neck, and the cup has an extruded rim for covering on an edge of the neck thereby sealing the neck and going against pressure created by any clothing covering the breast pump.

17. A portable, hands-free and visually friendly breast pump system according to claim 12, wherein the collection bag is printed with a graduation scale to show the amount of milk collected in the bag.

18. A portable, hands-free and visually friendly breast pump according to claim 1, further comprising a control means for controlling operation of the servomotor mechanism.

19. A portable, hands-free and visually friendly breast pump according to claim 18, wherein the control means includes means for controlling at least one of a cycle rate and a vacuum level of the servomotor mechanism.

20. A portable, hands-free and visually friendly breast pump according to claim 19, wherein the control means includes at least one variable switch on the housing.

21. A portable, hands-free and visually friendly breast pump according to claim 18, wherein the control means includes a microprocessor.

22. A portable, hands-free and visually friendly breast pump according to claim 21, wherein the microprocessor controls the pump to mimic the natural suck-hold-release-relax cycling and force of a nursing baby.

23. A portable, hands-free and visually friendly breast pump according to claim 1, wherein the servomotor mechanism is formed from one of an electric motor and a tethered hand pump device.

24. A portable, hands-free and visually friendly breast pump according to claim 1, wherein the servomotor mechanism is located outside the housing.

25. A portable, hands-free and visually friendly breast pump according to claim 24, wherein the servomotor mechanism is connected to the housing with an adapter.

26. A portable, hands-free and visually friendly breast pump according to claim 1, wherein the servomotor mechanism includes an electric motor, a lever arm operatively connected to the electric motor, and a rear piston operatively positioned to move linearly by the lever arm so as to press on a top of the flange toward the breast thereby pressing the air out of the chamber to create the vacuum on withdrawal.

27. A collection bag for collecting and storing breast milk obtained through a portable breast pump system, comprising:

a collection chamber; and

a receiving neck connected to the collection chamber for receiving breast milk to be stored in the collection chamber.

28. A collection bag according to claim 27, wherein the collection bag is formed from a thin, synthetic, leak-proof material.

29. A collection bag according to claim 27, wherein the neck is formed for snugly receiving a guiding element through which breast milk flows to be collected.

30. A collection bag according to claim 27, wherein the neck is formed for self-sealing after the breast milk has been collected.

31. A collection bag according to claim 27, wherein the collection chamber is printed with a graduation scale to show the amount of milk collected in the bag.

32. A collection bag according to claim 27, wherein a plurality of collection bags are formed together in a roll adjacent one of the plurality of collection bags being formed with perforations therebetween so as to facilitate separation of individual collection bags.

33. A carrying case for transporting a portable breast pump system, comprising:

a first storage compartment having a flat horizontal panel therein so as to provide a portable working surface for a user to manipulate components of the breast pump system; and

a second storage compartment having insulated walls and a cooling element for storing containers of the collected breast milk.

34. A carrying case according to claim 33, wherein the second storage compartment has concave seats for receiving the containers.

35. A miniature servomotor mechanism for a portable breast pump system, comprising:

a pump element for generating a cyclical pumping motion;

a lever arm operatively connected to the pump element;

a piston operatively positioned to move linearly by the lever arm so as to impart an alternating stroking action via the lever arm; and

an elastic chamber portion of the portable breast pump system operatively connected to the piston, wherein the alternating stroking action of the piston generates a displacement and vacuum alternating motion in the chamber portion.

36. A miniature servomotor mechanism according to claim 35, wherein the pump element is formed from one of an electric motor and a tethered hand pump device.

37. A portable, hands-free and visually friendly breast pump according to claim 36, wherein the servomotor mechanism is located outside the housing.

38. A miniature servomotor mechanism according to claim 35, further comprising: a power supply including at least one battery.

39. A method for stimulating milk expression by mimicking a baby's suckling movements with a breast pump on a breast of a nursing mother to trigger the nursing mother's natural reaction to produce milk.

40. A method according to claim 39, wherein the baby's suckling movements include at least one non-nutritive suck and at least one nutritive suck.

41. A method according to claim 40, wherein the non-nutritive suck incurs at a vacuum level lower than a threshold suckling level of the nutritive suck.

42. A method according to claim 40, wherein the non-nutritive suck occurs at a cycle rate exceeding 60 cycles/min.

43. A method according to claim 41, wherein threshold vacuum level of the nutritive suck is 70-220 mmHg.

44. A method according to claim 41, wherein the threshold suckling level of the nutritive suck remains consistent for at least twice as long as a releasing time from the threshold vacuum level.

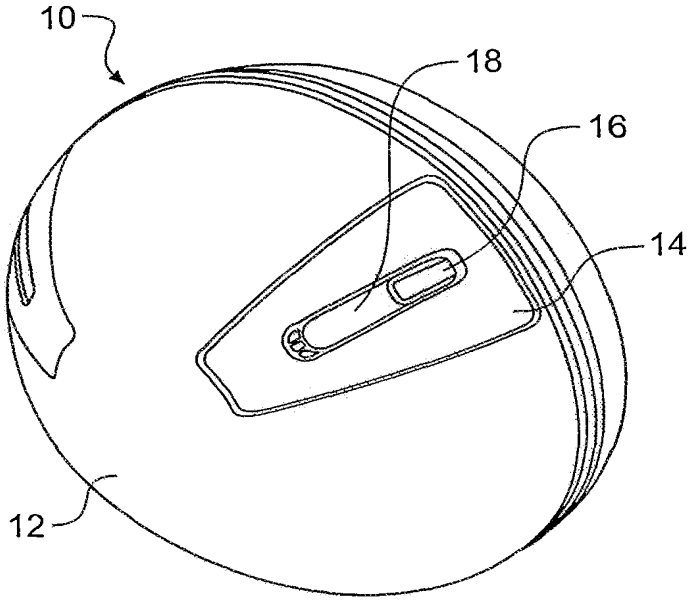

FIG. 1A

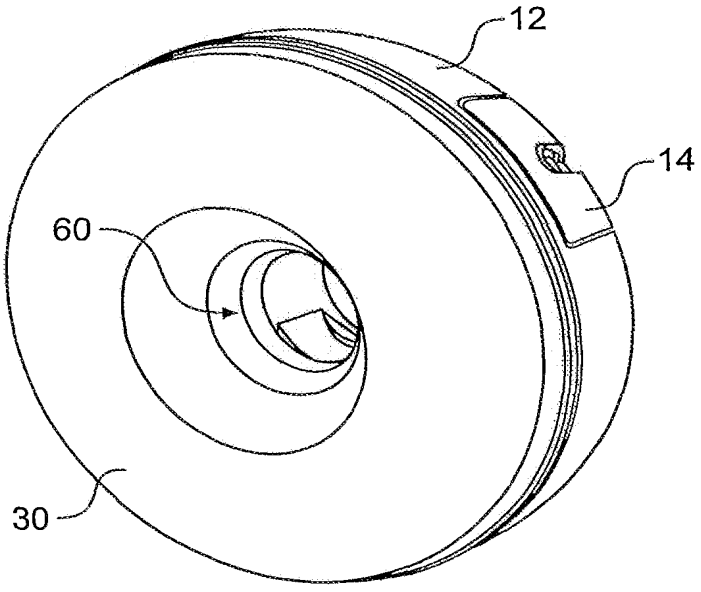

FIG. 1B

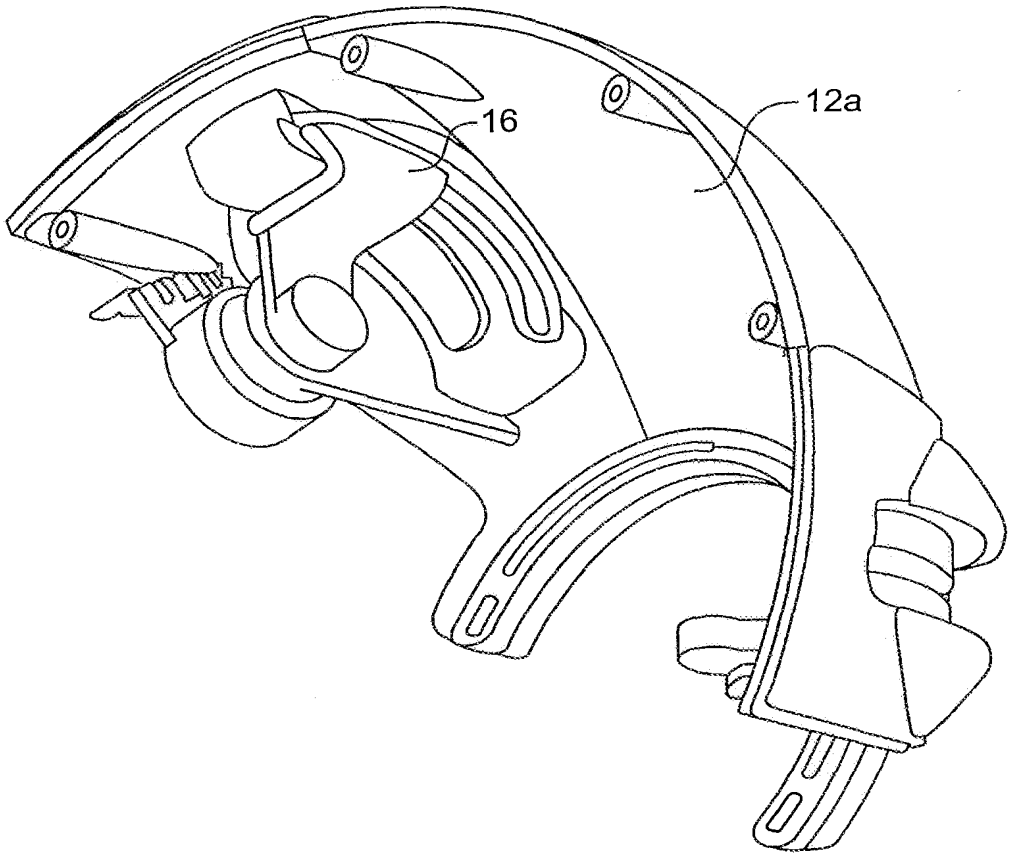

FIG. 2

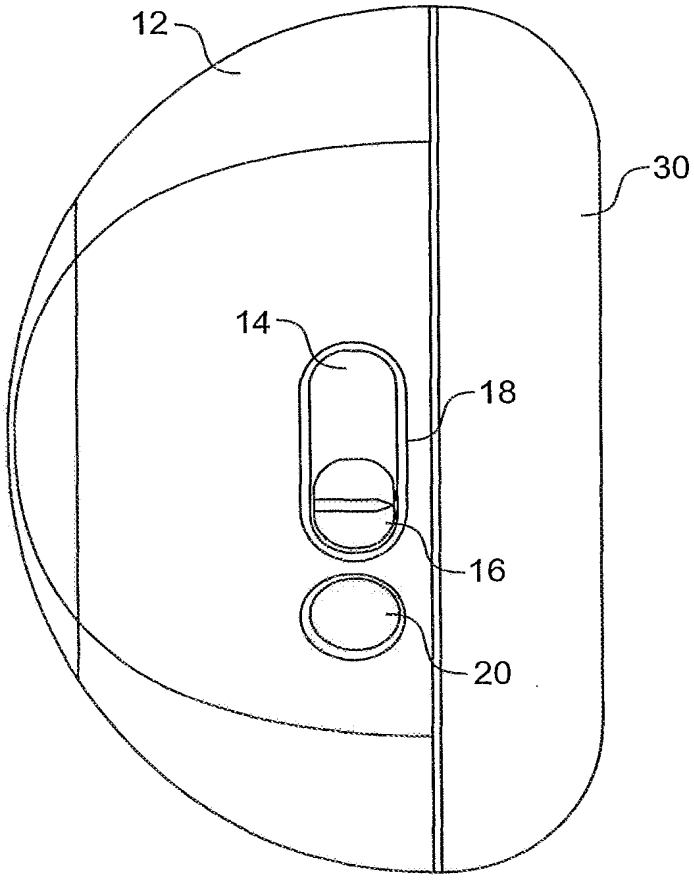

FIG. 3

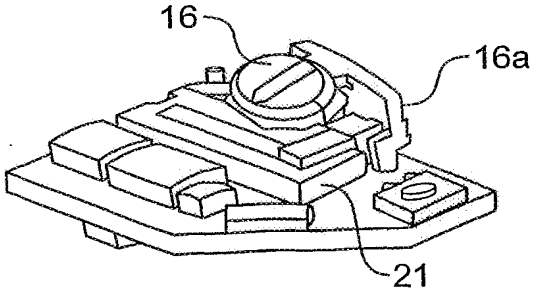

FIG. 4

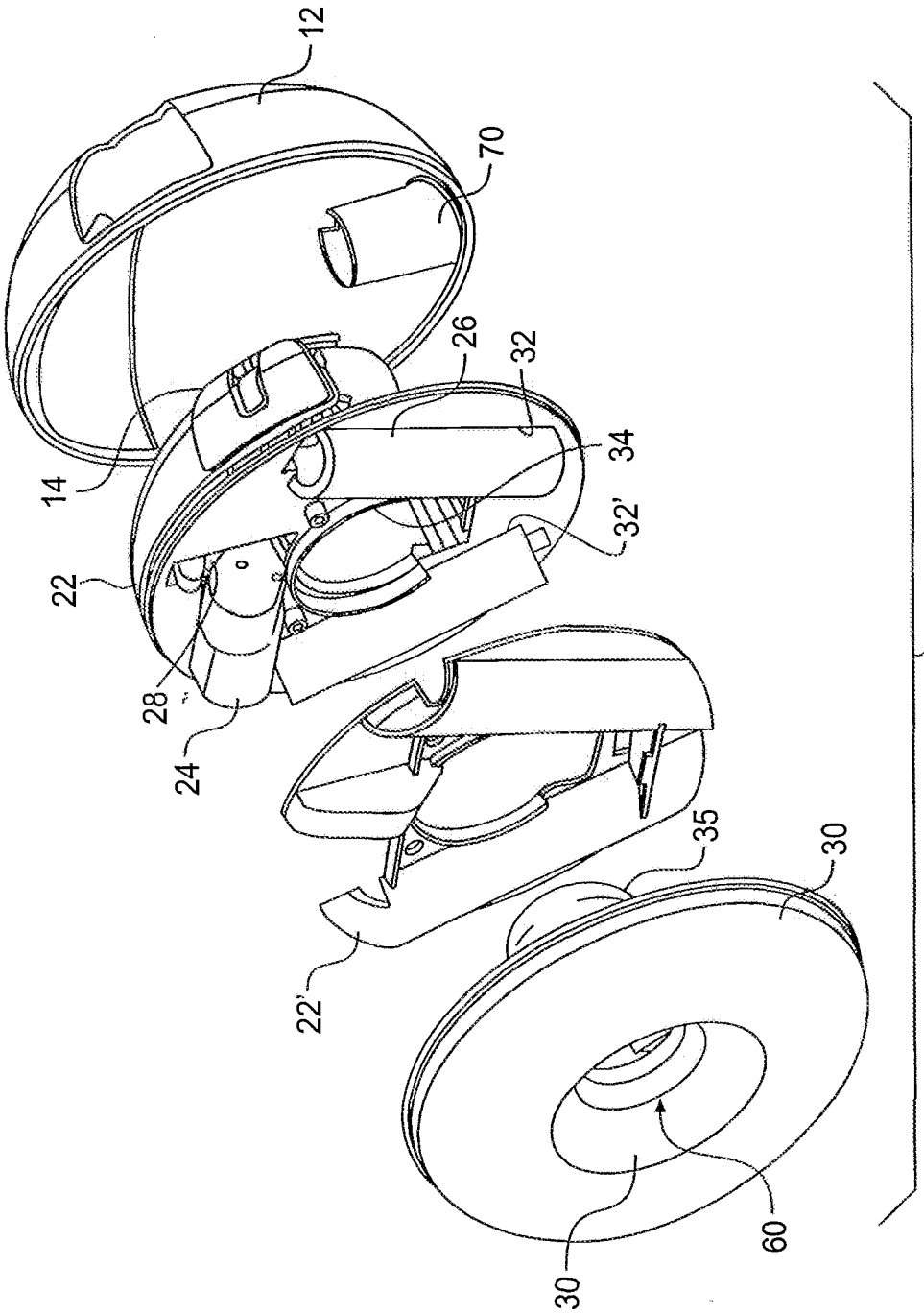

FIG. 5

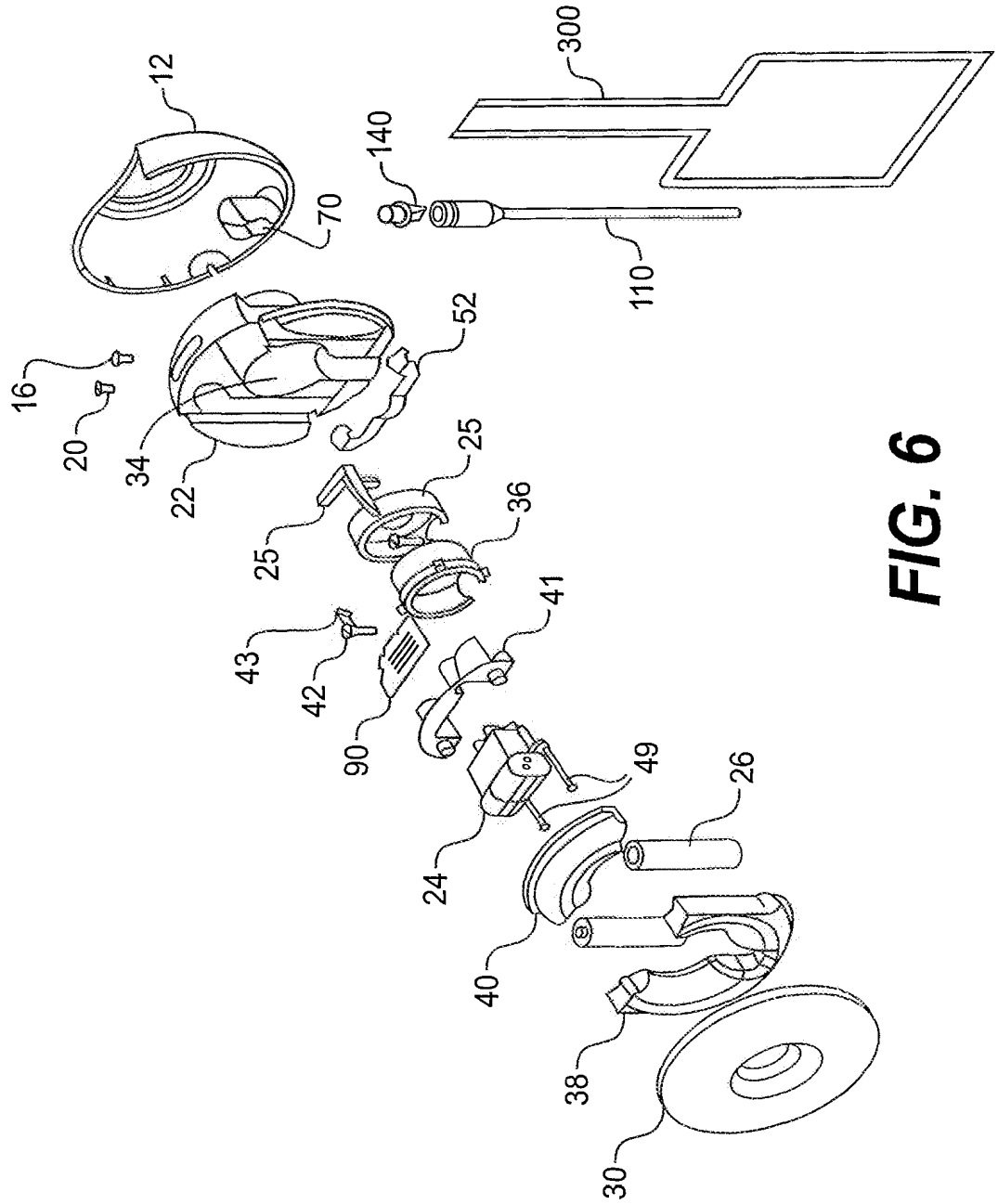

FIG. 6

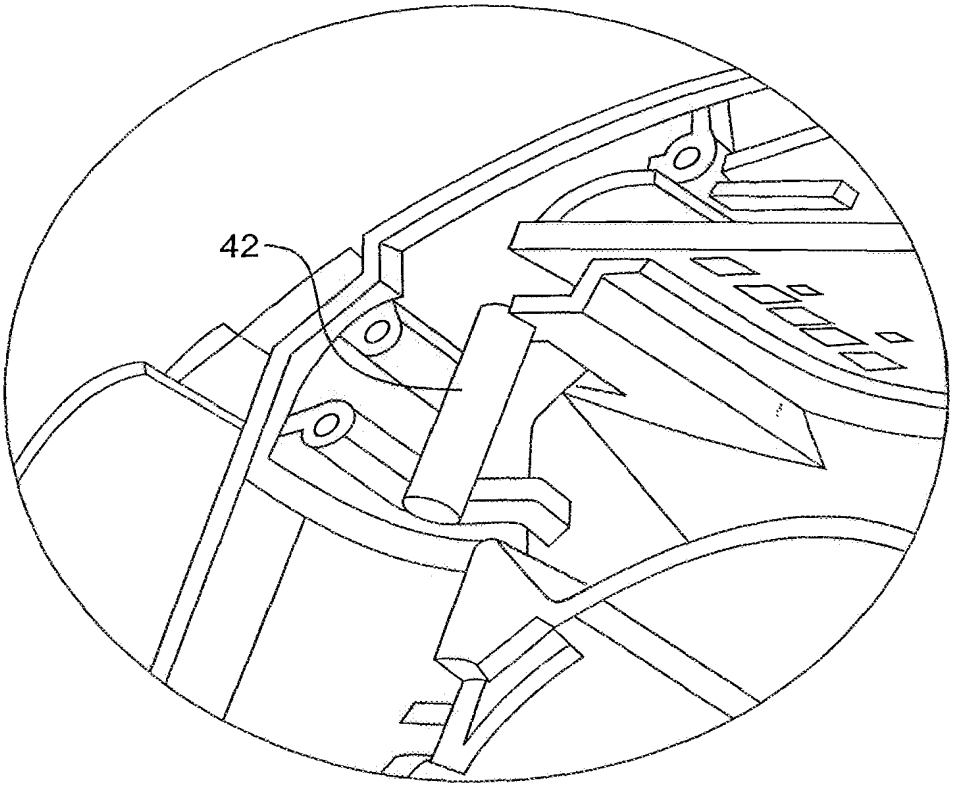

FIG. 7

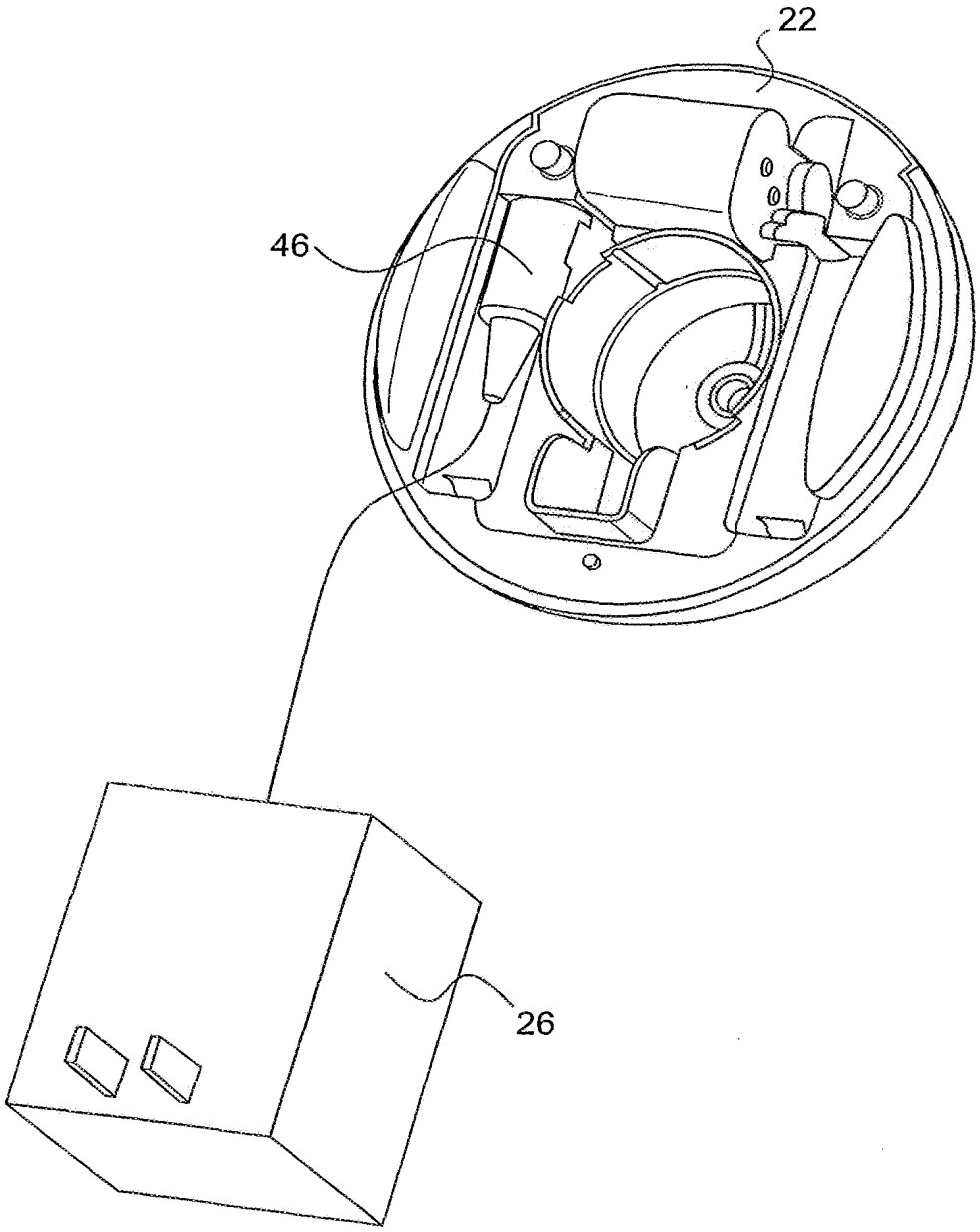

FIG. 8A

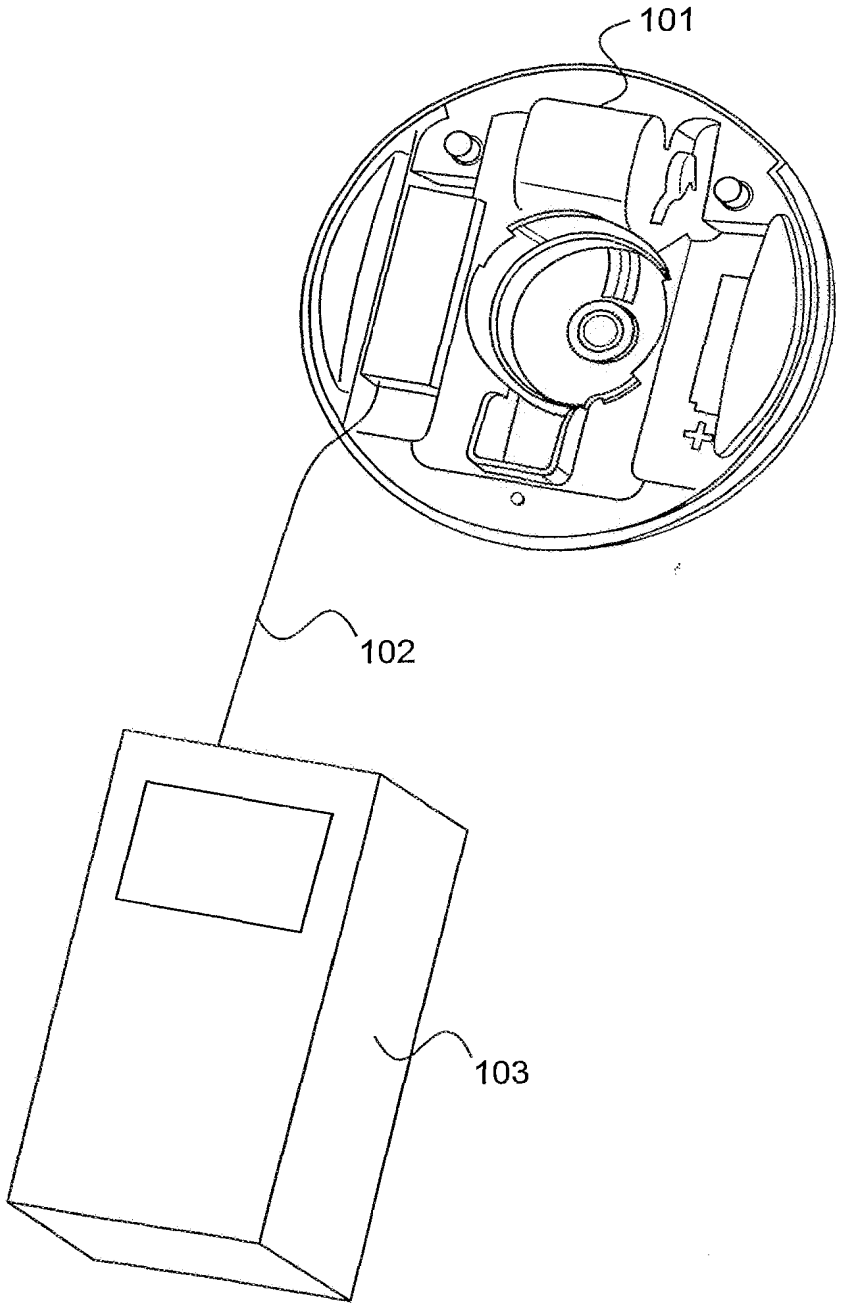

FIG. 8B

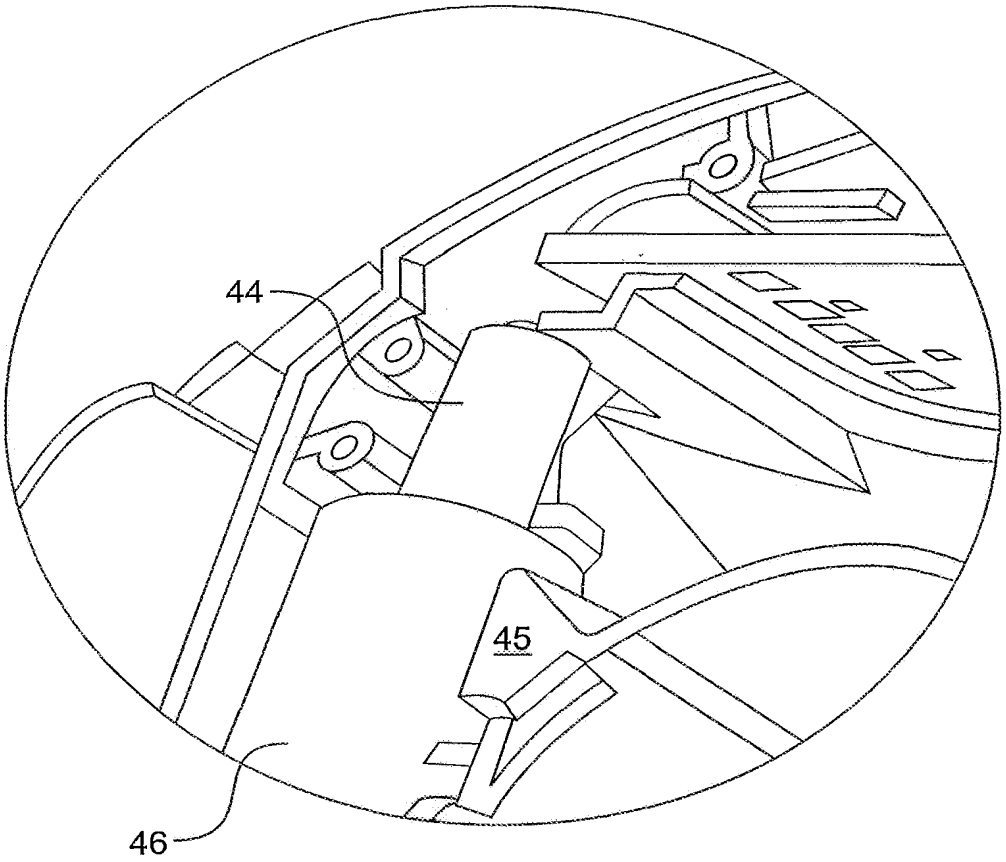

FIG. 9

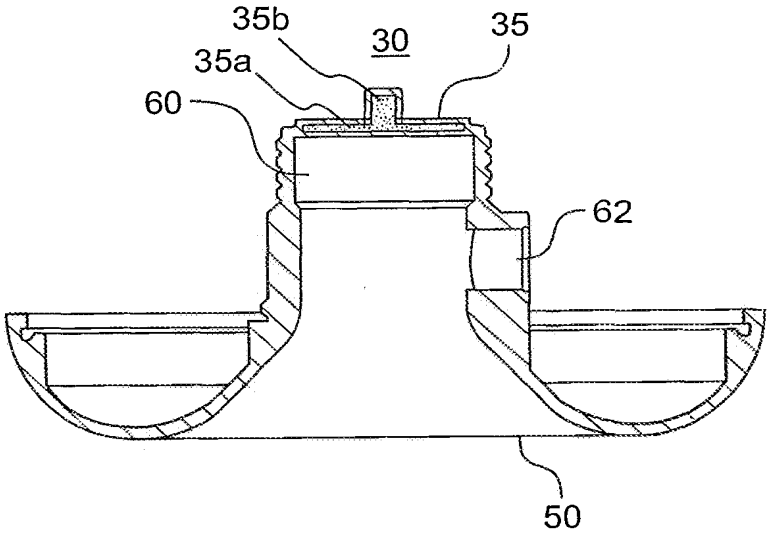

FIG. 10A

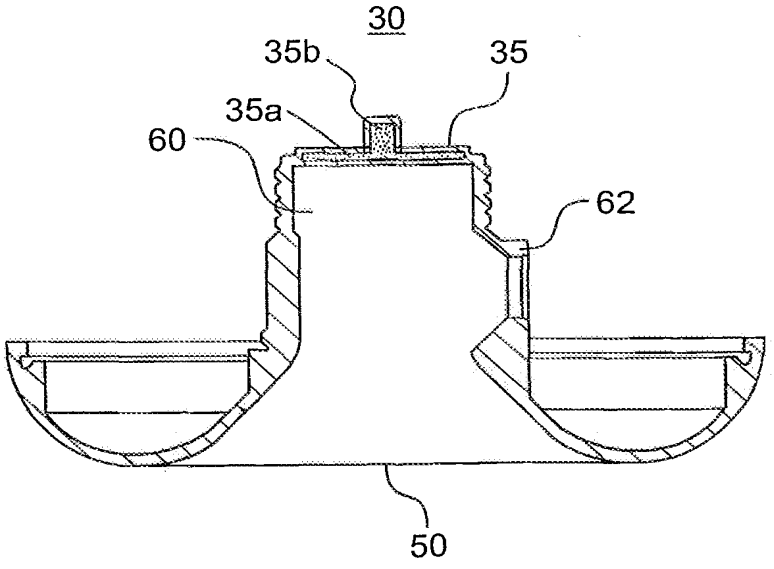

FIG. 10B

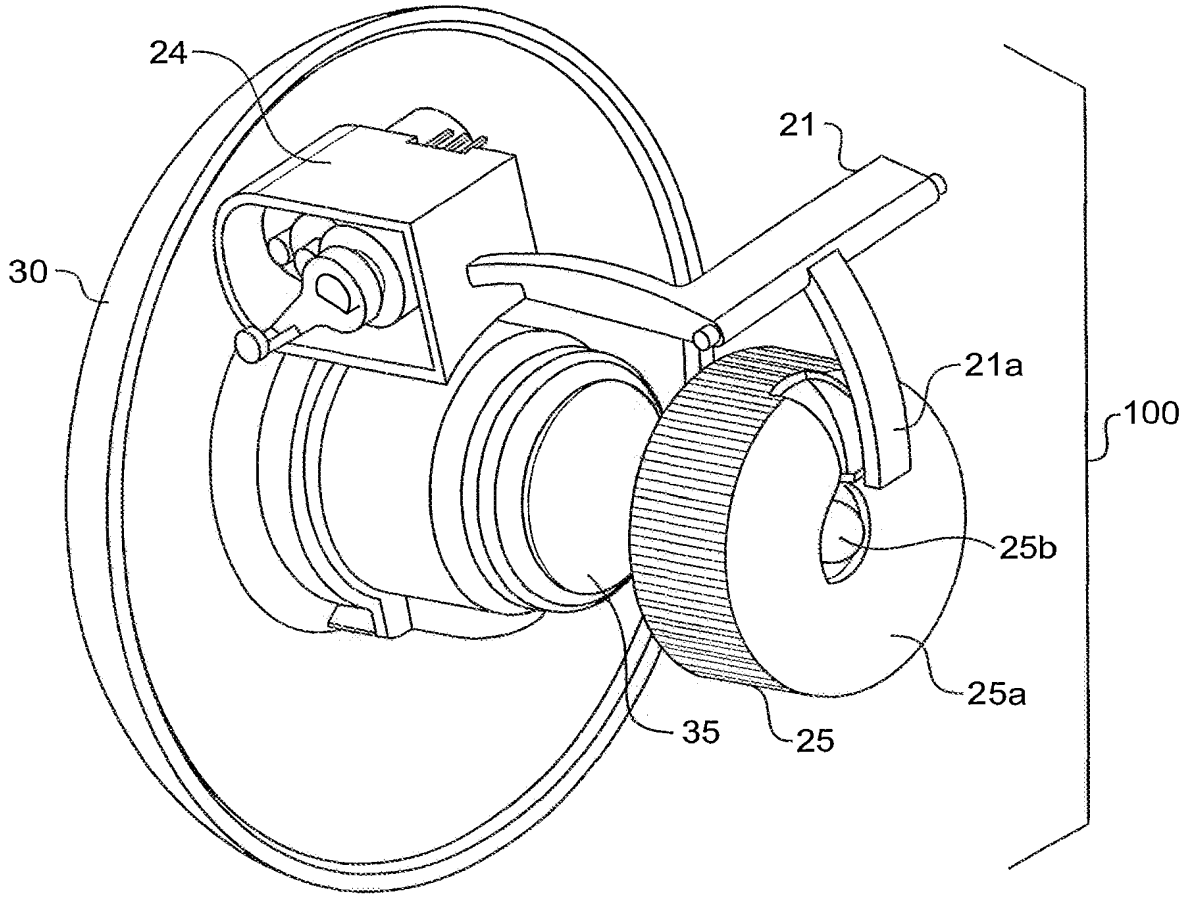

FIG. 11A

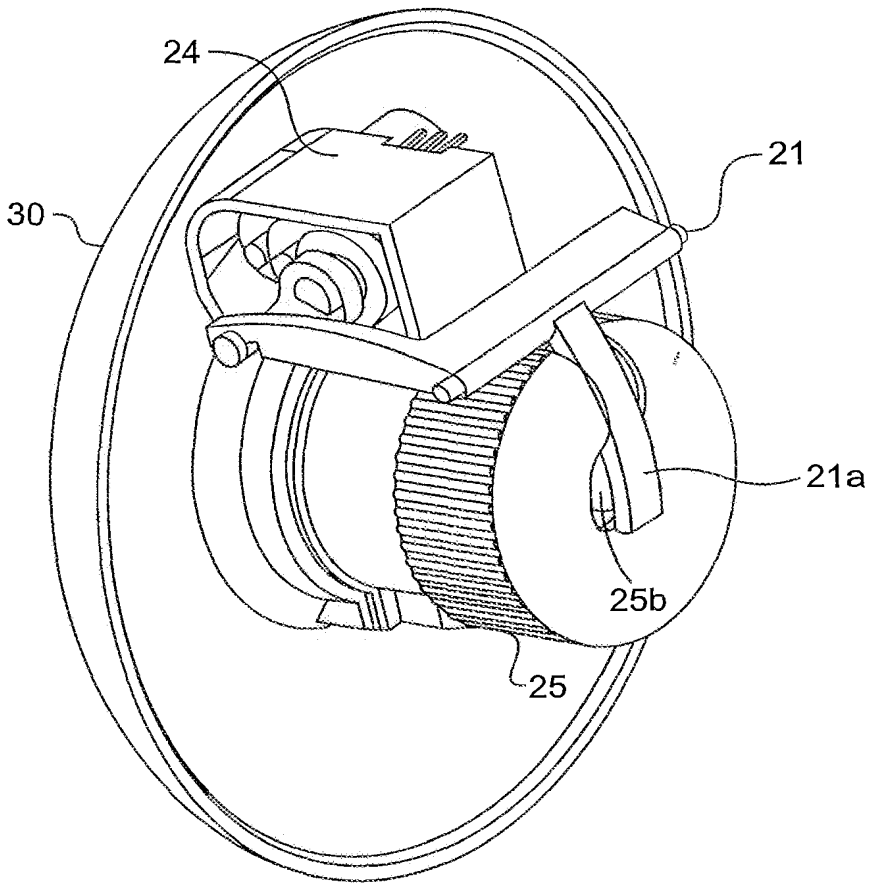

FIG. 11B

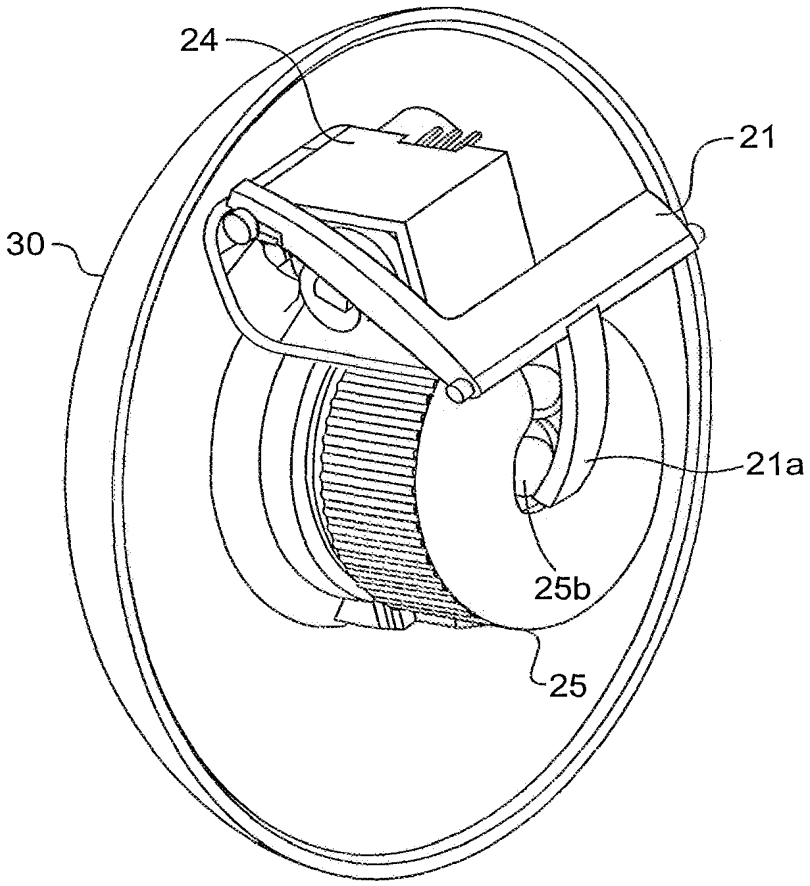

FIG. 11C

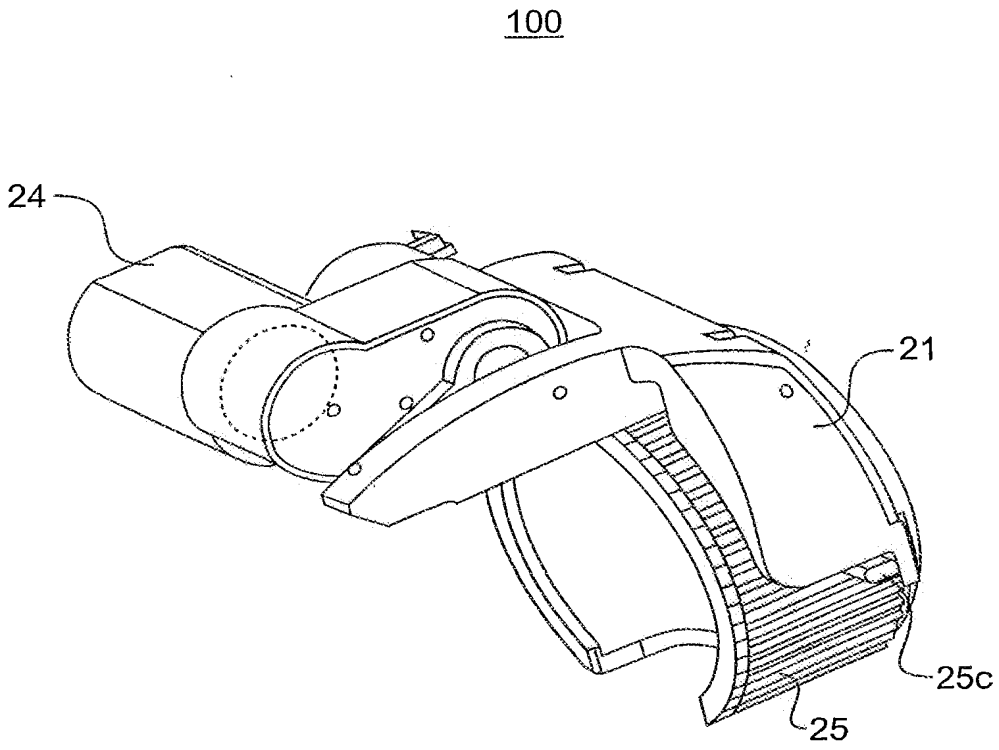

FIG. 12

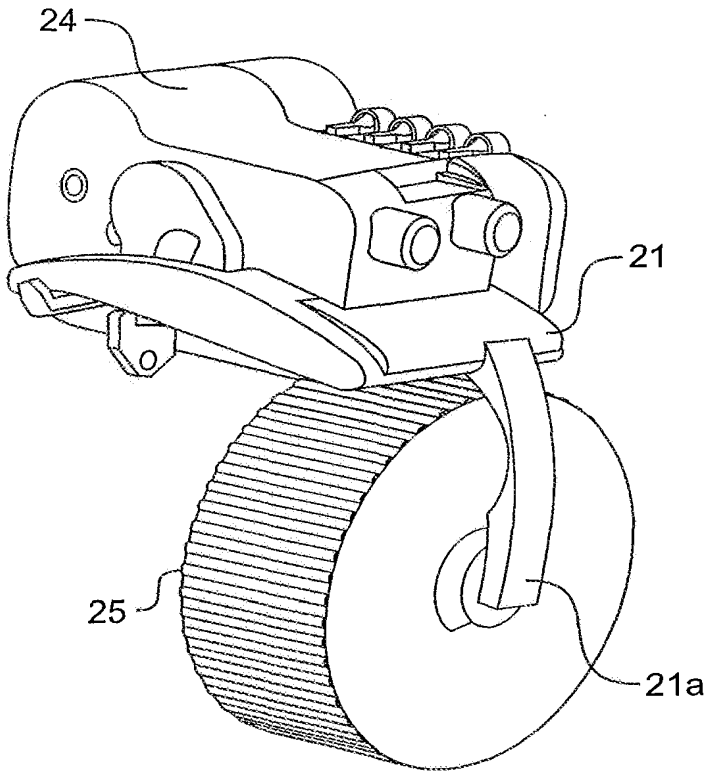

FIG. 13

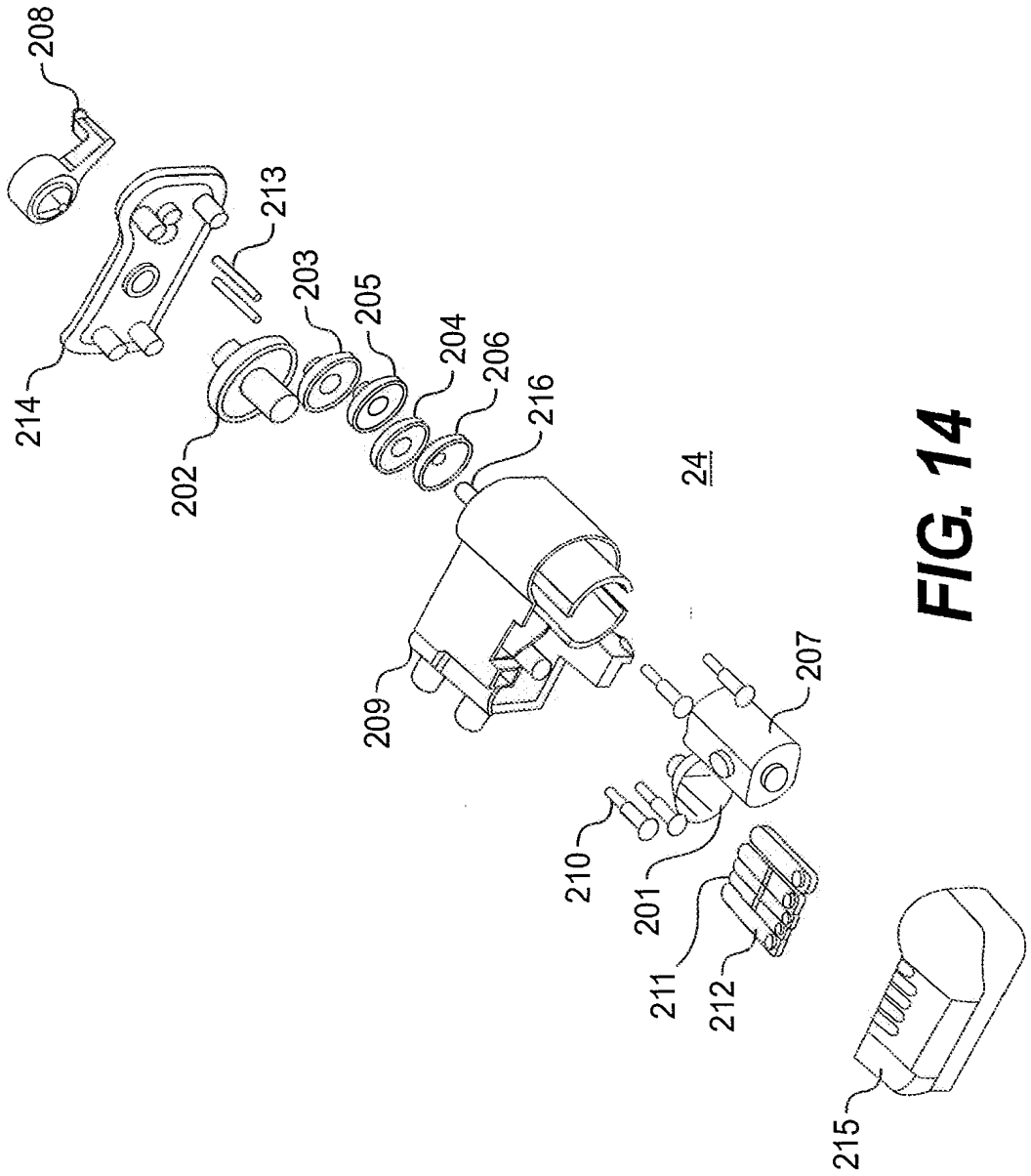
208
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FIG. 14

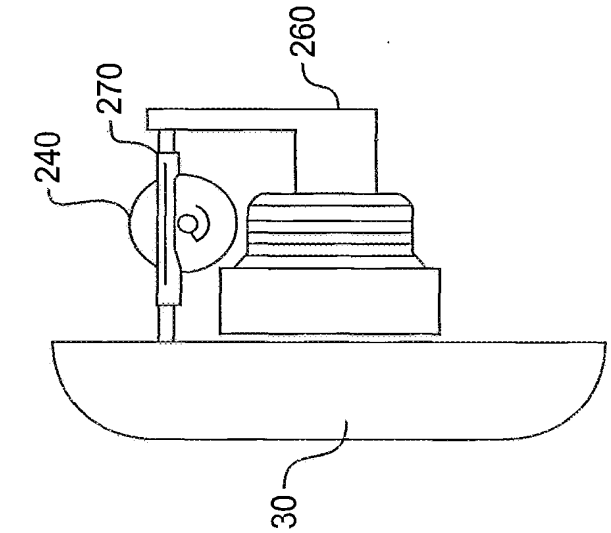


FIG. 16

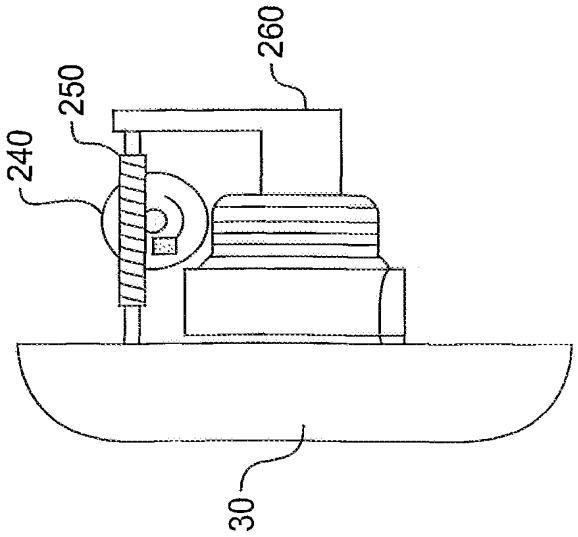


FIG. 15

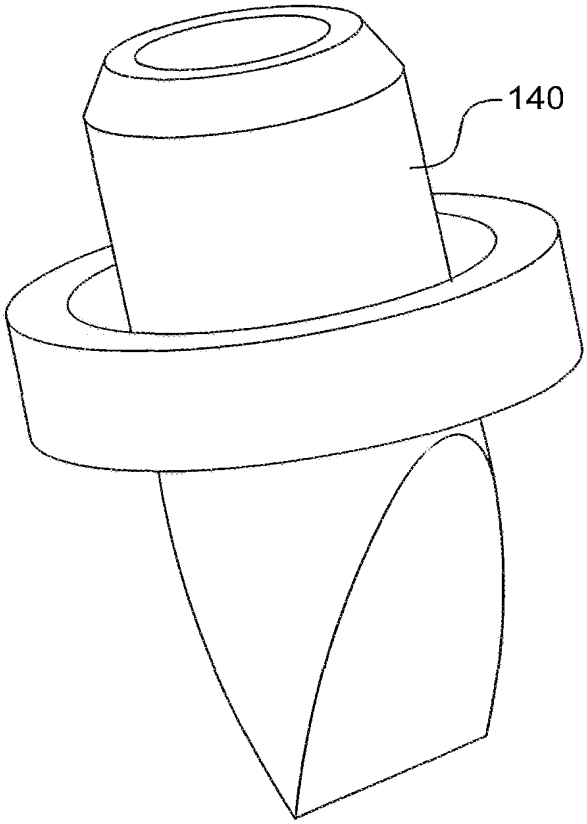


FIG. 17

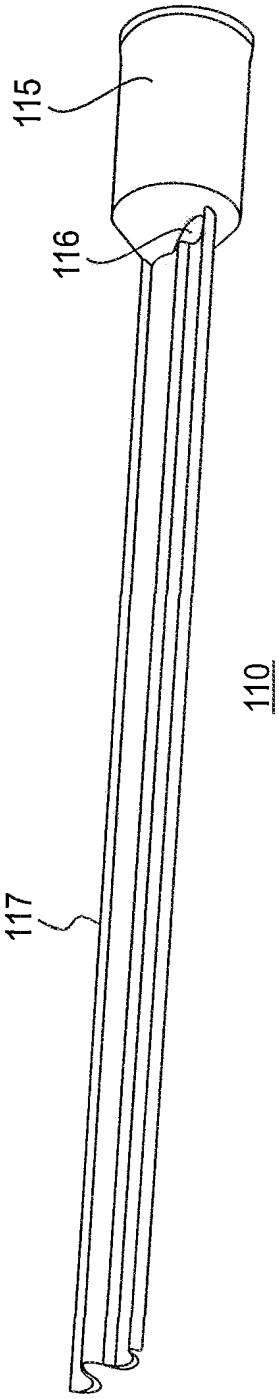


FIG. 18A

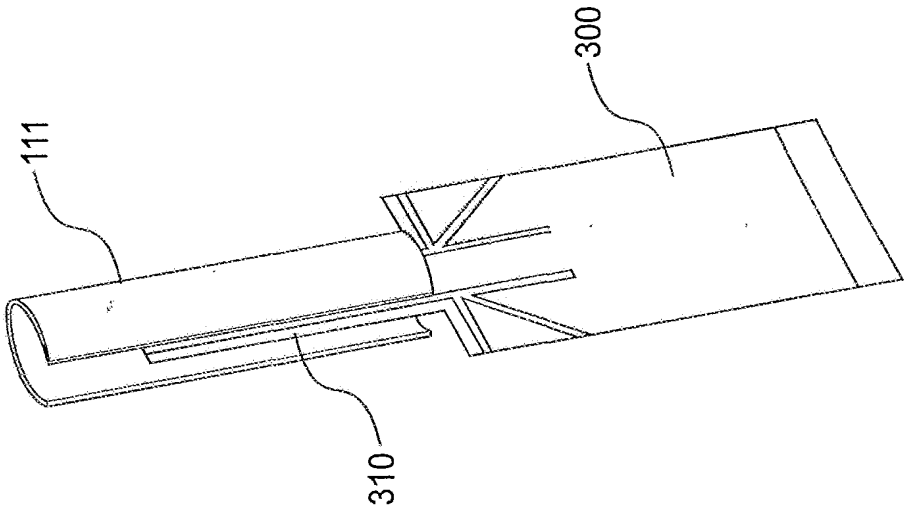


FIG. 18B

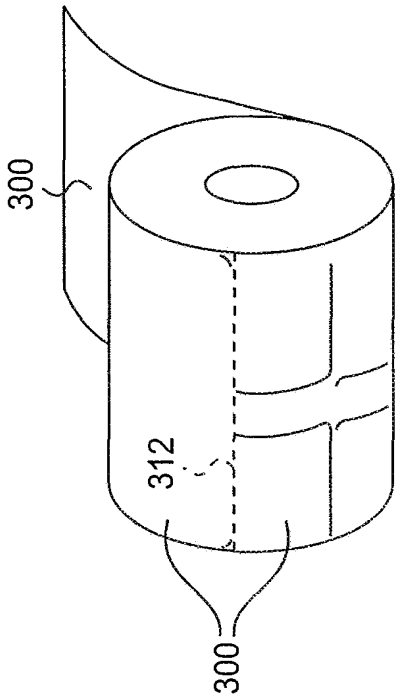


FIG. 19B

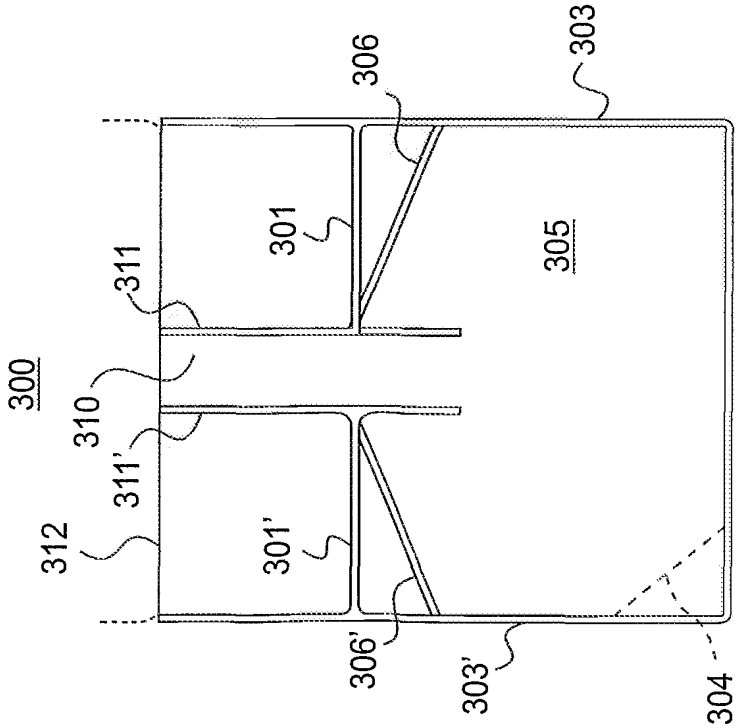


FIG. 19A

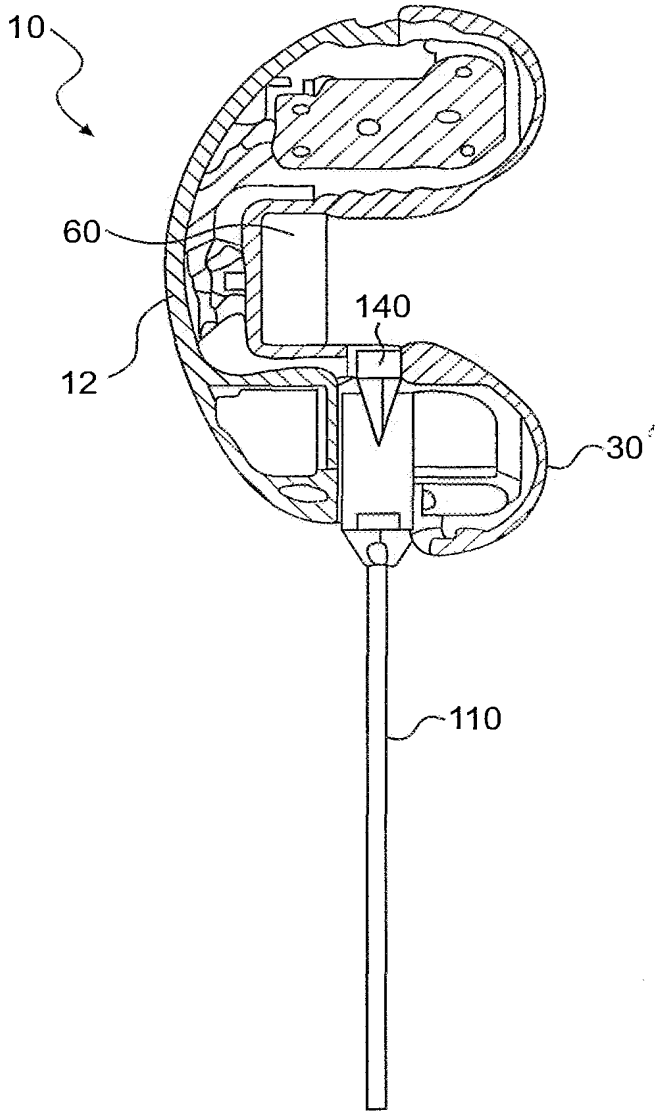


FIG. 20A

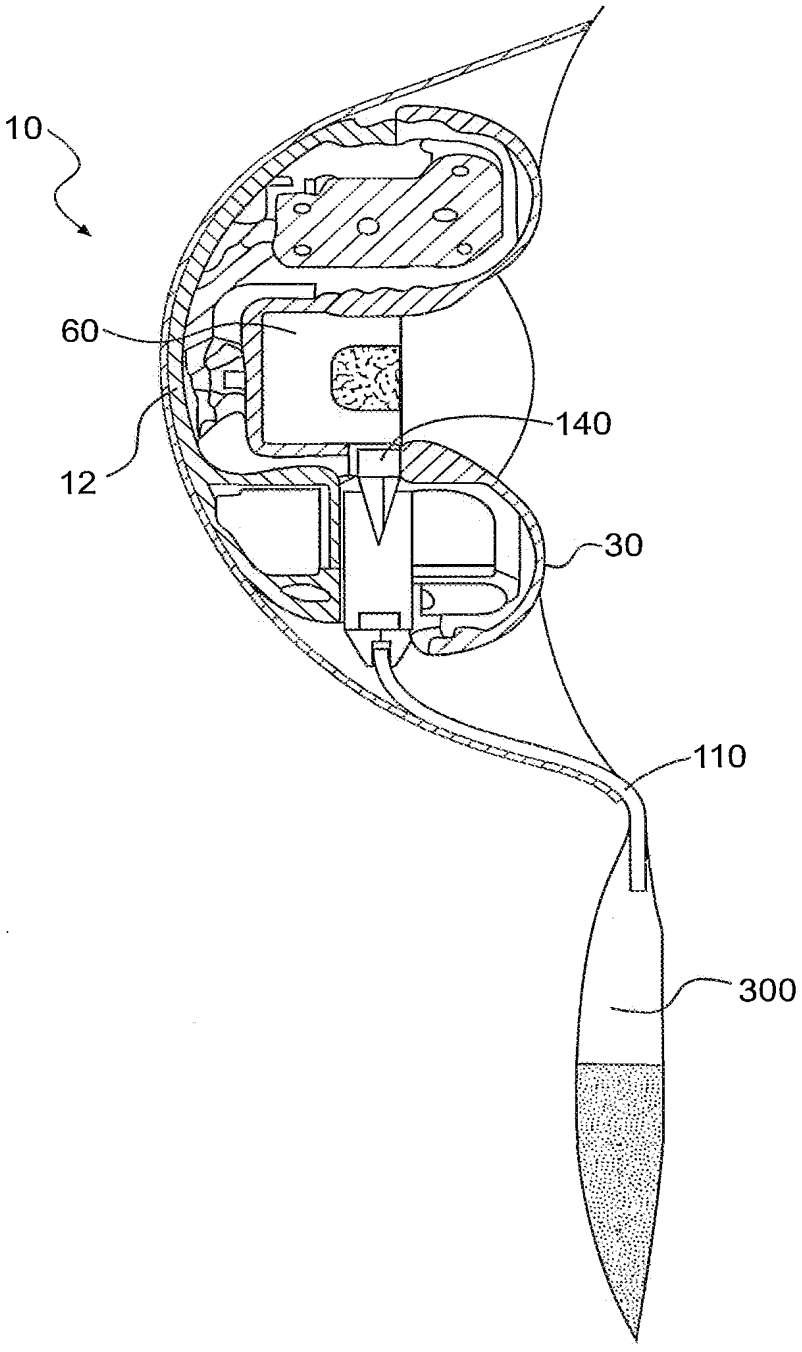


FIG. 20B

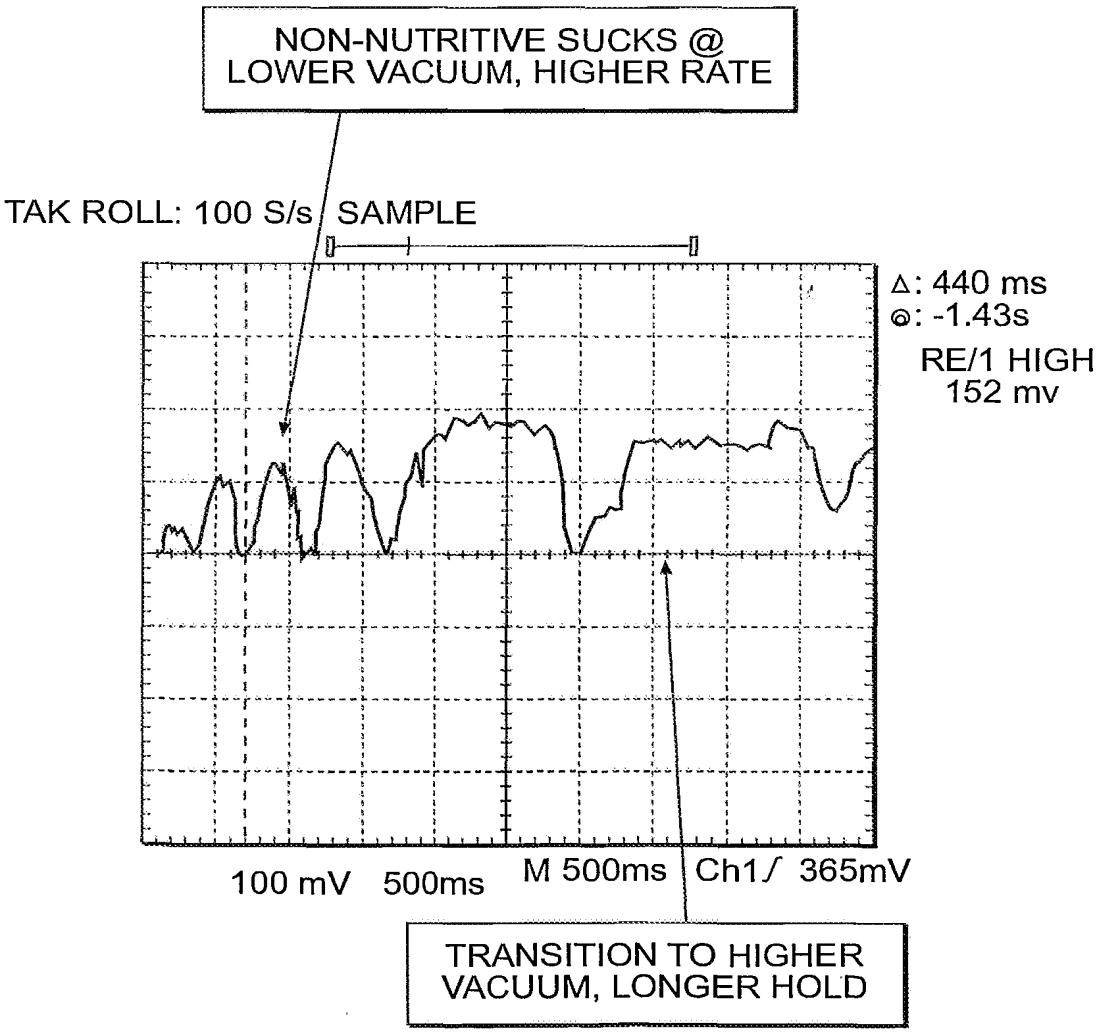

NON-NUTRITIVE SUCKS @ LOWER VACUUM, HIGHER RATE
TAK ROLL: 100 S/s SAMPLE
Δ: 440 ms
⊙: -1.43s
RE/1 HIGH 152 mv
100 mV 500ms
M 500ms Ch1 365mV
TRANSITION TO HIGHER VACUUM, LONGER HOLD

FIG. 21A

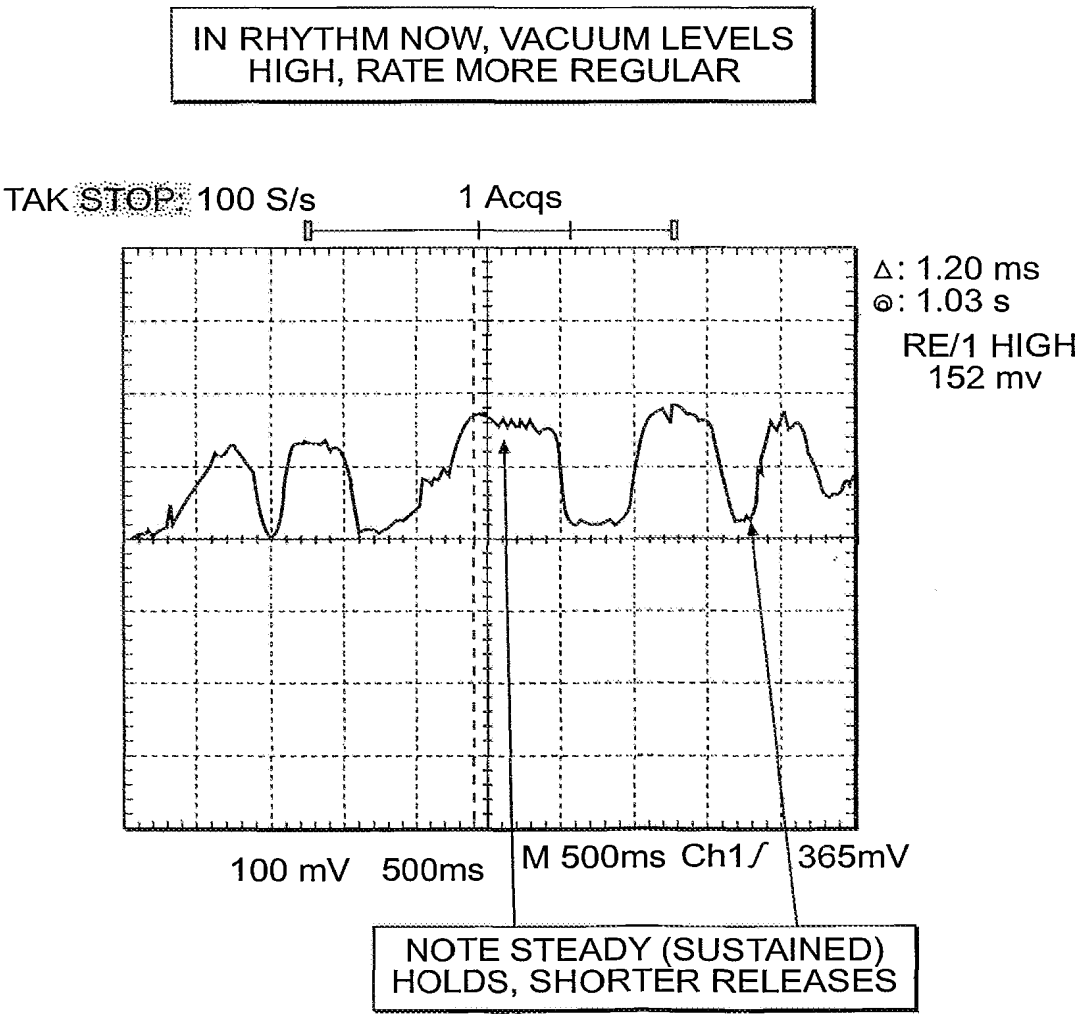

IN RHYTHM NOW, VACUUM LEVELS HIGH, RATE MORE REGULAR
TAK STOP: 100 S/s
1 Acqs
Δ: 1.20 ms
@: 1.03 s
RE/1 HIGH
152 mv
100 mV
500ms
M 500ms Ch1
365mV
NOTE STEADY (SUSTAINED) HOLDS, SHORTER RELEASES

FIG. 21B

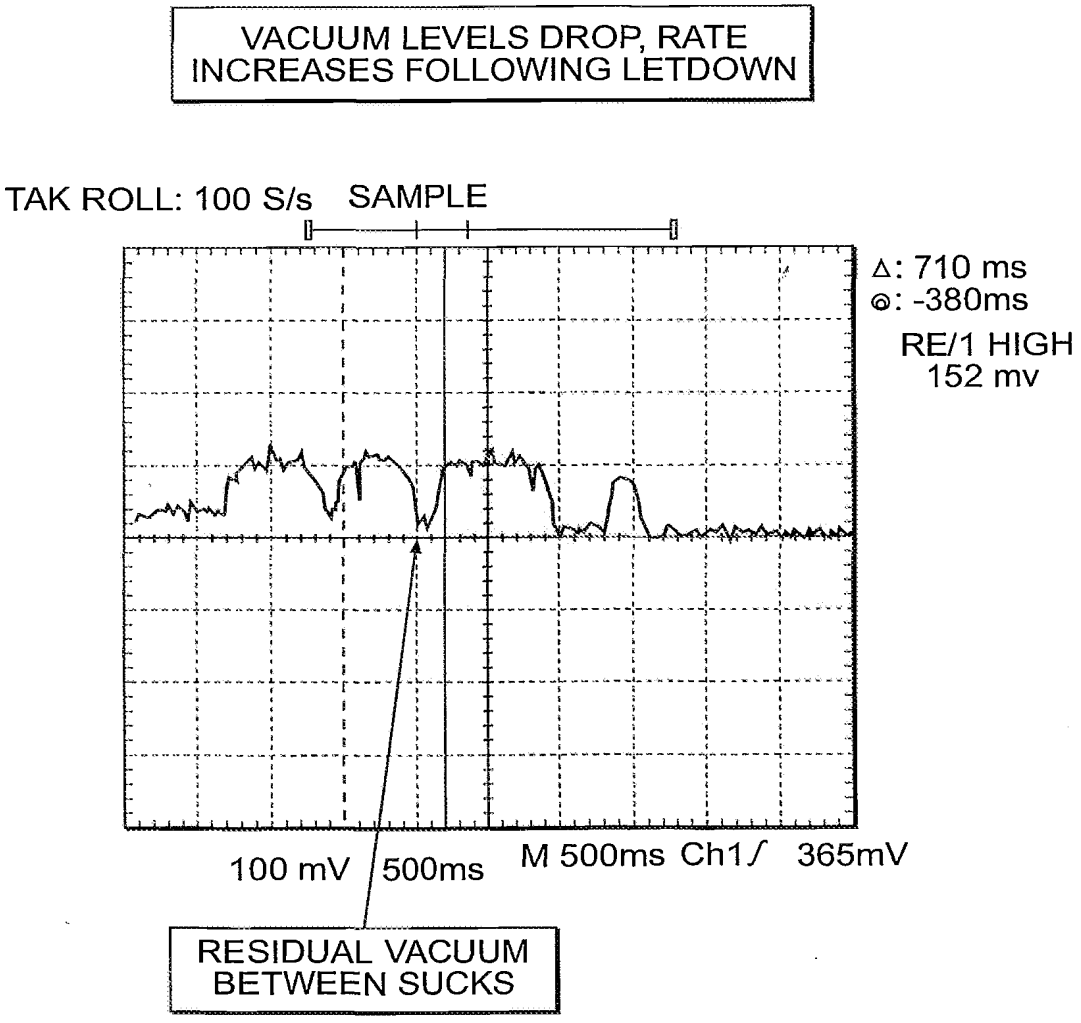
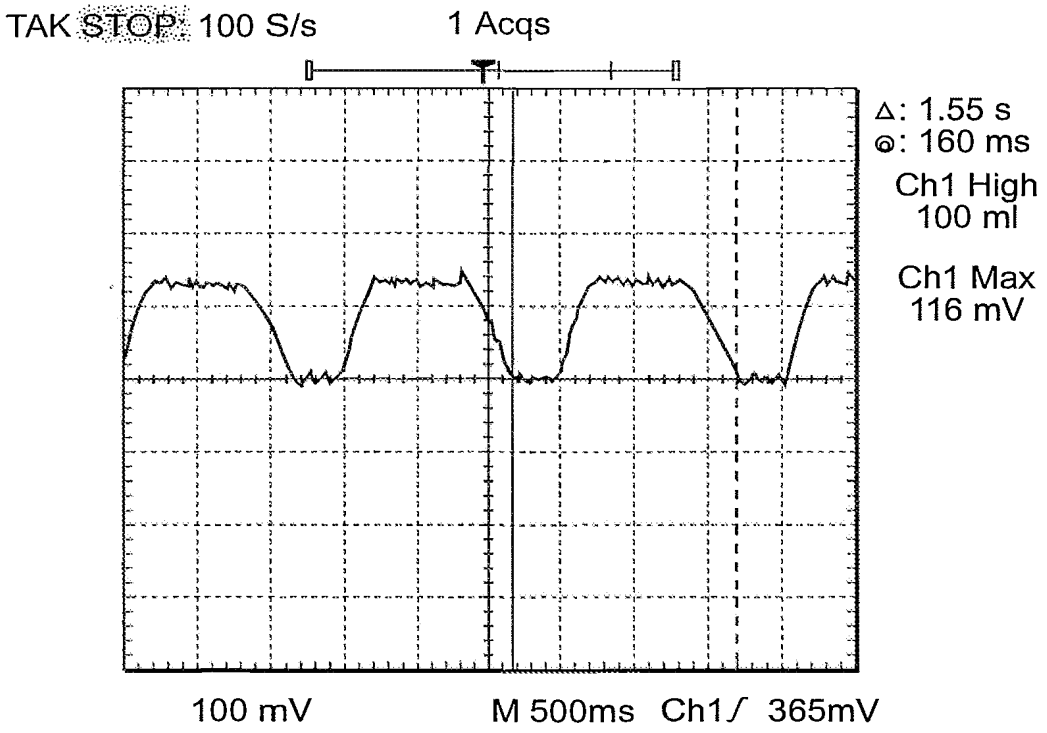
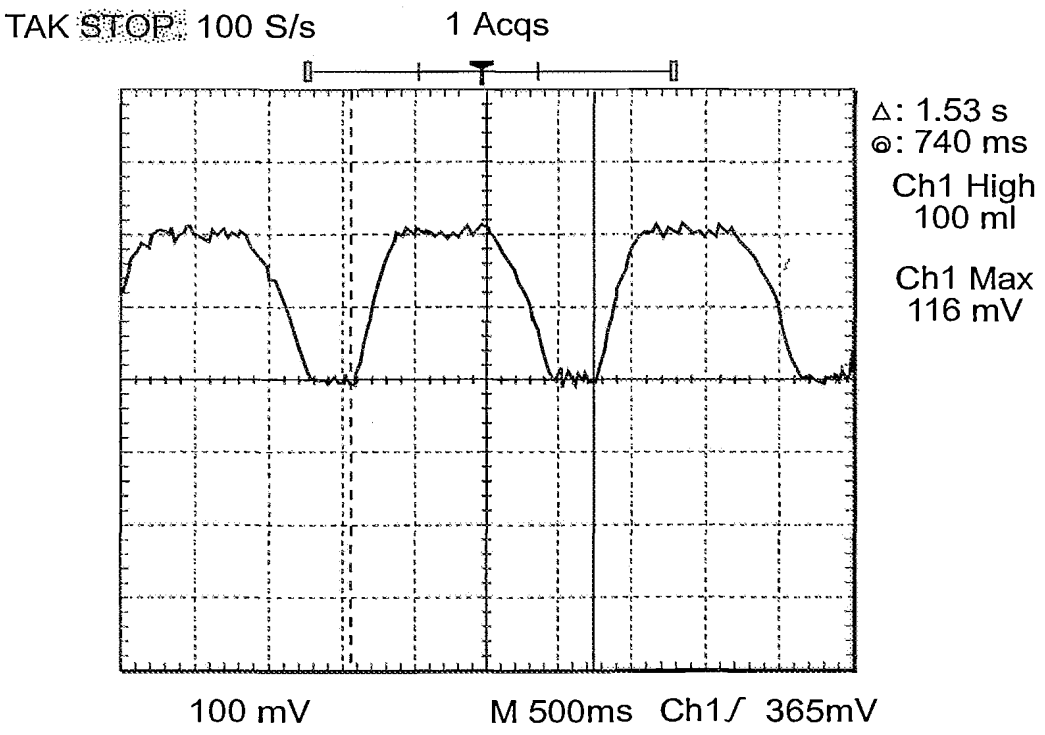

VACUUM LEVELS DROP, RATE INCREASES FOLLOWING LETDOWN
TAK ROLL: 100 S/s SAMPLE
Δ: 710 ms
⊙: -380ms
RE/1 HIGH
152 mv
100 mV
500ms
M 500ms Ch1 365mV
RESIDUAL VACUUM BETWEEN SUCKS

FIG. 21C



Max Vacuum (mmHg):	136
Rate (cyc/min):	39

FIG. 22A



Max Vacuum (mmHg):	204
Rate (cyc/min):	36

FIG. 22B

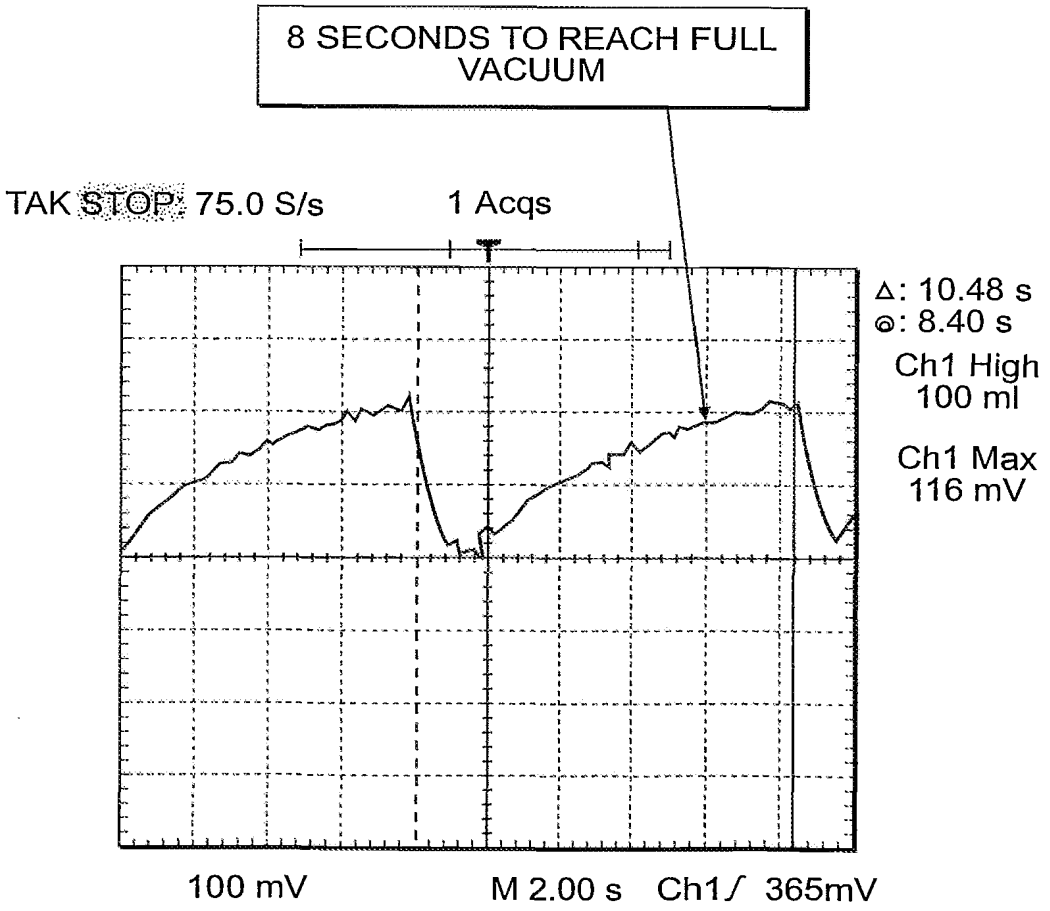


FIG. 23
PRIOR ART

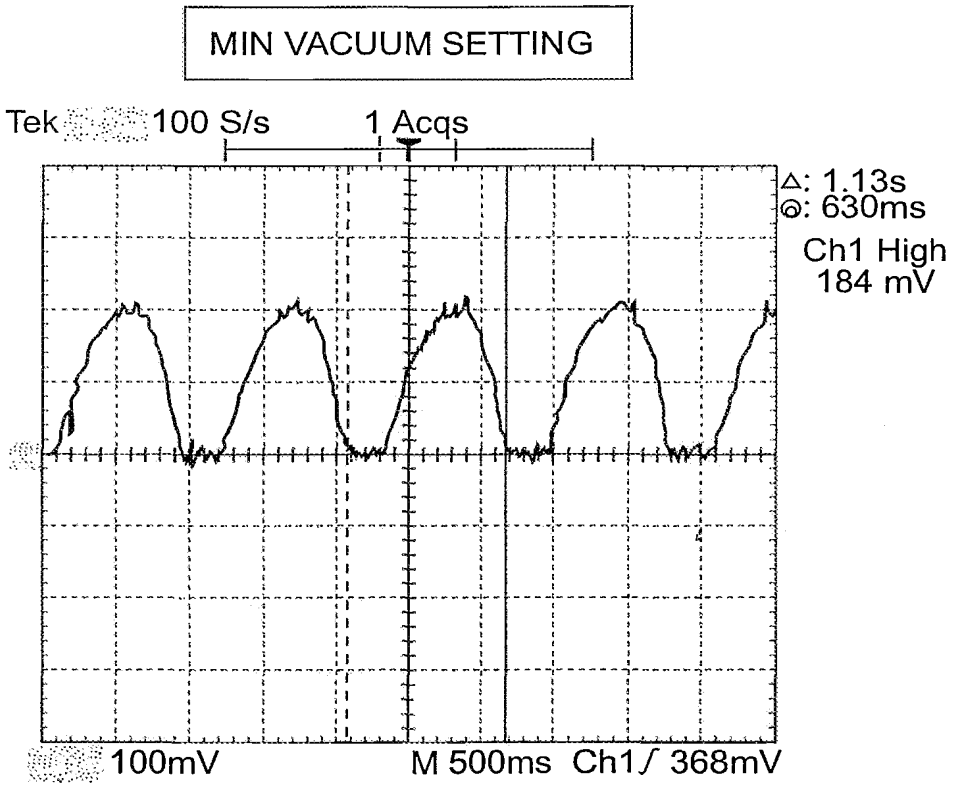


FIG. 24A
PRIOR ART

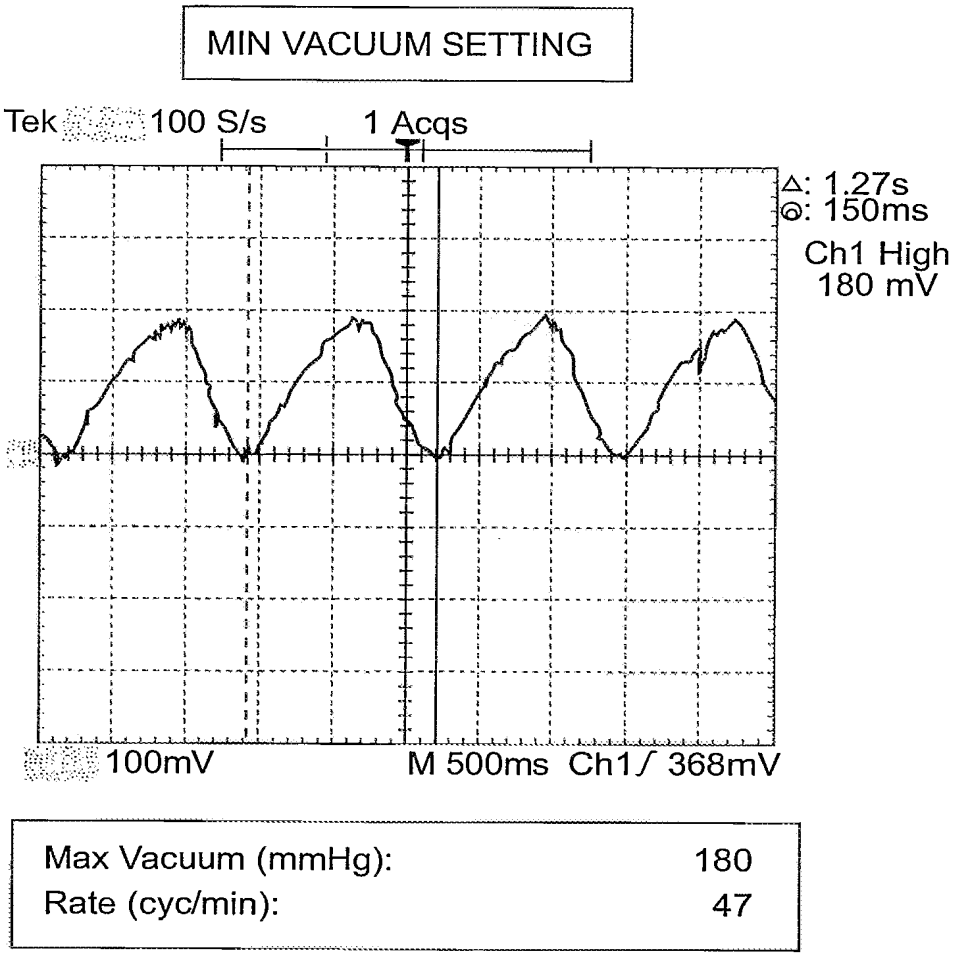
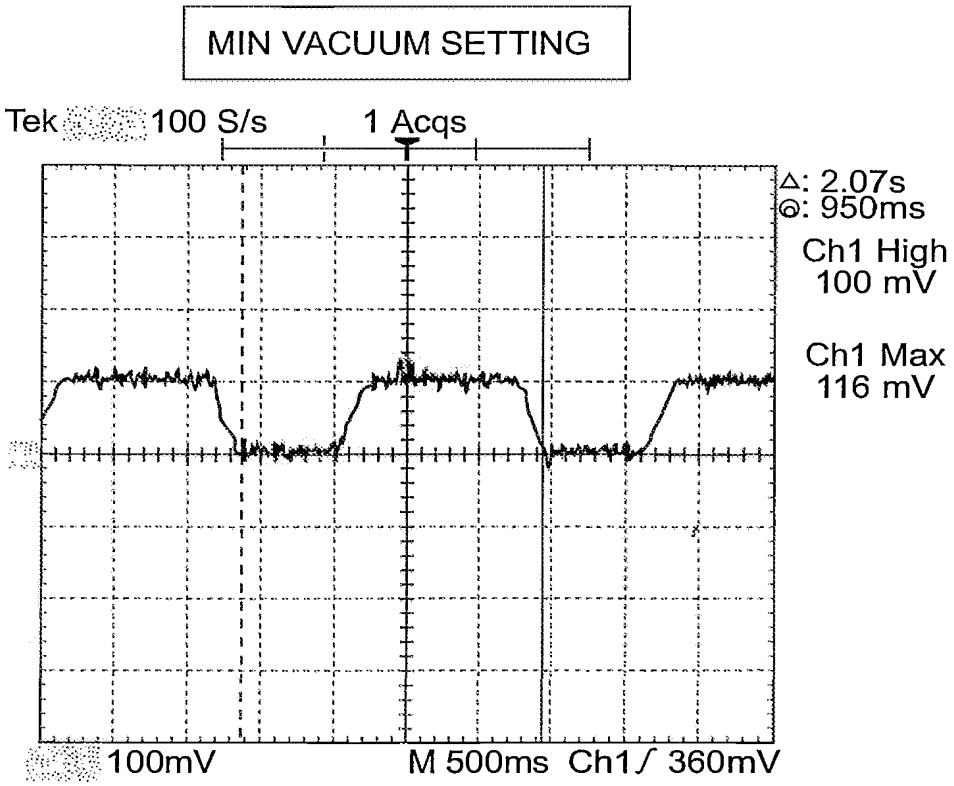


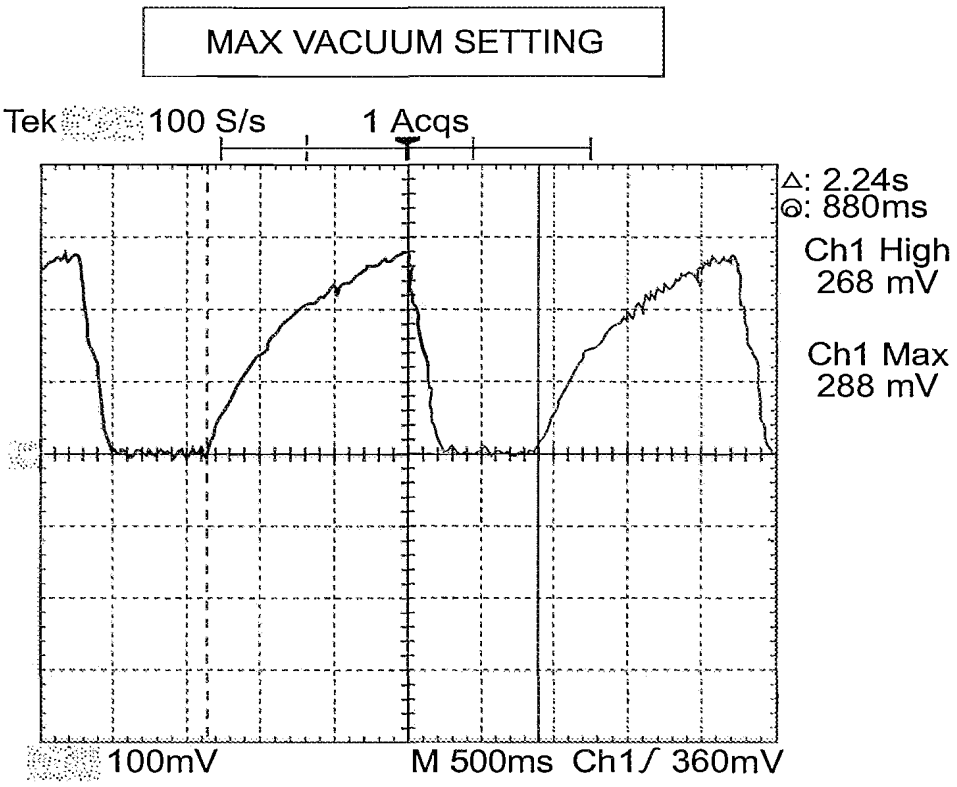
FIG. 24B
PRIOR ART



Max Vacuum (mmHg):	100
Rate (cyc/min):	29
>100 mmHg Hold (sec):	1
<50 mmHg Release (sec):	.9

Pump Settings:	
Vacuum:	Min
Cycles:	N/A

FIG. 25A
PRIOR ART



Max Vacuum (mmHg):	270
Rate (cyc/min):	271
>100 mmHg Hold (sec):	1.4
<50 mmHg Release (sec):	.9

Pump Settings:	
Vacuum:	Max
Cycles:	N/A

FIG. 25B
PRIOR ART

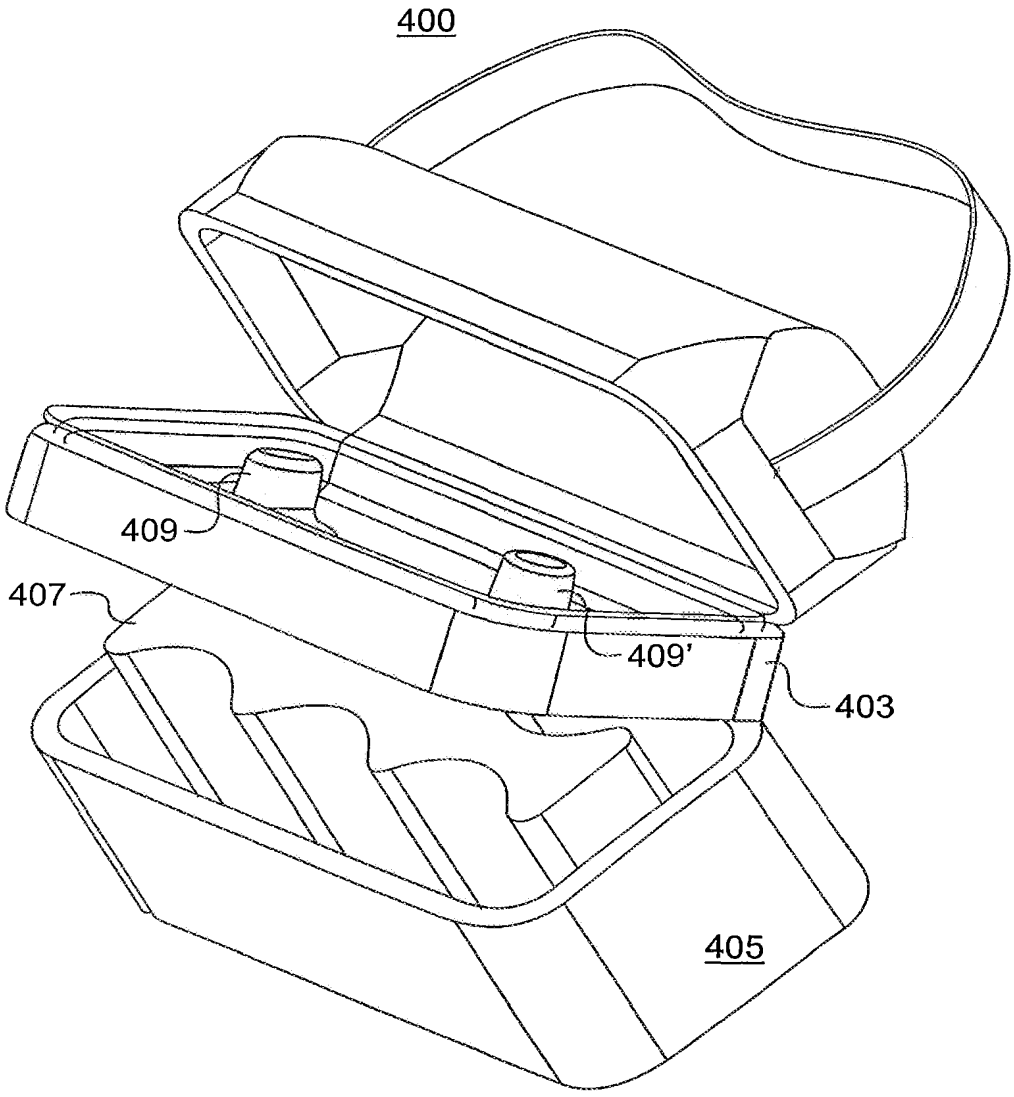


FIG. 26

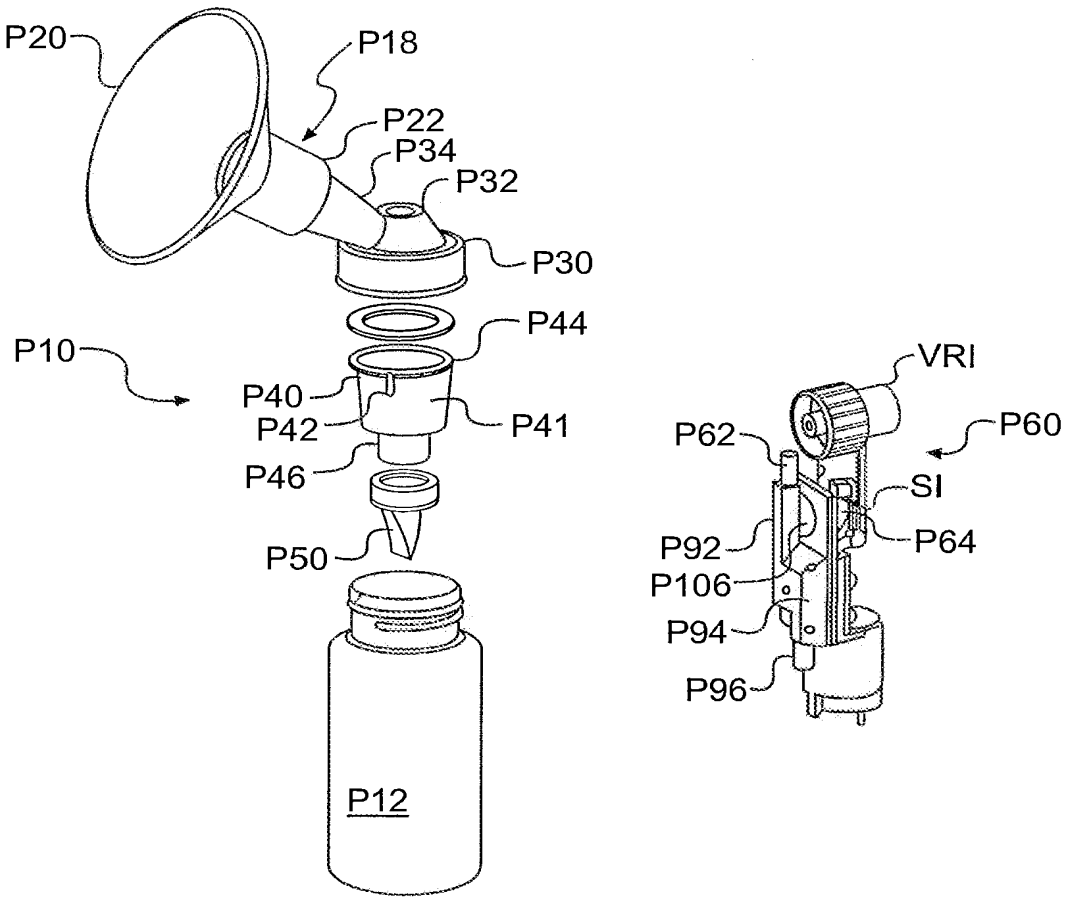


FIG. 27
PRIOR ART

(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

(19) Weltorganisation für geistiges Eigentum
Internationales Büro

(43) Internationales Veröffentlichungsdatum
29. März 2018 (29.03.2018)

WIPO | PCT

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14. September 2017 (14.09.2017)

(25) Einreichungssprache: Deutsch

(26) Veröffentlichungssprache: Deutsch

(30) Angaben zur Priorität:
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(84) Bestimmungsstaaten *(soweit nicht anders angegeben, für jede verfügbare regionale Schutzrechtsart)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), eurasisches (AM, AZ, BY, KG, KZ, RU, TJ, TM), europäisches (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

(54) **Title:** BREASTSHIELD UNIT

(54) **Bezeichnung:** BRUSTHAUBENEINHEIT

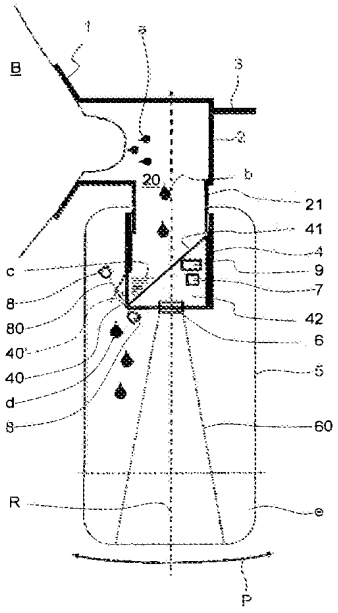

FIG. 1

(57) **Abstract:** A breastshield unit of a breast pump for expressing human breastmilk has a breastshield (1) to be placed onto a mother's breast, a milk collection container (5) for receiving expressed breastmilk, an adapter (2) for connecting the breastshield (1) to the milk collection container (5), and a valve head (4). A milk channel extends from the breastshield (1) through the adapter (2) and the valve head (4) into the milk collection container (5). The valve head (4) has a valve (40) which closes and opens the milk channel during the expressing action, wherein a fill level sensor (6) for measuring a fill level of the milk collection container (5) is arranged in the valve head (4). The breastshield unit according to the invention allows a fill level to be measured without structurally modifying the breastshield and milk collection container. It also permits data exchange with external information memories and/or information processors.

(57) **Zusammenfassung:** Eine Brusthaubeneinheit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch weist eine Brusthaube (1) zur Auflage an eine Mutterbrust, einen Milchsammelbehälter (5) zur Aufnahme von abgepumpter Muttermilch, einen Adapter (2) zur Verbindung der Brusthaube (1) mit dem Milchsammelbehälter (5) sowie einen Ventilkopf (4) auf. Ein Milchkanal erstreckt sich von der Brusthaube (1) durch den Adapter (2) und den Ventilkopf (4) in den Milchsammelbehälter (5). Der Ventilkopf (4) weist ein Ventil (40) auf, welches den Milchkanal während des Abpumpens schliesst und öffnet, wobei im Ventilkopf (4) ein Füllstandsensor (6) angeordnet ist zur Messung eines Füllstandes des Milchsammelbehälters (5). Die erfindungsgemässe Brusthaubeneinheit ermöglicht eine Füllstandmessung ohne bauliche Veränderung der Brusthaube und Milchsammelbehälter. Sie ermöglicht zudem einen Datenaustausch mit externen Informationsspeicher- und/oder Informationsverarbeitungseinheiten.

WO 2018/054758 A1

[Fortsetzung auf der nächsten Seite]

Veröffentlicht:

— *mit internationalem Recherchenbericht (Artikel 21 Absatz 3)*

TITEL

BRUSTHAUBENEINHEIT

TECHNISCHES GEBIET

Die vorliegende Erfindung betrifft eine Brusthaubeneinheit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch sowie einen Ventilkopf einer derartigen Brusthaubeneinheit.

STAND DER TECHNIK

Zum Abpumpen von menschlicher Muttermilch wird auf die Mutterbrust eine Brusthaube aufgesetzt, welche mit einer Vakuumpumpe verbunden ist, um die Brust mit einem zyklisch variierenden Unterdruck zu beaufschlagen. Die abgepumpte Milch gelangt durch einen Milchkanal von der Brusthaube in einen Milchsammelbehälter. Um das Totvolumen beim Abpumpen möglichst klein zu halten, ist ein Milchkanal von der Brusthaube zum Milchsammelbehälter üblicherweise mit einem Rückschlagventil versehen, welches sich für den Einlass der abgepumpten Milch in den Milchsammelbehälter öffnet. Dieses Rückschlagventil ist vorzugsweise an einem Adapter angeordnet, welcher die Brusthaube mit dem Milchsammelbehälter und üblicherweise auch die Brusthaube mit der Vakuumpumpe oder mit einem zur Vakuumpumpe führenden Vakuumschlauch verbindet. Das Rückschlagventil kann auf einem Ventilkopf angeordnet sein, welcher fest oder lösbar mit dem Adapter, auch Kopplungsteil genannt, verbunden ist.

Eine derartige Vorrichtung ist beispielsweise aus WO 2014/161099 A1 bekannt. Die dort beschriebene Brusthaubeneinheit weist einen Durchflusssensor auf, welcher die Veränderung einer Ventilklappe des Rückschlagventils detektiert, so dass Rückschlüsse auf den Durchfluss der Milch von der Brusthaube in den Milchsammelbehälter gezogen werden können.

US 2016/0082166 A1 offenbart einen Adapter mit einem Sensor zur Detektion der Milchproduktion, wobei der Sensor über eine drahtlose Verbindung mit einem mobilen Datenempfänger oder mit der Milchpumpe kommuniziert.

WO 2006/003655 A1 zeigt ein Brusthütchen, welches während dem Stillen eines Babys auf die Mutterbrust aufgesetzt wird. Dieses Brusthütchen ist mit einem Sensor versehen, welches das aus der Brust austretende Milchvolumen misst.

WO 2009/081313 A1 offenbart eine Brusthaube mit mindestens einem Sensor zur Optimierung und Personalisierung des Pumpvorgangs.

Diese Brusthaubeneinheiten sind relativ aufwändig und deshalb kostenintensiv aufgebaut. Da die Brusthauben und Milchsammelbehälter oft jedoch nur einmal oder wenige Male verwendet werden können oder dürfen, sollten sie möglichst kostensparend gefertigt werden können und/oder sie sollten einfach zu reinigen sein.

DARSTELLUNG DER ERFINDUNG

Es ist deshalb eine Aufgabe der Erfindung, eine möglichst kostengünstige Brusthaubeneinheit zu schaffen, welche aber dennoch eine Erfassung der abgepumpten Milchmenge erlaubt.

Diese Aufgabe lösen eine Brusthaubeneinheit sowie ein Ventilkopf mit den Merkmalen des Patentanspruchs 1 bzw. 15.

Die erfindungsgemässe Brusthaubeneinheit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch weist eine Brusthaube zur Auflage an eine Mutterbrust, einen Milchsammelbehälter zur Aufnahme von abgepumpter Muttermilch, einen Adapter zur Verbindung der Brusthaube mit dem Milchsammelbehälter sowie einen Ventilkopf auf. Ein Milchkanal erstreckt sich von der Brusthaube durch den Adapter und durch den Ventilkopf in den Milchsammelbehälter. Der Ventilkopf weist ein Ventil auf, welches den Milchkanal während des Abpumpens schliesst und öffnet, wobei im Ventilkopf ein

Füllstandsensor angeordnet ist zur Messung eines Füllstandes des Milchsammelbehälters.

Da der Füllstandsensor im Ventilkopf angeordnet ist, lassen sich die Brusthaube, der Adapter und der Milchsammelbehälter kostengünstig ausbilden. Es lassen sich insbesondere Standardteile verwenden. Vorteilhaft ist ferner, dass sich der Ventilkopf so ausbilden lässt, dass er in bereits vorhandenen Brusthaubeneinheiten als Zubehörteil verwendet werden kann. Ein Redesign bekannter Brusthaubeneinheiten erübrigt sich dadurch.

Vorzugsweise ist der Milchsammelbehälter steif oder halbsteif ausgebildet. Vorzugsweise ist er eine Milchflasche, welche nach dem Entfernen des Ventilkopfes, des Adapters und der Brusthaube mit einem Deckel luftdicht verschliessbar ist. Vorzugsweise lässt sich dieselbe Flasche gemeinsam mit einem im Gebrauch aufzusetzenden Sauger als Saugflasche zur Verabreichung der Muttermilch an einen Säugling verwenden.

Durch die Messung des Füllstandes im Milchsammelbehälter wird ein genaues Mass über die tatsächlich zur Verfügung stehende Muttermilch erhalten. Die Messung wird vorzugsweise während des Abpumpens durchgeführt. Die Angabe zum Füllstand wird vorzugsweise während des Abpumpens zeitnah aktualisiert.

Die Messdaten lassen sich als Rohdaten oder als mittels einer im Ventilkopf integrierten Elektronikeinheit bereits ausgewertete Daten an eine Auswerteeinheit und/oder eine Steuerung und/oder eine Anzeige der Brustpumpe weiterleiten. In einer einfachen Ausführungsform zeigt die Brustpumpe diese Daten lediglich an. In anderen Ausführungsformen werden die Daten zusätzlich oder alternativ zur aktuellen oder späteren Steuerung der Pumpe verwendet, z.B. um automatisch von einem Stimulations- in einen Expressionsmodus oder umgekehrt zu schalten. In weiteren Ausführungsformen werden die Daten alternativ oder zusätzlich zur automatischen Veränderung der Pumpparameter oder der Muster der Vakuumkurven verwendet, wobei auch dies je nach Ausführungsform für den aktuellen und/oder für einen späteren Pumpvorgang durchgeführt wird.

Die Rohdaten und/oder die ausgewerteten Daten lassen sich auch an andere Empfänger

senden, beispielsweise an ein Smart Device wie einem Smartphone oder an ein anderes persönliches Gerät der Mutter. Dies erleichtert ihr die Erfassung der Füllstandmenge, auch wenn sie den Milchsammelbehälter nicht sehen kann. Zudem lassen sich die Daten direkt dem Internet, beispielsweise einer Cloud, zuführen, um auch Dritten zur Verfügung zu stehen.

Dank der Messung der Füllstandmenge lässt sich das abgepumpte Milchvolumen bestimmen. Durch Ableitung des Volumensignals lässt sich auch der Milchfluss detektieren.

Vorzugsweise ist der Füllstandsensor ein Distanzsensor zur Messung einer Distanz von einer Oberfläche der im Milchsammelbehälter befindlichen abgepumpten Muttermilch, d.h. des im Behälter befindlichen Milchsees. Auf diese Weise lässt sich der Füllstand auf einfache Weise messen, ohne dass der Behälter selber mit einem Füllstandsensor versehen werden muss und ohne dass die Milch mit mechanischen Mitteln kontaktiert werden muss.

Als Füllstandsensor eignet sich insbesondere ein Laufzeitverfahren-Sensor, auch TOF Sensor genannt (Time of flight Sensor). Es hat sich gezeigt, dass sich derartige TOF Sensoren zur Füllstandmessung von Milch eignen, obwohl sie beispielsweise für eine Füllstandmessung von Wasser ungeeignet sind.

Der Distanzsensor, insbesondere der TOF Sensor, erlaubt eine Distanzmessung vom Sensor bis zur Füllstandhöhe innerhalb des Milchsammelbehälters. Sofern die Geometrie des Milchsammelbehälters bekannt ist, vorzugsweise wenn zusätzlich der Lagewinkel des Milchsammelbehälters im dreidimensionalen Raum bekannt ist, lässt sich damit der Füllstand und somit das Milchvolumen berechnen.

Wird ein TOF Sensor verwendet, so ist eine optische Verbindung vom Sensor zum gegenüberliegenden Boden des Milchsammelbehälters notwendig. Vorzugsweise ist der TOF Sensor so positioniert, dass er sich auf einer Längsmittelachse des Milchsammelbehälters befindet. Vorzugsweise bildet diese Längsmittelachse eine Rotationssymmetrieachse des Milchsammelbehälters.

In einer einfachen Ausführungsform ist im Ventilkopf lediglich der Füllstandsensor angeordnet, welcher als Parameter den Füllstand der Milch im Behälter misst. Vorzugsweise ist im Ventilkopf jedoch mindestens ein zusätzlicher Sensor, vorzugsweise sind zwei oder mehrere zusätzliche Sensoren zum Messen von weiteren Parametern vorhanden.

Ein derartiger zusätzlicher Sensor ist beispielweise ein Durchflusssensor, welcher den Durchfluss durch das Ventil misst. Dieser Durchflusssensor ist beispielsweise ein optischer Sensor, welcher eine Auslenkung einer Ventilklappe des Ventils detektiert. Vorzugsweise ist der Sensor eine Lichtschranke, welche die Position der Ventilklappe detektiert. Vorzugsweise ist auf der Ventilklappe hierfür ein vorstehender Flügel angeordnet, welcher den Lichtpfad der Lichtschranke durchdringt. Ein derartiger Durchflusssensor ist beispielsweise in WO 2014/161099 offenbart.

Diese zusätzliche Messung des Durchflusses ermöglicht eine Korrektur der Füllstandmessung durch den Füllstandsensor insbesondere wenn sich erst kleine Milchvolumen im Milchsammelbehälter befinden. Auch lässt sich dieser Durchflusssensor während Bewegungen des Milchsammelbehälters verwenden, um die Messungen des während dieses Zeitraums ungenauen Füllstandsensors zu korrigieren oder ganz zu ersetzen. Des Weiteren lässt sich dieser Durchflusssensor als Kontrollmittel einsetzen, welches feststellt, ob sich das Ventil überhaupt geöffnet hat bzw. wie oft und/oder wann es sich öffnet. Diese Angaben lassen sich zur Steuerung des Füllstandsensors verwenden. Beispielsweise erübrigt sich eine Füllstandmessung, wenn sich das Ventil nicht geöffnet hat und somit keine neue Milch in den Milchsammelbehälter gelangt ist.

Alternativ oder zusätzlich ist als weiterer Sensor vorzugsweise ein Positionssensor vorhanden, welcher die Lage des Milchsammelbehälters im dreidimensionalen Raum und somit seine Kipplage im dreidimensionalen Raum detektiert. Als Positionssensor eignet sich insbesondere ein Beschleunigungssensor. Die Daten des Positionssensors werden vorzugsweise verwendet, um die Signale des Füllstandsensors in Kipplagen des Milchsammelbehälters zu kompensieren. Der Positionssensor wird vorzugsweise zusätzlich dazu verwendet, um festzustellen, ob der Milchsammelbehälter überhaupt in einer Position ist, um eine sinnvolle Füllstandmessung zu gewährleisten.

Der Füllstandsensor und mindestens der Positionssensor, vorzugsweise auch alle anderen weiteren Sensoren, sind vorzugsweise zueinander lagefixiert im Ventilkopf angeordnet.

Die Signale, auch Rohdaten genannt, des Füllstandsensors und falls vorhanden, des mindestens einen weiteren Sensors, werden vorzugsweise direkt an externe Einheiten weitergeleitet, wie beispielsweise an eine Auswerte- und Steuereinheit der Brustpumpe oder an eine andere externe Auswerteeinheit.

Vorzugsweise ist jedoch im Ventilkopf eine Elektronikeinheit zur Verarbeitung der Signale des Füllstandsensors angeordnet. Vorzugsweise verarbeitet diese interne Elektronikeinheit auch die Signale des mindestens einen weiteren Sensors, falls vorhanden.

Vorzugsweise ist die Elektronikeinheit zum Datenaustausch mit mindestens einer der folgenden Einheiten ausgebildet: Brustpumpe, informationstechnisch aufgerüstetes „Smart Device“ wie Smartphone; externe Datenverarbeitungseinheit wie Personal Computer; Cloud; Internet, Internetzugangseinheit.

Zur einfachen Verwendung des Ventilkopfes ist dieser vorzugsweise nach aussen kabellos und bezüglich elektronischen Steckern steckerlos ausgebildet. Dies erleichtert zudem die Reinigung und ermöglicht eine mehrfache Wiederverwendung des Ventilkopfes.

In einer Ausführungsform ist der Ventilkopf ein integraler Bestandteil des Adapters. In diesem Fall kann der gesamte Adapter als Ventilkopf ausgebildet sein, d.h. die weiteren Sensoren können über den Adapter verteilt angeordnet sein und müssen sich nicht benachbart zum Anschluss an den Milchsammelbehälter befinden.

In einer anderen Ausführungsform ist der Ventilkopf lösbar mit dem Adapter und/oder dem Milchsammelbehälter verbindbar. Diese Ausführungsform eignet sich insbesondere als Nachrüstset.

Vorzugsweise sind der Füllstandsensor und falls vorhanden der mindestens eine weitere Sensor sowie falls ebenfalls vorhanden die Elektronikeinheit gegen Eindringen von

Flüssigkeit geschützt. Vorzugsweise ist der Ventilkopf spülmaschinenfest ausgebildet.

Weitere Ausführungsformen sind in den abhängigen Ansprüchen angegeben.

KURZE BESCHREIBUNG DER ZEICHNUNGEN

Eine bevorzugte Ausführungsform der Erfindung ist im Folgenden anhand der Zeichnungen beschrieben, die lediglich zur Erläuterung dienen und nicht einschränkend auszulegen sind. In den Zeichnungen zeigen:

Figur 1 eine schematische Darstellung einer erfindungsgemässen Brusthaubeneinheit bei Anlage auf einer Mutterbrust und

Figur 2 eine schematische Darstellung der Brusthaubeneinheit gemäss Figur 1 in Kommunikation mit externen Einheiten.

BESCHREIBUNG BEVORZUGTER AUSFÜHRUNGSFORMEN

In Figur 1 ist eine erfindungsgemässe Brusthaubeneinheit dargestellt. Sie weist eine Brusthaube 1 zur Aufnahme einer Mutterbrust B, insbesondere der Brustwarze, auf. Die Brusthaube 1 ist fest oder vorzugsweise lösbar mit einem Adapter 2, auch Kopplungsteil genannt, verbunden. Der Adapter 2 kann direkt mit einer manuell oder elektromotorisch betriebenen Brustpumpe verbunden sein. Vorzugsweise ist er, wie hier dargestellt, über eine Vakuumleitung 3, insbesondere über einen Silikonschlauch, mit der Brustpumpe verbunden. Die Brustpumpe ist in Figur 2 dargestellt und dort mit dem Bezugszeichen 30 versehen.

Der Adapter weist einen Innenraum 20 auf, welcher einen Teil eines Milchkanals von der Brusthaube 1 zu einem Milchsammelbehälter 5 bildet. Der Milchsammelbehälter 5 ist an einem Anschlussstutzen 21 des Adapters 2 lösbar befestigt.

Am Adapter 2 ist ein Ventilkopf 4 fest oder lösbar angeordnet, wobei der Ventilkopf 4 vorzugsweise lagefixiert zum Adapter 2 ist. Beispielsweise ist der Ventilkopf 4 gemeinsam einstückig mit dem Adapter 2 ausgebildet oder über eine Steck- oder Schraubverbindung mit ihm verbindbar.

Der Adapter 2 und der Ventilkopf 4 sind vorzugsweise aus einem steifen Kunststoff gefertigt. Der Milchsammelbehälter 5 ist vorzugsweise steif oder halbsteif ausgebildet. Vorzugsweise besteht auch der Milchsammelbehälter 5 aus Kunststoff. Er kann durchsichtig, halbdurchsichtig oder opak ausgebildet sein.

Der Ventilkopf 4 ragt vorzugsweise in den Milchsammelbehälter 5 hinein. Der Ventilkopf 4 weist ein Rückschlagventil auf. In diesem Ausführungsbeispiel weist das Ventil eine einseitig angelenkte Ventilklappe 40 auf. Das Bezugszeichen 40' bezeichnet die Ventilklappe in geöffneter Stellung, das Bezugszeichen 40 in geschlossener Position.

Der Weg der abgepumpten Milch ist in Figur 1 durch einzelne Milchtropfen dargestellt. Die aus der Mutterbrust B austretende Milch ist mit dem Bezugszeichen a bezeichnet, die in den Ventilkopf 4 fliessende, üblicherweise fallende Milch mit b, die sich vor der geschlossenen Ventilklappe 40 sammelnde Milch mit c und die schliesslich in den Milchsammelbehälter 5 gelangende Milch mit d. Der Milchsee im Milchsammelbehälter 5, also die bereits gesammelte Milch, ist mit dem Bezugszeichen e versehen. Je nach Ausführungsform öffnet die Ventilklappe 40 aufgrund der herrschenden Druckverhältnisse bei jedem Saugzyklus oder erst, wenn sich genügend Milch c vor der Klappe angesammelt hat, um diese zu öffnen. Andere Arten, das Ventil zu öffnen, sind auch möglich.

Im Bereich der Ventilklappe 40 ist vorzugsweise ein Durchflusssensor 8, hier ein als Lichtschranke ausgebildeter optischer Sensor vorhanden. In der schematischen Darstellung gemäss Figur 1 erscheint er innerhalb des Milchsammelbehälters 5 zu schweben. Er ist jedoch ebenfalls am Ventilkopf 4 befestigt.

Der Durchflusssensor 8 misst den Öffnungswinkel der Ventilklappe 40. Der Erfassungsbereich des Durchflusssensors 8, d.h. der Lichtpfad, ist in Figur 1 mit dem Bezugszeichen 80 versehen. Der Öffnungswinkel der Ventilklappe 40 ist in etwa

proportional zur „abfliessenden“ Milchmenge d. Um die Messgenauigkeit zu optimieren, wird der Öffnungswinkel der Ventilklappe 40 vorzugsweise mit mindestens 30 Messungen/sec abgetastet. Dieses Messsignal wird, wie eingangs erwähnt, zur Korrektur der Messung des nachfolgend beschriebenen Füllstandsensors verwendet, insbesondere bei kleinen Füllhöhen. Zudem lässt sich mittels dieses Sensors feststellen, ob und wann sich die Ventilklappe 40 geöffnet hat.

In einem von vom Milchkanal getrennten Elektronikbereich 42 des Ventilkopfes 4 ist ein Füllstandsensor 6 angeordnet. Der Elektronikbereich 42 ist vorzugsweise als geschlossene Kammer ausgebildet. Die Trennung vom restlichen Ventilkopf kann beispielsweise über eine Trennwand 41 erfolgen. Ist diese schräg ausgebildet, erleichtert sie zudem den Milchfluss zur Ventilklappe 40.

Der Füllstandsensor 6 weist einen Erfassungsbereich 60 auf, welcher zum gegenüberliegenden Boden des Milchsammelbehälters 5 hin gerichtet ist. Der Füllstandsensor 6 ist deshalb vorzugsweise an der unteren Stirnfläche des Ventilkopfes 4 angeordnet. Bevorzugterweise befindet sich der Füllstandsensor 6 auf der Längsmittelachse des Milchsammelbehälters 5, welche vorzugsweise gleichzeitig die Rotationssymmetrieachse R des Milchsammelbehälters 5 bildet. Der Füllstandsensor 6 ist vorzugsweise ein Distanzsensor, bevorzugt ein optischer Distanzsensor und noch bevorzugter ein TOF Sensor (Time of flight Sensor).

Der TOF Sensor misst eine Distanz von der Sensoroberfläche bis zur Milchoberfläche. Diese Distanz wird, unter Einbezug der Flaschengeometrie, von einem Mikrokontroller einer Elektronikeinheit 9 in Volumen umgerechnet. Die Abstrahlung und somit der Erfassungsbereich 60 des TOF Sensors ist üblicherweise konisch oder kollimiert.

Im Elektronikbereich 42 ist vorzugsweise zudem ein Positionssensor 7, hier ein Bewegungssensor, angeordnet. Dieser Positionssensor 7 misst die Bewegung oder Kipplage des Ventilkopfes 4 und somit des mit diesem über den Adapter 2 verbundenen Milchsammelbehälters 5. Die Signale oder Daten werden an die oben genannte Elektronikeinheit 9, insbesondere demselben Mikrokontroller, geliefert. Sie dienen der Kompensation der Signale des Füllstandsensors 6 bei Kipplagen des

Milchsammelbehälters 5 und erhöhen somit die Genauigkeit der Messung. Die Kipplage ist in Figur 1 mit einem Doppelpfeil und dem Bezugszeichen P bezeichnet.

Der Füllstandsensor 6 sowie der Positionssensor 7 sind zueinander lagefixiert angeordnet; d.h. gerät der eine Sensor in eine Kipplage und/oder wird er bewegt, so gilt gleiches für den anderen Sensor. Vorzugsweise gilt gleiches auch für den Durchflusssensor 8. Der Milchsammelbehälter 5 ist ebenfalls lagefixiert zum Füllstandsensor 6 und, falls vorhanden, zum Positionssensor 7 angeordnet. Dies erfolgt über die entsprechende Verbindung mit dem Adapter 2 und der entsprechenden Verbindung zwischen Adapter 2 und Ventilkopf 4.

Die oben genannte Elektronikeinheit 9 ist vorzugsweise ebenfalls im Elektronikbereich 42 des Ventilkopfes 4 angeordnet. Vorzugsweise verfügt sie über eine im Ventilkopf 4 integrierte Energieversorgung, insbesondere einen Energiespeicher. Vorzugsweise führen keine Kabel oder Steckverbindungen nach aussen. Der Datentransfer von der Elektronikeinheit 9 nach aussen und falls vorhanden, auch von aussen zur Elektronikeinheit 9, findet vorzugsweise drahtlos statt. Die Energieübertragung erfolgt vorzugsweise ebenfalls drahtlos. Der Elektronikbereich 42 ist vorzugsweise flüssigkeitsdicht nach aussen abgeschottet.

In Figur 2 sind verschiedene Kommunikationswege 90 der erfindungsgemässen Brusthaubeneinheit mit externen Informationsspeicher- und/oder Informationsverarbeitungs-Einheiten dargestellt. Die Messwerte geben der Mutter, Stillberaterinnen oder anderen Experten Auskunft über die abgepumpte Milchmenge. Da die Mutter den Milchsammelbehälter 5 während des Abpumpens nicht unbedingt sehen kann, wird es ihr ermöglicht, diese Füllstandmenge auf einem Display der Brustpumpe 30, auf einem Smart Device SD, wie beispielsweise ihr Smartphone oder ihr Tablet, oder auf einem anderen geeigneten Gerät anzeigen lassen. Zudem können diese Daten ohne weiteres Zutun der Mutter über eine Internetzugangseinheit I dem Internet zur Verfügung gestellt werden. Sie können beispielsweise in eine dafür geeignete Cloud C gespeichert werden oder einer anderen Einheit OD, wie zum Beispiel einem Personal Computer, übermittelt werden. Diese gemessenen Füllstandmengenverläufe lassen sich zur zeitgleichen oder späteren Optimierung von Abpumpparametern oder Messalgorithmen

einsetzen. Abpumpparameter sind beispielsweise Vakuumhöhe und Pumpfrequenz, Dauer eines Stimulationsprogramms (let-down) der Pumpe vor einem automatischen oder manuellen Wechsel auf den expressiven, d.h. normalen Abpumpvorgang und ähnliches.

Die erfindungsgemässe Brusthaubeneinheit und der erfindungsgemässe Ventilkopf ermöglichen eine Füllstandmessung ohne bauliche Veränderung der Brusthaube und Milchsammelbehälter. Sie ermöglichen zudem einen Datenaustausch mit externen Informationsspeicher- und/oder Informationsverarbeitungseinheiten.

BEZUGSZEICHENLISTE

1	Brusthaube
2	Adapter
20	Innenraum
21	Anschlussstutzen
3	Vakuumleitung
30	Brustpumpe
4	Ventilkopf
40	Ventilklappe
40‘	Ventilklappe in geöffneter Stellung
41	Trennwand
42	Elektronikbereich
5	Milchsammelbehälter
6	Füllstandsensor
60	Erfassungsbereich des Füllstandsensors
7	Positionssensor
8	Durchflusssensor
80	Erfassungsbereich des Durchflusssensors
9	Elektronikeinheit
90	Kommunikationsweg
B	Mutterbrust
a	aus der Mutterbrust austretende Milch
b	in den Ventilkopf fallende Milch
c	im Ventilkopf sich sammelnde Milch
d	aus dem Ventilkopf austretende Milch
e	im Milchsammelbehälter gesammelte Milch
P	Drehposition des Milchsammelbehälters im Raum
I	Internetzugangseinheit
SD	Smart Device
C	Cloud
OD	Andere Einheiten
R	Rotationsachse

PATENTANSPRÜCHE

1. Brusthaubeneinheit einer Brustpumpe zum Abpumpen von menschlicher Muttermilch, wobei die Brusthaubeneinheit eine Brusthaube (1) zur Auflage an eine Mutterbrust, einen Milchsammelbehälter (5) zur Aufnahme von abgepumpter Muttermilch, einen Adapter (2) zur Verbindung der Brusthaube (1) mit dem Milchsammelbehälter (5) sowie einen Ventilkopf (4) aufweist, wobei sich ein Milchkanal von der Brusthaube (1) durch den Adapter (2) und den Ventilkopf (4) in den Milchsammelbehälter (5) erstreckt und wobei der Ventilkopf (4) ein Ventil (40) aufweist, welches den Milchkanal während des Abpumpens schliesst und öffnet, dadurch gekennzeichnet, dass im Ventilkopf (4) ein Füllstandsensor (6) angeordnet ist zur Messung eines Füllstandes des Milchsammelbehälters (5).

2. Brusthaubeneinheit nach Anspruch 1, wobei der Füllstandsensor (6) ein Distanzsensor zur Messung einer Distanz von einer Oberfläche der im Milchsammelbehälter (5) befindlichen abgepumpten Muttermilch, vorzugsweise ein Laufzeitverfahen-Sensor (Time of flight Sensor), ist.

3. Brusthaubeneinheit nach einem der Ansprüche 1 bis 2, wobei im Ventilkopf (4) mindestens ein weiterer Sensor (7, 8) angeordnet ist.

4. Brusthaubeneinheit nach Anspruch 3, wobei einer des mindestens einen weiteren Sensors ein Durchflusssensor (8) ist, welcher den Durchfluss durch das Ventil (40) misst.

5. Brusthaubeneinheit nach Anspruch 4, wobei der Durchflusssensor (8) ein optischer Sensor ist, welcher eine Auslenkung einer Ventilklappe (40) des Ventils detektiert.

6. Brusthaubeneinheit nach einem der Ansprüche 1 bis 5, wobei einer des mindestens einen weiteren Sensors ein Positionssensor (7) ist, welcher die Position des Milchsammelbehälters (5) im dreidimensionalen Raum und somit

seine Schräglage im dreidimensionalen Raum detektiert.

7. Brusthaubeneinheit nach Anspruch 6, wobei der Positionssensor (7) ein Beschleunigungssensor ist.

8. Brusthaubeneinheit nach einem der Ansprüche 6 oder 7, wobei der Füllstandsensor (6) und der Positionssensor (7) zueinander lagefixiert im Ventilkopf (4) angeordnet sind.

9. Brusthaubeneinheit nach einem der Ansprüche 1 bis 8, wobei im Ventilkopf (4) eine Elektronikeinheit (9) zur Verarbeitung von Signalen des Füllstandsensors (6) angeordnet ist.

10. Brusthaubeneinheit nach Anspruch 9 und mindestens einem der Ansprüche 4 bis 8, wobei die Elektronikeinheit (9) zur Verarbeitung von Signalen des mindestens einen weiteren Sensors (7, 8) ausgebildet ist.

11. Brusthaubeneinheit nach einem der Ansprüche 9 oder 10, wobei die Elektronikeinheit (9) zum Datenaustausch (91, 92, 93, 94, 95, 96, 97) mit mindestens einer der folgenden Einheiten ausgebildet ist: Brustpumpe (30), informationstechnisch aufgerüstetes „Smart Device" (SD) wie Smartphone, externe Datenverarbeitungseinheit wie Computer (OD), Cloud (C), Internet, Internetzugangseinheit (I).

12. Brusthaubeneinheit nach einem der Ansprüche 1 bis 11, wobei der Ventilkopf (4) nach aussen kabellos und bezüglich elektronischen Steckern steckerlos ausgebildet ist.

13. Brusthaubeneinheit nach einem der Ansprüche 1 bis 12, wobei der Ventilkopf (4) integraler Bestandteil des Adapters (2) ist.

14. Brusthaubeneinheit nach einem der Ansprüche 1 bis 13, wobei der Ventilkopf (4) lösbar mit dem Adapter (2) und/oder dem Milchsammelbehälter (5) verbindbar

ist.

15. Ventilkopf einer Brusthaubeneinheit nach einem der Ansprüche 1 bis 14, wobei der Ventilkopf (4) ein Ventil (40) aufweist, welches den Milchkanal während des Abpumpens schliesst und öffnet, und wobei im Ventilkopf ein Füllstandsensor (6) angeordnet ist zur Messung eines Füllstandes des Milchsammelbehälters (5).

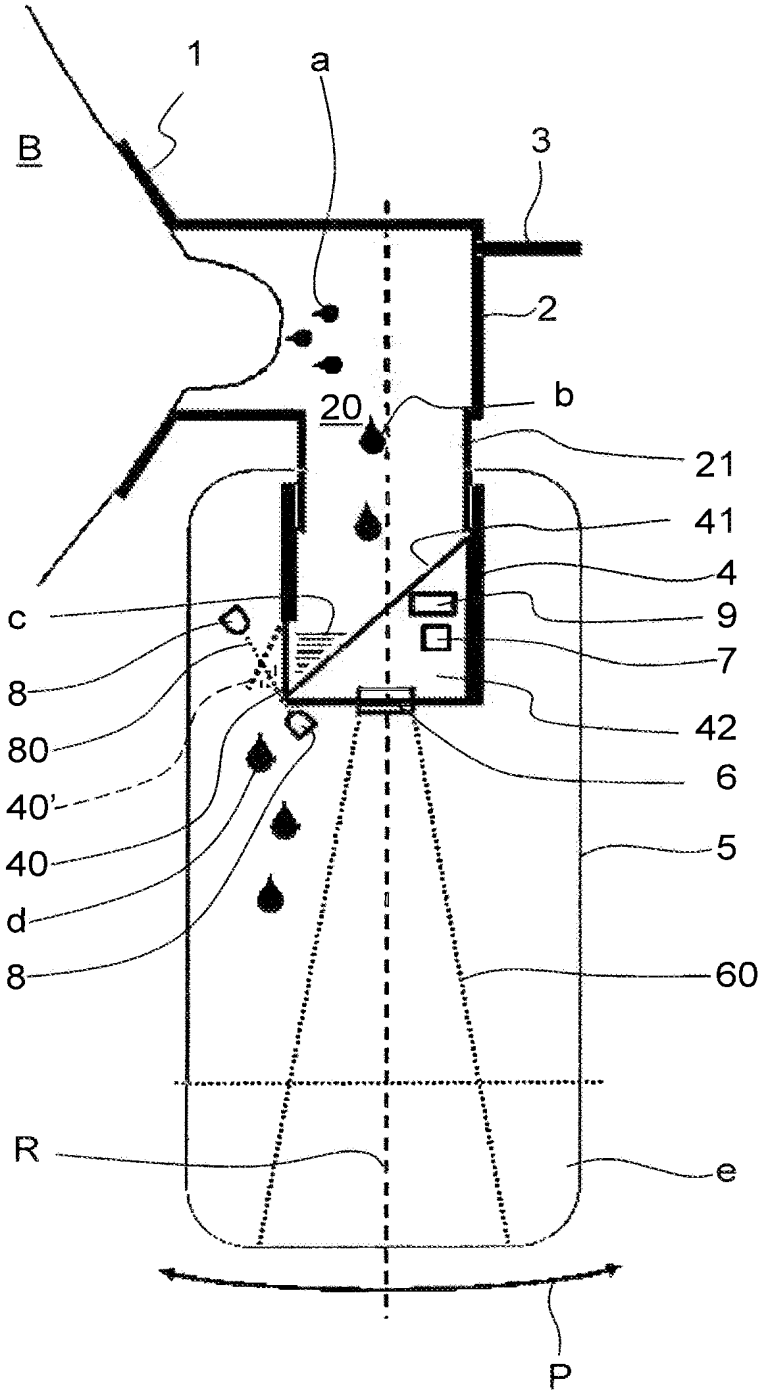

FIG. 1

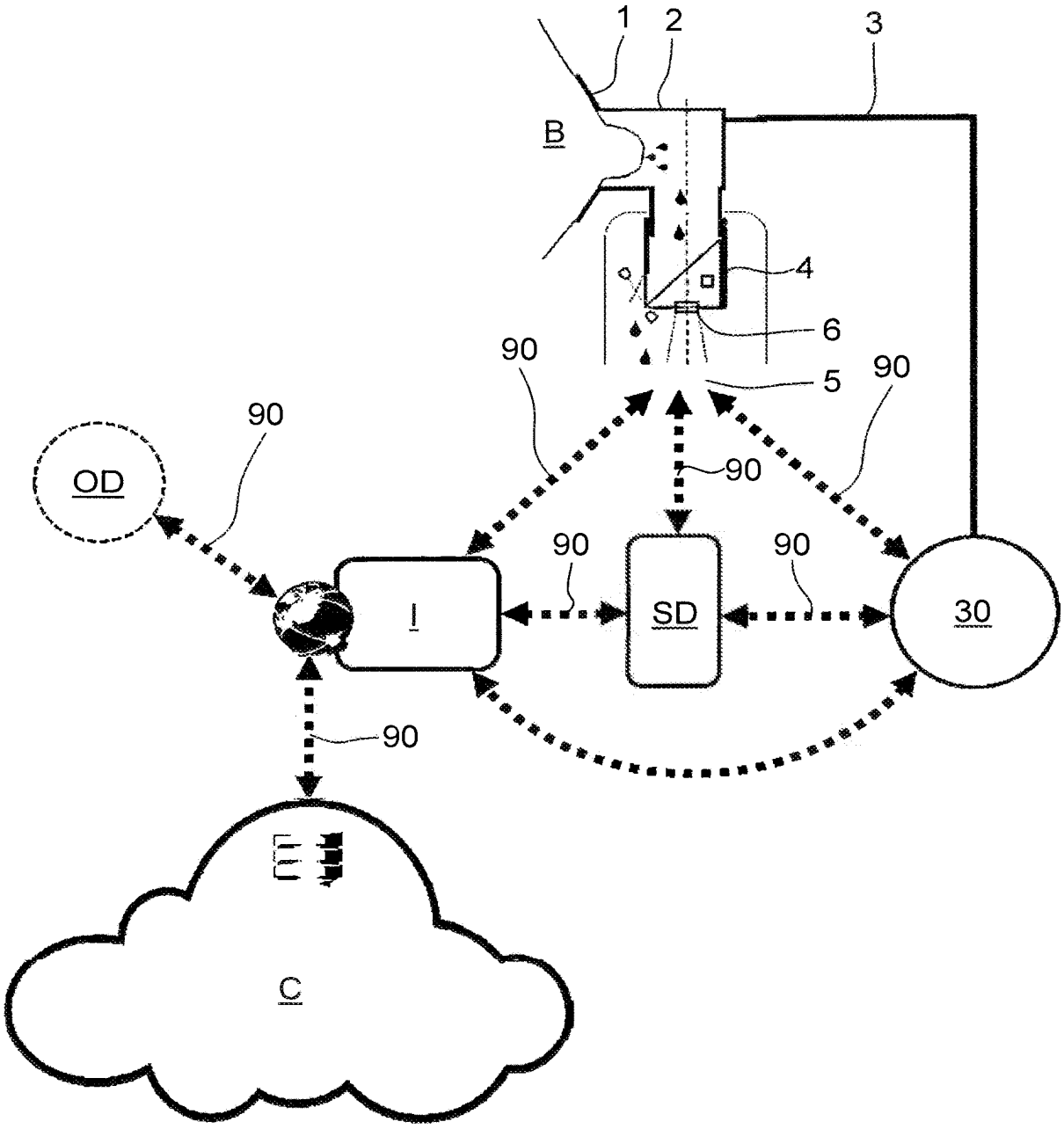

FIG. 2

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/073155

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/06
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2016/082165 A1 (ALVAREZ JEFFERY B [US] ET AL) 24 March 2016 (2016-03-24) paragraphs [0107] - [0120], [0151] - [0152] figures 1, 11c-e, h, j 25 -----	1,3,4, 6-15 2
X	US 2016/220743 A1 (GUTHRIE GABRIELLE V [US] ET AL) 4 August 2016 (2016-08-04) paragraphs [0063] - [0071] figures 5-8, 10-12 -----	1,3,4,15
X	US 2015/038945 A1 (MCCABE JILL C [US]) 5 February 2015 (2015-02-05) paragraphs [0015] - [0024] figures 1, 2 -----	1,13-15
	-/--	

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
15 November 2017	28/11/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Schlaug, Martin

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2016/082166 A1 (GUTHRIE GABRIELLE V [US] ET AL) 24 March 2016 (2016-03-24) cited in the application paragraphs [0025], [0037] - [0038] figures 1-3, 5	1,9-15
X	WO 2014/161099 A1 (MEDELA HOLDING AG [CH]) 9 October 2014 (2014-10-09) cited in the application page 6, line 10 - page 9, line 10 figures 1, 6-9	1,3-5,9, 15
Y	EP 0 266 590 A2 (BRAUN MELSUNGEN AG [DE]) 11 May 1988 (1988-05-11) page 3, lines 29-40	2

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2017/073155

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		CN 107205356 A	26-09-2017
		EP 3193587 A1	26-07-2017
		US 2016082165 A1	24-03-2016
		WO 2016044802 A1	24-03-2016
US 2016220743 A1	04-08-2016	US 2016220743 A1	04-08-2016
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US 2015038945 A1	05-02-2015	CA 2897763 A1	25-01-2016
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		CH 707857 A1	15-10-2014
		CN 105228667 A	06-01-2016
		EP 2981306 A1	10-02-2016
		HK 1218268 A1	10-02-2017
		TW 201509444 A	16-03-2015
		US 2016038662 A1	11-02-2016
		WO 2014161099 A1	09-10-2014
EP 0266590 A2	11-05-1988	DE 3637771 C1	10-12-1987
		EP 0266590 A2	11-05-1988
		ES 2021672 B3	16-11-1991
		GR 3002145 T3	30-12-1992
		JP H0459915 B2	24-09-1992
		JP S63132666 A	04-06-1988
		US 4832689 A	23-05-1989

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/EP2017/073155

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
INV. A61M1/06
ADD.

Nach der Internationalen Patentklassifikation (IPC) oder nach der nationalen Klassifikation und der IPC

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
A61M

Recherchierte, aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
EPO-Internal, WPI Data

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X Y	US 2016/082165 A1 (ALVAREZ JEFFERY B [US] ET AL) 24. März 2016 (2016-03-24) Absätze [0107] - [0120], [0151] - [0152] Abbildungen 1, 11c-e, h, j 25	1,3,4, 6-15 2
X	US 2016/220743 A1 (GUTHRIE GABRIELLE V [US] ET AL) 4. August 2016 (2016-08-04) Absätze [0063] - [0071] Abbildungen 5-8, 10-12	1,3,4,15
X	US 2015/038945 A1 (MCCABE JILL C [US]) 5. Februar 2015 (2015-02-05) Absätze [0015] - [0024] Abbildungen 1, 2	1,13-15

-/--

[X] Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen [X] Siehe Anhang Patentfamilie

* Besondere Kategorien von angegebenen Veröffentlichungen :
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"&" Veröffentlichung, die Mitglied derselben Patentfamilie ist

Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
15. November 2017	28/11/2017

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Schlaug, Martin

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Internationales Aktenzeichen
PCT/EP2017/073155

C. (Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	US 2016/082166 A1 (GUTHRIE GABRIELLE V [US] ET AL) 24. März 2016 (2016-03-24) in der Anmeldung erwähnt Absätze [0025], [0037] - [0038] Abbildungen 1-3, 5	1,9-15
X	WO 2014/161099 A1 (MEDELA HOLDING AG [CH]) 9. Oktober 2014 (2014-10-09) in der Anmeldung erwähnt Seite 6, Zeile 10 - Seite 9, Zeile 10 Abbildungen 1, 6-9	1,3-5,9, 15
Y	EP 0 266 590 A2 (BRAUN MELSUNGEN AG [DE]) 11. Mai 1988 (1988-05-11) Seite 3, Zeilen 29-40	2

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INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationales Aktenzeichen
PCT/EP2017/073155

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
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		TW 201509444 A	16-03-2015
		US 2016038662 A1	11-02-2016
		WO 2014161099 A1	09-10-2014
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		EP 0266590 A2	11-05-1988
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		GR 3002145 T3	30-12-1992
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		JP S63132666 A	04-06-1988
		US 4832689 A	23-05-1989

(19)日本国特許庁(JP)　(12)公表特許公報(A)　(11)特許出願公表番号
特表2016-508804
(P2016-508804A)
(43)公表日　平成28年3月24日(2016.3.24)

(51)Int.Cl.		F I		テーマコード（参考）
A61M 1/06	(2006.01)	A61M	1/06	4C077

審査請求 未請求　予備審査請求 未請求　（全 26 頁）

(21)出願番号	特願2015-560666 (P2015-560666)
(86)(22)出願日	平成26年3月5日 (2014.3.5)
(85)翻訳文提出日	平成27年9月30日 (2015.9.30)
(86)国際出願番号	PCT/EP2014/054197
(87)国際公開番号	WO2014/135553
(87)国際公開日	平成26年9月12日 (2014.9.12)
(31)優先権主張番号	61/772,597
(32)優先日	平成25年3月5日 (2013.3.5)
(33)優先権主張国	米国 (US)
(31)優先権主張番号	13157739.7
(32)優先日	平成25年3月5日 (2013.3.5)
(33)優先権主張国	欧州特許庁 (EP)

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(74)代理人　110001690
特許業務法人M&Sパートナーズ

最終頁に続く

(54)【発明の名称】搾乳器のライナー及び乳房インターフェース

(57)【要約】
乳房インターフェース７０に使用するライナー１００である。当該ライナーは、乳房接触面１１８を画成する前壁部１１２と、乳房接触面に設けられた開口１１６ｂとを含み、乳房接触面１１８は、使用時に、女性の乳房に当接する一方で、乳房の乳首は、開口１１６ｂを通り少なくとも部分的に突出する前部セクション１１０と、前部セクション１１０に接続され、後端開口を有する管状壁部１７１を含む後部セクション１７０とを含み、前部セクション１１０及び後部セクション１７０は共に、乳房接触面１１８における開口１１６ｂから管状壁部１７１における後端開口まで延在し、後方方向において下方向に傾斜する乳用通路１９０を画成する。

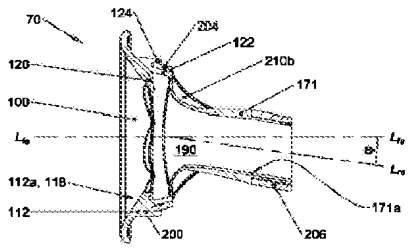

Fig. 7A

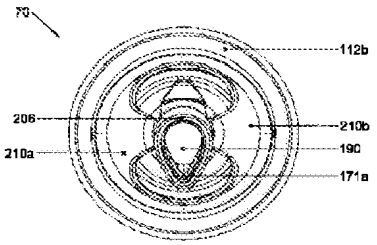

Fig. 7B

【特許請求の範囲】
【請求項１】
乳房インターフェースにおける使用のためのライナーであって、
乳房接触面を画成する前壁部と、前記乳房接触面に設けられた開口とを含み、前記乳房接触面は、使用時に、女性の乳房に当接する一方で、前記乳房の乳首は、前記開口を通り少なくとも部分的に突出する、前部セクションと、
前記前部セクションに接続され、後端開口を有する管状壁部を含む後部セクションと、
を含み、
前記前部セクション及び前記後部セクションは共に、前記乳房接触面における前記開口から前記管状壁部における前記後端開口まで延在する乳用通路を少なくとも部分的に画成し、
前記ライナーは、前記前部セクションの長手軸が実質的に水平に延在する使用姿勢に関連付けられる一方で、前記後部セクションの前記管状壁部は、前記乳用通路を部分的に境界付け、また、前記使用姿勢において、後方方向において見た場合に、前記長手軸に対して下方向に傾斜する下部内側表面部分を有し、前記後部セクションの前記管状壁部は、ティアドロップ形状の横断面を有し、前記ティアドロップ形状の横断面の細い部分は、溝を画定し、前記溝の底部は、前記下部内側表面部分によって画成される、ライナー。
【請求項２】
前記前部セクションの前記長手軸は、前記乳房接触面における前記開口の平面に実質的に垂直に延在する、請求項１に記載のライナー。
【請求項３】
前記下部内側表面部分は、前記後部セクションの前記管状壁部の実質的に全長に亘って延在する、請求項１又は２に記載のライナー。
【請求項４】
前記下部内側表面部分は、実質的に一定の傾斜角度で、前記前部セクションの前記長手軸に対して下方向に傾斜する、請求項１乃至３の何れか一項に記載のライナー。
【請求項５】
前記使用姿勢において、前記下部内側表面部分は、前記前部セクションの前記長手軸に対して１０～４５度の範囲内の平均下方向傾斜角度を有する、請求項１乃至４の何れか一項に記載のライナー。
【請求項６】
前記ライナーの前記前部セクションは、前記ライナーの前部円周エッジと後部円周エッジの径方向位置間の径方向位置において、前記前壁部の背面に接続し、前記前壁部の前記背面から、後方方向に延在する環状基部壁部を含み、前記前壁部は、環状の（乳）逆流バリアを形成するように、前記環状基部壁部を越えて径方向内側に延在する、請求項１乃至５の何れか一項に記載のライナー。
【請求項７】
前記前部セクションと前記後部セクションとの間に、前記後部セクションが前記前部セクションに中間セクションを介して接続されるように配置され、後部のテーパする漏斗状壁部を含む、前記中間セクションを更に含む、請求項１乃至６の何れか一項に記載のライナー。
【請求項８】
搾乳器用の乳房インターフェースであって、
ライナーの少なくとも一部を受容するライナー支持フレーム内部空間を画成し、前部リングと、後部リングと、前記前部リング及び前記後部リングを、前記前部リング及び前記後部リングが軸方向において離間されているように、相互接続する少なくとも１つのアームと、を含む、ライナー支持フレームと、
請求項１乃至７の何れか一項に記載のライナーと、
を含み、
前記ライナーの前記前部セクションは、前記ライナー支持フレームの前記前部リングに

係合する一方で、前記ライナーの前記後部セクションの前記管状壁部は、前記ライナー支持フレームの前記後部リングによって、嵌るように受容される、乳房インターフェース。

【請求項９】

前記ライナーの前記後部セクションの前記管状壁部の後端には、前記ライナー支持フレームの前記後部リングの内径よりも大きい外径を有し、また、前記乳房インターフェースの組み立てられた状態では、端部において、前記後部リングに当接する第１の環状フランジが設けられ、

前記後部リングは、前記ライナーの前記フランジが付いた後端の通過を容易とするように、互いに対して再配置可能である少なくとも２つの相補形の円周後部リング部分を含む分割後部リングである、請求項８に記載の乳房インターフェース。

【請求項１０】

請求項８又は９に記載の乳房インターフェースを含む搾乳器。

【発明の詳細な説明】

【技術分野】

【０００１】

本開示は、搾乳器に使用する乳房インターフェースに関し、当該乳房インターフェースは、フレキシブルライナーと、概して剛性であるライナー支持フレームとを含む。

【背景技術】

【０００２】

搾乳器は、当技術分野においてよく知られている。搾乳器は、通常、乳房にフィットする乳房インターフェース又は乳房シールドと、乳房インターフェース内に真空（負圧）を発生させるために乳房インターフェースと接続可能である真空ポンプとを含む。真空によって、乳房インターフェースは、乳房に引っ張られ、乳を搾り出すために乳房をマッサージする。搾り出された乳は、乳房インターフェースから集乳器に流れる。集乳器は、搾乳器に取り外し可能に接続される。

【０００３】

米国特許出願公開第２００９／０１７１２７０号は、搾乳器の付属装置について開示している。付属装置は、長手軸を有する漏斗形適用部と、適用部に隣接し、固定部によって接合される接続部とを有する。適用部は、適用部の長手軸が、固定部の回転軸に対し１８０°から逸れる角度位置に配置されるように、固定部に対してピボット可能に構成される。

【０００４】

米国特許出願公開第２００６／０１１６６３２号には、通路を形成する乳房シールドを含むリクライニング搾乳システムが開示されている。通路の一端に隣接する材料が、女性の乳首の周りの乳房にフィットするように成形されるフランジを形成する。通路のもう一端から延在する材料は、管を形成する。乳房の乳輪に平行な平面が、管の軸に垂直な平面から実質的に傾斜されて、管の偏差角が規定される。

【０００５】

米国特許出願公開第２００５／０２２２５３６号は、搾乳器の乳房シールドについて開示している。乳房シールドの第１の端は、広い横断面を有し、概して断面形状は円形である。第１の端は更に、円周フランジを含む。乳首トンネルが第１の端へと開き、第２の及び下流の端に向かって長手方向に延在する。乳房シールドの本体全体は、概して円筒形であり、乳房シールドは、その長手方向の長さに沿って湾曲していてもよい。

【０００６】

米国特許第６，９７４，４３９号は、乳房にフィットするカップアセンブリを有する少なくとも１つのエキスプレッサを含む搾乳デバイスについて開示している。カップアセンブリは、ベル状のハウジングと、比較的柔らかいドーナツ型パッドと、フレキシブルライナーとを含む。ライナーは、乳の入口開口付近では相対的に細い部分を、細い部分とカップアセンブリの出口端との間では広い部分とを有する。

【発明の概要】

【発明が解決しようとする課題】
【０００７】
従来の乳房インターフェースに関連付けられる問題は、それを使用する女性が、自身の乳房から搾り出された乳が確実に集乳器に向かい、その中に流れるように、前傾になる必要がある点である。１回の搾乳セッションには時間がかかり、特には３０分以上にも及ぶため、前傾姿勢は不快となる。
【０００８】
本開示は、上記問題を解決する又は少なくとも軽減するライナー及び当該ライナーを含む乳房インターフェースを提供することを目的とする。
【課題を解決するための手段】
【０００９】
このために、本開示の第１の態様は、乳房インターフェースに使用するライナーに関する。当該ライナーは、乳房接触面を画成する前壁部と、乳房接触面に設けられた開口とを含む前部セクションを含む。乳房接触面は、使用時に、女性の乳房に当接する一方で、乳房の乳首は、開口を通り少なくとも部分的に突出する。ライナーは更に、前部セクションに接続され、ライナーから乳を放出するための後端開口を有する管状壁部を含む後部セクションを含む。前部及び後部セクションは共に、乳房接触面における開口から管状壁部における後端開口まで延在する乳用通路を少なくとも部分的に画成する。更に、ライナーは、通常は、乳房接触面における開口の平面に実質的に垂直に延在する前部セクションの長手軸が実質的に水平に延在する使用姿勢に関連付けられる一方で、後部セクションの管状壁部は、乳用通路を部分的に境界付け、また、使用姿勢において、後方方向において見た場合に、長手軸に対して下方向に傾斜する下部内側表面部分を有する。後部セクションの管状壁部は、ティアドロップ形状の横断面を有する。ティアドロップ形状の横断面の細い部分は、溝を画定し、溝の底部は、下部内側表面部分によって画成される。
【００１０】
使用時、ここに開示されるライナーは、当該ライナーの前部セクションの乳房接触面が女性の乳房に接触するように、その使用姿勢に保持される。ライナーの前部セクションの長手軸は、実質的に水平に延在するが、後部セクションの管状壁部の下部内側表面部分は、それに対して下方向に傾斜する。したがって、乳房から搾り出された乳は、乳用通路を通り、管状壁部の後端開口に向かって自然に導かれ、後部開口に、動作上、接続される集乳器内に放出される。重力の作用による乳のライナーを通る自然な流れは、乳を搾り出す女性が前傾する必要をなくす。
【００１１】
ライナーの好適な実施形態では、下部内側表面は、後部セクションの管状壁部の実質的に全長に亘って延在する。下部内側表面部分は、好適には、実質的に一定の傾斜角度（φ）で、前部セクションの長手軸に対して下方向に傾斜する。使用姿勢において、下部内側表面部分は、前部セクションの長手軸に対して、好適には、１０～４５度の範囲内の平均下方向傾斜角度を有する。
【００１２】
本開示の第２の態様は、乳房インターフェースに関する。当該乳房インターフェースは、ライナーの少なくとも一部も受容するライナー支持フレーム内部空間を画成するライナー支持フレームを含む。ライナー支持フレームは、前部リングと、後部リングと、前部リング及び後部リングを、前部リング及び後部リングが軸方向において離間されているように、相互接続する少なくとも１つのアームとを含む。当該乳房インターフェースは更に、本開示の第１の態様によるライナーも含み、ライナーの前部セクションは、ライナー支持フレームの前部リングに係合する一方で、ライナーの後部セクションの管状壁部は、ライナー支持フレームの後部リングによって、嵌るように受容される。
【００１３】
特に好都合に組み立て可能な乳房インターフェースを詳細に説明すると、ライナーの後部セクションの管状壁部の後端には、ライナー支持フレームの後部リングの内径よりも大

きい外径を有し、また、乳房インターフェースの組み立てられた状態では、端部において、後部リングに当接する第１の環状フランジが設けられる。また、後部リングは、ライナーのフランジが付いた後端の通過を容易とするように、互いに対して再配置可能である少なくとも２つの相補形の円周後部リング部分を含む分割後部リングである。

【００１４】

本開示の第３の態様は、本開示の第２の態様による乳房インターフェースを含む搾乳器に関する。

【００１５】

本発明のこれらの及び他の特徴及び利点は、本発明を例示するものであって限定することを意図していない添付図面と共に参照することによって、本発明の特定の実施形態の以下の詳細な説明からより深く理解できよう。

【図面の簡単な説明】

【００１６】

【図１Ａ】図１Ａは、女性の乳房に接触する乳房インターフェースの第１の例示的な実施形態を含む、本開示による搾乳器の一実施形態を概略的に示す斜視図である。

【図１Ｂ】図１Ｂは、女性の乳房に接触する乳房インターフェースの第１の例示的な実施形態を含む、本開示による搾乳器の一実施形態を概略的に示す部分的に分解された側断面図である。

【図２Ａ】図２Ａは、ライナーとライナー支持フレームとの両方を含む図１に示される搾乳器の乳房インターフェースの第１の例示的な実施形態を概略的に示す斜視図である。

【図２Ｂ】図２Ｂは、ライナーとライナー支持フレームとの両方を含む図１に示される搾乳器の乳房インターフェースの第１の例示的な実施形態を概略的に示す側面図である。

【図２Ｃ】図２Ｃは、ライナーとライナー支持フレームとの両方を含む図１に示される搾乳器の乳房インターフェースの第１の例示的な実施形態を概略的に示す、図２Ｄと相互に垂直な側断面図である。

【図２Ｄ】図２Ｄは、ライナーとライナー支持フレームとの両方を含む図１に示される搾乳器の乳房インターフェースの第１の例示的な実施形態を概略的に示す、図２Ｃと相互に垂直な側断面図である。

【図３Ａ】図３Ａは、図２に示される乳房インターフェースの第１の例示的な実施形態のライナーを切り離して概略的に示す斜視図である。

【図３Ｂ】図３Ｂは、図２に示される乳房インターフェースの第１の例示的な実施形態のライナーを切り離して概略的に示す側面図である。

【図３Ｃ】図３Ｃは、図２に示される乳房インターフェースの第１の例示的な実施形態のライナーを切り離して概略的に示す正面図である。

【図３Ｄ】図３Ｄは、図２に示される乳房インターフェースの第１の例示的な実施形態のライナーを切り離して概略的に示す背面図である。

【図４Ａ】図４Ａは、図２に示される乳房インターフェースの第１の例示的な実施形態のライナー支持フレームを概略的に示す斜視図である。

【図４Ｂ】図４Ｂは、図２に示される乳房インターフェースの第１の例示的な実施形態のライナー支持フレームを概略的に示す側面図である。

【図４Ｃ】図４Ｃは、図２に示される乳房インターフェースの第１の例示的な実施形態のライナー支持フレームを概略的に示す正面図である。

【図５Ａ】図５Ａは、ライナー支持フレームが２つの取り外し可能な相補形の半体を含む、本開示による乳房インターフェースの第２の例示的な実施形態を概略的に示す斜視図である。

【図５Ｂ】図５Ｂは、ライナー支持フレームが２つの取り外し可能な相補形の半体を含む、本開示による乳房インターフェースの第２の例示的な実施形態を概略的に示す斜視図である。

【図６Ａ】図６Ａは、ライナー支持フレームがヒンジを介して接続される２つの相補形の半体を含む、本開示による乳房インターフェースの第３の例示的な実施形態を概略的に示

す斜視図である。
【図６Ｂ】図６Ｂは、ライナー支持フレームがヒンジを介して接続される２つの相補形の半体を含む、本開示による乳房インターフェースの第３の例示的な実施形態を概略的に示す斜視図である。
【図７Ａ】図７Ａは、ライナーがティアドロップ形の内側断面形状を有する管状後部セクションを含む、本開示による乳房インターフェースの第４の例示的な実施形態を概略的に示す側断面図である。
【図７Ｂ】図７Ｂは、ライナーがティアドロップ形の内側断面形状を有する管状後部セクションを含む、本開示による乳房インターフェースの第４の例示的な実施形態を概略的に示す背面図である。
【発明を実施するための形態】
【００１７】
図１は、本開示による例示的な搾乳器１を、斜視図で概略的に示す。搾乳器１は、真空ポンプ１０と、連結器３０と、例えば哺乳瓶である集乳器５０と、第１の例示的な実施形態の乳房インターフェース７０とを含む。
【００１８】
連結器３０は、第１のチャネル３４を画成する第１の略垂直に延在する管状セグメント３２と、第１の管状セグメント３２から斜めに及び／又は外側に延在し、第１のチャネル３４と流体連通する第２のチャネル３８を画成する第２の管状セグメント３６とを含む。第１の管状セグメント３２の下端において、連結器３０は、集乳器５０とのねじ込み接続のための内側ねじ山を有するねじ込みソケット４０を含み、集乳器５０の上端には、相補形の外側ねじ山が設けられている。第１の管状セグメント３２の反対側の上端は、第１のチャネル３４及び第２のチャネル３８に真空を与える真空ポンプ１０に接続される。真空ポンプ１０は、図示される実施形態にあるように、手動の真空ポンプであっても、電気的真空ポンプであってもよく、真空ポンプ自体は、従来のデザインであり、本明細書では説明されない。第２の管状セグメント３６の外側端は更に、真空ポンプ１０と、集乳器５０と、乳房インターフェース７０とが連結器３０を介して空気圧連結する一方で、集乳器５０と乳房インターフェース７０との間で流体連通が可能であるように、乳房インターフェース７０の後端を、圧入式に受容する受容路４２を画成する。当然ながら、搾乳器１の様々な実施形態は、上記され、図示されたものとは異なる形状及び構造を有する連結器３０を含んでもよく、また、特に真空ポンプ１０及び集乳器５０を連結器３０に接続するために使用される接続の種類は、例えばねじ山、スナップ式等の任意の適切なタイプであってよい。
【００１９】
概念的に、乳房インターフェース７０は、２つのコンポーネント、即ち、フレキシブルライナー１００と、頑丈で比較的硬く、即ち、剛性のライナー支持フレーム２００とを含む。ライナー１００及びライナー支持フレーム２００は、通常は、２つの別個の構造コンポーネントとして形成され、これらは、使用時には、乳房インターフェース７０を形成するように合せて組み立てられる必要があり、また、コンポーネントのうちの片方を洗浄及び交換し易くするために、後に、分解されてもよい。しかし、ライナー１００及びライナー支持フレーム２００は、乳房インターフェース７０の構造部品の数を少なくするように、或いは、単一の構造コンポーネントとして一体に形成される（例えばコモールドされる）ことも考えられる。
【００２０】
以下、本開示による乳房インターフェース７０のライナー１００及びライナー支持フレーム２００の構造について説明される。まず、図１乃至図４に示される乳房インターフェース７０の第１の例示的な実施形態のライナー１００及びライナー支持フレーム２００について、幾つかの考えられる変形態様も考慮しながら、説明される。続いて、図５、図６及び図７をそれぞれ参照して、乳房インターフェース７０の特に有利な第２の、第３の及び第４の例示的な実施形態について説明される。

【００２１】
ここでは、特に図２及び図３を参照する。ライナー１００は、３つの、通常は、一体に形成されるセクション、即ち、前部セクション１１０、中間セクション１４０、及び、後部セクション１７０を含む。各セクションは、各セクションを画成する少なくとも１つの壁部を含む。
【００２２】
ライナー１００の前部セクション１１０は、後方向にテーパする略円錐又はカップ状の前壁部１１２を含み、当該前壁部１１２は、前部開口１１６ａを境界付ける前部の径方向外側の円周エッジ１１４ａと、中央後部開口１１６ｂを境界付ける後部の径方向内側の円周エッジ１１４ｂとの間で延在する。円周エッジ１１４ａ、１１４ｂの間で軸方向に、前壁部１１２の前面１１２ａは、略円錐状の乳房接触面１１８を画成する。
【００２３】
ライナー１００の前部セクション１１０は更に、環状基部壁部１２２を含む。環状基部壁部１２２は、前壁部１１２の背面１１２ｂに、前部円周エッジ１１４ａと後部円周エッジ１１４ｂの径方向位置間の径方向位置において、接続し、前壁部１１２の背面１１２ｂから、後方方向に延在する。したがって、これらの環状接合部に沿って、前壁部１１２は、環状（乳）逆流バリア１２０が形成されるように、基部壁部１２２を越えて径方向内側に延在すると見なされる。
【００２４】
前部セクション１１０は、環状リップ壁部１２４も含む。環状基部壁部１２２と同様に、環状リップ壁部１２４は、前壁部１１２の背面１１２ｂに、前部円周エッジ１１４ａと後部円周エッジ１１４ｂの径方向位置間の径方向位置において、接続し、前壁部１１２の背面１１２ｂから、後方方向に延在する。環状リップ壁部１２４及び環状基部壁部１２２は、互いに円周方向において平行に延在する。環状リップ壁部１２４は、径方向外側のリップ壁部１２４と径方向内側の基部壁部１２２との間に、環状溝１２６が画成されるように、より大きい動径座標において延在する。環状溝１２６は、ライナー支持フレーム２００の前部リング２０４（図２Ｃ及び図２Ｄを参照）を受容係合し、したがって、前部リング２０４の（略径方向の）幅に等しい又は当該幅よりも僅かに小さい（略径方向の）幅を有する。
【００２５】
使用中、ライナー１００の前部セクション１１０は、円錐状の前壁部１１２によって境界付けられる内部空間が乳房の容器として機能を果たすように、女性の乳房に置かれ、乳房は、この内部空間内に少なくとも部分的に受容される。乳房の乳輪及び乳首、又は、少なくとも乳首は、前壁部１１２にある中央後部開口１１６ｂを通り突出する一方で、乳房接触面１１８は、乳房がライナー１００のより奥に挿入又は吸い込まれないように、乳房の乳輪の周囲部分に当接する止め具として機能する。
【００２６】
ライナー１００の前部セクション１１０は、使用中にその形状を実質的に維持するように構成される。即ち、前部セクション１１０は、著しく変形することを意図していない。しかし、ライナー１００の上記された中間セクション１４０は、動作中に乳房の乳首上に左右対称に凹むように構成される。中間セクション１４０は、前部セクション１１０（の基部壁部１２２）の後端に接続される。ライナー１００の中間セクション１４０が、制御されたやり方で、確実に左右対称に凹むのを促進するように、ライナー１００の前部セクション１１０の環状溝１２６と、その中に受容されるライナー支持フレーム２００の前部リング２０４とは、異なる円周形状を有する。形状の違いは、乳房インターフェース７０の組立ての際に、前部リング２０４は環状溝１２６に挿入され、前部セクション１１０（したがって、そこに接続されている中間セクション１４０）は、第１の径方向に沿って伸張され／広げられ、第１の径方向に実質的に垂直な第２の径方向に沿って圧縮される／狭くされるような違いであることが好適である。
【００２７】

一実施形態では、例えば環状溝１２６は、円形の円周形状を有する一方で、ライナー支持フレーム２００の前部リング２０４は、楕円形状を有する。前部リング２０４の楕円形状は、長軸及び短軸の観点から説明される。これらの軸は共に、乳房インターフェース７０のコンテキストでは、径方向に延在する軸である。これは、乳房インターフェース７０の長手軸Ｌに垂直に延在するからである。長軸は、円形溝の直径よりも僅かに大きい長さを有する一方で、短軸は、円形溝の直径よりも僅かに小さい長さを有する。したがって、ライナー１００の前部セクション１１０は、環状溝１２６内に前部リング２０４が挿入されると、圧縮応力が掛けられる。つまり、前部セクション１１０は、楕円形の前部リング２０４の長軸に沿って伸張され、前部リング２０４の短軸に沿って圧縮される。前部セクション１１０、したがって、そこに接続される中間セクション１４０のこの圧縮応力は、短軸に沿った中間セクションの左右対称の圧潰を促進する。

【００２８】

環状溝１２６と楕円形前部リング２０４とを含む乳房インターフェース７０の上記実施形態の欠点は、ライナー１００の中間セクション１４０の特定の壁剛性分布との前部リング２０４の短軸及び／又は長軸の回転位置ずれの影響を受けやすい点である。以下において明確にされるように、ライナー１００の中間セクション１４０は、その壁部に、細長い、比較的剛性の部分１４６（例えばリブ）を含む。リブ１４６は、中間セクション１４０の両側の壁部１４２、１４４上に延在し、ライナーの内部１８０が排気された時に、ライナー１００の制御された左右対称の圧潰を促進する。このようなリブ１４６を含む一実施形態では、中間セクション１４０のリブは、２つの特徴、即ち、壁剛性分布と、円形の環状溝１２６と楕円形の前部リング２０４との形状差異とである２つの特徴が、左右両側の圧潰をもたらす際に、互いに協働し、強化するように、前部リング２０４の長軸と回転位置合わせされることが好適である。しかし、乳房インターフェース７０の組立ての際、ライナー支持フレーム２００の前部リング２０４の主軸及び短軸は、例えば前部リングの短軸がリブと回転位置合わせされるように、ライナー１００の中間セクション１４０の壁剛性分布と容易に位置ずれし、これは、２つの特徴が、互いの意図された効果を妨害してしまう。

【００２９】

可能な位置ずれの問題を防止するために、乳房インターフェース７０の好適な実施形態は、その前部セクション１１０がｘ個の対称軸（を有する円周形状）を有する環状溝１２６を含むライナー１００と、ｙ個の対称軸（を有する円周形状）を有する環状前部リング２０４を含むライナー支持フレーム２００とを特徴とする。このとき、ｘ＜ｙである。このような好適な実施形態では、壁剛性分布に関連する非対称性と、ライナーの制御された左右両側の圧潰を促進する環状溝１２６と前部リング２０４との形状差異とは共に、製造時にライナー１００に組み込まれ、これは、組立て時におけるユーザによるライナー１００とライナー支持フレーム２００との可能な回転位置ずれの問題を未然に防ぐ。１つの好適な実施形態では、例えばライナー１００は、例えば楕円形（２つの対称軸）又は長円形（１つの対称軸）である非円形の環状溝１２６を含む前部セクションを有し、ライナー支持フレーム２００は、当該溝に挿入するための円形の前部リング２０４（無限の対称軸）を有する。図３に、このようなライナー実施形態１００が示される。図３Ｄの背面図には、楕円形の環状溝１２６の長軸A_{maj}及び短軸A_{min}と、中間セクション１４０の壁部１４２、１４４に延在する２つの向かい合うリブ１４６とが特定されている。図面から分かるように、楕円形の環状溝１２６の短軸A_{min}は、リブ１４６が離間されている方向と回転位置合わせされ、これにより、ライナー支持フレーム２００の前部リング２０４のライナー１００の前部セクション１１０の環状溝１２６内への挿入が、ライナーに短軸A_{min}に沿って圧縮応力を掛け、長軸A_{maj}に沿ったライナーの圧潰を促進する。別の実施形態では、ライナーは、長方形で、非正方形の溝（２つの対称軸）を含む前部セクションを有し、ライナー支持フレームは、正方形の前部リング（４つの対称軸）を有してもよい。

【００３０】

一般に、ユーザが、操作時に、乳房、具体的には、乳首を観察できることが望ましい。このために、ライナー１００は、透明である一方で、ライナー支持フレーム２００は、以下により詳細に説明されるように、ライナー支持フレーム内部空間２０２の視覚検査を可能とするようにアクセス窓２１２を画成するアーム２１０ａ、２１０ｂを有する開放フレーム構造体を含んでもよい。しかし、ライナー支持フレーム２００のアーム２１０ａ、２１０ｂが、偶然に、ライナー１００の中間セクション１４０の壁部の圧潰しない部分に、回転位置合わせされた場合、アーム２１０ａ、２１０ｂは、壁部のこれらの圧潰しない部分を介した乳房の良好な視界を妨げる。圧潰しない壁部分が、アクセス窓２１２の前に、明白に位置決めされるように、ユーザが乳房インターフェース７０を組み立てるのに役立つように、ライナー１００、特にその前部セクション１１０には、少なくとも１つのマーク１２８が設けられていてもよい。マーク１２８は、組立ての際に、ライナー支持フレーム２００のアーム２１０ａ、２１０ｂと回転位置合わせされる。当然ながら、マーク１２８は、マーク１２８のアーム２１０ａ、２１０ｂとの回転位置合わせが、アクセス窓２１２を介する壁部の圧潰しない部分の望ましい視認性がもたらされるように位置付けられるべきである。一実施形態では、ライナー１００上のマーク１２８の数は、ライナー支持フレーム２００のアーム２１０ａ、２１０ｂの数と一致してもよく、これにより、各マーク１２８は、対応するアーム２１０ａ、２１０ｂと位置合わせされる。マーク１２８は、ライナー１００の外側にエンボス加工された矢じり、又は、マークが位置合わせされる必要のあるアーム２１０ａ、２１０ｂの（接線方向）幅と略等しい（接線方向）幅を有する隆起された表面部分といった様々な形態であってよい。

【００３１】

原則的に、前壁部１１２によって画成される中央後部開口１１６ｂは、任意の適切な円周形状を有してよい。一実施形態では、例えば中央後部開口１１６ｂは円形である。しかし、円形の中央後部開口は、幾つかの欠点を有する。１つのそのような欠点は、操作中、搾乳器１は、女性の乳房に真空を印加することがあるという事実に関連する。この真空は、乳房の皮膚、特に、皮膚が中央後部開口１１６ｂの円形の円周エッジ１１４ｂに接触する場所の発赤を引き起こす。乳房に付いた円周エッジ１１４ｂの赤みを帯びた跡は、白癬といった真菌感染症の兆候として誤って受け取られてしまうことがある。円形の中央後部開口のもう１つの欠点は、逆流バリア１２０及び基部壁部１２２によって画成されるアンダーカットが著しい場合がある点である。これは、製造時のモールドからのライナー１００の取り外しと、使用後のライナーの適切な洗浄との両方を妨げる。

【００３２】

これらの欠点を解決する又は少なくとも軽減するために、ライナー１００の好適な実施形態は、非円形の形状を有する中央後部開口１１６ｂを画成する前壁部１１２を含む。中央後部開口部１１６ｂは、例えば図３Ｃに明らかに示されるように、５枚の花びらを有する花といった花の形状を有する。例えば図３Ｃに示されるものとは花びらの数が異なる及び／又は花びらの形状が異なる様々な花の形状、又は、星形といった全く異なる形状が使用されてもよい。中央後部開口１１６ｂの円周エッジ１１４ｂの形状の径方向における変動によって、非円形の開口は、概して、乳房に赤みを帯びた円形の跡が付くことを阻止し、アンダーカットをよりアクセスし易くすることによって、アンダーカットを洗浄し易くする。中央後部開口１１６ｂの非円形の形状は、外観があまり機械的でなく、搾乳器１を使用する女性に装飾的及び魅力的に見えるという追加のメリットを提供する。

【００３３】

ライナー１００の中間セクション１４０は、２つの壁部、即ち、（ｉ）Ｓ字形曲線を有する接続壁部１４２と、（ｉｉ）後部のテーパする漏斗状壁部１４４とを含む。Ｓ字形曲線を有する接続壁部は、前部セクション１１０の基部壁部１２２（の後端）を、中間セクション１４０の漏斗状壁部１４４の広い前端に接続する。

【００３４】

中間セクション１４０によって境界付けられる内部空間１８０は、圧力チャンバを画成する。使用時、搾乳器１の真空ポンプ１０は、圧力チャンバ１８０に真空を印加し、これ

により、ライナー１００の中間セクション１４０が、交互に、（ｉ）乳房の乳首上に圧潰し、（ｉｉ）その弛緩形状を再確立する又はその弛緩形状に戻るように広がる。

【００３５】

Ｓ字形曲線を有する接続壁部１４２は、圧力チャンバ１８０が真空の影響を受ける時の中間セクション１４０の圧潰と、真空が除去された場合のその弛緩形状の再確立との両方を容易にする働きをする。Ｓ字形曲線を有する接続壁部は、その名称の由来が、その長手方向の断面形状（弛緩状態における）にある。当該長手方向の断面形状は、図２Ｃにおいて最もよく見えるように、Ｓ字形曲線、即ち、二重曲げ又は二重ひだを規定する。Ｓ字形曲線は、ライナー１００の前部セクション１１０の基部壁部１２２（の後端）にすぐ隣に配置され、ライナー１００の長手軸Ｌの周りに回転対称である。Ｓ字形曲線を有する接続壁部１４２は、事実上、圧力チャンバ１８０が真空の影響を受ける時に、ライナー１００の中間セクション１４０が容易に変形し、したがって、内側に圧潰することを可能とする余分の壁部材料を提供する。更に、Ｓ字形曲線を有する接続壁部１４２は、圧力チャンバ１８０内の真空が取り消されると、その弛緩形状に戻るように変形するように構成される。

【００３６】

ライナー１００の中間セクション１４０は、後部から前部にかけて生じる、乳首へのその安全で、繰り返し可能で、左右両側での蠕動性の圧潰を確実とするように構成されることが好適である。このような圧潰を確実とすることに役立つように、中間セクション１４０の一方又は両方の壁部１４２、１４４は、長手軸Ｌの周りに２回転対称を有する剛性分布を有する。このために、壁部１４２、１４４は、例えば、対応する壁部１４２、１４４に沿って又は対応する壁部１４２、１４４内で、略径方向／長手方向に延在する例えば壁部の比較的剛性部分である細長いリブ１４６を含む。一実施形態では、このようなリブ１４６は、壁部の比較的厚い部分によって形成され、これは、ライナー１００が、単一の均質材料、又は、少なくとも、ライナー１００の壁部全体に亘って一様である弾性係数を有する材料から製造できるという利点を提供する。別の実施形態では、リブ１４６は、相互に異なる弾性係数を有する少なくとも２つの構成材料を使用して実現されてもよい。このような実施形態では、リブ１４６は、第１の構成材料で作られる一方で、Ｓ字形曲線を有する壁部１４２及び／又は漏斗状壁部１４４の隣接する又は周囲の部分は、第１の構成材料の弾性係数よりも小さい弾性係数を有する第２の構成材料で作られる。

【００３７】

図３に示されるライナー１００の実施形態では、ライナーの中間セクション１４０は、Ｓ字形曲線を有する接続壁部１４２と漏斗状壁部１４４との両方の壁部の比較的厚い部分によって画成される２つの（接線方向に）広く、（長手方向に）細長いリブ１４６を含む。リブ１４６は、中間セクション１４０の直径方向において両側に位置付けられる。使用時、真空が圧力チャンバ１８０に印加されると、壁部１４２、１４４のリブ付き部分は、その直径方向において両側にあるリブなし部分よりも多くの圧潰に対する抵抗を提供し、これにより、リブなし部分の互いに向かう左右両側の圧潰の方が好まれる。

【００３８】

ライナー１００の後部セクション１７０は、略軸方向に延在する管状又はパイプ状壁部を含み、ライナーの中間セクション１４０の漏斗状壁部１４４によって画成される漏斗の延長部を形成すると見なされる。したがって、中間セクション１４０の漏斗状壁部１４４の後端は、後部セクション１７０の管状壁部の前端に接続される。

【００３９】

ライナー１００の後部セクション１７０の管状壁部は、原則的に、任意の内側及び／又は外側横断面を有する。例えば図２乃至図４に示されるライナー１００の第１の例示的な実施形態は、略円形の内側及び／又は外側横断面を有する後部セクション１７０を有する。或いは、後部セクション１７０の管状壁部は、図７に示される第４の例示的な実施形態にあるように、例えば略ティアドロップ形の内側及び／又は外側横断面を有してもよい。１つの対称軸を有し、（長円形とは異なり）曲線の広い部分がその狭い部分に合流すると

ころで排他的に凸状ではない滑らかな平面閉曲線によって画成されるティアドロップ形状は、操作時のライナー１００の上記の左右両側の圧潰を支援する。ティアドロップ形状の内側断面を含む管状後部セクション１７０を有するライナー１００の一実施形態では、ティアドロップ形状の細い部分が、乳房から搾り出された乳を集乳器５０へ導く乳用の溝の機能を果たす。このような実施形態では、ティアドロップ形状の横断面の細い部分の（ティアドロップの対称軸に沿って測定される）長さは、ティアドロップ形状の横断面の細い部分によって画成される乳用の溝が、後方への軸方向において深くなる、即ち、下方向に傾斜するように、後部セクション１７０の後方への軸方向において増加する。

【００４０】

後部セクション１７０は更に、１つ以上の外部の、概して環状のフランジを含む。フランジは、管状壁部と一体に形成され、そこから径方向外側に延在する。第１のフランジ１７２は、管状壁部の後端に設けられる。第２のフランジ１７４は、第１のフランジ１７２の前に設けられ、第１のフランジ１７２から、又は、少なくとも管状壁部の後端から、軸方向に離間される。両フランジ１７２、１７４は、以下に説明されるライナー支持フレーム２００の後部リング２０６の内径よりも大きい外径を有する。第１のフランジ１７２及び第２のフランジ１７４の両方を含む実施形態において、それらの間の軸方向の間隔は、通常、ライナー支持フレーム２００の後部リング２０６の軸方向の長さと一致する。第２のフランジ１７４は、通常、第１のフランジ１７２よりも幾分（軸方向において）広く、及び／又は、（径方向において）高い。以下、「シーリングリップ」及び「フィンガグリップリング」とそれぞれ呼ばれる第１のフランジ１７２及び第２のフランジ１７４の機能は、乳房インターフェース７０の組立てについて説明される以下において明らかにされる。

【００４１】

ライナー１００は、例えば熱可塑性エラストマー、ゴム、ラテックス又は液状シリコーンゴム（ＬＳＲ）といったフレキシブルで、好適には弾性を有する材料から一体部品として製造される。一実施形態では、ライナー１００は、射出成形を介して製造される。この処理では、ライナーは、その弛緩状態で固定又は硬化される。ライナー材料は透明であってよく、これにより、女性が、使用時に、ライナー１００の中で何が起きているのかを視覚的に観察することができる。

【００４２】

次に、ライナー支持フレーム２００の構造の説明に移る。図４Ａ乃至図４Ｃは、それぞれ、図２Ａ乃至図２Ｄに示される乳房インターフェース７０の第１の例示的な実施形態のライナー支持フレーム２００を、斜視図（図４Ａ）、側面図（図４Ｂ）及び正面図（図４Ｃ）で概略的に示す。

【００４３】

その名称が示すように、ライナー支持フレーム２００は、ライナー１００に機械的な支持を提供する働きをする。このために、ライナー支持フレーム２００は、ライナー支持フレーム内部空間２０２を画成し、その中に、乳房インターフェース７０の組み立てられた状態において、ライナー１００が（外部から）ライナー支持フレーム２００によって係合され、嵌めこまれるように、ライナー１００の少なくとも一部を受容することができる。図２Ａ乃至図２Ｄを参照されたい。その支持機能を果たすために、ライナー支持フレーム２００は、その構造が実質的に剛性であり、操作時に、大きく変形することなく、ライナー１００によってそこにかかる任意の力に耐えることができるように（ライナー１００に比べて）比較的硬い材料から作られる。ライナー支持フレーム２００は、例えば射出成形されたプラスチックといった任意の適切な材料から製造されてもよい。

【００４４】

ライナー支持フレーム２００は、透明であってもよいし、透明又は非透明のライナー１００と組み合わせて使用されてもよいが、透明なライナー１００と不透明なライナー支持フレーム２００との組み合わせが、ユーザ機能性を最大にし、２つの部品間のコントラストを最適にする。このコントラストによって、ユーザが乳房インターフェース７０を組立

て、組立ての正確さを確認する能力を高める。

【００４５】

ライナー支持フレーム２００は、２つの軸方向に離間されたリング、即ち、前部リング２０４と後部リング２０６とを含む。なお、明確にするために、本テキストにおいて使用される「リング」との用語は、広く解釈されるべきである。当該用語は、典型的には円形であるが、非円形（例えば多角形）であってもよいその円周形状に関係なく、任意の連続的又は不連続的／分割された環状要素を包含することを意図している。２つのリング２０４、２０６は、少なくとも１つの比較的硬く、略軸方向に延在するアーム又はストラットによって相互に接続される。図４Ａ乃至図４Ｃの第１の例示的な実施形態では、ライナー支持フレーム２００は、２つの硬いが、弾力のあるアーム２１０ａ、２１０ｂを含む。これらのアームは、構造上同一である。前部リング２０４は、通常、後部リング２０６よりも大きい内径及び外径を有する。したがって、複数のアーム２１０ａ、２１０ｂを有する実施形態では、２つのリング２０４、２０６を相互接続するアーム２１０ａ、２１０ｂは、前部リング２０４から、後方方向において、後部リング２０６に合流すると見なされる。後部リング２０６の内径は、ライナー１００の管状後部セクション１７０の外径に合せられる。即ち、当該外径に略等しい。後部リング２０６は、連結器３０との真空気密接続を可能とするように、管状後部セクション１７０を嵌めるように受容する（図２Ａ乃至図２Ｄを参照）。

【００４６】

図４Ａ乃至図４Ｃの第１の例示的な実施形態において見られるように、ライナー１００の前部セクション１１０における環状溝１２６に受容されるように構成される前部リング２０４は、単一の部品で、連続的又は閉リングである（前部リングが分割されている図５及び図６の第２及び第３の例示的な実施形態と比較されたい）。前部リング２０４の略軸方向の長さは、乳房インターフェース７０の組み立てられた状態において、前部リング２０４の後端（アーム２１０ａ、２１０ｂとの接合部は無視する）が、壁部１２２、１２４のうちの少なくとも一方、即ち、リップ壁部１２４の後端及び基部壁部１２２の後端のうちの少なくとも一方と実質的に同一平面にあるように、環状溝１２６を画成する壁部１２２、１２４の少なくとも一方の略軸方向の長さに一致することが好適である。図示される実施形態では、図２Ｄの側断面図において最もよく見えるように、前部リング２０４の後端は、基部壁部１２２の後端と同一平面に位置する。組立ての際、これらの後端の面一性は、前部リング２０４の環状溝１２６への挿入が完了したことを知らせる合図をユーザに提供する。

【００４７】

ライナー１００の管状後部セクション１７０に嵌るように、また、場合により、締め付けるように構成される後部リング２０６は、後部リング２０６自体が後部セクションの２つのフランジ１７２、１７４の間で軸方向にぴったりと受容可能であるように（図２Ａ乃至図２Ｄを参照）、分割された又は二重不連続リングであることが好適である。つまり、後部リング２０６は、後部リングを少なくとも２つの実質的に剛性の相補形の円周部分に分割する少なくとも２つの円周不連続部を含む。相補形の円周部分は、後部リング２０６の断面開口／通路領域が、一時的に拡大されるように、移動可能であり、したがって、互いに対し再配置可能であり、任意選択的に、互いから取り外すことも可能である。図４Ａ乃至図４Ｃの第１の例示的な実施形態では、例えば後部リング２０６は、当該リングを２つの別個の相補形の半体２０６ａ、２０６ｂに分割する実際の割れ目又はスリットの形態の２つの円周不連続部を有する。図５及び図６の第２及び第３の実施形態を参照するに、これらの実施形態は共に、分割された後部リング２０６を同様に含む。図６の実施形態を考慮すると、相補形の後部リング部分を接続する、図６におけるフォイルヒンジ２０１といったヒンジが、概して円周不連続部を形成すると見なされる。これは、ヒンジは、後部リング２０６の円周形状の画成に貢献する場合であっても、その（内）周に沿って、後部リングの実質的な剛性の不連続部を表すからである。即ち、ヒンジは、２つの実質的に剛性の相補形の円周後部リング部分を、それらの空間的再配置を可能とするために、意図的

に接続するに過ぎないからである。

【００４８】

図４Ａ乃至図４Ｃの第１の例示的な実施形態において見られるように、各相補形の後部リング部分２０６ａ、２０６ｂは、様々なアーム２１０ａ、２１０ｂを介して、前部リング２０４に接続される。ライナー支持フレーム２００は、比較的硬いが、この分割後部リング構造は、後部リングの相補形の円周部分２０６ａ、２０６ｂが（各アーム２１０ａ、２１０ｂによって加えられる適度な径方向内側へのバネ作用に逆らって）径方向／接線方向に離れることを可能とすること（これにより、各アーム２１０ａ、２１０ｂは、径方向外側に動く）によって、乳房インターフェース７０の組立てを容易にし、これにより、ライナー１００の管状後部セクション１７０を、円周部分の間で、軸方向に通す作業を簡単にする。これは、特に、ライナー１００の管状後部セクション１７０の後部端にフランジ又はシーリングリップ１７２を含む実施形態において、言えることである。

【００４９】

分割後部リング２０６における上記された少なくとも２つの円周不連続部は、当該リングを２つの相補形の部分２０６ａ、２０６ｂに分ける対応する割れ目２０８によって形成される。割れ目２０８は、図示される実施形態において見られるように、同一の形状を有してよいが、これは必須ではない。２つの相補形の円周後部リング部分２０６ａ、２０６ｂ間の割れ目２０８の形状は、基本的には任意の形状を有してもよい。一実施形態では、割れ目の形状は、真っ直ぐ又は線形である。しかし、真っ直ぐな割れ目形状は、後部リング２０６の相補形の円周部分２０６ａ、２０６ｂ間の相対的な軸方向の移動を容易にしてしまうという欠点があり、これは、ライナー支持フレーム２００における望ましくない機械的応力につながる。このような比較的軸方向の移動は、特に、乳房インターフェース７０の搾乳器１への接続の際に生じる。即ち、乳房インターフェース７０の後端が、連結器３０の受容路４２内に押し込まれる時に生じる。真っ直ぐな割れ目形状のもう１つの欠点は、後部リング２０６が、偶然に壊れたかのように見える点である。これらの欠点を解決するために、割れ目の形状は、図示される実施形態に示されるように、略Ｃ字形である。滑らかなＣ字形の割れ目形状は、相補形の後部リング部分２０６ａ、２０６ｂの正しい相対的な軸方向の位置合わせを維持するのに役立ち、後部リング２０６が誤って壊れていると見られないように、意図する通りに見える。

【００５０】

後部リング２０６の（径方向）内面は滑らかである。しかし、滑らかな内面は、例えばシリコーン製のライナー１００の後部セクション１７０と後部リング２０６との間の摩擦を促進することが分かっており、これは、乳房インターフェース７０の組立てを複雑にする可能性がある。ライナー１００の後部セクション１７０と後部リング２０６の内面との間の摩擦を減少させるために、内面には、例えばマット仕上げを有するように表面テクスチャが施される。表面テクスチャは、スパーク（sparked）仕上げであってもよい。

【００５１】

合わせて、ライナー支持フレーム２００のアーム２１０ａ、２１０ｂも、ライナー支持フレーム２００のライナー支持フレーム内部空間２０２を完全に接線方向又は円周方向において包囲しないことが好適である。ライナー支持フレーム内部空間２０２を共に完全に包囲するアーム２１０ａ、２１０ｂは、乳房インターフェース７０の組立て及び組立て分解を妨げる場合があり、また、使用中におけるユーザのライナー１００の視野を遮る可能性がある。当該視野は、特にライナーの圧潰の過程に関する情報、また、透明のライナーを使用する実施形態では、乳首の配置及び乳の流れに関する情報を提供する。したがって、ライナー支持フレーム２００のアーム２１０ａ、２１０ｂのうちの少なくとも一方が、少なくとも１つのアクセス窓２１２を画成することが好適である。より具体的には、２つの接線方向の隣接するアーム２１０ａ、２１０ｂは共に、それらの間に（接線方向に）アクセス窓１２１を画成し、当該アクセス窓２１２は、ライナー支持フレーム内部空間２０２への手動及び視覚的アクセスを可能にする。図４Ａ乃至図４Ｃに示されるライナー支持フレーム２００の実施形態は、ライナー支持フレーム２００の両側に２つのこのようなア

クセス窓を有する。組立ての際に、１つのアクセス窓２１２は、ライナー支持フレーム内部空間２０２の視覚的な観察のために使用され、もう１つのアクセス窓２１２は、そこへの手動アクセスのために使用される。

【００５２】

ライナー支持フレーム２００のロバスト性を高めるために、各アーム２１０ａ、２１０ｂと前部リング２０４との接合部又は接続部は、各アームと後部リング２０６との接合部よりも（接線方向に）広いことが好適である。したがって、アーム２１０ａ、２１０ｂの（接線方向の）幅は、後方方向にテーパする。これに加えて又は代えて、前部リング２０４における接合部は、例えば前部リング２０４の半径の少なくとも半分である曲率半径である比較的大きい曲率半径２１６を規定することが好適である。このような大きい半径は、アーム２１０ａ、２１０ｂの屈曲に対する剛性を増加させ、したがって、使用時に、乳房インターフェース７０が垂れた感じがあまりしない。

【００５３】

ライナー支持フレーム２００のアーム２１０ａ、２１０ｂが、その後部リング２０６に接合する場所において、段部２２０が画成されることが好適である。段部２２０は、角度の比較的急激な変化によって特徴付けられる。段部２２０は、乳房インターフェース７０の後部の搾乳器１の連結器３０内の受容路４２への挿入の際に、連結器の外面に対抗して付勢される止め部として働く。段部２２０があることによって、ユーザが、乳房インターフェースの後部を、連結器にある受容路４２内に、段部２２０が連結器に当接する点まで付勢することを促し、これにより、乳房インターフェース７０と連結器３０との間に適切な真空シールが実現され、また、乳房インターフェース７０の分割後部リング２０６が、定位置に固定され、ライナー支持フレーム２００にその剛性の一部が提供される。

【００５４】

ライナー支持フレーム２００のアーム２１０ａ、２１０ｂ各々には、ライナー１００の後部セクション１７０にある第２のフランジ１７４と協働するフランジ相互作用部材２２２が設けられている。フランジ相互作用部材２２２は、それが設けられているアーム２１０ａ、２１０ｂの内面から内側に突出する。長手方向の側断面図（図２Ｃを参照）において見られるように、フランジ相互作用部材２２２は、概して鋸歯状であり、後方方向において見た場合に、径方向内側に傾斜する傾斜面２２４と、実質的に径方向に延在する後部止め面２２６とを含む。止め面２２６は、当該止め面２２６と後部リング２０６の前端との間に軸方向の間隙２２８があるように、後部リング２０６の前端の隣にあるが、当該前端から軸方向に離間されて配置される。ライナー支持フレームのアーム２１０ａ、２１０ｂと後部リング２０６との間の接合部が、段部２２０を画成する実施形態では、フランジ相互作用部材２２２の止め面２２６は、段部２２０の内側に面する。

【００５５】

フランジ相互作用部材２２２は、乳房インターフェース７０の第１の例示的な実施形態の組立て処理の説明から明らかとなるように、幾つかの目的を果たす。

【００５６】

乳房インターフェース７０が、ライナー１００と、ライナー支持フレーム２００とを別個の構造コンポーネントとして含む場合、図２乃至図４の乳房インターフェースは、次の通りに組み立てられる。ユーザは、ライナー１００上に設けられるマーク１２８が、ライナー支持フレーム２００のアーム２１０ａ、２１０ｂと回転位置合わせされるように、ライナーの管状後部セクション１７０を、ライナー支持フレーム２００の前部リング２０４を通して軸方向に挿入する。ユーザは、ライナー支持フレーム２００に設けられたアクセス窓２１２のうちの１つ以上を介して指を入れ、ライナー１００の後部セクション１７０に設けられた第２のフランジ又はフィンガグリップリング１７４を掴む。第２のフランジ１７４を掴みつつ、ユーザは、ライナー１００を後方に押す又は引っ張る。その際に、第２のフランジ１７４は、アーム２１０ａ、２１０ｂの内面に設けられたフランジ相互作用部材２２２に接触する。その結果、ライナー支持フレーム２００のアーム２１０ａ、２１０ｂは、ライナー１００が更に後方に動かされるのにつれて、径方向に離れるように徐々

に広がるようにされる。アーム２１０ａ、２１０ｂの広がりは、ライナー支持フレーム２００の分割後部リング２０６の相補形の円周部分２０６ａ、２０６ｂの広がりを引き起こし、これは、相補形の円周部分間で、第１のフランジ１７２を通過し易くする。第２のフランジ１７４が、フランジ相互作用部材２２２の止め面２２６の軸方向の位置に到達すると、第２のフランジは、止め面２２６と後部リング２０６の前端との間の軸方向の間隙２２８内に嵌り込む。同時に、２つのアーム２１０ａ、２１０ｂは、相補形の円周後部リング部分２０６ａ、２０６ｂが、第１のフランジ１７２と第２のフランジ１７４との間に延在するライナー１００の管状後部セクション１７０の一部分に嵌合係合するように、再び弛緩し、互いに向かって動く。これは、少なくとも後端において、ライナー１００のライナー支持フレーム２００への挿入が完了したという視覚的確認をユーザに提供するだけでなく、シーリングリップ１７２及びフィンガグリップリング１７４、従って、ライナー１００も、更なる軸方向の移動に対して係止する。組立てを完了するために、ユーザは、ライナー支持フレーム２００の前部リング２０４が、ライナー１００の前部セクション１１０における環状溝１２６にきっちりと受容されたことを確認し、また、必要に応じて、好適には、前部リング２０４が、環状溝１２６を画成する壁部１２２、１２４の少なくとも一方の後端と同一平面であるように、前部リング２０４の環状溝１２６への適切な配置を確実にしてもよい。

【００５７】

乳房インターフェース７０自体が組み立てられると、その後部、具体的には、ライナー１００の管状後部セクション１７０とライナー支持フレーム２００の後部リング２０６とは、搾乳器１の連結器３０によって提供される受容路４２内に挿入される。受容路４２は、適切な真空シーリングが実現されるように、乳房インターフェース７０の後部が圧入受容されるような寸法にされることが好適である。

【００５８】

乳房インターフェース７０と連結器３０との間の第１の真空シールが、シーリングリップ１７２と、受容路４２の内面との間に形成される。このために、シーリングリップ１７２の外径は、受容路４２の内径よりも僅かに大きいことが好適である。ライナー材料の柔軟性によって、シーリングリップ１７２は、乳房インターフェース７０の後部の受容路４２への挿入時に変形する。これにより、シーリングリップ１７２の外周と、受容路４２の内周との間の形状における差異が調整され、効果的な真空シールが生成される。第２の真空シールが、分割後部リング２０６の外面と、受容路４２の内面との間に形成される。この第２の真空シールを実現するために、２つの、通常、剛性であるコンポーネント４２、２０６の表面は、実質的に形状が同一である必要があり、例えば同じ直径、テーパ等を有さなければならない。シーリングリップ１７２及びフィンガグリップリング１７４が、それらの間で軸方向において後部リング２０６に係合するにつれて、第３の真空シールが、フィンガグリップリング１７４との協働によってシーリングリップ１７２によって形成されてもよい。

【００５９】

図１乃至図４を参照して、乳房インターフェース７０の第１の例示的な実施形態について説明した。次に、幾つかの特定の及び有利な変形態様を示す幾つかの更なる例示的な実施形態に注目する。

【００６０】

なお、図１乃至図４の第１の例示的な実施形態のライナー支持フレーム２００は、単一部品コンポーネントであるが、代替実施形態のライナー支持フレーム２００は、複数の取り外し可能に接続可能な部品を含んでもよい。

【００６１】

一実施形態（図示せず）では、例えば前部リングと後部リングとを相互接続する少なくとも１つのアームは、実質的にアームの全軸方向長さに亘って、ライナー支持フレームの長手軸に対し１２０°～１８０°の範囲の角度に対応する。このような広い、「ハーフパイプ」アームは、追加のアームを不必要にする十分な剛性を有するクレードル状のライナ

一容器を提供する。このような実施形態では、前部リング２０４及び／又は後部リング２０６は、２つの取り外し可能に接続可能な相補形の円周部分を含む。各リングについて、相補形の円周部分のうちの一方は、ハーフパイプアームと一体にされ、もう一方は、例えばクリップの形で、ハーフパイプアームに取り外し可能に接続可能である。後者のリング部分の分離された状態では、ライナー１００の前者のアームが取り付けられた部分への挿入が容易にされる一方で、両部分の閉じた状態では、ライナーは、両部分間の適切な位置にしっかりと保持される。

【００６２】

図５の第２の例示的な実施形態といった後者の実施形態を更に詳細に説明するために、ライナー支持フレーム２００全体が、２つの取り外し可能に接続可能な部分又は半体２００ａ、２００ｂに分割されてもよい。図示されるように、この実施形態では、前部リング２０４及び後部リング２０６が共に分割され、各リング２０４、２０６は、第１のアーム２１０ａに固定して接続される１つの部分２０４ａ、２０６ａと、第２のアーム２１０ｂに固定して接続されるもう１つの相補形の部分２０４ｂ、２０６ｂとを有する。乳房インターフェース７０の組立ての際に、２つのフレーム部分又は半体２００ａ、２００ｂは、具体的には、（ｉ）前部リング部分２０４ａ、２０６ｂを、ライナー１００の環状溝１２６内に位置付けることによって、また、（ｉｉ）その後部リング部分２０６ａ、２０６ｂの後端を、シーリングリップ１７２に接して、場合により、シーリングリップ１７２により画成される環状溝１７３（図６Ａ参照）内に位置付けることによって、順々に、ライナー１００と係合される。続いて、乳房インターフェース７０は、搾乳器１の連結器３０によって提供される受容路４２内に圧入される。

【００６３】

図５の２パートライナー支持フレーム２００は、乳房インターフェース７０の組立ての際に、シーリングリップ１７２を、後部リング２０６を通して挿入するためにユーザがかなりの力を加える必要をなくすが、ライナー支持フレーム２００のマルチパートデザインは、フレームの様々な部品が一緒に保持されず、気が付かないうちに紛失する可能性があるという欠点を有する。この問題を回避するために、ライナー支持フレームの２つの相補形の半体２００ａ、２００ｂは、取り外し可能に接続可能であるようには作られず、その代わりに、図６の第３の例示的な実施形態にあるように、例えばフォイルヒンジ２０１によって、ヒンジを介して接続されてもよい。

【００６４】

図７Ａ及び図７Ｂは、本開示による乳房インターフェース７０の第４の実施形態を、側断面図（図７Ａ）及び後面斜視図（図７Ｂ）で概略的に示す。

【００６５】

図１乃至図４の乳房インターフェース７０の第１の例示的な実施形態に関連付けられる問題は、それを使用する女性が、自身の乳房から搾り出された乳が確実に集乳器５０に向かい、その中へと流れるように、前傾になる必要がある点である。１回の搾乳セッションには時間がかかり、特には３０分以上にも及ぶため、前傾姿勢は不快となる。

【００６６】

不快感の問題を解決するために、乳房インターフェース７０、及び、具体的にはそのライナー１００は、上部側又は頂部側及び下部側又は底部側を有する使用姿勢（use orientation）と関連付けられる。更に、ライナー１００の前部セクション１１０は、乳房接触面１１８（図２Ｃも参照）における開口１１６ｂの平面に実質的に垂直に延在する、また、上記の使用姿勢において、実質的に水平に延在する長手軸L_{fs}に関連付けられる。即ち、使用時、前部セクション１１０の乳房接触面１１８が、女性の乳房に接触すると、前部セクション１１０の長手軸L_{fs}は、実質的に水平に延在する。ライナー１００の構造は更に、ライナー１００の中間セクション１４０の後方にテーパする漏斗状壁部１４４及び／又は後部セクション１７０の管状壁部１７１が、乳房接触面１１８における（乳首を受容する）開口１１６ｂから、管状壁部１７１の後端（乳放出）開口にまで延在し、また、上記の使用姿勢において、前部セクション１１０の長手軸L_{fs}に対して下方向に傾斜

する細長い内側下部／底部表面部分１７１ａによって少なくとも部分的に境界付けられる乳用の導管１９０を画成するように、適応される。後部セクション１７０（の底部表面部分１７１ａ）の下方向への傾斜によって、乳房から搾り出された乳は、重力の作用によって、後部セクション１７０の管状壁部１７１を通り、その後端開口に向かって、自然に流れる。したがって、女性が、使用時に前傾する必要はない。

【００６７】

この解決策によれば、乳房インターフェース７０の長手軸Ｌは、乳房インターフェース７０の当該長手軸Ｌが２つの真っ直ぐで位置合わせされないセクションを含むように（下方向の）キンク又は屈曲を含むことが好適である（図７Ａを参照）。長手軸の第１のセクションL_{fs}は、ライナー１００の前部セクション１１０とライナー支持フレーム２００の前部リング２０４とに関連付けられ、長手軸の第２のセクションL_{rs}は、ライナー１００の後部セクション１７０と、ライナー支持フレーム２００の少なくとも１つのアーム２１０ａ、２１０ｂ及び後部リング２０６とに関連付けられる。乳房インターフェース７０の長手軸Ｌの２つのセクションL_{fs}、L_{rs}は、約１０～４５度の範囲内の角度φを含むことが好適である。後部セクション１７０の少なくとも管状壁部１７１の断面形状は、円形であるが、円形である必要はない。図示される実施形態では、例えば後部セクション１７０の管状壁部１７１は、上記され、かつ、図７Ｂに示されるように、（逆さまにされた）ティアドロップ形状の内側断面形状を有する。したがって、管状壁部１７１は、「下方向に傾斜する溝」を有する乳用の導管１９０である長手方向の部分を画成し、その底部は、細長い底部表面部分１７１ａによって形成される。

【００６８】

本明細書に開示される乳房インターフェースの例示的な実施形態が、部分的に添付図面を参照して、上で説明されたが、当然ながら、本開示は、これらの実施形態に限定されない。開示された実施形態の変形態様が、当業者によって、図面、開示及び添付の特許請求の範囲の検討から、乳房インターフェースを実施する際に、理解及び実現されてもよい。本明細書全体を通して「１つの実施形態」、「一実施形態」等との言及は、実施形態に関連して説明される特定の特徴、構造又は特性が、乳房インターフェースの少なくとも１つの実施形態に含まれてもよいことを意味する。したがって、本明細書全体に亘って様々な場所において出現する「１つの実施形態では」又は「一実施形態では」との表現は、必ずしもすべて同じ実施形態を指しているわけではない。なお、１つ以上の実施形態の特定の特徴、構造又は特性は、明示的には説明されていないが新しい実施形態を形成するために、任意の適切な態様で組み合わされてもよい。同様に、１つ以上の実施形態の特定の特徴、構造又は特性は、明示的には説明されていないが新しい実施形態を形成するために、明示的に説明されている実施形態から取り除かれてもよい。例えば図７の第４の例示的な実施形態を参照して説明されたライナーの「下方向に傾斜する後部セクション」という特徴は、新しい実施形態を形成するために、説明されたどの他の実施形態に組み込まれてもよい。同様に、他の実施形態を参照して説明された特徴も、明示的には説明されていないが新しい実施形態を形成するために、第４の実施形態に含めることも考えられる。

【００６９】

要素のリスト

１　搾乳器
１０　真空ポンプ
３０　連結器
３２　第１の管状セグメント
３４　第１のチャネル
３６　第２の管状セグメント
３８　第２のチャネル
４０　第１の管状セグメントの下端におけるねじ込みソケット
４２　乳房インターフェースの後端を受容するための受容路
５０　集乳器

７０　乳房インターフェース
１００　ライナー
１１０　前部セクション
１１２　円錐状前壁部
１１２ａ　前壁部の前面
１１２ｂ　前壁部の背面
１１４ａ　径方向外側の円周エッジ
１１４ｂ　径方向内側の円周エッジ
１１６ａ　前部開口
１１６ｂ　後部開口
１１８　乳房接触面
１２０　逆流バリア
１２２　基部壁部
１２４　リップ壁部
１２６　基部壁部とリップ壁部との間の環状溝
１２８　回転位置合わせマーク
１４０　中間セクション
１４２　Ｓ字形曲線を有する接続壁部
１４４　後部のテーパする漏斗状壁部
１４６　長手方向リブ
１７０　後部セクション
１７１　管状壁部
１７１ａ　下部内側表面部分
１７２　第１のフランジ／シーリングリップ
１７３　前方向に曲げられた第１のフランジによって画成される環状溝
１７４　第２のフランジ／フィンガグリップリング
１８０　内部圧力チャンバ
１９０　乳用通路
２００　ライナー支持フレーム
２００ａ　ライナー支持フレームの第１の相補形の部分
２００ｂ　ライナー支持フレームの第２の相補形の部分
２０１　（フォイル）ヒンジ
２０２　ライナー支持フレーム内部空間
２０４　前部リング
２０４ａ　第１の相補形の前部リング部分
２０４ｂ　第２の相補形の前部リング部分
２０６　分割後部リング
２０６ａ　第１の相補形の後部リング部分
２０６ｂ　第２の相補形の後部リング部分
２０８　リング半体間の割れ目
２１０ａ　第１のアーム
２１０ｂ　第２のアーム
２１２　第１のアームと第２のアームとの間のアクセス窓
２１４　アームと前部リングとの接合部
２１６　アームと前部リングとの接合部における大きい半径
２１８　アームと後部リングとの接合部
２２０　段部
２２２　フランジ相互作用部材
２２４　傾斜面
２２６　止め面

２２８　止め面と後部リングの前端との間の軸方向間隙
A_{maj}　楕円形環状溝の長軸
A_{min}　楕円形環状溝の短軸
L　乳房インターフェースの長手軸
L_{fs}　ライナーの前部セクション／フレームの前部リングの長手軸
L_{rs}　ライナーの後部セクション／フレームのアーム及び後部リングの長手軸
R　径方向
φ　長手軸セクションL_{fs}、L_{rs}によって挟まれる角度

【図１Ａ】

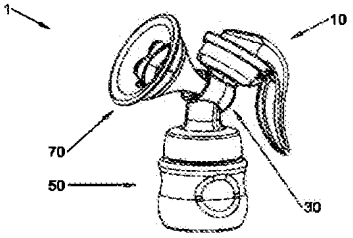

Fig. 1A

【図１Ｂ】

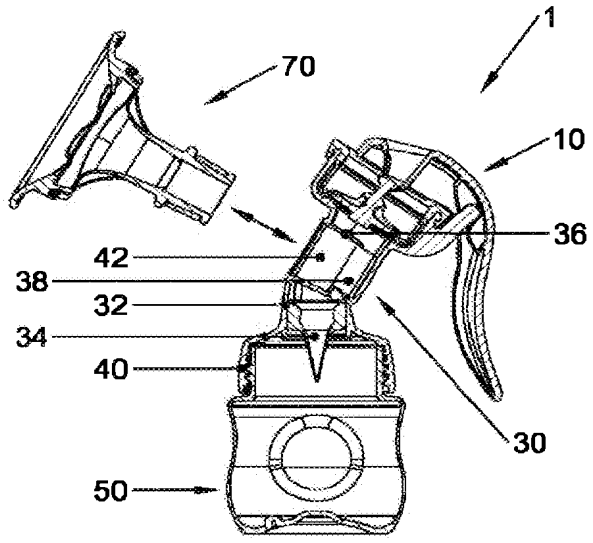

Fig. 1B

【図２Ａ】

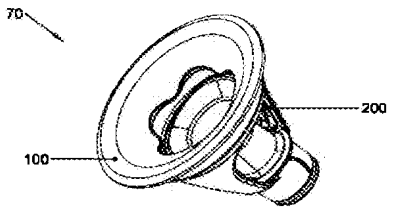

Fig. 2A

【図２Ｂ】

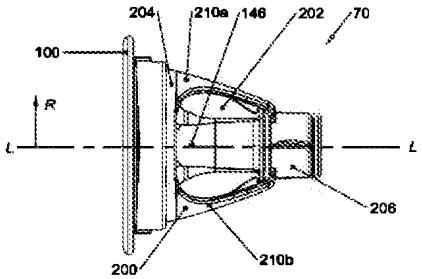

Fig. 2B

【図２Ｃ】

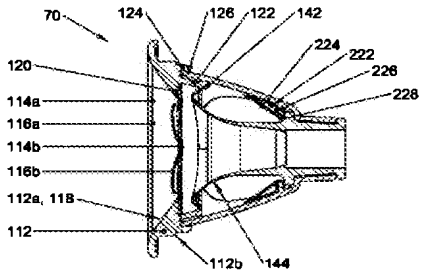

Fig. 2C

【図２Ｄ】

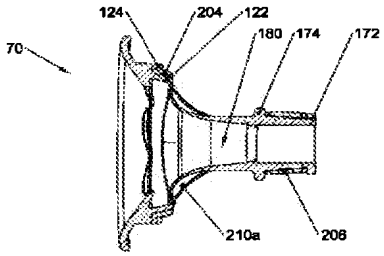

Fig. 2D

【図３Ａ】

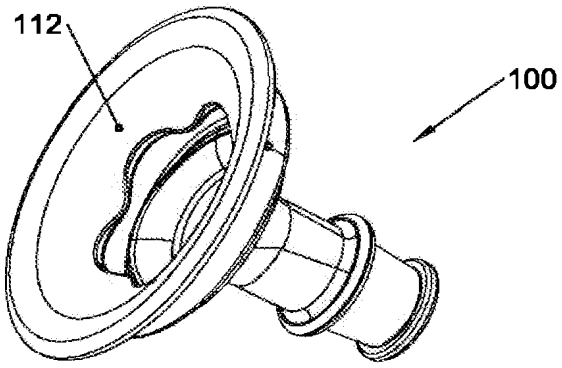

Fig. 3A

【図３Ｂ】

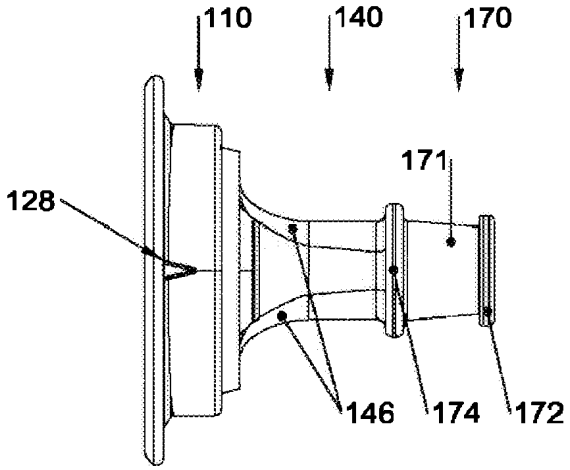

Fig. 3B

【図３Ｃ】

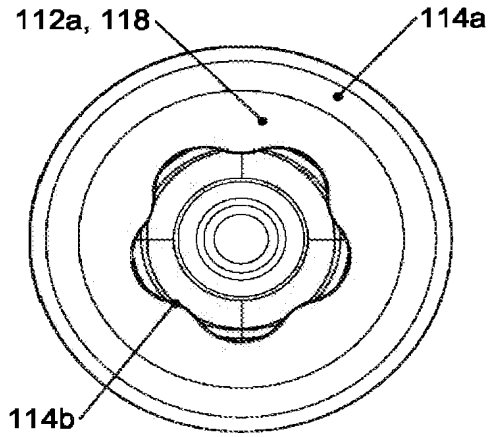

Fig. 3C

【図３Ｄ】

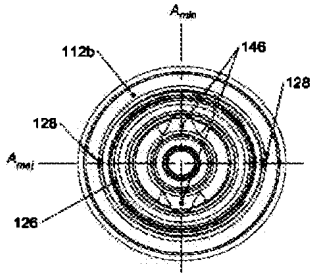

Fig. 3D

【図４Ａ】

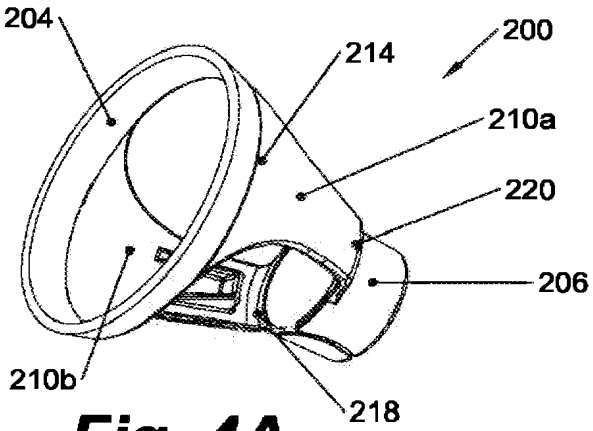

Fig. 4A

【図４Ｂ】

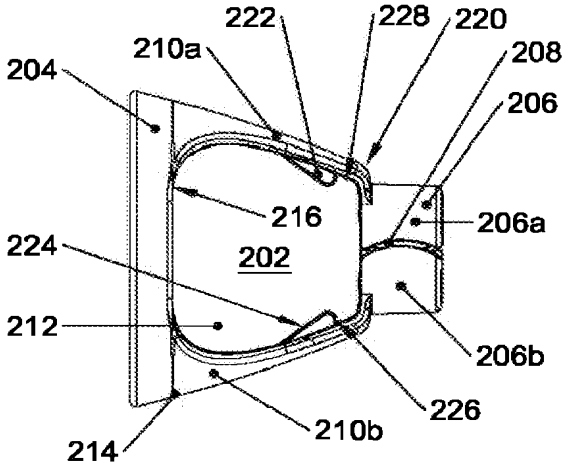

Fig. 4B

【図４Ｃ】

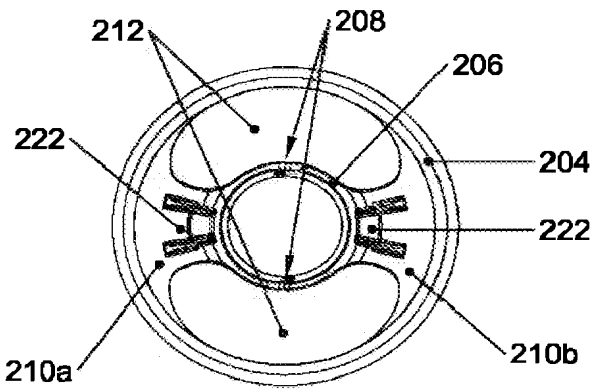

Fig. 4C

【図５Ａ】

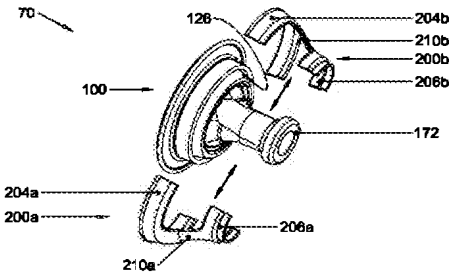

Fig. 5A

【図５Ｂ】

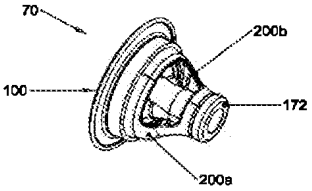

Fig. 5B

【図６Ａ】

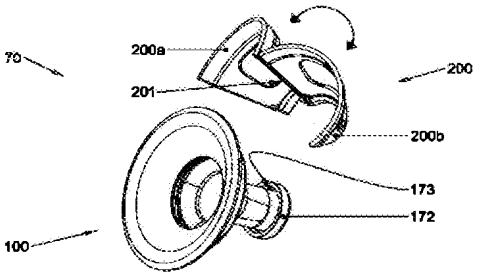

Fig. 6A

【図６Ｂ】

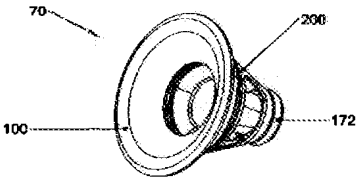

Fig. 6B

【図７Ａ】

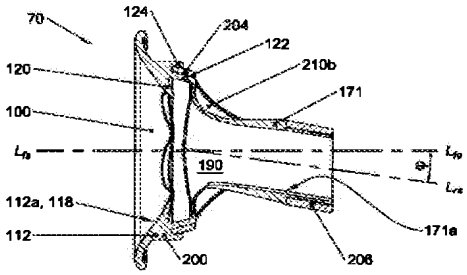

Fig. 7A

【図７Ｂ】

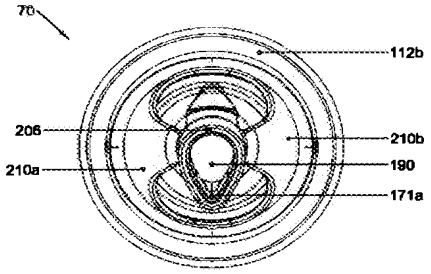

Fig. 7B

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2014/054197

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A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2009/171270 A1 (ROEHRIG PETER [AT]) 2 July 2009 (2009-07-02) abstract; figures 1,4-5 paragraph [0035] -----	1-7
Y	US 6 974 439 B1 (MCKENDRY BRUCE [US]) 13 December 2005 (2005-12-13) abstract; figures 2,6 column 4, line 18 - column 5, line 13 -----	1-10
Y	US 6 673 037 B1 (SILVER BRIAN H [US]) 6 January 2004 (2004-01-06) figures 1-2 column 2, lines 1-18 column 3, lines 9-40 -----	1-10

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A	US 2006/116632 A1 (GILLAN JONATHAN C [US]) 1 June 2006 (2006-06-01) abstract; figure 3 paragraphs [0040] - [0044] -----	1-10
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INTERNATIONAL SEARCH REPORT

Information on patent family members

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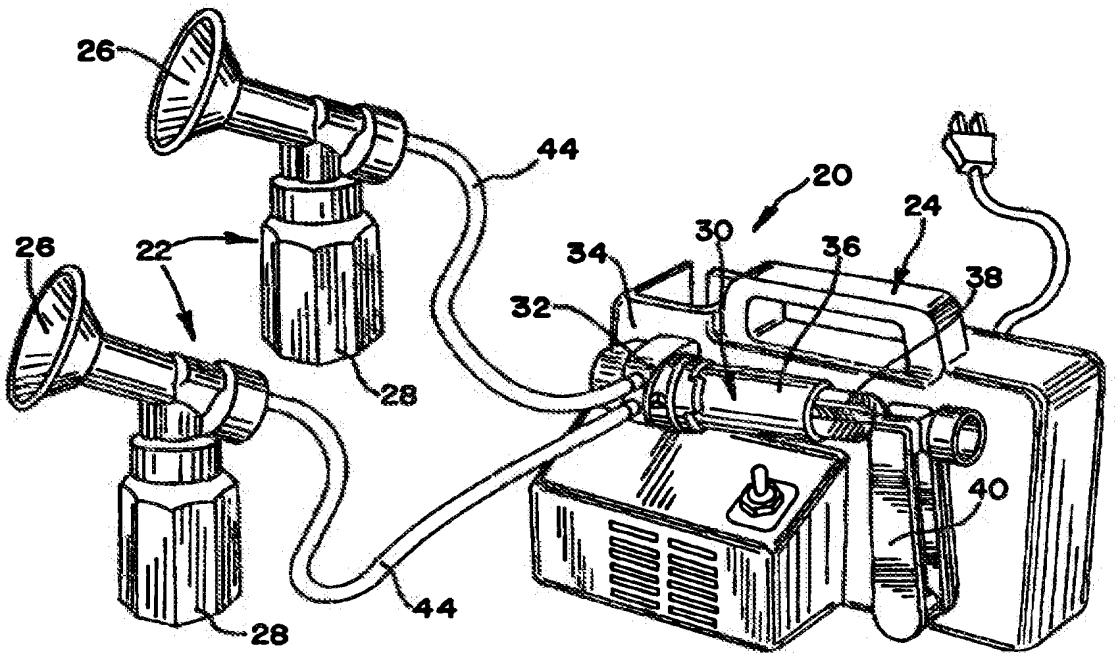

(57) Abstract

An improved breast pump assembly (20) allows two breast pumps (22) to be connected to a motor drive unit (24) for simultaneous breast pumping. In a preferred embodiment, the improved breast pump assembly (20) can be adjusted for either single breast pumping or for double breast pumping, depending on the particular woman's needs.

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IMPROVED BREAST PUMP ASSEMBLY AND METHOD OF USING SAME

BACKGROUND OF THE INVENTION

The present invention is directed generally to breastmilk pumps and, more particularly, to an improved breast pump assembly for expressing mothers' milk, which may be used in a manually-driven mode as well as a motor-driven mode.

Breast pumps for extracting or expressing breastmilk from a woman's breasts for later use by an infant have been available for years. Typically, these breast pumps include a funnel-shaped hood, or shield, that is placed over the nipple and a substantial portion of the breast. A reduced pressure or vacuum is intermittently generated in the hood in a manner which causes milk to be expressed from the breast within the hood. The milk then typically flows from the hood to a storage container for later use.

Generally, two types of breast pumps have been marketed for use by nursing women: motor-driven pumps; and manually-operated pumps. In manually-operated breast pumps, the intermittent suction action is typically generated by means of a compressible bulb or, more frequently, a piston-type pump. The piston pump

generally includes a piston cylinder connected to the hood, and a piston slidably disposed within the piston cylinder and which is reciprocated by a hand-drivable piston rod. Motor-driven pumps typically either have a separate vacuum pump attached to the hood by tubing, or the motor is built into the hood assembly itself.

U.S. Patent No. 5,007,899 discloses a drive unit to which the piston pump of an otherwise manually-operated breast pump can be attached for motorized breast pumping. The present invention is the particular result of improvements to the breast pump assembly disclosed in U.S. Patent No. 5,007,899, and to the LACTINA breast pump assembly manufactured and sold by Medela, Inc. to which the foregoing patent relates.

SUMMARY OF THE INVENTION

The present invention provides an improved breast pump assembly which enables easy and effective vacuum connection of one or two breast hoods, or shields, to a piston pump, particularly where the piston pump is mounted to be driven by a motor drive unit. In a preferred embodiment of the present invention, the improved breast pump assembly can be readily adjusted through use of a selector element for either single breast pumping or for double breast pumping, depending on the particular woman's needs.

According to a first aspect of the present invention, the improved breast pump assembly includes at least one and preferably two breast pumps (i.e., shield, bottle, valving) each having a breast shield connected to an adapter device which is

attached to a piston pump. The breast shields are each connected to the adapter by means of an airline (tube) between the shield and the adapter. Each of the tubes includes a male connector at one end for insertion into a mating female receptacle formed in the adapter. The connector design provides for easy manipulation of the tube end to assure a good connection. The piston pump is preferably connected via the adapter (here, a piston cylinder holder) to a motor drive unit for reciprocating movement, but it will be seen that the inventive adapter is useful even in a manual mode of operation of the piston pump.

The present invention further provides an improved adapter for the piston pump. In a preferred embodiment of the invention, the adapter is provided with an easily-manipulated selector for connecting the vacuum generated by the piston pump to either or both of the breast pumps for single or double breast pumping. This enables quick and easy selection of one or both breast pumps by a simple single hand manipulation of the selector, leaving a hand free. It also enables shifting from one breast pump to the other by simply moving the selector.

These and other features and advantages of the present invention will be further understood upon consideration of the following detailed description of the present invention, taken in conjunction with the accompanying drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view showing a preferred embodiment of an improved breast pump assembly of the present invention;

Fig. 2 is a side elevational view of the improved adapter, or cylinder holder, shown in Fig. 1, with the selector ring removed;

Fig. 3 is a front view of the cylinder holder taken along line 3-3 of Fig. 2, with a flap-valve removed for clarity;

Figs. 3A and 3B are a front and a side view of a flap valve;

Fig. 4 is a rear view of the cylinder holder taken along line 4-4 of Fig. 2;

Fig. 5 is a top view of the cylinder holder taken along line 5-5 of Fig. 2;

Fig. 6 is an elevational view of the cylinder holder taken along line 6-6 of Fig. 3;

Fig. 7 is a cross-sectional view taken along line 7-7 of Fig. 5;

Fig. 8 is a cross-sectional view taken along line 8-8 of Fig. 5;

Fig. 9 is a cross-sectional view taken along line 9-9 of Fig. 3;

Fig. 10 is an enlarged view of detail 10 shown in Fig. 7;

Fig. 11 is an enlarged view of detail 11 shown in Fig. 9;

Fig. 12 is an enlarged view of detail 12 shown in Fig. 9;

Fig. 13 is a plan view of a selector ring used with the cylinder holder shown in Figs. 1-12 and 19-21;

Fig. 14 is a view of the selector ring taken along line 14-14 of Fig. 13;

Fig. 15 is a view of the selector ring taken along line 15-15 of Fig. 13;

Fig. 16 is a view of the selector ring taken along line 16-16 of Fig. 13;

Fig. 17 is a cross-sectional view taken along line 17-17 of Fig. 13;

Fig. 18 is a cross-sectional view taken along line 18-18 of Fig. 13;

Fig. 19 is a view identical to that shown in Fig. 9, but with the addition of the selector ring in place;

Fig. 20 is a view identical to that shown in Fig. 7, but with the addition of the selector ring, which is set to the double breast pumping position;

Fig. 21 is a view identical to that shown in Fig. 20, with the selector ring set to a single breast pumping position;

Fig. 22 is a perspective view of a male connector for connecting the tubing of a breast pump to the cylinder holder;

Fig. 23 is an elevational view of the male connector shown in Fig. 22;

Fig. 24 is an elevational view looking at the left-hand side of Fig. 23;

Fig. 25 is an elevational view looking at the right-hand side of Fig. 23;

Fig. 26 is an end view of the bottom of the male connector shown in Fig. 23; and

Fig. 27 is an end view of the top of the male connector shown in Fig. 23.

DETAILED DESCRIPTION OF A PRESENTLY PREFERRED EMBODIMENT

A. General Organization of Elements

As shown in Fig. 1, this embodiment of the improved breast pump assembly 20 of the present invention includes two breast pump units 22 and a motor drive unit 24. The breast pump units 22 have a hood assembly 26, and a container 28, such as a bottle, for collecting and storing the breast milk, which is connected to the lower portion of the hood assembly 26. The breast pumps 22 are adapted to be used with a piston pump 30. The piston cylinder of the piston pump 30 is connectable to the breast hood assembly 26 to operate the breast pump 22 in a manually-driven mode (i.e., the piston pump is reciprocated by hand). Details of this type of breast pump and the piston pump can be gleaned from U.S. Patents No. 4,929,229 and 4,857,051.

The motor drive unit 24 is adapted to receive and hold the piston pump 30 of one of the breast pumps 22 when it is removed therefrom, and to mechanically drive the piston pump 30. The motor drive unit 24 is substantially as shown and described in U.S. Patent No. 5,007,899, the disclosure of which is hereby incorporated by reference. An improved adapter or cylinder holder 32 is attachable to the casing 34 of the motor drive unit 24, and is a subject of the present application.

The piston cylinder 36 of the piston pump 30 is received in the cylinder holder 32, and the piston rod 38 is releasably held at one end of an arm 40. Arm 40 is mounted at its other end to the casing 34 to a drive system for reciprocal movement of the piston rod 38. As will be described in detail below, the cylinder holder 32 includes two ports 42 (see Fig. 2) for

variously connecting the vacuum tubes 44 to the hood assemblies 26 of the respective breast pumps 22.

In brief, the motor drive 24 reciprocally moves the piston rod 38 in piston cylinder 36. The rearward stroke of the piston rod 38 generates a vacuum (negative pressure) transmitted through the cylinder holder 32 and the tubes 44 to one or both of the breast pumps 22.

B. The Adapter/Cylinder Holder

Turning once again to the drawings, Figs. 2-21 depict various views of a preferred embodiment of the cylinder holder 32 of the present invention. As perhaps best shown in Figs. 2-9, the improved cylinder holder 32 includes a cap portion 46 which is match-threaded at 48 for substantially airtight attachment to the forward end of piston cylinder 36. Figs. 4, 9, 11 and 19 show that the inside of the cap portion 46 has a seal ring 47 disposed therearound for sealing engagement with the inner edge of piston cylinder 36.

Inside of the cap portion 46 is a vacuum chamber 58 that communicates with the piston cylinder 36 and, through the ports 42, with the breast pumps 22. The ports 42 are surrounded by non-circular female receptacles 52 (e.g., see Fig. 2), which are sized and shaped to snugly receive the mating male connectors 54 attached to the ends of the vacuum tubes 44, as described below and shown in Figs. 22-27. Further, the cylinder holder 32 includes a hollow post 56 which is received within a post hole (not shown) in the casing 34 to mount the cylinder holder 32 to the motor drive unit 24. A flange 51 is formed on the exterior sidewall of the cap portion 46. The flange 51 slides into an

enlarged slot (also not shown) when the post 56 is inserted in the post-hole and the cylinder holder 32 rotated into place (in a similar manner as described in U.S. Patent No. 5,007,899). Other means for mounting the cylinder holder to the casing can be readily employed, of course.

As shown in Figs. 2, 3 and 7, the vacuum chamber 58 communicates with three holes 60a, 60b and 60c disposed within a collar portion 53 formed on the forward extension of cylinder holder 32. These holes are the outlets for internal passages 59a, 59b and 59c, respectively. As shown in Figs. 7, 9 and 19-21, and as will be described in further detail hereinafter, the vacuum generated within the piston cylinder 36 is directed through the vacuum chamber 58, then through passage 59b to one or both of the passages 59a, 59c and ultimately to respective ports 42. Also, and again as described in more detail below, and as best shown in Figs. 7 and 10, the vacuum chamber 58 includes a leakage hole 63 that connects the vacuum chamber to atmosphere in single-pumping modes of operation. This serves to allow a predetermined amount of air to enter the vacuum chamber to compensate for the reduced air volume presented when single breast pumping, so that the vacuum pressure applied to the breast remains relatively constant whether single or double-pumping.

As shown in Figs. 7, 8, 20 and 21, passages 66a and 66c extend from passages 59a and 59c, respectively, to communicate with a respective port 42. (Two of the holes 64 which are depicted are non-functional in operation, but are part of the molding process.) The cylinder holder 32 includes a selector ring 70 for directing the vacuum to either or both of the ports

42 and then to breast pumps 22, as described in more detail hereafter.

With reference to Fig. 3, a flexible thin-disk 64 flap valve seal (Figs. 3A and 3B) is positioned over a plurality of holes 64, 65 (and 66a, 66c) formed in the forward end portion 62 of the cylinder holder. A central post 67 formed integral with the flap valve 64 is received within hole 61 to secure the flap valve in place. When the piston rod 38 is pushed into the piston cylinder 36 on its return stroke, the air present in the chamber 58 is forced through the vacuum chamber 58 and the holes 65 (see Fig. 4) past the flap seal. On the other hand, when the piston rod 38 is pulled from the piston cylinder 36, the flap seal is pulled tight over the holes 65, 66a and 66c to create a seal. Consequently, a vacuum is formed in the chamber 58 on the pulling stroke. Such a flap valve and its operation are described in U.S. Patent No. 4,929,229.

Figs. 13-21 depict the selector ring 70 in detail. The selector ring includes an upraised indicator lever 72, an internal vacuum flow channel 74 and a plurality of small recessed channels 76. Referring to Fig. 2, the selector ring is received in a snug but rotatable fit around the collar 53, with the internal channel 74 overlying the holes 60a, 60b and 60c. The selector ring 70 is shown in place in Figs. 19-21, for example. Markings (not depicted) provided on cowl 57 of the cylinder holder serve to orient the selector ring 70 in use. The middle marker corresponds to the "double breast pumping" setting for the breast pump assembly 20, and the side markers correspond, respectively, to the "single breast pumping" setting for either

the left or the right breast pump 22 shown in Fig. 1. To select the desired breast pumping function of the breast pumping assembly 20, the indicator 72 of the selector 70 is rotated to the corresponding marker. A bead 49 is formed around the collar 53 to help keep the selector ring 70 in place on the collar 53.

As best shown in Fig. 20, when the selector 70 is rotated on the collar 53 of cylinder holder 32 such that the indicator 72 is set to the "double pumping" marker, the vacuum flow channel 74 communicates with the passage 59b (which communicates with the vacuum chamber 58) and both of the passages 59a and 59c (which in turn are connected to the respective ports 42 via passages 66a and 66c). As can be understood, the vacuum generated in the piston cylinder 36 is drawn through the vacuum chamber 58 and through the passage 59b, which in turn draws vacuum through the channels 59a, 59c then through channels 66a, 66c to the ports 42. Thus, the vacuum is transmitted through the vacuum tubes 44 to the breast hoods 26 of each of the breast pumps 22. In addition, in the position shown in Fig. 20, the selector 70 blocks the leakage hole 63 in the double-pumping mode to prevent a reduction in vacuum pressure by air intake through hole 63.

As shown in Fig. 21, when the selector 70 is rotated to a marker for "single breast pumping" (by either the left or right breast pump 22), the vacuum flow channel 74 communicates with only the vacuum chamber 58 via passage 59b and one of the passages 59a, 59c. In Fig. 21, the selector 70 covers the hole 60c, preventing a vacuum connection between the vacuum chamber 58 and the passages 59c, 66c. Thus, the vacuum is transmitted

through only one port 42 and vacuum tube 44 to the respective breast pump 22 (in Fig. 21, via passages 59a, 66a).

Moreover, in the "single breast pumping" setting, one of the recess channels 76 formed in the selector 70 serves to uncover the leakage hole 63 to allow outside air to flow into the vacuum chamber 58, thereby reducing the vacuum pressure, in a predetermined manner, which otherwise would be generated by the piston pump 30. This is desirable to compensate for the reduced air volume in the system presented by only a single breast pump, so as to maintain substantially the same vacuum pressure to the breast pumps 22 whether one or both are being used. The recessed channels 76 also cooperate with elongated bosses 77 (Figs. 5 and 6, for example) formed on the exterior of the collar 53 to position the selector ring 70 and hold it in place. A stop 79 is additionally provided to prevent over-rotation of the selector ring 70 when the stop hits recess 78 (see Fig. 15).

C. The Vacuum Connection

As shown in Figs. 22-27, the vacuum tubes 44 terminate in male connectors 54, which are insertable into mating female receptacles 52 formed on the cylinder holder 32. This arrangement serves to provide an easily manipulated secure connection of the vacuum tubes 44 to the ports 42 on the cylinder holder 32.

The male connectors 54 include necked-in middle portion 80 and a port connector end 82. The middle portion 80 includes a number of ridges 84 for gripping the connector 54 and inserting or removing it into the corresponding female receptacle 52. Additionally, the male connectors 54 each include a sealing

surface 86 for sealing the vacuum tubes 44 to the interior sidewalls of the receptacles 52. Moreover, a stop 88 is provided on each of the male connectors 54 to limit the engagement depth of the connectors 54 within the female receptacles 52.

D. Method of Breast Pumping

The present invention also provides an improved method for breast pumping that utilizes the above-described breast pump assembly 20. A woman desiring to express breastmilk removes the piston pump 30 from her manually-operated breast pump. The piston pump 30 is attached to an adapter, such as the aforedescribed cylinder holder 32, and mounted on a motor drive unit 24 that reciprocally moves the piston rod 38 within the piston cylinder 36 of the piston pump 30 to generate a vacuum. Two separate breast pumps 22 are attached, in a preferred embodiment, via separate vacuum tubes 44 to the piston pump 30. The cylinder holder is provided with a vacuum selector, such as selector ring 70, that allows the operator to quickly and easily select either or both of the breast pumps 22 for breast pumping, and to switch from one breast to the other. The woman then supports either or both of the breast pumps 22 on her breasts, depending on the mode of breast pumping that she desires, and activates the motor drive unit 24 for breast pumping. While it is conceivable that the foregoing method could be practiced without the use of the motor drive, i.e. manually, difficulties would be presented in maintaining the two breast pumps in place while also handling the piston pump.

It should be appreciated that the improved breast pump assembly 20 of the present invention may be modified or

configured as appropriate for the desired application. The embodiment described above is to be considered in all respects only as illustrative and not restrictive. Changes may be made without departing from the spirit of the invention. All changes which come within the literal meaning as well as the range of equivalency of the claims are to be embraced within their scope.

WHAT IS CLAIMED IS:

1. An improved breast pump assembly comprising:

a motor drive unit for reciprocally moving a piston rod within the interior of a piston cylinder to generate a vacuum, said piston cylinder having an output end and an end through which said piston rod extends in use,

a cylinder holder connected to said output end of said piston cylinder, said cylinder holder being adapted to be mounted to said motor drive unit for reciprocal movement of said piston rod, said cylinder holder having two ports which communicate with said piston cylinder interior;

two breast pumping units each comprising a breast hood which is adapted to receive a woman's breast therein for the expression of milk, a container for expressed milk which is in fluid communication with said breast hood, and a tube connected at one end to a respective one of said two ports and at the other end to a respective breast hood; and

a selector on said cylinder holder, said selector being operable to connect a vacuum generated within said piston cylinder interior to one or both of said two ports.

2. The assembly of claim 1 wherein the selector is rotatably connected to the cylinder holder.

3. The assembly of claim 1 wherein the cylinder holder further comprises a non-circular cross-section female receptacle disposed around each of said two ports, and each said tube has a mating cross-section male connector at one end.

4. The assembly of claim 1 wherein the cylinder holder further comprises a leakage hole formed in said cylinder holder and extending between ambient atmosphere and a vacuum chamber formed within said cylinder holder, which vacuum chamber is in communication with said piston cylinder interior, said leakage hole being adapted to reduce the vacuum pressure generated within said vacuum chamber when only a single breast pumping unit is being used, such that the vacuum generated within a breast hood is essentially the same for a given piston stroke whether one or both of said breast pumping units are being used, and means for engaging and disengaging said leakage hole with ambient atmosphere.

5. The assembly of claim 4 wherein said leakage hole is disengaged by said selector when said selector connects the vacuum to both of said breast pumping units, and further wherein said leakage hole is engaged when said selector connects the vacuum to either one but not both of said breast pumping units.

6. A breast pump assembly for pumping a single breast as well as two breasts simultaneously, comprising:

a source of intermittent vacuum,

two breast pumping units each comprising a breast hood which is adapted to receive a woman's breast therein for the expression of milk, a container for expressed milk which is in fluid communication with said breast hood, and a tube connected at one end to a respective breast hood; and

a connector device for selectively connecting said vacuum source to said breast pumping units such that intermittent vacuum can thereby be generated in each said breast hood to

effect the expression of milk from a breast, said connector device having an internal chamber in communication with said vacuum source and a pair of ports in communication with said internal chamber, each said port being adapted to receive another end of a respective tube therein to place said breast hood in communication with said vacuum source, and a selector on said connector device, said selector being operable to connect and disconnect either port as well as both ports simultaneously to said internal chamber to effect single and double pumping.

7. The assembly of claim 6 wherein said connector device is in the form of a cylinder holder which is received on an output end of a piston cylinder of a piston pump, said piston pump being used to generate said intermittent vacuum through reciprocation of a piston rod within the interior of said piston cylinder to generate a vacuum, said piston cylinder having an end through which said piston rod extends in use.

8. The assembly of claim 7 further including a motor drive unit for reciprocally moving said piston rod within said piston cylinder to generate a vacuum, said cylinder holder being adapted to be mounted on said motor drive, said motor drive having means to reciprocate said piston rod within said piston cylinder.

9. The assembly of claim 8 wherein said selector is rotatably carried on said cylinder holder.

10. The assembly of claim 9 wherein said cylinder holder further comprises a leakage hole formed in said cylinder holder and extending between ambient atmosphere and a vacuum chamber formed within said cylinder holder, which vacuum chamber is in communication with said piston cylinder interior, said leakage

hole being adapted to reduce the vacuum pressure generated within said vacuum chamber when only a single breast pumping unit is being used, such that the vacuum generated within a breast hood is essentially the same for a given piston stroke whether one or both of said breast pumping units are being used, and means for engaging and disengaging said leakage hole with ambient atmosphere.

11. The assembly of claim 10 wherein said leakage hole is disengaged by said selector when said selector connects the vacuum to both of said breast pumping units, and further wherein said leakage hole is engaged when said selector connects the vacuum to either one but not both of said breast pumping units.

12. An improved breast pump assembly comprising:

a source of intermittent vacuum,

at least one breast pumping unit including a breast hood which is adapted to receive a woman's breast therein for the expression of milk, a container for expressed milk which is in fluid communication with said breast hood, and a tube connected at one end to a respective breast hood; and

a connector device for connecting said vacuum source to said breast pumping unit such that intermittent vacuum can thereby be generated in said breast hood to effect the expression of milk from a breast, said connector device having an internal pathway in communication with said vacuum source and a port in communication with said internal chamber, said port having sidewalls and being formed as a female receptacle of non-circular axial cross-section, and

a male connector on another end of said tube which male connector has a non-circular axial cross-section matched to that of said female receptacle such that said male connector is adapted to be snugly received within said female receptacle in a substantially airtight engagement with said sidewalls.

13. The improved breast pump assembly of claim 12 wherein two breast pumping units are provided, said connecting device having two ports formed thereon for receiving a respective male connector of said breast pumping units, and further including a selector on said connector device, said selector being operable to connect and disconnect either port as well as connect both ports simultaneously to said internal chamber to effect single and double pumping.

14. The improved breast pump assembly of claim 13 wherein said connector device is in the form of a cylinder holder which is received on an output end of a piston cylinder of a piston pump, said piston pump further having a piston rod which is received through another end of said piston cylinder to drive a piston head to generate said intermittent vacuum through reciprocation of said piston rod within the interior of said piston cylinder, said piston cylinder having an end through which said piston rod extends in use.

15. The improved breast pump assembly of claim 14 further including a motor drive unit for reciprocally moving said piston rod within said piston cylinder to generate a vacuum, said cylinder holder being adapted to be mounted on said motor drive, said motor drive having means to reciprocate said piston rod within said piston cylinder with said piston cylinder received

in said cylinder holder and said cylinder holder mounted on said motor drive.

16. The improved breast pump assembly of claim 13 wherein said selector is a ring which is rotatably mounted on said cylinder holder, and said cylinder holder has a first hole extending therethrough which is in communication with one of said ports, a second hole extending therethrough which is in communication with the other of said ports, and a third hole extending therethrough which is in communication with said internal pathway, said selector ring having a cavity formed therein which overlies said three holes in a first position to place both said first and second holes in communication with said vacuum source via said third hole, said selector ring when rotated from said first position selectively covering one of said first and second holes in a second position such that only one of said first and second holes is placed in communication with said vacuum source.

17. The improved breast pump assembly of claim 16 wherein said cylinder holder further comprises a leakage hole formed in said cylinder holder and extending between ambient atmosphere and said internal pathway, said leakage hole being adapted to reduce the vacuum pressure generated when only a single breast pumping unit is being used, such that the vacuum generated within a breast hood is essentially the same for a given piston stroke whether one or both of said breast pumping units are being used, and wherein said selector ring selectively covers and uncovers said leakage hole when said selector ring is rotated to engage and disengage said leakage hole with ambient atmosphere.

18. The breast pump assembly of claim 6 wherein said selector is rotatably mounted on said connector device, and said connector device has a first hole extending therethrough which is in communication with one of said ports, a second hole extending therethrough which is in communication with the other of said ports, and a third hole extending therethrough which is in communication with said internal pathway, said selector having a base with a cavity formed therein, said base having a substantially airtight engagement with said connector device in the vicinity of said cavity such that said cavity forms an air channel which overlies said three holes in a first position to place both said first and second holes in communication with said vacuum source via said third hole, said selector when rotated from said first position selectively covering one of said first and second holes in a second position such that only the other of said first and second holes is placed in communication with said vacuum source.

19. The breast pump assembly of claim 18 wherein said connector device further comprises a leakage hole formed in said connector device and extending between ambient atmosphere and said vacuum chamber, said leakage hole being adapted to reduce the vacuum pressure generated within said vacuum chamber when only a single breast pumping unit is being used, such that the vacuum generated within a breast hood is essentially the same for a given piston stroke whether one or both of said breast pumping units are being used, and wherein said selector selectively covers and uncovers said leakage hole when said selector is

rotated to engage and disengage said leakage hole with ambient atmosphere.

20. A method for pumping a single breast as well as two breasts simultaneously, comprising the steps of:

providing a source of intermittent vacuum,

providing two breast pumping units each comprising a breast hood which is adapted to receive a woman's breast therein for the expression of milk, a container for expressed milk which is in fluid communication with said breast hood, and a tube connected at one end to a respective breast hood;

providing a connector device for selectively connecting said vacuum source to said breast pumping units such that intermittent vacuum can thereby be generated in each said breast hood to effect the expression of milk from a breast, said connector device having an internal chamber in communication with said vacuum source and a pair of ports in communication with said internal chamber, each said port being adapted to receive another end of a respective tube therein to place said breast hood in communication with said vacuum source, and a selector on said connector device, and

operating said selector to connect and disconnect either port as well as connecting both ports simultaneously to said internal chamber to effect single and double pumping.

FIG.1

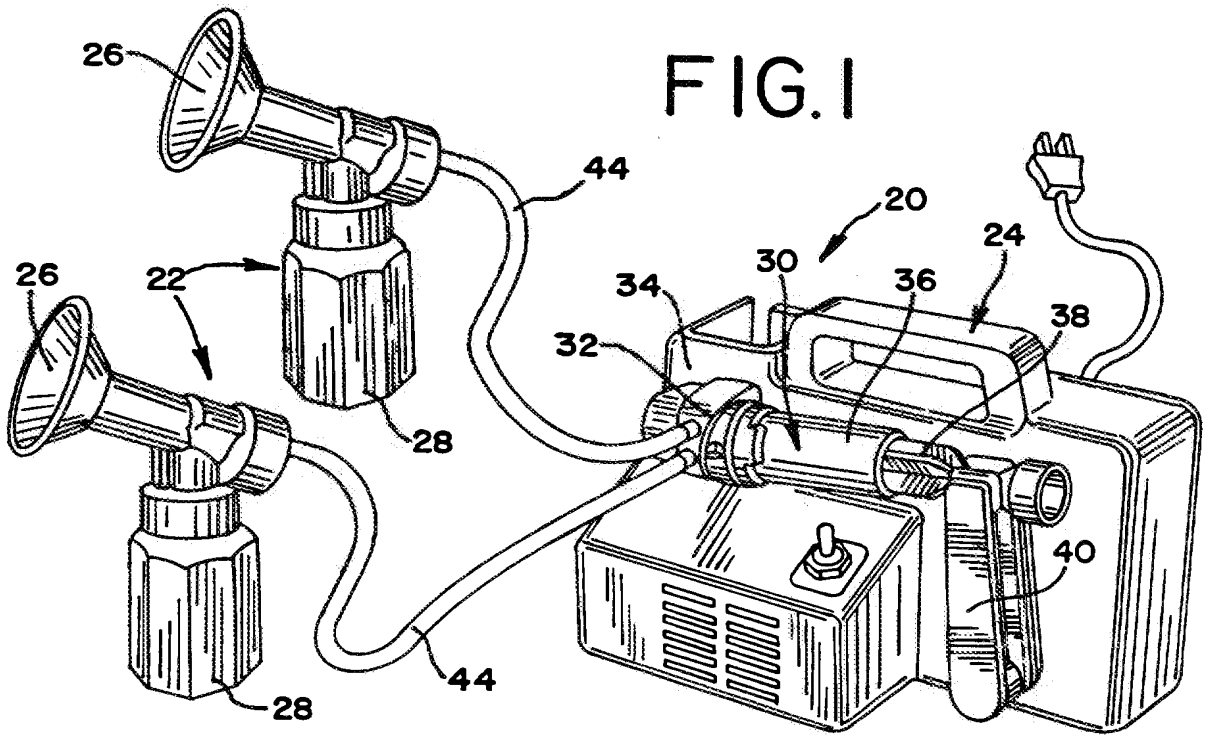


FIG.2

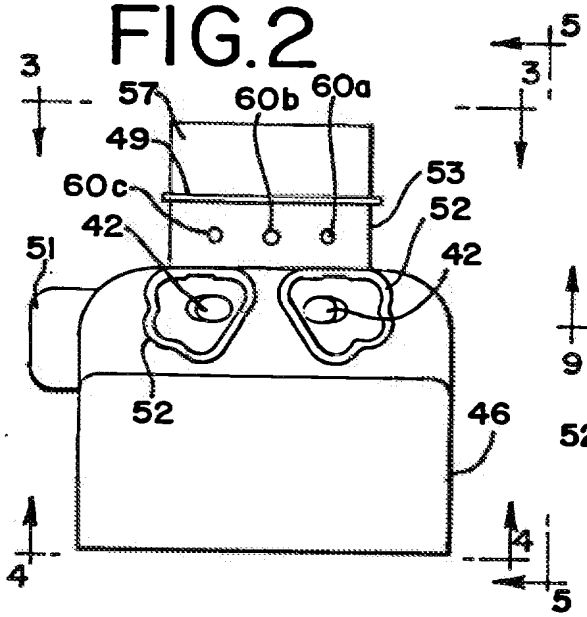


FIG.3

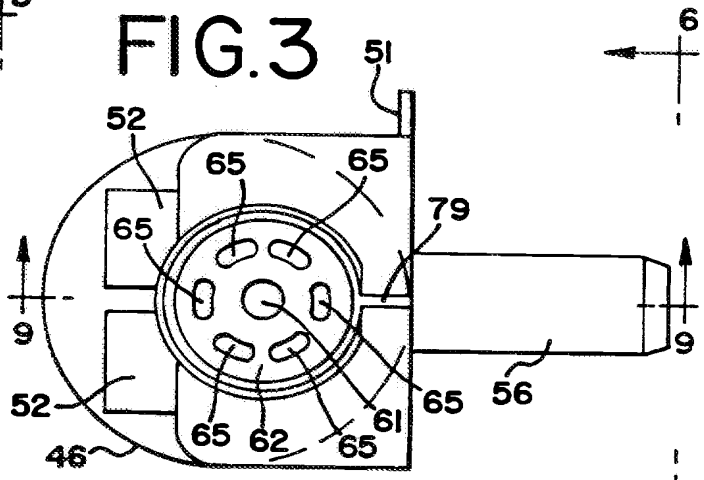


FIG.3A

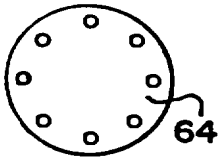


FIG.3B

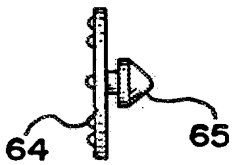


FIG.4

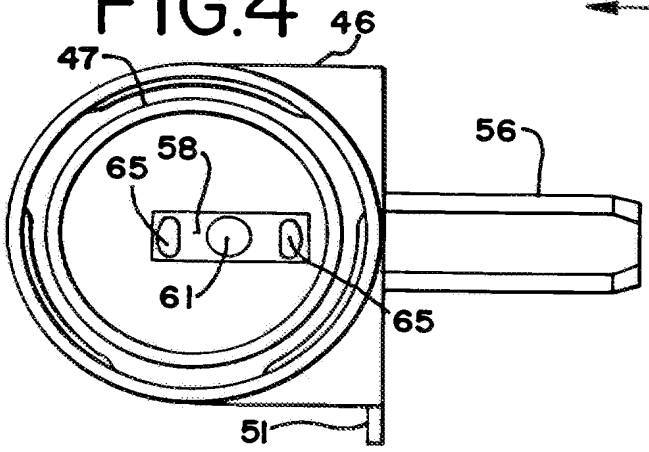


FIG.5

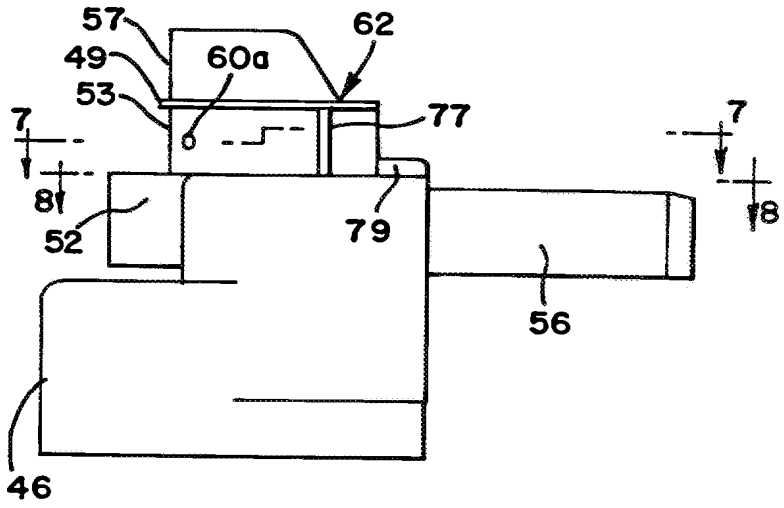


FIG.6

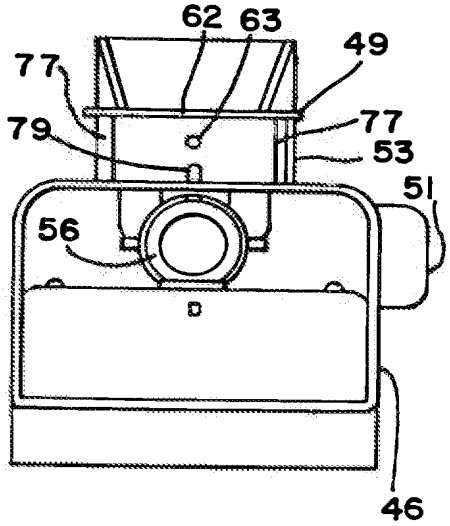


FIG.7

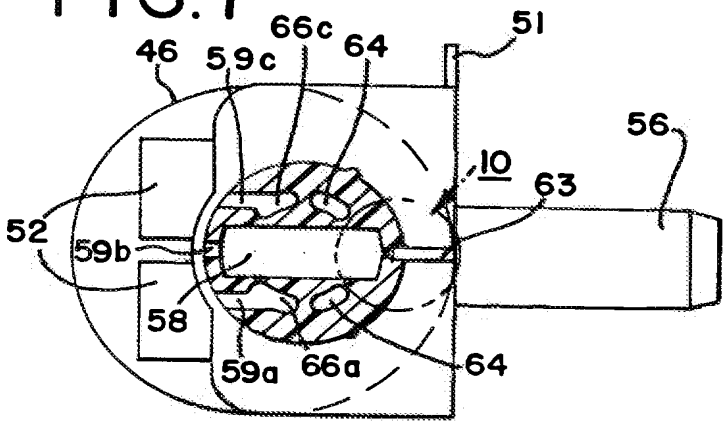


FIG.8

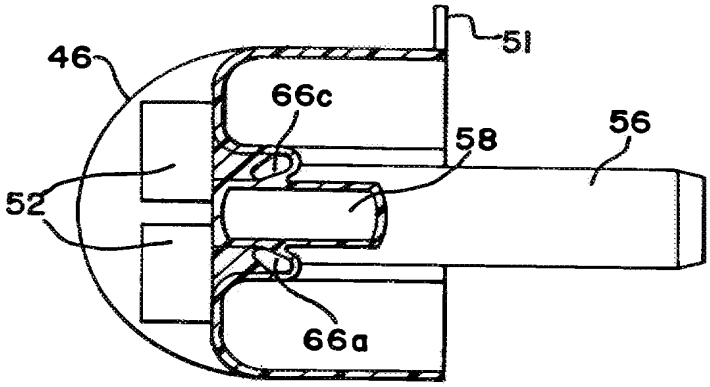


FIG.9

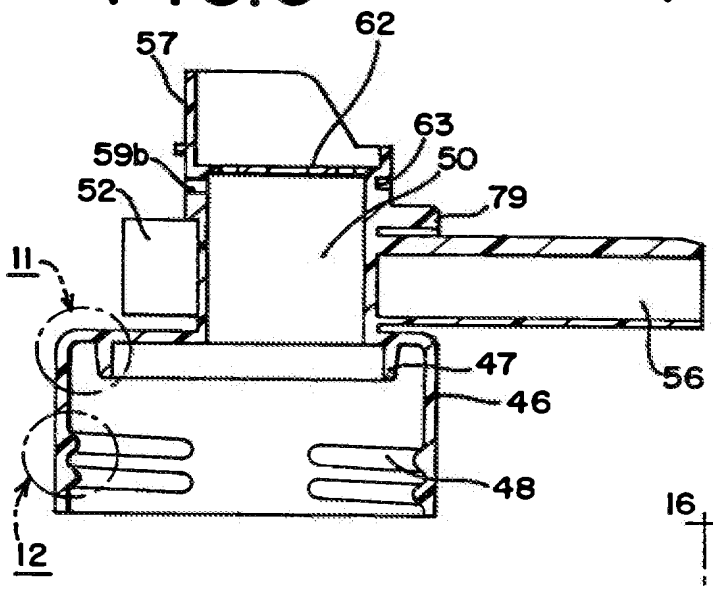


FIG.10

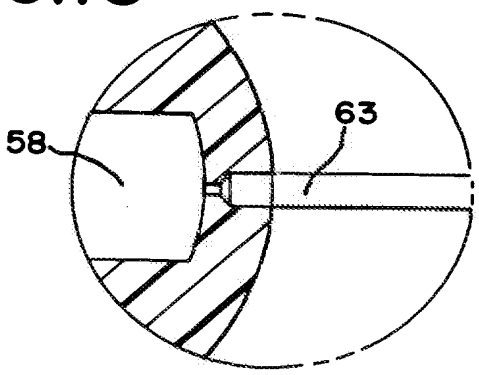


FIG.13

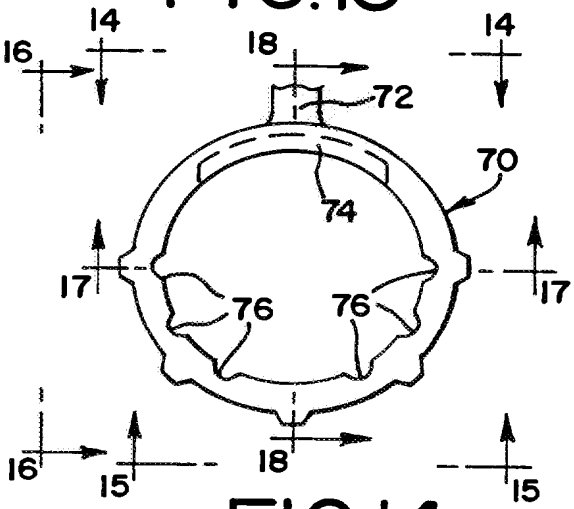


FIG.11

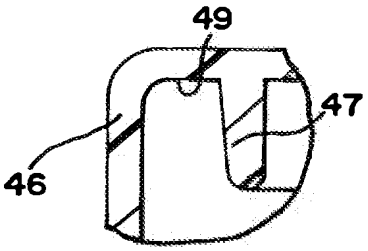


FIG.12

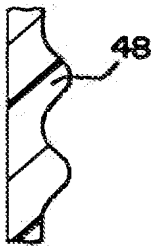


FIG.14

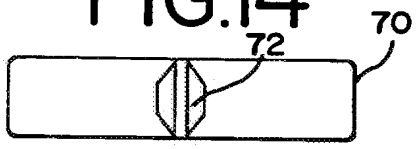


FIG.15

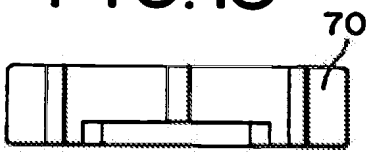


FIG.16

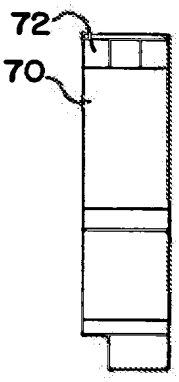


FIG.18

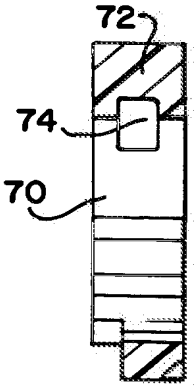


FIG.17

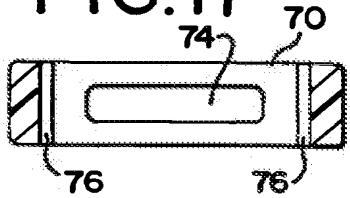


FIG.19

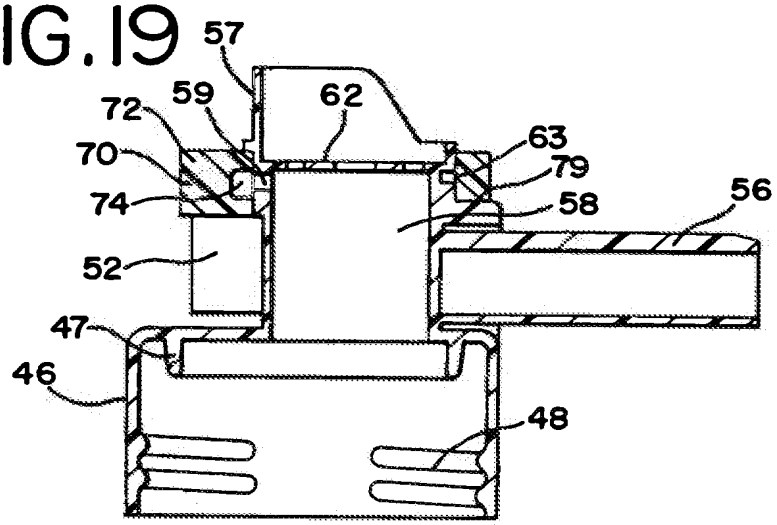


FIG.20

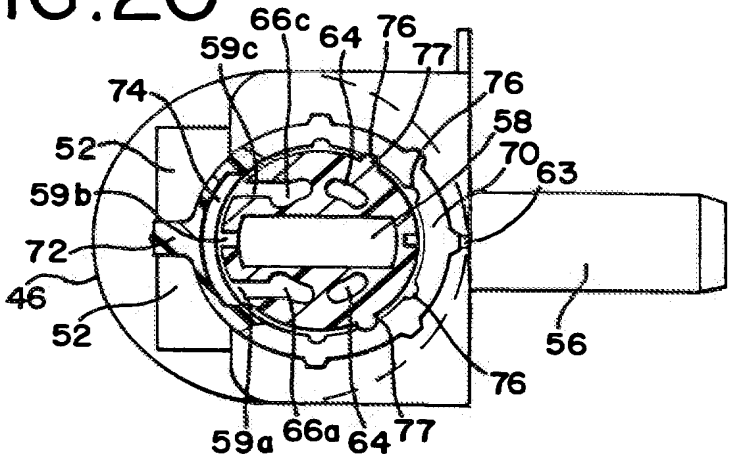


FIG.21

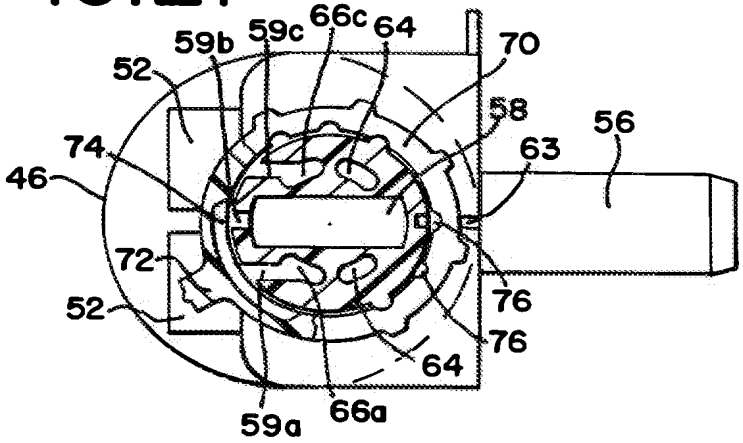


FIG. 22

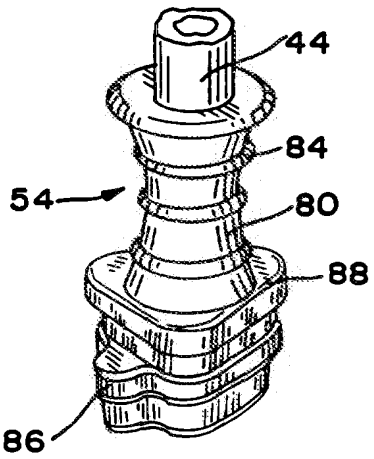


FIG. 23

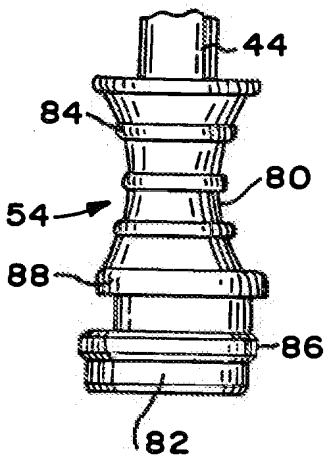


FIG. 24

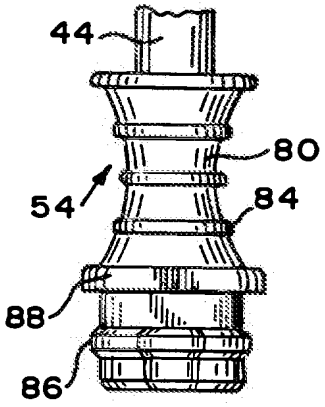


FIG. 25

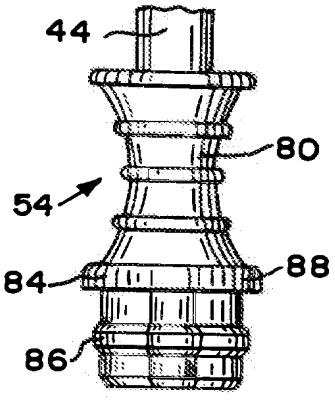


FIG. 27

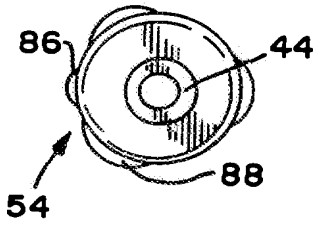
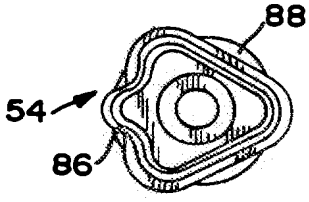


FIG. 26



INTERNATIONAL SEARCH REPORT

Inte. onal application No.
PCT/US96/01911

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 1/06; A61F 5/44
US CL : 604/74, 75, 76, 152, 154, 346
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/74, 75, 76, 152, 154, 346

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,007,899 (LARSSON) 16 April 1991, Note the entire reference.	1-20
Y	US, A, 4,857,051 (LARSSON) 15 Agust 1989, Note the entire reference.	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 25 APRIL 1996	Date of mailing of the international search report 12 JUN 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer for A. T. NGUYEN Telephone No. (703) 308-2154

Form PCT/ISA/210 (second sheet)(July 1992)*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: CHIARO TECHNOLOGY LIMITED	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, COURTNEY B
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Supplemental Information Disclosure Statement

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

Listed on accompanying IDS Forms PTO/SB/08a or its equivalent and PTO/SB/08b or its equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Applicant has listed dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) and is being filed within three months of the date of filing of a national application other than a continued

prosecution application (CPA), OR within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, OR before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

Document **US1** (10,195,321 B2) is submitted herewith as the English-language counterpart of document **FP2** (JP 2016508804 A).

Copies of documents **FP1-FP4** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2)(ii), no copies of the U.S. patents and patent application publications cited on the attached IDS Forms are submitted.

It is expected that the examiner will review the prosecution and cited art in the parent Application No. 16/009,547, filed June 15, 2018, in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Yangbeini Wang #800,005/

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Attorney for Applicant
Registration No. 800,005

Date: March 26, 2024

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202-371-2600

21575601.1

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet | 1 | of | 3

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-10195321-B2	02-05-2019	TATTERFIELD et al.	
	002	US-10335525-B2	07-02-2019	FELBER; Armin et al.	
	003	US-11806454-B2	11-07-2023	DE BECDELIEVRE; Thibault et al.	
	004	US-20060106334-A1	05-18-2006	JORDAN; Alan, et al.	
	005	US-20080171970-A1	07-17-2008	LUZBETAK; Mark A. et al.	
	006	US-20120136325-A1	05-31-2012	ALLEN; Julie et al.	
	007	US-20160174728-A1	06-23-2016	KARP et al.	
	008	US-20160304004-A1	10-20-2016	SANDBOTHE et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]–Number[4]–Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	CN-109621041-A	04-16-2019	BINHAI CHANGZHENG ENTERPRISE MAN CO LTD [CN]		☐
	002	JP-2016508804-A	03-24-2016	KONINKLIJKE PHILIPS N.V. [NL]		☐
	003	WO-2018229504-A1	12-20-2018	CHIARO TECH LIMITED [GB]		☐
	004	WO-9625187-A1	08-22-1996	MEDELA INC [US]		☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author(in CAPITAL LETTERS),title of the article(when appropriate), title of the item (book,magazine,journal,serial,symposium,catalog,etc.),date,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
		None	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO				Complete if Known	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	17/181,057
				Filing Date	02-22-2021
				First Named Inventor	O'TOOLE; Jonathan
				Art Unit	3783
				Examiner Name	COURTNEY B FREDRICKSON
Sheet	3	of	3	Attorney Docket Number	4944.0120006

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Yangbeini Wang #800,005/	Date (YYYY-MM-DD)	2024-03-26
Name/Print	Yangbeini Wang	Registration Number	800,005

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(71) Applicant: **CHIARO TECHNOLOGY LIMITED** [GB/GB]; 63 - 66 Hatton Garden, London EC1N 8LE (GB).

(72) Inventors: **O'TOOLE, Jonathan**; c/o Chiaro Technology Limited, 63 - 66 Hatton Garden, London EC1N 8LE (GB). **ROLLO, Adam**; c/o Chiaro Technology Limited, 63 - 66 Hatton Garden, London EC1N 8LE (GB). **CARR, Andrew**; c/o Chiaro Technology Limited, 63 - 66 Hatton Garden, London EC1N 8LE (GB). **LEVY, Benjamin**; c/o Chiaro Technology Limited, 63 - 66 Hatton Garden, London EC1N 8LE (GB). **COGGINS, Jack**; c/o Chiaro Technology Limited, 63 - 66 Hatton Garden, London EC1N 8LE (GB). **ROSS, Clare**; c/o Chiaro Technology Limited, 63 - 66 Hatton Garden, London EC1N 8LE (GB). **POOLE, Rebecca**; c/o Chiaro Technology Limited, 63 - 66 Hatton Garden, London EC1N 8LE (GB). **PESTANA, Nestor**; c/o Chiaro Technology Limited, 63 - 66 Hatton Garden, London EC1N 8LE (GB).

(74) Agent: **ORIGIN LIMITED**; Twisden Works, Twisden Road, London NW5 1DN (GB).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA,

(54) Title: BREAST PUMP SYSTEM

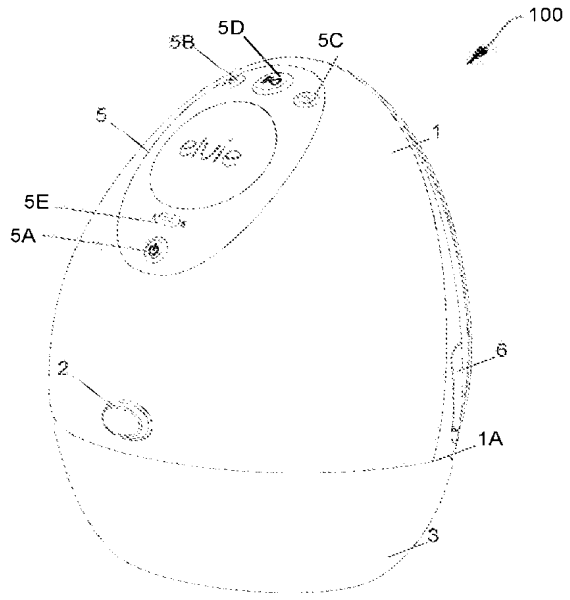

FIGURE 1

(57) Abstract: The invention is a wearable breast pump system including a housing shaped at least in part to fit inside a bra and a piezo air-pump. The piezo air-pump is fitted in the housing and forms part of a closed loop system that drives a separate, deformable diaphragm to generate negative air pressure. The diaphragm is removably mounted on a breast shield.

WO 2018/229504 A1

[Continued on next page]

SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

BREAST PUMP SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

The field of the invention relates to a breast pump system; one implementation of the system is a wearable, electrically powered breast pump system for extracting milk from a mother.

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2. Description of the Prior Art

The specification of the present disclosure is broad and deep. We will now describe the prior art in relation to key aspects of the present disclosure.

Prior art related to breast pump systems

A breast pump system is a mechanical or electro-mechanical device that extracts milk from the breasts of a lactating woman.

A typical breast pump design is as shown in WO 96/25187 A1. A large suction generating device is provided, which is freestanding. This is attached by air lines to one or two breast shields which engage with the user's breasts. A pressure cycle is applied from the suction generating device, via the air lines, to the breast shields. This generates a pressure cycle on the user's breasts to simulate the suction generated by a feeding child.

The suction generating device is a large component that connects to mains power to operate the pumps therein. Milk collection bottles are provided to store the expressed

breast milk. In the system of WO 96/36298 A1 separate bottles are provided attached to each breast shield. A single bottle with tubing connecting to each breast shield may also be used. But for a mother to use this discretely, such as in an office environment, specialised bras must be used. In particular, breast-pumping bras which have a central slit, for the nipple tunnel of the breast shield to extend through, are typically used. The breast shield is held within the bra, with the suction generating device and milk bottle outside the bra.

The fundamental breast pump system has not significantly evolved from this approach, only minor technical improvements have been made.

However, these systems present a number of significant disadvantages. As the suction generating device is a large freestanding unit connected to mains power, the user may feel tethered to the wall. The known devices typically also require a specific user posture and undressing to function normally. This is obviously difficult for a user to do discretely, such as in an office setting. The known devices are also typically noisy, uncomfortable, and hard to clean.

Fully integrated wearable breast pump systems have begun to enter the market, such as described in US 2016 0206794 A1. In such pump systems, the suction source, power supply and milk container are contained in a single, wearable device; there is no need for bulky external components or connections. Such devices can be provided with a substantially breast shaped convex profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations. The internal breast shield is naturally convex to fit over a breast.

In US 2016 0206794 A1, when viewed from the front, the breast pump device has a 'tear-drop' rounded shape, fuller at its base than at its top. But it uses collapsible bags as milk collection devices. As the collection bag systems are collapsible, it can be difficult for a user to extract all of their milk from the bag, due to the small cut opening that is needed and the capillary action between the bonded plastic sheets that form the bag. This waste can be disheartening for the user, as this is food for their child. The bags are also not re-usable, so the user is required to purchase and maintain a stock of these. As well as presenting a recurring cost, if the user runs out of stock they are unable to use the

product until more bags are purchased.

Furthermore, as a result of the collapsible bags, a complex and somewhat noisy pumping arrangement is necessary. In particular, the breast shield connects to a tube which is provided with compression units which "step" the expressed milk through the tube to the collection bag. This uses the breast milk as a hydraulic fluid to generate suction on the breast. In order to carry this out, a complex sequenced pulsing arrangement must be implemented.

In addition to these systems being particularly complex and wasteful, only a relatively small bag can be used. In US 2016 206794, approximately 110 ml (4 fluid ounces) of milk can be collected before the bag must be changed. While this may be sufficient for some users, others may produce much more milk in a session.

A further integrated wearable breast pump system is shown in US 2013 0023821 A1. In the third embodiment in this document, the breast pump system includes a motor driven vacuum pump and power source. An annular (or punctured disc) membrane is provided, with the flow path of the milk going through the centre of the annulus. The membrane is housed in separate housing and is sealed at its inner and outer edges. The breast shield has a small protrusion to engage with these housing components. However, the design of this breast pump system results in a number of problems. The use of an annular membrane, with the fluid flow path running through the opening of the annulus is undesirable as it results in a large and bulky device. There is therefore a need for improved integrated breast pump systems.

Prior Art related to liquid measurement systems

In the context of breast pump systems, it is useful to measure the quantity of expressed milk. One way to do this is to have a clear container for the breast pump, through which the level of expressed milk inside the container can be seen. However, viewing the milk bottle is not always possible, for example in a breast pump that collects milk while being worn inside a maternity bra.

An existing apparatus for detecting the level of liquid inside a container of a breast pump is that disclosed in US 2016/296681. In this apparatus, a sensing mechanism is provided

at the top of a container, which detects droplets of liquid, specifically breast milk, entering the container. By detecting these droplets entering the container, the apparatus can determine the quantity of liquid which enters the container. In this apparatus, an accurate indication of the level of liquid in the container is reliant on the sensing mechanism being able to accurately record every droplet entering the container.

Particularly at times when liquid enters the container at a high flow rate, this accuracy cannot be guaranteed, leading to significant cumulative errors. An accurate indication of the level of liquid in the container in this apparatus is also reliant on the sensing mechanism always being on during the pumping process, so that power consumption of the sensing mechanism is correspondingly high.

In view of the above, there is the need for an improved way to determine the level of liquid inside a container connected to a breast pump.

Prior Art related to bra clips

Many specialised bras (or brassieres) exist for maternity use and that facilitate nursing and/or breast pumping for milk collection, without the need to remove the bra itself. In a traditional nursing bra, this is achieved with the use of an at least partially detachable cup, which can be unhooked for feeding and/or pumping.

Further specialised bras are known which are provided with cut-out portions or slits which substantially align with the wearer's areola and nipple. Traditional breast pump systems comprise an elongate breast shield which extends away from the breast towards an external bottle and source of suction. The breast shield is arranged to extend through the cut-out portion or slit, with the collection bottle and pumping apparatus placed outside of the bra. These systems require the user to remove or unbutton any over-garments, and are uncomfortable when not pumping.

Integrated, wearable breast pump systems have begun to enter the market, such as previously noted US 2016 0206794 A1. In such pumps, the suction source, power supply and milk container are all in a single, wearable device, as noted above, without the need for bulky external components or connections. Such devices can be provided with a substantially breast shaped profile so as to fit within a user's bra for discrete pumping, as

well as pumping on-the-go without any tethers to electrical sockets or collection stations.

Maternity (or nursing) bras such as disclosed in US 4,390,024 A have partially detachable cups, with several hooks provided along the bra strap for attaching the cups to the strap. The cups can then be attached to different hooks in order to adjust the bra strap length. However, these attachment points are fixed. Additionally, this bra has been designed to accommodate the change in breast size before and after the feeding/pumping process. It is not designed to accommodate a breast pump. Accordingly, there is a need for a better system to accommodate integrated wearable breast pumps.

SUMMARY OF THE INVENTION

The invention is a wearable breast pump system including: a housing shaped at least in part to fit inside a bra; a piezo air-pump fitted in the housing and forming part of a closed loop system that drives a separate, deformable diaphragm to generate negative air pressure, that diaphragm being removably mounted on a breast shield.

BRIEF DESCRIPTION OF THE FIGURES

Aspects of the invention will now be described, by way of example(s), with reference to the following Figures, which each show features of various implementations of the invention including optional features that may be utilised:

Figure 1 is a front view of an assembled breast pump system.

Figure 2 is a rear view of the assembled breast pump system of Figure 1.

Figure 3 is a front view of a partially disassembled breast pump system.

Figure 4 is a rear view of the partially disassembled breast pump system of Figure 3.

Figure 5 is a front view of a further partially disassembled breast pump system.

Figure 6 is a rear view of the further partially disassembled breast pump system of Figure 5.

Figure 7 is a front view of the breast pump system of Figure 1, with the outer shell translucent for ease of explanation.

Figure 8 is a further front view of the breast pump system of Figure 1, with the front of the outer shell removed for ease of explanation.

Figure 9 is a schematic view of a nipple tunnel for a breast shield.

Figure 10 is a schematic of a pneumatic system for a breast pump system.

Figure 11 is a schematic of an alternative pneumatic system for a breast pump system.

Figure 12 is a schematic of a further alternative pneumatic system for a breast pump system.

Figure 13 is a graph depicting measured pressure in the breast pump system of Figure 12 over time.

Figure 14 shows schematics for breast shield sizing and nipple alignment.

Figure 15 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 16 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 17 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 18 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 19 shows a screenshot of an application running on a device connected to the

breast pump system.

Figure 20 shows a screenshot of an application running on a connected device.

Figure 21 shows a screenshot of an application running on a connected device.

Figure 22 shows a screenshot of an application running on a connected device.

Figure 23 shows a screenshot of an application running on a connected device.

Figure 24 shows a screenshot of an application running on a connected device.

Figure 25 shows a screenshot of an application running on a connected device.

Figure 26 shows a diagram of a breast pump sensor network,

Figure 27 shows a sectional view of a device being used to determine the level of liquid in a container;

Figure 28 shows a sectional view of the device and the container from Figure 27 being used at a different orientation.

Figure 29 shows a sectional view of the device and the container from Figure 27 being used whilst undergoing acceleration.

Figure 30 shows a sectional view of the device from Figure 27 being used as part of a breast pump assembly.

Figure 31 shows a sectional view of a device connected between a container and its lid, and which is operable to determine the level of liquid inside the container.

Figure 32 depicts a prior art design for a maternity bra;

Figure 33 depicts a clip and clasp being fitted to a maternity bra.

Figure 34 depicts an alternative clip for adjustment of a maternity bra.

Figure 35 depicts the alternative clip of Figure 34.

Figure 36 depicts an alternative clip for adjustment of a maternity bra.

Figure 37 depicts an alternative clip for adjustment of a maternity bra.

Figure 38 depicts an alternative clip for adjustment of a maternity bra.

Figure 39 depicts adjustment of the maternity bra of Figure 37.

Figure 40 shows a configuration with two piezo pumps mounted in series.

Figure 41 shows a configuration of two piezo pumps mounted in parallel.

Figure 42 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in series and mounted in parallel respectively.

Figure 43 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration.

Figure 44 shows a figure of a pump including two piezo pumps in which each piezo pump is connected to a heat sink.

DETAILED DESCRIPTION

We will now describe an implementation of the invention, called the Elvie™ pump, in the following sections:

Section A: The Elvie™ Breast Pump System

Section B: An IR System

Section C: A Bra Clip

Section D: Piezo Pumps and Wearable Devices

Section A: The Elvie™ Breast Pump System

1. Elvie™ Breast Pump System Overview

An implementation of the invention, called the Elvie™ pump, is a breast pump system that is, at least in part, wearable inside a bra. The breast pump system comprises a breast shield for engagement with the user's breast, a housing for receiving at least a portion of the breast shield and a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user, with a milk-flow pathway defined from an opening in the breast shield to the milk collection container. The housing inside also includes a pump for generating a negative pressure in the breast shield, as well as battery and control electronics Unlike other wearable breast pumps, the only parts of the system that come into contact with milk in normal use are the breast shield and the milk container; milk only flows through the breast shield and then directly into the milk container. Milk does not flow through any parts of the housing at all, for maximum hygiene and ease of cleaning.

With reference to Figure 1 and Figure 2, the assembled breast pump system 100 includes a housing 1 shaped to substantially fit inside a bra. The housing 1 includes one or more pumps and a rechargeable battery. The breast pump system includes two parts that are directly connected to the housing 1: the breast shield 7 and a milk container 3. The breast shield 7 and the milk container 3 are directly removable or attachable from the housing 1 in normal use or during normal dis-assembly (most clearly shown in Figure 5). All other parts that are user-removable in normal use or during normal dis-assembly are attached to either the breast shield 7 or the milk container 3. The breast shield 7 and milk container 3 may be removed or attached for example using a one click or one press action or a push button or any other release mechanism. Audible and/or haptic feedbacks confirm that the pump is properly assembled.

The modularity of the breast pump allows for easy assembly, disassembly and replacement of different parts such as the breast shield and milk collection container. This also allows for different parts of the pump to be easily washed and/or sterilised. The breast shield and bottle assembly, both of which are in contact with milk during

pumping, may therefore be efficiently and easily cleaned; these are the only two items that need to be cleaned; in particular, the housing does not need to be cleaned.

The housing 1, breast shield 7 that is holding a flexible diaphragm, and milk container 3 attach together to provide a closed-loop pneumatic system powered by piezoelectric pumps located in the housing 1. This system then applies negative pressure directly to the nipple, forms an airtight seal around the areola, and provides a short path for expressed milk to collect in an ergonomically shaped milk container 3.

The different parts of the breast shield system are also configured to automatically self-seal under negative pressure for convenience of assembly and disassembly and to reduce the risk of milk spillage. Self-sealing refers to the ability of sealing itself automatically or without the application of adhesive, glue, or moisture (such as for example a self-sealing automobile tire or self-sealing envelopes). Hence once the breast pump system is assembled it self-seals under its assembled condition without the need to force seals into interference fits to create sealed chambers. A degree of interference fitting is usual however, but is not the predominating attachment mechanism. Self-sealing enables simple components to be assembled together with a light push: for example, the diaphragm just needs to be placed lightly against the diaphragm housing; it will self-seal properly and sufficiently when the air-pump applies sufficient negative air-pressure. The diaphragm itself self-seals against the housing when the breast shield is pushed into the housing. Likewise, the breast shield self-seals against the milk container when the milk container is pushed up to engage the housing. This leads to simple and fast assembly and dis-assembly, making it quick and easy to set the device up for use, and to clean the device after a session.

Self-sealing has a broad meaning and may also relate to any, wholly or partly self-energising seals. It may also cover any interference seals, such as a press seal or a friction seal, which are achieved by friction after two parts are pushed together.

Whilst one particular embodiment of the invention's design and a specific form of each of the parts of the breast pump system is detailed below, it can be appreciated that the overall description is not restrictive, but an illustration of topology and function that the design will embody, whilst not necessary employing this exact form or number of

discrete parts.

The breast pump system 100 comprises a housing 1 and a milk collection container (or bottle) 3. The housing 1 (including the one or more pumps and a battery) and the container 3 are provided as a unit with a convex outer surface contoured to fit inside a bra. The milk collection container 3 is attached to a lower face 1A of the housing 1 and forms an integral part of the housing when connected, such that it can be held comfortably inside a bra. While the breast pump 100 may be arranged to be used with just the right or the left breast specifically, the breast pump 100 is preferably used with both breasts, without modification. To this end, the outer surfaces of the breast pump 100 are preferably substantially symmetrical.

Preferably, the width of the complete breast pump device (housing 1 and milk container 3) is less than 110 mm and the height of the complete breast pump device is less than 180 mm.

Overall, the breast pump system 100 gives discrete and comfortable wear and use. The system weighs about 224 grams when the milk container is empty, making it relatively lighter as compared to current solutions; lightness has been a key design goal from the start, and has been achieved through a lightweight piezo pump system and engineering design focussed on minimising the number of components.

The breast pump system 100 is small enough to be at least in part held within any bra without the need to use a specialized bra, such as a maternity bra or a sports bra. The rear surface of the breast pump is also concave so that it may sit comfortably against the breast. The weight of the system has also been distributed to ensure that the breast pump is not top heavy, ensuring comfort and reliable suction against the breast. The centre of gravity of the pump system is, when the container is empty, substantially at or below the horizontal line that passes through the filling point on the breast shield, so that the device does not feel top-heavy to a person while using the pump.

Preferably, when the container is empty, the centre of gravity is substantially at or below the half-way height line of the housing so that the device does not feel top-heavy to a user using the pump.

The centre of gravity of the breast pump, as depicted by Figure 1, is at around 60mm high on the centreline from the base of the breast pump when the milk container is empty. During normal use, and as the milk container gradually receives milk, the centre of gravity lowers, which increases the stability of the pump inside the bra. It reduces to around 40mm high on the centreline from the base of the breast pump when the milk container is full.

The centre of gravity of the breast pump is at about 5.85mm below the centre of the nipple tunnel when the milk container is empty, and reduced to about 23.60mm below the centre of the nipple tunnel when the milk container is full. Generalising, the centre of gravity should be at least 2mm below the centre of the nipple tunnel when the container is empty.

The breast pump 100 is further provided with a user interface 5. This may take the form of a touchscreen and/or physical buttons. In particular, this may include buttons, sliders, any form of display, lights, or any other componentry necessary to control and indicate use of the breast pump 100. Such functions might include turning the breast pump 100 on or off, specifying which breast is being pumped, increasing or decreasing the peak pump pressure. Alternatively, the information provided through the user interface 5 might also be conveyed through haptic feedback, such as device vibration, driven from a miniature vibration motor within the pump housing 1.

In the particular embodiment of the Figures, the user interface 5 comprises power button 5A for turning the pump on and off. The user interface 5 further comprises pump up button 5B and pump down button 5C. These buttons adjust the pressure generated by the pump and hence the vacuum pressure applied to the user's breast. In preferable embodiments, the pump up button 5B could be physically larger than the pump down button 5C. A play/pause button 5D is provided for the user to interrupt the pumping process without turning the device off.

The user interface 5 further comprises a breast toggle button 5E for the user to toggle a display of which breast is being pumped. This may be used for data collection, e.g. via an application running on a connected smartphone; the app sends data to a remote server, where data analysis is undertaken (as discussed in more detail later), or for the user to keep track of which breast has most recently been pumped. In particular, there may be a

pair of LEDs, one to the left of the toggle button 5E and one to the right. When the user is pumping the left breast, the LED to the right of the toggle button 5E will illuminate, so that when the user looks down at the toggle it is the rightmost LED from their point of view that is illuminated. When the user then wishes to switch to the right breast, the toggle button can be pressed and the LED to the left of the toggle button 5E, when the user looks down will illuminate. The connected application can automatically track and allocate how much milk has been expressed, and when, by each breast.

The breast pump system also comprises an illuminated control panel, in which the level of illumination can be controlled at night or when stipulated by the user. A day time mode, and a less bright night time mode that are suitable to the user, are available. The control of the illumination level is either implemented in hardware within the breast pump system itself or in software within a connected device application used in combination with the breast pump system.

As depicted in Figure 1, the housing 1 and milk collection container 3 form a substantially continuous outer surface, with a generally convex shape. This shape roughly conforms with the shape of a 'tear-drop' shaped breast. This allows the breast pump 100 to substantially fit within the cup of a user's bra. The milk collection container 3 is retained in attachment with the housing 1 by means of a latch system, which is released by a one-click release mechanism such as a push button 2 or any other one-handed release mechanism. An audible and/or haptic feedback may also be used to confirm that the milk collection container 3 has been properly assembled.

The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting an additional 2 cm difference. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc. In preferred embodiments, the breast pump 100 of the present invention corresponds to an increase of between 3 or 4 cup sizes of the user according to EN 13402.

A plane-to-plane depth of the breast pump can also be defined. This is defined as the distance between two parallel planes, the first of which is aligned with the innermost

point of the breast pump 100, and the second of which is aligned with the outermost point of the breast pump 100. This distance is preferably less than 100 mm.

Figure 2 is a rear view of the breast pump 100 of Figure 1. The inner surface of the housing 1 and milk collection container 3 are shown, along with a breast shield 7. The housing 1, milk collection container 3 and breast shield 7 form the three major subcomponents of the breast pump system 100. In use, these sub-components clip together to provide the functioning breast pump system 100. The breast shield 7 is designed to engage with the user's breast, and comprises a concave inner flange 7A which contacts the breast. To allow the breast pump 100 to be used on either of the user's breasts, the breast shield 7 is preferably substantially symmetrical on its inner flange 7A.

The inner flange 7A is substantially oval-shaped. While the inner flange 7A is concave, it is relatively shallow such that it substantially fits the body form of the user's breast. In particular, when measured side-on the inner-most point of the flange 7A and the outer-most point may be separated by less than 25 mm. By having a relatively shallow concave surface, the forces applied can be spread out over more surface area of the breast. The flatter form also allows easier and more accurate location of the user's nipple. In particular, the flange 7A of the breast shield 7 may extend over the majority of the inner surface of the housing 1 and milk collection container 3. Preferably, it may extend over 80% of this surface. By covering the majority of the inner surface, the breast shield is the only component which contact's the wearer's breast. This leaves fewer surfaces which require thorough cleaning as it reduces the risk of milk contacting a part of the device which cannot be easily sterilized. Additionally, this also helps to disperse the pressure applied to the user's breast across a larger area.

The breast shield 7 substantially aligns with the outer edge 1B of the housing 1. The milk collection container 3 may be provided with an arcuate groove for receiving a lower part of the breast shield 7. This is best shown in later Figures. In the assembled arrangement of Figures 1 and 2, the inner surface of the breast pump 100 is substantially continuous.

The breast shield 7 comprises a shield flange for engaging the user's breast, and an elongate nipple tunnel 9) aligned with the opening and extending away from the user's

breast. Breast shield nipple tunnel 9 extends from a curved section 7B in the breast shield 7. In preferable embodiments the nipple tunnel 9 is integral with the breast shield 7. However, it is appreciated that separate removable/interchangeable nipple tunnels may be used. Curved section 7B is positioned over the user's nipple and areola in use. The breast shield 7 forms an at least partial seal with the rest of the user's breast around this portion, under the negative air pressure created by an air-pressure pump.

This breast shield nipple tunnel 9 defines a milk-flow path from the inner surface of the breast shield 7A, through the breast shield nipple tunnel 9 and into the milk collection container 3. The breast shield nipple tunnel 9 is preferably quite short in order to minimise the length of the milk-flow path in order to minimise losses. By reducing the distance covered by the milk, the device is also reduced in size and complexity of small intermediate portions. In particular, the breast shield nipple tunnel 9 may extend less than 70 mm from its start to end, more preferably less than 50 mm. In use, the nipple tunnel 9 is substantially aligned with the user's nipple and areolae. The nipple tunnel comprises a first opening 9A for depositing milk into the collection container and a second opening 19A for transferring negative air pressure generated by the pump to the user's nipple.

The shield flange 7A and nipple tunnel 9 may be detachable from the housing 1 together. The shield flange 7A and nipple tunnel 9 being detachable together helps further simplify the design, and reduce the number of components which must be removed for cleaning and sterilization. However, preferably, the nipple tunnel 9 will be integral with the breast shield 7, in order to simplify the design and reduce the number of components which must be removed for cleaning and sterilisation.

Figures 3 and 4 are of a partially disassembled breast pump 100 of the present invention. In these Figures, the breast shield 7 has been disengaged from the housing 1 and milk collection bottle 3. As shown in Figure 4, the housing 1 comprises a region or slot 11 for receiving the breast shield nipple tunnel 9 of the breast shield 7. The breast shield is held in place thanks to a pair of channels (9B) included in the nipple tunnel 9, each channel including a small indent. When pushing the housing 1 onto the breast shield 7, which has been placed over the breast, ridges in the housing (9C) engage with the channels, guiding the housing into position; a small, spring plunger, such as ball bearing in each

ridge facilitates movement of the housing on to the nipple tunnel 9. The ball bearings locate into the indent to secure the housing on to the nipple tunnel with a light clicking sound. In this way, the user can with one hand place and position the breast shield 7 onto her breast and with her other hand, position and secure the housing 1 on to the breast shield 7. The breast shield 7 can be readily separated from the housing 1 since the ball bearing latch only lightly secures the breast shield 7 to the housing 1.

Alternatively, the breast shield 7 may also be held in place by means of a clip engaging with a slot located on the housing. The clip may be placed at any suitable point on the shield 7, with the slot in a corresponding location.

The breast shield nipple tunnel 9 of the breast shield 7 is provided with an opening 9A on its lower surface through which expressed milk flows. This opening 9A is configured to engage with the milk collection bottle 3.

The breast pump 100 further comprises a barrier or diaphragm for transferring the pressure from the pump to the milk-collection side of the system. In the depicted example, this includes flexible rubber diaphragm 13 seated into diaphragm housing 19A. The barrier could be any other suitable component such as a filter or an air transmissive material. Diaphragm housing 19A includes a small air hole into the nipple tunnel 9 to transfer negative air pressure into nipple tunnel 9 and hence to impose a sucking action on the nipple placed in the nipple tunnel 9.

Hence, the air pump acts on one side of the barrier or diaphragm 13 to generate a negative air pressure on the opposite, milk-flow side of the barrier. The barrier has an outer periphery or surface, i.e. the surface of diaphragm housing 19A that faces towards the breast, and the milk-flow pathway extends underneath the outer periphery or surface of the barrier or diaphragm housing 19A. The milk-flow path extending under the outer periphery or surface of the barrier 19A allows for a simpler and more robust design, without the milk-flow pathway extending through the barrier. This provides increased interior space and functionality for the device.

As noted, the milk-flow pathway extends beneath or under the barrier 13 or surface of diaphragm housing 19A. This provides an added benefit of having gravity move the milk down and away from the barrier.

Preferably the milk-flow pathway does not pass through the barrier 32. This results in a simpler and smaller barrier design.

As noted, the diaphragm 13 is mounted on diaphragm housing 19A that is integral to the breast shield. This further helps increase the ease of cleaning and sterilisation as all of the components on the "milk" flow side can be removed.

The barrier 13 may also provide a seal to isolate the air pump from the milk-flow side of the barrier. This helps to avoid the milk becoming contaminated from the airflow or pumping side (i.e. the non-milk-flow side).

Alternatively, the only seal is around an outer edge of the barrier 13. This is a simple design as only a single seal needs to be formed and maintained. Having multiple seals, such as for an annular membrane, introduces additional complexity and potential failure points.

As illustrated in Figures 3 and 4, the barrier may include a flexible diaphragm 13 formed by a continuous circular disc shaped membrane which is devoid of any openings or holes. This provides a larger effective "working" area of the diaphragm (i.e. the area of the surface in contact with the pneumatic gasses) than an annular membrane and hence the membrane may be smaller in diameter to have the same working area.

The diaphragm 13 is arranged so that the milk-flow pathway extends below and past the outer surface or periphery of the diaphragm 13. This means that the milk-flow pathway does not extend through the diaphragm 13. In particular, the milk-flow pathway is beneath the diaphragm 13. However, the diaphragm 13 may be offset in any direction with respect to the milk-flow pathway, provided that the milk-flow pathway does not extend through the diaphragm 13.

Preferably, the diaphragm 13 is a continuous membrane, devoid of any openings. The diaphragm 13 is held in a diaphragm housing 19, which is formed in two parts. The first half 19A of the diaphragm housing 19 is provided on the outer surface of the breast shield 7, above the breast shield nipple tunnel 9 and hence the milk-flow pathway. In

preferred embodiments, the first half 19A of the diaphragm housing 19 is integral with the breast shield. The second half 19B of the diaphragm housing is provided in a recessed portion of the housing 1. The diaphragm 13 self-seals in this diaphragm housing 19 around its outer edge, to form a watertight and airtight seal. Preferably, the self-seal around the outer edge of the diaphragm 13 is the only seal of the diaphragm 13. This is beneficial over systems with annular diaphragms which must seal at an inner edge as well. Having the diaphragm 13 mounted in the breast pump 100 in this manner ensures that it is easily accessible for cleaning and replacement. It also ensures that the breast shield 7 and diaphragm 13 are the only components which need to be removed from the pump 100 for cleaning. Because the diaphragm 13 self-seals under vacuum pressure, it is easily removed for cleaning when the device is turned off.

Figures 5 and 6 show a breast pump 100 according to the present invention in a further disassembled state. In addition to the breast shield 7 and diaphragm 13 being removed, the milk collection container 3 has been unclipped. Preferably, the milk collection container 3 is a substantially rigid component. This ensures that expressed milk does not get wasted, while also enhancing re-usability. In some embodiments, the milk collection container 3 may be formed of three sections: a front bottle potion, a rear bottle potion, and a cap. These three sections may clip together to form the milk collection container 3. This three-part system is easy to empty, easily cleanable since it can be dis-assembled, and easily re-usable. The milk collection container or milk bottle may be formed of at least two rigid sections which are connectable. This allows simple cleaning of the container for re-use. Alternatively, the container may be a single container made using a blow moulding construction, with a large opening to facilitate cleaning. This large opening is then closed with a cap with an integral spout 35 or 'sealing plate' (which is bayonet-mounted and hence more easily cleaned than a threaded mount spout). A flexible rubber valve 37 (or 'sealing plate seal') is mounted onto the cap or spout 35 and includes a rubber duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump; this ensures that negative air-pressure does not need to be applied to the milk container and hence adds to the efficiency of the system. The flexible valve 37 self-seals against opening 9A in nipple tunnel 9. Because it self-seals under vacuum pressure, it automatically releases when the system is off, making it easy to remove the milk container.

Preferably, the milk collection container resides entirely below the milk flow path defined by the breast shield when the breast pump system 100 is positioned for normal use, hence ensuring fast and reliable milk collection.

The milk collection container 3 has a capacity of approximately 5 fluid ounces (148 ml). Preferably, the milk collection container has a volume of greater than 120 ml. More preferably, the milk collection container has a volume of greater than 140 ml. To achieve this, the milk collection container 3 preferably has a depth in a direction extending away from the breast in use, of between 50 to 80 mm, more preferably between 60 mm to 70 mm, and most preferably between 65 mm to 68 mm.

The milk collection container 3 further preferably has a height, extending in the direction from the bottom of the container 3 in use to the cap or spout or sealing plate 35, of between 40 mm to 60 mm, more preferably between 45 mm to 55 mm, and most preferably between 48 mm to 52 mm. The cap 35 may screw into the milk collection bottle 3. In particular, it may be provided with a threaded connection or a bayonet and slot arrangement.

Further preferably, the milk collection container has a length, extending from the leftmost point to the rightmost point of the container 3 in use, of between 100 mm to 120 30 mm, more preferably between 105 mm to 115 mm, and most preferably between 107 mm to 110 mm.

This cap 35 is provided with a one-way valve 37, through which milk can flow only into the bottle. This valve 37 prevents milk from spilling from the bottle once it has been collected. In addition, the valve 37 automatically seals completely unless engaged to the breast shield 7. This ensures that when the pump 100 is dismantled immediately after pumping, no milk is lost from the collection bottle 3. It can be appreciated that this one-way valve 37 might also be placed on the breast shield 7 rather than in this bottle cap 35.

Alternatively, the milk bottle 3 may form a single integral part with a cap 35. Cap 35 may include an integral milk pouring spout.

In certain embodiments, a teat may be provided to attach to the annular protrusion 31A

or attach to the spout that is integral with cap 35, to allow the container 3 to be used directly as a bottle. This allows the milk container to be used directly as a drinking vessel for a child. The milk collection container may also be shaped with broad shoulders such that it can be adapted as a drinking bottle that a baby can easily hold.

Alternatively, or in addition, a spout may be provided to attach to the protrusion 31A for ease of pouring. A cap may also be provided to attach to the protrusion 31A in order to seal the milk collection bottle 3 for easy storage.

The pouring spout, drinking spout, teat or cap may also be integral to the milk collection container.

Further, the removable milk collection container or bottle includes a clear or transparent wall or section to show the amount of milk collected. Additionally, measurement markings (3A) may also be present on the surface of the container. This allows the level of milk within the container to be easily observed, even while pumping. The milk collection container or bottle may for example be made using an optically clear, dishwasher safe polycarbonate material such as Tritan™.

The milk collection container or bottle may include a memory or a removable tag, such as a tag including an NFC chip, that is programmed to store the date and time it was filled with milk, using data from the breast pump system or a connected device such as a smartphone. The container therefore includes wireless connectivity and connects to a companion app. The companion app then tracks the status of multiple milk collection containers or bottles to select an appropriate container or bottle for feeding. The tag of the bottle may also be programmed to store the expiry date of the milk as well as the quantity of the milk stored.

Figures 7 and 8 show front views of a breast pump system 100. The outer-surface of the housing 1 has been drawn translucent to show the components inside. The control circuitry 71 for the breast pump 100 is shown in these figures. The control circuitry in the present embodiment comprises four separate printed circuit boards, but it is appreciated that any other suitable arrangement may be used.

The control circuitry may include sensing apparatus for determining the level of milk in the container 3. The control circuitry may further comprise a wireless transmission device for communicating over a wireless protocol (such as Bluetooth) with an external device. This may be the user's phone, and information about the pumping may be sent to this device. In embodiments where the user interface comprises a breast toggle button 5E, information on which breast has been selected by the user may also be transmitted with the pumping information. This allows the external device to separately track and record pumping and milk expression data for the left and right breasts.

There should also be a power charging means within the control circuitry 71 for charging the battery 81. While an external socket, cable or contact point may be required for charging, a form of wireless charging may instead be used such as inductive or resonance charging. In the Figures, charging port 6 is shown for charging the battery 81. This port 6 may be located anywhere appropriate on the housing 1.

Figure 8 shows the location of the battery 81 and the pumps 83A, 83B mounted in series inside the housing 1. While the depicted embodiment shows two pumps 83A, 83B it is appreciated that the present invention may have a single pump. Preferably, an air filter 86 is provided at the output to the pumps 83A, 83B. In preferable embodiments, the pumps 83A, 83B are piezoelectric air pumps (or piezo pumps), which operate nearly silently and with minimal vibrations. A suitable piezo pump is manufactured by TTP Ventus, which can deliver in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free flow. The rear side of the second half of the diaphragm housing 19B in the housing 1 is provided with a pneumatic connection spout. The pumps 83A, 83B are pneumatically connected with this connection spout.

Operation of the breast pump 100 will now be described. Once the breast pump 100 is activated and a pumping cycle is begun, the pumps 83A, 83B generates a negative air pressure which is transmitted via an air channel to a first side of the diaphragm 13 mounted on the diaphragm housing 19A. This side of the diaphragm 13 is denoted the pumping side 13B of the diaphragm 13.

The diaphragm 13 transmits this negative air pressure to its opposite side (denoted the milk-flow side 13A). This negative pressure is transferred through a small opening in the

diaphragm housing 19A to the breast shield nipple tunnel 9 and the curved opening 7B of the breast shield 7 that contacts the breast. This acts to apply the pressure cycle to the breast of the user, in order to express milk. The milk is then drawn through the nipple tunnel 9, to the one way valve 37 that remains closed whilst negative pressure is applied. When the negative air pressure is released, the valve 37 opens and milk flows under gravity past the valve 37 and into milk container 3. Negative air pressure is periodically (e.g. cyclically, every few seconds) applied to deliver pre-set pressure profiles such as profiles that imitate the sucking of a child.

While the depicted embodiment of the breast pump 100 is provided with two pumps, the following schematics will be described with a single pump 83. It is understood that the single pump 83 could be replaced by two separate piezo air-pumps 83A, 83B as above.

Figure 9 depicts a schematic of a further embodiment of a breast shield nipple tunnel 9 for a breast pump 100. The breast shield nipple tunnel 9 is provided with an antechamber 91 and a separation chamber 93. A protrusion 95 extends from the walls of the breast shield nipple tunnel 9 to provide a tortuous air-liquid labyrinth path through the breast shield nipple tunnel 9. In the separation chamber 93 there are two opening 97, 99. An air opening 97 is provided in an upper surface 93A of the separation chamber 93. This upper surface 93 is provided transverse to the direction of the breast shield nipple tunnel 9. This opening 97 connects to the first side of the diaphragm housing 19A and is the source of the negative pressure. This airflow opening 97 also provides a route for air to flow as shown with arrow 96. It is appreciated that the tortuous pathway is not necessary and that a breast shield nipple tunnel 9 without such a pathway will work.

The other opening 99 is a milk opening 99. The milk opening 99 is provided on a lower surface 93B of the separation chamber 93 and connects in use to the container 3. After flowing through the tortuous breast shield nipple tunnel 9 pathway, the milk is encouraged to flow through this opening 99 into the container 3. This is further aided by the transverse nature of the upper surface 93A. In this manner, expressed milk is kept away from the diaphragm 13. As such, the breast pump 100 can be separated into a "air" side comprising the pump 83, the connection spout 85 and the pumping side 13B of the diaphragm 13 and a "milk-flow" side comprising the breast shield 7, the milk collection container 3 and the milk-flow side 13A of the diaphragm 13. This ensures that all of the

"milk-flow" components are easily detachable for cleaning, maintenance and replacement. Additionally, the milk is kept clean by ensuring it does not contact the mechanical components. While the present embodiment discusses the generation of negative pressure with the pump 83, it will be appreciated that positive pressure may instead be generated.

While the embodiments described herein use a diaphragm 13, any suitable structure to transmit air pressure while isolating either side of the system may be used.

The breast pump may further comprise a pressure sensor in pneumatic connection with the piezo pump. This allows the output of the pump to be determined.

Figure 10 shows a schematic of a basic pneumatic system 200 for a breast pump 100. In the system 200 milk expressed into the breast shield 7 is directed through the breast shield nipple tunnel 9 through the torturous air-liquid labyrinth interface 95. The milk is directed through the non-return valve 37 to the collection container 3. This side of the system forms the "milk-flow" side 201.

The rest of the pneumatic system 200 forms the air side 202 and is separated from contact with milk. This is achieved by way of a flexible diaphragm 13 which forms a seal between the two sides of the system. The diaphragm 13 has a milk-flow side 13A and an air side or pumping side 13B.

The air side 202 of the system 200 is a closed system. This air side 202 may contain a pressure sensor 101 in pneumatic connection with the diaphragm 13 and the pump 83. Preferably, the pump 83 is a piezoelectric pump (or piezo pump). Due to their low noise, strength and compact size, piezoelectric pumps are ideally suited to the embodiment of a small, wearable breast pump. The pump 83 has an output 83A for generating pressure, and an exhaust to the atmosphere 83B. In a first phase of the expression cycle, the pump 83 gradually applies negative pressure to half of the closed system 202 behind the diaphragm 13. This causes the diaphragm 13 to extend away from the breast, and thus the diaphragm 13 conveys a decrease in pressure into the breast shield 7. The reduced pressure encourages milk expression from the breast, which is directed through the tortuous labyrinth system 95 and the one-way valve 37 to the collection bottle 3.

While in the depicted embodiment the air exhaust 83B is not used, it may be used for functions including, but not limited to, cooling of electrical components, inflation of the bottle to determine milk volume (discussed further later) or inflation of a massage bladder or liner against the breast. This massage bladder may be used to help mechanically encourage milk expression. More than one massage bladder may be inflated regularly or sequentially to massage one or more parts of the breast. Alternatively, the air pump may be used to provide warm air to one or more chambers configured to apply warmth to one or more parts of the breast to encourage let-down.

The air side 202 further comprises a two-way solenoid valve 103 connected to a filtered air inlet 105 and the pump 83. Alternatively, the filter could be fitted on the pump line 83A. If the filter is fitted here, all intake air is filtered but the performance of the pump may drop. After the negative pressure has been applied to the user's breast, air is bled into the system 202 through the valve 103 in a second phase of the expression cycle. In this embodiment, the air filter 105 is affixed to this inlet to protect the delicate components from degradation. In particular, in embodiments with piezoelectric components, these are particularly sensitive.

The second phase of the expression cycle and associated switching of valve 103 is actioned once a predefined pressure threshold has been reached. The pressure is detected by a pressure sensor 101.

In certain embodiments, if the elasticity and extension of the diaphragm 13 may be approximated mathematically at different pressures, the pressure measured by sensor 101 can be used to infer the pressures exposed to the nipple on the opposite side of the diaphragm 13. Figure 11 shows an alternative pneumatic system 300. The core architecture of this system is the same as the system shown in Figure 10.

In this system 300, the closed loop 202 is restricted with an additional three way solenoid valve 111. This valve 111 allows the diaphragm 13 to be selectively isolated from the rest of the closed loop 202. This additional three way valve 111 is located between the diaphragm 13 and the pump 83. The pressure sensor 101 is on the pump 83 side of the three way valve 111. The three way valve 111 is a single pole double throw (SPDT) valve,

wherein: the pole 111A is in pneumatic connection with the pump 83 and pressure sensor; one of the throws 11 is in pneumatic connection with the diaphragm 13; and the other throw 111C is in pneumatic connection with a dead-end 113. This dead-end 113 may either be a simple closed pipe, or any component(s) that does not allow the flow of air into the system 202. This could include, for example, an arrangement of one-way valves.

In this system 300, therefore, the pump 83 has the option of applying negative pressure directly to the pressure sensor 101. This allows repeated testing of the pump in order to calibrate pump systems, or to diagnose issues with the pump in what is called a dead end stop test. This is achieved by throwing the valve to connect the pump 83 to the dead end 113. The pump 83 then pulls directly against the dead end 113 and the reduction of pressure within the system can be detected by the pressure sensor 101.

The pressure sensor detects when pressure is delivered and is then able to measure the output of the pumping mechanism. The results of the pressure sensor are then sent to an external database for analysis such as a cloud database, or are fed back to an on-board microcontroller that is located inside the housing of the breast pump system.

Based on the pressure sensor measurements, the breast pump system is able to dynamically tune the operation of the pumping mechanism (i.e. the duty or pump cycle, duration of a pumping session, the voltage applied to the pumping mechanism, the peak negative air pressure) in order to ensure a consistent pressure performance across different breast pump systems.

In addition, the breast pump system, using the pressure sensor measurements, is able to determine if the pump is working correctly, within tolerance levels. Material fatigue of the pump is therefore directly assessed by the breast pump system. Hence, if the output of the pumping mechanism degrades over time, the breast pump system can tune the pumping mechanism operation accordingly. As an example, the breast pump system may increase the duration of a pumping session or the voltage applied to the pumping mechanism to ensure the expected pressures are met.

This ensures that the user experience is not altered, despite the changing output of the pump as it degrades over time. This is particularly relevant for piezo pumps where the output of the pump may vary significantly.

The microcontroller can also be programmed to deliver pre-set pressure profiles. The pressure profiles may correspond to, but not necessarily, any suction patterns that would mimic the sucking pattern of an infant. The patterns could mimic for example the sucking pattern of a breastfed infant during a post birth period or at a later period in lactation.

The profiles can also be manually adjusted by the user using a control interface on the housing of the breast pump system or on an application running on a connected device.

Additionally, the user is able to manually indicate the level of comfort that they are experiencing when they are using the system. This can be done using a touch or voice-based interface on the housing of the breast pump system itself or on an application running on a connected device.

The system stores the user-indicated comfort levels together with associated parameters of the pumping system. The pressure profiles may then be fine scaled in order to provide the optimum comfort level for a particular user.

The profiles or any of the pumping parameters may be calculated in order to correlate with maximum milk expression rate or quantity.

The pressure profiles or any of the pumping parameters may also be dynamically adjusted depending on the real time milk expression rate or quantity of milk collected. The pressure profiles or any of the pumping parameters may also be dynamically adjusted when the start of milk let-down has been detected.

Additionally, the system is also able to learn which parameters improve the breast pump system efficiency. The system is able to calculate or identify the parameters of the pumping mechanism that correlate with the quickest start of milk let-down or the highest volume of milk collected for a certain time period. The optimum comfort level for a particular user may also be taken into account.

Figure 12 shows a schematic for a system 400 for a breast pump 100 which can estimate the volume of milk collected in the collection container 3 from data collected on the air-side part 202 of the system 400.

The pump 83 is connected to the circuit via two bleed valves 126, 128. The first bleed valve 126 is arranged to function when the pump 83 applies a negative pressure. As such, this valve 126 is connected to a "bleed in" 127, for supplying atmospheric air to the system 202.

The second bleed valve 128 is arranged to function when the pump 83 applies a positive pressure. As such, this valve 128 is connected to a "bleed out" 129 for bleeding air in the system 202 to the atmosphere.

Although Section C describes the preferred embodiment for measuring or inferring the volume of milk collected in the milk collection container using IR sensors, an alternative method for measuring or inferring the volume of milk collected in the milk collection container using pressure sensors is described also below.

During a milking pump cycle, the pump 83 applies negative pressure on the air side 13B of the diaphragm 13 which causes its extension towards the pump 83. This increases the volume of the space on the milk side 13B of the diaphragm 13. This conveys the decrease in pressure to the breast to encourage expression of milk. A set of three non-return valves 121, 123, 125 ensure that this decrease in pressure is applied only to the breast (via the breast shield 7) and not the milk collection container 3. To measure the volume of milk collected in the container 3, the pump 83 is used instead to apply positive pressure to the diaphragm 13. The diaphragm 13 is forced to extend away from the pump 83 and conveys the pressure increase to the milk side 201 of the system 400. The three non-return valves 121, 123, 125 ensure that this increase in pressure is exclusively conveyed to the milk collection container 13.

The breast pump may further comprise: a first non-return valve between the milk flow side of the diaphragm and the breast shield, configured to allow only a negative pressure to be applied to the breast shield by the pump; a second non-return valve between the milk-flow side of the diaphragm and the milk collection container configured to allow only a positive pressure to be applied to the milk collection container by the pump; and a pressure sensor in pneumatic connection with the pressure-generation side of the diaphragm.

The resulting pressure increase is monitored behind the diaphragm 13 from the air-side 202 by a pressure sensor 101. Preferably, the pressure sensor 101 is a piezoelectric pressure sensor (piezo pressure sensor). The rate at which the pump 83 (at constant strength) is able to increase the pressure in the system 400 is a function of the volume of air that remains in the milk collection container 3. As air is many times more compressible than liquid, the rate at which pressure increases in the system 400 can be expressed as an approximate function of the volume of milk held in the collection container 3.

Thus by increasing the pressure in this fashion, the rate of pressure increase can be determined, from which the volume of milk held in the container 3 is calculable. Figure 13 shows repeated milking and volume measurement cycles as the collection container 3 is filled. To determine the rate of pressure increase the pump 83 was run for a fixed time. As pumping proceeds and the volume of air reduces in the system 400, the pump 83 is able to achieve a higher pressure. Each milking cycle is represented by a positive pressure spike 41. There is a clear upwards trend 43 in magnitude of positive pressures achieved as the collection container 3 is filled.

A method of estimating the pressure applied by a breast pump may comprise the steps of: selecting a pressure cycle from a pre-defined list of pressure cycles; applying pressure with the pump to stimulate milk expression; reading the output of the pressure sensor; and adjusting the applied pressure of the pump to match the pressure profile selected. This allows for repeatable application of force to the breast, even as the pump performance degrades.

Preferably the method further comprises the steps of: approximating the elasticity and extension of the diaphragm at the relevant pressure; and calculating an estimated applied pressure based upon the output of the pressure sensor and the approximated elasticity and extension of the diaphragm.

Alternatively, a method of estimating the milk collected by a breast pump may comprise the steps of: generating a positive pressure with the pump; transmitting the positive pressure via the diaphragm and second non-return valve to only the milk collection

container; measuring the increase in pressure by the pressure sensor in pneumatic connection with the diaphragm; estimating the volume of milk inside the milk collection container based upon the rate of increase of pressure. In this manner, the volume of milk can be estimated remotely.

In this manner, an estimate can be obtained for the volume of milk in the container 3 based upon the measured pressures.

Figure 13 also shows a dead end stop pump test 45 as described above. The negative spike shows the application of negative pressure directly to the pressure sensor 101.

2. Breast shield sizing and nipple alignment

The correct sizing of the breast shield and the alignment of the nipple in the breast shield are key for an efficient and comfortable use of the breast pump. However breast shape, size as well as nipple size and position on the breast vary from one person to another and one breast from another. In addition, women's bodies often change during the pumping life cycle and consequently breast shield sizing may also need to be changed. Therefore, a number of breast shield sizes are available. Guide lines for correct nipple alignment are also provided.

With reference to Figure 14, three breast shield sizes are shown (A1, B1, C1). The substantially clear breast shield gives an unobstructed view of the breast and allows a user to easily confirm that she has the appropriate sized shield for her breast.

In order to determine the correct breast shield size and nipple alignment, the breast shield and the diaphragm are detached from the housing and placed on the breast with the sizing symbol facing upwards (with the diaphragm positioned below the nipple) and the nipple aligned in the centre of the fit lines (as shown in A2, B2, C2). The transparent breast shield allows the user to observe the nipple while adjusting the position of the breast shield in order to align the nipple correctly near the centre of the breast shield nipple tunnel. Prior to using the pump, the nipple is aligned correctly, and the breast shield is pushed into place ensuring the seal is correctly positioned on the breast shield. The fit lines should be directly aligned with the outside of the nipple. The correct

alignment is illustrated B2.

When the nipple is correctly aligned, the user then rotates the breast shield in order for the diaphragm to be positioned on top of the nipple. The user may then quickly assemble the rest of the breast pump (i.e. the housing and the milk container) on the breast shield via a one-click attachment mechanism confirming correct engagement, which may be performed one-handed. Nipple alignment may therefore be easily maintained. Audio and/or haptic feedback may also be provided to further confirm correct engagement.

3. Connected Device Application

Figures 15 to 20 show examples of screenshots of a connected device application that may be used in conjunction with the breast pump system as described above. The interface shown here is an example only and the same data may be presented via any conceivable means including animated graphics, device notifications, audio or text descriptions.

Figure 15 shows a homepage of the application with different functions provided to the user which can be accessed either directly while pumping or at a later time in order for example: to review pump settings or the history of previous pumping sessions.

Figure 16 shows a status page with details of remaining battery life, pumping time elapsed and volume of milk inside the milk container.

Figure 17 shows screenshots of a control page, in which a user is able to control different pump parameters for a single breast pump (A) or two breast pumps (B). The user may press on the play button to either start, pause, or resume a pumping activity. The user may also directly increase or decrease the rate of expression using the (+) or (-) buttons. When only one breast is being pumped (A), the user may also indicate if it is either the right or left breast that is being pumped. The user may also control the pump peak pressure or alternatively may switch between different pre-programmed pressure profiles such as one mimicking the sucking pattern of a baby during expression or stimulation cycle.

Figure 18 shows a page providing a summary of the last recorded pumping session.

Figure 19 shows a page providing a history of previous pumping sessions. The user may scroll down through the page and visualize the data related to specific pumping sessions as a function of time.

The application is also capable of providing notifications relating to pumping. Figure 20 shows a screenshot of the application, in which a user is provided a notification when the milk collection bottle is full. Other generated notifications may include warnings about battery life, Bluetooth connection status or any other wireless communication status, status of miss-assembly, excessive movement or lack of expression.

Figure 21 shows a further example with a screenshot of an application running on a connected device. The page shows the pumping status when a user is using a double pump mode of operation with a pump on each breast. The user is able to manually control each pump individually and may start, stop or change a pumping cycle, increase or decrease each pump peak pressure, or switch between different pre-program pressure profiles such as one mimicking the sucking pattern of a baby during an expression or stimulation cycle. The application also notifies the user when a milk collection container is nearly full as shown in Figure 22.

Figure 23 shows a status page with an alert notifying the user that the milk collection container of the pump on the right breast is full. A message is displayed that the pump session has paused and that the milk collection container should be changed or emptied before resuming pumping.

With reference to Figure 24, when the left and right pump are stopped or paused, the application displays the elapsed time since the start of each session (right and left), the total volume of milk collected in each bottle.

With reference to Figure 25, a page summarising the last session (with a double pump mode) is displayed.

In addition to the data provided to the user, and their interactions with the application, the app will also hold data that the user does not interact with. For example, this may include data associated with pump diagnostics. In addition to all functions and sources of

data discussed above, the application may itself generate metadata associated with its use or inputs, notes or files uploaded by the user. All data handled within the mobile application can be periodically transferred to a cloud database for analysis. An alternative embodiment of the breast pump system may include direct contact between the database and the pump, so that pumping data may be conveyed directly, without the use of a smartphone application.

In addition to providing data to the cloud, the application may also provide a platform to receive data including for example firmware updates.

4. Breast pump data analysis

The discreet, wearable and fully integrated breast pump may offer live expression monitoring and intelligent feedback to the user in order to provide recommendations for improving pump efficiency or performance, user comfort or other pumping/sensing variables, and to enable the user to understand what variables correlate to good milk flow.

Examples of variables automatically collected by the device are: time of day, pump speed, pressure level setting, measured pressure, pressure cycle or duty cycle, voltage supplied to pumps, flow rate, volume of milk, tilt,, temperature, events such as when let-down happens, when a session is finished. The user can also input the following variables: what side they have pump with (left or right or both), and the comfort level.

This is in part possible because the live milk volume measurement system functions reliably (as discussed in Section B). The breast pump system includes a measurement sub system including IR sensors that measures or infers milk flow into the milk container, and that enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. The generated data may then be distributed to a connected device and/or to a cloud server for analysis in order to provide several useful functions.

Figure 26 illustrates an outline of a smart breast pump system network which includes the breast pump system (100) in communication with a peripheral mobile device and application (270) and several cloud-based databases (268, 273). The breast pump system

(100) includes several sensors (262). Sensor data refers to a broad definition including data generated from any sensor or any other analogue/digital reading directly from the motherboard or any other component. However, within the embodiment detailed, these measurements include one or more of the following, but not limited to: milk volume measurements, temperature sensor readings, skin temperature sensing, pressure sensor readings, accelerometer data and user inputs through any physical device interface.

The device also contains a number of actuators, including, but not restricted to: piezoelectric pump(s), solenoid valve(s), IREDs and an LED display. Sensors and actuators within the device are coordinated by the CPU (263). In addition, any interactions, and data from these components, may be stored in memory (264).

Further to these components, the device also contains a communication chip, such as a Bluetooth chip (265) which can be used to communicate wirelessly with connected devices such as a peripheral mobile device (270). Through this connection any sensor data (267) generated in the breast pump can be sent to the connected device. This user data, along with any other metadata generated from a connected device app, can be provided to an online database which aggregates all user data (273). In addition, the communication chip will also allow the sending of user control data / firmware updates from the connected device to the breast pump system (266).

Raw data (271) collected from the measurement sub-system including sensors (262) may be analysed on a cloud database and the analysed data may be stored on the cloud (272). Through inferences provided by the analysed data, firmware updates (269) may be developed. These can be provided for download to the pump through, for example, an online firmware repository or bundled with the companion app in the connected device app store (268).

In addition, it should be appreciated that despite the sophistication of the proposed breast pump network, the breast pump still retains complete functionality without wireless integration into this network. Relevant data may be stored in the device's memory (264) which may then be later uploaded to the peripheral portion of the system when a connection is established, the connection could be via USB cable or wireless.

The measurement sub-system may analyse one or more of the following:

- the quantity of the liquid in the container above its base;
- the height of the liquid in the container above its base;
- the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.

Based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase, a haptic and/or visual indicator indicates if the pump is operating correctly to pump milk. For example, the visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.

The visual indicator may provide:

- an estimation of the flow rate;
- an estimation of the fill rate;
- an indication of how much of the container has been filled.

As a further example, an accelerometer may infer the amount of movement or tilt angle during a pumping session. If the tilt angle excesses a threshold, the system warns or alerts the user of an imminent spillage, or provides the user with an alert to change position. Alternatively, the system may also stop pumping to prevent spillage, and once the tilt angle reduces below the threshold, pumping may resume automatically. By sensing the movement or title angle during a pumping session, the system may also derive the user's activity such as walking, standing or lying.

Many variables can affect milk expression and data analysis of these multiple variables can help mothers to achieve efficient pumping regimes and improve the overall user experience.

Therefore, the measurement sub-system measures or infers milk flow into the milk container and enables a user to understand what variables (e.g. time of day, pump setting) correlates to good milk flow. The amount of milk expressed over one or more sessions is recorded as well as additional metrics such as: time of day, pump setting, length of a single pumping session, vacuum level, cycle times, comfort, liquids consumed by the mother. Live data or feedback is then provided to the user to ensure the breast pump is

being used properly and to support the user in understanding the variables that would correspond to the specific individual optimum use of the breast pump.

Furthermore, live data can be used to automatically and intelligently affect specific pumping parameters in order to produce the most efficient pumping session. For example, if the rate of expression increases, the milking cycle might be adjusted accordingly to achieve a more efficient, or more comfortable pumping cycle.

The measurement sub-system also enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. Collected metrics are transferred through wireless connections between the pump, a connected device or app and a cloud database. Additionally, the application can also connect to other apps residing on the connected device, such as fitness app or social media app or any other apps. Further metrics may also include the behaviour or specific usage of the user associated with the connected device while using the pump (detection of vision and/or audio cues, internet usage, application usage, calls, text message).

Different aspects of pumping can be automatically changed based on dynamic sensor feedback within the breast pump device. The data analysis system is able to access real-time data of pumping sessions and may be used to perform one or more of the following functions, but not limited to:

- indicate whether the milk is flowing or not flowing,
- measure or infer the quantity and/or height of the liquid in the container above its base,
- give recommendations to the mother for optimal metrics for optimal milk flow,
- give recommendations to the mother for optimal metrics for weaning,
- give recommendations to the mother for optimal metrics for increasing milk supply (e.g. power pumping),
- give recommendations to the mother for optimal metrics if an optimal session start time or a complete session has been missed,
- automatically set metrics for the pumping mechanism, such as length of a single pumping session, vacuum level, cycle times.
- automatically stop pumping when the milk container is full,
- automatically adjust one or more pumping parameters to achieve an optimum

pumping session,

- automatically adjust one or more pumping parameters to achieve a comfortable pumping session,
- automatically change the pumping cycle from a programmed cycle to another different programmed cycle, such as from a stimulation cycle to an expression cycle.

In addition, sensor feedback might be used to improve the physical function of the breast pump system itself. For example, an array of piezoelectric pumps may be dynamically adjusted in response to their operating temperatures so as to optimise the total life of the component whist maintaining peak pressures.

Many additional embodiments may be described for these simple feedback systems, yet the premise remains: real-time sensor feedback is used to automatically and dynamically adjust actuator function. Each feedback program may feasibly include any number and combination of data sources and affect any arrangement of actuators.

The data generated can also be used to generate large datasets of pumping parameters, user metadata and associated expression rates, therefore allowing the analysis of trends and the construction of associations or correlations that can be used to improve pumping efficiency, efficacy or any function related to effective milk expression. The analysis of large user datasets may yield useful general associations between pumping parameters and expression data, which may be used to construct additional feedback systems to include on firmware updates.

Multiple data sources can be interpreted simultaneously and several different changes to pumping might be actuated to increase pumping efficiency, user experience or optimize pump performance.

Collected metrics may be anonymised and exported for sharing to other apps, community or social media platforms on the connected device, or to an external products and services, such as community or social media platform. By contrasting the performance of different users in the context of associated metadata, users may be grouped into discrete 'Pumper profiles' or communities, which may then be used to

recommend, or action the most appropriate selection of intelligent feedback systems to encourage efficient expression. For example, a higher peak pressure may be recommended for women who tend to move more whilst pumping, so as to achieve more efficient expression.

5

SECTION B: IR SYSTEM

This section describes the milk detecting system used in the Elvie™ pump.

With reference to Figures 27 and 28, there is shown a device 270 for use in detecting the level of liquid inside a container 275. The device 270 is formed of a housing 271 in which is located a sensing assembly 272 comprising a series of optical emitters 273 (an array of three optical emitters is used on one implementation) which are relative to, and each located at a distance from, an optical receiver 274. In operation of the device as will be described, each optical emitter 273 is operable to emit radiation which is received by the optical receiver 274. In an embodiment of the invention, the series of optical emitters are each located equidistant from the optical receiver 274.

The optical emitters 273 and the optical receiver 274 from the sensing assembly 272 are located in a portion 276 of the device 270 which faces the container 275 when the device is connected to the container 275. The portion 276 of the device 270 containing the optical emitters 273 and the optical receiver 274 comprises a window 277 of material which is transparent to optical radiation. In this way, each of the optical emitters 273 and the optical receiver 274 have a line of sight through the window 277 into the container 275 when the device 270 is connected thereto.

A controller 278 comprising a CPU 279 and a memory 280 is provided in the device 270 for controlling the operation of the sensing assembly 272. An accelerometer 281 is also provided in the housing 271, which is operatively connected to the controller 278. Operation of the device 270 when connected to the container 275 will now be described.

In a principal mode of operation, to determine the level L of liquid inside the container 275, the controller 278 instructs the optical emitters 273 to each emit radiation towards the surface of the liquid inside the container 275 at a given intensity. The optical receiver 274 receives the reflected radiation from each optical emitter 273 via the surface of the liquid and each of these intensities is recorded by the controller.

For each operation of the sensing assembly 272, the controller 278 records the intensities of radiation emitted by each of the optical emitters 273 as intensities IE1; IE2...IEn

(where n is the total number of optical emitters), and records the intensities of radiation received by the optical receiver 274 from each of the optical emitters 273 as received intensities IR1; IR2...IRn.

By comparing the emitted radiation intensities IE1; IE2...IEn with the received radiation intensities IR1; IR2...IRn, the controller 278 calculates a series of intensity ratios IE1:IR1; IE2:IR2...IEn:IRn, which are then used to determine the level of the liquid inside the container. At the most basic level, if the intensity ratio of IE1:IR1 is the same as IE2:IR2, given the optical emitters 273 are equidistant from the optical receiver 274, this indicates that the level of the liquid inside the container is parallel to the top of the bottle, as shown in Figure 27. In contrast, if these two intensity ratios are different, this indicates that the liquid level is at a different angle, such as that shown in Figure 28.

To accurately determine the level and the quantity of liquid inside the container 275, the controller 278 processes the recorded intensity ratios using a database located in the memory 280. The database contains an individual record for each container which is operable to connect with the device 270. Each record from the database contains a look-up table of information, which contains expected intensity ratios (IE1:IR1 and IE2:IR2) for the container 275 when filled at different orientations, and with different quantities of liquid.

By comparing the information from the look-up table with the recorded intensity ratios, the controller 278 calculates the level and quantity of liquid inside the container 275 and stores this information in the memory 280.

In situations where a container 275 to the device 270 contains no stored record in the database, the sensing assembly 272 can be used in a calibration mode to create a new record. In the calibration mode, the sensing assembly 272 is operated as the container is filled from empty, and as it is positioned at different orientations. At each point during the calibration mode, the controller 278 calculates the recorded intensity ratios (IE1:IR1 and IE2:IR2) and stores them in the record relating to the container 275. For each set of recorded intensity ratios, the user includes information in the record relating to the orientation and fill level of liquid inside of the container 275.

To improve the accuracy of the results obtained by the device 270 during its use, the controller 278 when recording each intensity ratio also records a parameter from the accelerometer 281 relating to the acceleration experienced by the device 270. For each recorded acceleration parameter, the controller 278 determines whether the parameter 278 exceeds a predetermined threshold acceleration parameter stored in the memory 280. The predetermined threshold is indicative of an excessive acceleration, which causes sloshing of liquid inside the container 275 connected to the device 270. In the event of a recorded acceleration parameter exceeding the predetermined threshold acceleration parameter, the controller 278 flags the recorded intensity ratios associated with the recorded acceleration parameter as being unreliable (due to sloshing).

Even without the use of the accelerometer 281, the controller 278 is nonetheless operable to determine whether a set of recorded intensity ratios occur during a period of excess acceleration. In this regard, for each set of intensity ratios recorded at a given time, the controller 278 checks whether any of these intensity ratios is of a predetermined order of magnitude different than the remaining recorded intensity ratios from the set. In the event that the controller 278 determines that this is the case, this indicates that the liquid inside the container has 'sloshed' as a result of the excess acceleration, as shown in Figure 29. In this event, the controller 278 flags the set of recorded intensity ratios as being unreliable.

It will be appreciated that instead of recording the relative intensities of radiation emitted by the optical emitters 273 with the radiation received by the optical emitter 274, the controller 278 could instead record the time taken for radiation emitted by each of the optical emitters 273 to be received by the optical receiver 274. In this arrangement, the look up table would instead contain time periods as opposed to intensity ratios.

In terms of the applications for the device 270, it will be appreciated that the device can be used in a wide variety of applications. One possible application is the use of the device 270 to determine the level of liquid located within a container 275, such as a baby bottle, used as part of a breast pump assembly. In this arrangement, the device 270 is associated with a breast pump 301 which assists with the expression of milk from a breast. The breast pump may be located in the housing 271 of the device 270 as shown in Figure 30, or it may be realisably connected to the housing 271.

Either way, the device 270 would be connectable to the container 275 such that milk expressed by the breast pump can pass from the pump via a channel 302 into the container 275.

The breast pump may be any type of breast pump system including any shapes of milk container or bottle and may comprise a pump module for pumping milk from a breast. The pump module being contained within the housing may comprise: a coupling, a container attachable to the housing via the coupling to receive milk from the pump, a sensing assembly within the housing and comprising at least one optical emitter operable to emit optical radiation towards the surface of the body of milk held in the container when the housing is connected to the container, an optical receiver for receiving the reflected radiation from the surface of the milk, and a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the milk inside the container based on the reflected radiation received by the optical receiver.

By determining the level of milk inside the container based on reflected radiation from the surface of the milk in the container, there is no need to monitor the individual droplets of milk entering the container, such that the sensing assembly can avoid errors associated with measuring these droplets. For example, because we take multiple reflection-based measurements once the container is filled, we can generate an average measurement that that is more accurate than a single measurement. But with systems that rely in counting individual droplets, that is not possible – further, systemic errors (e.g. not counting droplets below a certain size) will accumulate over time and render the overall results unreliable. Furthermore, by not needing to measure these droplets, the sensing assembly from the breast pump need not always be on during the pumping process, which saves power.

When at least two optical emitters are used, the sensing assembly from the breast pump may determine the level of milk inside the container more accurately and irrespective of the orientation of the liquid level inside the container.

Each optical emitter may be equidistant from the optical receiver in order for the

controller to easily calculate the level of the milk inside the container based on the reflected radiation originating from each optical emitter. The signals from the optical receiver preferably comprise information relating to the intensity of the radiation received by the optical receiver.

Each optical emitter may be operable to emit radiation at a different wavelength, or at a different time, than the other optical emitters. In this way, the controller can more easily process the signals from the optical receiver, and more easily distinguish between the radiation emitted by each of the optical emitters.

The optical emitter may emit radiation in the visible range of wavelengths. Alternatively, it may be UV or IR light. The emitted wavelength may be for example between 10nm and 1mm.

The sensing assembly may also comprise at least one accelerometer electrically connected to the controller. The controller may be configured to record an accelerometer parameter from the accelerometer and determine whether the accelerometer parameter exceeds a predetermined threshold. The predetermined threshold may be indicative of an excessive acceleration, which might cause sloshing of milk inside any container connected to the breast pump.

Another application for the device 270 is as a collar for detecting the level/quantity of liquid in a container 275, such as a baby bottle, via its lid 310. An example of the device 270 being used as such a collar is shown in Figure 31. In this arrangement, the device 270 is located between the container 275 and the lid 310, and comprises a first end 311 having a first coupling 312 for attaching the collar to the lid 310. The device comprises a second end 313 having a second coupling 314 for attaching the device 270 to the container 275. The second coupling may be a screw thread, shown in Figure 31, on the inside surface of the container 275. In this way, the distinctive bottom inside surface can be used by the sensing assembly 272 to more easily calibrate itself to the container 275 on which the distinctive bottom inside surface is located. The distinctive bottom may also be used to help identify which container 275 the device is connected to, and thus which record should be used from the database when the device 270 is used.

To further improve the accuracy of the sensing assembly 272, the controller 278 may also be configured to use the recorded information from the accelerometer 281, in situations where the record acceleration is below the predetermined threshold acceleration parameter, to calculate a more accurate liquid level and/or quantity of liquid located inside the container which is compensated for acceleration.

In one particular arrangement, the controller 278 may poll the accelerometer 281 prior to each operation of the sensing assembly 272 to verify that the device 270 is not currently undergoing excessive acceleration. In the event of the controller 278 determining excessive acceleration in the device 270, the controller 278 would continually re-poll the accelerometer, and not operate the sensing assembly 272, until the parameter from the accelerometer is determined as being below the predetermined threshold acceleration parameter stored in the memory 280.

It will also be appreciated that for each container record stored in the database, the container record may comprise a plurality of look up tables, wherein each look up table is associated with a particular liquid used in the container, and wherein each look up table contains its own set of intensity ratios. In this way, the device 270 can more accurately determine the level/quantity of different liquids used in a particular container 275.

As described herein, the sensing assembly 272 has been described as having a plurality of optical emitters 273. It will be appreciated however that the sensing assembly could operate using a single optical emitter 273 and plurality of optical receivers 274. In this arrangement, each record from the database would contain a plurality of ratios relating to the emitted radiation from the optical emitter 273 as received by each of the optical receivers 274. In use of the device 270, the controller 278 would then similarly record the emitted radiation from the optical emitter 273 as received by each of the optical receivers 274. In an alternate arrangement, there may be provided a plurality of optical emitters 273 and a plurality of optical receivers 274, wherein each optical emitter 273 is associated with a respective optical receiver 274. In its simplest arrangement, the sensing assembly 272 may comprise a single optical emitter 273 and a single optical receiver 274.

In certain configurations, the optical emitters 273 may together emit radiation having the same wavelength. In other configurations, the optical emitters 273 may each emit

radiation having a different wavelength. In this latter configuration, the optical receiver 274 would then be able to determine which optical emitter 273 is associated with any given received radiation, based on the wavelength of the received radiation.

The optical emitters 273 may also each emit radiation at different times, such to allow the controller 278 to more easily process the signals from the optical receiver 274, and more easily distinguish between the radiation emitted by each of the optical emitters 273.

In relation to the electrical connection between the controller 278 and the sensing assembly 272, it will be appreciated this electrical connection may be either a wired/wireless connection as required.

Although not shown in the Figures, the device 270 herein described is preferably powered by a battery or some other power source located in the device 270. In other embodiments, the device 270 may be powered using mains electricity.

In one configuration, it is also envisaged that rather than the controller 278 comparing the information from the look-up table with the recorded intensity ratios to calculate the level and quantity of liquid inside the container 275, the controller 278 could instead process the recorded intensity ratios through a liquid-level equation stored in the memory 280. In this configuration, the liquid-level equation could be a generalised equation covering a family of different containers, or could be an equation specific to a container having a given shape and/or type of liquid inside.

It will also be appreciated that in some applications of the device 270, the device could be used to detect the level of a solid, as opposed to a liquid, in a container. As used herein, the terms 'optical emitter' and 'optical receiver' are intended to cover sensors which can emit radiation in or close to the optical wavelength. Any type of radiation at or close to the optical wavelength is suitable provided that it does not have any harmful effects. The exact wavelength is not important in the context of the invention. Such sensors thus include those which can emit visible radiation (such as radiation having wavelengths in the region of 400nm-700nm), and/or those which can emit IR radiation (such as radiation having wavelengths in the region of 700nm-1mm and/or those which can emit UV radiation (such as radiation having wavelengths in the region of 10nm to

400nm).

Existing prior art for such a sensor module is the apparatus disclosed in RU2441367. In this apparatus, the container is an industrially sized milk tank, which only includes a single laser mounted at the top of the tank. Whilst this apparatus is suited for large-sized containers, which do not move in use, the apparatus is less-suited for applications where the container moves in use, or where the liquid level inside the container is non perpendicular to the laser beam shone into the container. In contrast, the sensor module described above can be used in a variety of different applications, is conveniently located within a housing, and which by virtue of it having at least two optical emitters, can determine the level of liquid even inside containers of irregular shapes, and which can determine the level of liquid inside a container irrespective of the orientation of the liquid level inside the container.

Further to the embodiments of the fluid measurement system in different contexts, it can be appreciated that different functions entirely may be possible using the same component structure. For example, it is known that certain molecules within breast milk absorb specific wavelengths of light at characteristic propensities. Whilst the proposed system uses multiplexed IREDs at the same wavelengths to perform proximity measurements, the same array of IREDs may instead be used to emit several different wavelengths of light and determine their absorption upon reflection. If appropriately calibrated, the system may be able to report on the presence or concentration of specific compounds in the expressed milk, such as fat, lactose or protein content.

In addition to this embodiment, it is feasible that the system might be applied to monitor the change in volume of any other container of liquid, given there is sufficient reflection of IR off its surface. These embodiments might include for example: liquid vessel measurement such as for protein shakes, cement or paint, or volume measurements within a sealed beer keg.

SECTION C: BRA CLIP

This section describes a bra clip that forms an accessory to the Elvie™ pump.

It relates to a system allowing a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump. As such, the user does not need a specialised adjustable bra; instead the present system works with all conventional maternity bras. The user also does not have to purchase any larger bras to wear while pumping.

As shown in Figure 32, a typical maternity bra 320 comprises a support structure made up of shoulder straps 321 which support the bra 320 on the wearer's shoulders, and a bra band 322 for extending around a user's ribcage, comprising two wings 323 and a central panel or bridge 324. The straps 321 are typically provided with adjustment mechanisms 325 for varying the length of the straps 321 to fit the bra 320 to the wearer. At the outermost end of each wing, an attachment region 326 is provided. Typically, hooks 327 and loops 328 are provided for securing the bra 320 at the user's back. However, any other suitable attachment mechanism may be used. Alternatively, the attachment region 326 may be provided at the front of the bra 320 in the bridge region 324, with a continuous wing 323 extending continuously around the wearer's back. Typically, a number of sets of loops 328 are provided to allow for variation in the tightness of the bra 320 on the wearer. While shown as having a separation in Figure 32, the wings 323 and bridge 324 may form a single continuous piece in certain designs. Likewise, while shown with a distinct separation in Figure 32, the shoulder straps 321 and the wings 323 may likewise form a single continuous piece.

The maternity bra 320 is further provided with two breast-supporting cups 329 attached to the support structure. The cups 329 define a cup size, which defines the difference in protrusion of the cups 329 from the band 322. The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting a 2 cm difference between the protrusion of the cups 329 from the band 322. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes

of S, M, L, XL, etc.

The cups 329 may be stitched to the bra band 321. At least one of the cups 329, is in detachable attachment with the corresponding strap 321. In particular, this is achieved at attachment point 330 where a hook 331 attached to the bra strap 321 engages with a clasp 331 attached to the cup 329. The hook 331 and the bra strap adjuster 325 are set such that in the closed position, the cup size of the bra 320 fits the wearer's breasts.

In Figure 32, the left cup 329 is shown attached to its attachment point 330, which the right cup 329 is unattached. In this manner, the wearer is able to detach the cup 329 to expose their breast for feeding or for breast pumping. Once this is completed, the cup 329 is reattached and the maternity bra 320 continues to function as a normal bra.

While in the depicted embodiments, a hook 331 is shown on the bra strap 321 and a clasp 332 is shown on the cup 329, it is appreciated that the provision of these may be reversed, or that alternative attachment mechanisms may be used.

A maternity bra therefore may comprise a support structure comprising shoulder straps and a bra band and a first and a second cup each attached to the support structure to provide a first cup size, at least one cup being at least partially detachable from the support structure at an attachment point.

In other embodiments, the detachable attachment point 330 may be provided at a different location, such as at the attachment between the bra band 322 and the cup 329. The mechanism for such an attachment point is the same as described above.

A clip has been designed such that it is configured to be attached to the support structure at a position away from the attachment point. This results in the original attachment point being usable, with the clip providing an alternative attachment point to give, in effect, an adjusted cup size.

Alternatively, the clip may also be attachable to the support structure at a plurality of non-discrete positions. This ensures essentially infinite adjustment of the clip position such that the perfect position for the user can be found.

The clip can also extend between an unextended and an extended state, and can attach to the support structure at the attachment point; the first cup size is providable when the at least partially detachable cup is attached to the clip when the clip is an unextended state; the second cup size is providable when the at least partially detachable cup is attached to the clip when the clip is in an extended state. An extendable clip like this allows quick switching between the two states in use.

Figure 33 depict a clip 335 according to the present invention, along with a clasp 332 shown in isolation from the bra cup 329 it is normally attached to. The clip comprises a first engagement mechanism and at least one second engagement mechanism(s). The clip is attachable in a releasable manner to the support structure at a first position via the first engagement mechanism and attachable in a releasable manner to one of the partially detachable cups via the second engagement mechanism to provide a second cup size different to the first cup size. The clip 335 is provided with a material pathway 336 which receives a portion of the bra strap 321. In the particular embodiment of these Figures, the clip 335 is substantially U-shaped, with a narrowing profile towards its open end. However, it is appreciated that any other suitable shape with a material pathway may be used, such as an S-shape or E-shape. The clip 335 is designed to be attached to the bra strap 321 in a releasable manner, with the slot 336 acting as a support engaging mechanism. The releasable manner means that the clip 335 may be simply removed from the bra 320 without causing any damage to the functioning of the bra 320. To enhance the ease of attachment, the clip 335 may be provided with outwardly extending wings 204 which help direct the bra strap 321 into the clip 335. The clip 335 is further provided with a hook 220 acting as a cup engaging mechanism which can engage with the clasp 332.

Figure 33 (c) shows the clip 335 being attached to a bra strap 321 in order to provide a second attachment point 337 for the clasp 332 to attach to, and hence to provide a second cup size for the bra 320. In this particular embodiment, the clip 335 is attached in a portion of strap 321A below the original attachment point 330 and hence the second attachment point 337 is likewise below the original attachment point. This results in a second cup size larger than the first cup size. In preferred embodiments, as shown in these Figures, the clip 335 engages with the support structure in a direction transverse to

the direction in which it engages with the cup.

Figure 33 (d) and (e) show how a wearer is able to move between the first and second cup sizes. In 33(d), the cup 329 is attached at the first attachment point 330 to provide a first cup size. The wearer then disengages the clasp 332 from the hook 331 at the hook 338 at the second engagement point 239. In this manner, the wearer is easily able to transition between the two cup sizes.

Figures 34 and 35 show an alternative design for a clip 340. This clip 340 is substantially "E-shaped", with a back portion 341 and first, second and 5 third prongs 342A, 342B, 342C extending transverse from this back portion 341. The three prongs 342A, 342B, 342C are spaced apart along the length of the back portion 341. The first and third prongs 342A, 342C are provided with attachment clips 343A, 343B.

These attachment clips 343A, 343B can engage with the clasp 332 of a bra to provide the second cup size. Depending upon the orientation of the clip 300, one or the other of the attachment clips 343A, 343B will be used to attach the clasp 332 of the bra. By providing these clips 343A, 343B on both of the first and the third prongs 342A, 342C the clip is easily reversible so it can be used on either side of the bra. Preferably the clip 340 is also symmetrical, to aid the reversibility of the clip 340.

Figure 35 shows the clip 340 attached to a bra. As can be seen, the first and third prongs 342A, 342C extend on the front side of the bra strap, with the second prong 342B extending on the rear side of the bra strap. In this manner, the clip 340 is attached to the strap. In preferable embodiments, a grip-enhancing member 344 such as a number of projections and/or roughened patches can be provided on the second prong 342B in order to strengthen this grip.

In alternative embodiments, the attachment clip could be provided on the second, centremost prong 342B. In such an arrangement, the centremost prong 342B would be on the outside of the bra, with the first and third prongs 342A, 342C on the inside.

The provision of the attachable clip allows maternity bras already owned by the wearer to be quickly transformed into bras with quick switchable double cup size options.

This allows the use of integrated wearable breast pumps which increase the user's required cup size. This allows more design freedom for the breast pump in terms of size and shape, while still allowing the user to discretely pump with the pump held within their bra. By allowing conversion of the user's existing maternity bras, they are not forced to purchase specially designed bras to wear with the pump. The bra is hence normally at the first engagement point 330 when the breast pump device is not being used. As shown in Figure 33, the clasp 332 is then engaged by the user to discretely switch between the two configurations, and the user then inserts the pump without any complex adjustment or removal of clothing.

Preferably, the clip will be relatively unobtrusive in size and shape and hence can be left in place when the bra is first put on and used when necessary. To this end, the clip is preferably machine washable without significant damage or degradation.

In some embodiments, the clip may be switchable between positions for engaging with each cup so that a single clip may be used on either side of the bra. To achieve this, the clip is preferably reversible. This may provide the user with a visual indication of which breast has produced milk most recently so switching can take place.

In a preferred embodiment, the first engagement mechanism engages with the support structure in a first direction and the second engagement mechanism engages with the cup in a second direction transverse to the first direction. This increases ease of attachment as with this structure the sideways engagement of the clip to the support structure ensures that the second attachment mechanism is correctly orientated for the cup.

The second engagement mechanism may be one or more of a hook or a snap or a clip. This ensures easy interfacing with the traditional hook and clasp systems already provided on maternity bras.

Preferably the clip further comprises two distinct second engagement mechanisms which can be used interchangeably dependent upon the orientation of the clip. This makes the clip easier to use as it can be quickly switched between each bra strap, and the user does not have to worry which way up to put the clip on.

Preferably, the clip comprises a material pathway with an opening for receiving a portion of the support structure as the first engagement mechanism for securing the clip to the bra. This ensures a quick and simple method for attaching the clip to the bra. In particular, the clip may substantially U-shaped, and the material pathway is between the arms of the U.

Preferably, the clip comprises three prongs extending from a central support, the three prongs arranged as a central prong and two outer prongs so as to receive the support structure on one side of the central prong and on the opposite side of each respective outer prong, at least one prong being provided with the second engagement mechanism. This ensures a strong attachment to the bra and a simple design.

Preferably, both outer prongs are each provided with a respective second engagement mechanism. This ensures that the clip is reversible for easier attachment to the bra.

A method of adjusting the cup size of a maternity bra is provided according to the present invention, comprising: providing a maternity bra comprising: a support structure comprising shoulder straps and a bra band; and a first and second cup each attached to the support structure to provide a first cup size, the at least one cup being detachable from the support structure at an attachment point, providing a clip comprising first and section engagement mechanisms, attaching the first engagement mechanism of the clip in a releasable manner to a first position of the support structure of the maternity bra, attaching one of the detachable cup to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

This clip and method allow a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump.

Preferably, the method further comprises the step of inserting a breast pump into the detachable cup. The adjustment of the size of the bra allows the bra to support the breast pump against the user's breast for comfort and ease.

Preferably, the method further comprises the steps of: detaching the first engagement mechanism of the clip from the first position support structure of the maternity bra; attaching the first engagement mechanism of the clip in a releasable manner to a second position of the support structure of the maternity bra; and attaching the other of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size. This allows the user to use a single clip on either of the cups.

An alternative embodiment may be provided, with an extendable clip 360 as shown in Figure 36. In such an embodiment the clip is attached to the hook 331 on the strap 321 in a releasable manner, with the clasp 332 attached to an expandable portion of the clip. The clip is then able to expand between an unexpanded state where the clasp 332 is held in substantially the same position as the first attachment point 330 to provide the first cup size, and an expanded state, where the clasp 332 is held in a second position away from the first attachment point 330 to provide the second cup size.

For example, an elongate clip with first and second opposite ends may be provided. A first attachment point for attaching to the hook 331 is provided at the first end, and a second attachment point for attaching to the clasp 332 is provided at the second end. The elongate clip is hinged between the two ends, such that the clip can be folded between an elongate configuration to a closed configuration where the second end touches the first end. A clasp can be provided on the clip to hold the second end in this closed configuration. Thus, in the closed position the clasp 332 is held in substantially the same location as the first attachment point 330 to provide the first cup size, and in the open position the clasp is held away from the first attachment point 330 to provide the second cup size.

Other extendable clip embodiments are also possible, for example sliding clips or elastic clips.

Additional embodiments of a maternity bra adjuster are provided in Figures 37 and 38. The alternative proposed solution is a small adapter device, which comprises a first portion 370 including a clasp 373 and a second portion 372 including a hook 374, in which the first and second portions are separated by a small distance 371 in order to

provide two different adjustable sizes. The first portion includes a clasp 373 that is designed to attach to the hook on the bra strap 321. It may also include a top hook 375 positioned underneath the clasp, and a clip 376 on the rear side. The second portion includes a bottom hook 372.

The clasp 332 that is present on the cup 329 of the maternity bra, may then either engage with the top hook (321) to provide a first cup size, and engage with the bottom hook (332) to provide a second cup size that is different from the first cup size, as illustrated in Figure 39. The user may then discretely switch between a non pumping position, provided by the first cup size, and a second pumping position without any complex adjustment or removal of clothing needed, while using a wearable breast pump system (100).

The first portion and second portion may be made of plastic and may be separated by a stretchy material such as elastic or elastomeric material. The first portion may also include a clip on the rear side, the purpose of which is to allow the user to leave the clip attached to the bra for an extended time period.

Section D: Use of Piezo Pump in Wearables

As described in Section A, the breast pump system includes a piezo air pump, resulting in a fully wearable system that delivers a quiet, comfortable and discreet operation in normal use. This section gives further information on the piezo air pump.

In comparison with other pumps of comparable strength, piezo pumps are smaller, lighter and quieter.

Each individual Piezo pump weighs approximately 6gm and may, with material and design improvements, weigh less than 6gm.

In operation, the Elvie breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise; tests indicate that it makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

Piezo pumps also have lower current draw, allowing for increased battery life. A piezo pump is therefore ideally suited for wearable devices with its low noise, high strength and compact size. Further, as shown in the breast pump system of Figures 7 and 8, more than one piezo pump may be used.

Whilst a breast pump system is largely described in previous sections, the use of piezo mounted either in series or in parallel can also be implemented in any medical wearable devices or any wearable device. The piezo pump may pump air as well as any liquid.

With reference to Figure 40, a diagram illustrating a configuration of two piezo pumps mounted in series is shown.

With reference to Figure 41, a diagram illustrating a configuration of two piezo pumps mounted in parallel is shown.

With reference to Figure 42, the air pressure generated as a function of time by two piezo pumps mounted in series and two piezo pumps mounted in parallel are compared. In

this example, the parallel configuration produces higher flow rate and achieves -100mmHg negative air pressure faster than the series configuration. In comparison, the series configuration produces lower flow rate and takes slightly longer to reach 100mmHg. However, the parallel configuration cannot achieve as high as a vacuum as the series configuration and plateaus at -140mmHg. In comparison, the series configuration is able to generate about -240mmHg.

A dual configuration is also implemented in which more than one piezo pump is configured such that they can easily switch between a parallel mode and a series mode. This dual configuration would suit wearable devices that would need to achieve either lower or higher pressure faster.

Figure 43 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration. In this dual configuration, the piezo pumps first start with a parallel mode in order to benefit from faster flow rate, and then switch to a series mode (as indicated by the switch-over point) when stronger vacuums are required, enabling to save up to 500ms on cycle time with elastic loads.

Additionally, a piezo pump may be used in combination with a heat sink in order to efficiently manage the heat produced by the wearable pump. This configuration may be used to ensure that the wearable device can be worn comfortably. The heat sink or heat sinks are configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin (especially prolonged contact for greater than 1 minute) are no more than 48°C and preferably no more than 43°C.

The heat sink may store the heat produced by a piezo pump in order to help diverting the heat produced to another location. This not only ensures that the wearable system can be worn comfortably, but also increases the lifetime of a piezo pump.

Figure 44 shows a picture of a wearable breast pump housing including multiple piezo pumps (440). The breast pump system is wearable and the housing is shaped at least in part to fit inside a bra. By applying a voltage to the piezo pumps, the pressure provided by the pumps increase. The generation of higher pressure by the piezo pumps also means higher heat produced that needs to be managed. Each piezo pump is therefore

connected to a heat sink (441), such as a thin sheet of copper. The heat sink has a long thermal path length that diverts the heat away from the piezo pump.

The use of a heat sink in combination with a piezo pump is particularly relevant when the wearable device is worn directly or near the body, and where the management of heat induced by the piezo pump is crucial.

A wearable device including a piezo pump may therefore include a thermal cut out, and may allow for excess heat to be diverted to a specific location. The heat sink may be connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere. For example, the wearable system is a breast pump system and the heat sink stores heat, which can then be diverted to warm the breast shield of the breast pump system.

Use cases application include but are not limited to:

- Wound therapy;
- High degree burns;
- Sleep apnoea;
- Deep vein thrombosis;
- Sports injury.

APPENDIX: SUMMARY OF KEY FEATURES

In this section, we summarise the various features implemented in the Elvie™ pump system. We organize these features into six broad categories:

A. **Elvie Breast Pump: General Usability Feature Cluster**

B. **Elvie Piezo Air Pump Feature Cluster**

C. **Elvie Milk Container Feature Cluster**

D. **Elvie IR System Feature Cluster**

E. **Elvie Bra Clip Feature Cluster**

F. **Other Features, outside the breast pump context**

Drilling down, we now list the features for each category:

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is wearable and includes only two parts that are removable from the pump main housing in normal use.

Feature 2 Elvie is wearable and includes a clear breast shield giving an unobstructed view of the breast for easy nipple alignment.

Feature 3 Elvie is wearable and includes a clear breast shield with nipple guides for easy breast shield sizing.

Feature 4 Elvie is wearable and includes a breast shield that audibly attaches to the housing.

Feature 5 Elvie is wearable and includes a breast shield that attaches to the housing with a single push.

Feature 6 Elvie is wearable and not top heavy, to ensure comfort and reliable suction against the breast.

Feature 7 Elvie is wearable and has a Night Mode for convenience.

Feature 8 Elvie is wearable and includes a haptic or visual indicator showing when milk is flowing or not flowing well.

Feature 9 Elvie is wearable and collects data to enable the mother to understand what variables (e.g. time of day, pump speed etc.) correlate to good milk-flow.

Feature 10 Elvie is wearable and collects data that can be exported to social media.

Feature 11 Elvie is wearable and has a smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 12 A smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 13 Elvie is wearable and includes a sensor to infer the amount of movement or tilt angle during normal use.

Feature 14 Elvie includes a control to toggle between expressing milk from the left breast and the right breast.

Feature 15 Elvie includes a pressure sensor.

Feature 16 Elvie includes a microcontroller to enable fine tuning between pre-set pressure profiles.

Feature 17 Elvie enables a user to set the comfort level they are experiencing.

Feature 18 Elvie includes a microcontroller to dynamically and automatically alter pump operational parameters.

Feature 19 Elvie automatically learns the optimal conditions for let-down.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is wearable and has a piezo air-pump for quiet operation.

Feature 21 Elvie has a piezo air-pump and self-sealing diaphragm

Feature 22 Elvie uses more than one piezo air pump in series.

Feature 23 Elvie is wearable and has a piezo air-pump, a breast shield and a diaphragm that fits directly onto the breast shield.

Feature 24 Elvie is wearable and has a piezo air-pump for quiet operation and a re-useable, rigid milk container for convenience.

Feature 25 Elvie has a piezo-pump for quiet operation and is a connected device.

Feature 26 Elvie uses a piezo in combination with a heat sink that manages the heat produced by the pump.

Feature 27 Elvie is wearable and gently massages a mother's breast using small bladders inflated by air from its negative pressure air-pump.

Feature 28 Elvie is wearable and gently warms a mother's breast using small chambers inflated by warm air from its negative pressure air-pump.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is wearable and includes a re-useable, rigid milk container that forms the lower part of the pump, to fit inside a bra comfortably.

Feature 30 Elvie is wearable and includes a milk container that latches to the housing with a simple push to latch action.

Feature 31 Elvie is wearable and includes a removable milk container with an integral milk pouring spout for convenience.

Feature 32 Elvie is wearable and includes a removable milk container below the milk flow path defined by a breast shield for fast and reliable milk collection.

Feature 33 Elvie is wearable and includes a breast shield and removable milk container of optically clear, dishwasher safe plastic for ease of use and cleaning.

Feature 34 Elvie is wearable and includes various components that self-seal under negative air pressure, for convenience of assembly and disassembly.

Feature 35 Elvie is wearable and includes a spout at the front edge of the milk container for easy pouring.

Feature 36 Elvie is wearable and includes a milk container that is shaped with broad shoulders and that can be adapted as a drinking bottle that baby can easily hold.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the quantity of milk in the container for fast and reliable feedback.

Feature 38 The separate IR puck for liquid quantity measurement.

Feature 39 The separate IR puck combined with liquid tilt angle measurement.

E. Bra Clip Feature

Feature 40 Bra Adjuster.

F. Other Features that can sit outside the breast pump context

Feature 41 Wearable device using more than one piezo pump connected in series or in parallel.

Feature 42 Wearable medical device using a piezo pump and a heat sink attached together.

We define these features in terms of the device; methods or process steps which correspond to these features or implement the functional requirements of a feature are also covered.

We'll now explore each feature 1 – 42 in depth. Note that each feature can be combined with any other feature; any sub-features described as 'optional' can be combined with any other feature or sub-feature.

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is wearable and includes only two parts that are removable from the pump main housing in normal use

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a rigid or non-collapsible milk container;

and in which the breast pump system includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and the rigid, non-collapsible milk container.

Optional:

- The only parts of the system that come into contact with milk in normal use are the breast shield and the milk container.
- Milk only flows through the breast shield and then directly into the milk container.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings, in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- No other parts are removable from the breast shield, apart from the flexible diaphragm.
- The milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.
- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

- No other parts are removable from the milk container, apart from the cap and the valve.
- All parts that are user-removable in normal use are attached to either the breast shield or the milk container.
- Audible or haptic feedback confirms the pump system is properly assembled for normal use with the milk container locked to the housing and the breast shield locked to the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 2 Elvie is wearable and includes a clear breast shield giving an unobstructed view of the breast for easy nipple alignment

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel, shaped to receive a nipple, providing to the mother placing the breast shield onto her breast a clear and unobstructed view of the nipple when positioned inside the nipple tunnel, to facilitate correct nipple alignment.

Optional:

- The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is completely out, of or separated from, the housing.
- The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is partially out of, or partially separated from, the housing.
- Entire breast shield is substantially transparent.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.

- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

Feature 3 Elvie is wearable and includes a clear breast shield with nipple guides for easy breast shield sizing

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel shaped to receive a nipple, the nipple tunnel including guide lines that define the correct spacing of the nipple from the side walls of the nipple tunnel.

Optional:

- The guide lines run generally parallel to the sides of the nipple placed within the nipple tunnel.
- Breast shield is selected by the user from a set of different sizes of breast shield to give the correct spacing.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers in the housing locate into small indents in the breast shield.

- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 4 Elvie is wearable and includes a breast shield that audibly attaches to the housing.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield that is attachable to the housing with a mechanism that latches with an audible click when the breast shield is slid on to or against the housing with sufficient force.

Optional:

- The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.

- Breast shield is removable from the housing with an audible click when the breast shield is pulled away from the housing with sufficient force.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.

- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 5 Elvie is wearable and includes a breast shield that attaches to the housing with a single push

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield configured to attach to the housing with a single, sliding push action.

Optional:

- The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.
- The single push action overcomes a latching resistance.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into a nipple tunnel in the breast shield to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield when the breast shield has been placed onto a breast using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b)

transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

- The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.
- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

Feature 6 Elvie is wearable and not top heavy, to ensure comfort and reliable suction against the breast

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism

(b) and a breast shield;

(c) a milk container;

and in which the centre of gravity of the pump system is, when the milk container is empty, substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through a nipple tunnel or filling point on a breast shield, so that the device is not top-heavy for a woman using the pump.

Optional:

- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- In which the centre of gravity only moves lower during use as the milk container gradually receives milk, which increases the stability of the pump inside the bra.
- In which milk only passes downwards when moving to the milk container, passing through the nipple tunnel and then through an opening in the lower surface of the nipple tunnel directly into the milk container, or components that are attached to the milk container.
- System is configured so that its centre of gravity is no more than 60mm up from the base of the milk container also below the top of the user's bra cup.
- In which the pumping mechanism and the power supply for that mechanism are positioned within the housing to provide a sufficiently low centre of gravity.
- In which the pumping mechanism is one or more piezo air pumps, and the low weight of the piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.
- In which the pumping mechanism is one or more piezo air pumps, and the small size of the piezo air pumps enables the components in the housing to be arranged so that the centre of gravity is substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.
- In which the pumping mechanism is one or more piezo air pumps, and the low weight of the battery or batteries needed to power that piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of

the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.

- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 7 Elvie is wearable and has a Night Mode for convenience

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) an illuminated control panel;

(c) a control system that reduces or adjusts the level or colour of illumination of the control panel at night or when stipulated by the user.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Control system is implemented in hardware in the pump itself using a 'night mode' button.
- Control system is implemented in software within a connected device app running on the user's smartphone.
- Control system is linked to the illumination level on a connected device app., so that when the connected app is in 'night mode', the illuminated control panel is also in 'night mode', with a lower level of illumination, and when the illuminated control panel on the housing is in 'night mode', then the connected app is also in 'night mode'.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast. The pumping mechanism is one or more piezo air pumps, selected for quiet operation.

Feature 8 Elvie is wearable and includes a haptic or visual indicator showing when milk is flowing or not flowing well

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a milk container that is configured to be concealed within a bra and is hence not visible to the mother in normal use;

(c) a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

Optional:

- A haptic and/or visual indicator indicates if the pump is operating correctly to pump milk, based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase
- The visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.
- The haptic and/or visual indicator provides an indication of an estimation of the flow rate.
- The visual indicator provides a colour-coded indication of an estimation of the flow rate.
- The visual indicator provides an indication of how much of the container has been filled.
- The visual indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.
- The haptic indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.
- A sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect

light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

- Sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- A sub-system measures or infers the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.
- A haptic and/or visual indicator indicates if the amount of milk in the milk container has reached a preset quantity or level.
- A haptic and/or visual indicator indicates if there is too much movement of the breast pump system for viable operation.
- Milk container is attached to the lower part of the housing and forms the base of the breast pump system.
- Milk container is made of transparent material.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 9 Elvie is wearable and collects data to enable the mother to understand what variables (e.g. time of day, pump speed etc.) correlate to good milk-flow

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a measurement sub-system that measures or infers milk flow into the milk container;

and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- User-defined requirement is to enhance or increase milk-flow.
- User-defined requirement is to reduce milk-flow.
- The data analysis system analyses data such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system determines metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.
- The data analysis system determines metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.
- Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.
- measurement sub-system measures or infers the quantity and/or the height of the liquid in the container above its base.
- Measurement sub-system measures or infers angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.
- Data analysis system gives recommended metrics for improving milk flow
- Data analysis system gives recommended metrics for weaning.
- Data analysis system gives recommended metrics for increasing milk supply (e.g. power pumping).
- Data analysis system gives recommended metrics if an optimal session start time or a complete session has been missed.

- Data analysis system leads to automatic setting of metrics for the pumping mechanism, such as pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session.
- Data analysis system enables sharing across large numbers of connected devices or apps information that in turn optimizes the milk pumping or milk weaning efficacy of the breast pump.
- Metrics include the specific usage of the connected device by a woman while using the pump (for example by the detection of vision and/or audio cues).
- The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- The measurement sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the measurement sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 10 Elvie is wearable and collects data that can be exported to social media.

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a data sub-system that collects and provides data to a connected device or remote application or remote server;

(d) and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.
- The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.
- Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.
- The social media or community function or platform organizes the collected data into different profiles.
- The social media or community function or platform enables a user to select a matching profile from a set of potential profiles.
- each profile is associated with a specific kind of milk expression profile, and provides information or advice that is specifically relevant to each milk expression profile.
- Information or advice includes advice on how to increase milk expression by varying parameters, such as time of milk expression, frequency of a milk

expression session, pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session and any other parameter that can be varied by a mother to help her achieve her milk expression goals.

- The application is connected to other applications residing on the connected device, such as a fitness app.
- The collected data includes data received from other connected apps.
- The collected data is anonymised before it is shared.
- The sub-system includes a wi-fi connectivity component for direct connectivity to a remote server.
- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 11 Elvie is wearable and has a smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh

A breast pump system including a pumping mechanism and a milk container and including:

(a) a housing including the pumping mechanism;

(b) a milk container;

(c) and in which the milk container or any associated part, such as a lid, includes a memory or tag that is automatically programmed to store the time and/or date it was filled with milk.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Memory or tag is programmed to store the quantity of milk in the milk container.
- Memory or tag stores the milk expiry date.

- Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.
- System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.
- Clock is in the housing.
- Clock is in the milk container.
- Milk container includes a display that shows the time and/or date it was filled with milk.
- Milk container includes a display that shows the quantity of milk that it was last filled with milk.
- Milk container includes a display that shows whether the left or right breast was used to fill the milk container.
- Memory or tag is connected to a data communications sub-system.
- Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone, and have the time and/or date that container was filled with milk, displayed on the reader device.
- Reader device shows the time and/or date a specific milk container was filled with milk.
- Reader device shows the quantity of milk that a specific milk container was last filled with.
- Reader device shows the time and/or date and/or quantity that each of several different milk containers were filled with.
- Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.
- A sub-system measures or infers milk flow into the milk container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/Tr the height of the liquid in the container.
- The sub-system is in the housing.
- Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 12 A smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

A smart bottle or container that includes or is associated with a memory or a tag that is programmed to store the date and time it is filled using data from a pump or a connected device, such as a smartphone.

Optional:

- The container includes wireless connectivity and connects to a companion app.
- The memory or tag includes an NFC chip and is read using a NFC reader.
- The memory or tag stores also an expiry date.
- Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.
- The memory or tag stores also the quantity of milk stored.
- System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.
- Clock is in the housing.
- Clock is in the container.
- Milk container includes a display that shows the time and/or date it was filled with milk.
- Milk container includes a display that shows the quantity of milk that it was last filled with milk.

- Milk container includes a display that shows whether the left or right breast was used to fill the milk contained.
- Milk container includes a display that shows the expiry date.
- memory or tag is connected to a data communications sub-system.
- Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone.
- Reader device shows the time and/or date a specific milk container was filled with milk.
- Reader device shows the quantity of milk that a specific milk container was last filled with.
- Reader device shows the time and/or date and/or quantity that each of several different containers were filled with.
- Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.
- Reader device shows the expiry date.
- Container includes wireless connectivity and connects to a companion application.
- An application tracks status of one or more smart containers and enables a user to select an appropriate smart container for a feeding session.
- The pump is wearable.
- The pump is in a housing shaped to fit inside a bra and the container is a milk container that is connected to the housing and is positioned to form the base of the housing.
- Container is used for liquids other than milk.

Feature 13 Elvie is wearable and includes a sensor to infer the amount of movement or tilt angle during normal use.

A breast pump system including:

(a) a housing;

(b) a milk container;

(c) the housing including a sensor, such as an accelerometer, that measures or determines the movement and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by warning or alerting the mother of a potential imminent spillage (e.g. from milk flowing back out of a breast shield) using an audio, or visual or haptic alert, or a combination of audio, haptic and visual alerts.
- If the tilt angle of the housing exceeds a threshold, then the system automatically adjusts the operation of the system by stopping the pump to prevent spillage.
- When the tilt angle of the housing reduces below the threshold, the system automatically adjusts the operation of the system by causing pumping to resume automatically.
- If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by providing the mother with an alert to change position.
- The container includes an optically clear region.
- There are one or more light emitters and detectors positioned in the base of the housing, the light emitters and receivers operating as part of a sub-system that measures or infers the tilt angle of the milk in the container.
- The sub-system measures the quantity of liquid in the milk container and also takes the measured tilt angle of the housing into account.
- If the tilt angle is above a certain threshold, the system ignores the quantity of liquid measured.
- The sub-system derives or infers the mother's activity, such as walking, standing or lying activities, from the sensor.
- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

- Sub-system stores a time-stamped record of movement and/or tilt angles of the housing in association with milk flow data.
- System includes a breast shield that attaches to the housing.
- System includes a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 14 Elvie includes a control to toggle between recording whether milk is being expressed from the left breast and the right breast.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a control interface that the user can select to indicate or record if milk is being expressed from the left or the right breast.

Optional:

- Control interface is a physical interface on the housing.
- Control interface is a single button on the housing.
- Control interface is from an application running on a device, such as a smartphone or smart ring.
- Visual indicators on the housing indicate whether the breast pump system is being set up the left or the right breast.
- The visual indicator for the left breast is on the right-hand side of the housing, when viewed from the front; and the visual indicator for the right breast is on the left-hand side of the housing, when viewed from the front.
- The housing includes a button labeled to indicate the left breast and a button labeled to indicate the right breast, that are respectively illuminated to indicate from which breast the milk is being expressed.
- Breast pump system is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 15 Elvie includes a pressure sensor.

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) an air pressure sensor configured to measure the negative pressure delivered by the negative air-pressure mechanism and (iii) a measurement sub-system that measures or infers milk flow or milk volume.

Optional:

- The system also includes a control sub-system that combines or relates the air-pressure measurements with the milk flow or milk volume measurements
- The control sub-system automatically adjusts the negative air-pressure to give the optimal milk flow or milk volume.
- The control sub-system automatically adjusts the negative air-pressure during a pumping session to give the optimal milk flow or milk volume within comfort constraints defined by the user.
- The air pressure sensor detects pressure created by the pumping mechanism.
- Sensor is a piezo air pressure sensor
- Air pressure sensor measures the negative air pressure during a normal milk expression session.
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that it deliver consistent performance over time.
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that different pumping mechanisms in different breast pump systems all deliver consistent performance
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to determine if the pumping mechanism is working correctly, within tolerance levels.
- The operation of the pumping mechanism is varied by altering the duty or pump cycle.
- The operation of the pumping mechanism is varied by altering the voltage applied to the pumping mechanism.
- Pumping mechanism is a piezo air pump.

- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 16 Elvie includes a microcontroller to enable fine tuning between pre-set pressure profiles

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to cause the pumping mechanism to deliver various pre-set pressure profiles and to permit the user to manually vary the pressure to a value or values that are in-between the values available from a pre-set pressure profile.

Optional:

- The user manually varies the pressure using a control interface on a housing of the breast pump system
- The user manually varies the pressure using a control interface on an application running on a wireless device such as a smartphone that is wirelessly connected to the breast pump system.
- The user manually varies the pressure by altering a control parameter of the pumping mechanism.
- The user manually varies the pressure by altering the duty cycle or timing of the

pumping mechanism.

- The user manually varies the pressure by altering the voltage applied to the pumping mechanism.
- The system includes an air pressure sensor configured to measure the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Pressure profile defines one or more maximum negative air pressure levels.
- Pressure profile defines one or more maximum negative air pressure levels, each for a pre-set time.
- Pressure profile defines one or more cycle time.
- Pressure profile defines peak flow rate.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 17 Elvie enables a user to set the comfort level they are experiencing

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to control the pumping mechanism and to permit the user to manually indicate the level of comfort that they are experiencing when the system is in use.

Optional:

- The user manually indicates the level of comfort that they are experiencing using a touch or voice-based interface on a housing of the breast pump system
- The user manually indicate the level of comfort that they are experiencing using a touch or voice-based interface on an application running on a wireless device, such as a smartphone, that is wirelessly connected to the breast pump system.
- The system stores user-indicated comfort levels together with associated parameters of the pumping system.
- The system is a connected device and a remote server stores user-indicated comfort levels together with associated parameters of the pumping system.
- The parameters of the pumping system include one or more of: pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System automatically varies parameters of the pumping system and then enables the user to indicate which parameters are acceptable.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the

intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 18 Elvie includes a microcontroller to dynamically and automatically alter pump operational parameters

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to automatically change one or more parameters of the pumping mechanism, and to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

Optional:

- The milk expression data includes one or more of the following: milk expression rate or quantity; comfort; optimal pumping mode; optimal pumping mode given remaining battery power.
- The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters.
- The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters if the comfort experienced by the user when those parameters are used is above a threshold.
- The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user.
- The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user and enables the user to manually select those parameters if they are acceptable.
- Parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.

- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 19 Elvie automatically learns the optimal conditions for let-down

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to dynamically change one or more parameters of the pumping mechanism, and to automatically detect the start of milk let-down.

Optional:

- The microcontroller is programmed to dynamically change one or more parameters of the pumping mechanism, to enable it to learn or optimize the parameters relating to milk let-down.
- The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down.
- The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and uses that set of parameters if the comfort experienced by the user when those

parameters are used is above a threshold or are otherwise acceptable to the user.

- The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down to the user.
- The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and enables the user to manually select those parameters if they are acceptable.
- parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is wearable and has a piezo air-pump for quiet operation

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a separate, deformable diaphragm to generate negative air pressure.

Optional:

- The deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- Deformable diaphragm is removably mounted against a part of a breast shield.
- Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.
- Deformable diaphragm is not physically connected to the piezo air-pump.
- Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield
- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

- The piezo pump is fed by air that passes through an air filter.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 21 Elvie has a piezo air-pump and self-sealing diaphragm

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a physically separate, deformable, self-sealing diaphragm, to generate negative air pressure.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement .
- The closed system is separated from a 'milk' side by the flexible diaphragm.
- Deformable diaphragm is removably mounted against a part of a breast shield.
- Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.
- Deformable diaphragm is not physically connected to the piezo air-pump.
- Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield.
- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing,

and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- The piezo pump is fed by air that passes through an air filter.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 22 Elvie uses more than one piezo air pump in series

A breast pump system including:

(a) a housing;

(b) multiple piezo air-pumps in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure; in which the multiple piezo air-pumps can be operated at different times in series-connected and in parallel-connected modes.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Parallel connected mode is used during a first part of a pumping cycle to reach a defined negative air pressure more quickly than series connected mode would, and then the system switches to a series connected mode to reach a greater negative air pressure than series connected mode can reach.
- An actuator switches the system from parallel-connected piezo pump mode to series-connected piezo pump mode.

- Each piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- Each piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- Each piezo pump is fed by air that passes through an air filter.
- Each piezo air pump forms part of a closed or closed loop system.
- Each piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- The piezo-air pumps are a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

Feature 23 Elvie is wearable and has a piezo air-pump, a breast shield and a diaphragm that fits directly onto the breast shield

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a breast shield that attaches to the housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm that fits directly onto the breast shield.

Optional:

- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Deformable diaphragm is removable from the diaphragm housing for cleaning.

- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- Piezo air pump is position at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum. power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.The piezo pump is fed by air that passes through an air filter.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Feature 24 Elvie is wearable and has a piezo air-pump for quiet operation and a re-useable, rigid milk container for convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing;

(c) and a re-useable, rigid or non-collapsible milk container that when connected to the housing forms an integral part of the housing and that is also removable from the housing.

Optional:

- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The closed system is separated from a 'milk' side by a flexible diaphragm.

- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- The deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.

Feature 25 Elvie has a piezo-pump for quiet operation and is a connected device

A breast pump system including

(a) a housing;

(b) a piezo air-pump in the housing;

(c) a milk container;

(d) a data connectivity module that enables data collection relating to the operation of the piezo air-pump and transmission of that data to a data analysis system.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Transmission is to an application running on a connected device such as a smartphone, or a server, or the cloud.
- The data collection and transmission relates to any other operational data of the system.
- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- A sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with the data connectivity module.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level,

peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.

- The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.

Feature 26 Elvie uses a piezo in combination with a heat sink that manages the heat produced by the pump.

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure;

(c) a heat sink to manage the heat produced by the piezo-air pump to ensure it can be worn comfortably.

Optional:

- The heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48°C and preferably no more than 43°C.
- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Heat sink is connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere.
- Heat sink warms a breast shield.
- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.

- There are two or more piezo air pumps, each connected to its own or a shared heat sink.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- The deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

Feature 27 Elvie is wearable and gently massages a mother's breast using small bladders inflated by air from its negative pressure air-pump

A breast pump system including:

(a) a housing;

(b) an air-pump in the housing that drives a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides air to regularly or sequentially inflate one or more air bladders or liners that are configured to massage one or more parts of the breast.

Optional:

- Air-pump is a piezo pump.
- Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- Bladders or liners are formed in a breast shield that attaches to the housing.

Feature 28 Elvie is wearable and gently warms a mother's breast using small chambers inflated by warm air from its negative pressure air-pump

A breast pump system including:

(a) a housing;

(b) an air-pump, such as a piezo pump, in the housing that drive a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides warm air to regularly or sequentially inflate one or more air chambers that are configured to apply warmth to one or more parts of the breast.

Optional:

- Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- The air chamber is a deformable diaphragm positioned on a breast shield that attaches to the housing.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is wearable and includes a re-useable, rigid milk container that forms the lower part of the pump, to fit inside a bra comfortably

A wearable breast pump system configured including:

(a) a housing shaped at least in part with a curved surface to fit inside a bra and including a pumping mechanism;

(b) and a re-useable rigid or non-collapsible milk container that when connected to the housing forms an integral, lower part of the housing, with a surface shaped to continue the curved shape of the housing, so that the pump system can be held comfortably inside the bra.

Optional:

- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is attached to the housing with a push action.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture, spout or lid that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a

breast shield, and milk flows under gravity through the opening into the milk container.

- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump mechanism to ensure that negative air-pressure is not applied to the milk container.
- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 30 Elvie is wearable and includes a milk container that latches to the housing with a simple push to latch action

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that is attachable to the housing with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

Optional:

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Milk container, when connected to the housing, forms an integral, lower part of the housing and that is removable from the housing with a release mechanism that can be operated with one hand.

- Mechanism that releasably attaches or latches is a mechanical or magnetic mechanism.
- Mechanical mechanism includes flanges on the top of the milk container, or the sealing plate that seals the opening to the milk contained, that engage with and move past a surface to occupy a latched position over that surface when the milk container is pressed against the housing to lock into the housing.
- The housing includes a button that when pressed releases the milk container from the housing by flexing the surface away from the flanges so that the flanges no longer engage with and latch against the surface.
- Mechanism that attaches or latches the milk container into position does so with an audible click.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing by releasing the latch and moving the housing off the milk container.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.

- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 31 Elvie is wearable and includes a removable milk container with an integral milk pouring spout for convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a re-useable milk container that is connected to the housing with a surface shaped to continue the curved or breast-like shape of the pump, so that the pump can be held comfortably inside a bra and where the milk container includes a pouring spout for pouring milk.

Optional:

- Spout is integral to the milk container.
- Spout is integral to a removable lid to the milk container.
- Spout is positioned at or close to the front edge of the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.

- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 32 Elvie is wearable and includes a removable milk container below the milk flow path defined by a breast shield for fast and reliable milk collection

A wearable breast pump system including:

(a) a housing including a pumping mechanism, the housing being shaped at least in part to fit inside a bra;

(b) and a breast shield including a nipple tunnel shaped to receive a nipple, and including an opening that defines the start of a milk flow path;

(c) a re-useable milk container that when connected to the housing is positioned entirely below the opening or the milk flow path, when the breast pump is positioned or oriented for normal use.

Optional:

- The milk container includes an aperture that sits directly underneath the opening in the nipple tunnel in the breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- Milk flows from the opening directly into the milk container.
- Milk flows from the opening directly into the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against the opening in the breast shield, and milk flows under gravity through the opening into the milk container.
- Milk flows from the opening directly onto a valve that is attached to the milk container, the valve closing whilst there is sufficient negative air pressure in the volume of air between the valve and the breast shield opening, and then opening to release the milk into the container when the air pressure rises sufficiently.
- Milk flows from the opening directly onto a valve that is attached to a spout, that is in turn attached to the milk container.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the milk container cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container, and milk flows towards and is retained by the duck bill valve whilst the valve is closed, and flows past the valve into the milk container when the negative air pressure is released and the valve opens.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 33 Elvie is wearable and includes a breast shield and removable milk container of optically clear, dishwasher safe plastic for ease of use and cleaning

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) and a breast shield defining a region shaped to receive a nipple, the region defining the start of a milk flow path;

(c) a re-useable, rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the breast shield and the milk container are made substantially of an optically clear, dishwasher safe material.

Optional:

- The material is a polycarbonate material, such as Tritan™.

- breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield operates with a flexible diaphragm that flexes when negative air pressure is applied to it by an air pump system in the housing, and transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 34 Elvie is wearable and includes various components that self-seal under negative air pressure, for convenience of assembly and disassembly

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including an air pumping mechanism;

(b) a breast shield;

(c) a diaphragm that flexes in response to changes in air pressure caused by the air pumping mechanism and that seals to the breast shield;

(d) a re-useable milk container that seals to the breast shield;

and in which either or both of the diaphragm and the re-useable milk container substantially self-seal under the negative air pressure provided by the pumping mechanism.

Optional:

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a

breast shield, and milk flows under gravity through the opening into the milk container.

- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.
- The 1 way valve is attached to the milk container, or a lid or spout of the milk container with an interference fit and is readily removed in normal use for separate cleaning.
- The diaphragm partly or wholly self-seals to the breast shield under the negative air pressure provided by the pumping mechanism.
- The diaphragm partly or wholly self-seals to the housing under the negative air pressure provided by the pumping mechanism.
- The diaphragm is attached to the diaphragm housing using elastomeric or rubber latches and is readily removed in normal use for separate cleaning.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.

- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 35 Elvie is wearable and includes a spout at the front edge of the milk container for easy pouring

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that forms an integral part of the housing;

(c) a re-useable pouring spout that is positioned at or close to the front edge of the milk container.

Optional:

- Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigeratable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.
- Spout is integral to a removable lid to the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- By placing the spout at or close to the front edge of the milk container, the milk container fully empties more readily than where the spout is placed in the middle of the lid of a milk container.
- The spout sits generally under an opening in the breast shield spout or nipple tunnel through which expressed milk flows.
- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Feature 36 Elvie is wearable and includes a milk container that is shaped with broad shoulders and that can be adapted as a drinking bottle that baby can easily hold

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a milk container that is removable from the housing and is shaped or configured to also serve as a drinking bottle that is readily held by a baby because it is wider than it is tall.

Optional:

- Teat is attachable directly to the milk container.
- Pouring or drinking spout is integral to the milk container.
- The shoulders are at least 2cm in width, and the neck is no more than 1 cm in height, to enable a baby to readily grip and hold the container when feeding from the milk in the container.
- Spout/teat/straw resides near the edge of the container's rim.
- Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigertable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.
- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals

against the conduit under the negative air pressure provided by the pumping mechanism.

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Spout is integral to the milk container.
- Spout is integral to a removable lid to the milk container.
- Spout is positioned at or close to the front edge of the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the quantity of milk in the container for fast and reliable feedback

A system for milk volume determination, for use as part of a breast pump, or breast milk collecting device, including:

(a) a re-useable rigid or non-collapsible milk container;
(b) at least one light emitter, configured to direct radiation towards the surface of the milk;
(c) at least one light detector, configured to detect reflected radiation from the surface of the milk;

wherein the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container.

Optional:

The wearable breast pump system includes:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield;

(c) a re-useable rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the top of the container includes an optically clear region that is aligned below one or more light emitters positioned in the base of the housing.

- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

- The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.
- Where the quantity or level exceeds a threshold, then the pumping mechanism automatically changes mode, e.g. from a stimulation mode to an expression mode.
- Where the quantity or level exceeds a threshold, then the pumping mechanism automatically stops.
- Milk-flow data is captured and stored.
- If milk-flow falls below a threshold, then a notification is provided to the mother.

Feature 38 The separate IR puck for liquid quantity measurement

A liquid-level measuring system for measuring the quantity of liquid in a container for a breast pump; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to detect light from the light emitters that has been reflected from the liquid;

(c) a sub-system that infers, measures or calculates the quantity in the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

- The quantity of milk is measured as milk enters the container or as milk is removed from the container.
- Measured property includes the reflected light intensity

Feature 39 The separate IR puck combined with liquid tilt angle measurement

A liquid-level measuring system for measuring the tilt angle of liquid in a container; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to measure properties of the light reflected from the liquid;

(c) a sub-system including an accelerometer that infers, measures or calculates the tilt angle of the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

- Measured property includes the reflected light intensity
- The quantity of liquid is measured as liquid enters the container or as liquid is removed from the container.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.

Generally applicable optional features

- Weight of the entire unit, unfilled, is under 250g and preferably 214g.
- Silver based bactericide is used on all parts that are not steam or heat sterilized in normal cleaning.
- Housing includes a rechargeable battery.
- System is self-contained.
- System is a closed loop system.
- Breast pump system is a self-contained, wearable device that includes an integral rechargeable battery, control electronics, and one or more air pumps operating as a closed system, driving a flexible diaphragm that in turn delivers negative air-pressure to the breast, to cause milk to be expressed.
- Housing has a generally rounded or convex front surface and has a generally tear-drop shape when seen from the front.

E. Bra Clip Feature Cluster

Feature 40 Bra Adjuster

A bra adjuster for a nursing or maternity bra, the nursing or maternity bra including a bra cup with a flap that can be undone to expose the nipple, and the flap attaching to the shoulder strap using a clasp, hook or other fastener attached to the flap, and a corresponding fastener attached to the shoulder strap;

and in which the bra adjuster is attachable at one end to the fastener attached to the flap, and at its other end to the fastener attached to the shoulder strap, and hence increases the effective bra cup size sufficiently to accommodate a wearable breast pump, and is also detachable from the flap and shoulder strap.

Optional:

- Bra adjuster is retained in position on the bra during normal wearing of the bra, even when the flap is attached directly to the shoulder strap, and is used to increases the effective bra cup size only when the wearable breast pump is used.
- Bra adjuster is extensible or elastic.
- Bra adjuster is of a fixed length.
- Bra adjuster includes a clip that the user can slide onto the bra strap to secure the bra adjuster in position.
- Bra adjuster is machine-washing washable.

F. Other Features that can sit outside the breast pump context

Feature 41 Wearable device using more than one piezo pump connected in series or in parallel

A wearable device including multiple piezo pumps mounted together either in series or in parallel.

Optional:

- The wearable device is a medical wearable device.
- The piezo pumps air or any liquid etc.
- The system can switch between a parallel mode and a series mode to arrive to lower or higher pressure quicker.

Feature 42 Wearable medical device using a piezo pump and a heat sink attached together.

A wearable medical device including a piezo pump and a heat sink attached together.

Optional

- The wearable device uses more than one piezo pump connected in series.
- The wearable device uses more than one piezo pump connected in parallel.
- Each piezo pump is connected to its own heat sink, or to a common heat sink.
- The or each heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48°C and preferably no more than 43°C
- The wearable device includes a thermal cut out.
- Excess heat is diverted to a specific location on the device that is selected to not be in prolonged contact with the skin of the user, in normal use.
- Use cases application:
    - Wound therapy
    - High degree burns
    - Sleep apnea
    - Deep vein thrombosis
    - Sports injury.
- Wearable medical device is powered/charged via USB.

Note

It is to be understood that the above-referenced arrangements are only illustrative of the application for the principles of the present invention. Numerous modifications and alternative arrangements can be devised without departing from the spirit and scope of

the present invention. While the present invention has been shown in the drawings and fully described above with particularity and detail in connection with what is presently deemed to be the most practical and preferred example(s) of the invention, it will be apparent to those of ordinary skill in the art that numerous modifications can be made without departing from the principles and concepts of the invention as set forth herein.

CLAIMS

1. A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump fitted in the housing and forming part of a closed loop system that drives a separate, deformable diaphragm to generate negative air pressure, that diaphragm being removably mounted on a breast shield.

2. The wearable breast pump system of Claim 1, configured as a self-contained, wearable device with an internal rechargeable battery.

3. The wearable breast pump system of Claim 1 or 2, in which the piezo air-pump is positioned at or close to the base of the housing.

4. The wearable breast pump system of any preceding Claim, in which the piezo air-pump comprises two or more individual piezo air-pumps.

5. The wearable breast pump system of Claim 4, in which the individual piezo air-pumps are mounted in a series arrangement.

6. The wearable breast pump system of Claim 4 or 5, in which the individual piezo air-pumps are mounted in a parallel arrangement.

7. The wearable breast pump system of any preceding Claim, in which the deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of the breast shield.

8. The wearable breast pump system of any preceding Claim, in which the deformable diaphragm is not physically connected to the piezo air-pump.

9. The wearable breast pump system of any preceding Claim, in which the deformable diaphragm is a flexible generally circular diaphragm that removably sits over a diaphragm housing that is an integral part of the breast shield.

10. The wearable breast pump system of any preceding Claim, in which a diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

11. The wearable breast pump system of any preceding Claim, in which the piezo air-pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

12. The wearable breast pump system of any preceding Claim, in which the piezo air-pump weighs less than 10gm.

13. The wearable breast pump system of any preceding Claim, in which, in normal operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

14. The wearable breast pump system of any preceding Claim, in which the piezo air-pump is fed by air that passes through an air filter.

15. The wearable breast pump system of any preceding Claim, which includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and a rigid, non-collapsible milk container.

16. The wearable breast pump system of any preceding Claim, in which the breast shield is configured to attach to the housing with a single, sliding push action.

17. The wearable breast pump system of any preceding Claim, including a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

18. The wearable breast pump system of any preceding Claim, in which the housing includes a sensor, such as an accelerometer, that measures or determines the movement

and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

19. The wearable breast pump system of any preceding Claim, including a control interface that the user selects to indicate or record if milk is being expressed from the left or the right breast.

20. The wearable breast pump system of any preceding Claim, including (i) an air pressure sensor configured to measure the negative pressure and (ii) a measurement sub-system that measures or infers milk flow or milk volume.

21. The wearable breast pump system of any preceding Claim, including:

(a) a re-useable rigid or non-collapsible milk container;

(b) at least one light emitter, configured to direct radiation towards the surface of the milk;

(c) at least one light detector, configured to detect reflected radiation from the surface of the milk;

and in which the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container.

22. The wearable breast pump system of any preceding Claim, in which the centre of gravity of the pump system is, when a milk container attached to the housing is empty, substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through a nipple tunnel or filling point on a breast shield, so that the device is not top-heavy for a woman using the pump.

23. The wearable breast pump system of any preceding Claim, including a measurement sub-system that measures or infers milk flow into the milk container; and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

24. The wearable breast pump system of any preceding Claim, including a data sub-system that collects and provides data to a connected device or remote application or

remote server; and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

25. The wearable breast pump system of any preceding Claim, including a microcontroller programmed to control the pumping mechanism and to permit the user to manually indicate the level of comfort that they are experiencing when the system is in use.

26. The wearable breast pump system of any preceding Claim, including a microcontroller programmed to automatically change one or more parameters of the pumping mechanism, and to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

27. The wearable breast pump system of any preceding Claim, including a re-useable rigid or non-collapsible milk container that when connected to the housing forms an integral, lower part of the housing, with a surface shaped to continue a curved shape of the housing, so that the pump system can be held comfortably inside the bra.

28. The wearable breast pump system of any preceding Claim, including a milk container that is attachable to the housing with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

29. The wearable breast pump system of any preceding Claim, in which the breast shield includes a nipple tunnel shaped to receive a nipple, and includes an opening that defines the start of a milk flow path; and the system includes a re-useable milk container that when connected to the housing is positioned entirely below the opening or the milk flow path, when the breast pump is positioned or oriented for normal use.

30. The wearable breast pump system of any preceding Claim, including a milk container that is removable from the housing and is shaped or configured to also serve as a drinking bottle that is readily held by a baby because it is wider than it is tall.

Independents

31. A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a rigid or non-collapsible milk container;

and in which the breast pump system includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and the rigid, non-collapsible milk container.

32. A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel, shaped to receive a nipple, providing to the mother placing the breast shield onto her breast a clear and unobstructed view of the nipple when positioned inside the nipple tunnel, to facilitate correct nipple alignment.

33. A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel shaped to receive a nipple, the nipple tunnel including guide lines that define the correct spacing of the nipple from the side walls of the nipple tunnel.

34. A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield that is attachable to the housing with a mechanism that latches with an audible click when the breast shield is slid on to or against the housing with sufficient force.

35. A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield configured to attach to the housing with a single, sliding push action.

36. A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism

(b) a breast shield;

(c) a milk container;

and in which the centre of gravity of the pump system is, when the milk container is empty, substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through a nipple tunnel or filling point on a breast shield, so that the device is not top-heavy for a woman using the pump.

37. A breast pump system including:

(a) a housing including a pumping mechanism;

(b) an illuminated control panel;

(c) a control system that reduces or adjusts the level or colour of illumination of the control panel at night or when stipulated by the user.

38. A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a milk container that is configured to be concealed within a bra and is hence not visible to the mother in normal use;

(c) a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

39. A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a measurement sub-system that measures or infers milk flow into the milk container;

and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

40. A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a data sub-system that collects and provides data to a connected device or remote application or remote server;

(d) and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

41. A breast pump system including a pumping mechanism and a milk container and including:

(a) a housing including the pumping mechanism;

(b) a milk container;

(c) and in which the milk container or any associated part, such as a lid, includes a memory or tag that is automatically programmed to store the time and/or date it was filled with milk.

42. A smart bottle or container that includes or is associated with a memory or a tag that is programmed to store the date and time it is filled using data from a pump or a connected device, such as a smartphone.

43. A breast pump system including:

(a) a housing;

(b) a milk container;

(c) the housing including a sensor, such as an accelerometer, that measures or determines the movement and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

44. A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a control interface that the user can select to indicate or record if milk is being expressed from the left or the right breast.

45. A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) an air pressure sensor configured to measure the negative pressure delivered by the negative air-pressure mechanism and (iii) a measurement sub-system that measures or infers milk flow or milk volume.

46. A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to cause the pumping mechanism to deliver various pre-set pressure profiles and to permit the user to manually vary the pressure to a value or values that are in-between the values available from a pre-set pressure profile.

47. A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to control the pumping mechanism and to permit the user to manually indicate the level of comfort that they are experiencing when the system is in use.

48. A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to automatically change one or more parameters of the pumping mechanism, and to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

49. A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to dynamically change one or more parameters of the pumping mechanism, and to automatically detect the start of milk let-down.

50. A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a separate, deformable diaphragm to generate negative air pressure.

51. A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a physically separate, deformable, self-sealing diaphragm, to generate negative air pressure.

52. A breast pump system including:

(a) a housing;

(b) multiple piezo air-pumps in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure; in which the multiple piezo air-pumps can be operated at different times in series-connected and in parallel-connected modes.

53. A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a breast shield that attaches to the housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm that fits directly onto the breast shield.

54. A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing;

(c) and a re-useable, rigid or non-collapsible milk container that when connected to the housing forms an integral part of the housing and that is also removable from the housing.

55. A breast pump system including

(a) a housing;

(b) a piezo air-pump in the housing;

(c) a milk container;

(d) a data connectivity module that enables data collection relating to the operation of the piezo air-pump and transmission of that data to a data analysis system.

56. A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure;

(c) a heat sink to manage the heat produced by the piezo-air pump to ensure it can be worn comfortably.

57. A breast pump system including:

(a) a housing;

(b) an air-pump in the housing that drives a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides air to regularly or sequentially inflate one or more air bladders or liners that are configured to massage one or more parts of the breast.

58. A breast pump system including:

(a) a housing;

(b) an air-pump, such as a piezo pump, in the housing that drive a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides warm air to regularly or sequentially inflate one or more air chambers that are configured to apply warmth to one or more parts of the breast.

59. A wearable breast pump system configured including:

(a) a housing shaped at least in part with a curved surface to fit inside a bra and including a pumping mechanism;

(b) and a re-useable rigid or non-collapsible milk container that when connected to the housing forms an integral, lower part of the housing, with a surface shaped to continue the curved shape of the housing, so that the pump system can be held comfortably inside the bra.

60. A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that is attachable to the housing with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

61. A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a re-useable milk container that is connected to the housing with a surface shaped to continue the curved or breast-like shape of the pump, so that the pump can be held comfortably inside a bra and where the milk container includes a pouring spout for pouring milk.

62. A wearable breast pump system including:

(a) a housing including a pumping mechanism, the housing being shaped at least in part to fit inside a bra;

(b) and a breast shield including a nipple tunnel shaped to receive a nipple, and including an opening that defines the start of a milk flow path;

(c) a re-useable milk container that when connected to the housing is positioned entirely below the opening or the milk flow path, when the breast pump is positioned or oriented for normal use.

63. A breast pump system including:

(a) a housing including a pumping mechanism;

(b) and a breast shield defining a region shaped to receive a nipple, the region defining the start of a milk flow path;

(c) a re-useable, rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the breast shield and the milk container are made substantially of an optically clear, dishwasher safe material.

64. A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including an air pumping mechanism;

(b) a breast shield;

(c) a diaphragm that flexes in response to changes in air pressure caused by the air pumping mechanism and that seals to the breast shield;

(d) a re-useable milk container that seals to the breast shield;

and in which either or both of the diaphragm and the re-useable milk container substantially self-seal under the negative air pressure provided by the pumping mechanism.

65. A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that forms an integral part of the housing;

(c) a re-useable pouring spout that is positioned at or close to the front edge of the milk container.

66. A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a milk container that is removable from the housing and is shaped or configured to also serve as a drinking bottle that is readily held by a baby because it is wider than it is tall.

67. A system for milk volume determination, for use as part of a breast pump, or breast milk collecting device, including:

(a) a re-useable rigid or non-collapsible milk container;

(b) at least one light emitter, configured to direct radiation towards the surface of the milk;

(c) at least one light detector, configured to detect reflected radiation from the surface of the milk;

wherein the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container.

68. A liquid-level measuring system for measuring the quantity of liquid in a container for a breast pump; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to detect light from the light emitters that has been reflected from the liquid;

(c) a sub-system that infers, measures or calculates the quantity in the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

69. A liquid-level measuring system for measuring the tilt angle of liquid in a container; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to measure properties of the light reflected from the liquid;

(c) a sub-system including an accelerometer that infers, measures or calculates the tilt angle of the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

70. A bra adjuster system for a nursing or maternity bra, the nursing or maternity bra including a bra cup with a flap that can be undone to expose the nipple, and the flap attaching to the shoulder strap using a clasp, hook or other fastener attached to the flap, and a corresponding fastener attached to the shoulder strap;

and in which the bra adjuster is attachable at one end to the fastener attached to the flap, and at its other end to the fastener attached to the shoulder strap, and hence increases the effective bra cup size sufficiently to accommodate a wearable breast pump, and is also detachable from the flap and shoulder strap.

71. A wearable device including multiple piezo pumps mounted together either in series or in parallel.

72. A wearable medical device including a piezo pump and a heat sink attached together.

Breast shield

73. The system of any preceding Claim in which the only parts of the system that come into contact with milk in normal use are a breast shield and a milk container.

74. The system of any preceding Claim in which milk only flows through a breast shield and then directly into a milk container.

75. The system of any preceding Claim in which a breast shield and a milk container are each pressed or pushed into engagement with the housing.

76. The system of any preceding Claim in which a breast shield and milk container are each pressed or pushed into a latched engagement with the housing.

77. The system of any preceding Claim in which there are two user-removable parts, namely a breast shield and milk container, and each is insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

78. The system of any preceding Claim in which a breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

79. The system of any preceding Claim in which a breast shield slides into the housing using guide members.

80. The system of any preceding Claim in which the housing is configured to slide onto a breast shield, when the breast shield has been placed onto a breast, using guide members.

81. The system of any preceding Claim in which a breast shield latches into position against the housing.

82. The system of any preceding Claim in which a breast shield latches into position against the housing when spring plungers, such as ball bearings, in the housing locate into small indents in the breast shield.

83. The system of any preceding Claim in which a breast shield latches into position against the housing using magnets.

84. The system of any preceding Claim in which a breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an

air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

85. The system of any preceding Claim in which a breast shield includes a nipple tunnel that includes on its lower surface an opening through which expressed milk flows directly into the milk container.

86. The system of any preceding Claim in which no other parts are removable from the breast shield, apart from the flexible diaphragm.

Milk container

87. The system of any preceding Claim in which a milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.

88. The system of any preceding Claim in which a milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

89. The system of any preceding Claim in which a milk container mechanically or magnetically latches to the housing.

90. The system of any preceding Claim in which a milk container is released by the user pressing a button on the housing.

91. The system of any preceding Claim in which a milk container includes a removable cap and a removable valve that is seated on the lid.

92. The system of any preceding Claim in which in normal use, the milk container is positioned entirely within a bra.

93. The system of any preceding Claim in which no parts are removable from the milk container, apart from a cap and a valve.

94. The system of any preceding Claim in which all parts that are user-removable in normal use are attached to either a breast shield or a milk container.

95. The system of any preceding Claim in which audible or haptic feedback confirms the pump system is properly assembled for normal use with the milk container locked to the housing and the breast shield locked to the housing.

Pump

96. The system of any preceding Claim in which a pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

97. The system of any preceding Claim which also includes a control sub-system that combines or relates the air-pressure measurements with the milk flow or milk volume measurements

98. The system of any preceding Claim in which a control sub-system automatically adjusts the negative air-pressure to give the optimal milk flow or milk volume.

99. The system of any preceding Claim in which a control sub-system automatically adjusts the negative air-pressure during a pumping session to give the optimal milk flow or milk volume within comfort constraints defined by the user.

100. The system of any preceding Claim in which an air pressure sensor detects pressure created by the pumping mechanism.

101. The system of any preceding Claim in which an air pressure sensor is a piezo air pressure sensor.

102. The system of any preceding Claim in which an air pressure sensor measures the negative air pressure during a normal milk expression session.

103. The system of any preceding Claim in which an air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary

the operation of the pumping mechanism so that it deliver consistent performance over time.

104. The system of any preceding Claim in which an air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that different pumping mechanisms in different breast pump systems all deliver consistent performance

105. The system of any preceding Claim in which an air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to determine if the pumping mechanism is working correctly, within tolerance levels.

106. The system of any preceding Claim in which the operation of a pumping mechanism is varied by altering the duty or pump cycle.

107. The system of any preceding Claim in which the operation of a pumping mechanism is varied by altering the voltage applied to the pumping mechanism.

Piezo air-pump

108. The system of any preceding Claim in which a pumping mechanism is a piezo air pump.

109. The system of any preceding Claim in which a piezo air pump forms part of a closed or closed loop system.

110. The system of any preceding Claim in which a piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.

111. The system of any preceding Claim in which a piezo air pump is positioned at or close to the base of the housing.

112. The system of any preceding Claim in which there are two or more piezo air pumps.

113. The system of any preceding Claim in which there are two or more piezo air pumps mounted in a series arrangement.

114. The system of any preceding Claim in which there are two or more piezo air pumps mounted in a parallel arrangement.

115. The system of any preceding Claim in which a piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

116. The system of any preceding Claim in which a piezo air pump weighs less than 25gm, or less than 10gm.

117. The system of any preceding Claim in which in operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

118. The system of any preceding Claim in which in operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise. The piezo pump is fed by air that passes through an air filter.

119. The system of any preceding Claim in which a piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Diaphragm

120. The system of any preceding Claim in which a closed system is separated from a 'milk' side by a flexible diaphragm.

121. The system of any preceding Claim in which a deformable diaphragm is removably mounted against a part of a breast shield.

122. The system of any preceding Claim in which a deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.

123. The system of any preceding Claim in which a deformable diaphragm is not physically connected to the piezo air-pump.

124. The system of any preceding Claim in which an air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield.

125. The system of any preceding Claim in which a deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

126. The system of any preceding Claim in which an edge of a flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.

127. The system of any preceding Claim in which a diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Flow measurement and indication

128. The system of any preceding Claim in which a haptic and/or visual indicator indicates if the pump is operating correctly to pump milk, based on whether the quantity and/or the height of the liquid in a milk container above its base is increasing above a threshold rate of increase

129. The system of any preceding Claim in which a haptic and/or visual indicator that indicates if the pump is operating correctly to pump milk, is a row of LEDs that changes appearance as the quantity of milk increases.

130. The system of any preceding Claim in which a haptic and/or visual indicator provides an indication of an estimation of the milk flow rate.

131. The system of any preceding Claim in which a visual indicator provides a colour-coded indication of an estimation of the milk flow rate.

132. The system of any preceding Claim in which a visual indicator provides an indication of how much of the container has been filled with milk.

133. The system of any preceding Claim in which a milk flow or quantity visual indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.

134. The system of any preceding Claim in which a milk flow or quantity haptic indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.

135. The system of any preceding Claim in which a sub-system measures or infers the quantity and/or the height of the liquid in a milk container.

136. The system of any preceding Claim in which a sub-system measures or infers the quantity and/or the height of the liquid in a milk container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

137. The system of any preceding Claim in which a sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in a milk container.

138. The system of any preceding Claim in which a sub-system measures or infers the angle the top surface of the liquid in a milk container makes with respect to a baseline, such as the horizontal.

139. The system of any preceding Claim in which a haptic and/or visual indicator indicates if the amount of milk in a milk container has reached a preset quantity or level.

140. The system of any preceding Claim in which a haptic and/or visual indicator indicates if there is too much movement of the breast pump system for viable operation.

141. The system of any preceding Claim in which, if the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by warning or alerting the mother of a potential imminent spillage (e.g. from milk flowing back out of a breast shield) using an audio, or visual or haptic alert, or a combination of audio, haptic and visual alerts.

142. The system of any preceding Claim in which, if the tilt angle of the housing exceeds a threshold, then the system automatically adjusts the operation of the system by stopping the pump to prevent spillage.

143. The system of any preceding Claim in which, when the tilt angle of the housing reduces below the threshold, the system automatically adjusts the operation of the system by causing pumping to resume automatically.

144. The system of any preceding Claim in which, if the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by providing the mother with an alert to change position.

145. The system of any preceding Claim in which there are one or more light emitters and detectors positioned in the base of the housing, the light emitters and receivers operating as part of a sub-system that measures or infers the tilt angle of the milk in the container.

146. The system of any preceding Claim in which a sub-system measures the quantity of liquid in the milk container and also takes the measured tilt angle of the housing into account.

147. The system of any preceding Claim in which, if the tilt angle is above a certain threshold, the system ignores the quantity of liquid measured.

148. The system of any preceding Claim in which a sub-system derives or infers the mother's activity, such as walking, standing or lying activities, from the sensor.

149. The system of any preceding Claim in which a sub-system stores a time-stamped record of movement and/or tilt angles of the housing in association with milk flow data.

150. The system of any preceding Claim in which one or more visual indicators on the housing indicate whether the breast pump system is being set up the left or the right breast.

151. The system of any preceding Claim in which a visual indicator for the left breast is on the right-hand side of the housing, when viewed from the front; and the visual indicator for the right breast is on the left-hand side of the housing, when viewed from the front.

152. The system of any preceding Claim in which the housing includes a button labeled to indicate the left breast and a button labeled to indicate the right breast, that are respectively illuminated to indicate from which breast the milk is being expressed.

153. The system of any preceding Claim in which a sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.

154. The system of any preceding Claim in which, where the expressed milk quantity or level exceeds a threshold, then the pumping mechanism automatically changes mode, e.g. from a stimulation mode to an expression mode.

155. The system of any preceding Claim in which, where the quantity or level exceeds a threshold, then the pumping mechanism automatically stops.

156. The system of any preceding Claim in which milk-flow data is captured and stored.

157. The system of any preceding Claim in which, if milk-flow falls below a threshold, then a notification is provided to the mother.

158. A method of expressing and collecting milk, comprising the step of using a system as defined in any preceding Claim.

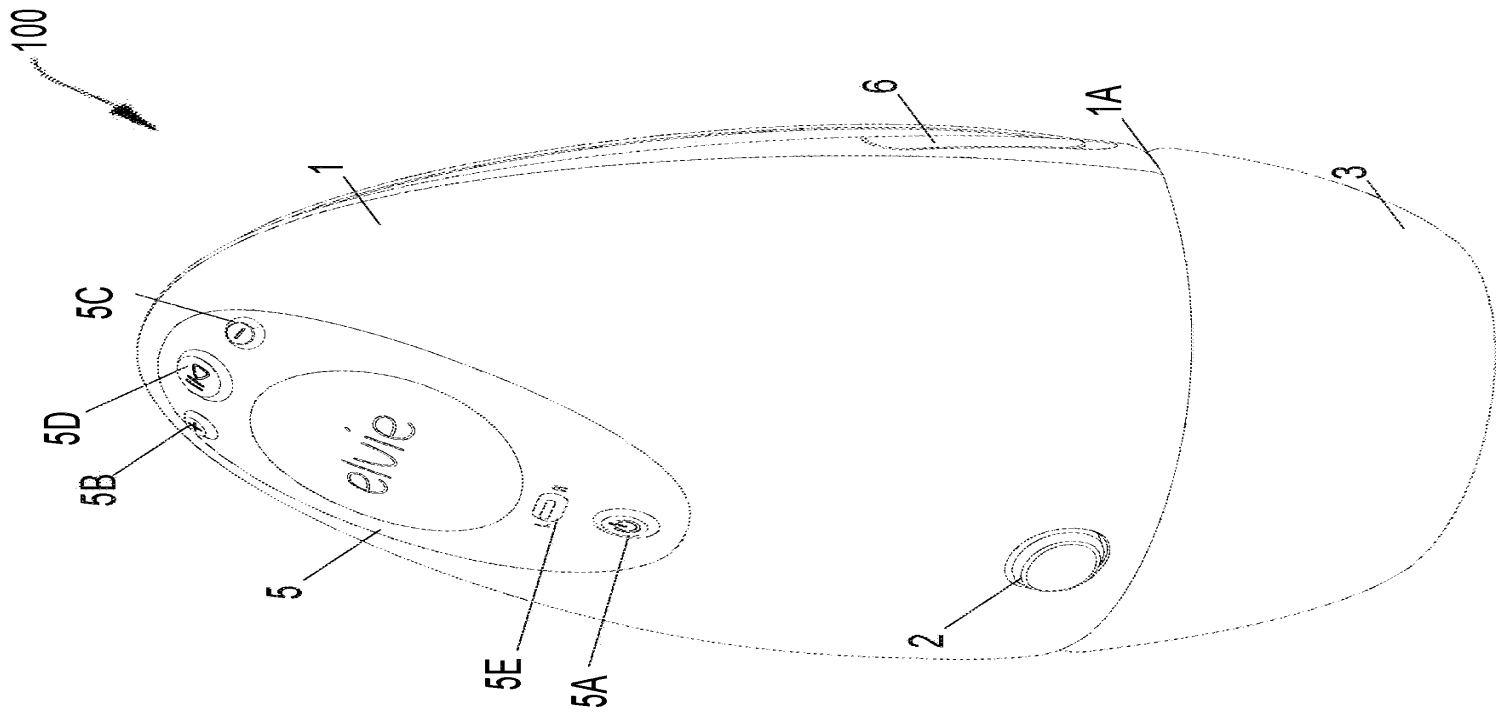

FIGURE 1

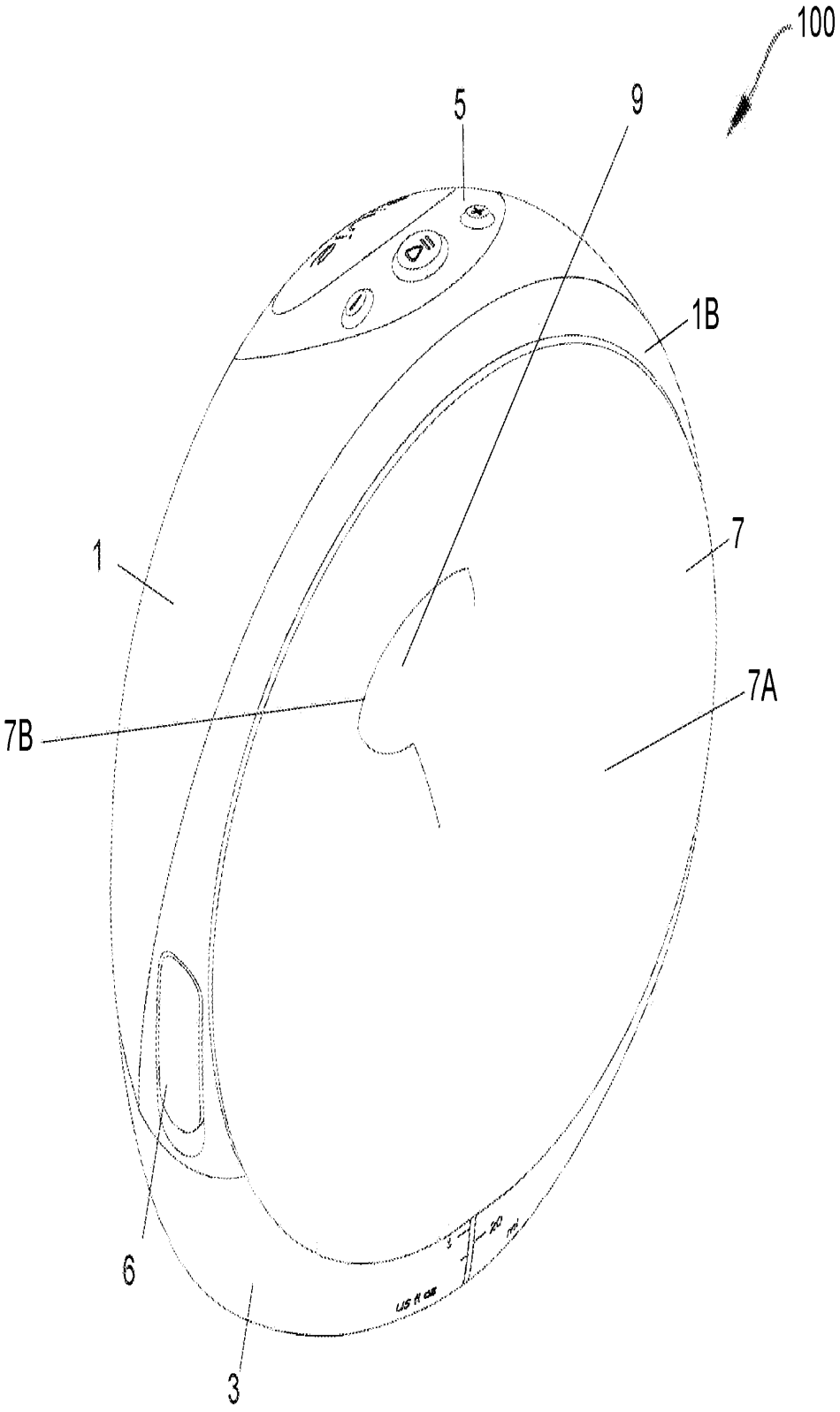

FIGURE 2

FIGURE 3

FIGURE 4

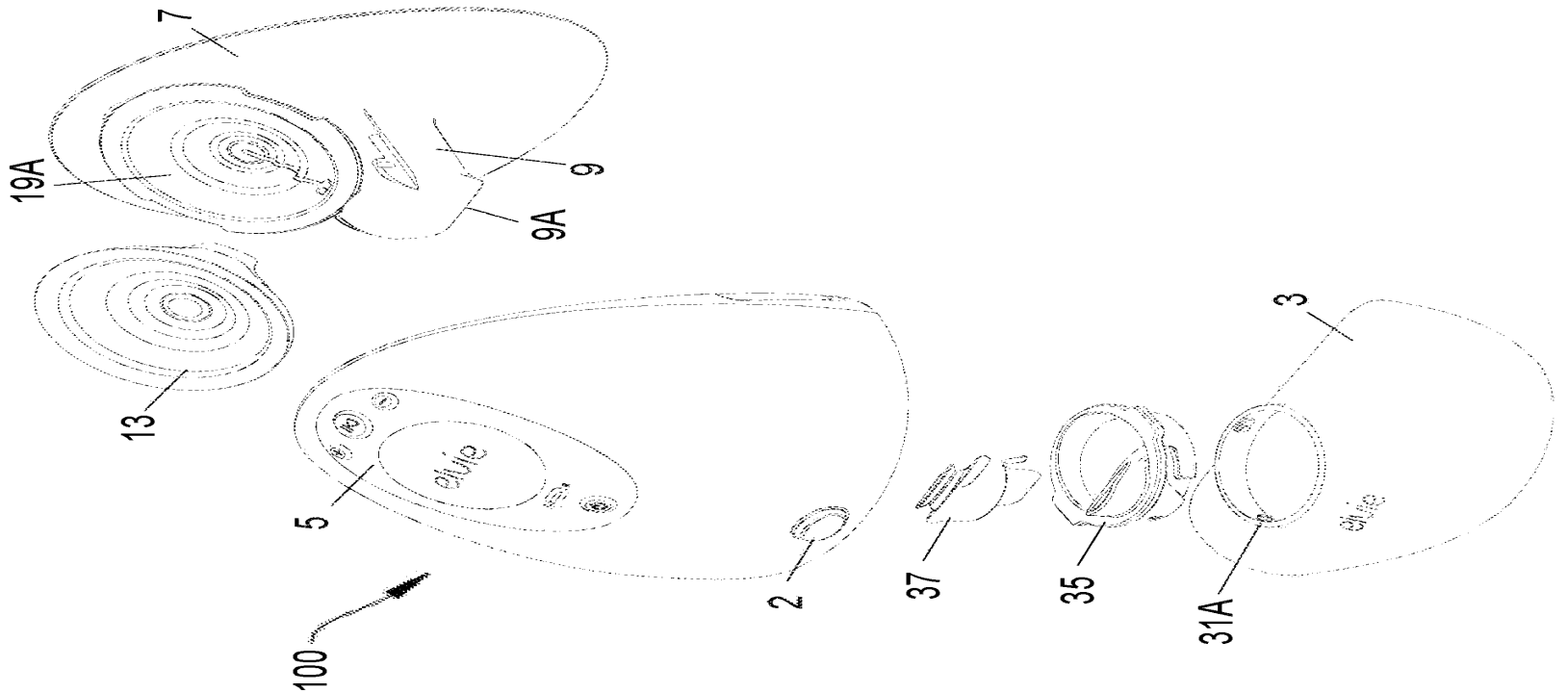

FIGURE 5

FIGURE 6

FIGURE 7

FIGURE 8

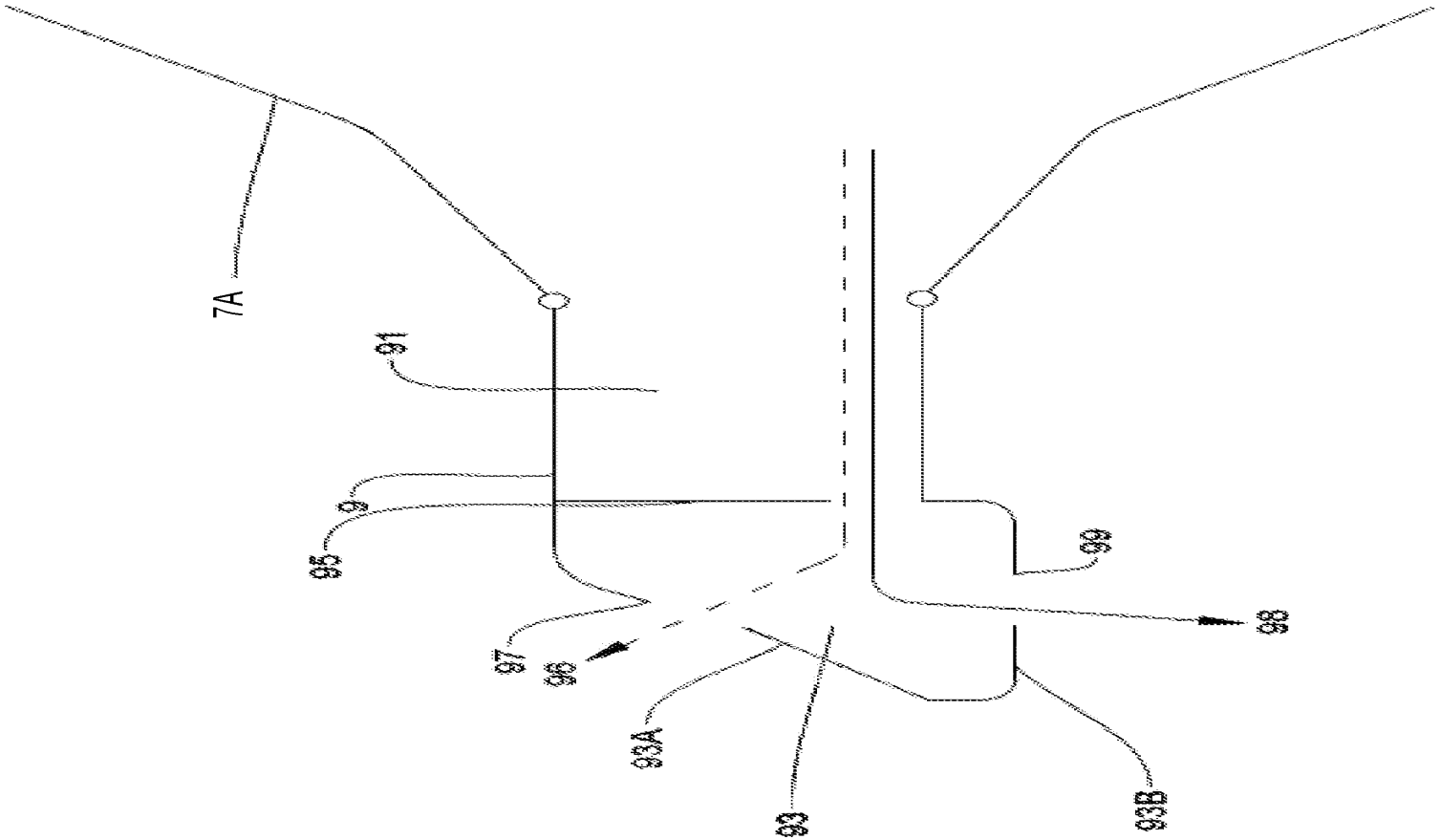

FIGURE 9

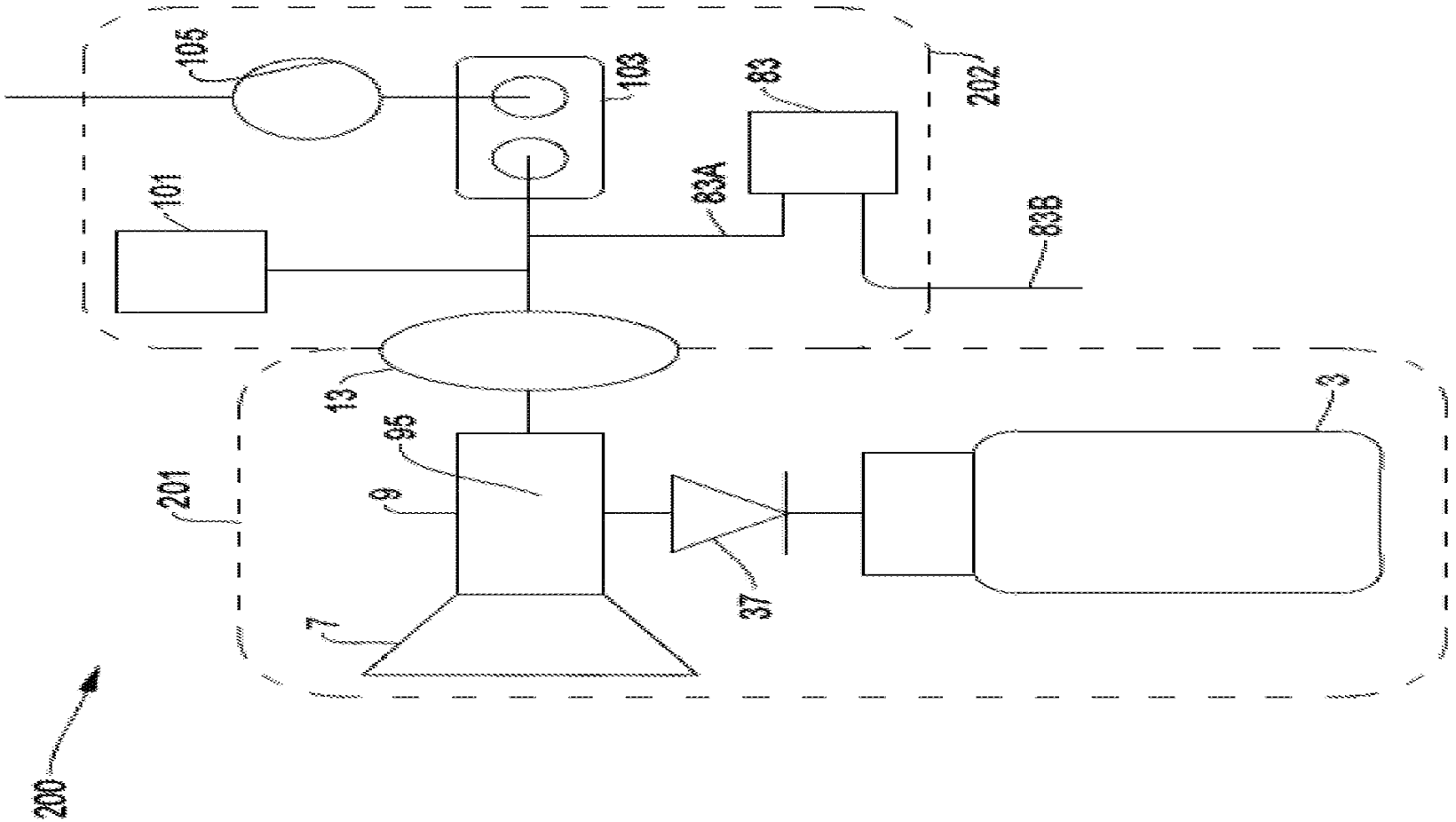

FIGURE 10

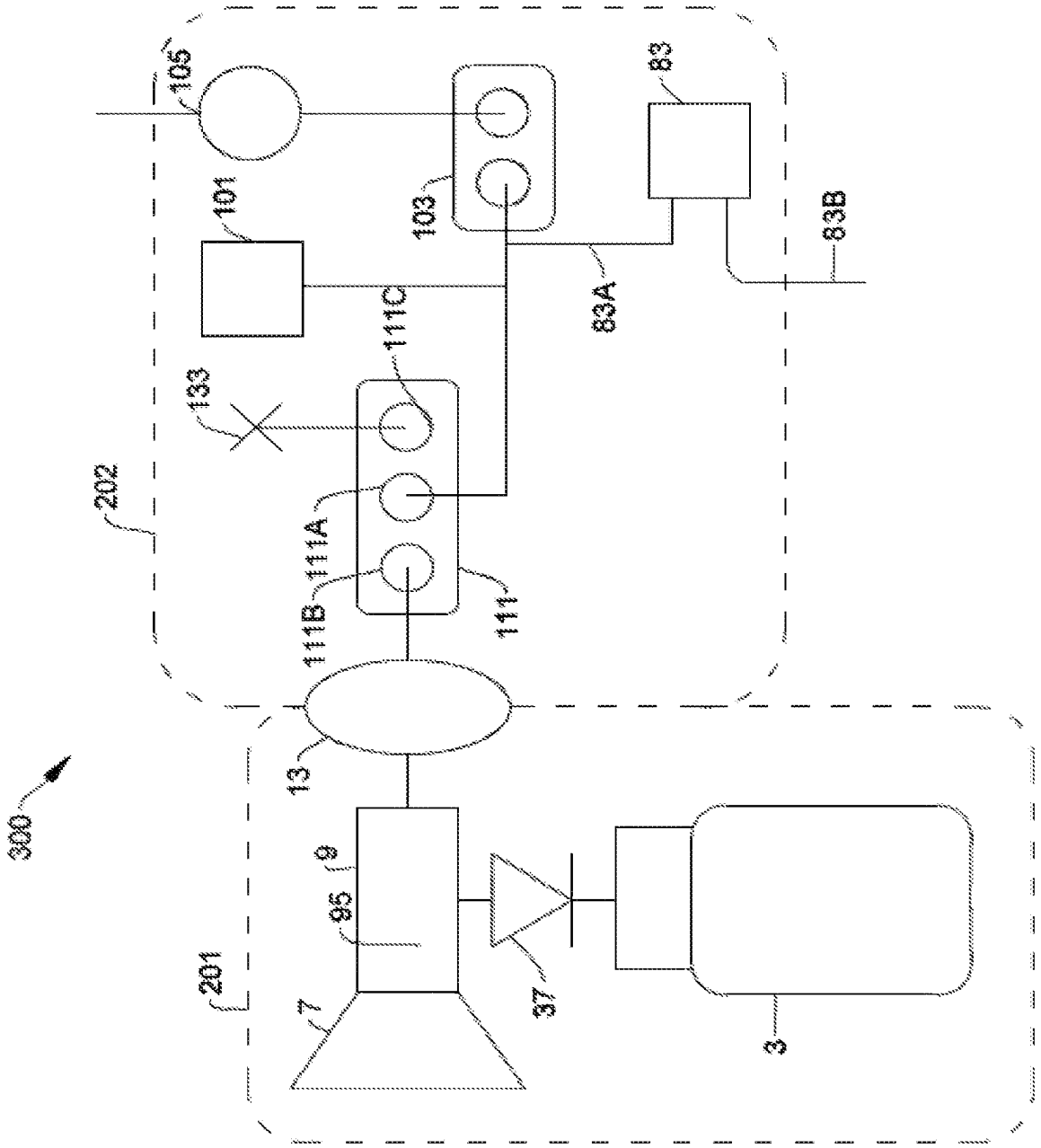
300
105
101
103
83
83B
83A
111C
133
202
111A
111B
111
13
9
95
201
7
37
3

FIGURE 11

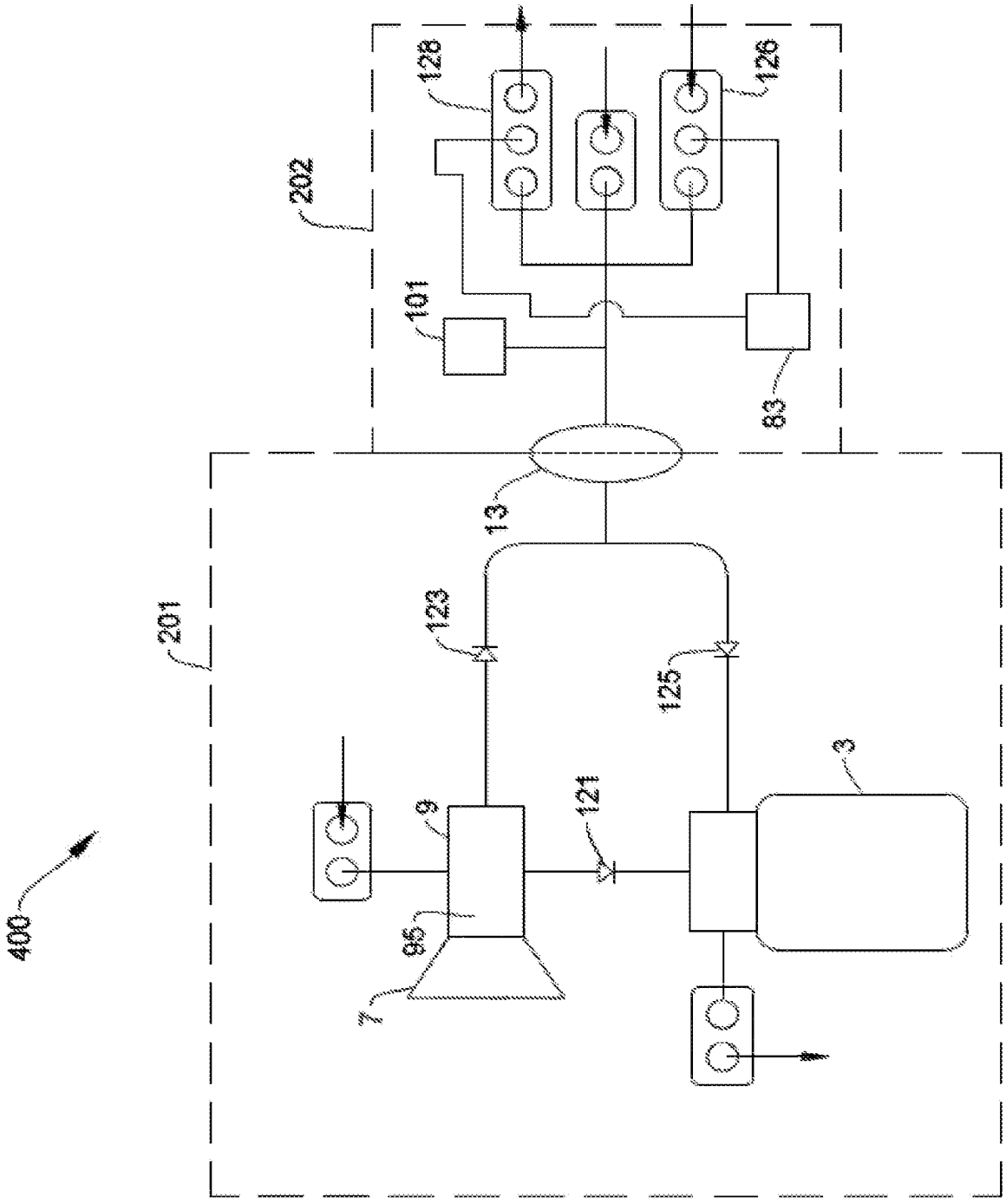

FIGURE 12

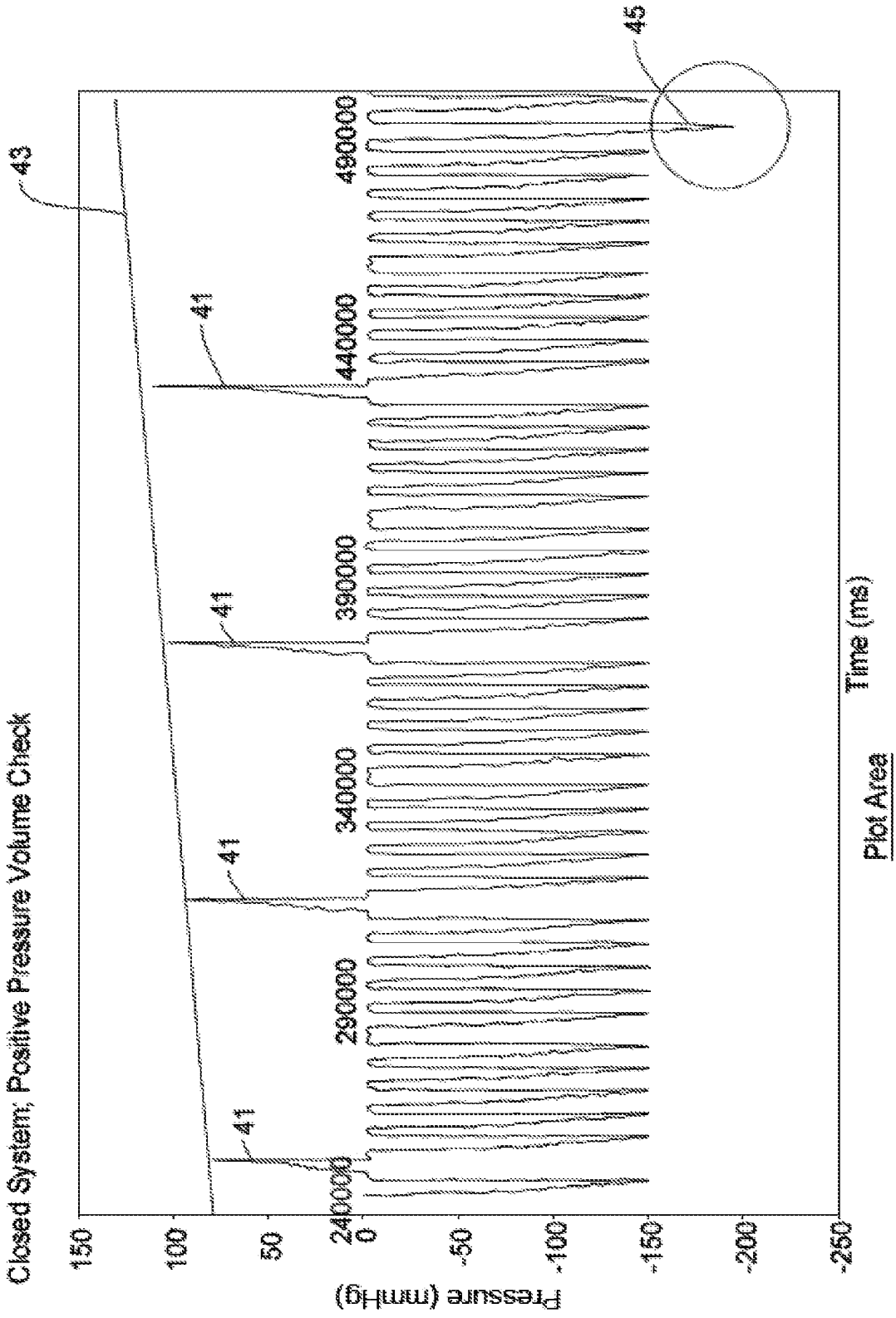
Closed System; Positive Pressure Volume Check
43
41
41
41
41
45
240000
290000
340000
390000
440000
490000
150
100
50
0
-50
-100
-150
-200
-250
Pressure (mmHg)
Time (ms)
Plot Area

FIGURE 13

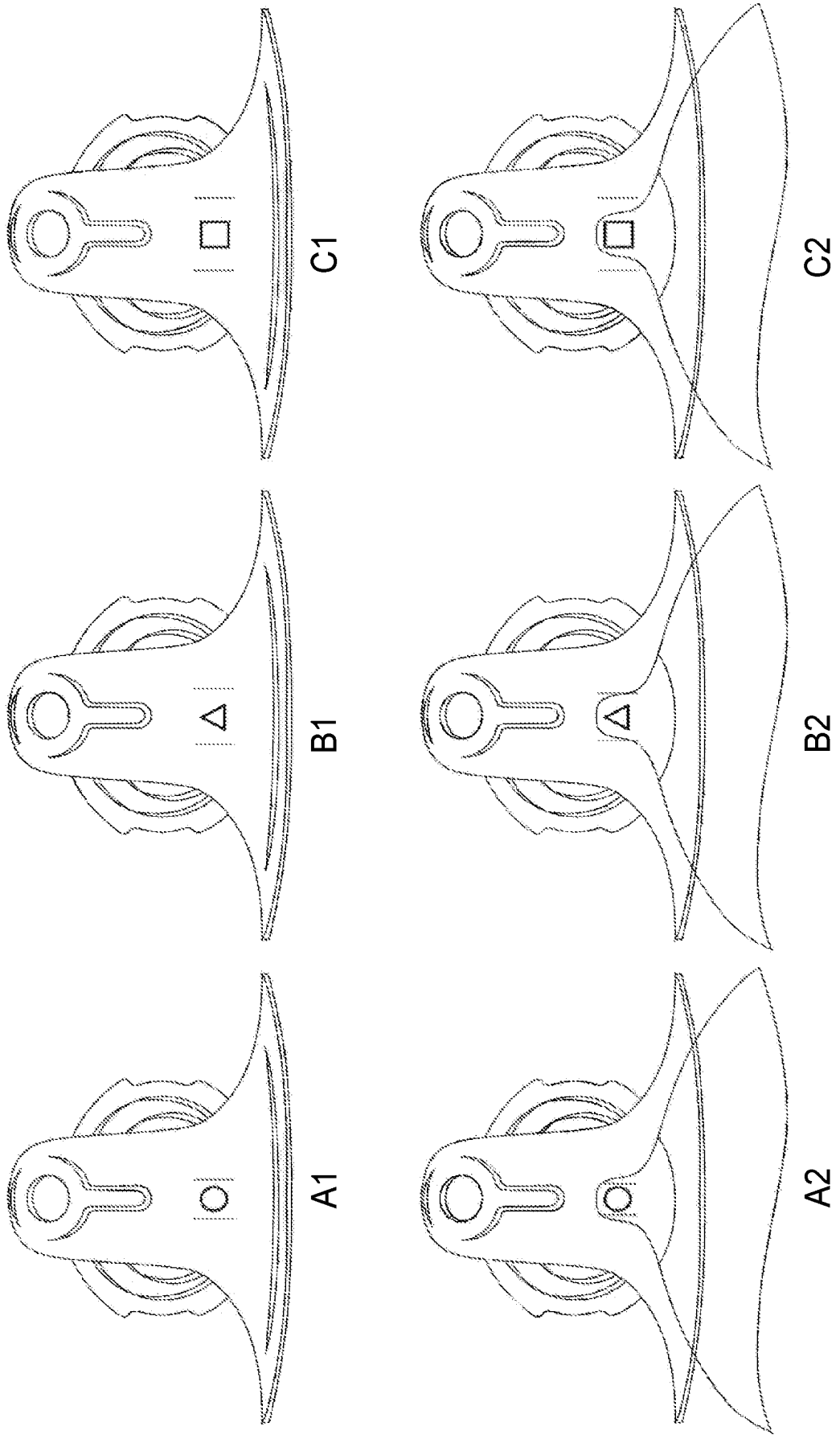

FIGURE 14

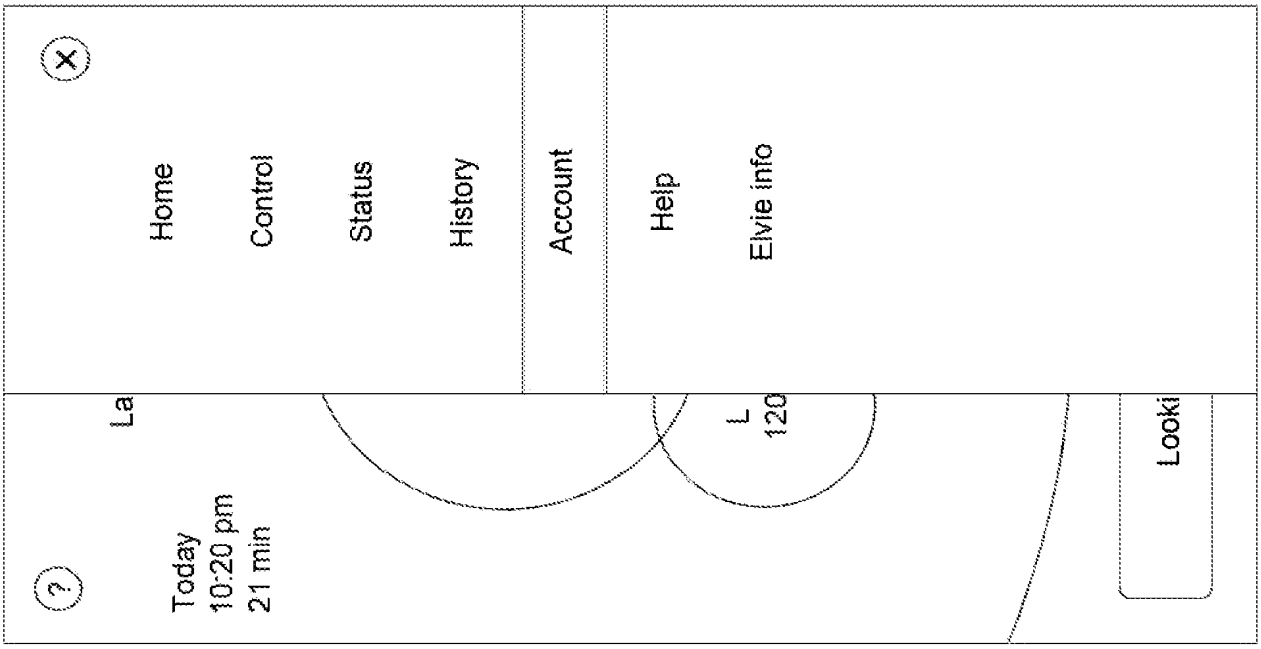
Home
Control
Status
History
Account
Help
Elvie info
Today
10:20 pm
21 min
Looki

FIGURE 15

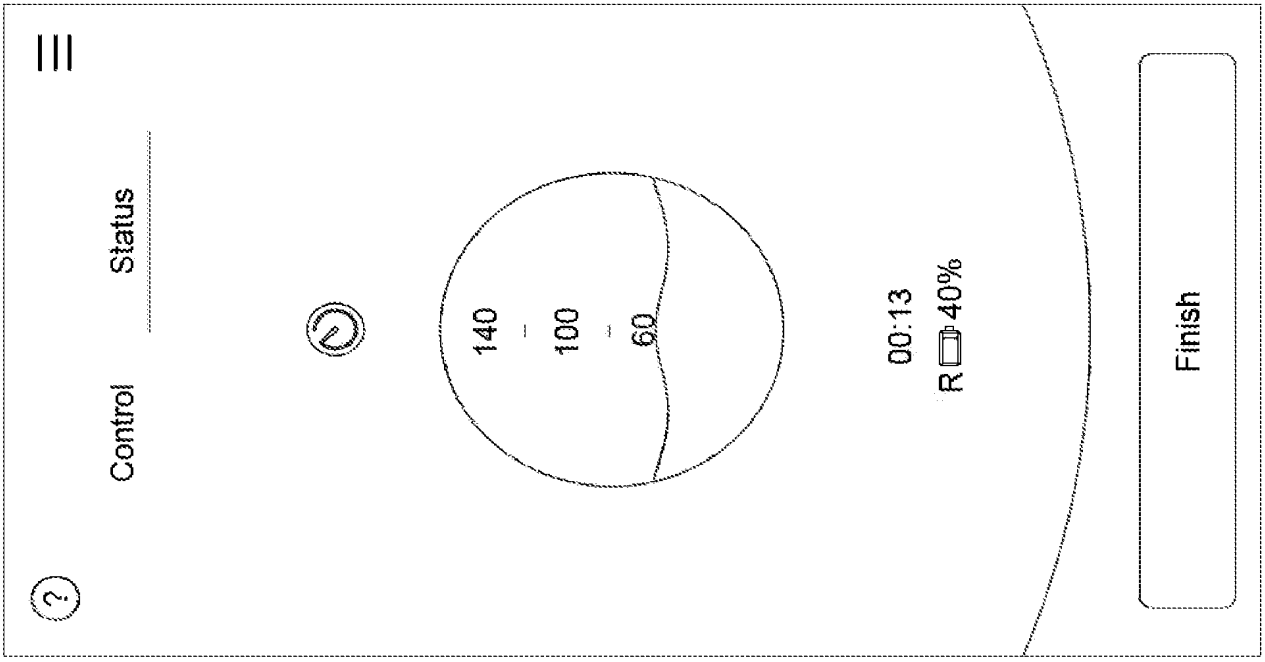

FIGURE 16

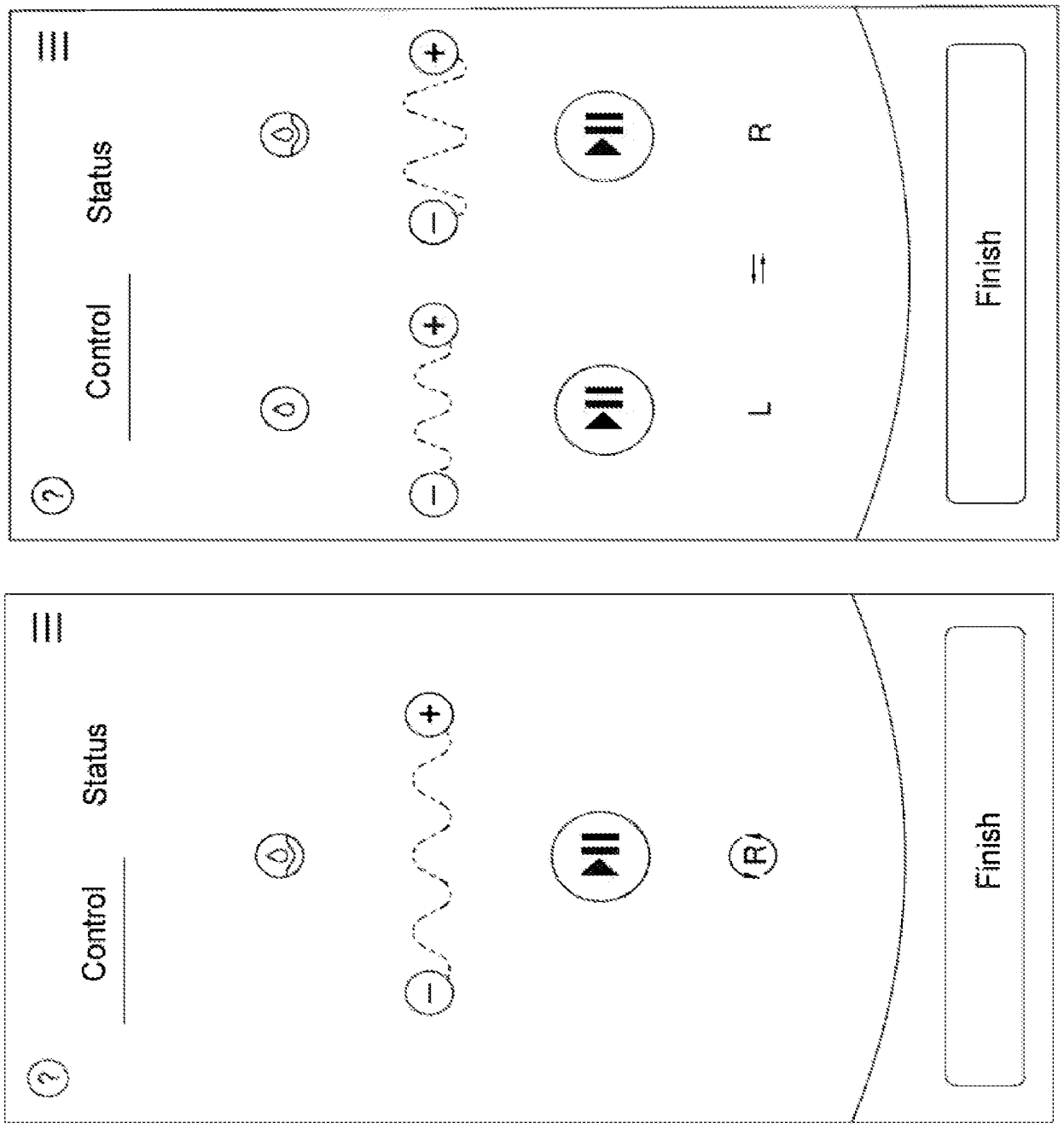

FIGURE 17

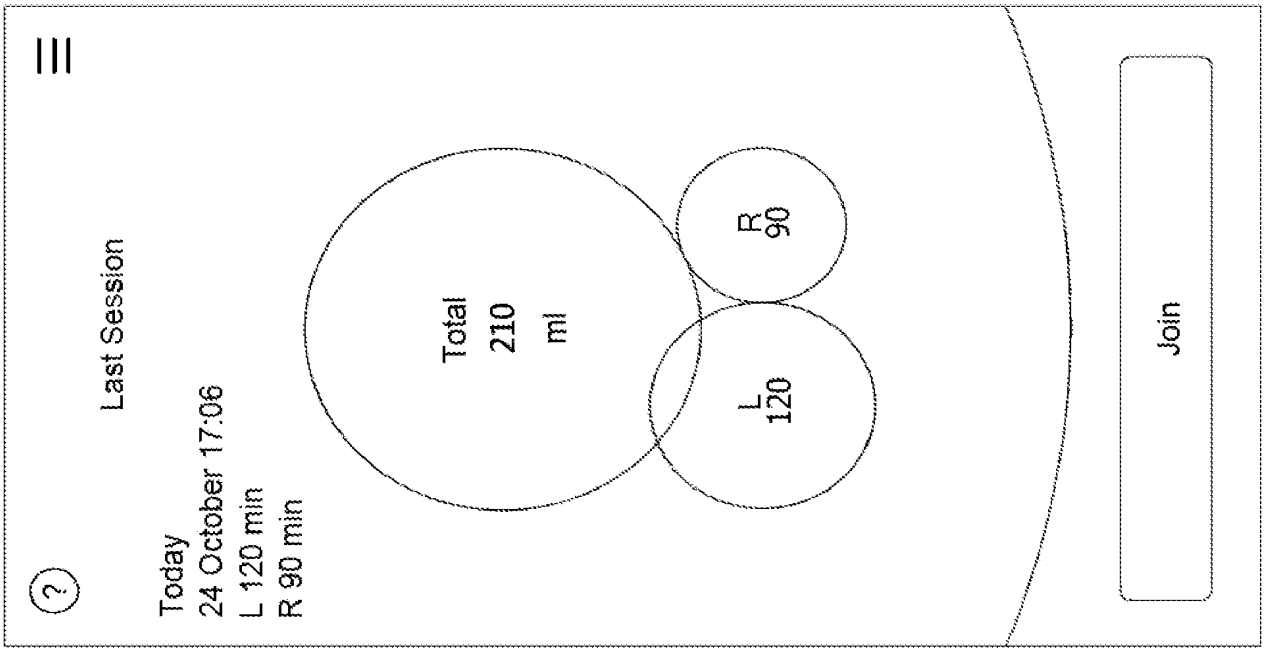
Last Session
Today
24 October 17:06
L 120 min
R 90 min
Total
210
ml
L
120
R
90
Join

FIGURE 18

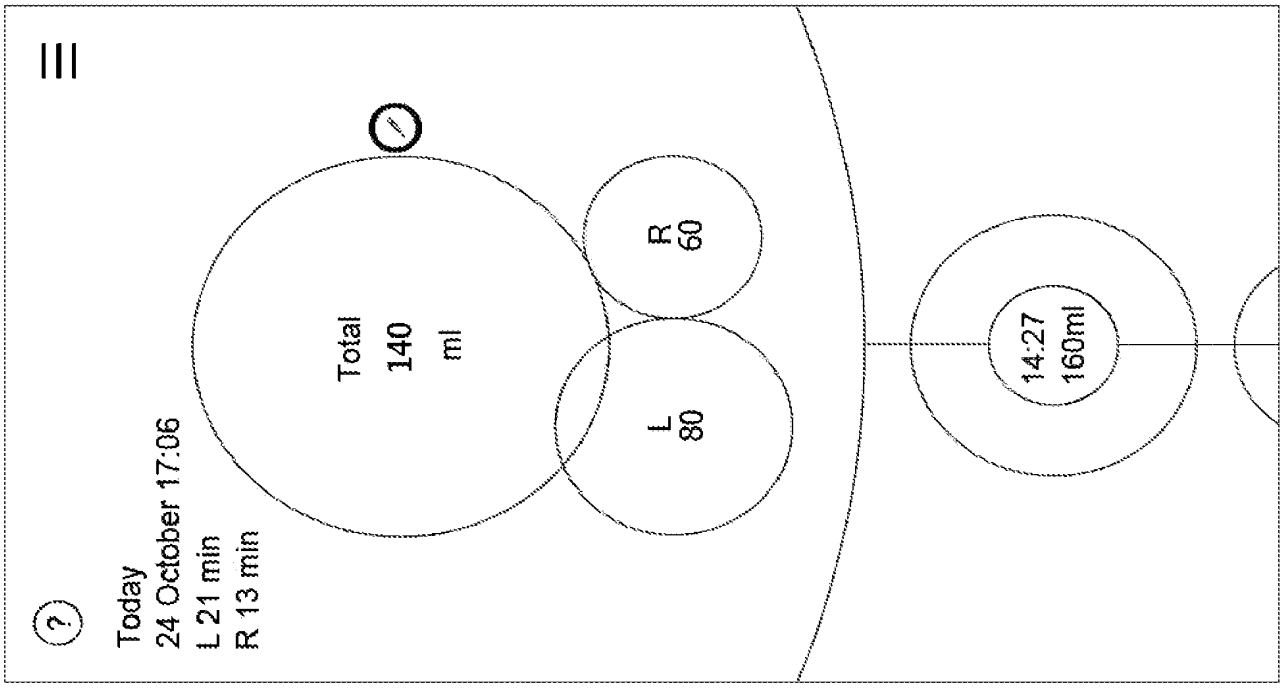
Today
24 October 17:06
L 21 min
R 13 min
Total
140
ml
L
80
R
60
14:27
160ml

FIGURE 19

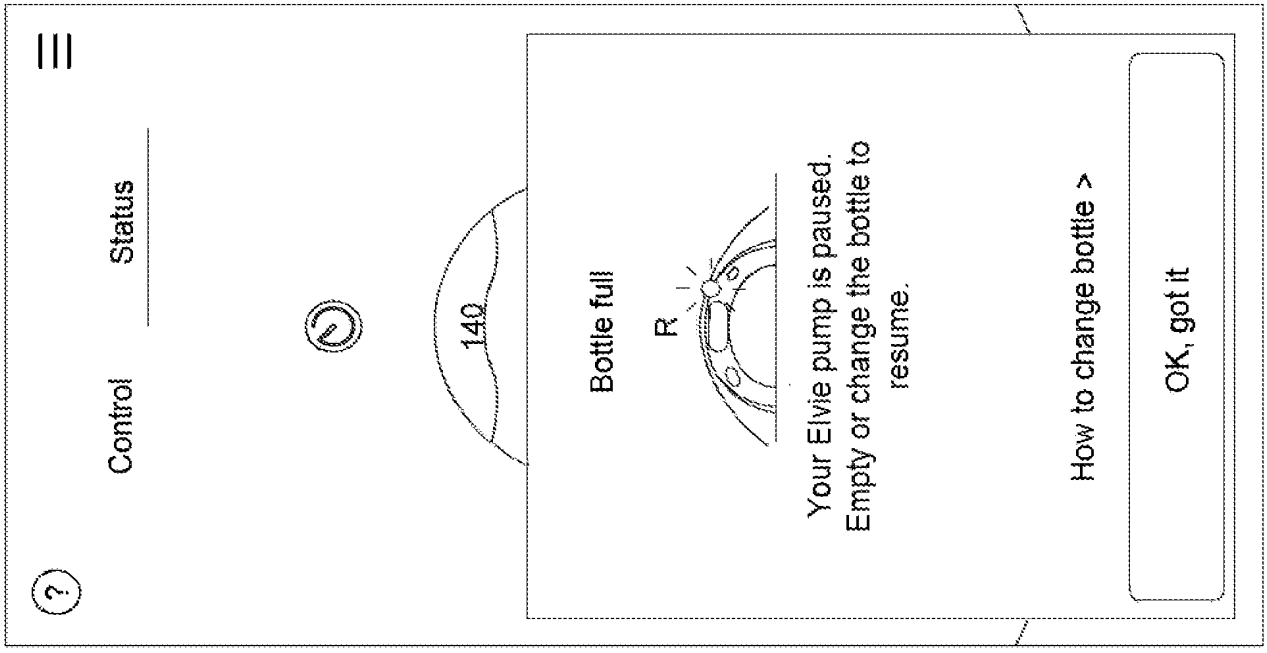
Control
Status
140
Bottle full
R
Your Elvie pump is paused.
Empty or change the bottle to resume.
How to change bottle >
OK, got it

FIGURE 20

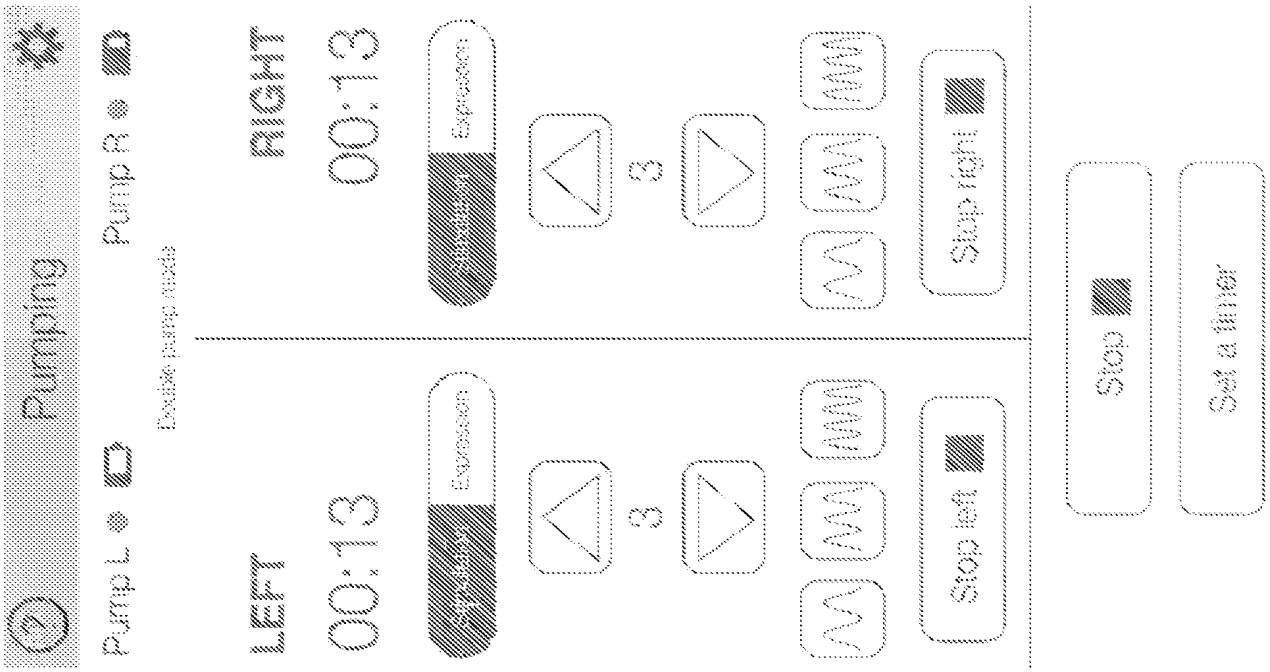
Pumping
Pump L
Pump R
Double pump mode
LEFT
00:13
Expression
RIGHT
00:13
Expression
Stop left
Stop right
Stop
Set a timer

FIGURE 21

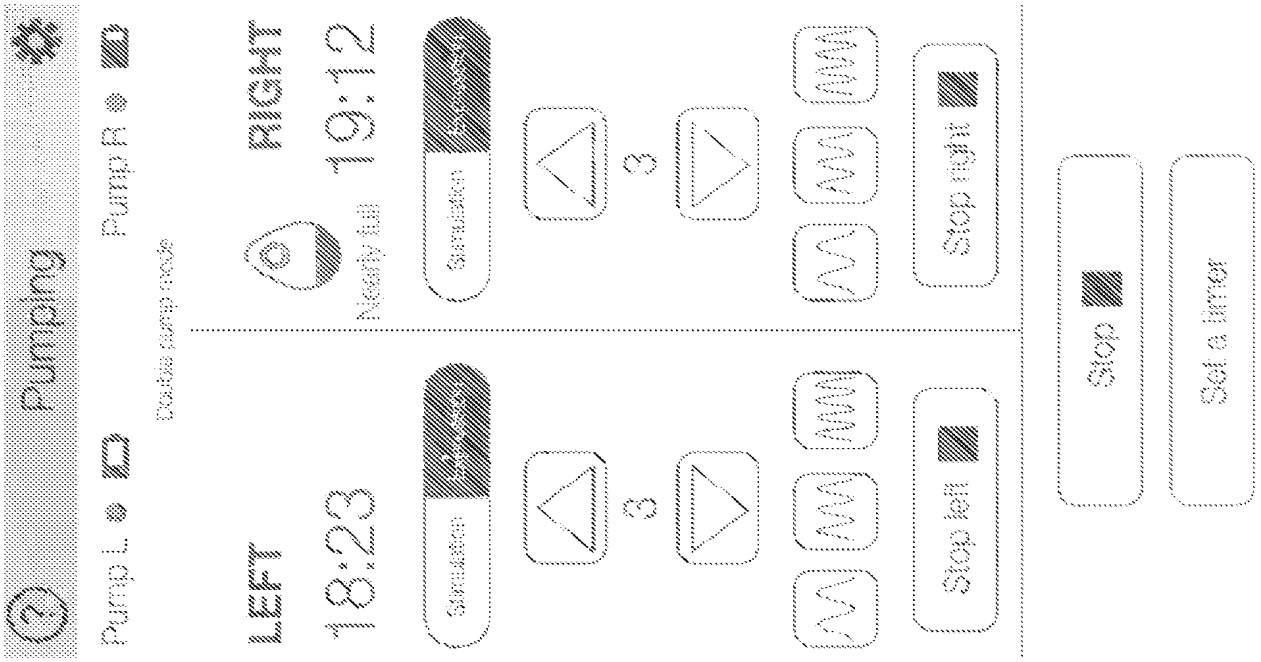
Pumping
Pump L
Pump R
Double pump mode
LEFT
18:23
Sensation
3
Stop left
RIGHT
19:12
Nearly full
Sensation
3
Stop right
Stop
Set a timer

FIGURE 22

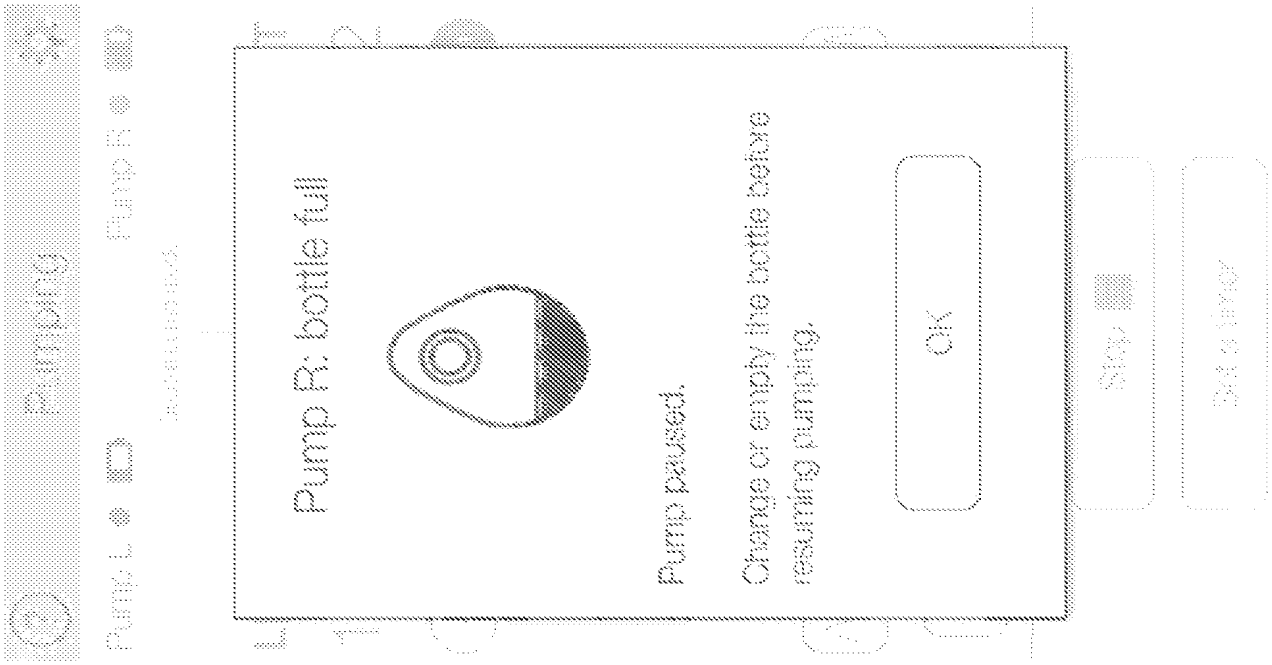
Pumping
Pump L
Pump R
Pump R: bottle full
Pump paused.
Change or empty the bottle before resuming pumping.
OK
Stop
Set a timer

FIGURE 23

Stopped
Pump L
Pump R
Select pump mode
LEFT
21:02
STOPPED
RIGHT
20:38
STOPPED
Total volume in bottle:
60 ml
Tick if you emptied or changed the bottle
Resume left
Total volume in bottle:
65 ml
Tick if you emptied or changed the bottle
Resume right
Resume
End session

FIGURE 24

PUMP
Pump L
25%
Pump R
Double pump mode
LAST SESSION
Start time: 3:50pm today
Total volume: 125ml
LEFT
20mins 16s
60ml
RIGHT
18mins 10s
65ml
Full history >
NEW SESSION
Start

FIGURE 25

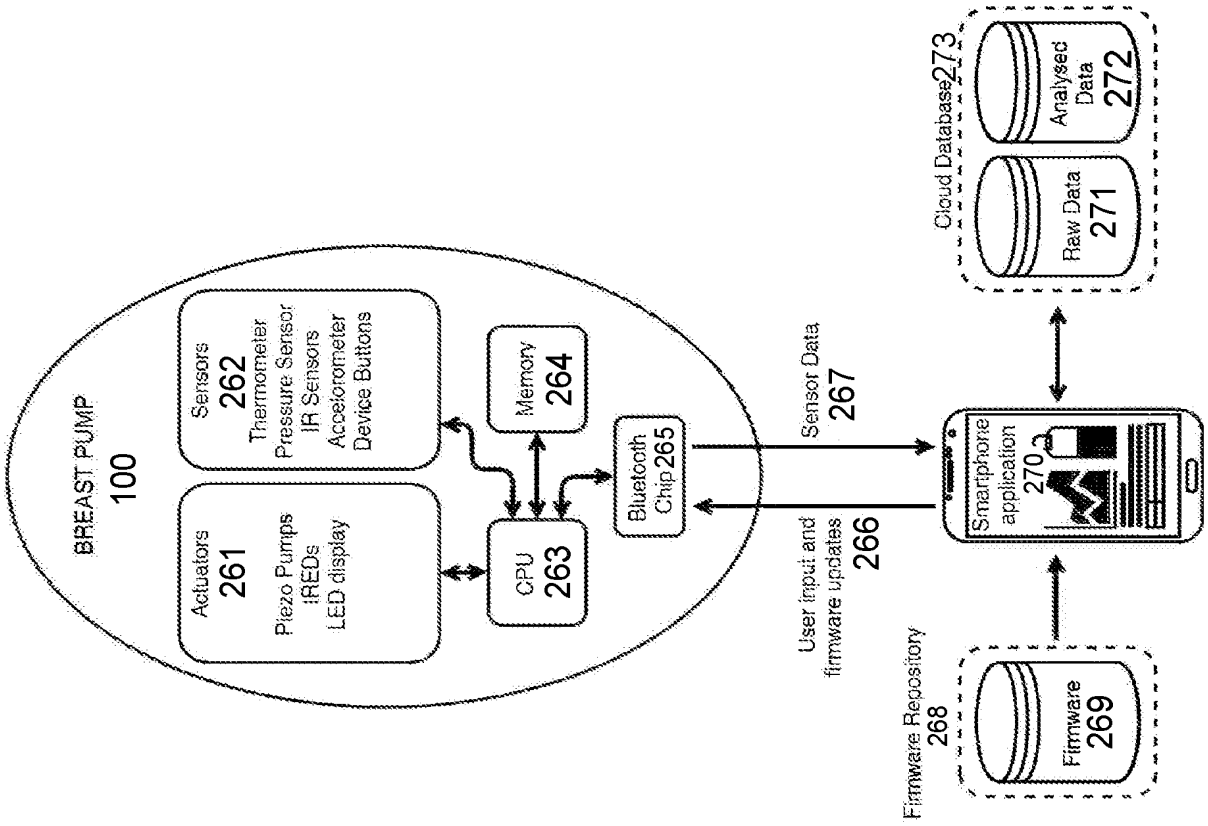
BREAST PUMP
100
Actuators
261
Piezo Pumps
IREDs
LED display
Sensors
262
Thermometer
Pressure Sensor
IR Sensors
Accelorometer
Device Buttons
CPU
263
Memory
264
Bluetooth
Chip 265
Sensor Data
267
User input and
firmware updates
266
Smartphone
application
270
Cloud Database 273
Raw Data
271
Analysed
Data
272
Firmware Repository
268
Firmware
269

FIGURE 26

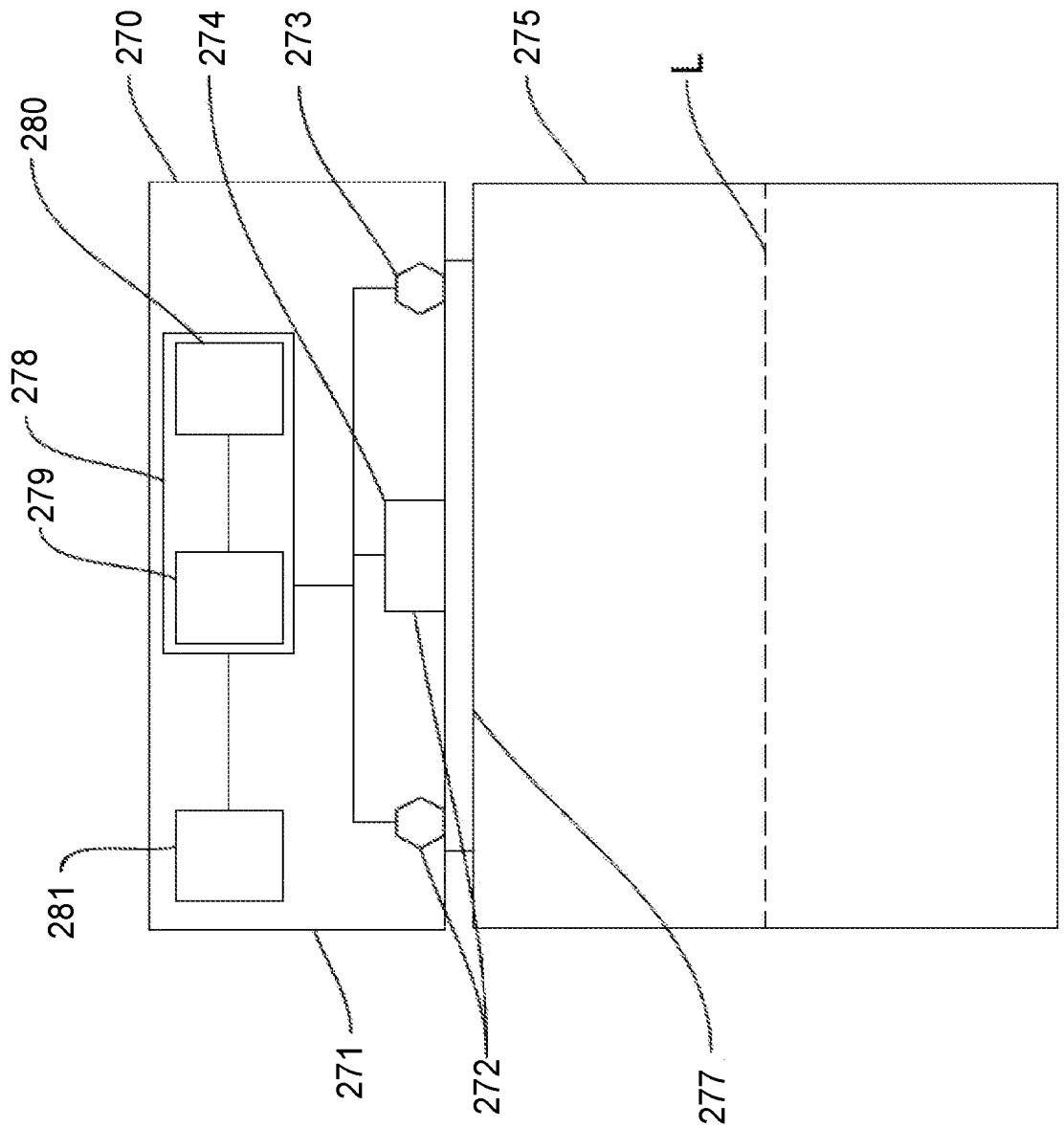

FIGURE 27

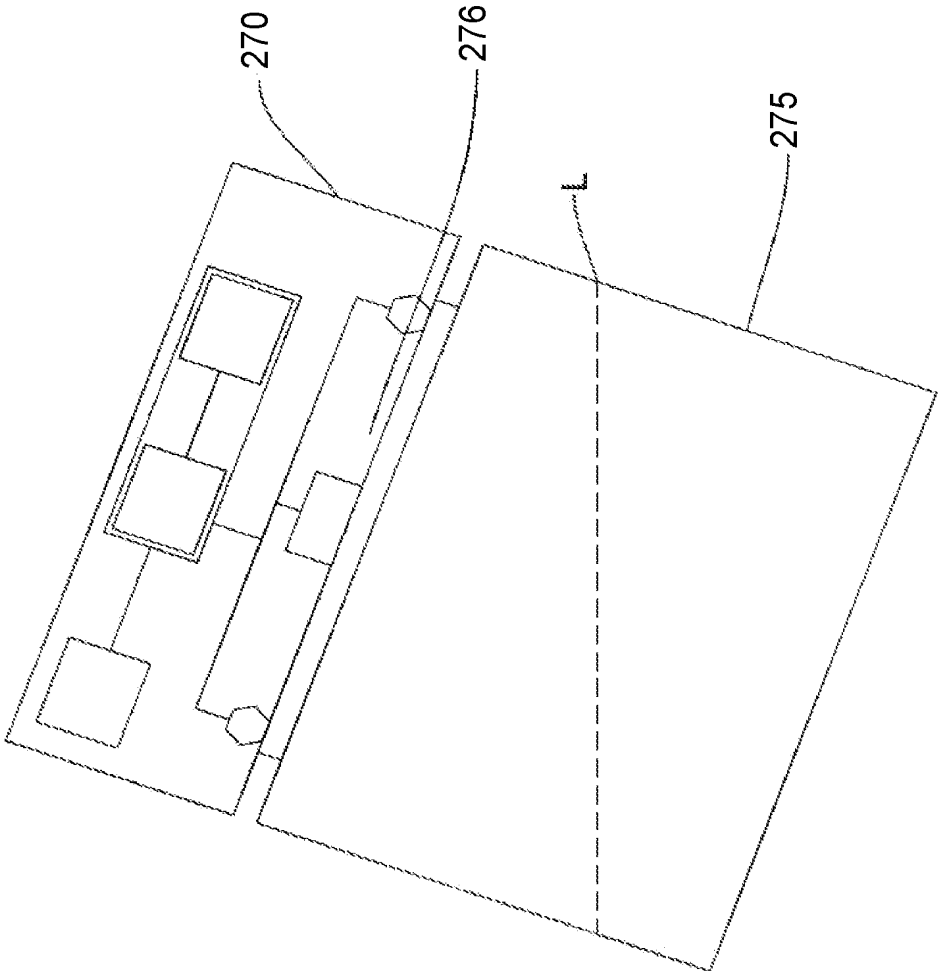

FIGURE 28

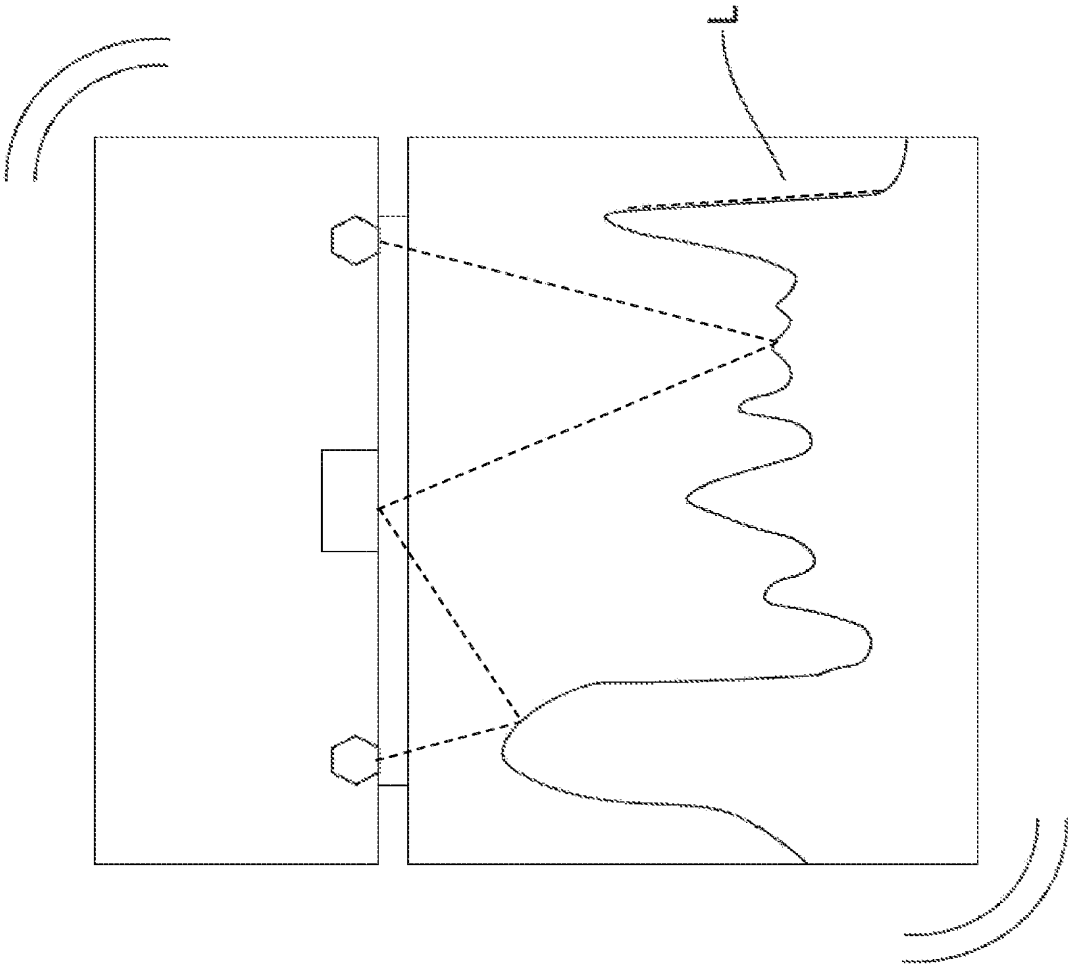

FIGURE 29

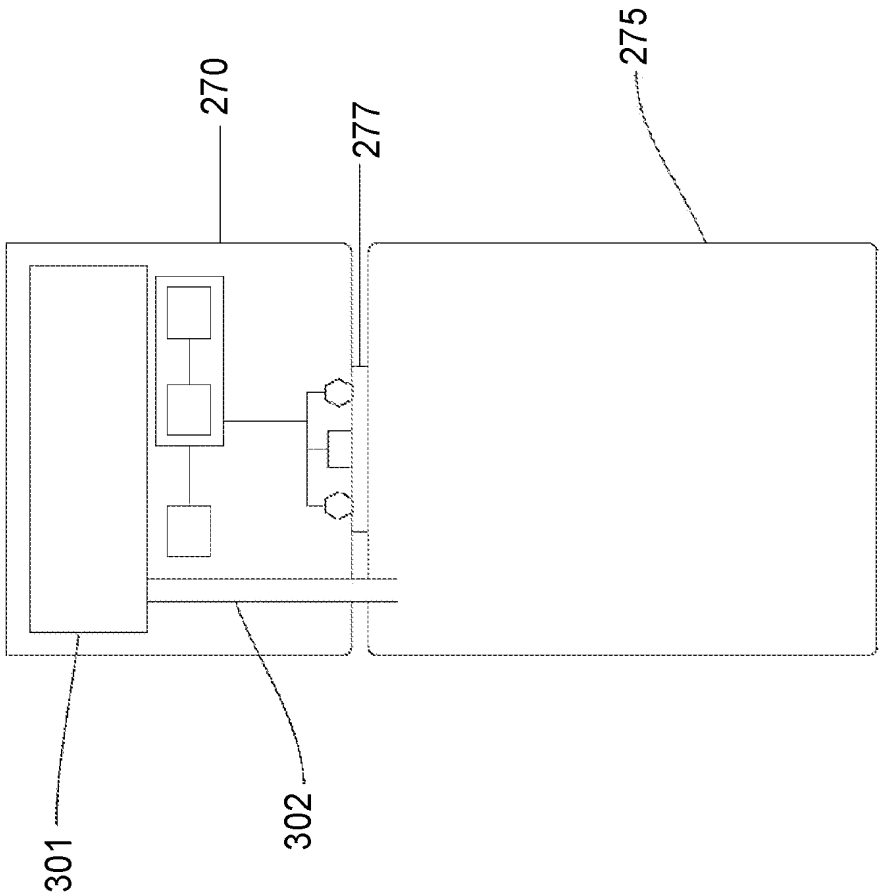

FIGURE 30

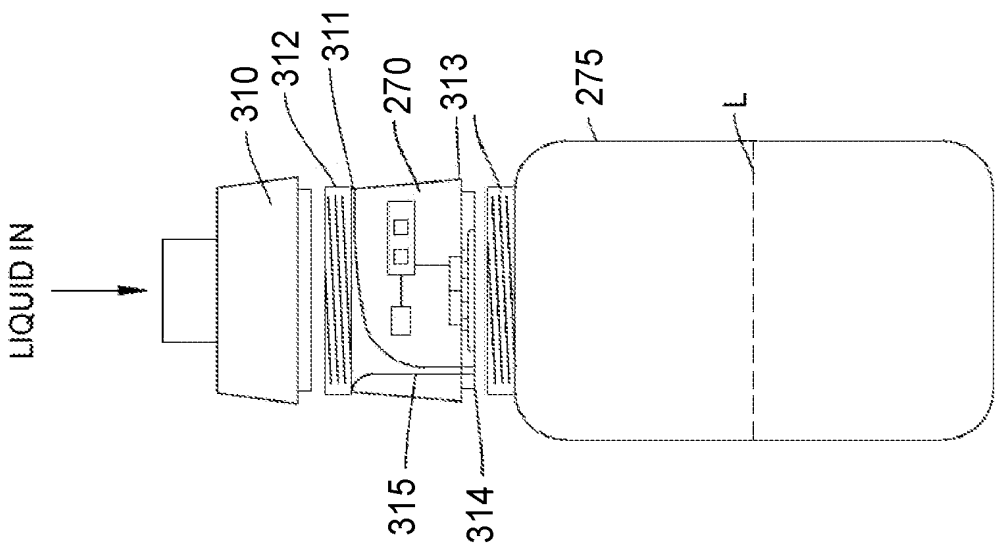

FIGURE 31

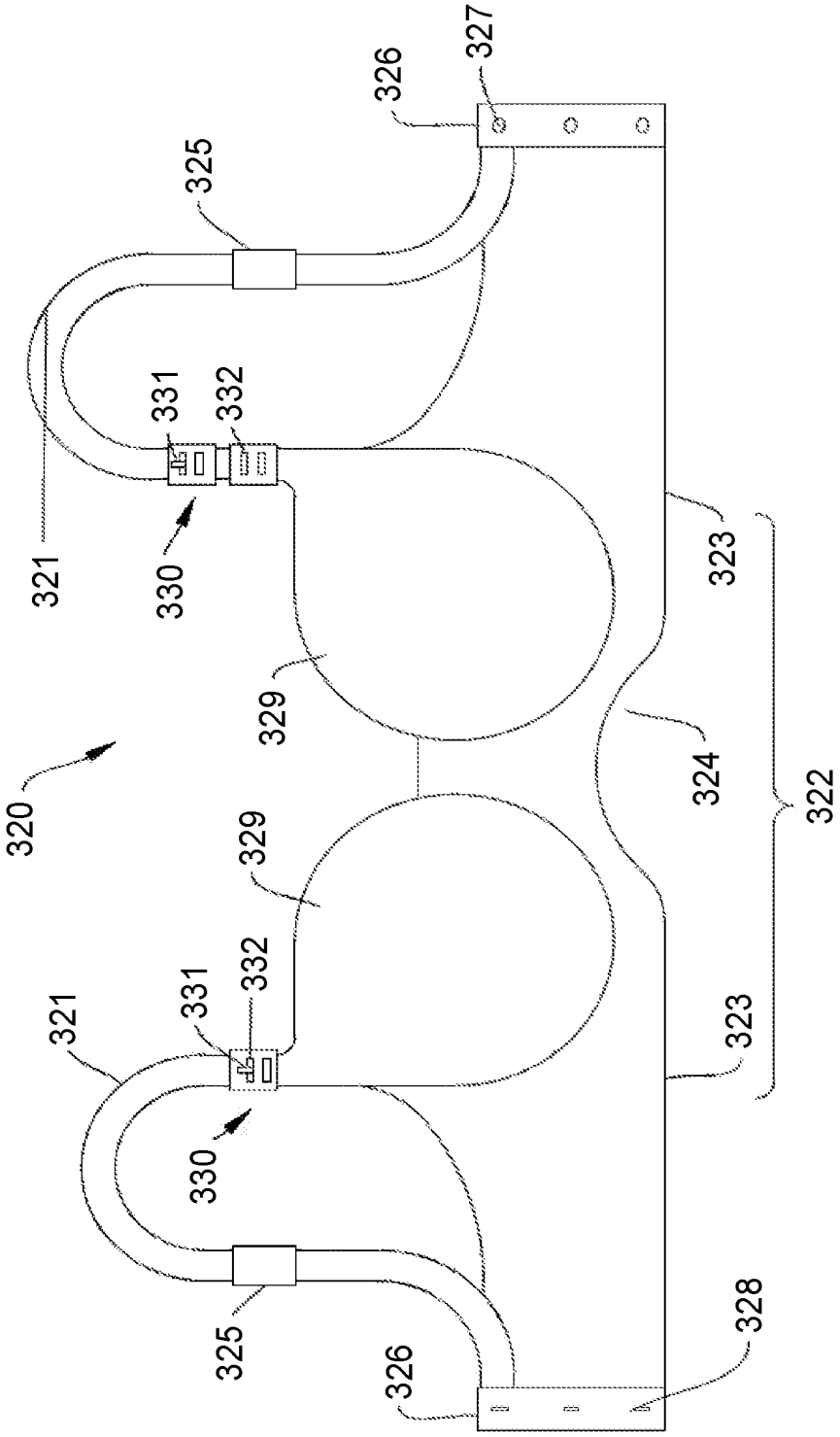

FIGURE 32

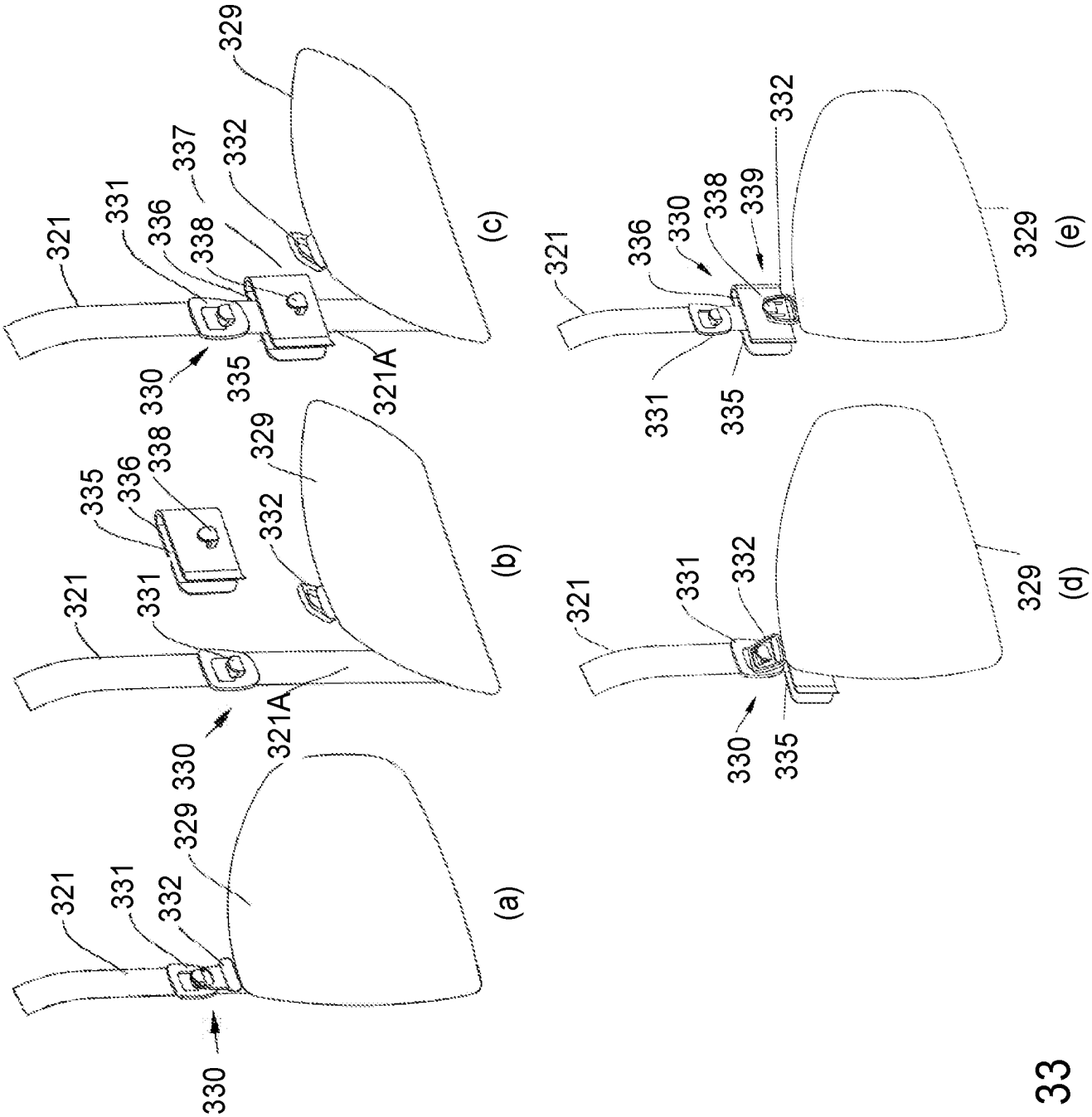
321
331
332
329
330
(a)
321
331
335
336
338
329
332
330
321A
(b)
321
331
336
338
337
332
329
330
335
321A
(c)
321
336
330
338
339
332
329
331
335
(e)
321
331
332
329
330
335
(d)

FIGURE 33

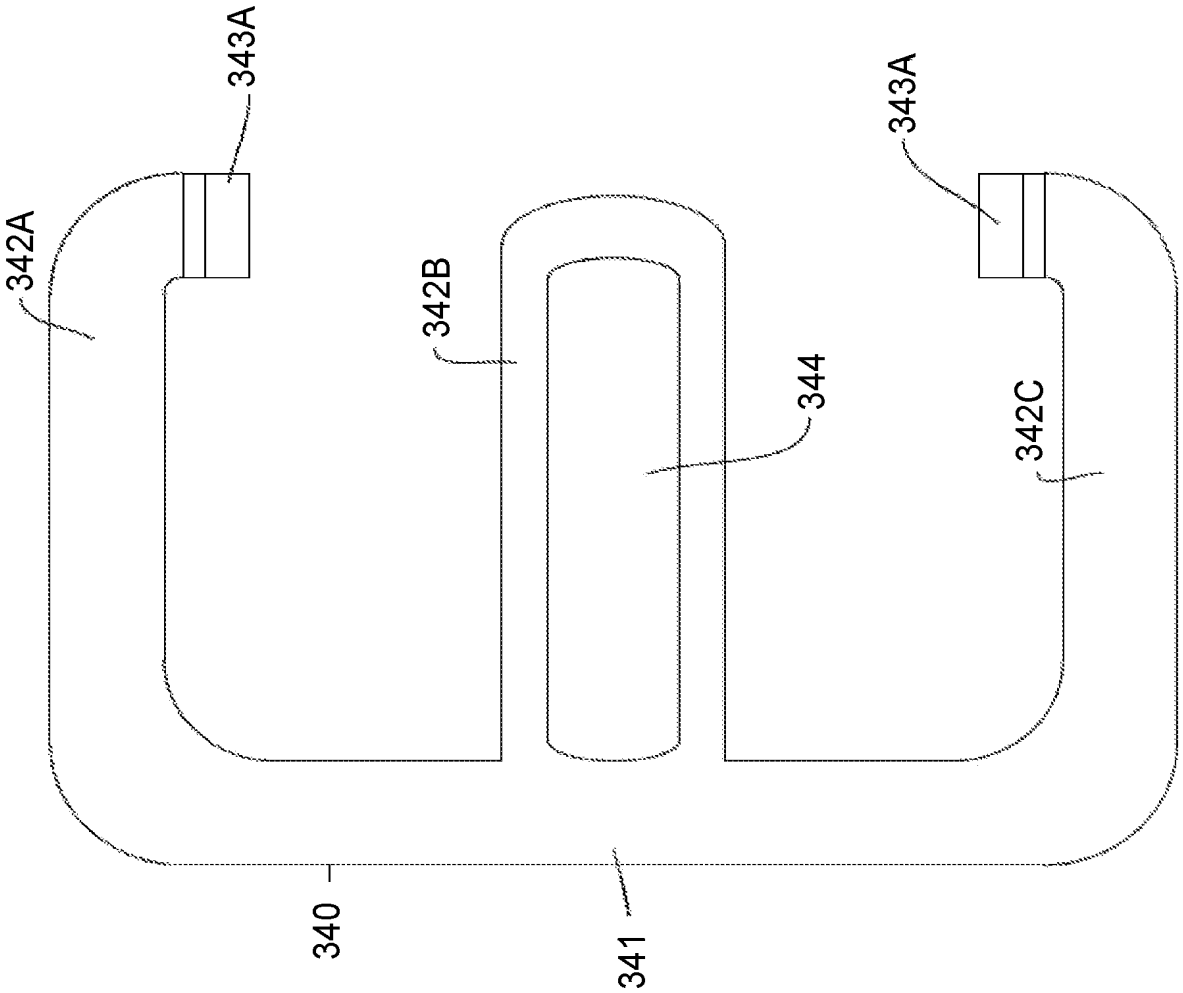

FIGURE 34

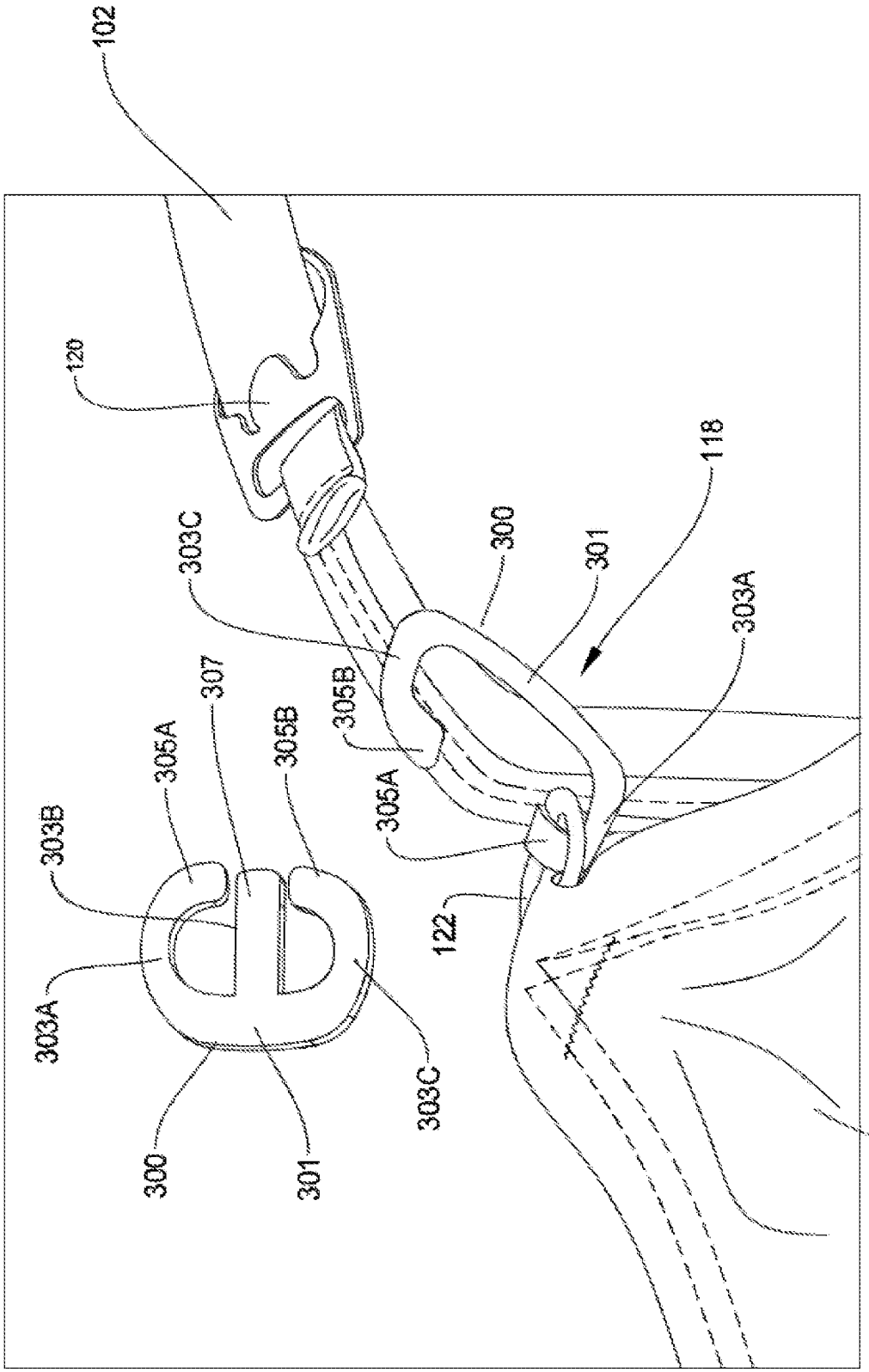
102
120
303C
300
301
118
303A
307
305B
305A
303B
305A
305B
122
303A
303C
300
301
116

FIGURE 35

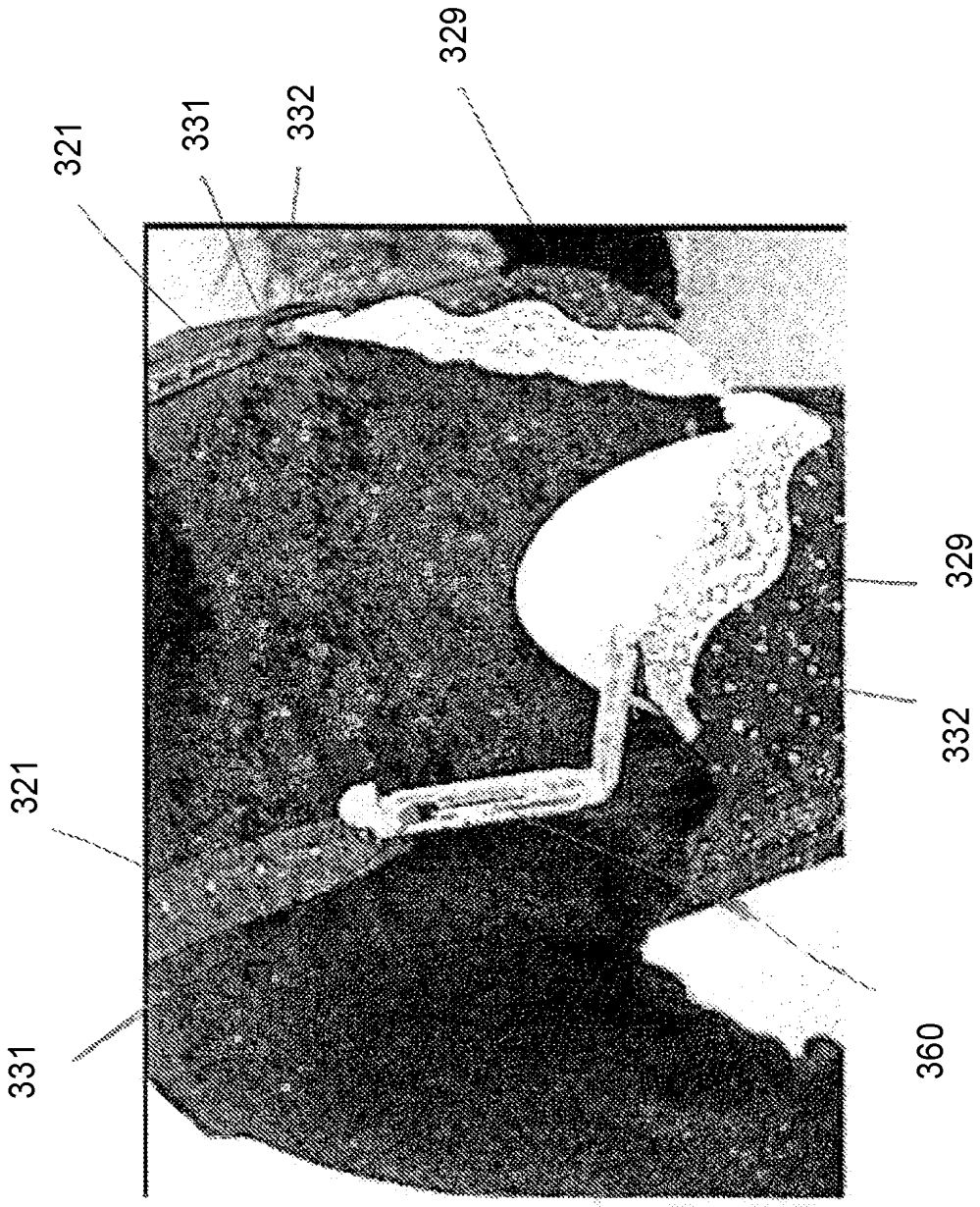

FIGURE 36

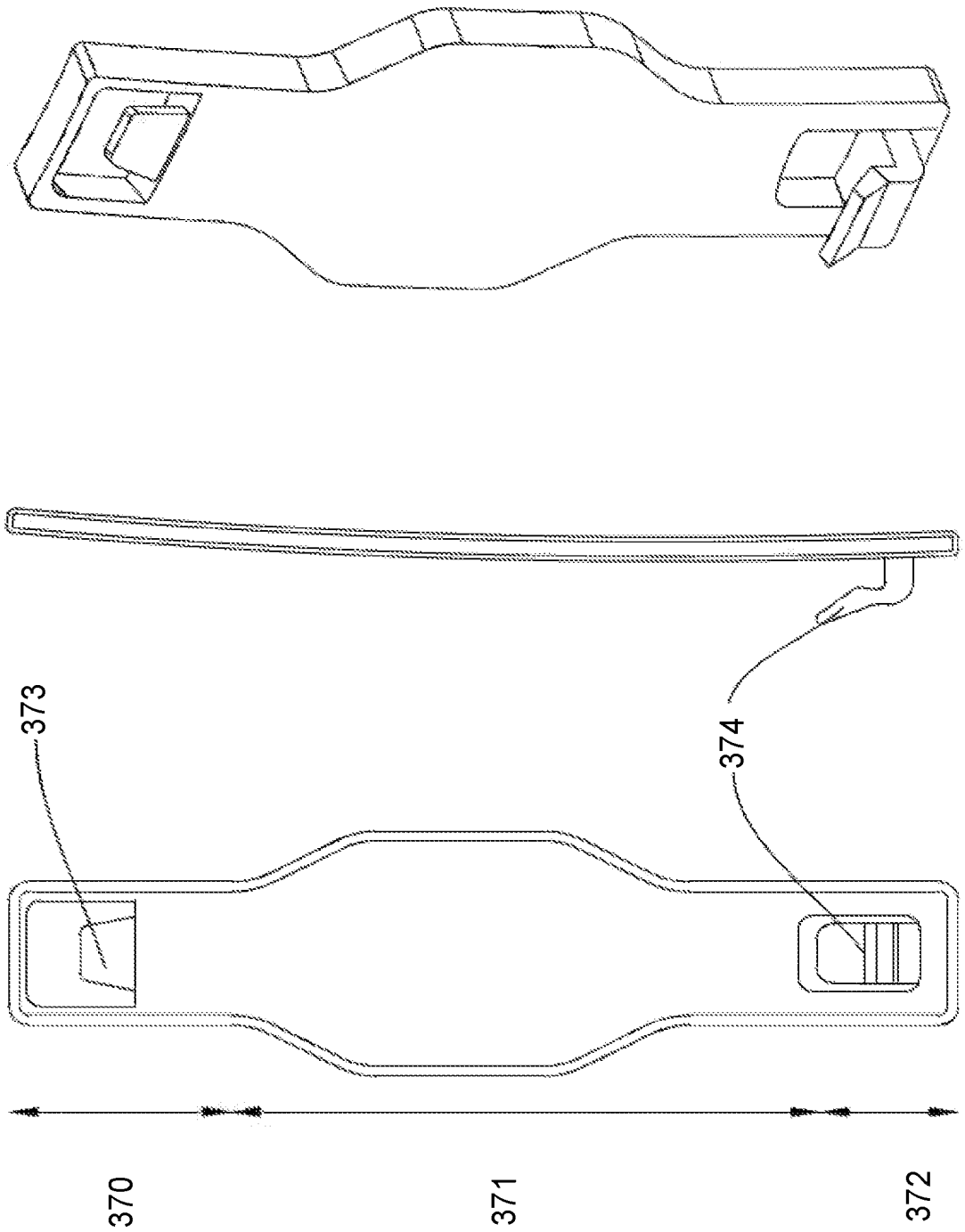

FIGURE 37

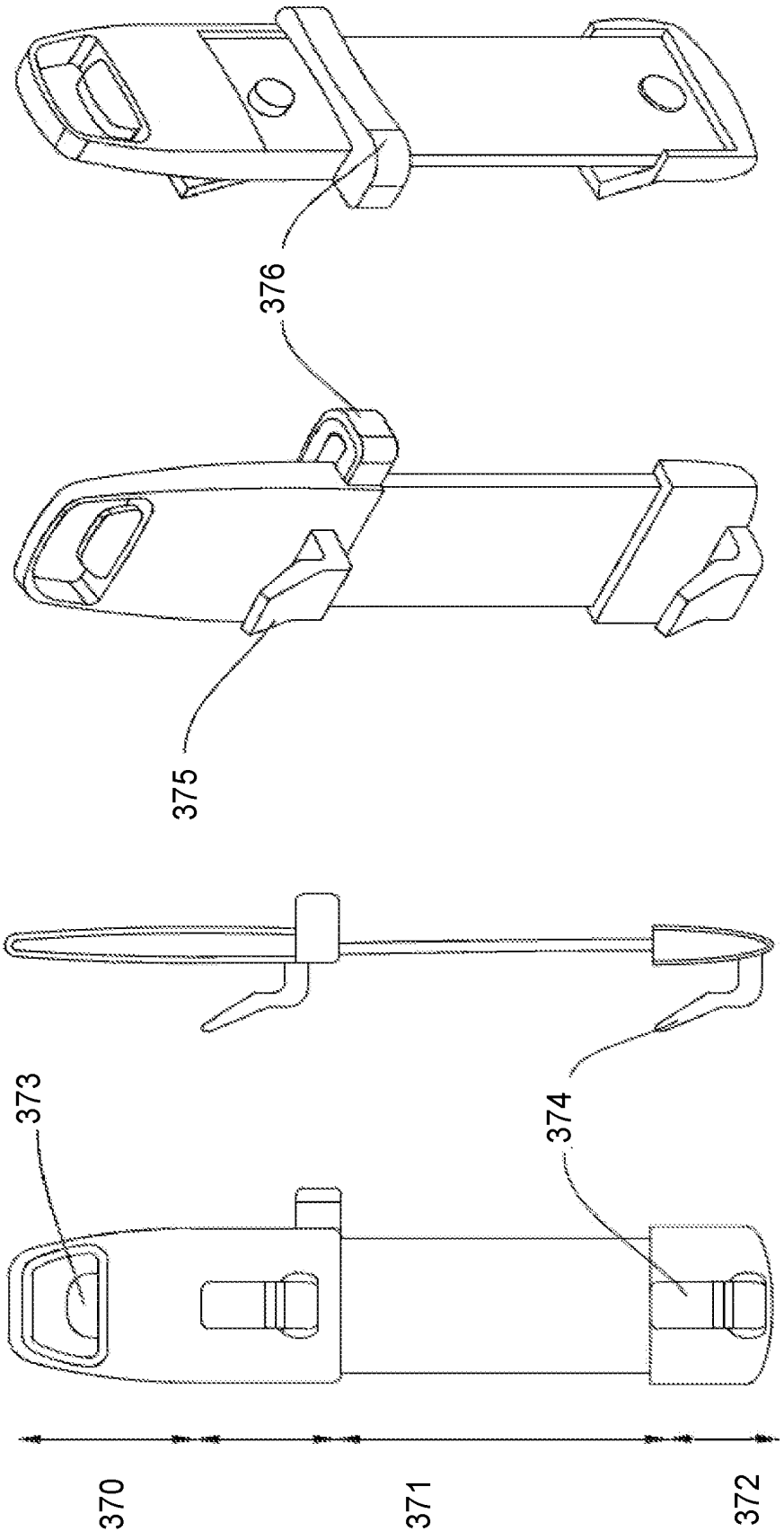

FIGURE 38

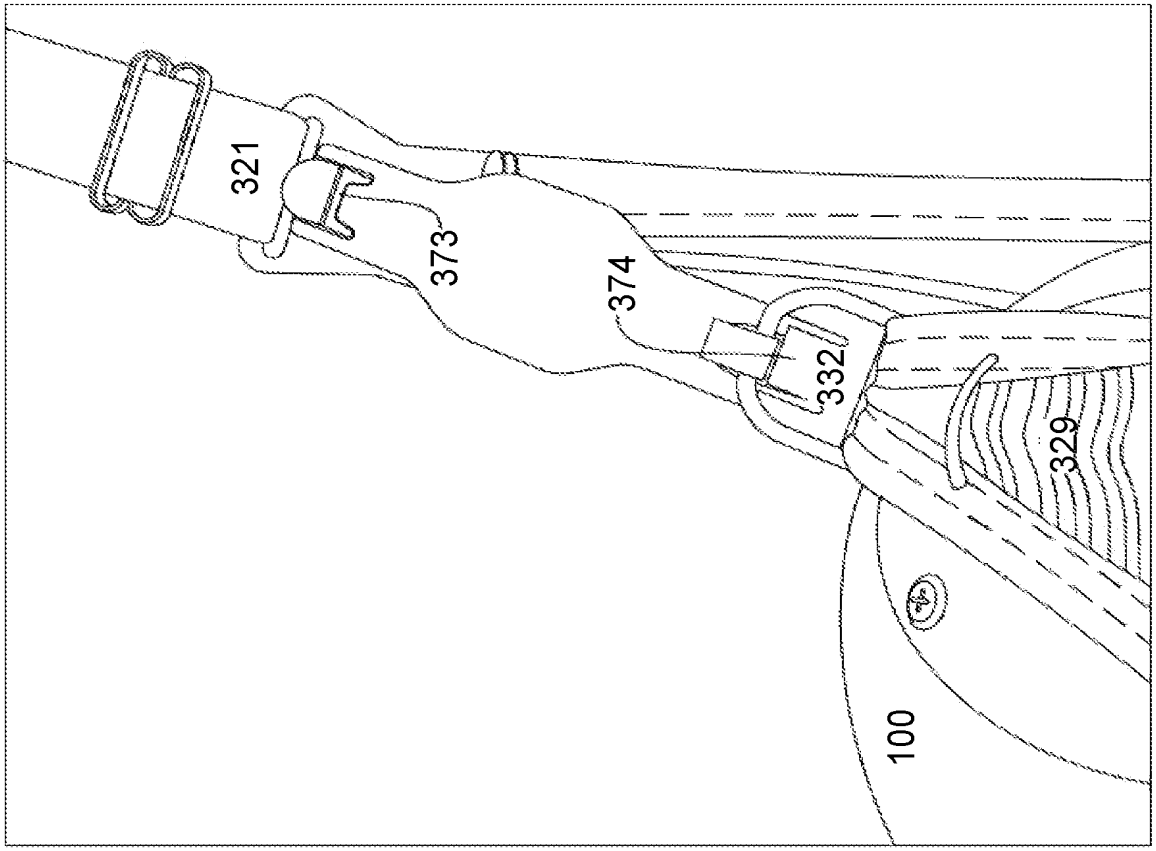

FIGURE 39

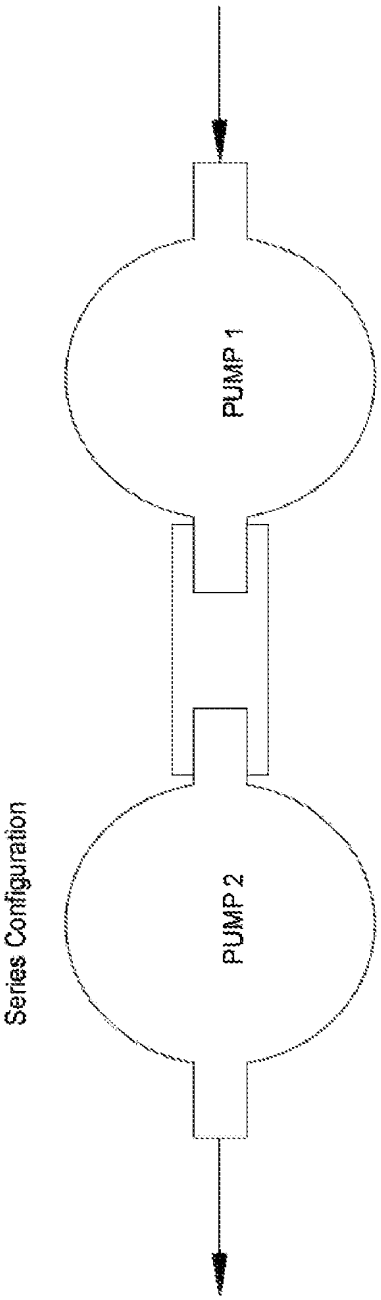

FIGURE 40

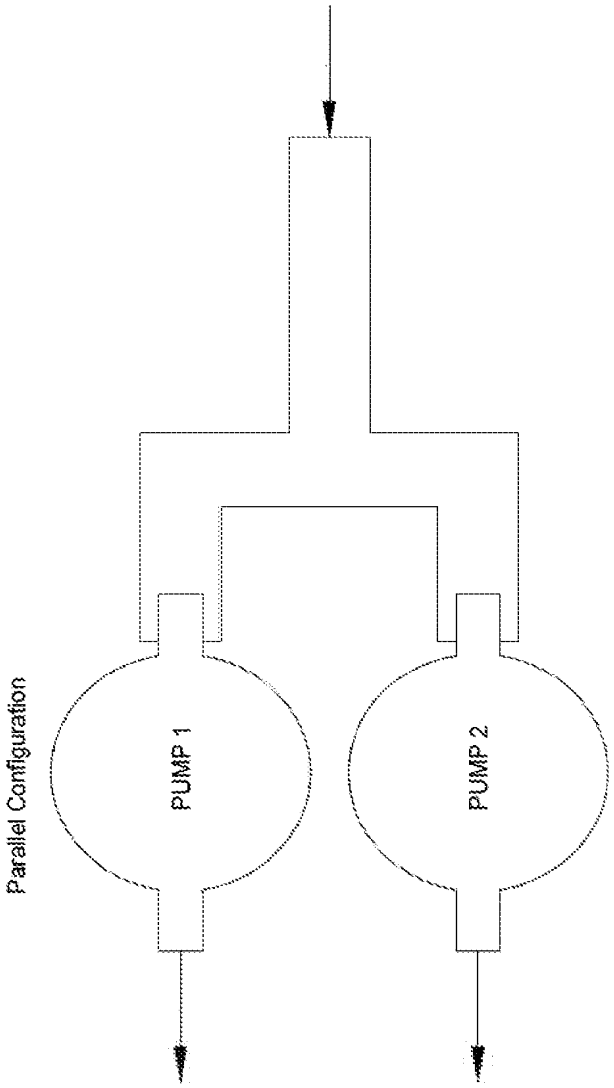

FIGURE 41

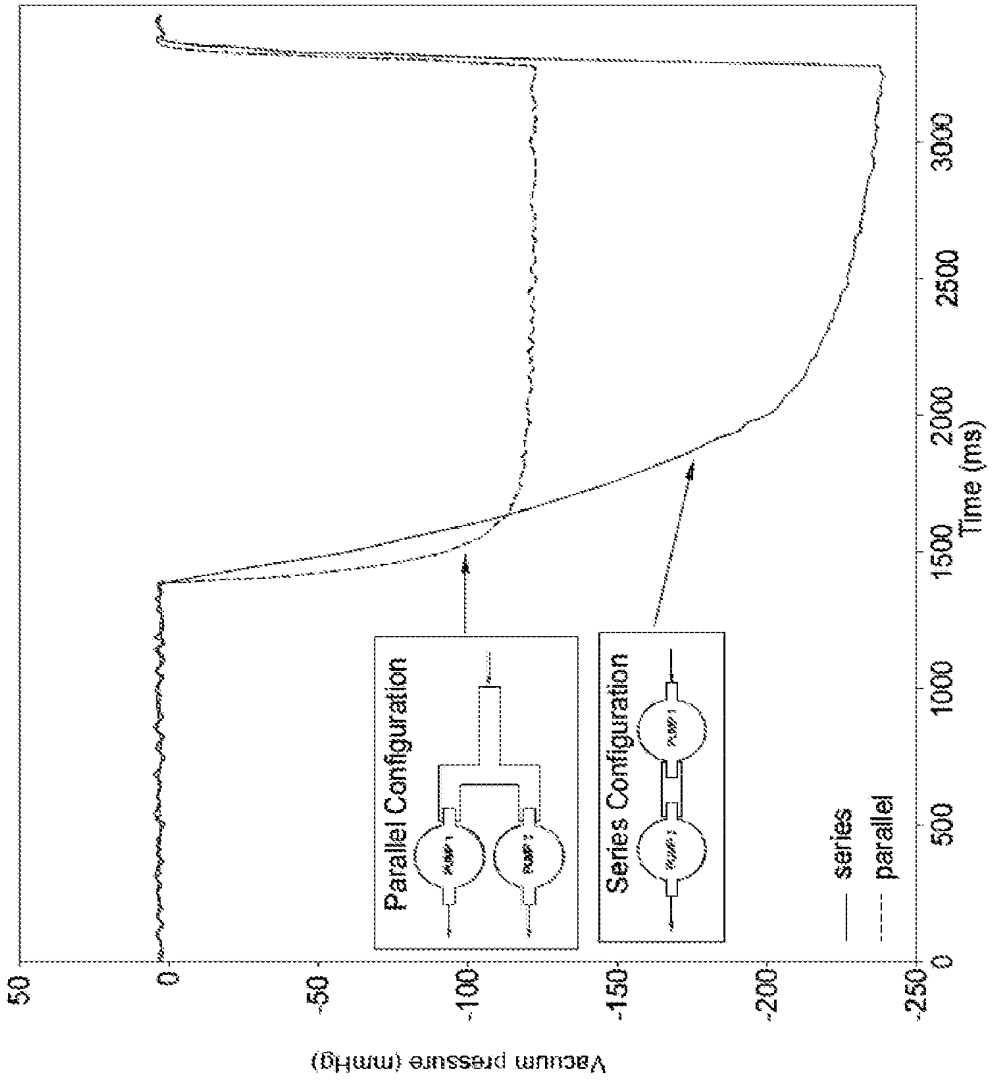
Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
series
parallel
Parallel Configuration
Series Configuration

FIGURE 42

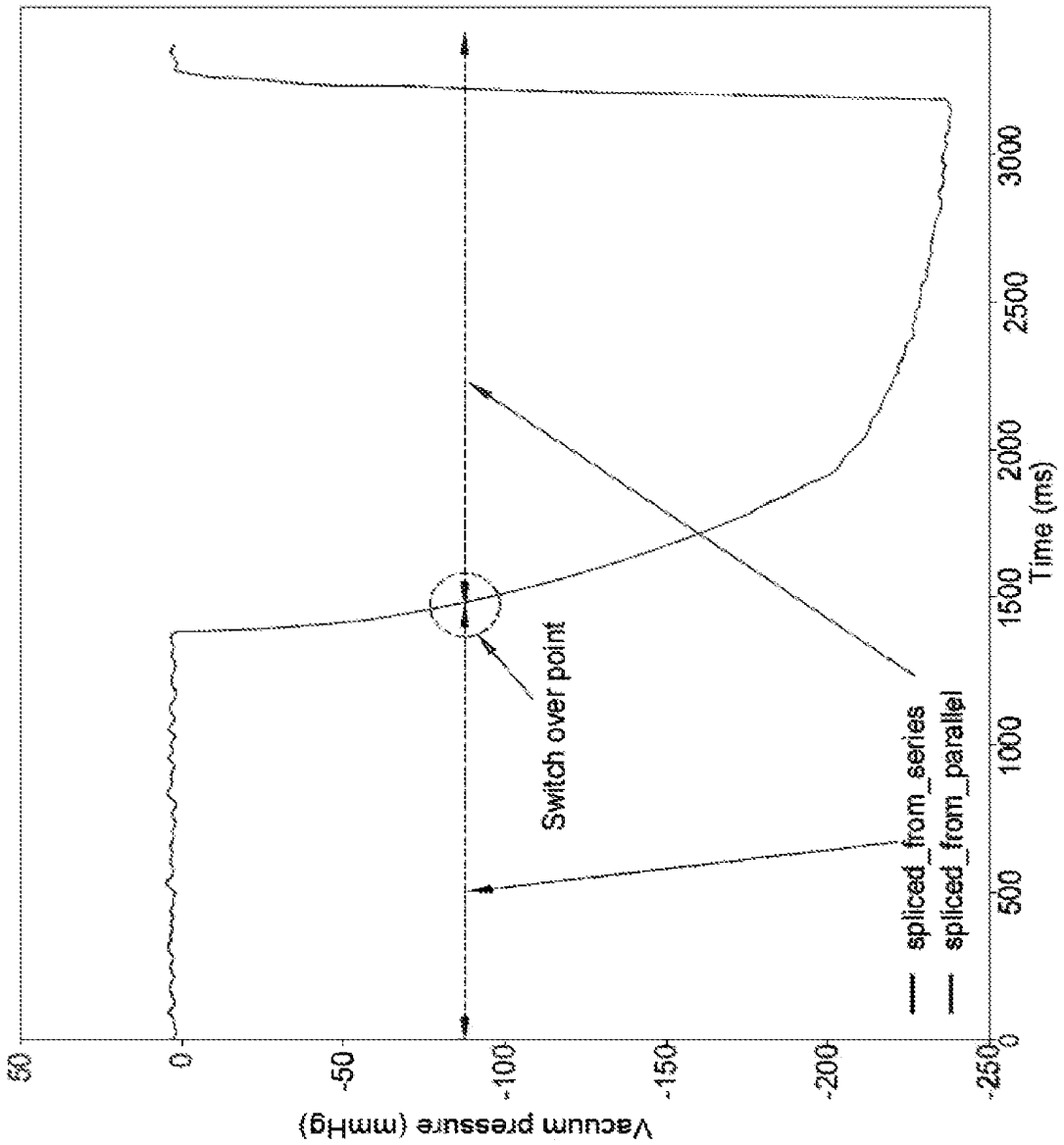
Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
Switch over point
spliced_from_series
spliced_from_parallel

FIGURE 43

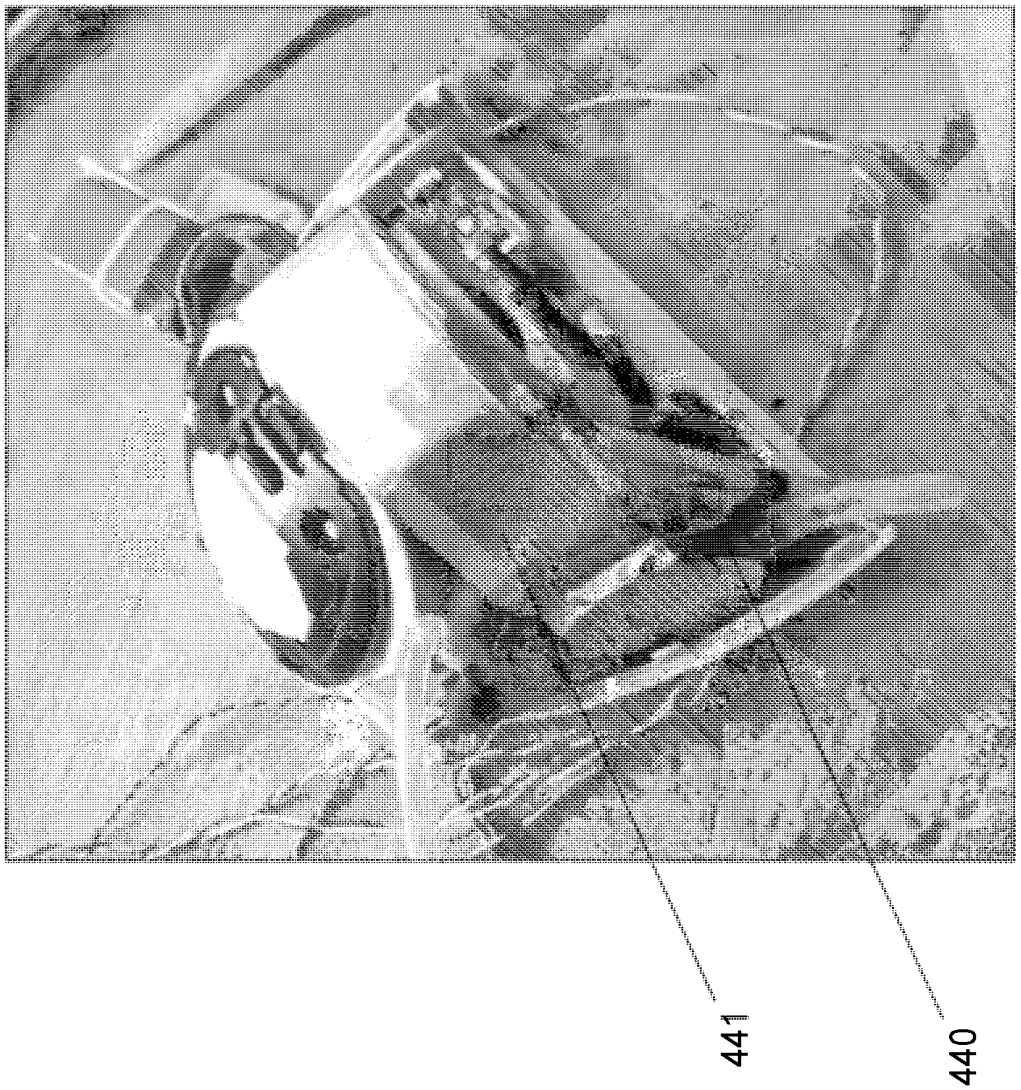

FIGURE 44

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2018/051659

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/06
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M F04B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JP 2016 010524 A (MURATA MANUFACTURING CO) 21 January 2016 (2016-01-21) abstract figures 1-5,8	1-6, 11-14, 108-119, 158
X	US 2013/023821 A1 (KHALIL GAMAL [CH] ET AL) 24 January 2013 (2013-01-24) cited in the application page 3, paragraph 51-53 page 4, paragraph 66 - paragraph 69 figures 3-5,9-11	1-6, 11-14, 108-119, 158

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 September 2018	04/12/2018

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Kempeneers, Johanna

2

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2018/051659

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 31-72(completely); 73-158(partially)
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-6, 11-14, 108-119(completely); 158(partially)

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2017/095599 A1 (KONDO DAISUKE [JP] ET AL) 6 April 2017 (2017-04-06) page 3, paragraph 55 - paragraph 57 page 7, paragraph 146 - page 8, paragraph 175 figures 1,15,16	1,2,4-6, 108, 112-114, 158
A	US 2016/271305 A1 (KURIHARA KIYOSHI [JP] ET AL) 22 September 2016 (2016-09-22) page 3, paragraph 51 - paragraph 56 page 4, paragraph 61 page 6, paragraph 91 - paragraph 93 figures 1,2,6	1,2,14, 118,158

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2018/051659

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
JP 2016010524 A	21-01-2016	NONE	
US 2013023821 A1	24-01-2013	AU 2012286462 A1	13-02-2014
		BR 112014001185 A2	21-02-2017
		CH 705295 A1	31-01-2013
		CN 103687634 A	26-03-2014
		EP 2734250 A1	28-05-2014
		IL 230280 A	28-06-2018
		JP 6062937 B2	18-01-2017
		JP 2014529312 A	06-11-2014
		KR 20140040232 A	02-04-2014
		MY 166874 A	24-07-2018
		PL 2734250 T3	31-03-2017
		RU 2014104019 A	27-08-2015
		TW 201304827 A	01-02-2013
		US 2013023821 A1	24-01-2013
		WO 2013010286 A1	24-01-2013
US 2017095599 A1	06-04-2017	JP 6213677 B2	18-10-2017
		JP WO2016002606 A1	27-04-2017
		US 2017095599 A1	06-04-2017
		WO 2016002606 A1	07-01-2016
US 2016271305 A1	22-09-2016	EP 3037116 A1	29-06-2016
		JP 6245280 B2	13-12-2017
		JP 2017205654 A	24-11-2017
		JP WO2015115516 A1	23-03-2017
		US 2016271305 A1	22-09-2016
		WO 2015115516 A1	06-08-2015

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-6, 11-14, 108-119(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the piezo air-pump; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump.

1.1. claims: 2(completely); 158(partially)

A wearable breast pump system as in claim 1, configured as a self-contained wearable device with an internal rechargeable battery; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

---

2. claims: 7-10, 120-127(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the diaphragm.

---

3. claims: 15, 27, 28, 30, 87-95(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the milk container; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

---

4. claims: 16, 29, 73-86(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the breast shield; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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5. claims: 17-19, 21, 23, 128-157(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features related to flow measurement and indication; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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6. claims: 22(completely); 158(partially)

A wearable breast pump system as in claim 1, in which the centre of gravity with an empty milk container attached to te housing is at or below (i) the half-way height line of the housing or (ii) the horizontal line passing through a nipple tunnel or filling point on a breast shield (so that

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

the device that is not top-heavy for a woman using the pump); A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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7. claims: 24(completely); 158(partially)

A wearable breast pump system as in claim 1, including a data sub-system that collects and provides data to a connected device or remote application or remote sensor; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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8. claims: 20, 25, 26, 96-107(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the pump (control); A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 31-72(completely); 73-158(partially)

The present application contains 158 claims, of which 44 are independent.
There is no clear distinction between several of the 44 independent claims because of overlapping scope. Various independent claims directed to subject-matter that does not (completely) overlap do not meet the requirements of unity of invention (Rule 13 PCT).
According to what can be understood from the description, it seems that a protection is sought after for several a spects of a breast pump system:
- wearability (including a housing shaped at least in part to fit inside a bra)
- technical features of the breast shield
- technical features of the milk container
- technical features of the pump and its control to improve user comfort
- the pump is specifically a piezo air-pump (possibly two piezo air-pumps in series or in parallel), and details thereof
- a separate deformable diaphragm to generate negative air pressure inside the breast shield, the diaphragm as such separating the (piezo) air-pump from the breast shield such that the (piezo) air-pump forms part of a closed loop system
- a flow measurement and milk volume indication means

The 44 independent claims are either directed to one of the above aspects, or to what appears to be an aleatory mix and match of two or several of these aspects.
Moreover, from the 114 dependent claims, 85 claims are dependent on any of the 41 independent claims directed to a "system" (as well as on any of the other dependent claims). They too are directed to one of the above aspects, or to what appears to be an aleatory mix and match of two or several of these aspects.
There are thus so many claims, and they are drafted in such a way that the claims as a whole are not in compliance with the provisions of clarity and conciseness of Article 6 PCT, as it is particularly burdensome for a skilled person to establish the subject-matter for which protection is sought.
The non-compliance with the s ubstantive provisions is to such an extent, that the search was performed taking into consideration the non-compliance in determining the extent of the search (PCT Guidelines 9.19 and 9.25).
The search was based on the subject-matter that is expected to be claimed later in the procedure, and the corresponding independent claim 1. Moreover, independent claim 158, directed to a method of expressing and collecting milk, comprising the step of using a system as defined in claim 1, has also been searched. Independent claims 31-72 and independent claim 158 when referring to any of the independent

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

claims 31-72 were not searched. Claims 73-157 when being dependent on any of claims 31-72 were also not searched.
Since the claims dependent on
claim 1 are not complying with unity of invention (Rule 13 PCT) (see non unity reasoning), the extent of the search was further limited to the technical features as claimed in claim 1 in combination with the first and second invention for which protection is sought, namely dependent claim 2 and the dependent claims further specifying details concerning the piezo air-pump (claims 3-6, 11-14, 108-119).

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

A hidden on the milk collecting device inside of the breast pump main machine

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Abstract

The invention claims a hidden on the milk collecting device inside of the breast pump main machine, comprising a three-way, air bag and a duckbill valve, the tee comprising a pressure end, milk sucking end and milk-flowing end, whole-embedded under the breast pump main machine end, breast pump main machine comprises a vacuum negative pressure device, air bag is set in the air pressure end and sealing connected with the vacuum negative pressure device, milk sucking end is flared and arranged to face the inner side of the breast pump main machine pointing to the breast, duckbill valve fixedly set on the milk flow end. the milk collecting device is integrated at the lower end of the breast pump main machine, it realizes the reduction of the whole breast volume to nursing mothers; on the other hand, by integrating mounting effectively avoids occurrence of line constraint problem. At the same time, the connectable device can host computer and the breast milk storage bottle connection as a whole so as to bear on the lower functional efficiency, so that volume of the breast can be made thinner and smaller.

Description

INVENTION-TITLE

technical field

The invention claims baby appliance field, especially claims a hidden on the milk collecting device inside of the breast pump main machine.

background technology

electric breast pump is used by nursing mothers, refers to instrument for extrusion (absorbing) the accumulation in the breast milk of the tool. the inner vacuum negative pressure pump changes inside air pressure changes, namely the circulation playing emulator allow suction breast milk of infant action.

the existing electric breast pump, mainly comprises the integrated pump and split type breast pump, the breast it is necessary to hand with hand supporting brassiere. the negative voltage output using split type breast pump breast milk collecting needed when the tee and bottle hung in front of the chest by air path hose connected to the breast pump main machine as breast, this line constraint exists and is difficult to assemble; and the integrated pump are integrated together, although the restriction of line, it makes the installation relatively simple, but the structure manner and appearance volume of them wearing and hidden.

summary of the invention

The purpose of the invention is to provide a hidden on the milk collecting device inside of the breast pump main machine, so as to solve the above background technology proposed in the prior art.

The technical solution to solve the technical problem is: a kind of hidden in the milk collecting device of breast pump main machine inside, comprising a tee, air bag and a duckbill valve, the tee comprising a pressure end, milk sucking end and milk-flowing end, the whole way to the breast pump main machine end, pump main machine comprises a vacuum negative pressure device, air bag is set in the air pressure end and sealing connected with the vacuum negative pressure device, milk sucking end is flared and arranged to face the inner side of the breast pump main machine pointing to the breast, duckbill valve fixedly set on the milk flow end.

As an improvement, the air bag is flat U shape, pressure end is set into flat U shape consistent with the air bag, the lower end of the breast pump main machine provided with a containing pressure end of U-shaped cavity.

As an improvement, said air bag is made of liquid silica gel material.

As an improvement, the inner top of the U-shaped cavity is provided with air bag cover, air bag cover is provided with a first air hole and a second air hole, the vacuum negative pressure device comprises a vacuum pump and the air release valve, a first air hole is connected with the vacuum pump, the second air hole connected with the air escape valve, air bag sealing connection on the air bag cover.

As an improvement, the air bag cover is provided with a deformation guide surface, deformation guide surface guiding the air bag under the vacuum negative pressure to the breast to form a flat shape.

As an improvement, the end sealing connected with a storage bottle, the milk bottle is jointed at the lower end of the breast pump main machine.

As an improvement, the duckbill valve is provided with a first valve and a second valve, the first valve comprises a first deformable wall at the two side part of the arc-shaped. two first deformation wall from up to down gradually close and form a first elongate-shaped incisions at the end, milk-flowing end and storage bottle connected the first valve, the second valve comprising a second deformable wall at the two side part of the arc-shaped, two second deformation wall from up to down gradually close and form second elongated-shaped incisions at the end, the second valve connecting the outside atmospheric pressure and storage bottle.

As an improvement, the duckbill valve made of food-grade material of liquid silica gel.

As an improvement, the outer side of said breast pump main machine set into the first curved surface, outer side of said storage bottle is set to the second curved surface, the first curved surface and the second curved surface connected to form the bra and abutted surface matched with the arc curved surface.

As an improvement, the inner side face of said breast pump main machine and the inner side are coplanar in the storage bottle surface contact surface of the milk sucking end and the inner side of the breast pump main machine face.

Beneficial effect of this invention, the milk collecting device is integrated on the lower end part of the breast pump main machine, it realizes the reduction of the whole breast volume to nursing mothers; on the other hand, by integrating mounting effectively avoids occurrence of line constraint problem. At the same time, the connectable device can host computer and the breast milk storage bottle connection as a whole so as to bear on the lower functional efficiency, so that volume of the breast can be made thinner and smaller.

Description

With reference to the accompanying drawings and embodiments, this invention can be further explained:

Picture 1 the assembling schematic hand hidden breast;

FIG. 2 is a hand perspective view hidden breast;

FIG. 3 is a left side view of FIG. 2;

FIG. 4 is a inside structure diagram of the breast pump main machine;

FIG. 5 is a structure diagram of a device;

FIG. 6 is a sectional diagram of the breast pump, air bag in the image in the natural state;

FIG. 7 is a sectional diagram of the breast pump, air bag is in negative pressure state in the image;

FIG. 8 is a breast pump work when the duckbill valve of the first valve open state diagram;

FIG. 9 is a breast pump work when the duckbill valve of the first valve closed state diagram;

FIG. 10 is a front view of the air bag;

FIG. 11 is a A-A sectional view in FIG. 10;

Picture 12 the three-dimensional structure schematic diagram of the duckbill valve;

FIG. 13 is a mammalian mother worn on free hand view of hidden-type breast pump;

FIG. 14 is a nursing mother worn on hand-free view of the hidden type pump.

Specific implementation methods

Referring to FIG. 3 to FIG. 1, the embodiment of a hand concealed breast pump, the breast pump main machine 1, a milk collecting device (3) and the milk bottle 2 and other components. breast pump main machine 1 is provided with a main control circuit board with a vacuum negative pressure device and connected with the vacuum negative pressure device 16, the main control circuit board 16 connected with

the breast pump main machine 1 the outer surface of the control panel 11. In FIG. 2, the control panel 11 set on the breast pump main machine top 1, on the one hand, it can convenient for nursing mothers to operation, on the other hand, it also can avoid worn inside the bra when the control panel 11 is pressed. The control panel 11 is provided with a breast pump power on/off key, suction the upshift operation key, suction downshift operation keys and lactation and milk mode switching key, and also equipped with suction gear, pump charging state indicating lamp. feeding mother combining actual condition to operate the control panel 11 sends an instruction to the main control circuit board 16, the main control circuit board 16 control the working state of the vacuum negative pressure device. When the host 1 is in the charging state, charging state indicating lamp for prompting. At the same time, pump main machine 1 is further provided with a wireless communication module for receiving electric signal of mobile terminal 18. electric signal in this embodiment, the mobile terminal is a mobile phone, and a wireless communication module 18 for analysis and the mobile phone communication protocol, receiving the mobile phone sends, and sends the electric signal to the main control circuit board 16, the wireless communication module 18 using the Bluetooth or WIFI communication mode. display a plurality of control options in the APP program on the mobile phone, the control option is basically consistent with the control option panel 11, to realize the adjustment of the pump working state. meanwhile, the APP program may further display residual electric suction-gear state and quantity information. to control the working state of the breast through the mobile terminal, greatly convenient the nursing mother in public places using a breast pump, the breast pump is hand hidden breast, nursing mother can wear well in advance, when needing to absorb milk, it only needs opening controlled by the mobile terminal, it is convenient and fast.

As shown in FIG. 4, the breast pump main machine 1 is further provided with a charging and discharging of the lithium battery 15 and charging interface 17, using an adapter can be convenient charging. located at the vacuum negative pressure device in the host unit 1 includes a vacuum pump 13 and the air release valve 14, pump lower end of the main machine 1 is provided with a U-shaped cavity 12, the milk collecting device 3 provided in the U-shaped cavity 12, milk collecting device 3 one end sealing connected with the vacuum negative pressure device. the other end and the sealing connecting a storage bottle 2, a bottle 2 with the breast pump main machine 1 the lower end joint, breast pump main machine outer side of 1 set to first surface, the storage bottle 2 of outer side is disposed at the second curved surface, the first curved surface and the second curved surface connected to form the bra and abutted surface matched with the arc curved surface; breast pump main machine 1 the inner side surface and the storage bottle 2 the inner side surface is set to be coplanar.

the breast pump main machine 1 the provided control panel 11, working condition of controlling and adjusting breast pump convenient for breast feeding mother. At the same time, highly integrated, a vacuum negative pressure device and a milk collecting device 3 are integrally installed on the inside of the breast pump main machine 1, compact structure, pipeline without any restriction. and combining the engineering, the breast pump main machine 1 the outer side is disposed at the bra and abutted surface matching the first curved surface, the outer side of the storage bottle 2 set to match the second curved surface jointed with the bra, first curved surface and second curved surface are connected to form the bra and abutted surface matched with the arc curved surface, nursing mothers can be easy and natural breast in brassiere; breast pump main machine 1 the inner side surface and the storage bottle 2 inner side face is set into plane to joint with one side of the breast. the reasonable layout at the same time to minimize volume of the whole breast. the whole appearance is exquisite, smooth, suitable for wearing and hidden, the nursing mother in public places simply hidden and elegant and decent movement of the breast.

As shown in FIG. 5 is the milk collecting device 3, 3 is hidden in the milk collecting device 1 inside of the breast pump main machine, specifically comprising a tee 32, air bag 31 and duckbill valve 33, tee joint 32 comprises an air pressure end, milk sucking end and flow nipple end. the tee 32 is embedded into the U-shaped cavity 12 lower end host 1, air bag 31 is set in the air pressure end and sealing connected with the vacuum negative pressure device, milk sucking end is flared and arranged to host 1 by breast pump in side surface pointing to the breast, the abutting surface of the milk sucking end 1 with the breast pump main machine inner side face. ensure the inner side of the breast surface is completely flat, the nursing mother to

wear comfort. a duckbill valve 33 fixedly set on the milk-flowing end and end hermetically connected with the storage bottle 2, breast milk through the duckbill valve 33 into the storage bottle 2. the water storage bottle 2 via the screw tooth thread of bottle mouth is connected with the milk-flowing end, convenient for dismounting and cleaning. At the same time, the U-shaped cavity 12 of the inner top is provided with air bag cover, air bag cover is provided with a first air hole and a second air hole, first air hole is connected with the vacuum pump 13 through the tube, second air hole connected with the air escape valve 14 through the tube, the sealing air bag 31 connected on the air bag cover, the air bag 31 with the vacuum pump 13 and release valve 14.

the milk collecting device 3 integrated in the breast pump main machine 1 the lower end, it realizes the reduction of the whole breast volume to nursing mothers; on the other hand, by integrating mounting effectively avoids occurrence of line constraint problem. At the same time, the milk collecting device 3 can be the host computer 1 with the storage bottle 2 connecting as a whole so as to bear on the functional effect, so that volume of the breast can be made thinner and smaller.

the air bag 31 made by liquid silica gel material of food grade materials, which has better elasticity and fatigue resistance, which is mainly used for isolating the air pressure and breast milk. The FIG. 10 and FIG. 11, the air bag 31 is flat U shape, pressure end is set into a flat U-shape of the air bag 31 the same. air bag 31 opposite the wide milk sucking end is provided, the thickness of the two wide surface is small, which is beneficial for reducing the whole breast thinness, convenient nursing mother wearing the bra and the breast pump inside. At the same time, air bag between two narrow surface 31 of large distance, which is good for increasing the whole volume of the air bag 31, further increases in the whole tee 32 the pressure difference change greatly, so as to provide sufficient pressure to the breast. air bag cover is provided with a deformation guide surface, deformation guide surface of the air bag 31 the two narrow surface is correspondingly provided, deformation guide surface guiding the air bag 31 under the vacuum negative pressure to the breast to form a flat shape. As shown in FIG. 7, when the air bag 31 is flat by negative pressure, air bag 31 integrally from the breast, so as to increase the gap 31 between the breast and the air bag, convenient emulsion from tee 32 to smoothly flow to flow nipple end. deformation guiding face may be provided to be jointed with the surface of the air bag 31 folded, the folded folding sides are vertical to the air bag 31, so as to realize the offset guide 31 of the air bag.

FIG. 6 two states of FIG. 7 respectively show the pump working when air bag 31. In FIG. 6, the air bag 31 is in the natural state, the release valve 14 is in the open state, the air bag 31 connected with the atmospheric pressure, way 32 does not form negative pressure, the whole breast is in playing state. the state mainly for convenient liquid smoothly flows into the storage bottle 2. In FIG. 7, the air bag 31 is in the negative pressure state, then the bleed valve 14 is in the closed state, air bag 31 only connected with the vacuum pump 13 and is completely vacuumed way so as to form negative pressure because of the reduced air bag 31 volume in 32. the whole breast is in the absorbing state of the emulsion in the breast.

a duckbill valve 33 set on the milk-flowing end, has the function of anti-reflux. As shown in FIG. 12, the duckbill valve 33 is provided with a first valve 331 and second valve 332, first valve 331 comprises a first deformable wall at the two side part of the arc-shaped 3311. two first deformation wall 3311 from top to bottom gradually close and elongate-shaped first notch 3312 and first valve 331 formed at the end connected with the flow nipple end and the milk bottle 2, the second valve 332 includes a second deformable wall at the two side part of the arc-shaped 3321, two second deformation wall 3321 from top to bottom gradually close and elongate-shaped second notch 3322 formed at the end. the second valve 332 connects with the external atmospheric pressure and the storage bottle 2. The duckbill valve 33 by liquid silica gel made of food-grade material, which has better leak tightness, anti-tear strength, elasticity, anti-yellowing property, thermal stability, heat aging resistance and compressive deformation. first deformable wall 3311 and second deforming wall 3321 wall thickness is 0.4~0.6mm, the deformation wall design of large and thin area, ensuring easy rebound and the stress is easily deformed.

by deformation of the first deformable wall 3311 and second deformation wall 3321 can easily realize the first

notch 3312 and the second notch 3322 of the opening and closing state of the switching. wherein the second valve 332 connected with the external atmospheric pressure, second deformable wall 3321 and not subject to negative pressure of extrusion, so it is in normally open state, so that the bottle 2 to maintain ventilation state, the milk liquid can continuously flow into the milk bottle 2 through first incision 3312, and first valve 331 following the switching of the vacuum negative pressure and the normal pressure to open or close. releasing the negative pressure when the tee 32, first notch 3312 opened and milk immediately flows into the storage bottle 2. the storage bottle 2 during the vibration, milk extruding first deformable wall 3311 and second deformable wall 3321 from the outside so that the first notch 3312 and the second notch 3322 is closed, liquid cannot flow out from the storage bottle 2, effectively preventing the leakage and the backflow of milk.

As a preferred embodiment, first valve 331 and second valve 332 are connected on the gasket 333, the first notch 3312 and second notch 3322 are pointing to the inner cavity of the storing bottle 2, sealing pad 333 periphery of the port is sealed and jointed with the storage bottle 2. When the milk bottle 2 threaded connection when the flow nipple end, port storage bottle 2 against the lower side of the sealing pad 333, at the same time, is screwed can provide pressure so that the sealing pad 333 of upper side surface and milk-flowing end tightly, which effectively guarantees the sealing of milk-flowing end and storage bottle 2 connection. At the same time, seal pad 333 formed in part of separated first pneumatic chamber and a second pneumatic chamber, end are respectively formed with inserted to the first air pressure cavity of the first connecting part and the second connecting part is inserted to the second air pressure cavity, first valve 331 set on the lower end of the first air pressure cavity, the second valve 332 set on the lower end of the second air pressure chamber, first atmospheric pressure cavity is connected with the milk flow end, the second air pressure cavity is connected with the outside atmospheric pressure. the first air pressure cavity and the first connecting part in interference fit connection, a second air pressure cavity is connected with the second connection part in interference fit connection, it can avoid the valve failure caused by large deformation of the upper end part of the first valve 331 and second valve 332.

FIG. 8 and FIG. 9 respectively show the breast pump when working duckbill valve first valve 331 of the state diagram 33. In FIG. 8, the air bag 31 is in the natural state, the tee 32 is normal pressure, first cut 3312 naturally in open state, collecting the milk of the milk of the flow through first valve 331 flow into the milk bottle 2. In FIG. 9, the air bag 31 is in the negative pressure state, is negative pressure tee 32, first notch 3312 under the compression of the negative pressure in the closed state, the suction of liquid milk to milk-flowing end and stays at the first valve 331 the front.

FIG. 13 and FIG. 14 are nursing mothers worn on free hand hidden effect schematic diagram of breast pump, the hand hidden type breast pump can be well hidden in the brassiere, which is greatly convenient for the nursing mother in public places of breast.

on the drawings embodiments of the invention has been described in detail, but the present invention is not limited to the above embodiment, in the technical field of common technician has the knowledge range, but also can under the premise of not departing from the spirit of making various changes.

Claims

1. A hidden on the milk collecting device inside of the breast pump main machine, wherein it comprises a tee, air bag and a duckbill valve, the tee comprises a pressure end, milk sucking end and milk-flowing end, whole-embedded under the breast pump main machine end, a breast pump main machine comprises a vacuum negative pressure device, air bag is set in the air pressure end and sealing connected with the vacuum negative pressure device, milk sucking end is flared and arranged to face the inner side of the breast pump main machine pointing to the breast, duckbill valve fixedly set on the milk flow end.
2. The hidden according to claim 1 the milk collecting device of breast pump main machine inside, wherein the air bag is flat U shape, pressure end is set into flat U shape consistent with the air bag, the lower end of the breast pump main machine provided with a containing pressure end of U-shaped cavity.

3. The hidden according to claim 2 the milk collecting device of breast pump main machine inside, wherein the air bag is made of liquid silica gel material.
4. The hidden according to claim 3 the milk collecting device inside of the breast pump main machine, wherein the top of the U-shaped cavity is provided with an air bag cover, air bag cover is provided with a first air hole and a second air hole, the vacuum negative pressure device comprises a vacuum pump and the air release valve, a first air hole is connected with the vacuum pump, the second air hole connected with the air escape valve, air bag sealing connection on the air bag cover.
5. The hidden according to claim 4 the milk collecting device of breast pump main machine inside, wherein the air bag cover is provided with a deformation guide surface, deformation guide surface guides the air bag under the vacuum negative pressure to the breast to form a flat shape.
6. The hidden according to claim 1 the milk collecting device of breast pump main machine inside, wherein the end sealing connected with milk storage bottle, the milk bottle is jointed at the lower end of the breast pump main machine.
7. The hidden according to claim 6 the milk collecting device of breast pump main machine inside, wherein the duckbill valve is provided with a first valve and a second valve, the first valve comprises a first deformable wall at the two side part of the arc-shaped. two first deformation wall from up to down gradually close and form a first elongate-shaped incisions at the end, milk-flowing end and storage bottle connected the first valve, the second valve comprising a second deformable wall at the two side part of the arc-shaped, two second deformation wall from up to down gradually close and form second elongated-shaped incisions at the end, the second valve connecting the outside atmospheric pressure and storage bottle.
8. The hidden according to claim 7 the milk collecting device of breast pump main machine inside, wherein the duckbill valve is liquid silica gel food-grade material.
9. any one of said hidden on the milk collecting device inside of the breast pump main machine, wherein the outer side of said breast pump main machine set to the first curved surface, outer side of the milk bottle is set to a second curved surface, the first curved surface and the second curved surface connected to form the bra and abutted surface matched with the arc curved surface according to claim 6~8.
10. The hidden according to claim 9 the milk collecting device of breast pump main machine inside, wherein the inner side face of said breast pump main machine and the inner side are coplanar in the storage bottle surface contact surface of the milk sucking end and the inner side of the breast pump main machine face.

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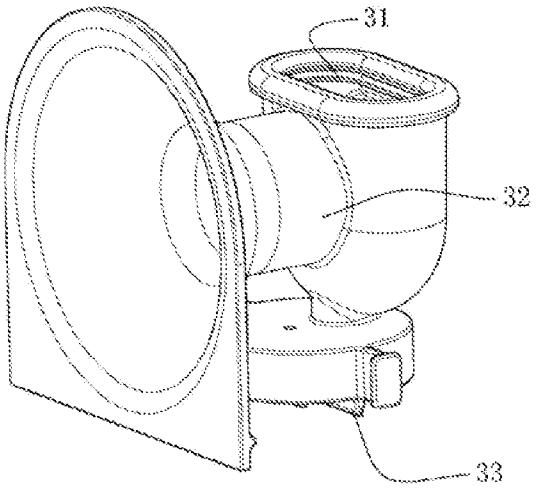
(54)发明名称

一种隐藏在吸奶器主机内部的集奶装置

(57)摘要

本发明公开了一种隐藏在吸奶器主机内部的集奶装置，包括三通、气囊以及鸭嘴阀，所述三通包括气压端、吸奶端以及流奶端，整个三通嵌入至吸奶器主机下端部，吸奶器主机包括真空负压装置，气囊设置在气压端内且与真空负压装置密封连接，吸奶端呈喇叭状且设置成经吸奶器主机的内侧面指向乳房，鸭嘴阀固定设置在流奶端。集奶装置集成在吸奶器主机的下端部，一方面实现了整个吸奶器体积的缩小，以便哺乳妈妈穿戴；另一方面，通过集成安装有效避免了管线约束问题的发生。同时，通过该集奶装置可将吸奶器主机与储奶瓶连接为一体，起到了承上启下的功能效果，进而使得吸奶器的体积可以做到更薄更小。



CN 109621041 A

1.一种隐藏在吸奶器主机内部的集奶装置，其特征在于：包括三通、气囊以及鸭嘴阀，所述三通包括气压端、吸奶端以及流奶端，整个三通嵌入至吸奶器主机下端部，吸奶器主机包括真空负压装置，气囊设置在气压端内且与真空负压装置密封连接，吸奶端呈喇叭状且设置成经吸奶器主机的内侧面指向乳房，鸭嘴阀固定设置在流奶端。

2.根据权利要求1所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述气囊呈扁平U形状，气压端设置成与气囊相一致的扁平U形状，吸奶器主机的下端部设置有用于容置气压端的U形腔体。

3.根据权利要求2所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述气囊由液态硅胶材质制成。

4.根据权利要求3所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：在U形腔体的内顶设置有气囊盖，气囊盖上设有第一气孔和第二气孔，所述真空负压装置包括真空泵和泄气阀，第一气孔与真空泵连通，第二气孔与泄气阀连通，气囊密封连接在气囊盖上。

5.根据权利要求4所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述气囊盖上设置有变形导向面，变形导向面引导气囊在真空负压下偏离于乳房贴合形成扁平状。

6.根据权利要求1所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述流奶端密封连接有储奶瓶，储奶瓶对接在吸奶器主机的下端部。

7.根据权利要求6所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述鸭嘴阀上设置有第一阀门和第二阀门，第一阀门包括位于其两侧部的呈弧形状的第一变形壁，两个第一变形壁由上至下逐渐靠拢且在末端形成细长状的第一切口，所述第一阀门连通流奶端和储奶瓶；第二阀门包括位于其两侧部的呈弧形状的第二变形壁，两个第二变形壁由上至下逐渐靠拢且在末端形成细长状的第二切口，所述第二阀门连通外界大气压和储奶瓶。

8.根据权利要求7所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述鸭嘴阀由食品级材质的液态硅胶制成。

9.根据权利要求6～8任一项所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述吸奶器主机的外侧面设置成第一曲面，所述储奶瓶的外侧面设置成第二曲面，第一曲面与第二曲面衔接形成与文胸贴合面匹配的弧形曲面。

10.根据权利要求9所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述吸奶器主机的内侧面和储奶瓶的内侧面呈共面设置，吸奶端的抵接面与吸奶器主机的内侧面平齐。

一种隐藏在吸奶器主机内部的集奶装置

技术领域

[0001] 本发明涉及母婴电器领域，特别涉及一种隐藏在吸奶器主机内部的集奶装置。

背景技术

[0002] 电动吸奶器是供哺乳妈妈产后使用的仪器，是指用于挤(吸)出积聚在乳腺里的母乳的工具。通过内部真空负压泵改变内部气压变化，即循环“吸”“放”去仿效婴儿吸允母乳的动作。

[0003] 就现有的电动吸奶器，主要分为一体式吸奶器和分体式吸奶器，完成免手扶吸奶则需要配合免手扶文胸。使用分体式吸奶器采集母乳时需要将三通和奶瓶悬挂在胸前，用气路软管连接吸奶器主机做吸奶的负压输出，这就存在管线约束以及装配困难的问题；而一体式吸奶器将吸奶器集成于一体，虽然减去了管线的约束，使得装配相对简单，但他们的结构方式和外观体积不利于穿戴和隐藏。

发明内容

[0004] 本发明的目的在于提供一种隐藏在吸奶器主机内部的集奶装置，以解决上述背景技术中提出的问题。

[0005] 为解决上述技术问题所采用的技术方案：一种隐藏在吸奶器主机内部的集奶装置，包括三通、气囊以及鸭嘴阀，所述三通包括气压端、吸奶端以及流奶端，整个三通嵌入至吸奶器主机下端部，吸奶器主机包括真空负压装置，气囊设置在气压端内且与真空负压装置密封连接，吸奶端呈喇叭状且设置成经吸奶器主机的内侧面指向乳房，鸭嘴阀固定设置在流奶端。

[0006] 作为上述方案的改进，所述气囊呈扁平U形状，气压端设置成与气囊相一致的扁平U形状，吸奶器主机的下端部设置有用于容置气压端的U形腔体。

[0007] 作为上述方案的改进，所述气囊由液态硅胶材质制成。

[0008] 作为上述方案的改进，在U形腔体的内顶设置有气囊盖，气囊盖上设有第一气孔和第二气孔，所述真空负压装置包括真空泵和泄气阀，第一气孔与真空泵连通，第二气孔与泄气阀连通，气囊密封连接在气囊盖上。

[0009] 作为上述方案的改进，所述气囊盖上设置有变形导向面，变形导向面引导气囊在真空负压下偏离于乳房贴合形成扁平状。

[0010] 作为上述方案的改进，所述流奶端密封连接有储奶瓶，储奶瓶对接在吸奶器主机的下端部。

[0011] 作为上述方案的改进，所述鸭嘴阀上设置有第一阀门和第二阀门，第一阀门包括位于其两侧部的呈弧形状的第一变形壁，两个第一变形壁由上至下逐渐靠拢且在末端形成细长状的第一切口，所述第一阀门连通流奶端和储奶瓶；第二阀门包括位于其两侧部的呈弧形状的第二变形壁，两个第二变形壁由上至下逐渐靠拢且在末端形成细长状的第二切口，所述第二阀门连通外界大气压和储奶瓶。

[0012] 作为上述方案的改进，所述鸭嘴阀由食品级材质的液态硅胶制成。

[0013] 作为上述方案的改进，所述吸奶器主机的外侧面设置成第一曲面，所述储奶瓶的外侧面设置成第二曲面，第一曲面与第二曲面衔接形成与文胸贴合面匹配的弧形曲面。

[0014] 作为上述方案的改进，所述吸奶器主机的内侧面和储奶瓶的内侧面呈共面设置，吸奶端的抵接面与吸奶器主机的内侧面平齐。

[0015] 有益效果：本发明中，集奶装置集成在吸奶器主机的下端部，一方面实现了整个吸奶器体积的缩小，以便哺乳妈妈穿戴；另一方面，通过集成安装有效避免了管线约束问题的发生。同时，通过该集奶装置可将吸奶器主机与储奶瓶连接为一体，起到了承上启下的功能效果，进而使得吸奶器的体积可以做到更薄更小。

附图说明

[0016] 下面结合附图和实施例对本发明做进一步的说明：

[0017] 图1为免手扶隐藏式吸奶器的装配示意图；

[0018] 图2为免手扶隐藏式吸奶器的立体图；

[0019] 图3为图2的左侧视图；

[0020] 图4为吸奶器主机的内部结构示意图；

[0021] 图5为集奶装置的结构示意图；

[0022] 图6为吸奶器的剖面示意图，该图中气囊处于自然状态；

[0023] 图7为吸奶器的剖面示意图，该图中气囊处于负压贴合状态；

[0024] 图8为吸奶器工作时鸭嘴阀中的第一阀门打开的状态示意图；

[0025] 图9为吸奶器工作时鸭嘴阀中的第一阀门关闭的状态示意图；

[0026] 图10为气囊的正视图；

[0027] 图11为图10中A-A剖面示意图；

[0028] 图12为鸭嘴阀的立体结构示意图；

[0029] 图13为哺乳妈妈穿戴上免手扶隐藏式吸奶器的侧视图；

[0030] 图14为哺乳妈妈穿戴上免手扶隐藏式吸奶器的正视图。

具体实施方式

[0031] 参照图1至图3，为本实施例一种免手扶隐藏式吸奶器，该吸奶器由吸奶器主机1、集奶装置3以及储奶瓶2等零部件组成。吸奶器主机1内设置有真空负压装置以及与真空负压装置连接的主控电路板16，主控电路板16连接有设置于吸奶器主机1外表的控制面板11。图2中，控制面板11设置在吸奶器主机1的顶部，一方面可方便哺乳妈妈操作，另一方面也可避免穿戴在文胸内部时控制面板11受到挤压。该控制面板11上设置有吸奶器的开机/关机按键、吸力大小加档操作按键、吸力大小减档操作按键以及催乳和吸奶模式的切换按键，同时还设置有吸力档位提示灯，吸奶器充电状态提示灯等。哺乳妈妈结合实际情况对控制面板11进行操作，发送指令给主控电路板16，主控电路板16控制调节真空负压装置的工作状态。当吸奶器主机1处于充电转态时，充电状态提示灯予以提示。同时，吸奶器主机1内还设置有用于接收移动终端电信号的无线通讯模块18。本实施例中，移动终端为手机，无线通讯模块18用于解析与手机的通讯协议，接收手机发出的电信号，并将电信号发送至主控电路

板16，无线通讯模块18采用蓝牙或WIFI通信模式。手机上的APP程序中显示有多个控制选项，该控制选项基本与控制面板11上的选项相一致，用以实现吸奶器工作状态的调节。同时该APP程序中还可以显示吸力档位状态以及吸奶器的剩余电量等信息。通过移动终端对吸奶器的工作状态进行控制，极大方便了哺乳妈妈在公共场所使用吸奶器，由于该吸奶器为免手扶隐藏式吸奶器，哺乳妈妈可事先穿戴好，当需要吸奶时，只需通过移动终端控制开启即可，方便快捷。

[0032] 如图4所示，该吸奶器主机1内还设置有充放电的锂电池15和充电接口17，使用适配器可对其进行便捷充电。位于吸奶器主机1内的真空负压装置包括真空泵13和泄气阀14，吸奶器主机1的下端部设置有U形腔体12，集奶装置3设置在U形腔体12内，集奶装置3一端与真空负压装置密封连接，另一端与储奶瓶2密封连接，储奶瓶2与吸奶器主机1的下端对接，吸奶器主机1的外侧面设置成第一曲面，储奶瓶2的外侧面设置成第二曲面，第一曲面与第二曲面衔接形成与文胸贴合面匹配的弧形曲面，吸奶器主机1的内侧面和储奶瓶2的内侧面设置成共面。

[0033] 通过在吸奶器主机1的外表设置控制面板11，方便哺乳妈妈控制和调节吸奶器的工作情况。同时，整机高度集成，真空负压装置和集奶装置3均集成安装于吸奶器主机1的内部，结构紧凑，无任何管线约束。并且，结合人体工程学，将吸奶器主机1的外侧面设置成与文胸贴合面匹配第一曲面，将储奶瓶2的外侧面设置成与文胸贴合面匹配第二曲面，第一曲面和第二曲面衔接形成与文胸贴合面匹配的弧形曲面，哺乳妈妈可轻松自然的将吸奶器放入哺乳文胸中；吸奶器主机1的内侧面以及储奶瓶2的内侧面设置成平面状以便与乳房一侧贴合。在布局合理的同时实现了整个吸奶器的体积最小化。该吸奶器整体外形精巧、圆滑，非常适合穿戴和隐藏，满足哺乳妈妈在公共场合实现简单隐蔽且动作优雅得体的吸奶。

[0034] 如图5所示为集奶装置3，该集奶装置3隐藏在吸奶器主机1内部，具体包括三通32、气囊31以及鸭嘴阀33，三通32包括气压端、吸奶端以及流奶端，整个三通32嵌入至吸奶器主机1下端部的U形腔体12内，气囊31设置在气压端内且与真空负压装置密封连接，吸奶端呈喇叭状且设置成经吸奶器主机1的内侧面指向乳房，吸奶端的抵接面与吸奶器主机1的内侧面平齐，保证吸奶器的内侧面完全平整，增加哺乳妈妈穿戴的舒适度。鸭嘴阀33固定设置在流奶端，流奶端密封连接有储奶瓶2，吸奶器吸出的奶液经鸭嘴阀33流入至储奶瓶2。该储奶瓶2通过瓶口的螺牙螺接于流奶端，方便拆卸清洗。同时，在U形腔体12的内顶设置有气囊盖，气囊盖上设有第一气孔和第二气孔，第一气孔通过软管与真空泵13连通，第二气孔通过软管与泄气阀14连通，气囊31密封连接在气囊盖上，实现气囊31同时与真空泵13以及泄气阀14连通。

[0035] 集奶装置3集成在吸奶器主机1的下端部，一方面实现了整个吸奶器体积的缩小，以便哺乳妈妈穿戴；另一方面，通过集成安装有效避免了管线约束问题的发生。同时，通过该集奶装置3可将吸奶器主机1与储奶瓶2连接为一体，起到了承上启下的功能效果，进而使得吸奶器的体积可以做到更薄更小。

[0036] 上述气囊31由食品级材质的液态硅胶材质制成，具有较优的弹性和耐疲劳性，其主要用于气压与母乳的隔离。如图10和图11所示，该气囊31呈扁平U形状，气压端设置成与气囊31相一致的扁平U形状。气囊31的宽面正对吸奶端设置，两个宽面之间的厚度较小，有利于减小整个吸奶器薄度，方便哺乳妈妈将吸奶器穿戴与文胸内部。同时，气囊31的两个窄

面之间的距离较大，有利于增加整个气囊31的体积，进而增大整个三通32内的气压差的变大幅度，以便提供充足的压力进行吸奶。气囊盖上设置有变形导向面，变形导向面与气囊31的两个窄面对应设置，变形导向面引导气囊31在真空负压下偏离于乳房贴合形成扁平状。如图7所示，当气囊31受负压贴合呈扁平状时，气囊31整体偏离于乳房，进而增加了乳房与气囊31之间的间隙，方便乳液从三通32内顺畅的流入至流奶端。变形导向面具体可设置成与气囊31表面贴合的折面，折面的对折处呈竖向偏离于气囊31设置，进而实现整个气囊31的偏离导向。

[0037] 图6和图7分别示出了吸奶器工作时气囊31的两种状态。图6中，气囊31处于自然状态，此时泄气阀14处于打开状态，气囊31与大气压相通，三通32内未形成负压，整个吸奶器处于“放”的状态，该状态主要是为了方便奶液顺利的流入至储奶瓶2中；图7中，气囊31处于负压贴合状态，此时泄气阀14处于关闭状态，气囊31仅与真空泵13连通且被完全抽真空，三通32内由于气囊31体积的缩小而形成负压，整个吸奶器处于“吸”的状态，实现乳房内乳液的吸出。

[0038] 鸭嘴阀33设置于流奶端，具有防逆流的作用。如图12所示，鸭嘴阀33上设置有第一阀门331和第二阀门332，第一阀门331包括位于其两侧部的呈弧形状的第一变形壁3311，两个第一变形壁3311由上至下逐渐靠拢且在末端形成细长状的第一切口3312，第一阀门331连通流奶端和储奶瓶2；第二阀门332包括位于其两侧部的呈弧形状的第二变形壁3321，两个第二变形壁3321由上至下逐渐靠拢且在末端形成细长状的第二切口3322，第二阀门332连通外界大气压和储奶瓶2。该鸭嘴阀33由食品级材质的液态硅胶制成，其有较优的密封性、抗撕裂强度、回弹性、抗变黄性、热稳定性、耐热老化性以及耐压缩变形的特点。第一变形壁3311和第二变形壁3321的壁厚为0.4～0.6mm，变形壁设计的面积大而薄，保证易回弹且受力易变形。

[0039] 通过第一变形壁3311和第二变形壁3321的变形可轻松实现第一切口3312和第二切口3322的打开和关闭状态的切换。其中，第二阀门332与外界大气压连通，第二变形壁3321并未受到负压的挤压，因此处于常开状态，进而使得储奶瓶2维持透气状态，奶液可以不断地经第一切口3312流入至储奶瓶2；而第一阀门331跟随真空负压与常压之间的切换而打开或关闭。当三通32解除负压时，第一切口3312打开，奶液立即流入至储奶瓶2。当储奶瓶2发生晃动时，奶液从外侧挤压第一变形壁3311和第二变形壁3321，进而使得第一切口3312和第二切口3322关闭，奶液无法从储奶瓶2中流出，有效了防止了奶液的外漏和逆流。

[0040] 作为优选，第一阀门331和第二阀门332共同连接在密封垫333上，第一切口3312和第二切口3322均指向储奶瓶2的内腔，密封垫333的周边与储奶瓶2的端口密封贴合。当储奶瓶2螺纹连接在流奶端时，储奶瓶2的端口紧抵在密封垫333的下侧面，同时，螺接的方式可提供压力使得密封垫333的上侧面与流奶端紧贴，有效保证了流奶端与储奶瓶2之间的密封连接。同时，密封垫333的中部形成相互隔开的第一气压腔和第二气压腔，流奶端分别形成有插入至第一气压腔的第一连接部以及插入至第二气压腔的第二连接部，第一阀门331设置在第一气压腔的下端，第二阀门332设置在第二气压腔的下端，第一气压腔与流奶端相通，第二气压腔与外界大气压相通。第一气压腔和第一连接部过盈配合连接，第二气压腔与第二连接部过盈配合连接，可避免因第一阀门331和第二阀门332上端部变形过大而导致的阀门失效。

[0041] 图8和图9分别示出了吸奶器工作时鸭嘴阀33中的第一阀门331的状态示意图。图8中，气囊31处于自然状态，三通32内为常压，第一切口3312自然处于打开状态，汇集在流奶端的奶液经第一阀门331流入至储奶瓶2；图9中，气囊31处于负压贴合状态，三通32内为负压，第一切口3312在负压的挤压下处于闭合状态，吸出来的奶液汇入至流奶端且停留在第一阀门331前端。

[0042] 图13和图14均为哺乳妈妈穿戴上免手扶隐藏式吸奶器的效果示意图，该免手扶隐藏式吸奶器的确能很好的隐藏于文胸内，大大方便了哺乳妈妈在公共场所随意的吸奶。

[0043] 上面结合附图对本发明的实施方式作了详细说明，但是本发明不限于上述实施方式，在所述技术领域普通技术人员所具备的知识范围内，还可以在不脱离本发明宗旨的前提下作出各种变化。

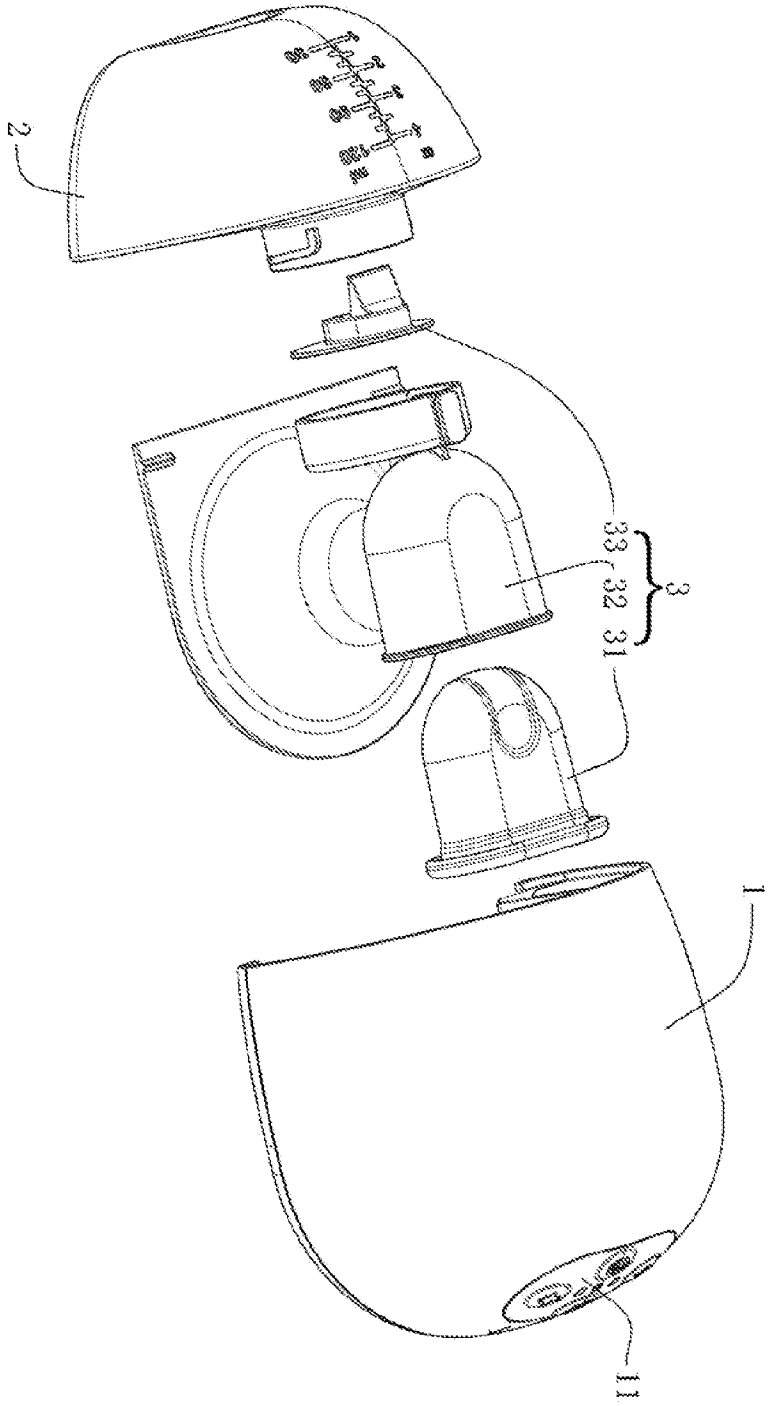


图1

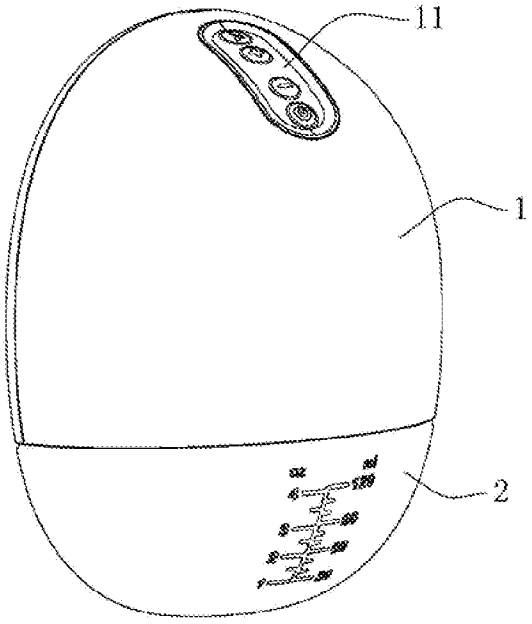


图2

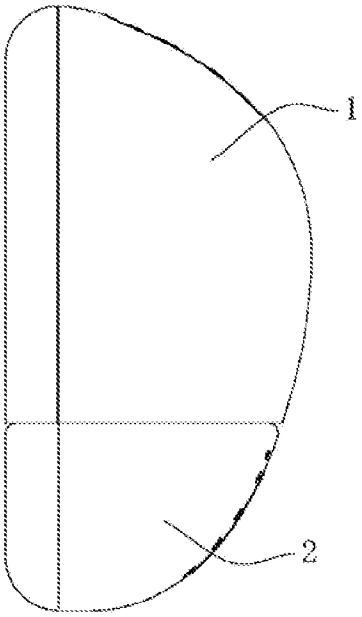


图3

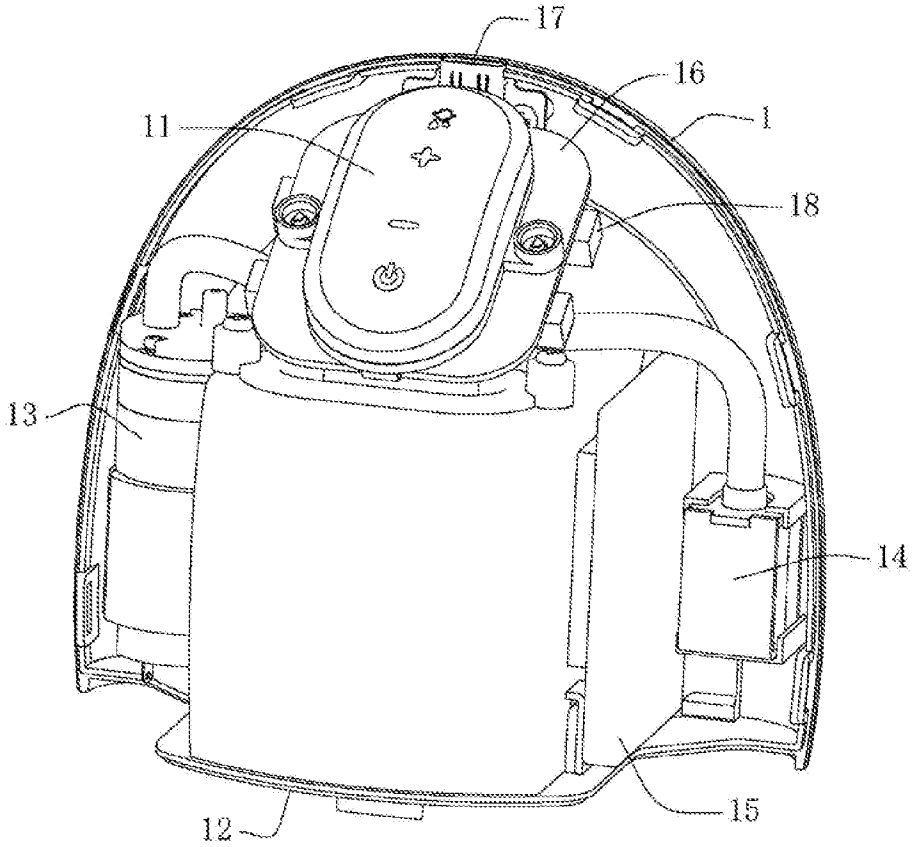


图4

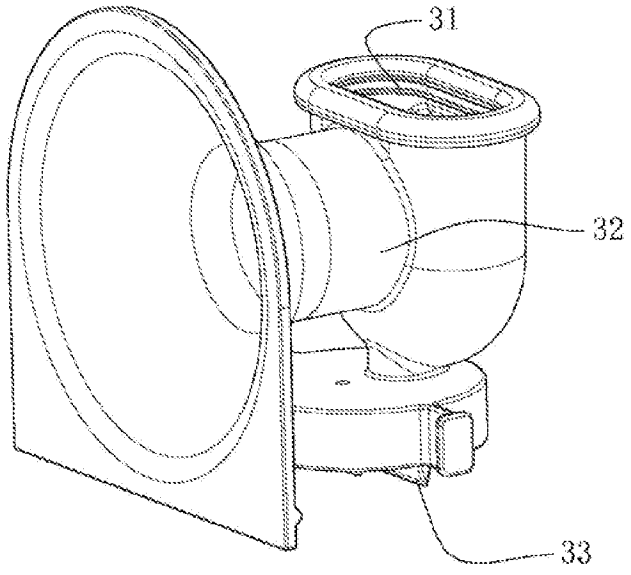


图5

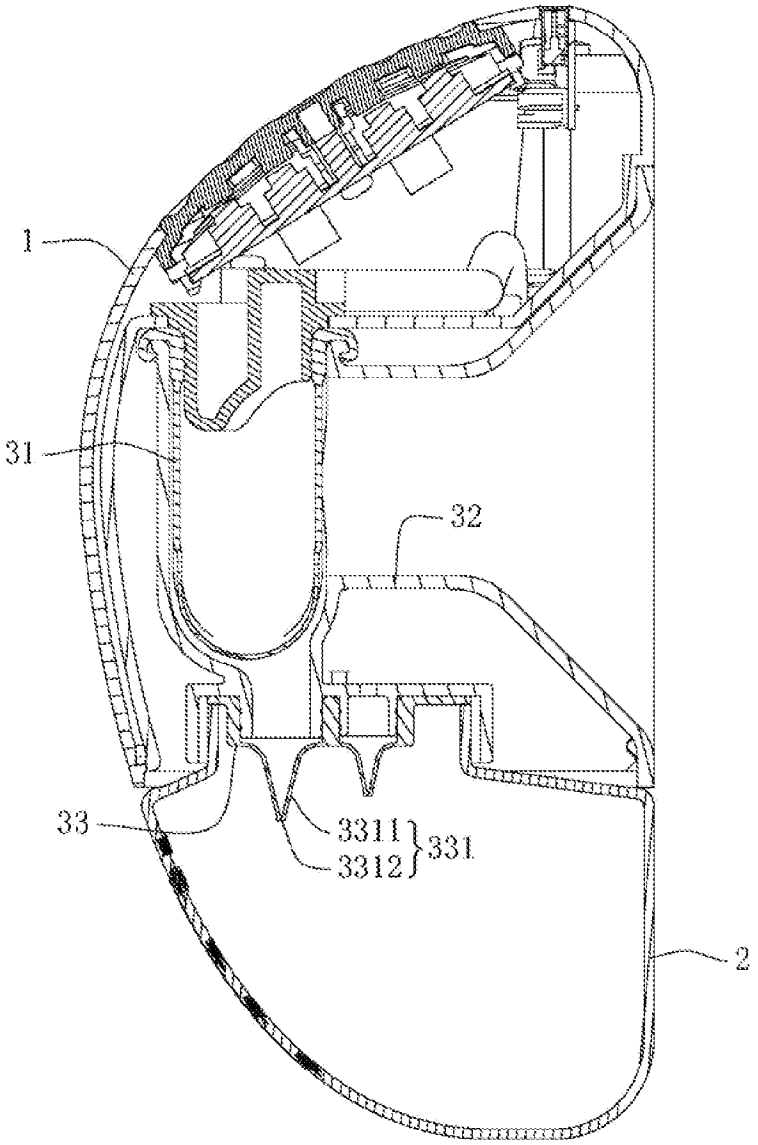


图6

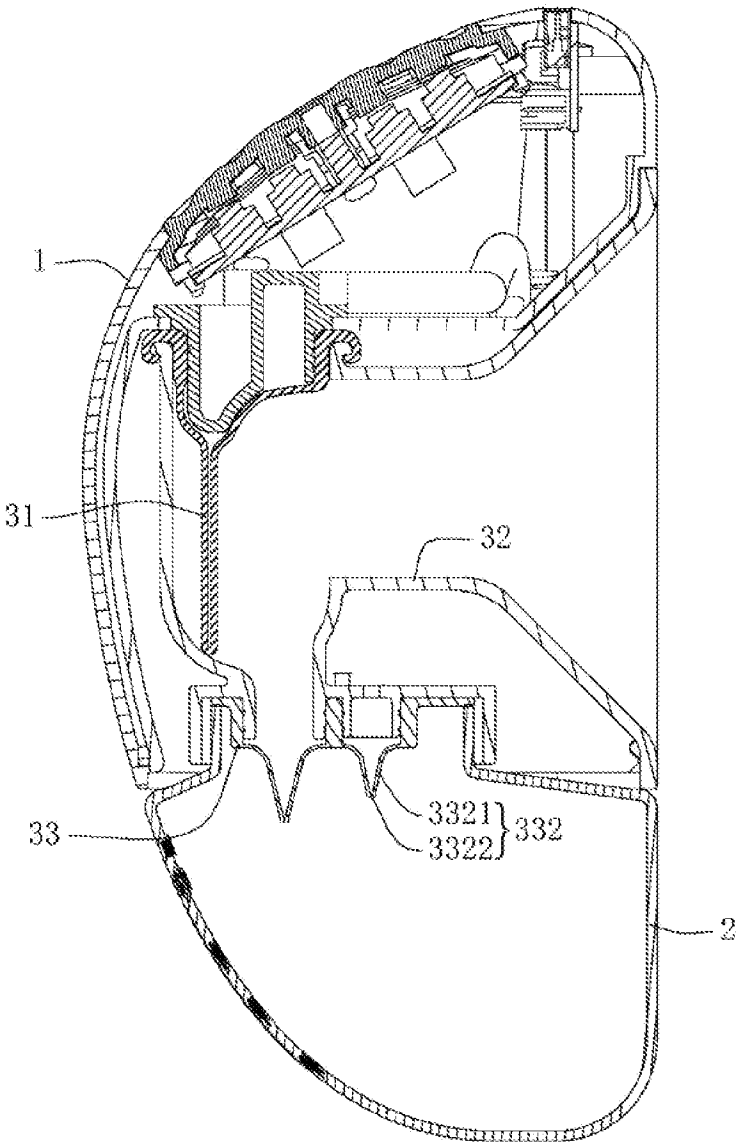


图7

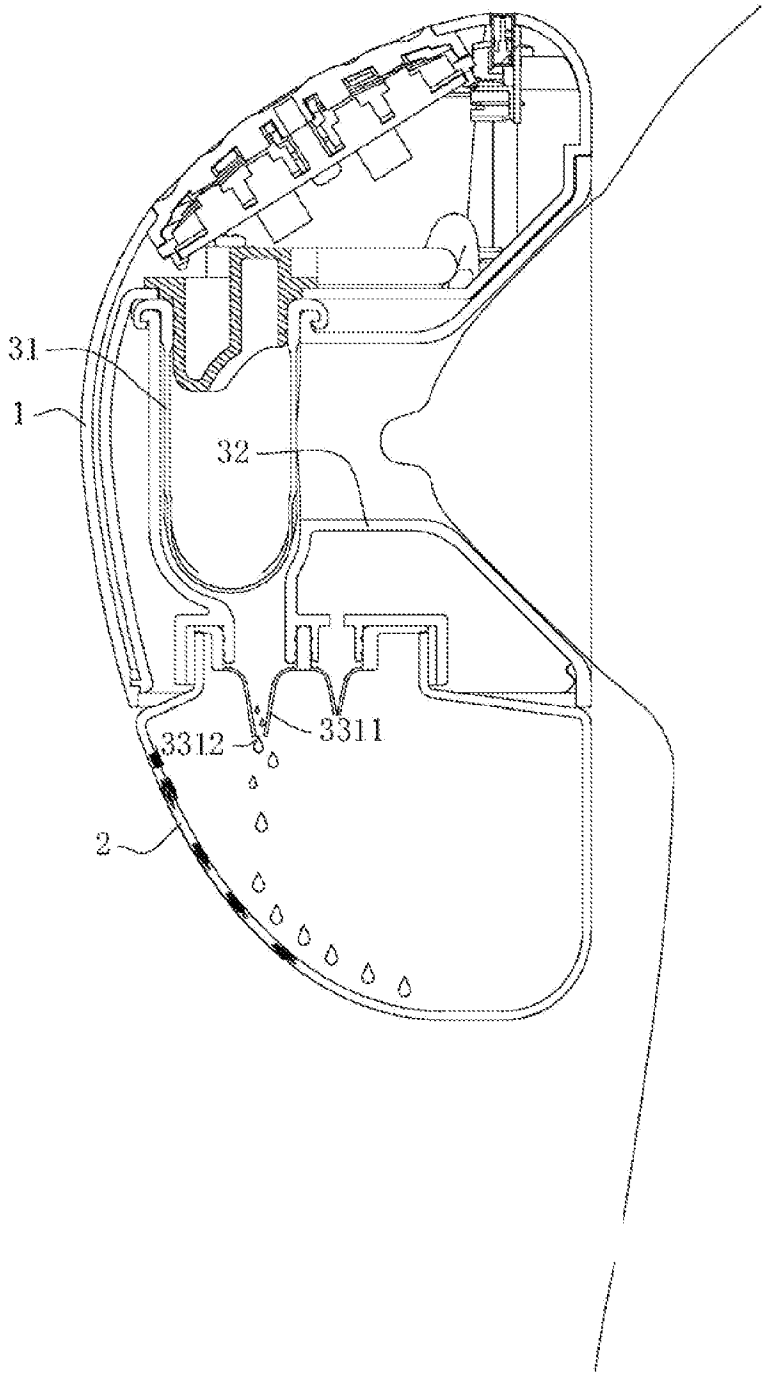


图8

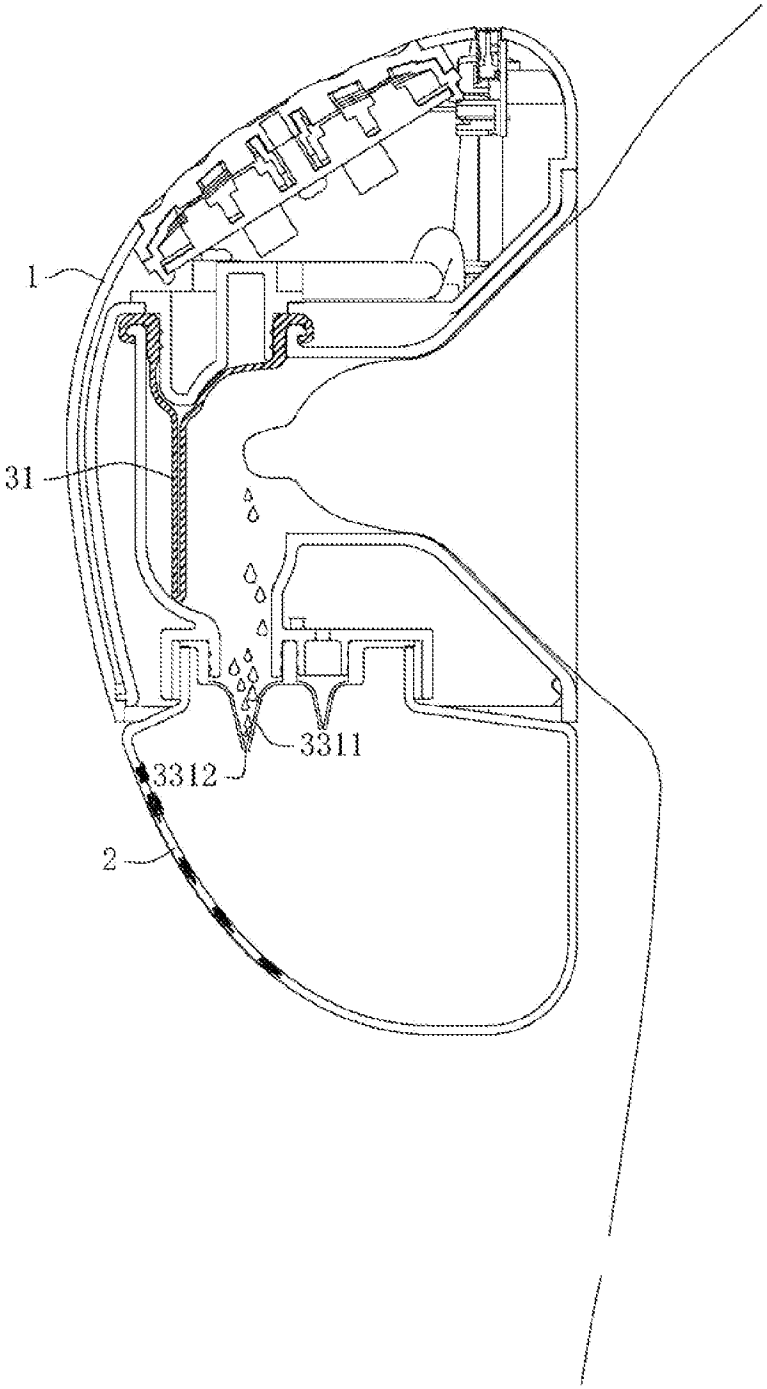


图9

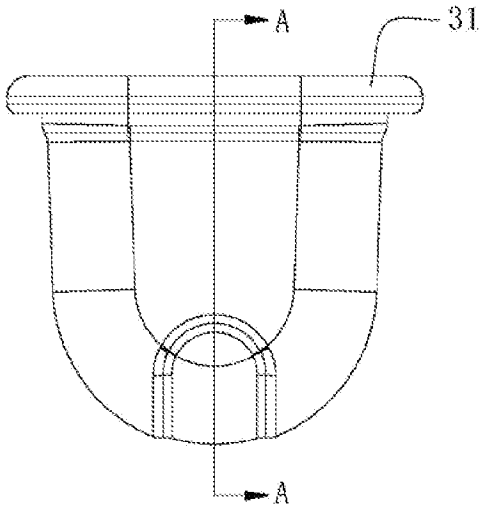


图10

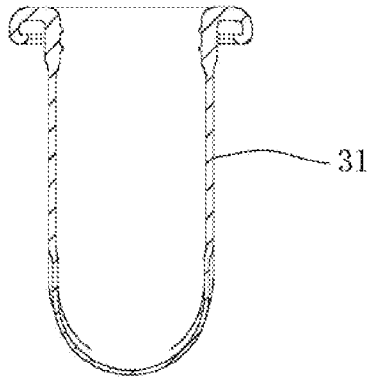


图11

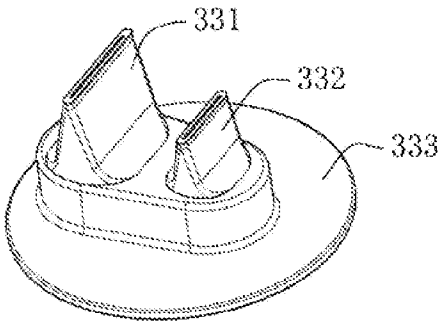


图12

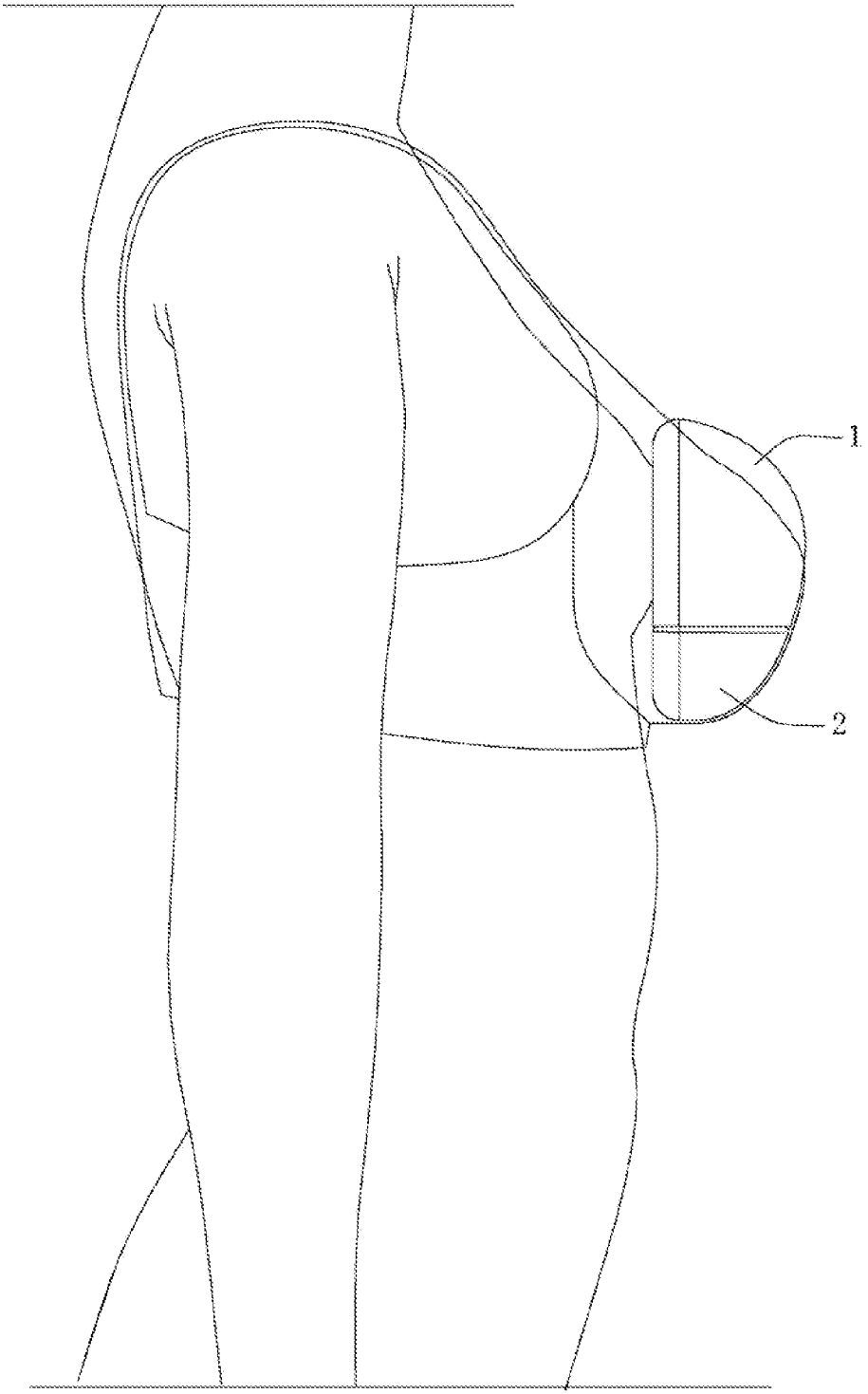


图13

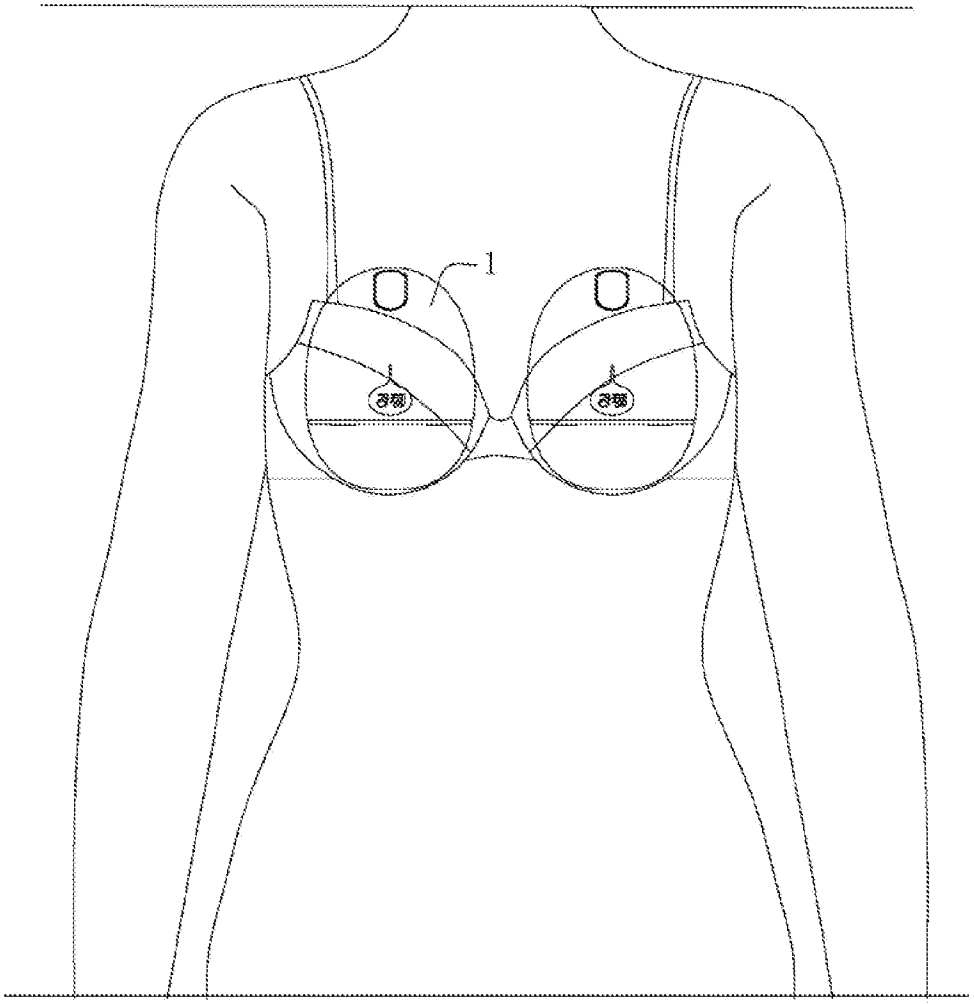


图14

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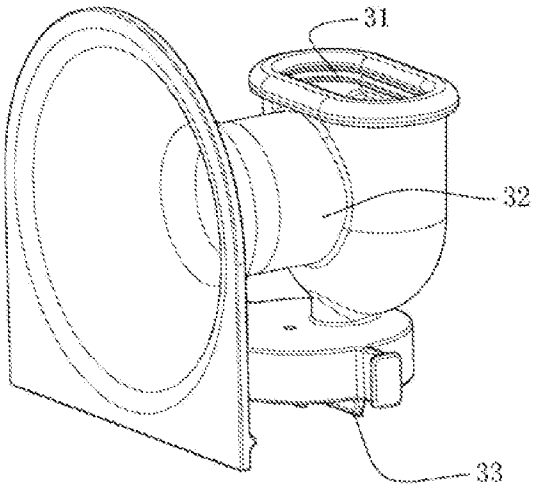
权利要求书1页 说明书5页 附图10页

(54)发明名称

一种隐藏在吸奶器主机内部的集奶装置

(57)摘要

本发明公开了一种隐藏在吸奶器主机内部的集奶装置，包括三通、气囊以及鸭嘴阀，所述三通包括气压端、吸奶端以及流奶端，整个三通嵌入至吸奶器主机下端部，吸奶器主机包括真空负压装置，气囊设置在气压端内且与真空负压装置密封连接，吸奶端呈喇叭状且设置成经吸奶器主机的内侧面指向乳房，鸭嘴阀固定设置在流奶端。集奶装置集成在吸奶器主机的下端部，一方面实现了整个吸奶器体积的缩小，以便哺乳妈妈穿戴；另一方面，通过集成安装有效避免了管线约束问题的发生。同时，通过该集奶装置可将吸奶器主机与储奶瓶连接为一体，起到了承上启下的功能效果，进而使得吸奶器的体积可以做到更薄更小。



CN 109621041 A

1.一种隐藏在吸奶器主机内部的集奶装置，其特征在于：包括三通、气囊以及鸭嘴阀，所述三通包括气压端、吸奶端以及流奶端，整个三通嵌入至吸奶器主机下端部，吸奶器主机包括真空负压装置，气囊设置在气压端内且与真空负压装置密封连接，吸奶端呈喇叭状且设置成经吸奶器主机的内侧面指向乳房，鸭嘴阀固定设置在流奶端。

2.根据权利要求1所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述气囊呈扁平U形状，气压端设置成与气囊相一致的扁平U形状，吸奶器主机的下端部设置有用于容置气压端的U形腔体。

3.根据权利要求2所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述气囊由液态硅胶材质制成。

4.根据权利要求3所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：在U形腔体的内顶设置有气囊盖，气囊盖上设有第一气孔和第二气孔，所述真空负压装置包括真空泵和泄气阀，第一气孔与真空泵连通，第二气孔与泄气阀连通，气囊密封连接在气囊盖上。

5.根据权利要求4所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述气囊盖上设置有变形导向面，变形导向面引导气囊在真空负压下偏离于乳房贴合形成扁平状。

6.根据权利要求1所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述流奶端密封连接有储奶瓶，储奶瓶对接在吸奶器主机的下端部。

7.根据权利要求6所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述鸭嘴阀上设置有第一阀门和第二阀门，第一阀门包括位于其两侧部的呈弧形状的第一变形壁，两个第一变形壁由上至下逐渐靠拢且在末端形成细长状的第一切口，所述第一阀门连通流奶端和储奶瓶；第二阀门包括位于其两侧部的呈弧形状的第二变形壁，两个第二变形壁由上至下逐渐靠拢且在末端形成细长状的第二切口，所述第二阀门连通外界大气压和储奶瓶。

8.根据权利要求7所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述鸭嘴阀由食品级材质的液态硅胶制成。

9.根据权利要求6～8任一项所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述吸奶器主机的外侧面设置成第一曲面，所述储奶瓶的外侧面设置成第二曲面，第一曲面与第二曲面衔接形成与文胸贴合面匹配的弧形曲面。

10.根据权利要求9所述的隐藏在吸奶器主机内部的集奶装置，其特征在于：所述吸奶器主机的内侧面和储奶瓶的内侧面呈共面设置，吸奶端的抵接面与吸奶器主机的内侧面平齐。

一种隐藏在吸奶器主机内部的集奶装置

技术领域

[0001] 本发明涉及母婴电器领域，特别涉及一种隐藏在吸奶器主机内部的集奶装置。

背景技术

[0002] 电动吸奶器是供哺乳妈妈产后使用的仪器，是指用于挤(吸)出积聚在乳腺里的母乳的工具。通过内部真空负压泵改变内部气压变化，即循环“吸”“放”去仿效婴儿吸允母乳的动作。

[0003] 就现有的电动吸奶器，主要分为一体式吸奶器和分体式吸奶器，完成免手扶吸奶则需要配合免手扶文胸。使用分体式吸奶器采集母乳时需要将三通和奶瓶悬挂在胸前，用气路软管连接吸奶器主机做吸奶的负压输出，这就存在管线约束以及装配困难的问题；而一体式吸奶器将吸奶器集成于一体，虽然减去了管线的约束，使得装配相对简单，但他们的结构方式和外观体积不利于穿戴和隐藏。

发明内容

[0004] 本发明的目的在于提供一种隐藏在吸奶器主机内部的集奶装置，以解决上述背景技术中提出的问题。

[0005] 为解决上述技术问题所采用的技术方案：一种隐藏在吸奶器主机内部的集奶装置，包括三通、气囊以及鸭嘴阀，所述三通包括气压端、吸奶端以及流奶端，整个三通嵌入至吸奶器主机下端部，吸奶器主机包括真空负压装置，气囊设置在气压端内且与真空负压装置密封连接，吸奶端呈喇叭状且设置成经吸奶器主机的内侧面指向乳房，鸭嘴阀固定设置在流奶端。

[0006] 作为上述方案的改进，所述气囊呈扁平U形状，气压端设置成与气囊相一致的扁平U形状，吸奶器主机的下端部设置有用于容置气压端的U形腔体。

[0007] 作为上述方案的改进，所述气囊由液态硅胶材质制成。

[0008] 作为上述方案的改进，在U形腔体的内顶设置有气囊盖，气囊盖上设有第一气孔和第二气孔，所述真空负压装置包括真空泵和泄气阀，第一气孔与真空泵连通，第二气孔与泄气阀连通，气囊密封连接在气囊盖上。

[0009] 作为上述方案的改进，所述气囊盖上设置有变形导向面，变形导向面引导气囊在真空负压下偏离于乳房贴合形成扁平状。

[0010] 作为上述方案的改进，所述流奶端密封连接有储奶瓶，储奶瓶对接在吸奶器主机的下端部。

[0011] 作为上述方案的改进，所述鸭嘴阀上设置有第一阀门和第二阀门，第一阀门包括位于其两侧部的呈弧形状的第一变形壁，两个第一变形壁由上至下逐渐靠拢且在末端形成细长状的第一切口，所述第一阀门连通流奶端和储奶瓶；第二阀门包括位于其两侧部的呈弧形状的第二变形壁，两个第二变形壁由上至下逐渐靠拢且在末端形成细长状的第二切口，所述第二阀门连通外界大气压和储奶瓶。

[0012] 作为上述方案的改进，所述鸭嘴阀由食品级材质的液态硅胶制成。

[0013] 作为上述方案的改进，所述吸奶器主机的外侧面设置成第一曲面，所述储奶瓶的外侧面设置成第二曲面，第一曲面与第二曲面衔接形成与文胸贴合面匹配的弧形曲面。

[0014] 作为上述方案的改进，所述吸奶器主机的内侧面和储奶瓶的内侧面呈共面设置，吸奶端的抵接面与吸奶器主机的内侧面平齐。

[0015] 有益效果：本发明中，集奶装置集成在吸奶器主机的下端部，一方面实现了整个吸奶器体积的缩小，以便哺乳妈妈穿戴；另一方面，通过集成安装有效避免了管线约束问题的发生。同时，通过该集奶装置可将吸奶器主机与储奶瓶连接为一体，起到了承上启下的功能效果，进而使得吸奶器的体积可以做到更薄更小。

附图说明

[0016] 下面结合附图和实施例对本发明做进一步的说明：

[0017] 图1为免手扶隐藏式吸奶器的装配示意图；

[0018] 图2为免手扶隐藏式吸奶器的立体图；

[0019] 图3为图2的左侧视图；

[0020] 图4为吸奶器主机的内部结构示意图；

[0021] 图5为集奶装置的结构示意图；

[0022] 图6为吸奶器的剖面示意图，该图中气囊处于自然状态；

[0023] 图7为吸奶器的剖面示意图，该图中气囊处于负压贴合状态；

[0024] 图8为吸奶器工作时鸭嘴阀中的第一阀门打开的状态示意图；

[0025] 图9为吸奶器工作时鸭嘴阀中的第一阀门关闭的状态示意图；

[0026] 图10为气囊的正视图；

[0027] 图11为图10中A-A剖面示意图；

[0028] 图12为鸭嘴阀的立体结构示意图；

[0029] 图13为哺乳妈妈穿戴上免手扶隐藏式吸奶器的侧视图；

[0030] 图14为哺乳妈妈穿戴上免手扶隐藏式吸奶器的正视图。

具体实施方式

[0031] 参照图1至图3，为本实施例一种免手扶隐藏式吸奶器，该吸奶器由吸奶器主机1、集奶装置3以及储奶瓶2等零部件组成。吸奶器主机1内设置有真空负压装置以及与真空负压装置连接的主控电路板16，主控电路板16连接有设置于吸奶器主机1外表的控制面板11。图2中，控制面板11设置在吸奶器主机1的顶部，一方面可方便哺乳妈妈操作，另一方面也可避免穿戴在文胸内部时控制面板11受到挤压。该控制面板11上设置有吸奶器的开机/关机按键、吸力大小加档操作按键、吸力大小减档操作按键以及催乳和吸奶模式的切换按键，同时还设置有吸力档位提示灯，吸奶器充电状态提示灯等。哺乳妈妈结合实际情况对控制面板11进行操作，发送指令给主控电路板16，主控电路板16控制调节真空负压装置的工作状态。当吸奶器主机1处于充电转态时，充电状态提示灯予以提示。同时，吸奶器主机1内还设置有用于接收移动终端电信号的无线通讯模块18。本实施例中，移动终端为手机，无线通讯模块18用于解析与手机的通讯协议，接收手机发出的电信号，并将电信号发送至主控电路

板16，无线通讯模块18采用蓝牙或WIFI通信模式。手机上的APP程序中显示有多个控制选项，该控制选项基本与控制面板11上的选项相一致，用以实现吸奶器工作状态的调节。同时该APP程序中还可以显示吸力档位状态以及吸奶器的剩余电量等信息。通过移动终端对吸奶器的工作状态进行控制，极大方便了哺乳妈妈在公共场所使用吸奶器，由于该吸奶器为免手扶隐藏式吸奶器，哺乳妈妈可事先穿戴好，当需要吸奶时，只需通过移动终端控制开启即可，方便快捷。

[0032] 如图4所示，该吸奶器主机1内还设置有充放电的锂电池15和充电接口17，使用适配器可对其进行便捷充电。位于吸奶器主机1内的真空负压装置包括真空泵13和泄气阀14，吸奶器主机1的下端部设置有U形腔体12，集奶装置3设置在U形腔体12内，集奶装置3一端与真空负压装置密封连接，另一端与储奶瓶2密封连接，储奶瓶2与吸奶器主机1的下端对接，吸奶器主机1的外侧面设置成第一曲面，储奶瓶2的外侧面设置成第二曲面，第一曲面与第二曲面衔接形成与文胸贴合面匹配的弧形曲面，吸奶器主机1的内侧面和储奶瓶2的内侧面设置成共面。

[0033] 通过在吸奶器主机1的外表设置控制面板11，方便哺乳妈妈控制和调节吸奶器的工作情况。同时，整机高度集成，真空负压装置和集奶装置3均集成安装于吸奶器主机1的内部，结构紧凑，无任何管线约束。并且，结合人体工程学，将吸奶器主机1的外侧面设置成与文胸贴合面匹配第一曲面，将储奶瓶2的外侧面设置成与文胸贴合面匹配第二曲面，第一曲面和第二曲面衔接形成与文胸贴合面匹配的弧形曲面，哺乳妈妈可轻松自然的将吸奶器放入哺乳文胸中；吸奶器主机1的内侧面以及储奶瓶2的内侧面设置成平面状以便与乳房一侧贴合。在布局合理的同时实现了整个吸奶器的体积最小化。该吸奶器整体外形精巧、圆滑，非常适合穿戴和隐藏，满足哺乳妈妈在公共场合实现简单隐蔽且动作优雅得体的吸奶。

[0034] 如图5所示为集奶装置3，该集奶装置3隐藏在吸奶器主机1内部，具体包括三通32、气囊31以及鸭嘴阀33，三通32包括气压端、吸奶端以及流奶端，整个三通32嵌入至吸奶器主机1下端部的U形腔体12内，气囊31设置在气压端内且与真空负压装置密封连接，吸奶端呈喇叭状且设置成经吸奶器主机1的内侧面指向乳房，吸奶端的抵接面与吸奶器主机1的内侧面平齐，保证吸奶器的内侧面完全平整，增加哺乳妈妈穿戴的舒适度。鸭嘴阀33固定设置在流奶端，流奶端密封连接有储奶瓶2，吸奶器吸出的奶液经鸭嘴阀33流入至储奶瓶2。该储奶瓶2通过瓶口的螺牙螺接于流奶端，方便拆卸清洗。同时，在U形腔体12的内顶设置有气囊盖，气囊盖上设有第一气孔和第二气孔，第一气孔通过软管与真空泵13连通，第二气孔通过软管与泄气阀14连通，气囊31密封连接在气囊盖上，实现气囊31同时与真空泵13以及泄气阀14连通。

[0035] 集奶装置3集成在吸奶器主机1的下端部，一方面实现了整个吸奶器体积的缩小，以便哺乳妈妈穿戴；另一方面，通过集成安装有效避免了管线约束问题的发生。同时，通过该集奶装置3可将吸奶器主机1与储奶瓶2连接为一体，起到了承上启下的功能效果，进而使得吸奶器的体积可以做到更薄更小。

[0036] 上述气囊31由食品级材质的液态硅胶材质制成，具有较优的弹性和耐疲劳性，其主要用于气压与母乳的隔离。如图10和图11所示，该气囊31呈扁平U形状，气压端设置成与气囊31相一致的扁平U形状。气囊31的宽面正对吸奶端设置，两个宽面之间的厚度较小，有利于减小整个吸奶器薄度，方便哺乳妈妈将吸奶器穿戴与文胸内部。同时，气囊31的两个窄

面之间的距离较大，有利于增加整个气囊31的体积，进而增大整个三通32内的气压差的变大幅度，以便提供充足的压力进行吸奶。气囊盖上设置有变形导向面，变形导向面与气囊31的两个窄面对应设置，变形导向面引导气囊31在真空负压下偏离于乳房贴合形成扁平状。如图7所示，当气囊31受负压贴合呈扁平状时，气囊31整体偏离于乳房，进而增加了乳房与气囊31之间的间隙，方便乳液从三通32内顺畅的流入至流奶端。变形导向面具体可设置成与气囊31表面贴合的折面，折面的对折处呈竖向偏离于气囊31设置，进而实现整个气囊31的偏离导向。

[0037] 图6和图7分别示出了吸奶器工作时气囊31的两种状态。图6中，气囊31处于自然状态，此时泄气阀14处于打开状态，气囊31与大气压相通，三通32内未形成负压，整个吸奶器处于“放”的状态，该状态主要是为了方便奶液顺利的流入至储奶瓶2中；图7中，气囊31处于负压贴合状态，此时泄气阀14处于关闭状态，气囊31仅与真空泵13连通且被完全抽真空，三通32内由于气囊31体积的缩小而形成负压，整个吸奶器处于“吸”的状态，实现乳房内乳液的吸出。

[0038] 鸭嘴阀33设置于流奶端，具有防逆流的作用。如图12所示，鸭嘴阀33上设置有第一阀门331和第二阀门332，第一阀门331包括位于其两侧部的呈弧形状的第一变形壁3311，两个第一变形壁3311由上至下逐渐靠拢且在末端形成细长状的第一切口3312，第一阀门331连通流奶端和储奶瓶2；第二阀门332包括位于其两侧部的呈弧形状的第二变形壁3321，两个第二变形壁3321由上至下逐渐靠拢且在末端形成细长状的第二切口3322，第二阀门332连通外界大气压和储奶瓶2。该鸭嘴阀33由食品级材质的液态硅胶制成，其有较优的密封性、抗撕裂强度、回弹性、抗变黄性、热稳定性、耐热老化性以及耐压缩变形的特点。第一变形壁3311和第二变形壁3321的壁厚为0.4～0.6mm，变形壁设计的面积大而薄，保证易回弹且受力易变形。

[0039] 通过第一变形壁3311和第二变形壁3321的变形可轻松实现第一切口3312和第二切口3322的打开和关闭状态的切换。其中，第二阀门332与外界大气压连通，第二变形壁3321并未受到负压的挤压，因此处于常开状态，进而使得储奶瓶2维持透气状态，奶液可以不断地经第一切口3312流入至储奶瓶2；而第一阀门331跟随真空负压与常压之间的切换而打开或关闭。当三通32解除负压时，第一切口3312打开，奶液立即流入至储奶瓶2。当储奶瓶2发生晃动时，奶液从外侧挤压第一变形壁3311和第二变形壁3321，进而使得第一切口3312和第二切口3322关闭，奶液无法从储奶瓶2中流出，有效了防止了奶液的外漏和逆流。

[0040] 作为优选，第一阀门331和第二阀门332共同连接在密封垫333上，第一切口3312和第二切口3322均指向储奶瓶2的内腔，密封垫333的周边与储奶瓶2的端口密封贴合。当储奶瓶2螺纹连接在流奶端时，储奶瓶2的端口紧抵在密封垫333的下侧面，同时，螺接的方式可提供压力使得密封垫333的上侧面与流奶端紧贴，有效保证了流奶端与储奶瓶2之间的密封连接。同时，密封垫333的中部形成相互隔开的第一气压腔和第二气压腔，流奶端分别形成有插入至第一气压腔的第一连接部以及插入至第二气压腔的第二连接部，第一阀门331设置在第一气压腔的下端，第二阀门332设置在第二气压腔的下端，第一气压腔与流奶端相通，第二气压腔与外界大气压相通。第一气压腔和第一连接部过盈配合连接，第二气压腔与第二连接部过盈配合连接，可避免因第一阀门331和第二阀门332上端部变形过大而导致的阀门失效。

[0041] 图8和图9分别示出了吸奶器工作时鸭嘴阀33中的第一阀门331的状态示意图。图8中，气囊31处于自然状态，三通32内为常压，第一切口3312自然处于打开状态，汇集在流奶端的奶液经第一阀门331流入至储奶瓶2；图9中，气囊31处于负压贴合状态，三通32内为负压，第一切口3312在负压的挤压下处于闭合状态，吸出来的奶液汇入至流奶端且停留在第一阀门331前端。

[0042] 图13和图14均为哺乳妈妈穿戴上免手扶隐藏式吸奶器的效果示意图，该免手扶隐藏式吸奶器的确能很好的隐藏于文胸内，大大方便了哺乳妈妈在公共场所随意的吸奶。

[0043] 上面结合附图对本发明的实施方式作了详细说明，但是本发明不限于上述实施方式，在所述技术领域普通技术人员所具备的知识范围内，还可以在不脱离本发明宗旨的前提下作出各种变化。

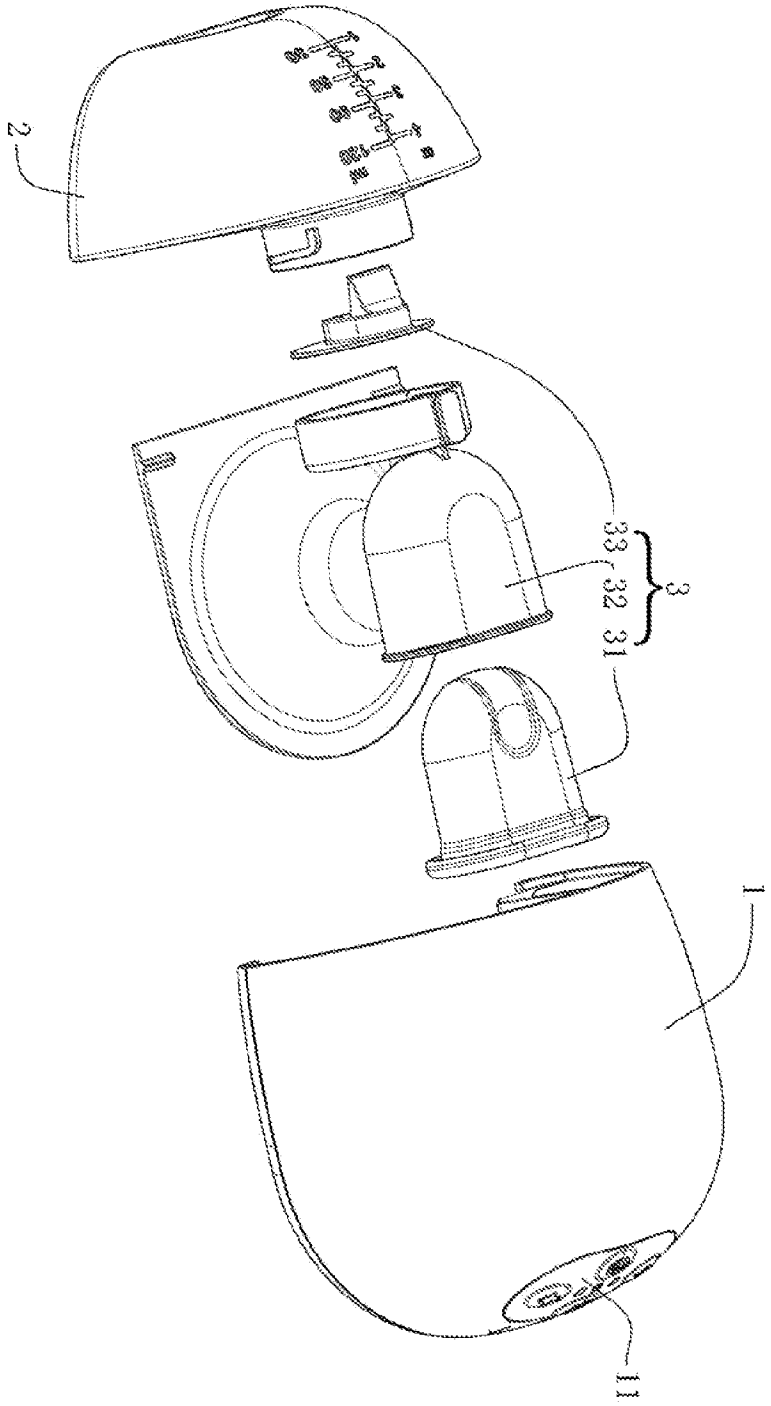


图1

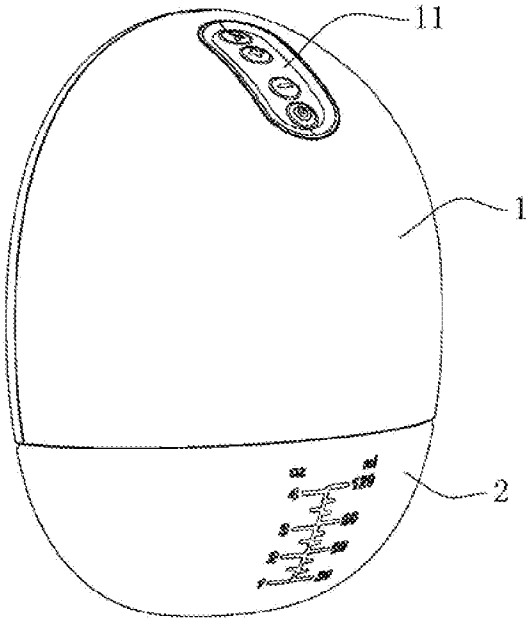


图2

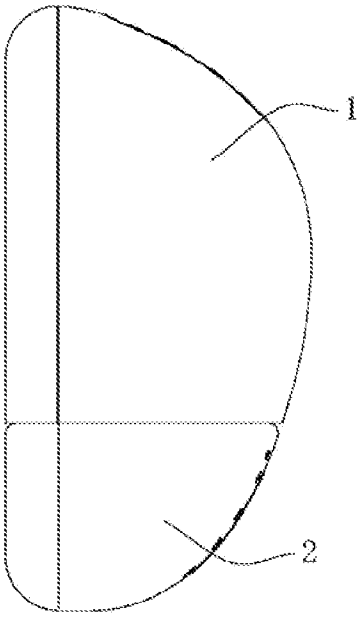


图3

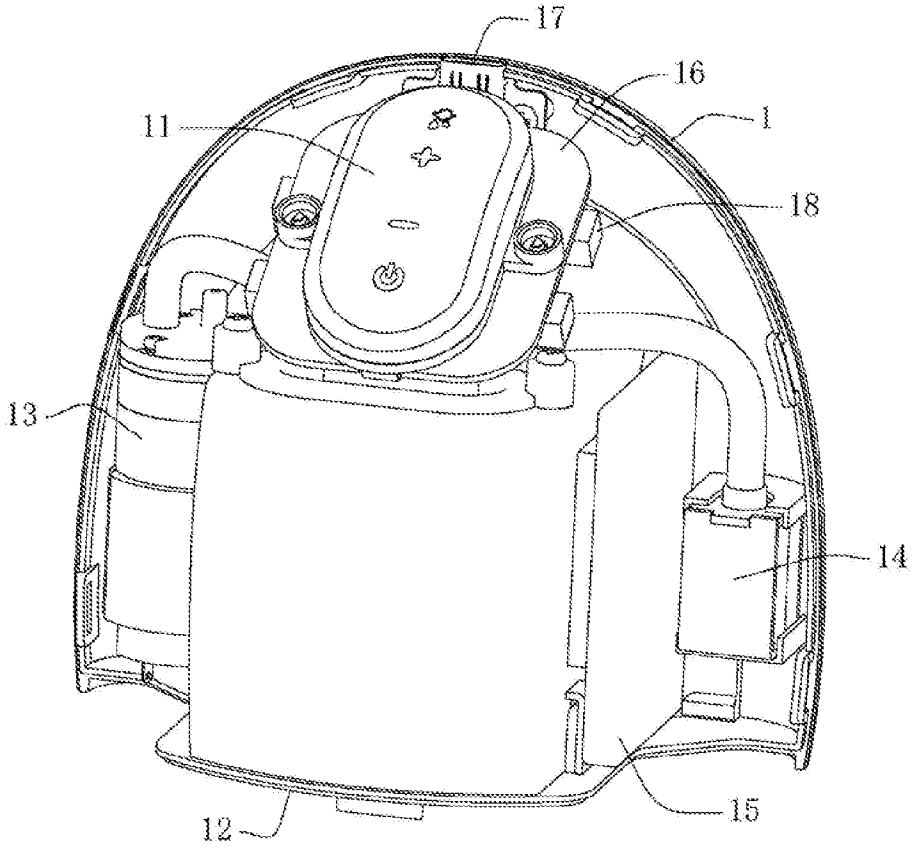
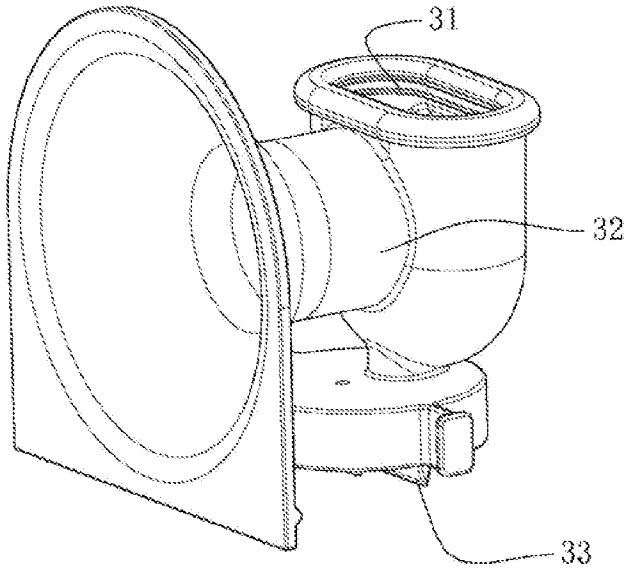


图4



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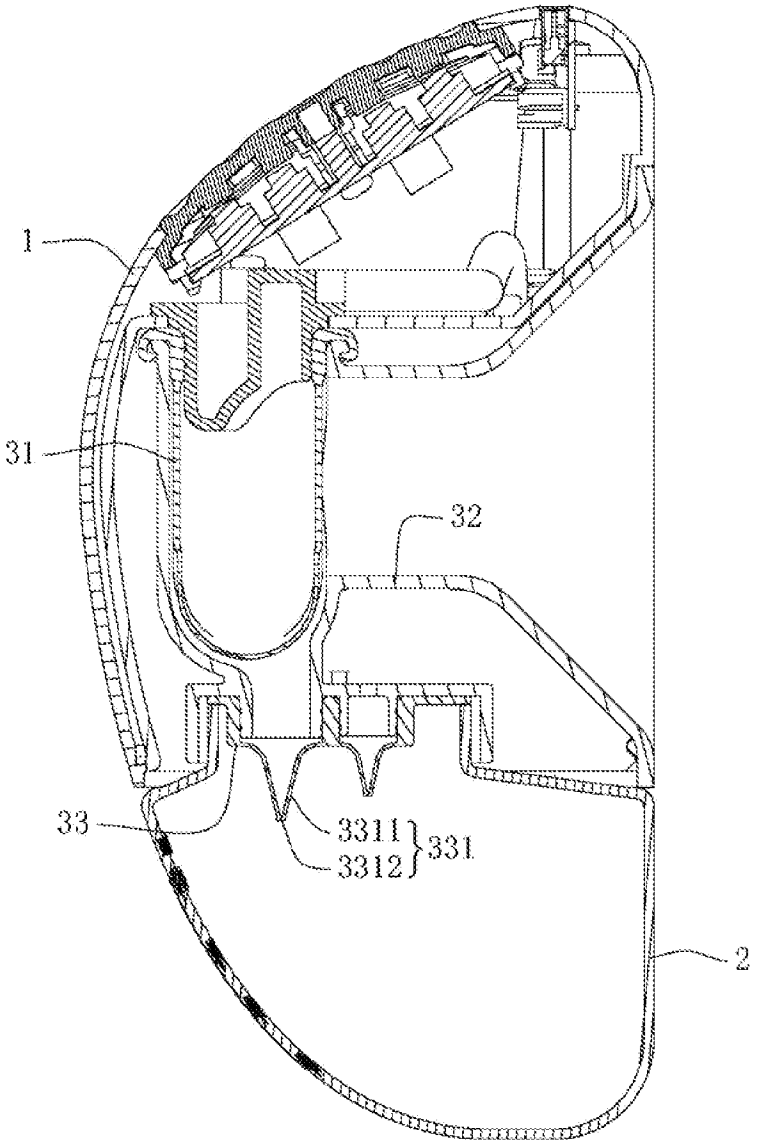

图6

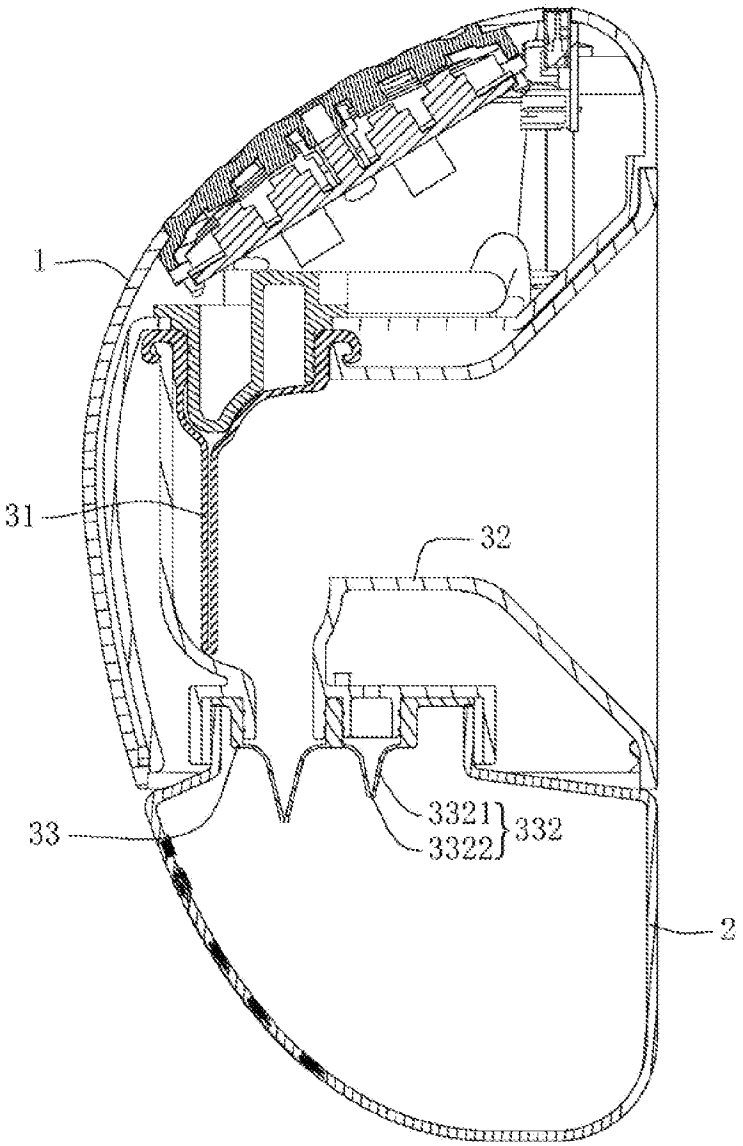

图7

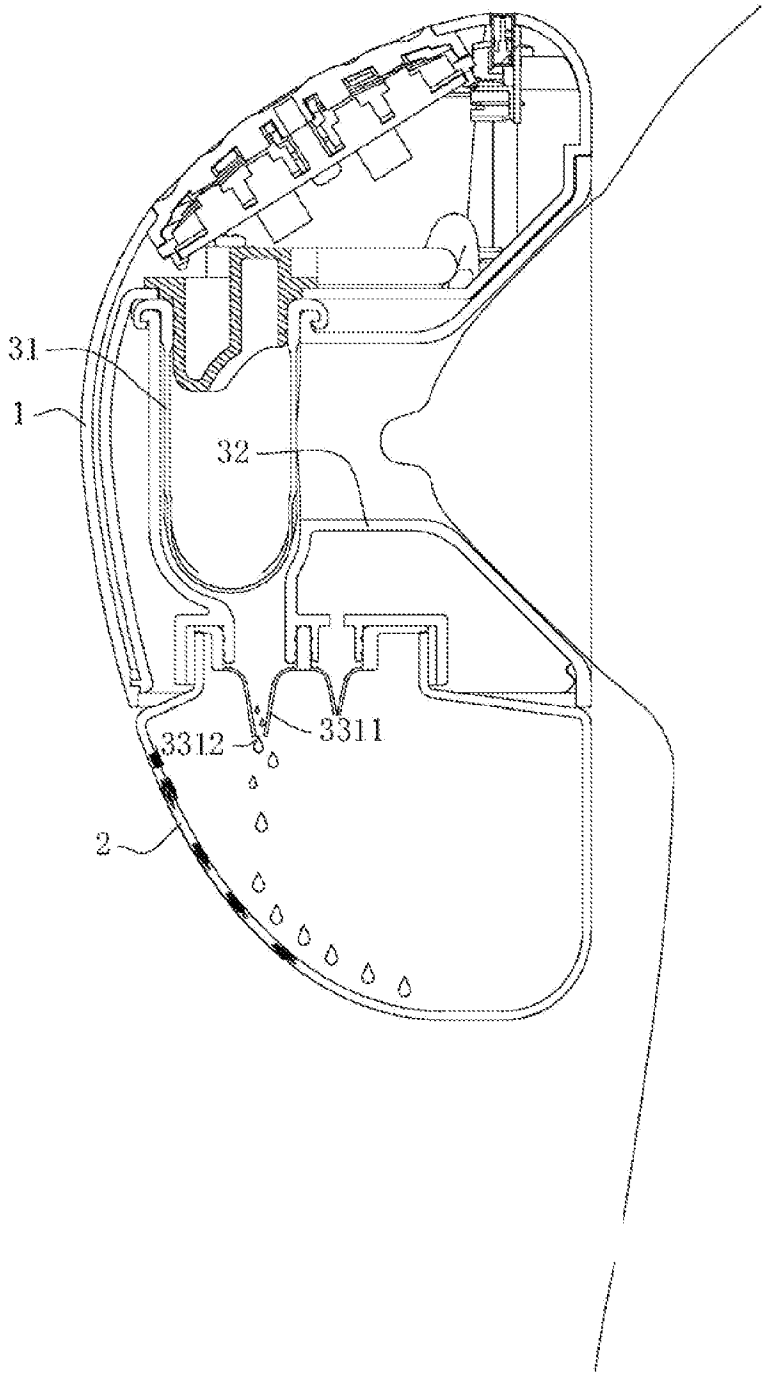

图8

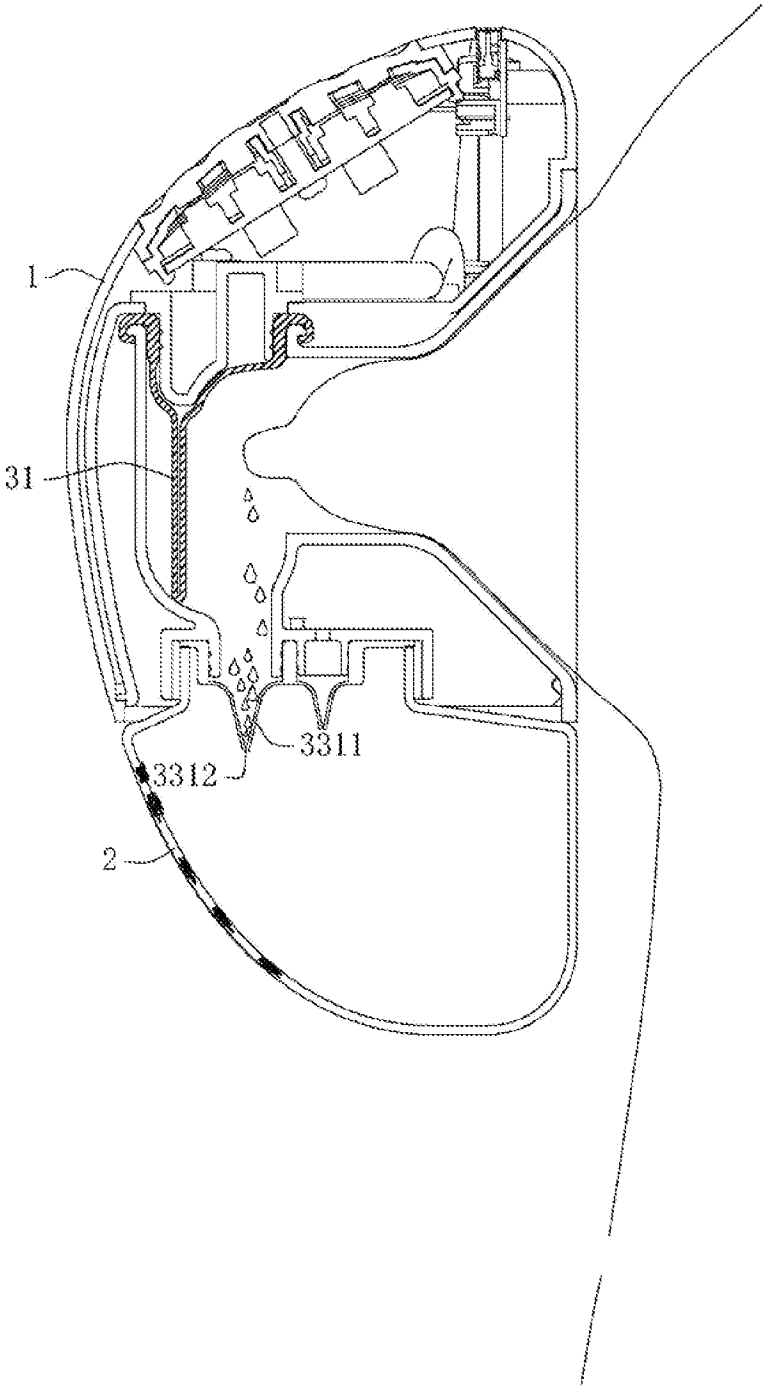

图9

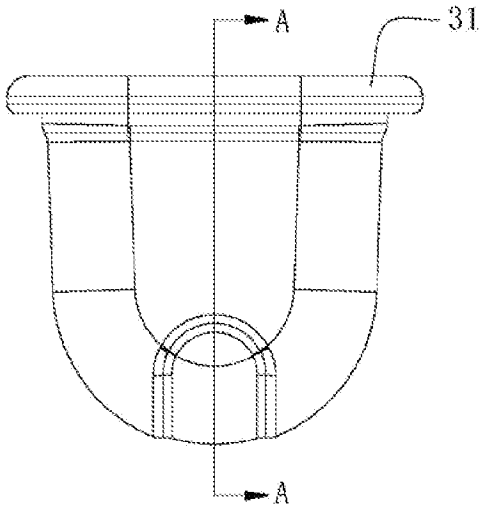

图10

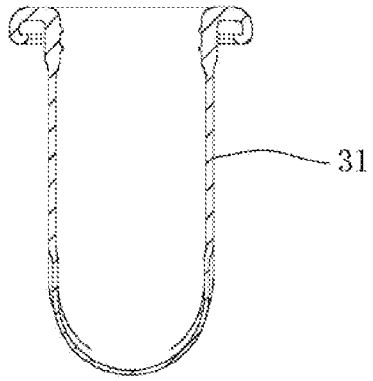

图11

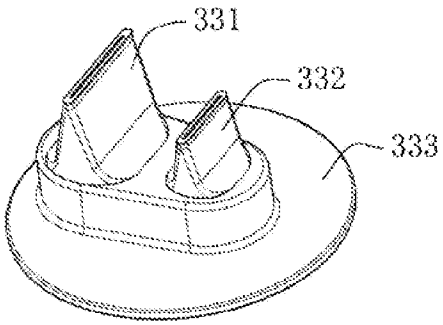

图12

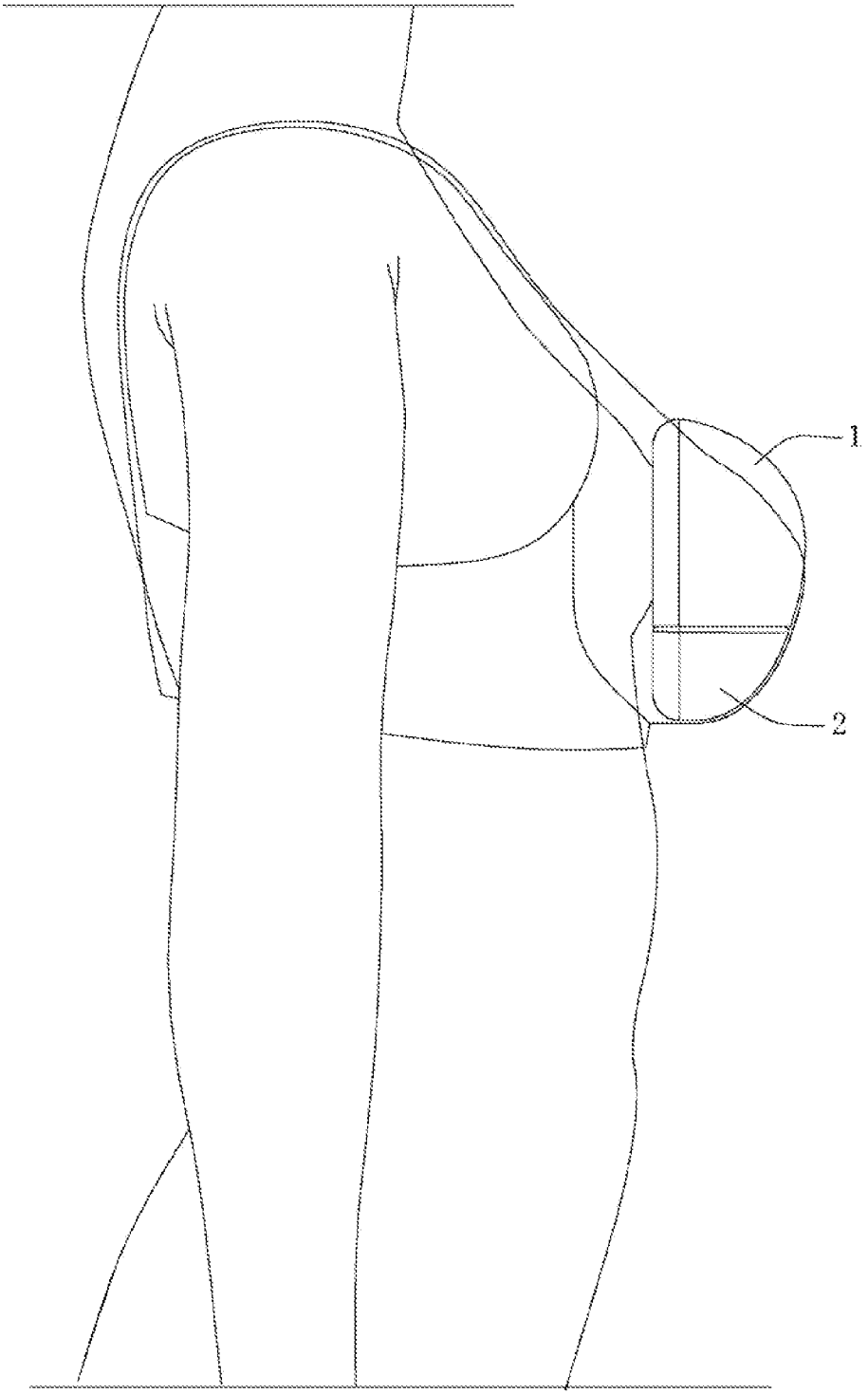

图13

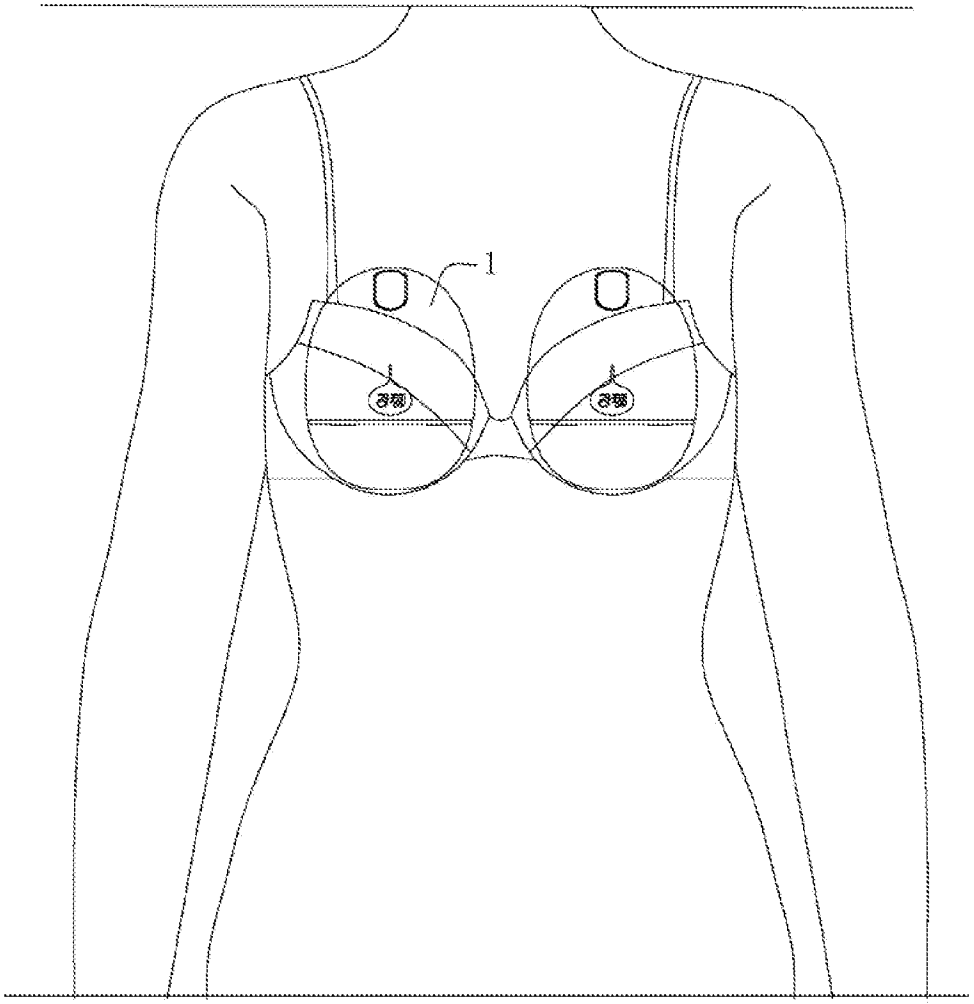

图14

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Printed name	Yangbeini Wang		
Date	March 26, 2024	Reg. No.	800,005

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PTO/SB/30 (11-17)
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Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDRICKSON, Courtney B.
Attorney Docket Number	4944.0120006

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. Submission required under 37 CFR 1.114 Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

   a. [✔] Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

      i. [ ] Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

      ii. [✔] Other Amendment and Reply Under 37 C.F.R. § 1.116 filed on February 12, 2024.

   b. [ ] Enclosed

      i. [ ] Amendment/Reply

      ii. [ ] Affidavit(s)/ Declaration(s)

      iii. [ ] Information Disclosure Statement (IDS)

      iv. [ ] Other _____

2. Miscellaneous

   a. [ ] Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

   b. [ ] Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

   a. [✔] The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 19-0036.

      i. [✔] RCE fee required under 37 CFR 1.17(e)

      ii. [✔] Extension of time fee (37 CFR 1.136 and 1.17)

      iii. [ ] Other _____

   b. [ ] Check in the amount of $ _____ enclosed

   c. [ ] Payment by credit card (Form PTO-2038 enclosed)

   d. [■] Payment by EFS-Web

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	/Yangbeini Wang #800,005/	Date	March 6, 2024
Name (Print/Type)	Yangbeini Wang	Registration No.	800,005

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being EFS-Web transmitted to the United States Patent and Trademark Office (USPTO), deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the USPTO on the date shown below.

Signature			
Name (Print/Type)		Date	

A Federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with an information collection subject to the requirements of the Paperwork Reduction Act of 1995, unless the information collection has a currently valid OMB Control Number. The OMB Control Number for this information collection is 0651-0031. Public burden for this form is estimated to average 12 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 or email InformationCollection@uspto.gov. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **If filing this completed form by mail, send to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDRICKSON, Courtney B.
Attorney Docket Number	4944.0120006

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
- ☑ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☑ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
  Request for Continued Examination Transmittal (PTO/SB/30EFS)

Remarks

Online Credit Card Authorization for $2,420.00 to cover:

$420.00 - 2nd Month Extension of Time Fee; $2,000.00 to cover the RCE Fee.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any over payment, to our Deposit Account No. 19-0036.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Yangbeini Wang #800,005/		
Printed name	Yangbeini Wang		
Date	March 6, 2024	Reg. No.	800,005

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Signature			
Typed or printed name		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**03/07/2024 06:43:16 PM Z ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Kim Perry
PATENT CENTER #	64597343	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 3

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2024-03-07-EOT-4944-0120006.pdf	1	Extension of Time	238 KB
2024-03-07-Transmittal-Form-4944-0120006.pdf	1	Transmittal Letter	201 KB
2024-03-07-RCE-4944-0120006.pdf	1	Request for Continued Examination (RCE)	265 KB

Warning: This is not a USPTO supplied RCE fillable form. Data in the form cannot be automatically loaded to other USPTO systems.

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)

2024-03-07-EOT-4944-0120006.pdf	6E0D3E9467891B0D673F8340A43625DA0FF54B3566AD15D5CD2D40AF73F53D7E774A95225B555D5A3E11C6C196AF2132BCA043740CCB42A80F31B18E98B13F69
2024-03-07-Transmittal-Form-4944-0120006.pdf	71FA5FE161B3FA7044FF914B88ABB74D7FE5E6E40C7F8F0BECE5F63FFDB477860BD9929E336A78A8C4101DDF1B032BC51F9F2FA6021B075CB68CE037631CE1FA
2024-03-07-RCE-4944-0120006.pdf	13EECAACB12EEF6F4DDF0E0230CE9C2BDC78670096174BC523B050AC50B6ACBCA158FB9E8825386E5A6D7C9F7B18BE36B76D3A6D9099EDFA00767D418473CAC3

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/AIA/22 (12-22)
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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional): 4944.0120006

Application Number: 17/181,057

Filed: 02/22/2021

For: BREAST PUMP SYSTEM

Art Unit: 3783

Examiner: FREDRICKSON, Courtney B.

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	Micro Entity Fee	
☐ One month (37 CFR 1.17(a)(1))	$220	$88	$44	$
☑ Two months (37 CFR 1.17(a)(2))	$640	$256	$128	$ 420
☐ Three months (37 CFR 1.17(a)(3))	$1,480	$592	$296	$
☐ Four months (37 CFR 1.17(a)(4))	$2,320	$928	$464	$
☐ Five months (37 CFR 1.17(a)(5))	$3,160	$1,264	$632	$

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 19-0036.

☑ Payment made via USPTO's patent electronic filing system (Patent Center or EFS-Web).

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant.

☑ attorney or agent of record. Registration number 800,005.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/Yangbeini Wang #800,005/
Signature

March 6, 2024
Date

Yangbeini Wang
Typed or printed name

(202) 371-2600
Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☐ * Total of _____ forms are submitted.

A Federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with an information collection subject to the requirements of the Paperwork Reduction Act of 1995, unless the information collection has a currently valid OMB Control Number. The OMB Control Number for this information collection is 0651-0031. Public burden for this form is estimated to average 6 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 or email InformationCollection@uspto.gov. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.** If filing this completed form by mail, send to: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**03/07/2024 06:43:16 PM Z ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Kim Perry
PATENT CENTER #	64597343	AUTHORIZED BY	Yangbeini Wang
CUSTOMER #	26111	FILING DATE	02/22/2021
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jonathan O'TOOLE

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 3007	**E202437I46249254**	**Kim Perry**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1252	EXTENSION FOR RESPONSE WITHIN SECOND MONTH	420.00	1	420.00
1820	REQUEST FOR CONTINUED EXAMINATION (RCE)- 2ND AND SUBSEQUENT REQUEST (SEE 37 CFR 1.114)	2000.00	1	2000.00
			TOTAL AMOUNT:	**$2,420.00**

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement

Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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ACKNOWLEDGEMENT OF LOSS OF ENTITLEMENT TO ENTITY STATUS DISCOUNT

APPLICATION #	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET #	REQUEST ID
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	177963

The entity status change request below filed through Patent Center on 03/07/2024 has been accepted.

Certifications

APPLICANT CHANGING TO REGULAR UNDISCOUNTED FEE STATUS

Signature

I certify, in accordance with 37 CFR 1.4(d)(4), that I am one of the signatories making the entity status change.

Signature	Name	Registration #
/Yangbeini Wang/	Yangbeini Wang	800005

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/181,057	Filing Date 02/22/2021	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $480 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	03/07/2024	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 30	Minus	** 30	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/MONIQUE BENJAMIN/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

26111 7590 02/22/2024

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1101 K Street, NW
10th Floor
WASHINGTON, DC 20005

EXAMINER
FREDRICKSON, COURTNEY B

ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
02/22/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

e-office@sternekessler.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 17/181,057	**Applicant(s)** O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	**Art Unit** 3783	**AIA (FITF) Status** Yes

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 February 2024 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☑ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:
   a) ☑ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection.The current period for reply expires ____ months from the mailing date of *the prior Advisory Action* or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.
   Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANTS FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37CFR 41.37(a).

AMENDMENTS

3. ☑ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   a) ☑ They raise new issues that would require further consideration and/or search (see NOTE below);
   b) ☐ They raise the issue of new matter (see NOTE below);
   c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: See Continuation Sheet (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☑ For purposes of appeal, the proposed amendment(s):(a) ☑ will not be entered, or (b) ☐ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____
9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☑ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: Further search and consideration of the proposed amendments is required..
13. ☑ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
14. ☑ Other: PTO-2323.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:
    Claim(s) allowed:_____.
    Claim(s) objected to:_____.
    Claim(s) rejected:1,3-22,24-25 and 28-34.
    Claim(s) withdrawn from consideration:_____.

/COURTNEY B FREDRICKSON/ Primary Examiner, Art Unit 3783	

Continuation of 3. NOTE: The amendment presents limitations which were not previously considered and which change the scope of the claim. Further time in excess of that allowed under the AFCP pilot is required to determine if the amendments would place the application in condition for allowance.

AFCP 2.0 Decision

Application No.	Applicant(s)	
17/181,057	O'TOOLE et al.	
Examiner	**Art Unit**	**AIA (FITF) Status**
COURTNEY FREDRICKSON	3783	Yes

This is in response to the After Final Consideration Pilot request filed 12 February 2024.

1. **Improper Request** – The AFCP 2.0 request is improper for the following reason(s) and the after final amendment submitted with the request will be treated under pre-pilot procedure.

   ☐ An AFCP 2.0 request form PTO/SB/434 (or equivalent document) was not submitted.

   ☐ A non-broadening amendment to at least one independent claim was not submitted.

   ☐ The request is not the first proper AFCP 2.0 request submitted in response to the most recent final rejection.

   ☐ Other: _____

2. **Proper Request**

   A. After final amendment submitted with the request will not be treated under AFCP 2.0.
   The after final amendment cannot be reviewed and a search conducted within the guidelines of the pilot program.

   ☑ The after final amendment will be treated under pre-pilot procedure.

   B. Updated search and/or completed additional consideration.
   The examiner performed an updated search and/or completed additional consideration of the after final amendment within the time authorized for the pilot program. The result(s) of the updated search and/or completed additional consideration are:

   ☐ 1. All of the rejections in the most recent final Office action are overcome and a Notice of Allowance is issued herewith.

   ☐ 2. The after final amendment would not overcome all of the rejections in the most recent final Office action . See attached interview summary for further details.

   ☐ 3. The after final amendment was reviewed, and it raises a new issue(s). See attached interview summary for further details.

   ☐ 4. The after final amendment raises new issues, but would overcome all of the rejections in the most recent final Office action. A decision on determining allowability could not be made within the guidelines of the pilot. See attached interview summary for further details, including any newly discovered prior art.

   ☐ 5. Other: _____

   Examiner Note: Please attach an interview summary when necessary as described above.

Amendment Under 37 C.F.R. § 1.116
Expedited Procedure – Art Unit 3783

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor**:** Jonathan O'Toole	Confirmation No.: 4690
Applicant: Chiaro Technology Limited	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, Courtney B.
Filing Date or 371(c) Date: February 22, 2021	Atty. Docket: 4944.0120006
Title: **BREAST PUMP SYSTEM**	

Amendment and Reply Under 37 C.F.R. § 1.116

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Mail Stop AF

Commissioner:

In reply to the Office Action dated **October 12, 2023**, Applicant submits the following Amendment and Remarks.

It is not believed that extensions of time are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any additional fees required to continue prosecution or appeal of this application (including issue fee, fees for net addition of claims or forwarding to appeal) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Equivalent of Form PTO/SB/08

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	2001/0044593 A1	11-22-2001	Lundy	
	US2	2009/0254028 A1	10-08-2009	Brittner	
	US3	2011/0144636 A1	06-16-2011	Alexander et al.	
	US4	2018/0154055 A1	06-07-2018	Alvarez et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.B.F./

Page 861 of 922

Equivalent of Form PTO/SB/08

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 2 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]

Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	02/13/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.B.F./

Equivalent of Form PTO/SB/08

Substitute for form 1449/PTO				Complete if Known	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	17/181,057
				Filing Date	02/22/2021
				First Named Inventor	Jonathan O'TOOLE
				Art Unit	3783
				Examiner Name	FREDERICKSON, Courtney B
Sheet	3	of	3	Attorney Docket Number	4944.0120006

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Yangbeini Wang #800,005 /	Date (YYYY-MM-DD)	2023-12-01
Name/Print	Yangbeini Wang	Registration Number	800,005

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.B.F./

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**02/12/2024 03:25:37 PM Z ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Rolonda Lee
PATENT CENTER #	64286342	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 6

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
2024-02-12-Request-AFCP-4944-0120006.pdf		2	After Final Consideration Program Request	203 KB
2024-02-12-Amendment-Reply-116-4944-0120006.pdf		12	-	251 KB
2024-02-12-Amendment-Reply-116-4944-0120006-A.NE.pdf	(1-1)	1	Response After Final Action	103 KB
2024-02-12-Amendment-Reply-116-4944-0120006-CLM.pdf	(2-6)	5	Claims	81 KB
2024-02-12-Amendment-Reply-116-4944-0120006-REM.pdf	(7-12)	6	Applicant Arguments/Remarks Made in an Amendment	238 KB

2024-02-12-Transmittal-Form-4944-0120006.pdf	1	Transmittal Letter	165 KB
2024-02-12-EOT-4944-0120006.pdf	1	Extension of Time	222 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2024-02-12-Request-AFCP-4944-0120006.pdf	D77CA6632710E4D6C4BAF96E4B201FAC9201A7D1BE55901722C548EEF7A44E5172F2D0FE4119268BC23B63E881F232D6ADBF4A699B2ABC562256C0B4F78166AA
2024-02-12-Amendment-Reply-116-4944-0120006.pdf	B09A28F30EB9A77EFA69CF59FB44EDD922F5AFF0CBEDE407A70E079F30AEE862A51619DF0FB80CB44E30AB75569714838161B69A1EFABEF15894948F9A27C617
2024-02-12-Amendment-Reply-116-4944-0120006-A.NE.pdf	070F37E929CC4DFF45941210EA75A73FADAFE7276D8B04405F79C0C39C891179FCB9D1407AB2F7FC60847E6E71D175A37C79481584968145220C4092118DCA04
2024-02-12-Amendment-Reply-116-4944-0120006-CLM.pdf	B943BE66F8AF7575B65011C291E486878F2BA405D8A95E22DC634B2A29DFE9AD158D35758F0BF3EEA81A562F7C5A8262BE64D8614699EF718F15FD0B298F9BD0
2024-02-12-Amendment-Reply-116-4944-0120006-REM.pdf	665A9D00775416E60C833D1A33427B539C8254CAF5D10CB09A1584CF671BD05C3F786EB319DEFD4C9ECB3467B231587ECD2EDAF4E3DCC4FF54899D5DEF9D48A5
2024-02-12-Transmittal-Form-4944-0120006.pdf	04D1C32F382AFC6E1027203CD46D140DE1330FE8BC00286F57CD649A04C778E8955050E34A41586A708A4702B91CF9A60E582D2CE35C66073C2836955659D064
2024-02-12-EOT-4944-0120006.pdf	29E841F0CC6976E66FDD602A587CDC7827CDA5FB3E3C357D81FB68E3E9BC561EB1D24911DC40F63F15F39A9E37313A4968EE4924C54B24C7E2D159BF5B7A30CC

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/AIA/22 (12-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional): 4944.0120006

Application Number: 17/181,057

Filed: 02/22/2021

For: BREAST PUMP SYSTEM

Art Unit: 3783

Examiner: FREDRICKSON, Courtney B.

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

		Fee	Small Entity Fee	Micro Entity Fee	
☑	One month (37 CFR 1.17(a)(1))	$220	$88	$44	$ 220
☐	Two months (37 CFR 1.17(a)(2))	$640	$256	$128	$
☐	Three months (37 CFR 1.17(a)(3))	$1,480	$592	$296	$
☐	Four months (37 CFR 1.17(a)(4))	$2,320	$928	$464	$
☐	Five months (37 CFR 1.17(a)(5))	$3,160	$1,264	$632	$

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 19-0036.

☑ Payment made via USPTO's patent electronic filing system (Patent Center or EFS-Web).

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant.

☑ attorney or agent of record. Registration number 800,005.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/Yangbeini Wang #800,005/ — Signature

February 8, 2024 — Date

Yangbeini Wang — Typed or printed name

(202) 371-2600 — Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☐ * Total of _____ forms are submitted.

A Federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with an information collection subject to the requirements of the Paperwork Reduction Act of 1995, unless the information collection has a currently valid OMB Control Number. The OMB Control Number for this information collection is 0651-0031. Public burden for this form is estimated to average 6 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 or email InformationCollection@uspto.gov. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.** If filing this completed form by mail, send to: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

PTO/SB/21 (07-09)
Approved for use through 12/31/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDRICKSON, Courtney B.
Attorney Docket Number	4944.0120006

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
- ☑ Fee Attached
- ☑ Amendment/Reply
- ☑ After Final
- ☐ Affidavits/declaration(s)
- ☑ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
- ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation
- ☐ Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
- ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please identify below):

Certification and Request for Consideration Under the After Final Consideration Pilot Program 2.0

Remarks

Online Credit Card Authorization for $220.00 to cover the 1 Month Extension of Time Fee.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any over payment, to our Deposit Account No. 19-0036.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Yangbeini Wang #800,005/		
Printed name	Yangbeini Wang		
Date	February 8, 2024	Reg. No.	800,005

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**02/12/2024 03:25:37 PM Z ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Rolonda Lee
PATENT CENTER #	64286342	AUTHORIZED BY	Yangbeini Wang
CUSTOMER #	26111	FILING DATE	02/22/2021
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jonathan O'TOOLE

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 1005	**E20242BF27016926**	**Rolonda Lee**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1251	EXTENSION FOR RESPONSE WITHIN FIRST MONTH	220.00	1	220.00
			TOTAL AMOUNT:	**$220.00**

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage

submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Amendment Under 37 C.F.R. § 1.116
Expedited Procedure – Art Unit 3783

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor**:** Jonathan O'Toole	Confirmation No.: 4690
Applicant: Chiaro Technology Limited	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, Courtney B.
Filing Date or 371(c) Date: February 22, 2021	Atty. Docket: 4944.0120006
Title: **BREAST PUMP SYSTEM**	

Amendment and Reply Under 37 C.F.R. § 1.116

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Mail Stop AF

Commissioner:

In reply to the Office Action dated **October 12, 2023**, Applicant submits the following Amendment and Remarks.

It is not believed that extensions of time are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any additional fees required to continue prosecution or appeal of this application (including issue fee, fees for net addition of claims or forwarding to appeal) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently Amended) A breast pump device comprising:

a housing comprising:

a battery, and

a pump configured to generate negative air pressure;

a breast shield of a plurality of interchangeable breast shields, each of the plurality of interchangeable breast shields having a different size and being configured to slide in and out of the housing, the breast shield comprising a breast flange and a nipple tunnel comprising a side wall and a front end, and ~~fit lines~~ guide lines, wherein the breast shield is transparent or optically clear; and

a milk container configured to be attached to and removed from the housing,

wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast, and

wherein the ~~fit lines~~ guide lines are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved and to visually define a correct spacing of the nipple from the side wall of the nipple tunnel.

2. (Canceled)

3. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is rigid.

4. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is a dishwasher safe, plastic breast shield.

5. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to be attached using magnets to the housing.

6. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast.

7. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to present, in use, a single continuous surface to a nipple and a breast.

8. (Previously Presented) The breast pump device of claim 1, wherein the breast flange and the nipple tunnel are integrally formed.

9. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to be generally symmetrical about a center-line running from a top to a bottom of the breast shield when positioned upright for normal use.

10. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to slide into the housing with a single push action.

11. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to slide out from the housing, together with a membrane that is configured to prevent milk from flowing into the pump.

12. (Previously Presented) The breast pump device of claim 1, wherein the milk container is rigid.

13. (Previously Presented) The breast pump device of claim 1, wherein the milk container is an optically clear, dishwasher safe, plastic milk container.

14. (Previously Presented) The breast pump device of claim 1, wherein the milk container is configured to attach to a lower part of the housing and forms a base of the breast pump device.

15. (Previously Presented) The breast pump device of claim 1, wherein the milk container is configured to magnetically attach to the housing.

16. (Currently Amended) The breast pump device of claim 1, wherein the ~~fit lines~~ guide lines are configured to run parallel along one or more sides of the nipple tunnel.

17. (Previously Presented) The breast pump device of claim 1, wherein the nipple tunnel comprises an air hole or passage, and wherein the pump is configured to transfer negative air pressure into the nipple tunnel via the air hole or passage.

18. (Previously Presented) The breast pump device of claim 1, wherein the nipple tunnel comprises on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container.

19. (Previously Presented) The breast pump device of claim 1, wherein the pump comprises one or more piezo air pumps.

20. (Previously Presented) The breast pump device of claim 1, wherein the housing further comprises a Universal Serial Bus (USB) charging socket.

21. (Previously Presented) The breast pump device of claim 1, wherein the housing comprises a left or right breast selector or toggle switch that, when selected for a particular pumping session, is configured to send data to a connected application configured to track pumping sessions, to indicate whether that particular session is associated with a left or a right breast.

22. (Previously Presented) The breast pump device of claim 1, wherein the housing is configured to be shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra.

23. (Canceled)

24. (Previously Presented) The breast pump device of claim 1, wherein the breast pump device is configured to deliver a maximum suction of approximately 240 mmHg.

25. (Previously Presented) The breast pump device of claim 1, wherein the breast pump device comprises a sensor that is configured to directly measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container.

26. (Canceled)

27. (Canceled)

28. (Previously Presented) The breast pump device of claim 1, wherein the pump is configured to deliver in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

29. (Previously Presented) The breast pump device of claim 1, wherein the pump is a lightweight air pump that enables a total mass of the breast pump device, unfilled with milk, to be less than 250 gm.

30. (Previously Presented) The breast pump device of claim 1, wherein the breast pump device is configured to make less than 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

31. (Previously Presented) A kit, comprising:

the breast pump device of claim 1; and

the plurality of interchangeable breast shields.

32. (Currently Amended) The kit of claim 31, wherein the ~~fit lines~~ guide lines are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel.

33. (Previously Presented) The breast pump device of claim 1, wherein the battery is a rechargeable battery, and wherein the housing further comprises:

a power charging circuit configured to control the charging of the rechargeable battery, and

control electronics configured to be powered by the rechargeable battery.

34. (Previously Presented) The breast pump device of claim 1, wherein a length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same.

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1, 3–22, 24, 25, and 28–34 are pending in the application. Claim 1 is an independent claim. Claims 1, 16, and 32 are amended. These changes introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Office reconsider all outstanding rejections and that they be withdrawn.

Allowable Subject Matter

Applicant thanks the Examiner for indicating that claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Office Action 37. Upon entry of above amendment and based on the following remarks, Applicant respectfully submits that all pending claims are in condition for allowance.

Rejections under 35 U.S.C. § 103

Independent claim 1

Claims 1, 3, 6–8, 10, 11, 14, 16–18, 22, 24, 31, 32, and 34 are rejected under 35 U.S.C. § 103 as unpatentable over U.S. Applicant No. 2008/0275386 to Myers, in view of EP 2502640 to Cook et al., and in further view of U.S. Patent Applicant Publication No. 2002/0198489 to Silver et al.

Claims 1, 6–10, 14, 17, 18, 20, 22, 31, 32, and 34 are rejected under 35 U.S.C. § 103 as unpatentable over U.S. Patent Applicant Publication No. 2013/0023821 to Khalil et al. in view of Myers, in view of Cook, and further in view of Silver.

Without agreeing to the propriety of the rejections, claim 1 is amended and now recites, "wherein the guide lines are configured to be aligned with the outside of the nipple when a correct

nipple alignment is achieved and to visually define a correct spacing of the nipple from the side wall of the nipple tunnel." The applied references do not teach or suggest at least this feature of claim 1.

The Office acknowledges that Myers, Cook, and Khalil do not teach that the nipple tunnel comprises a guide line configured to define the spacing of the nipple from the side wall of the nipple tunnel, and only relies on Sliver for this feature. Office Action, 6–8 and 11–13.

Silver discloses a breastshield 1095 formed with a skeletal frame, and the skeletal frame comprises a series of stiffening longitudinally extending ribs 1160, 1164, and 1166, which allegedly correspond to the recited guide lines. Silver, FIG. 28; Office Action, 8. However, Silver is silent on how ribs 1160, 1164, and 1166 can define a correct spacing of the nipple from the side of the nipple tunnel.

The Office in response contends that the ribs of Silver is configured to define a corrected space of the nipple from the side of the nipple tunnel because if a user *feels* the ribs against the breast/nipple, it signals that the breast shield is improperly sized. Office Action, 3. The ribs of Silver, however, does not *visually* define a correct spacing of the nipple from the side wall of the nipple tunnel, as recited in amended claim 1.

In addition, claim 1 recites, "a breast shield of a plurality of interchangeable breast shields, each of the plurality of interchangeable breast shields having a different size." The person of skill in the art would have understood that on breast shields of different sizes, the guide lines that visually define a correct spacing of the nipple from the side wall of the nipple tunnel would be positioned differently, as shown in FIG. 14 of the present application (reproduced below). In contrast, the ribs of Silver, as the skeletal frame for structural support, would not be positioned differently on differently sized breast shields. Indeed, Silver does not discloses a plurality of interchangeable breast shields having different sizes, so Silver does not provide the motivation to position the ribs on different locations as a visual signal reflecting differently sized breast shields.

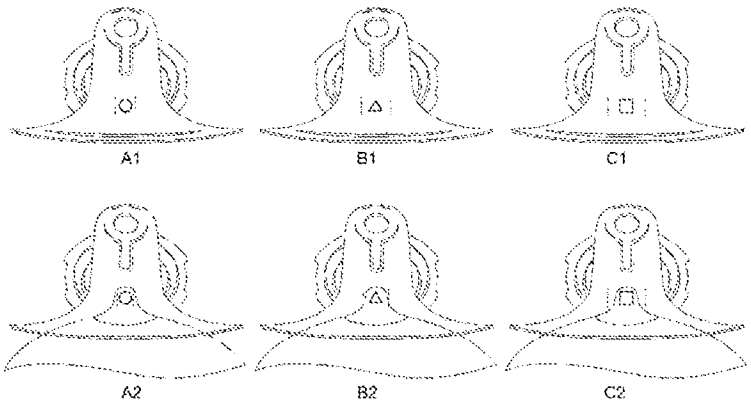

FIG. 14 of Present Application

Accordingly, amended claim 1 and its dependent claims would not have been obvious over the applied references. Applicant respectfully requests reconsideration and withdrawal of the § 103 rejections of claims 1, 3, 6–10, 11, 14, 16–18, 20, 22, 24, 31, 32, and 34.

Dependent claims

Claim 4 is rejected under 35 U.S.C. § 103 as unpatentable over Myers in view of Cook in view of Silver and further in view of U.S. Patent Application Publication No. 2005/0228342 to Yuen.

Claim 5 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers in view of Cook in view of Silver and further in view of U.S. Patent Applicant Publication No. 2018/0333523 to Chang et al.

Claims 12 and 13 are rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers in view of Cook in view of Silver and further in view of U.S. Patent Applicant Publication No. 2016/0296682 to Phillips et al.

Claim 15 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers in view of Cook in view of Silver as applied and in further view of U.S. Patent Applicant Publication No. 2007/0228059 to Karsan.

Claim 19 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers in view of Cook in view of Silver and further in view of U.S. Patent Applicant Publication No. 2012/0277636 to Blondheim et al.

Claims 20 and 21 are rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers in view of Cook in view of Silver and further in view of U.S. Patent Applicant Publication No. 2014/0378895 to Barak.

Claim 25 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers in view of Cook in view of Silver and further in view of U.S. Patent Applicant Publication No. 2016/0220743 to Guthrie et al.

Claim 29 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers in view of Cook in view of Silver and further in view of U.S. Patent No. 6,227,936 to Mendoza.

Claim 30 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers in view of Cook in view of Silver and further in view of U.S. Patent Applicant Publication No. 2009/0281485 to Baker et al.

Claim 33 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers in view of Cook in view of Silver as applied and further in view of U.S. Patent No. 5,542,921 to Meyers ("Meyers '921").

Each of claims 4, 5, 12, 13, 15, 19–21, 25, 29, 30, and 33 depends from and adds features to independent claim 1. The additionally applied references do not overcome the deficiencies of Myers, Cook, Silver, and Khalil as discussed above. Accordingly, claims 4, 5, 12, 13, 15, 19–21, 25, 29, 30, and 33 would not have been obvious over the applied references. Applicant respectfully requests reconsideration and withdrawal of the § 103 rejections of claims 4, 5, 12, 13, 15, 19–21, 25, 29, 30, and 33.

Double Patenting Rejection

Claims 1, 3–22, 24, 25, and 29–34 are rejected on the grounds of non-statutory obviousness type double patenting based on the following patents and applications in view of Myers, Cook, and Silver.

- U.S. Applicant No. 17/203050 (U.S. Patent No. 11357893)
- U.S. Applicant No. 17/203079 (U.S. Patent No. 11376352)
- U.S. Applicant No. 17/203216 (U.S. Patent No. 11357894)
- U.S. Applicant No. 17/203259 (U.S. Patent No. 11324866)
- U.S. Applicant No. 17/203327 (U.S. Patent No. 11413380)

Claims 1, 3–22, 24, 25, and 28–34 are rejected on the grounds of non-statutory obviousness type double patenting based on the following patents and applications in view of Myers and Cook, and Silver.

- U.S. Applicant No. 17/203109 (U.S. Patent No. 11260151)
- U.S. Applicant No. 17/203313 (U.S. Patent No. 11311654)

Claims 1, 3–22, 24, 25, and 29–34 are rejected on the grounds of non-statutory obviousness type double patenting based on the following patents and applications in view of Myers, Cook, and Silver. Office Action, 34–38.

- U.S. Applicant No. 17/203150
- U.S. Applicant No. 17/203179
- U.S. Applicant No. 17/203292
- U.S. Applicant No. 17/203355
- U.S. Applicant No. 17/203384
- U.S. Applicant No. 17/203397
- U.S. Applicant No. 17/203418

Applicant respectfully requests that the currently asserted double patenting rejections be held in abeyance until the claimed subject matter is otherwise deemed allowable. After analyzing the final allowed claim scope, Applicant will consider filing a terminal disclaimer if necessary to overcome any obviousness-type double patenting rejections.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Office reconsider all presently outstanding rejections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Office believes, for any reason, that personal communication will expedite prosecution of this application, the Office is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Yangbeini Wang #800,005/

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21115358.1

Doc Code: A.NE.AFCP
Document Description: After Final Consideration Pilot Program Request

PTO/SB/434 (05-13)

CERTIFICATION AND REQUEST FOR CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0

Practitioner Docket No.:	Application No.:	Filing Date:
4944.0120006	17/181,057	02/22/2021
First Named Inventor:	**Title:**	
Jonathan O'TOOLE	BREAST PUMP SYSTEM	

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 (AFCP 2.0) OF THE ACCOMPANYING RESPONSE UNDER 37 CFR 1.116.

1. The above-identified application is (i) an original utility, plant, or design nonprovisional application filed under 35 U.S.C. 111(a) (a continuing application (*e.g.*, a continuation or divisional application) is filed under 35 U.S.C. 111(a) and is eligible under (i)), or (ii) an international application that has entered the national stage in compliance with 35 U.S.C. 371(c).
2. The above-identified application contains an outstanding final rejection.
3. Submitted herewith is a response under 37 CFR 1.116 to the outstanding final rejection. The response includes an amendment to at least one independent claim, and the amendment does not broaden the scope of the independent claim in any aspect.
4. This certification and request for consideration under AFCP 2.0 is the only AFCP 2.0 certification and request filed in response to the outstanding final rejection.
5. Applicant is willing and available to participate in any interview requested by the examiner concerning the present response.
6. This certification and request is being filed electronically using the Office's electronic filing system (EFS-Web).
7. Any fees that would be necessary consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, extension of time fees, are being concurrently filed herewith. [There is no additional fee required to request consideration under AFCP 2.0.]
8. By filing this certification and request, applicant acknowledges the following:
   - Reissue applications and reexamination proceedings are not eligible to participate in AFCP 2.0.
   - The examiner will verify that the AFCP 2.0 submission is compliant, *i.e.*, that the requirements of the program have been met (see items 1 to 7 above). For compliant submissions:
     - The examiner will review the response under 37 CFR 1.116 to determine if additional search and/or consideration (i) is necessitated by the amendment and (ii) could be completed within the time allotted under AFCP 2.0. If additional search and/or consideration is required but cannot be completed within the allotted time, the examiner will process the submission consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, by mailing an advisory action.
     - If the examiner determines that the amendment does not necessitate additional search and/or consideration, or if the examiner determines that additional search and/or consideration is required and could be completed within the allotted time, then the examiner will consider whether the amendment places the application in condition for allowance (after completing the additional search and/or consideration, if required). If the examiner determines that the amendment does not place the application in condition for allowance, then the examiner will contact the applicant and request an interview.
       - The interview will be conducted by the examiner, and if the examiner does not have negotiation authority, a primary examiner and/or supervisory patent examiner will also participate.
       - If the applicant declines the interview, or if the interview cannot be scheduled within ten (10) calendar days from the date that the examiner first contacts the applicant, then the examiner will proceed consistent with current practice concerning responses after final rejection under 37 CFR 1.116.

Signature	Date
/Yangbeini Wang #800,005/	February 8, 2024
Name (Print/Typed) Yangbeini Wang	**Practitioner Registration No.** 800,005

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.*

☐ * Total of _____ forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/181,057	Filing Date 02/22/2021	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $240 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	02/12/2024	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 30	Minus	** 30	= 0		x $40 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $192 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	PROGRAM SUPPORT SPECIALIST
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/FIKIRTE A GEREMEW/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Amendment Under 37 C.F.R. § 1.116
Expedited Procedure – Art Unit 3783

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor**:** Jonathan O'Toole	Confirmation No.: 4690
Applicant: Chiaro Technology Limited	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, Courtney B.
Filing Date or 371(c) Date: February 22, 2021	Atty. Docket: 4944.0120006
Title: **BREAST PUMP SYSTEM**	

Amendment and Reply Under 37 C.F.R. § 1.116

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Commissioner:

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Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

Total Number of Pages in This Submission

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
- ☑ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☑ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) (please Identify below):

Remarks

The Office may charge any fee deficiency for any submission made with this transmittal to Deposit Account 19-0036.

Online Credit Card Payment Authorization in the Amount of $104.00 to Cover:
$104.00 - Information Disclosure Statement fee

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Yangbeini Wang #800,005/		
Printed name	Yangbeini Wang		
Date	December 1, 2023	Reg. No.	800,005

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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UNITED STATES
PATENT AND TRADEMARK OFFICE

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**12/01/2023 03:27:11 PM Z ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	63458258	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 3

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-12-01-Transmittal-Form-sIDS-4944-0120006.pdf	1	Miscellaneous Incoming Letter	161 KB
2023-12-01-sIDS-Pleading-4944-0120006.pdf	3	Transmittal Letter	98 KB
2023-12-01-sIDS-Form-SB08-4944-0120006.pdf	3	Information Disclosure Statement (IDS) Form (SB08)	146 KB

Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-12-01-Transmittal-Form-sIDS-4944-0120006.pdf	42A213C30FDFC9CBAFB29ED3858F85EC0E4F8E03DB5F0B3B17526420960D0A10E35622FF1E94CCB48AF49461E1D59C957E5C1953F97A9A4A89F13088B96B97A2
2023-12-01-sIDS-Pleading-4944-0120006.pdf	DC8DAB7C8ABD72459EF6C4E63D1912880F3406BDEFED2DCDFE1C9698398A195661574BA2246B9AF3C9CBB38C89556F7455A4BDE36E527DEA63DF43123B48CE9D
2023-12-01-sIDS-Form-SB08-4944-0120006.pdf	1023928D0A85853F6ABAFCC5D3BED061D344D45646182E7BA0289541BC2BD007BAA366ACA822A5DDA55AD186186C18424C13C4D5A8D95D1385819AB3859814AF

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: CHIARO TECHNOLOGY LIMITED	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, COURTNEY B
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Supplemental Information Disclosure Statement

Mail Stop AF

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

Listed on accompanying IDS Forms PTO/SB/08a or its equivalent and PTO/SB/08b or its equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Applicant has listed dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(c) and is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an

action that otherwise closes prosecution in the application. The required fee is provided through online credit card payment authorization in the amount of **$104.00** in payment of the fee under 37 C.F.R. § 1.17(p); in addition:

> I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), no copies of the U.S. patents and patent application publications cited on the attached IDS Forms are submitted.

It is expected that the examiner will review the prosecution and cited art in the parent Application No. 16/009,547, filed June 15, 2018, in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Yangbeini Wang #800,005/

Yangbeini Wang
Attorney for Applicant
Registration No. 800,005

Date: December 1, 2023

1101 K Street, NW
10th Floor
Washington, D.C. 20005
Main: 202-371-2600
Direct: 202-772-8833

21279079.1

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	2001/0044593 A1	11-22-2001	Lundy	
	US2	2009/0254028 A1	10-08-2009	Brittner	
	US3	2011/0144636 A1	06-16-2011	Alexander et al.	
	US4	2018/0154055 A1	06-07-2018	Alvarez et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 2 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO				Complete if Known	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	17/181,057
				Filing Date	02/22/2021
				First Named Inventor	Jonathan O'TOOLE
				Art Unit	3783
				Examiner Name	FREDERICKSON, Courtney B
Sheet	3	of	3	Attorney Docket Number	4944.0120006

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Yangbeini Wang #800,005 /	Date (YYYY-MM-DD)	2023-12-01
Name/Print	Yangbeini Wang	Registration Number	800,005

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	12/01/2023 03:27:11 PM Z ET	4944.0120006

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	63458258	AUTHORIZED BY	Yangbeini Wang
CUSTOMER #	26111	FILING DATE	02/22/2021
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jonathan O'TOOLE

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 1008	E2023B1F28228758	Jon Baitlon

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2806	SUBMISSION OF AN INFORMATION DISCLOSURE STATEMENT	104.00	1	104.00
			TOTAL AMOUNT:	$104.00

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

26111 7590 10/12/2023

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1101 K Street, NW
10th Floor
WASHINGTON, DC 20005

EXAMINER	
FREDRICKSON, COURTNEY B	

ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
10/12/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

e-office@sternekessler.com

Office Action Summary	Application No. 17/181,057	Applicant(s) O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	Art Unit 3783	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 30June2023.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1,3-22,24-25 and 28-34 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1,3-22,24-25 and 28-34 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 22February2021 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☑ All b)☐ Some** c)☐ None of the:

1.☑ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Response to Amendment

This office action is responsive to the amendment filed on June 30, 2023. As directed by the amendment: claims 1, 16, and 32 have been amended. Thus, claims 1, 3-22, 24, 25, and 238-34 are presently pending in this application.

Applicant's amendments to the Specification, Drawings, and Claims have overcome each and every objection and 112(b) rejections previously set forth in the Non-Final Office Action mailed March 30, 2023.

Response to Arguments

Applicant's arguments filed June 30, 2023 have been fully considered but they are not persuasive.

Applicant argues on pg. 8 of the Remarks that "*Silver is silent on how ribs 1160, 1164, and 1166 can define a correct spacing of the nipple from the side of the nipple tunnel or assist with correct nipple alignment. Furthermore, Silver does not disclose that ribs 1160, 1164, and 1166 are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved*". The examiner respectfully disagrees and notes that the claim is not directed towards guide lines which define a correct spacing of the nipple from the side of the nipple tunnel. The claims are merely drawn to fit lines which are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved. The examiner further notes that "correct nipple alignment" is

also not further defined. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the case of Silver, the longitudinal ribs (1160, 1164, and 1166 in fig. 28) are capable of being positioned so that the ribs are alongside the outside of the nipple when the shield is fitted onto a breast when the nipple is "correctly" aligned with this correct alignment being the nipple received in the nipple tunnel. Additionally, the ribs of Silver are fully configured to define a correct spacing of the nipple from the side of the nipple tunnel and to signify to a user that the shield is sized for a nipple of the user. As seen in fig. 28, the ribs are shown to be positioned interior to the shield (see dotted lines in fig. 28). A user would be able to see (Myers discloses the shield is transparent, paragraph 65) and feel the ribs to ascertain if the shield is too small. For example, if a user feels the ribs against the breast/nipple, this could signal to a user that the shield is improperly sized for their nipples. For this reason, the rejection is maintained.

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

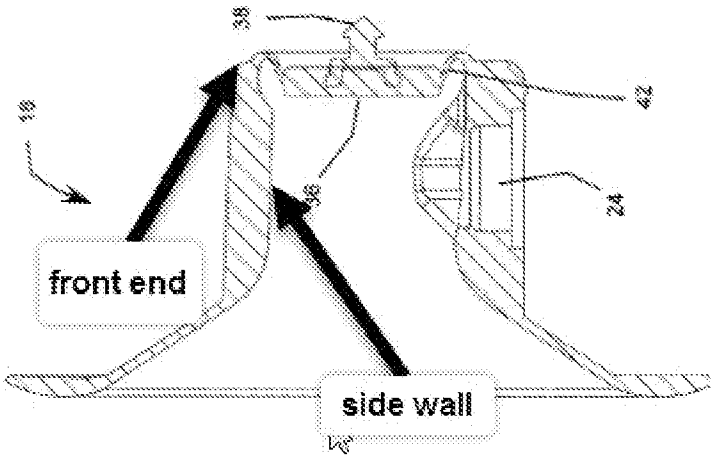
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 6-8, 10, 11, 14, 16-18, 22, 24, 31, 32, and 34 is/are rejected under 35 U.S.C. 103 as being unpatentable over Myers (US 20080275386) and in further view of Cook (EP 2502640) and in further view of Silver (US 20020198489).

Regarding claim 1, Myers discloses a breast pump device comprising:

(i) a housing (outer housing 16 in fig. 1) comprising (a) a battery (AA battery 51 in fig. 10), and (b) a pump configured to generate negative air pressure (motor 54 in fig. 10);

(ii) a breast shield (breast cup 16 in fig. 1) being configured to slide in and out of the housing (paragraph 58 discloses that the cup “clicks” into place within the housing; paragraph 42 discloses the breast cup being removable), the breast shield comprising a breast flange (outer flange area 50 in fig. 5) and a nipple tunnel (nipple tunnel 46 in fig. 5) comprising a side wall and a front end (see below), in which the breast shield is transparent or optically clear (paragraph 65); and

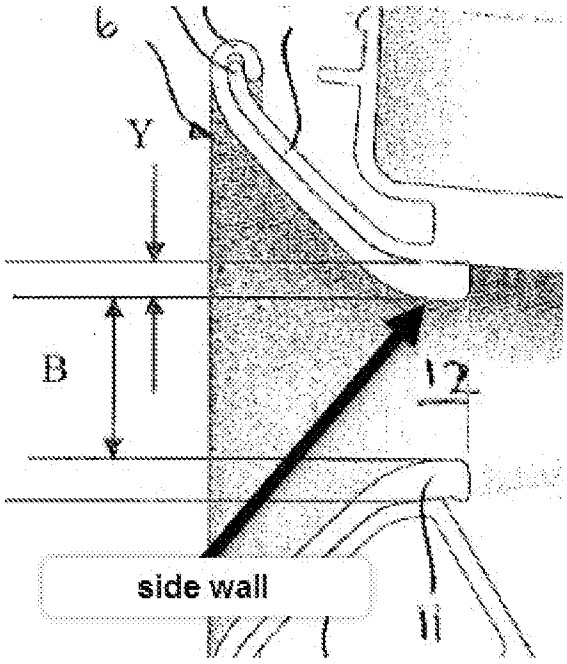


(iii) a milk container that is configured to be attached to and removed from the housing (collection bag 28 is shown to be operatively attached to the housing and is physically engaged to the bottom portion of the housing).

However, Myers does not teach or disclose the breast shield being of a plurality of interchangeable breast shields each of the plurality of interchangeable breast shields having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast; and the nipple tunnel comprises fit lines, wherein the fit lines are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see below) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different

wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple).



Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in fig. 28). Silver further teaches that the nipple tunnel has fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved

(longitudinal ribs 1164 and 1166 in fig. 28 are capable of being positioned so they run alongside the outside of the nipple when the nipple is correctly aligned in the nipple tunnel, see response to arguments above). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of modified Myers to include fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

Regarding claim 3, in the modified device of Myers, Myers discloses the breast shield is rigid (paragraph 47 discloses the nipple tunnel, which is part of the breast shield, is rigid).

Regarding claim 6, in the modified device of Myers, Myers discloses the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast (the shield of Myers is functionally capable of being rotated smoothly around a nipple since the claim does not require that the shield be fully latched onto the nipple for this rotation to occur).

Regarding claim 7, in the modified device of Myers, Myers discloses the breast shield presents, in use, a single continuous surface to a nipple and a breast (fig. 9A/B shows a singular inner surface which would extend from the nipple to the breast).

Regarding claim 8, in the modified device of Myers, Myers discloses the breast shield integrates the breast flange and the nipple tunnel as a single item (fig. 5 shows a singular item).

Regarding claim 10, in the modified device of Myers, Myers discloses the breast shield is configured to slide into the housing with a single push action (paragraph 58 discloses the shield can click into place).

Regarding claim 11, in the modified device of Myers, Myers discloses the breast shield is configured to slide out from the housing, together with a membrane that prevents milk from flowing into the pump (flange top 36 in fig. 9A).

Regarding claim 14, in the modified device of Myers, Myers discloses milk container attaches to a lower part of the housing (fig. 1 shows a part of the collection bag attached to the bottom part of the housing 16) and forms a base of the breast pump device (fig. 1).

Regarding claim 16, in the modified device of Myers, Silver discloses the fit lines are configured to run parallel along one or more sides of the nipple tunnel (fig. 28 shows the lines 1166 and 1164 are longitudinal lines).

Regarding claim 17, in the modified device of Myers, Myers discloses the nipple tunnel includes an air hole or passage (24 in fig. 9A), and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage (paragraph 52).

Regarding claim 18, in the modified device of Myers, Myers discloses the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container (outlet 24 in fig. 9A).

Regarding claim 22, in the modified device of Myers, Myers discloses the housing is shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra (fig. 1; paragraph 40).

Regarding claim 24, in the modified device of Myers, Myers discloses the breast pump device is configured to deliver a maximum suction of approximately 240 mmHg (paragraph 72).

Regarding claim 31, modified Myers teaches a kit comprising the breast pump device of claim 1 (see discussion above); and the plurality of interchangeable breast shields (fig. 2a/b of Cook).

Regarding claim 32, modified Myers teaches the fit lines in a nipple tunnel of that breast shield (Silver discloses longitudinal ribs 1164 and 1166 in fig. 28) that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel (since Myers discloses that the breast shield is transparent in paragraph 65, a user would be able to assess the spacing between the ribs and the nipple, see response to arguments above).

Regarding claim 34, in the modified device of Myers, Cook discloses length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same (paragraph 43).

Claim 4 is/are rejected under 35 U.S.C. 103 as being unpatentable over Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Phillips (US 20160296682), as evidenced by Yuen (US 20050228342).

Regarding claim 4, modified Myers teaches all of the claimed limitations set forth in claim 1, as discussed above. Myers further teaches the breast shield is made from plastic (paragraph 40 discloses the breast cup being made from silicone, which is

a type of plastic, as evidenced by Yuen in paragraph 24). However, modified Myers does not teach or disclose breast shield is dishwasher safe.

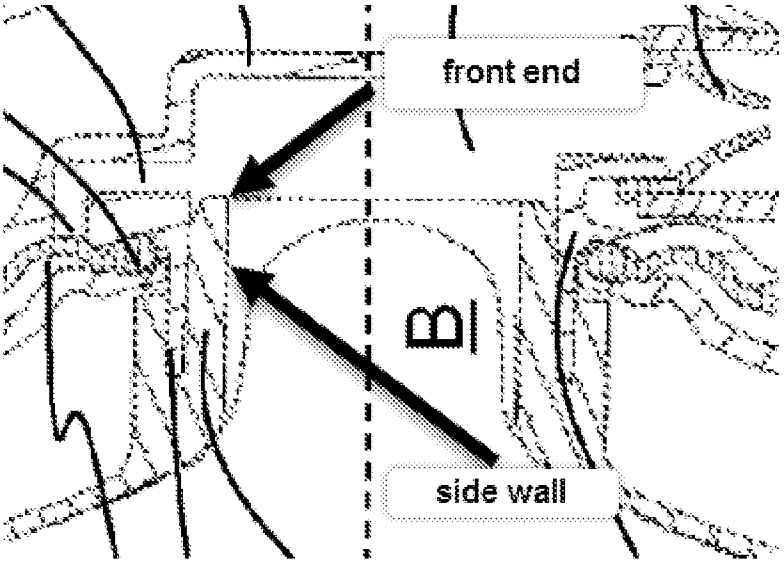
Phillips teaches a breast pump device (fig. 1) comprising a breast shield (110 in fig. 1). Phillips further teaches that the shield can be washed in a dishwasher (paragraph 60). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield of modified Myers to be dishwasher safe for the purpose of enabling the shield to be cleaned in the dishwasher for reuse, as taught by Phillips (paragraph 60).

Claims 1, 6-10, 14, 17-18, 20-22, 31, 32, and 34 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil (US 20130023821) in view of Myers (US 20080275386) and in further view of Cook and in further view of Silver.

Regarding claim 1, Khalil discloses a breast pump device comprising:

(i) a housing (6' and 6" form a housing as shown in fig. 9) that includes (a) a power source (paragraph 32 discloses the power source integrated into the housing), and (b) a pump generating negative air pressure (vacuum pump 81 in fig. 10);

(ii) a breast shield (breast interface 1 in fig. 11) being configured to slide in and out of the housing (breast interface 1 is configured to slide in/out from the housing by attaching/detaching the lip 11 to the flange 62 of the housing as shown in fig. 4), the breast shield made up of a breast flange (base part 12 in fig. 4) and a nipple tunnel (stub 10 in fig. 4) comprising a side wall and a front end (see below); and



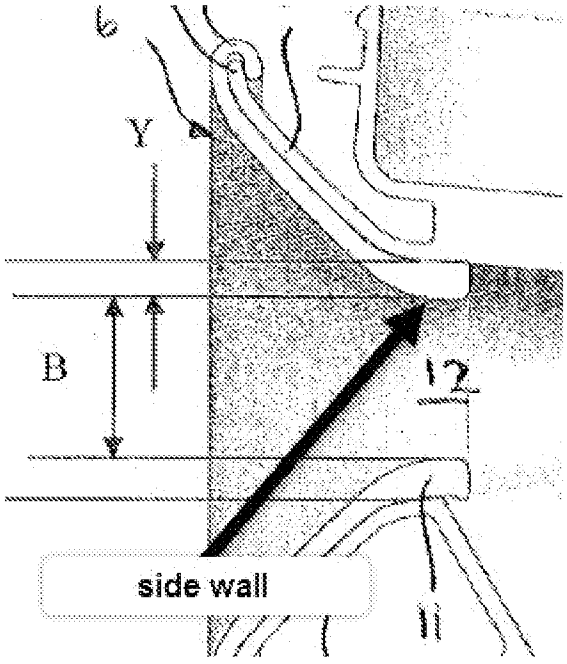
(iii) a milk container that is configured to be attached to and removed from the housing (milk collection container 7' in fig. 11; paragraph 69 discloses the container being releasably connected to the housing part 6').

However, Khalil does not teach or disclose the power source being a battery and the breast shield being transparent or optically clear and being of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast; and the nipple tunnel comprises fit lines, wherein the fit lines are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved.

Myers teaches a similar breast pump system (fig. 1) having a housing (outer housing 16 in fig. 1) which comprises a battery (battery 52 in fig. 10) and a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent). Therefore, it would have been obvious to one of ordinary skill

before the effective filing date of the claimed invention to have modified the housing to include a battery, as taught by Myers, for the purpose of providing power to the device and to have made the breast shield transparent to enable a user to view the condition of a nipple (paragraph 65).

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see below) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple).



Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality

of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in fig. 28). Silver further teaches that the nipple tunnel has fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved (longitudinal ribs 1164 and 1166 in fig. 28 are capable of being positioned so they run alongside the outside of the nipple when the nipple is correctly aligned in the nipple tunnel, see response to arguments above). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of modified Myers to include fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

Regarding claim 6, in the modified device of Khalil, Khalil discloses the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast (the shield of Khalil is functionally capable of being rotated smoothly around a nipple since the claim does not require that the shield be fully latched onto the nipple for this rotation to occur).

Regarding claim 7, in the modified device of Khalil, Khalil discloses the breast shield presents, in use, a single continuous surface to a nipple and a breast (fig. 11).

Regarding claim 8, in the modified device of Khalil, Khalil discloses the breast shield integrates the breast flange and the nipple tunnel as a single item (fig. 11).

Regarding claim 9, in the modified device of Khalil, Khalil discloses the breast shield is generally symmetrical about a centre-line running from a top to a bottom of the breast shield when positioned upright for normal use (fig. 11).

Regarding claim 10, in the modified device of Khalil, Khalil discloses the breast shield is configured to slide into the housing with a single push action (the shield of Khalil is functionally capable of being pushed into the housing so that the nipple tunnel is located in the housing).

Regarding claim 14, in the modified device of Khalil, Khalil discloses milk container attaches to a lower part of the housing and forms a base of the breast pump device (fig. 9).

Regarding claim 16, in the modified device of Khalil, Silver discloses the fit lines are configured to run parallel along one or more sides of the nipple tunnel (fig. 28 shows the lines 1166 and 1164 are longitudinal lines).

Regarding claim 17, in the modified device of Khalil, Khalil discloses the nipple tunnel includes an air hole or passage (opening 13 in fig. 3), and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage (figs. 4 and 5).

Regarding claim 18, in the modified device of Khalil, Khalil discloses the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which

expressed milk flows into the milk container (opening 13 in fig. 3 is considered to be on a “lower” surface of the nipple tunnel since “lower” is not further defined; see fig. 5).

Regarding claim 22, in the modified device of Khalil, Khalil discloses the housing is shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra (fig. 9).

Regarding claim 31, modified Khalil teaches a kit comprising the breast pump device of claim 1 (see discussion above); and the plurality of interchangeable breast shields (fig. 2a/b of Cook).

Regarding claim 32, modified Myers teaches the fit lines in a nipple tunnel of that breast shield (Silver discloses longitudinal ribs 1164 and 1166 in fig. 28) that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel (since Myers discloses that the breast shield is transparent in paragraph 65, a user would be able to assess the spacing between the ribs and the nipple, see response to arguments above).

Regarding claim 34, in the modified device of Khalil, Cook discloses length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same (paragraph 43).

Claim 5 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Chang (US 20180333523).

Regarding claim 5, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast shield is configured to attach using magnets to the housing.

Chang teaches a substantially similar self-contained breast pump system (breast pump system 10 in fig. 1A) having a breast shield (flange 14 in fig. 1A) attached to a housing (housing 12 in fig. 1A) and configured to attach to the housing using one or more magnets (paragraph 108 discloses the shield uses magnets 118 attached to the shield to determine if the shield is properly attached to the housing). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield of modified Khalil to be configured to attach using magnets to the housing since Chang teaches this configuration provides a safeguard such that the system will not operate unless all components are fully connected (paragraph 108).

Claims 12 and 13 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Phillips (US 20160296682).

Regarding claim 12, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Although it appears based on fig. 11 of Khalil that the container would be rigid, modified Khalil does not explicitly teach or disclose this limitation.

Phillips teaches a breast pump system (fig. 1) comprising a milk collection container ("collection container" 120 in fig. 1) which is substantially rigid (paragraph 57 discloses the container being made from Tritan; pg. 21 of Applicant's specification discloses that Tritan is a polycarbonate material, which is a known rigid material). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the container of modified Khalil to be

made of Tritan for the purpose of enabling the container to maintain its strength when a vacuum is applied, as taught by Phillips (paragraph 57).

Regarding claim 13, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses the milk container is an optically clear, plastic container (paragraph 69 discloses the container is made of plastic like cover 6" and is transparent in its entirety). However, Khalil does not explicitly teach or disclose the milk container is dishwasher safe.

Phillips teaches a breast pump system (fig. 1) comprising a milk collection container ("collection container" 120 in fig. 1) which is dishwasher safe (paragraph 57 discloses the container being made from Tritan; pg. 21, lines 13-18 of Applicant's specification discloses that Tritan a dishwasher safe material). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the container of modified Khalil to be made of Tritan for the purpose of enabling the container to maintain its strength when a vacuum is applied, as taught by Phillips (paragraph 57).

Claim 15 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Karsan (US 20070228059).

Regarding claim 15, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the milk container is configured to magnetically attach to the housing.

Khalil teaches that the milk container latches to the housing by a locking lug (paragraph 69 discloses a locking lug formed on the container latches engages into a

corresponding recess). Karsan teaches a container (1 in fig. 1) having a case (2 in fig. 3) and a base (fig. 3) which are releasably held together (paragraph 51 discloses the connection being releasable) via a latch mechanism (5 and 6 in fig. 3). Karsan further teaches that the latching mechanism is embodied as a lug and recess (5 and 6, respectively in fig. 3; paragraph 65) but may alternatively be embodied as a magnetic means so that the two components may be magnetically latched (paragraph 65).

In Applicant's invention, Applicant uses the magnets to removably secure the milk container to the housing. Thus, Karsan is reasonably pertinent to the problem faced by the inventor since Karsan teaches using magnets as a removable latching connection between two components. As Karsan teaches that the magnetic means (paragraph 65) are functional equivalents to a locking lug and recess (paragraph 65), it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have substituted the locking lug/recess configuration of Khalil with the magnetic means, as taught by Karsan. The substitution would have resulted in providing an equivalent secure attachment of the milk container to the housing.

Claim 19 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Blondheim (US 20120277636).

Regarding claim 19, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the pump comprises one or more piezo air pumps.

Blondheim is directed towards a breast pump device (fig. 1) which comprises an air pump (66 in fig. 6). Blondheim further teaches that the air pump can be a

piezoelectric pump (paragraph 36). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the pump of modified Khalil to be a piezoelectric pump, as taught by Blondheim for the purpose of rendering the pump small in size (paragraph 36).

Claims 20 and 21 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Barak (US 20140378895).

Regarding claim 20, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the housing further includes a Universal Serial Bus (USB) charging socket.

Barack is directed towards a breast pump device (fig. 1) which comprises a housing which houses a pump (fig. 1 shows a pump 20 which would necessarily have some sort of housing since it is disclosed to have a USB port and a user interface). Barack further teaches a USB charging socket (USB port 34 in fig. 1; paragraph 45). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing of modified Khalil to include the USB charging socket, as taught by Khalil, for the purpose of enabling the device to interface with an external memory (paragraph 45).

Regarding claim 21, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the housing includes a left or right breast selector or toggle switch, that, when selected for a particular pumping session, sends data to a connected application configured to track

pumping sessions, to indicate whether that particular session is associated with a left or a right breast.

Barack teaches a breast pump device (fig. 1) which has a control electronics (controller 22 in fig. 1) and a control interface (user interface 30 in fig. 1) that is user selectable to indicate or record if milk is being expressed from the left or right breast (paragraph 43) and that, when selected for a particular pumping session, sends data to a connected application, running on a device, such as a smartphone, that tracks pumping sessions, to indicate whether that session is associated with the left or the right breast (paragraph 46 discloses transmitting via transceiver the parameters that have been entered at the user interface 30 to a remove device; paragraph 43 discloses that one parameter entered at the user interface is which breast is selected).

Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing of modified Khalil to include a left or right breast selector or toggle switch, that, when selected for a particular pumping session, sends data to a connected application configured to track pumping sessions, to indicate whether that particular session is associated with a left or a right breast, as taught by Barack. This modification would enable a user to track which parameters are best suited for each breast to optimize pumping, as taught by Barack (paragraphs 8 and 43).

Claim 25 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Guthrie (US 20160220743).

Regarding claim 25, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast pump device includes a sensor that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container.

Guthrie is directed towards a breast pump device comprising a sensor (detector 607 in fig. 6B) that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container (paragraph 63 discloses that the emitter 606 and the detector 607 operate to detect light reflecting off the opaque surface of the milk). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the device to include a sensor that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container, as taught by Guthrie, for the purpose of measuring volume of milk pumped (paragraph 54).

Claim 29 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Mendoza (US 6227936).

Regarding claim 29, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the pump is a

lightweight air pump that enables the total mass of the breast pump system, unfilled with milk, to be less than 250gm.

Mendoza teaches a bra which is designed to support a breast pump to allow the mother's hands to remain free (1:8-12). Mendoza further discloses that the bra must be able to support up to 8 ounces when the pump is full (1:58-62). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the system of modified Khalil to be a lightweight air pump that enables the total weight of the system, unfilled with milk, to be less than 250gm, as taught by Mendoza since Mendoza teaches that a lightweight system is crucial for enabling the system to be supported by a bra.

Claim 30 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, in further view of Baker (US 20090281485).

Regarding claim 30, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast pump device makes less than 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

Baker is directed towards a device for removing fluid from a body (fig. 6) using a vacuum pump embodied as a motor (motor 9 in fig. 6; paragraph 243). Baker further teaches that the device makes less than 20 decibel of noise at full power (paragraph 121) by sound proofing the walls of the housing and by adding a counter balance to the motor (paragraph 144). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the device of

modified Khalil to have the device make less than 20 dB of noise during maximum power for the purpose of making the device for discrete and comfortable for the user and others around the user.

Claim 33 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, in further view of Meyers (US 5542921).

Regarding claim 33, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further teaches control electronics ("control elements and a display" in paragraph 51) which would be powered by the battery (the power source of Khalil is understood to power the device).

However, Khalil does not teach or disclose the battery to be rechargeable and the housing further including a power charging circuit for controlling the charging of the rechargeable battery.

Meyers is directed to a breast pump device (fig. 1) comprising a battery configured to be recharged (9:50-52 discloses recharging the batteries) and a power charging circuit for controlling the charging of the rechargeable battery ("circuit" in 9:50-52). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the battery of modified Khalil to be rechargeable and to have incorporated a power charging circuit for controlling the charging of the rechargeable battery, as taught by Meyers to enable the batteries to be reused.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1, 3-22, 24, 25, 29-34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of the issued patents below in view of Myers, Cook, Silver, and the teachings below (see table).

- **17203050 (US Patent 11357893)**
- **17203079 (US Patent 11376352)**
- **17203216 (US Patent 11357894)**
- **17203259 (US Patent 11324866)**
- **17203327 (US Patent 11413380)**

Claim 1 of the issued patent claims all of the features claimed in reference claim 1 except in that claim 1 of the patent does not claim a breast shield of a plurality of interchangeable breast shields each being transparent or optically clear and having a different size and being configured to slide in and out of the housing, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of

interchangeable breast shields is placed onto a breast; and the nipple tunnel having fit lines are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to

provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in fig. 28). Silver further teaches that the nipple tunnel has fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved (longitudinal ribs 1164 and 1166 in fig. 28 are capable of being positioned so they run alongside the outside of the nipple when the nipple is correctly aligned in the nipple tunnel, see response to arguments above). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of the reference claim to include fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.

7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		Silver teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.

29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Silver and Myers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Claims 1, 3-22, 24, 25, 28-34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of the following US Patents in view of Myers, Cook and the teachings below (see table).

- **17203109 (US Patent 11260151)**
- **17203313 (US Patent 11311654)**

Claim 1 of the issued patent claims all of the features claimed in reference claim 1 except in that claim 1 of the patent does not claim a breast shield of a plurality of interchangeable breast shields each being transparent or optically clear and having a different size and being configured to slide in and out of the housing, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast; and the nipple tunnel having fit lines are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches

that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in fig. 28). Silver further teaches that the nipple tunnel has fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved (longitudinal ribs 1164 and 1166 in fig. 28 are capable of being positioned so they run alongside the outside of the nipple when the nipple is correctly aligned in the nipple tunnel, see response to arguments above). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of the reference claim to include fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.

8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		Silver teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.

24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
28	18 ('151 patent), 13 ('654 patent)	
29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Silver and Myers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Claims 1, 3-22, 24, 25, 29-34 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of the following copending applications in view Myers, Cook and the teachings below.

- **17203150**
- **17203179**
- **17203292**
- **17203355**
- **17203384**
- **17203397**

- **17203418**

Claim 1 of the reference claim claims all of the features claimed in reference claim 1 except in that claim 1 of the reference claim does not claim a breast shield of a plurality of interchangeable breast shields each being transparent or optically clear and having a different size and being configured to slide in and out of the housing, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast; and the nipple tunnel having fit lines are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of

interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in fig. 28). Silver further teaches that the nipple tunnel has fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved (longitudinal ribs 1164 and 1166 in fig. 28 are capable of being positioned so they run alongside the outside of the nipple when the nipple is correctly aligned in the nipple tunnel, see response to arguments above). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of the reference claim to include fit lines configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		Silver teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.

20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Silver and Myers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Allowable Subject Matter

Except for the double patenting rejections above, **claim 28** would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not teach or suggest the pump delivers the claimed stall pressure and free air flow.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COURTNEY FREDRICKSON whose telephone number is (571)270-7481. The examiner can normally be reached Monday-Friday (9 AM - 5 PM EST).

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NATHAN PRICE can be reached on 571-270-5421. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COURTNEY B FREDRICKSON/
Primary Examiner, Art Unit 3783

UNITED STATES
PATENT AND TRADEMARK OFFICE

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Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**03/26/2024 05:04:13 PM Z ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	64835546	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 7

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2024-03-26-Transmittal-Form-sIDS-4944-0120006.pdf	1	Miscellaneous Incoming Letter	167 KB
2024-03-26-sIDS-Pleading-4944-0120006.pdf	3	Letter specifying the conditions for filing under 37 CFR 1.97	99 KB
2024-03-26-sIDS-Form-SB08-4944-0120006.pdf	3	Information Disclosure Statement (IDS) Form (SB08)	110 KB
Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.			
FOR_1_CN109621041A.pdf	41	Foreign Reference	855 KB
FOR_2_JP2016508804A.pdf	26	Foreign Reference	899 KB
FOR_3_WO9625187A1.pdf	29	Foreign Reference	635 KB

FOR_4_WO2018229504A1.pdf	198	Foreign Reference	2923 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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FOR_3_WO9625187A1.pdf	32253180C889CB070524A505D5172328624AD6E0C1BF4271F54D30C4BBA779A143FE23288A66BA4A2766DDF2BD6DF27EDE72BF2C7A0116A34643273FF26494D8
FOR_4_WO2018229504A1.pdf	F87168DFA19CF7A3C9B38EF0F69478DBC54F306C42ABE768B51F914C9E536E1F0AFE03F59A2B67A0E9A3FB319E70E4EDCFC6A7E38DF3CF1C15AFD00E812F7BD2

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security,

and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

CPC - Searched*		
Symbol	Date	Examiner
a61m1/06-069	01/12/2022	cbf

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
see SEARCH history	01/12/2022	cbf
searched inventors in PALM and SEARCH	01/12/2022	cbf
consulted child search history	01/12/2022	cbf
Updated search history	10/17/2022	cbf
Updated search	03/24/2023	cbf
Updated search	10/06/2023	cbf

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/COURTNEY B FREDRICKSON/ Examiner, Art Unit 3783	

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/12/2022	10/17/2022	03/24/2023	10/06/2023					
	1	✓	✓	✓	✓					
	2	✓	-	-	-					
	3	✓	✓	✓	✓					
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	26	-	-	-	-					
	27	-	-	-	-					
	28	✓	✓	✓	✓					
	29	✓	✓	✓	✓					
	30	✓	✓	✓	✓					
	31	✓	✓	✓	✓					
	32	✓	✓	✓	✓					
	33	✓	✓	✓	✓					
	34		✓	✓	✓					

Equivalent of Form PTO/SB/08

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	2003/0069536 A1	04-10-2003	Greter et al.	
	US2	2007/0054651 A1	03-08-2007	Farmer et al.	
	US3	2014/0227112 A1	08-14-2014	Felber	
	US4	2019/0365966 A1	12-05-2019	Bächler et al.	
	US5	2020/0016307 A1	01-16-2020	Edelman et al.	
	US6	2020/0300237 A1	09-24-2020	Marbet et al.	

FOREIGN PATENT DOCUMENTS

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	FP1	EP 3482782 A1	05-15-2019	MEDELA HOLDING AG		

Examiner Signature		Date Considered	

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Sheet 2 of 3

Complete if Known	
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Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

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Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]

Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	10/06/2023

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				Art Unit	3783
				Examiner Name	FREDERICKSON, Courtney B
Sheet	3	of	3	Attorney Docket Number	4944.0120006

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Yangbeini Wang #800,005/	Date (YYYY-MM-DD)	2023-05-15
Name/Print	Yangbeini Wang	Registration Number	800,005

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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	US1	2002/0062103 A1	05-23-2002	Larsson et al.	
	US2	2008/0009815 A1	01-10-2008	Grabenkort et al.	
	US3	2015/0314053 A1	11-05-2015	Furrer et al.	

FOREIGN PATENT DOCUMENTS

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Examiner Name	FREDERICKSON, Courtney B
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Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	10/06/2023

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Sheet	3	of	3	Attorney Docket Number	4944.0120006

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☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Richard D. Coller III/	Date (YYYY-MM-DD)	2023-04-20
Name/Print	Richard D. Coller III	Registration Number	60,390

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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	US1	US20040024351A1	02-05-2004	GRETER; Andy et al.	
	US2	US20050228342A1	10-13-2005	YUEN; Yat Keung William	
	US3	US2015/0157775A1	06-11-2015	HU	
	US4	US20170173232A1	06-22-2017	CHANG; John Y. et al.	
	US5	US20180021491A1	01-25-2018	RIGERT; Mario et al.	
	US6	US20190209748A1	07-11-2019	ANALYTIS et al.	
	US7	US20210093761A1	04-01-2021	HWANG et al.	
	US8	US20230111110A1	04-13-2023	DE BECDELIEVRE et al.	
	US9	US20230143842A1	05-11-2023	O'TOOLE et al.	
	US10	US20230158215A1	05-25-2023	O'TOOLE et al.	
	US11	US4,673,388A	06-16-1987	SCHLENSOG et al.	
	US12	US9498565B2	11-22-2016	NOWROOZI et al.	
	US13	US11260151B2	03-01-2022	O'TOOLE; Jonathan et al.	
	US14	US11311654B2	04-26-2022	O'TOOLE; Jonathan et al.	
	US15	US11324866B2	05-10-2022	O'TOOLE; Jonathan et al.	
	US16	US11357894B2	06-14-2022	O'TOOLE; Jonathan et al.	
	US17	US11357893B2	06-14-2022	O'TOOLE; Jonathan et al.	
	US18	US11376352B2	07-05-2022	O'TOOLE; Jonathan et al.	
	US19	US11413380B2	08-16-2022	O'TOOLE; Jonathan et al.	

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	NPL1	Amended Complaint in Shenzhen Root Technology Co., Ltd. v. Chiaro Technology, Ltd., WDWA-2-23-cv-00631, filed June 2, 2023; 24 pages.	

Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	10/06/2023

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SIGNATURE

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Signature	/Yangbeini Wang #800,005 /	Date (YYYY-MM-DD)	2023-06-22
Name/Print	Yangbeini Wang	Registration Number	800,005

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.B.F./

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	1	17/181057.app.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:05 PM
L2	128	((("O'TOOLE") near3 ("Jonathan")) OR (("ROLLO") near3 ("Adam")) OR (("CARR") near3 ("Andrew"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/12/31 01:05 PM
L3	8470	a61m1/06-069.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
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			SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L9	126	("10881766" OR "10926011" OR "20040087898" OR "20090281482" OR "20100292636" OR "20120165729" OR "20140263611" OR "20160228625" OR "20180110900" OR "20210196873" OR "20210196874" OR "20210196875" OR "20210196876" OR "20210205511" OR "20210205512" OR "20210205513" OR "20210205514" OR "20210205515" OR "20210205516" OR "20210205517" OR "20210205518" OR "20210228789" OR "20210268158" OR "7666162" OR "8608685" OR "20070135761" OR "20070179439" OR "20090281485" OR "20110009824" OR "20160271305" OR "20160296682" OR "20160325031" OR "20170095599" OR "20170112983" OR "20180028733" OR "20180333523" OR "5542921" OR "7833190" OR "10039871" OR "20020193731" OR "20040056641" OR "20040074281" OR "20040267215" OR "20050219302" OR "20060122575" OR "20070051172" OR "20070051727" OR "20080177224" OR "20080262420" OR "20080275386" OR "20110004154" OR "20110196291" OR "20110274566" OR "20120277636" OR "20130023821" OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/01/12 05:14 PM

		"20140031744" OR "20140052056" OR "20140275857" OR "20140323962" OR "20140378895" OR "20150217036" OR "20150217037" OR "20150283311" OR "20160000980" OR "20160058928" OR "20160058929" OR "20160082165" OR "20160082166" OR "20160151551" OR "20160158424" OR "20160166745" OR "20160206794" OR "20160220743" OR "20160220745" OR "20160256617" OR "20160287767" OR "20160296681" OR "20160310650" OR "20170021068" OR "20170035951" OR "20170043065" OR "20170072117" OR "20170072118" OR "20170143879" OR "20170220753" OR "20180021490" OR "20180110906" OR "2849881" OR "4390024" OR "4535627" OR "5474683" OR "5941847" OR "5973770" OR "6045529" OR "6090065" OR "6227936" OR "6328709" OR "6358226" OR "6383163" OR "6440100" OR "6461324" OR "6547756" OR "6579258" OR "6663587" OR "6749582" OR "7048519" OR "7201735" OR "7312554" OR "7314400" OR "7662018" OR "7776008" OR "8057425" OR "8118772" OR				

		"8187227" OR "8262606" OR "8282596" OR "8376986" OR "8702646" OR "8801495" OR "8876760" OR "8926556" OR "9033913" OR "9173587" OR "9345274" OR "9539377" OR "D548831").pn.					
L10	45	9 AND (transparent)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/12 06:05 PM
L11	105	3 AND (batter$4) AND ((interface flange shield cup) WITH (clear transparent))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/13 02:07 PM
L12	382	3 AND (silicone WITH plastic)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 10:40 AM
L13	2	("20180333523").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 11:50 AM
L14	43	3 AND ((USB "universal service bus") WITH (charg$4 recharg$4))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:19 PM
L15	2	("20160220743").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD,	OR	ON	ON	2022/01/14 12:42 PM

			DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L16	5	("5542921").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:52 PM
L20	256	3 AND ((shield cup interface flange) WITH (siz$4) WITH different)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 01:23 PM
L21	2	("20120165729").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 01:31 PM
L22	2	("10881766").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:23 PM
L23	2	("10926011").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:38 PM
L24	12	("20080275386" "20140378895" "20130023821" "20180333523" "20160296682" "20070228059" "20120277636" "20160220743" "6227936" "20090281485" "20120165729"	(US-PGPUB; USPAT)	OR	ON	ON	2022/01/14 03:55 PM

		"5542921").pn.					
L25	267	3 AND (nipple WITH (chang$4 differ$4 adjust$4 dissimilar$4) WITH (size width))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/17 03:06 PM
L26	2	"44148977".fmid.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; JPO)	OR	ON	ON	2022/10/17 03:31 PM
L27	1	("10926011").pn.	(USPAT)	OR	ON	ON	2022/10/19 04:47 PM
L28	11	("0000002" OR "10864306" OR "20050245860" OR "20070236584" OR "20080299517" OR "20120109083" OR "20140142501" OR "20160135998" OR "20180008758" OR "20180104396" OR "5406063").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/24 04:55 PM
L29	91	3 AND (nipple WITH (siz$4 spac$4 dimension$4) WITH (indicator line guid$4 symbol indicia))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:26 PM
L30	17	3 AND (nipple WITH (siz$4 spac$4 dimension$4) WITH (mark$4 label))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:31 PM
L31	2	("20020198489").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR,	OR	ON	ON	2023/03/24 05:34 PM

			GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L32	19	(breast WITH shield) AND (size WITH label$4)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:55 PM
L33	1	(09/888322).APP.	(USPAT; USOCR)	OR	ON	ON	2023/03/24 05:56 PM
L34	1	1 AND (correct WITH nipple WITH align$6)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/06 02:29 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: O'TOOLE *et al.*	Confirmation No.: 4690
Applicant: Chiaro Technology Limited	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, Courtney B.
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006
Title: **BREAST PUMP SYSTEM**	

Amendment and Reply Under 37 C.F.R. § 1.111

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Mail Stop Amendment

Commissioner:

In reply to the Office Action dated **March 30, 2023**, Applicant submits the following Amendment and Remarks.

It is not believed that extensions of time are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any additional fees required to continue prosecution or appeal of this application (including issue fee, fees for net addition of claims or forwarding to appeal) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently Amended) A breast pump device comprising:

a housing comprising:

a battery, and

a pump configured to generate negative air pressure;

a breast shield of a plurality of interchangeable breast shields, each of the plurality of interchangeable breast shields having a different size and being configured to slide in and out of the housing, the breast shield comprising a breast flange and a nipple tunnel comprising a side wall and a front end, and ~~a guide line~~ fit lines, wherein the breast shield is transparent or optically clear; and

a milk container configured to be attached to and removed from the housing,

wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast, and

wherein the ~~guide line is~~ fit lines are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved ~~define the spacing of the nipple from the side wall of the nipple tunnel~~.

2. (Canceled)

3. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is rigid.

4. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is a dishwasher safe, plastic breast shield.

5. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to be attached using magnets to the housing.

6. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast.

7. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to present, in use, a single continuous surface to a nipple and a breast.

8. (Previously Presented) The breast pump device of claim 1, wherein the breast flange and the nipple tunnel are integrally formed.

9. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to be generally symmetrical about a center-line running from a top to a bottom of the breast shield when positioned upright for normal use.

10. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to slide into the housing with a single push action.

11. (Previously Presented) The breast pump device of claim 1, wherein the breast shield is configured to slide out from the housing, together with a membrane that is configured to prevent milk from flowing into the pump.

12. (Previously Presented) The breast pump device of claim 1, wherein the milk container is rigid.

13. (Previously Presented) The breast pump device of claim 1, wherein the milk container is an optically clear, dishwasher safe, plastic milk container.

14. (Previously Presented) The breast pump device of claim 1, wherein the milk container is configured to attach to a lower part of the housing and forms a base of the breast pump device.

15. (Previously Presented) The breast pump device of claim 1, wherein the milk container is configured to magnetically attach to the housing.

16. (Currently Amended) The breast pump device of claim 1, wherein the ~~guide line is~~ fit lines are configured to run parallel along one or more sides of the nipple tunnel.

17. (Previously Presented) The breast pump device of claim 1, wherein the nipple tunnel comprises an air hole or passage, and wherein the pump is configured to transfer negative air pressure into the nipple tunnel via the air hole or passage.

18. (Previously Presented) The breast pump device of claim 1, wherein the nipple tunnel comprises on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container.

19. (Previously Presented) The breast pump device of claim 1, wherein the pump comprises one or more piezo air pumps.

20. (Previously Presented) The breast pump device of claim 1, wherein the housing further comprises a Universal Serial Bus (USB) charging socket.

21. (Previously Presented) The breast pump device of claim 1, wherein the housing comprises a left or right breast selector or toggle switch that, when selected for a particular pumping session, is configured to send data to a connected application configured to track pumping sessions, to indicate whether that particular session is associated with a left or a right breast.

22. (Previously Presented) The breast pump device of claim 1, wherein the housing is configured to be shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra.

23. (Canceled)

24. (Previously Presented) The breast pump device of claim 1, wherein the breast pump device is configured to deliver a maximum suction of approximately 240 mmHg.

25. (Previously Presented) The breast pump device of claim 1, wherein the breast pump device comprises a sensor that is configured to directly measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container.

26. (Canceled)

27. (Canceled)

28. (Previously Presented) The breast pump device of claim 1, wherein the pump is configured to deliver in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

29. (Previously Presented) The breast pump device of claim 1, wherein the pump is a lightweight air pump that enables a total mass of the breast pump device, unfilled with milk, to be less than 250 gm.

30. (Previously Presented) The breast pump device of claim 1, wherein the breast pump device is configured to make less than 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

31. (Previously Presented) A kit, comprising:

the breast pump device of claim 1; and

the plurality of interchangeable breast shields.

32. (Currently Amended) The kit of claim 31, wherein ~~each of the plurality of interchangeable breast shields comprises~~ the fit lines ~~in a nipple tunnel of that breast shield that~~ are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel.

33. (Previously Presented) The breast pump device of claim 1, wherein the battery is a rechargeable battery, and wherein the housing further comprises:

a power charging circuit configured to control the charging of the rechargeable battery, and

control electronics configured to be powered by the rechargeable battery.

34. (Previously Presented) The breast pump device of claim 1, wherein a length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same.

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1, 3–22, 24, 25, and 28–34 are pending in the application. Claims 1 is an independent claim. Claims 1, 16, and 32 are amended. These changes introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Office reconsider and withdraw all outstanding objections and rejections.

Allowable Subject Matter

Applicant thanks Examiner Fredrickson for indicating that claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Office Action, 28.

Claim Objections

Claim 1 is objected to for informalities. Office Action, 3.

Without agreeing to the propriety of the objection, relevant language of claim 1 is deleted. Therefore, the objection is now moot. Applicant respectfully requests that the objection be withdrawn.

Rejections under 35 U.S.C. § 112

Claims 1, 3–22, 24, 25, and 28–34 are rejected under 35 U.S.C. § 112(b) as allegedly being indefinite. Office Action, 3–4.

Without agreeing to the propriety of the rejections, relevant language of claim 1 is deleted, thereby rendering the rejection of claim 1 moot, and claim 1 is amended to recite, "the breast shield comprising a breast flange and a nipple tunnel comprising a side wall and a front end, and *fit lines*," thereby providing antecedent basis for claim 32. Accordingly, Applicant respectfully requests that the § 112 rejections of claims 1, 3–22, 24, 25, and 28–34 be withdrawn.

Rejections under 35 U.S.C. § 103

Independent claim 1

Claims 1, 3, 6–8, 10, 11, 14, 16–18, 22, 24, 31, 32, and 34 are rejected under 35 U.S.C. § 103 as unpatentable over U.S. Applicant No. 2008/0275386 to Myers, in view of EP 2502640 to Cook et al., and in further view of U.S. Patent Applicant Publication No. 2002/0198489 to Silver et al. Office Action, 5–10.

Claims 1, 6–10, 14, 17, 18, 20, 22, 31, 32, and 34 are rejected under 35 U.S.C. § 103 as unpatentable over U.S. Patent Applicant Publication No. 2013/0023821 to Khalil et al. in view of Myers, in view of Cook, and further in view of Silver. Office Action, 11–16.

Without agreeing to the propriety of the rejections, claim 1 is amended and now recites, "wherein the fit lines are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved." The applied references do not teach or suggest at least this feature of claim 1.

The Office acknowledges that Myers, Cook, and Khalil do not teach that the nipple tunnel comprises a guide line configured to define the spacing of the nipple from the side wall of the nipple tunnel, and only relies on Sliver for this feature. Office Action, 6–8 and 12–14.

Silver discloses a breastshield 1095 formed with a skeletal frame, and the skeletal frame comprises a series of stiffening longitudinally extending ribs 1160, 1164, and 1166. Silver, ¶¶ [0200]-[0201] and FIG. 28. The Office interprets ribs 1160, 1164, and 1166 to allegedly correspond to the recited guide line. Office Action, 8. However, Silver is silent on how ribs 1160, 1164, and 1166 can define a correct spacing of the nipple from the side of the nipple tunnel or assist with correct nipple alignment. Furthermore, Silver does not disclose that ribs 1160, 1164, and 1166 are configured to be aligned with the outside of the nipple when a correct nipple alignment is achieved, as recited in amended claim 1.

Accordingly, amended claim 1 and its dependent claims would not have been obvious over the applied references. Applicant respectfully requests reconsideration and withdrawal of the § 103 rejections of claims 1, 3, 6–10, 11, 14, 16–18, 20, 22, 24, 31, 32, and 34.

Dependent claims

Claim 4 is rejected under 35 U.S.C. § 103 as unpatentable over Myers in view of Cook, in view of Silver, as applied to claim 1 above, in view of U.S. Patent Applicant Publication No. 2016/0296682 to Phillips et al., and further in view of U.S. Patent Applicant Publication No. 2005/0228342 to Yuen. Office Action, 10–11.

Claim 5 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers, in view of Cook, in view of Silver, as applied to claim 1 above, and further in view of U.S. Patent Applicant Publication No. 2018/0333523 to Chang et al. Office Action, 16–17.

Claims 12 and 13 are rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers, in view of Cook, in view of Silver, as applied to claim 1 above, and further in view of Phillips. Office Action, 17–18.

Claim 15 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers, in view of Cook, in view of Silver, as applied to claim 1 above, and further in view of U.S. Patent Applicant Publication No. 2007/0228059 to Karsan. Office Action, 18–19.

Claim 19 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers, in view of Cook, in view of Silver, as applied to claim 1 above, and further in view of U.S. Patent Applicant Publication No. 2012/0277636 to Blondheim et al. Office Action, 19–20.

Claims 20 and 21 are rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers, in view of Cook, in view of Silver, as applied to claim 1 above, and further in view of U.S. Patent Applicant Publication No. 2014/0378895 to Barak. Office Action, 20–21.

Claim 25 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers, in view of Cook, in view of Silver, as applied to claim 1 above, and further in view of U.S. Patent Applicant Publication No. 2016/0220743 to Guthrie et al. Office Action, 21–22.

Claim 29 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers, in view of Cook, in view of Silver, as applied to claim 1 above, and further in view of U.S. Patent No. 6,227,936 to Mendoza. Office Action, 22–23.

Claim 30 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers, in view of Cook, in view of Silver, as applied to claim 1 above, and further in view of U.S. Patent Applicant Publication No. 2009/0281485 to Baker et al. Office Action, 23–24.

Claim 33 is rejected under 35 U.S.C. § 103 as unpatentable over Khalil in view of Myers, in view of Cook, in view of Silver, as applied to claim 1 above, and further in view of U.S. Patent No. 5,542,921 to Meyers et al. Office Action, 24.

Each of claims 4, 5, 12, 13, 15, 19–21, 25, 29, 30, and 33 depends from and adds features to independent claim 1. The additionally applied references do not overcome the deficiencies of Myers, Cook, Silver, and Khalil as discussed above. Accordingly, claims 4, 5, 12, 13, 15, 19–21, 25, 29, 30, and 33 would not have been obvious over the applied references. Applicant respectfully requests reconsideration and withdrawal of the § 103 rejections of claims 4, 5, 12, 13, 15, 19–21, 25, 29, 30, and 33.

Double Patenting Rejection

Claims 1, 3–22, 24, 25, and 29–34 are rejected on the grounds of non-statutory obviousness type double patenting based on the following patents and applications in view of Myers, Cook, and Silver. Office Action, 26–30.

- U.S. Applicant No. 17/203050 (U.S. Patent No. 11357893)
- U.S. Applicant No. 17/203079 (U.S. Patent No. 11376352)
- U.S. Applicant No. 17/203216 (U.S. Patent No. 11357894)
- U.S. Applicant No. 17/203259 (U.S. Patent No. 11324866)
- U.S. Applicant No. 17/203327 (U.S. Patent No. 11413380)

Claims 1, 3–22, 24, 25, and 28–34 are rejected on the grounds of non-statutory obviousness type double patenting based on the following patents and applications in view of Myers, Cook, and Silver. Office Action, 30–34.

- U.S. Applicant No. 17/203109 (U.S. Patent No. 11260151)
- U.S. Applicant No. 17/203313 (U.S. Patent No. 11311654)

Claims 1, 3–22, 24, 25, and 29–34 are rejected on the grounds of non-statutory obviousness type double patenting based on the following patents and applications in view of Myers, Cook, and Silver. Office Action, 34–38.

- U.S. Applicant No. 17/203150
- U.S. Applicant No. 17/203179
- U.S. Applicant No. 17/203292
- U.S. Applicant No. 17/203355
- U.S. Applicant No. 17/203384
- U.S. Applicant No. 17/203397
- U.S. Applicant No. 17/203418

Applicant respectfully requests that the currently asserted double patenting rejections be held in abeyance until the claimed subject matter is otherwise deemed allowable. After analyzing the final allowed claim scope, Applicant will consider filing a terminal disclaimer if necessary to overcome any obviousness-type double patenting rejections.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Office reconsider and withdraw all presently outstanding objections and rejections. A full and complete reply has been made to the outstanding Office Action and, as such, the present application is in

condition for allowance. If the Office believes, for any reason, that personal communication will expedite prosecution of this application, the Office is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Yangbeini Wang #800,005/

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Attorney for Applicant
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Date: June 30, 2023

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Total Number of Pages in This Submission

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDRICKSON, Courtney B.
Attorney Docket Number	4944.0120006

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☑ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) (please identify below):

Remarks

The Office may charge any fee deficiency for any submission made with this transmittal to Deposit Account 19-0036.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Yangbeini Wang #800,005/		
Printed name	Yangbeini Wang		
Date	June 30, 2023	Reg. No.	800,005

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1 14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**06/30/2023 10:56:14 AM ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Rolonda Lee
PATENT CENTER #	62369354	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 4

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
2023-06-30-Transmittal-Form-4944-0120006.PDF		1	Transmittal Letter	162 KB
2023-06-30-Amendment-Reply-111-4944-0120006.PDF		12	-	153 KB
2023-06-30-Amendment-Reply-111-4944-0120006-A....pdf	(1-1)	1	Amendment/Request for Reconsideration-After Non-Final Rejection	117 KB
2023-06-30-Amendment-Reply-111-4944-0120006-CLM.pdf	(2-6)	5	Claims	81 KB

2023-06-30-Amendment-Reply-111-4944-0120006-REM.pdf	(7-12)	6	Applicant Arguments/Remarks Made in an Amendment	140 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-06-30-Transmittal-Form-4944-0120006.PDF	4152C7FF2F44E9494452F5C72E161884957F7855894618E34BFC024FD2B6A9C7DC5F03F8E33494C7A544AA198E23D101209FBD08F9C7FC9B9F2E1AC351A27373
2023-06-30-Amendment-Reply-111-4944-0120006.PDF	D9CE5CF94EE165AC04CF761F0987FA9EC7279B9DC53D90506B81B1323A99D85543D36FEB4C768ABBF8136607C8C76FD402EFB2CD151C33BD68F1E42DFE985583
2023-06-30-Amendment-Reply-111-4944-0120006-A....pdf	49C07B0B4B1416D30B214F3A9E192E7C478AC100841BC15FA2738B9FF0EBCE4F9D66E5ECB4DAEF3F12B90FD2AD8C07DD88B08537806175CFC2E1B4D142401206
2023-06-30-Amendment-Reply-111-4944-0120006-CLM.pdf	406F2101C60741B14BA57E750378F3AE1F3CE962D3B0261335F94C99CEC9D70D43B0CB93AF1334D0D9BDFA9CA68FD002EC48065FAFFE9C93B9817B94B2B194E1
2023-06-30-Amendment-Reply-111-4944-0120006-REM.pdf	A4CEF82F872A82584B06C05286A7463418D928BE04C6943A621E90C78D14D35CF9F6DE18256FF63FEA23398DFE430AA64CEC6789702264B164647C771BF271F6

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/181,057	Filing Date 02/22/2021	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $240 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	06/30/2023	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 30	Minus	** 30	= 0		x $40 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $192 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/LISA R WRIGHT/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	US20040024351A1	02-05-2004	GRETER; Andy et al.	
	US2	US20050228342A1	10-13-2005	YUEN; Yat Keung William	
	US3	US2015/0157775A1	06-11-2015	HU	
	US4	US20170173232A1	06-22-2017	CHANG; John Y. et al.	
	US5	US20180021491A1	01-25-2018	RIGERT; Mario et al.	
	US6	US20190209748A1	07-11-2019	ANALYTIS et al.	
	US7	US20210093761A1	04-01-2021	HWANG et al.	
	US8	US20230111110A1	04-13-2023	DE BECDELIEVRE et al.	
	US9	US20230143842A1	05-11-2023	O'TOOLE et al.	
	US10	US20230158215A1	05-25-2023	O'TOOLE et al.	
	US11	US4,673,388A	06-16-1987	SCHLENSOG et al.	
	US12	US9498565B2	11-22-2016	NOWROOZI et al.	
	US13	US11260151B2	03-01-2022	O'TOOLE; Jonathan et al.	
	US14	US11311654B2	04-26-2022	O'TOOLE; Jonathan et al.	
	US15	US11324866B2	05-10-2022	O'TOOLE; Jonathan et al.	
	US16	US11357894B2	06-14-2022	O'TOOLE; Jonathan et al.	
	US17	US11357893B2	06-14-2022	O'TOOLE; Jonathan et al.	
	US18	US11376352B2	07-05-2022	O'TOOLE; Jonathan et al.	
	US19	US11413380B2	08-16-2022	O'TOOLE; Jonathan et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 2 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
	NPL1	Amended Complaint in Shenzhen Root Technology Co., Ltd. v. Chiaro Technology, Ltd., WDWA-2-23-cv-00631, filed June 2, 2023; 24 pages.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 3 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Yangbeini Wang #800,005 /	Date (YYYY-MM-DD)	2023-06-22
Name/Print	Yangbeini Wang	Registration Number	800,005

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**06/22/2023 05:46:14 PM ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	62321111	AUTHORIZED BY	Yangbeini Wang
CUSTOMER #	26111	FILING DATE	02/22/2021
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jonathan O'TOOLE

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 1005	E20236LH47176578	Jon Baitlon

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2806	SUBMISSION OF AN INFORMATION DISCLOSURE STATEMENT	104.00	1	104.00
			TOTAL AMOUNT:	**$104.00**

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New Applications Under 35 U.S.C. 111

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New International Application Filed with the USPTO as a Receiving Office

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Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
Approved for use through 12/31/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

Total Number of Pages in This Submission

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
- ☑ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☑ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
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- ☐ Drawing(s)
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- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

Copy of NPL1.

Remarks

The Office may charge any fee deficiency for any submission made with this transmittal to Deposit Account 19-0036.

Online Credit Card Payment Authorization in the Amount of $104.00 to Cover:
$104.00 - Information Disclosure Statement fee

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Yangbeini Wang #800,005/		
Printed name	Yangbeini Wang		
Date	June 22, 2023	Reg. No.	800,005

CERTIFICATE OF TRANSMISSION/MAILING

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Signature			
Typed or printed name		Date	

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PATENT AND TRADEMARK OFFICE

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Alexandria, VA 22313 - 1450
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
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Title of Invention

BREAST PUMP SYSTEM

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PATENT CENTER #	62321111	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 4

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-06-22-Transmittal-Form-sIDS-4944-0120006.pdf	1	Miscellaneous Incoming Letter	161 KB
2023-06-22-sIDS-Pleading-4944-0120006.pdf	2	Transmittal Letter	99 KB
2023-06-22-sIDS-Form-SB08-4944-0120006.pdf	3	Information Disclosure Statement (IDS) Form (SB08)	149 KB
Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.			
NPL_1_Amended-Complaint.pdf	24	Non Patent Literature	304 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-06-22-Transmittal-Form-sIDS-4944-0120006.pdf	B32E6BCCDC2633E53E463D7E0EE4E65F5EB2ED92B259C64F25FBA0FCC0A40F3ECB0B3002BAA3FC0E62D178B83602A75704EEE33D219FB78C11C9CCD74DCD6460
2023-06-22-sIDS-Pleading-4944-0120006.pdf	B21766329C44FDD244CB6049CDBDAA67FDBCC95797C467E162F6C50BDAEFA939EE988961AEE7EEA7992C0E826D1E30F1CC3C15391B465491DBA05950F497D8D8
2023-06-22-sIDS-Form-SB08-4944-0120006.pdf	D574E7D735F0C271DE3D94EC290C816EE17C1DD95203DA85B00427BFF1C390FB02662F6D22E21BDEC12E94D47A753FDDF54F5189A972936FD883437CAFAB4CEA
NPL_1_Amended-Complaint.pdf	0689BD6CB3C7261D12519D347B8C0BA90106F9A82F5EDFF2CFCA991A41F5DD6062586413A5BB4A3635FD59FFEF8835335CB14B154E8924BE9E35D7074B78F5D7

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National Stage of an International Application under 35 U.S.C. 371

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New International Application Filed with the USPTO as a Receiving Office

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: CHIARO TECHNOLOGY LIMITED	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, COURTNEY B
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Supplemental Information Disclosure Statement

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

Listed on accompanying IDS Forms PTO/SB/08a or its equivalent and PTO/SB/08b or its equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Applicant has listed dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(c) and is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an

action that otherwise closes prosecution in the application. The required fee is provided through online credit card payment authorization in the amount of **$104.00** in payment of the fee under 37 C.F.R. § 1.17(p).

Copy of document **NPL1** is submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2)(ii), no copies of the U.S. patents and patent application publications cited on the attached IDS Forms are submitted.

It is expected that the examiner will review the prosecution and cited art in the parent Application No. 16/009,547, filed June 15, 2018, in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Yangbeini Wang #800,005/

Yangbeini Wang
Attorney for Applicant
Registration No. 800,005

Date: June 22, 2023

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20347793.1

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	2003/0069536 A1	04-10-2003	Greter et al.	
	US2	2007/0054651 A1	03-08-2007	Farmer et al.	
	US3	2014/0227112 A1	08-14-2014	Felber	
	US4	2019/0365966 A1	12-05-2019	Bächler et al.	
	US5	2020/0016307 A1	01-16-2020	Edelman et al.	
	US6	2020/0300237 A1	09-24-2020	Marbet et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	FP1	EP 3482782 A1	05-15-2019	MEDELA HOLDING AG		

Examiner Signature		Date Considered	

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 2 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 3 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Yangbeini Wang #800,005/	Date (YYYY-MM-DD)	2023-05-15
Name/Print	Yangbeini Wang	Registration Number	800,005

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	05/15/2023 03:27:41 PM ET	4944.0120006

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	62088330	AUTHORIZED BY	Yangbeini Wang
CUSTOMER #	26111	FILING DATE	02/22/2021
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jonathan O'TOOLE

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
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			TOTAL AMOUNT:	$104.00

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National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

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Doc Code: TRAN.LET

Document Description: Transmittal Letter

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Approved for use through 12/31/2020. OMB 0651-0031
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	

Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
- ☑ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
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- ☑ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
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- ☐ Petition to Convert to a Provisional Application
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- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

Copy of FP1.

Remarks

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Yangbeini Wang #800,005/		
Printed name	Yangbeini Wang		
Date	May 15, 2023	Reg. No.	800,005

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(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

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(54) MEDIZINISCHE SAUGPUMPE

(57) Eine motorbetriebene medizinische Saugpumpe weist ein Pumpaggregat zur Erzeugung eines Unterdrucks, einen Pumpaggregatträger (3) zur Halterung des Pumpaggregats (7) und eine Aufnahme (35) zur Aufnahme eines Energiespeichers (7) auf. Das im Pumpaggregatträger (3) angeordnete Pumpaggregat (7) definiert eine erste Längsachse (L_1) und die Aufnahme (35) definiert eine zweite Längsachse (L_2). Der Pumpaggregatträger (3) bildet die Aufnahme (35). Die zweite Längsachse (L_2) verläuft in einem Winkel zur ersten Längsachse (L_1). Diese Saugpumpe ist klein und kompakt und weist eine gute Schalldämpfung auf.

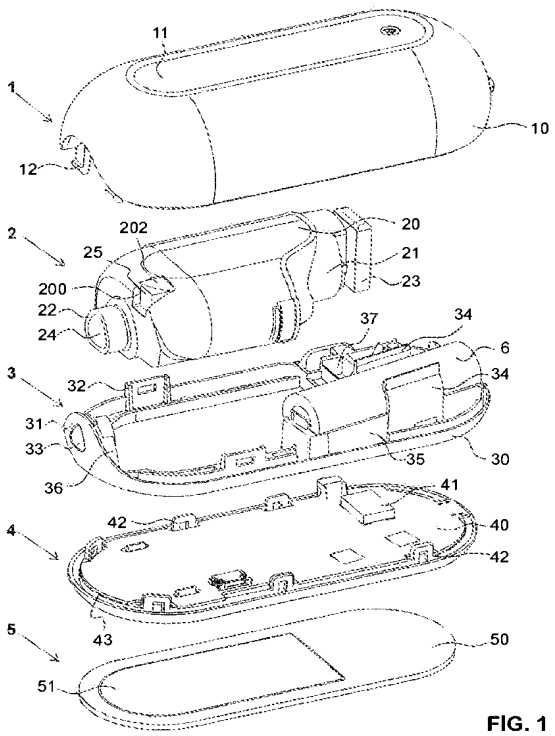

FIG. 1

EP 3 482 782 A1

Beschreibung

TECHNISCHES GEBIET

[0001] Die vorliegende Erfindung betrifft eine medizinische Saugpumpe, insbesondere eine motorbetriebene medizinische Saugpumpe. Derartige Saugpumpen sind insbesondere Brustpumpen zum Abpumpen von menschlicher Muttermilch oder Drainagepumpen zum Absaugen von Körperflüssigkeiten, wie beispielsweise für die Thoraxdrainage oder für die Wunddrainage.

STAND DER TECHNIK

[0002] Medizinische Saugpumpen, auch Vakuumpumpen genannt, sind für die verschiedensten Anwendungen bekannt. Beispielsweise werden sie als Brustpumpen zum Abpumpen von menschlicher Muttermilch oder als Drainagepumpen zum Absaugen von Körperflüssigkeiten verwendet. Derartige Saugpumpen weisen als Pumpaggregat Kolbenpumpen oder Membranpumpen auf. Die Verwendung einer Pumpmembran hat den Vorteil, dass die Saugpumpe als Ganzes relativ klein und leicht und im Gebrauch tragbar ausgebildet werden kann. Ein sehr kleines und trotzdem die hohen Anforderungen an eine Brustpumpe erfüllendes motorbetriebenes Pumpaggregat ist aus WO 2006/032156 A1 bekannt. Tragbare Saugpumpen weisen üblicherweise auch einen Energiespeicher zum Betreiben eines Motors des Pumpaggregats auf. Die Grösse des Energiespeichers und des Pumpaggregat bestimmen somit im Wesentlichen die Grösse des Pumpengehäuses.

[0003] Eine weitere Anforderung an derartige Saugpumpen ist die Schalldämpfung. Das Pumpaggregat ist oft relativ laut und rhythmisch wiederkehrende Geräusche stören den Benützer. Es ist deshalb bekannt, das Pumpaggregat in eine schalldämmende bzw. schalldämpfende Umgebung einzubetten. In diesem Text wird Schalldämmung und Schalldämpfung gleichwertig behandelt und jeweils als Schalldämpfung bezeichnet.

[0004] WO 2017/157691 A1 offenbart eine medizinische Saugpumpe mit einer elastischen Lagerung des Pumpaggregats innerhalb eines Pumpengehäuses.

[0005] In WO 2015/109934 A1 ist das Pumpaggregat in einem geschlossenen inneren Gehäuse angeordnet und eine Batterie ist parallel zum inneren Gehäuse in einem äusseren Pumpengehäuse angeordnet.

[0006] In WO 2017/140562 A1 ist das Pumpaggregat mittels Federn in einem äusseren Pumpengehäuse befestigt.

DARSTELLUNG DER ERFINDUNG

[0007] Es ist deshalb eine Aufgabe der Erfindung, eine medizinische Saugpumpe zu schaffen, welche möglichst kompakt, jedoch robust ausgebildet ist.

[0008] Diese Aufgabe löst eine motorbetriebene medizinische Saugpumpe mit den Merkmalen des Patentanspruchs 1.

[0009] Die erfindungsgemässe motorbetriebene medizinische Saugpumpe weist ein Pumpaggregat zur Erzeugung eines Unterdrucks, einen Pumpaggregatträger zur Halterung des Pumpaggregats und eine Aufnahme zur Aufnahme eines Energiespeichers auf, wobei das im Pumpaggregatträger angeordnete Pumpaggregat eine erste Längsachse definiert und die Aufnahme eine zweite Längsachse definiert. Erfindungsgemäss bildet der Pumpaggregatträger die Aufnahme und die zweite Längsachse verläuft in einem Winkel zur ersten Längsachse.

[0010] Da der Pumpaggregatträger die Aufnahme für den Energiespeicher bildet und dank der winkligen Anordnung von Pumpaggregat und Energiespeicher sind praktisch keine Leerräume vorhanden und die Grösse der Saugpumpe insgesamt ist minimiert. Da Pumpaggregat und Energiespeicher von demselben Pumpaggregatträger gehalten sind, ist die Vorrichtung insgesamt relativ steif ausgebildet. Dies erhöht nicht nur die Robustheit der Vorrichtung sondern dies minimiert auch Schwingungen beim Betrieb des Pumpaggregats und reduziert somit die Geräuschbildung bzw. -weiterleitung.

[0011] In bevorzugten Ausführungsformen ist der Pumpaggregatträger im Wesentlichen als Rahmen ausgebildet. Der Rahmen kann eine beliebige Form aufweisen. Vorzugsweise weist er jedoch eine im Wesentlichen längliche abgerundete Grundform, insbesondere eine elliptische oder ovale Grundform, auf. Die Ausbildung als Rahmen ermöglicht eine Leichtbauweise und erhöht zudem die Steifigkeit. Zudem ist ein Minimum an Material notwendig, was die Herstellungskosten entsprechend minimiert. Der Rahmen ist vorzugsweise einstückig ausgebildet. Vorzugsweise ist er im Spritzgussverfahren aus Kunststoff hergestellt.

[0012] Vorzugsweise umfasst die Saugpumpe ein erstes Pumpgengehäuseteil und ein zweites Pumpengehäuseteil, wobei der Pumpaggregatträger zwischen dem ersten und dem zweiten Pumpengehäuseteil gehalten ist. Dadurch wird er in seiner Lage fixiert und seine Steifigkeit wird erhöht.

[0013] In bevorzugten Ausführungsformen bildet der Pumpaggregatträger einen Teil des Pumpengehäuses. Er bildet vorzugsweise ein von aussen sichtbares Verbindungsteil zwischen dem ersten und dem zweiten Pumpengehäuseteil. Dies erleichtert den Zusammenbau der einzelnen Bauteile und eine weitere Lagerung des Pumpaggregatträgers inner-

halb des Pumpengehäuses lässt sich dadurch vermeiden.

[0014] Vorzugsweise ist der gesamte Pumpaggregatträger einstückig ausgebildet.

[0015] In bevorzugten Ausführungsformen sind mindestens zwei elastische Lager zur Lagerung des Pumpaggregats im Pumpaggregatträger vorhanden. Dadurch lässt sich die Übertragung von Vibrationen und Körperschall vom Pumpaggregat auf den Pumpaggregatträger und somit auf das Pumpengehäuse minimieren bzw. vermeiden. Zudem ist das Pumpaggregat dadurch definiert gehalten und trotzdem flexibel aufgehängt, so dass die Geräuschentwicklung reduziert und/oder gedämpft wird. Vorzugsweise ist eine Zweipunktlagerung vorhanden. Es ist jedoch auch möglich, eine Drei- oder Mehrpunktlagerung einzusetzen. Die Lager sind vorzugsweise aus einem Elastomer gebildet.

[0016] Vorzugsweise bildet mindestens ein erstes dieser Lager einen Vakuumanschluss. Mindestens ein zweites dieser Lager, welches vorzugsweise das Gegenlager zum ersten Lager bildet, ist vorzugsweise an einem motorseitigen Ende des Pumpaggregats und in Verlängerung einer Motorachse des Pumpaggregats, d.h. in der Flucht der Motorachse, angeordnet.

[0017] Vorzugsweise sind genau zwei Lager vorhanden, welche entlang der ersten Längsachse an gegenüberliegenden Enden des Pumpaggregats angeordnet sind. Vorzugsweise sind diese zwei Lager bezüglich der ersten Längsachse versetzt zueinander angeordnet. Die Verwendung von genau zwei elastischen Lagern und/oder die genannte Anordnung der Lager minimiert die Grösse der Saugpumpe insgesamt und führt zudem dazu, dass sich Vibrationen und Körperschall nicht oder nur begrenzt ausbreiten können.

[0018] Die Schalldämpfung ist optimiert, wenn das Pumpaggregat in einem Schalldämpfungsgehäuse angeordnet ist und das Schalldämpfungsgehäuse im Pumpaggregatträger gehalten ist.

[0019] Vorzugsweise ist eine Lufteinlassöffnung vorhanden, welche von einem Schalldämpfungselement überdeckt ist. Vorzugsweise ist die Lufteinlassöffnung im Schalldämpfungsgehäuse angeordnet, welches Zischgeräusche beim Einsaugen der Umgebungsluft minimiert. Das Schalldämpfungselement besteht vorzugsweise aus Schaumstoff oder aus einem anderen geeigneten porösen oder luftdurchlässigen Material. Das Pumpengehäuse ist vorzugsweise auf bekannte Art und Weise undicht ausgebildet, so dass über mehrere Stellen ein Luftaustausch vom Innenraum des Pumpgengehäuses in die Umgebung und umgekehrt stattfinden kann.

[0020] Vorzugsweise weist das Schalldämpfungsgehäuse ein Etui mit einer Aufnahmeöffnung zur Aufnahme des Pumpaggregats und einen das Etui verschliessenden Deckel auf, wobei der Deckel gebogen ausgebildet ist. Dies erleichtert den Zusammenbau der Vorrichtung und ermöglicht eine möglichst platzsparende Ausbildung des Schalldämpfungsgehäuses. Das Etui ist vorzugsweise aus einem steifen oder halbsteifen Material, insbesondere aus einem Kunststoff, und der Deckel ist vorzugsweise aus einem weichen Material gefertigt.

[0021] Vorzugsweise ist das Schalldämpfungsgehäuse mittels der mindestens zwei elastischen Lager im Pumpaggregatträger gelagert. Vorzugsweise lagern die mindestens zwei elastischen Lager einerseits das Schalldämpfungsgehäuse im Pumpengehäuse und andererseits das Pumpaggregat innerhalb des Schalldämpfungsgehäuses. D.h. dieselben Lager weisen Doppelfunktionen auf, vorzugsweise weist jedes Lager auf zwei gegenüberliegenden Seiten entsprechende Flächen oder Ausbildungen auf. Dadurch reduziert sich die Anzahl der benötigten Lager. Die Lagerung ist genau definiert und optimiert. Zudem benötigt sie wenig Platz und ein Minimum an Bauteilen. Die Schalldämpfung ist verbessert, der Zusammenbau erleichtert und die Herstellungskosten minimiert.

[0022] Vorzugsweise ist das erste Lager ein Lagermodul in Form eines elastischen Einsatzelements, welches im Schalldämpfungsgehäuse gehalten ist und dieses durchsetzt. Das gesamte Einsatzelement ist vorzugsweise weich und einstückig hergestellt, beispielsweise aus Silikon oder TPE (thermoplastisches Elastomer). Das Einsatzelement dient als zweiseitiges Lager und verschliesst zudem das Schalldämpfungsgehäuse.

[0023] Vorzugsweise ist das zweite Lager ein Deckel oder ein Lagermodul in Form eines Teils eines Deckels des Schalldämpfungsgehäuses, wobei der gesamte Deckel elastisch ausgebildet ist. Vorzugsweise besteht er aus einem weichen Material, wie z.B. Silikon oder TPE. Durch Wahl der Form des Deckels lässt sich die Steifigkeit der Lagerstelle definieren. Der Deckel an sich kann das zweite Lager bilden oder zumindest Teile dieses Lagers bilden.

[0024] Einzelne Elemente lassen sich auch ohne die winklige Anordnung von Pumpaggregat und Energiespeicher bzw. ohne die Anordnung dieser zwei Bauteile auf einem gemeinsamen Pumpaggregatträger zu anderen erfindungsgemässen Saugpumpen zusammensetzen. Beispiele hierfür sind nachfolgend angegeben, welche als separate Erfindungen ebenfalls beansprucht sind. Die oben genannten bevorzugten Ausführungsformen, insbesondere die Merkmale der abhängigen Patentansprüche, lassen sich auch entsprechend mit diesen Beispielen ohne Verwendung aller Merkmale des Patentanspruchs 1 kombinieren.

[0025] In einer bevorzugten, ebenfalls als Erfindung beanspruchten Ausführungsform weist eine medizinische Saugpumpe ein Pumpengehäuse, ein im Pumpengehäuse angeordnetes Pumpaggregat zur Erzeugung eines Unterdrucks und mindestens ein erstes elastisches Lager und ein zweites elastisches Lager zur Lagerung des Pumpaggregats im Pumpengehäuse auf. Das erste elastische Lager befindet sich an einem ersten Ende des Pumpaggregats und das zweite elastische Lager befindet sich an einem zweiten, dem ersten Ende gegenüberliegenden Ende des Pumpaggregats. Dabei bildet das erste elastische Lager einen Vakuumanschluss. Diese Anordnung ist äusserst platzsparend und vermindert in optimaler Weise Vibrationen.

[0026] In einer anderen, ebenfalls als Erfindung beanspruchten Ausführungsform weist eine medizinische Saugpumpe ein Pumpaggregat, ein Schalldämpfungsgehäuse zur Aufnahme des Pumpaggregats und ein Pumpengehäuse zur Aufnahme des Schalldämpfungsgehäuses auf. Das Schalldämpfungsgehäuse weist ein Etui zur Aufnahme des Pumpaggregats und einen das Etui verschliessenden Deckel auf. Der Deckel ist elastisch ausgebildet und er weist ein elastisches Lager zur Lagerung des Schalldämpfungsgehäuses im Pumpengehäuse auf. Diese Ausbildung ermöglicht einen einfachen Zusammenbau der Vorrichtung, da das Pumpaggregat lediglich in das Etui eingeschoben werden muss. Der elastische, insbesondere weiche Deckel verhindert auf optimale Weise Vibrationen und die Verbreitung von Körperschall.

[0027] In bevorzugten Ausführungsformen sind diese zwei Varianten miteinander kombiniert. D.h. das erste Lager bildet den Vakuumanschluss und das zweite Lager den Deckel.

[0028] In einer weiteren bevorzugten Ausführungsform, welche ebenfalls als separate Erfindung beansprucht wird, weist eine medizinische Saugpumpe ein Pumpaggregat, ein Schalldämpfungsgehäuse zur Aufnahme des Pumpaggregats und ein Pumpengehäuse zur Aufnahme des Schalldämpfungsgehäuses auf. Mindestens ein erstes und ein zweites elastisches Lager sind vorhanden, wobei mindestens eines dieser zwei elastischen Lager einerseits das Schalldämpfungsgehäuse im Pumpengehäuse lagert und andererseits das Pumpaggregat innerhalb des Schalldämpfungsgehäuses lagert. Vorzugsweise lagern beide elastischen Lager sowohl das Schalldämpfungsgehäuse bezüglich des Pumpengehäuses wie auch das Pumpaggregat bezüglich des Schalldämpfungsgehäuses. Das heisst, vorzugsweise sind beide elastischen Lager als Module ausgebildet, welche auf zwei gegenüberliegenden Seiten Lagerstellen bilden. Wie oben bereits erwähnt, ist hier die Lagerung sowie die Schalldämpfung optimiert und eine äusserst kompakte Bauweise ermöglicht. Diese Ausführungsform lässt sich beispielsweise erreichen, indem der Deckel und/oder der Vakuumanschluss als Lager ausgebildet sind und jeweils an den entsprechenden Stellen oder gesamthaft weich bzw. flexibel ausgebildet sind.

[0029] Weitere Ausführungsformen sind in den abhängigen Ansprüchen angegeben.

KURZE BESCHREIBUNG DER ZEICHNUNGEN

[0030] Bevorzugte Ausführungsformen der Erfindung werden im Folgenden anhand der Zeichnungen beschrieben, die lediglich zur Erläuterung dienen und nicht einschränkend auszulegen sind. In den Zeichnungen zeigen:

Figur 1 eine Explosionsdarstellung einer erfindungsgemässen Saugpumpe in einer ersten Ausführungsform;

Figur 2 einen ersten Querschnitt durch die Saugpumpe gemäss Figur 1;

Figur 3 einen zweiten Querschnitt durch die Saugpumpe gemäss Figur 1;

Figur 4 eine Explosionsdarstellung eines Schalldämpfungsgehäuses mit einem Pumpaggregat der Saugpumpe gemäss Figur 1;

Figur 5 eine perspektivische Darstellung eines Teils der Saugpumpe gemäss Figur 1 ohne Schalldämpfungselement;

Figur 6 eine perspektivische Darstellung eines Teils der Saugpumpe gemäss Figur 1 mit Schalldämpfungselement;

Figur 7 eine perspektivische Darstellung eines ersten Lagermoduls der Saugpumpe gemäss Figur 1;

Figur 8 eine Ansicht des ersten Lagermoduls gemäss Figur 7 von oben;

Figur 9a einen Querschnitt durch eine Anschlussöffnung des ersten Lagermoduls gemäss Figur 7 in einer ersten Variante;

Figur 9b einen Querschnitt durch eine Anschlussöffnung des ersten Lagermoduls gemäss Figur 7 in einer zweiten Variante;

Figur 9c einen Querschnitt durch eine Anschlussöffnung des ersten Lagermoduls gemäss Figur 7 in einer dritten Variante;

Figur 10 eine perspektivische Darstellung eines zweiten Lagermoduls der Saugpumpe gemäss Figur 1;

Figur 11 eine Ansicht des zweiten Lagermoduls gemäss Figur 10 von oben;

Figur 12a einen Querschnitt durch eine Anschlussöffnung des zweiten Lagermoduls gemäss Figur 11 in einer ersten Variante;

Figur 12b einen Querschnitt durch eine Anschlussöffnung des zweiten Lagermoduls gemäss Figur 11 in einer zweiten Variante;

Figur 12c einen Querschnitt durch eine Anschlussöffnung des zweiten Lagermoduls gemäss Figur 11 in einer dritten Variante und

Figur 12d einen Querschnitt durch eine Anschlussöffnung des zweiten Lagermoduls gemäss Figur 11 in einer vierten Variante.

BESCHREIBUNG BEVORZUGTER AUSFÜHRUNGSFORMEN

[0031] In Figur 1 ist ein bevorzugtes Ausführungsbeispiel einer erfindungsgemässen Saugpumpe dargestellt. Es handelt sich um eine Brustpumpe zum Abpumpen von menschlicher Muttermilch.

[0032] Die Saugpumpe weist ein erstes Pumpengehäuseteil 1, ein Schalldämpfungsgehäuse 2, einen Pumpaggregatträger 3, ein zweites Pumpengehäuseteil 4 sowie eine Abdeckung 5 auf. Im zusammengesetzten Zustand der Saugpumpe befindet sich das Schalldämpfungsgehäuse 2 innerhalb eines Pumpengehäuses, welches im Wesentlichen durch das erste Pumpengehäuseteil 1, das zweite Pumpengehäuseteil 4 und den dazwischen angeordneten und zwischen diesen zwei Teilen 1, 4 eingeklemmten Pumpaggregatträger 3 gebildet ist. Der Pumpaggregatträger 3 ist somit vorzugsweise von aussen als umlaufender Streifen erkennbar.

[0033] Das erste Pumpengehäuseteil 1 bildet den Boden der Saugpumpe. Es weist einen schalenförmigen Grundkörper 10 auf, dessen Unterseite, welche hier nach oben gerichtet ist, nahezu flach ausgebildet ist und eine Auflagefläche 11 bildet. Im Längsschnitt ist der Grundkörper 10 oval ausgebildet. Am Umfang des Grundkörpers 10 verteilt sind erste Verbindungselemente 12, vorzugsweise Schnappelemente oder andere bekannte Verbindungsmittel, angeordnet.

[0034] Das zweite Pumpengehäuseteil 4 weist eine im Wesentlichen ovale Grundplatte 40 und eine umlaufende Rinne 43 zur Aufnahme des Pumpaggregatträgers 3 auf. Auf der Grundplatte 40 sind die in Saugpumpen üblichen elektronischen Bauteile angeordnet. Sie sind hier lediglich schematisch dargestellt. Eine Steuer- und Elektronikeinheit ist mit dem Bezugszeichen 41 versehen. Über dem Umfang des zweiten Pumpengehäuseteils 4 verteilt sind zweite Verbindungselemente 42 angeordnet, die in den Rahmen 30 eingreifen.

[0035] Die Abdeckung 5 bildet zusammen mit dem zweiten Pumpengehäuseteil 4 das obere Teil des Pumpengehäuses, auch wenn diese Bauteile in dieser Darstellung unten angeordnet sind. Die Abdeckung 5 lässt sich auf dem zweiten Pumpengehäuseteil 4 befestigen. Sie weist vorzugsweise eine planparallele steife und ovale Deckplatte 50 mit einem Anzeige- und Betätigungsfenster 51 auf. Mittels des Anzeige- und Betätigungsfensters 51 lassen sich beispielsweise Benutzereingaben eingeben und die Funktionsweise der Saugpumpe optisch darstellen.

[0036] Der Pumpaggregatträger 3 ist vorzugsweise steif oder halbsteif ausgebildet. Vorzugsweise ist er aus einem Kunststoff gefertigt und vorzugsweise ist er einstückig. Er weist einen ovalen Rahmen 30 auf. An einer schmalen Stirnseite geht der Rahmen 30 in eine erhöhte Stirnwand 31 über, welche eine Durchgangsöffnung 33 aufweist. Die Rückseite der Stirnwand 31 ist mit einer ersten Lageraufnahme 36 versehen, welche die Durchgangsöffnung 33 umgibt. Verteilt über dem Umfang des Rahmens 30 sind dritte Verbindungselemente 32 vorhanden, die in das erste Pumpengehäuseteil 1 eingreifen, um das Pumpengehäuse zusammenzuhalten.

[0037] An dem der Durchgangsöffnung 33 gegenüberliegenden Ende des Rahmens 30 ist eine Energiespeicheraufnahme 35 angeordnet. Sie ist entsprechend der Form eines Energiespeichers 6 geformt. Der Energiespeicher 6 ist in diesem Beispiel eine zylinderförmige, wieder aufladbare Batterie. Andere Formen und Arten von Energiespeichern lassen sich auch verwenden. Die Energiespeicheraufnahme 35 ist als ein in der Figur 1 nach oben offener Kasten ausgebildet, wobei auf zwei gegenüberliegenden Seiten je ein Klammerelement 34 nach oben ragt. All diese Elemente sind vorzugsweise einstückig gemeinsam mit dem Rahmen 30 ausgebildet.

[0038] Benachbart zur Energiespeicheraufnahme 35 ist eine zweite Lageraufnahme 37 ausgebildet. Auch diese ist in diesem Beispiel als rechteckförmiger, nach oben offen ausgebildeter Kasten einstückig am Rahmen 30 angeformt. Das hintere, der Durchgangsöffnung 33 entgegengesetzte Ende des Rahmens 30 ist als Stromanschluss 38 ausgebildet. Dies ist in den Figuren 2 und 3 gut erkennbar.

[0039] Das Schalldämpfungsgehäuse 2 weist ein Etui 20 zur Aufnahme eines Pumpaggregats 7 auf. Das Etui 20 ist vorzugsweise steif oder halbsteif ausgebildet, insbesondere besteht es aus Kunststoff. Vorzugsweise weist es eine zur Pumpgehäuseform passende ovale abgerundete Form auf, wobei das Etui 20 im Bereich seiner Öffnung abgeschrägt ist. Die Abschrägung ist vorzugsweise geschwungen, so dass das Etui stufenförmig und auf einer Seite länger ausgebildet

ist als auf der anderen Seite. Dies ist in Figur 1 gut erkennbar.

[0040] Dieser stufenförmige Rand ist mittels eines Deckels 21 geschlossen. Der Deckel 21 weist einen entsprechend geschwungen ausgebildeten, d.h. gebogenen Verschlusskörper 210 auf. Dieser geht vorzugsweise einstückig in einen annähernd zylinderförmigen Übergangsbereich 211 über. Der Durchmesser dieses Übergangsbereichs 211 entspricht vorzugsweise annähernd dem Durchmesser des längeren Bereichs des Etuis 20. Dem Übergangsbereich 211 folgt ein Verbindungsstift 212, an welchem sich ein zweites Lagermodul 23 anschliesst. Dies ist in den Figuren 2 und 3 gut erkennbar. Ein erstes Lagermodul 22 befindet sich am gegenüberliegenden Ende des Etuis 20 und wird weiter unten im Text ausführlicher beschrieben.

[0041] Das zweite Lagermodul 23 kann auf den Verbindungsstift 212 aufgesteckt sein. Vorzugsweise ist es jedoch einstückig mit diesem und dem gesamten restlichen Deckel 21 ausgebildet. Vorzugsweise ist der Deckel 21 mit dem zweiten Lager 23 elastisch ausgebildet. Insbesondere ist er weich. Vorzugsweise ist er aus einem Elastomer oder aus Silikon gefertigt.

[0042] Das Etui 20 weist im Bereich des ersten Lagermoduls 22 eine Ausnehmung 200 auf, welche im oberen Bereich ein Fenster 202 aufweist. In dieser Ausnehmung 200 ist ein Schalldämpfungselement 25, hier ein Schaumstoffwürfel, angeordnet.

[0043] In Figur 2 ist die Anordnung des Schalldämpfungsgehäuses 2 sowie des Energiespeichers 6 innerhalb des Rahmens 30 des Pumpaggregatträgers 3 gut erkennbar. Das Schalldämpfungsgehäuse 2, genauer das Etui 20, ist mittels des ersten Lagermoduls 22 in der ersten Lageraufnahme 36 gelagert. Das zweite Lagermodul 23 befindet sich in der zweiten Lageraufnahme 37 des Pumpaggregatträgers 3, so dass das Schalldämpfungsgehäuse 2 auch an diesem gegenüberliegenden Ende im Pumpaggregatträger 3 gelagert ist. Somit ist eine Zweipunktlagerung vorhanden.

[0044] Eine Durchgangsöffnung des ersten Lagermoduls 22, welche hier einen Vakuumanschluss 24 bildet, fluchtet mit der Durchgangsöffnung 33 des Pumpaggregatträgers 3, wie dies in Figur 3 gut erkennbar ist. Diese Durchgangsöffnung 33 bildet somit eine Aufnahme für einen Stecker eines Saugschlauchs, welcher zu einer Brusthaube zum Anlegen an die Mutterbrust führt. Stecker, Saugschlauch und Brusthaube sind hier nicht dargestellt. Sie sind jedoch aus dem Stand der Technik hinlänglich bekannt.

[0045] Wie in Figur 2 erkennbar ist, definiert das Etui 20 eine erste Längsachse L_1, welche mit der Längsmittelachse des Vakuumanschlusses 24 fluchtet. Der Energiespeicher 6 definiert einen zweite Längsachse L_2, welche in einem Winkel zu dieser ersten Längsachse L_1 verläuft. Das zweite Lagermodul 23 definiert mit seiner Längsmittelachse eine dritte Längsachse L_3, welche parallel versetzt zur ersten Längsachse L_1 verläuft.

[0046] Wie in den Figuren 2 und 3 gut erkennbar ist, ist der Platz innerhalb des Pumpaggregatträgers durch die Abschrägung des Etuis 20 sowie durch die schräge Anordnung des Energiespeichers 6 optimal genutzt und Leerräume sind weitgehend vermieden. Das Pumpengehäuse kann insgesamt sehr klein und kompakt ausgebildet werden. Es ist schallgedämpft und trotzdem steif und robust.

[0047] Die Anordnung des Pumpaggregats 7 innerhalb des Schalldämpfungsgehäuses 2 ist in Figur 3 dargestellt. Eine passende Explosionsdarstellung dazu findet sich in Figur 4.

[0048] Vorzugsweise entspricht das Pumpaggregat 7 im Wesentlichen dem in WO 2006/032156 A1 beschriebenen Pumpaggregat. Es lassen sich jedoch auch andere Formen und Ausgestaltungen in der erfindungsgemässen Vorrichtung verwenden. Vorzugsweise umfasst das Pumpaggregat jedoch einen Elektromotor sowie eine Pumpeinheit, insbesondere eine Membranpumpe, vorzugsweise eine Pumpkammer mit einer Pumpmembran.

[0049] Der Elektromotor ist in den Figuren mit dem Bezugszeichen 70 versehen, die Pumpeinheit mit dem Bezugszeichen 71. Die dritte Längsachse L_3 des zweiten Lagermoduls 23 bildet die Flucht einer nicht dargestellten Motorachse des Elektromotors 70. Der Elektromotor 70 ist somit benachbart zum zweiten Lagermodul 23 angeordnet.

[0050] Die Pumpeinheit 71 weist eine Entlüftungsöffnung 710, eine Vakuumöffnung 711 sowie eine Belüftungsöffnung 712 auf. Dies ist in Figur 3 gut erkennbar.

[0051] Die Belüftungsöffnung 712 schliesst sich im zusammengebauten Zustand der Vorrichtung an eine Lufteinlassöffnung 201 an, welche sich in der Ausnehmung des Schalldämpfungsgehäuses 2 befindet. Diese Lufteinlassöffnung 201 ist in Figur 5 gut erkennbar. Sie ist vom Schalldämpfungselement 25 überdeckt, wie dies in Figur 6 dargestellt ist. Ein Fenster 202 ist aus spritzgusstechnischen Gründen im Etui 20 vorhanden.

[0052] Die Entlüftungsöffnung 710 führt in das Innere des Schalldämpfungsgehäuses 2, genauer des Etuis 20. Luft, welche über diese Entlüftungsöffnung 710 aus der Pumpeinheit 71 entweicht, verlässt das Schalldämpfungsgehäuse 2 über undichte Stellen wie beispielsweise über ein Aufnahmeelement 26 einer Steckverbindung mit einem Einsteckelement 213 des Deckels 21.

[0053] Die Vakuumöffnung 711 fluchtet mit einem Verbindungskanal 222 des ersten Lagermoduls 22, wie dies in Figur 4 erkennbar ist. Der Verbindungskanal 222 weist im Innern des ersten Lagermoduls 22 einen abgewinkelten, d.h. nicht geradlinigen Verlauf auf und endet im Vakuumanschluss 24, genauer in der darin vorhandenen Anschlussöffnung 225. Diese Anschlussöffnung 225 ist in Figur 7 gut erkennbar.

[0054] Das Pumpaggregat 7 ist mittels des ersten Lagermoduls 22 vakuumseitig im Schalldämpfungsgehäuse 2 gelagert und mittels des zweiten Lagermoduls 23, genauer des Deckels 21, motorseitig im Schalldämpfungsgehäuse 2

gelagert. Der Deckel 21 ist hierfür lediglich auf dem Etui 20 aufzustecken und mit den bereits erwähnten Einsteckelementen 213 in die entsprechenden Aufnahmeelemente 26 einzustecken.

[0055] Das erste Lagermodul 22 ist nicht wie in Figur 4 dargestellt dem Etui 20 vorgelagert, sondern es befindet sich innerhalb des Etuis 20. Es lässt sich hierfür einfach über die gebogene Öffnung einschieben und durch eine stirnseitige Durchgangsöffnung 27 des Etuis 20 teilweise durchschieben. Ein Anschlusskörper 221 ragt aus der Öffnung heraus, ein Hals 226 ist freigestellt und ein Grundkörper 220 dichtet gegenüber dem Innenraum des Etuis 20 an dessen Innenseite. Diese Teile sind in den Figuren 7 und 8 gut erkennbar. Zur Befestigung des Grundkörpers 220 im Etui 20 dient vorzugsweise ein Klemmelement 223 in der Form einer federnden Zunge. Diese Zunge 223 dichtet ebenfalls gegenüber dem Innenraum des Etuis 20.

[0056] Der Grundkörper 220 weist einen Belüftungskanal 224 auf, welcher die Verbindung zwischen der Belüftungsöffnung 712 der Pumpeinheit 71 und der Lufteinlassöffnung 201 des Etuis 20 schafft.

[0057] Das gesamte erste Lagermodul 22 ist einstückig und vorzugsweise elastisch, insbesondere weich ausgebildet. Es bildet somit an zwei gegenüberliegenden Seiten Lagerstellen aus: auf einer ersten Seite zwischen dem Schalldämpfungsgehäuse 2 und dem Pumpaggregatträger 3 und somit dem Pumpengehäuse und auf einer gegenüberliegenden Seite zwischen dem Schalldämpfungsgehäuse 2 und dem Pumpaggregat 7, genauer der Pumpeinheit 71.

[0058] Auch der Deckel mit dem zweiten Lagermodul 23 ist einstückig und vorzugsweise elastisch, insbesondere weich ausgebildet. Auch dieses bildet somit an zwei gegenüberliegenden Seiten Lagerstellen aus: auf einer ersten Seite zwischen dem Schalldämpfungsgehäuse 2 und dem Pumpaggregatträger 3 und somit dem Pumpengehäuse und auf einer gegenüberliegenden Seite zwischen dem Schalldämpfungsgehäuse 2 und dem Pumpaggregat 7, genauer dem Elektromotor 70. Da der Pumpaggregatträger 3 Teil des äusseren Pumpengehäuses ist, erübrigt sich eine weitere Lagerung.

[0059] Die Schalldämpfung bzw. die Vibrationsdämpfung lässt sich weiterhin optimieren, indem die Anschlussöffnung 225 entsprechend gewählt wird. Bewährt haben sich Formen, wie sie in den Figuren 9a bis 9c dargestellt sind. Es ist der Hals 226 des ersten Lagermoduls 22 im Querschnitt gezeigt sowie die sich darin befindliche Anschlussöffnung 225. Die Querschnitte des Halses 226 sowie die Formen der Anschlussöffnung 225 lassen sich beliebig miteinander kombinieren. In Figur 9a ist der Hals 226 kreuzförmig und die Anschlussöffnung 225 ist rund. In Figur 9b sind der Hals 226 und die Anschlussöffnung 225 oval und in Figur 9c sind sie rund. Die Kombination gemäss Figur 9b ist am meisten bevorzugt.

[0060] In den Figuren 10 bis 12d ist der Deckel 21 mit dem zweiten Lagermodul 23 dargestellt. Er weist wie bereits beschrieben den gebogenen Verschlusskörper 210, den Übergangsbereich 211, den Verbindungsstift 212 und das zweite Lagermodul 23 auf. Das zweite Lagermodul 23 weist vorzugsweise einen quaderförmigen Rahmen mit darin verlaufenden Verbindungsstreben auf. Dadurch ist er elastisch und passt sich seiner zugehörigen zweiten Lageraufnahme 37 optimal an.

[0061] Im Übergangsbereich 211 sind vorzugsweise Kabeldurchführungen 214 in Form von Durchgangsöffnungen vorhanden, um den Elektromotor 70 über die Grundplatte 40 mit der Steuer- und Elektronikeinheit 41 zu verbinden. Am gebogenen Verschlusskörper 210 sind die Einsteckelemente 213 angeformt.

[0062] Die Schalldämpfung und die Lagerung lassen sich durch die Formgebung des Verbindungsstifts 212 zusätzlich optimieren. In den Figuren 12a bis 12 sind bevorzugte Varianten dargestellt. Vorzugsweise ist der Verbindungsstift 212 vollflächig, also massiv ausgebildet. Vorzugsweise ist er relativ steif.

[0063] In Figur 12a ist sein Querschnitt kreuzförmig, in Figur 12b rund, in Figur 12c rechteckig und in Figur 12d oval. Vorzugsweise ist er kreuzförmig.

[0064] Die erfindungsgemässe Saugpumpe ist klein und kompakt und weist eine gute Schalldämpfung auf.

BEZUGSZEICHENLISTE

[0065]

1	erstes Pumpengehäuseteil	30	Rahmen
10	schalenförmiger Grundkörper	31	Stirnwand
11	Auflagefläche	32	drittes Verbindungselement
12	erstes Verbindungselement	33	Durchgangsöffnung
		34	Klammerelement
2	Schalldämpfungsgehäuse	35	Energiespeicheraufnahme
20	Etui	36	erste Lageraufnahme
200	Ausnehmung	37	zweite Lageraufnahme
201	Lufteinlassöffnung	38	Stromanschluss
202	Fenster		

(fortgesetzt)

21	Deckel	4	zweites Pumpengehäuseteil
210	gebogener Verschlusskörper	40	Grundplatte
211	Übergangsbereich	41	Steuer- und Elektronikeinheit
212	Verbindungsstift	42	zweites Verbindungselement
213	Einsteckelement	43	Rinne
214	Kabeldurchführungen		
22	erstes Lagermodul	5	Abdeckung
220	Grundkörper	50	Deckplatte
221	Anschlusskörper	51	Anzeige- und Betätigungsfenster
222	Verbindungskanal		
223	Klemmelement		
224	Belüftungskanal	6	Energiespeicher
225	Anschlussöffnung		
226	Hals	7	Pumpaggregat
23	zweites Lagermodul	70	Elektromotor
24	Vakuumanschluss	71	Pumpeinheit
25	Schalldämpfungselement	710	Entlüftungsöffnung
26	Aufnahmeelement	711	Vakuumöffnung
27	Durchgangsöffnung	712	Belüftungsöffnung
3	Pumpaggregatträger	L_1	erste Längsachse
L_2	zweite Längsachse		
L_3	dritte Längsachse		

Patentansprüche

1. Motorbetriebene medizinische Saugpumpe mit einem Pumpaggregat zur Erzeugung eines Unterdrucks, mit einem Pumpaggregatträger (3) zur Halterung des Pumpaggregats (7) und mit einer Aufnahme (35) zur Aufnahme eines Energiespeichers (7), wobei das im Pumpaggregatträger (3) angeordnete Pumpaggregat (7) eine erste Längsachse (L_1) definiert und die Aufnahme (35) eine zweite Längsachse (L_2) definiert, **dadurch gekennzeichnet, dass** der Pumpaggregatträger (3) die Aufnahme (35) bildet und dass die zweite Längsachse (L_2) in einem Winkel zur ersten Längsachse (L_1) verläuft.

2. Motorbetriebene medizinische Saugpumpe nach Anspruch 1, wobei der Pumpaggregatträger (3) im Wesentlichen als Rahmen (30) ausgebildet ist und eine im Wesentlichen längliche abgerundete Grundform, insbesondere einen elliptische oder ovale Grundform, aufweist.

3. Motorbetriebene medizinische Saugpumpe nach einem der Ansprüche 1 oder 2, wobei sie ein Pumpengehäuse mit einem ersten Pumpengehäuseteil (1) und einem zweiten Pumpengehäuseteil (4) umfasst und wobei der Pumpaggregatträger (3) zwischen dem ersten und dem zweiten Pumpengehäuseteil (1, 4) gehalten ist.

4. Motorbetriebene medizinische Saugpumpe nach einem der Ansprüche 1 bis 3, wobei eine Lufteinlassöffnung (201) vorhanden ist, welche von einem Schalldämpfungselement (25) überdeckt ist.

5. Motorbetriebene medizinische Saugpumpe nach einem der Ansprüche 1 bis 4, wobei mindestens zwei elastische Lager (22, 23) vorhanden sind zur Lagerung des Pumpaggregats (7) im Pumpaggregatträger (3).

6. Motorbetriebene medizinische Saugpumpe nach Anspruch 5, wobei mindestens ein erstes dieser Lager (22) einen Vakuumanschluss (24) bildet und mindestens ein zweites dieser Lager (23) an einem motorseitigen Ende des Pumpaggregats (7) und in Verlängerung einer Motorachse des Pumpaggregats (7) angeordnet ist.

7. Motorbetriebene medizinische Saugpumpe nach einem der Ansprüche 5 oder 6, wobei genau zwei Lager (22, 23) vorhanden sind, welche entlang der ersten Längsachse (L_1) an gegenüberliegenden Enden des Pumpaggregats

angeordnet sind.

8. Motorbetriebene medizinische Saugpumpe nach Anspruch 7, wobei die zwei Lager (22, 23) bezüglich der ersten Längsachse (L_1) versetzt zueinander angeordnet sind.

9. Motorbetriebene medizinische Saugpumpe nach einem der Ansprüche 1 bis 8, wobei das Pumpaggregat (7) in einem Schalldämpfungsgehäuse (2) angeordnet ist und das Schalldämpfungsgehäuse (2) im Pumpaggregatträger (3) gehalten ist.

10. Motorbetriebene medizinische Saugpumpe nach Anspruch 9, wobei das Schalldämpfungsgehäuse (2) ein Etui (20) mit einer Aufnahmeöffnung zur Aufnahme des Pumpaggregats (7) und einen das Etui (20) verschliessenden Deckel (21) aufweist, wobei der Deckel (21) gebogen ausgebildet ist.

11. Motorbetriebene medizinische Saugpumpe nach den Ansprüchen 5 und 9, wobei das Schalldämpfungsgehäuse (2) mittels der mindestens zwei elastischen Lager (22, 23) im Pumpaggregatträger (3) gelagert ist.

12. Motorbetriebene medizinische Saugpumpe nach Anspruch 11, wobei die mindestens zwei elastischen Lager (22, 23) einerseits das Schalldämpfungsgehäuse (2) im Pumpengehäuse (1, 3, 4) lagern und andererseits das Pumpaggregat (7) innerhalb des Schalldämpfungsgehäuses (2) lagern.

13. Motorbetriebene medizinische Saugpumpe nach Anspruch 12, wobei das erste Lager (22) ein elastisches Einsatzelement ist, welches im Schalldämpfungsgehäuse (2) gehalten ist und dieses durchsetzt.

14. Motorbetriebene medizinische Saugpumpe nach einem der Ansprüche 12 oder 13, wobei das zweite Lager (23) Teil eines Deckels (21) des Schalldämpfungsgehäuses (2) ist, wobei der gesamte Deckel (21) elastisch ausgebildet ist.

15. Medizinische Saugpumpe mit einem Pumpengehäuse (1, 3, 4), mit einem im Pumpengehäuse (1, 3, 4) angeordneten Pumpaggregat (7) zur Erzeugung eines Unterdrucks und mit mindestens einem ersten elastischen Lager (22) und einem zweiten elastischen Lager (23) zur Lagerung des Pumpaggregats (7) im Pumpengehäuse (1, 3, 4), wobei das erste elastische Lager (22) sich an einem ersten Ende des Pumpaggregats (7) befindet und das zweite elastische Lager (23) sich an einem zweiten, dem ersten Ende gegenüberliegenden Ende des Pumpaggregats (7) befindet, **dadurch gekennzeichnet, dass** das erste elastische Lager (22) einen Vakuumanschluss (24) bildet.

16. Medizinische Saugpumpe mit einem Pumpaggregat (7), einem Schalldämpfungsgehäuse (2) zur Aufnahme des Pumpaggregats (7) und mit einem Pumpengehäuse (1, 3, 4) zur Aufnahme des Schalldämpfungsgehäuses (2), **dadurch gekennzeichnet, dass** das Schalldämpfungsgehäuse (2) ein Etui (20) zur Aufnahme des Pumpaggregats (7) und einen das Etui (20) verschliessenden Deckel (21) aufweist, wobei der Deckel (21) elastisch ausgebildet ist und ein elastisches Lager (23) zur Lagerung des Schalldämpfungsgehäuses (2) im Pumpengehäuse (1, 3, 4) aufweist.

17. Medizinische Saugpumpe mit einem Pumpaggregat (7), einem Schalldämpfungsgehäuse (2) zur Aufnahme des Pumpaggregats (7) und mit einem Pumpengehäuse (1, 3, 4) zur Aufnahme des Schalldämpfungsgehäuses (2), **dadurch gekennzeichnet, dass** mindestens ein erstes und ein zweites elastisches Lager (22, 23) vorhanden sind, wobei mindestens eines dieser zwei elastischen Lager (22, 23) einerseits das Schalldämpfungsgehäuse (2) im Pumpengehäuse (1, 3, 4) lagert und andererseits das Pumpaggregat (7) innerhalb des Schalldämpfungsgehäuses (2) lagert.

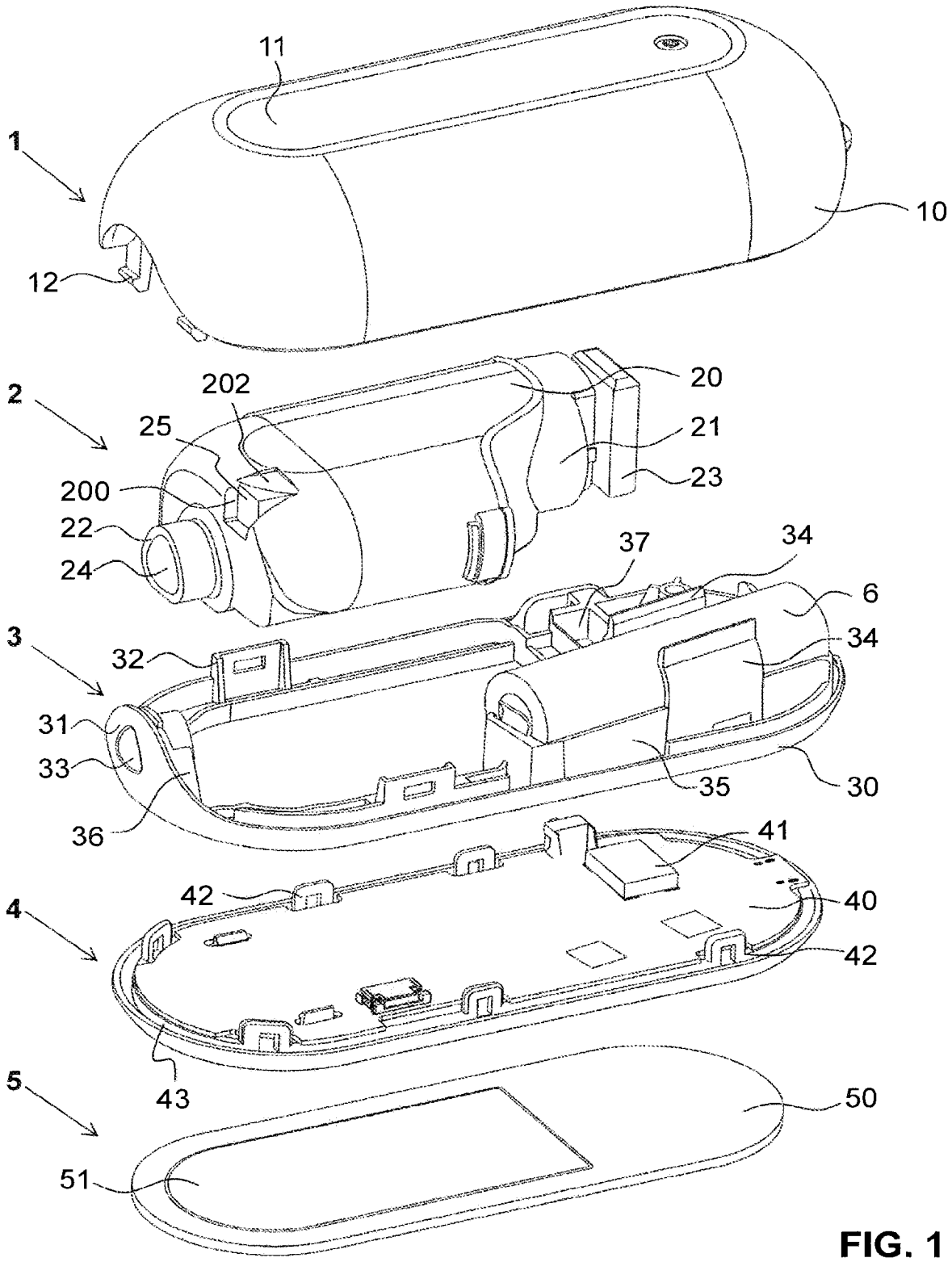
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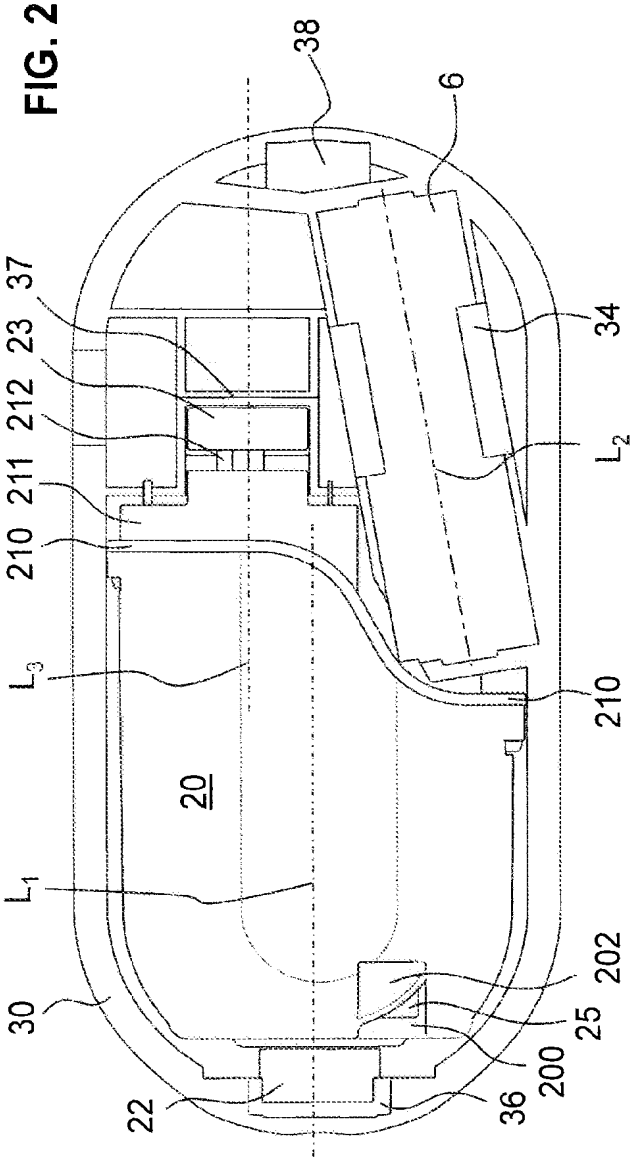
FIG. 1

FIG. 2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L_3
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L_1
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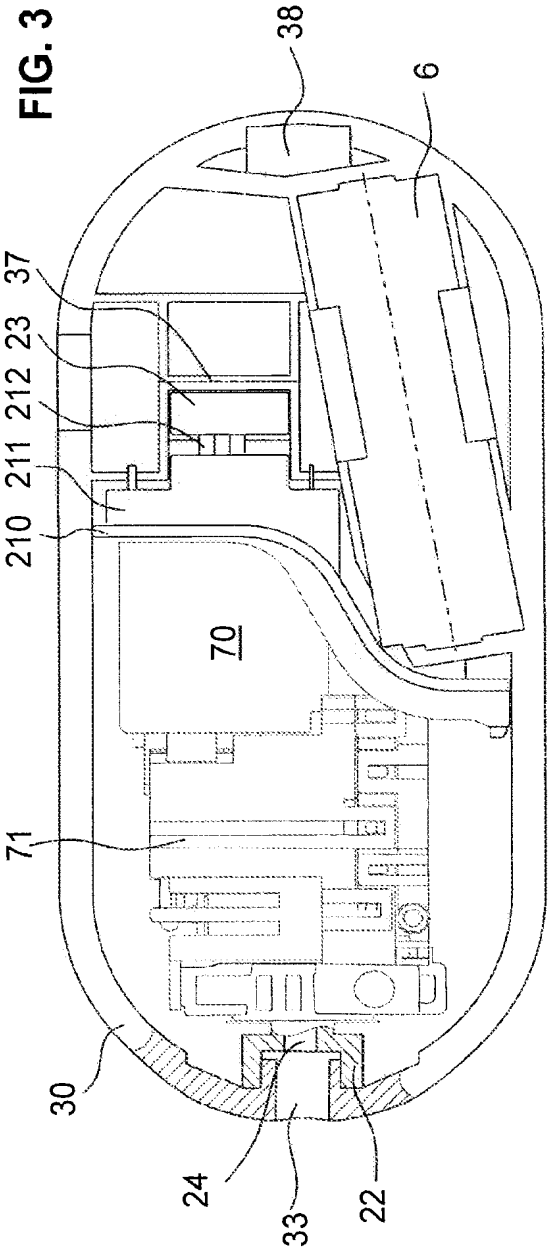
FIG. 3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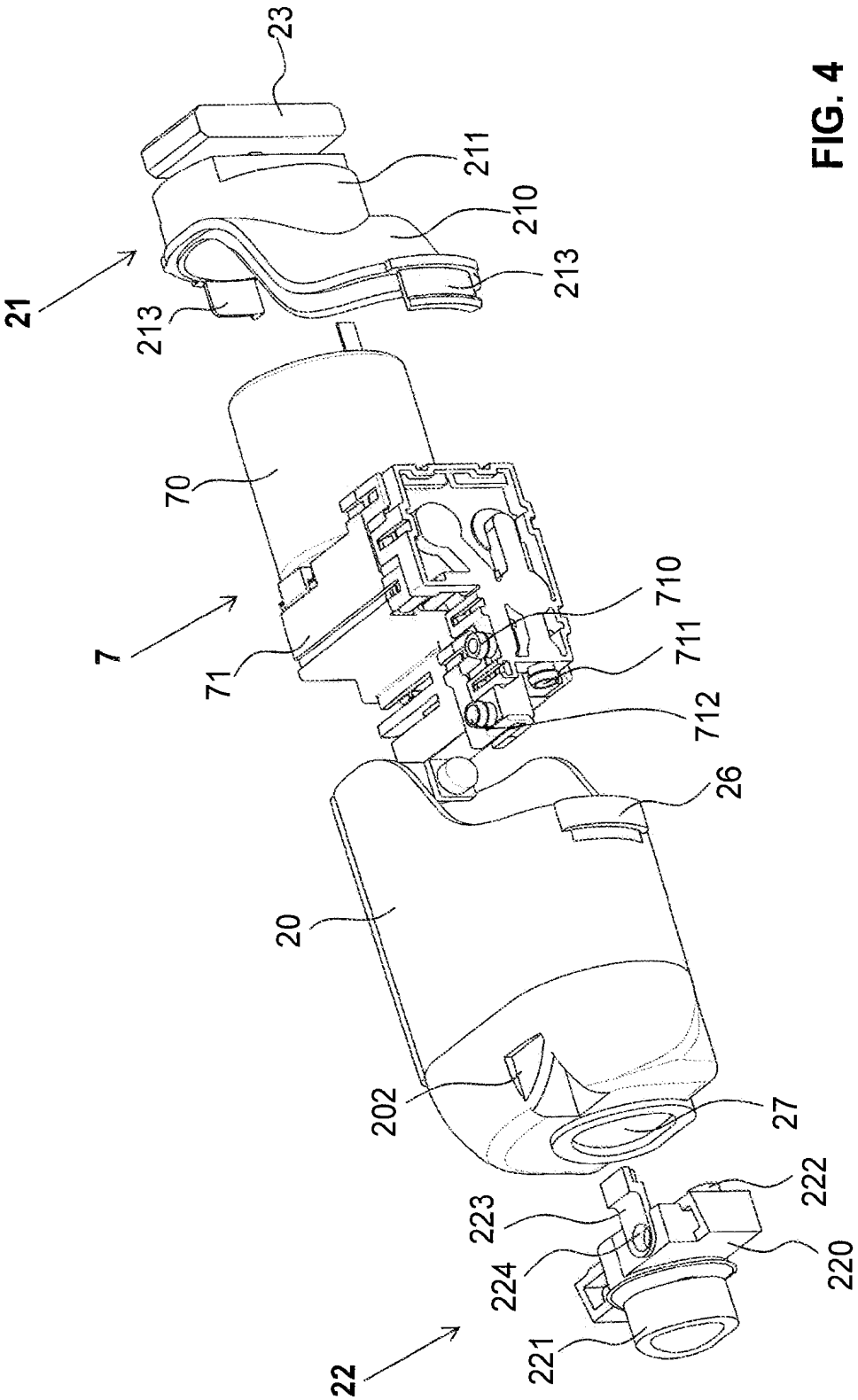
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FIG. 4

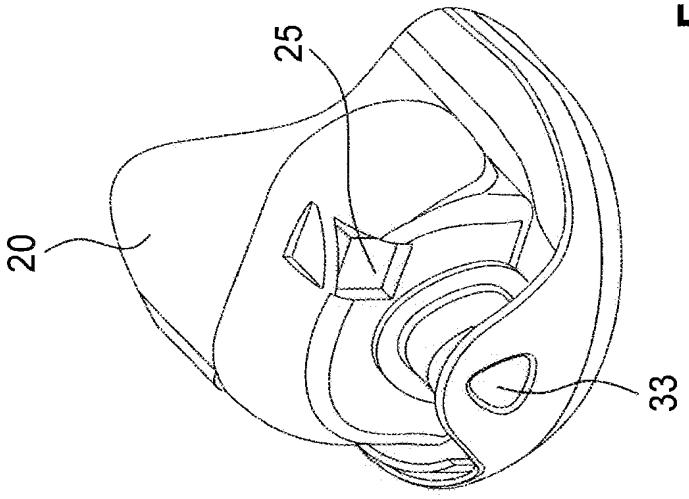

FIG. 6

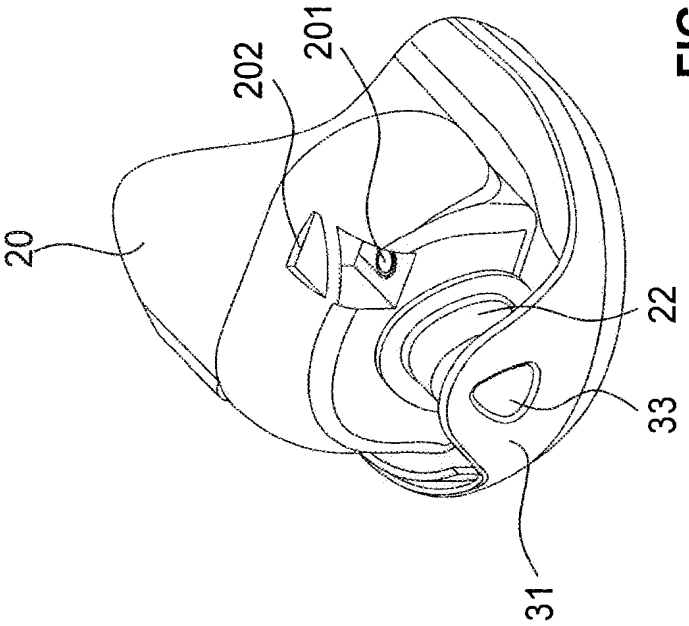

FIG. 5

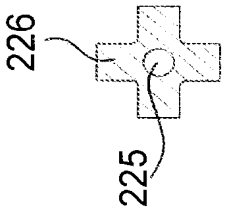

FIG. 9a

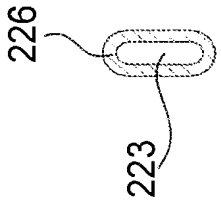

FIG. 9b

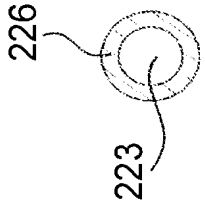

FIG. 9c

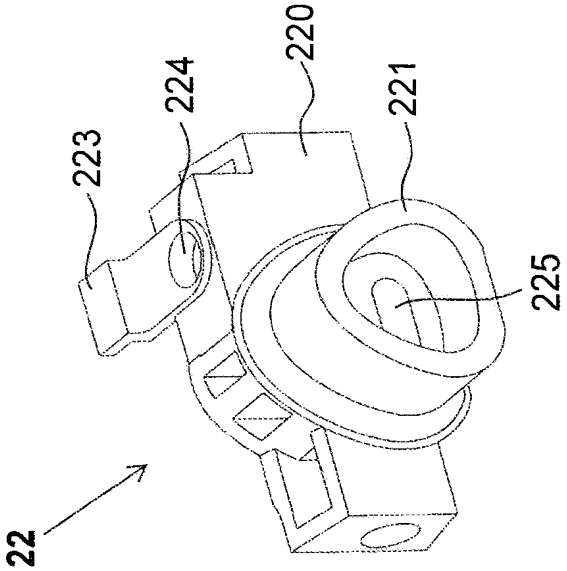

FIG. 7

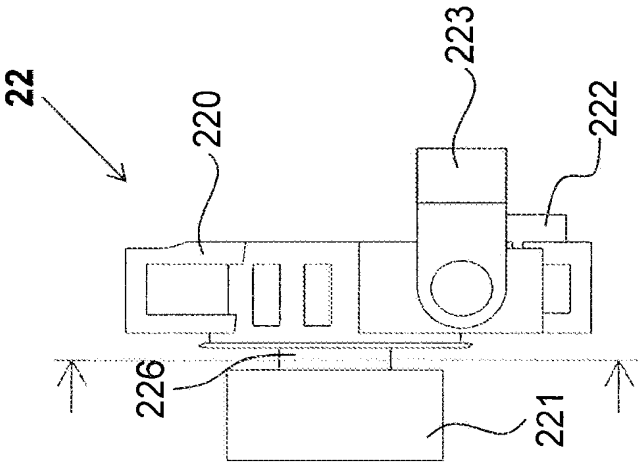

FIG. 8

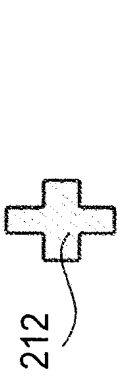

FIG. 12a

FIG. 12b

FIG. 12c

FIG. 12d

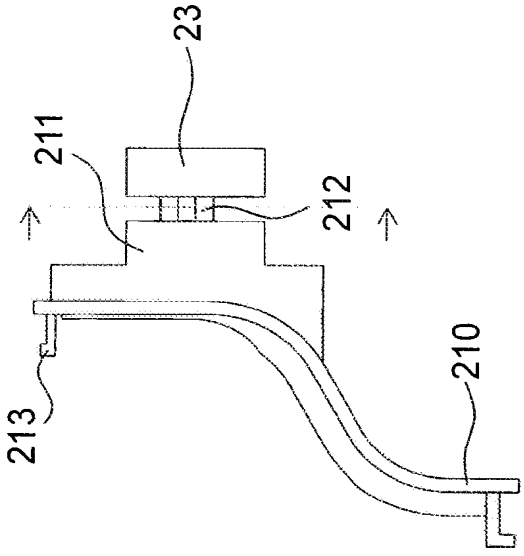

FIG. 11

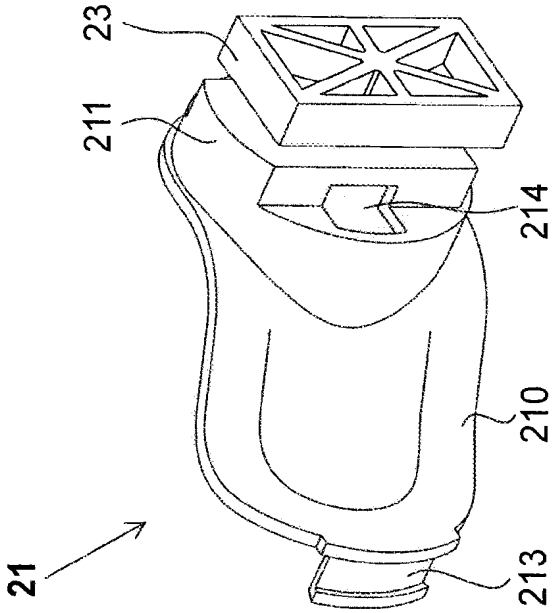

FIG. 10

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EUROPÄISCHER RECHERCHENBERICHT

Nummer der Anmeldung
EP 17 20 1540

EINSCHLÄGIGE DOKUMENTE

Kategorie	Kennzeichnung des Dokuments mit Angabe, soweit erforderlich, der maßgeblichen Teile	Betrifft Anspruch	KLASSIFIKATION DER ANMELDUNG (IPC)
X	WO 2017/139437 A1 (EXPLORAMED NC7 INC [US]) 17. August 2017 (2017-08-17) * Absätze [0080] - [0083]; Abbildungen 2,6A *	1-14	INV. A61M1/00
X	US 2015/025482 A1 (BEGIN MILES [US] ET AL) 22. Januar 2015 (2015-01-22) * Absätze [0044] - [0049]; Abbildung 2E *	1-14	
X	WO 2009/047524 A2 (TALLEY GROUP LTD [GB]; BYBORDI FARHAD [US]) 16. April 2009 (2009-04-16) * Seite 9, Zeilen 3-29; Abbildung 2B *	1-14	
X	WO 2016/103031 A1 (SMITH & NEPHEW [GB]) 30. Juni 2016 (2016-06-30) * Absätze [0155], [0211]; Abbildungen 13-14, 20 *	15	

RECHERCHIERTE SACHGEBIETE (IPC)

A61M

Der vorliegende Recherchenbericht wurde für alle Patentansprüche erstellt

Recherchenort	Abschlußdatum der Recherche	Prüfer
Den Haag	18. Juni 2018	Westsson, David

KATEGORIE DER GENANNTEN DOKUMENTE

X : von besonderer Bedeutung allein betrachtet
Y : von besonderer Bedeutung in Verbindung mit einer anderen Veröffentlichung derselben Kategorie
A : technologischer Hintergrund
O : nichtschriftliche Offenbarung
P : Zwischenliteratur

T : der Erfindung zugrunde liegende Theorien oder Grundsätze
E : älteres Patentdokument, das jedoch erst am oder nach dem Anmeldedatum veröffentlicht worden ist
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L : aus anderen Gründen angeführtes Dokument

& : Mitglied der gleichen Patentfamilie, übereinstimmendes Dokument

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EP 17 20 1540

GEBÜHRENPFLICHTIGE PATENTANSPRÜCHE

Die vorliegende europäische Patentanmeldung enthielt bei ihrer Einreichung Patentansprüche, für die eine Zahlung fällig war.

☐ Nur ein Teil der Anspruchsgebühren wurde innerhalb der vorgeschriebenen Frist entrichtet. Der vorliegende europäische Recherchenbericht wurde für jene Patentansprüche erstellt, für die keine Zahlung fällig war, sowie für die Patentansprüche, für die Anspruchsgebühren entrichtet wurden, nämlich Patentansprüche:

☐ Keine der Anspruchsgebühren wurde innerhalb der vorgeschriebenen Frist entrichtet. Der vorliegende europäische Recherchenbericht wurde für die Patentansprüche erstellt, für die keine Zahlung fällig war.

MANGELNDE EINHEITLICHKEIT DER ERFINDUNG

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Siehe Ergänzungsblatt B

☒ Alle weiteren Recherchengebühren wurden innerhalb der gesetzten Frist entrichtet. Der vorliegende europäische Recherchenbericht wurde für alle Patentansprüche erstellt.

☐ Da für alle recherchierbaren Ansprüche die Recherche ohne einen Arbeitsaufwand durchgeführt werden konnte, der eine zusätzliche Recherchengebühr gerechtfertigt hätte, hat die Recherchenabteilung nicht zur Zahlung einer solchen Gebühr aufgefordert.

☐ Nur ein Teil der weiteren Recherchengebühren wurde innerhalb der gesetzten Frist entrichtet. Der vorliegende europäische Recherchenbericht wurde für die Teile der Anmeldung erstellt, die sich auf Erfindungen beziehen, für die Recherchengebühren entrichtet worden sind, nämlich Patentansprüche:

☐ Keine der weiteren Recherchengebühren wurde innerhalb der gesetzten Frist entrichtet. Der vorliegende europäische Recherchenbericht wurde für die Teile der Anmeldung erstellt, die sich auf die zuerst in den Patentansprüchen erwähnte Erfindung beziehen, nämlich Patentansprüche:

☐ Der vorliegende ergänzende europäische Recherchenbericht wurde für die Teile der Anmeldung erstellt, die sich auf die zuerst in den Patentansprüchen erwähnte Erfindung beziehen (Regel 164 (1) EPÜ).

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EP 17 20 1540

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1. Ansprüche: 1-14

Motorbetriebene medizinische Saugpumpe mit einem Pumpaggregat zur Erzeugung eines Unterdrucks, mit einem Pumpaggregatträger zur Halterung des Pumpaggregats und mit einer Aufnahme zur Aufnahme eines Energiespeichers, wobei das im Pumpaggregatträger angeordnete Pumpaggregat eine erste Längsachse (L) definiert und die Aufnahme eine zweite Längsachse (L2) definiert,dadurch gekennzeichnet, dassder Pumpaggregatträger die Aufnahme bildet und dass die zweite Längsachse (L2) in einem Winkel zur ersten Längsachse (L]) verläuft.

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2. Anspruch: 15

Medizinische Saugpumpe mit einem Pumpengehäuse, mit einem im Pumpengehäuse angeordneten Pumpaggregat zur Erzeugung eines Unterdrucks und mit mindestens einem ersten elastischen Lager und einem zweiten elastischen Lager zur Lagerung des Pumpaggregats im Pumpengehäuse, wobei das erste elastische Lager sich an einem ersten Ende des Pumpaggregats befindet und das zweite elastische Lager sich an einem zweiten, dem ersten Ende gegenüberliegenden Ende des Pumpaggregats befindet,dadurch gekennzeichnet, dassdas erste elastische Lager einen Vakuumanschluss bildet.

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3. Anspruch: 15

Medizinische Saugpumpe mit einem Pumpengehäuse, mit einem im Pumpengehäuse angeordneten Pumpaggregat zur Erzeugung eines Unterdrucks und mit mindestens einem ersten elastischen Lager und einem zweiten elastischen Lager zur Lagerung des Pumpaggregats im Pumpengehäuse, wobei das erste elastische Lager sich an einem ersten Ende des Pumpaggregats befindet und das zweite elastische Lager sich an einem zweiten, dem ersten Ende gegenüberliegenden Ende des Pumpaggregats befindet,dadurch gekennzeichnet, dassdas erste elastische Lager einen Vakuumanschluss bildet.

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4. Anspruch: 16

Medizinische Saugpumpe mit einem Pumpaggregat, einem Schalldämpfungsgehäuse zur Aufnahme des Pumpaggregats und mit einem Pumpengehäuse zur Aufnahme des Schalldämpfungsgehäuses,dadurch gekennzeichnet, dassdas Schalldämpfungsgehäuse ein Etui zur Aufnahme des Pumpaggregats und einen das Etui verschliessenden Deckel aufweist, wobei der Deckel elastisch ausgebildet ist und ein

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elastisches Lager zur Lagerung des Schalldämpfungsgehäuses im Pumpengehäuse aufweist.

---

5. Anspruch: 17

Medizinische Saugpumpe mit einem Pumpaggregat, einem Schalldämpfungsgehäuse zur Aufnahme des Pumpaggregats und mit einem Pumpengehäuse zur Aufnahme des Schalldämpfungsgehäuses,dadurch gekennzeichnet, dassmindestens ein erstes und ein zweites elastisches Lager vorhanden sind, wobei mindestens eines dieser zwei elastischen Lager einerseits das Schalldämpfungsgehäuse im Pumpengehäuse lagert und andererseits das Pumpaggregat innerhalb des Schalldämpfungsgehäuses lagert.

ANHANG ZUM EUROPÄISCHEN RECHERCHENBERICHT ÜBER DIE EUROPÄISCHE PATENTANMELDUNG NR. EP 17 20 1540

In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten europäischen Recherchenbericht angeführten Patentdokumente angegeben.
Die Angaben über die Familienmitglieder entsprechen dem Stand der Datei des Europäischen Patentamts am
Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

18-06-2018

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
WO 2017139437 A1	17-08-2017	KEINE	
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		WO 2016103035 A2	30-06-2016

EPO FORM P0461

Für nähere Einzelheiten zu diesem Anhang : siehe Amtsblatt des Europäischen Patentamts, Nr.12/82

IN DER BESCHREIBUNG AUFGEFÜHRTE DOKUMENTE

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In der Beschreibung aufgeführte Patentdokumente

- WO 2006032156 A1 **[0002] [0048]**
- WO 2017157691 A1 **[0004]**
- WO 2015109934 A1 **[0005]**
- WO 2017140562 A1 **[0006]**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: CHIARO TECHNOLOGY LIMITED	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, COURTNEY B
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Supplemental Information Disclosure Statement

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

Listed on accompanying IDS Forms PTO/SB/08a or its equivalent and PTO/SB/08b or its equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Applicant has listed dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(c) and is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an

action that otherwise closes prosecution in the application. The required fee is provided through online credit card payment authorization in the amount of **$104.00** in payment of the fee under 37 C.F.R. § 1.17(p).

A concise explanation of the relevance of the non-English language document(s) appears below in accordance with 37 C.F.R. § 1.98(a)(3).

Document **US6** (2020/0300237 A1) is submitted herewith as the English-language counterpart of document **FP1** (EP 3482782 A1).

A copy of document **FP1** is submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2)(ii), no copies of the U.S. patents and patent application publications cited on the attached IDS Forms are submitted.

It is expected that the examiner will review the prosecution and cited art in the parent Application No. 16/009,547, filed June 15, 2018, in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Yangbeini Wang #800,005/

Yangbeini Wang
Attorney for Applicant
Registration No. 800,005

Date: May 15, 2023

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Washington, D.C. 20005-3934
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20260440.1

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**05/15/2023 03:27:41 PM ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	62088330	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Yangbeini Wang

Documents

TOTAL DOCUMENTS: 4

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-05-15-Transmittal-Form-sIDS-4944-0120006.pdf	1	Miscellaneous Incoming Letter	161 KB
2023-05-15-sIDS-Pleading-4944-0120006.pdf	3	Transmittal Letter	100 KB
2023-05-15-sIDS-Form-SB08-4944-0120006.pdf	3	Information Disclosure Statement (IDS) Form (SB08)	147 KB
Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.			
FOR_1_EP3482782A1.pdf	21	Foreign Reference	442 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-05-15-Transmittal-Form-sIDS-4944-0120006.pdf	F0C4DDBAE8E49C2EC106418E9E2150D705E82025A01C7AF8F616FAB4E5FE746B9732D8F408D760356DD627385F01A15A981570FF9160D9DBD7A75D6FB33DD89F
2023-05-15-sIDS-Pleading-4944-0120006.pdf	A4CA1114BD069621DF3F359B9F2D4DDE9E6F2AC05793A27D00C7C014D4B9ACF67B9688923A566F1B01130FC6BD7FD83A96B9508EA333F1E16A25929D7BD57224
2023-05-15-sIDS-Form-SB08-4944-0120006.pdf	15FEC9EE4BCEC7CFB4164C440BA5A1569F55FE22487FE695BA511C59D69167C785AD43EC91D8A66DDC17706AAFEBF1057461A3E4ABF20865AAE3B7777FFEF740
FOR_1_EP3482782A1.pdf	0A4794FB75138AF6B1F20955E40340F7D8470ADA20062553DF4C0F08FF07D8C66A0E17A8A211AB8592F5D46EFC71AE7573646AD8E14ABA1BF7CA3E1FD42142A9

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	2002/0062103 A1	05-23-2002	Larsson et al.	
	US2	2008/0009815 A1	01-10-2008	Grabenkort et al.	
	US3	2015/0314053 A1	11-05-2015	Furrer et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 2 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 3 of 3

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Richard D. Coller III/	Date (YYYY-MM-DD)	2023-04-20
Name/Print	Richard D. Coller III	Registration Number	60,390

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

UNITED STATES
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P.O. Box 1450
Alexandria, VA 22313 - 1450
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	**04/20/2023 04:08:22 PM ET**	**4944.0120006**

Title of Invention

BREAST PUMP SYSTEM

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	4690	FILED BY	Jon Baitlon
PATENT CENTER #	61955806	FILING DATE	02/22/2021
CUSTOMER #	26111	FIRST NAMED INVENTOR	Jonathan O'TOOLE
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Richard Coller

Documents

TOTAL DOCUMENTS: 3

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
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Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-04-20-Transmittal-Form-sIDS-4944-0120006.pdf	D4933E5E447819C7BB67851D70E380B09815BAC1C0301E0281D3BD955EE1185F7A1F2EE619BDF067358DCB869A6D26F37C0F1375948880B64EBC0711C4BBB6A3
2023-04-20-sIDS-Pleading-4944-0120006.pdf	0A219C2D41BC79F1BE81840ACC1903037F0AC1762BA30097684D680A64405A3D8C9D337B2F5B5E01F09751450DC05DBA1917C7898287CCE81CEB4F52F477531C
2023-04-20-sIDS-Form-SB08-4944-0120006.pdf	E6481901DF45F7ECA7CF0FDF46AB3516A376C0C688D6F619E63D010B23F07A84A300E0535383C9E38D48FD5CC4AE006FFDF815B8DCCE7B9229F91BF3368F831A

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

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PTO/SB/21 (07-09)
Approved for use through 12/31/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDERICKSON, Courtney B
Attorney Docket Number	4944.0120006

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
- ☑ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☑ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) (please identify below):

Remarks

The Office may charge any fee deficiency for any submission made with this transmittal to Deposit Account 19-0036.

Online Credit Card Payment Authorization in the Amount of $104.00 to Cover:
$104.00 - Information Disclosure Statement fee

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Richard D. Coller III/		
Printed name	Richard D. Coller III		
Date	April 20, 2023	Reg. No.	60,390

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: CHIARO TECHNOLOGY LIMITED	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, COURTNEY B
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

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Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. The required fee is provided through online credit card payment authorization in the amount of **$104.00** in payment of the fee under 37 C.F.R. § 1.17(p).

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Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Richard D. Coller III
Attorney for Applicant
Registration No. 60,390

Date: April 20, 2023

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

20127596.1

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/181,057	04/20/2023 04:08:22 PM ET	4944.0120006

Title of Invention

BREAST PUMP SYSTEM

Application Information

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PATENT CENTER #	61955806	AUTHORIZED BY	Richard Coller
CUSTOMER #	26111	FILING DATE	02/22/2021
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jonathan O'TOOLE

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 1008	E20234JG10346942	Jon Baitlon

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2806	SUBMISSION OF AN INFORMATION DISCLOSURE STATEMENT	104.00	1	104.00
			TOTAL AMOUNT:	$104.00

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

26111 7590 03/30/2023

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER
FREDRICKSON, COURTNEY B

ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
03/30/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

e-office@sternekessler.com

Office Action Summary	Application No. 17/181,057	Applicant(s) O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	Art Unit 3783	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 26January2023.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1,3-22,24-25 and 28-34 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1,3-22,24-25 and 28-34 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 22February2021 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☑ All b)☐ Some** c)☐ None of the:

1.☑ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 26, 2023 has been entered.

Information Disclosure Statement

The information disclosure statement (IDS) submitted is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Amendment

This office action is responsive to the amendment filed on January 26, 2023. As directed by the amendment: claims 1, 16, and 34 have been amended. Thus, claims 1, 3-22, 24, 25, and 28-34 are presently pending in this application.

Applicant's amendments to the Specification, Drawings, and Claims have overcome each and every objection previously set forth in the Final Office Action mailed October 26, 2022.

Response to Arguments

Applicant's arguments, see pg. 8, filed January 26, 2023, with respect to the rejection(s) of claim(s) 1 under 35 U.S.C 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Applicant's amendments.

Claim Objections

Claim 1 is objected to because of the following informalities: the claim should be amended to recite "to define a spacing…" in the second to last line to provide antecedent basis for the claim terminology. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-22, 24, 25, and 28-34 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

Regarding claim 1, the claim was amended to include a guide line which is configured to define the spacing of the nipple from the side of the wall of the nipple tunnel. It is unclear, in light of the specification, how a singular guide line would be able

to perform this function as it appears that two guide lines would be required to perform the function. With a singular guide line, the shield can be rotated 360° so that the guide line can be located anywhere relative to the nipple and would not be able to perform the function.

Further regarding claim 1, it is unclear how the guide line defines the spacing of the nipple from the side wall of the nipple tunnel. It appears that a spacing (even if the spacing is zero) would inherently exist in every combination of nipple and nipple tunnel. A review of Applicant's specification shows that the guide line(s) are configured to define the correct spacing of the nipple from the side wall of the nipple tunnel (paragraph 452 of the published application). For examination purposes, this interpretation was used.

Regarding claim 32, the claim is drawn to "fit lines" and is dependent on claim 1 which was amended to include a "guide line". It is unclear if the fit lines are a part of the guide line or if the fit lines are separate from the guide line. For examination purposes, the fit lines are considered the same/a part of the guide line of claim 1.

Claims 3-22, 24, 25, 28-31, 33, and 34 are also rejected by virtue of being dependent on claim 1.

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

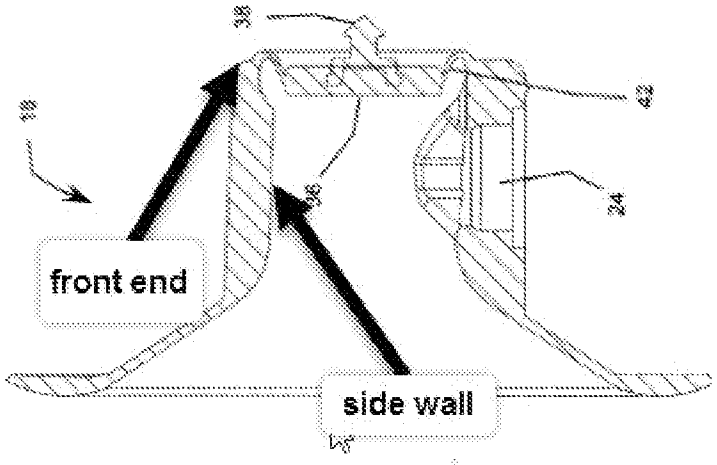
Claims 1, 3, 6-8, 10, 11, 14, 16-18, 22, 24, 31, 32, and 34 is/are rejected under 35 U.S.C. 103 as being unpatentable over Myers (US 20080275386) and in further view of Cook (EP 2502640) and in further view of Silver (US 20020198489).

Regarding claim 1, Myers discloses a breast pump device comprising:

(i) a housing (outer housing 16 in fig. 1) comprising (a) a battery (AA battery 51 in fig. 10), and (b) a pump configured to generate negative air pressure (motor 54 in fig. 10);

(ii) a breast shield (breast cup 16 in fig. 1) being configured to slide in and out of the housing (paragraph 58 discloses that the cup “clicks” into place within the housing; paragraph 42 discloses the breast cup being removable), the breast shield comprising a breast flange (outer flange area 50 in fig. 5) and a nipple tunnel (nipple tunnel 46 in fig.

5) comprising a side wall and a front end (see below), in which the breast shield is transparent or optically clear (paragraph 65); and

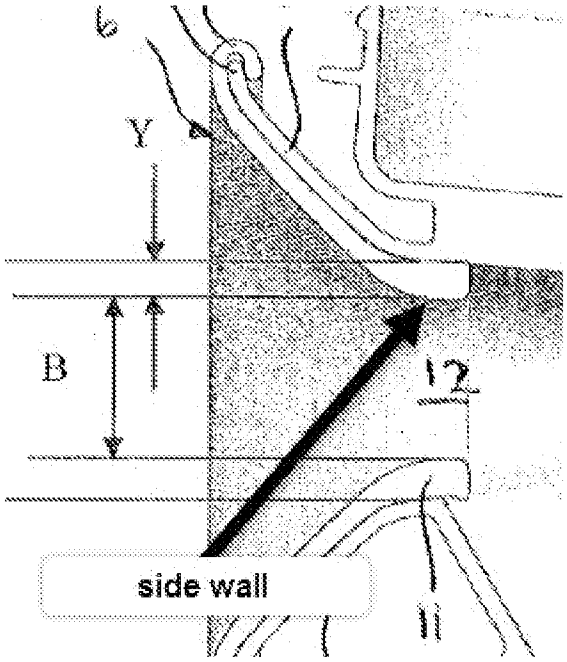


(iii) a milk container that is configured to be attached to and removed from the housing (collection bag 28 is shown to be operatively attached to the housing and is physically engaged to the bottom portion of the housing).

However, Myers does not teach or disclose the breast shield being of a plurality of interchangeable breast shields each of the plurality of interchangeable breast shields having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast; and the nipple tunnel comprises a guide line, wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple

tunnel (see below) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple).



Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in

fig. 28). Silver further teaches that the nipple tunnel has a guide line (longitudinal rib 1160 in fig. 28) which is configured to define the correct spacing of the nipple from the side of the nipple tunnel (a user can use the rib as a guide for the correct spacing; if a rib physically touches the user's nipple, for example, the spacing between the nipple and the side wall may not be optimal). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of modified Myers to include a guide line, wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

Regarding claim 3, in the modified device of Myers, Myers discloses the breast shield is rigid (paragraph 47 discloses the nipple tunnel, which is part of the breast shield, is rigid).

Regarding claim 6, in the modified device of Myers, Myers discloses the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast (the shield of Myers is functionally capable of being rotated smoothly around a nipple since the claim does not require that the shield be fully latched onto the nipple for this rotation to occur).

Regarding claim 7, in the modified device of Myers, Myers discloses the breast shield presents, in use, a single continuous surface to a nipple and a breast (fig. 9A/B shows a singular inner surface which would extend from the nipple to the breast).

Regarding claim 8, in the modified device of Myers, Myers discloses the breast shield integrates the breast flange and the nipple tunnel as a single item (fig. 5 shows a singular item).

Regarding claim 10, in the modified device of Myers, Myers discloses the breast shield is configured to slide into the housing with a single push action (paragraph 58 discloses the shield can click into place).

Regarding claim 11, in the modified device of Myers, Myers discloses the breast shield is configured to slide out from the housing, together with a membrane that prevents milk from flowing into the pump (flange top 36 in fig. 9A).

Regarding claim 14, in the modified device of Myers, Myers discloses milk container attaches to a lower part of the housing (fig. 1 shows a part of the collection bag attached to the bottom part of the housing 16) and forms a base of the breast pump device (fig. 1).

Regarding claim 16, in the modified device of Myers, Silver discloses the guide line configured to run parallel along one or more sides of the nipple tunnel (fig. 28 shows the lines 1160 as longitudinal lines).

Regarding claim 17, in the modified device of Myers, Myers discloses the nipple tunnel includes an air hole or passage (24 in fig. 9A), and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage (paragraph 52).

Regarding claim 18, in the modified device of Myers, Myers discloses the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container (outlet 24 in fig. 9A).

Regarding claim 22, in the modified device of Myers, Myers discloses the housing is shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra (fig. 1; paragraph 40).

Regarding claim 24, in the modified device of Myers, Myers discloses the breast pump device is configured to deliver a maximum suction of approximately 240 mmHg (paragraph 72).

Regarding claim 31, modified Myers teaches a kit comprising the breast pump device of claim 1 (see discussion above); and the plurality of interchangeable breast shields (fig. 2a/b of Cook).

Regarding claim 32, modified Myers teaches each of the plurality of interchangeable breast shields comprises fit lines in a nipple tunnel of that breast shield (Silver discloses longitudinal ribs 1160, 1164, and 1166 in fig. 28) that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel (since Myers discloses that the breast shield is transparent in paragraph 65, a user would be able to assess the spacing between the ribs and the nipple).

Regarding claim 34, in the modified device of Myers, Cook discloses length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same (paragraph 43).

Claim 4 is/are rejected under 35 U.S.C. 103 as being unpatentable over Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Phillips (US 20160296682), as evidenced by Yuen (US 20050228342).

Regarding claim 4, modified Myers teaches all of the claimed limitations set forth in claim 1, as discussed above. Myers further teaches the breast shield is made from plastic (paragraph 40 discloses the breast cup being made from silicone, which is a type of plastic, as evidenced by Yuen in paragraph 24). However, modified Myers does not teach or disclose breast shield is dishwasher safe.

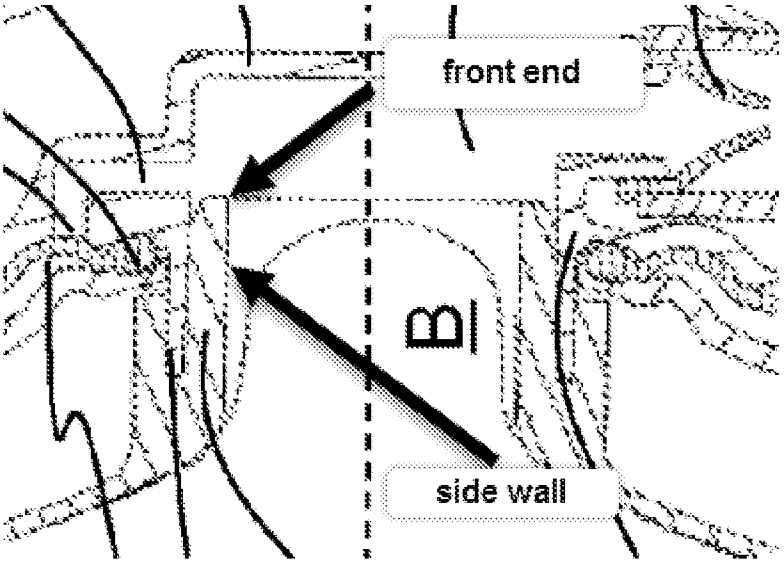
Phillips teaches a breast pump device (fig. 1) comprising a breast shield (110 in fig. 1). Phillips further teaches that the shield can be washed in a dishwasher (paragraph 60). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield of modified Myers to be dishwasher safe for the purpose of enabling the shield to be cleaned in the dishwasher for reuse, as taught by Phillips (paragraph 60).

Claims 1, 6-10, 14, 17-18, 20-22, 31, 32, and 34 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil (US 20130023821) in view of Myers (US 20080275386) and in further view of Cook and in further view of Silver.

Regarding claim 1, Khalil discloses a breast pump device comprising:

(i) a housing (6' and 6" form a housing as shown in fig. 9) that includes (a) a power source (paragraph 32 discloses the power source integrated into the housing), and (b) a pump generating negative air pressure (vacuum pump 81 in fig. 10);

(ii) a breast shield (breast interface 1 in fig. 11) being configured to slide in and out of the housing (breast interface 1 is configured to slide in/out from the housing by attaching/detaching the lip 11 to the flange 62 of the housing as shown in fig. 4), the breast shield made up of a breast flange (base part 12 in fig. 4) and a nipple tunnel (stub 10 in fig. 4) comprising a side wall and a front end (see below); and



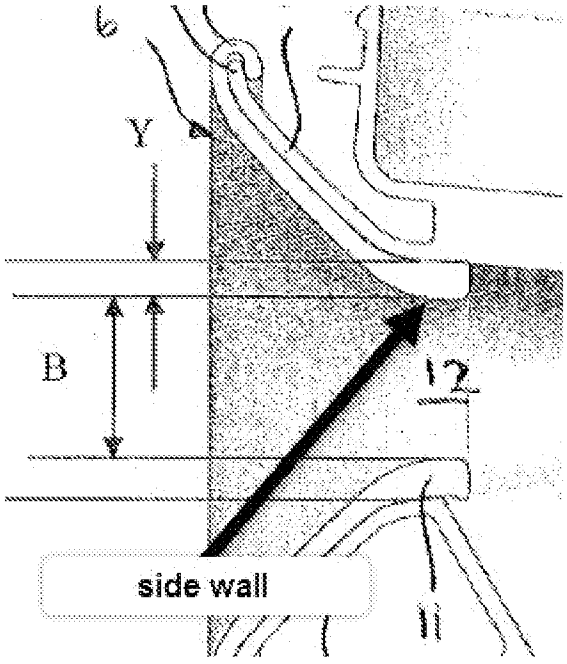
(iii) a milk container that is configured to be attached to and removed from the housing (milk collection container 7' in fig. 11; paragraph 69 discloses the container being releasably connected to the housing part 6').

However, Khalil does not teach or disclose the power source being a battery and the breast shield being transparent or optically clear and being of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast; and the nipple tunnel having a guide line, wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel.

Myers teaches a similar breast pump system (fig. 1) having a housing (outer housing 16 in fig. 1) which comprises a battery (battery 52 in fig. 10) and a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent). Therefore, it would have been obvious to one of ordinary skill

before the effective filing date of the claimed invention to have modified the housing to include a battery, as taught by Myers, for the purpose of providing power to the device and to have made the breast shield transparent to enable a user to view the condition of a nipple (paragraph 65).

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see below) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple).



Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality

of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in fig. 28). Silver further teaches that the nipple tunnel has a guide line (longitudinal rib 1160 in fig. 28) which is configured to define the correct spacing of the nipple from the side of the nipple tunnel (a user can use the rib as a guide for the correct spacing; if a rib physically touches the user's nipple, for example, the spacing between the nipple and the side wall may not be optimal). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of modified Khalil to include a guide line, wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

Regarding claim 6, in the modified device of Khalil, Khalil discloses the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast (the shield of Khalil is functionally capable of being rotated smoothly around a nipple since the claim does not require that the shield be fully latched onto the nipple for this rotation to occur).

Regarding claim 7, in the modified device of Khalil, Khalil discloses the breast shield presents, in use, a single continuous surface to a nipple and a breast (fig. 11).

Regarding claim 8, in the modified device of Khalil, Khalil discloses the breast shield integrates the breast flange and the nipple tunnel as a single item (fig. 11).

Regarding claim 9, in the modified device of Khalil, Khalil discloses the breast shield is generally symmetrical about a centre-line running from a top to a bottom of the breast shield when positioned upright for normal use (fig. 11).

Regarding claim 10, in the modified device of Khalil, Khalil discloses the breast shield is configured to slide into the housing with a single push action (the shield of Khalil is functionally capable of being pushed into the housing so that the nipple tunnel is located in the housing).

Regarding claim 14, in the modified device of Khalil, Khalil discloses milk container attaches to a lower part of the housing and forms a base of the breast pump device (fig. 9).

Regarding claim 16, in the modified device of Khalil, Silver discloses the guide line is configured to run parallel along one or more sides of the nipple tunnel (fig. 28).

Regarding claim 17, in the modified device of Khalil, Khalil discloses the nipple tunnel includes an air hole or passage (opening 13 in fig. 3), and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage (figs. 4 and 5).

Regarding claim 18, in the modified device of Khalil, Khalil discloses the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container (opening 13 in fig. 3 is considered to be on a “lower” surface of the nipple tunnel since “lower” is not further defined; see fig. 5).

Regarding claim 22, in the modified device of Khalil, Khalil discloses the housing is shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra (fig. 9).

Regarding claim 31, modified Khalil teaches a kit comprising the breast pump device of claim 1 (see discussion above); and the plurality of interchangeable breast shields (fig. 2a/b of Cook).

Regarding claim 32, modified Khalil teaches each of the plurality of interchangeable breast shields comprises fit lines in a nipple tunnel of that breast shield (Silver discloses longitudinal ribs 1160, 1164, and 1166 in fig. 28) that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel (since Myers discloses that the breast shield is transparent in paragraph 65, a user would be able to assess the spacing between the ribs and the nipple).

Regarding claim 34, in the modified device of Khalil, Cook discloses length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same (paragraph 43).

Claim 5 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Chang (US 20180333523).

Regarding claim 5, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast shield is configured to attach using magnets to the housing.

Chang teaches a substantially similar self-contained breast pump system (breast pump system 10 in fig. 1A) having a breast shield (flange 14 in fig. 1A) attached to a housing (housing 12 in fig. 1A) and configured to attach to the housing using one or more magnets (paragraph 108 discloses the shield uses magnets 118 attached to the shield to determine if the shield is properly attached to the housing). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield of modified Khalil to be configured to attach using magnets to the housing since Chang teaches this configuration provides a safeguard such that the system will not operate unless all components are fully connected (paragraph 108).

Claims 12 and 13 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Phillips (US 20160296682).

Regarding claim 12, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Although it appears based on fig. 11 of Khalil that the container would be rigid, modified Khalil does not explicitly teach or disclose this limitation.

Phillips teaches a breast pump system (fig. 1) comprising a milk collection container ("collection container" 120 in fig. 1) which is substantially rigid (paragraph 57 discloses the container being made from Tritan; pg. 21 of Applicant's specification discloses that Tritan is a polycarbonate material, which is a known rigid material). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the container of modified Khalil to be

made of Tritan for the purpose of enabling the container to maintain its strength when a vacuum is applied, as taught by Phillips (paragraph 57).

Regarding claim 13, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses the milk container is an optically clear, plastic container (paragraph 69 discloses the container is made of plastic like cover 6" and is transparent in its entirety). However, Khalil does not explicitly teach or disclose the milk container is dishwasher safe.

Phillips teaches a breast pump system (fig. 1) comprising a milk collection container ("collection container" 120 in fig. 1) which is dishwasher safe (paragraph 57 discloses the container being made from Tritan; pg. 21, lines 13-18 of Applicant's specification discloses that Tritan a dishwasher safe material). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the container of modified Khalil to be made of Tritan for the purpose of enabling the container to maintain its strength when a vacuum is applied, as taught by Phillips (paragraph 57).

Claim 15 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Karsan (US 20070228059).

Regarding claim 15, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the milk container is configured to magnetically attach to the housing.

Khalil teaches that the milk container latches to the housing by a locking lug (paragraph 69 discloses a locking lug formed on the container latches engages into a

corresponding recess). Karsan teaches a container (1 in fig. 1) having a case (2 in fig. 3) and a base (fig. 3) which are releasably held together (paragraph 51 discloses the connection being releasable) via a latch mechanism (5 and 6 in fig. 3). Karsan further teaches that the latching mechanism is embodied as a lug and recess (5 and 6, respectively in fig. 3; paragraph 65) but may alternatively be embodied as a magnetic means so that the two components may be magnetically latched (paragraph 65).

In Applicant's invention, Applicant uses the magnets to removably secure the milk container to the housing. Thus, Karsan is reasonably pertinent to the problem faced by the inventor since Karsan teaches using magnets as a removable latching connection between two components. As Karsan teaches that the magnetic means (paragraph 65) are functional equivalents to a locking lug and recess (paragraph 65), it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have substituted the locking lug/recess configuration of Khalil with the magnetic means, as taught by Karsan. The substitution would have resulted in providing an equivalent secure attachment of the milk container to the housing.

Claim 19 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Blondheim (US 20120277636).

Regarding claim 19, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the pump comprises one or more piezo air pumps.

Blondheim is directed towards a breast pump device (fig. 1) which comprises an air pump (66 in fig. 6). Blondheim further teaches that the air pump can be a

piezoelectric pump (paragraph 36). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the pump of modified Khalil to be a piezoelectric pump, as taught by Blondheim for the purpose of rendering the pump small in size (paragraph 36).

Claims 20 and 21 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Barak (US 20140378895).

Regarding claim 20, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the housing further includes a Universal Serial Bus (USB) charging socket.

Barack is directed towards a breast pump device (fig. 1) which comprises a housing which houses a pump (fig. 1 shows a pump 20 which would necessarily have some sort of housing since it is disclosed to have a USB port and a user interface). Barack further teaches a USB charging socket (USB port 34 in fig. 1; paragraph 45). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing of modified Khalil to include the USB charging socket, as taught by Khalil, for the purpose of enabling the device to interface with an external memory (paragraph 45).

Regarding claim 21, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the housing includes a left or right breast selector or toggle switch, that, when selected for a particular pumping session, sends data to a connected application configured to track

pumping sessions, to indicate whether that particular session is associated with a left or a right breast.

Barack teaches a breast pump device (fig. 1) which has a control electronics (controller 22 in fig. 1) and a control interface (user interface 30 in fig. 1) that is user selectable to indicate or record if milk is being expressed from the left or right breast (paragraph 43) and that, when selected for a particular pumping session, sends data to a connected application, running on a device, such as a smartphone, that tracks pumping sessions, to indicate whether that session is associated with the left or the right breast (paragraph 46 discloses transmitting via transceiver the parameters that have been entered at the user interface 30 to a remove device; paragraph 43 discloses that one parameter entered at the user interface is which breast is selected).

Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing of modified Khalil to include a left or right breast selector or toggle switch, that, when selected for a particular pumping session, sends data to a connected application configured to track pumping sessions, to indicate whether that particular session is associated with a left or a right breast, as taught by Barack. This modification would enable a user to track which parameters are best suited for each breast to optimize pumping, as taught by Barack (paragraphs 8 and 43).

Claim 25 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Guthrie (US 20160220743).

Regarding claim 25, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast pump device includes a sensor that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container.

Guthrie is directed towards a breast pump device comprising a sensor (detector 607 in fig. 6B) that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container (paragraph 63 discloses that the emitter 606 and the detector 607 operate to detect light reflecting off the opaque surface of the milk). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the device to include a sensor that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container, as taught by Guthrie, for the purpose of measuring volume of milk pumped (paragraph 54).

Claim 29 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, and further in view of Mendoza (US 6227936).

Regarding claim 29, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the pump is a

lightweight air pump that enables the total mass of the breast pump system, unfilled with milk, to be less than 250gm.

Mendoza teaches a bra which is designed to support a breast pump to allow the mother's hands to remain free (1:8-12). Mendoza further discloses that the bra must be able to support up to 8 ounces when the pump is full (1:58-62). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the system of modified Khalil to be a lightweight air pump that enables the total weight of the system, unfilled with milk, to be less than 250gm, as taught by Mendoza since Mendoza teaches that a lightweight system is crucial for enabling the system to be supported by a bra.

Claim 30 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, in further view of Baker (US 20090281485).

Regarding claim 30, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast pump device makes less than 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

Baker is directed towards a device for removing fluid from a body (fig. 6) using a vacuum pump embodied as a motor (motor 9 in fig. 6; paragraph 243). Baker further teaches that the device makes less than 20 decibel of noise at full power (paragraph 121) by sound proofing the walls of the housing and by adding a counter balance to the motor (paragraph 144). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the device of

modified Khalil to have the device make less than 20 dB of noise during maximum power for the purpose of making the device for discrete and comfortable for the user and others around the user.

Claim 33 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers in view of Cook and in further view of Silver, as applied to claim 1 above, in further view of Meyers (US 5542921).

Regarding claim 33, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further teaches control electronics ("control elements and a display" in paragraph 51) which would be powered by the battery (the power source of Khalil is understood to power the device).

However, Khalil does not teach or disclose the battery to be rechargeable and the housing further including a power charging circuit for controlling the charging of the rechargeable battery.

Meyers is directed to a breast pump device (fig. 1) comprising a battery configured to be recharged (9:50-52 discloses recharging the batteries) and a power charging circuit for controlling the charging of the rechargeable battery ("circuit" in 9:50-52). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the battery of modified Khalil to be rechargeable and to have incorporated a power charging circuit for controlling the charging of the rechargeable battery, as taught by Meyers to enable the batteries to be reused.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1, 3-22, 24, 25, 29-34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of the issued patents below in view of Myers, Cook, Silver, and the teachings below (see table).

- **17203050 (US Patent 11357893)**
- **17203079 (US Patent 11376352)**
- **17203216 (US Patent 11357894)**
- **17203259 (US Patent 11324866)**
- **17203327 (US Patent 11413380)**

Claim 1 of the issued patent claims all of the features claimed in reference claim 1 except in that claim 1 of the patent does not claim a breast shield of a plurality of interchangeable breast shields each being transparent or optically clear and having a different size and being configured to slide in and out of the housing, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of

interchangeable breast shields is placed onto a breast; and the nipple tunnel having a guide line, the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to

provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in fig. 28). Silver further teaches that the nipple tunnel has a guide line (longitudinal rib 1160 in fig. 28) which is configured to define the correct spacing of the nipple from the side of the nipple tunnel (a user can use the rib as a guide for the correct spacing; if a rib physically touches the user's nipple, for example, the spacing between the nipple and the side wall may not be optimal). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of the reference claim to include a guide line, wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.

7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		Silver teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.

29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Silver and Myers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Claims 1, 3-22, 24, 25, 28-34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of the following US Patents in view of Myers, Cook and the teachings below (see table).

- **17203109 (US Patent 11260151)**
- **17203313 (US Patent 11311654)**

Claim 1 of the issued patent claims all of the features claimed in reference claim 1 except in that claim 1 of the patent does not claim a breast shield of a plurality of interchangeable breast shields each being transparent or optically clear and having a different size and being configured to slide in and out of the housing, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast; and the nipple tunnel having a guide line, the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches

that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in fig. 28). Silver further teaches that the nipple tunnel has a guide line (longitudinal rib 1160 in fig. 28) which is configured to define the correct spacing of the nipple from the side of the nipple tunnel (a user can use the rib as a guide for the correct spacing; if a rib physically touches the user's nipple, for example, the spacing between the nipple and the side wall may not be optimal). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of the reference claim to include a guide line, wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.

8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		Silver teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.

24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
28	18 ('151 patent), 13 ('654 patent)	
29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Silver and Myers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Claims 1, 3-22, 24, 25, 29-34 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of the following copending applications in view Myers, Cook and the teachings below.

- **17203150**
- **17203179**
- **17203292**
- **17203355**
- **17203384**
- **17203397**

- **17203418**

Claim 1 of the reference claim claims all of the features claimed in reference claim 1 except in that claim 1 of the reference claim does not claim a breast shield of a plurality of interchangeable breast shields each being transparent or optically clear and having a different size and being configured to slide in and out of the housing, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast; and the nipple tunnel having a guide line, the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of

interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Silver teaches a breast shield (inner shield part 1094 in fig. 28) which comprises a flange (conical section 1120 in fig. 28) and a nipple tunnel (tubular extension 1126 in fig. 28). Silver further teaches that the nipple tunnel has a guide line (longitudinal rib 1160 in fig. 28) which is configured to define the correct spacing of the nipple from the side of the nipple tunnel (a user can use the rib as a guide for the correct spacing; if a rib physically touches the user's nipple, for example, the spacing between the nipple and the side wall may not be optimal). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of the reference claim to include a guide line, wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel, as taught by Silver, since Silver teaches that these lines reduce the tendency of the breast shield to expand or contract along the longitudinal length (paragraph 202).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		Silver teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.

20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Silver and Myers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Allowable Subject Matter

Except for the double patenting rejections above, **claim 28** would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not teach or suggest the pump delivers the claimed stall pressure and free air flow.

Conclusion

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COURTNEY FREDRICKSON whose telephone number is (571)270-7481. The examiner can normally be reached Monday-Friday (9 AM - 5 PM EST).

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NATHAN PRICE can be reached on 571-270-5421. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center,

visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COURTNEY B FREDRICKSON/
Examiner, Art Unit 3783

Notice of References Cited	Application/Control No. 17/181,057	Applicant(s)/Patent Under Reexamination O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	Art Unit 3783	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20020198489-A1	12-2002	Silver, Brian H.	A61M1/066	119/14.47
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

CPC - Searched*		
Symbol	Date	Examiner
a61m1/06-069	01/12/2022	cbf

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
see SEARCH history	01/12/2022	cbf
searched inventors in PALM and SEARCH	01/12/2022	cbf
consulted child search history	01/12/2022	cbf
Updated search history	10/17/2022	cbf
Updated search	03/24/2023	cbf

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/COURTNEY B FREDRICKSON/ Examiner, Art Unit 3783	

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/12/2022	10/17/2022	03/24/2023						
	1	✓	✓	✓						
	2	✓	-	-						
	3	✓	✓	✓						
	4	✓	✓	✓						
	5	✓	✓	✓						
	6	✓	✓	✓						
	7	✓	✓	✓						
	8	✓	✓	✓						
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	25	✓	✓	✓						
	26	-	-	-						
	27	-	-	-						
	28	✓	✓	✓						
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	31	✓	✓	✓						
	32	✓	✓	✓						
	33	✓	✓	✓						
	34		✓	✓						

Equivalent of Form PTO/SB/08

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet	1	494	4

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	2012/0109083 A1	05-03-2012	Coulthard et al.	
	US2	2016/0135998 A1	05-19-2016	Riesinger	
	US3	2014/0142501 A1	05-22-2014	Clark et al.	
	US4	2018/0104396 A1	04-19-2018	Park	
	US5	10,864,306 B2	12-15-2020	Fujisaki	
	US6	5,406,063 A	04-11-1995	Jelen	
	US7	2005/0245860 A1	11-03-2005	Britto et al.	
	US8	2007/0236584 A1	10-11-2007	Frost-Ruebling et al.	
	US9	2018/0008758 A1	01-11-2018	Garbez et al.	
	US10	2008/0299517 A1	12-04-2008	Delaney, II	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	FP1	JP 2013-545519 A	12-26-2013	KCI Licensing, Inc.		X
	FP2	JP 2016-524490 A	08-18-2016	BSN Medical GmbH		X
	FP3	WO 2013/064852 A1	05-10-2013	Smith & Nephew PLC		
	FP4	JP 2014-532498 A	12-08-2014	Smith & Nephew PLC		X
	FP5	WO 2016/006458 A1	01-14-2016	Murata Manufacturing Co., Ltd.		X
	FP6	JP H 11-178917 A	07-06-1999	Hirose Electric Co., Ltd.		X
	FP7	JP 2000-350527 A	12-19-2000	Pigeon Corp.		X
	FP8	WO 2016/007561 A1	01-14-2016	Naya Health Inc.		
	FP9	WO 2016/025405 A1	02-18-2016	Barral et al.		
	FP10	WO 2004/108184 A2	12-16-2004	Playtex Products, Inc.		
	FP11	JP 2016-526396 A	09-05-2016	Koninklijke Philips NV		X

Examiner Signature		Date Considered	

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Attorney Docket Number	4944.0120006

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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	FP12	WO 2014/160614 A1	10-02-2014	Naia Health, Inc.		
	FP13	JP 2017-503552 A	02-02-2017	Nestec SA		X

Examiner Signature		Date Considered	

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	17/181,057
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				Examiner Name	COURTNEY B FREDRICKSON
Sheet	3	494	4	Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author(in CAPITAL LETTERS),title of the article(when appropriate), title of the item (book,magazine,journal,serial,symposium,catalog,etc.),date,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
	NPL1	International Search Report issued in International Application No. PCT/GB2021/050764, mailed July 6, 2021, 5 pages.	☐
	NPL2	Japanese Search Report issued in Japanese Application No. 2020-519188, mailed June 24, 2022, 20 pages.	☐
	NPL3	Extended European Search Report issued in European Application No. 22174446.9, mailed October 11, 2022; 26 pages.	☐

/COURTNEY B FREDRICKSON/ 03/24/2023

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Sheet	4	494	4

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First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Richard D. Coller III/	Date (YYYY-MM-DD)	2023-01-26
Name/Print	Richard D. Coller III	Registration Number	60,390

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	1	17/181057.app.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:05 PM
L2	128	((("O'TOOLE") near3 ("Jonathan")) OR (("ROLLO") near3 ("Adam")) OR (("CARR") near3 ("Andrew"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/12/31 01:05 PM
L3	8470	a61m1/06-069.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
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L6	8	("20130023821" "20070219486" "20160296682").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:14 PM
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L8	2	("7824363").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU,	OR	ON	ON	2022/01/01 01:04 PM

			SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L9	126	("10881766" OR "10926011" OR "20040087898" OR "20090281482" OR "20100292636" OR "20120165729" OR "20140263611" OR "20160228625" OR "20180110900" OR "20210196873" OR "20210196874" OR "20210196875" OR "20210196876" OR "20210205511" OR "20210205512" OR "20210205513" OR "20210205514" OR "20210205515" OR "20210205516" OR "20210205517" OR "20210205518" OR "20210228789" OR "20210268158" OR "7666162" OR "8608685" OR "20070135761" OR "20070179439" OR "20090281485" OR "20110009824" OR "20160271305" OR "20160296682" OR "20160325031" OR "20170095599" OR "20170112983" OR "20180028733" OR "20180333523" OR "5542921" OR "7833190" OR "10039871" OR "20020193731" OR "20040056641" OR "20040074281" OR "20040267215" OR "20050219302" OR "20060122575" OR "20070051172" OR "20070051727" OR "20080177224" OR "20080262420" OR "20080275386" OR "20110004154" OR "20110196291" OR "20110274566" OR "20120277636" OR "20130023821" OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/01/12 05:14 PM

		"20140031744" OR "20140052056" OR "20140275857" OR "20140323962" OR "20140378895" OR "20150217036" OR "20150217037" OR "20150283311" OR "20160000980" OR "20160058928" OR "20160058929" OR "20160082165" OR "20160082166" OR "20160151551" OR "20160158424" OR "20160166745" OR "20160206794" OR "20160220743" OR "20160220745" OR "20160256617" OR "20160287767" OR "20160296681" OR "20160310650" OR "20170021068" OR "20170035951" OR "20170043065" OR "20170072117" OR "20170072118" OR "20170143879" OR "20170220753" OR "20180021490" OR "20180110906" OR "2849881" OR "4390024" OR "4535627" OR "5474683" OR "5941847" OR "5973770" OR "6045529" OR "6090065" OR "6227936" OR "6328709" OR "6358226" OR "6383163" OR "6440100" OR "6461324" OR "6547756" OR "6579258" OR "6663587" OR "6749582" OR "7048519" OR "7201735" OR "7312554" OR "7314400" OR "7662018" OR "7776008" OR "8057425" OR "8118772" OR					

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L11	105	3 AND (batter$4) AND ((interface flange shield cup) WITH (clear transparent))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/13 02:07 PM
L12	382	3 AND (silicone WITH plastic)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 10:40 AM
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L14	43	3 AND ((USB "universal service bus") WITH (charg$4 recharg$4))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:19 PM
L15	2	("20160220743").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD,	OR	ON	ON	2022/01/14 12:42 PM

			DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L16	5	("5542921").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:52 PM
L20	256	3 AND ((shield cup interface flange) WITH (siz$4) WITH different)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 01:23 PM
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L22	2	("10881766").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:23 PM
L23	2	("10926011").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:38 PM
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		"5542921").pn.					
L25	267	3 AND (nipple WITH (chang$4 differ$4 adjust$4 dissimilar$4) WITH (size width))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/17 03:06 PM
L26	2	"44148977".fmid.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; JPO)	OR	ON	ON	2022/10/17 03:31 PM
L27	1	("10926011").pn.	(USPAT)	OR	ON	ON	2022/10/19 04:47 PM
L28	11	("0000002" OR "10864306" OR "20050245860" OR "20070236584" OR "20080299517" OR "20120109083" OR "20140142501" OR "20160135998" OR "20180008758" OR "20180104396" OR "5406063").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/24 04:55 PM
L29	91	3 AND (nipple WITH (siz$4 spac$4 dimension$4) WITH (indicator line guid$4 symbol indicia))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:26 PM
L30	17	3 AND (nipple WITH (siz$4 spac$4 dimension$4) WITH (mark$4 label))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:31 PM
L31	2	("20020198489").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR,	OR	ON	ON	2023/03/24 05:34 PM

			GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L32	19	(breast WITH shield) AND (size WITH label$4)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/03/24 05:55 PM
L33	1	(09/888322).APP.	(USPAT; USOCR)	OR	ON	ON	2023/03/24 05:56 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet	1	494	4

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	2012/0109083 A1	05-03-2012	Coulthard et al.	
	US2	2016/0135998 A1	05-19-2016	Riesinger	
	US3	2014/0142501 A1	05-22-2014	Clark et al.	
	US4	2018/0104396 A1	04-19-2018	Park	
	US5	10,864,306 B2	12-15-2020	Fujisaki	
	US6	5,406,063 A	04-11-1995	Jelen	
	US7	2005/0245860 A1	11-03-2005	Britto et al.	
	US8	2007/0236584 A1	10-11-2007	Frost-Ruebling et al.	
	US9	2018/0008758 A1	01-11-2018	Garbez et al.	
	US10	2008/0299517 A1	12-04-2008	Delaney, II	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	FP1	JP 2013-545519 A	12-26-2013	KCI Licensing, Inc.		X
	FP2	JP 2016-524490 A	08-18-2016	BSN Medical GmbH		X
	FP3	WO 2013/064852 A1	05-10-2013	Smith & Nephew PLC		
	FP4	JP 2014-532498 A	12-08-2014	Smith & Nephew PLC		X
	FP5	WO 2016/006458 A1	01-14-2016	Murata Manufacturing Co., Ltd.		X
	FP6	JP H 11-178917 A	07-06-1999	Hirose Electric Co., Ltd.		X
	FP7	JP 2000-350527 A	12-19-2000	Pigeon Corp.		X
	FP8	WO 2016/007561 A1	01-14-2016	Naya Health Inc.		
	FP9	WO 2016/025405 A1	02-18-2016	Barral et al.		
	FP10	WO 2004/108184 A2	12-16-2004	Playtex Products, Inc.		
	FP11	JP 2016-526396 A	09-05-2016	Koninklijke Philips NV		X

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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Sheet	2	494	4

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Attorney Docket Number	4944.0120006

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	FP12	WO 2014/160614 A1	10-02-2014	Naia Health, Inc.		
	FP13	JP 2017-503552 A	02-02-2017	Nestec SA		X

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author(in CAPITAL LETTERS),title of the article(when appropriate), title of the item (book,magazine,journal,serial,symposium,catalog,etc.),date,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
	NPL1	International Search Report issued in International Application No. PCT/GB2021/050764, mailed July 6, 2021, 5 pages.	☐
	NPL2	Japanese Search Report issued in Japanese Application No. 2020-519188, mailed June 24, 2022, 20 pages.	☐
	NPL3	Extended European Search Report issued in European Application No. 22174446.9, mailed October 11, 2022; 26 pages.	☐

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet	4	494	4

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Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Richard D. Coller III/	Date (YYYY-MM-DD)	2023-01-26
Name/Print	Richard D. Coller III	Registration Number	60,390

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	17/181,057	Filing Date	2021-02-22	Docket Number (if applicable)	4944.0120006	Art Unit	3783
First Named Inventor	Jonathan O'TOOLE			Examiner Name	FREDRICKSON, Courtney B.		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 190036

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

Applicant Signature

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Signature of Registered U.S. Patent Practitioner			
Signature	/Richard D. Coller III/	Date (YYYY-MM-DD)	2023-01-26
Name	Richard D. Coller III	Registration Number	60390

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

(19)日本国特許庁(JP)　(12)公表特許公報(A)　(11)特許出願公表番号
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A61M 31/00	(2006.01)	A61M	31/00	4C167

審査請求 未請求　予備審査請求 未請求　（全 37 頁）

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(31)優先権主張番号	61/418,730
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(33)優先権主張国	米国(US)

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最終頁に続く

(54)【発明の名称】無線ポンプを使用する減圧システム、ドレッシング、および方法

(57)【要約】
減圧ポンプに無線で電力を供給することを含む、患者の組織部位に減圧をもたらすためのシステム、方法、およびドレッシングが提供される。一例では、ＲＦＩＤアンテナを使用して、導管によって減圧ドレッシングに流体的に結合される減圧ポンプに電力を供給する。別の例では、減圧ドレッシングが、マイクロポンプと、マイクロポンプに電力を供給するために使用されるＲＦＩＤアンテナとを組み込む。他のシステム、方法、および装置が提供される。
【選択図】図１

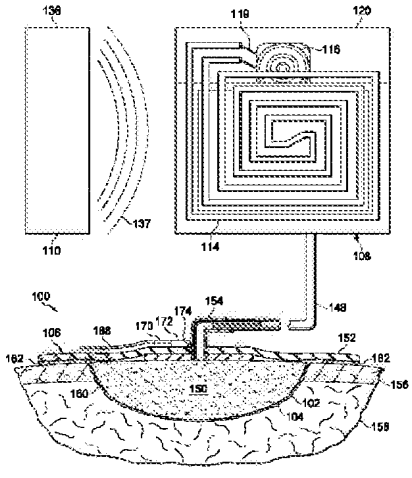

FIG. 1

【特許請求の範囲】
【請求項１】
減圧によって組織部位を治療するシステムにおいて、前記システムが：
前記組織部位に近接して配置される減圧ドレッシングと；
前記減圧ドレッシングに流体的に結合された無線減圧ポンプであって、
ＲＦＩＤアンテナ、
前記ＲＦＩＤアンテナに結合された第１のプロセッサ、
前記第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置、および
前記マイクロポンプ装置に流体的に結合された液溜め
を含む無線減圧ポンプと；
ＲＦＩＤリーダを有するベースユニットと；
を含み、
前記ＲＦＩＤリーダが、前記ＲＦＩＤアンテナに電力をもたらし、前記マイクロポンプ装置に電力供給を行うように構成されることを特徴とする、システム。
【請求項２】
請求項１に記載のシステムにおいて、第１のポンプシール部材および第２のポンプシール部材をさらに含み、前記第１のポンプシール部材および前記第２のポンプシール部材が、少なくとも部分的に結合してポンプ用パウチを形成し、そこに前記マイクロポンプ装置が配置されていることを特徴とする、システム。
【請求項３】
請求項１または２に記載のシステムにおいて、前記無線減圧ポンプには、前記ＲＦＩＤアンテナ以外の動力源が設置されていないことを特徴とする、システム。
【請求項４】
請求項１～３のいずれか１項に記載のシステムにおいて、前記無線減圧ポンプが、前記減圧ドレッシングおよび前記第１のプロセッサに流体的に結合されて前記組織部位における圧力を感知する圧力感知装置をさらに含むことを特徴とする、システム。
【請求項５】
請求項１～３のいずれか１項に記載のシステムにおいて、
前記無線減圧ポンプが、前記第１のプロセッサに結合された圧力感知装置をさらに含み、
前記ベースユニットが、前記ＲＦＩＤリーダに結合された第２のプロセッサを含み、および
前記第２のプロセッサおよび前記ＲＦＩＤリーダが、前記無線減圧ポンプの前記第１のプロセッサに圧力問合せ信号を送信しかつそれに応答して前記第１のプロセッサから圧力メッセージ信号を受信するように構成されることを特徴とする、システム。
【請求項６】
請求項１～３のいずれか１項に記載のシステムにおいて、
前記無線減圧ポンプが、前記第１のプロセッサに結合された圧力感知装置をさらに含み、
前記ベースユニットが、前記ＲＦＩＤリーダに結合された第２のプロセッサを含み、
前記第２のプロセッサおよび前記ＲＦＩＤリーダが、前記無線減圧ポンプの前記第１のプロセッサに圧力問合せ信号を送信しかつそれに応答して前記第１のプロセッサから圧力メッセージ信号を受信するように構成され、
前記第１のプロセッサおよび前記圧力感知装置が、前記圧力問合せ信号に応答して前記圧力メッセージ信号を準備するように構成され、
前記第１のプロセッサおよび前記ＲＦＩＤアンテナが、前記圧力メッセージ信号を送信するように構成され、および
前記第２のプロセッサが、前記圧力メッセージ信号を受信し、制御信号を準備するように構成され、および前記第２のプロセッサおよびＲＦＩＤが、前記無線減圧ポンプに前記

制御信号を送信して、前記マイクロポンプ装置を作動または動作停止させる制御信号をもたらすように構成されていることを特徴とする、システム。

【請求項７】

請求項１～３のいずれか１項に記載のシステムにおいて、

前記無線減圧ポンプが、前記第１のプロセッサに結合された圧力感知装置をさらに含み、

前記圧力感知装置が、圧力メッセージ信号を生成するように動作可能であり、および

前記第１のプロセッサが、前記圧力メッセージ信号を受信しかつ制御信号を生成して前記マイクロポンプ装置を作動させるまたはその動作を停止させるように動作可能であることを特徴とする、システム。

【請求項８】

請求項１に記載のシステムにおいて、

前記減圧ドレッシングおよび前記第１のプロセッサに流体的に結合されて前記組織部位における圧力を感知する圧力感知装置と；

第１の分配マニホールドと、

吸収層と、

ダイバータ層と、

ポンプシール部材と、

第２のポンプシール部材と

をさらに含み、

前記第１の分配マニホールド、前記吸収層、および前記ダイバータ層が、ポンプシール部材および第２のポンプシール部材によって形成されたポンプ用パウチ内に配置され；

前記マイクロポンプ装置が圧電ポンプを含み；

前記減圧ドレッシングが：

前記組織部位に近接して配置されるインターフェース分配マニホールド、

ドレッシングシール部材、および

減圧インターフェース

を含み、および

前記ＲＦＩＤアンテナが前記ベースユニットから５センチメートル未満であることを特徴とする、システム。

【請求項９】

無線減圧ポンプにおいて：

第１のチャンバおよび第２のチャンバを形成する少なくとも１つの壁部材と；

ＲＦＩＤアンテナと

前記ＲＦＩＤアンテナに結合された第１のプロセッサと；

前記第１のプロセッサに結合されてそこから電力を受信しかつ減圧および正圧を発生させるマイクロポンプ装置と；

前記第１のチャンバに流体的に結合された複数の膨張式支持部材と；

前記第２のチャンバを含む液溜めと

を含み、

前記マイクロポンプ装置が、前記第１のチャンバに流体的に結合されてそこに正圧を排出する通気口と、前記第２のチャンバに流体的に結合されてそこに減圧を供給する流入口とを有することを特徴とする、無線減圧ポンプ。

【請求項１０】

請求項９に記載の無線減圧ポンプにおいて、前記第１のチャンバに流体的に結合された第１の圧力逃がし弁をさらに含み、前記第１の圧力逃がし弁が、第１の閾値圧力を上回る正圧を放出するように動作可能であることを特徴とする、無線減圧ポンプ。

【請求項１１】

請求項９または１０に記載の無線減圧ポンプにおいて、前記第１のチャンバおよび前記第２のチャンバが、ピラミッドの一部分の形状であることを特徴とする、無線減圧ポンプ

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【請求項１２】
請求項９または１０乃至１１の何れか１項に記載の無線減圧ポンプにおいて、前記ＲＦＩＤアンテナ以外の動力源が設置されていないことを特徴とする、無線減圧ポンプ。
【請求項１３】
減圧によって患者の組織部位を治療するシステムの製造方法において、前記方法が：
前記組織部位に近接して配置される減圧ドレッシングを提供するステップと；
無線減圧ポンプを提供するステップであって、前記無線減圧ポンプが：
ＲＦＩＤアンテナ、
前記ＲＦＩＤアンテナに結合された第１のプロセッサ、
前記第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置、および
前記マイクロポンプ装置に流体的に結合された液溜め
を含むステップと；
ＲＦＩＤリーダを有するベースユニットを提供するステップと
を含み、
前記ＲＦＩＤリーダが、前記ＲＦＩＤアンテナに電力をもたらし、前記マイクロポンプ装置に電力供給を行うように構成されていることを特徴とする、方法。
【請求項１４】
請求項１３に記載の製造方法において、第１のポンプシール部材および第２のポンプシール部材をさらに含み、前記第１のポンプシール部材および第２のポンプシールが、少なくとも部分的に結合して、前記マイクロポンプ装置が配置されるポンプ用パウチを形成することを特徴とする、方法。
【請求項１５】
請求項１３に記載の製造方法において、前記無線減圧ポンプを前記減圧ドレッシングに流体的に結合する減圧導管を設けるステップをさらに含むことを特徴とする、方法。
【請求項１６】
請求項１３に記載の製造方法において、圧力感知装置を提供するステップと、前記圧力感知装置を前記減圧ドレッシングに結合するステップとをさらに含むことを特徴とする、方法。
【請求項１７】
減圧によって患者の組織部位を治療する方法において、
前記組織部位に近接して減圧ドレッシングを配置するステップと；
無線減圧ポンプを提供するステップであって、前記無線減圧ポンプが：
ＲＦＩＤアンテナ、
前記ＲＦＩＤアンテナに結合された第１のプロセッサ、
前記第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置、および
前記マイクロポンプ装置に流体的に結合された液溜め
を含むステップと；
前記無線減圧ポンプを前記減圧ドレッシングに流体的に結合するステップと；
ＲＦＩＤリーダおよび第２のプロセッサを有するベースユニットを提供するステップと；
前記ベースユニットを作動させ、それにより、前記ＲＦＩＤリーダおよび前記第２のプロセッサが、前記無線減圧ポンプに作動信号を送信して、前記無線減圧ポンプを作動させるステップと
を含むことを特徴とする、方法。
【請求項１８】
請求項１７に記載の方法において、前記無線減圧ポンプが：
第１のポンプシール部材と；

第２のポンプシール部材であって、前記第１のポンプシール部材および第２のポンプシールが少なくとも部分的に結合して、前記マイクロポンプ装置が配置されるポンプ用パウチを形成する、第２のポンプシール部材と
をさらに含むことを特徴とする、方法。
【請求項１９】
請求項１７または１８に記載の方法において、前記マイクロポンプ装置が必要とする電力が全て前記ＲＦＩＤリーダによって供給されることを特徴とする、方法。
【請求項２０】
請求項１７または１８乃至１９の何れか１項に記載の方法において、前記ＲＦＩＤリーダを前記無線減圧ポンプの前記ＲＦＩＤアンテナから５センチメートル以内に配置するステップをさらに含むことを特徴とする、方法。
【請求項２１】
請求項１８に記載の方法において、
前記無線減圧ポンプには、前記ＲＦＩＤアンテナ以外の動力源が設置されておらず；
前記無線減圧ポンプが：
前記減圧ドレッシングおよび前記第１のプロセッサに流体的に結合されて前記組織部位における圧力を感知する圧力感知装置、
第１の分配マニホールド、
吸収層、
ダイバータ層
をさらに含み、
前記第１の分配マニホールド、前記吸収層、および前記ダイバータ層が、前記第１のポンプシール部材および前記第２のポンプシール部材によって形成された前記ポンプ用パウチ内に配置され、および
前記マイクロポンプ装置が圧電ポンプを含み；および
前記減圧ドレッシングが：
前記組織部位に近接して配置されるインターフェース分配マニホールド、
ドレッシングシール部材、および
減圧インターフェース
を含むことを特徴とする、方法。
【請求項２２】
減圧によって組織部位を治療する減圧システムにおいて、前記減圧システムが：
無線減圧ドレッシングであって：
前記組織部位に近接して配置されるインターフェース分配マニホールド、
前記インターフェース分配マニホールドから流体を受け取って保持する吸収部材、
ＲＦＩＤアンテナ、
前記ＲＦＩＤアンテナに結合された第１のプロセッサ、
前記第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置であって、流入口および排出口を有するマイクロポンプ装置、
前記組織部位を覆って密閉空間を形成する第１のシール部材、および
前記マイクロポンプ装置の前記排出口を外部に流体的に結合する通気口；
を含み、前記マイクロポンプが前記密閉空間に流体的に結合されて、そこに減圧を供給する、無線減圧ドレッシングと；
ＲＦＩＤリーダを含むベースユニットであって、無線減圧ドレッシングにポンプ信号を供給して前記マイクロポンプ装置を付勢するように動作可能なベースユニットと
を含むことを特徴とする、減圧システム。
【請求項２３】
請求項２２に記載のシステムにおいて、前記無線減圧ドレッシングに第１の圧力センサをさらに含み、前記第１の圧力センサは前記第１のプロセッサに結合され、前記第１のプロセッサおよび前記ＲＦＩＤアンテナが、圧力問合せ信号を受信しかつ圧力メッセージ信

号を生成し、それを前記ベースユニットに送信するように動作可能であることを特徴とする、システム。

【請求項２４】

請求項２２に記載のシステムにおいて、前記無線減圧ドレッシングに第１の圧力センサをさらに含み、前記第１の圧力センサが前記第１のプロセッサに結合され、前記第１のプロセッサおよび前記ＲＦＩＤアンテナが、圧力問合せ信号を受信しかつ圧力メッセージ信号を生成してそれを前記ベースユニットに送信するように動作可能であり、前記ベースユニットが第２のプロセッサをさらに含み、前記第２のプロセッサが、前記圧力メッセージ信号を受信しかつポンプ制御信号を生成するように動作可能であることを特徴とする、システム。

【請求項２５】

請求項２２に記載のシステムにおいて、前記無線減圧ドレッシングに第１の圧力センサをさらに含み、前記第１の圧力センサは前記第１のプロセッサに結合され、および前記第１のプロセッサは、前記第１の圧力センサから圧力メッセージ信号を受信しかつ制御信号を生成して前記マイクロポンプ装置を制御するように構成されることを特徴とする、システム。

【請求項２６】

請求項２２に記載されたシステムにおいて、前記無線減圧ポンプには、前記ＲＦＩＤアンテナ以外の動力源が設置されておらず、および前記減圧ドレッシングに供給される減圧のみが前記マイクロポンプ装置からのものであることを特徴とする、システム。

【請求項２７】

請求項２２または２３乃至２６の何れか１項に記載のシステムにおいて、前記無線減圧ドレッシングには導管もワイヤも結合されていないことを特徴とする、システム。

【請求項２８】

減圧によって患者の組織部位を治療する方法において、

前記組織部位に近接して無線減圧ドレッシングを配置するステップであって、前記無線減圧ドレッシングが：

前記組織部位に近接して配置されるインターフェース分配マニホールド、

前記インターフェース分配マニホールドから流体を受け取って保持する吸収部材、

ＲＦＩＤアンテナ、

前記ＲＦＩＤアンテナに結合された第１のプロセッサ、

前記第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させ、かつ流入口および排出口を有するマイクロポンプ装置、

前記組織部位を覆いかつ密閉空間を形成する第１のシール部材、および

前記排出口を外部に流体的に結合する通気口

を含むステップと；

ＲＦＩＤリーダを含むベースユニットを提供するステップであって、前記ベースユニットが、前記無線減圧ドレッシングにポンプ信号を供給して前記マイクロポンプ装置を付勢するように構成されているステップと；

前記ベースユニットを作動して前記無線減圧ドレッシングに前記ポンプ信号を供給するステップと

を含むことを特徴とする、方法。

【請求項２９】

無線減圧ポンプにおいて、

ＲＦＩＤアンテナと；

前記ＲＦＩＤアンテナに結合された第１のプロセッサと；

前記第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置と

を含むことを特徴とする、無線減圧ポンプ。

【請求項３０】

請求項２９に記載の無線減圧ポンプにおいて、前記マイクロポンプ装置に流体的に結合された液溜めをさらに含むことを特徴とする、無線減圧ポンプ。

【請求項３１】

請求項２９または３０に記載の無線減圧ポンプにおいて、

第１のポンプシール部材と；

第２のポンプシール部材であって、前記第１のポンプシール部材および第２のポンプシールが、少なくとも部分的に結合して、前記マイクロポンプ装置が配置されるポンプ用パウチを形成する、第２のポンプシール部材と

をさらに含むことを特徴とする、無線減圧ポンプ。

【請求項３２】

請求項２９～３１のいずれか１項に記載の無線減圧ポンプにおいて、前記ＲＦＩＤアンテナ以外の動力源が設置されていないことを特徴とする、無線減圧ポンプ。

【請求項３３】

請求項２９または３０乃至３２の何れか１項に記載の無線減圧ポンプにおいて、前記減圧ドレッシングおよび前記第１のプロセッサに流体的に結合されて前記組織部位における圧力を感知する圧力感知装置をさらに含むことを特徴とする、無線減圧ポンプ。

【請求項３４】

請求項２９または３０乃至３２の何れか１項に記載の無線減圧ポンプにおいて、

前記無線減圧ポンプが、前記第１のプロセッサに結合された圧力感知装置をさらに含み；

前記ＲＦＩＤリーダに結合された第２のプロセッサを含むベースユニットをさらに含み；および

前記第２のプロセッサおよび前記ＲＦＩＤリーダが、前記無線減圧ポンプの前記第１のプロセッサに圧力問合せ信号を送信しかつそれに応答して前記第１のプロセッサから圧力メッセージ信号を受信するように構成されていることを特徴とする、無線減圧ポンプ。

【請求項３５】

請求項２９または３０乃至３２の何れか１項に記載の無線減圧ポンプにおいて、

前記無線減圧ポンプが、前記第１のプロセッサに結合された圧力感知装置をさらに含み、

前記ＲＦＩＤリーダに結合された第２のプロセッサを含むベースユニットをさらに含み、

前記第２のプロセッサおよび前記ＲＦＩＤリーダが、前記無線減圧ポンプの前記第１のプロセッサに圧力問合せ信号を送信しかつそれに応答して前記第１のプロセッサから圧力メッセージ信号を受信するように構成され、

前記第１のプロセッサおよび前記圧力感知装置が、前記圧力問合せ信号に応答して前記圧力メッセージ信号を準備するように構成され、

前記第１のプロセッサおよび前記ＲＦＩＤアンテナが、前記圧力メッセージ信号を送信するように構成され、および

前記第２のプロセッサが、前記圧力メッセージ信号を受信し、制御信号を準備するように構成され、および前記第２のプロセッサおよびＲＦＩＤが、前記無線減圧ポンプに前記制御信号を送信して、前記マイクロポンプ装置を作動または動作停止させる制御信号をもたらすように構成されていることを特徴とする、無線減圧ポンプ。

【請求項３６】

請求項２９または３０乃至３２の何れか１項に記載の無線減圧ポンプにおいて、

前記無線減圧ポンプが、前記第１のプロセッサに結合された圧力感知装置をさらに含み、

前記圧力感知装置が、圧力メッセージ信号を生成するように動作可能であり、および

前記第１のプロセッサが、前記圧力メッセージ信号を受信しかつ制御信号を生成して、前記マイクロポンプ装置を作動させるまたはその動作を停止させるように動作可能であることを特徴とする、無線減圧ポンプ。

【請求項３７】
請求項２９または３０乃至３２の何れか１項に記載の無線減圧ポンプにおいて、前記無線減圧ポンプが：
第１のチャンバおよび第２のチャンバを形成する少なくとも１つの壁部材と、
前記第１のチャンバに流体的に結合された第１の圧力逃がし弁であって、第１の閾値圧力を上回る正圧を放出するように動作可能である第１の圧力逃がし弁と、
前記第１のチャンバに流体的に結合された複数の膨張式支持部材と
をさらに含み、
前記マイクロポンプ装置が、前記第１のチャンバに流体的に結合されて、そこに正圧を供給する通気口と、前記第２のチャンバに流体的に結合されて、そこに減圧を供給する流入口とを有し、
前記液溜めが前記第２のチャンバを含むことを特徴とする、無線減圧ポンプ。
【請求項３８】
請求項２９または３０に記載の無線減圧ポンプにおいて、前記無線減圧ポンプが：
ピラミッドの一部分の形状である第１のチャンバおよび第２のチャンバと；
前記第１のチャンバに流体的に結合された第１の圧力逃がし弁であって、第１の閾値圧力を上回る正圧を放出するように動作可能である第１の圧力逃がし弁と；
前記第１のチャンバに流体的に結合された複数の膨張式支持部材と；
をさらに含み、
前記マイクロポンプ装置が、前記第１のチャンバに流体的に結合された通気口を有し；
前記液溜めが前記第２のチャンバを含むことを特徴とする、無線減圧ポンプ。
【請求項３９】
請求項２９または３０に記載の無線減圧ポンプにおいて、
前記無線減圧ポンプには前記ＲＦＩＤアンテナ以外の動力源が設置されておらず；
前記無線減圧ポンプが：
前記減圧ドレッシングおよび前記第１のプロセッサに流体的に結合されて前記組織部位における圧力を感知する圧力感知装置、
第１の分配マニホールド、
吸収層、
ダイバータ層
をさらに含み、
前記第１の分配マニホールド、前記吸収層、および前記ダイバータ層が、前記第１のポンプシール部材および前記第２のポンプシール部材によって形成された前記ポンプ用パウチ内に配置され；
前記マイクロポンプ装置が圧電ポンプを含み；
前記減圧ドレッシングが：
前記組織部位に近接して配置されているインターフェース分配マニホールド、
ドレッシングシール部材、および
減圧インターフェース
を含み；
前記ＲＦＩＤアンテナが、前記ベースユニットから約５センチメートル未満にあり；および
減圧導管が減圧インターフェースを前記無線減圧ポンプに流体的に結合していることを特徴とする、無線減圧ポンプ。
【発明の詳細な説明】
【技術分野】
【０００１】
関連出願の相互参照
本発明は、３５ＵＳＣ§１１９（ｅ）下において、２０１０年１０月２７日出願の米国仮特許出願第６１／４０７，１９４号（「Ｓｙｓｔｅｍ ａｎｄ Ｍｅｔｈｏｄｓ Ｆｏ

ｒ Ｅｌｅｃｔｒｉｃａｌｌｙ Ｄｅｔｅｃｔｉｎｇ Ｔｈｅ Ｐｒｅｓｅｎｃｅ ｏｆ Ｅｘｕｄａｔｅ Ｉｎ Ｒｅｄｕｃｅｄ－Ｐｒｅｓｓｕｒｅ Ｄｒｅｓｓｉｎｇｓ」（あらゆる目的のために本願明細書に援用する）［ＶＡＣ．０９７５ＰＲＯ１］；２０１０年１２月１日出願の米国仮特許出願第６１／４１８，７３０号（「Ｓｙｓｔｅｍｓ ａｎｄ Ｍｅｔｈｏｄｓ ｆｏｒ Ｅｌｅｃｔｒｉｃａｌｌｙ Ｄｅｔｅｃｔｉｎｇ ｔｈｅ Ｐｒｅｓｅｎｃｅ ｏｆ Ｅｘｕｄａｔｅ ｉｎ Ｄｒｅｓｓｉｎｇｓ」（あらゆる目的のために本願明細書に援用する）［ＶＡＣ．０９７５ＰＲＯ２］；２０１１年２月２２日出願の米国仮特許出願第６１／４４５，３８３号（「Ｉｎｔｅｒａｃｔｉｖｅ，Ｗｉｒｅｌｅｓｓ Ｒｅｄｕｃｅｄ－Ｐｒｅｓｓｕｒｅ Ｄｒｅｓｓｉｎｇｓ，Ｍｅｔｈｏｄｓ，ａｎｄ Ｓｙｓｔｅｍｓ」（あらゆる目的のために本願明細書に援用する）［ＶＡＣ．０９９９ＰＲＯ］；および２０１１年２月２２日出願の米国仮特許出願第６１／４４５，３３８号（「Ｒｅｄｕｃｅｄ－Ｐｒｅｓｓｕｒｅ Ｓｙｓｔｅｍｓ，Ｄｒｅｓｓｉｎｇｓ，ａｎｄ Ｍｅｔｈｏｄｓ Ｅｍｐｌｏｙｉｎｇ ａ Ｗｉｒｅｌｅｓｓ Ｐｕｍｐ」（あらゆる目的のために本願明細書に援用する）［ＶＡＣ．１０００ＰＲＯ］の利益を主張する。

【０００２】

本開示は、概して治療システムに関し、より詳細には、限定するものではないが、組織部位に減圧を行うポンプに無線で電力を供給することを含むシステム、ドレッシング、および方法に関する。

【背景技術】

【０００３】

臨床試験および実習において、組織部位に近接して減圧をもたらすことによって、組織部位における新しい組織の増殖を増強および加速することが示されている。この現象の適用例は多数あるが、減圧を行うことは、創傷の治療においてかなり成功している。この治療（医学界では「陰圧閉鎖療法」、「減圧療法」、または「真空療法」と呼ばれることが多い）は、いくつもの利点を提供し、それら利点には、迅速な治癒、および肉芽組織の形成加速化が含まれ得る。一般に、減圧は、開放創に行われるとき、多孔質パッドまたは他のマニホールド装置を通して組織に行われる。多孔質パッドは、減圧を組織に分配し、および組織から引き出された流体を送る。減圧はまた、腹腔などの体洞から流体を除去するのにも使用し得る。

【発明の概要】

【０００４】

例示的実施形態によれば、減圧によって組織部位を治療するシステムは、組織部位に近接して配置される減圧ドレッシングと、減圧ドレッシングに流体的に結合された無線減圧ポンプとを含む。無線減圧ポンプは、無線周波数認証（ＲＦＩＤ：Ｒａｄｉｏ Ｆｒｅｑｕｅｎｃｙ Ｉｄｅｎｔｉｆｉｃａｔｉｏｎ）アンテナと、ＲＦＩＤアンテナに結合された第１のプロセッサと、電力を受信しかつ減圧を発生させるためにプロセッサに結合されたマイクロポンプ装置と、第１のポンプシール部材と、液溜めと、第２のポンプシール部材とを含む。第１のポンプシール部材および第２のポンプシールは、少なくとも部分的に結合されて、マイクロポンプが配置されるポンプ用パウチを形成する。このシステムは、ＲＦＩＤリーダを有するベースユニットをさらに含む。ＲＦＩＤリーダは、ＲＦＩＤアンテナに電力をもたらし、マイクロポンプに電力供給を行うように構成される。

【０００５】

別の例示的実施形態によれば、減圧によって患者の組織部位を治療するシステムの製造方法は、組織部位に近接して配置される減圧ドレッシングを提供するステップと、無線減圧ポンプを提供するステップとを含む。無線減圧ポンプは、ＲＦＩＤアンテナと、ＲＦＩＤアンテナに結合された第１のプロセッサと、電力を受信しかつ減圧を発生させるために第１のプロセッサに結合されたマイクロポンプ装置と、第１のポンプシール部材と、液溜めと、第２のポンプシール部材とを含む。第１のポンプシール部材および第２のポンプシールは、少なくとも部分的に結合されて、マイクロポンプが配置されるポンプ用パウチを

形成する。この方法は、無線減圧ポンプを減圧ドレッシングに流体的に結合するために減圧供給導管を設けるステップをさらに含み得る。この方法は、ＲＦＩＤリーダを有するベースユニットを提供するステップをさらに含む。ＲＦＩＤリーダは、ＲＦＩＤアンテナに電力をもたらし、マイクロポンプに電力供給を行うように構成される。

【０００６】

別の例示的実施形態によれば、減圧によって患者の組織部位を治療する方法は、組織部位に近接して減圧ドレッシングを配置するステップと、無線減圧ポンプを提供するステップとを含む。無線減圧ポンプは、ＲＦＩＤアンテナと、ＲＦＩＤアンテナに結合された第１のプロセッサと、電力を受信しかつ減圧を発生させるためにプロセッサに結合されたマイクロポンプ装置と、第１のポンプシール部材と、液溜めと、第２のポンプシール部材とを含む。第１のポンプシール部材および第２のポンプシールは、少なくとも部分的に結合されて、マイクロポンプが配置されるポンプ用パウチを形成する。この方法は、無線減圧ポンプを減圧ドレッシングに流体的に結合するステップと、ＲＦＩＤリーダおよび第２のプロセッサを有するベースユニットを提供するステップと、ベースユニットを作動させ、それにより、ＲＦＩＤリーダおよび第２のプロセッサが、無線減圧ポンプに作動信号を送信して、無線減圧ポンプを作動させるステップとをさらに含む。

【０００７】

別の例示的実施形態によれば、減圧によって組織部位を治療する減圧システムが、減圧ドレッシングを含む。減圧ドレッシングは、組織部位に近接して配置される第１の分配マニホールドと、第１の分配マニホールドから流体を受け取って保持する吸収層と、ＲＦＩＤアンテナと、ＲＦＩＤアンテナに結合された第１のプロセッサと、第１のプロセッサに結合されて、そこから電力を受信しかつ減圧を発生させるマイクロポンプとを含む。マイクロポンプは流入口および排出口を有する。このシステムはまた、組織部位およびマイクロポンプの上側を覆って密閉空間を形成する第１のシール部材と、マイクロポンプの排出口を外部に流体的に結合する通気口とを含む。このシステムは、ＲＦＩＤリーダを含むベースユニットをさらに含む。ベースユニットは、減圧ドレッシングにポンプ信号を供給してマイクロポンプを付勢するように動作可能である。

【０００８】

別の例示的実施形態によれば、減圧によって患者の組織部位を治療する方法が、組織部位に近接して無線減圧ドレッシングを配置するステップを含む。無線減圧ドレッシングは、組織部位に近接して配置される第１の分配マニホールドと、第１の分配マニホールドから流体を受け取って保持する吸収層と、ＲＦＩＤアンテナと、ＲＦＩＤアンテナに結合された第１のプロセッサと、第１のプロセッサに結合されて、そこから電力を受信しかつ減圧を発生させるマイクロポンプとを含む。マイクロポンプは、流入口および排出口と、組織部位およびマイクロポンプの上側を覆って密閉空間を形成する第１のシール部材と、マイクロポンプの排出口を外部に流体的に結合する通気口とを有する。この方法は、ＲＦＩＤリーダを含むベースユニットを提供するステップをさらに含む。ベースユニットは、無線減圧ドレッシングにポンプ信号を供給してマイクロポンプを付勢するように動作可能である。この方法はまた、ベースユニットを作動させて無線減圧ドレッシングにポンプ信号を供給するステップを含む。

【０００９】

例示的実施形態の他の特徴、および利点は、以下の図面および詳細な説明を参照することにより明らかとなる。

【図面の簡単な説明】

【００１０】

【図１】図１は、減圧によって組織部位を治療するシステムの例示的実施形態の一部分を断面で示す概略図である。

【図２】図２は、図１のシステムの一部として使用される無線減圧ポンプの例示的実施形態の概略的な分解斜視図である。

【図３】図３は、追加的な態様およびいくつかの代替例を示す図１のシステムの一部分を

断面で示す概略図である。
【図４】図４は、無線減圧ポンプの例示的実施形態の概略的な部分断面図である。
【図５】図５は、図１にあるような減圧によって組織部位を治療するシステムの一部として使用するマイクロポンプ装置の例示的一実施形態の概略的な断面図である。
【図６】図６は、無線減圧ポンプの例示的実施形態の概略的な斜視図である。
【図７】図７は、無線減圧ポンプの別の例示的実施形態の概略的な断面図である。
【図８】図８は、図７の無線減圧ポンプの概略的な斜視図である。
【図９】図９は、減圧によって組織部位を治療する減圧システムの例示的実施形態の一部分を斜視図で示す概略図である。
【図１０】図１０は、線１０－１０に沿って取った図９に示す減圧ドレッシングの概略的な断面図である。
【図１１】図１１は、図９～１０の減圧ドレッシングの概略的な分解斜視図である。
【図１２】図１２は、減圧によって組織部位を治療するシステムの例示的実施形態の概略的な断面図である。
【図１３】図１３は、減圧ドレッシングの別の例示的実施形態の概略的な分解斜視図である。
【発明を実施するための形態】
【００１１】
以下の例示的非限定的な実施形態の詳細な説明において、本明細書の一部をなす添付図面を参照する。これらの実施形態は、当業者が本発明を実施できるようにするのに十分な程度、詳細に説明し、および、本発明の趣旨または範囲から逸脱せずに、他の実施形態を使用し得ること、および論理的な構造上の、機械的な、電気的なおよび化学的な変更がなされ得ることが理解される。当業者が、本明細書で説明する実施形態を実施できるようにするのに必要ではない詳細を避けるために、説明では、当業者に公知の特定の情報を省略し得る。以下の詳細な説明は、限定的ととられるべきではなく、例示的実施形態の範囲は、添付の特許請求の範囲によってのみ定義される。
【００１２】
本明細書の例示的実施形態は、無線周波数認証（ＲＦＩＤ）または高性能タイプ（ｅｎｈａｎｃｅｄ　ｔｙｐｅ）の無線周波数認証（ＲＦＩＤ）技術を使用して、減圧ドレッシングにあるマイクロポンプ装置を付勢することを含む。ＲＦＩＤは、伝統的に、標的上にあるＲＦＩＤタグまたはラベルと、ＲＦＩＤタグを付勢してそこからの信号を読み取るＲＦＩＤリーダとを使用する。１つの一般的な例は料金タグである。ほとんどのＲＦＩＤタグは、情報を記憶しかつ処理する集積回路と、変調器と、復調器とを含む。ＲＦＩＤタグは、パッシブタグ、アクティブＲＦＩＤタグ、およびバッテリー付きパッシブタグとし得る。一般的に、パッシブタグは、バッテリーを使用せず、かつ、ＲＦＩＤリーダによって付勢されない限り、情報を送信しない。アクティブタグは搭載バッテリーを有して、自律的に（すなわち、ＲＦＩＤリーダによって付勢されずに）送信できる。バッテリー付きパッシブタグは、一般に、ＲＦＩＤリーダが存在することで起動される小型のバッテリーが搭載されている。ＲＦＩＤタグの性能を高めるために、減圧ドレッシングにマイクロコントローラおよびセンサが組み込まれてもよい。ＲＦＩＤタグ、マイクロコントローラおよびセンサは、感知機能、および任意選択的なコンピュータによる機能を可能にする。さらに、ＲＦＩＤタグおよびマイクロコントローラは、部分的にまたは完全にマイクロポンプに電力を供給する。
【００１３】
例示的一実施形態では、高性能ＲＦＩＤ技術は、ＷＩＳＰ（Ｗｉｒｅｌｅｓｓ　Ｉｄｅｎｔｉｆｉｃａｔｉｏｎ　ａｎｄ　Ｓｅｎｓｉｎｇ　Ｐｌａｔｆｏｒｍ）装置である。ＷＩＳＰは、ＲＦＩＤタグ（またはラベル）と似て、ＲＦＩＤリーダを用いてＷＩＳＰ装置に電力を供給しかつそれを読み取ることを含む。ＷＩＳＰ装置は、ＲＦＩＤリーダが発した無線信号から電力を得て、かつ感知機能を実行する（および任意選択的にコンピュータによる機能を実行する）。ＷＩＳＰ装置は、情報を備える無線信号をＲＦＩＤリーダに送

信する。ＷＩＳＰ装置はＲＦＩＤリーダから電力を受信する。ＷＩＳＰ装置は、エネルギーを得るタグまたはアンテナと、サンプリングセンサなどの、様々なタスクを実行できるマイクロコントローラ（またはプロセッサ）とを有する。ＷＩＳＰ装置はＲＦＩＤリーダにデータを報告する。例示的一実施形態では、ＷＩＳＰ装置は、電力源（ｐｏｗｅｒ ｈａｒｖｅｓｔｉｎｇ）回路を備える集積回路、復調器、変調器、マイクロコントローラ、センサを含み、かつエネルギーを蓄積するために１つ以上のコンデンサを含んでもよい。ＷＩＳＰ技術の一形態は、Ｉｎｔｅｌ Ｒｅｓｅａｒｃｈ Ｓｅａｔｔｌｅ（ｗｗｗ．ｓｅａｔｔｌｅ．ｉｎｔｅｌ－ｒｅｓｅａｒｃｈ．ｎｅｔ／ｗｉｓｐ／）によって開発された。本明細書では、ＲＦＩＤ装置はＷＩＳＰ装置も含む。

【００１４】

ここで図面、初めに図１～５を参照して、減圧によって組織部位１０２、例えば創傷１０４、または空洞を治療するシステム１００の例示的実施形態を説明する。システム１００は、組織部位１０２に近接して配置される減圧ドレッシング１０６；減圧ドレッシング１０６に流体的に結合された無線減圧ポンプ１０８；およびＲＦＩＤリーダ１１２を有するベースユニット１１０を含む。無線減圧ポンプ１０８は、第１のＲＦＩＤアンテナ１１４およびマイクロポンプ装置１１６を含む。ＲＦＩＤリーダ１１２は、第１のＲＦＩＤアンテナ１１４に電力をもたらすポンプ信号を発生させかつ送信するように構成される。第１のＲＦＩＤアンテナ１１４によって受信されたポンプ信号によって、マイクロポンプ装置１１６に電力を供給する。マイクロポンプ装置１１６に遠くから電力供給することによって、いくつもの潜在的利益が提供される。これら利益には、適用が容易であることが含まれ得る。さらに、無線減圧ポンプ１０８は、内蔵型の使い捨てユニットとし得る。図示のシステム１００の潜在的な変形例のいくつかを示すために、図面間でいくらかの違いがあることに留意されたい。

【００１５】

システム１００は、様々な異なるタイプの組織部位１０２で使用し得る。組織部位１０２は、骨組織、脂肪組織、筋組織、皮膚組織、脈管組織、結合組織、軟骨、腱、靭帯、体洞、または任意の他の組織を含む、任意のヒト、動物、または他の生物の体の組織とし得る。組織部位１０２の治療は、流体、例えば滲出液や腹水の除去を含み得る。

【００１６】

無線減圧ポンプ１０８は第１のＲＦＩＤアンテナ１１４を含み、このＲＦＩＤアンテナは、導線１１９によって第１のプロセッサ１１８に結合される。第１のプロセッサ１１８は、マイクロポンプ装置１１６、すなわちマイクロポンプに結合されて、電力を受信する。第１のプロセッサ１１８はマイクロポンプ装置１１６に組み込まれてもよい。第１のプロセッサ１１８およびマイクロポンプ装置１１６は、ポンプ用パウチ１２０内に配置され得る。

【００１７】

ポンプ用パウチ１２０は、第１のポンプシール部材１２２を第２のポンプシール部材１２４に結合するように形成し得る。ポンプ用パウチ１２０はまた、ポリマーからポンプ用パウチ１２０を注入成形するなど、他の技術によって形成してもよい。ポンプ用パウチ１２０の少なくとも一部分は、組織部位１０２から流体１２７を受け取って保持する液溜め１２６を含む。マイクロポンプ装置１１６は、圧電ポンプ、蠕動ポンプ、または最小限の所要電力で減圧を生じさせる他の小型ポンプとし得る。第１のプロセッサ１１８は、圧力感知装置１３８から圧力メッセージ信号を受信するように動作可能である。圧力メッセージ信号の受信に応答して、第１のプロセッサ１１８は制御信号を生成して、マイクロポンプ装置１１６を作動させるまたはその動作を停止させる。圧力感知装置１３８は、変換器としてもよいし、または十分な減圧が存在すると作動される単純なスイッチとしてもよい。

【００１８】

主に図３を参照して説明すると、ベースユニット１１０は、ＲＦＩＤリーダ１１２に結合された第２のプロセッサ１２８を含む。コントロールパネル１３０（例えばユーザイン

ターフェース）、第１のディスプレイ１３２、および電源１３４（例えば、バッテリーまたは電気的接続）も第２のプロセッサ１２８に結合され得る。ベースユニット１１０はベースハウジング１３６を含み得る。第２のプロセッサ１２８およびＲＦＩＤリーダ１１２は、信号１３７、例えばポンプ信号や圧力問合せ信号を、第１のＲＦＩＤアンテナ１１４に送信するように構成される。

【００１９】

減圧ポンプ１０８の第１のＲＦＩＤアンテナ１１４は、第１のプロセッサ１１８に、導線１１９によってまたは無線結合（ｗｉｒｅｌｅｓｓ　ｃｏｕｐｌｉｎｇ）によって結合される。第１のプロセッサ１１８はマイクロポンプ装置１１６に結合されて、マイクロポンプ装置１１６に電力を供給しかつそれを制御する。第１のプロセッサ１１８に追加的な電力をもたらすために第１の電源１４０が含まれ得る。第１のプロセッサ１１８には圧力感知装置１３８が結合され得る。圧力感知装置１３８は、圧力感知ルーメン１６６（すなわち通気路１７４またはインターフェース分配マニホールド１５０）に流体的に結合されて、その内部の圧力を感知する。マイクロポンプ装置１１６は液溜め１２６に流体的に結合される。液溜め１２６は、減圧ルーメ１６４からすなわちインターフェース分配マニホールド１５０から流体１２７を受け取って保持する。

【００２０】

ベースユニット１１０によって送信されたポンプ信号は、第１のＲＦＩＤアンテナ１１４によって受信され、かつマイクロポンプ装置１１６を付勢して減圧を生じる。圧力問合せ信号は、第２のプロセッサ１２８およびＲＦＩＤリーダ１１２によって無線減圧ポンプ１０８の第１のプロセッサ１１８に送信される。それに応じて、無線減圧ポンプ１０８の第１のプロセッサ１１８および圧力感知装置１３８は、減圧ドレッシング１０６が受けている圧力を示す圧力メッセージ信号をベースユニット１１０に送信する。

【００２１】

第２のプロセッサ１２８は、無線減圧ポンプ１０８から圧力メッセージ信号を受信し、かつ制御信号を準備するように構成される。第２のプロセッサ１２８およびＲＦＩＤリーダ１１２は、制御信号を無線減圧ポンプ１０８に送信して、マイクロポンプ装置１１６を作動させるまたはその動作を停止させるように構成される。別の例示的実施形態では、上述の通り、第１のプロセッサ１１８は、圧力感知装置１３８から圧力メッセージ信号を受信しかつ制御信号を生成して、マイクロポンプ装置１１６を作動させるまたはその動作を停止させるように動作可能である。

【００２２】

ここで主に図２および図４を参照して説明すると、無線減圧ポンプ１０８は減圧を生成し、その減圧は組織部位１０２に供給される。無線減圧ポンプ１０８は、組織部位１０２から流体を受け取って保持する。減圧は、概して、治療を施されている組織部位における周囲圧力に達しない圧力を指す。ほとんどの場合、この減圧は、患者がいる場所の気圧に達しない。あるいは、減圧は、組織部位における静水圧未満とし得る。他に指定のない限り、本明細書で挙げられた圧力の値はゲージ圧である。供給される減圧は、一定であってもまたは変動しても（パターン化またはランダム）よく、連続的にまたは断続的に供給され得る。本明細書での使用に一致して、他に指定のない限り、減圧または真空圧の上昇は、一般に、絶対圧の相対的低下を指す。

【００２３】

無線減圧ポンプ１０８はシステム１００のために減圧をもたらす。無線減圧ポンプ１０８は、第１の分配マニホールド１４２、ダイバータ層１４４、および吸収層１４６を含み得る。通気口１７６を使用して、排気路をマイクロポンプ装置１１６から無線減圧ポンプ１０８の外部に流体的に結合する。第１の分配マニホールド１４２は、マイクロポンプ装置１１６によって生成された減圧を分配する働きをする。マイクロポンプ装置１１６と第１の分配マニホールド１４２との間に空気液体分離器１４３、例えば疎水性フィルタを配置して、マイクロポンプ装置１１６に液体が入らないようにする。吸収層１４６は、組織部位１０２から流体を受け取って保持する働きをする。吸収層１４６は、組織部位１０２

から滲出液などの液体を吸収することができる任意の材料から作製し得る。

【００２４】

吸収層１４６は超吸収繊維から作製し得る。超吸収繊維は、繊維への物理的または化学的な変化を伴って、液体を保持しても、または液体に結びついてもよい。非限定的な一例では、超吸収繊維は、Ｔｅｃｈｎｉｃａｌ Ａｂｓｏｒｂｅｎｔｓ，Ｌｔｄ．（Ｇｒｉｍｓｂｙ、Ｕｎｉｔｅｄ Ｋｉｎｇｄｏｍ）からのＳｕｐｅｒ Ａｂｓｏｒｂｅｎｔ Ｆｉｂｅｒ（ＳＡＦ）材を含み得る。吸収層１４６は、繊維が組織部位１０２からの液体を吸収する繊維性材料のシートまたはマットとし得る。繊維を含む吸収層１４６の構造は、織構造でもまたは不織構造でもよい。吸収層１４６の繊維は、液体と接触するとゲルとなってもよく、それにより、液体を捕捉する。繊維間の空間または空隙によって、吸収層１４６に行われる減圧が吸収層１４６内をおよびそこを通って伝達することができるようにし得る。例示的一実施形態では、吸収層１４６内の繊維の繊維密度は、１ミリメートル当たり約１．４グラムとし得る。

【００２５】

ダイバータ層１４４は、吸収層１４６および第１の分配マニホールド１４２に隣接して配置される。ダイバータ層１４４は、液不透過性材料から形成されるが、複数のアパーチャ１４５を含んでいる。複数のアパーチャ１４５によって、マイクロポンプ装置１１６からの減圧を、ダイバータ層１４４を通して所望の個所に伝達する。ダイバータ層１４４は、吸収層１４６に適用されるときの減圧のパターンを制御するのを助ける。減圧は、第１の分配マニホールド１４２によってダイバータ層１４４に分配される。アパーチャ１４５は、吸収層１４６の複数の部分に減圧を行うパターンで配置されて、吸収層１４６が組織部位１０２からより多くの流体を吸収するときに、組織部位１０２への減圧の伝達を継続する吸収層１４６の性能を高め得る。

【００２６】

複数のアパーチャ１４５は、ダイバータ層１４４の中心から離れてダイバータ層１４４の周辺部分を取り囲むパターンで位置決めして、減圧が、吸収層１４６の中心領域から離れて、吸収層１４６で行われるようにし得る。ダイバータ層１４４は、第１の分配マニホールド１４２と共に作用して、ダイバータ層１４４と併用されない吸収層１４６と比較すると吸収層１４６の吸収能力および吸収効率が確実に高まるようにする。吸収層１４６全体にわたって液体の分配を良好に行うことによって、ダイバータ層１４４はまた、無線減圧ポンプ１０８の有効容量を多くし、かつ治療時間を長くする。

【００２７】

ダイバータ層１４４は、隣接する吸収層の減圧伝達能力および貯蔵能力を高める任意の材料から作製し得る。例えば、ダイバータ層１４４は、液体および気体に対して実質的に不透過性でありかつアパーチャ１４５を通過するように減圧の流れをそらす材料から作製し得る。その代わりにまたはそれに加えて、ダイバータ層１４４が作製される材料は、予め定められた透湿度（ｍｏｉｓｔｕｒｅ ｖａｐｏｒ ｔｒａｎｓｆｅｒ ｒａｔｅ）を有してもよく、それはガス透過性と一致している。いずれの例でも、ダイバータ層１４４は、依然として、アパーチャのないガス透過性材料で可能な量よりも大量の液体または気体を伝達するアパーチャのパターンを含み得る。しかしながら、液体ではなく気体に対するダイバータ層１４４の透過性は、ドレッシングを通る減圧の伝達率を高めるが、依然として液体の流れをダイバータ層１４４の周囲またはその付近へ向けることができることを留意されたい。

【００２８】

第１の分配マニホールド１４２、ダイバータ層１４４、および吸収層１４６は、ポンプ用パウチ１２０内に配置され得る。無線減圧ポンプ１０８はまた、圧力感知のために減圧ドレッシング１０６に流体的に結合されかつ第１のプロセッサ１１８と通信する圧力感知装置１３８を含み得る。減圧導管１４８は、減圧ドレッシング１０６からの流体を無線減圧ポンプ１０８へ供給する。例示的一実施形態では、減圧導管１４８は吸収層１４６に直接配置される。別の例示的実施形態では、減圧導管１４８と吸収層１４６をインターフェ

ース（図示せず）が流体的に結合する。

【００２９】

ここで主に図１および図３を参照して説明すると、減圧ドレッシング１０６は組織部位１０２に配置される。組織部位１０２は、例えば、表皮１５６を通って皮下組織１５８に至る創傷１０４、または任意の他の組織部位とし得る。減圧ドレッシング１０６は、組織部位１０２に減圧をもたらしかつ組織部位１０２から流体を受け取る任意の装置とし得る。例えば、減圧ドレッシング１０６は、発泡体部材、複数の画成されたチャネルを備える構造、吸引管、または他の装置によって形成し得る。例示的一実施形態では、減圧ドレッシング１０６は、組織部位１０２に近接して配置されるインターフェース分配マニホールド１５０と、ドレッシングシール部材１５２と、減圧インターフェース１５４とを含み得る。

【００３０】

マニホールドは、一般的に、組織部位１０２に減圧を行う、流体を供給する、またはそこから流体を除去するのを支援するために設けられる物体または構造を指す。インターフェース分配マニホールド１５０は、一般に、流体を、インターフェース分配マニホールド１５０の周りの組織部位１０２にもたらしかつそこから除去するように分配させる複数の流路または流れ経路を含む。例示的一実施形態では、流路または流れ経路は相互に接続されて、組織部位１０２に提供されるまたはそこから除去される流体の分配を改善する。インターフェース分配マニホールド１５０はまた、組織部位１０２と接触して配置されかつ組織部位１０２に減圧を分配させることができる生体適合性材料とし得る。インターフェース分配マニホールドの例としては、限定はされないが、以下を含み得る：流路を形成するように配置された構造要素を有する装置、例えば、気泡質の発泡体、連続気泡発泡体、多孔性組織集合体、液体、ゲル、および流路を含むまたは硬化して流路を含む発泡体；発泡体；ガーゼ；フェルトのマット；または特定の生物学的適用に好適な任意の他の材料。

【００３１】

一実施形態では、インターフェース分配マニホールド１５０は多孔質発泡体であり、かつ流路の機能を果たす複数の連続気泡または細孔を含む。多孔質発泡体は、ポリウレタン製の連続気泡の網状発泡体、例えばＫｉｎｅｔｉｃ Ｃｏｎｃｅｐｔｓ，Ｉｎｃｏｒｐｏｒａｔｅｄ（Ｓａｎ Ａｎｔｏｎｉｏ、Ｔｅｘａｓ）から入手可能なＧｒａｎｕＦｏａｍ（登録商標）材とし得る。場合によっては、インターフェース分配マニホールド１５０はまた、薬剤、抗菌薬、成長因子、および様々な溶液などの流体を組織部位１０２に分配するためにも使用し得る。インターフェース分配マニホールド１５０にまたはインターフェース分配マニホールド１５０上に、吸収材料、ウィッキング材料、疎水性材料、および親水性材料などの他の層も含まれ得る。

【００３２】

例示的一実施形態では、インターフェース分配マニホールド１５０の全体または一部分は、減圧ドレッシング１０６の使用後に、患者の体に残ってもよい生体再吸収性（ｂｉｏｒｅｓｏｒｂａｂｌｅ）材料から構成し得る。好適な生体再吸収性材料は、限定はされないが、ポリ乳酸（ＰＬＡ）とポリグリコール酸（ＰＧＡ）とのポリマーブレンドを含み得る。ポリマーブレンドはまた、限定はされないが、ポリカーボネート、ポリフマレート、およびカプララクトンを含み得る。インターフェース分配マニホールド１５０は、新しい細胞増殖のための足場としての機能をさらに果たしてもよいし、または細胞増殖を促進するためにインターフェース分配マニホールド１５０と足場材料が一緒に使用されてもよい。足場は、細胞増殖または組織形成を増進させるまたは促進するのに使用される物体または構造であり、例えば、細胞増殖のテンプレートを提供する三次元の多孔質構造である。足場材料の例示的例は、リン酸カルシウム、コラーゲン、ＰＬＡ／ＰＧＡ、コーラルヒドロキシアパタイト（ｃｏｒａｌ ｈｙｄｒｏｘｙ ａｐａｔｉｔｅ）、カーボネート、または加工された同種移植片材料を含む。

【００３３】

インターフェース分配マニホールド１５０はドレッシングシール部材１５２によって覆

われる。ドレッシングシール部材１５２は、流体シールをもたらす任意の材料とし得る。流体シールは、特定の減圧源または関連のサブシステムによって与えられた減圧を所望の部位に維持するのに適切なシールである。ドレッシングシール部材１５２は、例えば、不透過性または半透過性のエラストマー性材料とし得る。エラストマー性材料は、エラストマーの特性を有する。一般的に、ゴムのような特性を有するポリマー材料を指す。より具体的には、ほとんどのエラストマーは、１００％超の極限伸びおよび相当の弾力性を有する。材料の弾力性は、弾性変形から回復する材料の能力を指す。エラストマーの例は、限定されるものではないが、天然ゴム、ポリイソプレン、スチレンブタジエンゴム、クロロプレンゴム、ポリブタジエン、ニトリルゴム、ブチルゴム、エチレンプロピレンゴム、エチレンプロピレンジエンモノマー、クロロスルホン化ポリエチレン、多硫化ゴム、ポリウレタン（ＰＵ）、ＥＶＡフィルム、コーポリエステル、およびシリコーンを含む。ドレッシングシール部材材料の追加的な具体例は、シリコーンドレープ、３Ｍ Ｔｅｇａｄｅｒｍ（登録商標）ドレープ、Ａｖｅｒｙ Ｄｅｎｎｉｓｏｎ Ｃｏｒｐｏｒａｔｉｏｎ（Ｐａｓａｄｅｎａ、Ｃａｌｉｆｏｒｎｉａ）から入手可能なポリウレタン（ＰＵ）ドレープを含む。ドレッシングシール部材１５２は、組織部位１０２の上側を覆う密閉空間１６０を形成し、そこに、マイクロポンプ装置１１６を含んでもよい。

【００３４】

取付装置１６２を使用して、ドレッシングシール部材１５２を患者の表皮１５６または別の層、例えばガスケットまたは追加的なシール部材に保持してもよい。取付装置１６２は多くの形態を取り得る。例えば、取付装置１６２は、医学的に容認できる感圧接着剤としてもよく、これは、ドレッシングシール部材１５２の周辺にまたは全てに延在する、または表皮１５６を覆う患者対面側面のドレッシングシール部材１５２の少なくとも一部分を覆う。

【００３５】

減圧インターフェース１５４を使用して、減圧導管１４８と減圧ドレッシング１０６の密閉空間１６０との間に流体連通をもたらし得る。減圧は、減圧導管１４８を通って減圧インターフェース１５４に、その後密閉空間１６０に供給され得る。例示的一実施形態では、減圧インターフェース１５４は、ＫＣＩ（Ｓａｎ Ａｎｔｏｎｉｏ、Ｔｅｘａｓ）から入手可能なＴ．Ｒ．Ａ．Ｃ．（登録商標）ＰａｄまたはＳｅｎｓａ Ｔ．Ｒ．Ａ．Ｃ．（登録商標）Ｐａｄである。減圧導管１４８は、図１に示すように一体型導管として形成されたまたは図３に示すように別個に形成された減圧ルーメン１６４および圧力感知ルーメン１６６を含んでもよい。

【００３６】

図１に示す例示的一実施形態では、圧力感知能力を減圧ドレッシング１０６に付加して、圧力感知装置１３８に追加してまたはその装置の代わりに機能するようにしてもよい。減圧ドレッシング１０６は、第２のＲＦＩＤアンテナ１６８、第３のプロセッサ１７０、および第２の圧力感知装置１７２を含み得る。第３のプロセッサ１７０は、第２のＲＦＩＤアンテナ１６８および第２の圧力感知装置１７２に結合されている。通気路１７４が密閉空間１６０と第２の圧力感知装置１７２との間に流体連通をもたらす。第３のプロセッサ１７０および第２の圧力感知装置１７２は、ベースユニット１１０から圧力問合せ信号を受信し、密閉空間１６０内の圧力を示す圧力メッセージ信号によって応答するように動作可能である。

【００３７】

例示的一実施形態では、無線減圧ポンプ１０８は無線式のパッシブな（すなわちバッテリーがない）装置である。そのようなものとして、無線減圧ポンプ１０８には、第１のＲＦＩＤアンテナ１１４によって供給される電力以外の動力源が設置されていない。一部の実施形態では、無線減圧ポンプ１０８は、電気エネルギーを蓄積するためのコンデンサを含み得る。別の例示的実施形態では、図３に示すような第１の電源１４０は、第１のＲＦＩＤアンテナ１１４によって供給される電力を増大するかまたはマイクロポンプ装置１１６を動作させるように設けてもよい。第１の電源１４０は、第１のＲＦＩＤアンテナ１１

４からの電力によって再充電されてもよい。

【００３８】

マイクロポンプ装置１１６は、圧電ポンプ、蠕動ポンプ、または他の小型ポンプなどの多数の形態を取り得る。ここで主に図５を参照して、無線減圧ポンプ１０８の一態様として使用するのに好適なマイクロポンプ装置１１６の例示的実施形態を説明する。マイクロポンプ装置１１６は、第１の端壁１８０、第２の端壁１８２、および環状側壁１８４によって画成された空洞１７８を含む。空洞１７８は、実質的に円形形状とし得るが、楕円形などの他の形状も可能である。例示的一実施形態では、空洞１７８は、約１０ｍｌの流体を保持してもよいし、またはより多くのまたはより少ない流体を保持してもよい。

【００３９】

空洞１７８はノード様流入口１８６を備え、そこは弁付きでもまたは弁付きでなくてもよい。空洞１７８はまた、弁付き排出口１９０を有してもよい。第１の端壁１８０はディスク１９２とし得る。ディスク１９２上には、アクチュエータ１９４、例えば圧電ディスク、磁歪装置、またはソレノイド作動装置がある。アクチュエータ１９４は駆動回路に電気的に結合され、この駆動回路はプロセッサによって制御される。駆動回路は、交流電気信号をアクチュエータ１９４に印加して、ディスク１９２に振動を誘起する。振動の周波数は、チャンバの固有周波数に適合するように調整できる。圧電ディスクは、厚さが１ｍｍ未満とし、および５００Ｈｚ超で、１０ｋＨｚ超、または２０ｋＨｚ超でも動作するように同調され得る。作動すると、アクチュエータ１９４は、図示の通りの空洞１７８の平面に実質的に垂直な方向において振動してもよく、それにより、空洞１７８内の流体に半径方向の圧力振動を生成する。１つ以上のマイクロポンプ装置１１６を並列にまたは直列に使用してもよい。

【００４０】

例示的一実施形態では、マイクロポンプ装置１１６は、空洞１７８に流体を有し、かつ第１の端壁１８０、第２の端壁１８２、および側壁１８４によって囲まれる実質的にシリンダー形状を有する。少なくとも２つのアパーチャ、例えば、流入口１８６および排出口１９０が、空洞１７８を形成する壁１８０、１８２、１８４を通って形成される。空洞１７８は半径ｒおよび高さｈを有し、およびｒ／ｈ＞１．２およびｈ^{2}／ｒ＞４×１０$^{-10}$ｍである。圧電ディスクであるアクチュエータ１９４は、端壁１８０、１８２の一方に、第１の端壁１８０および第２の端壁１８２の平面に対して実質的に垂直な方向の振動運動を生じる。端壁１８０、１８２の軸方向振動は、空洞１７８に流体圧力の半径方向の振動を発生させ、かつ減圧を生じるポンピングを可能にする。マイクロポンプ装置１１６は、音響ポンプのように、空洞１７８内に音響共振を生じる。流入口１８６を使用して流体を引き込み、および排出口１９０は通気口、例えば図４の通気口１７６に結合され、外部に排出する。他のマイクロポンプ装置を使用してもよい。マイクロポンプ装置１１６は、米国特許出願公開第２００９／０２４０１８５号明細書（米国特許出願第１２／３９８，９０４号；２００９年３月５日出願）（「Ｄｒｅｓｓｉｎｇ ａｎｄ Ｍｅｔｈｏｄ ｆｏｒ Ａｐｐｌｙｉｎｇ Ｒｅｄｕｃｅｄ Ｐｒｅｓｓｕｒｅ Ｔｏ ａｎｄ Ｃｏｌｌｅｃｔｉｎｇ Ａｎｄ Ｓｔｏｒｉｎｇ Ｆｌｕｉｄ ｆｒｏｍ ａ Ｔｉｓｓｕｅ Ｓｉｔｅ」）に示すマイクロポンプのタイプとし得る。この文献をあらゆる目的のために本願明細書に援用する。

【００４１】

ここで主に図１～３を参照して説明すると、例示的一実施形態によれば、システム１００の動作中、減圧ドレッシング１０６は組織部位１０２に適用される。特に、インターフェース分配マニホールド１５０は組織部位１０２に近接して配置される。その後、インターフェース分配マニホールド１５０および組織部位１０２がドレッシングシール部材１５２によって覆われて、密閉空間１６０を生成する。ドレッシングシール部材１５２の患者対面側面上の取付装置１６２は、患者の表皮１５６の一部分に流体シールをもたらすのを助け得る。減圧インターフェース１５４がまだ設置されていない場合には、例えばドレッシングシール部材１５２に小さなアパーチャの切り込みを入れ、アパーチャまたは孔を覆

ってまたはそこを通して減圧インターフェース１５４を固定するなどによって、減圧インターフェースを適用し得る。

【００４２】

その後、無線減圧ポンプ１０８が提供され、減圧導管１４８によって減圧インターフェース１５４に流体的に結合される。第１のＲＦＩＤアンテナ１１４をベースユニット１１０の動作範囲内に配置するように、無線減圧ポンプ１０８を位置決めする。例示的一実施形態では、第１のＲＦＩＤアンテナ１１４は、ベースユニット１１０のＲＦＩＤリーダ１１２から数ミリメートル内に配置する。別の例示的実施形態では、第１のＲＦＩＤアンテナ１１４は、ＲＦＩＤリーダ１１２から１０メートル離れた個所に配置してもよい。所与の範囲内の任意の距離を容易に使用し得る。

【００４３】

その後、ベースユニット１１０を使用者が作動させる。ベースユニット１１０は、無線減圧ポンプ１０８にポンプ信号１３７を送信する。ポンプ信号は第１のＲＦＩＤアンテナ１１４によって受信され、およびポンプ信号のエネルギーが第１のプロセッサ１１８に供給される。第１のプロセッサ１１８はマイクロポンプ装置１１６にエネルギーを供給する。マイクロポンプ１１６は減圧を生じ、それが、減圧導管１４８に流体的に結合されている液溜め１２６に供給される。それゆえ、減圧は、減圧導管１４８を通して減圧ドレッシング１０６に供給される。組織部位１０２からの流体がインターフェース分配マニホールド１５０、減圧インターフェース１５４、および減圧導管１４８を通って液溜め１２６まで流れる。

【００４４】

組織部位１０２における圧力が、圧力感知装置、例えば図３の圧力感知装置１３８または図１の第２の圧力感知装置１７２を使用して直接または間接的に監視され得る。第１の例示的例では、ベースユニット１１０の第２のプロセッサ１２８およびＲＦＩＤリーダ１１２は、ポンプ信号とは別にまたはポンプ信号と共に、無線減圧ポンプ１０８に圧力問合せ信号を送信する。圧力問合せ信号に応答して、第１のプロセッサ１１８および圧力感知装置１３８は圧力メッセージ信号を準備し、組織部位における圧力の測定値を通信し得る。その後、圧力メッセージ信号を、第１のプロセッサ１１８による別の処理に使用して、必要とされ得るときにマイクロポンプ１１６を作動または動作停止させるポンプ制御信号を発生させる。その代わりにまたはそれに加えて、第１のプロセッサ１１８は、第１のＲＦＩＤアンテナ１１４を介してＲＦＩＤリーダ１１２に圧力メッセージ信号を送信し得る。圧力メッセージ信号は、ＲＦＩＤリーダ１１２に達した後、第２のプロセッサ１２８に供給される。圧力メッセージ信号を使用して、第２のプロセッサ１２８はポンプ制御信号を準備し、そのポンプ制御信号は、ＲＦＩＤリーダ１１２によって無線減圧ポンプ１０８に送信されて、必要に応じマイクロポンプ１１６を動作停止または作動させる。

【００４５】

適切な時間間隔を経た後、圧力が所望の動作範囲外に留まっている場合、ベースユニット１１０または無線減圧ポンプ１０８によって警報信号が生成される。警報は、別個の可聴装置、視覚警報としてもよいし、またはマイクロポンプ１１６が異なる周波数範囲、例えば低周波数で機能して、警報のための可聴雑音を生成してもよい。

【００４６】

第２の例示的手法では、減圧ドレッシング１０６は、第３のプロセッサ１７０に結合される第２のＲＦＩＤアンテナ１６８を含み、その第３のプロセッサは、第２の圧力感知装置１７２に結合されている。第２の圧力感知装置１７２は、通気路１７４を介して密閉空間１６０内の圧力を受ける。ベースユニット１１０は、第２のＲＦＩＤアンテナ１６８に圧力問合せ信号を送信する。それに応答して、第２の圧力感知装置１７２および第３のプロセッサ１７０は圧力メッセージ信号を生成し、それが、第２のＲＦＩＤアンテナ１６８によってベースユニット１１０に送信される。上述の通り、その後、ベースユニット１１０はポンプ制御信号を生成して、それが無線減圧ポンプ１０８に送信され、マイクロポンプ１１６を作動させるまたはその動作を停止させる。あるいは、第３のプロセッサ１７０

は、圧力を見積もり、かつ、フィードバックまたは制御ループの一部としてポンプ制御信号を準備し得る。

【００４７】

ここで主に図４および図６を参照して、無線減圧ポンプ１０８の例示的実施形態を説明する。この例示的実施形態では、無線減圧ポンプ１０８は、ポール１９６上のベースユニット１１０に取り外し可能に固定され得る内蔵型の使い捨てパウチ設計とし得る。既に説明したように、ポンプ用パウチ１２０は、第１のポンプシール部材１２２および第２のポンプシール部材１２４によって形成される。ポンプ用パウチ１２０の外辺部は、第１のフランジ１２３および第２のフランジ１２５を含み得る。ポンプ用パウチ１２０は、所望の場合には多数の区画に分割または区分され得る。例えば、ある区画（明示せず）は、区画内にマイクロポンプ１１６を有して形成されてもよく、および別の区画は、吸収層１４６を含んで形成されてもよい。

【００４８】

ポンプ用パウチ１２０の例示的実施形態でのフランジ１２３、１２５は、溶接、ボンディング、またはそうでなければ第１のポンプシール部材１２２および第２のポンプシール部材１２４の取り付け部分によって形成され得る。第１のフランジ１２３は、１つ以上のポスト１９８を収容するための１つ以上のアパーチャ１２９を含み得る。ポスト１９８は、ポンプ用パウチ１２０をベースユニット１１０に隣接させて固定する。減圧導管１４８は、第２のフランジ１２５にあるアパーチャ１４９を通って入り込んでもよく、封止された締まり嵌めを提供するか、または封止接続をもたらすカップリングを有する。他の接続を使用してもよい。

【００４９】

図４から最もよく分かるように、第１のＲＦＩＤアンテナ１１４をベースユニット１１０の最も近くに配置して、第１のＲＦＩＤアンテナ１１４がベースユニット１１０のＲＦＩＤリーダ１１２に直接隣接するようにし得る。非限定的な一例では、第１のＲＦＩＤアンテナ１１４は、ＲＦＩＤリーダ１１２から２ミリメートルまたは１ミリメートル（１ｍｍ）またはそれより近くに位置決めされる。ＲＦＩＤリーダ１１２および第１のＲＦＩＤアンテナ１１４は実質的に適合されかつ位置合わせされ得る。別の例示的実施形態では、図１に提案するように、第１のＲＦＩＤアンテナ１１４が、遠くに配置されたベースユニット１１０の方へ外側に向くような状態で、無線減圧ポンプ１０８はポスト１９８に取り付けられ得る。例えば、ベースユニット１１０は中心のハブ領域に配置されてもよく、そこで、無線減圧ポンプ１０８は、１０メートル以上離れていてもよいベースユニット１１０を使用して監視されかつ電力供給される。

【００５０】

ここで主に図６を参照して説明すると、ベースユニット１１０は、コントロールパネル１３０および１つ以上のディスプレイ１３２を含んでもよい。ベースユニット１１０は、ベースハウジングまたはベース本体１３６を含み得る。ベースハウジングまたは本体１３６は、無線減圧ポンプ１０８が組織部位１０２からの流体で満たされるときに無線減圧ポンプ１０８の一部分に物理的な支持をもたらし得る棚部分１９９を含み得る。この点について、図６に示す無線減圧ポンプ１０８は、使用前の状態を示すことに留意されたい。図４および図６の実施形態では、無線減圧ポンプ１０８が流体を保持する容量に達したら、マイクロポンプ１１６は動作停止されてもよく、および使用者は無線減圧ポンプ１０８全体を廃棄してもよい。

【００５１】

ここで主に図７および図８を参照して、無線減圧ポンプ２００の別の例示的実施形態を説明する。無線減圧ポンプ２００を、組織部位を治療するシステム、例えば図１のシステムの一部として使用し得る。無線減圧ポンプ２００は複数の壁部材２０２を含み、第１のチャンバ２０４および第２のチャンバ２０６を形成する。複数の壁部材２０２の１つが、第１のチャンバ２０４を第２のチャンバ２０６から区分する区画壁２０８である。既に説明した図面のマイクロポンプ１１６と類似しているマイクロポンプ２１０が、第１のチャ

ンバ２０４内に配置され得る。マイクロポンプ１１６は、流体を受け取る（または前記別の方法では、減圧を排出する）流入口２１２が第２のチャンバ２０６に流体的に結合されるように構成される。マイクロポンプ２１０は、第１のチャンバ２０４に流体的に結合される排出口または通気口２１４を有する。マイクロポンプ２１０は、排出口または通気口２１４を通って第１のチャンバ２０４まで正圧を放出する。

【００５２】

第１のチャンバ２０４を形成する複数の壁部材２０２の１つの一部分は、アパーチャ２１６を含む。任意選択的な逃がし弁２１８がアパーチャ２１６に結合される。逃がし弁２１８は、圧力が第１の閾値圧力を上回るときに、第１のチャンバ２０４内の圧力が無線減圧ポンプ２００の外部に放出されるように構成される。第２のチャンバ２０６を構成する複数の壁部材２０２の少なくとも一部分は、膨張式支持部材、典型的には複数の膨張式支持部材２２０を含む。複数の膨張式支持部材２２０を示すが、単一の膨張式支持部材を使用して第２のチャンバ２０６を形成し得ることを理解されたい。

【００５３】

膨張式支持部材２２０は、複数のアパーチャ２２２を通してなど、第１のチャンバ２０４と流体連通している。それゆえ、第１のチャンバ２０４内の正圧が複数の膨張式支持部材２２０を満たす。複数の膨張式支持部材２２０が十分な流体で満たされると、複数の膨張式支持部材２２０は、相対的に剛性を得て、第２のチャンバ２０６に体積部を形成するのを助ける構造体を提供する。組織部位からの流体２２３は、減圧導管２２４を通って第２のチャンバ２０６の体積部に収容される。ピラミッド形状で示す無線減圧ポンプ２００は、他の形状、例えば、ボックス、シリンダー、または任意の他の形状をとるように形成してもよい。

【００５４】

既に説明した実施形態のように、マイクロポンプ２１０は、ＲＦＩＤアンテナ２２６に供給されたポンプ信号によって、全体的にまたは部分的に、電力供給される。ＲＦＩＤアンテナ２２６は第１のプロセッサ２２８に結合されている。第１のプロセッサ２２８は、導線２３０によってマイクロポンプ２１０に電気的に結合されており、この導線は複数の壁部材２０２の１つに含まれ得るが、図７では別個に示す。図８に示すように、複数の壁部材２０２の床部分２３２がプラットフォーム部材２３４内に含まれ得る。

【００５５】

ここで主に図７および図８を参照して説明すると、例示的一実施形態による動作では、減圧導管２２４は、減圧ドレッシング、例えば図１および図３の減圧ドレッシング１０６に結合される。ベースユニット、例えば図１のベースユニット１１０を使用して、無線減圧ポンプ２００のＲＦＩＤアンテナ２２６にポンプ信号またはポンプ作動信号を送信する。ＲＦＩＤアンテナ２２６によって受信されるポンプ信号が、第１のプロセッサ２２８に供給される。第１のプロセッサ２２８からマイクロポンプ２１０へ電力が供給され、マイクロポンプ２１０を付勢する。マイクロポンプ２１０が付勢されると、減圧が第２のチャンバ２０６に供給され、かつ正圧が第１のチャンバ２０４に供給される。圧力が第１のチャンバ２０４内で高まると、圧力が複数の膨張式支持部材２２０に充填されて、無線減圧ポンプ２００が、しぼんだ状態から膨張状態に変化する。流入口２１２をスペーサ部材（図示せず）が覆って、膨張式支持部材２２０が充填される前の始動中の気閉塞を防止する。

【００５６】

膨張式支持部材２２０が膨張すると、第２のチャンバ２０６の最大体積が達成される。それと同時に、第２のチャンバ２０６の減圧が減圧導管２２４に供給される。流体２２３（液体を含む）が第２のチャンバ２０６に注入される。

【００５７】

明示しないが、例えば図３の圧力感知装置１３８に類似した減圧感知装置が第２のチャンバ２０６の一部分に組み込まれて、第２のチャンバ２０６の圧力を測定し得ることを理解されたい。ここでも、明示しないが、例えば図３の圧力感知装置１３８に類似した減圧

感知装置が、減圧ポンプ２００に含まれてもよいことを理解されたい。減圧導管２２４はまた、分配マニホールドにおける圧力を測定するための減圧感知装置に流体的に結合される圧力感知ルーメンを有し得る。どちらの例でも、圧力感知装置は第１のプロセッサ２２８に結合されて、圧力メッセージ信号を発生させる。圧力メッセージ信号は、ベースユニットからの圧力問合せ信号に応答して、または第１のプロセッサ２２８によって自然発生して供給され得る。第１のプロセッサ２２８は圧力メッセージ信号を使用してポンプ制御信号を発生させ、それがマイクロポンプ２１０に供給され得る。あるいは、圧力メッセージ信号はベースユニットに送信され、そこで、ベースユニット内のプロセッサが、既に説明した実施形態と同様のポンプ制御信号を発生させ得る。

【００５８】

代替的な実施形態では、既に説明した無線減圧ポンプ１０８、２００が、ＲＦＩＤアンテナを有する代わりに、ポンプとベースとの間に導線またはソケットおよびプラグを有する。導線またはソケットおよびプラグは、電力および信号をやり取りするために互いに容易に差し込み得る。

【００５９】

ここで主に図９～１１を参照して、減圧によって組織部位３０２を治療する減圧システム３００の例示的実施形態を説明する。減圧システム３００は、無線減圧ドレッシング３０４およびベースユニット３０６を含む。ベースユニット３０６は電源コネクタ３０７を含んでもよい。無線減圧ドレッシング３０４は、ベースユニット３０６から電力を受信しかつ制御を受ける内蔵型の使い捨てドレッシングである。ベースユニット３０６は、無線減圧ドレッシング３０４に実質的に隣接し得る、例えば、１または２ミリメートル以内に、または１０メートルまでまたはそれ以上離れて、またはそれらの間のどこかにあり得る。一実施形態では、マイクロポンプ３１６は、吸収層または吸収部材３１０から分離していてもよく、使用後に、マイクロポンプ３１６を容易に分離し得る。そのため、マイクロポンプ３１６を修理および再使用してもよい。

【００６０】

無線減圧ドレッシング３０４は、組織部位３０２に近接して配置されるインターフェース分配マニホールド３０８を含む。無線減圧ドレッシング３０４はまた、吸収層３１０、ＲＦＩＤアンテナ３１２、および第１のプロセッサ３１４を含んでもよい。ＲＦＩＤアンテナ３１２は第１のプロセッサ３１４に電気的に結合される。第１のプロセッサ３１４はマイクロポンプ３１６に電気的に結合される。インターフェース分配マニホールド３０８、吸収層３１０、ＲＦＩＤアンテナ３１２、第１のプロセッサ３１４、およびマイクロポンプ３１６は全て適所に保持され、かつ１つ以上のシール部材、例えばシール部材３２０によって密閉空間３１８内に固定される。追加的な層および構成要素を無線減圧ドレッシング３０４に含めてもよい。

【００６１】

図９～１１の例示的実施形態は、追加的な層および構成要素を含む。追加的な層および構成要素は、異なる順序で配置してもよい。シール層３２２を使用して、組織部位３０２の周りで無線減圧ドレッシング３０４を封止する。シール層３２２はアパーチャ３２３を備えて形成され、インターフェース分配マニホールド３０８に流体連通をもたらす。インターフェース分配マニホールド３０８および組織部位３０２と流体連通して第１の内部分配マニホールド３２４が位置決めされる。吸収層３１０は、第１の内部分配マニホールド３２４、インターフェース分配マニホールド３０８、および組織部位３０２と流体連通して位置決めされる。吸収層３１０に隣接してダイバータ層３２６が位置決めされる。ダイバータ層３２６に流体連通して第２の内部分配マニホールド３２８が位置決めされる。ダイバータ層３２６は、複数のアパーチャ３２７を備えて形成され、それらアパーチャは、多数のパターンおよび形態をとり得る。ダイバータ層３２６は、この特定の例示的実施形態では、正方形のパターンを形成する複数のアパーチャ３２７を備えて示す。正方形のパターンでは、角にあるアパーチャが他のアパーチャよりも大きい。第２の内部分配マニホールド３２８に隣接して気液分離装置３３０が位置決めされる。

【００６２】
マイクロポンプ３１６、ＲＦＩＤアンテナ３１２、および第１のプロセッサ３１４は、気液分離装置３３０に隣接し得る。マイクロポンプ３１６の排出口３３４を覆ってチャコールフィルタ３３２または他の臭気除去装置を位置決めし得る。シール部材３２０は、アパーチャ３３６を備えて形成され、マイクロポンプ３１６の排出口３３４が無線減圧ドレッシング３０４の外部に排気できるようにする。排出口３３４およびアパーチャ３３６は共に通気口３３８を形成する。
【００６３】
マイクロポンプ３１６は、統合無線減圧ドレッシング３０４を組織部位３０２に維持できるようにするのに十分に小型かつ軽量なマイクロポンプとし得る。さらに、マイクロポンプ３１６は、統合減圧ドレッシング３０４が組織部位３０２を引っ張らないまたは他の方法で悪影響を与えないようなサイズおよび重量にし得る。例示的一実施形態では、マイクロポンプ３１６は、上述したものと同様の圧電アクチュエータを有するディスク型ポンプとし得る。米国特許出願公開第２００９／００８７３２３号明細書および米国特許出願公開第２００９／０２４０１８５号明細書（これらをあらゆる目的のために本願明細書に援用する）に示されているポンプも参照する。代替的な実施形態では、マイクロポンプ３１６は、様々な流体をくみ上げるために使用する蠕動ポンプとし得る。代替的なポンプ技術を用いてもよいこと、および回転ポンプ、リニアポンプ、または他の構成のポンプを用いてもよいことを理解されたい。
【００６４】
マイクロポンプ３１６は、創傷治療に治療力のある十分な減圧を生成する。例示的一実施形態では、マイクロポンプ３１６は、減圧治療を継続的に行うことができるように十分な流量特性、減圧特性、および動作寿命特性を有する。流量は約５～１０００ｍｌ／分の範囲、および減圧は約－５０～－２００ｍｍ　Ｈｇ（－６．６～－２６．６ｋＰａ）の範囲とし得る。統合無線減圧ドレッシング３０４の構成、創傷のサイズ、または創傷のタイプに依存して、代替的な範囲を使用してもよいことを理解されたい。例示的一実施形態では、複数のポンプを単一のドレッシングに位置決めして、必要に応じて流量または真空レベルを上昇させて供給してもよい。
【００６５】
マイクロポンプ３１６はドレッシング内に配置されて、創傷の滲出液を収集するための導管および外部キャニスタの使用を回避する。マイクロポンプ３１６は、減圧ドレッシング３０４から空気を放出するまたは排気するための排出口３３４を含む。排出口３３４を使用する場合、排出口３３４は、シール部材３２０のアパーチャ３３６と流体連通しているか、またはその内部に位置決めされ得る。あるいは、シール部材３２０は、マイクロポンプ３１６の出口ポートの周りで封止され、マイクロポンプ３１６からのガスが、アパーチャ３３６を通って直接排気できるようにし得る。図９～１１の例示的実施形態では、マイクロポンプ３１６の排出口３３４は、気液分離装置３３０（または疎水性フィルタ）から離れる方向に向けられて、無線減圧ドレッシング３０４に空気を加えないようにする。一方向弁を含み得るシール部材３２０のアパーチャ３３６を通って空気は排出される。あるいは、空気または別のガスは、減圧を維持するシール部材３２０の能力が影響を受けない限り、シール部材３２０のガス透過性部分を通って排出され得る。
【００６６】
マイクロポンプ３１６が圧電ポンプであるとき、マイクロポンプ３１６に関連付けられた圧電アクチュエータは、ときには、異なる周波数で駆動されてブザーまたは振動性警告システムの機能を果たし得る。警告システムは、警報状況を使用者に警告し得る。例えば、警報状況は、ドレッシングに漏れが存在すること、センサによって測定された減圧が変化したこと、ドレッシングが、インジケータによって示され得るような最大容量の液体を吸収したこと、または１つ以上の層がもはや効率的に減圧を多岐的に分配（ｍａｎｉｆｏｌｄｉｎｇ）しないことを示し得る。
【００６７】

制御電子回路が第１のプロセッサ３１４の一部として物理的にまたは機能的に組み込まれ得る。制御電子回路は、マイクロポンプ３１６の動作を制御するために使用し得る。制御電子回路は、アナログでもまたはデジタルでもよく、およびマイクロポンプ３１６が動作する速度またはデューティサイクルを調整する調整器を備えて構成し得る。さらに、制御電子回路は、センサまたはスイッチ、例えば、圧力感知装置（図１２の３４０参照）からの感知信号を受信するコントローラを備えて構成し得る。センサは無線減圧ドレッシング３０４全体にわたって配置され、パラメータ、例えば圧力、温度、湿度、化学的性質、臭気、またはマイクロポンプ３１６の管理および制御に用い得る任意の他のパラメータを感知し得る。制御電子回路は、コンピュータプロセッサまたはプログラマブル・ゲート・アレイまたは他の制御装置を含んでもよい。制御電子回路は、本明細書で説明する機能を実行するデジタルまたはアナログ構成要素の任意の形態を含み得ることを理解されたい。制御電子回路は、第１のプロセッサ３１４としてもよいし、またはそれを含んでもよい。

【００６８】

制御電子回路は、いくつかの状態、例えば、（ｉ）低圧、（ｉｉ）過度の漏れ、（ｉｉｉ）吸収層レベル、および（ｉｖ）バッテリー状態（含まれる場合）に関して監視しかつ警報を発するように配置され得る。それゆえ、制御電子回路は、パラメータの各々を監視しかつスピーカ、バイブレータ、または照明装置、例えば発光ダイオード（ＬＥＤ）を使用して警報信号（例えば、高音のビープ音、振動、または光）を生成するエレクトロニクスを含み得る。それゆえ、制御電子回路は、医療専門家、患者、または家族の一員に、パラメータが所望の範囲外にあることを通知し得る。例えば、組織部位３０２における圧力が治療レベルを下回る場合、連続音調が生成され得る。別の例として、吸収層３１０が飽和する場合、連続的なビープ音が生成され得る。バッテリーが、ある電圧レベルよりも下がる場合、異なる可聴周波数が生成され得るか、またはＬＥＤが作動され得る。様々な異なる警報信号が、医療専門家に特定の行動をとるように通知するために確立され得る。

【００６９】

ＲＦＩＤアンテナ３１２を使用して、マイクロポンプ３１６および制御電子回路に電気出力をもたらす。バッテリー３４２はまた、ＲＦＩＤアンテナ３１２からの出力を増大するために蓄積エネルギーをもたらすように使用してもよい。バッテリー３４２は、任意のサイズおよび形状としてもよく、および任意の材料、例えばポリマーとし得る。バッテリー３４２は、必要な電力全体またはその一部分をもたらし得る。バッテリー３４２は、ＲＦＩＤアンテナ３１２からの電力によって再充電し得る。

【００７０】

例示的一実施形態では、バッテリー３４２は、制御電子回路によって監視される電圧レベルセンサを備えて構成してもよく、および制御電子回路は、低電力レベルが検出されると警報を発生し得る。バッテリー３４２は、マイクロポンプ３１６に直接接続され得る。あるいは、バッテリー３４２は、バッテリー３４２からの電力を使用してマイクロポンプ３１６を駆動させる制御電子回路または１つまたは複数のプロセッサに接続され得る。制御電子回路は、連続的な変調電力、例えばパルス幅変調（ＰＷＭ）信号を使用して、マイクロポンプ３１６を駆動し得る。

【００７１】

シール層３２２は、減圧ドレッシング３０４の構成要素に掛けるかそうでなければ覆うために使用されるシール部材３２０に、接着されるまたは他の方法で接続される。シール層３２２は、患者の創傷の周りの表皮と真空シールを形成するのに十分に強力な医療グレードの接着材料または他のシール装置を含み得る。シール層３２２は、気液分離装置３３０または他の層の幾何学的なパラメータよりもわずかに大きい、アパーチャ３２３を有する帯状体としてもよく、シール部材３２０が患者の組織部位３０２の周りの表皮と接触するようにする。シール部材３２０は、流体、例えば空気および液体に対し不透過性である。

【００７２】

別の例示的実施形態では、シール部材３２０はダイバータ層３２６に接着してもよく、

およびダイバータ層３２６はシール部材３２０に接着して、上部ドレッシング部分および下部ドレッシング部分を形成する。上部ドレッシング部分は、シール部材３２０、マイクロポンプ３１６および関連の構成要素、気液分離装置３３０、第２の内部分配マニホールド３２８、およびダイバータ層３２６を含み得る。下部ドレッシング部分は、吸収層３１０、第１の内部分配マニホールド３２４、シール層３２２、およびインターフェース分配マニホールド３０８を含み得る。無線減圧ドレッシング３０４は、無線減圧ドレッシングが流体を最大容量吸収したら、下部ドレッシング部分を交換できるように構成し得る。上部ドレッシング部分は、下部ドレッシング部分の交換後に再使用してもよい。これにより、マイクロポンプ３１６を複数回使用することができるようになるが、ドレッシングの使い捨て部分は交換してもよい。別の例示的実施形態では、マイクロポンプ３１６、第１のプロセッサ３１４、およびＲＦＩＤアンテナ３１２は、再使用するためにドレッシングから取り除き、およびドレッシングの残りの層を交換してもよい。さらに別の例示的実施形態では、吸収層３１０のみを交換してもよい。さらに別の例示的実施形態では、吸収層３１０およびインターフェース分配マニホールド３０８のみを交換してもよい。

【００７３】

チャコールフィルタ３３２を無線減圧ドレッシング３０４に用いて、組織部位３０２によって生じかつ無線減圧ドレッシング３０４から広まった臭気を低減させてもよい。チャコールフィルタ３３２は、弁またはマイクロポンプ３１６からの他の排出用の通気口の上方に配置されて、マイクロポンプ３１６からの排気を統合減圧ドレッシング３０４から放出される前にろ過し得る。あるいは、チャコールフィルタ３３２は、マイクロポンプ３１６の上方または下方に構成および配置してもよいことを理解されたい。別の例示的実施形態では、チャコールフィルタを使用するのではなく、チャコールを、統合減圧ドレッシング３０４に用いられる異なる層のいずれかまたは全てに組み込んでもよい。

【００７４】

例示的一実施形態によれば、動作中、図９～１１の減圧システム３００は、組織部位３０２に近接させてインターフェース分配マニホールド３０８を配置することによって適用される。アパーチャ３２３がインターフェース分配マニホールド３０８の上側になるように、インターフェース分配マニホールド３０８の上側にシール層３２２を配置する。第１の内部分配マニホールド３２４は、第１のインターフェース分配マニホールド３０８に、およびおそらくシール層３２２の一部分に隣接して配置される。吸収層３１０は第１の内部分配マニホールド３２４に隣接して配置される。ダイバータ層３２６は、そのように示される構成要素の全てを覆って配置され得る。その後、第２の内部分配マニホールド３２８は、気液分離装置３３０と共に、ダイバータ層３２６の一部分に隣接して配置され得る。マイクロポンプ３１６、ＲＦＩＤアンテナ３１２、および第１のプロセッサ３１４が適用され得る。本明細書で述べた構成要素はまた、ドレッシング積層体として予め組み立てられ得る。

【００７５】

シール部材３２０を使用して、密閉空間３１８を形成するシールを生成する。ベースユニット３０６を使用して、既に述べたように、ＲＦＩＤアンテナ３１２にポンプ信号を送信し、ポンプ信号は第１のプロセッサ３１４によって受信され、かつマイクロポンプ３１６に電力を供給するために使用される。第１のプロセッサ３１４は、電力または１つ以上のバッテリー、例えば再充電可能なバッテリーを保持するために１つ以上のコンデンサをさらに含んでもよい。ポンプ信号は、マイクロポンプ３１６によって減圧が発生されるようにする。減圧は組織部位３０２に伝達されて、流体を除去するまたは減圧療法をもたらす。組織部位３０２から除去された流体は、減圧ドレッシング３０４内において吸収層３１０に伝達され、そこで、流体は保持されるかまたは実質的に保持される。図１２に関連して説明するように、圧力感知装置は無線減圧ドレッシング３０４の一部として含まれ、ベースユニット３０６に圧力メッセージ信号をもたらしてもよい。

【００７６】

ここで主に図１２を参照して、減圧システム３００の別の例示的実施形態を説明する。

既に述べたように、減圧システム３００は、無線減圧ドレッシング３０４およびベースユニット３０６を含む。図１２の減圧システム３００は、無線減圧ドレッシング３０４が含む構成要素数が少数であること、および無線減圧ドレッシング３０４が、第１のプロセッサ３１４に電気的に結合された圧力感知装置３４０を追加で含むことを除いて、図９～１１に示すシステムと類似している。さらに、任意選択的なバッテリー３４２が含まれる。バッテリー３４２は、ＲＦＩＤアンテナ３１２によってもたらされた電力を補い得るか、または主電源として使用されて、ＲＦＩＤアンテナ３１２によって再充電され得る。ＲＦＩＤアンテナ３１２は、ベースユニット３０６から電力を受信する。シール部材３２０は、取付装置３４６によって表皮３４４に固定されて示す。図９～１１で説明したドレッシングに含まれた構成要素には同じ参照符号を付し、ここでは必ずしもさらに説明をしない。

【００７７】

例示的実施形態によれば、動作中、図１２の減圧システム３００は、組織部位３０２に隣接してインターフェース分配マニホールド３０８をまず適用することによって使用され得る。吸収層３１０は、インターフェース分配マニホールド３０８と流体連通して配置され得る。気液分離装置３３０は吸収層３１０の上側に配置され得る。その後、ＲＦＩＤアンテナ３１２、圧力感知装置３４０、第１のプロセッサ３１４、マイクロポンプ３１６、およびバッテリー３４２が気液分離装置３３０上に配置される。あるいは、構成要素のいくつか、例えばマイクロポンプ３１６が、気液分離装置３３０に隣接し得る。シール部材３２０は、組織部位３０２の上側を覆って適用されて密閉空間３１８を形成し、かつ上述の構成要素を全て覆う。既に説明した構成要素は、全部または部分的に予め組み立てられ得る。ベースユニット３０６は、減圧ドレッシング３０４にポンプ信号またはポンプ作動信号を送信し、それによりマイクロポンプ３１６を作動させる。マイクロポンプ３１６は、密閉空間３１８から空気または他の流体を除去し、それにより、減圧による組織部位３０２の治療を開始する。

【００７８】

ベースユニット３０６からＲＦＩＤアンテナ３１２へポンプ作動信号またはポンプ信号を供給することに加え、ベースユニット３０６はまた、圧力問合せ信号を送信し得る。圧力問合せ信号を受信すると、ＲＦＩＤアンテナ３１２、第１のプロセッサ３１４、および圧力感知装置３４０が圧力メッセージ信号を発生させ、それが、ＲＦＩＤアンテナによってベースユニット３０６のＲＦＩＤリーダ（明示せず）に送信される。ベースユニット３０６はプロセッサ（明示せず）を含み、そのプロセッサは、圧力メッセージ信号を受信し、かつマイクロポンプ３１６を作動させるまたはその動作を停止させるポンプ制御信号を発生させ得る。減圧が所望の治療範囲内にあるとき、マイクロポンプ３１６は、動作が停止され得る。同様に、圧力が絶対尺度で大きすぎる場合、ベースユニット３０６は、より減圧をもたらすように、マイクロポンプ３１６を作動させるまたは継続させるポンプ信号を送信し得る。所望の圧力に達しない経過時間が十分すぎるほど過ぎたら、警報がベースユニット３０６によってトリガされ得る。無線減圧ドレッシング３０４はガルバニ電池（明示せず）を含んで、滲出液または他の体液が２つの電極を電気的に結合すると、フル表示メッセージ信号をもたらす。フル表示メッセージ信号は、ＲＦＩＤアンテナ３１２によってベースユニット３０６に送信され、ドレッシングが満杯であることを示す。

【００７９】

ここで主に図１３を参照して、無線減圧ポンプ４３０を含む減圧ドレッシング４００の別の例示的実施形態を説明する。減圧ドレッシング４００は分解図として示し、患者４０４の組織部位４０２、例えば創傷を覆う。減圧ドレッシング４００は、組織部位４０２に近接して配置されるインターフェース分配マニホールド４０６を含む。インターフェース分配マニホールド４０６は、任意のマニホールド材料、例えばＧｒａｎｕＦｏａｍ（登録商標）材、または既に説明した任意の他のマニホールド材料から形成され得る。

【００８０】

減圧ドレッシング４００は、下部ドレープまたはダイバータ４０８をさらに含む。下部

ドレープ４０８は、下側面（組織対面側面）に接着剤を有するポリエチレン材料とし、治療される組織部位４０２を取り囲んで患者４０４に付着し得る。下部ドレープ４０８は、アパーチャまたは穿孔を含み、インターフェース分配マニホールド４０６を通して組織部位４０２に減圧を伝えかつ組織部位４０２から創傷液（液体または気体）を引き出し得る。下部ドレープ４０８はまたシールリング４１０を含み、追加的な接着強度をもたらして、減圧を所望の治療レベルに維持し得る。最初はシールリング４１０を保護用剥離ライナー４１２が覆っている。下部ドレープ４０８が患者４０４に位置決めされる前に、保護用剥離ライナー４１２を下部ドレープ４０８の下側から取り外す。

【００８１】

減圧ドレッシング４００は、不織ファブリックとし得る吸収層４１４を含み、下部ドレープ４０８のアパーチャを通って引き込まれる創傷液を吸収する。吸収層４１４は、創傷液を吸収層４１４に逃がすおよび分配する２つのウィッキング層４１６と４１８との間に挟まれている。ウィッキング層４１６、４１８の高密度側は、吸収層４１４から外方に向いている。ウィッキング層４１６、４１８はそれらの間に吸収層４１４を挟み、流体貯蔵装置４２０を形成する。

【００８２】

減圧ドレッシング４００は、ポリエチレンで形成された無孔の閉鎖的バリアとし得る上部ドレープ４２２をさらに含む。上部ドレープ４２２の平滑側は、上部ウィッキング層４１６に対面している。上部ドレープ４２２は、アパーチャまたは開口部４２４を含む。アパーチャまたは開口部４２４は、吸収層４１４内に創傷液や滲出液を含ませるために液体から空気を分離する疎水性フィルタ４２６によって覆われ得る。疎水性フィルタ４２６は、同時に、疎水性フィルタ４２６に減圧が行われる結果、吸収層４１４からのガスの流れを可能にする。上部ドレープ４２２および疎水性フィルタ４２６は、流体貯蔵装置４２０を覆う減圧ドレッシング４００の最上層４２８を含む。剥離ライナー４１２を除く上述のドレッシングアセンブリの要素は全て、まとめて、減圧ドレッシング４００の「創傷ドレッシング」部分と呼ぶ。

【００８３】

減圧ドレッシング４００は、無線減圧ポンプ、またはポンプ部分４３０をさらに含む。ポンプ部分４３０は、上部ドレープ４２２の上部に位置決めされたマイクロポンプアセンブリ４３２を含み、疎水性フィルタ４２６、流体貯蔵装置４２０、およびインターフェース分配マニホールド４０６を通して空気を引き出す減圧をもたらす。マイクロポンプアセンブリ４３２は圧電ディスクポンプ４３４を含み、この圧電ディスクポンプは、予め定められた周波数で振動して、圧電ディスクポンプ４３４の入力側で所望の減圧を生成する。圧電ディスクポンプ４３４は、図１２のマイクロポンプ３１６に類似し得る。マイクロポンプアセンブリ４３２の圧電ディスクポンプ４３４は、上部ドレープ４２２の下側で組織部位４０２から吸収層４１４に引き込まれた液体が少しでも圧電ディスクポンプ４３４の入力ポートに入ると、動作しないとし得る。疎水性フィルタ４２６は、創傷液や滲出液がマイクロポンプアセンブリ４３２の圧電ディスクポンプ４３４に流入しないようにする。

【００８４】

減圧ドレッシング４００はまた、疎水性フィルタ４２６と圧電ディスクポンプ４３４の流入口との間に位置決めされたスペーサーリングまたはリングシール４３６を含み、マイクロポンプアセンブリ４３２の圧電ディスクポンプ４３４に空気の流れのための空洞をもたらし得る。マイクロポンプアセンブリ４３２は、第１の発泡体クッション４３８と第２の発泡体クッション４４０との間に挟まれ得る。マイクロポンプアセンブリ４３２、第１のクッション４３８、および第２のクッション４４０は、外側プライ４４２と内側プライ４４４との間に挟まれ、かつ上部ドレープ４２２に取り外し可能に取り付けられる単一の複合パッケージを形成する。外側プライ４４２は、マイクロポンプアセンブリ４３２の排出用の排出経路をもたらすアパーチャまたは穿孔４４６を含む。

【００８５】

圧電ディスクポンプ４３４または他のマイクロポンプは、第１のプロセッサ４４８およ

び他の制御電子回路によって制御され得る。圧電ディスクポンプ４３４は、第１のパワーユニット４５０および第２のパワーユニット４５２によって電力供給され得る。パワーユニット４５０、４５２はバッテリーとし得る。別の代替的な実施形態では、第１のパワーユニット４５０または第２のパワーユニット４５２は、第１のプロセッサ４４８および圧電ディスクポンプ４３４に電力を供給するＲＦＩＤアンテナを含み得る。

【００８６】

実施形態によれば、減圧によって組織部位を治療するシステムは、組織部位に近接して配置される減圧ドレッシング；および減圧ドレッシングに流体的に結合された無線減圧ポンプを含む。無線減圧ポンプは、ＲＦＩＤアンテナと、ＲＦＩＤアンテナに結合された第１のプロセッサと、第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置と、マイクロポンプ装置に流体的に結合された液溜めとを含む。システムは、ＲＦＩＤリーダを有するベースユニットをさらに含む。ＲＦＩＤリーダは、ＲＦＩＤアンテナに電力をもたらし、マイクロポンプ装置に電力供給を行うように構成される。システムは、第１のポンプシール部材および第２のポンプシール部材をさらに含み得る。第１のポンプシール部材および第２のポンプシール部材は、少なくとも部分的に結合されてポンプ用パウチを形成し、そこにマイクロポンプ装置が配置される。無線減圧ポンプは、ＲＦＩＤアンテナ以外の動力源がない状態で機能する。無線減圧ポンプは、組織部位における圧力を感知するために減圧ドレッシングおよび第１のプロセッサに流体的に結合された圧力感知装置をさらに含む。無線減圧ポンプは、第１のプロセッサに結合された圧力感知装置をさらに含む。ベースユニットは、ＲＦＩＤリーダに結合された第２のプロセッサをさらに含み、かつ、第２のプロセッサおよびＲＦＩＤリーダは、無線減圧ポンプの第１のプロセッサに圧力問合せ信号を送信しかつそれに応答して第１のプロセッサから圧力メッセージ信号を受信するように構成され得る。

【００８７】

前段落で説明したシステムに関して、無線減圧ポンプは、第１のプロセッサに結合された圧力感知装置をさらに含み得る。ベースユニットは、ＲＦＩＤリーダに結合された第２のプロセッサを含み得る。第２のプロセッサおよびＲＦＩＤリーダは、無線減圧ポンプの第１のプロセッサに圧力問合せ信号を送信しかつそれに応答して第１のプロセッサから圧力メッセージ信号を受信するように構成し得る。第１のプロセッサおよび圧力感知装置は、圧力問合せ信号に応答して圧力メッセージ信号を準備するように構成し得る。第１のプロセッサおよびＲＦＩＤアンテナは、圧力メッセージ信号を送信するように構成し得る。および、第２のプロセッサは、圧力メッセージ信号を受信し、制御信号を準備するように構成し得る。第２のプロセッサおよびＲＦＩＤは、無線減圧ポンプに制御信号を送信して、マイクロポンプ装置を作動または動作停止させる制御信号をもたらすように構成し得る。

【００８８】

前段落で説明したシステムに関して、無線減圧ポンプは、第１のプロセッサに結合された圧力感知装置をさらに含み得る。圧力感知装置は、圧力メッセージ信号を生成するように動作可能である。第１のプロセッサは、圧力メッセージ信号を受信しかつ制御信号を生成してマイクロポンプ装置を作動させるまたはその動作を停止させるように動作可能である。

【００８９】

前段落で説明したシステムの別の実施形態では、システムは、減圧ドレッシングおよび第１のプロセッサに流体的に結合されて組織部位における圧力を感知する圧力感知装置と；第１の分配マニホールドと、吸収層と、ダイバータ層と、ポンプシール部材と、第２のポンプシール部材とをさらに含み、第１の分配マニホールド、吸収層、およびダイバータ層が、ポンプシール部材および第２のポンプシール部材によって形成されるポンプ用パウチ内に配置され；マイクロポンプ装置が圧電ポンプを含む。減圧ドレッシングは、組織部位に近接して配置されるインターフェース分配マニホールドと、ドレッシングシール部材と、減圧インターフェースとを含む。一実施形態では、ＲＦＩＤアンテナは、ベースユニ

ットから５センチメートル未満のところにある。

【００９０】

別の例示的実施形態によれば、無線減圧ポンプは、第１のチャンバおよび第２のチャンバを形成する少なくとも１つの壁部材と；ＲＦＩＤアンテナと；ＲＦＩＤアンテナに結合された第１のプロセッサと；第１のプロセッサに結合されてそこから電力を受信しかつ減圧および正圧を発生させるマイクロポンプ装置とを含む。マイクロポンプ装置は、第１のチャンバに流体的に結合されてそこに正圧を排出する通気口と、第２のチャンバに流体的に結合されてそこに減圧を供給する流入口とを有する。ポンプは、第１のチャンバに流体的に結合された複数の膨張式支持部材と；第２のチャンバを含む液溜めとをさらに含む。ポンプは、第１のチャンバに流体的に結合された第１の圧力逃がし弁をさらに含み得る。第１の圧力逃がし弁は、第１の閾値圧力を上回る正圧を放出するように動作可能である。第１のチャンバおよび第２のチャンバは、ピラミッドの一部分の形状とし得る。ポンプは、ＲＦＩＤアンテナ以外の動力源がない状態で機能し得る。

【００９１】

別の例示的実施形態によれば、減圧によって患者の組織部位を治療するシステムの製造方法は、組織部位に近接して配置される減圧ドレッシングを提供するステップと、無線減圧ポンプを提供するステップとを含む。無線減圧ポンプは：ＲＦＩＤアンテナと、ＲＦＩＤアンテナに結合された第１のプロセッサと、第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置と、マイクロポンプ装置に流体的に結合された液溜めとを含む。この方法は、ＲＦＩＤリーダを有するベースユニットを提供するステップをさらに含む。ＲＦＩＤリーダは、ＲＦＩＤアンテナに電力をもたらし、マイクロポンプ装置に電力供給を行うように構成し得る。この製造方法は、第１のポンプシール部材および第２のポンプシール部材をさらに含み得る。第１のポンプシール部材および第２のポンプシールは、少なくとも部分的に結合されてポンプ用パウチを形成し、そこにマイクロポンプ装置が配置される。この製造方法は、無線減圧ポンプを減圧ドレッシングに流体的に結合する減圧導管を設けるステップをさらに含み得る。この製造方法は、圧力感知装置を提供するステップと、圧力感知装置を減圧ドレッシングに結合するステップとをさらに含む。

【００９２】

別の例示的実施形態によれば、減圧によって患者の組織部位を治療する方法は、組織部位に近接して減圧ドレッシングを配置するステップと、無線減圧ポンプを提供するステップとを含む。無線減圧ポンプは：ＲＦＩＤアンテナと、ＲＦＩＤアンテナに結合された第１のプロセッサと、第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置と、マイクロポンプ装置に流体的に結合された液溜めとを含む。この方法はまた、無線減圧ポンプを減圧ドレッシングに流体的に結合するステップと；ＲＦＩＤリーダおよび第２のプロセッサを有するベースユニットを提供するステップと；ベースユニットを作動させ、それにより、ＲＦＩＤリーダおよび第２のプロセッサが無線減圧ポンプに作動信号を送信して、無線減圧ポンプを作動させるステップとを含む。無線減圧ポンプは、第１のポンプシール部材および第２のポンプシール部材をさらに含み得る。第１のポンプシール部材および第２のポンプシールは、少なくとも部分的に結合されてポンプ用パウチを形成し、そこにマイクロポンプ装置が配置される。マイクロポンプ装置が必要とする電力は全て、ＲＦＩＤリーダによって供給され得る。この方法は、無線減圧ポンプのＲＦＩＤアンテナから５センチメートル以内にＲＦＩＤリーダを配置するステップをさらに含み得る。

【００９３】

前段落の方法に関して、無線減圧ポンプは、ＲＦＩＤアンテナ以外の動力源が設置されておらず、および無線減圧ポンプは：減圧ドレッシングおよび第１のプロセッサに流体的に結合されて組織部位における圧力を感知する圧力感知装置と、第１の分配マニホールドと、吸収層と、ダイバータ層とをさらに含む。第１の分配マニホールド、吸収層、およびダイバータ層は、第１のポンプシール部材および第２のポンプシール部材によって形成さ

れたポンプ用パウチ内に配置され得る。マイクロポンプ装置は圧電ポンプとし得る。減圧ドレッシングは：組織部位に近接して配置されるインターフェース分配マニホールドと、ドレッシングシール部材と、減圧インターフェースとを含み得る。

【００９４】

別の例示的実施形態によれば、減圧によって組織部位を治療する減圧システムは：組織部位に近接して配置されるインターフェース分配マニホールドと、インターフェース分配マニホールドから流体を受け取って保持する吸収部材と、ＲＦＩＤアンテナと、ＲＦＩＤアンテナに結合された第１のプロセッサと、第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置であって、流入口および排出口を有するマイクロポンプ装置と、組織部位を覆って密閉空間を形成する第１のシール部材と、マイクロポンプ装置の排出口を外部に流体的に結合する通気口とを含む無線減圧ドレッシングを含む。マイクロポンプは、密閉空間に流体的に結合され、そこに減圧を供給する。システムは、ＲＦＩＤリーダを含むベースユニットをさらに含む。ベースユニットは、ポンプ信号を無線減圧ドレッシングに供給して、マイクロポンプ装置を付勢するように動作可能である。システムは、第１のプロセッサに結合された無線減圧ドレッシングに第１の圧力センサをさらに含む。第１のプロセッサおよびＲＦＩＤアンテナは、圧力問合せ信号を受信しかつ圧力メッセージ信号を生成してベースユニットに送信するように動作可能である。

【００９５】

前段落で説明したシステムの別の実施形態では、システムは、第１のプロセッサに結合される無線減圧ドレッシングの第１の圧力センサをさらに含み得る。第１のプロセッサおよびＲＦＩＤアンテナは、圧力問合せ信号を受信しかつ圧力メッセージ信号を生成してベースユニットに送信するように動作可能である。ベースユニットは第２のプロセッサをさらに含む。第２のプロセッサは、圧力メッセージ信号を受信しかつポンプ制御信号を生成するように動作可能である。

【００９６】

前段落で説明したシステムの別の実施形態では、システムは、第１のプロセッサに結合される無線減圧ドレッシングに第１の圧力センサをさらに含んでもよく、および第１のプロセッサは、第１の圧力センサから圧力メッセージ信号を受信しかつ制御信号を生成してマイクロポンプ装置を制御するように構成される。前段落で説明したシステムの別の実施形態では、無線減圧ポンプは、ＲＦＩＤアンテナ以外の動力源がない状態で機能し得る。さらに、減圧ドレッシングに供給される減圧のみが、マイクロポンプ装置からのものとし得る。このシステムは、導管またはワイヤが無線減圧ドレッシングに結合されないように組み立てられ得る。

【００９７】

別の例示的実施形態によれば、減圧によって患者の組織部位を治療する方法は、組織部位に近接して無線減圧ドレッシングを配置するステップを含む。無線減圧ドレッシングは、組織部位に近接して配置されるインターフェース分配マニホールドと、インターフェース分配マニホールドから流体を受け取って保持する吸収部材と、ＲＦＩＤアンテナと、ＲＦＩＤアンテナに結合された第１のプロセッサと、第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させ、かつ流入口および排出口を有するマイクロポンプ装置と、組織部位を覆いかつ密閉空間を形成する第１のシール部材と、排出口を外部に流体的に結合する通気口とを含む。この方法は、ＲＦＩＤリーダを含むベースユニットを提供するステップであって、ベースユニットが、無線減圧ドレッシングにポンプ信号を供給してマイクロポンプ装置を付勢するように構成されているステップと；ベースユニットを作動させて無線減圧ドレッシングにポンプ信号を供給するステップとをさらに含む。

【００９８】

別の例示的実施形態によれば、無線減圧ポンプであって、無線減圧ポンプが、ＲＦＩＤアンテナと；ＲＦＩＤアンテナに結合された第１のプロセッサと；第１のプロセッサに結合されてそこから電力を受信しかつ減圧を発生させるマイクロポンプ装置とを含む。無線

減圧ポンプは、マイクロポンプ装置に流体的に結合された液溜めをさらに含み得る。無線減圧ポンプはまた、第１のポンプシール部材および第２のポンプシール部材をさらに含んでもよく、第１のポンプシール部材および第２のポンプシールは少なくとも部分的に結合してポンプ用パウチを形成し、そこにマイクロポンプ装置が配置される。無線減圧ポンプは、ＲＦＩＤアンテナ以外の動力源がない状態で機能し得る。無線減圧ポンプは、減圧ドレッシングおよび第１のプロセッサに流体的に結合されて組織部位における圧力を感知する圧力感知装置をさらに含み得る。

【００９９】

前段落の無線減圧ポンプに関して、ポンプは、第１のプロセッサに結合された圧力感知装置と、ＲＦＩＤリーダに結合された第２のプロセッサを含むベースユニットとをさらに含み得る。第２のプロセッサおよびＲＦＩＤリーダは、無線減圧ポンプの第１のプロセッサに圧力問合せ信号を送信しかつそれに応答して第１のプロセッサから圧力メッセージ信号を受信するように構成され得る。

【０１００】

前段落の無線減圧ポンプに関して、無線減圧ポンプは、第１のプロセッサに結合された圧力感知装置と、ＲＦＩＤリーダに結合された第２のプロセッサを含むベースユニットとをさらに含み得る。第２のプロセッサおよびＲＦＩＤリーダは、無線減圧ポンプの第１のプロセッサに圧力問合せ信号を送信しかつそれに応答して第１のプロセッサから圧力メッセージ信号を受信するように構成され得る。第１のプロセッサおよび圧力感知装置は、圧力問合せ信号に応答して圧力メッセージ信号を準備するように構成される。第１のプロセッサおよびＲＦＩＤアンテナは、圧力メッセージ信号を送信するように構成される。第２のプロセッサは、圧力メッセージ信号を受信し、制御信号を準備するように構成され、および第２のプロセッサおよびＲＦＩＤは、無線減圧ポンプに制御信号を送信し、マイクロポンプ装置を作動または動作停止させるための制御信号をもたらすように構成される。無線減圧ポンプは、第１のプロセッサに結合された圧力感知装置をさらに含んでもよく；圧力感知装置は、圧力メッセージ信号を生成するように動作可能であり、および第１のプロセッサは、圧力メッセージ信号を受信しかつ制御信号を生成してマイクロポンプ装置を作動させるまたはその動作を停止させるように動作可能である。

【０１０１】

一般論として、患者の組織部位に減圧をもたらすシステム、方法、およびドレッシングは、減圧ポンプに無線で電力をもたらすことを含むと説明される。一例では、ＲＦＩＤアンテナを使用して、導管によって減圧ドレッシングに流体的に結合された減圧ポンプに電力供給する。別の例では、減圧ドレッシングは、マイクロポンプと、マイクロポンプに電力供給するのに使用されるＲＦＩＤアンテナとを含む。本明細書では他のシステム、方法、および装置が説明される。

【０１０２】

本発明およびその利点を、いくつかの例示的非限定的な実施形態に照らして説明したが、添付の特許請求の範囲によって定義された本発明の範囲から逸脱せずに、様々な変更、代用、交換、および修正をなすことができることを理解されたい。任意の一実施形態に関連して説明された任意の特徴はまた、任意の他の実施形態にも適用可能であることを理解されたい。

【０１０３】

上述の利益および利点は、一実施形態に関連し得ること、またはいくつかの実施形態に関連し得ることを理解されたい。「１つの」品目への言及は、１つ以上のそれら品目を指すことをさらに理解されたい。

【０１０４】

本明細書で説明した方法のステップは、任意の好適な順序で、または適切な場合には同時に実施し得る。

【０１０５】

適切な場合には、上述の実施形態のいずれかの態様を、説明の任意の他の実施形態の態

様と組み合わせて、類似のまたは異なる特性を有しかつ同じまたは異なる問題に対処する別の例を形成する。

【０１０６】

好ましい実施形態の上述の説明は例示にすぎず、当業者は様々な修正をなし得ることを理解されたい。上述の明細書、例およびデータは、本発明の例示的な実施形態の構造および使用の完全な説明を提供する。本発明の様々な実施形態を、ある程度詳細に、または１つ以上の個々の実施形態を参照して上記で説明したが、当業者は、特許請求の範囲から逸脱せずに、開示の実施形態に多数の修正をなすことができる。

【図１】

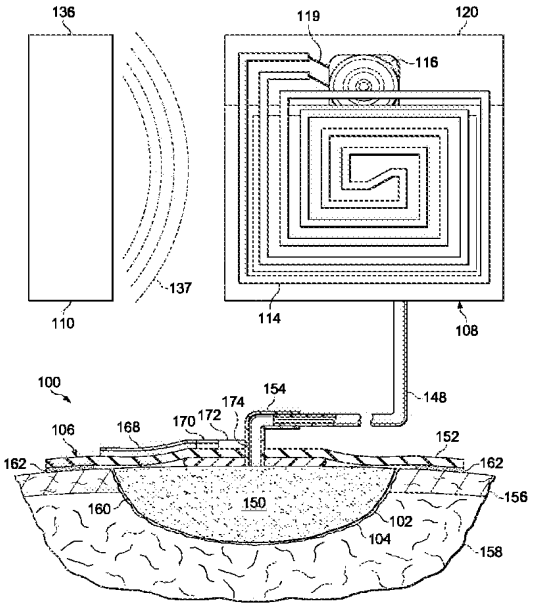

FIG. 1

【図２】

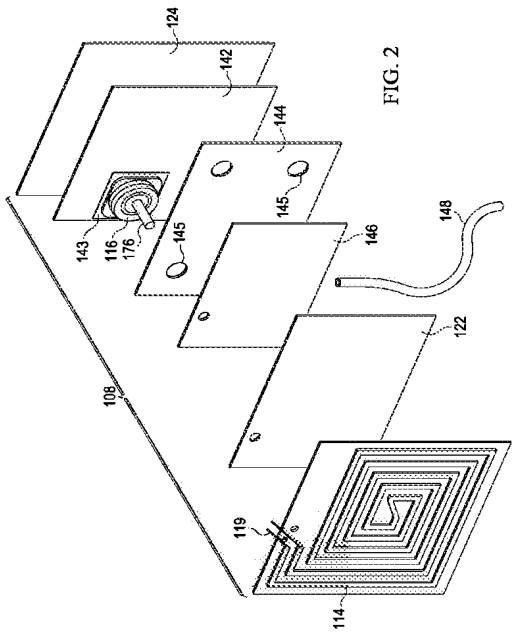

FIG. 2

【図３】

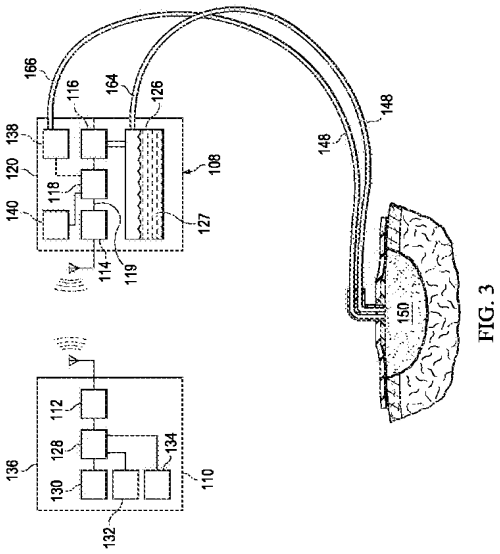

FIG. 3

【図４】

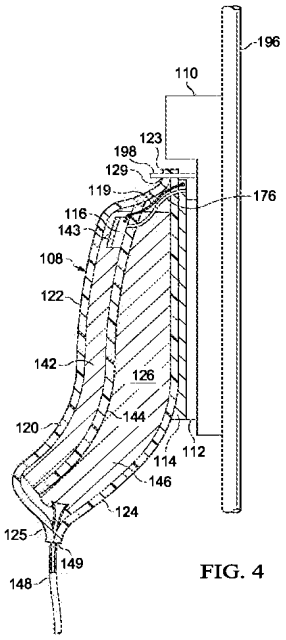

FIG. 4

【図５】

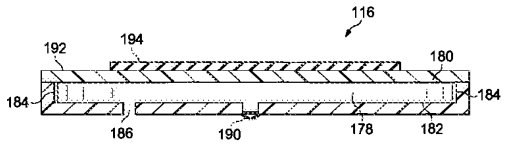

FIG. 5

【図６】

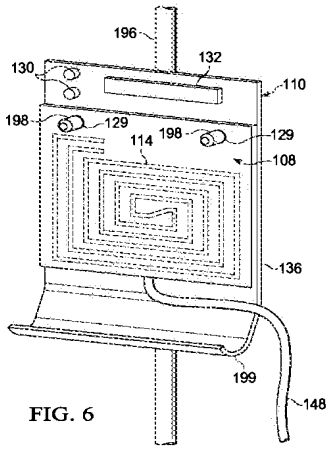

FIG. 6

【図７】

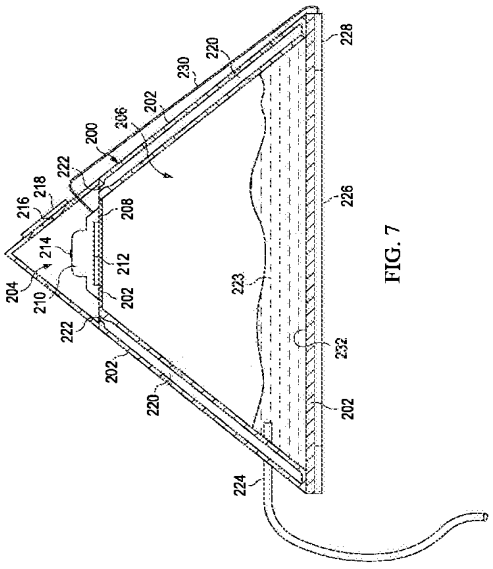

FIG. 7

【図８】

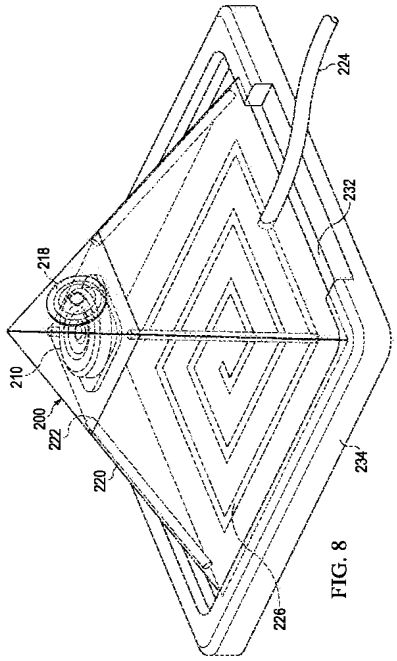

FIG. 8

【図９】

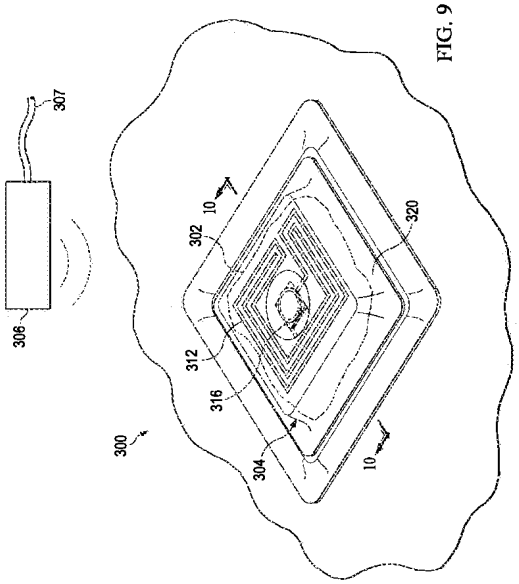

FIG. 9

【図１０】

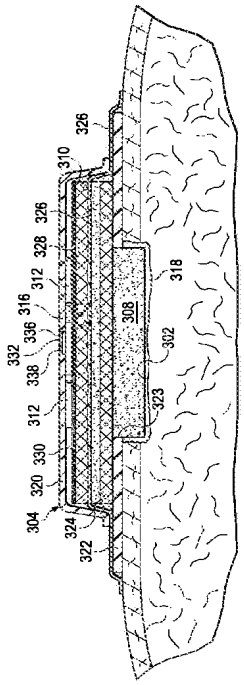

FIG. 10

【図１１】

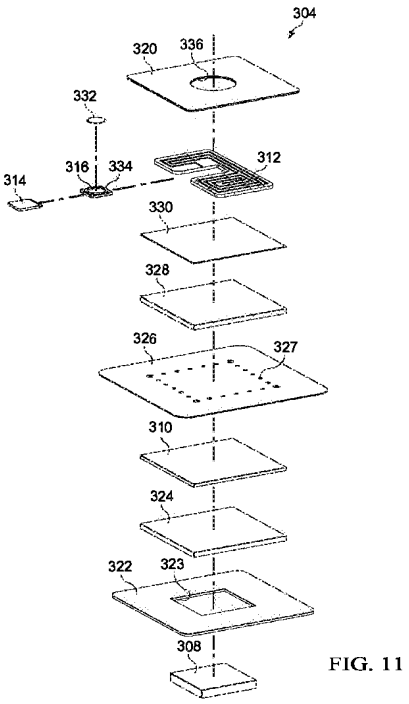

FIG. 11

【図１２】

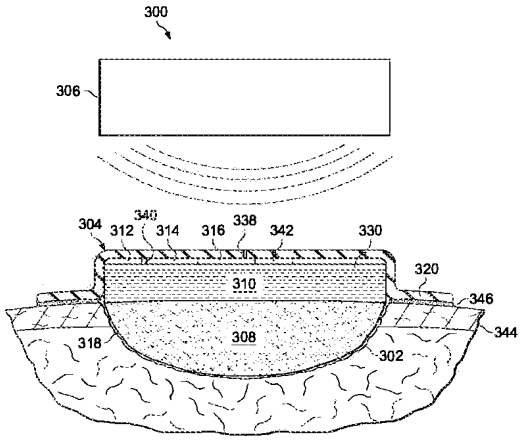

FIG. 12

【図１３】

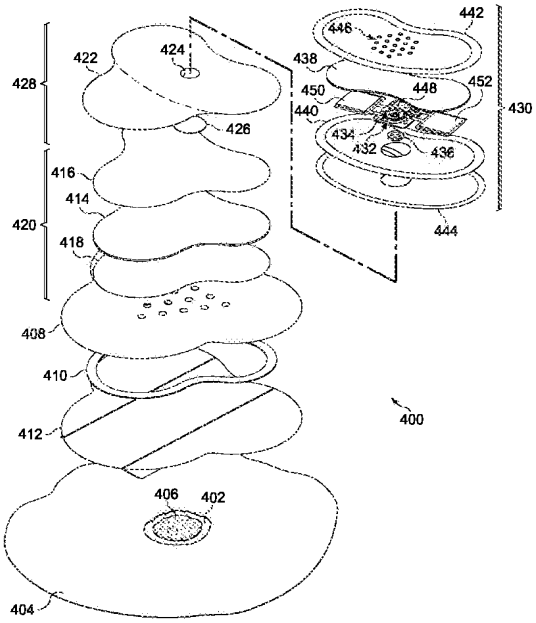

FIG. 13

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/044187

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F13/02 A61B17/08 A61M1/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	KR 2002 0032508 A (COSMOGENOME INC [KR]) 3 May 2002 (2002-05-03)	29-33,36
A	abstract; figure 3	1-28,34, 35,37-39
A	WO 2008/051924 A2 (ABBOTT DIABETES CARE INC [US]; STAFFORD GARY ASHLEY [US]) 2 May 2008 (2008-05-02) paragraphs [0006] - [0011]; figures 1-3	1-39
A	US 2009/227969 A1 (JAEB JONATHAN PAUL [US] ET AL) 10 September 2009 (2009-09-10) paragraphs [0006] - [0015]; figures 1-20	1-39

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 September 2011	24/10/2011

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Mangin, Sophie

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2011/044187

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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WO 2008051924 A2	02-05-2008	AU 2007309070 A1	02-05-2008
		CA 2667305 A1	02-05-2008
		CN 101528282 A	09-09-2009
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		WO 2009111657 A2	11-09-2009

Form PCT/ISA/210 (patent family annex) (April 2005)

フロントページの続き

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(32)優先日 平成23年2月22日(2011.2.22)
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(81)指定国 AP(BW,GH,GM,KE,LR,LS,MW,MZ,NA,SD,SL,SZ,TZ,UG,ZM,ZW),EA(AM,AZ,BY,KG,KZ,MD,RU,TJ,TM),EP(AL,AT,BE,BG,CH,CY,CZ,DE,DK,EE,ES,FI,FR,GB,GR,HR,HU,IE,IS,IT,LT,LU,LV,MC,MK,MT,NL,NO,PL,PT,RO,RS,SE,SI,SK,SM,TR),OA(BF,BJ,CF,CG,CI,CM,GA,GN,GQ,GW,ML,MR,NE,SN,TD,TG),AE,AG,AL,AM,AO,AT,AU,AZ,BA,BB,BG,BH,BR,BW,BY,BZ,CA,CH,CL,CN,CO,CR,CU,CZ,DE,DK,DM,DO,DZ,EC,EE,EG,ES,FI,GB,GD,GE,GH,GM,GT,HN,HR,HU,ID,IL,IN,IS,JP,KE,KG,KM,KN,KP,KR,KZ,LA,LC,LK,LR,LS,LT,LU,LY,MA,MD,ME,MG,MK,MN,MW,MX,MY,MZ,NA,NG,NI,NO,NZ,OM,PE,PG,PH,PL,PT,RO,RS,RU,SC,SD,SE,SG,SK,SL,SM,ST,SV,SY,TH,TJ,TM,TN,TR,TT,TZ,UA,UG,US,UZ,VC,VN,ZA,ZM,ZW

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Ｆターム(参考) 4C066 AA01 AA07 BB05 CC01 DD02
4C167 AA39 CC04 CC06 GG02 GG03 GG05 GG11 GG12 GG36 GG43

Patents JP 2013-545519 A

Pressure reducing system, dressing and method using wireless pump

Abstract

translated from Japanese

Systems, methods, and dressings are provided for providing reduced pressure to a patient's tissue site, including wirelessly powering a reduced pressure pump. In one example, an RFID antenna is used to power a vacuum pump that is fluidly coupled by a conduit to a vacuum dressing. In another example, a reduced pressure dressing incorporates a micropump and an RFID antenna that is used to power the micropump. Other systems, methods, and apparatus are provided.
[Selection] Figure 1

Images (13)

FIG. 5

Classifications

- A61M1/0023 Suction drainage systems

View 22 more classifications

JP2013545519A

Japan

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Other languages: Japanese

Inventor: クルサード、リチャード、グニエル、ジョン、ロック、クリストファー、ブライアン、ストークス、ベンジャミン

Current Assignee : KCI Licensing Inc

Worldwide applications

2011 US ~~WS~~ CN WO AU ~~JP~~ CA ~~SN~~ EP ~~CA~~ AU EP JP WO TW TW
2013 US

Application JP2013536610A events

2010-10-27 Priority to US40719410P
2011-07-15 Application filed by KCI Licensing Inc
2013-12-26 Publication of JP2013545519A
2014-08-14 Publication of JP2013545519A5
2016-01-13 Application granted
2016-01-13 Publication of JP5843296B2
Status Expired - Fee Related
2031-07-15 Anticipated expiration

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External links: Espacenet, Global Dossier, Discuss

Claims (39)

Hide Dependent
translated from Japanese

In a system for treating a tissue site by decompression, the system includes:
A reduced pressure dressing positioned proximate to the tissue site,
A wireless vacuum pump fluidly coupled to the vacuum dressing.
RFID antenna,
A first processor coupled to the RFID antenna;
A micropump device coupled to the first processor for receiving power therefrom and generating a depressurization; and a wireless depressurization pump including a reservoir fluidly coupled to the micropump device;
A base unit having an RFID reader;
Including
The system, wherein the RFID reader is configured to provide power to the RFID antenna and provide power to the micropump device. The system of claim 1, further comprising a first pump seal member and a second pump seal member, wherein the first pump seal member and the second pump seal member are at least partially coupled. A system characterized in that a pump pouch is formed, on which the micropump device is arranged. 3. The system according to claim 1, wherein a power source other than the RFID antenna is not installed in the wireless decompression pump. 4. The system according to any one of claims 1-3, wherein the wireless vacuum pump is fluidly coupled to the vacuum dressing and the first processor to sense pressure at the tissue site. The system further comprising. The system according to any one of claims 1 to 3,
The wireless vacuum pump further comprises a pressure sensing device coupled to the first processor;
The base unit includes a second processor coupled to the RFID reader, and the second processor and the RFID reader transmit a pressure inquiry signal to the first processor of the wireless decompression pump and to it A system configured to receive a pressure message signal from the first processor in response. The system according to any one of claims 1 to 3,
The wireless vacuum pump further comprises a pressure sensing device coupled to the first processor;
The base unit includes a second processor coupled to the RFID reader;
The second processor and the RFID reader are configured to send a pressure inquiry signal to the first processor of the wireless decompression pump and receive a pressure message signal from the first processor in response thereto;
The first processor and the pressure sensing device are configured to prepare the pressure message signal in response to the pressure inquiry signal;
The first processor and the RFID antenna are configured to transmit the pressure message signal, and the second processor is configured to receive the pressure message signal

and prepare a control signal, and The system, wherein the second processor and RFID are configured to send the control signal to the wireless vacuum pump to provide a control signal to activate or deactivate the micropump device. The system according to any one of claims 1 to 3,
The wireless vacuum pump further comprises a pressure sensing device coupled to the first processor;
The pressure sensing device is operable to generate a pressure message signal, and the first processor receives the pressure message signal and generates a control signal to activate the micropump device or A system characterized in that it is operable to stop operation. The system of claim 1, wherein
A pressure sensing device fluidly coupled to the reduced pressure dressing and the first processor to sense pressure at the tissue site;
A first distribution manifold;
An absorbent layer,
The diverter layer,
A pump seal member;
A second pump seal member,
The first distribution manifold, the absorbent layer, and the diverter layer are disposed within a pump pouch formed by a pump seal member and a second pump seal member;
The micropump device includes a piezoelectric pump;
Said reduced pressure dressing.
An interface distribution manifold disposed proximate to the tissue site;
A system comprising, a dressing seal member; and a vacuum interface; and wherein the RFID antenna is less than 5 centimeters from the base unit. In wireless vacuum pump:
At least one wall member forming a first chamber and a second chamber;
An RFID antenna and a first processor coupled to the RFID antenna;
A micropump device coupled to the first processor for receiving power therefrom and generating reduced pressure and positive pressure,
A plurality of inflatable support members fluidly coupled to the first chamber;
A liquid reservoir containing the second chamber;
The micropump device is fluidly coupled to the first chamber and exhausts positive pressure thereto, and an inlet fluidly coupled to the second chamber and supplies reduced pressure thereto. A wireless decompression pump, comprising: 10. The wireless vacuum pump according to claim 9, further comprising a first pressure relief valve fluidly coupled to the first chamber, wherein the first pressure relief valve is a positive pressure above a first threshold pressure. A wireless vacuum pump, characterized in that it is operable to release pressure. The wireless decompression pump according to claim 9 or 10, wherein the first chamber and the second chamber are in the shape of a part of a pyramid. The wireless decompression pump according to any one of claims 9 and 10 to 11, wherein a power source other than the RFID antenna is not installed. In a method of manufacturing a system for treating a tissue site of a patient by decompression, the method comprises
Providing a reduced pressure dressing positioned proximate to the tissue site;
Providing a wireless vacuum pump, the wireless vacuum pump comprising:
RFID antenna,
A first processor coupled to the RFID antenna;
A micropump device coupled to the first processor for receiving power therefrom and generating a reduced pressure; and a reservoir fluidly coupled to the micropump device;
Providing a base unit having an RFID reader,
A method wherein the RFID reader is configured to provide power to the RFID antenna and provide power to the micropump device. 14. The manufacturing method according to claim 13, further comprising a first pump seal member and a second pump seal member, wherein the first pump seal member and the second pump seal are at least partially coupled, Forming a pumping pouch in which the micropump device is arranged. 14. The method of claim 13, further comprising providing a vacuum conduit that fluidly couples the wireless vacuum pump to the vacuum dressing. 14. The method of claim 13, further comprising providing a pressure sensing device and coupling the pressure sensing device to the reduced pressure dressing. In a method of treating a tissue site of a patient by decompression,
Placing a reduced pressure dressing proximate to the tissue site;
Providing a wireless vacuum pump, the wireless vacuum pump comprising,
RFID antenna,
A first processor coupled to the RFID antenna;
A micropump device coupled to the first processor for receiving power therefrom and generating a reduced pressure; and a reservoir fluidly coupled to the micropump device;
Fluidly coupling the wireless vacuum pump to the vacuum dressing;
Providing a base unit having an RFID reader and a second processor;
Activating the base unit, whereby the RFID reader and the second processor send an activation signal to the wireless decompression pump to activate the wireless decompression pump. Method. 18. The method of claim 17, wherein the wireless vacuum pump is:
A first pump seal member;
A second pump seal member, wherein the first pump seal member and the second pump seal are at least partially combined to form a pump pouch in which the micropump device is disposed; And a pump seal member 19. A method according to claim 17 or 18, characterized in that all the power required by the micropump device is supplied by the RFID reader. 20. A method according to any of claims 17 or 18 to 19, further comprising the step of positioning the RFID reader within 5 centimeters of the RFID antenna of the wireless vacuum pump. The method of claim 18, wherein
No power source other than the RFID antenna is installed in the wireless decompression pump.
The wireless vacuum pump is:
A pressure sensing device fluidly coupled to the reduced pressure dressing and the first processor to sense pressure at the tissue site,
A first distribution manifold,
Absorption layer,
Further including a diverter layer,
The first distribution manifold, the absorbent layer, and the diverter layer are disposed in the pump pouch formed by the first pump seal member and the second pump seal member, and the micropump device Comprises a piezoelectric pump; and the vacuum dressing comprises:
An interface distribution manifold disposed proximate to the tissue site;
A method comprising: a dressing seal member; and a vacuum interface. In a decompression system for treating a tissue site by decompression, the decompression system includes:
Wireless decompression dressing:
An interface distribution manifold disposed proximate to the tissue site;
An absorbent member for receiving and holding fluid from the interface distribution manifold;
RFID antenna,
A first processor coupled to the RFID antenna;
A micropump device coupled to the first processor for receiving power therefrom and generating a reduced pressure, the micropump device having an inlet and an outlet,
A first seal member that covers the tissue site and forms a sealed space; and a vent hole that fluidly couples the discharge port of the micropump device to the outside.
A wireless reduced pressure dressing, wherein the micropump is fluidly coupled to the enclosed space and supplies reduced pressure thereto,
A decompression system comprising a base unit including an RFID reader, the base unit operable to supply a pump signal to a wireless decompression dressing to energize the micropump device. 23. The system of claim 22, further comprising a first pressure sensor in the wireless decompression dressing, wherein the first pressure sensor is coupled to

the first processor, and the first processor and the RFID antenna are: A system operable to receive a pressure inquiry signal and generate a pressure message signal and send it to the base unit. 23. The system of claim 22, further comprising a first pressure sensor in the wireless decompression dressing, wherein the first pressure sensor is coupled to the first processor, and the first processor and the RFID antenna are: Operable to receive a pressure interrogation signal and generate a pressure message signal and send it to the base unit, the base unit further comprising a second processor, wherein the second processor comprises the pressure A system operable to receive a message signal and generate a pump control signal. 23. The system of claim 22, further comprising a first pressure sensor in the wireless decompression dressing, the first pressure sensor coupled to the first processor, and the first processor comprising the first processor. A system configured to receive a pressure message signal from a plurality of pressure sensors and generate a control signal to control the micropump device. 23. The system of claim 22, wherein the wireless decompression pump is not provided with a power source other than the RFID antenna, and only the decompression supplied to the decompression dressing is from the micropump device. A system characterized by being. 27. A system according to any one of claims 22 or 23 to 26, wherein no conduit or wire is coupled to the wireless vacuum dressing. In a method of treating a tissue site of a patient by decompression,

Placing a wireless vacuum dressing proximate to the tissue site, the wireless vacuum dressing comprising:

An interface distribution manifold disposed proximate to the tissue site,

An absorbent member for receiving and holding fluid from the interface distribution manifold,

RFID antenna,

A first processor coupled to the RFID antenna;

A micropump device coupled to the first processor for receiving power therefrom and generating a vacuum and having an inlet and an outlet;

A first sealing member that covers the tissue site and forms a sealed space, and a vent that fluidly couples the outlet to the outside,

Providing a base unit including an RFID reader, wherein the base unit is configured to provide a pump signal to the wireless decompression dressing to energize the micropump device;

Activating the base unit to provide the pump signal to the wireless decompression dressing. In wireless decompression pump,

With an RFID antenna;

A first processor coupled to the RFID antenna;

And a micropump device coupled to the first processor for receiving power therefrom and generating a vacuum. 30. The wireless vacuum pump according to claim 29, further comprising a reservoir fluidly coupled to the micropump device. The wireless decompression pump according to claim 29 or 30,

A first pump seal member;

A second pump seal member, wherein the first pump seal member and the second pump seal are at least partially joined to form a pump pouch in which the micropump device is disposed. And a pump seal member. The wireless decompression pump according to any one of claims 29 to 31, wherein a power source other than the RFID antenna is not installed. 33. The wireless vacuum pump according to any one of claims 29 or 30 to 32, further comprising a pressure sensing device fluidly coupled to the vacuum dressing and the first processor to sense pressure at the tissue site. A wireless decompression pump characterized by that. A wireless decompression pump according to any one of claims 29 or 30 to 32.

The wireless vacuum pump further includes a pressure sensing device coupled to the first processor;

A base unit including a second processor coupled to the RFID reader; and the second processor and the RFID reader transmit a pressure interrogation signal to the first processor of the wireless vacuum pump and to it A wireless decompression pump configured to receive a pressure message signal from the first processor in response. A wireless decompression pump according to any one of claims 29 or 30 to 32,

The wireless vacuum pump further comprises a pressure sensing device coupled to the first processor;

A base unit including a second processor coupled to the RFID reader;

The second processor and the RFID reader are configured to send a pressure inquiry signal to the first processor of the wireless decompression pump and receive a pressure message signal from the first processor in response thereto;

The first processor and the pressure sensing device are configured to prepare the pressure message signal in response to the pressure inquiry signal;

The first processor and the RFID antenna are configured to transmit the pressure message signal, and the second processor is configured to receive the pressure message signal and prepare a control signal, and The wireless decompression, wherein the second processor and RFID are configured to send the control signal to the wireless decompression pump to provide a control signal to activate or deactivate the micropump device pump. A wireless decompression pump according to any one of claims 29 or 30 to 32,

The wireless vacuum pump further comprises a pressure sensing device coupled to the first processor;

The pressure sensing device is operable to generate a pressure message signal, and the first processor receives the pressure message signal and generates a control signal to activate the micropump device, or A wireless decompression pump, characterized in that it is operable to stop its operation. 33. The wireless vacuum pump according to any one of claims 29 or 30 to 32, wherein the wireless vacuum pump is:

At least one wall member forming a first chamber and a second chamber;

A first pressure relief valve fluidly coupled to the first chamber, the first pressure relief valve operable to release a positive pressure above a first threshold pressure;

A plurality of inflatable support members fluidly coupled to the first chamber,

The micropump device is fluidly coupled to the first chamber and has a vent for supplying positive pressure thereto, and a fluid fluidly coupled to the second chamber and for supplying reduced pressure thereto. And an entrance

The wireless pressure reducing pump, wherein the liquid reservoir includes the second chamber. 31. The wireless vacuum pump according to claim 29 or 30, wherein the wireless vacuum pump is:

A first chamber and a second chamber in the form of a portion of a pyramid;

A first pressure relief valve fluidly coupled to the first chamber, the first pressure relief valve operable to release a positive pressure above a first threshold pressure;

A plurality of inflatable support members fluidly coupled to the first chamber;

Further including

The micropump device has a vent fluidly coupled to the first chamber;

The wireless pressure reducing pump, wherein the liquid reservoir includes the second chamber. The wireless decompression pump according to claim 29 or 30,

No power source other than the RFID antenna is installed in the wireless decompression pump;

The wireless vacuum pump is:

A pressure sensing device fluidly coupled to the reduced pressure dressing and the first processor to sense pressure at the tissue site;

A first distribution manifold,

Absorption layer,

Further including a diverter layer,

The first distribution manifold, the absorbent layer, and the diverter layer are disposed within the pump pouch formed by the first pump seal member and the second pump seal member;

The micropump device includes a piezoelectric pump;

Said reduced pressure dressing:

An interface distribution manifold disposed proximate to the tissue site,

Including a dressing seal member, and a vacuum interface;

A wireless decompression pump, wherein the RFID antenna is less than about 5 centimeters from the base unit; and a decompression conduit fluidly couples a decompression interface to the wireless decompression pump

Description translated from Japanese

CROSS REFERENCE TO RELATED APPLICATIONS The present invention is incorporated under 35 USC §119 (e), US Provisional Patent Application No. 61 / 407,194, filed Oct. 27, 2010 ("System and Methods For Electrical The Presentation Of Excluded Int. Reduced-Pressure Dressing "(incorporated herein for all purposes) [VAC. 0975PRO1]; US Provisional Patent Application No. 61 / 418,730, filed Dec. 1, 2010 (" Systems and Methods for Electrically "). Detecting the Presence of Update in Dressing " (incorporated herein by reference for all purposes) [VAC 0975PRO2]; US Provisional Patent Application No. 61 / 445,383, filed Feb. 22, 2011 ("Interactive, Wireless Reduced-Pressures, Methods, and Systems" (incorporated herein by reference for all purposes)). [VAC. 0999PRO]; and U.S. Provisional Patent Application No. 61 / 445,338, filed February 22, 2011 ("Reduce-Pressure Systems, Dressings, and Methods Employing a Wireless Pump"). Insist on the benefits of [VAC.1000PRO].

The present disclosure relates generally to treatment systems, and more particularly, but not exclusively, to systems, dressings, and methods that include wirelessly powering a pump that applies a vacuum to a tissue site.

In clinical trials and practice, it has been shown to enhance and accelerate the growth of new tissue at a tissue site by providing a reduced pressure in proximity to the tissue site. Although there are many applications of this phenomenon, reducing the pressure has been quite successful in treating wounds. This treatment (often referred to in the medical community as "negative pressure closure therapy", "decompression therapy", or "vacuum therapy") offers a number of benefits, including rapid healing and granulation tissue Acceleration of formation may be included. In general, when reduced pressure is applied to an open wound, it is applied to the tissue through a porous pad or other manifold device. The porous pad distributes the vacuum to the tissue and delivers fluid drawn from the tissue. Reduced pressure can also be used to remove fluid from a body sinus such as the abdominal cavity.

According to an exemplary embodiment, a system for treating a tissue site with reduced pressure includes a reduced pressure dressing disposed proximate to the tissue site and a wireless reduced pressure pump fluidly coupled to the reduced pressure dressing. A wireless decompression pump includes a radio frequency identification (RFID) antenna, a first processor coupled to the RFID antenna, a micropump device coupled to the processor for receiving power and generating decompression. , A first pump seal member, a liquid reservoir, and a second pump seal member. The first pump seal member and the second pump seal are at least partially joined to form a pump pouch in which the micropump is disposed. The system further includes a base unit having an RFID reader. The RFID reader is configured to provide power to the RFID antenna and power the micropump.

According to another exemplary embodiment, a method of manufacturing a system for treating a patient tissue site by decompression provides a decompression dressing disposed proximate to the tissue site, and provides a wireless decompression pump, including. The wireless decompression pump includes an RFID antenna, a first processor coupled to the RFID antenna, a micropump device coupled to the first processor for receiving power and generating decompression, and a first pump seal. A member, a reservoir, and a second pump seal member. The first pump seal member and the second pump seal are at least partially joined to form a pump pouch in which the micropump is disposed. The method may further include providing a vacuum supply conduit to fluidly couple the wireless vacuum pump to the vacuum dressing. The method further includes providing a base unit having an RFID reader. The RFID reader is configured to provide power to the RFID antenna and power the micropump.

According to another exemplary embodiment, a method of treating a patient tissue site by decompression includes placing a decompression dressing proximate the tissue site and providing a wireless decompression pump. The wireless decompression pump includes an RFID antenna, a first processor coupled to the RFID antenna, a micropump device coupled to the processor for receiving power and generating decompression, a first pump seal member, A liquid reservoir and a second pump seal member are included. The first pump seal member and the second pump seal are at least partially joined to form a pump pouch in which the micropump is disposed. The method includes fluidly coupling a wireless vacuum pump to a vacuum dressing, providing a base unit having an RFID reader and a second processor, activating the base unit, thereby providing the RFID reader and the second The processor further sends an activation signal to the wireless vacuum pump to activate the wireless vacuum pump.

According to another exemplary embodiment, a reduced pressure system for treating a tissue site with reduced pressure includes a reduced pressure dressing. The reduced pressure dressing includes a first distribution manifold disposed proximate to a tissue site, an absorbent layer for receiving and retaining fluid from the first distribution manifold, an RFID antenna, and a first processor coupled to the RFID antenna. And a micropump coupled to the first processor for receiving power therefrom and generating a decompression. The micropump has an inlet and an outlet. The system also includes a first seal member that forms a sealed space over the tissue site and the top of the micropump, and a vent that fluidly couples the micropump outlet to the outside. The system further includes a base unit that includes an RFID reader. The base unit is operable to supply a pump signal to the decompression dressing to energize the micropump.

According to another exemplary embodiment, a method of treating a patient tissue site by decompression includes placing a wireless decompression dressing proximate to the tissue site. The wireless decompression dressing includes a first distribution manifold disposed proximate to the tissue site, an absorbent layer that receives and retains fluid from the first distribution manifold, an RFID antenna, and a first coupled to the RFID antenna. A processor and a micropump coupled to the first processor for receiving power therefrom and generating a vacuum. The micropump includes an inlet and an outlet, a first seal member that covers the tissue site and the upper side of the micropump to form a sealed space, and a vent that fluidly couples the outlet of the micropump to the outside. Have. The method further includes providing a base unit that includes an RFID reader. The base unit is operable to provide a pump signal to the wireless vacuum dressing to energize the micropump. The method also includes activating the base unit to provide a pump signal to the wireless vacuum dressing.

Other features and advantages of the exemplary embodiments will become apparent with reference to the drawings and detailed description that follow.

FIG. 1 is a schematic diagram illustrating, in cross section, a portion of an exemplary embodiment of a system for treating a tissue site with reduced pressure. 2 is a schematic exploded perspective view of an exemplary embodiment of a wireless vacuum pump used as part of the system of FIG. FIG. 3 is a schematic diagram illustrating a portion of the system of FIG. FIG. 4 is a schematic partial cross-sectional view of an exemplary embodiment of a wireless vacuum pump. FIG. 5 is a schematic cross-sectional view of an exemplary embodiment of a micropump device for use as part of a system for treating a tissue site with reduced pressure as in FIG. FIG. 6 is a schematic perspective view of an exemplary embodiment of a wireless vacuum pump. FIG. 7 is a schematic cross-sectional view of another exemplary embodiment of a wireless vacuum pump. FIG. 8 is a schematic perspective view of the wireless decompression pump of FIG. FIG. 9 is a schematic diagram illustrating, in perspective view, a portion of an exemplary embodiment of a reduced pressure system that treats a tissue site with reduced pressure. 10 is a schematic cross-sectional view of the vacuum dressing shown in FIG. 9 taken along line 10-10. FIG. 11 is a schematic exploded perspective view of the vacuum dressing of FIGS. FIG. 12 is a schematic cross-sectional view of an exemplary embodiment of a system for treating a tissue site with reduced pressure. FIG. 13 is a schematic exploded perspective view of another exemplary embodiment of a vacuum dressing.

In the following detailed description of exemplary, non-limiting embodiments, reference is made to the accompanying drawings that form a part hereof. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and other embodiments may be used without departing from the spirit or scope of the invention. It is understood that mechanical, electrical and chemical changes can be made on the logical structure. To avoid details not necessary to enable one skilled in the art to implement the embodiments described herein, the description may omit certain information known to those skilled in the art. The following detailed description is not to be taken in a limiting sense, and the scope of the exemplary embodiments is defined only by the appended claims.

Exemplary embodiments herein use radio frequency authentication (RFID) or enhanced type radio frequency authentication (RFID) technology to power a micropump device in a vacuum dressing. Including. RFID traditionally uses an RFID tag or label on the target and an RFID reader that activates the RFID tag and reads signals therefrom. One common example is a price tag. Most RFID tags include an integrated circuit that stores and processes information, a modulator, and a demodulator.

RFID tags can be passive tags, active RFID tags, and passive tags with batteries. In general, passive tags do not use batteries and do not transmit information unless activated by an RFID reader. An active tag has an on-board battery and can transmit autonomously (ie, not energized by an RFID reader). Generally, a passive tag with a battery is equipped with a small battery that is activated by the presence of an RFID reader. To enhance the performance of the RFID tag, a microcontroller and sensor may be incorporated into the reduced pressure dressing. RFID tags, microcontrollers and sensors allow for sensing functions and optional computer functions. In addition, RFID tags and microcontrollers partially or fully power the micropump.

In one exemplary embodiment, the high performance RFID technology is a WISP (Wireless Identification and Sensing Platform) device. WISP, similar to RFID tags (or labels), includes using an RFID reader to power and read the WISP device. The WISP device obtains power from the radio signal emitted by the RFID reader and performs a sensing function (and optionally performs a computer function). The WISP device transmits a wireless signal comprising information to the RFID reader. The WISP device receives power from the RFID reader. A WISP device has a tag or antenna to obtain energy and a microcontroller (or processor) that can perform various tasks, such as a sampling sensor. The WISP device reports data to the RFID reader. In one exemplary embodiment, a WISP device includes an integrated circuit with a power harvesting circuit, a demodulator, a modulator, a microcontroller, a sensor, and includes one or more capacitors to store energy. But you can. One form of WISP technology was developed by Intel Research Seattle (www.seattle.intell-research.net/wisp/). As used herein, RFID devices also include WISP devices.

Referring now to the drawings, and initially to FIGS. 1-5, an exemplary embodiment of a system 100 for treating a tissue site 102, eg, a wound 104, or cavity by reduced pressure will be described. The system 100 includes a base unit 110 having a reduced pressure dressing 106 disposed proximate to a tissue site 102, a wireless reduced pressure pump 108 fluidly coupled to the reduced pressure dressing 106, and an RFID reader 112. The wireless decompression pump 108 includes a first RFID antenna 114 and a micropump device 116. The RFID reader 112 is configured to generate and transmit a pump signal that provides power to the first RFID antenna 114. Power is supplied to the micropump device 116 by the pump signal received by the first RFID antenna 114. Powering the micropump device 116 from a distance provides a number of potential benefits. These benefits can include ease of application. Further, the wireless vacuum pump 108 can be a built-in disposable unit. It should be noted that there are some differences between the drawings to illustrate some of the potential variations of the illustrated system 100.

System 100 may be used with a variety of different types of tissue sites 102. The tissue site 102 can be any human, animal, or other, including bone tissue, adipose tissue, muscle tissue, skin tissue, vascular tissue, connective tissue, cartilage, tendon, ligament, body sinus, or any other tissue It can be the body tissue of any organism. Treatment of the tissue site 102 may include removal of fluids such as exudates and ascites.

The wireless decompression pump 108 includes a first RFID antenna 114 that is coupled to the first processor 118 by a conductor 119. The first processor 118 is coupled to the micropump device 116, i.e. the micropump, and receives power. The first processor 118 may be incorporated into the micropump device 116. The first processor 118 and the micropump device 116 may be disposed within the pump pouch 120.

The pump pouch 120 can be formed to couple the first pump seal member 122 to the second pump seal member 124. The pump pouch 120 may also be formed by other techniques, such as casting the pump pouch 120 from a polymer. At least a portion of the pump pouch 120 includes a reservoir 126 that receives and retains fluid 127 from the tissue site 102. The micropump device 116 can be a piezoelectric pump, a peristaltic pump, or other small pump that produces a vacuum with minimal power requirements. The first processor 118 is operable to receive a pressure message signal from the pressure sensing device 138. In response to receiving the pressure message signal, the first processor 118 generates a control signal to activate or deactivate the micropump device 116. The pressure sensing device 138 may be a transducer or a simple switch that is activated when sufficient vacuum is present.

Referring primarily to FIG. 3, the base unit 110 includes a second processor 128 coupled to the RFID reader 112. A control panel 130 (eg, a user interface), a first display 132, and a power source 134 (eg, a battery or electrical connection) may also be coupled to the second processor 128. Base unit 110 may include a base housing 136. The second processor 128 and RFID reader 112 are configured to transmit a signal 137, such as a pump signal or a pressure interrogation signal, to the first RFID antenna 114.

The first RFID antenna 114 of the vacuum pump 108 is coupled to the first processor 118 by a conductor 119 or by wireless coupling. The first processor 118 is coupled to the micropump device 116 to supply power to and control the micropump device 116. A first power supply 140 may be included to provide additional power to the first processor 118. A pressure sensing device 138 may be coupled to the first processor 118. Pressure sensing device 138 is fluidly coupled to pressure sensing lumen 166 (ie, air passage 174 or interface distribution manifold 150) to sense the pressure therein. Micropump device 116 is fluidly coupled to reservoir 126. Reservoir 126 receives and holds fluid 127 from vacuum lumen 164, ie, interface distribution manifold 150.

The pump signal transmitted by the base unit 110 is received by the first RFID antenna 114 and energizes the micropump device 116 to produce a reduced pressure. The pressure inquiry signal is transmitted by the second processor 128 and the RFID reader 112 to the first processor 118 of the wireless vacuum pump 108. In response, the first processor 118 and the pressure sensing device 138 of the wireless decompression pump 108 send a pressure message signal to the base unit 110 indicating the pressure that the decompression dressing 106 is experiencing.

The second processor 128 is configured to receive a pressure message signal from the wireless vacuum pump 108 and prepare a control signal. The second processor 128 and RFID reader 112 are configured to send a control signal to the wireless vacuum pump 108 to activate or deactivate the micropump device 116. In another exemplary embodiment, as described above, the first processor 118 receives the pressure message signal from the pressure sensing device 138 and generates a control signal to activate or deactivate the micropump device 116. It is possible to operate.

Referring now primarily to FIGS. 2 and 4, the wireless vacuum pump 108 generates a vacuum that is supplied to the tissue site 102. The wireless vacuum pump 108 receives and holds fluid from the tissue site 102. Depressurization generally refers to a pressure that does not reach ambient pressure at the tissue site being treated. In most cases, this reduced pressure does not reach the air pressure where the patient is. Alternatively, the reduced pressure can be less than the hydrostatic pressure at the tissue site. Unless otherwise specified, the pressure values listed herein are gauge pressures. The reduced pressure supplied can be constant or variable (patterned or random) and can be supplied continuously or intermittently. Consistent with the use herein, unless otherwise specified, an increase in vacuum or vacuum generally refers to a relative decrease in absolute pressure.

The wireless vacuum pump 108 provides vacuum for the system 100. The wireless vacuum pump 108 can include a first distribution manifold 142, a diverter layer 144, and an absorption layer 146. A vent 176 is used to fluidly couple the exhaust path from the micropump device 116 to the exterior of the wireless vacuum pump 108. The first distribution manifold 142 serves to distribute the reduced pressure generated by the micropump device 116. An air liquid separator 143, for example, a hydrophobic filter, is disposed between the micropump device 116 and the first distribution manifold 142 to prevent liquid from entering the micropump device 116. Absorbent layer 146 serves to receive and retain fluid from tissue site 102. The absorbent layer 146 can be made of any material that can absorb liquids such as exudates from the tissue site 102.

The absorbent layer 146 can be made from superabsorbent fibers. Superabsorbent fibers may hold liquids or bind to liquids with physical or chemical changes to the fibers. In one non-limiting example, superabsorbent fibers can be obtained from Technical Absorbents, Ltd. Super Absorbent Fiber (SAF) material from (Grimsby, United Kingdom) may be included. Absorbent layer 146 may be a sheet or mat of fibrous material in which the fibers absorb liquid from tissue site 102. The structure of the absorbent layer 146 containing fibers may be woven or non-woven. The fibers of the absorbent layer 146 may become a gel when in contact with the liquid, thereby

trapping the liquid. The spaces or voids between the fibers may allow the reduced pressure applied to the absorbent layer 146 to be transmitted through and through the absorbent layer 146. In one exemplary embodiment, the fiber density of the fibers in the absorbent layer 146 may be about 1 4 grams per millimeter.

The diverter layer 144 is disposed adjacent to the absorbent layer 146 and the first distribution manifold 142. The diverter layer 144 is formed from a liquid impervious material, but includes a plurality of apertures 145. A plurality of apertures 145 transmit the reduced pressure from the micropump device 116 through the diverter layer 144 to a desired location. The diverter layer 144 helps to control the pattern of vacuum when applied to the absorbent layer 146. The reduced pressure is distributed to the diverter layer 144 by the first distribution manifold 142. Apertures 145 are arranged in a pattern that reduces the pressure on multiple portions of absorbent layer 146 and continues to transmit the reduced pressure to tissue site 102 as absorbent layer 146 absorbs more fluid from tissue site 102. The performance of the absorption layer 146 can be improved.

The plurality of apertures 145 may be positioned in a pattern that surrounds the peripheral portion of the diverter layer 144 away from the center of the diverter layer 144 so that decompression is performed at the absorbent layer 146 away from the central region of the absorbent layer 146. . The diverter layer 144 works with the first distribution manifold 142 to ensure that the absorption capacity and absorption efficiency of the absorbent layer 146 is increased compared to the absorbent layer 146 not used with the diverter layer 144. By providing good liquid distribution throughout the absorbent layer 146, the diverter layer 144 also increases the effective capacity of the wireless vacuum pump 108 and increases the treatment time.

The diverter layer 144 can be made from any material that enhances the vacuum transfer capacity and storage capacity of the adjacent absorbent layer. For example, the diverter layer 144 may be made of a material that is substantially impermeable to liquids and gases and that diverts the reduced pressure flow through the aperture 145. Alternatively or additionally, the material from which the diverter layer 144 is made may have a predetermined moisture transfer rate, which is consistent with gas permeability. In either example, the diverter layer 144 may still include a pattern of apertures that transmit a greater amount of liquid or gas than is possible with an apertureless gas permeable material. However, it should be noted that the permeability of the diverter layer 144 to gas rather than liquid increases the transfer rate of vacuum through the dressing, but still allows the liquid flow to be directed around or near the diverter layer 144.

The first distribution manifold 142, the diverter layer 144, and the absorbent layer 146 can be disposed within the pump pouch 120. The wireless vacuum pump 108 may also include a pressure sensing device 138 that is fluidly coupled to the vacuum dressing 106 and communicates with the first processor 118 for pressure sensing. The decompression conduit 148 supplies fluid from the decompression dressing 106 to the wireless decompression pump 108. In one exemplary embodiment, the vacuum conduit 148 is disposed directly on the absorbent layer 146. In another exemplary embodiment, an interface (not shown) fluidly couples the vacuum conduit 148 and the absorbent layer 146.

Referring now primarily to FIGS. 1 and 3, the reduced pressure dressing 106 is disposed at the tissue site 102. The tissue site 102 can be, for example, the wound 104 through the epidermis 156 to the subcutaneous tissue 158, or any other tissue site. The reduced pressure dressing 106 can be any device that provides reduced pressure to the tissue site 102 and receives fluid from the tissue site 102. For example, the vacuum dressing 106 may be formed by a foam member, a structure with a plurality of defined channels, a suction tube, or other device. In one exemplary embodiment, the reduced pressure dressing 106 may include an interface distribution manifold 150, a dressing seal member 152, and a reduced pressure interface 154 disposed proximate to the tissue site 102.

A manifold generally refers to an object or structure that is provided to assist in reducing pressure, supplying fluid, or removing fluid therefrom. The interface distribution manifold 150 generally includes a plurality of channels or flow paths that allow fluid to be distributed to and removed from the tissue site 102 around the interface distribution manifold 150. In one exemplary embodiment, the flow paths or flow paths are interconnected to improve the distribution of fluid provided to or removed from the tissue site 102. The interface distribution manifold 150 may also be a biocompatible material that can be placed in contact with the tissue site 102 and allow the reduced pressure to be distributed to the tissue site 102. Examples of interface distribution manifolds may include, but are not limited to: devices having structural elements arranged to form a flow path, eg, cellular foam, open cell foam, porous tissue Aggregates, liquids, gels, and foams that contain or cure the flow path; foams; gauze; felt mats; or any other material suitable for a particular biological application.

In one embodiment, the interface distribution manifold 150 is a porous foam and includes a plurality of open cells or pores that serve as flow paths. The porous foam may be an open cell reticulated foam made of polyurethane, such as GranuFoam® material available from Kinetic Concepts, Incorporated (San Antonio, Texas). In some cases, interface distribution manifold 150 may also be used to distribute fluids such as drugs, antimicrobial agents, growth factors, and various solutions to tissue site 102. Other layers such as absorbent material, wicking material, hydrophobic material, and hydrophilic material may also be included in or on the interface distribution manifold 150.

In one exemplary embodiment, all or a portion of the interface distribution manifold 150 may be composed of a bioresorbable material that may remain on the patient's body after use of the reduced pressure dressing 106. Suitable bioresorbable materials can include, but are not limited to, polymer blends of polylactic acid (PLA) and polyglycolic acid (PGA). The polymer blend can also include, but is not limited to, polycarbonate, polyfumarate, and coupler lactone. The interface distribution manifold 150 may further serve as a scaffold for new cell growth, or the interface distribution manifold 150 and scaffold material may be used together to promote cell growth. A scaffold is an object or structure used to enhance or promote cell growth or tissue formation, eg, a three-dimensional porous structure that provides a template for cell growth. Illustrative examples of scaffold materials include calcium phosphate, collagen, PLA / PGA, coral hydroxyapatite, carbonate, or processed allograft material.

The interface distribution manifold 150 is covered by a dressing seal member 152. The dressing seal member 152 may be any material that provides a fluid seal. A fluid seal is a suitable seal to maintain the reduced pressure provided by a particular reduced pressure source or associated subsystem at the desired site. The dressing seal member 152 may be, for example, an impermeable or semi-permeable elastomeric material. Elastomeric materials have elastomeric properties. Generally refers to a polymer material having rubber-like properties. More specifically, most elastomers have an ultimate elongation of more than 100% and considerable elasticity. The elasticity of a material refers to the ability of the material to recover from elastic deformation. Examples of elastomers include, but are not limited to, natural rubber, polyisoprene, styrene butadiene rubber, chloroprene rubber, polybutadiene, nitrile rubber, butyl rubber, ethylene propylene rubber, ethylene propylene diene monomer, chlorosulfonated polyethylene, polysulfide rubber , Polyurethane (PU), EVA film, co-polyester, and silicone. Additional examples of dressing seal member materials include silicone drapes, 3M Tegaderm® drapes, polyurethane (PU) drapes available from Avery Dennison Corporation (Pasadena, Calif). The dressing seal member 152 may form a sealed space 160 that covers the upper side of the tissue site 102 and may include the micropump device 116 therein.

The attachment device 162 may be used to hold the dressing seal member 152 to the patient's epidermis 156 or another layer, such as a gasket or additional seal member. The attachment device 162 can take many forms. For example, the attachment device 162 may be a medically acceptable pressure sensitive adhesive that extends around or all around the dressing seal member 152 or covers the epidermis 156 on the patient facing side. Covering at least a portion of

A vacuum interface 154 may be used to provide fluid communication between the vacuum conduit 148 and the enclosed space 160 of the vacuum dressing 106. The reduced pressure can be supplied through the reduced pressure conduit 148 to the reduced pressure interface 154 and then to the enclosed space 160. In one exemplary embodiment, the vacuum interface 154 is a T.D. available from KCI (San Antonio, Texas). R. A. C. (Registered trademark) Pad or Sensa T. R. A. C. (Registered trademark) Pad. The decompression conduit 148 may include a decompression lumen 164 and a pressure sensing lumen 166 formed as an integral conduit as shown in FIG. 1 or separately formed as shown in FIG.

In the exemplary embodiment shown in FIG. 1, pressure sensing capability may be added to the reduced pressure dressing 106 to function in addition to or instead of the pressure sensing device 138. The reduced pressure dressing 106 may include a second RFID antenna 168, a third processor 170, and a second pressure sensing device 172. The third processor 170 is coupled to the second RFID antenna 168 and the second pressure sensing device 172. An air passage 174 provides fluid communication between the enclosed space 160 and the second pressure sensing device 172. Third processor 170 and second pressure sensing device 172 are operable to receive a pressure interrogation signal from base unit 110 and respond with a pressure message signal indicative of the pressure in enclosed space 160.

In one exemplary embodiment, the wireless vacuum pump 108 is a wireless passive (ie, no battery) device. As such, the wireless decompression pump 108 is not provided with a power source other than the power supplied by the first RFID antenna 114. In some embodiments, the wireless vacuum pump 108 may include a capacitor for storing electrical energy. In another exemplary embodiment, a first power supply 140 as shown in FIG. 3 may be provided to increase the power supplied by the first RFID antenna 114 or to operate the micropump device 116. . The first power supply 140 may be recharged with power from the first RFID antenna 114.

The micropump device 116 may take many forms, such as a piezoelectric pump, a peristaltic pump, or other small pump. Referring now primarily to FIG. 5, an exemplary embodiment of a micropump device 116 suitable for use as an aspect of the wireless vacuum pump 108 will be described. Micropump device 116 includes a cavity 178 defined by a first end wall 180, a second end wall 182, and an annular side wall 184. The cavity 178 may be substantially circular in shape, but other shapes such as an ellipse are possible. In an exemplary embodiment, the cavity 178 may hold about 10 ml of fluid, or may hold more or less fluid.

Cavity 178 includes a nozzle-like inlet 186, which may or may not be valved. The cavity 178 may also have a valved outlet 190. The first end wall 180 may be a disk 192. On the disk 192 is an actuator 194, such as a piezoelectric disk, a magnetostrictor, or a solenoid actuator. Actuator 194 is electrically coupled to a drive circuit, which is controlled by the processor. The drive circuit applies an alternating electrical signal to the actuator 194 to induce vibration in the disk 192. The frequency of vibration can be adjusted to match the natural frequency of the chamber. Piezoelectric discs can be tuned to be less than 1 mm thick and to operate above 500 Hz, above 10 kHz, or above 20 kHz. In operation, the actuator 194 may vibrate in a direction substantially perpendicular to the plane of the cavity 178 as shown, thereby creating a radial pressure oscillation in the fluid in the cavity 178. One or more micropump devices 116 may be used in parallel or in series.

In one exemplary embodiment, micropump device 116 has a substantially cylindrical shape with fluid in cavity 178 and surrounded by first end wall 180, second end wall 182, and side wall 184. At least two apertures, such as an inlet 186 and an outlet 190 are formed through the walls 180, 182, 184 that define the cavity 178. The cavity 178 has a radius r and a height h, and $r / h > 1.2$ and $h^2 / r > 4 \times 10^{-10}$ m. The actuator 194, which is a piezoelectric disk, causes an oscillating motion in a direction substantially perpendicular to the plane of the first end wall 180 and the second end wall 182 on one of the end walls 180, 182. The axial vibration of the end walls 180, 182 causes the cavity 178 to generate a radial vibration of fluid pressure and allows pumping to cause a vacuum. The micropump device 116 produces an acoustic resonance in the cavity 178, like an acoustic pump. Inlet 186 is used to draw fluid and outlet 190 is coupled to a vent, such as vent 176 in FIG. Other micropump devices may be used. The micropump device 116 is disclosed in U.S. Patent Application Publication No. 2009/024185 (U.S. Patent Application No. 12 / 398,904; filed on March 5, 2009) ("Dressing and Method for Applying Reduced Pressure To and Collecting And." "Storing Fluid from Tissue Site"). This document is incorporated herein for all purposes

Referring now primarily to FIGS. 1-3, according to an exemplary embodiment, the reduced pressure dressing 106 is applied to the tissue site 102 during operation of the system 100. In particular, interface distribution manifold 150 is positioned proximate to tissue site 102. Thereafter, the interface distribution manifold 150 and the tissue site 102 are covered by a dressing seal member 152 to create a sealed space 160. The attachment device 162 on the patient facing side of the dressing seal member 152 may help provide a fluid seal to a portion of the patient's epidermis 156. If the decompression interface 154 is not yet installed, the decompression interface may be applied, for example, by making a small aperture cut in the dressing seal member 152 and securing the decompression interface 154 over or through the aperture or hole .

A wireless vacuum pump 108 is then provided and fluidly coupled to the vacuum interface 154 by a vacuum conduit 148. The wireless decompression pump 108 is positioned so that the first RFID antenna 114 is disposed within the operating range of the base unit 110. In an exemplary embodiment, the first RFID antenna 114 is located within a few millimeters from the RFID reader 112 of the base unit 110. In another exemplary embodiment, the first RFID antenna 114 may be located 10 meters away from the RFID reader 112. Any distance within a given range can easily be used.

Thereafter, the user operates the base unit 110. The base unit 110 transmits a pump signal 137 to the wireless decompression pump 108. The pump signal is received by the first RFID antenna 114 and the energy of the pump signal is supplied to the first processor 118. The first processor 118 supplies energy to the micropump device 116. The micropump 116 creates a vacuum that is fed to a sump 126 that is fluidly coupled to a vacuum conduit 148. Therefore, reduced pressure is supplied to the reduced pressure dressing 106 through the reduced pressure conduit 148. Fluid from the tissue site 102 flows through the interface distribution manifold 150, the vacuum interface 154, and the vacuum conduit 148 to the sump 126.

The pressure at the tissue site 102 may be monitored directly or indirectly using a pressure sensing device, such as the pressure sensing device 138 of FIG. 3 or the second pressure sensing device 172 of FIG. In the first illustrative example, the second processor 128 and RFID reader 112 of the base unit 110 send a pressure inquiry signal to the wireless vacuum pump 108 separately from or in conjunction with the pump signal. In response to the pressure interrogation signal, the first processor 118 and pressure sensing device 138 may prepare a pressure message signal and communicate pressure measurements at the tissue site. The pressure message signal is then used for further processing by the first processor 118 to generate a pump control signal that activates or deactivates the micropump 116 when it may be needed. Alternatively or additionally, the first processor 118 may send a pressure message signal to the RFID reader 112 via the first RFID antenna 114. The pressure message signal is provided to the second processor 128 after reaching the RFID reader 112. Using the pressure message signal, the second processor 128 prepares a pump control signal, which is sent by the RFID reader 112 to the wireless vacuum pump 108 to deactivate or deactivate the micropump 116 as needed. Operate.

After a suitable time interval, an alarm signal is generated by the base unit 110 or the wireless decompression pump 108 if the pressure remains outside the desired operating range. The alarm may be a separate audible device, a visual alarm, or the micropump 116 may function at a different frequency range, such as a low frequency, to generate audible noise for the alarm.

In a second exemplary approach, the reduced pressure dressing 106 includes a second RFID antenna 168 coupled to a third processor 170 that is coupled to a second pressure sensing device 172. . The second pressure sensing device 172 receives the pressure in the sealed space 160 via the ventilation path 174. The base unit 110 transmits a pressure inquiry signal to the second RFID antenna 168. In response, the second pressure sensing device 172 and the third processor 170 generate a pressure message signal that is transmitted by the second RFID antenna 168 to the base unit 110. As described above, the base unit 110 then generates a pump control signal that is sent to the wireless vacuum pump 108 to activate or deactivate the micropump 116. Alternatively, the third processor 170 may estimate the pressure and prepare a pump control signal as part of the feedback or control loop

An exemplary embodiment of the wireless vacuum pump 108 will now be described primarily with reference to FIGS. 4 and 6. In this exemplary embodiment, the wireless vacuum pump 108 may be a self-contained disposable pouch design that can be removably secured to the base unit 110 on the pole 196. As already described, the pump pouch 120 is formed by the first pump seal member 122 and the second pump seal member 124. The outer side of the pump pouch 120 may include a first flange 123 and a second flange 125. The pump pouch 120 can be divided or partitioned into multiple compartments if desired. For example, one compartment (not explicitly shown) may be formed with the micropump 116 in the compartment, and another compartment may be formed including the absorbent layer 146.

The flanges 123, 125 in the exemplary embodiment of the pump pouch 120 may be formed by welding, bonding, or otherwise attaching portions of the first pump seal member 122 and the second pump seal member 124. The first flange 123 may include one or more apertures 129 for receiving one or more posts 198. The post 198 fixes the pump pouch 120 adjacent to the base unit 110. The decompression conduit 148 may enter through an aperture 149 in the second flange 125 and has a coupling that provides a sealed interference fit or provides a sealed connection. Other connections may be used.

As best seen in FIG. 4, the first RFID antenna 114 may be placed closest to the base unit 110 such that the first RFID antenna 114 is directly adjacent to the RFID reader 112 of the base unit 110. In one non-limiting example, the first RFID antenna 114 is positioned 2 millimeters or 1 millimeter (1 mm) or closer from the RFID reader 112. The RFID reader 112 and the first RFID antenna 114 can be substantially adapted and aligned. In another exemplary embodiment, as proposed in FIG. 1, the wireless decompression pump 108 is a post 198 with the first RFID antenna 114 facing outwardly toward a remotely located base unit 110. Can be attached to. For example, the base unit 110 may be located in a central hub area, where the wireless vacuum pump 108 is monitored and powered using the base unit 110, which may be 10 meters or more away.

Referring now primarily to FIG. 6, the base unit 110 may include a control panel 130 and one or more displays 132. The base unit 110 may include a base housing or base body 136. Base housing or body 136 may include a shelf portion 199 that may provide physical support to a portion of wireless vacuum pump 108 when wireless vacuum pump 108 is filled with fluid from tissue site 102. In this regard, it should be noted that the wireless vacuum pump 108 shown in FIG. 6 shows a state before use. In the embodiment of FIGS. 4 and 6, once the wireless vacuum pump 108 reaches the capacity to hold fluid, the micropump 116 may be deactivated and the user may discard the entire wireless vacuum pump 108. .

With reference now mainly to FIGS. 7 and 8, another exemplary embodiment of a wireless vacuum pump 200 will be described. The wireless vacuum pump 200 may be used as part of a system for treating a tissue site, such as the system of FIG. The wireless vacuum pump 200 includes a plurality of wall members 202 and forms a first chamber 204 and a second chamber 206. One of the plurality of wall members 202 is a partition wall 208 that separates the first chamber 204 from the second chamber 206. A micropump 210 similar to the micropump 116 of the previously described drawings can be disposed in the first chamber 204. The micropump 116 is configured such that an inlet 212 that receives fluid (or otherwise discharges reduced pressure) is fluidly coupled to the second chamber 206. Micropump 210 has an outlet or vent 214 that is fluidly coupled to first chamber 204. The micropump 210 discharges positive pressure through the outlet or vent 214 to the first chamber 204.

One portion of the plurality of wall members 202 that form the first chamber 204 includes an aperture 216. An optional relief valve 218 is coupled to the aperture 216. The relief valve 218 is configured such that the pressure in the first chamber 204 is released to the outside of the wireless decompression pump 200 when the pressure exceeds a first threshold pressure. At least a portion of the plurality of wall members 202 constituting the second chamber 206 includes an inflatable support member, typically a plurality of inflatable support members 220. Although multiple inflatable support members 220 are shown, it should be understood that a single inflatable support member can be used to form the second chamber 206.

Inflatable support member 220 is in fluid communication with first chamber 204, such as through a plurality of apertures 222. Therefore, the positive pressure in the first chamber 204 fills the plurality of inflatable support members 220. When the plurality of inflatable support members 220 are filled with sufficient fluid, the plurality of inflatable support members 220 provide a structure that is relatively rigid and helps form a volume in the second chamber 206. provide. Fluid 223 from the tissue site is contained in the volume of the second chamber 206 through the vacuum conduit 224. The wireless vacuum pump 200 shown in a pyramid shape may be formed to take other shapes, such as a box, cylinder, or any other shape.

As in the previously described embodiment, the micropump 210 is powered in whole or in part by a pump signal supplied to the RFID antenna 226. The RFID antenna 226 is coupled to the first processor 228. The first processor 228 is electrically coupled to the micropump 210 by a conductor 230, which may be included in one of the plurality of wall members 202, but is shown separately in FIG. As shown in FIG. 8, a floor portion 232 of a plurality of wall members 202 may be included within the platform member 234.

Referring now primarily to FIGS. 7 and 8, in operation according to an exemplary embodiment, the vacuum conduit 224 is coupled to a vacuum dressing, such as the vacuum dressing 106 of FIGS. 1 and 3. A base unit, such as the base unit 110 of FIG. 1, is used to send a pump signal or pump actuation signal to the RFID antenna 226 of the wireless vacuum pump 200. A pump signal received by the RFID antenna 226 is provided to the first processor 228. Power is supplied from the first processor 228 to the micropump 210 and energizes the micropump 210. When the micropump 210 is energized, a reduced pressure is supplied to the second chamber 206 and a positive pressure is supplied to the first chamber 204. When the pressure increases in the first chamber 204, the pressure is filled in the plurality of inflatable support members 220, and the wireless vacuum pump 200 changes from the deflated state to the expanded state. A spacer member (not shown) covers the inlet 212 to prevent air blockage during start-up before the inflatable support member 220 is filled.

When the inflatable support member 220 is expanded, the maximum volume of the second chamber 206 is achieved. At the same time, the reduced pressure in the second chamber 206 is supplied to the reduced pressure conduit 224. A fluid 223 (including liquid) is injected into the second chamber 206.

Although not explicitly shown, it should be understood that a reduced pressure sensing device, eg, similar to the pressure sensing device 136 of FIG. 3, may be incorporated into a portion of the second chamber 206 to measure the pressure in the second chamber 206. Again, it should be understood that a reduced pressure sensing device similar to, for example, the pressure sensing device 138 of FIG. The vacuum conduit 224 may also have a pressure sensing lumen that is fluidly coupled to a vacuum sensing device for measuring pressure in the distribution manifold. In either example, the pressure sensing device is coupled to the first processor 228 to generate a pressure message signal. The pressure message signal may be supplied in response to a pressure interrogation signal from the base unit or naturally generated by the first processor 228. The first processor 228 uses the pressure message signal to generate a pump control signal that can be provided to the micropump 210. Alternatively, the pressure message signal is sent to the base unit, where a processor in the base unit can generate a pump control signal similar to the previously described embodiments.

In an alternative embodiment, the previously described wireless vacuum pump 108, 200 has a lead or socket and plug between the pump and base instead of having an RFID antenna. Leads or sockets and plugs can be easily plugged into one another to exchange power and signals.

Referring now primarily to FIGS. 9-11, an exemplary embodiment of a reduced pressure system 300 for treating a tissue site 302 with reduced pressure will be described. The decompression system 300 includes a wireless decompression dressing 304 and a base unit 306. The base unit 306 may include a power connector 307. The wireless decompression dressing 304 is a built-in disposable dressing that receives power from the base unit 306 and is controlled. The base unit 306 can be substantially adjacent to the wireless vacuum dressing 304, for example, within 1 or 2 millimeters, or up to 10 meters or more, or somewhere in between. In one embodiment, the micropump 316 may be separated from the absorbent layer or absorbent member 310, and the micropump 316 can be easily separated after use. Therefore, the micropump 316 may be repaired and reused.

The wireless vacuum dressing 304 includes an interface distribution manifold 308 disposed proximate to the tissue site 302. The wireless decompression dressing 304 may also include an absorption layer 310, an RFID antenna 312, and a first processor 314. The RFID antenna 312 is electrically coupled to the first processor 314. The first processor 314 is electrically coupled to the micropump 316. The interface distribution manifold 308, the absorbent layer 310, the RFID antenna 312, the first processor 314, and the micropump 316 are all held in place and secured within the enclosed space 318 by one or more seal members, eg, seal members 320. The Additional layers and components may be included in the wireless vacuum dressing 304.

The exemplary embodiments of FIGS. 9-11 include additional layers and components. Additional layers and components may be arranged in different orders. Seal layer 322 is used to seal wireless vacuum dressing 304 around tissue site 302. Seal layer 322 is formed with aperture 323 and provides fluid communication to interface distribution manifold 308. A first internal distribution manifold 324 is positioned in fluid communication with the interface distribution manifold 308 and the tissue site 302. Absorbent layer 310 is positioned in fluid communication with first internal distribution manifold 324, interface distribution manifold 308, and tissue site 302. A diverter layer 326 is positioned adjacent to the absorbent layer 310. A second internal distribution manifold 328 is positioned in fluid communication with the diverter layer 326. The diverter layer 326 is formed with a plurality of apertures 327, which can take a number of patterns and forms. The diverter layer 326 is shown with a plurality of apertures 327 forming a square pattern in this particular exemplary embodiment. In the square pattern, the aperture at the corner is larger than the other apertures. A gas / liquid separator 330 is positioned adjacent to the second internal distribution manifold 328.

Micropump 316, RFID antenna 312, and first processor 314 may be adjacent to gas-liquid separator 330. A charcoal filter 332 or other odor removal device may be positioned over the outlet 334 of the micropump 316. The seal member 320 is formed with an aperture 336 so that the discharge port 334 of the micropump 316 can be exhausted to the outside of the wireless decompression dressing 304. Together, the outlet 334 and the aperture 336 form a vent 338.

The micropump 316 can be a micropump that is small and lightweight enough to allow the integrated wireless vacuum dressing 304 to be maintained at the tissue site 302. Further, the micropump 316 may be sized and weighted so that the integrated vacuum dressing 304 does not pull or otherwise adversely affect the tissue site 302. In an exemplary embodiment, the micropump 316 may be a disk-type pump having a piezoelectric actuator similar to that described above. Reference is also made to the pumps shown in US 2009/0087323 and US 2009/0240185, which are hereby incorporated by reference for all purposes. In an alternative embodiment, the micropump 316 may be a peristaltic pump that is used to pump a variety of fluids. It should be understood that alternative pumping techniques may be used and rotary pumps, linear pumps, or other configurations of pumps may be used.

The micropump 316 generates a sufficient reduced pressure that is therapeutic for wound healing. In an exemplary embodiment, the micropump 316 has sufficient flow characteristics, reduced pressure characteristics, and operating life characteristics so that reduced pressure treatment can be performed continuously. The flow rate may be in the range of about 5 to 1000 ml / min, and the reduced pressure may be in the range of about −50 to −200 mm Hg (−6.6 to −26.6 kPa). It should be understood that alternative ranges may be used depending on the configuration of the integrated wireless vacuum dressing 304, the size of the wound, or the type of wound. In an exemplary embodiment, multiple pumps may be positioned in a single dressing and supplied with increased flow or vacuum levels as needed.

The micropump 316 is placed within the dressing to avoid the use of conduits and external canisters to collect wound exudate. Micropump 316 includes an outlet 334 for releasing or evacuating air from vacuum dressing 304. When using the outlet 334, the outlet 334 may be in fluid communication with or positioned within the aperture 336 of the seal member 320. Alternatively, the seal member 320 may be sealed around the outlet port of the micropump 316 so that gas from the micropump 316 can be exhausted directly through the aperture 336. In the exemplary embodiment of FIGS. 9-11, the outlet 334 of the micropump 316 is oriented away from the gas-liquid separator 330 (or hydrophobic filter) to prevent air from being added to the wireless vacuum dressing 304. To dc. Air is exhausted through aperture 336 in seal member 320, which may include a one-way valve. Alternatively, air or another gas can be exhausted through the gas permeable portion of the seal member 320 as long as the ability of the seal member 320 to maintain a reduced pressure is not affected.

When the micropump 316 is a piezoelectric pump, the piezoelectric actuator associated with the micropump 316 can sometimes be driven at a different frequency to function as a buzzer or oscillating warning system. The alert system can alert the user of an alarm condition. For example, an alarm condition may be that there is a leak in the dressing, that the reduced pressure measured by the sensor has changed, that the dressing has absorbed the maximum volume of liquid as indicated by the indicator, or one or more layers May no longer efficiently manifold the vacuum.

Control electronics may be physically or functionally incorporated as part of the first processor 314. The control electronics can be used to control the operation of the micropump 316. The control electronics may be analog or digital and may be configured with a regulator that adjusts the speed or duty cycle at which the micropump 316 operates. In addition, the control electronics may be configured with a controller that receives a sensing signal from a sensor or switch, eg, a pressure sensing device (see 340 in FIG. 12). Sensors are placed throughout the wireless vacuum dressing 304 and may sense parameters such as pressure, temperature, humidity, chemistry, odor, or any other parameter that can be used to manage and control the micropump 316. The control electronics may include a computer processor or programmable gate array or other control device. It should be understood that the control electronics may include any form of digital or analog component that performs the functions described herein. The control electronics may be or include the first processor 314.

The control electronics will monitor and issue alarms for several conditions, eg, (i) low voltage, (ii) excessive leakage, (iii) absorber layer level, and (iv) battery condition (if included). Can be arranged. Therefore, the control electronics monitor each of the parameters and generate alarm signals (eg, high-pitched beeps, vibrations, or light) using speakers, vibrators, or lighting devices such as light emitting diodes (LEDs) Electronics may be included. Thus, the control electronics may notify a medical professional, patient, or family member that the parameter is outside the desired range. For example, if the pressure at the tissue site 302 is below the treatment level, a continuous tone can be generated. As another example, a continuous beep can be generated when the absorbing layer 310 is saturated. If the battery falls below a certain voltage level, a different audible frequency can be generated or the LED can be activated. A variety of different alert signals can be established to notify the medical professional to take a specific action.

The RFID antenna 312 is used to provide electrical output to the micropump 316 and control electronics. The battery 342 may also be used to provide stored energy to increase the output from the RFID antenna 312. The battery 342 may be any size and shape, and may be any material, such as a polymer. The battery 342 can provide all or part of the required power. The battery 342 can be recharged with power from the RFID antenna 312.

In one exemplary embodiment, the battery 342 may be configured with a voltage level sensor that is monitored by the control electronics, and the control electronics may generate an alarm when a low power level is detected. The battery 342 can be directly connected to the micropump 316. Alternatively, the battery 342 can be connected to control electronics or one or more processors that use the power from the battery 342 to drive the micropump 316. The control electronics may drive the micropump 316 using continuous modulated power, such as a pulse width modulation (PWM) signal.

Seal layer 322 is glued or otherwise connected to seal member 320 that is used to hang or otherwise cover the components of vacuum dressing 304. Seal layer 322 may include a medical grade adhesive material or other sealing device that is strong enough to form a vacuum seal with the epidermis around the patient's wound. The sealing layer 322 may be a band having an aperture 323 that is slightly larger than the geometric parameters of the gas-liquid separator 330 or other layers, and the sealing member 320 is connected to the epidermis around the patient tissue site 302. Make contact. The seal member 320 is impermeable to fluids such as air and liquid.

In another exemplary embodiment, seal member 320 may adhere to diverter layer 326 and diverter layer 326 adheres to seal member 320 to form an upper dressing portion and a lower dressing portion. The upper dressing portion can include a seal member 320, a micropump 316 and related components, a gas-liquid separator 330, a second internal distribution manifold 328, and a diverter layer 326. The lower dressing portion may include an absorbent layer 310, a first internal distribution manifold 324, a seal layer 322, and an interface distribution manifold 308. The wireless vacuum dressing 304 may be configured to allow the lower dressing portion to be replaced once the wireless vacuum dressing has absorbed the maximum volume of fluid. The upper dressing portion may be reused after replacement of the lower dressing portion. This allows the micropump 316 to be used multiple times, but the disposable part of the dressing may be replaced. In another exemplary embodiment, the micropump 316, the first processor 314, and the RFID antenna 312 may be removed from the dressing for reuse and the remaining layers of the dressing replaced. In yet

another exemplary embodiment, only the absorbent layer 310 may be replaced. In yet another exemplary embodiment, only the absorbent layer 310 and the interface distribution manifold 308 may be replaced.

Charcoal filter 332 may be used in wireless reduced pressure dressing 304 to reduce odors caused by tissue site 302 and spread from wireless reduced pressure dressing 304. A charcoal filter 332 may be placed over a valve or other exhaust vent from the micropump 316 to filter the exhaust from the micropump 316 before it is discharged from the integrated vacuum dressing 304. Alternatively, it should be understood that the charcoal filter 332 may be configured and arranged above or below the micropump 316. In another exemplary embodiment, rather than using a charcoal filter, charcoal may be incorporated into any or all of the different layers used in the integrated decompression dressing 304.

According to one exemplary embodiment, in operation, the reduced pressure system 300 of FIGS. 9-11 is applied by positioning the interface distribution manifold 308 proximate to the tissue site 302. A seal layer 322 is disposed on the upper side of the interface distribution manifold 308 so that the aperture 323 is on the upper side of the interface distribution manifold 308. The first internal distribution manifold 324 is disposed on the first interface distribution manifold 308 and possibly adjacent a portion of the seal layer 322. The absorbent layer 310 is disposed adjacent to the first internal distribution manifold 324. The diverter layer 326 may be placed over all of the components so shown. The second internal distribution manifold 328 can then be placed adjacent to a portion of the diverter layer 326 along with the gas-liquid separator 330. A micropump 316, an RFID antenna 312 and a first processor 314 may be applied. The components described herein can also be preassembled as a dressing laminate.

Seal member 320 is used to create a seal that forms a sealed space 318. The base unit 306 is used to transmit a pump signal to the RFID antenna 312 as described above, which is received by the first processor 314 and used to power the micropump 316. . The first processor 314 may further include one or more capacitors to hold power or one or more batteries, eg, rechargeable batteries. The pump signal causes a vacuum to be generated by the micropump 316. The reduced pressure is transmitted to the tissue site 302 to remove fluid or provide reduced pressure therapy. The fluid removed from the tissue site 302 is transferred to the absorbent layer 310 in the reduced pressure dressing 304 where the fluid is retained or substantially retained. As described in connection with FIG. 12, a pressure sensing device may be included as part of the wireless decompression dressing 304 to provide a pressure message signal to the base unit 306.

With reference now primarily to FIG. 12, another exemplary embodiment of a vacuum system 300 will be described. As already mentioned, the vacuum system 300 includes a wireless vacuum dressing 304 and a base unit 306. The vacuum system 300 of FIG. 12 includes a small number of components that the wireless vacuum dressing 304 includes, and the wireless vacuum dressing 304 additionally includes a pressure sensing device 340 that is electrically coupled to the first processor 314. Except that, it is similar to the system shown in FIGS. In addition, an optional battery 342 is included. The battery 342 may supplement the power provided by the RFID antenna 312 or may be used as a main power source and recharged by the RFID antenna 312. The RFID antenna 312 receives power from the base unit 306. Seal member 320 is shown secured to skin 344 by attachment device 346. Components included in the dressing described in FIGS. 9-11 are given the same reference numerals and are not necessarily further described here.

According to an exemplary embodiment, in operation, the reduced pressure system 300 of FIG. 12 may be used by first applying an interface distribution manifold 308 adjacent to the tissue site 302. Absorbent layer 310 may be disposed in fluid communication with interface distribution manifold 308. The gas-liquid separation device 330 may be disposed on the upper side of the absorption layer 310. Thereafter, the RFID antenna 312, the pressure sensing device 340, the first processor 314, the micropump 316, and the battery 342 are disposed on the gas-liquid separation device 330. Alternatively, some of the components, such as micropump 316, may be adjacent to gas-liquid separator 330. A seal member 320 is applied over the top of the tissue site 302 to form a sealed space 318 and covers all of the components described above. The components already described can be preassembled in whole or in part. Base unit 306 sends a pump signal or pump actuation signal to decompression dressing 304, thereby actuating micropump 316. The micropump 316 removes air or other fluid from the enclosed space 318, thereby initiating treatment of the tissue site 302 with reduced pressure.

In addition to providing a pump actuation signal or pump signal from the base unit 306 to the RFID antenna 312, the base unit 306 may also transmit a pressure inquiry signal. Upon receipt of the pressure interrogation signal, the RFID antenna 312, the first processor 314, and the pressure sensing device 340 generate a pressure message signal that is transmitted by the RFID antenna to the RFID reader (not explicitly shown) of the base unit 306. The Base unit 306 includes a processor (not explicitly shown) that may receive a pressure message signal and generate a pump control signal that activates or deactivates micropump 316. When the reduced pressure is within the desired treatment range, the micropump 316 can be deactivated. Similarly, if the pressure is too large on an absolute scale, the base unit 306 may send a pump signal that activates or continues the micropump 316 to provide more vacuum. An alarm can be triggered by the base unit 306 if the elapsed time for not reaching the desired pressure is too long. The wireless decompression dressing 304 includes a galvanic cell (not explicitly shown) to provide a full display message signal when exudate or other bodily fluid electrically couples the two electrodes. A full indication message signal is sent by RFID antenna 312 to base unit 306 to indicate that the dressing is full.

Referring now primarily to FIG. 13, another exemplary embodiment of a vacuum dressing 400 that includes a wireless vacuum pump 430 will be described. The reduced pressure dressing 400 is shown as an exploded view and covers a tissue site 402 of the patient 404, such as a wound. The reduced pressure dressing 400 includes an interface distribution manifold 406 disposed proximate to the tissue site 402. The interface distribution manifold 406 may be formed from any manifold material, such as GranFoam® material, or any other manifold material already described.

The reduced pressure dressing 400 further includes a lower drape or diverter 408. The lower drape 408 is a polyethylene material with an adhesive on the lower side (tissue-facing side) and may surround the tissue site 402 to be treated and adhere to the patient 404. The lower drape 408 may include an aperture or perforation to communicate reduced pressure to the tissue site 402 through the interface distribution manifold 406 and draw wound fluid (liquid or gas) from the tissue site 402. The lower drape 408 may also include a seal ring 410 to provide additional adhesive strength to maintain the reduced pressure at the desired therapeutic level. Initially, the protective release liner 412 covers the seal ring 410. The protective release liner 412 is removed from the lower side of the lower drape 408 before the lower drape 408 is positioned on the patient 404.

The reduced pressure dressing 400 includes an absorbent layer 414, which can be a nonwoven fabric, to absorb wound fluid drawn through the aperture in the lower drape 408. Absorbent layer 414 is sandwiched between two wicking layers 416 and 418 that allow wound fluid to escape and distribute to absorbent layer 414. The high-density side of the wicking layers 416 and 418 faces outward from the absorption layer 414. Wicking layers 416, 418 sandwich an absorbent layer 414 therebetween to form a fluid storage device 420.

The vacuum dressing 400 further includes an upper drape 422 that can be a non-porous, closed barrier formed of polyethylene. The smooth side of the upper drape 422 faces the upper wicking layer 416. Upper drape 422 includes an aperture or opening 424. The aperture or opening 424 may be covered by a hydrophobic filter 426 that separates air from the liquid to include wound fluid or exudate within the absorbent layer 414. The hydrophobic filter 426 simultaneously allows gas flow from the absorbent layer 414 as a result of the depressurization of the hydrophobic filter 426. Upper drape 422 and hydrophobic filter 426 include a top layer 428 of vacuum dressing 400 that covers fluid reservoir 420. All of the above-described dressing assembly elements except the release liner 412 are collectively referred to as the "wound dressing" portion of the vacuum dressing 400.

The vacuum dressing 400 further includes a wireless vacuum pump, or pump portion 430. The pump portion 430 includes a micropump assembly 432 positioned on top of the upper drape 422 to provide a vacuum that draws air through the hydrophobic filter 426, the fluid reservoir 420, and the interface distribution manifold 406. The

micropump assembly 432 includes a piezoelectric disk pump 434 that oscillates at a predetermined frequency to generate a desired reduced pressure on the input side of the piezoelectric disk pump 434. Piezoelectric disk pump 434 may be similar to micropump 316 of FIG. The piezoelectric disk pump 434 of the micropump assembly 432 may not operate if any liquid drawn from the tissue site 402 to the absorbent layer 414 below the upper drape 422 enters the input port of the piezoelectric disk pump 434. The hydrophobic filter 426 prevents wound fluid or exudate from flowing into the piezoelectric disk pump 434 of the micropump assembly 432.

The vacuum dressing 400 also includes a spacer ring or ring seal 436 positioned between the hydrophobic filter 426 and the inlet of the piezoelectric disk pump 434 for air flow to the piezoelectric disk pump 434 of the micropump assembly 432. Can result in a cavity. The micropump assembly 432 can be sandwiched between the first foam cushion 438 and the second foam cushion 440. Micropump assembly 432, first cushion 438, and second cushion 440 form a single composite package that is sandwiched between outer ply 442 and inner ply 444 and removably attached to upper drape 422. To do. Outer ply 442 includes an aperture or perforation 446 that provides a discharge path for the discharge of micropump assembly 432.

The piezoelectric disk pump 434 or other micropump can be controlled by the first processor 448 and other control electronics. The piezoelectric disk pump 434 can be powered by a first power unit 450 and a second power unit 452. The power units 450 and 452 can be batteries. In another alternative embodiment, the first power unit 450 or the second power unit 452 may include an RFID antenna that provides power to the first processor 448 and the piezoelectric disk pump 434.

According to embodiments, a system for treating a tissue site with reduced pressure includes a reduced pressure dressing disposed proximate to the tissue site; and a wireless reduced pressure pump fluidly coupled to the reduced pressure dressing. The wireless decompression pump includes an RFID antenna, a first processor coupled to the RFID antenna, a micropump device coupled to the first processor for receiving power therefrom and generating decompression, and a fluid in the micropump device. And a fluidly coupled reservoir. The system further includes a base unit having an RFID reader. The RFID reader is configured to provide power to the RFID antenna and provide power to the micropump device. The system may further include a first pump seal member and a second pump seal member. The first pump seal member and the second pump seal member are at least partially joined to form a pump pouch, on which the micropump device is disposed. The wireless decompression pump functions in the absence of a power source other than the RFID antenna. The wireless vacuum pump further includes a pressure sensing device fluidly coupled to the vacuum dressing and the first processor for sensing pressure at the tissue site. The wireless vacuum pump further includes a pressure sensing device coupled to the first processor. The base unit further includes a second processor coupled to the RFID reader, and the second processor and the RFID reader send a pressure interrogation signal to the first processor of the wireless vacuum pump and in response the first processor. It may be configured to receive a pressure message signal from one processor.

With respect to the system described in the previous paragraph, the wireless vacuum pump may further include a pressure sensing device coupled to the first processor. The base unit may include a second processor coupled to the RFID reader. The second processor and RFID reader may be configured to send a pressure interrogation signal to the first processor of the wireless vacuum pump and receive a pressure message signal from the first processor in response thereto. The first processor and the pressure sensing device may be configured to prepare a pressure message signal in response to the pressure inquiry signal. The first processor and the RFID antenna may be configured to transmit a pressure message signal. And the second processor may be configured to receive the pressure message signal and prepare the control signal. The second processor and RFID may be configured to send a control signal to the wireless vacuum pump to provide a control signal that activates or deactivates the micropump device.

With respect to the system described in the previous paragraph, the wireless vacuum pump may further include a pressure sensing device coupled to the first processor. The pressure sensing device is operable to generate a pressure message signal. The first processor is operable to receive the pressure message signal and generate a control signal to activate or deactivate the micropump device.

In another embodiment of the system described in the previous paragraph, the system includes: a pressure sensing device that is fluidly coupled to the reduced pressure dressing and the first processor to sense pressure at the tissue site; a first distribution manifold; A first distribution manifold, an absorbent layer, and a diverter layer are formed by the pump seal member and the second pump seal member. A micropump device includes a piezoelectric pump. The reduced pressure dressing includes an interface distribution manifold disposed proximate to the tissue site, a dressing seal member, and a reduced pressure interface. In one embodiment, the RFID antenna is less than 5 centimeters from the base unit.

According to another exemplary embodiment, a wireless vacuum pump includes at least one wall member that forms a first chamber and a second chamber, an RFID antenna; a first processor coupled to the RFID antenna; And a micropump device coupled to the first processor for receiving power therefrom and generating reduced pressure and positive pressure. The micropump device has a vent fluidly coupled to the first chamber for exhausting positive pressure therein, and an inlet fluidly coupled to the second chamber for supplying reduced pressure thereto. The pump further includes a plurality of inflatable support members fluidly coupled to the first chamber; and a reservoir containing the second chamber. The pump may further include a first pressure relief valve fluidly coupled to the first chamber. The first pressure relief valve is operable to release a positive pressure that exceeds the first threshold pressure. The first chamber and the second chamber may be in the form of a portion of a pyramid. The pump can function in the absence of a power source other than the RFID antenna.

According to another exemplary embodiment, a method of manufacturing a system for treating a patient tissue site by decompression provides a decompression dressing disposed proximate to the tissue site, and provides a wireless decompression pump, including. The wireless vacuum pump includes: an RFID antenna, a first processor coupled to the RFID antenna, a micropump device coupled to the first processor for receiving power therefrom and generating decompression; and a fluid in the micropump device And a fluidly coupled reservoir. The method further includes providing a base unit having an RFID reader. The RFID reader may be configured to provide power to the RFID antenna and provide power to the micropump device. The manufacturing method may further include a first pump seal member and a second pump seal member. The first pump seal member and the second pump seal are at least partially coupled to form a pump pouch, on which the micropump device is disposed. The manufacturing method may further include providing a vacuum conduit that fluidly couples the wireless vacuum pump to the vacuum dressing. The manufacturing method further includes providing a pressure sensing device and coupling the pressure sensing device to a reduced pressure dressing.

According to another exemplary embodiment, a method of treating a patient tissue site by decompression includes placing a decompression dressing proximate the tissue site and providing a wireless decompression pump. The wireless vacuum pump includes: an RFID antenna; a first processor coupled to the RFID antenna; a micropump device coupled to the first processor for receiving power therefrom and generating decompression; and a fluid in the micropump device And a fluidly coupled reservoir. The method also includes fluidly coupling a wireless vacuum pump to the vacuum dressing, providing a base unit having an RFID reader and a second processor, activating the base unit, whereby the RFID reader and the second Two processors sending an activation signal to the wireless decompression pump to activate the wireless decompression pump. The wireless decompression pump may further include a first pump seal member and a second pump seal member. The first pump seal member and the second pump seal are at least partially coupled to form a pump pouch, on which the micropump device is disposed. All the power required by the micropump device can be supplied by the RFID reader. The method may further include positioning the RFID reader within 5 centimeters from the RFID antenna of the wireless vacuum pump.

With respect to the method of the previous paragraph, the wireless vacuum pump has no power source other than the RFID antenna, and the wireless vacuum pump is: fluid pressure coupled to the vacuum dressing and the first processor to sense pressure at the tissue site A pressure sensing device, a first distribution manifold, an absorbent layer, and a diverter layer. The first distribution manifold, the absorbent layer, and the diverter layer may be disposed in a pump pouch formed by the first pump seal member and the second pump seal member. The micropump device can be a piezoelectric pump. The reduced pressure dressing may include: an interface distribution manifold disposed proximate to the tissue site, a dressing seal member, and a reduced pressure interface.

According to another exemplary embodiment, a decompression system for treating a tissue site by decompression includes: an interface distribution manifold disposed proximate to the tissue site, an absorbent member that receives and retains fluid from the interface distribution manifold, and RFID An antenna, a first processor coupled to the RFID antenna, and a micropump device coupled to the first processor for receiving power therefrom and generating a decompression, the micropump having an inlet and an outlet A wireless vacuum dressing including a device, a first seal member that forms a sealed space over the tissue site, and a vent that fluidly couples the outlet of the micropump device to the outside. The micropump is fluidly coupled to the enclosed space and supplies a reduced pressure thereto. The system further includes a base unit including an RFID reader. The base unit is operable to supply a pump signal to the wireless vacuum dressing to energize the micropump device. The system further includes a first pressure sensor in a wireless vacuum dressing coupled to the first processor. The first processor and the RFID antenna are operable to receive a pressure interrogation signal and generate a pressure message signal and send it to the base unit.

In another embodiment of the system described in the previous paragraph, the system may further include a first pressure sensor in a wireless vacuum dressing coupled to the first processor. The first processor and the RFID antenna are operable to receive a pressure interrogation signal and generate a pressure message signal and send it to the base unit. The base unit further includes a second processor. The second processor is operable to receive the pressure message signal and generate a pump control signal.

In another embodiment of the system described in the previous paragraph, the system may further include a first pressure sensor in a wireless vacuum dressing coupled to the first processor, and the first processor A pressure message signal is received from the sensor and a control signal is generated to control the micropump device. In another embodiment of the system described in the previous paragraph, the wireless vacuum pump can function in the absence of a power source other than an RFID antenna. Furthermore, only the reduced pressure supplied to the reduced pressure dressing can come from the micropump device. The system can be assembled such that the conduit or wire is not coupled to a wireless vacuum dressing.

According to another exemplary embodiment, a method of treating a patient tissue site by decompression includes placing a wireless decompression dressing proximate to the tissue site. The wireless decompression dressing includes an interface distribution manifold disposed proximate to a tissue site, an absorbent member that receives and retains fluid from the interface distribution manifold, an RFID antenna, a first processor coupled to the RFID antenna, A micropump device coupled to and receiving power from and generating pressure reduction and having an inlet and an outlet, a first seal member covering a tissue site and forming a sealed space, and a drain And a vent for fluidly coupling the outlet to the outside. The method includes providing a base unit including an RFID reader, the base unit configured to supply a pump signal to a wireless vacuum dressing to energize the micropump device, And providing a pump signal to the wireless decompression dressing.

According to another exemplary embodiment, a wireless decompression pump, wherein the wireless decompression pump is coupled to an RFID antenna; a first processor coupled to the RFID antenna, And a micropump device for receiving and generating a reduced pressure. The wireless vacuum pump may further include a reservoir fluidly coupled to the micropump device. The wireless vacuum pump may also further include a first pump seal member and a second pump seal member, wherein the first pump seal member and the second pump seal are at least partially combined to form a pump pouch. The micropump device is arranged there. The wireless vacuum pump can function in the absence of a power source other than the RFID antenna. The wireless vacuum pump may further include a pressure sensing device that is fluidly coupled to the vacuum dressing and the first processor to sense pressure at the tissue site.

With respect to the wireless decompression pump of the previous paragraph, the pump may further include a pressure sensing device coupled to the first processor and a base unit including a second processor coupled to the RFID reader. The second processor and RFID reader may be configured to send a pressure interrogation signal to the first processor of the wireless vacuum pump and receive a pressure message signal from the first processor in response.

With respect to the wireless vacuum pump of the previous paragraph, the wireless vacuum pump may further include a pressure sensing device coupled to the first processor and a base unit including a second processor coupled to the RFID reader. The second processor and RFID reader may be configured to send a pressure interrogation signal to the first processor of the wireless vacuum pump and receive a pressure message signal from the first processor in response. The first processor and the pressure sensing device are configured to prepare a pressure message signal in response to the pressure inquiry signal. The first processor and the RFID antenna are configured to transmit a pressure message signal. The second processor is configured to receive a pressure message signal and prepare a control signal, and the second processor and RFID send a control signal to the wireless vacuum pump to activate or deactivate the micropump device Configured to provide a control signal. The wireless vacuum pump may further include a pressure sensing device coupled to the first processor, the pressure sensing device is operable to generate a pressure message signal, and the first processor is configured to generate the pressure message signal. And generating a control signal to activate or deactivate the micropump device.

In general terms, systems, methods, and dressings that provide reduced pressure to a patient's tissue site are described as including wirelessly supplying power to a reduced pressure pump. In one example, an RFID antenna is used to power a vacuum pump that is fluidly coupled to a vacuum dressing by a conduit. In another example, the reduced pressure dressing includes a micropump and an RFID antenna that is used to power the micropump. Other systems, methods, and apparatus are described herein.

Although the invention and its advantages have been described in light of several exemplary, non-limiting embodiments, various modifications, substitutions have been made without departing from the scope of the invention as defined by the appended claims. It should be understood that changes, exchanges, and modifications can be made. It should be understood that any feature described in connection with any one embodiment is also applicable to any other embodiment.

It should be understood that the benefits and advantages described above may relate to one embodiment or may relate to several embodiments. It is further understood that reference to "a" item refers to one or more of those items.

The method steps described herein may be performed in any suitable order or simultaneously, where appropriate.

Where appropriate, another example of combining any aspect of the above-described embodiments with aspects of any other described embodiment, having similar or different characteristics and addressing the same or different issues Form.

It should be understood that the above description of the preferred embodiments is exemplary only, and that various modifications may be made by those skilled in the art. The above specification, examples and data provide a complete description of the structure and use of exemplary embodiments of the invention. Although various embodiments of the invention have been described above in some detail or with reference to one or more individual embodiments, those skilled in the art will recognize that the disclosed embodiments can be used without departing from the scope of the claims. Many modifications can be made.

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GB0508194D0	2005-04-22	2005-06-01	The Technology Partnership Plc	Pump
WO2007002154A2 *	2005-06-21	2007-01-04	Medrad, Inc.	Medical fluid injection and inflation system
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US8088710B2 *	2006-03-09	2011-12-27	The Invention Science Fund I, Llc	Acoustically controlled substance delivery device
US7779625B2 *	2006-05-11	2010-08-24	Kalypto Medical, Inc.	Device and method for wound therapy
WO2008021306A2 *	2006-08-15	2008-02-21	Bio-Innovative Operations, Inc.	Computer adjusted pressure wound care devices,

				systems & methods
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ES2382595T3 *	2008-01-08	2012-06-11	Bluesky Medical Group Inc.	Wound treatment through variable and sustained negative pressure and method to control it
WO2009093116A1	2008-01-25	2009-07-30	The University Of Cape Town	Wound dressing system and method
KR100916616B1 *	2008-02-27	2009-09-14	인하대학교 산학협력단	Medical treatment bandage made with cellulose-chitosan composit film, RFID sensor and biosensor, and Method thereof
US8449505B2 *	2008-03-05	2013-05-28	Kci Licensing, Inc.	Dressing and method for applying reduced pressure to and collecting and storing fluid from a tissue site
BRPI0906527A2 *	2008-04-04	2016-09-06	3Mm Innovative Properties Company	apparatus for applying bandages to wounds and medical bandages
US20100022990A1 *	2008-07-25	2010-01-28	Boehringer Technologies, L.P.	Pump system for negative pressure wound therapy and improvements thereon
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JP2019514479A *	2016-05-03	2019-06-06	スミス アンド ネフュー ピーエルシー Smith & Nephew Public Limited Company	Optimization of power transfer to negative pressure source in negative pressure therapy system
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JP2020044359A *	2014-07-07	2020-03-26	株式会社村田製作所	Negative pressure closure treatment device
KR20200116707A *	2019-04-02	2020-10-13	한국광기술원	Wearable wound treatment device
JP2021500141A *	2017-10-23	2021-01-07	ケーシーアイ ライセンシング インコーポレイテッド	Area management of tissue sites on joint joints
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EP2345436B2	2008-03-05	2021-12-15	KCI Licensing, Inc.	Dressing for applying reduced pressure to and collecting and storing fluid from a tissue site
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CA3089920A1	2010-10-12	2012-04-19	Smith & Nephew, Inc.	Medical device
US9084845B2	2011-11-02	2015-07-21	Smith & Nephew Plc	Reduced pressure therapy apparatuses and methods of using same
CN105726211B	2011-12-16	2020-04-28	凯希特许有限公司	Releasable medical drape
US10940047B2	2011-12-16	2021-03-09	Kci Licensing, Inc.	Sealing systems and methods employing a hybrid switchable drape

AU2013216970A1 *	2012-02-10	2014-06-05	Kci Licensing, Inc.	Systems and methods for monitoring a disc pump system using RFID
MX2014011080A	2012-03-12	2015-03-20	Smith & Nephew	Reduced pressure apparatus and methods.
EP2830555B1	2012-03-28	2017-08-02	KCI Licensing, Inc.	Reduced-pressure systems and dressings facilitating separation of electronic and clinical component parts
WO2013155199A1 *	2012-04-12	2013-10-17	Elwha Llc	Computational methods and systems for reporting information regarding appurtenances to wound dressings
US9024751B2	2012-04-12	2015-05-05	Elwha Llc	Dormant to active appurtenances for reporting information regarding wound dressings
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US10226212B2 *	2012-04-12	2019-03-12	Elwha Llc	Appurtenances to cavity wound dressings
US9427505B2	2012-05-15	2016-08-30	Smith & Nephew Plc	Negative pressure wound therapy apparatus
EP2866851B1 *	2012-06-28	2019-09-11	KCI Licensing, Inc.	Wound connection pad with rfid and integrated strain gauge pressure sensor
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EP3174570B1 *	2014-07-31	2021-03-17	Smith & Nephew, Inc	Inventory management and location tracking of medical devices
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CN107708758B	2014-12-22	2021-06-08	史密夫及内修公开有限公司	Negative pressure wound therapy device and method
US10828403B2	2014-12-29	2020-11-10	Smith & Nephew Plc	Negative pressure wound therapy apparatus and methods for operating the apparatus
CN113367890A	2015-04-27	2021-09-10	史密夫及内修公开有限公司	Pressure reducing device

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JP6942698B2	2015-10-07	2021-09-29	スミス アンド ネフュー インコーポレイテッド	Systems and methods for performing decompression therapy
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EP3416568A4 *	2016-02-16	2019-10-16	Insera Therapeutics, Inc.	Aspiration devices and anchored flow diverting devices
US11311231B2 *	2016-03-29	2022-04-26	Walgreen Health Solutions, Llc	Dressing assembly
WO2017191184A1	2016-05-03	2017-11-09	Smith & Nephew Plc	Negative pressure wound therapy device activation and control
GB201608099D0	2016-05-09	2016-06-22	Convatec Technologies Inc	Negative pressure wound dressing
AU2017292876B2	2016-07-08	2022-01-20	Convatec Technologies Inc.	Fluid collection apparatus
CN109689005B	2016-07-08	2022-03-04	康沃特克科技公司	Fluid flow sensing
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US20200008981A1 *	2016-12-12	2020-01-09	Smith & Nephew Plc	Wound dressing
TWI629028 *	2017-01-13	2018-07-11	慶門慧慈醫療器材有限公司	Suction disc
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US10624794B2	2018-02-12	2020-04-21	Healyx Labs, Inc.	Negative pressure wound therapy systems, devices, and methods
GB201805584D0 *	2018-04-05	2018-05-23	Smith & Nephew	Negative pressure wound treatment apparatuses and methods with integrated electronics
GB201809007D0	2018-06-01	2018-07-18	Smith & Nephew	Restriction of sensor-monitored region for sensor-enabled wound dressings
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US8449508B2	2013-05-28	Dressing and method for applying reduced pressure to and collecting and storing fluid from a tissue site
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Priority And Related Applications

Priority Applications (9)

Application	Priority date	Filing date	Title
US40719410P	2010-10-27	2010-10-27	*US Provisional Application*
US61/407,194		2010-10-27	
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PCT/US2011/044187	2010-10-27	2011-07-15	Reduced-pressure systems, dressings, and methods employing a wireless pump

Legal Events

Date	Code	Title	Description
2014-06-27	A521	Request for written amendment filed	**Free format text**: JAPANESE INTERMEDIATE CODE: A523 **Effective date**: 20140626
2014-06-27	A621	Written request for application examination	**Free format text**: JAPANESE INTERMEDIATE CODE: A621 **Effective date**: 20140626
2015-04-30	A131	Notification of reasons for refusal	**Free format text**: JAPANESE INTERMEDIATE CODE: A131 **Effective date**: 20150428
2015-05-01	A977	Report on retrieval	**Free format text**: JAPANESE INTERMEDIATE CODE: A971007 **Effective date**: 20150430
2015-07-27	A521	Request for written amendment filed	**Free format text**: JAPANESE INTERMEDIATE CODE: A523 **Effective date**: 20150727

2015-10-02	TRDD	Decision of grant or rejection written	
2015-10-14	A01	Written decision to grant a patent or to grant a registration (utility model)	**Free format text**: JAPANESE INTERMEDIATE CODE: A01 **Effective date**: 20151013
2015-11-19	A61	First payment of annual fees (during grant procedure)	**Free format text**: JAPANESE INTERMEDIATE CODE: A61 **Effective date**: 20151111
2015-11-27	R150	Certificate of patent or registration of utility model	**Ref document number**: 5843296 **Country of ref document**: JP **Free format text**: JAPANESE INTERMEDIATE CODE: R150
2018-11-06	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2019-11-12	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2020-11-04	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2021-03-01	S111	Request for change of ownership or part of ownership	**Free format text**: JAPANESE INTERMEDIATE CODE: R313113
2021-03-31	R360	Written notification for declining of transfer of rights	**Free format text**: JAPANESE INTERMEDIATE CODE: R360
2021-05-10	R360	Written notification for declining of transfer of rights	**Free format text**: JAPANESE INTERMEDIATE CODE: R360
2021-05-10	R371	Transfer withdrawn	**Free format text**: JAPANESE INTERMEDIATE CODE: R371
2021-06-03	S111	Request for change of ownership or part of ownership	**Free format text**: JAPANESE INTERMEDIATE CODE: R313113
2021-06-29	R350	Written notification of registration of transfer	**Free format text**: JAPANESE INTERMEDIATE CODE: R350
2021-11-27	LAPS	Cancellation because of no payment of annual fees	

Concepts

machine-extracted

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tissues		claims,abstract,description	130	0.000
reduced		claims,abstract,description	120	0.000
distribution		claims,description	80	0.000
fluid		claims,description	67	0.000
absorbent		claims,description	57	0.000
absorbent		claims,description	57	0.000
liquid		claims,description	35	0.000
response		claims,description	17	0.000
absorption reaction		claims,description	9	0.000
coupling		claims,description	8	0.000
coupling process		claims,description	8	0.000
coupling reaction		claims,description	8	0.000
manufacturing process		claims,description	7	0.000
activating		claims,description	5	0.000
sealing		claims,description	4	0.000

activation	claims,description	3	0.000
pumping	claims,description	3	0.000

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(33)優先権主張国　ドイツ(DE)

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最終頁に続く

(54)【発明の名称】開放可能な窓を含む、負圧雰囲気による創傷治療用創傷ケアデバイス

(57)【要約】
本発明の主題は、患者の皮膚に取り付けることが可能な創傷被覆要素および流体媒質を吸引するための接続デバイスを含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイスであって、前記創傷被覆要素は開放可能な窓を含み、前記窓は気密性の閉鎖物によって創傷被覆要素上に配置されている、創傷ケアデバイスである（図４ｂ）。

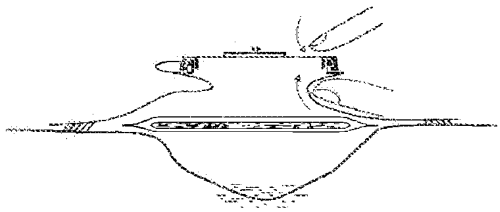

Fig. 4b

【特許請求の範囲】
【請求項１】
創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイスであって、
患者の皮膚に取り付けることが可能な創傷被覆要素および流体媒質を吸引するための接続デバイスを含み、
前記創傷被覆要素は開放可能な窓を有し、前記窓は気密性の閉鎖物によって創傷被覆要素上に配置されていることを特徴とする、創傷ケアデバイス。
【請求項２】
前記気密性の閉鎖物が連結シールの形態で具体化されていることを特徴とする、請求項１に記載の創傷ケアデバイス。
【請求項３】
前記創傷被覆要素が、所定の身体位置の解剖学的形態に対応するように事前に形成されていることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項４】
前記創傷被覆要素が、前記の所定の身体位置の動きに沿って動くことができるように具体化されていることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項５】
前記創傷被覆要素を、以下：
・アクリル接着剤
・シリコーン
・親水コロイド接着剤
・酸化亜鉛接着剤、および／または
・ラテックス接着剤
を含む群から選択される接着性材料によって患者の皮膚に取り付けることができることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項６】
前記デバイスが創傷の滲出液を取り出す吸収要素も含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項７】
前記吸収要素が少なくとも一つの超吸収物質、変性セルロース、発泡材、および／またはアルギン酸塩を含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項８】
前記吸収要素がセルロース繊維を含むフリースも含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項９】
前記デバイスが、流体浸透性の創傷対向創傷接触格子も含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項１０】
流体媒体の吸引用の接続デバイスの領域に、流体不浸透性の障壁があることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項１１】
前記デバイスが負圧雰囲気の生成のための設備も含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項１２】
負圧雰囲気の生成のための前記設備が前記創傷ケアデバイス上に直接配置されていることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項１３】
負圧雰囲気を発生させるための前記設備と、前記創傷被覆要素または創傷滲出液を取り出す前記吸収要素との間に、カップリング、ブロッキングバルブ、および／または三方バルブがあることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。

【請求項１４】
前記吸収要素が流体浸透性のカバーで囲まれていることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項１５】
前記デバイスが更にスペーサーも含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項１６】
前記デバイスが、重金属、好ましくは、銅もしくは銀、またはこれらの一つを含有する塩を含む層をも含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項１７】
前記創傷被覆要素が流体および／または気体に対して不透過性であることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項１８】
前記創傷被覆要素が水蒸気に対して透過性であることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項１９】
負圧雰囲気を発生させるための前記設備のポンピング方向が反転可能であることを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項２０】
前記開放可能な窓が、非弾性的バックパネルを含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項２１】
前記開放可能な窓が、弾性的バックパネルを含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項２２】
前記開放可能な窓が、可塑性の可鍛性材料で作製されたバックパネルを含むことを特徴とする、前述の請求項の一項に記載の創傷ケアデバイス。
【請求項２３】
軟組織の欠陥、外科的創面切除後の感染した創傷、リンパ系瘻孔、胸骨の傷感染症、胸壁孔、床ずれ、静脈性潰瘍、慢性的傷癒合障害、放射線潰瘍、腹部隔室症候群、敗血性腹腔、腸管瘻孔、および／または一つまたは幾つかの浮腫に起因する創傷などの創傷治療の目的の、皮膚移植の固定のための、傷の状態調節のための、ならびに／または縫い目および切開の手術後のケアのための、
前述の請求項の一項に記載の創傷ケアデバイスの適用。
【請求項２４】
傷圧縮系における、前述の請求項の一項に記載の創傷ケアデバイスの適用。
【発明の詳細な説明】
【技術分野】
【０００１】
本発明は、開放可能な窓を含む、負圧雰囲気による創傷治療用創傷ケアデバイスに関する。
【背景技術】
【０００２】
負圧雰囲気による創傷治療用の従来のシステムおよびデバイスは、気密性の創創傷被覆、ドレナージ（排出）ホース、外部に配置される真空ポンプ、および排出される滲出液を集めるための容器から成っている。
【０００３】
このようなデバイスは、例えば、特許文献１に記載されている。特許文献２には、負圧雰囲気による創傷治療用創傷ケアデバイスが記載されている。この創傷ケアデバイスは、開放可能な窓を随意に特徴として有してよく、これは「気密性治療窓」、または「可倒式

閉鎖要素」とも呼ばれる。
【０００４】
負圧雰囲気によって創傷治療をするデバイスは、例えば、切開部の手術後治療（目的が滲出液の排出であり、および、そのため面倒な事態をより少なくして、縫合部分のより速い治癒を可能にすることであるとき）に対して、ならびに、例えば床ずれまたは静脈性潰瘍の場合の、深く窪んだ浮腫の治療（この場合、深い内側から傷の流体を積極的に取得することは、慢性の傷の治癒に対する前提条件である）に対して使用される。
【０００５】
典型的には、この治療形態において、６０と２００mmHgの間の相対的負圧が使用される。特許文献２に記載された開放可能な窓は、その下に配置された創傷接触要素、例えば吸収要素または副次的ケア用品が、気密性創傷被覆によって作られた空間に挿入されること、またはその空間から除去されることを可能なものにしている。このようにして、前記創傷接触要素、または前記ケア用品は、例えば創傷の洗浄またはその要素の交換を目的として、創傷周囲の患者の皮膚に好ましく取り付けられている創傷ケアデバイスの全体を取り換えることを必要とせずに、創傷空間から取り除くことができる。このことにより、傷治療工程における外傷性治療介入が減り、また、コスト関連の利点も有する。
【０００６】
大気の条件に基づいて、前記開放可能な窓は、窓が閉じられた位置にあるときは、気密性であることが必要である。このことは、空気が非常に低粘度の媒体であることから、些細なことではない。更に、多くの種類の気密性結合材は、強い物理的結合も必要となり、これは傷との接触の観点から望ましくない。このような強い物理的結合は、一方で一定の高さと一定の重さを特徴とし、かつ、他方では、開閉時の一定の復元力、言い換えると、開閉が手の強さで行われることを特徴とする。
【０００７】
しかしながら、現在の情況において、創傷領域に力を加えることは、しばしば患者を苦痛に曝す結果となり得るので、これは大いに望ましくない。もし、例えば、治療窓を閉じるのに力の使用を必要とするなら、患者は、特に瘢痕、床ずれ、および静脈性潰瘍の場合には、これを外傷性治療介入として経験するであろう。
【先行技術文献】
【特許文献】
【０００８】
【特許文献１】米国特許７１９８０４６号公報
【特許文献２】欧州特許１８１４６０９号公報
【発明の概要】
【発明が解決しようとする課題】
【０００９】
本発明の課題は、それ故、前述の不利な点を伴わずに、創傷接触要素またはケア用品の交換を可能にする真空傷治療を提供することである。
【課題を解決するための手段】
【００１０】
本発明は、患者の皮膚に取り付けることが可能な創傷被覆要素、および流体媒質を吸引するための接続デバイスを含み、上記創傷被覆要素は開放可能な窓を有し、この窓は気密性の閉鎖物によって創傷被覆要素上に配置されている、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイスを提供する。
【図面の簡単な説明】
【００１１】
【図１】図１は、創傷ケアデバイスの一般原理を示す。
【図２】図２は、開放可能な窓１０を示す。
【図３】図３中に、前記連結シール１８、４０の断面を詳細に示す。
【図４】図４も、開放可能な窓を示す。

【図５】図５ａは、連結シールの異なる形態を示す。図５ｂは、接着性シールの形態の気密性の閉鎖物を示す。
【図６】図６は、創傷ケアデバイス６０を示す。
【図７】図７は、創傷ケアデバイス７０を示す。
【図８】図８は、創傷ケアデバイス８０を示す。
【図９】図９は、創傷ケアデバイス９０を示す。
【図１０】図１０は、創傷ケアデバイス１００を示す。
【図１１】図１１ａは、創傷ケアデバイス１１０を示す。図１１ｂは、図１１ａ中のデバイスに類似のデバイスを特徴として有するが、吸収要素１１８が、創傷対向側で、開放可能な窓１１７に取り付けられている点が異なる。
【図１２】図１２は、創傷ケアデバイス１２０を示す。
【図１３】図１３は、接着性シールの形の気密性の閉鎖物の更なる実施態様を示す。
【図１４】図１４は、創傷ケアデバイス１４０を示す。
【図１５】図１５は、創傷ケアデバイス１５０を示す。
【図１６】図１６ａは、発明された創傷ケアデバイスの配置を示す。図１６ｂは、図１６ａ中の配置と類似の配置を示すが、より後での配置である。
【図１７】更なる実施態様を図１７中に見ることができる。
【図１８】図１８は、本発明に係る創傷被覆要素のフレーム１８０を通り抜けた断面である。
【図１９】図１９は、創傷治療用創傷ケアデバイスを示す。
【図２０】ポンプ１９３は、図２０に見られるように、着脱可能なように具体化されている。
【図２１】図２１は、創傷ケアデバイスの分解図を示す。
【図２２】図２２は、更なる創傷治療用創傷ケアデバイスを示す。
【発明を実施するための形態】
【００１２】
前記開放可能な窓は、多くの利点を特徴として有する。従って、例えば、その窓によって、

その下にある傷の、より容易なリンスまたは洗浄
医薬品またはケア用品によるその創傷治療
創傷被覆材または吸収要素の非外傷性交換
その傷の視診および評価、および
試料、例えば綿棒採取標本の取得

が、創傷ケアデバイス全体を取り除くことを必要とせずに、可能になる。
「開放可能な窓」の概念は、完全に透明な窓、透明でない窓またはその下に非透明性物質を有する窓、および透明部を特徴として有する窓、を包含する。
【００１３】
好ましくは、創傷被覆要素は、特定の身体位置の解剖学的浮彫に対応するように事前に形成されている。例えば、それは、創傷被覆要素が肘、尻、または膝の区域に適用されるとき、有効であろう。深絞りする工程は、例えば、前述の身体位置の解剖学的浮彫に対応するように創傷被覆要素の事前形成を可能なものにしている。
【００１４】
また好ましくは、創傷被覆要素は、一定の身体位置の動きに順応できるように具体化されている。これらの目的のため、例えば、創傷被覆要素および気密性の閉鎖物は、弾性的であるように具体化されていてもよい。更に、ひだ付き配列物、または一つまたは幾つかのストレッチベローズ（伸縮する蛇腹）を備えてよい。
【００１５】
前述の実施態様では、前述の気密性の閉鎖物は、これらの悪化条件下においてすら、その気密特性を維持するであろうことは、特に重要である。
【００１６】

好ましくは、前述の気密性の閉鎖物は、連結シールの形態で具体化されている。以下において、「連結シール」の概念は、さねはぎ原理に従って機能するすべての種類の開示された連結シールを指す。

【００１７】

これらの目的のため、シールによって互いに接続されるべき両方の部分は、シールを適用したとき相互に噛みあうリップを特徴として有する。好ましくは、これらのリップは、合成もしくは天然ゴム、ポリエチレン、またはポリプロピレン等の弾性的材料からなる。

【００１８】

このようなシールは、例えば、飛行機旅行の間の化粧品運搬用の再封可能な機内持ち込みポーチ、冷凍食品保存用の再封可能な保存バッグ、または再封可能な保存箱（「タッパーウェアー」）から公知である。

【００１９】

前述の連結シールは、「ジップロック」、「ミニグリップ」、すなわち滑り封止物の仮名でも知られている。後者の場合、滑動部を備えることができ、滑動部はジッパーの様にシールされるべきリップに沿って滑り、またリップをシールされた位置に動かす。

【００２０】

いわゆるバルジロックは、例えばＷＯ０３０１３９７６Ａ１に記載されているように、「連結シール」の概念の中に包含される。

【００２１】

前述のシールは、窓が閉じられた位置にあるとき開放可能な前記窓の気密性の閉鎖物として適していること、および更に、これらシールは低い高さおよび軽い重量を有しているか、または必要としていること、ならびにシールを閉めたりまたは開けたりするためにほんの少しの力しか必要としないことも、重要である。このようにして、患者を苦痛に曝すことなく、開閉を行うことができる。

【００２２】

後者は、例えば滑動部を用いる実施態様（図９および明細書を参照）、または舌および溝オプションを用いる実施態様（図４および明細書を参照）によって達成できる。

【００２３】

前述の実施態様の代替物として、前記気密性の閉鎖物は、磁性シールの形態で具体化されていてもよい。これらの目的のため、可撓性の強磁性細片が特に備えられていてもよい。前述の磁性シールは、操作性に関して同様の利点を特徴として有する。磁性シールは、同様に、気密な形態で具体化されていてもよい。磁性シールは、また前述の悪化条件下においてもなお、その気密性を維持するように、技術的に具体化されていてもよい。

【００２４】

前述の実施態様の代替物として、前記気密性の閉鎖物は、接着性シールの形態で具体化されていてもよい。これらの目的のため、２枚の薄片はシール帯域において互いに貼り付けられる。開用の紐によって、第一の薄片を第二の薄片から容易に分離することができ、これは凹所に一体化された接着層を露出する。下のシートは、ポリエステルの支持層、感圧性の接着層、および一体化された移動障壁を有するシール層から成る。強度は２００と５００μｍとの間である。前述の接着性シールは、例えば、ＥＰ２０６７７１７から公知であり、操作性に関して同様の利点を特徴として有する。接着性シールは、同様に、気密な形態で具体化されていてもよい。接着性シールは、また前述の悪化条件下においてもなお、その気密性を維持するように、技術的に具体化されていてもよい。

【００２５】

前述の実施態様の代替物として、前記気密性の閉鎖物は、舌部と溝部のシールの形態で、恐らくは内部のシールリップを特徴として、具体化されていてもよい。前述の舌部と溝部のシールは、操作性に関して同様の利点を特徴として有する。舌部と溝部のシールは、同様に、気密な形態で具体化されるであろう。舌部と溝部のシールは、また前述の悪化条件下においてもなお、その気密性を維持するように、技術的に具体化されていてもよい。

【００２６】

前述の実施態様の代替物として、前記気密性の閉鎖物は、ゴムシールまたはゴムチューブの形態で、恐らくは加圧手段を伴って、具体化されていてもよい。前述の実施態様の代替物として、前記気密性の閉鎖物は、コルク細片の形態で、恐らくは加圧手段を伴って、具体化されていてもよい。

【００２７】

この加圧手段は、例えば、ブラケットとして、または前述の舌部と溝部のシールとして、具体化されていてもよい。

【００２８】

前述の実施態様の代替物として、前記気密性の閉鎖物は、接着性シールの形態で、例えば、好ましくはフィルムまたは塗布物の形態でフレーム側面または窓側面に付けられた低接着性シリコーン接着剤によって、具体化されていてもよい。アクリル接着剤も同様に用いられていてよい。好ましいシール特性および接着特性とは別に、これらは生理学的に安全であるという利点を有する。

【００２９】

好ましくは、創傷被覆要素を、接着性材料によって患者の皮膚に取り付けることができる。これらの目的のために、あらゆる種類の生理的に受け入れられる接着剤、特に医学グレードの接着剤を使用できる。特に好ましいのは以下を含む群から選択される材料である：

・アクリル接着剤
・シリコーン
・親水コロイド接着剤
・酸化亜鉛接着剤、および／または
・ラテックス接着剤。

【００３０】

親水コロイド接着剤は、一般に、自己接着性物質に塗布される薄いポリマーフィルムから成る。担体物質（合成ゴム種等、例えばポリイソブチレン）は膨潤粒子を含有し、これら膨潤粒子は製造者に依存して、様々である。しばしば、カルボキシメチルセルロースまたはカルボキシメチルセルロースナトリウム等の膨潤粒子が含まれる。更に、これら膨潤粒子は、特に暖かいとき、非常に展性がある。親水コロイド接着剤は、表面に組み入れられるのに適しており、特に湿気を除くことができる。これらはペースト形態で入手でき、パネルまたは細片形態でも入手できる。

【００３１】

似たようなことがシリコーン物質に当てはまる。皮膚に対する接着度は、これらの物質で調節可能であり、それゆえに、接着性にかかわらず創傷被覆材の非外傷性の交換が確実に可能である。

【００３２】

好ましくは、このようなシリコーン接着剤は、分離できる自己接着性の積層体の形態で具体化でき、積層体は、例えばシリコーンゲルの形態で疎水性ゲルが塗布されている創傷対向側、および、例えばアクリル接着剤の形態で接着剤を担持する創傷から離れて対向する側、を有する構造層を含む。このような層の一つが、例えばＥＰ２００１４２４Ｂ１に説明されていた。

【００３３】

好ましくは、前記接着性材料は、接着性端部として「縁取り包帯」の形態で具体化され、これは 創傷被覆要素を周辺的に囲む。

【００３４】

前記接着性材料は、創傷被覆要素が距離を隔てて位置するパネルまたは細片の形態で具体化されていてもよい。この実施態様では、前記パネルまたは細片は、中央の開口を特徴とし、これは傷の上部に配置されることが意図されている。この実施態様では、前記パネルまたは細片はフレームの形状をとる。あるいは、前記パネルまたは細片は、形状に関して傷の輪郭に対応して、窓がパネルまたは細片に切り込まれていてよいように、具体化さ

れていてもよい。これらの目的に対して、傷の輪郭をその上に描き、次いで一対のはさみで切り出してよい。あるいは、テンプレートを用いてよく、テンプレートにより傷の輪郭をパネルもしくは細片に転写することができ、またはテンプレートにより傷の輪郭（に対応する開口）をパネルもしくは細片から切り出すことができる。

【００３５】

前記パネルまたは前記フレームは、例えば、ここに説明した通り親水コロイド材料から成る。前記細片は、例えば、いわゆる切り込み薄片から成り、切り込み薄片は高分子材料から作製された自己接着性薄片である。

【００３６】

あるいは、前記パネルまたは前記フレームは、発泡材および／またはスペーサー布から成る。好ましくは、これは気密性被覆に組み込まれる。前述の接着剤が、皮膚対向側に塗布されていてもよい。

【００３７】

更に好ましくは、このデバイスは創傷の滲出液を取り出す吸収要素を特徴として有する。

【００３８】

この吸収要素によって、負圧治療により生じた全ての創傷滲出液を外部のキャニスターに導く必要がないこと、および少なくともその一部は創傷空間に残ること、を確実にすることが可能なものとなる。滲出液は、次いで吸収要素の単なる交換によって除去され、かつ、それが吸収要素に結合しているので、それを滲出液キャニスターよりも容易、かつ衛生的な方法で廃棄できる。

【００３９】

その結果、外部キャニスターなしで済ませる可能性には、追加的な利点がある。例えば、このデバイスは、患者の可動性を維持する（患者が自分のベッドを離れ、かつ日課を遂行することができる）ように具体化されていてもよい。

【００４０】

更に好ましくは、吸収要素は少なくとも一つの超吸収物質、変性セルロース、発泡材、および／またはアルギン酸塩を特徴として有する。

特に好ましくは、吸収要素は、セルロース繊維を含むフリースも特徴として有する。

【００４１】

超吸収ポリマー類（ＳＡＰｓ）は、それら自身の重量の多重倍、それらの自身の重量の１０００倍、までの流体を吸収可能な合成材料である。化学用語では、これらはアクリル酸（プロペン酸、$C_3H_4O_2$）とアクリル酸ナトリウム（アクリル酸由来のナトリウム塩、$NaC_3H_3O_2$）とのコポリマーであり、そのコポリマーにおいては、二種のモノマー間の相互関係は変化していてよい。更に、いわゆるコア架橋剤（ＣＸＬ）はモノマー溶液に添加され、形成された長鎖ポリマー分子をところどころ、化学的橋によって連結する。これらの橋の結果、ポリマーは水に不溶になる。水または食塩水溶液がポリマー粒子に浸透すると、粒子は大きく膨潤し、分子レベル結合のこの網状組織を引き伸ばし、水はもはや助け無しに漏れ出すことができなくなる。超吸収ポリマーは、本発明に係る創傷ケアデバイスにおいて、顆粒、紛体、充填剤、ペレット、発泡体の形態で、繊維、または繊維構造、マット、フリース、および／または繊維塊の形態で用いることができる。

【００４２】

好ましくは、変性セルロースはセルロース誘導体であり、好ましくはスルホアルキルセルロースとその誘導体、好ましくはスルホン酸エチルセルロース、カルボキシアルキルセルロース、好ましくはカルボキシメチルセルロース、カルボキシエチルセルロース、および／またはカルボキシプロピルセルロース、スルホエチルカルボキシメチルセルロース、カルボキシメチルヒドロキシエチルセルロース、ヒドロキシプロピルメチルセルロース等のより複雑なセルロース誘導体、およびカルボキシメチルセルロースアミドまたはカルボキシプロピルセルロースアミド等のアミド化セルロース誘導体である。カルボキシメチルセルロースは、特にカルボキシメチルセルロースナトリウムの形態で入手でき、「水性繊

維」として市販品を入手できる。衛生および創傷ケア用品において、繊維は平らなマトリクスで使用される。創傷滲出液由来の流体の吸収によって、繊維は、流体を保持しかつ放出しないゲルピローに徐々に変わる。繊維は、創傷滲出液を垂直方向でのみ吸収するように構成されている。これは、容量が十分である限り、滲出液は傷の端を超えて流れないことを意味する。これによって、傷の端の浸軟を効果的に妨ぐことが可能になる。

【００４３】

前記水活性ポリマーは、アルギン酸塩であってもよい。アルギン酸塩は褐色藻類から導かれ、そして繊維質フリースに織り込まれる。化学的には、これらは多糖類であり、具体的にはアルギン酸のカルシウム塩および／またはナトリウム塩である。アルギン酸塩は流体中でそれらの自身の重量の２０倍まで吸収することができ、創傷滲出液は中空の空間に蓄えられる。アルギン酸塩格子中のCa^{2+}イオンは、アルギン酸塩がNa^{+}イオンで飽和されるまで、滲出液由来のNa^{+}イオンに交換される。これによって、創傷被覆材の膨潤と、繊維の膨潤によるアルギン酸塩繊維のゲル体への転換が引き起こされる。

【００４４】

前記水活性ポリマーは、２－ヒドロキシエチルメタクリレート（ＨＥＭＡ）および／または２－ヒドロキシプロピルメタクリレート（ＨＰＭＡ）等の、ヒドロキシ末端メタクリル系モノマーを含むヒドロゲルナノ粒子であってもよく、これらはAltrazealとして市販されている。

【００４５】

更に好ましい実施態様では、吸収要素は≧４０重量％の超吸収ポリマーを含有する。特に好ましくは、超吸収ポリマーの重量配分は、≧４５、５０、５５、６０、６５または７０重量％である。

特に好ましくは、吸収要素はセルロース繊維を含むフリースを特徴として有する。

【００４６】

好ましくは、吸収要素は、超吸収ポリマーが内部に分配された吸収性フリースから成る、吸収性材料で作製された本質的に平らな吸収要素を特徴として有する。これらは、顆粒、紛体、充填剤、ペレット、発泡体の形態で、繊維、または繊維織物、マット、フリースおよび／または繊維塊の形態で加わっていてもよい。

【００４７】

吸収要素は、マット、特に、取り込まれた超吸収ポリマーを伴う超吸収ポリマーの前記糸もしくは繊維で作製されたエアレイド、および／または超吸収ポリマーの緩い充填物を含む群から選ばれる少なくとも一つの材料を特徴として有する。好ましくは、前記エアレイドマットは、例えば超吸収ポリマーを取り込んだ前述の繊維由来の吸収性フリースから成る、吸収性材料で作製された本質的に平らな材料部を特徴として有する。

【００４８】

この吸収要素は、例えばＷＯ０３０９４８１３、ＷＯ２００７０５１５９９、およびＷＯ０１５２７８０に開示された、および「sorbion sachet」の商品名で市販されている、本発明の出願人の創傷被覆材に含まれる吸収性挿入物に対応していてよい。前述の文献の開示内容は、その全範囲において、本文献の開示内容に加えられる。

【００４９】

異なる実施態様では、吸収要素は、多分柔毛性の、超吸収ポリマーからなる繊維または糸、および顆粒の形態の超吸収ポリマーを含むコアを形成していてもよく、顆粒が種々の濃度で繊維もしくは糸に貼りつけられ、または溶着させられ、ならびに顆粒が、顆粒および繊維が混合されている区域を含有するコアの少なくとも一部分の高さ全体の５０％を超えて分配されていてもよい。好ましくは、超吸収ポリマーの割合は１０～２５重量％の範囲である。類似の構造体が従来の失禁用材料から公知であり、これらは生理用ナプキンの緩衝特性に類似の緩衝特性で公知である。前記コアは、いくつかの区域でそれと重なる被覆で囲まれていてよく、またその被覆は接着性縫い目を覆っていてもよく、またはそのようなものの一部であってよい。

【００５０】

特に好ましくは、吸収要素は超吸収性繊維類（「ＳＡＦｓ」、好ましくはポリアクリレート）から成る、またはそれらを成分として含有する、フリース、好ましくは不織布もしくはエアレイドを特徴として有する。上記繊維は綿毛パルプ（セルロース）またはポリエステル繊維と混合してもよく、例えば、代わりにまたは加えて、積層構造で特徴付けられる。

【００５１】

【表１】

型	1	2	3	4	5	6
構造１	層状構造:ラミネート不織布を有する熱結合したエアレイド	短く切られたポリエステル繊維 40%; SAF60%	SAF と熱可塑性材料との二成分繊維	層状構造:ラミネート不織布を有する熱結合したエアレイド	ポリエステル 25%; SAF75%	短く切られたポリエステル繊維 40%; SAF60%
構造２	SAF と熱可塑性材料との二成分繊維+綿毛パルプ	ニードルフェルト	毛羽立て熱結合した不織布	SAF と熱可塑性材料との二成分繊維+綿毛パルプ	ニードルフェルト	ニードルフェルト
SAF 繊維型	101/6/10	102/52/10	102/52/10	101/6/10		
重量(g/m²)	560	540	1000	350	150	380
厚さ(mm)	6	5.4	20	3.5	2.4	3.8
吸収容量	31.2l 水/m²	> 20 g 水/g	> 16 g 水/g または 16,000g 水/m²	19.5l 水/m²	> 25 g 0.9% 食卓塩/g	> 17 g 水/g または 6,400 g/m²
圧力下吸収容量 (0.2 psi の圧力での ml 0.9% 食卓塩/m²)	16			16		
超吸収ポリマーの全含有量 (% w/w)	18	40	50	18	75	60
引っ張り強度 (N/5 cm)					16 ± 13	16 ± 13
弾性率(%)					60 ± 18	60 ± 18

【００５２】

もう一つの実施態様として、吸収要素は、顆粒状の超吸収ポリマーが貼りつけられた超

吸収ポリマーからなる繊維または糸を含む少なくとも一つの平らな層も含んでいてもよい。これにより、２つの被覆層が超吸収ポリマーを含む一つの層を取り囲む、少なくとも３層を含む本体の構造の好ましい実施態様が得られる。

【００５３】

ここで、一つの濃度での繊維と超吸収ポリマーの混合物は存在せず、それら２つの材料の隣接配置が存在するだけである。好ましい実施態様では、追加的な層は、もし設けられるなら、回転、加圧、カレンダリング、または類似の手順によって、互いに、物理的にぎっしりと詰められていてもよい。

【００５４】

【表２】

型	1	2	3	4	5	6	7	8
重量(g/m²)	450	300	150	50	100	120	140	440
厚さ(mm)	1.3	1.2	0.9	0.7	0.7	0.76	1	1.2
流体保持率(g/g)	28	33	28	15	25	28	11.5	38
引っ張り強度(n/5cm)	25	55	20	20	20	20	15	20
吸収容量(g/g)	45	20	50	20	40	50	28	55

【００５５】

更に、この本体は、チェックのパターン、穴開けパターン等の、繰り返しパターンまたは繰り返し織地を特徴として有していてよい。

【００５６】

特に好ましくは、前記吸収要素は、表面の大きさが、５×５、５×１０、５×２０、１０×１０、１０×１５、１０×２０、１５×１５、２０×２０、または２０×４０cmの特徴を有する。

【００５７】

特に好ましくは、前記吸収要素は、超吸収ポリマーを含む層に加えて、少なくとも第二の隣接層を含み、この第二の隣接層は超吸収ポリマーを含まないか、超吸収ポリマーを含む量が少なく、また、その表面は前者の層を超えて延びている。このようにして、超吸収ポリマーを含む層は、この層が第二の層によって隠されているため、体積増加が外部から見えることなく、流体を吸収する結果として体積を得ることができる。

【００５８】

発泡材は、閉じたまたは開いた孔を有する発泡材であってよい。好ましくは、これらの材料は同様に平らな層として具体化され、一方では流体吸収性を特徴として有し、他方では緩衝特性を特徴として有する。これらは更に高い復元力によって特徴づけられる。

【００５９】

特に好ましくは、コールドフォームとして知られる種類の発泡体が用いられる。

前記発泡体の代わりにまたは前記発泡体に加えて、SNS Nano Fiber社が製造したもの等の、いわゆる「ナノファイバーマトリクス」も同様に用いられてよい。

【００６０】

更に、前記発泡体は、Smith & Nephew社のAllevyn Plus製品等の、超吸収材も含有していてよい。

更に好ましくは、デバイスは、流体浸透性の創傷対向創傷接触格子も含有する。

【００６１】

好ましくは、この様な創傷接触格子は、合成材料（好ましくは、例えば、シリコーン材料またはナイロン材料を含む）、穿孔された発泡材、スペーサー布、および／または穿孔された薄片で作られた格子である。

【００６２】

好ましくは、商品名「sorbion plus」で市販され、ＥＰ２００４１１６Ａ１に記載され

ている格子のような、三次元の創傷接触格子が設けられる。

【００６３】

創傷接触格子は、一方では、フレーム中では緩やかに、またはフレームに固定されて、傷対向側に配置されていてもよい。

【００６４】

このような創傷接触格子は顆粒形成を防ぎ、それ故、創傷被覆材の非外傷性交換を可能にする。創傷接触格子は更に、生物フィルム溶解効果ならびにバルブ効果を有し、これにより滲出液の還流が減少する。

【００６５】

出願人は、「非活性」創傷被覆材から公知であるこれらの特性は、ここに記載された「活性」真空支持創傷被覆材にも特に有利であることを実証できた。

【００６６】

創傷接触格子は、被覆側にも配置されていてもよい。このようにすることにより、創傷接触格子は、超吸収ポリマーを含む介在吸収要素によって、流体吸収の結果としてこれらがゲルを形成するときに、引き起こされ得るゲルブロッキングを防ぐことができ、上記ゲルは、さもなければ、流体吸引工程を妨害するであろうものである。

【００６７】

原則として、前述の流体媒体の吸引用の接続デバイスは、流体および／または気体の吸引を可能にするように具体化することができる。これらの目的のため、これは、ホースおよび／またはポンプの接続を可能にするカップリング（Luer-Lockシステムにおけるような）の形態で具体化されていてもよい。

【００６８】

その製品は、追加のバルブ、減圧器または開放可能な追加の窓をも、更に含んでいてよい。これにより、デバイスは、例えば、病院で頻繁に見ることができる真空壁ポートにつながれる場合のような、過度に強い負圧においてすら、使用可能となる。前記バルブ、減圧器または窓は、その後、負圧を減少させるために開放可能である。

【００６９】

更に好ましくは、流体媒体の吸引用の接続デバイスの領域に、流体不浸透性の障壁が設置される。

これは、どんな流体もポンプ中に入らないことを確実にするためである。後者は、創傷被覆の内部に残り、創傷滲出液を取り出す吸収要素によって吸収される。

好ましくは、前記障壁は、半浸透性膜、例えば、Goretex等の材料で作ったものを含む。

【００７０】

好ましくは、流体媒体の吸引用の一つの接続デバイスと、気体媒体の吸引用の一つの接続デバイスを設けることができる。

【００７１】

更に好ましくは、デバイスは負圧雰囲気の生成のための設備も含む。

前記の負圧雰囲気を生成させる設備は、好ましくは、以下を含む群から選択される：

ａ）電気的に操作される真空ポンプ

ｂ）手動で操作される負圧源、および／または

ｃ）減圧真空容器。

【００７２】

前記真空ポンプは単独のポンプであってよいが、クリニックでしばしば用いられるような、集中化真空化システムの一部であってもよい。病室には、しばしば真空壁ポートが取り付けられ、その壁ポートには発明された創傷治療用ドレナージデバイスを接続できる。この場合、前記真空ポンプは、本発明に係る創傷治療用ドレナージデバイスの多数に負圧をかけることができる。

【００７３】

好ましくは、この真空ポンプは、大きさおよび／または重量が、多少なりとも患者を煩

わせることなく、または妨害することなく、容易に前述のタイプの創傷被覆要素に適用できるような、マイクロポンプである。

【００７４】

例えば、このポンプは、ピエゾまたはメンブレンポンプである。特に好ましくは、ピエゾポンプであり、このピエゾポンプは、ポンピング容量がピエゾ電気要素によって引き起こされるポンプである。これらのポンプは、その小さいサイズにもかかわらず、十分に高いポンピング容量を有している。これらは更に操作音が低く、かつエネルギー消費が低い。あるいは、これらのポンプは、マイクロシステム技術推進体駆動真空ポンプであってもよい。このタイプの適切なポンプは、例えば、Schwarzer Precision、KNF、またはBartels Mikrotechnikによって製造されている。

【００７５】

好ましくは、このようなポンプはチェックバルブを備え、このチェックバルブによって、形成された負圧を再び低下させる操作休止の間、リークの発生なしに、ポンプを、インターバルモードで、または初期にのみ負圧を発生させるために、または負圧を維持するためだけに、操作することが可能となる。

【００７６】

好ましくは、前記ポンプは、－６０～－２００mmHgの負圧を発生させることができる。特に好ましくは、ポンプは－６０、－７０、－８０、－８５、－９０、－１００、－１１０、－１２０、－１３０、－１４０、－１５０、－１６０、－１７０、－１８０、－１９０または２００mmHgの負圧を発生させることができる。

【００７７】

好ましくは、ポンプは流体を輸送できるように選択または備えられている。

【００７８】

好ましくは、ポンプの操作音は６５dBの音圧レベルを超えない。特に好ましくは、音圧レベルは６３dB、６０dB、５８dB、５５dB、５３dB、５０dB、４８dB、４５dB、４２dB、４０dB、３８dB、３５dB、３２dB、３０dB、２８dB、２５dB、２２dB、または２０dBですら超えない。

【００７９】

好ましくは、ポンプは０．５ml・min^{-1}と１００ml・min^{1}との間の輸送速度を特徴として有する。好ましくは、輸送速度は２ml min^{-1}と５０ml・min^{1}との間である。特に好ましくは、輸送速度は１０ml・min^{-1}と２０ml・min^{-1}との間である。

【００８０】

前述の減圧容器は、既知のRedonボトルと類似のように、発明された創傷治療用デバイスに接続でき、かつ創傷治療用デバイスに負圧をかけることができる。前記減圧容器は、好ましくは内張りの形態の、流体吸収性ポリマーを含有する挿入物を含む。

【００８１】

特に好ましくは、前記減圧容器はカートリッジの形態で具体化することができ、これは発明された傷治療用ドレナージデバイスと既に接続されているマウント中に配置される。カートリッジが一杯のときは、カートリッジを取り除き廃棄することができ、そして新しい減圧カートリッジをマウント中に置くことができる。

【００８２】

前述した複数の実施態様は特に有利である。なぜなら、これら実施態様によって、自身のポンプの必要性がなくなり、その代わりに減圧容器が用いられることになるからであり、これによって、デバイスが可動的になり、かつ電力網から独立し、その結果、患者自身が移動可能になる。更に、これにより、より小さい構成物が可能になり、患者はデバイスを個々に隠すことが可能になる。この点で特に有利なのは、前記減圧容器またはマウントの、解剖学的に調整された実施態様であり、これによって、例えば脚の上に、それらを目立たずに運ぶことが可能になる。

【００８３】

更に、このようなデバイスは、操作音を発せず、また操作が非常に容易である。

【００８４】
同様なことが、前述の手動操作負圧源に当てはまる。最も簡単な実施態様では、この負圧源は十分に大きい容積があるプラスチック注射器であってよい。他の選択可能物はゴムボール、ベローズ等の形状のポンプである。
【００８５】
更に好ましくは、負圧雰囲気を発生させる設備は創傷ケアデバイス上に直接配置されている。
【００８６】
このことは、例えば、前記設備を直接創傷被覆要素上に配置することにより達成可能である。このようにして、製造上の課題（真空条件下で圧壊しないようにするための、十分な剛性）および衛生上の問題（汚染の危険性）を包含する別個の真空ホースを、除去することができ、または非常に短く保つことができる。
【００８７】
更に好ましくは、カップリング、ブロッキングバルブ、および／または三方バルブは、負圧雰囲気を発生させるための設備と、創傷被覆要素または創傷滲出液を取り出す吸収要素との間に配置されている。
【００８８】
このデバイスは、ａ）負圧雰囲気を発生させるための設備は、デバイスのテストから接続を切ることができる、ｂ）一旦発生させられた負圧は、可能な限り最長時間維持することができる、および／またはｃ）電池を節約する目的で、または電池が空のとき、外部のポンプまたは外部の真空容器を使用して、負圧を発生または回復させることができる。
【００８９】
前記外部のポンプまたは前記外部の真空容器は、例えば、クリニックの中で、または患者の家で、固定されていてよいが、可動形態で具体化されてもよい（例えば、スーツケースの形態で、または患者の衣類に一体化されて、または患者のベルトに取り付けられて）。これは、創傷上のデバイスが小さく目立たないままであることを確実にするためであり、その理由は、その主要な任務が、真空を維持することであるが、効果的な治療を可能にするために必要に応じて、十分なポンピング容量を提供することだからである。
【００９０】
更に好ましくは、吸収要素は流体浸透性のカバーで囲まれている。好ましくは、デバイスは更にスペーサーを含む。好ましくは、このスペーサーは創傷と創傷被覆要素との間に配置されるが、該当する場合、吸収要素と創傷被覆要素との間、または創傷と吸収要素との間にも置かれる。このようなスペーサーは、負圧がかけられたときに、確実に創傷ケアデバイスが全体的に圧壊しないようにする。圧壊してしまうと、デバイスが、結果的に気体または流体を抽出できなくなるからである。
【００９１】
更に好ましくは、デバイスは重金属、好ましくは、銅もしくは銀、またはこれらの一つを含有する塩を含む層を特徴として有する。具体的には、創傷上での適用期間が延びた場合に、層は細菌の成長を遅らせるので、このような層は大変役立つものとなり得る。
【００９２】
更に好ましくは、創傷被覆要素は流体および／または気体に対して不透過性である。これによって、真空の適用が可能となり、創傷被覆要素はその状況で汚染されている可能性のある流体の漏れを防ぐことになる。
【００９３】
好ましくは、前記創傷被覆要素は弾性材料で具体化される。これらの目的で、創傷被覆要素は、例えば、ポリプロピレン、ポリエチレン、ラテックス、シリコーン、またはゴムから成る。更に、創傷被覆要素は、内側に発泡材が取り付けられていてよい。
【００９４】
更に好ましくは、創傷被覆要素は水蒸気に対して透過性である。好ましくは、更に、創傷被覆要素は透明性をもって具体化される。

【００９５】
更に好ましくは、負圧雰囲気を発生させるための設備のポンピング方向は反転可能である。これによって、設備を、薬物、洗浄溶液等用の制御可能な投薬ポンプとして使用することが可能となる。
【００９６】
更に好ましくは、前記開放可能な窓は、非弾性的バックパネルを特徴として有する。ここにおける「バックパネル」の概念は、例えば、符号Ｎｏ．２３によって示されたようなカバーを意味する。この実施態様では、例えば、前述のポンプは、開放可能な窓のバックパネル上に直接配置することができる。
【００９７】
更に好ましくは、前記開放可能な窓は、弾性的バックパネルを特徴として有する。この態様では、例えば、バックパネルは、滲出液の吸収の結果起こる、内在吸収要素の体積増加を引き起こすように、具体化されていてもよい。これによって、気密性を保証するために窓が患者の動きを追随することが確実となる。
【００９８】
好ましくは、この弾性的バックパネルはシリコーン材料を特徴として有するか、またはそのような材料で作られる。特に好ましくは、例えば、バックパネルの下側、言い換えると、患者対向側は、シリコーンおよび／または発泡材で覆われ、またはそのような材料の上端に存在している。
【００９９】
更に好ましくは、前記開放可能な窓は、可塑性の可鍛性材料で作製されたバックパネルを特徴として有する。
【０１００】
この実施態様では、例えば、バックパネルは熱可塑性的に可鍛性の深絞り薄片から成っていてよい。これによって、例えば、その中に予備の吸収要素が準備され得る貯蔵器の作製が可能となる。
【０１０１】
好ましいのは、更に、軟組織の欠陥、外科的創面切除後の感染した創傷、リンパ系瘻孔、胸骨の傷感染症、胸壁孔、床ずれ、静脈性潰瘍、慢性的傷癒合障害、放射線潰瘍、腹部隔室症候群、敗血性腹腔、腸管瘻孔、および／または一つまたは幾つかの浮腫に起因する創傷、を含む創傷治療のための、皮膚移植の固定のための、傷の状態調節のための、ならびに／または縫い目および切開の手術後のケアのための、創傷ケアデバイスの適用である。
【０１０２】
更に、傷圧縮系における、先行する請求項の一項に係る創傷ケアデバイスの適用が考案されている。
【０１０３】
イメージ
図１は、患者の皮膚に取り付けることが可能な創傷被覆要素３、および流体媒体の吸引用の接続デバイス（図示せず）を含む、創傷領域を負圧雰囲気にして創傷を治療するための創傷ケアデバイスの一般原理を示す。創傷被覆要素は、開放可能な窓２３を特徴として有し、これは創傷被覆要素上の気密性の閉鎖物（図示せず）によって位置決めされている。窓２３を開いた後、創傷被覆材２を容易に取り除き、廃棄し、および別の創傷被覆材で置換えることができる。
【０１０４】
図２は、フレーム１２、フレーム１２と窓カバー４６との間の接続紐３６、および連結シール１８，４０として具体化された気密性の閉鎖物を含む、開放可能な窓１０を示す。
【０１０５】
図３中に、前記連結シール１８、４０の断面を詳細に示す。
【０１０６】

図４も、連結シール４２、４３で、開放可能な窓を示す。前述の連結シールは、舌と溝のオプションを特徴として有し、これによって連結シールの閉または開は軽度の力しか必要ないことが確実になる。このようにして、開または閉は、患者を苦痛に曝すことなく実行できる。更に、シールは低い高さと低い重量で特徴づけられる。

【０１０７】

図５ａは、ジッパーに類似してシールされることになるリップに沿って滑り、かつこれらをシールされた位置に動かす、滑動部３８の形態で、本発明と共に使用することができる連結シールの異なる形態を示す。

【０１０８】

図５ｂは、接着性シールの形態の気密性の閉鎖物を示す。

【０１０９】

図６は、患者の皮膚に取り付けることが可能な創傷被覆要素６１、および流体媒体の吸引用の接続デバイス６２を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイス６０を示す。創傷被覆要素は開放可能な窓６３を特徴とし、この窓は創傷被覆要素上の気密性の閉鎖物によって位置決めされている。

【０１１０】

創傷被覆要素は、更に、接着性材料６５を含む周囲の縁６４を特徴として有する。これは、いわゆる「縁取り包帯」の実施である。

【０１１１】

図７は、患者の皮膚に取り付けることが可能な創傷被覆要素７１、および流体媒体の吸引用の接続デバイス（図示せず）を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイス７０を示す。創傷被覆要素は開放可能な窓７３を特徴とし、この窓は気密性の閉鎖物によって創傷被覆要素上に位置決めされている。

【０１１２】

デバイスは、パネルまたはフレーム７４を特徴として有し、その上に距離を隔てて創傷被覆要素が配置されている。この実施態様では、前記パネルまたは細片は、例えば、創傷の上方に配置される、中央開口を特徴として有していてもよい。この実施態様では、前記パネルまたは細片は、フレームの形態をとる。あるいは、前記パネルまたは細片は、窓が、傷の輪郭の形状に対応するパネルまたは細片に切られるように具体化されていてもよい。前記パネルは、例えば、ここに記載された親水コロイド材料から成り得る。前記細片は、例えば、上記したように切開薄片から成り、これはポリマー材料で作った自己接着性薄片である。

【０１１３】

図８は、患者の皮膚に取り付けることが可能な創傷被覆要素８１、および流体媒体の吸引用接続デバイス８２を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイス８０を示す。創傷被覆要素は開放可能な窓８３を特徴とし、この窓は気密性の閉鎖物によって創傷被覆要素上に位置決めされている。

【０１１４】

開放可能な窓には、耐圧性内張りが取り付けられ、超吸収ポリマーを含む吸収要素８４用の空間を与える。圧力耐性に起因して、吸収要素がその吸収容量を十分に利用できるように、開放可能な窓はつぶれない。

【０１１５】

更に、発泡材で作製された連続体８５、および三次元の創傷接触格子８６が、創傷対向側に備わっている。

【０１１６】

図９は、患者の皮膚に取り付けることが可能な創傷被覆要素９１、および流体媒体の吸引用接続デバイス９２を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイス９０を示す。

【０１１７】

創傷被覆要素は、開放可能な窓９３を特徴として有し、この窓は気密性連結シール９４

によって創傷被覆要素上に位置決めされている。前述の連結シールは、「Ziplock」、「Minigrip」またはスライディングクロージャーの仮名でも知られている。これらは高さが低く、重さも軽く、またこれらは閉または開に対してほんの軽度の力しか必要としない。

【０１１８】

開放可能な窓９３の下に、耐圧性内張りを有する区画９８が考案されており、これによって超吸収ポリマーを含む吸収要素９５に対する空間が提供される。前記区画は、流体に対して透過性なので、創傷対向側に具体化されている。圧力に対する抵抗によって、吸収要素がその全吸収容量を利用できるように、開放可能な窓はつぶれない。この容量に達したとき、この区画を包含する窓全体およびその中に含まれる吸収要素を廃棄し、新しいものと交換できる。

【０１１９】

更に、発泡材で作製された連続体９６、および三次元創傷接触格子９７が創傷対向側に設けられている。区画９８以外の連続体は、圧力に対して抵抗性ではなく、それ故、圧力が増加すると体積を減らす。

【０１２０】

図１０は、患者の皮膚に取り付けることが可能な創傷被覆要素１０１、および流体媒体の吸引用接続デバイス１０２を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイス１００を示す。

【０１２１】

創傷被覆要素は、開放可能な窓１０３を特徴として有し、この窓は気密性連結シール１０４によって創傷被覆要素上に位置決めされている。前述の連結シールは、「Ziplock」、「Minigrip」またはスライディングクロージャーの仮名でも知られている。これらは高さが低く、重さも軽く、またこれらは閉または開に対してほんの軽度の力しか必要としない。

【０１２２】

更に、吸収要素１０５が考案され、これは窓を開いた後に取り除くこと、または挿入することが可能である。

【０１２３】

図１１ａは、患者の皮膚に取り付けることが可能な創傷被覆要素１１１、および流体媒体の吸引用接続デバイス１１２を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイス１１０を示す。

【０１２４】

創傷被覆要素は、開放可能な窓１１３を特徴とし、この窓は気密性連結シール１１４によって創傷被覆要素上に位置決めされている。前述の連結シールは、「Ziplock」、「Minigrip」またはスライディングクロージャーの仮名でも知られている。これらは高さが低く、重さも軽く、またこれらは閉または開に対してほんの軽度の力しか必要としない。

【０１２５】

開放可能な窓１１３の下に、格子１１５が備えられており、これは、例えば超吸収ポリマーを含んでもよい吸収要素（図示せず）に対する空間を提供する。前述の吸収要素は格子中に置くことができ、その後、開放可能な窓を連結シールによって被覆要素に取り付けることができる。窓が再度開かれたあと、例えばその全吸収容量に到達したあと、吸収要素を取り除いて、廃棄するまたは交換することができる。

【０１２６】

更に、追加の吸収要素１１６は創傷対向側に備えられており、これは、流体保持力の程度が先に挙げた吸収要素より低いことを特徴として有してよい。

【０１２７】

図１１ｂは、図１１ａ中のデバイスに類似のデバイスを特徴として有するが、吸収要素１１８が、創傷対向側で、開放可能な窓１１７に取り付けられている点が異なる。吸収要素１１８が、その全吸収容量に到達したとき、窓に取り付けられた吸収要素を含んだ窓全体を、廃棄し、新しいものと交換することができる。

【０１２８】
図１２は、患者の皮膚に取り付けることが可能な創傷被覆要素、および流体媒体の吸引用接続デバイス１２２を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイス１２０を示す。
【０１２９】
創傷被覆要素は、開放可能な窓１２１を特徴とし、この窓は取り囲んでいる排気可能なダクト１２３により創傷被覆要素上に位置決めされている。
【０１３０】
図１３は、接着性シールの形の気密性の閉鎖物の更なる実施態様を示す。
【０１３１】
図１４は、患者の皮膚に取り付けることが可能な創傷被覆要素、および流体媒体の吸引用接続デバイス（図示せず）を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイス１４０を示す。
【０１３２】
創傷被覆要素は、舌部と溝部のシール１４２によって創傷被覆要素に取り付けることができる、開放可能な窓１４１を特徴として有する。更に、取り囲んでいるゴムチューブ１４３が中間に設けられ、これは舌部と溝部のシールによって圧縮されて、気密性の閉鎖物を作りだしている。ゴムチューブの代替品として、ゴムシール、コルク細片または類似の物を備えることができる。
【０１３３】
更に、ヒンジ１４４が備えられ、このヒンジは、創傷被覆要素が折り返せるが、全体として除かれないように、一方の側で開放可能な窓を、創傷被覆要素と接続させる。
【０１３４】
図１５は、患者の皮膚に取り付けることが可能な創傷被覆要素、および流体媒体の吸引用接続デバイス（図示せず）を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイス１４０を示す。
【０１３５】
創傷被覆要素は、磁性シール１５２によって創傷被覆要素に取り付けることができる、開放可能な窓１５１を特徴として有する。更に、取り囲んでいるゴムチューブ１５３が中間に設けられ、これは舌部と溝部のシールによって圧縮されて、気密性の閉鎖物を作りだしている。ゴムチューブの代替品として、ゴムシール、コルク細片または類似の物を備えることができる。
【０１３６】
図１６ａは、弾性的薄片様要素８１および／または弾性的覆い８２、およびその傷の基部８４に滲出液８５を有する深い傷８３のある、吸収要素８０を伴う、発明された創傷ケアデバイスの配置を示す。図８中とは異なり、覆い８２は、少なくとも部分的に、例えば傷から離れて面する領域において、薄片様要素の不可欠な構成物であってよい。弾性的薄片様要素８１および／または弾性的覆い８２は、負圧をかけたとき、吸収要素が傷の基部８４に引きつけられ、または基部に押し付けられることができる（矢印で記したように）ことを確実にし、このことは、吸収されるべき滲出液８５と接触させるために、特に深い傷の場合、必要である。
【０１３７】
図１６ｂは、図１６ａ中の配置と類似の配置を示すが、より後での配置である。吸収要素８０は、既に大量の滲出液を吸収している。弾性的薄片様要素８１および／または弾性的覆い８２は、後者が、流体吸収による吸収要素の膨張の結果として妨害されることはないことを確実にする。これによって、吸収要素がその全吸収容量を発揮できることを確実にする。このとき、カップリング設備８６（および、それ故接続された負圧デバイス（図示せず））は、既に切り離されていてよく、または代替として、負圧デバイスはスイッチが切られ、もはや負圧をかけることはない。
【０１３８】

負圧をかけることが、吸収されるべき滲出液との接触を行うために、吸収要素を傷の基部８４に引きつけ、または吸収要素を基部に押し付ける目的だけに役立つようにも装備し得る。この接触が行われるとすぐに、真空デバイスは切り離され、またはスイッチが切られるように装備され得る。この

【０１３９】

更なる実施態様を図１７中に見ることができる。この実施態様では、発泡材本体は、負圧源用、例えばポンプ用の区画として特に設計された凹部を特徴として有して考案されている。好ましくは、チェックバルブ（図示せず）が連続的開口５７中に置かれている。前述の発泡材本体は創傷被覆要素（図示せず）によって覆われている。

【０１４０】

図１８は、本発明に係る創傷被覆要素のフレーム１８０を通り抜けた断面である。そのフレームは、例えば、その上にラミネートされた気密性ベース薄片１８２および気密性被覆薄片１８３中にラミネートされている、発泡材１８１から成っていてよい。前者は患者の皮膚への接触表面であり、および、例えば、ここでは他のどこかで塗布されたように、接着剤が塗布されていてよい。後者は開放可能な窓に対する支持表面を形成する。好ましくは、それは除菌可能なように具体化されていてもよい。

【０１４１】

図１９～２２は、発明された創傷ケアデバイスの具体的実施態様を示す。

【０１４２】

図１９は、例えば、生理学的に安全な接着剤によって、下にある薄片１９４を介して、患者の皮膚に取り付けることができるフレーム形態の創傷被覆要素１９１を含む、創傷領域の負圧雰囲気による創傷治療用創傷ケアデバイスを示し、創傷被覆要素は、気密性の閉鎖物、例えば低接着性シリコーン塗装によって創傷被覆要素上に位置決めされている開放可能な窓１９２を特徴として有する。創傷被覆要素は、例えば、気密性材料中にラミネートされた発泡材またはスペーサー布を特徴として有する。その窓は、例えば気密性薄片または塗装でシールされた発泡材またはスペーサー布を特徴とし得るベース層を特徴として有する。さらに、ポンプ１９３が示され、このポンプは流体媒体の吸引用接続デバイスを介して創傷ケアデバイスに接続されている。開放可能な窓１９２は、その材料中の凹部を特徴として有し、この凹部はポンプ１９３用の区画を形成する。

【０１４３】

ポンプ１９３は、図２０に見られるように、着脱可能なように具体化されている。

【０１４４】

図２１は、例えば、生理学的に安全な接着剤によって、下にある薄片２１４を介して、患者の皮膚に取り付けることができるフレーム形態の創傷被覆要素２１１を有する、創傷ケアデバイスの分解図を示す。創傷被覆要素２１１の発泡材またはスペーサー布２１５も示されている。

【０１４５】

図２１は、また、気密性の閉鎖物、例えば低接着性シリコーン塗装によって創傷被覆要素上に位置決めされている開放可能な窓２１２、および気密性薄片または塗装によってシールされている、窓の下にある発泡材またはスペーサー布２１６も特徴として示す。

【０１４６】

さらに、流体媒体の吸引用接続デバイスを介して創傷ケアデバイスに接続されているポンプ２１３、およびポンプ用区画を形成する窓の中の凹部を見ることができる。

【０１４７】

その上、創傷接触格子２１７が示され、創傷接触格子は、（ｉ）傷対向側、かつ緩くフレーム内側に配置され、もしくはフレームに接続されていてもよい、または（ｉｉ）被覆側、のいずれかに配置されていてもよい。

【０１４８】

図２２は、創傷領域の負圧雰囲気による、更なる創傷治療用創傷ケアデバイスを示し、その中でポンプは手動操作ポンプとして具体化されている。

【図１】

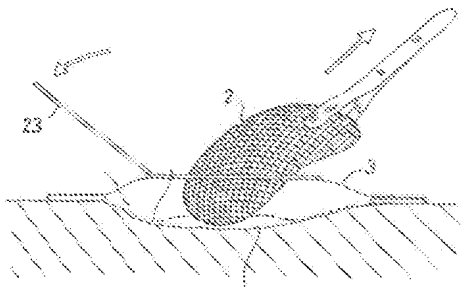

図１

【図２】

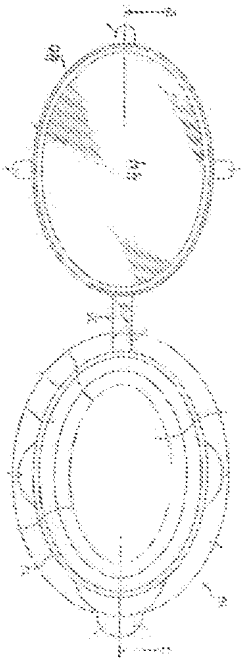

図２

【図３】

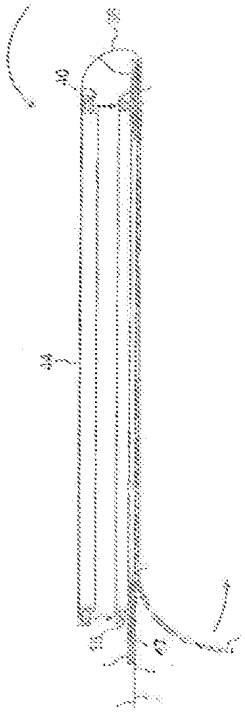

図３

【図４】

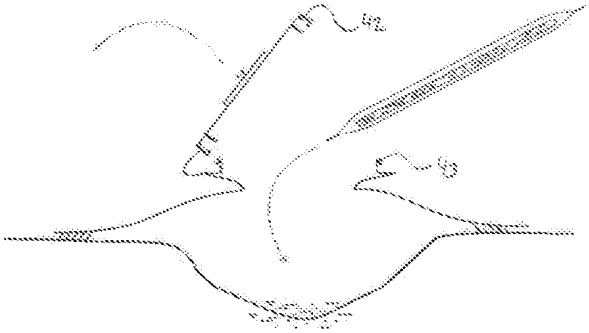

図４ａ

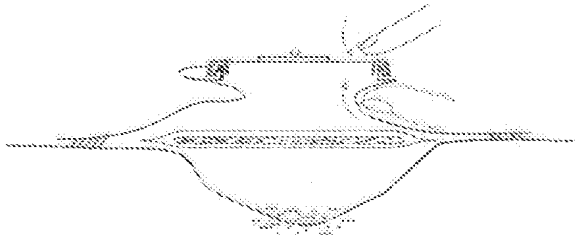

図４ｂ

【図５】

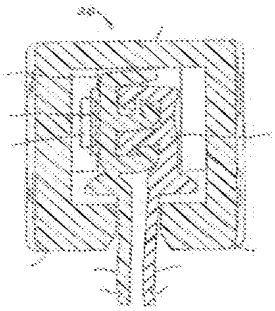

図5a

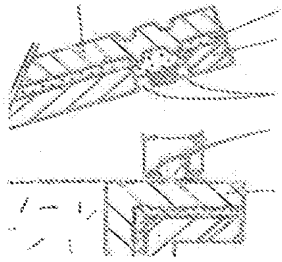

図5b

【図６】

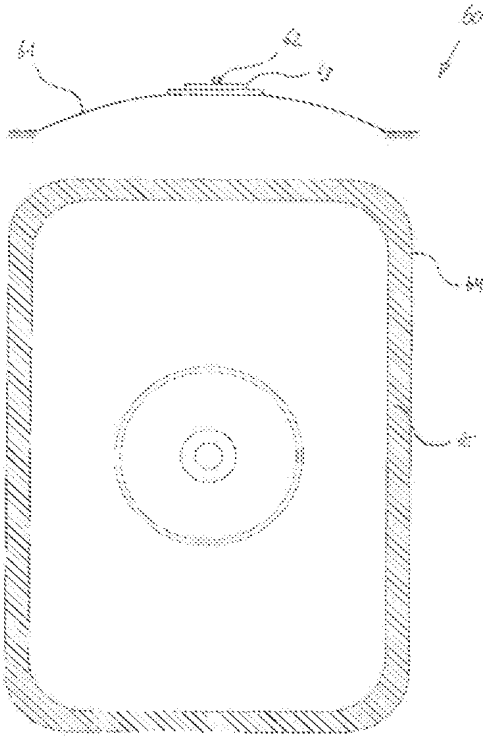

図6

【図７】

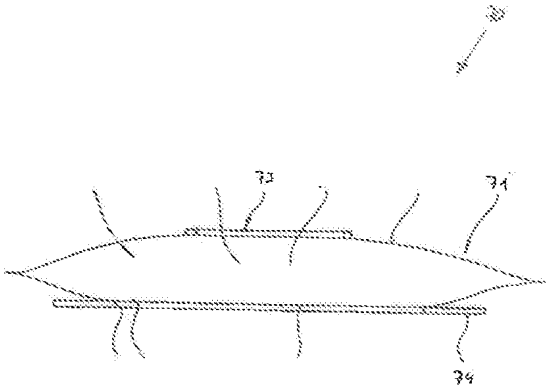

図7

【図８】

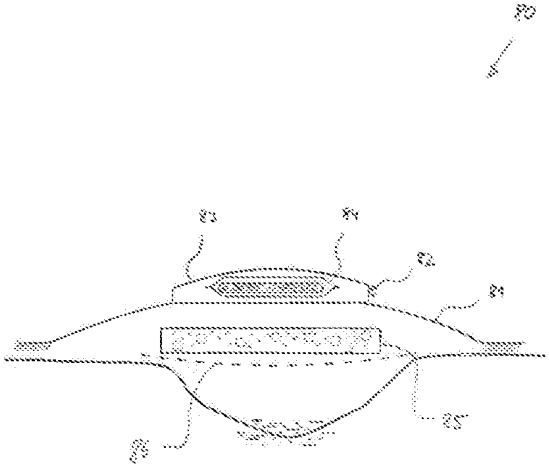

図8

【図９】

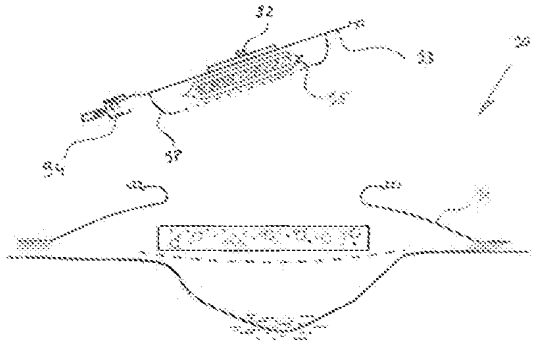

図9a

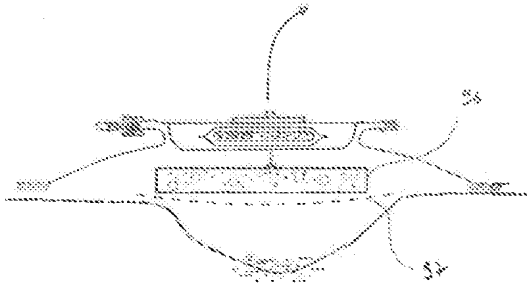

図9b

【図１０】

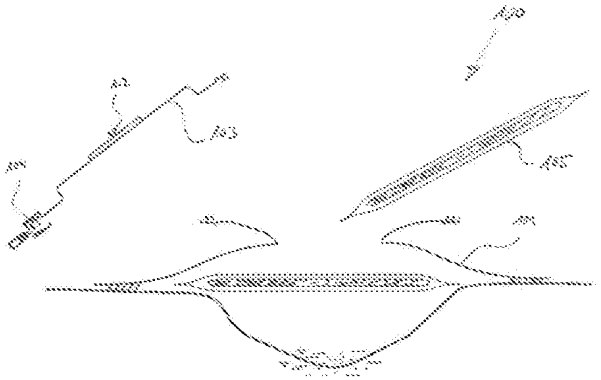

図10a

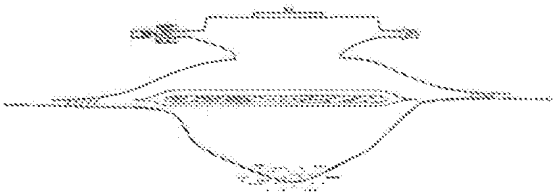

図10b

【図１１】

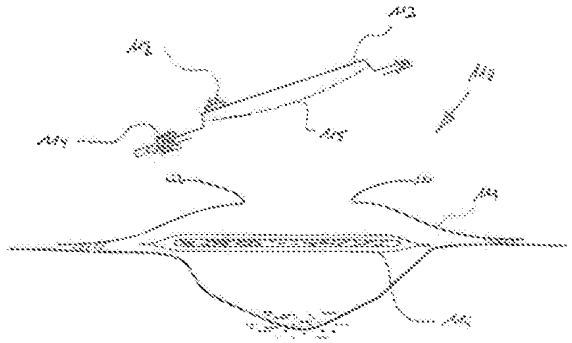

図11a

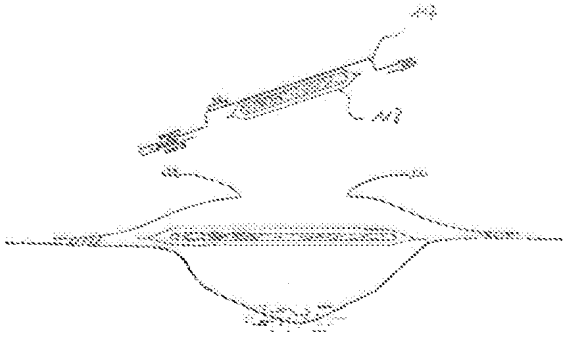

図11b

【図１２】

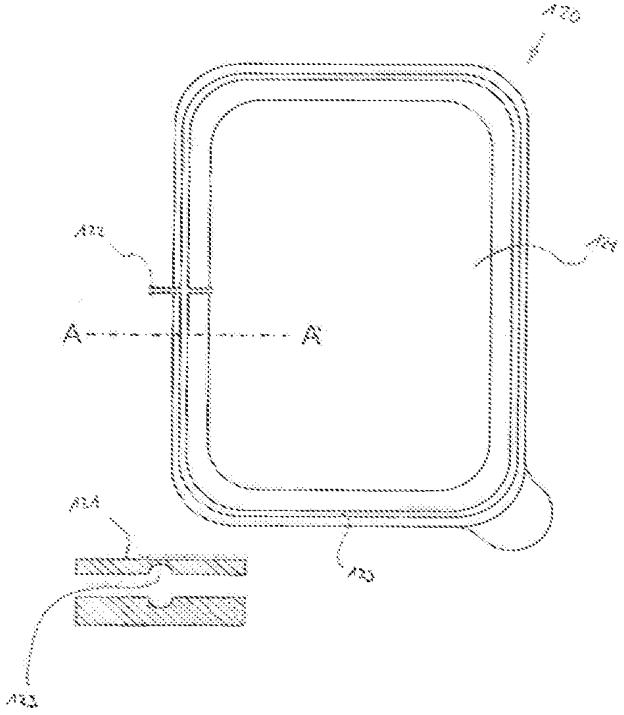

図12

【図１３】

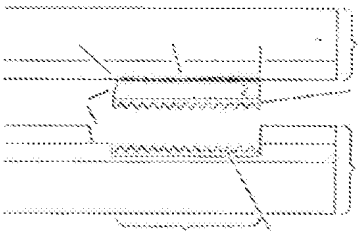

図13

【図１４】

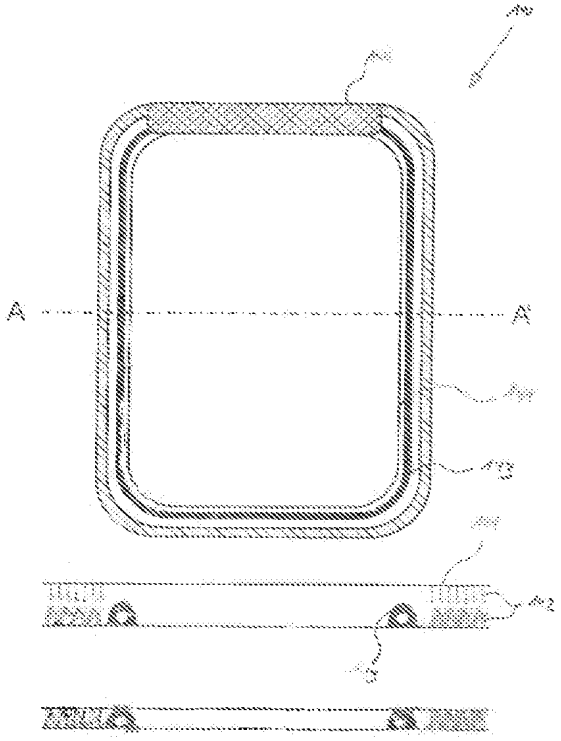

図14

【図１５】

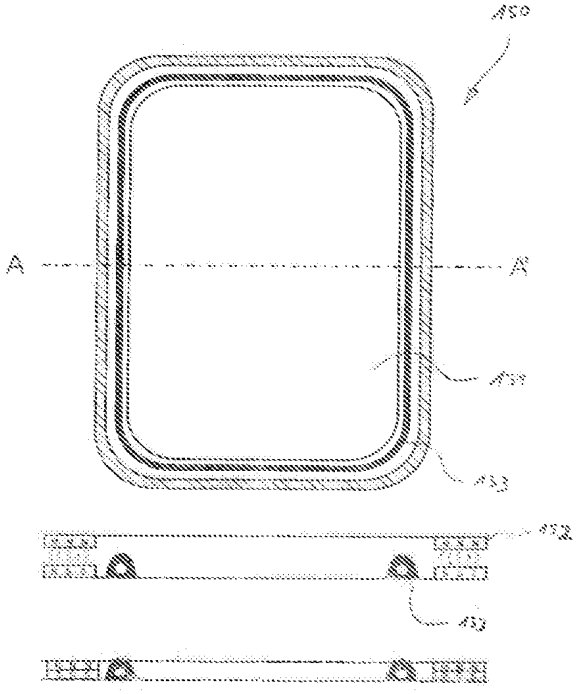

図15

【図１６】

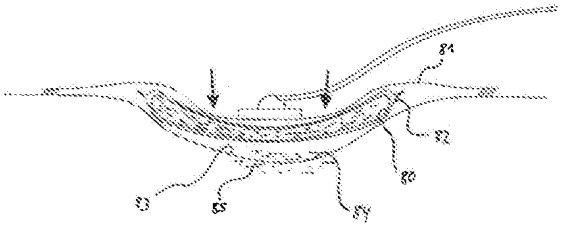

図16a

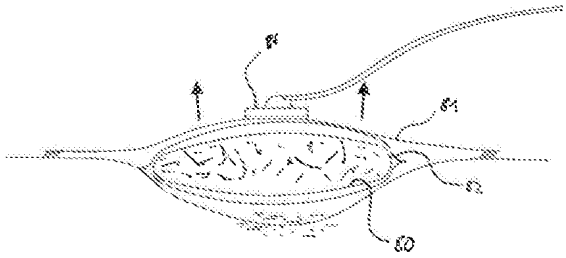

図16b

【図１７】

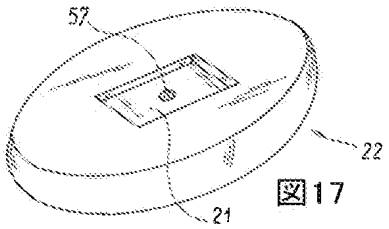

図17

【図１８】

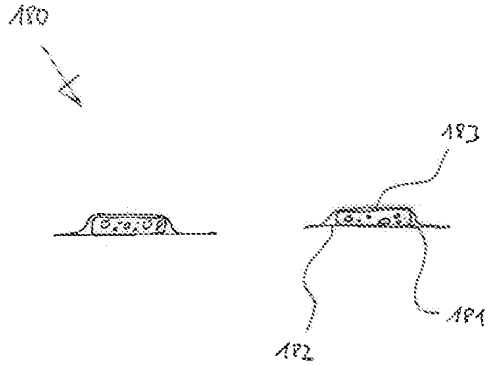

図18

【図１９】

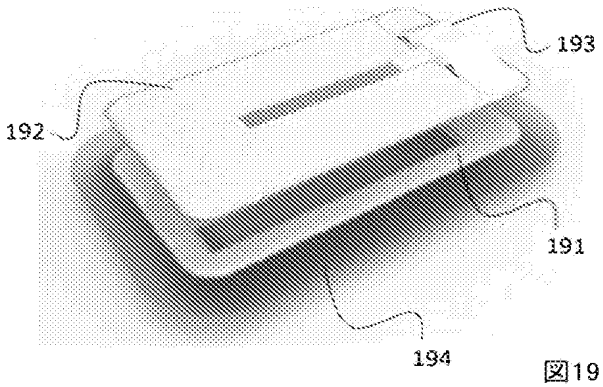

図19

【図２０】

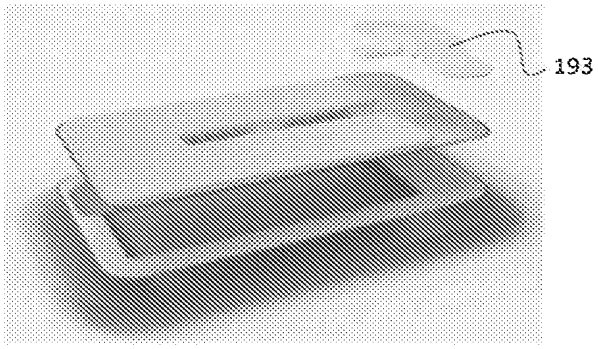

図20

【図２１】

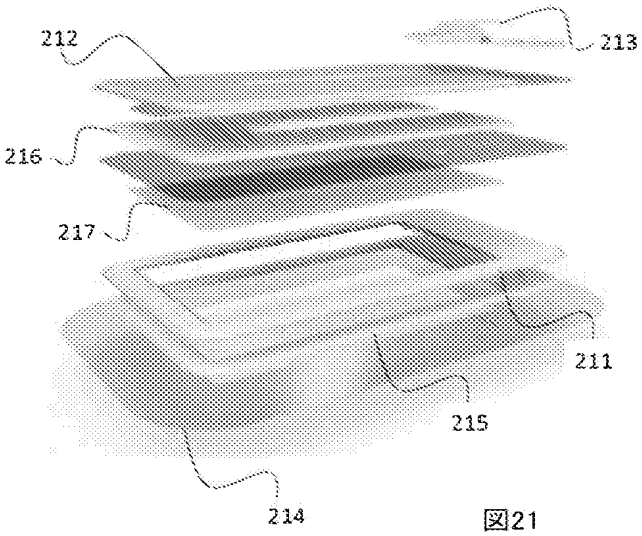

図21

【図２２】

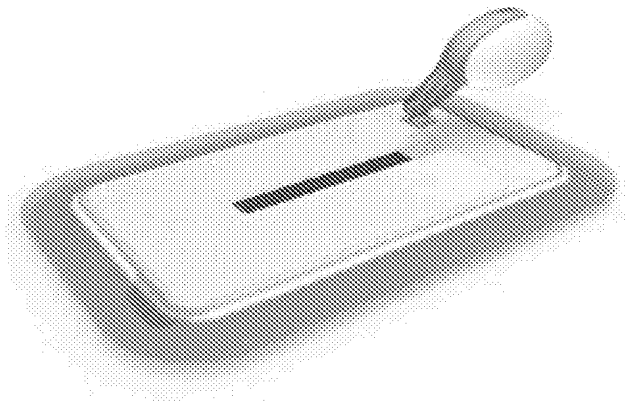

図22

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2014/060133

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F13/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X	EP 1 814 609 A1 (RIESINGER BIRGIT [DE]) 8 August 2007 (2007-08-08) cited in the application paragraphs [0010] - [0027], [0029], [0034], [0036], [0044] - [0046]; figures 1,2	1-24
X	WO 2012/168298 A1 (RIESINGER BIRGIT [DE]) 13 December 2012 (2012-12-13) page 2, line 18 - page 3, line 26 page 21, line 26 - page 22, line 6; figure 6c	1-24

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 September 2014	11/09/2014

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Westberg, Erika

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2014/060133

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 1814609 A1	08-08-2007	AT 390941 T	15-04-2008
		AU 2005309089 A1	01-06-2006
		CA 2589312 A1	01-06-2006
		CN 101065158 A	31-10-2007
		DE 202004018245 U1	07-07-2005
		DK 1814609 T3	04-08-2008
		EP 1814609 A1	08-08-2007
		ES 2304730 T3	16-10-2008
		PL 1814609 T3	30-09-2008
		US 2008119802 A1	22-05-2008
		US 2011172617 A1	14-07-2011
		WO 2006056294 A1	01-06-2006
WO 2012168298 A1	13-12-2012	EP 2717935 A1	16-04-2014
		US 2014163486 A1	12-06-2014
		WO 2012168298 A1	13-12-2012

Form PCT/ISA/210 (patent family annex) (April 2005)

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/EP2014/060133

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
INV. A61F13/00
ADD.

Nach der Internationalen Patentklassifikation (IPC) oder nach der nationalen Klassifikation und der IPC

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
A61F

Recherchierte, aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
EPO-Internal, WPI Data

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	EP 1 814 609 A1 (RIESINGER BIRGIT [DE]) 8. August 2007 (2007-08-08) in der Anmeldung erwähnt Absätze [0010] - [0027], [0029], [0034], [0036], [0044] - [0046]; Abbildungen 1,2	1-24
X	WO 2012/168298 A1 (RIESINGER BIRGIT [DE]) 13. Dezember 2012 (2012-12-13) Seite 2, Zeile 18 - Seite 3, Zeile 26 Seite 21, Zeile 26 - Seite 22, Zeile 6; Abbildung 6c	1-24

☐ Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen ☒ Siehe Anhang Patentfamilie

* Besondere Kategorien von angegebenen Veröffentlichungen :
"A" Veröffentlichung, die den allgemeinen Stand der Technik definiert, aber nicht als besonders bedeutsam anzusehen ist
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"&" Veröffentlichung, die Mitglied derselben Patentfamilie ist

Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
2. September 2014	11/09/2014

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Westberg, Erika

Formblatt PCT/ISA/210 (Blatt 2) (April 2005)

INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationales Aktenzeichen
PCT/EP2014/060133

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
EP 1814609 A1	08-08-2007	AT 390941 T	15-04-2008
		AU 2005309089 A1	01-06-2006
		CA 2589312 A1	01-06-2006
		CN 101065158 A	31-10-2007
		DE 202004018245 U1	07-07-2005
		DK 1814609 T3	04-08-2008
		EP 1814609 A1	08-08-2007
		ES 2304730 T3	16-10-2008
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		US 2011172617 A1	14-07-2011
		WO 2006056294 A1	01-06-2006
WO 2012168298 A1	13-12-2012	EP 2717935 A1	16-04-2014
		US 2014163486 A1	12-06-2014
		WO 2012168298 A1	13-12-2012

Formblatt PCT/ISA/210 (Anhang Patentfamilie) (April 2005)

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(51)Int.Cl.	F I		テーマコード（参考）
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	Ａ６１Ｌ 15/28	１１０	
	Ａ６１Ｌ 15/60	１１０	

(81)指定国 AP(BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), EA(AM, AZ, BY, KG, KZ, RU, TJ, TM), EP(AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OA(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG), AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US

Ｆターム(参考) 4C081 AA03 AA12 BB01 CA081 CA082 CA122 CA272 CB041 CD021 CD042
DA04 DA05
4C167 AA39 AA40 BB24 CC01 GG14 GG21 GG36 HH17 HH18 HH19
HH20

Patents JP 2016-524490 A

Wound care device for wound treatment with negative pressure atmosphere, including openable window

Abstract

translated from Japanese

The subject of the present invention is a wound care device for wound treatment with a negative pressure atmosphere in a wound area, comprising a wound covering element that can be attached to the skin of a patient and a connection device for aspirating a fluid medium. The covering element comprises a window that can be opened, said window being a wound care device arranged on the wound covering element by an airtight closure (FIG. 4b).

Classifications

A61F13/00068 Accessories for dressings specially adapted for application or removal of fluid, e.g. irrigation or drainage of wounds, under-pressure wound-therapy

View 6 more classifications

JP2016524490A

Japan

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Other languages: Japanese

Inventor: ビルギット リージンガー, ビルギット リージンガー

Current Assignee : BSN Medical GmbH

Worldwide applications

2014 JP CN CA CN EP AU WO 8R 2015 US

Application JP2016513395A events

2013-05-16 Priority to DE102013108063.8

2013-05-16 Priority to DE102013108063.8A

2013-07-12 Priority to DE102013107399.9

2013-07-12 Priority to DE102013107399

2014-05-16 Application filed by BSN Medical GmbH

2014-05-16 Priority to PCT/EP2014/060133

2016-08-18 Publication of JP2016524490A

Status Pending

Info: Patent citations (18), Cited by (3), Legal events, Similar documents, Priority and Related Applications

External links: Espacenet, Global Dossier, Discuss

Claims (24)

Hide Dependent

translated from Japanese

A wound care device for wound treatment with a negative pressure atmosphere in the wound area,
A wound dressing element capable of being attached to a patient's skin and a connection device for aspirating a fluid medium,
The wound care device, wherein the wound covering element has an openable window, the window being arranged on the wound covering element by an airtight closure. 2. A wound care device according to claim 1, characterized in that the airtight closure is embodied in the form of a connecting seal. A wound care device according to one of the preceding claims, characterized in that the wound covering element is pre-formed to correspond to a predetermined body location anatomy. A wound care device according to one of the preceding claims, characterized in that the wound covering element is adapted to move along with the movement of the predetermined body position. The wound dressing element is:
An acrylic adhesive, a silicone, a hydrocolloid adhesive, a zinc oxide adhesive, and / or an adhesive material selected from the group comprising a latex adhesive and characterized in that it can be attached to the patient's skin The wound care device according to claim 1. A wound care device according to one of the preceding claims, characterized in that the device also comprises an absorbent element for removing wound exudate. A wound care device according to one of the preceding claims, characterized in that the absorbent element comprises at least one superabsorbent material, modified cellulose, foam and / or alginate. A wound care device according to one of the preceding claims, characterized in that the absorbent element also comprises a fleece comprising cellulose fibers A wound care device according to one of the preceding claims, characterized in that the device also comprises a fluid permeable wound-opposing wound contact grid. A wound care device according to one of the preceding claims, characterized in that there is a fluid-impermeable barrier in the area of the connection device for suction of the fluid medium. A wound care device according to one of the preceding claims, characterized in that the device also comprises equipment for the generation of a negative pressure atmosphere. A wound care device according to one of the preceding claims, characterized in that the facility for the generation of a negative pressure atmosphere is arranged directly on the wound care device. A coupling, blocking valve, and / or a three-way valve between said equipment for generating a negative pressure atmosphere and said absorbent element for removing said wound covering element or wound exudate, A wound care device according to one of the claims. A wound care device according to one of the preceding claims, characterized in that the absorbent element is surrounded by a fluid permeable cover. A wound care device according to one of the preceding claims, characterized in that the device further comprises a spacer. A wound care device according to one of the preceding claims, characterized in that the device also comprises a layer comprising a heavy metal, preferably copper or silver, or a salt containing one of these. A wound care device according to one of the preceding claims, characterized in that the wound dressing element is impermeable to fluids and / or gases. A wound care device according to one of the preceding claims, characterized in that the wound dressing element is permeable to water vapor. The wound care device according to one of the preceding claims, characterized in that the pumping direction of the equipment for generating a negative pressure atmosphere is reversible. A wound care device according to one of the preceding claims, characterized in that the openable window comprises an inelastic back panel. A wound care device according to one of the preceding claims, characterized in that the openable window comprises an elastic back panel. A wound care device according to one of the preceding claims, characterized in that the openable window comprises a back panel made of a plastic malleable material. Soft tissue defect, infected wound after surgical debridement, lymphatic fistula, sternum wound infection, chest wall hole, bedsores, venous ulcer, chronic wound healing disorder, radiation ulcer, abdominal compartment syndrome, septic abdominal cavity , Intestinal fistulas, and / or wound healing purposes such as wounds caused by one or several

edemas, for fixation of skin grafts, for wound conditioning and / or surgery for seams and incisions For later care,
Application of a wound care device according to one of the preceding claims. Application of a wound care device according to one of the preceding claims in a wound compression system.

Description

translated from Japanese

The present invention relates to a wound care device for treating wounds with a negative pressure atmosphere, including an openable window.

Conventional systems and devices for wound treatment with a negative pressure atmosphere consist of an airtight wound wound covering, a drainage (drainage) hose, an externally placed vacuum pump, and a container for collecting drained exudate Yes.

Such a device is described in Patent Document 1, for example. Patent Document 2 describes a wound care device for wound treatment using a negative pressure atmosphere. The wound care device may optionally feature an openable window, also referred to as an "airtight treatment window" or "collapseable closure element".

Devices that treat wounds with a negative pressure atmosphere, for example, post-surgical treatment of the incision (the goal is drainage of exudate, and therefore less mess, allowing faster healing of the sutured area As well as for the treatment of deeply depressed edema, for example in the case of bedsores or venous ulcers (in this case, actively acquiring wound fluid from deep inside is a chronic wound) Is a precondition for healing).

Typically, in this form of treatment, a relative negative pressure between 60 and 200 mmHg is used The openable window described in US Pat. No. 6,057,049 is a wound contact element disposed underneath, such as an absorbent element or secondary care product inserted into a space created by an airtight wound covering, or Making it possible to be removed from that space In this way, the wound contact element, or the care article, replaces the entire wound care device preferably attached to the patient's skin around the wound, for example for the purpose of cleaning the wound or replacing the element. It can be removed from the wound space without need. This reduces traumatic intervention in the wound healing process and also has cost related advantages.

Based on atmospheric conditions, the openable window needs to be airtight when the window is in the closed position. This is not trivial because air is a very low viscosity medium. In addition, many types of hermetic binders also require strong physical bonding, which is undesirable from the standpoint of scratch contact. Such a strong physical connection is characterized on the one hand by a constant height and a constant weight, and on the other hand, by a constant restoring force during opening and closing, in other words, opening and closing is done with the strength of the hand. Features.

However, in the current situation, applying force to the wound area can often result in exposing the patient to pain, which is highly undesirable. If, for example, it requires the use of force to close the treatment window, the patient will experience this as a traumatic treatment intervention, especially in the case of scars, bedsores, and venous ulcers.

U.S. Pat. No. 7,198046 European Patent No. 1814609

The object of the present invention is therefore to provide a vacuum wound treatment which allows the replacement of a wound contact element or a care product without the disadvantages mentioned above.

The present invention includes a wound dressing element that can be attached to a patient's skin, and a connection device for aspirating a fluid medium, the wound dressing element having an openable window that is hermetically closed There is provided a wound care device for wound treatment with a negative pressure atmosphere in a wound area disposed by an object on a wound covering element.

FIG. 1 shows the general principle of a wound care device. FIG. 2 shows a window 10 that can be opened. In FIG. 3, the cross section of the said connection seals 18 and 40 is shown in detail. FIG. 4 also shows an openable window. FIG. 5a shows a different form of coupling seal. FIG. 5b shows an airtight closure in the form of an adhesive seal. FIG. 6 shows a wound care device 60. FIG. 7 shows a wound care device 70. FIG. 8 shows a wound care device 80. FIG. 9 shows a wound care device 90. FIG. 10 shows a wound care device 100. FIG. 11 a shows the wound care device 110. FIG. 11b features a device similar to that in FIG. 11a, except that an absorbent element 118 is attached to the openable window 117 on the wound-opposing side. FIG. 12 shows a wound care device 120. FIG. 13 shows a further embodiment of an airtight closure in the form of an adhesive seal. FIG. 14 shows a wound care device 140. FIG. 15 shows a wound care device 150. FIG. 16a shows the arrangement of the invented wound care device. FIG. 16b shows an arrangement similar to that in FIG. 16a, but a later arrangement. A further embodiment can be seen in FIG. FIG. 18 is a cross section through the frame 180 of a wound dressing element according to the present invention. FIG. 19 shows a wound care device for wound treatment. The pump 193 is embodied so as to be detachable as seen in FIG. FIG. 21 shows an exploded view of the wound care device. FIG. 22 shows a wound care device for further wound treatment.

The openable window features a number of advantages. So, for example, by the window,
Easier rinsing or cleaning of the underlying wound The wound treatment with a medicinal product or care article Atraumatic exchange of the wound dressing or absorbent element The inspection and evaluation of the wound and the acquisition of a sample, e.g. a swab sample, This is possible without the need to remove the entire wound care device.
The concept of "openable windows" includes completely transparent windows, non-transparent windows or windows with non-transparent material under them, and windows characterized by transparency.

Preferably, the wound dressing element is preformed to accommodate an anatomical relief of a particular body location. For example, it may be effective when the wound dressing element is applied to the elbow, hip, or knee area. The deep drawing step enables pre-formation of the wound dressing element to accommodate, for example, the aforementioned anatomical relief of the body position.

Also preferably, the wound dressing element is embodied such that it can adapt to certain body position movements. For these purposes, for example, the wound dressing element and the airtight closure may be embodied to be elastic. In addition, a pleated array or one or several stretch bellows may be provided.

In the embodiment described above, it is particularly important that the hermetic closure described above will maintain its hermetic properties even under these exacerbated conditions.

Preferably, the aforementioned airtight closure is embodied in the form of a connecting seal. In the following, the concept of "link seal" refers to all kinds of disclosed link seals that function according to the principle of tongue and groove.

For these purposes, both parts to be connected to each other by a seal feature lips that interlock with each other when the seal is applied. Preferably, these lips are made of an elastic material such as synthetic or natural rubber, polyethylene, or polypropylene.

Such seals are, for example, resealable carry-on pouches for carrying cosmetics during air travel, resealable storage bags for storing frozen foods, or resealable storage boxes ("Tupperware") Are known.

The aforementioned connecting seal is also known as "ziplock", "minigrip", or pseudonym of sliding seal. In the latter case, a slide can be provided, which slides along the lip to be sealed like a zipper and moves the lip to a sealed position.

So-called bulge locks are encompassed within the concept of "connected seals", as described, for example, in WO03013976A1.

The aforementioned seals are suitable as hermetic closures of the windows that can be opened when the windows are in a closed position, and furthermore, these seals have a low height and light weight, or it is also important that what is needed and that only a little force is required to close or open the seal. In this way, the patient can be opened and closed without exposing the patient to pain

The latter can be achieved, for example, by an embodiment using a slide (see FIG. 9 and the specification) or an embodiment using a tongue and groove option (see FIG. 4 and the specification).

As an alternative to the previous embodiment, the hermetic closure may be embodied in the form of a magnetic seal. For these purposes, flexible ferromagnetic strips may be provided in particular. The magnetic seal described above has similar advantages in terms of operability. The magnetic seal may likewise be embodied in an airtight form. The magnetic seal may also be technically embodied so as to maintain its hermeticity even under the aforementioned deterioration conditions.

As an alternative to the previous embodiment, the hermetic closure may be embodied in the form of an adhesive seal. For these purposes, the two laminae are stuck together in the sealing zone. With the opening string, the first flake can be easily separated from the second flake, which exposes the adhesive layer integrated in the recess. The lower sheet consists of a polyester backing layer, a pressure sensitive adhesive layer, and a sealing layer with an integrated transfer barrier. The intensity is between 200 and 500 μm. Such adhesive seals are known, for example, from EP 2067717 and are characterized by similar advantages in terms of operability. The adhesive seal may likewise be embodied in an airtight form. The adhesive seal may also be technically embodied so as to maintain its hermeticity even under the aforementioned deteriorating conditions.

As an alternative to the previous embodiment, the hermetic closure may be embodied in the form of a tongue and groove seal, possibly featuring an internal sealing lip. The tongue and groove seals described above have similar advantages in terms of operability. The tongue and groove seals will be embodied in an airtight manner as well. The seal between the tongue and the groove may also be technically embodied so as to maintain its airtightness even under the aforementioned deterioration conditions.

As an alternative to the previous embodiment, the hermetic closure may be embodied in the form of a rubber seal or rubber tube, possibly with pressure means. As an alternative to the previous embodiment, the airtight closure may be embodied in the form of a cork strip, possibly with pressurizing means.

This pressurizing means may be embodied, for example, as a bracket or as a seal between the aforementioned tongue and groove.

As an alternative to the previous embodiment, the hermetic closure is in the form of an adhesive seal, for example, preferably in the form of a film or application, a low adhesion silicone adhesive applied to the frame side or window side. May be embodied. Acrylic adhesives may be used as well. Apart from the preferred sealing and adhesive properties, they have the advantage of being physiologically safe.

Preferably, the wound dressing element can be attached to the patient's skin by an adhesive material. For these purposes, all kinds of physiologically acceptable adhesives, in particular medical grade adhesives, can be used. Particularly preferred are materials selected from the group comprising:
• Acrylic adhesives • Silicones • Hydrocolloid adhesives • Zinc oxide adhesives and / or • Latex adhesives.

Hydrocolloid adhesives generally consist of a thin polymer film that is applied to a self-adhesive material. The carrier material (synthetic rubber species, such as polyisobutylene) contains swollen particles, which can vary depending on the manufacturer. Often, swollen particles such as carboxymethylcellulose or sodium carboxymethylcellulose are included. Furthermore, these swollen particles are very malleable, especially when warm. Hydrocolloid adhesives are suitable for incorporation into the surface and can in particular remove moisture. These are available in paste form and are also available in panel or strip form.

Similar applies to silicone materials. The degree of adhesion to the skin can be adjusted with these substances, thus ensuring a non-traumatic exchange of the wound dressing regardless of adhesion.

Preferably, such a silicone adhesive can be embodied in the form of a separable self-adhesive laminate, the laminate being a wound-opposing side to which a hydrophobic gel is applied, for example in the form of a silicone gel, and A structural layer having a side facing away from the wound carrying the adhesive, for example in the form of an acrylic adhesive. One such layer has been described, for example, in EP2001424B1.

Preferably, the adhesive material is embodied in the form of an "edge bandage" as an adhesive end, which surrounds the wound dressing element peripherally.

The adhesive material may be embodied in the form of panels or strips on which the wound dressing elements are located at a distance. In this embodiment, the panel or strip is characterized by a central opening, which is intended to be placed on top of the wound. In this embodiment, the panel or strip takes the form of a frame. Alternatively, the panel or strip may be embodied such that a window may be cut into the panel or strip corresponding to the contour of the wound with respect to shape. For these purposes, the outline of the wound may be drawn on it and then cut with a pair of scissors. Alternatively, a template may be used, and the wound contour may be transferred to the panel or strip by the template, or the wound contour (corresponding opening) may be cut from the panel or strip by the template.

The panel or the frame is made of, for example, a hydrocolloid material as described herein. The strip is made of, for example, a so-called cut slice, and the cut slice is a self-adhesive slice made of a polymer material.

Alternatively, the panel or the frame is made of a foam material and / or a spacer cloth. Preferably this is incorporated into the hermetic coating. The aforementioned adhesive may be applied to the skin facing side.

More preferably, the device features an absorbent element that removes wound exudate.

This absorbent element makes it possible to ensure that all wound exudate produced by negative pressure treatment does not have to be directed to an external canister and at least part of it remains in the wound space. . The exudate is then removed by simple replacement of the absorbent element and can be disposed of in an easier and hygienic manner than the exudate canister because it is coupled to the absorbent element.

As a result, the possibility of eliminating the need for an external canister has an additional advantage. For example, the device may be embodied to maintain patient mobility (the patient can leave his bed and perform his daily routine).

More preferably, the absorbent element features at least one superabsorbent material, modified cellulose, foam, and / or alginate.
Particularly preferably, the absorbent element is also characterized by a fleece comprising cellulose fibers.

Superabsorbent polymers (SAPs) are synthetic materials that can absorb fluids up to multiples of their own weight, up to 1000 times their own weight. In chemical terms, these are copolymers of acrylic acid (propenoic acid, $C_3H_4O_2$) and sodium acrylate (sodium salt derived from acrylic acid, $NaC_3H_3O_2$). The interrelationship

between the species monomers may vary. In addition, so-called core crosslinkers (CXL) are added to the monomer solution to link the formed long chain polymer molecules at some places by chemical bridges. As a result of these bridges, the polymer becomes insoluble in water. As water or saline solution penetrates into the polymer particles, the particles swell greatly and stretch this network of molecular level bonds, and water can no longer escape without help. The superabsorbent polymer can be used in the wound care device according to the invention in the form of granules, powders, fillers, pellets, foams, in the form of fibers or fiber structures, mats, fleeces and / or fiber masses. it can.

Preferably, the modified cellulose is a cellulose derivative, preferably a sulfoalkyl cellulose and its derivatives, preferably ethyl cellulose sulfonate, carboxyalkyl cellulose, preferably carboxymethyl cellulose, carboxyethyl cellulose, and / or carboxypropyl cellulose, sulfoethyl carboxymethyl cellulose, More complex cellulose derivatives such as carboxymethyl hydroxyethyl cellulose, hydroxypropyl methyl cellulose, and amidated cellulose derivatives such as carboxymethyl cellulose amide or carboxypropyl cellulose amide. Carboxymethylcellulose is available in particular in the form of sodium carboxymethylcellulose and is commercially available as "aqueous fiber". In hygiene and wound care products, the fibers are used in a flat matrix. Upon absorption of fluid from the wound exudate, the fibers gradually turn into gel pillows that retain and do not release fluid. The fibers are configured to absorb wound exudate only in the vertical direction. This means that as long as the volume is sufficient, exudate will not flow beyond the edge of the wound. This can effectively prevent the maceration of the wound edges.

The water active polymer may be an alginate. Alginate is derived from brown algae and woven into a fibrous fleece. Chemically, these are polysaccharides, specifically the calcium and / or sodium salts of alginic acid. Alginates can absorb up to 20 times their own weight in the fluid and the wound exudate is stored in a hollow space. Ca^{2+} ions alginate lattice until alginate is saturated with Na^{+} ions are exchanged for Na^{+} ions from the exudate. This causes swelling of the wound dressing and conversion of the alginate fiber into a gel body due to fiber swelling.

The water active polymer may be hydrogel nanoparticles containing hydroxy-terminated methacrylic monomers, such as 2-hydroxyethyl methacrylate (HEMA) and / or 2-hydroxypropyl methacrylate (HPMA), which are commercially available as Altrazeal. ing.

In a further preferred embodiment, the absorbent element contains ≧ 40% by weight of superabsorbent polymer. Particularly preferably, the weight distribution of the superabsorbent polymer is ≧ 45, 50, 55, 60, 65 or 70% by weight.
Particularly preferably, the absorbent element is characterized by a fleece comprising cellulose fibers.

Preferably, the absorbent element features an essentially flat absorbent element made of an absorbent material consisting of an absorbent fleece with superabsorbent polymer distributed therein. These may be added in the form of granules, powders, fillers, pellets, foams, in the form of fibers or textiles, mats, fleeces and / or fiber masses.

The absorbent element is at least one material selected from the group comprising a mat, in particular an airlaid made of said yarn or fiber of superabsorbent polymer with incorporated superabsorbent polymer, and / or a loose filler of superabsorbent polymer As a feature. Preferably, the airlaid mat is characterized by an essentially flat material part made of an absorbent material, for example consisting of an absorbent fleece derived from the aforementioned fibers incorporating a superabsorbent polymer.

This absorbent element corresponds to the absorbent insert contained in the Applicant's wound dressing disclosed in, for example, WO03094813, WO2007051599, and WO0152780, and marketed under the trade name "sorbion sachet". It may be. The disclosure content of the above-mentioned document is added to the disclosure content of this document in its entire scope.

In different embodiments, the absorbent element may form a core comprising fibers or yarns of possibly superficial, superabsorbent polymer, and superabsorbent polymer in the form of granules, with the granules in various concentrations. Alternatively, it may be affixed or welded to the yarn and the granules may be distributed over 50% of the total height of at least a portion of the core containing the area where the granules and fibers are mixed. Preferably, the proportion of superabsorbent polymer is in the range of 10-25% by weight. Similar structures are known from conventional incontinence materials, and these are known for buffering properties similar to those of sanitary napkins. The core may be surrounded by a covering that overlaps in several areas, and the covering may cover an adhesive seam or may be part of such.

Particularly preferably, the absorbent element is characterized by fleece, preferably non-woven or airlaid, consisting of superabsorbent fibers ("SAFs", preferably polyacrylates) or containing them as components. The fibers may be mixed with fluff pulp (cellulose) or polyester fibers, for example, alternatively or additionally, characterized by a laminated structure.

In another embodiment, the absorbent element may also include at least one flat layer comprising fibers or threads made of superabsorbent polymer with a granular superabsorbent polymer attached thereto. This provides a preferred embodiment of the structure of the body comprising at least three layers, with two covering layers surrounding one layer containing the superabsorbent polymer.

Here, there is no mixture of fiber and superabsorbent polymer at one concentration, only an adjacent arrangement of the two materials. In preferred embodiments, the additional layers, if provided, may be physically packed together by rotation, pressurization, calendering, or similar procedures.

Further, the body may feature a repeating pattern or a repeated woven fabric, such as a check pattern, a drilling pattern, or the like.

Particularly preferably, the absorbent element has a surface size of 5 × 5, 5 × 10, 5 × 20, 10 × 10, 10 × 15, 10 × 20, 15 × 15, 20 × 20, or 20 ×. It has the characteristics of 40cm.

Particularly preferably, the absorbent element comprises at least a second adjacent layer in addition to a layer comprising a superabsorbent polymer, the second adjacent layer being free of superabsorbent polymer or having an amount comprising superabsorbent polymer. Less and its surface extends beyond the former layer. In this way, the layer containing the superabsorbent polymer can gain volume as a result of absorbing fluid without the volume increase being visible from the outside, since this layer is hidden by the second layer.

The foam may be a foam with closed or open pores. Preferably, these materials are likewise embodied as a flat layer, characterized on the one hand by fluid absorbency and on the other hand by cushioning properties. These are characterized by a higher resilience.

Particular preference is given to using a type of foam known as cold foam.
Instead of or in addition to the foam, so-called "nanofiber matrices" such as those manufactured by SNS Nano Fiber may be used as well.

Furthermore, the foam may also contain a superabsorbent, such as the Allevyn Plus product from Smith & Nephew.
More preferably, the device also contains a fluid permeable wound facing wound contact grid.

Preferably, such a wound contact grid is a grid made of synthetic material (preferably including, for example, silicone material or nylon material), perforated foam, spacer fabric, and / or perforated flakes. is there.

Preferably, a three-dimensional wound contact grid is provided, such as the grid sold under the trade name "sorbion plus" and described in EP2004116A1.

The wound contact grid, on the one hand, may be arranged on the wound-opposing side, loosely in the frame or fixed to the frame.

Such a wound contact grid prevents granulation and therefore allows atraumatic exchange of the wound dressing. The wound contact grid further has a biofilm dissolution effect as well as a valve effect, which reduces exudate reflux.

Applicants have been able to demonstrate that these properties known from "non-active" wound dressings are also particularly advantageous for the "active" vacuum-supported wound dressings described herein.

The wound contact grid may also be arranged on the covering side. In this way, the wound contact grid can prevent gel blocking that can be caused by intervening absorbent elements comprising superabsorbent polymers when they form a gel as a result of fluid absorption, the gel being Otherwise it will interfere with the fluid suction process.

In principle, the connecting device for suction of the fluid medium described above can be embodied so as to allow suction of fluid and / or gas. For these purposes, this may be embodied in the form of a coupling (such as in the Luer-Lock system) that allows the connection of hoses and / or pumps.

The product may further include additional valves, pressure reducers, or additional windows that can be opened. This allows the device to be used even at excessively negative pressures, such as when connected to a vacuum wall port that can be frequently seen in hospitals, for example. The valve, pressure reducer or window can then be opened to reduce negative pressure.

More preferably, a fluid-impermeable barrier is provided in the region of the connection device for suction of the fluid medium.
This is to ensure that no fluid enters the pump. The latter remains inside the wound covering and is absorbed by the absorbent element that removes the wound exudate.
Preferably, the barrier comprises a semi-permeable membrane, for example made of a material such as Goretex.

Preferably, one connection device for suction of the fluid medium and one connection device for suction of the gaseous medium can be provided.

More preferably, the device also includes equipment for the generation of a negative pressure atmosphere.
The equipment for generating the negative pressure atmosphere is preferably selected from the group comprising:
a) an electrically operated vacuum pump b) a manually operated negative pressure source, and / or c) a vacuum chamber.

The vacuum pump may be a single pump, but may also be part of a centralized vacuum system, such as is often used in clinics. Hospital rooms are often fitted with vacuum wall ports to which the invented wound treatment drainage device can be connected. In this case, the vacuum pump can apply a negative pressure to many of the wound treatment drainage devices according to the present invention.

Preferably, the vacuum pump is a micropump whose size and / or weight can be easily applied to a wound dressing element of the aforementioned type without any patient annoyance or interference. is there.

For example, the pump is a piezo or membrane pump. Particularly preferred is a piezo pump, which is a pump whose pumping capacity is caused by a piezoelectric element. These pumps have a sufficiently high pumping capacity despite their small size. These have a lower operating sound and lower energy consumption. Alternatively, these pumps may be microsystem technology propellant driven vacuum pumps. Suitable pumps of this type are manufactured, for example, by Schwarzer Precision, KNF or Bartels Mikrotechnik.

Preferably, such a pump is provided with a check valve that allows the pump to be negative in interval mode or only initially during the operational pause to reduce the formed negative pressure again without any leaks. it is possible to operate only to generate pressure or to maintain negative pressure.

Preferably, the pump can generate a negative pressure of −60 to −200 mmHg. Particularly preferably, the pump is -60, -70, -80, -85, -90, -100, -110, -120, -130, -140, -150, -160, -170, -180, -190. Alternatively, a negative pressure of 200 mmHg can be generated.

Preferably, the pump is selected or provided so that it can transport fluid.

Preferably, the pump operating sound does not exceed a sound pressure level of 65 dB. Particularly preferably, the sound pressure level does not exceed 63 dB, 60 dB, 58 dB, 55 dB, 53 dB, 50 dB, 48 dB, 45 dB, 42 dB, 40 dB, 38 dB, 35 dB, 32 dB, 30 dB, 28 dB, 25 dB, 22 dB, or even 20 dB.

Preferably, the pump is characterized by a transport rate between 0.5 ml · min $^{-1}$ and 100 ml · min ^{1} . Preferably, the transport rate is between 2 ml min $^{-1}$ and 50 ml min ^{1} . Particularly preferably, the transport rate is between 10 ml · min $^{-1}$ and 20 ml · min $^{-1}$.

The vacuum container described above can connect to the invented wound treatment device and apply negative pressure to the wound treatment device, similar to known Redon bottles. The vacuum vessel includes an insert containing a fluid-absorbing polymer, preferably in the form of a lining.

Particularly preferably, the vacuum container can be embodied in the form of a cartridge, which is arranged in a mount that is already connected to the invented wound healing drainage device. When the cartridge is full, the cartridge can be removed and discarded, and a new vacuum cartridge can be placed in the mount.

The embodiments described above are particularly advantageous. Because these embodiments eliminate the need for their own pumps and instead use a vacuum vessel, which makes the device movable and independent of the power grid, resulting in The patient himself can move. In addition, this allows for a smaller configuration and allows the patient to hide the device individually. Particularly advantageous in this respect is an anatomically adjusted embodiment of the vacuum vessel or mount, which makes it possible to carry them inconspicuously, for example on a leg.

Furthermore, such a device does not emit operational sounds and is very easy to operate.

The same applies to the aforementioned manually operated negative pressure source. In the simplest embodiment, the negative pressure source may be a plastic syringe with a sufficiently large volume. Other selectables are pumps in the form of rubber balls, bellows or the like.

More preferably, the equipment for generating a negative pressure atmosphere is located directly on the wound care device.

This can be achieved, for example, by placing the equipment directly on the wound dressing element. In this way, it is possible to remove a separate vacuum hose that includes manufacturing challenges (sufficient rigidity to prevent crushing under vacuum conditions) and hygiene issues (risk of contamination). Can or can be kept very short.

More preferably, the coupling, blocking valve, and / or three-way valve is disposed between the facility for generating a negative pressure atmosphere and the absorbent element for removing wound dressing or wound exudate.

This device is a) equipment for generating a negative pressure atmosphere can be disconnected from the test of the device, b) the negative pressure once generated can be maintained for the longest possible time, And / or c) negative pressure can be generated or restored for the purpose of conserving the battery, or when the battery is empty, using an external pump or an external vacuum vessel.

The external pump or the external vacuum vessel may be fixed, for example in a clinic or at a patient's home, but may be embodied in a mobile form (e.g. in the form of a suitcase, Or integrated into the patient's clothing or attached to the patient's belt). This is to ensure that the device on the wound remains small and unobtrusive, because its primary mission is to maintain a vacuum, but allows for effective treatment This is because it provides sufficient pumping capacity as needed.

More preferably, the absorbent element is surrounded by a fluid permeable cover. Preferably, the device further comprises a spacer. Preferably, this spacer is placed between the wound and the wound dressing element, but where applicable, it is also placed between the absorbent element and the wound dressing element or between the wound and the absorbent element. Such a spacer ensures that the wound care device does not collapse overall when negative pressure is applied. This is because if the device is crushed, the device cannot extract gas or fluid as a result.

More preferably, the device features a layer comprising a heavy metal, preferably copper or silver, or a salt containing one of these. In particular, such a layer can be very useful as the layer slows down bacterial growth when the application period on the wound is extended.

More preferably, the wound dressing element is impermeable to fluids and / or gases. This allows for the application of a vacuum and prevents the wound dressing element from leaking fluid that may be contaminated in the situation.

Preferably, the wound dressing element is embodied in an elastic material. For these purposes, the wound dressing element consists of, for example, polypropylene, polyethylene, latex, silicone or rubber. Furthermore, the wound dressing element may have foam attached to the inside.

More preferably, the wound dressing element is permeable to water vapor. Preferably, the wound covering element is further embodied with transparency.

More preferably, the pumping direction of the equipment for generating the negative pressure atmosphere can be reversed. This allows the facility to be used as a controllable dosing pump for drugs, cleaning solutions and the like.

More preferably, the openable window features an inelastic back panel. The concept of "back panel" here is, for example, the code No. Means a cover as indicated by 23. In this embodiment, for example, the aforementioned pump can be placed directly on the back panel of the openable window.

More preferably, the openable window features an elastic back panel. In this aspect, for example, the back panel may be embodied to cause an increase in the volume of the intrinsic absorbent element that occurs as a result of absorption of exudate. This ensures that the window follows the patient's movement to ensure hermeticity.

Preferably, this elastic back panel features or is made of a silicone material. Particularly preferably, for example, the lower side of the back panel, in other words the patient-facing side, is covered with silicone and / or foam or is present at the upper end of such a material.

More preferably, the openable window features a back panel made of a plastic malleable material.

In this embodiment, for example, the back panel may comprise a thermoplastically malleable deep drawn flake. This makes it possible, for example, to create a reservoir in which a spare absorbent element can be prepared.

Preference is also given to soft tissue defects, infected wounds after surgical debridement, lymphatic fistulas, sternum wound infections, chest wall holes, bedsores, venous ulcers, chronic wound healing disorders, radiation ulcers, abdominal septum For the treatment of wounds, including chamber syndrome, septic abdominal cavity, intestinal fistula, and / or wounds caused by one or several edemas, for fixation of skin grafts, for wound conditioning, and Application of wound care devices for post-surgical care of seams and incisions.

Furthermore, the application of a wound care device according to one of the preceding claims in a wound compression system has been devised.

FIG. 1 shows a wound area with a negative pressure atmosphere for treating a wound, including a wound covering element 3 that can be attached to the skin of a patient and a connection device (not shown) for suction of a fluid medium. 1 shows the general principle of a wound care device. The wound dressing element features an openable window 23, which is positioned by an airtight closure (not shown) on the wound dressing element. After opening the window 23, the wound dressing 2 can be easily removed, discarded, and replaced with another wound dressing

FIG. 2 shows the openable window 10 including the frame 12, the connecting string 36 between the frame 12 and the window cover 46, and a hermetic closure embodied as a coupling seal 18, 40.

In FIG. 3, the cross section of the said connection seals 18 and 40 is shown in detail.

FIG. 4 also shows a window that can be opened with connecting seals 42, 43. The aforementioned coupling seal features a tongue and groove option, which ensures that closing or opening the coupling seal requires only a slight force. In this way, opening or closing can be performed without exposing the patient to pain. Furthermore, the seal is characterized by a low height and low weight.

FIG. 5a is a different articulated seal that can be used with the present invention in the form of a slide 38 that slides along lips to be sealed similar to a zipper and moves them to a sealed position. The form is shown.

FIG. 5b shows an airtight closure in the form of an adhesive seal.

FIG. 6 shows a wound care device 60 for wound treatment with a negative pressure atmosphere in the wound area, including a wound covering element 61 that can be attached to the patient's skin and a connection device 62 for suction of the fluid medium. The wound dressing element features an openable window 63, which is positioned by an airtight closure on the wound dressing element.

The wound dressing element further features a peripheral edge 64 that includes an adhesive material 65. This is the implementation of a so-called "border bandage".

FIG. 7 shows a wound care device 70 for wound treatment with a negative pressure atmosphere in the wound area, comprising a wound covering element 71 that can be attached to the patient's skin and a connection device (not shown) for suction of a fluid medium. Show. The wound dressing element features an openable window 73, which is positioned on the wound dressing element by an airtight closure.

The device features a panel or frame 74 on which wound dressing elements are disposed at a distance. In this embodiment, the panel or strip may feature a central opening, for example, located above the wound. In this embodiment, the panel or strip takes the form of a frame. Alternatively, the panel or strip may be embodied such that the window is cut into a panel or strip corresponding to the shape of the wound contour. The panel can be made of, for example, the hydrocolloid materials described herein. The strip consists of, for example, an incision slice as described above, which is a self-adhesive slice made of a polymer material.

FIG. 8 shows a wound care device 80 for wound treatment with a negative pressure atmosphere in the wound area, including a wound dressing element 81 that can be attached to the patient's skin and a connection device 82 for suction of the fluid medium. The wound dressing element features an openable window 83, which is positioned on the wound dressing element by an airtight closure.

The openable window is fitted with a pressure resistant lining to provide space for an absorbent element 84 that includes a superabsorbent polymer. Due to pressure tolerance, the openable window does not collapse so that the absorbent element can fully utilize its absorbent capacity.

In addition, a continuum 85 made of foam and a three-dimensional wound contact grid 86 are provided on the opposite side of the wound.

FIG. 9 shows a wound care device 90 for wound treatment with a negative pressure atmosphere in the wound area, including a wound covering element 91 that can be attached to the patient's skin and a connection device 92 for suction of the fluid medium.

The wound dressing element features an openable window 93 that is positioned on the wound dressing element by an airtight interlocking seal 94. Such connecting seals are also known as "Ziplock", "Minigrip" or the pseudonym of a sliding closure. They are low in height and light in weight, and they require only a slight force for closing or opening.

Under the openable window 93, a section 98 with a pressure-resistant lining has been devised, which provides a space for the absorbent element 95 comprising superabsorbent polymer. The compartment is embodied on the opposite side of the wound because it is permeable to fluid. The resistance to pressure does not collapse the openable window so that the absorbent element can utilize its full absorption capacity. When this capacity is reached, the entire window containing this compartment and the absorbent element contained therein can be discarded and replaced with a new one.

Furthermore, a continuous body 96 made of foam material and a three-dimensional wound contact grid 97 are provided on the wound facing side. The continuum other than compartment 98 is not resistant to pressure and therefore decreases in volume as pressure increases.

FIG. 10 shows a wound care device 100 for wound treatment with a negative pressure atmosphere in the wound area, including a wound covering element 101 that can be attached to a patient's skin and a connection device 102 for suction of a fluid medium.

The wound dressing element features an openable window 103 that is positioned on the wound dressing element by an airtight interlocking seal 104. Such connecting seals are also known as "Ziplock", "Minigrip" or the pseudonym of a sliding closure. They are low in height and light in weight, and they require only a slight force for closing or opening.

In addition, an absorbent element 105 is devised which can be removed or inserted after opening the window.

FIG. 11a shows a wound care device 110 for wound treatment with a negative pressure atmosphere in the wound area, including a wound dressing element 111 that can be attached to the patient's skin and a connection device 112 for suction of a fluid medium.

The wound dressing element features an openable window 113 that is positioned on the wound dressing element by an airtight interlocking seal 114. Such connecting seals are also known as "Ziplock", "Minigrip" or the pseudonym of a sliding closure. They are low in height and light in weight, and they require only a slight force for closing or opening.

Below the openable window 113, a grating 115 is provided, which provides space for an absorbent element (not shown), which may include, for example, a superabsorbent polymer. The aforementioned absorbent elements can be placed in a grid, after which an openable window can be attached to the covering element by a connecting seal. After the window has been reopened, for example after reaching its full absorption capacity, the absorption element can be removed and discarded or replaced.

Furthermore, an additional absorbent element 116 is provided on the opposite side of the wound, which may be characterized by a lower degree of fluid retention than the absorbent elements listed above.

FIG. 11b features a device similar to that in FIG. 11a, except that an absorbent element 118 is attached to the openable window 117 on the wound-opposing side. When the absorbent element 118 reaches its full absorbent capacity, the entire window including the absorbent element attached to the window can be discarded and replaced with a new one.

FIG. 12 shows a wound care device 120 for wound treatment with a negative pressure atmosphere in the wound area, including a wound dressing element that can be attached to the patient's skin and a connection device 122 for suction of the fluid medium.

The wound dressing element features an openable window 121, which is positioned on the wound dressing element by an enclosing exhaustable duct 123

FIG. 13 shows a further embodiment of an airtight closure in the form of an adhesive seal.

FIG. 14 shows a wound care device 140 for wound treatment with a negative pressure atmosphere in the wound area, including a wound dressing element that can be attached to the patient's skin and a connection device (not shown) for suction of a fluid medium.

The wound dressing element features an openable window 141 that can be attached to the wound dressing element by a tongue and groove seal 142. In addition, a surrounding rubber tube 143 is provided in the middle, which is compressed by a tongue and groove seal to create an airtight closure. As an alternative to rubber tubes, rubber seals, cork strips or the like can be provided.

In addition, a hinge 144 is provided that connects the openable window on one side with the wound dressing element so that the wound dressing element can be folded back but not removed as a whole.

FIG. 15 shows a wound care device 140 for wound treatment with a negative pressure atmosphere in the wound area, including a wound dressing element that can be attached to the patient's skin and a connection device (not shown) for suction of a fluid medium.

The wound dressing element features an openable window 151 that can be attached to the wound dressing element by a magnetic seal 152. In addition, a surrounding rubber tube 153 is provided in the middle, which is compressed by the tongue and groove seals to create an airtight closure. As an alternative to rubber tubes, rubber seals, cork strips or the like can be provided.

FIG. 16a shows an invented wound care device arrangement with an absorbent element 80 with an elastic flake-like element 81 and / or an elastic covering 82 and a deep wound 83 with exudate 85 at the base 84 of the wound. Indicates. Unlike in FIG. 8, the covering 82 may be an integral component of the flake-like element, at least in part, for example in a region facing away from the wound. The elastic flake-like element 81 and / or the elastic covering 82 allows the absorbent element to be attracted to or pressed against the wound base 84 when negative pressure is applied (as indicated by the arrows) This is necessary, especially in the case of deep wounds, to contact the exudate 85 to be absorbed.

FIG. 16b shows an arrangement similar to that in FIG. 16a, but a later arrangement. The absorbent element 80 has already absorbed a large amount of exudate. The elastic flake-like element 81 and / or the elastic covering 82 ensure that the latter is not disturbed as a result of expansion of the absorbent element due to fluid absorption. This ensures that the absorbent element can exert its full absorption capacity. At this time, the coupling facility 86 (and therefore the connected negative pressure device (not shown)) may already be disconnected, or alternatively, the negative pressure device is switched off and no longer applies negative pressure. Don't hang.

The application of negative pressure may also be equipped to serve only the purpose of attracting the absorbent element to the wound base 84 or pressing the absorbent element against the base in order to make contact with the exudate to be absorbed. As soon as this contact is made, the vacuum device can be disconnected or equipped to be switched off. this

A further embodiment can be seen in FIG. In this embodiment, the foam body is devised with features of a recess specifically designed as a compartment for a negative pressure source, for example a pump. Preferably, a check valve (not shown) is placed in the continuous opening 57. The aforementioned foam body is covered by a wound dressing element (not shown).

FIG. 18 is a cross section through the frame 180 of a wound dressing element according to the present invention. The frame may, for example, consist of a foam 181 laminated on an airtight base flake 182 and an airtight covering flake 183 laminated thereon. The former is the contact surface to the patient's skin, and the adhesive may be applied, for example as applied elsewhere here. The latter forms a support surface for the openable window. Preferably, it may be embodied so that it can be sterilized.

19-22 show specific embodiments of the invented wound care device.

FIG. 19 shows a wound with a negative pressure atmosphere in the wound area, including a wound dressing element 191 in the form of a frame that can be attached to the patient's skin, for example with a physiologically safe adhesive, via an underlying flake 194 Fig. 4 shows a therapeutic wound care device, wherein the wound covering element features an openable window 192 positioned on the wound covering element by an airtight closure, such as a low adhesion silicone coating. The wound dressing element features, for example, a foam or spacer fabric laminated in an airtight material. The window is characterized by a base layer, which can for example be characterized by an airtight flake or a foam or spacer cloth sealed with paint. In addition, a pump 193 is shown, which is connected to the wound care device via a fluid medium suction connection device. The openable window 192 features a recess in the material that forms a compartment for the pump 193.

The pump 193 is embodied so as to be detachable as seen in FIG.

FIG. 21 shows an exploded view of a wound care device having a wound dressing element 211 in the form of a frame that can be attached to the patient's skin, for example with a physiologically safe adhesive, via an underlying flake 214. . Also shown is the foam or spacer fabric 215 of the wound dressing element 211.

FIG. 21 also shows an openable window 212 positioned on the wound dressing element by a hermetic closure, such as a low adhesion silicone paint, and a window sealed by a hermetic flake or paint. Some foam or spacer fabric 216 is also featured.

In addition, the pump 213 connected to the wound care device via the fluid medium suction connection device and the recess in the window forming the pump compartment can be seen.

In addition, a wound contact grid 217 is shown, which can either be (i) wound-opposed and loosely placed inside the frame or connected to the frame, or (ii) the coated side it may be arranged.

FIG. 22 shows a further wound care wound care device with a negative pressure atmosphere in the wound area, in which the pump is embodied as a manually operated pump.

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KR101796287B1	2016-06-01	2017-11-10	고려대학교 산학협력단	Wound healing accelerator pad
JPWO2019177156A1 *	2018-03-16	2021-03-11	ニチバン株式会社	Wound dressing
CN109124712B *	2018-09-20	2021-05-07	上海锦辰医药科技有限公司	Wound closure device
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BR202019024885U2 *	2019-11-26	2021-06-08	Gustavo Moreira Costa De Souza	dressing for negative pressure wound therapy

* Cited by examiner, † Cited by third party, ‡ Family to family citation

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Publication	Publication Date	Title
US11154426B2	2021-10-26	Wound care device for the treatment of wounds by means of atmospheric negative pressure, comprising a window that can be opened
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JP6705916B2	2015-04-22	Depressurized medical supplies assembly for applying closure force
JP7000419B2	2022-01-19	Medical systems and dressings used under pressure
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US20050186260A1	2005-08-25	Medicated gel foam and method of use
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JP5322002B2	2013-10-23	Wound device and wound device using the wound device
CN115068670A	2022-09-20	Pump assembly and wound therapy device

CN115038870A	2022-09-09	Pump assembly and wound therapy device

Priority And Related Applications

Priority Applications (5)

Application	Priority date	Filing date	Title
DE102013105063.8		2013-05-16	
DE102013105063.8A	2013-05-16	2013-05-16	WOUND CARE DEVICE FOR TREATING WOUNDS USING ATMOSPHERIC UNDERPRESSURE SHOWN AS AN OPEN WINDOW
DE102013107399.9		2013-07-12	
DE102013107399		2013-07-12	
PCT/EP2014/060133	2013-05-16	2014-05-16	Wound care device for treating wounds by means of atmospheric negative pressure, comprising a window that can be opened

Legal Events

Date	Code	Title	Description
2017-04-14	A621	Written request for application examination	**Free format text**: JAPANESE INTERMEDIATE CODE: A621 **Effective date**: 20170414
2017-10-24	A711	Notification of change in applicant	**Free format text**: JAPANESE INTERMEDIATE CODE: A711 **Effective date**: 20171024
2017-11-10	A521	Request for written amendment filed	**Free format text**: JAPANESE INTERMEDIATE CODE: A821 **Effective date**: 20171024
2017-12-25	A521	Request for written amendment filed	**Free format text**: JAPANESE INTERMEDIATE CODE: A523 **Effective date**: 20171225
2018-01-23	A711	Notification of change in applicant	**Free format text**: JAPANESE INTERMEDIATE CODE: A712 **Effective date**: 20171024
2018-02-23	A977	Report on retrieval	**Free format text**: JAPANESE INTERMEDIATE CODE: A971007 **Effective date**: 20180221
2018-02-27	A131	Notification of reasons for refusal	**Free format text**: JAPANESE INTERMEDIATE CODE: A131 **Effective date**: 20180227
2018-02-28	RD04	Notification of resignation of power of attorney	**Free format text**: JAPANESE INTERMEDIATE CODE: A7424 **Effective date**: 20180228
2018-05-25	A521	Request for written amendment filed	**Free format text**: JAPANESE INTERMEDIATE CODE: A523 **Effective date**: 20180525
2018-10-30	A131	Notification of reasons for refusal	**Free format text**: JAPANESE INTERMEDIATE CODE: A131 **Effective date**: 20181030
2019-01-28	A601	Written request for extension of time	**Free format text**: JAPANESE INTERMEDIATE CODE: A601 **Effective date**: 20190128
2019-03-26	A601	Written request for extension of time	**Free format text**: JAPANESE INTERMEDIATE CODE: A601 **Effective date**: 20190326
2019-04-26	A521	Request for written amendment filed	**Free format text**: JAPANESE INTERMEDIATE CODE: A523 **Effective date**: 20190426

2019-09-24	A02	Decision of refusal	**Free format text**: JAPANESE INTERMEDIATE CODE: A02 **Effective date**: 20190924

Concepts

machine-extracted

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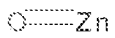
Name	Image	Sections	Count	Query match
fluid		claims,abstract,description	41	0.000
Skin		claims,abstract,description	23	0.000
wound		claims,description	265	0.000
absorbent		claims,description	60	0.000
absorbent		claims,description	60	0.000
adhesive		claims,description	40	0.000
adhesive		claims,description	37	0.000
material		claims,description	32	0.000
Exudates and Transudates		claims,description	21	0.000
foam		claims,description	21	0.000
cellulose		claims,description	11	0.000
cellulose		claims,description	11	0.000
polysiloxane		claims,description	11	0.000
alginic acid		claims,description	9	0.000
alginic acid		claims,description	9	0.000
coupling		claims,description	8	0.000
coupling process		claims,description	8	0.000
coupling reaction		claims,description	8	0.000
alginate		claims,description	7	0.000
water		claims,description	7	0.000
hydrocolloid		claims,description	6	0.000
pumping		claims,description	5	0.000
wound healing		claims,description	5	0.000
Pressure Ulcer		claims,description	4	0.000
Varicose Ulcer		claims,description	4	0.000
gas		claims,description	4	0.000
zinc monoxide		claims,description	4	0.000
Cellulose fiber		claims,description	3	0.000
Latex		claims,description	3	0.000

Oedema	claims,description	3	0.000
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latex	claims,description	3	0.000
plastic	claims,description	3	0.000
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sodium chloride	claims,description	3	0.000
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Intestinal Fistula	claims,description	2	0.000
Lymphatic fistula	claims,description	2	0.000
Sternum	claims,description	2	0.000
Thoracic Wall	claims,description	2	0.000
Ulcers	claims,description	2	0.000
Wound infection	claims,description	2	0.000
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compression	claims,description	2	0.000
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zinc oxide	claims,description	2	0.000
Abdominal compartment syndrome	claims	1	0.000
anatomy	claims	1	0.000
reversible	claims	1	0.000
surgical procedure	claims	1	0.000

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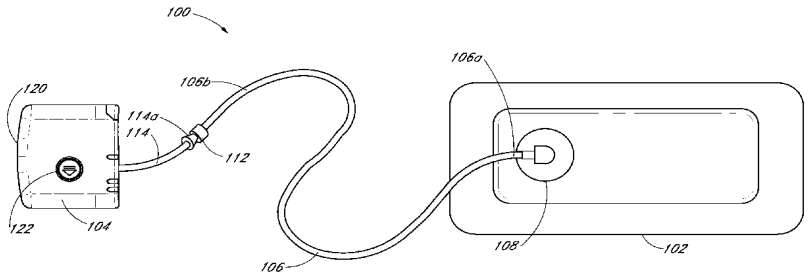


FIG. 1

(57) **Abstract**: Some embodiments comprise a pump assembly for reduced pressure wound therapy, comprising a housing, a flow pathway through the pump, one or more valves in communication with the flow pathway, a pump supported within or by the housing, and a one-way flow valve in fluid communication with the pump. The pump assembly can have a pressure sensor in communication with the flow pathway through the pump, and at least one switch or button supported by the housing, the at least one switch or button being accessible to a user and being in communication with the controller. The one-way flow valve can be configured to substantially prevent a flow of gas through the one-way flow valve in a direction of flow away from the pump. The pump assembly can have a controller supported within or by the housing, the controller being configured to control an operation of the pump. The pump has been sterilized following the assembly of the pump such that an inside and an outside of the housing, the flow pathway, the one or more valves, the pump, the controller, the battery compartment, and the at least one switch or button have been sterilized.

WO 2013/064852 A1

REDUCED PRESSURE THERAPY APPARATUSES AND METHODS OF USING SAME

INCORPORATION BY REFERENCE

[0001] This application incorporates by reference U.S. Patent Application No. 13/092,042, filed April 21, 2011 (titled WOUND DRESSING AND METHOD OF USE), U.S. Patent Application No. 11/922,894, filed May 21, 2008 (titled ANTIMICROBIAL BIGUANIDE METAL COMPLEXES), U.S. Provisional Application No. 61/511,950 (titled METHODS AND APPARATUSES FOR DETECTING LEAKS AND CONTROLLING PUMP OPERATION IN A NEGATIVE PRESSURE WOUND THERAPY SYSTEM), filed July 26, 2011, PCT Patent Application No. PCT/GB11/000622 (titled WOUND DRESSING), filed on April 21, 2011, PCT Patent Application No. PCT/GB11/000621 (titled WOUND PROTECTION), filed on April 21, 2011, PCT Patent Application No. PCT/GB11/000625 (titled WOUND DRESSING), filed on April 21, 2011, PCT Patent Application No. PCT/GB11/000626 (titled MULTIPORT DRESSING), filed on April 21, 2011, PCT Patent Application No. PCT/GB11/000628 (titled SUCTION PORT), filed on April 21, 2011, and PCT Patent Application No. PCT/GB11/051745 (titled PRESSURE CONTROL APPARATUS), filed on September 16, 2011. Each and all of the foregoing patent applications are hereby incorporated by reference in their entireties and made part of this disclosure. Additionally, co-pending Patent Application No. 13/XXX,XXX (Attorney Docket No. SMNPH.194A), entitled "SYSTEMS AND METHODS FOR CONTROLLING OPERATION OF A REDUCED PRESSURE THERAPY SYSTEM," filed on November 2, 2011, and co-pending PCT Patent Application No. PCT/US11/XXXXXX (Attorney Docket No. SMNPH.194WO), entitled "SYSTEMS AND METHODS FOR CONTROLLING OPERATION OF A REDUCED PRESSURE THERAPY SYSTEM," filed on November 2, 2011 are also hereby incorporated by reference in their entireties as if set forth herein.

BACKGROUND

Field of the Disclosure

[0002] Embodiments disclosed herein relate to methods and apparatuses for dressing and treating a wound with topical negative pressure (TNP) therapy. For example but without limitation, some embodiments disclosed herein relate to treating a wound with reduced pressure provided from a pump kit. Although not required, some embodiments of the pump kit can be sterile. As another non-limiting example, some embodiments disclosed herein relate to apparatuses and methods for controlling the operation of a TNP system.

Description of the Related Art

[0003] Many different types of wound dressings are known for aiding in the healing process of a human or animal. These different types of wound dressings include many different types of materials and layers, for example, gauze, pads, foam pads or multi-layer wound dressings. Topical negative pressure ("TNP") therapy, sometimes referred to as vacuum assisted closure, negative pressure wound therapy, or reduced pressure wound therapy, is widely recognized as a beneficial mechanism for improving the healing rate of a wound. Such therapy is applicable to a broad range of wounds such as incisional wounds, open wounds and abdominal wounds or the like.

[0004] TNP therapy assists in the closure and healing of wounds by reducing tissue oedema; encouraging blood flow; stimulating the formation of granulation tissue; removing excess exudates and may reduce bacterial load and thus, infection to the wound. Furthermore, TNP therapy permits less outside disturbance of the wound and promotes more rapid healing.

SUMMARY OF SOME EMBODIMENTS

[0005] Some embodiments disclosed herein relate to a pump assembly for reduced pressure wound therapy, comprising a housing, a pump supported within or by the housing, a flow pathway through the pump assembly, and a one-way flow valve in fluid communication with the pump and supported by the housing. Some embodiments of the one-way flow valve can be configured to substantially prevent a flow of gas through the flow pathway in a direction of flow away from the pump. The pump can have a motor, an inlet

and an outlet, a first valve supported by the pump and configured to control a flow of a fluid through the inlet, and a second valve supported by the pump and configured to control a flow of a fluid through the outlet.

[0006] Some embodiments disclosed herein relate to a pump assembly for reduced pressure wound therapy, comprising a housing, a pump supported within or by the housing, a one-way flow valve in fluid communication with the pump, and a flow pathway through the pump assembly. The one-way flow valve can be configured to substantially prevent a flow of gas through the flow pathway in a direction of flow away from the pump. The pump can comprise a motor, an inlet, and an outlet. In any of the pump embodiments disclosed herein, though not required, the pump can also have a first valve configured to control a flow of a fluid through the inlet, and a second valve configured to control a flow of a fluid through the outlet. Some pump embodiments disclosed herein can use orifices or other features or components to control a flow or rate of flow of fluid through the pump.

[0007] Some embodiments disclosed herein relate to a negative pressure therapy kit for reduced pressure wound therapy, comprising a pump assembly comprising a housing, a pump supported within the housing, and a controller supported within or by the housing, and at least one switch or button supported by the housing. As used throughout this specification, the phrase "some embodiments" or "in some embodiments" is meant to refer to any embodiment described, illustrated, incorporated by reference, or otherwise disclosed herein. The at least one switch or button can be in communication with the controller and can be accessible to a user so as to permit a user to control one or more modes of operation of the pump. In some embodiments, though not required, the negative pressure therapy kit can comprise a dressing configured to form a substantially fluid tight seal over a wound, a conduit coupleable with the dressing and the pump assembly and configured to provide a substantially or completely enclosed fluid flow pathway from the pump assembly to the dressing, and a first packaging element for packaging the pump assembly, the one or more batteries, the dressing, and the conduit. In some embodiments, the controller can be configured to control an operation of the pump and the valve. Some embodiments of the negative pressure therapy kit can be configured such that the negative pressure therapy kit has been sterilized. The negative pressure therapy kit can be sterilized such that at least an inside and an outside of the housing, the at least one valve, the pump, the controller, and the at least

one switch or button have been sterilized. In some embodiments, the pump can have a pump motor, an inlet and an outlet, at least one valve configured to control a flow of fluid through at least one of the inlet and the outlet, and a flow pathway through at least the inlet, the outlet, and the at least one valve.

[0008] Some embodiments disclosed herein relate to reduced pressure treatment of wounds with a reduced pressure pump. The pump embodiments disclosed herein are not required to be sterilized. However, sterilizing the reduced pressure pump before use and providing the pump and/or dressing or pump kit components in a sterile condition can permit the use of the pump in an operating room (also referred to as an operating theater) or any other location where sterility of the devices is required. For example and without limitation, some embodiments are directed to a sterile pump kit comprising a sterile pump, a sterile dressing, and a sterile conduit connectable to the dressing and the pump that can be used in an operating room.

[0009] Some embodiments disclosed herein relate to a negative pressure therapy kit for reduced pressure wound therapy, comprising a pump having a flow rate of approximately 350 milliliters per minute or less, and a dressing comprising a cover layer. The dressing can have a wound contact surface that is covered with a silicone based adhesive.

[0010] Some embodiments disclosed herein relate to a canisterless pump for reduced pressure wound therapy, comprising a housing, a flow pathway through the pump, one or more valves in communication with the flow pathway, and a pump supported within or by the housing, wherein the pump is canisterless. Some embodiments disclosed herein relate to a canisterless pump assembly for reduced pressure wound therapy, comprising a housing and a pump supported within or by the housing. The pump can have a motor, an inlet and an outlet, a first valve supported by the pump and configured to control a flow of a fluid through the inlet, and a second valve supported by the pump and configured to control a flow of a fluid through the outlet. The pump or pump assembly can be canisterless. Further, though not required for all embodiments disclosed herein, and the first and second valves can each have a leakage rate of from approximately 0.1 mL/min to approximately 10 mL/min at nominal working pressures and/or during nominal sterilization pressures, or from 0.1 mL/min or less to 5 mL/min or more, or from 1 mL/min or less to 3 mL/min or more, or between any two values in any of the foregoing ranges at nominal working pressures. In some

embodiments, the leakage rate can be from approximately 0.4 mL/min to 0.7mL/min at nominal working pressures and/or during nominal sterilization pressures.

[0011] Some embodiments of the pump assembly can have a piezoelectric pump, such as without limitation the piezoelectric pump disclosed in US 7,550,034 and/or US 2011/186765. Some piezoelectric pumps can have orifices to perform the valve functions such that, when the pump is at rest, the flow rate through the pump can be as high as 200 mL/min. Therefore, in some embodiments, where the pump rate can be as high as approximately 300 mL/min or 320 mL/min or otherwise, the first and second valves (which can be orifices) can each have a leakage rate of up to approximately 200 mL/min.

[0012] Some embodiments disclosed herein relate to a sterile pump kit, comprising any of the pump embodiments disclosed herein, a dressing, a conduit coupleable with the dressing and the sterile pump and configured to provide a fluid pathway of reduced pressure to the dressing, one or more batteries, and a first packaging element and a second packaging element configured to be removably coupled with the first packaging element. In some embodiments, at least one of the first and second packaging elements can have recesses for receiving the sterile pump, a dressing, a conduit coupleable with the dressing and the sterile pump and configured to provide a fluid pathway of reduced pressure to the dressing. The sterile pump kit can be been sterilized after the pump, the dressing, the conduit, and the one or more batteries have been supported inside at least one of the first packaging element and the second packaging element.

[0013] Some embodiments disclosed herein relate to a method for initiating treatment of a wound in an operating room, comprising applying a sterile dressing over a wound so as to create a substantially fluid tight seal over the wound, coupling a sterile pump to dressing via a sterile conduit, and reducing a level of pressure between the dressing and the wound in an operating room by activating the pump in the operating room.

[0014] Some embodiments disclosed herein relate to apparatuses and methods for controlling operation of a negative pressure wound therapy system. In particular, but without limitation, embodiments disclosed herein relate to negative pressure therapy apparatuses and dressings, and methods and algorithms for operating such negative pressure therapy systems. In some embodiments, though not required, an apparatus can comprise a dressing configured to be placed over a wound and to create a substantially fluid impermeable seal over the

wound. An apparatus can comprise a source of negative pressure configured to be coupled to the dressing. The apparatus can further comprise a controller configured to activate the source of negative pressure, monitor a duty cycle of the source of negative pressure, and determine if the duty cycle exceeds a duty cycle threshold. In some embodiments, the controller can be configured to monitor a plurality of duty cycles of the source of negative pressure over a plurality of consecutive and equal time durations, and determine if a duty cycle of the plurality of duty cycles exceeds a duty cycle threshold. The duty cycle can reflect an amount of time the source of negative pressure is active during a period of time or during a time duration of the plurality of consecutive and equal time durations

[0015] In some embodiments, the controller can be configured to determine if a number of duty cycles exceed the duty cycles threshold and if that number exceeds an overload threshold. In some embodiments, the controller can be configured to determine if a set of duty cycles from the plurality of duty cycles exceeds a duty cycle threshold and determine if the number of duty cycles in the set exceeds an overload threshold. The controller can be configured to determine if the number of duty cycles that exceeds the duty cycle threshold are consecutive. In some embodiments, the overload threshold can comprise 30 duty cycles, the period of time or time duration can comprise one minute, and/or the duty cycle threshold can comprise 9%. In some embodiments, the controller can be configured to continuously monitor the duty cycle or the plurality of duty cycles.

[0016] Some embodiments of the apparatus comprise a switch configured to pause the source of negative pressure for a period of time and the controller can be configured to restart the source of negative pressure upon expiration of the period of time. The period of time can be variable. In some embodiments, the apparatus can be enclosed in a housing comprising an exterior surface and the switch comprises a button located on the exterior surface of the housing.

[0017] Some embodiments of the apparatus comprise a controller configured to provide an indication of an operating condition. The operation condition can comprise determining that the duty cycle exceeds the duty cycle threshold and the indication can comprise deactivating the source of negative pressure to indicate a leak in the seal. In some embodiments, the operating condition comprises whether the source of negative pressure is paused and the controller can be configured to provide a first indication when the source of

negative pressure is active and a second indication when the source of negative pressure is paused, wherein the second indication is different from the first indication.

[0018] In some embodiments, the controller can be configured to activate the source of negative pressure to attempt to generate a desired negative pressure level under the dressing and if upon expiration of a first time interval, a pressure level under the dressing has not reached the desired negative pressure level, the controller can deactivate the source of negative pressure for a second time interval. Upon expiration of the second time interval, the controller can activate the source of negative pressure to attempt to generate the desired negative pressure level under the dressing. The controller can be configured to vary the second time interval based on a number of times the pressure level under the dressing has not reached the desired negative pressure level. For example, the controller can be configured to double the second time interval provided that a resulting value does not exceed a second interval threshold. The apparatus can comprise a sensor configured to sense pressure under the dressing and to communicate the sensed pressure to the controller.

[0019] In some embodiments, the controller can be configured to deactivate the source of negative pressure when the pressure level under the dressing has reached the desired negative pressure level and activate the source of negative pressure when the pressure level under the dressing rises above a negative pressure threshold, wherein the desired negative pressure level corresponds to a pressure that is more negative than the negative pressure threshold.

[0020] In some embodiments, the source of negative pressure can be operated by positioning a dressing over a wound to create a substantially fluid impermeable seal over the wound, delivering negative pressure to the dressing from the source of negative pressure, monitoring a duty cycle of the source of negative pressure, and providing an indication if the duty cycle is determined to exceed a duty cycle threshold. The duty cycle can reflect an amount of time the source of negative pressure is active during a period of time, such as once per minute.

[0021] Some embodiments of the apparatus can be configured to monitor a total elapsed time since an initial activation and disable the activation of the source of negative pressure when the total elapsed time reaches a lifetime threshold. The life time threshold can comprise, for example, 7 days.

[0022] In some embodiments, the apparatus for applying negative pressure to a wound comprises a dressing configured to be placed over the wound and to create a substantially fluid impermeable seal over the wound, a source of negative pressure configured to be coupled to the dressing, and a controller configured to activate the source of negative pressure, monitor a duty cycle of the source of negative pressure, and provide an indication if the duty cycle exceeds a duty cycle threshold.

[0023] In some embodiments, the apparatus comprises a dressing configured to be placed over the wound and to create a substantially fluid impermeable seal over a wound, and a pump is configured to be coupled to the dressing, a switch configured to pause the pump for a period of time, and a controller configured to restart the pump upon expiration of the period of time. The period of time can be variable. Some embodiments of the apparatus comprise a miniature diaphragm pump operated by a motor or a miniature diaphragm pump operated by a piezoelectric transducer. In some embodiments, the pump can comprise a miniature piston pump and a miniature diaphragm pump.

[0024] Some embodiments disclose a method of operating a source of negative pressure (e.g., a negative pressure pump), the method comprising positioning a dressing over a wound to create a substantially fluid impermeable seal over the wound, delivering negative pressure to the dressing from the pump, pausing the pump for a period of time, and restarting the pump upon expiration of the period of time. The period of time can be variable.

[0025] In some embodiments, a negative pressure pump can be operated by positioning a dressing over a wound to create a substantially fluid impermeable seal over the wound, aspirating fluid from the wound using the negative pressure pump, measuring a level of activity of the pump, comparing the level of activity of the pump to a threshold, and providing an indication if the level of activity exceeds the threshold. Measuring the level of activity can comprise determining a duty cycle of the pump, determining a flow rate of the fluid aspirated from the wound (e.g., by using a flow meter), measuring a rate of change of pressure under the dressing using a pressure sensor, etc. or any combination thereof.

[0026] Some embodiments disclose a method for operating a negative pressure pump, comprising positioning a dressing over a wound to create a substantially fluid impermeable seal over the wound, delivering negative pressure to the dressing from the pump to draw pressure under the dressing toward a first negative pressure set point, activating the

pump to draw pressure under the dressing toward the first set point if the level of negative pressure under the dressing rises above a second negative pressure set point, monitoring an amount of time the pump has been operating, and providing an indication if the amount of time exceeds a predetermined amount of time. The method can further comprise determining the amount of time that the pump has been operating over a period of time and providing the indication if the amount of time exceeds 9% of the period of time. In some embodiments, providing the indication further comprises determining the amount of time that the pump has been operating over a period of time. In some embodiments, providing the indication further comprises activating an alarm.

[0027] In some embodiments, the apparatus can be configured to activate a source of negative pressure to draw a pressure under a negative pressure wound therapy dressing to a desired negative pressure value, such as a value between a first set point and a second set point or approximately equal to the second set point value. The level of pressure under the dressing can be measured. The apparatus can be configured to activate the source of negative pressure to draw the pressure under the dressing toward a second desired negative pressure level (e.g., the second set point value) if pressure under the dressing decays above a threshold (e.g., decays to the first set point value). The amount of time that the source of negative pressure has been operating, for example, continuously, can be monitored. The operation of the source of negative pressure can be paused or discontinued if the source of negative pressure has been operating for a predetermined amount of time without establishing approximately the second desired negative pressure level under the dressing (e.g., the second set point value).

[0028] Some embodiments disclose a method of operating a source of negative pressure, comprising positioning a dressing over a wound to create a substantially fluid impermeable seal over the wound and delivering negative pressure to the dressing from the source of negative pressure. Delivering negative pressure to the dressing from the source of negative pressure comprises activating the source of negative pressure to attempt to generate a desired negative pressure level under the dressing and updating a first count of activations; if upon expiration of a first time interval, negative pressure under the dressing has not reached the desired negative pressure level, deactivating the source of negative pressure for a second time interval, provided that the first count of activations is less than a first retry

threshold; if the first count of activations is not less than the first retry threshold, deactivating the source of negative pressure for a third time interval, resetting the first count of activations, and, upon expiration of the third time interval, activating the source of negative pressure to attempt to generate the desired negative pressure level under the dressing; activating the source of negative pressure upon expiration of the second time interval to attempt to generate the desired negative pressure level under the dressing and updating the first count of activations; deactivating the source of negative pressure when the negative pressure under the dressing has reached the desired negative pressure level, resetting the first count of activations, and monitoring negative pressure under the dressing; when negative pressure under the dressing rises above a negative pressure threshold, activating the source of negative pressure and updating a second count of activations, wherein the desired negative pressure level corresponds to a pressure that is more negative than the negative pressure threshold; if before expiration of a fourth time interval negative pressure under the dressing has reached the desired negative pressure level, deactivating the source of negative pressure, monitoring negative pressure under the dressing, and resetting the second count of activations; if upon expiration of the fourth time interval negative pressure under the dressing has not reached the desired negative pressure level, deactivating the source of negative pressure for the second time interval, provided that the second count of activations is less than a second retry threshold; if the second count of activations is not less that the second retry threshold, deactivating the source of negative pressure for the third time interval, resetting the second count of activations, and, upon expiration of the third time interval, activating the source of negative pressure to attempt to generate the desired negative pressure level under the dressing and updating the first count of activations; continuously monitoring a duty cycle of the source of negative pressure; tracking a number of duty cycles that exceed a duty cycle threshold; and deactivating the source of negative pressure for a duration of the third time interval when the number of duty cycles that exceed the duty cycle threshold exceeds an overload threshold.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] Embodiments of the present invention will now be described hereinafter, by way of example only, with reference to the accompanying drawings in which:

[0030] Figure 1 illustrates an embodiment of a reduced pressure wound therapy apparatus comprising a pump, a dressing, and a conduit.

[0031] Figures 2A-2F are various views of the embodiment of the pump illustrated in Figure 1.

[0032] Figure 3A illustrates an embodiment of a wound dressing kit comprising a dressing, a pump, a conduit, two batteries, and one or more sealing strips supported in a first packaging element.

[0033] Figure 3B is a bottom isometric view of the embodiment of the wound dressing kit of Figure 3A.

[0034] Figure 3C is an exploded view of the embodiment of the wound dressing kit of Figure 3A.

[0035] Figure 4A is a first exploded view of the embodiment of the pump of Figure 1.

[0036] Figure 4B is a second exploded view of the embodiment of the pump of Figure 1.

[0037] Figures 5A and 5B are first and second views of the first housing member.

[0038] Figures 6A and 6B are first and second views of the second housing member.

[0039] Figures 7A-7D illustrate the use of an embodiment of a TNP wound treatment system being used to treat a wound site on a patient.

[0040] Figures 8A – 20H are top isometric, bottom isometric, top plane, bottom plane, front, back, first side, and second side views, respectively, of embodiments of packaging elements that can be used with any of the embodiments of the wound dressing apparatuses disclosed herein, including a variety of differently sized wound dressing apparatuses.

[0041] Figure 21 illustrates a pump assembly according to some embodiments.

[0042] Figure 22 illustrates a cross-sectional view showing the interior of a pump assembly according to some embodiments.

[0043] Figure 23 illustrates a system schematic of a pump assembly according to some embodiments.

[0044] Figure 24 illustrates an electrical component schematic of a pump assembly according to some embodiments.

[0045] Figure 25 illustrates a top level state diagram of operation of a pump assembly according to some embodiments.

[0046] Figure 26 illustrates an operational state diagram of operation of a pump assembly according to some embodiments.

[0047] Figure 27 illustrates another state diagram of operation of a pump assembly according to some embodiments.

[0048] Figure 28 illustrates a graph depicting a duty cycle determination for a pump assembly according to some embodiments.

[0049] Figure 29 illustrates operation of a pump assembly in presence of a low leak according to some embodiments.

[0050] Figure 30 illustrates operation of a pump assembly in presence of a high leak according to some embodiments.

[0051] Figure 31 illustrates operation of a pump assembly in presence of a very high leak according to some embodiments.

[0052] Figure 32 illustrates operation of a pump assembly in presence of an extremely high leak according to some embodiments.

[0053] In the drawings like reference numerals refer to like parts.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0054] Embodiments disclosed herein relate to apparatuses and methods of treating a wound with reduced pressure. As is used herein, reduced or negative pressure levels, such as –X mmHg, represent pressure levels that are below standard atmospheric pressure, which corresponds to 760 mmHg (or 1 atm, 29.93 inHg, 101.325 kPa, 14.696 psi, etc.). Accordingly, a negative pressure value of –X mmHg reflects absolute pressure that is X mmHg below 760 mmHg or, in other words, an absolute pressure of (760–X) mmHg. In addition, negative pressure that is "less" or "smaller" than X mmHg corresponds to pressure that is closer to atmospheric pressure (e.g., –40 mmHg is less than –60 mmHg). Negative pressure that is "more" or "greater" than –X mmHg corresponds to pressure that is further from atmospheric pressure (e.g., –80 mmHg is more than –60 mmHg).

[0055] Some of the embodiments comprise a pump and/or a pump and dressing kit. Some embodiments are directed to a pump and/or pump and dressing kit that have been sterilized before delivery to the hospital, operating room or theatre, or to the medical practitioner using such devices such that the sterile pump and/or a sterile pump/dressing kit can be applied immediately following the surgical or operating procedures. One advantage of this is that the surgeon can release the patient from the operating room knowing that the reduced pressure pump is operating and that the reduced pressure therapy has been started at the earliest point in time possible. A further advantage of applying the dressing kit immediately following the surgical or other procedure is that doing so can reduce the chance of infection by eliminating a subsequent dressing change that may otherwise be required in the ward. In other words, for those patients where a dressing (but not a pump) is applied in the operating theatre and then a problem is found thereafter, such as a leak or other issue with the dressing, if the dressing is required to be removed to be repositioned, replaced, or otherwise after the patient is released from the operating theater, the patient's wound may be exposed to infection risk when the dressing is repositioned, replaced, or otherwise outside of the operating theater. However, with the embodiments disclosed herein, if the pump is applied and tested while the patient is in the operating theater, any issues with the dressing that may require the dressing to be removed, repositioned, or otherwise, can be handled in the sterile operating room environment, thereby significantly reducing or eliminating the risk of exposure to pathogens, bacteria, or other contaminants. Further, it is generally not possible for a hospital to sterilize a traditional pump once it has been received by the hospital, and therefore the hospital may resort to bagging the pumps in sterile bags but risk compromising the operating room sterile field with this approach, particularly once the device is turned on and pathogens, bacteria, or other contaminants that may be inside the pump are release due to the operation of the pump.

[0056] In some embodiments, the pump can be configured to be amenable to gas sterilization, having features, components, and other characteristics that make the pump amenable to full sterilization gas exposure and penetration throughout the components of the pump. For example, without limitation, one or more pump valves have been selected or configured to permit a sufficient flow of sterilization gas therethrough such that the entire fluid pathway within the pump can be exposed to the sterilization gas. As will be explained

in greater detail below, in some embodiments, the pump can have other components, such as without limitation, strategically positioned one way flow valves, to complement the other valves within the pump, which can improve the efficiency of the pump by reducing leakage through the flow pathway within the pump assembly.

[0057] Additionally, where provided, the sterile pump/dressing kit can also be designed and configured to be amenable to gas sterilization. As described below, the sterile pump/dressing kit can be configured such that all of the components comprising the sterile pump/dressing kit, including the pump assembly, are packaged together in at least a first packaging element before sterilization, permitting all of the components to be sterilized together. Furthermore, as will be described, the components comprising the sterile pump/dressing kit can be arranged in the packaging such that at least some of the components can be removed in a predefined order, making it easier for the surgeon or medical practitioner to assemble and apply the dressing to the patient.

[0058] There are a number of benefits to being able to begin treatment of a wound in the operating theater, including without limitation providing a substantially sealed barrier over the wound while the wound is in a sterile condition and environment that will inhibit or prevent bacteria or other contaminants from getting into the wound. Additionally, initiating the reduced pressure treatment at the earliest stage possible is also advantageous to healing of the wound.

[0059] Additionally, embodiments disclosed or incorporated by reference herein, such as those disclosed in U.S. Patent Application No. 13/092,042, Great Britain Patent Application Nos. 1015656.0, 1006986.2, 1006983.9, 1006985.4, 1006988.8, and 1008347.5 comprise improved wound dressing components. All embodiments, components, features, and other details of such disclosures are hereby incorporated by reference herein as if made part of this disclosure, and can be used in place of or in combination with any of the components, features, and other details of the embodiments disclosed herein. For example, in some embodiments, the wound dressing can be configured to act as a buffer to help prevent compression or shear forces exerted on the wound dressing, for example due to patient movement, from harming a healing wound. Embodiments of the wound dressing may act as a waste canister to collect and store wound exudate removed from a wound site, and also relate to the management of solid build-up in a wound dressing covering a wound site

whilst TNP therapy is applied. Further, embodiments disclosed herein relate to a method and suction port for applying negative pressure to a wound dressing and a method of manufacturing a suction port and wound dressing.

[0060] Moreover, some embodiments disclosed herein are directed to systems that include negative pressure therapy apparatuses and dressings, and methods and algorithms for operating such negative pressure therapy apparatuses for use with negative pressure therapy dressings. In some embodiments, a negative pressure therapy apparatus comprises a pump assembly configured to, *inter alia*, provide negative pressure to a wound. Some embodiments of pump assemblies disclosed herein comprise novel and inventive control logic configured to control the operation of the pump assembly. For example, some embodiments comprise novel and inventive control logic configured to control the operation of a pump assembly in response to monitoring and detecting various operating conditions, such as presence and/or severity of a leak or leaks in the system, rate of flow of fluid (e.g., air, liquid and/or solid exudate, etc.) aspirated from a wound, and the like. In some embodiments, the control logic can be configured to detect a leak or leaks in a system (e.g., leak or leaks in the dressing that is in fluid communication with the pump, leak or leaks in the seal created by the dressing over the wound, etc.) as well as to control the operation of the pump assembly when such leak or leaks are detected. In some embodiments, the pump assembly can be configured to distinguish between at least a normal or low leak (e.g., a leak that has a relatively low flow rate), a high leak (e.g., a leak that has a relatively high flow rate), and a very high leak (e.g., a leak that has a relatively very high flow rate). Some embodiments can further be configured to also distinguish between the aforementioned leaks and an extremely high leak.

[0061] In some embodiments, the pump assembly can comprise a source of negative pressure, such as a miniature, disposable pump, powered by a power source, such as a battery source. The pump assembly can be configured to provide therapy for a predetermined period of time, such as approximately 1 day, 2-10 days, etc. In some embodiments, the pump assembly can be required to provide uninterrupted therapy for such period of time. In some embodiments, the pump assembly can be configured to deactivate itself a predetermined period of time (e.g., 7 days) after an initial activation. The algorithms or logic disclosed herein can help the pump assembly operate more efficiently and conserve power, for example but without limitation, battery power.

[0062] In some embodiments, the pump assembly can be configured to monitor the duty cycle of the source of negative pressure (e.g., a pump). As is used herein, "duty cycle" reflects the amount of time the source of negative pressure is active or running over a period of time. In other words, the duty cycle reflects time that the source of negative pressure is in an active state as a fraction of total time under consideration. This can be represented mathematically as:

[0063] $DC = t / T,$ (1)

[0064] where DC is the duty cycle, t is the duration that the source of negative pressure is active, and T is the total time under consideration. Duty cycle can be measured as an absolute value (e.g., X seconds), a proportion (e.g., 1/X), a percentage (e.g., X%), etc. For example, if over a period of 1 minute the source of negative pressure has been on (or operating) for 6 seconds and off (or not operating) for 54 seconds, the duty cycle can be represented as 6 seconds, 1/10, 10%, etc.

[0065] In some embodiments, the pump assembly can include a controller configured to monitor the duty cycle of the source of negative pressure. Duty cycle measurements can reflect a level of activity of the source of negative pressure. For example, duty cycle can indicate that the source of negative pressure is operating normally, working hard, working extremely hard, etc. Moreover, duty cycle measurements, such as periodic duty cycle measurements, can reflect various operating conditions, such as presence and/or severity of leaks in the system, rate of flow of fluid (e.g., air, liquid and/or solid exudate, etc.) aspirated from a wound, and the like. Based on the duty cycle measurements, such as by comparing the measured duty cycle with a set of thresholds (e.g., determined in calibration), the controller can execute and/or be programmed to execute algorithms or logic that control the operation of the system in accordance with various system requirements. For example, duty cycle measurements can indicate presence of a high leak in the system, and the controller can be programmed to indicate this condition to a user (e.g., patient, caregiver, physician, etc.) and/or temporarily suspend or pause operation of the source of negative pressure in order to conserve power.

[0066] In some embodiments, the system can be configured to monitor the rate of flow by any other suitable means. The pump assembly can be configured to use flow meters (e.g., mechanical, pressure-based, optical, mass, thermal mass, electromagnetic, sonic,

ultrasonic, laser Doppler, etc.), anemometers, pressure transducers or sensors, electromagnetic sensors (e.g., sensors configured to measure pump speed, such as Hall sensors), electromagnetic measurements (e.g., measuring the current and/or power draw of the pump, measuring current and/or power drain of the power source, measuring the remaining capacity of the power source, etc.) or any combination thereof. Based on the monitored rate of flow, such as by comparing the rate of flow with a set of thresholds (e.g., determined in calibration), the controller can execute and/or be programmed to execute algorithms or logic that control the operation of the system in accordance with various system requirements. For example, the controller can be configured to obtain periodic measurements from a pressure sensor or obtain periodic feedback from a pump motor. The pressure sensor can measure pressure under the dressing. The controller can determine the rate of flow, for example, by determining a pressure gradient, rate of change of pressure, and/or pressure decay rate. For instance, a positive pressure gradient (e.g., one that is increasing) can reflect an increasing rate of flow as (e.g., a leak) in relation to a threshold, and the controller can be programmed to indicate this condition to the user.

[0067] In some embodiments, the system can be provided for treatment of a wound. The dressing can create a substantially sealed or closed space around the wound (e.g., under the dressing), and the pump assembly can have a sensor which can periodically or continuously measure or monitor a level of pressure in this space. The pump assembly or a controller thereof can be configured to control the level of pressure in the space (e.g., under the dressing) between a first negative pressure set point limit and at least a second negative pressure set point limit. In some embodiments, the first set point limit can be approximately –70 mmHg, or from approximately –60 mmHg or less to approximately –80 mmHg or more. In some embodiments, the second set point limit can be approximately –90 mmHg, or from approximately –80 mmHg or less to approximately –100 mmHg or more.

[0068] In some embodiments, the system can be configured to include "retry" functionality and/or logic. The pump assembly can be configured to monitor a level of negative pressure under the dressing (which can correspond to the level of negative pressure in the wound cavity), compare the monitored level to a desired negative pressure level (e.g., first set point, second set point, etc.), and suspend or pause therapy if the desired negative pressure level is not reached during a certain time interval. Following the suspension or

pause of therapy, the pump assembly can be configured to restart therapy (e.g., restart the source of negative pressure) and attempt to again generate the desired negative pressure level under the dressing. Retry functionality can, for instance, conserve battery power and allow transient and/or non-transient leaks to become resolved without user intervention or allow the user to fix the leak (e.g., straighten the dressing, fix the seal, check the connection or connections, etc.). In some embodiments, a controller can execute and/or be programmed to execute retry functionality and/or logic.

[0069] In some embodiments, the system can be configured to provide "play/pause" functionality and/or logic via a switch, button, etc. located on the exterior of the pump assembly's housing or any other suitable place where it can be accessed by the user. Play/pause functionality can allow the user to suspend and/or restart therapy (e.g., pause and/or restart the pump). The pump assembly can be configured to automatically restart therapy following a certain predetermined or variable pause interval. The pump assembly can be configured to automatically restart therapy upon expiration of such interval and/or indicate to the user expiration of such interval.

[0070] In some embodiments, the system can be configured to provide indication, alarms, etc. to the user reflecting operating conditions. The system can include visual, audible, tactile, and other types of indicators and/or alarms configured to signal to the user various operating conditions. Such conditions include system on/off, standby, pause, normal operation, dressing problem, leak, error, and the like. The indicators and/or alarms can include speakers, displays, light sources, etc., and/or combinations thereof. For example, indication can be provided by activating or deactivating the source of negative pressure, reducing negative pressure level generated by the source of negative, lowering the amount of power used by the source of negative pressure, etc. or any combination thereof.

[0071] Figure 1 illustrates an embodiment of a reduced pressure wound treatment apparatus 100 comprising a wound dressing 102 in combination with a pump assembly 104. In any of the apparatus embodiments disclosed herein, as in the embodiment illustrated in Figure 1, the pump assembly can be a canisterless pump assembly (meaning that the pump assembly does not have an exudate or liquid collection canister). However, any of the pump embodiments disclosed herein can be configured to include or support a canister. Additionally, in any of the apparatus embodiments disclosed herein, any of the pump

assembly embodiments can be mounted to or supported by the dressing, or adjacent to the dressing. The dressing 102 may be placed over a wound (not illustrated) as described in greater detail in U.S. Patent Application No. 13/092,042, which disclosure is hereby incorporated by reference and made part of this disclosure, and a conduit 106 may then be connected to the dressing 102. Dressing 102 or any other dressing disclosed herein can have any of the materials, sizes, components, or other details of any of the dressing embodiments disclosed in U.S. Patent Application No. 13/092,042, and such embodiments and illustrations thereof are hereby incorporated by reference in their entireties as if made part of this disclosure. The conduit 106 or any other conduit disclosed herein can be formed from polyurethane, PVC, nylon, polyethylene, silicone, or any other suitable material.

[0072] Some embodiments of the dressing 102 can have a port 108 configured to receive an end of the conduit 106 (e.g., the first end 106a of the conduit 106), though such port 108 is not required. In some embodiments, the conduit can otherwise pass through and/or under the dressing 108 to supply a source of reduced pressure to a space between the dressing 102 and the wound so as to maintain a desired level of reduced pressure in such space. Some embodiments of the apparatus 100 con be configured such that the first end 106a of the conduit 106 is preattached to the port 108. The conduit 106 can be any suitable article configured to provide at least a substantially sealed fluid flow pathway between the pump assembly 104 and the dressing 102, so as to supply the reduced pressure provided by the pump assembly 104 to the dressing 102.

[0073] The dressing 102 can be provided as a single article with all wound dressing elements (including the port 108) pre-attached and integrated into a single unit. The wound dressing 102 may then be connected, via the conduit 106, to a source of negative pressure such as the pump assembly 104. In some embodiments, though not required, the pump assembly 104 can be miniaturized and portable, although larger conventional pumps such as the EZ CARE (TM) pump can also be used with the dressing 102.

[0074] It will be understood that embodiments of the present invention are generally applicable to use in topical negative pressure ("TNP") therapy systems. Briefly, negative pressure wound therapy assists in the closure and healing of many forms of "hard to heal" wounds by reducing tissue oedema, encouraging blood flow and granular tissue formation, and/or removing excess exudate and can reduce bacterial load (and thus infection

risk). In addition, the therapy allows for less disturbance of a wound leading to more rapid healing. TNP therapy systems can also assist in the healing of surgically closed wounds by removing fluid and by helping to stabilize the tissue in the apposed position of closure. A further beneficial use of TNP therapy can be found in grafts and flaps where removal of excess fluid is important and close proximity of the graft to tissue is required in order to ensure tissue viability.

[0075] The wound dressing 102 can be located over a wound site to be treated. The dressing 102 can form a substantially sealed cavity or enclosure over the wound site. It will be appreciated that throughout this specification reference is made to a wound. In this sense it is to be understood that the term wound is to be broadly construed and encompasses open and closed wounds in which skin is torn, cut or punctured or where trauma causes a contusion, or any other surficial or other conditions or imperfections on the skin of a patient or otherwise that benefit from reduced pressure treatment. A wound is thus broadly defined as any damaged region of tissue where fluid may or may not be produced. Examples of such wounds include, but are not limited to, acute wounds, chronic wounds, surgical incisions and other incisions, subacute and dehisced wounds, traumatic wounds, flaps and skin grafts, lacerations, abrasions, contusions, burns, diabetic ulcers, pressure ulcers, stoma, surgical wounds, trauma and venous ulcers or the like. In some embodiments, the components of the TNP system described herein can be particularly suited for incisional wounds that exude a small amount of wound exudate.

[0076] Some embodiments of the apparatus are designed to operate without the use of an exudate canister. The dressing 102 can be configured to have a film having a high water vapour permeability to enable the evaporation of surplus fluid, and can have a superabsorbing material contained therein to safely absorb wound exudate. Some embodiments of the apparatus are designed for single-use therapy and can be disposed of in an environmentally friendly manner after an approximately maximum usage of from seven to eleven days. The pump can be programmed to automatically terminate therapy after a desired number of days, e.g., after seven days, further operation of the pump will not be possible. Some embodiments are designed for longer or repeated usage, and can be configured to support an exudate canister.

[0077] The apparatus 100 can be manufactured in a wide variety of different models or versions, wherein the size of the dressing 100 can be varied to accommodate a wide range of wound sizes. For example, apparatuses 100 can be made having the following sizes of dressings 102 and wound pads (i.e., absorbent elements, not illustrated in Figure 1).

Approximate Dressing Size	Approximate Wound Pad Size
10 cm x 30 cm (4 in x 11.75 in)	5 cm x 20 cm (2 in x 8 in)
15 cm x 15 cm (6 in x 6 in)	10 cm x 10 cm (4 in x 4 in)
15 cm x 20 cm (6 in x 8 in)	10 cm x 15 cm (4 in x 6 in)
10 cm x 20 cm (4 in x 8 in)	5 cm x 10 cm (2 in x 4 in)
20 cm x 20 cm (8 in x 8 in)	15 cm x 15 cm (6 in x 6 in)

[0078] Some embodiments of the overlay or dressing can be substantially impervious to air flow and the flow of bacteria or other contaminants through the overlay layer, while being pervious to vapor transmission.

[0079] In some embodiments, it may be preferable for the wound site to be filled partially or completely with a wound packing material. This wound packing material is optional, but may be desirable in certain wounds, for example deeper wounds. The wound packing material can be used in addition to the wound dressing 102. The wound packing material generally can comprise a porous and conformable material, for example foam (including reticulated foams), and gauze. Preferably, the wound packing material is sized or shaped to fit within the wound site so as to fill any empty spaces. The wound dressing 102 can then be placed over the wound site and wound packing material overlying the wound site. When a wound packing material is used, once the wound dressing 102 is sealed over the wound site, TNP is transmitted from a pump through the wound dressing 102, through the wound packing material, and to the wound site. This negative pressure draws wound exudate and other fluids or secretions away from the wound site.

[0080] In some embodiments, the tubing 106 can have a connector 112 positioned at a second end 106b of the tubing 106. The connector 112 can be configured to couple with a short length of conduit 114 projecting from the pump assembly 104, with a mating connector 114a in communication with the short length of conduit 114, with a connector

supported by the pump housing (as described in greater detail below), or otherwise. The length of the tubing 114 in some embodiments can be approximately 14 mm (.55 in), or from approximately .5 in to approximately 5 inches. The short length of conduit or tubing 114 can decrease the discomfort to a patient while laying or otherwise resting on the pump and connector 112. Configuring the pump assembly 104 and tubing 106 so that the tubing 106 can be quickly and easily removed from the pump assembly 104 can facilitate or improve the process of dressing or pump changes, if necessary. Any of the pump embodiments disclosed herein can be configured to have any of the connection configurations disclosed herein between the tubing and the pump.

[0081] In some embodiments, as in the illustrated embodiment, the pump assembly 104 can be of a sufficiently small and portable size to be supported on a user's body or in a user's clothing. For example, the pump assembly 104 can be sized to be attached using adhesive medical tape or otherwise to a person's skin in a comfortable location, adjacent to or on the dressing 102 or otherwise. Further, the pump assembly 104 can be sized to fit within a person's pants or shirt pocket, or can be tethered to a person's body using a lanyard, pouch, or other suitable device or article.

[0082] In some embodiments, the pump assembly 104 can be powered by one or more batteries (for example, two batteries) and can weigh approximately 84 grams, or less than 90 grams, including the weight of the batteries. In some embodiments, the pump assembly 104 can have any desired number of batteries and can weigh from approximately 80 grams to approximately 90 grams, or from approximately 75 grams to approximately 100 grams, or between any values within the foregoing ranges. For example, the weight and/or size of the pump assembly 104 could be reduced by reducing the battery size and/or weight (to, for example, AAA sized batteries, or smaller) or the pump size and/or weight.

[0083] Further, some embodiments of the pump assembly 104 can be sized to have a total volume defined by an outside surface of the pump of approximately 92.5 cubic centimeters (approximately 5.6 cubic inches), or 92.5 cubic centimeters (5.6 cubic inches) or less, or between 75 cubic centimeters or less and 115 cubic centimeters or more, or between 85 cubic centimeters and 100 cubic centimeters. Additionally, the pump assembly 104 can be further miniaturized using techniques known to one of ordinary skill in the art to sizes in the range of approximately 40 cubic centimeters, or 40 cubic centimeters or less, or between 30

cubic centimeters or less and 60 cubic centimeters or more. Some embodiments of the pump assembly 104 can be sized to have a total volume of between 2 cubic inches or less and 6.5 cubic inches or more, or from approximately 4 cubic inches to approximately 6 cubic inches, or between any values within the foregoing ranges.

[0084] The pump assembly 104 can have an overall outside size that is approximately 7.2 cm x approximately 6.4 cm x approximately 2.1 cm (or 7.2 cm x 6.4 cm x 2.1 cm), or a maximum of approximately 8.5 cm x approximately 8.5 cm x approximately 3 cm. Additionally, the pump assembly 104 can have an overall outside size that is approximately 5.5 cm x approximately 4.8 cm x approximately 1.5 cm (or 5.5 cm x 4.8 cm x 1.5 cm). As mentioned, the size and weight of the pump assembly 104 can be optimized, as it is in the embodiments disclosed herein, to make it more comfortable to wear or carry by the user, thereby affording increased mobility.

[0085] The negative pressure range for some embodiments of the present disclosure can be approximately -80 mmHg, or between about -20 mmHg and -200 mmHg. Note that these pressures are relative to normal ambient atmospheric pressure thus, -200 mmHg would be about 560 mmHg in practical terms. In some embodiments, the pressure range can be between about -40 mmHg and -150 mmHg. Alternatively a pressure range of up to -75 mmHg, up to -80 mmHg or over -80 mmHg can be used. Also in other embodiments a pressure range of below -75 mmHg can be used. Alternatively a pressure range of over approximately -100 mmHg, or even 150 mmHg, can be supplied by the apparatus 100. Other details regarding the operation of the pump assembly 104 are set forth in U.S. Patent Application No. 13/092,042, and such embodiments, configurations, details, and illustrations thereof are hereby incorporated by reference in their entireties as if made part of this disclosure.

[0086] Figures 2A-2F are various views of the embodiment of the pump assembly 104 illustrated in Figure 1. Figure 3A illustrates an embodiment of a wound dressing kit 100 comprising a dressing 102 (which can be any of the dressing embodiments disclosed or incorporated by reference herein), a pump assembly 104, a conduit 140, one or more batteries 142 (two being shown), and one or more sealing strips 148 supported in a first packaging element 150. Figure 3B is a bottom isometric view of the embodiment of the wound dressing

kit 100 of Figure 3A. Figure 3C is an exploded view of the embodiment of the wound dressing kit 100 of Figure 3A.

[0087] With reference to Figures 2A-3C, the pump assembly 104 can have a housing 120 comprising a first housing member 120a and a second housing member 120b, a control button 122 (which can also be a switch or other similar component), a battery cover 124, a connector 128, and one or more lights, which can be LED lights. In some embodiments, the pump assembly 104 can have more than one button 122, and can have three or more lights 132. The lights 132 can be configured to alert a user to a variety of operating and/or failure conditions of the pump assembly 104, including alerting the user to normal or proper operating conditions, pump failure, power supplied to the pump or power failure, the condition or voltage level of the batteries, detection of a leak within the dressing or flow pathway, suction blockage, or any other similar or suitable conditions or combinations thereof.

[0088] The housing 120 can be configured such that a sterilization gas, such as ethylene dioxide, can penetrate into the housing such that the internal components of the pump assembly 104 are exposed to the sterilization gas during normal sterilization processes. Typically, the pump will be exposed to the sterilization gas in a chamber that has been substantially evacuated of air or any other gas, so that the sterilization gas is drawn into the pump housing 120 and into the other spaces and chambers within the pump assembly 104. For example, some embodiments of the pump housing 120 can have an unsealed gap surrounding the connector 128 through which the sterilization gas can pass. Also, in some embodiments, the first housing member 120a can be joined to the second housing member 120b without the use of a seal therebetween.

[0089] For the sterilization process, in some embodiments, the components to be sterilized can be subjected to the following steps, inter alia, in any order. The components can be placed in a chamber or container that is evacuated to approximately 70 mBarA (or between 67 mBar A and 80 mBarA) for between approximately 15 minutes and 1 hour and 15 minutes. The components can also be subjected to inert dilution, steam pressure or conditioning, or nitrogen cycles, which can be followed by further evacuation cycles. Ethylene oxide or any other suitable sterilization gas can be introduced into the chamber or container at a pressure set point of approximately 482 mBarA (or from approximately 467

mBarA to approximately 500 mBarA). The components can be exposed to the sterilization gas at a temperature of approximately 46 degrees Celsius (or from approximately 42 degrees Celsius to 49 degrees Celsius), or up to 60 degrees Celsius. The components can be exposed to the sterilization gas for approximately 10 minutes (short cycle) or approximately 1 hour (long cycle), or from approximately 9 minutes to approximately 11 minutes (short cycle), or from approximately 59 minutes to approximately 1 hour (long cycle), or longer. The components or chamber can be flushed with nitrogen and/or air and/or degassed thereafter.

[0090] The pump assembly 104 can be powered by one or more batteries 142. The batteries 142 can be lithium chloride or any other suitable batteries that are suitable for exposure to ethylene dioxide and/or other sterilization gases. The batteries 142 can be supported outside of the pump housing 120 so as to minimize or eliminate the chance of an electrical spark which could cause an explosion in the presence of the sterilization gas or an explosive gas during the sterilization process when supported in the packaging element or elements. Additionally, where there are a plurality of batteries 142, the batteries can be spaced apart or otherwise separated in the packaging to prevent any power loss or sparking of the batteries during the sterilization process or otherwise before usage.

[0091] With reference to Figure 3A, the batteries 142 and the sealing strip or strips 148 can be positioned beneath the dressing 102 so that the dressing 102 must be removed from the first packaging element 150 before the batteries 142 are removed, thereby suggesting an order by which the components of dressing kit 100 are removed from the packaging 150 and/or applied to the patient or assembled to the other components comprising the apparatus 100.

[0092] In some embodiments, the conduit 140 can be positioned within the packaging 150 so that both ends of the conduit 140 are free or otherwise disconnected from the other components of the apparatus 100 to improve the exposure of the internal surfaces of the conduit 140 to and/or to ensure complete exposure of the tubing to the sterilization gas. The ends of the conduit 140 can be supported within recesses formed in the first packaging element 150.

[0093] The first packaging element 150 can have one or more recesses configured to receive and support the components of the apparatus 100, including a recess 190 for receiving the pump assembly 104, a recess 192 for receiving the dressing 102, a recess 194

for receiving the one or more sealing strips 148 and/or the conduit 140, a recess 196 for receiving the conduit 114 and/or connector 114a, if present, and spaced apart recesses 200a and 200b for the batteries 142. Spacing apart the batteries can reduce or eliminate the risk of explosion during sterilization procedures due to the potentially flammable nature of ethylene oxide.

[0094] In some embodiments, the first packaging element 150 can be made from a material or combination of materials that is sufficiently rigid and/or robust to hold the batteries, pump and/or other components in place during processing or transportation of the dressing kit. For example, some embodiments of the first packaging element 150 can be configured to provide a compression or interference fit for the components, such as the batteries, the pump, or other components, sufficient to withstand accelerations of between approximately 15G and approximately 25G, or between 1G and 40G, or between 1G and 20G, or between 25G and 40G. Some embodiments of the first packaging element 150 can be configured to tightly hold the pump, batteries, tubing (with tubing pinches or recesses) and other components sufficient to prevent movement or dislodgement of components which could lead to short circuit or melting/abrasion of the packaging, resulting in damage to the packaging or bacterial ingress while not impeding the ability of the user to remove such components from the packaging when needed.

[0095] Additionally, as illustrated, the first packaging element 150 can have grooves or recesses 193 sized and configured to facilitate the surgeon's or user's access and removal of the various components of the apparatus 100, both with and without a gloved hand. Further, bosses or projections 195 can be formed in the first packaging element 150 to provide additional support and protection to the packaging and kit components. The first packaging element 150 can be made from any suitable material that can be sterilized, including a recyclable virgin PETG Blue tinted 0.80 Eastman 6763 medical grade provided by Nelipak Custom Thermoformed Products. The packaging element 150 can be extruded and thermoformed from EASTAR (TM) Chemical Product EASTAR copolyester resin. For example, the raw material, which can be an extruded sheet or film, can be thermoformed using a vacuum and press over a dye tool under elevated temperatures. Other suitable materials for the first packaging element 150 include polycarbonate, PVC, or any other suitable resin or plastic material. In some embodiments, the first packaging element can be

made from a material (including a plate, sheet, film, or otherwise) having a thickness of 0.8 mm (or approximately 0.8), or a thickness of 0.8 mm or less, or 1.0 mm or less, or between approximately 0.7 mm and 1.2 mm.

[0096] A gas permeable cover 151 (also referred to herein as a second packaging element) can be sealingly positioned over the first packaging element 150 to provide a bacteria and contaminant barrier to the contents of the dressing kit 100. For example, a sheet-like layer or film of TYVEK (TM), paper, or any other suitable material can be sealed to a rim portion 153 of the first packaging element 150. The cover 151 can be made from any suitable material, including TYVEK, which is permeable to the sterilization gas but provides a barrier to bacteria and other contamination. The cover 151 can be opaque, clear, or translucent.

[0097] The cover 151 can be sealingly coupled with the first packaging element 150 after all of the dressing kit components assembled therein. Thereafter, the first packaging element 150, cover 151, and the dressing kit components can be positioned within a sealed, impermeable bag having a TYVEK or other sterilization gas permeable patch of material over an opening formed in the bag to permit the sterilization gas to enter the bag and sterilize the components of the dressing kit.

[0098] Figures 4A and 4B are first and second exploded views of the embodiment of the pump assembly 104 of Figure 1, showing the first housing member 120a separated from the second housing member 120b. Figures 5A and 5B are first and second views of the first housing member 120a. Figures 6A and 6B are first and second views of the second housing member 120b. With reference to Figures 4A-6B, some embodiments of the pump assembly 104 can have a battery compartment 220 supported or formed within the housing 120. One or more battery contacts 222 can be supported within the battery compartment 220. One or more electrical wires 224 can connect the battery contacts 222 to a pump 232 and/or a control board 230. The pump assembly 104 can be assembled in a clean room to reduce the risk of contamination or bioburden that the pump is exposed to or can collect during assembly.

[0099] In some embodiments, the pump 232 can comprise a motor, an inlet port or connector 250, and an outlet port 252. The pump 232 can have one or more valves therein. For example, a first valve can be positioned within the pump 232 adjacent the inlet

port 250. Additionally, a second valve can be positioned within the pump 232 adjacent the outlet port 252. The pump 232 can define a flow pathway through the inlet port 250, through the first and second valves, and out the outlet port 252.

[0100] In some embodiments, the battery contacts 222 can also be configured to have polarity protection. For example, similar to the one or more protrusions 124d adjacent to the battery contact 125, the one or more of the battery contacts 222 can have plastic or other protrusions (not illustrated) adjacent to the contacts to inhibit the contact between the battery contact 222 and the incorrect side of a battery that is inserted into the battery compartment in the incorrect orientation. For example, the one or more protrusions can be sized and configured to prevent the negative side of a standard cylindrical battery from contacting the battery contact 222 adjacent to the one or more protrusions, while permitting a positive side of such battery to contact the battery contact 222. Generally, with this configuration, the battery can generally only make contact with the contact 222 if the battery is inserted in the battery compartment 220 in the correct orientation, thereby providing polarity protection to the pump assembly 104. The protrusions will preferably be made from a non-conductive material. Alternatively or additionally, the control board 230 can be configured to have polarity protective features or components. Additionally, the control board 230 can have one or more fuses to protect against overpower conditions or surge power conditions.

[0101] The pump assembly 104 can have a flow manifold 240 and a one-way flow valve 246 in communication with a fluid flow pathway within the pump assembly 104. The one-way flow valve 246 (also referred to as a check valve) can be a diaphragm valve made from silicone or any other suitable elastomeric or soft material, including without limitation, polyurethane, viton, nitrile rubber, neoprene, Teflon, and other suitable materials. Other suitable valves for the one-way flow valve are, for example and without limitation, umbrella valves, ball valves, reed valves, duckbill valves. In some embodiments, the leakage rate of the one-way flow valve 246 can be approximately 0.05 mL/minute. In some embodiments, the one-way flow valve 246 can be positioned within the pump 232 or in place of one of the valves positioned within the pump 232.

[0102] The manifold 240 and/or the one-way flow valve 246 can be in communication with the connector 128. In some embodiments, the one-way flow valve 246

can be supported within the manifold 240, and the manifold 240 can be substantially sealingly coupled with the inlet port or connector 250 on the pump 232 or otherwise supported within the housing 120 so as to be in fluid communication with the inlet port or connector 250. For example, with reference to Figures 4A and 4B, the manifold 240 can be assembled with the pump 232 such that the inlet connector 250 is received within the opening 261 formed in the manifold 240. Air and or other gas can exit the pump 232 through outlet port or connector 252. During sterilization, the pump 232 can be configured such that the sterilization gas can penetrate into the internal spaces or chambers of the pump 232, to ensure that the entire pump 232 (both internally and externally) have been sterilized. One or more valves (which can be umbrella valves or any other suitable valve) can be positioned in the pump 232. For example, without limitation, one or more valves can be supported in the pump 232, one being positioned adjacent to each of the inlet port 250 and the outlet port 252.

[0103] For optimal sterilization, in some embodiments, the sterilization gas can be introduced slowly to optimize the flow of the sterilization gas through the valves and to prevent the pressure from the sterilization gas from completely closing the valves. As mentioned, the valves (such as the first and second valves) can be configured to be somewhat leaky, thereby permitting the flow of sterilization gas to advance past the valves to sterilize the internal components of the pump 232. For example, the valves can permit a leakage flow rate of fluid therethrough (i.e., flow rate through the valve when the valve is in a closed position) at a rate of between 0.1 mL/min and 10 mL/min or more at nominal or typical working pressures (i.e., at nominal working pressures of the fluid in the conduit) or at nominal or typical sterilization pressures. In some configurations, the portion of the flow pathway between the two valves, or between the valves and the one-way valve, can be the most challenging portion of the flow path or pump assembly 104 to sterilize.

[0104] Some embodiments of the pump assembly can have a piezoelectric pump. Some piezoelectric pumps or other pumps disclosed herein can have or can be configured to have orifices to perform the valve functions such that, when the pump is at rest, the flow rate through the pump can be as high as 200 mL/min. Therefore, in some embodiments, where the pump rate can be as high as approximately 300 mL/min or 320 mL/min or otherwise, the first and second valves (which can be orifices) can each have a leakage rate of up to approximately 200 mL/min.

[0105] The pump 232 can be of any suitable type such as, without limitation, a rotary diaphragm pump or other diaphragm pump, a piezoelectric pump, a peristaltic pump, a piston pump, a rotary vane pump, a liquid ring pump, a scroll pump, a diaphragm pump operated by a piezoelectric transducer, or any other suitable pump or micropump or any combinations of the foregoing. The pump 232 can be, for example, a standard off-the-shelf vacuum pump such as the Koge Electronics KPV8A-3A pump. The pump 232 can also be a KNF diaphragm pump or any suitable KNF pump.

[0106] Some embodiments of the pump can be as light as approximately 10 grams, or between approximately 6 grams and 15 grams, or between any values within the foregoing range. The pump 232 can have a pump capacity of approximately 500 mL per minute, or between approximately 300 mL per minute or less and approximately 600 mL per minute or more, or between approximately 400 mL per minute and approximately 500 mL per minute, or between any values within the foregoing ranges. In some embodiments, the pump assembly 104 could comprise two or more pumps 232. For example, the pump assembly 104 could have a first pump having a high flow rate, configured to provide a rapid drawdown of the space between the wound overlay and the wound, and a second, smaller capacity pump configured to maintain the level of reduced pressure of the space between the wound overlay and the wound after the initial draw down. In some embodiments, the pump flow rate can be approximately 20 times the leak alarm flow rate, which can be set at approximately 15 milliliters per minute.

[0107] As mentioned, the connector 128 can be a threaded connector (as illustrated) that can threadingly receive a mating threaded connector coupled with the end of the tubing 106. The threaded connector 128 can be of a non-standard size as compared to other medical connectors, to prevent a medical practitioner from inadvertently attaching a standard luer connector (such as a connector from an intravenous line) thereto.

[0108] Alternatively, not illustrated, the connector 128 can be a standard tubing connector (such as a nipple connector) configured to sealingly receive the tubing thereover such that a separate mating connector on the end of the tubing 106 can be omitted.

[0109] The manifold 240 can have a separate port 260 which can be configured to receive a conduit or connector 262 of a pressure monitor. The pressure monitor can be supported by the control board 230 and can be configured to monitor a level of pressure in

the fluid flow passageway. The pressure monitor can be configured to protect the motor 232 from exceeding a predefined threshold pressure. In some embodiments, the pressure monitor can be calibrated to not exceed 175 +/- 50 mmHg. In some embodiments, the pressure monitor can be calibrated to not exceed 235 mmHg. The pressure monitor can be configured to cut power to the motor if the pressure reading reaches a predetermined value, and be configured to resume when the pressure level drops below the predetermined value or a second predetermined value that can be higher or lower than the first predetermined value. Additionally, the pump assembly 104 can be programmed to prevent such over-pressurization. The pump assembly 104 can be configured such that the software provides the primary mechanism for preventing over-pressurization, and the pressure monitor can provide backup over-pressurization protection.

[0110] The pump 232 can have a layer of open foam or other material wrapped at least partially around an outside surface of the pump 232 to reduce the noise and vibration produced by the pump 232. All of these components can be supported within the first and second pump housing members 120a, 120b, which can be secured together with any suitable fasteners 270 (for example, a pair of screws). One or more labels 270 can be affixed to an outside surface of the housing 120. Additionally, in some embodiments, the pump 232 can have one or more weights, cushions, foam (such as a viscoelastic foam), plastic (such as ABS, polyurethane, urethane, or otherwise), or other pads, panels, sheets, or segments supported by the pump 232 or positioned adjacent to one or more outside surfaces of the pump. Some embodiments can have mass based or compliant damping materials. Such components or materials (not illustrated) can damp vibration and/or attenuate noise produced by the pump.

[0111] For example, one or more weights (made from steel, metal, or any other suitable material) can be supported or attached to an outside surface of the pump 232 or any other pump embodiment disclosed herein. The steel weights can weigh approximately 1.8 grams, 3.8 grams, or 5.8 grams, or between 1 gram and 10 grams or more, or between 1.5 grams and 6 grams. Two or more weights can be supported or attached to an outside surface of the pump 232 or any other pump embodiment disclosed herein. Two steel weights each weighing approximately 1.8 grams, 3.8 grams, or 5.8 grams, or between 1 gram and 10 grams or more, or between 1.5 grams and 6 grams, can be attached to an outside surface of the

pump 232. Each of the two plates can be positioned on opposite sides of the motor 232, or otherwise. In some embodiments, four steel weights each weighing approximately 1.8 grams, 3.8 grams, or 5.8 grams, or between 1 gram and 10 grams or more, or between 1.5 grams and 6 grams, can be attached to an outside surface of the pump 232. The plates can be arranged such that two plates are positioned on each of two opposite sides of the motor 232, or otherwise. In some embodiments, weights can be positioned adjacent to three or more sides of the pump 232 including, for example and without limitation, the sides and top surfaces of the pump 232.

[0112] With reference to Figure 4A, the battery cover 124 can have a latch or tab member 124a that can be configured to engage with mating feature on the housing 120 to inhibit the battery cover 124 from becoming inadvertently opened when in the closed position. Additionally, guides or protrusions 124b can be formed on the battery cover 124 to facilitate the ease with which the battery cover 124 can be opened and closed. The guides 124b can engage mating guides or channels 120c formed in the housing 120. The battery cover 124 can be configured to have a gripping surface, for single finger use. For example, without limitation, a plurality of depressions 124c can be formed on a surface of the battery cover 124 to enhance the grip between a user's finger or other object and the batter cover 124, to facilitate the opening and closing of the battery cover 124.

[0113] With reference to Figure 4B, the battery cover 124 can support one or more battery contacts or terminals 125 thereon, configured to provide a connection between the two batteries. The battery cover 124 can further support one or more protrusions 124d adjacent to the battery contact 125. The one or more protrusions 124d can be sized and configured to prevent the negative side of a standard cylindrical battery from contacting the battery contact 125 adjacent to the one or more protrusions 124d, while permitting a positive side of such battery to contact the battery contact 125. With this configuration, the battery can generally only make contact with the contact 125 if the battery is inserted in the battery compartment 220 in the correct orientation, thereby providing polarity protection to the pump assembly 104.

[0114] With reference to Figures 4A and 4B, the housing 120 can have one or more tabs 121 and depressions or channels 123 configured to receive the tabs 121 to improve the connection between the two members 120a, 120b of the housing. The tabs 121 and

depressions 123 can hold the edges of the housing 120 together better to improve the strength of the housing 120 and to make the connection tighter between the two members 120a, 120b of the housing. The control board 230 can be assembled to the housing 12 with similar features.

[0115] As described in U.S. Patent Application No. 13/092,042, which disclosure is hereby incorporated by reference as if fully set forth herein, a lower surface of any of the wound dressing 102 embodiments disclosed herein can have an optional wound contact layer. Any of the dressing embodiments disclosed herein can be made without the wound contact layer. The wound contact layer can be a polyurethane layer or polyethylene layer or other flexible layer which can be made porous or perforated, for example via a hot pin process, laser ablation process, ultrasound process or in some other way or otherwise made permeable to liquid and gas. The perforations can enable fluid and/or gas to flow through the layer. The wound contact layer can help prevent tissue ingrowth into the other material of the wound dressing.

[0116] The perforations can be sized small enough to meet this requirement but still allow fluid through. For example, perforations formed as slits or holes having a size ranging from 0.025 mm to 1.2 mm are considered small enough to help prevent tissue ingrowth into the wound dressing while allowing wound exudate to flow into the dressing. The wound contact layer helps hold the whole wound dressing together and helps to create an air tight seal around the absorbent pad in order to maintain negative pressure at the wound. The wound contact layer also acts as a carrier for an optional lower and upper adhesive layer (not shown). For example, a lower pressure sensitive adhesive can be provided on the underside surface 101 of the wound dressing whilst an upper pressure sensitive adhesive layer can be provided on the upper surface 103 of the wound contact layer. The pressure sensitive adhesive, which can be a silicone, hot melt, hydrocolloid or acrylic based adhesive or other such adhesives, can be formed on both sides or optionally on a selected one or none of the sides of the wound contact layer. When a lower pressure sensitive adhesive layer is utilized this helps adhere the wound dressing to the skin around a wound site.

[0117] As mentioned, any dressing embodiments for use in the dressing kits disclosed or incorporated by reference herein can have an adhesive covered bottom (e.g., wound contacting) surface. In some embodiments, as mentioned, the adhesive can be a

silicone adhesive including, for example, polysiloxanes or polyorganosiloxanes or other polymeric pressure sensitive silicone adhesives. For example, polydimethylsiloxane or the like can be used. The adhesive formulation may be a mixture of alkyl pendant siloxanes, which can be spread and cast as a two part mix with a catalyst such that a final polymerisation step takes place following casting or spreading. In some embodiments, a dressing layer can have a non-perforated silicone adhesive coating (coat weight 130 gsm nominal) and full spread acrylic adhesive (27 to 37 gsm) coated onto opposite sides of an extruded EU30 polyurethane clear film (27 to 37 gsm). Moisture vapour permeability of some embodiments of such an arrangement can be between approximately 367 gm^{-2}/24hrs to approximately 405 gm^{-2}/24hrs, or a mean moisture vapour permeability of 382 gm^{-2}/24hrs.

[0118] Some embodiments or arrangements of a silicone adhesive layer suitable for dressing embodiments disclosed herein can have a moisture vapour transmission rate between approximately 350 gm^{-2}/24hrs and approximately 410 gm^{-2}/24hrs. Aptly, the average moisture vapour permeability of some embodiments or arrangements of a silicone adhesive layer suitable for dressing embodiments disclosed herein can be approximately 380 gm^{-2}/24hrs. Some of the dressing embodiments disclosed herein can have a Wacker silres PSA 45 pressure sensitive adhesive coated thereon.

[0119] Additionally, any of the dressing embodiments disclosed herein can have an anti-microbial agent or substance incorporated into the dressing or coated on one or more surfaces of the dressing. For example, without limitation, a wound contact layer of any dressing embodiments disclosed herein can have nanocrystalline silver agents, silver salts, copper salts, or gold salts such as, without limitation, those disclosed in U.S. Patent Application No. 11/922,894 (titled ANTIMICROBIAL BIGUANIDE METAL COMPLEXES), filed May 21, 2008, which application is incorporated by reference herein as if made part of this disclosure, PHMB, chlorohexadine, peroxide, hypochloride, or other bleaches therein or thereon. Further, an absorbent layer of any dressing embodiments disclosed herein can have silver sulphur diazine or any of the previously mentioned substances or active agents therein or thereon. These may be used separately or together. These respectively can eliminate micro-organisms in the wound and micro-organisms in the absorption matrix. As a still further option, other active components, for example, pain suppressants such as ibuprofen or healing agents can be incorporated into the dressing. Also

agents which enhance cell activity, such as growth factors or that inhibit enzymes, such as matrix metalloproteinase inhibitors, such as tissue inhibitors of metalloproteinase (TIMPS) or zinc chelators, can be incorporated into the dressing. Odor trapping elements such as activated carbon, cyclodextrine, zeolite or the like can also be included in the absorbent layer or other portions or components of the dressing, or above the filter layer.

[0120] A layer of porous material can be located above the wound contact layer. This porous layer, or transmission layer, allows transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing. In particular, the transmission layer can ensure that an open air channel can be maintained to communicate negative pressure over the wound area even when the absorbent layer has absorbed substantial amounts of exudates. The layer should remain open under the typical pressures that will be applied during negative pressure wound therapy as described above, so that the whole wound site sees an equalized negative pressure. The layer can be formed of a material having a three dimensional structure. For example, a knitted or woven spacer fabric (for example Baltex 7970 weft knitted polyester) or a non-woven fabric can be used. Other materials can be utilized, and examples of such materials are described in U.S. Patent Application No. 13/092,042, which are hereby incorporated by reference and made part of this disclosure.

[0121] In some embodiments, the transmission layer can have a 3D polyester spacer fabric layer. This layer can have a top layer (that is to say, a layer distal from the wound-bed in use) which is a 84/144 textured polyester, and a bottom layer (that is to say, a layer which lies proximate to the wound bed in use) which can be a 100 denier flat polyester and a third layer formed sandwiched between these two layers which is a region defined by a knitted polyester viscose, cellulose or the like monofilament fiber. Other suitable materials and other linear mass densities of fiber can be used.

[0122] This differential between filament counts in the spaced apart layers helps control moisture flow across the transmission layer. Particularly, by having a filament count greater in the top layer, that is to say, the top layer is made from a yarn having more filaments than the yarn used in the bottom layer, liquid tends to be wicked along the top layer more than the bottom layer. In use, this differential tends to draw liquid away from the wound bed

and into a central region of the dressing where the absorbent layer helps lock the liquid away or itself wicks the liquid onwards towards the cover layer where it can be transpired.

[0123] Preferably, to improve the liquid flow across the transmission layer (that is to say perpendicular to the channel region formed between the top and bottom spacer layers, the 3D fabric is treated with a dry cleaning agent (such as, but not limited to, Perchloro Ethylene) to help remove any manufacturing products such as mineral oils, fats and/or waxes used previously which might interfere with the hydrophilic capabilities of the transmission layer. In some embodiments, an additional manufacturing step can subsequently be carried in which the 3D spacer fabric is washed in a hydrophilic agent (such as, but not limited to, Feran Ice 30g/l available from the Rudolph Group). This process step helps ensure that the surface tension on the materials is so low that liquid such as water can enter the fabric as soon as it contacts the 3D knit fabric. This also aids in controlling the flow of the liquid insult component of any exudates.

[0124] Again, as described in greater detail in U.S. Patent Application No. 13/092,042, a layer of absorbent material can be provided above the transmission layer. The absorbent material which can be a foam or non-woven natural or synthetic material and which can optionally include or be super-absorbent material forms a reservoir for fluid, particularly liquid, removed from the wound site and draws those fluids towards a cover layer. The material of the absorbent layer can prevent liquid collected in the wound dressing from flowing in a sloshing manner. The absorbent layer can also help distribute fluid throughout the layer via a wicking action so that fluid is drawn from the wound site and stored throughout the absorbent layer. This helps prevent agglomeration in areas of the absorbent layer. The capacity of the absorbent material must be sufficient to manage the exudates flow rate of a wound when negative pressure is applied. Since in use the absorbent layer experiences negative pressures the material of the absorbent layer is chosen to absorb liquid under such circumstances. A number of materials exist that are able to absorb liquid when under negative pressure, for example superabsorber material. The absorbent layer can be manufactured from ALLEVYN™ foam, Freudenberg 114-224-4 and/or Chem-Posite™11C-450, or any other suitable material.

[0125] In some embodiments, the absorbent layer can be a layer of non-woven cellulose fibers having super-absorbent material in the form of dry particles dispersed

throughout. Use of the cellulose fibers introduces fast wicking elements which help quickly and evenly distribute liquid taken up by the dressing. The juxtaposition of multiple strand-like fibers leads to strong capillary action in the fibrous pad which helps distribute liquid. In this way, the super-absorbent material is efficiently supplied with liquid. Also, all regions of the absorbent layer are provided with liquid.

[0126] The wicking action also assists in bringing liquid into contact with the upper cover layer to aid increase transpiration rates of the dressing. The wicking action also assists in delivering liquid downwards towards the wound bed when exudation slows or halts. This delivery process helps maintain the transmission layer and lower wound bed region in a moist state which helps prevent crusting within the dressing (which could lead to blockage) and helps maintain an environment optimized for wound healing.

[0127] In some embodiments, the absorbent layer can be an air-laid material. Heat fusible fibers can optionally be used to assist in holding the structure of the pad together. It will be appreciated that rather than using super-absorbing particles or in addition to such use, super-absorbing fibers can be utilized according to some embodiments of the present invention. An example of a suitable material is the Product Chem-Posite™ 11 C available from Emerging Technologies Inc (ETi) in the USA.

[0128] Optionally, the absorbent layer can include synthetic stable fibers and/or bi-component stable fibers and/or natural stable fibers and/or super-absorbent fibers. Fibers in the absorbent layer can be secured together by latex bonding or thermal bonding or hydrogen bonding or a combination of any bonding technique or other securing mechanism. In some embodiments, the absorbent layer is formed by fibers which operate to lock super-absorbent particles within the absorbent layer. This helps ensure that super-absorbent particles do not move external to the absorbent layer and towards an underlying wound bed. This is particularly helpful because when negative pressure is applied there is a tendency for the absorbent pad to collapse downwards and this action would push super-absorbent particle matter into a direction towards the wound bed if they were not locked away by the fibrous structure of the absorbent layer.

[0129] The absorbent layer can comprise a layer of multiple fibers. Preferably, the fibers are strand-like and made from cellulose, polyester, viscose or the like. Preferably, dry absorbent particles are distributed throughout the absorbent layer ready for use. In some

embodiments, the absorbent layer comprises a pad of cellulose fibers and a plurality of super absorbent particles. In additional embodiments, the absorbent layer is a non-woven layer of randomly orientated cellulose fibers.

[0130] Super-absorber particles/fibers can be, for example, sodium polyacrylate or carbomethoxycellulose materials or the like or any material capable of absorbing many times its own weight in liquid. In some embodiments, the material can absorb more than five times its own weight of 0.9% W/W saline, etc. In some embodiments, the material can absorb more than 15 times its own weight of 0.9% W/W saline, etc. In some embodiments, the material is capable of absorbing more than 20 times its own weight of 0.9% W/W saline, etc. Preferably, the material is capable of absorbing more than 30 times its own weight of 0.9% W/W saline, etc. The absorbent layer can have one or more through holes located so as to underlie the suction port.

[0131] The dressing 102 can have a gas impermeable, but moisture vapor permeable, cover layer extending across the width of the wound dressing. The cover layer, which can for example be a polyurethane film (for example, Elastollan SP9109) or any other suitable material having a pressure sensitive adhesive on one side, is substantially gas impermeable, thereby creating a substantially sealed enclosure over the wound. In this way an effective chamber is made between the cover layer and a wound site where a negative pressure can be established. The cover layer can be sealed to the wound contact layer in a border region around the circumference of the dressing, ensuring that no air is drawn in through the border area, for example via adhesive or welding techniques. The cover layer can protect the wound from external bacterial contamination (bacterial barrier) and allows liquid from wound exudates to be transferred through the layer and evaporated from the film outer surface. The cover layer can have a polyurethane film and an adhesive pattern spread onto the film. The polyurethane film is moisture vapor permeable and may be manufactured from a material that has an increased water transmission rate when wet.

[0132] An orifice can be provided in the cover film to allow a negative pressure to be applied to the dressing 102. As mentioned, in some embodiments, a suction port 108 can be sealed to the top of the cover film over the orifice, which can communicate negative pressure through the orifice. The port may be adhered and sealed to the cover film using an adhesive such as an acrylic, cyanoacrylate, epoxy, UV curable or hot melt adhesive. The port

108 can be formed from a soft polymer, for example a polyethylene, a polyvinyl chloride, a silicone or polyurethane having a hardness of 30 to 90 on the Shore A scale.

[0133] The dressing 102 can have a filter element that is impermeable to liquids, but permeable to gases. The filter element can act as a liquid barrier, to substantially prevent or inhibit liquids from escaping from the wound dressing, as well as an odor barrier. The filter element may also function as a bacterial barrier. In some embodiments, the pore size of the filter element can be approximately 0.2µm. Suitable materials for the filter material of the filter element include 0.2 micron Gore™ expanded PTFE from the MMT range, PALL Versapore™ 200R, and Donaldson™ TX6628. The filter element thus enables gas to be exhausted through the orifice. Liquid, particulates and pathogens however are contained in the dressing. Other details regarding the filter are disclosed in U.S. Patent Application No. 13/092,042 and incorporated by reference herein.

[0134] The wound dressing 102 and its methods of manufacture and use as described herein may also incorporate features, configurations and materials described in the following patents and patent applications, each of which is incorporated by reference in their entireties herein as if made part of this disclosure: U.S. Patent Nos. 7,524,315, 7,708,724, and 7,909,805; U.S. Patent Application Publication Nos. 2005/0261642, 2007/0167926, 2009/0012483, 2009/0254054, 2010/0160879, 2010/0160880, 2010/0174251, 2010/0274207, 2010/0298793, 2011/0009838, 2011/0028918, 2011/0054421, and 2011/0054423; as well as U.S. App. Serial. Nos. 12/941,390, filed November 8, 2010, 29/389,782, filed April 15, 2011, and 29/389,783, filed April 15, 2011. From these incorporated by reference patents and patent applications, features, configurations, materials and methods of manufacture or use for similar components to those described in the present disclosure may be substituted, added or implemented into embodiments of the present application.

[0135] In operation, the wound dressing 102 is sealed over a wound site forming a wound cavity. The pump assembly 104 provides a source of a negative pressure to the dressing 102. Fluid is drawn towards the orifice through the wound dressing from a wound site below the wound contact layer. The fluid moves towards the orifice through the transmission layer. As the fluid is drawn through the transmission layer, wound exudate is absorbed into the absorbent layer.

[0136] The general shape of the wound dressing can be square, ovular, rectangular, or otherwise. The dressing can have rounded corner regions. It will be appreciated that wound dressings according to other embodiments of the present invention can be shaped differently such as square, circular or elliptical dressings, or the like.

[0137] The desired size of the wound dressing 102 can be selected based on the size and type of wound it will be used in. In some embodiments, the wound dressing 102 can measure between 20 and 40 cm on its long axis, and between 10 to 25 cm on its short axis. For example, dressings can be provided in sizes of approximately 10 x 20 cm, 10 x 30 cm, 10 x 40 cm, 15 x 20 cm, and 15 x 30 cm, as described above.

[0138] In some embodiments, the wound dressing 102 can be a square-shaped dressing with sides measuring between 15 and 25 cm (e.g., 15 x 15 cm, 20 x 20 cm and 25 x 25 cm). The absorbent layer can have a smaller area than the overall dressing, and in some embodiments may have a length and width that are both about 3 to 10 cm shorter, more preferably about 5 cm shorter, than that of the overall dressing 102. In some rectangular-shape embodiments, the absorbent layer may measure between approximately 10 and 35 cm on its long axis, and between 5 and 10 cm on its short axis. For example, absorbent layers can be provided in sizes of 5.6 x 15 cm or 5 x 10 cm (for 10 x 20 cm dressings), 5.6 x 25 cm or 5 x 20 cm (for 10 x 30 cm dressings), 5.6 x 35 cm or 5 x 30 cm (for 10 x 40 cm dressings), 10 x 15 cm (for 15 x 20 cm dressings), and 10 x 25 cm (for 15 x 30 cm dressings). In some square-shape embodiments, the absorbent layer may have sides that are between 10 and 20 cm in length (e.g., 10 x 10 cm for a 15 x 15 cm dressing, 15 x 15 cm for a 20 x 20 cm dressing, or 20 x 20 cm for a 25 x 25 cm dressing). The transmission layer can be of a smaller size than the absorbent layer, and in some embodiments can have a length and width that are both about 0.5 to 2 cm shorter, more preferably about 1 cm shorter, than that of the absorbent layer. In some rectangular-shape embodiments, the transmission layer may measure between 9 and 34 cm on its long axis and between 3 and 5 cm on its short axis. For example, transmission layers may be provided in sizes of 4.6 x 14 cm or 4 x 9 cm (for 10 x 20 cm dressings), 4.6 x 24 cm or 4 x 19 cm (for 10 x 30 cm dressings), 4.6 x 34 cm or 4 x 29 cm (for 10 x 40 cm dressings), 9 x 14 cm (for 15 x 20 cm dressings), and 9 x 24 cm (for 15 x 30 cm dressings). In some square-shape embodiments, the transmission layer may have sides

that are between 9 and 19 cm in length (e.g., 9 x 9 cm for a 15 x 15 cm dressing, 14 x 14 cm for a 20 x 20 cm dressing, or 19 x 19 cm for a 25 x 25 cm dressing).

[0139] The dressing can contain anti-microbial e.g. nanocrystalline silver agents on the wound contact layer and/or silver sulphur diazine in the absorbent layer. These may be used separately or together. These respectively kill micro-organisms in the wound and micro-organisms in the absorption matrix. As a still further option other active components, for example, pain suppressants, such as ibuprofen, may be included. Also agents which enhance cell activity, such as growth factors or that inhibit enzymes, such as matrix metalloproteinase inhibitors, such as tissue inhibitors of metalloproteinase (TIMPS) or zinc chelators could be utilized. As a still further option odor trapping elements such as activated carbon, cyclodextrine, zeolite or the like may be included in the absorbent layer or as a still further layer above the filter layer.

[0140] Whilst some embodiments of the present invention have so far been described in which the transmission layer is formed as a 3D knit layer, e.g., two layers spaced apart by a monofilament layer, it will be appreciated that some embodiments of the present invention are not restricted to the use of such a material. In some embodiments, as an alternative to such a 3D knit material, one or more layers of a wide variety of materials could be utilized. In each case, according to embodiments of the present invention, the openings presented by layers of the transmission layer are wider and wider as one moves away from the side of the dressing which, in use will be located proximate to the wound. In some embodiments, the transmission layer may be provided by multiple layers of open celled foam. In some embodiments, the foam is reticulated open cell foam. The foam can be hydrophilic or able to wick aqueous based fluids. The pore size in each layer is selected so that in the foam layer most proximate to the wound side in use the pores have a smallest size. If only one further foam layer is utilized that includes pore sizes which are greater than the pore sizes of the first layer. This helps avoid solid particulate being trapped in the lower layer which thus helps maintain the lower layer in an open configuration in which it is thus able to transmit air throughout the dressing. In some embodiments, two, three, four or more foam layers may be included. The foam layers may be integrally formed, for example, by selecting a foam having a large pore size and then repeatedly dipping this to a lesser and lesser extent into material which will clog the pores or alternatively, the transmission layer formed by the

multiple foam layers may be provided by laminating different types of foam in a layered arrangement or by securing such layers of foam in place in a known manner.

[0141] Figures 7A-7D illustrate the use of an embodiment of a TNP wound treatment system being used to treat a wound site on a patient. Figure 7A shows a wound site W being cleaned and prepared for treatment. Here, the healthy skin surrounding the wound site W is preferably cleaned and excess hair removed or shaved. The wound site W may also be irrigated with sterile saline solution if necessary. Optionally, a skin protectant may be applied to the skin surrounding the wound site W. If necessary, a wound packing material, such as foam or gauze, may be placed in the wound site W. This may be preferable if the wound site W is a deeper wound.

[0142] After the skin surrounding the wound site W has been prepared, the cover 151 can be removed from the first packaging element 150 to provide access to the components. The dressing 102 can be removed from the packaging 150 and, as illustrated in Figure 7B, be positioned and placed over the wound site W. The wound dressing 102 can be placed with the wound contact layer of the dressing 102 over and/or in contact with the wound site W. In some embodiments, an adhesive layer can be provided on a lower surface of the wound contact layer, which may in some cases be protected by an optional release layer to be removed prior to placement of the wound dressing 102 over the wound site W. The dressing 102 can be positioned such that the port 108 is in a raised position with respect to the remainder of the dressing 102 so as to avoid fluid pooling around the port 108. In some embodiments, the dressing 102 is positioned so that the port 108 is not directly overlying the wound, and is level with or at a higher point than the wound. To help ensure adequate sealing for TNP, the edges of the dressing 102 can be smoothed over to avoid creases or folds. The dressing and the adhesive formed thereon can be configured such that the dressing can be lifted away from the skin or wound and repositioned to remove creases and folds, or to simply reposition the dressing over the wound, or for other reasons, without sacrificing the performance of the adhesive. The tubing 106 can be connected to the dressing 102 either before or after placement of the dressing 102 over the wound.

[0143] Thereafter, the pump assembly 104 can be removed from the packaging 150 and connected to the tubing 106, as illustrated in Figure 7C. The batteries 142 can be removed from the packaging 150 and installed in the pump assembly 104 either before or

after the pump is attached to the conduit 106. The pump assembly 104 can be configured to apply negative pressure to the wound site via the dressing 102, and typically through the tubing or conduit 106. In some embodiments, a connector may be used to join the conduit 106 to the dressing 102 and to the pump assembly 104. Upon the application of negative pressure with the pump assembly 104, the dressing 102 may in some embodiments partially collapse and present a wrinkled appearance as a result of the evacuation of some or all of the air underneath the dressing 102. In some embodiments, the pump assembly 104 may be configured to detect if any leaks are present in the dressing 102, such as at the interface between the dressing 102 and the skin surrounding the wound site W. Should a leak be found, such leak is preferably remedied prior to continuing treatment. The leak can be remedied by repositioning the dressing 102, smoothing out wrinkles or folds in the dressing, or by applying fixation strips 148 around the periphery of the dressing 102.

[0144] Turning to Figure 7D, as mentioned, fixation strips 148 can be attached around the peripheral edges of the dressing 102 or otherwise. Such fixation strips 148 can be advantageous in some situations so as to provide additional sealing against the skin of the patient surrounding the wound site W. For example, the sealing or fixation strips 148 can provide additional sealing for when a patient is more mobile. In some cases, the fixation strips 148 may be used prior to activation of the pump assembly 104, particularly if the dressing 102 is placed over a difficult to reach or contoured area. In some embodiments, the dressing kit 100 can be provided with up to five sealing strips.

[0145] Treatment of the wound site W preferably continues until the wound has reached a desired level of healing. In some embodiments, it may be desirable to replace the dressing 102 after a certain time period has elapsed, or if the dressing is full of wound fluids. During such changes, the pump assembly 104 may be kept, with just the dressing 102 being changed.

[0146] Figures 8A – 20H are top isometric, bottom isometric, top plane, bottom plane, front, back, first side, and second side views, respectively, of embodiments of packaging elements that can be used with any of the embodiments of the wound dressing apparatuses disclosed herein, including a variety of differently sized wound dressing apparatuses. Any of the embodiments of the packaging elements illustrated in Figures 8A – 20H or otherwise disclosed in this application can have any of the same features, materials, or

other details of any of the other packaging elements disclosed herein, including first packaging element 150 discussed above.

[0147] The packaging element 300 illustrated in Figures 8A-8H is configured to support a dressing that has an approximate 10 cm x 20 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 310 illustrated in Figures 9A-9H is configured to support a dressing that has an approximate 10 cm x 20 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 320 illustrated in Figures 10A-10H is configured to support a dressing that has an approximate 10 cm x 30 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 330 illustrated in Figures 11A-11H is configured to support a dressing that has an approximate 10 cm x 30 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 300 illustrated in Figures 12A-12H is configured to support a dressing that has an approximate 10 cm x 40 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 350 illustrated in Figures 13A-13H is configured to support a dressing that has an approximate 10 cm x 40 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 360 illustrated in Figures 14A-14H is configured to support a dressing that has an approximate 15 cm x 15 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 365 illustrated in Figures 14I-14P is configured to support a dressing that has an approximate 15 cm x 15 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein.

[0148] The packaging element 370 illustrated in Figures 15A-15H is configured to support a dressing that has an approximate 15 cm x 20 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 380 illustrated in Figures 16A-16H is configured to support a dressing that has an approximate 15 cm x 20 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 390 illustrated in Figures 17A-17H is configured to support a dressing that has an approximate 20 cm x 20 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 395

illustrated in Figures 17I-17P is configured to support a dressing that has an approximate 20 cm x 20 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 400 illustrated in Figures 18A-18H is configured to support a dressing that has an approximate 15 cm x 30 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 405 illustrated in Figures 18I-18P is configured to support a dressing that has an approximate 15 cm x 30 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 410 illustrated in Figures 19A-19H is configured to support a dressing that has an approximate 25 cm x 25 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 420 illustrated in Figures 20A-20H is configured to support a dressing that has an approximate 25 cm x 25 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein.

[0149] Figure 21 illustrates a pump assembly 1000 according to some embodiments. Any of the embodiments of the pump assembly 1000 disclosed herein can have any of the same or similar components, features, materials, sizes, configurations, and other details of any other pump assembly embodiments disclosed or incorporated by reference herein, including the embodiment of the pump assembly 104 described above. Preferably, the pump assembly 1000 can be miniaturized and portable, although larger conventional portable or non-portable (e.g., wall suction) pumps can also be used. The pump assembly 1000 can include a switch or a button 1002, illustrated as a play/pause button located on the exterior of the housing of the pump assembly. As is explained below, the button 1002 can be configured to stop, pause, and/or restart therapy. Although illustrated as a press button 1002, other types of switches or buttons can be included, such as a touchpad, touch screen, keyboard, and so on.

[0150] The pump assembly can further include a connector 1050 (for connecting a conduit, e.g., conduit 106), and three LED indicators 1062, 1064, and 1066. As is illustrated, LED indicator 1062 (e.g., OK indicator) can be configured to indicate normal/abnormal operation of the system. For example, an active (e.g., lit) indicator 1062 can represent normal operation. LED indicator 1064 (e.g., dressing indicator) can be configured to indicate a leak in the system. For example, an active (e.g., lit) indicator 1064 can represent a leak. LED

indicator 1066 (e.g., battery indicator) can be configured to indicate the remaining capacity or life of a power source (e.g., batteries). For example, an active (e.g., lit) indicator 1066 can represent a low capacity. In some embodiments, the indicators 1062, 1064, and 1066 can be of a different color, two different colors (e.g., two indicators can share the same color), or same color. Although the pump assembly preferably includes three LED indicators and a push play/pause button, other configurations, locations, and types of indicators, alarms, and switches can alternatively be used. In some embodiments, the pump assembly 1000 can include visual, audible, tactile, and other types of indicators or alarms configured to signal to the user various operating conditions. Such conditions include system on/off, standby, pause, normal operation, dressing problem, leak, error, and the like. The indicators can include speakers, displays, light sources, etc., and/or combinations thereof.

[0151] Figure 22 illustrates a cross-sectional view showing the interior of the pump assembly 1000 according to some embodiments. As is illustrated, a housing 1020 can enclose the pump assembly. A one-way flow valve 1030 can be configured to maintain a level of negative pressure when the source of negative pressure is not active (e.g., prevent leaks) and prevent fluids and/or exudate aspirated or removed from the wound from entering the pump assembly via the connector 1050. A control board 1040, such as a printed circuit board assembly (PCBA), can be configured to mechanically support and electrically connect various electrical/electronic components, which are described below. The PCBA can be single-sided or double-sided. A negative pressure source 1090, such as pump, can aspirate fluid and/or exudate from a wound. In any of the embodiments disclosed herein, the negative pressure source 1090 can have any of the same components, features, limitations, or other details of any of other negative pressure source embodiment disclosed herein, including without limitation the pump 232 disclosed above. Various pumps can be used for the negative pressure source, including peristaltic pumps, piston pumps, rotary vane pumps, liquid ring pumps, scroll pumps, diaphragm pumps, piezoelectric pumps (e.g., a diaphragm pump operated by a piezoelectric transducer), etc. or combinations thereof. Although the pump assembly preferably includes a miniature, low noise, low power pump, any suitable pump can alternatively be used. The pump assembly 1000 includes indicators 1060 (e.g., LEDs), a pressure sensor 1070 for monitoring pressure in the system, such as pressure under the dressing, and a battery cover 1080 configured to provide access to a battery compartment

1100. Although the pump assembly is preferably powered by two standard, disposable alkaline batteries (e.g., 2 AA batteries), any type of power source, including rechargeable batteries and external power, can alternatively be used.

[0152] Figure 23 illustrates a system schematic of the pump assembly 1000 according to some embodiments. The pump assembly includes a press button 1002, a control board 1040, and indicators 1060. The pump assembly 1000 can be powered by a battery cell 1130. The pump assembly also includes a pump 1090, such as a diaphragm pump powered by an electric motor 1092, and a pressure sensor 1070. An inlet 1120 can be configured to connect the pump assembly 1000 to a dressing, for example, via a conduit. The inlet 1120 can be connected to a one-way valve 1030, which can be configured to help maintain a level of negative pressure when the source of negative pressure is not active, avoid leaks, and prevent fluids and/or exudate aspirated or removed from the wound from entering the pump assembly 1000. The pump 1090 can also be connected to an outlet 1110. In some embodiments, the outlet 1110 can be configured to vent air to the atmosphere. In some embodiments, a filter (not shown) can be interposed between the outlet and the atmosphere. The filter can be a bacterial filter, odor filter, etc. or any combination thereof.

[0153] Figure 24 illustrates an electrical component schematic of the pump assembly 1000 according to some embodiments. Module 1140, which can be a control board (e.g., PCBA), can include an input/output (I/O) module 1150, controller 1160, and memory 1170. In some embodiments, module 1140 can include additional electric/electronic components, for example, fuse or fuses. The controller 1160 can be a microcontroller, processor, microprocessor, etc. or any combination thereof. For example, the controller 1160 can be of STM8L MCU family type from ST Microelectronics, such as STM8L 151G4U6, or of MC9S08QE4/8 series type from Freescale, such as MC9S08QE4CWJ. Preferably, the controller 1160 is a low power or ultra low power device, but other types of devices can alternatively be used. Memory 1170 can include one or more of volatile and/or nonvolatile memory modules, such as one or more of read-only memory (ROM), write once read many memory (WORM), random access memory (e.g.., SRAM,. DRAM. SDRAM, DDR, etc.), solid-state memory, flash memory, magnetic storage, etc. or any combination thereof. Memory 1170 can be configured to store program code or instructions (executed by the controller), system parameters, operational data, user data, etc. or any combination thereof.

[0154] The I/O module 1150 can be configured to function as an interface between the controller 1160 and other system components that provide and/or are responsive to electromagnetic signals. In other words, the I/O module 1150 can be configured to allow the controller 1160 to monitor the operation of the system and to control other components of the system. In some embodiments, as is illustrated, the I/O module 1150 can be in electromagnetic communication with a button 1002, indicators 1060, pressure sensor 1070, power source 1130, and source of negative pressure 1090. The I/O module can comprise an interface or multiple interfaces configured to communicate with various components. The interface can include standard and/or non-standard ports, such as serial ports, parallel ports, bus interfaces, etc. or any combination thereof.

[0155] In some embodiments, the pump assembly 1000 can be configured to control the operation of system. For example, the pump assembly 1000 can be configured to provide a suitable balance between uninterrupted delivery of therapy and/or avoidance of inconveniencing the user by, for example, frequently or needlessly pausing or suspending therapy and a desire to conserve power, limit noise and vibration generated by the negative pressure source, etc. Figure 25 illustrates a top level state diagram 1200 of operation of the pump assembly according to some embodiments. In some embodiments, the controller 1140 can be configured to implement the flow of the state diagram 1200. As is illustrated in Figure 25, the operation of the pump assembly can, in some embodiments, be grouped into four general state categories: inactive/initialization (states 1206 and 1202), active 1210, operational 1250, and end of life (state 1214). As is illustrated in Figures 25 and 26, state categories 1210 and 1250 each comprises multiple states and transitions between states.

[0156] In some embodiments, so long as the power source is not connected, removed (as is illustrated by the transition 1204), or the pump assembly has not been activated (e.g., by pulling an activation strip, triggering the switch, or the like), the pump assembly remains in state 1206. While remaining in this state, the pump assembly can remain inactive. When the power source is connected and/or the pump assembly has been activated for a first time, the pump assembly transitions to state 1202, where power on self test(s) (POST) can be performed. Power on self test(s) can include performing various checks to ensure proper functionality of the system, such as testing the memory 1170 (e.g., performing a check, such as a cyclic redundancy check, of the program code to determine its

integrity, testing the random access memory, etc.), reading the pressure sensor 1070 to determine whether the pressure values are within suitable limits, reading the remaining capacity or life of the power source (e.g., battery voltage, current, etc.) to determine whether it is within suitable limits, testing the negative pressure source, and the like. As is illustrated, indicators 1060 (e.g., LEDs) can be configured to indicate to the user (e.g., by blinking or flashing once) that the pump assembly is undergoing POST test(s).

[0157] In some embodiments, if one or more of POST test(s) fail, the pump assembly can transition to non-recoverable error state 1214. While in this state, the pump assembly can deactivate therapy, and the indicators 1060 can be configured and indicate to the user that an error was encountered. In some embodiments, all indicators can be configured to remain active. Based on the severity of error, in some embodiments, the pump assembly can be configured to recover from the error and continue operation (or transition to the non-recoverable error state 1214). As is illustrated, the pump assembly can transition to state 1214 upon encountering a fatal error during operation. Fatal errors can include program memory errors, program code errors (e.g., encountering an invalid variable value), controller operation errors (e.g., watchdog timer expires without being reset by the controller 1160), component failure (e.g., inoperative negative pressure source, inoperative pressure sensor 1070, etc.), and any combination thereof.

[0158] When POST test(s) pass, in some embodiments, the pump assembly can transition to a manually paused state 1216. As is illustrated, this transition can be indicated to the user by deactivating one of indicators 1060 (e.g., battery indicator 1066). When the pump assembly transitions into and remains in the manually paused state 1216, the user can be provided an indication, such as by deactivating indicators 1062 (OK indicator) and 1064 (dressing indicator). In some embodiments, therapy can be suspended while the pump assembly remains in the manually paused state 1216. For example, the source of negative pressure (e.g., pump 1090) can be deactivated (or turned off). In some embodiments, indication can be provided by deactivating the source of negative pressure.

[0159] In some embodiments, the pump assembly can be configured to make a transition 1224 from the manually paused state 1216 to the operational state category 1250 (where the pump assembly is configured to deliver therapy) in response to receiving a signal from the switch. For example, the user can press a button to start, suspend, and/or restart

therapy. In some embodiments, the pump assembly can be configured to monitor the duration of time the pump assembly remains in the manually paused state 1216. This can be accomplished, for example, by maintaining a timer (in firmware, software, hardware or any combination thereof), which can be reset and started when the pump assembly transitions into the manually paused state 1216. The pump assembly can be configured to automatically make the transition 1224 from the manually paused state 1216 to the operational state category 1250 when the time duration exceeds a threshold. In some embodiments, such threshold can be a preset value, such as between 1 minute or less and 1 hour or more. In some embodiments, the threshold can be set or changed by the user. In some embodiments, the threshold can be varied based on various operating conditions or on any combination thereof. For example, as the pump assembly nears the end of life (as is explained below), the threshold can be decreased. In some embodiments, the user can pause therapy by activating the switch (e.g., pressing the button), thereby causing the pump assembly to make a transition 1222 from the operational state category 1250 to the manually paused state 1216. In some embodiments, the pump assembly can be configured so that the user can only pause therapy, whereas disconnecting the power source (e.g., removing batteries) stops therapy.

[0160] In some embodiments, the pump assembly can be configured to include a paused state 1218. When the pump assembly transitions into and remains in the paused state 1218, the user can be provided an indication. For example, the pump assembly can be configured to deactivate the OK indicator 1062 and cause the dressing indicator 1064 to flash or blink. In some embodiments, therapy can be suspended while the pump assembly remains in the manually paused state 1216. For example, the source of negative pressure (e.g., pump 1090) can be deactivated (or turned off), which provides the indication to the user that the pump assembly is in the paused state 1218. As is explained below, in some embodiments, the pump assembly can be configured to transition from the operational state category 1250 into the paused state 1218 when a number of retry cycles exceeds a retry limit (transition 1228) or when duty cycle is determined to exceed a duty cycle limit (transition 1230). In some embodiments, transitions 1228 and 1230 can reflect the presence of a leak in the system.

[0161] In some embodiments, the pump assembly can be configured to make a transition 1226 from the paused state 1218 to the operational state category 1250 (where the

pump assembly is configured to activate the pump to deliver therapy) in response to receiving a signal from the switch (e.g., the user pressing a button to restart therapy). In some embodiments, the pump assembly can be configured to monitor the duration of time the pump assembly remains in the paused state 1218. For example, this can be accomplished by maintaining a timer (in firmware, software, hardware or any combination thereof), which can be reset and started when the pump assembly transitions into the paused state 1218. The pump assembly can be configured to automatically make the transition 1226 from the paused state 1218 to the operational state category 1250 when the time duration exceeds a threshold. The threshold can be the same or different than the threshold of the manually paused state 1216 described above. In some embodiments, the threshold can be a preset value, such as between 1 minute or less and 1 hour or more. In some embodiments, the threshold can be set or changed by the user. In some embodiments, the threshold can be varied based on various operating conditions or on any combination thereof. For example, as the pump assembly nears the end of life (as is explained below), the threshold can be decreased.

[0162] In some embodiments, the pump assembly includes both the manually paused state 1216 and the paused state 1218 in order to differentiate between various causes for pausing therapy. Such ability to differentiate can allow the pump assembly to provide the user with an indication of a particular cause for pausing therapy (e.g., manually paused state 1216 and paused state 1218 can provide different indications). For example, therapy can be paused due to the user manually pressing the button, in which case the pump assembly can make the transition 1222 from the operational state category 1250 to the manually paused state 1216. As another example, therapy can be paused due to detecting a leak, in which case the pump assembly can make the transition 1228 and/or 1230 from the operational state category 1250 to the paused state 1218. In some embodiments, the pump assembly can be configured to include one state indicating a suspension or pause in the delivery of therapy or more than two such states.

[0163] In some embodiments, the pump assembly can be configured to monitor the remaining capacity or life of the power source (e.g., by periodically reading or sampling the battery voltage, current, etc.). The pump assembly can be configured to indicate to the user the remaining capacity. For example, if the power source is determined to have a normal remaining capacity (e.g., as a result of comparison to a threshold, such as 2.7V, 2.6V, 2.5V,

etc.), the battery indicator 1066 can be deactivated. If the power source is determined to have low remaining capacity, the pump assembly can be configured to provide an indication to the user by, for example, causing the battery indicator 1066 to blink or flash, as is illustrated by the transition 1220. In some embodiments, the battery indicator 1066 can be configured to be blinking or flashing intermittently or continuously regardless of the state the pump assembly is in or only in particular states.

[0164] In some embodiments, when the remaining capacity of the power source is determined to be at or near a critical level (e.g., as a result of comparison to a threshold, such as 2.4V, 2.3V, 2.2V, etc.), the pump assembly can be configured to transition into a battery critical state 1212. In some embodiments, the pump assembly can be configured to remain in this state until the capacity of the power source is increased, such as by replacing or recharging the power source. The pump assembly can be configured to deactivate therapy while remaining in the battery critical state 1212. In addition, as is illustrated, the pump assembly can be configured to indicate to the user that the power source is at or near the critical level by, for example, deactivating all indicators.

[0165] In some embodiments, the pump assembly can be configured to provide therapy for a predetermined period of time, such as approximately 1 day, 2-10 days, etc. following a first activation. In some embodiments, such period of time can be a preset value, changed by the user, and/or varied based on various operating conditions or on any combination thereof. The pump assembly can be disposed upon the expiration of such period of time. In some embodiments, the first activation can be reflected by a transition into the active state category 1210, by pulling the activation strip (e.g., transition into state 1202), etc. Once the pump assembly has been activated, the pump assembly can be configured to monitor the duration it has remained active. In some embodiments, the pump assembly can be configured to monitor the cumulative duration of remaining in the active state category 1210. This can be accomplished, for example, by maintaining a timer (in firmware, software, hardware or any combination thereof), that reflects such duration.

[0166] When the duration reaches or exceeds a threshold (e.g., 7 days), the pump assembly can be configured to transition to an end of life (EOL) state 1240. The pump assembly can be configured to deactivate therapy while remaining in state 1240 and to indicate to the user that end of pump assembly' usable life has been reached. For example,

the pump assembly can be configured to deactivate all indicators and/or deactivate the button. In some embodiments, when the pump assembly is disposable, transitioning to the end of life state 1240 means that the pump assembly can be disposed of. The pump assembly can be configured to disable reactivation of the pump assembly once the end of life has been reached. For example, the pump assembly can be configured to not allow reactivation even if the power source is disconnected and reconnected later, which can be accomplished by storing an indication, value, flag, etc. in the read only memory.

[0167] Figure 26 illustrates the operational flow in state category 1250 of the pump assembly 1000 according to some embodiments. The pump assembly can be configured to deliver therapy, monitor leaks in the system, provide indication(s) to the user, and the like. As is explained below, in some embodiments, the pump assembly can be configured to deliver therapy by initially attempting to establish a first desired negative pressure level (e.g., negative pressure between -5 mmHg or less and -200 mmHg or more, such as -100 mmHg) under the dressing 1010. In some embodiments, the first desired negative pressure level can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. Once the first desired negative pressure level is established under the dressing 1010, the pump assembly can be configured to deactivate the source of negative pressure (e.g., pump). When negative pressure under the dressing 1010 decreases (i.e., gravitates toward standard atmospheric pressure) due to leaks in the system, the pump assembly can be configured to restore negative pressure under the dressing by activating the pump to establish a second desired negative pressure level under the dressing (e.g., negative pressure between -5 mmHg or less and -200 mmHg or more, such as -100 mmHg). In some embodiments, the second desired negative pressure level can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. In some embodiments, the first and second desired negative pressure levels can be the same. In some embodiments, the first and second desired negative pressure levels can be different, that is, the second negative pressure level can be less than the first negative pressure level or vice versa.

[0168] In some embodiments, the pump assembly can transition from the manually paused state 1216 and/or paused state 1218 to state 1252. As is explained above, this transition can be caused by the user pressing the button to start/restart therapy and/or

upon expiration of duration of time, such as 1 hour. The pump assembly can be configured to immediately transition to an initial pump down (IPD) state 1260, where the pump can be activated to establish the first desired negative pressure level under the dressing 1010. In some embodiments, the pump can be activated if the pressure level under the dressing is above (less than) the first desired negative pressure level. Activating the source of negative pressure to establish the first desired negative pressure level under the dressing 1010 can be referred to herein as the "initial pump down." The pump assembly can be configured to indicate to the user that it is performing the initial pump down by, for example, causing the OK indicator 1062 to blink or flash and deactivating the dressing indicator 1064. In some embodiments, the indication can be provided by, for example, activating the source of negative pressure. The pump assembly can be configured to measure the level of pressure under the dressing 1010 by reading or sampling the sensor 1070.

[0169] In some embodiments, the pump assembly can be configured to monitor the duration of time the pump assembly remains in the IPD state 1260. This can be accomplished, for example, by maintaining a timer (in firmware, software, hardware or any combination thereof), which can be reset and started when the pump assembly transitions into the IPD state 1260. In some embodiments, in order to conserve power, limit the noise and/or vibration generated by the pump, etc., the pump assembly can be configured to suspend the initial pump down operation for a period of time and, later, retry the initial pump down. This functionality can, for example, conserve battery power and allow transient and/or non-transient leaks to become resolved without user intervention or allow the user to fix the leak (e.g., straighten the dressing, fix the seal, check the connection or connections, etc.).

[0170] In some embodiments, when the duration of time for remaining in the IPD state 1260 equals or exceeds a threshold (e.g., 30 seconds), the pump assembly can be configured to make the transition 1264 to state 1266. In some embodiments, the threshold can be a preset value, such as between 5 seconds or lower and 5 minutes or higher. In some embodiments, the threshold can be set or changed by the user. In some embodiments, the threshold can be varied based on various operating conditions or on any combination thereof. In some embodiments, the pump assembly can be configured to deactivate the pump when making the transition 1264. The pump assembly can be configured to monitor a number attempts (e.g., by maintaining a counter which can be reset in state 1252 and updated in wait

state 1270) made to establish the first desired negative pressure under the dressing 1010. In some embodiments, the pump assembly can be configured to provide a limited or maximum number of IPD retry attempts in order, for example, to conserve power. Preferably, the pump assembly can be configured to provide a limited number of consecutive IPD retry attempts, although the pump assembly can be configured to provide a limited number of non-consecutive IPD retry attempts or a mix of consecutive and non-consecutive IPD retry attempts. The threshold for IPD retry attempts can be 1, 2, 3, 4, 5, and so on. In some embodiments, the threshold can be a preset value. In some embodiments, the threshold can be set or changed by the user. In some embodiments, the threshold can be varied based on various operating conditions or on any combination thereof.

[0171] In some embodiments, the pump assembly can be configured to determine in state 1266 whether the number of IPD retry attempts made is equal to or exceeds the threshold (e.g., 1 retry attempt). In case the number of IPD retry attempts made is equal or exceeds the threshold, the pump assembly can be configured to make the transition 1228a to the paused state 1218, where therapy is paused or suspended as is described above. Otherwise, the pump assembly can be configured to make the transition 1268 to the wait state 1270. In some embodiments, the pump assembly can be configured to deactivate the source of negative pressure in state 1266, which can provide an indication to the user that the pump assembly transitioned to state 1266.

[0172] In some embodiments, the pump assembly can be configured to deactivate the pump in the wait state 1270, thereby pausing therapy for a period of time (e.g., between 1 second or less and 1 minute or more, such as 15 seconds). This can be accomplished, for example, by maintaining a timer (in firmware, software, hardware or any combination thereof), which can be reset and started when the pump assembly transitions into the wait state 1270. This period of time in the wait state 1270 can be preset or variable (e.g., automatically or by the user). In some embodiments, the period of time can be varied based on various operating conditions or on any combination thereof. The period of time the pump assembly remains in the wait state 1270 can be decreased or increased (e.g., multiplied by a factor between 0.1 or less and 4.0 or more, such as 2), on each transition into the wait state 1270. The period of time can be decreased or increased on each successive transition into the wait state 1270. The period of time can be decreased or increased until it equals or passes a

threshold (e.g., between 1 second or less and 5 minutes or more, such as 4 minutes). In addition, the period of time can be reset to an initial value upon transition to a monitor pressure state 1280, transition to the manually paused state 1216, transition to the paused state 1218, etc.

[0173] In some embodiments, the pump assembly can be configured to indicate to the user that the pump assembly is in the wait state 1270. For example, the pump assembly can be configured to cause the OK indicator 1062 to flash or blink and deactivate the dressing indicator 1064. In some embodiments, deactivating the pump can provide indication that the pump assembly is in the wait state 1270. Upon expiration of the period of time in the wait state, the pump assembly can be configured to make the transition 1272 from the wait state 1270 to the IPD state 1260, where the pump assembly can attempt to establish the first desired negative pressure level under the dressing 1010. In some embodiments, the pump assembly can be configured to ensure that the negative pressure level under the dressing remains above a certain safety level. For example, the pump assembly can be configured to maintain the negative pressure level under the dressing 1010 above a safety level between -150 mmHg or less and -250 mmHg or more, such as -225 mmHg.

[0174] In some embodiments, when the first desired negative pressure level under the dressing 1010 has been established, the pump assembly can be configured to make the transition 1276 to a monitor state 1280. The pump assembly can be configured to reset the number of IPD retry attempts when making the transition 1276. The pump assembly can be configured to indicate the transition to the monitor state 1280 to the user by, for example, causing the OK indicator 1062 to blink or flash and deactivating the dressing indicator 1064. While remaining in the monitor state 1280, the pump assembly can be configured to deactivate the pump (which can provide an indication to the user that the pump assembly is in the monitor state 1280) and periodically or continuously monitor the level of pressure under the dressing 1010. The pump assembly can be configured to measure the level of pressure under the dressing 1010 by reading or sampling the sensor 1070.

[0175] In some embodiments, the pump assembly can be configured to determine whether, for example, due to leaks in the system, the level of negative pressure under the dressing 1010 decreases to reach and/or pass (e.g., become less than) a threshold. The threshold can be selected from the range between -10 mmHg or less and -100 mmHg or

more, such as -60 mmHg. In some embodiments, the threshold can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. If the threshold is determined to be reached or passed, the pump assembly can be configured to restore the level of negative pressure under the dressing 1010. In some embodiments, the pump assembly can be configured to reestablish the first desired negative pressure level or establish another, different negative pressure level. This can be accomplished by making the transition 1282 to a maintenance pump down (MPD) state 1290.

[0176] In some embodiments, the pump assembly can be configured to activate the pump to establish the desired level of negative pressure under the dressing 1010 (e.g., the first desired level) while the pump assembly remains in the MPD state 1290. The pump assembly can be configured to provide an indication to the user, for example, by causing the OK indicator 1062 to blink or flash and deactivating the dressing indicator 1064. In some embodiments, the pump assembly activating the source of negative pressure can provide an indication to the user that the pump assembly transitioned to state 1290. In some embodiments, the pump assembly can be configured to generate less noise and vibration when the pump is activated in the MPD state 1290 than when the pump is activated in the IPD state 1264. For example, the difference in the noise level can be between 1 dB or less and 30 dB or more, such as approximately 7 dB, approximately 20 dB, etc. As another example, the difference in the noise level can be between 30 dB or less to 80 dB or more, such as approximately 45 dB, approximately 50 dB, approximately 65 dB, etc.

[0177] In some embodiments, the pump assembly can be configured to monitor the duration of time it remains in the MPD state 1290. This can be accomplished, for example, by maintaining a timer (in firmware, software, hardware or any combination thereof), which can be reset and started when the pump assembly makes the transition 1282 into the MPD state 1290. In some embodiments, in order to conserve power, limit the noise and/or vibration generated by the pump, etc., the pump assembly can be configured to suspend the maintenance pump down operation for a period of time and, later, retry the initial pump down and/or maintenance pump down. This functionality can, for example, conserve battery power and allow transient and/or non-transient leaks to become resolved without user intervention or allow the user to fix the leak (e.g., straighten the dressing, fix the seal, check the connection or connections, etc.).

[0178] In some embodiments, when the duration of time in the MPD state 1290 equals or exceeds a threshold (e.g., a value between 5 seconds or lower and 5 minutes or higher, such as 10 seconds) and the pressure level under the dressing 1010 has not reached the desired negative pressure level, the pump assembly can be configured to make the transition 1292 to state 1294. The threshold can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. In some embodiments, the pump assembly can be configured to deactivate the pump when making the transition 1292, which can provide an indication to the user that the pump assembly is making the transition. The pump assembly can be configured to monitor a number of MPD attempts (e.g., by maintaining a counter which can be reset in the state 1252 and/or when making the transition 1228b and updated when making the transition 1296) made to establish the desired negative pressure under the dressing 1010. In some embodiments, the pump assembly can be configured to provide a limited or maximum number of MPD retry attempts (e.g., to conserve power). Preferably, the pump assembly can be configured to provide a limited number of consecutive MPD retry attempts, although the pump assembly can be configured to provide a limited number of non-consecutive MPD retry attempts or a mix of consecutive and non-consecutive retry attempts. The threshold for MPD retry attempts can be 1, 2, 3, 4, 5, and so on. In some embodiments, the threshold can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. The pump assembly can be configured to set the number of IPD and MPD retry attempts to the same or different value. The pump assembly can be configured to determine in state 1294 whether the number of MPD retry attempts made is equal to or exceeds the threshold (e.g., 3 retry attempts). In case the number of MPD retry attempts made is equal or exceeds the threshold, the pump assembly can be configured to make the transition 1228b to the paused state 1218, where therapy is paused or suspended as is described above. Otherwise, the pump assembly can be configured to make the transition 1296 to the wait state 1270, where therapy is paused or suspended as is described above. Alternatively, the pump assembly can be configured to make the transition to the IPD state 1260 or MPD state 1290.

[0179] In some embodiments, the pump assembly can be configured to make the transition 1284 to the monitor state 1280 if the level of pressure under the dressing reaches or

exceeds (e.g., become greater than) the desired negative pressure level. The pump assembly can also be configured to reset the number of MPD retry attempts when making the transition 1284.

[0180] In some embodiments, the pump assembly can be configured to monitor the duty cycle of the source of negative pressure (e.g., pump). The pump assembly can be configured to monitor the duty cycle periodically and/or continuously. Duty cycle measurements can reflect various operating conditions of the system, such as presence and/or severity of leaks, rate of flow of fluid (e.g., air, liquid and/or solid exudate, etc.) aspirated from wound, and so on. For example, duty cycle measurements can indicate presence of a high leak, and the pump assembly can be configured to indicate this condition and/or temporarily suspend or pause operation of the pump in order to conserve power. This functionality can, for example, conserve battery power and allow transient and/or non-transient leaks to become resolved without user intervention or allow the user to fix the leak (e.g., straighten the dressing, fix the seal, check the connection or connections, etc.).

[0181] In some embodiments, the pump assembly can be configured to periodically monitor the duty cycle, such as once between every 10 seconds or less and 5 minutes or more. In some embodiments, the pump assembly can be configured to monitor the duty cycle once per minute. This can be accomplished by maintaining a timer (in firmware, software, hardware or any combination thereof), which can be set to expire every minute (e.g., as is indicated by an interrupt or via polling) and can be restarted (e.g., by clearing an interrupt). In some embodiments, the time interval for measuring the duty cycle can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. In some embodiments, the pump assembly can be configured to monitor the duty cycle when the pump assembly is in the operational state category 1250 (i.e., any of states 1260, 1266, 1270, 1280, 1290, 1294 and/or any transitions between any of the states), as the pump assembly is configured to activate the pump in this state category. In some embodiments, the pump assembly can be configured to monitor the duty cycle when the pump assembly is in a particular state and/or state transition or subset of states and/or state transitions of the operational state category 1250. In some embodiments, the pump assembly can be configured to monitor the duty cycle when the pump assembly is in a particular state and/or state transition, subset of states and/or state transitions, or all states

and/or state transitions of the active state category 1210 or any combination of any states and/or state transitions disclosed herein. As is illustrated in Figure 26, the pump assembly can make the transition 1302 from any of states 1260, 1266, 1270, 1280, 1290, 1294 and/or transitions between any of the states to state 1300, where the pump assembly determines the duty cycle of the pump during the elapsed minute. The duty cycle can be determined according to the equation:

[0182] $DC = t / T,$ (2)

[0183] where DC is the duty cycle, t is the duration that the source of negative pressure is active, and T is the total time under consideration. In case of monitoring the duty cycle once per minute (i.e., T = 60 seconds), the duty cycle can be expressed (e.g., in percent) as:

[0184] DC = (Pump run time during the elapsed minute / 60) * 100% (3)

[0185] In order to determine the duty cycle, the pump assembly can be configured to monitor the duration of time that the pump has been active (e.g., the pump run time) and/or inactive.

[0186] In some embodiments, the pump assembly can be configured to compare the determined duty cycle to a duty cycle threshold, which can be selected from the range between 1% or less and 50% or more. The comparison can, for example, indicate presence of a leak in the system. In other words, if the pump is remains active over a period of time so that the duty cycle threshold is reached or exceeded, the pump may be working hard to overcome the leak. In such cases, the pump assembly can be configured to suspend or pause the delivery of therapy. The pump assembly can be configured to provide an indication to the user that the pump is working hard (e.g., duty cycle exceeds the duty cycle threshold) by, for example, deactivating the source of negative pressure. In some embodiments, the duty cycle threshold can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. As is illustrated in Figure 26, the pump assembly can be configured to compare the determined duty cycle to the duty cycle threshold (e.g., 9%). The pump assembly can be configured to monitor the number of duty cycles that exceed the threshold by, for example, maintaining and updating an overload counter, which can be reset when the pump assembly transitions from state 1252 to the IPD state 1260.

[0187] In some embodiments, the pump assembly can be configured to update the overload counter in state 1300. If the determined duty cycle does not exceed the duty cycle threshold, the pump assembly can decrement the overload counter. In some embodiments, the minimum value of overload counter can be set to zero, that is the overload counter cannot become negative. Conversely, if the determined duty cycle is equal to or exceeds the duty cycle threshold, the pump assembly can increment the overload counter.

[0188] In some embodiments, the pump assembly can be configured to monitor a total or aggregate number of duty cycles that equal to or exceed the duty cycle threshold. This approach can help to smooth or average the duty cycle variation in order to, for example, prevent one or several erratic cycles that may be caused by a transient leak from interrupting therapy. In some embodiments, the pump assembly can be configured to monitor consecutive or non-consecutive duty cycles exceeding the duty cycle threshold. In some embodiments, the threshold can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. If the number of duty cycles that exceed the duty cycle threshold is determined to exceed an overload threshold (e.g., a number between 1 and 60 or more, such as 30), the pump assembly can be configured to make the transition 1230 to the paused state 1216, where therapy is suspended or paused as is described above. In some embodiments, the pump assembly can be configured to deactivate the source of negative pressure, which can provide an indication to the user that the pump is working hard (e.g., duty cycle exceeds the overload threshold). If the number of duty cycles that exceed the duty cycle threshold is not determined to exceed the overload threshold, the pump assembly can be configured to make the transition 1304 and remain in the operational state category 1250. In some embodiments, the pump assembly can be configured to return to the same state and/or transition between states from which the pump assembly made the transition 1302. In some embodiments, the pump assembly can be configured to transition to a different state and/or transition between states.

[0189] In some embodiments the pump assembly is further configured to suspend or pause therapy if the user presses the button 1002 while the pump assembly is in the operational state category 1250. In some embodiments, the pump assembly can be configured to transition to the manually paused state 1216.

[0190] Figure 27 illustrates another state diagram of operation of the pump assembly 1000 according to some embodiments. In some embodiments, the controller 1140 can be configured to implement the flow of the state diagram 1400. In some embodiments, the flow 1400 can be largely similar to the flow illustrated in Figures 25-26. State 1402 corresponds to state 1202, state 1406 corresponds to state 1260, state category 1410 corresponds to state category 1210, state 1414 corresponds to state 1214, state 1416 corresponds to state 1216, state 1418 corresponds to state 1218, transition 1420 corresponds to transition 1220, transition 1422 corresponds to transition 1222, transition 1424 corresponds to the transition 1224, transition 1426 corresponds to transition 1226, and state 1440 corresponds to state 1240. In addition, state category 1450 corresponds to state category 1250, state 1460 corresponds to state 1260, transition 1464 corresponds to transition 1264, state 1466 corresponds to transition 1266, transition 1468 corresponds to transition 1268, transition 1428a corresponds to transition 1228a, state 1470 corresponds to state 1270, and transition 1472 corresponds to transition 1272. Further, transition 1476 corresponds to transition 1276, state 1480 corresponds to state 1280, transition 1482 corresponds to transition 1282, state 1490 corresponds to state 1290, transition 1492 corresponds to transition 1292, state 1494 corresponds to state 1294, transition 1496 corresponds to transition 1296, and transition 1428b corresponds to transition 1228b.

[0191] In some embodiments, the pump assembly can be configured to monitor the duty cycle after a desired negative pressure level is established under the dressing 1010 in the MPD state 1490. In some embodiments, the pump assembly can also take into account the duration of time that the pump has been active while the pump assembly remains in the IPD state 1460. As is illustrated, the device can be configured to make the transition 1484 from the MPD state 1490. Transition 1484 can be similar to the transition 1284, but instead of transitioning directly to the IPD state 1480, the pump assembly can be configured to monitor the duty cycle in state 1500. In some embodiments, the pump assembly can be configured to monitor the duty cycle during a cumulative period of time that the pump assembly has remained in the monitor state 1480 and MPD state 1490. In some embodiments, the pump assembly can be configured to monitor the duty cycle over the cumulative period of time during the immediately preceding or previous monitor and MPD cycles. For example, immediately before transitioning to state 1500 the pump assembly

could have remained in the MPD state 1490 for time duration X (during which the pump was active). In addition, assuming that immediately before transitioning to the MPD state 1490, the pump assembly remained in the monitor state 1480 for a time duration Y (during which the pump was not active), the duty cycle (DC) can be expressed (e.g., in percent) as:

[0192] $DC = 100\% * [X / (X + Y)]$. (4)

[0193] In order to determine the duty cycle, the pump assembly can be configured to monitor the duration of time that the pump has been active and/or inactive.

[0194] In some embodiments, the pump assembly can be configured to compare the determined duty cycle to a duty cycle threshold (e.g., 9%), as is described above. In some embodiments, the threshold can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. If the duty cycle is determined to be below the threshold, the pump assembly can be configured to make the transition 1502 to the monitor state 1480. Conversely, if the duty cycle is determined to be equal to or exceed the threshold, the pump assembly can be configured to make the transition 1504 to state 1506. In some embodiments, the pump assembly can provide an indication that the duty cycle exceeds the threshold by, for example, deactivating the pump.

[0195] In some embodiments, the pump assembly can be configured to monitor a total or aggregate time over which the duty cycle is equal to or exceeds the threshold. This approach can help to smooth or average the duty cycle variation in order to, for example, prevent one or several erratic cycles that may be caused by a transient leak from interrupting therapy. Monitoring can be accomplished by maintaining a timer (in firmware, software, hardware or any combination thereof), which can be restarted (e.g., on the transition 1476) and updated (e.g., in state 1506). In some embodiments, the pump assembly can be configured to determine whether the duty cycle equals to or exceeds the threshold over a certain aggregate period of time, which can be compared to an aggregate duration threshold. The threshold can be selected from a range between 5 minutes or less and 2 hours or more, such as 30 minutes. In some embodiments, the threshold can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. If the aggregate period of time equals to or exceeds the threshold, the pump assembly can be configured to make the transition 1508 to the paused state 1418, where the pump assembly can be configured to suspend or pause the delivery of therapy. In

some embodiments, the pump assembly can indicate this transition to the user by, for example, deactivating the pump. Conversely, if the aggregate period of time is determined to be less than the threshold, the pump assembly can be configured to make the transition 1510 to the monitor state 1480. The pump assembly can be configured to indicate the transition 1510 to the user by, for example, causing the OK indicator 1062 to blink or flash and deactivating the dressing indicator 1064.

[0196] Figure 28 illustrates a graph 1600 depicting a duty cycle determination for the pump assembly 1000 according to some embodiments. The x-axis represents time and the y-axis represents pressure. In some embodiments, the pump assembly can be configured to establish a negative pressure level of -100 mmHg under the dressing 1010, as is represented by position 1606. For example, this can be performed during the initial pump down in state 1260. The pump assembly can be configured to monitor the level of negative pressure under the dressing 1010. For example, this can be performed in the monitor state 1280. As is illustrated, the pump assembly can monitor pressure over the period of time a, as represented by interval 1602. The level of negative pressure under the dressing 1010 can decay over time (e.g., due to leaks in the system), as is illustrated by line 1620.

[0197] In some embodiments, the pump assembly can be configured to restore or reestablish the negative pressure level under the dressing 1010 when that pressure decays to reach or pass a threshold of approximately -70 mmHg, as is represented by position 1608. In some embodiments, the pump assembly can be configured to activate the pump, as is illustrated by line 1622. For example, this can be performed by transitioning to the maintenance pump down state 1290. As is illustrated, the pump assembly can activate the pump for a time duration b (1604) until the negative pressure level of -100 mmHg is reestablished under the dressing 1010. The pump assembly can be configured to deactivate the pump when the level of pressure under the dressing 1010 reaches -100 mmHg at position 1610. For example, this can be performed by transition to the monitor state 1280. The duty cycle (DC) over the period illustrated in 1600 (i.e., a + b) can be expressed (e.g., in percent) as:

[0198] $DC = 100\% * [b / (a + b)]$. (5)

[0199] Figure 29 illustrates a non-limiting example of a normal (e.g., no leak or low leak) operation 1700 of some embodiments of the pump assembly 1000. The pump

assembly can be configured to establish a desired level of negative pressure under the dressing 1010, as is illustrated in box 1702. The pump assembly can be configured such that, if the level of pressure under the dressing 1010 rises above a desired level (e.g., first set point value, such as –70 mmHg), the source of negative pressure (e.g., a pump) will be activated and will start operating to reduce the level of pressure under the dressing 1010 to the desired value. For example, the desired value can be approximately within the interval between the first and second set point value or approximately the second set point value (e.g., -100 mmHg). In some embodiments, this can be accomplished in the initial pump down state 1260.

[0200] In some embodiments, when the level of pressure under the dressing 1010 reaches the desired value, the pump assembly can be configured to deactivate the pump and monitor the level of pressure under the dressing, as is illustrated in box 1704. For example, this can be accomplished in the monitor state 1280. The pump assembly can be configured to periodically or continuously monitor the level of pressure under the dressing 1010 by, for example, reading or sampling the sensor 1070. Based on the monitored pressure, the pump assembly can determine in box 1706 whether the pump needs to be activated or restarted to reestablish the desired level of negative pressure under the dressing 1010. If the monitored pressure is determined to be low (e.g., less than or less than or equal to the first set point value), the pump assembly can be configured to activate the pump, as is illustrated in box 1708. For example, this can be accomplished by transitioning to the MPD state 1290. Conversely, if the monitored level of pressure is not determined to be low (e.g., greater than or greater than or equal to the first set point value), the pump assembly can be configured to continue monitoring the level of pressure under the dressing 1010. During this operational flow, the pump assembly can be configured to indicate to the user that it is operating normally. As is illustrated in 1060a, the pump assembly can activate or cause to blink or flash the OK indicator 1062, which is depicted as 1062a. In addition, the pump assembly can deactivate the dressing indicator 1064 and the battery indicator 1066, which are depicted as 1064a and 1066a respectively.

[0201] Figure 30 illustrates a non-limiting example of operation 1800 of some embodiments of the pump assembly 1000 in presence of a high leak. As is described above in connection with Figure 29, the pump assembly can be configured to establish a desired

level of negative pressure under the dressing 1010, as is illustrated in box 1802. In some embodiments, when the level of pressure under the dressing 1010 reaches the desired value, the pump assembly can be configured to deactivate the pump and monitor the level of pressure under the dressing, as is illustrated in box 1804. The pump assembly can be configured to periodically or continuously monitor the level of pressure under the dressing 1010 by, for example, reading or sampling the sensor 1070. Based on the monitored level of pressure, the pump assembly can determine whether the pump needs to be activated or restarted to reestablish the desired level of negative pressure under the dressing 1010. If the monitored level of pressure is determined to be low (e.g., less than or less than or equal to the first set point value), the pump assembly can be configured to activate the pump, as is illustrated in box 1808. Once the desired level of pressure has been reestablished under the dressing 1010, the pump assembly can recommence monitoring the level of negative pressure under the dressing (e.g., transition to the monitor state 1280).

[0202] In some embodiments, due to presence of a leak or leaks in the system, the pump assembly 1010 can be configured to carry out multiple cycles of monitoring and reactivating the pump. During this operational flow, the pump assembly can be configured to indicate to the user that the pump assembly is operating normally. As is illustrated in 1060b, the pump assembly can activate or cause to blink or flash the OK indicator 1062, which is depicted as 1062b. In addition, the pump assembly can deactivate the dressing indicator 1064 and the battery indicator 1066, which are depicted as 1064b and 1066b respectively. The pump assembly can be configured to continuously or periodically determine whether the pump is pumping too often, as is illustrated in box 1810. As is illustrated, in some embodiments, the pump assembly can be configured to use the duty cycle as a proxy for determining whether the pump is pumping too often. For example, the pump assembly can be configured to determine whether the pump is "working hard," that is determine whether the pump is on for more than a threshold duration, such as 9% of the total therapy time. In other words, the pump assembly can be configured to determine whether the duty cycle of the pump reaches or exceeds the duty cycle threshold.

[0203] In some embodiments, the pump assembly can be configured to suspend or pause operation of the pump if the pump is determined to be working hard over a duration of time (e.g., the pump is on for more than about 2 hours a day, or is on for more than a

predetermined amount of time), even if the desired level of negative pressure (e.g., second set point value) has been established. As is illustrated in box 1812, the pump assembly can be configured to determine whether the pump is working hard for a duration of 30 minutes or more. For example, the pump assembly can be configured to determine whether duty cycle (or cycles) monitored over the past 30 minutes exceed the duty cycle threshold. For example, the pump assembly can determine whether the pump has been on for about 2 minutes and 42 seconds or longer over the last 30 minutes, which corresponds to 9% duty cycle threshold.

[0204] In some embodiments, the pump assembly can be configured to pause or suspend therapy if the pump is determined to be working hard, as is illustrated in box 1814. The pump assembly can be further configured to turn a "Leak alarm" indicator on. As is illustrated in 1060c, the pump assembly can activate or cause to blink or flash the dressing indicator 1064, which is depicted as 1064b, and deactivate the OK indicator 1062 and the battery indicator 1066, which are depicted as 1062c and 1066c respectively. To restart the therapy, the user may need to straighten the dressing, to fix the leak, and/or to activate the pump once again. In some embodiments, the pump can be activated again by pressing the start or operating button on the pump, because of a timeout, etc.

[0205] In the case of a leak or leaks being present in the dressing, in some embodiments, the pump assembly 1000 can be programmed or otherwise configured to suspend or pause therapy if the second set point value is not reached after a predetermined amount of operating time of the pump. For example, in some embodiments, if the pump has been running continuously for X minutes and the second set point pressure value has not been reached, the pump assembly can activate an alarm which can comprise an LED indicator, a "leak detected" LED indicator 1064, or other alarm, and pause the therapy. In some embodiments, the predetermined amount of time can be approximately 5% of the total planned duration of the negative pressure therapy for the system, or from approximately 3% or less to approximately 15% or more of the total planned duration of the negative pressure therapy for the system. In some embodiments, the predetermined amount of time can be approximately 9 minutes, or from approximately 4 minutes or less to approximately 40 minutes or more, or from approximately 6 minutes to approximately 10 minutes.

[0206] Figure 31 illustrates a non-limiting example of operation 1900 of some embodiments of the pump assembly 1000 in presence of a very high leak. As is described

above in connection with Figure 29, the pump assembly can be configured to establish a desired level of negative pressure under the dressing 1010, as is illustrated in box 1902. In some embodiments, when the level of pressure under the dressing 1010 reaches the desired value, the pump assembly can be configured to deactivate the pump and monitor the level of pressure under the dressing, as is illustrated in box 1904. The pump assembly can be configured to periodically or continuously monitor the level of pressure under the dressing 1010 by, for example, reading or sampling the sensor 1070. Based on the monitored level of pressure, the pump assembly can determine whether the pump needs to be activated or restarted to reestablish the desired level of negative pressure under the dressing 1010. If the monitored level of pressure is determined to be low (e.g., less than or less than or equal to the first set point value), the pump assembly can be configured to activate the pump, as is illustrated in box 1908. During this operational flow, the pump assembly can be configured to indicate to the user that the pump assembly is operating normally. As is illustrated in 1060d, the pump assembly can activate or cause to blink or flash the OK indicator 1062, which is depicted as 1062d. In addition, the pump assembly can deactivate the dressing indicator 1064 and the battery indicator 1066, which are depicted as 1064d and 1066d respectively.

[0207] In some embodiments, due to a leak or leaks (e.g., a leak that has a relatively very high flow rate), the pump assembly may not be able to reach a desired negative pressure level and/or the second set point value under the dressing 1010. If after a predetermined amount of operating time, the desired negative pressure level is not reached under the dressing, the pump assembly can be configured to suspend or pause the pump, as is illustrated in box 1914. For example, this can be accomplished by transitioning to the wait state 1270. In some embodiments, the predetermined amount of pump operating time can be 10 seconds (as is illustrated in Figure 31). In some embodiments, the predetermined amount of pump operating time can be from approximately 5 seconds or less to approximately 60 seconds or more.

[0208] In some embodiments, the pump assembly can be configured to provide a limited number of retry cycles before pausing or suspending therapy. As illustrated in boxes 1920, 1922, and 1924, the pump assembly can be configured to go through three retry cycles before suspending or pausing therapy (1914) and/or activating an alarm, such as the "Leak

alarm." Some embodiments of the pump assembly can go through two retry cycles, four retry cycles, etc. before pausing therapy and/or activating an alarm. As is illustrated in 1060e, the pump assembly can activate or cause to blink or flash the dressing indicator 1064, which is depicted as 1064e, and deactivate the OK indicator 1062 and the battery indicator 1066, which are depicted as 1062e and 1066e respectively.

[0209] Figure 32 illustrates a non-limiting example of operation 2000 of some embodiments of the pump assembly 1000 in presence of an extremely high leak. The pump assembly can be configured to quickly go into a therapy pause or suspend mode to avoid wasting the batteries trying to cope with a high flow rate leak. As is illustrated in box 2001, the pump assembly can be turned on, which can be accomplished, for example, by transitioning into the operational state category 1250. As is described above in connection with Figure 29, the pump assembly can be configured to establish a desired level of negative pressure under the dressing 1010, as is illustrated in box 2002.

[0210] In some embodiments, if the leak is extremely high, such as when the pump is turned on but not yet connected to the dressing or not properly connected to the dressing, the pump assembly can be configured to operate for a predetermined amount of time while attempting to draw the pressure under the dressing 1010 to a desired negative pressure level. (e.g., approximately the second set point value or a value within the interval between the first and second set point values). The pump assembly can be configured to suspend or pause therapy upon expiration of the predetermined amount of time. For example, this can be accomplished by transitioning to the wait state 1270. As is illustrated, the pump assembly can be configured to operate the pump for 30 seconds. If during this period of time the pressure under the dressing 1010 has not been drawn to the desired negative pressure, the pump assembly can go into a timeout mode 2020 for another predetermined amount of time (e.g., for 15 seconds, as illustrated in Figure 32). During this operational flow, the pump assembly can be configured to indicate to the user that the pump assembly is operating normally. As is illustrated in 1060f, the pump assembly can activate or cause to blink or flash the OK indicator 1062, which is depicted as 1062f. In addition, the pump assembly can deactivate the dressing indicator 1064 and the battery indicator 1066, which are depicted as 1064f and 1066f respectively.

[0211] In some embodiments, the pump assembly can be configured to provide a limited number of retry cycles for establishing the desired level of negative pressure under the dressing 1010. As is illustrated, after the first trial (or any number of additional trials), the pump assembly can be configured to establish or reestablish the desired negative pressure level under the dressing, as is illustrated in box 2002. In some embodiments, as is illustrated in box 2014, if the pump assembly operates for another predetermined amount of time without drawing the pressure under the dressing 1010 to the desired level (e.g., approximately the second set point value or to a value within the interval between the first and second set point values) after a first attempt, the pump assembly can be configured to suspend or pause therapy without retrying the pump down. The pump assembly can be configured to remain in the suspended or paused state until the pump assembly is reactivated (e.g., due to a timeout, due to the user pressing the button, etc.) The pump assembly can be configured to activate an alarm in this state. During this operational flow, the pump assembly can be configured to indicate to the user that a leak or leaks are present. As is illustrated in 1060g, the pump assembly can activate or cause to blink or flash the dressing indicator 1064, which is depicted as 1064g, and deactivate the OK indicator 1062 and the battery indicator 1066, which are depicted as 1062g and 1066g respectively.

[0212] Throughout the description and claims of this specification, the words "comprise" and "contain" and variations of the words, for example "comprising" and "comprises", mean "including but not limited to", and is they are not intended to (and does not) exclude other moieties, additives, components, integers or steps.

[0213] Throughout the description and claims of this specification, the singular encompasses the plural unless the context otherwise requires. In particular, where the indefinite article is used, the specification is to be understood as contemplating plurality as well as singularity, unless the context requires otherwise. Further, in some embodiments, the term approximately is meant to refer to values within 10% of the stated values, unless otherwise stated herein.

[0214] Any value of a threshold, limit, duration, timeout, retry count, etc. provided herein is not intended to be absolute and, thereby, can be approximate. In addition, any threshold, limit, duration, timeout, retry count, etc. provided herein can be fixed or varied either automatically or by the user. Furthermore, as is used herein relative terminology such

as exceeds, greater than, less than, etc. in relation to a reference value is intended to also encompass being equal to the reference value. For example, exceeding a reference value that is positive can encompass being equal to or greater than the reference value.

[0215] Features, integers, characteristics, compounds, chemical moieties or groups described in conjunction with a particular aspect, embodiment, or example are to be understood to be applicable to any other aspect, embodiment or example described herein unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive. The protection is not restricted to the details of any foregoing embodiments. The protection extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

[0216] While certain embodiments have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of protection. Indeed, the novel methods and systems described herein may be embodied in a variety of other forms. Furthermore, various omissions, substitutions and changes in the form of the methods and systems described herein may be made. Those skilled in the art will appreciate that in some embodiments, the actual steps taken in the processes illustrated and/or disclosed may differ from those shown in the figures. Depending on the embodiment, certain of the steps described above may be removed, others may be added. Accordingly, the scope of the present disclosure is intended to be defined only by reference to the appended claims. The accompanying claims and their equivalents are intended to cover such forms or modifications as would fall within the scope and spirit of the protection. For example, the various components illustrated in the figures may be implemented as software and/or firmware on a processor, controller, ASIC, FPGA, and/or dedicated hardware. Furthermore, the features and attributes of the specific embodiments disclosed above may be combined in different ways to form additional embodiments, all of which fall within the scope of the present disclosure. Although the present disclosure provides certain preferred embodiments and applications, other embodiments that are apparent to those of ordinary skill in the art,

including embodiments which do not provide all of the features and advantages set forth herein, are also within the scope of this disclosure. Accordingly, the scope of the present disclosure is intended to be defined only by reference to the appended claims.

WHAT IS CLAIMED IS:

1. A pump assembly for reduced pressure wound therapy, comprising:

a housing;

a pump supported within or by the housing, the pump comprising:

a motor;

an inlet and an outlet;

a first valve configured to control a flow of a fluid through the inlet; and

a second valve configured to control a flow of a fluid through the outlet;

a flow pathway through the pump assembly; and

a one-way flow valve in fluid communication with the pump, the one-way flow valve being configured to substantially prevent a flow of gas through the flow pathway in a direction of flow away from the pump.

2. The pump assembly of Claim 1, wherein the pump assembly is canisterless.

3. The pump assembly of any one of the previous claims, further comprising a controller supported within or by the housing, the controller being configured to control an operation of the pump.

4. The pump assembly of any one of the previous claims, further comprising a pressure sensor in communication with the flow pathway.

5. The pump assembly of any one of the previous claims, further comprising only one switch or button supported by the housing, the at least one switch or button being accessible to a user and being in communication with the controller.

6. The pump assembly of any one of the previous claims, wherein the first valve and the second valve leak at a rate of approximately 0.1 mL/min and 10 mL/min at nominal working pressures.

7. The pump assembly of any one of the previous claims, wherein the pump assembly has been sterilized such that at least an inside and an outside of the housing, the flow pathway, the first and second valves, and the pump have been sterilized.

8. The pump assembly of any one of the previous claims, further comprising one or more LED lights supported by the housing.

9. The pump assembly of any one of the previous claims, wherein the pump assembly comprises one or more batteries and weighs between 80 and 90 grams, including the weight of the one or more batteries.

10. The pump assembly of any one of the previous claims, wherein an outside surface of the pump assembly defines a volume of between 60 and 80 cubic centimeters.

11. A negative pressure therapy kit, comprising:

the pump assembly of any one of the previous claims;

a dressing;

a conduit coupleable with the dressing and the pump assembly and configured to provide a fluid pathway of reduced pressure to the dressing;

one or more batteries; and

a first packaging element and a second packaging element configured to be removably coupled with the first packaging element, at least one of the first and second packaging elements having recesses for receiving the pump assembly, the dressing, the conduit, and the one or more batteries.

12. The negative pressure therapy kit of Claim 11, wherein the negative pressure kit is sterile, having been sterilized after the pump assembly, the dressing, the conduit, and the one or more batteries have been supported inside at least one of the first packaging element and the second packaging element.

13. The negative pressure therapy kit of any one of Claims 11-12, further comprising one or more adhesive sealing strips.

14. The negative pressure therapy kit of any one of Claims 11-13, wherein the one or more batteries are supported outside the housing.

15. The negative pressure therapy kit of any one of Claims 11-14, wherein the negative pressure therapy kit is sterilized with ethylene oxide.

16. The negative pressure therapy kit of any one of Claims 11-15, wherein the dressing comprises:

a transmission layer;

an absorbent layer for absorbing wound exudate, the absorbent layer overlying the transmission layer; and

a cover layer overlying the absorbent layer and comprising an orifice therethrough.

17. The negative pressure therapy kit of any one of Claims 11-16, wherein the dressing comprises a suction port for applying negative pressure to the dressing for the application of topical negative pressure at a wound site.

18. The negative pressure therapy kit of Claim 17, wherein the suction port comprises a connector portion for connecting the suction port to the pump assembly and a sealing surface for sealing the suction port to the cover layer of the dressing.

19. The negative pressure therapy kit of any one of Claims 11-18, wherein the dressing comprises a liquid impermeable gas permeable filter element arranged to prevent a liquid from entering the connector portion.

20. The negative pressure therapy kit of any one of Claims 11-19, wherein the first packaging element comprises PETG.

21. A negative pressure therapy system, comprising:

the pump assembly of any one of Claims 1-10; and

a dressing.

22. The negative pressure therapy kit of Claim 21, wherein a wound facing surface of the dressing is at least partially covered by a silicone based adhesive configured to create a low leak rate seal with skin surrounding the wound.

23. A method of treating a wound with negative pressure, comprising:

providing a dressing;

applying the dressing over the wound so as to create a substantially fluid tight seal over the wound; and

delivering negative pressure to the wound through the dressing using the pump assembly of any one of Claims 1-10.

24. The method of treating a wound with negative pressure of Claim 23, wherein applying the dressing over the wound so as to create a substantially fluid tight seal over the wound and delivering negative pressure to the wound through the dressing using the pump assembly of any one of Claims 1-10 is performed in an operating room.

25. A negative pressure therapy kit for reduced pressure wound therapy, comprising:

a pump assembly comprising:

a housing;

a pump supported within the housing, comprising:

a pump motor;

an inlet and an outlet;

at least one valve configured to control a flow of fluid through at least one of the inlet and the outlet; and

a flow pathway through at least the inlet, the outlet, and the at least one valve;

a controller supported within or by the housing, the controller being configured to control an operation of the pump and the valve; and

at least one switch or button supported by the housing, the at least one switch or button being in communication with the controller and being accessible to a user so as to permit a user to control one or more modes of operation of the pump;

a dressing configured to form a substantially fluid tight seal over a wound;

a conduit coupleable with the dressing and the pump assembly and configured to provide a substantially or completely enclosed fluid flow pathway from the pump assembly to the dressing; and

a first packaging element for packaging the pump assembly, the one or more batteries, the dressing, and the conduit;

wherein the negative pressure therapy kit has been sterilized such that at least an inside and an outside of the housing, the at least one valve, the pump, the controller, and the at least one switch or button have been sterilized.

26. The negative pressure therapy kit of Claim 25, further comprising one or more adhesive sealing strips.

27. The negative pressure therapy kit of any one of Claims 21-26, further comprising one or more batteries configured to provide a source of power to at least the pump and the controller.

28. The negative pressure therapy kit of Claim 27, further comprising a second packaging element configured to couple with the first packaging element, wherein the first packaging element has a plurality of recesses for receiving one or more of the pump assembly, the one or more batteries, the dressing, the conduit, and one or more adhesive sealing strips.

29. The negative pressure therapy kit of Claim 28, wherein the second packaging element is permeable to a sterilization gas and impermeable to bacteria.

30. The negative pressure therapy kit of any one of Claims 25-29, wherein the first packaging element supports the one or more batteries so that the one or more batteries are supported outside the housing during sterilization of the negative pressure therapy kit.

31. The negative pressure therapy kit of any one of Claims 25-30, wherein the pump is a diaphragm pump, a rotary diaphragm pump, or a piezoelectric pump.

32. The negative pressure therapy kit of any one of Claims 25-31, wherein the negative pressure therapy kit is sterilized with ethylene oxide.

33. The negative pressure therapy kit of any one of Claims 25-32, wherein the at least one valve is configured to permit a flow of sterilization gas through the at least one valve during the sterilization process.

34. The negative pressure therapy kit of any one of Claims 25-33, wherein the pump assembly further comprises a flow manifold, the flow manifold being in fluid communication with a pressure sensor, the pump, and at least one of a conduit or a connector for a conduit.

35. The negative pressure therapy kit of Claim 34, further comprising a one-way flow valve supported by the manifold.

36. The negative pressure therapy kit of any one of Claims 25-35, comprising a one-way flow valve positioned between the pump and the dressing, the one-way flow valve being configured to substantially prevent the flow of gas through the one-way flow valve in a direction of flow from the pump toward the dressing.

37. The negative pressure therapy kit of Claim 36, wherein the one-way flow valve is supported within the housing.

38. The negative pressure therapy kit of any one of Claims 25-37, further comprising a pressure sensor configured to monitor a level of pressure of a gas within a fluid flow pathway between the pump and the dressing or within the pump assembly.

39. The negative pressure therapy kit of any one of Claims 25-38, wherein one end of the conduit is connected to the dressing when packaged in the first packaging element.

40. The negative pressure therapy kit of any one of Claims 25-39, wherein the conduit comprises a first end and a second end, the first end being connected or connectable to the dressing and the second end comprising a connector configured to couple with the housing.

41. The negative pressure therapy kit of any one of Claims 25-40, wherein the housing is not sealed.

42. The negative pressure therapy kit of any one of Claims 25-41, wherein the pump assembly does not comprise a canister.

43. The negative pressure therapy kit of any one of Claims 25-42, further comprising an open foam layer surrounding at least a portion of the pump to reduce the noise and vibration produced by the pump.

44. The negative pressure therapy kit of any one of Claims 25-43, wherein the dressing comprises:

a transmission layer;

an absorbent layer for absorbing wound exudate, the absorbent layer overlying the transmission layer;

a cover layer overlying the absorbent layer;

a suction port for receiving an end portion of a conduit; and

a liquid impermeable gas permeable filter element arranged to prevent a liquid from passing through the suction port.

45. The negative pressure therapy kit of any one of Claims 25-44, wherein the pump assembly comprises a battery compartment supported by or formed within the housing.

46. The negative pressure therapy kit of any one of Claims 25-45, wherein the negative pressure therapy kit comprises a wound dressing having a silicone based adhesive configured to create a low leak rate seal with skin surrounding the wound, and wherein the

pump assembly weighs between 70 and 90 grams, including the weight of the one or more batteries.

47. The negative pressure therapy kit of any one of Claims 25-46, wherein the pump assembly weighs between 70 and 90 grams, including the weight of the one or more batteries.

48. The negative pressure therapy kit of any one of Claims 25-47, wherein an outside surface of the pump assembly defines a volume of from approximately 3 cubic inches to approximately 5 cubic inches.

49. The negative pressure therapy kit of any one of Claims 25-48, wherein the negative pressure therapy kit is configured such that the dressing must be removed from the first packaging element before the sealing strips can be removed from the first packaging element.

50. A negative pressure therapy kit for reduced pressure wound therapy, comprising:

a pump assembly comprising a pump having a flow rate of approximately 350 milliliters per minute or less; and

a dressing comprising a cover layer, the dressing having a wound contact surface that is covered with a silicone based adhesive.

51. The negative pressure therapy kit of Claim 50, wherein the pump assembly comprises a one-way flow valve in fluid communication with the pump, the one-way flow valve being configured to substantially prevent a flow of gas through the flow path in a direction of flow away from the pump.

52. The negative pressure therapy kit of any one of Claims 50-51, wherein the dressing comprises a transmission layer comprising a 3D knitted or fabric material configured to remain open upon application of negative pressure to the dressing.

53. The negative pressure therapy kit of any one of Claims 50-52, wherein the dressing comprises an absorbent layer for absorbing wound exudate, the absorbent layer overlying the transmission layer.

54. The negative pressure therapy kit of any one of Claims 50-53, wherein the dressing comprises a cover layer overlying the absorbent layer and comprising an orifice, wherein the cover layer is moisture vapor permeable.

55. The negative pressure therapy kit of any one of Claims 50-54, wherein the dressing comprises a suction port for applying negative pressure to the dressing for the application of topical negative pressure at a wound site, the suction port comprising a connector portion for connecting the suction port to the pump assembly and a sealing surface for sealing the suction port to the cover layer of the dressing.

56. The negative pressure therapy kit of any one of Claims 50-55, wherein the dressing comprises a liquid impermeable gas permeable filter element arranged to prevent a liquid from entering the connector portion.

57. The negative pressure therapy kit of any one of Claims 50-56, wherein the pump assembly is canisterless.

58. The negative pressure therapy kit of any one of Claims 50-57, further comprising a controller supported within or by a housing of the pump assembly, the controller being configured to control an operation of the pump.

59. The negative pressure therapy kit of any one of Claims 50-58, further comprising a pressure sensor in communication with a flow pathway through the pump assembly.

60. The negative pressure therapy kit of any one of Claims 50-59, further comprising at least one switch or button supported by a housing of the pump assembly, the at least one switch or button being accessible to a user and being in communication with the controller.

61. The negative pressure therapy kit of any one of Claims 50-60, further comprising a battery compartment supported by the pump assembly.

62. The negative pressure therapy kit of any one of Claims 50-61, wherein the pump assembly has been sterilized following the assembly of the pump assembly such that at least an inside and an outside of the pump assembly has been sterilized.

63. The negative pressure therapy kit of any one of Claims 50-62, wherein the pump assembly has one or more LED lights.

64. The negative pressure therapy kit of any one of Claims 50-63, wherein the pump assembly comprises one or more batteries and weighs between 80 and 90 grams, including the weight of the one or more batteries.

65. The negative pressure therapy kit of any one of Claims 50-64, wherein an outside surface of the pump assembly defines a volume of between 60 and 80 cubic centimeters.

66. A canisterless pump assembly for reduced pressure wound therapy, comprising:

a housing; and

a pump supported within or by the housing, the pump comprising:

a motor;

an inlet and an outlet;

a first valve configured to control a flow of a fluid through the inlet; and

a second valve configured to control a flow of a fluid through the outlet;

wherein:

the pump assembly is canisterless; and

the first and second valves each has a leakage rate of between approximately 5 mL/min and approximately 10 mL/min at nominal working pressures.

67. The pump assembly of Claim 66, wherein the pump assembly comprises a one-way flow valve in fluid communication with the pump, the one-way flow valve being configured to substantially prevent a flow of gas through the flow path in a direction of flow away from the pump.

68. The pump assembly of any one of Claims 66-67, further comprising a controller supported within or by the housing, the controller being configured to control an operation of the pump.

69. The pump assembly of any one of Claims 66-68, further comprising a pressure sensor in communication with the flow pathway through the pump assembly.

70. The pump assembly of any one of Claims 66-69, further comprising at least one switch or button supported by the housing, the at least one switch or button being accessible to a user and being in communication with the controller.

71. The pump assembly of any one of Claims 66-70, further comprising a battery compartment supported by or formed within the housing.

72. The pump assembly of any one of Claims 66-71, wherein the pump assembly has been sterilized following the assembly of the pump assembly such that at least an inside and an outside of the housing, the flow pathway, the one or more valves, and the pump have been sterilized.

73. The pump assembly of any one of Claims 66-72, further comprising one or more LED lights supported by the housing.

74. The pump assembly of any one of Claims 66-73, wherein the pump assembly comprises one or more batteries and weighs between 80 and 90 grams, including the weight of the one or more batteries.

75. The pump assembly of any one of Claims 66-74, wherein an outside surface of the pump assembly defines a volume of between 60 and 80 cubic centimeters.

76. A sterile pump kit, comprising:

the pump assembly of any one of Claims 66-75;

a dressing;

a conduit coupleable with the dressing and the pump assembly and configured to provide a fluid pathway of reduced pressure to the dressing;

one or more batteries; and

a first packaging element and a second packaging element configured to be removably coupled with the first packaging element, at least one of the first and second packaging elements having recesses for receiving the pump assembly, a dressing, a conduit coupleable with the dressing and the pump assembly and configured to provide a fluid pathway of reduced pressure to the dressing;

wherein the sterile pump kit has been sterilized after the pump assembly, the dressing, the conduit, and the one or more batteries have been supported inside at least one of the first packaging element and the second packaging element.

77. The sterile pump kit of Claim 76, wherein the pump assembly, the dressing, the conduit, and the one or more batteries are supported within at least one of the first packaging element and the second packaging element before the pump assembly, the dressing, the conduit, or the one or more batteries are sterilized.

78. The sterile pump kit of any one of Claims 76-77, further comprising one or more adhesive sealing strips.

79. The sterile pump kit of any one of Claims 76-78, wherein the one or more batteries are supported outside the housing.

80. The sterile pump kit of any one of Claims 76-79, wherein the sterile pump kit is sterilized with ethylene oxide.

81. The sterile pump kit of any one of Claims 76-80, wherein the dressing comprises:

a transmission layer;

an absorbent layer for absorbing wound exudate, the absorbent layer overlying the transmission layer; and

a cover layer overlying the absorbent layer.

82. The sterile pump kit of any one of Claims 76-81, wherein the dressing comprises a suction port for applying negative pressure to the dressing for the application of topical negative pressure at a wound site.

83. The sterile pump kit of Claim 82, wherein the suction port comprises a connector portion for connecting the suction port to the pump assembly and a sealing surface for sealing the suction port to the cover layer of the dressing.

84. The sterile pump kit of any one of Claims 76-83, wherein the dressing comprises a liquid impermeable gas permeable filter element arranged to prevent a liquid from entering the connector portion.

85. The sterile pump kit of any one of Claims 76-84, wherein the first packaging element comprises PETG.

86. A method for initiating treatment of a wound in an operating room, comprising:

applying a sterile dressing over a wound so as to create a substantially fluid tight seal over the wound;

coupling a sterile pump assembly to dressing via a sterile conduit; and

reducing a level of pressure between the dressing and the wound in an operating room by activating the pump assembly in the operating room.

87. The method of Claim 86, further comprising applying one or more sealing strips over at least one peripheral edge of the dressing so as to improve the seal between the dressing and skin surrounding the wound.

88. The method of any one of Claims 86-87, further comprising removing one or more batteries from a first packaging element and installing the one or more batteries in the pump assembly.

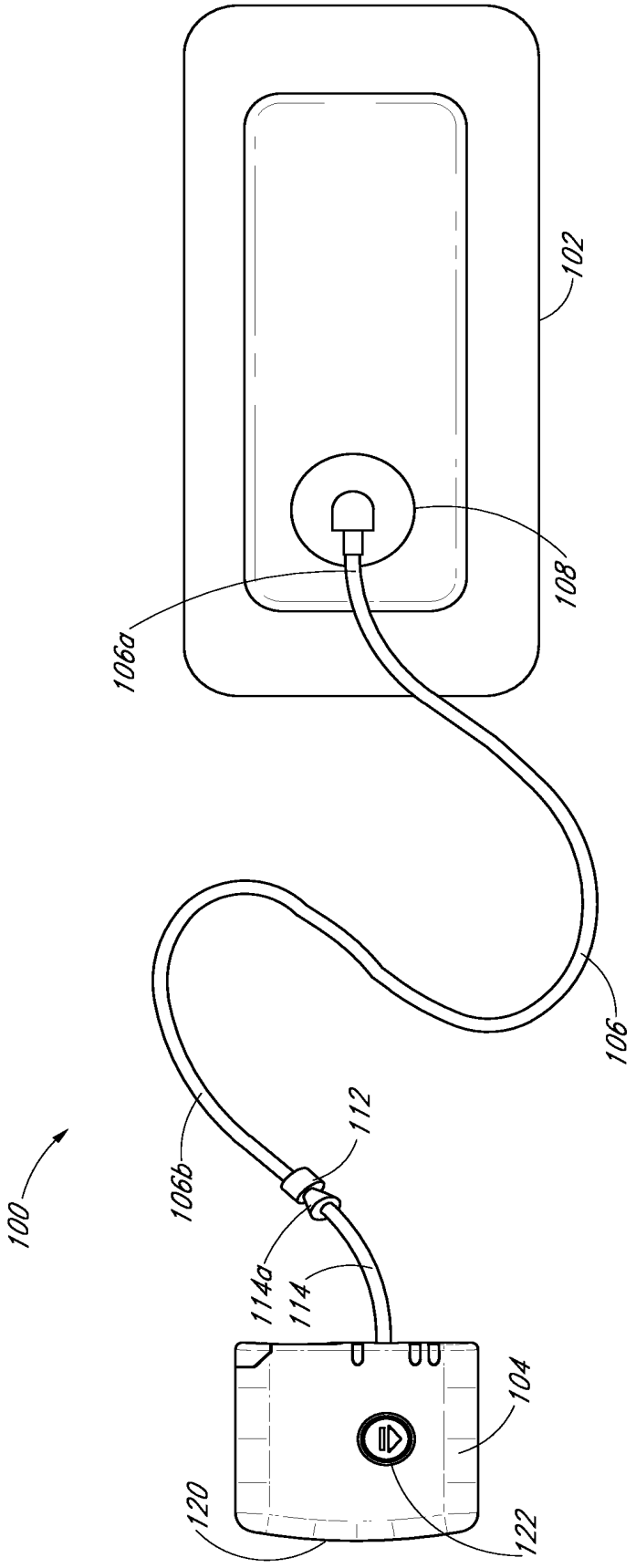


FIG. 1

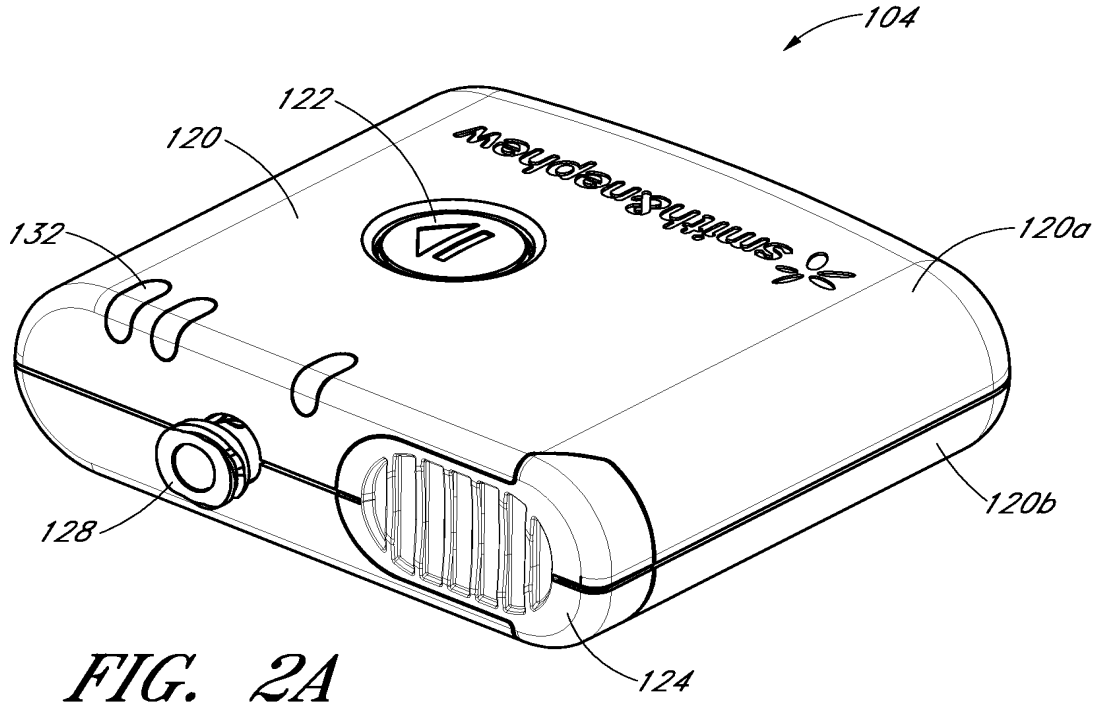


FIG. 2A

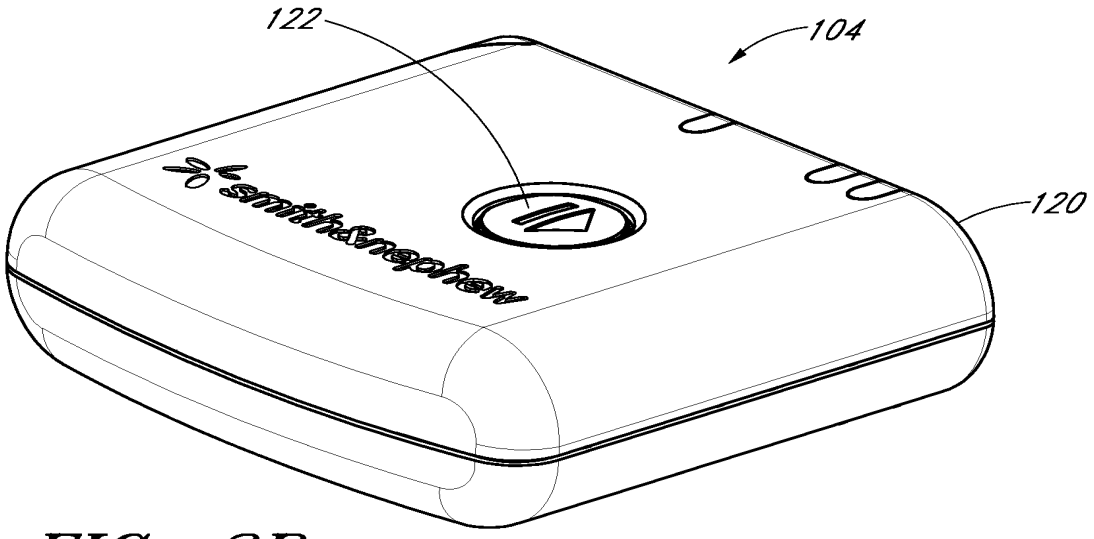


FIG. 2B

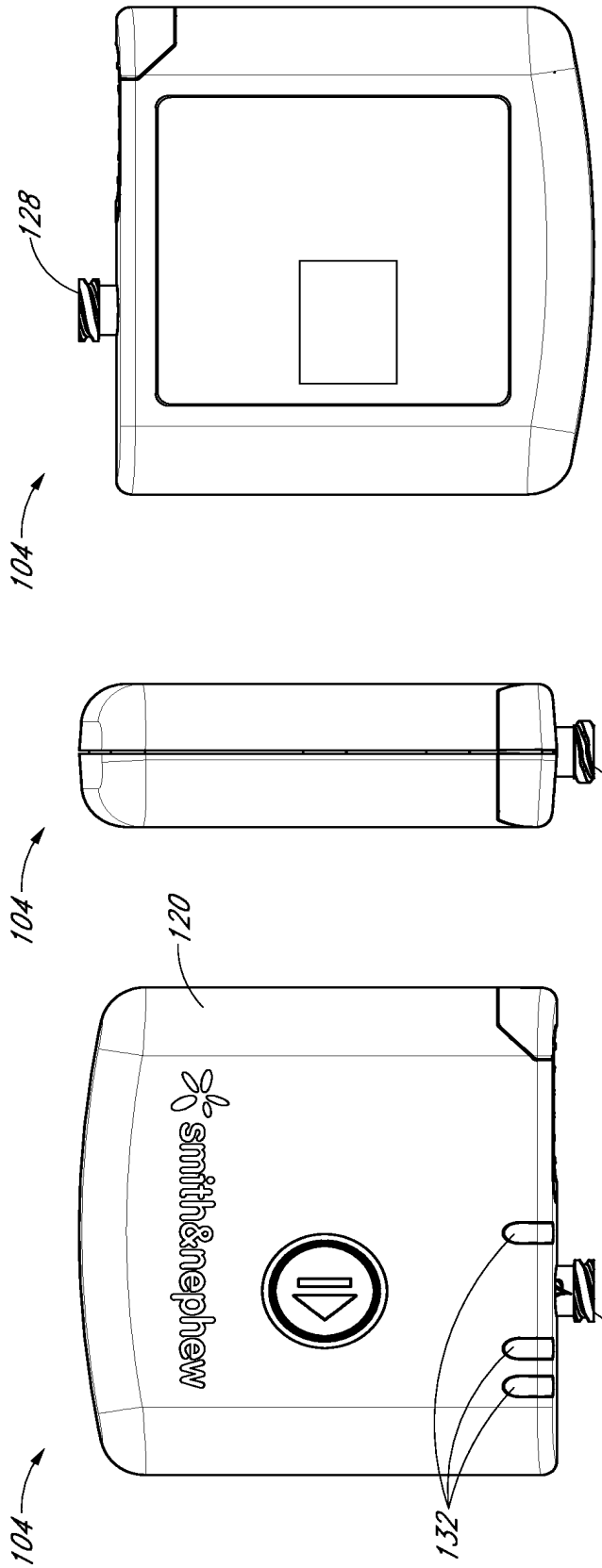


FIG. 2E

FIG. 2D

FIG. 2C

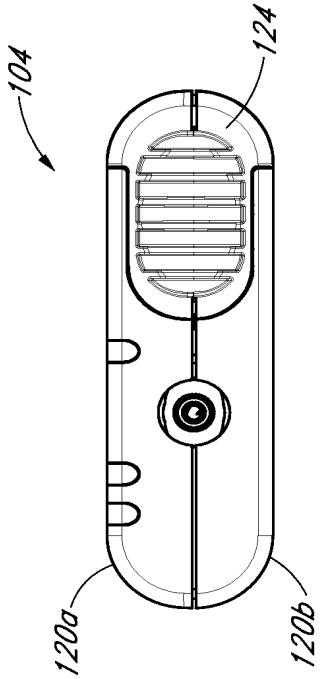


FIG. 2F

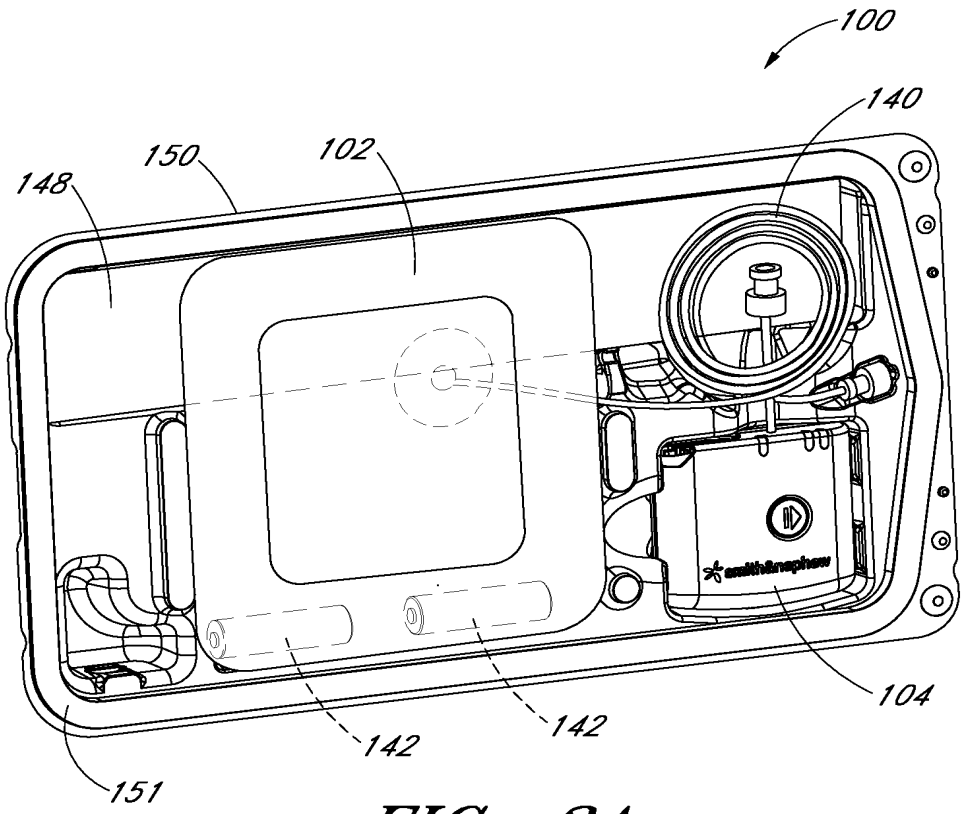


FIG. 3A

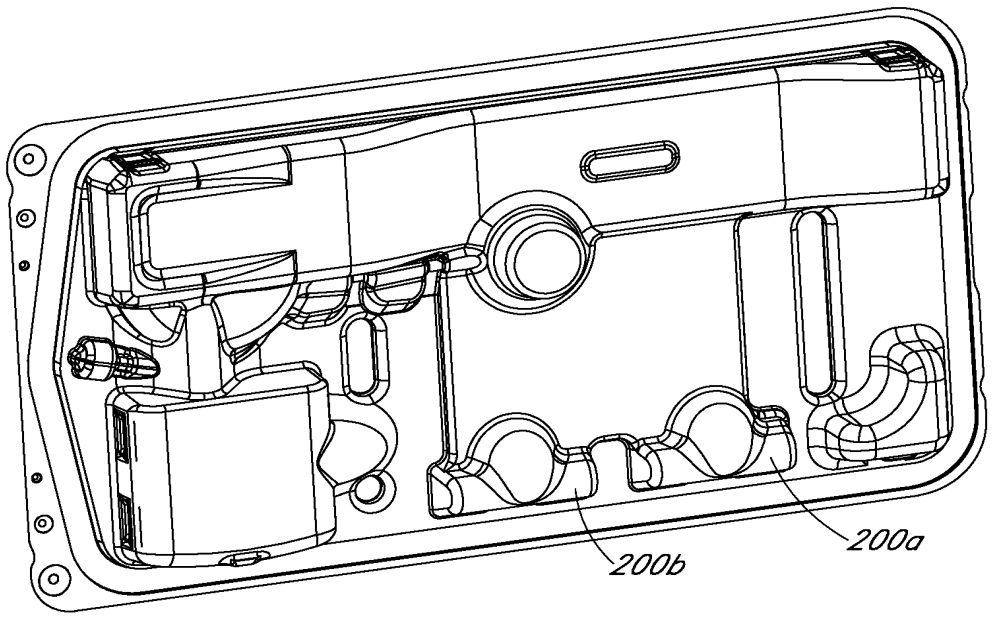
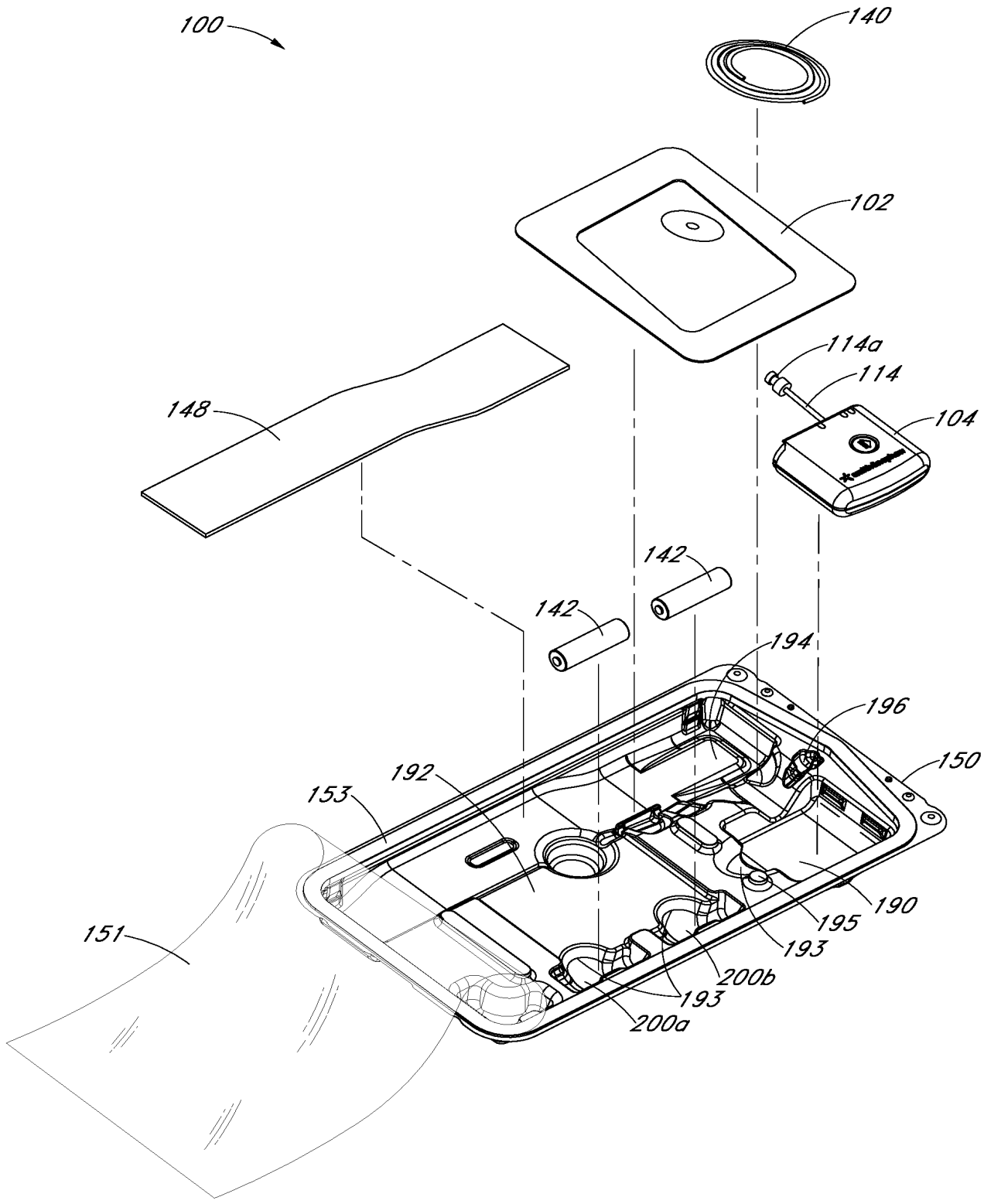


FIG. 3B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192
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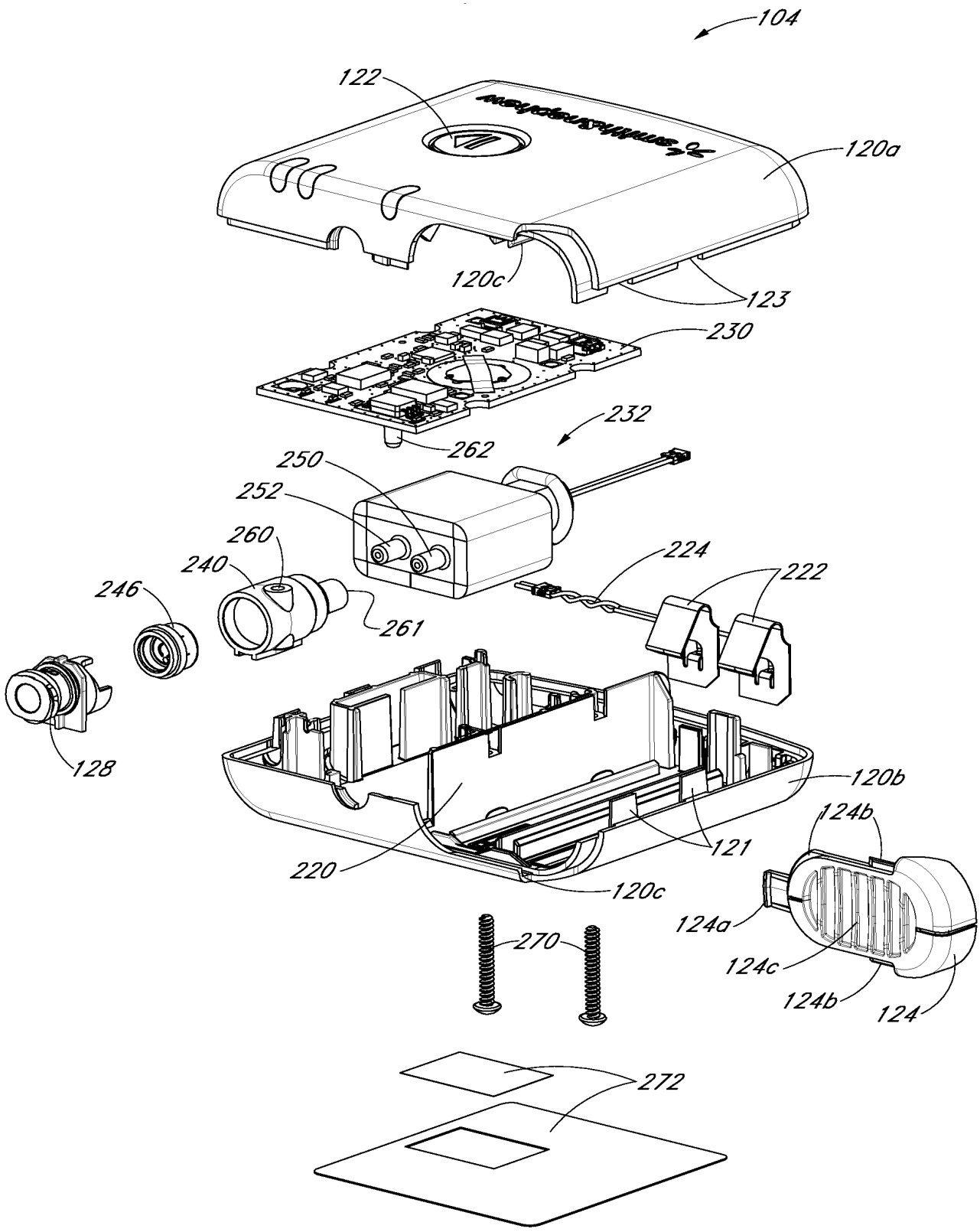
190
195
193
200b
193
200a

FIG. 3C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120c
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120b
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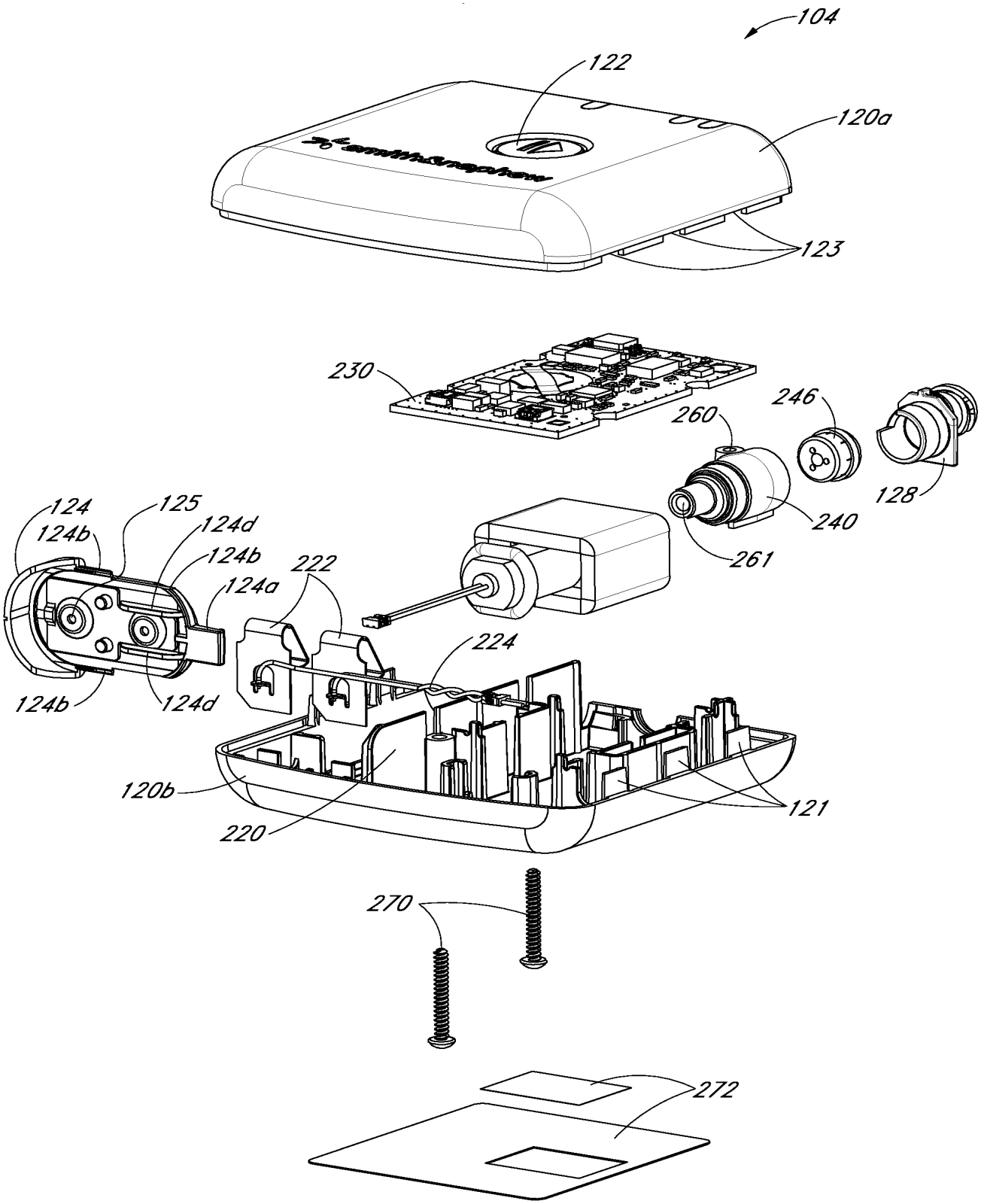
121
220
120c
124a
124c
124b
124
270
272

FIG. 4A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128
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124b
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124d
124b
124a
222
224
124b
124d
120b
121
220
270
272

FIG. 4B

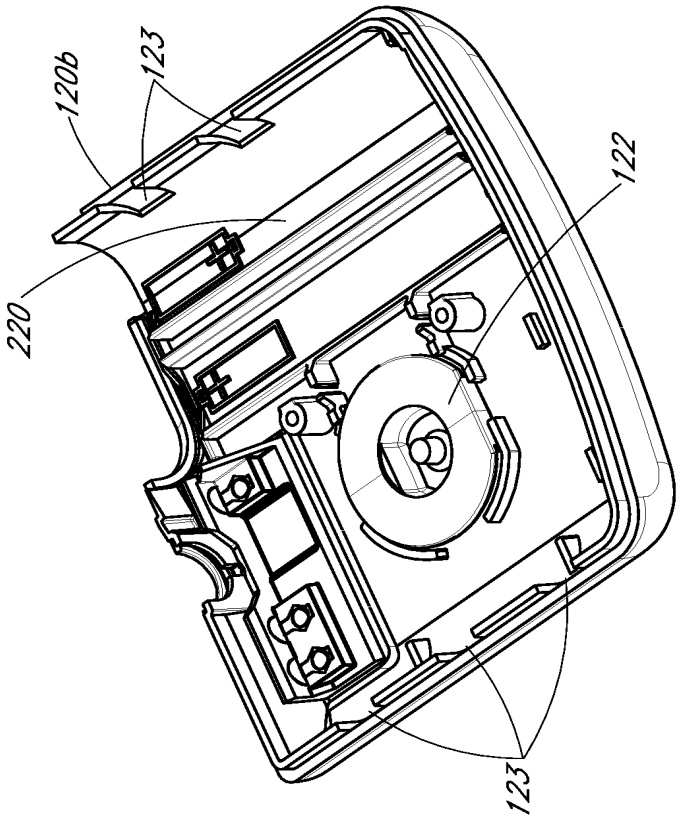


FIG. 5B

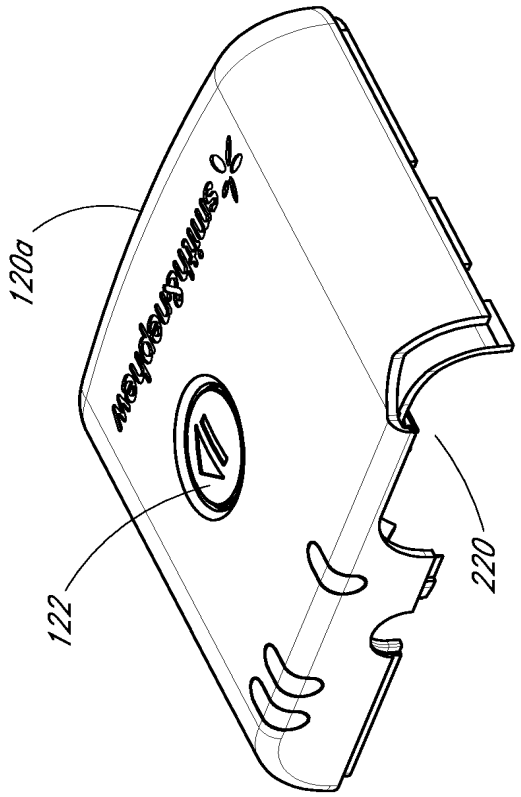


FIG. 5A

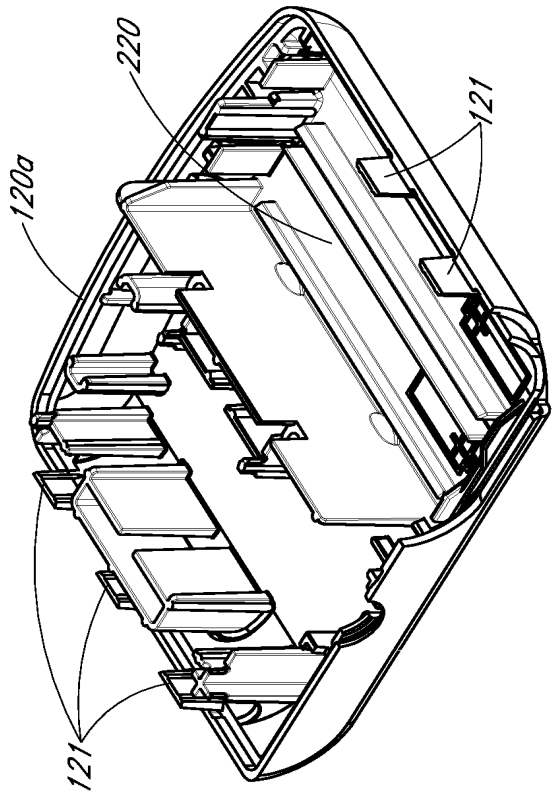


FIG. 6B

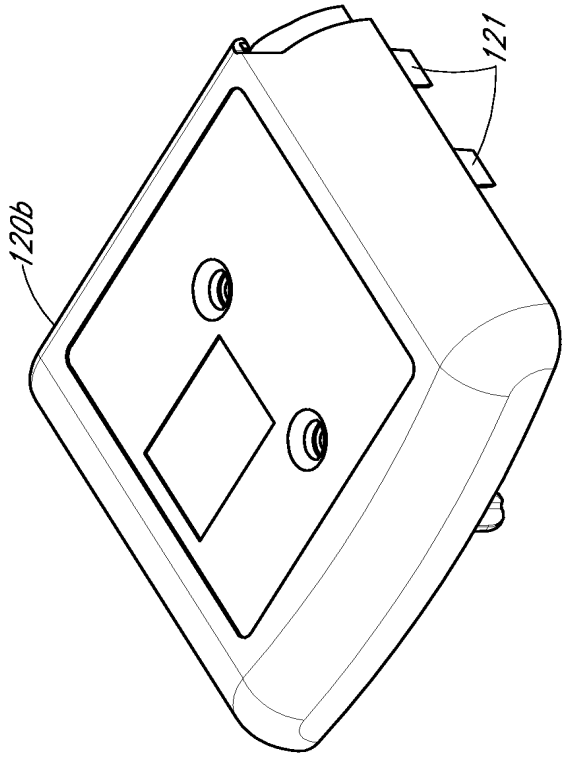


FIG. 6A

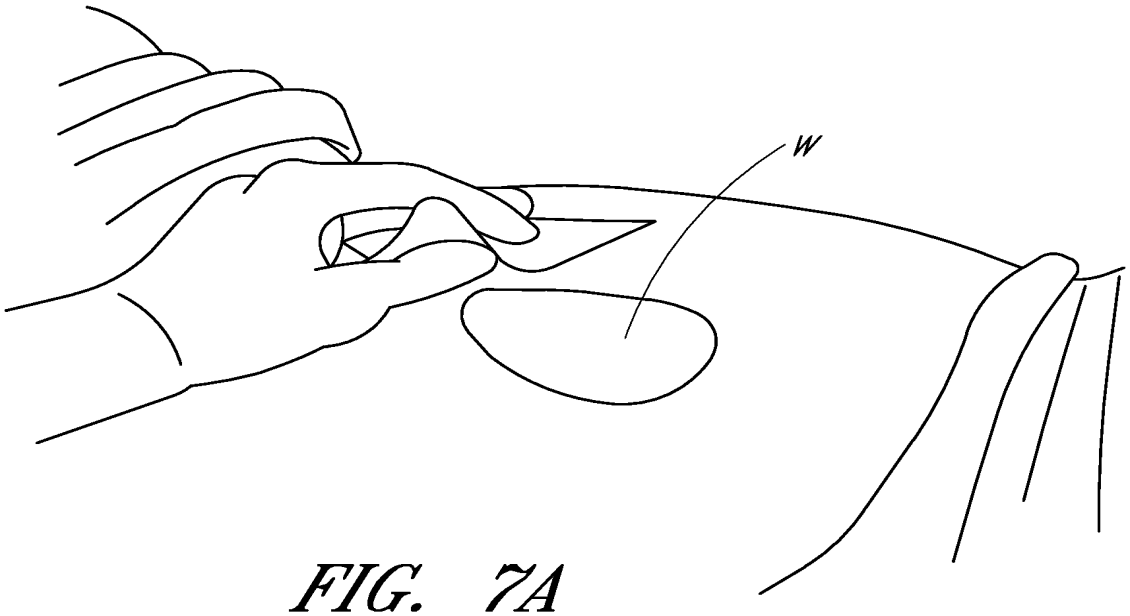


FIG. 7A

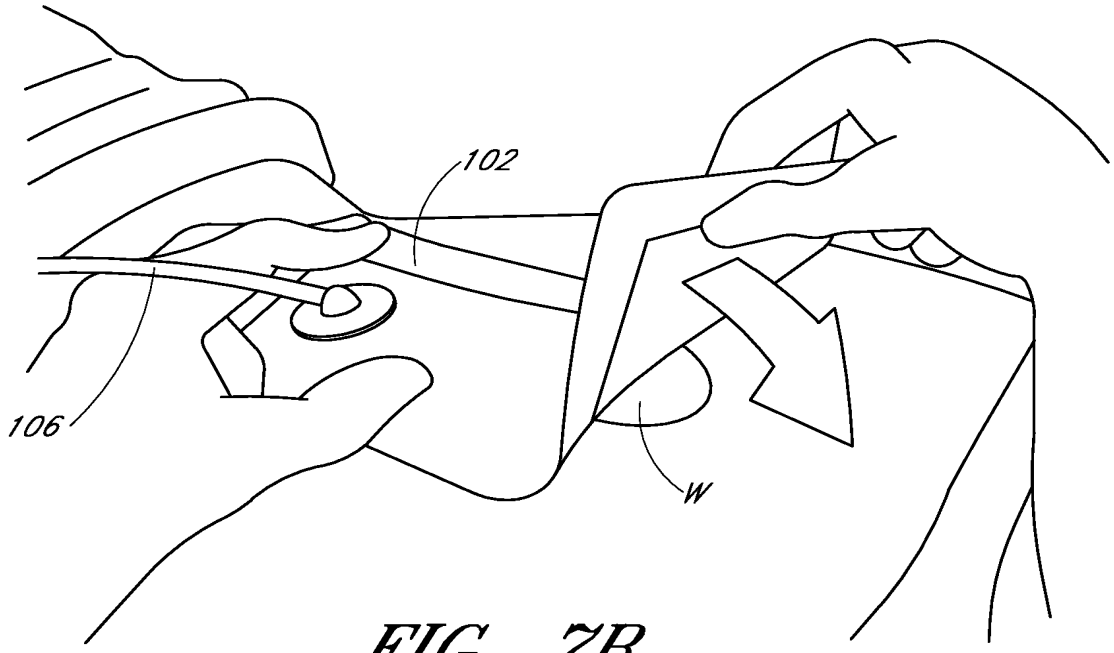


FIG. 7B

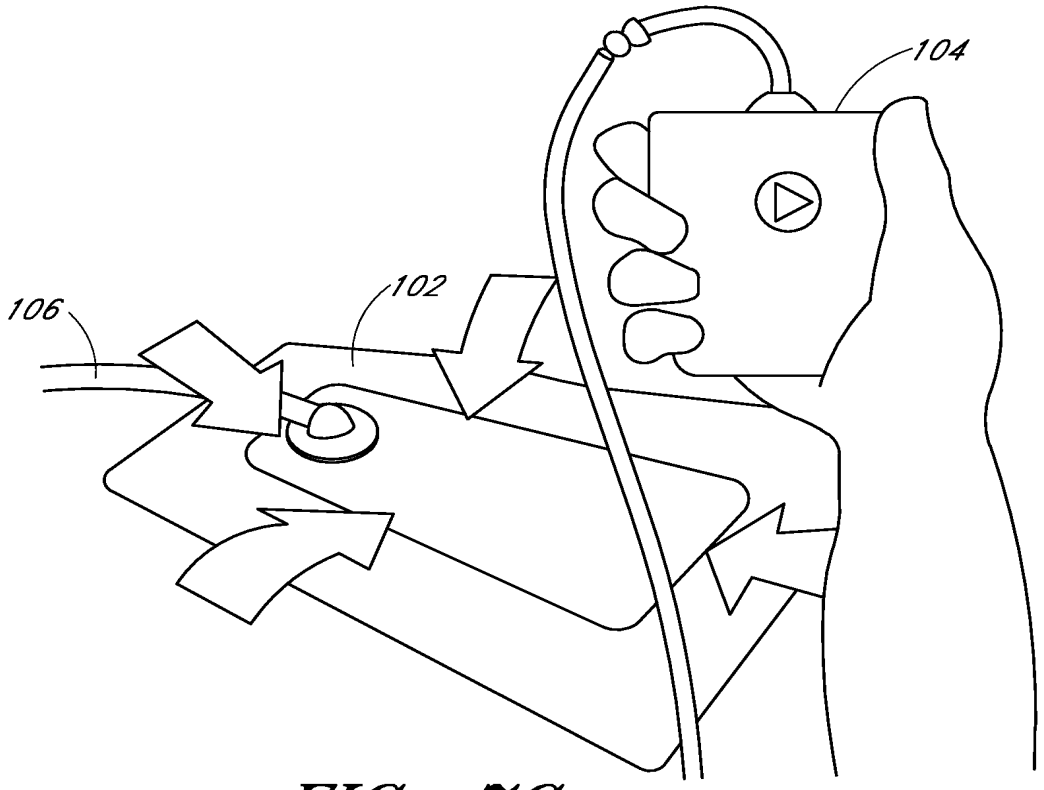


FIG. 7C

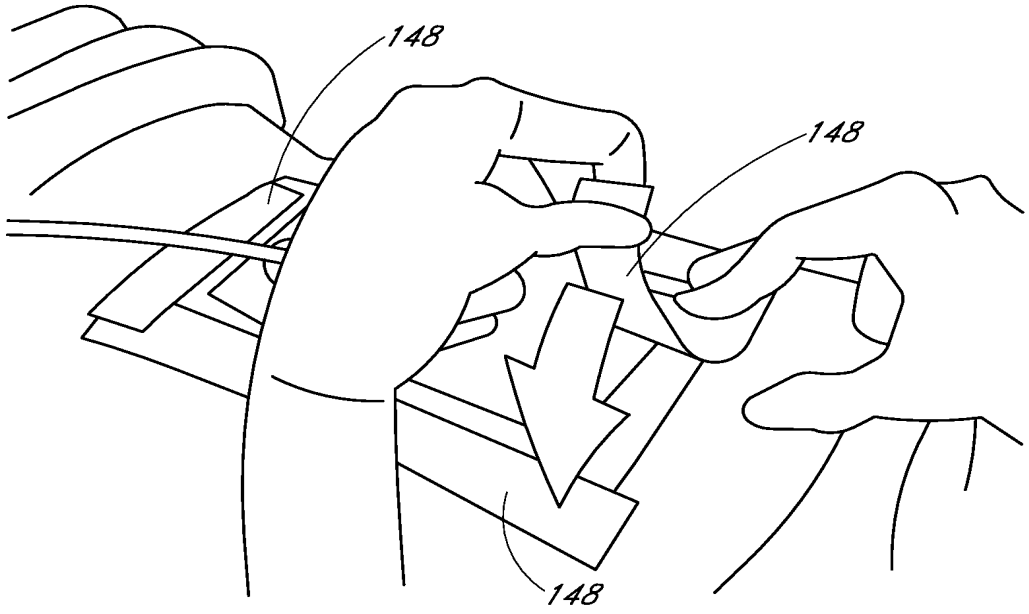


FIG. 7D

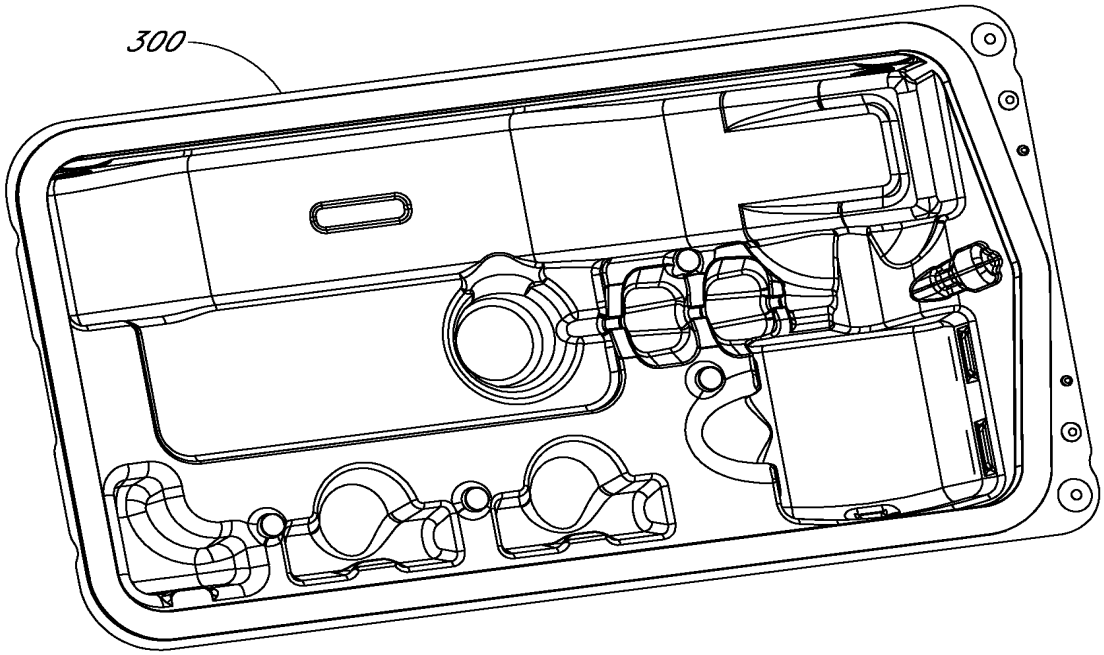


FIG. 8A

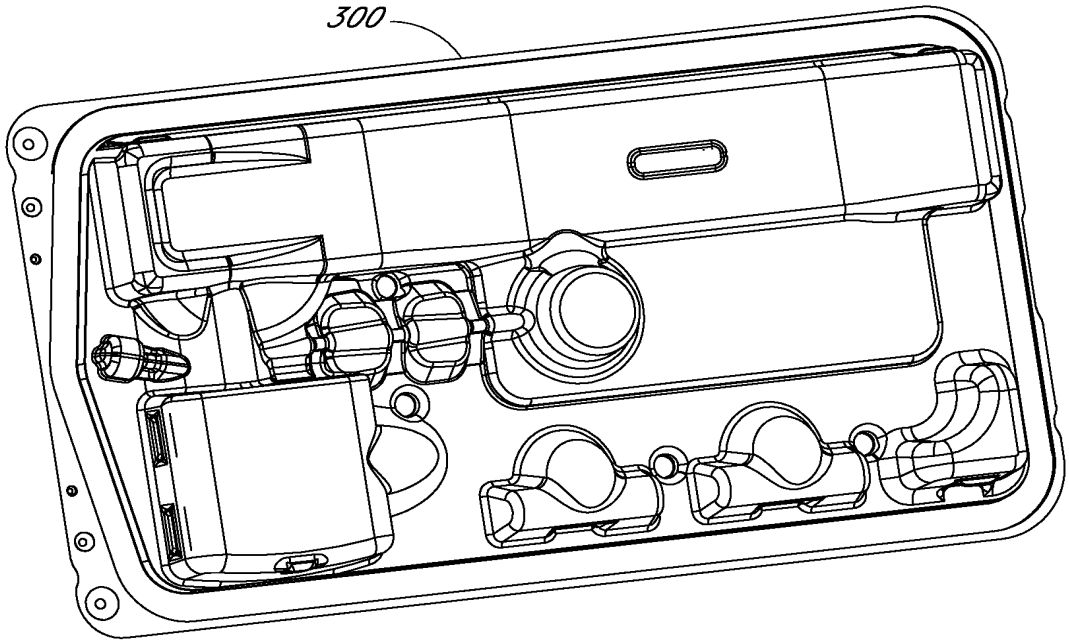


FIG. 8B

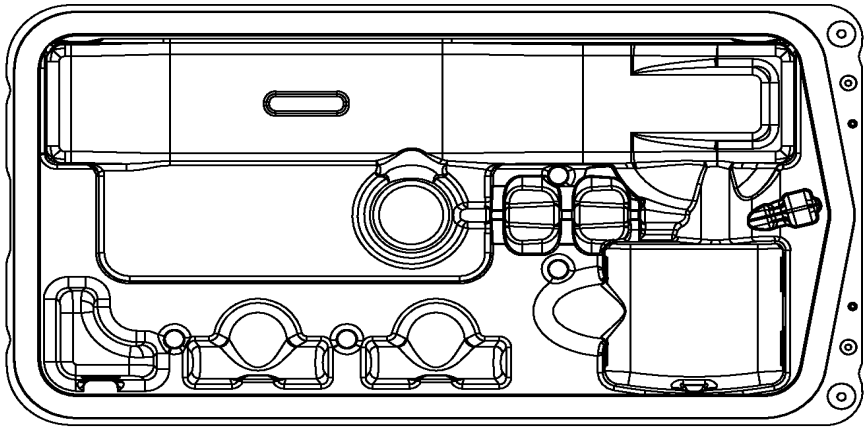


FIG. 8C

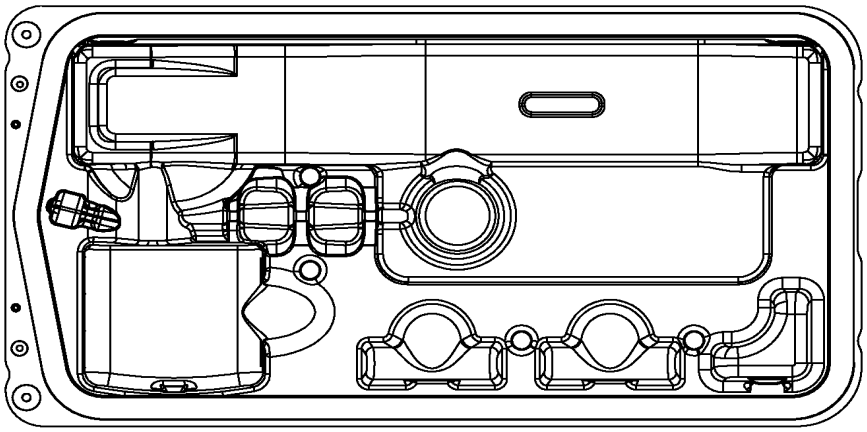


FIG. 8D

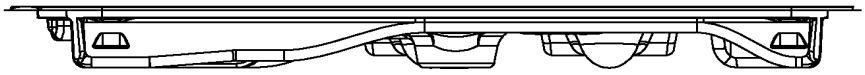


FIG. 8E

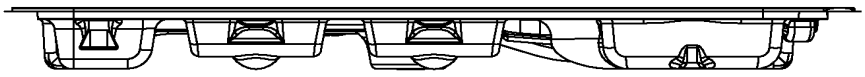


FIG. 8F

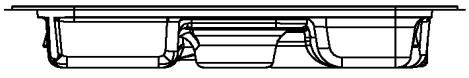


FIG. 8G

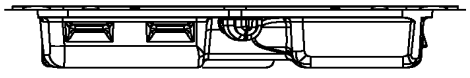


FIG. 8H

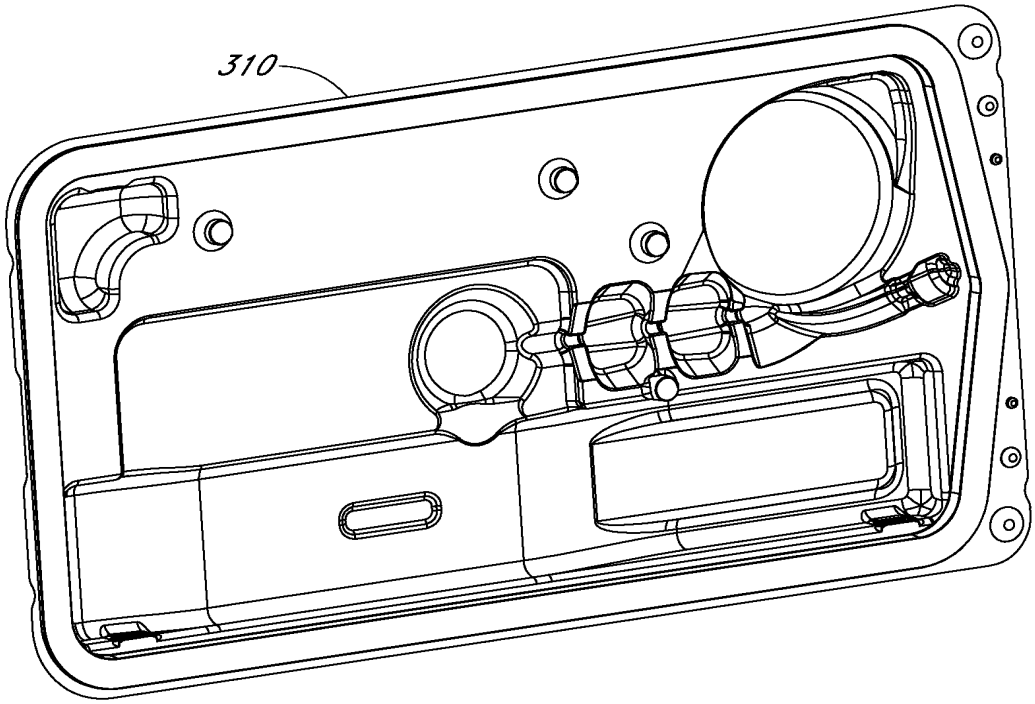


FIG. 9A

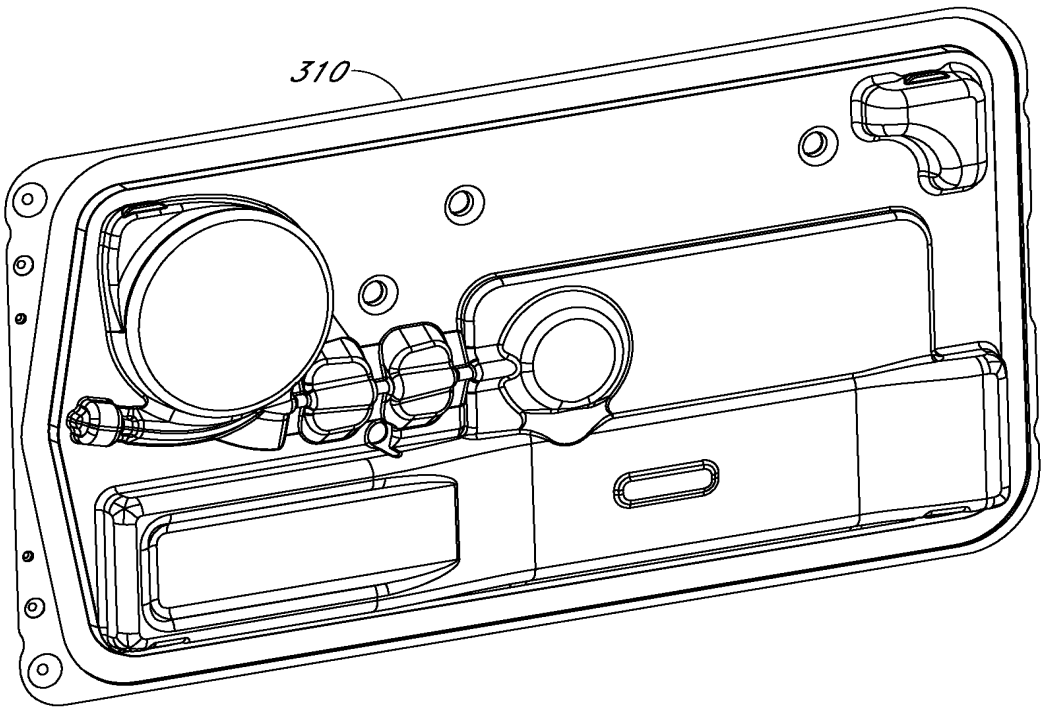


FIG. 9B

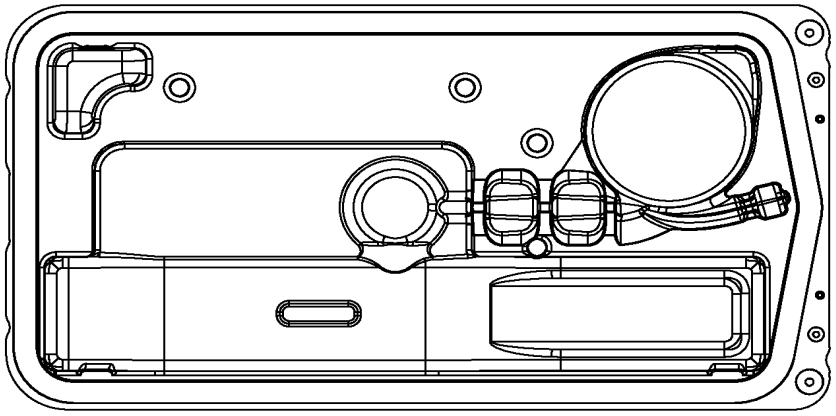


FIG. 9C

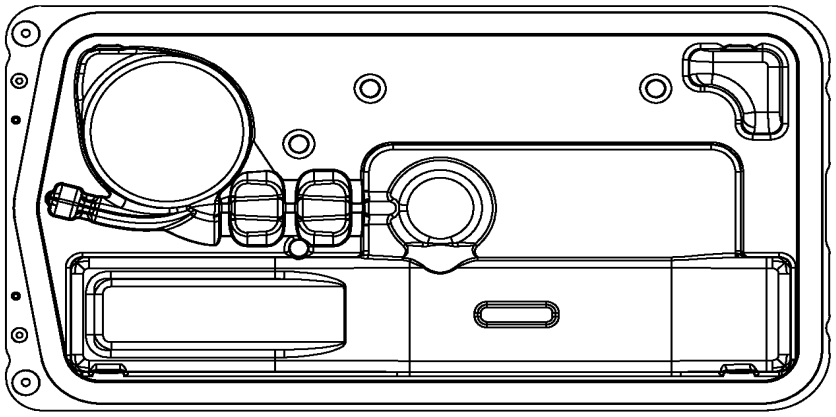


FIG. 9D

FIG. 9E

FIG. 9F

FIG. 9G

FIG. 9H

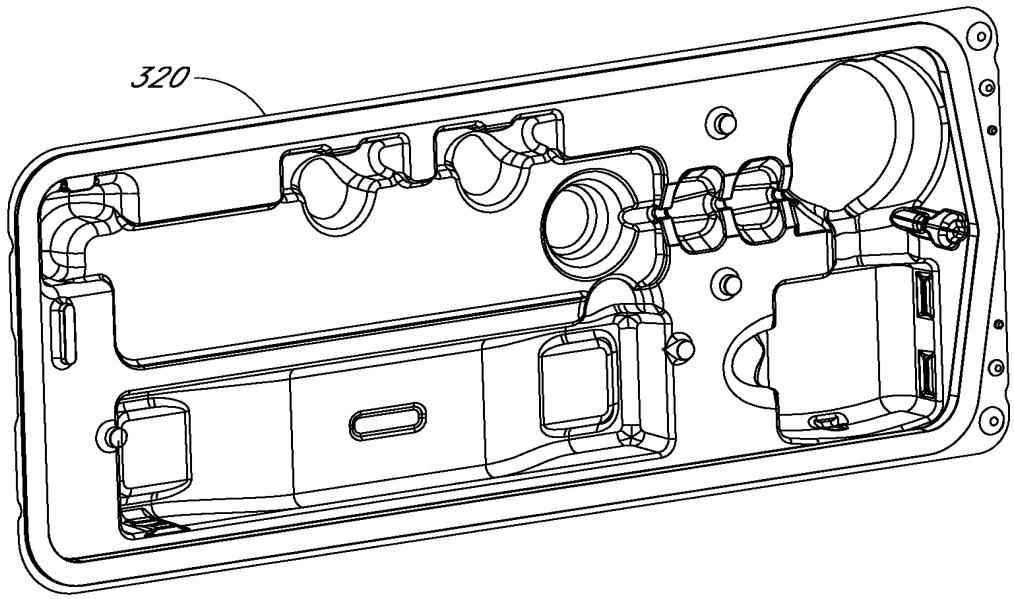


FIG. 10A

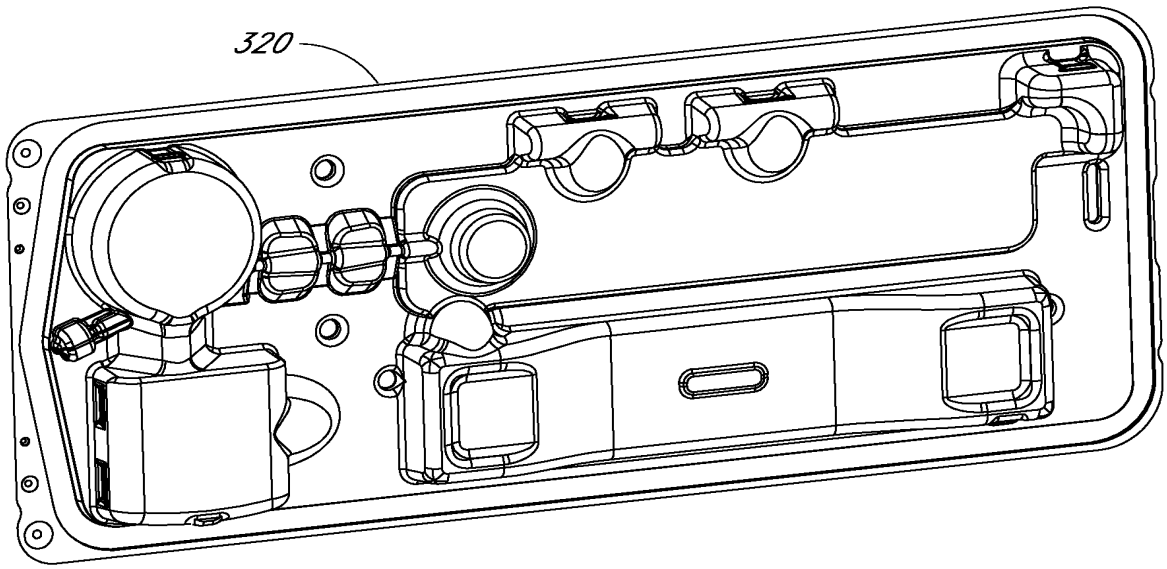


FIG. 10B

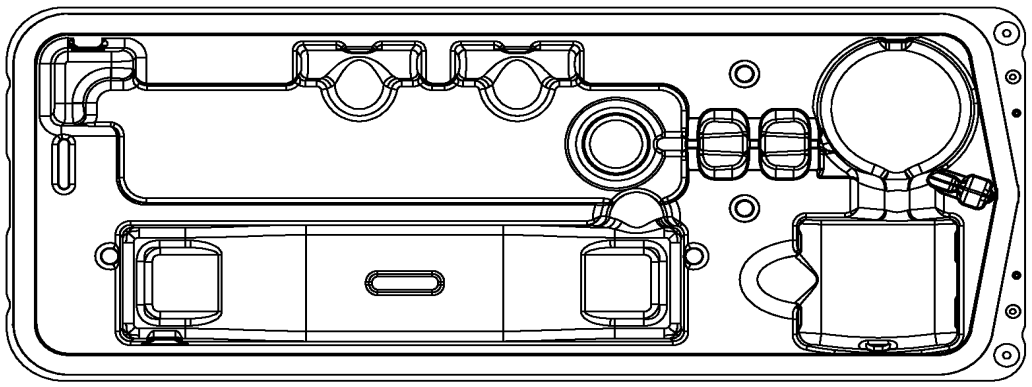


FIG. 10C

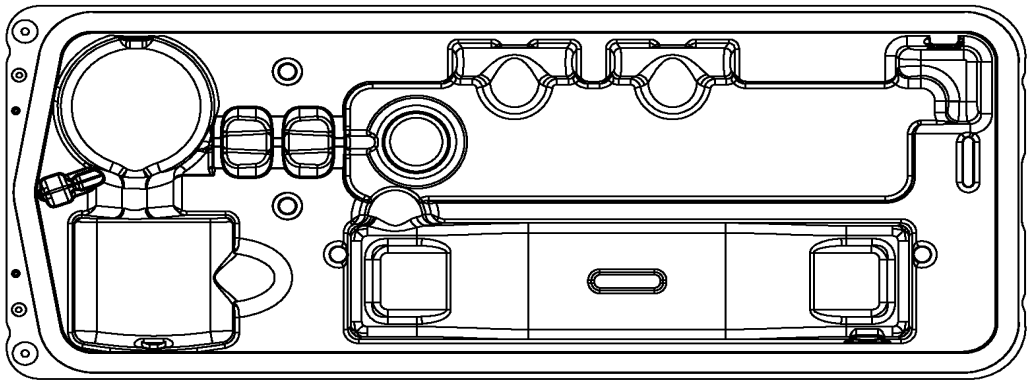


FIG. 10D

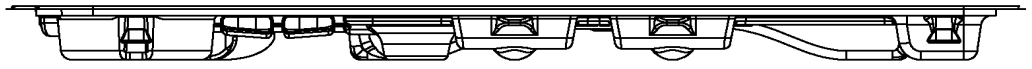


FIG. 10E

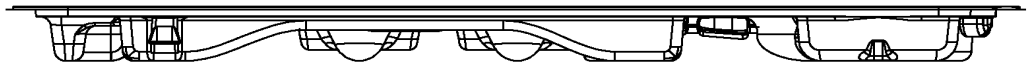


FIG. 10F

FIG. 10G

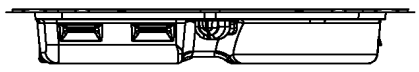


FIG. 10H

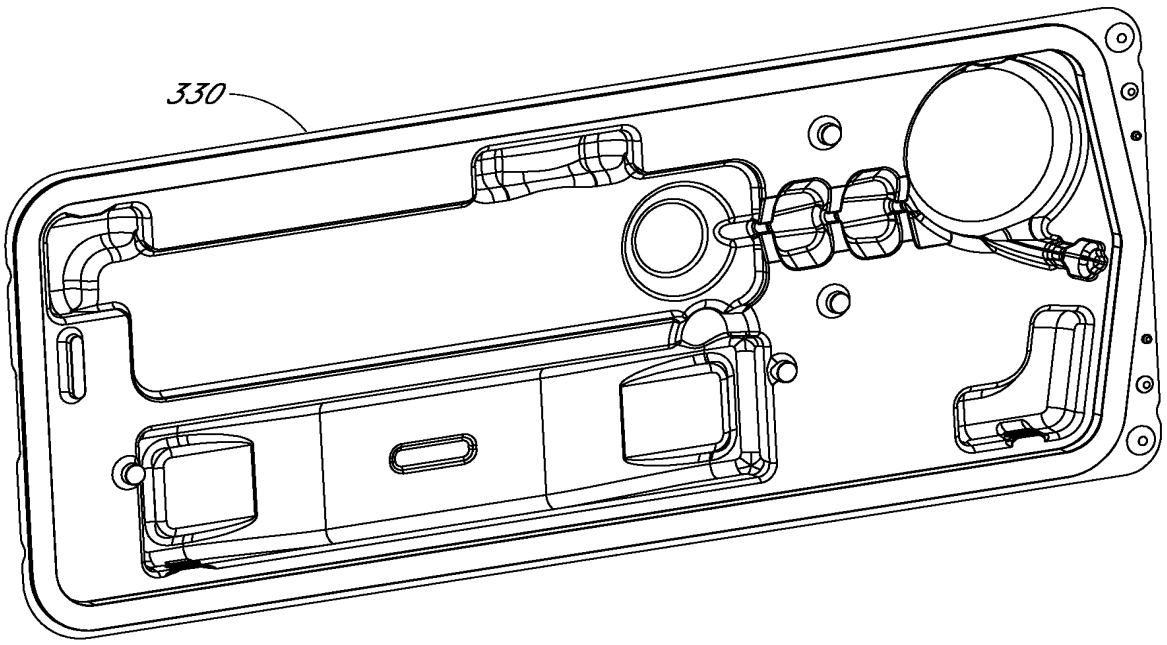


FIG. 11A

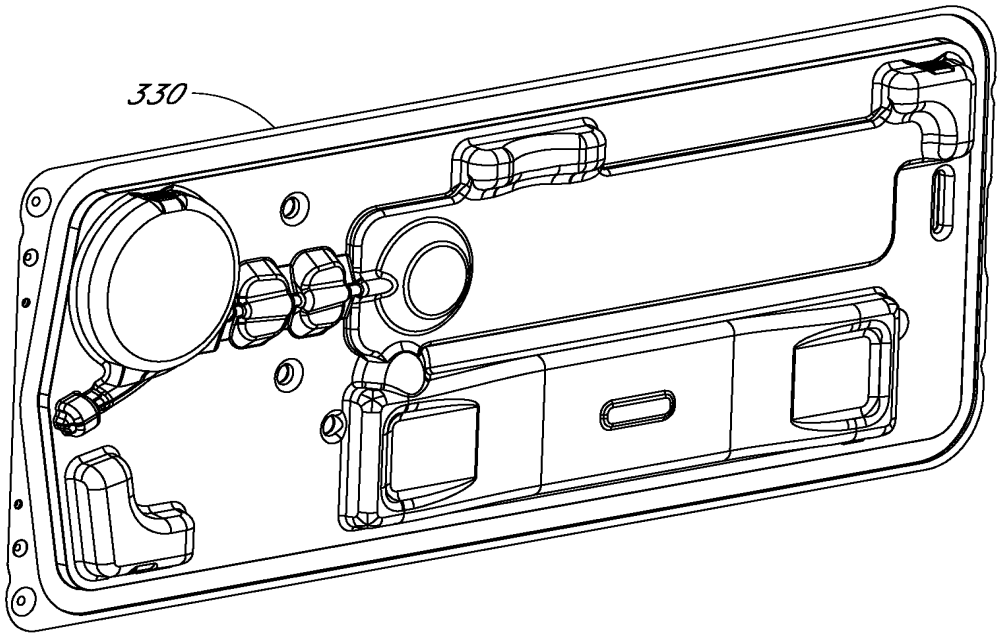


FIG. 11B

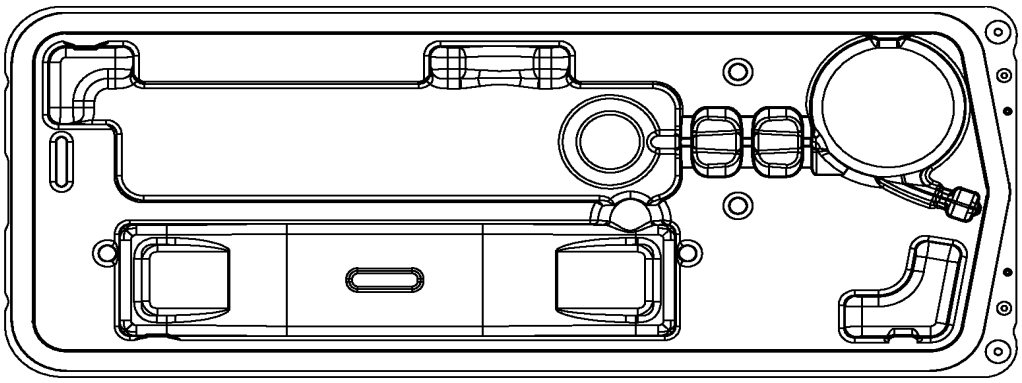


FIG. 11C

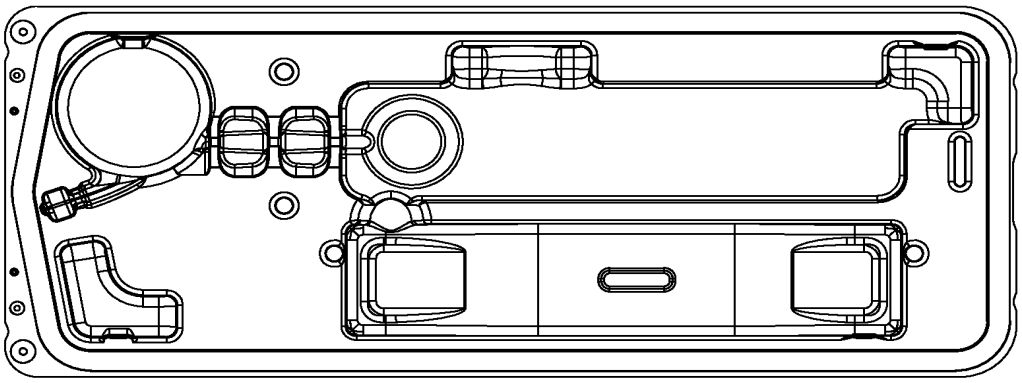


FIG. 11D

FIG. 11E

FIG. 11F

FIG. 11G

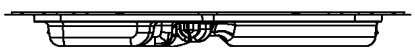


FIG. 11H

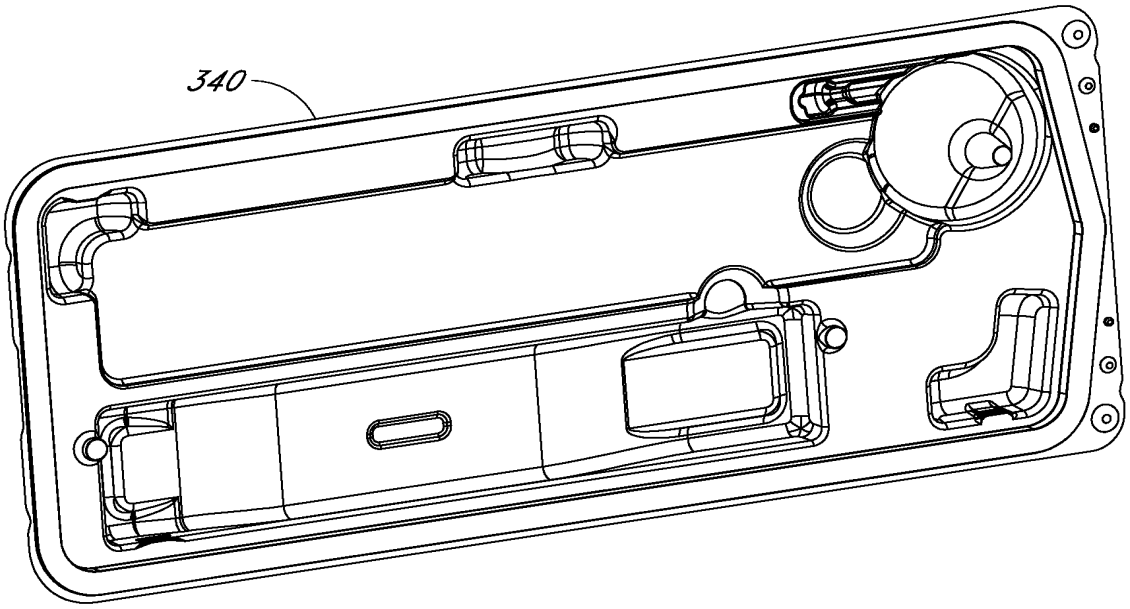


FIG. 12A

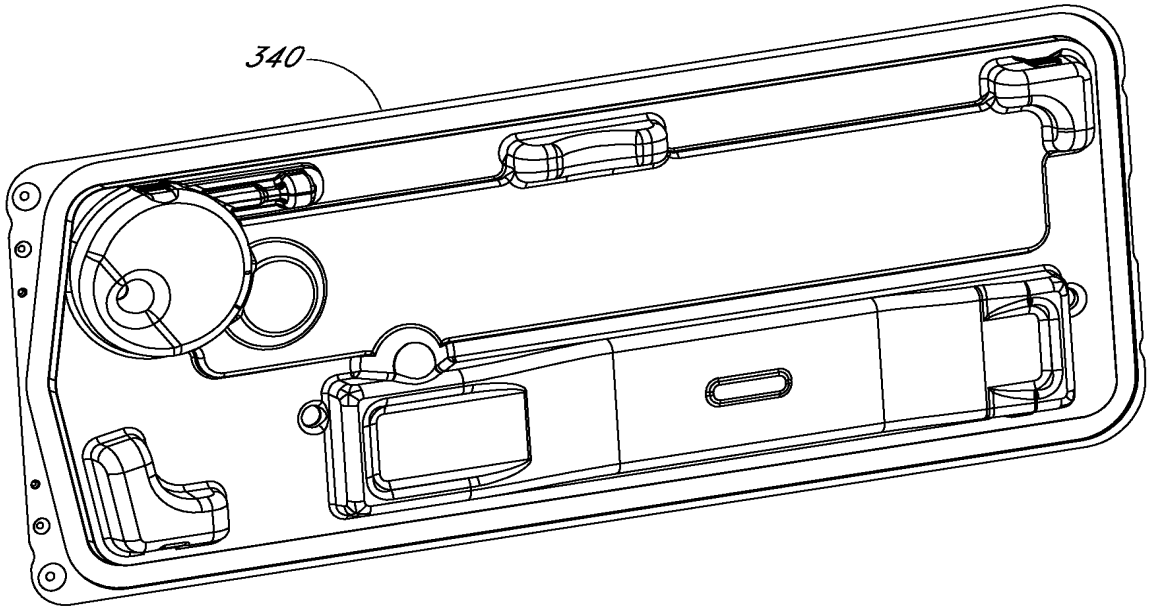


FIG. 12B

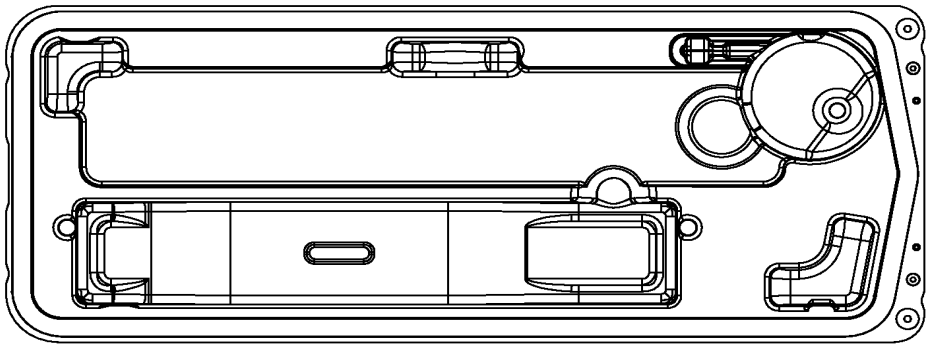


FIG. 12C

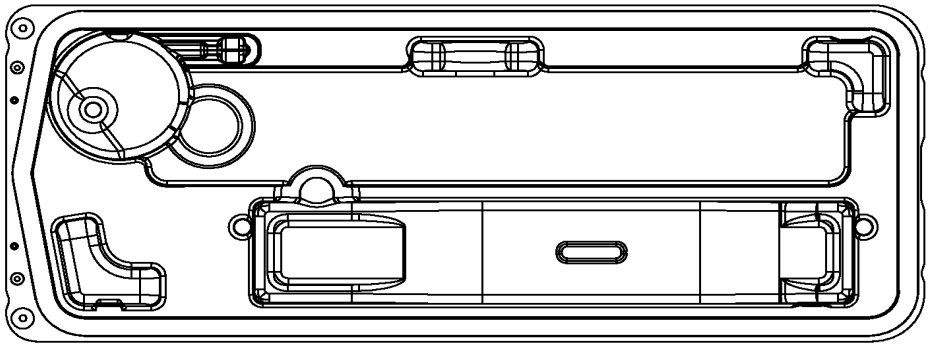


FIG. 12D

FIG. 12E

FIG. 12F

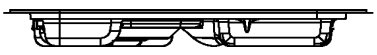


FIG. 12G

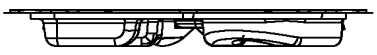


FIG. 12H

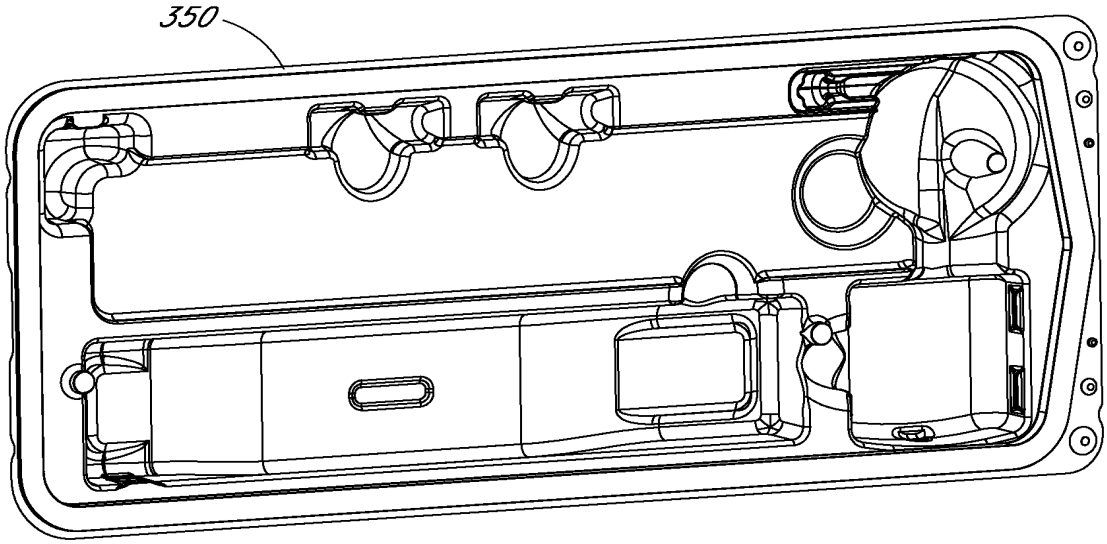


FIG. 13A

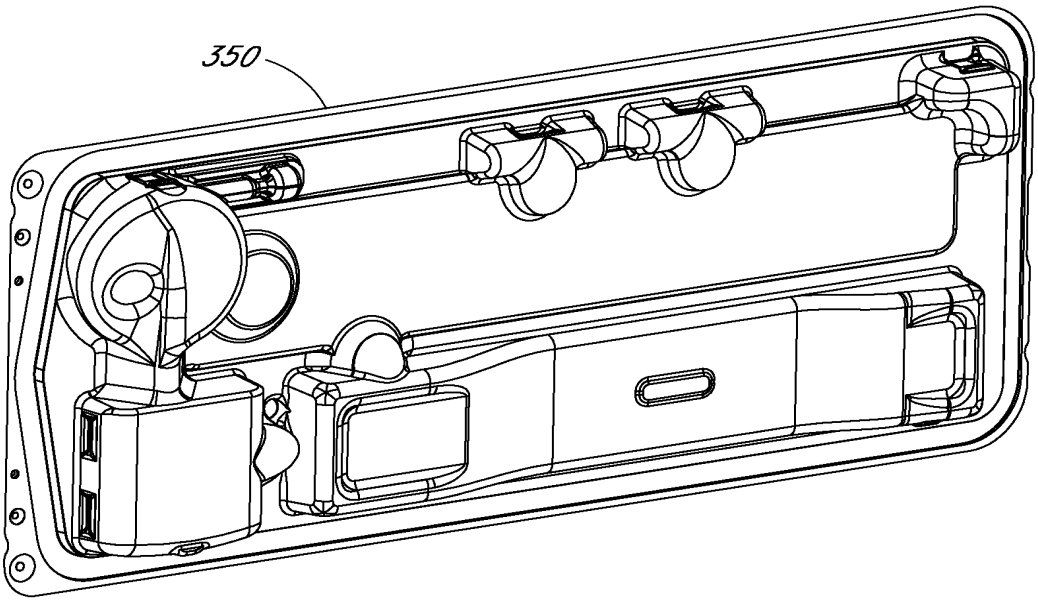


FIG. 13B

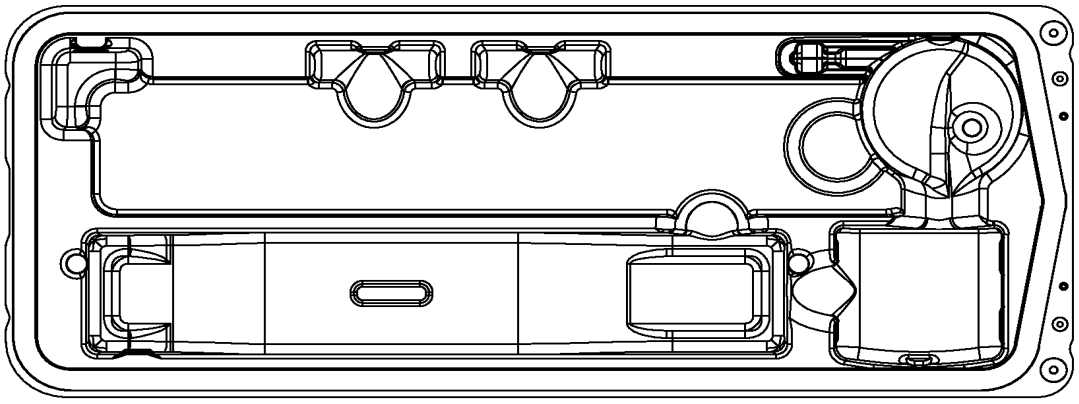


FIG. 13C

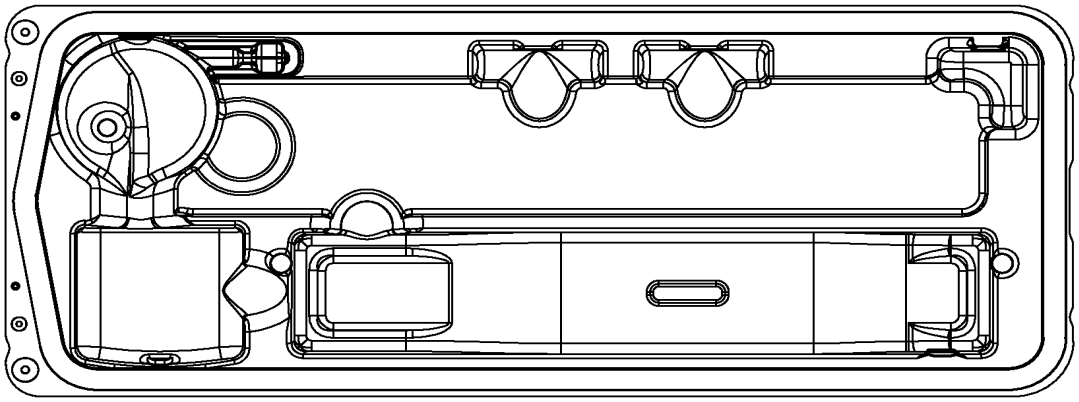


FIG. 13D

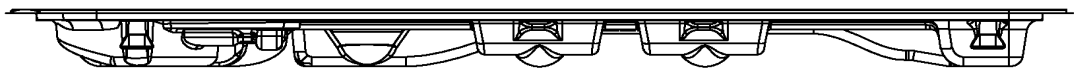


FIG. 13E

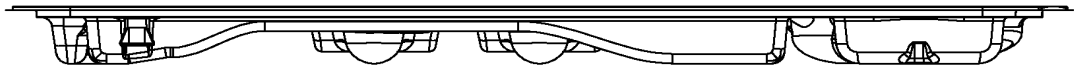


FIG. 13F

FIG. 13G

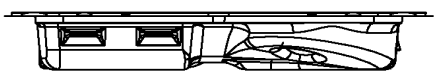


FIG. 13H

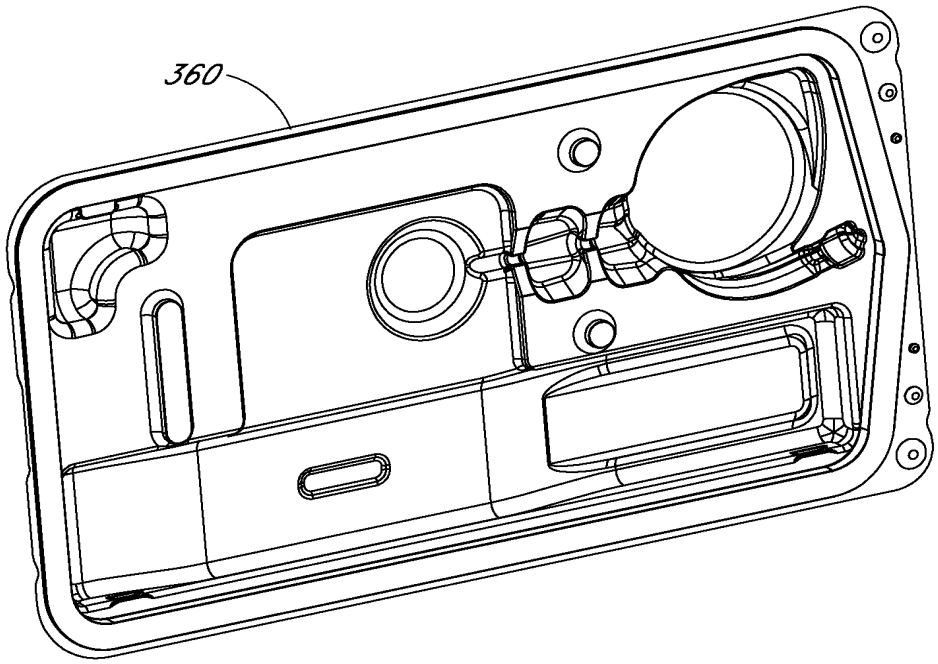


FIG. 14A

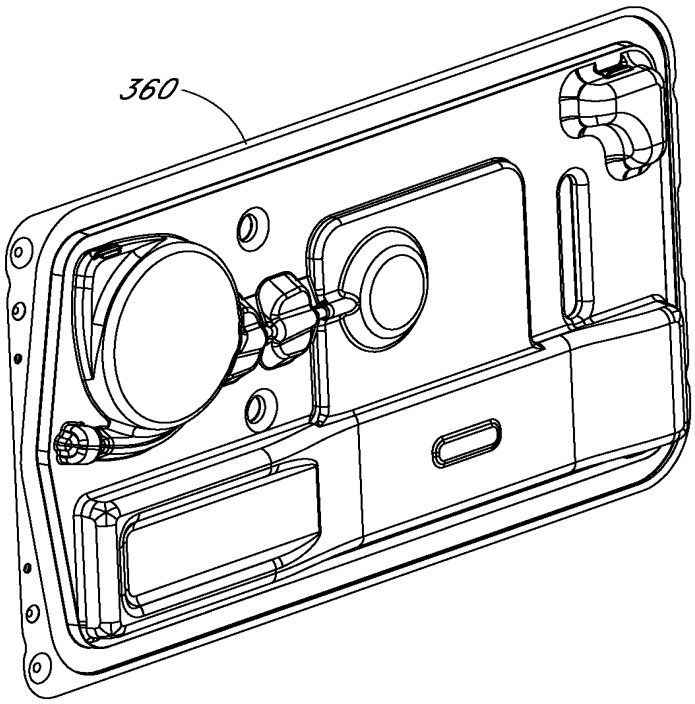


FIG. 14B

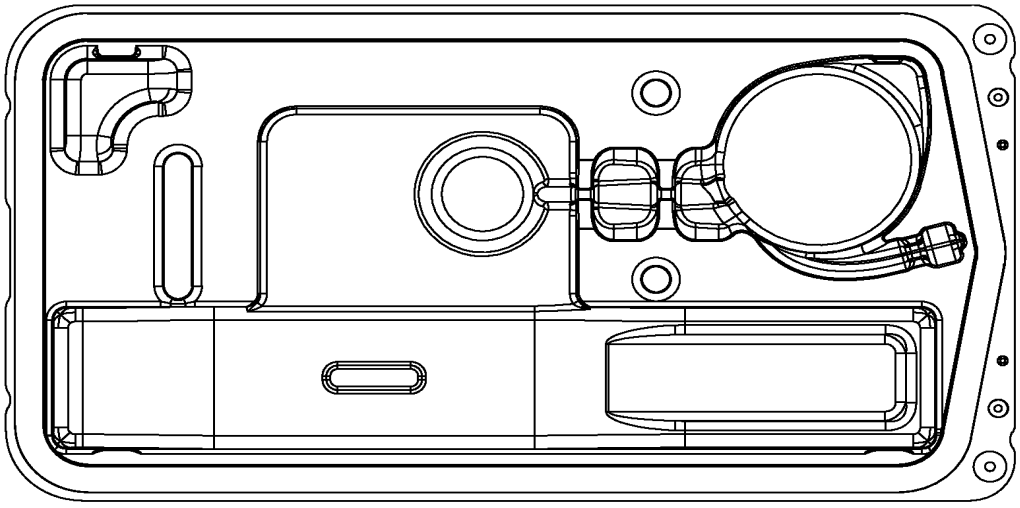


FIG. 14C

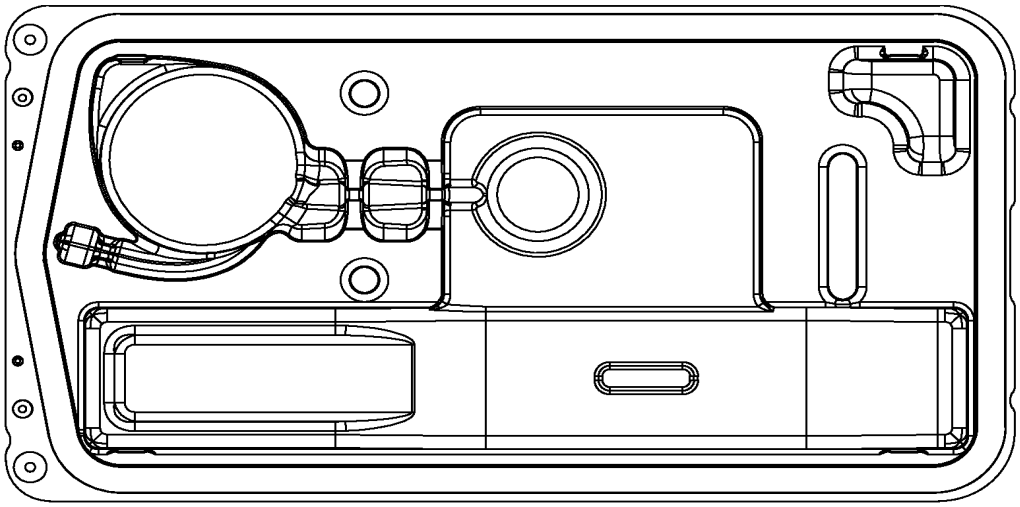


FIG. 14D

FIG. 14E

FIG. 14F

FIG. 14G

FIG. 14H

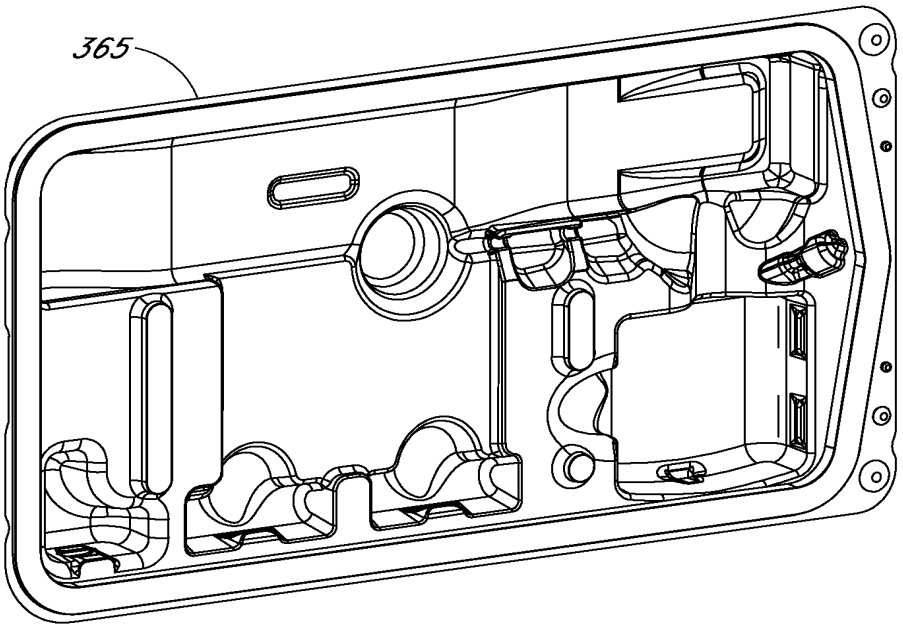


FIG. 14I

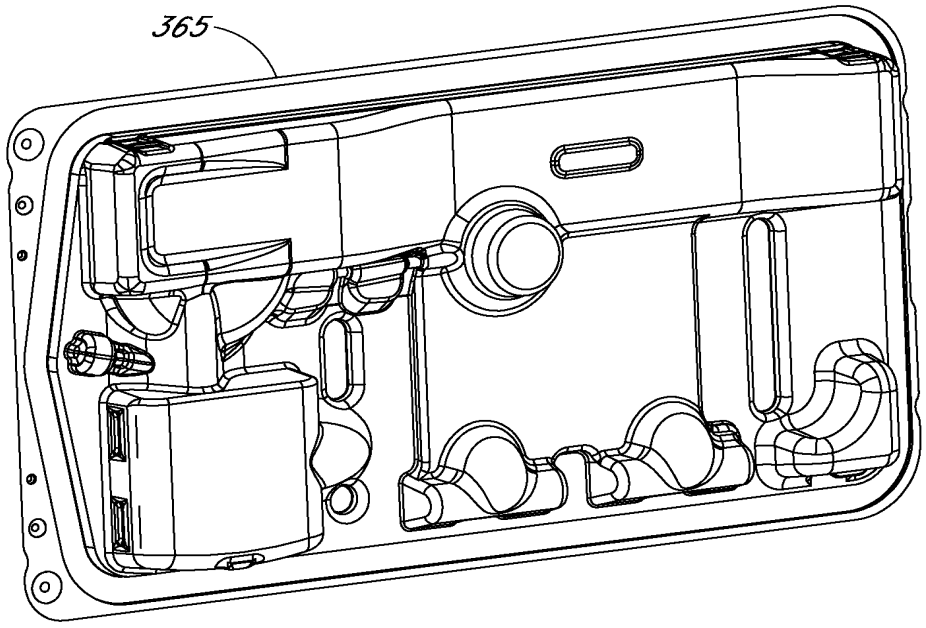


FIG. 14J

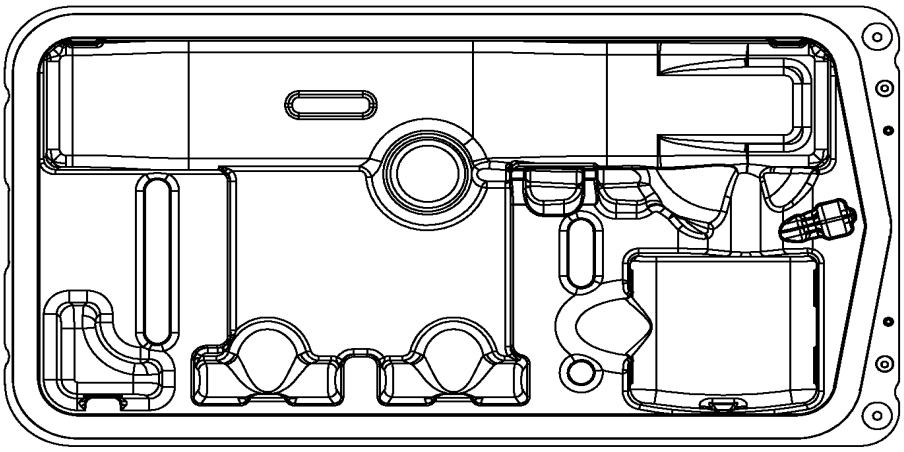


FIG. 14K

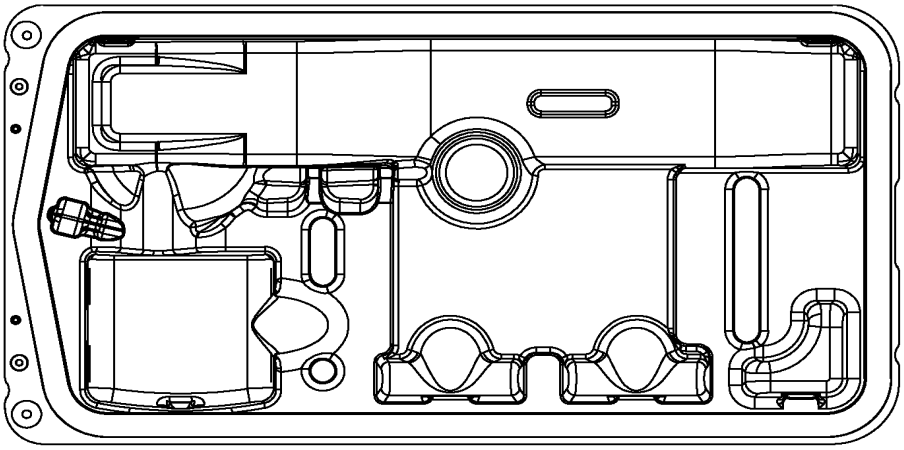


FIG. 14L

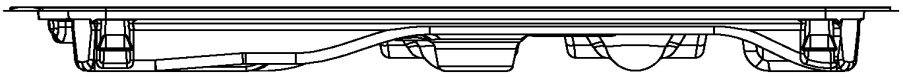


FIG. 14M

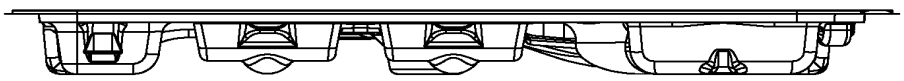


FIG. 14N

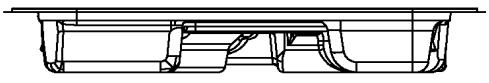


FIG. 140

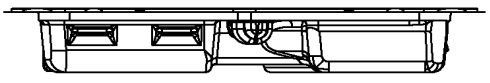


FIG. 14P

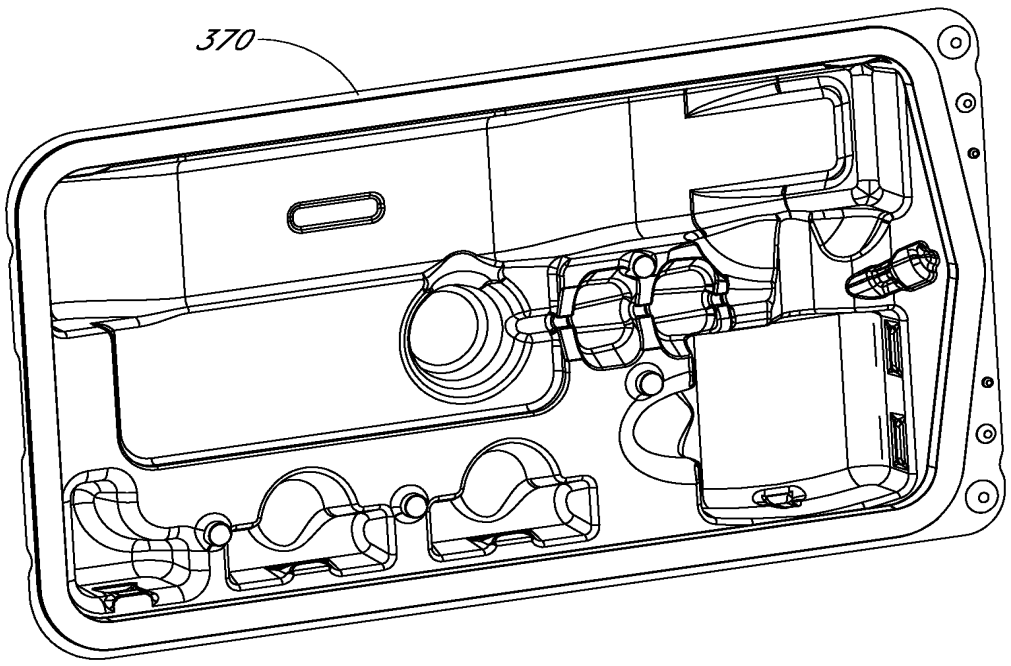


FIG. 15A

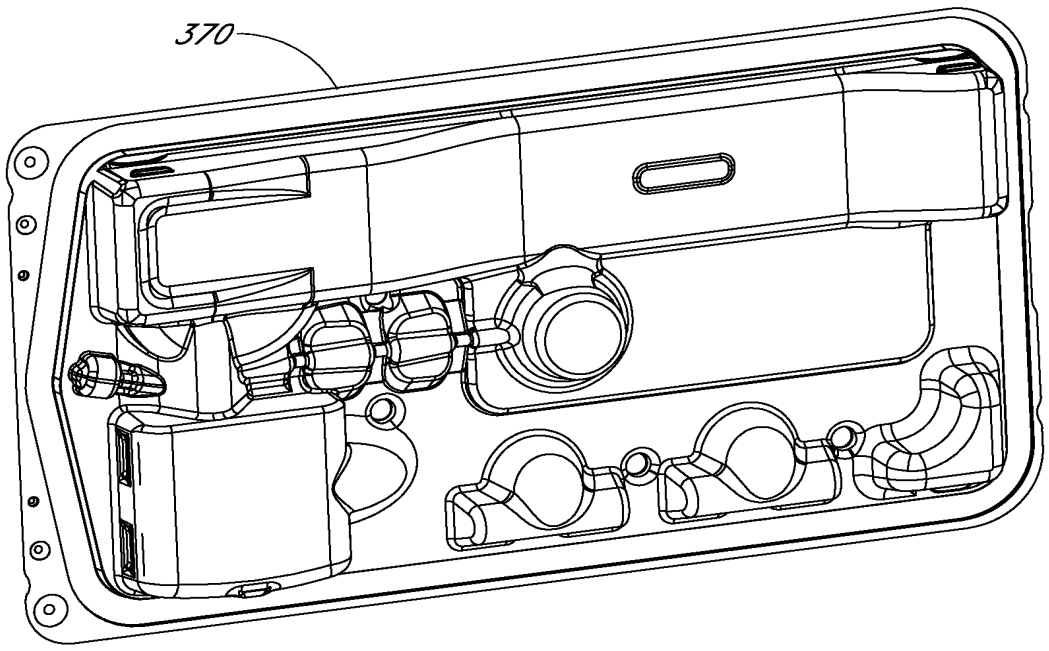


FIG. 15B

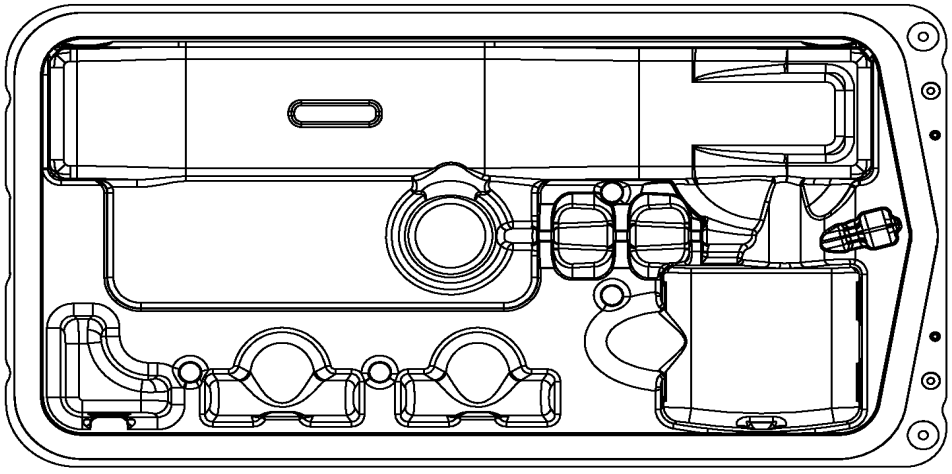


FIG. 15C

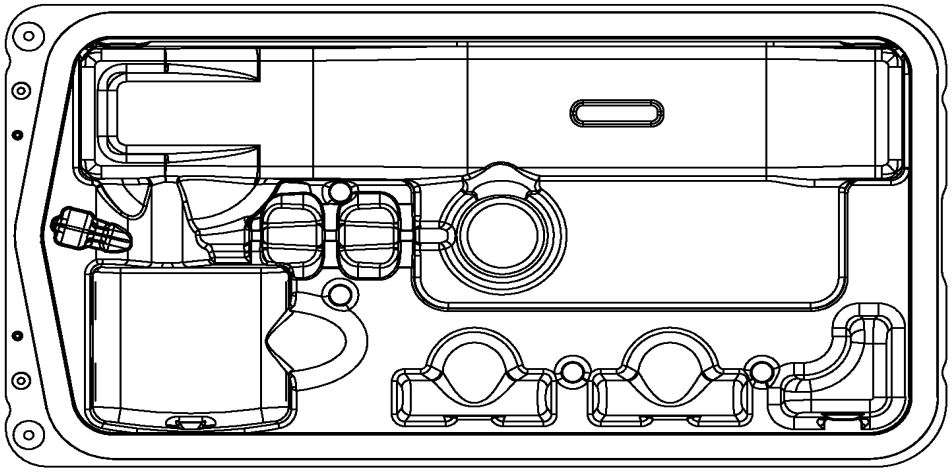


FIG. 15D

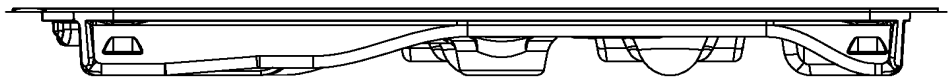


FIG. 15E

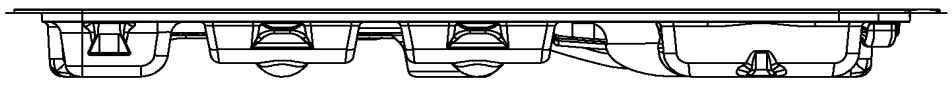


FIG. 15F

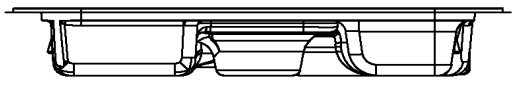


FIG. 15G

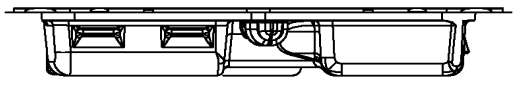


FIG. 15H

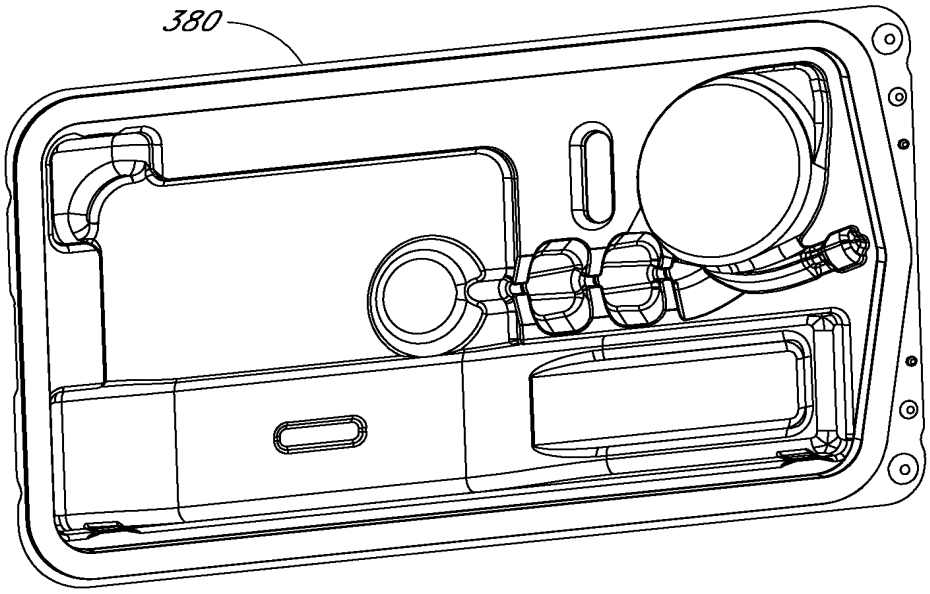


FIG. 16A

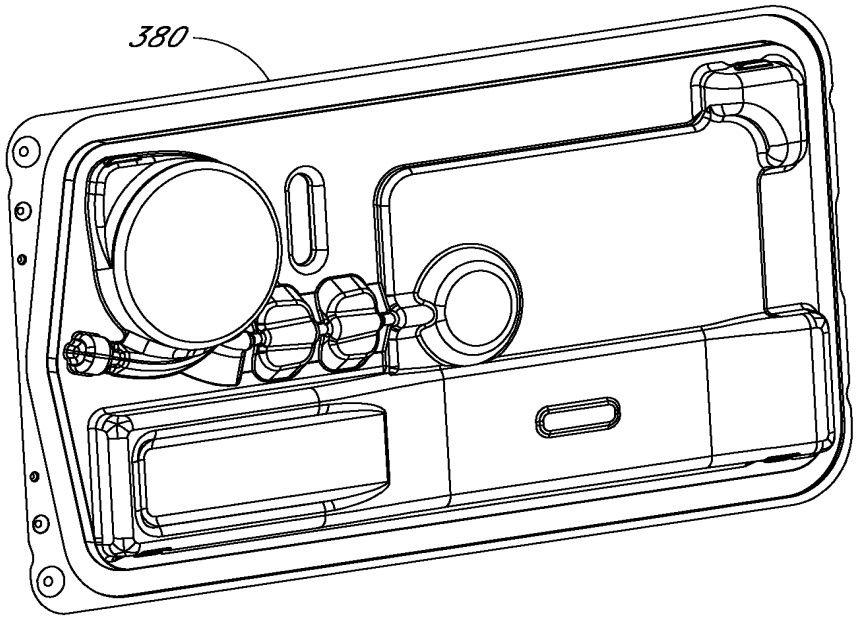


FIG. 16B

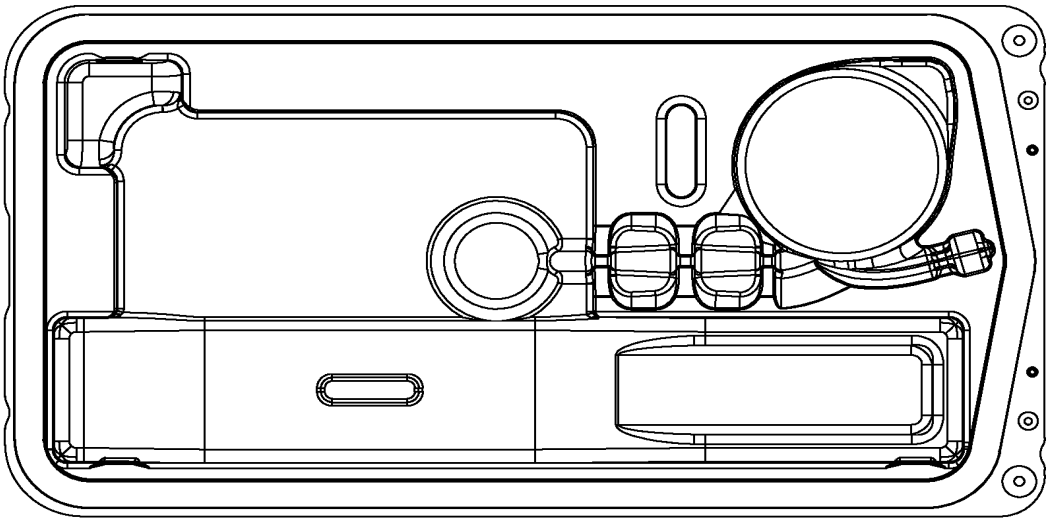


FIG. 16C

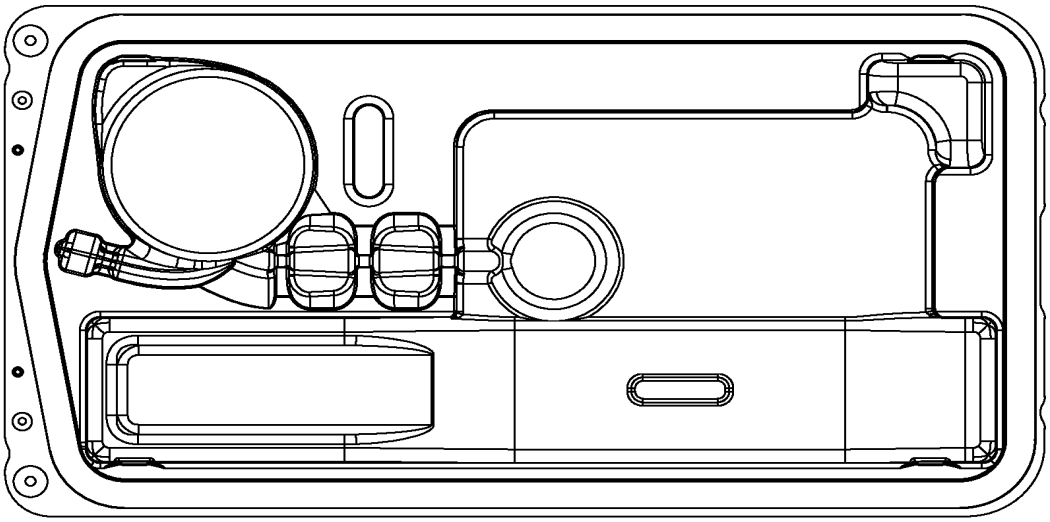


FIG. 16D

FIG. 16E

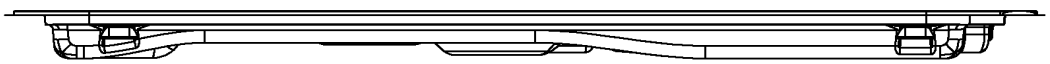


FIG. 16F

FIG. 16G

FIG. 16H

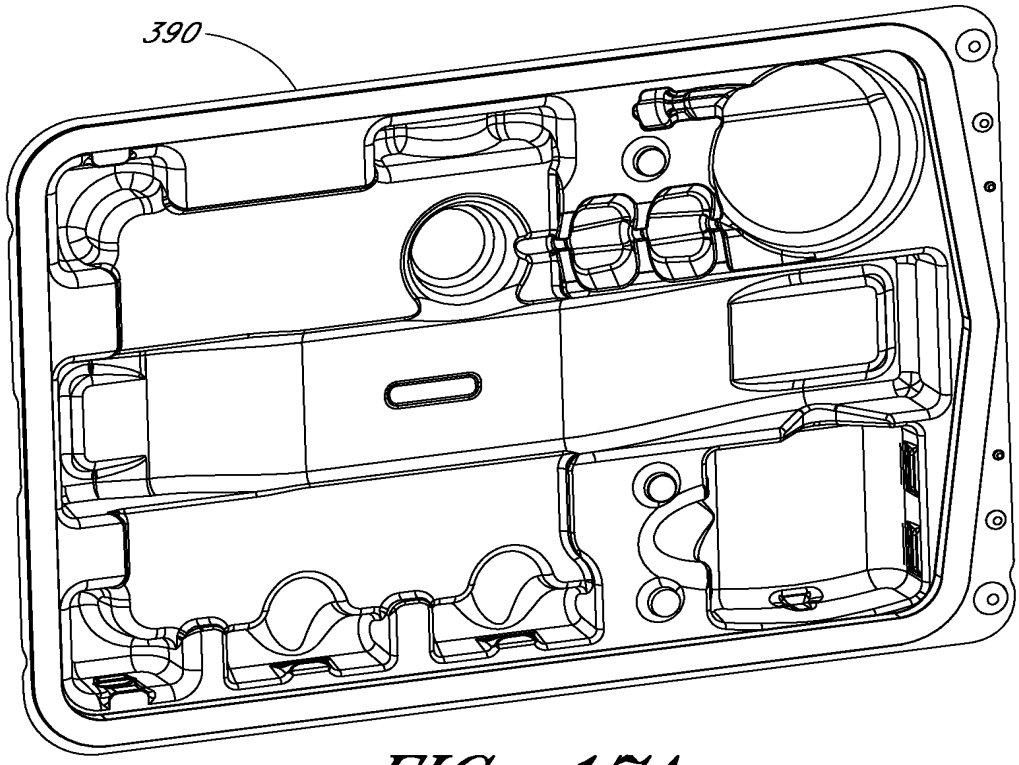


FIG. 17A

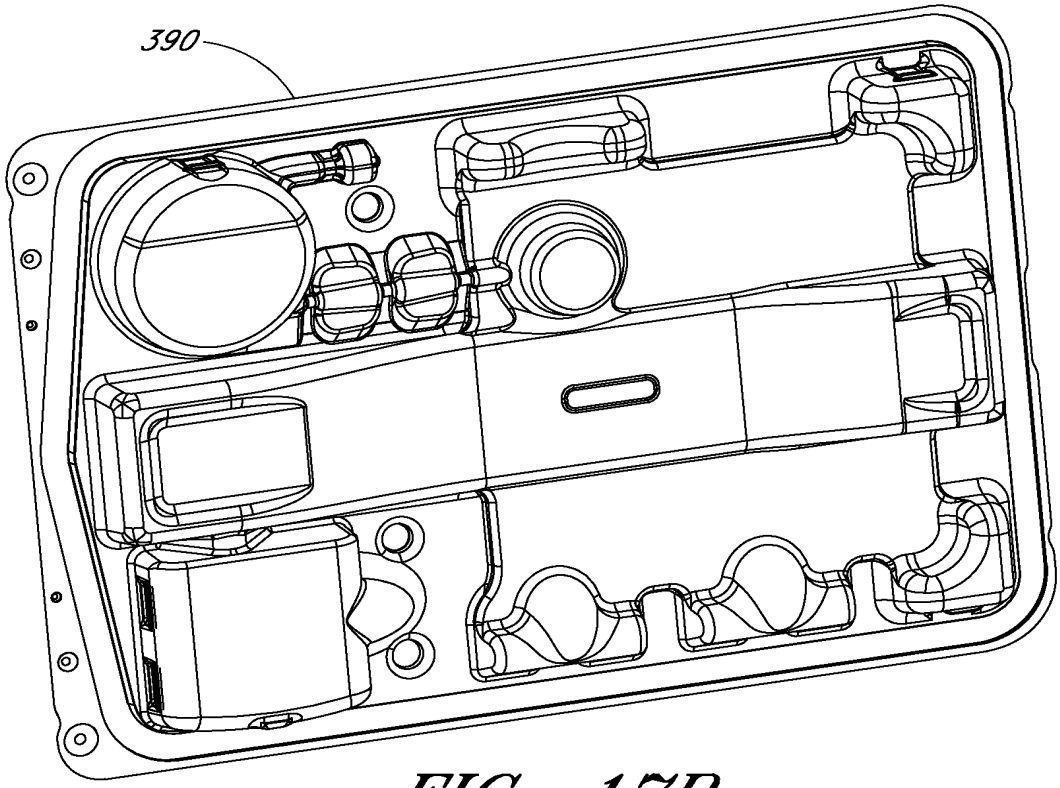


FIG. 17B

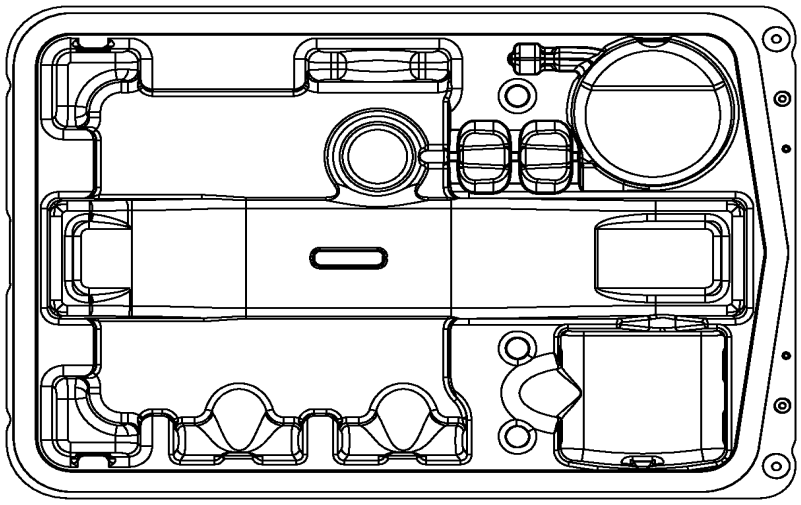


FIG. 17C

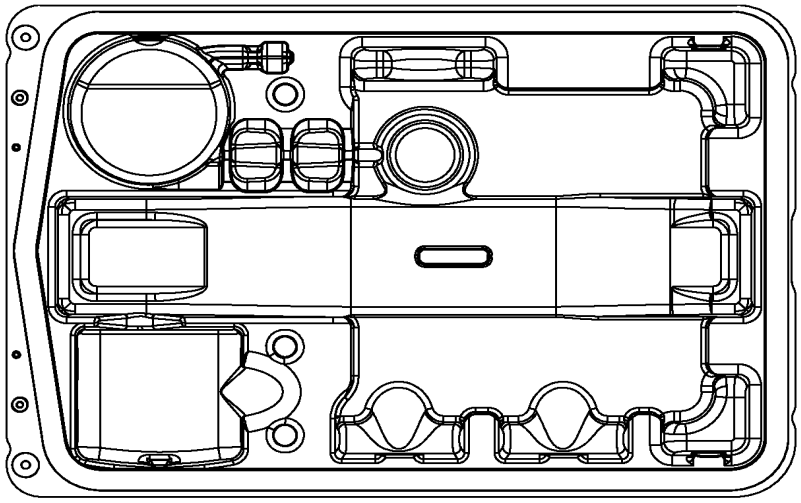


FIG. 17D

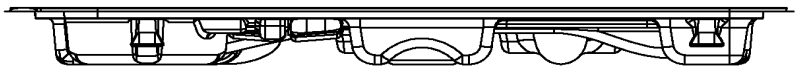


FIG. 17E

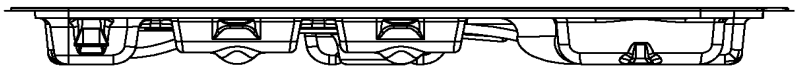


FIG. 17F

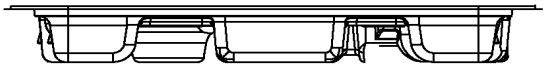


FIG. 17G

FIG. 17H

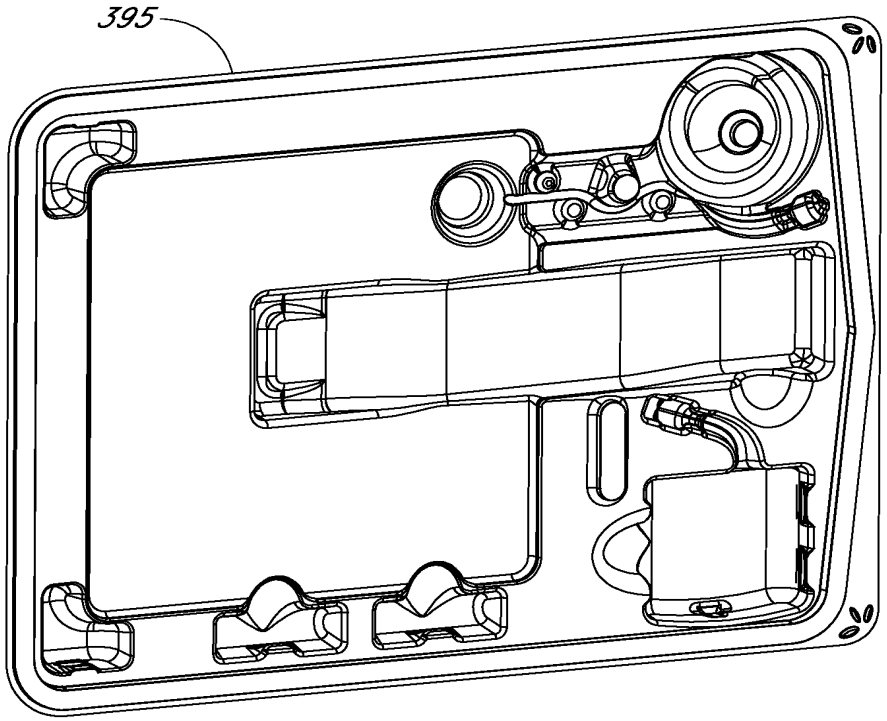


FIG. 17I

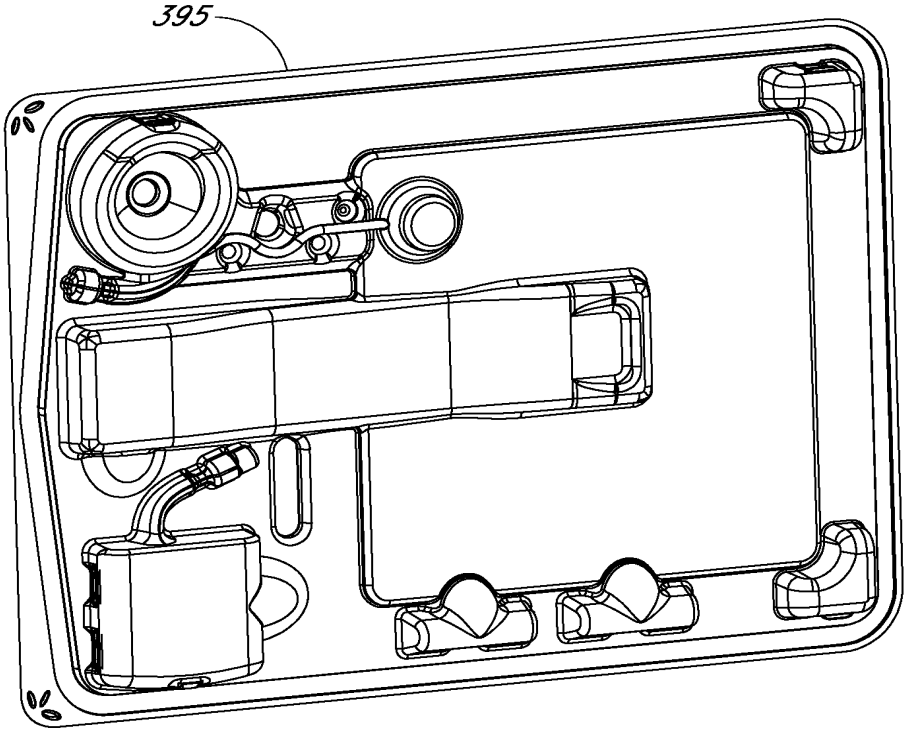


FIG. 17J

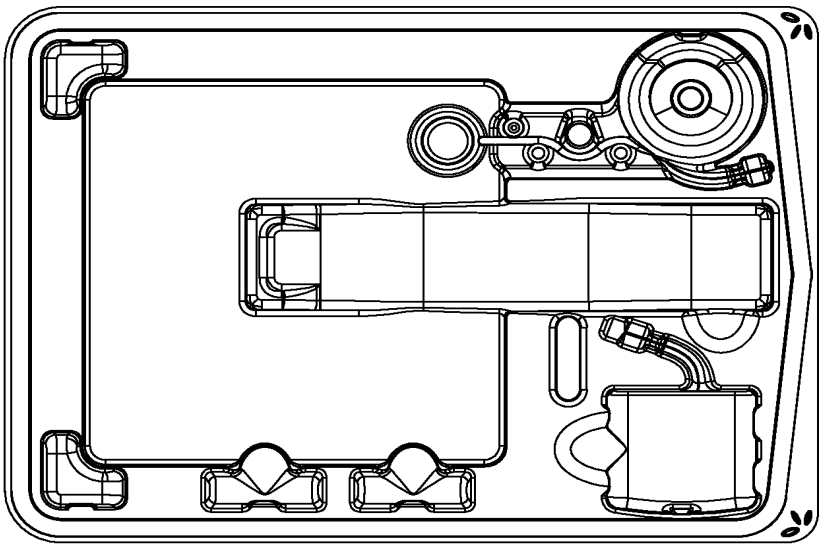


FIG. 17K

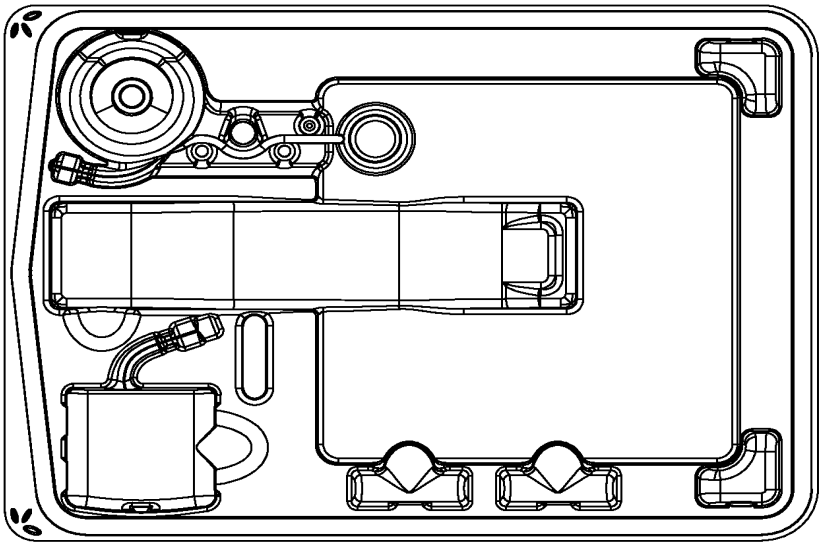


FIG. 17L

FIG. 17M

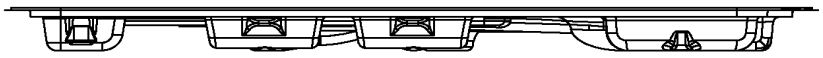


FIG. 17N

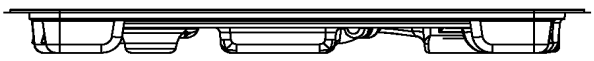


FIG. 17O

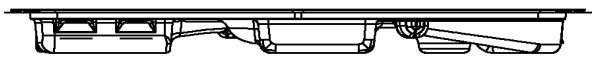


FIG. 17P

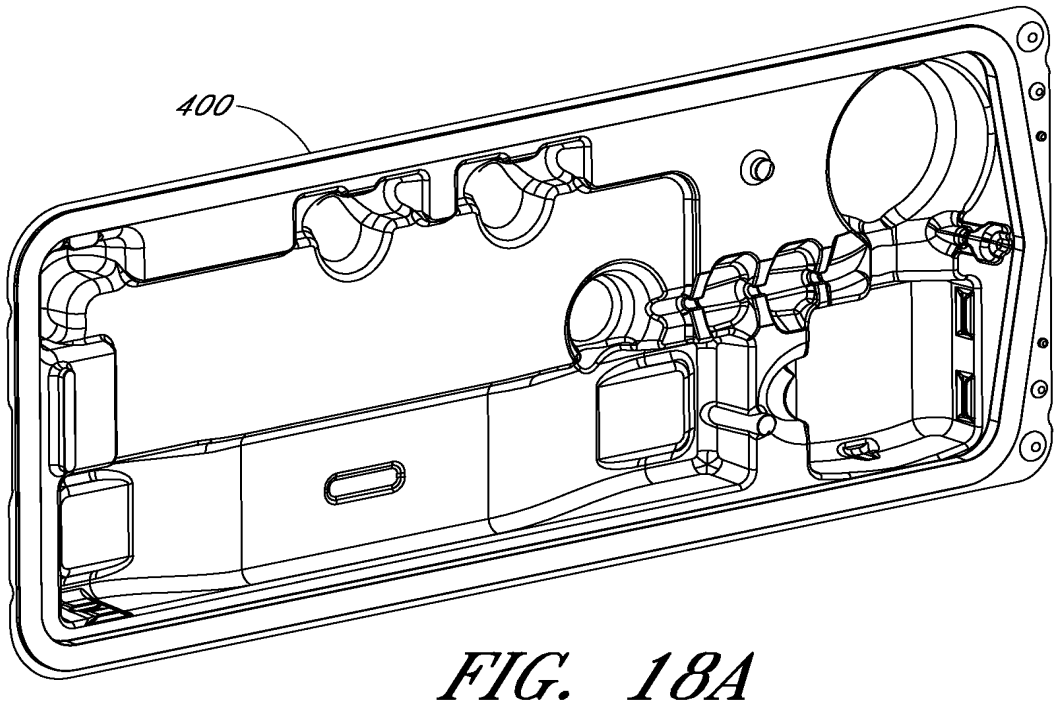


FIG. 18A

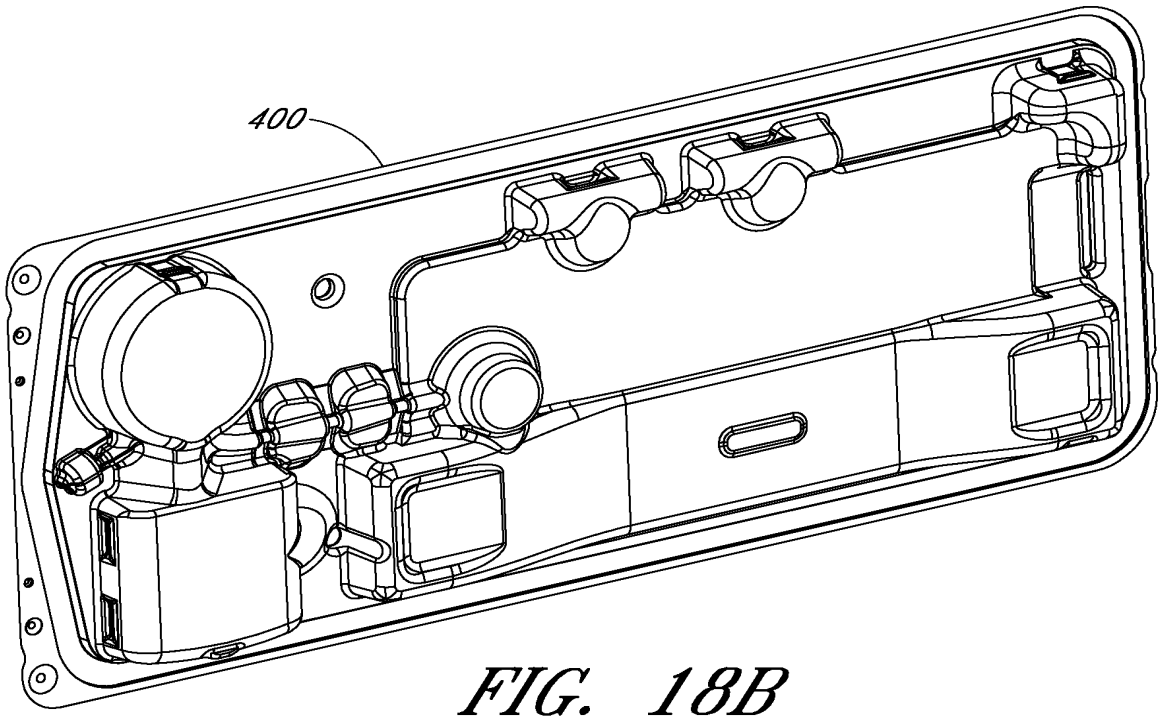


FIG. 18B

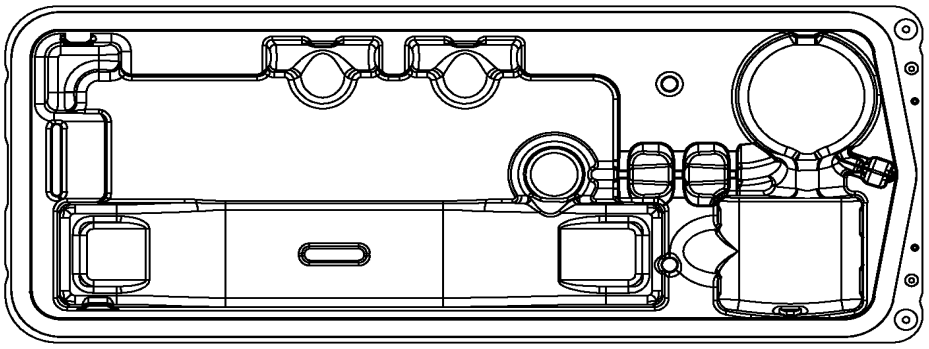


FIG. 18C

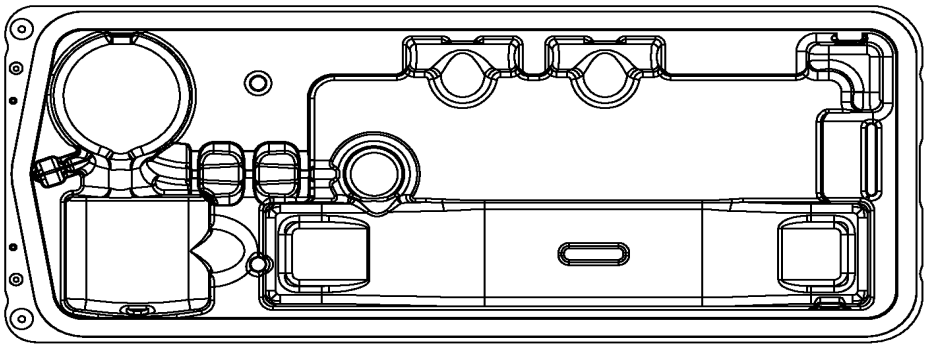


FIG. 18D

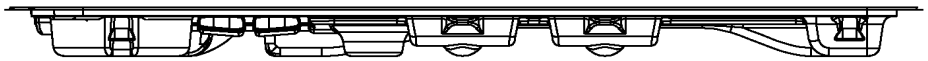


FIG. 18E

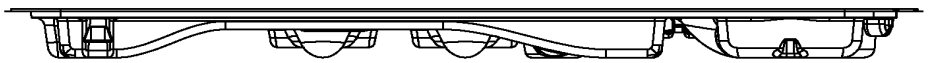


FIG. 18F

FIG. 18G

FIG. 18H

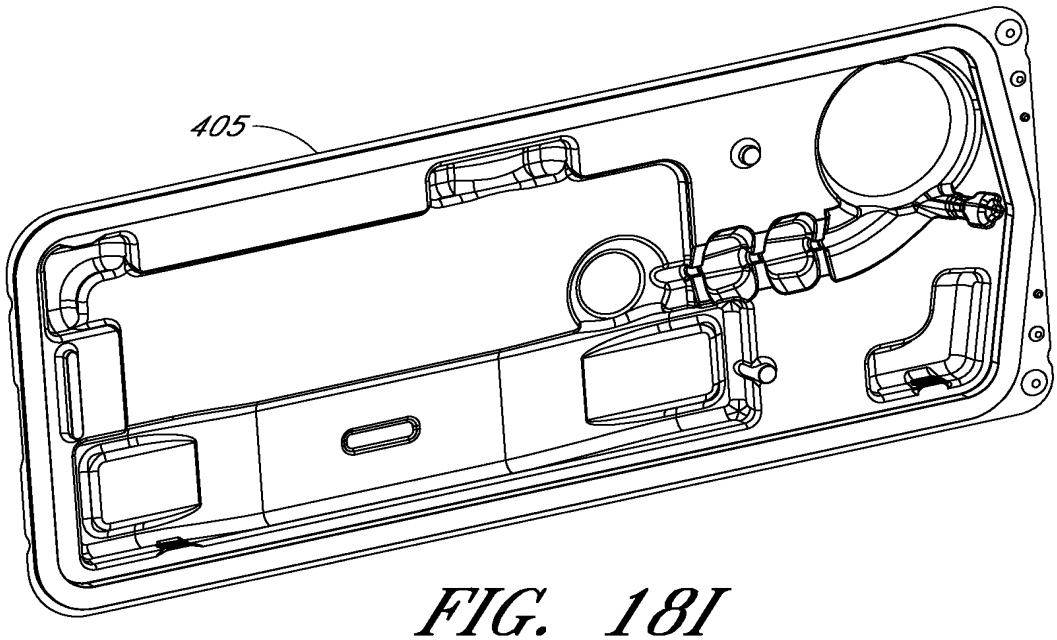


FIG. 18I

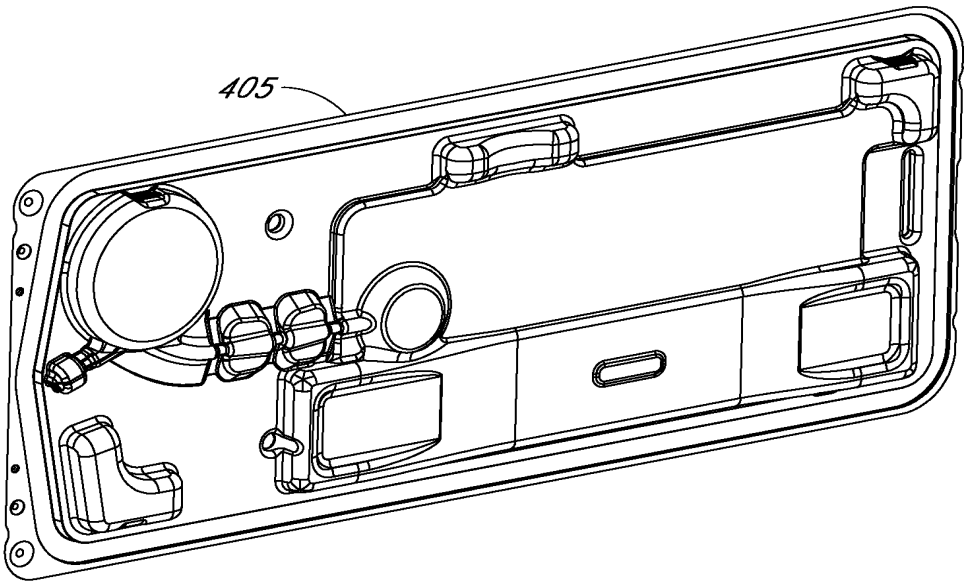


FIG. 18J

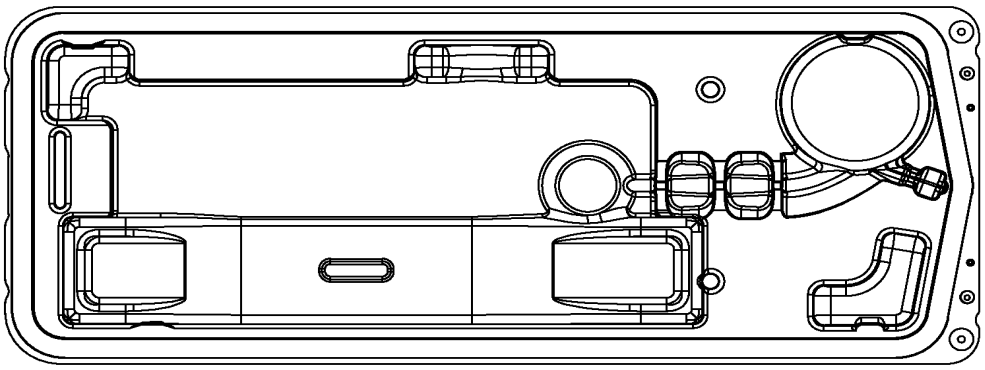


FIG. 18K

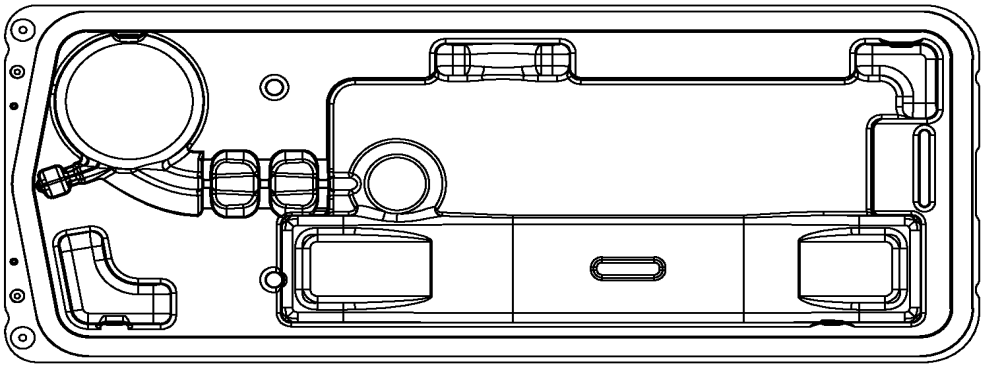


FIG. 18L

FIG. 18M

FIG. 18N

FIG. 180

FIG. 18P

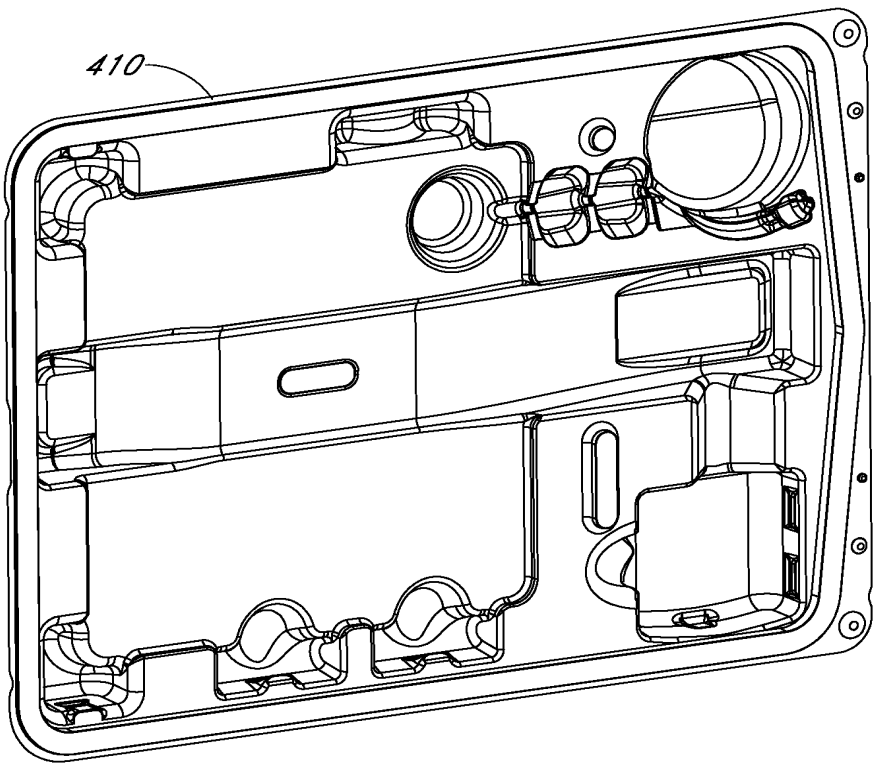


FIG. 19A

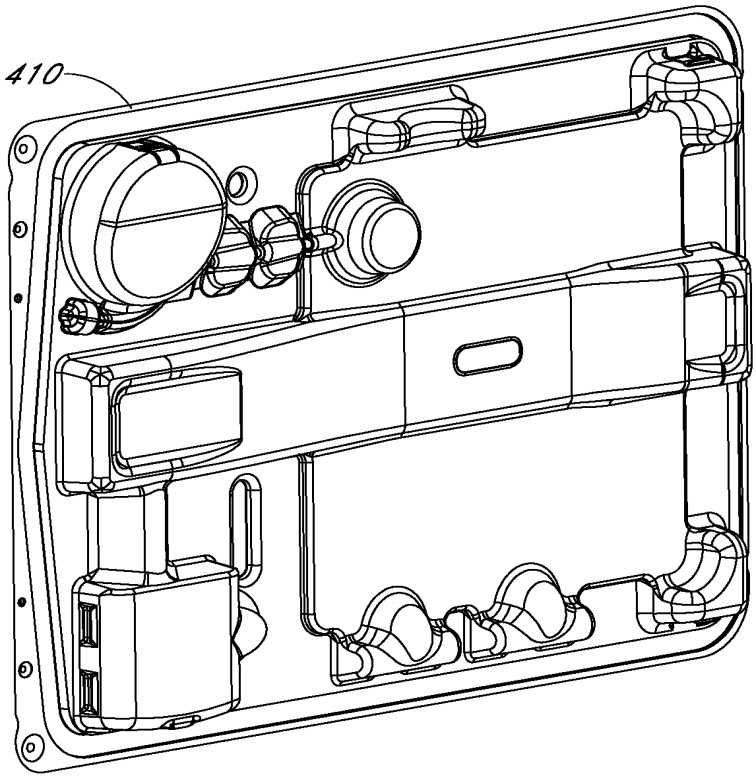


FIG. 19B

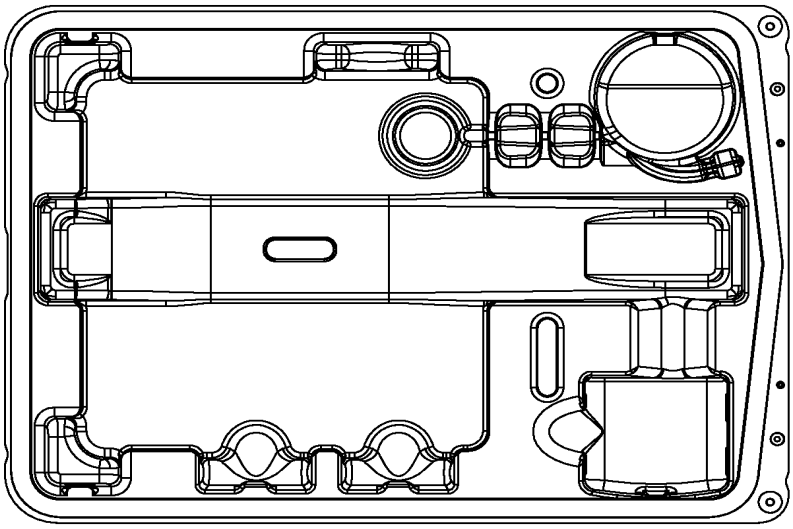


FIG. 19C

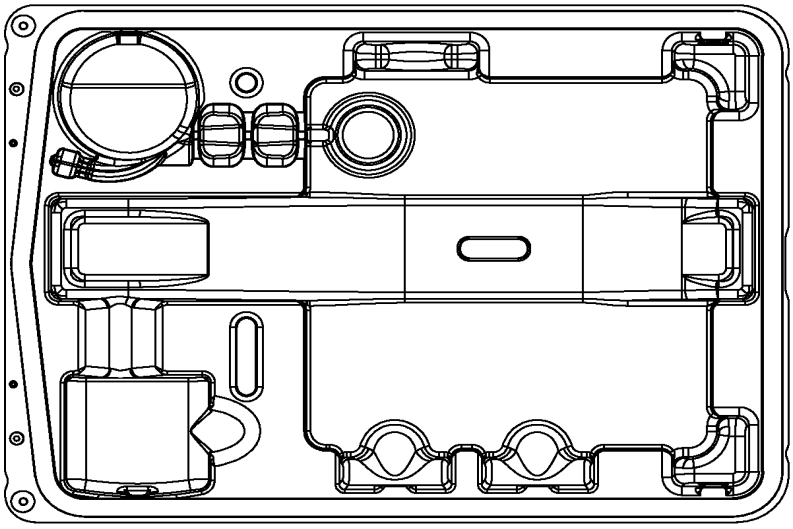


FIG. 19D

FIG. 19E

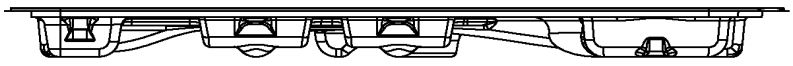


FIG. 19F

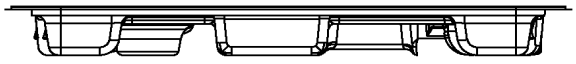


FIG. 19G

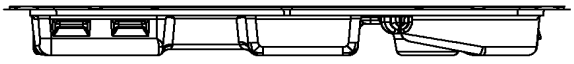


FIG. 19H

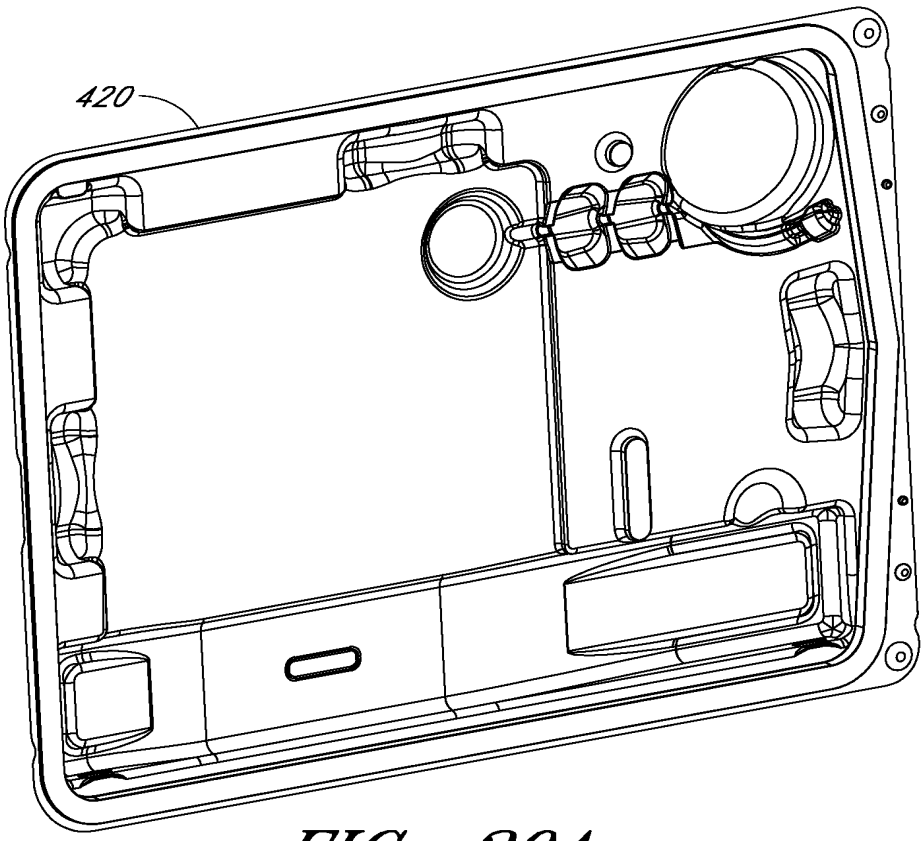


FIG. 20A

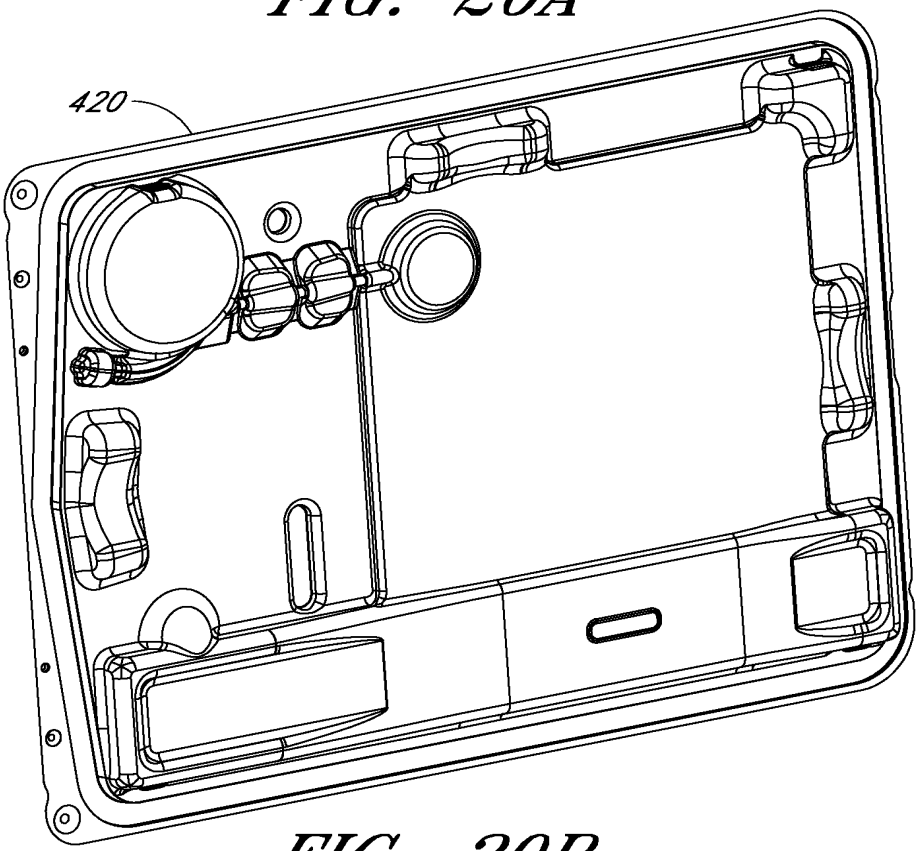


FIG. 20B

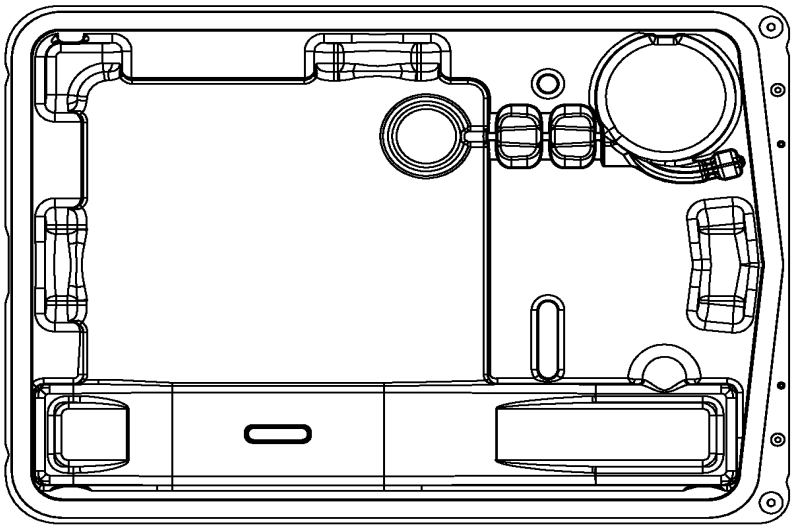


FIG. 20C

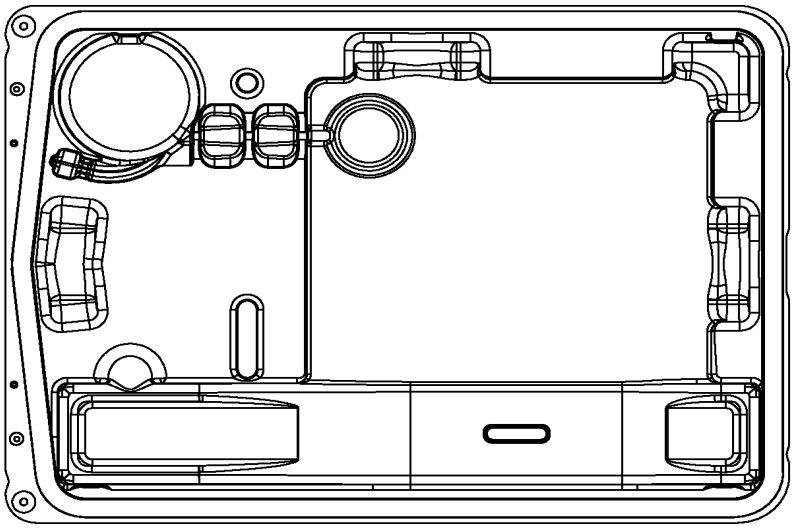


FIG. 20D

FIG. 20E

FIG. 20F

FIG. 20G

FIG. 20H

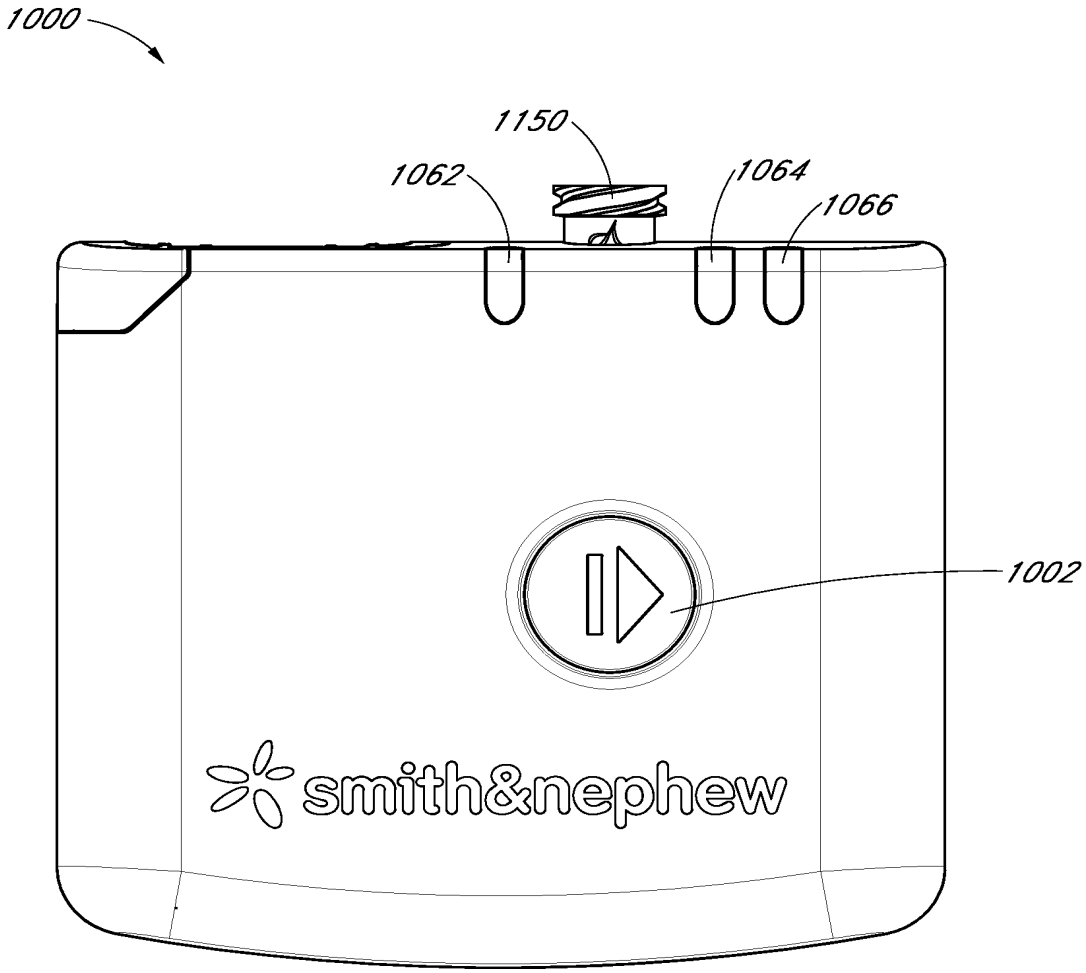


FIG. 21

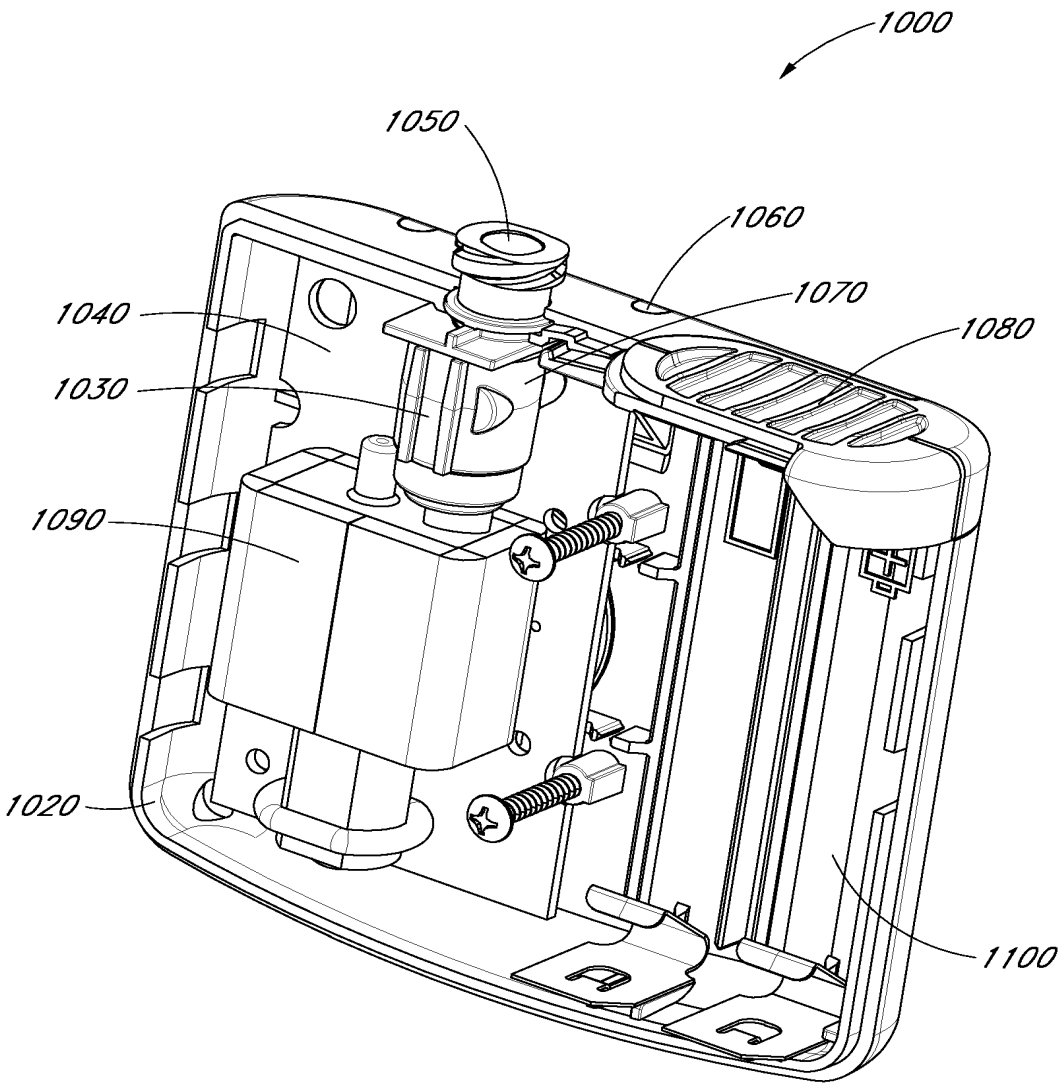


FIG. 22

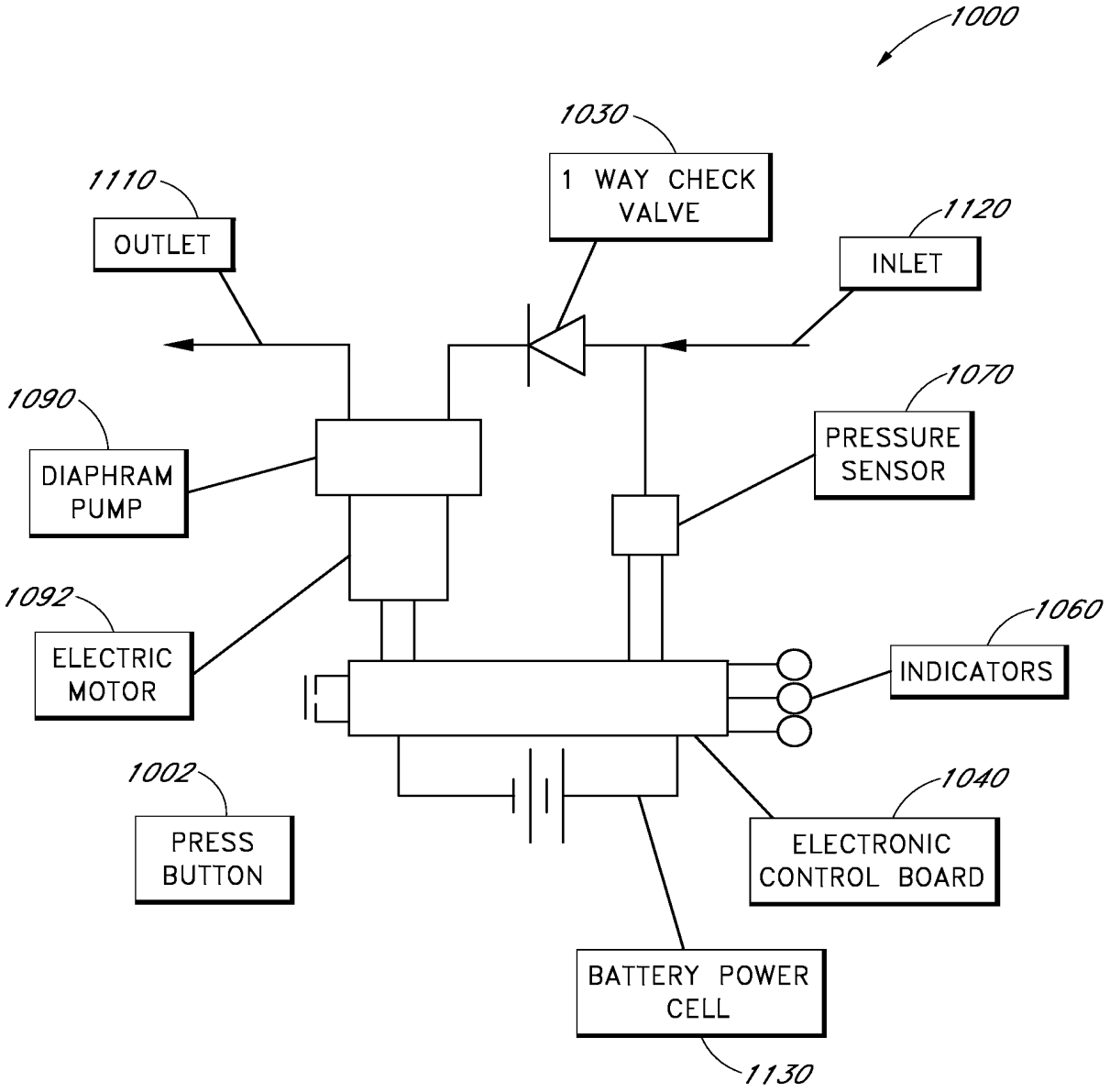

1000
1030
1 WAY CHECK VALVE
1110
OUTLET
1120
INLET
1090
DIAPHRAM PUMP
1070
PRESSURE SENSOR
1092
ELECTRIC MOTOR
1060
INDICATORS
1002
PRESS BUTTON
1040
ELECTRONIC CONTROL BOARD
BATTERY POWER CELL
1130

FIG. 23

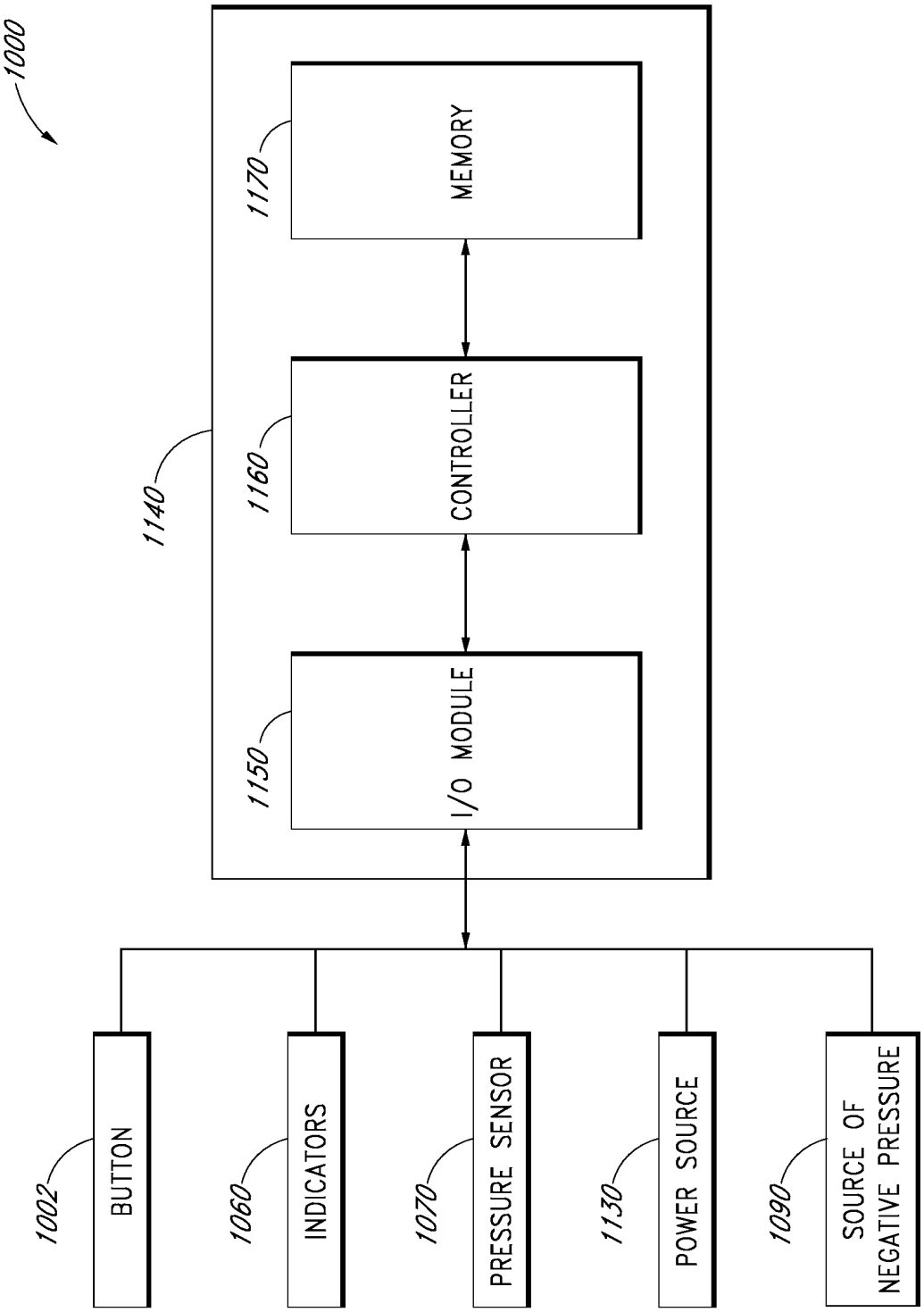

1000
1140
1170
MEMORY
1160
CONTROLLER
1150
I/O MODULE
1002
BUTTON
1060
INDICATORS
1070
PRESSURE SENSOR
1130
POWER SOURCE
1090
SOURCE OF NEGATIVE PRESSURE

FIG. 24

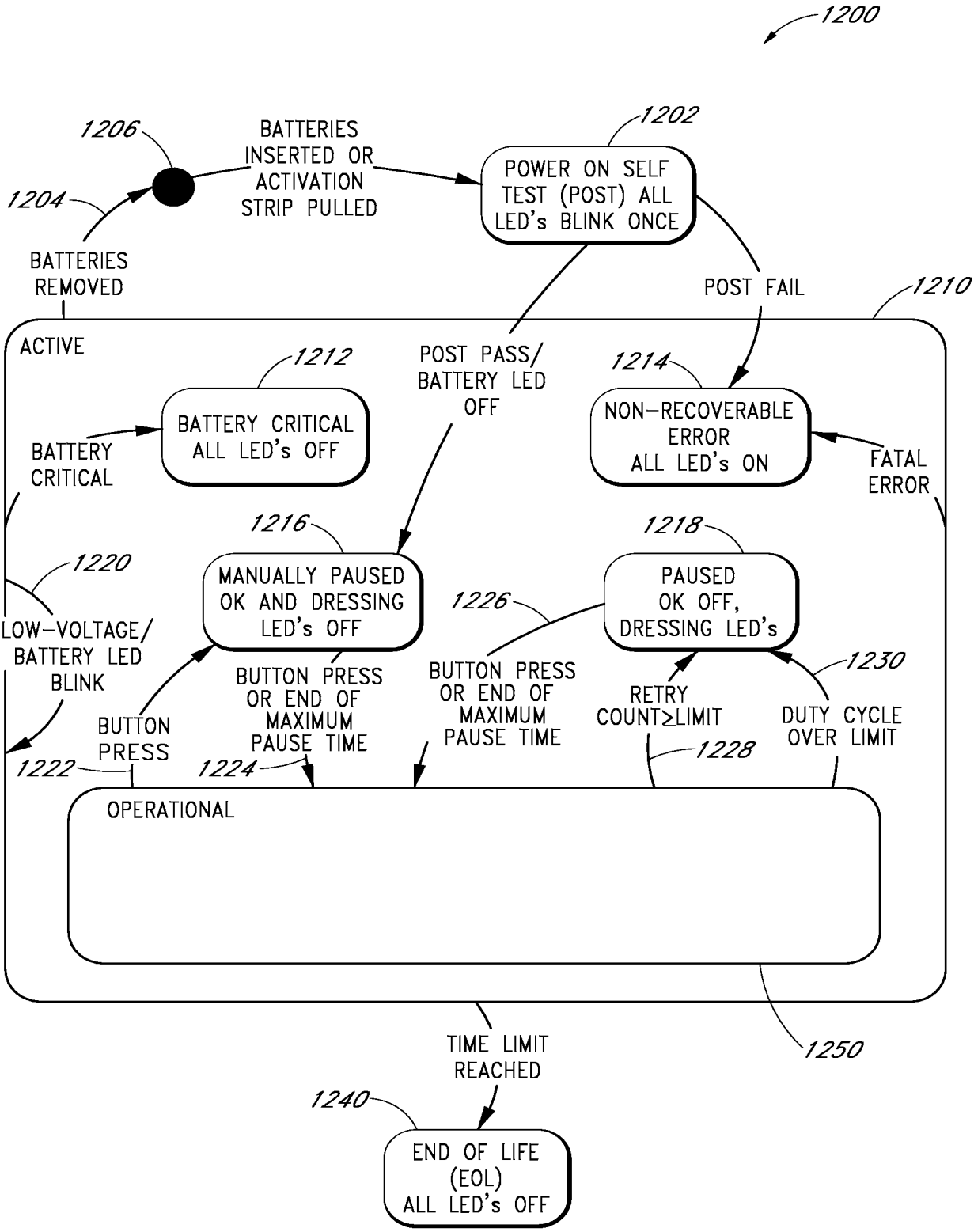

1200
1206
BATTERIES INSERTED OR ACTIVATION STRIP PULLED
1202
POWER ON SELF TEST (POST) ALL LED's BLINK ONCE
1204
BATTERIES REMOVED
POST FAIL
1210
ACTIVE
1212
BATTERY CRITICAL ALL LED's OFF
POST PASS/ BATTERY LED OFF
1214
NON-RECOVERABLE ERROR ALL LED's ON
BATTERY CRITICAL
FATAL ERROR
1216
MANUALLY PAUSED OK AND DRESSING LED's OFF
1218
PAUSED OK OFF, DRESSING LED's
1220
LOW-VOLTAGE/ BATTERY LED BLINK
1226
BUTTON PRESS OR END OF MAXIMUM PAUSE TIME
1230
RETRY COUNT≥LIMIT
DUTY CYCLE OVER LIMIT
BUTTON PRESS
BUTTON PRESS OR END OF MAXIMUM PAUSE TIME
1222
1224
1228
OPERATIONAL
1250
TIME LIMIT REACHED
1240
END OF LIFE (EOL) ALL LED's OFF

FIG. 25

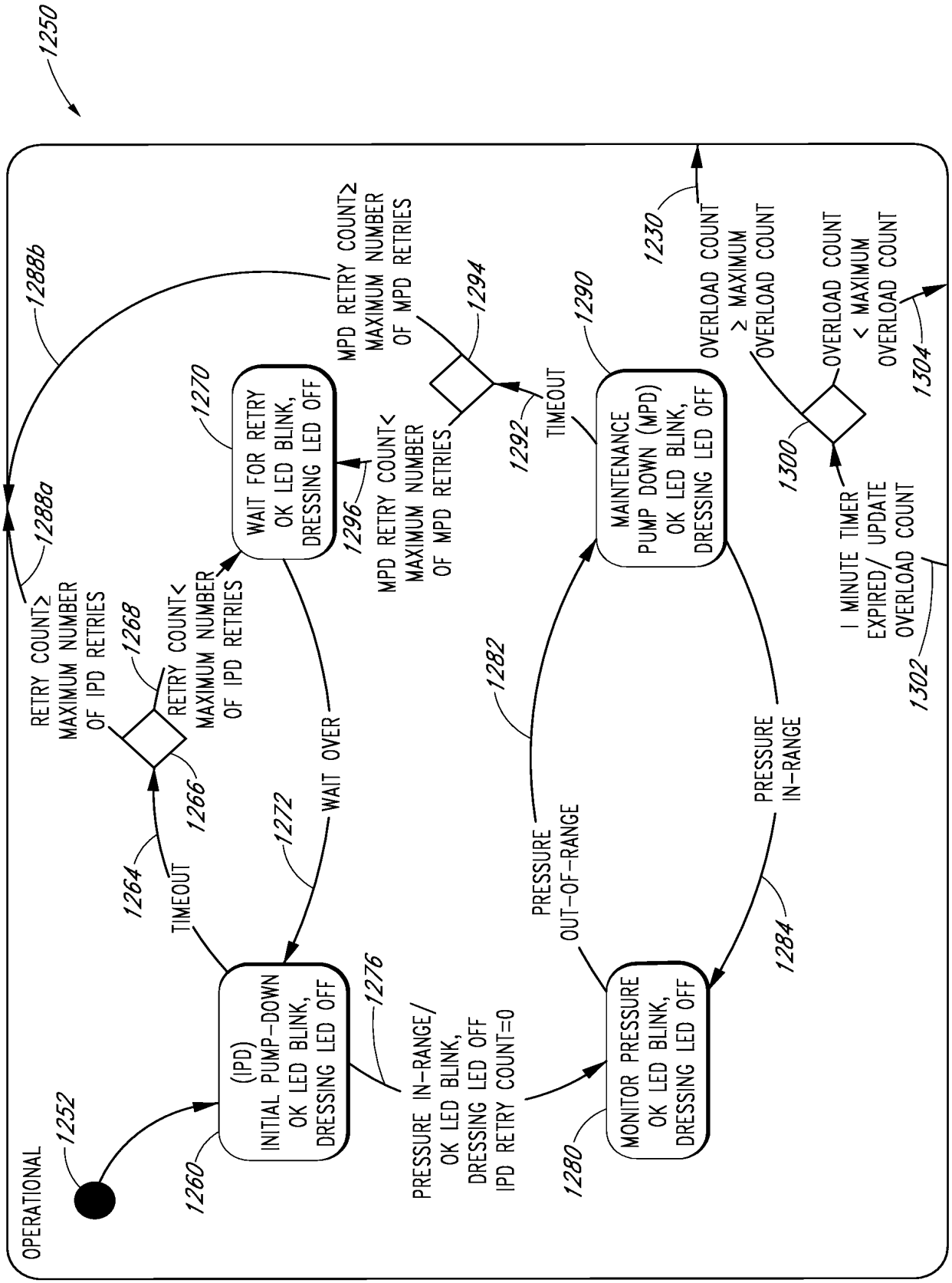

1250
OPERATIONAL
1252
1260
(IPD)
INITIAL PUMP-DOWN
OK LED BLINK,
DRESSING LED OFF
1276
PRESSURE IN-RANGE/
OK LED BLINK,
DRESSING LED OFF
IPD RETRY COUNT=0
1264
TIMEOUT
1266
RETRY COUNT≥
MAXIMUM NUMBER
OF IPD RETRIES
1268
RETRY COUNT<
MAXIMUM NUMBER
OF IPD RETRIES
1272
WAIT OVER
1270
WAIT FOR RETRY
OK LED BLINK,
DRESSING LED OFF
1296
MPD RETRY COUNT<
MAXIMUM NUMBER
OF MPD RETRIES
1294
MPD RETRY COUNT≥
MAXIMUM NUMBER
OF MPD RETRIES
1292
TIMEOUT
1290
MAINTENANCE
PUMP DOWN (MPD)
OK LED BLINK,
DRESSING LED OFF
1230
OVERLOAD COUNT
≥ MAXIMUM
OVERLOAD COUNT
1300
OVERLOAD COUNT
< MAXIMUM
OVERLOAD COUNT
1304
1 MINUTE TIMER
EXPIRED/ UPDATE
OVERLOAD COUNT
1302
1282
PRESSURE
OUT-OF-RANGE
1284
PRESSURE
IN-RANGE
1280
MONITOR PRESSURE
OK LED BLINK,
DRESSING LED OFF
1288a
1288b

FIG. 26

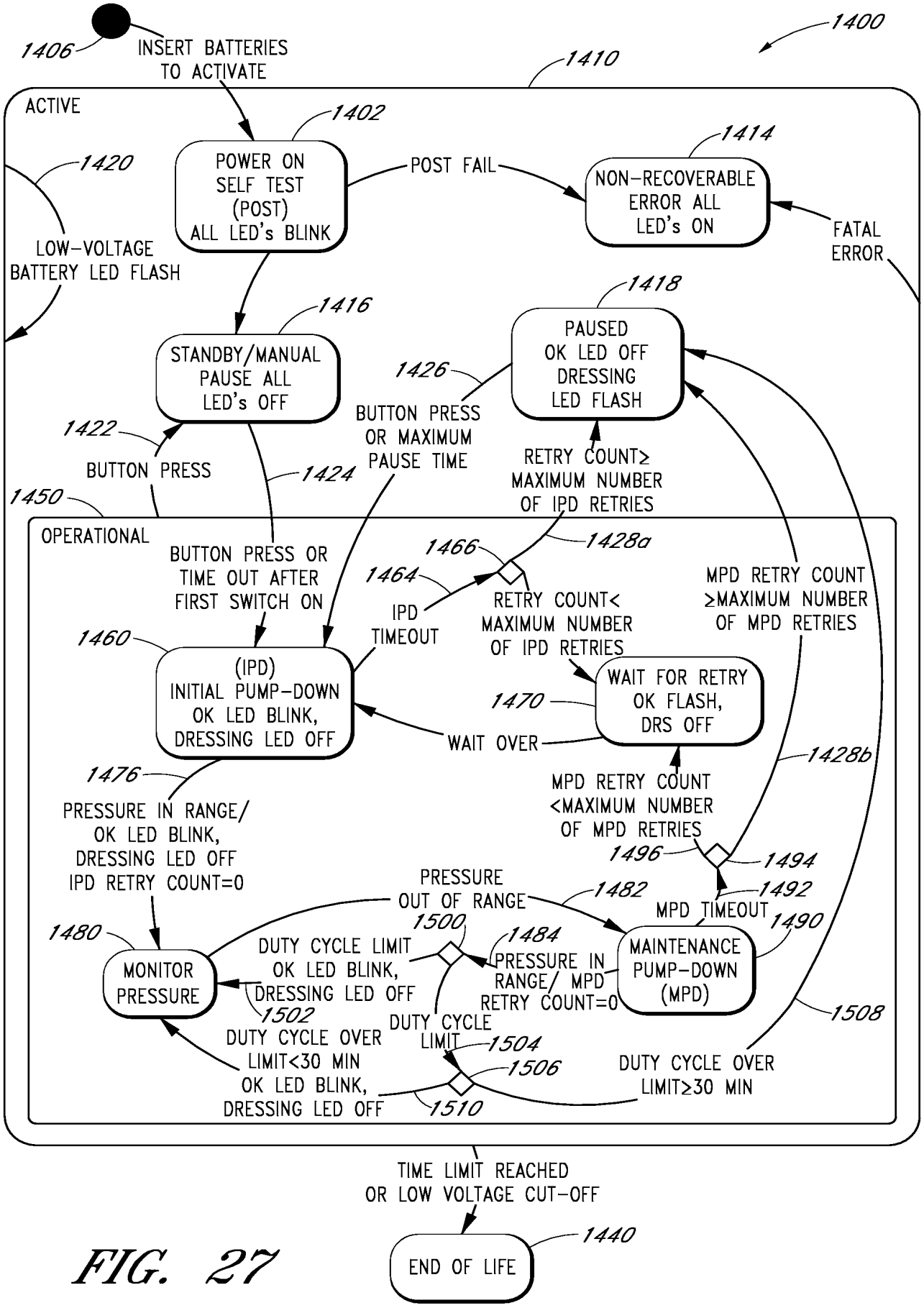

1400
1406
INSERT BATTERIES TO ACTIVATE
1410
ACTIVE
1402
POWER ON SELF TEST (POST) ALL LED's BLINK
POST FAIL
1414
NON-RECOVERABLE ERROR ALL LED's ON
FATAL ERROR
1420
LOW-VOLTAGE BATTERY LED FLASH
1418
PAUSED OK LED OFF DRESSING LED FLASH
1426
BUTTON PRESS OR MAXIMUM PAUSE TIME
1416
STANDBY/MANUAL PAUSE ALL LED's OFF
1422
BUTTON PRESS
1424
RETRY COUNT≥ MAXIMUM NUMBER OF IPD RETRIES
1450
OPERATIONAL
BUTTON PRESS OR TIME OUT AFTER FIRST SWITCH ON
1466
1428a
1464
IPD TIMEOUT
RETRY COUNT< MAXIMUM NUMBER OF IPD RETRIES
MPD RETRY COUNT ≥MAXIMUM NUMBER OF MPD RETRIES
1460
(IPD) INITIAL PUMP-DOWN OK LED BLINK, DRESSING LED OFF
1470
WAIT FOR RETRY OK FLASH, DRS OFF
WAIT OVER
1428b
1476
PRESSURE IN RANGE/ OK LED BLINK, DRESSING LED OFF IPD RETRY COUNT=0
MPD RETRY COUNT <MAXIMUM NUMBER OF MPD RETRIES
1496
1494
PRESSURE OUT OF RANGE
1482
1492
MPD TIMEOUT
1500
1490
1480
DUTY CYCLE LIMIT OK LED BLINK, DRESSING LED OFF
1484
PRESSURE IN RANGE/ MPD RETRY COUNT=0
MAINTENANCE PUMP-DOWN (MPD)
MONITOR PRESSURE
1502
1508
DUTY CYCLE LIMIT
1504
DUTY CYCLE OVER LIMIT<30 MIN OK LED BLINK, DRESSING LED OFF
1506
DUTY CYCLE OVER LIMIT≥30 MIN
1510
TIME LIMIT REACHED OR LOW VOLTAGE CUT-OFF
1440
END OF LIFE

FIG. 27

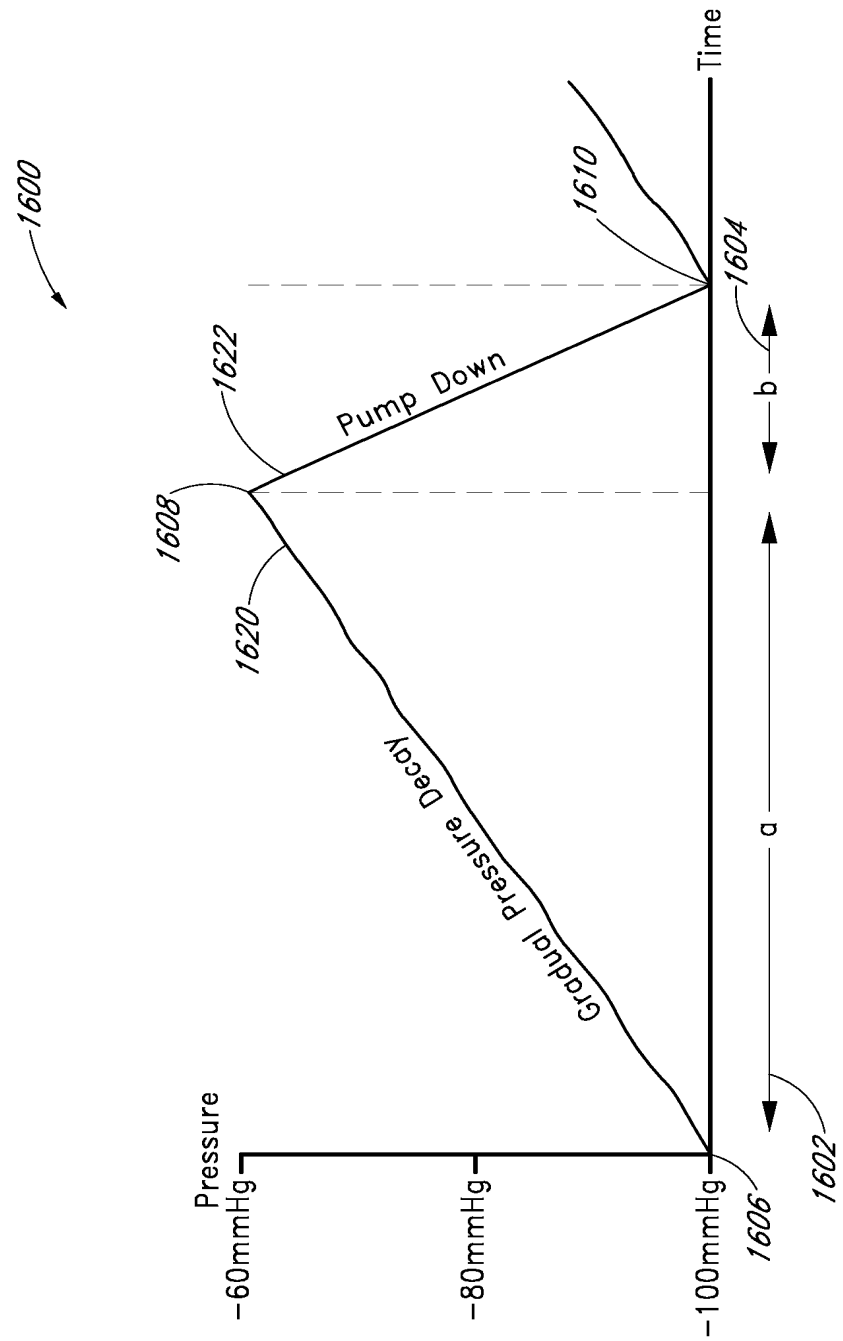

1600
Time
1610
1604
1622
Pump Down
b
1608
1620
Gradual Pressure Decay
a
Pressure
−60mmHg
−80mmHg
−100mmHg
1606
1602

FIG. 28

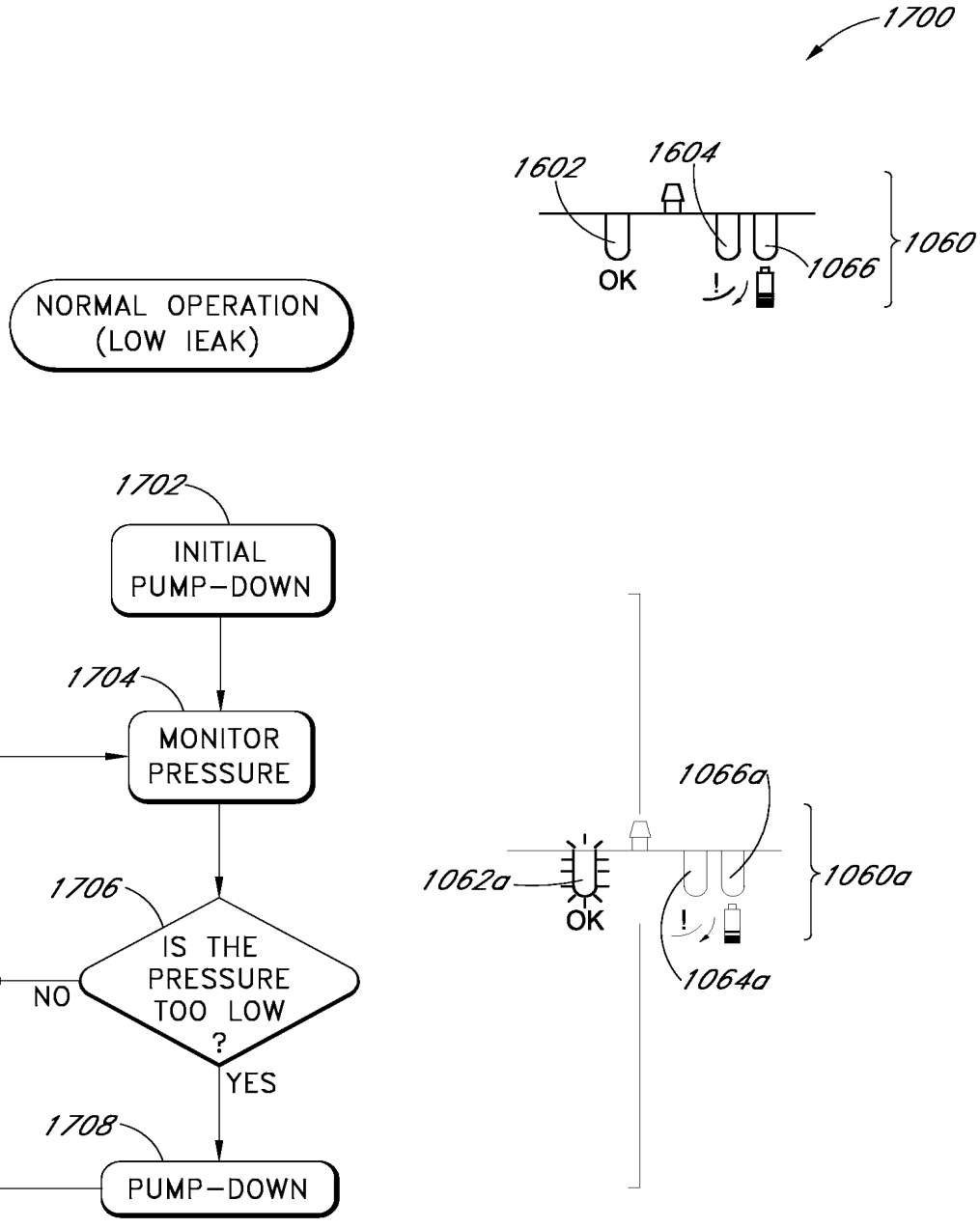
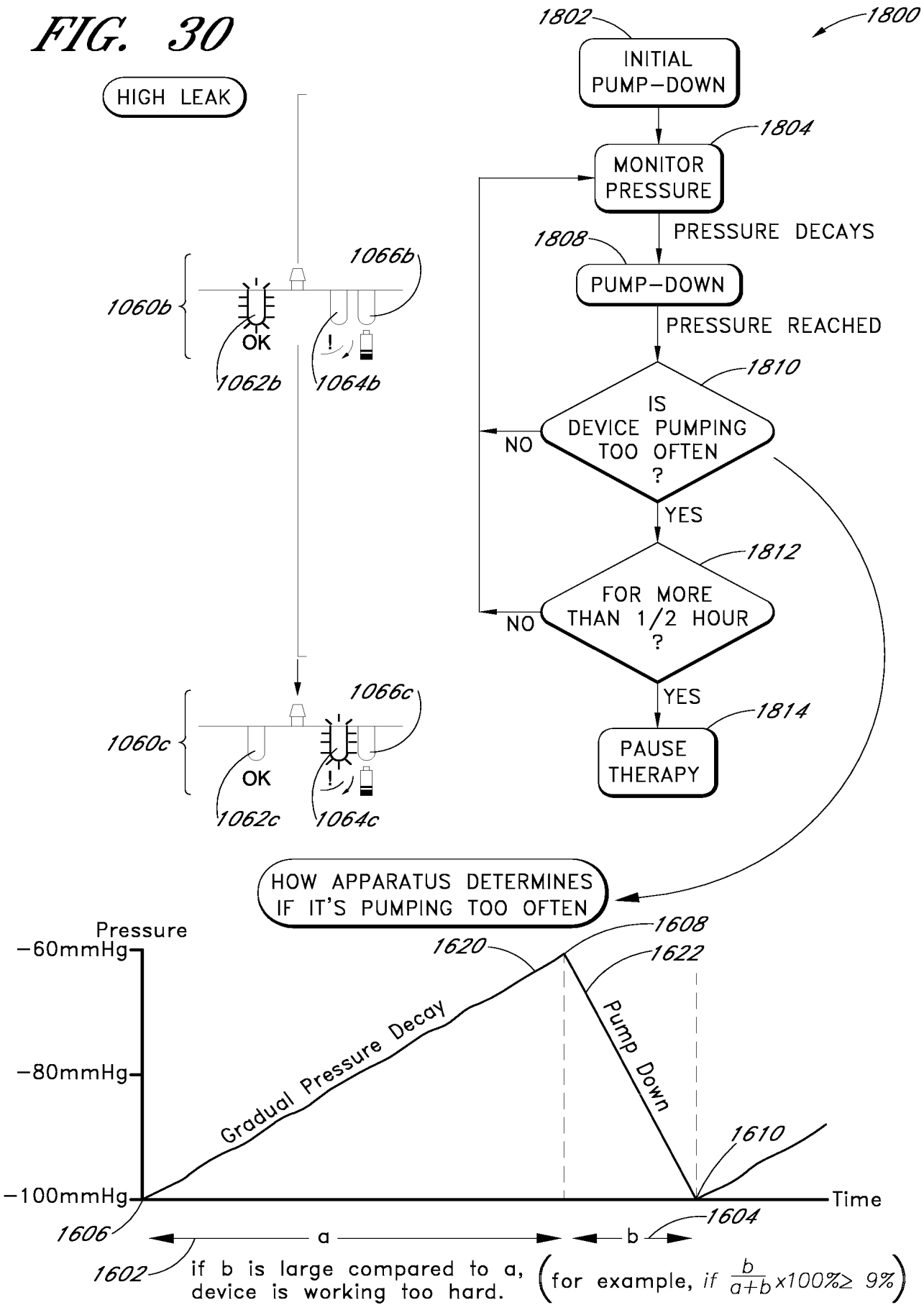

1700
1602
1604
OK
1066
1060
NORMAL OPERATION
(LOW IEAK)
1702
INITIAL
PUMP-DOWN
1704
MONITOR
PRESSURE
1706
IS THE
PRESSURE
TOO LOW
?
NO
YES
1708
PUMP-DOWN
1066a
1062a
OK
1060a
1064a

FIG. 29

FIG. 30


HIGH LEAK
1060b
1066b
OK
1062b
1064b
1060c
1066c
OK
1062c
1064c
1800
1802
INITIAL PUMP-DOWN
1804
MONITOR PRESSURE
PRESSURE DECAYS
1808
PUMP-DOWN
PRESSURE REACHED
1810
IS DEVICE PUMPING TOO OFTEN ?
NO
YES
1812
FOR MORE THAN 1/2 HOUR ?
NO
YES
1814
PAUSE THERAPY
HOW APPARATUS DETERMINES IF IT'S PUMPING TOO OFTEN
Pressure
-60mmHg
-80mmHg
-100mmHg
1608
1620
1622
Gradual Pressure Decay
Pump Down
1610
Time
1606
1604
a
b
1602
if b is large compared to a, device is working too hard.
(for example, if $\frac{b}{a+b} \times 100\% \geq 9\%$)

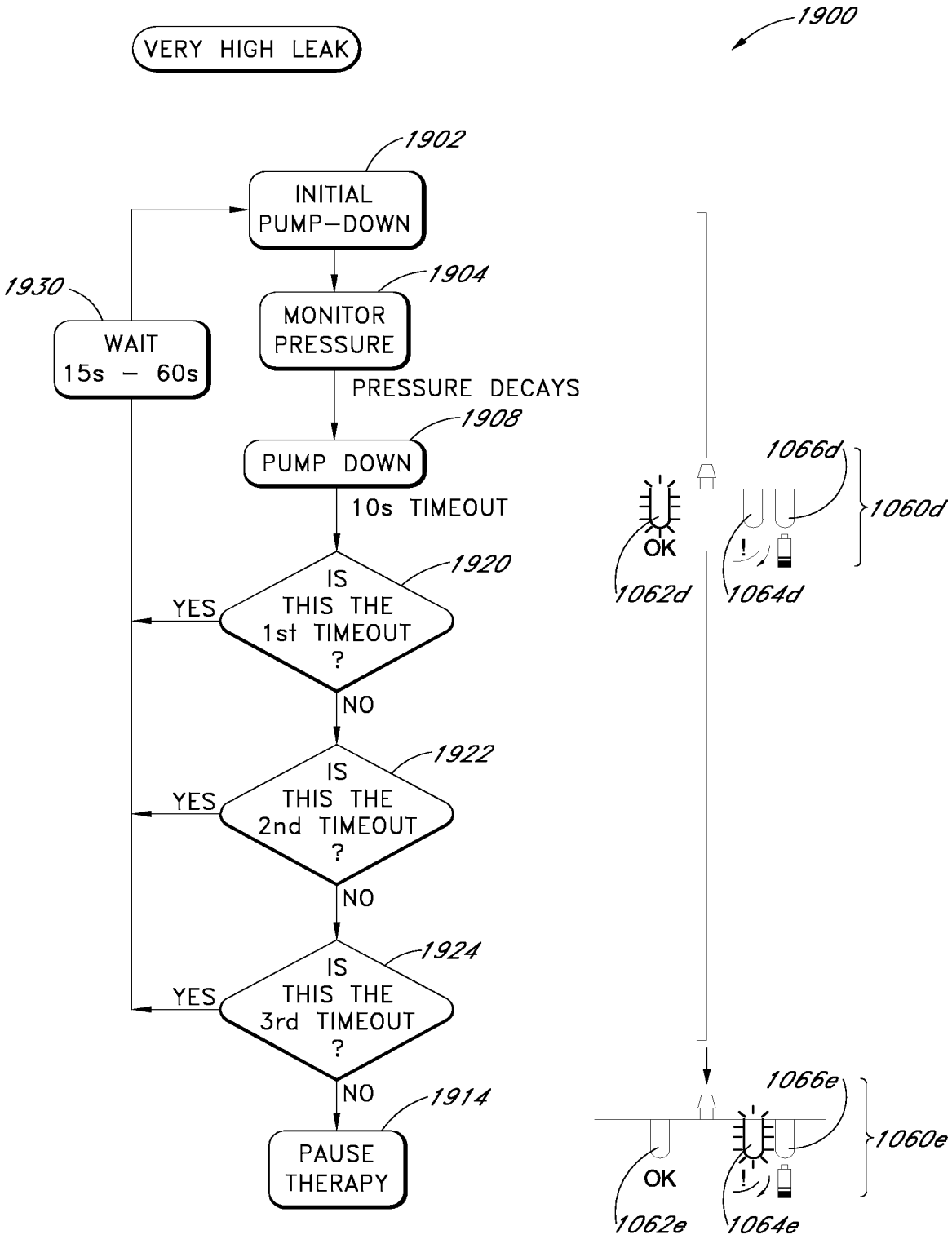

1900
VERY HIGH LEAK
1902
INITIAL PUMP–DOWN
1904
MONITOR PRESSURE
PRESSURE DECAYS
1908
PUMP DOWN
10s TIMEOUT
1920
IS THIS THE 1st TIMEOUT ?
YES
NO
1922
IS THIS THE 2nd TIMEOUT ?
YES
NO
1924
IS THIS THE 3rd TIMEOUT ?
YES
NO
1914
PAUSE THERAPY
1930
WAIT 15s – 60s
1066d
1060d
OK
!
1062d
1064d
1066e
1060e
OK
!
1062e
1064e

FIG. 31

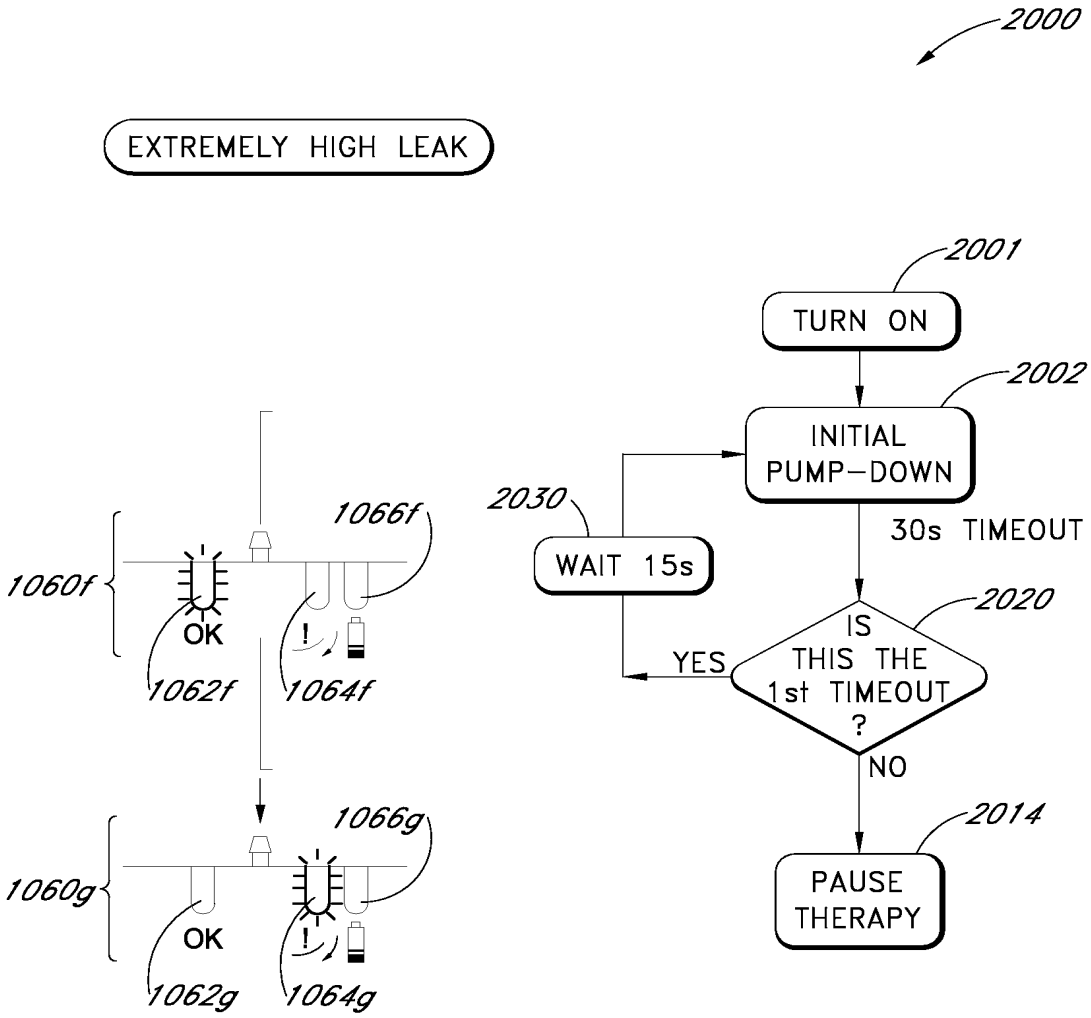

2000
EXTREMELY HIGH LEAK
2001
TURN ON
2002
INITIAL PUMP-DOWN
30s TIMEOUT
2030
WAIT 15s
2020
IS THIS THE 1st TIMEOUT ?
YES
NO
2014
PAUSE THERAPY
1066f
1060f
OK
!
1062f
1064f
1066g
1060g
OK
!
1062g
1064g

FIG. 32

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/002943

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61L2/00 A61M1/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M A61L F04B F04C F04D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/125004 A1 (SHEN TE-YANG [TW] ET AL) 14 May 2009 (2009-05-14) paragraphs [0001], [0025], [0029] - [0030], [0035]; claim 4; figures 2,4	1-10,21, 22
A	US 4 643 641 A (CLAUSEN EARL W [US] ET AL) 17 February 1987 (1987-02-17) the whole document	1-10,21, 22
A	WO 2010/126444 A1 (MOELNLYCKE HEALTH CARE AB [SE]; JOHANNISON ULF [SE]) 4 November 2010 (2010-11-04) the whole document	1-10,21, 22

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 December 2012	28/01/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Westsson, David

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/057307 A1 (HILL ROM SERVICES INC [US]; LOCKWOOD JEFFREY S [US]; PETROSENKO ROBERT) 17 July 2003 (2003-07-17) page 15, line 32 - page 16, line 56; figures 1,4	11-20
A	WO 2010/093753 A1 (PERFUZIA MEDICAL INC [US]; BRINK-DANAN SAGI [US]; SCHUBERT SHAI Y [US]) 19 August 2010 (2010-08-19) paragraphs [0063], [0089]	11-15
X	WO 2009/047524 A2 (TALLEY GROUP LTD [GB]; BYBORDI FARHAD [US]) 16 April 2009 (2009-04-16) page 9, lines 13-29; figures 1, 2a-b, 3a-d	11-20
A	US 4 969 880 A (ZAMIEROWSKI DAVID S [US]) 13 November 1990 (1990-11-13) column 5, lines 20-28	11
A	US 2011/257572 A1 (LOCKE CHRISTOPHER BRIAN [GB] ET AL) 20 October 2011 (2011-10-20) paragraphs [0030] - [0031]; figures 2,3	16-18, 35-37,51
X	WO 2009/089390 A2 (BLUESKY MEDICAL GROUP INC [US]; SMITH & NEPHEW [GB]; WESTON RICHARD SC) 16 July 2009 (2009-07-16) paragraph [0030]; figure 4a	25-49, 66-85
A	WO 2008/135997 A2 (ADAHAN CARMELI [IL]) 13 November 2008 (2008-11-13) page 22, line 23 - page 23, line 3	25
A	WO 2007/087811 A1 (COLOPLAST AS [DK]; NIELSEN BRIAN [DK]; FREDERIKSEN JESPER MADS BARTRO) 9 August 2007 (2007-08-09) page 12, lines 20-32; figure 1	25
X	WO 2011/087871 A2 (SMITH & NEPHEW INC [US]; ALBERT SEAN [US]; ARMSTRONG ED [US]; BEAUDOIN) 21 July 2011 (2011-07-21) paragraphs [0118], [0142], [0155]	50-65
A	WO 2006/046060 A2 (SMITH & NEPHEW [GB]; MARTIN ROBIN [GB]) 4 May 2006 (2006-05-04) paragraph [0058]	52
A	US 2009/292264 A1 (HUDSPETH MICHAEL D [US] ET AL) 26 November 2009 (2009-11-26) paragraphs [0035] - [0036]; figure 1	52
A	US 2009/012441 A1 (MULLIGAN SHARON [US]) 8 January 2009 (2009-01-08) paragraph [0033]; figure 1	66

-/--

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2007/219532 A1 (KARPOWICZ JOHN [US] ET AL) 20 September 2007 (2007-09-20) paragraph [0055]	66

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2011/002943

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 23, 24, 86-88
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-10, 21, 22

   A pump assembly comprising: a pump having a first valve at the inlet and second valve at the outlet; a flow path; a one-way flow valve configured to substantially prevent a flow of gas through the flow path away from the pump.

   ---

2. claims: 11-20

   A pump assembly as in the first group of claims additionally comprising a dressing, one or more batteries and a first and second packaging element.

   ---

3. claims: 25-49

   A negative pressure therapy kit comprising a pump assembly comprising: a pump having at least one valve configured to control the flow through at least one of the inlet and the outlet; a controller; at least one switch button in communication with the controller; a first packaging element.

   ---

4. claims: 50-65

   A negative pressure therapy kit comprising: a pump assembly having a flow rate of approx. 350 ml/min or less; a dressing with a cover layer and a wound contact layer covered with a silicone based adhesive.

   ---

5. claims: 66-88

   A canisterless pump assembly comprising; a pump having a first and second valve controlling the flow at the inlet and outlet respectively, wherein the leakage rate of the valves is between approx. 5-10 ml/min at nominal working pressure.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 23, 24, 86-88

Claims 23-24 refer to a method for treatment of the human or animal body by therapy, which is against Rule 39.1(iv) PCT and Rule 67.1(iv). The reason is that they include the step of delivering negative pressure to a wound. Claims 86-88 refer to a method for treatment of the human or animal body by therapy, which is against Rule 39.1(iv) PCT and Rule 67.1(iv). The reason is that they include the step applying a sterile dressing over a wound and reducing a level of pressure between the dressing and the wound.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2011/002943

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2009125004 A1	14-05-2009	TW 200920418 A	16-05-2009
		US 2009125004 A1	14-05-2009
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		CA 2468309 A1	17-07-2003
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		JP 3152398 B2	03-04-2001
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		AU 2011239552 A1	29-11-2012
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		WO 2011130549 A1	20-10-2011
		WO 2011130570 A1	20-10-2011
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		AU 2009204140 A1	16-07-2009
		CA 2711620 A1	16-07-2009

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2011/002943

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		DK 2242522 T3	18-06-2012
		EP 2242522 A2	27-10-2010
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最終頁に続く

(54)【発明の名称】減圧治療装置及びその使用方法

(57)【要約】
幾つかの実施形態は、ハウジングと、ポンプを通る流路と、流路と連通する１つ又は複数の弁と、ハウジング内で又はハウジングによって支持されるポンプと、ポンプと流体連通する一方向フロー弁とを備える減圧創傷治療用のポンプアセンブリを備える。ポンプアセンブリは、ポンプを通る流路と連通する圧力センサ、及びハウジングによって支持される少なくとも１つのスイッチ又はボタンを有することができ、少なくとも１つスイッチ又はボタンがユーザにとってアクセス可能であり、コントローラと連通している。一方向フロー弁は、ポンプから離れるフロー方向で一方向フロー弁を通ってガスが流れるのを実質的に防ぐように構成することができる。ポンプアセンブリは、ハウジング内で又はハウジングによって支持され、ポンプの動作を制御するように構成されているコントローラを有することができる。ポンプは、ハウジングの内部及び外部、流路、１つ又は複数の弁、ポンプ、コントローラ、電池区画、及び少なくとも１つのスイッチ又はボタンが滅菌されたものであるようにポンプの組み立てに続いて滅菌される。

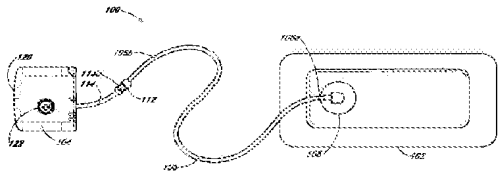


FIG. 1

【特許請求の範囲】
【請求項１】
ハウジングと、
前記ハウジング内で又はハウジングによって支持されるポンプとを備える減圧創傷治療用のポンプアセンブリにおいて、前記ポンプが、
モータと、
入口及び出口と、
前記入口を通る流体のフローを制御するように構成された第１の弁と、
前記出口を通る流体のフローを制御するように構成された第２の弁と、
前記ポンプアセンブリを通る流路と、
前記ポンプと流体連通し、前記ポンプから離れるフロー方向で前記流路を通ってガスが流れるのを実質的に防ぐように構成されている一方向フロー弁と
を備える、ポンプアセンブリ。
【請求項２】
前記ポンプアセンブリが無容器型である、請求項１に記載のポンプアセンブリ。
【請求項３】
前記ハウジング内で又は前記ハウジングによって支持されるコントローラであって、前記ポンプの動作を制御するように構成されているコントローラをさらに備える、請求項１又は２に記載のポンプアセンブリ。
【請求項４】
前記流路と連通している圧力センサをさらに備える、請求項１から３のいずれか一項に記載のポンプアセンブリ。
【請求項５】
前記ハウジングによって支持される１つのみのスイッチ又はボタンをさらに備え、前記少なくとも１つのスイッチ又はボタンがユーザにとってアクセス可能であり、コントローラと連通していることができる、請求項１から４のいずれか一項に記載のポンプアセンブリ。
【請求項６】
前記第１の弁及び前記第２の弁が、公称の動作圧力で約０．１ｍＬ／分及び１０ｍＬ／分の速度で漏れる、請求項、請求項１から５のいずれか一項に記載のポンプアセンブリ。
【請求項７】
前記ポンプアセンブリが、前記ハウジングの少なくとも内部及び外部、前記流路、前記第１及び第２の弁、及び前記ポンプが滅菌されたものであるように滅菌される、請求項１から６のいずれか一項に記載のポンプアセンブリ。
【請求項８】
前記ハウジングによって支持される１つ又は複数のＬＥＤライトをさらに備える、請求項１から７のいずれか一項に記載のポンプアセンブリ。
【請求項９】
前記ポンプアセンブリが１つ又は複数の電池を備え、前記１つ又は複数の電池の重量を含めて８０ｇと９０ｇの間の重量である、請求項１から８のいずれか一項に記載のポンプアセンブリ。
【請求項１０】
前記ポンプアセンブリの外表面が６０立方センチメートルと８０立方センチメートルの間の体積を画成する、請求項１から９のいずれか一項に記載のポンプアセンブリ。
【請求項１１】
陰圧治療キットであって、
請求項１から１０のいずれか一項に記載の前記ポンプアセンブリと、
包帯と、
前記包帯及び前記ポンプアセンブリと連結可能であり、前記包帯までの減圧の流体経路を提供するように構成された導管と、

１つ又は複数の電池と、
第１のパッケージング要素、及び前記第１のパッケージング要素と取外し可能に連結されるように構成された第２のパッケージング要素であって、前記第１及び第２のパッケージング要素の少なくとも一方は、前記ポンプアセンブリと、前記包帯と、前記導管と、前記１つ又は複数の電池とを受け入れるための陥凹部を有する第１及び第２のパッケージング要素と
を備える陰圧治療キット。
【請求項１２】
前記陰圧治療キットが、滅菌性であり、前記ポンプアセンブリ、前記包帯、前記導管、及び前記１つ又は複数の電池を、前記第１のパッケージング要素及び前記第２のパッケージング要素の少なくとも一方の内部で支持した後に滅菌される、請求項１１に記載の陰圧治療キット。
【請求項１３】
１つ又は複数の接着剤シールストリップをさらに備える、請求項１１又は１２に記載の陰圧治療キット。
【請求項１４】
前記１つ又は複数の電池が、前記ハウジングの外部で支持される、請求項１１から１３のいずれか一項に記載の陰圧治療キット。
【請求項１５】
前記陰圧治療キットが酸化エチレンによって滅菌される、請求項１１から１４のいずれか一項に記載の陰圧治療キット。
【請求項１６】
前記包帯が、
透過層と、
創傷浸出物を吸収するための吸収性層であって、前記透過層を覆う吸収性層と、
前記吸収性層を覆い、そこを通るオリフィスを備えるカバー層と
を備える、請求項１１から１５のいずれか一項に記載の陰圧治療キット。
【請求項１７】
前記包帯が、創傷部位に局所陰圧を加えるために前記包帯に陰圧を加えるための吸気ポートを備える、請求項１１から１６のいずれか一項に記載の陰圧治療キット。
【請求項１８】
前記吸気ポートが、前記吸気ポートを前記ポンプアセンブリに接続するためのコネクタ部分、及び前記吸気ポートを前記包帯のカバー層にシールするためのシール面を備える、請求項１７に記載の陰圧治療キット。
【請求項１９】
前記包帯が、液体がコネクタ部分に入るのを防ぐようになされた液体不透過性ガス透過性フィルタ要素を備える、請求項１１から１８のいずれか一項に記載の陰圧治療キット。
【請求項２０】
前記第１のパッケージング要素がＰＥＴＧを備える、請求項１１から１９のいずれか一項に記載の陰圧治療キット。
【請求項２１】
陰圧治療システムであって、
請求項１から１０のいずれか一項に記載の前記ポンプアセンブリと、
包帯と
を備える陰圧治療システム。
【請求項２２】
前記包帯の創傷に向く面が、前記創傷を取り囲む皮膚と漏れ量の少ないシールを形成するように構成されたシリコーン系接着剤によって少なくとも部分的に覆われている、請求項２１に記載の陰圧治療キット。
【請求項２３】

陰圧を用いて創傷を治療する方法であって、
包帯を用意するステップと、
前記創傷の上に実質的に液密のシールを形成するように前記創傷の上に前記包帯を当てるステップと、
請求項１から１０のいずれか一項に記載の前記ポンプアセンブリを使用して前記包帯を通して前記創傷に陰圧を送達するステップと
を含む方法。
【請求項２４】
創傷の上に実質的に液密のシールを形成するように前記創傷の上に包帯を当てるステップ、及び請求項１から１０のいずれか一項に記載の前記ポンプアセンブリを使用して前記包帯を通して創傷に陰圧を送達するステップが、手術ルームで行われる、請求項２３に記載の陰圧を用いて創傷を治療する方法。
【請求項２５】
ポンプアセンブリであって、
ハウジングと、
ポンプモータ、
入口及び出口、
前記入口及び前記出口のうちの少なくとも１つを通して流体のフローを制御するように構成された少なくとも１つの弁、及び
少なくとも前記入口、前記出口、及び前記少なくとも１つの弁を通る流路
を備えるハウジング内で支持されるポンプと、
前記ハウジング内で又は前記ハウジングによって支持されるコントローラであって、前記ポンプ及び前記弁の動作を制御するように構成されているコントローラと、
少なくとも１つのスイッチ又はボタンであって、前記ハウジングで支持され、前記コントローラと連通し、ユーザがポンプの１つ又は複数の動作モードを制御できるように、ユーザにとってアクセス可能である少なくとも１つのスイッチ又はボタンと
を備えるポンプアセンブリと、
創傷の上に実質的に液密のシールを形成するように構成された包帯と、
前記包帯及び前記ポンプアセンブリと連結可能であり、前記ポンプアセンブリから前記包帯までの実質的に又は完全に包囲された流体流路を設けるように構成された導管と、
前記ポンプアセンブリ、前記１つ又は複数の電池、前記包帯、及び前記導管をパッケージングするための第１のパッケージング要素と
を備える、減圧創傷治療用の陰圧治療キットにおいて、
前記陰圧治療キットが、前記ハウジングの少なくとも内部及び外部、前記少なくとも１つの弁、前記ポンプ、前記コントローラ、及び前記少なくとも１つのスイッチ又はボタンが滅菌されたものであるように滅菌される、減圧創傷治療用の陰圧治療キット。
【請求項２６】
１つ又は複数の接着剤シールストリップをさらに備える、請求項２５に記載の陰圧治療キット。
【請求項２７】
動力を少なくとも前記ポンプ及びコントローラに供給するように構成された１つ又は複数の電池をさらに備える、請求項２１から２６のいずれか一項に記載の陰圧治療キット。
【請求項２８】
第１のパッケージング要素と連結するように構成された第２のパッケージング要素をさらに備え、前記第１のパッケージング要素が、前記ポンプアセンブリ、前記１つ又は複数の電池、前記包帯、導管、及び１つ又は複数の接着剤シールストリップのうちの１つ又は複数を受け入れるための複数の陥凹部を有する、請求項２７に記載の陰圧治療キット。
【請求項２９】
前記第２のパッケージング要素が、滅菌ガスに対して透過性であり、細菌に対して不透過性である、請求項２８に記載の陰圧治療キット。

【請求項３０】
第１のパッケージング要素が前記１つ又は複数の電池を支持し、それによって前記陰圧治療キットの滅菌処理中に前記１つ又は複数の電池が前記ハウジングの外部で支持される、請求項２５から２９のいずれか一項に記載の陰圧治療キット。
【請求項３１】
前記ポンプが、ダイヤフラムポンプ、回転ダイヤフラムポンプ、又は圧電ポンプである、請求項２５から３０のいずれか一項に記載の陰圧治療キット。
【請求項３２】
前記陰圧治療キットが酸化エチレンによって滅菌される、請求項２５から３１のいずれか一項に記載の陰圧治療キット。
【請求項３３】
前記少なくとも１つの弁が、滅菌プロセスの際に前記少なくとも１つの弁を通る滅菌ガスのフローを可能にするように構成された、請求項２５から３２のいずれか一項に記載の陰圧治療キット。
【請求項３４】
前記ポンプアセンブリが、フローマニホルドをさらに備え、前記フローマニホルドが、圧力センサ、前記ポンプ、及び導管、導管用コネクタのうちの少なくとも１つと流体連通している、請求項２５から３３のいずれか一項に記載の陰圧治療キット。
【請求項３５】
マニホルドによって支持された一方向フロー弁をさらに備える、請求項３４に記載の陰圧治療キット。
【請求項３６】
前記ポンプと前記包帯の間に位置付けられた一方向フロー弁を備え、前記一方向フロー弁が、前記ポンプから前記包帯に向かうフロー方向で前記一方向フロー弁を通るガスの前記フローを実質的に防ぐように構成されている、請求項２５から３５のいずれか一項に記載の陰圧治療キット。
【請求項３７】
前記一方向フロー弁が、前記ハウジング内で支持される、請求項３６に記載の陰圧治療キット。
【請求項３８】
前記ポンプと前記包帯の間、又は前記ポンプアセンブリ内で流体流路内のガスの圧力レベルを監視するように構成された圧力センサをさらに備える、請求項２５から３７のいずれか一項に記載の陰圧治療キット。
【請求項３９】
第１のパッケージング要素にパッケージングされた場合に導管の一方の端部が前記包帯に接続される、請求項２５から３８のいずれか一項に記載の陰圧治療キット。
【請求項４０】
導管が第１の端部及び第２の端部を備え、前記第１の端部が前記包帯に接続され、又は接続可能であり、前記第２の端部が前記ハウジングと連結するように構成されたコネクタを備える、請求項２５から３９のいずれか一項に記載の陰圧治療キット。
【請求項４１】
前記ハウジングがシールされない、請求項２５から４０のいずれか一項に記載の陰圧治療キット。
【請求項４２】
前記ポンプアセンブリが容器を備えない、請求項２５から４１のいずれか一項に記載の陰圧治療キット。
【請求項４３】
前記ポンプによって生成される雑音及び振動を低減するため前記ポンプの少なくとも一部分を取り囲む、解放した発泡体層をさらに備える、請求項２５から４２のいずれか一項に記載の陰圧治療キット。

【請求項４４】
前記包帯が、
透過層と、
創傷浸出物を吸収するための吸収性層であって、前記透過層を覆う吸収性層と、
前記吸収性層を覆うカバー層と、
導管の端部を受け入れるための吸気ポートと、
液体が前記吸気ポートを通過するのを防ぐようになされた液体不透過性ガス透過性フィルタ要素と
を備える、請求項２５から４３のいずれか一項に記載の陰圧治療キット。
【請求項４５】
前記ポンプアセンブリが、前記ハウジングにより支持され、又は前記ハウジング内に形成された電池区画を備える、請求項２５から４４のいずれか一項に記載の陰圧治療キット。
【請求項４６】
前記陰圧治療キットが、創傷を取り囲む皮膚と漏れ量の少ないシールを形成するように構成されたシリコーン系接着剤を有する創傷包帯を備え、前記ポンプアセンブリが前記１つ又は複数の電池の重量を含めて７０ｇと９０ｇの間の重量である、請求項２５から４５のいずれか一項に記載の陰圧治療キット。
【請求項４７】
前記ポンプアセンブリが、前記１つ又は複数の電池の重量を含めて７０ｇと９０ｇの間の重量である、請求項２５から４６のいずれか一項に記載の陰圧治療キット。
【請求項４８】
前記ポンプアセンブリの外表面が、約３立方インチ（４９．１６立方センチメートル）から約５立方インチ（８１．９４立方センチメートル）の体積を画成する、請求項２５から４７のいずれか一項に記載の陰圧治療キット。
【請求項４９】
前記陰圧治療キットが、シールストリップを第１のパッケージング要素から除去できる前に、前記包帯を前記第１のパッケージング要素から除去しなければならないように構成される、請求項２５から４８のいずれか一項に記載の陰圧治療キット。
【請求項５０】
約３５０ｍＬ／分以下の流量を有するポンプを備えるポンプアセンブリと、
カバー層を備える包帯であって、シリコーン系接着剤によって覆われている創傷接触面を有する包帯と
を備える、減圧創傷治療用の陰圧治療キット。
【請求項５１】
前記ポンプアセンブリが前記ポンプと流体連通している一方向フロー弁を備え、前記一方向フロー弁が前記ポンプから離れるフロー方向で流路を通ってガスが流れるのを実質的に防ぐように構成されている、請求項５０に記載された陰圧治療キット。
【請求項５２】
前記包帯が、前記包帯に陰圧を加えたときに開いたままであるように構成された３Ｄ編成材料又は布地材料を備える透過層を備える、請求項５０又は５１に記載の陰圧治療キット。
【請求項５３】
前記包帯が創傷浸出物を吸収するための吸収性層を備え、前記吸収性層が透過層を覆う、請求項５０から５２のいずれか一項に記載の陰圧治療キット。
【請求項５４】
前記包帯が、吸収性層を覆うカバー層を備え、オリフィスを備え、前記カバー層が水蒸気透過性である、吸収性層が透過層を覆う、請求項５０から５３のいずれか一項に記載の陰圧治療キット。
【請求項５５】

前記包帯が、創傷部位に局所陰圧を加えるために、陰圧を前記包帯に加えるための吸気ポートを備え、前記吸気ポートが、前記吸気ポートを前記ポンプアセンブリに接続するためのコネクタ部分、及び前記吸気ポートを前記包帯の前記カバー層にシールするためのシール面を備える、請求項５０から５４のいずれか一項に記載の陰圧治療キット。

【請求項５６】

前記包帯が、液体がコネクタ部分に入るのを防ぐようになされた液体不透過性ガス透過性フィルタ要素を備える、請求項５０から５５のいずれか一項に記載の陰圧治療キット。

【請求項５７】

前記ポンプアセンブリが無容器型である、請求項５０から５６のいずれか一項に記載の陰圧治療キット。

【請求項５８】

前記ポンプアセンブリのハウジング内で又は前記ポンプアセンブリのハウジングによって支持されるコントローラであって、前記ポンプの動作を制御するように構成されているコントローラをさらに備える、請求項５０から５７のいずれか一項に記載の陰圧治療キット。

【請求項５９】

前記ポンプアセンブリを通る流路と連通している圧力センサをさらに備える、請求項５０から５８のいずれか一項に記載の陰圧治療キット。

【請求項６０】

前記ポンプアセンブリのハウジングによって支持される少なくとも１つのスイッチ又はボタンをさらに備え、前記少なくとも１つスイッチ又はボタンがユーザにとってアクセス可能であり、コントローラと連通していることができる、請求項５０から５９のいずれか一項に記載の陰圧治療キット。

【請求項６１】

前記ポンプアセンブリにより支持された電池区画をさらに備える、請求項５０から６０のいずれか一項に記載の陰圧治療キット。

【請求項６２】

前記ポンプアセンブリの少なくとも内部及び外部が滅菌されているように、前記ポンプアセンブリが、前記ポンプアセンブリの組み立てに続いて滅菌される、請求項５０から６１のいずれか一項に記載の陰圧治療キット。

【請求項６３】

前記ポンプアセンブリが１つ又は複数のＬＥＤライトを有する、請求項５０から６２のいずれか一項に記載の陰圧治療キット。

【請求項６４】

前記ポンプアセンブリが、１つ又は複数の電池を備え、前記１つ又は複数の電池の重量を含めて８０ｇと９０ｇの間の重量である、請求項５０から６３のいずれか一項に記載の陰圧治療キット。

【請求項６５】

前記ポンプアセンブリの外表面が６０立方センチメートルと８０立方センチメートルの間の体積を画成する、請求項５０から６４のいずれか一項に記載の陰圧治療キット。

【請求項６６】

減圧創傷治療用の無容器型ポンプアセンブリであって、

ハウジングと、

ハウジング内で又はハウジングによって支持されるポンプとを備えるポンプアセンブリにおいて、前記ポンプが、

モータと、

入口及び出口と、

前記入口を通る流体のフローを制御するように構成された第１の弁と、

前記出口を通る流体のフローを制御するように構成された第２の弁と

を備える容器型ポンプアセンブリにおいて、

前記ポンプアセンブリが無容器型であり、
前記第１及び第２の弁が、それぞれ公称の動作圧力で約５Ｌ／分と約１０Ｌ／分の間の漏れ速度を有する、容器型ポンプアセンブリ。
【請求項６７】
前記ポンプアセンブリが前記ポンプと流体連通している一方向フロー弁を備え、前記一方向フロー弁が前記ポンプから離れるフロー方向で流路を通ってガスが流れるのを実質的に防ぐように構成された、請求項６６に記載のポンプアセンブリ。
【請求項６８】
前記ハウジング内で又は前記ハウジングによって支持されるコントローラであって、前記ポンプの動作を制御するように構成されているコントローラをさらに備える、請求項６６又は６７に記載のポンプアセンブリ。
【請求項６９】
前記ポンプアセンブリを通る流路と連通している圧力センサをさらに備える、請求項６６から６８のいずれか一項に記載のポンプアセンブリ。
【請求項７０】
前記ハウジングによって支持される少なくとも１つのスイッチ又はボタンをさらに備え、前記少なくとも１つスイッチ又はボタンがユーザにとってアクセス可能であり、コントローラと連通していることができる、請求項６６から６９のいずれか一項に記載のポンプアセンブリ。
【請求項７１】
前記ハウジングにより支持され、又は前記ハウジング内に形成された電池区画をさらに備える、請求項６６から７０のいずれか一項に記載のポンプアセンブリ。
【請求項７２】
前記ハウジングの少なくとも内部及び外部、流路、前記１つ又は複数の弁、及び前記ポンプが滅菌されたものであるように、前記ポンプアセンブリの組み立てに続いて滅菌される、請求項６６から７１のいずれか一項に記載のポンプアセンブリ。
【請求項７３】
前記ハウジングによって支持される１つ又は複数のＬＥＤライトをさらに備える、請求項６６から７２のいずれか一項に記載のポンプアセンブリ。
【請求項７４】
前記ポンプアセンブリが１つ又は複数の電池を備え、前記１つ又は複数の電池の重量を含めて８０ｇ及び９０ｇの重量である、請求項６６から７３のいずれか一項に記載のポンプアセンブリ。
【請求項７５】
前記ポンプアセンブリの外表面が６０立方センチメートルと８０立方センチメートルの間の体積を画成する、請求項６６から７４のいずれか一項に記載のポンプアセンブリ。
【請求項７６】
滅菌ポンプキットであって、
請求項６６から７５のいずれか一項に記載の前記ポンプアセンブリと、
包帯と、
前記包帯及び前記ポンプアセンブリと連結可能であり、前記包帯までの減圧の流体経路を提供するように構成された導管と、
１つ又は複数の電池と、
第１のパッケージング要素、及び前記第１のパッケージング要素と取外し可能に連結されるように構成された第２のパッケージング要素であって、前記第１及び第２のパッケージング要素の少なくとも一方は、前記ポンプアセンブリと、包帯と、前記包帯及び前記ポンプアセンブリと連結可能であり、前記包帯までの減圧の流体経路を提供するように構成された前記導管とを受け入れるための陥凹部を有する滅菌ポンプキットにおいて、
前記滅菌ポンプキットが、前記ポンプアセンブリ、前記包帯、前記導管、及び前記１つ又は複数の電池が、前記第１のパッケージング要素及び前記第２のパッケージング要素の

少なくとも一方の内部で支持された後に滅菌される、滅菌ポンプキット。
【請求項７７】
前記ポンプアセンブリ、前記包帯、前記導管、及び前記１つ又は複数の電池が滅菌される前に、前記ポンプアセンブリ、前記包帯、前記導管、及び前記１つ又は複数の電池が、前記第１のパッケージング要素及び前記第２のパッケージング要素の少なくとも一方の内部で支持される、請求項７６に記載の滅菌ポンプキット。
【請求項７８】
１つ又は複数の接着剤シールストリップをさらに備える、請求項７６又は７７に記載の滅菌ポンプキット。
【請求項７９】
前記１つ又は複数の電池が、前記ハウジングの外表面で支持される、請求項７６から７８のいずれか一項に記載の滅菌ポンプキット。
【請求項８０】
前記滅菌ポンプキットが酸化エチレンによって滅菌される、請求項７６から７９のいずれか一項に記載の滅菌ポンプキット。
【請求項８１】
前記包帯が、
透過層と、
創傷浸出物を吸収するための吸収性層であって、前記吸収性層が前記透過層を覆う吸収性層と、
前記吸収性層を覆うカバー層と
を備える請求項７６から８０のいずれか一項に記載の滅菌ポンプキット。
【請求項８２】
前記包帯が、創傷部位に局所陰圧を加えるために前記包帯に陰圧を加えるための吸気ポートを備える、請求項７６から８１のいずれか一項に記載の滅菌ポンプキット。
【請求項８３】
前記吸気ポートが、前記吸気ポートを前記ポンプアセンブリに接続するためのコネクタ部分、及び前記吸気ポートを前記包帯のカバー層にシールするためのシール面を備える、請求項８２に記載の滅菌ポンプキット。
【請求項８４】
前記包帯が、液体がコネクタ部分に入るのを防ぐようになされた液体不透過性ガス透過性フィルタ要素を備える、請求項７６から８３のいずれか一項に記載の滅菌ポンプキット。
【請求項８５】
前記第１のパッケージング要素がＰＥＴＧを備える、請求項７６から８４のいずれか一項に記載の滅菌ポンプキット。
【請求項８６】
手術ルームにおいて創傷の治療を開始するための方法であって、
創傷の上に滅菌包帯を当てて、前記創傷の上に実質的に液密のシールを作り出すステップと、
滅菌導管を介して滅菌ポンプアセンブリを包帯に連結するステップと、前記手術ルームで前記滅菌ポンプアセンブリを動作させることによって手術ルームで前記包帯と前記創傷との間の圧力レベルを低減するステップと
を含む、方法。
【請求項８７】
少なくとも１つの前記包帯の外周縁部の上に１つ又は複数のシールストリップを当てて、前記包帯と前記創傷を取り囲む皮膚の間の前記シールを改善するためのステップをさらに含む、請求項８６に記載の方法。
【請求項８８】
１つ又は複数の電池を第１のパッケージング要素から取り出すステップと、前記１つ又

は複数の電池を前記滅菌ポンプアセンブリに取り付けるステップをさらに含む、請求項８６又は８７に記載の方法。

【発明の詳細な説明】

【技術分野】

【０００１】

［参照による組込み］

本出願は、２０１１年４月２１日出願の（ＷＯＵＮＤ ＤＲＥＳＳＩＮＧ ＡＮＤ ＭＥＴＨＯＤ ＯＦ ＵＳＥという名称の）米国特許出願第１３／０９２，０４２号、２００８年５月２１日出願の（ＡＮＴＩＭＩＣＲＯＢＩＡＬ ＢＩＧＵＡＮＩＤＥ ＭＥＴＡＬ ＣＯＭＰＬＥＸＥＳという名称の）米国特許出願第１１／９２２，８９４号、２０１１年７月２６日出願の（ＭＥＴＨＯＤＳ ＡＮＤ ＡＰＰＡＲＡＴＵＳＥＳ ＦＯＲ ＤＥＴＥＣＴＩＮＧ ＬＥＡＫＳ ＡＮＤ ＣＯＮＴＲＯＬＬＩＮＧ ＰＵＭＰ ＯＰＥＲＡＴＩＯＮ ＩＮ Ａ ＮＥＧＡＴＩＶＥ ＰＲＥＳＳＵＲＥ ＷＯＵＮＤ ＴＨＥＲＡＰＹ ＳＹＳＴＥＭという名称の）米国特許仮出願第６１／５１１，９５０号、２０１１年４月２１日出願の（ＷＯＵＮＤ ＤＲＥＳＳＩＮＧという名称の）ＰＣＴ特許出願第ＰＣＴ／ＧＢ １１／０００６２２号、２０１１年４月２１日出願の（ＷＯＵＮＤ ＰＲＯＴＥＣＴＩＯＮという名称の）ＰＣＴ特許出願第ＰＣＴ／ＧＢ １１／０００６２１号、２０１１年４月２１日出願の（ＷＯＵＮＤ ＤＲＥＳＳＩＮＧという名称の）ＰＣＴ特許出願第ＰＣＴ／ＧＢ １１／０００６２５号、２０１１年４月２１日出願の（ＭＵＬＴＩ ＰＯＲＴ ＤＲＥＳＳＩＮＧという名称の）ＰＣＴ特許出願第ＰＣＴ／ＧＢ １１／０００６２６号、２０１１年４月２１日出願の（ＳＵＣＴＩＯＮ ＰＯＲＴという名称の）ＰＣＴ特許出願第ＰＣＴ／ＧＢ １１／０００６２８号、２０１１年９月１６日出願の（ＰＲＥＳＳＵＲＥ ＣＯＮＴＲＯＬ ＡＰＰＡＲＡＴＵＳという名称の）ＰＣＴ特許出願第ＰＣＴ／ＧＢ １１／０５１７４５号を参照によって組み込む。各及びすべての上記の特許出願は、その全体が参照によって本明細書に組み込まれ、本開示の一部分を成す。さらに、２０１１年１１月２日出願の「ＳＹＳＴＥＭＳ ＡＮＤ ＭＥＴＨＯＤＳ ＦＯＲ ＣＯＮＴＲＯＬＬＩＮＧ ＯＰＥＲＡＴＩＯＮ ＯＦ Ａ ＲＥＤＵＣＥＤ ＰＲＥＳＳＵＲＥ ＴＨＥＲＡＰＹ ＳＹＳＴＥＭ」という名称の同時係属中の特許出願第１３／ＸＸＸ，ＸＸＸ号（代理人整理番号ＳＭＮＰＨ．１９５Ａ）、及び２０１１年１１月２日出願の「ＳＹＳＴＥＭＳ ＡＮＤ ＭＥＴＨＯＤＳ ＦＯＲ ＣＯＮＴＲＯＬＬＩＮＧ ＯＰＥＲＡＴＩＯＮ ＯＦ Ａ ＲＥＤＵＣＥＤ ＰＲＥＳＳＵＲＥ ＴＨＥＲＡＰＹ ＳＹＳＴＥＭ」という名称の同時係属中のＰＣＴ特許出願第ＰＣＴ／ＵＳ１１／ＸＸＸ，ＸＸＸ号（代理人整理番号ＳＭＮＰＨ．１９４ＷＯ）もその全体があたかも本明細書に明記したごとく参照によって本明細書に組み込まれる。

【０００２】

本明細書に開示する実施形態は、局所陰圧（ＴＮＰ）療法を用いて創傷を包帯で処置し、治療するための方法及び装置に関する。例えば、ただし非限定的に、本明細書に開示する幾つかの実施形態は、ポンプキットから与えられる減圧を用いて創傷を治療することに関する。必須ではないが、ポンプキットの幾つかの実施形態は滅菌性とすることができる。別の非限定例として、本明細書に開示する幾つかの実施形態は、ＴＮＰシステムの動作を制御するための装置及び方法に関する。

【背景技術】

【０００３】

ヒト又は動物の治癒プロセスに役立つ、多くの異なるタイプの創傷包帯が知られている。これらの異なるタイプの創傷包帯としては、多くの異なるタイプの材料及び層、例えばガーゼ、パッド、フォームパッド、又は多層創傷包帯が挙げられる。局所陰圧（「ＴＮＰ」）療法は、真空補助閉鎖療法、陰圧創傷療法、又は減圧創傷療法と呼ばれることがあるが、創傷の治癒速度を改善するための有益な機序として広く認識されている。かかる療法は、切開創、開放創、及び腹部創など、広範囲の創傷に適用可能である。

【０００４】

ＴＮＰ療法は、組織浮腫を軽減し、血流を促進し、肉芽組織の形成を刺激し、過剰な浸出物を除去することによって、創傷の閉鎖及び治癒を支援し、また細菌負荷を、ひいては創傷に対する感染を低減し得る。さらに、ＴＮＰ療法は、創傷の外部障害（ｏｕｔｓｉｄｅ　ｄｉｓｔｕｒｂａｎｃｅ）をより少なくすることができ、より迅速な治癒を推進する。

【先行技術文献】
【特許文献】
【０００５】
【特許文献１】米国特許第７５５００３４号明細書
【特許文献２】米国特許出願公開第２０１１／１８６７６５号明細書
【特許文献３】米国特許出願第１３／０９２０４２号明細書
【特許文献４】英国特許出願第１０１５６５６．０号明細書
【特許文献５】英国特許出願第１００６９８６．２号明細書
【特許文献６】英国特許出願第１００６９８３．９号明細書
【特許文献７】英国特許出願第１００６９８５．４号明細書
【特許文献８】英国特許出願第１００６９８８．８号明細書
【特許文献９】英国特許出願第１００８３４７．５号明細書
【特許文献１０】米国特許出願第１１／９２２８９４号明細書
【特許文献１１】米国特許第７５２４３１５号明細書
【特許文献１２】米国特許第７７０８７２４号明細書
【特許文献１３】米国特許第７９０９８０５号明細書
【特許文献１４】米国特許出願公開第２００５／０２６１６４２号明細書
【特許文献１５】米国特許出願公開第２００７／０１６７９２６号明細書
【特許文献１６】米国特許出願公開第２００９／００１２４８３号明細書
【特許文献１７】米国特許出願公開第２００９／０２５４０５４号明細書
【特許文献１８】米国特許出願公開第２０１０／０１６０８７９号明細書
【特許文献１９】米国特許出願公開第２０１０／０１６０８８０号明細書
【特許文献２０】米国特許出願公開第２０１０／０１７４２５１号明細書
【特許文献２１】米国特許出願公開第２０１０／０２７４２０７号明細書
【特許文献２２】米国特許出願公開第２０１０／０２９８７９３号明細書
【特許文献２３】米国特許出願公開第２０１１／０００９８３８号明細書
【特許文献２４】米国特許出願公開第２０１１／００２８９１８号明細書
【特許文献２５】米国特許出願公開第２０１１／００５４４２１号明細書
【特許文献２６】米国特許出願公開第２０１１／００５４４２３号明細書
【特許文献２７】米国特許出願第１２／９４１３９０号明細書
【特許文献２８】米国特許出願第２９／３８９７８２号明細書
【特許文献２９】米国特許出願第２９／３８９７８３号明細書
【発明の概要】
【課題を解決するための手段】
【０００６】
本明細書に開示する幾つかの実施形態は、減圧創傷治療用のポンプアセンブリに関し、このポンプアセンブリは、ハウジングと、ハウジング内で又はハウジングによって支持されるポンプと、ポンプアセンブリを通る流路と、ポンプと流体連通しておりハウジングによって支持される一方向フロー弁とを備える。一方向フロー弁の幾つかの実施形態は、ポンプから離れるフロー方向で流路を通ってガスが流れるのを実質的に防ぐように構成することができる。ポンプは、モータと、入口及び出口と、ポンプによって支持され、入口を通る流体のフローを制御するように構成された第１の弁と、ポンプによって支持され、出口を通る流体のフローを制御するように構成された第２の弁とを有することができる。
【０００７】
本明細書に開示する幾つかの実施形態は、減圧創傷治療用のポンプアセンブリに関し、

このポンプアセンブリは、ハウジングと、ハウジング内で又はハウジングによって支持されるポンプと、ポンプと流体連通している一方向フロー弁と、ポンプアセンブリを通る流路とを備える。一方向フロー弁は、ポンプから離れるフロー方向で流路を通ってガスが流れるのを実質的に防ぐように構成することができる。ポンプは、モータと、入口と、出口とを備えることができる。本明細書に開示するポンプの実施形態のいずれにおいても、必須ではないものの、ポンプは、入口を通る流体のフローを制御するように構成された第１の弁と、出口を通る流体のフローを制御するように構成された第２の弁とを有することもできる。本明細書に開示する幾つかのポンプの実施形態は、オリフィス又は他の機構もしくは構成要素を使用して、ポンプを通る流体のフロー又は流量を制御することができる。

【０００８】

本明細書に開示する幾つかの実施形態は、減圧創傷治療用の陰圧治療キットに関し、この陰圧治療キットは、ハウジングと、ハウジング内で支持されるポンプと、ハウジング内で又はハウジングによって支持されるコントローラと、ハウジングによって支持される少なくとも１つのスイッチ又はボタンとを備えるポンプアセンブリを備える。本明細書全体に亘って使用されるとき、「幾つかの実施形態」又は「幾つかの実施形態では」という語句は、本明細書に記載されるか、例証されるか、参照により組み込まれるか、又は別の形で開示される任意の実施形態を指すことを意味する。少なくとも１つのスイッチ又はボタンは、コントローラと連通していることができ、ユーザがポンプの１つ又は複数の動作モードを制御できるように、ユーザにとってアクセス可能であることができる。幾つかの実施形態では、必須ではないものの、陰圧治療キットは、創傷の上に実質的に液密のシールを形成するように構成された包帯と、包帯及びポンプアセンブリと連結可能であって、ポンプアセンブリから包帯までの実質的に又は完全に包囲された流体流路を設けるように構成された導管と、ポンプアセンブリ、１つ又は複数の電池、包帯、及び導管をパッケージングするための第１のパッケージング要素とを備えることができる。幾つかの実施形態では、コントローラは、ポンプ及び弁の動作を制御するように構成することができる。陰圧治療キットの幾つかの実施形態は、陰圧治療キットが滅菌されたものであるように構成することができる。陰圧治療キットは、ハウジングの少なくとも内部及び外部、少なくとも１つの弁、ポンプ、コントローラ、ならびに少なくとも１つのスイッチ又はボタンが滅菌されたものであるように、滅菌することができる。幾つかの実施形態では、ポンプは、ポンプモータと、入口及び出口と、入口及び出口の少なくとも一方を通る流体のフローを制御するように構成された少なくとも１つの弁と、少なくとも入口、出口、及び少なくとも１つの弁を通る流路とを有することができる。

【０００９】

本明細書に開示する幾つかの実施形態は、減圧ポンプを用いた創傷の減圧治療に関する。本明細書に開示するポンプの実施形態は、滅菌することを必須としない。しかし、減圧ポンプを使用前に滅菌し、ポンプ及び／又は包帯もしくはポンプのキットの構成要素を滅菌状態で提供することによって、デバイスの滅菌性が求められる手術ルーム（手術室とも呼ばれる）又は他の任意の場所でポンプを使用するのを可能にすることができる。例示的且つ非限定的な幾つかの実施形態は、手術ルームで使用することができる、滅菌ポンプと、滅菌包帯と、包帯及びポンプに接続可能な滅菌導管とを備える、滅菌ポンプキットを対象とする。

【００１０】

本明細書に開示する幾つかの実施形態は、減圧創傷治療用の陰圧治療キットに関し、この陰圧治療キットは、約３５０ｍＬ／分以下の流量を有するポンプと、カバー層を備える包帯とを備える。包帯は、シリコーン系接着剤で覆われた創傷接触面を有することができる。

【００１１】

本明細書に開示する幾つかの実施形態は、減圧創傷治療用の無容器ポンプ（ｃａｎｉｓｔｅｒｌｅｓｓ　ｐｕｍｐ）に関し、この無容器ポンプは、ハウジングと、ポンプを通る流路と、流路と連通している１つ又は複数の弁と、ハウジング内で又はハウジングによっ

て支持される、無容器型のポンプとを備える。本明細書に開示する幾つかの実施形態は、減圧創傷治療用の無容器ポンプアセンブリに関し、この無容器ポンプアセンブリは、ハウジングと、ハウジング内で又はハウジングによって支持されるポンプとを備える。ポンプは、モータと、入口及び出口と、ポンプによって支持され、入口を通る流体のフローを制御するように構成された第１の弁と、ポンプによって支持され、出口を通る流体のフローを制御するように構成された第２の弁とを有することができる。ポンプ又はポンプアセンブリは無容器型であることができる。さらに、本明細書に開示するすべての実施形態に関して必須ではないが、第１及び第２の弁はそれぞれ、公称動作圧力で、かつ／又は公称滅菌圧力の間、約０．１ｍＬ／分～約１０ｍＬ／分の漏れ速度を、あるいは公称動作圧力で、０．１ｍＬ／分以下～５ｍＬ／分以上の間、又は１ｍＬ／分以下～３ｍＬ／分以上の間、又は上記範囲のいずれかにおける任意の２つの値の間の漏れ速度を有することができる。幾つかの実施形態では、漏れ速度は、公称動作圧力で、かつ／又は公称滅菌圧力の間、約０．４ｍＬ／分～０．７ｍＬ／分であることができる。

【００１２】

ポンプアセンブリの幾つかの実施形態は、非限定的に、特許文献１及び／又は特許文献２に開示されている圧電ポンプなどの、圧電ポンプを有することができる。幾つかの圧電ポンプは、ポンプが停止中のとき、ポンプを通る流量が２００ｍＬ／分程度の多量であることができるように、弁機能を実施するためのオリフィスを有することができる。したがって、幾つかの実施形態では、ポンプ速度が約３００ｍＬ／分又は３２０ｍＬ／分又はその他の高い速度であることができる場合、第１及び第２の弁（オリフィスであり得る）はそれぞれ、約２００ｍＬ／分以下の漏れ速度を有することができる。

【００１３】

本明細書に開示する幾つかの実施形態は、滅菌ポンプキットに関し、この滅菌ポンプキットは、本明細書に開示するポンプの実施形態のいずれかと、包帯と、包帯及び滅菌ポンプと連結可能であって、包帯までの減圧の流体経路を提供するように構成された導管と、１つ又は複数の電池と、第１のパッケージング要素及び第１のパッケージング要素と取外し可能に連結されるように構成された第２のパッケージング要素とを備える。幾つかの実施形態では、第１及び第２のパッケージング要素の少なくとも一方は、滅菌ポンプと、包帯と、包帯及び滅菌ポンプと連結可能であって、包帯までの減圧の流体経路を提供するように構成された導管とを受け入れるための、陥凹部を有することができる。滅菌ポンプキットは、ポンプ、包帯、導管、及び１つ又は複数の電池を、第１のパッケージング要素及び第２のパッケージング要素の少なくとも一方の内部で支持した後に、滅菌することができる。

【００１４】

本明細書に開示する幾つかの実施形態は、手術ルームにおいて創傷の治療を開始するための方法に関し、この方法は、創傷の上に滅菌包帯を当てて、創傷の上に実質的に液密のシールを作り出すステップと、滅菌導管を介して滅菌ポンプを包帯に連結するステップと、手術ルームでポンプを動作させることによって手術ルームで包帯と創傷との間の圧力レベルを低減するステップとを含む。

【００１５】

本明細書に開示する幾つかの実施形態は、陰圧創傷治療システムの動作を制御するための装置及び方法に関する。特に、ただし非限定的に、本明細書に開示する実施形態は、陰圧治療装置及び包帯、ならびにかかる陰圧治療システムを動作させるための方法及びアルゴリズムに関する。幾つかの実施形態では、必須ではないものの、装置は、創傷の上に配置されるとともに、創傷の上に実質的に流体不透過性のシールを作り出すように構成された包帯を備えることができる。装置は、包帯に連結されるように構成された陰圧源を備えることができる。装置は、陰圧源を動作させ、陰圧源のデューティサイクルを監視し、デューティサイクルがデューティサイクル閾値を超えたか否かを判定するように構成された、コントローラをさらに備えることができる。幾つかの実施形態では、コントローラは、複数の連続した均等な持続時間に亘って陰圧源の複数のデューティサイクルを監視し、複

数のデューティサイクルのうちのあるデューティサイクルがデューティサイクル閾値を超えたか否かを判定するように構成することができる。デューティサイクルは、所定の期間の間、又は複数の連続した均等な持続時間のうちのある持続時間の間、陰圧源が活性である時間量を反映することができる。

【００１６】

幾つかの実施形態では、コントローラは、デューティサイクルの数がデューティサイクル閾値を超えたか、またその数が過負荷閾値を超えたか否かを判定するように構成することができる。幾つかの実施形態では、コントローラは、複数のデューティサイクルのうち一組のデューティサイクルがデューティサイクル閾値を超えたか否かを判定し、その組におけるデューティサイクルの数が過負荷閾値を超えたか否かを判定するように構成することができる。コントローラは、デューティサイクル閾値を超えるデューティサイクルの数が連続的であるか否かを判定するように構成することができる。幾つかの実施形態では、過負荷閾値は３０デューティサイクルを含むことができ、期間もしくは持続時間は１分を含むことができ、かつ／又はデューティサイクル閾値は９％を含むことができる。幾つかの実施形態では、コントローラは、デューティサイクル又は複数のデューティサイクルを継続的に監視するように構成することができる。

【００１７】

装置の幾つかの実施形態は、所定の期間の間、陰圧源を一時停止するように構成されたスイッチを備え、コントローラは、その期間が経過すると陰圧源を再始動させるように構成することができる。期間は可変であることができる。幾つかの実施形態では、装置は、外表面を含むハウジングに包囲することができ、スイッチは、ハウジングの外表面上に配置されたボタンを含むことができる。

【００１８】

装置の幾つかの実施形態は、動作状態の指示を提供するように構成されたコントローラを備える。動作状態は、デューティサイクルがデューティサイクル閾値を超えていることの判定を含むことができ、指示は、陰圧源を動作停止してシールの漏れを指示することを含むことができる。幾つかの実施形態では、動作状態は、陰圧源が一時停止されているか否かを含み、コントローラは、陰圧源が活動状態であるときの第１の指示と、陰圧源が一時停止されているときの第２の指示とを提供するように構成することができ、その場合、第２の指示は第１の指示とは異なる。

【００１９】

幾つかの実施形態では、コントローラは、包帯の下に所望の陰圧レベルを発生させるように試みるため、陰圧源を動作させるように構成することができ、また、第１の時間間隔が経過したときに、包帯の下の圧力レベルが所望の陰圧レベルに達していない場合、コントローラは、第２の時間間隔の間、陰圧源を動作停止することができる。第２の時間間隔が経過すると、コントローラは、包帯の下に所望の陰圧レベルを発生させるように試みるため、陰圧源を動作させることができる。コントローラは、包帯の下の圧力レベルが所望の陰圧レベルに達していなかった回数に基づいて、第２の時間間隔を変更するように構成することができる。例えば、コントローラは、結果として得られる値が第２の間隔閾値を超えないという条件で、第２の時間間隔を二倍にするように構成することができる。装置は、包帯の下の圧力を感知し、感知した圧力をコントローラに通信するように構成されたセンサを備えることができる。

【００２０】

幾つかの実施形態では、コントローラは、包帯の下の圧力レベルが所望の陰圧レベルに達していると、陰圧源を動作停止し、包帯の下の圧力レベルが陰圧閾値を上回ると、陰圧源を動作させるように構成することができ、その際、所望の陰圧レベルは陰圧閾値よりも負性の圧力に相当する。

【００２１】

幾つかの実施形態では、陰圧源は、創傷の上に包帯を位置付けて、創傷の上に実質的に流体不透過性のシールを作り出し、陰圧源から包帯に陰圧を送達し、陰圧源のデューティ

サイクルを監視し、デューティサイクルがデューティサイクル閾値を超えていると判定された場合に指示を提供することによって、動作させることができる。デューティサイクルは、１分につき一回など、所定の期間の間に陰圧源が活動状態である時間量を反映することができる。

【００２２】

装置の幾つかの実施形態は、最初の動作以降の合計経過時間を監視し、合計経過時間が寿命閾値に達すると、陰圧源の動作を不能にするように構成することができる。寿命閾値は、例えば７日間を含むことができる。

【００２３】

幾つかの実施形態では、創傷に陰圧を加えるための装置は、創傷の上に配置されて、創傷の上に実質的に流体不透過性のシールを作り出すように構成された包帯と、包帯に連結されるように構成された陰圧源と、陰圧源を動作させ、陰圧源のデューティサイクルを監視し、デューティサイクルがデューティサイクル閾値を超えた場合に、指示を提供するように構成されたコントローラとを備える。

【００２４】

幾つかの実施形態では、装置は、創傷の上に配置されて、創傷の上に実質的に流体不透過性のシールを作り出すように構成された包帯と、包帯に連結するように構成されたポンプと、所定の期間の間、ポンプを一時停止するように構成されたスイッチと、その期間が経過するとポンプを再始動するように構成されたコントローラとを備える。期間は可変であることができる。装置の幾つかの実施形態は、モータによって動作する小型のダイヤフラムポンプ、又は圧電変換器によって動作する小型のダイヤフラムポンプを含む。幾つかの実施形態では、ポンプは、小型のピストンポンプ及び小型のダイヤフラムポンプを含むことができる。

【００２５】

幾つかの実施形態は、陰圧源（例えば、陰圧ポンプ）を動作させる方法を開示し、方法は、包帯を創傷の上に位置付けて、創傷の上に実質的に流体不透過性のシールを作り出すステップと、ポンプから包帯に陰圧を送達するステップと、所定の期間の間、ポンプを一時停止するステップと、その期間が経過するとポンプを再始動するステップとを含む。期間は可変であることができる。

【００２６】

幾つかの実施形態では、陰圧ポンプは、創傷の上に包帯を位置付けて、創傷の上に実質的に流体不透過性のシールを作り出し、陰圧ポンプを使用して創傷から流体を吸引し、ポンプの活動レベルを測定し、ポンプの活動レベルを閾値と比較し、活動レベルが閾値を超えている場合に、指示を提供することによって動作させることができる。活動レベルの測定は、ポンプのデューティサイクルの判定、（例えば、流量計を使用することによる）創傷から吸引される流体の流量の判定、圧力センサを使用した包帯の下の圧力変化率の測定など、又はそれらの組合せを含むことができる。

【００２７】

幾つかの実施形態は、陰圧ポンプを動作させる方法を開示し、この方法は、創傷の上に包帯を位置付けて、創傷の上に実質的に流体不透過性のシールを作り出すステップと、包帯の下の圧力を第１の陰圧設定値に近付けるため、ポンプから包帯に陰圧を送達するステップと、包帯の下の陰圧レベルが第２の陰圧設定値よりも高くなった場合に、包帯の下の圧力を第１の陰圧設定値に近付けるため、ポンプを動作させるステップと、ポンプが動作している時間量を監視するステップと、時間量が所定の時間量を超えた場合に、指示を提供するステップとを含む。方法は、所定の期間に亘ってポンプが動作していた時間量を判定するステップと、時間量が期間の９％を超えた場合に、指示を提供するステップとをさらに含むことができる。幾つかの実施形態では、指示を提供するステップは、所定の期間に亘ってポンプが動作していた時間量を判定するステップをさらに含む。幾つかの実施形態では、指示を提供するステップは、アラームを動作させるステップをさらに含む。

【００２８】

幾つかの実施形態では、装置は、陰圧源を動作させて、陰圧創傷治療用包帯の下の圧力を、第１の陰圧設定値と第２の陰圧設定値との間の値、又は第２の陰圧設定値の値にほぼ等しい値など、所望の陰圧値に近付けるように構成することができる。包帯の下の圧力レベルを測定することができる。装置は、包帯の下の圧力が閾値の上まで減少（例えば、第１の陰圧設定値の値まで減少）した場合に、陰圧源を動作させて、包帯の下の圧力を第２の所望の陰圧レベル（例えば、第２の陰圧設定値の値）に近付けるように構成することができる。陰圧源が例えば継続的に動作していた時間量を、監視することができる。包帯の下にほぼ第２の所望の陰圧レベル（例えば、第２の陰圧設定値の値）を確立することなく、陰圧源が所定の時間量の間、動作していた場合、陰圧源の動作を一時停止又は中断することができる。

【００２９】

幾つかの実施形態は、陰圧源を動作させる方法を開示し、この方法は、包帯を創傷の上に位置付けて、創傷の上に実質的に流体不透過性のシールを作り出すステップと、陰圧源から包帯に陰圧を送達するステップとを含む。陰圧源から包帯に陰圧を送達するステップは、包帯の下に所望の陰圧レベルを発生させるように試みるため、陰圧源を動作させるとともに、第１の動作カウントを更新するステップと、第１の時間間隔が経過したときに、包帯の下の陰圧が所望の陰圧レベルに達していなかった場合、第１の動作カウントが第１の再試行閾値未満であるという条件で、第２の時間間隔の間、陰圧源を動作停止するステップと、第１の動作カウントが第１の再試行閾値以上である場合、第３の時間間隔の間、陰圧源を動作停止し、第１の動作カウントをリセットするとともに、第３の時間間隔が経過したときに、包帯の下に所望の陰圧レベルを発生させるように試みるため、陰圧源を動作させるステップと、第２の時間間隔が経過したときに、包帯の下に所望の陰圧レベルを発生させるように試みるため、陰圧源を動作させるとともに、第１の動作カウントを更新するステップと、包帯の下の陰圧が所望の陰圧レベルに達していると、陰圧源を動作停止し、第１の動作カウントをリセットするとともに、包帯の下の陰圧を監視するステップと、包帯の下の陰圧が陰圧閾値を上回ると、陰圧源を動作させ、第２の動作カウントを更新するステップであって、所望の陰圧レベルが陰圧閾値よりも負性の圧力に相当する、更新するステップと、第４の時間間隔が経過する前に包帯の下の陰圧が所望の陰圧レベルに達した場合に、陰圧源を動作停止し、包帯の下の陰圧を監視するとともに、第２の動作カウントをリセットするステップと、第４の時間間隔が経過したときに、包帯の下の陰圧が所望の陰圧レベルに達していなかった場合、第２の動作カウントが第２の再試行閾値未満であるという条件で、第２の時間間隔の間、陰圧源を動作停止するステップと、第２の動作カウントが第２の再試行閾値以上である場合、第３の時間間隔の間、陰圧源を動作停止し、第２の動作カウントをリセットするとともに、第３の時間間隔が経過したときに、包帯の下に所望の陰圧レベルを発生させるように試みるため、陰圧源を動作させ、第１の動作カウントを更新するステップと、陰圧源のデューティサイクルを継続的に監視するステップと、デューティサイクル閾値を超えるデューティサイクルの数を追跡するステップと、デューティサイクル閾値を超えるデューティサイクルの数が過負荷閾値を超えると、第３の時間間隔の持続時間の間、陰圧源を動作停止するステップとを含む。

【００３０】

本発明の実施形態について、添付図面を参照して、単なる例証として以下に記載する。

【図面の簡単な説明】

【００３１】

【図１】ポンプ、包帯、及び導管を備える減圧創傷治療装置の一実施形態を示す図である。

【図２Ａ】図１に示されるポンプの実施形態を示す図である。

【図２Ｂ】図１に示されるポンプの実施形態を示す図である。

【図２Ｃ】図１に示されるポンプの実施形態を示す図である。

【図２Ｄ】図１に示されるポンプの実施形態を示す図である。

【図２Ｅ】図１に示されるポンプの実施形態を示す図である。

【図２Ｆ】図１に示されるポンプの実施形態を示す図である。
【図３Ａ】第１のパッケージング要素内で支持されている、包帯、ポンプ、導管、２つの電池、及び１つ又は複数のシールストリップを備える、創傷包帯キットの一実施形態を示す図である。
【図３Ｂ】図３Ａの創傷包帯キットの実施形態を示す下面等角図である。
【図３Ｃ】図３Ａの創傷包帯キットの実施形態を示す分解組立図である。
【図４Ａ】図１のポンプの実施形態を示す第１の分解組立図である。
【図４Ｂ】図１のポンプの実施形態を示す第２の分解組立図である。
【図５Ａ】第１のハウジング部材を示す第１の図である。
【図５Ｂ】第１のハウジング部材を示す第２の図である。
【図６Ａ】第２のハウジング部材を示す第１の図である。
【図６Ｂ】第２のハウジング部材を示す第２の図である。
【図７Ａ】患者の創傷部位を治療するのに使用されているＴＮＰ創傷治療システムの一実施形態の使用を示す図である。
【図７Ｂ】患者の創傷部位を治療するのに使用されているＴＮＰ創傷治療システムの一実施形態の使用を示す図である。
【図７Ｃ】患者の創傷部位を治療するのに使用されているＴＮＰ創傷治療システムの一実施形態の使用を示す図である。
【図７Ｄ】患者の創傷部位を治療するのに使用されているＴＮＰ創傷治療システムの一実施形態の使用を示す図である。
【図８Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図８Ｂ】図８Ａの実施形態の下面等角図である。
【図８Ｃ】図８Ａの実施形態の上面図である。
【図８Ｄ】図８Ａの実施形態の下面図である。
【図８Ｅ】図８Ａの実施形態の前面図である。
【図８Ｆ】図８Ａの実施形態の後面図である。
【図８Ｇ】図８Ａの実施形態の第１の側面図である。
【図８Ｈ】図８Ａの実施形態の第２の側面図である。
【図９Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図９Ｂ】図９Ａの実施形態の下面等角図である。
【図９Ｃ】図９Ａの実施形態の上面図である。
【図９Ｄ】図９Ａの実施形態の下面図である。
【図９Ｅ】図９Ａの実施形態の前面図である。
【図９Ｆ】図９Ａの実施形態の後面図である。
【図９Ｇ】図９Ａの実施形態の第１の側面図である。
【図９Ｈ】図９Ａの実施形態の第２の側面図である。
【図１０Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１０Ｂ】図１０Ａの実施形態の下面等角図である。
【図１０Ｃ】図１０Ａの実施形態の上面図である。
【図１０Ｄ】図１０Ａの実施形態の下面図である。
【図１０Ｅ】図１０Ａの実施形態の前面図である。
【図１０Ｆ】図１０Ａの実施形態の後面図である。
【図１０Ｇ】図１０Ａの実施形態の第１の側面図である。
【図１０Ｈ】図１０Ａの実施形態の第２の側面図である。

【図１１Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１１Ｂ】図１１Ａの実施形態の下面等角図である。
【図１１Ｃ】図１１Ａの実施形態の上面図である。
【図１１Ｄ】図１１Ａの実施形態の下面図である。
【図１１Ｅ】図１１Ａの実施形態の前面図である。
【図１１Ｆ】図１１Ａの実施形態の後面図である。
【図１１Ｇ】図１１Ａの実施形態の第１の側面図である。
【図１１Ｈ】図１１Ａの実施形態の第２の側面図である。
【図１２Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１２Ｂ】図１２Ａの実施形態の下面等角図である。
【図１２Ｃ】図１２Ａの実施形態の上面図である。
【図１２Ｄ】図１２Ａの実施形態の下面図である。
【図１２Ｅ】図１２Ａの実施形態の前面図である。
【図１２Ｆ】図１２Ａの実施形態の後面図である。
【図１２Ｇ】図１２Ａの実施形態の第１の側面図である。
【図１２Ｈ】図１２Ａの実施形態の第２の側面図である。
【図１３Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１３Ｂ】図１３Ａの実施形態の下面等角図である。
【図１３Ｃ】図１３Ａの実施形態の上面図である。
【図１３Ｄ】図１３Ａの実施形態の下面図である。
【図１３Ｅ】図１３Ａの実施形態の前面図である。
【図１３Ｆ】図１３Ａの実施形態の後面図である。
【図１３Ｇ】図１３Ａの実施形態の第１の側面図である。
【図１３Ｈ】図１３Ａの実施形態の第２の側面図である。
【図１４Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１４Ｂ】図１４Ａの実施形態の下面等角図である。
【図１４Ｃ】図１４Ａの実施形態の上面図である。
【図１４Ｄ】図１４Ａの実施形態の下面図である。
【図１４Ｅ】図１４Ａの実施形態の前面図である。
【図１４Ｆ】図１４Ａの実施形態の後面図である。
【図１４Ｇ】図１４Ａの実施形態の第１の側面図である。
【図１４Ｈ】図１４Ａの実施形態の第２の側面図である。
【図１４Ｉ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１４Ｊ】図１４Ｉの実施形態の下面等角図である。
【図１４Ｋ】図１４Ｉの実施形態の上面図である。
【図１４Ｌ】図１４Ｉの実施形態の下面図である。
【図１４Ｍ】図１４Ｉの実施形態の前面図である。
【図１４Ｎ】図１４Ｉの実施形態の後面図である。
【図１４Ｏ】図１４Ｉの実施形態の第１の側面図である。
【図１４Ｐ】図１４Ｉの実施形態の第２の側面図である。

【図１５Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１５Ｂ】図１５Ａの実施形態の下面等角図である。
【図１５Ｃ】図１５Ａの実施形態の上面図である。
【図１５Ｄ】図１５Ａの実施形態の下面図である。
【図１５Ｅ】図１５Ａの実施形態の前面図である。
【図１５Ｆ】図１５Ａの実施形態の後面図である。
【図１５Ｇ】図１５Ａの実施形態の第１の側面図である。
【図１５Ｈ】図１５Ａの実施形態の第２の側面図である。
【図１６Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１６Ｂ】図１６Ａの実施形態の下面等角図である。
【図１６Ｃ】図１６Ａの実施形態の上面図である。
【図１６Ｄ】図１６Ａの実施形態の下面図である。
【図１６Ｅ】図１６Ａの実施形態の前面図である。
【図１６Ｆ】図１６Ａの実施形態の後面図である。
【図１６Ｇ】図１６Ａの実施形態の第１の側面図である。
【図１６Ｈ】図１６Ａの実施形態の第２の側面図である。
【図１７Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１７Ｂ】図１７Ａの実施形態の下面等角図である。
【図１７Ｃ】図１７Ａの実施形態の上面図である。
【図１７Ｄ】図１７Ａの実施形態の下面図である。
【図１７Ｅ】図１７Ａの実施形態の前面図である。
【図１７Ｆ】図１７Ａの実施形態の後面図である。
【図１７Ｇ】図１７Ａの実施形態の第１の側面図である。
【図１７Ｈ】図１７Ａの実施形態の第２の側面図である。
【図１７Ｉ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１７Ｊ】図１７Ｉの実施形態の下面等角図である。
【図１７Ｋ】図１７Ｉの実施形態の上面図である。
【図１７Ｌ】図１７Ｉの実施形態の下面図である。
【図１７Ｍ】図１７Ｉの実施形態の前面図である。
【図１７Ｎ】図１７Ｉの実施形態の後面図である。
【図１７Ｏ】図１７Ｉの実施形態の第１の側面図である。
【図１７Ｐ】図１７Ｉの実施形態の第２の側面図である。
【図１８Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１８Ｂ】図１８Ａの実施形態の下面等角図である。
【図１８Ｃ】図１８Ａの実施形態の上面図である。
【図１８Ｄ】図１８Ａの実施形態の下面図である。
【図１８Ｅ】図１８Ａの実施形態の前面図である。
【図１８Ｆ】図１８Ａの実施形態の後面図である。
【図１８Ｇ】図１８Ａの実施形態の第１の側面図である。
【図１８Ｈ】図１８Ａの実施形態の第２の側面図である。

【図１８Ｉ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１８Ｊ】図１８Ｉの実施形態の下面等角図である。
【図１８Ｋ】図１８Ｉの実施形態の上面図である。
【図１８Ｌ】図１８Ｉの実施形態の下面図である。
【図１８Ｍ】図１８Ｉの実施形態の前面図である。
【図１８Ｎ】図１８Ｉの実施形態の後面図である。
【図１８Ｏ】図１８Ｉの実施形態の第１の側面図である。
【図１８Ｐ】図１８Ｉの実施形態の第２の側面図である。
【図１９Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１９Ｂ】図１９Ａの実施形態の下面等角図である。
【図１９Ｃ】図１９Ａの実施形態の上面図である。
【図１９Ｄ】図１９Ａの実施形態の下面図である。
【図１９Ｅ】図１９Ａの実施形態の前面図である。
【図１９Ｆ】図１９Ａの実施形態の後面図である。
【図１９Ｇ】図１９Ａの実施形態の第１の側面図である。
【図１９Ｈ】図１９Ａの実施形態の第２の側面図である。
【図２０Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図２０Ｂ】図２０Ａの実施形態の下面等角図である。
【図２０Ｃ】図２０Ａの実施形態の上面図である。
【図２０Ｄ】図２０Ａの実施形態の下面図である。
【図２０Ｅ】図２０Ａの実施形態の前面図である。
【図２０Ｆ】図２０Ａの実施形態の後面図である。
【図２０Ｇ】図２０Ａの実施形態の第１の側面図である。
【図２０Ｈ】図２０Ａの実施形態の第２の側面図である。
【図２１】幾つかの実施形態によるポンプアセンブリを示す図である。
【図２２】幾つかの実施形態によるポンプアセンブリの内部を示す断面図である。
【図２３】幾つかの実施形態によるポンプアセンブリのシステム概略図である。
【図２４】幾つかの実施形態によるポンプアセンブリの電気的構成要素の概略図である。
【図２５】幾つかの実施形態によるポンプアセンブリの動作を示す上位状態図である。
【図２６】幾つかの実施形態によるポンプアセンブリの動作を示す動作状態図である。
【図２７】幾つかの実施形態によるポンプアセンブリの動作を示す別の状態図である。
【図２８】幾つかの実施形態によるポンプアセンブリに対するデューティサイクルの判定を示すグラフである。
【図２９】幾つかの実施形態による少量の漏れが存在する状態でのポンプアセンブリの動作を示す図である。
【図３０】幾つかの実施形態による多量の漏れが存在する状態でのポンプアセンブリの動作を示す図である。
【図３１】幾つかの実施形態による非常に多量の漏れが存在する状態でのポンプアセンブリの動作を示す図である。
【図３２】幾つかの実施形態による極めて多量の漏れが存在する状態でのポンプアセンブリの動作を示す図である。
【発明を実施するための形態】
【００３２】
図面中、類似の参照番号は類似の部分を指す。

【００３３】
本明細書に開示する実施形態は、減圧を用いて創傷を治療する装置及び方法に関する。本明細書で使用するとき、－Ｘ　ｍｍＨｇなどの減圧又は陰圧レベルは、７６０ｍｍＨｇ（又は、１気圧、２９．９３水銀柱インチ、１０１．３２５ｋＰａ、１４．６９６ｐｓｉなど）に相当する標準大気圧未満の圧力レベルを表す。したがって、－Ｘ　ｍｍＨｇの陰圧値は、７６０ｍｍＨｇよりもＸ　ｍｍＨｇ低い絶対圧力、又は換言すれば（７６０－Ｘ）ｍｍＨｇの絶対圧力を反映する。それに加えて、Ｘ　ｍｍＨｇよりも「低い」又は「小さい」陰圧は、大気圧により近い圧力に相当する（例えば、－４０ｍｍＨｇは－６０ｍｍＨｇよりも低い）。－Ｘ　ｍｍＨｇよりも「高い」又は「大きい」陰圧は、大気圧からより遠い圧力に相当する（例えば、－８０ｍｍＨｇは－６０ｍｍＨｇよりも高い）。

【００３４】
実施形態のいくつかは、ポンプ及び／又はポンプと包帯のキットを備える。幾つかの実施形態は、病院、手術ルーム、又は手術室への納入前、又はかかるデバイスを使用する医療従事者への納入前に滅菌されているポンプ及び／又はポンプと包帯のキットを対象とし、したがって、滅菌ポンプ及び／又は滅菌ポンプ／包帯キットは、外科処置もしくは手術処置の直後に使用することができる。これの１つの利点は、減圧ポンプが動作中であること、及び可能な限り最も早い時点で減圧療法が開始されていることを知って、外科医は患者を手術ルームから解放することができる点である。外科処置又は他の処置の直後に包帯キットを当てることのさらなる利点は、そうすることによって、普通なら病棟で必要とされることがある感染の機会を、後の包帯交換を排除することによって低減できる点である。換言すれば、手術室で包帯（ポンプではなく）が当てられ、その後に漏れ又は包帯に関する他の問題などの事態が見つかるそのような患者に関しては、患者が手術室から解放された後に、包帯を再配置され、交換され、又は別の形がなされるために取り外す必要がある場合、患者の創傷は、手術室の外で包帯が再配置され、交換され、又は別の形がなされるときに、感染リスクに暴露されることがある。しかし、本明細書に開示する実施形態を用いると、患者が手術室にいる間にポンプが使用され試験された場合、包帯は除去され、再配置され、又は別の形がなされることが必要なこともある包帯に関するあらゆる問題を、滅菌された手術ルーム環境で取り扱うことができ、それによって、病原菌、細菌、又は他の汚染物質に暴露されるリスクが大幅に低減又は排除される。さらに、従来のポンプが一旦病院に受け入れられた後でそれを病院側で滅菌することは一般的に不可能であり、したがって、病院は、ポンプを滅菌バッグに入れるという手段を取ることがあるが、この方策によって手術ルームの滅菌野を危険に晒すリスクがあり、特に一旦デバイスをオンにすると、ポンプ内部にあることがある病原菌、細菌、又は他の汚染物質がポンプの動作によって放出される。

【００３５】
幾つかの実施形態では、ポンプを、ポンプの構成要素全体にわたる滅菌ガスへの完全な暴露及びその浸透に適したものにする、機構、構成要素、及び他の特性を有する、ガス滅菌に適したものであるように構成することができる。例えば、非限定的に、ポンプ内の流体経路全体を滅菌ガスに暴露することができるように、十分な滅菌ガスのフローを流すことを可能にする、１つ又は複数のポンプ弁が選択又は構成されている。より詳細に後述するように、幾つかの実施形態では、ポンプは、非限定的に、戦略的に位置付けられた一方向フロー弁など、ポンプアセンブリ内の流路を通る漏れを低減することによってポンプの効率を改善することができる、ポンプ内の他の弁を補完する他の構成要素を有することができる。

【００３６】
それに加えて、提供された場合、滅菌ポンプ／包帯キットもまた、ガス滅菌に適したものであるように設計し構成することができる。後述するように、滅菌ポンプ／包帯キットは、ポンプアセンブリを含む、滅菌ポンプ／包帯キットを備える構成要素がすべて、滅菌前に少なくとも第１のパッケージング要素にともにパッケージングされて、構成要素をすべてともに滅菌できるように構成することができる。さらに、後述するように、滅菌ポン

プ／包帯キットを備える構成要素は、構成要素の少なくともいくつかを予め定義された順序で除去することができるようにパッケージング内で配列することができるので、外科医又は医療従事者が組み立て、包帯を患者に当てることがより簡単になる。

【００３７】

手術室で創傷の治療を始められることには、非限定的に、創傷が滅菌状態及び環境にある状態で、創傷の上に実質的にシールされたバリアを提供し、それによって細菌又は他の汚染物質が創傷に入り込むのを阻害もしくは防止することを含む、多数の利益がある。それに加えて、可能な限り最も早い段階で減圧治療を開始することも、創傷の治癒にとって有利である。

【００３８】

それに加えて、特許文献３、特許文献４、特許文献５、特許文献６、特許文献７、特許文献８、及び特許文献９に開示されているものなど、本明細書に開示するか又は参照により組み込まれている実施形態は、改善された創傷包帯の構成要素を備える。かかる開示のすべての実施形態、構成要素、機構、及び他の詳細は、本開示の一部を成すものとして参照により本明細書に組み込まれているとともに、本明細書に開示する実施形態の構成要素、機構、及び他の詳細のいずれかの代わりに、又はそれらと組み合わせて使用することができる。例えば、幾つかの実施形態では、創傷包帯は、例えば患者の動きによって創傷包帯に掛かる圧縮力又は剪断力が、治癒途中の創傷を傷つけるのを防ぐ助けとなる、緩衝材として作用するように構成することができる。創傷包帯の実施形態は、創傷部位から除去された創傷浸出物を回収し格納する廃棄物容器として作用してもよく、また、ＴＮＰ療法が適用されている間、創傷部位を覆う創傷包帯における固形物の蓄積の管理に関する。さらに、本明細書に開示する実施形態は、創傷包帯に陰圧を加えるための方法及び吸気ポート、ならびに吸気ポート及び創傷包帯を製造する方法に関する。

【００３９】

さらに、本明細書に開示する幾つかの実施形態は、陰圧治療装置及び包帯を含むシステム、ならびに陰圧治療用包帯とともに使用される、かかる陰圧治療装置を動作させるための方法及びアルゴリズムを対象とする。幾つかの実施形態では、陰圧治療装置は、特に陰圧を創傷に提供するように構成された、ポンプアセンブリを備える。本明細書に開示するポンプアセンブリの幾つかの実施形態は、ポンプアセンブリの動作を制御するように構成された新規で独創的な制御論理を含む。例えば、幾つかの実施形態は、システムにおける１つ又は複数の漏れの存在ならびに／又は深刻度、創傷から吸引された流体（例えば、空気、液体、及び／もしくは固体浸出物など）の流量など、様々な動作状態の監視ならびに検出に応答して、ポンプアセンブリの動作を制御するように構成された、新規で独創的な制御論理を含む。幾つかの実施形態では、制御論理は、システムにおける１つ又は複数の漏れ（例えば、ポンプと流体連通している包帯における１つ又は複数の漏れ、創傷の上の包帯によって作り出されるシールにおける１つ又は複数の漏れなど）を検出するとともに、かかる１つ又は複数の漏れが検出されたときのポンプアセンブリの動作を制御するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、少なくとも正常な又は少量の漏れ（例えば、相対的に低い流量を有する漏れ）、多量の漏れ（例えば、相対的に高い流量を有する漏れ）、及び非常に多量の漏れ（例えば、相対的に非常に高い流量を有する漏れ）の間で区別するように構成することができる。幾つかの実施形態はさらに、上記の漏れと極めて多量の漏れとの間で区別するように構成することができる。

【００４０】

幾つかの実施形態では、ポンプアセンブリは、電池電源などの電源によって動力供給される、小型の使い捨てポンプなどの陰圧源を備えることができる。ポンプアセンブリは、約１日間、２～１０日間など、所定の期間の間、治療を提供するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、かかる期間の間、中断されない治療を提供するように求められる場合がある。幾つかの実施形態では、ポンプアセンブリは、最初の動作後の所定の期間（例えば、７日間）で、それ自体を動作停止するように構成することができる。本明細書に開示するアルゴリズム又は論理は、ポンプアセンブリをより

効率的に動作させ、電力を、例えば非限定的に電池電力を節約する助けとすることができる。

【００４１】

幾つかの実施形態では、ポンプアセンブリは、陰圧源（例えば、ポンプ）のデューティサイクルを監視するように構成することができる。本明細書で使用するとき、「デューティサイクル」は、所定の期間に亘って陰圧源が活動状態であるか又は稼働している時間量を反映する。換言すれば、デューティサイクルは、検討中の合計時間の一部として、陰圧源が活動状態にある時間を反映する。これは、次式のように数学的に表すことができる。

【００４２】

ＤＣ＝ｔ／Ｔ　　（１）

【００４３】

式中、ＤＣはデューティサイクル、ｔは陰圧源が活動状態である持続時間、Ｔは検討中の合計時間である。デューティサイクルは、絶対値（例えば、Ｘ秒）、割合（例えば、１／Ｘ）、百分率（例えば、Ｘ％）などとして測定することができる。例えば、１分の期間に亘って、陰圧源が６秒間オンであり（すなわち、動作している）、５４秒間オフである（すなわち、動作していない）場合、デューティサイクルは、６秒、１／１０、１０％などとして表すことができる。

【００４４】

幾つかの実施形態では、ポンプアセンブリは、陰圧源のデューティサイクルを監視するように構成されたコントローラを含むことができる。デューティサイクル測定は、陰圧源の活動レベルを反映することができる。例えば、デューティサイクルは、陰圧源が正常に動作している、酷使されている、極めて酷使されているなどを指示することができる。さらに、周期的なデューティサイクル測定などのデューティサイクル測定は、システムにおける漏れの存在ならびに／又は深刻度、創傷から吸引された流体（例えば、空気、液体、及び／もしくは固体浸出物など）の流量など、様々な動作状態を反映することができる。デューティサイクル測定に基づいて、測定されたデューティサイクルを閾値の組（例えば、較正で決定される）と比較することなどによって、コントローラは、様々なシステム要件にしたがって、システムの動作を制御するアルゴリズムもしくは論理を実行し、かつ／又はそれらを実行するようにプログラムすることができる。例えば、デューティサイクル測定は、システムにおける多量の漏れの存在を指示することができ、この条件をユーザ（例えば、患者、介護者、医師など）に対して指示し、かつ／又は電力を節約するために陰圧源の動作を一時的に保留又は一時停止するように、コントローラをプログラムすることができる。

【００４５】

幾つかの実施形態では、システムは、他の任意の適切な手段によって流量を監視するように構成することができる。ポンプアセンブリは、流量計（例えば、機械的、圧力ベース、光学、質量、熱質量、電磁、音波、超音波、レーザー、ドップラーなど）、風速計、圧力変換器又はセンサ、電磁センサ（例えば、ホールセンサなど、ポンプ速度を測定するように構成されたセンサ）、電磁測定（例えば、ポンプの電流及び／もしくは電力の引込みを測定する、電源の電流及び／もしくは電力のドレインを測定する、電源の残容量を測定するなど）、あるいはそれらの任意の組合せを使用するように構成することができる。監視された流量に基づいて、流量を閾値の組（例えば、較正で決定される）と比較することなどによって、コントローラは、様々なシステム要件にしたがって、システムの動作を制御するアルゴリズムもしくは論理を実行し、かつ／又はそれらを実行するようにプログラムすることができる。例えば、コントローラは、圧力センサから周期的な測定値を得るか、又はポンプモータから周期的なフィードバックを得るように構成することができる。圧力センサは、包帯の下の圧力を測定することができる。コントローラは、例えば、圧力勾配、圧力変化率、及び／又は圧力減少率を判定することによって、流量を判定することができる。例えば、正の圧力勾配（例えば、増加するもの）は、閾値と関連して増加する流量（例えば、漏れ）を反映することができ、コントローラは、この条件をユーザに対して

指示するようにプログラムすることができる。

【００４６】

幾つかの実施形態では、創傷の治療のためのシステムを提供することができる。包帯は、創傷の周りに（例えば、包帯の下に）実質的にシール又は閉止された空間を作り出すことができ、ポンプアセンブリは、この空間における圧力レベルを周期的もしくは継続的に測定又は監視することができる、センサを有することができる。ポンプアセンブリ又はそのコントローラは、第１の陰圧設定値限界と少なくとも第２の陰圧設定値限界との間で、空間（例えば、包帯の下）の圧力レベルを制御するように構成することができる。幾つかの実施形態では、第１の陰圧設定値限界は、約－７０ｍｍＨｇ、又は約－６０ｍｍＨｇ以下～約－８０ｍｍＨｇ以上の間であることができる。幾つかの実施形態では、第２の陰圧設定値限界は、約－９０ｍｍＨｇ、又は約－８０ｍｍＨｇ以下～約－１００ｍｍＨｇ以上の間であることができる。

【００４７】

幾つかの実施形態では、システムは「再試行」の機能性及び／又は論理を含むように構成することができる。ポンプアセンブリは、包帯の下の陰圧レベル（創腔の陰圧レベルに相当する場合がある）を監視し、監視したレベルを所望の陰圧レベル（例えば、第１の陰圧設定値、第２の陰圧設定値など）と比較し、特定の時間間隔の間に所望の陰圧レベルに達していない場合は治療を保留又は一時停止するように構成することができる。治療の保留又は一時停止に続いて、ポンプアセンブリは、治療を再開し（例えば、陰圧源を再始動し）、包帯の下に所望の陰圧レベルを再度発生させるように試みるように構成することができる。再試行の機能性は、例えば、電池電力を節約し、ユーザの介在なしに過渡的及び／又は非過渡的な漏れを解決できるようにするか、あるいはユーザが漏れを直す（例えば、包帯を真っ直ぐにする、シールを直す、１つ又は複数の接続を確認するなど）ことができるようにすることができる。幾つかの実施形態では、コントローラは、再試行の機能性及び／もしくは論理を実行し、かつ／又はそれらを実行するようにプログラムすることができる。

【００４８】

幾つかの実施形態では、システムは、ポンプアセンブリのハウジングの外部、又はユーザがアクセスすることができる他の任意の適切な場所に配置されたスイッチ、ボタンなどを介して、「稼働／一時停止」の機能性及び／又は論理を提供するように構成することができる。稼働／一時停止の機能性によって、ユーザが治療を保留及び／又は再開する（例えば、ポンプを一時停止及び／又は再始動する）のを可能にすることができる。ポンプアセンブリは、特定の所定の又は可変の一時停止間隔にしたがって、治療を自動的に再開するように構成することができる。ポンプアセンブリは、かかる間隔が経過すると治療を自動的に再開し、かつ／又はかかる間隔が経過したことをユーザに指示するように構成することができる。

【００４９】

幾つかの実施形態では、システムは、動作状態を反映して、ユーザに対して表示、アラームなどを提供するように構成することができる。システムは、ユーザに対して様々な動作状態を信号で通知するように構成された、視覚、聴覚、触覚、及び他のタイプのインジケータならびに／又はアラームを含むことができる。かかる状態は、システムのオン／オフ、スタンバイ、一時停止、通常動作、包帯の問題、漏れ、エラーなどを含む。インジケータならびに／あるいはアラームは、スピーカー、ディスプレイ、光源など、及び／又はそれらの組合せを含むことができる。例えば、指示は、陰圧源を動作させるか又は動作停止すること、陰圧源によって発生する陰圧レベルを軽減すること、陰圧源によって使用される電力量を低下させることなど、あるいはそれらの任意の組合せによって、提供することができる。

【００５０】

図１は、ポンプアセンブリ１０４と組み合わせて創傷包帯１０２を備える、減圧創傷治療装置１００の一実施形態を示す。本明細書に開示する装置の実施形態のいずれにおいて

も、図１に示される実施形態のように、ポンプアセンブリは無容器ポンプアセンブリ（ポンプアセンブリが浸出物又は液体の回収容器を有さないことを意味する）であることができる。しかし、本明細書に開示するポンプの実施形態のいずれも、容器を含む又は支持するように構成することができる。それに加えて、本明細書に開示する装置の実施形態のいずれにおいても、ポンプアセンブリの実施形態のいずれかを包帯に装着する、もしくは包帯に隣接して装着するか、又は包帯によって支持する、もしくは包帯に隣接して支持することができる。包帯１０２は、参照によりその開示を本明細書に組み込み本開示の一部と成す特許文献３により詳細に記載されているように、創傷（図示せず）の上に配置されてもよく、次に導管１０６が包帯１０２に接続されてもよい。包帯１０２又は本明細書に開示する他の任意の包帯は、特許文献３に開示されている包帯の実施形態のいずれかにおける材料、サイズ、構成要素、又は他の詳細のいずれかを有することができ、該出願のかかる実施形態及び例証の全体を、本開示の一部を成すものとして参照により本明細書に組み込まれている。導管１０６又は本明細書に開示する他の任意の導管は、ポリウレタン、ＰＶＣ、ナイロン、ポリエチレン、シリコーン、又は他の任意の適切な材料から形成することができる。

【００５１】

包帯１０２の幾つかの実施形態は、導管１０６の端部（例えば、導管１０６の第１の端部１０６ａ）を受け入れるように構成されたポート１０８を有することができるが、かかるポート１０８は必須ではない。幾つかの実施形態では、導管は、別の形で包帯１０２の中及び／又は下を通って、包帯１０２と創傷との間の空間に陰圧源を供給し、それによってかかる空間における所望の陰圧レベルを維持することができる。装置１００の幾つかの実施形態は、導管１０６の第１の端部１０６ａがポート１０８に予め取り付けられるように構成することができる。導管１０６は、ポンプアセンブリ１０４と包帯１０２との間に少なくとも実質的にシールされた流体流路を提供し、それによって、ポンプアセンブリ１０４によって提供される陰圧を包帯１０２に供給するように構成された、任意の適切な物品であることができる。

【００５２】

包帯１０２は、すべての創傷包帯要素（ポート１０８を含む）が予め取り付けられ、単一の単位体へと統合された、単一の物品として提供することができる。次に、創傷包帯１０２は、導管１０６を介してポンプアセンブリ１０４などの陰圧源に接続されてもよい。幾つかの実施形態では、必須ではないものの、ポンプアセンブリ１０４は小型化され可搬型であることができるが、ＥＺ　ＣＡＲＥ（商標）ポンプなどのより大型の従来のポンプも、包帯１０２と共に使用することができる。

【００５３】

本発明の実施形態は、概して、局所陰圧（「ＴＮＰ」）治療システムで使用するのに適用可能であることが理解されるであろう。簡潔には、陰圧創傷療法は、組織浮腫を軽減し、血流及び肉芽組織の形成を促進し、かつ／又は過剰な浸出物を除去することによって、多くの形態の「難治性」創傷の閉鎖及び治癒を支援するとともに、細菌負荷（及び、ひいては感染のリスク）を低減することができる。それに加えて、療法によって創傷の障害をより少なくすることができ、より迅速な治癒に結び付く。ＴＮＰ治療システムはまた、流体を除去することによって、かつ閉鎖の並置位置にある組織を安定化させるのを助けることによって、外科的に閉鎖された創傷の治癒を支援することができる。ＴＮＰ療法のさらなる有益な使用は、過剰な流体を除去することが重要であり、組織の生存度を担保するために移植片が組織に近接していることが求められる、移植片及びフラップにおいて見出すことができる。

【００５４】

創傷包帯１０２は、治療すべき創傷部位の上に配置することができる。包帯１０２は、実質的にシールされた腔又はエンクロージャを創傷部位の上に形成することができる。本明細書全体を通して、創傷に関して言及することが認識されるであろう。この意味で、創傷という用語は広く解釈され、皮膚が断裂、切開、もしくは穿孔される、又は外傷によっ

て挫傷が引き起こされる開放創及び閉鎖創、あるいは患者の皮膚における他の任意の表層もしくは他の部分の状態又は欠陥、あるいは減圧治療によって利益を得る他のものを包含することを理解されたい。したがって、創傷は、流体が生成されることもされないこともある、組織の任意の損傷領域として広く定義される。かかる創傷の例としては、急性創傷、慢性創傷、外科的切開及び他の切開、亜急性創傷及び裂開創傷、外傷性創傷、フラップ及び皮膚移植片、裂傷、擦傷、挫傷、火傷、糖尿病性潰瘍、褥瘡性潰瘍、ストーマ、術創、外傷性潰瘍及び静脈性潰瘍などが挙げられるが、それらに限定されない。幾つかの実施形態では、本明細書に開示するＴＮＰシステムの構成要素は、少量の創傷浸出物を浸出する切開創傷に特に適したものであり得る。

【００５５】

装置の幾つかの実施形態は、浸出物容器を使用することなく動作するように設計されている。包帯１０２は、余剰の流体を蒸発させることができるように、高い水蒸気透過性を有するフィルムを有するように構成することができ、創傷浸出物を安全に吸収するように、超吸収性材料を中に含めることができる。装置の幾つかの実施形態は、使い捨ての治療用に設計されており、最大約７～１１日間の使用後に環境に優しい形で廃棄することができる。ポンプは、所望の日数後に、例えば７日後に治療を自動的に終了し、ポンプのさらなる動作が不可能であるようにプログラムすることができる。幾つかの実施形態は、より長い使用又は繰返しの使用向けに設計され、浸出物容器を支持するように構成することができる。

【００５６】

装置１００は、種々の異なるモデル又はバージョンで製造することができ、その際、広範囲の創傷サイズに適応するように包帯１０２のサイズを変更することができる。例えば、以下のサイズの包帯１０２及び創傷パッド（すなわち、図１に図示されない吸収性要素）を有する装置１００を作ることができる。

【００５７】

【表１】

おおよその包帯サイズ	おおよその創傷パッドサイズ
10cm×30cm(4in×11.75in)	5cm×20cm(2in×8in)
15cm×15cm(6in×6in)	10cm×10cm(4in×4in)
15cm×20cm(6in×8in)	10cm×15cm(4in×6in)
10cm×20cm(4in×8in)	5cm×10cm(2in×4in)
20cm×20cm(8in×8in)	15cm×15cm(6in×6in)

【００５８】

オーバーレイ又は包帯の幾つかの実施形態は、オーバーレイ層を通る空気流及び細菌又は他の汚染物質のフローに対して実質的に不浸透性である一方で、蒸気の通過に対しては浸透性であることができる。

【００５９】

幾つかの実施形態では、創傷部位を創傷充填材で部分的に又は完全に充填するのが好ましいことがある。この創傷充填材は任意選択であるが、特定の創傷、例えばより深い創傷において望ましいことがある。創傷充填材は、創傷包帯１０２に加えて使用することができる。創傷充填材は、概して、多孔質で適合性のある材料、例えば発泡体（網状発泡体を含む）、及びガーゼを含むことができる。好ましくは、創傷充填材は、任意の空の空間を充填するように、創傷部位に嵌合するようにサイズ決めされるか、又は形作られる。次に、創傷包帯１０２を、創傷部位及び創傷部位を覆う創傷充填材の上に配置することができる。創傷充填材が使用されるとき、一旦創傷包帯１０２が創傷部位の上でシールされると、ＴＮＰが創傷包帯１０２を通して、かつ創傷充填材を通して、ポンプから創傷部位へと伝達される。この陰圧は、創傷浸出物及び他の流体又は分泌物を創傷部位から遠ざける。

【００６０】

幾つかの実施形態では、管材１０６は、管材１０６の第２の端部１０６ｂに位置付けられたコネクタ１１２を有することができる。コネクタ１１２は、嵌合するコネクタ１１４ａを短い長さの導管１１４と連通させ、コネクタをポンプハウジング（より詳細に後述する）によって支持させるか、又は別の形で、ポンプアセンブリ１０４から突出する短い長さの導管１１４と連結するように構成することができる。管材１１４の長さは、幾つかの実施形態では、約０．５５インチ（１４ｍｍ）、又は約０．５～約５インチ（１２．７～１２７ｍｍ）であることができる。短い長さの導管又は管材１１４は、患者がポンプ及びコネクタ１１２の上に横たわるか又は別の形でその上にいるときの不快感を減少させることができる。管材１０６をポンプアセンブリ１０４から迅速かつ簡単に除去できるように、ポンプアセンブリ１０４及び管材１０６を構成することによって、必要であれば包帯又はポンプを交換するプロセスを容易にし、あるいは改善することができる。本明細書に開示するポンプの実施形態のいずれも、管材とポンプとの間に、本明細書に開示する接続構成のいずれかを有するように構成することができる。

【００６１】

幾つかの実施形態では、図示される実施形態のように、ポンプアセンブリ１０４は、ユーザの身体上又はユーザの衣服内で支持するのに十分に小さく可搬型のサイズのものであることができる。例えば、ポンプアセンブリ１０４は、接着性の医療用テープを使用するか又は別の形で、包帯１０２に隣接して、もしくは包帯１０２上に、又は別の形で、ヒトの皮膚の快適な場所に取り付けられるようにサイズ決めすることができる。さらに、ポンプアセンブリ１０４は、ヒトのズボン又はシャツのポケットに収まるようにサイズ決めすることができ、あるいは、吊りひも、ポーチ、又は他の適切なデバイスもしくは物品を使用して、ヒトの身体に繋ぎとめることができる。

【００６２】

幾つかの実施形態では、ポンプアセンブリ１０４は、１つ又は複数の電池（例えば、２つの電池）によって電力供給することができ、電池の重量を含めて、約８４ｇ、又は９０ｇ未満の重量であることができる。幾つかの実施形態では、ポンプアセンブリ１０４は、任意の所望の数の電池を有することができ、約８０ｇ～約９０ｇ、又は約７５ｇ～約１００ｇ、又は上記範囲内の任意の値の間の重量であることができる。例えば、ポンプアセンブリ１０４の重量及び／又はサイズは、電池のサイズ及び／又は重量を（例えば、単４電池以下のサイズに）、あるいはポンプのサイズ及び／又は重量を低減することによって、低減することができる。

【００６３】

さらに、ポンプアセンブリ１０４の幾つかの実施形態は、ポンプの外表面によって画成される総体積が、約５．６立方インチ（約９２．５ｃｍ^3）、又は５．６立方インチ（９２．５ｃｍ^3）以下、又は７５ｃｍ^{3}以下～１１５ｃｍ^{3}以上の間、又は８５ｃｍ^3～１００ｃｍ^{3}であるようにサイズ決めすることができる。それに加えて、ポンプアセンブリ１０４は、当業者には知られている技術を使用して、約４０ｃｍ^3、又は４０ｃｍ^{3}以下、又は３０ｃｍ^{3}以下～６０ｃｍ^{3}以上の間の範囲のサイズまでさらに小型化することができる。ポンプアセンブリ１０４の幾つかの実施形態は、２立方インチ（３２．８ｃｍ^3）以下～６．５立方インチ（１０６．５ｃｍ^3）以上の間、又は約４立方インチ（６５．５ｃｍ^3）～約６立方インチ（９８．３ｃｍ^3）、又は上記範囲内の任意の値の間の総体積を有するようにサイズ決めすることができる。

【００６４】

ポンプアセンブリ１０４は、約７．２ｃｍ×約６．４ｃｍ×約２．１ｃｍ（もしくは、７．２ｃｍ×６．４ｃｍ×２．１ｃｍ）の全外形サイズ、又は約８．５ｃｍ×約８．５ｃｍ×約３ｃｍの最大値を有することができる。それに加えて、ポンプアセンブリ１０４は、約５．５ｃｍ×約４．８ｃｍ×約１．５ｃｍ（もしくは、５．５ｃｍ×４．８ｃｍ×１．５ｃｍ）の全外形サイズを有することができる。上述したように、ポンプアセンブリ１０４のサイズ及び重量は、本明細書に開示する実施形態のように、ユーザが着用又は携行するのにより快適になり、それによって移動性の向上がもたらされるように、最適化する

ことができる。

【００６５】

本開示の幾つかの実施形態に関する陰圧範囲は、約－８０ｍｍＨｇ、又は約－２０ｍｍＨｇ～－２００ｍｍＨｇであることができる。これらの圧力は、正常な周囲気圧に対する相対値であり、つまり、実用的用語では、－２００ｍｍＨｇは約５６０ｍｍＨｇであることに留意されたい。幾つかの実施形態では、圧力範囲は約－４０ｍｍＨｇ～－１５０ｍｍＨｇであることができる。あるいは、－７５ｍｍＨｇ以下、－８０ｍｍＨｇ以下、又は８０ｍｍＨｇ超過の圧力範囲を使用することができる。また、他の実施形態では、－７５ｍｍＨｇ未満の圧力範囲を使用することができる。あるいは、約－１００ｍｍＨｇ超過、又はさらには１５０ｍｍＨｇの圧力範囲を、装置１００によって供給することができる。ポンプアセンブリ１０４の動作に関する他の詳細は、特許文献３に記載されており、該特許文献のかかる実施形態、構成、詳細、及び例証の全体を、本開示の一部を成すものとして参照により本明細書に組み込まれている。

【００６６】

図２Ａ～図２Ｆは、図１に示されるポンプアセンブリ１０４の実施形態の様々な図である。図３Ａは、第１のパッケージング要素１５０内で支持されている、包帯１０２（本明細書に開示するか又は参照により組み込まれている包帯の実施形態のいずれかであることができる）と、ポンプアセンブリ１０４と、導管１４０と、１つ又は複数の電池１４２（２つが図示されている）と、１つ又は複数のシールストリップ１４８とを備える、創傷包帯キット１００の一実施形態を示す。図３Ｂは、図３Ａの創傷包帯キット１００の実施形態の下面等角図、図３Ｃは、図３Ａの創傷包帯キット１００の実施形態の分解組立図である。

【００６７】

図２Ａ～図３Ｃを参照すると、ポンプアセンブリ１０４は、第１のハウジング部材１２０ａ及び第２のハウジング部材１２０ｂを備えるハウジング１２０と、制御ボタン１２２（スイッチもしくは他の類似の構成要素であることもできる）と、電池カバー１２４と、コネクタ１２８と、ＬＥＤライトであることができる１つ又は複数のライトとを有することができる。幾つかの実施形態では、ポンプアセンブリ１０４は、２つ以上のボタン１２２を有することができ、３つ以上のライト１３２を有することができる。ライト１３２は、正常のもしくは適切な動作状態、ポンプの故障、ポンプに供給される電力もしくは電源異常、電池の状態もしくは電圧レベル、包帯もしくは流路内の漏れの検出、吸気の阻害、又は他の任意の類似のもしくは適切な状態、あるいはそれらの組合せをユーザに警告することを含む、ポンプアセンブリ１０４の様々な動作状態及び／又は故障状態をユーザに警告するように構成することができる。

【００６８】

ハウジング１２０は、二酸化エチレンなどの滅菌ガスがハウジング内に侵入し、それによって、通常の滅菌プロセスの間、ポンプアセンブリ１０４の内部構成要素が滅菌ガスに暴露されるように構成することができる。一般的に、ポンプは、空気又は他の任意のガスを実質的に排気してあるチャンバ内で滅菌ガスに暴露されるので、滅菌ガスは、ポンプハウジング１２０内に、かつポンプアセンブリ１０４内の他の空間及びチャンバ内に引き込まれる。例えば、ポンプハウジング１２０の幾つかの実施形態は、滅菌ガスが通過することができる、コネクタ１２８を取り囲むシールされていない間隙を有することができる。また、幾つかの実施形態では、間にシールを使用することなく、第１のハウジング部材１２０ａを第２のハウジング部材１２０ｂに接合することができる。

【００６９】

滅菌プロセスに関しては、幾つかの実施形態では、滅菌される構成要素を、とりわけ、任意の順序で、次のステップに晒すことができる。構成要素は、約１５分～１時間１５分の間、約７０ｍＢａｒＡ（又は６７ｍＢａｒＡ～８０ｍＢａｒＡ）まで排気される、チャンバ又はコンテナ内に配置することができる。構成要素はまた、不活性希釈、蒸気圧もしくは調節、又は窒素サイクルに晒すことができ、その後にさらなる排気サイクルを続ける

ことができる。酸化エチレン又は他の任意の適切な滅菌ガスを、約４８２ｍＢａｒＡ（又は約４６７ｍＢａｒＡ～約５００ｍＢａｒＡ）の圧力設定値で、チャンバ又はコンテナに導入することができる。構成要素は、約４６℃（又は約４２℃～４９℃）、又は６０℃以下の温度で、滅菌ガスに暴露することができる。構成要素は、約１０分間（短サイクル）もしくは約１時間（長サイクル）、又は約９分～約１１分間（短サイクル）、又は約５９分～約１時間（長サイクル）、又はそれ以上、滅菌ガスに暴露することができる。構成要素又はチャンバは、窒素及び／もしくは空気で洗い流し、かつ／又はその後に脱気することができる。

【００７０】

ポンプアセンブリ１０４は、１つ又は複数の電池１４２によって電力供給することができる。電池１４２は、二酸化エチレン及び／又は他の滅菌ガスに暴露するのに適している、塩化リチウム又は他の任意の適切な電池であることができる。電池１４２は、１つ又は複数のパッケージング要素内で支持したとき、滅菌プロセス中に滅菌ガスもしくは爆発性ガスの存在下で爆発を引き起こす場合がある、電気火花が起こる可能性を最小限に抑えるか又は排除するように、ポンプハウジング１２０の外部で支持することができる。それに加えて、複数の電池１４２がある場合、滅菌プロセス中の、又は別の使用前における、電池の何らかの電力損失又は火花発生を防ぐため、パッケージング内で電池を離隔するか又は別の形で分離することができる。

【００７１】

図３Ａを参照すると、電池１４２及び１つ又は複数のシールストリップ１４８を包帯１０２の下方に位置付けることができるので、電池１４２を除去する前に包帯１０２を第１のパッケージング要素１５０から除去しなければならず、それによって、包帯キット１００の構成要素をパッケージング１５０から除去する、かつ／又は患者に当てるか、もしくは装置１００を備える他の構成要素に組み合わせる順序が提示される。

【００７２】

幾つかの実施形態では、導管１４０の両端が自由であるか、又は別の形で装置１００の他の構成要素から分断されて、滅菌ガスに対する導管１４０の内表面の暴露が改善され、かつ／又は滅菌ガスに対する管材の完全な暴露が担保されるように、導管１４０をパッケージング１５０内で位置付けることができる。導管１４０の端部は、第１のパッケージング要素１５０に形成された陥凹部内で支持することができる。

【００７３】

第１のパッケージング要素１５０は、ポンプアセンブリ１０４を受け入れる陥凹部１９０、包帯１０２を受け入れる陥凹部１９２、１つ又は複数のシールストリップ１４８及び／又は導管１４０を受け入れる陥凹部１９４、導管１１４及び／又はコネクタ１１４ａ（存在する場合）を受け入れる陥凹部１９６、ならびに電池１４２のための離隔した陥凹部２００ａ及び２００ｂを含む、装置１００の構成要素を受け入れ支持するように構成された１つ又は複数の陥凹部を有することができる。電池を離隔することによって、酸化エチレンの潜在的に可燃性の性質により、滅菌処置中に爆発するリスクを低減又は排除することができる。

【００７４】

幾つかの実施形態では、第１のパッケージング要素１５０は、包帯キットの処理又は運搬中、電池、ポンプ、及び／又は他の構成要素を適所で保持するのに十分に剛性及び／又は堅牢性である、材料又は材料の組合せから作ることができる。例えば、第１のパッケージング要素１５０の幾つかの実施形態は、約１５Ｇ～約２５Ｇ、又は１Ｇ～４０Ｇ、又は１Ｇ～２０Ｇ、又は２５Ｇ～４０Ｇの加速に耐えるのに十分な、電池、ポンプ、又は他の構成要素などの構成要素の圧縮嵌めもしくは締まり嵌めをもたらすように構成することができる。第１のパッケージング要素１５０の幾つかの実施形態は、パッケージングの短絡もしくは溶融／磨耗に結び付く可能性があり、結果としてパッケージングの損傷もしくは細菌の進入につながる、構成要素の移動又はずれを防ぐのに十分である一方で、ユーザがかかる構成要素を必要なときにパッケージングから除去できることを妨害しないように、

ポンプ、電池、管材（管材のピンチ又は陥凹部を含む）、及び他の構成要素をしっかり保持するように構成することができる。

【００７５】

それに加えて、図示されるように、第１のパッケージング要素１５０は、手袋をはめた手及びはめていない手の両方で、外科医又はユーザがアクセスし、装置１００の様々な構成要素を除去するのを容易にするように、サイズ決めされ構成された溝又は陥凹部１９３を有することができる。さらに、隆起又は突起１９５を第１のパッケージング要素１５０に形成して、パッケージング及びキットの構成要素に対する付加的な支持及び保護を提供することができる。第１のパッケージング要素１５０は、Ｎｅｌｉｐａｋ Ｃｕｓｔｏｍ Ｔｈｅｒｍｏｆｏｒｍｅｄ Ｐｒｏｄｕｃｔｓによって提供される、再生利用可能な未使用のＰＥＴＧを青色に染色した０．８０ Ｅａｓｔｍａｎ ６７６３医療用グレードを含む、滅菌することができる任意の適切な材料から作ることができる。パッケージング要素１５０は、ＥＡＳＴＡＲ（商標）、Ｃｈｅｍｉｃａｌ ＰｒｏｄｕｃｔのＥＡＳＴＡＲコポリエステル樹脂から押し出し、熱成形することができる。例えば、押出しシート又はフィルムであり得る原料を、高温下での真空及び染色ツール上への圧迫を使用して、熱成形することができる。第１のパッケージング要素１５０に適した他の材料としては、ポリカーボネート、ＰＶＣ、又は他の任意の適切な樹脂もしくはプラスチック材料が挙げられる。幾つかの実施形態では、第１のパッケージング要素は、０．８ｍｍ（もしくは約０．８）の厚さ、又は０．８ｍｍ以下、もしくは１．０ｍｍ以下、もしくは約０．７ｍｍ～１．２ｍｍの厚さを有する材料（プレート、シート、フィルムなどを含む）から作ることができる。

【００７６】

ガス透過性のカバー１５１（本明細書では、第２のパッケージング要素とも呼ばれる）は、第１のパッケージング要素１５０の上にシール可能に位置付けて、包帯キット１００の内容物に対する細菌及び汚染物質のバリアを提供することができる。例えば、ＴＹＶＥＫ（商標）、紙、又は他の任意の適切な材料のシート状の層もしくはフィルムを、第１のパッケージング要素１５０の周縁部分１５３にシールすることができる。カバー１５１は、滅菌ガスに対して透過性であるが、細菌及び他の汚染物質に対してはバリアを提供する、ＴＹＶＥＫを含む任意の適切な材料から作ることができる。カバー１５１は、不透明、透明、又は半透明であることができる。

【００７７】

カバー１５１は、包帯キットの構成要素をすべて中で組み立てた後に、第１のパッケージング要素１５０とシール可能に連結することができる。その後、第１のパッケージング要素１５０、カバー１５１、及び包帯キットの構成要素を、滅菌ガスがバッグに入り包帯キットの構成要素を滅菌できるように、バッグに形成された開口部の上でＴＹＶＥＫ又は他の滅菌ガス透過性の材料パッチを有するシールされた不透過性のバッグ内に位置付けることができる。

【００７８】

図４Ａ及び図４Ｂは、第２のハウジング部材１２０ｂから分離された第１のハウジング部材１２０ａを示す、図１のポンプアセンブリ１０４の実施形態の第１及び第２の分解組立図である。図５Ａ及び図５Ｂは、第１のハウジング部材１２０ａの第１及び第２の図である。図６Ａ及び図６Ｂは、第２のハウジング部材１２０ｂの第１及び第２の図である。図４Ａ～図６Ｂを参照すると、ポンプアセンブリ１０４の幾つかの実施形態は、ハウジング１２０内で支持される、又はハウジング１２０内に形成される電池区画２２０を有することができる。１つ又は複数の電池接点２２２は、電池区画２２０内で支持することができる。１つ又は複数の電線２２４は、電池接点２２２をポンプ２３２及び／又は制御盤２３０に接続することができる。ポンプアセンブリ１０４は、組み立て中にポンプが暴露されるか又はポンプが受け取る可能性がある、汚染もしくはバイオバーデンのリスクを低減するため、クリーンルーム内で組み立てることができる。

【００７９】

幾つかの実施形態では、ポンプ２３２は、モータと、入口ポート又はコネクタ２５０と、出口ポート２５２とを備えることができる。ポンプ２３２は、１つ又は複数の弁を中に有することができる。例えば、第１の弁は、入口ポート２５０に隣接してポンプ２３２内に位置付けることができる。それに加えて、第２の弁は、出口ポート２５２に隣接してポンプ２３２内に位置付けることができる。ポンプ２３２は、入口ポート２５０を通り、第１及び第２の弁を通り、出口ポート２５２を出る流路を画成することができる。

【００８０】

幾つかの実施形態では、電池接点２２２は、極性保護を有するように構成することもできる。例えば、電池接点１２５に隣接した１つ又は複数の突出部１２４ｄと同様に、電池接点２２２の１つ又は複数は、電池接点２２２と、正しくない向きで電池区画に挿入された電池の正しくない側との接触を阻害するため、接点に隣接したプラスチック又は他の突出部（図示せず）を有することができる。例えば、１つ又は複数の突出部は、標準的な円筒形電池の負極が、１つ又は複数の突出部に隣接した電池接点２２２に接触するのを防ぐ一方で、かかる電池の正極が電池接点２２２に接触するのを可能にするように、サイズ決めし構成することができる。概して、この構成を用いて、電池は概して、電池を電池区画２２０に正しい向きで挿入した場合にのみ接点２２２と接触することができ、それによってポンプアセンブリ１０４に極性保護がもたらされる。突出部は、好ましくは非導電性材料から作られる。別の方法として、又はそれに加えて、制御盤２３０を、極性保護の機構又は構成要素を有するように構成することができる。それに加えて、制御盤２３０は、過電力状態又はサージ電力状態に対する保護のため、１つ又は複数のヒューズを有することができる。

【００８１】

ポンプアセンブリ１０４は、ポンプアセンブリ１０４内の流体流路と連通している、フローマニホルド２４０及び一方向フロー弁２４６を有することができる。一方向フロー弁２４６（逆止め弁とも呼ばれる）は、シリコーン、あるいは非限定的に、ポリウレタン、バイトン、ニトリルゴム、ネオプレン、テフロン（登録商標）、及び他の適切な材料を含む他の任意の適切なエラストマー材料又は軟質材から作られた、ダイヤフラム弁であることができる。一方向フロー弁に対する他の適切な弁は、例えば非限定的に、アンブレラ弁、玉弁、リード弁、ダックビル弁である。幾つかの実施形態では、一方向フロー弁２４６の漏れ速度は約０．０５ｍＬ／分であることができる。幾つかの実施形態では、一方向フロー弁２４６は、ポンプ２３２内に、又はポンプ２３２内に位置付けられた弁の１つの代わりに位置付けることができる。

【００８２】

マニホルド２４０及び／又は一方向フロー弁２４６は、コネクタ１２８と連通していることができる。幾つかの実施形態では、一方向フロー弁２４６はマニホルド２４０内で支持することができ、マニホルド２４０は、ポンプ２３２の入口ポートもしくはコネクタ２５０と実質的にシール可能に連結するか、又は別の形でハウジング１２０内で支持して、入口ポートもしくはコネクタ２５０と流体連通するようにすることができる。例えば、図４Ａ及び図４Ｂを参照すると、マニホルド２４０は、入口コネクタ２５０がマニホルド２４０に形成された開口部２６１内に受け入れられるように、ポンプ２３２とともに組み立てることができる。空気及び／又は他のガスは、出口ポートもしくはコネクタ２５２を通してポンプ２３２を出ることができる。滅菌中、ポンプ２３２は、滅菌ガスがポンプ２３２の内部空間又はチャンバに侵入して、ポンプ２３２全体（内部及び外部の両方）が滅菌されていることを担保することができるように構成することができる。１つ又は複数の弁（アンブレラ弁もしくは他の任意の適切な弁であり得る）を、ポンプ２３２内に位置付けることができる。例えば、非限定的に、１つ又は複数の弁を、入口ポート２５０及び出口ポート２５２それぞれに隣接して位置付けて、ポンプ２３２内で支持することができる。

【００８３】

最適な滅菌のため、幾つかの実施形態では、滅菌ガスをゆっくり導入して、弁を通る滅菌ガスのフローを最適化するとともに、滅菌ガスによる圧力が弁を完全に閉止するのを防

ぐことができる。上述したように、弁（第１及び第２の弁など）は、ある程度漏れ性であるように構成し、それによって滅菌ガスのフロー が弁を超えて先に進んでポンプ２３２の内部構成要素を滅菌できるようにすることができる。例えば、弁は、公称のもしくは一般的な動作圧力で（すなわち、導管内の流体の公称動作圧力で）、又は公称のもしくは一般的な滅菌圧力で、０．１ｍＬ／分～１０ｍＬ／分以上の速度でそこを通る流体の漏れ流量（すなわち、弁が閉止位置にあるときに弁を通る流量）を可能にすることができる。幾つかの構成では、２つの弁の間、又は弁と一方向弁との間にある流路の部分は、流路又はポンプアセンブリ１０４を滅菌するのに最も難しい部分であり得る。

【００８４】

ポンプアセンブリの幾つかの実施形態は、圧電ポンプを有することができる。本明細書に開示する幾つかの圧電ポンプ又は他のポンプは、ポンプが停止中のとき、ポンプを通る流量が２００ｍＬ／分程度の多量であることができるように、弁機能を実施するオリフィスを有するか、あるいはオリフィスを有するように構成することができる。したがって、幾つかの実施形態では、ポンプ速度が約３００ｍＬ／分又は３２０ｍＬ／分又はその他の高い速度であることができる場合、第１及び第２の弁（オリフィスであり得る）はそれぞれ、約２００ｍＬ／分以下の漏れ速度を有することができる。

【００８５】

ポンプ２３２は、非限定的に、回転ダイヤフラムポンプもしくは他のダイヤフラムポンプ、圧電ポンプ、蠕動ポンプ、ピストンポンプ、回転翼ポンプ、液封ポンプ（ｌｉｑｕｉｄ ｒｉｎｇ ｐｕｍｐ）、スクロールポンプ、圧電変換器によって動作するダイヤフラムポンプ、又は他の任意の適切なポンプもしくはマイクロポンプ、あるいは上記のものの任意の組合せなど、任意の適切なタイプのものであることができる。ポンプ２３２は、例えば、Ｋｏｇｅ ＥｌｅｃｔｒｏｎｉｃｓのＫＰＶ８Ａ－３Ａポンプなどの、標準的な既製の真空ポンプであることができる。ポンプ２３２は、ＫＮＦダイヤフラムポンプ又は任意の適切なＫＮＦポンプであることもできる。

【００８６】

ポンプの幾つかの実施形態は、約１０ｇ、又は約６ｇ～１５ｇ、又は上記範囲内の任意の値と値の間のような軽量であることができる。ポンプ２３２は、約５００ｍＬ／分、又は約３００ｍＬ／分以下～約６００ｍＬ／分以上の間、又は約４００ｍＬ／分～約５００ｍＬ／分の間、又は上記範囲内の任意の値の間のポンプ容量を有することができる。幾つかの実施形態では、ポンプアセンブリ１０４は２つ以上のポンプ２３２を備えることができる。例えば、ポンプアセンブリ１０４は、創傷のオーバーレイと創傷との間の空間の迅速なドローダウンをもたらすように構成された、高い流量を有する第１のポンプと、最初のドローダウン後に創傷のオーバーレイと創傷との間の空間の減圧レベルを維持するように構成された、第２のより少ない容量のポンプとを有することができる。幾つかの実施形態では、ポンプ流量は、約１５ｍＬ／分に設定することができる、漏れアラームの流量の約２０倍であることができる。

【００８７】

上述したように、コネクタ１２８は、管材１０６の端部と連結された噛合するねじ山付きのコネクタを螺合可能に受け入れることができる、ねじ山付きのコネクタ（図示されるようなもの）であることができる。ねじ山付きのコネクタ１２８は、医療従事者が標準的なルアーコネクタ（静脈ラインからのコネクタなど）を不用意に取り付けるのを防ぐため、他の医療用コネクタと比較して標準的ではないサイズのものであってもよい。

【００８８】

あるいは、図示されないが、コネクタ１２８は、管材１０６の端部上における別個の噛合するコネクタを省略できるように、管材をその上にシール可能に受け入れるように構成された、標準的な管材コネクタ（ニップルコネクタなど）であることができる。

【００８９】

マニホルド２４０は、圧力モニタの導管又はコネクタ２６２を受け入れるように構成することができる、別個のポート２６０を有することができる。圧力モニタは、制御盤２３

０によって支持することができ、流体流路内の圧力レベルを監視するように構成することができる。圧力モニタは、モータ２３２を保護して予め定義された閾値圧力を超過しないように構成することができる。幾つかの実施形態では、圧力モニタは１７５＋／－５０ｍｍＨｇを超過しないように較正することができる。幾つかの実施形態では、圧力モニタは２３５ｍｍＨｇを超過しないように較正することができる。圧力モニタは、圧力の読取り値が所定の値に達した場合にモータに対する電力を停止するように構成することができ、圧力レベルが所定の値を、又は第１の所定の値よりも高いもしくは低い場合がある第２の所定の値を下回ると、電力を再開するように構成することができる。それに加えて、ポンプアセンブリ１０４は、かかる過圧を防ぐようにプログラムすることができる。ポンプアセンブリ１０４は、ソフトウェアが過圧を防ぐ主要機構を提供するように構成することができ、圧力モニタが過圧保護のバックアップを提供することができる。

【００９０】

ポンプ２３２は、ポンプ２３２によって生成される雑音及び振動を低減するため、ポンプ２３２の外表面の周りに少なくとも部分的に巻き付けられる、連続気泡発泡体又は他の材料の層を有することができる。これらの構成要素はすべて、任意の適切な締結具２７０（例えば、一対のねじ）でともに固定することができる、第１及び第２のポンプハウジング部材１２０ａ、１２０ｂ内で支持することができる。１つ又は複数のラベル２７２を、ハウジング１２０の外表面に付着させることができる。それに加えて、幾つかの実施形態では、ポンプ２３２は、ポンプ２３２によって支持されるか、又はポンプの１つ又は複数の外表面に隣接して位置付けられる、１つ又は複数の重り、クッション、発泡体（粘弾性発泡体など）、プラスチック（ＡＢＳ、ポリウレタン、ウレタンなど）、あるいは他のパッド、パネル、シート、又はセグメントを有することができる。幾つかの実施形態は、質量ベースの、又は柔軟な制振材料を有することができる。かかる構成要素又は材料（図示せず）は、ポンプによって生成される振動を減衰し、かつ／又は雑音を弱めることができる。

【００９１】

例えば、１つ又は複数の重り（鋼、金属、もしくは他の任意の適切な材料から作られる）を、ポンプ２３２又は本明細書に開示する他の任意のポンプの実施形態の外表面で支持するか、あるいはそれに取り付けることができる。鋼製重りは、約１．８ｇ、３．８ｇ、もしくは５．８ｇ、又は１ｇ～１０ｇ以上、もしくは１．５ｇ～６ｇの重量であることができる。２つ以上の重りを、ポンプ２３２又は本明細書に開示する他の任意のポンプの実施形態の外表面で支持するか、あるいはそれに取り付けることができる。それぞれ約１．８ｇ、３．８ｇ、もしくは５．８ｇ、又は１ｇ～１０ｇ以上、もしくは１．５ｇ～６ｇの重量である２つの鋼製重りを、ポンプ２３２の外表面に取り付けることができる。２つのプレートをそれぞれ、モータ２３２の対向面に、又は別の形で位置付けることができる。幾つかの実施形態では、それぞれ約１．８ｇ、３．８ｇ、もしくは５．８ｇ、又は１ｇ～１０ｇ以上、もしくは１．５ｇ～６ｇの重量である４つの鋼製重りを、ポンプ２３２の外表面に取り付けることができる。プレートは、２つのプレートがモータ２３２の２つの対向面それぞれに位置付けられるように、又は別の形で配列することができる。幾つかの実施形態では、例えば非限定的に、ポンプ２３２の側面及び上面を含む、ポンプ２３２の３つ以上の面に隣接して重りを位置付けることができる。

【００９２】

図４Ａを参照すると、電池カバー１２４は、電池カバー１２４が閉止位置にあるときに不用意に開くのを阻害するため、ハウジング１２０の噛合する機構と係合するように構成することができる、ラッチ又はタブ部材１２４ａを有することができる。それに加えて、電池カバー１２４を開閉することができる容易さを促進するため、ガイド又は突出部１２４ｂを電池カバー１２４に形成することができる。ガイド１２４ｂは、ハウジング１２０に形成された噛合するガイド又はチャネル１２０ｃを係合することができる。電池カバー１２４は、一本の指で使用するために、把持面を有するように構成することができる。例えば、非限定的に、複数の窪み１２４ｃを電池カバー１２４の表面に形成して、ユーザの

指又は他の物体と電池カバー１２４との間の把持を向上させ、電池カバー１２４の開閉を容易にすることができる。

【００９３】

図４Ｂを参照すると、電池カバー１２４は、２つの電池間の接続を提供するように構成された、１つ又は複数の電池接点又は端子１２５をその上で支持することができる。電池カバー１２４は、電池接点１２５に隣接した１つ又は複数の突出部１２４ｄをさらに支持することができる。１つ又は複数の突出部１２４ｄは、標準的な円筒形電池の負極が、１つ又は複数の突出部１２４ｄに隣接した電池接点１２５に接触するのを防ぐ一方で、かかる電池の正極が電池接点１２５に接触するのを可能にするように、サイズ決めし構成することができる。この構成を用いて、電池は概して、電池を電池区画２２０に正しい向きで挿入した場合にのみ接点１２５と接触することができ、それによってポンプアセンブリ１０４に極性保護がもたらされる。

【００９４】

図４Ａ及び図４Ｂを参照すると、ハウジング１２０は、ハウジングの２つの部材１２０ａ、１２０ｂの間の接続を改善するため、１つ又は複数のタブ１２１と、タブ１２１を受け入れるように構成された窪み又はチャネル１２３とを有することができる。タブ１２１及び窪み１２３は、ハウジング１２０の縁部をともにより良好に保持して、ハウジング１２０の強度を改善するとともに、ハウジングの２つの部材１２０ａ、１２０ｂの間の接続をよりきつくすることができる。制御盤２３０は、同様の機構を用いてハウジング１２０に組み合わせることができる。

【００９５】

本明細書に全体が記載されているものとして参照により本明細書にその開示を組み込まれている、特許文献３に記載されているように、本明細書に開示する創傷包帯１０２の実施形態のいずれかの下面は、任意の創傷接触層を有することができる。本明細書に開示する包帯の実施形態のいずれも、創傷接触層を有さずに作ることができる。創傷接触層は、例えば、ホットピンプロセス（ｈｏｔ　ｐｉｎ　ｐｒｏｃｅｓｓ）、レーザーアブレーションプロセス、超音波プロセスによって、又は他の何らかの手法で多孔性もしくは有孔にすることができる、あるいは別の方法で液体及びガス透過性にすることができる、ポリウレタン層又はポリエチレン層又は他の可撓性層であることができる。貫通孔によって、液体及び／又はガスが層を通って流れることを可能にすることができる。創傷接触層は、創傷包帯の別の材料内への組織の内成長を防ぐ助けとなり得る。

【００９６】

貫通孔は、この要件を満たすのに十分な小ささであるが、依然として流体を通すことができるようにサイズ決めすることができる。例えば、０．０２５ｍｍ～１．２ｍｍの範囲のサイズを有するスリット又は穴として形成された貫通孔は、創傷包帯内への組織の内成長を防ぐ助けとなるのに十分な小ささである一方で、創傷浸出物が包帯に流入するのを可能にするものと見なされる。創傷接触層は、創傷包帯全体をともに保持する助けとなるとともに、創傷における陰圧を維持するため、吸収性パッドの周りに気密シールを作り出す助けとなる。創傷接触層は、任意の下側及び上側の接着剤層（図示せず）の担体としても作用する。例えば、下側の感圧性接着剤層を創傷包帯の下面１０１に提供することができ、その一方で、上側の感圧性接着剤層を創傷接触層の上面１０３に提供することができる。シリコーン、ホットメルト、ヒドロコロイド、もしくはアクリル系の接着剤、又は他のかかる接着剤であることができる感圧性接着剤は、創傷接触層の両面に、又は任意選択で創傷接触層の選択された一面に形成するか、もしくはいずれの面にも形成しないことができる。下側の感圧性接着剤層が利用される場合、このことは、創傷包帯を創傷部位の周りで皮膚に接着する助けとなる。

【００９７】

上述したように、本明細書に開示するか又は参照により組み込まれている包帯キットで使用される、任意の包帯の実施形態は、接着剤で覆われた下面（例えば、創傷接触面）を有することができる。幾つかの実施形態では、上述したように、接着剤は、例えばポリシ

ロキサン又はポリオルガノシロキサンを含むシリコーン接着剤、あるいは他のポリマー性の感圧性シリコーン接着剤であることができる。例えば、ポリジメチルシロキサンなどを使用することができる。接着剤配合物は、流延（ｃａｓｔｉｎｇ）又は塗り広げる（ｓｐｒｅａｄｉｎｇ）に続いて最終重合ステップが行われるように、触媒との二液混合物として塗り広げ流延することができる、アルキルペンダントシロキサンの混合物であってもよい。幾つかの実施形態では、包帯層は、押出しＥＵ３０ポリウレタン透明フィルム（２７～３７ｇｓｍ）の対向面上にコーティングされた、無孔のシリコーン接着剤コーティング（コート重量は公称１３０ｇｓｍ）及び十分に流延されたアクリル接着剤（２７～３７ｇｓｍ）を有することができる。かかる配置の幾つかの実施形態の水蒸気透過性は、約３６７ｇｍ$^{-2}$／２４時間～約４０５ｇｍ$^{-2}$／２４時間、又は平均水蒸気透過性３８２ｇｍ$^{-2}$／２４時間であることができる。

【００９８】

本明細書に開示する包帯の実施形態に適したシリコーン接着剤層の幾つかの実施形態又は配置は、約３５０ｇｍ$^{-2}$／２４時間～約４１０ｇｍ$^{-2}$／２４時間の水蒸気透過率を有することができる。適切には、本明細書に開示する包帯の実施形態に適したシリコーン接着剤層の幾つかの実施形態又は配置の平均水蒸気透過性は、約３８０ｇｍ$^{-2}$／２４時間であることができる。本明細書に開示する包帯の実施形態のいくつかは、Ｗａｃｋｅｒ　ｓｉｌｒｅｓ　ＰＳＡ　４５感圧性接着剤が上にコーティングされたものであることができる。

【００９９】

それに加えて、本明細書に開示する包帯の実施形態のいずれも、包帯に組み込まれた、又は包帯の１つ又は複数の表面にコーティングされた、抗菌剤又は抗菌物質を有することができる。例えば、非限定的に、本明細書に開示する任意の包帯の実施形態の創傷接触層は、非限定的に、本開示の一部を成すものとして参照により本明細書に組み込まれている、２００８年５月２１日に出願された特許文献１０（「ＡＮＴＩＭＩＣＲＯＢＩＡＬ　ＢＩＧＵＡＮＩＤＥ　ＭＥＴＡＬ　ＣＯＭＰＬＥＸＥＳ」という名称）に開示されているものなどの、ナノ結晶質の銀剤、銀塩、銅塩、又は金塩、ＰＨＭＢ、クロロヘキサジン、過酸化物、次亜塩素酸、あるいはその中又は上の他の漂白剤を有することができる。さらに、本明細書に開示する任意の包帯の実施形態の吸収性層は、銀硫黄ジアジン、あるいはその中もしくは上の上述した物質又は活性剤のいずれかを有することができる。これらは、別個に又は併せて使用されてもよい。これらはそれぞれ、創傷の中の微生物及び吸収マトリックスの中の微生物を排除することができる。さらなる他の選択肢として、他の活性成分、例えばイブプロフェンなどの痛み抑制剤又は治癒薬を、包帯に組み込むことができる。また、成長因子などの細胞活性を向上させる薬剤、又はメタロプロテイナーゼの組織阻害剤（ＴＩＭＰＳ）などのマトリックスメタロプロテイナーゼ阻害剤もしくは亜鉛キレート剤など、酵素を阻害する薬剤を包帯に組み込むことができる。活性炭、シクロデキストリン、ゼオライトなどの臭気捕集要素も、包帯の吸収性層又は他の部分もしくは構成要素に、あるいはフィルタ層の上に含めることができる。

【０１００】

多孔質材料の層は、創傷接触層の上に配置することができる。この多孔質層、つまり透過層によって、液体及びガスを含む流体を創傷部位から離して創傷包帯の上層へと透過させることが可能になる。特に、透過層は、吸収性層がかなりの量の浸出物を吸収しているときであっても、開放空気チャネルを維持して創傷範囲の上に陰圧を伝達できることを担保することができる。層は、上述したような陰圧創傷治療の間、加えられる一般的な圧力下で、開いたままであるべきであり、それによって、創傷部位全体に均等化された陰圧が見込まれる。層は、三次元構造を有する材料で形成することができる。例えば、編成もしくは織成したスペーサ布地（ｓｐａｃｅｒ　ｆａｂｒｉｃ）（例えば、Ｂａｌｔｅｘ　７９７０横編みポリエステル）、又は不織布を使用することができる。他の材料を利用することができ、かかる材料の例は、参照により本明細書に組み込まれているとともに本開示の一部を成す、特許文献３に記載されている。

【０１０１】
幾つかの実施形態では、透過層は３Ｄポリエステルスペーサ布地層を有することができる。この層は、８４／１４４テクスチャードポリエステルである上層（すなわち、使用中は創傷床から遠位側にある層）と、１００デニールのフラットポリエステルであることができる下層（すなわち、使用中は創傷床に近接して位置する層）と、これら２つの層の間に挟まれて形成される、編成ポリエステルビスコース、セルロースなどのモノフィラメント繊維によって画成される領域である、第３の層とを有することができる。他の適切な材料、及び繊維の他の線形的な質量密度を使用することができる。
【０１０２】
離隔した層におけるフィラメント計数の間のこの差分は、透過層を横切る水分フローを制御する助けとなる。特に、最上層のフィラメント計数をより多くすることによって、すなわち、最下層で使用される糸よりも多数のフィラメントを有する糸で最上層を作ることによって、液体は、最下層よりも最上層に沿ってウィッキングされる傾向がある。使用の際、この差分により、液体が創傷床から離れるように吸い出され、包帯の中央領域に吸い込まれる傾向になり、そこで、吸収性層が液体を閉じ込めるか、又はそれ自体が液体を、蒸散させることができるカバー層に向かって前方にウィッキングする助けとなる。
【０１０３】
好ましくは、透過層を横切る（すなわち、上側スペーサ層と下側スペーサ層との間に形成されるチャネル領域に垂直な）液体のフローを改善するため、３Ｄ布地はドライクリーニング剤（ペルクロロエチレンなどであるが、それに限定されない）で処理されて、透過層の親水性を妨げることがある、以前は使用されていた鉱物油、油脂、及び／又はワックスなどの任意の工業製品を除去する助けとなる。幾つかの実施形態では、親水性薬剤（Ｒｕｄｏｌｐｈ　Ｇｒｏｕｐから入手可能なＦｅｒａｎ　Ｉｃｅ　３０ｇ／Ｌなどであるがそれに限定されない）で３Ｄスペーサ布地が洗浄される、追加の製造ステップを続いて行うことができる。このプロセスステップは、材料上の表面張力が低く、水などの液体が３Ｄ編地に接触するとすぐに布地に入ることができる程度であることを担保する助けとなる。これは、任意の浸出物の液体障害成分（ｌｉｑｕｉｄ　ｉｎｓｕｌｔ　ｃｏｍｐｏｎｅｎｔ）のフローを制御するのにも役立つ。
【０１０４】
やはり、特許文献３により詳細に記載されているように、吸水性材料層を透過層の上に設けることができる。発泡体又は不織布の天然もしくは合成材料であることができ、任意選択で超吸収性材料を含む又は超吸収性材料とすることができる、吸収性材料は、流体、特に創傷部位から除去された液体のリザーバを形成し、カバー層に向かってそれらの流体を吸い取る。吸収性層の材料は、創傷包帯に回収された液体が飛び散るように流れるのを防ぐことができる。吸収性層はまた、流体が創傷部位から吸い出され、吸収性層全体に亘って蓄積されるように、ウィッキング作用を介して層全体に流体を分配させる助けとなり得る。これは、吸収性層の範囲における凝集を防ぐことに役立つ。吸収材料の容量は、陰圧が加えられたときの創傷の浸出物流量を管理するのに十分でなければならない。使用の際、吸収性層は陰圧を受けるので、吸収性層の材料は、かかる状況下で液体を吸収するように選ばれる。陰圧下で液体を吸収することができる多数の材料、例えば超吸収性材料が存在する。吸収性層は、ＡＬＬＥＶＹＮ（商標）発泡体、Ｆｒｅｕｄｅｎｂｅｒｇ　１１４－２２４－４、及び／又はＣｈｅｍ－Ｐｏｓｉｔｅ（商標）１１Ｃ－４５０、あるいは他の任意の適切な材料から製造することができる。
【０１０５】
幾つかの実施形態では、吸収性層は、乾燥粒子の形態の超吸収性材料が全体的に分散されている、不織布セルロース繊維の層であることができる。セルロース繊維を使用することで、包帯によって吸収された液体を迅速かつ均一に分配する助けとなる高速ウィッキング要素が導入される。複数のストランド状繊維を並置することは、液体を分配する助けとなる繊維状パッドにおける強力な毛管作用に結び付く。このように、超吸収性材料に液体が効率的に供給される。さらに、吸収性層の領域にはすべて、液体がもたらされる。

【０１０６】
ウィッキング作用はまた、包帯の蒸散速度を増加させるのに役立つように、液体を上側カバー層と接触させるのを支援する。ウィッキング作用はまた、浸出物が低速であるか又は停止したときに、液体を創傷床に向かって下方に送達するのを支援する。この送達プロセスは、透過層及び下側の創傷床領域を湿潤状態で維持する助けとなり、それが包帯内での痂皮形成（阻害に結び付き得る）を防ぐ助けとなるとともに、創傷治癒に対して最適化された環境を維持する助けとなる。

【０１０７】
幾つかの実施形態では、吸収性層はエアレイド材料であることができる。熱融着性繊維を任意選択で使用して、パッドの構造をともに保持するのを支援することができる。超吸収性粒子を使用するのではなく、又はそれを使用するのに加えて、本発明の幾つかの実施形態による超吸収性繊維を利用することができることが認識されるであろう。適切な材料の一例は、米国のＥｍｅｒｇｉｎｇ　Ｔｅｃｈｎｏｌｏｇｉｅｓ　Ｉｎｃ　（ＥＴｉ）から入手可能な製品Ｃｈｅｍ－Ｐｏｓｉｔｅ（商標）１１Ｃである。

【０１０８】
任意選択で、吸収性層は、合成の安定した繊維及び／又は二成分の安定した繊維及び／又は天然の安定した繊維及び／又は超吸収性繊維を含むことができる。吸収性層中の繊維は、ラテックス結合又は熱結合又は水素結合又は任意の結合技術の組合せ又は他の固定機構によって、互いに固定することができる。幾つかの実施形態では、吸収性層は、吸収性層内で超吸収性粒子を閉じ込めるように動作する繊維によって形成される。これにより、吸収性層の外部に、かつ下にある創傷床に向かって超吸収性粒子が移動しないことを担保する助けとなる。このことは特に有用であるが、それは、陰圧が加えられると、吸収性パッドが下向きに潰れる傾向があり、この作用によって超吸収性粒子状物質が、吸収性層の繊維構造によって閉じ込められていなかった場合に、創傷床に向かう方向へと押し込まれるためである。

【０１０９】
吸収性層は複数の繊維の層を含むことができる。好ましくは、繊維はストランド状であり、セルロース、ポリエステル、ビスコースなどで作られる。好ましくは、乾燥した吸収性粒子が、準備ができている吸収性層全体に亘って分配される。幾つかの実施形態では、吸収性層は、セルロース繊維のパッドと複数の超吸収性粒子とを含む。追加の実施形態では、吸収性層は、ランダムに向きを付けられたセルロール繊維の不織布層である。

【０１１０】
超吸収性粒子／繊維は、例えば、ポリアクリル酸ナトリウムもしくはカルボメトキシセルロース材料など、又は液体中における自身の重量の何倍も吸収することができる任意の材料とすることができる。幾つかの実施形態では、材料は、０．９％重量食塩水自体の重量の５倍を超えて吸収することができる。幾つかの実施形態では、材料は、０．９％重量食塩水自体の重量の１５倍を超えて吸収することができる。幾つかの実施形態では、材料は、０．９％重量食塩水自体の重量の２０倍を超えて吸収することができる。好ましくは、材料は、０．９％重量食塩水自体の重量の３０倍を超えて吸収することができる。吸収性層は、吸引ポートの下になるように配置された１つ又は複数の通し穴を有することができる。

【０１１１】
包帯１０２は、ガス不透過性であるが水蒸気透過性である、創傷包帯の幅を横切って延在するカバー層を有することができる。カバー層は、例えばポリウレタンフィルム（例えば、Ｅｌａｓｔｏｌｌａｎ　ＳＰ９１０９）、又は一面に感圧性接着剤を有する他の任意の適切な材料であることができ、実質的にガス不透過性であり、それによって実質的にシールされたエンクロージャが創傷の上に作られる。このように、有効なチャンバがカバー層と創傷部位との間に作られて、陰圧を確立することができる。カバー層は、包帯の周面の周りの境界領域で創傷接触層にシールすることができ、例えば接着又は溶接技術によって、境界範囲を通って空気が引き込まれないことが担保される。カバー層は、外部の細菌

汚染から創傷を保護することができ（細菌バリア）、創傷浸出物からの液体が層を通って移行し、フィルムの外表面から蒸発することを可能にしている。カバー層は、ポリウレタンフィルムと、フィルム上に流延された接着剤パターンとを有することができる。ポリウレタンフィルムは水蒸気透過性であり、湿潤したときの水透過率が増加する材料から製造されてもよい。

【０１１２】

陰圧を包帯１０２に加えることができるように、カバーフィルムにオリフィスを設けることができる。上述したように、幾つかの実施形態では、吸引ポート１０８は、オリフィスの上のカバーフィルム上にシールすることができ、それによってオリフィスを通して陰圧を伝達することができる。ポートは、アクリル、シアノアクリレート、エポキシ、ＵＶ硬化性、又はホットメルト接着剤などの接着剤を使用して、カバーフィルムに接着されシールされてもよい。ポート１０８は、軟質ポリマー、例えば、ショアＡスケールで３０～９０の硬さを有する、ポリエチレン、ポリ塩化ビニル、シリコーン、又はポリウレタンから形成することができる。

【０１１３】

包帯１０２は、液体に対しては不透過性であるが、ガスに対しては透過性であるフィルタ要素を有することができる。フィルタ要素は、液体が創傷包帯から逃げるのを実質的に防ぐか又は阻害する液体バリアとして、ならびに臭気バリアとして作用することができる。フィルタ要素はまた、細菌バリアとして機能してもよい。幾つかの実施形態では、フィルタ要素の孔径は約０．２μｍであることができる。フィルタ要素のフィルタ材料に適した材料としては、ＭＭＴ範囲から延伸された０．２ミクロンのＧｏｒｅ（商標）ＰＴＦＥ、ＰＡＬＬ　Ｖｅｒｓａｐｏｒｅ（商標）２００Ｒ、及びＤｏｎａｌｄｓｏｎ（商標）ＴＸ６６２８が挙げられる。このようにして、フィルタ要素によって、オリフィスを通してガスを排出することができる。しかし、液体、微粒子、及び病原菌は包帯に含まれている。フィルタに関する他の詳細は、米国特許出願第１３／０９２，０４２号に開示されており、参照により本明細書に組み込まれている。

【０１１４】

本明細書に記載するような創傷包帯１０２ならびにその製造方法及び使用方法はまた、次の特許及び特許出願に記載されている特徴、構成、及び材料を組み込んでもよく、それらのそれぞれは、本開示の一部を成すものとして、その全体が参照により本明細書に組み込まれている。特許文献１１、特許文献１２、及び特許文献１３、特許文献１４、特許文献１５、特許文献１６、特許文献１７、特許文献１８、特許文献１９、特許文献２０、特許文献２１、特許文献２２、特許文献２３、特許文献２４、特許文献２５、及び特許文献２６、ならびに２０１０年１１月８日に出願された特許文献２７、２０１１年４月１５日に出願された特許文献２８、及び２０１１年４月１５日に出願された特許文献２９。これらの参照により組み込まれる特許及び特許出願から、本開示に記載するものに類似した構成要素の特徴、構成、材料、及び製造又は使用の方法が、本出願の実施形態へと代用され、追加され、又は実装されてもよい。

【０１１５】

動作の際、創傷包帯１０２は、創腔を形成する創傷部位の上にシールされる。ポンプアセンブリ１０４は、包帯１０２に対する陰圧源を提供する。流体は、創傷接触層の下にある創傷部位から創傷包帯を通ってオリフィスに向かって吸い取られる。流体は透過層を通ってオリフィスに向かって移動する。流体が透過層を通って引かれるのにつれて、創傷浸出物が吸収性層に吸収される。

【０１１６】

創傷包帯の全体形状は、正方形、卵形、長方形、又は別の形であることができる。包帯は丸角領域を有することができる。本発明の他の実施形態による創傷包帯は、正方形、円形、又は楕円形の包帯など、異なるように形作ることができることが認識されるであろう。

【０１１７】

創傷包帯１０２の所望のサイズは、それが使用される創傷のサイズ及びタイプに基づいて選択することができる。幾つかの実施形態では、創傷包帯１０２は、その長軸で２０～４０ｃｍの間、その短軸で１０～２５ｃｍの間の寸法であることができる。例えば、上述したように、約１０×２０ｃｍ、１０×３０ｃｍ、１０×４０ｃｍ、１５×２０ｃｍ、及び１５×３０ｃｍのサイズで包帯を提供することができる。

【０１１８】

幾つかの実施形態では、創傷包帯１０２は、１５～２５ｃｍの間の寸法の辺を有する正方形の包帯（例えば１５×１５ｃｍ、２０×２０ｃｍ、及び２５×２５ｃｍ）であることができる。吸収性層は包帯全体よりも小さい面積を有することができ、幾つかの実施形態では、包帯１０２全体よりも、ともに約３～１０ｃｍ短い、より好ましくは約５ｃｍ短い、長さ及び幅を有してもよい。幾つかの長方形の実施形態では、吸収性層は、その長軸で約１０～３５ｃｍ、その短軸で５～１０ｃｍの間の寸法であってもよい。例えば、吸収性層は、５．６×１５ｃｍ又は５×１０ｃｍ（１０×２０ｃｍの包帯の場合）、５．６×２５ｃｍ又は５×２０ｃｍ（１０×３０ｃｍの包帯の場合）、５．６×３５ｃｍ又は５×３０ｃｍ（１０×４０ｃｍの包帯の場合）、１０×１５ｃｍ（１５×２０ｃｍの包帯の場合）、及び１０×２５ｃｍ（１５×３０ｃｍの包帯の場合）のサイズで提供することができる。幾つかの正方形の実施形態では、吸収性層は、１０～２０ｃｍの間の長さの辺を有してもよい（例えば、１５×１５ｃｍの包帯の場合は１０×１０ｃｍ、２０×２０ｃｍの包帯の場合は１５×１５ｃｍ、又は２５×２５ｃｍの包帯の場合は２０×２０ｃｍ）。透過層は吸収性層よりも小さいサイズのものであることができ、幾つかの実施形態では、吸収性層よりも、ともに約０．５～２ｃｍ短い、より好ましくは約１ｃｍ短い、長さ及び幅を有することができる。幾つかの長方形の実施形態では、透過層は、その長軸で９～３４ｃｍの間、その短軸で３～５ｃｍの間の寸法であってもよい。例えば、透過層は、４．６×１４ｃｍ又は４×９ｃｍ（１０×２０ｃｍの包帯の場合）、４．６×２４ｃｍ又は４×１９ｃｍ（１０×３０ｃｍの包帯の場合）、４．６×３４ｃｍ又は４×２９ｃｍ（１０×４０ｃｍの包帯の場合）、９×１４ｃｍ（１５×２０ｃｍの包帯の場合）、及び９×２４ｃｍ（１５×３０ｃｍの包帯の場合）のサイズで提供されてもよい。幾つかの正方形の実施形態では、透過層には、９～１９ｃｍの間の長さの辺を有してもよい（例えば、１５×１５ｃｍの包帯の場合は９×９ｃｍ、２０×２０ｃｍの包帯の場合は１４×１４ｃｍ、又は２５×２５ｃｍの包帯の場合は１９×１９ｃｍ）。

【０１１９】

包帯は、抗菌物質を、例えば、創傷接触層上のナノ結晶質の銀剤及び／又は吸収性層内の銀硫黄ジアジンを含むことができる。これらは、別個に又は共に使用されてもよい。これらはそれぞれ、創傷中の微生物を、かつ吸収マトリックス中の微生物を殺す。さらなる他の選択肢として、他の有効成分、例えばイブプロフェンなどの痛み抑制剤が含まれてもよい。また、成長因子などの細胞活性を向上させる薬剤、又はメタロプロテイナーゼの組織阻害剤（ＴＩＭＰＳ）などのマトリックスメタロプロテイナーゼ阻害剤もしくは亜鉛キレート剤など、酵素を阻害する薬剤を利用することができる。さらなる他の選択肢として、活性炭、シクロデキストリン、ゼオライトなどの臭気捕集要素が、吸収性層に、又はフィルタ層の上のさらなる別の層として含まれてもよい。

【０１２０】

透過層が３Ｄ編成層として、例えばモノフィラメント層によって離隔された２つの層として形成される本発明の幾つかの実施形態についてここまで記載してきたが、本発明の幾つかの実施形態はかかる材料を使用することに制約されないことが認識されるであろう。幾つかの実施形態では、かかる３Ｄ編成材料の代替物として、種々の材料の１つ又は複数の層を利用することができる。いずれも場合も、本発明の実施形態によれば、透過層の複数層によって示される開口部は、使用中は創傷に近接して配置されるであろう包帯の側面から離れる方向に移動するのにしたがって広くなっていく。幾つかの実施形態では、透過層は連続気泡発泡体の複数層によって提供されてもよい。幾つかの実施形態では、発泡体は網状連続気泡発泡体である。発泡体は、親水性であることができ、又は水性系の流体を

ウィッキングすることができる。各層の孔径は、発泡体層中において、使用中に最も創傷部位に近接する孔が最も小さい径を有するように選択される。１つのさらなる発泡体層のみが利用される場合、それは第１の層の孔径よりも大きい孔径を含む。このことが、固体粒子が下層に捕捉されるのを回避する助けとなり、それが結果として、下層を開いた構成で維持する助けとなり、その構成によって包帯を空気が透過することができる。幾つかの実施形態では、２つ、３つ、４つ、又はそれ以上の発泡体層が含まれてもよい。発泡体層は、例えば、大きな孔径を有する発泡体を選択し、これを孔を詰まらせる材料に浸漬する程度を徐々に減らしながら繰り返し浸漬することによって一体的に形成されてもよく、あるいは、複数の発泡体層によって形成される透過層は、異なるタイプの発泡体を層状の配列で積層するか、又はかかる発泡体の層を既知のやり方で適所に固定することによって提供されてもよい。

【０１２１】

図７Ａ～図７Ｄは、患者の創傷部位を治療するのに使用されているＴＮＰ創傷治療システムの一実施形態の使用を示す図である。図７Ａは、創傷部位Ｗが清浄にされ、治療のために準備されていることを示す。ここでは、創傷部位Ｗを取り囲む健康な皮膚は、好ましくは清浄にされ、余分な毛は除去又は剃毛される。必要であれば、創傷部位Ｗも滅菌生理食塩水で潅注されてもよい。任意選択で、皮膚保護薬が創傷部位Ｗを取り囲む皮膚に塗布されてもよい。必要であれば、発泡体又はガーゼなどの創傷充填材が創傷部位Ｗに配置されてもよい。これは、創傷部位Ｗがより深い創傷である場合に好ましいことがある。

【０１２２】

創傷部位Ｗを取り囲む皮膚が準備された後、カバー１５１を第１のパッケージング要素１５０から取り出して、構成要素に対するアクセスを提供することができる。包帯１０２は、パッケージング１５０から取り出すことができ、図７Ｂに示されるように、創傷部位Ｗの上に位置付け、配置することができる。創傷包帯１０２は、包帯１０２の創傷接触層が創傷部位Ｗの上にあるように、かつ／又はそこと接触するように配置することができる。幾つかの実施形態では、接着剤層を創傷接触層の下面に提供することができ、それは、場合によっては、創傷包帯１０２を創傷部位Ｗの上に配置するのに先立って除去される任意の剥離層によって保護されていてもよい。包帯１０２は、ポート１０８が包帯１０２の残りの部分に対して隆起した位置にあってポート１０８の周りに流体が貯留するのを回避するようにして、位置付けることができる。幾つかの実施形態では、包帯１０２は、ポート１０８が創傷の上に直接重なり合わず、創傷と同じ高さか又はそれよりも上にあるようにして位置付けられる。ＴＮＰに対して適切なシールを担保する助けとするため、包帯１０２の縁部を平滑にして、たたみ目又は折り目を回避することができる。包帯及びその上に形成される接着剤は、接着剤の性能を犠牲にすることなく、包帯を皮膚又は創傷から離れる方向に持ち上げ、位置付けし直してたたみ目及び折り目を除去するか、又は他の理由で単に包帯を創傷の上で位置付けし直すことができるように構成することができる。管材１０６は、包帯１０２を創傷の上に配置する前又は配置した後のどちらかに、包帯１０２に接続することができる。

【０１２３】

その後、図７Ｃに示されるように、ポンプアセンブリ１０４をパッケージング１５０から取り出し、管材１０６に接続することができる。電池１４２をパッケージング１５０から取り出し、ポンプを導管１０６に取り付ける前又は後のどちらかに、ポンプアセンブリ１０４に設置することができる。ポンプアセンブリ１０４は、包帯１０２を介して、一般的には管材又は導管１０６を通して、創傷部位に陰圧を加えるように構成される。幾つかの実施形態では、導管１０６を包帯１０２に、かつポンプアセンブリ１０４に接合するのにコネクタが使用されてもよい。ポンプアセンブリ１０４によって陰圧を加える際、包帯１０２は、幾つかの実施形態では、包帯１０２の下にある空気の一部又はすべてを排気した結果として、部分的に潰れ、しわが寄った外観を示してもよい。幾つかの実施形態では、ポンプアセンブリ１０４は、包帯１０２と創傷部位Ｗを取り囲む皮膚との間の接合部分などで、包帯１０２に何らかの漏れがあった場合にそれを検出するように構成されてもよ

い。漏れが見つかった場合、かかる漏れは好ましくは治療を継続する前に修正される。漏れは、包帯１０２を位置付けし直すか、包帯のしわもしくは折り目を伸ばすか、又は包帯１０２の外周の周りに固定用ストリップ１４８を当てることによって修正することができる。

【０１２４】

図７Ｄに移ると、上述したように、固定用ストリップ１４８を包帯１０２の外周縁部の周りに、又は別の方法で取り付けることができる。かかる固定用ストリップ１４８は、創傷部位Ｗを取り囲む患者の皮膚に対して追加のシールを提供するために、幾つかの状況で有利であり得る。例えば、シール又は固定用ストリップ１４８は、患者の動きがより活発なときに追加のシールを提供することができる。場合によっては、固定用ストリップ１４８は、特に包帯１０２が手の届きにくい、又は起伏のある範囲の上に配置される場合に、ポンプアセンブリ１０４を動作させる前に使用されてもよい。幾つかの実施形態では、包帯キット１００は５つ以下のシールストリップを備えることができる。

【０１２５】

創傷部位Ｗの治療は、好ましくは、創傷が所望の治癒レベルに達するまで継続する。幾つかの実施形態では、特定の期間が経過した後に、又は包帯が創傷流体でいっぱいになった場合に、包帯１０２を交換するのが望ましいことがある。そのような交換の間、ポンプアセンブリ１０４は保持され、包帯１０２のみが交換されてもよい。

【０１２６】

図８Ａ～図２０Ｈはそれぞれ、様々な異なるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図、下面等角図、上面図、下面図、前面図、後面図、第１の側面図、及び第２の側面図である。図８Ａ～図２０Ｈに示される、又は別の形で本出願に開示するパッケージング要素の実施形態のいずれも、上述した第１のパッケージング要素１５０を含む、本明細書に開示する他のパッケージング要素のいずれかと同じ特徴、材料、又は他の詳細のいずれかを有することができる。

【０１２７】

図８Ａ～図８Ｈに示されるパッケージング要素３００は、約１０ｃｍ×２０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図９Ａ～図９Ｈに示されるパッケージング要素３１０は、約１０ｃｍ×２０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１０Ａ～図１０Ｈに示されるパッケージング要素３２０は、約１０ｃｍ×３０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１１Ａ～図１１Ｈに示されるパッケージング要素３３０は、約１０ｃｍ×３０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１２Ａ～図１２Ｈに示されるパッケージング要素３４０は、約１０ｃｍ×４０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１３Ａ～図１３Ｈに示されるパッケージング要素３５０は、約１０ｃｍ×４０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１４Ａ～図１４Ｈに示されるパッケージング要素３６０は、約１５ｃｍ×１５ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１４Ｉ～図１４Ｐに示されるパッケージング要素３６５は、約１５ｃｍ×１５ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。

【０１２８】

図１５Ａ～図１５Ｈに示されるパッケージング要素３７０は、約１５ｃｍ×２０ｃｍの

サイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１６Ａ～図１６Ｈに示されるパッケージング要素３８０は、約１５ｃｍ×２０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１７Ａ～図１７Ｈに示されるパッケージング要素３９０は、約２０ｃｍ×２０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１７Ｉ～図１７Ｐに示されるパッケージング要素３９５は、約２０ｃｍ×２０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１８Ａ～図１８Ｈに示されるパッケージング要素４００は、約１５ｃｍ×３０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１８Ｉ～図１８Ｐに示されるパッケージング要素４０５は、約１５ｃｍ×３０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１９Ａ～図１９Ｈに示されるパッケージング要素４１０は、約２５ｃｍ×２５ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図２０Ａ～図２０Ｈに示されるパッケージング要素４２０は、約２５ｃｍ×２５ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。

【０１２９】

図２１は、幾つかの実施形態によるポンプアセンブリ１０００を示す。本明細書に開示するポンプアセンブリ１０００の実施形態のいずれも、上述したポンプアセンブリ１０４の実施形態を含む、本明細書に開示するか又は本明細書に参照により組み込まれている他の任意のポンプアセンブリの実施形態と同じもしくは類似の構成要素、特徴、材料、サイズ、構成、及び他の詳細のいずれかを有することができる。好ましくは、ポンプアセンブリ１０００は小型化され可搬型であることができるが、より大きな従来の可搬型又は非可搬型（例えば、壁面吸込み）のポンプも使用することができる。ポンプアセンブリ１０００は、ポンプアセンブリのハウジングの外部に位置する稼働／一時停止ボタンとして図示される、スイッチ又はボタン１００２を含むことができる。後述するように、ボタン１００２は、治療を停止、一時停止、及び／又は再開させるように構成することができる。押しボタン１００２として図示されているが、タッチパッド、タッチスクリーン、キーボードなど、他のタイプのスイッチ又はボタンを含むことができる。

【０１３０】

ポンプアセンブリは、コネクタ１０５０（導管を、例えば導管１０６を接続するためのもの）と、３つのＬＥＤインジケータ１０６２、１０６４、及び１０６６とをさらに含むことができる。図示されるように、ＬＥＤインジケータ１０６２（例えば、ＯＫインジケータ）は、システムの正常／異常動作を指示するように構成することができる。例えば、活動状態の（例えば、点灯している）インジケータ１０６２は、正常動作を表すことができる。ＬＥＤインジケータ１０６４（例えば、包帯インジケータ）は、システムの漏れを指示するように構成することができる。例えば、活動状態の（例えば、点灯している）インジケータ１０６４は、漏れを表すことができる。ＬＥＤインジケータ１０６６（例えば、電池インジケータ）は、電源（例えば、電池）の残容量又は寿命を指示するように構成することができる。例えば、活動状態の（例えば、点灯している）インジケータ１０６６は、低容量を表すことができる。幾つかの実施形態では、インジケータ１０６２、１０６４、及び１０６６は、異なる色、２つの異なる色（例えば、２つのインジケータが同じ色を共有することができる）、又は同じ色であることができる。ポンプアセンブリは、好ましくは３つのＬＥＤインジケータ及び１つの稼働／一時停止押しボタンを含むが、他の構成、場所、及びタイプのインジケータ、アラーム、ならびにスイッチを代わりに使用することができる。幾つかの実施形態では、ポンプアセンブリ１０００は、ユーザに対して様

々な動作状態を信号で通知するように構成された、視覚、聴覚、触覚、及び他のタイプのインジケータ又はアラームを含むことができる。そのような状態は、システムのオン／オフ、スタンバイ、一時停止、正常動作、包帯の問題、漏れ、エラーなどを含む。インジケータは、スピーカー、ディスプレイ、光源など、及び／又はそれらの組合せを含むことができる。

【０１３１】

図２２は、幾つかの実施形態によるポンプアセンブリ１０００の内部を示す断面図を示す。図示されるように、ハウジング１０２０はポンプアセンブリを包囲することができる。一方向フロー弁１０３０は、陰圧源が活動状態でないときに陰圧レベルを維持し（例えば、漏れを防ぎ）、創傷から吸引もしくは除去された流体及び／又は浸出物が、コネクタ１０５０を介してポンプアセンブリに入るのを防ぐように構成することができる。プリント回路基板アセンブリ（ＰＣＢＡ）などの制御盤１０４０は、後述する様々な電気的／電子的構成要素を機械的に支持し、電気的に接続するように構成することができる。ＰＣＢＡは片面又は両面であることができる。ポンプなどの陰圧源１０９０は、流体及び／又は浸出物を創傷から吸引することができる。本明細書に開示する実施形態のいずれかにおいて、陰圧源１０９０は、上述したポンプ２３２を非限定的に含む、本明細書に開示する他の陰圧源の実施形態のいずれかと同じ構成要素、特徴、限定、又は他の詳細のいずれかを有することができる。蠕動ポンプ、ピストンポンプ、回転翼ポンプ、液封ポンプ、スクロールポンプ、ダイヤフラムポンプ、圧電ポンプ（例えば、圧電変換器によって動作するダイヤフラムポンプ）など、又はそれらの組合せを含む、様々なポンプを陰圧源に使用することができる。ポンプアセンブリは、好ましくは、小型の低雑音低電力ポンプを含むが、任意の適切なポンプを代わりに使用することができる。ポンプアセンブリ１０００は、インジケータ１０６０（例えば、ＬＥＤ）と、包帯の下の圧力など、システムの圧力を監視する圧力センサ１０７０と、電池区画１１００へのアクセスを提供するように構成された電池カバー１０８０とを含む。ポンプアセンブリは、好ましくは、２つの標準的な使い捨てアルカリ電池（例えば、２つの単三電池）によって電力供給されるが、充電式電池及び外部電力を含む、任意のタイプの電源を代わりに使用することができる。

【０１３２】

図２３は、幾つかの実施形態によるポンプアセンブリ１０００のシステム概略図を示す。ポンプアセンブリは、押しボタン１００２、制御盤１０４０、及びインジケータ１０６０を含む。ポンプアセンブリ１０００は、電池セル１１３０によって電力供給することができる。ポンプアセンブリはまた、電気モータ１０９２によって電力供給されるダイヤフラムポンプなどのポンプ１０９０と、圧力センサ１０７０とを含む。入口１１２０は、例えば導管を介して、ポンプアセンブリ１０００を包帯に接続するように構成することができる。入口１１２０は、一方向弁１０３０に接続することができ、陰圧源が活動状態でないときに陰圧レベルを維持するのを助け、漏れを回避し、創傷から吸引もしくは除去した流体及び／又は浸出物がポンプアセンブリ１０００に入るのを防ぐように構成することができる。ポンプ１０９０はまた、出口１１１０に接続することができる。幾つかの実施形態では、出口１１１０は、空気を雰囲気へと放出するように構成することができる。幾つかの実施形態では、フィルタ（図示せず）を出口と雰囲気との間に差し挟むことができる。フィルタは、細菌フィルタ、臭気フィルタなど、又はそれらの任意の組合せであることができる。

【０１３３】

図２４は、幾つかの実施形態によるポンプアセンブリ１０００の電気的構成要素の概略図を示す。制御盤（例えば、ＰＣＢＡ）であることができるモジュール１１４０は、入／出力（Ｉ／Ｏ）モジュール１１５０、コントローラ１１６０、及びメモリ１１７０を含むことができる。幾つかの実施形態では、モジュール１１４０は、追加の電気的／電子的構成要素、例えば１つ又は複数のヒューズを含むことができる。コントローラ１１６０は、マイクロコントローラ、プロセッサ、マイクロプロセッサなど、又はそれらの任意の組合せであることができる。例えば、コントローラ１１６０は、ＳＴＭ８Ｌ　１５１Ｇ４Ｕ６

など、ＳＴ　Ｍｉｃｒｏｅｌｅｃｔｒｏｎｉｃｓ製のＳＴＭ８Ｌ　ＭＣＵファミリータイプのもの、又はＭＣ９Ｓ０８ＱＥ４ＣＷＪなど、Ｆｒｅｅｓｃａｌｅ製のＭＣ９Ｓ０８ＱＥ４／８直列タイプのものであることができる。好ましくは、コントローラ１１６０は低電力又は超低電力デバイスであるが、他のタイプのデバイスを代わりに使用することができる。メモリ１１７０は、リードオンリーメモリ（ＲＯＭ）、ライトワンスリードメニーメモリ（ＷＯＲＭ）、ランダムアクセスメモリ（例えば、ＳＲＡＭ、ＤＲＡＭ、ＳＤＲＡＭ、ＤＤＲなど）、固体メモリ、フラッシュメモリ、磁気記憶装置など、又はそれらの任意の組合せの１つ又は複数など、揮発性及び／又は不揮発性メモリモジュールの１つ又は複数を含むことができる。メモリ１１７０は、プログラムコードもしくは命令（コントローラによって実行される）、システムパラメータ、動作データ、ユーザデータなど、又はそれらの任意の組合せを格納するように構成することができる。

【０１３４】

Ｉ／Ｏモジュール１１５０は、コントローラ１１６０と、電磁信号を提供する、かつ／又は電磁信号に応答する他のシステム構成要素との間のインターフェースとして機能するように構成することができる。換言すれば、Ｉ／Ｏモジュール１１５０は、コントローラ１１６０がシステムの動作を監視し、システムの他の構成要素を制御することが可能になるように構成することができる。幾つかの実施形態では、図示されるように、Ｉ／Ｏモジュール１１５０は、ボタン１００２、インジケータ１０６０、圧力センサ１０７０、電源１１３０、及び陰圧源１０９０と電磁気的に連通していることができる。Ｉ／Ｏモジュールは、様々な構成要素と通信するように構成されたインターフェース又は複数のインターフェースを備えることができる。インターフェースは、シリアルポート、パラレルポート、バスインターフェースなど、又はそれらの任意の組合せなどの、規格及び／又は規格外のポートを含むことができる。

【０１３５】

幾つかの実施形態では、ポンプアセンブリ１０００は、システムの動作を制御するように構成することができる。例えば、ポンプアセンブリ１０００は、中断されずに治療を送達すること、ならびに／あるいは例えば、頻繁にもしくは不必要に治療を一時停止又は延期することによって、ユーザに不便を掛けるのを回避すること、及び電力を節約し、陰圧源によって発生する雑音と振動を制限したいという要求の間の適切なバランスを提供するように構成することができる。図２５は、幾つかの実施形態によるポンプアセンブリの動作の上位状態図１２００を示す。幾つかの実施形態では、コントローラ１１４０は、状態図１２００のフローを実施するように構成することができる。図２５に示されるように、ポンプアセンブリの動作は、幾つかの実施形態では、非活動状態／初期設定（状態１２０６及び１２０２）、活動状態１２１０、動作中１２５０、ならびに寿命末期（状態１２１４）の４つの一般状態カテゴリーにグループ化することができる。図２５及び図２６に示されるように、状態カテゴリー１２１０及び１２５０はそれぞれ、複数の状態を含み、状態間で遷移する。

【０１３６】

幾つかの実施形態では、電源が接続されておらず、除去されている（遷移１２０４によって図示される）限り、又はポンプアセンブリを（例えば、動作ストリップを引っ張るか、スイッチを起動するなどによって）動作させていない限り、ポンプアセンブリは状態１２０６に留まる。この状態に留まっている間、ポンプアセンブリは非活動状態に留まっていることができる。電源が接続されると、かつ／又はポンプアセンブリを最初に動作させると、ポンプアセンブリは状態１２０２に遷移して、１つ又は複数の電源投入時自己診断（ＰＯＳＴ）を実施することができる。電源投入時自己診断（複数可）は、メモリ１１７０を検査すること（例えば、プログラムコードの周期的冗長検査などのチェックを実施してその保全性を判定する、ランダムアクセスメモリを検査するなど）、圧力センサ１０７０を読み取って圧力値が適切な限界内にあるか否か否かを判定すること、電源の残容量もしくは寿命（例えば、電池電圧、電流など）を読み取ってそれが適切な限界内にあるか否か否かを判定すること、及び陰圧源を検査することなど、システムの適正な機能性を担保

するために様々なチェックを実施することを含むことができる。図示されるように、インジケータ１０６０（例えば、ＬＥＤ）は、ポンプアセンブリがＰＯＳＴ検査（複数可）を受けていることをユーザに（例えば、一度明滅又は点滅させることによって）指示するように構成することができる。

【０１３７】

幾つかの実施形態では、ＰＯＳＴ検査（複数可）のうち１つ又は複数が不合格だった場合、ポンプアセンブリは回復不能なエラー状態１２１４に遷移することができる。この状態にある間、ポンプアセンブリは治療を動作停止することができ、インジケータ１０６０は、エラーに遭遇したことをユーザに指示するように構成することができる。幾つかの実施形態では、すべてのインジケータが活動状態に留まるように構成することができる。エラーの深刻度に基づいて、幾つかの実施形態では、ポンプアセンブリは、エラーから回復し、動作を継続する（又は回復不能なエラー状態１２１４に遷移する）ように構成することができる。図示されるように、ポンプアセンブリは、動作中に決定的エラーに遭遇すると、状態１２１４へと遷移することができる。決定的エラーは、プログラムメモリエラー、プログラムコードエラー（例えば、無効な変数値に遭遇する）、コントローラ動作エラー（例えば、コントローラ１１６０によってリセットされることなく、ウォッチドッグタイマーが終了する）、構成要素の故障（例えば、陰圧源の動作不能、圧力センサ１０７０の動作不能など）、及びそれらの任意の組合せを含むことができる。

【０１３８】

ＰＯＳＴ検査（複数可）に合格すると、幾つかの実施形態では、ポンプアセンブリは手動一時停止状態１２１６に遷移することができる。図示されるように、インジケータ１０６０（例えば、電池インジケータ１０６６）の１つを動作停止することによって、この遷移をユーザに指示することができる。ポンプアセンブリが手動一時停止状態１２１６に遷移し、そのまま留まっているとき、インジケータ１０６２（ＯＫインジケータ）及び１０６４（包帯インジケータ）を動作停止することなどによって、ユーザに指示を提供することができる。幾つかの実施形態では、ポンプアセンブリが手動一時停止状態１２１６に留まっている間、治療を延期することができる。例えば、陰圧源（例えば、ポンプ１０９０）を動作停止する（又はオフにする）ことができる。幾つかの実施形態では、指示は、陰圧源を動作停止することによって提供することができる。

【０１３９】

幾つかの実施形態では、ポンプアセンブリは、スイッチからの信号の受信に応答して、手動一時停止状態１２１６から動作状態カテゴリー１２５０への遷移１２２４を行うように構成することができる（ポンプアセンブリが治療を送達するように構成されている場合）。例えば、ユーザがボタンを押して、治療を開始、延期、及び／又は再開することができる。幾つかの実施形態では、ポンプアセンブリは、ポンプアセンブリが手動一時停止状態１２１６に留まっている持続時間を監視するように構成することができる。これは、例えば、ポンプアセンブリが手動一時停止状態１２１６に遷移するとリセットし開始することができる、（ファームウェア、ソフトウェア、ハードウェア、もしくはそれらの任意の組合せの）タイマーを維持することによって、達成することができる。ポンプアセンブリは、持続時間が閾値を超えたときに、手動一時停止状態１２１６から動作状態カテゴリー１２５０への遷移１２２４を自動的に行うように構成することができる。幾つかの実施形態では、かかる閾値は、１分以下～１時間以上の間などの設定値であることができる。幾つかの実施形態では、閾値をユーザによって設定又は変更することができる。幾つかの実施形態では、閾値は様々な動作状態又はそれらの任意の組合せに基づいて変えることができる。例えば、ポンプアセンブリが寿命末期に近付くにつれて（後述するように）、閾値を減少させることができる。幾つかの実施形態では、ユーザは、スイッチを動作させる（例えば、ボタンを押す）ことによって治療を一時停止することができ、それによって、ポンプアセンブリが動作状態カテゴリー１２５０から手動一時停止状態１２１６への遷移１２２２を行う。幾つかの実施形態では、ユーザが単に治療を一時停止することができるように、ポンプアセンブリを構成することができるが、電源を分断する（例えば、電池を除

去する）ことによって治療が停止する。

【０１４０】

幾つかの実施形態では、ポンプアセンブリは一時停止状態１２１８を含むように構成することができる。ポンプアセンブリが一時停止状態１２１８に遷移し、そこに留まっているとき、ユーザに指示を提供することができる。例えば、ポンプアセンブリは、ＯＫインジケータ１０６２を動作停止し、包帯インジケータ１０６４を点滅又は明滅させるように構成することができる。幾つかの実施形態では、ポンプアセンブリが手動一時停止状態１２１６に留まっている状態で治療を延期することができる。例えば、陰圧源（例えば、ポンプ１０９０）を動作停止する（又はオフにする）ことができ、それによって、ポンプアセンブリが一時停止状態１２１８にあるという指示がユーザに提供される。後述するように、幾つかの実施形態では、ポンプアセンブリは、再試行サイクルの回数が再試行限界を超えたとき（遷移１２２８）、又はデューティサイクルがデューティサイクル限界を超えたと判定されたとき（遷移１２３０）、動作状態カテゴリー１２５０から一時停止状態１２１８に遷移するように構成することができる。幾つかの実施形態では、遷移１２２８及び１２３０は、システムにおける漏れの存在を反映することができる。

【０１４１】

幾つかの実施形態では、ポンプアセンブリは、スイッチからの信号（例えば、ユーザがボタンを押して治療を再開させる）を受信したのに応答して、一時停止状態１２１８から動作状態カテゴリー１２５０（ポンプアセンブリがポンプを動作させて、治療を送達する）への遷移１２２６を行うように構成することができる。幾つかの実施形態では、ポンプアセンブリは、ポンプアセンブリが一時停止状態１２１８に留まっている持続時間を監視するように構成することができる。例えば、これは、ポンプアセンブリが一時停止状態１２１８に遷移するとリセットし開始することができる、（ファームウェア、ソフトウェア、ハードウェア、もしくはそれらの任意の組合せの）タイマーを維持することによって達成することができる。ポンプアセンブリは、持続時間が閾値を超えたときに、一時停止状態１２１８から動作状態カテゴリー１２５０への遷移１２２６を自動的に行うように構成することができる。閾値は、上述の手動一時停止状態１２１６の閾値と同じものであるか、又は異なるものであることができる。幾つかの実施形態では、閾値は、１分以下～１時間以上の間などの設定値であることができる。幾つかの実施形態では、閾値をユーザによって設定又は変更することができる。幾つかの実施形態では、閾値は様々な動作状態又はそれらの任意の組合せに基づいて変えることができる。例えば、ポンプアセンブリが寿命末期に近付くにつれて（後述するように）、閾値を減少させることができる。

【０１４２】

幾つかの実施形態では、ポンプアセンブリは、治療を一時停止する様々な原因を区別するため、手動一時停止状態１２１６及び一時停止状態１２１８の両方を含む。かかる区別の能力によって、ポンプアセンブリが、治療を一時停止するための特定の原因の指示をユーザに提供できるようにすることができる（例えば、手動一時停止状態１２１６及び一時停止状態１２１８は異なる指示を提供することができる）。例えば、治療は、ユーザが手動でボタンを押すことによって一時停止することができ、その場合、ポンプアセンブリは、動作状態カテゴリー１２５０から手動一時停止状態１２１６への遷移１２２２を行うことができる。別の例として、治療は、漏れを検出することによって一時停止することができ、その場合、ポンプアセンブリは、動作状態カテゴリー１２５０から一時停止状態１２１８への遷移１２２８及び／又は１２３０を行うことができる。幾つかの実施形態では、ポンプアセンブリは、治療の送達の延期もしくは一時停止を示す１つの状態、又は２つを超えるかかる状態を含むように構成することができる。

【０１４３】

幾つかの実施形態では、ポンプアセンブリは、電源の残容量又は寿命を（例えば、電池電圧、電流などを周期的に読み取るか、もしくはサンプリングすることによって）監視するように構成することができる。ポンプアセンブリは残容量をユーザに指示するように構成することができる。例えば、電源が正常な残容量（例えば、閾値と比較した結果として

、２．７Ｖ、２．６Ｖ、２．５Ｖなど）を有すると判定された場合、電池インジケータ１０６６を動作停止することができる。電源が低い残容量を有すると判定された場合、ポンプアセンブリは、例えば、遷移１２２０によって示されるように、電池インジケータ１０６６を明滅又は点滅させることによって、ユーザに指示を提供するように構成することができる。幾つかの実施形態では、電池インジケータ１０６６は、ポンプアセンブリがどの状態にあるか、又は特定の状態のみにあるかに係わらず、断続的もしくは継続的に明滅又は点滅するように構成することができる。

【０１４４】

幾つかの実施形態では、電源の残容量が臨界レベル又はその付近（例えば、閾値と比較した結果として、２．４Ｖ、２．３Ｖ、２．２Ｖなど）であると判定されると、ポンプアセンブリは、電池臨界状態１２１２に遷移するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、電源を交換又は再充電することなどによって電源容量が増加するまで、この状態に留まるように構成することができる。ポンプアセンブリは、電池臨界状態１２１２に留まっている間、治療を動作停止するように構成することができる。それに加えて、図示されるように、ポンプアセンブリは、例えばすべてのインジケータを動作停止することによって、電源が臨界レベル又はその付近にあることをユーザに指示するように構成することができる。

【０１４５】

幾つかの実施形態では、ポンプアセンブリは、第１の動作に続いて、約１日間、２～１０日間などの所定の期間、治療を提供するように構成することができる。幾つかの実施形態では、かかる期間は、ユーザによって変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる、設定値であることができる。ポンプアセンブリは、かかる期間が終了すると廃棄することができる。幾つかの実施形態では、第１の動作は、動作ストリップを引っ張ること（例えば、状態１２０２への遷移）などによって、活動状態カテゴリー１２１０への遷移によって反映することができる。一旦ポンプアセンブリが動作されると、ポンプアセンブリは、活動状態に留まっていた持続時間を監視するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、活動状態カテゴリー１２１０に留まっている累積持続時間を監視するように構成することができる。これは、例えば、かかる持続時間を反映する、（ファームウェア、ソフトウェア、ハードウェア、又はそれらの任意の組合せの）タイマーを維持することによって達成することができる。

【０１４６】

持続時間が閾値（例えば、７日間）に達するか、又はそれを超えると、ポンプアセンブリは寿命末期（ＥＯＬ）状態１２４０に遷移するように構成することができる。ポンプアセンブリは、状態１２４０に留まっている状態で治療を動作停止し、ポンプアセンブリの有効寿命の終わりに達したことをユーザに指示するように構成することができる。例えば、ポンプアセンブリは、すべてのインジケータを動作停止する、かつ／又はボタンを動作停止するように構成することができる。幾つかの実施形態では、ポンプアセンブリが使い捨てであるとき、寿命末期状態１２４０に遷移することは、ポンプアセンブリを廃棄できることを意味する。ポンプアセンブリは、一旦寿命末期に達すると、ポンプアセンブリを再び動作させることができないように構成することができる。例えば、ポンプアセンブリは、電源が分断され、その後再接続された場合であっても、再び動作させることができないように構成することができ、それは、指示、値、フラグなどをリードオンリーメモリに格納することによって達成することができる。

【０１４７】

図２６は、幾つかの実施形態によるポンプアセンブリ１０００の状態カテゴリー１２５０における動作フローを示す。ポンプアセンブリは、治療を送達し、システムの漏れを監視し、指示（複数可）をユーザに提供するなどのために構成することができる。後述するように、幾つかの実施形態では、ポンプアセンブリは、包帯１０１０の下で第１の所望の陰圧レベル（例えば、－１００ｍｍＨｇなど、－５ｍｍＨｇ以下～－２００ｍｍＨｇ以上

の間の陰圧）を確立することを最初に試みることによって、治療を送達するように構成することができる。幾つかの実施形態では、第１の所望の陰圧レベルは、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる、設定値であることができる。一旦第１の所望の陰圧レベルが包帯１０１０の下で確立されると、ポンプアセンブリは、陰圧源（例えば、ポンプ）を動作停止するように構成することができる。システムの漏れによって包帯１０１０の下の陰圧が減少する（すなわち、標準大気圧に向かって下降する）と、ポンプアセンブリは、ポンプを動作させて包帯の下の第２の所望の陰圧レベル（例えば、－１００ｍｍＨｇなど、－５ｍｍＨｇ以下～－２００ｍｍＨｇ以上の間の陰圧）を確立することによって、包帯の下の陰圧を回復するように構成することができる。幾つかの実施形態では、第２の所望の陰圧レベルは、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる、設定値であることができる。幾つかの実施形態では、第１及び第２の所望の陰圧レベルは同じであることができる。幾つかの実施形態では、第１及び第２の所望の陰圧レベルは異なることができ、すなわち、第２の陰圧レベルは第１の陰圧レベルよりも低いか、又はその逆であることができる。

【０１４８】

幾つかの実施形態では、ポンプアセンブリは、手動一時停止状態１２１６及び／又は一時停止状態１２１８から状態１２５２に遷移することができる。上述したように、この遷移は、ユーザがボタンを押して治療を開始／再開することによって、かつ／又は１時間などの持続時間が経過すると引き起こすことができる。ポンプアセンブリは、ポンプを動作させて包帯１０１０の下の第１の所望の陰圧レベルを確立することができる、初期ポンプダウン（ｉｎｉｔｉａｌ　ｐｕｍｐ　ｄｏｗｎ：ＩＰＤ）状態１２６０に即座に遷移するように構成することができる。幾つかの実施形態では、包帯の下の圧力レベルが第１の所望の陰圧レベルの上（未満）である場合、ポンプを動作させることができる。陰圧源を動作させて、包帯１０１０の下の第１の所望の陰圧レベルを確立することは、本明細書では、「初期ポンプダウン」と呼ぶことができる。ポンプアセンブリは、例えば、ＯＫインジケータ１０６２を明滅又は点滅させ、包帯インジケータ１０６４を動作停止することによって、初期ポンプダウンを実施していることをユーザに指示するように構成することができる。幾つかの実施形態では、例えば、陰圧源を動作させることによって、指示を提供することができる。ポンプアセンブリは、センサ１０７０を読み取るか又はサンプリングすることによって、包帯１０１０の下の圧力レベルを測定するように構成することができる。

【０１４９】

幾つかの実施形態では、ポンプアセンブリは、ポンプアセンブリがＩＰＤ状態１２６０に留まっている持続時間を監視するように構成することができる。これは、例えば、ポンプアセンブリがＩＰＤ状態１２６０へと遷移したときにリセットし開始することができる、（ファームウェア、ソフトウェア、ハードウェア、又はそれらの任意の組合せの）タイマーを維持することによって達成することができる。幾つかの実施形態では、電力の節約、ポンプによって発生する雑音及び／又は振動の制限などのために、ポンプアセンブリは、所定の期間の間、初期ポンプダウン動作を延期し、その後で初期ポンプダウンを再試行するように構成することができる。この機能性は、例えば、電池電力を節約し、ユーザの介在なしに過渡的及び／又は非過渡的な漏れを解決できるようにするか、あるいはユーザが漏れを直すこと（例えば、包帯を真っ直ぐにする、シールを直す、１つ又は複数の接続を確認するなど）ができるようにすることができる。

【０１５０】

幾つかの実施形態では、ＩＰＤ状態１２６０に留まっている持続時間が閾値（例えば、３０秒間）に等しいか又はそれを超えると、ポンプアセンブリは、状態１２６６への遷移１２６４を行うように構成することができる。幾つかの実施形態では、閾値は、５秒以下～５分以上の間などの設定値であることができる。幾つかの実施形態では、ユーザは閾値を設定又は変更することができる。幾つかの実施形態では、閾値は、様々な動作状態又は

それらの任意の組合せに基づいて変えることができる。幾つかの実施形態では、ポンプアセンブリは、遷移１２６４を行うときにポンプを動作停止するように構成することができる。ポンプアセンブリは、包帯１０１０の下の第１の所望の陰圧を確立するために行われる試みの回数を、（例えば、状態１２５２でリセットし、待機状態１２７０で更新することができるカウンタを維持することによって）監視するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、例えば電力を節約するために、限定数又は最大数のＩＰＤ再試行の試みを提供するように構成することができる。好ましくは、ポンプアセンブリは、限定数の連続的なＩＰＤ再試行の試みを提供するように構成することができるが、ポンプアセンブリは、限定数の連続的でないＩＰＤ再試行の試み、又は連続的及び連続的でないＩＰＤ再試行の試みの混合を提供するように構成することができる。ＩＰＤ再試行の試みの閾値は、１、２、３、４、５などであることができる。幾つかの実施形態では、閾値は設定値であることができる。幾つかの実施形態では、ユーザによって閾値を設定又は変更することができる。幾つかの実施形態では、閾値は、様々な動作状態又はそれらの任意の組合せに基づいて変えることができる。

【０１５１】

幾つかの実施形態では、ポンプアセンブリは、状態１２６６で、行われたＩＰＤ再試行の試みの回数が閾値（例えば、１回の再試行の試み）に等しいか又はそれを超えているか否か否かを判定するように構成することができる。行われたＩＰＤ再試行の試みの回数が閾値に等しいか又はそれを超えている場合、ポンプアセンブリは、上述したように治療が一時停止又は延期される、一時停止状態１２１８への遷移１２２８ａを行うように構成することができる。そうでなければ、ポンプアセンブリは、待機状態１２７０への遷移１２６８を行うように構成することができる。幾つかの実施形態では、ポンプアセンブリは、状態１２６６で陰圧源を動作停止するように構成することができ、それによって、ポンプアセンブリが状態１２６６に遷移したことの指示をユーザに提供することができる。

【０１５２】

幾つかの実施形態では、ポンプアセンブリは、待機状態１２７０のポンプを動作停止し、それによって治療を所定の期間の間（例えば、１５秒間など、１秒以下～１分以上の間）一時停止するように構成することができる。これは、例えば、ポンプアセンブリが待機状態１２７０へと遷移したときにリセットし開始することができる、（ファームウェア、ソフトウェア、ハードウェア、又はそれらの任意の組合せの）タイマーを維持することによって達成することができる。待機状態１２７０におけるこの期間は、プリセット又は変数（例えば、自動的、もしくはユーザによる）であることができる。幾つかの実施形態では、期間は、様々な動作状態又はそれらの任意の組合せに基づいて変えることができる。ポンプアセンブリが待機状態１２７０に留まっている期間は、待機状態１２７０への遷移のたびに、増加又は減少させる（例えば、２など、０．１以下～４．０以上の間の係数で乗算する）ことができる。期間は、待機状態１２７０への一連の遷移それぞれにおいて増加又は減少させることができる。期間は、閾値（例えば、４分など、１秒以下～５分以上の間）に等しくなるか又はそれを過ぎるまで、増加又は減少させることができる。それに加えて、期間は、監視圧力状態１２８０への遷移、手動一時停止状態１２１６への遷移、一時停止状態１２１８への遷移の際に、初期値にリセットすることができる。

【０１５３】

幾つかの実施形態では、ポンプアセンブリは、ポンプアセンブリが待機状態１２７０にあることをユーザに指示するように構成することができる。例えば、ポンプアセンブリは、ＯＫインジケータ１０６２を点滅又は明滅させ、包帯インジケータ１０６４を動作停止するように構成することができる。幾つかの実施形態では、ポンプの動作停止によって、ポンプアセンブリが待機状態１２７０にあるという指示を提供することができる。待機状態の期間が経過すると、ポンプアセンブリは、待機状態１２７０からＩＰＤ状態１２６０への遷移１２７２を行うように構成することができ、その際、ポンプアセンブリは、包帯１０１０の下の第１の所望の陰圧レベルを確立するように試みることができる。幾つかの実施形態では、ポンプアセンブリは、包帯の下の陰圧レベルが特定の安全レベルを上回っ

たまま留まることを担保するように構成することができる。例えば、ポンプアセンブリは、－２２５ｍｍＨｇなど、－１５０ｍｍＨｇ以下～－２５０ｍｍＨｇ以上の間の安全レベルを上回る、包帯１０１０の下の陰圧レベルを維持するように構成することができる。

【０１５４】

幾つかの実施形態では、包帯１０１０の下の第１の所望の陰圧レベルが確立されていると、ポンプアセンブリは、監視状態１２８０への遷移１２７６を行うように構成することができる。ポンプアセンブリは、遷移１２７６を行うときに、ＩＰＤ再試行の試みの回数をリセットするように構成することができる。ポンプアセンブリは、例えば、ＯＫインジケータ１０６２を明滅又は点滅させ、包帯インジケータ１０６４を動作停止することによって、監視状態１２８０への遷移をユーザに指示するように構成することができる。監視状態１２８０に留まっているまま、ポンプアセンブリは、ポンプを動作停止し（それによって、ポンプアセンブリが監視状態１２８０にあるという、ユーザに対する指示を提供することができる）、包帯１０１０の下の圧力レベルを周期的又は継続的に監視するように構成することができる。ポンプアセンブリは、センサ１０７０を読み取るか又はサンプリングすることによって、包帯１０１０の下の圧力レベルを測定するように構成することができる。

【０１５５】

幾つかの実施形態では、ポンプアセンブリは、例えばシステムの漏れによって、包帯１０１０の下の陰圧レベルが、閾値に達するか、かつ／又は閾値を過ぎる（例えば、閾値よりも低くなる）まで減少しているか否か否かを判定するように構成することができる。閾値は、－６０ｍｍＨｇなど、－１０ｍｍＨｇ以下～－１００ｍｍＨｇ以上の間の範囲から選択することができる。幾つかの実施形態では、閾値は、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる設定値であることができる。閾値に達したか又は閾値を過ぎたと判定された場合、ポンプアセンブリは、包帯１０１０の下の陰圧レベルを回復するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、第１の所望の陰圧レベルを再度確立するように、又は別の異なる陰圧レベルを確立するように構成することができる。これは、保守ポンプダウン（ｍａｉｎｔｅｎａｎｃｅ　ｐｕｍｐ　ｄｏｗｎ：ＭＰＤ）状態１２９０への遷移１２８２を行うことによって達成することができる。

【０１５６】

幾つかの実施形態では、ポンプアセンブリは、ポンプアセンブリがＭＰＤ状態１２９０に留まっている状態で、ポンプを動作させて、包帯１０１０の下の所望の陰圧レベル（例えば、第１の所望のレベル）を確立するように構成することができる。ポンプアセンブリは、例えば、ＯＫインジケータ１０６２を明滅又は点滅させ、包帯インジケータ１０６４を動作停止することによって、ユーザに対して指示を提供するように構成することができる。幾つかの実施形態では、陰圧源を動作させるポンプアセンブリは、ポンプアセンブリが状態１２９０に遷移したことの指示をユーザに提供することができる。幾つかの実施形態では、ポンプアセンブリは、ＩＰＤ状態１２６４でポンプを動作させたときよりも、ＭＰＤ状態１２９０でポンプを動作させたときの方が、発生する雑音及び振動が少ないように構成することができる。例えば、雑音レベルの差は、約７ｄＢ、約２０ｄＢなど、１ｄＢ以下～３０ｄＢ以上の間であることができる。別の例として、雑音レベルの差は、約４５ｄＢ、約５０ｄＢ、約６５ｄＢなど、３０ｄＢ以下～８０ｄＢ以上の間であることができる。

【０１５７】

幾つかの実施形態では、ポンプアセンブリは、ＭＰＤ状態１２９０に留まっている持続時間を監視するように構成することができる。これは、例えば、ポンプアセンブリがＭＰＤ状態１２９０への遷移１２８２を行うときにリセットし開始することができる、（ファームウェア、ソフトウェア、ハードウェア、又はそれらの任意の組合せの）タイマーを維持することによって達成することができる。幾つかの実施形態では、電力の節約、ポンプによって発生する雑音及び／又は振動の制限などのために、ポンプアセンブリは、所定の

期間の間、保守ポンプダウン動作を延期し、その後で初期ポンプダウン及び／又は保守ポンプダウンを再試行するように構成することができる。この機能性は、例えば、電池電力を節約し、ユーザの介在なしに過渡的及び／又は非過渡的な漏れを解決できるようにするか、あるいはユーザが漏れを直すこと（例えば、包帯を真っ直ぐにする、シールを直す、１つ又は複数の接続を確認するなど）ができるようにすることができる。

【０１５８】

幾つかの実施形態では、ＭＰＤ状態１２９０の持続時間が閾値（例えば、１０秒など、５秒以下～５分以上の間の値）に等しいか又はそれを超え、包帯１０１０の下の圧力レベルが所望の陰圧レベルに達していないとき、ポンプアセンブリは、状態１２９４への遷移１２９２を行うように構成することができる。閾値は、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる設定値であることができる。幾つかの実施形態では、ポンプアセンブリは、遷移１２９２を行うときにポンプを動作停止するように構成することができ、それによって、ポンプアセンブリが遷移を行っていることの指示をユーザに提供することができる。ポンプアセンブリは、包帯１０１０の下の所望の陰圧を確立するために行われるＭＰＤの試みの回数を、（例えば、状態１２５２で、かつ／又は遷移１２２８ｂを行うときにリセットし、遷移１２９６を行うときに更新することができるカウンタを維持することによって）監視するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、（例えば、電力を節約するために）限定数又は最大数のＭＰＤ再試行の試みを提供するように構成することができる。好ましくは、ポンプアセンブリは、限定数の連続的なＭＰＤ再試行の試みを提供するように構成することができるが、ポンプアセンブリは、限定数の連続的でないＭＰＤ再試行の試み、又は連続的及び連続的でない再試行の試みの混合を提供するように構成することができる。ＭＰＤ再試行の試みの閾値は、１、２、３、４、５などであることができる。幾つかの実施形態では、閾値は、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる設定値であることができる。ポンプアセンブリは、ＩＰＤ及びＭＰＤの再試行の試みの回数を、同じ値又は異なる値に設定するように構成することができる。ポンプアセンブリは、状態１２９４で、行われたＭＰＤ再試行の試みの回数が閾値（例えば、３回の再試行の試み）に等しいか又はそれを超えているか否か否かを判定するように構成することができる。行われたＭＰＤ再試行の試みの回数が閾値に等しいか又はそれを超えている場合、ポンプアセンブリは、上述したように治療が一時停止又は延期される、一時停止状態１２１８への遷移１２２８ｂを行うように構成することができる。そうでなければ、ポンプアセンブリは、上述したように治療が一時停止又は延期される、待機状態１２７０への遷移１２９６を行うように構成することができる。あるいは、ポンプアセンブリは、ＩＰＤ状態１２６０又はＭＰＤ状態１２９０に遷移するように構成することができる。

【０１５９】

幾つかの実施形態では、ポンプアセンブリは、包帯の下の圧力レベルが所望の陰圧レベルに達するか又はそれを超えた（例えば、それよりも大きくなった）場合、監視状態１２８０への遷移１２８４を行うように構成することができる。ポンプアセンブリはまた、遷移１２８４を行ったときに、ＭＰＤ再試行の試みの回数をリセットするように構成することができる。

【０１６０】

幾つかの実施形態では、ポンプアセンブリは、陰圧源（例えば、ポンプ）のデューティサイクルを監視するように構成することができる。ポンプアセンブリは、デューティサイクルを周期的にかつ／又は連続的に監視するように構成することができる。デューティサイクル測定は、漏れの存在ならびに／又は深刻度、創傷から吸引された流体（例えば、空気、液体、及び／もしくは固体浸出物など）の流量など、システムの様々な動作状態を反映することができる。例えば、デューティサイクル測定は多量の漏れの存在を指示することができ、ポンプアセンブリは、この状態を指示し、かつ／又は電力を節約するためにポンプの動作を一時的に延期もしくは一時停止するように構成することができる。この機能

性は、例えば、電池電力を節約し、ユーザの介在なしに過渡的及び／又は非過渡的な漏れを解決できるようにするか、あるいはユーザが漏れを直すこと（例えば、包帯を真っ直ぐにする、シールを直す、１つ又は複数の接続を確認するなど）ができるようにすることができる。

【０１６１】

幾つかの実施形態では、ポンプアセンブリは、毎１０秒以下～毎５分以上の間に一回など、周期的にデューティサイクルを監視するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、デューティサイクルを１分につき一回監視するように構成することができる。これは、（例えば、割込みによって、もしくはポーリングを介して示されるように）１分ごとに期限が来るように設定することができ、（例えば、割込みをクリアすることによって）再始動することができる、（ファームウェア、ソフトウェア、ハードウェア、又はそれらの組合せの）タイマーを維持することによって達成することができる。幾つかの実施形態では、デューティサイクルを測定する時間間隔は、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる設定値であることができる。幾つかの実施形態では、ポンプアセンブリは、動作状態カテゴリー１２５０（すなわち、状態１２６０、１２６６、１２７０、１２８０、１２９０、１２９４のいずれか、及び／又はいずれかの状態間のいずれかの遷移）にあるときにポンプを動作させるように構成されているので、この状態カテゴリーにあるときに、デューティサイクルを監視するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、ポンプアセンブリが、動作状態カテゴリー１２５０の特定の状態及び／又は状態遷移、あるいは状態及び／又は状態遷移の部分集合にあるときに、デューティサイクルを監視するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、ポンプアセンブリが、活動状態カテゴリー１２１０の特定の状態及び／もしくは状態遷移、状態及び／もしくは状態遷移の部分集合、又はすべての状態及び／もしくは状態遷移、あるいは本明細書に開示する任意の状態及び／又は状態遷移のいずれかの組合せにあるときに、デューティサイクルを監視するように構成することができる。図２６に示されるように、ポンプアセンブリは、状態１２６０、１２６６、１２７０、１２８０、１２９０、１２９４のいずれかからの遷移１３０２、及び／又は状態のいずれかから状態１３００への遷移を行うことができ、ここで、ポンプアセンブリは、経過した分の間のポンプのデューティサイクルを判定することができる。デューティサイクルは、次式にしたがって判定することができる。

【０１６２】

ＤＣ＝ｔ／Ｔ　　（２）

【０１６３】

式中、ＤＣはデューティサイクル、ｔは陰圧源が活動状態である持続時間、Ｔは検討中の合計時間である。デューティサイクルを１分につき一回監視する場合（すなわち、Ｔ＝６０秒）、デューティサイクルは次式のように（例えば、百分率で）表すことができる。

【０１６４】

ＤＣ＝（経過した分の間のポンプ稼働時間／６０）＊１００％　　（３）

【０１６５】

デューティサイクルを判定するために、ポンプアセンブリは、ポンプが活動状態（例えば、ポンプ稼働時間）及び／又は非活動状態であった持続時間を監視するように構成することができる。

【０１６６】

幾つかの実施形態では、ポンプアセンブリは、判定されたデューティサイクルを、１％以下～５０％以上の間の範囲から選択することができるデューティサイクル閾値と比較するように構成することができる。比較は、例えば、システムの漏れの存在を示すことができる。換言すれば、ポンプが、デューティサイクル閾値に達するか又は超えるような期間に亘って活動状態に留まっていた場合、ポンプは漏れを克服するために酷使されていることがある。かかる場合、ポンプアセンブリは、治療の送達を延期又は一時停止するように

構成することができる。ポンプアセンブリは、例えば、陰圧源を動作停止することによって、ポンプが酷使されている（例えば、デューティサイクルがデューティサイクル閾値を超えている）ことの指示をユーザに提供するように構成することができる。幾つかの実施形態では、デューティサイクル閾値は、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる設定値であることができる。図２６に示されるように、ポンプアセンブリは、判定されたデューティサイクルをデューティサイクル閾値（例えば、９％）と比較するように構成することができる。ポンプアセンブリは、例えば、ポンプアセンブリが状態１２５２からＩＰＤ状態１２６０に遷移したときにリセットすることができる、過負荷カウンタを維持し更新することによって、閾値を超えるデューティサイクルの数を監視するように構成することができる。

【０１６７】

幾つかの実施形態では、ポンプアセンブリは、状態１３００において過負荷カウンタを更新するように構成することができる。判定されたデューティサイクルがデューティサイクル閾値を超えない場合、ポンプアセンブリは過負荷カウンタを減分することができる。幾つかの実施形態では、過負荷カウンタの最小値はゼロに設定することができ、すなわち過負荷カウンタが負になることはない。反対に、判定されたデューティサイクルがデューティサイクル閾値に等しいか又はそれを超える場合、ポンプアセンブリは過負荷カウンタを増分することができる。

【０１６８】

幾つかの実施形態では、ポンプアセンブリは、デューティサイクル閾値に等しいか又はそれを超えるデューティサイクルの合計数もしくは総数を監視するように構成することができる。この方策は、例えば、治療を中断することによる過渡的な漏れによって引き起こされることがある、１つ又は幾つかの不安定なサイクルを防ぐために、デューティサイクルの変動を平滑化又は平均化する助けとすることができる。幾つかの実施形態では、ポンプアセンブリは、デューティサイクル閾値を超える連続的又は非連続的なデューティサイクルを監視するように構成することができる。幾つかの実施形態では、閾値は、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる設定値であることができる。デューティサイクル閾値を超えるデューティサイクルの数が過負荷閾値（例えば、３０など、１～６０以上の間）を超えると判定された場合、ポンプアセンブリは、上述したように治療が延期又は一時停止される、一時停止状態１２１６への遷移１２３０を行うように構成することができる。幾つかの実施形態では、ポンプアセンブリは陰圧源を動作停止するように構成することができ、それによって、ポンプが酷使されている（例えば、デューティサイクルが過負荷閾値を超える）という指示をユーザに提供することができる。デューティサイクル閾値を超えるデューティサイクルの数が過負荷閾値を超えると判定されなかった場合、ポンプアセンブリは、遷移１３０４を行い、かつ動作状態カテゴリー１２５０に留まるように構成することができる。幾つかの実施形態では、ポンプアセンブリは、同じ状態に戻る、かつ／又はポンプアセンブリがそこから遷移１３０２を行った状態の間で遷移するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、異なる状態へ遷移する、かつ／又は状態間で遷移するように構成することができる。

【０１６９】

幾つかの実施形態では、ポンプアセンブリは、ポンプアセンブリが動作状態カテゴリー１２５０にある状態でユーザがボタン１００２を押した場合に、治療を延期又は一時停止するようにさらに構成される。幾つかの実施形態では、ポンプアセンブリは、手動一時停止状態１２１６に遷移するように構成することができる。

【０１７０】

図２７は、幾つかの実施形態によるポンプアセンブリ１０００の動作の別の状態図を示す。幾つかの実施形態では、コントローラ１１４０は、状態図１４００のフローを実施するように構成することができる。幾つかの実施形態では、フロー１４００は、概して図２５～図２６に示されるフローに類似していることができる。状態１４０２は状態１２０２

に相当し、状態１４０６は状態１２６０に相当し、状態カテゴリー１４１０は状態カテゴリー１２１０に相当し、状態１４１４は状態１２１４に相当し、状態１４１６は状態１２１６に相当し、状態１４１８は状態１２１８に相当し、遷移１４２０は遷移１２２０に相当し、遷移１４２２は遷移１２２２に相当し、遷移１４２４は遷移１２２４に相当し、遷移１４２６は遷移１２２６に相当し、かつ状態１４４０は状態１２４０に相当する。それに加えて、状態カテゴリー１４５０は状態カテゴリー１２５０に相当し、状態１４６０は状態１２６０に相当し、遷移１４６４は遷移１２６４に相当し、状態１４６６は遷移１２６６に相当し、遷移１４６８は遷移１２６８に相当し、遷移１４２８ａは遷移１２２８ａに相当し、状態１４７０は状態１２７０に相当し、かつ遷移１４７２は遷移１２７２に相当する。さらに、遷移１４７６は遷移１２７６に相当し、状態１４８０は状態１２８０に相当し、遷移１４８２は遷移１２８２に相当し、状態１４９０は状態１２９０に相当し、遷移１４９２は遷移１２９２に相当し、状態１４９４は状態１２９４に相当し、遷移１４９６は遷移１２９６に相当し、かつ遷移１４２８ｂは遷移１２２８ｂに相当する。

【０１７１】

幾つかの実施形態では、ポンプアセンブリは、ＭＰＤ状態１４９０において包帯１０１０の下で所望の陰圧レベルが確立された後、デューティサイクルを監視するように構成することができる。幾つかの実施形態では、ポンプアセンブリはまた、ポンプアセンブリがＩＰＤ状態１４６０に留まっているままポンプが活動状態であった持続時間を考慮に入れることができる。図示されるように、デバイスは、ＭＰＤ状態１４９０からの遷移１４８４を行うように構成することができる。遷移１４８４は遷移１２８４に類似したものであり得るが、ＩＰＤ状態１４８０に直接遷移する代わりに、ポンプアセンブリを、状態１５００のデューティサイクルを監視するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、ポンプアセンブリが監視状態１４８０及びＭＰＤ状態１４９０に留まっている累積期間の間、デューティサイクルを監視するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、直前又は過去の監視及びＭＰＤサイクル中の累積期間に亘って、デューティサイクルを監視するように構成することができる。例えば、状態１５００に遷移する直前には、ポンプアセンブリは、持続時間Ｘ（その間ポンプが活動状態である）の間、ＭＰＤ状態１４９０に留まっていることができる。それに加えて、ＭＰＤ状態１４９０に遷移する直前に、ポンプアセンブリが持続時間Ｙ（その間、ポンプが非活動状態であった）の間、監視状態１４８０に留まっていたと仮定して、デューティサイクル（ＤＣ）を次式のように（例えば、百分率で）表すことができる。

【０１７２】

ＤＣ＝１００％＊［Ｘ／（Ｘ＋Ｙ）］　　（４）

【０１７３】

デューティサイクルを判定するために、ポンプアセンブリを、ポンプが活動状態及び／又は非活動状態であった持続時間を監視するように構成することができる。

【０１７４】

幾つかの実施形態では、ポンプアセンブリは、上述したように、判定されたデューティサイクルをデューティサイクル閾値（例えば、９％）と比較するように構成することができる。幾つかの実施形態では、閾値は、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる設定値であることができる。デューティサイクルが閾値未満であると判定された場合、ポンプアセンブリは、監視状態１４８０への遷移１５０２を行うように構成することができる。反対に、デューティサイクルが閾値に等しいか又はそれを超えると判定された場合、ポンプアセンブリは、状態１５０６への遷移１５０４を行うように構成することができる。幾つかの実施形態では、ポンプアセンブリは、例えばポンプを動作停止することによって、デューティサイクルが閾値を超えているという指示を提供することができる。

【０１７５】

幾つかの実施形態では、ポンプアセンブリは、デューティサイクルが閾値に等しいか又はそれを超える合計時間もしくは総時間を監視するように構成することができる。この方

策は、例えば、治療を中断することによる過渡的な漏れによって引き起こされることがある、１つ又は幾つかの不安定なサイクルを防ぐために、デューティサイクルの変動を平滑化又は平均化する助けとすることができる。監視は、再始動（例えば、遷移１４７６の際に）し更新（例えば、状態１５０６で）することができる、（ファームウェア、ソフトウェア、ハードウェア、又はそれらの任意の組合せの）タイマーを維持することによって達成することができる。幾つかの実施形態では、ポンプアセンブリは、総持続時間閾値と比較することができる特定の総期間に亘って、デューティサイクルが閾値に等しいか又はそれを超えるか否か否かを判定するように構成することができる。閾値は、３０分など、５分以下～２時間以上の間の範囲から選択することができる。幾つかの実施形態では、閾値は、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる設定値であることができる。総期間が閾値に等しいか又はそれを超える場合、ポンプアセンブリは、ポンプアセンブリが治療の送達を延期又は一時停止するように構成することができる、一時停止状態１４１８への遷移１５０８を行うように構成することができる。幾つかの実施形態では、ポンプアセンブリは、例えばポンプを動作停止することによって、この遷移をユーザに指示することができる。反対に、総期間が閾値未満であると判定された場合、ポンプアセンブリは、監視状態１４８０への遷移１５１０を行うように構成することができる。ポンプアセンブリは、例えば、ＯＫインジケータ１０６２を明滅又は点滅させ、包帯インジケータ１０６４を動作停止することによって、遷移１５１０をユーザに指示するように構成することができる。

【０１７６】

図２８は、幾つかの実施形態によるポンプアセンブリ１０００のためのデューティサイクル判定を示すグラフ１６００を示す。Ｘ軸は時間を表し、Ｙ軸は圧力を表す。幾つかの実施形態では、ポンプアセンブリは、位置１６０６によって表されるように、包帯１０１０の下の－１００ｍｍＨｇの陰圧レベルを確立するように構成することができる。例えば、これは、状態１２６０の初期ポンプダウン中に実施することができる。ポンプアセンブリは、包帯１０１０の下の陰圧レベルを監視するように構成することができる。例えば、これは監視状態１２８０において実施することができる。図示されるように、間隔１６０２によって表されるように、ポンプアセンブリは期間ａ全体に亘って圧力を監視することができる。包帯１０１０の下の陰圧レベルは、線１６２０によって示されるように、時間全体に亘って減少する（例えば、システムの漏れに起因する）ことができる。

【０１７７】

幾つかの実施形態では、ポンプアセンブリは、位置１６０８によって表されるように、圧力減少が約－７０ｍｍＨｇの閾値に達するか又はそれを過ぎると、包帯１０１０の下の陰圧レベルを回復するか又は再度確立するように構成することができる。幾つかの実施形態では、線１６２２によって示されるように、ポンプアセンブリはポンプを動作させるように構成することができる。例えば、これは、保守ポンプダウン状態１２９０に遷移することによって実施することができる。図示されるように、ポンプアセンブリは、－１００ｍｍＨｇの陰圧レベルが包帯１０１０の下で再度確立されるまで、持続時間ｂ（１６０４）に亘ってポンプを動作させることができる。ポンプアセンブリは、包帯１０１０の下の圧力レベルが位置１６１０において－１００ｍｍＨｇに達すると、ポンプを動作停止するように構成することができる。例えば、これは、監視状態１２８０に遷移することによって実施することができる。１６００で示される期間（すなわち、ａ＋ｂ）全体にわたるデューティサイクル（ＤＣ）は、次式のように（例えば、百分率で）表すことができる。

【０１７８】

ＤＣ＝１００％＊［ｂ／（ａ＋ｂ）］　　（５）

【０１７９】

図２９は、ポンプアセンブリ１０００の幾つかの実施形態の正常な（例えば、漏れがないかもしくは少量の漏れ）動作１７００の非限定例を示す。ポンプアセンブリは、ボックス１７０２に示されるように、包帯１０１０の下の所望の陰圧レベルを確立するように構成することができる。ポンプアセンブリは、包帯１０１０の下の圧力レベルが所望のレベ

ル（例えば、－７０ｍｍＨｇなどの第１の陰圧設定値の値）を超えて上昇した場合、陰圧源（例えば、ポンプ）が動作し、包帯１０１０の下の圧力レベルを所望の値まで低減する動作を開始するように構成することができる。例えば、所望の値は、ほぼ第１の陰圧設定値の値と第２の陰圧設定値の値との間の間隔内であることができ、又はほぼ第２の陰圧設定値の値（例えば、－１００ｍｍＨｇ）であることができる。幾つかの実施形態では、これは初期ポンプダウン状態１２６０において達成することができる。

【０１８０】

幾つかの実施形態では、包帯１０１０の下の圧力レベルが所望の値に達すると、ポンプアセンブリは、ボックス１７０４に示されるように、ポンプを動作停止し、包帯の下の圧力レベルを監視するように構成することができる。例えば、これは監視状態１２８０において達成することができる。ポンプアセンブリは、例えば、センサ１０７０を読み取るか又はサンプリングすることによって、包帯１０１０の下の圧力レベルを周期的又は継続的に監視するように構成することができる。監視された圧力に基づいて、ポンプアセンブリは、ボックス１７０６において、包帯１０１０の下の所望の陰圧レベルを再度確立するために、ポンプを動作又は再始動させる必要があるか否か否かを判定することができる。監視された圧力が低い（例えば、第１の陰圧設定値の値未満か、もしくはそれ以下）と判定された場合、ポンプアセンブリは、ボックス１７０８に示されるように、ポンプを動作させるように構成することができる。例えば、これは、ＭＰＤ状態１２９０に遷移することによって達成することができる。反対に、監視された圧力レベルが低くない（例えば、第１の陰圧設定値の値を超えるか、もしくはそれ以上）と判定された場合、ポンプアセンブリは、包帯１０１０の下の圧力レベルを監視し続けるように構成することができる。この動作フローの間、ポンプアセンブリは、正常に動作していることをユーザに指示するように構成することができる。１０６０ａに示されるように、ポンプアセンブリを動作させるか、又は１０６２ａとして示されるように、ＯＫインジケータ１０６２を明滅もしくは点滅させることができる。それに加えて、ポンプアセンブリは、１０６４ａ及び１０６６ａとしてそれぞれ示される、包帯インジケータ１０６４及び電池インジケータ１０６６を動作停止させることができる。

【０１８１】

図３０は、多量の漏れが存在する状態におけるポンプアセンブリ１０００の幾つかの実施形態の動作１８００の非限定例を示す。図２９に関して上述したように、ポンプアセンブリは、ボックス１８０２に示されるように、包帯１０１０の下の所望の陰圧レベルを確立するように構成することができる。幾つかの実施形態では、包帯１０１０の下の圧力レベルが所望の値に達すると、ポンプアセンブリは、ボックス１８０４に示されるように、ポンプを動作停止し、包帯の下の圧力レベルを監視するように構成することができる。ポンプアセンブリは、例えば、センサ１０７０を読み取るか又はサンプリングすることによって、包帯１０１０の下の圧力レベルを周期的又は継続的に監視するように構成することができる。監視された圧力レベルに基づいて、ポンプアセンブリは、包帯１０１０の下の所望の陰圧レベルを再度確立するために、ポンプを動作又は再始動させる必要があるか否か否かを判定することができる。監視された圧力レベルが低い（例えば、第１の陰圧設定値の値未満か、もしくはそれ以下）と判定された場合、ポンプアセンブリは、ボックス１８０８に示されるように、ポンプを動作させるように構成することができる。一旦所望の圧力レベルが包帯１０１０の下で再度確立されると、ポンプアセンブリは、包帯の下の陰圧レベルの監視を再び始める（例えば、監視状態１２８０に遷移する）ことができる。

【０１８２】

幾つかの実施形態では、システムにおける１つ又は複数の漏れの存在により、ポンプアセンブリ１０１０は、ポンプの監視及び再動作の複数サイクルを実施するように構成することができる。この動作フローの間、ポンプアセンブリは、ポンプアセンブリが正常に動作していることをユーザに指示するように構成することができる。１０６０ｂに示されるように、ポンプアセンブリを動作させるか、又は１０６２ｂとして示される、ＯＫインジケータ１０６２を明滅もしくは点滅させることができる。それに加えて、ポンプアセンブ

リは、１０６４ｂ及び１０６６ｂとしてそれぞれ示される、包帯インジケータ１０６４及び電池インジケータ１０６６を動作停止させることができる。ポンプアセンブリは、ボックス１８１０に示されるように、ポンプが頻繁に給送しすぎているか否かを継続的又は周期的に判定するように構成することができる。図示されるように、幾つかの実施形態では、ポンプアセンブリは、ポンプが頻繁に給送しすぎているか否かの判定の代用として、デューティサイクルを使用するように構成することができる。例えば、ポンプアセンブリは、ポンプが「酷使されている」か否か否かを判定するように構成することができ、それによって、合計治療時間の９％などの閾値持続時間を超える間、ポンプがオンであるか否かが判定される。換言すれば、ポンプアセンブリは、ポンプのデューティサイクルがデューティサイクル閾値に達するか又はそれを超えるか否か否かを判定するように構成することができる。

【０１８３】

幾つかの実施形態では、ポンプアセンブリは、ポンプがある持続時間に亘って酷使されている（例えば、ポンプが１日約２時間を超えてオンであるか、もしくは所定の時間量を超えてオンである）と判定された場合、所望の陰圧レベル（例えば、第２の陰圧設定値の値）が確立されている場合であっても、ポンプの動作を延期又は一時停止するように構成することができる。ボックス１８１２に示されるように、ポンプアセンブリは、ポンプが３０分以上の持続時間に亘って酷使されているか否か否かを判定するように構成することができる。例えば、ポンプアセンブリは、過去３０分間に亘って監視されたデューティサイクル（複数可）がデューティサイクル閾値を超えるか否か否かを判定するように構成することができる。例えば、ポンプアセンブリは、ポンプが直近の３０分間で約２分４２秒以上オンであったか否か否かを判定することができ、これは、９％のデューティサイクル閾値に相当する。

【０１８４】

幾つかの実施形態では、ポンプアセンブリは、ボックス１８１４に示されるように、ポンプが酷使されていると判定された場合、治療を一時停止又は延期するように構成することができる。ポンプアセンブリはさらに、「漏れアラーム」インジケータをオンにするように構成することができる。１０６０ｃに示されるように、ポンプアセンブリを動作させるか、又は１０６４ｂとして示される、包帯インジケータ１０６４を明滅又は点滅させ、１０６２ｃ及び１０６６ｃとしてそれぞれ示される、ＯＫインジケータ１０６２及び電池インジケータ１０６６を動作停止することができる。治療を再開するため、ユーザは、包帯を真っ直ぐにし、漏れを直し、かつ／又はポンプを再び動作させることが必要なことがある。幾つかの実施形態では、ポンプは、タイムアウトなどのため、ポンプ上のスタート又は動作ボタンを押すことによって、再び動作させることができる。

【０１８５】

１つ又は複数の漏れが包帯に存在している場合、幾つかの実施形態では、ポンプアセンブリ１０００は、所定のポンプの動作時間量の後に第２の陰圧設定値の値に達していない場合に、治療を延期もしくは一時停止するようにプログラムするか、又は別の形でそのように構成することができる。例えば、幾つかの実施形態では、ポンプがＸ分間継続的に稼働しており、第２の陰圧設定値の圧力値に達していない場合、ポンプアセンブリは、ＬＥＤインジケータ、「漏れ検出」ＬＥＤインジケータ１０６４、もしくは他のアラームを含むことができるアラームを動作させ、治療を一時停止することができる。幾つかの実施形態では、所定の時間量は、システムの陰圧治療の合計計画持続時間の約５％であるか、又はシステムの陰圧治療の合計計画持続時間の約３％以下～約１５％以上であることができる。幾つかの実施形態では、所定の時間量は、約９分、又は約４分以下～約４０分以上、又は約６分～約１０分であることができる。

【０１８６】

図３１は、非常に多量の漏れが存在する状態におけるポンプアセンブリ１０００の幾つかの実施形態の動作１９００の非限定例を示す。図２９に関して上述したように、ポンプアセンブリは、ボックス１９０２に示されるように、包帯１０１０の下の所望の陰圧レベ

ルを確立するように構成することができる。幾つかの実施形態では、包帯１０１０の下の圧力レベルが所望の値に達すると、ポンプアセンブリは、ボックス１９０４に示されるように、ポンプを動作停止し、包帯の下の圧力レベルを監視するように構成することができる。ポンプアセンブリは、例えば、センサ１０７０を読み取るか又はサンプリングすることによって、包帯１０１０の下の圧力レベルを周期的又は継続的に監視するように構成することができる。監視された圧力レベルに基づいて、ポンプアセンブリは、包帯１０１０の下の所望の陰圧レベルを再度確立するために、ポンプを動作又は再始動させる必要があるか否か否かを判定することができる。監視された圧力レベルが低い（例えば、第１の陰圧設定値の値未満か、もしくはそれ以下）と判定された場合、ポンプアセンブリは、ボックス１９０８に示されるように、ポンプを動作させるように構成することができる。この動作フローの間、ポンプアセンブリは、ポンプアセンブリが正常に動作していることをユーザに指示するように構成することができる。１０６０ｄに示されるように、ポンプアセンブリを動作させるか、又は１０６２ｄとして示される、ＯＫインジケータ１０６２を明滅もしくは点滅させることができる。それに加えて、ポンプアセンブリは、１０６４ｄ及び１０６６ｄとしてそれぞれ示される、包帯インジケータ１０６４及び電池インジケータ１０６６を動作停止させることができる。

【０１８７】

幾つかの実施形態では、１つ又は複数の漏れ（例えば、相対的に非常に高い流量を有する漏れ）により、ポンプアセンブリは、包帯１０１０の下の所望の陰圧レベル及び／又は第２の陰圧設定値の値に達することができないことがある。所定の動作時間量の後に、包帯の下の所望の陰圧レベルに達していない場合、ポンプアセンブリは、ボックス１９１４に示されるように、ポンプを延期又は一時停止するように構成することができる。例えば、これは待機状態１２７０に遷移することによって達成することができる。幾つかの実施形態では、所定のポンプ動作時間量は（図３１に示されるように）１０秒であることができる。幾つかの実施形態では、所定のポンプ動作時間量は、約５秒以下～約６０秒以上であることができる。

【０１８８】

幾つかの実施形態では、ポンプアセンブリは、治療を一時停止又は延期する前に、限定数の再試行サイクルを提供するように構成することができる。ボックス１９２０、１９２２、及び１９２４に示されるように、ポンプアセンブリは、治療を延期もしくは一時停止する（１９１４）前に、かつ／又は「漏れアラーム」などのアラームを動作させる前に、３回の再試行サイクルを経るように構成することができる。ポンプアセンブリの幾つかの実施形態は、治療の一時停止及び／又はアラームの動作の前に、２回の再試行サイクル、４回の再試行サイクルなどを経ることができる。１０６０ｅに示されるように、ポンプアセンブリを動作させるか、又は１０６４ｅとして示される、包帯インジケータ１０６４を明滅又は点滅させ、１０６２ｅ及び１０６６ｅとしてそれぞれ示される、ＯＫインジケータ１０６２及び電池インジケータ１０６６を動作停止することができる。

【０１８９】

図３２は、極めて多量の漏れが存在する状態におけるポンプアセンブリ１０００の幾つかの実施形態の動作２０００の非限定例を示す。ポンプアセンブリは、高い流量の漏れに対処しようとして電池を消耗するのを回避するため、治療の一時停止又は延期モードに迅速に入るように構成することができる。ボックス２００１に示されるように、ポンプアセンブリをオンにすることができ、それは例えば、動作状態カテゴリー１２５０へと遷移することによって達成することができる。図２９に関して上述したように、ポンプアセンブリは、ボックス２００２に示されるように、包帯１０１０の下の所望の陰圧レベルを確立するように構成することができる。

【０１９０】

幾つかの実施形態では、ポンプがオンにされたがまだ包帯に接続されていないか、もしくは包帯に適切に接続されていないときなど、漏れが極めて多量である場合、ポンプアセンブリは、包帯１０１０の下の圧力を所望の陰圧レベル（例えば、おおよそ第２の陰圧設

定値の値、もしくは第１及び第２の陰圧設定値の値の間の間隔内にある値）に近付けるように試みながら、所定の時間量の間、動作するように構成することができる。ポンプアセンブリは、所定の時間量が経過すると、治療を延期又は一時停止するように構成することができる。例えば、これは待機状態１２７０に遷移することによって達成することができる。図示されるように、ポンプアセンブリは、３０秒間ポンプを動作させるように構成することができる。この期間の間、包帯１０１０の下の圧力が所望の陰圧に近付けられていない場合、ポンプアセンブリは、別の所定の時間量（例えば、図３２に示されるように、１５秒間）の間、タイムアウトモード２０２０に入ることができる。この動作フローの間、ポンプアセンブリは、ポンプアセンブリが正常に動作していることをユーザに指示するように構成することができる。１０６０ｆに示されるように、ポンプアセンブリを動作させるか、１０６２ｆとして示されるＯＫインジケータ１０６２を明滅又は点滅させることができる。それに加えて、ポンプアセンブリは、１０６４ｆ及び１０６６ｆとしてそれぞれ示される、包帯インジケータ１０６４及び電池インジケータ１０６６を動作停止することができる。

【０１９１】

幾つかの実施形態では、ポンプアセンブリは、包帯１０１０の下の所望の陰圧レベルを確立するために、限定数の再試行サイクルを提供するように構成することができる。図示されるように、第１の試行（もしくは任意の数の追加の試行）の後、ポンプアセンブリは、ボックス２００２に示されるように、包帯の下の所望の陰圧レベルを確立又は再度確立するように構成することができる。幾つかの実施形態では、ボックス２０１４に示されるように、第１の試行後に包帯１０１０の下の圧力が所望のレベル（例えば、おおよそ第２の陰圧設定値の値、もしくは第１及び第２の陰圧設定値の値の間の間隔内にある値）に近付くことなく、ポンプアセンブリが別の所定の時間量の間、動作する場合、ポンプアセンブリは、ポンプダウンを再試行することなく治療を延期又は一時停止するように構成することができる。ポンプアセンブリは、ポンプアセンブリが（例えば、タイムアウトによって、ユーザがボタンを押すことによって）再動作されるまで、延期又は一時停止状態に留まるように構成することができる。ポンプアセンブリは、この状態でアラームを動作させるように構成することができる。この動作フローの間、ポンプアセンブリは、１つ又は複数の漏れが存在することをユーザに指示するように構成することができる。１０６０ｇに示されるように、ポンプアセンブリを動作させるか、又は１０６４ｇとして示される、包帯インジケータ１０６４を明滅又は点滅させ、１０６２ｇ及び１０６６ｇとしてそれぞれ示される、ＯＫインジケータ１０６２及び電池インジケータ１０６６を動作停止することができる。

【０１９２】

本明細書の説明及び請求項全体を通して、「備える（ｃｏｍｐｒｉｓｅ）」及び「含む（ｃｏｎｔａｉｎ）」という用語、ならびにその用語の変形、例えば「ｃｏｍｒｉｓｉｎｇ」及び「ｃｏｍｐｒｉｓｅｓ」は、「～を含むがそれに限定されない（ｉｎｃｌｕｄｉｎｇ　ｂｕｔ　ｎｏｔ　ｌｉｍｉｔｅｄ　ｔｏ）」ことを意味し、他の部分、追加物、構成要素、整数値、又はステップを除外することを意図しない（かつ除外しない）。

【０１９３】

本明細書の説明及び特許請求の範囲全体を通して、文脈において別の形で求められない限り、単数形は複数形を包含する。特に、不定冠詞が使用される場合、本明細書は、文脈において別の形で求められない限り、複数ならびに単数を企図するものとして理解されるべきである。さらに、幾つかの実施形態では、約という用語は、本明細書において別の形で提示されない限り、提示される値の１０％以内の値を指すことを意味する。

【０１９４】

本明細書に提供される、閾値、限界、持続時間、タイムアウト、再試行カウントなどの任意の値は、絶対値であることを意図せず、それにより、近似であることができる。それに加えて、本明細書に提供される、任意の閾値、限界、持続時間、タイムアウト、再試行カウントなどは、固定であるか、又は自動的にもしくはユーザによって変えることができ

る。さらに、本明細書で使用するとき、基準値に対して、～を超える、～よりも大きい、～よりも少ないなどの相対的な語は、基準値に等しいことも包含することが意図される。例えば、正である基準値を超えるということは、基準値に等しい、又はそれよりも大きいことを包含することができる。

【０１９５】

特定の態様、実施形態、又は例と併せて記載される特徴、整数値、特性、化合物、化学的部分、もしくは群は、不適合性でない限り、本明細書に記載される他の任意の態様、実施形態、又は例に適用可能であることが理解されるべきである。本明細書（任意の添付の請求項、要約書、及び図面を含む）に開示する特徴のすべて、ならびに／あるいは本明細書に開示する任意の方法又はプロセスのステップのすべては、かかる特徴及び／又はステップの少なくともいくつかが相互に排他的である組合せを除いて、任意の組合せで組み合わされてもよい。保護は、任意の上述の実施形態の詳細に限定されない。保護は、本明細書（任意の添付の特許請求の範囲、要約書、及び図面を含む）に開示する特徴の任意の新規なもの、もしくは任意の新規な組合せにまで、あるいは本明細書に開示する任意の方法又はプロセスのステップの任意の新規なもの、もしくは任意の新規な組合せにまで及ぶ。

【０１９６】

特定の実施形態について記載してきたが、これらの実施形態は単なる例示として提示してきたものであり、保護の範囲を限定しようとするものではない。実際には、本明細書に記載した新規な方法及びシステムは、様々な他の形態で具体化されてもよい。さらに、本明細書に記載した方法及びシステムの形態における、様々な省略、置換、及び変更が行われてもよい。当業者であれば、幾つかの実施形態では、図示及び／又は開示されるプロセスで行われる実際のステップは、図面に示されるものと異なっていることがあることを認識するであろう。実施形態に応じて、上述したステップの特定のものが除去されてもよく、他のものが追加されてもよい。したがって、本開示の範囲は、添付の特許請求の範囲を参照することによってのみ定義されるものとする。添付の特許請求の範囲及びそれらの等価物は、保護の範囲及び趣旨内にある形態又は修正を網羅するものとする。例えば、図面に示される様々な構成要素は、プロセッサにおけるソフトウェア及び／もしくはファームウェア、コントローラ、ＡＳＩＣ、ＦＰＧＡ、ならびに／又は専用ハードウェアとして実現されてもよい。さらに、上述した特定の実施形態の特徴及び属性は、追加の実施形態を形成するのに異なる手法で組み合わされてもよく、それらすべてが本開示の範囲内にある。本開示は、特定の好ましい実施形態及び用途を提供するが、本明細書に記載した特徴及び利点のすべては提供しない実施形態を含む、当業者には明白である他の実施形態も、本開示の範囲内にある。したがって、本開示の範囲は、添付の特許請求の範囲を参照することによってのみ定義されるものとする。

【符号の説明】

【０１９７】

１００　減圧創傷治療装置
１０２　創傷包帯
１０４　ポンプアセンブリ
１０６　導管
１０６ａ　第１の端部
１０６ｂ　第２の端部
１０８　ポート
１１２　コネクタ
１１４　導管
１１４ａ　コネクタ
１２０　ハウジング
１２０ａ　第１のハウジング部材
１２０ｂ　第２のハウジング部材
１２０ｃ　ガイド、チャネル

１２１　タブ
１２２　制御ボタン
１２３　窪み
１２４　電池カバー
１２４ａ　ラッチ、タブ部材
１２４ｂ　ガイド、突出部
１２４ｃ　窪み
１２４ｄ　突出部
１２５　電池接点
１２８　コネクタ
１３２　ライト
１４０　導管
１４２　電池
１４８　シールストリップ
１５０　第１のパッケージング要素
１５１　カバー
１５３　周縁部分
１９０、１９２、１９３、１９４、１９６、２００ａ、２００ｂ　陥凹部
１９５　隆起
２２０　電池区画
２２２　電池接点
２２４　電線
２３０　制御盤
２３２　ポンプ
２４０　マニホルド
２４６　一方向フロー弁
２５０　入口ポート
２５２　出口ポート
２６０　ポート
２６１　開口部
２６２　導管
２７０　締結具
２７２　ラベル
３００、３１０、３２０、３３０、３４０、３５０、３６０、３６５、３７０、３８０、３９０、３９５、４００、４０５、４１０、４２０　パッケージング要素
１０００　ポンプアセンブリ
１００２　ボタン
１０２０　ハウジング
１０３０　一方向フロー弁
１０４０　制御盤
１０５０　コネクタ
１０６０、１０６２、１０６４、１０６６　インジケータ
１０７０　圧力センサ
１０８０　電池カバー
１０９０　陰圧源
１０９２　電気モータ
１１００　電池区画
１１１０　出口
１１２０　入口
１１３０　電池セル、電源

１１４０　モジュール
１１５０　入／出力モジュール
１１６０　コントローラ
１１７０　メモリ

【図１】

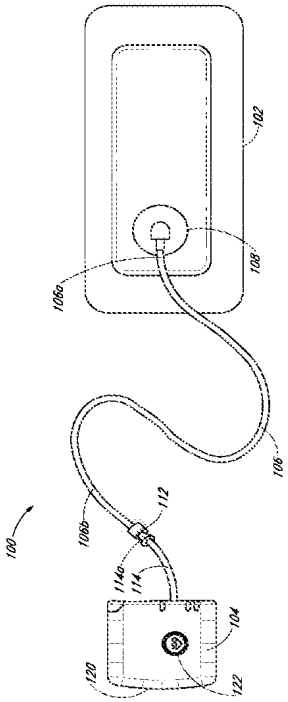


FIG. 1

【図２Ａ】

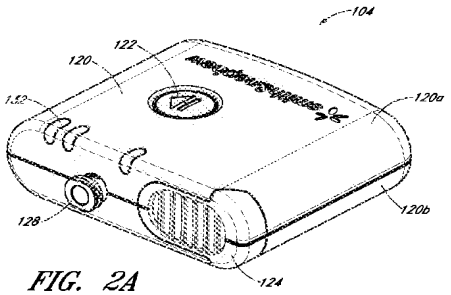


FIG. 2A

【図２Ｂ】

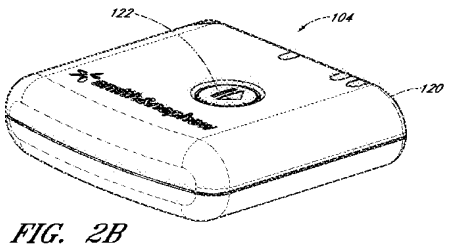


FIG. 2B

【図２Ｃ】

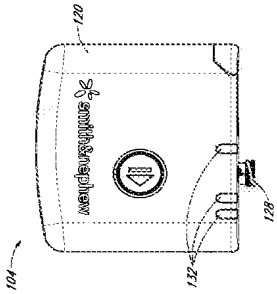


FIG. 2C

【図２Ｄ】

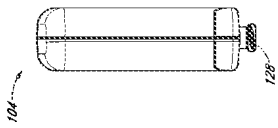


FIG. 2D

【図２Ｅ】

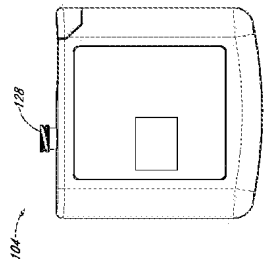


FIG. 2E

【図２Ｆ】

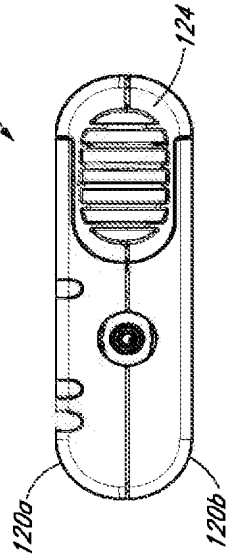


FIG. 2F

【図３Ａ】

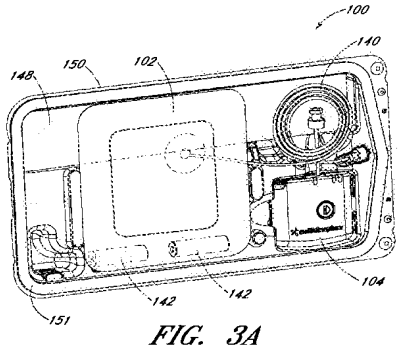


FIG. 3A

【図３Ｂ】

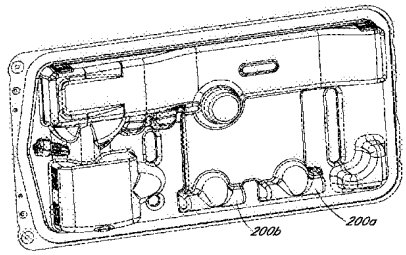


FIG. 3B

【図３Ｃ】

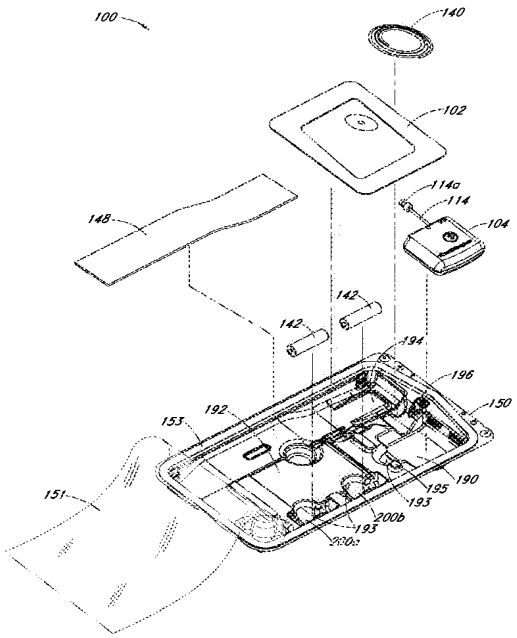


FIG. 3C

【図４Ａ】

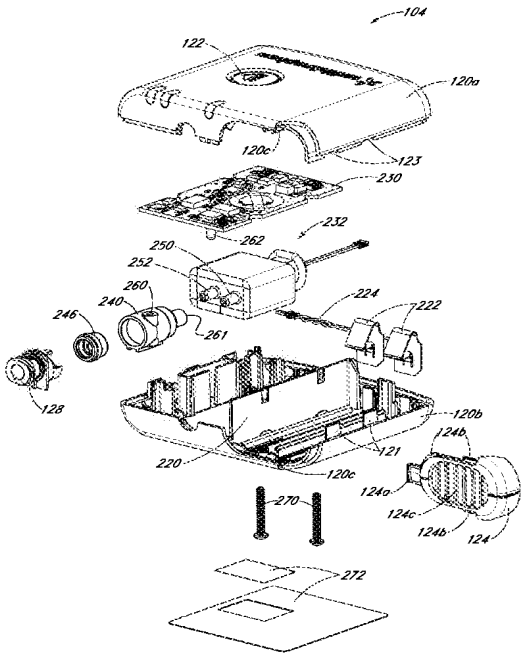


FIG. 4A

【図４Ｂ】

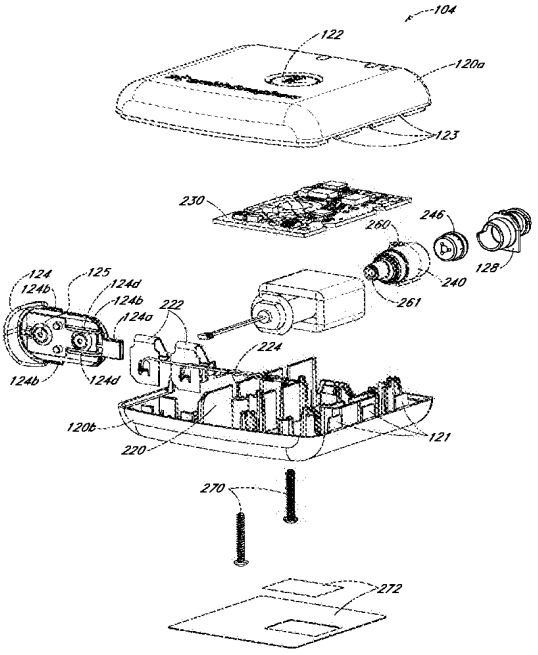


FIG. 4B

【図５Ａ】

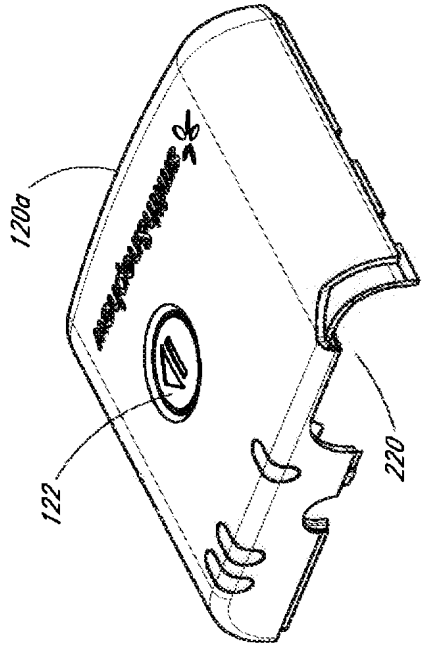


FIG. 5A

【図５Ｂ】

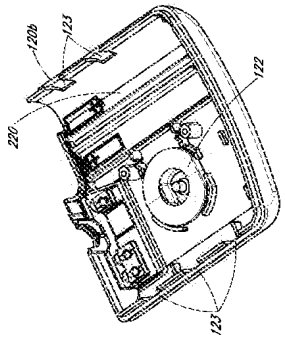


FIG. 5B

【図６Ａ】

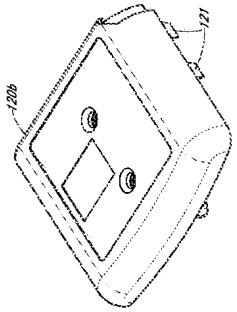


FIG. 6A

【図６Ｂ】

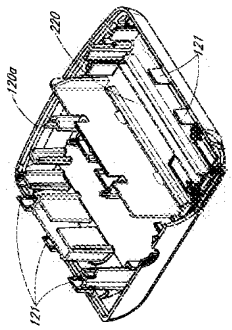


FIG. 6B

【図７Ａ】

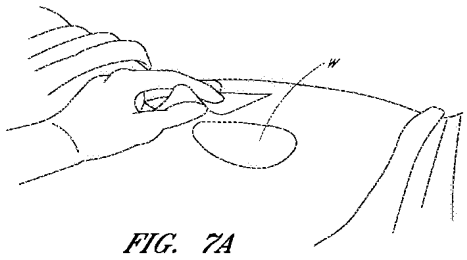


FIG. 7A

【図７Ｂ】

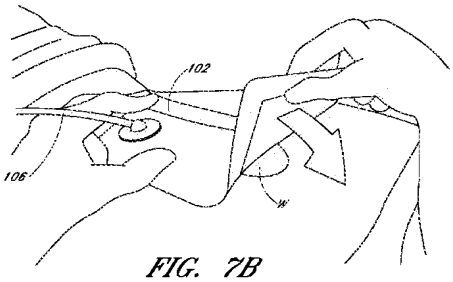


FIG. 7B

【図７Ｃ】

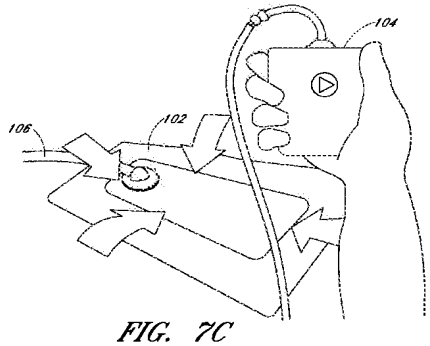


FIG. 7C

【図７Ｄ】

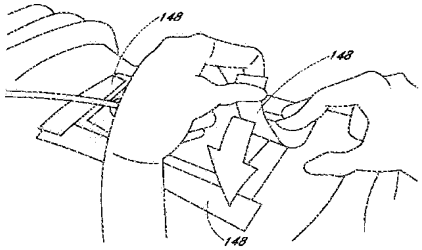


FIG. 7D

【図８Ｂ】

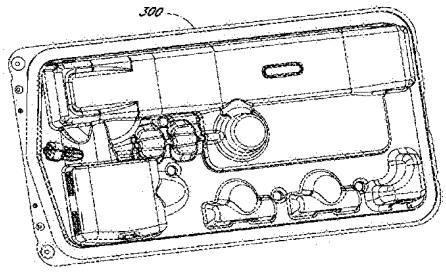


FIG. 8B

【図８Ａ】

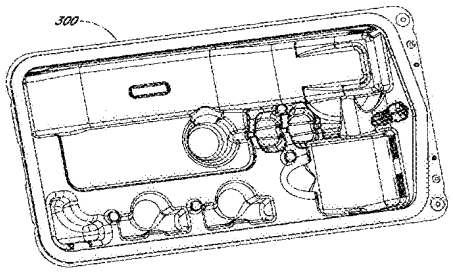


FIG. 8A

【図８Ｃ】

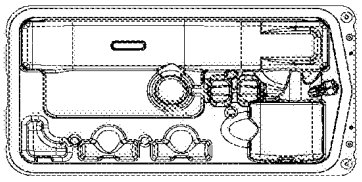


FIG. 8C

【図８Ｄ】

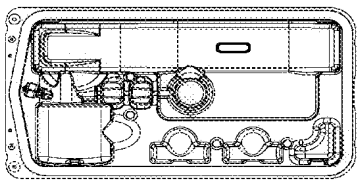


FIG. 8D

【図８Ｅ】

FIG. 8E

【図８Ｆ】

FIG. 8F

【図８Ｇ】

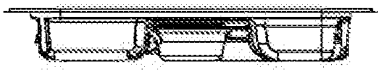


FIG. 8G

【図８Ｈ】

FIG. 8H

【図９Ａ】

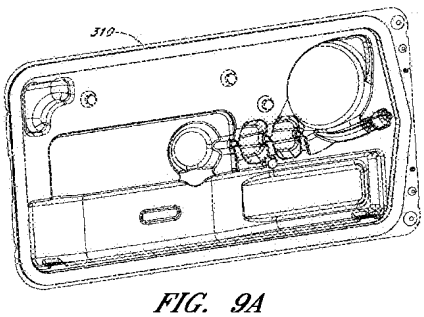


FIG. 9A

【図９Ｂ】

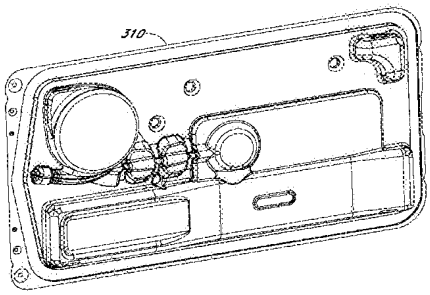


FIG. 9B

【図９Ｃ】

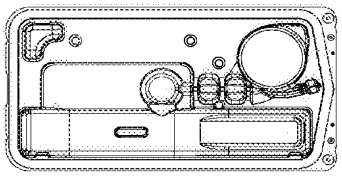


FIG. 9C

【図９Ｄ】

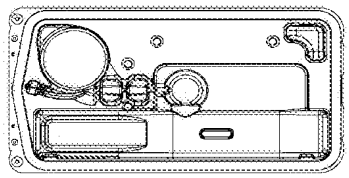


FIG. 9D

【図９Ｅ】

FIG. 9E

【図９Ｆ】

FIG. 9F

【図９Ｇ】

FIG. 9G

【図９Ｈ】

FIG. 9H

【図１０Ａ】

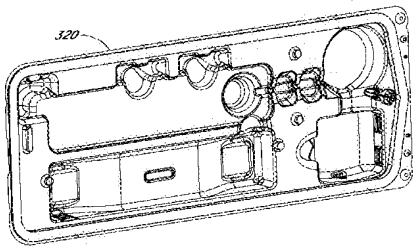


FIG. 10A

【図１０Ｂ】

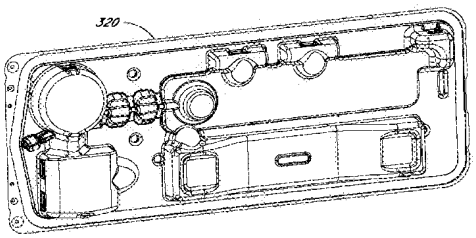


FIG. 10B

【図１０Ｃ】

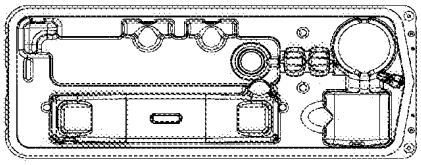


FIG. 10C

【図１０Ｄ】

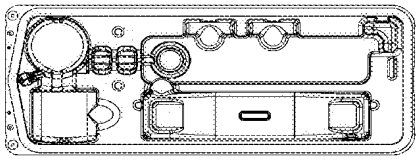


FIG. 10D

【図１０Ｅ】

FIG. 10E

【図１０Ｆ】

FIG. 10F

【図１０Ｇ】

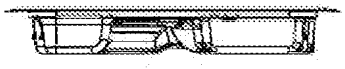


FIG. 10G

【図１０Ｈ】

FIG. 10H

【図１１Ａ】

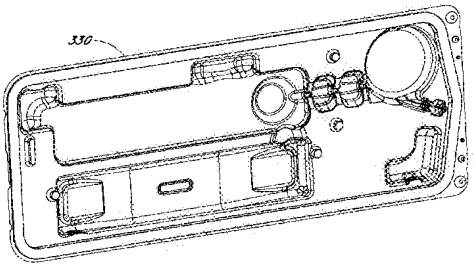


FIG. 11A

【図１１Ｂ】

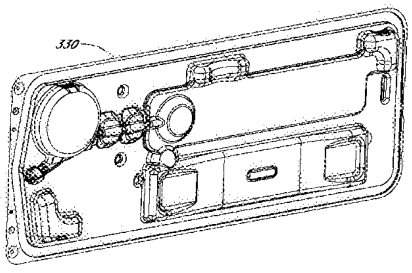


FIG. 11B

【図１１Ｃ】

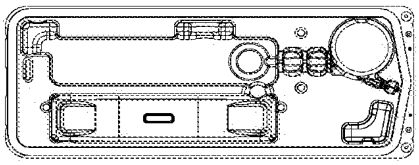


FIG. 11C

【図１１Ｄ】

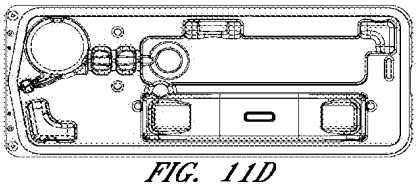


FIG. 11D

【図１１Ｅ】

FIG. 11E

【図１１Ｆ】

FIG. 11F

【図１１Ｇ】

FIG. 11G

【図１１Ｈ】

FIG. 11H

【図１２Ａ】

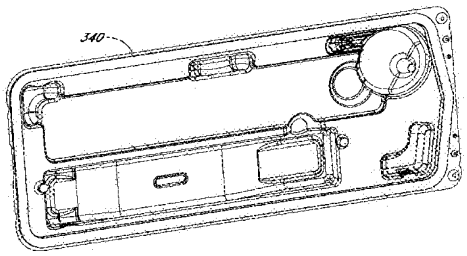


FIG. 12A

【図１２Ｂ】

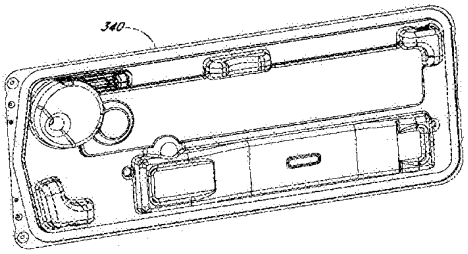


FIG. 12B

【図１２Ｃ】

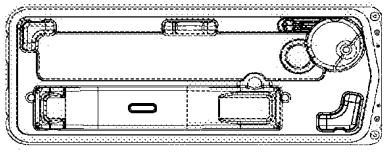


FIG. 12C

【図１２Ｄ】

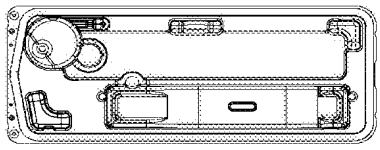


FIG. 12D

【図１２Ｅ】

FIG. 12E

【図１２Ｆ】

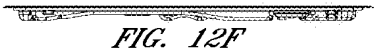


FIG. 12F

【図１２Ｇ】

FIG. 12G

【図１２Ｈ】

FIG. 12H

【図１３Ａ】

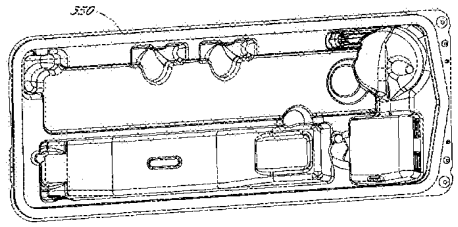


FIG. 13A

【図１３Ｂ】

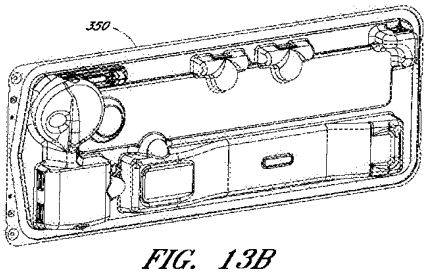


FIG. 13B

【図１３Ｃ】

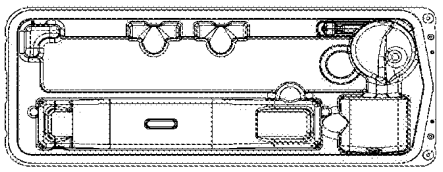


FIG. 13C

【図１３Ｄ】

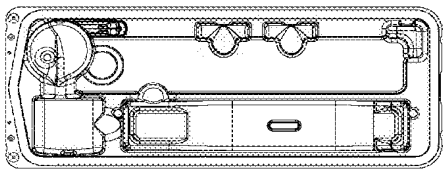


FIG. 13D

【図１３Ｅ】

FIG. 13E

【図１３Ｆ】

FIG. 13F

【図１３Ｇ】

FIG. 13G

【図１３Ｈ】

FIG. 13H

【図１４Ａ】

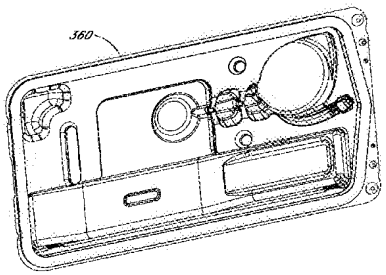


FIG. 14A

【図１４Ｂ】

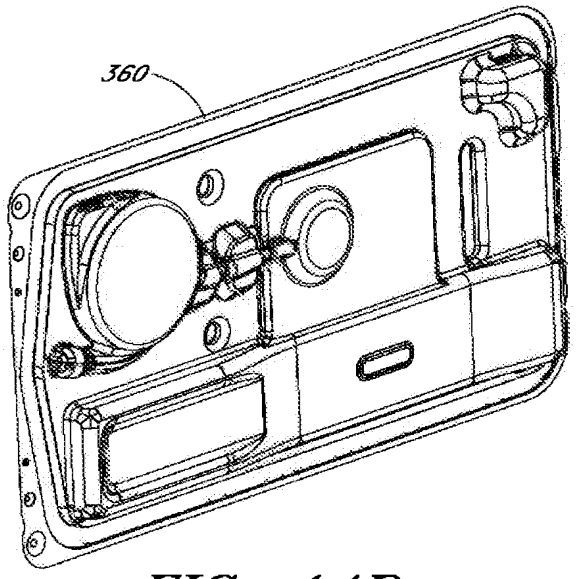


FIG. 14B

【図１４Ｃ】

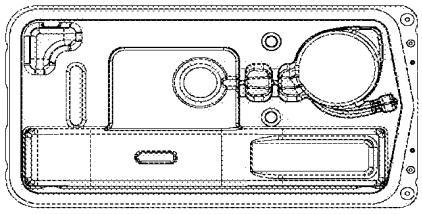


FIG. 14C

【図１４Ｄ】

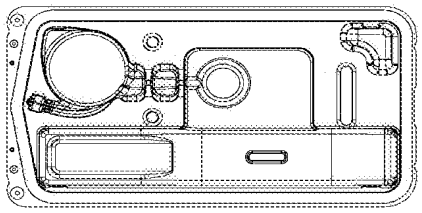


FIG. 14D

【図１４Ｅ】

FIG. 14E

【図１４Ｆ】

FIG. 14F

【図１４Ｇ】

FIG. 14G

【図１４Ｈ】

FIG. 14H

【図１４Ｉ】

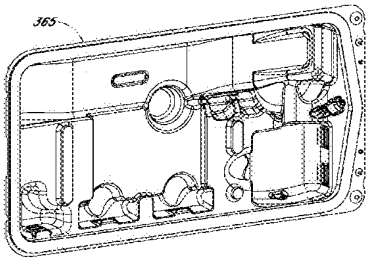


FIG. 14I

【図１４Ｊ】

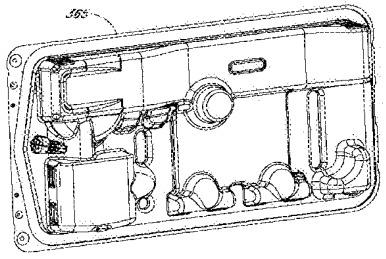


FIG. 14J

【図１４Ｋ】

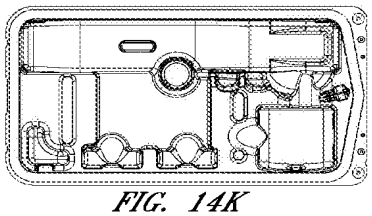


FIG. 14K

【図１４Ｌ】

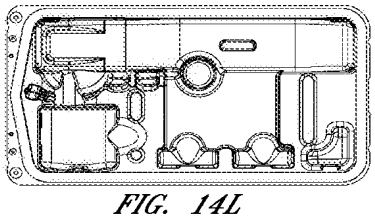


FIG. 14L

【図１４Ｍ】

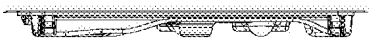


FIG. 14M

【図１４Ｎ】

FIG. 14N

【図１４Ｏ】

FIG. 140

【図１４Ｐ】

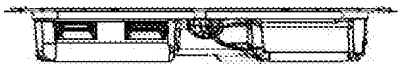


FIG. 14P

【図１５Ａ】

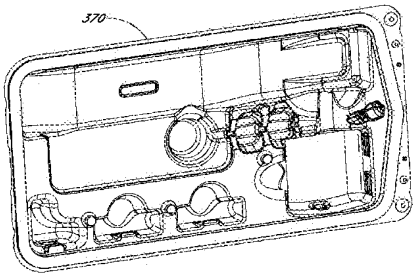


FIG. 15A

【図１５Ｂ】

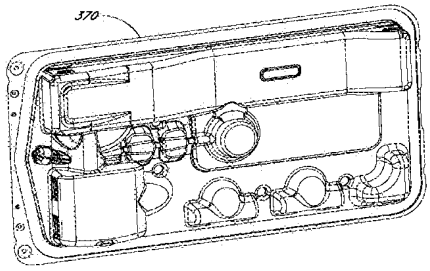


FIG. 15B

【図１５Ｃ】

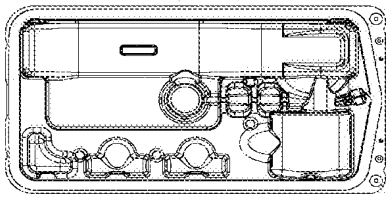


FIG. 15C

【図１５Ｄ】

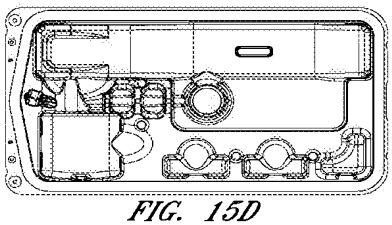


FIG. 15D

【図１５Ｅ】

FIG. 15E

【図１５Ｆ】

FIG. 15F

【図１５Ｇ】

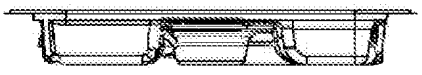


FIG. 15G

【図１５Ｈ】

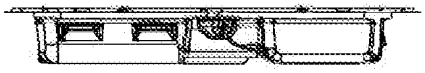


FIG. 15H

【図１６Ａ】

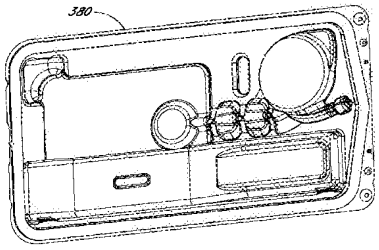


FIG. 16A

【図１６Ｂ】

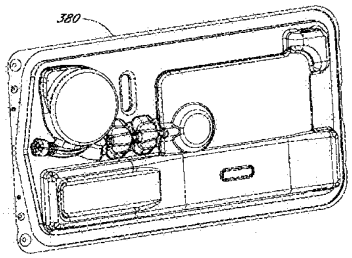


FIG. 16B

【図１６Ｃ】

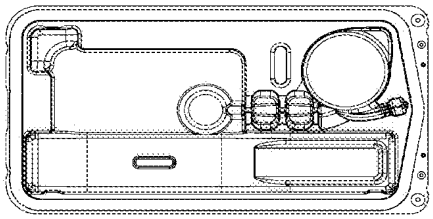


FIG. 16C

【図１６Ｄ】

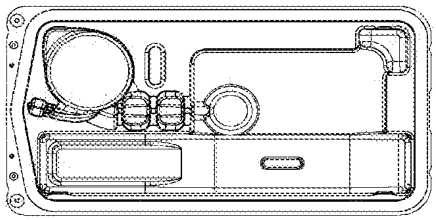


FIG. 16D

【図１６Ｅ】

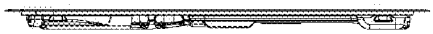


FIG. 16E

【図１６Ｆ】

FIG. 16F

【図１６Ｇ】

FIG. 16G

【図１６Ｈ】

FIG. 16H

【図１７Ａ】

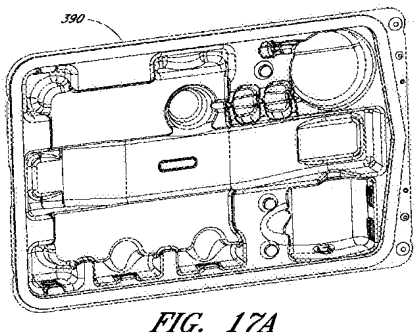


FIG. 17A

【図１７Ｂ】

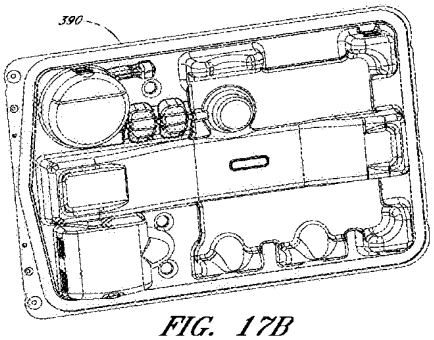


FIG. 17B

【図１７Ｃ】

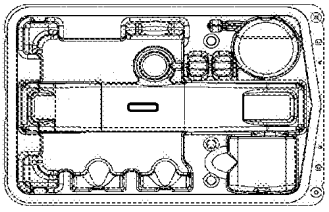


FIG. 17C

【図１７Ｄ】

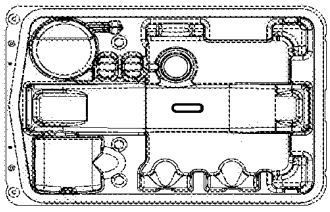


FIG. 17D

【図１７Ｅ】

FIG. 17E

【図１７Ｆ】

FIG. 17F

【図１７Ｇ】

FIG. 17G

【図１７Ｈ】

FIG. 17H

【図１７Ｉ】

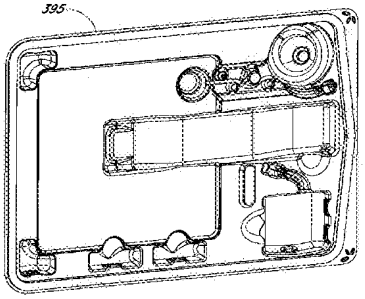


FIG. 17I

【図１７Ｊ】

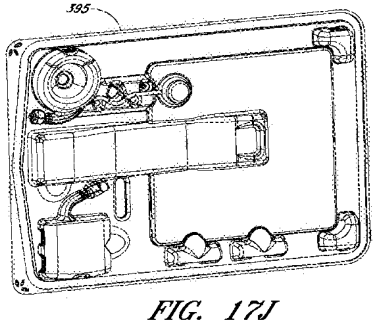


FIG. 17J

【図１７Ｋ】

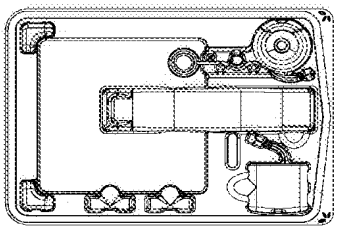


FIG. 17K

【図１７Ｌ】

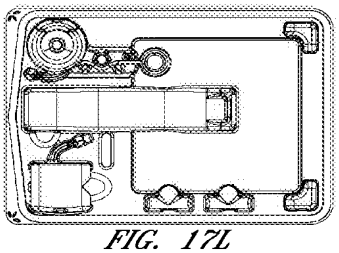


FIG. 17L

【図１７Ｍ】

FIG. 17M

【図１７Ｎ】

FIG. 17N

【図１７Ｏ】

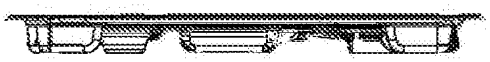


FIG. 17O

【図１７Ｐ】

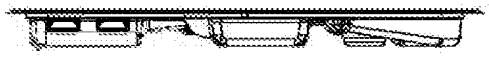


FIG. 17P

【図１８Ａ】

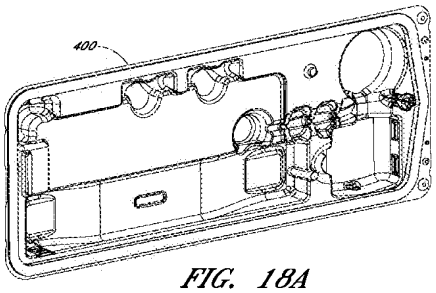


FIG. 18A

【図１８Ｂ】

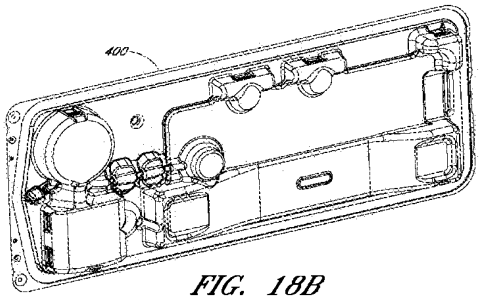


FIG. 18B

【図１８Ｃ】

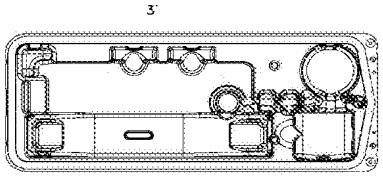


FIG. 18C

【図１８Ｄ】

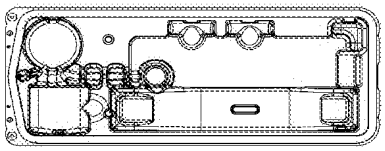


FIG. 18D

【図１８Ｅ】

FIG. 18E

【図１８Ｆ】

FIG. 18F

【図１８Ｇ】

FIG. 18G

【図１８Ｈ】

FIG. 18H

【図１８Ｉ】

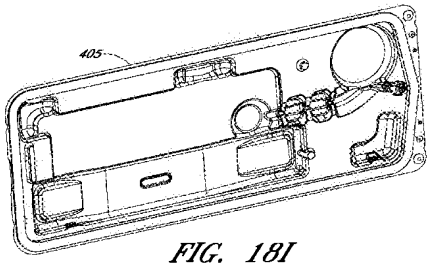


FIG. 18I

【図１８Ｊ】

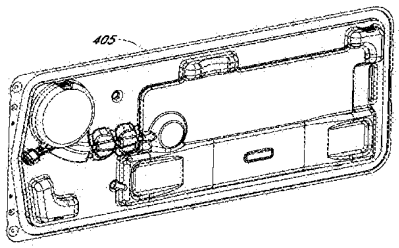


FIG. 18J

【図１８Ｋ】

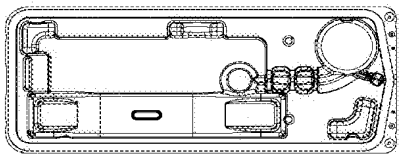


FIG. 18K

【図１８Ｌ】

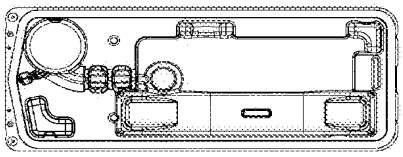


FIG. 18L

【図１８Ｍ】

FIG. 18M

【図１８Ｎ】

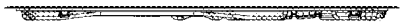


FIG. 18N

【図１８Ｏ】

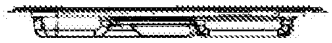


FIG. 180

【図１８Ｐ】

FIG. 18P

【図１９Ａ】

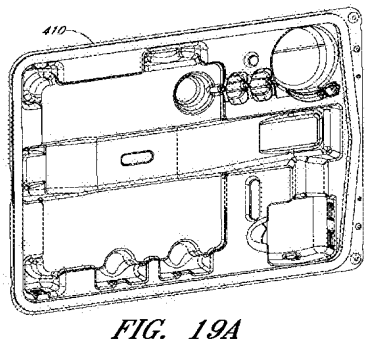


FIG. 19A

【図１９Ｂ】

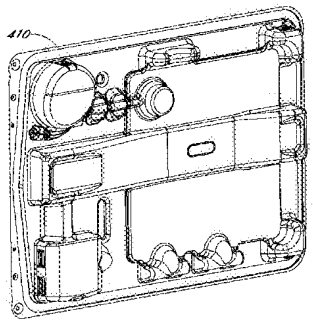


FIG. 19B

【図１９Ｃ】

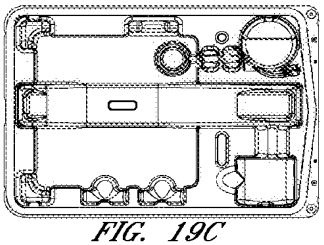


FIG. 19C

【図１９Ｄ】

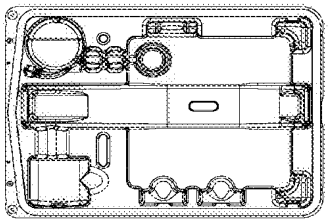


FIG. 19D

【図１９Ｅ】

FIG. 19E

【図１９Ｆ】

FIG. 19F

【図１９Ｇ】

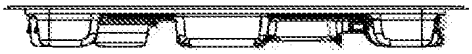


FIG. 19G

【図１９Ｈ】

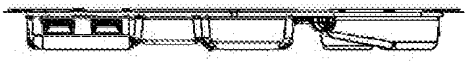


FIG. 19H

【図２０Ａ】

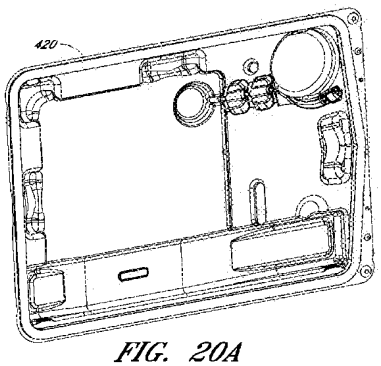


FIG. 20A

【図２０Ｂ】

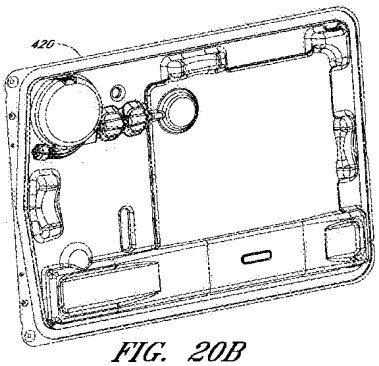


FIG. 20B

【図２０Ｃ】

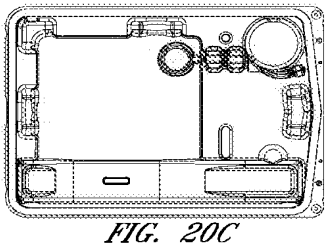


FIG. 20C

【図２０Ｄ】

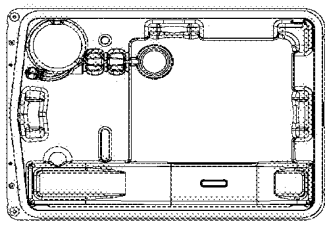


FIG. 20D

【図２０Ｅ】

FIG. 20E

【図２０Ｆ】

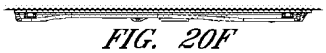


FIG. 20F

【図２０Ｇ】

FIG. 20G

【図２０Ｈ】

FIG. 20H

【図２１】

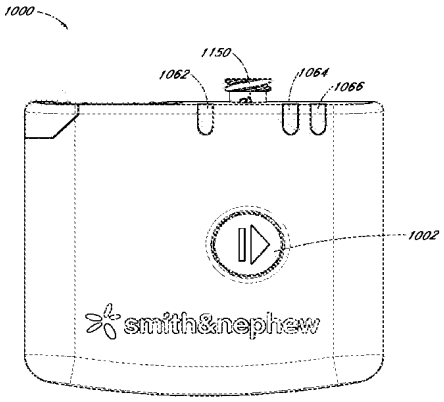


FIG. 21

【図２２】

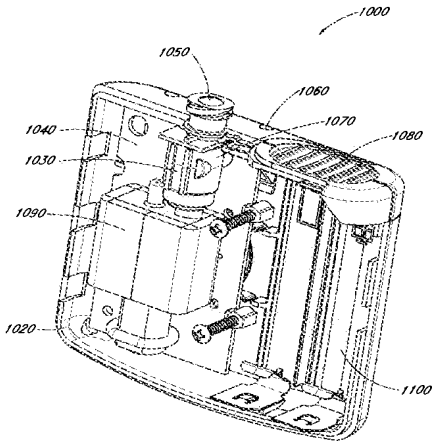


FIG. 22

【図２３】

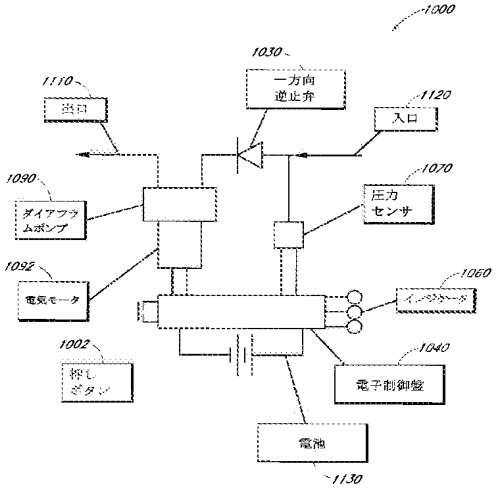


FIG. 23

【図２４】

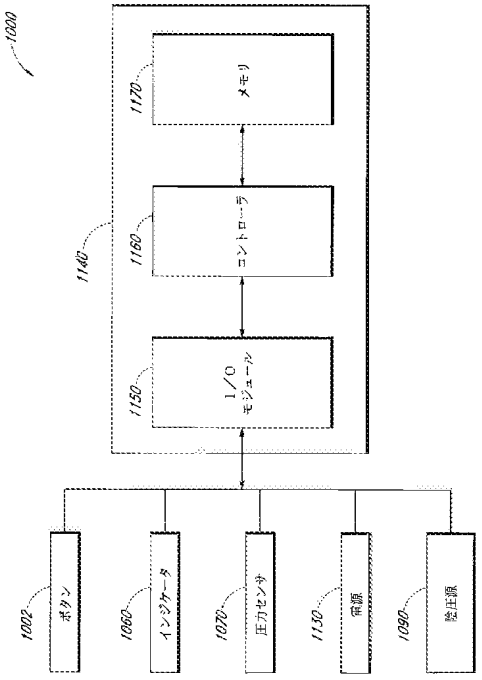


FIG. 24

【図２５】

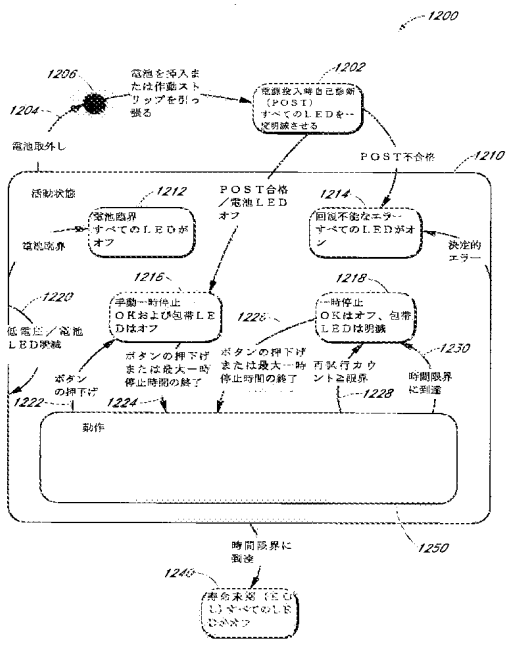


FIG. 25

【図２６】

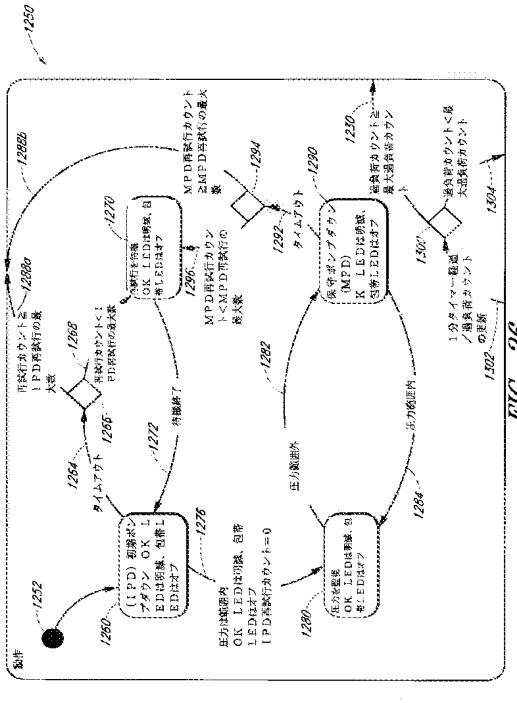


FIG. 26

【図２７】

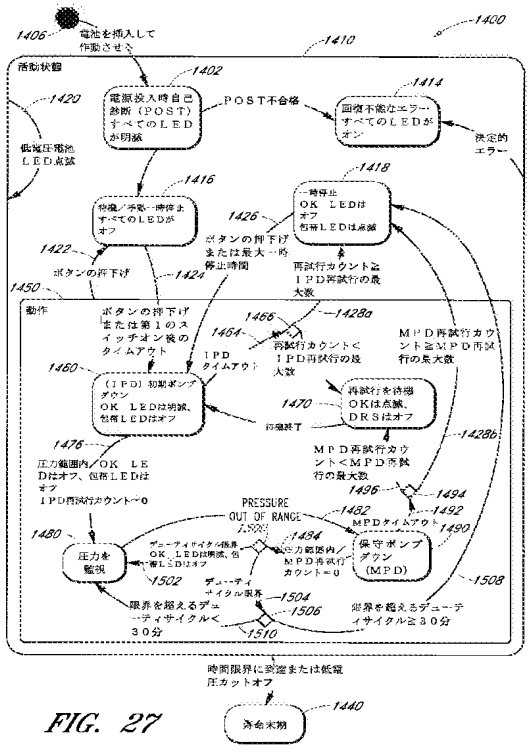


FIG. 27

【図２８】

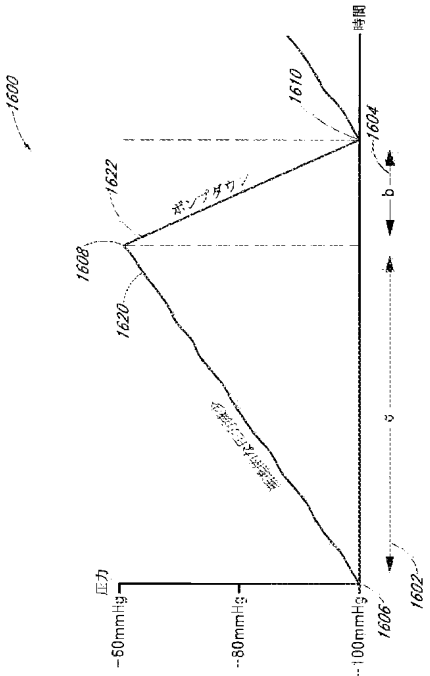


FIG. 28

【図２９】

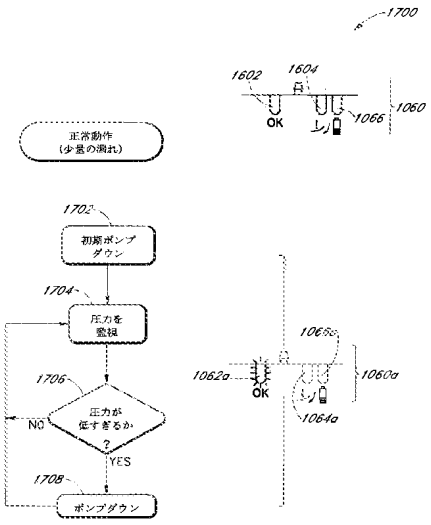
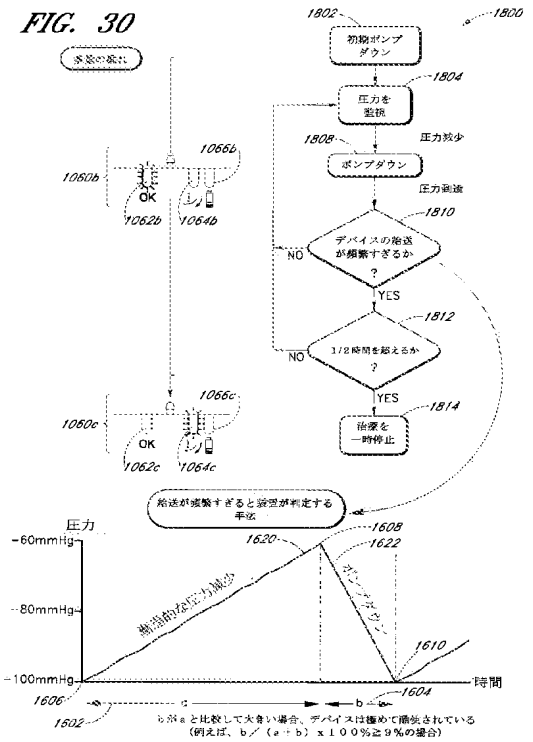


FIG. 29

【図３０】

FIG. 30



【図３１】

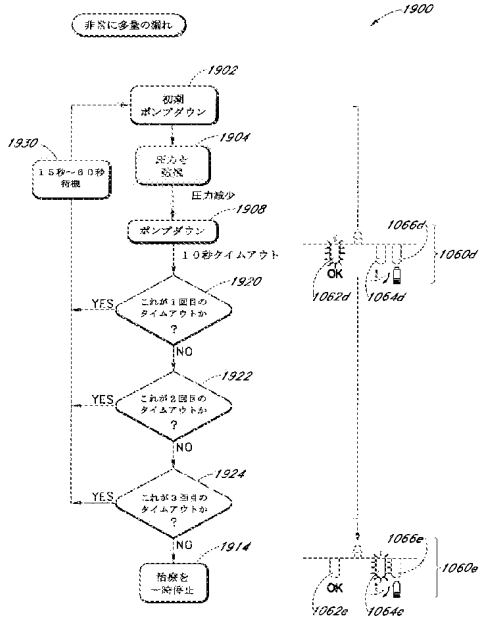


FIG. 31

【図３２】

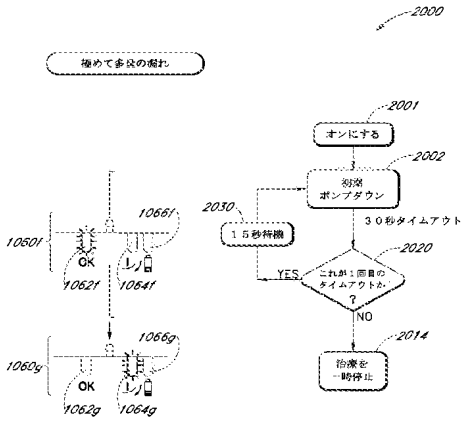


FIG. 32

【手続補正書】
【提出日】平成26年7月16日(2014.7.16)
【手続補正１】
【補正対象書類名】特許請求の範囲
【補正対象項目名】全文
【補正方法】変更
【補正の内容】
【特許請求の範囲】
【請求項１】
ハウジングと、
前記ハウジング内で又はハウジングによって支持されるポンプとを備える減圧創傷治療用のポンプアセンブリにおいて、前記ポンプが、
モータと、
入口及び出口と、
前記入口を通る流体のフローを制御するように構成された第１の弁と、
前記出口を通る流体のフローを制御するように構成された第２の弁と、
前記ポンプアセンブリを通る流路と、
前記ポンプと流体連通し、前記ポンプから離れるフロー方向で前記流路を通ってガスが流れるのを実質的に防ぐように構成されている一方向フロー弁と
を備える、ポンプアセンブリ。
【請求項２】
前記ポンプアセンブリが無容器型である、請求項１に記載のポンプアセンブリ。
【請求項３】
前記ハウジング内で又は前記ハウジングによって支持されるコントローラであって、前記ポンプの動作を制御するように構成されているコントローラをさらに備える、請求項１又は２に記載のポンプアセンブリ。
【請求項４】
前記流路と連通している圧力センサをさらに備える、請求項１から３のいずれか一項に記載のポンプアセンブリ。
【請求項５】
前記ハウジングによって支持される１つのみのスイッチ又はボタンをさらに備え、前記スイッチ又はボタンがユーザにとってアクセス可能であり、コントローラと連通していることができる、請求項１から４のいずれか一項に記載のポンプアセンブリ。
【請求項６】
前記第１の弁及び前記第２の弁が、公称の動作圧力で約０．１ｍＬ／分及び１０ｍＬ／分の速度で漏れる、請求項１から５のいずれか一項に記載のポンプアセンブリ。
【請求項７】
前記ポンプアセンブリが、前記ハウジングの少なくとも内部及び外部、前記流路、前記第１及び第２の弁、及び前記ポンプが滅菌されたものであるように滅菌される、請求項１から６のいずれか一項に記載のポンプアセンブリ。
【請求項８】
前記ハウジングによって支持される１つ又は複数のＬＥＤライトをさらに備える、請求項１から７のいずれか一項に記載のポンプアセンブリ。
【請求項９】
前記ポンプアセンブリが１つ又は複数の電池を備え、前記１つ又は複数の電池の重量を含めて８０ｇと９０ｇの間の重量である、請求項１から８のいずれか一項に記載のポンプアセンブリ。
【請求項１０】
前記ポンプアセンブリの外表面が６０立方センチメートルと８０立方センチメートルの間の体積を画成する、請求項１から９のいずれか一項に記載のポンプアセンブリ。

【請求項１１】
陰圧治療キットであって、
請求項１から１０のいずれか一項に記載の前記ポンプアセンブリと、
包帯と、
前記包帯及び前記ポンプアセンブリと連結可能であり、前記包帯までの減圧の流体経路を提供するように構成された導管と、
１つ又は複数の電池と、
第１のパッケージング要素、及び前記第１のパッケージング要素と取外し可能に連結されるように構成された第２のパッケージング要素であって、前記第１及び第２のパッケージング要素の少なくとも一方は、前記ポンプアセンブリと、前記包帯と、前記導管と、前記１つ又は複数の電池とを受け入れるための陥凹部を有する第１及び第２のパッケージング要素と
を備える陰圧治療キット。
【請求項１２】
前記陰圧治療キットが、滅菌性であり、前記ポンプアセンブリ、前記包帯、前記導管、及び前記１つ又は複数の電池を、前記第１のパッケージング要素及び前記第２のパッケージング要素の少なくとも一方の内部で支持した後に滅菌される、請求項１１に記載の陰圧治療キット。
【請求項１３】
１つ又は複数の接着剤シールストリップをさらに備える、請求項１１又は１２に記載の陰圧治療キット。
【請求項１４】
前記１つ又は複数の電池が、前記ハウジングの外部で支持される、請求項１１から１３のいずれか一項に記載の陰圧治療キット。
【請求項１５】
前記陰圧治療キットが酸化エチレンによって滅菌される、請求項１１から１４のいずれか一項に記載の陰圧治療キット。
【請求項１６】
前記包帯が、
透過層と、
創傷浸出物を吸収するための吸収性層であって、前記透過層を覆う吸収性層と、
前記吸収性層を覆い、そこを通るオリフィスを備えるカバー層と
を備える、請求項１１から１５のいずれか一項に記載の陰圧治療キット。
【請求項１７】
前記包帯が、創傷部位に局所陰圧を加えるために前記包帯に陰圧を加えるための吸気ポートを備える、請求項１１から１６のいずれか一項に記載の陰圧治療キット。
【請求項１８】
前記吸気ポートが、前記吸気ポートを前記ポンプアセンブリに接続するためのコネクタ部分、及び前記吸気ポートを前記包帯のカバー層にシールするためのシール面を備える、請求項１７に記載の陰圧治療キット。
【請求項１９】
前記包帯が、液体がコネクタ部分に入るのを防ぐようになされた液体不透過性ガス透過性フィルタ要素を備える、請求項１１から１８のいずれか一項に記載の陰圧治療キット。
【請求項２０】
前記第１のパッケージング要素がＰＥＴＧを備える、請求項１１から１９のいずれか一項に記載の陰圧治療キット。
【請求項２１】
陰圧治療システムであって、
請求項１から１０のいずれか一項に記載の前記ポンプアセンブリと、
包帯と

を備える陰圧治療システム。
【請求項２２】
前記包帯の創傷に向く面が、前記創傷を取り囲む皮膚と漏れ量の少ないシールを形成するように構成されたシリコーン系接着剤によって少なくとも部分的に覆われている、請求項２１に記載の陰圧治療キット。
【請求項２３】
陰圧を用いて創傷を治療する方法であって、
包帯を用意するステップと、
前記創傷の上に実質的に液密のシールを形成するように前記創傷の上に前記包帯を当てるステップと、
請求項１から１０のいずれか一項に記載の前記ポンプアセンブリを使用して前記包帯を通して前記創傷に陰圧を送達するステップと
を含む方法。
【請求項２４】
創傷の上に実質的に液密のシールを形成するように前記創傷の上に包帯を当てるステップ、及び請求項１から１０のいずれか一項に記載の前記ポンプアセンブリを使用して前記包帯を通して創傷に陰圧を送達するステップが、手術ルームで行われる、請求項２３に記載の陰圧を用いて創傷を治療する方法。
【請求項２５】
ポンプアセンブリであって、
ハウジングと、
ポンプモータ、
入口及び出口、
前記入口及び前記出口のうちの少なくとも１つを通して流体のフローを制御するように構成された少なくとも１つの弁、及び
少なくとも前記入口、前記出口、及び前記少なくとも１つの弁を通る流路
を備えるハウジング内で支持されるポンプと、
前記ハウジング内で又は前記ハウジングによって支持されるコントローラであって、前記ポンプ及び前記弁の動作を制御するように構成されているコントローラと、
少なくとも１つのスイッチ又はボタンであって、前記ハウジングで支持され、前記コントローラと連通し、ユーザがポンプの１つ又は複数の動作モードを制御できるように、ユーザにとってアクセス可能である少なくとも１つのスイッチ又はボタンと
を備えるポンプアセンブリと、
創傷の上に実質的に液密のシールを形成するように構成された包帯と、
前記包帯及び前記ポンプアセンブリと連結可能であり、前記ポンプアセンブリから前記包帯までの実質的に又は完全に包囲された流体流路を設けるように構成された導管と、
前記ポンプアセンブリ、前記１つ又は複数の電池、前記包帯、及び前記導管をパッケージングするための第１のパッケージング要素と
を備える、減圧創傷治療用の陰圧治療キットにおいて、
前記陰圧治療キットが、前記ハウジングの少なくとも内部及び外部、前記少なくとも１つの弁、前記ポンプ、前記コントローラ、及び前記少なくとも１つのスイッチ又はボタンが滅菌されたものであるように滅菌される、減圧創傷治療用の陰圧治療キット。
【請求項２６】
１つ又は複数の接着剤シールストリップをさらに備える、請求項２５に記載の陰圧治療キット。
【請求項２７】
動力を少なくとも前記ポンプ及びコントローラに供給するように構成された１つ又は複数の電池をさらに備える、請求項２１から２６のいずれか一項に記載の陰圧治療キット。
【請求項２８】
第１のパッケージング要素と連結するように構成された第２のパッケージング要素をさ

らに備え、前記第１のパッケージング要素が、前記ポンプアセンブリ、前記１つ又は複数の電池、前記包帯、導管、及び１つ又は複数の接着剤シールストリップのうちの１つ又は複数を受け入れるための複数の陥凹部を有する、請求項２７に記載の陰圧治療キット。
【請求項２９】
前記第２のパッケージング要素が、滅菌ガスに対して透過性であり、細菌に対して不透過性である、請求項２８に記載の陰圧治療キット。
【請求項３０】
第１のパッケージング要素が前記１つ又は複数の電池を支持し、それによって前記陰圧治療キットの滅菌処理中に前記１つ又は複数の電池が前記ハウジングの外部で支持される、請求項２５から２９のいずれか一項に記載の陰圧治療キット。
【請求項３１】
前記ポンプが、ダイヤフラムポンプ、回転ダイヤフラムポンプ、又は圧電ポンプである、請求項２５から３０のいずれか一項に記載の陰圧治療キット。
【請求項３２】
前記陰圧治療キットが酸化エチレンによって滅菌される、請求項２５から３１のいずれか一項に記載の陰圧治療キット。
【請求項３３】
前記少なくとも１つの弁が、滅菌プロセスの際に前記少なくとも１つの弁を通る滅菌ガスのフローを可能にするように構成された、請求項２５から３２のいずれか一項に記載の陰圧治療キット。
【請求項３４】
前記ポンプアセンブリが、フローマニホルドをさらに備え、前記フローマニホルドが、圧力センサ、前記ポンプ、及び導管、導管用コネクタのうちの少なくとも１つと流体連通している、請求項２５から３３のいずれか一項に記載の陰圧治療キット。
【請求項３５】
マニホルドによって支持された一方向フロー弁をさらに備える、請求項３４に記載の陰圧治療キット。
【請求項３６】
前記ポンプと前記包帯の間に位置付けられた一方向フロー弁を備え、前記一方向フロー弁が、前記ポンプから前記包帯に向かうフロー方向で前記一方向フロー弁を通るガスの前記フローを実質的に防ぐように構成されている、請求項２５から３５のいずれか一項に記載の陰圧治療キット。
【請求項３７】
前記一方向フロー弁が、前記ハウジング内で支持される、請求項３６に記載の陰圧治療キット。
【請求項３８】
前記ポンプと前記包帯の間、又は前記ポンプアセンブリ内で流体流路内のガスの圧力レベルを監視するように構成された圧力センサをさらに備える、請求項２５から３７のいずれか一項に記載の陰圧治療キット。
【請求項３９】
第１のパッケージング要素にパッケージングされた場合に導管の一方の端部が前記包帯に接続される、請求項２５から３８のいずれか一項に記載の陰圧治療キット。
【請求項４０】
導管が第１の端部及び第２の端部を備え、前記第１の端部が前記包帯に接続され、又は接続可能であり、前記第２の端部が前記ハウジングと連結するように構成されたコネクタを備える、請求項２５から３９のいずれか一項に記載の陰圧治療キット。
【請求項４１】
前記ハウジングがシールされない、請求項２５から４０のいずれか一項に記載の陰圧治療キット。
【請求項４２】

前記ポンプアセンブリが容器を備えない、請求項２５から４１のいずれか一項に記載の陰圧治療キット。
【請求項４３】
前記ポンプによって生成される雑音及び振動を低減するため前記ポンプの少なくとも一部分を取り囲む、解放した発泡体層をさらに備える、請求項２５から４２のいずれか一項に記載の陰圧治療キット。
【請求項４４】
前記包帯が、
透過層と、
創傷浸出物を吸収するための吸収性層であって、前記透過層を覆う吸収性層と、
前記吸収性層を覆うカバー層と、
導管の端部を受け入れるための吸気ポートと、
液体が前記吸気ポートを通過するのを防ぐようになされた液体不透過性ガス透過性フィルタ要素と
を備える、請求項２５から４３のいずれか一項に記載の陰圧治療キット。
【請求項４５】
前記ポンプアセンブリが、前記ハウジングにより支持され、又は前記ハウジング内に形成された電池区画を備える、請求項２５から４４のいずれか一項に記載の陰圧治療キット。
【請求項４６】
前記陰圧治療キットが、創傷を取り囲む皮膚と漏れ量の少ないシールを形成するように構成されたシリコーン系接着剤を有する創傷包帯を備え、前記ポンプアセンブリが前記１つ又は複数の電池の重量を含めて７０ｇと９０ｇの間の重量である、請求項２５から４５のいずれか一項に記載の陰圧治療キット。
【請求項４７】
前記ポンプアセンブリが、前記１つ又は複数の電池の重量を含めて７０ｇと９０ｇの間の重量である、請求項２５から４６のいずれか一項に記載の陰圧治療キット。
【請求項４８】
前記ポンプアセンブリの外表面が、約３立方インチ（４９．１６立方センチメートル）から約５立方インチ（８１．９４立方センチメートル）の体積を画成する、請求項２５から４７のいずれか一項に記載の陰圧治療キット。
【請求項４９】
前記陰圧治療キットが、シールストリップを第１のパッケージング要素から除去できる前に、前記包帯を前記第１のパッケージング要素から除去しなければならないように構成される、請求項２５から４８のいずれか一項に記載の陰圧治療キット。
【請求項５０】
約３５０ｍＬ／分以下の流量を有するポンプを備えるポンプアセンブリと、
カバー層を備える包帯であって、シリコーン系接着剤によって覆われている創傷接触面を有する包帯と
を備える、減圧創傷治療用の陰圧治療キット。
【請求項５１】
前記ポンプアセンブリが前記ポンプと流体連通している一方向フロー弁を備え、前記一方向フロー弁が前記ポンプから離れるフロー方向で流路を通ってガスが流れるのを実質的に防ぐように構成されている、請求項５０に記載された陰圧治療キット。
【請求項５２】
前記包帯が、前記包帯に陰圧を加えたときに開いたままであるように構成された３Ｄ編成材料又は布地材料を備える透過層を備える、請求項５０又は５１に記載の陰圧治療キット。
【請求項５３】
前記包帯が創傷浸出物を吸収するための吸収性層を備え、前記吸収性層が透過層を覆う

、請求項５０から５２のいずれか一項に記載の陰圧治療キット。
【請求項５４】
前記包帯が、吸収性層を覆うカバー層を備え、オリフィスを備え、前記カバー層が水蒸気透過性である、吸収性層が透過層を覆う、請求項５０から５３のいずれか一項に記載の陰圧治療キット。
【請求項５５】
前記包帯が、創傷部位に局所陰圧を加えるために、陰圧を前記包帯に加えるための吸気ポートを備え、前記吸気ポートが、前記吸気ポートを前記ポンプアセンブリに接続するためのコネクタ部分、及び前記吸気ポートを前記包帯の前記カバー層にシールするためのシール面を備える、請求項５０から５４のいずれか一項に記載の陰圧治療キット。
【請求項５６】
前記包帯が、液体がコネクタ部分に入るのを防ぐようになされた液体不透過性ガス透過性フィルタ要素を備える、請求項５０から５５のいずれか一項に記載の陰圧治療キット。
【請求項５７】
前記ポンプアセンブリが無容器型である、請求項５０から５６のいずれか一項に記載の陰圧治療キット。
【請求項５８】
前記ポンプアセンブリのハウジング内で又は前記ポンプアセンブリのハウジングによって支持されるコントローラであって、前記ポンプの動作を制御するように構成されているコントローラをさらに備える、請求項５０から５７のいずれか一項に記載の陰圧治療キット。
【請求項５９】
前記ポンプアセンブリを通る流路と連通している圧力センサをさらに備える、請求項５０から５８のいずれか一項に記載の陰圧治療キット。
【請求項６０】
前記ポンプアセンブリのハウジングによって支持される少なくとも１つのスイッチ又はボタンをさらに備え、前記少なくとも１つスイッチ又はボタンがユーザにとってアクセス可能であり、コントローラと連通していることができる、請求項５０から５９のいずれか一項に記載の陰圧治療キット。
【請求項６１】
前記ポンプアセンブリにより支持された電池区画をさらに備える、請求項５０から６０のいずれか一項に記載の陰圧治療キット。
【請求項６２】
前記ポンプアセンブリの少なくとも内部及び外部が滅菌されているように、前記ポンプアセンブリが、前記ポンプアセンブリの組み立てに続いて滅菌される、請求項５０から６１のいずれか一項に記載の陰圧治療キット。
【請求項６３】
前記ポンプアセンブリが１つ又は複数のＬＥＤライトを有する、請求項５０から６２のいずれか一項に記載の陰圧治療キット。
【請求項６４】
前記ポンプアセンブリが、１つ又は複数の電池を備え、前記１つ又は複数の電池の重量を含めて８０ｇと９０ｇの間の重量である、請求項５０から６３のいずれか一項に記載の陰圧治療キット。
【請求項６５】
前記ポンプアセンブリの外表面が６０立方センチメートルと８０立方センチメートルの間の体積を画成する、請求項５０から６４のいずれか一項に記載の陰圧治療キット。
【請求項６６】
減圧創傷治療用の無容器型ポンプアセンブリであって、
ハウジングと、
ハウジング内で又はハウジングによって支持されるポンプとを備えるポンプアセンブリ

において、前記ポンプが、
モータと、
入口及び出口と、
前記入口を通る流体のフローを制御するように構成された第１の弁と、
前記出口を通る流体のフローを制御するように構成された第２の弁と
を備える容器型ポンプアセンブリにおいて、
前記ポンプアセンブリが無容器型であり、
前記第１及び第２の弁が、それぞれ公称の動作圧力で約５Ｌ／分と約１０Ｌ／分の間の漏れ速度を有する、容器型ポンプアセンブリ。
【請求項６７】
前記ポンプアセンブリが前記ポンプと流体連通している一方向フロー弁を備え、前記一方向フロー弁が前記ポンプから離れるフロー方向で流路を通ってガスが流れるのを実質的に防ぐように構成された、請求項６６に記載のポンプアセンブリ。
【請求項６８】
前記ハウジング内で又は前記ハウジングによって支持されるコントローラであって、前記ポンプの動作を制御するように構成されているコントローラをさらに備える、請求項６６又は６７に記載のポンプアセンブリ。
【請求項６９】
前記ポンプアセンブリを通る流路と連通している圧力センサをさらに備える、請求項６６から６８のいずれか一項に記載のポンプアセンブリ。
【請求項７０】
前記ハウジングによって支持される少なくとも１つのスイッチ又はボタンをさらに備え、前記少なくとも１つスイッチ又はボタンがユーザにとってアクセス可能であり、コントローラと連通していることができる、請求項６６から６９のいずれか一項に記載のポンプアセンブリ。
【請求項７１】
前記ハウジングにより支持され、又は前記ハウジング内に形成された電池区画をさらに備える、請求項６６から７０のいずれか一項に記載のポンプアセンブリ。
【請求項７２】
前記ハウジングの少なくとも内部及び外部、流路、前記１つ又は複数の弁、及び前記ポンプが滅菌されたものであるように、前記ポンプアセンブリの組み立てに続いて滅菌される、請求項６６から７１のいずれか一項に記載のポンプアセンブリ。
【請求項７３】
前記ハウジングによって支持される１つ又は複数のＬＥＤライトをさらに備える、請求項６６から７２のいずれか一項に記載のポンプアセンブリ。
【請求項７４】
前記ポンプアセンブリが１つ又は複数の電池を備え、前記１つ又は複数の電池の重量を含めて８０ｇ及び９０ｇの重量である、請求項６６から７３のいずれか一項に記載のポンプアセンブリ。
【請求項７５】
前記ポンプアセンブリの外表面が６０立方センチメートルと８０立方センチメートルの間の体積を画成する、請求項６６から７４のいずれか一項に記載のポンプアセンブリ。
【請求項７６】
滅菌ポンプキットであって、
請求項６６から７５のいずれか一項に記載の前記ポンプアセンブリと、
包帯と、
前記包帯及び前記ポンプアセンブリと連結可能であり、前記包帯までの減圧の流体経路を提供するように構成された導管と、
１つ又は複数の電池と、
第１のパッケージング要素、及び前記第１のパッケージング要素と取外し可能に連結さ

れるように構成された第２のパッケージング要素であって、前記第１及び第２のパッケージング要素の少なくとも一方は、前記ポンプアセンブリと、包帯と、前記包帯及び前記ポンプアセンブリと連結可能であり、前記包帯までの減圧の流体経路を提供するように構成された前記導管とを受け入れるための陥凹部を有する滅菌ポンプキットにおいて、
前記滅菌ポンプキットが、前記ポンプアセンブリ、前記包帯、前記導管、及び前記１つ又は複数の電池が、前記第１のパッケージング要素及び前記第２のパッケージング要素の少なくとも一方の内部で支持された後に滅菌される、滅菌ポンプキット。
【請求項７７】
前記ポンプアセンブリ、前記包帯、前記導管、及び前記１つ又は複数の電池が滅菌される前に、前記ポンプアセンブリ、前記包帯、前記導管、及び前記１つ又は複数の電池が、前記第１のパッケージング要素及び前記第２のパッケージング要素の少なくとも一方の内部で支持される、請求項７６に記載の滅菌ポンプキット。
【請求項７８】
１つ又は複数の接着剤シールストリップをさらに備える、請求項７６又は７７に記載の滅菌ポンプキット。
【請求項７９】
前記１つ又は複数の電池が、前記ハウジングの外表面で支持される、請求項７６から７８のいずれか一項に記載の滅菌ポンプキット。
【請求項８０】
前記滅菌ポンプキットが酸化エチレンによって滅菌される、請求項７６から７９のいずれか一項に記載の滅菌ポンプキット。
【請求項８１】
前記包帯が、
透過層と、
創傷浸出物を吸収するための吸収性層であって、前記吸収性層が前記透過層を覆う吸収性層と、
前記吸収性層を覆うカバー層と
を備える請求項７６から８０のいずれか一項に記載の滅菌ポンプキット。
【請求項８２】
前記包帯が、創傷部位に局所陰圧を加えるために前記包帯に陰圧を加えるための吸気ポートを備える、請求項７６から８１のいずれか一項に記載の滅菌ポンプキット。
【請求項８３】
前記吸気ポートが、前記吸気ポートを前記ポンプアセンブリに接続するためのコネクタ部分、及び前記吸気ポートを前記包帯のカバー層にシールするためのシール面を備える、請求項８２に記載の滅菌ポンプキット。
【請求項８４】
前記包帯が、液体がコネクタ部分に入るのを防ぐようになされた液体不透過性ガス透過性フィルタ要素を備える、請求項７６から８３のいずれか一項に記載の滅菌ポンプキット。
【請求項８５】
前記第１のパッケージング要素がＰＥＴＧを備える、請求項７６から８４のいずれか一項に記載の滅菌ポンプキット。
【請求項８６】
手術ルームにおいて創傷の治療を開始するための方法であって、
創傷の上に滅菌包帯を当てて、前記創傷の上に実質的に液密のシールを作り出すステップと、
滅菌導管を介して滅菌ポンプアセンブリを包帯に連結するステップと、前記手術ルームで前記滅菌ポンプアセンブリを動作させることによって手術ルームで前記包帯と前記創傷との間の圧力レベルを低減するステップと
を含む、方法。

【請求項８７】
少なくとも１つの前記包帯の外周縁部の上に１つ又は複数のシールストリップを当てて、前記包帯と前記創傷を取り囲む皮膚の間の前記シールを改善するためのステップをさらに含む、請求項８６に記載の方法。
【請求項８８】
１つ又は複数の電池を第１のパッケージング要素から取り出すステップと、前記１つ又は複数の電池を前記滅菌ポンプアセンブリに取り付けるステップをさらに含む、請求項８６又は８７に記載の方法。

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/002943

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61L2/00 A61M1/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M A61L F04B F04C F04D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/125004 A1 (SHEN TE-YANG [TW] ET AL) 14 May 2009 (2009-05-14) paragraphs [0001], [0025], [0029] - [0030], [0035]; claim 4; figures 2,4	1-10,21, 22
A	US 4 643 641 A (CLAUSEN EARL W [US] ET AL) 17 February 1987 (1987-02-17) the whole document	1-10,21, 22
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[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 December 2012	28/01/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Westsson, David

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/002943

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/002943

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2011/002943

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 23, 24, 86-88
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos..
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[X] No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (April 2005)

International Application No. PCT/IB2011/002943

FURTHER INFORMATION CONTINUED FROM PCT/ISA/210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-10, 21, 22

A pump assembly comprising: a pump having a first valve at the inlet and second valve at the outlet; a flow path; a one-way flow valve configured to substantially prevent a flow of gas through the flow path away from the pump.

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2. claims: 11-20

A pump assembly as in the first group of claims additionally comprising a dressing, one or more batteries and a first and second packaging element.

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3. claims: 25-49

A negative pressure therapy kit comprising a pump assembly comprising: a pump having at least one valve configured to control the flow through at least one of the inlet and the outlet; a controller; at least one switch button in communication with the controller; a first packaging element.

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4. claims: 50-65

A negative pressure therapy kit comprising: a pump assembly having a flow rate of approx. 350 ml/min or less; a dressing with a cover layer and a wound contact layer covered with a silicone based adhesive.

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5. claims: 66-88

A canisterless pump assembly comprising; a pump having a first and second valve controlling the flow at the inlet and outlet respectively, wherein the leakage rate of the valves is between approx. 5-10 ml/min at nominal working pressure.

International Application No. PCT/IB2011/002943

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 23, 24, 86-88

Claims 23-24 refer to a method for treatment of the human or animal body by therapy, which is against Rule 39.1(iv) PCT and Rule 67.1(iv). The reason is that they include the step of delivering negative pressure to a wound. Claims 86-88 refer to a method for treatment of the human or animal body by therapy, which is against Rule 39.1(iv) PCT and Rule 67.1(iv). The reason is that they include the step applying a sterile dressing over a wound and reducing a level of pressure between the dressing and the wound.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2011/002943

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Form PCT/ISA/210 (patent family annex) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2011/002943

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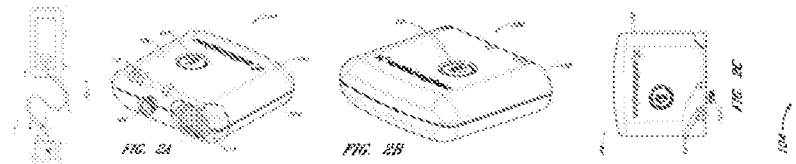
Decompression treatment device and method of using the same

Abstract

translated from Japanese

Some embodiments include a housing, a flow path through the pump, one or more valves in communication with the flow path, a pump in or supported by the housing, and a one-way flow in fluid communication with the pump. A reduced pressure wound therapy pump assembly comprising a valve. The pump assembly may have a pressure sensor in communication with the flow path through the pump, and at least one switch or button supported by the housing, at least one switch or button being accessible to the user and in communication with the controller. is doing. The one-way flow valve can be configured to substantially prevent gas from flowing through the one-way flow valve in the flow direction away from the pump. The pump assembly can have a controller that is supported in or by the housing and configured to control the operation of the pump. The pump is sterilized following assembly of the pump such that the interior and exterior of the housing, flow path, one or more valves, pump, controller, battery compartment, and at least one switch or button are sterilized. The

Images (160)



Classifications

- A61M1/80 Suction pumps

View 12 more classifications

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External links: Espacenet, Global Dossier, Discuss

Claims (88)

Hide Dependent

translated from Japanese

A housing;
A reduced pressure wound therapy pump assembly comprising a pump supported in or by the housing, the pump comprising:
A motor,
An inlet and an outlet,
A first valve configured to control the flow of fluid through the inlet;
A second valve configured to control the flow of fluid through the outlet;
A flow path through the pump assembly;
A pump assembly comprising: a one-way flow valve in fluid communication with the pump and configured to substantially prevent gas from flowing through the flow path in a flow direction away from the pump. The pump assembly of claim 1, wherein the pump assembly is containerless. The pump assembly of claim 1 or 2, further comprising a controller supported within or by the housing, the controller configured to control operation of the pump. The pump assembly according to any one of claims 1 to 3, further comprising a pressure sensor in communication with the flow path. 5. The method of claim 1, further comprising only one switch or button supported by the housing, wherein the at least one switch or button is accessible to a user and can be in communication with a controller. The pump assembly according to claim 1. 6. The pump according to claim 1, wherein the first valve and the second valve leak at a rate of about 0.1 mL / min and 10 mL / min at nominal operating pressure. assembly. 7. The pump assembly of any of claims 1 to 6, wherein the pump assembly is sterilized such that at least the interior and exterior of the housing, the flow path, the first and second valves, and the pump are sterilized. The pump assembly according to claim 1. The pump assembly according to any one of the preceding claims, further comprising one or more LED lights supported by the housing. 9. A pump assembly according to any one of the preceding claims, wherein the pump assembly comprises one or more batteries and has a weight between 80g and 90g including the weight of the one or more batteries. . The pump assembly according to any one of the preceding claims, wherein the outer surface of the pump assembly defines a volume between 60 cubic centimeters and 80 cubic centimeters. A negative pressure treatment kit,
The pump assembly according to any one of claims 1 to 10,
Bandages,
A conduit connectable with the bandage and the pump assembly and configured to provide a reduced pressure fluid path to the bandage;

One or more batteries;
A first packaging element and a second packaging element configured to be removably coupled to the first packaging element, wherein at least one of the first and second packaging elements A negative pressure treatment kit comprising: the pump assembly; the bandage; the conduit; and first and second packaging elements having recesses for receiving the one or more batteries. The negative pressure treatment kit is sterile, and the pump assembly, the bandage, the conduit, and the one or more batteries are connected to at least one of the first packaging element and the second packaging element. The negative pressure treatment kit according to claim 11, which is sterilized after being supported inside. 13. The negative pressure treatment kit according to claim 11 or 12, further comprising one or more adhesive seal strips. The negative pressure treatment kit according to any one of claims 11 to 13, wherein the one or more batteries are supported outside the housing. 15. The negative pressure treatment kit according to any one of claims 11 to 14, wherein the negative pressure treatment kit is sterilized with ethylene oxide. The bandage is
A transmission layer;
An absorbent layer for absorbing wound exudate, the absorbent layer covering the permeable layer;
The negative pressure treatment kit according to any one of claims 11 to 15, further comprising a cover layer that covers the absorbent layer and includes an orifice passing therethrough. 17. The negative pressure treatment kit according to any one of claims 11 to 16, wherein the bandage comprises an inspiratory port for applying a negative pressure to the bandage to apply a local negative pressure to a wound site. 18. The negative pressure treatment kit of claim 17, wherein the intake port comprises a connector portion for connecting the intake port to the pump assembly, and a sealing surface for sealing the intake port to a cover layer of the bandage. . 19. A negative pressure treatment kit according to any one of claims 11 to 18, wherein the bandage comprises a liquid impermeable gas permeable filter element adapted to prevent liquid from entering the connector portion. 20. The negative pressure treatment kit according to any one of claims 11 to 19, wherein the first packaging element comprises PETG. A negative pressure treatment system,
The pump assembly according to any one of claims 1 to 10,
A negative pressure treatment system comprising a bandage. 23. The negative pressure of claim 21, wherein the wound-facing surface of the dressing is at least partially covered by a silicone adhesive configured to form a low-leakage seal with the skin surrounding the wound. Treatment kit. A method of treating a wound using negative pressure,
Preparing a bandage;
Applying the bandage over the wound to form a substantially fluid tight seal over the wound;
Delivering negative pressure through the bandage to the wound using the pump assembly according to any one of the preceding claims. 11. A bandage is applied over the wound to form a substantially fluid tight seal over the wound, and through the bandage using the pump assembly according to any one of claims 1-10. 24. A method of treating a wound using negative pressure according to claim 23, wherein delivering negative pressure to the wound is performed in an operating room. A pump assembly comprising:
A housing;
Pump motor;
Entrance and exit,
In a housing comprising at least one valve configured to control fluid flow through at least one of the inlet and the outlet, and a flow path through at least the inlet, the outlet, and the at least one valve. A pump supported by
A controller supported within or by the housing, the controller configured to control operation of the pump and the valve;
At least one switch or button supported by the housing, in communication with the controller, and accessible to the user so that the user can control one or more modes of operation of the pump, A pump assembly comprising a button;
A bandage configured to form a substantially fluid tight seal over the wound;
A conduit connectable with the bandage and the pump assembly and configured to provide a substantially or completely enclosed fluid flow path from the pump assembly to the bandage;
A negative pressure treatment kit for treating a reduced pressure wound comprising the pump assembly, the one or more batteries, the bandage, and a first packaging element for packaging the conduit,
The reduced pressure wound wherein the negative pressure treatment kit is sterilized such that at least the interior and exterior of the housing, the at least one valve, the pump, the controller, and the at least one switch or button are sterilized Negative pressure treatment kit for treatment. 26. The negative pressure treatment kit of claim 25, further comprising one or more adhesive seal strips. 27. A negative pressure therapy kit according to any one of claims 21 to 26, further comprising one or more batteries configured to supply power to at least the pump and controller. A second packaging element configured to be coupled to the first packaging element, the first packaging element comprising the pump assembly, the one or more batteries, the bandage, a conduit, 28. The negative pressure treatment kit of claim 27, and having a plurality of recesses for receiving one or more of the one or more adhesive seal strips. 29. The negative pressure treatment kit of claim 28, wherein the second packaging element is permeable to sterilizing gas and impermeable to bacteria. 26. A first packaging element supports the one or more batteries, whereby the one or more batteries are supported outside the housing during a sterilization process of the negative pressure treatment kit. 30. The negative pressure treatment kit according to any one of to 29. 31. The negative pressure treatment kit according to any one of claims 25 to 30, wherein the pump is a diaphragm pump, a rotary diaphragm pump, or a piezoelectric pump. 32. The negative pressure treatment kit according to any one of claims 25 to 31, wherein the negative pressure treatment kit is sterilized with ethylene oxide. 33. Negative pressure treatment kit according to any one of claims 25 to 32, wherein the at least one valve is configured to allow a flow of sterilization gas through the at least one valve during a sterilization process. . 34. The pump assembly of claim 25, further comprising a flow manifold, wherein the flow manifold is in fluid communication with at least one of a pressure sensor, the pump, and a conduit, a conduit connector. The negative pressure treatment kit according to 1. 35. The negative pressure therapy kit of claim 34, further comprising a one-way flow valve supported by a manifold. A one-way flow valve positioned between the pump and the bandage, wherein the one-way flow valve substantially passes the flow of gas through the one-way flow valve in a flow direction from the pump toward the bandage. 36. The negative pressure treatment kit according to any one of claims 25 to 35, configured to prevent. 37. The negative pressure therapy kit of claim 36, wherein the one-way flow valve is supported within the housing. 38. The pressure sensor of any one of claims 25 to 37, further comprising a pressure sensor configured to monitor a pressure level of a gas in a fluid flow path between the pump and the bandage or within the pump assembly. Negative pressure treatment kit. 39. A negative pressure treatment kit according to any one of claims 25 to 38, wherein one end of a conduit is connected to the bandage when packaged in a first packaging element. A conduit includes a first end and a second end, wherein the first end is connected to or connectable to the bandage, and the second end is configured to couple with the housing. 40. The negative pressure treatment kit according to any one of claims 25 to 39, further comprising a connected connector. 41. The negative pressure treatment kit according to any one of claims 25 to 40, wherein the housing is not sealed. 42. The negative pressure treatment kit according to any one of claims 25 to 41, wherein the pump assembly does not comprise a container.
43. The negative pressure treatment kit according to any one of claims 25 to 42, further comprising a released foam layer surrounding at least a portion of the pump to reduce noise and vibration generated by the pump. The bandage is
A transmission layer;
An absorbent layer for absorbing wound exudate, the absorbent layer covering the permeable layer;
A cover layer covering the absorbent layer,
An intake port for receiving the end of the conduit;
44. A negative pressure therapy kit according to any one of claims 25 to 43, comprising a liquid impermeable gas permeable filter element adapted to prevent liquid from passing through the intake port. 45. A negative pressure treatment kit according to any one of claims 25 to 44, wherein the pump assembly comprises a battery compartment supported by or formed within the housing. The negative pressure treatment kit includes a wound dressing having a silicone adhesive configured to form a low-leakage seal with the skin surrounding the wound, the pump assembly weighing the one or more batteries. 46. The negative pressure treatment kit according to any one of claims 25 to 45, wherein the weight is between 70 g and 90 g. 47. The negative pressure treatment kit according to any one of claims 25 to 46, wherein the pump assembly has a weight between 70 g and 90 g including the weight of the one or more batteries. 48. The shade of any one of claims 25 to 47, wherein the outer surface of the pump assembly defines a volume of about 3 cubic inches (49.16 cubic centimeters) to about 5 cubic inches (81.94 cubic centimeters). Pressure treatment kit. 49. The negative pressure treatment kit is configured such that the bandage must be removed from the first packaging element before a sealing strip can be removed from the first packaging element. The negative pressure treatment kit according

to any one of the above. A pump assembly comprising a pump having a flow rate of about 350 mL / min or less;
A negative pressure treatment kit for reduced-pressure wound treatment comprising a bandage comprising a cover layer and having a wound contact surface covered with a silicone adhesive. The pump assembly includes a one-way flow valve in fluid communication with the pump, the one-way flow valve configured to substantially prevent gas from flowing through the flow path in a flow direction away from the pump. The negative pressure treatment kit according to claim 50. 52. The negative pressure treatment kit of claim 50 or 51, wherein the bandage comprises a permeable layer comprising a 3D knitted or fabric material configured to remain open when negative pressure is applied to the bandage. 53. The negative pressure treatment kit according to any one of claims 50 to 52, wherein the dressing comprises an absorbent layer for absorbing wound exudate, and the absorbent layer covers a permeable layer. 54. The dressing according to any one of claims 50 to 53, wherein the bandage comprises a cover layer covering the absorbent layer, comprises an orifice, the cover layer is water vapor permeable, and the absorbent layer covers the permeable layer. Negative pressure treatment kit. The bandage includes an intake port for applying negative pressure to the bandage to apply a local negative pressure to the wound site, the intake port connecting a portion of the intake port to the pump assembly; and 55. The negative pressure treatment kit according to any one of claims 50 to 54, comprising a sealing surface for sealing the intake port to the cover layer of the bandage. 56. A negative pressure treatment kit according to any one of claims 50 to 55, wherein the dressing comprises a liquid impermeable gas permeable filter element adapted to prevent liquid from entering the connector portion. 57. The negative pressure treatment kit according to any one of claims 50 to 56, wherein the pump assembly is containerless. 58. The controller of any one of claims 50 to 57, further comprising a controller supported in or by the pump assembly housing, the controller configured to control operation of the pump. The negative pressure treatment kit according to 1 59. The negative pressure treatment kit according to any one of claims 50 to 58, further comprising a pressure sensor in communication with a flow path through the pump assembly. 60. The apparatus of claim 50-59, further comprising at least one switch or button supported by a housing of the pump assembly, wherein the at least one switch or button is accessible to a user and can be in communication with a controller. The negative pressure treatment kit according to any one of the above. 61. The negative pressure treatment kit according to any one of claims 50 to 60, further comprising a battery compartment supported by the pump assembly. 62. The negative pressure treatment kit according to any one of claims 50 to 61, wherein the pump assembly is sterilized subsequent to assembly of the pump assembly such that at least the interior and exterior of the pump assembly are sterilized. . 63. A negative pressure therapy kit according to any one of claims 50 to 62, wherein the pump assembly comprises one or more LED lights. 64. The shade according to any one of claims 50 to 63, wherein the pump assembly comprises one or more batteries and has a weight between 80 g and 90 g including the weight of the one or more batteries. Pressure treatment kit. 65. The negative pressure treatment kit according to any one of claims 50 to 64, wherein the outer surface of the pump assembly defines a volume between 60 cubic centimeters and 80 cubic centimeters. A containerless pump assembly for the treatment of vacuum wounds,
A housing,
A pump assembly comprising a pump supported in or by the housing, the pump comprising:
A motor,
An inlet and an outlet.
A first valve configured to control the flow of fluid through the inlet,
A container-type pump assembly comprising a second valve configured to control the flow of fluid through the outlet;
The pump assembly is containerless;
A container pump assembly, wherein the first and second valves each have a leak rate between about 5 L / min and about 10 L / min at nominal operating pressure. The pump assembly includes a one-way flow valve in fluid communication with the pump, the one-way flow valve configured to substantially prevent gas from flowing through the flow path in a flow direction away from the pump. 68. A pump assembly according to claim 66. 68. A pump assembly according to claim 66 or 67, further comprising a controller supported in or by the housing and configured to control operation of the pump. 69. A pump assembly according to any one of claims 66 to 68, further comprising a pressure sensor in communication with a flow path through the pump assembly. 70. Any one of claims 66 to 69, further comprising at least one switch or button supported by the housing, wherein the at least one switch or button is accessible to a user and can be in communication with a controller. The pump assembly according to item. 71. A pump assembly according to any one of claims 66 to 70, further comprising a battery compartment supported by or formed within the housing. 72. The sterilization following assembly of the pump assembly such that at least the interior and exterior of the housing, the flow path, the one or more valves, and the pump are sterilized. A pump assembly according to any one of the preceding claims. 73. A pump assembly according to any one of claims 66 to 72, further comprising one or more LED lights supported by the housing. 74. A pump assembly according to any one of claims 66 to 73, wherein the pump assembly comprises one or more batteries and weighs 80g and 90g including the weight of the one or more batteries. 75. A pump assembly according to any one of claims 66 to 74, wherein the outer surface of the pump assembly defines a volume between 60 cubic centimeters and 80 cubic centimeters. A sterilization pump kit,
76. The pump assembly according to any one of claims 66 to 75,
Bandages,
A conduit connectable with the bandage and the pump assembly and configured to provide a reduced pressure fluid path to the bandage;
One or more batteries;
A first packaging element and a second packaging element configured to be removably coupled to the first packaging element, wherein at least one of the first and second packaging elements Sterilization having a recess for receiving the pump assembly, the bandage, and the conduit connectable to the bandage and the pump assembly and configured to provide a reduced pressure fluid path to the bandage. In the pump kit,
The sterilization pump kit includes the pump assembly, the bandage, the conduit, and the one or more batteries supported within at least one of the first packaging element and the second packaging element. Sterile pump kit, which is sterilized later. Before the pump assembly, the bandage, the conduit, and the one or more batteries are sterilized, the pump assembly, the bandage, the conduit, and the one or more batteries are in the first package. 77. The sterilization pump kit of claim 76, supported within at least one of a packaging element and the second packaging element. 78. The sterilization pump kit of claim 76 or 77, further comprising one or more adhesive seal strips. 79. A sterilization pump kit according to any one of claims 76 to 78, wherein the one or more batteries are supported on an outer surface of the housing. 80. The sterilization pump kit according to any one of claims 76 to 79, wherein the sterilization pump kit is sterilized with ethylene oxide. The bandage is
A transmission layer;
An absorbent layer for absorbing wound exudate, wherein the absorbent layer covers the permeable layer,
The sterilization pump kit according to any one of claims 76 to 80, further comprising a cover layer that covers the absorbent layer. 82. A sterile pump kit according to any one of claims 76 to 81, wherein the bandage comprises an inhalation port for applying a negative pressure to the bandage to apply a local negative pressure to the wound site. 84. The sterilization pump kit of claim 82, wherein the intake port comprises a connector portion for connecting the intake port to the pump assembly, and a sealing surface for sealing the intake port to a cover layer of the bandage. 84. A sterilization pump kit according to any one of claims 76 to 83, wherein the bandage comprises a liquid impermeable gas permeable filter element adapted to prevent liquid from entering the connector portion. 85. A sterilization pump kit according to any one of claims 76 to 84, wherein the first packaging element comprises PETG. A method for initiating wound treatment in an operating room comprising:
Applying a sterile bandage over the wound to create a substantially fluid tight seal over the wound;
Coupling a sterilization pump assembly to the bandage via a sterilization conduit and reducing the pressure level between the bandage and the wound in the operating room by operating the sterilizing pump assembly in the operating room. ,Method. 87. The method of claim 86, further comprising applying one or more sealing strips on an outer peripheral edge of at least one of the bandages to improve the seal between the bandage and the skin surrounding the wound. The method described. 88 The method of claim 86 or 87, further comprising removing one or more batteries from the first packaging element and attaching the one or more batteries to the sterilization pump assembly.

Description translated from Japanese

[incorporation by reference]
This application is filed on April 21, 2011, U.S. Patent Application No. 13 / 092,042 (named WOUND DRESSING AND METHOD OF USE), filed on May 21, 2008 (named

ANTIMICROBIAL METAL COMPLEXES).) US Patent Application No. 11 / 922,894, filed July 26, 2011 (METHODS AND APPARATUSES FOR DETECTING LEAKS AND CONTROLLING PUMP OPERATION IN A NEGATIVE PRESSURE WORLD 61) No. 950, filed April 21, 2011 (named WOUND DRESSING) PCT Patent Application No. PCT / GB 11/000622, PCT Patent Application No. PCT / GB 11/000621 (named WOUND PROTECTION) filed on April 21, 2011 (WOUND DRESSING) filed April 21, 2011 PCT Patent Application No. PCT / GB 11/000625, PCT Patent Application No. PCT / GB 11/000626, filed April 21, 2011, filed Apr. 21, 2011 (filed MULTIPORT DRESSING) PCT Patent Application No. PCT / GB 11/000628 (named SUCTION PORT), PCT Patent Application No. PCT / GB 11/05 filed September 16, 2011 (named PRESSURE CONTROL APPARATUS) The No. 745 incorporated by reference. Each and all of the above patent applications are hereby incorporated by reference in their entirety and form part of the present disclosure. Further, copending patent application No. 13 / XXX, XXX (Attorney Docket No. 5), filed on November 2, 2011, entitled "SYSTEMS AND METHODS FOR CONTROLLING OPERATION OF A REDUCED PRESURE THERAPY SYSTEM". And the co-pending PCT patent application No. PCT / US11 / XXX, XXX, XXX, entitled "SYSTEMS AND METHODS FOR CONTROLLING OPERATION OF A REDUCED PRESURE THERAPY SYSTEM", filed on November 2, 2011.) Is incorporated herein by reference in its entirety as if explicitly set forth herein.

Embodiments disclosed herein relate to methods and devices for bandaging and treating wounds using local negative pressure (TNP) therapy. For example, but without limitation, some embodiments disclosed herein relate to treating a wound using reduced pressure provided from a pump kit. Although not required, some embodiments of the pump kit can be sterile. As another non-limiting example, some embodiments disclosed herein relate to an apparatus and method for controlling the operation of a TNP system.

Many different types of wound dressings are known to help the human or animal healing process. These different types of wound dressings include many different types of materials and layers, such as gauze, pads, foam pads, or multilayer wound dressings. Local negative pressure ("TNP") therapy, sometimes referred to as vacuum assisted closure therapy, negative pressure wound therapy, or vacuum wound therapy, is widely recognized as a beneficial mechanism for improving wound healing rates. Yes. Such therapy is applicable to a wide range of wounds such as incisional wounds, open wounds, and abdominal wounds.

TNP therapy helps to close and heal wounds by reducing tissue edema, promoting blood flow, stimulating granulation tissue formation, removing excess exudates, and reducing bacterial load and thus wounds. Can reduce infection. Furthermore, TNP therapy can result in less outside disturbance of the wound and promotes faster healing.

US Pat. No. 7550034 US Patent Application Publication No. 2011/186765 US Patent Application No. 13/092042 UK patent application No. 101566.06.0 UK Patent Application No. 1006986.2 UK Patent Application No. 1006983.9 UK Patent Application No. 1006985.4 UK Patent Application No. 1006988.8 UK Patent Application No. 1008347.5 Specification US Patent Application No. 11/922894 US Pat. No. 7,524,315 US Patent No. 7,708,724 US Pat. No. 7,909,805 US Patent Application Publication No. 2005/0261642 US Patent Application Publication No. 2007/0167926 US Patent Application Publication No. 2009/0012483 US Patent Application Publication No. 2009/0254054 US Patent Application Publication No. 2010/0160879 US Patent Application Publication No. 2010/0160880 US Patent Application Publication No. 2010/0174251 US Patent Application Publication No. 2010/0274207 US Patent Application Publication No. 2010/0298793 US Patent Application Publication No. 2011/0009838 US Patent Application Publication No. 2011/0028918 US Patent Application Publication No. 2011/0054421 US Patent Application Publication No. 2011/0054423 US patent application Ser. No. 12/941390 US Patent Application No. 29 / 389,782 U.S. Patent Application No. 29 / 389,783

Some embodiments disclosed herein relate to a reduced pressure wound therapy pump assembly that includes a housing, a pump within or supported by the housing, a flow path through the pump assembly, A one-way flow valve in fluid communication with the pump and supported by the housing. Some embodiments of the one-way flow valve can be configured to substantially prevent gas from flowing through the flow path in the flow direction away from the pump. The pump is supported by the motor, inlet and outlet, a first valve configured to control the flow of fluid through the inlet, and is supported by the pump and controls the flow of fluid through the outlet. And a second valve configured as described above.

Some embodiments disclosed herein relate to a pump assembly for reduced pressure wound therapy, wherein the pump assembly is in fluid communication with a housing, a pump within or supported by the housing, and a pump. A directional flow valve and a flow path through the pump assembly. The one-way flow valve can be configured to substantially prevent gas from flowing through the flow path in the flow direction away from the pump. The pump can include a motor, an inlet, and an outlet. Although not required in any of the pump embodiments disclosed herein, the pump has a first valve configured to control the flow of fluid through the inlet and the flow of fluid through the outlet. And a second valve configured to control. Some pump embodiments disclosed herein can use an orifice or other mechanism or component to control the flow or flow rate of fluid through the pump.

Some embodiments disclosed herein relate to a negative pressure treatment kit for reduced pressure wound therapy, the negative pressure treatment kit being supported within a housing, a pump supported within the housing, and within or by the housing. And a pump assembly comprising a controller and at least one switch or button supported by the housing. As used throughout this specification, the phrase "some embodiments" or "in some embodiments" is described herein, exemplified, or incorporated by reference. Or is meant to refer to any embodiment disclosed otherwise. At least one switch or button can be in communication with the controller and can be accessible to the user so that the user can control one or more modes of operation of the pump. In some embodiments, although not required, the negative pressure treatment kit is connectable with a bandage configured to form a substantially fluid tight seal over the wound, and the bandage and pump assembly. A conduit configured to provide a substantially or completely enclosed fluid flow path from the pump assembly to the bandage, and a first assembly for packaging the pump assembly, the one or more batteries, the bandage, and the conduit. 1 packaging element. In some embodiments, the controller can be configured to control the operation of the pump and valve. Some embodiments of negative pressure treatment kits can be configured such that the negative pressure treatment kit is sterilized. The negative pressure treatment kit can be sterilized such that at least the interior and exterior of the housing, at least one valve, pump, controller, and at least one switch or button are sterilized. In some embodiments, the pump includes a pump motor, an inlet and an outlet, at least one valve configured to control the flow of fluid through the inlet and / or the outlet, at least the inlet, the outlet, and And a flow path through the at least one valve.

Some embodiments disclosed herein relate to reduced pressure treatment of wounds using reduced pressure pumps. The pump embodiments disclosed herein do not require sterilization. However, by sterilizing the vacuum pump before use and providing the pump and / or bandage or pump kit components in a sterile state, the operating room (also referred to as the operating room) or other devices where sterility of the device is required It may be possible to use the pump at any location. Some exemplary and non-limiting embodiments are directed to a sterilization pump kit comprising a sterilization pump, a sterilization bandage, and a sterilization conduit connectable to the bandage and pump, which can be used in an operating room. To do.

Some embodiments disclosed herein relate to a negative pressure treatment kit for reduced pressure wound treatment, the negative pressure treatment kit comprising a pump having a flow rate of about 350 mL / min or less and a bandage comprising a cover layer. Prepare. The bandage can have a wound contact surface covered with a silicone adhesive.

Some embodiments disclosed herein relate to a containerless pump for treating a reduced pressure wound, the containerless pump being in communication with a housing, a flow path through the pump, and a flow path. One or more valves and a containerless pump supported in or by the housing. Some embodiments disclosed herein relate to a containerless pump assembly for reduced pressure wound therapy, the containerless pump assembly comprising a housing and a pump supported in or by the housing. The pump is supported by the motor, inlet and outlet, a first valve configured to control the flow of fluid through the inlet, and is supported by the pump and controls the flow of fluid through the outlet. And a second valve configured as described above. The pump or pump assembly can be containerless. Further, although not required for all embodiments disclosed herein, the first and second valves are each at a nominal operating pressure and / or during a nominal sterilization pressure from about 0.1 mL / min to about A leak rate of 10 mL / min, or at nominal operating pressure, between 0.1 mL / min and below to 5 mL / min or above, or between 1 mL.

/ min and below to 3 mL / min or above, or any of the above ranges it can have a leak rate between the two values. In some embodiments, the leak rate can be about 0.4 mL / min to 0.7 mL / min at nominal operating pressure and / or during nominal sterilization pressure.

Some embodiments of the pump assembly may include a piezoelectric pump, such as, but not limited to, the piezoelectric pump disclosed in US Pat. Some piezoelectric pumps can have an orifice to perform the valve function so that when the pump is stopped, the flow rate through the pump can be as high as 200 mL / min. Thus, in some embodiments, the first and second valves (which can be orifices) are each about 200 mL when the pump rate can be about 300 mL / min or 320 mL / min or other high rate. Can have a leak rate of less than / minute.

Some embodiments disclosed herein relate to a sterilization pump kit, which can be coupled to any of the pump embodiments disclosed herein, a bandage, a bandage and a sterilization pump. A conduit configured to provide a reduced pressure fluid path to the bandage, the one or more batteries, and the first packaging element and the first packaging element to be removably coupled. A configured second packaging element. In some embodiments, at least one of the first and second packaging elements is connectable to a sterilization pump, a bandage, and the bandage and sterilization pump so as to provide a reduced pressure fluid path to the bandage. And a recess for receiving a conduit configured in the housing. The sterilization pump kit can be sterilized after the pump, bandage, conduit, and one or more batteries are supported within at least one of the first packaging element and the second packaging element.

Some embodiments disclosed herein relate to a method for initiating treatment of a wound in an operating room, the method comprising applying a sterile bandage over the wound and substantially liquid-tight over the wound. A sterilization pump connected to the bandage via a sterilization conduit, and reducing the pressure level between the bandage and the wound in the operating room by operating the pump in the operating room. .

Some embodiments disclosed herein relate to an apparatus and method for controlling the operation of a negative pressure wound treatment system. In particular, but not exclusively, embodiments disclosed herein relate to negative pressure therapy devices and bandages, and methods and algorithms for operating such negative pressure therapy systems. In some embodiments, although not required, the device can include a bandage disposed on the wound and configured to create a substantially fluid-impermeable seal over the wound. . The device can comprise a negative pressure source configured to be coupled to the bandage. The apparatus can further comprise a controller configured to operate the negative pressure source, monitor the duty cycle of the negative pressure source, and determine whether the duty cycle exceeds a duty cycle threshold. In some embodiments, the controller monitors multiple duty cycles of the negative pressure source over a plurality of consecutive equal durations, and whether one of the plurality of duty cycles exceeds a duty cycle threshold. It can be configured to determine whether or not. The duty cycle can reflect the amount of time that the negative pressure source is active for a predetermined period of time or for a duration of a plurality of consecutive equal durations.

In some embodiments, the controller can be configured to determine whether the number of duty cycles exceeds a duty cycle threshold and whether the number exceeds an overload threshold. In some embodiments, the controller determines whether a set of duty cycles out of a plurality of duty cycles exceeds a duty cycle threshold and whether the number of duty cycles in the set exceeds an overload threshold. Can be configured to determine. The controller can be configured to determine whether the number of duty cycles that exceed the duty cycle threshold is continuous. In some embodiments, the overload threshold can include 30 duty cycles, the duration or duration can include 1 minute, and / or the duty cycle threshold can include 9%. In some embodiments, the controller can be configured to continuously monitor the duty cycle or multiple duty cycles.

Some embodiments of the apparatus comprise a switch configured to pause the negative pressure source for a predetermined period of time, and the controller is configured to restart the negative pressure source when that period of time has elapsed. be able to. The period can be variable. In some embodiments, the device can be enclosed in a housing that includes an outer surface, and the switch can include a button disposed on the outer surface of the housing.

Some embodiments of the apparatus comprise a controller configured to provide an indication of operating conditions. The operating condition can include a determination that the duty cycle exceeds a duty cycle threshold, and the indication can include deactivating the negative pressure source to indicate a leak in the seal. In some embodiments, the operating state includes whether or not the negative pressure source is paused, and the controller is configured to provide a first indication when the negative pressure source is active and the negative pressure source is paused. And a second instruction when being provided, in which case the second instruction is different from the first instruction.

In some embodiments, the controller can be configured to operate a negative pressure source to attempt to generate a desired negative pressure level under the bandage, and the first time interval has elapsed. If the pressure level under the bandage does not reach the desired negative pressure level, the controller can deactivate the negative pressure source for the second time interval. When the second time interval has elapsed, the controller can operate the negative pressure source to attempt to generate the desired negative pressure level under the bandage. The controller can be configured to change the second time interval based on the number of times the pressure level under the bandage has not reached the desired negative pressure level. For example, the controller can be configured to double the second time interval provided that the resulting value does not exceed the second interval threshold. The apparatus can comprise a sensor configured to sense pressure under the bandage and communicate the sensed pressure to a controller.

In some embodiments, the controller deactivates the negative pressure source when the pressure level under the bandage reaches the desired negative pressure level, and when the pressure level under the bandage exceeds the negative pressure threshold, The negative pressure source can be configured to operate, wherein the desired negative pressure level corresponds to a pressure that is more negative than the negative pressure threshold.

In some embodiments, the negative pressure source positions the bandage over the wound, creates a substantially fluid impermeable seal over the wound, delivers negative pressure from the negative pressure source to the bandage, Operation can be performed by monitoring the duty cycle of the pressure source and providing an indication if it is determined that the duty cycle exceeds the duty cycle threshold. The duty cycle can reflect the amount of time that the negative pressure source is active during a predetermined period, such as once per minute.

Some embodiments of the device may be configured to monitor the total elapsed time since the first operation and disable the operation of the negative pressure source when the total elapsed time reaches a life threshold. The lifetime threshold can include, for example, 7 days.

In some embodiments, a device for applying negative pressure to a wound is disposed on the wound and configured to create a substantially fluid impermeable seal over the wound; A negative pressure source configured to be coupled to and configured to operate the negative pressure source, monitor the duty cycle of the negative pressure source, and provide an indication if the duty cycle exceeds the duty cycle threshold Controller.

In some embodiments, the device is configured to be disposed on the wound and configured to couple to the bandage configured to create a substantially fluid impermeable seal over the wound. A pump, a switch configured to temporarily stop the pump for a predetermined period, and a controller configured to restart the pump when the period elapses. The period can be variable. Some embodiments of the apparatus include a small diaphragm pump operated by a motor or a small diaphragm pump operated by a piezoelectric transducer. In some embodiments, the pump can include a small piston pump and a small diaphragm pump.

Some embodiments disclose a method of operating a negative pressure source (eg, a negative pressure pump), the method positioning a bandage over the wound and a substantially fluid impermeable seal over the wound. Generating negative pressure from the pump to the bandage, pausing the pump for a predetermined period of time, and restarting the pump when that period has elapsed. The period can be variable.

In some embodiments, the negative pressure pump positions the bandage over the wound to create a substantially fluid impermeable seal over the wound and uses the negative pressure pump to aspirate fluid from the wound. It can be operated by measuring the activity level of the pump, comparing the activity level of the pump with a threshold, and providing an indication if the activity level exceeds the threshold. Activity level measurements include determining the pump duty cycle, determining the flow rate of fluid drawn from the wound (eg, by using a flow meter), measuring the rate of pressure change under the bandage using a pressure sensor, etc. , Or a combination thereof.

Some embodiments disclose a method of operating a negative pressure pump, the method positioning a bandage over a wound to create a substantially fluid impermeable seal over the wound; Delivering a negative pressure from the pump to the bandage to bring the pressure below the first negative pressure set value, and when the negative pressure level under the bandage becomes higher than the second negative pressure set value , The step of operating the pump to monitor the pressure under the bandage close to the first negative pressure set value, the step of monitoring the amount of time the pump is operating, and the amount of time exceeds a predetermined amount of time Providing instructions. The method can further include determining an amount of time that the pump has been operating for a predetermined period of time, and providing an indication if the amount of time exceeds 9% of the period. In some embodiments, providing the instructions further includes determining an amount of time that the pump has been operating for a predetermined period of time. In some embodiments, providing the indication further comprises activating an alarm.

In some embodiments, the device operates a negative pressure source to increase the pressure under the negative pressure wound dressing to a value between the first negative pressure setting and the second negative pressure setting. Or a value that is substantially equal to the value of the second negative pressure set value, such as a value close to a desired negative pressure value. The pressure level under the bandage can be measured. When the pressure under the bandage decreases above a threshold (eg, decreases to the value of the first negative pressure setpoint), the device operates the negative pressure source to reduce the pressure under the bandage to the second It can be configured to approach a desired negative pressure level (for example, the value of the second negative pressure set value). The amount of time that the negative pressure source has been operating, for example, can be monitored. If the negative pressure source has been operating for a predetermined amount of time without establishing a second desired negative pressure level under the bandage (eg, the value of the second negative pressure setting), The operation of the pressure source can be paused or interrupted.

Some embodiments disclose a method of operating a negative pressure source, the method comprising positioning a bandage over the wound to create a substantially fluid impermeable seal over the wound; Delivering negative pressure from the pressure source to the bandage. Delivering negative pressure from the negative pressure source to the bandage, operating the negative pressure source and updating the first motion count to attempt to generate a desired negative pressure level under the bandage; If the negative pressure under the bandage has not reached the desired negative pressure level when the first time interval has elapsed, the first action count is less than the first retry threshold, Deactivating the negative pressure source for two time intervals, and deactivating the negative pressure source for a third time interval if the first operation count is greater than or equal to the first retry threshold, Activating a negative pressure source to reset the first operational count and attempt to generate a desired negative pressure level under the bandage when the third time interval has elapsed. When the time interval has passed, the desired under the bandage Activating the negative pressure source to attempt to generate a pressure level and updating the first operational count, and if the negative pressure under the bandage has reached the desired negative pressure level, the negative pressure source And monitoring the negative pressure under the bandage and operating the negative pressure source when the negative pressure under the bandage exceeds the negative pressure threshold, An update count, wherein the desired negative pressure level corresponds to a pressure that is more negative than the negative pressure threshold, and the negative pressure under the bandage before the fourth time interval elapses. When the pressure reaches the desired negative pressure level, the negative pressure source is deactivated, the negative pressure under the bandage is monitored, the second operation count is reset, and a fourth time interval has elapsed. When the negative pressure under the bandage is the desired negative pressure level If not, deactivating the negative pressure source for a second time interval, provided that the second motion count is less than the second retry threshold; If the retry threshold is greater than 2, the negative pressure source is deactivated during the third time interval, the second operation count is reset, and when the third time interval elapses, Operating the negative pressure source to update the first operation count, continuously monitoring the negative pressure source duty cycle, and a duty cycle threshold. Tracking the number of duty cycles exceeding, and deactivating the negative pressure source for the duration of the third time interval when the number of duty cycles exceeding the duty cycle threshold exceeds the overload threshold Including the step of.

Embodiments of the present invention will now be described by way of example only with reference to the accompanying drawings.

1 illustrates one embodiment of a reduced pressure wound therapy apparatus that includes a pump, a bandage, and a conduit. FIG. It is a figure which shows embodiment of the pump shown by FIG. It is a figure which shows embodiment of the pump shown by FIG. It is a figure which shows embodiment of the pump shown by FIG. It is a figure which shows embodiment of the pump shown by FIG. It is a figure which shows embodiment of the pump shown by FIG. It is a figure which shows embodiment of the pump shown by FIG. FIG. 4 shows an embodiment of a wound dressing kit comprising a dressing, pump, conduit, two batteries, and one or more seal strips supported in a first packaging element. 3B is a bottom isometric view illustrating the embodiment of the wound dressing kit of FIG. 3A. FIG. 3B is an exploded view illustrating the embodiment of the wound dressing kit of FIG. 3A. FIG. FIG. 2 is a first exploded view showing an embodiment of the pump of FIG. 1. FIG. 3 is a second exploded view showing the embodiment of the pump of FIG. 1. It is the 1st figure showing the 1st housing member. It is a 2nd figure which shows a 1st housing member. It is a 1st figure which shows the 2nd housing member. It is the 2nd figure showing the 2nd housing member. FIG. 2 illustrates the use of one embodiment of a TNP wound treatment system being used to treat a patient's wound site. FIG. 2 illustrates the use of one embodiment of a TNP wound treatment system being used to treat a patient's wound site. FIG. 2 illustrates the use of one embodiment of a TNP wound treatment system being used to treat a patient's wound site. FIG. 2 illustrates the use of one embodiment of a TNP wound treatment system being used to treat a patient's wound site. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 8B is a bottom isometric view of the embodiment of FIG. 8A. FIG. 8B is a top view of the embodiment of FIG. 8A. FIG. 8B is a bottom view of the embodiment of FIG. 8A. FIG. 8B is a front view of the embodiment of FIG. 8A. FIG. 8B is a rear view of the embodiment of FIG. 8A. FIG. 8B is a first side view of the embodiment of FIG. 8A. FIG. 8B is a second side view of the embodiment of FIG. 8A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 9B is a bottom isometric view of the embodiment of FIG. 9A. FIG. 9B is a top view of the embodiment of FIG. 9A. FIG. 9B is a bottom view of the embodiment of FIG. 9A. FIG. 9B is a front view of the embodiment of FIG. 9A. FIG. 9B is a rear view of the embodiment of FIG. 9A. FIG. 9B is a first side view of the embodiment of FIG. 9A. FIG. 9B is a second side view of the embodiment of FIG. 9A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 10B is a bottom isometric view of the embodiment of FIG. 10A. FIG. 10B is a top view of the embodiment of FIG. 10A. FIG. 10B is a bottom view of the embodiment of FIG. 10A. FIG. 10B is a front view of the embodiment of FIG. 10A. FIG. 10B is a rear view of the embodiment of FIG. 10A. FIG. 10B is a first side view of the embodiment of FIG. 10A. FIG. 10B is a second side view of the embodiment of FIG. 10A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 11B is a bottom isometric view of the embodiment of FIG. 11A. FIG. 11B is a top view of the embodiment of FIG. 11A. FIG. 11B is a bottom view of the embodiment of FIG. 11A. FIG. 11B is a front view of the embodiment of FIG. 11A. FIG. 11B is a rear view of the embodiment of FIG. 11A. FIG. 11B is a first side view of the embodiment of FIG. 11A. FIG. 11B is a second side view of the embodiment of FIG. 11A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 12B is a bottom isometric view of the embodiment of FIG. 12A. FIG. 12B is a top view of the embodiment of FIG. 12A. FIG. 12B is a bottom view of the embodiment of FIG. 12A. FIG. 12B is a front view of the embodiment of FIG. 12A. FIG. 12B is a rear view of the embodiment of FIG. 12A. FIG. 12B is a first side view of the embodiment of FIG. 12A. FIG. 12B is a second side view of the embodiment of FIG. 12A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size

of the wound dressing device. FIG. FIG. 13B is a bottom isometric view of the embodiment of FIG. 13A. FIG. 13B is a top view of the embodiment of FIG. 13A. FIG. 13B is a bottom view of the embodiment of FIG. 13A. FIG. 13B is a front view of the embodiment of FIG. 13A. FIG. 13B is a rear view of the embodiment of FIG. 13A. FIG. 13B is a first side view of the embodiment of FIG. 13A. FIG. 13B is a second side view of the embodiment of FIG. 13A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 14B is a bottom isometric view of the embodiment of FIG. 14A. FIG. 14B is a top view of the embodiment of FIG. 14A. FIG. 14B is a bottom view of the embodiment of FIG. 14A. FIG. 14B is a front view of the embodiment of FIG. 14A. FIG. 14B is a rear view of the embodiment of FIG. 14A. FIG. 14B is a first side view of the embodiment of FIG. 14A. FIG. 14B is a second side view of the embodiment of FIG. 14A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 14D is a bottom isometric view of the embodiment of FIG. 14I. FIG. 14D is a top view of the embodiment of FIG. 14I. FIG. 14D is a bottom view of the embodiment of FIG. 14I. FIG. 14D is a front view of the embodiment of FIG. 14I. FIG. 14D is a rear view of the embodiment of FIG. 14I. FIG. 14D is a first side view of the embodiment of FIG. 14I. FIG. 14D is a second side view of the embodiment of FIG. 14I. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 15B is a bottom isometric view of the embodiment of FIG. 15A. FIG. 15B is a top view of the embodiment of FIG. 15A. FIG. 15B is a bottom view of the embodiment of FIG. 15A. FIG. 15B is a front view of the embodiment of FIG. 15A. FIG. 15B is a rear view of the embodiment of FIG. 15A. FIG. 15B is a first side view of the embodiment of FIG. 15A. FIG. 15B is a second side view of the embodiment of FIG. 15A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 16B is a bottom isometric view of the embodiment of FIG. 16A. FIG. 16B is a top view of the embodiment of FIG. 16A. FIG. 16B is a bottom view of the embodiment of FIG. 16A. FIG. 16B is a front view of the embodiment of FIG. 16A. FIG. 16B is a rear view of the embodiment of FIG. 16A. FIG. 16B is a first side view of the embodiment of FIG. 16A. FIG. 16B is a second side view of the embodiment of FIG. 16A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 17B is a bottom isometric view of the embodiment of FIG. 17A. FIG. 17B is a top view of the embodiment of FIG. 17A. FIG. 17B is a bottom view of the embodiment of FIG. 17A. FIG. 17B is a front view of the embodiment of FIG. 17A. FIG. 17B is a rear view of the embodiment of FIG. 17A. FIG. 17B is a first side view of the embodiment of FIG. 17A. FIG. 17B is a second side view of the embodiment of FIG. 17A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 17B is a bottom isometric view of the embodiment of FIG. 17I. FIG. 172 is a top view of the embodiment of FIG. 17I. FIG. 17B is a bottom view of the embodiment of FIG. 17I. FIG. 18B is a front view of the embodiment of FIG. 17I. FIG. 18B is a rear view of the embodiment of FIG. 17I. FIG. 18B is a first side view of the embodiment of FIG. 17I. FIG. 18B is a second side view of the embodiment of FIG. 17I. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 18B is a bottom isometric view of the embodiment of FIG. 18A. FIG. 18B is a top view of the embodiment of FIG. 18A. FIG. 18B is a bottom view of the embodiment of FIG. 18A. FIG. 18B is a front view of the embodiment of FIG. 18A. FIG. 18B is a rear view of the embodiment of FIG. 18A. FIG. 18B is a first side view of the embodiment of FIG. 18A. FIG. 18B is a second side view of the embodiment of FIG. 18A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 19 is a bottom isometric view of the embodiment of FIG. 18I. FIG. 191 is a top view of the embodiment of FIG. 18I. FIG. 191 is a bottom view of the embodiment of FIG. 18I. FIG. 191 is a front view of the embodiment of FIG. 18I. FIG. 218 is a rear view of the embodiment of FIG. 18I. FIG. 191 is a first side view of the embodiment of FIG. 18I. FIG. 218 is a second side view of the embodiment of FIG. 18I. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 19B is a bottom isometric view of the embodiment of FIG. 19A. FIG. 19B is a top view of the embodiment of FIG. 19A. FIG. 19B is a bottom view of the embodiment of FIG. 19A. FIG. 19B is a front view of the embodiment of FIG. 19A. FIG. 19B is a rear view of the embodiment of FIG. 19A. FIG. 19B is a first side view of the embodiment of FIG. 19A. FIG. 19B is a second side view of the embodiment of FIG. 19A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 20B is a bottom isometric view of the embodiment of FIG. 20A. FIG. 20B is a top view of the embodiment of FIG. 20A. FIG. 20B is a bottom view of the embodiment of FIG. 20A. FIG. 20B is a front view of the embodiment of FIG. 20A. FIG. 20B is a rear view of the embodiment of FIG. 20A. FIG. 20B is a first side view of the embodiment of FIG. 20A. FIG. 20B is a second side view of the embodiment of FIG. 20A. FIG. 2 illustrates a pump assembly according to some embodiments. FIG. 2 is a cross-sectional view showing the interior of a pump assembly according to some embodiments. 1 is a system schematic diagram of a pump assembly according to some embodiments. FIG. FIG. 2 is a schematic diagram of electrical components of a pump assembly according to some embodiments. FIG. 6 is a high-level state diagram illustrating operation of a pump assembly according to some embodiments. FIG. 6 is an operational state diagram illustrating operation of a pump assembly according to some embodiments. FIG. 6 is another state diagram illustrating operation of a pump assembly according to some embodiments. 6 is a graph illustrating determination of duty cycle for a pump assembly according to some embodiments. FIG. 6 illustrates operation of the pump assembly in the presence of a small amount of leakage according to some embodiments. FIG. 6 illustrates operation of the pump assembly in the presence of a large amount of leakage in accordance with some embodiments. FIG. 5 illustrates operation of the pump assembly in the presence of a very large amount of leakage in accordance with some embodiments. FIG. 6 illustrates operation of the pump assembly in the presence of a very large amount of leakage in accordance with some embodiments.

In the drawings, like reference numerals refer to like parts.

Embodiments disclosed herein relate to an apparatus and method for treating a wound using reduced pressure. As used herein, a reduced pressure or negative pressure level, such as -X mmHg, is less than standard atmospheric pressure corresponding to 760 mmHg (or 1 atmosphere, 29.93 inches of mercury, 101.325 kPa, 14.696 psi, etc.). Represents the pressure level. Thus, the negative pressure value of -X mmHg reflects an absolute pressure that is X mmHg lower than 760 mmHg, or in other words, an absolute pressure of (760-X) mmHg. In addition, a negative pressure "lower" or "smaller" than X mmHg corresponds to a pressure closer to atmospheric pressure (eg, −40 mmHg is lower than −60 mmHg). A negative pressure "higher" or "larger" than −X mmHg corresponds to a pressure farther from atmospheric pressure (eg, −80 mmHg is higher than −60 mmHg).

Some embodiments comprise a pump and / or pump and bandage kit. Some embodiments are directed to pumps and / or pump and bandage kits that have been sterilized prior to delivery to a hospital, operating room, or operating room, or to medical personnel using such devices. Thus, the sterile pump and / or sterile pump / bandage kit can be used immediately after a surgical or surgical procedure. One advantage of this is that the surgeon can release the patient from the operating room, knowing that the vacuum pump is in operation and that vacuum therapy has begun at the earliest possible time. is there. A further advantage of applying a bandage kit immediately after a surgical procedure or other procedure is to reduce the chance of infection that would otherwise be required in the ward by eliminating subsequent bandage changes. This is a possible point. In other words, for such patients where a bandage (not a pump) is applied in the operating room, after which circumstances such as leakage or other problems with the bandage are found, the bandage is removed after the patient is released from the operating room. If the patient's wound needs to be repositioned, replaced, or removed to be otherwise shaped, the patient's wound will be replaced when the bandage is repositioned, replaced, or otherwise shaped outside the operating room. May be exposed to the risk of infection. However, with the embodiments disclosed herein, if the pump is used and tested while the patient is in the operating room, the bandage needs to be removed, repositioned, or otherwise shaped Any problems with a bandage that can be handled can be handled in a sterile operating room environment, thereby greatly reducing or eliminating the risk of exposure to pathogens, bacteria, or other contaminants. In addition, once a conventional pump has been accepted by the hospital, it is generally impossible for the hospital to sterilize it, so the hospital may take steps to place the pump in a sterilization bag. This approach risks putting the sterilization field of the operating room at risk, especially once the device is turned on, pathogens, bacteria, or other contaminants that may be inside the pump are released by the operation of the pump.

In some embodiments, suitable for gas sterilization, with mechanisms, components, and other characteristics that make the pump suitable for complete exposure to and penetration of sterilization gas across the pump components. Can be configured to be. For example, without limitation, one or more pump valves are selected or configured to allow a flow of sufficient sterilization gas to allow the entire fluid path in the pump to be exposed to sterilization gas. Has been. As described in more detail below, in some embodiments, the pump is pumped by reducing leakage through a flow path in the pump assembly, such as, but not limited to, a strategically positioned one-way flow valve. It can have other components that complement other valves in the pump that can improve the efficiency of the pump.

In addition, if provided, the sterilization pump / bandage kit can also be designed and configured to be suitable for gas sterilization. As described below, the sterilization pump / bandage kit includes all components comprising the sterilization pump / bandage kit, including the pump assembly, all packaged together in at least a first packaging element prior to sterilization. Both can be configured to be sterilizable. Further, as described below, the components comprising the sterile pump / bandage kit can be arranged in the packaging so that at least some of the components can be removed in a predefined order, so that the surgeon Or it is easier for the health care worker to assemble and apply the bandage to the patient.

Initiating wound treatment in the operating room includes, but is not limited to, providing a substantially sealed barrier over the wound while the wound is in a sterile and environmental condition, thereby allowing bacteria or other There are a number of benefits, including inhibiting or preventing contaminants from entering the wound. In addition, it is also advantageous for wound healing to start decompression treatment at the earliest possible stage.

In addition, those disclosed in Patent Document 3, Patent Document 4, Patent Document 5, Patent Document 6, Patent Document 7, Patent Document 8, and Patent Document 9 are disclosed in this specification or by reference. The incorporated embodiment comprises an improved wound dressing component. All embodiments, components, features, and other details of such disclosure are incorporated herein by reference as part of this disclosure, and the configurations of the embodiments disclosed herein. It can be used in place of or in combination with any of the elements, mechanisms, and other details. For example, in some embodiments, the wound dressing is configured to act as a cushioning material that helps prevent compressive or shear forces applied to the wound dressing, eg, by patient movement, from damaging the healing wound. can do. Embodiments of the wound dressing may act as a waste container for collecting and storing wound exudate removed from the wound site, and solids in the wound dressing that covers the wound site while TNP therapy is being applied. It relates to management of material accumulation. Furthermore, embodiments disclosed herein relate to a method and an inspiratory port for applying negative pressure to a wound dressing, and a method of manufacturing an inspiratory port and a wound dressing.

Further, some embodiments disclosed herein provide a system including a negative pressure treatment device and a bandage, and a method and algorithm for operating such a negative pressure treatment device for use with a negative pressure treatment bandage. set to target. In some embodiments, the negative pressure therapy device comprises a pump assembly that is specifically configured to provide negative pressure to the wound. Some embodiments of the pump assembly disclosed herein include novel and original control logic configured to control the operation of the pump assembly. For example, some embodiments may include the presence and / or severity of one or more leaks in the system, the flow rate of fluid aspirated from the wound (eg, air, liquid, and / or solid exudate, etc.), etc. Includes novel and original control logic configured to control the operation of the pump assembly in response to monitoring and detection of various operating conditions. In some embodiments, the control logic may control one or more leaks in the system (eg, one or more leaks in the bandage in fluid communication with the pump, one in the seal created by the bandage over the wound. Or a plurality of leaks) and the operation of the pump assembly when such one or more leaks are detected. In some embodiments, the pump assembly has at least normal or low leakage (eg, leakage with a relatively low flow), high leakage (eg, leakage with a relatively high flow), and very It can be configured to distinguish between a large amount of leaks (eg, leaks having a relatively very high flow rate). Some embodiments can be further configured to distinguish between the above leakage and a very large amount of leakage.

In some embodiments, the pump assembly can include a negative pressure source, such as a small disposable pump, powered by a power source, such as a battery power source. The pump assembly can be configured to provide therapy for a predetermined period of time, such as about 1 day, 2-10 days. In some embodiments, the pump assembly may be required to provide uninterrupted treatment for such a period. In some embodiments, the pump assembly can be configured to deactivate itself for a predetermined period of time (eg, 7 days) after initial operation. The algorithms or logic disclosed herein can help the pump assembly to operate more efficiently and save power, such as but not limited to battery power.

In some embodiments, the pump assembly can be configured to monitor the duty cycle of the negative pressure source (eg, pump). As used herein, "duty cycle" reflects the amount of time that the negative pressure source is active or running over a predetermined period of time. In other words, the duty cycle reflects the time that the negative pressure source is active as part of the total time under consideration. This can be expressed mathematically as:

DC = t / T (1)

Where DC is the duty cycle, t is the duration that the negative pressure source is active, and T is the total time under consideration. The duty cycle can be measured as an absolute value (eg, X seconds), a percentage (eg, 1 / X), a percentage (eg, X%), and the like. For example, if the negative pressure source is on (ie, operating) for 6 seconds and off (ie, not operating) for 54 seconds over a period of 1 minute, the duty cycle is 6 seconds, 1/10, 10%, etc.

In some embodiments, the pump assembly can include a controller configured to monitor the duty cycle of the negative pressure source. The duty cycle measurement can reflect the activity level of the negative pressure source. For example, the duty cycle can indicate that the negative pressure source is operating normally, being overworked, being overworked, etc. In addition, duty cycle measurements, such as periodic duty cycle measurements, can include the presence and / or severity of leaks in the system, the flow rate of fluid aspirated from the wound (eg, air, liquid, and / or solid exudates), etc. Various operating states can be reflected. Based on the duty cycle measurement, such as by comparing the measured duty cycle with a set of thresholds (eg, determined by calibration), the controller can control the operation of the system according to various system requirements or Logic can be executed and / or programmed to execute them. For example, a duty cycle measurement can indicate the presence of a large amount of leakage in the system, to indicate this condition to a user (eg, patient, caregiver, doctor, etc.) and / or to save power. The controller can be programmed to temporarily suspend or pause the operation of the negative pressure source.

In some embodiments, the system can be configured to monitor the flow rate by any other suitable means. Pump assemblies can be flow meters (eg, mechanical, pressure-based, optical, mass, thermal mass, electromagnetic, sonic, ultrasonic, laser, Doppler, etc.), anemometers, pressure transducers or sensors, electromagnetic sensors (eg, halls) Sensors configured to measure pump speed, such as sensors), electromagnetic measurements (eg, measuring pump current and / or power draw, measuring power source current and / or power drain, remaining power source Etc.), or any combination thereof may be used. Based on the monitored flow rate, the controller executes algorithms or logic that controls the operation of the system according to various system requirements, such as by comparing the flow rate to a set of thresholds (eg, determined by calibration) And / or can be programmed to perform them. For example, the controller can be configured to obtain periodic measurements from a pressure sensor or to obtain periodic feedback from a pump motor. The pressure sensor can measure the pressure under the bandage. The controller can determine the flow rate, for example, by determining a pressure gradient, a rate of pressure change, and / or a rate of pressure decrease. For example, a positive pressure gradient (e.g., increasing) can reflect an increasing flow rate (e.g., leak) relative to a threshold, and the controller can be programmed to indicate this condition to the user can do.

In some embodiments, a system for the treatment of wounds can be provided. The bandage can create a substantially sealed or closed space around the wound (eg, under the bandage), and the pump assembly measures or monitors the pressure level in this space periodically or continuously. Can have a sensor. The pump assembly or its controller may be configured to control the pressure level in the space (eg, under the bandage) between the first negative pressure setpoint limit and at least the

second negative pressure setpoint limit. it can. In some embodiments, the first negative pressure setpoint limit can be between about −70 mmHg, or between about −60 mmHg and lower to about −80 mmHg and higher. In some embodiments, the second negative pressure setpoint limit can be between about −90 mmHg, or between about −80 mmHg and lower to about −100 mmHg and higher.

In some embodiments, the system may be configured to include "retry" functionality and / or logic. The pump assembly monitors the negative pressure level under the bandage (which may correspond to the negative pressure level of the wound cavity), and the monitored level is the desired negative pressure level (eg, the first negative pressure setting, The negative pressure setting value (eg, 2) may be configured to suspend or pause treatment if the desired negative pressure level has not been reached during a particular time interval. Following suspension or suspension of treatment, the pump assembly is configured to resume treatment (eg, restart the negative pressure source) and attempt to regenerate the desired negative pressure level under the bandage. be able to. Retry functionality can, for example, save battery power and allow transient and / or non-transient leaks to be resolved without user intervention, or the user can correct the leak (eg, straighten the bandage). , Repair seals, check one or more connections, etc.). In some embodiments, the controller may perform and / or be programmed to perform retry functionality and / or logic.

In some embodiments, the system "run / pause" via a switch, button, etc. located outside the housing of the pump assembly or in any other suitable location that the user can access. Can be configured to provide the functionality and / or logic. Operation / pause functionality may allow the user to hold and / or resume therapy (eg, pause and / or restart the pump). The pump assembly can be configured to automatically resume therapy according to certain predetermined or variable pause intervals. The pump assembly can be configured to automatically resume therapy when such an interval has elapsed and / or to indicate to the user that such interval has elapsed.

In some embodiments, the system can be configured to provide an indication, alarm, etc. to the user reflecting the operating state. The system can include visual, auditory, tactile, and other types of indicators and / or alarms configured to signal various operational states to the user. Such conditions include system on / off, standby, pause, normal operation, bandage problems, leaks, errors, etc. Indicators and / or alarms can include speakers, displays, light sources, etc., and / or combinations thereof. For example, the instructions may activate or deactivate the negative pressure source, reduce the negative pressure level generated by the negative pressure source, reduce the amount of power used by the negative pressure source, etc. Any combination can be provided.

FIG. 1 illustrates one embodiment of a reduced-pressure wound treatment apparatus 100 that includes a wound dressing 102 in combination with a pump assembly 104. In any of the apparatus embodiments disclosed herein, the pump assembly, as in the embodiment shown in FIG. 1, is a containerless pump assembly (that the pump assembly does not have a leachable or liquid collection container. Meaning). However, any of the pump embodiments disclosed herein can be configured to include or support a container. In addition, in any of the device embodiments disclosed herein, any of the pump assembly embodiments are attached to, attached to, or supported by the bandage, or it can be supported adjacent to the bandage. The bandage 102 may be placed over a wound (not shown) as described in more detail in US Pat. No. 6,099,028, the disclosure of which is incorporated herein by reference and made a part of this disclosure. A conduit 106 may be connected to the bandage 102. The bandage 102 or any other bandage disclosed herein may have any of the materials, sizes, components, or other details in any of the bandage embodiments disclosed in US Pat. All such embodiments and illustrations of that application are hereby incorporated by reference as part of the present disclosure. The conduit 106 or any other conduit disclosed herein can be formed from polyurethane, PVC, nylon, polyethylene, silicone, or any other suitable material.

Although some embodiments of the bandage 102 may have a port 108 configured to receive the end of the conduit 106 (eg, the first end 106a of the conduit 106), such port 108 is not required. Absent. In some embodiments, the conduit otherwise passes through and / or below the bandage 102 to provide a source of negative pressure to the space between the bandage 102 and the wound, thereby providing a desired amount in such space. Negative pressure level can be maintained. Some embodiments of the device 100 can be configured such that the first end 106 a of the conduit 106 is pre-attached to the port 108. The conduit 106 is configured to provide an at least substantially sealed fluid flow path between the pump assembly 104 and the bandage 102, thereby supplying the bandage 102 with the negative pressure provided by the pump assembly 104. It can be any suitable article.

The dressing 102 can be provided as a single article with all wound dressing elements (including the port 108) pre-attached and integrated into a single unit. The wound dressing 102 may then be connected to a negative pressure source, such as the pump assembly 104, via a conduit 106. In some embodiments, although not required, the pump assembly 104 can be miniaturized and portable, but larger conventional pumps such as EZ CARE ™ pumps can also be used with the bandage 102. Can do.

It will be appreciated that embodiments of the present invention are generally applicable for use in local negative pressure ("TNP") treatment systems. Briefly, negative pressure wound therapy reduces the number of tissue edema, promotes blood flow and granulation tissue formation, and / or removes excess exudate, thereby reducing the number of forms of "refractory" wounds. Helps with closure and healing, and reduces bacterial load (and thus the risk of infection). In addition, the therapy can reduce wound damage and lead to faster healing. The TNP treatment system can also assist in the healing of surgically closed wounds by removing fluids and helping stabilize tissue in the closed apposition position. A further beneficial use of TNP therapy is found in grafts and flaps where it is important to remove excess fluid and the graft is required to be in close proximity to the tissue to ensure tissue viability. be able to.

The wound dressing 102 can be placed over the wound site to be treated. The bandage 102 can form a substantially sealed cavity or enclosure over the wound site. It will be appreciated that throughout this specification reference will be made to wounds. In this sense, the term wound is to be interpreted broadly. open and closed wounds where the skin is torn, incised or perforated, or caused by a trauma, or any other surface or other part of the patient's skin It should be understood to encompass other conditions or defects, or others that benefit from reduced pressure treatment. Thus, a wound is broadly defined as any damaged area of tissue in which fluid may or may not be generated. Examples of such wounds include acute wounds, chronic wounds, surgical incisions and other incisions, subacute wounds and dehiscence wounds, traumatic wounds, flaps and skin grafts, lacerations, abrasions, contusions, burns, diabetic ulcers , Pressure ulcers, stomas, surgical wounds, traumatic ulcers, venous ulcers and the like. In some embodiments, the components of the TNP system disclosed herein may be particularly suitable for an incision wound that exudes a small amount of wound exudate.

Some embodiments of the device are designed to operate without the use of a leachable container. The bandage 102 can be configured to have a film with high water vapor permeability so that excess fluid can evaporate, and the superabsorbent material can be placed inside to safely absorb wound exudate. Can be included. Some embodiments of the device are designed for disposable treatment and can be disposed of in an environmentally friendly manner after up to about 7-11 days of use. The pump can be programmed to automatically terminate therapy after a desired number of days, such as 7 days, and no further operation of the pump is possible. Some embodiments are designed for longer or repeated use and can be configured to support a leachable container.

The device 100 can be manufactured in a variety of different models or versions, where the bandage 102 can be resized to accommodate a wide range of wound sizes. For example, a device 100 can be made having a bandage 102 and wound pad (ie, an absorbent element not shown in FIG. 1) of the following size:

Some embodiments of the overlay or bandage are substantially impermeable to air flow and bacterial or other contaminant flows through the overlay layer while being permeable to vapor passage. Can be.

In some embodiments, it may be preferable to partially or completely fill the wound site with a wound filler. This wound filler is optional but may be desirable in certain wounds, such as deeper wounds. The wound filler can be used in addition to the wound dressing 102. Wound fillers can generally include porous and compatible materials such as foam (including reticulated foam) and gauze. Preferably, the wound filler is sized or shaped to fit into the wound site so as to fill any empty space. The wound dressing 102 can then be placed over the wound site and the wound filler covering the wound site. When a wound filler is used, once the wound dressing 102 is

sealed over the wound site, TNP is transferred from the pump to the wound site through the wound dressing 102 and through the wound filler. This negative pressure moves the wound exudate and other fluids or secretions away from the wound site.

In some embodiments, the tubing 106 can have a connector 112 positioned at the second end 106 b of the tubing 106. Connector 112 communicates with mating connector 114a with a short length of conduit 114 and allows the connector to be supported by a pump housing (discussed in more detail below) or otherwise protrudes from pump assembly 104 with a short length. Can be configured to couple with the conduit 114. The length of the tubing 114 may in some embodiments be about 0.55 inches (14 mm), or about 0.5 to about 5 inches (12.7 to 127 mm). The short length of conduit or tubing 114 can reduce discomfort when the patient is lying on or otherwise over the pump and connector 112. By configuring the pump assembly 104 and tubing 106 so that the tubing 106 can be quickly and easily removed from the pump assembly 104, the process of replacing the dressing or pump can be facilitated or improved if necessary. Any of the pump embodiments disclosed herein can be configured to have any of the connection configurations disclosed herein between the tubing and the pump.

In some embodiments, as in the illustrated embodiment, the pump assembly 104 can be of a portable size that is small enough to be supported on the user's body or in the user's clothing. For example, the pump assembly 104 may use an adhesive medical tape or otherwise, adjacent to or on the bandage 102 or otherwise in a comfortable place on the human skin. Can be sized to be attached. Further, the pump assembly 104 can be sized to fit in a human trouser or shirt pocket, or can be attached to the human body using a strap, pouch, or other suitable device or article. You can stop

In some embodiments, the pump assembly 104 can be powered by one or more batteries (eg, two batteries) and weighs less than about 84 g, or 90 g, including the weight of the battery. be able to. In some embodiments, the pump assembly 104 can have any desired number of batteries, and has a weight between about 80 g to about 90 g, or about 75 g to about 100 g, or any value within the above range. Can be. For example, the weight and / or size of the pump assembly 104 may be reduced by reducing the size and / or weight of the battery (eg, to a size below the AAA battery) or by reducing the size and / or weight of the pump. Can do.

Further, some embodiments of the pump assembly 104 may have a total volume defined by the outer surface of the pump of about 5.6 cubic inches (about 92.5 cm^3), or 5.6 cubic inches (92.5 cm). $^{3)}$ or less, or 75 cm^3 or less ~ 115Cm^3 or more, or between 85cm^3 can be sized such that 100 cm^3. In addition, the pump assembly 104, those in the skill in the art using known techniques, to about 40 cm^3, or 40 cm^3 or less, or even smaller to a size ranging between 30 cm^3 or less ~ 60Cm^3 or more can do. Some embodiments of the pump assembly 104 may be between 2 cubic inches (32.8 cm^3) or less to 6.5 cubic inches (106.5 cm^3) or more, or from about 4 cubic inches (65.5 cm^3) to about It can be sized to have a total volume between 6 cubic inches (98.3 cm^3), or any value within the above range.

The pump assembly 104 has an overall outer size of about 7.2 cm × about 6.4 cm × about 2.1 cm (or 7.2 cm × 6.4 cm × 2.1 cm), or about 8.5 cm × about 8.5 cm ×. It can have a maximum value of about 3 cm. In addition, the pump assembly 104 can have a total outer size of about 5.5 cm × about 4.8 cm × about 1.5 cm (or 5.5 cm × 4.8 cm × 1.5 cm). As described above, the size and weight of the pump assembly 104 is more comfortable for a user to wear or carry, such as the embodiments disclosed herein, thereby providing improved mobility. Can be optimized.

The negative pressure range for some embodiments of the present disclosure can be about -80 mmHg, or about -20 mmHg to -200 mmHg. Note that these pressures are relative to normal ambient pressure, that is, in practical terms -200 mmHg is about 560 mmHg. In some embodiments, the pressure range can be about -40 mmHg to -150 mmHg. Alternatively, a pressure range of -75 mmHg or less, -80 mmHg or less, or greater than 80 mmHg can be used. In other embodiments, a pressure range of less than -75 mmHg can be used. Alternatively, a pressure range above about -100 mmHg or even 150 mmHg can be provided by the device 100. Other details regarding the operation of the pump assembly 104 are described in U.S. Patent No. 6,057,086, and such embodiments, configurations, details, and illustrations of that patent document are incorporated herein by reference as part of this disclosure. It is incorporated in the description.

2A-2F are various views of the embodiment of the pump assembly 104 shown in FIG. FIG. 3A shows a bandage 102 (which can be any of the bandage embodiments disclosed herein or incorporated by reference) supported within a first packaging element 150, 1 illustrates one embodiment of a wound dressing kit 100 comprising a pump assembly 104, a conduit 140, one or more batteries 142 (two are shown), and one or more seal strips 148. 3B is a bottom isometric view of the embodiment of the wound dressing kit 100 of FIG. 3A, and FIG. 3C is an exploded view of the embodiment of the wound dressing kit 100 of FIG. 3A

Referring to FIGS. 2A-3C, the pump assembly 104 may be a housing 120 comprising a first housing member 120a and a second housing member 120b and a control button 122 (a switch or other similar component).), A battery cover 124, a connector 128, and one or more lights, which can be LED lights. In some embodiments, the pump assembly 104 can have more than one button 122 and can have more than two lights 132. Light 132 may be in a normal or proper operating condition, pump failure, power or power supply failure supplied to the pump, battery condition or voltage level, detection of leaks in bandages or flow paths, obstruction of inspiration, or other it can be configured to alert the user to various operational and / or fault conditions of the pump assembly 104, including alerting the user to any similar or appropriate condition, or combination thereof.

The housing 120 can be configured such that a sterilizing gas, such as ethylene dioxide, enters the housing, thereby exposing the internal components of the pump assembly 104 to the sterilizing gas during the normal sterilization process. In general, since the pump is exposed to sterilization gas in a chamber that is substantially evacuated of air or any other gas, the sterilization gas is contained in the pump housing 120 and elsewhere in the pump assembly 104. Drawn into the space and chamber. For example, some embodiments of the pump housing 120 can have an unsealed gap surrounding the connector 128 through which sterilizing gas can pass. Also, in some embodiments, the first housing member 120a can be joined to the second housing member 120b without using a seal in between

With respect to the sterilization process, in some embodiments, the components to be sterilized can be subjected to the next step, among other things, in any order. The component can be placed in a chamber or container that is evacuated to about 70 mBarA (or 67 mBarA to 80 mBarA) for about 15 minutes to 1 hour and 15 minutes. The component can also be exposed to inert dilution, vapor pressure or regulation, or a nitrogen cycle, followed by further exhaust cycles. Ethylene oxide or any other suitable sterilization gas can be introduced into the chamber or container at a pressure setting of about 482 mBarA (or about 467 mBarA to about 500 mBarA). The component can be exposed to sterile gas at a temperature of about 46 ° C. (or about 42 ° C. to 49 ° C.), or 60 ° C. or less. The component is about 10 minutes (short cycle) or about 1 hour (long cycle), or about 9 minutes to about 11 minutes (short cycle), or about 59 minutes to about 1 hour (long cycle), or more, Can be exposed to sterile gas. The component or chamber can be flushed with nitrogen and / or air and / or subsequently degassed.

The pump assembly 104 can be powered by one or more batteries 142. Battery 142 can be lithium chloride or any other suitable battery that is suitable for exposure to ethylene dioxide and / or other sterilizing gases. The battery 142, when supported in one or more packaging elements, minimizes the possibility of electrical sparks that may cause an explosion in the presence of sterilizing or explosive gases during the sterilization process. It can be supported outside of the pump housing 120 to eliminate or eliminate. In addition, if there are multiple batteries 142, separate or otherwise separate the batteries within the packaging to prevent any power loss or sparking of the battery during the sterilization process or prior to another use. Can be separated.

Referring to FIG. 3A, since the battery 142 and one or more seal strips 148 can be positioned below the bandage 102, the bandage 102 must be removed from the first packaging element 150 before the battery 142 is removed. The order in which the components of the bandage kit 100 are removed from the packaging 150 and / or applied to the patient or combined with other components comprising the device 100 must be presented.

In some embodiments, both ends of the conduit 140 are free or otherwise disconnected from other components of the device 100 to improve exposure of the inner surface of the conduit 140 to sterilizing gas, and / or Alternatively, the conduit 140 can be positioned within the packaging 150 such that complete exposure of the tubing

to sterilization gas is ensured. The end of the conduit 140 can be supported in a recess formed in the first packaging element 150.

The first packaging element 150 includes a recess 190 that receives the pump assembly 104, a recess 192 that receives the bandage 102, a recess 194 that receives one or more seal strips 148 and / or a conduit 140, a conduit 114 and / or One or more recesses configured to receive and support components of the device 100, including a recess 196 that receives the connector 114a (if present) and spaced recesses 200a and 200b for the battery 142. Can have. By separating the batteries, the potentially flammable nature of ethylene oxide can reduce or eliminate the risk of explosion during the sterilization procedure.

In some embodiments, the first packaging element 150 is sufficiently rigid and / or robust to hold the battery, pump, and / or other components in place during processing or transportation of the bandage kit. Can be made from materials or combinations of materials. For example, some embodiments of the first packaging element 150 include a battery, pump, sufficient to withstand about 15G to about 25G, or 1G to 40G, or 1G to 20G, or 25G to 40G. Or it can be configured to provide a compression or interference fit of components such as other components. Some embodiments of the first packaging element 150 may lead to packaging shorts or melting / wearing, resulting in component movement or misalignment that leads to packaging damage or bacterial ingress. Pumps, batteries, tubing (including tubing pinches or recesses), and other configurations so as not to prevent users from being able to remove such components from packaging when needed, while being sufficient to prevent It can be configured to hold the element firmly.

In addition, as shown, the first packaging element 150 can be accessed by a surgeon or user with both gloved and non-gloved hands to remove various components of the device 100. It may have a groove or recess 193 that is sized and configured to facilitate this. In addition, ridges or protrusions 195 can be formed in the first packaging element 150 to provide additional support and protection for the packaging and kit components. The first packaging element 150 is any suitable that can be sterilized, including 0.80 Eastman 6763 medical grade, blue-stained with recyclable unused PETG, provided by Nelipak Custom Thermoformed Products. Can be made from any material. The packaging element 150 can be extruded and thermoformed from EASTAR ™, Chemical Product's EASTAR copolyester resin. For example, the raw material, which can be an extruded sheet or film, can be thermoformed using a vacuum at elevated temperatures and pressing on a dyeing tool. Other materials suitable for the first packaging element 150 include polycarbonate, PVC, or any other suitable resin or plastic material. In some embodiments, the first packaging element is 0.8 mm (or about 0.8) thick, or 0.8 mm or less, or 1.0 mm or less, or about 0.7 mm to 1.2 mm. Can be made from materials having a thickness of (including plates, sheets, films, etc.).

A gas permeable cover 151 (also referred to herein as a second packaging element) is sealably positioned over the first packaging element 150 to provide bacteria and contaminants to the contents of the dressing kit 100. Barriers can be provided. For example, a sheet-like layer or film of TYVEK ™, paper, or any other suitable material can be sealed to the peripheral portion 153 of the first packaging element 150. The cover 151 can be made from any suitable material, including TYVEK, that is permeable to sterilization gases but provides a barrier against bacteria and other contaminants. The cover 151 can be opaque, transparent, or translucent.

The cover 151 can be sealably connected to the first packaging element 150 after all the components of the bandage kit have been assembled therein. Thereafter, the first packaging element 150, the cover 151, and the bandage kit components may be TYVEK or over the opening formed in the bag so that sterilization gas can enter the bag and sterilize the bandage kit components. It can be positioned in a sealed, impermeable bag with other sterile gas permeable material patches.

4A and 4B are first and second exploded views of the embodiment of the pump assembly 104 of FIG. 1 showing the first housing member 120a separated from the second housing member 120b. 5A and 5B are first and second views of the first housing member 120a. 6A and 6B are first and second views of the second housing member 120b. With reference to FIGS. 4A-6B, some embodiments of the pump assembly 104 can have a battery compartment 220 supported within or formed within the housing 120. One or more battery contacts 222 may be supported within battery compartment 220. One or more electrical wires 224 may connect battery contacts 222 to pump 232 and / or control board 230. The pump assembly 104 can be assembled in a clean room to reduce the risk of contamination or bioburden that the pump is exposed to or may receive during assembly.

In some embodiments, the pump 232 can include a motor, an inlet port or connector 250, and an outlet port 252. The pump 232 can have one or more valves therein. For example, the first valve can be positioned in the pump 232 adjacent to the inlet port 250. In addition, a second valve can be positioned in the pump 232 adjacent to the outlet port 252. The pump 232 can define a flow path through the inlet port 250, through the first and second valves, and out of the outlet port 252.

In some embodiments, the battery contacts 222 can also be configured with polarity protection. For example, as with the one or more protrusions 124d adjacent to the battery contact 125, one or more of the battery contacts 222 may include the battery contact 222 and an incorrect side of a battery inserted into the battery compartment in an incorrect orientation. In order to prevent contact with the plastic, it may have plastic or other protrusions (not shown) adjacent to the contacts. For example, the one or more protrusions prevent the negative electrode of a standard cylindrical battery from contacting the battery contact 222 adjacent to the one or more protrusions, while the positive electrode of such a battery is the battery contact. It can be sized and configured to allow contact with 222. Generally, using this configuration, the battery can generally contact the contacts 222 only when the battery is inserted into the battery compartment 220 in the correct orientation, thereby providing polarity protection to the pump assembly 104. The protrusion is preferably made from a non-conductive material. Alternatively, or in addition, the control panel 230 can be configured with a polarity protection mechanism or component. In addition, the control board 230 can have one or more fuses for protection against overpower or surge power conditions.

The pump assembly 104 can have a flow manifold 240 and a one-way flow valve 246 in communication with a fluid flow path within the pump assembly 104. The one-way flow valve 246 (also referred to as a check valve) may be silicone or any other suitable material including, but not limited to, polyurethane, viton, nitrile rubber, neoprene, Teflon, and other suitable materials. It can be a diaphragm valve made from a flexible elastomeric material or a soft material. Other suitable valves for one-way flow valves are, for example, without limitation, umbrella valves, ball valves, reed valves, duckbill valves. In some embodiments, the leak rate of the one-way flow valve 246 can be about 0.05 mL / min. In some embodiments, the one-way flow valve 246 can be positioned in the pump 232 or instead of one of the valves positioned in the pump 232.

Manifold 240 and / or one-way flow valve 246 can be in communication with connector 128. In some embodiments, the one-way flow valve 246 can be supported within the manifold 240, which can be substantially sealably coupled to the inlet port or connector 250 of the pump 232 or otherwise. Can be supported in the housing 120 to be in fluid communication with the inlet port or connector 250. For example, referring to FIGS. 4A and 4B, the manifold 240 can be assembled with the pump 232 such that the inlet connector 250 is received within an opening 261 formed in the manifold 240. Air and / or other gases can exit the pump 232 through an outlet port or connector 252. During sterilization, the pump 232 may be configured such that sterilization gas can enter the interior space or chamber of the pump 232 to ensure that the entire pump 232 (both internal and external) is sterilized. It can. One or more valves (which can be umbrella valves or any other suitable valve) can be positioned in the pump 232. For example, without limitation, one or more valves may be supported within pump 232, positioned adjacent to each of inlet port 250 and outlet port 252.

For optimal sterilization, in some embodiments, sterilization gas can be introduced slowly to optimize the flow of sterilization gas through the valve and prevent the pressure from the sterilization gas from completely closing the valve. It can. As described above, the valves (such as the first and second valves) are configured to be leaky to some extent so that the flow of sterilization gas proceeds past the valve to allow the internal components of the pump 232 to Can be sterilized. For example, the valve may be 0.1 mL / min to 10 mL / min or more at nominal or general operating pressure (ie, at the nominal operating pressure of the fluid in the conduit) or at nominal or general sterilization pressure. A leakage flow rate of fluid passing therethrough at a velocity (ie, a flow rate through the valve when the valve is in the closed position) can be allowed. In some configurations, the portion of the flow path between the two valves, or between the valve and the one-way valve, may be the most difficult part to sterilize the flow path or pump assembly 104.

Some embodiments of the pump assembly may have a piezoelectric pump. Some piezoelectric pumps or other pumps disclosed herein have an orifice that performs the valve function so that when the pump is stopped, the flow rate through the pump can be as high as 200 mL / min. Or have an orifice. Thus, in some embodiments, the first and second valves (which can be orifices) are each about 200 mL when the pump rate can be about 300 mL / min or 320 mL / min or other high rate. Can have a leak rate of less than / minute.

The pump 232 includes, but is not limited to, a rotary diaphragm pump or other diaphragm pump, a piezoelectric pump, a peristaltic pump, a piston pump, a rotary blade pump, a liquid ring pump, a scroll pump, a diaphragm operated by a piezoelectric transducer. It can be of any suitable type, such as a pump, or any other suitable pump or micropump, or any combination of the above. Pump 232 can be a standard off-the-shelf vacuum pump, such as, for example, Koge Electronics' KPV8A-3A pump. Pump 232 can also be a KNF diaphragm pump or any suitable KNF pump.

Some embodiments of the pump can be lightweight, such as about 10 g, or about 5-15 g, or between any value within the above range. Pump 232 has a pump capacity of about 500 mL / min, or between about 300 mL / min or less to about 600 mL / min or more, or between about 400 mL / min to about 500 mL / min, or any value within the above range. Can have. In some embodiments, the pump assembly 104 can include more than one pump 232. For example, the pump assembly 104 may include a first pump with a high flow rate configured to provide rapid drawdown of the space between the wound overlay and the wound, and the wound overlay and wound after the initial drawdown. And a second lesser capacity pump configured to maintain a reduced pressure level of the space between them. In some embodiments, the pump flow rate can be about 20 times the leak alarm flow rate, which can be set to about 15 mL / min.

As described above, the connector 128 is a threaded connector (as shown) that can threadably receive a mating threaded connector coupled to the end of the tubing 106. be able to. The threaded connector 128 is of a non-standard size compared to other medical connectors to prevent medical personnel from inadvertently attaching standard luer connectors (such as connectors from a venous line). It may be a thing.

Alternatively, although not shown, the connector 128 is a standard tubing connector (nipple) configured to sealably receive tubing thereon so that a separate mating connector on the end of tubing 106 can be omitted. Connector etc.).

Manifold 240 may have a separate port 260 that may be configured to receive a pressure monitor conduit or connector 262. The pressure monitor can be supported by the control board 230 and can be configured to monitor the pressure level in the fluid flow path. The pressure monitor can be configured to protect the motor 232 so that a predefined threshold pressure is not exceeded. In some embodiments, the pressure monitor can be calibrated to not exceed 175 +/- 50 mmHg. In some embodiments, the pressure monitor can be calibrated to not exceed 235 mmHg. The pressure monitor can be configured to stop power to the motor when the pressure reading reaches a predetermined value, and the pressure level is higher than the predetermined value, or higher than the first predetermined value, or it may be configured to resume power when below a second predetermined value, which may be low. In addition, the pump assembly 104 can be programmed to prevent such overpressure. The pump assembly 104 can be configured such that the software provides a primary mechanism to prevent overpressure, and a pressure monitor can provide backup for overpressure protection.

The pump 232 can have a layer of open cell foam or other material that is at least partially wrapped around the outer surface of the pump 232 to reduce noise and vibration generated by the pump 232. All of these components can be supported within the first and second pump housing members 120a, 120b, which can be secured together with any suitable fastener 270 (eg, a pair of screws). One or more labels 272 can be attached to the outer surface of the housing 120. In addition, in some embodiments, the pump 232 is supported by the pump 232 or positioned adjacent to one or more outer surfaces of the pump, one or more weights, cushions, foams It can have a body (such as a viscoelastic foam), plastic (such as ABS, polyurethane, urethane), or other pad, panel, sheet, or segment. Some embodiments can have a mass-based or flexible damping material. Such components or materials (not shown) can damp vibrations generated by the pump and / or attenuate noise.

For example, one or more weights (made of steel, metal, or any other suitable material) are supported on the outer surface of pump 232 or any other pump embodiment disclosed herein. Or it can be attached to it. The steel weight can be about 1.8 g, 3.8 g, or 5.8 g, or 1 g to 10 g or more, or 1.5 g to 6 g. Two or more weights can be supported on or attached to the outer surface of pump 232 or any other pump embodiment disclosed herein. Two steel weights, each weighing about 1.8 g, 3.8 g, or 5.8 g, or 1 g to 10 g or more, or 1.5 g to 6 g, can be attached to the outer surface of the pump 232. Each of the two plates can be positioned on the opposite surface of the motor 232 or otherwise. In some embodiments, four steel weights weighing about 1.8 g, 3.8 g, or 5.8 g, or 1 g to 10 g or more, or 1.5 g to 6 g, respectively, are applied to the outer surface of the pump 232. Can be attached to. The plates can be arranged such that the two plates are positioned on each of the two opposing surfaces of the motor 232 or otherwise. In some embodiments, weights can be positioned adjacent to more than two surfaces of the pump 232, including, but not limited to, the sides and top surface of the pump 232, for example.

Referring to FIG. 4A, the battery cover 124 may be configured to engage the mating mechanism of the housing 120 to prevent inadvertent opening when the battery cover 124 is in the closed position. Or it can have the tab member 124a. In addition, a guide or protrusion 124b can be formed on the battery cover 124 to facilitate the ease with which the battery cover 124 can be opened and closed. The guide 124b can engage a mating guide or channel 120c formed in the housing 120. The battery cover 124 can be configured to have a gripping surface for use with a single finger. For example, without limitation, a plurality of depressions 124c are formed on the surface of the battery cover 124 to improve gripping between the user's finger or other object and the battery cover 124, and the battery cover 124 can be easily opened and closed. can do.

Referring to FIG. 4B, the battery cover 124 can support thereon one or more battery contacts or terminals 125 configured to provide a connection between two batteries. The battery cover 124 may further support one or more protrusions 124 d adjacent to the battery contact 125. The one or more protrusions 124d prevent the negative electrode of a standard cylindrical battery from contacting the battery contact 125 adjacent to the one or more protrusions 124d, while the positive electrode of such a battery is the battery contact. 125 can be sized and configured to allow contact. With this configuration, the battery can generally contact the contact 125 only when the battery is inserted into the battery compartment 220 in the correct orientation, thereby providing polarity protection to the pump assembly 104.

Referring to FIGS. 4A and 4B, the housing 120 may include one or more tabs 121 and recesses configured to receive the tabs 121 to improve the connection between the two members 120a, 120b of the housing. Channel 123. The tabs 121 and indents 123 can better hold the edges of the housing 120 together to improve the strength of the housing 120 and make the connection between the two members 120a, 120b of the housing tighter. The control panel 230 can be combined with the housing 120 using a similar mechanism.

Of an embodiment of the wound dressing 102 disclosed herein, as described in US Pat. No. 8,637,097, the disclosure of which is incorporated herein by reference as if fully set forth herein. Either lower surface can have an optional wound contact layer. Any of the bandage embodiments disclosed herein can be made without a wound contact layer. The wound contact layer can be made porous or perforated, for example, by a hot pin process, a laser ablation process, an ultrasonic process, or in some other manner, or otherwise liquid and gas it can be a polyurethane layer or a polyethylene layer or other flexible layer, which can be permeable. Through holes may allow liquid and / or gas to flow through the layers. The wound contact layer can help prevent tissue ingrowth into another material of the wound dressing.

The through hole is small enough to meet this requirement, but can still be sized to allow fluid to pass through. For example, a through-hole formed as a slit or hole having a size in the range of 0.025 mm to 1.2 mm is small enough to help prevent tissue ingrowth into the wound dressing It is considered to allow wound exudate to flow into the bandage. The wound contact layer helps hold the entire wound dressing together and helps create a hermetic seal around the absorbent pad to maintain negative pressure in the wound. The wound contact layer also acts as a carrier for any lower and upper adhesive layers (not shown). For example, a lower pressure sensitive

adhesive layer can be provided on the lower surface 101 of the wound dressing, while an upper pressure sensitive adhesive layer can be provided on the upper surface 103 of the wound contact layer. The pressure sensitive adhesive, which can be a silicone, hot melt, hydrocolloid, or acrylic adhesive, or other such adhesive, is selected on both sides of the wound contact layer, or optionally on the wound contact layer. It can be formed on one side or not on any side. If the lower pressure sensitive adhesive layer is utilized, this helps adhere the wound dressing to the skin around the wound site.

As described above, any bandage embodiment used in the bandage kit disclosed herein or incorporated by reference has an adhesive-coated lower surface (eg, a wound contact surface). be able to. In some embodiments, as described above, the adhesive can be, for example, a silicone adhesive comprising polysiloxane or polyorganosiloxane, or other polymeric pressure sensitive silicone adhesive. For example, polydimethylsiloxane can be used. The adhesive blend is a mixture of alkyl pendant siloxanes that can be spread and cast as a two-part mixture with the catalyst so that the final polymerization step follows the casting or spreading. It may be. In some embodiments, the bandage layer is coated on the opposite side of an extruded EU30 polyurethane transparent film (27-37 gsm) with a non-porous silicone adhesive coating (coat weight nominally 130 gsm) and fully cast. Acrylic adhesive (27-37 gsm). The water vapor permeability of some embodiments of such an arrangement can be from about 367 gm $^{-2}$ / 24 hours to about 405 gm $^{-2}$ / 24 hours, or an average water vapor permeability of 382 gm $^{-2}$ / 24 hours.

Some embodiments or arrangements of silicone adhesive layers suitable for the bandage embodiments disclosed herein may have a water vapor transmission rate of about 350 gm $^{-2}$ / 24 hours to about 410 gm $^{-2}$ / 24 hours. it can. Suitably, the average water vapor permeability of some embodiments or arrangements of silicone adhesive layers suitable for the bandage embodiments disclosed herein can be about 380 gm $^{-2}$ / 24 hours. Some of the bandage embodiments disclosed herein may be coated with Wacker silres PSA 45 pressure sensitive adhesive

In addition, any of the bandage embodiments disclosed herein can have an antimicrobial agent or substance incorporated into the bandage or coated on one or more surfaces of the bandage. For example, without limitation, the wound contact layer of any bandage embodiment disclosed herein is incorporated herein by reference as part of, but not limited to, Nanocrystalline silver agent, silver salt, copper salt, or gold salt, such as those disclosed in Patent Document 10 (named "ANTIMPROBIAL BIGUANIDE METAL COMPLEX") filed on May 21, 2008, PHMB Chlorohexazine, peroxide, hypochlorous acid, or other bleaching agents in or on it. Further, the absorbent layer of any bandage embodiment disclosed herein can have silver sulfur diazine, or any of the above-described substances or activators in or thereon. These may be used separately or in combination. Each of these can eliminate microorganisms in the wound and microorganisms in the absorbent matrix. As yet another option, other active ingredients can be incorporated into the bandage, for example pain inhibitors or healing agents such as ibuprofen. Also, agents that inhibit cellular activity such as growth factors, or agents that inhibit enzymes such as matrix metalloproteinase inhibitors or zinc chelators such as metalloproteinase tissue inhibitors (TIMPS) can be incorporated into the dressing. Odor trapping elements such as activated carbon, cyclodextrin, zeolite, etc. may also be included in the absorbent layer or other part or component of the bandage or on the filter layer

A layer of porous material can be disposed over the wound contact layer. This porous layer, i.e., the permeable layer, allows fluids including liquids and gases to permeate away from the wound site and into the upper layer of the wound dressing. In particular, the permeable layer can ensure that an open air channel can be maintained and negative pressure transmitted over the wound area, even when the absorbent layer is absorbing a significant amount of exudate. . The layer should remain open under the general pressure applied during negative pressure wound treatment as described above, thereby allowing a uniform negative pressure across the wound site. The layer can be formed of a material having a three-dimensional structure. For example, a knitted or woven spacer fabric (eg, Baltex 7970 weft knitted polyester) or a non-woven fabric can be used. Other materials can be utilized, and examples of such materials are described in US Pat. No. 6,057,028, which is incorporated herein by reference and forms part of the present disclosure.

In some embodiments, the transmission layer can have a 3D polyester spacer fabric layer. This layer has an upper layer that is 84/144 textured polyester (ie, a layer distal to the wound bed in use) and a lower layer that can be 100 denier flat polyester (ie, the wound bed in use). And a third layer, which is a region defined by monofilament fibers such as knitted polyester viscose and cellulose formed between the two layers. be able to. Other suitable materials and other linear mass densities of fibers can be used.

This difference between the filament counts in the separated layers helps to control the moisture flow across the permeation layer. In particular, by increasing the filament count of the top layer, i.e. making the top layer with yarns that have more filaments than the yarn used in the bottom layer, the liquid will flow along the top layer rather than the bottom layer. Tend to be wicked. In use, this difference tends to draw the liquid away from the wound bed and into the central area of the bandage, where the absorbent layer traps the liquid or itself transpirations the liquid. Helps to wick forward toward the cover layer that can be allowed to.

Preferably, the 3D fabric is a dry cleaning agent (such as perchlorethylene) to improve the flow of liquid across the permeable layer (ie, perpendicular to the channel region formed between the upper and lower spacer layers). With the aid of removing any previously used industrial products such as mineral oils, oils and / or waxes that may be treated with, but not limited to, the hydrophilicity of the permeable layer Become. In some embodiments, an additional manufacturing step can be followed in which the 3D spacer fabric is washed with a hydrophilic agent (such as but not limited to Feran Ice 30 g / L available from Rudolph Group) . This process step helps to ensure that the surface tension on the material is low and that a liquid such as water can enter the fabric as soon as it contacts the 3D knitted fabric. This also helps to control the flow of liquid insult components of any exudate.

Again, as described in more detail in U.S. Patent No. 6,063,831, a water absorbent material layer can be provided on the permeable layer. The absorbent material, which can be a natural or synthetic material of foam or non-woven fabric, optionally comprising or being a superabsorbent material, is a fluid, in particular a liquid removed from the wound site The reservoir and sucking those fluids towards the cover layer. The material of the absorbent layer can prevent the liquid collected in the wound dressing from flowing away. The absorbent layer can also help distribute the fluid throughout the layer via a wicking action so that fluid is drawn from the wound site and accumulates throughout the absorbent layer. This helps to prevent aggregation in the area of the absorbent layer. The volume of absorbent material must be sufficient to manage wound exudate flow when negative pressure is applied. In use, since the absorbent layer is subjected to negative pressure, the material of the absorbent layer is chosen to absorb the liquid under such circumstances. There are many materials that can absorb liquids under negative pressure, for example superabsorbent materials. The absorbent layer can be made from ALLEVYN ™ foam, Freudenberg 114-224-4, and / or Chem-Posite ™ 11C-450, or any other suitable material.

In some embodiments, the absorbent layer can be a layer of nonwoven cellulose fibers in which superabsorbent material in the form of dry particles is dispersed throughout. The use of cellulose fibers introduces a high speed wicking element that helps to quickly and uniformly distribute the liquid absorbed by the bandage. The juxtaposition of multiple strand-like fibers leads to a strong capillary action in the fibrous pad that helps to distribute the liquid. In this way, the liquid is efficiently supplied to the superabsorbent material. Furthermore, all areas of the absorbent layer are provided with liquid.

The wicking action also assists in contacting the liquid with the upper cover layer to help increase the transpiration rate of the bandage. The wicking action also assists in delivering fluid down toward the wound bed when the exudate is slow or stops. This delivery process helps maintain the permeable layer and the underlying wound bed area in a moist state, which helps to prevent scab formation (which can lead to inhibition) within the bandage, and against wound healing Helps maintain an optimized environment.

In some embodiments, the absorbent layer can be an airlaid material. Thermally fusible fibers can optionally be used to help hold the pad structure together. It will be appreciated that superabsorbent fibers according to some embodiments of the present invention can be utilized rather than or in addition to using superabsorbent particles. An example of a suitable material is the product Chem-Posit ™ 11C available from Emerging Technologies Inc (ETI), USA.

Optionally, the absorbent layer can comprise synthetic stable fibers and / or bicomponent stable fibers and / or natural stable fibers and / or superabsorbent fibers. The fibers in the absorbent layer can be secured together by latex bonding or thermal bonding or hydrogen bonding or any combination of bonding techniques or other fixing mechanisms. In some embodiments, the absorbent layer is formed by fibers that operate to confine superabsorbent particles within the absorbent layer. This helps to ensure that the superabsorbent particles do not move out of the absorbent layer and toward the underlying wound bed. This is particularly useful as it tends to collapse the absorbent pad downwards when negative pressure is applied, and this action traps the superabsorbent particulate matter by the fibrous structure of the absorbent layer. This is because if not, it is pushed in the direction toward the wound bed.

The absorbent layer can include a plurality of fiber layers. Preferably, the fibers are strands and are made of cellulose, polyester, viscose, and the like. Preferably, the dried absorbent particles are distributed throughout the ready absorbent layer. In some embodiments, the absorbent layer includes a pad of cellulose fibers and a plurality of superabsorbent particles. In additional embodiments, the absorbent layer is a randomly oriented nonwoven layer of cellulose fibers.

The superabsorbent particles / fibers can be, for example, sodium polyacrylate or carbomethoxycellulose materials, or any material that can absorb many times its own weight in the liquid. In some embodiments, the material can absorb more than 5 times the weight of 0.9% weight saline solution itself. In some embodiments, the material can absorb more than 15 times the weight of 0.9% weight saline solution itself. In some embodiments, the material can absorb more than 20 times the weight of 0.9% weight saline solution itself. Preferably, the material can absorb more than 30 times the weight of the 0.9% weight saline solution itself. The absorbent layer can have one or more through holes arranged to be under the suction port.

The dressing 102 can have a cover layer that extends across the width of the wound dressing that is gas impermeable but water vapor permeable. The cover layer can be, for example, a polyurethane film (eg, Elastollan SP9109), or any other suitable material having a pressure sensitive adhesive on one side, and is substantially gas impermeable, thereby substantially A sealed enclosure is made over the wound. In this way, an effective chamber can be created between the cover layer and the wound site to establish a negative pressure. The cover layer can be sealed to the wound contact layer at the boundary area around the circumference of the bandage, ensuring that no air is drawn through the boundary area, for example by gluing or welding techniques. The cover layer can protect the wound from external bacterial contamination (bacterial barrier), allowing liquid from the wound exudate to migrate through the layer and evaporate from the outer surface of the film. The cover layer can have a polyurethane film and an adhesive pattern cast on the film. Polyurethane films are water vapor permeable and may be made from materials that increase water permeability when wet.

An orifice can be provided in the cover film so that negative pressure can be applied to the bandage 102. As described above, in some embodiments, the suction port 108 can be sealed onto the cover film over the orifice, thereby transmitting negative pressure through the orifice. The port may be adhered and sealed to the cover film using an adhesive such as acrylic, cyanoacrylate, epoxy, UV curable, or hot melt adhesive. The port 108 can be formed from a soft polymer, such as polyethylene, polyvinyl chloride, silicone, or polyurethane having a hardness of 30-90 on the Shore A scale.

The bandage 102 may have a filter element that is impermeable to liquid but permeable to gas. The filter element can act as a liquid barrier that substantially prevents or inhibits liquid from escaping from the wound dressing, as well as an odor barrier. The filter element may also function as a bacterial barrier. In some embodiments, the pore size of the filter element can be about 0.2 μm. Suitable materials for the filter material of the filter element include 0.2 micron Gore ™ PTFE, PALL Versapore ™ 200R, and Donaldson ™ TX6628 stretched from the MMT range. In this way, gas can be discharged through the orifice by the filter element. However, liquids, particulates, and pathogens are included in the bandage. Other details regarding filters are disclosed in US patent application Ser. No. 13 / 092,042, which is incorporated herein by reference.

Wound dressings 102 as described herein and methods of making and using the same may also incorporate the features, configurations, and materials described in the following patents and patent applications, each of which is disclosed in this disclosure. Which is incorporated herein by reference in its entirety. Patent Literature 11, Patent Literature 12, Patent Literature 13, Patent Literature 14, Patent Literature 15, Patent Literature 16, Patent Literature 17, Patent Literature 18, Patent Literature 19, Patent Literature 20, Patent Literature 21, Patent Literature 22, Patent Document 23, Patent Document 24, Patent Document 25, and Patent Document 26, Patent Document 27 filed on November 8, 2010, Patent Document 28 filed on April 15, 2011, and April 2011 Patent Document 29 filed on the 15th. From patents and patent applications incorporated by these references, the features, configurations, materials, and methods of manufacture or use of components similar to those described in this disclosure have been substituted and added to the embodiments of this application. Or may be implemented.

In operation, the wound dressing 102 is sealed over the wound site forming the wound cavity. The pump assembly 104 provides a negative pressure source for the bandage 102. Fluid is drawn from the wound site beneath the wound contact layer, through the wound dressing, and toward the orifice. The fluid moves through the permeable layer toward the orifice. As fluid is drawn through the permeable layer, wound exudate is absorbed into the absorbent layer

The overall shape of the wound dressing can be square, oval, rectangular, or another shape. The bandage can have a rounded corner area. It will be appreciated that wound dressings according to other embodiments of the present invention can be shaped differently, such as square, circular, or elliptical dressings.

The desired size of the wound dressing 102 can be selected based on the size and type of wound in which it is used. In some embodiments, the wound dressing 102 can be sized between 20-40 cm on its long axis and 10-25 cm on its short axis. For example, as described above, bandages can be provided in sizes of about 10 × 20 cm, 10 × 30 cm, 10 × 40 cm, 15 × 20 cm, and 15 × 30 cm.

In some embodiments, the wound dressing 102 can be a square dressing (eg, 15 × 15 cm, 20 × 20 cm, and 25 × 25 cm) with sides sized between 15 and 25 cm. The absorbent layer can have a smaller area than the entire bandage, and in some embodiments, have a length and width that are both about 3-10 cm shorter, more preferably about 5 cm shorter than the entire bandage 102. May be. In some rectangular embodiments, the absorbent layer may have a dimension between about 10-35 cm on its long axis and 5-10 cm on its short axis. For example, the absorbent layer is 5.6 × 15 cm or 5 × 10 cm (for a 10 × 20 cm bandage), 5.6 × 25 cm or 5 × 20 cm (for a 10 × 30 cm bandage), 5.6 × 35 cm Or 5 × 30 cm (for 10 × 40 cm bandages), 10 × 15 cm (for 15 × 20 cm bandages), and 10 × 25 cm (for 15 × 30 cm bandages). In some square embodiments, the absorbent layer may have sides between 10 and 20 cm long (eg, 10 × 10 cm for a 15 × 15 cm bandage, 20 × 20 cm bandage) In the case of a bandage of 15 × 15 cm or 25 × 25 cm). The transmission layer can be smaller in size than the absorbent layer, and in some embodiments, both about 0.5-2 cm shorter than the absorbent layer, more preferably about 1 cm shorter, Can have a width. In some rectangular embodiments, the transmission layer may be sized between 9-34 cm on its long axis and 3-5 cm on its short axis. For example, the transmission layer may be 4.6 × 14 cm or 4 × 9 cm (for a 10 × 20 cm bandage), 4.6 × 24 cm or 4 × 19 cm (for a 10 × 30 cm bandage), 4.6 × 34 cm or It may be provided in sizes of 4 × 29 cm (for 10 × 40 cm bandage), 9 × 14 cm (for 15 × 20 cm bandage), and 9 × 24 cm (for 15 × 30 cm bandage). In some square embodiments, the transmission layer may have sides between 9 and 19 cm long (eg, 9 × 9 cm for a 15 × 15 cm bandage, 20 × 20 cm bandage) In the case of 14 × 14 cm, or 19 × 19 cm in the case of a 25 × 25 cm bandage).

The dressing can include an antimicrobial substance, for example, a nanocrystalline silver agent on the wound contact layer and / or silver sulfur diazine in the absorbent layer. These may be used separately or together. Each of these kills microorganisms in the wound and microorganisms in the absorbent matrix. As yet another option, other active ingredients may be included, for example pain suppressors such as ibuprofen. In addition, agents that improve cellular activity such as growth factors, or agents that inhibit enzymes such as matrix metalloproteinase inhibitors or zinc chelators such as metalloproteinase tissue inhibitors (TIMPS) can be used. As yet another option, odor trapping elements such as activated carbon, cyclodextrin, zeolite, etc. may be included in the absorbent layer or as a further separate layer above the filter layer.

Although several embodiments of the present invention have been described so far in which the transmissive layer is formed as a 3D knitted layer, for example as two layers separated by a monofilament layer, some embodiments of the present invention provide such materials. It will be appreciated that it is not constrained to use. In some embodiments, one or more layers of various materials can be utilized as an alternative to such 3D knitted materials. In either case, according to embodiments of the present invention, the opening represented by the layers of the permeable layer moves away from the side of the bandage that would be placed close to the wound during use. It gets wider as you go. In some embodiments, the permeable layer may be provided by multiple layers of open cell foam. In some embodiments, the foam is a reticulated open cell foam. The foam can be hydrophilic or can wick aqueous based fluids. The pore size of each layer is selected so that the pores closest to the wound site in use in the foam layer have the smallest diameter. If only one additional foam layer is utilized, it includes a pore size that is larger than the pore size of the first layer. This helps avoid solid particles being trapped in the lower layer, which in turn helps to maintain the lower layer in an open configuration, which allows air to permeate the bandage. In some embodiments, two, three, four, or more foam layers may be included. The foam layer may be formed integrally by, for example, selecting a foam having a large pore diameter and repeatedly immersing it while gradually reducing the degree of immersing it in a material that clogs the pores, or a plurality of foam layers may be formed. The permeable layer formed by the foam layer may be provided by laminating different types of foam in a layered arrangement, or by fixing such foam layers in place in a known manner.

7A-7D illustrate the use of one embodiment of a TNP wound treatment system being used to treat a patient's wound site. FIG. 7A shows that the wound site W has been cleaned and is ready for treatment. Here, the healthy skin surrounding the wound site W is preferably cleaned and excess hair is removed or shaved. If necessary, the wound site W may also be irrigated with sterile saline. Optionally, a skin protectant may be applied to the skin surrounding the wound site W. If necessary, a wound filler such as foam or gauze may be placed at the wound site W. This may be preferred when the wound site W is a deeper wound.

After the skin surrounding the wound site W is prepared, the cover 151 can be removed from the first packaging element 150 to provide access to the components. The bandage 102 can be removed from the packaging 150 and can be positioned and placed over the wound site W as shown in FIG. 7B. The wound dressing 102 can be positioned such that the wound contact layer of the dressing 102 is above and / or in contact with the wound site W. In some embodiments, an adhesive layer can be provided on the underside of the wound contact layer, which may optionally be removed prior to placing the wound dressing 102 over the wound site W. It may be protected by a release layer. The bandage 102 may be positioned such that the port 108 is in a raised position relative to the rest of the bandage 102 and avoids fluid accumulation around the port 108. In some embodiments, the bandage 102 is positioned such that the port 108 does not directly overlap the wound, but is at or above the wound. To help ensure a proper seal against TNP, the edges of the bandage 102 can be smoothed to avoid folds or folds. The bandage and the adhesive formed thereon may be used to lift and reposition the bandage away from the skin or wound, without sacrificing the performance of the adhesive. For reasons it can simply be configured so that the bandage can be repositioned on the wound. Tubing 106 can be connected to bandage 102 either before or after placing bandage 102 over the wound.

The pump assembly 104 can then be removed from the packaging 150 and connected to the tubing 106, as shown in FIG. 7C. The battery 142 can be removed from the packaging 150 and installed in the pump assembly 104 either before or after the pump is attached to the conduit 106. The pump assembly 104 is configured to apply negative pressure to the wound site through the bandage 102, typically through tubing or conduit 106. In some embodiments, a connector may be used to join the conduit 106 to the bandage 102 and to the pump assembly 104. When applying negative pressure by the pump assembly 104, the bandage 102, in some embodiments, has a partially collapsed, wrinkled appearance as a result of exhausting some or all of the air under the bandage 102. May be shown. In some embodiments, the pump assembly 104 may be configured to detect any leaks in the bandage 102, such as at the junction between the bandage 102 and the skin surrounding the wound site W. Good. If a leak is found, it is preferably corrected before continuing treatment. Leakage can be corrected by repositioning the bandage 102, extending the wrinkles or folds of the bandage, or applying a fastening strip 148 around the circumference of the bandage 102.

Turning to FIG. 7D, the fixation strip 148 may be attached around the outer periphery of the bandage 102 or otherwise as described above. Such a fixation strip 148 may be advantageous in some situations to provide an additional seal against the patient's skin surrounding the wound site W. For example, the seal or anchoring strip 148 can provide an additional seal when patient movement is more active. In some cases, the fixation strip 148 may be used prior to operating the pump assembly 104, particularly when the bandage 102 is placed over an inaccessible or undulating area. In some embodiments, the bandage kit 100 can include no more than five seal strips.

Treatment of the wound site W is preferably continued until the wound reaches the desired level of healing. In some embodiments, it may be desirable to replace the bandage 102 after a certain period of time has elapsed or when the bandage is full of wound fluid. During such replacement, the pump assembly 104 may be retained and only the bandage 102 may be replaced.

8A-20H each illustrate a top surface of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including a variety of differently sized wound dressing devices, etc. FIG. 4 is a square view, a bottom isometric view, a top view, a bottom view, a front view, a rear view, a first side view, and a second side view. Other packaging disclosed herein, wherein any of the packaging element embodiments shown in FIGS. 8A-20H or otherwise disclosed in the present application include the first packaging element 150 described above. It may have any of the same features, materials, or other details as any of the ring elements.

The packaging element 300 shown in FIGS. 8A-8H supports one or more bandages having a size of about 10 cm × 20 cm and / or other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 310 shown in FIGS. 9A-9H supports one or more bandages having a size of about 10 cm × 20 cm and / or other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 320 shown in FIGS. 10A-10H supports a dressing having a size of about 10 cm × 30 cm and / or one or more of the other components of any of the TNP treatment kits disclosed herein. Configured to do. The packaging element 330 shown in FIGS. 11A-11H supports a bandage having a size of about 10 cm × 30 cm and / or one or more of the other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 340 shown in FIGS. 12A-12H supports one or more of a bandage having a size of about 10 cm × 40 cm and / or other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 350 shown in FIGS. 13A-13H supports one or more of the bandages having a size of about 10 cm × 40 cm and / or other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 360 shown in FIGS. 14A-14H supports one or more bandages having a size of about 15 cm × 15 cm and / or other components of any of the TNP treatment kits disclosed herein. Configured to do. The packaging element 365 shown in FIGS. 14I-14P supports one or more of a bandage having a size of about 15 cm × 15 cm and / or other components of any TNP treatment kit disclosed herein. Configured to do.

The packaging element 370 shown in FIGS. 15A-15H supports a bandage having a size of about 15 cm × 20 cm and / or one or more of the other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 380 shown in FIGS. 16A-16H supports one or more of a bandage having a size of about 15 cm × 20 cm and / or other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 390 shown in FIGS. 17A-17H supports one or more of a bandage having a size of about 20 cm × 20 cm and / or other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 395 shown in FIGS. 17I-17P supports a dressing having a size of about 20 cm × 20 cm and / or one or more of the other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 400 shown in FIGS. 18A-18H supports a dressing having a size of about 15 cm × 30 cm and / or one or more of the other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 405 shown in FIGS. 18I-18P supports a bandage having a size of about 15 cm × 30 cm and / or one or more of the other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 410 shown in FIGS. 19A-19H supports one or more bandages having a size of about 25 cm × 25 cm and / or other components of any TNP treatment kit disclosed herein. Configured to

do. The packaging element 420 shown in FIGS. 20A-20H supports one or more bandages having a size of about 25 cm × 25 cm and / or other components of any TNP treatment kit disclosed herein. Configured to do.

FIG. 21 illustrates a pump assembly 1000 according to some embodiments. Any of the embodiments of the pump assembly 1000 disclosed herein include any of the other pumps disclosed herein or incorporated herein by reference, including the embodiments of the pump assembly 104 described above. It may have any of the same or similar components, features, materials, sizes, configurations, and other details as the assembly embodiment. Preferably, the pump assembly 1000 can be miniaturized and portable, but larger conventional portable or non-portable (eg, wall suction) pumps can also be used. The pump assembly 1000 can include a switch or button 1002, illustrated as an enable / pause button located outside the housing of the pump assembly. As described below, button 1002 can be configured to stop, pause, and / or resume treatment. Although illustrated as push button 1002, other types of switches or buttons may be included, such as a touchpad, touch screen, keyboard, and the like.

The pump assembly can further include a connector 1050 (for connecting a conduit, eg, for connecting the conduit 106) and three LED indicators 1062, 1064, and 1066. As shown, LED indicator 1062 (eg, an OK indicator) can be configured to indicate normal / abnormal operation of the system. For example, an active (eg, lit) indicator 1062 can represent normal operation. An LED indicator 1064 (eg, a bandage indicator) can be configured to indicate a leak in the system. For example, an active (eg, lit) indicator 1064 can represent a leak. The LED indicator 1066 (eg, battery indicator) can be configured to indicate the remaining capacity or life of the power source (eg, battery). For example, an active (eg, lit) indicator 1066 can represent a low capacity. In some embodiments, the indicators 1062, 1064, and 1066 can be different colors, two different colors (eg, two indicators can share the same color), or the same color. The pump assembly preferably includes three LED indicators and one on / off push button, but other configurations, locations, and types of indicators, alarms, and switches can be used instead. In some embodiments, the pump assembly 1000 can include visual, audible, tactile, and other types of indicators or alarms configured to signal various operating conditions to the user. . Such conditions include system on / off, standby, pause, normal operation, bandage problems, leaks, errors and the like. The indicator can include a speaker, a display, a light source, etc., and / or combinations thereof.

FIG. 22 illustrates a cross-sectional view illustrating the interior of a pump assembly 1000 according to some embodiments. As shown, the housing 1020 can enclose the pump assembly. The one-way flow valve 1030 maintains a negative pressure level when the negative pressure source is not active (eg, prevents leakage), and fluids and / or exudates that are aspirated or removed from the wound via the connector 1050 It can be configured to prevent entry into the pump assembly. A control board 1040, such as a printed circuit board assembly (PCBA), can be configured to mechanically support and electrically connect various electrical / electronic components described below. PCBA can be single-sided or double-sided. A negative pressure source 1090, such as a pump, can aspirate fluid and / or exudate from the wound. In any of the embodiments disclosed herein, negative pressure source 1090 is the same component as any of the other negative pressure source embodiments disclosed herein, including but not limited to pump 232 described above. , Features, limitations, or other details. Negative pressure sources for various pumps, including peristaltic pumps, piston pumps, rotor blade pumps, liquid ring pumps, scroll pumps, diaphragm pumps, piezoelectric pumps (eg, diaphragm pumps operated by piezoelectric transducers), etc., or combinations thereof Can be used for The pump assembly preferably includes a small, low noise, low power pump, although any suitable pump can be used instead. The pump assembly 1000 includes an indicator 1060 (eg, an LED), a pressure sensor 1070 that monitors system pressure, such as the pressure under the bandage, and a battery cover 1080 configured to provide access to the battery compartment 1100. including. The pump assembly is preferably powered by two standard disposable alkaline batteries (eg, two AA batteries), but uses any type of power source instead, including rechargeable batteries and external power be able to.

FIG. 23 shows a system schematic diagram of a pump assembly 1000 according to some embodiments. The pump assembly includes a push button 1002, a control panel 1040, and an indicator 1060. The pump assembly 1000 can be powered by the battery cell 1130. The pump assembly also includes a pump 1090 such as a diaphragm pump powered by an electric motor 1092 and a pressure sensor 1070. The inlet 1120 can be configured to connect the pump assembly 1000 to the bandage. eg, via a conduit. Inlet 1120 can be connected to a one-way valve 1030 to help maintain negative pressure levels when the negative pressure source is inactive, avoid leakage, and fluid and / or leaching that is aspirated or removed from the wound It can be configured to prevent objects from entering the pump assembly 1000. Pump 1090 can also be connected to outlet 1110. In some embodiments, the outlet 1110 can be configured to release air into the atmosphere. In some embodiments, a filter (not shown) can be sandwiched between the outlet and the atmosphere. The filter can be a bacterial filter, an odor filter, etc., or any combination thereof.

FIG. 24 shows a schematic diagram of the electrical components of a pump assembly 1000 according to some embodiments. Module 1140, which can be a control board (eg, PCBA), can include an input / output (I / O) module 1150, a controller 1160, and a memory 1170. In some embodiments, the module 1140 can include additional electrical / electronic components, such as one or more fuses. The controller 1160 can be a microcontroller, processor, microprocessor, etc., or any combination thereof. For example, the controller 1160 can be of the STM8L MCU family type from ST Microelectronics, such as STM8L 151G4U6, or the MC9S08QE4 / 8 series type from Freescale, such as MC9S08QE4CWJ. Preferably, the controller 1160 is a low power or ultra low power device, although other types of devices can be used instead. The memory 1170 may be a read only memory (ROM), a write once read many memory (WORM), a random access memory (eg, SRAM, DRAM, SDRAM, DDR, etc.), a solid state memory, a flash memory, a magnetic storage device, etc. One or more of volatile and / or nonvolatile memory modules may be included, such as one or more of any combination. The memory 1170 may be configured to store program code or instructions (executed by the controller), system parameters, operational data, user data, etc., or any combination thereof.

The I / O module 1150 may be configured to function as an interface between the controller 1160 and other system components that provide and / or respond to electromagnetic signals. In other words, the I / O module 1150 can be configured to allow the controller 1160 to monitor system operation and control other components of the system. In some embodiments, as shown, the I / O module 1150 can be in electromagnetic communication with a button 1002, an indicator 1060, a pressure sensor 1070, a power source 1130, and a negative pressure source 1090. An I / O module may comprise an interface or multiple interfaces configured to communicate with various components. Interfaces can include standard and / or non-standard ports, such as serial ports, parallel ports, bus interfaces, etc., or any combination thereof.

In some embodiments, the pump assembly 1000 can be configured to control the operation of the system. For example, the pump assembly 1000 delivers treatment without interruption and / or avoids inconvenience to the user, for example by frequently or unnecessarily suspending or postponing treatment, and it can be configured to conserve power and provide an appropriate balance between the desire to limit noise and vibration generated by the negative pressure source. FIG. 25 illustrates a high-level diagram 1200 of operation of a pump assembly according to some embodiments. In some embodiments, the controller 1140 can be configured to implement the flow of state diagram 1200. As shown in FIG. 25, the operation of the pump assembly is, in some embodiments, inactive / initialized (states 1206 and 1202), active state 1210, operating 1250, and end of life (state 1214). Can be grouped into four general state categories. As shown in FIG. 25 and FIG. 26, the state categories 1210 and 1250 each include a plurality of states and transition between the states.

In some embodiments, as long as the power source is not connected and removed (illustrated by transition 1204) or the pump assembly is operated (eg, by pulling on an operating strip or activating a switch, etc.) Unless otherwise, the pump assembly remains in state 1206. While remaining in this state, the pump assembly can remain inactive. When power is connected and / or when the pump assembly is first operated, the pump assembly may transition to state 1202 to perform one or more power-on self tests (POST). Power-on self-diagnosis (s) include inspecting the memory 1170 (eg, performing a check such as periodic redundancy check of program code to determine its integrity, inspecting random access memory, etc.) Reading the pressure sensor 1070 to determine whether or not the pressure value is within appropriate limits, reading the remaining capacity or life of the power source (eg, battery voltage, current, etc.) and making it within the appropriate limits It may include performing various checks to ensure proper functionality of the system, such as determining whether or not there is, and examining the negative pressure source. As shown, the indicator 1060 (eg, LED) may be configured to indicate to the user (eg, by blinking or blinking once) that the pump assembly is undergoing a POST test (s). Can do.

In some embodiments, the pump assembly can transition to an unrecoverable error state 1214 if one or more of the POST test (s) fail. While in this state, the pump assembly can be deactivated and the indicator 1060 can be configured to indicate to the user that an error has been encountered. In some embodiments, all indicators can be configured to remain active. Based on the severity of the error, in some embodiments, the pump assembly can be configured to recover from the error and continue operation (or transition to an unrecoverable error state 1214). As shown, the pump assembly may transition to state 1214 if it encounters a critical error during operation. Deterministic errors include program memory errors, program code errors (eg, encountering invalid variable values), controller operating errors (eg. watchdog timer expires without being reset by controller 1160), component Faults (eg, negative pressure source inoperability, pressure sensor 1070 inoperability, etc.) and any combination thereof may be included.

Upon passing the POST test (s), in some embodiments, the pump assembly can transition to a manual pause state 1216. As shown, this transition can be indicated to the user by deactivating one of the indicators 1060 (eg, battery indicator 1066). When the pump assembly transitions to the manual pause state 1216 and remains there, instructions can be provided to the user, such as by deactivating indicators 1062 (OK indicator) and 1064 (bandage indicator). In some embodiments, treatment can be postponed while the pump assembly remains in the manual pause state 1216. For example, a negative pressure source (eg, pump 1090) can be deactivated (or turned off). In some embodiments, the indication can be provided by deactivating the negative pressure source.

In some embodiments, the pump assembly can be configured to make a transition 1224 from a manual pause state 1216 to an operational state category 1250 in response to receiving a signal from the switch (the pump assembly is treated). If configured to deliver). For example, the user can press a button to start, postpone, and / or resume treatment. In some embodiments, the pump assembly can be configured to monitor the duration that the pump assembly remains in the manual pause state 1216. This can be accomplished, for example, by maintaining a timer (of firmware, software, hardware, or any combination thereof) that can be reset and started when the pump assembly transitions to the manual pause state 1216. Can do. The pump assembly can be configured to automatically make a transition 1224 from a manual pause state 1216 to an operational state category 1250 when the duration exceeds a threshold. In some embodiments, such a threshold can be a set value, such as between 1 minute or less and 1 hour or more. In some embodiments, the threshold can be set or changed by the user. in some embodiments, the threshold can be varied based on various operating conditions or any combination thereof. For example, the threshold can be decreased as the pump assembly approaches the end of life (as described below). In some embodiments, the user can pause therapy by actuating a switch (eg, pressing a button), which causes the pump assembly to move from an operational category 1250 to a manual suspended state 1216. Transition 1222 is performed. in some embodiments, the pump assembly can be configured so that the user can simply suspend treatment, but the treatment is stopped by disconnecting the power source (eg, removing the battery).

In some embodiments, the pump assembly can be configured to include a paused state 1218. An indication can be provided to the user when the pump assembly transitions to and remains in the paused state 1218. For example, the pump assembly can be configured to deactivate the OK indicator 1062 and blink or blink the bandage indicator 1064. In some embodiments, treatment can be postponed while the pump assembly remains in the manual pause state 1216. For example, a negative pressure source (eg, pump 1090) can be deactivated (or turned off), thereby providing the user with an indication that the pump assembly is in a paused state 1218. As will be described below, in some embodiments, the pump assembly may be configured when the number of retry cycles exceeds the retry limit (transition 1228) or when the duty cycle is determined to exceed the duty cycle limit (transition). 1230), and can be configured to transition from the operational state category 1250 to the paused state 1218. In some embodiments, transitions 1228 and 1230 may reflect the presence of a leak in the system.

In some embodiments, the pump assembly is responsive to receiving a signal from a switch (eg, a user pressing a button to resume therapy) from a paused state 1218 to an operational state category 1250 (where the pump assembly is The pump can be operated to transition 1226 to deliver therapy. In some embodiments, the pump assembly can be configured to monitor the duration that the pump assembly remains in the paused state 1218. For example, this can be accomplished by maintaining a timer (of firmware, software, hardware, or any combination thereof) that can be reset and started when the pump assembly transitions to a paused state 1218. . The pump assembly can be configured to automatically make a transition 1226 from the paused state 1218 to the operational state category 1250 when the duration exceeds a threshold. The threshold can be the same as or different from the threshold of the manual pause state 1216 described above. in some embodiments, the threshold can be a set value, such as between 1 minute or less and 1 hour or more. In some embodiments, the threshold can be set or changed by the user. In some embodiments, the threshold can be varied based on various operating conditions or any combination thereof. For example, the threshold can be decreased as the pump assembly approaches the end of life (as described below).

In some embodiments, the pump assembly includes both a manual pause state 1216 and a pause state 1218 to distinguish different causes of suspending treatment. Such discriminating ability may allow the pump assembly to provide the user with a specific cause indication for suspending therapy (eg, manual pause state 1216 and pause state 1218 may provide different indications). Can be provided). For example, therapy can be paused by a user manually pressing a button, in which case the pump assembly can make a transition 1222 from an operational state category 1250 to a manual pause state 1216. As another example, treatment can be paused by detecting a leak, in which case the pump assembly can make a transition 1228 and / or 1230 from an operational state category 1250 to a paused state 1218. . In some embodiments, the pump assembly can be configured to include one state that indicates a postponement or suspension of treatment delivery, or more than two such states.

In some embodiments, the pump assembly can be configured to monitor the remaining capacity or life of the power source (eg, by periodically reading or sampling battery voltage, current, etc.). The pump assembly can be configured to indicate the remaining capacity to the user. For example, when it is determined that the power supply has a normal remaining capacity (for example, 2.7 V, 2.6 V, 2.5 V, etc. as a result of comparison with a threshold), the battery indicator 1066 can be deactivated. If it is determined that the power source has a low remaining capacity, the pump assembly may be configured to provide instructions to the user, for example, by blinking or blinking the battery indicator 1066, as shown by transition 1220. it can. In some embodiments, the battery indicator 1066 can be configured to blink or blink intermittently or continuously, regardless of which state the pump assembly is in or only certain states. .

In some embodiments, once it is determined that the remaining capacity of the power source is at or near a critical level (e.g., 2.4V, 2.3V, 2.2V, etc. as compared to a threshold), the pump assembly Can be configured to transition to a battery critical state 1212. In some embodiments, the pump assembly can be configured to remain in this state until the power supply capacity is increased, such as by replacing or recharging the power supply. The pump assembly can be configured to deactivate the therapy while remaining in the battery critical state 1212. In addition, as shown, the pump assembly can be configured to indicate to the user that the power source is at or near a critical level, for example, by deactivating all indicators.

In some embodiments, the pump assembly can be configured to provide therapy for a predetermined period of time, such as about 1 day, 2-10 days, etc. following the first operation. In some embodiments, such time period can be a set value that is changed by the user and / or changed based on various operating conditions or any combination thereof. The pump assembly can be discarded at the end of such period. In some embodiments, the first motion can be reflected by a transition to the active state category 1210, such as by pulling the motion strip (eg, transition to state 1202). Once the pump assembly is operated, the pump assembly can be configured to monitor the duration that it has remained active. In some embodiments, the pump assembly can be configured to monitor the cumulative duration remaining in the activity category 1210. This can be accomplished, for example, by maintaining a timer (of firmware, software, hardware, or any combination thereof) that reflects such duration.

When the duration reaches or exceeds a threshold (eg, 7 days), the pump assembly may be configured to transition to an end of life (EOL) state 1240. The pump assembly may be configured to deactivate the therapy while remaining in state 1240 and indicate to the user that the end of the useful life of the pump assembly has been reached. For example, the pump assembly can be configured to deactivate all indicators and / or deactivate buttons. In some embodiments, when the pump

assembly is disposable, transitioning to the end of life state 1240 means that the pump assembly can be discarded. The pump assembly can be configured such that once the end of life is reached, the pump assembly cannot be operated again. For example, the pump assembly can be configured so that it cannot be operated again even if the power is disconnected and then reconnected, which stores instructions, values, flags, etc. in a read-only memory Can be achieved.

FIG. 26 illustrates an operational flow in the state category 1250 of the pump assembly 1000 according to some embodiments. The pump assembly can be configured to deliver therapy, monitor system leaks, provide instruction (s) to the user, and the like. As described below, in some embodiments, the pump assembly provides a first desired negative pressure level (e.g., a negative pressure between −5 mmHg or lower to −200 mmHg or higher, such as −100 mmHg) under the bandage 1010. The treatment can be configured to be delivered by first trying to establish. in some embodiments, the first desired negative pressure level may be a set value that is set or changed by the user and / or changed based on various operating conditions or any combination thereof. it can. Once the first desired negative pressure level is established under the bandage 1010, the pump assembly can be configured to deactivate the negative pressure source (eg, pump). When the negative pressure under the bandage 1010 decreases due to system leakage (i.e., decreases toward normal atmospheric pressure), the pump assembly operates the pump to provide a second desired negative pressure level under the bandage (For example, by establishing a negative pressure between −5 mmHg or less and −200 mmHg or more, such as −100 mmHg, it can be configured to recover the negative pressure under the bandage. In some embodiments, the second desired negative pressure level may be a set value that is set or changed by the user and / or changed based on various operating conditions or any combination thereof. it can. In some embodiments, the first and second desired negative pressure levels can be the same. In some embodiments, the first and second desired negative pressure levels can be different, i.e., the second negative pressure level is lower than the first negative pressure level or vice versa. Can do.

In some embodiments, the pump assembly can transition from manual pause state 1216 and / or pause state 1218 to state 1252. As described above, this transition can be caused by the user pressing a button to start / resume treatment and / or when a duration such as one hour has elapsed. The pump assembly is configured to immediately transition to an initial pump down (IPD) state 1260 where the pump can be operated to establish a first desired negative pressure level under the bandage 1010. be able to. In some embodiments, the pump can be operated when the pressure level under the bandage is above (less than) the first desired negative pressure level. Operating the negative pressure source to establish a first desired negative pressure level under the bandage 1010 may be referred to herein as "initial pump down". The pump assembly can be configured to indicate to the user that an initial pump down is being performed, for example, by blinking or blinking the OK indicator 1062 and deactivating the bandage indicator 1064. in some embodiments, the indication can be provided, for example, by operating a negative pressure source. The pump assembly can be configured to measure the pressure level under the bandage 1010 by reading or sampling the sensor 1070.

In some embodiments, the pump assembly can be configured to monitor the duration that the pump assembly remains in the IPD state 1260. This can be accomplished, for example, by maintaining a timer (of firmware, software, hardware, or any combination thereof) that can be reset and started when the pump assembly transitions to IPD state 1260. Can do. In some embodiments, to conserve power, limit noise and / or vibrations generated by the pump, etc., the pump assembly postpones the initial pump down operation for a predetermined period of time, after which the initial pump down is Can be configured to retry. This functionality, for example, saves battery power and allows transient and / or non-transient leaks to be resolved without user intervention, or allows the user to correct the leak (eg, straighten the bandage). , Repair seal, check one or more connections, etc.).

In some embodiments, the pump assembly may be configured to make a transition 1264 to state 1266 when the duration of stay in IPD state 1260 is equal to or exceeds a threshold (eg, 30 seconds). Can do. In some embodiments, the threshold can be a set value, such as between 5 seconds or less and 5 minutes or more. In some embodiments, the user can set or change the threshold. In some embodiments, the threshold can be varied based on various operating conditions or any combination thereof. In some embodiments, the pump assembly can be configured to deactivate the pump when performing transition 1264. The pump assembly maintains a counter that can be reset in state 1252 and updated in wait state 1270, for example, the number of attempts made to establish the first desired negative pressure under the bandage 1010. Can be configured to monitor). In some embodiments, the pump assembly can be configured to provide a limited or maximum number of IPD retry attempts. eg, to conserve power. Preferably, the pump assembly may be configured to provide a limited number of consecutive IPD retry attempts, but the pump assembly may be configured to provide a limited number of non-consecutive IPD retry attempts, or continuous and It can be configured to provide a mix of non-sequential IPD retry attempts. The threshold for IPD retry attempts may be 1, 2, 3, 4, 5, etc. In some embodiments, the threshold can be a set value. In some embodiments, the threshold can be set or changed by the user. In some embodiments, the threshold can be varied based on various operating conditions or any combination thereof.

In some embodiments, the pump assembly, in state 1266, determines whether the number of IPD retry attempts made is equal to or exceeds a threshold (eg, one retry attempt). Can be configured to determine. If the number of IPD retry attempts made is equal to or exceeds the threshold, the pump assembly makes transition 1228a to pause state 1218 where treatment is paused or postponed as described above. It can be constituted as follows. Otherwise, the pump assembly can be configured to make a transition 1268 to the standby state 1270. In some embodiments, the pump assembly can be configured to deactivate the negative pressure source at state 1266, thereby providing an indication to the user that the pump assembly has transitioned to state 1266. it can.

In some embodiments, the pump assembly deactivates the stand-by 1270 pump, thereby suspending the therapy for a predetermined period of time (eg, between 1 second and 1 minute, such as 15 seconds). It can be constituted as follows. This can be accomplished, for example, by maintaining a timer (of firmware, software, hardware, or any combination thereof) that can be reset and started when the pump assembly transitions to standby state 1270. Can do. This period in the wait state 1270 can be preset or variable (eg, automatically or by the user). In some embodiments, the time period can vary based on various operating conditions or any combination thereof. The period during which the pump assembly remains in the standby state 1270 is increased or decreased at each transition to the standby state 1270 (eg, multiplied by a factor between 0.1 and less than 4.0, such as 2, etc.). be able to. The period can be increased or decreased in each series of transitions to the wait state 1270. The time period can be increased or decreased until it equals or exceeds a threshold (eg, between 1 second and 5 minutes or more, such as 4 minutes). In addition, the time period can be reset to an initial value upon transition to the monitored pressure state 1280, transition to the manual pause state 1216, and transition to the pause state 1218.

In some embodiments, the pump assembly can be configured to indicate to the user that the pump assembly is in a standby state 1270. For example, the pump assembly can be configured to blink or blink the OK indicator 1062 and deactivate the bandage indicator 1064. In some embodiments, shutting down the pump can provide an indication that the pump assembly is in a standby state 1270. Once the standby period has elapsed, the pump assembly can be configured to make a transition 1272 from the standby state 1270 to the IPD state 1260, wherein the pump assembly is configured with a first desired underneath bandage 1010. Attempts can be made to establish negative pressure levels. In some embodiments, the pump assembly can be configured to ensure that the negative pressure level under the bandage remains above a certain safety level. For example, the pump assembly can be configured to maintain a negative pressure level below the bandage 1010 that exceeds a safety level between −150 mmHg or lower to −250 mmHg or higher, such as −225 mmHg

In some embodiments, the pump assembly can be configured to make a transition 1276 to the monitoring state 1280 once the first desired negative pressure level under the bandage 1010 has been established. The pump assembly may be configured to reset the number of IPD retry attempts when making transition 1276. The pump assembly may be configured to instruct the user to transition to the monitoring state 1280, for example, by blinking or blinking the OK indicator 1062 and deactivating the bandage indicator 1064. While remaining in the monitoring state 1280, the pump assembly deactivates the pump (thus providing an indication to the user that the pump assembly is in the monitoring state 1280) and the pressure level below the bandage 1010. Can be configured to be monitored periodically or continuously. The pump assembly can be configured to measure the pressure level under the bandage 1010 by reading or sampling the sensor 1070.

In some embodiments, the pump assembly decreases until the negative pressure level under the bandage 1010 reaches a threshold and / or exceeds (eg, falls below) the threshold, eg, due to a system leak. It can be configured to determine whether or not. The threshold value can be selected from a range between −10 mmHg or less and −100 mmHg or more, such as −50 mmHg. In some embodiments, the threshold value can be a set value that is set or changed by the user and / or changed based on various operating conditions or any combination thereof. If it is determined that the threshold has been reached or passed, the pump assembly can be configured to restore the negative pressure level under the bandage 1010. In some embodiments, the pump assembly can be configured to re-establish the first desired negative pressure level or to establish another different negative pressure level. This can be accomplished by making a transition 1282 to a maintenance pump down (MPD) state 1290.

In some embodiments, the pump assembly operates the pump with the pump assembly remaining in the MPD state 1290 to provide a desired negative pressure level under the bandage 1010 (eg, a first desired level). Can be configured to establish. The pump assembly can be configured to provide instructions to the user, for example, by blinking or blinking the OK indicator 1062 and deactivating the bandage indicator 1064. In some embodiments, the pump assembly that operates the negative pressure source can provide an indication to the user that the pump assembly has transitioned to state 1290. In some embodiments, the pump assembly may be configured to generate less noise and vibration when the pump is operated in the MPD state 1290 than when the pump is operated in the IPD state 1264. Can do. For example, the noise level difference can be between 1 dB or less and 30 dB or more, such as about 7 dB, about 20 dB. As another example, the noise level difference can be between 30 dB and 80 dB or more, such as about 45 dB, about 50 dB, about 65 dB, and the like.

In some embodiments, the pump assembly can be configured to monitor the duration that it remains in the MPD state 1290. This is accomplished, for example, by maintaining a timer (of firmware, software, hardware, or any combination thereof) that can be reset and started when the pump assembly makes a transition 1282 to MPD state 1290. can do. In some embodiments, the pump assembly postpones maintenance pump down operation for a predetermined period of time, such as to conserve power, limit noise and / or vibrations generated by the pump, and then the initial pump down. And / or may be configured to retry maintenance pump down. This functionality, for example, saves battery power and allows transient and / or non-transient leaks to be resolved without user intervention, or allows the user to correct the leak (eg, straighten the bandage). , Repair seal, check one or more connections, etc.).

In some embodiments, the duration of the MPD state 1290 is equal to or exceeds a threshold (eg, a value between 5 seconds and 5 minutes or more, such as 10 seconds) and the pressure level below the bandage 1010 is When the desired negative pressure level has not been reached, the pump assembly can be configured to make a transition 1292 to state 1294. The threshold can be a set value that is set or changed by the user and / or changed based on various operating states or any combination thereof. In some embodiments, the pump assembly can be configured to deactivate the pump when performing transition 1292, thereby providing the user with an indication that the pump assembly is performing the transition. Can do. The pump assembly resets the number of MPD attempts made to establish the desired negative pressure under the bandage 1010 (e.g., at state 1252 and / or when performing transition 1228b and performs transition 1296 it can be configured to monitor (by maintaining a counter that can sometimes be updated). In some embodiments, the pump assembly can be configured to provide a limited or maximum number of MPD retry attempts (eg, to conserve power). Preferably, the pump assembly can be configured to provide a limited number of consecutive MPD retry attempts, but the pump assembly can be configured to provide a limited number of non-consecutive MPD retry attempts, or continuous and It can be configured to provide a mixture of non-sequential retry attempts. The threshold for MPD retry attempts may be 1, 2, 3, 4, 5, etc. In some embodiments, the threshold value can be a set value that is set or changed by the user and / or changed based on various operating conditions or any combination thereof. The pump assembly can be configured to set the number of IPD and MPD retry attempts to the same or different values. The pump assembly is configured to determine, at state 1294, whether the number of MPD retry attempts made is equal to or exceeding a threshold (eg, 3 retry attempts). can do. If the number of MPD retry attempts made is equal to or exceeds the threshold, the pump assembly makes transition 1228b to pause state 1218 where treatment is paused or postponed as described above. It can be constituted as follows. Otherwise, the pump assembly can be configured to make a transition 1296 to a wait state 1270 where treatment is suspended or postponed as described above. Alternatively, the pump assembly can be configured to transition to IPD state 1260 or MPD state 1290.

In some embodiments, the pump assembly may transition 1284 to a monitoring state 1280 if the pressure level under the bandage reaches or exceeds (eg, becomes greater than) the desired negative pressure level. Can be configured. The pump assembly may also be configured to reset the number of MPD retry attempts when making transition 1284.

In some embodiments, the pump assembly can be configured to monitor the duty cycle of the negative pressure source (eg, pump). The pump assembly can be configured to monitor the duty cycle periodically and / or continuously. Duty cycle measurements may reflect various operating conditions of the system, such as the presence and / or severity of leaks, the flow rate of fluid aspirated from the wound (eg, air, liquid, and / or solid exudates). it can. For example, a duty cycle measurement can indicate the presence of a large amount of leakage, and the pump assembly can indicate this condition and / or temporarily postpone or pause pump operation to save power. Can be configured. This functionality, for example, saves battery power and allows transient and / or non-transient leaks to be resolved without user intervention, or allows the user to correct the leak (eg, straighten the bandage). , Repair seal, check one or more connections, etc.).

In some embodiments, the pump assembly can be configured to monitor the duty cycle periodically, such as once every 10 seconds or less to once every 5 minutes or more. In some embodiments, the pump assembly can be configured to monitor the duty cycle once per minute. This can be set to expire every minute (eg, as indicated by an interrupt or via polling) and restarted (eg, by clearing the interrupt) , (By firmware, software, hardware, or a combination thereof). In some embodiments, the time interval for measuring the duty cycle can be a set value that is set or changed by the user and / or changed based on various operating conditions or any combination thereof. In some embodiments, the pump assembly is in an operational state category 1250 (ie, any of states 1260, 1256, 1270, 1280, 1290, 1294, and / or any transition between any states). Since it is sometimes configured to operate the pump, it can be configured to monitor the duty cycle when in this state category. In some embodiments, the pump assembly monitors the duty cycle when the pump assembly is in a particular state and / or state transition, or a subset of states and / or state transitions, of the operational state category 1250. Can be configured. In some embodiments, the pump assembly is configured such that the pump assembly is a specific state and / or state transition of an active state category 1210, a subset of states and / or state transitions, or all states and / or state transitions, or The duty cycle may be configured to be monitored when in any combination of any states and / or state transitions disclosed herein. As shown in FIG. 26, the pump assembly may perform a transition 1302 from any of states 1260, 1256, 1270, 1280, 1290, 1294 and / or a transition from any of the states to state 1300. Here, the pump assembly can determine the duty cycle of the pump during the elapsed minutes. The duty cycle can be determined according to the following equation:

DC = t / T (2)

Where DC is the duty cycle, t is the duration that the negative pressure source is active, and T is the total time under consideration. If the duty cycle is monitored once per minute (ie, T = 60 seconds), the duty cycle can be expressed as (eg, as a percentage):

DC = (pump operating time during elapsed time / 60) * 100% (3)

To determine the duty cycle, the pump assembly can be configured to monitor the duration that the pump has been active (eg, pump run time) and / or inactive.

In some embodiments, the pump assembly can be configured to compare the determined duty cycle to a duty cycle threshold that can be selected from a range between 1% or less and 50% or more. The comparison can indicate the presence of a system leak, for example. In other words, if the pump remains active for a period of time that reaches or exceeds the duty cycle threshold, the pump may be overworked to overcome the leak. In such cases, the pump assembly can be configured to postpone or suspend delivery of therapy. The pump assembly may be configured to provide an indication to the user that the pump is overworked (eg, the duty cycle

exceeds a duty cycle threshold), for example, by deactivating the negative pressure source. it can. In some embodiments, the duty cycle threshold may be a set value that is set or changed by a user and / or that is changed based on various operating conditions or any combination thereof. As shown in FIG. 26, the pump assembly can be configured to compare the determined duty cycle to a duty cycle threshold (eg, 9%). The pump assembly is configured to monitor the number of duty cycles that exceed a threshold, for example, by maintaining and updating an overload counter that can be reset when the pump assembly transitions from state 1252 to IPD state 1260. can do.

In some embodiments, the pump assembly can be configured to update an overload counter in state 1300. If the determined duty cycle does not exceed the duty cycle threshold, the pump assembly can decrement the overload counter. In some embodiments, the minimum value of the overload counter can be set to zero, i.e., the overload counter never becomes negative. Conversely, if the determined duty cycle is equal to or exceeds the duty cycle threshold, the pump assembly can increment the overload counter.

In some embodiments, the pump assembly can be configured to monitor the total number or total number of duty cycles equal to or exceeding the duty cycle threshold. This strategy helps smooth or average duty cycle variations to prevent one or several unstable cycles that may be caused by, for example, transient leakage by interrupting therapy. can do. In some embodiments, the pump assembly can be configured to monitor continuous or non-continuous duty cycles that exceed a duty cycle threshold. In some embodiments, the threshold value can be a set value that is set or changed by the user and / or changed based on various operating conditions or any combination thereof. If it is determined that the number of duty cycles that exceed the duty cycle threshold exceeds an overload threshold (e.g., between 1 and 60 or more, such as 30,), the pump assembly is postponed or suspended as described above. It can be configured to make a transition 1230 to the paused state 1216. In some embodiments, the pump assembly can be configured to deactivate the negative pressure source, thereby providing an indication to the user that the pump is overworked (eg, the duty cycle exceeds an overload threshold). Can be provided. If it is not determined that the number of duty cycles that exceed the duty cycle threshold exceeds the overload threshold, the pump assembly may be configured to make transition 1304 and remain in the operational state category 1250. In some embodiments, the pump assembly can be configured to return to the same state and / or transition between states from which the pump assembly has made transition 1302. in some embodiments, the pump assembly can be configured to transition to different states and / or transition between states.

In some embodiments, the pump assembly is further configured to postpone or pause treatment if the user presses button 1002 while the pump assembly is in the operational category 1250. In some embodiments, the pump assembly can be configured to transition to a manual pause state 1216.

FIG. 27 illustrates another state diagram of the operation of the pump assembly 1000 according to some embodiments. In some embodiments, the controller 1140 can be configured to implement the flow of state diagram 1400. In some embodiments, the flow 1400 can be generally similar to the flows shown in FIGS. State 1402 corresponds to state 1202, state 1406 corresponds to state 1260, state category 1410 corresponds to state category 1210, state 1414 corresponds to state 1214, state 1416 corresponds to state 1216, state 1418 Corresponding to state 1218, transition 1420 corresponds to transition 1220, transition 1422 corresponds to transition 1222, transition 1424 corresponds to transition 1224, transition 1426 corresponds to transition 1226, and state 1440 corresponds to state 1240. To do. In addition, state category 1450 corresponds to state category 1250, state 1460 corresponds to state 1260, transition 1464 corresponds to transition 1264, state 1466 corresponds to transition 1266, and transition 1468 corresponds to transition 1268. , Transition 1428a corresponds to transition 1228a, state 1470 corresponds to state 1270, and transition 1472 corresponds to transition 1272. Further, transition 1476 corresponds to transition 1276, state 1480 corresponds to state 1280, transition 1482 corresponds to transition 1282, state 1490 corresponds to state 1290, transition 1492 corresponds to transition 1292, state 1494 Corresponding to state 1294, transition 1496 corresponds to transition 1296, and transition 1428b corresponds to transition 1228b.

In some embodiments, the pump assembly can be configured to monitor the duty cycle after a desired negative pressure level is established under bandage 1010 in MPD state 1490. In some embodiments, the pump assembly can also take into account the duration that the pump was active while the pump assembly remained in the IPD state 1460. As shown, the device can be configured to make a transition 1484 from MPD state 1490. Transition 1484 may be similar to transition 1284, but instead of transitioning directly to IPD state 1460, the pump assembly may be configured to monitor the duty cycle of state 1500. In some embodiments, the pump assembly can be configured to monitor the duty cycle for the cumulative period during which the pump assembly remains in the monitoring state 1480 and the MPD state 1490. in some embodiments, the pump assembly may be configured to monitor the duty cycle over the previous or past monitoring and accumulation period during the MPD cycle. For example, just prior to transitioning to state 1500, the pump assembly may remain in MPD state 1490 for duration X (while the pump is active). in addition, just prior to transitioning to MPD state 1490, assuming that the pump assembly remained in monitoring state 1480 for duration Y (while the pump was inactive), the duty cycle (DC) Can be expressed as (for example, as a percentage):

DC = 100% * [X / (X + Y)] (4)

To determine the duty cycle, the pump assembly can be configured to monitor the duration that the pump has been active and / or inactive.

In some embodiments, the pump assembly can be configured to compare the determined duty cycle to a duty cycle threshold (eg, 9%), as described above. in some embodiments, the threshold value can be a set value that is set or changed by the user and / or changed based on various operating conditions or any combination thereof. If it is determined that the duty cycle is less than the threshold, the pump assembly may be configured to make a transition 1502 to the monitoring state 1480. Conversely, if it is determined that the duty cycle is equal to or exceeds the threshold, the pump assembly can be configured to make a transition 1504 to state 1506. In some embodiments, the pump assembly can provide an indication that the duty cycle exceeds a threshold, for example by deactivating the pump.

In some embodiments, the pump assembly can be configured to monitor the total time or total time for which the duty cycle is equal to or exceeds the threshold. This strategy helps smooth or average duty cycle variations to prevent one or several unstable cycles that may be caused by, for example, transient leakage by interrupting therapy. can do. Monitoring is by maintaining a timer (of firmware, software, hardware, or any combination thereof) that can be restarted (eg, during transition 1476) and updated (eg, in state 1506). Can be achieved. In some embodiments, the pump assembly is configured to determine whether the duty cycle is equal to or exceeds the threshold over a specific total period that can be compared to a total duration threshold. Can be configured. The threshold can be selected from a range between 5 minutes or less and 2 hours or more, such as 30 minutes. In some embodiments, the threshold value can be a set value that is set or changed by the user and / or changed based on various operating conditions or any combination thereof. If the total duration is equal to or exceeds the threshold, the pump assembly is configured to make a transition 1508 to a pause state 1418 that can be configured to postpone or pause the delivery of therapy. can do. In some embodiments, the pump assembly can indicate this transition to the user, for example, by deactivating the pump. Conversely, if it is determined that the total duration is less than the threshold, the pump assembly can be configured to make a transition 1510 to the monitoring state 1480. The pump assembly can be configured to indicate a transition 1510 to the user, for example, by blinking or blinking the OK indicator 1062 and deactivating the bandage indicator 1064.

FIG. 28 illustrates a graph 1600 illustrating duty cycle determination for a pump assembly 1000 according to some embodiments. The X axis represents time and the Y axis represents pressure. in some embodiments, the pump assembly can be configured to establish a negative pressure level of −100 mmHg below the bandage 1010, as represented by position 1606. For example, this can be done during the initial pump down of state 1260. The pump assembly can be configured to monitor the negative pressure level under the bandage 1010. For example, this can be implemented in the monitoring state 1280. As shown, the pump assembly can monitor pressure over time period a, as represented by interval 1602. The negative pressure level under the bandage 1010 can decrease over time (eg, due to system leakage), as indicated by line 1620.

In some embodiments, the pump assembly may restore the negative pressure level under the bandage 1010 when the pressure reduction reaches or exceeds a threshold of about −70 mmHg, as represented by position 1608, or it can be configured to re-establish. In some embodiments, the pump assembly can be configured to operate the pump, as indicated by line 1622. For example, this can be done by transitioning to the maintenance pump down state 1290. As shown, the pump assembly can operate the pump for a duration b (1604) until a negative pressure level of −100 mmHg is re-established under the bandage 1010. The pump assembly can be configured to shut down the pump when the pressure level below the bandage 1010 reaches −100 mmHg at position 1610. For example, this can be done by transitioning to a monitoring state 1280. The duty cycle (DC) over the time period indicated by 1600 (ie, a + b) can be expressed as (eg, as a percentage):

DC = 100% * [b / (a + b)] (5)

FIG. 29 illustrates a non-limiting example of normal (eg, no or small leak) operation 1700 of some embodiments of the pump assembly 1000. The pump assembly can be configured to establish a desired negative pressure level under the bandage 1010, as shown in box 1702. If the pressure level under the bandage 1010 rises above a desired level (eg, a first negative pressure setting value such as -70 mmHg), the pump assembly will operate a negative pressure source (eg, pump). The pressure level under the bandage 1010 can be configured to begin to reduce to a desired value. For example, the desired value can be approximately within the interval between the value of the first negative pressure set value and the value of the second negative pressure set value, or is approximately the value of the second negative pressure set value. (E.g., -100 mmHg). In some embodiments, this can be achieved in the initial pump down state 1260.

In some embodiments, when the pressure level below the bandage 1010 reaches a desired value, the pump assembly shuts down the pump and monitors the pressure level below the bandage, as shown in box 1704. Can be configured. For example, this can be achieved in the monitoring state 1280. The pump assembly can be configured to periodically or continuously monitor the pressure level under the bandage 1010, for example, by reading or sampling the sensor 1070. Based on the monitored pressure, the pump assembly determines whether the pump needs to be operated or restarted in box 1706 to re-establish the desired negative pressure level under the bandage 1010. can do. If it is determined that the monitored pressure is low (eg, less than or less than the first negative pressure setpoint value), the pump assembly is configured to operate the pump, as shown in box 1708. can do. For example, this can be achieved by transitioning to MPD state 1290. Conversely, if it is determined that the monitored pressure level is not low (eg, exceeds or exceeds the value of the first negative pressure setpoint), the pump assembly monitors the pressure level below the bandage 1010. Can be configured to continue. During this operational flow, the pump assembly can be configured to indicate to the user that it is operating normally. As shown at 1060a, the pump assembly can be operated, or the OK indicator 1062 can blink or blink, as shown as 1062a. In addition, the pump assembly can deactivate the bandage indicator 1064 and battery indicator 1066, shown as 1064a and 1066a, respectively

FIG. 30 illustrates a non-limiting example of operation 1800 of some embodiments of the pump assembly 1000 in the presence of a large amount of leakage. As described above with respect to FIG. 29, the pump assembly may be configured to establish a desired negative pressure level under the bandage 1010, as shown in box 1802. In some embodiments, when the pressure level below the bandage 1010 reaches a desired value, the pump assembly may deactivate the pump and monitor the pressure level below the bandage, as shown in box 1804. Can be configured. The pump assembly can be configured to periodically or continuously monitor the pressure level under the bandage 1010, for example, by reading or sampling the sensor 1070. Based on the monitored pressure level, the pump assembly may determine whether the pump needs to be operated or restarted to re-establish the desired negative pressure level under the bandage 1010. it can. If it is determined that the monitored pressure level is low (eg, less than or equal to the first negative pressure setpoint value), the pump assembly is configured to operate the pump, as shown in box 1808. Can be configured. Once the desired pressure level is re-established under the bandage 1010, the pump assembly can begin monitoring the negative pressure level under the bandage again (eg, transition to the monitoring state 1280).

In some embodiments, due to the presence of one or more leaks in the system, the pump assembly 1010 can be configured to perform multiple cycles of pump monitoring and reactivation. During this operational flow, the pump assembly can be configured to indicate to the user that the pump assembly is operating normally. As shown at 1060b, the pump assembly can be operated, or an OK indicator 1062, shown as 1062b, can blink or blink. In addition, the pump assembly can deactivate the bandage indicator 1064 and battery indicator 1066, shown as 1064b and 1066b, respectively. The pump assembly may be configured to continuously or periodically determine whether the pump is delivering too often, as shown in box 1810. As shown, in some embodiments, the pump assembly can be configured to use a duty cycle as an alternative to determining whether the pump is delivering too often. For example, the pump assembly can be configured to determine whether or not the pump is "overworked", so that the pump can be used while exceeding a threshold duration, such as 9% of the total treatment time. It is determined whether it is on. In other words, the pump assembly can be configured to determine whether the pump duty cycle reaches or exceeds the duty cycle threshold.

In some embodiments, the pump assembly is overworked for a certain duration (eg, the pump is on for more than about 2 hours a day, or is on for more than a predetermined amount of time). If the desired negative pressure level (for example, the value of the second negative pressure set value) is established, the pump operation is postponed or paused. can do. As shown in box 1812, the pump assembly can be configured to determine whether the pump has been overworked for a duration of 30 minutes or more. For example, the pump assembly can be configured to determine whether the duty cycle (s) monitored over the past 30 minutes exceeds a duty cycle threshold. For example, the pump assembly can determine whether the pump has been on for about 2 minutes 42 seconds or more in the last 30 minutes, which corresponds to a 9% duty cycle threshold.

In some embodiments, the pump assembly can be configured to suspend or postpone therapy if it is determined that the pump is overworked, as shown in box 1814. The pump assembly may be further configured to turn on a "leak alarm" indicator. As shown at 1060c, operating the pump assembly or blinking or blinking the bandage indicator 1064, shown as 1064b, and deactivating the OK indicator 1062 and battery indicator 1066, shown as 1062c and 1066c, respectively. it can. In order to resume treatment, the user may need to straighten the bandage, correct the leak, and / or operate the pump again. In some embodiments, the pump can be run again by pressing a start or run button on the pump, such as due to a timeout.

If one or more leaks are present in the bandage, in some embodiments, the pump assembly 1000 does not reach the second negative pressure setpoint value after a predetermined amount of pump operating time. In addition, the treatment can be programmed to be postponed or suspended, or otherwise configured as such. For example, in some embodiments, if the pump has been running continuously for X minutes and the pressure value of the second negative pressure setpoint has not been reached, the pump assembly may include an LED indicator, a "leak detection" LED indicator. Alarms, which can include 1064, or other alarms, can be activated to pause treatment. In some embodiments, the predetermined amount of time is about 5% of the total planned duration of the negative pressure treatment of the system, or about 3% or less to about 15 of the total planned duration of the negative pressure treatment of the system. % Or more. In some embodiments, the predetermined amount of time can be about 9 minutes, or about 4 minutes or less to about 40 minutes or more, or about 6 minutes to about 10 minutes.

FIG. 31 illustrates a non-limiting example of operation 1900 of some embodiments of pump assembly 1000 in the presence of a very large amount of leakage. As described above with respect to FIG. 29, the pump assembly can be configured to establish a desired negative pressure level under the bandage 1010, as shown in box 1902. In some embodiments, when the pressure level below the bandage 1010 reaches a desired value, the pump assembly may deactivate the pump and monitor the pressure level below the bandage, as shown in box 1904. Can be configured. The pump assembly can be configured to periodically or continuously monitor the pressure level under the bandage 1010, for example, by reading or sampling the sensor 1070. Based on the monitored pressure level, the pump assembly may determine whether the pump needs to be operated or restarted to re-establish the desired negative pressure level under the bandage 1010. it can. If it is determined that the monitored pressure level is low (eg, less than or equal to the first negative pressure setpoint value), the pump assembly is configured to operate the pump, as shown in box 1908. Can be configured. During this operational flow, the pump assembly can be configured to indicate to the user that the pump assembly is operating normally. As shown at

1060d, the pump assembly can be operated, or the OK indicator 1062, shown as 1062d, can blink or blink. In addition, the pump assembly can deactivate the bandage indicator 1064 and battery indicator 1066, shown as 1064d and 1066d, respectively.

In some embodiments, one or more leaks (eg, leaks having a relatively very high flow rate) cause the pump assembly to have a desired negative pressure level and / or a second negative pressure under the bandage 1010. The pressure setpoint value may not be reached. If the desired negative pressure level under the bandage has not been reached after a predetermined amount of operating time, the pump assembly can be configured to postpone or pause the pump, as shown in box 1914. For example, this can be accomplished by transitioning to a wait state 1270. In some embodiments, the predetermined amount of pumping time can be 10 seconds (as shown in FIG. 31). In some embodiments, the predetermined amount of pumping time can be about 5 seconds or less to about 60 seconds or more.

In some embodiments, the pump assembly can be configured to provide a limited number of retry cycles before suspending or delaying treatment. As shown in boxes 1920, 1922, and 1924, the pump assembly may be reactivated three times before deferring or suspending treatment (1914) and / or before operating an alarm such as a "leak alarm". It can be configured to go through a trial cycle. Some embodiments of the pump assembly may go through two retry cycles, four retry cycles, etc. prior to treatment suspension and / or alarm action. As shown at 1060e, operating the pump assembly or blinking or blinking the bandage indicator 1064, shown as 1064e, and deactivating the OK indicator 1062 and battery indicator 1066, shown as 1062e and 1066e, respectively. it can.

FIG. 32 illustrates a non-limiting example of operation 2000 of some embodiments of pump assembly 1000 in the presence of a very large amount of leakage. The pump assembly can be configured to quickly enter a suspend or postpone mode of treatment to avoid draining the battery in an attempt to deal with high flow leaks. As shown in box 2001, the pump assembly can be turned on, which can be accomplished, for example, by transitioning to operational state category 1250. As described above with respect to FIG. 29, the pump assembly can be configured to establish a desired negative pressure level under the bandage 1010, as shown in box 2002.

In some embodiments, if the leak is very high, such as when the pump is turned on but not yet connected to the bandage or is not properly connected to the bandage, the pump assembly may be Attempts to bring the lower pressure closer to the desired negative pressure level (eg, approximately the value of the second negative pressure setpoint, or a value that is within the interval between the first and second negative pressure setpoint values). However, it can be configured to operate for a predetermined amount of time. The pump assembly can be configured to postpone or pause treatment after a predetermined amount of time has elapsed. For example, this can be accomplished by transitioning to a wait state 1270. As shown, the pump assembly can be configured to operate the pump for 30 seconds. During this period, if the pressure under the bandage 1010 is not approaching the desired negative pressure, the pump assembly may be engaged for another predetermined amount of time (eg, 15 seconds as shown in FIG. 32). A timeout mode 2020 can be entered. During this operational flow, the pump assembly can be configured to indicate to the user that the pump assembly is operating normally. As shown at 1060f, the pump assembly can be operated or the OK indicator 1062 shown as 1062f can blink or blink. In addition, the pump assembly can deactivate the bandage indicator 1064 and battery indicator 1066, shown as 1064f and 1066f, respectively.

In some embodiments, the pump assembly can be configured to provide a limited number of retry cycles to establish a desired negative pressure level under the bandage 1010. As shown, after the first trial (or any number of additional trials), the pump assembly establishes or reestablishes the desired negative pressure level under the bandage, as shown in box 2002. It can be constituted as follows. In some embodiments, as shown in box 2014, after the first trial, the pressure under the bandage 1010 is at a desired level (eg, approximately the value of the second negative pressure setpoint, or the first and second values). If the pump assembly operates for another predetermined amount of time without approaching a value that is within the interval between the negative pressure setpoint values, the pump assembly is treated without retrying the pump down. Can be configured to be postponed or suspended. The pump assembly can be configured to remain in a postponed or paused state until the pump assembly is reactivated (eg, by a user pressing a button due to a timeout). The pump assembly can be configured to operate an alarm in this state. During this operational flow, the pump assembly can be configured to indicate to the user that one or more leaks are present. Operate the pump assembly or blink or blink the bandage indicator 1064, shown as 1064g, and deactivate the OK indicator 1062 and battery indicator 1066, shown as 1062g and 1066g, respectively, as shown at 1060g. It can.

Throughout the description and claims throughout this specification, the terms "comprise" and "contain", as well as variations of that term, eg, "comrising" and "comprises" include "but are not limited to". Means "including but not limited to" and is not intended (and not excluded) to exclude other parts, additions, components, integer values, or steps.

Throughout the description and claims, the singular includes the plural unless the context dictates otherwise. In particular, where indefinite articles are used, this specification should be understood as contemplating plural as well as singular unless the context requires otherwise. Further, in some embodiments, the term about is meant to refer to a value within 10% of the value presented, unless otherwise presented herein.

Any values provided herein, such as thresholds, limits, durations, timeouts, retry counts, etc. are not intended to be absolute values and can thus be approximate. In addition, any thresholds, limits, durations, timeouts, retry counts, etc. provided herein are fixed or can be changed automatically or by the user. Further, as used herein, relative terms such as greater than, greater than, less than, etc. with respect to a reference value are also intended to encompass being equal to the reference value. . For example, exceeding a reference value that is positive can encompass being equal to or greater than the reference value.

A feature, integer value, property, compound, chemical moiety, or group described in conjunction with a particular aspect, embodiment, or example is not incompatible with any other aspect described herein, It should be understood that it is applicable to the embodiments or examples. All of the features disclosed in this specification (including any appended claims, abstracts, and drawings) and / or all of the steps of any method or process disclosed in this specification are such features and / or Or it may be combined in any combination except combinations where at least some of the steps are mutually exclusive. Protection is not limited to the details of any of the above embodiments. Protection is disclosed to any novel or any novel combination of features disclosed herein (including any appended claims, abstracts, and drawings), or disclosed herein. Extends to any new or any new combination of steps of any method or process.

Although specific embodiments have been described, these embodiments have been presented by way of example only and are not intended to limit the scope of protection. Indeed, the novel methods and systems described herein may be embodied in various other forms. In addition, various omissions, substitutions, and changes may be made in the form of the methods and systems described herein. One skilled in the art will recognize that in some embodiments, the actual steps performed in the illustrated and / or disclosed process may differ from those shown in the drawings. Depending on the embodiment, certain of the above steps may be removed and others may be added. Accordingly, the scope of the present disclosure should be defined only by reference to the appended claims. The appended claims and their equivalents are intended to cover forms or modifications that fall within the scope and spirit of protection. For example, the various components shown in the drawings may be implemented as software and / or firmware in a processor, controller, ASIC, FPGA, and / or dedicated hardware. Moreover, the features and attributes of the specific embodiments described above may be combined in different ways to form additional embodiments, all of which are within the scope of this disclosure. While this disclosure provides certain preferred embodiments and applications, other embodiments that will be apparent to those skilled in the art are also disclosed, including embodiments that do not provide all of the features and advantages described herein. It is in the range. Accordingly, the scope of the present disclosure should be defined only by reference to the appended claims.

100 Depressurized Wound Treatment Device 102 Wound Dressing 104 Pump Assembly 106 Conduit 106a First End 106b Second End 108 Port 112 Connector 114 Conduit 114a Connector 120 Housing 120a First Housing Member 120b Second Housing Member 120c Guide, Channel 121 Tab 122 Control button 123 Depression 124 Battery cover 124a Latch, Tab member 124b Guide, Protrusion 124c Depression 124d Protrusion 125 Battery contact 128 Connector 132 Light 140 Conduit 142 Battery 148 Seal strip 150 First packaging element 151 Cover 153 Peripheral portion 190, 192, 193, 194, 196, 200a, 200b Recess 195 Raised 220 Battery compartment 222

Battery contact 22 4 Electric wire 230 Control panel 232 Pump 240 Manifold 246 One-way flow valve 250 Inlet port 252 Outlet port 260 Port 261 Opening 262 Conduit 270 Fastener 272 Label 300, 310, 320, 330, 340, 350, 360, 365, 370, 380, 390, 395, 400, 405, 410, 420 Packaging element 1000 Pump assembly 1002 Button 1020 Housing 1030 One-way flow valve 1040 Control panel 1050 Connector 1060, 1062, 1064, 1066 Indicator 1070 Pressure sensor 1080 Battery cover 1090 Negative pressure Source 1092 Electric motor 1100 Battery compartment 1110 Outlet 1120 Inlet 1130 Battery cell, power source 1140 Module 1150 Input / output module Lumpur 1160 controller 1170 memory

Patent Citations (70)

Publication number	Priority date	Publication date	Assignee	Title
JP2003521962A *	1999-04-09	2003-07-22	ケーシーアイ ライセンシング インコーポレイテッド	Wound treatment device
JP2008194294A *	2007-02-14	2008-08-28	Asahi Kasei Kuraray Medical Co Ltd	Sterilization method of hollow fiber membrane type blood purifier
JP2009509695A *	2005-10-03	2009-03-12	ケーシーアイ ライセンシング インコーポレイテッド	Patient interface system and method applied from outside
WO2009047524A2 *	2007-10-10	2009-04-16	Talley Group Limited	Medical apparatus for use in negative pressure wound therapy
US20090125004A1 *	2007-11-09	2009-05-14	Industrial Technology Research Institute	Detachable pump and the negative pressure wound therapy system using the same
JP2009523568A *	2006-01-23	2009-06-25	ケーシーアイ ライセンシング インク	System and method for treating wounds using ultrasonic debridement
JP2010515540A *	2007-01-10	2010-05-13	ウェイク フォーレスト ユニバーシティ ヘルス サイエンシーズ	Apparatus and method for wound treatment using periodic decompression
JP2010137084A *	2003-10-28	2010-06-24	Smith & Nephew Plc	Wound cleansing apparatus in-situ
WO2010144089A1 *	2009-06-10	2010-12-16	Tyco Healthcare Group Lp	Fluid collection canister including canister top with filter membrane and negative pressure wound therapy systems including same
JP2011504391A *	2007-11-21	2011-02-10	スミス アンド ネフュー ピーエルシー	Wound dressing
JP2011513003A *	2008-03-05	2011-04-28	ケーシーアイ ライセンシング インコーポレイテッド	Method for applying pressure to a dressing and a tissue site to collect and contain liquid from the tissue site
WO2011087871A2 *	2009-12-22	2011-07-21	Smith & Nephew, Inc.	Apparatuses and methods for negative pressure wound therapy
JP2011521739A *	2008-05-30	2011-07-28	ケーシーアイ ライセンシング インコーポレイテッド	Medical article assembly for wound treatment using reduced pressure
JP2011525383A *	2008-06-23	2011-09-22	カーメリ・アダハン	Tissue enclosure
WO2011130549A1 *	2010-04-16	2011-10-20	Kci Licensing, Inc	Evaporative body-fluid containers and methods
JP2012502748A *	2008-09-18	2012-02-02	ケーシーアイ ライセンシング インコーポレイテッド	Layered dressing, system and method for applying reduced pressure to a tissue site
JP2012507385A *	2008-10-29	2012-03-29	ケーシーアイ ライセンシング インコーポレイテッド	Depressurized abdominal treatment system and method
JP2012508037A *	2008-11-07	2012-04-05	ケーシーアイ ライセンシング インコーポレイテッド	Vacuum wound treatment dressing and system
JP2012508621A *	2008-11-14	2012-04-12	ケーシーアイ ライセンシング インコーポレイテッド	Fluid sac, system, and method for accumulating fluid from a tissue site
JP2012509723A *	2008-11-25	2012-04-26	スパイラキュア インコーポレイテッド	Device for delivering reduced pressure to the body surface
JP2012523915A *	2009-04-14	2012-10-11	ケーシーアイ ライセンシング インコーポレイテッド	Reduced pressure treatment system and method using variable cover
JP2012530539A *	2009-06-18	2012-12-06	タイコ ヘルスケア グループ リミテッド パートナーシップ	Vacuum bridging and / or exudate collection device

JP2013517996A *	2010-01-20	2013-05-16	ケーシーアイ ライセンシング インク	Wound connection pad and system and method for fluid perfusion and negative pressure wound closure therapy
JP2013517839A *	2010-01-22	2013-05-20	ケーシーアイ ライセンシング インク	Foaming fluid irrigation device, system and method for negative pressure wound therapy
JP2013524867A *	2010-03-16	2013-06-20	ケーシーアイ ライセンシング インコーポレイテッド	Patterned neoplastic epithelial dressing, system, and method
Family To Family Citations				
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GB1008347A	1963-07-23	1965-10-27	Cross Mfg Co 1938 Ltd	Improvements in stuffing boxes and packing therefor
GB1006983A	1963-11-26	1965-10-06	Eutectic Welding Alloys	Improvements in or relating to welding apparatus
GB1006986A	1964-01-24	1965-10-06	Telecomputing Corp	Ceramic materials and methods of preparation
GB1006988A	1964-06-03	1965-10-06	Arthur Stainthorpe	A method of and apparatus for utilising low grade heat for heating water for domestic use
US4643641A	1984-09-10	1987-02-17	Mici Limited Partnership Iv	Method and apparatus for sterilization of a centrifugal pump
US4969880A *	1989-04-03	1990-11-13	Zamierowski David S	Wound dressing and treatment method
US5178083A	1990-12-11	1992-12-22	Adahan Inc.	One-way umbrella valve and portable fluid pumping device including same
US7723560B2 *	2001-12-26	2010-05-25	Lockwood Jeffrey S	Wound vacuum therapy dressing kit
US7087036B2 *	2002-05-24	2006-08-08	Baxter International Inc.	Fail safe system for operating medical fluid valves
US7815616B2	2002-09-16	2010-10-19	Boehringer Technologies, L.P.	Device for treating a wound
GB0224986D0	2002-10-28	2002-12-04	Smith & Nephew	Apparatus
GB0308197D0	2003-04-09	2003-05-14	The Technology Partnership Plc	Gas flow generator
US20040219059A1 *	2003-05-03	2004-11-04	Novosci Corp.	Heart bypass system incorporating minimized extracorporeal blood circulation system and related method of use
US7708724B2	2004-04-05	2010-05-04	Blue Sky Medical Group Incorporated	Reduced pressure wound cupping treatment system
US7909805B2	2004-04-05	2011-03-22	Bluesky Medical Group Incorporated	Flexible reduced pressure treatment appliance
GB0409446D0	2004-04-28	2004-06-02	Smith & Nephew	Apparatus
US8062272B2	2004-05-21	2011-11-22	Bluesky Medical Group Incorporated	Flexible reduced pressure treatment appliance
GB0424046D0 *	2004-10-29	2004-12-01	Smith & Nephew	Apparatus
US7857806B2 *	2005-07-14	2010-12-28	Boehringer Technologies, L.P.	Pump system for negative pressure wound therapy
EP1986729A1 *	2006-02-02	2008-11-05	Coloplast A/S	A suction system
CN101378795A *	2006-02-02	2009-03-04	科洛普拉斯特公司	Device, pump and system for stimulating the healing of a wound
EP3932441A1 *	2006-02-06	2022-01-05	3M Innovative Properties Co.	Systems for improved connection to wound dressings in conjunction with reduced pressure wound treatment
GB0606661D0	2006-04-03	2006-05-10	Brightwake Ltd	Improvements relating to dressings
US8061360B2 *	2006-09-19	2011-11-22	Kci Licensing, Inc.	System and method for locating fluid leaks at a drape of a reduced pressure delivery system
RU2440150C2 *	2007-02-20	2012-01-20	КейСиАй Лайсенсинг Инк.	System and method of differentiating state of leak and state of reservoir disconnection in system of processing with lower pressure
JP2010525916A *	2007-05-07	2010-07-29	カルメリ アダハン	Suction system
GB0712737D0	2007-07-02	2007-08-08	Smith & Nephew	Apparatus
US7790946B2 *	2007-07-06	2010-09-07	Tyco Healthcare Group Lp	Subatmospheric pressure wound therapy dressing
RU70627U1 *	2007-09-17	2008-02-10	Вадим Владимирович Белов	DEVICE FOR VACUUM THERAPY OF PURULENT RAS

GB0722820D0	2007-11-21	2008-01-02	Smith & Nephew	Vacuum assisted wound dressing
US8764732B2	2007-11-21	2014-07-01	Smith & Nephew Plc	Wound dressing
ES2382895T3 *	2008-01-08	2012-06-11	Bluesky Medical Group Inc.	Wound treatment through variable and sustained negative pressure and method to control it
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CN102046120B	2008-04-04	2014-09-03	3M创新有限公司	Medical dressings with valve and kits containing same
US8048046B2 *	2008-05-21	2011-11-01	Tyco Healthcare Group Lp	Wound therapy system with housing and canister support
US20090299306A1	2008-05-27	2009-12-03	John Buan	Control unit with pump module for a negative pressure wound therapy device
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CA2752229C *	2009-02-12	2018-11-20	Perfuzia Medical, Inc.	Devices and methods for manipulating circulation in the circulatory system of a patient
EP2325525B1	2009-04-10	2018-11-07	KCI Licensing, Inc.	Devices for applying closed incision negative pressure wound therapy
SE533726C2 *	2009-04-30	2010-12-14	Moelnlycke Health Care Ab	Apparatus with negative pressure for treatment of wounds
US20110196321A1 *	2009-06-10	2011-08-11	Tyco Healthcare Group Lp	Fluid Collection Canister Including Canister Top with Filter Membrane and Negative Pressure Wound Therapy Systems Including Same
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CN201958601U	2010-12-20	2011-08-31	惠州市华阳多媒体电子有限公司	Miniature negative pressure pump
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Publication number	Priority date	Publication date	Assignee	Title
JP2018504949A *	2014-12-10	2018-02-22	ワールドワイドイノベーティブヘルスケア，インコーポレイテッド	Fixable tape and skin dressing without support
Family To Family Citations				
GB0325129D0	2003-10-28	2003-12-03	Smith & Nephew	Apparatus in situ
US8764732B2	2007-11-21	2014-07-01	Smith & Nephew Plc	Wound dressing
GB0723855D0	2007-12-06	2008-01-16	Smith & Nephew	Apparatus and method for wound volume measurement
GB201015656D0	2010-09-20	2010-10-27	Smith & Nephew	Pressure control apparatus
MX337627B	2010-11-25	2016-03-10	Smith & Nephew	Composition i-ii and products and uses thereof.
GB201108229D0	2011-05-17	2011-06-29	Smith & Nephew	Tissue healing
DK2773383T3	2011-11-02	2018-06-18	Smith & Nephew	Device for pressure ulcer treatment
US9084845B2	2011-11-02	2015-07-21	Smith & Nephew Plc	Reduced pressure therapy apparatuses and methods of using same
AU2013237095B2	2012-03-20	2017-10-05	Smith & Nephew Plc	Controlling operation of a reduced pressure therapy system based on dynamic duty cycle threshold determination
US9427505B2	2012-05-15	2016-08-30	Smith & Nephew Plc	Negative pressure wound therapy apparatus
DK2852418T3	2012-05-23	2018-07-16	Smith & Nephew	Apparatus for wound care with negative pressure
JP6307504B2	2012-08-01	2018-04-04	スミス アンド ネフュー ピーエルシー Smith & Nephew Public Limited Company	Wound dressing
US10695226B2	2013-03-15	2020-06-30	Smith & Nephew Plc	Wound dressing and method of treatment
AU2014227777B2	2013-03-15	2018-03-08	Smith & Nephew Plc	Wound dressing and method of treatment
JP6584431B2	2014-05-18	2019-10-02	スミス アンド ネフュー ピーエルシー Smith	Wound dressing and method of treatment

			& Nephew Public Limited Company	
WO2016010792A1 *	2014-07-18	2016-01-21	Kci Licensing, Inc.	Instillation cartridge and therapy system for negative-pressure therapy and instillation therapy
CN107708758B	2014-12-22	2021-06-08	史密夫及内修公开有限公司	Negative pressure wound therapy device and method
US10828403B2	2014-12-29	2020-11-10	Smith & Nephew Plc	Negative pressure wound therapy apparatus and methods for operating the apparatus
US11090193B2	2015-12-30	2021-08-17	Smith & Nephew Plc	Absorbent negative pressure wound therapy dressing
CN108472160B	2015-12-30	2022-02-22	史密夫及内修公开有限公司	Negative pressure wound therapy apparatus
WO2017132770A1 *	2016-02-04	2017-08-10	O.R. Science Inc.	Wound dressings and methods
CN106806064A *	2016-08-27	2017-06-09	浙江保尔曼生物科技有限公司	Wound healing and bone regeneration instrument and its application method
EP3506868A1 *	2016-08-31	2019-07-10	Smith & Nephew PLC	Systems and methods for controlling operation of a reduced pressure therapy system to detect leaks
WO2018150263A1 *	2017-02-15	2018-08-23	Smith & Nephew Pte. Limited	Negative pressure wound therapy apparatuses and methods for using the same
JP2020508794A *	2017-03-06	2020-03-26	ケーシーアイ ライセンシング インコーポレイテッド	System and method for improving battery life in portable negative pressure therapy through hysteresis control
EP3687592A1	2017-09-29	2020-08-05	T.J. Smith & Nephew, Limited	Negative pressure wound therapy apparatus with removable panels
CN109985283B *	2017-12-29	2021-08-13	厦门圣慈医疗器材有限公司	Negative pressure wound therapy devices, systems, and methods
US10624794B2	2018-02-12	2020-04-21	Healyx Labs, Inc.	Negative pressure wound therapy systems, devices, and methods
US11145196B2	2018-06-04	2021-09-20	T.J.Smith And Nephew, Limited	Device communication management in user activity monitoring systems
GB201813282DD *	2018-08-15	2018-09-26	Smith & Nephew	System for medical device activation and opertion
RU2723731C2 *	2019-09-30	2020-06-17	Геннадий Леонидович Багич	Method for simultaneous and periodic exposure of pressure to human skin areas and device for implementation thereof

* Cited by examiner, † Cited by third party, ‡ Family to family citation

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Publication	Publication Date	Title
JP6714535B2	2020-06-24	System and method for controlling the operation of a reduced pressure treatment system
JP5897724B2	2016-03-30	Decompression treatment device and method of using the same
US11258839B2	2022-02-22	Reduced pressure therapy apparatuses and methods of using same
US20190307934A1	2019-10-10	Systems and methods for controlling operation of a reduced pressure therapy system
JP2014532498A5	2015-01-22	
JP2014526924A5	2014-12-25	
JP2016127998A	2016-07-14	Pressure reduction treatment device and use method thereof

Priority And Related Applications

Child Applications (1)

Application	Priority date	Filing date	Relation	Title
JP2016038770A	2016-03-01	2016-03-01	Division	Pressure reduction treatment device and use method thereof

Priority Applications (1)

Application	Priority date	Filing date	Title
PCT/IB2011/002943	2011-11-02	2011-11-02	Reduced pressure therapy apparatuses and methods of using same

Legal Events

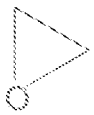
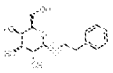
Date	Code	Title	Description
2014-11-05	A521	Request for written amendment filed	**Free format text**: JAPANESE INTERMEDIATE CODE: A523 **Effective date**: 20141104
2014-11-05	A621	Written request for application examination	**Free format text**: JAPANESE INTERMEDIATE CODE: A621 **Effective date**: 20141104
2015-09-29	A131	Notification of reasons for refusal	**Free format text**: JAPANESE INTERMEDIATE CODE: A131 **Effective date**: 20150928
2015-10-01	A977	Report on retrieval	**Free format text**: JAPANESE INTERMEDIATE CODE: A971007 **Effective date**: 20150930
2015-12-25	A521	Request for written amendment filed	**Free format text**: JAPANESE INTERMEDIATE CODE: A523 **Effective date**: 20151225
2016-01-26	TRDD	Decision of grant or rejection written	
2016-02-02	A01	Written decision to grant a patent or to grant a registration (utility model)	**Free format text**: JAPANESE INTERMEDIATE CODE: A01 **Effective date**: 20160201
2016-03-10	A61	First payment of annual fees (during grant procedure)	**Free format text**: JAPANESE INTERMEDIATE CODE: A61 **Effective date**: 20160302
2016-03-11	R150	Certificate of patent or registration of utility model	**Ref document number**: 5897724 **Country of ref document**: JP **Free format text**: JAPANESE INTERMEDIATE CODE: R150
2019-03-05	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2019-07-08	R531	Written request for registration of change of domicile	**Free format text**: JAPANESE INTERMEDIATE CODE: R313531
2019-07-17	R350	Written notification of registration of transfer	**Free format text**: JAPANESE INTERMEDIATE CODE: R350
2020-02-28	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2021-02-26	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2022-02-28	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250

Concepts

machine-extracted

Download Filter table

Name	Image	Sections	Count	Query match
fluid		claims,abstract,description	74	0.000
therapeutic procedure		claims,abstract,description	48	0.000
reduced		claims,abstract,description	26	0.000
communication		claims,abstract,description	24	0.000
wound		claims,description	305	0.000

packaging method and process	claims,description	107	0.000
sterilising	claims,description	72	0.000
sterilization and disinfection	claims,description	63	0.000
material	claims,description	61	0.000
absorbent	claims,description	56	0.000
absorbent	claims,description	56	0.000
liquid	claims,description	39	0.000
adhesive	claims,description	24	0.000
adhesive	claims,description	24	0.000
Exudates and Transudates	claims,description	22	0.000
foam	claims,description	22	0.000
method	claims,description	21	0.000
Skin	claims,description	14	0.000
polysiloxane	claims,description	14	0.000
water	claims,description	11	0.000
biological transmission	claims,description	9	0.000
fabric	claims,description	7	0.000
Bacteria	claims,description	6	0.000
oxane 	claims,description	5	0.000
(2R,3R,4S,5R,6S)-2-(hydroxymethyl)-6-(2-phenylethylsulfanyl)oxane-3,4,5-triol 	claims,description	3	0.000
initiatory	claims,description	3	0.000
inspiratory	claims,description	3	0.000
peripheral	claims,description	3	0.000
polyethylene terephthalate glycol copolymer	claims,description	3	0.000
weighing	claims,description	3	0.000
sealing	claims	8	0.000
coupling	claims	1	0.000
coupling process	claims	1	0.000
coupling reaction	claims	1	0.000

Show all concepts from the description section

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(12) 特許協力条約に基づいて公開された国際出願

(19) 世界知的所有権機関
国際事務局

(43) 国際公開日
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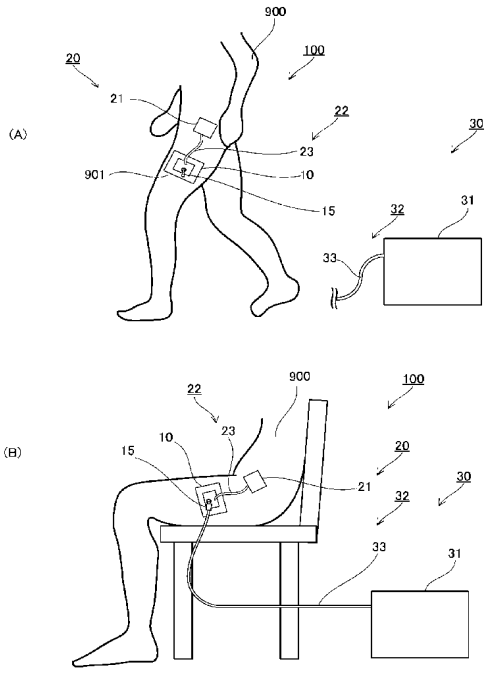
— 国際調査報告（条約第 21 条(3)）

(54) **Title**: NEGATIVE-PRESSURE CLOSURE THERAPY DEVICE

(54) 発明の名称 : 陰圧閉鎖治療装置



(57) **Abstract**: Provided is a negative-pressure closure therapy device with which an adequate suction flow rate can be used to apply, when necessary, negative pressure to a closed space formed by a wound dressing and a wound area, even if a pump device is miniaturized. In this therapy device (100), a pump device (30) having a high suction flow rate is fitted to a wound dressing (10) at times of extraordinary use when a high suction flow rate is necessary, and air is sucked from a closed space (904) formed by a wound area (903) and the wound dressing (10). Accordingly, an adequate suction flow rate can be ensured at times of extraordinary use, even if a pump device (20) for everyday use is miniaturized and the suction flow rate of the pump device (20) is reduced. As a result, the pressure value of the closed space (904) can be reduced to a desired value more swiftly.

(57) 要約: ポンプ装置が小型化されても、必要なときに十分な吸引流量で創傷包帯及び創傷部位によって形成される閉鎖空間を陰圧にする陰圧閉鎖治療装置を提供する。 治療装置（１００）は、多くの吸引流量が必要な非日常使用時に、吸引流量が多いポンプ装置（３０）が、創傷包帯（１０）に装着されて、創傷部位（９０３）及び創傷包帯（１０）によって形成される閉鎖空間（９０４）から気体を吸引するため、日常的使用のためのポンプ装置（２０）が小型化されてポンプ装置（２０）の吸引流量が少なくなっても、非日常使用時に十分な吸引流量を確保することができる。その結果、閉鎖空間（９０４）の圧力値は、より早く所望値まで低下する。

WO 2016/006458 A1

明　細　書

発明の名称 ： 陰圧閉鎖治療装置

技術分野

[0001] 本発明は、創傷部位の表面に陰圧をかけることにより、創傷部位の回復を促進させるための陰圧閉鎖治療装置に関する。

背景技術

[0002] 近年、創傷部位の表面に陰圧をかけることにより、創傷部位の回復を促進させる陰圧閉鎖治療が知られている。例えば、特許文献１には、創傷部位を覆う創傷包帯と、創傷包帯及び創傷部位によって形成される閉鎖空間から気体を吸引するポンプ装置と、を備える陰圧閉鎖治療装置が開示されている。特許文献１に記載の陰圧閉鎖治療装置は、ポンプ装置が閉鎖空間から気体を吸引することにより、当該閉鎖空間を陰圧にする。

[0003] また、特許文献１に記載の陰圧閉鎖治療装置では、ポンプ装置は、創傷部位の表面から滲み出た滲出液も吸引する。吸引された滲出液は、貯留部（収集キャニスタ）で貯留される。

[0004] 特許文献１に記載の陰圧閉鎖治療装置に限らず、利用者への装着を鑑みると、陰圧閉鎖治療装置のポンプ装置は、小型であることが望ましい。利用者は、ポンプ装置が小型であれば、例えばポンプ装置を携行して使用することができる。

先行技術文献

特許文献

[0005] 特許文献1：特開２０１３－２５５８２４号公報

発明の概要

発明が解決しようとする課題

[0006] しかしながら、ポンプ装置は、小型化されると、吸引を実現するポンプも小型化されるため吸引流量が低下してしまう。その結果、ポンプ装置の吸引流量は、当該ポンプ装置が小型化されると、閉鎖空間をより早く陰圧にする

ことが必要なときに、足りなくなる場合がある。

[0007] 同様に、滲出液を貯留する貯留部は、小型化されると、貯留容量が少なくなってしまう。その結果、貯留部の貯留容量は、当該貯留部が小型化されると、滲出液を多く貯留する必要があるときに、足りなくなる場合がある。

[0008] そこで、本発明の目的は、ポンプ装置が小型化されても、必要なときに十分な吸引流量で創傷包帯及び創傷部位によって形成される閉鎖空間を陰圧にする陰圧閉鎖治療装置を提供することにある。

課題を解決するための手段

[0009] 本発明の陰圧閉鎖治療装置は、主面の外周部が創傷部位の外周の皮膚表面に密着することで、該主面の中央部及び前記創傷部位の間に閉鎖空間を形成する創傷包帯と、前記創傷包帯に装着される第１流路と、前記閉鎖空間に前記第１流路を介して連通する第１吸引口と、を有する第１ポンプ装置と、前記創傷包帯に着脱自在に装着される第２流路と、前記閉鎖空間に前記第２流路を介して連通する第２吸引口と、を有する第２ポンプ装置と、を備える。

[0010] そして、前記第２ポンプ装置の吸引流量は、前記第１ポンプ装置の吸引流量より多く、前記第１ポンプ装置は、前記第１流路及び前記第１吸引口を介して前記閉鎖空間から流体を吸引し、前記第２ポンプ装置は、前記第２流路が前記創傷包帯に装着されているとき、前記第２流路及び前記第２吸引口を介して前記閉鎖空間から流体を吸引する。

[0011] 第１ポンプ装置の吸引流量が第２ポンプ装置の吸引流量より少ないため、第１ポンプ装置の吸引を実現するポンプは、第２ポンプ装置のポンプに比べて小型で済む。従って、第１ポンプ装置は第２ポンプ装置に比べて小型に実現可能である。

[0012] 例えば、利用者の日常的な使用のために第１ポンプ装置は駆動して閉鎖空間から流体を吸引し、利用者の非日常的な使用のために第２ポンプ装置を駆動して閉鎖空間から流体を吸引する。

[0013] 陰圧閉鎖治療装置の日常的な使用とは、閉鎖空間から吸引される流体の流量（吸引流量）が少なくてよいときの使用である。例えば、利用者は、既に

閉鎖空間が十分に陰圧になっているときに、陰圧閉鎖治療装置の日常的な使用として、第２流路を創傷包帯から取り外し、小型に実現可能な第１ポンプ装置を使用する。すなわち、利用者は、陰圧閉鎖治療装置の日常的な使用では、第２ポンプ装置を創傷包帯から取り外して、第１ポンプ装置のみを使用する。陰圧閉鎖治療装置の非日常的な使用とは、多くの吸引流量を必要とする使用である。例えば、利用者は、非日常的な使用として、創傷包帯を創傷部位に装着したばかりで、閉鎖空間をより早く陰圧にする必要があるときに、第２流路を創傷包帯に装着することにより、吸引流量が多い第２ポンプ装置を使用する。

[0014] 本発明の陰圧閉鎖治療装置は、多くの吸引流量が必要なときに、吸引流量が多い第２ポンプ装置が創傷包帯に装着されて、創傷部位及び創傷包帯によって形成される閉鎖空間から流体を吸引するため、利用者の日常的な使用のための第１ポンプ装置が小型化されても、必要なときに十分な吸引流量を確保して当該閉鎖空間を陰圧にすることができる。

[0015] また、前記第２流路が前記創傷包帯に装着されているとき、前記第１ポンプ装置及び前記第２ポンプ装置は、同時に駆動する態様であっても構わない。

[0016] これにより、陰圧閉鎖治療装置は、第２ポンプ装置の吸引流量が第１ポンプ装置の吸引流量を補助するため、必要なときにより多くの吸引流量を確保することができる。

[0017] また、本発明は、第２ポンプ装置の吸引流量が第１ポンプ装置より多いことに限らず、単に、前記第２流路が前記創傷包帯に装着されているとき、前記第１ポンプ装置及び前記第２ポンプ装置は、同時に駆動する態様であっても構わない。

[0018] 例えば、利用者は、第１ポンプ装置の吸引流量と第２ポンプ装置の吸引流量とが等しくても、非日常的使用時に第２ポンプ装置を補助的に使用する。

[0019] また、第１ポンプ装置は、前記第１流路の途中に設けられ、液体を貯留する第１貯留部を備え、第２ポンプ装置は、前記第２流路の途中に設けられ、

液体を貯留する第２貯留部を備え、前記第２貯留部の貯留容量は、前記第１貯留部の貯留容量より多くてもよい。

[0020] 第２貯留部は、第２流路が創傷包帯に着脱自在であるため、創傷包帯に着脱自在である。この構成では、陰圧閉鎖治療装置は、吸引流量が必要なときに、十分な吸引流量を確保するだけでなく、創傷部位からの滲出液を第２貯留部に貯留することにより、必要なときに十分な貯留容量を確保することもできる。

[0021] また、陰圧閉鎖治療装置は、前記創傷包帯に装着される第３流路と、前記第３流を介して前記閉鎖空間に連通し、前記創傷部位の洗浄用の洗浄液を貯留する第３貯留部と、を有する洗浄器具、を備えてもよい。

[0022] 洗浄液は、第３流路から閉鎖空間を介して第１流路及び第２流路へ順に流れることにより、創傷部位を洗浄する。この態様では、陰圧閉鎖治療装置は、洗浄液の流量が必要なときに第２ポンプ装置が駆動するため、第１ポンプ装置が小型化されても、十分な流量の洗浄液で閉鎖空間の創傷部位を洗浄することができる。

[0023] また、第１ポンプ装置を小型化するためには、以下のように構成するとよい。例えば、前記第１ポンプ装置は、圧電素子によって駆動するポンプ、を備える。

[0024] すなわち、第１ポンプ装置は、小型化のために、圧電ポンプを備えることが望ましい。圧電ポンプは、例えば、圧電素子と、当該圧電素子に接合される振動板と、を備える。圧電素子は、交番電圧が印加されると、主面の面方向に沿った伸縮を繰り返す。圧電素子は、主面の面方向に沿った伸縮を繰り返すと、接合された振動板を屈曲振動させる。圧電ポンプは、電磁ポンプ等に比べて小型化が容易である。また、圧電ポンプは、電磁ポンプ等に比べて振動が小さい点においても優れる。さらに、交番電圧の周波数を２０ｋＨｚ以上にすれば、振動板の振動音は、可聴周波数帯域外の２０ｋＨｚ以上となるため、利用者に聞こえにくくなる。

発明の効果

[0025] この発明の陰圧閉鎖治療装置は、吸引流量が必要なときに、第２ポンプ装置が創傷包帯に装着されて、創傷部位及び創傷包帯によって形成される閉鎖空間から流体を吸引するため、第１ポンプ装置が小型化されても、必要なときに十分な吸引流量を確保して当該閉鎖空間を陰圧にすることができる。

図面の簡単な説明

[0026] [図1]実施形態１に係る治療装置の上面側からの斜視図である。

[図2]実施形態１に係る治療装置の創傷包帯の装着時の側面断面図である。

[図3]実施形態１に係る治療装置の第１ポンプ装置の本体部の構成の一部を示すブロック図である。

[図4]（Ａ）は、実施形態１に係る治療装置の日常的な使用を説明するための図であり、（Ｂ）は、当該治療装置の非日常的な使用を説明するための図である。

[図5]実施形態１に係る治療装置の変形例に係る治療装置の非日常的な使用を説明するための図である。

[図6]実施形態２に係る治療装置の非日常的な使用を説明するための図である。

[図7]実施形態３に係る治療装置の創傷包帯の上面側からの斜視図である。

[図8]実施形態３に係る治療装置の非日常的な使用を説明するための図である。

発明を実施するための形態

[0027] 実施形態１に係る治療装置１００について、図１、図２、及び図３を用いて説明する。なお、図２は、治療装置１００の創傷包帯１０と生体内部９０２とを断面した図であるが、創傷包帯１０の断面のみを薄墨に示し、生体内部９０２を薄墨に示していない。また、図１及び図２において、高さ方向を上側とし、高さ方向と反対方向を下側とする。

[0028] 治療装置１００は、創傷部位の表面に陰圧をかけることにより、創傷部位の回復を促進する陰圧閉鎖治療のためのものである。

[0029] 図１に示すように、治療装置１００は、創傷包帯１０、ポンプ装置２０（

第１ポンプ装置に相当する。）、及びポンプ装置３０（第２ポンプ装置に相当する。）を備えている。

[0030] 図２に示すように、創傷包帯１０は、フィルム１１、吸収部材１７、ガーゼ１８、及び被覆部材１９を備えている。

[0031] フィルム１１は、液体及び気体の通過を防止する。吸収部材１７は、液体を吸収し、吸収した液体を保持する。吸収部材１７としては、例えば、綿、及び高給水性高分子が分散されてなるゲル、等が利用可能である。被覆部材１９は、液体を通過させる多孔質材料である。被覆部材１９としては、成形しやすいポリウレタンフォーム、等が利用可能である。

[0032] 図２に示す装着例では、ガーゼ１８は、創傷包帯１０の面方向（幅方向及び奥行方向）において、範囲９０３に示す創傷部位（以下、創傷部位９０３と称す。）より内側の創傷床９０５の表面に当接する。被覆部材１９は、創傷床９０５の形状に応じて成形された後、創傷床９０５を埋めるようにガーゼ１８より上側に配置されている。吸収部材１７は、被覆部材１９より上側に配置されている。フィルム１１は、吸収部材１７及び創傷部位９０３を上側から覆うように配置されている。具体的には、フィルム１１は、創傷包帯１０の平面視において、下面の外周部が、創傷部位９０３より外側の皮膚表面９０１に貼り付けられている。これにより、創傷包帯１０は、フィルム１１の中央部１２（外周部より内側の領域）と、創傷部位９０３と、の間に閉鎖空間９０４を形成している。

[0033] 図１に示すように、ポンプ装置２０は、本体部２１と、流路２２と、を備えている。流路２２の説明は後述する。

[0034] 図３に示すように、ポンプ装置２０の本体部２１は、圧電ポンプ２５、圧力センサ２６、及び制御部２７を備えている。圧電ポンプ２５、圧力センサ２６、及び制御部２７は、共通のＢＵＳに電気的に接続されている。なお、圧電ポンプ２５、圧力センサ２６、及び制御部２７は、本体部２１に備えられるバッテリからの電力供給によって動作する。

[0035] 圧電ポンプ２５は、第１主面及び第２主面を有する振動板と、当該振動板

の第１主面及び第２主面の少なくとも一方の主面に設けられる圧電素子（いずれも不図示）と、を備えている。当該圧電素子に交番電圧が印加されると、圧電素子は、主面方向に伸縮を繰り返す。振動板は、圧電素子の伸縮の繰り返しに伴って、屈曲振動する。圧電ポンプ２５は、振動板の屈曲振動を利用して、吸引口から吐出口へ気体を輸送する。

[0036] 圧電ポンプ２５は、電流と磁場とを利用した電磁ポンプ等に比べて、小型かつ低背である。ポンプ装置２０の本体部２１は、小型かつ低背である圧電ポンプ２５を備えることにより、利用者が携行しやすいように小型かつ薄型に実現されている。

[0037] また、圧電ポンプ２５の振動は、電磁ポンプ等の振動に比べて小さい。さらに、圧電ポンプ２５の圧電素子に印加される交番電圧を可聴周波数帯域より高い周波数（例えば２０ｋＨｚ以上）とすれば、圧電ポンプ２５の振動音は、利用者に聞こえにくくなる。

[0038] 圧力センサ２６は、圧電ポンプ２５の吸引口の圧力値を検出する。圧力センサ２６は、検出した圧力値に応じた検出信号を制御部２７に出力する。制御部２７は、圧力センサ２６からの検出信号に示す圧力値を用いて、圧電ポンプ２５の吸引口の圧力値が７５ｍｍＨｇから１２５ｍｍＨｇの範囲になるように、圧電ポンプ２５の駆動をフィードバック制御する。ただし、圧力センサ２６は、圧電ポンプ２５の吸引口に限らず、当該吸引口に連通する空間であれば、いずれの位置の圧力値を検出しても構わない。

[0039] 図１に戻り、ポンプ装置３０は、本体部３１と、流路３２と、を備えている。ポンプ装置３０の本体部３１は、例えば、電磁ポンプ（不図示）を備えている。電磁ポンプは、ポンプ装置２０の圧電ポンプ２５に比べて、大型である。従って、ポンプ装置３０の吸引流量（ｍｌ／ｓ）は、ポンプ装置３０の吸引を実現する電磁ポンプが圧電ポンプ２５より大型であるため、ポンプ装置２０の吸引流量よりも多くなっている。ただし、ポンプ装置３０は、電磁ポンプに代えて、例えば並列駆動する複数の圧電ポンプ２５を備えてもよい。

[0040] 次に、ポンプ装置２０の流路２２と、ポンプ装置３０の流路３２とについて説明する。図１及び図２に戻り、流路２２は、閉鎖空間９０４から圧電ポンプ２５の吸引口までである。流路２２の一部は、ゴム管２３の一端がフィルム１１の中央部１２に装着され、他端が本体部２１に装着されることによって、形成されている。

[0041] 流路３２は、閉鎖空間９０４から本体部３１の電磁ポンプの吸引口までである。流路３２の一部は、ゴム管３３の一端がフィルム１１の中央部１２に装着され、他端が本体部３１に装着されることによって、形成されている。

[0042] 流路３２について、より具体的には、創傷包帯１０は、図２に示すように、取付口１３を備えている。取付口１３は、フィルム１１の中央部１２に形成されている。取付口１３は、逆止弁１４と、ジョイント管１５とを備えている。逆止弁１４は、閉鎖空間９０４への流体の流れを防止する。ジョイント管１５は、例えば内径がゴム管３３の外径に略等しい。ゴム管３３の一端は、ジョイント管１５管に挿嵌されている。

[0043] ポンプ装置３０の流路３２は、ジョイント管１５に対するゴム管３３の挿抜によって、創傷包帯１０に着脱自在である。ただし、流路３２の創傷包帯１０への着脱は、ジョイント管１５を用いず、他の方法で実現されても構わない。

[0044] 治療装置１００は、圧電ポンプ２５の吸入口及びポンプ装置３０の電磁ポンプの吸入口に液体が流入することを防止するために、液体を通過させず、気体のみを通過させるフィルタ１６を２枚備えている。図２に示す例では、一方のフィルタ１６は、閉鎖空間９０４においてゴム管２３の口を覆うように配置され、他方のフィルタ１６は、閉鎖空間９０４において取付口１３を覆うように配置されている。

[0045] 次に、治療装置１００の使用について、図４（Ａ）及び図４（Ｂ）を用いて説明する。ここで、利用者９００による治療装置１００の日常的な使用とは、閉鎖空間９０４から吸引される流体の流量（以下、吸引流量と称す。）が少なくてよいときの使用とする。例えば、利用者９００は、創傷床９０５

の表面からの滲出液が少ないとき、治療装置１００を日常的に使用する。また、例えば、利用者９００は、既に創傷部位９０３の表面に十分に陰圧がかかっているときに、治療装置１００を日常的に使用する。

[0046] 利用者９００による治療装置１００の非日常的な使用とは、多くの吸引流量を必要とするときの使用とする。例えば、利用者９００は、創傷包帯１０が皮膚表面９０１に装着されたばかりで、閉鎖空間９０４をより早く陰圧にする必要があるときに、治療装置１００を非日常的に使用する。また、利用者９００は、創傷床９０５の表面からの滲出液が多いときに、治療装置１００を非日常的に使用する。

[0047] 図４（Ａ）に示すように、治療装置１００の日常使用では、ポンプ装置３０の流路３２は、ゴム管３３がジョイント管１５から挿去されることによって、創傷包帯１０から取り外される。治療装置１００の日常使用では、ポンプ装置２０は、圧電ポンプ２５を駆動させることにより、流路２２を介して閉鎖空間９０４から気体を吸引する。すると、閉鎖空間９０４の圧力値は、徐々に低下する。

[0048] 図４（Ｂ）に示すように、治療装置１００の非日常使用では、ポンプ装置３０の流路３２は、ゴム管３３がジョイント管１５に挿嵌されることによって、創傷包帯１０に装着される。治療装置１００の非日常使用では、ポンプ装置３０は、流路３２を介して閉鎖空間９０４から気体を吸引する。すると、閉鎖空間９０４の圧力値は、徐々に低下する。

[0049] なお、創傷床９０５からの滲出液は、陰圧側に配置される吸収部材１７へ流れ、吸収部材１７に吸収されて保持される。

[0050] 上述したように、ポンプ装置３０の吸引流量は、ポンプ装置２０の吸引流量より多い。閉鎖空間９０４が十分に陰圧（例えば圧力値が１００ｍｍＨｇ）となるまでの時間は、ポンプ装置２０及びポンプ装置３０の吸引流量に依存する。より多い吸引流量で閉鎖空間９０４から気体が吸引されると、閉鎖空間９０４の圧力値はより早く低下する。

[0051] 本実施形態に係る治療装置１００は、多くの吸引流量が必要な非日常使用

時に、吸引流量が多いポンプ装置３０が、創傷包帯１０に装着されて、創傷部位９０３及び創傷包帯１０によって形成される閉鎖空間９０４から気体を吸引するため、日常的使用のためのポンプ装置２０が小型化されてポンプ装置２０の吸引流量が少なくなっても、非日常使用時に十分な吸引流量を確保することができる。その結果、閉鎖空間９０４の圧力値は、より早く所望値まで低下する。

[0052] なお、治療装置１００では、非日常使用時に、ポンプ装置３０と、ポンプ装置２０と、は、同時に駆動してもよい。すなわち、ポンプ装置３０は、ポンプ装置２０の吸引流量を補助するように、ポンプ装置２０の駆動と同時に駆動してもよい。これにより、閉鎖空間９０４の圧力値はさらに早く所望値まで低下する。

[0053] また、治療装置１００は、１台のポンプ装置３０に限らず、２台以上のポンプ装置３０を備えてもよい。この場合、２台以上のポンプ装置３０は、非日常使用時にそれぞれ駆動する。さらに、２台以上のポンプ装置３０は、非日常使用時に、ポンプ装置２０の駆動と同時に駆動してもよい。

[0054] 上述の例では、非日常使用時に駆動するポンプ装置３０は、ポンプ装置２０よりも吸引流量が多かったが、非日常使用時に２台以上のポンプ装置が同時に駆動すれば、非日常使用時のみに駆動するポンプ装置の吸引流量は、日常使用時に駆動するポンプ装置の吸引流量と等しいか、又は、日常使用時に駆動するポンプ装置の吸引流量より少なくてもよい。

[0055] 例えば、図５の変形例に示すように、治療装置１００Ａは、ポンプ装置３０に代えて、ポンプ装置２０Ａを備えている。ポンプ装置２０Ａは、流路３２Ａ以外の各構成がポンプ装置２０と同じである。すなわち、ポンプ装置２０Ａの吸引流量は、ポンプ装置２０の吸引流量に等しい。流路３２Ａは、閉鎖空間９０４から、ポンプ装置２０Ａの本体部２１の圧電ポンプ２５の吸引口までである。この流路３２Ａの一部は、ゴム管３３Ａによって形成されている。ゴム管３３Ａの一端は、ジョイント管１５に挿抜自在である。

[0056] 利用者９００は、治療装置１００Ａの非日常使用時に、ゴム管３３Ａの一

端をジョイント管１５に挿嵌することにより、ポンプ装置２０Ａの流路３２Ａを創傷包帯１０に装着する。治療装置１００Ａは、ポンプ装置２０Ａの吸引流量がポンプ装置２０の吸引流量と等しくても、ポンプ装置２０の吸引流量をポンプ装置２０Ａの吸引流量で補助するため、非日常使用時に十分な吸引流量を確保することができる。

[0057] 次に、実施形態２に係る治療装置１００Ｂについて、図６を用いて説明する。上述の例では、創傷床９０５の表面からの滲出液を吸収して保持する吸収部材１７は、閉鎖空間９０４に配置されていたが、実施形態２に係る治療装置１００Ｂは、当該滲出液を貯留するキャニスタ２８（第１貯留部に相当する。）及びキャニスタ３４（第２貯留部に相当する。）を閉鎖空間９０４の外部に備えるものである。実施形態１と重複する構成の説明は省略する。

[0058] 図６に示すように、具体的には、治療装置１００Ｂは、創傷包帯１０Ｂと、ポンプ装置２０Ｂと、ポンプ装置３０Ｂと、を備えている。なお、図６は、滲出液の貯留を説明するためにキャニスタ３４のみを断面して示している。

[0059] 創傷包帯１０Ｂは、２枚のフィルタ１６を省略した点において、実施形態１に係る創傷包帯１０と相違する。

[0060] ポンプ装置２０Ｂは、本体部２１と、流路２２Ｂと、キャニスタ２８と、を備えている。流路２２Ｂは、途中にキャニスタ２８が設けられる点と、滲出液が流れる点と、について、実施形態１に係る流路２２と相違する。図６に示す例では、キャニスタ２８は、本体部２１の内部に配置されている。キャニスタ２８は、創傷床９０５からの滲出液を貯留する密閉容器である。キャニスタ２８は、流路２２Ｂの途中に設けられるため、圧電ポンプ２５が駆動すると、陰圧になる。なお、図示しないが、ポンプ装置２０Ｂは、圧電ポンプ２５の吸引口に滲出液が流入しないための構成（例えばフィルタ）を備えている。

[0061] ポンプ装置３０Ｂは、本体部３１と、流路３２Ｂと、キャニスタ３４と、を備えている。流路３２Ｂは、一部がゴム管３３Ｂ及びゴム管３６によって

形成される点と、途中にキャニスタ３４が設けられる点と、滲出液が流れる点と、において実施形態１に係る流路３２と相違する。図６に示す例では、キャニスタ３４は、本体部３１の外部に配置されている。キャニスタ３４は、創傷床９０５からの滲出液を貯留する密閉容器である。ゴム管３３Ｂは、一端がジョイント管１５に挿勘され、他端がキャニスタ３４に挿入されている。ゴム管３６は、一端がキャニスタ３４に挿入され、他端が本体部３１に装着されている。ゴム管３６の一端は、キャニスタ３４に輸送される滲出液３５がゴム管３６に流入しないように、例えば、キャニスタ３４の上部に挿入されている。

[0062] キャニスタ３４の滲出液の貯留容量は、キャニスタ２８の滲出液の貯留流量より多い。

[0063] キャニスタ３４は、本体部３１の外部に配置されているため、ゴム管３３Ｂ及びゴム管３６のキャニスタ３４からの挿去のみで、交換が可能である。

[0064] ポンプ装置２０Ｂが駆動して閉鎖空間９０４が陰圧になると、閉鎖空間９０４の滲出液は、流路２２Ｂの一部を介して、キャニスタ２８へ輸送される。キャニスタ２８は、輸送された滲出液を貯留する。

[0065] ポンプ装置３０Ｂが駆動して、閉鎖空間９０４が陰圧になると、閉鎖空間９０４の滲出液は、流路３２Ｂのうちゴム管３３Ｂを介して、キャニスタ３４へ輸送される。キャニスタ３４は、輸送された滲出液３５を貯留する。

[0066] 治療装置１００Ｂの日常使用では、ポンプ装置３０Ｂは、ゴム管３３Ｂがジョイント管１５から挿去されることによって、創傷包帯１０Ｂから取り外される。利用者９００の治療装置１００Ｂの非日常使用では、ポンプ装置３０Ｂは、ゴム管３３がジョイント管１５に挿嵌されることによって、創傷包帯１０Ｂに装着される。ポンプ装置３０Ｂが創傷包帯１０Ｂに装着されると、キャニスタ３４も、流路３２Ｂのうちゴム管３３Ｂを介して創傷包帯１０Ｂに装着される。

[0067] 本実施形態に係る治療装置１００Ｂは、必要なときに十分な吸引流量で閉鎖空間９０４を陰圧にすることができるだけでなく、多くの滲出液を貯留す

る必要があるときに、貯留容量が多いキャニスタ３４を備えるポンプ装置３０Ｂが創傷包帯１０Ｂに装着されるため、キャニスタ２８が小型化されてキャニスタ２８の貯留容量が少なくなっても、必要なときに多くの滲出液を貯留することができる。

[0068] なお、キャニスタ３４の貯留容量は、キャニスタ２８の貯留容量と等しいか、又はキャニスタ２８の貯留容量より少なくても構わない。キャニスタ３４の貯留容量がキャニスタ２８の貯留容量と等しいか、又はキャニスタ２８の貯留容量より少ない場合、ポンプ装置２０Ｂとポンプ装置３０Ｂとは、同時に駆動して、キャニスタ２８及びキャニスタ３４に滲出液を同時に貯留させる。

[0069] 次に、実施形態３に係る治療装置１００Ｃについて、図７及び図８を用いて説明する。治療装置１００Ｃは、洗浄液タンク４１の洗浄液を用いて、創傷部位９０３を洗浄するものである。

[0070] 治療装置１００Ｃは、創傷包帯１０Ｃ、及び洗浄器具４０を備える点において、実施形態３に係る治療装置１００Ｂと相違する。治療装置１００Ｂと重複する構成の説明は省略する。

[0071] 図７に示すように、創傷包帯１０Ｃは、中央部１２に取付口１３Ｃ及び取付口４４を備える点と、ゴム管２３の装着位置が異なる点と、において実施形態３に係る創傷包帯１０Ｂと相違する。取付口１３Ｃは、配置が異なる点について、実施形態３に係る取付口１３と相違する。より具体的には、取付口１３Ｃは、中央部１２において、幅方向の端部側に配置されている。ポンプ装置２０Ｂの流路２２Ｂの一部を形成するゴム管２３は、図７に示すように、中央部１２において、幅方向の端部側に装着されている。取付口４４は、中央部１２において、幅方向と反対方向の端部側に配置されている。取付口４４は、ジョイント管１５を備えている。

[0072] 取付口１３Ｃの位置、取付口４４の位置、ゴム管２３の中央部１２への装着位置は、上述の例に限らないが、創傷包帯１０Ｃの面方向（幅方向及び奥行方向）において、取付口４４は、取付口１３Ｃの位置及びゴム管２３の装

着位置から離れて配置されることが望ましい。

[0073] 図８に示すように、洗浄器具４０は、洗浄液タンク４１と、流路４２と、を備えている。流路４２は、洗浄液タンク４１から閉鎖空間９０４までである。流路４２の一部は、ゴム管４３によって形成されている。ゴム管４３は、一端が洗浄液タンク４１に装着され、他端がフィルム１１の中央部１２に装着されている。具体的には、ゴム管４３の他端は、図７に示すように、取付口４４のジョイント管１５に挿嵌されている。洗浄器具４０は、ゴム管４３の他端が取付口４４のジョイント管１５に挿抜自在であるため、創傷包帯１０Ｃに着脱自在である。

[0074] 利用者９００は、ポンプ装置３０Ｂを創傷包帯１０Ｃから取り外し、洗浄器具４０を創傷包帯１０Ｃに装着し、治療装置１００Ｃを日常的に使用する。ポンプ装置２０Ｂが駆動すると、洗浄液タンク４１の洗浄液は、流路４２を介して閉鎖空間９０４へ流入する。創傷部位９０３の表面は、閉鎖空間９０４に流入した洗浄液によって洗浄される。その後、洗浄液は、流路２２Ｂの一部を介してキャニスタ２８へ輸送される。キャニスタ２８は、創傷部位９０３の洗浄後の洗浄液を貯留する。

[0075] 利用者９００は、洗浄器具４０及びポンプ装置３０Ｂを創傷包帯１０Ｃに装着し、治療装置１００Ｃを非日常的に使用する。ポンプ装置３０Ｂが駆動すると、洗浄液タンク４１の洗浄液は、流路４２を介して閉鎖空間９０４へ流入する。創傷部位９０３の表面は、閉鎖空間９０４に流入した洗浄液によって洗浄される。その後、洗浄液は、流路３２Ｂのうちゴム管３３Ｂを介してキャニスタ３４へ輸送される。キャニスタ３４は、創傷部位９０３の洗浄後の洗浄液３７を貯留する。

[0076] 本実施形態に係る治療装置１００Ｃは、必要なときに十分な吸引流量で閉鎖空間９０４を陰圧にすることができるだけでなく、多くの洗浄液で創傷部位９０３を洗浄する必要があるときに吸引流量が多いポンプ装置３０Ｂが創傷包帯１０Ｂに装着されるため、ポンプ装置２０Ｂの吸引流量が少なくても必要なときに十分な流量で洗浄液を創傷部位９０３に送ることにより、創傷

部位９０３を多くの洗浄液で洗浄することができる。

[0077] また、治療装置１００Ｃは、洗浄後の洗浄液が多くなるときに、貯留容量が多いキャニスタ３４を備えるポンプ装置３０Ｂが創傷包帯１０Ｃに装着されるため、必要なときに洗浄後の洗浄液をより多く貯留することができる。

[0078] ただし、ポンプ装置３０Ｂの吸引流量は、ポンプ装置３０Ｂとポンプ装置２０Ｂとが同時に駆動すれば、ポンプ装置２０Ｂの吸引流量に等しいか、又はポンプ装置２０Ｂの吸引流量より少なくても構わない。

符号の説明

[0079] １０，１０Ｂ，１０Ｃ…創傷包帯

１１…フィルム

１２…中央部

１３，１３Ｃ…取付口

１４…逆止弁

１５…ジョイント管

１６…フィルタ

１７…吸収部材

１８…ガーゼ

１９…被覆部材

２０，２０Ａ，２０Ｂ…ポンプ装置

２１…本体部

２２，２２Ｂ…流路

２３…ゴム管

２５…圧電ポンプ

２６…圧力センサ

２７…制御部

２８…キャニスタ

３０，３０Ｂ…ポンプ装置

３１…本体部

３２，３２Ａ，３３Ｂ…流路

３３，３３Ａ，３３Ｂ…ゴム管

３４…キャニスタ

３５…滲出液

３６…ゴム管

３７…洗浄液

４０…洗浄器具

４１…洗浄液タンク

４２…流路

４３…ゴム管

４４…取付口

１００，１００Ａ，１００Ｂ，１００Ｃ，１００Ｄ…治療装置

請求の範囲

[請求項1] 主面の外周部が創傷部位の外周の皮膚表面に密着することで、該主面の中央部及び前記創傷部位の間に閉鎖空間を形成する創傷包帯と、

前記創傷包帯に装着される第１流路と、前記閉鎖空間に前記第１流路を介して連通する第１吸引口と、を有する第１ポンプ装置と、

前記創傷包帯に着脱自在に装着される第２流路と、前記閉鎖空間に前記第２流路を介して連通する第２吸引口と、を有する第２ポンプ装置と、

を備え、

前記第２ポンプ装置の吸引流量は、前記第１ポンプ装置の吸引流量より多く、

前記第１ポンプ装置は、前記第１流路及び前記第１吸引口を介して前記閉鎖空間から流体を吸引し、

前記第２ポンプ装置は、前記第２流路が前記創傷包帯に装着されているとき、前記第２流路及び前記第２吸引口を介して前記閉鎖空間から流体を吸引する、

陰圧閉鎖治療装置。

[請求項2] 前記第２流路が前記創傷包帯に装着されているとき、前記第１ポンプ装置及び前記第２ポンプ装置は、同時に駆動する、

請求項１に記載の陰圧閉鎖治療装置。

[請求項3] 主面の外周部が創傷部位の外周の皮膚表面に密着することで、該主面の中央部及び前記創傷部位の間に閉鎖空間を形成する創傷包帯と、

前記創傷包帯に装着される第１流路と、前記閉鎖空間に前記第１流路を介して連通する第１吸引口と、を有する第１ポンプ装置と、

前記創傷包帯に着脱自在に装着される第２流路と、前記閉鎖空間に前記第２流路を介して連通する第２吸引口と、を有する第２ポンプ装置と、

を備え、

前記第２流路が前記創傷包帯に装着されているとき、前記第１ポンプ装置及び前記第２ポンプ装置は、同時に駆動し、

前記第１ポンプ装置は、駆動すると、前記第１流路及び前記第１吸引口を介して前記閉鎖空間から流体を吸引し、

前記第２ポンプ装置は、駆動すると、前記第２流路及び前記第２吸引口を介して前記閉鎖空間から流体を吸引する、

陰圧閉鎖治療装置。

[請求項4] 第１ポンプ装置は、前記第１流路の途中に設けられ、液体を貯留する第１貯留部を備え、

第２ポンプ装置は、前記第２流路の途中に設けられ、液体を貯留する第２貯留部を備え、

前記第２貯留部の貯留容量は、前記第１貯留部の貯留容量より多い、

請求項１乃至請求項３のいずれかに記載の陰圧閉鎖治療装置。

[請求項5] 前記創傷包帯に装着される第３流路と、前記第３流路を介して前記閉鎖空間に連通し、前記創傷部位の洗浄用の洗浄液を貯留する第３貯留部と、を有する洗浄器具、を備える、

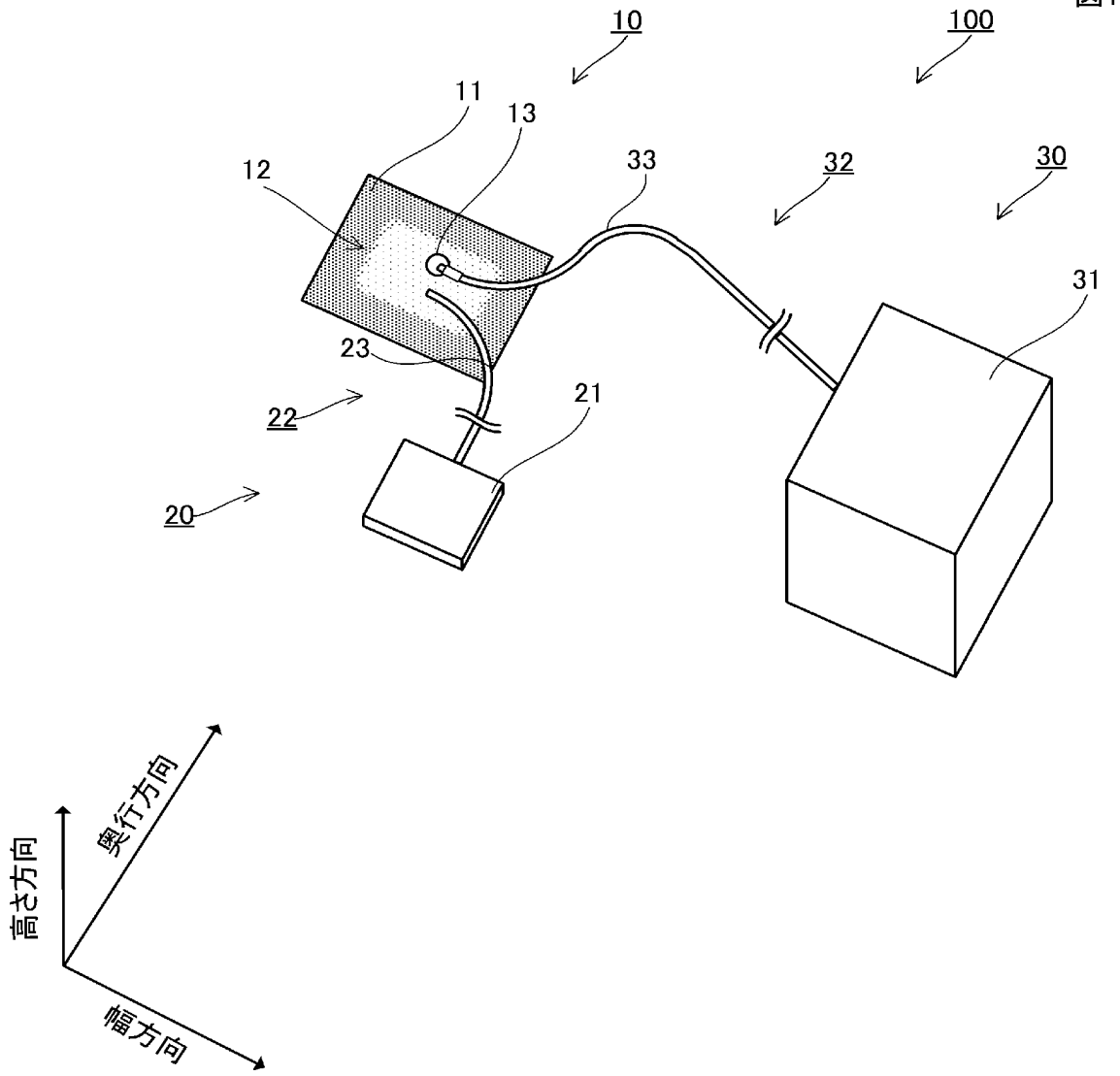
請求項４に記載の陰圧閉鎖治療装置。

[請求項6] 前記第１ポンプ装置は、圧電素子によって駆動するポンプ、を備える、

請求項１乃至請求項５のいずれかに記載の陰圧閉鎖治療装置。

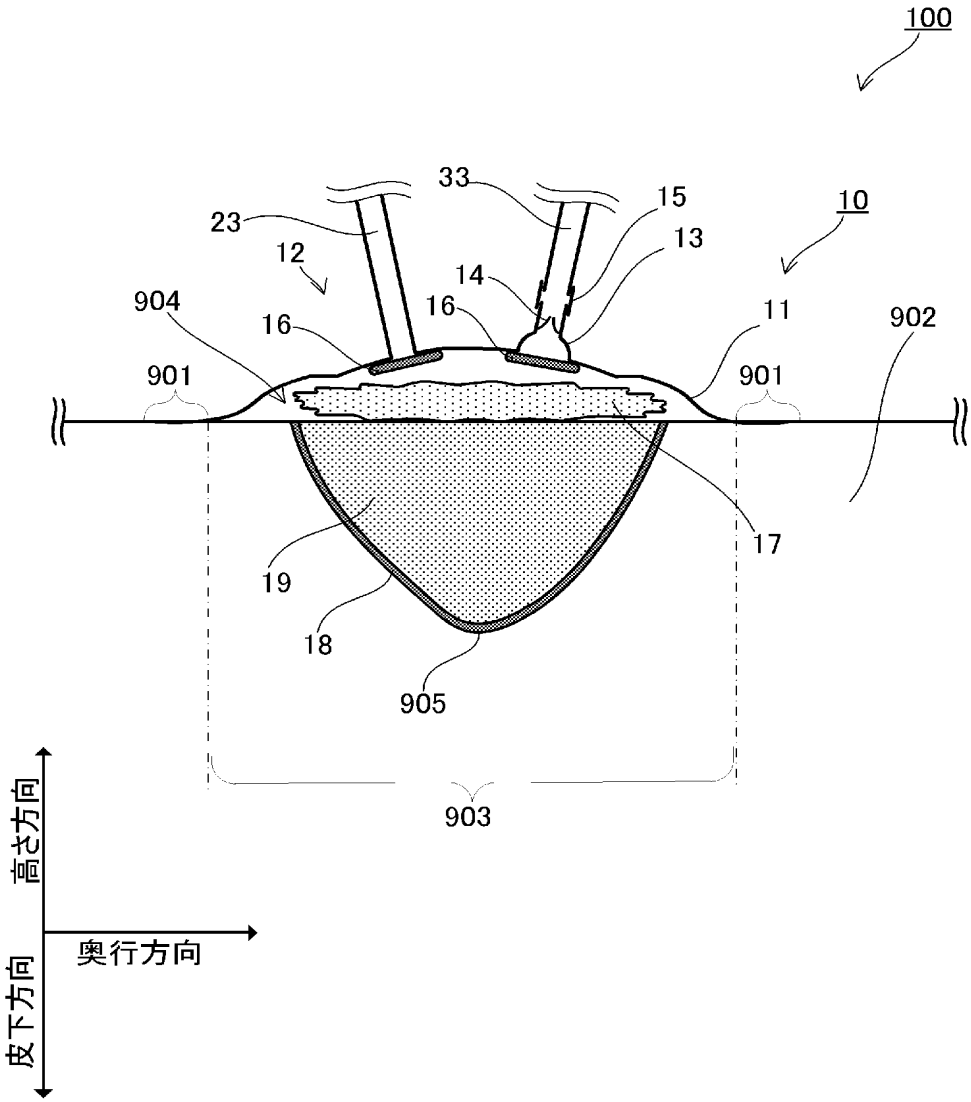
[図1]

図1



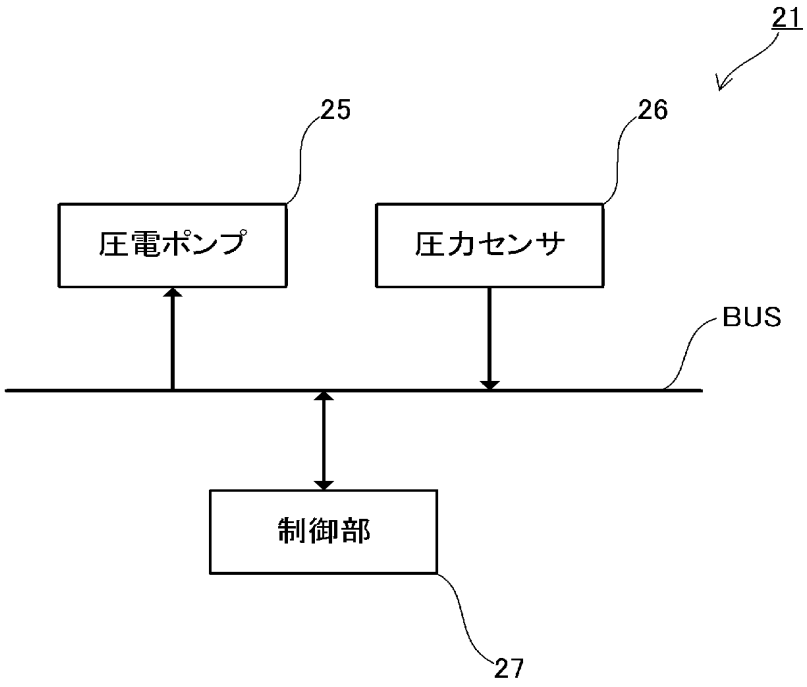
[図2]

図2


100
33
15
10
23
13
12
14
904
16
16
11
902
901
901
17
19
18
905
903
高さ方向
奥行方向
皮下方向

[図3]

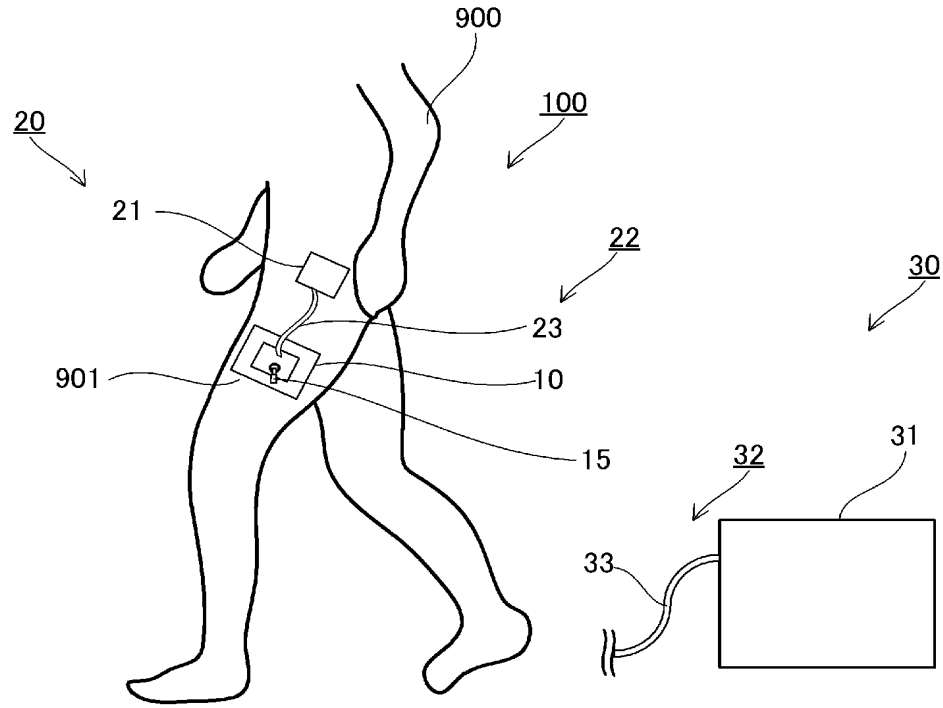
図3



[図4]

図4

(A)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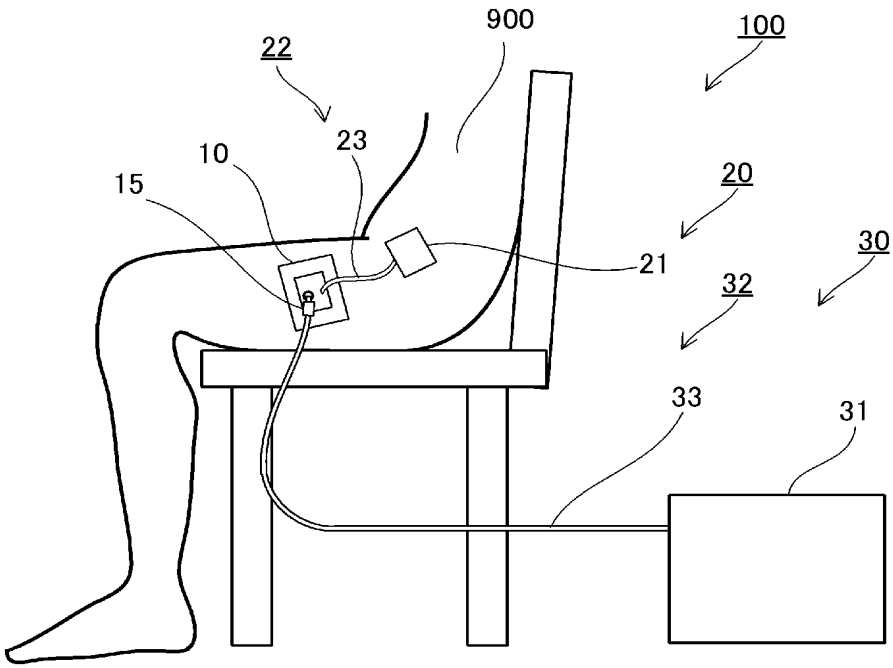
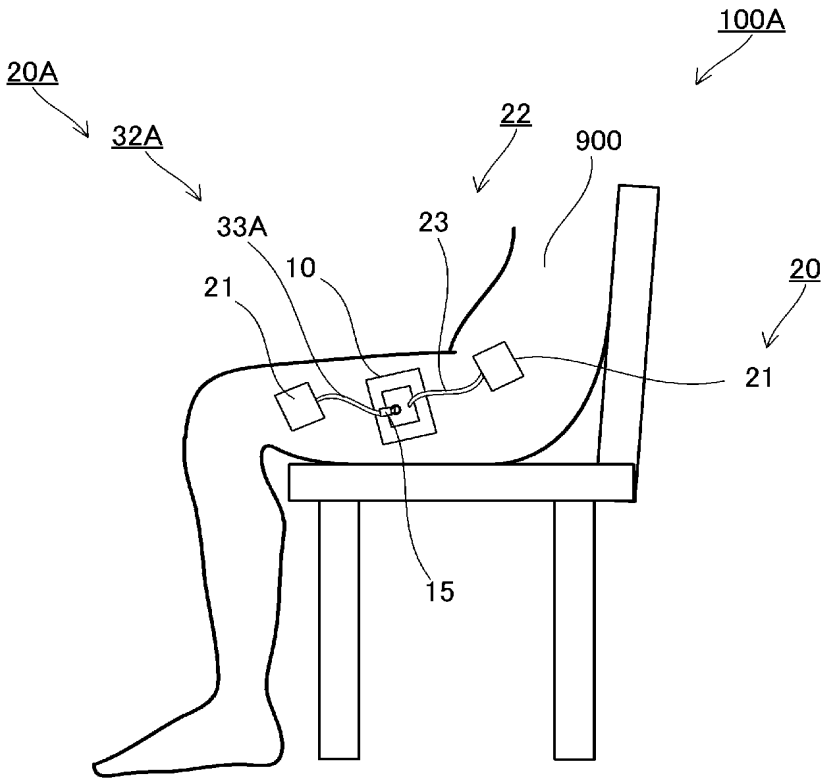
100
20
21
22
30
23
901
10
15
32
31
33

(B)


900
100
22
23
10
15
20
21
30
32
33
31

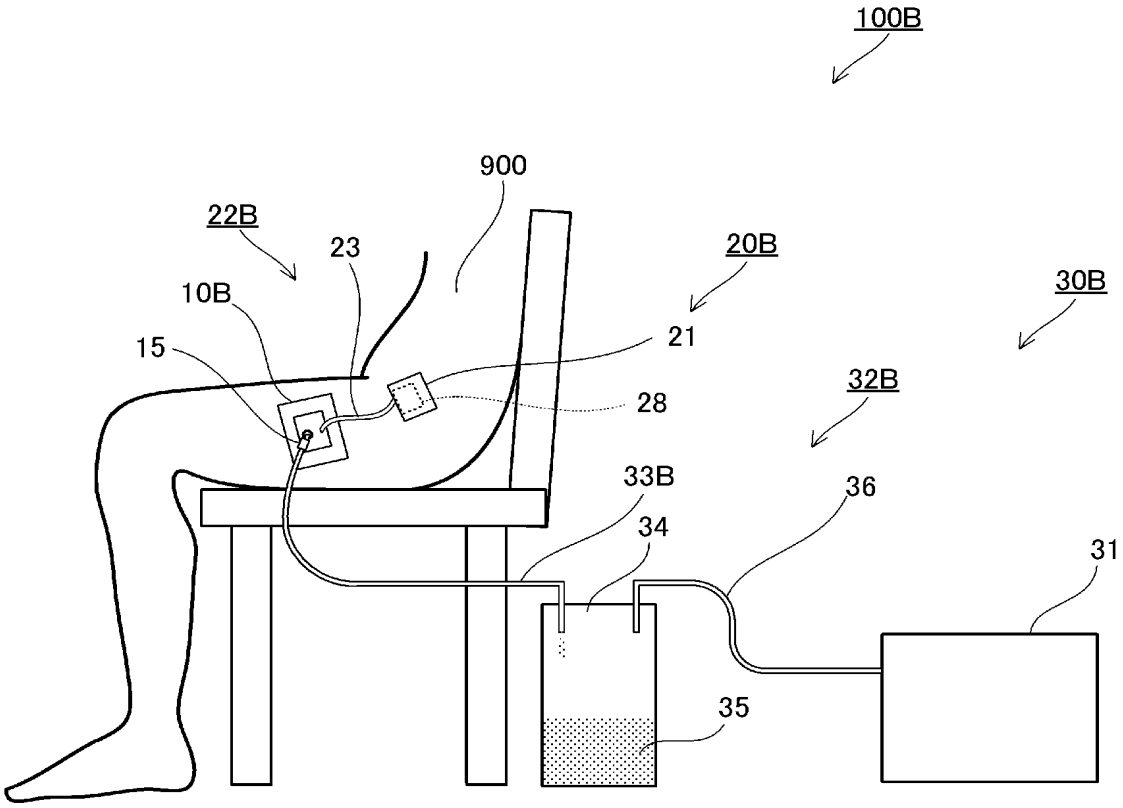
[図5]

図5


100A
20A
32A
22
900
33A
23
10
21
20
21
15

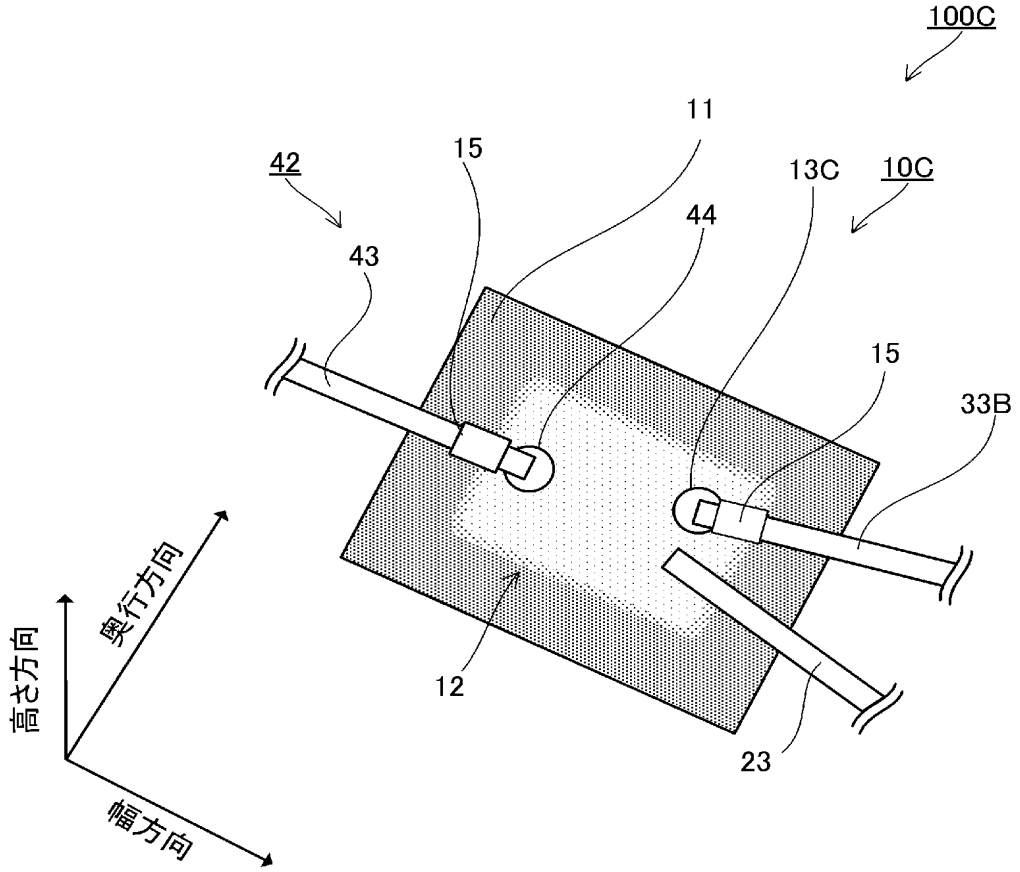
[図6]

図6


100B
900
22B
23
20B
30B
10B
15
21
28
32B
33B
36
34
31
35

[図7]

図7


100C
11
15
42
13C
10C
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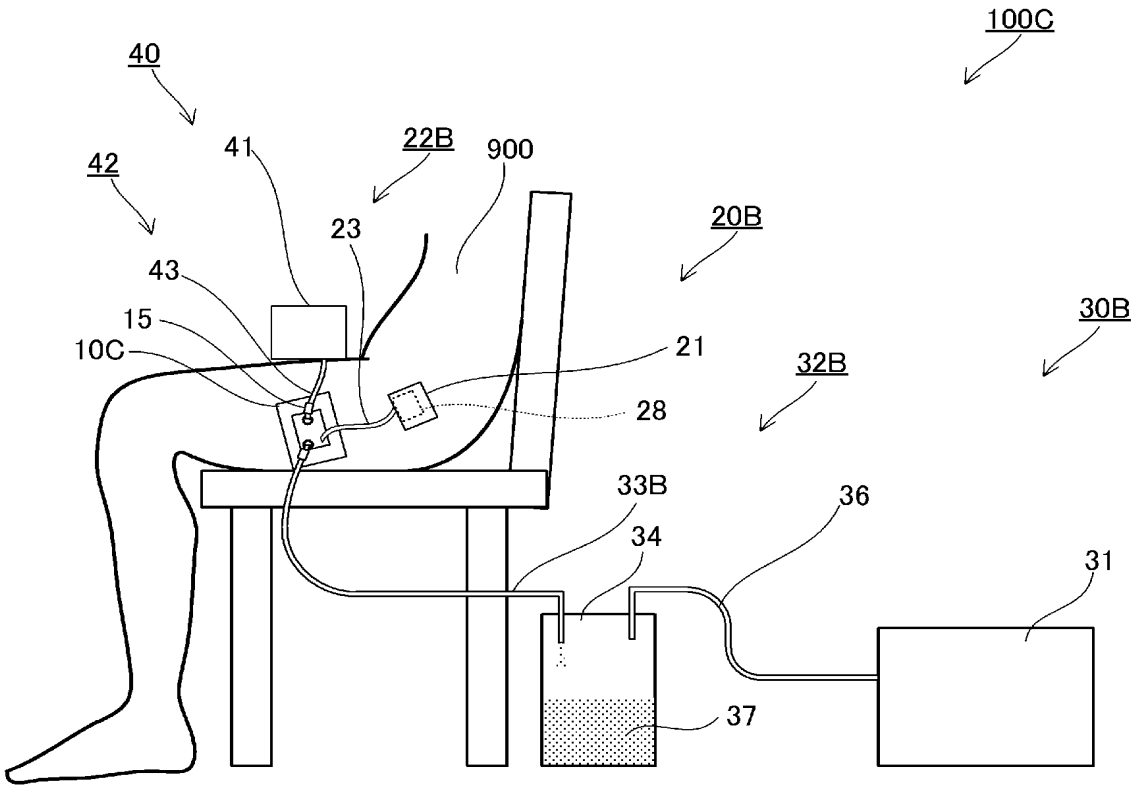
43
15
33B
奥行方向
高さ方向
12
23
幅方向

[図8]

図8


100C
40
41
22B
900
42
20B
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43
30B
15
10C
21
32B
28
33B
36
34
31
37

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2015/068284

A. CLASSIFICATION OF SUBJECT MATTER
A61M27/00(2006.01)i, *A61F13/00*(2006.01)i, *A61M1/00*(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M27/00, A61F13/00, A61M1/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Jitsuyo Shinan Koho 1922-1996 Jitsuyo Shinan Toroku Koho 1996-2015
Kokai Jitsuyo Shinan Koho 1971-2015 Toroku Jitsuyo Shinan Koho 1994-2015

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	JP 2011-512202 A (Spiracur Inc.), 21 April 2011 (21.04.2011), paragraphs [0043] to [0046], [0077] to [0080]; fig. 1, 11A to 12 & US 2010/0042021 A1 & WO 2009/103031 A1 & EP 2586470 A2 & CN 102006895 A	1-4 5-6
Y	JP 2012-90813 A (Gunze Ltd.), 17 May 2012 (17.05.2012), paragraphs [0020] to [0023]; fig. 1 to 2 (Family: none)	5-6
Y	JP 2012-525202 A (Mölnlycke Health Care AB), 22 October 2012 (22.10.2012), paragraph [0041]; fig. 1 to 2 & US 2012/0046625 A1 & WO 2010/126444 A1 & CN 102421464 A & KR 10-2012-0020103 A	6

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
03 September 2015 (03.09.15)	15 September 2015 (15.09.15)
Name and mailing address of the ISA/ Japan Patent Office 3-4-3,Kasumigaseki,Chiyoda-ku, Tokyo 100-8915,Japan	Authorized officer Telephone No.

Form PCT/ISA/210 (second sheet) (July 2009)

国際調査報告

国際出願番号　ＰＣＴ／ＪＰ２０１５／０６８２８４

Ａ．　発明の属する分野の分類（国際特許分類（ＩＰＣ））

Int.Cl.　A61M27/00(2006.01)i, A61F13/00(2006.01)i, A61M1/00(2006.01)i

Ｂ．　調査を行った分野

調査を行った最小限資料（国際特許分類（ＩＰＣ））

Int.Cl.　A61M27/00, A61F13/00, A61M1/00

最小限資料以外の資料で調査を行った分野に含まれるもの

日本国実用新案公報	１９２２－１９９６年
日本国公開実用新案公報	１９７１－２０１５年
日本国実用新案登録公報	１９９６－２０１５年
日本国登録実用新案公報	１９９４－２０１５年

国際調査で使用した電子データベース（データベースの名称、調査に使用した用語）

WPI

Ｃ．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
X Y	JP 2011-512202 A（スパイラキュア　インコーポレイテッド）2011.04.21, 段落［００４３］－［００４６］,［００７７］－［００８０］, 第１，１１Ａ－１２図 & US 2010/0042021 A1 & WO 2009/103031 A1 & EP 2586470 A2 & CN 102006895 A	１－４ ５－６
Y	JP 2012-90813 A（グンゼ株式会社）2012.05.17, 段落［００２０］－［００２３］, 第１－２図（ファミリーなし）	５－６

☑　Ｃ欄の続きにも文献が列挙されている。　　☐　パテントファミリーに関する別紙を参照。

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「Ｅ」国際出願日前の出願または特許であるが、国際出願日以後に公表されたもの
「Ｌ」優先権主張に疑義を提起する文献又は他の文献の発行日若しくは他の特別な理由を確立するために引用する文献（理由を付す）
「Ｏ」口頭による開示、使用、展示等に言及する文献
「Ｐ」国際出願日前で、かつ優先権の主張の基礎となる出願の日の後に公表された文献
「Ｔ」国際出願日又は優先日後に公表された文献であって出願と矛盾するものではなく、発明の原理又は理論の理解のために引用するもの
「Ｘ」特に関連のある文献であって、当該文献のみで発明の新規性又は進歩性がないと考えられるもの
「Ｙ」特に関連のある文献であって、当該文献と他の１以上の文献との、当業者にとって自明である組合せによって進歩性がないと考えられるもの
「＆」同一パテントファミリー文献

国際調査を完了した日 ０３．０９．２０１５	国際調査報告の発送日 １５．０９．２０１５
国際調査機関の名称及びあて先 日本国特許庁（ＩＳＡ／ＪＰ） 郵便番号１００－８９１５ 東京都千代田区霞が関三丁目４番３号	特許庁審査官（権限のある職員）　３Ｅ　９２４２ 田中　玲子 電話番号　０３－３５８１－１１０１　内線　３３４６

様式ＰＣＴ／ＩＳＡ／２１０（第２ページ）（２００９年７月）

Ｃ（続き）．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
Ｙ	JP 2012-525202 A（メンリッケ・ヘルス・ケア・アーベー）2012.10.22, 段落［００４１］, 第１－２図 & US 2012/0046625 A1 & WO 2010/126444 A1 & CN 102421464 A & KR 10-2012-0020103 A	６

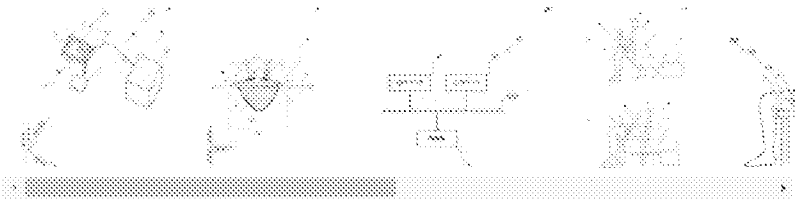
Patents WO 2016/006458 A1

Negative-pressure closure therapy device

Abstract

Provided is a negative-pressure closure therapy device with which an adequate suction flow rate can be used to apply, when necessary, negative pressure to a closed space formed by a wound dressing and a wound area, even if a pump device is miniaturized. In this therapy device (100), a pump device (30) having a high suction flow rate is fitted to a wound dressing (10) at times of extraordinary use when a high suction flow rate is necessary, and air is sucked from a closed space (904) formed by a wound area (903) and the wound dressing (10). Accordingly, an adequate suction flow rate can be ensured at times of extraordinary use, even if a pump device (20) for everyday use is miniaturized and the suction flow rate of the pump device (20) is reduced. As a result, the pressure value of the closed space (904) can be reduced to a desired value more swiftly.

Images (8)



Classifications

- A61M1/74 Suction control

View 8 more classifications

WO2016006458A1

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Claims (6)

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1. A wound dressing that forms a closed space between the central portion of the main surface and the wound site by allowing the outer periphery of the main surface to adhere to the skin surface of the outer periphery of the wound site;
A first pump device having a first flow path mounted on the wound dressing and a first suction port communicating with the closed space via the first flow path;
A second pump device having a second flow path detachably attached to the wound dressing, and a second suction port communicating with the closed space via the second flow path;
With
The suction flow rate of the second pump device is greater than the suction flow rate of the first pump device,
The first pump device sucks fluid from the closed space through the first flow path and the first suction port,
The second pump device sucks fluid from the enclosed space via the second channel and the second suction port when the second channel is attached to the wound dressing.
Negative pressure closure treatment device.

2. When the second channel is attached to the wound dressing, the first pump device and the second pump device are driven simultaneously.
The negative pressure closure treatment device according to claim 1.

3. A wound dressing that forms a closed space between the central portion of the main surface and the wound site by allowing the outer periphery of the main surface to adhere to the skin surface of the outer periphery of the wound site;
A first pump device having a first flow path mounted on the wound dressing and a first suction port communicating with the closed space via the first flow path;
A second pump device having a second flow path detachably attached to the wound dressing, and a second suction port communicating with the closed space via the second flow path;
With
When the second channel is attached to the wound dressing, the first pump device and the second pump device are driven simultaneously,
When the first pump device is driven, the first pump device sucks fluid from the closed space via the first flow path and the first suction port,
When the second pump device is driven, the second pump device sucks fluid from the closed space via the second flow path and the second suction port.
Negative pressure closure treatment device.

4. The first pump device includes a first reservoir that is provided in the middle of the first flow path and stores the liquid.
The second pump device includes a second reservoir that is provided in the middle of the second flow path and stores the liquid.
The storage capacity of the second storage part is greater than the storage capacity of the first storage part,
The negative pressure closure treatment device according to any one of claims 1 to 3.

5. A cleaning instrument comprising: a third flow path to be attached to the wound dressing; and a third storage section that communicates with the closed space via the third flow path and stores a cleaning liquid for cleaning the wound site; Comprising
The negative pressure closure treatment apparatus according to claim 4.

6. The first pump device includes a pump driven by a piezoelectric element.
The negative pressure closure treatment apparatus according to any one of claims 1 to 5.

Description

Negative pressure closure therapy device

The present invention relates to a negative pressure closure treatment device for promoting recovery of a wound site by applying a negative pressure to the surface of the wound site.

In recent years, negative pressure closure treatment that promotes recovery of a wound site by applying a negative pressure to the surface of the wound site is known. For example, Patent Document 1 discloses a negative pressure closed treatment device including a wound dressing that covers a wound site and a pump device that sucks gas from a closed space formed by the wound dressing and the wound site. In the negative pressure closed treatment device described in Patent Literature 1, the pump device draws gas from the closed space, thereby making the closed space have a negative pressure.

Also, in the negative pressure closure treatment device described in Patent Document 1, the pump device also sucks exudate that has exuded from the surface of the wound site. The sucked exudate is stored in a storage unit (collection canister).

In view of not only the negative pressure closure treatment device described in Patent Document 1 but also the user's wearing, it is desirable that the pump device of the negative pressure closure treatment device is small. If the pump device is small, the user can carry and use the pump device, for example.

JP 2013-255824 A

However, when the pump device is miniaturized, the pump for realizing suction is also miniaturized and the suction flow rate is reduced. As a result, the suction flow rate of the pump device may become insufficient when the pump device is miniaturized when it is necessary to make the closed space negative pressure earlier.

Similarly, when the reservoir for storing exudate is reduced in size, the storage capacity is reduced. As a result, the storage capacity of the storage part may become insufficient when the storage part is downsized when a large amount of exudate needs to be stored.

SUMMARY OF THE INVENTION Accordingly, an object of the present invention is to provide a negative pressure closed treatment device that makes a closed space formed by a wound dressing and a wound site negative pressure with a sufficient suction flow rate when necessary even if the pump device is downsized. There is.

The negative pressure closure treatment device of the present invention includes a wound dressing that forms a closed space between the central portion of the main surface and the wound site by bringing the outer peripheral portion of the main surface into close contact with the skin surface on the outer periphery of the wound site. A first pump device having a first flow path attached to the wound dressing, and a first suction port communicating with the closed space via the first flow path, and detachably attached to the wound dressing And a second pump device having a second suction port communicating with the closed space via the second flow path.

The suction flow rate of the second pump device is larger than the suction flow rate of the first pump device, and the first pump device draws fluid from the closed space via the first flow path and the first suction port. The second pump device sucks fluid from the closed space through the second channel and the second suction port when the second channel is attached to the wound dressing.

Since the suction flow rate of the first pump device is smaller than the suction flow rate of the second pump device, the pump realizing the suction of the first pump device can be smaller than the pump of the second pump device. Therefore, the first pump device can be realized smaller than the second pump device.

For example, the first pump device is driven to suck fluid from the enclosed space for daily use of the user, and the second pump device is driven to exit from the closed space for extraordinary use of the user. Aspirate fluid.

Daily use of the negative pressure closure treatment device is when the flow rate (suction flow rate) of the fluid sucked from the closed space may be small. For example, when the closed space is already sufficiently negative pressure, the user can remove the second flow path from the wound dressing and use the negative pressure closed treatment device as a daily use of the negative pressure closing treatment device. Use a pump device. That is, the user removes the second pump device from the wound dressing and uses only the first pump device in daily use of the negative pressure closure treatment device. Unusual use of negative pressure closure treatment devices is use that requires a large amount of suction flow. For example, the user may attach the second flow path to the wound dressing when it is just worn on the wound site for extraordinary use and the closed space needs to be negatively pressured earlier. Therefore, the second pump device having a large suction flow rate is used.

In the negative pressure closure treatment device of the present invention, when a large amount of suction flow is required, a second pump device having a high suction flow rate is attached to the wound dressing to draw fluid from the wound space and the closed space formed by the wound dressing. Even if the first pump device for daily use by the user is downsized, the closed space can be maintained at a negative pressure by securing a sufficient suction flow rate when necessary.

Further, when the second flow path is attached to the wound dressing, the first pump device and the second pump device may be driven simultaneously.

Thereby, since the suction flow rate of the second pump device assists the suction flow rate of the first pump device, the negative pressure closure treatment device can secure a larger suction flow rate when necessary.

Further, the present invention is not limited to the suction flow rate of the second pump device being higher than that of the first pump device, and simply when the second flow path is attached to the wound dressing, the first pump device and the The second pump device may be driven at the same time.

For example, even if the suction flow rate of the first pump device and the suction flow rate of the second pump device are equal, the user uses the second pump device as an auxiliary during non-daily use.

The first pump device includes a first storage section that is provided in the middle of the first flow path and stores the liquid, and the second pump device is provided in the middle of the second flow path to store the liquid. A storage capacity of the second storage section may be greater than a storage capacity of the first storage section.

The second reservoir is detachable from the wound dressing because the second channel is detachable from the wound dressing. In this configuration, the negative pressure closure treatment device not only ensures a sufficient suction flow rate when a suction flow rate is required, but also stores the exudate from the wound site in the second reservoir when necessary. A sufficient storage capacity can be secured.

Further, the negative pressure closure treatment device communicates with the closed space via the third flow path to be attached to the wound dressing and the third flow, and stores a cleaning liquid for cleaning the wound site. And a cleaning instrument having a portion.

The cleaning liquid flows from the third flow path to the first flow path and the second flow path through the closed space in order to clean the wound site. In this aspect, since the second pump device is driven when the flow rate of the irrigation liquid is necessary, the negative pressure closure treatment apparatus can be used to clean the wound site in the closed space with a sufficient amount of irrigation liquid even if the first pump device is downsized. Can be washed.

Also, in order to reduce the size of the first pump device, the following configuration is preferable. For example, the first pump device includes a pump driven by a piezoelectric element

That is, the first pump device desirably includes a piezoelectric pump for miniaturization. The piezoelectric pump includes, for example, a piezoelectric element and a diaphragm bonded to the piezoelectric element. When an alternating voltage is applied, the piezoelectric element repeatedly expands and contracts along the surface direction of the main surface When the piezoelectric element repeatedly expands and contracts along the surface direction of the main surface, the bonded vibration plate bends and vibrates. Piezoelectric pumps can be easily downsized compared to electromagnetic pumps and the like. In addition, the piezoelectric pump is excellent in that the vibration is smaller than that of an electromagnetic pump or the like. Furthermore, if the frequency of the alternating voltage is set to 20 kHz or more, the vibration sound of the diaphragm becomes 20 kHz or more outside the audible frequency band, so that it is difficult for the user to hear.

The negative pressure closure treatment device of the present invention is configured such that when a suction flow rate is required, the second pump device is attached to the wound dressing to suck fluid from the closed space formed by the wound site and the wound dressing. Even if the pump device is reduced in size, a sufficient suction flow rate can be secured when necessary to make the closed space negative pressure.

It is a perspective view from the upper surface side of the treatment apparatus concerning Embodiment 1. FIG. It is side surface sectional drawing at the time of mounting | wearing of the wound dressing of the treatment apparatus which concerns on Embodiment 1. FIG. It is a block diagram which shows a part of structure of the main-body part of the 1st pump apparatus of the treatment apparatus which concerns on Embodiment 1. FIG. (A) is a figure for demonstrating the daily use of the treatment apparatus which concerns on Embodiment 1, (B) is a figure for demonstrating the unusual use of the said treatment apparatus. It is a figure for demonstrating the non-daily use of the treatment apparatus which concerns on the modification of the treatment apparatus which concerns on Embodiment 1. FIG. It is a figure for demonstrating the unusual use of the treatment apparatus which concerns on Embodiment 2. FIG. It is a perspective view from the upper surface side of the wound dressing of the treatment apparatus concerning Embodiment 3. It is a figure for demonstrating the non-daily use of the treatment apparatus which concerns on Embodiment 3. FIG.

The treatment apparatus 100 according to Embodiment 1 will be described with reference to FIGS. 1, 2, and 3. FIG. 2 is a cross-sectional view of the wound dressing 10 and the living body interior 902 of the treatment apparatus 100, but only the cross section of the wound dressing 10 is shown in light ink, and the living body interior 902 is not shown in light ink. 1 and 2, the height direction is the upper side, and the direction opposite to the height direction is the lower side.

The treatment device 100 is for negative pressure closure treatment that promotes recovery of the wound site by applying negative pressure to the surface of the wound site.

As shown in FIG. 1, the treatment device 100 includes a wound dressing 10, a pump device 20 (corresponding to a first pump device), and a pump device 30 (corresponding to a second pump device).

As shown in FIG. 2, the wound dressing 10 includes a film 11, an absorbent member 17, a gauze 18, and a covering member 19.

The film 11 prevents the passage of liquid and gas. The absorbing member 17 absorbs the liquid and holds the absorbed liquid. As the absorbent member 17, for example, cotton, a gel in which a high water supply polymer is dispersed, or the like can be used. The covering member 19 is a porous material that allows liquid to pass through. As the covering member 19, it is possible to use polyurethane foam that can be easily molded.

In the wearing example shown in FIG. 2, the gauze 18 is in the wound bed 905 inside the wound site (hereinafter referred to as the wound site 903) shown in the range 903 in the surface direction (width direction and depth direction) of the wound dressing 10. Contact the surface. The covering member 19 is formed in accordance with the shape of the wound bed 905 and then disposed above the gauze 18 so as to fill the wound bed 905. The absorbing member 17 is disposed above the covering member 19. The film 11 is arrange | positioned so that the absorption member 17 and the wound site | part 903 may be covered from the upper side. Specifically, in the film 11, the outer peripheral portion of the lower surface is attached to the skin surface 901 outside the wound site 903 in the plan view of the wound dressing 10. Thereby, the wound dressing 10 forms the closed space 904 between the center part 12 (area | region inside an outer peripheral part) of the film 11, and the wound site | part 903. FIG.

As shown in FIG. 1, the pump device 20 includes a main body 21 and a flow path 22. The description of the flow path 22 will be described later.

As shown in FIG. 3, the main body 21 of the pump device 20 includes a piezoelectric pump 25, a pressure sensor 26, and a control unit 27. The piezoelectric pump 25, the pressure sensor 26, and the control unit 27 are electrically connected to a common BUS. The piezoelectric pump 25, the pressure sensor 26, and the control unit 27 operate by supplying power from a battery provided in the main body unit 21.

The piezoelectric pump 25 includes a vibration plate having a first main surface and a second main surface, and a piezoelectric element (not shown) provided on at least one main surface of the first main surface and the second main surface of the vibration plate. And. When an alternating voltage is applied to the piezoelectric element, the piezoelectric element repeatedly expands and contracts in the main surface direction. The diaphragm vibrates flexibly with repeated expansion and contraction of the piezoelectric element. The piezoelectric pump 25 transports gas from the suction port to the discharge port using the bending vibration of the diaphragm.

The piezoelectric pump 25 is small and low-profile compared to an electromagnetic pump that uses an electric current and a magnetic field. The main body 21 of the pump device 20 includes a piezoelectric pump 25 having a small size and a low profile, so that it is small and thin so that the user can easily carry it.

Also, the vibration of the piezoelectric pump 25 is smaller than that of an electromagnetic pump or the like. Furthermore, if the alternating voltage applied to the piezoelectric element of the piezoelectric pump 25 is set to a frequency higher than the audible frequency band (for example, 20 kHz or more), the vibration sound of the piezoelectric pump 25 becomes difficult to be heard by the user.

The pressure sensor 26 detects the pressure value of the suction port of the piezoelectric pump 25. The pressure sensor 26 outputs a detection signal corresponding to the detected pressure value to the control unit 27. The control unit 27 feedback-controls the driving of the piezoelectric pump 25 using the pressure value indicated in the detection signal from the pressure sensor 26 so that the pressure value of the suction port of the piezoelectric pump 25 is in the range of 75 mmHg to 125 mmHg. However, the pressure sensor 26 is not limited to the suction port of the piezoelectric pump 25, and may detect the pressure value at any position as long as it is a space communicating with the suction port.

1, the pump device 30 includes a main body 31 and a flow path 32. The main body 31 of the pump device 30 includes, for example, an electromagnetic pump (not shown). The electromagnetic pump is larger than the piezoelectric pump 25 of the pump device 20. Therefore, the suction flow rate (ml / s) of the pump device 30 is larger than the suction flow rate of the pump device 20 because the electromagnetic pump that realizes the suction of the pump device 30 is larger than the piezoelectric pump 25. However, the pump device 30 may include, for example, a plurality of piezoelectric pumps 25 that are driven in parallel instead of the electromagnetic pump.

Next, the flow path 22 of the pump device 20 and the flow path 32 of the pump device 30 will be described. Returning to FIGS. 1 and 2, the flow path 22 extends from the closed space 904 to the suction port of the piezoelectric pump 25. A part of the flow path 22 is formed by attaching one end of the rubber tube 23 to the central portion 12 of the film 11 and attaching the other end to the main body portion 21.

The flow path 32 is from the closed space 904 to the suction port of the electromagnetic pump of the main body 31. A part of the flow path 32 is formed by attaching one end of the rubber tube 33 to the central portion 12 of the film 11 and attaching the other end to the main body portion 31.

More specifically, the wound dressing 10 is provided with the attachment port 13 as shown in FIG. The attachment port 13 is formed in the central portion 12 of the film 11. The attachment port 13 includes a check valve 14 and a joint pipe 15. The check valve 14 prevents fluid flow to the closed space 904. For example, the inner diameter of the joint pipe 15 is substantially equal to the outer diameter of the rubber pipe 33. One end of the rubber tube 33 is inserted into the joint tube 15 tube.

The flow path 32 of the pump device 30 is detachable from the wound dressing 10 by inserting and removing the rubber tube 33 with respect to the joint tube 15. However, the attachment / detachment of the flow path 32 to the wound dressing 10 may be realized by other methods without using the joint tube 15.

In order to prevent liquid from flowing into the suction port of the piezoelectric pump 25 and the suction port of the electromagnetic pump of the pump device 30, the treatment device 100 includes two filters 16 that allow only the gas to pass without passing the liquid. ing. In the example shown in FIG. 2, one filter 16 is disposed so as to cover the mouth of the rubber tube 23 in the closed space 904, and the other filter 16 is disposed so as to cover the attachment port 13 in the closed space 904. .

Next, the use of the treatment device 100 will be described with reference to FIGS. 4 (A) and 4 (B). Here, the daily use of the treatment device 100 by the user 900 is used when the flow rate of fluid sucked from the closed space 904 (hereinafter referred to as suction flow rate) may be small. For example, the user 900 uses the treatment apparatus 100 on a daily basis when there is little exudate from the surface of the wound bed 905. In addition, for example, the user 900 uses the treatment apparatus 100 on a daily basis when the surface of the wound site 903 is already sufficiently subjected to negative pressure.

The extraordinary use of the treatment device 100 by the user 900 is used when a large amount of suction flow is required. For example, the user 900 uses the treatment device 100 extraordinarily when the wound dressing 10 has just been attached to the skin surface 901 and the closed space 904 needs to be subjected to negative pressure earlier. Moreover, the user 900 uses the treatment apparatus 100 extraordinarily when there is much exudate from the surface of the wound bed 905

4A, in the daily use of the treatment device 100, the flow path 32 of the pump device 30 is removed from the wound dressing 10 by inserting the rubber tube 33 from the joint tube 15. In daily use of the treatment apparatus 100, the pump apparatus 20 sucks gas from the closed space 904 through the flow path 22 by driving the piezoelectric pump 25. Then, the pressure value in the closed space 904 gradually decreases.

As shown in FIG. 4B, in the non-daily use of the treatment device 100, the flow path 32 of the pump device 30 is attached to the wound dressing 10 by inserting the rubber tube 33 into the joint tube 15. . In extraordinary use of the treatment device 100, the pump device 30 sucks gas from the closed space 904 through the flow path 32. Then, the pressure value in the closed space 904 gradually decreases.

The exudate from the wound bed 905 flows to the absorption member 17 disposed on the negative pressure side, and is absorbed and held by the absorption member 17.

As described above, the suction flow rate of the pump device 30 is larger than the suction flow rate of the pump device 20. The time until the closed space 904 becomes sufficiently negative pressure (for example, the pressure value is 100 mmHg) depends on the suction flow rates of the pump device 20 and the pump device 30. When the gas is sucked from the closed space 904 with a larger suction flow rate, the pressure value in the closed space 904 decreases more quickly.

The therapeutic device 100 according to the present embodiment is formed by the wound site 903 and the wound dressing 10 by attaching the pump device 30 having a large suction flow rate to the wound dressing 10 during non-daily use that requires a large amount of suction flow. Since the gas is sucked from the closed space 904, even if the pump device 20 for daily use is miniaturized and the suction flow rate of the pump device 20 decreases, a sufficient suction flow rate can be secured during non-daily use. . As a result, the pressure value of the closed space 904 decreases to a desired value more quickly.

In the treatment device 100, the pump device 30 and the pump device 20 may be driven simultaneously during non-daily use. That is, the pump device 30 may be driven simultaneously with the driving of the pump device 20 so as to assist the suction flow rate of the pump device 20. As a result, the pressure value in the closed space 904 is further reduced to a desired value.

Further, the treatment device 100 is not limited to one pump device 30 and may include two or more pump devices 30. In this case, the two or more pump devices 30 are each driven during non-daily use. Further, the two or more pump devices 30 may be driven simultaneously with the driving of the pump device 20 during non-daily use.

In the above example, the pump device 30 driven during non-daily use has a higher suction flow rate than the pump device 20, but if two or more pump devices are driven simultaneously during non-daily use, the pump device 30 can be used only during non-daily use. The suction flow rate of the pump device to be driven may be equal to or lower than the suction flow rate of the pump device to be driven during daily use.

For example, as shown in the modification of FIG. 5, the treatment device 100A includes a pump device 20A instead of the pump device 30. The configuration of the pump device 20A is the same as that of the pump device 20 except for the flow path 32A. That is, the suction flow rate of the pump device 20 </ b> A is equal to the suction flow rate of the pump device 20. The flow path 32A is from the closed space 904 to the suction port of the piezoelectric pump 25 of the main body 21 of the pump device 20A. A part of the flow path 32A is formed by a rubber tube 33A. One end of the rubber tube 33 </ b> A can be inserted into and removed from the joint tube 15.

The user 900 attaches the flow path 32A of the pump device 20A to the wound dressing 10 by inserting one end of the rubber tube 33A into the joint tube 15 when the treatment device 100A is not used everyday. Even if the suction flow rate of the pump device 20A is equal to the suction flow rate of the pump device 20, the treatment device 100A assists the suction flow rate of the pump device 20 with the suction flow rate of the pump device 20A. Can be secured.

Next, the treatment apparatus 100B according to the second embodiment will be described with reference to FIG. In the above example, the absorbing member 17 that absorbs and holds exudate from the surface of the wound bed 905 is disposed in the closed space 904. However, the treatment device 100B according to the second embodiment stores the exudate. The canister 28 (corresponding to the first reservoir) and the canister 34 (corresponding to the second reservoir) are provided outside the closed space 904. The description of the same configuration as that of the first embodiment is omitted

As shown in FIG. 6, specifically, the treatment device 100B includes a wound dressing 10B, a pump device 20B, and a pump device 30B. FIG. 6 shows only the canister 34 in cross section in order to explain the storage of exudate.

The wound dressing 10B is different from the wound dressing 10 according to the first embodiment in that the two filters 16 are omitted.

The pump device 20B includes a main body 21, a flow path 22B, and a canister 28. The channel 22B is different from the channel 22 according to the first embodiment in that the canister 28 is provided in the middle and the exudate flows. In the example shown in FIG. 6, the canister 28 is disposed inside the main body 21. The canister 28

is a sealed container that stores exudate from the wound bed 905. Since the canister 28 is provided in the middle of the flow path 22B, when the piezoelectric pump 25 is driven, a negative pressure is generated. Although not shown, the pump device 20B has a configuration (for example, a filter) for preventing exudate from flowing into the suction port of the piezoelectric pump 25.

The pump device 30B includes a main body 31, a flow path 32B, and a canister 34. The flow path 32B is different from the flow path 32 according to the first embodiment in that a part thereof is formed by the rubber tube 33B and the rubber tube 36, a point where the canister 34 is provided in the middle, and a point where exudate flows. To do. In the example shown in FIG. 6, the canister 34 is disposed outside the main body 31. The canister 34 is a sealed container that stores exudate from the wound bed 905. The rubber tube 33B has one end inserted into the joint tube 15 and the other end inserted into the canister 34. The rubber tube 36 has one end inserted into the canister 34 and the other end attached to the main body 31. One end of the rubber tube 36 is inserted into, for example, the upper portion of the canister 34 so that the exudate 35 transported to the canister 34 does not flow into the rubber tube 36.

The storage capacity of the exudate in the canister 34 is larger than the storage flow rate of the exudate in the canister 28.

Since the canister 34 is disposed outside the main body 31, the canister 34 can be replaced only by inserting the rubber tube 33 </ b> B and the rubber tube 36 from the canister 34.

When the pump device 20B is driven and the closed space 904 becomes negative pressure, the exudate in the closed space 904 is transported to the canister 28 via a part of the flow path 22B. The canister 28 stores the transported exudate.

When the pump device 30B is driven and the closed space 904 becomes negative pressure, the exudate in the closed space 904 is transported to the canister 34 via the rubber tube 33B in the flow path 32B. The canister 34 stores the transported exudate 35.

In daily use of the treatment device 100B, the pump device 30B is removed from the wound dressing 10B by inserting the rubber tube 33B from the joint tube 15. In extraordinary use of the treatment device 100B of the user 900, the pump device 30B is attached to the wound dressing 10B by inserting the rubber tube 33 into the joint tube 15. When the pump device 30B is attached to the wound dressing 10B, the canister 34 is also attached to the wound dressing 10B via the rubber tube 33B in the channel 32B.

The treatment apparatus 100B according to the present embodiment can not only make the closed space 904 negative pressure with a sufficient suction flow rate when necessary, but also has a large storage capacity when it is necessary to store a large amount of exudate. Since the pump device 30B including the canister 34 is attached to the wound dressing 10B, even if the canister 28 is downsized and the storage capacity of the canister 28 is reduced, a large amount of exudate can be stored when necessary.

The storage capacity of the canister 34 may be equal to the storage capacity of the canister 28 or may be smaller than the storage capacity of the canister 28. When the storage capacity of the canister 34 is equal to or less than the storage capacity of the canister 28, the pump device 20 </ b> B and the pump device 30 </ b> B are driven at the same time, and exudate is simultaneously applied to the canister 28 and the canister 34. Store.

Next, a treatment apparatus 100C according to Embodiment 3 will be described with reference to FIGS. The treatment apparatus 100 </ b> C cleans the wound site 903 using the cleaning liquid in the cleaning liquid tank 41.

The treatment apparatus 100C is different from the treatment apparatus 100B according to the third embodiment in that the treatment apparatus 100C includes a wound dressing 10C and a cleaning instrument 40. A description of the same configuration as that of the treatment device 100B is omitted.

As shown in FIG. 7, the wound dressing 10 </ b> C is different from the wound dressing 10 </ b> B according to the third embodiment in that the attachment portion 13 </ b> C and the attachment port 44 are provided in the central portion 12 and the attachment position of the rubber tube 23 is different. To do. The mounting port 13C is different from the mounting port 13 according to the third embodiment in that the arrangement is different. More specifically, the attachment port 13 </ b> C is disposed on the end portion side in the width direction in the central portion 12. As shown in FIG. 7, the rubber tube 23 forming a part of the flow path 22B of the pump device 20B is attached to the end portion side in the width direction in the central portion 12. The attachment port 44 is disposed on the end portion side in the direction opposite to the width direction in the central portion 12. The attachment port 44 includes a joint pipe 15.

The position of the attachment port 13C, the position of the attachment port 44, and the attachment position of the rubber tube 23 to the central portion 12 are not limited to the above example, but in the surface direction (width direction and depth direction) of the wound dressing 10C, the attachment port 44 is preferably arranged away from the position of the attachment port 13 </ b> C and the mounting position of the rubber tube 23.

As shown in FIG. 8, the cleaning instrument 40 includes a cleaning liquid tank 41 and a flow path 42. The flow path 42 is from the cleaning liquid tank 41 to the closed space 904. A part of the flow path 42 is formed by a rubber tube 43. The rubber tube 43 has one end attached to the cleaning liquid tank 41 and the other end attached to the central portion 12 of the film 11. Specifically, the other end of the rubber tube 43 is inserted into the joint tube 15 of the attachment port 44 as shown in FIG. Since the other end of the rubber tube 43 can be inserted into and removed from the joint tube 15 of the attachment port 44, the cleaning device 40 is detachable from the wound dressing 10C.

User 900 removes pump device 30B from wound dressing 10C, attaches cleaning instrument 40 to wound dressing 10C, and uses treatment device 100C on a daily basis. When the pump device 20 </ b> B is driven, the cleaning liquid in the cleaning liquid tank 41 flows into the closed space 904 through the flow path 42. The surface of the wound site 903 is cleaned by the cleaning liquid that has flowed into the closed space 904. Thereafter, the cleaning liquid is transported to the canister 28 through a part of the flow path 22B. The canister 28 stores the cleaning liquid after cleaning the wound site 903.

User 900 attaches cleaning instrument 40 and pump device 30B to wound dressing 10C, and uses treatment device 100C on a non-daily basis. When the pump device 30 </ b> B is driven, the cleaning liquid in the cleaning liquid tank 41 flows into the closed space 904 through the flow path 42. The surface of the wound site 903 is cleaned by the cleaning liquid that has flowed into the closed space 904. Thereafter, the cleaning liquid is transported to the canister 34 through the rubber tube 33B in the flow path 32B. The canister 34 stores a cleaning liquid 37 after cleaning the wound site 903.

The treatment apparatus 100C according to the present embodiment can not only make the closed space 904 negative pressure with a sufficient suction flow rate when necessary, but also the suction flow rate when it is necessary to clean the wound site 903 with a large amount of cleaning liquid. Since the pump device 30B having a large amount is attached to the wound dressing 10B, even when the suction flow rate of the pump device 20B is small, the cleaning liquid is sent to the wound site 903 at a sufficient flow rate when necessary, so that a lot of cleaning liquid can be washed with.

In addition, when the cleaning liquid after cleaning increases, the treatment device 100C is mounted on the wound dressing 10C with the pump device 30B including the canister 34 having a large storage capacity, so that more cleaning liquid after cleaning is stored when necessary. can do.

However, the suction flow rate of the pump device 30B may be equal to or less than the suction flow rate of the pump device 20B as long as the pump device 30B and the pump device 20B are driven simultaneously.

DESCRIPTION OF SYMBOLS 10, 10B, 10C ... Wound dressing 11 ... Film 12 ... Center part 13, 13C ... Attachment port 14 ... Check valve 15 ... Joint pipe 16 ... Filter 17 ... Absorbing member 18 .. Gauze 19 ... Covering member 20, 20A, 20B . . Pump device 21... Main body portions 22 and 22 B .. Channel 23... Rubber tube 25. Piezoelectric pump 26. Pressure sensor 27... Control unit 28 ... Canisters 30 and 30 B. , 33A, 33B ... rubber tube 34 ... canister 35 ... exudate 36 ... rubber tube 37 ... cleaning solution 40 ... cleaning device 41 ... cleaning solution tank 42 ... flow path 43 ... rubber tube 44 ... mounting port 100, 100A, 100B, 100C, 100D ... treatment device

Patent Citations (8)

Publication number	Priority date	Publication date	Assignee	Title
JP2011512202A *	2008-02-14	2011-04-21	スパイラキュア インコーポレイテッド	Apparatus and method for treatment of damaged tissue
JP2012090813A *	2010-10-27	2012-05-17	Gunze Ltd	Negative pressure therapy device and control method thereof
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Family To Family Citations				
GB0508529D0 *	2005-04-27	2005-06-01	Smith & Nephew	Sai with microstress
ES2340085T5	2006-09-28	2014-04-16	Smith & Nephew, Inc.	Portable wound therapy system
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Publication number	Priority date	Publication date	Assignee	Title
WO2017191158A1 *	2016-05-03	2017-11-09	Smith & Nephew Plc	Systems and methods for driving negative pressure sources in negative pressure therapy systems
WO2020203099A1 *	2019-03-29	2020-10-08	株式会社村田製作所	Atomizer
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Family To Family Citations				
CN113367690A	2015-04-27	2021-09-10	史密夫及内修公开有限公司	Pressure reducing device
EP4049692A1	2016-04-26	2022-08-31	Smith & Nephew PLC	Wound dressings and methods of use with integrated negative pressure source having a fluid ingress inhibition component
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WO2017191154A1	2016-05-03	2017-11-09	Smith & Nephew Plc	Negative pressure wound therapy device activation and control
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Publication	Publication Date	Title
JP6455515B2	2019-01-23	Negative pressure closure therapy device
JP6838639B2	2021-03-03	Negative pressure wound treatment device
US9155821B2	2015-10-13	Fluid collection canister including canister top with filter membrane and negative pressure wound therapy systems including same
JP6575573B2	2019-09-18	Inhaler
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Priority And Related Applications

Child Applications (1)

Application	Priority date	Filing date	Relation	Title
US15/400,007	2014-07-08	2017-01-06	Continuation	Negative-pressure wound therapy apparatus

Priority Applications (2)

Application	Priority date	Filing date	Title
JP2014-140147		2014-07-08	
JP2014140147		2014-07-08	

Applications Claiming Priority (2)

Application	Filing date	Title
JP2016532869A	2015-06-25	Negative pressure closure therapy device
US15/400,007	2017-01-06	Negative-pressure wound therapy apparatus

Legal Events

Date	Code	Title	Description
2016-02-24	121	Ep: the epo has been informed by wipo that ep was designated in this application	**Ref document number**: 15819503 **Country of ref document**: EP **Kind code of ref document**: A1
2016-12-16	ENP	Entry into the national phase	**Ref document number**: 2016532869 **Country of ref document**: JP **Kind code of ref document**: A

2017-01-09	NENP	Non-entry into the national phase	**Ref country code**: DE
2017-08-02	122	Ep: pct application non-entry in european phase	**Ref document number**: 15819503 **Country of ref document**: EP **Kind code of ref document**: A1

Concepts

machine-extracted

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Skin		claims,description	5	0.000
everyday		abstract,description	2	0.000

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(19)日本国特許庁（ＪＰ）　(12) **公開特許公報**（Ａ）　(11)特許出願公開番号

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Ａ６１Ｍ　1/06		Ａ６１Ｍ　1/06

審査請求　未請求　請求項の数10　ＯＬ　（全 8 頁）

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(22)出願日　平成９年(1997)12月25日

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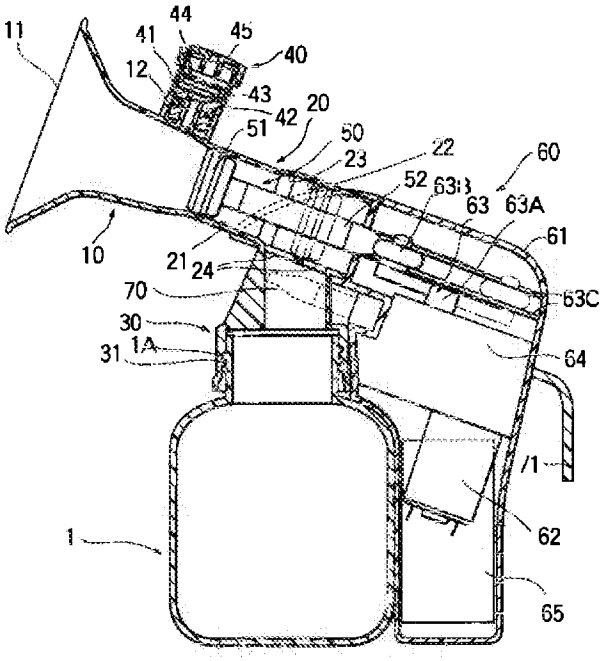
最終頁に続く

(54)【発明の名称】　吸引圧脈動式搾乳器

(57)【要約】

【解決手段】　吸引圧脈動式搾乳器は、乳房覆い部と、シリンダ部と、シリンダ部内に挿着されたピストン部と、ピストン部をシリンダ部内のシリンダ空間内において往復動させて乳房覆い部内に脈動的に吸引圧を作り出すようにさせるための駆動部とを備え、シリンダ空間を定めるシリンダ部の内壁寸法は、乳房覆い部に近い側においては、ピストン部のピストン頭の外周を密着させて所定の長さの吸引部を与え、乳房覆い部から遠い側においては、ピストン部のピストン頭の外周との間に若干の隙間を与えて、吸引圧によって搾乳された乳を外部へと収集させるための乳収集部を与えるように選定されており、乳収集部に対応するシリンダ部の底部には、そこに収集された乳を外部へと送出しうるようにする穴部が形成されている。

【効果】　構造が非常に簡単で、小型とでき、消費電力も少なくてすみ、それだけコストを低減でき、しかも衛生状態を容易に保つことが可能である。



【特許請求の範囲】
【請求項１】　使用に際して乳房に対して装着され乳頭部を受け入れる開口部を有した乳房覆い部と、該乳房覆い部の前記開口部とは反対側において該乳房覆い部内と連通するシリンダ空間を定めるシリンダ部と、該シリンダ部内に挿着されたピストン部と、該ピストン部を前記シリンダ空間内において往復動させて前記乳房覆い部内に脈動的に吸引圧を作り出すようにさせるための駆動部とを備えており、前記シリンダ空間を定めるシリンダ部の内壁寸法は、前記乳房覆い部に近い側においては、前記ピストン部のピストン頭の外周を密着させて所定の長さの吸引部を与え、前記乳房覆い部から遠い側においては、前記ピストン部のピストン頭の外周との間に若干の隙間を与えて、前記吸引圧によって搾乳された乳を外部へと収集させるための乳収集部を与えるように選定されており、前記乳収集部に対応する前記シリンダ部の底部には、そこに収集された乳を外部へと送出しうるようにする穴部が形成されていることを特徴とする吸引圧脈動式搾乳器。
【請求項２】　前記シリンダ部の内壁には、前記吸引部と前記乳収集部との間の遷移部に対応する部分においてテーパ部が形成されている請求項１記載の吸引圧脈動式搾乳器。
【請求項３】　前記シリンダ部には、前記穴部を包囲する位置において、搾乳された乳を捕集するための乳捕集容器を接続するための容器接続手段が設けられている請求項１または２記載の吸引圧脈動式搾乳器。
【請求項４】　前記駆動部は、電気モータと、該電気モータの回転軸に接続され該回転軸の回転運動を前記シリンダ空間の軸方向にそう往復運動へと変換するためのクランク手段とを備えており、前記ピストン部のピストン軸は、前記クランク手段に連結されている請求項１または２または３記載の吸引圧脈動式搾乳器。
【請求項５】　前記乳房覆い部には、吸引圧調節手段が設けられている請求項１または２または３または４記載の吸引圧脈動式搾乳器。
【請求項６】　前記乳房覆い部と前記シリンダ部とは、第１の構成部分として一体的に形成されており、前記駆動部は、前記第１の構成部分に対して着脱自在な第２の構成部分として形成されたハウジングの内部に配置されている請求項１から５のうちのいずれかに記載の吸引圧脈動式搾乳器。
【請求項７】　前記ピストン部は、前記ハウジングが前記第１の構成部分から外されるときには、該ハウジングと共に前記シリンダ部から外されるようにされており、前記ピストン部の前記ピストン頭は、前記ピストン軸の先端部に対して着脱自在なものとされている請求項６記載の吸引圧脈動式搾乳器。
【請求項８】　前記ハウジングの内壁には、前記ピストン部の前記ピストン軸を直線的に往復動させるためのピストン軸ガイドが形成されている請求項６または７記載の吸引圧脈動式搾乳器。
【請求項９】　前記ハウジングには、前記第１の構成部分に対して固定するためのバックルが設けられている請求項６または７または８記載の吸引圧脈動式搾乳器。
【請求項１０】　前記バックルには、片手で把持しうるようにするグリップ部が設けられている請求項９記載の吸引圧脈動式搾乳器。
【発明の詳細な説明】
【０００１】
【発明の属する技術分野】本発明は、搾乳器に関するものであり、より詳細に述べるならば、新生児に後で飲ますことができるように貯蔵するために、母乳を乳房から抽出するための搾乳器に関するものである。
【０００２】
【従来の技術】この種の搾乳器は、乳房ポンプとも称されることがあり、代表的には、２つのタイプに分かれる。すなわち、モータによって駆動されるものと、手動のものとがある。この種の、いわゆる乳房ポンプは、モータ駆動のものでも手動のものでも、実際乳児が母乳を吸うのと同じ効果を出し易い等の理由から、往復動ピストンポンプを使用して脈動的に吸引圧を乳房に掛けることにより搾乳する吸引圧脈動式のものが主流である。
【０００３】このような吸引圧脈動式搾乳器の従来例としては、例えば、特開平１－３１７４４８号公報や米国特許第４９２９２２９号明細書に開示されたようなものがある。これら従来の吸引圧脈動式搾乳器は、使用に際して乳房に対して装着され乳頭部を受け入れる開口部を有した乳房覆い部と、この乳房覆い部の内部に連通して搾乳された乳を収集するための収集室部と、乳房覆い部の内部に吸引圧を作り出すための往復動ピストンポンプ部と、乳房覆い部と往復動ピストンポンプ部とを接続するための接続部とを、主として備えてなっている。
【０００４】収集室部には、往復動ピストンポンプ部によって乳房覆い部内に吸引圧を作り出す際には、収集室部の内部を外部に対して密閉するが、そこに収集された乳を外部へと送出するために収集室部内部を外部へと開放させるように作動するディスクが設けられている。また、乳房覆い部と収集室部との間で且つ往復動ピストンポンプ部への真空ラインの途中には、搾乳された乳が往復動ピストンポンプ部の方へ入り込んでしまわないようにするための分離壁等も設けられている。
【０００５】このような従来の吸引圧脈動式搾乳器によれば、収集室部に適当な容器を接続し、乳房覆い部を乳房の部分に装着して、往復動ピストンポンプ部を作動させれば、乳房覆い部内に脈動的に発生される負圧または真空のために、乳首および隣接部分が乳首覆い部内の狭い部分に吸引され引っ張られる。このような引っ張り作用は、乳児が吸引するように乳房をマッサージして圧縮し、母乳の抽出を生じさせる。乳首覆い部内に抽出され

た母乳は、収集室部へと導かれて、収集室部のディスクが外部への開放を許すときに、そこに接続された容器内へと捕集されるのである。

【０００６】

【発明が解決しようとする課題】しかしながら、このような従来の搾乳器は、乳房覆い部や収集室部等の内部構造が複雑で、それだけコスト高となっており、また、使用後の清掃も非常に難しく、衛生上の問題もあった。

【０００７】搾乳された母乳が、その後の使用のために容器へと捕集される前に、乳房覆い部の分離壁や収集室部のディスク等に接触するので、それだけ母乳の衛生状態を良好に保つのが難しい。

【０００８】また、分離壁を越えてピストンポンプ部へと流れ込んでしまった母乳は、廃棄するしかなく、それだけ、母乳の捕集率が低くなってしまう。

【０００９】ディスクに母乳がへばり付き易く、動作不良が生じ易い。また、母乳が捕集容器へと送出されるタイミングも不規則となり易い。

【００１０】ピストンポンプ部によって発生される吸引圧は、接続部および収集室部を通して乳房覆い部の内部へと及ぼされねばならないので、負圧空間が大きく、必要な吸引圧を発生させるためには、それだけ大きな動力が必要となる。したがって、ピストンポンプを電気モータにて駆動するような場合には、それだけ消費電力が大きくなってしまう。電池電源の場合には、特に、この点は重大な問題となる。

【００１１】本発明の目的は、前述したような従来の技術の問題点を解消しうるような吸引圧脈動式搾乳器を提供することである。

【００１２】

【課題を解決するための手段】本発明による吸引圧脈動式搾乳器は、使用に際して乳房に対して装着され乳頭部を受け入れる開口部を有した乳房覆い部と、該乳房覆い部の前記開口部とは反対側において該乳房覆い部内と連通するシリンダ空間を定めるシリンダ部と、該シリンダ部内に挿着されたピストン部と、該ピストン部を前記シリンダ空間内において往復動させて前記乳房覆い部内に脈動的に吸引圧を作り出すようにさせるための駆動部とを備えており、前記シリンダ空間を定めるシリンダ部の内壁寸法は、前記乳房覆い部に近い側においては、前記ピストン部のピストン頭の外周を密着させて所定の長さの吸引部を与え、前記乳房覆い部から遠い側においては、前記ピストン部のピストン頭の外周との間に若干の隙間を与えて、前記吸引圧によって搾乳された乳を外部へと収集させるための乳収集部を与えるように選定されており、前記乳収集部に対応する前記シリンダ部の底部には、そこに収集された乳を外部へと送出しうるようにする穴部が形成されていることを特徴とする。

【００１３】本発明の一つの実施の形態によれば、前記シリンダ部の内壁には、前記吸引部と前記乳収集部との間の遷移部に対応する部分においてテーパ部が形成されている。

【００１４】本発明の一つの実施例によれば、前記シリンダ部には、前記穴部を包囲する位置において、搾乳された乳を捕集するための乳捕集容器を接続するための容器接続手段が設けられている。

【００１５】本発明の一つの実施の形態によれば、前記駆動部は、電気モータと、該電気モータの回転軸に接続され該回転軸の回転運動を前記シリンダ空間の軸方向にそう往復運動へと変換するためのクランク手段とを備えており、前記ピストン部のピストン軸は、前記クランク手段に連結されている。

【００１６】本発明の別の実施の形態によれば、前記乳房覆い部には、吸引圧調節手段が設けられている。

【００１７】本発明のさらに別の実施の形態によれば、前記乳房覆い部と前記シリンダ部とは、第１の構成部分として一体的に形成されており、前記駆動部は、前記第１の構成部分に対して着脱自在な第２の構成部分として形成されたハウジングの内部に配置されている。

【００１８】本発明の一つの好ましい実施例によれば、前記ピストン部は、前記ハウジングが前記第１の構成部分から外されるときには、該ハウジングと共に前記シリンダ部から外されるようにされており、前記ピストン部の前記ピストン頭は、前記ピストン軸の先端部に対して着脱自在なものとされている。

【００１９】本発明の一つの好ましい実施例によれば、前記ハウジングの内壁には、前記ピストン部の前記ピストン軸を直線的に往復動させるためのピストン軸ガイドが形成されている。

【００２０】本発明の別の好ましい実施例によれば、前記ハウジングには、前記第１の構成部分に対して固定するためのバックルが設けられている。

【００２１】本発明の実施例によれば、前記バックルには、片手で把持しうるようにするグリップ部が設けられている。

【００２２】

【発明の実施の形態】次に、添付図面に基づいて、本発明の実施例について、本発明をより詳細に説明する。

【００２３】図１は、本発明の一実施例としての吸引圧脈動式搾乳器を、組立てた状態において乳捕集容器を接続した状態で示す概略断面図であり、図２は、図１の吸引圧脈動式搾乳器の幾つかの構成部分を分解した状態で示す概略断面図である。これら図１および図２に示されるように、この実施例の吸引圧脈動式搾乳器は、主として、使用に際して乳房に対して装着され乳頭部を受け入れる開口部１１を有した乳房覆い部１０と、乳房覆い部１０の開口部１１とは反対側において乳房覆い部１０内と連通するシリンダ空間を定めるシリンダ部２０と、シリンダ部２０内に挿着されたピストン部５０と、ピストン部５０をシリンダ空間内において往復動させて乳房覆

い部１０内に脈動的に吸引圧を作り出すようにさせるための駆動部６０とを備えている。

【００２４】この実施例においては、シリンダ空間を定めるシリンダ部２０の内壁寸法は、乳房覆い部１０に近い側においては、後述するようなピストン部５０のピストン頭５１の外周を密着させて所定の長さの吸引部２１を与え、乳房覆い部１０から遠い側においては、ピストン部５０のピストン頭５１の外周との間に若干の隙間を与えて、吸引圧によって搾乳された乳を外部へと収集させるための乳収集部２２を与えるように選定されている。そして、シリンダ部２０の内壁には、吸引部２１と乳収集部２２との間の遷移部に対応する部分においてテーパ部２３が形成されている。

【００２５】乳収集部２２に対応するシリンダ部２０の底部には、そこに収集された乳を外部へと送出しうるようにする穴部２４が形成されている。図３の部分横断面図によく示されているように、この実施例では、この穴部２４は、ピストン頭５１の最後退位置（図１において仮想線で示した位置）を境にして前に配置された１対のほぼ四角形状の前方穴２４Ａと、ピストン頭５１の最後退位置を境にして後に配置されたほぼ四角形状の後方中央穴２４Ｂおよびほぼ四半円形状の左右一対の後方側部穴２４Ｃとから形成されている。

【００２６】さらに、この実施例においては、シリンダ部２０には、穴部２４を包囲する位置において、搾乳された乳を捕集するための乳捕集容器１を接続するための容器接続部３０が設けられている。この容器接続部３０は、シリンダ部２０の乳収集部２２の底面部から下方へと延長するようにして、全体として円筒状に形成されている。そして、図１によく示されるように、この容器接続部３０の下端部の内周には、乳捕集容器１の口部のネジ部１Ａをねじ込むためのネジ部３１が形成されている。

【００２７】また、この実施例では、乳房覆い部１０には、吸引圧調節部４０を着脱自在に取り付けるための取付け部１２が形成されている。この取付け部１２は、乳覆い部１０の壁部に形成された通気穴１３を取り囲むようにして形成された二重の円筒壁で構成されている。吸引圧調節部４０の詳細構造および動作については、後述する。この実施例では、図２によく示されるように、取付け部１２を含む乳覆い部１０と、容器接続部３０を含むシリンダ部２０とは、第１の構成部分として、適当な材料、例えば、プラスチック材料にて一体的に成形されている。

【００２８】ピストン部５０は、この実施例では、ピストン頭５１と、このピストン頭５１を前端に着脱自在に取り付けうるようにしたピストン軸５２とからなっている。図２によく示されるように、ピストン軸５２の前端の軸中心には、雌ネジ穴５２Ａが形成されており、ピストン頭５１の後端軸に雄ネジ５１Ａが形成されており、雌ネジ穴５２Ａへ雄ネジ５１Ａをねじ込むことにより、ピストン頭５１をピストン軸５２に取り付け固定できるようになっている。

【００２９】駆動部６０は、この実施例では、乳覆い部１０、取付け部１２、シリンダ部２０および容器接続部３０を構成する第１の構成部分に対して着脱自在とされた第２の構成部分として形成されたハウジング６１を備えている。このハウジング６１も、適当な材料、例えば、プラスチック材料にて一体的に成形されている。そして、駆動部６０は、このハウジング６１内に配置された、電気モータ６２と、電気モータ６２の回転軸に接続され、この回転軸の回転運動をシリンダ空間の軸方向にそう往復運動へと変換するためのクランク機構６３とを備えている。この実施例では、電気モータ６２とクランク機構６３との間には、ギヤユニット６４が介在しており、ギヤユニット６４は、電気モータ６２の回転軸の回転速度を適当に変速して、クランク機構６３へ伝える。ハウジング６１内には、電気モータ６２を付勢するための電源としての電池を装着しうるようになった電池部６５も設けられている。勿論、ハウジング６１には、外部から、このような電池電源をオンオフしうる適当なスイッチ（図示していない）が設けられている。

【００３０】クランク機構６３は、この実施例においては、図４の部分横断面図によく示されているように、電気モータ６２の回転速度を変速して出力するギヤユニット６４の出力軸に接続されて回転されるクランクアーム６３Ａと、このクランクアーム６３Ａの自由端を遊動的に係合させた、ほぼＯ字状の移動子６３Ｂと、ハウジング６１の内壁にそって平行に形成された１対のピストン軸ガイド６３Ｃとからなっている。ピストン軸ガイド６３Ｃは、移動子６３Ｂの両側縁を挟み込むようにして、ピストン部５０のピストン軸５２を一層直線的に往復動させるように、移動子６３Ｂの移動を案内するものである。シリンダ部２０の軸方向にそう移動子６３Ｂの直線運動自体は、ハウジング６１の対向する平行内壁に、移動子６３Ｂの両側面が規制されることによって行われる。ピストン部５０のピストン軸５２の後端は、クランク機構６３の移動子６３Ｂの中心部に連結されている。

【００３１】さらにまた、この実施例では、ハウジング６１の周囲には、バックル７０が取付けられるようになっており、このバックル７０は、乳覆い部１０、取付け部１２、シリンダ部２０および容器接続部３０を構成する第１の構成部分に対して、第２の構成部分であるハウジング６０を、図１に示す如く組み付けたときに、容器接続部３０の外周に係合して、両者の組み付け状態を固定する作用を果たす。また、このバックル７０には、このように組み合わせられた搾乳器全体を片手で把持しうるようにするグリップ部７１が設けられている。

【００３２】次に、乳覆い部１０の取付け部１２に挿着される吸引圧調節部４０の詳細構造および動作につい

て、特に、図５および図６を参照して説明する。図５は、吸引圧調節部４０の分解部品配列斜視図であり、図６は、その吸引圧調節部４０のケースの構造の詳細を示すための一部破断斜視図である。この実施例における吸引圧調節部４０は、加圧開放弁としての機能も果たすものであり、図５によく示されるように、例えば、プラスチック材料にて形成されたケース４１と、例えば、金属の薄い板で形成されたプレート４２と、例えば、ゴム材料で形成されたクッション４３と、例えば、プラスチック材料で形成されたコマ４４と、例えば、プラスチック材料で形成された調節ツマミ４５とを備えている。

【００３３】先ず、ケース４１は、全体として円筒状に成形されたものであり、下端部は、図１によく示されるように、乳覆い部１０の取付け部１２に挿着しうる寸法とされている。その下端部の外周には、図６によく示されるように、Ｏリング４６を装着するための周囲溝４１Ａが設けられている。このＯリング４６は、ケース４１の下端部を取付け部１２へ挿着したときの密着性を高めるためのものである。ケース４１の上端部は、プレート４２、クッション４３およびコマ４４を収納しうる凹部を作り出しており、この凹部の底面部には、乳覆い部１０の通気穴１３と連通する貫通穴４１Ｂを有した底部溝４１Ｃが形成されている。また、この凹部の底面部には、プレート４２およびクッション４３を取り付け固定するための取付け溝４１Ｄおよび取付け柱４１Ｅが形成されている。

【００３４】プレート４２は、周囲の一個所に、比較的に大きな直径を有する圧力開放弁用の穴４２Ａと、この穴４２Ａの両側で複数個所に、比較的に直径の小さな圧力調整用の穴４２Ｂとが形成されている。これらの穴４２Ｂは、後述するようなピストン－シリンダの作用により、乳覆い部１０内に負圧が形成されようとするときに、外気を乳覆い部１０内へと吸い込めるようにして、その負圧の大きさを調整できるようにするものである。さらに、このプレート４２には、ケース４１の取付け柱４１Ｅを挿通させる取付け穴４２Ｃと、後述するクッション４３の取付け凸部４３Ｃを挿通させる挿通穴４２Ｄとが形成されている。

【００３５】クッション４３には、その中心部に、カンチレバー型の弁４３Ａが形成されており、周辺には、プレート４２に形成された穴４２Ｂのそれぞれと一致する位置に、圧力調整用の穴４３Ｂが形成されている。弁４３Ａは、プレート４２の圧力開放弁用の穴４２Ａを、常時は、閉じているが、後述するようなピストン－シリンダの作用により、乳覆い部１０内が加圧されようとするときには、その穴４２Ａを開放してその加圧力を開放させる作用をするものである。また、クッション４３の上面の穴４３Ｂの周辺部は、盛り上げられており、後述するコマ４４の下面とクッション４３の上面との間に空間が作り出されるようにしている。さらに、このクッション４３の下面には、プレート４２の挿通穴４２Ｄに挿通されて、さらに、ケース４１の取付け溝４１Ｄに嵌まり込みうる取付け凸部４３Ｃが設けられており、また、ケース４１の取付け柱４１Ｅの先端を受け入れる受入穴（図示していない）が設けられている。

【００３６】コマ４４は、調節ツマミ４５の下面内側に取付け固定される形状とされていて、その下面の外周の一部分に、圧力調整用の切欠き凹部４４Ａが形成されている。すなわち、クッション４３の上面にコマ４４の下面が接触した状態においては、そのコマ４４の下面の切欠き凹部４４Ａに対応する位置にある穴４３Ｂのみが外気を吸込みうるものとされるのである。一方、プレート４２の圧力開放弁用の穴４２Ａが弁４３Ａによって開放されたときには、前述したようなクッション４３の上面とコマ４４の下面との間に形成された空間を通して、圧力が開放されうるのである。

【００３７】調節ツマミ４５の下面の詳細は、図に現れていないが、コマ４４の上端部を取付け固定しうるような形状とされている。図１によく示されているように、この調節ツマミ４５は、ケース４１の上端に対して回転しうるように挿着されるような形状とされている。すなわち、調節ツマミ４５をケース４１に対して回転させると、コマ４４が一緒に回動させられることにより、その切欠き凹部４４Ａによって開放されるクッション４３の穴４３Ｂおよびプレート４２の穴４２Ｂの数が変化させられ、それにより、圧力調整を行えるようになっている。

【００３８】次に、前述したような構成を有する吸引圧脈動式搾乳器の全体的な動作について説明する。搾乳を行おうとするユーザは、先ず、図１に示すように、乳捕集容器１のネジ部１Ａを容器接続部３０のネジ部３１にねじ込むことにより、乳捕集容器１を組み付けると共に、ピストン部５０をシリンダ部２０内に挿着するようにして駆動部６０を乳覆い部１０に対して合体させて、バックル７０にてこの合体をロックする。

【００３９】それから、ユーザは、グリップ部７１を把持して、このようにして組み立てられた搾乳器の乳覆い部１０の開口部１１を通して、自身の乳房に対して乳覆い部１０を押し付けるようにして被せる。そして、吸引圧調節部４０の調節ツマミ４５を回動させて、吸引圧を所望値に設定する。その後、駆動部６０に設けられた電源スイッチ（図示していない）をオンに切り換える。

【００４０】すると、電気モータ６２が付勢されて、電気モータ６２の回転軸の回転により、ギヤユニット６４を介して、所定の回転速度にて、クランク機構６３のクランクアーム６３Ａが回転させられる。このようなクランクアーム６３Ａの回転により、移動子６３Ｂがハウジング６１の両側内壁およびピストン軸ガイド６３Ｃによって案内されて、図１および図４において実線で示した位置と仮想線で示した位置との間で往復動させられるよ

Page 1505 of 2922

うになる。したがって、この移動子６３Ｂに接続されたピストン軸５２も往復動させられ、ピストン頭５１が、シリンダ部２０内において、図１に実線で示した位置と仮想線で示した位置との間で往復動させられる。

【００４１】このようなピストン頭５１のシリンダ部２０内での往復動作によって搾乳が行われるのであるが、次に、その動作の詳細について説明する。先ず、図１においてピストン頭５１は、仮想線で示す位置、すなわち、乳収集部２２の底部の穴部２４の前方穴２４Ａと、後方中央穴２４Ｂおよび後方側部穴２４Ｃとの間の位置にあると仮定する。この位置は、ピストン頭５１の最後退位置である。この位置からピストン頭５１が前方へと移動させられて、テーパ部２３を越えて、吸引部２１内へと入って行くとき、乳覆い部１０内の空気が圧縮され始めて、圧力が高まろうとする。しかし、乳覆い部１０内の空気は、その圧力の高まりにより、圧力調節部４０の弁４３Ａが開くことにより、通気穴１３および圧力開放弁用の穴４２Ａを通して外部へと逃がされる。したがって、ピストン頭５１は、シリンダ部２０の吸引部２１内へとスムーズに押し込まれうる。そして、ピストン頭５１は、図１において実線で示す位置、すなわち、最前進位置へと移動する。

【００４２】次いで、ピストン頭５１は、この最前進位置から後方へと移動させられ始める。すると、この吸引部２１においては、ピストン頭５１の外周はシリンダ部の内壁に密着しているので、乳覆い部１０内に吸引圧が生ぜしめられ始める。このような吸引圧により、乳覆い部１０に装着された乳房が絞られ、搾乳が行われ始める。このような搾乳作用は、ピストン頭５１が、吸引部２１と乳収集部２２との間の遷移部に相当するテーパ部２３へと後退するまで続けられる。ピストン頭５１がテーパ部２３を越えて後退すると、乳収集部２２では、ピストン頭５１の外周とシリンダ部２０の内壁との密着性が失われるので、それ以上の吸引圧の発生は停止させられる。そして、ピストン頭５１が仮想線で示す最後退位置に達すると、搾乳された乳は、開放された穴部２４の、主として、前方穴２４Ａを通して且つ容器接続部３０の内部を通して、そこに接続された容器１内へと落下して、そこに捕集される。ピストン頭５１の外周とシリンダ部２０の内壁との間の若干の隙間を通して、ピストン頭５１の後ろへと回り込んだ乳も、穴部２４の後方中央穴２４Ｂおよび後方側部穴２４Ｃを通して、容器１内に捕集できる。

【００４３】この最後退位置からピストン頭５１は、再び、前方へと移動させられて、前述したような動作が繰り返されることになる。こうして、乳覆い部１０内に装着された乳房には、脈動的に吸引圧が加えられて、実際に乳児が母乳を吸うのと同じような動作にて、搾乳が続けられることになる。ユーザは、このような搾乳動作中において、吸引圧に違和感を感ずる場合には、調節ネジ４５を回動させて、その吸引圧を違和感のないものに調整することも可能である。

【００４４】このようにして適当量の搾乳がなされた後には、ユーザは、自分の乳房から搾乳器を外し、容器１を容器接続部３０から取り外して、容器１そのままで適当な場所に保管しておき、後に乳児に飲ますことができる。勿論、容器１から別の適当な容器へと搾乳された母乳を移して保管することも自由である。この搾乳器のその後の使用を衛生的なものとするために、使用後は、すぐに、乳覆い部１０、シリンダ部２０および容器接続部３０の第１の構成部分から、駆動部６０およびピストン部５０の第２の構成部分を取り外し、さらに、取付け部１２から圧力衝接部４０も取り外し、ピストン軸５２の先端からピストン頭５１も取り外して、各部分を清掃しておくとよい。

【００４５】なお、前述した実施例では、ピストン部の駆動源として電気モータを使用しているが、本発明は、これに限らず、例えば、ピストン部を手動にて動作させるようなものとすることもできる。

【００４６】

【発明の効果】乳覆い部に対してシリンダ部を直結した構成としたことにより、構造が非常に簡単となり、それだけコストの低減ができ、しかも、使用後の清掃も非常に簡単となり、衛生上の問題もない。

【００４７】搾乳された母乳は、その後の使用のために容器へと直接的に捕集され得るので、それだけ母乳の衛生状態を良好に保つのが容易である。

【００４８】搾乳された母乳は、シリンダ部の乳収集部２２の穴部２４を通してほとんどすべて容器へと捕集できるので、母乳の捕集率を高めることができる。

【００４９】搾乳された母乳の流路が非常に簡単な構造とされているので、母乳が構成部分にへばり付いてしまうようなことはなく、したがって、動作不良が生じたり、母乳が捕集容器へと送出されるタイミングが不規則とされてしまうようなことはない。

【００５０】ピストンポンプ部によって発生すべき吸引圧は、乳覆い部とシリンダ部の一部分である吸引部との内部だけですむので、負圧空間が最小限とされ、必要な吸引圧を発生させるために必要な動力は最小限ですみ、したがって、ピストンポンプを電気モータにて駆動するような場合には、それだけ消費電力が少なくてすむ。使用する電気モータも小型とすることができるので、それだけ搾乳器全体の大きさも小型とすることができる。

【００５１】一定周期の一定吸引圧で、より乳児が母乳を吸う感覚に近い搾乳が行える。

【００５２】乳覆い部に、吸引圧調節部と加圧開放弁とを共有化した加圧開放弁付調節部を設けることにより、簡単に搾乳しながら吸引圧を調節でき、違和感の伴わない搾乳を行わせることができる。

【００５３】この加圧開放弁付調節部は、乳覆い部に対

して着脱自在なものとしておくことにより、簡単な構造の乳覆い部の清掃が容易となる。

【００５４】搾乳された母乳を容器へと捕集するために乳収集部に設ける穴部の構成を工夫することにより、搾乳された母乳の捕集率をより高めることができる。

【図面の簡単な説明】

【図１】本発明の一実施例としての吸引圧脈動式搾乳器を、組立てた状態において乳捕集容器を接続した状態で示す概略断面図である。

【図２】図１の吸引圧脈動式搾乳器の幾つかの構成部分を分解した状態で示す概略断面図である。

【図３】図１の搾乳器の乳収集部の穴部の構成を詳細に示すための部分横断面図である。

【図４】図１の搾乳器のクランク機構の詳細を示すための部分横断面図である。

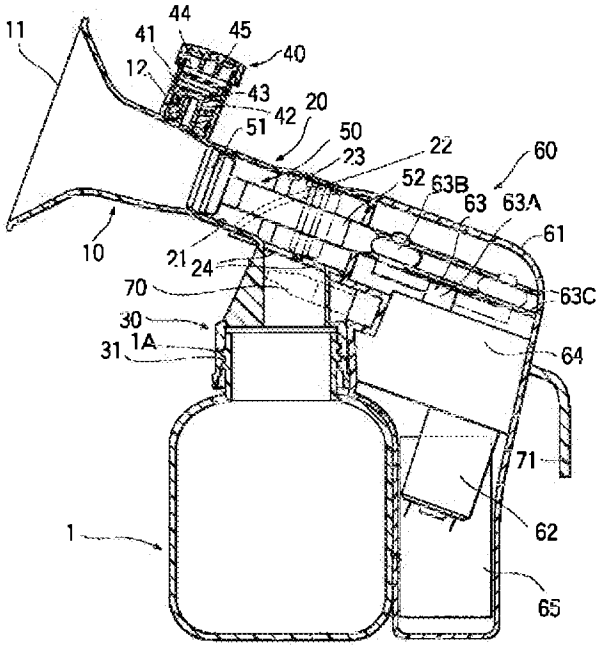
【図５】図１の搾乳器の吸引圧調節部４０の分解部品配列斜視図である。

【図６】図５の吸引圧調節部のケースの構造の詳細を示すための一部破断斜視図である。

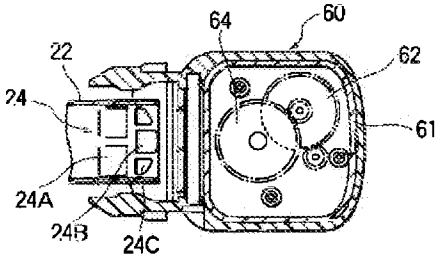
【符号の説明】

１　乳捕集容器
１０　乳覆い部
１１　開口部
２０　シリンダ部
２１　吸引部
２２　乳収集部
２３　テーパ部
２４　穴部
３０　容器接続部
４０　吸引圧調節部
５０　ピストン部
５１　ピストン頭
５２　ピストン軸
６０　駆動部
６１　ハウジング
６２　電気モータ
６３　クランク機構
６３Ａ　クランクアーム
６３Ｂ　移動子
６３Ｃ　ピストン軸ガイド
６４　ギヤユニット
６５　電池部

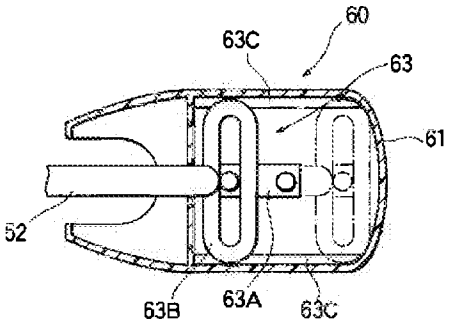
【図１】



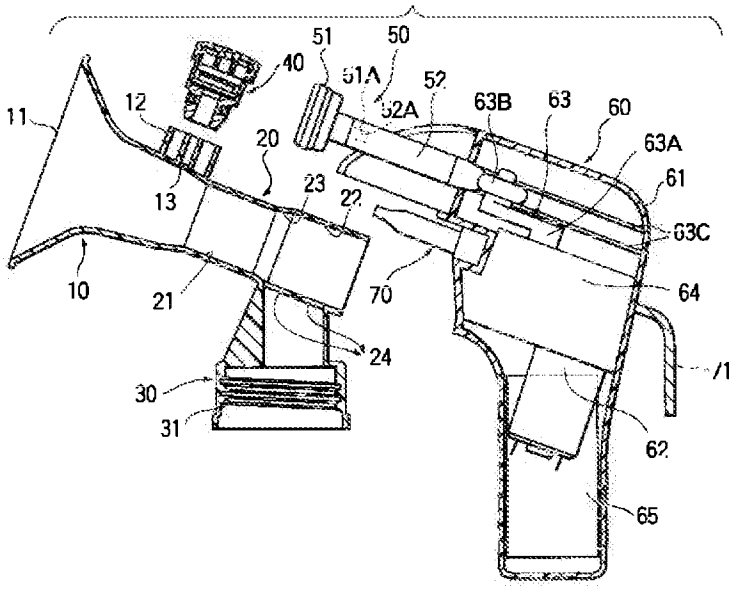
【図３】



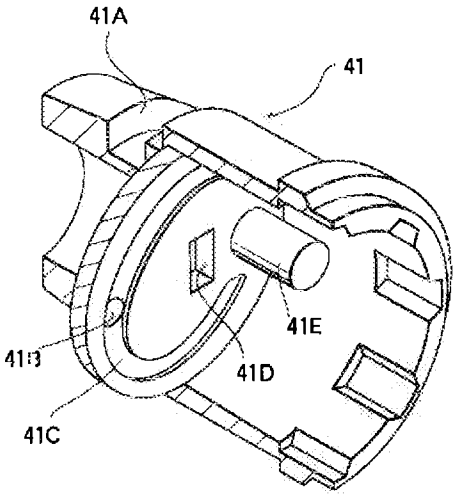
【図４】



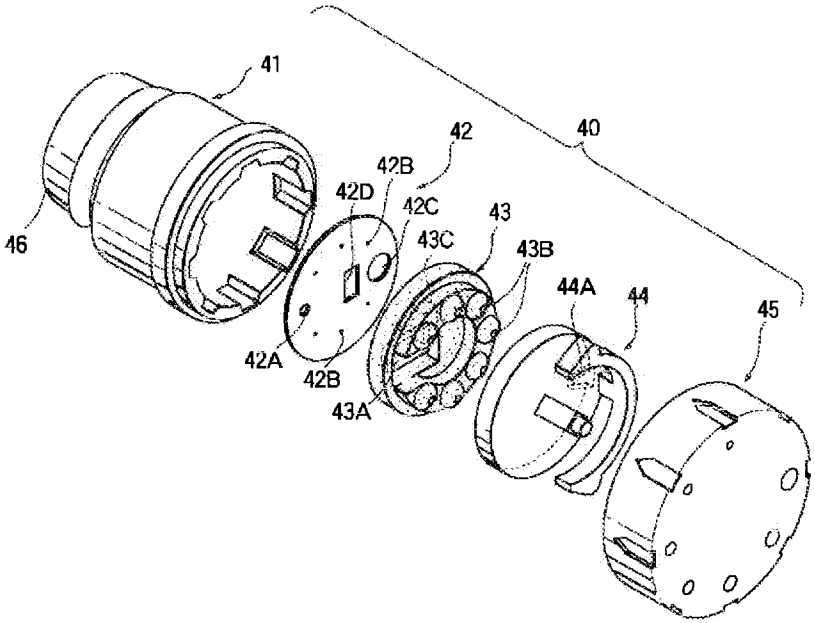
【図２】



【図６】



【図５】



フロントページの続き

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Pulsating suction force milking machine

Abstract

PROBLEM TO BE SOLVED: To provide a pulsating suction force milking machine which has simple structure, is small, of low power consumption, cost effective, and easily keeps good sanitary conditions. SOLUTION: This pulsating suction force milking machine is provided with a breast cover 10, cylinder 20, piston 50 installed in the cylinder 20, drive section 60 which reciprocates the piston 50 within the cylinder area in the cylinder 20 to make pulsating suction force in the udder cover 10. The inside wall size of the cylinder 20 defining the area of the cylinder is designed in such a manner that at the area near the udder cover 10, the circumference of the piston head 51 of the piston 50 is adhered to create a suction area 21 of a specified length, and at an area far from the udder cover 10, there is a clearance between the inside wall and the piston head 51 of the piston 50, and a milk collecting section 22 is made in which milk collected by suction force is guided to the outside, and at an area of the bottom of the cylinder 20 corresponding to the milk collecting section 22, an aperture 24 is made to feed collected milk to the outside.

Classifications

- A61M1/06 Milking pumps

View 2 more classifications

JPH11178917A

Japan

Find Prior Art Similar

Other languages: Japanese

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Current Assignee : Hirose Electric Co Ltd, Pigeon Corp

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Status · Expired - Fee Related

Info: Cited by (3), Legal events, Similar documents, Priority and Related Applications

External links: Espacenet, Global Dossier, Discuss

Claims (10)

Hide Dependent

translated from Japanese

[Claims] 1. A breast cover having an opening which is attached to a breast and receives a nipple in use, and a cylinder space which communicates with the inside of the breast cover at a side of the breast cover opposite to the opening. A cylinder portion to be defined, a piston portion inserted into the cylinder portion, and a drive portion for causing the piston portion to reciprocate in the cylinder space to generate pulsating suction pressure in the breast covering portion. The inner wall dimension of the cylinder portion that defines the cylinder space, on the side close to the breast covering portion, tightly contact the outer circumference of the piston head of the piston portion to provide a suction portion of a predetermined length, On the side far from the breast covering part, a slight clearance is provided between the piston part and the outer periphery of the piston head to collect milk pumped by the suction pressure to the outside. The bottom of the cylinder portion corresponding to the milk collecting unit is formed with a hole that allows the collected milk to be

sent out to the outside. Pulsating breast pump with suction pressure. 2. A suction pressure pulsating breast pump according to claim 1, wherein a tapered portion is formed on an inner wall of said cylinder portion at a portion corresponding to a transition portion between said suction portion and said milk collecting portion. 3. A cylinder connection means for connecting a milk collection container for collecting milked milk at a position surrounding the hole portion in the cylinder portion. Or the suction pulsation milking machine according to 2. 4. The driving unit includes an electric motor and crank means connected to a rotating shaft of the electric motor for converting a rotating motion of the rotating shaft into a reciprocating motion in an axial direction of the cylinder space. The suction pressure pulsation type breast pump according to claim 1, wherein a piston shaft of the piston portion is connected to the crank means. 5. The suction pulsation type breast pump according to claim 1, wherein said breast covering portion is provided with suction pressure adjusting means. 6. The breast covering part and the cylinder part,

The drive part is integrally formed as a first component, and the drive unit is disposed inside a housing formed as a second component detachable from the first component. A suction pressure pulsation milking machine according to any one of 1 to 5. 7. The piston portion is detached from the cylinder portion together with the housing when the housing is detached from the first component.

The suction pressure pulsating breast pump according to claim 6, wherein the piston head of the piston portion is detachable from a tip portion of the piston shaft. 8. The suction pressure pulsating breast pump according to claim 6, wherein a piston shaft guide for linearly reciprocating the piston shaft of the piston portion is formed on an inner wall of the housing. 9. The suction pressure pulsation type breast pump according to claim 6, wherein the housing is provided with a buckle for fixing to the first component. 10. The suction pressure pulsating breast pump according to claim 9, wherein the buckle is provided with a grip portion that can be gripped with one hand.

Description

translated from Japanese

DETAILED DESCRIPTION OF THE INVENTION

[0001]

FIELD OF THE INVENTION The present invention relates to breast pumps and, more particularly, to a breast pump for extracting breast milk from the breast for storage in a newborn for later consumption. It is about a vessel.

[0002]

2. Description of the Related Art This type of breast pump is sometimes called a breast pump, and is typically divided into two types. That is, there are a type driven by a motor and a type driven manually. This kind of so-called breast pump, whether it is motor-driven or manual, has a pulsating suction pressure using a reciprocating piston pump, because it is easy to actually achieve the same effect as a baby sucking breast milk. The mainstream is the suction pressure pulsation type in which the milk is milked by hanging it on the breast.

[0003] Conventional examples of such a suction pressure pulsation type breast pump include those disclosed in, for example, Japanese Patent Application Laid-Open No. 1-317448 and US Pat. No. 4,929,229. These conventional suction-pressure pulsating breast pumps communicate with the breast cover having an opening that is attached to the breast and receives the nipple during use and collects the milk expressed by the inside of the breast cover. A reciprocating piston pump for generating suction pressure inside the breast cover, and a connection for connecting the breast cover and the reciprocating piston pump. ing.

When a suction pressure is created in the breast cover by the reciprocating piston pump in the collection chamber, the interior of the collection chamber is sealed from the outside, but the milk collected there is discharged to the outside. A disc is provided which operates to open the interior of the collection chamber to the outside in order to send out. Also, between the breast cover and the collection chamber and in the middle of the vacuum line to the reciprocating piston pump, milked milk is prevented from entering the reciprocating piston pump. Separation walls and the like are also provided.

According to such a conventional suction pressure pulsation type breast pump, an appropriate container is connected to the collection chamber, the breast cover is attached to the breast, and the reciprocating piston pump is operated. For example, the nipple and adjacent parts may be sucked and pulled into a narrow portion within the nipple cover due to the negative pressure or vacuum pulsatingly generated within the breast cover. Such a pulling action massages and compresses the breast so that the baby can suck, causing the extraction of breast milk. The breast milk extracted into the nipple cover is guided to the collection chamber, where it is collected into a container connected to the collection chamber when the disc is allowed to open to the outside.

[0006]

However, such a conventional breast pump has a complicated internal structure such as a breast cover portion and a collection room portion, which increases the cost, and also requires cleaning after use. It was very difficult and there were hygiene issues.

Before the milked milk is collected in a container for subsequent use, it comes into contact with the separation wall of the breast cover, the disk of the collection chamber, and the like, so that the sanitary condition of the milk is improved accordingly. Difficult to keep in.

[0008] Further, the breast milk that has flowed into the piston pump section over the separation wall has to be discarded, and the collection rate of the breast milk is accordingly reduced.

[0009] Breast milk tends to stick to the disk, and malfunctions are likely to occur. In addition, the timing at which breast milk is delivered to the collection container tends to be irregular.

[0010] Since the suction pressure generated by the piston pump section must be applied to the inside of the breast covering section through the connection section and the collection chamber section, the negative pressure space is large, and in order to generate the required suction pressure. , So much power is needed. Therefore, when the piston pump is driven by the electric motor, the power consumption increases accordingly. This is a significant problem, especially in the case of battery power.

It is an object of the present invention to provide a suction pulsating breast pump which can solve the problems of the prior art as described above.

[0012]

SUMMARY OF THE INVENTION A suction pulsating breastpump according to the present invention is provided with a breast cover having an opening which is attached to the breast for use and receives a nipple, and the opening of the breast cover. On the opposite side, a cylinder part that defines a cylinder space communicating with the inside of the breast cover part, a piston part inserted in the cylinder part, and the piston part reciprocates in the cylinder space to enter the breast cover part. A drive unit for generating suction pressure in a pulsating manner, wherein an inner wall dimension of the cylinder unit that defines the cylinder space is, on a side close to the breast covering unit, an outer periphery of a piston head of the piston unit. To provide a suction portion of a predetermined length in close contact, and on the side far from the breast covering portion, to give a slight gap between the piston portion and the outer periphery of the piston head, It is selected so as to provide a milk collecting section for collecting milk expressed by drawing under pressure, and the bottom of the cylinder section corresponding to the milk collecting section is provided with milk collected there. A hole is formed so as to be capable of being sent to the outside.

According to one embodiment of the present invention, a tapered portion is formed on an inner wall of the cylinder portion at a portion corresponding to a transition portion between the suction portion and the milk collecting portion.

According to one embodiment of the present invention, the cylinder portion has a container connection for connecting a milk collecting container for collecting milked milk at a position surrounding the hole. Means are provided.

According to one embodiment of the present invention, the driving section is connected to an electric motor and a rotating shaft of the electric motor, so that the rotating motion of the rotating shaft is reciprocated in the axial direction of the cylinder space. And a crank means for converting the piston into a piston. The piston shaft of the piston portion is connected to the crank means.

According to another embodiment of the present invention, the breast cover is provided with suction pressure adjusting means.

According to yet another embodiment of the present invention,
The breast cover and the cylinder are integrally formed as a first component, and the driving unit is formed as a second component that is detachable from the first component. Located inside the housing.

According to one preferred embodiment of the present invention,
The piston portion is detached from the cylinder portion together with the housing when the housing is detached from the first component, and the piston head of the piston portion is provided at a tip end of the piston shaft. The part is detachable.

According to one preferred embodiment of the present invention,
A piston shaft guide for linearly reciprocating the piston shaft of the piston portion is formed on an inner wall of the housing.

According to another preferred embodiment of the present invention, the housing is provided with a buckle for fixing to the first component.

According to an embodiment of the present invention, the buckle is provided with a grip portion which can be gripped with one hand.

[0022]

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS Next, the present invention will be described in more detail with reference to the accompanying drawings.

FIG. 1 is a schematic sectional view showing a suction pulsation type breast pump as one embodiment of the present invention in a state where a milk collecting container is connected in an assembled state, and FIG. It is a schematic sectional drawing which shows some components of a suction pressure pulsation type breast pump in the disassembled state. As shown in FIGS. 1 and 2, the suction-pulsation-type breast pump of this embodiment mainly includes a breast covering part 10 having

an opening 11 which is attached to a breast in use and receives a nipple, A cylinder section 20 that defines a cylinder space communicating with the inside of the breast covering section 10 on the opposite side of the opening section 11 of the breast covering section 10, a piston section 50 inserted into the cylinder section 20, and the piston section 50. And a drive unit 60 for reciprocating within the breast cover 10 so as to generate pulsating suction pressure in the breast covering unit 10.

In this embodiment, the inner wall dimension of the cylinder portion 20 that defines the cylinder space is set to a predetermined value on the side close to the breast cover portion 10 by closely contacting the outer periphery of a piston head 51 of the piston portion 50 as described later. Length suction unit 21
On the side remote from the breast covering portion 10 to provide a slight gap between the piston portion 50 and the outer periphery of the piston head 51 to collect milk milked by suction pressure to the outside. The part 22 is selected to provide. Further, a tapered portion 23 is formed on the inner wall of the cylinder portion 20 at a portion corresponding to a transition portion between the suction portion 21 and the milk collecting portion 22.

A hole 24 is formed in the bottom of the cylinder 20 corresponding to the milk collecting unit 22 so that the milk collected there can be sent out. As shown in the partial cross-sectional view of FIG. 3, in this embodiment, the hole 24 is located at the most backward position of the piston head 51 (the position shown by the phantom line in FIG. 1). , A pair of substantially square front holes 24A, a substantially square rear central hole 24B disposed after the rearmost position of the piston head 51, and a pair of right and left rear sides substantially quadrant. 24C.

Further, in this embodiment, the cylinder connecting portion 30 is connected to the container connecting portion 30 for connecting the milk collecting container 1 for collecting milked milk at a position surrounding the hole portion 24. Is provided. This container connection part 30
Is formed in a cylindrical shape as a whole so as to extend downward from the bottom surface of the milk collecting part 22 of the cylinder part 20. As shown in FIG. 1, a screw portion 31 for screwing the screw portion 1 </ b> A at the mouth of the milk collecting container 1 is formed on the inner periphery of the lower end of the container connecting portion 30.

In this embodiment, an attachment portion 12 for detachably attaching the suction pressure adjusting portion 40 is formed in the breast covering portion 10. The mounting portion 12 is formed of a double cylindrical wall formed so as to surround a ventilation hole 13 formed in the wall of the milk covering portion 10. The detailed structure and operation of the suction pressure adjusting unit 40 will be described later. In this embodiment, as best shown in FIG. 2, the milk wrap 10 including the mounting portion 12 and the cylinder 20 including the container connection 30 are made of a suitable material such as a first component, for example, It is integrally formed of a plastic material.

In this embodiment, the piston section 50 comprises a piston head 51 and a piston shaft 52 so that the piston head 51 can be detachably attached to the front end. As shown in FIG. 2, a female screw hole 52 </ b> A is formed at the center of the front end of the piston shaft 52, and a male screw 51 </ b> A is formed at the rear end shaft of the piston head 51.
By screwing the male screw 51A into the female screw hole 52A,
The piston head 51 can be attached and fixed to a piston shaft 52.

In this embodiment, the drive unit 60 has a second structure which is detachably attached to the first components of the milk cover unit 10, the attachment unit 12, the cylinder unit 20, and the container connection unit 30. It has a housing 61 formed as a part. The housing 61 is also integrally formed of a suitable material, for example, a plastic material. The drive unit 60 is connected to an electric motor 62 and a rotating shaft of the electric motor 62 disposed in the housing 61, and converts the rotating motion of the rotating shaft into a reciprocating motion in the axial direction of the cylinder space. And a crank mechanism 63 for performing the operation. In this embodiment, a gear unit 64 is interposed between the electric motor 62 and the crank mechanism 63. The gear unit 64 appropriately changes the rotation speed of the rotating shaft of the electric motor 62, and Tell 63
A battery unit 6 in which a battery as a power source for energizing the electric motor 62 can be mounted is provided in the housing 61.
5 is also provided. Of course, the housing 61 is provided with a suitable switch (not shown) that can turn on and off such a battery power supply from outside.

In this embodiment, the crank mechanism 63 is connected to an output shaft of a gear unit 64 for changing the rotation speed of the electric motor 62 and outputting the same, as is well shown in the partial cross-sectional view of FIG. A crank arm 63A which is rotated and rotated, a substantially O-shaped mover 63B in which a free end of the crank arm 63A is loosely engaged, and a pair formed in parallel along the inner wall of the housing 61. And a piston shaft guide 63C. Piston shaft guide 6
3C sandwiches both side edges of the mover 63B,
This guides the movement of the movable member 63B so that the piston shaft 52 of the piston portion 50 reciprocates more linearly. The linear movement itself of the moving member 63B in the axial direction of the cylinder portion 20 is performed by the opposing parallel inner walls of the housing 61 restricting both side surfaces of the moving member 63B. The rear end of the piston shaft 52 of the piston portion 50 is connected to the center of the moving member 63B of the crank mechanism 63.

Further, in this embodiment, a buckle 70 is mounted around the housing 61, and the buckle 70 is connected to the milk cover part 10, the mounting part 12, the cylinder part 20, and the container connecting part. When a housing 60 as a second component is assembled as shown in FIG. 1 with respect to the first component constituting the component 30, the housing 60 engages with the outer periphery of the container connection portion 30, and the two components are assembled. Serves to fix the In addition, the buckle 70 is provided with a grip portion 71 that enables the whole breast pump combined in this way to be gripped with one hand.

Next, the detailed structure and operation of the suction pressure adjusting section 40 inserted into the mounting section 12 of the milk covering section 10 will be described with reference to FIGS. 5 and 6. FIG.
6 is a perspective view of an exploded component arrangement of the suction pressure adjusting unit 40, and FIG. 6 is a partially cutaway perspective view showing details of the structure of the case of the suction pressure adjusting unit 40. The suction pressure adjusting unit 40 in this embodiment also functions as a pressure release valve, and as shown in FIG. 5, for example, a case 41 formed of a plastic material and a metal It includes a plate 42 formed of a thin plate, a cushion 43 formed of, for example, a rubber material, a top 44 formed of, for example, a plastic material, and an adjustment knob 45 formed of, for example, a plastic material. .

First, the case 41 is formed into a cylindrical shape as a whole, and the lower end portion is sized so as to be able to be inserted into the mounting portion 12 of the milk covering portion 10, as is well shown in FIG. ing. On the outer periphery of the lower end, as shown in FIG.
A is provided. The O-ring 46 is attached to the case 41
This is for improving the adhesiveness when the lower end of the base is inserted into the mounting portion 12. The upper end of the case 41 has a recess capable of accommodating the plate 42, the cushion 43, and the top 44, and the bottom of the recess has a milk cover 1
A bottom groove 41C having a through hole 41B communicating with the zero ventilation hole 13 is formed. Further, a mounting groove 41D and a mounting column 41E for mounting and fixing the plate 42 and the cushion 43 are formed on the bottom surface of the concave portion.

The plate 42 is provided with a pressure relief valve hole 42A having a relatively large diameter at one location and a pressure adjustment hole with a relatively small diameter at a plurality of locations on both sides of the hole 42A. 42B are formed. These holes 4
2B, when a negative pressure is to be formed in the milk cover 10 by the action of a piston-cylinder as described later, so that outside air can be sucked into the milk cover 10 and
The magnitude of the negative pressure can be adjusted.
Further, the plate 42 has an attachment hole 42C through which the attachment column 41E of the case 41 is inserted, and an insertion hole 42D through which an attachment protrusion 43C of the cushion 43 described later is inserted
Are formed.

The cushion 43 has a cantilever type valve 43A formed at the center thereof, and a pressure adjusting hole 43B formed at a position corresponding to each of the holes 42B formed in the plate 42 at the periphery thereof. Are formed. Valve 4

3A normally closes the hole 42A for the pressure release valve of the plate 42, but when the inside of the milk covering part 10 is to be pressurized by the action of the piston-cylinder as described later, the hole is used. 42A is released to release the pressing force. The periphery of the hole 43 </ b> B on the upper surface of the cushion 43 is raised, so that a space is created between the lower surface of the top 44 and the upper surface of the cushion 43, which will be described later. Further, on the lower surface of the cushion 43, there is provided a mounting projection 43C which is inserted through the insertion hole 42D of the plate 42 and can be fitted into the mounting groove 41D of the case 41. A receiving hole (not shown) for receiving the tip of the column 41E is provided.

The top 44 has a shape fixed to the inside of the lower surface of the adjustment knob 45, and a notch concave portion 44A for pressure adjustment is formed in a part of the outer periphery of the lower surface. That is, when the lower surface of the top 44 is in contact with the upper surface of the cushion 43, only the hole 43B located at a position corresponding to the cutout recess 44A on the lower surface of the top 44 can suck outside air. On the other hand, when the pressure release valve hole 42A of the plate 42 is opened by the valve 43A, the pressure can be released through the space formed between the upper surface of the cushion 43 and the lower surface of the top 44 as described above. is there.

The details of the lower surface of the adjustment knob 45 are not shown in the figure, but are shaped so that the upper end of the top 44 can be attached and fixed. As best shown in FIG.
The adjustment knob 45 is shaped so as to be rotatable with respect to the upper end of the case 41. That is, when the adjustment knob 45 is rotated with respect to the case 41, the top 44 is rotated together, so that the number of the holes 43 </ b> B of the cushion 43 and the number of the holes 42 </ b> B of the plate 42 opened by the cutout recesses 44 </ b> A are reduced. It is varied so that a pressure adjustment can be made.

Next, the overall operation of the suction pressure pulsation type breast pump having the above-described configuration will be described. The user who wants to perform milking first attaches the milk collecting container 1 by screwing the screw portion 1A of the milk collecting container 1 into the screw portion 31 of the container connecting portion 30 as shown in FIG. The drive unit 60 is combined with the milk cover unit 10 by inserting the unit 50 into the cylinder unit 20,
This union is locked by the buckle 70.

Then, the user grasps the grip 71 and pushes the milk cover 10 against his / her breast through the opening 11 of the milk cover 10 of the breast pump assembled in this way. Cover. Then, the adjustment knob 45 of the suction pressure adjusting section 40 is turned to set the suction pressure to a desired value. Thereafter, a power switch (not shown) provided in the drive unit 60 is turned on.

Then, the electric motor 62 is energized, and the rotation of the rotating shaft of the electric motor 62 causes the gear unit 64 to rotate.
, The crank arm 63A of the crank mechanism 63 is rotated at a predetermined rotation speed. Due to the rotation of the crank arm 63A, the mover 63B is guided by the inner wall on both sides of the housing 61 and the piston shaft guide 63C, and moves between the position indicated by the solid line and the position indicated by the imaginary line in FIGS. To reciprocate. Therefore, the piston shaft 52 connected to the mover 63B is also reciprocated, and the piston head 51
The cylinder is reciprocated in the cylinder section 20 between a position indicated by a solid line and a position indicated by a virtual line in FIG.

The cylinder part 2 of the piston head 51 as described above
Milking is performed by reciprocating motion within 0,
Next, details of the operation will be described. First, in FIG. 1, the piston head 51 is located at a position indicated by an imaginary line, that is, a front hole 24 </ b> A of the hole 24 at the bottom of the milk collecting unit 22.
Assume that it is located between rear center hole 24B and rear side hole 24C. This position is the last retreat position of the piston head 51. From this position, when the piston head 51 is moved forward and crosses the taper portion 23 and enters the suction portion 21, the air in the milk cover portion 10 starts to be compressed, and the pressure increases. I do. However, the breast cover 10
The air inside is increased by the pressure control unit 40 due to the increase in the pressure.
When the valve 43A is opened, it escapes to the outside through the vent hole 13 and the hole 42A for the pressure release valve. Therefore, the piston head 51 is connected to the suction section 21 of the cylinder section 20.
it can be pushed in smoothly. Then, the piston head 51 moves to the position shown by the solid line in FIG. 1, that is, to the most advanced position

Next, the piston head 51 starts to be moved backward from the most advanced position. Then, in the suction section 21, since the outer periphery of the piston head 51 is in close contact with the inner wall of the cylinder section, suction pressure starts to be generated in the milk covering section 10. With such a suction pressure, the breast attached to the milk covering part 10 is squeezed, and milking starts. Such a milking action is continued until the piston head 51 retreats to the taper portion 23 corresponding to a transition portion between the suction portion 21 and the milk collection portion 22. When the piston head 51 retreats beyond the taper portion 23, the milk collecting unit 22 loses the adhesion between the outer periphery of the piston head 51 and the inner wall of the cylinder unit 20, so that further generation of suction pressure is stopped. . When the piston head 51 reaches the last retracted position indicated by the imaginary line, the milked milk is removed from the opened hole 24.
Mainly through the front hole 24A and the container connection 3
Through the interior of 0, it falls into the container 1 connected thereto and is collected there. The milk that has wrapped around the rear of the piston head 51 through a slight gap between the outer periphery of the piston head 51 and the inner wall of the cylinder portion 20 also passes through the rear central hole 24B and the rear side hole 24C of the hole portion 24, and the container. 1 can be collected.

From this last retreat position, the piston head 51 is moved forward again, and the above-described operation is repeated. Thus, the suction pressure is applied to the breast mounted in the milk cover part 10 in a pulsating manner, and the milking is continued by the same operation as the actual sucking of the breast milk by the infant. If the user feels uncomfortable with the suction pressure during such a milking operation, the user can also rotate the adjustment knob 45 to adjust the suction pressure to one that does not cause uncomfortable feeling.

After an appropriate amount of milking has been performed in this way, the user removes the breast pump from his / her breast, and
Can be detached from the container connection portion 30 and stored in an appropriate place with the container 1 as it is, so that it can be later consumed by an infant. Of course, it is free to transfer and store the milked milk from the container 1 to another suitable container. In order to make the subsequent use of this breast pump sanitary, immediately after use, the milking part 10, the cylinder part 20 and the first component part of the container connection part 30 are immediately replaced by the drive part 60 and the piston. It is preferable to remove the second component of the portion 50, further remove the pressure contact portion 40 from the mounting portion 12, and remove the piston head 51 from the tip of the piston shaft 52, and clean each portion.

In the above-described embodiment, the electric motor is used as the driving source of the piston portion.
However, the invention is not limited to this. For example, the piston unit may be manually operated.

[0046]

According to the construction in which the cylinder portion is directly connected to the milk cover portion, the structure becomes very simple, the cost can be reduced accordingly, and the cleaning after use becomes very simple, and the sanitary condition is improved. No problem

[0047] Milked milk can be collected directly into containers for subsequent use, so that it is easier to maintain good milk hygiene.

[0048] Almost all of the milk that has been milked can be collected in the container through the hole 24 of the milk collecting unit 22 of the cylinder unit, so that the collection rate of breast milk can be increased.

Since the passage of the milked milk has a very simple structure, there is no possibility that the milk sticks to the constituent parts, so that malfunctions occur or the milk is collected. There is no irregularity in the timing of the delivery to the container.

Since the suction pressure to be generated by the piston pump section only needs to be inside the milk cover section and the suction section which is a part of the cylinder section, the negative pressure space is minimized and the necessary suction pressure is generated. Requires minimal power,
Therefore, when the piston pump is driven by the electric motor, the power consumption is reduced accordingly. Since the electric motor used can also be small, the overall size of the breast pump can be reduced accordingly.

With a constant suction pressure at a constant cycle, milking can be performed more like a baby sucking breast milk.

By providing a control unit with a pressure release valve that shares the suction pressure control unit and the pressure release valve in the milk cover unit,
The sucking pressure can be adjusted while milking easily, and milking without discomfort can be performed.

The adjusting section with the pressure release valve is detachable from the milk covering section, thereby facilitating cleaning of the milk covering section having a simple structure.

By devising the configuration of the hole provided in the milk collecting section for collecting the milked milk into the container, the collection rate of the milked milk can be further increased.

[Brief description of the drawings]

FIG. 1 is a schematic cross-sectional view showing a suction pressure pulsation type breast pump as one embodiment of the present invention in a state where a milk collecting container is connected in an assembled state.

FIG. 2 is a schematic sectional view showing some components of the suction pressure pulsation type breast pump of FIG. 1 in an exploded state.

FIG. 3 is a partial cross-sectional view showing in detail a configuration of a hole of a milk collecting unit of the breast pump of FIG. 1;

FIG. 4 is a partial cross-sectional view showing details of a crank mechanism of the breast pump of FIG. 1;

FIG. 5 is an exploded perspective view of a disassembled component of a suction pressure adjusting unit 40 of the breast pump of FIG. 1;

FIG. 6 is a partially broken perspective view showing details of the structure of a case of a suction pressure adjusting unit in FIG. 5,

[Explanation of symbols]

DESCRIPTION OF SYMBOLS 1 Milk collection container 10 Milk covering part 11 Opening 20 Cylinder part 21 Suction part 22 Milk collecting part 23 Taper part 24 Hole part 30 Container connection part 40 Suction pressure adjustment part 50 Piston part 51 Piston head 52 Piston shaft 60 Drive part 61 Housing 62 Electric motor 63 Crank mechanism 63A Crank arm 63B Mover 63C Piston shaft guide 64 Gear unit 65 Battery unit

----------続き Continuing from the front page (72) Inventor Kazuhiko Takano 5-5-23 Osaki, Shinagawa-ku, Tokyo Hirose Electric Co., Ltd. (72) Inventor Hiroyuki Uehara 5-1-1 Kanda Toyama-cho, Chiyoda-ku, Tokyo Inside the corporation

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JP2013532540A *	2010-07-27	2013-08-19	コーニンクレッカ フィリップス エレクトロニクス エヌ ヴィ	Milking machine

Family To Family Citations

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Priority And Related Applications

Priority Applications (1)

Application	Priority date	Filing date	Title
JP35684897A	1997-12-25	1997-12-25	Suction pressure pulsating breast pump

Applications Claiming Priority (1)

Application	Filing date	Title
JP35684897A	1997-12-25	Suction pressure pulsating breast pump

Legal Events

Date	Code	Title	Description
2004-12-09	A621	Written request for application examination	**Free format text**: JAPANESE INTERMEDIATE CODE: A621 **Effective date**: 20041208
2007-07-11	A977	Report on retrieval	**Free format text**: JAPANESE INTERMEDIATE CODE: A971007 **Effective date**: 20070711
2007-07-11	TRDD	Decision of grant or rejection written	
2007-07-24	A01	Written decision to grant a patent or to grant a registration (utility model)	**Free format text**: JAPANESE INTERMEDIATE CODE: A01 **Effective date**: 20070723
2007-08-02	A61	First payment of annual fees (during grant procedure)	**Free format text**: JAPANESE INTERMEDIATE CODE: A61 **Effective date**: 20070730
2007-08-03	R150	Certificate of patent or registration of utility model	**Free format text**: JAPANESE INTERMEDIATE CODE: R150
2007-08-06	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text**: PAYMENT UNTIL: 20100803 **Year of fee payment**: 3
2010-08-13	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text**: PAYMENT UNTIL: 20110803 **Year of fee payment**: 4
2010-08-13	S111	Request for change of ownership or part of ownership	**Free format text**: JAPANESE INTERMEDIATE CODE: R313117
2010-08-23	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text**: PAYMENT UNTIL: 20110803 **Year of fee payment**: 4
2010-08-23	R350	Written notification of registration of transfer	**Free format text**: JAPANESE INTERMEDIATE CODE: R350
2011-06-30	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text**: PAYMENT UNTIL: 20110803 **Year of fee payment**: 4
2011-07-05	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text**: PAYMENT UNTIL: 20120803 **Year of fee payment**: 5
2012-06-14	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text**: PAYMENT UNTIL: 20120803 **Year of fee payment**: 5
2012-06-19	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text**: PAYMENT UNTIL: 20130803

			Year of fee payment: 6
2013-06-18	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2014-06-24	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2015-08-11	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2016-06-21	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2017-08-03	LAPS	Cancellation because of no payment of annual fees	

Concepts

machine-extracted

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Name	Image	Sections	Count	Query match
Breast		claims,abstract,description	84	0.000
Milk		claims,abstract,description	77	0.000
milk		claims,abstract,description	77	0.000
milk		claims,abstract,description	77	0.000
corresponding		claims,abstract,description	10	0.000
Clearance		claims,abstract	2	0.000
clearance		claims,abstract	2	0.000
Nipples		claims,description	7	0.000

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(19)日本国特許庁（ＪＰ）　(12) **公開特許公報**（Ａ）　(11)特許出願公開番号
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Ａ０１Ｊ　5/04		Ａ０１Ｊ　5/04	

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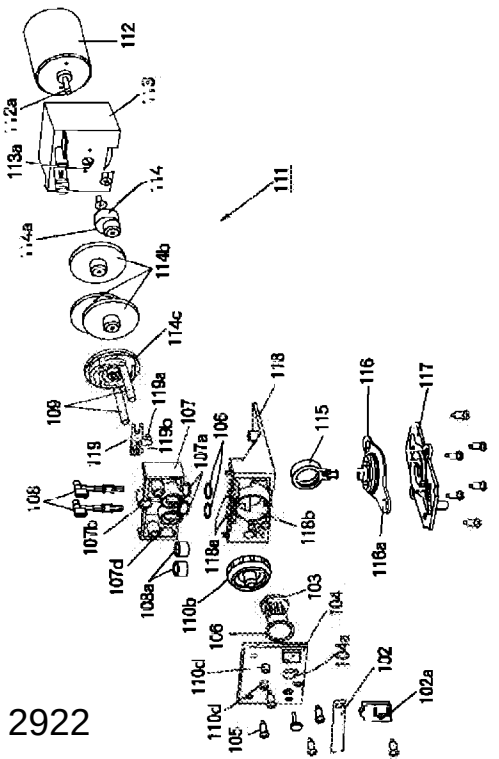
(54)【発明の名称】　脈動搾乳器

(57)【要約】　（修正有）
【課題】　部品交換が容易で、使い勝手が良好な脈動搾乳器の提供。
【解決手段】　陰圧発生部１１６と、この陰圧発生部により、その内部が陰圧となる陰圧用空間部と、この陰圧用空間部と連結されて形成されている脈動用空間部と、を有する搾乳器本体と、使用者の乳房等に設置し、使用者の母乳を吸引、貯蔵する吸引貯蔵部と、を備える脈動搾乳器において、上記陰圧用空間部１１８と上記脈動用空間部１０７とが相互に分離可能に配置されていることを特徴とする脈動搾乳器。



【特許請求の範囲】
【請求項１】　陰圧発生部と、
この陰圧発生部により、その内部が陰圧となる陰圧用空間部と、
この陰圧用空間部と連結されて形成されている脈動用空間部と、を有する搾乳器本体と、
使用者の乳房等に設置し、使用者の母乳を吸引、貯蔵する吸引貯蔵部と、を備える脈動搾乳器において、
上記陰圧用空間部と上記脈動用空間部とが相互に分離可能に配置されていることを特徴とする脈動搾乳器。
【請求項２】　上記脈動用空間部には、上記陰圧用空間部と連結するための連結凸部が設けられ、この陰圧用空間部には、この脈動用空間部と連結するための連結凹部が設けられ、且つ、これら脈動用空間部と陰圧用空間部相互の連結を保持させるための保持部が設けられていることを特徴とする請求項１に記載の脈動搾乳器。
【請求項３】　上記吸引貯蔵部と上記搾乳器本体の間には、これらを接続するための接続部が設けられており、上記吸引貯蔵部の上記接続部側には、空気室が設けられており、この空気室の内部に凹凸部が形成されていることを特徴とする請求項１又は請求項２に記載の脈動搾乳器。
【請求項４】　上記吸引貯蔵部は、使用者の母乳を吸引するための吸引部と使用者の母乳を貯蔵するための貯蔵部を有しており、この貯蔵部には、この吸引部で吸引された使用者の母乳を上記貯蔵部へ移動させるための弁が設けられ、この弁の略中心部が、上記吸引部側に撓んで形成されていることを特徴とする請求項１乃至請求項３の何れかに記載の脈動搾乳器。
【請求項５】　上記搾乳器本体の両側及び上記吸引貯蔵部を載置可能に形成されているホルダ部には、このホルダ部をこの搾乳器本体に取付けるための係合部がそれぞれ備えられていることを特徴とする請求項１乃至請求項４の何れかに記載の脈動搾乳器。
【発明の詳細な説明】
【０００１】
【発明の属する技術分野】本発明は、使用者が母乳を搾乳する際に用いる搾乳器に関し、特に、間欠的に母乳の吸引を行う所謂、脈動搾乳器に関するものである。
【０００２】
【従来の技術】搾乳器には、大きく分けて、手動式搾乳器と電動式搾乳器がある。このうち、手動式搾乳器は、使用者が自己の手等でポンプを動かし、このポンプの力で搾乳を行うものである。一方、電動式搾乳器は、モータ等の力を用い、ダイヤフラム等を動作させ、一定の空間に陰圧を形成させるようになっている。この陰圧状態は、この空間と使用者の乳房と間の存在するようになっているため、母乳は吸引され、所定のボトル内に収容されるようになっている。この電動搾乳器の陰圧を発生させるポンプユニットとしては、例えば図２４に示すようなものがある。図２４に示すように、ポンプユニット１０は、モータ１１の動力が減速ギヤ１２、１２、１２、１２を介して伝わるようになっている。具体的には、先ず、モータ１１の軸には、図示しない偏心カムが装着されており、この偏心カムに図２５に示すコネクションロッド１３が係合するようになっている。このコネクションロッド１３は、ダイヤフラム裏板１５上に設けられているダイヤフラム１４と接続されている。
【０００３】このため、モータ１１の軸の回転が図で示す上下運動となり、ダイヤフラム１４を上下に動かすことになる。このダイヤフラムの弁１４ａは、図２５に示すシャーシ１６の陰圧空間部１６ａに設けられた孔と接続されている。したがって、ダイヤフラムの弁１４ａの動きによって、この陰圧空間部１６ａには、陰圧空間が形成されることになる。次に、上記陰圧空間部１６ａの上には、２つの脈動用空間部１６ｂ、１６ｂが、この陰圧空間部１６ａと一体に形成されている。そして、これら２つの脈動用空間部１６ｂ、１６ｂの低部には、それぞれ孔が設けられ、陰圧空間部１６ａとこの孔を介して連通して形成されている。これら２つの脈動用空間部１６ｂ、１６ｂには、図２５に示すコントロール軸１７、１７が、それぞれ上部の開口より挿入され、これらコントロール軸１７、１７の下端部には、図示しないコントロール弁が取り付けられることになる。このコントロール弁は、コントロール軸１７が図において下方向に移動すると、上記脈動用空間部１６ｂの低部に設けられた孔を塞ぎ、その下に設けられている陰圧空間部１６ａとの連通状態を遮断することになる。また、このコントロール弁が、コントロール軸１７が図において下方向に移動すると、この脈動用空間部１６ｂの上部の開口部を開口状態にすることになる。
【０００４】このような働きをするコントロール弁付きコントロール軸１７、１７は、図２５に示すシーソー１８と係合している。そして、このシーソー１８は、図２４に示す減速ギヤ１２、１２、１２、１２と歯合している図示しないコントロールギヤにより、揺動させられることになる。このシーソー１８の揺動により、上記２つのコントロール軸１７、１７は、交互に上下運動を行うことになる。ところで、上記２つの脈動用空間部１６ｂ、１６ｂは、図２４に示すノズル１９、１９と連通しており、このノズル１９、１９は、図示しない母乳収容用ボトルとホース等で接続されている。この母乳収容用ボトルには、使用者の乳房に密着させる碗状の母乳受け部が設けられている。このように構成される電動搾乳器のポンプユニット１０を動作させると、モータ１１の回転により、ダイヤフラム１４が動き、陰圧空間部１６ａを陰圧とする。一方、モータ１１の回転により、上記コントロールギヤが回転し、シーソー１８を揺動させ、２つのコントロール軸１７、１７を交互に上下動させることになる。このコントロール軸１７が下に動いた、一方

の脈動用空間部１６ｂは、陰圧空間部１６ａとの連通が遮断され、陰圧ではなく開放状態になる。また、コントロール軸１７が上に動いた、一方の脈動用空間部１６ｂは、陰圧状態となる。

【０００５】ここにおいて、上記母乳収容用ボトルを、ホースにて、一方のノズル１９（図２４参照）と接続させて、使用する場合、この母乳収容用ボトルと連通している脈動用空間部１６ｂは、一方のみであるため、一方のコントロール軸１７の上下動によって、陰圧状態と開放状態が繰り返えされることになる。これにより、連続的な吸引ではない、乳幼児が行う吸引に近い状態、すなわち脈動状態の吸引が可能となり、より効果的な搾乳ができることとなる。

【０００６】

【発明が解決しようとする課題】このような脈動搾乳器のモータユニット１０のシャーシ１６を形成する陰圧空間部１６ａと脈動用空間部１６ｂは、脈動搾乳器の吸引力となる陰圧を効果的に発生させるための重要な部品である。したがって、僅かな不具合がこれらの部品に発生しても、脈動搾乳器の吸引力に大きな影響を与えるため、不具合が生じた部品は取り替える必要があった。この不具合は、シャーシ１６の陰圧空間部１６ａ又は脈動用空間部１６ｂの何れか一方にのみ生じる場合が多いが、この場合でも、これら陰圧空間部１６ａと脈動空間部１６ｂが上述のように一体に形成されているため、シャーシ１６全体を取り替える必要がるという問題があった。

【０００７】本発明は、以上の点に鑑み、部品交換が容易で、使い勝手が良好な脈動搾乳器を提供することを目的とする。

【０００８】

【課題を解決するための手段】上記目的は、本発明によれば、陰圧発生部と、この陰圧発生部により、その内部が陰圧となる陰圧用空間部と、この陰圧用空間部と連結されて形成されている脈動用空間部と、を有する搾乳器本体と、使用者の乳房等に設置し、使用者の母乳を吸引、貯蔵する吸引貯蔵部と、を備える脈動搾乳器において、上記陰圧用空間部と上記脈動用空間部とが相互に分離可能に配置されていることを特徴とする脈動搾乳器により達成される。

【０００９】上記構成によれば、上記陰圧用空間部と上記脈動用空間部とが相互に分離可能に配置されているので、何れか一方のみを分離して交換することができる。

【００１０】好ましくは、請求項１の構成において、上記脈動用空間部には、上記陰圧用空間部と連結するための連結凸部が設けられ、この陰圧用空間部には、この脈動用空間部と連結するための連結凹部が設けられ、且つ、これら脈動用空間部と陰圧用空間部相互の連結を保持させるための保持部が設けられていることを特徴とする脈動搾乳器である。

【００１１】上記構成によれば、上記脈動用空間部には、上記陰圧用空間部と連結するための連結凸部が設けられ、この陰圧用空間部には、この脈動用空間部と連結するための連結凹部が設けられているので、これら連結凸部と連結凹部を組み合わせることで容易に脈動用空間部と陰圧用空間部を連結することができる。また、上記脈動用空間部と上記陰圧用空間部相互の連結を保持させるための保持部が設けられているので、脈動用空間部と陰圧用空間部との連結をより強固にすることができる。

【００１２】好ましくは、請求項１又は請求項２の構成において、上記吸引貯蔵部と上記搾乳器本体の間には、これらを接続するための接続部が設けられており、上記吸引貯蔵部の上記接続部側には、空気室が設けられており、この空気室の内部に凹凸部が形成されていることを特徴とする脈動搾乳器である。

【００１３】上記構成によれば、上記吸引貯蔵部の上記接続部側には、空気室が設けられているので、母乳が上記接続部へ流入するのを防ぐことができる。また、この空気室の内部に凹凸部が形成されているので、この空気室の内部面積が増加し、より母乳の水蒸気が、この空気室の内部に付着するので、母乳が上記接続部へ流入するのをより防ぐことができる。

【００１４】また、好ましくは、請求項１乃至請求項３の何れかの構成において、上記吸引貯蔵部は、使用者の母乳を吸引するための吸引部と使用者の母乳を貯蔵するための貯蔵部を有しており、この貯蔵部には、この吸引部で吸引された使用者の母乳を上記貯蔵部へ移動させるための弁が設けられ、この弁の略中心部が、上記吸引部側に撓んで形成されていることを特徴とする脈動搾乳器である。

【００１５】上記構成によれば、上記弁の略中心部が、上記吸引部側に撓んで形成されているので、この弁が閉じる方向に撓まされることになる。これにより陰圧状態がより確実になる。

【００１６】なお、好ましくは、請求項１乃至請求項４の何れかの構成において、上記搾乳器本体の両側及び上記吸引貯蔵部を載置可能に形成されているホルダ部には、このホルダ部をこの搾乳器本体に取付けるための係合部がそれぞれ備えられていることを特徴とする脈動搾乳器である。

【００１７】上記構成によれば、上記搾乳器本体の両側及び上記吸引貯蔵部を載置可能に形成されているホルダ部には、このホルダ部をこの搾乳器本体に取付けるための係合部がそれぞれ備えられているので、このホルダ部を上記搾乳器本体の両側又は片側に容易に取り付けることができる。

【００１８】

【発明の実施の形態】以下、この発明の好適な実施形態を図１乃至図２３を参照しながら、詳細に説明する。尚、以下に述べる実施形態は、本発明の好適な具体例で

あるから、技術的に好ましい種々の限定が付されているが、本発明の範囲は、以下の説明において特に本発明を限定する旨の記載がない限り、これらの態様に限られるものではない。

【００１９】図１は、本発明の実施の形態に係る脈動搾乳器１００を示す図である。脈動搾乳器１００は、搾乳器本体であるポンプユニット１１０と、その両側に配置されているホルダ部であるボトルホルダ１２０、１２０を有している。また、脈動搾乳器１００は、吸引貯蔵部であるボトルユニット１３０、１３０を例えば２つ備えている。さらに、脈動搾乳器１００は、上記ボトルユニット１３０とポンプユニット１１０を接続するための接続部である吸気チューブ１４０、１４０が２本備えられている。また、上記ポンプユニット１１０の表面には、図１に示すように、電源スイッチ１１０ａと吸引圧調節ダイヤル１１０ｂが配置されている。図２は、上記ポンプユニット１１０とボトルホルダ１２０、１２０を、図１の裏側より見た図である。図２に示すように、ポンプユニット１１０には、吸気チューブ１４０、１４０を接続するためのノズル１１０ｄ、１１０ｄが例えば２つ設けられている。また、このポンプユニット１１０には、電源である例えば電池を収納するための電池収納部１１０ｃが設けられている。また、電源としてＡＣ電源を用いることもできる。この場合、図２に示すＡＣ電源用接続端子１１０ｅにＡＣ電源を接続して使用しすることになる。このポンプユニット１１０は、使用者である母親の母乳を吸引するための吸引圧を発生させるものであるため、以下、詳細に説明する。

【００２０】図３は、図１及び図２に示す上記ポンプユニット１１０のケーシングを外し、ポンプユニット１１０の中枢部であるポンプユニットの中枢部を示した図である。また、図４は、図３に示すポンプユニットの中枢部１１０を分解して示した分解斜視図である。図４に示すように、モータ１１２は、モータプレート１１３に収容されている。このとき、モータ１１２のモータ軸１１２ａは、モータプレート１１３のモータプレート孔１１３ａに挿入され、その先端に偏心カム１１４が取り付けられる。この偏心カム１１４の先端には、ギヤ１１４ａが設けられている。この偏心カム１１４は、陰圧発生部であるダイヤフラム１１６と接続されているコネクションロッド１１５と係合されている。また、このダイヤフラム１１６は、ダイヤフラム裏板１１７上に載置されるようになっている。なお、このコネクションロッド１１５は、陰圧用空間部であるシャーシ１１８に設けられている丸穴に挿入された状態で、偏心カム１１４と係合することとなる。

【００２１】一方、上記ギヤ１１４ａは、減速ギヤ１１４ｂと歯合し、さらに２枚の減速ギヤ１１４ｂ、１１４ｂが歯合状態で連なっている。さらに、この減速ギヤ１１４ｂと歯合されているのが、コントロールギヤ１１４ｃであり、このコントロールギヤ１１４ｃと係合しているのがシーソー１１９である。なお、上記減速ギヤ１１４ｂ、１１４ｂ、１１４ｂとコントロールギヤ１１４ｃは、ステンレス棒１０９、１０９により支持されている。また、上記シーソー１１９は、２つのコントロール軸１０８、１０８と係合されており、この２つのコントロール軸１０８、１０８は、脈動用空間部であるシーソーベース１０７の上部に設けられた開口部より下方向に挿入されることにより、ノズル用開口部１０７ｄ、１０７ｄ内に予め配置されているコントロール弁１０８ａ、１０８ａに取り付けられることになる。このシーソーベース１０７の下部には、上記シャーシ１１８と接続するための連結凸部であるシーソーベース連結部１０７ａが２個設けられている。このシーソーベース連結部１０７ａ、１０７ａにＯリング１０６が装着することになる。一方、シャーシ１１８の上部には、連結凹部であるシャーシ連結部１１８ａが２つ設けられている。したがって、このシャーシ連結部１１８ａ、１１８ａに上記シーソーベース連結部１０７ａ、１０７ａを挿入することで、シーソーベース１０７とシャーシ１１８は一体的に連結されることになる。このとき、シーソーベース連結部１０７ａ、１０７ａには、Ｏリング１０６が装着されているため、気密性を維持しつつ接続される。

【００２２】また、シャーシ１１８には、シャーシ開口部１１８ｂが設けられており、このシャーシ開口部１１８ｂに対応するように、図４に示すバルブ１０３及びＯリング１０６が配置されている。このバルブ１０３とＯリング１０６は、シャーシカバー１０４の吸引圧調節用孔１０４ａを介して図示しない留め具でリーフスプリング１０２に固定されている。そして、このシャーシカバー１０４には、吸引圧調整ダイヤル１１０ｂが配置されている。この吸引圧調整ダイヤル１１０ｂには、溝が設けられており、この溝に当接して配置されているのが調節ピン１０５である。この調節ピン１０５は、吸引圧調整ダイヤル１１０ｂの回転によって、図において左右方向に移動するようになっている。ところで、保持部であるシャーシカバー１０４は、シャーシ１１８に押しつけられ、固定されることになる。このとき、シャーシカバー１０４は、シャーシ１１８のみならずシーソーベース１０７をも押さえるように配置されるため、シーソーベース１０７とシャーシ１１８との連結状態がより強固になる。ところで、このシャーシカバー１０４には、板金製のリーフスプリング１０２が配置されている。このリーフスプリング１０２の一端部は、リーフスプリング押さえ１０２ａによって固定されている。しかし、このリーフスプリング１０２の他端部は、固定されておらず、リーフスプリング１０２自体の有する弾性によって、シャーシカバー１０４の表面に押しつけられている。また、このリーフスプリング１０２の他端部には、上述の調整ピン１０５の先端が当接しているため、この調整ピ

ン105の移動により、リーフスプリング102が移動し、これと接続されているバルブ103がシャーシ118のシャーシ開口部118bに対して移動することになる。

【0023】図4に示すポンプユニットの中枢部111は、以上のように構成されて、以下のように動作する。先ず、使用者が図1に示す電源スイッチ110aをON状態にすると、図2に示す電池収納部110cに収納されている電池を電源として、モータ112が回転を始める。このモータ112の回転により、偏心カム114が偏心状態で回転することになる。この偏心カム114は、ダイヤフラム116に接続されているコネクションロッド115と係合しているため、コネクションロッド115が上下運動することになる。この状態を示したのが、図5である。図5の矢印Aに示すように、ダイヤフラム116は上下運動を行い、これにより、矢印Bに示すような空気の流れが生じる。このときダイヤフラム116のダイヤフラム弁116aの近傍にあるダイヤフラム孔116bは、シャーシ118のダイヤフラム用連結孔118cと接続されているので、シャーシ118内に陰圧を発生させることになる。このダイヤフラム用連結孔118cを示したのが、図6である。図6は、シャーシ118の底面図を示した図である。図6に示すように、シャーシ118の底面にダイヤフラム用連結孔118cが設けられている。このダイヤフラム用連結孔118cは、図7に示すシャーシ118のシャーシ開口部118bの図において底部に設けられてるため、このシャーシ開口部118とダイヤフラム孔116bは、連通していることになる。

【0024】このシャーシ開口部118には、図7に示すようにシャーシ連結部118a、118aに繋がる部分か2つに分かれて形成されており、シャーシ118の平面図である図8を見ると、このシャーシ連結部118a、118aが開口状態になっているのが分かる。このように、シャーシ118は、シャーシ開口部118b、ダイヤフラム連結用孔118c及びシャーシ連結部118a、118a以外の部分は、閉空間となっている。そして、シャーシ開口部118bは、上述のように、シャーシカバー104で塞がれてしまうため、ダイヤフラム116によってシャーシ118の内部は、陰圧状態となる。このシャーシ118の陰圧状態は、上記シーソベース107のシーソベース連結部107a、107aを介して、シーソベース107の内部にも陰圧状態を惹起することとなる。ところで、上記モータ112が回転すると、偏心カム114以外に図4に示すギャ114aも回転を始め、このギヤ114aと歯合している減速ギヤ114bにより減速されることになる。そして、3枚目の減速ギヤ114bと歯合しているコントロールギヤ114cが回転を始めることとなる。このコントロールギヤ114cは、図4に示すように特有の溝が形成されており、この溝の一部にシーソー119が係合することとなる。

【0025】この状態を示したのが、図9である。図9に示すように、コントロールギヤ114cの下部の設けられた円弧状の溝部にシーソ119のシーソー凸部119aが係合することになる。このコントロールギヤ114cの円運動は、この溝部によりシーソー119の揺動に変化することになる。なお、このシーソー119の揺動の支点は、図4に示すシーソーの支点119bであり、このシーソーの支点119bは、シーソーベース107のシーソー受け部107bに挿入されることになる。また、このシーソー119には、図4に示す2つのコントロール軸108が取り付けられることになる。この状態を示したのが図10である。図10に示すように、2つのコントロール軸108、108は、シーソー119の両側にある切り欠き部に係合されることになる。また、このコントロール軸108、108は、上述のように、シーソーベース107内に挿入され、その下部にコントロール弁108a、108aが取付けられることになる。図11は、このシーソーベース107を示す正面図であり、図12は、シーソーベース107の平面図である。図12に示すようにシーソーベース107には、コントロール軸108を挿入するためのコントロール軸用孔107cが2つ形成されている。そして、このコントロール軸用孔107cは、図11に示すノズル用開口部107dと連通している。

【0026】しかし、これら2つのノズル用開口部107d、107d及び2つのコントロール軸用孔107c、107cは、相互に連通されておらず、それぞれが別々にシーソーベース連結部107a、107aと連通されている。このような、コントロール軸用孔107c、107c内にコントロール軸108、108は、それぞれ、配置される。この状態で、上記シーソー119が揺動運動を行うと、図10に示すようにコントロール軸108、108が交互に上下運動を行うことになる。このコントロール軸108が、下方向に動き、図11に示すノズル用開口部107d，107dの底部まで達すると、このコントロール軸108に付いているコントロール弁108aによりシーソー連結部107aが塞がれることになる。このとき、塞がれたシーソーベース107の内部空間には、上述のシャーシ118の陰圧状態が伝わらず、むしろシーソーベース107のコントロール軸用孔107cに生じるコントロール軸108との隙間によって大気開放状態となる。一方、コントロール軸108が、上方向に動くと、このコントロール軸108に付いているコントロール弁108aと、シーソー連結部107aの間に空間が生じると共に、このコントロール弁108aの上端がコントロール軸用孔107cの下端を塞ぐことになる。したがって、上述のシャーシ118内の陰圧状態が、このシーソーベース107内にも生じ

ることになる。このように陰圧状態と大気開放状態を、コントロール軸１０８、１０８の動きによって交互に生じさせることで、後述する脈動が生じることになる。

【００２７】ところで、このシーソーベース１０７に設けられた２つのノズル用開口部１０７ｄ、１０７ｄは、図４に示すようにシャーシカバーの１０４のノズル１１０ｄ、１１０ｄとそれぞれ対応して配置され、このノズル１１０ｄ、１１０ｄには、図１に示すように吸気チューブ１４０、１４０が接続されることになる。また、母親がシャーシ１１８の内部に生じている陰圧を調整するには、図４に示す吸引圧調整ダイヤル１１０ｂを、母親が操作することにより行う。すなわち、吸引圧調整ダイヤル１１０ｂは、具体的には、図１３に示すようになっている。図１３（１）に示すように、吸引圧調整ダイヤル１１０ｂには、螺旋状に厚みのことなる溝が設けられており、この溝に調整ピン１０５が当接するようになっている。この吸引圧調整ダイヤル１１０ｂは、図１に示すようにポンプユニット１１０の外部から母親が操作できるようになっている。そこで、母親がこの吸引圧調整ダイヤル１１０ｂを操作して、回すと調整ピン１０５が当接している吸引圧調整ダイヤル１１０ｂの溝の厚みが変化する。ここにおいて、例えば、溝の厚みが厚くなる場合、調整ピン１０５が図１３（２）のようにリーフスプリング１０２を押すことになる。このリーフスプリング１０２と図４に示すバルブ１０３とは、上述のように接続されているため、このバルブ１０３もシャーシ１１８のシャーシ開口部１１８ｂから離反する方向に動き、陰圧（吸引圧）は小となる。逆に、吸引圧調整ダイヤル１１０ｂの溝の厚みが薄くなれば、バルブ１０３は、シャーシ開口部１１８ｂの内部に押し込まれることになり、陰圧（吸引圧）は大となる。このようにして母親は、陰圧を調整することになる。

【００２８】以上のようにポンプユニット１１０は、構成され動作するが、このポンプユニット１１０と吸気チューブ１４０を介して接続されているボトルユニット１３０について以下、説明する。図１４は、ボトルユニット１３０の分解斜視図である。図示のようにボトルユニット１３０は、母親の母乳を吸引するための吸引部と、母乳を貯蔵するための貯蔵部とを有している。この吸引部を構成するものとしては、搾乳キャップ１３３、円板１３４、中栓１３５、円筒１３６及びブレストシールド１３７が挙げられる。このうち、ブレストシールド１３７は、その一部に母親が自己の乳房に装着させる部分である母乳受け部１３７ａを有している。この母乳受け部には、図示しない別体の滑り止め部を用いても良い。すなわち、母親の乳房に当接する部分に凹凸部が配置されるように滑り止め部を、母乳受け部の内面に装着する場合である。このブレストシールド１３７の断面は、図１５に示すようになっている。形成したをこのおり、その断面は、図１５に示すようになっている。すなわち、図１５に示すように、ブレストシールド１３７の内部では、母乳受け部１３７ａの内部空間と連通されており、図において上方及び下方に導くように形成されている。

【００２９】このブレストシールド１３７の上部の開口部１３７ｂには、図１４に示す円筒１３６と円板１３４を伴った中栓１３５が挿入されることになる。この中栓１３５等が挿入された状態を示すのが図１５のＡの部分である。この中栓１３５等の構造を具体的に示したのが、図１６である。図１６に示すように、円板１３４の中心部に、円板孔１３４ａが設けられており、この円板孔１３４ａは、中栓１３５の中栓孔１３５ａ、１３５ａを介して、図１５のブレストシールド１３７内に連通している。また、中栓１３５の中栓本体１３５ｂは、図において上下方向に移動可能となっており、上方向に中栓本体１３５ｂが移動して、中栓１３５の中栓凸部１３５ｃ、１３５ｃが、円板１３４に当接すると、この移動が止まると共に、上記円板１３５の円板孔１３４ａと中栓本体１３５の中栓孔１３５ａとの間が連通状態でなくなることになる。また、この中栓１３５等の上には、図１４に示すように、空気室である搾乳口キャップ１３３が設けられている。この搾乳キャップ１３３の構造を示すのが、図１７である。図１７に示すように搾乳口キャップ１３３の上部には、図１に示す吸気チューブ１４０を接続するための吸気チューブ用孔１３３ａが設けられている。また、搾乳キャップ１３３の内周部１３３ｂには、凹凸部が設けられている。

【００３０】この凹凸部の形成は、例えば腐食加工により行う。この腐食加工は、搾乳キャップ１３３の内周部１３３ｂに、化学薬品を用いてエッチングし、不要部分を取り除く等して凹凸部を形成するものである。また、凹凸部を形成する他の方法としては、金型に砂等を吹き付けることにより、金型に傷を付けるブラスト処理の方法等もある。このように、その内周部１３３ｂに凹凸部を設けられた搾乳口キャップ１３３は、図１４に示すブレストシールド１３７に対して固定される。一方、母乳を貯蔵するための貯蔵部を構成するものとしては、図１４に示すボトル本体１３１、弁１３２及びチェックバルブ１３９等が挙げられる。このチェックバルブ１３９は、図１５に示すブレストシールド１３７の下端に差し込むように装着される。このチェックバルブ１３９の下端には、弁１３２が取り付けられている。この弁１３２は、図１８に示すように、可動片１３２ａが可動することにより弁１３２を閉状態にしたり、開状態にしたりするものである。また、図１９は、この弁１３２の断面を示した図である。図１９に示すように弁１３２の両側の上端部は、それ以外の部分と比べ肉厚に構成されている。このため、この弁１３２を、上記チェックバルブ１３９に取り付けると、上記肉厚の部分が外側に広がることになる。その結果、この弁１３２の略中心部である可動片１３２ａが、図において上方向に撓むこととなる。

そして、このように弁１３２の可動片１３２ａが上方に撓むと、この可動片１３２ａは、弁１３２を閉状態に保持する方向に配置されることになる。

【００３１】以上のように構成されているボトルユニット１３０の動作等を以下、説明する。先ず、図１に示すように、ポンプユニット１３０の搾乳口キャップ１３３に吸気チューブ１４０を取付ける。そして、２つのボトルユニット１３０のブレストシールド１３７、１３７の母乳受け部１３７ａ、１３７ａを、図２０に示すように、それぞれ使用者である母親の両方の乳房に密着させる。この状態で、ポンプユニット１１０の電源スイッチ１１０ａをＯＮ状態にすると、上述のように、ポンプユニットの中枢部１１１が動き出すことになる。このポンプユニットの中枢部１１１の動作により、ポンプユニット１１０の２つノズル１１０ｄ、１１０ｄは、交互に吸引と大気開放を繰り返すことになる。この２つノズル１１０ｄ、１１０ｄにおける吸引と大気開放は、吸気チューブ１４０、１４０を介してボトルユニット１３０、１３０に伝わることになる。すなわち、吸引状態の場合は、吸引圧が吸気チューブ１４０を通り、搾乳口キャップ１３０を介し、図１６に示す円板孔１３４ａを通り、中栓孔１３５ａを通って、図１５に示すブレストシールド１３７内に達することになる。

【００３２】ところで、このブレストシールド１３７の下端部には弁１３２を有するチェックバルブ１３９が設けられているため、この吸引圧によって、図１９の弁１３２の可動片１３２ａは図において上方に引っ張られることになり、これにより、弁１３２が閉状態に保持されることになる。このとき、たとえ吸引圧が若干、小さくても、弁１３２の可動片１３２ａが、上述のように上方に向かって撓んで保持されているため、可動片１３２ａが下方向に移動して、吸引圧を弱めてしまうことがない。このようにブレストシールド１３７の下端部は、弁１３２によって閉状態となっているため、ブレストシールド１３７内の吸引圧は、母乳受け部１３７ａに達し、そこに配置されている母親の乳房を吸引することになる。この吸引圧によって搾乳された母乳は、図１５に示す母乳受け部１３７ａに沿ってブレストシールド１３７内に流れ込み、チェックバルブ１３９を通り、弁１３２に達することになる。このとき、脈動により吸引が止まるのとほぼ同時に、母乳が弁１３２近傍で溜まると、その重みで弁１３２の可動片１３２ａが下方向に動き、母乳をボトル本体１３１内に落下させることになる。

【００３３】また、搾乳量が多く、母乳が自重でボトル本体１３１内に落下する前に、母乳がブレストシールド１３７内に溜まってしまう場合は、その溜まった母乳が図１６に示す円筒１３６を押し上げ、この円筒１３６の上昇で、中栓本体１３５ｂを押し上げ、中栓凸部１３５ｃが円板１３４に当たって、中栓本体１３５ｂより下方の空間との円板１３４より上方の空間の連通を遮断することになる。この遮断でポンプユニット１１０の吸引圧は、円板１３４部分と途切れるため、それ以上、ポンプユニット１１０側に母乳が移動することはなく、ポンプユニット１１０側へ母乳が流入することが防げることになる。このように、ポンプユニット１１０へ母乳が流入することが防ぐことで、ポンプユニット１１０の故障も防ぐことができる。また、この中栓１３５等の上には搾乳口キャップ１３３が配置され、この搾乳口キャップ１３３の内周部１３３ｂ（図１７参照）に凹凸部が設けられているため、この凹凸部によって表面積が増し吸着量が増すことにより、母乳の水蒸気等が保持され、ポンプユニット１１０へ水蒸気等が流れ込むのが有効に防止されることになる。さらに、搾乳口キャップ１３３の吸気チューブ用孔１３３ａが、図１７に示すように搾乳口キャップ１３３の上端に付いているため、より母乳の影響を受け難い位置となっている。

【００３４】一方、ポンプユニット１１０が大気開放と成っている場合は、ボトルユニット１３０において搾乳は、行われないことになる。このように、本実施の形態のポンプユニット１１０及びボトルユニット１３０等を用いれば、両方の乳房を同時に搾乳するすることができると共に、この搾乳は、吸引と大気開放を繰り返す所謂、脈動で行うことができる。また、ポンプユニット１１０のシャーシ１１８とシーソーベース１０７が分離可能に成っているため、いずれか一方が壊れても、他方のみを交換できるため、コストダウンが図れ、使い勝手が向上する。以上のようにポンプユニット１１０とボトルユニット１３０等を用いて搾乳を行った後、この２つのボトルユニット１３０、１３０を載置する場所として、ホルダ部であるボトルホルダ１２０が、図１に示すようにポンプユニット１１０の両側に設けられている。したがって、搾乳を終わった母親は、２つのボトルユニット１３０，１３０を、これらのボトルホルダ１２０、１２０に載置することができるようになっている。また、このボトルホルダ１２０、１２０は、ポンプユニット１１０に容易に取り付けられ、且つ、容易に取り外すことができるようになっている。具体的には、図２１に示すように、ポンプユニット１１０の両側にはボトルホルダ１２０を取り付けるための係合凸部１１０ｅ、１１０ｅが設けられている。この係合凸部１１０ｅは、図２２に示すように半楕円形を成している。

【００３５】一方、ボトルホルダ１２０には、図２３に示すように、この係合凸部１１０ｅに対応するようにボトルホルダ係合凹部１２０ａが設けられている。したがって、このボトルホルダ係合凹部１２０ａに、ポンプユニット１１０の係合凸部１１０ｅを差し込むことにより、ポンプユニット１１０にボトルホルダ１２０が取付けられることになる。また、使用者である母親が１つのボトルユニット１３０のみを使用する場合は、１つのボトルホルダ１２０をポンプユニット１１０の何れか一方

に取り付ければよく、脈動搾乳器１００を置いておくスペースが少なくて済む。

【００３６】

【発明の効果】以上述べたように、本発明によれば、部品交換が容易で、使い勝手が良好な脈動搾乳器を提供することができる。

【図面の簡単な説明】

【図１】本発明の実施の形態にかかる脈動搾乳器を示す概略斜視図である。

【図２】図１の脈動搾乳器のポンプユニット等を示す概略斜視図である。

【図３】ポンプユニットの中枢部を示す概略斜視図である。

【図４】図３のポンプユニットの中枢部の分解斜視図である。

【図５】図４のモータとダイヤフラムの関係を示す説明図である。

【図６】図４のシャーシの底面図である。

【図７】図４のシャーシの正面図である。

【図８】図４のシャーシの平面図である。

【図９】図４のコントロールギヤとシーソーとの関係を示す説明図である。

【図１０】図４のシーソーとコントロール軸との関係を示す説明図である。

【図１１】図４のシーソーベースの正面図である。

【図１２】図４のシーソーベースの平面図である。

【図１３】（１）吸引圧調整ダイヤルと調整ピンとの関係を示す説明図である。（２）吸引圧調整ダイヤルとリーフスプリングとの関係を示す説明図である。

【図１４】図１の脈動搾乳器のボトルユニットを示す分解斜視図である。

【図１５】図１４のブレストシールドを示す断面図である。

【図１６】図１４の円板、中栓、円筒を接続した状態を示す概略断面図である。

【図１７】図１４の搾乳口キャップを示す断面図である。

【図１８】図１４の弁を示す平面図である。

【図１９】図１４の弁を示す断面図である。

【図２０】母親が脈動搾乳器を使用している状態を示す図である。

【図２１】図１のポンプユニットと係合凸部との関係を示す平面図である。

【図２２】図２１のポンプユニットの側面図である。

【図２３】図１のポンプユニットとボトルホルダの係合状態を示す平面図である。

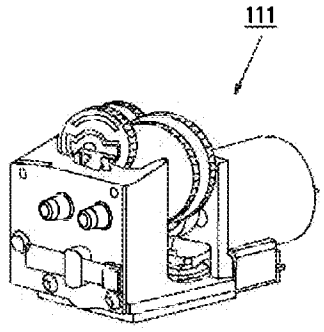
【図２４】従来のポンプユニットを示す斜視図である。

【図２５】図２４のポンプユニットの概略分解図である。

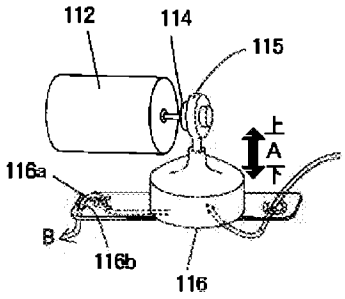
【符号の説明】

１００・・・脈動搾乳器、１０２・・リーフスプリング、１０３・・・バルブ、１０４・・・シャーシカバー、１０５・・・調節ピン、１０６・・・Ｏリング、１０７・・・シーソーベース、１０８・・・コントロール軸、１０９・・・ステンレス棒、１１０・・・ポンプユニット、１１２・・・モータ、１１３・・・モータプレート、１１４・・・偏心カム、１１５・・・コネクションロッド、１１６・・・ダイヤフラム、１１７・・・ダイタフラム裏板、１１８・・・シャーシ、１１９・・・シーソー、１２０・・・ボトルホルダ、１３０・・・ボトルユニット、１３１・・・ボトル本体、１３２・・・弁、１３３・・・搾乳口キャップ、１３４・・・円板、１３５・・・中栓、１３６・・・円筒、１３７・・・ブレストシールド、１３９・・・チェックバルブ

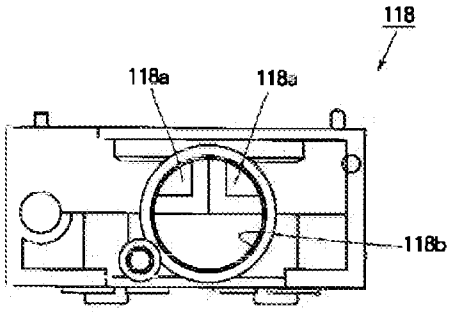
【図3】



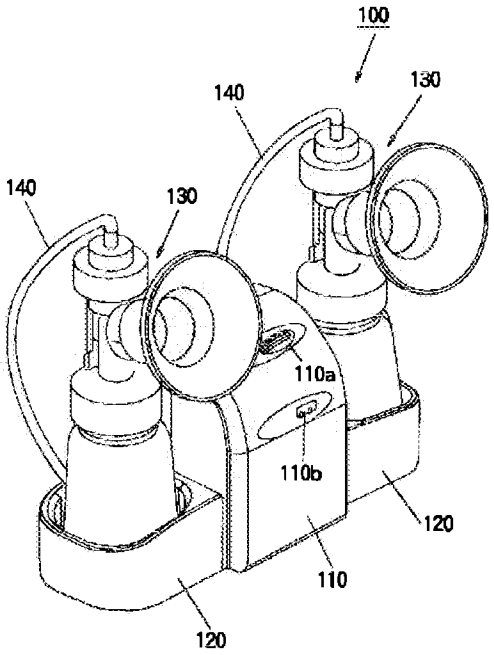
【図5】



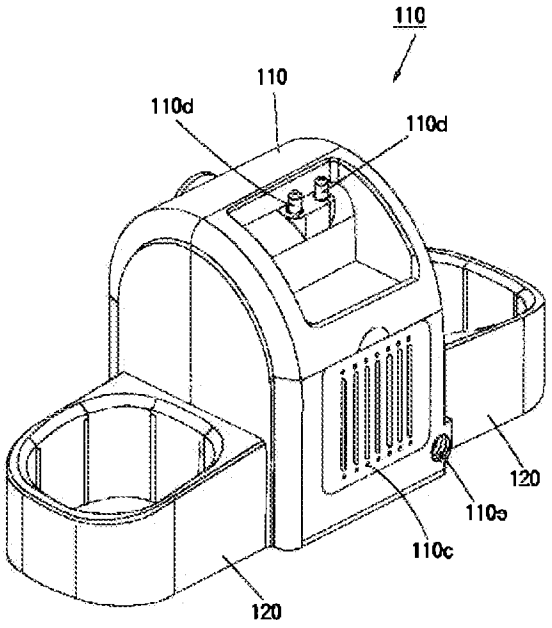
【図7】



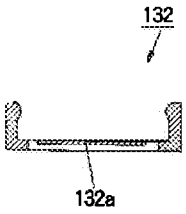
【図1】



【図2】



【図19】



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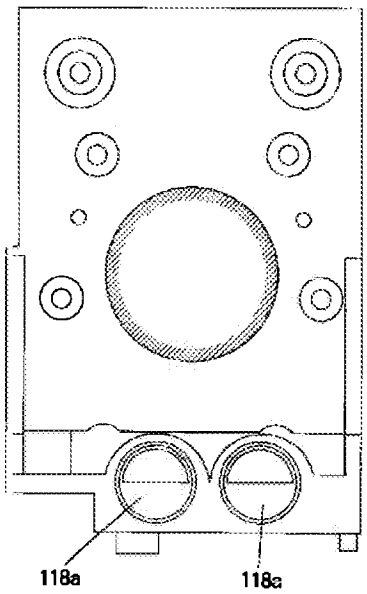

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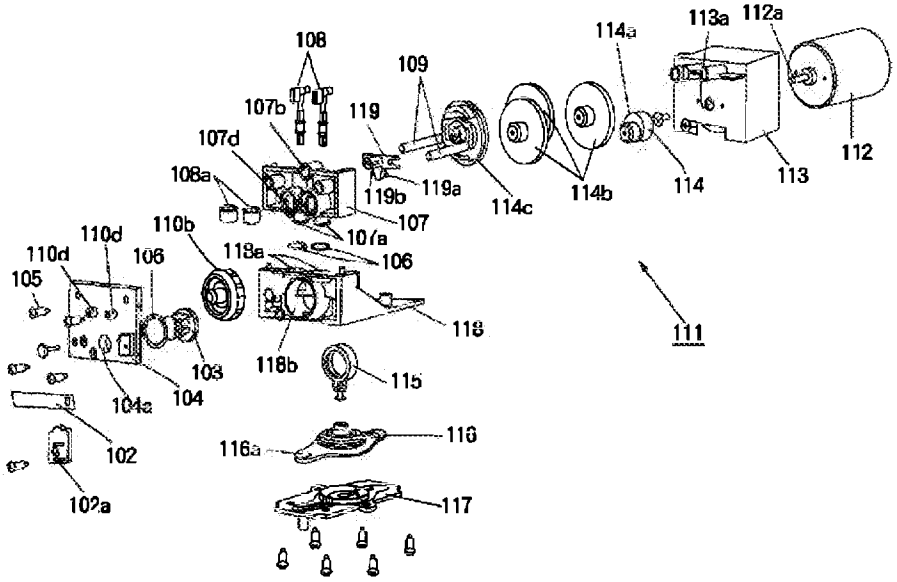

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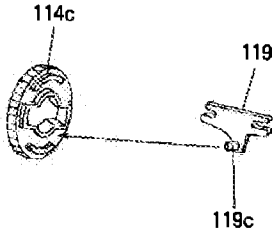

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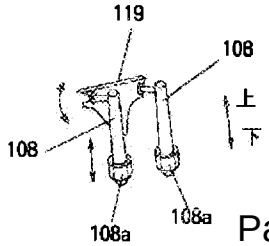

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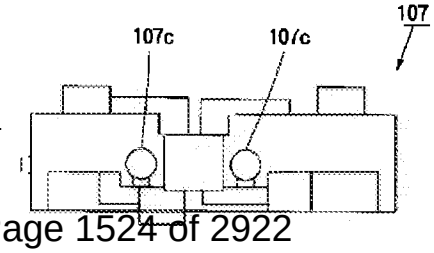

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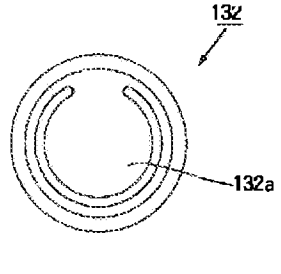

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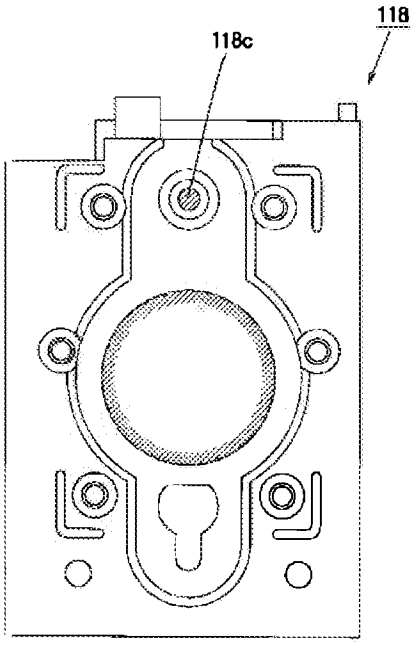

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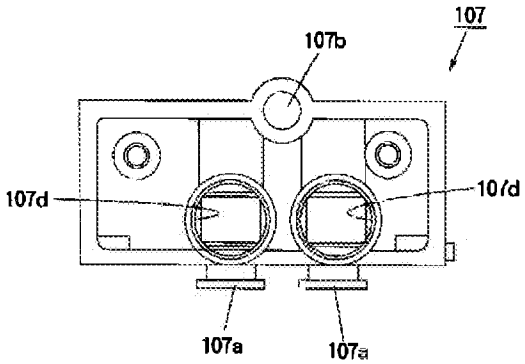

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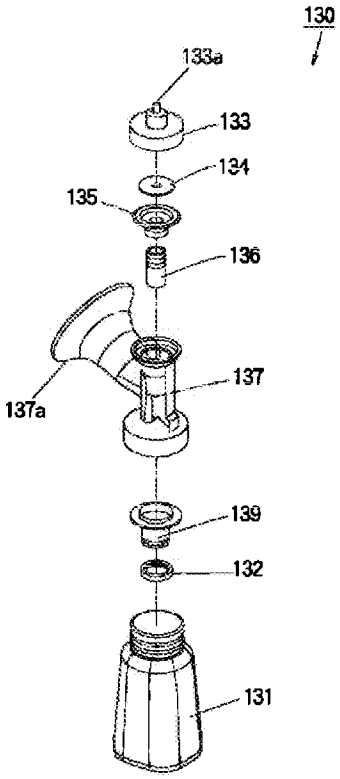

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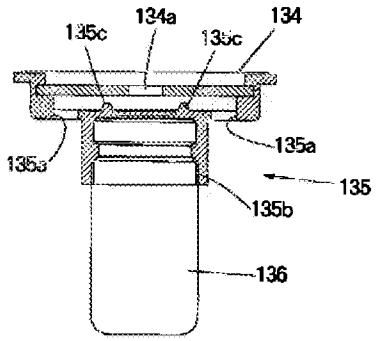

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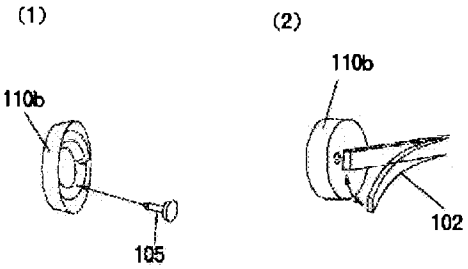

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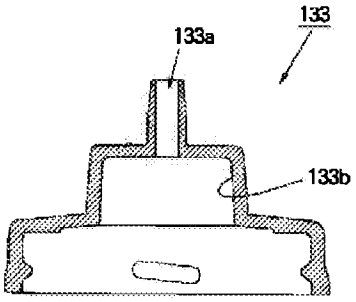

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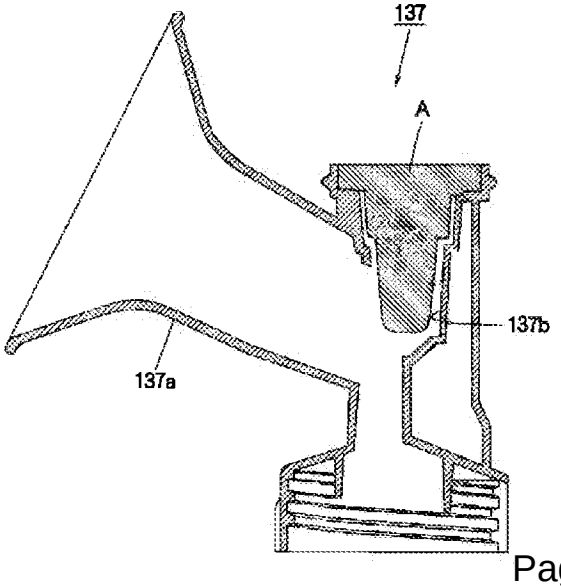

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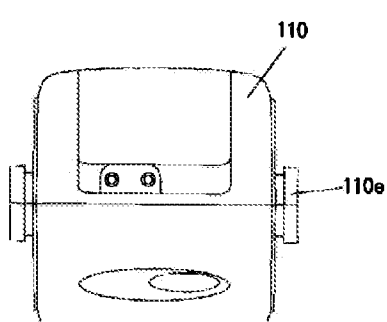

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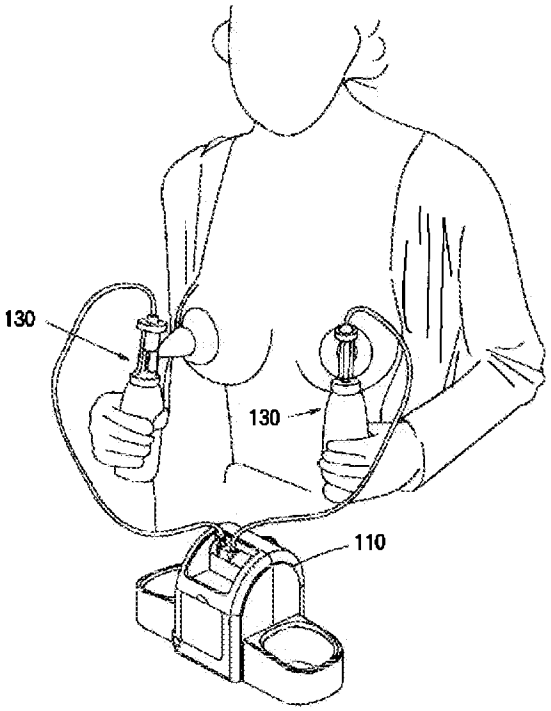

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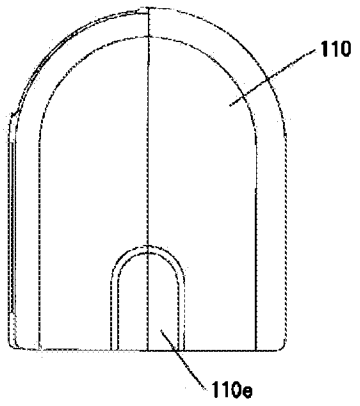

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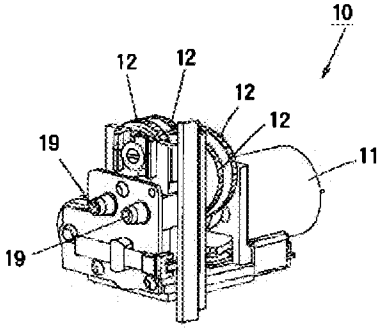

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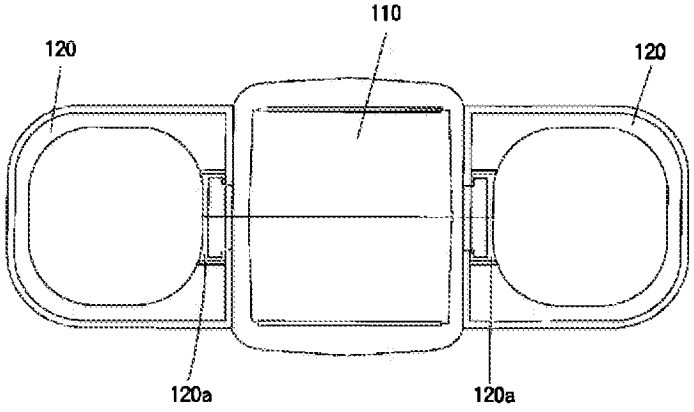

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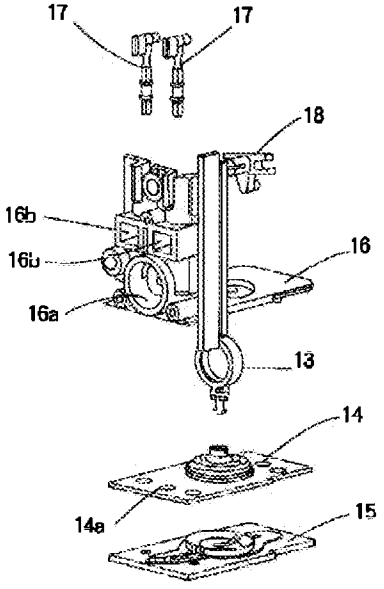

Pulsating milking machine

Abstract

PROBLEM TO BE SOLVED: To provide a user-friendly pulsating milking machine capable of readily exchanging parts. SOLUTION: This pulsating milking machine is equipped with a pulsating milking machine body having a negative pressure-generating part 116, a space part 118 for negative pressure whose interior becomes negative pressure and a space part 107 for pulsation formed in coupling to the space part 118 for negative pressure and a sucking storage part installed in the breasts, etc., of users and used for sucking and storing mother milk of users. The pulsating milking machine feathers being arranged so that the space part 118 for negative pressure and the space part 107 for pulsation are mutually separable.

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Japan

First Prior Art | Similar

Other languages: Japanese

Inventor: Yasushi Ishimaru, Hiroyuki Uehara

Current Assignee : Pigeon Corp

Worldwide applications

1999 · JP

Application JP11163044A events

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Status • Expired - Lifetime

Info: Legal events, Similar documents, Priority and Related Applications

External links: Espacenet, Global Dossier, Discuss

Claims (5)

Hide Dependent

translated from Japanese

[Claims] A negative pressure generating section; a negative pressure generating section in which the negative pressure is generated by the negative pressure generating section; a pulsating space formed by being connected to the negative pressure generating section; In a pulsating breast pump comprising: a breast pump body having: a suction storage unit that is installed on a user's breast or the like and sucks and stores the user's breast milk, wherein the negative pressure space portion and the pulsation space portion are A pulsating breast pump, which is arranged to be separable from each other. 2. The pulsation space portion is provided with a connection protrusion for connecting to the negative pressure space portion, and the connection recess portion for connecting to the pulsation space portion is provided in the negative pressure space portion. 2. The pulsating breast pump according to claim 1, further comprising a holding portion for holding the connection between the pulsating space portion and the negative pressure space portion. 3. A connection section for connecting the suction storage section and the breast pump body is provided between the suction storage section and the breast pump body.

The pulsating milking according to claim 1 or 2, wherein an air chamber is provided on the connection section side of the suction storage section, and an uneven portion is formed inside the air chamber. vessel. 4. The suction storage section has a suction section for sucking the breast milk of the user and a storage section for storing the breast milk of the user. A valve for moving the sucked user's breast milk to the storage unit is provided, and a substantially central portion of the valve is formed to bend toward the suction unit side. Item 3

The pulsating breast pump according to any one of the above. 5. A holder formed on both sides of the breast pump main body and on which the suction storage section can be placed is provided with an engagement portion for attaching the holder to the breast pump main body. The pulsating breast pump according to any one of claims 1 to 4, wherein

Description

translated from Japanese

DETAILED DESCRIPTION OF THE INVENTION

[0001]

BACKGROUND OF THE INVENTION 1. Field of the Invention The present invention relates to a breast pump used when a user expresses breast milk, and more particularly to a so-called pulsating breast pump for intermittently sucking breast milk.

[0002]

2. Description of the Related Art There are two main types of breast pumps: manual breast pumps and electric breast pumps. Of these, the manual breast pump is The user operates the pump with his / her own hand and milks with the power of the pump. On the other hand, the electric breast pump uses a force of a motor or the like to operate a diaphragm or the like to generate a negative pressure in a certain space. Since this negative pressure state exists between this space and the user's breast. breast milk is sucked and stored in a predetermined bottle. As a pump unit for generating a negative pressure of the electric breast pump, for example, there is one as shown in FIG. As shown in FIG.

0 means that the power of the motor 11 is the reduction gears 12, 12, 12,

12. Specifically, first, an eccentric cam (not shown) is mounted on the shaft of the [illegible] and [illegible] shown in FIG. 25 is engaged with the eccentric cam. This connection rod 13 is connected to a diaphragm 14 provided on a diaphragm back plate 15.

[0003] As a result, the rotation of the shaft of the motor 11 causes a vertical movement as shown in the figure, and the diaphragm 14 is moved up and down. The valve 14a of the diaphragm is connected to a hole provided in the negative pressure space 16a of the chassis 16 shown in FIG. Therefore, the negative pressure space is formed in the negative pressure space 16a by the movement of the diaphragm valve 14a. Next, on the negative pressure space 16a, two pulsation spaces 16b, 16b are formed integrally with the negative pressure space 16a. Holes are provided in the lower portions of these two pulsation spaces 16b, 16b, respectively, and are formed so as to communicate with the negative pressure space 16a via the holes. These two pulsation spaces 1
The control shaft 17 shown in FIG.
The control shafts 17 are inserted through upper openings, and control valves (not shown) are attached to lower ends of the control shafts 17, 17, respectively. When the control shaft 17 moves downward in the figure, the control valve closes the hole provided in the lower part of the pulsation space 16b, and communicates with the negative pressure space 16a provided thereunder. Will be cut off. When the control shaft 17 moves downward in the figure, the control valve opens the upper opening of the pulsation space 16b

A control shaft 17 with a control valve having such a function is mounted on a seesaw 1 shown in FIG.
8 is engaged. And this seesaw 18 is shown in FIG.
The control gear (not shown) meshed with the reduction gears 12, 12, 12, 12 shown in FIG. The swing of the seesaw 18 causes the two control shafts 17 to alternately move up and down. By the way, the two pulsation spaces 16
The nozzles b and 16b communicate with the nozzles 19 and 19 shown in FIG. 24. The nozzles 19 and 19 are connected to a breast milk storage bottle (not shown) by a hose or the like. The breast milk storage bottle is provided with a bowl-shaped breast milk receiving portion that is in close contact with the breast of the user. When the pump unit 10 of the electric breast pump constructed as described above is operated, the diaphragm 14 moves by the rotation of the motor 11, and the negative pressure space 16a
is negative pressure. On the other hand, the rotation of the motor 11 causes the control gear to rotate, causing the seesaw 18 to swing,
The two control shafts 17, 17 are alternately moved up and down. The pulsation space 16b, in which the control shaft 17 has moved downward, is disconnected from the negative pressure space 16a and is opened instead of the negative pressure. In addition, one pulsation space 16b in which the control shaft 17 has moved upward.
is in a negative pressure state.

[0005] Here, the bottle for storing breast milk is
When the hose is connected to one of the nozzles 19 (see FIG. 24) using a hose, only one of the pulsation spaces 16b communicates with the breast milk storage bottle. ,
The negative pressure state and the open state are repeated. Thereby, it is possible to perform suction in a state that is not continuous suction but close to suction performed by an infant, that is, in a pulsating state, and more effective milking can be performed.

[0006]

The negative pressure space 16a and the pulsating space 16b forming the chassis 16 of the motor unit 10 of such a pulsating breast pump have a negative pressure acting as a suction force of the pulsating breast pump. It is an important part for generating the noise. Therefore, even if a slight defect occurs in these parts, it greatly affects the suction force of the pulsating breast pump, and the defective part has to be replaced. This problem often occurs only in one of the negative pressure space 16a and the pulsation space 16b of the chassis 16, but even in this case, the negative pressure space 16a and the pulsation space 16b are connected as described above. Since it is formed integrally, there is a problem that the entire chassis 16 needs to be replaced.

[0007] In view of the above, an object of the present invention is to provide a pulsating breast pump in which parts can be easily replaced and which is easy to use.

[0008]

SUMMARY OF THE INVENTION According to the present invention, there is provided a negative pressure generating section, a negative pressure generating section having a negative pressure inside the negative pressure generating section, and a negative pressure generating section. A pulsating breast pump comprising: a breast pump body having a pulsation space portion formed by being connected to a breast pump, and a suction storage section installed in a breast or the like of a user to suck and store the breast milk of the user. The pulsating breast pump is characterized in that the negative pressure space portion and the pulsation space portion are arranged so as to be separable from each other.

According to the above configuration, since the negative pressure space portion and the pulsation space portion are arranged so as to be separable from each other, only one of them can be separated and replaced.

Preferably, in the structure of the first aspect, the pulsation space is provided with a connecting projection for connecting to the negative pressure space, and the pulsation space is provided in the negative pressure space. A pulsating breast pump, characterized in that a coupling concave portion for coupling with the pulsating portion is provided, and a holding portion for holding the connection between the pulsating space portion and the negative pressure space portion is provided.

According to the above construction, the pulsation space is provided with a connection projection for connecting to the negative pressure space, and the negative pressure space is connected to the pulsation space. For this reason, the pulsation space and the negative pressure space can be easily connected by combining the connection protrusions and the connection recesses. In addition, since the holding portion for holding the connection between the pulsation space portion and the negative pressure space portion is provided, the connection between the pulsation space portion and the negative pressure space portion can be further strengthened.

Preferably, in the configuration of claim 1 or 2, between the suction storage unit and the breast pump body,
A connection part for connecting these is provided, and an air chamber is provided on the connection part side of the suction storage part, and an uneven part is formed inside the air chamber. Pulsating breast pump.

According to the above configuration, since the air chamber is provided on the connection portion side of the suction storage portion, it is possible to prevent breast milk from flowing into the connection portion. In addition, since an uneven portion is formed inside the air chamber, the internal area of the air chamber increases, and the water vapor of the milk adheres to the inside of the air chamber, so that the milk flows into the connection portion. Can be prevented.

Preferably, claims 1 to 3 are provided.
in any of the above configurations, the suction storage unit includes a suction unit for sucking the breast milk of the user and a storage unit for storing the breast milk of the user, and the storage unit includes the suction unit. A pulsating breast pump, characterized in that a valve is provided for moving the breast milk of the user sucked in the part to the storage part, and a substantially central part of the valve is bent toward the suction part side. It is.

According to the above configuration, the substantially central portion of the valve is
Since the valve is bent toward the suction portion, the valve is bent in the closing direction. This ensures a negative pressure condition.

Preferably, claims 1 to 4 are provided.
in any one of the above configurations, the holder portions formed on both sides of the breast pump main body and the suction storage portion are provided with engaging portions for attaching the holder portion to the breast pump main body. A pulsating breast pump characterized in that it is used.

According to the above arrangement, the holder for mounting the suction storage section on both sides of the breast pump main body and the holder section on which the suction storage section can be placed is provided with an engaging section for attaching the holder section to the breast pump main body. Since each of them is provided, the holder can be easily attached to both sides or one side of the breast pump body.

[0018]

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS Preferred embodiments of the present invention will be described below in detail with reference to FIGS. The embodiment described below is a preferred specific example of the present invention, and thus various technically preferable limitations are added. However, the scope of the present invention particularly limits the present invention in the following description. The embodiment is not limited to these embodiments unless otherwise stated

FIG. 1 is a view showing a pulsating breast pump 100 according to an embodiment of the present invention. The pulsating breast pump 100 includes a pump unit 110 that is a breast pump body and bottle holders 120 and 120 that are holder units disposed on both sides thereof.
have. In addition, the pulsating breast pump 100 includes, for example, two bottle units 130, which are suction storage units. Further, the pulsating breast pump 100 is provided with two suction tubes 140, 140, which are connection portions for connecting the bottle unit 130 and the pump unit 110. Also, on the surface of the pump unit 110,
As shown in FIG. 1, a power switch 110a and a suction pressure adjustment dial 110b are arranged. FIG. 2 is a view of the pump unit 110 and the bottle holders 120, 120 viewed from the back side of FIG. As shown in FIG. 2, the pump unit 110 is provided with, for example, two nozzles 110d for connecting the intake tubes 140, 140. In addition, this pump unit 110 includes:
Battery storage unit 11 for storing a battery, for example, a power supply
0c is provided. Alternatively, an AC power supply can be used as the power supply. In this case, an AC power supply is connected to the AC power supply connection terminal 110e shown in FIG. 2 for use. Since the pump unit 110 generates a suction pressure for sucking the mother's milk as a user, the pump unit 110 will be described in detail below.

FIG. 3 shows a state in which the casing of the pump unit 110 shown in FIGS.
FIG. 5 is a view showing a central portion of a pump unit which is a central portion of the pump unit. FIG. 4 is an exploded perspective view showing the central part 110 of the pump unit shown in FIG. 3 in an exploded manner. As shown in FIG. 4, the motor 112 is accommodated in a motor plate 113. At this time, the motor shaft 11 of the motor 112
2a is the motor plate hole 11 of the motor plate 113;
3a, and the eccentric cam 114 is attached to the tip thereof. The tip of the eccentric cam 114 has a gear 114a
is provided. The eccentric cam 114 is engaged with a connection rod 115 connected to a diaphragm 116 which is a negative pressure generating section. The diaphragm 116 is mounted on the diaphragm back plate 117. The connection rod 11
5 is engaged with the eccentric cam 114 in a state where it is inserted into a round hole provided in a chassis 118 which is a negative pressure space.

On the other hand, the gear 114a is
4b, and two reduction gears 114b, 114
b are connected in a meshing state. Furthermore, this reduction gear 1
14b is engaged with the control gear 114.
The seesaw 119 is engaged with the control gear 114c. The reduction gear 11
4b, 114b, 114b and control gear 114c
Are supported by stainless steel bars 109, 109. The seesaw 119 is engaged with two control shafts 108, 108. The two control shafts 108, 108 are lower than an opening provided on an upper portion of a seesaw base 107 which is a pulsating space. The nozzle openings 107d, 10d
7d, a control valve 108a previously arranged in
108a. Below the seesaw base 107, two seesaw base connecting portions 107a, which are connecting protrusions for connecting to the chassis 118, are provided. This seesaw base connecting part 107
The O-ring 106 is mounted on the a and 107a.
On the other hand, on the upper part of the chassis 118, two chassis connecting portions 118a, which are connecting concave portions, are provided. Therefore, the seesaw base 107 and the chassis 118 are integrally connected by inserting the seesaw base connecting portions 107a and 107a into the chassis connecting portions 118a and 118a. At this time, since the O-ring 106 is mounted on the seesaw base connecting portions 107a, 107a, they are connected while maintaining airtightness.

The chassis 118 is provided with a chassis opening 118b.
8b, the valves 103 and O shown in FIG.
A ring 106 is arranged. This valve 103 and O
The ring 106 is fixed to the leaf spring 102 with a fastener (not shown) via a suction pressure adjusting hole 104 a of the chassis cover 104. A suction pressure adjusting dial 110b is arranged on the chassis cover 104. The suction pressure adjustment dial 110b is provided with a groove, and the adjustment pin 105 is disposed in contact with the groove. The adjustment pin 105 is configured to move in the left and right direction in the figure by rotating the suction pressure adjustment dial 110b. By the way, the chassis cover 104 as the holding portion is pressed against the chassis 118 and fixed. At this time, since the chassis cover 104 is disposed so as to press not only the chassis 118 but also the seesaw base 107, the connection state between the seesaw base 107 and the chassis 118 is further strengthened. By the way, a leaf spring 102 made of sheet metal is arranged on the chassis cover 104. One end of the leaf spring 102 is fixed by a leaf spring retainer 102a. However, the other end of the leaf spring 102 is not fixed,
The leaf spring 102 is pressed against the surface of the chassis cover 104 by the elasticity of the leaf spring 102 itself. Further, since the tip of the above-described adjustment pin 105 is in contact with the other end of the leaf spring 102, the movement of the adjustment pin 105 causes the leaf spring 102 to move, and the valve 103 connected thereto. Is chassis 11
8 with respect to the chassis opening 118b.

The central part 111 of the pump unit shown in FIG.
is configured as described above and operates as follows.
First, the user turns on the power switch 110a shown in FIG.
In this state, the motor 112 starts to rotate using the battery housed in the battery housing 110c shown in FIG. 2 as a power source. The rotation of the motor 112 causes the eccentric cam 114 to rotate in an eccentric state. This eccentric cam 114
is engaged with the connection rod 115 connected to the diaphragm 116, so that the connection rod 115 moves up and down. FIG. 5 shows this state. As shown by the arrow A in FIG. 5, the diaphragm 116 moves up and down, thereby generating a flow of air as shown by the arrow B. At this time, diaphragm 1
Since the diaphragm holes 116b near the 16 diaphragm valves 116a are connected to the diaphragm connection holes 118c of the chassis 118, a negative pressure is generated in the chassis 118. FIG. 6 shows the diaphragm connection hole 118c. FIG. 6 is a bottom view of the chassis 118. As shown in FIG. 6, the connecting hole 11 for the diaphragm is formed on the bottom of the chassis 118.
8c is provided. This diaphragm connection hole 11
8c is a chassis opening 1 of the chassis 118 shown in FIG.
18b, the chassis opening 118 and the diaphragm hole 116b communicate with each other.

As shown in FIG. 7, the chassis opening 118 is formed into two portions or two portions connected to the chassis connecting portions 118a, 118a. Referring to FIG. This chassis connecting portion 118
it can be seen that a and 118a are open. Thus, the chassis 118 has a chassis opening 118b,
Diaphragm connection hole 118c and chassis connection portion 11
Portions other than 8a and 118a are closed spaces. Then, since the chassis opening 118b is closed by the chassis cover 104 as described above, the inside of the

chassis 118 is brought into a negative pressure state by the diaphragm 116. The negative pressure state of the chassis 118 also causes a negative pressure state inside the seesaw base 107 via the seesaw base connecting portions 107a of the seesaw base 107. By the way, when the motor 112 rotates, the gear 114a shown in FIG. 4 starts rotating in addition to the eccentric cam 114, and the reduction gear 1 meshed with the gear 114a.
The speed is reduced by 14b. The control gear 11 meshed with the third reduction gear 114b
4c starts to rotate. The control gear 114c has a specific groove as shown in FIG. 4, and the seesaw 119 is engaged with a part of the groove.

FIG. 9 shows this state. FIG.
As shown in the figure, the seesaw convex portion 11 of the seesaw 119
9a will engage. This control gear 11
The circular motion of 4c is changed into swing of the seesaw 119 by the groove. The pivot of the seesaw 119 is a pivot 119b of the seesaw shown in FIG. 4, and the pivot 119b of the seesaw is
07 is inserted into the seesaw receiving portion 107b. Also, two control shafts 108 shown in FIG. 4 are attached to the seesaw 119. FIG. 10 shows this state. As shown in FIG. 10, the two control shafts 108, 108 will be engaged with cutouts on both sides of the seesaw 119. The control shafts 108, 108 are inserted into the seesaw base 107 as described above, and the control valves 108a, 108a are mounted below the control shafts. FIG. 11 is a front view showing the seesaw base 107, and FIG. 12 is a plan view of the seesaw base 107. As shown in FIG.
Are formed with two control shaft holes 107c into which the control shaft 108 is inserted. The control shaft hole 107c communicates with the nozzle opening 107d shown in FIG.

However, these two nozzle openings 10
7d, 107d and two control shaft holes 107
c and 107c are not communicated with each other, but each are separately communicated with the seesaw base coupling portions 107a and 107a. Such a control shaft hole 107
Control shafts 108 and 108 are arranged in c and 107c, respectively. In this state, the seesaw 119 is
When the rocking motion is performed, the control shafts 108 alternately move up and down as shown in FIG.
When the control shaft 108 moves downward and reaches the bottom of the nozzle openings 107d and 107d shown in FIG. 11, the seesaw connecting portion 107a is closed by the control valve 108a provided on the control shaft 108. Become. At this time, the closed seesaw base 10
In the internal space 7, the above-described negative pressure state of the chassis 118 is not transmitted, but rather, it is opened to the atmosphere due to a gap between the control shaft 108 and the control shaft hole 107 c of the seesaw base 107. On the other hand, control axis 1
When 08 moves upward, a space is created between the control valve 108a attached to the control shaft 108 and the seesaw connecting portion 107a, and the upper end of the control valve 108a closes the lower end of the control shaft hole 107c. Will be. Therefore, the above-described chassis 118
, A negative pressure condition will also occur in the seesaw base 107. Thus, the negative pressure state and the atmosphere open state
Pulsation, which will be described later, is caused by alternately causing the movement of the control shafts 108, 108.

By the way, the two nozzle openings 107d, 107d provided in the seesaw base 107 are
As shown in FIG. 4, the nozzle 11 of the chassis cover 104
0d and 110d, respectively, and intake tubes 140 and 140 are connected to the nozzles 110d and 110d as shown in FIG. In order for the mother to adjust the negative pressure generated inside the chassis 118, the mother operates the suction pressure adjustment dial 110b shown in FIG. 4 by operating the mother. That is, the suction pressure adjustment dial 110b is specifically configured as shown in FIG. As shown in FIG. 13A, the suction pressure adjusting dial 110b is provided with a spiral groove having a different thickness, and the adjusting pin 105 comes into contact with the groove. The suction pressure adjusting dial 110b can be operated by the mother from outside the pump unit 110 as shown in FIG. Therefore, when the mother operates and turns the suction pressure adjustment dial 110b, the thickness of the groove of the suction pressure adjustment dial 110b with which the adjustment pin 105 is in contact changes. Here, for example, when the thickness of the groove is increased, the adjustment pin 105 pushes the leaf spring 102 as shown in FIG. Since the leaf spring 102 and the valve 103 shown in FIG. 4 are connected as described above, the valve 103 is also connected to the chassis 11.
8 moves in a direction away from the chassis opening 118b,
The negative pressure (suction pressure) becomes small. Conversely, when the thickness of the groove of the suction pressure adjustment dial 110b is reduced, the valve 103 is pushed into the inside of the chassis opening 118b, and the negative pressure (suction pressure) increases. In this way, the mother adjusts the negative pressure.

As described above, the pump unit 110 is configured and operates, but the bottle unit 1 connected to the pump unit 110 via the suction tube 140 is operated.
30 will be described below. FIG. 14 is an exploded perspective view of the bottle unit 130. As shown, the bottle unit 130 has a suction unit for sucking mother's milk,
And a storage unit for storing breast milk. The suction unit includes a milking cap 133, a disk 134, an inner plug 135, a cylinder 136, and a breast shield 137. Among them, breast shield 13
Numeral 7 has a breast milk receiving portion 137a, which is a part that the mother wears on her own breast. A separate non-slip portion (not shown) may be used for the breast milk receiving portion. That is, this is a case where the non-slip portion is mounted on the inner surface of the breast milk receiving portion so that the uneven portion is arranged in a portion that comes into contact with the mother's breast. The cross section of the breast shield 137 is shown in FIG.
As shown in FIG. The formed cage has a cross section as shown in FIG. That is, as shown in FIG. 15, inside the breast shield 137, the breast shield 137 communicates with the internal space of the breast milk receiving portion 137a.
It is formed so as to guide upward and downward in the figure.

An opening 137b above the breast shield 137 has a cylinder 136 and a disc 134 shown in FIG.
is inserted. FIG. 15A shows a state in which the inner plug 135 and the like are inserted. FIG. 16 specifically shows the structure of the inner plug 135 and the like. As shown in FIG. 16, a disc hole 134a is provided at the center of the disc 134, and the disc hole 134a is used for the inner plug holes 135a and 135a of the inner plug 135. Through the breast shield 137 of FIG. In addition, the inner plug main body 135b of the inner plug 135 is vertically movable in the drawing, and the inner plug main body 135b is moved upward, so that the inner plug convex portion 135 of the inner plug 135 is moved.
When c and 135c come into contact with the disk 134, this movement stops and the communication between the disk hole 134a of the disk 135 and the inner plug hole 135a of the inner plug main body 135 is stopped. Also, on the inner stopper 135 and the like, FIG.
As shown in FIG. 4, a milking port cap 133 that is an air chamber is provided. FIG. 17 shows the structure of the milking cap 133. As shown in FIG. 17, an intake tube hole 133a for connecting the intake tube 140 shown in FIG. 1 is provided in the upper part of the milking opening cap 133. Further, an uneven portion is provided on the inner peripheral portion 133b of the milking cap 133.

The formation of the uneven portions is performed by, for example, corrosion processing. In this corrosion process, the inner peripheral portion 133b of the milking cap 133 is etched using a chemical to remove an unnecessary portion, thereby forming an uneven portion. Also,
As another method of forming the uneven portion, there is a blasting method of spraying sand or the like on the mold to damage the mold. In this way, the milking opening cap 133 having the concave and convex portions on the inner peripheral portion 133b is fixed to the breast shield 137 shown in FIG. On the other hand, what constitutes a storage unit for storing breast milk is shown in FIG.
4, a bottle 132, a valve 132, a check valve 139, and the like. This check valve 139
is mounted so as to be inserted into the lower end of the breast shield 137 shown in FIG. A valve 132 is attached to the lower end of the check valve 139. This valve 132
As shown in FIG. 18, the valve 132 is closed or opened by moving the movable piece 132a. FIG. 19 is a view showing a cross section of the valve 132. As shown in FIG.
19, the upper ends on both sides of the valve 132 are thicker than other portions. Therefore, this valve 132 is connected to the check valve 1
When attached to 39, the above-mentioned thick portion spreads outward. As a result, the movable piece 132a, which is a substantially central portion of the valve 132, is

bent upward in the drawing.
When the movable piece 132a of the valve 132 bends upward as described above, the movable piece 132a is arranged in a direction for holding the valve 132 in a closed state.

The operation and the like of the bottle unit 130 configured as described above will be described below. First, as shown in FIG.
Attach the intake tube 140 to. Then, the breast milk receiving portions 137a and 137a of the breast shields 137 and 137 of the two bottle units 130 are brought into close contact with both breasts of the mother as the user as shown in FIG. When the power switch 110a of the pump unit 110 is turned on in this state, the central part 111 of the pump unit starts to move as described above. Due to the operation of the central part 111 of the pump unit, the two nozzles 110d and 110d of the pump unit 110 alternately repeat suction and release to the atmosphere. These two nozzles 1
The suction and opening to the atmosphere at 10d and 110d are performed through the intake units 140 and 140, respectively.
30 will be transmitted. That is, in the case of the suction state, the suction pressure passes through the suction tube 140, passes through the milking mouth cap 130, passes through the disc hole 134a shown in FIG.
It passes through the inner stopper hole 135a and reaches the inside of the breast shield 137 shown in FIG.

At the lower end of the breast shield 137, a check valve 139 having a valve 132 is provided.
The movable piece 132a of the 32 will be pulled upward in the figure, whereby the valve 132 will be kept closed. At this time, even if the suction pressure is slightly small, since the movable piece 132a of the valve 132 is bent and held upward as described above, the movable piece 132a
Does not move downward to reduce the suction pressure. As described above, since the lower end of the breast shield 137 is closed by the valve 132, the suction pressure in the breast shield 137 reaches the breast milk receiving portion 137a,
The mother's breast placed there will be sucked. The breast milk milked by the suction pressure is moved along the breast shield 137 along the breast milk receiving portion 137a shown in FIG.
Through the check valve 139 and through the valve 132
Will be reached. At this time, when the sucking stops due to the pulsation and the breast milk accumulates in the vicinity of the valve 132, the movable piece 132a of the valve 132 moves downward by its weight, and the breast milk falls into the bottle main body 131.

If the breast milk is accumulated in the breast shield 137 before the milk is dropped into the bottle main body 131 by its own weight due to a large amount of milk, the accumulated breast milk pushes up the cylinder 136 shown in FIG. By raising the cylinder 136, the inner plug main body 135b is pushed up, and the inner plug convex portion 135 is raised.
c hits the disk 134, thereby blocking communication between the space below the inner plug body 135b and the space above the disk 134. With this cutoff, the suction pressure of the pump unit 110 is interrupted at the disk 134 portion, so that the milk does not move to the pump unit 110 side any more, and it is possible to prevent the milk from flowing into the pump unit 110 side. . Thus, by preventing the breast milk from flowing into the pump unit 110, the failure of the pump unit 110 can be prevented. A milking mouth cap 133 is disposed on the inner plug 135 and the like.
Since the inner peripheral portion 133b (see FIG. 17) of 33 is provided with an uneven portion, the uneven surface portion increases the surface area and the amount of adsorption Inflow will be effectively prevented. Furthermore, since the inlet tube hole 133a of the milking mouth cap 133 is provided at the upper end of the milking mouth cap 133 as shown in FIG. 17, the position is less affected by breast milk.

On the other hand, when the pump unit 110 is open to the atmosphere, milking is not performed in the bottle unit 130. Thus, by using the pump unit 110 and the bottle unit 130 of the present embodiment, both breasts can be milked at the same time, and this milking is performed by so-called pulsation that repeats suction and opening to the atmosphere. Can be. Pump unit 1
Since the ten chassis 118 and the seesaw base 107 are separable, if one of them is broken, only the other can be replaced, so that the cost can be reduced and the usability is improved. After performing milking using the pump unit 110 and the bottle unit 130 as described above, as a place where the two bottle units 130 and 130 are placed,
As shown in FIG. 1, bottle holders 120 serving as holder portions are provided on both sides of the pump unit 110. Thus, the mother who has finished milking will replace the two bottle units 130, 130 with these bottle holders 120, 12
0. In addition, the bottle holders 120, 120
9 and can be easily removed. More specifically, as shown in FIG.
20 are provided with engaging projections 110e, 110e. The engagement projection 110e has a semi-elliptical shape as shown in FIG.

On the other hand, as shown in FIG. 23, the bottle holder 120 is provided with a bottle holder engaging concave portion 120a corresponding to the engaging convex portion 110e. Therefore, the bottle holder 120 is attached to the pump unit 110 by inserting the engagement protrusion 110e of the pump unit 110 into the bottle holder engagement recess 120a. When the mother who is the user uses only one bottle unit 130, one bottle holder 120 may be attached to any one of the pump units 110, and the space where the pulsating breast pump 100 is placed is small. I'm done.

[0036]

As described above, according to the present invention, it is possible to provide a pulsating breast pump in which parts can be easily replaced and which is easy to use.

[Brief description of the drawings]

FIG. 1 is a schematic perspective view showing a pulsating breast pump according to an embodiment of the present invention.

FIG. 2 is a schematic perspective view showing a pump unit and the like of the pulsating breast pump of FIG. 1;

FIG. 3 is a schematic perspective view showing a central portion of a pump unit

FIG. 4 is an exploded perspective view of a central portion of the pump unit of FIG. 3;

FIG. 5 is an explanatory diagram showing a relationship between a motor and a diaphragm in FIG. 4;

FIG. 6 is a bottom view of the chassis of FIG. 4;

FIG. 7 is a front view of the chassis of FIG. 4;

FIG. 8 is a plan view of the chassis of FIG. 4;

FIG. 9 is an explanatory diagram showing the relationship between the control gear and the seesaw of FIG. 4;

FIG. 10 is an explanatory diagram showing a relationship between the seesaw of FIG. 4 and a control axis.

FIG. 11 is a front view of the seesaw base of FIG. 4;

FIG. 12 is a plan view of the seesaw base of FIG. 4;

FIG. 13 is an explanatory diagram showing a relationship between a suction pressure adjustment dial and an adjustment pin. (2) It is explanatory drawing which shows the relationship between a suction pressure adjustment dial and a leaf spring.

FIG. 14 is an exploded perspective view showing a bottle unit of the pulsating breast pump of FIG. 1;

FIG. 15 is a sectional view showing the breast shield of FIG. 14;

FIG. 16 is a schematic sectional view showing a state where the disk, inner plug, and cylinder of FIG. 14 are connected.

FIG. 17 is a sectional view showing the milking mouth cap of FIG. 14;

FIG. 18 is a plan view showing the valve of FIG.

FIG. 19 is a sectional view showing the valve of FIG. 14;

FIG. 20 is a diagram showing a state where the mother is using a pulsating breast pump.

FIG. 21 is a plan view showing the relationship between the pump unit of FIG. 1 and an engagement protrusion.

FIG. 22 is a side view of the pump unit of FIG. 21.

FIG. 23 is a plan view showing an engaged state between the pump unit and the bottle holder in FIG. 1;

FIG. 24 is a perspective view showing a conventional pump unit.

FIG. 25 is a schematic exploded view of the pump unit of FIG. 24;

[Explanation of symbols]

100: pulsating breast pump, 102: leaf spring, 103: valve, 104: chassis cover, 105: adjusting pin, 106: O-ring, 1
07: seesaw base, 108: control shaft, 109: stainless steel rod, 110: pump unit, 112: motor, 113: motor plate, 114: eccentric cam, 115 ..Connection rod, 116 ... diaphragm.
117 ... diaphragm back plate, 118 ... chassis, 119 ...
Seesaw, 120 ... bottle holder, 130 ... bottle unit, 131 ... bottle body, 132 ...
Valve 133: milking cap, 134. disk,
135: inside plug, 136: Cylindrical, 137: Breast shield, 139: Check valve

Similar Documents

Publication	Publication Date	Title
US4883464A	1989-11-28	Milking equipment
KR100611875B1	2006-08-11	Skin care device
EP1439149B1	2008-12-10	Diaphragm breast pump
US4319570A	1982-03-16	Tracheal suction pump designed primarily for aspiration purposes
JP2001082226A	2001-03-27	Oil feeding device of linear compressor
JPH07317661A	1995-12-05	Fluid suction pump mechanism
JP2000360527A	2000-12-19	Pulsating milking machine
CN212631316U	2021-03-02	Milk bowl and breast pump for breast pump
US20210275278A1	2021-09-09	Dental irrigator water tank and dental irrigator
CN210137718U	2020-03-13	Pet drinking machine
CN111588927A	2020-08-28	Milk bowl and breast pump for breast pump
JP4697674B2	2011-06-08	pot
KR101070592B1	2011-10-06	Pparatus extracting mother's milk
JP2001269023A	2001-09-25	Milking device
KR101546376B1	2015-08-21	The Milker
KR200215086Y1	2001-06-01	Suction hose withdrawal device for drinking water suction means for gas mask
CN212673317U	2021-03-09	Oil cup for range hood and range hood applying same
CN211310880U	2020-08-21	Water purifier
CN215019426U	2021-12-07	Intelligent sterilizing household tooth washing device
CN112439249B	2022-09-23	Water intaking subassembly and purifier of purifier
CN211215729U	2020-08-11	Water intaking subassembly and purifier of purifier
JP2857009B2	1999-09-25	Milking machine
CN210726232U	2020-06-12	Built-in check valve faucet

CN211226391U	2020-08-11	Water purifier
CN112441633B	2022-08-30	Water purifier

Priority And Related Applications

Priority Applications (1)

Application	Priority date	Filing date	Title
JP16304499A	1999-06-09	1999-06-09	Pulsating breast pump

Applications Claiming Priority (1)

Application	Filing date	Title
JP16304499A	1999-06-09	Pulsating breast pump

Legal Events

Date	Code	Title	Description
2005-04-19	A621	Written request for application examination	**Free format text**: JAPANESE INTERMEDIATE CODE: A621 **Effective date**: 20050418
2006-04-13	A977	Report on retrieval	**Free format text**: JAPANESE INTERMEDIATE CODE: A971007 **Effective date**: 20060413
2006-04-19	A131	Notification of reasons for refusal	**Free format text**: JAPANESE INTERMEDIATE CODE: A131 **Effective date**: 20060418
2006-06-20	A521	Written amendment	**Free format text**: JAPANESE INTERMEDIATE CODE: A523 **Effective date**: 20060619
2006-07-06	TRDD	Decision of grant or rejection written	
2006-07-12	A01	Written decision to grant a patent or to grant a registration (utility model)	**Free format text**: JAPANESE INTERMEDIATE CODE: A01 **Effective date**: 20060711
2006-08-03	A61	First payment of annual fees (during grant procedure)	**Free format text**: JAPANESE INTERMEDIATE CODE: A61 **Effective date**: 20060727
2006-08-04	R150	Certificate of patent or registration of utility model	**Free format text**: JAPANESE INTERMEDIATE CODE: R150 **Ref document number**: 3836627 **Country of ref document**: JP **Free format text**: JAPANESE INTERMEDIATE CODE: R150
2009-04-02	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text**: PAYMENT UNTIL: 20090804 **Year of fee payment**: 3
2009-04-07	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text**: PAYMENT UNTIL: 20100804 **Year of fee payment**: 4
2009-04-07	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2010-04-20	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text**: PAYMENT UNTIL: 20110804 **Year of fee payment**: 5
2010-04-20	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2011-05-31	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text**: PAYMENT UNTIL: 20120804 **Year of fee payment**: 6

2011-05-31	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2012-06-26	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text**: PAYMENT UNTIL: 20130804 **Year of fee payment**: 7
2012-06-26	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2013-08-13	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2014-07-29	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2015-08-04	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2016-08-02	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2017-08-08	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2018-07-10	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2019-06-09	EXPY	Cancellation because of completion of term	

Concepts

machine-extracted

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Name	Image	Sections	Count	Query match
Breast		claims,abstract,description	77	0.000
human milk		claims,abstract,description	36	0.000
Milk, Human		claims,description	35	0.000
coupling		abstract,description	4	0.000
coupling process		abstract,description	4	0.000
coupling reaction		abstract,description	4	0.000
Feathers		abstract	1	0.000

Show all concepts from the description section

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[Continued on next page]

(54) Title: METHODS AND APPARATUS FOR TRANSFERRING PRESSURE DURING EXPRESSION OF HUMAN BREAST MILK

(57) Abstract: A device for expression and collection of breast milk includes an actuatable assembly and a breast interface. The breast interface is sized to receive a breast and form a fluid tight seal against the breast. The breast interface includes an expandable membrane disposed within at least a portion of the breast interface. The expandable membrane reversibly deforms in response to actuation of the actuatable assembly, thereby applying vacuum pressure at the breast to express milk. The expandable membrane comprises a plurality of expandable pleats which extend radially outward from a central longitudinal axis of the breast interface.

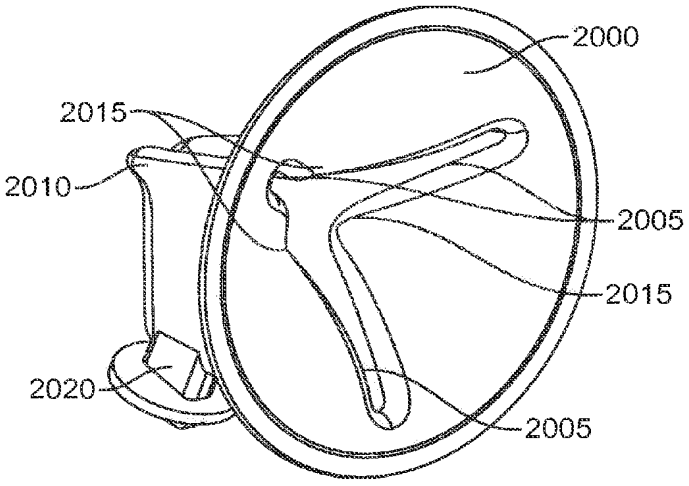

FIG. 20A

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METHODS AND APPARATUS FOR TRANSFERRING PRESSURE DURING EXPRESSION OF HUMAN BREAST MILK

CROSS-REFERENCE

[0001] This application claims the benefit of U.S. Provisional Application No. 62/021,597, filed July 7, 2014 [Attorney Docket No. 44936-706.101], the full disclosure of which is incorporated herein by reference.

[0002] This application is related to U.S. Patent Application No. 14/221,113, filed on March 20, 2014 [Attorney Docket No. 44936-703.201], U.S. Patent Application No. 14/616,557, filed on February 6, 2015 [Attorney Docket No. 44936-704.201], U.S. Provisional Application No. 62/021,601, filed on July 7, 2014 [Attorney Docket No. 44936-705.101], U.S. Provisional Application No. 62/021,604, filed July 7, 2014 [Attorney Docket No. 44936-707.101], and U.S. Provisional Application No. 62/028,219, filed on July 23, 2014 [Attorney Docket No. 44936-708.101], the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention. The present invention generally relates to medical devices and methods, and more particularly relates to devices and methods for expression and collection of human breast milk.

[0003] The exemplary embodiments disclosed herein are preferably directed at expression of breast milk, but one of skill in the art will appreciate that this is not intended to be limiting and that the devices, systems and methods disclosed herein may be used for other treatments requiring application of a differential pressure.

[0004] Breast pumps are commonly used to collect breast milk in order to allow mothers to continue breastfeeding while apart from their children. Currently, there are two primary types of breast pumps: manually-actuated devices, which are small, but inefficient and tiring to use; and electrically-powered devices, which are efficient, but large and bulky. Therefore, it would be desirable to provide improved breast pumps that are small and highly efficient for expression and collection of breast milk. Currently existing or proposed breast pumps also may employ membranes which help create negative pressure during expression of milk. These membranes may have unwanted motion during actuation and therefore improved membrane design is also desirable. At least some of these objectives will be satisfied by the devices and methods disclosed below.

2. Description of the Background Art. The following US patents are related to expression and collection of human breast milk: US Pat. Nos.: 6,673,036; 6,749,582; 6,840,918; 6,887,210; 7,875,000; 8,118,772; and 8,216,179.

SUMMARY OF THE INVENTION

[0005] The present invention generally relates to medical devices, systems and methods, and more particularly relates to devices, systems and methods for expression and collection of human breast milk.

[0006] In a first aspect, a device for expression of milk from a breast comprises an actuatable assembly and a breast interface sized to engage a breast and fluidly seal thereagainst. The breast interface comprises an expandable membrane disposed within at least a portion thereof, wherein the expandable membrane moves in response to actuation of the actuatable assembly, thereby applying vacuum pressure at the breast to express milk therefrom. The expandable membrane comprises a plurality of expandable pleats, each of the plurality of expandable pleats extending radially outward from a center of the expandable membrane.

[0007] The plurality of expandable pleats may be configured to expand radially outward or contract radially inward during acutation of the actuatable assembly. The device may further comprise a drain port disposed along a bottom portion of the expandable membrane, between pleats or in a section of the expandable membrane having no pleats. The drain port may be configured to remain in a substantially fixed longitudinal position during actuation of the actuatable assembly. Alternatively or in combination, the drain port may be disposed in a section of the expandable member having no pleats, such that the drain port is configured to remain in a substantially fixed radial position during actuation of the actuation assembly. The expandable membrane may further comprise a negative grade along a bottom portion thereof, configured to allow expressed milk to flow downhill into the drain port. The breast interface may further comprise a housing and a sealing member, the sealing member disposed around the drain port to secure the expandable membrane to the housing of the breast interface. The plurality of expandable pleats may be configured to converge at an apex, wherein the apex may be configured to remain in a substantially fixed position during actuation of the actuatable assembly.

[0008] The breast interface may further comprise a fluid reservoir operatively coupled to the actuatable assembly, wherein actuation of the actuatable assembly removes fluid from the fluid reservoir thereby expanding the expandable membrane, or wherein the actuation adds fluid to the fluid reservoir thereby contracting the expandable membrane. The actuatable assembly may be removably coupled to an actuatable assembly interface, the actuatable assembly interface

configured to operatively couple the actuatable assembly to the breast interface while maintaining physical separation between the actuatable assembly and the fluid. The actuatable assembly interface may comprise an interface membrane fluidly coupled to the fluid reservoir via an elongate tube. The interface membrane may be configured to operatively couple to an actuatable assembly membrane of the actuatable assembly, such that movement of the actuatable assembly membrane, affected by the actuation of the actuatable assembly, causes corresponding movement of the interface membrane, thereby causing movement of the fluid into or out of the fluid reservoir.

[0009] The actuatable assembly may comprise a one-way valve configured to allow air trapped between the actuatable assembly and the actuatable assembly interface to exit during actuation of the actuatable assembly. The actuatable assembly may comprise an alignment mechanism configured to couple the actuatable assembly with the actuatable assembly interface in a substantially fixed position and orientation. The actuatable assembly may be removably coupled to the actuatable assembly interface via one or more magnets. The one or more magnets may be configured to have a magnetic force greater than: (1) an exit force of air exiting a space between the actuatable assembly and the actuatable assembly interface via a one-way valve, and (2) a pull force generated by actuation of the actuatable assembly.

[0010] The breast interface may further comprise a housing, and the expandable membrane may comprise an enlarged edge configured to be disposed in a channel of the housing, so as to securely couple the expandable membrane to the housing. The breast interface may further comprise a flange comprising a resilient material that allows the breast interface to fluidly seal against the breast, wherein the breast interface further comprises a sealing member to seal the housing against the flange. The expandable membrane may be compressively fixed between the housing and the flange via an elastomeric pinch fixation to hold and seal the expandable membrane.

[0011] In another aspect, a method of expressing milk from a breast comprises engaging and fluidly sealing a breast interface with the breast, wherein the breast interface comprises an expandable membrane having a plurality of expandable pleats. The method further comprises actuating an actuatable assembly operatively coupled to the expandable membrane, thereby causing the plurality of expandable pleats to expand radially outward and apply vacuum pressure at the breast. The method further comprises expressing milk from the breast.

[0012] Actuation of the actuatable assembly may further cause the plurality of expandable pleats to contract radially inward, thereby returning the breast interface to atmospheric pressure or applying positive pressure at the breast interface, causing the expressed milk to drain into a collection vessel fluidly coupled to the breast interface. The plurality of expandable pleats may

apply a compressive force to a portion of the breast engaged with the plurality of expandable pleats, thereby facilitating expression of milk from the breast.

[0013] The breast interface may further comprise a drain port disposed along a bottom portion of the expandable membrane, wherein the drain port remains in a substantially fixed longitudinal position during actuation of the actuatable assembly. The method may further comprise collecting the expressed milk into a collection vessel fluidly coupled to the breast interface via the drain port, wherein the expandable membrane comprises a negative grade along a bottom portion of thereof to allow the expressed milk to flow downhill into the drain port.

[0014] The breast interface may further comprise a fluid reservoir fluidly coupled with the actuatable assembly, wherein actuation of the actuatable assembly removes fluid from the fluid reservoir thereby expanding the expandable membrane, or wherein the actuation adds fluid to the fluid reservoir thereby contracting the expandable membrane. The method may further comprise coupling the actuatable assembly to an actuatable assembly interface operatively coupled to the breast interface, thereby operatively coupling the actuatable assembly to the breast interface.

[0015] These and other embodiments are described in further detail in the following description related to the appended drawing figures.

INCORPORATION BY REFERENCE

[0016] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0018] Fig. 1 is a perspective view of an exemplary embodiment of a pumping device.

[0019] Fig. 2 is a perspective view of an exemplary embodiment of a pumping device.

[0020] Fig. 3 is a cross-section of an exemplary embodiment of a pumping device.

[0021] Fig. 4 illustrates an exemplary embodiment of an actuatable assembly coupled to a driving mechanism.

[0022] Figs. 5A-5B illustrate an exemplary embodiment of an actuatable assembly coupled to a pendant unit.

[0023] Fig. 6 is a cross-sectional view of an exemplary embodiment of a breast interface.

[0024] Fig. 7 is a cross-sectional view of another exemplary embodiment of a breast interface.

[0025] Fig. 8A is a cross-sectional view of an exemplary embodiment of an integrated valve in an open position.

[0026] Fig. 8B is a cross-sectional view of an exemplary embodiment of an integrated valve in a closed position.

[0027] Fig. 9A is a cross-sectional view of an exemplary embodiment of integrated sensors within a breast interface.

[0028] Fig. 9B is a cross-sectional view of another exemplary embodiment of integrated sensors within a breast interface.

[0029] Fig. 10 illustrates an exemplary embodiment of a pendant unit and a mobile device.

[0030] Fig. 11 illustrates an exemplary embodiment of a pendant unit in communication with a mobile device.

[0031] Fig. 12 is a cross-sectional view of an exemplary embodiment of a breast interface with a mechanical deformable member.

[0032] Fig. 13 is a cross-sectional view of an exemplary embodiment of a mechanical driver for a mechanical deformable member.

[0033] Fig. 14 is a graph illustrating the pump performance of an exemplary embodiment compared to a commercial device.

[0034] Fig. 15 is a graph illustrating the pumping efficiency of an exemplary embodiment compared to a commercial device.

[0035] Fig. 16 illustrates an exemplary embodiment of flexible radial bellows.

[0036] Fig. 17 illustrates a partial cross-section of a breast interface with the bellows in of Fig. 16.

[0037] Fig. 18 illustrates a cross-section of showing sealing of the breast interface and the radial bellows.

[0038] Fig. 19 illustrates a cross-section the bellows in Fig. 16.

[0039] Figs. 20A-20B illustrate another exemplary embodiment of an expandable membrane having radial pleats.

[0040] Fig. 21 is a cross-section of a breast interface comprising the expandable membrane illustrated in Figs. 20A-20B.

[0041] Fig. 22 is a cross-section of an exemplary embodiment of an expression device comprising an actuatable assembly interface.

[0042] Fig. 23 is a cross-section of an actuatable assembly coupled to an actuatable assembly interface as illustrated in Fig. 22.

DETAILED DESCRIPTION OF THE INVENTION

[0043] Specific embodiments of the disclosed devices and methods will now be described with reference to the drawings. Nothing in this detailed description is intended to imply that any particular component, feature, or step is essential to the invention. One of skill in the art will appreciate that various features or steps may be substituted or combined with one another.

[0044] The present invention will be described in relation to the expression and collection of breast milk. However, one of skill in the art will appreciate that this is not intended to be limiting, and the devices and methods disclosed herein may be used in other applications involving the creation and transmission of a pressure differential, such as in the treatment of sleep apnea and/or other remote pressure needs.

[0045] Fig. 1 illustrates an exemplary embodiment of the present invention. Pumping device 100 includes breast interfaces 105, a tube 110, and a controller or pendant unit 115 operatively coupled to breast interfaces 105 through tube 110. Breast interfaces 105 include resilient and conformable flanges 120, for engaging and creating a fluid seal against the breasts, and collection vessels 125. The device may optionally only have a single breast interface. Pendant unit 115 houses the power source and drive mechanism for pumping device 100, and also contains hardware for various functions, such as controlling pumping device 100, milk production quantification, and communication with other devices. Tube 110 transmits suitable energy inputs, such as mechanical energy inputs, from pendant unit 115 over a long distance to breast interfaces 105. Breast interfaces 105 convert the energy inputs into vacuum pressure against the breasts in a highly efficient manner, resulting in the expression of milk into collection vessels 125.

[0046] One of skill in the art will appreciate that components and features of this exemplary embodiment can be combined or substituted with components and features of any of the embodiments of the present invention as described below. Similarly, components and features of other embodiments disclosed herein may be substituted or combined with one another.

Hydraulic pumping device

[0047] Hydraulic or pneumatic systems can reduce pumping force requirements, and therefore also reduce the size of the pumping device, while maintaining high pumping efficiency. In a preferred embodiment, the pumping device can utilize a hydraulic or pneumatic pumping device to generate a pressure differential against the breast for the expression and collection of milk.

[0048] Exemplary hydraulic pumping devices are depicted in Figs. 2 and 3. Fig. 2 illustrates a pumping device 150 with a syringe 155 fluidly coupled to breast interface 160 by tube 165. Syringe 155 is coupled to tube 165 through a three-way valve 170. Breast interface 160 contains an exit port 175. The syringe 155 drives a fluid 180 contained within tube 165 against or away

from a flexible member contained within breast interface 160 to create the pressure differential necessary for milk expression from the breast.

[0049] Fig. 3 illustrates another embodiment of a pumping device 200. The actuatable assembly 205 includes an assembly housing 210, a driving element 215, radial seals 220, and a shaft 222. Driving element 215 is operatively coupled to a pendant unit, such as pendant unit 115, through shaft 222. The tube 225 contains a fluid 230 and is fluidly coupled to the actuatable assembly 205 and the breast interface 235. The breast interface 235 consists of an interface housing 240, a flexible membrane 245, a reservoir 250, a sealing element 255, an expression area 260, and a drain port 265. The sealing element 255 includes deformable portion 270. The drain port 265 is coupled to a collection vessel 275 and includes a flap valve 280.

[0050] Actuatable assembly 205 displaces fluid 230 contained within tube 225, which can be a flexible line. Fluid 230 occupies reservoir 250 within breast interface 235 and is coupled with flexible membrane 245. Flexible membrane 245 transmits vacuum pressure from fluid 230 to the deformable portion 270 of sealing element 255. When a breast is engaged into and fluidly sealed with breast interface 235 by sealing element 255, displacement of the actuatable element 215 produces substantial vacuum pressure against the breast through flexible membrane 245 and deformable portion 270, resulting in the expression of breast milk into expression area 260. The expressed milk drains through drain port 265 into collection vessel 275. Drain port 265 is configured with a flap valve 280 to provide passage of milk while maintaining vacuum pressure in expression area 260.

[0051] The fluid for the hydraulic pumping device can be any suitable fluid, such as an incompressible fluid. In many embodiments, the incompressible fluid can be water or oil. Alternatively, the fluid can be any suitable gas, such as air. Suitable incompressible fluids and gases for hydraulic systems are known to those of skill in the art.

[0052] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the hydraulic pumping device can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Actuation mechanism

[0053] Many actuation mechanisms known to those of skill in the art can be utilized for the actuatable assembly 205. Actuatable assembly 205 can be a piston assembly, a pump such as a diaphragm pump, or any other suitable actuation mechanism. The optimal configuration for actuatable assembly 205 can depend on a number of factors, such as: vacuum requirements; size, power, and other needs of the pumping device 200; and the properties of the fluid 230, such as viscosity, biocompatibility, and fluid life requirements.

[0054] Fig. 3 illustrates an exemplary embodiment in which actuatable assembly 205 is a piston assembly and driving element 215 is a piston. Actuatable assembly 205 includes radial seals 220, such as O-rings, sealing against assembly housing 210 to prevent undesired egress of fluid 230 and to enable driving of fluid 230.

[0055] Fig. 4 illustrates another exemplary embodiment of an actuatable assembly 300 including a pair of pistons 305.

[0056] In preferred embodiments, the actuatable assembly includes a driving element powered by a suitable driving mechanism, such as a driving mechanism residing in pendant unit 115. Many driving mechanisms are known to those of skill in the art. For instance, the driving element, such as driving element 215, may be actuated electromechanically by a motor, or manually by a suitable user-operated interface, such as a lever. Various drive modalities known to those of skill in the art can be used. In particular, implementation of the exemplary hydraulic pumping devices as described herein enables the use of suitable drive modalities such as direct drive and solenoids, owing to the reduced force requirements of hydraulic systems.

[0057] Referring now to the exemplary embodiment of Fig. 4, the pistons 305 include couplings 310 to a crankshaft 315. The crankshaft 315 is operatively coupled to a motor 320 through a belt drive 325. The crankshaft 315 drives the pair of pistons 305 with the same stroke timing in order to apply vacuum pressure against both breasts simultaneously, a feature desirable for increased milk production. Alternatively, the crankshaft 315 can drive the pair of pistons 305 with any suitable stroke timing, such as alternating or offset stroke cycles.

[0058] The driving mechanism can be powered by any suitable power source, such as a local battery or an AC adaptor. The driving mechanism can be controlled by hardware, such as onboard electronics located within pendant unit 115.

[0059] Fig. 5 illustrates an exemplary embodiment of an actuatable assembly 350 that includes releasable coupling 355. Preferably, actuatable assembly 350 is releasably coupled to a pendant unit 360 and the driving mechanism housed therein. The coupling can be a mechanical coupling or any suitable quick release mechanism known to those of skill in the art. The releasably coupled design allows for flexibility in the configuration and use of the pumping device. For instance, user comfort can be improved through the use of differently sized breast interfaces for compatibility with various breast sizes. Additionally, this feature enables a common pumping device to be used with interchangeable breast interfaces, thus reducing the risk of spreading pathogens. Furthermore, the releasable coupling enables easy replacement of individual parts of the pumping device.

[0060] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the actuation mechanism can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Flexible membrane

[0061] In many embodiments such as the embodiment depicted in Fig. 3, the flexible membrane 245 is located within breast interface 235 and disposed over at least portion thereof, forming reservoir 250 between the interface housing 240 and the flexible membrane 245. Preferably, the flexible membrane 245 deforms substantially when subject to the negative pressures created when the fluid 230 is displaced from reservoir 250 by actuatable assembly 205. The amount of deformation of the flexible membrane 245 can be controlled by many factors, (*e.g.*, wall thickness, durometer, surface area) and can be optimized based on the pumping device (*e.g.*, pump power, vacuum requirements).

[0062] Fig. 6 illustrates an exemplary flexible membrane 370 with a specified thickness and durometer.

[0063] Fig. 7 illustrates another embodiment of flexible membrane 375 with corrugated features 380 for increased surface area.

[0064] Suitable materials for the flexible membrane are known to those of skill in the art. In many embodiments, the flexible membrane can be made of a material designed to expand and contract when subject to pressures from the coupling fluid such as silicone, polyether block amides such as PEBAX, and polychloroprenes such as neoprene. Alternatively, the flexible membrane can be fabricated from a substantially rigid material, such as stainless steel, nitinol, high durometer polymer, or high durometer elastomer. In these embodiments, the rigid material would be designed with stress and/or strain distribution elements to enable the substantial deformation of the flexible membrane without surpassing the yield point of the material.

[0065] Figs. 8A and 8B illustrate preferred embodiments of a breast interface 400 in which an exit valve 405 is integrated into the flexible membrane 410 to control the flow of expressed milk through exit port 415. The exit valve 405 is opened to allow fluid flow when the flexible membrane 410 is relaxed, as shown in Fig. 8A, and is closed to prevent fluid flow when the flexible membrane 410 is deformed, as shown in Fig. 8B. The exit valve 405 enables substantial vacuum pressure to be present in expression area 420 during extraction, while allowing milk to drain during the rest phase of the pump stroke. While many conventional breast pump valves function on pressure differentials alone, the exit valve 405 can preferably be configured to also function on the mechanical movement of flexible membrane 410. Incorporation of an integrated exit valve 405 with mechanical functionality as described herein can improve the sealing of the breast interface 400 during vacuum creation. Furthermore, the implementation of an exit valve

integrally formed within the flexible membrane 410 such as exit valve 405 reduces the number of parts to be cleaned.

Radially Pleated Membrane

[0066] As discussed and best illustrated in Fig. 3, a drain port 265 and flap valve 280 may be coupled to the flexible membrane in order to allow milk to flow into collection vessel 275. Thus, as the flexible membrane is actuated and advanced and retracted, the drain portion 265 and flap valve 280 will typically also move forward and backward. This can cause unwanted stress on the junction between the drain port 265 and the membrane and the collection vessel 275 may also experience unwanted movement. Therefore, it may be desirable to isolate the drain port 265 and flap valve 280 from the membrane so that when the membrane is actuated, other portions of the device experience little or no unwanted motion.

[0067] Fig. 16 illustrates an exemplary embodiment of an expandable membrane that overcomes at least some of these challenges. The expandable membrane 1604 includes a plurality of expandable pleats 1606 that extend radially outward from the center of the expandable membrane. The pleats also have a longitudinal axis which runs substantially parallel to the longitudinal axis of the membrane, and the pleats extend around the circumference of the membrane. The spout or drain port 1602 is disposed along a bottom portion of the membrane in between pleats or in a section of the membrane having no pleats. Thus, actuation of the membrane will expand and contract the membrane radially outward and radially inward and axial motion along a longitudinal axis of the membrane will be minimized and substantially less than previous embodiments. Therefore, the spout or drain port 1602 will remain substantially stationary during actuation of membrane 1604, and the drain port will be substantially free of loads during expansion or contraction of the membrane.

[0068] Fig. 17 illustrates a cross-section of the breast interface which includes a flange 1708, the membrane 1604 with pleats 1606, output spout 1602 and housing 1712. The flange 1708 comprises a resilient material that allows the breast interface to be fluidly sealed against the breast. After collection, the expressed milk drains from output spout 1602 past valve 1716 into a collection vessel. A fluid reservoir 1710 is behind the membrane 1604 and fluid is pulled out to create a vacuum and pushed in to return to normal atmospheric pressure or to a positive pressure. The fluid is hydraulically displaced by movement of fluid in tubing 1714. Fluid movement in the tubing is actuated by any of the pumps or mechanisms disclosed in this specification. As previously discussed, a lower portion of the membrane does not substantially move in the axial direction, thereby holding the drain port or spout in a fixed axial position. This portion also may not move in the radial direction if there are no pleats in that section.

[0069] Fig. 18 is a close-up cross-sectional view of the interface between the membrane 1604 and the housing 1712. The expandable membrane may have enlarged edge 1806 that can be snapped or otherwise disposed in a channel in the housing 1712. An O-ring 1804 may be used to seal the housing against the flange 1708 (best seen in Fig. 17). Additionally the membrane may be pinched or compressively fixed between the housing and the flange using elastomeric pinch fixation 1808 to help hold and seal the membrane.

[0070] Fig. 19 is a cross-section of the expandable membrane 1604 with bellows or pleats 1606. Preferred embodiments include a negative grade 1902 that ensures that the expressed milk flows downhill into the drain port 1906. A housing seal 1904 may be positioned around the drain port to further secure the membrane and prevent leaks.

[0071] Figs. 20A and 20B illustrate another exemplary embodiment of an expandable membrane 2000 having radial pleats 2005. Fig. 20A is a view from the side of the membrane engaging the breast, while Fig. 20B is a view from of the side of the membrane engaging the breast interface housing. The expandable membrane 2000 comprises three expandable pleats 2005 extending radially outward from the center of the expandable membrane. The expandable pleats can be distributed evenly about the circumference of the membrane, for example at about 120 degrees away from one another as shown. The pleats comprise valleys 2015 that are configured to expand radially outwards when vacuum pressure is applied at the expandable membrane by an actuatable assembly operatively coupled to the breast interface. The valleys are further configured to contract radially inwards when the breast interface returns to normal atmospheric pressure, or when positive pressure is applied at the membrane. The pleats converge at the apex 2010, which can be configured to remain in a substantially fixed position during actuation of the actuatable assembly. The expandable membrane further comprises a drain port 2020, wherein milk expressed from the breast by the movement of the expandable membrane can drain through the drain port 2020 into a collection vessel. The drain port 2020 can be disposed at the base of the apex 2010, such that the drain port can remain in a substantially fixed position longitudinally and radially during actuation of the actuatable assembly.

[0072] Fig. 21 is a cross-section of a breast interface 2100 comprising the expandable membrane 2000 illustrated in Figs. 20A-20B. The breast interface 2100 comprises a housing 2105, within which the expandable membrane 2000 is disposed. The breast interface further comprises a flange 2110 configured to engage and fluidly seal against the breast, the flange often comprising a resilient material that can conform to the breast. The housing 2105 comprises a fluid reservoir 2115 disposed between the housing and the expandable membrane, wherein fluid can be added to or removed from the fluid reservoir in order to move the expandable membrane

and thereby generate pressure at the breast interface. The housing further comprises an outlet 2120 that can be coupled to a tube (not shown), wherein the tube is removably and operatively coupled to an actuatable assembly such as any of the pumps or actuatable mechanisms disclosed herein. The fluid in the fluid reservoir 2115 can be hydraulically displaced by movement of the fluid in the tubing when the actuatable assembly coupled to the tubing is actuated. When fluid is removed from the fluid reservoir, a vacuum is generated at the breast interface, causing the pleats of the expandable membrane 2000 to expand radially outwards such that the membrane moves in a direction away from the breast, and thereby apply vacuum pressure at the breast. The vacuum pressure and the movement of the membrane can cause breast tissue to be pulled into the membrane, and milk to be expressed from the breast. When fluid is added to the fluid reservoir, the pleats contract radially inwards such that the expandable membrane moves in a direction towards the breast. The contraction of the pleats can return the breast interface to normal atmospheric pressure and allow the expressed milk to drain through the drain port 2020, or apply positive pressure at the breast to force the expressed milk out through the drain port. Upon release of the vacuum pressure, the breast tissue that had been pulled into the membrane can be released and/or compressed, thereby facilitating the expression of milk from the breast.

Actuatable Assembly Interface

[0073] An actuatable assembly for a breast milk expression device as described herein can be configured to removably couple to a breast interface assembly, so as to keep the fluid carried in the transmission lines (such as the tubing described herein) and in the breast interface physically separate from the actuatable assembly. Such a physical separation between the actuatable assembly and the fluid in the breast interface can help prevent cross-contamination between the breast interface and the actuatable assembly. Further, the easy separation of various components of the expression device can facilitate the storage and maintenance of the device.

[0074] Fig. 22 is a cross-section of an exemplary embodiment of an expression device 2200 comprising an actuatable assembly interface 2300. The actuatable assembly interface 2300 can removably couple to the actuatable assembly 2205, so as to operatively couple the actuatable assembly to the breast interface 2210, while keeping the mechanisms of the actuatable assembly separate from the fluid 2220 in the tubing 2215 and in the breast interface 2210. When the actuatable assembly interface 2300 is coupled to the actuatable assembly 2205, the actuation of the actuatable assembly can cause the fluid 2220 to be pulled out of or pushed into the fluid reservoir of the breast interface, thereby causing an expandable membrane 2212 of the breast interface to apply pressure to the breast engaged into the breast interface.

[0075] Fig. 23 is a cross-section of an actuatable assembly 2205 coupled to an actuatable assembly interface 2300, as illustrated in Fig. 22. The actutable assembly interface 2300

comprises an actuatable assembly interface housing 2305 and an actuatable assembly interface membrane 2310 coupled thereto. The interface housing is configured to couple to tubing 2215, which is fluidly coupled to the fluid reservoir in the breast interface housing. The tubing 2215 is operatively coupled to the interface membrane 2310, such that movement of the interface membrane causes movement of the fluid 2220 carried by the tubing. The actuatable assembly 2205 comprises an actuatable assembly housing 2225 and an actuatable assembly membrane 2230 coupled thereto. The actuatable assembly membrane is operatively coupled to the driver mechanism 2235 of the actuatable assembly, such that actuation of the driver mechanism causes movement of the membrane 2230. The driver mechanism may comprise any pump mechanisms as described herein. For example, as shown in Fig. 23, the driver mechanism may comprise a piston assembly shown in Fig. 23, the piston configured to move in response to movement of the lead screw 2240 driven by a motor.

[0076] The actuatable assembly housing is configured to removably couple to the interface housing 2300, for example via one or more magnets 2315 as shown. The magnets may be embedded in the interface housing, the actuatable assembly housing, or both; accordingly, one or more of the interface housing and the actuatable assembly housing may comprise a metal material configured to be attracted to the magnets. The acutatable assembly may further comprise an alignment mechanism 2245, such as pins or screws configured to engage a portion of the actuatable assembly interface, in order to ensure correct alignment of the actuatable assembly with the actuatable assembly interface.

[0077] When the actuatable assembly and the actuatable assembly interface are coupled together, the actuatable assembly membrane 2230 and the interface membrane 2310 are brought into communication with one another. As the motor of the actuatable assembly is actuated, the driver mechanism 2235 pushes the membrane 2230 upward toward the interface membrane 2310, causing at least a portion of the air 2250 trapped between the two membranes to be pushed out via a one-way valve 2255 coupled to either the actuatable assembly or the interface. In order to ensure that the actuatable assembly interface does not separate from the actuatable assembly during coupling of the two members, the magnets 2315 may be configured to have a magnetic force that is greater than the exit force of air from the one-way valve.

[0078] Once the trapped air is pushed out through the valve outlet 2260, the interface membrane 2310 becomes operatively coupled to the actuatable assembly membrane 2230, such the interface membrane will follow the cyclical motions of the actuatable assembly membrane as the actuatable assembly is actuated. Movement of the interface membrane 2310 will cause corresponding movement of the fluid 2220 in the tubing 2215, causing fluid to be removed from or added to the fluid reservoir in the breast interface. In order to ensure that the actuatable

assembly interface does not separate from the actuatable assembly during actuation of the actuatable assembly, the magnets 2315 may be configured to have a magnetic force that is greater than the pull force of the actuatable assembly.

[0079] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the expandable membrane can be combined or substituted with components and features of any of the embodiments of the present invention as described herein. Additionally, one of skill in the art will appreciate that the expansion for either the radially expandable or axially expandable embodiments may also be in the form of deflection of material or stretching of material depending on geometry & construction.

Milk collection and quantification system

[0080] With reference to Fig. 3, expressed milk drains through exit port 265 in flexible membrane 245 into a collection vessel 275. Collection vessel 275 can be any suitable container, such as a bottle or a bag. In many embodiments, collection vessel 275 is removably coupled to flexible membrane 245. Collection vessel 275 can be coupled directly or remotely via any suitable device such as extension tubing.

[0081] In many instances, it can be desirable to track various data related to milk expression and collection, such as the amount of milk production. Currently, the tracking of milk production is commonly accomplished by manual measurements and record-keeping. Exemplary embodiments of the device described herein may provide digital-based means to automatically measure and track milk production for improved convenience, efficiency, and accuracy.

[0082] Figs. 9A and 9B illustrates exemplary embodiments of a breast interface 450 with one or more integrated sensors 455. Sensors 455 are preferably located in flap valve 460, but may also be located in exit valve 465, or any other suitable location for monitoring fluid flow. In a preferred embodiment, at least one sensor 455 is integrated into a valve that is opened by fluid flow and detects the length of time that the valve is opened. The sensor signal can be interrogated to quantify the fluid flow. Suitable sensors are known to those of skill in the art, such as accelerometers, Hall effect sensors, and photodiode/LED sensors. The breast interface can include a single sensor or multiple sensors to quantify milk production.

[0083] Fig. 10 illustrates an exemplary embodiment of pendant unit 500 in which milk expression data is shown on a display screen 505. In many embodiments, the pendant unit 500 collects, processes, stores, and displays data related to milk expression. Preferably, the pendant unit 500 can transmit the data to a second device, such as a mobile phone 510.

[0084] Fig. 11 illustrates data transmission 515 between pendant unit 500 and a mobile phone 510. Suitable methods for communication and data transmission between devices are known to those of skill in the art, such as Bluetooth or near field communication.

[0085] In exemplary embodiments, the pendant unit 500 communicates with a mobile phone 510 to transmit milk expression data, such as expression volume, duration, and date. The mobile phone 510 includes a mobile application to collect and aggregate the expression data and display it in an interactive format. Preferably, the mobile application includes additional features that allow the user to overlay information such as lifestyle choices, diet, and strategies for increasing milk production, in order to facilitate the comparison of such information with milk production statistics. Additionally, the pendant unit 500 can send information about the times of pump usage to the mobile phone 510 so that the mobile application can identify when pumping has occurred and set reminders at desired pumping times. Such reminders can help avoid missed pumping sessions, and thus reduce the incidence of associated complications such as mastitis.

[0086] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the milk collection and quantification system can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Mechanical pumping device

[0087] Fig. 12 illustrates an alternative embodiment of a breast interface 600 in which a mechanical deformable member 605 can be used in place of a flexible membrane. The mechanical deformable member 605 can be constructed from similar techniques as those used for the flexible membrane as described herein. The mechanical deformable member 605 is coupled to a tensile element 610. In some instances, tensile element 610 is disposed within an axial load absorbing member 615. The axial load absorbing member 615 is disposed within tube 620. Preferably, tensile element 610 is concentrically disposed within axial load absorbing member 615 and axial load absorbing member 615 is concentrically disposed within tube 620. Alternative arrangements of tensile element 610, axial load absorbing member 615, and tube 620 can also be used.

[0088] Fig. 13 illustrates the tensile element 610 coupled to driving element 625 of an actuatable assembly 630 within an assembly housing 635. Driving element 625 is operatively coupled to a driving mechanism, such as a driving mechanism housed within a pendant unit, through shaft 640. Axial load absorbing member 615 within tube 620 is fixedly coupled to the assembly housing 635. Displacement of the driving element 625 transmits tensile force through tensile element 610 to the mechanical deforming member 605 to create vacuum pressure against the breast.

[0089] The tensile element 610 can be any suitable device, such as a wire, coil, or rope, and can be made from any suitable material, such as metals, polymers, or elastomers. Axial load absorbing member 615 can be made from any suitable axially stiff materials, such as metals or polymers, and can be configured into any suitable axially stiff geometry, such as a tube or coil.

[0090] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the mechanical pumping device can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Experimental data

[0091] Figs. 14 and 15 illustrate experimental pumping data obtained from a commercial breast pump device and an exemplary embodiment of the present invention. The exemplary embodiment utilized an incompressible fluid for pumping and had a maximum hydraulic fluid volume of 4 cc, while the commercial device utilized air for pumping and had a maximum volume of 114 cc.

[0092] Fig. 14 illustrates a graph of the pump performance as quantified by vacuum pressure generated per run. For the exemplary embodiment, pressure measurements were taken for 1 cc, 2 cc, 3 cc, and 4 cc of fluid volume displaced by the pump, with the run number corresponding to the volume in cc. For the commercial device, measurements were taken with the pump set to one of seven equally incremented positions along the vacuum adjustment gauge representing 46 cc, 57 cc, 68 cc, 80 cc, 91 cc, 103 cc, and 114 cc of fluid volume displaced by the pump, respectively, with the run number corresponding to the position number. Curve 700 corresponds to the exemplary embodiment and curve 705 corresponds to the commercial device. The exemplary embodiment generated higher levels of vacuum pressure per displacement volume compared to the commercial device, with maximum vacuum pressures of -240.5 mmHg and -177.9 mmHg, respectively.

[0093] Fig. 15 illustrates a graph of the pump efficiency as measured by the maximum vacuum pressure per maximum volume of fluid displaced, with bar 710 corresponding to the exemplary embodiment and bar 715 corresponding to the commercial device. The exemplary embodiment demonstrated a 42-fold increase in pumping efficiency compared to the commercial device, with efficiencies of -71.1 mmHg/cc and -1.7 mmHg/cc, respectively.

[0094] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that

methods and structures within the scope of these claims and their equivalents be covered thereby.

CLAIMS

WHAT IS CLAIMED IS:

1. A device for expression of milk from a breast, said device comprising:

an actuatable assembly; and

a breast interface sized to engage a breast and fluidly seal thereagainst, the breast interface having an expandable membrane disposed within at least a portion thereof, wherein the expandable membrane moves in response to actuation of the actuatable assembly thereby applying vacuum pressure at the breast to express milk therefrom;

wherein the expandable membrane comprises a plurality of expandable pleats, each of the plurality of expandable pleats extending radially outward from a center of the expandable membrane.

2. The device of claim 1, wherein the plurality of expandable pleats is configured to expand radially outward or contract radially inward during acutation of the actuatable assembly.

3. A device as in any one of claims 1 or 2, further comprising a drain port disposed along a bottom portion of the expandable membrane, between pleats or in a section of the expandable membrane having no pleats.

4. The device of claim 3, wherein the drain port is configured to remain in a substantially fixed longitudinal position during actuation of the actuatable assembly.

5. A device as in any one of claims 3 or 4, where the drain port is disposed in a section of the expandable member having no pleats and is configured to remain in a substantially fixed radial position during actuation of the actuation assembly.

6. A device as in any one of claims 3, 4, or 5, wherein the expandable membrane comprises a negative grade along a bottom portion thereof, configured to allow expressed milk to flow downhill into the drain port.

7. A device as in any one of claims 3, 4, 5, or 6, wherein the breast interface further comprises a housing and a sealing member, the sealing member disposed around the drain port to secure the expandable membrane to the housing of the breast interface.

8. A device as in any one of the preceding claims, wherein the breast interface further comprises a fluid reservoir operatively coupled to the actuatable assembly, and wherein actuation of the actuatable assembly removes fluid from the fluid reservoir thereby expanding

the expandable membrane, or wherein the actuation adds fluid to the fluid reservoir thereby contracting the expandable membrane.

9. The device of claim 8, wherein the actuatable assembly is removably coupled to an actuatable assembly interface, the actuatable assembly interface configured to operatively couple the actuatable assembly to the breast interface while maintaining physical separation between the actuatable assembly and the fluid.

10. The device of claim 9, wherein the actuatable assembly interface comprises an interface membrane fluidly coupled to the fluid reservoir via an elongate tube, and wherein the interface membrane is configured to operatively couple to an actuatable assembly membrane of the actuatable assembly, such that movement of the actuatable assembly membrane, affected by the actuation of the actuatable assembly, causes corresponding movement of the interface membrane, thereby causing movement of the fluid into or out of the fluid reservoir.

11. A device as in any one of claims 9 or 10, wherein the actuatable assembly comprises a one-way valve configured to allow air trapped between the actuatable assembly and the actuatable assembly interface to exit during actuation of the actuatable assembly.

12. A device as in any one of claims 9, 10, or 11, wherein the actuatable assembly comprises an alignment mechanism configured to couple the actuatable assembly with the actuatable assembly interface in a substantially fixed position and orientation.

13. A device as in any one of claims 9, 10, 11, or 12, wherein the actuatable assembly is removably coupled to the actuatable assembly interface via one or more magnets.

14. The device of claim 13, wherein the one or more magnets are configured to have a magnetic force greater than: (1) an exit force of air exiting a space between the actuatable assembly and the actuatable assembly interface via a one-way valve, and (2) a pull force generated by actuation of the actuatable assembly.

15. A device as in any one of the preceding claims, wherein the breast interface further comprises a housing, and wherein the expandable membrane comprises an enlarged edge configured to be disposed in a channel of the housing so as to securely couple the expandable membrane to the housing.

16. A device as in any one of the preceding claims, wherein the breast interface further comprises a flange comprising a resilient material that allows the breast interface to

fluidly seal against the breast, and wherein the breast interface further comprises a sealing member to seal the housing against the flange.

17. A device as in any one of the preceding claims, wherein the expandable membrane is compressively fixed between the housing and the flange via an elastomeric pinch fixation to hold and seal the expandable membrane.

18. A device as in any one of the preceding claims, wherein the plurality of expandable pleats is configured to converge at an apex, and wherein the apex is configured to remain in a substantially fixed position during actuation of the actuatable assembly.

19. A method of expressing milk from a breast, said method comprising:

engaging and fluidly sealing a breast interface with the breast, wherein the breast interface comprises an expandable membrane having a plurality of expandable pleats;

actuating an actuatable assembly operatively coupled to the expandable membrane, thereby causing the plurality of expandable pleats to expand radially outward and apply vacuum pressure at the breast; and

expressing milk from the breast.

20. The method of claim 19, wherein actuation of the actuatable assembly further causes the plurality of expandable pleats to contract radially inward, thereby returning the breast interface to atmospheric pressure or applying positive pressure at the breast interface, causing the expressed milk to drain into a collection vessel fluidly coupled to the breast interface.

21. The method of claim 20, wherein the plurality of expandable pleats apply a compressive force to a portion of the breast engaged with the plurality of expandable pleats, thereby facilitating expression of milk from the breast.

22. A method as in any one of claims 19, 20, or 21, wherein the breast interface further comprises a drain port disposed along a bottom portion of the expandable membrane, and wherein the drain port remains in a substantially fixed longitudinal position during actuation of the actuatable assembly.

23. The method of claim 22, further comprising collecting the expressed milk into a collection vessel fluidly coupled to the breast interface via the drain port, wherein the expandable membrane comprises a negative grade along a bottom portion of thereof to allow the expressed milk to flow downhill into the drain port.

24. A method as in any one of claims 19, 20, 21, 22, or 23, wherein the breast interface further comprises a fluid reservoir fluidly coupled with the actuatable assembly, and wherein actuation of the actuatable assembly removes fluid from the fluid reservoir thereby expanding the expandable membrane, or wherein the actuation adds fluid to the fluid reservoir thereby contracting the expandable membrane.

25. A method as in any one of claims 19, 20, 21, 22, 23, or 24, further comprising coupling the actuatable assembly to an actuatable assembly interface operatively coupled to the breast interface, thereby operatively coupling the actuatable assembly to the breast interface.

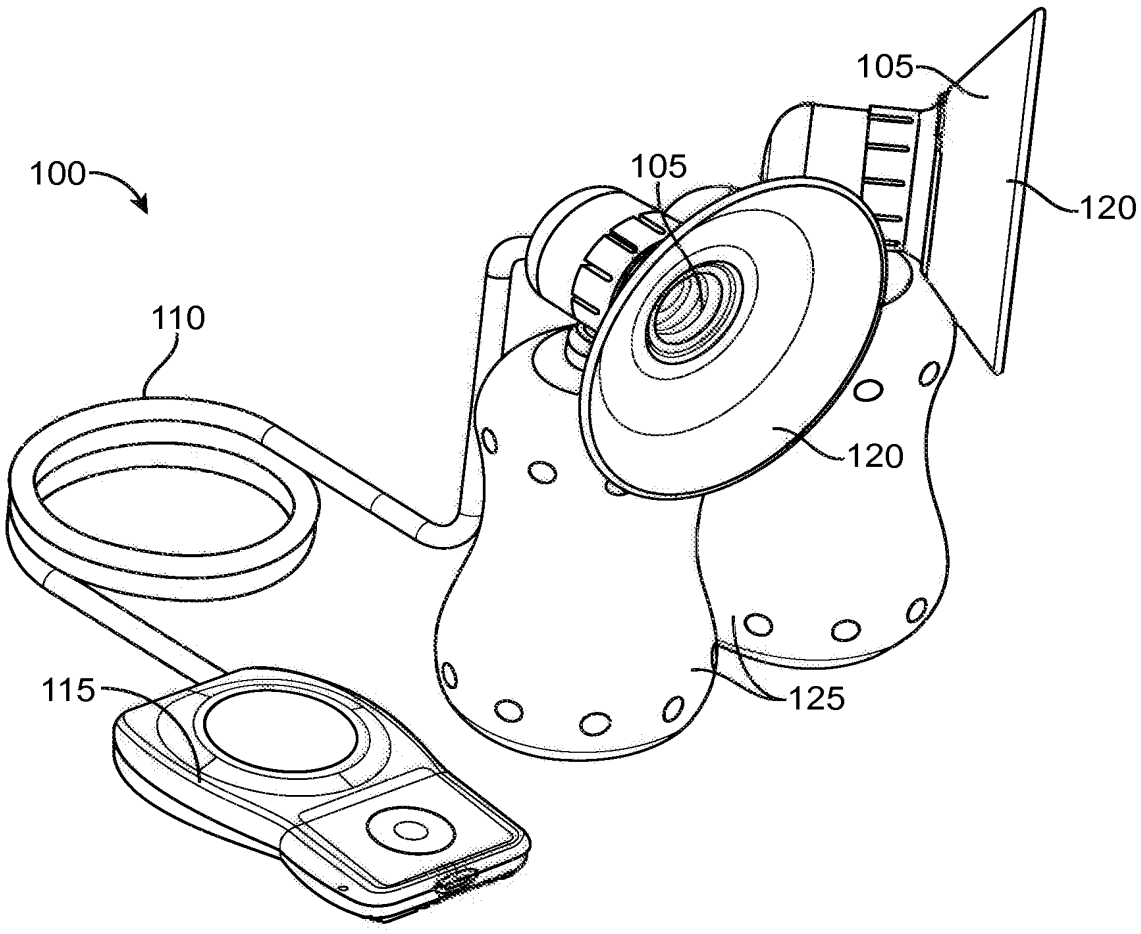

FIG. 1

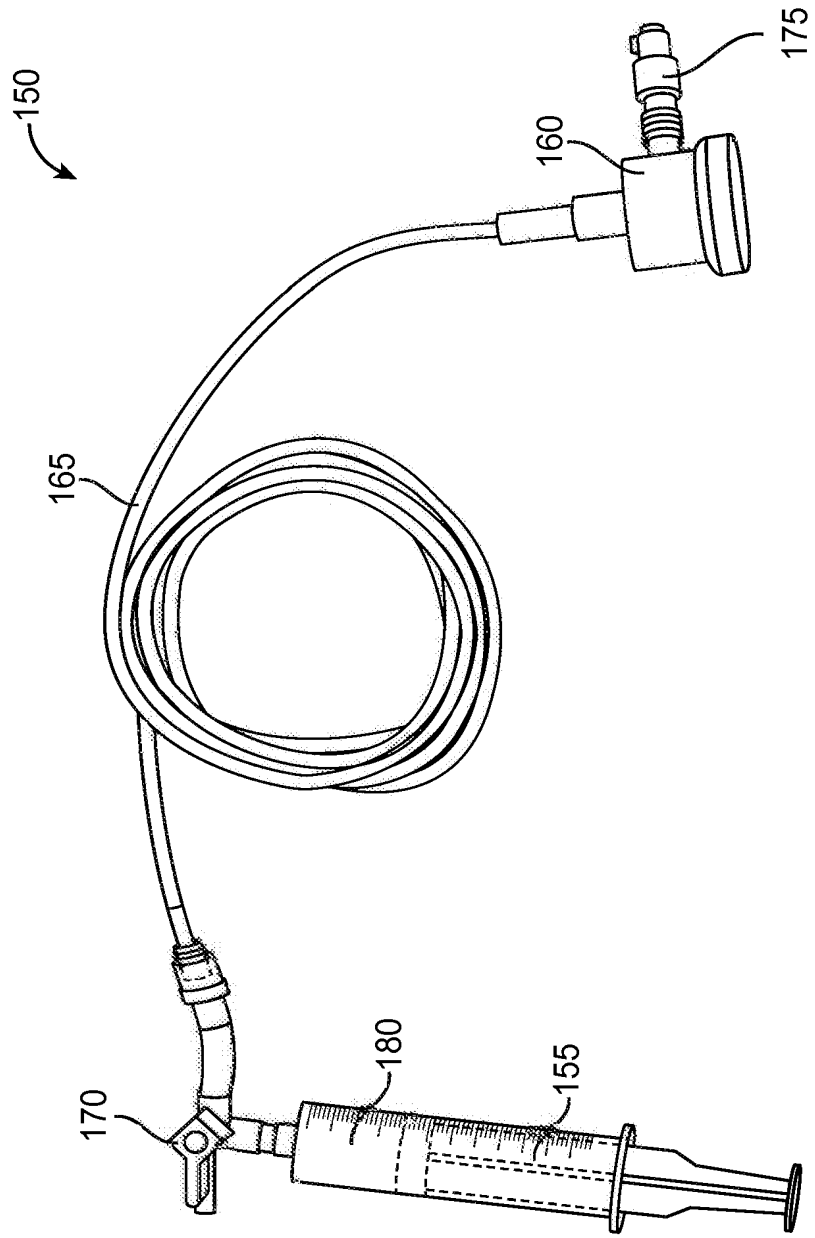

FIG. 2

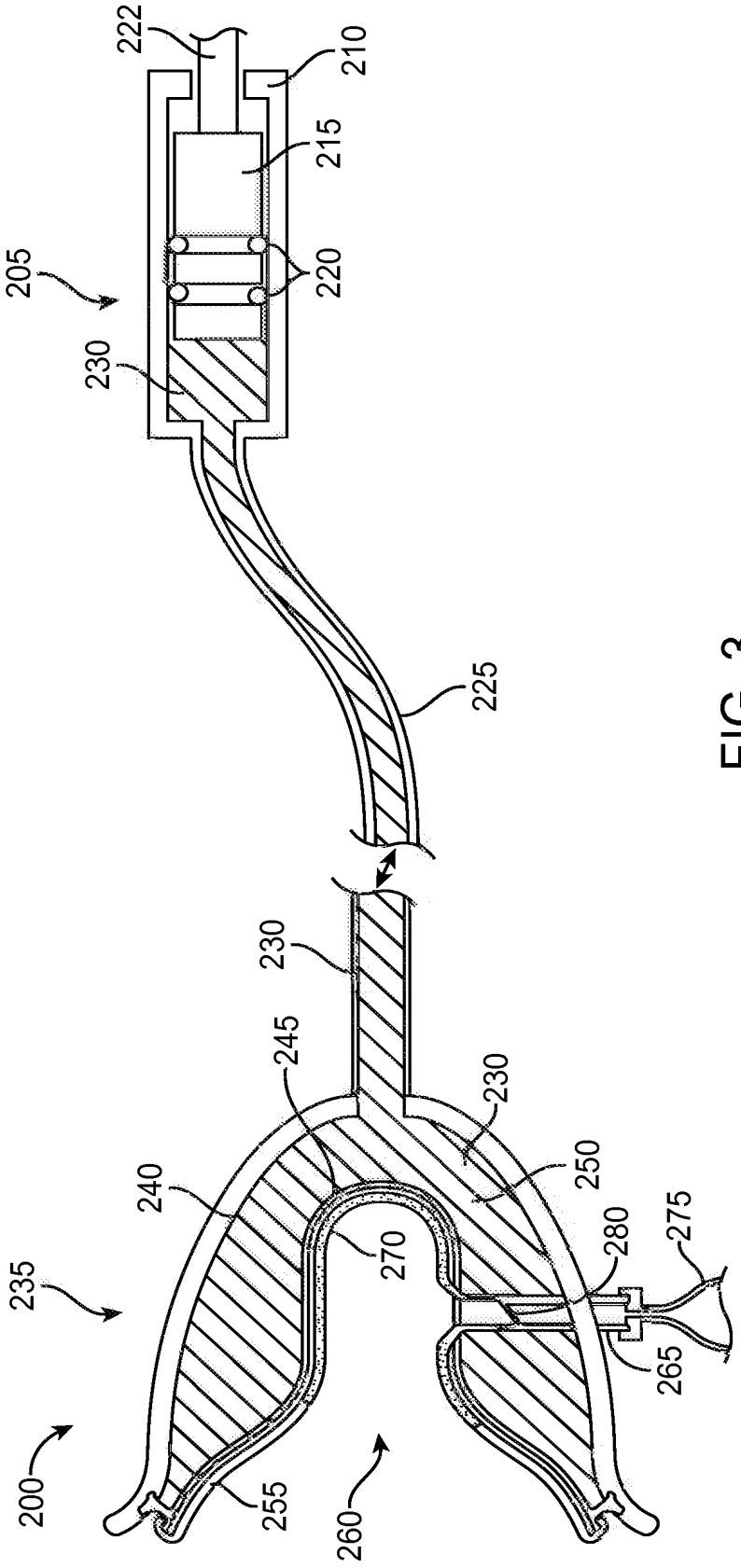
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FIG. 3

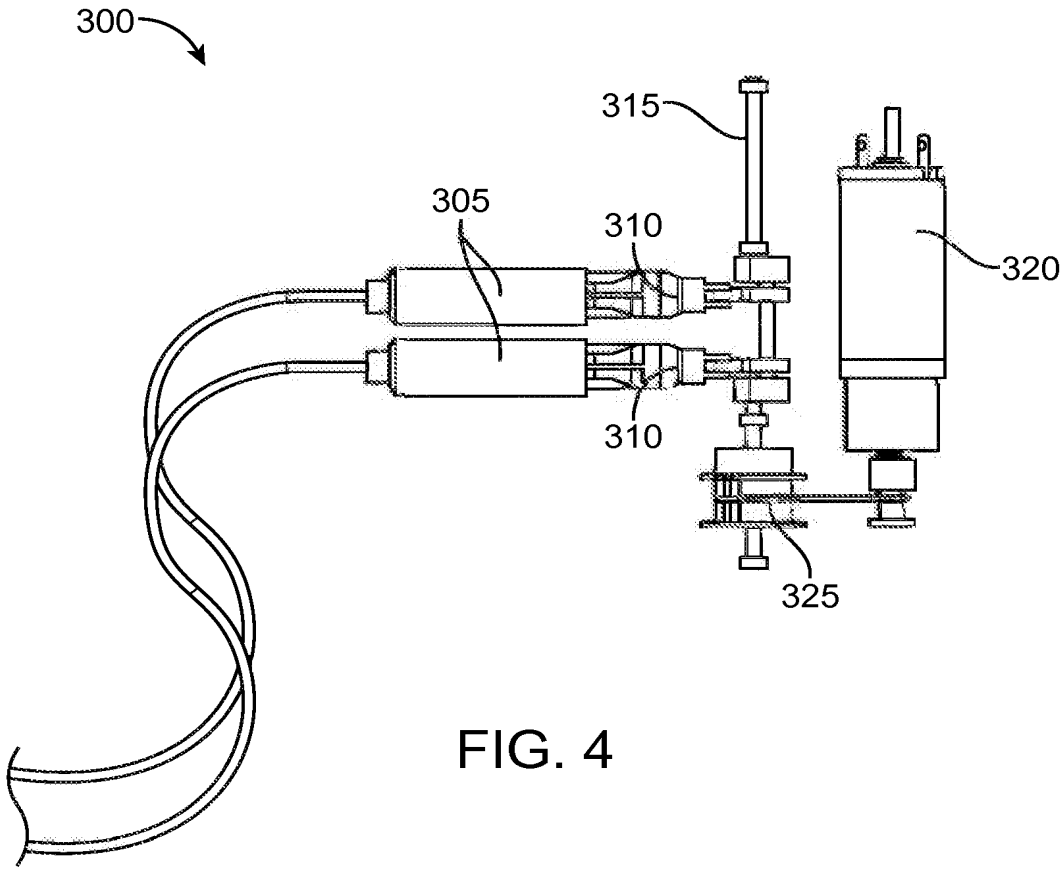


FIG. 4

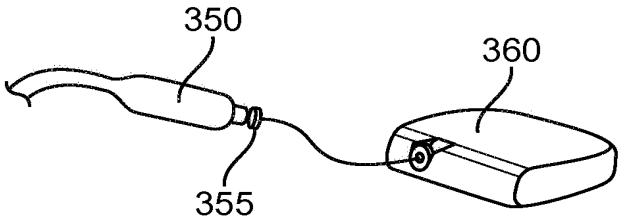


FIG. 5A

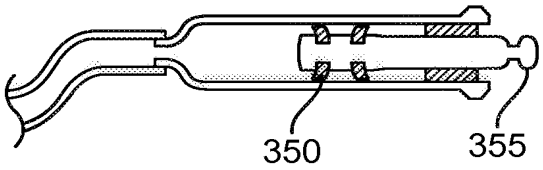


FIG. 5B

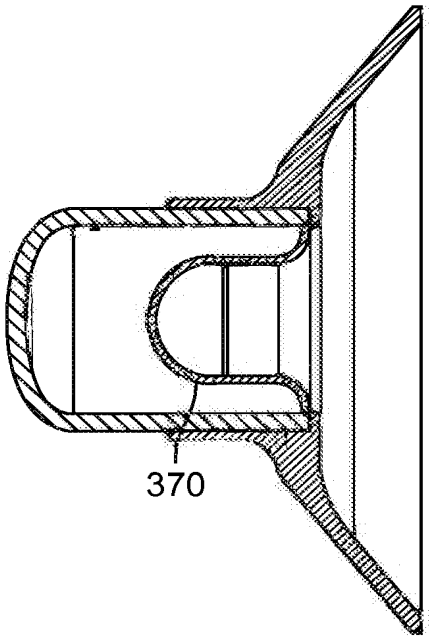


FIG. 6

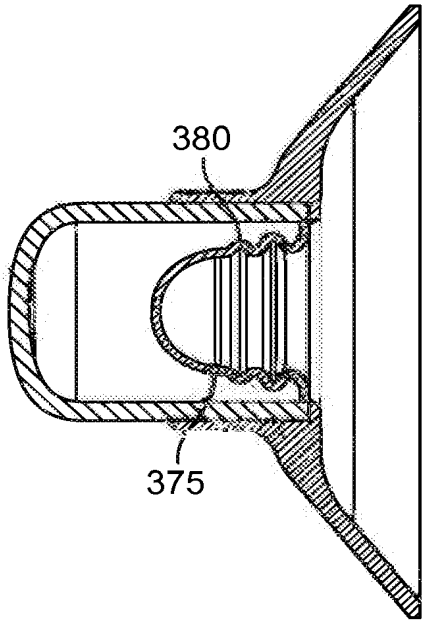


FIG. 7

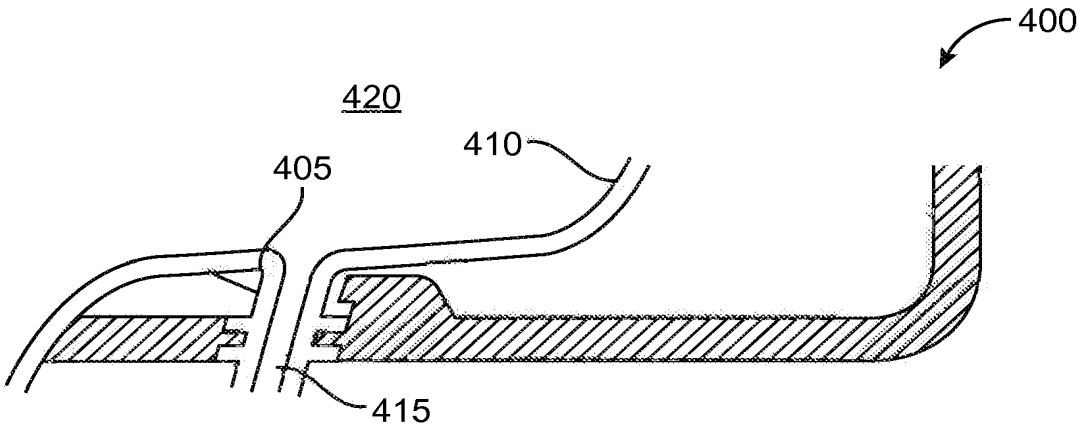


FIG. 8A

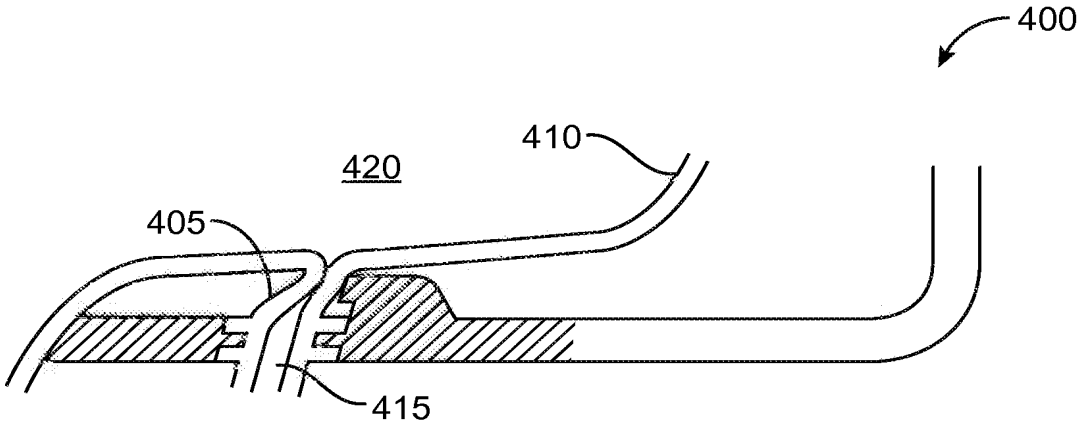


FIG. 8B

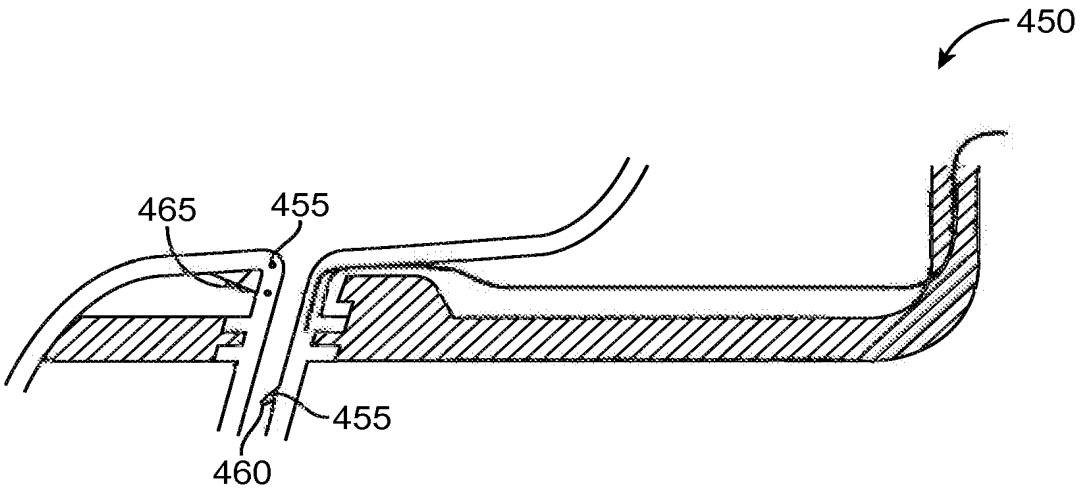


FIG. 9A

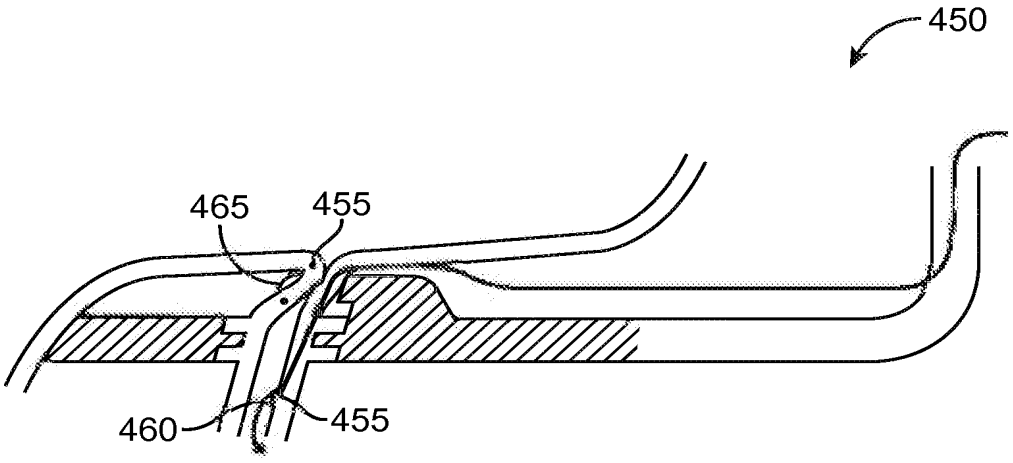
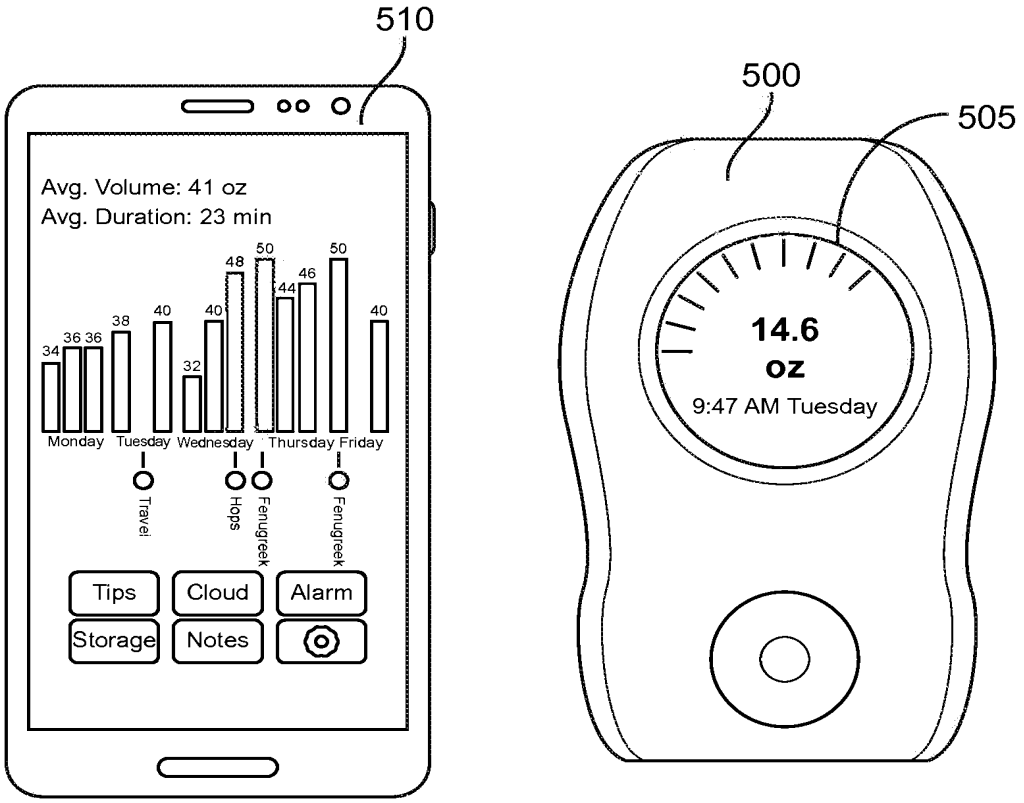


FIG. 9B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505
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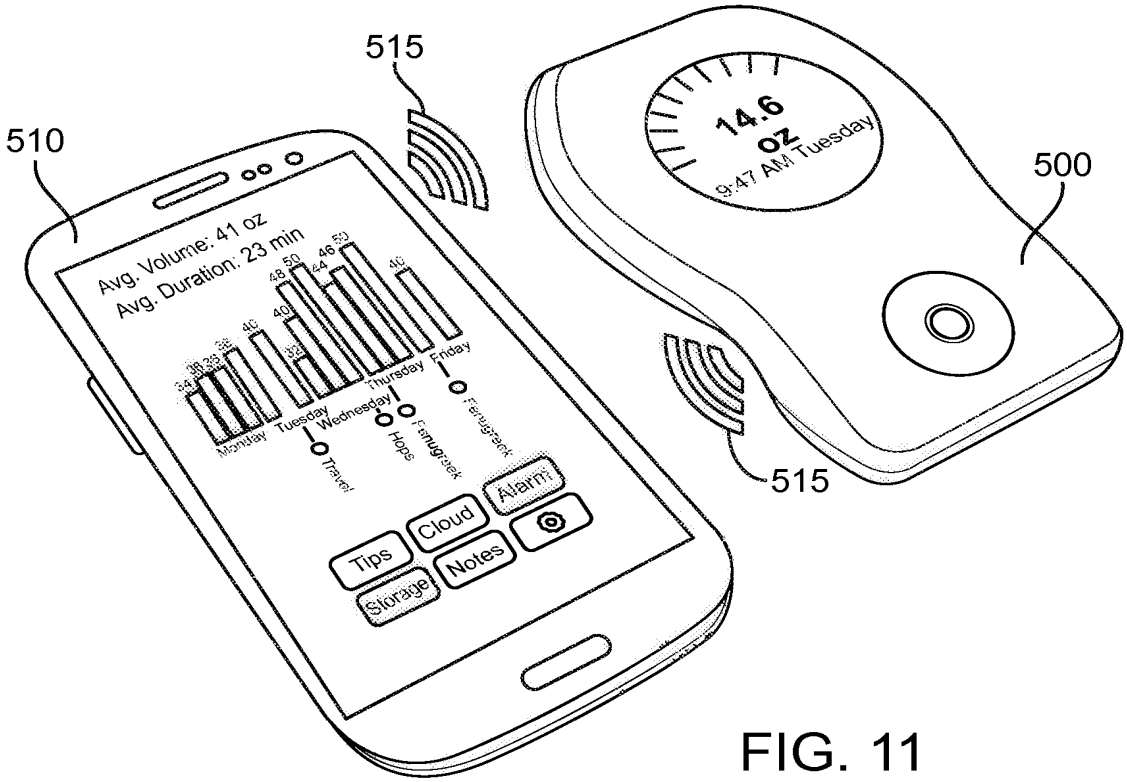
Avg. Duration: 23 min
34
36
36
38
40
32
40
48
50
44
46
50
40
Monday
Tuesday
Wednesday
Thursday
Friday
Travel
Hops
Fenugreek
Fenugreek
Tips
Cloud
Alarm
Storage
Notes
14.6
oz
9:47 AM Tuesday

FIG. 10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Thursday
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Tips
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oz
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FIG. 11

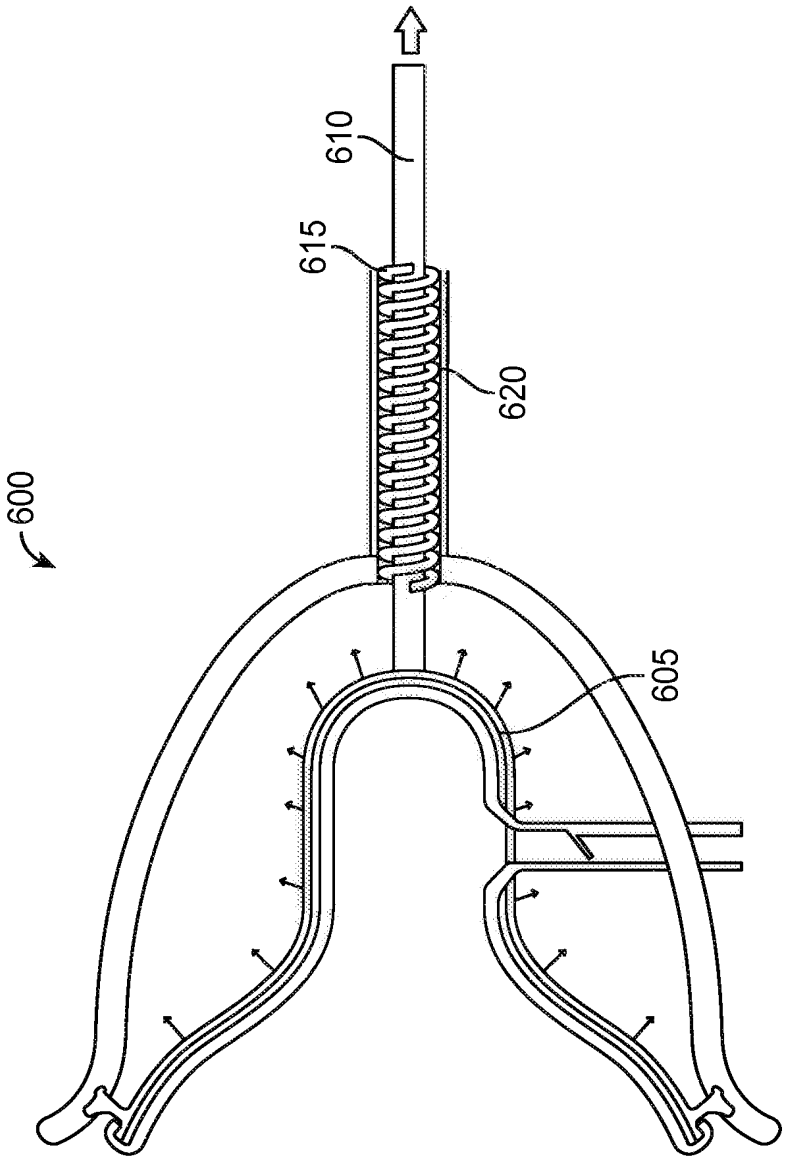


FIG. 12

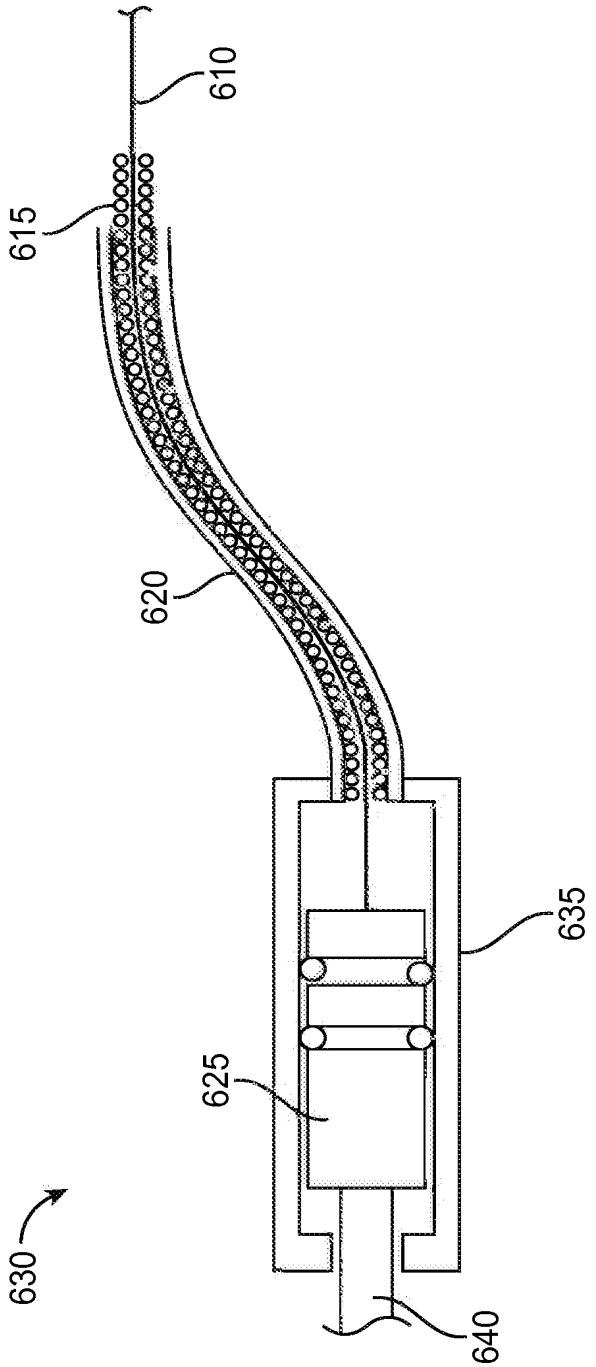
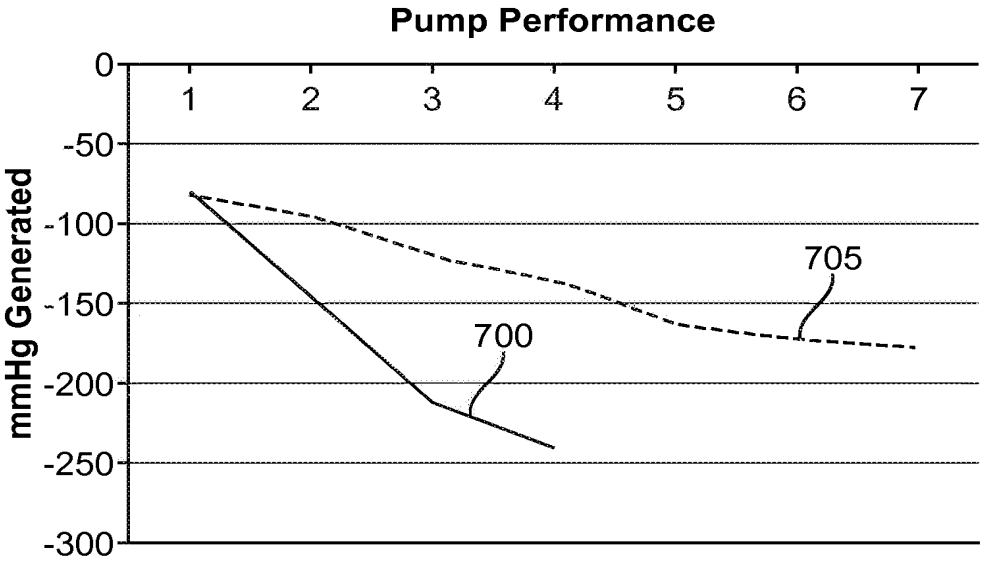


FIG. 13


Pump Performance
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-300
mmHg Generated
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2
3
4
5
6
7
705
700

FIG. 14

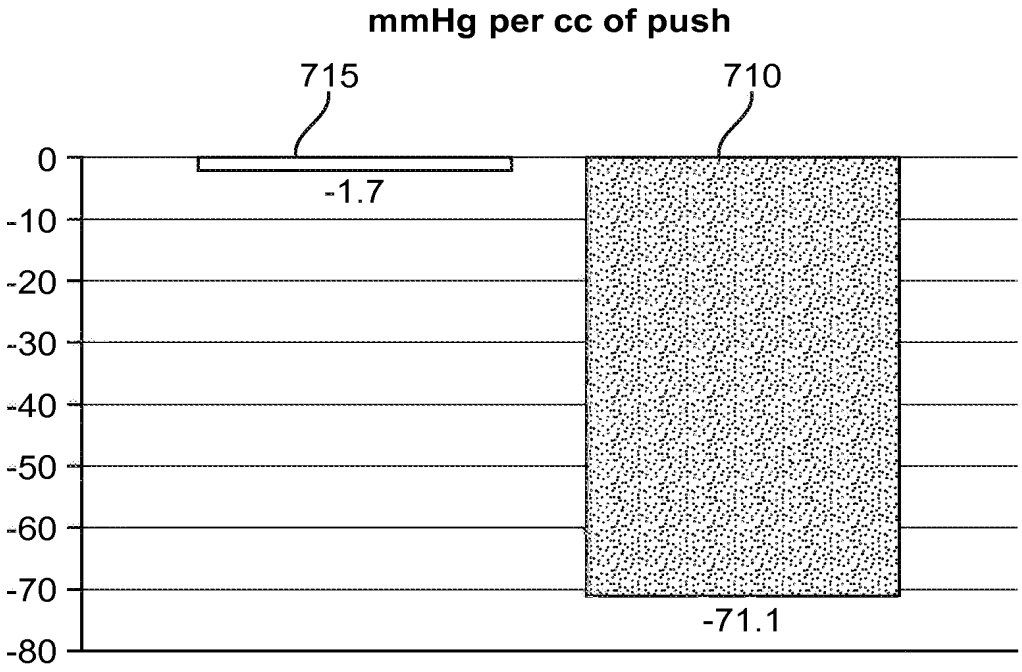

FIG. 15

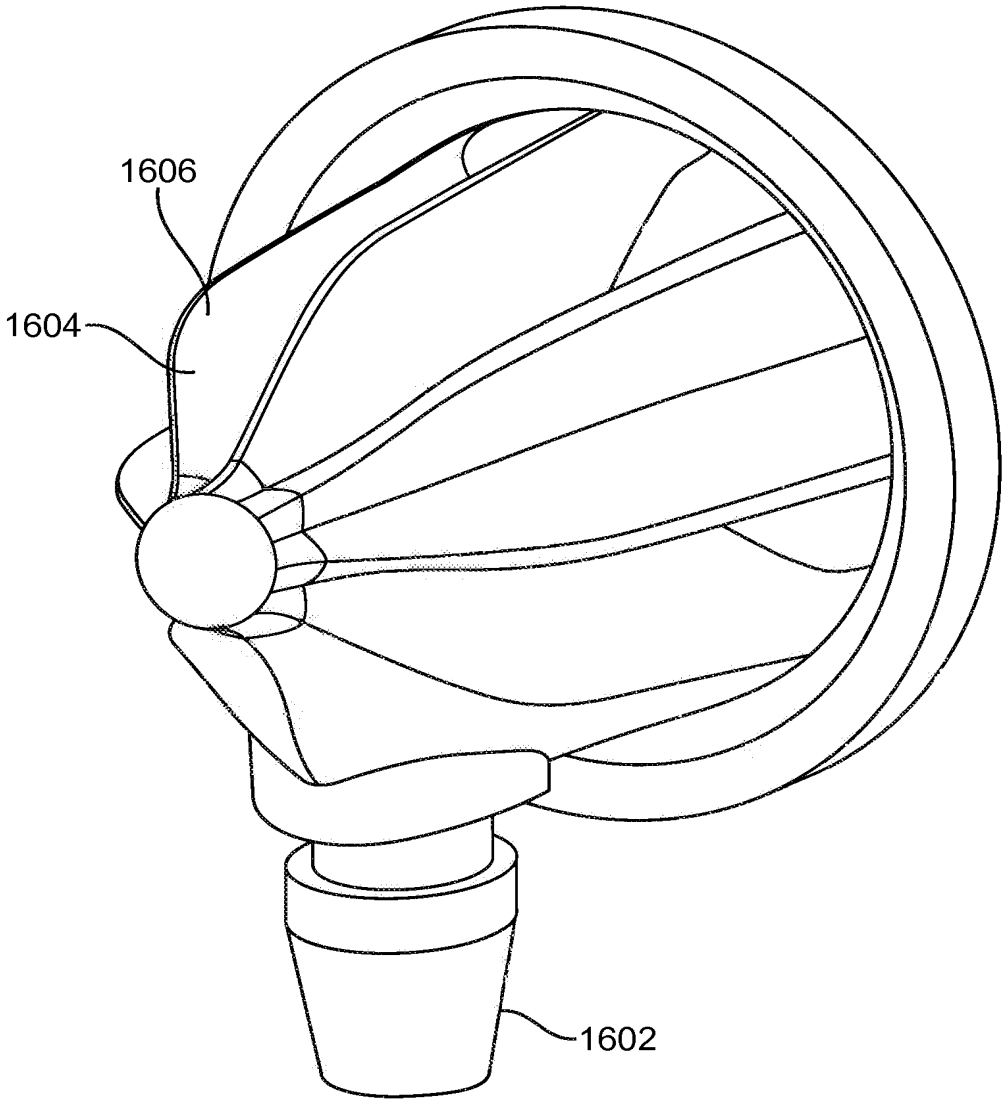

FIG. 16

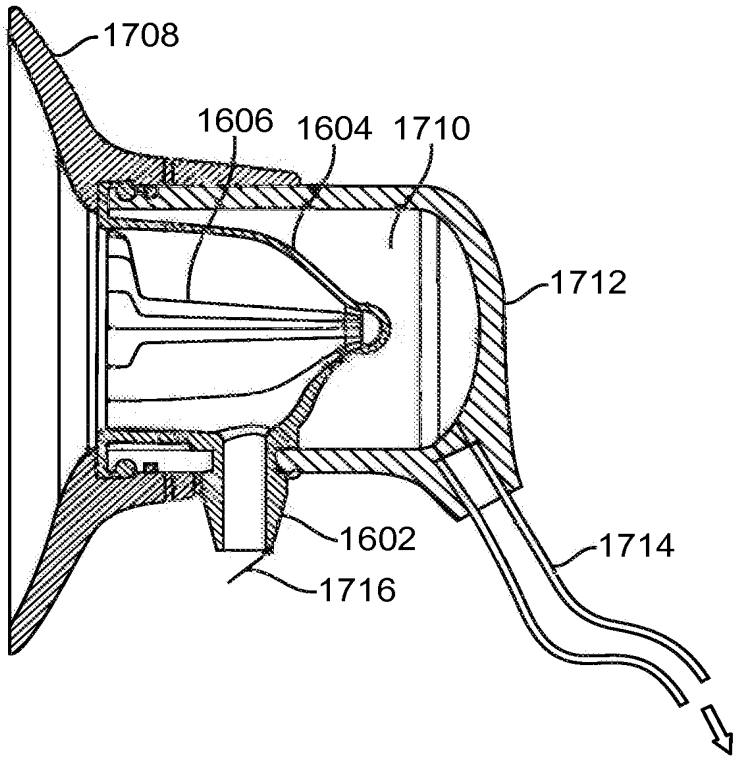
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FIG. 17

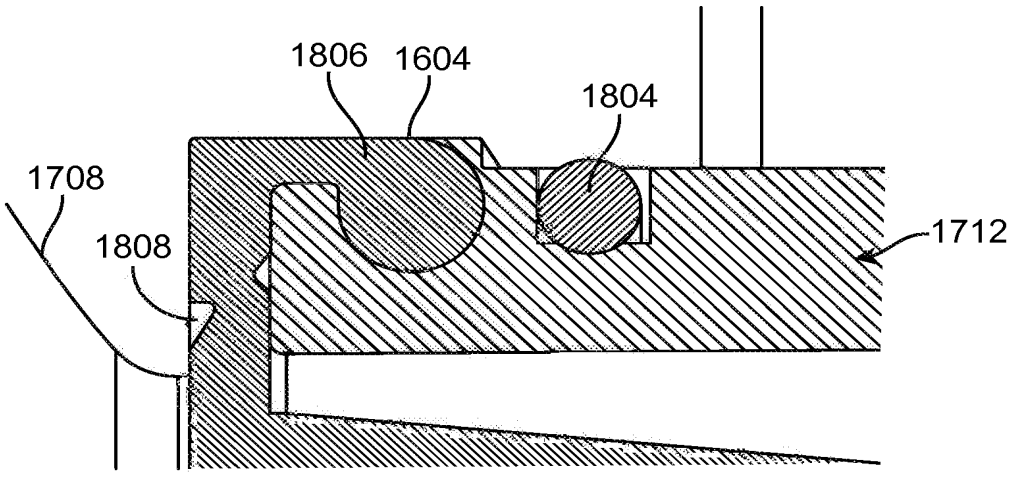
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FIG. 18

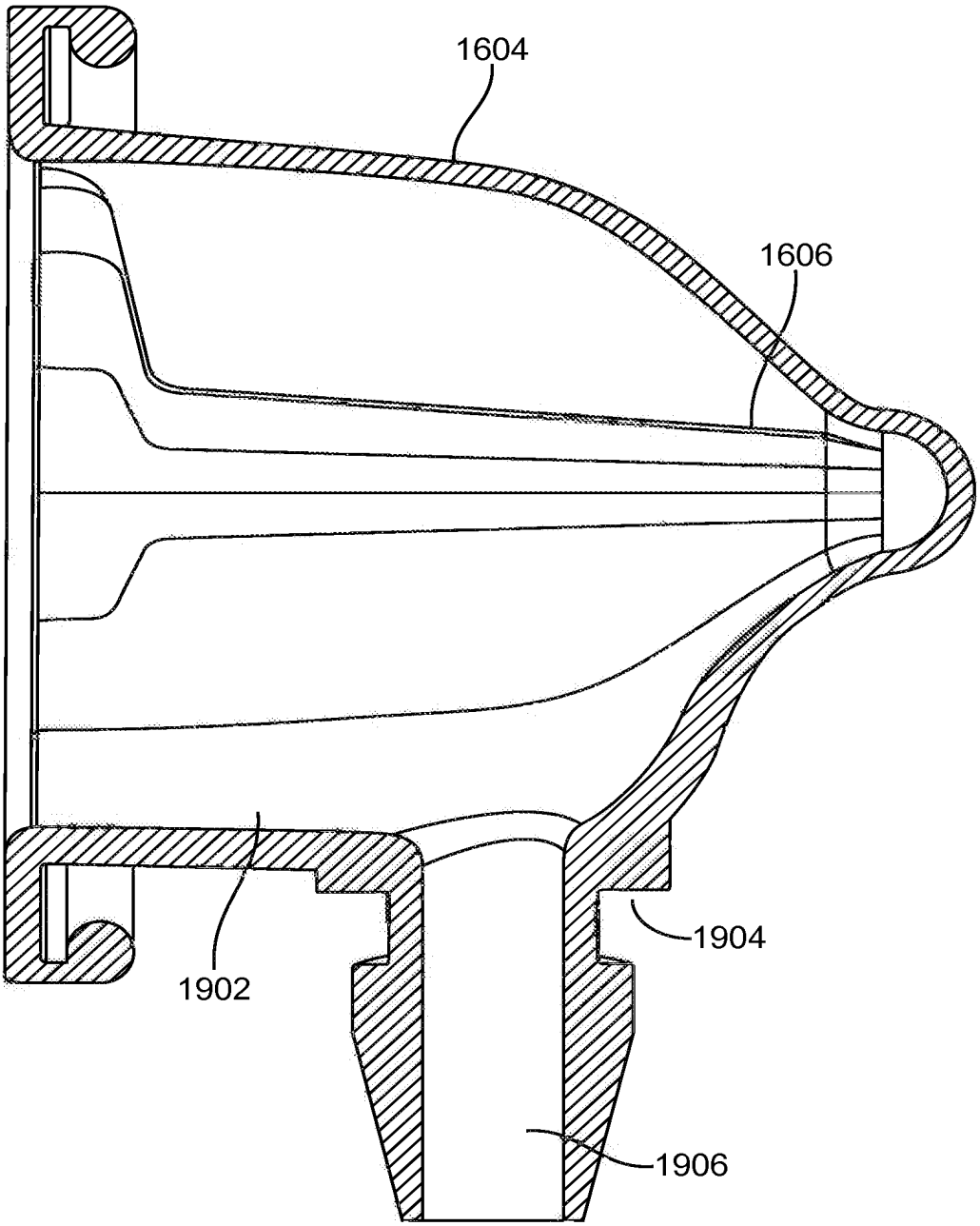


FIG. 19

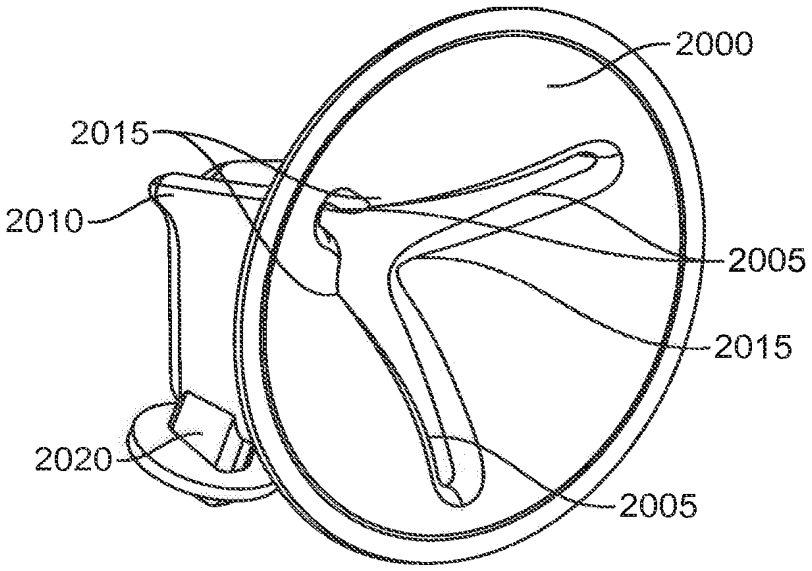


FIG. 20A

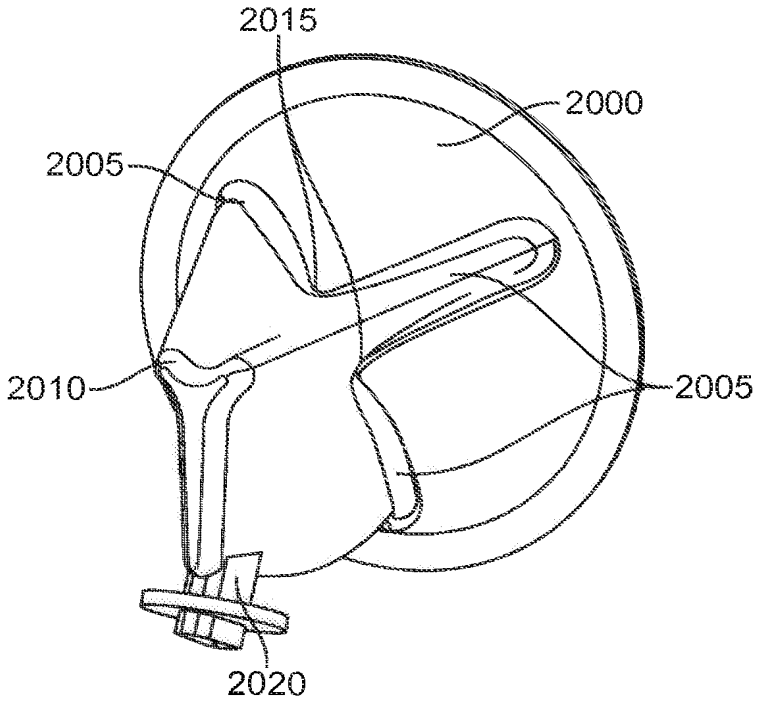


FIG. 20B

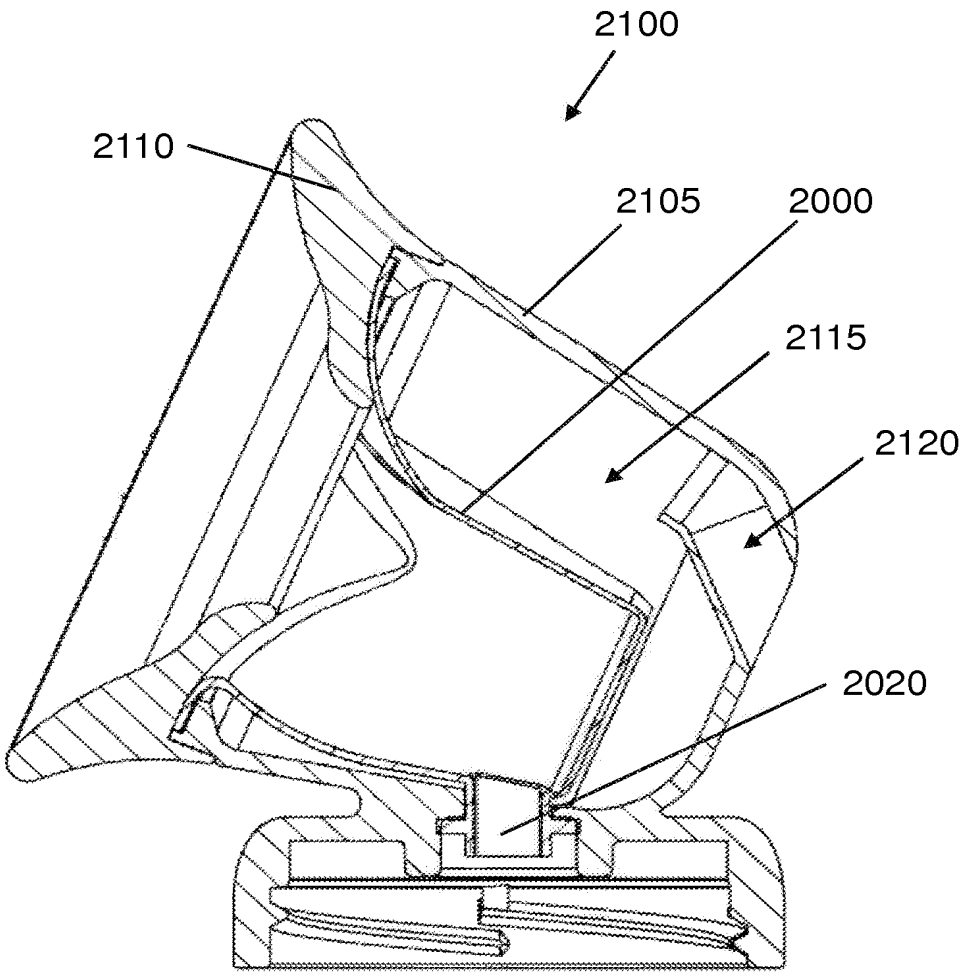


FIG. 21

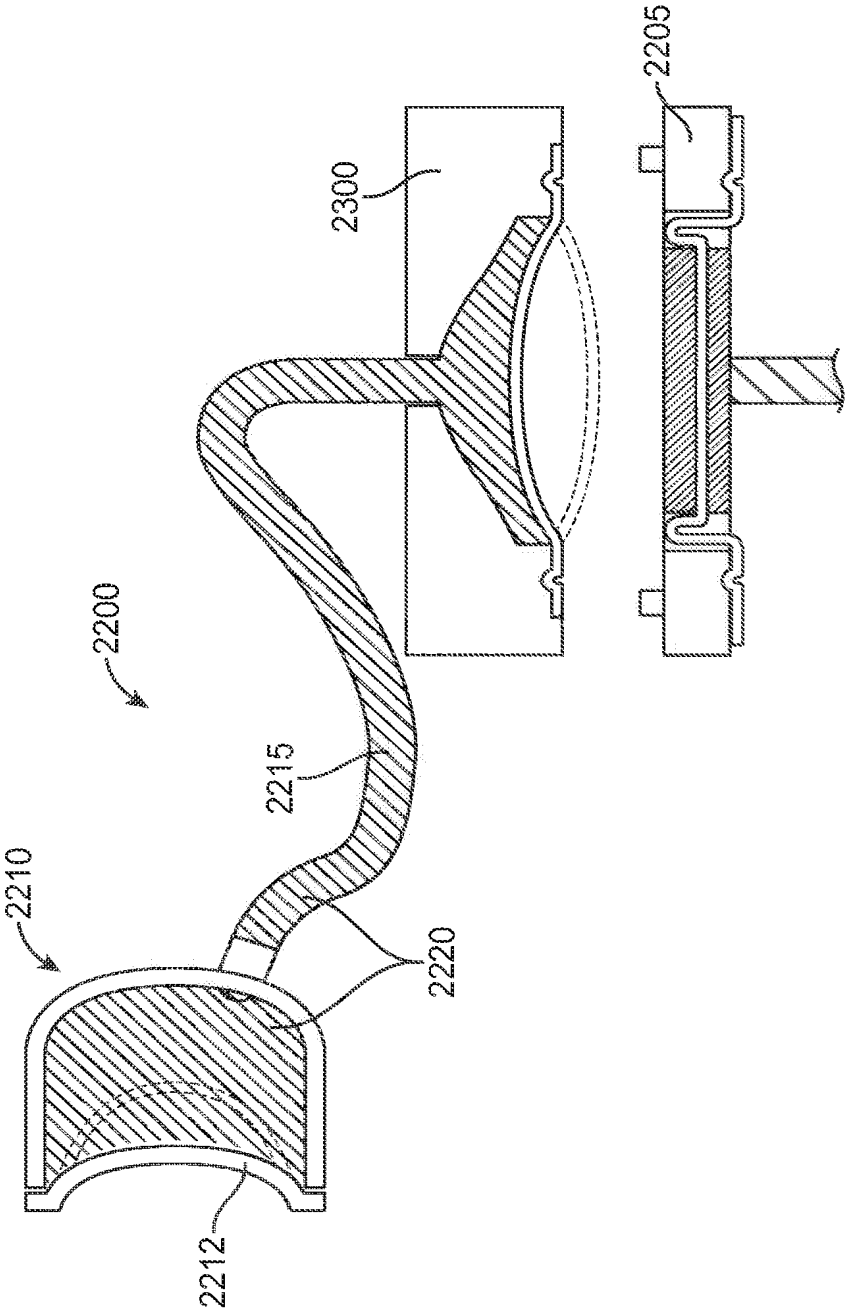
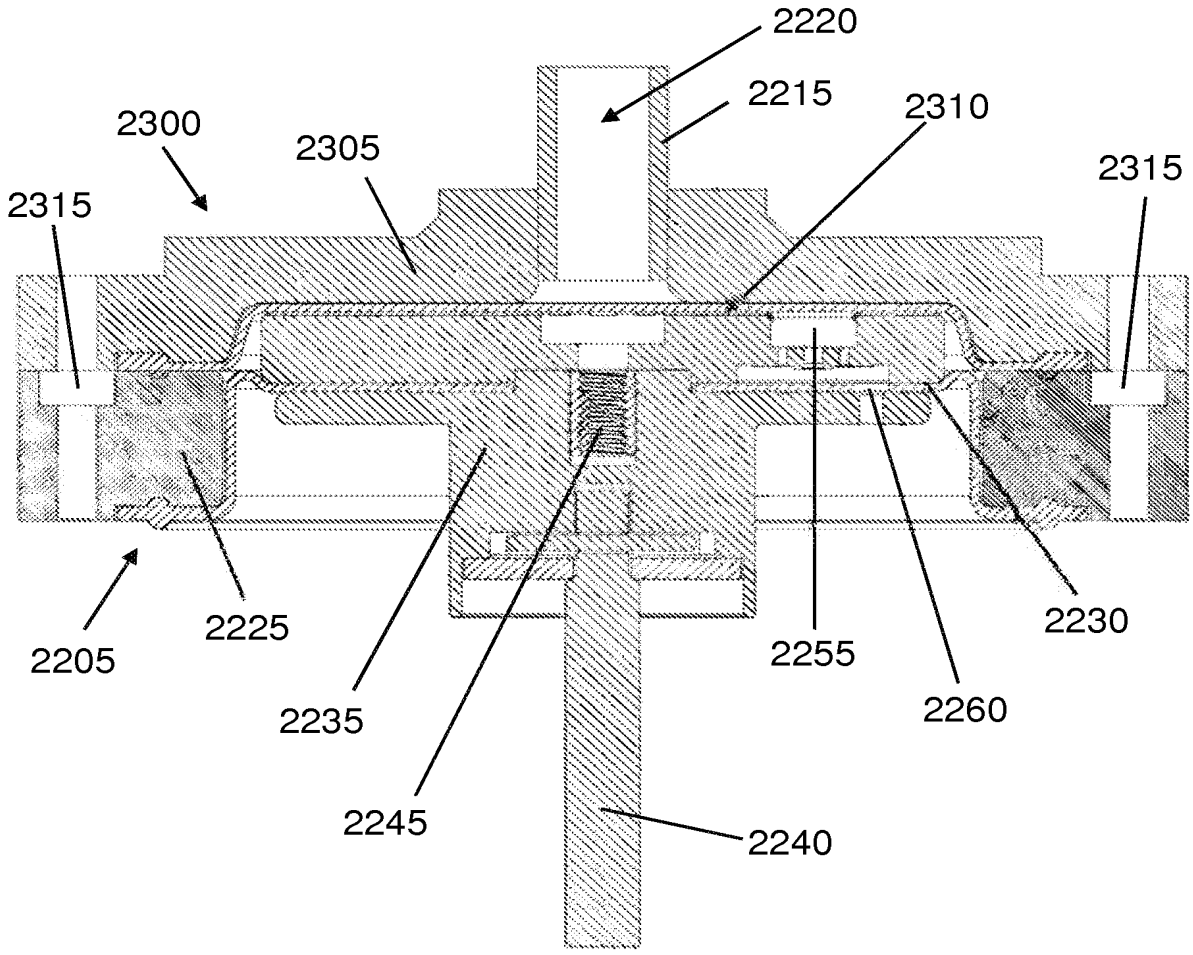


FIG. 22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2230
2260
2245
2240

FIG. 23

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/039453

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 1/06 (2015.01)
CPC - A61M 1/062 (2015.09)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61M 1/00, 1/06, 1/16 (2015.01)
CPC - A61M 1/0072, 1/062, 1/066 (2015.09)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 600/573; 604/73, 74
(keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Orbit, Google Patents, Google.
Search terms used: breast, milk, pleat, fold, crease, corrugate, bellows, membrane, diaphragh

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/0154348 A1 (LANTZ et al) 14 July 2005 (14.07.2005) entire document	1-4, 19-23
A	US 8,617,101 B2 (TACK) 31 December 2013 (31.12.2013) entire document	1-4, 19-23
A	US 2012/0004604 A1 (VAN DER KAMP et al) 05 January 2012 (05.01.2012) entire document	1-4, 19-23

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 September 2015	05 OCT 2015
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/039453

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 5-18, 24, 25
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 February 2016 (18.02.2016)

WIPO | PCT

(10) International Publication Number
WO 2016/025405 A1

(51) International Patent Classification:
A61M 1/06 (2006.01)

(21) International Application Number:
PCT/US2015/044521

(22) International Filing Date:
10 August 2015 (10.08.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/036,052 11 August 2014 (11.08.2014) US
62/060,264 6 October 2014 (06.10.2014) US

(72) Inventors; and
(71) Applicants : **BARRAL, Joelle K.** [FR/US]; 1623 Bonita Avenue, Mountain View, California 94040 (US). **CHANDRA, Venita** [US/US]; 400 Davey Glen Road, #4508, Belmont, California 94002 (US). **GARRETT, Mary K.** [US/US]; 424 Clinton Street, Redwood City, California 94062 (US). **HUDAK, Jessica A.** [US/US]; 529 S. Murphy Avenue, Sunnyvale, California 94086 (US). **NAYAK, Asha S.** [US/US]; 929 Exmoor Way, Sunnyvale, California 94087 (US). **PALMER, Erika T.** [US/US]; 335 Barton Place, Menlo Park, California 94025 (US). **RUGGLES, Sandra Waugh** [US/US]; 1542 Barton Drive, Sunnyvale, California 94087 (US). **TANG, Beverly T.** [US/US]; 827 Oregon Avenue, Palo Alto, California 94303 (US).

(74) Agents: **HUDAK, Jessica Anne** et al.; Hudak Consulting Group, LLC, 529 S. Murphy Avenue, Sunnyvale, California 94086 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) **Title**: SYNCHRONIZING BREAST PUMPING WITH INFANT FEEDING

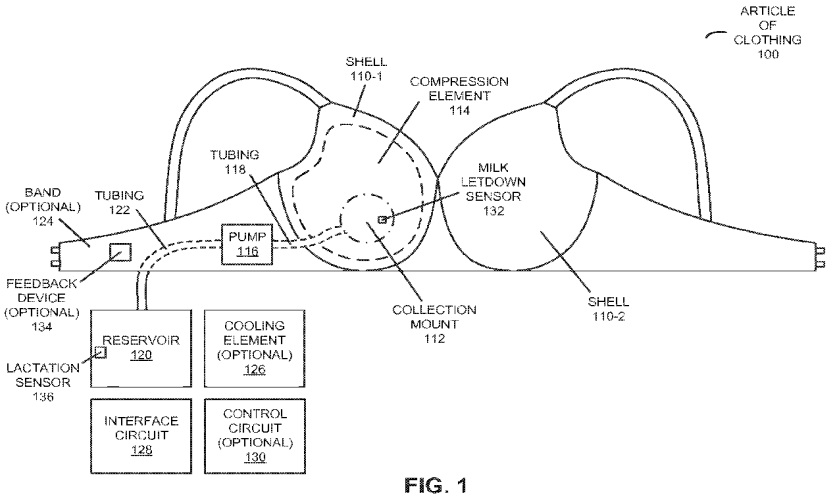

FIG. 1

(57) **Abstract**: A system for synchronizing one or more breast-pumping sessions of an individual (such as a mother) and milk consumption by a second individual (such as a baby or infant) is described. In particular, based on measurements of a volume of the collected milk as a function of time and received information specifying milk consumption by the second individual as a function of time, a control circuit may determine a need for milk. Then, the control circuit may provide feedback based on the determined need for milk that synchronizes the one or more breast-pumping sessions and the milk consumption. For example, the feedback may alert the individual to initiate a breast-pumping session and/or may provide a signal to a breast pump that initiates a breast-pumping session.

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SYNCHRONIZING BREAST PUMPING WITH INFANT FEEDING

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CROSS REFERENCE TO RELATED APPLICATION

[001] This application claims priority under 35 U.S.C. § 119(e) to: U.S. Provisional Application Ser. No. 62/036,052, entitled "Breast Pump," by Joelle K. Barral, Venita Chandra, Mary K. Garrett, Asha S. Nayak, Erika I. Palmer, Sandra Waugh Ruggles and Beverly T. Tang, filed on August 11, 2014; and to U.S. Provisional Application Ser. No. 62/060,264, entitled "Systems and Methods for Managing Breast Pumping," by Joelle K. Barral, Venita Chandra, Jessica A. Hudak, Erika I. Palmer, Sandra Waugh Ruggles and Beverly T. Tang, Attorney Docket No. 0004-700.101, filed on October 6, 2014, the contents of both of which are herein incorporated by reference.

BACKGROUND

Field

[002] The described embodiments relate to an article of clothing that includes a breast pump and techniques for using the breast pump, including synchronizing one or more breast-pumping sessions of a woman with milk consumption by a baby or an infant.

Related Art

[003] Studies indicate that breast milk provides important vitamins and nutrients for babies. However, sometimes direct breastfeeding is not an option or may not desirable.

[004] Breast pumps make it possible for a mother to extract breast milk for her infant(s). In addition, breast pumps can help a mother continue lactating at regular intervals so that she does not lose the ability to generate milk during times when she is away from her

infant or when a baby may not be nursing. For example, premature infants or babies born with defects may be put in a neonatal intensive care unit (*NICU*) at a hospital, and therefore may not be able to nurse for a time. In these cases, a breast pump not only keeps a mother lactating, but may allow a baby in a *NICU*, who is able, to receive breast milk.

[005] However, there are challenges associated with existing breast pumps. In particular, many breast pumps are noisy, and can require regular cleaning and maintenance, which are time-consuming and expensive. Moreover, collecting milk, transferring it to a clean container, and then finding a place to store the milk can be time-consuming and frustrating. In addition, these actions often require a lot of attention or focus, which can be difficult for a mother with a newborn baby. For example, a mother may need to hold a pump or manually pump a device to extract milk. Then, the mother may need to switch breasts and repeat these operations, all while holding and encouraging their child.

[006] Furthermore, existing breast pumps often do not cause sufficient milk letdown, such that mothers may have to wait several minutes or even hours for another milk letdown. This problem may be compounded by the uncertainty it causes, because a mother may not know when her body is going to be ready to produce milk again. In some instances, the mother may have to put away the breast pump only to subsequently have to get it out right away because her milk is coming. The whole process can, therefore, become time-consuming and frustrating.

[007] Hence, there is a need for an improved breast pump and a technique for using a breast pump.

SUMMARY

[008] One group of described embodiments includes an article of clothing. This article of clothing includes a collection mount having an inner surface that mechanically couples to an areola of a breast of an individual, where the collection mount has an opening from the inner surface to an outer surface of the collection mount that is defined by an edge. Moreover, the article of clothing includes a compression element that surrounds at least a portion of the breast, and a pump mechanically coupled to the collection mount by tubing embedded in the article of clothing. During operation, the compression element applies a type of compression pattern at a location on the breast to facilitate lactation. In addition, the pump, in conjunction with the compression element, collects milk. Furthermore, the article of clothing includes a reservoir mechanically coupled to the pump by second tubing embedded in the article of clothing, which stores the collected milk.

[009] For example, during operation the pump may apply a pressure less than atmospheric pressure to a cavity between the areola and the inner surface of the collection mount. In particular, the compression element and the pump may apply time-varying compression to the breast and time-varying suction on the areola to collect the milk. Because of the type of compression pattern concurrently applied by the compression element, a maximum magnitude of the pressure applied by the pump may be less than a pain threshold of the individual. Note that the maximum magnitude of the pressure applied by the pump may be selectable.

[010] In some embodiments, the article of clothing includes: a band that attaches around a circumference of a torso of the individual; and shells, having inner surfaces, which are mechanically coupled to the band. The shells may support breasts of the individual. Moreover, the collection mount and the compression element may be included within a cavity defined by an inner surface of one of the shells. Note that a portion of the tubing may be included in cavities in the one of the shells. Furthermore, the article of clothing may include a cooling element that, during operation, reduces a temperature of the cavities to a temperature below room temperature. Additionally, a stiffness of outer surfaces of the shells may be greater than a stiffness of the internal surfaces of the shells.

[011] Note that the type of compression pattern may include: a circular pattern, a spiral pattern, a rhythmic pattern, a random pattern, a programmable pattern, and/or a localized pattern. Moreover, the type of compression pattern and the location may be selectable.

[012] Furthermore, the compression element may include channels. During operation, the compression element may generate the type of compression pattern using a gas and/or a liquid in the channels. Alternatively or additionally, the compression element may include bearings, and during operation the compression element may generate the type of compression pattern using the bearings.

[013] In some embodiments, during operation, the cooling element reduces a temperature of the reservoir to a temperature below room temperature.

[014] Moreover, the article of clothing may include an interface circuit, electrically coupled to the compression element and the pump, which communicates with an electronic device using wireless communication. During operation, the interface circuit may receive an activation command from the electronic device to turn on the compression element and the pump and/or may subsequently receive a deactivation command from the electronic device to turn off the compression element and the pump.

[015] Furthermore, the article of clothing may include a milk letdown sensor electrically coupled to the compression element and the pump. During operation, the milk letdown sensor may detect when the individual's milk has letdown, and may provide an activation signal to turn on the compression element and the pump. Alternatively or additionally, when the milk letdown sensor detects that the individual's milk has letdown, the milk letdown sensor may provide feedback to the individual.

[016] In some embodiments, the article of clothing includes a feedback device. During operation of the compression element and the pump, the feedback device may provide, to the individual, encouragement and/or feedback about milk collection.

[017] Moreover, the article of clothing may include a lactation sensor. During operation of the compression element and the pump, the lactation sensor may measure: a milk flow rate, and/or a volume of collected milk.

[018] Another embodiment provides a method for collecting milk from the breast using the article of clothing. During operation of the article of clothing, the compression element may compress the location on the breast to facilitate lactation using the type of compression pattern. Moreover, the pump mechanically coupled by tubing to the collection mount may apply suction to the areola of the breast. Next, the reservoir collects the milk based on the compression and the suction.

[019] A second group of described embodiments includes a system. This system includes: a breast pump, a lactation sensor, an interface circuit that communicates with a consumption sensor associated with a bottle, and a control circuit. During operation, the breast pump collects milk from an individual during one or more breast-pumping sessions. Moreover, the lactation sensor measures a volume of the collected milk as a function of time. Furthermore, the interface circuit receives information specifying milk consumption by a second individual (such as a baby) as a function of time. Additionally, the control circuit determines a need for milk based on a temporal pattern of the volume of the collected milk and a temporal pattern of the milk consumption, and provides feedback based on the determined need for milk that synchronizes the one or more breast-pumping sessions and the milk consumption.

[020] Note that the feedback may alert the individual to initiate a breast-pumping session. Alternatively or additionally, the feedback may include a signal to the breast pump that initiates a breast-pumping session.

[021] Moreover, the system may include a sensor. During operation, the sensor may measure: a vital sign of the individual as a function of time, a biomarker of the individual as a function of time, and/or an activity pattern of the individual as a function of time.

Alternatively or additionally, the vital-sign measurements, a biomarker of the individual as a function of time, and/or the activity pattern may be received by the interface circuit. Then, the control circuit may determine the need for milk based on: a temporal pattern of the vital sign, a temporal pattern of the biomarker, and/or a temporal pattern of the activity pattern.

[022] Furthermore, the interface circuit may receive additional information specifying: a vital sign of the second individual as a function of time, a biomarker of the second individual as a function of time, and/or an activity pattern of the second individual as a function of time. Then, the control circuit may determine the need for milk based on: a temporal pattern of the vital sign of the second individual, a temporal pattern of the biomarker of the second individual, and/or a temporal pattern of the activity pattern of the second individual.

[023] In some embodiments, the control circuit determines the need for milk based on a day of the week (and, more generally, a timestamp).

[024] Note that the received information may specify: a temperature of milk in the bottle, and/or a time duration since the milk in the bottle was collected. The control circuit may determine the need for milk based on: the temperature of the milk in the bottle, and/or the time duration.

[025] Moreover, the system may include memory that stores a program module with instructions for determining the need for milk and providing the feedback, and the control circuit may include a processor. During operation, the processor may execute the program module.

[026] Furthermore, the determining may be based on a supervised-learning model that relates the need for milk, the temporal pattern of the volume of the collected milk, and the temporal pattern of the milk consumption.

[027] Note that the feedback may maximize an average volume of the milk collected during a given breast-pumping session.

[028] Additionally, the system may include a feedback device. During a given breast-pumping session, the feedback device may provide, to the individual, encouragement about milk collection.

[029] Another embodiment provides a computer-program product for use with the *A/V* hub. This computer-program product includes instructions for at least some of the operations performed by the system.

[030] Another embodiment provides a method for synchronizing the one or more breast-pumping sessions of the individual and milk consumption by the second individual. This method includes at least some of the operations performed by the system.

[031] This Summary is provided merely for purposes of illustrating some exemplary embodiments, so as to provide a basic understanding of some aspects of the subject matter described herein. Accordingly, it will be appreciated that the above-described features are merely examples and should not be construed to narrow the scope or spirit of the subject matter described herein in any way. Other features, aspects, and advantages of the subject matter described herein will become apparent from the following Detailed Description, Figures, and Claims.

BRIEF DESCRIPTION OF THE FIGURES

[032] FIG. 1 is a block diagram illustrating an article of clothing in accordance with an embodiment of the present disclosure.

[033] FIG. 2 is a drawing illustrating a side view of a breast and a collection mount in accordance with an embodiment of the present disclosure.

[034] FIG. 3 is a block diagram illustrating a compression element for use in the article of clothing of FIG. 1 in accordance with an embodiment of the present disclosure.

[035] FIG. 4 is a drawing illustrating a front view of a breast and the compression element of FIG. 3 in accordance with an embodiment of the present disclosure.

[036] FIG. 5 is a flow diagram illustrating a method for collecting milk from a breast using an article of clothing in accordance with an embodiment of the present disclosure.

[037] FIG. 6 is a block diagram illustrating a system in accordance with an embodiment of the present disclosure.

[038] FIG. 7 is a block diagram illustrating a bottle with a consumption sensor in accordance with an embodiment of the present disclosure.

[039] FIG. 8 is a block diagram illustrating a user interface in an electronic device in the system of FIG. 6 in accordance with an embodiment of the present disclosure.

[040] FIG. 9 is a block diagram illustrating a user interface in an electronic device in the system of FIG. 6 in accordance with an embodiment of the present disclosure.

[041] FIG. 10 is a flow diagram illustrating a method for synchronizing one or more breast-pumping sessions of an individual and milk consumption by a second individual in accordance with an embodiment of the present disclosure.

[042] FIG. 11 is a block diagram illustrating an electronic device in accordance with an embodiment of the present disclosure.

[043] Note that like reference numerals refer to corresponding parts throughout the drawings. Moreover, multiple instances of the same part are designated by a common prefix separated from an instance number by a dash.

DETAILED DESCRIPTION

[044] One group of embodiments provides an article of clothing with an embedded breast pump. This breast pump combines a type of compression pattern at a location on a woman's breast with suction or vacuum to the areola or a region proximate to the nipple provided by a pump to collect milk. For example, the compression element may apply time-varying compression to the breast and the pump may provide time-varying suction on the areola to collect the milk. However, because the type of compression pattern is concurrently applied with the suction, the pressure applied by the pump may be reduced. In addition, to making mechanical breast feeding more comfortable, the pump may be smaller and less noisy. In conjunction with embedding the breast pump in the article of clothing, these features may allow women to collect milk discretely and at a time and place that is convenient for them (such as while at work).

[045] A second group of embodiments provides a system for synchronizing one or more breast-pumping sessions of an individual (such as a mother) and milk consumption by a second individual (such as a baby or infant). In particular, based on measurements of a volume of the collected milk as a function of time and received information specifying milk consumption by the second individual as a function of time, a control circuit may determine a need for milk. Then, the control circuit may provide feedback based on the determined need for milk that synchronizes the one or more breast-pumping sessions and the milk consumption. For example, the feedback may alert the individual to initiate a breast-pumping session and/or may provide a signal to a breast pump that initiates a breast-pumping session.

[046] By facilitating effective breast pumping, the article of clothing and the system may increase a mother's milk production. In addition, by making breast pumping easier and more discrete, the article of clothing and the system may reduce the time needed and the frustration associated with existing breast pumps, and may improve the user experience of the mother when using the breast pump. Consequently, the article of clothing and the system may encourage breast pumping, thereby allowing mothers to breast feed for a longer time, thereby providing health benefits for babies and infants.

[047] We now describe embodiments of the article of clothing. FIG. 1 presents a block diagram illustrating an article of clothing 100. This article of clothing includes a collection mount 112. As illustrated in FIG. 2, which presents a drawing illustrating a side view of a breast 200, collection mount 112 has an inner surface 210 that mechanically couples to (and makes a seal with) an areola of breast 200 of an individual (such as a mother and, more generally, a woman that is lactating), and collection mount 112 has an opening 212

from inner surface 210 to an outer surface 214 that is defined by an edge 216. For example, collection mount 112 may include: silicone, plastic and/or a composite material.

[048] Referring back to FIG. 1, article of clothing 100 includes a compression element 114 (which is described further below with reference to FIG. 3) that surrounds at least a portion of the breast, and a pump 116 mechanically coupled to collection mount 112 by tubing 118 embedded or included in article of clothing 100. Alternatively, pump 116 may be mechanically coupled to collection mount 112 without using tubing.

[049] During operation, compression element 114 applies a type of compression pattern at one or more locations on the breast to facilitate lactation. In addition, pump 116, in conjunction with compression element 114, collects milk. In particular, the milk may be collected and stored in reservoir 120 in article of clothing 100, which is mechanically coupled to pump 116 by tubing 122 that is included in or embedded in article of clothing 100.

[050] For example, during operation pump 116 may apply a pressure less than atmospheric pressure to a cavity 208 (defined by inner surface 210 and the individual's skin) between the areola and inner surface 210 of collection mount 112 via tubing 118 and opening 212. In particular, compression element 114 and pump 116 may apply time-varying compression to breast 200 (FIG. 2) and time-varying suction on the areola to collect the milk (such as a push-pull arrangement with alternating suction and massage). Because of the type of compression pattern concurrently applied by compression element 114, a maximum magnitude of the pressure applied by pump 116 may be less than that applied by pumps in existing breast pumps, such as a maximum magnitude of the pressure that is less than a pain threshold of the individual. (Thus, pump 116 may include: a roughing pump, an insulin pump, a portable pump, etc.) Furthermore, because of the type of compression pattern concurrently applied by compression element 114, a cyclic suction pattern applied by pump 116 may have a smaller fundamental frequency than that applied by pumps in existing breast pumps or may even be reduced to zero (*i.e.*, no cyclic component), thereby reducing the noise level and enhancing discretion during a pumping session. Note that the maximum magnitude of the pressure applied by pump 116 may be selectable by the individual via a knob or button in a physical control interface (which is sometimes referred to as an input/output or *I/O* interface). Alternatively, as described further below, the maximum magnitude of the pressure may be remotely selectable using an electronic device (such as a cellular telephone of the individual) via interface circuit 128. In some embodiments, during breast pumping, steady pressure and/or heat from a heating element (not shown) are applied to one or more locations on breast 200 (FIG. 2).

[051] Article of clothing 100 may include a wide variety of types of clothing, such

as a shirt, a jacket, a backpack, a vest, an undergarment (such as a corset, a brassiere or another breast-supporting article), etc. In some embodiments, article of clothing 100 includes: an optional band 124 that attaches around a circumference of a torso of the individual; and optional shells 110, which are mechanically coupled to optional band 124. These optional shells may support the breasts of the individual. Moreover, as shown in FIG. 2, collection mount 112 and compression element 114 may be included within a cavity 218 defined by an inner surface (such as inner surface 220-1) of at least one of optional shells 110 (such as optional shell 110-1). Note that a portion of tubing 122 may be included in cavity 218. In some embodiments, pump 116 is held in place by its own straps or another support material (such as body tape or another body adhesive).

[052] Furthermore, article of clothing 100 (FIG. 1) may include an optional cooling element 126 in FIG. 1 (such as a Peltier cooling device) that, during operation, reduces a temperature of cavities 208 and/or 218 to a temperature below room temperature (*i.e.*, that cools cavities 208 and/or 218). In some embodiments, during operation, optional cooling element 126 reduces a temperature of reservoir 120 (FIG. 1) to a temperature below room temperature (*i.e.*, that cools reservoir 120 in FIG. 1).

[053] Additionally, a stiffness of outer surfaces of optional shells 110 (such as outer surface 222-1) may be greater than a stiffness of the internal surfaces of optional shells 110 (such as inner surface 220-1). Thus, optional shells 110 may have a hard exterior (such as a hard plastic, a metal, a composite, etc.) that hides or masks mechanical motion associated with compression element 114 (and, more generally, the breast pumping) and the inner surface may be a softer material (such as a soft plastic, *e.g.*, a thermoplastic, silicone, a fabric, a foam, etc.). In some embodiments, optional shells 110 include breast-soothing elements, such as a gel pad. Alternatively, the outer surfaces of optional shells 110 may be made of a softer, conformable material (such as a thermoplastic or silicone) to mimic the outer shape of a natural breast, while the inner surface of optional shells 110 may be comprised of a hard cavity that holds the breasts in place and contains, hides, or masks the mechanical motion associated with compression element 114 (and, more generally, the breast pumping).

[054] As noted previously, article of clothing 100 may include an interface circuit 128, electrically coupled to compression element 114 and pump 116, which communicates with an electronic device (such as a cellular telephone of the individual) using wireless communication. During operation, interface circuit 128 may receive an activation command from the electronic device to turn on compression element 114 and/or pump 116. Subsequently, interface circuit 128 may receive a deactivation command from the electronic device to turn off compression element 114 and/or pump 116. A description of wireless

communication with article of clothing 100 (such as with optional electronic device 616) is described further below with reference to FIG. 6.

[055] Moreover, article of clothing 100 may include a milk letdown sensor 132 electrically coupled to compression element 114 and pump 116. During operation, milk letdown sensor 132 may detect when the individual's milk is ejected or has letdown, and may provide an activation signal to turn on compression element 114 and/or pump 116. (Similarly, when milk ejection or flow has stopped or dropped below a predefined threshold, milk letdown sensor 132 may subsequently provide a deactivation signal to turn off compression element 114 and/or pump 116.) For example, milk letdown sensor 132 may detect the presence of milk below the surface or proximate to the nipple of the breast, such as via an optical or an electrical or conductivity measurement. Alternatively or additionally, when milk letdown sensor 132 detects that the individual's milk has letdown, milk letdown sensor 132 may provide feedback to the individual. For example, article of clothing 100 may include an optional feedback device 134 that provides the feedback (such as a vibration motor, one or more speakers, etc.). In addition, during operation of compression element 114 and/or pump 116, optional feedback device 134 may provide, to the individual, encouragement and/or feedback about milk collection (such as how long the individual has been breast pumping and/or how much milk has been collected).

[056] Furthermore, article of clothing 100 may include a lactation sensor 136. During operation of compression element 114 and/or pump 116, lactation sensor 136 may measure: a milk flow rate, and/or a volume of collected milk (such as the volume in reservoir 120). For example, lactation sensor 136 may include: an optical sensor, a flow sensor, a level sensor, and/or a resistance sensor. Lactation sensor 136 may indicate that reservoir 120 is full and/or that the milk is due to be cooled and/or stored separately from article of clothing 100.

[057] In some embodiments, article of clothing 100 includes an optional control circuit 130 (such as a processor) that coordinates functions of article of clothing 100, such as conveying or providing: the activation command, the deactivation command, the activation signal, the deactivation command, the feedback, the encouragement, and/or communication via interface circuit 128 (such as measurements of the milk flow rate and/or the volume of collected milk).

[058] FIG. 3 presents a block diagram illustrating a compression element 114. This compression element may include channels 310 that, during operation, are used to generate the type of compression pattern. For example, compression element 114 may generate the type of compression pattern by selectively filling or emptying one or more of channels 310

using a gas and/or a liquid. Note that while radial channels 310 are shown in FIG. 3, in other embodiments different channel shapes and/or configurations are used. Moreover, note that compression element 114 may include a sleeve that can be wrapped around breast 200 (FIG. 2) to encompass a portion of breast 200 (FIG. 2), such as around a circumference of a portion of breast 200 (FIG. 2). Alternatively or additionally, compression element 114 may include bearings (such as ball bearings), and during operation compression element 114 may generate the type of compression pattern using the bearings.

[059] FIG. 4 presents a drawing illustrating a front view of breast 200 and compression element 114. By varying the compression at one or more locations on breast 200 as a function of time, compression element 114 may generate the type of compression pattern. Note that the type of compression pattern may include: a circular pattern around a circumference of breast 200, a spiral pattern around a circumference of breast 200 that moves from proximal to distal towards the areola, a rhythmic pattern (such as one that includes one or more fundamental frequencies), a random pattern (in terms of locations on breast 200, amplitude and/or frequencies), a massage pattern, a programmable pattern (which may be provided remotely via interface circuit 128 in FIG. 1 and/or which may be selected by the individual), and/or a localized pattern (such as a particular location on breast 200, such as proximate to the areola). Moreover, as noted previously, the type of compression pattern, an amplitude of the compression pattern and/or the location may be selectable by the individual.

[060] In an exemplary embodiment, reservoir 120 (FIG. 1) includes a disposable fabric reservoir or bag. Alternatively, another type of storage unit may be used, such as a bottle. Therefore, the reservoir may be used to deliver milk to a baby or an infant, thereby eliminating the need to transfer milk between a pumping container to a bottle or another delivery container. In some embodiments, a nipple and/or a lid is included or attached to the reservoir. The nipple and/or lid may be changed, thereby allowing the size to be changed and/or to adapt to the needs of the baby or the infant, such as if the baby is in the hospital.

[061] However, in other embodiments, the reservoir is fixed in the article of clothing. Moreover, the reservoir may include compartments, which may allow lids, nipples, cleaning tools, repair tools, paper towels, and other items to be safely housed together with the reservoir. Therefore, instead of one reservoir, there may be multiple reservoirs. For example, a 'popsicle holder' type of storage may be provided in which the milk is put into multiple reservoirs or containers. This approach may allow the milk to be given in smaller quantities, thereby preserving the remaining milk for a later time. In addition, multiple reservoirs may facilitate storage because it allows more flexibility in the amount of milk that remains with the individual and the quantity (and thus weight) of milk that gets stored

subsequent use. In some embodiments, the reservoir includes channels in the article of clothing. These channels may have different colors or labels that indicate a time when the milk was collected in a given channel and/or a temperature of the milk.

[062] Furthermore, the reservoir may have a wide variety of shapes, thereby allowing it to provide both function and fashion. For example, the reservoir may take on the form of a camelback vest that includes one or more small channels of a coolant interwoven with one or more channels of breast milk. In this way, the breast milk may be maintained at a relatively cool or constant temperature that is desired. Alternatively or additionally, a heat source may be used to achieve the desired temperature. Note that the channels may have a variety of shapes, such as oblong forms, cylinders or other forms. The channels may be removable, so that they can be cleaned and/or stored. This may also allow the article of clothing to be used for other purposes, such as hiking. Note that the coolant may include a liquid (such as water, oil or another liquid) and/or a gas with suitable thermodynamic properties. The pump element that is coupled to the reservoir may also provide a mechanism for 'self-cleaning' of the reservoir (such as a purge or steam-clean) to obviate the need for separate cleaning of the reservoir.

[063] While the preceding embodiments illustrated the article of clothing including the reservoir, in some embodiments off-body storage is used, such as: in a purse, a backpack, a fanny pack, high tops, thigh bag, an arm band, and/or a hat.

[064] In addition to detecting milk letdown, or measuring the milk flow rate or the volume of milk collected, the article of clothing may include a sensor that measures (or may receive information that specifies): the time elapsed since milk was last collected, breast temperature, another parameter related to the breast, etc. Note that the sensors in the article of clothing may be at one or more locations, *i.e.*, the sensors may be localized or distributed, within the article of clothing (such as on its associated components) and/or on the individual's body (on the breast or another area, such as the stomach, neck, arms, back, flank, etc.).

[065] Optional feedback device 134 (FIG. 1) may allow automated reminders to be provided to the individual, such as a reminder after a time interval since a last breast-pumping session has occurred. Reminders may be provided in a variety of forms, such as a physiological signal (such as a noise, a vibration, an audible message, etc.), and/or a message communicated to the electronic device (such as an email, a text, a phone alert, etc.).

[066] In some embodiments, the article of clothing includes passive and/or active components that reduce or mask the sound associated with operation of the article of clothing. For example, the article of clothing may include acoustic insulation (such as sound-

proof foam) and/or muffler. However, in other embodiments these components are external to the article of clothing. Moreover, active sound cancellation or sound masking may be used, such as a white-noise generator and a speaker.

[067] In order to encourage milk production and milk letdown, in some embodiments the article of clothing mechanically (such as by massaging or providing pressure to the nipple or a pressure point *e.g.*, GB21, or providing a small amount of fluid to the nipple), electrically and/or chemically stimulates a portion of the breast (such as the nipple). For example, a hormone or another stimulant may be provided that encourages milk letdown.

[068] Although article of clothing 100 in FIG. 1 is shown as including pump 116, in other embodiments pump 116 is separate from article of clothing 100. For example, pump 116 is remotely located, such as in a separate room. A pump case may be personalized to make it unique to the individual. For example, the pump case may include an electronic image or a photograph of a baby or an infant. This may provide a visual stimulus that helps promote breast-milk production. Furthermore, instead of using one pump, in alternating fashion, between breasts, there may two pumps (one for each breast). However, in some embodiments, a single pump may be used, and the breasts may be pumped sequentially. This configuration may provide a smaller form factor with reduced power consumption and noise.

[069] In some embodiments, a cleaning tool is provided with pump 116 (FIG. 1). For example, the cleaning tool may include a cleaning element attached to a heating device that steam cleans the pump and the associated tubing. Moreover, pump 116 may be plugged into the cleaning tool in order to be cleaned
and sterilized. This approach may eliminate the need for a user (such as the individual) to remove and reassemble components, or to scrub and dry the components. However, in some embodiments components in the article of clothing reduce or eliminate the need for cleaning. For example, a hard plastic (such as a thermoset plastic) and/or silver-coated materials may be used.

[070] We now describe a method for using the article of clothing. FIG. 5 presents a flow diagram illustrating a method 500 for collecting milk from a breast using an article of clothing, such as article of clothing 100 (FIG. 1). During operation of the article of clothing, a compression element may compress a location on the breast (operation 510) to facilitate lactation using a type of compression pattern. Moreover, a pump mechanically coupled by tubing to a collection mount in the article of clothing may apply suction to an areola of the breast (operation 512). Next, a reservoir in the article of clothing collects the milk (operation 514) based on the compression and the suction.

[071] In these ways, the article of clothing and the breast-pumping technique may allow a woman to breast pump when she wants to (such as at a time and place that is convenient, including while she is at work), and in an efficient and a discrete manner. Moreover, the article of clothing may reduce the woman's frustration and may improve her overall user experience while breast pumping. Consequently, the article of clothing may encourage breast pumping, with the commensurate health benefits for babies and infants.

[072] We now describe embodiments of the system, which may be used in conjunction with or separately from the article of clothing. FIG. 6 presents a block diagram illustrating a system 600. This system includes: a breast pump 612, lactation sensor 136, electronic device 610 that communicates with one or more electronic devices (such as optional consumption sensor 614 associated with optional bottle 700 in FIG. 7 and/or optional electronic device 616), and a control circuit 618. During operation, breast pump 612 collects milk from an individual during one or more breast-pumping sessions. Moreover, lactation sensor 136 measures a volume of the collected milk as a function of time. Furthermore, electronic device 610 receives information (*e.g.*, from optional consumption sensor 614 and/or optional electronic device 616) specifying milk consumption by a second individual (such as a baby or an infant) as a function of time. Additionally, control circuit 618 determines a need for milk based on a temporal pattern of the volume of the collected milk and a temporal pattern of the milk consumption, and provides feedback based on the determined need for milk that synchronizes the one or more breast-pumping sessions and the milk consumption.

[073] For example, the feedback may be provided using optional feedback device 134. Alternatively or additionally, as described further below with reference to FIGs. 8 and 9, the feedback may be provided to optional electronic device 616 (*e.g.*, for display on a user interface). Note that the feedback may alert the individual to initiate a breast-pumping session. (In addition, as noted previously, the feedback may provide encouragement to the individual while breast pumping, such as a summary of the amount of milk collected.) Alternatively or additionally, the feedback may include a signal to breast pump 612 that initiates a breast-pumping session without action by the individual (*e.g.*, automatically). In some embodiments, the individual can manually override a determination by control circuit 618 to initiate a breast-pumping session (*e.g.*, the individual may stop a breast-pumping session that occurs at an inopportune time, may reinitiate a previously stopped breast-pumping session, or may specify a predefined delay until starting a breast-pumping session).

[074] In some embodiments, control circuit 618 determines the need for milk based on one or more additional inputs. For example, system 600 may include an optional sensor

620. During operation, optional sensor 620 may measure: a vital sign of the individual as a function of time, a biomarker of the individual as a function of time, and/or an activity pattern of the individual as a function of time (such as a sleep pattern, an eating or dietary pattern, an exercise pattern, a sedentary pattern, etc.). For example, optional sensor 620 may measure: a pulse rate, a respiration rate, blood pressure, skin temperature, skin electrical conductivity, chemical analysis of a biological sample (such as sweat, saliva or blood), gene-expression analysis of a biological sample, ribonucleic-acid analysis of a biological sample and/or deoxyribonucleic-acid of a biological sample. The optional sensor may measure a wide variety of biomarkers, such as: an electroencephalogram signal, an electromyography signal, one or more electrolytes (*e.g.*, sodium, chloride, potassium, and/or calcium), one or more metabolites (*e.g.*, lactate, creatinine, glucose, and/or uric acid), and/or one or more small molecules (*e.g.*, an amino acid, a steroid or a hormone, cortisol, a protein, an interleukin, and/or a neuropeptides). Alternatively or additionally, the vital-sign measurements, the biomarker and/or the activity pattern may be received by electronic device 610. Similarly, electronic device 610 may receive additional information specifying: a vital sign of the second individual as a function of time, a biomarker of the second individual as a function of time, and/or an activity pattern of the second individual as a function of time. Then, control circuit 618 may determine the need for milk based on: a temporal pattern of the vital sign of the individual, a temporal pattern of the biomarker of the individual, a temporal pattern of the activity pattern of the individual, a temporal pattern of the vital sign of the second individual, a temporal pattern of the biomarker of the second individual, and/or a temporal pattern of the activity pattern of the second individual.

[075] Moreover, control circuit 618 may determine the need for milk based on a day of the week (and, more generally, a timestamp). For example, a woman's lactation may be different on the weekend than during the workweek. Furthermore, the information received by electronic device 610 may specify: a temperature of milk in optional bottle 700 (FIG. 7), and/or a time duration since the milk in optional bottle 700 (FIG. 7) was collected (which may indicate whether the milk is still usable). Control circuit 618 may, therefore, determine the need for milk based on: the temperature of the milk in optional bottle 700 (FIG. 7), and/or the time duration.

[076] Note that control circuit 618 may determine the need for milk using a supervised-learning model that relates the need for milk with one or more of the preceding inputs. For example, the supervised-learning model, which may be developed using a wide variety of supervised-learning techniques, may include: a neural network, LASSO (a regularized linear regression technique like ridge regression, but with L_1-norm regularization

of the coefficients), a decision tree (such as classification and regression trees, with or without gradient boosting), a support vector machine, a model developed using Bayesian statistical analysis, least-squares regression, logistic regression, a non-parametric multivariate analysis technique, etc. Moreover, the supervised-learning technique may include a linear or a non-linear kernel. In some embodiments, the supervised-learning model is determined using data from one or more other individuals, such as by using collaborative filtering.

[077] In addition to initiating a breast-feeding session when a need for milk is determined, control circuit 188 may initiate a breast-pumping session: after a predefined time interval since a previous breast-feeding session (such as one hour, two hours, three hours, etc.), according to a predefined schedule, according to user preferences (such as different time intervals during the day or at night, or for different days of the week) and/or randomly after a minimum time interval (such as one hour) since a previous breast-feeding session. For example, the predefined schedule may systematically increase the time interval between breast-pumping sessions, such as when an infant is being weaned off of breast milk.

[078] While preceding embodiments illustrated automated collection of data using sensors or receiving information from one or more electronic devices, in other embodiments at least some of the data used by control circuit 618 is entered manually using a user interface (such as a keyboard, a user-interface device, a user interface displayed on a touch-sensitive display, voice recognition, etc.). In some embodiments, at least some of the data used by control circuit 618 is automatically generated based on a time of a most-recent feeding and a predefined feeding schedule and/or predefined user feeding preferences (such as one or more time intervals between feedings).

[079] As noted previously, electronic device 610 and optional electronic device 616 may include radios that communicate packets or frames in accordance with one or more communication protocols, such as: an Institute of Electrical and Electronics Engineers (*IEEE*) 802.11 standard (which is sometimes referred to as 'Wi-Fi®,' from the Wi-Fi® Alliance of Austin, Texas), Bluetooth® (from the Bluetooth Special Interest Group of Kirkland, Washington), a cellular-telephone communication protocol, a near-field-communication standard or specification (from the NFC Forum of Wakefield, Massachusetts), and/or another type of wireless interface. For example, the cellular-telephone communication protocol may include or may be compatible with: a 2nd generation or mobile telecommunication technology, a 4rd generation of mobile telecommunications technology (such as a communication protocol that complies with the International Mobile Telecommunications-2000 specifications by the International Telecommunication Union of Geneva, Switzerland), a 4th generation of mobile telecommunications technology (such as a communication protocol

that complies with the International Mobile Telecommunications Advanced specification by the International Telecommunication Union of Geneva, Switzerland), and/or another cellular-telephone communication technique. In some embodiments, the communication protocol includes Long Term Evolution or *LTE*. However, a wide variety of communication protocols may be used. In addition, the communication may occur via a wide variety of frequency bands.

[080] As shown in FIG. 6, during operation electronic device 610 and optional electronic device 616 may wirelessly communicate while: transmitting advertising frames on wireless channels, detecting one another by scanning wireless channels, establishing connections (for example, by transmitting association requests), and/or transmitting and receiving packets or frames (which may include the association requests and/or additional information as payloads, such as commands, measurements, feedback, etc.).

[081] Moreover, as described further below with reference to FIG. 11, electronic device 610 and optional electronic device 616 may include subsystems, such as: a networking subsystem, a memory subsystem and a processor subsystem. In addition, electronic device 610 and optional electronic device 616 may include radios 622 in the networking subsystems (such as interface circuit 128 in FIG. 1). (Note that radios 622 may be instances of the same radio or may be different from each other.) More generally, electronic device 610 and optional electronic device 616 can include (or can be included within) any electronic devices with the networking subsystems that enable electronic device 610 and optional electronic device 616 to wirelessly communicate with each other. This wireless communication can comprise transmitting advertisements on wireless channels to enable electronic devices to make initial contact or detect each other, followed by exchanging subsequent data/management frames (such as association requests and responses) to establish a connection, configure security options (*e.g.*, Internet Protocol Security), transmit and receive packets or frames via the connection, etc.

[082] As can be seen in FIG. 1, wireless signals 624 (represented by a jagged line) are transmitted from radio 622-1 in optional electronic device 616. These wireless signals are received by electronic device 610. In particular, optional electronic device 616 may transmit packets. In turn, these packets may be received by a radio 622-2 in electronic device 610. This may allow optional electronic device 616 to communicate information to electronic device 610. While FIG. 1 illustrates optional electronic device 616 transmitting packets, note that optional electronic device 616 may also receive packets from electronic device 610.

[083] In the described embodiments, processing of a packet or frame in electronic device 610 includes: receiving wireless signals 624 with the packet or frame;

decoding/extracting the packet or frame from received wireless signals 624 to acquire the packet or frame; and processing the packet or frame to determine information contained in the packet or frame (such as the information or the additional information).

[084] Although we describe the network environment shown in FIG. 1 as an example, in alternative embodiments, different numbers or types of electronic devices may be present. For example, some embodiments comprise more or fewer electronic devices. As another example, in another embodiment, different electronic devices are transmitting and/or receiving packets or frames. While electronic device 610 and optional electronic device 616 are illustrated with a single instance of radios 622, in other embodiments electronic device 610 and optional electronic device 616 may include multiple radios.

[085] FIG. 7 presents a block diagram illustrating a bottle 700 with an optional consumption sensor 614. As noted previously, optional consumption sensor 614 may measure or determine absolute or relative milk consumption by the second individual, and may communicate this information to electronic device 610 (FIG. 6). For example, optional consumption sensor 614 may include: an accelerometer, a velocity sensor, a position sensor, an orientation sensor (such as a gyroscope), an optical sensor, a flow sensor, a level sensor, and/or a resistance sensor. In an exemplary embodiment, when bottle 700 is tipped back by at least 45°, optional consumption sensor 614 may indicate that the baby or infant is feeding, as well as a timestamp when the feeding started (and/or ended). Alternatively or additionally, removing bottle 700 from a refrigerator and/or heating bottle 700 may cause optional consumption sensor 614 to communicate that feeding is about to start.

[086] In some embodiments, the feedback is communicated to optional electronic device 616, and is then displayed on a user interface. This is shown in FIG. 8, which presents a block diagram illustrating a user interface 800 in optional electronic device 616 (FIG. 6). In particular, user interface 800 may include a woman's time-varying lactation cycle or pattern and a baby or infant's time-varying consumption cycle or pattern, along with an option to initiate a breast-pumping session by activating a virtual icon (*e.g.*, by touching a display screen within a strike area associated with the virtual icon). Alternatively or additionally, electronic device 616 (FIG. 6) may include a button or a knob that can be used to initiate a breast-pumping session. In general, information about the woman's lactation cycle and the baby or infant's consumption cycle may include: a graph, a table, a chart, summary statistics, etc.

[087] FIG. 9 presents a block diagram illustrating a user interface 900 in optional electronic device 616 (FIG. 6) that displays statistical information about collected milk, such as: temperature, amount or volume of milk (such as milk consumed, milk remaining, etc.),

how long the milk can be used for (or is expected to last) and a location where the milk is currently stored.

[088] Note that other information may be display to assist the individual. For example, the other information may include information about: a lactation consultant, a childcare provider, freezing suggestions, breast-pumping or breast-feeding education and/or a portal or link to a user community, a chat room or a social network. Furthermore, system 600 (FIG. 6) may use optional electronic device 616 (FIG. 6) to present advice to the individual based on what works best for them or other women, such as: positions, types of compression patterns, a likely or probable breast-pumping schedule (so the individual can plan their day), an estimate of the cost savings obtained by breast pumping (as opposed to buying an equivalent volume of formula), etc. Collectively, this information may provide encouragement and support to the individual.

[089] In an exemplary embodiment, the system includes sensors or uses sensor data that is received from other electronic devices for parameters such as: breast skin temperature, ambient temperature, pressure, humidity, position, etc. These measurements may be used in supervised or machine learning of the pumping technique. The system may learn and remember lessons from prior breast-pumping session and may cumulatively apply them to future sessions, so that the learning is 'across' and 'between' sessions, not just 'within' a session.

[090] The sensor data may include flow and/or volume sensing of expressed milk that occurs 'in-line' or 'at the level of the stream' as opposed to 'on-bottle.' This may allow the collected milk to be monitored even when the milk is collected in a non-rigid container as envisioned with a wearable device.

[091] In some embodiments, the reservoir is adaptable or a one-size fits all reservoir that can be used with any pump size. The reservoir may be wearable beyond pumping times, and may refrigerate milk while keeping the skin warm.

[092] The system may allow pumping automation to synchronization with the baby's feed times/durations (including knowing when the baby is feeding at a remote location) and is able to alert the mother (at a minimum) to pump or actually initiate pumping in synchronization with the baby's feedings. Thus, there may be one or more sensors on the baby or baby's bottle to synchronize with the pump via a network.

[093] Sound insulation or sound cancellation may be used with the breast pump so that it is less noisy.

[094] As noted previously, machine learning may be used with the sensor data, including determining what you want to sense, calculate, learn, and 'do' with the learning.

This may achieve faster let-down by monitoring a mother's breast (at pump) conditions (such as heat, humidity, temp, etc.) and also on her body (such as stress levels via wearables measuring heart rate, perspiration, activity, etc.) and/or provide stimulation (such as even music, messages, pictures via cellphone) to improve her mental state. In addition, the system may sense the response to off-the-shelf stimulation to determine what rate, rhythm, and intensity of suction intensifies let down and under what conditions.

[095] The system may incorporate breast massage with the wearable device and/or with machine learning. For example, the machine learning may determine the best massage pattern to optimize let down and shorten pump duration while increasing the milk extracted. Alternatively or additionally, pressure points, heat and/or vibration may be used to stimulate the breast.

[096] We now describe another method. FIG. 10 presents a flow diagram illustrating a method 1000 for synchronizing one or more breast-pumping sessions of an individual and milk consumption by a second individual, which may be performed using one or more electronic devices in a system, such as electronic device 610 in system 600 (FIG. 6). During operation, the system measures, using a lactation sensor, a volume of milk collected as a function of time (operation 1010) using a breast pump, where the breast pump collects the milk from the individual during the one or more breast-pumping sessions. For example, the measurements may be at discrete times or they may be performed continuously. Then, the system receives, from a consumption sensor associated with a bottle, information specifying the milk consumption as a function of time (operation 1012). Similarly, the milk consumption may be specified at discrete times or continuously. Moreover, the system determines a need for milk (operation 1014) based on a temporal pattern of the volume of the collected milk and a temporal pattern of the milk consumption. Next, the system provides feedback (operation 1016) based on the determined need for milk that synchronizes the one or more breast-pumping sessions and the milk consumption.

[097] In these ways, the system and the breast-pumping technique may allow women to breast pump in an efficient and effective manner. For example, by synchronizing supply and demand, and by taking into account temporal variations in a woman's milk production, the system may increase a mother's milk production. In particular, the system (such as the feedback provided during breast pumping) may maximize an average volume of the milk collected during a given breast-pumping session. Moreover, the system may reduce the woman's frustration and may improve her overall user experience while breast pumping. Consequently, the system may encourage breast pumping, with the commensurate health benefits for babies and infants.

[098] In some embodiments of methods 500 (FIG. 5) and/or 1000, there may be additional or fewer operations. Moreover, the order of the operations may be changed, and/or two or more operations may be combined into a single operation.

[099] We now describe embodiments of an electronic device. FIG. 11 presents a block diagram illustrating an electronic device 1100, such as one or more components in article of clothing 100 (FIG.1), electronic device 610 and/or optional electronic device 616. This electronic device includes processing subsystem 1110, memory subsystem 1112, and networking subsystem 1114. Processing subsystem 1110 includes one or more devices configured to perform computational operations. For example, processing subsystem 1110 can include one or more microprocessors, application-specific integrated circuits (*ASICs*), microcontrollers, programmable-logic devices, and/or one or more digital signal processors (*DSPs*). One or more of these components in processing subsystem are sometimes referred to as a 'control mechanism' or a 'control circuit' (such as control circuit 618 in FIG. 6).

[0100] Memory subsystem 1112 includes one or more devices for storing data and/or instructions for processing subsystem 1110 and networking subsystem 1114. For example, memory subsystem 1112 can include dynamic random access memory (*DRAM*), static random access memory (*SRAM*), and/or other types of memory. In some embodiments, instructions for processing subsystem 1110 in memory subsystem 1112 include: one or more program modules or sets of instructions (such as program module 1122 or operating system 1124), which may be executed by processing subsystem 1110. Note that the one or more computer programs may constitute a computer-program mechanism. Moreover, instructions in the various modules in memory subsystem 1112 may be implemented in: a high-level procedural language, an object-oriented programming language, and/or in an assembly or machine language. Furthermore, the programming language may be compiled or interpreted, *e.g.*, configurable or configured (which may be used interchangeably in this discussion), to be executed by processing subsystem 1110.

[0101] In addition, memory subsystem 1112 can include mechanisms for controlling access to the memory. In some embodiments, memory subsystem 1112 includes a memory hierarchy that comprises one or more caches coupled to a memory in electronic device 1100. In some of these embodiments, one or more of the caches is located in processing subsystem 1110.

[0102] In some embodiments, memory subsystem 1112 is coupled to one or more high-capacity mass-storage devices (not shown). For example, memory subsystem 1112 can be coupled to a magnetic or optical drive, a solid-state drive, or another type of mass-storage device. In these embodiments, memory subsystem 1112 can be used by electronic device

1100 as fast-access storage for often-used data, while the mass-storage device is used to store less frequently used data.

[0103] Networking subsystem 1114 includes one or more devices configured to couple to and communicate on a wired and/or wireless network (*i.e.*, to perform network operations), including: control logic 1116, interface circuit 1118 and associated antenna(s) 1120. (While FIG. 11 includes antenna(s) 1120, in some embodiments electronic device 1100 includes one or more nodes, such as node(s) 1108, *e.g.*, pads, which can be coupled to antenna(s) 1120. Thus, electronic device 1100 may or may not include antenna(s) 1120.) For example, networking subsystem 1114 can include a Bluetooth networking system, a cellular networking system (*e.g.*, a 3G/4G network such as *UMTS*, *LTE*, etc.), a universal serial bus (*USB*) networking system, an Institute of Electrical and Electronics Engineers (*IEEE*) 802.15 standard (such as ZigBee® from the ZigBee® Alliance of San Ramon, California), a networking system based on the standards described in *IEEE* 802.11 (*e.g.*, a Wi-Fi networking system), an Ethernet networking system, and/or another networking system. Note that the combination of interface circuit 1118 and at least one of antenna(s) 1120 may constitute a radio. In some embodiments, networking subsystem 1114 communicates with one or more electronic devices via a wired interface.

[0104] Networking subsystem 1114 includes processors, controllers, radios/antennas, sockets/plugs, and/or other devices used for coupling to, communicating on, and handling data and events for each supported networking system. Note that mechanisms used for coupling to, communicating on, and handling data and events on the network for each network system are sometimes collectively referred to as a 'network interface' for the network system. Moreover, in some embodiments a 'network' between the electronic devices does not yet exist. Therefore, electronic device 1100 may use the mechanisms in networking subsystem 1114 for performing simple wireless communication between the electronic devices, *e.g.*, transmitting advertising or beacon frames and/or scanning for advertising frames transmitted by other electronic devices as described previously.

[0105] Within electronic device 1100, processing subsystem 1110, memory subsystem 1112, and networking subsystem 1114 are coupled together using bus 1128. Bus 1128 may include an electrical, optical, and/or electro-optical connection that the subsystems can use to communicate commands and data among one another. Although only one bus 1128 is shown for clarity, different embodiments can include a different number or configuration of electrical, optical, and/or electro-optical connections among the subsystems.

[0106] In some embodiments, electronic device 1100 includes a display subsystem 1126 for displaying information on a display (such as the communication warning message),

which may include a display driver, an *I/O* controller and the display, such as a liquid-crystal display, a multi-touch touchscreen (which is sometimes referred to as a touch-sensitive display), etc.

[0107] Electronic device 1100 can be (or can be included in) any electronic device with at least one network interface. For example, electronic device 1100 can be (or can be included in): a desktop computer, a laptop computer, a subnotebook/netbook, a tablet computer, a smartphone, a cellular telephone, a smartwatch, a portable computing device, and/or another electronic device.

[0108] Although specific components are used to describe electronic device 1100, in alternative embodiments, different components and/or subsystems may be present in electronic device 1100. For example, electronic device 1100 may include one or more additional processing subsystems, memory subsystems, networking subsystems, display subsystems, one or more *I/O* interfaces and/or optional feedback subsystem 1130. Moreover, one or more of the subsystems may not be present in electronic device 1100. Furthermore, in some embodiments, electronic device 1100 may include one or more additional subsystems that are not shown in FIG. 11 (such as a power subsystem with a non-rechargeable or a rechargeable power source). Also, although separate subsystems are shown in FIG. 11, in some embodiments, some or all of a given subsystem or component can be integrated into one or more of the other subsystems or component(s) in electronic device 1100. For example, in some embodiments program module 1122 is included in operating system 1124. More generally, two or more components may be combined into a single component or a single electronic device.

[0109] Moreover, the circuits and components in electronic device 1100 may be implemented using any combination of analog and/or digital circuitry, including: bipolar, *PMOS* and/or *NMOS* gates or transistors. Furthermore, signals in these embodiments may include digital signals that have approximately discrete values and/or analog signals that have continuous values. Additionally, components and circuits may be single-ended or differential, and power supplies may be unipolar or bipolar.

[0110] An integrated circuit may implement some or all of the functionality of networking subsystem 1114, such as one or more radios. Moreover, the integrated circuit may include hardware and/or software mechanisms that are used for transmitting wireless signals from electronic device 1100 and receiving signals at electronic device 1100 from other electronic devices. Aside from the mechanisms herein described, radios are generally known in the art and hence are not described in detail. In general, networking subsystem 1114 and/or the integrated circuit can include any number of radios.

[0111] In some embodiments, networking subsystem 1114 and/or the integrated circuit include a configuration mechanism (such as one or more hardware and/or software mechanisms) that configures the radios to transmit and/or receive on a given channel (*e.g.*, a given carrier frequency). For example, in some embodiments, the configuration mechanism can be used to switch the radio from monitoring and/or transmitting on a given channel to monitoring and/or transmitting on a different channel. (Note that 'monitoring' as used herein comprises receiving signals from other electronic devices and possibly performing one or more processing operations on the received signals, *e.g.*, determining if the received signal comprises an advertising frame, etc.)

[0112] The described embodiments may be used in a variety of network interfaces. Furthermore, while some of the operations in the preceding embodiments were implemented in hardware or software, in general the operations in the preceding embodiments can be implemented in a wide variety of configurations and architectures. Therefore, some or all of the operations in the preceding embodiments may be performed in hardware, in software or both. For example, at least some of the operations in the breast-pumping technique may be implemented using program module 1122, operating system 1124 (such as drivers for interface circuit 1118) and/or in firmware in interface circuit 1118. Alternatively or additionally, at least some of the operations in the breast-pumping technique may be implemented in a physical layer, such as hardware in interface circuit 1118.

[0113] In the preceding description, we refer to 'some embodiments.' Note that 'some embodiments' describes a subset of all of the possible embodiments, but does not always specify the same subset of embodiments.

[0114] The foregoing description is intended to enable any person skilled in the art to make and use the disclosure, and is provided in the context of a particular application and its requirements. Moreover, the foregoing descriptions of embodiments of the present disclosure have been presented for purposes of illustration and description only. They are not intended to be exhaustive or to limit the present disclosure to the forms disclosed. Accordingly, many modifications and variations will be apparent to practitioners skilled in the art, and the general principles defined herein may be applied to other embodiments and applications without departing from the spirit and scope of the present disclosure. Additionally, the discussion of the preceding embodiments is not intended to limit the present disclosure. Thus, the present disclosure is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein.

What is Claimed is:

1. A system, comprising:

a breast pump that, during operation, collects milk from an individual during one or more breast-pumping sessions;

a lactation sensor that, during operation, measures a volume of the collected milk as a function of time;

an interface circuit that, during operation, communicates with a consumption sensor associated with a bottle, wherein the communication includes receiving information specifying milk consumption by a second individual as a function of time;

a control circuit, electrically coupled to the lactation sensor and the interface circuit, which, during operation, determines a need for milk based on a temporal pattern of the volume of the collected milk and a temporal pattern of the milk consumption, and provides feedback based on the determined need for milk that synchronizes the one or more breast-pumping sessions and the milk consumption.

2. The system of claim 1, wherein the feedback alerts the individual to initiate a breast-pumping session.

3. The system of claim 1, wherein the feedback includes a signal to the breast pump that initiates a breast-pumping session.

4. The system of claim 1, wherein the system further comprises a sensor, electrically coupled to the control circuit, which, during operation, measures one of: a vital sign of the individual as a function of time, a biomarker of the individual as a function of time, and an activity pattern of the individual as a function of time; and

wherein the control circuit determines the need for milk based on one of: a temporal pattern of the vital sign, a temporal pattern of the biomarker, and a temporal pattern of the activity pattern.

5. The system of claim 1, wherein, during operation, the interface circuit receives additional information specifying one of: a vital sign of the second individual as a function of time, a biomarker of the second individual as a function of time, and an activity pattern of the second individual as a function of time; and

wherein the control circuit determines the need for milk based on one of: a temporal pattern of the vital sign, a temporal pattern of the biomarker, and a temporal pattern of the activity pattern.

6. The system of claim 1, wherein the control circuit determines the need for milk based on a day of the week.

7. The system of claim 1, wherein the received information specifies one of: a temperature of milk in the bottle; and a time duration since the milk in the bottle was collected; and

wherein the control circuit determines the need for milk based on one of: the temperature of the milk in the bottle, and the time duration.

8. The system of claim 1, further comprising memory that stores a program module with instructions for determining the need for milk and providing the feedback; and

wherein control circuit includes a processor that, during operation, executes the program module.

9. The system of claim 1, wherein the determining is based on a supervised-learning model that relates the need for milk, the temporal pattern of the volume of the collected milk, and the temporal pattern of the milk consumption.

10. The system of claim 1, wherein the feedback maximizes an average volume of the milk collected during a given breast-pumping session.

11. The system of clothing of claim 1, further comprising a feedback device; and

wherein, during a given breast-pumping session, the feedback device provides to the individual encouragement about milk collection.

12. A computer-program product for use in conjunction with an electronic device, the computer-program product comprising a non-transitory computer-readable storage medium and a computer-program mechanism embedded therein to synchronize one or more breast-pumping sessions of an individual and milk consumption by a second individual, the computer-program mechanism including:

instructions for measuring, using a lactation sensor, a volume of milk collected as a function of time using a breast pump, wherein the breast pump collects the milk from the individual during the one or more breast-pumping sessions;

instructions for receiving, from a consumption sensor associated with a bottle, information specifying the milk consumption as a function of time;

instructions for determining a need for milk based on a temporal pattern of the volume of the collected milk and a temporal pattern of the milk consumption; and

instructions for providing feedback based on the determined need for milk that synchronizes the one or more breast-pumping sessions and the milk consumption.

13. The computer-program product of claim 12, wherein the feedback alerts the individual to initiate a breast-pumping session.

14. The computer-program product of claim 12, wherein the feedback includes a signal to the breast pump that initiates a breast-pumping session.

15. The computer-program product of claim 12, wherein the computer-program mechanism comprises instructions for measuring, using a sensor, one of: a vital sign of the individual as a function of time, a biomarker of the individual as a function of time, and an activity pattern of the individual as a function of time; and

wherein determining the need for milk is based on one of: a temporal pattern of the vital sign, a temporal pattern of the biomarker, and a temporal pattern of the activity pattern.

16. The computer-program product of claim 12, wherein the computer-program mechanism comprises instructions for receiving additional information specifying one of: a vital sign of the second individual as a function of time, a biomarker of the second individual as a function of time, and an activity pattern of the second individual as a function of time; and

wherein determining the need for milk is based on one of: a temporal pattern of the vital sign, a temporal pattern of the biomarker, and a temporal pattern of the activity pattern.

17. The computer-program product of claim 12, wherein determining the need for milk is based on a day of the week.

18. The computer-program product of claim 12, wherein the feedback maximizes an average volume of the milk collected during a given breast-pumping session.

19. The computer-program product of claim 12, wherein the computer-program mechanism comprises instructions for providing to the individual encouragement about the milk collection.

20. A method for synchronizing one or more breast-pumping sessions of an individual and milk consumption by a second individual, wherein the method comprises:

measuring, using a lactation sensor, a volume of milk collected as a function of time using a breast pump, wherein the breast pump collects the milk from the individual during the one or more breast-pumping sessions;

receiving, from a consumption sensor associated with a bottle, information specifying the milk consumption as a function of time;

determining a need for milk based on a temporal pattern of the volume of the collected milk and a temporal pattern of the milk consumption; and

providing feedback based on the determined need for milk that synchronizes the one or more breast-pumping sessions and the milk consumption.

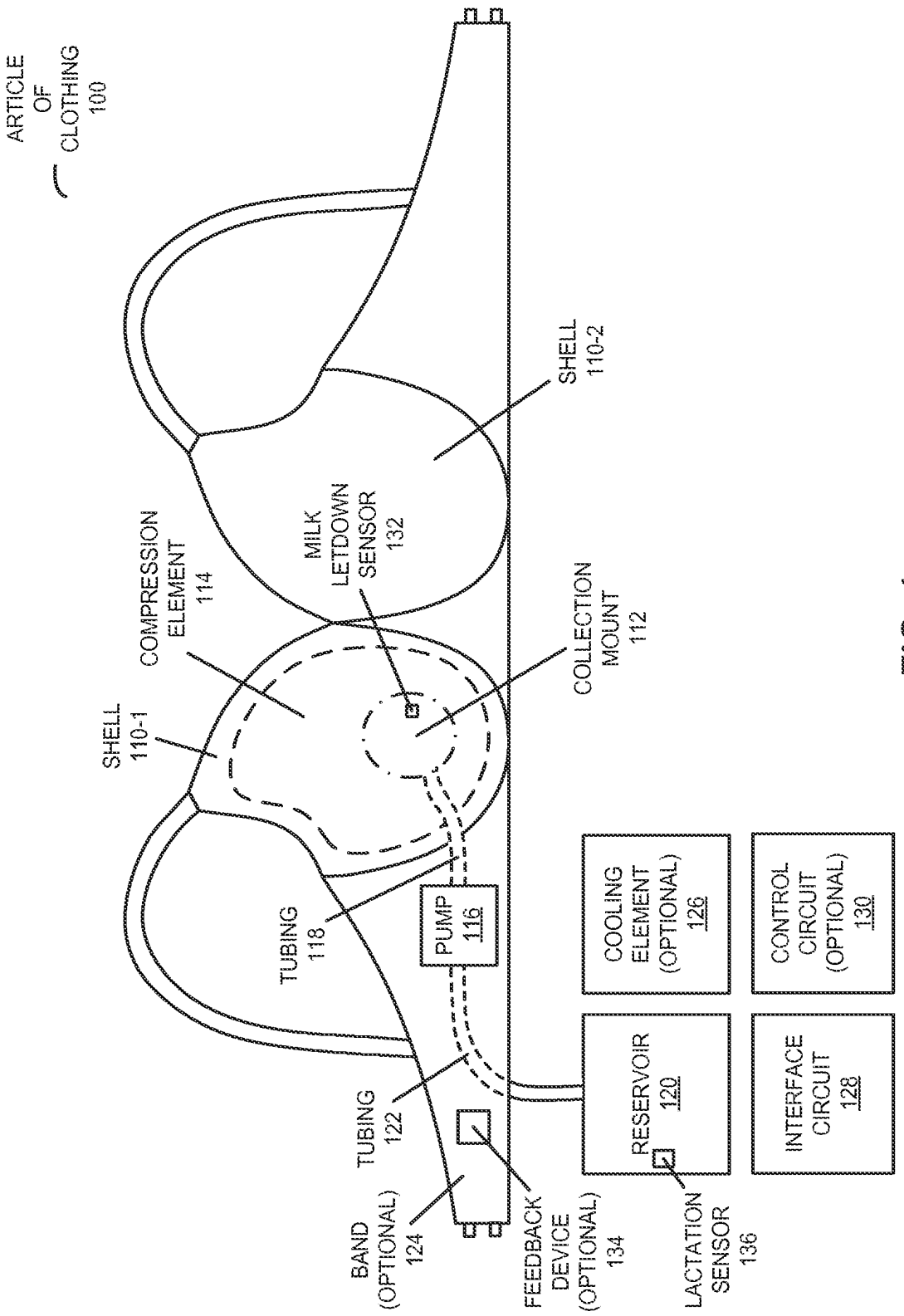
ARTICLE OF CLOTHING 100
SHELL 110-1
COMPRESSION ELEMENT 114
MILK LETDOWN SENSOR 132
SHELL 110-2
COLLECTION MOUNT 112
TUBING 118
PUMP 116
COOLING ELEMENT (OPTIONAL) 126
CONTROL CIRCUIT (OPTIONAL) 130
TUBING 122
RESERVOIR 120
INTERFACE CIRCUIT 128
BAND (OPTIONAL) 124
FEEDBACK DEVICE (OPTIONAL) 134
LACTATION SENSOR 136

FIG. 1

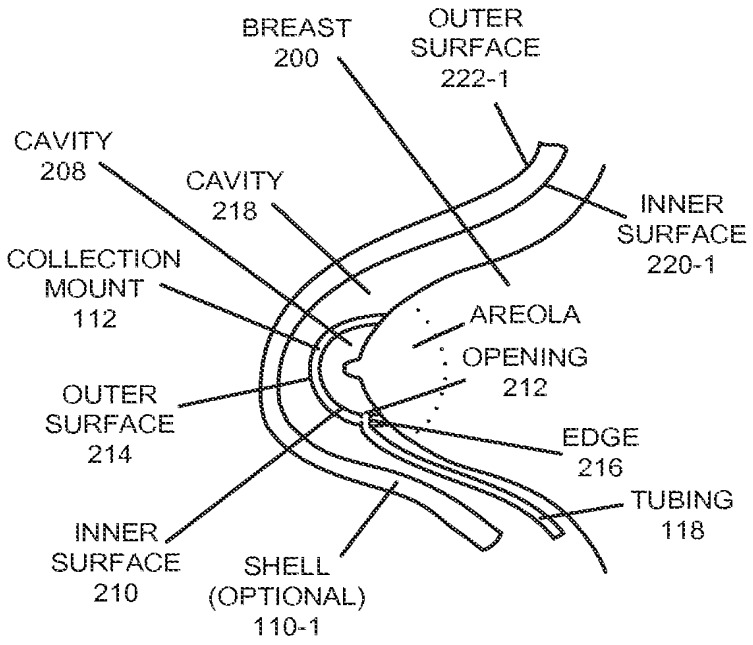
BREAST
200
OUTER
SURFACE
222-1
CAVITY
208
CAVITY
218
INNER
SURFACE
220-1
COLLECTION
MOUNT
112
AREOLA
OPENING
212
OUTER
SURFACE
214
EDGE
216
TUBING
118
INNER
SURFACE
210
SHELL
(OPTIONAL)
110-1

FIG. 2

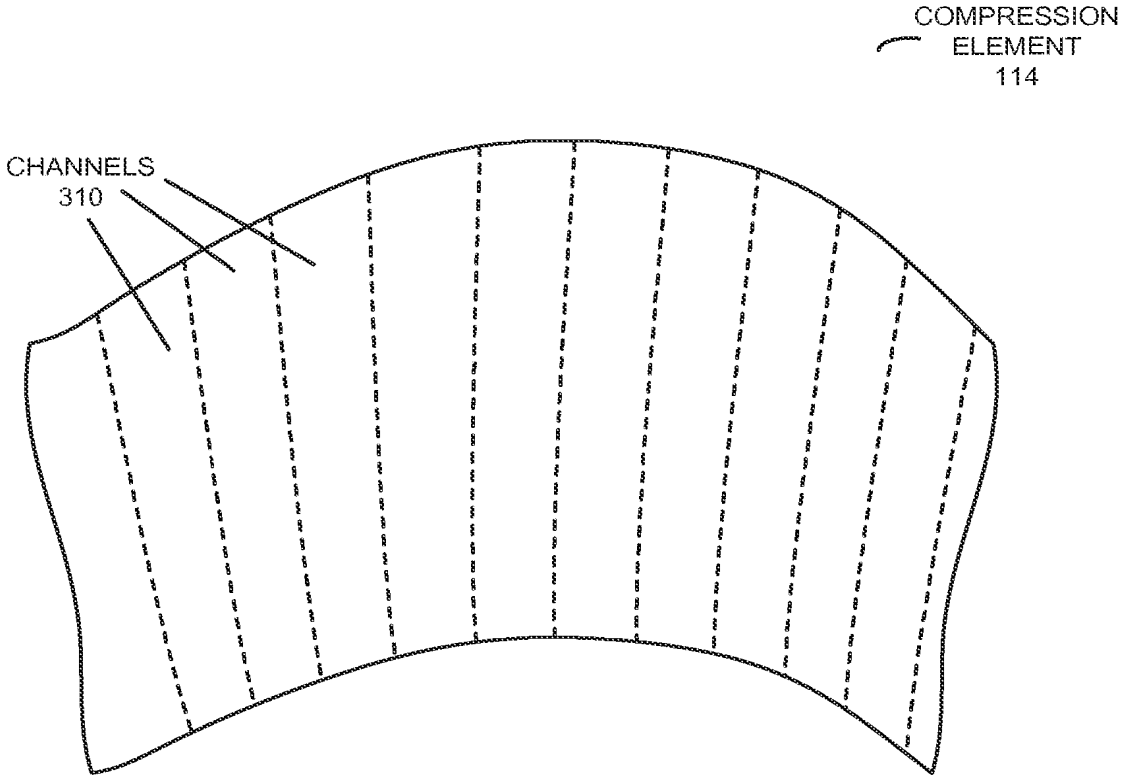

FIG. 3

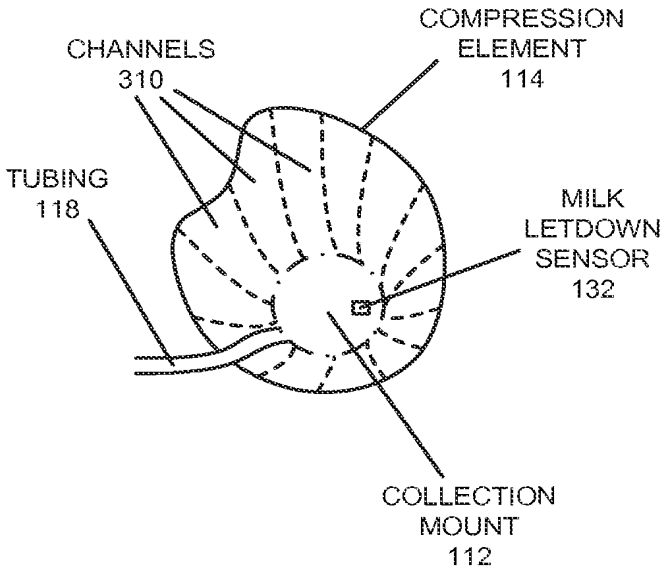
CHANNELS
310
COMPRESSION
ELEMENT
114
TUBING
118
MILK
LETDOWN
SENSOR
132
COLLECTION
MOUNT
112

FIG. 4

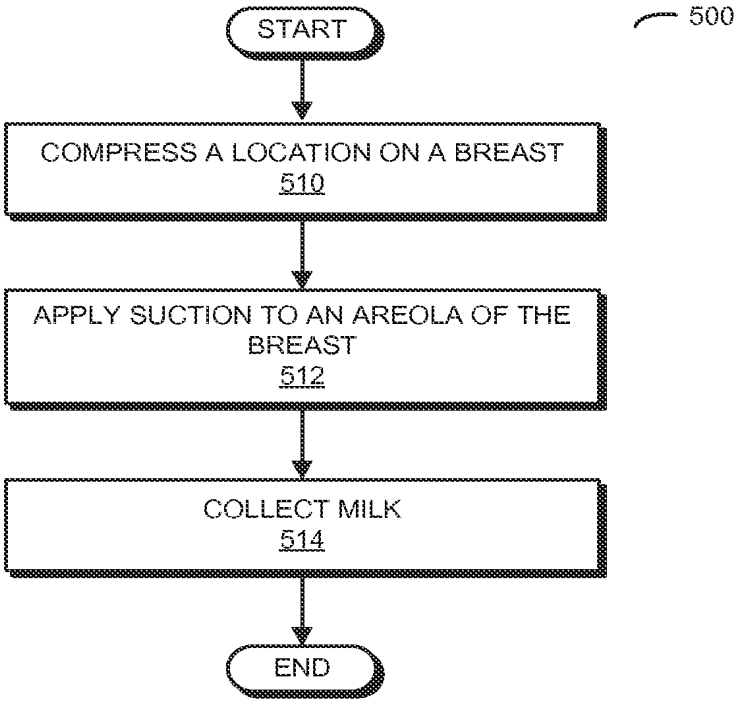
500
START
COMPRESS A LOCATION ON A BREAST
510
APPLY SUCTION TO AN AREOLA OF THE BREAST
512
COLLECT MILK
514
END

FIG. 5

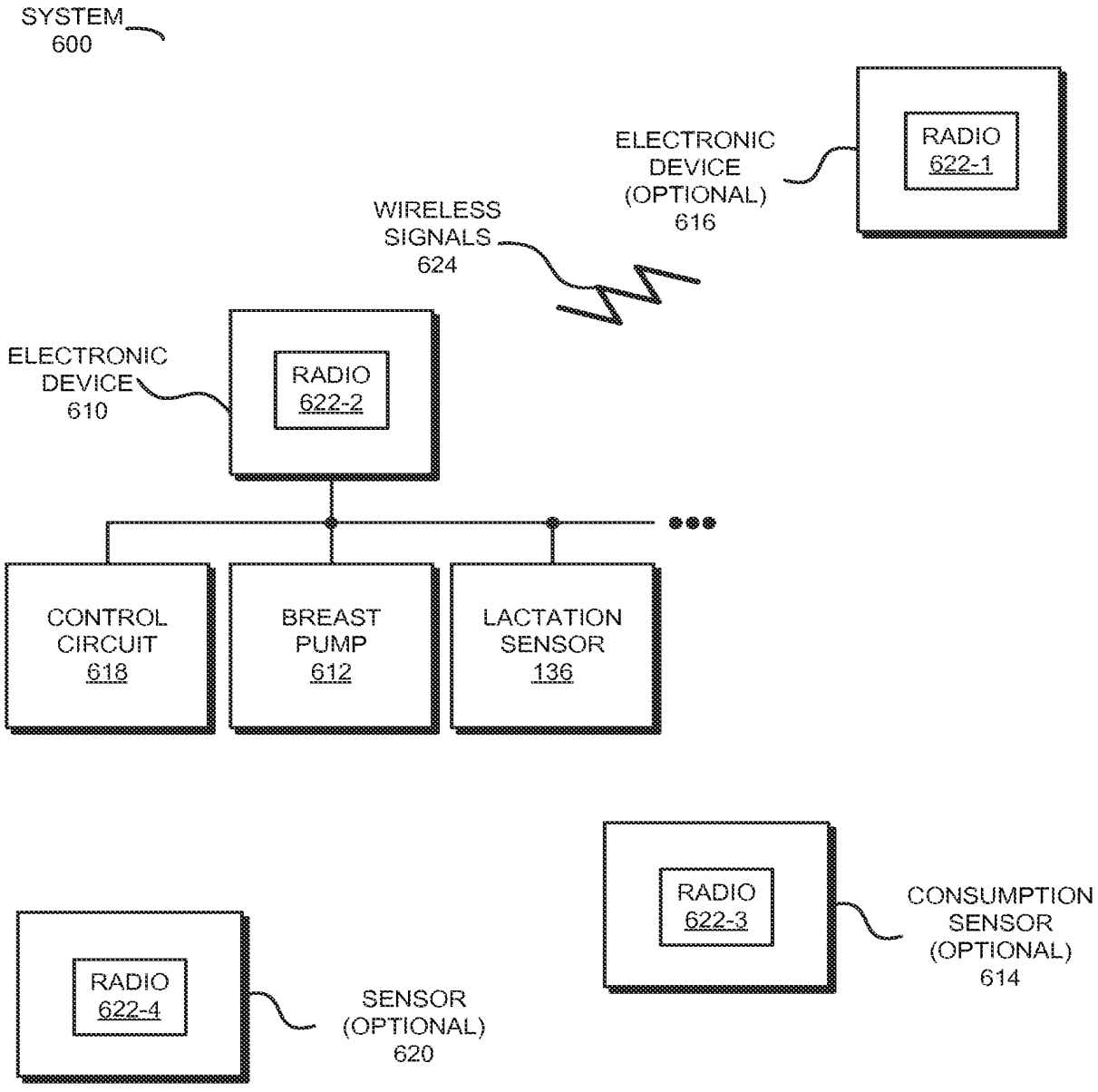
SYSTEM
600
ELECTRONIC
DEVICE
(OPTIONAL)
616
RADIO
622-1
WIRELESS
SIGNALS
624
ELECTRONIC
DEVICE
610
RADIO
622-2
CONTROL
CIRCUIT
618
BREAST
PUMP
612
LACTATION
SENSOR
136
RADIO
622-3
CONSUMPTION
SENSOR
(OPTIONAL)
614
RADIO
622-4
SENSOR
(OPTIONAL)
620

FIG. 6

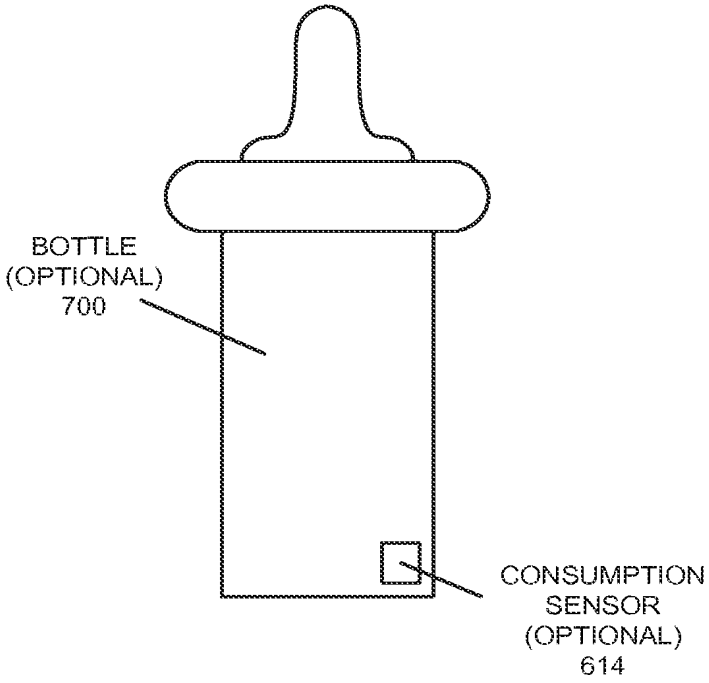

FIG. 7

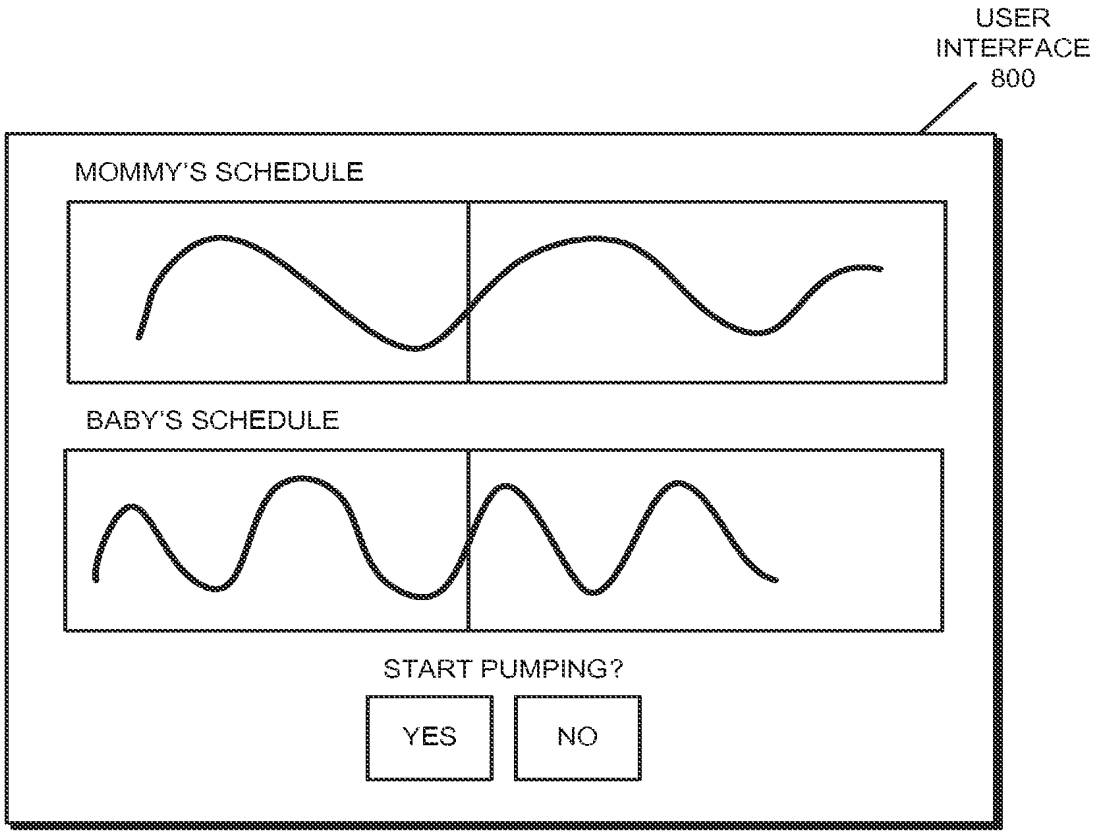
USER
INTERFACE
800
MOMMY'S SCHEDULE
BABY'S SCHEDULE
START PUMPING?
YES
NO

FIG. 8

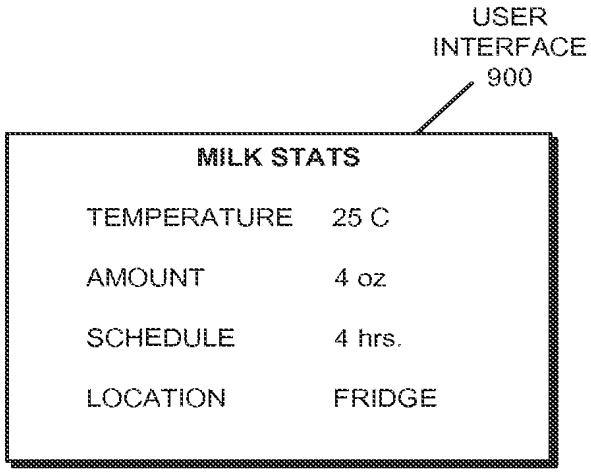
USER
INTERFACE
900
MILK STATS
TEMPERATURE 25 C
AMOUNT 4 oz
SCHEDULE 4 hrs.
LOCATION FRIDGE

FIG. 9

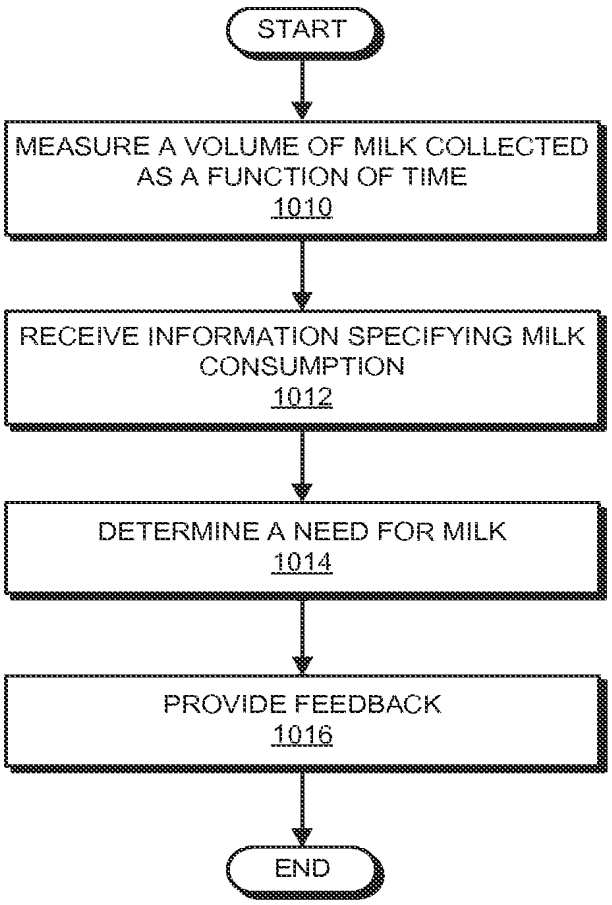
1000
START
MEASURE A VOLUME OF MILK COLLECTED AS A FUNCTION OF TIME
1010
RECEIVE INFORMATION SPECIFYING MILK CONSUMPTION
1012
DETERMINE A NEED FOR MILK
1014
PROVIDE FEEDBACK
1016
END

FIG. 10

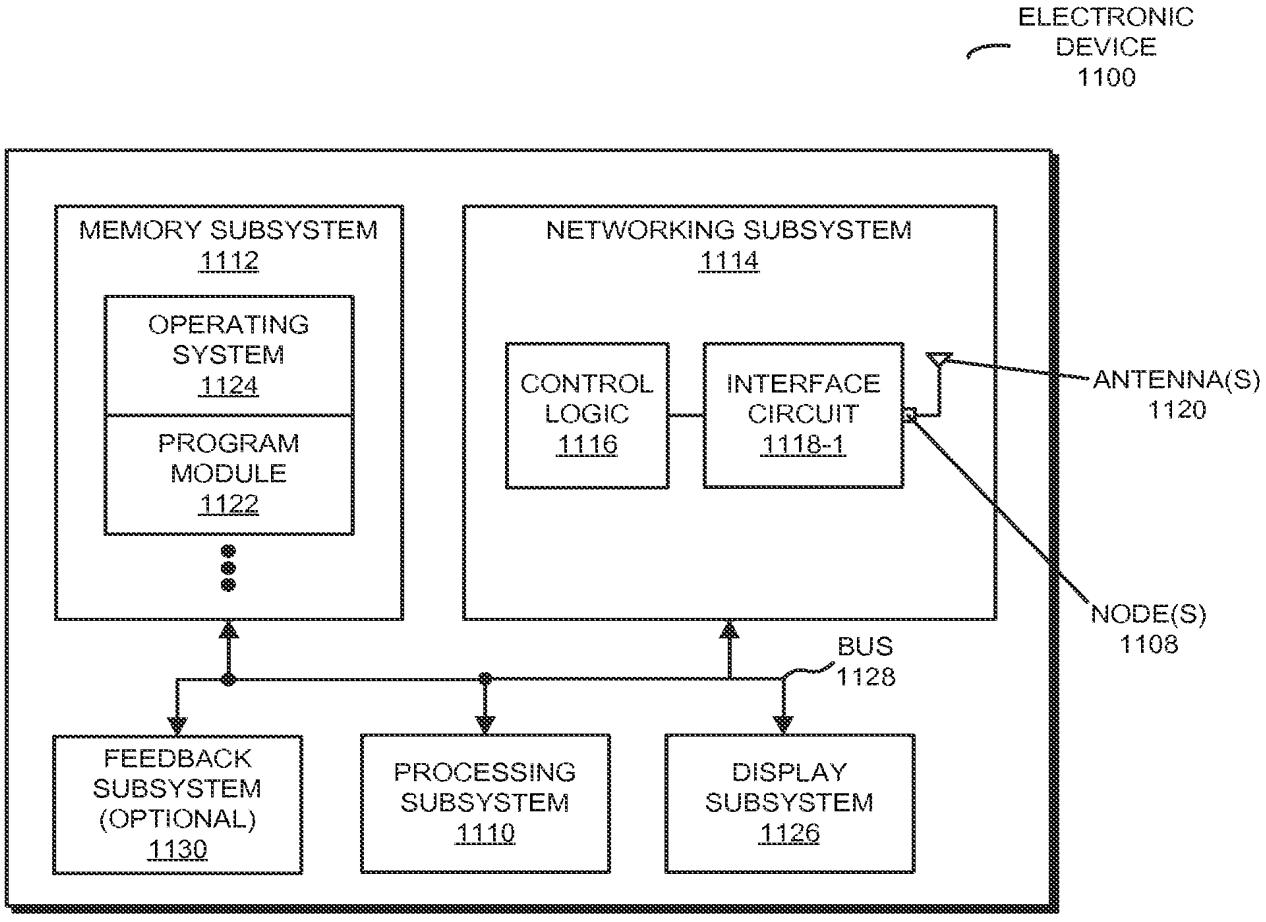
ELECTRONIC DEVICE 1100
MEMORY SUBSYSTEM 1112
OPERATING SYSTEM 1124
PROGRAM MODULE 1122
NETWORKING SUBSYSTEM 1114
CONTROL LOGIC 1116
INTERFACE CIRCUIT 1118-1
ANTENNA(S) 1120
NODE(S) 1108
BUS 1128
FEEDBACK SUBSYSTEM (OPTIONAL) 1130
PROCESSING SUBSYSTEM 1110
DISPLAY SUBSYSTEM 1126

FIG. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 15/44521

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 1/06 (2015.01)
CPC - A61M 1/06
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC (8) - A61M 1/06 (2015.01)
CPC - A61M 1/06

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61M 2001/064; A61M 2001/066 (See Keywords below)
USPC - 604/74, 235/375, 705/26.1, 705/26.2

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Thomsoninnovation.com; Patbase; Google Scholar; Google Patents; Gogole.com; Freepatentsonline; ProQuest Dialog
Search Terms: Breast pump, lactation, pattern, trend, consumption, volume, quantity, amount, collect, gather, activate, synchronize, need, requirement, temporal, time, session, milk, sensor, communicate, bottle, analysis, learn, etc.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2013/166462 A1 (GENADYNE BIOLTECHNOLOGIES), 07 November 2013 (07.11.2013), entire document, especially Abstract; page 1, ln 15-22; page 3, ln 7-18; page 13, ln 7 to page 14, ln 8	1-20
Y	WO 2013/187763 A1 (PATENTENTRANSFERIUM B.V.), 19 December 2013 (19.12.2013), entire document, especially Abstract; page 1, ln 10-20; page 8, ln 15-20; page 13, ln 25-35; page 14, ln 1-15	1-20
Y	US 2004/0186788 A1 (CZUCHRY, JR. et al.), 23 September 2004 (23.09.2004), entire document, especially Abstract; Para [0006], [0024], [0033]-[0036]	1-20
Y	US 2006/0278093 A1 (BIDERMAN et al.), 14 December 2006 (14.12.2006), entire document, especially Abstract; Para Para [0187]	5 and 16
A	US 2004/0122358 A1 (KENT et al.), 24 June 2004 (24.06.2004), entire document	1-20
A,P	US 2014/0263611 A1 (BAUER), 18 September 2014 (18.09.2014), entire document	1-20

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
09 October 2015 (09.10.2015)	23 NOV 2015
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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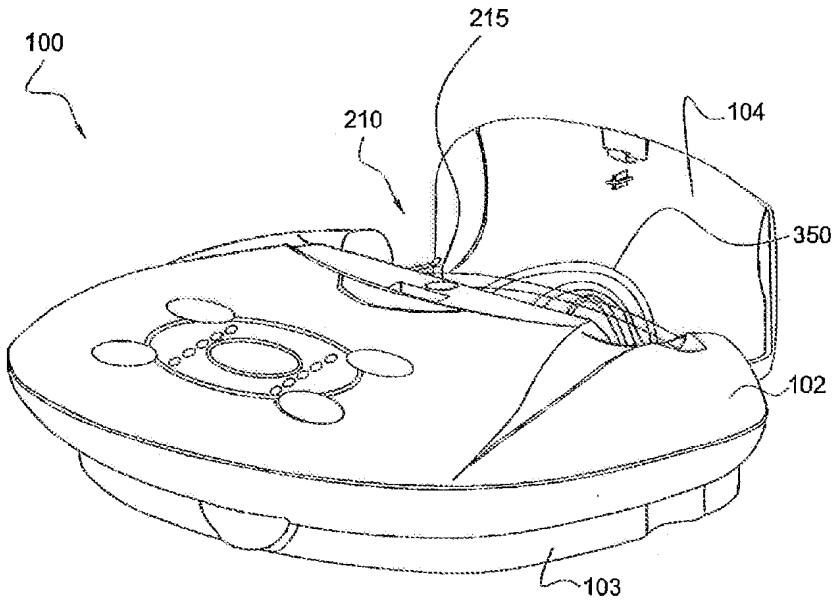
(74) Agent: **RUGGIERO, Charles, N., J.**; Ohlandt, Greeley, Ruggiero & Perle, LLP, One Landmark Square, 10th Floor, Stamford, CT 06901 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI,

[Continued on next page]

(54) Title: BREAST PUMP SYSTEM



(57) Abstract: A breast pump system for obtaining breast milk is provided. The system sealingly separates the air flow from the breast milk and uses a single air tube for both positive pressure and negative pressure to be applied to a woman's breast. The breast pump can have a piston/cylinder device for generating pressure that allows a user to control suction and cycle time.

WO 2004/108184 A2

SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

----- *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

BREAST PUMP SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to apparatus and methods for obtaining breast milk. More particularly, the present invention relates to a breast pump system that applies both a positive pressure and a negative pressure to a breast to express breast milk.

2. Description of the Related Art

Breast pump systems for obtaining breast milk, both manually and automatically, are known in the art. Conventional systems use a vacuum source to generate a negative pressure or vacuum that is transmitted through tubing to a breast hood or cup that is placed on the breast. This conventional device and method uses a negative pressure on the breast to express the breast milk. Such systems suffer from the drawback of applying only a vacuum source as negative pressure to the breast to induce the expression of breast milk.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a breast pump system for expressing milk that applies both a positive pressure and a negative pressure to a breast to express the milk.

It is another object of the present invention to provide such a system that supplies the positive and negative pressure from a single source.

It is still another object of the present invention to provide such a system that facilitates control of the positive and negative pressure applied to the breast.

These and other objects and advantages of the present invention are provided by a breast pump system having a pressure source for generating a positive pressure and a negative pressure, and a breast cup in fluid

communication with the pressure source, wherein the breast cup applies positive pressure and negative pressure to the breast.

The present invention also includes a breast pump system having a cylinder with a cylinder volume, a piston movably disposed in the cylinder, a motor operably connected to the piston to generate a pressure in the cylinder volume, and a breast cup in fluid communication with the cylinder volume, wherein the breast cup applies the pressure to the breast.

The present invention further includes a breast pump having a pressure source for generating a positive pressure and a negative pressure, and a controller operably connected to the pressure source, wherein the controller adjusts the positive and negative pressure and adjusts a cycle time between application of the positive and negative pressure to the breast.

The present invention additionally includes a breast pump having a pressure source for generating a pressure, and a controller operably connected to the pressure source, wherein the controller adjusts the pressure and adjusts a cycle time between application of the pressure to the breast. The controller also generates a wave signal in response to the pressure and the cycle time, and controls the pressure source in response to the wave signal.

The present invention includes a drive system for an expandable volume of a breast pump. The drive system has a motor having a first rotary output; a first gear system operably connected to the motor; and a second gear system operably connected to the first gear system and the expandable volume. The first gear system can have at least one belt. The second gear system has a rack gear and a pinion gear operably connected to the rack gear. The first gear system adjusts the rotary output provided to the second gear system to a second rotary output. The second gear system translates the second rotary output to a linear output.

The present invention includes a breast pump for supplying a pressure to a breast cup. The breast pump has an expandable volume in fluid

communication with the breast cup to supply the pressure; a motor having a first rotary output; a first gear system operably connected to the motor; and a second gear system operably connected to the first gear system and the expandable volume. The first gear system can have at least one belt. The second gear system has a rack gear and a pinion gear operably connected to the rack gear. The first gear system adjusts the rotary output provided to the second gear system to a second rotary output. The second gear system translates the second rotary output to a linear output.

The system can also have a channel and the breast cup can have an air orifice, wherein the channel is connected to the air orifice and the pressure source, and the pressure source supplies reciprocating air flow through the channel between the breast cup and the pressure source. The channel can be flexible tubing. The pressure source can be a piston movably disposed in a cylinder. There can be a motor, a rack having first teeth and a gear having second teeth. The rack is preferably connected to the piston, the gear is preferably operably connected to the motor, and the first teeth engage with the second teeth to reciprocally move the piston in the cylinder.

The piston can have a sealing member disposed between the piston and the cylinder. The sealing member can be an o-ring disposed on the piston. The piston can have a substantially cylindrical shape with a circumferential wall, and the sealing member can be a plurality of gaskets disposed on the circumferential wall. The piston can have a substantially cylindrical shape with a circumferential wall having a circumferential channel formed therein, and wherein the sealing member is at least partially disposed in the channel. The piston can have a v-shaped cross section with a leading edge and a trailing edge, and wherein the leading edge and the trailing edge form a sealing engagement with the cylinder.

The piston can be flexibly secured to the rack. The piston can have a recess and the rack can have a first end with an abutment formed therein, wherein the abutment is flexibly secured in the recess. The recess and the

first end can have detent structures. The cylinder can have a first diameter and an air hole, wherein the air hole has a second diameter and is in fluid communication with the atmosphere, and wherein the first diameter is significantly larger than the second diameter.

There can also be a controller operably connected to the motor, wherein the motor is reversible and the controller reverses the motor based upon a positive or negative pressure limit. There can be a controller operably connected to the motor, wherein the motor is a reversible motor, wherein the controller determines a distance that the piston has traveled relative to the cylinder and wherein the controller reverses the motor based upon the distance. There can be a photo-sensor that generates a signal in response to the distance, wherein the signal is transmitted to the controller, and wherein the controller reverses the motor in response to the signal.

The rack can have a plurality of openings formed therein, wherein the photo-sensor is operably aligned with the openings, and wherein the signal is generated based upon a count of the openings moving past the photo-sensor. There can also be a position switch, wherein the photo-sensor is operably aligned with the position switch to generate a position signal, wherein the position signal is transmitted to the controller, and wherein the controller resets the count in response to the position signal. There can be a controller operably connected to the motor, wherein the motor has variable speed, and the controller adjusts the speed based upon a desired cycle time for applying the positive or negative pressure to the breast. The controller can have a user interface, the desired cycle time can be inputted into the user interface, and the desired cycle time can be transmitted to the controller from the user interface.

There can be a controller having a user interface and operably connected to the pressure source, wherein the controller adjusts the positive or negative pressure generated by the pressure source in response to a signal transmitted from the user interface. There can also be a controller having a

user interface and operably connected to the pressure source, wherein the controller adjusts a cycle time for applying the positive or negative pressure to the breast in response to a signal transmitted to the controller from the user interface. There can be a controller that generates a wave signal in response to an amount of pressure and a cycle time between the positive and negative pressure, and controls the motor in response to the wave signal. There can be a user interface, wherein a desired wave signal is inputted into the user interface, the desired wave signal is transmitted to the controller from the user interface, and the controller adjusts the wave signal to correspond to the desired wave signal.

The cylinder can be in fluid communication with a pressure relief valve. The pressure relief valve can be adjustable. The pressure source can have a housing with a storage compartment formed therein, and wherein the flexible tubing is removably stored in the storage compartment. The housing can have an air outlet with a first end and a second end, wherein the first end is in fluid communication with the pressure source and the second end is disposed in the storage compartment.

There can be a t-connector having an inlet, a first outlet, a second outlet and a plug, wherein the inlet is in fluid communication with the first and second outlets, and wherein the plug is selectively sealingly engageable with the first outlet or the second outlet. The t-connector can have an outer surface and the plug is tethered to the outer surface. The controller can have a user interface, a desired level of the positive or negative pressure can be inputted into the user interface, and the controller can adjust the positive or negative pressure in response to a signal transmitted from the user interface.

The first gear system can have a first belt and a second belt. The first belt can be non-toothed and the second belt can be toothed. The first belt can be resilient. The first belt can be a plurality of belts. The first gear system can have a first pulley and a second pulley. The first pulley can have a first circumference and a first channel formed along the first circumference. The

second pulley can have a second circumference and a plurality of teeth formed along the second circumference. The first belt can be partially disposed in the first channel and the second belt can engages the plurality of teeth of the second pulley.

The motor can have a drive shaft with an annular channel formed therein. The first belt can be partially disposed in the annular channel. The second pulley can be secured to the pinion gear. The expandable volume can be a cylinder and a piston movable in the cylinder, with the rack gear secured to the piston. The rack gear can be flexibly secured to the piston. The cylinder can have a first diameter and an air hole. The air hole can have a second diameter and be in fluid communication with the atmosphere. The first diameter can be significantly larger than the second diameter.

BRIEF DESCRIPTION OF THE DRAWINGS

Other and further objects, advantages and features of the present invention will be understood by reference to the following:

Fig. 1 is a front perspective view of a breast pump of the breast pump system of the present invention;

Fig. 2 is a front perspective view of the breast pump of Fig. 1 in an opened position;

Fig. 3 is an exploded perspective view of the breast pump of Fig. 1;

Fig. 4 is a top view of the breast pump of Fig. 1 without the cover;

Fig. 5 is an exploded perspective view of a piston and cylinder of the present invention;

Fig. 6 is an exploded side view of a portion of the piston and cylinder of Fig. 5;

Fig. 7 is a front perspective view of the piston of Fig. 5;

Fig. 8 is an exploded perspective view of an alternative embodiment of the piston of the present invention;

Fig. 9 is an exploded perspective view of a pressure relief valve of the system of Fig. 1;

Fig. 10 is a cross-sectional plan view of the cylinder of Fig. 5;

Fig. 11 is a front perspective view of a breast cup of the present invention;

Fig. 12 is a side cross-sectional view of the breast cup of Fig. 11;

Fig. 13 is a rear perspective view of a T-connector of the present invention;

Fig. 14 is a flow chart depicting a method for pumping a breast according to the system of Figs. 1 and 11;

Fig. 15 is a top perspective view of a preferred embodiment of breast pump for the breast pump system of the present invention;

Fig. 16 is a top view of the breast pump of Fig. 15;

Fig. 17 is a top perspective view of the drive system of the breast pump of Fig. 15;

Fig. 18 is a side perspective view of the drive system of Fig. 17;

Fig. 19 is a top perspective view of a portion of the gear reduction system of the drive system of Fig. 15, partially assembled;

Fig. 20 is a top perspective view of an alternative embodiment of breast pump for the breast pump system of the present invention;

Fig. 21 is a top view of the breast pump of Fig. 20;

Fig. 22 is a top perspective view of the drive system of the breast pump of Fig. 20;

Fig. 23 is a side perspective view of the drive system of Fig. 20;

Fig. 24 is a top perspective view of the motor of the drive system of Fig. 20;

Fig. 25 is a top perspective view of a portion of the gear reduction system of the drive system of Fig. 20, partially assembled; and

Fig. 26 is a top perspective view of the gear reduction system of the drive system of Fig. 20, partially assembled.

DESCRIPTION OF THE INVENTION

Referring to the drawings and, in particular, Figs. 1 and 2, there is shown a breast pump of the present invention generally represented by reference numeral 100. Breast pump 100, along with breast cup 400 shown in Fig. 11, form the major components of the breast pump system of the present invention. Breast pump 100 has a top housing 102 and a bottom housing 103 that are adapted to form an assembled unit.

Referring to Figs. 1 through 3, top housing 102 has a substantially ellipsoidal shape with a flat front face 200 and a storage compartment 210 having a compartment door 104. Preferably, door 104 is hingedly connected to top housing 102 to form a selectively sealable storage compartment 210 for storing air tubing or conduit 350 that connects breast pump 100 to the other components of the system, which will be discussed later in greater detail.

Face 200 can receive a button pad 105 having an LED cover 106. Pad 105 is used by the consumer to control breast pump 100. Bottom housing 103 can securely house the various components of the breast pump, which include a rack gear 109, a pinion gear 110 that can engage the rack gear, a piston 112, a cylinder 113 that can receive the piston, and a motor 125 having a shaft 126 upon which the pinion gear is mounted. Due to this design, breast pump 100 provides pumping with low noise. Breast pump 100 can be made of any rigid material, such as, for example, plastic.

Referring to Figs. 3 through 7, breast pump 100 utilizes piston 112 and cylinder 113 to create both a positive pressure and a negative pressure for obtaining breast milk. Piston 112 is driven by rack gear 109, which is affixed thereto. Piston 112 has a substantially cylindrical-shape with a first head 3000 and a second head 3100. First and second heads 3000, 3100 preferably have annular channels 3020, 3120 formed therein, respectively. Channels 3020, 3120 are disposed along the outer circumference of first and second heads 3000, 3100, respectively. Preferably, channels 3020, 3120 are centrally located along the outer circumference of first head 3000 and second

head 3100. Seated in channels 3020, 3120 are sealing members 3050, 3150, respectively. Preferably, sealing members 3050, 3150 are o-ring gaskets. Sealing members 3050, 3150 have a diameter or width that is larger than the depth or height of channel 3020 and channel 3120. Sealing members 3050, 3150 extend beyond the outer circumference of first head 3000 and second head 3100 forming a sealing engagement with an inner surface 1130 of cylinder 113 as piston 112 is driven back and forth in the cylinder.

The use of multiple sealing members, i.e., o-ring gasket 3050 and o-ring gasket 3150 on piston 112, provide a double sealing to increase the efficiency of creating the positive pressure and negative pressure. While this embodiment uses two sealing members to create two separate sealing surfaces, any number of sealing members can be used to create any number of sealing surfaces for sealing piston 112 with cylinder 113. Additionally, while this embodiment uses piston 112 having o-ring sealing gaskets 3050, 3150, alternative sealing structures can be used between the piston and cylinder 113.

Rack gear 109 has teeth 1090 that engage with pinion gear 110 having teeth 1100. Pinion gear 110 is operatively connected to motor 125, preferably via shaft 126. When motor 125 is activated, shaft 126 and pinion gear 110 rotate. Teeth 1090 on rack 109 and teeth 1100 on pinion 110 mesh and translate the reciprocal rotational motion of motor 125 and shaft 126 into a reciprocal longitudinal motion along a single axis in both directions.

Preferably, rack gear 109 has a first end 1095 that engages with a recess 3200 formed in piston 112. Recess 3200 is preferably centrally located in piston 112. First end 1095 of rack gear 109 preferably has a snap fit or friction fit engagement with recess 3200 of piston 112. Preferably, there are detent structures 1096, 3296 formed on first end 1095 and recess 3200, respectively. This facilitates production of these components and also provides for any slight pivotal movement that may be required of piston 112 with respect to rack gear 109.

An alternative embodiment of a piston is shown in Fig. 8 and generally represented by reference numeral 8112. Piston 8112 has a substantially V-shape with a leading edge 8120 and a trailing edge 8121. Leading edge 8120 and trailing edge 8121 sealingly engage an inner surface 1130 of cylinder 113 as piston 8112 is driven back and forth in the cylinder. The use of multiple edges, i.e., leading edge 8120 and following edge 8121, on piston 8112 that sealingly engage inner surface 1130 of cylinder 113, provide a double sealing to increase the efficiency of creating the positive pressure and negative pressure.

Referring to Figs. 3 through 7, motor 125 is preferably variable speed. This allows a user to control and vary the cycle time of the pumping of the breast. Breast pump 100 further has a motor cover 107 and a bearing 108 to reduce vibration and to secure motor 125 to bottom housing 103.

The positive and negative pressures can be varied by changing the displacement of air volume in cylinder 113. In this embodiment, this is done by use of a photoelectric or photo-sensor system. The photo-sensor system has two or more photo-sensors 121 and a position switch 124. The photo-sensors 121 count the number of openings 50 on rack gear 109, as the rack gear moves back and forth. Thus, a user can control the distance that rack gear 109 travels and correspondingly control the air volume displacement in cylinder 113.

To ensure that piston 112 is properly moving to the front of cylinder 113, the photo-sensor system further includes position switch 124, preferably located at the front of the cylinder, which acts as a starter for the counter. Alternatively, the position switch can be an opening 50 having a different size or shape that is detectable by photo-sensor 121.

Rack gear 109 can also have a safety mechanism attached thereto. Photo-sensor 121 will be reading openings 50 as rack gear 109 moves backwards. If for some reason rack gear 109 misses its target and moves too far, the safety will trigger the position switch. When the position switch is

triggered while rack gear 109 is moving backwards, the software can trigger the system to move forward again and return to the position position.

Breast pump 100 has a guide cover 111 positioned over rack gear 109. Guide cover 111 provides added stability to the breast pump by guiding and vibration dampening the reciprocal movement of rack gear 109. Guide cover 111 also provides accuracy to the photo-sensor system by reducing the risk of misalignment of photo-sensors 121 and openings 50.

The photo-sensor system and motor 125 are preferably connected to a PC or circuit board 120. Thus, the distance piston 112 travels, which translates to the amount of positive and negative pressure, and the piston speed, which translates to the cycle time, are electronically controlled.

Referring to Figs. 15 through 19, a preferred embodiment of a drive system of the present invention is shown and generally represented by reference numeral 1500. Drive system 1500 is usable with breast pump 100 of Figs. 1 through 7 to provide the linear reciprocal movement of piston 112 with cylinder 113.

Drive system 1500 is a belt drive system for a rack and pinion drive having gear reduction incorporated therein. Drive system 1500 has a first drive wheel or pulley 1510; a second gear, drive wheel or pulley 1520 secured to the first drive wheel 1510; a third gear, drive wheel or pulley 4530; and a pinion gear 1540 secured to the third gear.

First drive wheel 1510 is operably connected to motor drive shaft 126 by a first belt 1550. In the preferred embodiment, first belt 1550 is a non-toothed belt. More preferably, first belt 1550 has resiliency or flexibility. The use of flexible or resilient belt 1550 provides a secure connection between drive shaft 126 and first drive wheel 1510 and also reduces noise and vibration. Drive shaft 126 and first drive wheel 1510 have smooth outer surfaces upon which the first belt 1550 is secured.

First drive wheel 1510 is operably connected to second gear 1520 by a first co-axial shaft 1515. In the preferred embodiment, first shaft 1515 is

rotatably mounted between opposing first bearings 1517. However, alternative rotatable mounting arrangements or securing structures could also be used. To reduce noise and vibration, motor shaft 126 and first drive wheel 1510 are made of metal. First drive wheel 1510 and second gear 1520 have different diameters that partially provide for gear reduction between motor shaft 126 and pinion gear 1540.

Second gear 1520 is operably connected to third gear 1530 by a second belt 1570. Preferably, second belt 1570 has teeth 1575 that mesh with teeth 1580 formed along the circumference of second gear 1520 and third gear 1530. Second and third gears 1520, 1530 have different diameters that partially provide for gear reduction between motor shaft 126 and pinion gear 1540. Drive system 1500 can also have a tension pulley 1580 that provides tension to second belt 1570.

Third gear 1530 is operably connected to pinion gear 1540 by a second co-axial shaft 1535. In the preferred embodiment, second shaft 1535 is rotatably mounted between opposing second bearings 1537. However, alternative rotatable mounting arrangements or securing structures could also be used. Preferably, third gear 1530 is integrally molded with pinion gear 1540 along second shaft 1535.

Pinion gear 1540 has teeth 1545 that engage with teeth 1090 of rack gear 109. When motor 125 is activated, the rotational motion of shaft 126 is translated into a reciprocal longitudinal motion along a single axis of rack gear 109 in both directions. Drive system 1500, through use of first and second belts 1550, 1570 and first, second and third drive wheels or gears 1510, 1520, 1530, is able to provide a desired ratio of movement between motor shaft 126 and pinion gear 1540, i.e., gear reduction.

The use of a combination of the non-toothed belt 1550 and the toothed belt 1570 reduces noise and vibration, while maintaining a secure, sturdy drive system 1500 that is able to provide the necessary back and forth linear motion at the desired speeds and pressure for breast pump 100.

Referring to Figs. 20 through 26, an alternative embodiment of a drive system of the present invention is shown and generally represented by reference numeral 4500. Drive system 4500 is also usable with breast pump 100 of Figs. 1 through 7 to provide the linear reciprocal movement of piston 112 with cylinder 113.

Drive system 4500 is a belt drive system having gear reduction incorporated therein. Drive system 4500 has a first gear, drive wheel or pulley 4510; a second gear, drive wheel or pulley 4520 secured to the first gear; a third gear, drive wheel or pulley 4530; and a pinion gear 4540 secured to the third gear.

First gear 4510 is operably connected to motor drive shaft 126 by a first belt 4550. In the preferred embodiment, first belt 4550 is a plurality of belts, and more preferably, three belts. First belts 4550 are preferably non-toothed belts. More preferably, first belts 4550 are o-rings having resiliency or flexibility. The use of flexible or resilient belts 4550, such as, for example, o-rings, provides a secure connection between drive shaft 126 and first gear 4510, and also reduces noise and vibration. Drive shaft 126 and first gear 4510 have annular channels 4555, 4560, formed therein, respectively. Annular channels 4555, 4560 are guides that assist in holding first belts 4550 in place and facilitate assembly of drive system 4500.

First gear 4510 is operably connected to second gear 4520 by a first co-axial shaft 4515. In this alternative embodiment, first shaft 4515 is rotatably mounted between opposing first bearings 4517. However, alternative rotatable mounting arrangements or securing structures could also be used. To reduce noise and vibration, motor shaft 126 and first gear 4510 are made of metal. First and second gears 4510, 4520 have different diameters that partially provide for gear reduction between motor shaft 126 and pinion gear 4540.

Second gear 4520 is operably connected to third gear 4530 by a second belt 4570. Preferably, second belt 4570 has teeth 4575 that mesh

with teeth 4580 formed along the circumference of second gear 4520 and third gear 4530. Second and third gears 4520, 4530 have different diameters that partially provide for gear reduction between motor shaft 126 and pinion gear 4540. Drive system 4500 can also have a tension pulley 4580 that provides tension to second belt 4570.

Third gear 4530 is operably connected to pinion gear 4540 by a second co-axial shaft 4535. In this alternative embodiment, second shaft 4535 is rotatably mounted between opposing second bearings 4537. However, alternative rotatable mounting arrangements or securing structures could also be used. Preferably, third gear 4530 is integrally molded with pinion gear 4540 along second shaft 4535.

Pinion gear 4540 has teeth 4545 that engage with teeth 1090 of rack gear 109. When motor 125 is activated, the rotational motion of shaft 126 is translated into a reciprocal longitudinal motion along a single axis of rack gear 109 in both directions. Drive system 4500, through use of first and second belts 4550, 4570 and first, second and third gears 4510, 4520, 4530, is able to provide a desired ratio of movement between motor shaft 126 and pinion gear 4540, i.e., gear reduction.

The use of a combination of the non-toothed o-ring belts 4550 and the toothed belt 4570 reduces noise and vibration, while maintaining a secure, sturdy drive system 4500 that is able to provide the necessary back and forth linear motion at the desired speeds and pressure for breast pump 100.

The embodiments of the drive systems 1500 and 4500 described above utilize belts for gear reduction. However, alternative embodiments can use a gear-box that reduces the gearing to the desired ratio that is transferred to the rack and pinion gearing that drives breast pump 100.

Referring back to Figs. 3 through 9, cylinder 113 has a supply tube 116 that is secured to a supply connector 115 for supplying the positive and negative pressure to breast cup 400. Preferably, supply connector has an outlet 215 disposed in storage compartment 210. Air tubing 350 can be

secured to outlet 215 and also secured to breast cup 400. Storage compartment 210 can be opened or closed during the pumping operation. Cylinder 113 is in fluid communication with a pressure relief valve 2000 (shown in Fig. 9) that is preferably set at about 1.5 in. Hg.

Pressure relief valve 2000 has an intake 2010 and an exhaust 2050. Intake 2010 is in fluid communication with cylinder 113 and exhaust 2050 is in fluid communication with breast cup 400, by tubing 350. Pressure relief valve 2000 has a relief exhaust 2100 that is in fluid communication with intake 2010 and exhaust 2050. Relief exhaust 2100 is substantially tubular and is secured to a relief assembly 2200.

Relief assembly 2200 has a flexible insert 2210, a biasing member 2220 and a retaining member 2230. Flexible insert 2210 sealing engages with the inner surface of relief exhaust 2100 to prevent air from exiting through the relief exhaust. Insert 2210 has a securing member 2215 that mates with biasing member 2200. In this embodiment, securing member 2215 is a cross-shaped structure that is received in the inner volume of biasing member 2200. Preferably, biasing member 2200 is a spring. More preferably, biasing member 2200 is a coil spring. Retaining member 2230 is a cap-like structure having opposing retaining arms 2235 that engage with a corresponding pair of engaging protrusions 2105 positioned on the outer surface of relief exhaust 2100. Insert 2210 and spring 2220 are held in the inner volume of relief exhaust 2100 by cap 2230.

Spring 2220 has a biasing strength or resistance that is equal to the relief pressure of relief pressure valve 2000. When a positive pressure exceeds the relief pressure, which in this embodiment is preferably set at about 1.5 in. Hg, the force created on the inner surface of insert 2210 overcomes the biasing force of spring 2220 and the insert moves toward cap 2230 and outside of the inner volume of relief exhaust 2100. Air exits pressure relief valve 2000 through relief exhaust 2100 until the positive pressure in the pressure relief valve decreases below the biasing strength of

spring 2220, at which time insert 2210 moves back in the inner volume of the relief exhaust, sealingly engaging the inner surfaces of the relief exhaust.

Alternatively, the pressure relief valve can be made adjustable so that the "massage strength", i.e., the amount of positive pressure on the user's breast, can be controlled. Circuit board 120, shown in Fig. 3, allows a user to program several levels of speed and several levels of suction.

In this embodiment, the speed (cycle time) ranges from about 45 cycles/minute (cpm) to about 75 cpm. The present invention provides for pre-set programming of a number of speed levels within the speed range. Preferably, the number of levels can be from about two to about eight levels. More preferably, the user can program five levels of speeds within the speed range. The present invention also envisions programming of the speed levels by the user.

The suction range for use with a single breast cup 400 and the preferred drive system 1500 shown in Figs. 15 through 21, is from about 3 in. Hg to about 10 in. Hg, and from about 3 in. Hg to about 8 in. Hg for two breast cups. The suction range for use with a single breast cup 400 and the gear box system shown in Figs. 3 and 4 is from about 3 in. Hg to about 9 in. Hg, and from about 3 in. Hg to about 8 in. Hg for two breast cups. The present invention provides for pre-set programming of a number of suction levels within the suction range. Preferably, the number of levels can be from about two to about eight levels. More preferably, the user can program five levels of suction within the suction range. The present invention also envisions programming of the suction levels by the user.

Computer software can also be used to control the amount of positive and negative pressure. This allows the amounts of positive and negative pressure to be personalized for the user and also varied over the duration of the pumping process to maximize efficiency.

Breast pump 100 is preferably controlled by a software-driven circuit board 120, along with a gear motor 125, a rack and pinion set 109, 110, and a

piston system 112, 113. The software and system are designed to provide maximum flexibility and to facilitate changing of the pressure curve or "wave." This is feasible because the software controls the speed of motor 120 and the distance that piston 112 will travel in cylinder 113. The distance piston 112 travels relates to the pressure levels. By controlling speed and pressure levels with software, the pressure curve or "wave" can be controlled.

Once a determination is made that there is a specific "wave" or pressure curve that is similar to the sucking of an infant or most comfortable to the mother, then the desired wave can be obtained by changing the timing (motor speed and piston distance). Through use of software, a user has the ability to apply memory to a particular pressure curve and the variation of that pressure curve over time so as to maximize the comfort for the user.

In this embodiment, a sine wave is used for the control of breast pump 100. This is based on the assumption that the most comfortable pressure curve would be one that increases and decreases in pressure gradually, similar to a sine wave, without sharp pressure peaks and valleys providing a pinching feeling on the user. The back and forth motion of piston 112 approximates the desired sine wave. However, to avoid sharp pressure peaks, the timing of piston 112 is slowed down at these peaks, and the pressure is held constant for a duration of time at the maximum and minimum suction points on the wave. This results in a pressure curve having a steady sine wave that is more comfortable to the user.

Alternative waves can also be used for the pressure curve if such a wave is determined to be desired by the mother. For example, if a mother prefers a "saw tooth" pressure curve with sharp peaks, the timing of piston 112 can be changed to simply cycle back and forth, minimizing the pause when piston 112 changes direction. Also, for example, if a mother prefers a "square curve", the timing of piston 112 can be changed to hold the piston position when the piston is ready to change direction, and then quickly ramp

down and hold its position again before it ramps back up. This will create a "square curve" wave.

Use of software control provides for numerous choices of waves or pressure curves. This further allows the flexibility to change or offer greater choice with one breast pump 100. In contrast, contemporary pumps have the drawback of not allowing the flexibility of changing pressure curve waves.

Cylinder 113 has a pressure differential hole 75. Preferably, pressure differential hole 75 is located along bottom face 80 of cylinder 113. Pressure differential hole 75 is substantially smaller than exhaust hole 1013 and supply tube 116 through which the air flows for generating the positive and negative pressure. Pressure differential hole 75 provides a variance in the amount of positive pressure as compared to the amount of negative pressure. Pressure differential hole 75 is effective for the higher ranges of vacuum to provide the "lost" air at the end of the vacuum stroke. On the positive pressure stroke, a small amount of air will be released through pressure differential hole 75 but the air will be reintroduced during the negative pressure stroke when the level of pressure is higher.

Referring to Fig. 10, cylinder 113 is formed as a zero- draft cylinder. The outer diameter of piston 112 creates a seal with the inner diameter d of cylinder 113 to move the volume of air inside the cylinder, creating vacuum and pressure on the breast. Breast pump 100 requires a cylinder 113 that has a consistent inner diameter d through the entire length of the cylinder to create an appropriate seal while minimizing interference or resistance to piston 112. Typical injection molded parts require a draft angle that would create a non-uniform inner diameter d of cylinder 113.

Cylinder 113 is preferably molded as a zero-draft cylinder that provides a uniform inner diameter d and more preferably, molded in a single piece. As shown in Fig. 10, cylinder 113 is a one piece, plastic injection molded part. A two-part cylinder or a machined-cylinder have drawbacks which the single piece, zero draft cylinder 133 overcomes. The two-part cylinder requires an

extruded tube attached to an end cap, with the two parts joined using a weld or using an adhesive. The machined part is typically a metal tube. One of the advantages to the zero-draft, one-piece cylinder 113 is that it is injection moldable.

Referring to Figs. 3 through 10, button pad 105 is the user interface or control mechanism for breast pump 100. Button pad 105 has a pair of positive and negative keys for increasing or decreasing the level of suction and speed. Pad 105 further includes an on/off switch.

Due to the reciprocal back and forth motion of piston 112 in cylinder 113, breast pump 100 supplies both a positive pressure and a negative pressure to a woman's breast through a single hose or tubing 350. While this embodiment uses a piston/cylinder mechanism to create positive and negative pressure, alternative expandable volumes or pressure sources can also be used. Such alternative embodiments include a bellows mechanism or a diaphragm that would require fewer parts.

Referring to Figs. 11 and 12, Breast Cup 400 of the present invention is shown. An example of breast cup 400 is disclosed in the co-pending and commonly owned U.S. Application Serial No. 10/331,183, filed December 27, 2002, the disclosure of which is incorporated herein by reference. Breast cup 400 has a housing 500 having an air orifice 560, a flexible insert 600, and a holder 700. Housing 500 is a rigid structure and flexible insert 600 is a flexible structure. Housing 500 is adapted for sealing engagement with insert 600 to form a displacement volume 510 between the housing and the insert. Air orifice 560 is in fluid communication with displacement volume 510.

Breast pump 100 is placed in fluid communication with breast cup 400 via air tubing 350 that is connected to air orifice 560 and in fluid communication with cylinder 113. Breast pump supplies both a positive and negative pressure to breast cup 400. The positive and negative pressure created by breast pump 100 causes air to flow through air orifice 560 into and out of displacement volume 510. The positive and negative pressure supplied

to breast cup 400 causes flexible insert 600 and, in particular, displacement volume 510 to expand and contract to apply reciprocating positive and negative forces on the user's breast.

Breast pump 100 and breast cup 400 are able to apply both a positive and a negative pressure to a user's breast through a single air tubing 350, which is connected to air orifice 560.

The volume disposed in displacement volume 510 is preferably between 22 to 52 cubic centimeters, and more preferably between 32 to 42 cubic centimeters. The expandable and contractible displacement volume 510 provides an upper limit to the amount of negative pressure that can be applied to a user's breast, which can further serve as a safety feature in use of breast pump 100. Additionally, the sealing engagement of insert 600 and housing 500 provides a barrier between the user's breast and breast pump 100 to prevent any breast milk from entering air tubing 350 or the breast pump.

While the preferred embodiment of the breast pump system uses breast cup 400 having a displacement volume 510 in fluid isolation from the user's breast, alternative breast cups can also be used with breast pump 100. The unique features of the breast pump system of the present invention can be used with other types of breast cups, such as, for example, the control system of the present invention or the rack and pinion driving mechanism.

Referring to Fig. 13, T-connector 300 is a triangular shaped valve that allows a user to utilize either a single breast cup 400 or two breast cups through use of a first orifice 310 and a second orifice 320. Breast pump 100 is connected to t-connector 300 through air tubing 350 at inlet 330. The single split valve configuration of t-connector 300 minimizes the amount of tubing 350 necessary for double pumping. T-connector 300 has a plug 340 for closing off either of first or second orifices 310, 320 if single pumping is desired. Preferably, plug 340 is tethered to an outer surface of t-connector 300 to facilitate engagement with first or second orifices 310, 320.

Referring to Fig. 14, a method of expressing breast milk according to the breast pump system of the present invention, is shown. The user commences the breast pumping operation by turning breast pump 100 "on," as in step 800. This causes power to be supplied to breast pump 100 (step 810). The user then inputs the cycle time and suction level that is desired, as in step 820. In the preferred embodiment, the user has five cycle times and suction levels from which to choose. The cycle time and suction level is inputted by use of button pad 105.

In step 830, PC board 120 sets the motor speed and target piston travel distance according to the user's inputted levels for cycle time and suction. The cycle time and suction level are then displayed to the user, as in step 840. In this embodiment, the cycle time and suction level are indicated by lights 225 with the number of illuminated lights corresponding to the level. In step 850, motor 125 is actuated causing piston 112 to move toward bottom 175 of cylinder 113. This creates a positive pressure that is supplied to breast cup 400 by air tubing 350.

In step 855, the PC Board monitors the home switch to determine whether it has been triggered by contact with piston 112. In step 860, it is determined whether the home switch has been triggered. If the home switch has been triggered then it is reset as in step 870. In step 880, motor 125 is then reversed causing piston 112 to move toward top 180 of cylinder 113. This creates a negative pressure that is supplied to breast cup 400 by air tubing 350. One of the advantages of the breast pump system of the present invention is that is supplies both a positive pressure and a negative pressure through the same air tubing 350. This reduces cleaning and simplifies the operation for a user.

To provide the proper amount of suction as inputted by the user, photo-sensors 121 count the number of rack openings 50, as in step 890. In step 900, PC board 120 determines if the number of rack openings 50 that have been counted is the equivalent of the target piston travel distance as inputted

by the user. In step 910, it is determined whether breast pump 100 is still "on." If breast pump 100 has been shut off then the pumping operation ends, as in step 915.

In step 920, it is determined whether the user has inputted a new cycle time or suction level. If a new cycle time or suction level has been inputted, then PC Board 120 sets the motor speed and target piston travel distance according to the user's inputted levels for cycle time and suction, reverting back to step 830 and repeating the above described steps. If the user has not inputted a new cycle time or suction level then the motor is again reversed causing piston 112 to move toward bottom 175 of cylinder 113. This creates a positive pressure that is supplied to breast cup 400 by air tubing 350. The process continues with breast pump 100 supplying positive pressure and then negative pressure to breast cup 400 until the breast pump is shut off (step 910).

The breast pump system of the present invention includes a number of components and can be used in remote locations, such as when a user is traveling. The various components can be disposed within a bag system for ease of use. An example of such a bag system, as well as the components of such a system, is disclosed in the co-pending and commonly owned U.S. Application Serial No. 10/331,130, filed December 27, 2002, the disclosure of which is incorporated herein by reference.

The present invention having been thus described with particular reference to the preferred forms thereof, it will be obvious that various changes and modifications may be made therein without departing from the spirit and scope of the present invention as defined in the appended claims.

WHAT IS CLAIMED IS:

1. A breast pump system for expressing breast milk from a breast, the system comprising:

a pressure source for generating a positive pressure and a negative pressure; and

a breast cup in fluid communication with said pressure source, wherein said breast cup applies said positive pressure and said negative pressure to said breast.

2. The system of claim 1, further comprising a channel, wherein said breast cup has an air orifice, wherein said channel is connected to said air orifice and said pressure source, and wherein said pressure source supplies reciprocating air flow through said channel between said breast cup and said pressure source.

3. The system of claim 2, wherein said channel is flexible tubing.

4. The system of claim 2, wherein said pressure source is a piston movably disposed in a cylinder.

5. The system of claim 4, further comprising a motor, a rack having first teeth and a gear having second teeth, wherein said rack is connected to said piston, said gear is operably connected to said motor, and said first teeth engage with said second teeth to reciprocally move said piston in said cylinder.

6. The system of claim 4, wherein said piston has a sealing member disposed between said piston and said cylinder.

7. The system of claim 6, wherein said sealing member is an o-ring disposed on said piston.

8. The system of claim 6, wherein said piston has a substantially cylindrical shape with a circumferential wall, and said sealing member is a plurality of gaskets disposed on said circumferential wall.

9. The system of claim 6, wherein said piston has a substantially cylindrical shape with a circumferential wall having a circumferential channel formed therein, and wherein said sealing member is at least partially disposed in said channel.

10. The system of claim 4, wherein said piston has a v-shaped cross section with a leading edge and a trailing edge, and wherein said leading edge and said trailing edge form a sealing engagement with said cylinder.

11. The system of claim 5, wherein said piston is flexibly secured to said rack.

12. The system of claim 11, wherein said piston has a recess and said rack has a first end with an abutment formed therein, and wherein said abutment is flexibly secured in said recess.

13. The system of claim 12, wherein said recess and said first end have detent structures.

14. The system of claim 5, wherein said cylinder has a first diameter and an air hole, wherein said air hole has a second diameter and is in fluid communication with said atmosphere, and wherein said first diameter is significantly larger than said second diameter.

15. The system of claim 5, further comprising a controller operably connected to said motor, wherein said motor is reversible and said controller reverses said motor based upon a positive or negative pressure limit.

16. The system of claim 5, further comprising a controller operably connected to said motor, wherein said motor is a reversible motor, wherein said controller determines a distance that said piston has traveled relative to said cylinder and wherein said controller reverses said motor based upon said distance.

17. The system of claim 16, further comprising a photo-sensor that generates a signal in response to said distance, wherein said signal is transmitted to said controller, and wherein said controller reverses said motor in response to said signal.

18. The system of claim 17, wherein said rack has a plurality of openings formed therein, wherein said photo-sensor is operably aligned with said openings, and wherein said signal is generated based upon a count of said openings moving past said photo-sensor.

19. The system of claim 18, further comprising a position switch, wherein said photo-sensor is operably aligned with said position switch to generate a position signal, wherein said position signal is transmitted to said controller, and wherein said controller resets said count in response to said position signal.

20. The system of claim 5, further comprising a controller operably connected to said motor, wherein said motor has variable speed, and said controller adjusts said speed based upon a desired cycle time for applying said positive or negative pressure to said breast.

21. The system of claim 20, wherein said controller has a user interface, said desired cycle time is inputted into said user interface, and said desired cycle time is transmitted to said controller from said user interface.

22. The system of claim 1, further comprising a controller having a user interface and operably connected to said pressure source, wherein said controller adjusts the positive or negative pressure generated by the pressure source in response to a signal transmitted from said user interface.

23. The system of claim 1, further comprising a controller having a user interface and operably connected to said pressure source, wherein said controller adjusts a cycle time for applying said positive or negative pressure to said breast in response to a signal transmitted to said controller from said user interface.

24. The system of claim 5, further comprising a controller that generates a wave signal in response to an amount of pressure and a cycle time between said positive and negative pressure, and controls said motor in response to said wave signal.

25. The system of claim 24, further comprising a user interface, wherein a desired wave signal is inputted into said user interface, said desired wave signal is transmitted to said controller from said user interface, and said controller adjusts said wave signal to correspond to said desired wave signal.

26. The system of claim 4, wherein said cylinder is in fluid communication with a pressure relief valve.

27. The system of claim 26, wherein said pressure relief valve is adjustable.

28. The system of claim 3, wherein said pressure source has a housing with a storage compartment formed therein, and wherein said flexible tubing is removably stored in said storage compartment.

29. The system of claim 28, wherein said housing has an air outlet with a first end and a second end, wherein said first end is in fluid communication with said pressure source and said second end is disposed in said storage compartment.

30. The system of claim 1, further comprising a t-connector having an inlet, a first outlet, a second outlet and a plug, wherein said inlet is in fluid communication with said first and second outlets, and wherein said plug is selectively sealingly engageable with said first outlet or said second outlet.

31. The system of claim 30, wherein said t-connector has an outer surface and said plug is tethered to said outer surface.

32. A breast pump system for expressing breast milk from a breast, the system comprising:

a cylinder having a cylinder volume;

a piston movably disposed in said cylinder;

a motor operably connected to said piston to generate a pressure in said cylinder volume; and

a breast cup in fluid communication with said cylinder volume, wherein said breast cup applies said pressure to said breast.

33. The system of claim 32, further comprising a channel, wherein said breast cup has an air orifice, wherein said channel is connected to said air orifice and said cylinder volume, and wherein said cylinder volume supplies reciprocating air flow through said channel.

34. The system of claim 33, wherein said channel is flexible tubing.

35. The system of claim 32, further comprising a rack having first teeth and a gear having second teeth, wherein said rack is connected to said piston, said gear is operably connected to said motor, and said first teeth engage with said second teeth to reciprocally move said piston in said cylinder.

36. The system of claim 32, wherein said piston has a sealing member disposed between said piston and said cylinder.

37. The system of claim 36, wherein said sealing member is an o-ring disposed on said piston.

38. The system of claim 36, wherein said piston has a substantially cylindrical shape with a circumferential wall, and said sealing member is a plurality of gaskets disposed on said circumferential wall.

39. The system of claim 36, wherein said piston has a substantially cylindrical shape with a circumferential wall having a circumferential channel formed therein, and wherein said sealing member is at least partially disposed in said channel.

40. The system of claim 32, wherein said piston has a v-shaped cross section with a leading edge and a trailing edge, and wherein said leading edge and said trailing edge form a sealing engagement with said cylinder.

41. The system of claim 35, wherein said piston is flexibly secured to said rack.

42. The system of claim 41, wherein said piston has a recess and said rack has a first end with an abutment formed therein, and wherein said abutment is flexibly secured in said recess.

43. The system of claim 42, wherein said recess and said first end have detent structures.

44. The system of claim 32, wherein said cylinder has a first diameter and an air hole, said air hole has a second diameter and is in fluid communication with said atmosphere, and said first diameter is significantly larger than said second diameter.

45. The system of claim 32, further comprising a controller operably connected to said motor, wherein said motor is reversible and said controller reverses said motor based upon a pressure limit.

46. The system of claim 35, further comprising a controller operably connected to said motor, wherein said motor is reversible, wherein said controller determines a distance that said piston has traveled relative to said cylinder and wherein said controller reverses said motor based upon said distance.

47. The system of claim 46, further comprising a photo-sensor that generates a signal in response to said distance, wherein said signal is transmitted to said controller.

48. The system of claim 47, wherein said rack has a plurality of openings formed therein, wherein said photo-sensor is operably aligned with said openings, and wherein said signal is generated based upon a count of said openings moving past said photo-sensor.

49. The system of claim 48, further comprising a position switch, wherein said photo-sensor is operably aligned with said position switch to generate a position signal, wherein said position signal is transmitted to said controller, and wherein said controller resets said count in response to said position signal.

50. The system of claim 32, further comprising a controller operably connected to said motor, wherein said motor is variable speed and said controller adjusts said speed based upon a desired cycle time for applying said pressure to said breast.

51. The system of claim 50, wherein said controller has a user interface, said desired cycle is inputted into said user interface, and said desired cycle time is transmitted to said controller from said user interface.

52. The system of claim 32, further comprising a controller having a user interface and operably connected to said motor, wherein said controller adjusts the pressure generated in said cylinder volume in response to a signal transmitted from said user interface.

53. The system of claim 32, further comprising a controller having a user interface and operably connected to said motor, wherein said controller adjusts a desired cycle time for applying said pressure to said breast in response to a signal transmitted to said controller from said user interface.

54. The system of claim 32, further comprising a controller that generates a wave signal in response to an amount of pressure and a cycle time for said pressure, and controls said motor in response to said wave signal.

55. The system of claim 54, further comprising a user interface, wherein a desired wave signal is inputted into said user interface, said desired wave signal is transmitted to said controller from said user interface, and wherein said controller adjusts said wave signal to correspond to said desired wave signal.

56. The system of claim 32, wherein said cylinder is in fluid communication with a pressure relief valve.

57. The system of claim 56, wherein said pressure relief valve is adjustable.

58. The system of claim 34, further comprising a housing having a storage compartment, wherein said motor, said piston and said cylinder are disposed in said housing, and wherein said flexible tubing is removably stored in said storage compartment.

59. The system of claim 58, wherein said housing has an air outlet with a first end and a second end, wherein said first end is in fluid communication with said cylinder volume and said second end is disposed in said storage compartment.

60. The system of claim 32, further comprising a t-connector having an inlet, a first outlet, a second outlet and a plug, wherein said inlet is in fluid communication with said first and second outlets, and wherein said plug is selectively sealingly engageable with said first outlet or said second outlet.

61. The system of claim 60, wherein said t-connector has an outer surface and said plug is tethered to said outer surface.

62. A breast pump for expressing breast milk from a breast, the pump comprising:

a pressure source for generating a positive pressure and a negative pressure; and

a controller operably connected to the pressure source, wherein said controller adjusts said positive and negative pressure and adjusts a cycle time between application of said positive and negative pressure to said breast.

63. The pump of claim 62, wherein said controller has a user interface, a desired cycle time is inputted into said user interface, said desired cycle time is transmitted to said controller from said user interface, and said controller adjusts said cycle time to correspond to said desired cycle time.

64. The pump of claim 62, wherein said controller has a user interface, a desired level of said positive or negative pressure is inputted into said user interface, and said controller adjusts said positive or negative pressure in response to a signal transmitted from said user interface.

65. The pump of claim 62, wherein said controller generates a wave signal in response to said pressure and said cycle time, and controls said pressure source in response to said wave signal.

66. The pump of claim 65, further comprising a user interface, wherein a desired wave signal is inputted into said user interface, said desired wave signal is transmitted to said controller from said user interface, and said controller adjusts said wave signal to correspond to said desired wave signal.

67. A breast pump for expressing breast milk from a breast, the pump comprising:

a pressure source for generating a pressure; and

a controller operably connected to the pressure source, wherein said controller adjusts said pressure and adjusts a cycle time between application of said pressure to said breast, and wherein said controller generates a wave signal in response to said pressure and said cycle time, and controls said pressure source in response to said wave signal.

68. The pump of claim 67, further comprising a user interface, wherein a desired wave signal is inputted into said user interface, said desired wave signal is transmitted to said controller from said user interface, and said controller adjusts said wave signal to correspond to said desired wave signal.

69. A drive system for an expandable volume of a breast pump, the system comprising:

a motor having a first rotary output;

a first gear system operably connected to said motor; and

a second gear system operably connected to said first gear system and the expandable volume, said second gear system having a rack gear and a pinion gear operably connected to said rack gear,

wherein said first rotary output is provided to said second gear system,

wherein said first gear system adjusts said first rotary output provided to said second gear system to a second rotary output, and

wherein said second gear system translates said second rotary output to a linear output.

70. The drive system of claim 69, wherein said first gear system has at least one belt.

71. The drive system of claim 70, wherein said at least one belt is a first belt and a second belt.

72. The drive system of claim 71, wherein said first belt is non-toothed and said second belt is toothed.

73. The drive system of claim 72, wherein said first belt is resilient.

74. The drive system of claim 73, wherein said first belt is a plurality of belts.

75. The drive system of claim 74, wherein said motor has a drive shaft with an annular channel formed therein, and wherein said first belt is partially disposed in said annular channel.

76. The drive system of claim 72, wherein said first gear system further comprises a first pulley and a second pulley, said first pulley having a first circumference and a first channel formed along said first circumference, said second pulley having a second circumference and a plurality of teeth formed along said second circumference, wherein said first belt is partially disposed in said first channel, and wherein said second belt engages said plurality of teeth of said second pulley.

77. The drive system of claim 76, wherein said second pulley is secured to said pinion gear.

78. A breast pump for supplying a pressure to a breast cup, said pump comprising:

an expandable volume in fluid communication with said breast cup to supply said pressure;

a motor having a first rotary output;

a first gear system operably connected to said motor; and

a second gear system operably connected to said first gear system and said expandable volume, said second gear system having a rack gear and a pinion gear operably connected to said rack gear,

wherein said first rotary output is provided to said second gear system,

wherein said first gear system adjusts said first rotary output provided to said second gear system to a second rotary output, and

wherein said second gear system translates said second rotary output to a linear output.

79. The drive system of claim 78, wherein said first gear system has at least one belt.

80. The drive system of claim 79, wherein said at least one belt is a first belt and a second belt.

81. The drive system of claim 80, wherein said first belt is non-toothed and said second belt is toothed.

82. The drive system of claim 81, wherein said first belt is resilient.

83. The drive system of claim 81, wherein said first belt is a plurality of belts.

84. The drive system of claim 83, wherein said motor has a drive shaft with an annular channel formed therein, and wherein said first belt is partially disposed in said annular channel.

85. The drive system of claim 81, wherein said first gear system further comprises a first pulley and a second pulley, said first pulley having a first circumference and a first channel formed along said first circumference,

said second pulley having a second circumference and a plurality of teeth formed along said second circumference, wherein said first belt is partially disposed in said first channel, and wherein said second belt engages said plurality of teeth of said second pulley.

86. The drive system of claim 85, wherein said second pulley is secured to said pinion gear.

87. The breast pump of claim 78, wherein said expandable volume comprises a cylinder and a piston movable in said cylinder, and wherein said rack gear is secured to said piston.

88. The breast pump of claim 87, wherein said rack gear is flexibly secured to said piston.

89. The breast pump of claim 87, wherein said cylinder has a first diameter and an air hole, said air hole has a second diameter and is in fluid communication with said atmosphere, and said first diameter is significantly larger than said second diameter.

90. The breast pump of claim 87, further comprising a controller operably connected to said motor, wherein said motor is reversible, wherein said controller determines a distance that said piston has traveled relative to said cylinder, and wherein said controller reverses said motor based upon said distance.

91. The breast pump of claim 78, further comprising a controller operably connected to said motor, wherein said motor is reversible and said controller reverses said motor based upon a pressure limit.

92. The breast pump of claim 78, further comprising a controller operably connected to said motor, wherein said motor is variable speed and said controller adjusts said speed based upon a desired cycle time for supplying said pressure to said breast cup.

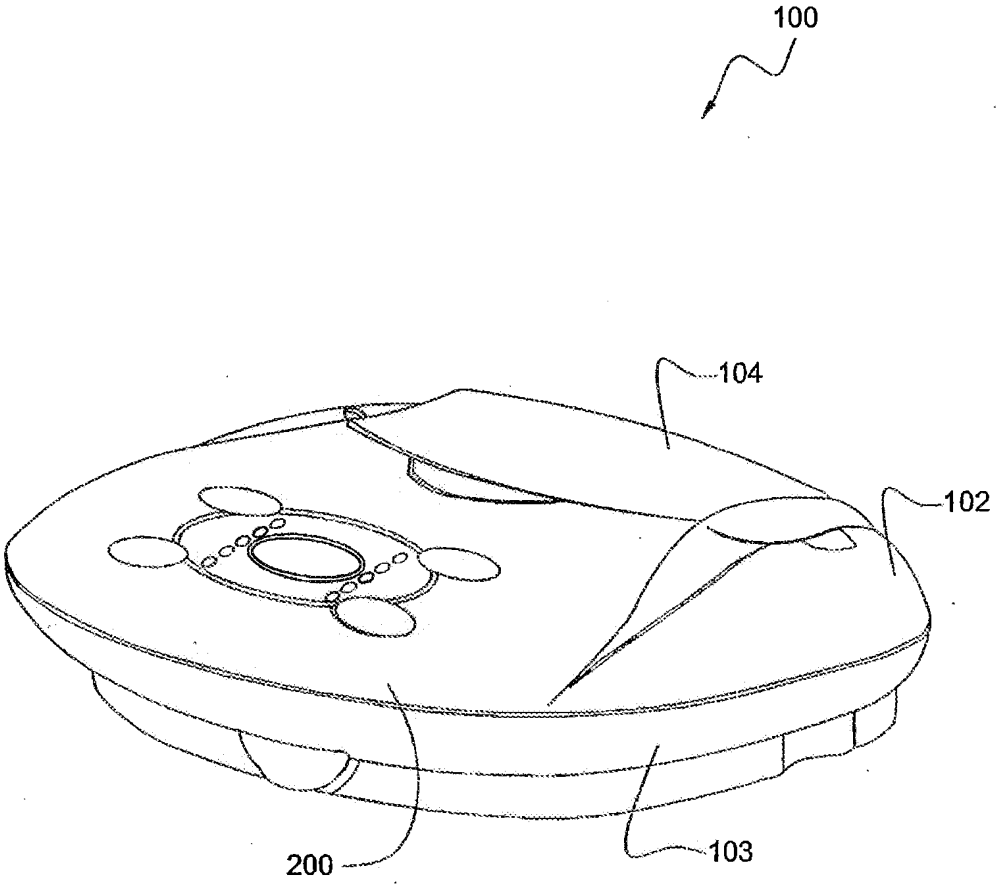


Fig. 1

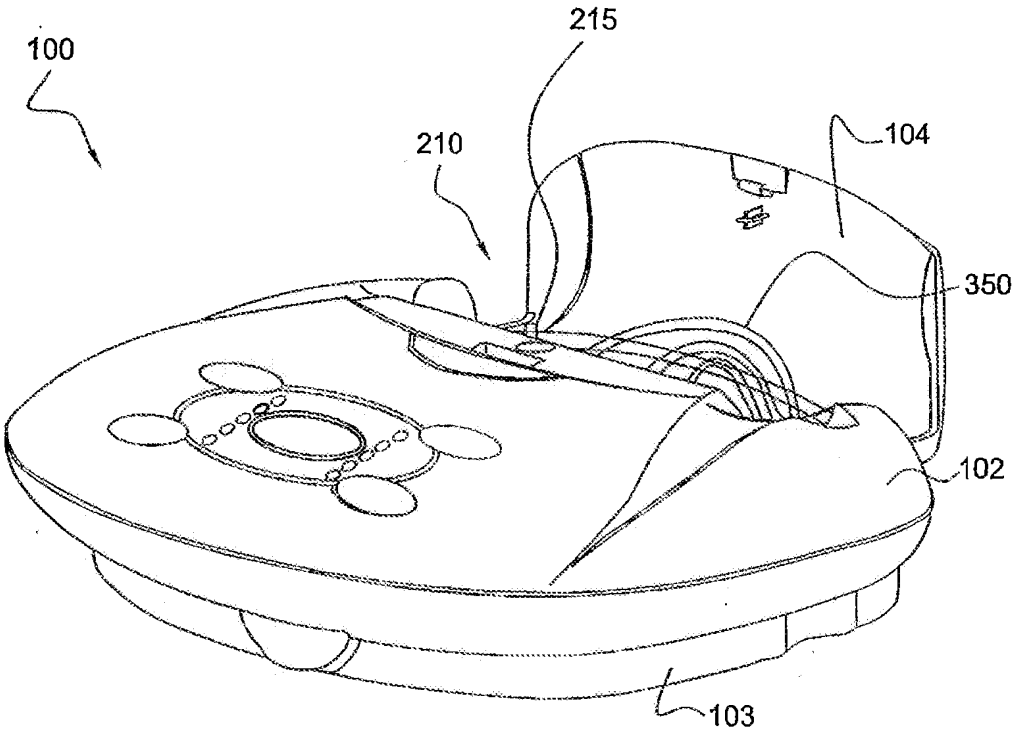


Fig. 2

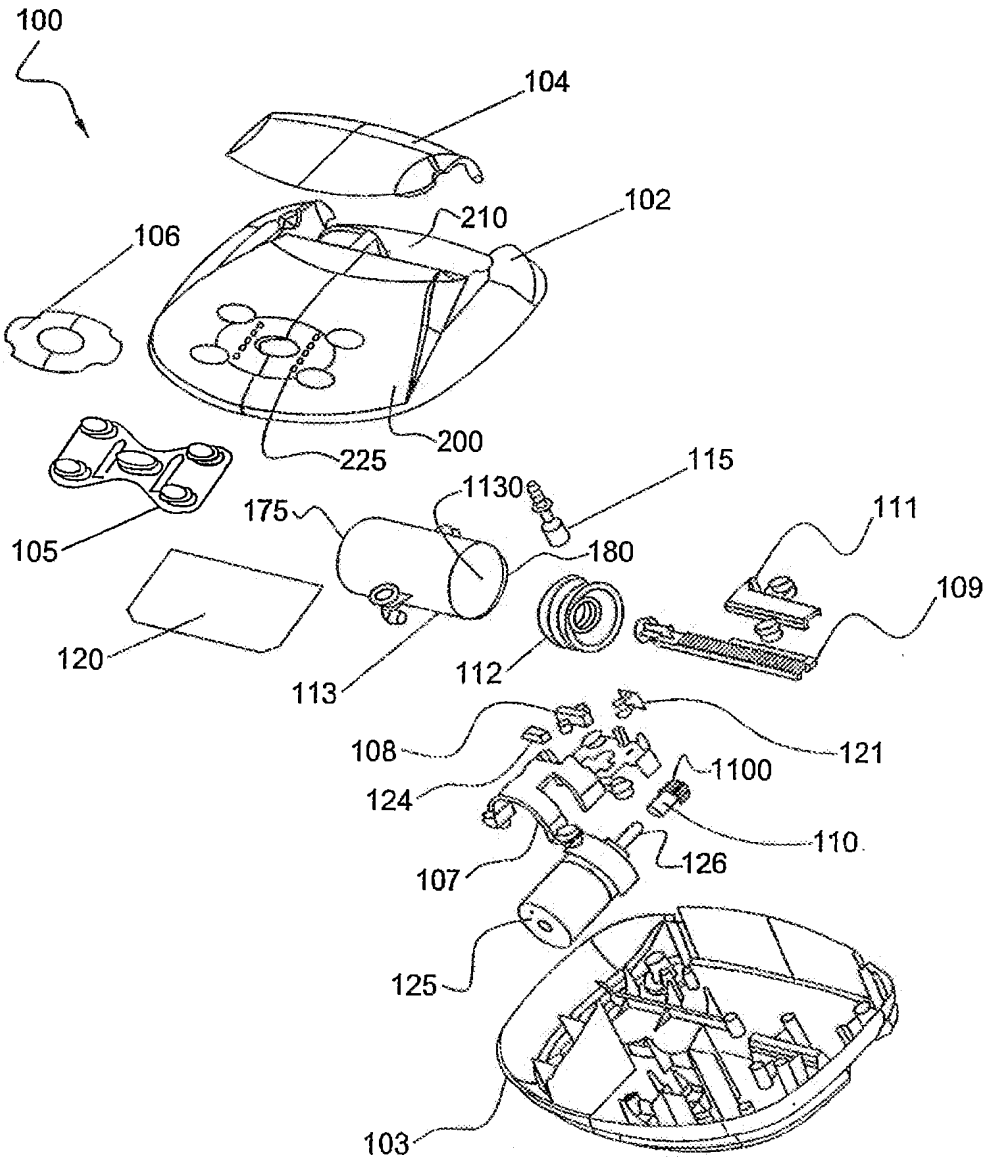

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Fig. 3

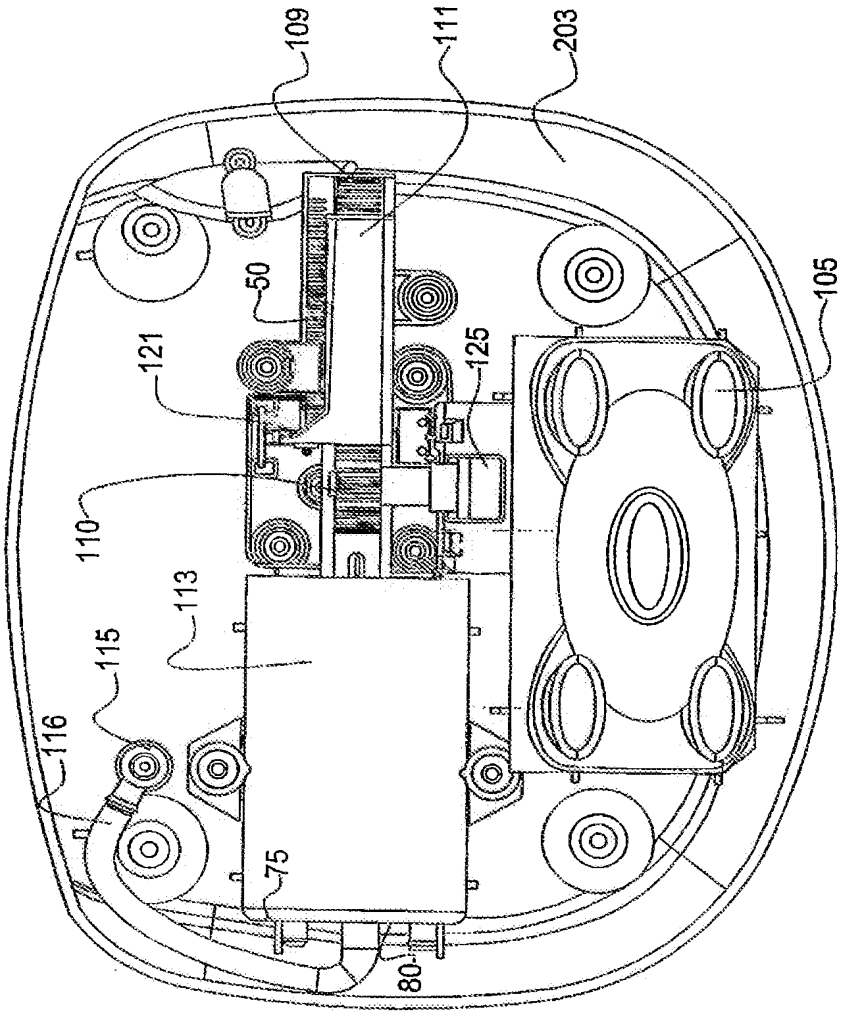

Fig. 4

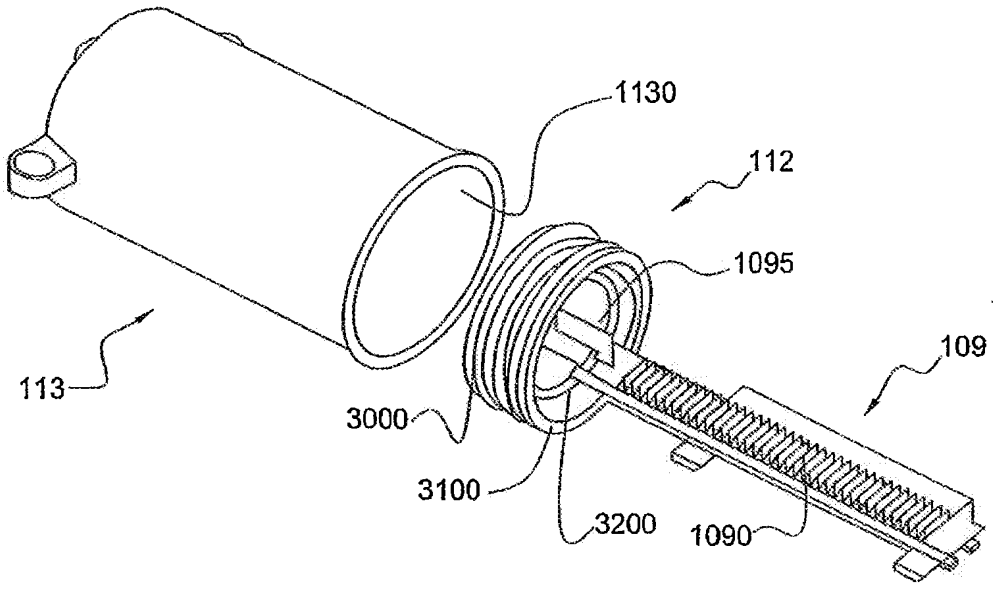
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Fig. 5

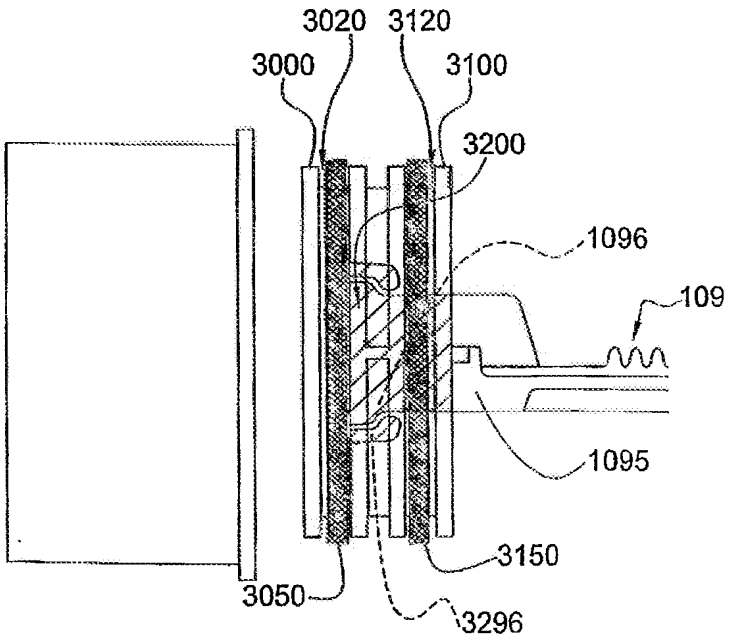
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Fig. 6

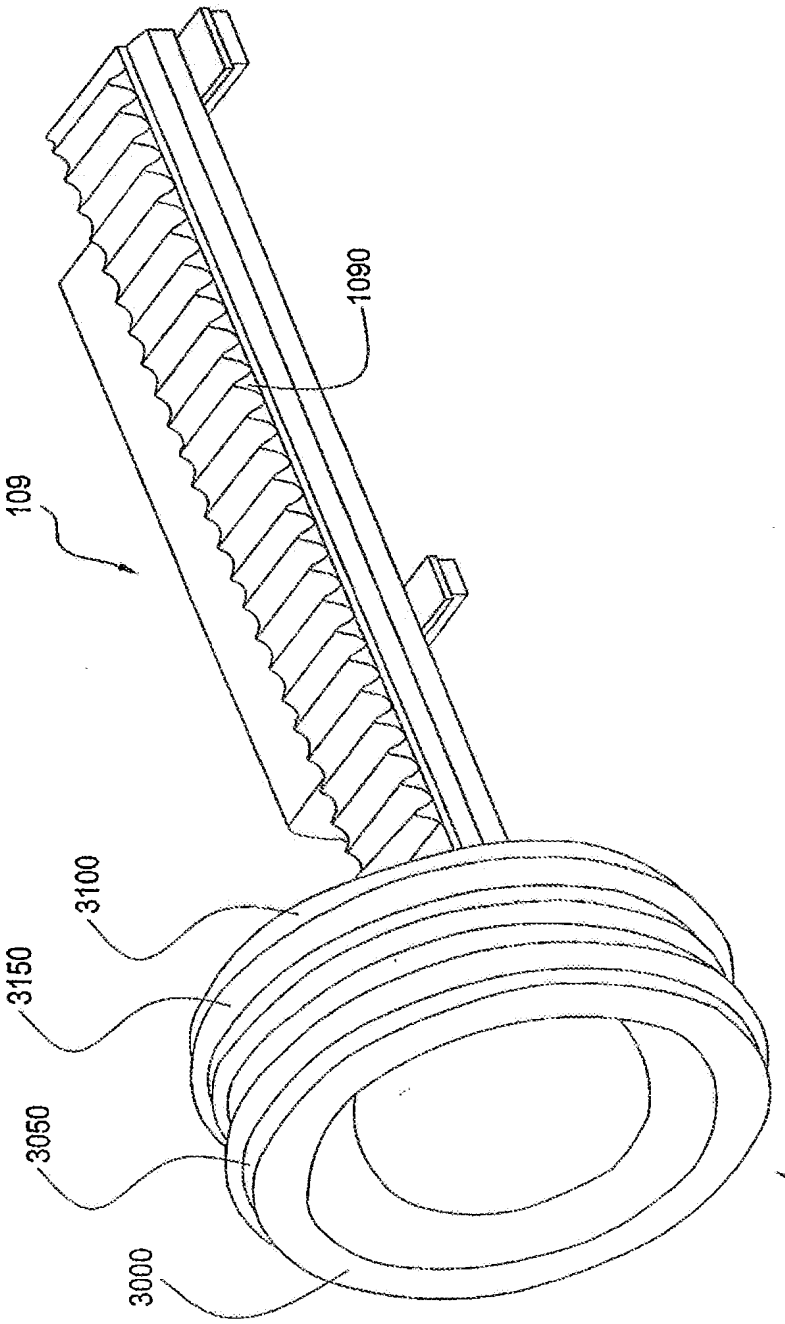

Fig. 7

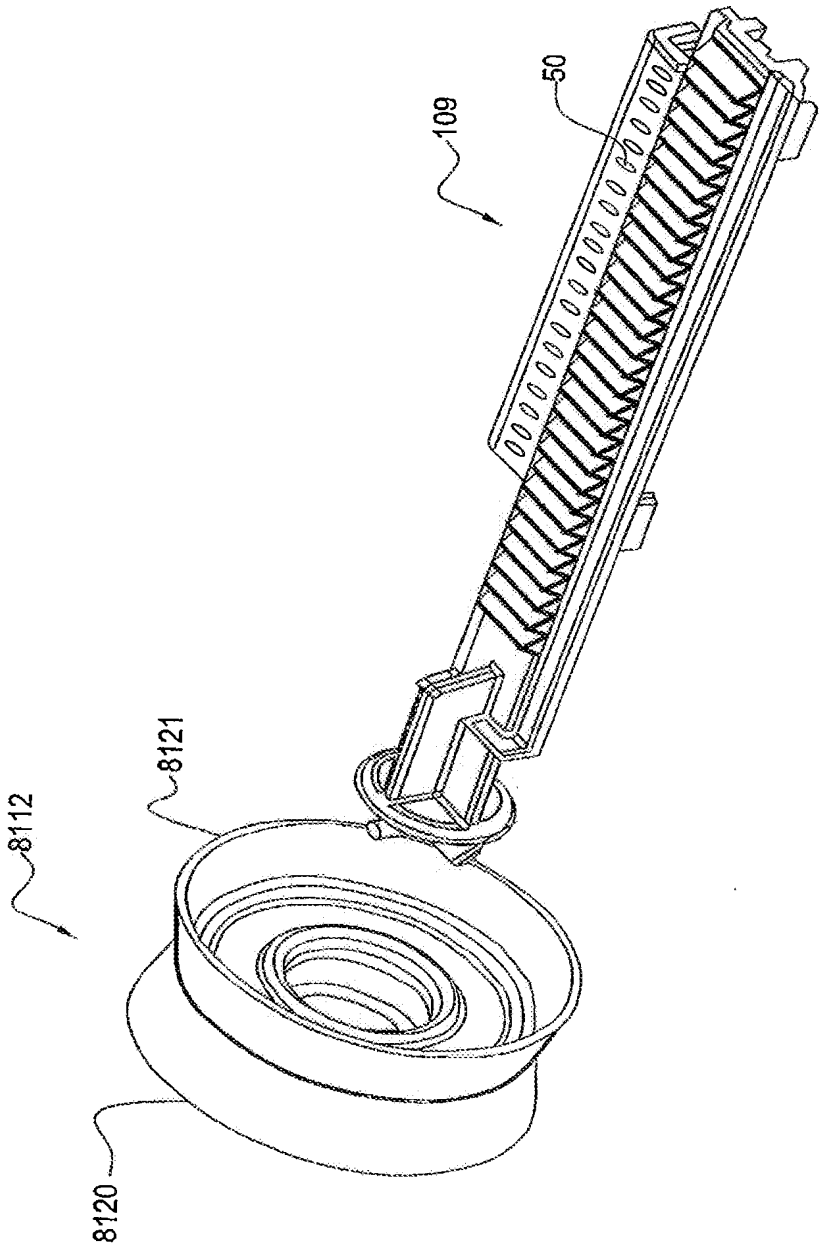

Fig. 8

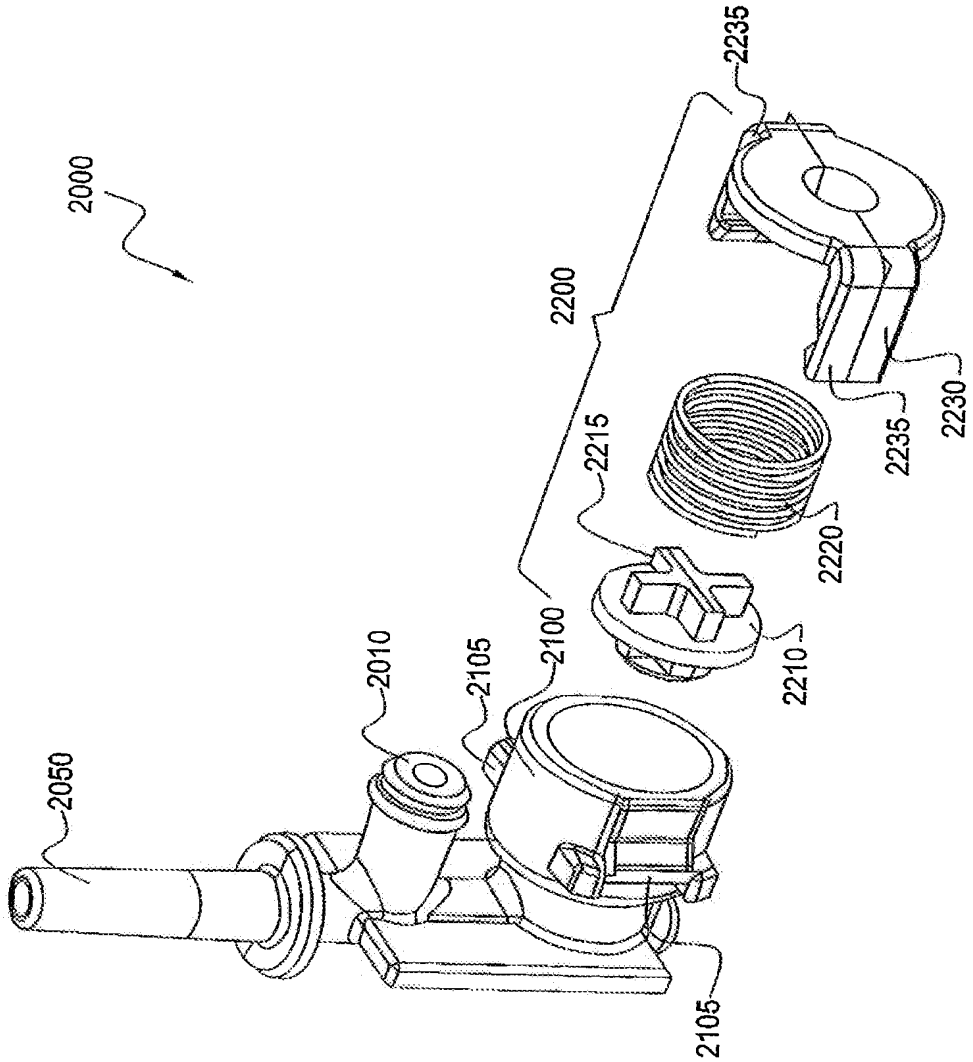
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Fig. 9

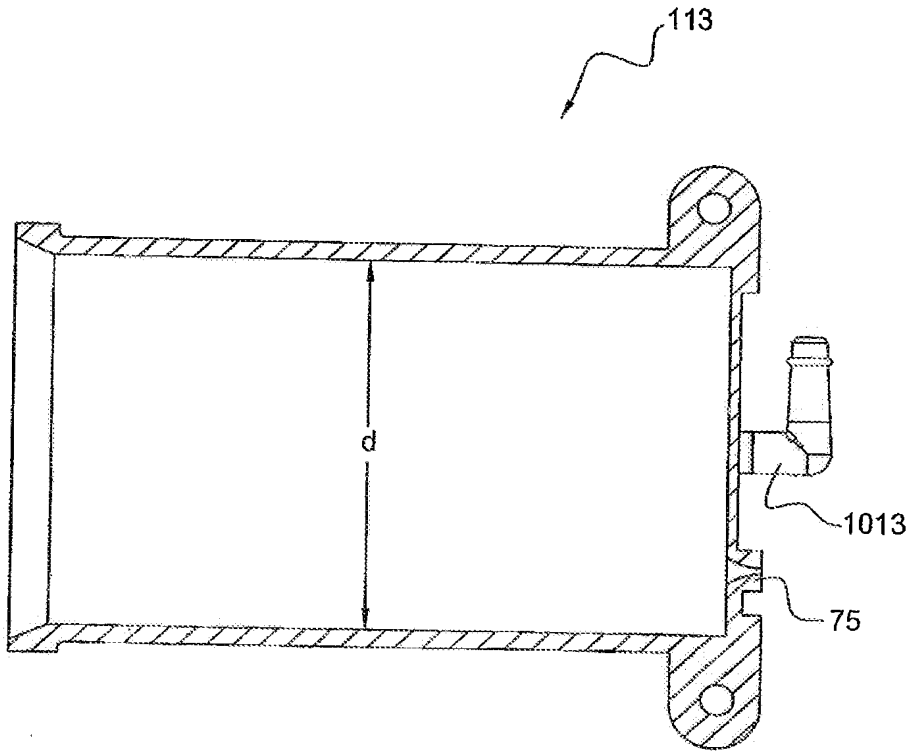

Fig. 10

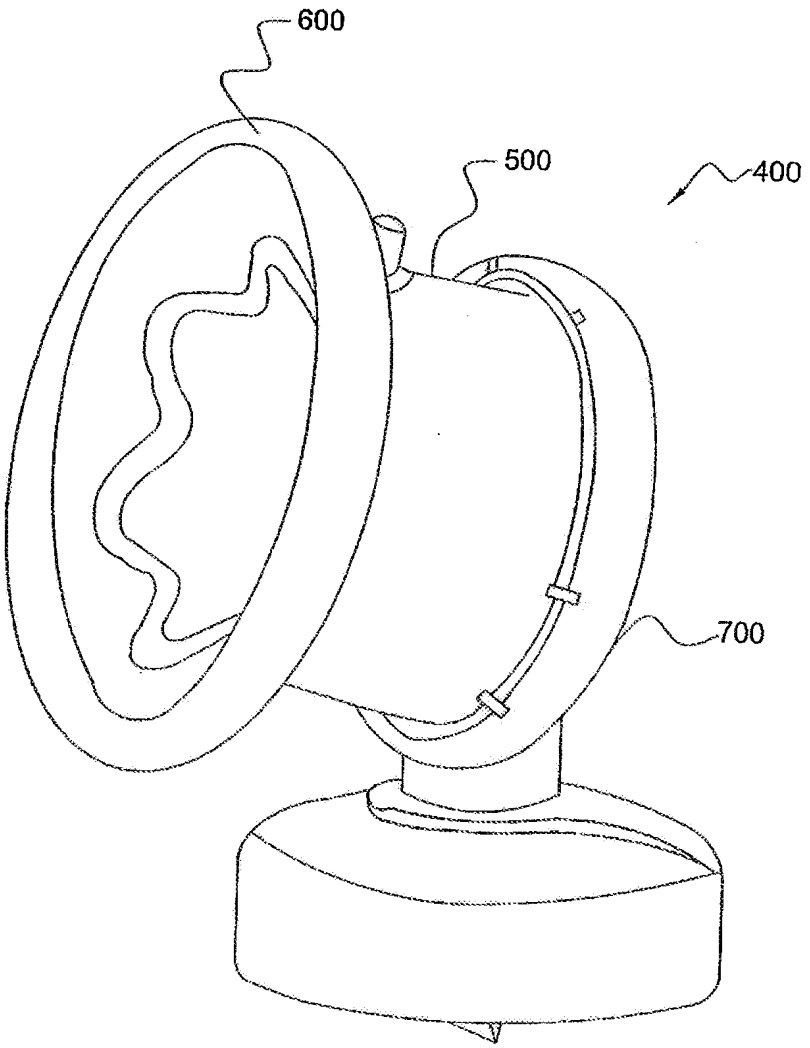

Fig. 11

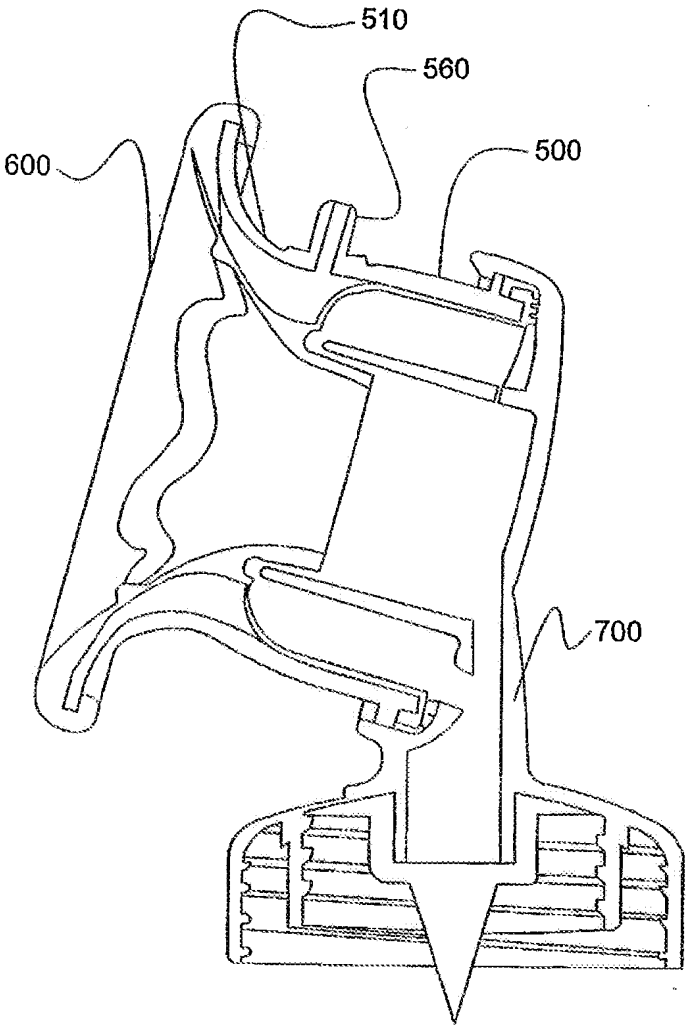

Fig. 12

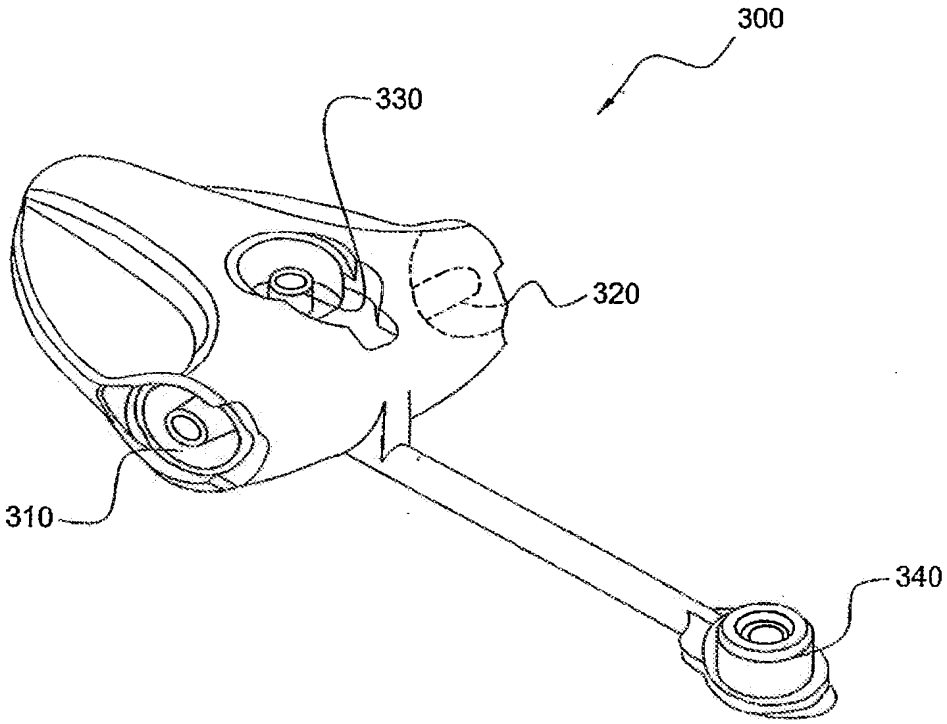

Fig. 13

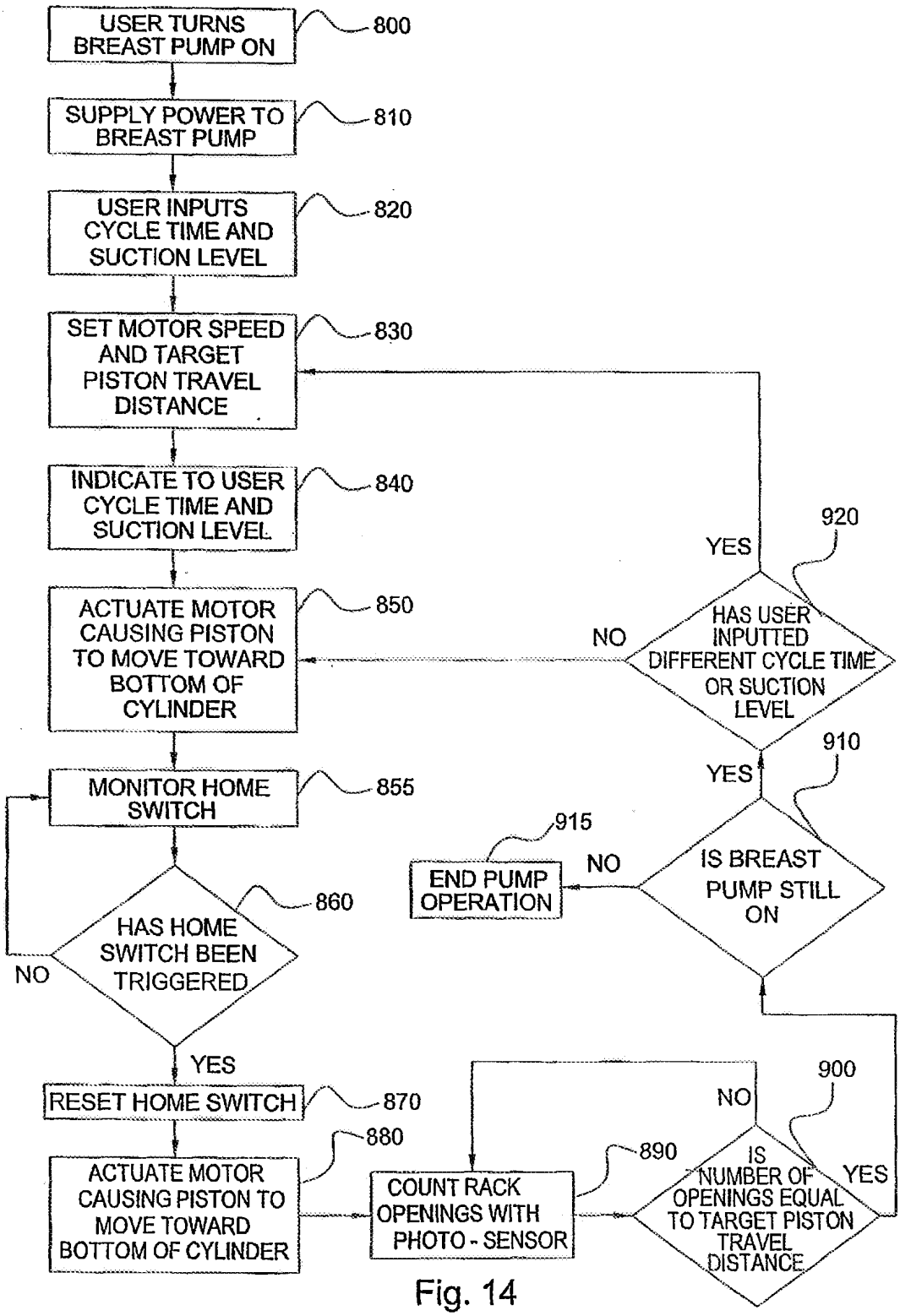
USER TURNS BREAST PUMP ON
800
SUPPLY POWER TO BREAST PUMP
810
USER INPUTS CYCLE TIME AND SUCTION LEVEL
820
SET MOTOR SPEED AND TARGET PISTON TRAVEL DISTANCE
830
INDICATE TO USER CYCLE TIME AND SUCTION LEVEL
840
ACTUATE MOTOR CAUSING PISTON TO MOVE TOWARD BOTTOM OF CYLINDER
850
MONITOR HOME SWITCH
855
HAS HOME SWITCH BEEN TRIGGERED
860
NO
YES
RESET HOME SWITCH
870
ACTUATE MOTOR CAUSING PISTON TO MOVE TOWARD BOTTOM OF CYLINDER
880
COUNT RACK OPENINGS WITH PHOTO - SENSOR
890
IS NUMBER OF OPENINGS EQUAL TO TARGET PISTON TRAVEL DISTANCE
900
NO
YES
IS BREAST PUMP STILL ON
910
NO
YES
END PUMP OPERATION
915
HAS USER INPUTTED DIFFERENT CYCLE TIME OR SUCTION LEVEL
920
NO
YES

Fig. 14

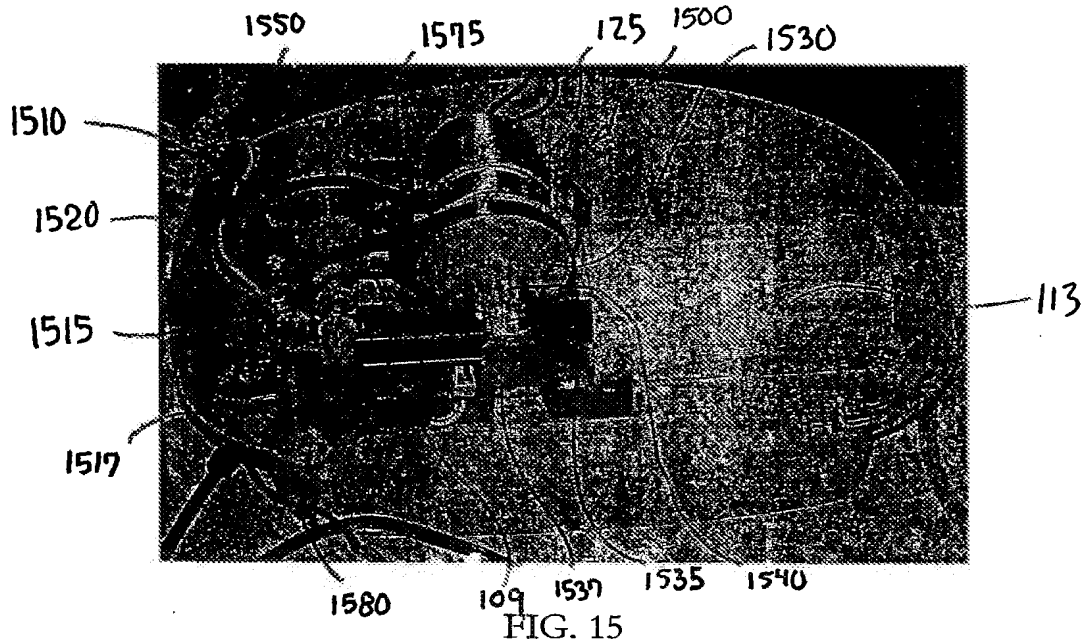
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FIG. 15

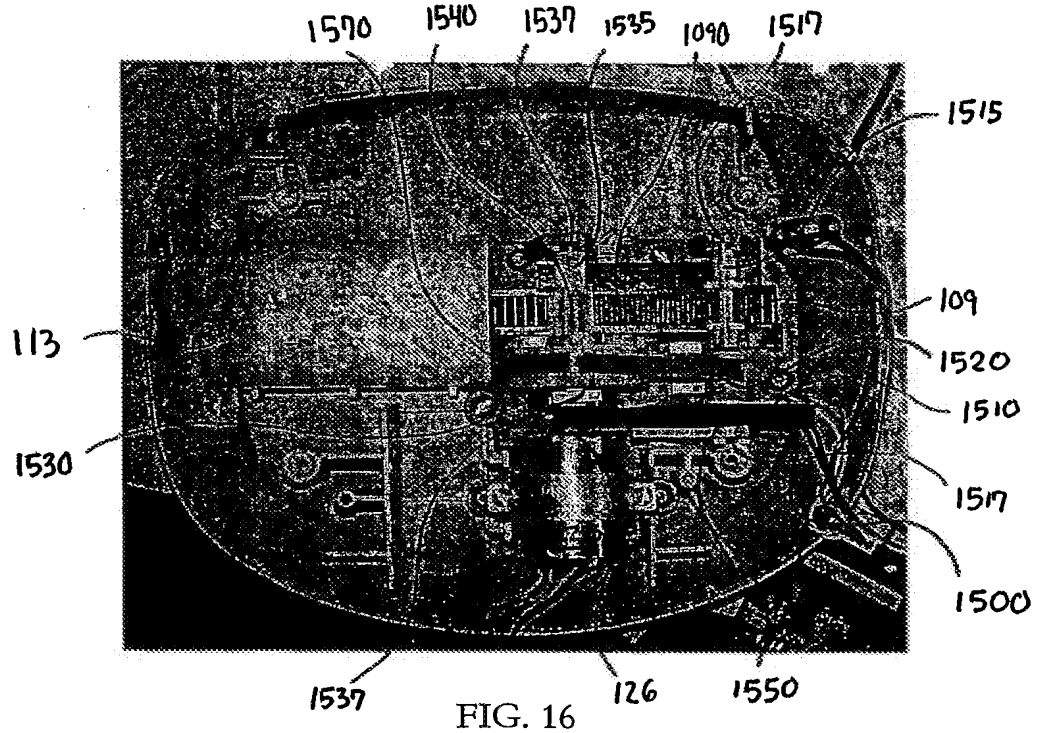
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FIG. 16

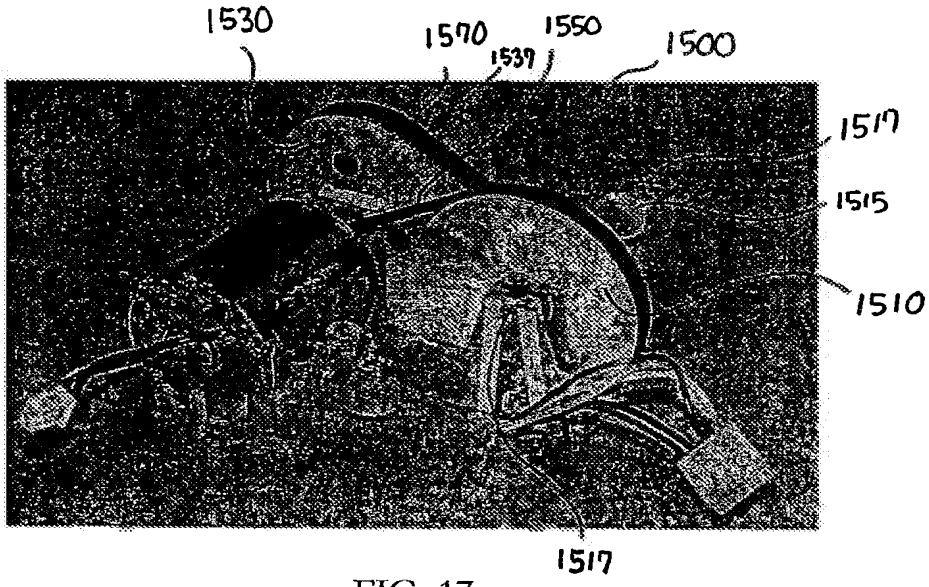
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FIG. 17

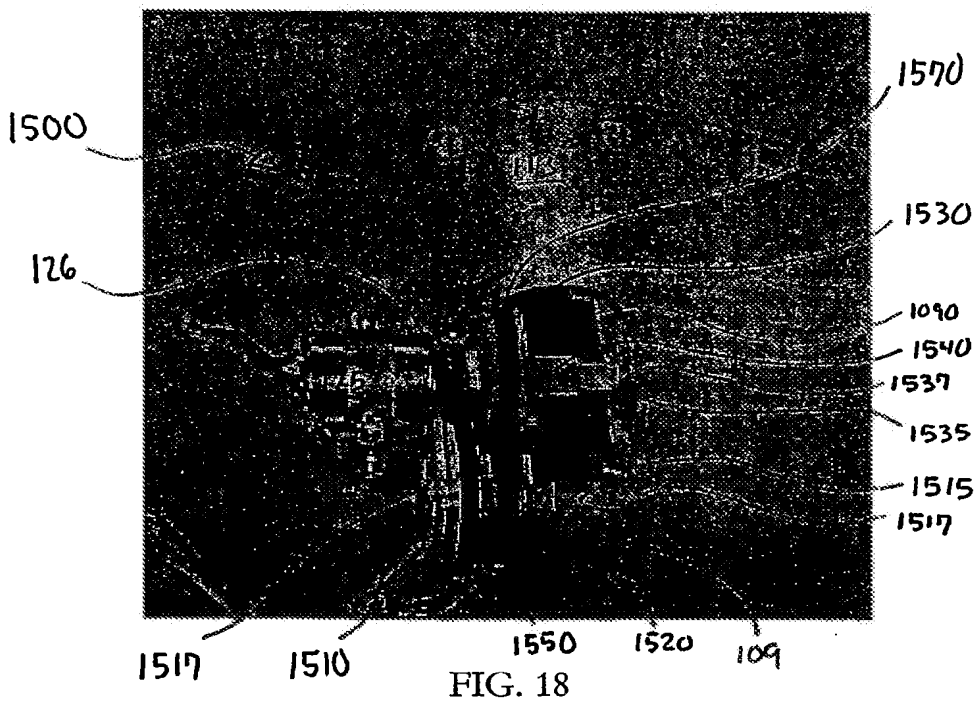
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FIG. 18

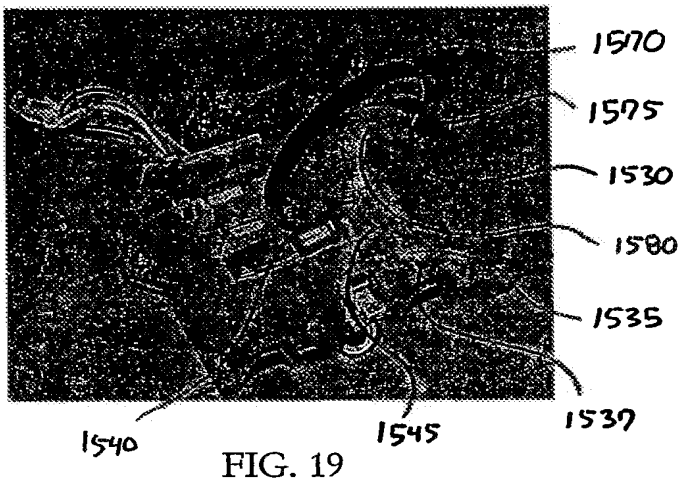
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FIG. 19

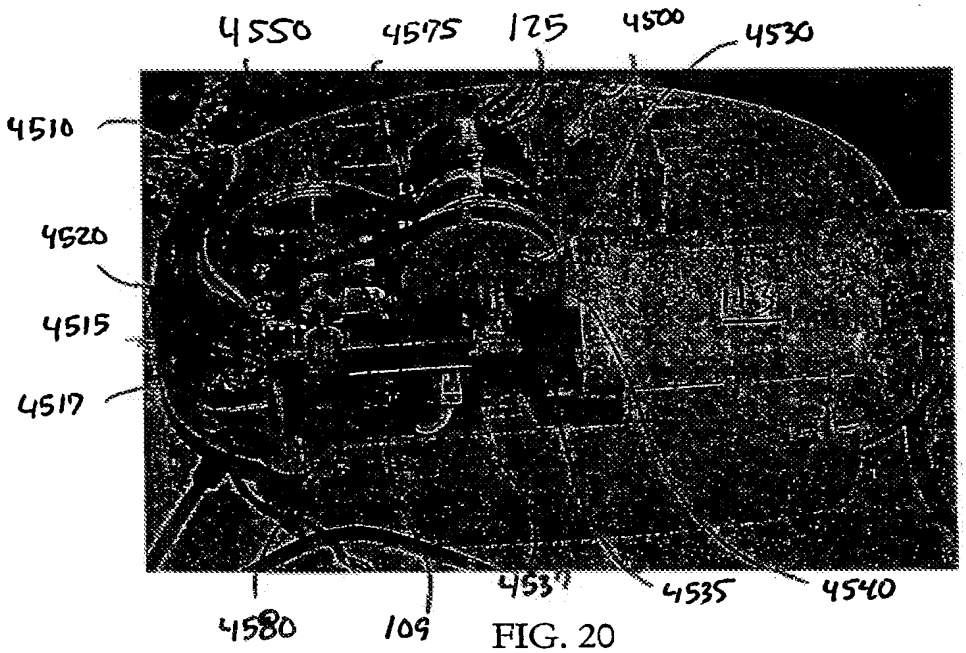
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FIG. 20

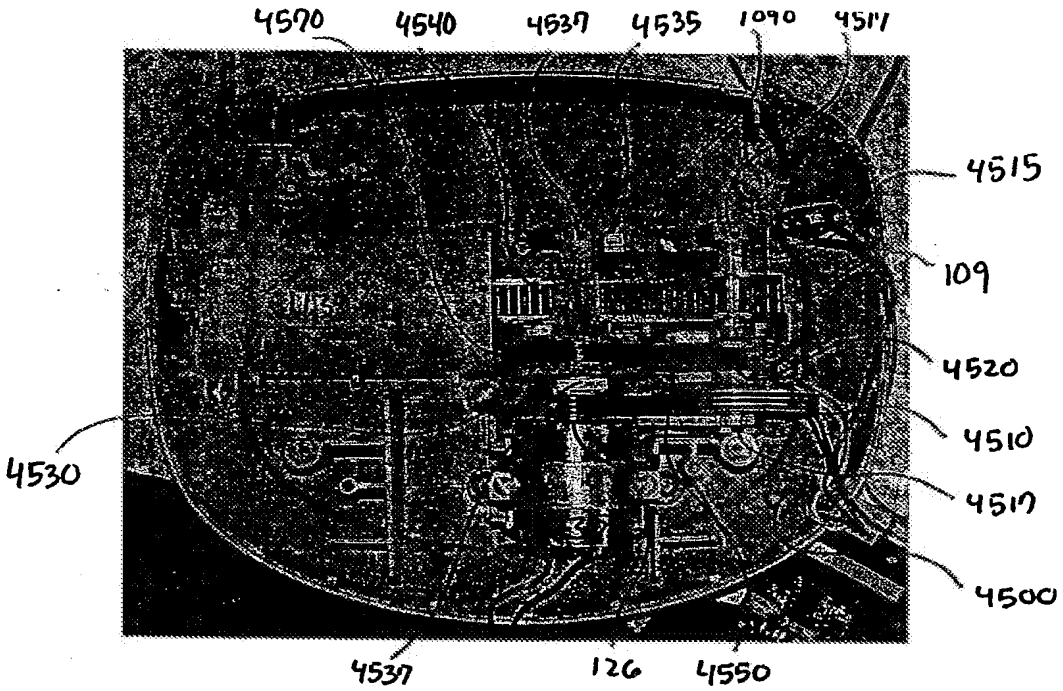
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FIG. 21

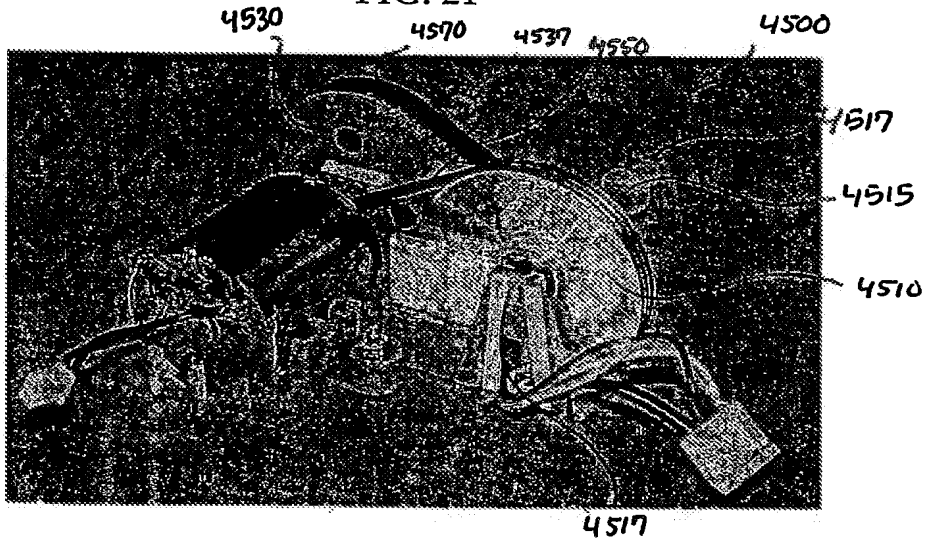
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FIG. 22

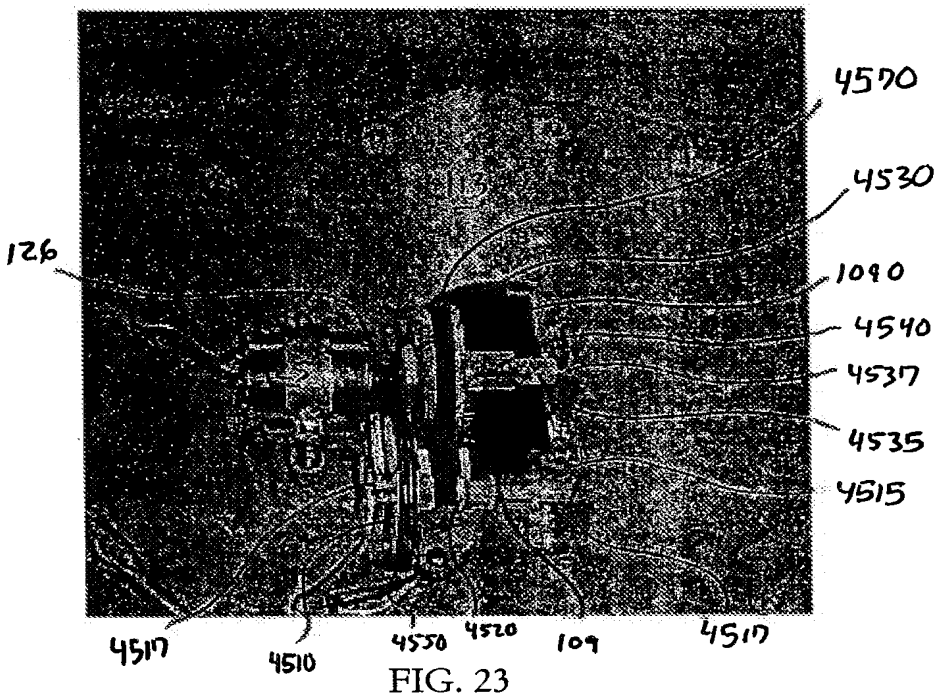
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FIG. 23

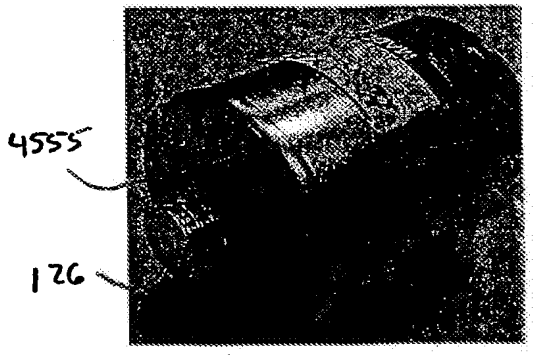
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FIG. 24

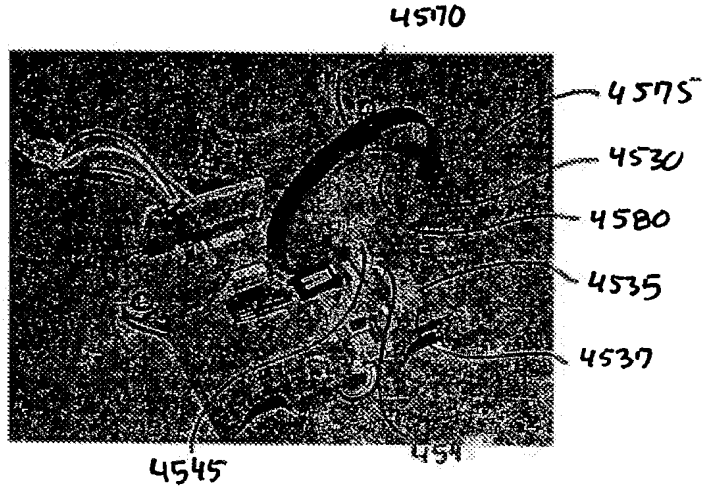
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FIG. 25

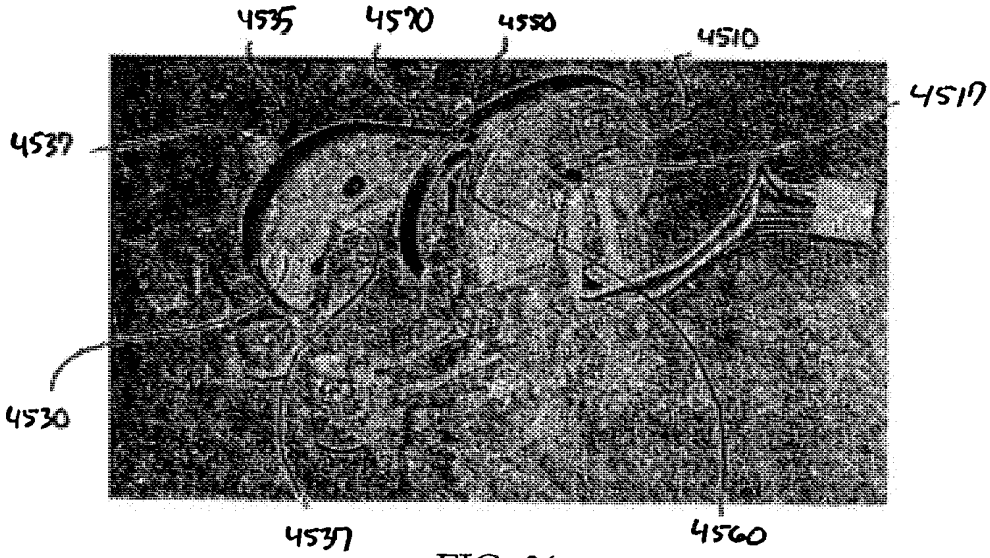
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FIG. 26

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ABSTRACT JP2016526396A

[]

13 The invention is an apparatus 1 for discharging a system 3, comprising a pump 5 suitable to be connected with said system 3 by a pump inlet 7, a pressure tank 11 and a directional control valve 13. , the pump 5 transports the medium from the system 3 and the pressure tank 11 to the external environment when the pressure tank 11 is connected to the pump inlet 7, and the directional control valve 13 is activated when predetermined criteria are met. , to a device arranged to switch the pressure tank 11 from the inlet 7 to the outlet 9 of the pump 5 . The invention further relates to a milking device 31 comprising an appliance 1 for emptying the system 3 and a receiving funnel 27 for receiving a female breast.

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(51)Int.Cl.		F I		テーマコード（参考）
A61M 1/06	(2006.01)	A61M	1/06	4C077

審査請求 有　予備審査請求 未請求　（全 20 頁）

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(33)優先権主張国　欧州特許庁 (EP)

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最終頁に続く

(54)【発明の名称】システムから排出するための機器及び方法

(57)【要約】
本発明は、システム３から排出するための機器１であって、ポンプ入口７によって前記システム３と接続されるのに適したポンプ５と、圧力タンク１１と、方向制御弁１３と、を有し、ポンプ５は、圧力タンク１１がポンプ入口７に接続されたときに、システム３及び圧力タンク１１から外部環境へと媒体を輸送し、方向制御弁１３は、所定の基準が満たされた場合に、ポンプ５の入口７から出口９へと圧力タンク１１を切り換えるよう構成された機器に関する。本発明は更に、システム３から排出するための機器１と、女性の胸部を受容するための受容漏斗２７と、を有する搾乳装置３１に関する。

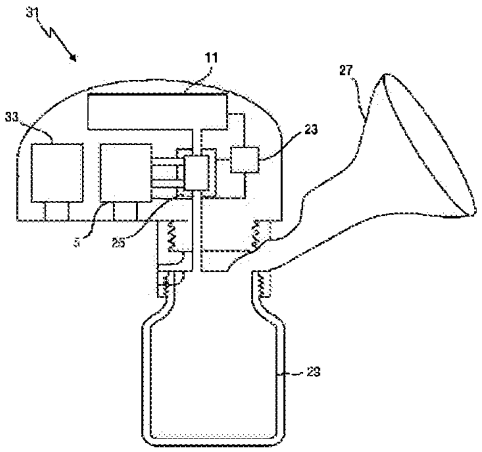

FIG.7

【特許請求の範囲】
【請求項１】
システムから排出するための機器であって、
ポンプ入口とポンプ出口との間の圧力の低下を生成するための、前記入口によって前記システムと接続されるのに適したポンプと、
かけられた圧力値を保持するための圧力タンクと、
前記ポンプ入口か又は前記ポンプ出口のいずれかに前記圧力タンクを切り換えるための方向制御弁と、
を有し、前記ポンプは、前記圧力タンクが前記ポンプ入口に接続されたときに、前記システム及び前記圧力タンクから外部環境へと媒体を輸送し、
前記方向制御弁は、所定の基準が満たされた場合に、前記ポンプ入口から前記ポンプ出口へと前記圧力タンクを切り換えるよう構成された機器。
【請求項２】
外部環境から前記ポンプ及び／又は前記圧力タンクへの流体の逆流を防ぐための、前記ポンプ出口と前記圧力タンクとの間に結合された一方弁を更に有する、請求項１に記載の機器。
【請求項３】
前記圧力タンクにおける圧力を決定するためのセンサを更に有する、請求項１に記載の機器。
【請求項４】
前記方向制御弁が、前記圧力タンクにおける圧力が所定の圧力閾値を下回ったときに、前記ポンプ入口から前記ポンプ出口へと前記圧力タンクを切り換えるよう構成された、請求項３に記載の機器。
【請求項５】
前記ポンプのスループットを決定するためのセンサを更に有する、請求項１に記載の機器。
【請求項６】
前記方向制御弁は、前記ポンプの前記スループットが所定のスループット閾値を超えたときに、前記ポンプ入口から前記ポンプ出口へと前記圧力タンクを切り換えるよう構成された、請求項５に記載の機器。
【請求項７】
前記システムから及び／又は前記圧力タンクから外部環境へと圧力を放出するための放出弁、及び／又は、前記圧力タンクから前記ポンプ出口への輸送される媒体の流量を制御するための流量制限器、を更に有する、請求項１に記載の機器。
【請求項８】
前記ポンプは、前記ポンプ入口から前記ポンプ出口へと、流体、特に気体を移動させるための、容積移送式ポンプである、請求項１に記載の機器。
【請求項９】
前記ポンプは、電動ポンプ、又は人間の手及び／又は足の動きによって駆動される機械式ポンプである、請求項１に記載の機器。
【請求項１０】
前記方向制御弁と前記一方弁とが、スマート弁に組み合わせられた、請求項２に記載の機器。
【請求項１１】
前記方向制御弁は、３つのポート及び２つの切り換え位置を持つ３／２弁である、請求項１に記載の機器。
【請求項１２】
前記方向制御弁は、電気的又は機械式に動作させられる弁である、請求項１に記載の機器。
【請求項１３】

前記ポンプ及び／又は前記方向制御弁を制御するためのコントローラを更に有する、請求項１に記載の機器。
【請求項１４】
請求項１に記載の機器と、女性の胸部を受容するための受容漏斗及び母乳を集めるための母乳槽を含むシステムと、を有する搾乳装置。
【請求項１５】
搾乳装置を制御するための方法であって、
システムにおける及び圧力タンクにおける圧力の低下を生成するためのポンプであって、前記圧力タンクがポンプ入口に接続されたときに、前記システム及び前記圧力タンクから外部環境へと媒体を輸送するポンプを構成するステップと、
所定の基準が満たされているか否かを決定するステップと、
前記所定の基準が満たされている場合、前記ポンプ入口からポンプ出口へと前記圧力タンクを切り換えるよう方向制御弁を構成するステップと、
を有する方法。
【発明の詳細な説明】
【技術分野】
【０００１】
本発明は、システムから排出するための機器、搾乳装置、及び搾乳装置を制御するための方法に関する。
【背景技術】
【０００２】
多くの用途において、種々の工業的、科学的及び医学的工程のため、（不完全な）真空を提供するための真空ポンプが必要とされる。これら種々の工程は、広範な種々のポンプタイプ及びポンピング原理に導く、種々の真空レベルを必要とする。真空ポンプの２つの主なパラメータは、達成可能流量及び達成可能真空レベル（即ち圧力レベル）である。いずれのポンピング原理も、特有の利点及び欠点を持ち、いずれの用途も、ポンプに対する特有の要件を持つ。通常、高いレベルの真空又は高い流量を提供することが可能なポンプは、大型であり、製造が難しいものである。従って、特定の用途のために真空ポンプを選択又は製造する際に、必要とされる流量、最高真空レベル、製造コスト、製造サイズ及びその他のパラメータの間に、妥協点が見出される必要がある。
【０００３】
真空ポンプのための一用途領域は、搾乳装置、即ち授乳中の女性の胸部から母乳を抽出するための装置の分野である。斯かる装置は通常、胸部から母乳を吸い出すため、女性の胸部に当てられる、（不完全な）真空をもたらすための真空ポンプを含む。国際特許出願公開WO2012/127405A1は、負圧を生成するよう動作可能な搾乳装置を開示している。搾乳装置によって実現され得る最大負圧は、使用される（不完全）真空ポンプが提供できる最大圧力値の関数である。高いレベルの真空が必要とされる場合には、通常は搾乳装置を大型化させ及び／又は製造するのが高価なものとしてしまう、異なるタイプのポンプが必要となる。
【０００４】
米国特許出願公開US2005/0283112A1において、搾乳器が開示されている。該装置は、胸部の乳頭上にフィットするよう適合された胸部シールドと、該胸部シールドに結合された流線と、を含む。該流線は、該流線を介して該胸部シールドに結合されたポンプを通して、空気が該流線を流れることを可能とするよう構成される。該ポンプは、ポンプ入口とポンプ出口とを含み、乳頭と該ポンプとの間に圧力降下を生成するよう動作可能であり、該圧力降下が、該流線における空気の圧力を低下させることによって該胸部シールドにおける吸引力を生成する。該流線と該ポンプとの間にブローバック弁が備えられ、該ブローバック弁は、弁ハウジングに配置された弁ピストンを持つ。該弁ハウジングは、該流線を介して該胸部シールドと連通する流線開口と、外部と該流線とを連通するよう構成された弁入口と、外部と該流線とを連通するよう構成された弁出口と、を含む。弁ピストンは、該

弁入口と該弁出口とを二者択一的に封止するよう構成される。

【０００５】

米国特許出願公開US2013/0165852A1においては、電気搾乳ポンプが開示されている。該ポンプは、電気モータと、該モータにより駆動されるポンプと、吸引カップと、吸引線における電気的に作動させられる第１の三方弁と、圧力線における電気的に作動させられる第２の三方弁と、電子制御システムと、を持ち、該電子制御システムが、スイッチの作動に依存して、電気モータを動作モード又はアイドリングモードに設定する。動作モードにおいては、電気モータがスイッチオンされ、ポンプの入口が第１の三方弁及びフロート弁を介して吸引カップに接続され、ポンプ出口が第２の三方弁を介して接続される、吸引フェーズを有するサイクルで、電気モータ並びに電気的に作動させられる第１及び第２の三方弁を動作させる。

【発明の概要】

【発明が解決しようとする課題】

【０００６】

本発明の目的は、コスト効率の良い製造及び小型の筐体における実装を可能としつつ、システムから排出し、適切な真空レベルを実現するための装置を提供することにある。本発明の更なる目的は、搾乳装置及び搾乳装置を制御するための方法を提供することにある。

【課題を解決するための手段】

【０００７】

本発明の第１の態様においては、システムから排出するための機器であって、ポンプ入口とポンプ出口との間の圧力の低下を生成するための、前記入口によって前記システムと接続されるのに適したポンプと、かけられた圧力値を保持するための圧力タンクと、前記ポンプ入口か又は前記ポンプ出口のいずれかに前記圧力タンクを切り換えるための方向制御弁と、を有し、前記ポンプは、前記圧力タンクが前記ポンプ入口に接続されたときに、前記システム及び前記圧力タンクから外部環境へと媒体を輸送し、前記方向制御弁は、所定の基準が満たされた場合に、前記ポンプ入口から前記ポンプ出口へと前記圧力タンクを切り換えるよう構成された機器が提供される。

【０００８】

本発明の更なる態様においては、以上に説明された機器と、女性の胸部を受容するための受容漏斗と母乳を集めるための母乳槽とを含むシステムと、を有する搾乳装置が提供される。

【０００９】

本発明の更に他の態様においては、搾乳装置を制御するための方法であって、システムにおける及び圧力タンクにおける圧力の低下を生成するためのポンプであって、前記圧力タンクがポンプ入口に接続されたときに、前記システム及び前記圧力タンクから外部環境へと媒体を輸送するポンプを構成するステップと、所定の基準が満たされているか否かを決定するステップと、前記所定の基準が満たされている場合、前記ポンプ入口からポンプ出口へと前記圧力タンクを切り換えるよう方向制御弁を構成するステップと、を有する方法が提供される。

【００１０】

本発明の好適な実施例は、従属請求項に定義される。請求される方法及び搾乳装置は、請求される機器及び従属請求項において定義されるものと同様の及び／又は同一の好適な実施例を持つことは理解されるべきである。

【００１１】

本発明による機器は、方向制御弁及び付加的な圧力タンクの利用によって、達成される真空レベルの増大を実現する。前記ポンプは、内側から外側へと媒体を輸送し、それによりこれらの間の圧力低下を生成する。輸送される媒体は、いずれの種類の流体即ち気体又は液体を含んでも良く、ポンプによってシステムから輸送されて出されるときに、該システムにおける圧力低下を引き起こす。ポンプの出口が外部環境と接続され、輸送される媒

体が外部環境へと放出される場合には、システム中の圧力は、外部環境の圧力に比べて低下する。

【００１２】

本発明によれば、該ポンプは、媒体をシステムから輸送するのみならず、圧力タンクに含まれる媒体をも輸送し、それによりシステム中の圧力及び圧力タンク中の圧力の両方が減少する。斯くして、該システム及び該圧力タンクの両方から、該ポンプによって吸い出されることとなる。

【００１３】

該圧力タンク（真空タンクとも呼ばれる）は、該タンクの内側及び外側において変化する圧力値にかかわらず変化しない一定値を提供することにより、かけられた（低）圧力値を保持することを可能とする。斯かる圧力タンクのとり得る実施例は、例えば、ポンプに接続されるべき単一の開口を備えた、剛性の気密な柔軟性のない金属体であっても良い。更に、本文脈においては、かけられた圧力値を保持するとは、例えば、圧力タンクから媒体を吸い出し、次いで圧力タンクの開口を閉じ又は封止し、圧力補償が実行される（例えばタンクを開いてタンク中の媒体を外部環境へと放出する又は外部環境からタンクへと媒体を通すことによって）まで該圧力タンク内の圧力を一定に保つことにより、圧力値をかける又は引き起こすことを指す。

【００１４】

圧力タンクから又は圧力タンクへと媒体をポンピングすることによって圧力タンク内の圧力を変化させる代わりに、圧力タンクを或る圧力レベル即ち圧力値に（受動的に）適合させ、次いで周囲の圧力が異なる領域に該タンクを輸送し、内部環境の圧力状態が保持されるようにすることも可能である。圧力タンクは、両方向に用いられることができ、即ち外部環境に対して低圧を保持することもできるし高圧を保持することもできる。

【００１５】

本発明によれば、圧力タンクは、方向制御弁によってポンプ入口又はポンプ出口に接続される。斯かる方向制御弁は、異なる経路への切り換えを可能とし、方向制御弁の設定に依存して、媒体が異なるポートへとガイドされることができる。本発明によれば、方向制御弁は特に、圧力タンクを、第１の設定においてポンプ入口に、第２の設定においてポンプ出口に切り換える機能を提供する。斯くして、圧力タンクの開口をポンプのいずれの側にも接続することが可能となる。

【００１６】

更に、本発明によれば、方向制御弁が、所定の基準が満たされたときに、斯かる切り換え手順、即ち圧力タンクをポンプの一方の側から他方へと切り換える手順を実行する。例えば、圧力タンクは最初にポンプ入口に接続され、システムからの媒体の吸い出し及び圧力タンクからの媒体の吸い出しを行わない。次いで、所定の基準が満たされるとすぐに、該圧力タンクはポンプ出口に接続される。この構成において、方向制御弁が第１の設定にある場合、ポンプはシステム及び圧力タンクから媒体を輸送して外部環境へと出す。次いで、方向制御弁を第２の設定へと切り換えた後には、媒体はポンプ入口において該システムから輸送され、ポンプ出口において圧力タンクへと輸送される。

【００１７】

本発明による機器の利点のひとつは、生成される圧力の低下又は全体的な低下が促進されることである。最初にポンプが、外部環境と該システム及び圧力タンクとの間に一定の圧力の低下を生成する。所定の基準が満たされるとすぐに、即ち圧力レベルがもう低下させられなくなると、方向制御弁によって該圧力タンクはポンプ出口に切り換えられる。切り換えの直後、このことはポンプ入口とポンプ出口における圧力の平衡に帰着する。次いで、ポンプ出口における圧力レベルが既に外部環境における圧力レベルよりも低い場合には、ポンプは外部環境に比べて該システムにおいて更に低い圧力を生成することができることを利用する。外部環境における圧力レベルとは独立して、該ポンプはポンプ入口とポンプ出口との間に圧力の低下を生成する。斯くして、ポンプ出口における圧力レベルが既に外部環境における圧力レベルよりも低い場合には、ポンプ入口における圧力レベルを更

に低下させることが可能となる。このことは、所定の基準が満たされたときに、ポンプ入口からポンプ出口へと圧力タンクを切り換えることができる方向制御弁によって、本発明により利用される。とりわけ、該ポンプの達成可能な圧力レベル又は真空レベルは、以上に概説されたように圧力タンクを切り換えることにより向上される。達成可能な真空レベル、即ち該ポンプを用いて生成されることができる最低圧力は、元の達成可能な真空レベルに比べて向上される。

【００１８】

本発明の第１の実施例においては、前記機器は更に、外部環境から前記ポンプ及び／又は前記圧力タンクへの流体の逆流を防ぐための、前記ポンプ出口と前記圧力タンクとの間に結合された一方弁を有する。一方弁は基本的に、媒体を或る方向には通すが、他の方向に媒体が通過することを防止するものである。本発明の第１の実施例によれば、該一方弁が、ポンプ出口に配置される。斯くして、圧力タンクが方向制御弁によってポンプ出口に接続されている場合であっても、外部環境から圧力タンク又はポンプへの輸送された媒体の逆流が防止される。最初に、圧力タンクがポンプ入口に接続されている限り、該一方弁は単に外部環境からポンプ出口を封止し、ポンプにより輸送された媒体が外部環境へと逃げることを可能とする。しかしながら、該一方弁の方向に反して、外部環境からポンプへと又は該システムへと媒体が逆流することはできない。次いで、以上に説明されたように、圧力タンクがポンプ入口からポンプ出口へと切り換えられるとすぐに、該一方弁は、外部環境から圧力タンクへ媒体が逆流することも防止する。この構成においては、ポンプ出口及び圧力タンクは、外部環境から一方向的に分離される。当該一方弁の利点のひとつは、外部環境における圧力に比べて圧力が保持されることができる点である。

【００１９】

本発明の更なる実施例によれば、前記機器は、前記圧力タンクにおける圧力を決定するためのセンサを有する。当該圧力センサは、例えば容量式、電磁式、圧電式又はピエゾ抵抗式の測定原理に基づくものであっても良く、該圧力タンク中の媒体又は流体の圧力についての情報を提供することができる。該センサは、該圧力タンクにおける絶対圧力についての情報を有するディジタルの補正された出力信号を提供するスマートセンサであっても良いし、又は該圧力タンクにおける圧力に依存した信号のアナログ値を提供するアナログセンサであっても良い。該センサにより生成された信号は、例えば該機器の特定のパラメータが、得られたセンサ信号に基づいて直接に構成される、閉ループ制御の使用を可能とすることによって、本発明による機器を制御することを可能とする。

【００２０】

当該センサの使用の一例は、本発明の他の実施例において更に詳細化され、前記方向制御弁が、前記圧力タンクにおける圧力が所定の圧力閾値を下回ったときに、前記ポンプ入口から前記ポンプ出口へと前記圧力タンクを切り換えるよう構成される。斯くして、以上に説明されたセンサにより決定される該圧力タンクにおける圧力は、ポンプ入口からポンプ出口への圧力タンクの切り換えがいつ実行されるべきかを決定するための基準として用いられる。特定の圧力閾値レベル即ち所定の閾値を定義することにより、該圧力タンクがポンプ入口に接続されている間、方向制御弁の構成が、該システムにおける圧力と同等である圧力タンクにおける現在の圧力と直接に関連付けられることができる。当該所定の閾値は、例えば達成可能な最大圧力差又は最大真空レベルといった、該ポンプの特性に依存して選択されても良い。選択された設定に依存して、本実施例の利点のひとつは、切り換え工程の制御が簡便となり、容易に実現され得ることである。

【００２１】

更に、本発明の他の実施例によれば、前記機器は、前記ポンプのスループットを決定するためのセンサを更に有する。斯かるスループットセンサは、例えば１つ又は複数の圧力センサ、熱流量計、力学的正変位計、又はその他のいずれかの流量センサ若しくは流量計として実現される流量センサであっても良い。当該流量センサは基本的に、以上に説明された圧力タンクにおける圧力を決定するためのセンサに代わるものとして用いられることができる。同等の機能が実現され得る。好適にも、ポンプのスループットを決定するため

の斯かるセンサの使用は、更なるユーザ入力の必要なく、切り換え手順を自動的に起動することを可能とする。

【００２２】

本発明の好適な実施例においては、前記方向制御弁は、前記スループットが所定のスループット閾値を超えたときに、前記ポンプ入口から前記ポンプ出口へと前記圧力タンクを切り換えるよう構成される。以上に説明されたように、ポンプのスループットを決定するための当該センサの測定値が評価され、得られたセンサ値が圧力タンクがポンプ入口からポンプ出口へと切り換えられるべきか否かを決定するための基準として用いられる。とりわけ、当該原理は、閾値即ち切り換えが実行されるべきスループット値が、ポンプの特性に基づいて決定される場合に、用いられても良い。当該閾値のとり得る設定のひとつは、該ポンプにより実現され得る最大スループットに対する特定の割合であっても良い。斯くして、ポンプが比較的低い効率で動作するとすぐに、圧力タンクが前記入口から前記出口へと切り換えられ、ポンプのスループットが増大させられる。最大の全圧低下が到達されるとすぐに、該センサは再び少ない流量のみを記録することとなる。

【００２３】

本発明の別の実施例においては、前記装置は更に、前記システムから及び／又は前記圧力タンクから外部環境へと圧力を放出するための放出弁を有する。幾つかの用途においては、意図される利用を継続するために、該システムから圧力又は特に真空を外部環境へと放出することが可能であることが必要となる。斯かる放出弁は、電気的に動作させられても良いし又は手動で動作させられても良く、単純なバタフライ弁又はその他のいずれのタイプの弁の形をとって実現されても良い。例えば圧力タンクが現在ポンプ出口に接続されている場合、当該放出弁の装着位置に依存して、該システム及び圧力タンクから又は該システムのみから圧力を放出することが可能となる。これにより該放出弁は好適にも、該システム又は圧力タンクと外部環境との間の圧力差の他にはいずれの外部入力をも必要とせずに、自動的に動作させられる。該放出弁はこのとき、ポンプの故障又は制御されない挙動の場合に、該システム又はタンクが過度に低い／高い圧力となることを防止する安全弁として機能することができる。例えば該排出システムが搾乳装置の母乳槽である場合、斯かる安全弁はユーザに害を及ぼすことを防止することができる。

【００２４】

本発明によるシステムから排出するための機器は更に、前記圧力タンクから前記ポンプ出口への輸送される媒体の流量を制御するための（任意に調節可能な）流量制限器を有する。斯かる流量制限器は、特に最大スループットの制限を可能とすることにより、より平滑な及び／又はなだらかなポンプ曲線を実現する。

【００２５】

本発明の好適な実施例においては、前記ポンプは、前記ポンプ入口から前記ポンプ出口へと、流体、特に気体を移動させるための、容積移送式真空ポンプである。当該ポンプは、本発明の別の実施例においては、電動ポンプか又は人間の手及び／又は足の動きによって動かされる機械式ポンプのいずれかであっても良い。用途に応じて、異なるタイプのポンプはそれぞれの利点及び欠点を持つ。とりわけ、気体が即ち気体分子がポンプ入口からポンプ出口へとポンピングされるべき場合には、容積移送式真空ポンプは有利である。斯かる容積移送式真空ポンプは、所与の容積の拡大に依存し、これにより該拡大させられた容積内の圧力が低下させられる。次いで、該容積の一部が分離され、再び拡大させられる。この手順は、数回繰り返されることにより真空のレベルを増大させても良く、気体をポンピングする際には容易に実装されることができる。このとき、主な関心事は、該ポンプが生成することができる真空レベル、即ち容積当たりに残る分子の最小の数である。斯かる容積移送式真空ポンプの利点のひとつは、単純な構成及び市場での入手可能性である。

【００２６】

どのポンピング原理が利用されるかにかかわらず、該機器に含まれるポンプは、例えばプロセッサ装置により制御されても良いし又は直接的なユーザインタフェースを提供しても良い、バッテリ又は電源により電力供給される電動ポンプであっても良い。代替として

は、該機器が、いずれの電気エネルギーも必要とはしないが、例えば人間の手及び／又は足の動きによる、手動の電力変換により電力供給を受けることができる、機械式ポンプを有することも可能である。斯かる機械式ポンプの可能性のひとつは、周期的に動かされ、例えば以上に説明された容積移送式原理のようなポンピング機構を動きに変換する、ハンドル部の使用である。機械式ポンプの利点は、バッテリの充電又はケーブル接続の利用を必要としない点を含む。また、故障のリスクや、例えば搾乳装置の場合にユーザを傷つけてしまリスクも軽減される。他方で、電動ポンプは、より使用が便利となり得る。

【００２７】

本発明の他の好適な実施例においては、方向制御弁と一方弁とがスマート弁へと組み合わせられる。斯かるスマート弁は、制御弁の機能と一方弁の機能とを１つの構成要素へと組み合わせる統合された部分であっても良い。２つの弁を１つの構成要素へと組み合わせることの利点は、構造的空間が削減され得る点である。更に、機器の構成要素の数が最小化されると、コストを低減することも可能となり得る。斯かるスマート弁は、更に放出弁を含んでも良く、これにより更に構成要素の数を削減しても良い。更に、安全弁の機能、即ち該機器のユーザ又は該機器自体の保護が、該スマート弁に組み込まれても良い。斯かるスマート弁は、完全に機械式に制御されても良く、圧力差及び機械的な利用に基づいて機能する、即ち特定の圧力差が材料を変形させ圧力を外部環境へと逃がすよう機能しても良い。該スマート弁はまた、圧力タンクとポンプとの間の流れを制御するための、調節可能な流量制限器を含んでも良い。

【００２８】

他の実施例においては、前記方向制御弁は、３つのポート及び２つの切り換え位置を持つ３／２弁である。斯かる３／２弁は基本的に、ポンプ入口からポンプ出口への圧力タンクの切り換えのために必要とされる機能を提供する、標準的な構成要素である。３／２弁の利点は、ポンプ入口からポンプ出口への圧力タンクの切り換えの機能が、単一の部品で実現され得る点である。ここでもまた、当該３／２弁は、圧力変化によって機械式に機能しても良いし、又は、例えばコントローラ装置によって若しくはユーザ入力によって起動される切り換え手順によって電気的に機能しても良い。

【００２９】

本発明の一実施例によれば、前記方向制御弁は、電気的に動作させられる弁であっても良いし、又は機械式に動作させられる弁であっても良い。該弁が電動弁である場合、ポンプを制御し切り換え工程を自動化するためにプロセッサを用いることが可能となる。代替としては、前記方向制御弁は、機械式に動作させられても良い。この場合には例えば、圧力が特定の閾値に到達するか又は超過するとすぐに、該方向制御弁の或る位置から他の位置への切り換えを起動するため、機械式の構成が用いられても良い。また、機械式の動作は、操作者が手動でポンプ入口からポンプ出口へと圧力タンクを切り換えることを可能とすることも予想され得る。

【００３０】

本発明の別の実施例においては、前記機器は更に、前記ポンプ及び／又は前記方向制御弁を制御するためのコントローラを有する。斯かるコントローラは、例えば所望の機能を実行するようプログラムされたマイクロコントローラ装置であっても良い。当該コントローラは、本発明による機器又は斯かる機器を有する装置における種々の弁、及び／又はその他の全ての構成要素及びその相互作用を制御するために用いられることができる。斯かるコントローラの利点のひとつは、搾乳装置における他の制御動作を実行するためにも用いられ得る点である。

【００３１】

本発明の更なる態様においては、以上に説明されたシステムから排出するための機器と、女性の胸部を受容するための受容漏斗及び母乳を集めるための母乳槽を含むシステムと、を有する搾乳装置が提供される。斯かる搾乳装置は、授乳中の女性の母乳を容器即ち母乳槽に集めるために用いられることができる。本発明の本態様によれば、システムから排出するための該機器は、女性の胸部に気密に接続された容器から排出する。当該容器は、

本発明による機器により生成された真空によって胸部から吸い出された授乳中の女性からの母乳を集めるための母乳槽として機能する。胸部に対する該容器の気密接続は通常、女性の胸部を収容するための、例えばプラスチック材料からつくられた、漏斗又は漏斗型の部分によって実現される。個々のユーザの要件に応じて、異なる形状の胸部を収容できるよう、交換可能な漏斗を用いることも可能である。

【００３２】

本発明の更に他の態様によれば、以上に説明された搾乳装置を制御するための方法が提供される。搾乳装置の設計に依存して、ポンプ、種々の弁及び／又は種々のセンサは、搾乳器を制御するための方法を実行する少なくとも１つのコントローラにより制御されても良い。斯かるコントローラは、必要な計算及び制御動作を実行するのに適したマイクロプロセッサ又はディジタル信号プロセッサであっても良い。該コントローラは、本発明による機器のそれぞれの弁、前記装置及び／又はセンサに接続されても良い。本発明による搾乳装置を制御するための方法は、決定された設定が、センサ値に直接に関連付けられる閉ループ制御に対応しても良いし、又はユーザフィードバックを含む開ループ制御に対応しても良い。斯かる方法の利点のひとつは、本発明による機器の又は搾乳装置の全ての機能が、適切に制御される及び／又は自動的に実行されることができる点である。種々の制御ステップを実行するために、ユーザ入力が必要ないか又は殆ど必要ない。

【００３３】

本発明のこれらの及び他の態様は、以下に説明される実施例を参照しながら説明され明らかとなるであろう。

【図面の簡単な説明】

【００３４】

【図１】本発明の第１の実施例の模式的な図を示す。

【図２】本発明により生成されるシステムにおける圧力減少の例を示す。

【図３】本発明の他の実施例の模式的な図を示す。

【図４】本発明の更なる実施例の模式的な図を示す。

【図５】本発明による機器の代替例の図を示す。

【図６】搾乳装置を制御するための方法を示す。

【図７】本発明の一態様による搾乳装置を示す。

【発明を実施するための形態】

【００３５】

図１において、本発明の第１の実施例によるシステムから排出するための機器１ａが模式的に示されている。機器１ａは、ポンプ入口７とポンプ出口９との間の圧力の減少をもたらすポンプであって、ポンプ入口７によってシステム３と接続された、ポンプ５を有する。ポンプ５は斯くして、ポンプ入口７からポンプ出口９へと媒体を輸送し、それにより圧力の減少をもたらす。機器１ａは更に、或る期間の間、かけられる圧力を保持することを可能とする、圧力タンク１１を有する。更に、ポンプ５の入口７か又は出口９へと圧力タンク１１を切り換えるための、方向制御弁１３が備えられる。本発明による機能を提供するため、即ちポンプ５のみを用いた場合と比べて高いレベルの真空を生成することを可能とするため、方向制御弁１３は、所定の基準が満たされたときに、ポンプ５の入口７から出口９へと圧力タンク１１を切り換えるよう構成される。それ故、方向制御弁１３は、媒体の吸入を可能とし、異なる構成に切り換えられることができる、異なる接続ポート即ち開口を提供する。

【００３６】

本発明の図示された実施例においては、方向制御弁１３は特に、３つのポートを持つ。これら３つのポートは、ポンプ入口７か又はポンプ出口９が圧力タンク１１に結合されるよう、切り換えられることができる。本文脈において、結合されるとは、方向制御弁１３の現在の設定に依存して、方向制御弁１３の或るポートから別のポートへと媒体が流れることができるよう接続されることを示す。当該切り換え機能を提供するため、方向制御弁は例えば、或る位置から別の位置へと機械式に又は電気的に動かされ、それにより或る経

路又は別の経路を通って媒体が流れることを可能とするスプールを円筒のなかに有する。

【００３７】

以上に概説されたように、本発明による機器は、ポンプ５のみを用いる場合と比べて、高いレベルの真空を実現することを可能とする。通常、ポンプ５は、該ポンプがポンプ入口７とポンプ出口９との間に生成することができる達成可能な最大の圧力低下によって特徴付けられる。斯くして、ポンプ５の出口９において既に低い圧力がかけられているとき、ポンプ５の入口における達成可能な圧力レベルは、ポンプ５の出口９が外部環境に直接に接続されている場合よりも高い。この挙動が、本発明により利用される。最初に、システム３及び圧力タンク１１の両方がポンプ５によって吸引され、システム３及び圧力タンク１１の両方において同じレベルの圧力（圧力レベル）が生成される。次いで、方向制御弁１３によって、圧力タンク１１がポンプ５の入口７からポンプ５の出口９へと切り換えられる。このことは、ポンプ５のみを用いる場合と比べて、システム３において更に高い真空レベル（低い圧力）を生成することを可能とする。

【００３８】

図２は、本発明による機器により生成される典型的な圧力低下を示す。圧力ｐは、時間ｔの関数として示されている。最初、システム３及び圧力タンク１１における圧力は、外部環境における圧力ｐ１と平衡状態にある。次いで、ｔ１においてポンプ５がスイッチオンされ、システム３及び圧力タンク１１の両方において圧力の低下をもたらす。特定の時点ｔ２において、この構成において達成可能な最高の真空レベルｐ２が到達される。ポンプ５の構成パラメータにより、ポンプ５はより高いレベルの真空（より低い圧力）を生成することはできない。所定の基準が満たされるとすぐに、方向制御弁１３が、圧力タンク１１をポンプ５の入口７から出口９へと切り換える。当該所定の基準は、例えば圧力閾値であっても良い。当該切り換えによって、該ポンプの入口７及び出口９における圧力レベルは一時的に再び平衡状態となる。ポンプ５はこのとき、システム３において更に高いレベルの真空（即ちより低い圧力）をもたらすことができる。しかしながら、この構成においても、システム３において特定の圧力値ｐ３が到達されると、ポンプ５は飽和状態となる。図２において、ｔ３においてポンプ５がスイッチオフされる及び／又は放出弁が開かれると、外部環境との圧力平衡に導かれる。

【００３９】

図３は、本発明による機器の別の実施例１ｂを示す。図１に示された機器１ａと比べると、ポンプ５の出口９及び圧力タンク１１に結合された一方弁１５が、更に備えられている。該一方弁１５は、輸送される媒体又はいずれかの種類の流体の、外部環境からポンプ５及び／又は圧力タンク１１への逆流を防ぐことができる。更に、圧力タンク１１のなかの圧力を決定するための第１のセンサ１７が示されている。該第１のセンサ１７は、圧力タンク１１における圧力が所定の閾値即ち圧力閾値を下回るとすぐに、ポンプ５の入口７から出口９への圧力タンク１１の切り換えを実行することを可能とする。また更に、図示される実施例は、ポンプ５のスループットを決定するための第２のセンサ１９を示している。当該第２のセンサ１９は、方向制御弁１３の切り換えを起動するため、センサ１７の代替として又はセンサ１７と組み合わせて用いられても良い。明瞭な可能性のひとつは、スループットセンサ１９によってスループットを決定し、連続して該スループットが所定の閾値を下回っているか否か、即ちポンプ５が少量の流体しか輸送しておらず、以上に説明されたような飽和状態にポンプ５が事実上あるか否かを決定することである。

【００４０】

図３は更に、システム３及び／又は圧力タンク１１から外部環境へと圧力を放出するための放出弁２１を示している。該放出弁２１は、リモートコントロールを可能とする制御接続部２２を有しても良い。

【００４１】

また更に、図３は、ポンプ５、方向制御弁１３、センサ１７及び１９を制御するための、並びに制御接続部２２を介して放出弁２１を制御するための、コントローラ２３を示している。本発明による機器の更なる実施例においては、コントローラ２３は、他のセンサ

又はその他の電子的に制御可能な構成要素をも制御しても良い。とりわけ、ポンプ５は、コントローラ２３により生成される特定の制御パルス又はその他の信号を必要とする、電動ポンプ又は機械式ポンプであっても良い。

【００４２】

該コントローラは、本発明の他の態様による搾乳装置の他の機能をも制御する、組み合わせられたコントローラであっても良く、これにより、ユーザフィードバックに応答して、吸引サイクル又はかけられる圧力の変動、信号若しくはユーザインタフェースに応じた機能の自動的な中断、又はその他の機能を可能としても良い。

【００４３】

本発明による機器の更に他の実施例１ｃが、図４に模式的に示されている。本実施例においては、機器１ｃは、方向制御弁１３、一方弁１５及び放出弁２１の機能を組み合わせた、スマート弁２５を有する。該スマート弁２５は、ポンプ５の入口７及び出口９、並びに圧力タンク１１に接続されている。種々の所望の機能を提供するためスマート弁２５を用いる主な利点のひとつは、複数の部品の代わりに１つの部品のみしか必要とされない点である。このことは、本発明による機器の、より安価な実装を可能とし得る。更に、斯かる統合された部品によって、故障率が低下させられ得る。スマート弁２５は更に、速度制御のための流量制限器を含んでも良い。

【００４４】

図５において、本発明による機器の実施例１ｄの更に他の模式的な図が示されている。方向制御弁１３は、種々の部分及びとり得る切り換え機能を強調するため、更に詳細化して示されている。斯かる３／２弁、即ち三方二位置方向制御弁は、ポンプ５の入口７から出口９へと圧力タンク１１を切り換えるための所望の機能を提供する。更に、本実施例においては、該方向制御弁とポンプ５の出口９との間に、調節可能な流量制限器２６が配置される。該調節可能な流量制限器は、特に最大スループットを調節可能に制限することにより、輸送される媒体の流量を制御することを可能とする。

【００４５】

本実施例においては、排出を実行されるべきシステム３は、漏斗２７及び母乳槽２９を有する。漏斗２７は、女性の胸部を収容する。ポンプ５により生成された不完全真空は次いで、該胸部にかけられ、母乳が搾出されることができる。該搾出された母乳は、槽２９に集められる。更に、外部環境から方向制御弁１３又はポンプ５への流体の逆流を防止するための一方弁１５が図示されている。とりわけ、本発明においては、ポンプ５は槽２９から空気を輸送して出し、該空気を一方弁１５を通して外部環境へと放出する。

【００４６】

図６において、本発明の一態様の実施例による搾乳装置を制御するための方法が示されている。斯かる方法は例えば、以上に説明された搾乳装置に含まれるコントローラにより実行されても良い。該コントローラは、より高い真空レベル（即ちより低い圧力）を達成するため、種々の構成要素（例えば弁、センサ、ポンプ又はその他）を制御しても良い。

【００４７】

図６に示された実施例によれば、ポンプは最初に、システム及び圧力タンクにおいて圧力の減少を生成するよう構成される（Ｓ１０）。ポンプのタイプ、及びコントローラへの接続のタイプに依存して、当該構成は特に、該ポンプの起動を含む。例えば該ポンプが異なるレベルで動作させられることができる場合には、当該構成はまた、適切なレベルを選択することを含んでも良い。次いで、所定の基準が満たされているか否かが決定される（Ｓ１２）。好適には、当該決定は、少なくとも１つのセンサ、特に圧力センサ又はスループットセンサから得られたセンサ値に基づく。従って、所定の基準が満たされているか否かの決定は、センサ（即ちスループットセンサ又は圧力センサ）からセンサ値を取得することを含む。このとき、該センサ値に基づいて、ことによるとユーザ入力とも組み合わせて、当該所定の基準が満たされているか否かが決定されても良い。本発明による搾乳器を制御するための方法は更に、該所定の基準が満たされている場合、ポンプの出口に圧力タンクを接続するよう、方向制御弁を切り換える（Ｓ１４）ことを有する（圧力タンクは最

初、ポンプの入口に接続されていた）。例えば該切り換えは、特定の閾値が該センサ値によって超過されたときに実行される。方向制御弁の切り換えは、必要な制御信号を接続ケーブルに送って、切り換え手順を起動することを示す。搾乳装置を制御するための該方法は更に、更なる弁（例えば方向制御弁及び／又は一方弁）及び装置（例えばポンプ）についての制御設定を決定し、該決定された制御設定に基づいてこれら弁及び装置を構成する（図示されていない）ことを有しても良い。ここでもまた、該構成は、必要な制御信号を接続ケーブルに送る（又は該信号を無線接続を介して送信する）ことを示す。該方法は、以上に概説されたように、閉ループ制御を表しても良いし、開ループ制御を表しても良い。

【００４８】

更に、本発明によるシステムから排出するための方法（図示されていない）は、システム及び圧力タンクにおける圧力の低下を生成すること、圧力タンクにおいてかけられている圧力値を保持すること、所定の基準が満たされたときに、ポンプ入口から出口へと圧力タンクを切り換えること、を有しても良い。

【００４９】

図７は、本発明の他の態様による搾乳装置３１を示す。受容漏斗２７は、女性の胸部を収容するような形状とされる。圧力低下、即ち不完全真空が胸部にかけられるとすぐに、母乳が搾出される。図７に示されるように、搾出された母乳は、槽２９に集められる。該槽は、スマート弁２５を通して該槽に接続されたポンプ５によって排出される。更に、圧力タンク１１及びコントローラ２３が含まれる。更に、種々の構成要素のために必要とされる電気エネルギーを供給するバッテリ３３が示されている。本実施例における図示されたスマート弁２５は、方向制御弁、一方弁及び放出弁の機能を包含している。該弁はまた、ポンプ５の故障の場合に、ユーザを損傷させることを防止する安全弁としても機能する。コントローラ２３は、スマート弁２５を制御し、圧力タンク１１のなかの圧力を測定し、ポンプ５を制御する。

【００５０】

図示されてはいないが、電動ポンプの代わりに機械式ポンプが用いられることも可能である。このことは、コントローラ２３が、ポンプ５に接続される必要がないことを意味する。機械式ポンプは通常、圧力の低下を生成するため、手動で力をかけるためのハンドル部を有する。更に、通常は、例えばユーザインタフェース（例えばボタン、タッチパッド、トラックボール又はその他の入力手段と組み合わせられた音響的、視覚的又は機械的なフィードバック手段）、電源（例えばバッテリ、太陽電池若しくはその他のエネルギー生成器、又は幹線電源接続器）、又は搾乳器の視覚的な知覚を改善するためのデザイン的要素のような、周辺装備（図示されていない）が備えられる。

【００５１】

ポンプの入口から出口への圧力タンクの切り換えの代わりに、或るポンプの出口が別のポンプの入口に直接に接続されるよう、複数のポンプを直列に接続することも可能である。このことは、真空レベルの向上も可能とする。

【００５２】

本発明は図面及び以上の記述において説明され記載されたが、斯かる説明及び記載は説明するもの又は例示的なものであり、限定するものではないとみなされるべきである。本発明は、開示された実施例に限定されるものではない。図面、説明及び添付される請求項を読むことにより、請求される本発明を実施化する当業者によって、開示された実施例に対する他の変形が理解され実行され得る。

【００５３】

請求項において、「有する（comprising）」なる語は他の要素又はステップを除外するものではなく、「１つの（a又はan）」なる不定冠詞は複数を除外するものではない。単一のプロセッサ又はその他のユニットが、請求項に列記された幾つかのアイテムの機能を実行しても良い。特定の手段が相互に異なる従属請求項に列挙されているという単なる事実は、これら手段の組み合わせが有利に利用されることができないことを示すものではな

い。

【００５４】

請求項におけるいずれの参照記号も、請求の範囲を限定するものとして解釈されるべきではない。

【図１】

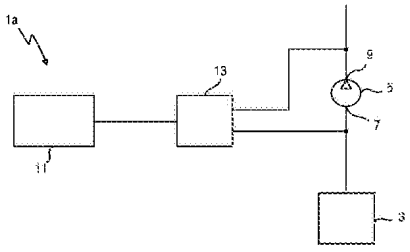

FIG.1

【図２】

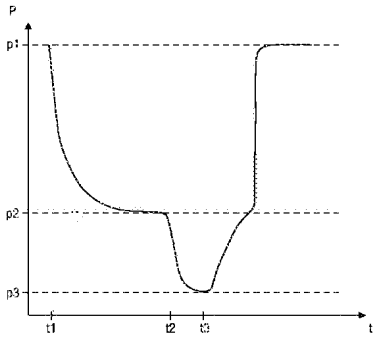

FIG.2

【図３】

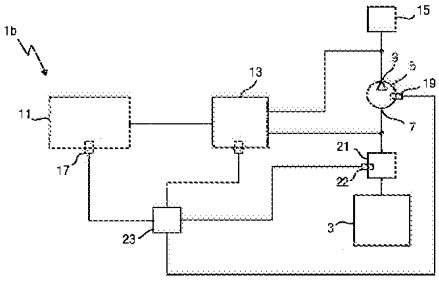

FIG.3

【図４】

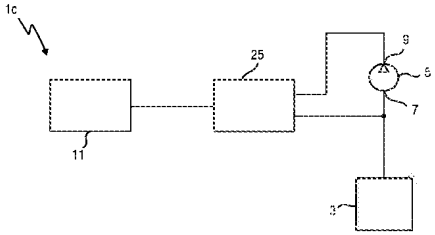

FIG.4

【図５】

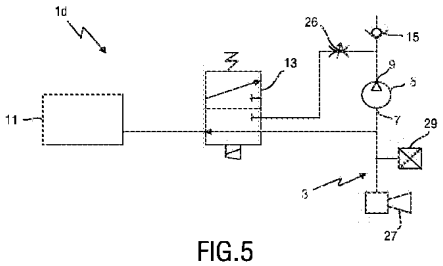

FIG.5

【図６】

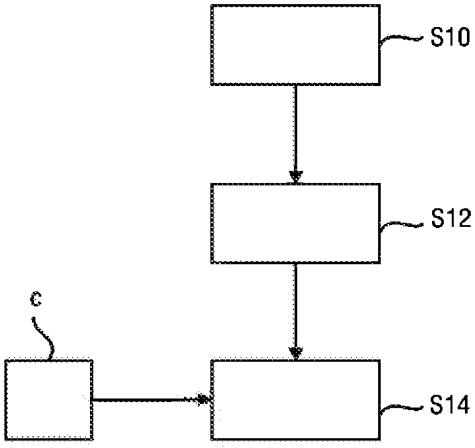

FIG.6

【図７】

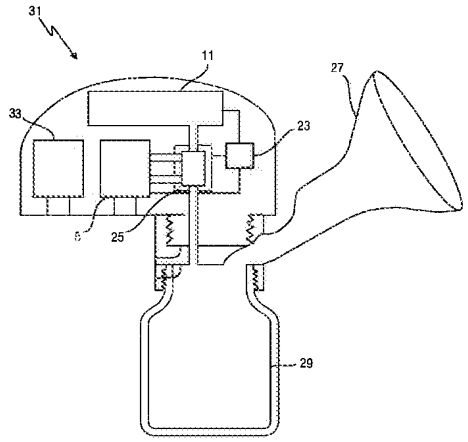

FIG.7

【手続補正書】
【提出日】平成28年1月15日(2016.1.15)
【手続補正１】
【補正対象書類名】特許請求の範囲
【補正対象項目名】全文
【補正方法】変更
【補正の内容】
【特許請求の範囲】
【請求項１】
システムから排出するための機器であって、
ポンプ入口とポンプ出口との間の圧力の低下を生成するための、前記入口によって前記システムと接続されるのに適したポンプと、
かけられた圧力値を保持するための圧力タンクと、
前記ポンプ入口か又は前記ポンプ出口のいずれかに前記圧力タンクを切り換えるための方向制御弁と、
を有し、前記ポンプは、前記圧力タンクが前記ポンプ入口に接続されたときに、前記システム及び前記圧力タンクから外部環境へと媒体を輸送し、
前記方向制御弁は、所定の基準が満たされた場合に、前記ポンプ入口から前記ポンプ出口へと前記圧力タンクを切り換えるよう構成された機器。
【請求項２】
外部環境から前記ポンプ及び／又は前記圧力タンクへの流体の逆流を防ぐための、前記ポンプ出口と前記圧力タンクとの間に結合された一方弁を更に有する、請求項１に記載の機器。
【請求項３】
前記圧力タンクにおける圧力を決定するためのセンサを更に有する、請求項１に記載の機器。
【請求項４】
前記方向制御弁が、前記圧力タンクにおける圧力が所定の圧力閾値を下回ったときに、前記ポンプ入口から前記ポンプ出口へと前記圧力タンクを切り換えるよう構成された、請求項３に記載の機器。
【請求項５】
前記ポンプのスループットを決定するためのセンサを更に有する、請求項１に記載の機器。
【請求項６】
前記方向制御弁は、前記ポンプの前記スループットが所定のスループット閾値を超えたときに、前記ポンプ入口から前記ポンプ出口へと前記圧力タンクを切り換えるよう構成された、請求項５に記載の機器。
【請求項７】
前記システムから及び／又は前記圧力タンクから外部環境へと圧力を放出するための放出弁、及び／又は、前記圧力タンクから前記ポンプ出口への輸送される媒体の流量を制御するための流量制限器、を更に有する、請求項１に記載の機器。
【請求項８】
前記ポンプは、前記ポンプ入口から前記ポンプ出口へと、流体を移動させるための、容積移送式ポンプである、請求項１に記載の機器。
【請求項９】
前記ポンプは、電動ポンプ、又は人間の手及び／又は足の動きによって駆動される機械式ポンプである、請求項１に記載の機器。
【請求項１０】
前記方向制御弁と前記一方弁とが、スマート弁に組み合わせられた、請求項２に記載の機器。

【請求項１１】
前記方向制御弁は、３つのポート及び２つの切り換え位置を持つ３／２弁である、請求項１に記載の機器。
【請求項１２】
前記方向制御弁は、電気的又は機械式に動作させられる弁である、請求項１に記載の機器。
【請求項１３】
前記ポンプ及び／又は前記方向制御弁を制御するためのコントローラを更に有する、請求項１に記載の機器。
【請求項１４】
請求項１に記載の機器と、女性の胸部を受容するための受容漏斗及び母乳を集めるための母乳槽を含むシステムと、を有する搾乳装置。
【請求項１５】
搾乳装置を制御するための方法であって、
システムにおける及び圧力タンクにおける圧力の低下を生成するためのポンプであって、前記圧力タンクがポンプ入口に接続されたときに、前記システム及び前記圧力タンクから外部環境へと媒体を輸送するポンプを構成するステップと、
所定の基準が満たされているか否かを決定するステップと、
前記所定の基準が満たされている場合、前記ポンプ入口からポンプ出口へと前記圧力タンクを切り換えるよう方向制御弁を構成するステップと、
を有する方法。

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2014/065574

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/06 F04B23/02 F04B37/14 F04B41/02
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M F04B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2005/283112 A1 (BRITTO JAMES J [US] BRITTO JAMES JOSEPH [US]) 22 December 2005 (2005-12-22) paragraphs [0018] - [0025], [0035] figures 1-3, 4c	1-15
A	US 2013/165852 A1 (JAEGER-WALDAU REINHOLD [DE]) 27 June 2013 (2013-06-27) paragraphs [0051] - [0072] figures 1a, b	1-15
A	US 2010/075285 A1 (STALLING DAVID L [US] ET AL) 25 March 2010 (2010-03-25) figure 2	1,15

-/--

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2014/065574

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

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DESCRIPTION JP2016526396A

10 Apparatus and Method for Evacuation from System

[0001]

14 The present invention relates to an apparatus for discharging from a system, a breast pump and a method for controlling a breast pump.

[0002]

19 In many applications, vacuum pumps are needed to provide (incomplete) vacuum for various industrial, scientific and medical processes. These various steps require various vacuum levels leading to a wide variety of pump types and pumping principles. The 2 main parameters of the vacuum pump are the achievable flow rate and the achievable vacuum level (i.e., pressure level). Both pumping principles have unique advantages and disadvantages, and both applications have unique requirements for pumps. Pumps capable of providing high levels of vacuum or high flow rates are typically large and difficult to manufacture. Therefore, when selecting or manufacturing a vacuum pump for a particular application, a compromise needs to be found between the required flow rate, maximum vacuum level, manufacturing cost, manufacturing size and other parameters.

[0003]

32 One application area for vacuum pumps is the field of breast pumping devices, i.e. devices for extracting breast milk from the breast of breastfeeding women.

34 Such devices typically include a vacuum pump to provide a (incomplete) vacuum applied to the female chest to draw breast milk from the chest. WO 2012/127405 A1 discloses a breast pump operable to generate negative pressure. The maximum negative pressure that can be achieved by the breast pump is a function of the maximum pressure value that the

(incomplete) vacuum pump used can provide. If a high level of vacuum is required, different types of pumps are required, which typically make the breast pump larger and/or more expensive to manufacture.

[0004]

44 In US 2005/02831112 A1 a breast pump is disclosed.

45 The apparatus includes a chest shield adapted to fit over a papilla of the chest and a streamline coupled to the chest shield. The streamline is configured to allow air to flow through the streamline through a pump coupled to the chest shield via the streamline. The pump includes a pump inlet and a pump outlet, and is operable to create a pressure drop between the nipple and the pump, the pressure drop creating a suction force at the chest shield by reducing the pressure of air at the streamline. A blowback valve is provided between the flow line and the pump, the blowback valve having a valve piston disposed in a valve housing. The valve housing includes a flow line opening in communication with the chest shield via the flow line, a valve inlet configured to communicate an exterior with the flow line, and a valve outlet configured to communicate the exterior with the flow line. The valve piston is configured to alternatively seal the valve inlet and the valve outlet.

[0005]

59 In US 2013/0165852 A1 an electric breast pump is disclosed.

60 The pump has an electric motor, a pump driven by the motor, a suction cup, an electrically operated 1st three-way valve in the suction line, an electrically operated 2nd three-way valve in the pressure line, and an electronic control system, which sets the electric motor in an operating mode or an idling mode depending on the actuation of the switch. In the operating mode, the electric motor and the electrically operated 1st and 2nd three-way valves are operated in a cycle with a suction phase in which the electric motor is switched on, the inlet of the pump is connected to the suction cup via the 1st three-way valve and the float valve, and the pump outlet is connected via the 2nd three-way valve.

[0006]

71 It is an object of the present invention to provide an apparatus for discharging from a system and achieving an appropriate vacuum level, while enabling cost-effective manufacturing and implementation in a compact housing.

74 A further object of the present invention is to provide a breast pump and a method for controlling a breast pump.

[0007]

79 In a first aspect of the invention there is provided an apparatus for discharging from a system,

comprising a pump suitable for being connected to the system by a pump inlet and a pump outlet for generating a drop in pressure between the pump inlet and the pump outlet, a pressure tank for holding an applied pressure value, and a directional control valve for switching the pressure tank to either the pump inlet or the pump outlet, wherein the pump transports media from the system and the pressure tank to an external environment when the pressure tank is connected to the pump inlet, and wherein the directional control valve is configured to switch the pressure tank from the pump inlet to the pump outlet when a predetermined criterion is met.

[0008]

91 In a further aspect of the invention there is provided a breast pump comprising the apparatus described above and a system comprising a receiving funnel for receiving a female chest and a breast milk reservoir for collecting breast milk.

[0009]

97 In yet another aspect of the invention, there is provided a method for controlling a breast pump, the method comprising: configuring a pump for generating a pressure drop in a system and in a pressure tank, the pump transporting a medium from the system and the pressure tank to an external environment when the pressure tank is connected to a pump inlet; determining whether a predetermined criterion is met; and configuring a directional control valve to switch the pressure tank from the pump inlet to a pump outlet if the predetermined criterion is met.

[0010]

107 Preferred embodiments of the invention are defined in the dependent claims. It should be understood that the claimed method and breast pump device have similar and/or identical preferred embodiments as defined in the claimed device and the dependent claims.

[0011]

113 The device according to the invention realizes an increase in the vacuum level achieved by the use of a directional control valve and an additional pressure tank.

115 The pump transports the medium from inside to outside, thereby creating a pressure drop therebetween. The transported medium may comprise any type of fluid, i.e. gas or liquid, which causes a pressure drop in the system when transported out of the system by the pump. If the outlet of the pump is connected to the external environment and the medium to be transported is released to the external environment, the pressure in the system drops compared to the pressure of the external environment.

[0012]

124 According to the invention, the pump not only transports the medium from the system, but also the medium contained in the pressure tank, whereby both the pressure in the system and the pressure in the pressure tank are reduced.

127 Thus, it will be pumped by the pump from both the system and the pressure tank.

[0013]

131 The pressure tank (also referred to as a vacuum tank) allows to retain the applied (low) pressure value by providing a constant value that does not change regardless of the pressure value that changes inside and outside the tank.

134 A possible embodiment of such a pressure tank may be a rigid, gas-tight, non-flexible metal body, for example with a single opening to be connected to the pump. Further, in the present context, holding the applied pressure value refers to applying or causing the pressure value, for example, by sucking out the medium from the pressure tank, then closing or sealing the opening of the pressure tank, and keeping the pressure in the pressure tank constant until pressure compensation is performed (e.g., by opening the tank to release the medium in the tank to the external environment or to pass the medium from the external environment to the tank).

[0014]

145 Instead of varying the pressure in the pressure tank by pumping the medium from or into the pressure tank, it is also possible to adapt the pressure tank (passively) to a pressure level or pressure value and then transport the tank to areas where the ambient pressure is different, so that the pressure state of the internal environment is maintained.

149 The pressure tank can be used in both directions, i.e. it can hold a low pressure or a high pressure with respect to the external environment.

[0015]

154 According to the invention, the pressure tank is connected to the pump inlet or the pump outlet by means of a directional control valve.

156 Such a directional control valve allows switching to different paths, and depending on the setting of the directional control valve, the medium can be guided to different ports. According to the invention, the directional control valve provides in particular the function of switching the pressure tank to the pump inlet in the 1st setting and to the pump outlet in the 2nd setting. Thus, it is possible to connect the opening of the pressure tank to either side of the pump.

[0016]

165 Furthermore, according to the invention, the directional control valve performs such a switching procedure, i.e. a procedure for switching the pressure tank from one side of the pump to the other, when a predetermined criterion is met.

168 For example, the pressure tank is initially connected to the pump inlet and does not draw media from the system and from the pressure tank. As soon as a predetermined criterion is met, the pressure tank is then connected to the pump outlet. In this configuration, when the directional control valve is in the 1st setting, the pump transports the medium from the system and the pressure tank to the external environment. After switching the directional control valve to the 2nd setting, the medium is then transported from the system at the pump inlet and to the pressure tank at the pump outlet.

[0017]

178 One advantage of the device according to the invention is that a reduction or overall reduction in the pressure generated is promoted.

180 Initially, the pump creates a constant pressure drop between the external environment and the system and pressure tank. As soon as a predetermined criterion is met, i.e. the pressure level is no longer lowered, the pressure tank is switched to the pump outlet by means of the directional control valve. Immediately after the switching, this results in a pressure equilibrium at the pump inlet and the pump outlet. Then, it is utilized that if the pressure level at the pump outlet is already lower than the pressure level in the external environment, the pump can generate a lower pressure in the system compared to the external environment. Independently of the pressure level in the external environment, the pump creates a pressure drop between the pump inlet and the pump outlet. Thus, if the pressure level at the pump outlet is already lower than the pressure level in the external environment, it is possible to further reduce the pressure level at the pump inlet. This is utilized according to the invention by means of a directional control valve which can switch the pressure tank from the pump inlet to the pump outlet when a predetermined criterion is met. In particular, the achievable pressure or vacuum level of the pump is improved by switching the pressure tank as outlined above. The achievable vacuum level, i.e. the lowest pressure that can be generated with the pump, is increased compared to the original achievable vacuum level.

[0018]

199 In a first embodiment of the invention, the device further comprises a one-way valve coupled between the pump outlet and the pressure tank to prevent backflow of fluid from the external environment to the pump and/or the pressure tank.

202 The valve, on the one hand, essentially allows the medium to pass in one direction, but prevents the medium from passing in the other direction. According to a first embodiment of the invention, the one-way valve is arranged at the pump outlet. Thus, even if the pressure tank is connected to the pump outlet by the directional control valve, backflow of the

transported medium from the external environment to the pressure tank or pump is prevented. Initially, as long as the pressure tank is connected to the pump inlet, the one-way valve simply seals the pump outlet from the external environment, allowing the medium transported by the pump to escape to the external environment. However, contrary to the direction of the one-way valve, no medium can flow back from the external environment to the pump or to the system. As soon as the pressure tank is then switched from the pump inlet to the pump outlet, as described above, the one-way valve also prevents medium from flowing back from the external environment to the pressure tank. In this configuration, the pump outlet and the pressure tank are separated unidirectionally from the external environment. One advantage of the one-way valve is that the pressure can be maintained compared to the pressure in the external environment.

[0019]

220 According to a further embodiment of the invention, the device comprises a sensor for determining a pressure in the pressure tank.

222 The pressure sensor may be based on, for example, capacitive, electromagnetic, piezoelectric or piezoresistive measurement principles and may provide information about the pressure of the medium or fluid in the pressure tank. The sensor may be a smart sensor that provides a digital corrected output signal with information about the absolute pressure in the pressure tank, or an analog sensor that provides an analog value of the pressure dependent signal in the pressure tank. The signal generated by the sensor makes it possible to control the device according to the invention, for example by enabling the use of a closed-loop control, in which specific parameters of the device are configured directly on the basis of the obtained sensor signal.

[0020]

234 An example of the use of the sensor is further detailed in another embodiment of the invention, wherein the directional control valve is configured to switch the pressure tank from the pump inlet to the pump outlet when a pressure in the pressure tank falls below a predetermined pressure threshold.

238 Thus, the pressure in the pressure tank determined by the sensor described above is used as a criterion for determining when a switching of the pressure tank from the pump inlet to the pump outlet is to be performed. By defining a particular pressure threshold level or predetermined threshold, the configuration of the directional control valve can be directly associated with the current pressure in the pressure tank that is equivalent to the pressure in the system while the pressure tank is connected to the pump inlet. The predetermined threshold value may be selected depending on the characteristics of the pump, for example the maximum pressure difference or the maximum vacuum level achievable. Depending on the selected setting, one of the advantages of the present embodiment is that the control of the switching process is simple and easy to implement.

[0021]

251 Further, according to another embodiment of the present invention, the apparatus further comprises a sensor for determining a throughput of the pump.

253 Such a throughput sensor may be a flow sensor implemented as, for example, one or more pressure sensors, a thermal flowmeter, a mechanical positive displacement meter, or any other flow sensor or flowmeter. The flow sensor can basically be used as an alternative to the sensor for determining the pressure in the pressure tank described above. Equivalent functions may be realized. Advantageously, the use of such sensors for determining the throughput of the pump allows the switching procedure to be activated automatically without the need for further user input.

[0022]

263 In a preferred embodiment of the invention, the directional control valve is configured to switch the pressure tank from the pump inlet to the pump outlet when the throughput exceeds a predetermined throughput threshold.

266 As explained above, the measured values of the sensor for determining the throughput of the pump are evaluated and the obtained sensor values are used as criteria for determining whether the pressure tank should be switched from the pump inlet to the pump outlet. In particular, the principle may be used if a threshold value, i.e. a throughput value, at which the switching is to be performed, is determined on the basis of the characteristics of the pump. One possible setting of the threshold may be a specific percentage of the maximum throughput that can be achieved by the pump. Thus, as soon as the pump operates at a relatively low efficiency, the pressure tank is switched from the inlet to the outlet, increasing the throughput of the pump. As soon as the maximum total pressure drop is reached, the sensor will again record only a small flow rate.

[0023]

279 In another embodiment of the invention, the device further comprises a discharge valve for discharging pressure from the system and/or from the pressure tank to the external environment.

282 In some applications, it is necessary to be able to release pressure or in particular vacuum from the system to the external environment in order to continue its intended use. Such a discharge valve may be electrically operated or manually operated and may be implemented in the form of a simple butterfly valve or any other type of valve. For example, if the pressure tank is currently connected to the pump outlet, it is possible to release pressure from the system and the pressure tank or only from the system, depending on the installation position of the release valve. This allows the release valve to be operated automatically, preferably without requiring any external input in addition to the pressure difference between the

system or pressure tank and the external environment. The discharge valve can then act as a safety valve which prevents the system or tank from becoming too low/high pressure in the event of a pump failure or uncontrolled behavior. For example, if the discharge system is a breast pump of a breast pump, such a safety valve can prevent harm to the user.

[0024]

297 The device for discharging from the system according to the invention further comprises a flow restrictor (optionally adjustable) for controlling the flow rate of the medium transported from the pressure tank to the pump outlet.

300 Such a flow restrictor realizes a smoother and/or gentler pump curve, in particular by allowing maximum throughput restriction.

[0025]

305 In a preferred embodiment of the invention, the pump is a positive displacement vacuum pump for transferring a fluid, in particular a gas, from the pump inlet to the pump outlet.

307 The pump may be either an electric pump or a mechanical pump that is moved by movement of the human hand and/or foot in another embodiment of the invention. Depending on the application, different types of pumps have their respective advantages and disadvantages. A positive displacement vacuum pump is advantageous, in particular, if the gas, i.e. the gas molecules, is to be pumped from the pump inlet to the pump outlet. Such a positive displacement vacuum pump relies on expansion of a given volume, which reduces the pressure in the expanded volume. A portion of the volume is then separated and reexpanded. This procedure may be repeated several times to increase the level of vacuum and can be easily implemented in pumping gas. The main concern here is the vacuum level that the pump can produce, i.e. the minimum number of molecules remaining per volume. One of the advantages of such a positive displacement vacuum pump is its simple construction and its availability on the market.

[0026]

322 Regardless of which pumping principle is utilized, the pump included in the device may be a battery or a powered electric pump powered by a power source, which may be controlled by, for example, a processor device or provide a direct user interface.

325 Alternatively, it is also possible that the device has a mechanical pump that does not require any electrical energy but can be powered by manual power conversion, for example by movement of the human hand and/or foot. One possibility of such a mechanical pump is the use of a handle portion which is moved periodically and converts a pumping mechanism, such as the volume transfer principle described above, into movement. The advantages of mechanical pumps include that they do not require charging of the battery or the use of a cable connection. The risk of failure and the risk of injury to the user, for example in the case

of a breast pump, is also reduced. On the other hand, the electric pump may be more convenient to use.

[0027]

337 In another preferred embodiment of the invention, the directional control valve and one-way valve are combined into a smart valve.

339 Such a smart valve may be an integrated part combining the function of the control valve and the function of the one-way valve into 1 component. The advantage of combining 2 valves into 1 component is that structural space can be reduced. Furthermore, when the number of components of the device is minimized, it may also be possible to reduce costs. Such smart valves may further include a discharge valve, which may further reduce the number of components. Furthermore, the function of the safety valve, i.e. the protection of the user of the device or of the device itself, may be integrated into the smart valve. Such smart valves may be fully mechanically controlled and may function based on pressure differentials and mechanical utilization, i.e., a particular pressure differential may function to deform the material and release the pressure to the external environment. The smart valve may also include an adjustable flow restrictor to control flow between the pressure tank and the pump.

[0028]

354 In another embodiment, the directional control valve is a 3/2 valve with 3 ports and 2 switching positions.

356 Such a 3/2 valve is basically a standard component that provides the functionality required for switching the pressure tank from the pump inlet to the pump outlet. The advantage of the 3/2 valve is that the function of switching the pressure tank from the pump inlet to the pump outlet can be realized in a single piece. Again, the 3/2 valve may function mechanically by pressure changes or electrically by a switching procedure, e.g., activated by a controller device or by user input.

[0029]

365 According to an embodiment of the present invention, the directional control valve may be an electrically operated valve or a mechanically operated valve.

367 If the valve is a motorized valve, a processor can be used to control the pump and automate the switching process. Alternatively, the directional control valve may be operated mechanically. In this case, for example, a mechanical arrangement may be used to activate a switch of the directional control valve from one position to another as soon as the pressure reaches or exceeds a certain threshold. It may also be expected that mechanical operation allows the operator to manually switch the pressure tank from the pump inlet to the pump outlet.

[0030]

377 In another embodiment of the invention, the device further comprises a controller for controlling the pump and/or the directional control valve.

379 Such a controller may be, for example, a microcontroller device programmed to perform the desired function. The controller can be used to control various valves and/or all other components and their interactions in the device according to the invention or in the device comprising such a device. One advantage of such a controller is that it can also be used to perform other control operations in the breast pump.

[0031]

387 In a further aspect of the invention there is provided a breast pump comprising a device for discharging from the system described above and a system comprising a receiving funnel for receiving a female chest and a breast milk reservoir for collecting breast milk.

390 Such a breast pump can be used to collect breast milk of a lactating woman in a container or breast tank. According to this aspect of the invention, the device for discharging from the system discharges from a container hermetically connected to the female chest. The container serves as a breast milk reservoir for collecting breast milk from a lactating woman that is drawn from the chest by the vacuum generated by the device according to the invention. The hermetic connection of the container to the chest is usually realized by a funnel or funnel-shaped part, for example made of plastic material, for receiving the female chest. Depending on the requirements of the individual user, it is also possible to use a replaceable funnel so that chests of different shapes can be accommodated.

[0032]

402 According to yet another aspect of the invention, a method for controlling a breast pump as described above is provided.

404 Depending on the design of the breast pump, the pumps, the various valves and/or the various sensors may be controlled by at least one controller performing the method for controlling the breast pump. Such a controller may be a microprocessor or digital signal processor suitable for performing the necessary computing and control operations. The controller may be connected to a respective valve, said device and/or sensor of the device according to the invention. The method for controlling a breast pump according to the invention may correspond to a closed-loop control in which the determined setting is directly associated with the sensor value or may correspond to an open-loop control comprising user feedback. One advantage of such a method is that all the functions of the device according to the invention or of the milking device can be controlled and/or automatically performed accordingly. There is no or little need for user input to perform the various control steps.

[0033]

418 These and other aspects of the invention will be described and apparent with reference to the examples described below.

[0034]

423 FIG. 1 shows a schematic diagram of a first embodiment of the present invention.

424 An example of pressure reduction in the system produced by the present invention is shown.

425 A schematic diagram of another embodiment of the present invention is shown.

426 A schematic illustration of a further embodiment of the invention is shown.

427 A diagram of an alternative example of the device according to the invention is shown.

428 A method for controlling a breast pump is shown.

429 A breast pump according to one embodiment of the present invention is shown.

[0035]

433 FIG. 1 schematically shows a device 1 afor discharging from a system according to a first embodiment of the invention.

435 The device 1 ahas a pump 5 which results in a reduction in pressure between the pump inlet 7 and the pump outlet 9, and which is connected to the system 3 by the pump inlet 7.

437 Pump 5 thus transports the medium from pump inlet 7 to pump outlet 9, thereby resulting in a reduction in pressure.

439 The device 1a further comprises a pressure tank 11 which allows to retain the pressure applied for a period of time.

441 Furthermore, a directional control valve 13 is provided for switching the pressure tank 11 to the inlet 7 or outlet 9 of the pump 5.

443 In order to provide the function according to the invention, i.e. to be able to generate a higher level of vacuum than with only the pump 5, the directional control valve 13 is configured to switch the pressure tank 11 from the inlet 7 to the outlet 9 of the pump 5 when a predetermined criterion is met.

447 The directional control valve 13 therefore provides different connection ports or openings that allow for the intake of the medium and that can be switched to different configurations.

[0036]

452 In the illustrated embodiment of the invention, the directional control valve 13 has in particular 3 ports.

454 These 3 ports can be switched such that the pump inlet 7 or the pump outlet 9 is coupled to the pressure tank 11.

456 In this context, coupled indicates that the directional control valve 13 is connected such that medium can flow from one port to another port of the directional control valve 13,

depending on the current setting of the directional control valve 13.

459 To provide the switching function, the directional control valve has, for example, a spool in the cylinder that is mechanically or electrically moved from one position to another, thereby allowing the medium to flow through one path or another.

[0037]

465 As outlined above, the device according to the invention makes it possible to achieve a higher level of vacuum than with the pump 5 alone.

467 Usually, the pump 5 is characterized by the maximum achievable pressure drop that the pump can produce between the pump inlet 7 and the pump outlet 9.

469 Thus, when already low pressure is applied at the outlet 9 of the pump 5, the achievable pressure level at the inlet of the pump 5 is higher than when the outlet 9 of the pump 5 is directly connected to the external environment.

472 This behavior is utilized according to the invention.

473 First, both the system 3 and the pressure tank 11 are sucked by the pump 5, and the same level of pressure (pressure level) is generated in both the system 3 and the pressure tank 11.

475 The pressure tank 11 is then switched from the inlet 7 of the pump 5 to the outlet 9 of the pump 5 by means of the directional control valve 13.

477 This allows for higher vacuum levels (lower pressures) to be generated in the system 3 compared to using only the pump 5.

[0038]

482 FIG. 2 shows a typical pressure drop produced by an apparatus according to the invention.

483 The pressure p is shown as a function of time t.

484 Initially, the pressure in the system 3 and the pressure tank 11 is in equilibrium with the pressure p1 in the external environment.

486 Pump 5 is then switched on at t1 resulting in a decrease in pressure in both system 3 and pressure tank 11.

488 At a particular point in time t2, the highest vacuum level p2 achievable in this configuration is reached.

490 Due to the configuration parameters of the pump 5, the pump 5 cannot generate a higher level of vacuum (lower pressure).

492 As soon as the predetermined criterion is met, the directional control valve 13 switches the pressure tank 11 from the inlet 7 to the outlet 9 of the pump 5.

494 The predetermined criterion may be, for example, a pressure threshold.

495 The switching temporarily causes the pressure levels at the inlet 7 and outlet 9 of the pump to be again in equilibrium.

497 Pump 5 can then provide a higher level of vacuum (i.e. lower pressure) in system 3.

498 However, also in this configuration, when a specific pressure value p 3 is reached in the system 3, the pump 5 is saturated.

500 In FIG. 2, when the pump 5 is switched off and/or the discharge valve is opened at t 3, pressure equilibrium with the external environment is induced.

[0039]

505 FIG. 3 shows another embodiment 1 bof the device according to the invention.

506 Compared with the device 1 ashown in FIG. 1, a one-way valve 15 is further provided, which is coupled to the outlet 9 of the pump 5 and to the pressure tank 11.

508 The one-way valve 15 can prevent backflow of the transported medium or any type of fluid from the external environment to the pump 5 and/or the pressure tank 11.

510 Furthermore, a first sensor 17 for determining the pressure in the pressure tank 11 is shown in FIG. 1.

512 The first sensor 17 makes it possible to perform a switching of the pressure tank 11 from the inlet 7 to the outlet 9 of the pump 5 as soon as the pressure in the pressure tank 11 falls below a predetermined threshold value, i.e. a pressure threshold value.

515 Still further, the illustrated embodiment shows a second sensor 19 for determining the throughput of the pump 5.

517 The 2nd sensor 19 may be used as an alternative to the sensor 17 or in combination with the sensor 17 in order to activate the switching of the directional control valve 13.

519 One of the clear possibilities is to determine the throughput by means of the throughput sensor 19 and to determine whether the throughput is continuously below a predetermined threshold, i.e. whether the pump 5 is transporting only a small amount of fluid and there is virtually no pump 5 in a saturation state as described above.

[0040]

526 FIG. 3 further shows a discharge valve 21 for discharging pressure from the system 3 and/or the pressure tank 11 to the external environment.

528 The release valve 21 may have a control connection 22 which allows remote control.

[0041]

532 Still further, FIG. 3 shows a controller 23 for controlling the pump 5, the directional control valve 13, the sensors 17 and 19 and for controlling the discharge valve 21 via the control connection 22.

535 In a further embodiment of the device according to the invention, the controller 23 may also control other sensors or other electronically controllable components.

537 In particular, the pump 5 may be an electric or mechanical pump that requires a specific control pulse or other signal generated by the controller 23.

[0042]

542 The controller may be a combined controller that also controls other functions of the breast pump according to other aspects of the invention, which may enable automatic interruption of the function in response to a suction cycle or a variation in pressure applied, a signal or user interface, or other functions in response to user feedback.

[0043]

549 A further embodiment 1c of the device according to the invention is schematically illustrated in FIG. 4.

551 In the present embodiment, the device 1c has a smart valve 25 that combines the functions of the directional control valve 13, the one-way valve 15 and the release valve 21.

553 The smart valve 25 is connected to the inlet 7 and the outlet 9 of the pump 5 and to the pressure tank 11.

555 One of the major advantages of using smart valve 25 to provide various desired functions is that only 1 part is required instead of multiple parts.

557 This may allow for a cheaper implementation of the device according to the invention.

558 Furthermore, such integrated parts may reduce the failure rate.

559 The smart valve 25 may further include a flow restrictor for speed control.

[0044]

563 In FIG. 5, a further schematic illustration of an embodiment 1 dof the device according to the invention is shown.

565 The directional control valve 13 is shown in more detail to highlight various parts and possible switching functions.

567 Such a 3/2 valve, i.e. a three-way two-position control valve, provides the desired function for switching the pressure tank 11 from the inlet 7 to the outlet 9 of the pump 5.

569 Furthermore, in the present embodiment, an adjustable flow restrictor 26 is arranged between the directional control valve and the outlet 9 of the pump 5.

571 The adjustable flow restrictor allows controlling the flow rate of the transported medium, in particular by adjustably limiting the maximum throughput.

[0045]

576 In the present embodiment, the system 3 to be discharged has a funnel 27 and a breast drum 29.

578 The funnel 27 houses the female chest.

579 The incomplete vacuum generated by the pump 5 is then applied to the chest and milk can be squeezed out.

581 The milk thus squeezed out is collected in a tank 29.

582 Furthermore, a one-way valve 15 is shown for preventing backflow of fluid from the external environment to the directional control valve 13 or pump 5.

584 In particular, in the present invention, the pump 5 transports air from the reservoir 29 and releases the air through the one-way valve 15 to the external environment.

[0046]

589 In FIG. 6, a method for controlling a breast pump according to an embodiment of the present invention is shown.

591 Such a method may be performed, for example, by a controller included in the milking apparatus described above.

593 The controller may control various components (e.g., valves, sensors, pumps, or the like) to achieve a higher vacuum level (i.e., lower pressure).

[0047]

598 According to the embodiment shown in FIG. 6, the pump is initially configured to generate a pressure reduction in the system and the pressure tank (S 10).

600 Depending on the type of pump and the type of connection to the controller, the arrangement comprises in particular the activation of the pump.

602 For example, if the pump can be operated at different levels, the configuration may also include selecting an appropriate level.

604 Next, it is determined whether or not a predetermined criterion is satisfied (S 12).

605 Preferably, the determination is based on sensor values obtained from at least one sensor, in particular a pressure sensor or a throughput sensor.

607 Thus, determining whether a predetermined criterion is met comprises obtaining a sensor value from the sensor (i.e., a throughput sensor or a pressure sensor).

609 At this time, it may be determined whether the predetermined criterion is satisfied based on the sensor value, possibly in combination with the user input.

611 The method for controlling a breast pump according to the invention further comprises switching (S 14) a directional control valve to connect a pressure tank to the outlet of the pump if the predetermined criterion is met (the pressure tank was initially connected to the inlet of the pump).

615 For example, the switching is performed when a certain threshold value is exceeded by the sensor value.

617 The switching of the directional control valve indicates that the necessary control signal is sent to the connection cable to activate the switching procedure.

619 The method for controlling a breast pump device may further comprise determining control settings for further valves (e.g. directional control valves and/or one-way valves) and devices (e.g. pumps) and configuring the valves and devices (not shown) based on the determined control settings.

623 Again, the configuration indicates that the necessary control signals are sent to the connection cable (or the signals are sent via a wireless connection).

625 The method may represent closed loop control or open loop control as outlined above.

[0048]

629 Furthermore, a method (not shown) for discharging from a system according to the invention may comprise generating a pressure drop in the system and the pressure tank, holding a pressure value being applied in the pressure tank, switching the pressure tank from the pump inlet to the outlet when a predetermined criterion is met.

[0049]

636 FIG. 7 shows a breast pump 31 according to another aspect of the invention.

637 The receiving funnel 27 is shaped to accommodate the female chest.

638 As soon as a pressure drop, i.e. an incomplete vacuum, is applied to the chest, the milk is squeezed out.

640 As shown in FIG. 7, the milk thus squeezed out is collected in a tank 29.

641 The reservoir is discharged by a pump 5 connected to the reservoir through a smart valve 25.

642 Further, a pressure tank 11 and a controller 23 are included.

643 Further, a battery 33 is shown which supplies the electrical energy required for the various components.

645 The smart valve 25 shown in the present embodiment includes the functions of a directional control valve, a one-way valve, and a discharge valve.

647 The valve also functions as a safety valve that prevents damage to the user in the event of a failure of the pump 5.

649 The controller 23 controls the smart valve 25, measures the pressure in the pressure tank 11, and controls the pump 5.

[0050]

654 Although not shown, a mechanical pump may be used instead of the electric pump.

655 This means that the controller 23 does not have to be connected to the pump 5.

656 Mechanical pumps typically have a handle portion for manually applying force to create a pressure drop.

658 In addition, peripheral equipment (not shown) is typically provided, such as, for example, a user interface (e.g., acoustic, visual or mechanical feedback means combined with buttons, touch pads, trackballs or other input means), a power source (e.g., a battery, solar cell or other energy generator, or trunk power connector), or design elements to improve visual perception of the breast pump.

[0051]

666 Instead of switching the pressure tank from the inlet to the outlet of the pump, it is also possible to connect a plurality of pumps in series such that the outlet of one pump is directly

connected to the inlet of another pump.

669 This also allows for an increase in vacuum level.

[0052]

673 While the invention has been described and described in the drawings and foregoing description, such description and description are to be regarded as illustrative or exemplary and not restrictive.

676 The invention is not limited to the disclosed embodiments.

677 Other variations to the disclosed embodiments may be understood and effected by those skilled in the art in practicing the claimed invention, from a reading of the drawings, the description, and the appended claims.

[0053]

683 In the claims, the word "comprising" does not exclude other elements or steps, and the indefinite article "1 (a or an)" does not exclude a plurality.

685 A single processor or other unit may perform the functions of several items listed in the claims.

687 The mere fact that certain measures are recited in mutually different dependent claims does not indicate that a combination of these measures cannot be used to advantage.

[0054]

692 Any reference signs in the claims should not be construed as limiting the claims.

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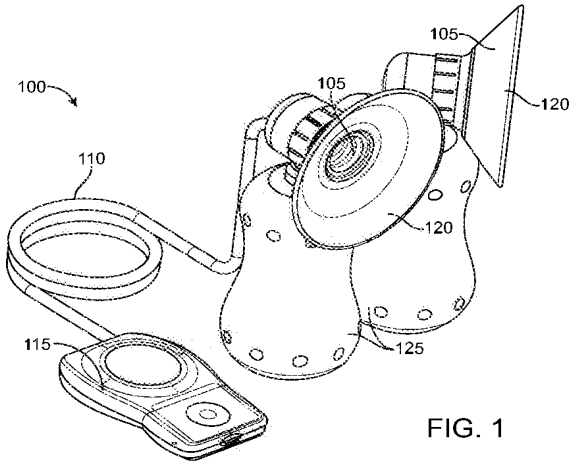

FIG. 1

(57) Abstract: A device for expression and collection of breast milk includes an actuatable assembly, a breast interface, and a tube. The breast interface is sized to receive a breast and form a fluid tight seal against the breast. The breast interface includes a deformable member disposed within at least a portion of the breast interface. The deformable member deforms in response to actuation of the actuatable assembly and applies vacuum pressure against the breast to express milk. The tube operatively couples the actuatable assembly to the breast interface.

WO 2014/160614 A1

METHOD, APPARATUS, AND SYSTEM FOR EXPRESSION AND QUANTIFICATION OF HUMAN BREAST MILK

CROSS-REFERENCE

[0001] The present application claims the benefit of U.S. Provisional Patent Application No. 61/804,722 (Attorney Docket No. 44396-702.101) filed March 24, 2013; U.S. Provisional Patent Application No. 61/879,055 (Attorney Docket No. 44396-703.102) filed September 17, 2013; and U.S. Patent Application No. 14/221,113 (Attorney Docket No. 44936-703.201) filed March 20, 2014; the entire contents of which are incorporate herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention. The present invention generally relates to medical devices and methods, and more particularly relates to devices and methods for expression and collection of human breast milk.

[0003] The exemplary embodiments disclosed herein are preferably directed at expression of breast milk, but one of skill in the art will appreciate that this is not intended to be limiting and that the devices, systems and methods disclosed herein may be used for other treatments requiring application of a differential pressure.

[0004] Breast pumps are commonly used to collect breast milk in order to allow mothers to continue breastfeeding while apart from their children. Currently, there are two primary types of breast pumps: manually-actuated devices, which are small, but inefficient and tiring to use; and electrically-powered devices, which are efficient, but large and bulky. Therefore, it would be desirable to provide improved breast pumps that are small and highly efficient for expression and collection of breast milk. Additional features such as milk production quantification and communication with mobile devices are further desirable for enhanced user convenience. At least some of these objectives will be satisfied by the devices and methods disclosed below.

[0005] 2. Description of the Background Art. The following US patents are related to expression and collection of human breast milk: US Pat. Nos.: 6,673,036; 6,749,582; 6,840,918; 6,887,210; 7,875,000; 8,118,772; and 8,216,179.

SUMMARY OF THE INVENTION

[0006] The present invention generally relates to medical devices, systems and methods, and more particularly relates to devices, systems and methods for expression and collection of human breast milk.

[0007] In a first aspect of the present invention, a device for expression and collection of breast milk comprises an actuatable assembly, a breast interface, and a tube. The breast interface is sized to engage a breast and fluidly seal thereagainst. The breast interface also includes a movable member disposed within at least a portion thereof. The movable member moves in response to actuation of the actuatable assembly and thereby forms a vacuum in the breast interface and applies the vacuum to the breast to express milk therefrom. The tube is operatively coupled to the actuatable assembly and to the breast interface.

[0008] The actuatable assembly may comprise a piston or a pump, or a pair of pistons or a pair of pumps. Actuation of the actuatable assembly may displace a fluid that is disposed in the tube.

[0009] The movable member may comprise a flexible membrane. The flexible membrane may have a corrugated region that is configured to expand and collapse. The flexible membrane may deform in response to actuation of the actuatable assembly, and actuation of the actuatable assembly may displace a fluid contained within the tube. The movable member may comprise a deformable member.

[0010] The breast interface may comprise a resilient and conformable flange for engaging and creating a fluid seal against the breast.

[0011] A fluid may be disposed in the tube. The fluid may be an incompressible fluid such as water or oil. In other embodiments, a tensile element may be disposed in the tube. The tensile element may comprise a rope, a wire, or a cable. The tensile element may be operatively coupled with the movable member and the actuatable assembly, and may also be concentrically disposed with an axial compressive element that absorbs reactive loads of the tensile element.

[0012] The device may further comprise a driving mechanism that is operatively coupled with the actuatable assembly, and that is configured to actuate the actuatable assembly. The driving mechanism may include electromechanical device such as a motor. The driving mechanism may be releasably coupled to the actuatable assembly.

[0013] The breast interface may comprise an exit valve that is configured to control flow of the expressed breast milk into a collection vessel. The exit valve may control the flow by preventing the expressed milk from flowing through the valve when the deformable member

is deformed, and allowing the expressed breast milk to flow through the valve when the deformable member is in an undeformed configuration. The exit valve may be integrally formed into the deformable member.

[0014] The device may further comprise a second actuatable assembly, a second breast interface and a second tube. The second breast interface may be sized to engage a second breast and fluidly seal thereagainst. The second breast interface may have a movable member disposed within at least a portion thereof, and the movable member may deform in response to actuation by either the actuatable assembly or the optional second actuatable assembly and thereby form a vacuum in the second breast interface which is applied to the second breast to express milk therefrom. The second tube may be operatively coupled to the second actuatable assembly and the second breast interface.

[0015] The device may further comprisea housing having a controller for controlling actuation of the actuatable assembly. The controller may control calculation and display of breast milk production information, and the controller may also control communication with other devices. A power source may be disposed in the housing and the power source provides power to the device for expression and collection of milk. The housing may have a drive mechanism disposed therein for actuating the actuatable assembly.

[0016] The device may further comprise a collection vessel fluidly coupled with the breast interface. The device may also comprise a sensor adjacent the breast interface, and that is configured to measure an aspect of mil passage therepast. The device may also comprise a display unit for displaying data related to the expression of the milk. A system for expression and collection of breast milk may include the device previously described above. Any of these components may be separate from the other components or they may be disposed in a housing or pendant.

[0017] In another aspect of the present invention, a device for applying pressure or vacuum to a patient comprises an actuatable assembly, a target tissue interface, and a tube. The target tissue interface is preferably sized to engage a target tissue and fluidly seal thereagainst. The target tissue interface has a deformable member disposed within at least a portion thereof, and the deformable member deforms in response to actuation of the actuatable assembly. This forms a vacuum or pressure in the target tissue interface and applies the vacuum or the pressure to the target tissue. The tube is operatively coupled to the actuatable assembly and the target tissue interface.

[0018] In yet another aspect of the present invention, a method for expressing and collecting breast milk comprises providing a breast expression and collection device having a breast

interface and an actuatable assembly operatively coupled to the breast interface. The breast interface comprises a deformable member. The method also comprises engaging and fluidly sealing a breast with the breast interface and actuating the actuatable assembly. The method also comprises deforming the deformable member in response to actuation of the actuatable assembly thereby creating and applying a vacuum to the breast, and expressing and collecting milk from the breast.

[0019] The engaging step may comprise engaging a resilient and conformable flange on the breast interface with the breast thereby creating a fluid seal between the breast interface and the breast.

[0020] Actuating the actuatable assembly may displace a fluid. The fluid may be disposed in a tube that is fluidly coupled with the actuatable assembly and the deformable member. Actuating the actuatable assembly may comprise moving a piston or applying a tension to a tensile element disposed in the tube. The method may further comprise releasing the actuatable assembly from a driving mechanism that is operatively coupled therewith.

[0021] The method may further comprise repeating the actuating, the deforming and the expressing steps. The method may further comprise quantifying production of the expressed milk and transmitting data related to the expression of breast milk between the breast expression and collection device and a mobile device. The mobile device may be a smart phone, tablet, or computing device. The data may be displayed on a display. The method may also comprise controlling flow of the expressed milk into a collection vessel with a valve fluidly coupled to the breast expression and collection device. Controlling the flow may comprise opening the valve when the deformable member is undeformed, and closing the valve when the deformable member is deformed. Aspects of breast milk may also be sensed with a sensor that may be fluidly or otherwise coupled with the breast interface.

[0022] The breast expression and collection device may further comprise a second breast interface and a second actuatable assembly operatively coupled to the second breast interface. The second breast interface may comprise a deformable member. The method may further comprise engaging and fluidly sealing a second breast with the second breast interface, and actuating the first or the second actuatable assembly. The method may also comprise deforming the deformable member in the second breast interface in response to actuation of the second actuatable assembly thereby creating and applying a vacuum to the second breast, and expressing and collecting milk from the second breast. Expressing and collecting milk from both breasts may occur simultaneously or it may alternate between both breasts.

[0023] In still another aspect of the present invention, a method of applying a differential pressure to a patient comprises providing a differential pressure device having an interface and an actuatable assembly operatively coupled to the differential pressure device. The interface comprises a deformable member and the method further comprises engaging and fluidly sealing the interface with a target region on the patient, and actuating the actuatable assembly. The method also comprises deforming the deformable member in response to actuation of the actuatable assembly thereby creating a positive pressure or a vacuum and applying the positive pressure or the vacuum to the target region. Any of the components may be separate from the other components, or they may be diposed in a housing or pendant.

[0024] Deforming the deformable member may create a positive pressure that is applied to the target region. The target region may comprise the mouth or nose, and applying the positive pressure reduces or eliminates apnea or similar disorders while the patient is sleeping. Deforming the flexible membrane may create a vacuum that is applied to the target region. The target region may comprise a body fluid reservoir, and thus the vacuum causes expression of a body fluid from the reservoir.

[0025] These and other embodiments are described in further detail in the following description related to the appended drawing figures.

INCORPORATION BY REFERENCE

[0026] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0028] Fig. 1 is a perspective view of an exemplary embodiment of a pumping device.

[0029] Fig. 2 is a perspective view of an exemplary embodiment of a pumping device.

[0030] Fig. 3 is a cross-section of an exemplary embodiment of a pumping device.

[0031] Fig. 4 illustrates an exemplary embodiment of an actuatable assembly coupled to a driving mechanism.

[0032] Figs. 5A-5B illustrate an exemplary embodiment of an actuatable assembly coupled to a pendant unit.

[0033] Fig. 6 is a cross-sectional view of an exemplary embodiment of a breast interface.

[0034] Fig. 7 is a cross-sectional view of another exemplary embodiment of a breast interface.

[0035] Fig. 8A is a cross-sectional view of an exemplary embodiment of an integrated valve in an open position.

[0036] Fig. 8B is a cross-sectional view of an exemplary embodiment of an integrated valve in a closed position.

[0037] Fig. 9A is a cross-sectional view of an exemplary embodiment of integrated sensors within a breast interface.

[0038] Fig. 9B is a cross-sectional view of another exemplary embodiment of integrated sensors within a breast interface.

[0039] Fig. 10 illustrates an exemplary embodiment of a pendant unit and a mobile device.

[0040] Fig. 11 illustrates an exemplary embodiment of a pendant unit in communication with a mobile device.

[0041] Fig. 12 is a cross-sectional view of an exemplary embodiment of a breast interface with a mechanical deformable member.

[0042] Fig. 13 is a cross-sectional view of an exemplary embodiment of a mechanical driver for a mechanical deformable member.

[0043] Fig. 14 is a graph illustrating the pump performance of an exemplary embodiment compared to a commercial device.

[0044] Fig. 15 is a graph illustrating the pumping efficiency of an exemplary embodiment compared to a commercial device.

DETAILED DESCRIPTION OF THE INVENTION

[0045] Specific embodiments of the disclosed devices and methods will now be described with reference to the drawings. Nothing in this detailed description is intended to imply that any particular component, feature, or step is essential to the invention. One of skill in the art will appreciate that various features or steps may be substituted or combined with one another.

[0046] The present invention will be described in relation to the expression and collection of breast milk. However, one of skill in the art will appreciate that this is not intended to be limiting, and the devices and methods disclosed herein may be used in other applications involving the creation and transmission of a pressure differential, such as in the treatment of sleep apnea and/or other remote pressure needs.

[0047] Fig. 1 illustrates an exemplary embodiment of the present invention. Pumping device 100 includes breast interfaces 105, a tube 110, and a controller or pendant unit 115 operatively coupled to breast interfaces 105 through tube 110. Breast interfaces 105 include resilient and conformable flanges 120, for engaging and creating a fluid seal against the breasts, and collection vessels 125. The device may optionally only have a single breast interface. Pendant unit 115 houses the power source and drive mechanism for pumping device 100, and also contains hardware for various functions, such as controlling pumping device 100, milk production quantification, and communication with other devices. Tube 110 transmits suitable energy inputs, such as mechanical energy inputs, from pendant unit 115 over a long distance to breast interfaces 105. Breast interfaces 105 convert the energy inputs into vacuum pressure against the breasts in a highly efficient manner, resulting in the expression of milk into collection vessels 125.

[0048] One of skill in the art will appreciate that components and features of this exemplary embodiment can be combined or substituted with components and features of any of the embodiments of the present invention as described below. Similarly, components and features of other embodiments disclosed herein may be substituted or combined with one another.

Hydraulic pumping device

[0049] Hydraulic systems can reduce pumping force requirements, and therefore also reduce the size of the pumping device, while maintaining high pumping efficiency. In a preferred embodiment, the pumping device can utilize a hydraulic pumping device to generate a pressure differential against the breast for the expression and collection of milk.

[0050] Exemplary hydraulic pumping devices are depicted in Figs. 2 and 3. Fig. 2 illustrates a pumping device 150 with a syringe 155 fluidly coupled to breast interface 160 by tube 165. Syringe 155 is coupled to tube 165 through a three-way valve 170. Breast interface 160 contains an exit port 175. The syringe 155 drives a fluid 180 contained within tube 165 against or away from a flexible member contained within breast interface 160 to create the pressure differential necessary for milk expression from the breast.

[0051] Fig. 3 illustrates another embodiment of a pumping device 200. The actuatable assembly 205 includes an assembly housing 210, a driving element 215, radial seals 220, and a shaft 222. Driving element 215 is operatively coupled to a pendant unit, such as pendant unit 115, through shaft 222. The tube 225 contains a fluid 230 and is fluidly coupled to the actuatable assembly 205 and the breast interface 235. The breast interface 235 consists of an interface housing 240, a flexible membrane 245, a reservoir 250, a sealing element 255, an expression area 260, and a drain port 265. The sealing element 255 includes deformable portion 270. The drain port 265 is coupled to a collection vessel 275 and includes a flap valve 280.

[0052] Actuatable assembly 205 displaces fluid 230 contained within tube 225, which can be a flexible line. Fluid 230 occupies reservoir 250 within breast interface 235 and is coupled with flexible membrane 245. Flexible membrane 245 transmits vacuum pressure from fluid 230 to the deformable portion 270 of sealing element 255. When a breast is engaged into and fluidly sealed with breast interface 235 by sealing element 255, displacement of the actuatable element 215 produces substantial vacuum pressure against the breast through flexible membrane 245 and deformable portion 270, resulting in the expression of breast milk into expression area 260. The expressed milk drains through drain port 265 into collection vessel 275. Drain port 265 is configured with a flap valve 280 to provide passage of milk while maintaining vacuum pressure in expression area 260.

[0053] The fluid for the hydraulic pumping device can be any suitable fluid, such as an incompressible fluid. In many embodiments, the incompressible fluid can be water or oil. Alternatively, the fluid can be any suitable gas, such as air. Suitable incompressible fluids and gases for hydraulic systems are known to those of skill in the art.

[0054] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the hydraulic pumping device can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Actuation mechanism

[0055] Many actuation mechanisms known to those of skill in the art can be utilized for the actuatable assembly 205. Actuatable assembly 205 can be a piston assembly, a pump such as a diaphragm pump, or any other suitable actuation mechanism. The optimal configuration for actuatable assembly 205 can depend on a number of factors, such as: vacuum requirements; size, power, and other needs of the pumping device 200; and the properties of the fluid 230, such as viscosity, biocompatibility, and fluid life requirements.

[0056] Fig. 3 illustrates an exemplary embodiment in which actuatable assembly 205 is a piston assembly and driving element 215 is a piston. Actuatable assembly 205 includes radial seals 220, such as O-rings, sealing against assembly housing 210 to prevent undesired egress of fluid 230 and to enable driving of fluid 230.

[0057] Fig. 4 illustrates another exemplary embodiment of an actuatable assembly 300 including a pair of pistons 305.

[0058] In preferred embodiments, the actuatable assembly includes a driving element powered by a suitable driving mechanism, such as a driving mechanism residing in pendant unit 115. Many driving mechanisms are known to those of skill in the art. For instance, the driving element, such as driving element 215, may be actuated electromechanically by a motor, or manually by a suitable user-operated interface, such as a lever. Various drive modalities known to those of skill in the art can be used. In particular, implementation of the exemplary hydraulic pumping devices as described herein enables the use of suitable drive modalities such as direct drive and solenoids, owing to the reduced force requirements of hydraulic systems.

[0059] Referring now to the exemplary embodiment of Fig. 4, the pistons 305 include couplings 310 to a crankshaft 315. The crankshaft 315 is operatively coupled to a motor 320 through a belt drive 325. The crankshaft 315 drives the pair of pistons 305 with the same stroke timing in order to apply vacuum pressure against both breasts simultaneously, a feature desirable for increased milk production. Alternatively, the crankshaft 315 can drive the pair of pistons 305 with any suitable stroke timing, such as alternating or offset stroke cycles.

[0060] The driving mechanism can be powered by any suitable power source, such as a local battery or an AC adaptor. The driving mechanism can be controlled by hardware, such as onboard electronics located within pendant unit 115.

[0061] Fig. 5 illustrates an exemplary embodiment of an actuatable assembly 350 that includes releasable coupling 355. Preferably, actuatable assembly 350 is releasably coupled to a pendant unit 360 and the driving mechanism housed therein. The coupling can be a mechanical coupling or any suitable quick release mechanism known to those of skill in the art. The releasably coupled design allows for flexibility in the configuration and use of the pumping device. For instance, user comfort can be improved through the use of differently sized breast interfaces for compatibility with various breast sizes. Additionally, this feature enables a common pumping device to be used with interchangeable breast interfaces, thus reducing the risk of spreading pathogens. Furthermore, the releasable coupling enables easy replacement of individual parts of the pumping device.

[0062] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the actuation mechanism can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Flexible membrane

[0063] In many embodiments such as the embodiment depicted in Fig. 3, the flexible membrane 245 is located within breast interface 235 and disposed over at least portion thereof, forming reservoir 250 between the interface housing 240 and the flexible membrane 245. Preferably, the flexible membrane 245 deforms substantially when subject to the negative pressures created when the fluid 230 is displaced from reservoir 250 by actuatable assembly 205. The amount of deformation of the flexible membrane 245 can be controlled by many factors, (*e.g.*, wall thickness, durometer, surface area) and can be optimized based on the pumping device (*e.g.*, pump power, vacuum requirements).

[0064] Fig. 6 illustrates an exemplary flexible membrane 370 with a specified thickness and durometer.

[0065] Fig. 7 illustrates another embodiment of flexible membrane 375 with corrugated features 380 for increased surface area.

[0066] Suitable materials for the flexible membrane are known to those of skill in the art. In many embodiments, the flexible membrane can be made of a material designed to expand and contract when subject to pressures from the coupling fluid such as silicone, polyether block amides such as PEBAX, and polychloroprenes such as neoprene. Alternatively, the flexible membrane can be fabricated from a substantially rigid material, such as stainless steel, nitinol, high durometer polymer, or high durometer elastomer. In these embodiments, the rigid material would be designed with stress and/or strain distribution elements to enable the substantial deformation of the flexible membrane without surpassing the yield point of the material.

[0067] Figs. 8A and 8B illustrate preferred embodiments of a breast interface 400 in which an exit valve 405 is integrated into the flexible membrane 410 to control the flow of expressed milk through exit port 415. The exit valve 405 is opened to allow fluid flow when the flexible membrane 410 is relaxed, as shown in Fig. 8A, and is closed to prevent fluid flow when the flexible membrane 410 is deformed, as shown in Fig. 8B. The exit valve 405 enables substantial vacuum pressure to be present in expression area 420 during extraction, while allowing milk to drain during the rest phase of the pump stroke. While many conventional breast pump valves function on pressure differentials alone, the exit valve 405

can preferably be configured to also function on the mechanical movement of flexible membrane 410. Incorporation of an integrated exit valve 405 with mechanical functionality as described herein can improve the sealing of the breast interface 400 during vacuum creation. Furthermore, the implementation of an exit valve integrally formed within the flexible membrane 410 such as exit valve 405 reduces the number of parts to be cleaned.

[0068] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the flexible membrane can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Milk collection and quantification system

[0069] With reference to Fig. 3, expressed milk drains through exit port 265 in flexible membrane 245 into a collection vessel 275. Collection vessel 275 can be any suitable container, such as a bottle or a bag. In many embodiments, collection vessel 275 is removably coupled to flexible membrane 245. Collection vessel 275 can be coupled directly or remotely via any suitable device such as extension tubing.

[0070] In many instances, it can be desirable to track various data related to milk expression and collection, such as the amount of milk production. Currently, the tracking of milk production is commonly accomplished by manual measurements and record-keeping. Exemplary embodiments of the device described herein may provide digital-based means to automatically measure and track milk production for improved convenience, efficiency, and accuracy.

[0071] Figs. 9A and 9B illustrates exemplary embodiments of a breast interface 450 with one or more integrated sensors 455. Sensors 455 are preferably located in flap valve 460, but may also be located in exit valve 465, or any other suitable location for monitoring fluid flow. In a preferred embodiment, at least one sensor 455 is integrated into a valve that is opened by fluid flow and detects the length of time that the valve is opened. The sensor signal can be interrogated to quantify the fluid flow. Suitable sensors are known to those of skill in the art, such as accelerometers, Hall effect sensors, and photodiode/LED sensors. The breast interface can include a single sensor or multiple sensors to quantify milk production.

[0072] Fig. 10 illustrates an exemplary embodiment of pendant unit 500 in which milk expression data is shown on a display screen 505. In many embodiments, the pendant unit 500 collects, processes, stores, and displays data related to milk expression. Preferably, the pendant unit 500 can transmit the data to a second device, such as a mobile phone 510.

[0073] Fig. 11 illustrates data transmission 515 between pendant unit 500 and a mobile phone 510. Suitable methods for communication and data transmission between devices are known to those of skill in the art, such as Bluetooth or near field communication.

[0074] In exemplary embodiments, the pendant unit 500 communicates with a mobile phone 510 to transmit milk expression data, such as expression volume, duration, and date. The mobile phone 510 includes a mobile application to collect and aggregate the expression data and display it in an interactive format. Preferably, the mobile application includes additional features that allow the user to overlay information such as lifestyle choices, diet, and strategies for increasing milk production, in order to facilitate the comparison of such information with milk production statistics. Additionally, the pendant unit 500 can send information about the times of pump usage to the mobile phone 510 so that the mobile application can identify when pumping has occurred and set reminders at desired pumping times. Such reminders can help avoid missed pumping sessions, and thus reduce the incidence of associated complications such as mastitis.

[0075] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the milk collection and quantification system can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Mechanical pumping device

[0076] Fig. 12 illustrates an alternative embodiment of a breast interface 600 in which a mechanical deformable member 605 can be used in place of a flexible membrane. The mechanical deformable member 605 can be constructed from similar techniques as those used for the flexible membrane as described herein. The mechanical deformable member 605 is coupled to a tensile element 610. In some instances, tensile element 610 is disposed within an axial load absorbing member 615. The axial load absorbing member 615 is disposed within tube 620. Preferably, tensile element 610 is concentrically disposed within axial load absorbing member 615 and axial load absorbing member 615 is concentrically disposed within tube 620. Alternative arrangements of tensile element 610, axial load absorbing member 615, and tube 620 can also be used.

[0077] Fig. 13 illustrates the tensile element 610 coupled to driving element 625 of an actuatable assembly 630 within an assembly housing 635. Driving element 625 is operatively coupled to a driving mechanism, such as a driving mechanism housed within a pendant unit, through shaft 640. Axial load absorbing member 615 within tube 620 is fixedly coupled to the assembly housing 635. Displacement of the driving element 625 transmits tensile force

through tensile element 610 to the mechanical deforming member 605 to create vacuum pressure against the breast.

[0078] The tensile element 610 can be any suitable device, such as a wire, coil, or rope, and can be made from any suitable material, such as metals, polymers, or elastomers. Axial load absorbing member 615 can be made from any suitable axially stiff materials, such as metals or polymers, and can be configured into any suitable axially stiff geometry, such as a tube or coil.

[0079] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the mechanical pumping device can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Experimental data

[0080] Figs. 14 and 15 illustrate experimental pumping data obtained from a commercial breast pump device and an exemplary embodiment of the present invention. The exemplary embodiment utilized an incompressible fluid for pumping and had a maximum hydraulic fluid volume of 4 cc, while the commercial device utilized air for pumping and had a maximum volume of 114 cc.

[0081] Fig. 14 illustrates a graph of the pump performance as quantified by vacuum pressure generated per run. For the exemplary embodiment, pressure measurements were taken for 1 cc, 2 cc, 3 cc, and 4 cc of fluid volume displaced by the pump, with the run number corresponding to the volume in cc. For the commercial device, measurements were taken with the pump set to one of seven equally incremented positions along the vacuum adjustment gauge representing 46 cc, 57 cc, 68 cc, 80 cc, 91 cc, 103 cc, and 114 cc of fluid volume displaced by the pump, respectively, with the run number corresponding to the position number. Curve 700 corresponds to the exemplary embodiment and curve 705 corresponds to the commercial device. The exemplary embodiment generated higher levels of vacuum pressure per displacement volume compared to the commercial device, with maximum vacuum pressures of -240.5 mmHg and -177.9 mmHg, respectively.

[0082] Fig. 15 illustrates a graph of the pump efficiency as measured by the maximum vacuum pressure per maximum volume of fluid displaced, with bar 710 corresponding to the exemplary embodiment and bar 715 corresponding to the commercial device. The exemplary embodiment demonstrated a 42-fold increase in pumping efficiency compared to the commercial device, with efficiencies of -71.1 mmHg/cc and -1.7 mmHg/cc, respectively.

[0083] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

CLAIMS

WHAT IS CLAIMED IS:

1. A device for expression and collection of breast milk, said device comprising:

an actuatable assembly;

a breast interface sized to engage a breast and fluidly seal thereagainst, the breast interface having a movable member disposed within at least a portion thereof, wherein the movable member moves in response to actuation of the actuatable assembly and thereby forms a vacuum in the breast interface and applies the vacuum to the breast to express milk therefrom; and

a tube operatively coupling the actuatable assembly to the breast interface.

2. The device of claim 1, wherein the actuatable assembly comprises a piston or a pump.

3. The device of claim 1, wherein the actuatable assembly comprises a pair of pistons or a pair of pumps.

4. The device of claim 1, wherein actuation of the actuatable assembly displaces a fluid disposed in the tube.

5. The device of claim 1, wherein the movable member comprises a flexible membrane.

6. The device of claim 5, wherein the flexible membrane has a corrugated region configured to expand and collapse.

7. The device of claim 5, wherein the flexible membrane deforms in response to actuation of the actuatable assembly, and wherein actuation of the actuatable assembly displaces a fluid contained within the tube.

8. The device of claim 1, wherein the movable member comprises a deformable member.

9. The device of claim 1, wherein the breast interface comprises a resilient and conformable flange for engaging and creating a fluid seal against the breast.

10. The device of claim 1, wherein a fluid is disposed in the tube.

11. The device of claim 10, wherein the fluid is an incompressible fluid.

12. The device of claim 1, wherein a tensile element is disposed in the tube.

13. The device of claim 12, wherein the tensile element comprises a rope, a wire, or a cable.

14. The device of claim 12, wherein the tensile element is operatively coupled with the movable member and the actuatable assembly.

15. The device of claim 1, further comprising a driving mechanism operatively coupled with the actuatable assembly, and configured to actuate the actuatable assembly.

16. The device of claim 15, wherein the driving mechanism is an electromechanical device.

17. The device of claim 15, wherein the driving mechanism comprises a motor.

18. The device of claim 15, wherein the driving mechanism is releasably coupled to the actuatable assembly.

19. The device of claim 1, wherein the breast interface comprises an exit valve, the exit valve configured to control flow of the expressed breast milk into a collection vessel.

20. The device of claim 19, wherein the exit valve controls the flow by preventing the expressed breast milk from flowing through the exit valve when the deformable member is deformed and allowing the expressed breast milk to flow through the exit valve when the deformable member is in an undeformed configuration.

21. The device of claim 19, wherein the exit valve is integrally formed into the deformable member.

22. The device of claim 1, further comprising:

a second breast interface sized to engage a second breast and fluidly seal thereagainst, the second breast interface having a movable member disposed within at least a portion thereof, wherein the movable member deforms in response to actuation of the actuatable assembly and thereby forms a vacuum in the second breast interface and applies the vacuum to the second breast to express milk therefrom; and

a second tube operatively coupling the actuatable assembly to the second breast interface.

23. The device of claim 1, further comprising:

a second actuatable assembly;

a second breast interface sized to engage a second breast and fluidly seal thereagainst, the second breast interface having a movable member disposed within at least a portion thereof, wherein the movable member deforms in response to actuation of the actuatable assembly or the second actuatable assembly and thereby forms a vacuum in the second breast interface and applies the vacuum to the second breast to express milk therefrom; and

a second tube operatively coupling the second actuatable assembly to the second breast interface.

24. The device of claim 1, further comprising a housing having a controller for controlling actuation of the actuatable assembly.

25. The device of claim 1, further comprising a housing having a controller for controlling calculation and display of breast milk production information, and for controlling communication with other devices.

26. The device of claim 1, further comprising a housing having a power source for providing power to the device for expression and collection of breast milk.

27. The device of claim 1, further comprising a housing having a drive mechanism for actuating the actuatable assembly.

28. The device of claim 1, further comprising a collection vessel fluidly coupled with the breast interface.

29. The device of claim 1, further comprising a sensor adjacent the breast interface, the sensor configured to sense at least one aspect of milk flowing therepast.

30. The device of claim 1, further comprising a display unit for displaying data related to the expression of the milk.

31. A system for expression and collection of breast milk, said system comprising: the device of claim 1.

32. A device for applying pressure or vacuum to a patient, said device comprising:
an actuatable assembly;
a target tissue interface sized to engage a target tissue and fluidly seal thereagainst, the target tissue interface having a deformable member disposed within at least a portion thereof, wherein the deformable member deforms in response to actuation of the actuatable assembly and thereby forms a vacuum or pressure in the target tissue interface and applies the vacuum or the pressure to the target tissue; and
a tube operatively coupling the actuatable assembly to the target tissue interface.

33. A method of expressing and collecting breast milk, said method comprising:
providing a breast expression and collection device having at least one breast interface and at least one actuatable assembly operatively coupled to the at least one breast interface, wherein the breast interface comprises a deformable member;
engaging and fluidly sealing a breast with the breast interface;
actuating the actuatable assembly;
deforming the deformable member in response to actuation of the actuatable assembly thereby creating and applying a vacuum to the breast; and
expressing and collecting milk from the breast.

34. The method of claim 33, wherein the engaging comprises engaging a resilient and conformable flange on the breast interface with the breast thereby creating a fluid seal between the breast interface and the breast.

35. The method of claim 33, wherein actuating the actuatable assembly displaces a fluid.

36. The method of claim 35, wherein the fluid is disposed in a tube fluidly coupled with the actuatable assembly and the deformable member.

37. The method of claim 33, wherein actuating the actuatable assembly comprises moving a piston.

38. The method of claim 33, wherein actuating the actuatable assembly comprises applying a tension to a tensile element disposed in the tube.

39. The method of claim 38, wherein an axial load absorbing member is concentrically disposed around the tensile element, the method further comprising absorbing reactive forces of teh tensile element.

40. The method of claim 33, further comprising releasing the actuatable assembly from a driving mechanism that is operatively coupled therewith.

41. The method of claim 33, further comprising repeating the actuating, the deforming and the expressing.

42. The method of claim 33, further comprising quantifying production of the expressed milk.

43. The method of claim 33, further comprising quantifying one or more aspects of the expressed milk.

44. The method of claim 33, further comprising transmitting data related to the expression of breast milk between the breast expression and collection device and a computing device.

45. The method of claim 44, wherein the mobile device comprises a smart phone.

46. The method of claim 44, further comprising displaying the data on a display.

47. The method of claim 33, further comprising controlling flow of the expressed milk into a collection vessel with a valve fluidly coupled to the breast expression and collection device.

48. The method of claim 47, wherein controlling flow comprises opening the valve when the deformable member is undeformed, and closing the valve when the deformable member is deformed.

49. The method of claim 33, further comprising sensing flow of the expressed breast milk with a sensor fluidly coupled with the breast interface.

50. The method of claim 33, wherein the breast expression and collection device further comprises a second breast interface and a second actuatable assembly operatively coupled to the second breast interface, and wherein the second breast interface comprises a deformable member, the method further comprising:

engaging and fluidly sealing a second breast with the second breast interface;

actuating the second actuatable assembly;

deforming the deformable member in the second breast interface in response to actuation of the second actuatable assembly thereby creating and applying a vacuum to the second breast; and

expressing and collecting milk from the second breast.

51. The method of claim 50, wherein expressing and collecting milk from both breasts occurs simultaneously.

52. The method of claim 50, wherein expressing and collecting milk alternates between both breasts.

53. A method of applying a differential pressure to a patient, said method comprising:

providing a differential pressure device having an interface and an actuatable assembly operatively coupled to the differential pressure device, wherein the interface comprises a deformable member;

engaging and fluidly sealing the interface with a target region on the patient;

actuating the actuatable assembly; and

deforming the deformable member in response to actuation of the actuatable assembly thereby creating a positive pressure or a vacuum and applying the positive pressure or the vacuum to the target region.

54. The method of claim 53, wherein deforming the deformable member creates a positive pressure applied to the target region, the target region comprising the mouth or nose, thereby reducing or eliminating apnea while the patient is sleeping.

55. The method of claim 53, wherein deforming the flexible membrane creates a vacuum applied to the target region, the target region comprising a body fluid reservoir, thereby expressing the body fluid therefrom.

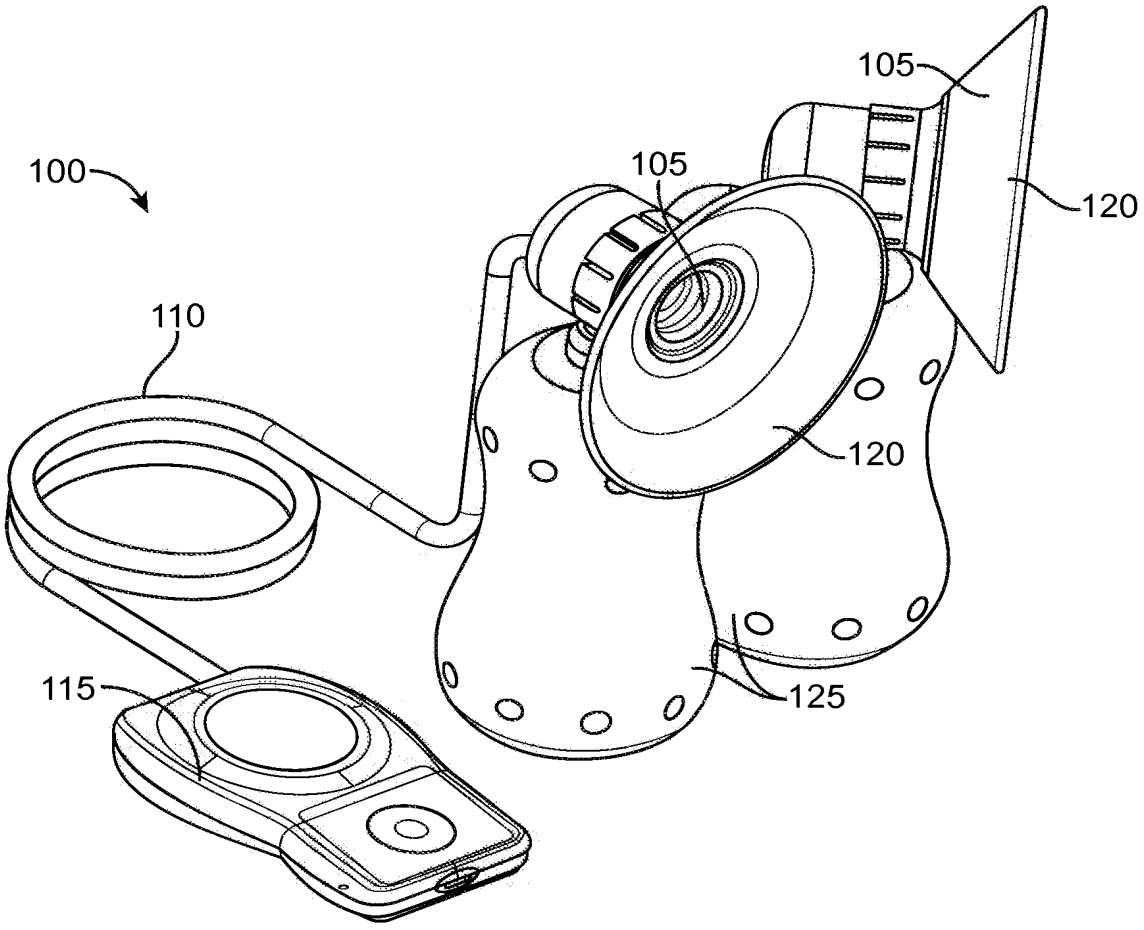

FIG. 1

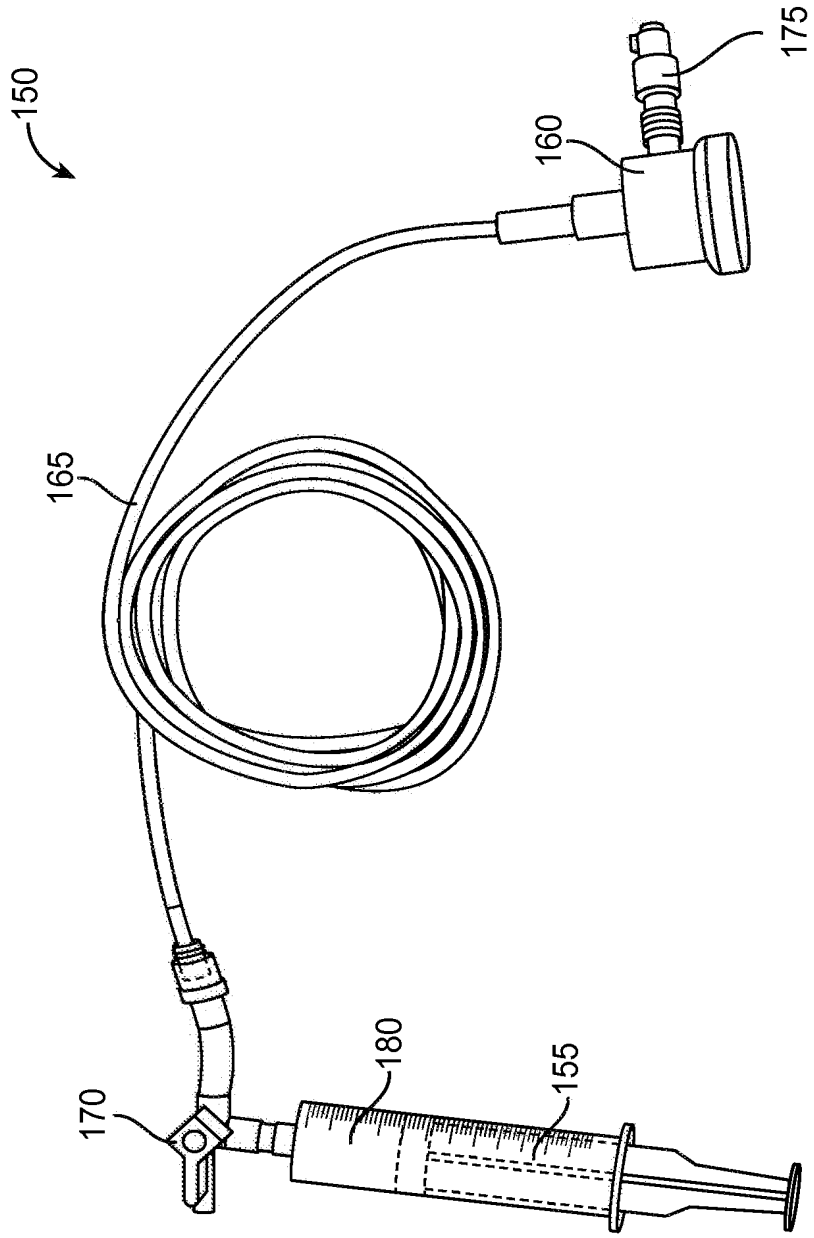

FIG. 2

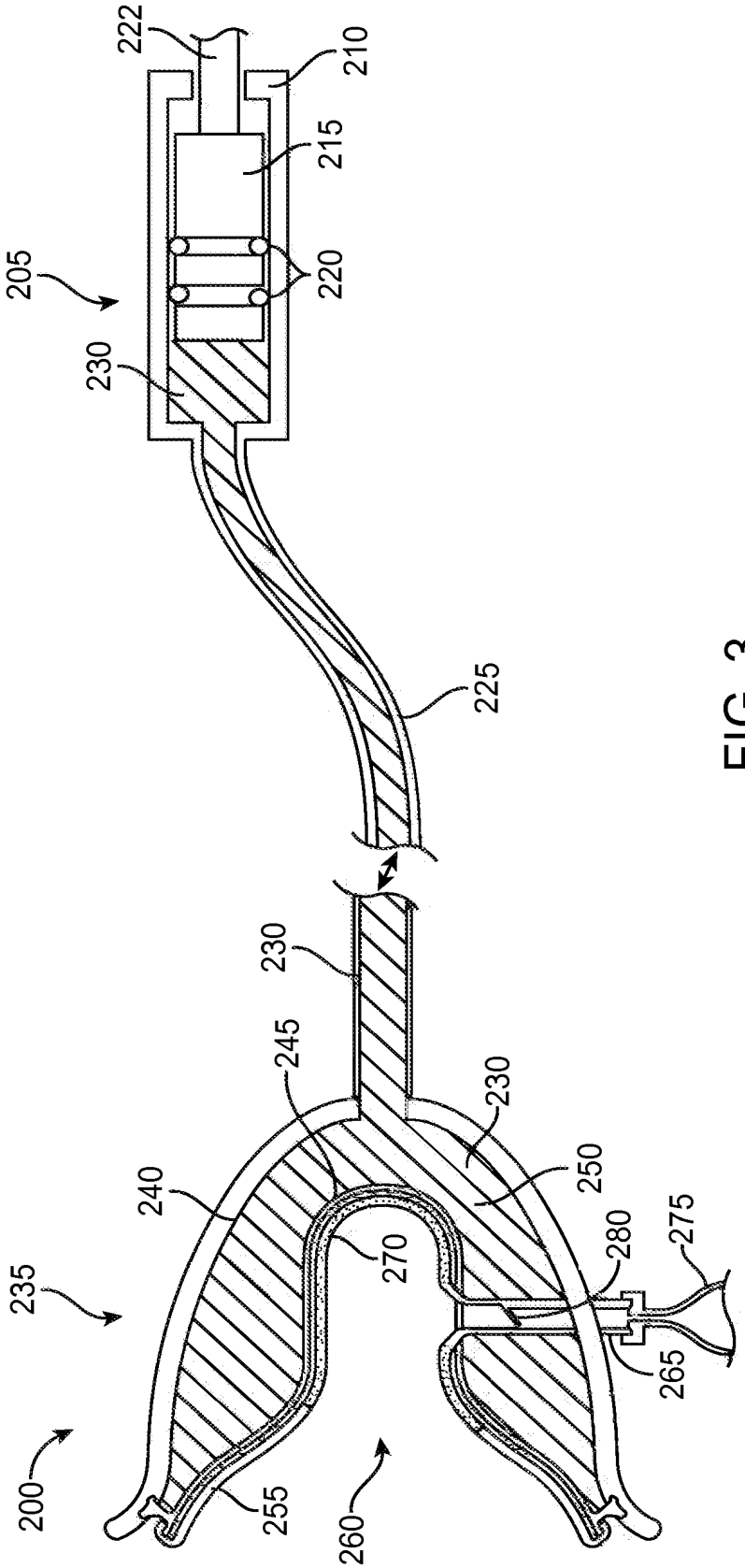
222
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FIG. 3

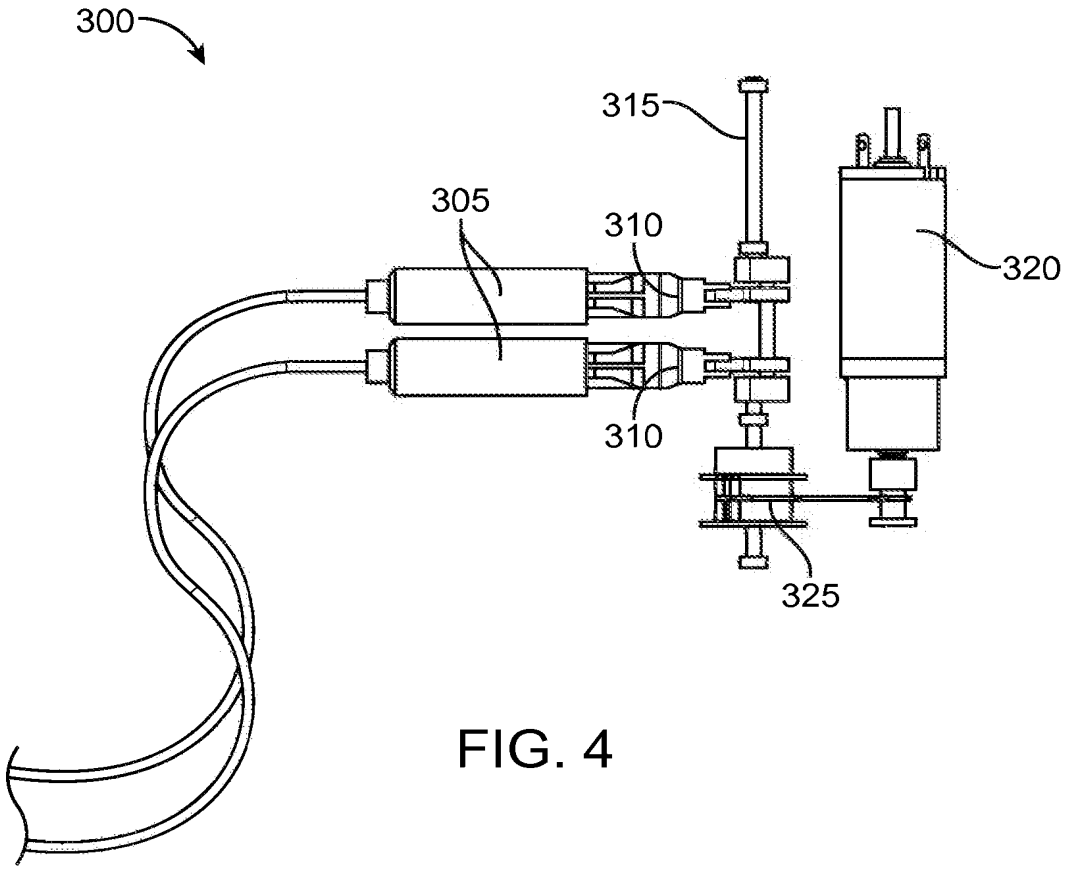


FIG. 4

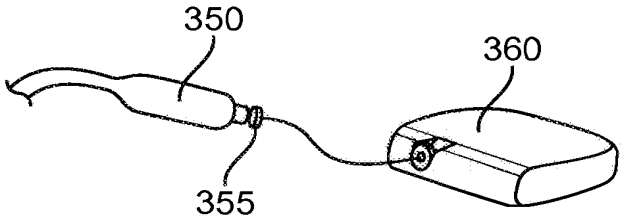


FIG. 5A

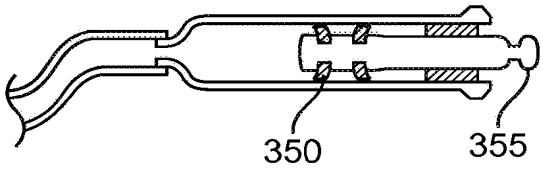


FIG. 5B

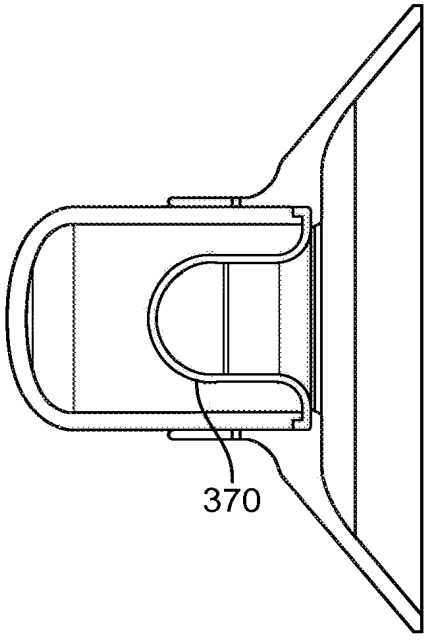


FIG. 6

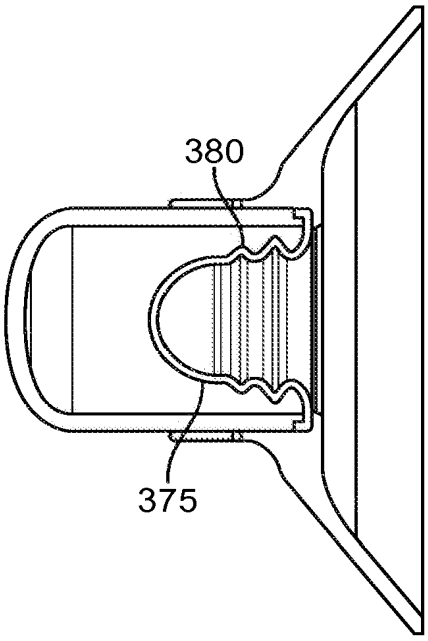


FIG. 7

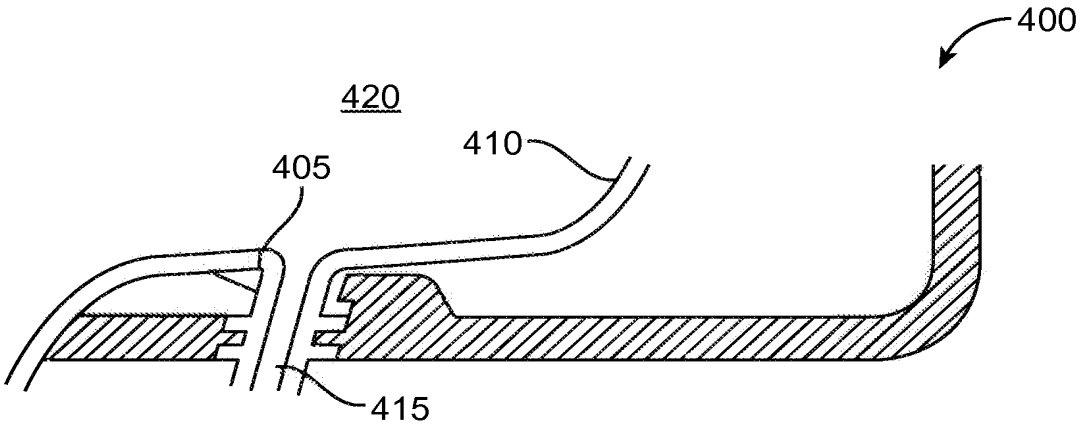


FIG. 8A

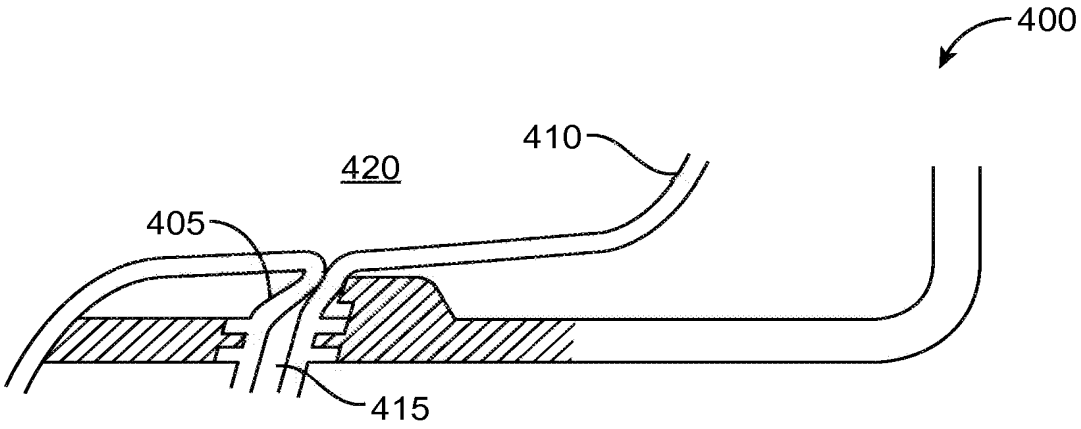


FIG. 8B

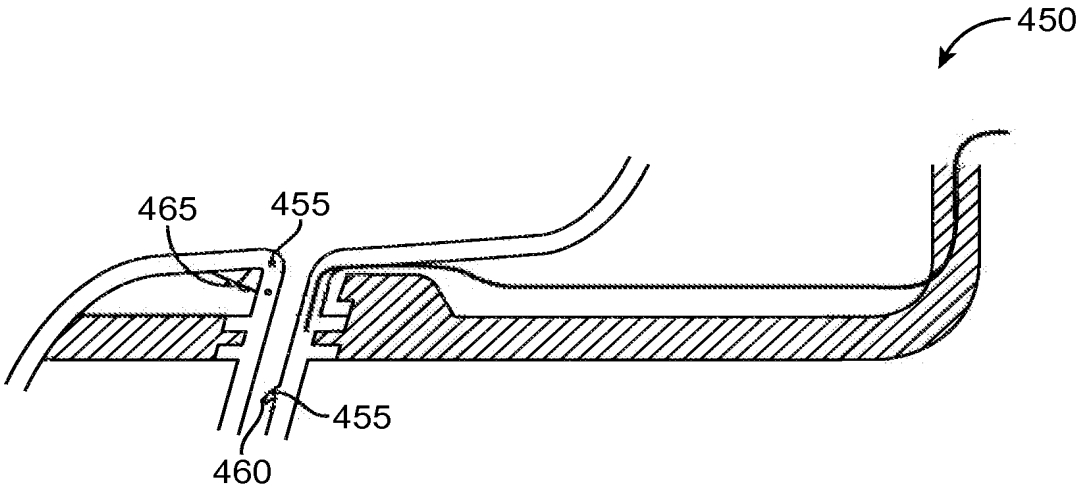


FIG. 9A

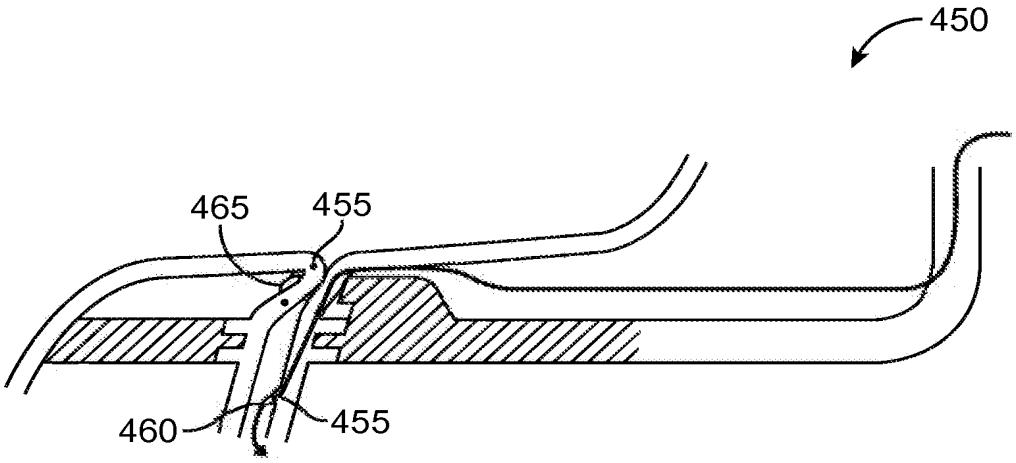
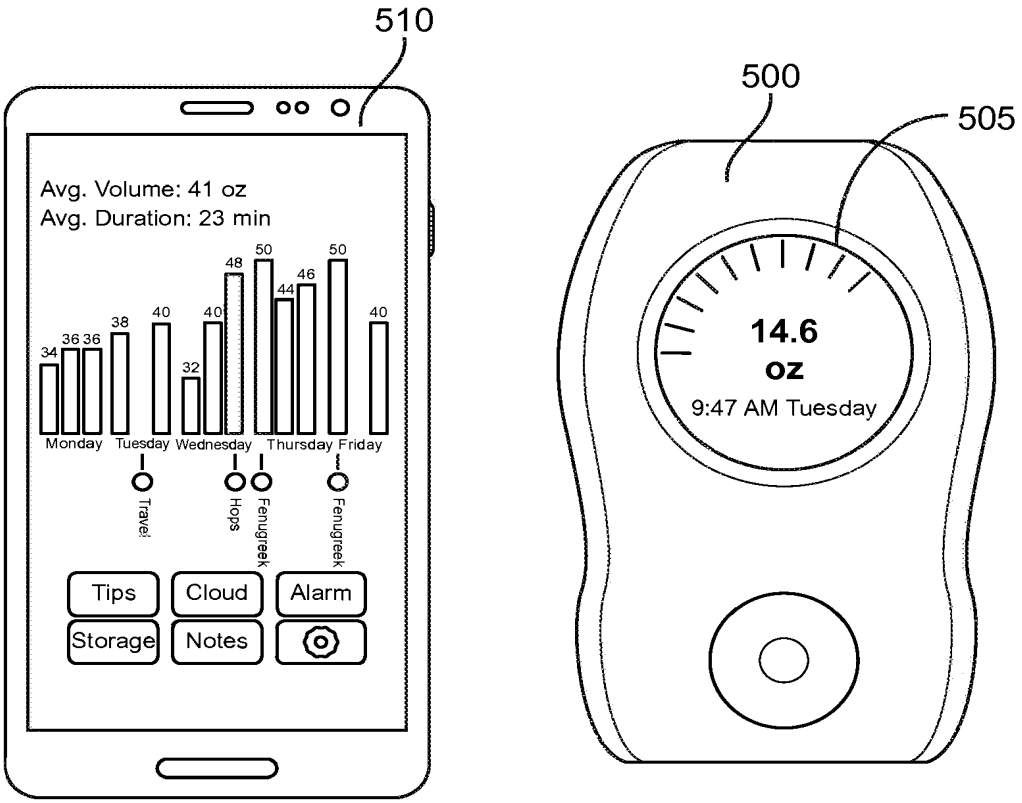


FIG. 9B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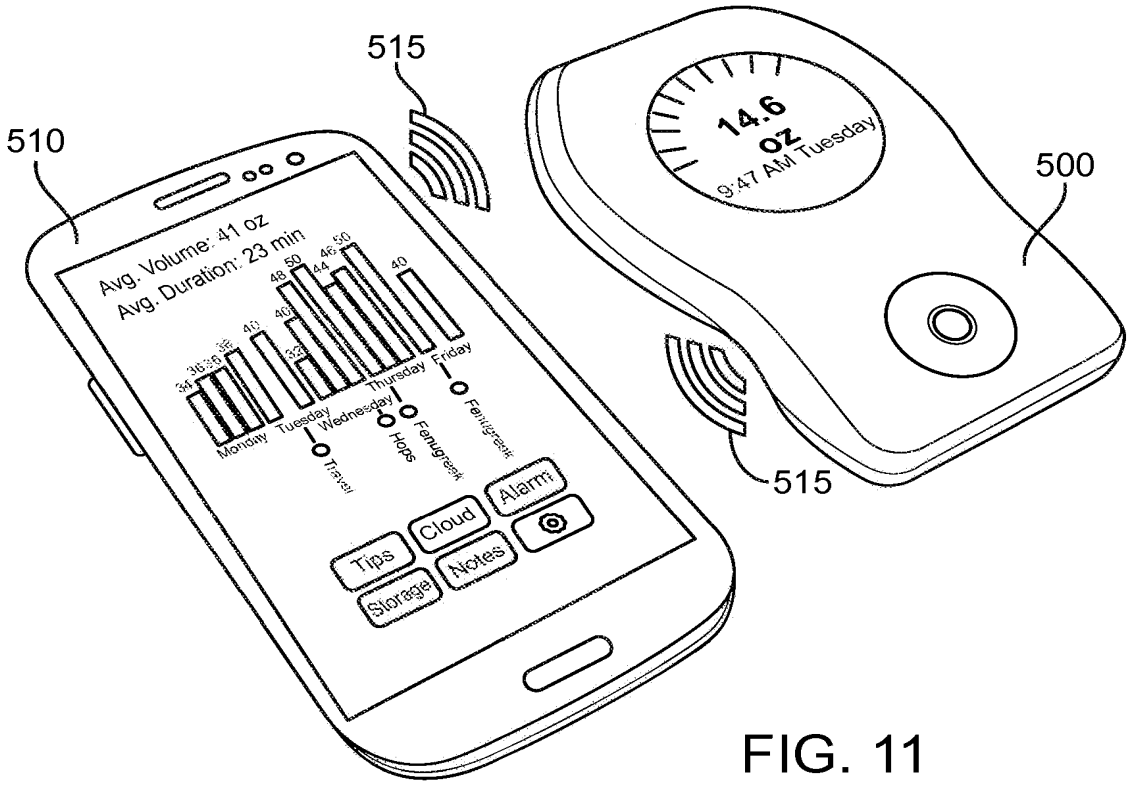
500
505
Avg. Volume: 41 oz
Avg. Duration: 23 min
34 36 36 38 40 32 40 48 50 44 46 50 40
Monday Tuesday Wednesday Thursday Friday
Travel
Hops
Fenugreek
Fenugreek
Tips
Cloud
Alarm
Storage
Notes
14.6
oz
9:47 AM Tuesday

FIG. 10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510
500
515
Avg. Volume: 41 oz
Avg. Duration: 23 min
Monday Tuesday Wednesday Thursday Friday
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Hops
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Fenugreek
Tips
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Alarm
Storage
Notes
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oz
9:47 AM Tuesday

FIG. 11

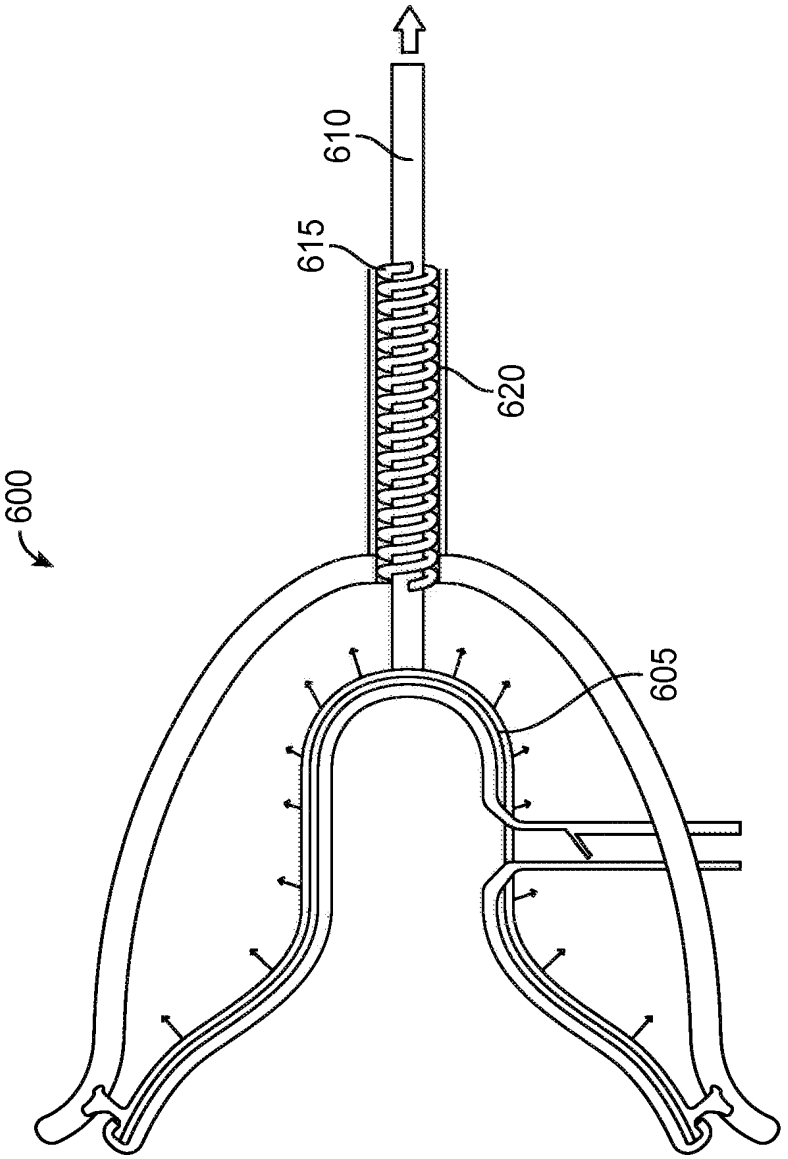


FIG. 12

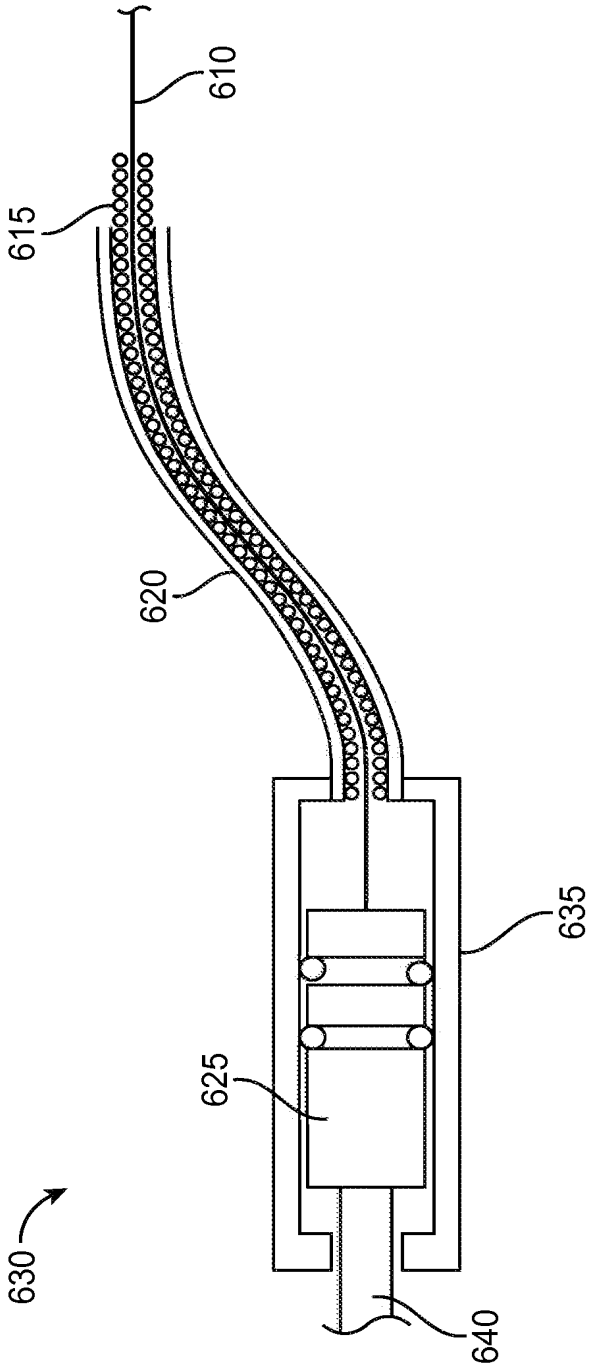
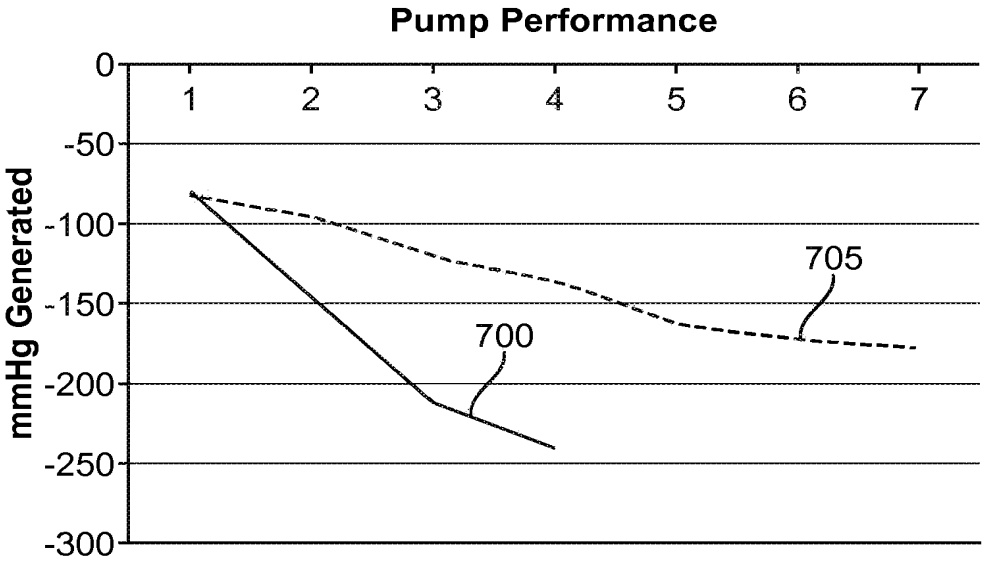


FIG. 13


Pump Performance
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-150
-200
-250
-300
mmHg Generated
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2
3
4
5
6
7
705
700

FIG. 14

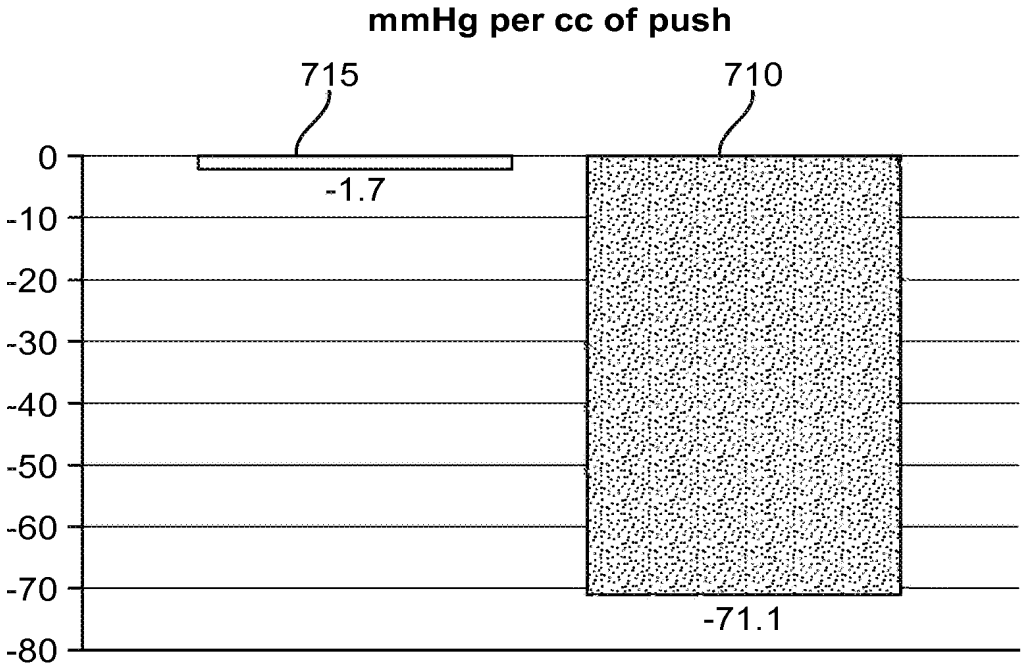

FIG. 15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/031510

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 1/06 (2014.01)
USPC - 604/74
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A41C 3/04; A61J 9/00, 11/00; A61M 1/06 (2014.01)
USPC - 215/11.1; 450/36, 37; 606/73, 74

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61M 1/06, 1/062, 1/064, 1/066 (2014.07)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Orbit, Google Patents, Google Scholar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/0316493 A1 (SCHLIENGER et al) 13 December 2012 (13.12.2012) entire document	1, 2, 4, 5, 7-11, 15-17, 19, 20, 26-28, 31-36, 41, 47, 48, 53, 55
Y		3, 6, 12-14, 18, 21-25, 29, 30, 37-40, 42-46, 49-52, 54
Y	WO 2012/014135 A1 (BOSMAN et al) 02 February 2012 (02.02.2012) entire document	3, 37
Y	US 2003/0153869 A1 (YTTEBORG) 14 August 2003 (14.08.2003) entire document	6
Y	US 2006/0106334 A1 (JORDAN et al) 18 May 2006 (18.05.2006) enire document	12-14, 38, 39
Y	US 5,007,899 A (LARSSON) 16 April 1991 (16.041991) entire document	18, 40
Y	US 2003/0191433 A1 (PRENTISS) 09 October 2003 (09.10.2003) entire document	21
Y	US 6,997,897 B1 (SILVER et al) 14 February 2006 (15.02.2006) entire document	22-24, 50-52
Y	US 2008/0039741 A1 (SHEMESH et al) 14 February 2008 (14.02.2008) entire document	25, 29, 30, 42-46,49
Y	US 2012/004603 A1 (HARARI et al) 05 January 2012 (05.01.2012) entire document	45
Y	US 2012/0325219 A1 (SMITH) 27 December 2012 (27.12.2012) entire document	54

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 August 2014	02 SEP 2014
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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ABSTRACT JP2017503552A

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13 The beverage preparation machine (1) is formed from illuminable parts (11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X) and inner parts (110, 120) and a control device (100, 105) for enabling and disabling illumination of the illuminable portion. and a user interface (10, 10', 20, 30, 40, 50). The controller may select a setting that activates only portions of the illuminable portion, e.g., sequentially activates successive portions in a rotational sequence around an inner portion, and optionally activates all portions after all portions. It has at least one setting for disabling simultaneously or for sequentially disabling previously enabled portions at the same speed as the speed of enabling or slower. [Selection drawing] Fig. 1a

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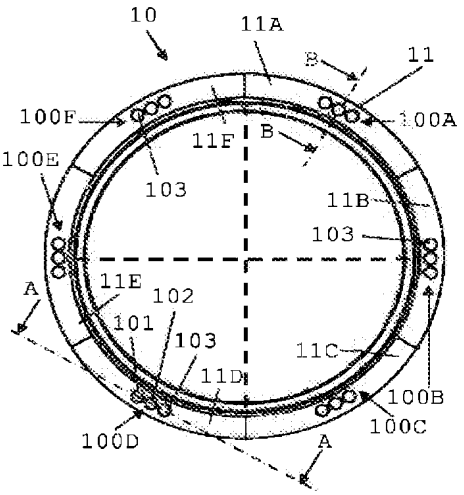
最終頁に続く

(54)【発明の名称】飲料マシンのための、単純な人間工学的ユーザインタフェース

(57)【要約】
飲料調製マシン（１）は、照明可能な部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）から形成され、内側部分（１１０、１２０）の周囲で延びる、概ね外周の照明可能装置（１１、１１’、２１、３１、４１、５１）と、照明可能部分の照明を有効化及び無効化するための制御装置（１００、１０５）とを有する、ユーザインタフェース（１０、１０’、２０、３０、４０、５０）を含む。制御装置は、照明可能部分の部分のみを有効化する設定、例えば、連続する部分を、内側部分を中心として回転シーケンスで順次有効化し、任意により、全ての部分を有効化した後に全ての部分を同時に無効化するか、又は先に有効化した部分を、有効化速度と同じ速度、若しくはより遅い速度で順次無効化するための、少なくとも１つの設定を有する。
【選択図】　図１ａ

Fig. 1a



【特許請求の範囲】
【請求項１】
給水源（２）、飲料調製ユニット（３）、及び飲料を飲料注出領域（４）に供給するための出口（３ａ）を有するマシンなどの、飲料調製マシン（１）であって、
照明可能部分（１１Ａ、１１Ｂ、１１Ｃ、１１Ｄ、１１Ｅ、１１Ｆ、１１Ａ’、１１Ｂ’、１１Ｃ’、１１Ｄ’、１１Ｅ’、１１Ｆ’、１１Ｇ’、１１Ｈ’、２１Ａ、２１Ｂ、２１Ｃ、２１Ｄ、２１Ｅ、２１Ｆ、２１Ｇ、３１Ａ、３１Ｂ、３１Ｃ、３１Ｄ、３１Ｅ、３１Ｆ、４１Ａ、４１Ｂ、５１Ａ、５１Ｂ、５１Ｃ、５１Ｄ、５１Ｅ、５１Ｆ、５１Ｇ、５１Ｈ、５１Ｘ）により形成され、内側部分（１１０、１２０）の周囲で延びる、概ね外周の照明可能装置（１１、１１’、２１、３１、４１、５１）と、
プログラミング可能な制御装置（１００、１０５）などの、前記照明可能部分の照明を有効化及び無効化するための制御装置（１００、１０５）であって、例えば、プリント回路基板ＰＣＢ（１００）、及び該ＰＣＢにコネクタ（１００’’’）により接続されたコントローラ（１０５）を備え、任意により、飲料調製ユニット（３）のＩＴモジュール、ポンプ、熱調節器、及び／又は動力部など、前記マシン（１）の他の機能部を制御する、制御装置と、を有するユーザインタフェース（１０、１０’、２０、３０、４０、５０）を備え、
前記ユーザインタフェース（１０、１０’、２０、３０、４０、５０）は、任意により、前記マシン（１）の上部（１ａ）、前部（１ｂ）、又は側部（１ｃ）にある、飲料調製マシンにおいて、
前記制御装置（１００、１０５）は、前記照明可能部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）の一部のみを有効化するための、プログラミングされた設定などの少なくとも１つの設定を有することを特徴とする、飲料調製マシン（１）。
【請求項２】
前記照明可能部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）は、前記概ね外周の照明可能装置（１１’）に沿って配置された、丸いスポット、又は、例えば、三角形、四角形、五角形、又は八角形のスポットなどの、多角形のスポットなどの１つ以上のスポット（１１Ａ’～１１Ｈ’）、及び／又は前記概ね外周の照明可能装置（１１、２１、３１、４１、５１）に沿って延びる１つ以上の細長いセグメントを有し、前記細長いセグメントは、
円形セクターに概ね沿って延びるセグメント（１１Ａ～１１Ｆ）、及び／又は楕円形セクターに概ね沿って延びるセグメント（５１Ａ～５１Ｘ）などの、湾曲セグメント（１１Ａ～１１Ｆ、５１Ａ～５１Ｘ）、
真っ直ぐなセグメント（２１Ａ、２１Ｃ、２１Ｅ、２１Ｆ、２１Ｇ、３１Ｂ、２１Ｃ、２１Ｄ、２１Ｅ）、
角度を成すセグメント（２１Ｂ、２１Ｄ、３１Ａ、３１Ｇ、４１Ａ、４１Ｂ）、
前記外周の照明可能装置（２１、３１、４１）の真っ直ぐな辺（２１Ａ、２１Ｂ、３１Ａ、４１Ａ、４１Ｂ）全体に沿って延びるセグメント、
前記外周の照明可能装置（２１、３１、４１）の、真っ直ぐな辺全体にわたって（２１Ｂ、３１Ａ、４１Ａ、４１Ｂ）、及び／若しくは真っ直ぐな辺の一部にわたって（２１Ｄ、３１Ａ、３１Ｆ、４１Ａ、４１Ｂ）延びる、角度を成すセグメント、並びに／又は前記外周の照明可能装置（２１、３１、４１）の、２つの真っ直ぐな辺のみに沿って（２１Ｂ、２１Ｄ、３１Ｆ、４１Ａ、４１Ｂ）、及び／若しくは３つ以上の辺に沿って（３１Ａ）延びるセグメントなど、前記外周の照明可能装置（２１、３１、４１）の複数の真っ直ぐな辺（２１Ｂ、３１Ａ、４１Ａ、４１Ｂ）に沿って延びる、角度を成すセグメント、並びに、
前記外周の照明可能装置（１１、２１、３１、４１、５１）の全長の部分にわたって延びるセグメントであって、この部分は全長（３１Ｃ、３１Ｄ、３１Ｅ）の約半分（３１Ａ、４１Ａ、４１Ｂ）、又は１／３（２１Ｂ）、又は１／４（３１Ｆ）、又は１／５、又

は１／６（１１Ａ～１１Ｆ、２１Ａ、２１Ｄ）、又は１／７、又は１／８（３１Ｂ）、又は１／９（５１Ａ～５１Ｘ）、又は１／１０、又は１／１２（２１Ｃ、２１Ｅ、２１Ｆ、２１Ｇ）、又は１／２４と対応する、セグメント、から選択され得るセグメントを含む、請求項１に記載のマシン。

【請求項３】

前記概ね外周の照明可能装置（１１、１１’、２１、３１、４１、５１）は、単一の内側部分（１１０）の周囲で延び、又は、一対の内側部分（１１０、１２０）などのいくつかの内側部分（１１０、１２０）の周囲で、例えば、前記概ね外周の照明可能装置（５１）が、離間した前記内側部分（１１０、１２０）の周囲及び間でほぼ８の形状になるように延び、任意により、単一の内側部分（１１０）は、複数の部分、例えば、複数の有効インタフェース部分（１１０Ａ、１１０Ｂ、１１０Ｃ、１１０Ｄ）、複数の無効インタフェース部分、又は少なくとも１つの有効インタフェース部分（１１０Ｅ）と少なくとも１つの無効インタフェース部分（１１０Ｆ）との組み合わせから作製され、例えば、前記有効インタフェース部分はユーザセレクタの形態であり、及び／又は無効ユーザインタフェース部分はハウジングの一部の形態である、請求項１又は２に記載のマシン。

【請求項４】

前記内側部分は、セレクタ（１１０Ｅ）若しくは複数のセレクタ（１１０Ａ、１１０Ｂ、１１０Ｃ、１１０Ｄ）などの、例えば、１つ以上のプッシュボタンの形態の、能動部分（１１０）、及び／又は、ハウジングの一部などの受動部分（１１０Ｆ、１２０）である、請求項１～３のいずれか一項に記載のマシン。

【請求項５】

前記概ね外周の照明可能装置（１１、１１’、２１、３１、４１、５１）は、以下の特徴：

発光素子（１０１、１０２、１０３）によって放出される光を拡散するための、半透明ウィンドなどの光拡散ウィンド（１１１）、

前記発光素子（１０１’）の形状をユーザに対して示すための、透明ウィンドなどの光透過ウィンド（１１１’）、

単一の色の発光素子（１０１’）、又は、白色、黄色、橙色、赤色、緑色、青色、及びピンク色、並びにこれらの混合から選択される色など、異なる色の発光素子（１０１、１０２、１０３）のグループ（１００Ａ、１００Ｂ、１００Ｃ、１００Ｄ、１００Ｅ、１００Ｆ）などの異なる色の発光素子（１０１、１０２、１０３）を含む、複数の発光素子（１０１、１０１’、１０２、１０３）、

単一の色の発光素子（１０１’）によって、又は異なる色の発光素子（１０１、１０２、１０３）のグループ（１００Ａ、１００Ｂ、１００Ｃ、１００Ｄ、１００Ｅ、１００Ｆ）によって照明可能である、前記外周の照明可能装置（１１、１１’、２１、３１、４１、５１）の各照明可能部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）であって、前記グループの前記発光素子は別個に又はグループで有効化可能である、各照明可能部分、並びに、

任意により、コネクタの対（１００’、１００’’）などのコネクタ（１００’、１００’’）により前記ＰＣＢ又はあるＰＣＢ１００に接続された、ＬＥＤなどの発光素子（１０１’、１０１、１０２、１０３）、の１つ以上を含む、請求項１～４のいずれか一項に記載のマシン。

【請求項６】

前記概ね外周の照明可能装置（１１、１１’、２１、３１、４１、５１）の前記照明可能部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）は、湾曲した及び／又は角度を成す線状構成など、前記内側部分（１１０、１２０）の周囲で横並びの線状構成にあり、任意により、前記概ね外周の照明可能装置の前記照明可能部分は、

単一の横並び線状構成（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）、又は２つ、３つ、若しくは

４つのほぼ平行な若しくは同心状の横並び線状構成にある、並びに／あるいは、
２つの隣接する照明可能部分が、互いに直接隣接している（１１Ａ～１１Ｆ、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）、又はハウジングの一部（１１ａ）などのスペーサによって離間している（１１Ａ’～１１Ｈ’）、横並び線状構成（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）にある、請求項１～５のいずれか一項に記載のマシン。

【請求項７】

照明可能部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）の前記照明が、実質的に、前記部分全体にわたって広がり、任意により、前記部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）の前記照明は、これらの部分全体にわたって、ほぼ均一な光強度、及び／又は、白色、黄色、橙色、赤色、緑色、青色、及びピンク、又はいくつかのこのような色の混合から生じる色から選択される色などの、ほぼ均一な色をもたらす、請求項１～６のいずれか一項に記載のマシン。

【請求項８】

前記制御装置（１００、１０５）は、連続する部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）、例えば、線状横並び構成の連続する部分を、前記内側部分（１１０、１２０）を中心として、ある回転シーケンスで順次有効化するための少なくとも１つの設定を有し、任意により、

ａ）時計方向及びその後の反時計方向の回転シーケンスで、又は、反時計方向及びその後の時計方向の回転シーケンスで順次有効化するための少なくとも１つの設定、

ｂ）前記回転シーケンスが完了すると、これを一度以上繰り返して順次有効化するための少なくとも１つの設定、

ｃ）回転シーケンスにわたって、及び／若しくは複数の連続する回転シーケンスの間で、例えば、

飲料調製手順、例えば、予備湿潤、及び抽出の連続する工程、及び／若しくは、

サービス手順、例えば、スケール除去手順の連続する工程、という異なる工程を示すように速度を変更し、順次有効化するための少なくとも１つの設定、

あるいは、

ｄ）特徴ａ）～ｃ）の少なくとも２つの組み合わせを有する、請求項１～７のいずれか一項に記載のマシン。

【請求項９】

前記制御装置（１００、１０５）は、前記連続する部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）を、前記内側部分（１１０、１２０）を中心として回転シーケンスで順次有効化し、全ての前記部分を有効化した後に、全ての前記部分を同時に無効化するための、少なくとも１つの設定を有する、請求項８に記載のマシン。

【請求項１０】

前記制御装置（１００、１０５）は、前記連続する部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）を、前記内側部分（１１０、１２０）を中心として回転シーケンスで順次有効化しながら、前に有効化した部分を前記回転シーケンスで順次無効化し、任意により、

ａ）前記部分は、等しい有効化速度及び無効化速度、又は、前記無効化速度よりも速い有効化速度などの、異なる有効化速度及び無効化速度を有する、及び／若しくは、

ｂ）少なくとも２つ又は３つの部分が同時に有効化状態になる、少なくとも１つの設定を有する、請求項８又は９に記載のマシン。

【請求項１１】

前記制御装置（１００、１０５）は、１つの部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）が間欠的に有効化及び無効化される、少なくとも１つの設定を有し、任意により、

ａ）前記内側部分（１１０、１２０）を中心に恒久的に有効化又は無効化された部分によって離間した、例えば、ほぼ均等に離間した、複数の部分又は部分のグループなどの複数の前記部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）が、同時に有効化及び無効化される、

ｂ）複数の２つの部分が交互に有効化及び無効化されるなど、前記部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）の２つが、交互に有効化及び無効化される、

ｃ）前記部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）は、一定の頻度で間欠的に有効化及び無効化され、例えば、いくつかの部分が一定の頻度で間欠的に有効化及び無化される、又は

ｄ）特徴ａ）、ｂ）、及びｃ）の２つ又は３つの組み合わせである、請求項１～１０のいずれか一項に記載のマシン。

【請求項１２】

前記設定に加えて、前記制御装置（１００、１０５）は、前記設定よりも速い速度で、部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）を有効化及び無効化して、例えば、

起動若しくはサービス（例えば、スケール除去）手順の実行など、異なる種類の手順の実行を区別するための少なくとも１つの更なる設定、及び／又は、

例えば、ルンゴ若しくはエスプレッソコーヒーの異なる飲料の調製手順などの同じ種類の異なる手順、又は、例えば、軽度の若しくは集中的スケール除去手順などの異なるサービス手順の実行を区別するための少なくとも１つの更なる設定を有する、請求項８～１１のいずれか一項に記載のマシン。

【請求項１３】

有効化可能及び無効化可能な前記部分に加えて、少なくとも１つの部分が、前記設定又は前記更なる設定において、恒久的に有効化又は無効化されたままである、請求項８～１２のいずれか一項に記載のマシン。

【請求項１４】

前記制御装置（１００、１０５）は、例えば、単一部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）、又は隣接する部分のグループなどの、少なくとも１つの部分が順次有効化される、少なくとも１つの設定を有する、請求項１～１３のいずれか一項に記載のマシン。

【請求項１５】

前記外周の照明可能装置（１１、１１’、２１、３１、４１、５１）は、細長い形状に概ね沿っており、

ａ）例えば、１つ以上の円（１１、１１’）及び／若しくは楕円（５１）、又はその一部などの曲線（１１、１１’）を形成する、

ｂ）三角形（４１）、例えば、正方形（３１）、矩形、台形、若しくは平行四辺形である、四角形（３１）、五角形、六角形（２１）、七角形、八角形（１１’）、九角形、十角形、十一角形、若しくは十二角形などの、規則的若しくは不規則的な多角形（２１、３１、４１）、又はその一部を形成する、

ｃ）ストライプ（１１、２１、３１、４１、５１）の形状、及び／又は、前記細長い形状に概ね沿って配置された、別個の発光素子などの別個の要素（１１’）、例えば、ＬＥＤ（１０１’）又は発光可能光ファイバーの一部の形状に延びる、あるいは、

ｄ）特徴ａ）、ｂ）、及びｃ）の少なくとも２つの組み合わせである、請求項１～１４のいずれか一項に記載のマシン。

【請求項１６】

前記制御装置（１００、１０５）は、ユーザに対して、

例えば、請求項８又は９に定義される設定による、加熱器の起動などの起動手順の実行を示すように、

例えば、請求項１４に定義される設定による、飲料調製の準備完了までに必要な時間に関する指標をインタフェースが提示するスタンバイ手順を示すように、

例えば、請求項８、９、又は１０に定義される設定による、飲料調製手順、例えば、請求項８の選択肢ｂ）と組み合わされた請求項１０など、請求項１０に定義される設定による、例えば、遠心処理の軸線（３ａ）を取り囲む前記概ね外周の照明可能装置（１１、１１’、２１、３１、４１、５１）による、遠心処理による飲料調製手順の実行を示すように、

例えば、請求項１４に定義される設定による、任意により、全ての前記部分が有効化されている（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）、ユーザ命令を受信する準備が完了した状態を示すように、

例えば、請求項１１に記載される設定による、原材料カプセルなどのカプセルから、又は、例えば、ネットワーク又はポータブルメモリ装置に接続される、マシンインタフェースからの情報を読み取る手順の実行を示すように、

例えば、請求項１１に定義される設定による、例えば、水の不足などの原材料の不足を示す、エラーの状態を示すように、

例えば、請求項１４に定義される設定による、飲料調製プロセスのパラメータを設定するため、又はスタンバイ若しくは自動停止プロセスに入るためのタイマーを設定するためなどの、ユーザプログラミングモードの有効化を示すように、

例えば、請求項８～１４のいずれか一項に定義される設定による、すすぎ、洗浄、スケール除去、又は水材料排出手順など、サービス手順の実行を示すように、かつ、

例えば、請求項１１に定義される設定による、例えば、少なくとも１つの部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）の有効化及び無効化シーケンスのいくつかにより、例えば、ユーザセレクタ（１１０、１１０Ａ、１１０Ｂ、１１０Ｃ、１１０Ｄ）による、ユーザ命令の獲得の完了を示すように、

前記概ね外周の照明可能装置（１１、１１’、２１、３１、４１、５１）を制御するための１つ以上の設定を含む、請求項１～１５のいずれか一項に記載のマシン。

【発明の詳細な説明】

【技術分野】

【０００１】

本発明の分野は、ユーザに情報を示すための、ユーザフレンドリーかつ人間工学的ユーザインタフェースを有する、飲料調製マシンに関する。例えば、典型的には、原材料容器内の飲料を淹出し、かつ飲料をそこから抽出するため、液体の原材料容器への循環、及び原材料容器の遠心作用によって飲料を調製するためのマシンなど、飲料調製マシンは、調製される飲料の原材料の、カプセルなどの容器を使用することがある。

【０００２】

本記載の目的のため、「飲料」は、茶、コーヒー、熱い又は冷たいチョコレート、牛乳、スープ、ベビーフードなど、人間が消費できる任意の液体物質を含むことが意図される。「カプセル」とは、気密又は空気透過性パッケージなどのいずれかの材料の（例えば、プラスチック、アルミニウム、再利用可能、及び／又は生分解性パッケージなど）、任意の形状及び構造の（原材料を含む軟質ポッド又は硬質カートリッジを含む）の封入パッケージ内に、香味料成分などの、任意の予め小分けにされた飲料原材料を含むことを意図されている。

【背景技術】

【０００３】

ある種の飲料調製マシンではカプセルを使用する。カプセルは、抽出若しくは溶解される原材料及び／又はマシン内にて保管され、自動的に供与されるか、そうでなければ、飲

料調製時に添加される原材料を収容する。いくつかの飲料マシンは充填手段を有する。充填手段は、液体（通常は水である）用のポンプを備える。ポンプは給水源から、低温であるか、実際、例えばサーモブロック等の加熱手段により加熱された液体を圧送する。

【０００４】

特にコーヒー調製の分野において、飲料原材料を収容するカプセルが淹出装置内に挿入されるマシンが広範に開発されてきた。淹出装置は、カプセルの周囲で確実に閉鎖され、カプセルの第１面に水が注入され、カプセルの閉じた容積内で飲料が生成され、淹出された飲料が、カプセルの第２面から放出されて、カップ又はグラスなどの容器に回収され得る。

【０００５】

淹出装置は、「新しい」カプセルの挿入、及び使用時のカプセルの取出しを容易にするように開発されてきた。典型的には、このような淹出装置は、カプセル内で原材料を淹出するための構造に対しカプセルを挿入／取り出すために、構造から相対的に可動な２つの部分を含む。淹出装置の可動部分の作動は電動化されてもよい。このようなシステムは例えば、欧州特許第１　７６７　１２９号に開示されている。淹出装置の他の実施例は、国際公開第２００９／０４３６３０号、同第２００５／００４６８３号、及び同第２００７／１３５１３６号に開示されている。

【０００６】

遠心力を使用した飲料の調製もまた既知である。このような飲料の調製は、例えば、カプセルなどの容器内に、例えば、粉末及び／又は葉などの、飲料原材料（香味料成分）を供給する工程と、液体を容器内に循環させ、容器内において液体の圧力の勾配を生じるのに十分な速度で容器を回転させながら、液体と原材料を確実に相互作用させる工程とを含む。このような圧力は、中央から、容器の周縁部に向かって徐々に増加する。液体がコーヒー層などの原材料を通過するにつれて、コーヒー生成物などの原材料の抽出が起こり、容器の周縁部にて流出する液体抽出が得られる。国際公開第２００８／１４８６０１号は、このような遠心原理を使用した装置の可能な実施例を記載している。この場合、原材料容器は、使用前に開けられる密封カプセルである。回転軸と位置合わせされた水注入器を含む、水連絡部分により、カプセルの中央に熱湯が供給される。容器はカプセルホルダに保持され、カプセルホルダは回転モータによって回転させられる。液体連絡部分、及びカプセル保持部分の両方は、ローラーベアリングに沿って取り付けられる。飲料は、容器の蓋に開口部を形成する、複数の周辺針によって、カプセルから抽出される。回転軸を中心としてカプセルに遠心力がかけられると、熱湯が飲料の原材料を通過して、材料と相互作用して液体抽出物を生成し、生じた液体抽出物は、遠心力の効果により周辺開口部を通り、コレクタの衝突壁部に対して射出される。飲料を構成する液体抽出物はその後、装置の飲料ダクトを通じて放出され、カップなどの容器内に回収される。国際公開第２００８／１４８６５０号は、例えば容器から出る遠心力を受けた液体により形成される圧力下で開くか、又は拡大する弁システムにより、容器、特にカプセルの下流に流れの制限が形成される装置について更に記載している。弁システムは、カプセルのリム部分に対して弾性的に付勢される、装置の可動制限部分によって形成され得る。米国特許第５，５６６，６０５号は、熱い飲料用の調製マシンのための、変形可能封止継手を有する、遠心タイプの抽出セルに関する。セルはドラム及びドラムと共に内部容積を画定するカバーを含む。カバーは、傾斜部と係合する取り付け耳部によってドラムと接続される。これらの先行技術の装置において、容器に水を供給する水連絡部分、及び容器を保持する保持部分は、バヨネットシステムなどのクロージャ機構によって、一緒に固定される装置のフレーム部分に沿って回転可能である。保持部分は一般的に、少なくとも１つのローラーベアリングにより、フレーム部分に取り付けられる。液体連絡部分もまた一般的に、これもまた少なくとも１つのローラーベアリングに沿って取り付けられたフレーム部分の一部である。遠心処理の間、高速で装置が回転されると、液体抽出物は、重要な軸方向及び径方向の力を生じ、この力はこれらの回転部分を分離する傾向にある。

【０００７】

マシンに対して動作命令を与えるか、又はマシンからフィードバックを得るべく、ユーザがこのようなマシンと相互作用することを可能にするため、例えば、以下の文献に開示されているような、様々なシステムが当該技術分野において開示されている：オーストリア特許第４１０　３７７号、スイス特許第６８２　７９８号、独国特許第４４　２９　３５３号、同第２０２　００　４１９号、同第２０　２００６　０１９　０３９号、同第２００７　００８　５９０号、欧州特許第１４４８０８４号、同第１６７６５０９号、同第０８１５５８５１．２号、仏国特許第２　６２４　８４４号、英国特許第２　３９７　５１０号、米国特許第４，３７７，０４９号、同第４，４５８，７３５号、同第４，５５４，４１９号、同第４，７６７，６３２号、同第４，９５４，６９７号、同第５，３１２，０２０号、同第５，３３５，７０５号、同第５，３７２，０６１第、同第５，３７５，５０８号、同第５，６４５，２３０号、同第５，６８５，４３５号、同第５，７３１，９８１号、同第５，８３６，２３６号、同第５，９５９，８６９号、同第６，１８２，５５５号、同第６，３５４，３４１号、同第６，７５９，０７２号、米国特許出願公開第２００７／０１５７８２０号、国際公開第９７／２５６３４号、同第９９／５０１７２号、同第２００４／０３０４３５号、同第２００４／０３０４３８号、同第２００６／０６３６４５、同第２００６／０９０１８３、同第２００７／００３０６２、同第２００７／００３９９０、同第２００８／１０４７５１、同第２００８／１３８７１０、同第２００８／１３８８２０号及び同第２０１０／００３９３２号。

【発明の概要】

【発明が解決しようとする課題】

【０００８】

したがって、例えば、コーヒー、チョコレート、カカオ、ミルク、スープ、又は茶調製マシンのインタフェースの人間工学性、相互作用性、直感性、ユーザフレンドリーであること、及び単純さから選択される飲料マシンインタフェースの少なくとも１つの特徴を改善することが、本発明の好ましい目的である。

【課題を解決するための手段】

【０００９】

本発明はしたがって、飲料調製マシンに関する。マシンは、給水源、飲料調製ユニット、及び飲料を飲料注出領域に供給するための出口を有し得る。

【００１０】

例えば、マシンは、コーヒー、茶、チョコレート、カカオ、牛乳、及び／又はスープマシン、例えば、挽いたコーヒーなど、調製する飲料の原材料を含むカプセルに、熱湯若しくは冷水、又は別の液体を通すことによって飲料を調製するためのマシンである。このようなマシンの例は、国際公開第２００７／０４２４１５号、同第２００７／０４２４１４号、同第２００７／１３４９６０号、同第２００９／０７４５５０号、同第２００９／１３００９９号、同第２０１３／１２７４７６号、及びこれらに引用される文献に開示されている。

【００１１】

例えば、飲料マシンは、少なくとも１つの原材料から飲料を調製し、このような調製された飲料を注出するための容器保持ユニットを有する。例えば、マシンは、コーヒー、茶、チョコレート、カカオ、牛乳、及び／又はスープを調製するように構成されている。例えば、マシンは、容器保持ユニットを含む飲料処理モジュール内において、挽いたコーヒー、茶、チョコレート、カカオ、又はミルク粉末など、調製する飲料の香味料成分などの原材料を含む、保持されるカプセルなどのユニット内に保持される容器に、熱湯若しくは冷水、又は別の液体を通すことによって飲料を調製するように構成されている。

【００１２】

このような飲料調製は典型的には、例えば、水とミルク粉末など、複数の飲料原材料を混合する工程、及び／又は、挽いたコーヒー、若しくは水と茶の注入など、飲料原材料を注入する工程を含む。例えば、１回分に対応する所定量の飲料が、ユーザのリクエストによって形成及び注出される。このような１回分の量は、飲料の種類によって２５～２５０

ｍＬの範囲（例えば、カップ又はマグを充填する量）であり得る。形成及び注出される飲料は、リステロット、エスプレッソ、ルンゴ、カプチーノ、カフェラテ、アメリカンコーヒー、茶などから選択され得る。例えば、コーヒーマシンは、エスプレッソを注出する（１回あたり２０～６０ｍＬの調節可能な量）、及び／又はルンゴを注出する（例えば、一回当たり７０～２００ｍＬの範囲の量）ように構成されてもよい。

【００１３】

有利な実施形態において、飲料マシンは、例えば、国際公開第２００８／１４８６０１号、同第２００８／１４８６０４号、同第２００８／１４８６４６号、同第２００８／１４８６５０号、同第２００８／１４８６５６号、同第２００９／１０６１７５号、同第２００９／１０６５９８号、同第２０１０／０６３６４４号、同第２０１０／０６６７３６号、同第２０１０／０８９３２９号、同第２０１１／０２３７１１号、ＰＣＴ／ＥＰ１３／０７７２７６号、及びＰＣＴ／ＥＰ１３／０７７２７５号に開示される、遠心処理により原材料を組み合わせるタイプのものである。したがって、マシンは、例えば、内部に液体が注入され、原材料と液体とを混合するために、遠心軸を中心とした遠心処理を受ける、原材料カプセルを収容するための原材料混合チャンバを含む場合がある。原材料混合チャンバは、回転して原材料を混合するために、開閉することができる。

【００１４】

本発明のマシンは、照明可能部分により形成され、内側部分の周囲で延びる、概ね外周の照明可能装置と、プログラミング可能な制御装置などの、照明可能部分の照明を有効化及び無効化するための制御装置とを有する、ユーザインタフェースを含む。例えば、制御装置は、プリント回路基板ＰＣＢ、及びあるＰＣＢにコネクタにより接続されたコントローラなどのコントローラを含む。ＰＣＢは、単一のプリント基板、又は電気的に、若しくは光学的に、ないしは別の方法により接続された、いくつかの並置された、若しくは離間したプリント基板から形成され得る。任意により、制御装置は、例えば、調製ユニットのＩＴモジュール、ポンプ、熱調節器、及び／又は動力部など、このようなマシンの他の機能部を制御する。

【００１５】

典型的な実施形態において、ユーザインタフェースは、このようなマシンの上部、又は前部、又は側部にある。

【００１６】

本発明により、制御装置は、照明可能部分の一部のみを有効化するために、少なくとも１つの設定を有する。

【００１７】

照明可能部分は、概ね外周の照明可能装置に沿って配置された、例えば、丸いスポット、又は多角形のスポットなどの１つ以上のスポット、及び／又は概ね外周の照明可能装置に沿って延びる１つ以上の細長いセグメントを含み得る。このような細長いセグメントは、

円形セクターに概ね沿って延びるセグメント、及び／又は楕円形セクターに概ね沿って延びるセグメントなどの、湾曲セグメント、

真っ直ぐなセグメント、

角度を成すセグメント、

外周の照明可能装置の真っ直ぐな辺全体に沿って延びるセグメント、

外周の照明可能装置の、真っ直ぐな辺の全体にわたって、及び／若しくは真っ直ぐな辺の一部にわたって延びる、角度を成すセグメント、並びに／又は外周の照明可能装置の、２つの真っ直ぐな辺のみに沿って、及び／若しくは３つ以上の辺に沿って延びるセグメントなど、外周の照明可能装置の複数の真っ直ぐな辺に沿って延びる、角度を成すセグメント、並びに、

外周の照明可能装置の全長の部分にわたって延びるセグメントであって、この部分は全長の、約半分、又は１／３、又は１／４、又は１／５、又は１／６、又は１／７、又は１／８、又は１／９、又は１／１０、又は１／１２、又は１／２４と対応する、セグメン

トと、から選択され得るセグメントを含む。

【００１８】

概ね外周の照明可能装置は、単一の内側部分の周囲で延び、又は一対の内側部分のようないくつかの内側部分の周囲で、例えば、概ね外周の照明可能装置が離間した内側部分の周囲及び間でほぼ８の形状になるように延びてよい。単一の内側部分は、複数の部分、例えば、複数の有効インタフェース部分、若しくは複数の無効インタフェース部分、又は少なくとも１つの有効インタフェース部分と少なくとも１つの無効インタフェース部分との組み合わせから作製され得る。例えば、このような有効インタフェース部分はユーザセレクタの形態である。無効ユーザインタフェース部分はハウジングの一部の形態であり得る。ハウジングの一部は、インタフェースのハウジングに属する、及び／又は外部マシンハウジングに属する。

【００１９】

内側部分は、セレクタ若しくは複数のセレクタなどの、例えば、１つ以上のプッシュボタンの形態の能動部分、及び／又は、例えば、ハウジングの一部などの受動部分であり得る。

【００２０】

概ね外周の照明可能装置は、以下の特徴：

発光素子によって放出される光を拡散するための、半透明ウィンドなどの光拡散ウィンド、

発光素子の形状をユーザに対して示すための、透明ウィンドなどの光透過ウィンド、

単一の色の発光素子、又は、白色、黄色、橙色、赤色、緑色、青色、及びピンク色、並びにこれらの混合から選択される色など、異なる色の発光素子のグループなどの異なる色の発光素子を含む、複数の発光素子、

単一の色の発光素子によって、又は異なる色の発光素子のグループによって照明可能である、外周の照明可能装置の各照明可能部分であって、このようなグループの発光素子は別個に又はグループで有効化可能である、各照明可能部分、並びに、

任意により、コネクタの対などのコネクタにより上記ＰＣＢ又はあるＰＣＢに接続された、ＬＥＤなどの発光素子、の１つ以上を含み得る。

【００２１】

異なる色の光を放出する発光素子は、異なる種類の信号を伝達するために使用されてもよい。例えば、赤色は、警告の指標、又は熱生成の指標を伝達するために使用されてもよい。青色は、冷たい状態に関連する指標を伝達するために使用されてもよい。緑色は、状態、又は準備完了したことを示すために使用されてもよい。赤色又は青色は、飲料を温める、又は冷やす処理の指標を伝達するために使用され得る。橙色又は黄色は、ユーザプログラミングモード、又はサービスモード、例えば、マシンのすすぎ、洗浄、又はスケール除去などを示すために使用されてもよい。したがって、ユーザに異なる指標を伝達するために、直感的なカラーコードを使用してもよい。

【００２２】

概ね外周の照明可能装置の照明可能な部分は、湾曲した及び／又は角度を成す線状構成など、内側部分の周囲で横並びの線状構成にあってもよい。例えば、概ね外周の照明可能装置の照明可能部分は、

単一の横並び線状構成、又は２つ、３つ、若しくは４つのほぼ平行な若しくは同心状の横並び線状構成にある、並びに／あるいは、

２つの隣接する照明可能部分が、互いに直接隣接している、又はハウジングの一部などのスペーサによって離間している、横並び線状構成にある。

【００２３】

各照明可能部分の照明は、実質的に、この部分全体にわたって広がっていてもよい。任意により、各部分の照明は、これらの部分全体にわたって、ほぼ均一な光強度、及び／又はほぼ均一な色をもたらす。色は、白色、黄色、橙色、赤色、緑色、青色、及びピンク、又はいくつかのこのような色の混合から選択され得る。

【００２４】
制御装置は、連続する部分、例えば、線状横並び構成の連続する部分を、内側部分を中心として、ある回転シーケンスで順次有効化するための少なくとも１つの設定を有することができ、例えば：
ａ）時計方向及びその後の反時計方向のシーケンスで、又は、反時計方向及びその後の時計方向のシーケンスで順次有効化するための少なくとも１つの設定、
ｂ）回転シーケンスが完了すると、これを一度以上繰り返して順次有効化するための少なくとも１つの設定、及び／又は、
ｃ）回転シーケンスにわたって、及び／若しくは複数の連続する回転シーケンスの間で、例えば、
飲料調製手順、例えば、予備湿潤、及び抽出の連続する工程、及び／若しくは、
サービス手順、例えば、スケール除去手順の連続する工程、という異なる工程を示すように速度を変更し、順次有効化するための少なくとも１つの設定で行われる。
【００２５】
このような設定は、例えば、起動サイクル、又は飲料調製サイクル、又は清掃サイクルなど、任意の時点におけるサイクルの動作を示すために使用され得る。有利な実施形態において、このような設定は、遠心処理による飲料調製サイクルを示すために使用されてもよく、外周の照明可能装置は、任意により遠心処理軸の周囲で延び、遠心処理は、遠心処理軸を中心とした遠心処理を示す、回転シーケンスの複数の繰り返しなどの回転シーケンスによって示される。
【００２６】
制御装置は、連続する部分を、内側部分を中心として回転シーケンスで順次有効化し、全ての部分を有効化した後に、全ての部分を同時に無効化するための、少なくとも１つの設定を有し得る。
【００２７】
制御装置は、連続する部分を、内側部分を中心として回転シーケンスで順次有効化しながら、前に有効化した部分を回転シーケンスで順次無効化するための、少なくとも１つの設定を有し得る。任意により、これらの部分は、等しい有効化速度及び無効化速度、又は、無効化速度よりも速い有効化速度などの、異なる有効化速度及び無効化速度を有する。少なくとも２つ又は３つの部分が同時に有効化状態になり得る。
【００２８】
制御装置は、１つの部分が、間欠的に有効化及び無効化されるような、少なくとも１つの設定を有し得る。
【００２９】
例えば、このような設定は、エラーの表示、又は、ユーザセレクタによりユーザ命令が適切に獲得されたことを確認するなどの、マシン１が情報を獲得したことを確認する表示と関連付けられ得る。
【００３０】
内側部分を中心に恒久的に有効化又は無効化された部分によって離間した、例えば、ほぼ均等に離間した、複数の部分又は部分のグループなどの複数の部分が、同時に有効化及び無効化されてもよい。
【００３１】
複数の２つの部品が、交互に有効化及び無効化されるなど、これらの部分の２つが、交互に有効化及び無効化されてもよい。
【００３２】
例えば、このような設定は、例えば、ユーザセレクタによるユーザ入力、又はユーザによる別のアクションのマシン１による期待値と関連付けられ得る。
【００３３】
部分は、一定の頻度で間欠的に有効化及び無効化されてもよく、例えば、いくつかの部分が一定の頻度で間欠的に有効化及び無効化されてもよい。

【００３４】
上記の設定のいずれかに加えて、制御装置は、上記の設定よりも速い速度で部分を有効化及び無効化するための、少なくとも１つの更なる設定を有してもよい。
【００３５】
例えば、異なる種類の手順の実行を区別するために、異なる速度が使用されてもよい。例えば、起動又はサービス（スケール除去）手順の実行が、比較的遅い速度における１つ以上の回転シーケンスによって示されてもよく、飲料調製手順は、比較的速い速度における１つ以上の回転シーケンスによって示されてもよい。
【００３６】
例えば、ルンゴ若しくはエスプレッソコーヒーの異なる飲料の調製手順などの同じ種類の異なる手順、又は、例えば、軽度の若しくは集中的スケール除去手順などの異なるサービス手順の実行を区別するために異なる速度が実施され得る。
【００３７】
有効化可能及び無効化可能な部分に加えて、少なくとも１つの部分が、上記の設定又は更なる設定において、恒久的に有効化又は無効化されたままであり得る。
【００３８】
制御装置は、例えば、単一の部分、又は隣接する部分のグループなどの、少なくとも１つの部分が順次有効化される、少なくとも１つの設定を有し得る。
【００３９】
外周の照明可能装置は、細長い形状に概ね沿っており、
ａ）例えば、１つ以上の円、及び／若しくは楕円、又はその一部などの曲線を形成する、
ｂ）三角形、例えば、正方形、矩形、台形、若しくは平行四辺形である、四角形、五角形、六角形、七角形、八角形、十角形、九角形、十角形、十一角形、若しくは十二角形などの、規則的若しくは不規則的な多角形、又はその一部を形成する、並びに／あるいは、
ｃ）ストライプの形状、及び／又は、細長い形状に概ね沿って配置された、別個の発光素子などの別個の要素、例えば、ＬＥＤ又は発光可能光ファイバーの一部の形状に延びる。
【００４０】
制御装置は、ユーザに対して、
例えば、連続する部分、例えば、線状横並び構成の連続する部分を、内側部分を中心として、ある回転シーケンスで順次有効化するための設定、及び任意により、全ての部分を有効化した後に、全ての部分を同時に無効化する種類の設定など、上記の設定による、加熱器の起動などの起動手順の実行を示すように、
例えば、単一部分、又は隣接する部分のグループなどの、少なくとも１つの部分が順次有効化される設定など、上記の設定による、飲料調製の準備完了までに必要な時間に関する指標をインタフェースが提示するスタンバイ手順を示すように、
例えば、連続する部分を内側部分を中心に回転シーケンスで順次有効化し、かつ全ての部分が有効化された後に全ての部分を同時に無効化するか、又は部分を有効化しながら、先に有効化された部分を、回転シーケンスで順次無効化する設定など、上記の設定による、飲料調製手順、例えば、回転シーケンスが完了すると、これを一度以上繰り返すこのような上記の設定のような、例えば、遠心処理の軸線を取り囲む概ね外周の照明可能装置による、遠心処理による飲料調製手順の実行を示すように、
例えば、上記の設定、例えば、少なくとも１つの部分が順次有効化され、任意により全ての部分が順次有効化される設定による、ユーザ命令を受信する準備が完了した状態を示すように、
例えば、上記の設定、例えば、１つの部分が間欠的に有効化及び無効化される設定による、原材料カプセルなどのカプセルから、又は、例えば、ネットワーク又はポータブルメモリ装置に接続される、マシンインタフェースからの情報を読み取る手順の実行を示すように、

例えば、上記の設定、例えば、１つの部分が間欠的に有効化及び無効化される設定による、例えば、例えば水の不足などの原材料の不足を示す、エラーの状態を示すように、

例えば、上記の設定、例えば、少なくとも１つの部分が順次有効化される設定による、飲料調製プロセスのパラメータを設定するため、又はスタンバイ若しくは自動停止プロセスに入るためのタイマーを設定するためなどの、ユーザプログラミングモードの有効化を示すように、

例えば、上記の設定、例えば、全ての部分が有効化された後に全ての部分が同時に無効化されるか、若しくは先に有効化された部分が、回転シーケンスで順次無効化されるようにして、連続する部分が、内側部分を中心にして、回転シーケンスで順次有効化される設定、１つの部分が間欠的に有効化及び無効化される設定、又は少なくとも１つの部分が順次有効化される設定などによる、すすぎ、洗浄、スケール除去、又は水材料排出手順など、サービス手順の実行を示すように、並びに、

例えば、上記の設定、例えば、１つの部分が、間欠的に、例えば２回又は３回、有効化及び無効化される設定による、例えば、ユーザセレクタによる、ユーザ命令の獲得の完了を示すように、概ね外周の照明可能装置を制御するための１つ以上の設定を含み得る。

【００４１】

本発明はここで、概略図を参照して説明される。

【図面の簡単な説明】

【００４２】

【図１】本発明による飲料調製マシンの丸いインタフェースを概略的に例示している。

【図１ａ】図１のインタフェースの水平方向断面図を示している。

【図１Ａ】直線Ａ－Ａに沿った、図１及び図１ａのインタフェースの拡大断面図を例示している。

【図１Ｂ】直線Ｂ－Ｂに沿った、図１及び図１ａのインタフェースの拡大断面図を例示している。

【図１ｘ】本発明によるマシンのインタフェースのバリエーションを例示している。

【図２】本発明によるマシンに設置され得る、多角形の異なるインタフェースを例示している。

【図３】本発明によるマシンに設置され得る、多角形の異なるインタフェースを例示している。

【図４】本発明によるマシンに設置され得る、多角形の異なるインタフェースを例示している。

【図５】本発明によるマシンに設置され得る、湾曲した形状のインタフェースを例示している。

【図６】本発明による飲料調製マシンを例示している。

【発明を実施するための形態】

【００４３】

図１～５は、本発明による飲料調製マシン１のための、異なるユーザインタフェース１０、２０、３０、４０、５０を例示している。インタフェース１０を備える飲料マシン１の実施例が図６に示される。

【００４４】

代表的な飲料調製マシン１は、給水源２、及び飲料調製ユニット３を有し得る。給水源２は、水タンクであり得る。あるいは、マシンの給水源は、飲料マシンのいずれかの水タンクを手動で補充する必要がないように、都市の配水システムに直接接続することが可能なコネクタを含んでもよい。

【００４５】

マシン１は、熱い又は冷たい飲料を調製するように構成されてもよい。マシン１は、例えば、水及び／又はミルクなどの液体キャリア、及び１つ以上の香味料成分並びに／又は質感成分（texturing ingredient）、例えば、チョコレート、カカオ、コーヒー、茶、牛乳、シロップ、砂糖、クリーム、乳化剤、乾燥又はゲルスープなどの、異なる原材料を組

み合わせるように構成され得る。原材料は、これを混合することにより、又は注入することにより、組み合わされ得る。好適なマシンは、例えば、国際公開第２００９／０７４５５０号及び同第２００９／１３００９９号により詳細に開示されている。有利な実施形態において、飲料マシン１は、例えば、国際公開第２００８／１４８６０１号、同第２００８／１４８６０４号、同第２００８／１４８６４６号、同第２００８／１４８６５０号、同第２００８／１４８６５６号、同第２００９／１０６１７５号、同第２００９／１０６５９８号、同第２０１０／０６３６４４号、同第２０１０／０６６７３６号、同第２０１０／０８９３２９号、同第２０１１／０２３７１１号、ＰＣＴ／ＥＰ１３／０７７２７６号、及びＰＣＴ／ＥＰ１３／０７７２７５号に開示される、遠心処理により原材料を組み合わせるタイプのものである。したがって、マシン１は、内部に液体が注入され、原材料と液体とを混合するために、遠心軸３ａを中心とした遠心処理を受ける、原材料カプセルを収容するための原材料混合チャンバ３ｂ（典型的にはマシン１内に配置され、図６に点線で示される）を含む場合がある。原材料混合チャンバ３ｂは、（例えば、ハンドル１ａを作動させることにより上部１ａを旋回させるか、又は昇降させて）開閉することができ、回転させて原材料を混合することができる。

【００４６】

飲料マシン１は、典型的には、単一の出口、又は二重出口であり得る、出口３ａを有する。出口３ａは、注出領域４に飲料を供給するように構成され得る。注出領域４は、グラス、カップ、又はマグなどの容器を受容するように構成され得る。注出領域は、例えば欧州特許第１８６７２６０号、又は国際公開第２００９／０７４５５７号に開示されるような、任意の種類のものであり得る。

【００４７】

飲料マシン１は、ユーザインタフェース１０を含み、これは、図１、図１Ａ、及び図１Ｂにより詳細に例示されている。あるいは、インタフェース１０は、図１ｘ～５に例示されるインタフェース１０’、２０、３０、４０、５０のいずれか、又は本発明の領域に包含される、そのバリエーションにより代替することができる。

【００４８】

ユーザインタフェース１０、１０’、２０、３０、４０、５０は全て、

照明可能部分１１Ａ、１１Ｂ、１１Ｃ、１１Ｄ、１１Ｅ、１１Ｆ、１１Ａ’、１１Ｂ’、１１Ｃ’、１１Ｄ’、１１Ｅ’、１１Ｆ’、１１Ｇ’、１１Ｈ’、２１Ａ、２１Ｂ、２１Ｃ、２１Ｄ、２１Ｅ、２１Ｆ、２１Ｇ、３１Ａ、３１Ｂ、３１Ｃ、３１Ｄ、３１Ｅ、３１Ｆ、４１Ａ、４１Ｂ、５１Ａ、５１Ｂ、５１Ｃ、５１Ｄ、５１Ｅ、５１Ｆ、５１Ｇ、５１Ｈ、５１Ｘにより形成され、内側部分１１０、１２０の周囲で延びる、概ね外周の照明可能装置１１、１１’、２１、３１、４１、５１と、

プログラミング可能な制御装置などの、照明可能部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘの照明を有効化及び無効化するための制御装置１００、１０５であって、例えば、プリント回路基板ＰＣＢ１００、及びＰＣＢにコネクタ１００’’’により接続されたコントローラなどのコントローラ１０５を備えたプログラミング可能な制御装置１００、１０５とを有する。

【００４９】

制御装置１００、１０５は、飲料調製ユニット３のＩＴモジュール、ポンプ、熱調節器、及び／又は動力部など、このようなマシン１の他の機能部を制御し得る。

【００５０】

典型的な実施形態において、ユーザインタフェース１０、１０’、２０、３０、４０、５０は、このようなマシン１の上部１ａ、前部１ｂ、又は側部１ｃにある。図６において、例えば、ユーザインタフェース１０は、マシン１の上部１ａに設けられている。

【００５１】

制御装置１００、１０５は、照明可能部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘの一部のみを有

効化するための、プログラミングされた設定などの少なくとも１つの設定を組み込んでもよい。

【００５２】

例えば、図１ｘに例示されるように、照明可能部分は、概ね外周の照明可能装置１１’に沿って配置された、丸い又は多角形のスポットなど、１つ以上の照明可能スポット１１Ａ’～１１Ｈ’を含む場合がある。例えば、図１、２、３、４、及び５に例示されるように、照明可能部分は、概ね外周の照明可能装置１１、２１、３１、４１、５１に沿って延びる１つ以上の細長いセグメント１１Ａ～１１Ｆ、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘを有する場合がある。

【００５３】

このような細長いセグメントは、

円形セクター１１Ａ～１１Ｆに概ね沿って延びるセグメント（図１）、及び／又は楕円形セクター５１Ａ～５１Ｘに概ね沿って延びるセグメント（図６）などの、湾曲セグメント１１Ａ～１１Ｆ、５１Ａ～５１Ｘ、

真っ直ぐなセグメント２１Ａ、２１Ｃ、２１Ｅ、２１Ｆ、２１Ｇ、３１Ｂ、２１Ｃ、２１Ｄ、２１Ｅ（図２～４）、

角度を成すセグメント２１Ｂ、２１Ｄ、３１Ａ、３１Ｇ、４１Ａ、４１Ｂ（図２～４）、

外周の照明可能装置２１、３１、４１の真っ直ぐな辺２１Ａ、２１Ｂ、３１Ａ、４１Ａ、４１Ｂ全体に沿って延びるセグメント（図２～４）、

外周の照明可能装置２１、３１、４１の、真っ直ぐな辺全体にわたって２１Ｂ、３１Ａ、４１Ａ、４１Ｂ、及び／若しくは真っ直ぐな辺の一部にわたって２１Ｄ、３１Ａ、３１Ｆ、４１Ａ、４１Ｂ延びる、角度を成すセグメント、並びに／又は外周の照明可能装置２１、３１、４１（図２～４）の、２つの真っ直ぐな辺のみに沿って２１Ｂ、２１Ｄ、３１Ｆ、４１Ａ、４１Ｂ、及び／若しくは３つ以上の辺に沿って３１Ａ延びるセグメントなど、外周の照明可能装置２１、３１、４１の複数の真っ直ぐな辺２１Ｂ、３１Ａ、４１Ａ、４１Ｂに沿って延びる、角度を成すセグメント、

外周の照明可能装置１１、２１、３１、４１、５１の全長の部分にわたって延びるセグメントであって、各部分は、外周の照明可能装置の全長の、約半分である３１Ａ、４１Ａ、４１Ｂ（図３及び図４）、又は１／３である２１Ｂ（図２）、又は１／４である３１Ｆ（図３）、又は１／５、又は１／６である１１Ａ～１１Ｆ、２１Ａ、２１Ｄ（図１及び図２）、又は１／７、又は１／８である３１Ｂ（図３）、又は１／９である５１Ａ～５１Ｘ（図５）、又は１／９、又は１／１２である２１Ｃ、２１Ｅ、２１Ｆ、２１Ｇ（図２）、又は１／２４である３１Ｃ、３１Ｄ、３１Ｅ（図３）と対応する、セグメントと、並びに

これらの組み合わせ、例えば、異なる長さのセグメント（図２～５）から、若しくは同じ長さのセグメント（図１）から作製される、及び／又は湾曲セグメント及び真っ直ぐなセグメントの組み合わせ（図示されない）から作製される、外周の照明可能装置であるセグメント、から選択され得る。

【００５４】

外周の照明可能装置１１、１１’、２１、３１、４１、５１は、単一の内側部分１１０（図１～４）、又はいくつかの内側部分１１０、１２０の周辺に延びることがある。例えば、このような配置は、例えば、外周の照明可能装置５１がほぼ８の形状になるように（図５）、一対の内側部分１１０、１２０の周囲で延びる。

【００５５】

単一の内側部分１１０は、いくつかの部分、例えば、複数の有効インタフェース部分１１０Ａ、１１０Ｂ、１１０Ｃ、１１０Ｄ（図１及び図２）、複数の無効インタフェース部分、又は少なくとも１つの有効インタフェース部分１１０Ｅと少なくとも１つの無効インタフェース部分１１０Ｆとの組み合わせ（図４）から作製されることができ、例えば、有効インタフェース部分はユーザセレクタの形態であり、及び／又は無効ユーザインタフェ

ース部分はハウジングの一部の形態である。

【００５６】

内側部分は、例えば、セレクタ１１０Ｅ若しくは複数のセレクタ１１０Ａ、１１０Ｂ、１１０Ｃ、１１０Ｄなどの、例えば、１つ以上のプッシュボタンの形態の、能動部分１１０、及び／又はハウジングの一部などの受動部分１１０Ｆ、１２０、から選択され得る。

【００５７】

ユーザセレクタ１１０、１１０Ａ、１１０Ｂ、１１０Ｃ、１１０Ｄ、１１０Ｅは典型的にはコントローラ１０５、又はＰＣＢ１００に接続され、例えば、生成すべき、所望の量及び／又は濃度、及び／又は味などのいくつかの特徴を有する飲料の調製を開始するか、又は、例えば、すすぎ若しくは洗浄、若しくはスケール除去などサービス手順を実行するため、又はマシン１をオン若しくはオフにするため、又はユーザプログラミングモードに入るための命令などの、ユーザ命令を受信するように設定されてもよい。ユーザセレクタ１１０、１１０Ａ、１１０Ｂ、１１０Ｃ、１１０Ｄ、１１０Ｅは、ユーザ命令のみを受けるように設定されてもよく、又はユーザに対して情報を示すように更に設定されてもよく、例えば、またユーザセレクタ自体がコントローラ１０５によって制御される発光装置を備えてもよい。例えば、ユーザセレクタは、セレクタと関連する機能部が、マシン１の使用時の所定の時点で利用可能であるかどうかによって、照明可能である。例えば、スケール除去プロセス中に飲料調製プロセスを開始することは不可能である。これは、対応するユーザセレクタの適切な照明によって示すことができる。これは、サービス手順中にはユーザが飲料を注文できないということを意味するものではなく、サービス手順が中断される必要があるか、又は最後まで実行されてから、飲料調製の命令を実行することを意味している。例えば、コントローラは、マシン１が、ユーザリクエストを実行可能な状態にある後の時点で実行するために、特定のユーザリクエストを記憶してもよい。例えば、記憶されたユーザリクエストを後で実行する実施例に関しては、例えば、国際公開第２０１１／０２０７７９号を参照せよ。当然、特定のプロセスを実行する入力を、このようなプロセスの実行が不可能であるかぎり、アクセプトしないように、マシンを設定することもまた可能である。

【００５８】

外周の照明可能装置１１、１１’、２１、３１、４１、５１は、以下の特徴：

発光素子１０１、１０２、１０３によって放出される光を拡散するための、半透明ウィンドなどの光拡散ウィンド１１１（図１、図１Ａ、及び図２Ｂ）、

発光素子１０１’の形状をユーザに対して示すための、透明ウィンドなどの光透過ウィンド１１１’（図２ｘ）、

単一の色の発光素子１０１’、又は、白色、黄色、橙色、赤色、緑色、青色、及びピンク色、並びにこれらの混合から選択される色など、異なる色の発光素子１０１、１０２、１０３（図１ａ、及び図１Ａ）のグループ１００Ａ、１００Ｂ、１００Ｃ、１００Ｄ、１００Ｅ、１００Ｆなどの異なる色の発光素子１０１、１０２、１０３を含む、複数の発光素子１０１、１０１’、１０２、１０３、

単一の色の発光素子１０１’によって、又は異なる色の発光素子１０１、１０２、１０４のグループ１００Ａ、１００Ｂ、１００Ｃ、１００Ｄ、１００Ｅ、１００Ｆによって照明可能である、外周の照明可能装置１１、１１’、２１、３１、４１、５１の各照明可能部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘであって、このようなグループの発光素子は別個に又はグループで有効化可能である、各照明可能部分、並びに、

任意により、コネクタの対１００’、１００’’などのコネクタ１００’、１００’’（図１ａ、図１Ａ及び図１Ｂ）により上記ＰＣＢ又はあるＰＣＢ１００に接続された、ＬＥＤなどの発光素子１０１’、１０１、１０２、１０３、の１つ以上を含んでもよい。

【００５９】

外周の照明可能装置１１、１１’、２１、３１、４１、５１の、照明可能部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１

Ａ～５１Ｈ、５１Ｘは、湾曲した構成（図１～１ｘ、及び図５）、及び／又は角度を成す線状構成（図２～４）など、内側部分１１０、１２０の周囲で横並びの線状構成にあってもよい。このような照明可能部分は、

単一の横並び線状構成１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ（図１～５）、又は２つ、若３つ、若しくは４つのほぼ平行な横並び線状構成にある、及び／あるいは、

２つの隣接する照明可能部分が、互いに直接隣接している１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ（図１、図２、図３、図４、及び図５）、又はハウジングの一部１１ａなどのスペーサによって離間している１１Ａ’～１１Ｈ’（図１ｘ）、横並び線状構成１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘにあり得る。

【００６０】

照明部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘの照明は、実質的に、これらの部分全体にわたって広がり得る。任意により、このような部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘの照明は、これらの部分全体にわたって、ほぼ均一な光強度、及び／又は、白色、黄色、橙色、赤色、緑色、青色、及びピンク、又はいくつかのこのような色の混合から生じる色から選択される色などの、ほぼ均一な色をもたらす。

【００６１】

制御装置１００、１０５は、連続する部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ、例えば、線状横並び構成の連続する部分を、内側部分１１０、１２０を中心として、ある回転シーケンスで順次有効化するための少なくとも１つの設定を有し得る。任意により、

ａ）時計方向及びその後の反時計方向のシーケンスで、又は、反時計方向及びその後の時計方向のシーケンスで順次有効化され、

ｂ）回転シーケンスが完了すると、これを一度以上繰り返して順次有効化され、及び／又は、

ｃ）回転シーケンスにわたって、及び／若しくは複数の連続する回転シーケンスの間で、

飲料調製手順、例えば、予備湿潤、及び抽出の連続する工程、及び／若しくは、

サービス手順、例えば、スケール除去手順の連続する工程、という異なる工程を示すように速度を変更し、順次有効化される。

【００６２】

このような設定は、例えば、起動サイクル、又は飲料調製サイクル、又は清掃サイクルなど、任意の時点におけるサイクルの動作を示すために使用され得る。有利な実施形態において、このような設定は、遠心処理による飲料調製サイクルを示すために使用されてもよく、外周の照明可能装置は、任意により遠心処理軸３ａの周囲で延び、遠心処理は、遠心処理軸３ａを中心とした遠心処理を示す、回転シーケンスの複数の繰り返しなどの回転シーケンスによって示される。

【００６３】

制御装置１００、１０５は、連続する部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘを、内側部分１１０、１２０を中心として回転シーケンスで順次有効化し、全ての部分を有効化した後に、全ての部分を同時に無効化するための、少なくとも１つの設定を有し得る。

【００６４】

制御装置１００、１０５は、連続する部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘを、内側部分１１０、１２０を中心として回転シーケンスで順次有効化しながら、前に有効化させた部分

を回転シーケンスで順次無効化するための、少なくとも１つの設定を有し得る。部分は、等しい有効化速度及び無効化速度、又は、無効化速度よりも速い有効化速度などの、異なる有効化速度及び無効化速度を有し得る。少なくとも２つ又は３つの部分が同時に有効化状態になり得る。

【００６５】

制御装置１００、１０５は、１つの部分、１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘが、間欠的に有効化及び無効化される、少なくとも１つの設定を有し得る。

【００６６】

例えば、このような設定は、エラーの表示、又は、ユーザセレクタによりユーザ命令が適切に獲得されたことを確認するなどの、マシン１が情報を獲得したことを確認する表示と関連付けられ得る。

【００６７】

複数のこのような部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘは、同時に有効化及び無効化されてもよい。例えば、複数の部分、又は部分のグループが、内側部分１１０、１２０を中心に他の恒久的に有効化又は無効化された部分により離間している。このような部品、又は部品のグループは、例えば、内側部分１１０、１２０を中心に均等に離間している。

【００６８】

このような部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘの２つが、交互に有効化及び無効化され得る。

【００６９】

例えば、２つの部分が、交互に有効化及び無効化される。

【００７０】

例えば、このような設定は、例えば、ユーザセレクタによるユーザ入力、又はユーザによる別のアクションのマシン１による期待値と関連付けられ得る。

【００７１】

このような部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘが、一定の頻度で間欠的に有効化及び無効化され得る。例えば、いくつかの部分が、一定の頻度で間欠的に有効化及び無効化される。

【００７２】

このような設定に加えて、制御装置１００、１０５は、上記の設定よりも速い速度で、部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘを有効化及び無効化するための少なくとも１つの他の設定を有し得る。

【００７３】

例えば、異なる種類の手順の実行を区別するために、異なる速度が使用されてもよい。例えば、起動又はサービス（例えば、スケール除去）手順の実行が、比較的遅い速度における１つ以上の回転シーケンスによって示されてもよく、飲料調製手順は、比較的速い速度における１つ以上の回転シーケンスによって示されてもよい。

【００７４】

例えば、異なる速度は、例えば、ルンゴ若しくはエスプレッソコーヒーの異なる飲料の調製手順などの同じ種類の異なる手順、又は軽度の若しくは集中的スケール除去手順などの異なるサービス手順実行を区別するために、実施され得る。

【００７５】

有効化可能及び無効化可能な部分に加えて、少なくとも１つの部分が、上記の設定又は上記の更なる設定において、恒久的に有効化又は無効化されたままであってもよい。

【００７６】

例えば、原材料（例えば、水）利用可能性が最低レベルに近づいているなど、非停止警告が、恒久的有効部分によって示されてもよい。非停止警告の別の例は、短い時間内にサービス（例えば、スケール除去）プロセスを行うことの必要性に関連し得る。

【００７７】

制御装置１００、１０５は、例えば、単一部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ、又は隣接する部分のグループなどの、少なくとも１つの部分が順次有効化される、少なくとも１つの設定を有し得る。

【００７８】

外周の照明可能装置１１、１１’、２１、３１、４１、５１は、細長い形状に概ね沿っており、

ａ）例えば、１つ以上の円１１、１１’（図１、図１ａ、及び図１ｘ）及び／若しくは楕円５１（図５）、又はその一部などの曲線１１，１１’を形成する、

ｂ）三角形４１（図４）、例えば、正方形３１（図３）、矩形、台形、若しくは平行四辺形である、四角形３１、五角形、六角形２１（図２）、七角形、八角形１１’（図１ｘ）、十角形、九角形、十角形、十一角形、若しくは十二角形などの、規則的若しくは不規則的な多角形２１、３１、４１、又はその一部を形成する、

ｃ）ストライプ１１、２１、３１、４１、５１（図１、図２～５）の形状、及び／又は細長い形状に概ね沿って配置された、別個の発光素子などの別個の要素１１’（図１ｘ）、例えば、ＬＥＤ１０１’又は発光可能光ファイバーの一部の形状に延びる、あるいは、

ｄ）湾曲部分、及び真っ直ぐ若しくは角度を成す部分から形成された外周の照明可能装置などの、特徴ａ）、ｂ）、及びｃ）の少なくとも２つの組み合わせである。

【００７９】

制御装置１００、１０５は、ユーザに対して、

例えば、連続する部分、例えば、線状横並び構成の連続する部分を、内側部分を中心として、ある回転シーケンスで順次有効化するための設定、及び任意により、全ての部分を有効化した後に、全ての部分を同時に無効化する種類の設定など、上記の設定による、加熱器の起動などの起動手順の実行を示すように、

例えば、単一部分、又は隣接する部分のグループなどの、少なくとも１つの部分が順次有効化される設定など、上記の設定による、飲料調製の準備完了までに必要な時間に関する指標をインタフェースが提示するスタンバイ手順を示すように、

例えば、連続する部分を内側部分を中心に回転シーケンスで順次有効化し、かつ全ての部分が有効化された後に全ての部分を同時に無効化するか、又は先に有効化された部分を、回転シーケンスで順次無効化する設定など、上記の設定による、飲料調製手順、例えば、回転シーケンスが完了すると、これを一度以上繰り返すこのような上記の設定のような、例えば、遠心処理の軸線を取り囲む概ね外周の照明可能装置による、遠心処理による飲料調製手順の実行を示すように、

例えば、上記の設定、例えば、少なくとも１つの部分が順次有効化され、任意により全ての部分が順次有効化される設定による、ユーザ命令を受信する準備が完了した状態を示すように、

例えば、上記の設定、例えば、１つの部分が間欠的に有効化及び無効化される設定による、原材料カプセルなどのカプセルから、又は、例えば、ネットワーク又はポータブルメモリ装置に接続される、マシンインタフェースからの情報を読み取る手順の実行を示すように、

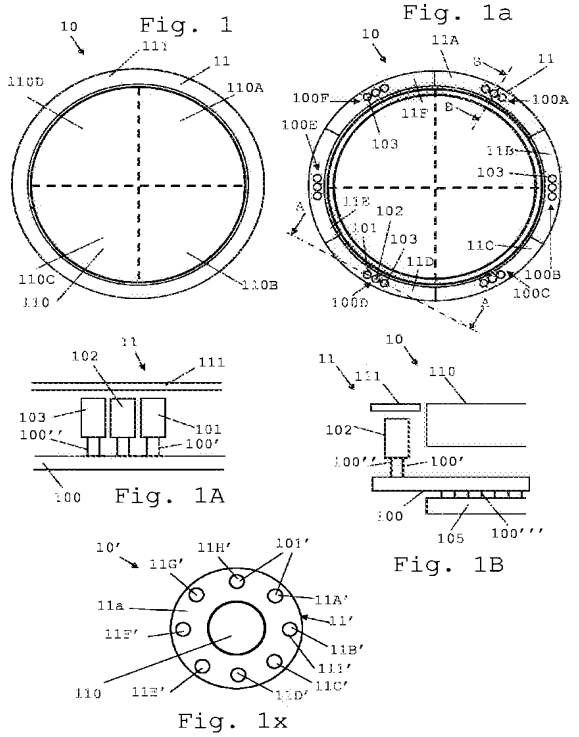
例えば、上記の設定、例えば、１つの部分が間欠的に有効化及び無効化される設定による、例えば、例えば水の不足などの原材料の不足を示す、エラーの状態を示すように、

例えば、上記の設定、例えば、少なくとも１つの部分が順次有効化される設定による、飲料調製プロセスのパラメータを設定するため、又はスタンバイ若しくは自動停止プロセスに入るためのタイマーを設定するためなどの、ユーザプログラミングモードの有効化を示すように、

例えば、上記の設定成、例えば、全ての部分が有効化された後に全ての部分が同時に無効化されるか、若しくは先に有効化された部分が、回転シーケンスで順次無効化されるようにして、連続する部分が、内側部分を中心にして、回転シーケンスで順次有効化される設定、１つの部分が間欠的に有効化及び無効化される設定、又は少なくとも１つの部分が順次有効化される設定などによる、すすぎ、洗浄、スケール除去、又は水材料排出手順など、サービス手順の実行を示すように、並びに、

例えば、上記の設定、例えば、１つの部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘが、間欠的に、例えば２回又は３回、有効化及び無効化される設定による、例えば、ユーザセレクタ１１０、１１０Ａ、１１０Ｂ、１１０Ｃ、１１０Ｄによる、ユーザ命令の獲得の完了を示すように、概ね外周の照明可能装置１１、１１’、２１、３１、４１、５１を制御するための１つ以上の設定を含み得る。

【図１－１ｘ】



【図２】

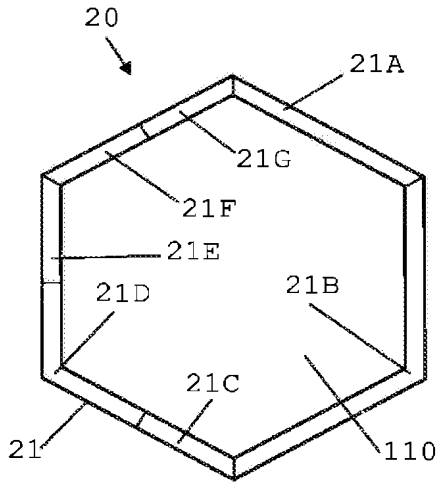


Fig. 2

【図３】

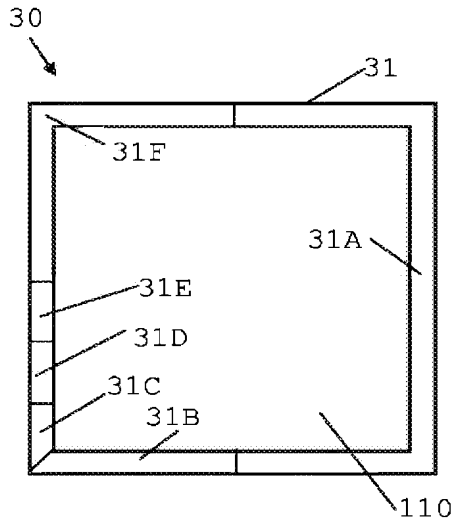


Fig. 3

【図４】

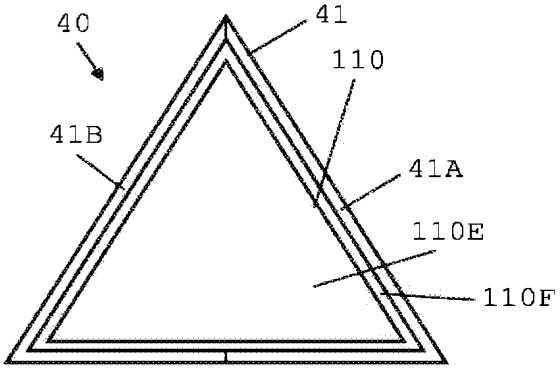


Fig. 4

【図５】

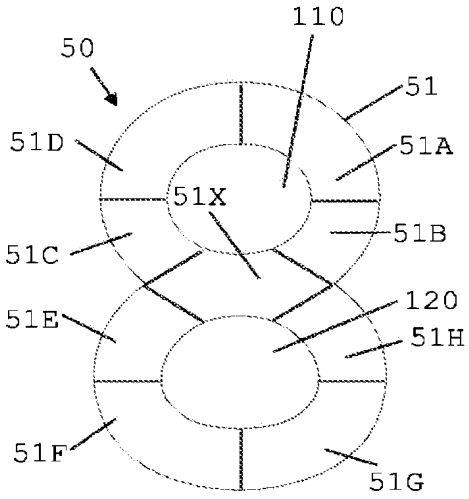


Fig. 5

【図６】

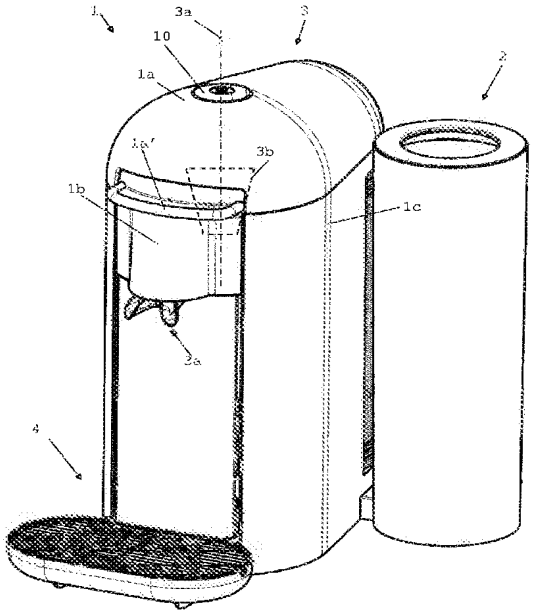


Fig. 6

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2014/077494

A. CLASSIFICATION OF SUBJECT MATTER
INV. A47J31/52 G07F9/02
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A47J G07F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 2 528 044 A1 (NESTEC SA [CH]) 28 November 2012 (2012-11-28) paragraph [0031] - paragraph [0053]; figures 1,2	1-16
X	WO 2010/037806 A1 (NESTEC SA [CH]; CAHEN ANTOINE [CH]; MOERI PETER [CH]) 8 April 2010 (2010-04-08) page 13, line 26 - page 23, line 28; figures 1-9	1-16
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[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 April 2015	14/04/2015

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Klintebäck, Daniel

1

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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2014/077494

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2014/077494

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DESCRIPTION JP2017503552A

10 Simple ergonomic user interface for beverage machines.

[0001]

14 The field of the invention relates to a beverage preparation machine having a user-friendly and ergonomic user interface for showing information to a user. For example, beverage preparation machines may use containers, such as capsules, of the raw materials of the beverage to be prepared, such as machines for preparing beverages by circulation of liquid into the raw material container and centrifugal action of the raw material container, typically to brew and extract beverages from the raw material container.

[0002]

23 For the purposes of this description, a "beverage" is intended to include any liquid substance that can be consumed by humans, such as tea, coffee, hot or cold chocolate, milk, soup, baby food, and the like.

26 "Capsules" are intended to include any pre-divided beverage ingredient, such as a flavoring ingredient, within an enclosed package of any material (e.g., plastic, aluminum, reusable, and/or biodegradable packages, etc.), any shape and structure (including soft pods or hard cartridges containing the ingredient), such as an air-tight or air-permeable package.

[0003]

33 Some beverage preparation machines use capsules.

34 The capsule contains the raw materials to be extracted or dissolved and/or stored in a machine and either automatically dispensed or otherwise added during beverage preparation.

36 Some beverage machines have a filling means.

37 The filling means comprises a pump for a liquid (usually water).

38 The pump pumps liquid from a water supply source, which is cold or in fact heated by heating means, for example thermoblocks.

[0004]

43 In particular in the field of coffee preparation, machines have been extensively developed in which capsules containing beverage ingredients are inserted into brewing devices.

45 The brewing device is reliably closed around the capsule, water is injected into the 1stside of the capsule, a beverage is produced in the closed volume of the capsule, and the brewed beverage can be released from the 2ndside of the capsule and collected in a container such as a cup or glass.

[0005]

52 The brewing device has been developed to facilitate the insertion of a "new" capsule and the removal of the capsule in use.

54 Typically, such brewing device comprises 2 parts that are relatively movable from the structure to insert/remove the capsule relative to the structure for brewing the raw material in the capsule.

57 The actuation of the movable part of the brewing device may be motorized.

58 Such a system is disclosed, for example, in EP 1 767 129.

59 Other examples of brewing devices are disclosed in WO 2009/04330, WO 2005/004683, and WO 2007/135136.

[0006]

64 Preparation of beverages using centrifugal force is also known.

65 Preparation of such beverages comprises the steps of providing beverage ingredients (flavour ingredients), such as, for example, powders and/or leaves, into a container, such as, for example, a capsule, and ensuring that the liquid and the ingredients interact while circulating the liquid into the container and rotating the container at a speed sufficient to create a gradient in the pressure of the liquid in the container.

70 Such pressure gradually increases from the center towards the periphery of the container.

71 As the liquid passes through the raw material, such as the coffee layer, extraction of the raw material, such as the coffee product, occurs, resulting in liquid extraction that flows out at the periphery of the container.

74 WO 2008/148601 describes a possible embodiment of a device using such a centrifugal principle.

76 In this case, the ingredient container is a sealed capsule that is opened before use.

77 The hot water is supplied to the center of the capsule by a water connection portion comprising a water injector aligned with the axis of rotation.

79 The container is held in a capsule holder, which is rotated by a rotary motor.

80 Both the liquid communication portion and the capsule holding portion are mounted along the roller bearing.

82 The beverage is extracted from the capsule by a plurality of peripheral needles forming an opening in the lid of the container.

84 When centrifugal force is applied to the capsule about the axis of rotation, hot water passes through the raw material of the beverage and interacts with the material to produce a liquid extract, which is injected against the impingement wall of the collector through the peripheral opening due to the effect of centrifugal force.

88 The liquid extract comprising the beverage is then released through the beverage duct of the device and collected in a container such as a cup.

90 WO 2008/148650 further describes a device in which a flow restriction is formed downstream of a container, in particular a capsule, for example by a valve system that opens or expands under pressure formed by a centrifugally-forced liquid exiting the container.

93 The valve system may be formed by a movement limiting portion of the device, which is resiliently biased against a rim portion of the capsule.

95 U.S. Pat. No. 5,566,605 relates to a centrifugal type extraction cell with a deformable sealing joint for a preparation machine for hot beverages.

97 The cell includes a drum and a cover defining an interior volume with the drum.

98 The cover is connected to the drum by means of a mounting lug that engages the ramp.

99 In these prior art devices, the water communication portion for supplying water to the container and the holding portion for holding the container are rotatable along the frame portion of the device secured together by a closure mechanism such as a bayonet system.

102 The retaining portion is generally attached to the frame portion by at least 1 roller bearing.

103 The liquid communication portion is also generally part of a frame portion which is also mounted along at least one roller bearing.

105 During the centrifugation process, when the device is rotated at high speed, the liquid extract creates significant axial and radial forces, which tend to separate these rotating parts.

[0007]

110 Various systems are disclosed in the art, for example as disclosed in the following documents, to allow a user to interact with such machines to provide operational instructions to or obtain feedback from the machines: Australian Patent 410 377; Swiss Patent 682 798; DE 44 29 353; 202 00 419; 20 2006 019 039; 2007 008 590; EP 1448084; 1676509; 08155851. 2, Korean Patent No. 2 624 844, GB Patent No. 2 397 510, U.S. Pat. Nos. 4,377,049, 4,458,735, 4,554,419, 4,767,632, 4,954,697, 5,312,020, 5,335,705, 5,372,061, 5,375,508, 5,645,230, 5,685,435, 5,731,981, 5,836,236, 5,959,869, 6,182,555, 6,354,341, 6,759,072, U.S. Patent Application Publication Nos. 2007/0157820, WO 97/25634, WO 99/50172, WO 2004/030435, WO 2004/030438, WO 2006/063645, WO 2006/090183, WO 2007/008138, WO 2008/00838, WO 2007/00838, WO 2007/00838, WO 2007/00838, WO 2007/00838, WO 2007/00838, WO 2008/00838, WO 2007/00838, WO 2007/00838, WO 2008/00838, WO 2008/00838, WO 2008/00838, WO

2008/00838, WO.

[0008]

126 It is therefore a preferred object of the invention to improve at least one feature of a beverage machine interface selected from, for example, ergonomics, interactions, insensitivity, user friendly and simplicity of an interface of a coffee, chocolate, cocoa, milk, soup or tea preparation machine.

[0009]

133 The present invention therefore relates to a beverage preparation machine.

134 The machine may have a water supply source, a beverage preparation unit and an outlet for supplying the beverage to the beverage dispensing area.

[0010]

139 For example, the machine is a machine for preparing beverages by passing hot or cold water, or another liquid, through a capsule comprising raw materials of the beverage to be prepared, such as coffee, tea, chocolate, cocoa, milk, and/or soup machines, for example ground coffee.

143 Examples of such machines are disclosed in WO 2007/042415, WO 2007/042414, WO 2007/134960, WO 2009/074550, WO 2009/130099, WO 2013/127476 and the literature cited therein.

[0011]

149 For example, a beverage machine has a container holding unit for preparing beverages from at least 1 raw material and dispensing such prepared beverages.

151 For example, the machine is configured to prepare coffee, tea, chocolate, cocoa, milk, and/or soup.

153 For example, the machine is configured to prepare a beverage by passing hot or cold water, or another liquid, through a container held in a beverage processing module comprising a container holding unit, such as a capsule to be held, comprising raw materials such as flavoring ingredients of the beverage to be prepared, such as ground coffee, tea, chocolate, cocoa, or milk powder.

[0012]

161 Such beverage preparation typically comprises mixing a plurality of beverage ingredients, such as, for example, water and milk powder, and/or injecting beverage ingredients, such as infusion of ground coffee or water and tea.

164 For example, a predetermined amount of beverage corresponding to 1 minute is formed and dispensed according to a user's request.

166 Such a 1 dose amount may range from 25 to 250 mL (e.g., the amount to fill a cup or mug) depending on the type of beverage.

168 The beverage formed and dispensed may be selected from Listeria, espresso, lungo, cappuccino, caffelate, American coffee, tea, and the like.

170 For example, the coffee machine may be configured to dispense espresso (20-60 mL adjustable amount per 1 time) and/or dispense lungo (e.g., an amount in the range of 70-200 mL per time).

[0013]

176 In advantageous embodiments, the beverage machine is of the type that combines raw materials by centrifugal treatment as disclosed, for example, in WO 2008/148601, WO 2008/148604, WO 2008/148646, WO 2008/148650, WO 2008/148656, WO 2009/106175, WO 2009/106598, WO 2010/063644, WO 2010/066736, WO 2010/089329, WO 2011/023711, PCT/EP13/077276, and PCT/EP13/077275.

181 Thus, the machine may comprise a raw material mixing chamber for accommodating raw material capsules, for example, into which a liquid is injected and which undergoes a centrifugal process about a centrifugal axis to mix the raw material and the liquid.

184 The raw material mixing chamber can be opened and closed to rotate and mix the raw materials.

[0014]

189 The machine of the present invention includes a user interface having a generally peripheral illuminable device formed by the illuminable portion and extending around the inner portion and a control device for enabling and disabling illumination of the illuminable portion, such as a programmable control device.

193 For example, the control device includes a controller, such as a printed circuit board PCB and a controller connected to a PCB by a connector.

195 The PCB may be formed from a single printed circuit board or several juxtaposed or spaced printed circuit boards connected electrically, optically or otherwise.

197 Optionally, the control device controls other functions of such a machine, such as, for example, the IT module, pump, heat regulator, and/or power unit of the preparation unit.

[0015]

202 In typical embodiments, the user interface is on the top, or front, or side of such a machine.

[0016]

206 According to the invention, the control device has at least 1 setting in order to enable only a part of the illuminable part.

[0017]

211 The illuminable portion may include 1 or more spots, such as, for example, round spots or polygonal spots, arranged along a generally peripheral illuminable device and/or 1 or more elongated segments extending along a generally peripheral illuminable device.

214 Such elongate segments include segments that may be selected from curved segments, such as segments extending generally along a circular sector and/or segments extending generally along an elliptical sector; straight segments; angled segments; segments extending along the entire straight side of the perimeter illuminable device; angled segments extending along a plurality of straight sides of the perimeter illuminable device, such as segments extending along only 2 straight sides and/or along more than 3 sides of the perimeter illuminable device; and segments extending over a portion of the entire length of the perimeter illuminable device, which portion may be selected from segments that correspond to about half, or 1/3, or 1/4, or 1/5, or 1/6, or 1/7, or 1/8, or 1/9, or 1/10, or 1/12, or 1/4 of the entire length.

[0018]

227 The generally peripheral illuminable device may extend around a single inner portion or around some inner portion, such as a pair of inner portions, for example, such that the generally peripheral illuminable device is generally 8 shaped around and between spaced inner portions.

231 A single inner portion may be made from a plurality of portions, e.g., a plurality of valid interface portions, or a plurality of invalid interface portions, or a combination of at least 1 valid interface portion and at least 1 invalid interface portion.

234 For example, such a valid interface portion is in the form of a user selector.

235 The invalid user interface portion may be in the form of a portion of the housing.

236 A portion of the housing belongs to the housing of the interface and/or belongs to the external machine housing.

[0019]

241 The inner portion may be an active portion, such as a selector or a plurality of selectors, for example in the form of one or more push buttons, and/or a passive portion, such as a portion of a housing, for example.

[0020]

247 The generally peripheral illuminable device may comprise one or more of the following

features: a light diffusing window, such as a translucent window, for diffusing light emitted by the light emitting elements; a light transmitting window, such as a transparent window, for indicating the shape of the light emitting elements to a user; a plurality of light emitting elements, including a single color light emitting element or a different color light emitting element, such as a color selected from white, yellow, orange, red, green, blue, and pink, and mixtures thereof; each illuminable portion of the peripheral illuminable device, illuminable by a single color light emitting element or by a group of different color light emitting elements, wherein the light emitting elements of such a group are separately or group-enabled; and a light emitting element, such as an LED, optionally connected to the PCB or a PCB by a connector, such as a pair of connectors.

[0021]

261 Light emitting elements that emit light of different colors may be used to transmit signals of different types.

263 For example, red color may be used to communicate an indication of warning or an indication of heat generation.

265 The blue color may be used to communicate an indication associated with cold conditions.

266 Green may be used to indicate a state or a ready state.

267 Red or blue may be used to communicate an indication of the process of warming or cooling the beverage.

269 Orange or yellow may be used to indicate a user programming mode or a service mode, such as machine rinsing, cleaning, or descaling.

271 Thus, intuitive color codes may be used to communicate different indicators to the user.

[0022]

275 The illuminable portions of the generally circumferential illuminable device may be in a line configuration that is side-by-side around the inner portion, such as a curved and/or angled line configuration.

278 For example, the illuminable portions of the generally peripheral illuminable device are in a single side-by-side linear configuration, or in 2, 3, or 4 generally parallel or concentric side-by-side linear configurations, and/or in a side-by-side linear configuration, wherein 2 adjacent illuminable portions are directly adjacent to one another or spaced apart by spacers, such as a portion of a housing.

[0023]

286 The illumination of each illuminable portion may spread substantially over the entire portion.

287 Optionally, illumination of each portion results in a substantially uniform light intensity and/or a substantially uniform color throughout these portions.

289 The color may be selected from white, yellow, orange, red, green, blue, and pink, or a mixture

of several such colors.

[0024]

294 The control device may have at least 1 setting for sequentially enabling successive portions, e.g. successive portions of a linear side-by-side configuration, in a rotational sequence about the inner portion, e.g.: a) at least 1 setting for sequentially enabling in a clockwise and subsequent counterclockwise sequence, or in a counterclockwise and subsequent clockwise sequence, b) at least 1 setting for sequentially enabling this repeatedly once or more once the rotational sequence is completed, and/or c) over the rotational sequence and/or between a plurality of successive rotational sequences, e.g., at least 1 setting for changing speed and sequentially enabling to indicate different steps: a beverage preparation procedure, e.g., a continuous pre-wetting and extraction step, and/or a service procedure, e.g., a continuous descaling procedure.

[0025]

307 Such settings may be used to indicate the operation of the cycle at any time point, such as, for example, an activation cycle, or a beverage preparation cycle, or a cleaning cycle.

309 In an advantageous embodiment, such a setting may be used to indicate a beverage preparation cycle by centrifugal processing, wherein the outer circumferential illuminable device optionally extends around a centrifugal processing axis, wherein the centrifugal processing is indicated by a rotational sequence, such as a plurality of iterations of a rotational sequence, indicating the centrifugal processing about the centrifugal processing axis.

[0026]

318 The control device may have at least 1 setting for sequentially enabling successive portions in a rotational sequence about the inner portion and disabling all portions simultaneously after enabling all portions.

[0027]

324 The control device may have at least 1 setting for sequentially disabling the previously enabled portion in the rotation sequence while sequentially enabling the successive portion in the rotation sequence about the inner portion.

327 Optionally, these portions have different activation and deactivation rates, such as equal activation and deactivation rates, or activation rates that are faster than the deactivation rates.

330 At least 2 or 3 portions may be simultaneously in the enabled state.

[0028]

334 The control device may have at least 1 setting such that 1 part is intermittently enabled and disabled.

[0029]

339 For example, such settings may be associated with an indication of an error or an indication confirming that the machine 1 has acquired information, such as confirming that the user instruction has been properly acquired by the user selector.

[0030]

345 Portions, such as portions or groups of portions, spaced apart, e.g., approximately evenly spaced apart, by permanently enabled or disabled portions about the inner portion may be enabled and disabled simultaneously.

[0031]

351 2 of these parts may be alternately enabled and disabled, such as 2 parts are alternately enabled and disabled.

[0032]

356 For example, such a setting may be associated with a user input by a user selector or an expectation by the machine 1 of another action by the user, for example.

[0033]

361 The portions may be intermittently enabled and disabled at a constant frequency, for example, some portions may be intermittently enabled and disabled at a constant frequency.

[0034]

366 In addition to any of the above settings, the controller may have at least 1 further setting to enable and disable the portion at a faster rate than the above settings.

[0035]

371 For example, different speeds may be used to distinguish between the execution of different types of procedures.

373 For example, execution of an activation or service (descaling) procedure may be indicated by

1 or more rotational sequences at a relatively slow speed, and a beverage preparation procedure may be indicated by 1 or more rotational sequences at a relatively fast speed.

[0036]

379 Different speeds may be implemented to distinguish between the execution of different procedures of the same type, such as for example different beverage preparation procedures of lungo or espresso coffee, or different service procedures, such as for example mild or intensive descaling procedures.

[0037]

386 In addition to the activatable and disableable portions, at least 1 portion may remain permanently activated or disabled in the above settings or further settings.

[0038]

391 The control device may have at least 1 setting, for example at least 1 part is sequentially enabled, such as a single part or a group of adjacent parts.

[0039]

396 The perimeter illuminable device extends generally along an elongated shape; a) forms a curve, such as, for example, 1 or more circles and/or ellipses, or portions thereof; b) forms a regular or irregular polygon, such as a triangle, e.g., a square, rectangle, trapezoid, or parallelogram, or portions thereof, such as a quadrangle, pentagon, hexagon, heptagon, octagon, dodecagon, nonagonal, dodecagon, or dodecagon; and/or c) forms a stripe shape and/or a separate element, such as a separate light emitting element, arranged generally along the elongated shape, such as an LED or a portion of a light-emitting optical fiber.

[0040]

406 For example, the control device may include a setting for sequentially enabling successive portions, for example, successive portions of a linear side-by-side configuration, in a rotation sequence about an inner portion, and optionally a setting of a type for simultaneously disabling all portions after enabling all portions, to indicate execution of an activation procedure, for example, activation of a heater, by the setting, such as a setting for sequentially enabling at least 1 portion, such as a single portion or a group of adjacent portions, to indicate execution of a beverage preparation procedure, for example, by a centrifugal process, such as a setting for sequentially enabling successive portions in a rotation sequence about an inner portion and simultaneously disabling all portions after all portions are enabled, or setting for sequentially disabling at least 1 or a setting for

sequentially disabling a previously enabled portion, such as a setting for sequentially disabling a user, such as a setting for sequentially disabling a setting for a setting for sequentially turning a user, such as a setting for sequentially disabling a setting for sequentially disabling a predetermined portion, such as a setting for sequentially turning a predetermined portion, such as a setting for sequentially turning a predetermined portion, such as a setting for sequentially turning a predetermined portion, such as a predetermined portion, such as

[0041]

426 The invention will now be described with reference to the schematic drawings.

[0042]

430 A round interface of a beverage preparation machine according to the invention is schematically illustrated.

432 FIG. 1 shows a horizontal cross-sectional view of the interface.

433 An enlarged cross-sectional view of the interface of FIGS. 1 and 1 a, taken along line A-A, is illustrated.

435 An enlarged cross-sectional view of the interface of FIGS. 1 and 1 a, taken along line B-B, is illustrated.

437 A variation of the interface of the machine according to the invention is illustrated.

438 The different interfaces of polygons are illustrated which may be installed in the machine according to the invention.

440 The different interfaces of polygons are illustrated which may be installed in the machine according to the invention.

442 The different interfaces of polygons are illustrated which may be installed in the machine according to the invention.

444 An example of a curved-shaped interface that can be installed in a machine according to the invention is shown.

446 A beverage preparation machine according to the invention is illustrated.

[0043]

450 FIGS. 1 to 5 illustrate different user interfaces 10, 20, 30, 40, 50 for a beverage preparation machine 1 according to the invention.

452 An embodiment of a beverage machine 1 comprising an interface 10 is shown in FIG. 6.

[0044]

456 The exemplary beverage preparation machine 1 may have a water supply source 2 and a beverage preparation unit 3.

458 The water supply source 2 may be a water tank.

459 Alternatively, the machine water supply may include a connector that can be directly connected to the urban water distribution system such that there is no need to manually refill any water tank of the beverage machine.

[0045]

465 The machine 1 may be configured to prepare hot or cold beverages.

466 The machine 1 may be configured to combine different raw materials, for example a liquid carrier such as water and/or milk, and one or more flavoring and/or texture ingredients (texturing agents), for example chocolate, cocoa, coffee, tea, milk, syrup, sugar, cream, emulsifier, dried or gel soup.

470 The raw materials may be combined by mixing or injecting them.

471 Suitable machines are disclosed in more detail, for example, in WO 2009/074550 and WO 2009/130099.

473 In an advantageous embodiment, the beverage machine 1 is of the type which combines raw materials by centrifugal treatment as disclosed, for example, in WO 2008/148601, WO 2008/148604, WO 2008/148646, WO 2008/148650, WO 2008/148656, WO 2009/106175, WO 2009/106598, WO 2010/063644, WO 2010/066736, WO 2010/089329, WO 2011/023711, PCT/EP13/077276 and PCT/EP13/077275.

478 Thus, the machine 1 may include a raw material mixing chamber 3 b(typically arranged in the machine 1 and shown in dotted lines in FIG. 6) for accommodating raw material capsules into which liquid is injected and which undergoes a centrifugal process about a centrifugal axis 3 ato mix the raw material and the liquid.

482 The raw material mixing chamber 3 bcan be opened and closed (e.g., by turning or raising and lowering the upper portion 1 aby actuating the handle 1 a) and can be rotated to mix the raw materials.

[0046]

488 The beverage machine 1 typically has an outlet 3 a, which may be a single outlet or a double outlet.

490 The outlet 3 amay be configured to supply beverage to the dispensing region 4.

491 The dispensing region 4 may be configured to receive a container such as a glass, cup or mug.

492 The dispensing region may be of any type, for example as disclosed in EP 1867260 or WO 2009/074557.

[0047]

497 The beverage machine 1 comprises a user interface 10, which is illustrated in more detail in FIGS. 1, 1A and 1B.

499 Alternatively, the interface 10 can be replaced by any of the interfaces 10', 20, 30, 40, 50

illustrated in FIGS. 1 x-5 or variations thereof encompassed within the scope of the present invention.

[0048]

505 The user interfaces 10, 10', 20, 30, 40, 50 all comprise: a generally peripheral illuminable device 11, 11', 21, 31, 41, 51 formed by illuminable portions 11A, 11B, 11C, 11D, 11E, 11F, 11A', 11B', 11C', 11D', 11E', 11F', 11H', 21A, 21B, 21C, 21D, 21E, 21F, 21G, 31A, 31B, 31C, 31D, 31E, 31F, 41A, 41B, 51A, 51B, 51C, 51D, 51E, 51F, 51G, 51H, 51X, extending around the inner portions 110, 120, and a controller 105, such as a PCB, 100', and a controller 105 for enabling and disabling illumination of the illuminable portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X, for example a PCB.

[0049]

515 The control device 100, 105 may control other functional parts of such a machine 1, such as IT modules, pumps, heat regulators and/or power parts of the beverage preparation unit 3.

[0050]

520 In an exemplary embodiment, the user interface 10, 10', 20, 30, 40, 50 is on the top 1a, front 1b or side 1c of such a machine 1.

522 In FIG. 6, for example, the user interface 10 is provided on the upper portion 1 aof the machine 1.

[0051]

527 The control device 100, 105 may incorporate at least one setting, such as a programmed setting, to enable only a portion of the illuminable portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X.

[0052]

533 For example, as illustrated in FIG. 1 x, the illuminable portion may include 1 or more illuminable spots 11A'-11H', such as round or polygonal spots, arranged along a generally circumferential illuminable device 11'.

536 For example, as illustrated in FIGS. 1, 2, 3, 4, and 5, the illuminable portion may have one or more elongated segments 11A-11F, 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X extending along a generally circumferential illuminable device 11, 21, 31, 41, 51.

[0053]

542 Such elongated segments may be selected from curved segments 11A-11F, 51A-51X, straight segments 21A, 21C, 21E, 21F, 21G, 31B, 21C, 21D, 21E (FIGS. 2-4), angled segments 21B, 21D, 31A, 31G, 41A, 41B (FIGS. 2-4), straight segments 21A, 21B, 31A, 31A, 41A, 41B (FIGS. 2-4), straight segments 21A, 21B, 31A, 41A, 41B (FIGS. 2-4), straight segments extending along the entire circumference of the outer circumference of the illuminable device 21, 31, 41 (FIGS. 2 to 4), straight segments extending along the entire circumference of the outer circumference of the illuminable device 21, 31A, 31A, 41B, and/or straight segments that are 1/ or more, or straight segments that are 1/ or 1/ or 1/ or 1/ or 1/ or 1 (FIGS. 2), or straight segments that are 1/ or 1/ or 1/ or 1/ or 1 or 1 or 1/ or 1/ or 1 or 1 or 1 or 1

[0054]

555 The perimeter illuminable devices 11, 11', 21, 31, 41, 51 may extend around a single inner portion 110 (FIGS. 1-4), or a number of inner portions 110, 120.

557 For example, such an arrangement extends around the pair of inner portions 110, 120, for example, such that the outer perimeter illuminable device 51 is approximately 8 shaped (FIG. 5).

[0055]

563 The single inner portion 110 can be made from several portions, for example, a plurality of valid interface portions 110A, 110B, 110C, 110D (FIGS. 1 and 2), a plurality of invalid interface portions, or a combination of at least 1 valid interface portion 110E and at least 1 invalid interface portion 110F (FIG. 4), for example, the valid interface portion is in the form of a user selector and/or the invalid user interface portion is in the form of a portion of the housing.

[0056]

572 The inner portion may be selected from the active portion 110 and/or the passive portion 110F, 120, such as a portion of the housing, for example in the form of one or more push buttons, such as the selector 110E or the plurality of selectors 110A, 110B, 110C, 110D.

[0057]

578 The user selectors 110, 110A, 110B, 110C, 110D, 110E are typically connected to the controller 105 or PCB 100 and may be configured to start preparing beverages having some characteristics such as, for example, desired amounts and/or concentrations and/or tastes to be generated, or to receive user instructions such as instructions to perform service procedures such as, for example, rinsing or cleaning or descaling, or to turn the machine 1 on or off, or to enter a user programming mode.

584 The user selectors 110, 110A, 110B, 110C, 110D, 110E may be configured to receive only user instructions, or may be further configured to indicate information to the user, for example, and the user selector itself may comprise a light emitting device controlled by the controller 105.

588 For example, the user selector can be illuminated by whether a function associated with the selector is available at a predetermined point in time when the machine 1 is in use.

590 For example, it is not possible to initiate the beverage preparation process during the descaling process.

592 This can be indicated by appropriate illumination of the corresponding user selector.

593 This does not mean that the user cannot order the beverage during the service procedure, but rather means that the service procedure needs to be interrupted or executed until the end, and then executes the instructions for beverage preparation.

596 For example, the controller may store a particular user request for execution at a later point in time when the machine 1 is in a state capable of executing the user request.

598 For example, for an embodiment in which a stored user request is executed later, see, for example, WO 2011/020779.

600 Of course, it is also possible to configure the machine such that the input to perform a particular process is not accepted as long as such a process cannot be performed.

[0058]

605 The peripheral illuminable devices 11, 11', 21, 31, 41, 51 may include: a light diffusion window 111 (FIGS. 1, 1A, and 2B), such as a translucent window, for diffusing light emitted by the light emitting elements 101, 102, 103, a light transmission window 111' (FIG. 2x), such as a transparent window, for indicating the shape of the light emitting element 101' to a user, a plurality of light emitting elements 101, 101', 102, 103, including different color light emitting elements 101, 102A, 100B, 100C, 100D, 100E, 100F, or a different color light emitting element 101, 102B, 100C, 100D, 100E, 100F, such as a color selected from white, yellow, orange, red, green, blue, pink, and mixtures thereof, and a connector 100A, 100B, 100C, 100D, 100E, 100F, such as a group of light emitting elements 101, 100A, 100A, 100A, 100A, or a connector 100A, 51A, or a connector 100A, 51B, or a connector 100A, 51B, or a connector 100A, 51B, or a connector

[0059]

619 The illuminatable portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X of the outer circumferential illuminatable devices 11, 11', 21, 31, 41, 51 may be in a line-like configuration that is side-by-side around the inner portion 110, 120, such as a curved configuration (FIGS. 1-1x and 5) and/or an angled line-like configuration (FIGS. 2-4).

623 Such illuminable portions may be in a single side-by-side linear configuration 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X (FIGS. 1-5), or 2, young 3, or 4 generally parallel side-by-side linear configurations, and/or in 11A-11F, 11A'-11H', 21A-21G, 31A-31F,

41A-41B, 51A-51H, 51X (FIGS. 1, 2, 3, 4, and 5), or 11A'-11H' (FIG. 1 x), side-by-side linear configurations 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X, which are directly adjacent to one another.

[0060]

632 The illumination of the illumination portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X may spread substantially across these portions.

634 Optionally, the illumination of such portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X results in a substantially uniform light intensity and/or a substantially uniform color, such as a color selected from white, yellow, orange, red, green, blue, and pink, or a color resulting from a mixture of several such colors, throughout these portions.

[0061]

641 The control device 100, 105 may have at least 1 setting for sequentially enabling successive portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X, e.g. successive portions of a linear side-by-side configuration, in a rotational sequence about the inner portion 110, 120.

645 Optionally, the speed is changed and sequentially validated to indicate different steps: a) in a clockwise and subsequent counterclockwise sequence, or in a counterclockwise and subsequent clockwise sequence; b) when the rotation sequence is completed, this is repeatedly and sequentially validated one or more times; and/or c) over the rotation sequence and/or between a plurality of consecutive rotation sequences: a continuous beverage preparation procedure, e.g., pre-wetting and extraction; and/or a continuous service procedure, e.g., descaling procedure.

[0062]

655 Such settings may be used to indicate the operation of the cycle at any time point, such as, for example, an activation cycle, or a beverage preparation cycle, or a cleaning cycle.

657 In an advantageous embodiment, such a setting may be used to indicate a beverage preparation cycle by centrifugal processing, wherein the outer circumferential illuminable device optionally extends around the centrifugal processing axis 3 a, wherein the centrifugal processing is indicated by a rotational sequence, such as a plurality of iterations of a rotational sequence, indicating the centrifugal processing about the centrifugal processing axis 3 a.

[0063]

666 The control device 100, 105 may have at least 1 setting for sequentially enabling the successive portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X in a

rotational sequence about the inner portions 110, 120 and simultaneously disabling all portions after enabling all portions.

[0064]

673 The control device 100, 105 may have at least one setting for sequentially enabling the successive portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X in a rotational sequence about the inner portions 110, 120 while sequentially disabling the previously enabled portions in a rotational sequence.

677 The portion may have different activation and deactivation rates, such as equal activation and deactivation rates, or activation rates that are faster than the deactivation rates.

679 At least 2 or 3 portions may be simultaneously in the enabled state.

[0065]

683 The control device 100, 105 may have at least 1 setting in which 1 part, 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X, is intermittently enabled and disabled.

[0066]

688 For example, such settings may be associated with an indication of an error or an indication confirming that the machine 1 has acquired information, such as confirming that the user instruction has been properly acquired by the user selector.

[0067]

694 The plurality of such portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X may be enabled and disabled simultaneously.

696 For example, portions, or groups of portions, are spaced apart by other permanently enabled or disabled portions about the inner portions 110, 120.

698 Such parts, or groups of parts, are equally spaced about the inner portions 110, 120, for example.

[0068]

703 2 of such portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X may be alternately enabled and disabled.

[0069]

708 For example, 2 parts are alternately enabled and disabled.

[0070]

712 For example, such a setting may be associated with a user input by a user selector or an expectation by the machine 1 of another action by the user, for example.

[0071]

717 Such portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X may be intermittently enabled and disabled at a constant frequency.

719 For example, some portions are intermittently enabled and disabled at a constant frequency.

[0072]

723 In addition to such settings, the controller 100, 105 may have at least 1 other setting for enabling and disabling the portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X at a faster rate than the above settings.

[0073]

729 For example, different speeds may be used to distinguish between the execution of different types of procedures.

731 For example, execution of an activation or service (e.g., descaling) procedure may be indicated by 1 or more rotational sequences at a relatively slow speed, and a beverage preparation procedure may be indicated by 1 or more rotational sequences at a relatively fast speed.

[0074]

737 For example, different speeds may be implemented to distinguish different service procedure runs, such as different beverage preparation procedures of, for example, lungo or espresso coffee, or mild or intensive descaling procedures.

[0075]

743 In addition to the activatable and disableable portions, at least 1 portion may remain permanently activated or disabled in the above configuration or in the above further configuration.

[0076]

749 For example, a non-stop warning may be indicated by the permanently active portion, such as raw material (e.g., water) availability approaching a minimum level.

751 Another example of a non-stop alert may relate to the need to perform a service (e.g.,

descaling) process within a short time.

[0077]

756 The control device 100, 105 may have at least 1 setting, for example, at least 1 part being sequentially enabled, such as a single part 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X, or a group of adjacent parts.

[0078]

762 The perimeter illuminable devices 11, 11', 21, 31, 41, 51 are generally along an elongated shape, a combination of at least one feature a, such as: a) forming a curve 11, 11', such as, for example, 1 or more circles 11, 11' (FIGS. 1, 1a, and 1x) and/or ellipses 51 (FIG. 5), or a portion thereof; b) forming a triangle 41 (FIG. 4), such as, for example, a square 31 (FIG. 3), a rectangle, a trapezoid, or a parallelogram, such as a square 31, a pentagon, a hexagon 21 (FIG. 2), a heptagon, an octagon 11' (FIG. 1x), a pentagon, a nonagon, a dodecagon, a dodecagon, or a dodecagon; c) forming a regular or irregular polygon 21, 31, 41, or a portion thereof, such as a stripe 11, 21, 31, 41, 51 (FIGS. 1, 2-5) and/or a separate element 11' (FIG. 1x), such as a separate light emitting element, disposed generally along an elongated shape, such as, for example, an LED 101' or a portion of

[0079]

775 For example, the control device 100, 105 may include a standby procedure for presenting an indication of the time required until preparation of beverage preparation by the above setting, such as a setting for sequentially enabling successive portions, for example, successive portions of a linear side-by-side configuration, in a rotation sequence about the inner portion, and optionally a setting of a type for simultaneously disabling all portions after enabling all portions, such as a setting for sequentially enabling at least 1 portion, such as a single portion or a group of adjacent portions, to indicate a standby procedure for presenting an indication of the time required until preparation of beverage preparation by the above setting, such as a setting for sequentially enabling successive portions in a rotation sequence about the inner portion and simultaneously disabling all portions after all portions are enabled, or a setting for sequentially disabling at least 1A to 11 or a setting for intermittently disabling at least 1A to 11 or a setting for sequentially disabling at least 1A to 11 or a setting for sequentially disabling at least 1A to 11 or a setting for intermittently disabling at least 1A to 11 or a setting for intermittently disabling at least 1A to 11 or a setting for selectively disabling at least 1A to 11 or a setting for intermittently disabling at least 1

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
LIMA-PCT		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/GB2021/050764	26 March 2021 (26-03-2021)	26 March 2020 (26-03-2020)
Applicant		
CHIARO TECHNOLOGY LIMITED		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language,** the international search was carried out on the basis of:

[X] the international application in the language in which it was filed

[ ] a translation of the international application into ..... which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [X] **Certain claims were found unsearchable** (See Box No. II)

3. [ ] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**

a. the figure of the **drawings** to be published with the abstract is Figure No. 1

[X] as suggested by the applicant

[ ] as selected by this Authority, because the applicant failed to suggest a figure

[ ] as selected by this Authority, because this figure better characterizes the invention

b. [ ] none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2021/050764

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 11-85
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2021/050764

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/06
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2016/007561 A1 (NAYA HEALTH INC [US]) 14 January 2016 (2016-01-14) paragraphs [0047] - [0070]; figures 3-7, 16-18	1-10
X	US 2018/104396 A1 (PARK CHO HEE [KR]) 19 April 2018 (2018-04-19) paragraphs [0037] - [0061]; figures 1-8	1

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 June 2021	06/07/2021

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Schlaug, Martin

2

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2021/050764

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2016007561 A1	14-01-2016	AU 2015287927 A1	02-02-2017
		AU 2020202382 A1	30-04-2020
		CN 106687155 A	17-05-2017
		EP 3166657 A1	17-05-2017
		US 2020246517 A1	06-08-2020
		WO 2016007561 A1	14-01-2016
US 2018104396 A1	19-04-2018	CN 107206135 A	26-09-2017
		KR 101622768 B1	19-05-2016
		US 2018104396 A1	19-04-2018
		WO 2016186452 A1	24-11-2016

Form PCT/ISA/210 (patent family annex) (April 2005)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 11-85

The present application contains 85 claims, 14 of which are independent. There is no clear distinction between the independent claims because of their overlapping scope. In view of the (excessive) number of claims and of their formulation, the claims as a whole do not satisfy the requirements of conciseness and clarity of Art. 6 PCT. Furthermore, the application does not meet the requirements of unity of invention laid down in Rule 13.1 PCT and, prima facie, it appears to relate to 9 separate inventions.

In the present case it is particularly burdensome for a skilled person to establish the subject-matter for which protection is sought. Although all claims relate in one way or another to breast pump systems or components thereof, they define so many different aspects and details of the system and its parts that it results unduly burdensome to determine the matter for which protection is sought.

The non-compliance with the substantive provisions is to such an extent, that a meaningful search of the whole claimed subject-matter cannot be carried out (Art. 17(2) PCT and PCT Guidelines 9.30).

Furthermore, the description contains so many different embodiments that no reasonable basis can be found in the application that clearly indicates the subject-matter which might be expected to form the subject of the claims later in the procedure.

The applicant was invited by this International Searching Authority to provide informal clarification on the issue indicated above, but has not responded to this invitation within the given time limit. Therefore the search has been limited to claims 1-10 as indicated in the formal invitation for clarification.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) PCT declaration be overcome.

Electronic Patent Application Fee Transmittal

Application Number:	17181057
Filing Date:	22-Feb-2021
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Filer:	Yangbeini Wang/Jon Baitlon
Attorney Docket Number:	4944.0120006

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
RCE- 1ST REQUEST	2801	1	544	544
		Total in USD ($)		**544**

Electronic Acknowledgement Receipt

EFS ID:	47435211
Application Number:	17181057
International Application Number:	
Confirmation Number:	4690
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	26111
Filer:	Yangbeini Wang/Kim Perry
Filer Authorized By:	Yangbeini Wang
Attorney Docket Number:	4944.0120006
Receipt Date:	26-JAN-2023
Filing Date:	22-FEB-2021
Time Stamp:	17:56:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$544
RAM confirmation Number	E20231PH56561609
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	2023-01-26-Transmittal-Form-4944-0120006.pdf	167793 8eab88c1da94fa5b396c752a49d654968836b2c5	no	1
Warnings:					
Information:					
2		2023-01-26-Amendment-Reply-114-4944-0120006.pdf	165348 ec793e86b9f242361253d7811783a105d4276ea8	yes	12

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment Submitted/Entered with Filing of Continued Prosecution Application (CPA)/Request for Continued Examination(RCE)	1	1
Claims	2	6
Applicant Arguments/Remarks Made in an Amendment	7	12

Warnings:					
Information:					
3	Transmittal Letter	2023-01-26-sIDS-Pleading-4944-0120006.pdf	118197 5634749b38b0c29022d1ba8d08a19a2e95fac853	no	2
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	2022-01-26-sIDS-Form-SB08-4944-0120006.pdf	203675 ec1b53148b4ba29e7d00efa80c774326fcb225ff	no	4
Warnings:					
Information:					
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5	Request for Continued Examination (RCE)	2023-01-26-RCE-4944-0120006.PDF	1349977 433b81065eabca7431344a3cbb28c8fb230e31c4	no	3
Warnings:					
Information:					
6	Foreign Reference	FP1_JP2013545519A-4944-0120006.PDF	985411 733b34af523197e67bb578e5ba232924adce39c7	no	59
Warnings:					
Information:					
7	Foreign Reference	FP2_JP2016524490A-4944-0120006.PDF	846613 c48f79665938f2f6fb35c4e14f5a827b70364e9a	no	43
Warnings:					
Information:					
8	Foreign Reference	FP3_WO2013064852A1-4944-0120006.PDF	1417100 3de7ad793b01dd9549292d9acb468550544c146b	no	148
Warnings:					
Information:					
9	Foreign Reference	FP4_JP2014532498A-4944-0120006.PDF	2524601 422967c9c33e52254ab3f30a009523003e5ad773	no	125
Warnings:					
Information:					
10	Foreign Reference	FP5_WO2016006458A1-4944-0120006.PDF	432120 a5a702fef4da6c9ac0ac4807025d4325f67aa5b9	no	36
Warnings:					
Information:					
11	Foreign Reference	FP6_JPH11178917A-4944-0120006.PDF	403589 d58a68b87c92a3048b9e734c89425c13403155a5	no	15
Warnings:					
Information:					

12	Foreign Reference	FP7_JP2000350527A-4944-0120006.PDF	511735 6a14725ef694fd7c556d6f69e87253027563bb5e	no	19
Warnings:					
Information:					
13	Foreign Reference	FP8_WO2016007561A1-4944-0120006.PDF	752974 c19726eb92c8598893266af5a3de342850226d7d	no	44
Warnings:					
Information:					
14	Foreign Reference	FP9_WO2016025405A1-4944-0120006.PDF	808719 4462946e981bddb5cab26008cc9e451236e02323	no	41
Warnings:					
Information:					
15	Foreign Reference	FP10_WO2004108184A2-4944-0120006.PDF	1650019 7821a8c9b8e0ce59bc167dc20b17b9a7ee315fea	no	58
Warnings:					
Information:					
16	Foreign Reference	FP11_JP2016526396A-4944-0120006.PDF	437026 b2c5d4292a1e7596dc75f4855ac6c0f938e6a03d	no	38
Warnings:					
Information:					
17	Foreign Reference	FP12_WO2014160614A1-4944-0120006.PDF	499411 0dea128c97e27bf073109128ad2ebe10898a21c8	no	34
Warnings:					
Information:					
18	Foreign Reference	FP13_JP2017503552A-4944-0120006.PDF	562118 f693f414124512e7a5aef6e2b3074332f7942c8c	no	45
Warnings:					
Information:					

19	Non Patent Literature	NPL1_ISR-4944-0120006.PDF	63565 cc12cc9b97dcb3ae51dade8d1b875bed8631dc19	no	5
Warnings:					
Information:					
20	Non Patent Literature	NPL2_JPSR-4944-0120006.PDF	311182 62560011fd8730f154e63e8fc5f2cd0d3909ed9a	no	20
Warnings:					
Information:					
21	Non Patent Literature	NPL3_EESR-4944-0120006.PDF	381670 e5873042c412e45b83ff6fbdbdaa359396b51381	no	26
Warnings:					
Information:					
22	Fee Worksheet (SB06)	fee-info.pdf	37660 2b259eeefb80a049929525106b5b8cb13c536d12	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	14630503	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
Approved for use through 12/31/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDRICKSON, Courtney B.
Attorney Docket Number	4944.0120006

Total Number of Pages in This Submission

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
- ☑ Fee Attached
- ☑ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☑ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

  Request for Continued Examination Transmittal (PTO/SB/30EFS); FP1-FP13 and NPL1-3.

Remarks

Online Credit Card Authorization for $544.00 to cover the RCE Fee (1st request).

The Office may charge any fee deficiency for any submission made with this transmittal to Deposit Account 19-0036.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Richard D. Coller III/		
Printed name	Richard D. Coller III		
Date	January 26, 2023	Reg. No.	60,390

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: O'TOOLE et al.	Confirmation No.: 4690
Applicant: Chiaro Technology Limited	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, Courtney B.
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Amendment and Reply Under 37 C.F.R. § 1.114

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313–1450

Mail Stop RCE

Commissioner:

In reply to the Office Action dated October 26, 2022, Applicant submits the following amendment and remarks.

If extensions of time are necessary to prevent abandonment of this application, then they are petitioned for under 37 C.F.R. § 1.136(a). Any additional fees required to continue prosecution or appeal of this application (including issue fee, fees for net addition of claims or forwarding to appeal) are hereby authorized to be charged to our Deposit Account No. 19–0036.

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently amended) A breast pump device comprising:

~~a self-contained, in-bra wearable device comprising:~~

a housing comprising:

a battery, and

a pump configured to generate negative air pressure;

a breast shield of a plurality of interchangeable breast shields, each of the plurality of interchangeable breast shields having a different size and being configured to slide in and out of the housing, the breast shield comprising a breast flange and a nipple tunnel comprising a side wall and a front end, and a guide line, wherein the breast shield is transparent or optically clear; and

a milk container configured to be attached to and removed from the housing,

wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast, and

wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel.

2. (Canceled)

3. (Previously presented) The breast pump device of claim 1, wherein the breast shield is rigid.

4. (Previously presented) The breast pump device of claim 1, wherein the breast shield is a dishwasher safe, plastic breast shield.

5. (Previously presented) The breast pump device of claim 1, wherein the breast shield is configured to be attached using magnets to the housing.

6. (Previously presented) The breast pump device of claim 1, wherein the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast.

7. (Previously presented) The breast pump device of claim 1, wherein the breast shield is configured to present, in use, a single continuous surface to a nipple and a breast.

8. (Previously presented) The breast pump device of claim 1, wherein the breast flange and the nipple tunnel are integrally formed.

9. (Previously presented) The breast pump device of claim 1, wherein the breast shield is configured to be generally symmetrical about a center-line running from a top to a bottom of the breast shield when positioned upright for normal use.

10. (Previously presented) The breast pump device of claim 1, wherein the breast shield is configured to slide into the housing with a single push action.

11. (Previously presented) The breast pump device of claim 1, wherein the breast shield is configured to slide out from the housing, together with a membrane that is configured to prevent milk from flowing into the pump.

12. (Previously presented) The breast pump device of claim 1, wherein the milk container is rigid.

13. (Previously presented) The breast pump device of claim 1, wherein the milk container is an optically clear, dishwasher safe, plastic milk container.

14. (Previously presented) The breast pump device of claim 1, wherein the milk container is configured to attach to a lower part of the housing and forms a base of the breast pump device.

15. (Previously presented) The breast pump device of claim 1, wherein the milk container is configured to magnetically attach to the housing.

16. (Currently amended) The breast pump device of claim 1, wherein the ~~nipple tunnel comprises~~ guide line[[s]] is configured to run[[ning]] parallel along one or more sides of the nipple tunnel.

17. (Previously presented) The breast pump device of claim 1, wherein the nipple tunnel comprises an air hole or passage, and wherein the pump is configured to transfer negative air pressure into the nipple tunnel via the air hole or passage.

18. (Previously presented) The breast pump device of claim 1, wherein the nipple tunnel comprises on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container.

19. (Previously presented) The breast pump device of claim 1, wherein the pump comprises one or more piezo air pumps.

20. (Previously presented) The breast pump device of claim 1, wherein the housing further comprises a Universal Serial Bus (USB) charging socket.

21. (Previously presented) The breast pump device of claim 1, wherein the housing comprises a left or right breast selector or toggle switch that, when selected for a particular pumping session, is configured to send data to a connected application configured to track pumping sessions, to indicate whether that particular session is associated with a left or a right breast.

22. (Previously presented) The breast pump device of claim 1, wherein the housing is configured to be shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra.

23. (Canceled)

24. (Previously presented) The breast pump device of claim 1, wherein the breast pump device is configured to deliver a maximum suction of approximately 240 mmHg.

25. (Previously presented) The breast pump device of claim 1, wherein the breast pump device comprises a sensor that is configured to directly measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container.

26. (Canceled)

27. (Canceled)

28. (Previously presented) The breast pump device of claim 1, wherein the pump is configured to deliver in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

29. (Previously presented) The breast pump device of claim 1, wherein the pump is a lightweight air pump that enables a total mass of the breast pump device, unfilled with milk, to be less than 250 gm.

30. (Previously presented) The breast pump device of claim 1, wherein the breast pump device is configured to make less than 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

31. (Previously presented) A kit, comprising:

the breast pump device of claim 1; and

the plurality of interchangeable breast shields.

32. (Previously presented) The kit of claim 31, wherein each of the plurality of interchangeable breast shields comprises fit lines in a nipple tunnel of that breast shield that are configured to

enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel.

33. (Previously presented) The breast pump device of claim 1, wherein the battery is a rechargeable battery, and wherein the housing further comprises:

a power charging circuit configured to control the charging of the rechargeable battery, and

control electronics configured to be powered by the rechargeable battery.

34. (Currently amended) The breast pump device of claim 1, wherein a length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same.

Remarks

Upon entry of the foregoing amendment claims 1, 3–22, 24–25, and 28–34 are pending in the application. Claim 1 is an independent claim. Claims 1, 16, and 34 are amended. Claim 2 is canceled without prejudice or disclaimer. These changes do not introduce any new matter, and Applicant respectfully requests their entry.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Office reconsider and withdraw all outstanding objections and rejections.

Allowable Subject Matter

The Office indicates claim 28 is allowable over the prior art of record excepting the double patenting rejection of the same. (Office Action dated October 26, 2022, p. 42.) Applicant appreciates the Office's indication that claim 28 would be allowable if the double patenting rejection of the same is overcome. (*Id.*) For at least the reasons discussed below, all pending claims are allowable over the cited art.

Claim Objection

The Office objects to claim 34 for an alleged informality. (*Id.*, 2.) Without acquiescing to the propriety of the objection and solely to expedite prosecution, claim 34 is amended.

Applicant asks the Office to withdraw the objection to claim 34.

Rejections under 35 U.S.C. § 103

Independent Claim 1 (Myers, Cook)

The Office rejects claims 1, 3, 6–8, 10–11, 14, 16–18, 22, 24, 31, and 34 under 35 U.S.C. § 103 as allegedly obvious over U.S. Publication No. 2008/0275386 to Myers in view of EP Publication No. 2502640 to Cook *et al.* (*Id.*, 3.)

Without acquiescing to the propriety of the objection and solely to expedite prosecution, claim 1 is amended to recite, in part, "a breast shield of a plurality of interchangeable breast shields … the breast shield comprising … a guide line … wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast,

wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel."

The Office acknowledges that Myers does not teach or disclose "the breast shield being of a plurality of interchangeable breast shields," "the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast." (*Id.*, 4–5.) Instead, the Office relies on Cook. (*Id.*, 5 (citing Cook, ¶ [0042], FIGS. 1A, 1B, refs. 9, 10, 11, 12).) However, both Myers and Cook fail to disclose or suggest at least the claimed guide line of the breast shield "configured to define the spacing of the nipple from the side wall of the nipple tunnel." (*See* Cook, ¶¶ [0042], [0044], FIGS. 2A, 2B.) Cook fails to disclose or suggest how, if at all, the dimensions of its varied diameters of apertures 10, 12 are communicated to a user. (*See id.*)

Accordingly, Myers and Cook, alone or in combination, fail to disclose or suggest these claimed features.

Applicant asks the Office to withdraw the § 103 rejections of claims 1, 3, 6–8, 10–11, 14, 16–18, 22, 24, 31, and 34.

Independent Claim 1 (Khalil, Myers, Cook)

The Office rejects claims 1, 6–10, 14, 17–18, 22, 31, and 34 under 35 U.S.C. § 103 as allegedly obvious over U.S. Publication No. 2013/0023821 to Khalil *et al.* in view of Myers and Cook.[1] (Office Action dated October 26, 2022, p. 8.)

As discussed above, claim 1 recites, in part, "a breast shield of a plurality of interchangeable breast shields … the breast shield comprising … a guide line … wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast, wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel."

The Office acknowledges that Khalil does not teach or disclose the breast shield "being of a plurality of interchangeable breast shields each having a different size, the plurality of

[1] The Office refers to claims 20-21 in this rejection. (*Id.*) However, the rejections of these claims over Khalil, Myers, and Cook are not explained. Applicant believes these claims were referred to in this rejection by mistake and responds accordingly.

interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast." (*Id.*, 9–10.) The Office relies on Cook to remedy this deficiency in Khalil. (*Id.*, 10 (citing Cook, ¶ [0042], FIGS. 1A, 1B, refs. 9, 10, 11, 12).) But Cook fails to disclose or suggest at least the claimed guide line of the breast shield "configured to define the spacing of the nipple from the side wall of the nipple tunnel," as discussed above. (*See* Cook, ¶¶ [0042], [0044], FIGS. 2A, 2B.) Khalil and Myers are also deficient.

Accordingly, Khalil, Myers, and Cook, alone or in combination, fail to disclose or suggest these claimed features.

Applicant asks the Office to withdraw the § 103 rejections of claims 1, 6–10, 14, 17–18, 22, 31, and 34.

Remaining Claims

The Office rejects claim 4 under 35 U.S.C. § 103 as allegedly obvious over Myers in view of Cook, in view of U.S. Publication No. 2016/0296682 to Phillips *et al.*, and U.S. Publication No. 2005/0228342 to Yuen. (*Id.*, 8.) Claim 4 depends from and adds features to independent claim 1. Phillips and Yuen do not overcome the deficiencies discussed above. Accordingly, claim 4 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 4.

The Office rejects claim 5 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and U.S. Publication No. 2018/0333523 to Chang *et al.* (*Id.*, 13.) Claim 5 depends from and adds features to independent claim 1. Chang does not overcome the deficiencies discussed above. Accordingly, claim 5 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 5.

The Office rejects claims 12–13 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and Phillips. (*Id.*, 14.) Claims 12–13 depend from and add features to independent claim 1. Phillips does not overcome the deficiencies discussed above. Accordingly, claims 12–13 are allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claims 12–13.

The Office rejects claim 15 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and U.S. Publication No. 2007/0228059 to Karsan. (*Id.*, 15.) Claim 15 depends

from and adds features to independent claim 1. Karsan does not overcome the deficiencies discussed above. Accordingly, claim 15 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 15.

The Office rejects claim 19 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and U.S. Publication No. 2012/0277636 to Blondheim *et al.* (*Id.*, 16.) Claim 19 depends from and adds features to independent claim 1. Blondheim does not overcome the deficiencies discussed above. Accordingly, claim 19 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 19.

The Office rejects claims 20–21 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and U.S. Publication No. 2014/0378895 to Barack.[2] (*Id.*, 17.) Claims 20–21 depend from and add features to independent claim 1. Barack does not overcome the deficiencies discussed above. Accordingly, claims 20–21 are allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claims 20–21.

The Office rejects claim 25 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and U.S. Publication No. 2016/0220743 to Guthrie *et al.* (*Id.*, 18.) Claim 25 depends from and adds features to independent claim 1. Guthrie does not overcome the deficiencies discussed above. Accordingly, claim 25 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 25.

The Office rejects claim 29 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and U.S. Patent No. 6,227,936 to Mendoza. (*Id.*, 19.) Claim 29 depends from and adds features to independent claim 1. Mendoza does not overcome the deficiencies discussed above. Accordingly, claim 29 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 29.

The Office rejects claim 30 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and U.S. Publication No. 2009/0281485 to Baker *et al.* (*Id.*, 20.) Claim 30 depends from and adds features to independent claim 1. Baker does not overcome the deficiencies discussed

[2] The Office Action appears to refer to the Barack publication as "Barak." (*Id.*) Applicant refers to this publication as "Barack" herein.

above. Accordingly, claim 30 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 30.

The Office rejects claim 32 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and U.S. Publication No. 2012/0165729 to Cudworth. (*Id.*) Claim 32 depends from and adds features to independent claim 1. Cudworth does not overcome the deficiencies discussed above. Accordingly, claim 32 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 32.

The Office rejects claim 33 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and U.S. Patent No. 5,542,921 to Meyers *et al.* (*Id.*, 21.) Claim 33 depends from and adds features to independent claim 1. Meyers does not overcome the deficiencies discussed above. Accordingly, claim 33 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 33.

Double Patenting Rejection

The Office rejects claims 1, 3–22, 24–25, and 29–34 on the grounds of non-statutory obviousness type double patenting as allegedly obvious over claim 1 of U.S. Patent No. 10,881,766 in view of Myers, Cook, Philips, Chang, Khalil, Karsan, Blondheim, Barack, Guthrie, Mendoza, Baker, Cudworth, and Meyers. (*Id.*, 23–27.) The Office rejects claims 1, 3–22, 24–25, and 28–34 on the grounds of non-statutory obviousness type double patenting as allegedly obvious over claim 1 of U.S. Patent No. 10,926,011 in view of Khalil, Myers, Cook, Philips, Chang, Khalil, Karsan, Blondheim, Barack, Guthrie, Mendoza, Baker, Cudworth, and Meyers. (*Id.*, 27–31.) The Office rejects claims 1, 3–22, 24–25, and 29–34 on the grounds of non-statutory obviousness type double patenting as obvious over claim 1 of U.S. Patent Nos. 11,357,893, 11,376,352. 11,357,894, 11,324,866, and 11,413,380, in view of Khalil, Myers, Cook, Philips, Chang, Khalil, Karsan, Blondheim, Barack, Guthrie, Mendoza, Baker, Cudworth, and Meyers. (*Id.*, 31–35.) The Office rejects claims 1, 3–22, 24–25, and 28–34 on the grounds of non-statutory obviousness type double patenting as allegedly obvious over claim 1 of U.S. Patent Nos. 11,260,151 and 11,311,654 in view of Khalil, Myers, Cook, Philips, Chang, Khalil, Karsan, Blondheim, Barack, Guthrie, Mendoza, Baker, Cudworth, and Meyers. (*Id.*, 35–38.) The Office rejects claims 1, 3–22, 24–25, and 29–34 are rejected on the grounds of non-statutory obviousness type double patenting as obvious over claims of U.S. Application Nos. 17/203,150, 17/203,179, 17/203,292, 17/203,355, 17/203,384,

17/203,397, and 17/203,418 in view of Khalil, Myers, Cook, Philips, Chang, Khalil, Karsan, Blondheim, Barack, Guthrie, Mendoza, Baker, Cudworth, and Meyers. (*Id.*, 38–42.)

Applicant respectfully requests that the remaining currently asserted double patenting rejections be held in abeyance until the claimed subject matter is otherwise deemed allowable. After analyzing the final allowed claim scope, Applicant will consider filing a terminal disclaimer if necessary to overcome any obviousness-type double patenting rejections.

Conclusion

All grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Office reconsider and withdraw them. A complete reply has been made to the outstanding Office Action. As such, the present application is in condition for allowance. If the Office believes, for any reason, that personal communication will expedite prosecution of this application, the Office is invited to telephone the undersigned at the number provided. Applicant respectfully requests prompt and favorable consideration of this amendment and reply.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Richard D. Coller III
Attorney for Applicant
Registration No. 60,390

Date: January 26, 2023

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: Chiaro Technology Limited	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, Courtney B.
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Supplemental Information Disclosure Statement

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

Listed on accompanying IDS Forms PTO/SB/08a or its equivalent and PTO/SB/08b or its equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Applicant has listed dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) and is being filed within three months of the date of filing of a national application other than a continued prosecution application (CPA), OR within three months of the date of entry of the national stage as

set forth in 37 C.F.R. § 1.491 in an international application, OR before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

Copies of documents **FP1-FP13** and **NPL1-NPL3** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2)(ii), no copies of the U.S. patents and patent application publications cited on the attached IDS Forms are submitted.

It is expected that the examiner will review the prosecution and cited art in the parent Application No. 16/009,547, filed June 15, 2018 (now U.S. Patent No. 10,926,022), in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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Date: January 26, 2023

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/181,057	Filing Date 02/22/2021	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED		(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A		N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A		N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A		N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =		*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =		*		x $240 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).					
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))						
* If the difference in column 1 is less than zero, enter "0" in column 2.					TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	01/26/2023	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 30	Minus	** 30	= 0		x $40 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $192 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/NICOLE L NICHOLSON/
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

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WASHINGTON, DC 20005

EXAMINER
FREDRICKSON, COURTNEY B

ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
10/26/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

e-office@sternekessler.com

Office Action Summary	Application No. 17/181,057	Applicant(s) O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	Art Unit 3783	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 27July2022.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1,3-22,24-25 and 28-34 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1,3-22,24-25 and 28-34 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 22February2021 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☑ All b)☐ Some** c)☐ None of the:

1.☑ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

The information disclosure statement (IDS) submitted is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Amendment

This office action is responsive to the amendment filed on July 12, 2022. As directed by the amendment: claims 1, 3-22, 24, 25, and 28-33 have been amended, claim 2 has been cancelled, and claim 34 has been added. Thus, claims 1, 3-22, 24, 25, and 28-34 are presently pending in this application.

Response to Arguments

Applicant's arguments, see pg. 8, filed July 12, 2022, with respect to the rejection(s) of claim(s) 1 under 35 U.S.C 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Applicant's amendments.

Claim Objections

Claim 34 is objected to because of the following informalities: it is recommended to amend the claim in line 1 to recite "a length" to correct for grammar. Appropriate correction is required.

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

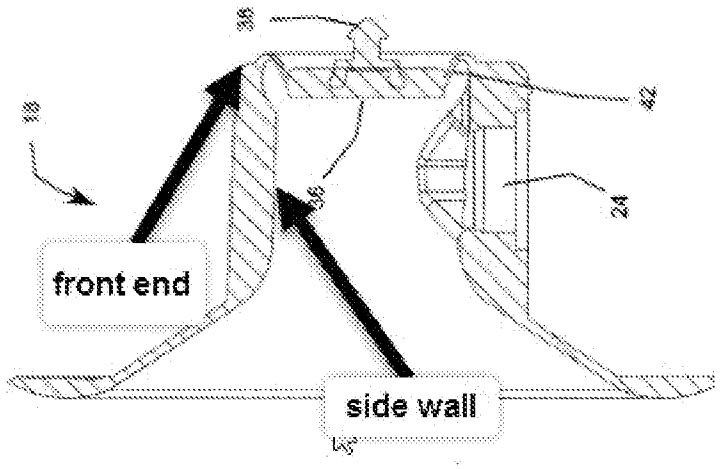
Claims 1, 3, 6-8, 10, 11, 14, 16-18, 22, 24, 31, and 34 is/are rejected under 35 U.S.C. 103 as being unpatentable over Myers (US 20080275386) and in further view of Cook (EP 2502640).

Regarding claim 1, Myers discloses a breast pump device comprising:

a self-contained, in-bra wearable device (breast pump 10 in fig. 1), comprising:

(i) a housing (outer housing 16 in fig. 1) comprising (a) a battery (AA battery 51 in fig. 10), and (b) a pump configured to generate negative air pressure (motor 54 in fig. 10);

(ii) a breast shield (breast cup 16 in fig. 1) being configured to slide in and out of the housing (paragraph 58 discloses that the cup "clicks" into place within the housing; paragraph 42 discloses the breast cup being removable), the breast shield comprising a breast flange (outer flange area 50 in fig. 5) and a nipple tunnel (nipple tunnel 46 in fig. 5) comprising a side wall and a front end (see below), in which the breast shield is transparent or optically clear (paragraph 65); and

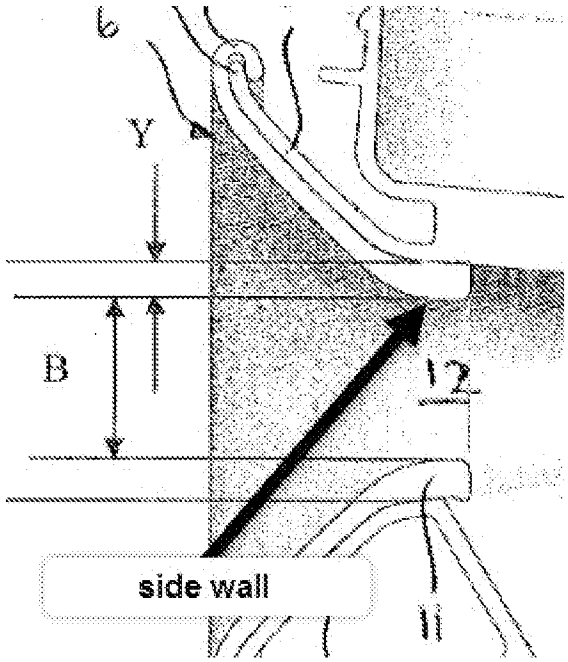


(iii) a milk container that is configured to be attached to and removed from the housing (collection bag 28 is shown to be operatively attached to the housing and is physically engaged to the bottom portion of the housing).

However, Myers does not teach or disclose the breast shield being of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a

nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see below) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple).



Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a

nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Regarding claim 3, in the modified device of Myers, Myers discloses the breast shield is rigid (paragraph 47 discloses the nipple tunnel, which is part of the breast shield, is rigid).

Regarding claim 6, in the modified device of Myers, Myers discloses the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast (the shield of Myers is functionally capable of being rotated smoothly around a nipple since the claim does not require that the shield be fully latched onto the nipple for this rotation to occur).

Regarding claim 7, in the modified device of Myers, Myers discloses the breast shield presents, in use, a single continuous surface to a nipple and a breast (fig. 9A/B shows a singular inner surface which would extend from the nipple to the breast).

Regarding claim 8, in the modified device of Myers, Myers discloses the breast shield integrates the breast flange and the nipple tunnel as a single item (fig. 5 shows a singular item).

Regarding claim 10, in the modified device of Myers, Myers discloses the breast shield is configured to slide into the housing with a single push action (paragraph 58 discloses the shield can click into place).

Regarding claim 11, in the modified device of Myers, Myers discloses the breast shield is configured to slide out from the housing, together with a membrane that prevents milk from flowing into the pump (flange top 36 in fig. 9A).

Regarding claim 14, in the modified device of Myers, Myers discloses milk container attaches to a lower part of the housing (fig. 1 shows a part of the collection bag attached to the bottom part of the housing 16) and forms a base of the breast pump device (fig. 1).

Regarding claim 16, in the modified device of Myers, Myers discloses the nipple tunnel includes guide lines running parallel along one or more sides of the nipple tunnel (detent tabs 52a/b in fig. 15 are shown to be extending in a parallel to the width direction of the nipple tunnel sides).

Regarding claim 17, in the modified device of Myers, Myers discloses the nipple tunnel includes an air hole or passage (24 in fig. 9A), and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage (paragraph 52).

Regarding claim 18, in the modified device of Myers, Myers discloses the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container (outlet 24 in fig. 9A).

Regarding claim 22, in the modified device of Myers, Myers discloses the housing is shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra (fig. 1; paragraph 40).

Regarding claim 24, in the modified device of Myers, Myers discloses the breast pump device is configured to deliver a maximum suction of approximately 240 mmHg (paragraph 72).

Regarding claim 31, modified Myers teaches a kit comprising the breast pump device of claim 1 (see discussion above); and the plurality of interchangeable breast shields (fig. 2a/b of Cook).

Regarding claim 34, in the modified device of Myers, Cook discloses length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same (paragraph 43).

Claim 4 is/are rejected under 35 U.S.C. 103 as being unpatentable over Myers in view of Cook, as applied to claim 1 above, and further in view of Phillips (US 20160296682), as evidenced by Yuen (US 20050228342).

Regarding claim 4, modified Myers teaches all of the claimed limitations set forth in claim 1, as discussed above. Myers further teaches the breast shield is made from plastic (paragraph 40 discloses the breast cup being made from silicone, which is a type of plastic, as evidenced by Yuen in paragraph 24). However, modified Myers does not teach or disclose breast shield is dishwasher safe.

Phillips teaches a breast pump device (fig. 1) comprising a breast shield (110 in fig. 1). Phillips further teaches that the shield can be washed in a dishwasher (paragraph 60). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield of modified Myers to be dishwasher safe for the purpose of enabling the shield to be cleaned in the dishwasher for reuse, as taught by Phillips (paragraph 60).

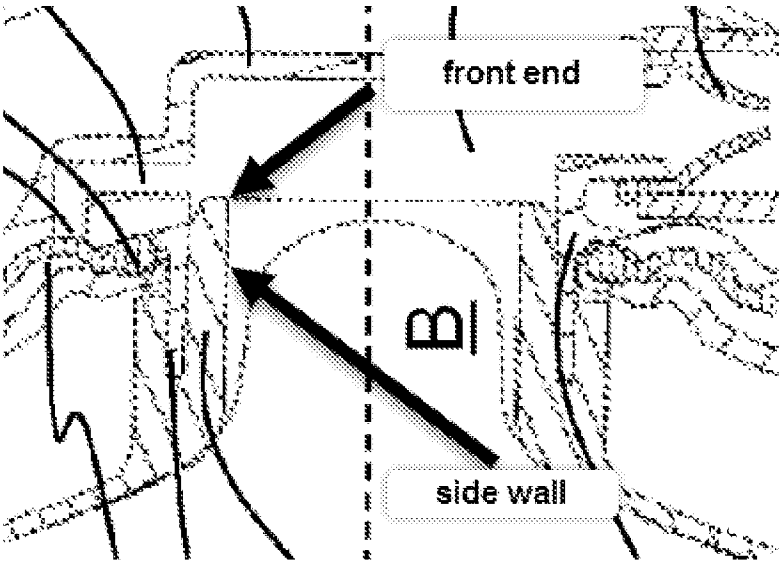
Claims 1, 6-10, 14, 17, 18, 20-22, 31, and 34 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil (US 20130023821) in view of Myers (US 20080275386) and in further view of Cook.

Regarding claim 1, Khalil discloses a breast pump device comprising:

a self-contained, in-bra wearable device (figs. 9-11), comprising:

(i) a housing (6' and 6" form a housing as shown in fig. 9) that includes (a) a power source (paragraph 32 discloses the power source integrated into the housing), and (b) a pump generating negative air pressure (vacuum pump 81 in fig. 10);

(ii) a breast shield (breast interface 1 in fig. 11) being configured to slide in and out of the housing (breast interface 1 is configured to slide in/out from the housing by attaching/detaching the lip 11 to the flange 62 of the housing as shown in fig. 4), the breast shield made up of a breast flange (base part 12 in fig. 4) and a nipple tunnel (stub 10 in fig. 4) comprising a side wall and a front end (see below); and



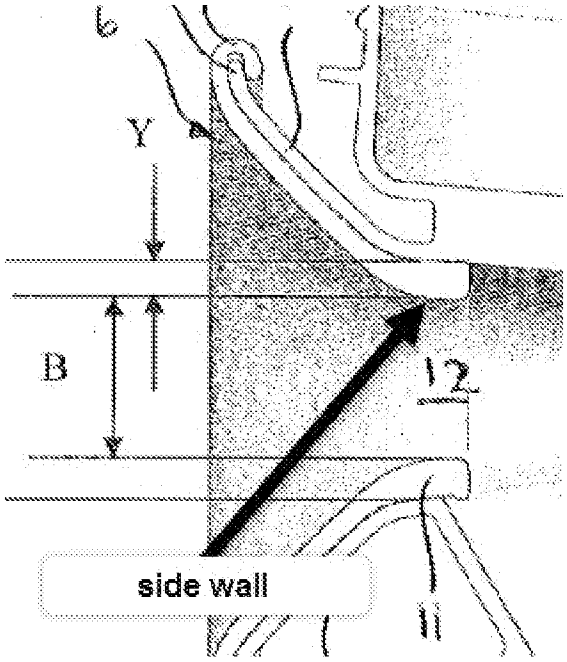
(iii) a milk container that is configured to be attached to and removed from the housing (milk collection container 7' in fig. 11; paragraph 69 discloses the container being releasably connected to the housing part 6').

However, Khalil does not teach or disclose the power source being a battery and the breast shield being transparent or optically clear and being of a plurality of

interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast.

Myers teaches a similar breast pump system (fig. 1) having a housing (outer housing 16 in fig. 1) which comprises a battery (battery 52 in fig. 10) and a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing to include a battery, as taught by Myers, for the purpose of providing power to the device and to have made the breast shield transparent to enable a user to view the condition of a nipple (paragraph 65).

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see below) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple).



Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Regarding claim 6, in the modified device of Khalil, Khalil discloses the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast (the shield of Khalil is functionally capable of being rotated smoothly around a nipple since the claim does not require that the shield be fully latched onto the nipple for this rotation to occur).

Regarding claim 7, in the modified device of Khalil, Khalil discloses the breast shield presents, in use, a single continuous surface to a nipple and a breast (fig. 11).

Regarding claim 8, in the modified device of Khalil, Khalil discloses the breast shield integrates the breast flange and the nipple tunnel as a single item (fig. 11).

Regarding claim 9, in the modified device of Khalil, Khalil discloses the breast shield is generally symmetrical about a centre-line running from a top to a bottom of the breast shield when positioned upright for normal use (fig. 11).

Regarding claim 10, in the modified device of Khalil, Khalil discloses the breast shield is configured to slide into the housing with a single push action (the shield of Khalil is functionally capable of being pushed into the housing so that the nipple tunnel is located in the housing).

Regarding claim 14, in the modified device of Khalil, Khalil discloses milk container attaches to a lower part of the housing and forms a base of the breast pump device (fig. 9).

Regarding claim 17, in the modified device of Khalil, Khalil discloses the nipple tunnel includes an air hole or passage (opening 13 in fig. 3), and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage (figs. 4 and 5).

Regarding claim 18, in the modified device of Khalil, Khalil discloses the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container (opening 13 in fig. 3 is considered to be on a “lower” surface of the nipple tunnel since “lower” is not further defined; see fig. 5).

Regarding claim 22, in the modified device of Khalil, Khalil discloses the housing is shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra (fig. 9).

Regarding claim 31, modified Khalil teaches a kit comprising the breast pump device of claim 1 (see discussion above); and the plurality of interchangeable breast shields (fig. 2a/b of Cook).

Regarding claim 34, in the modified device of Khalil, Cook discloses length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same (paragraph 43).

Claim 5 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 1 above, and further in view of Chang (US 20180333523).

Regarding claim 5, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast shield is configured to attach using magnets to the housing.

Chang teaches a substantially similar self-contained breast pump system (breast pump system 10 in fig. 1A) having a breast shield (flange 14 in fig. 1A) attached to a housing (housing 12 in fig. 1A) and configured to attach to the housing using one or more magnets (paragraph 108 discloses the shield uses magnets 118 attached to the shield to determine if the shield is properly attached to the housing). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield of modified Khalil to be configured to attach using magnets to the housing since Chang teaches this configuration provides a safeguard

such that the system will not operate unless all components are fully connected (paragraph 108).

Claims 12 and 13 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 1 above, and further in view of Phillips (US 20160296682).

Regarding claim 12, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Although it appears based on fig. 11 of Khalil that the container would be rigid, modified Khalil does not explicitly teach or disclose this limitation.

Phillips teaches a breast pump system (fig. 1) comprising a milk collection container ("collection container" 120 in fig. 1) which is substantially rigid (paragraph 57 discloses the container being made from Tritan; pg. 21 of Applicant's specification discloses that Tritan is a polycarbonate material, which is a known rigid material). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the container of modified Khalil to be made of Tritan for the purpose of enabling the container to maintain its strength when a vacuum is applied, as taught by Phillips (paragraph 57).

Regarding claim 13, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses the milk container is an optically clear, plastic container (paragraph 69 discloses the container is made of plastic like cover 6" and is transparent in its entirety). However, Khalil does not explicitly teach or disclose the milk container is dishwasher safe.

Phillips teaches a breast pump system (fig. 1) comprising a milk collection container ("collection container" 120 in fig. 1) which is dishwasher safe (paragraph 57 discloses the container being made from Tritan; pg. 21, lines 13-18 of Applicant's specification discloses that Tritan a dishwasher safe material). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the container of modified Khalil to be made of Tritan for the purpose of enabling the container to maintain its strength when a vacuum is applied, as taught by Phillips (paragraph 57).

Claim 15 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 1 above, and further in view of Karsan (US 20070228059).

Regarding claim 15, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the milk container is configured to magnetically attach to the housing.

Khalil teaches that the milk container latches to the housing by a locking lug (paragraph 69 discloses a locking lug formed on the container latches engages into a corresponding recess). Karsan teaches a container (1 in fig. 1) having a case (2 in fig. 3) and a base (fig. 3) which are releasably held together (paragraph 51 discloses the connection being releasable) via a latch mechanism (5 and 6 in fig. 3). Karsan further teaches that the latching mechanism is embodied as a lug and recess (5 and 6, respectively in fig. 3; paragraph 65) but may alternatively be embodied as a magnetic means so that the two components may be magnetically latched (paragraph 65).

In Applicant's invention, Applicant uses the magnets to removably secure the milk container to the housing. Thus, Karsan is reasonably pertinent to the problem faced by the inventor since Karsan teaches using magnets as a removable latching connection between two components. As Karsan teaches that the magnetic means (paragraph 65) are functional equivalents to a locking lug and recess (paragraph 65), it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have substituted the locking lug/recess configuration of Khalil with the magnetic means, as taught by Karsan. The substitution would have resulted in providing an equivalent secure attachment of the milk container to the housing.

Claim 19 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 1 above, and further in view of Blondheim (US 20120277636).

Regarding claim 19, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the pump comprises one or more piezo air pumps.

Blondheim is directed towards a breast pump device (fig. 1) which comprises an air pump (66 in fig. 6). Blondheim further teaches that the air pump can be a piezoelectric pump (paragraph 36). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the pump of modified Khalil to be a piezoelectric pump, as taught by Blondheim for the purpose of rendering the pump small in size (paragraph 36).

Claims 20 and 21 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 1 above, and further in view of Barak (US 20140378895).

Regarding claim 20, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the housing further includes a Universal Serial Bus (USB) charging socket.

Barack is directed towards a breast pump device (fig. 1) which comprises a housing which houses a pump (fig. 1 shows a pump 20 which would necessarily have some sort of housing since it is disclosed to have a USB port and a user interface). Barack further teaches a USB charging socket (USB port 34 in fig. 1; paragraph 45). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing of modified Khalil to include the USB charging socket, as taught by Khalil, for the purpose of enabling the device to interface with an external memory (paragraph 45).

Regarding claim 21, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the housing includes a left or right breast selector or toggle switch, that, when selected for a particular pumping session, sends data to a connected application configured to track pumping sessions, to indicate whether that particular session is associated with a left or a right breast.

Barack teaches a breast pump device (fig. 1) which has a control electronics (controller 22 in fig. 1) and a control interface (user interface 30 in fig. 1) that is user selectable to indicate or record if milk is being expressed from the left or right breast

(paragraph 43) and that, when selected for a particular pumping session, sends data to a connected application, running on a device, such as a smartphone, that tracks pumping sessions, to indicate whether that session is associated with the left or the right breast (paragraph 46 discloses transmitting via transceiver the parameters that have been entered at the user interface 30 to a remove device; paragraph 43 discloses that one parameter entered at the user interface is which breast is selected).

Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing of modified Khalil to include a left or right breast selector or toggle switch, that, when selected for a particular pumping session, sends data to a connected application configured to track pumping sessions, to indicate whether that particular session is associated with a left or a right breast, as taught by Barack. This modification would enable a user to track which parameters are best suited for each breast to optimize pumping, as taught by Barack (paragraphs 8 and 43).

Claim 25 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 1 above, and further in view of Guthrie (US 20160220743).

Regarding claim 25, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast pump device includes a sensor that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container.

Guthrie is directed towards a breast pump device comprising a sensor (detector 607 in fig. 6B) that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container (paragraph 63 discloses that the emitter 606 and the detector 607 operate to detect light reflecting off the opaque surface of the milk). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the device to include a sensor that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container, as taught by Guthrie, for the purpose of measuring volume of milk pumped (paragraph 54).

Claim 29 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 1 above, and further in view of Mendoza (US 6227936).

Regarding claim 29, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the pump is a lightweight air pump that enables the total mass of the breast pump system, unfilled with milk, to be less than 250gm.

Mendoza teaches a bra which is designed to support a breast pump to allow the mother's hands to remain free (1:8-12). Mendoza further discloses that the bra must be able to support up to 8 ounces when the pump is full (1:58-62). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed

invention to have modified the system of modified Khalil to be a lightweight air pump that enables the total weight of the system, unfilled with milk, to be less than 250gm, as taught by Mendoza since Mendoza teaches that a lightweight system is crucial for enabling the system to be supported by a bra.

Claim 30 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 1 above, in further view of Baker (US 20090281485).

Regarding claim 30, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast pump device makes less than 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

Baker is directed towards a device for removing fluid from a body (fig. 6) using a vacuum pump embodied as a motor (motor 9 in fig. 6; paragraph 243). Baker further teaches that the device makes less than 20 decibel of noise at full power (paragraph 121) by sound proofing the walls of the housing and by adding a counter balance to the motor (paragraph 144). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the device of modified Khalil to have the device make less than 20 dB of noise during maximum power for the purpose of making the device for discrete and comfortable for the user and others around the user.

Claim 32 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 31 above, in further view of Cudworth (US 20120165729).

Regarding claim 32, modified Khalil teaches all of the claimed limitations set forth in claim 31, as discussed above, but does not teach or disclose each of the plurality of interchangeable breast shields includes fit lines in a nipple tunnel of that breast shield that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel.

Cudworth teaches a breast pump system (fig. 1) having a shield (attachment 1) having a flange (cup 2 in fig. 2) and a nipple tunnel (cylindrical portion 3 in fig. 1). Cudworth further teaches the nipple tunnel includes fit lines in a nipple tunnel of that breast shield that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel (grooves 12 in fig. 1 are functionally capable of serving as "fit lines" to assist a user in determining if the breast shield is correctly sized and since the claimed fit lines are not further structurally defined). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of Khalil to include the claimed fit lines, as taught by Cudworth, for the purpose of providing a massaging pressure on the breast to help stimulate milk production (paragraph 30).

Claim 33 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 1 above, in further view of Meyers (US 5542921).

Regarding claim 33, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further teaches control electronics ("control

elements and a display" in paragraph 51) which would be powered by the battery (the power source of Khalil is understood to power the device).

However, Khalil does not teach or disclose the battery to be rechargeable and the housing further including a power charging circuit for controlling the charging of the rechargeable battery.

Meyers is directed to a breast pump device (fig. 1) comprising a battery configured to be recharged (9:50-52 discloses recharging the batteries) and a power charging circuit for controlling the charging of the rechargeable battery ("circuit" in 9:50-52). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the battery of modified Khalil to be rechargeable and to have incorporated a power charging circuit for controlling the charging of the rechargeable battery, as taught by Meyers to enable the batteries to be reused.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1, 3-22, 24, 25, 29-34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10881766 in view of Myers, Cook, and the teachings below (see table).

Regarding claim 1, claim 1 of the issued patent claims all of the limitations in instant claim 1 except claim 1 does not claim a self-contained device, the housing having a battery, the breast shield having a breast flange and nipple tunnel and being optically clear or transparent and being a part of a plurality of breast shields, wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast.

Khalil teaches a breast pump device (fig. 10) configured as a self-contained, in-bra wearable device (fig. 10; paragraph 70) having a breast shield (1 in fig. 11) having a flange (12in fig. 6) and a nipple tunnel (13 in fig. 6) and a milk container (7' in fig. 11)configured to be attached and removed from the housing (paragraph 69). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the reference claim to be a self-contained, in-bra wearable device having a breast shield with a flange and nipple tunnel and a milk container configured to be attached and removed from the housing, as taught by Khalil, for the purpose of enabling the device to be a small and hands-free (paragraph 70). The modification of the breast shield would enable the shield to interface with the breast and receive the nipple and the modification of the milk container would enable the milk to be collected after expression.

Myers teaches a self-contained, in bra breast pump (fig. 1) which comprises a breast shield (18 in fig. 2) having a flange (48 in fig. 5) and nipple tunnel (46 in fig. 5) and a housing (16 in fig. 2) for housing a pump (56 in fig. 10) and a battery for powering the pump (52 in fig. 10). Myers further teaches that the breast shield is optically clear

(paragraph 65). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield to be optically clear for the purpose of allowing a user to visualize the placement of the breast and nipple and to have modified the housing to include a battery, as taught by Myers, for the purpose of providing power to the device.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

App Claim	Ref Claim	Teaching
1	1	see discussion above

3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.

19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Cudworth teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Claims 1, 3-22, 24, 25, and 28-34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10926011 in view of Khalil, Myers, and Cook, and the teachings below (see table).

Regarding claim 1, claim 1 of the issued patent claims all of the limitations in instant claim 1 except claim 1 does not claim a self-contained device, the housing

having a battery, the breast shield having a breast flange and nipple tunnel and being optically clear or transparent and being a part of a plurality of breast shields, wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast.

Khalil teaches a breast pump device (fig. 10) configured as a self-contained, in-bra wearable device (fig. 10; paragraph 70) having a breast shield (1 in fig. 11) having a flange (12in fig. 6) and a nipple tunnel (13 in fig. 6) and a milk container (7' in fig. 11)configured to be attached and removed from the housing (paragraph 69). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the reference claim to be a self-contained, in-bra wearable device having a breast shield with a flange and nipple tunnel and a milk container configured to be attached and removed from the housing, as taught by Khalil, for the purpose of enabling the device to be a small and hands-free (paragraph 70). The modification of the breast shield would enable the shield to interface with the breast and receive the nipple and the modification of the milk container would enable the milk to be collected after expression.

Myers teaches a self-contained, in bra breast pump (fig. 1) which comprises a breast shield (18 in fig. 2) having a flange (48 in fig. 5) and nipple tunnel (46 in fig. 5) and a housing (16 in fig. 2) for housing a pump (56 in fig. 10) and a battery for powering the pump (52 in fig. 10). Myers further teaches that the breast shield is optically clear (paragraph 65). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield to be

optically clear for the purpose of allowing a user to visualize the placement of the breast and nipple and to have modified the housing to include a battery, as taught by Myers, for the purpose of providing power to the device.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.

4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.

20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
28	9	
29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Cudworth teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Claims 1, 3-22, 24, 25, 29-34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of the issued patents below in view of Myers, Cook and the teachings below (see table).

- **17203050 (US Patent 11357893)**

- **17203079 (US Patent 11376352)**
- **17203216 (US Patent 11357894)**
- **17203259 (US Patent 11324866)**
- **17203327 (US Patent 11413380)**

Claim 1 of the issued patent claims all of the features claimed in reference claim 1 except in that claim 1 of the patent does not claim a breast shield of a plurality of interchangeable breast shields each being transparent or optically clear and having a different size and being configured to slide in and out of the housing, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple

tunnel (see above with respect to rejection of claim 1) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.

10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Cudworth teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.

33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Claims 1, 3-22, 24, 25, 28-34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of the following US Patents in view of Myers, Cook and the teachings below (see table).

- **17203109 (US Patent 11260151)**
- **17203313 (US Patent 11311654)**

Claim 1 of the issued patent claims all of the features claimed in reference claim 1 except in that claim 1 of the patent does not claim a breast shield of a plurality of interchangeable breast shields each being transparent or optically clear and having a different size and being configured to slide in and out of the housing, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.

6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.

22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
28	18 ('151 patent), 13 ('654 patent)	
29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Cudworth teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Claims 1, 3-22, 24, 25, 29-34 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of the following copending applications in view Myers, Cook and the teachings below.

- **17203150**
- **17203179**
- **17203292**
- **17203355**

- **17203384**
- **17203397**
- **17203418**

Claim 1 of the reference claim claims all of the features claimed in reference claim 1 except in that claim 1 of the reference claim does not claim a breast shield of a plurality of interchangeable breast shields each being transparent or optically clear and having a different size and being configured to slide in and out of the housing, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of

interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.

11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Cudworth teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.

34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Allowable Subject Matter

Except for the double patenting rejections above, **claim 28** would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not teach or suggest the pump delivers the claimed stall pressure and free air flow.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COURTNEY FREDRICKSON whose telephone number is (571)270-7481. The examiner can normally be reached Monday-Friday (9 AM - 5 PM EST).

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NATHAN PRICE can be reached on 571-270-5421. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COURTNEY B FREDRICKSON/
Examiner, Art Unit 3783

/NATHAN R PRICE/
Supervisory Patent Examiner, Art Unit 3783

Notice of References Cited	Application/Control No. 17/181,057	Applicant(s)/Patent Under Reexamination O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	Art Unit 3783	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
	A					
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N	EP-2502640-A1	09-2012	EP	COOK G	A61M1/06
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/12/2022	10/17/2022							
	1	✓	✓							
	2	✓	-							
	3	✓	✓							
	4	✓	✓							
	5	✓	✓							
	6	✓	✓							
	7	✓	✓							
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	30	✓	✓							
	31	✓	✓							
	32	✓	✓							
	33	✓	✓							
	34		✓							

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

CPC - Searched*		
Symbol	Date	Examiner
a61m1/06-069	01/12/2022	cbf

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
see SEARCH history	01/12/2022	cbf
searched inventors in PALM and SEARCH	01/12/2022	cbf
consulted child search history	01/12/2022	cbf
Updated search history	10/17/2022	cbf

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/COURTNEY B FREDRICKSON/ Examiner, Art Unit 3783	

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(54) Breast pump

(57) A breast pump comprising a funnel (2) and at least two cone-shaped breast pump inserts (1) interchangeably mountable in said funnel (2) is disclosed. The breast pump inserts (1) each have a central aperture (10,12) therein through which a nipple protrudes when a breast is received in the funnel (2). The diameter of the aperture (10,12) in each breast pump insert (1) is different. A breast pump funnel (2) or insert (1) having a textured finish on a breast interface surface is also disclosed.

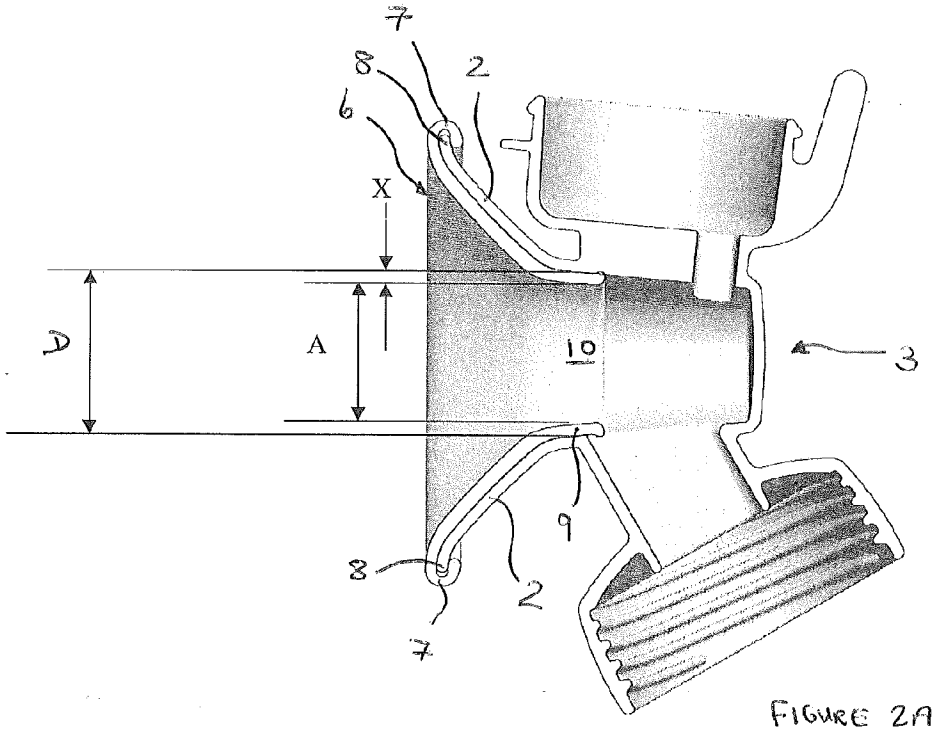

FIGURE 2A

EP 2 502 640 A1

(Cont. next page)

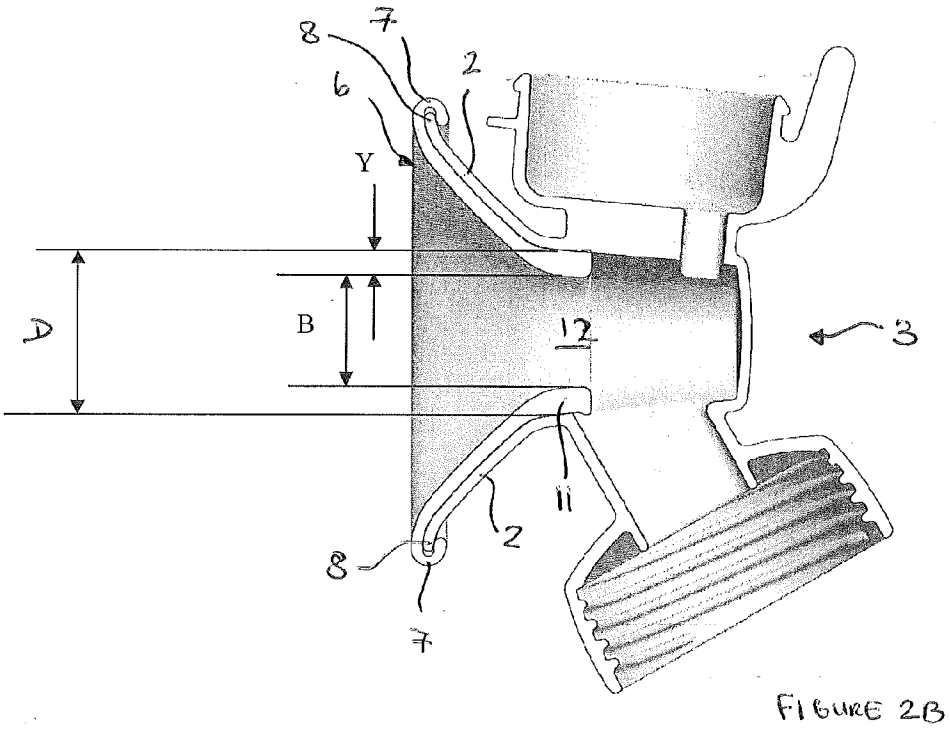

FIGURE 2B

Description

FIELD OF THE INVENTION

[0001] The present invention relates to a breast pump. It also relates to a modified breast pump insert to replace a standard breast pump insert supplied with a breast pump such that the breast pump can be used interchangeably with the standard or modified breast pump insert and, to a breast pump insert kit.

[0002] The invention also relates to a breast pump or breast pump insert that provides an enhanced level of comfort for a user.

BACKGROUND OF THE INVENTION

[0003] Breast pumps are well known devices for extracting milk from a breast of a user. A breast pump may be used if the baby or infant is not itself able to extract milk from the breast, or if the mother is separated from the baby or infant and is to be fed with breast milk by someone else. Breast pumps typically comprise a rigid funnel connected to a vacuum pump having a container for collecting the milk.

[0004] The funnel of a breast pump is the interface between the user's breast and nipple with the pump and so the sizing of the funnel is critical to maintaining the user's comfort whilst using the device. It is also important to ensure that the vacuum seal between the breast and the insert is maintained for optimal pumping. A problem with a conventional breast pump is that it has a funnel of fixed size, so it can only cater for a limited range of breast and nipple sizes. However, if the funnel is too small relative to the nipple, the nipple tends to fill the available space inside the funnel and is likely to touch on the sides of the funnel, resulting in chafing, friction and discomfort as negative pressure generated during use of the pump draws the nipple into the funnel. On the contrary, if the funnel is too large relative to the nipple, then there will be more dead space inside the funnel which will reduce the efficiency of the pump system and limit the negative pressure achievable. It also introduces the possibility that the nipple will be pulled deeper into the pump and that the skin on areola or breast area surrounding the nipple will be subjected to chafing.

[0005] Research has shown that nipple diameter and length varies throughout the population and across different geographic regions and also that the sizing of the nipple can be different before, during and after expressing. Therefore, as fit is an important consideration when attempting to achieve maximum comfort for a user, a breast pump that is capable of accommodating a wide range of breast and nipple sizes is desirable.

[0006] It is known to provide a breast pump body with a removable funnel that may be replaced with another funnel of a different size. However, removable funnels are generally made from a hard plastic material and do not generally offer the user with an enhanced level of comfort whilst using such a device.

[0007] It is also known to provide a soft elastomer insert that may be disposed within a rigid funnel of a breast pump and which is designed to adapt to the contour of the breast so as to provide comfort and a vacuum seal necessary for operating the pump. The resilience and compliance of such an insert helps to provide a vacuum and milk seal around the user's breast and also reduces friction on the breast and/or nipple when the negative pressure draws the breast and nipple in a direction into the pump. A separate cushion or insert also allows for the inclusion of a pressure ducting system on the cushion's rear surface which faces the funnel. A pressure ducting system may include a system of 'petals' that can move in and out to palpate the breast. These petals can be formed from a plurality of regions spaced around the circumference of the insert to define a void or reservoir. The wall thickness in the region of the petals may be less than the remainder of the insert so that they deform more easily in response to the generation of a negative pressure when the pump is in use.

[0008] A cushion or insert may be formed from silicon or thermoplastic elastomer (TPE) which, in addition to providing an enhanced level of comfort, can also provide a warmer feeling to the breast.

[0009] Although an insert may improve the comfort for a user, breast pumps equipped with an insert still suffer from the problem that the insert will only accommodate a relatively small range of breast and/or nipple sizes resulting in a poor fit between the breast and/or the nipple with the insert for a relatively large number of breastfeeding women, causing discomfort and poor vacuum pressure generation.

SUMMARY OF THE INVENTION

[0010] The present invention seeks to overcome or substantially alleviate the aforementioned problems.

[0011] Accordingly, the present invention provides a breast pump comprising a funnel and at least two funnel-shaped breast pump inserts interchangeably mountable in said funnel, each of said breast pump inserts having a central aperture therein through which a nipple extends when a breast is received therein, wherein the diameter of the aperture in each breast pump insert is different.

[0012] Preferably, each breast pump insert comprises a wall having a thickness. The thickness of said wall in a region of the aperture is different for each insert.

[0013] Each breast pump insert may have an outer diameter in the region of the aperture that is defined by the sum of twice the wall thickness and the diameter of the aperture.

[0014] Preferably, the outer diameter in the region of the aperture is substantially constant for all breast pump inserts.

[0015] In a preferred embodiment, each breast pump insert comprises a frustoconical section that tapers to a substantially cylindrical section. In this embodiment, the

aperture is formed at an end of the substantially cylindrical section.

[0016] Preferably, said region of the aperture is defined by the substantially cylindrical section such that the thickness of said wall forming said substantially cylindrical section is different for each insert.

[0017] According to the invention, there is also provided a modified breast pump insert to replace a standard breast pump insert supplied with a breast pump such that said breast pump can be used interchangeably with the standard or modified breast pump insert, each of said breast pump inserts having a central aperture therein through which a nipple extends when a breast is received therein and an overall outer diameter in a region of the aperture, wherein the diameter of the aperture in the modified breast pump insert is different to the diameter of the aperture in the standard breast pump insert, said overall outer diameter of the breast pump insert in the region of said aperture remaining the same in both the modified and standard breast pump inserts irrespective of the difference in the diameter of the aperture between said inserts.

[0018] According to the invention, there is also provided a breast pump insert kit comprising at least two funnel-shaped breast pump inserts interchangeably mountable in a funnel of a breast pump, each breast pump insert having a central aperture therein through which a nipple extends when a breast is received therein, wherein the diameter of the aperture in each breast pump insert is different.

[0019] Preferably, each breast pump insert comprises a wall having a thickness, and wherein the thickness of said wall in a region of the aperture is different for each insert.

[0020] Each breast pump insert may have an outer diameter in the region of the aperture defined by the sum of twice the wall thickness and the diameter of the aperture. Preferably, the outer diameter of all the breast pump inserts is the same.

[0021] In one embodiment, each breast pump insert comprises a frustoconical section that tapers to a substantially cylindrical section. The aperture is then formed at an end of the substantially cylindrical section. Preferably, the length of the cylindrical section remains constant across all the breast pump inserts, despite the change in diameter of the aperture.

[0022] The region of the aperture may be defined by the substantially cylindrical section such that the thickness of said wall forming said substantially cylindrical section is different for each insert.

[0023] According to the invention, the breast pump insert kit may also include a breast pump according to the invention.

[0024] It has been determined that a preferred setting for the let-down of breast milk is one where the woman's breast is warm and she feels relaxed. Many women hold a warm flannel to the breast before expressing and also create a comfortable environment in order to relax and to aid the process of milk let-down.

[0025] Using a breast pump requires the funnel, or a breast pump insert, to make contact with the breast. However, the plain engineering materials and finishes for the surface of the funnel or insert that touches the breast have been perceived as being cold and hard by the user which can potentially inhibit the ease of milk let-down or initially just feel cold and uncomfortable as the user starts their pumping session.

[0026] Furthermore, it has been found that silicon parts with polished surfaces can feel sticky to the touch, feely clammy, and pick up dirt and lint, giving the perception of being dirty or unhygienic.

[0027] The present invention also seeks to overcome or alleviate the aforementioned problems. This aspect of the invention may be independent to the previous aspect of the invention referred to above or, both aspects may be combined.

[0028] According to the present aspect of the invention, there is provided a breast pump having a funnel to receive a breast of a user, wherein a surface of said funnel that comes into contact with a breast received in said funnel has a textured surface finish.

[0029] According to the invention, there is also provided a breast pump insert positionable within the funnel of a breast pump to receive a breast of a user, wherein a surface finish of said breast pump insert that comes into contact with a breast received in said insert has a textured surface finish.

[0030] The surface finish may be created on the funnel or on a breast pump insert during the manufacturing process through virtue of the mould-tool surface. This creates an irregular non-smooth surface that may have an arithmetical mean roughness (Ra) in the order of single digits to tens of digits that reduces the overall surface contact between the user's skin and the breast pump. The arithmetical mean roughness can be between 1 and 50Ra or even 1 to 3 Ra.

[0031] The surface texture reduces the overall surface contact between the user's skin and the breast pump. This results in reduced energy transfer between the skin and insert or funnel, making it seem less cold than it is. Furthermore, the small air pockets trapped in the undulations create a heat isolation layer that results in a warmer and more pleasant overall sensation compared to the colder sensation when using a pump with a smooth surface at the breast interface.

[0032] A textured surface also makes it less sticky, which improves the user's perception of the feel, reducing the tendency for it to feel clammy. It also picks up much less dirt and lint compared to a smooth silicon surface.

[0033] It will be appreciated that a textured surface finish can be applied to the whole or only part of the surface of a funnel or a breast pump insert that may come into contact with a user's breast. Preferably, the textured surface finish is applied to the entire inner surface of a breast pump insert or, if no insert is to be used, the entire conical shaped portion of a breast pump funnel may have a tex-

tured surface. However, it will be appreciated that the textured surface may be applied in a series of repeated patterns or to sections of the surface of the insert or to the funnel.

[0034] In one embodiment, the insert or funnel may have a smooth annular region at its mouth or periphery so that the textured surface covers an inner portion of the funnel or insert. This improves the seal between the funnel or insert and the user's breast whilst still maintaining the benefits of a textured surface.

BRIEF DESCRIPTION OF THE DRAWINGS

[0035] Preferred embodiments will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figures 1A and 1B show perspective views of a two inserts according to one embodiment of the present invention;

Figure 2A shows a cross-sectional side elevation of a breast pump body fitted with the breast pump insert of Figure 1A; and

Figure 2B shows a cross-sectional side elevation of a breast pump body fitted with the breast pump insert of Figure 1B.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0036] Referring now to the drawings, Figures 1A shows a first breast pump insert 1. The insert 1 may be disposed in a funnel 2 of a breast pump body 3 for extracting milk, as shown in Figure 2A.

[0037] Figure 1B shows a second breast pump insert 4. The insert 4 may also be disposed in a funnel 2 of a breast pump body 3 for extracting milk, as shown in Figure 2B, in place of the insert 1 shown in Figure 1A.

[0038] The breast pump body 3, or at least the funnel 2 of the breast pump body 3, shown in Figures 2A and 2B may have identical dimensions.

[0039] Each of the breast pump inserts 1,4 have a generally frustoconical shaped wall 5 having a mouth area 6 through which a breast is inserted into the insert 1,4 when the insert 1,4 is located within a funnel 2 of the breast pump body 3. The wall 5 has a peripheral lip 7 around the mouth 6 that locates around the outer extremity 8 of the funnel 2 to releasably attach the insert 1,4 to the funnel 2.

[0040] The wall 5 of breast pump insert 1 tapers to a short cylindrical section 9 that terminates in an aperture 10. Similarly, the wall 5 of breast pump insert 4 tapers to a short cylindrical section 11 that terminates in an aperture 12. The user's nipple protrudes through the aperture 10,12 of the breast pump insert 1,4 when one of said inserts 1,4 is received within the funnel 2 of the breast pump body 3 and a breast is placed within the insert 1,4 through the mouth 6.

[0041] The short cylindrical section 9, 11 of each breast pump insert 1,4 has an outer, overall diameter (as indicated by dimension "D" in Figures 2A and 2B), that is substantially identical. However, the wall thickness (indicated by dimension "X" in Figure 2A and dimension "Y" in Figure 2B) is different. More specifically, the wall thickness "X" is smaller than the wall thickness "Y". Preferably, the overall outer geometry of the breast pump inserts 1,4 are identical, in addition to the outer diameter of the short cylindrical section 9,11.

[0042] As a result of the difference in wall thickness and as there is no alteration in the overall diameter of the short cylindrical section 9,11 between inserts 1,4, the diameter of the apertures 10,12 are different to each other. In particular, the diameter of the aperture 10 in Figure 2A (indicated by dimension A) is greater than the diameter of the aperture 12 in Figure 2B (indicated by dimension B).

[0043] In a preferred embodiment, the length of the cylindrical sections 9,11 of the inserts remains the same despite the change in diameter of the aperture 10,12. Most preferably, the overall length of the breast pump inserts is the same.

[0044] As at least the outer diameter of the short cylindrical section 9,11 of each breast pump insert 1,4 is the same, either breast pump insert 1,4 may be used interchangeably with the same breast pump 3 or funnel 2 and no modification to the pump body 3 or funnel 2 is required when the breast pump insert 1 is changed for the breast pump insert 4, and vice-versa. A user may select a preferred insert 1,4 depending on their breast and/or nipple size and/or depending on which insert provides them with the most comfort during pumping, and fit that insert 1,4 to the funnel 2 of their pump body 3, without any replacement of, or modification to, their pump body or funnel 2.

[0045] Each of the breast pump inserts 1,4 are formed from a compressible and resilient material such that they easily deform and adapt to the contour of the breast. Preferably, each breast pump insert 1,4 is formed from a silicone gel, silicone rubber material or thermoplastic elastomer (TPE), although it will be appreciated that any material having resilient, deformable properties, that will provide comfort to the user and achieve a vacuum by adapting to the shape of the breast can be used.

[0046] The invention caters for different nipple sizes by providing a number or range of breast pump inserts, each of which have a different diameter aperture in the breast pump insert through which the nipple protrudes or extends.

[0047] Despite the change in aperture diameter across the range of inserts, the outer dimension of the insert, at least in the region of the aperture, remains constant, thereby enabling any of the inserts to be fitted to the same breast pump body or funnel, without modification.

[0048] It will be appreciated that each insert may be provided with integral petals or other features to massage the breast during pumping.

[0049] Although the invention has been described with

reference to two breast pump inserts 1,4, it will be appreciated that any number or range of inserts may be provided, each of which have different aperture diameters, but the same overall or outer diameter, so that they will all fit the same pump body 3 or funnel 2.

[0050] It is envisaged that a breast pump may be provided with two or more inserts each having a different aperture diameter so that a user may select the most appropriate insert for maximum comfort. However, it is also envisaged that one or more modified breast pump inserts(s) may be made available to replace a standard breast pump insert that has previously been supplied with a breast pump. The same breast pump can then be used interchangeably with the standard or modified breast pump insert as the overall outer diameter of the breast pump insert in the region of said aperture remains the same in both the modified and standard breast pump inserts irrespective of the difference in the diameter of the aperture between said inserts. It is also envisaged that a breast pump insert kit may be provided, i.e. a set of two or more breast pump inserts, each of which have a different aperture diameter but the same overall outer diameter, at least in the region of the aperture. Each of the inserts of the kit may then be used interchangeably with the same breast pump.

[0051] In connection with the second aspect of the invention referred to above, it will be appreciated that one or both of the inserts of the first aspect of the invention may be provided with a textured surface. The present invention also includes within its scope a single breast pump insert having a textured breast interface contact surface, as well as a funnel for a breast pump having such a surface.

[0052] The textured surface may cover all or part of the funnel or insert. For example, there can be a series of repeated patterns extending around the circumference of the insert or cushion each of which have a surface texture. In one preferred embodiment, there is a ring of smooth or untextured surface extending around the circumference of the insert or funnel to ensure that a proper seal is formed with a breast inserted therein. The smooth region can be at the mouth of the insert or funnel, i.e. at the end or outer border where the breast is inserted or, it can be spaced inwardly so as to divide the textured surface into two regions separated by said ring.

[0053] If an insert is provided with a series of petals, as previously mentioned above, the surface texture could be associated with those petals, i.e. the surface texture may only be on the surface of the insert forming the petals. Alternatively, it could surround the petals.

[0054] The textured surface may be formed from a surface having an arithmetical mean roughness (Ra) in the order of single digits to tens of digits that reduces the overall surface contact between the user's skin and the breast pump. However, more preferably the arithmetical mean roughness is between 1 and 50Ra or even 1 to 3 Ra.

[0055] The invention has been described with reference to preferred embodiments only. Modifications and alterations to the embodiments falling within the scope of the appended claims are included within the scope of protection.

Claims

1. A breast pump comprising a funnel and at least two funnel-shaped breast pump inserts interchangeably mountable in said funnel, each of said breast pump inserts having a central aperture therein through which a nipple extends when a breast is received therein, wherein the diameter of the aperture in each breast pump insert is different.

2. A breast pump according to claim 1, wherein each breast pump insert has an outer diameter in a region of the aperture and comprises a wall having a thickness, and wherein the thickness of said wall in a region of the aperture is different for each insert.

3. A breast pump according to claim 2, wherein the outer diameter in the region of the aperture is defined by the sum of twice the wall thickness and the diameter of the aperture.

4. A breast pump according to claim 2 or claim 3, wherein the outer diameter of the breast pump inserts is substantially the same.

5. A breast pump according to any of claims 2 to 4, wherein each breast pump insert comprises a frustoconical section that tapers to a substantially cylindrical section, said aperture being formed at an end of the substantially cylindrical section.

6. A breast pump according to claim 5, wherein said region of the aperture is defined by the substantially cylindrical section such that the thickness of said wall forming said substantially cylindrical section is different for each insert.

7. A modified breast pump insert to replace a standard breast pump insert supplied with a breast pump such that said breast pump can be used interchangeably with the standard or modified breast pump insert, each of said breast pump inserts having a central aperture therein through which a nipple extends when a breast is received therein and an overall outer diameter in a region of the aperture, wherein the diameter of the aperture in the modified breast pump insert is different to the diameter of the aperture in the standard breast pump insert, said overall outer diameter of the breast pump insert in the region of said aperture remaining the same in both the modified and standard breast pump inserts irrespective of the difference in the diameter of the aperture be-

tween said inserts.

8. A breast pump insert kit comprising at least two funnel-shaped breast pump inserts interchangeably mountable in a funnel of a breast pump, each breast pump insert having a central aperture therein through which a nipple extends when a breast is received therein and a wall having a thickness, wherein the diameter of the aperture, and the thickness of the wall in a region of the aperture in each breast pump insert is different.

9. A kit according to claim 8, wherein each breast pump insert has an outer diameter in the region of the aperture defined by the sum of twice the wall thickness and the diameter of the aperture, the outer diameter of each breast pump insert being substantially the same.

10. A kit according to claims 8 or 9, wherein each breast pump insert comprises a frustoconical section that tapers to a substantially cylindrical section, said aperture being formed at an end of the substantially cylindrical section.

11. A breast pump according to claim 10, wherein said region of the aperture is defined by the substantially cylindrical section such that the thickness of said wall forming said substantially cylindrical section is different for each insert.

12. A kit according to any of claims 8 to 11, including a breast pump according to any of claims 1 to 6.

13. A breast pump having a funnel to receive a breast of a user, wherein a surface of said funnel that comes into contact with a breast received in said funnel has a textured surface finish.

14. A breast pump insert positionable within the funnel of a breast pump to receive a breast of a user, wherein a surface finish of said breast pump insert that comes into contact with a breast received in said insert has a textured surface finish.

15. A breast pump according to claim 13 or a breast pump insert according to claim 14, wherein the textured surface finish has an arithmetical mean roughness (Ra) in the order of single digits to tens of digits that reduces the overall surface contact between the user's skin and the breast pump.

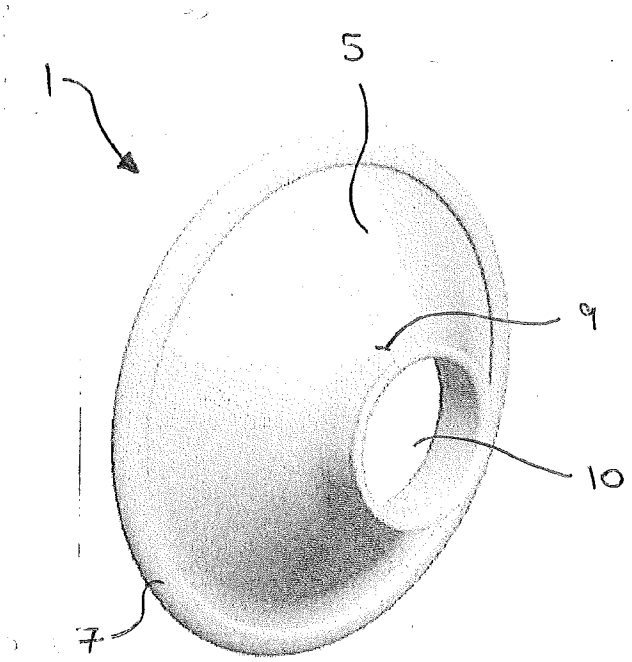

FIGURE 1A

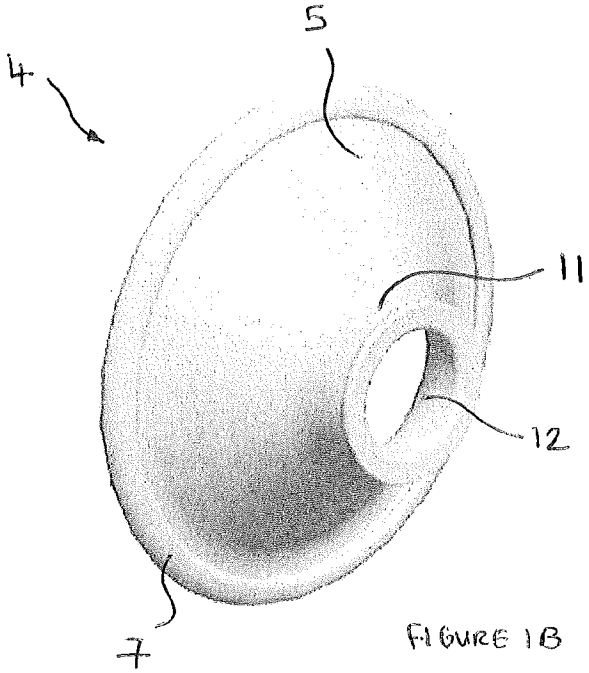

FIGURE 1B

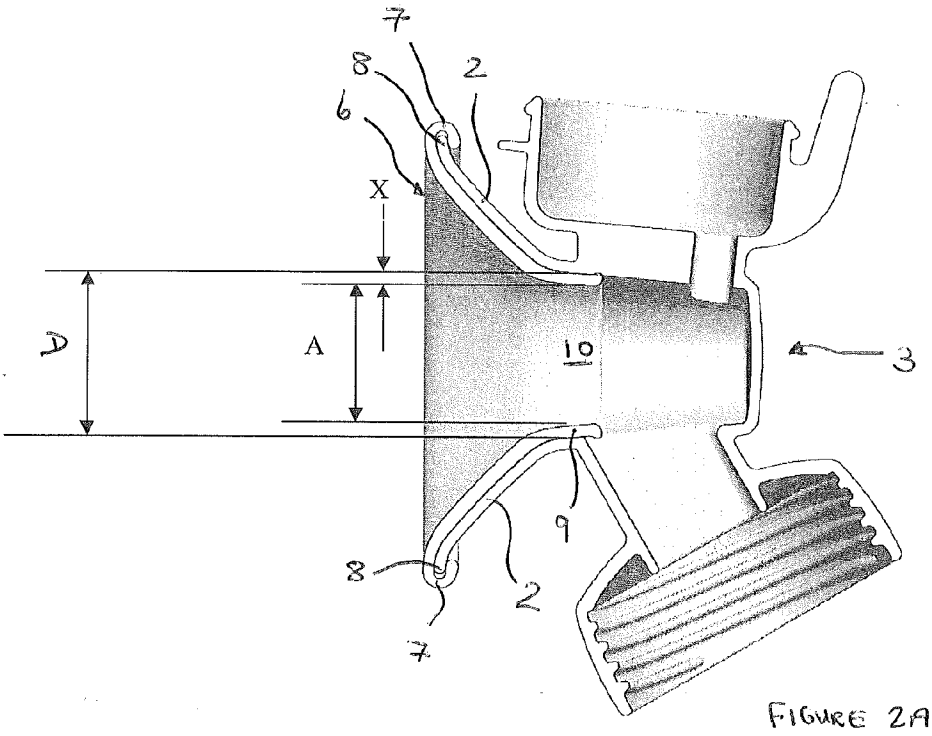

FIGURE 2A

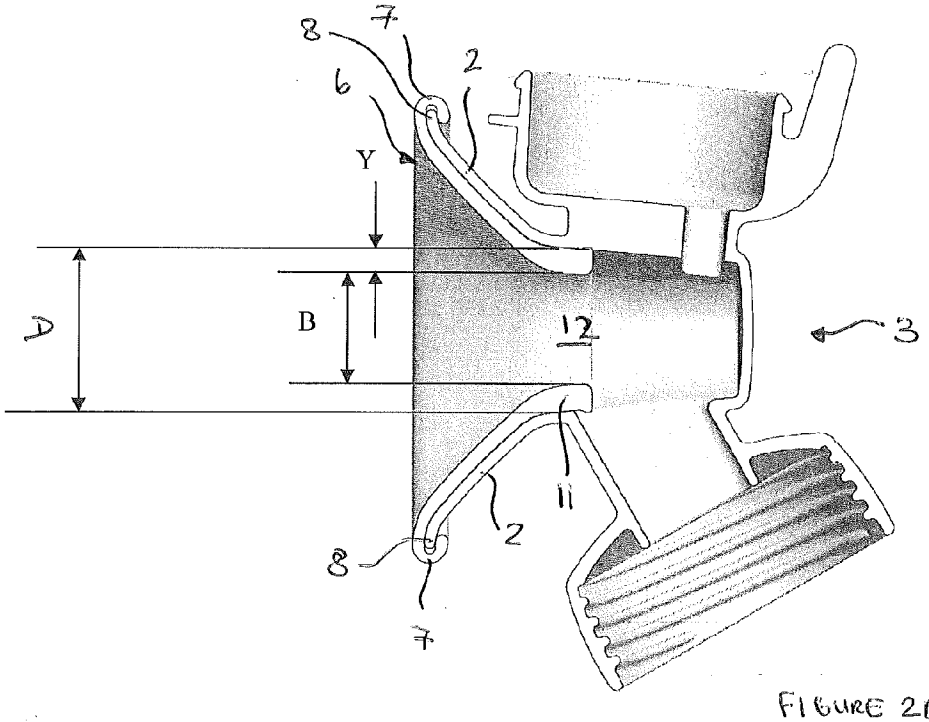

FIGURE 2B

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EUROPEAN SEARCH REPORT

Application Number
EP 11 15 8960

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 4 857 051 A (LARSSON KARL O A H [CH]) 15 August 1989 (1989-08-15) * column 3, lines 48-65 * * column 7, lines 16-62 * * figure 2 *	1-12	INV. A61M1/06
X	US 4 323 067 A (ADAMS FRANK H) 6 April 1982 (1982-04-06) * column 4, line 15 - column 5, line 2 * * figures 1, 2 *	1-12	
X	GB 2 392 626 A (UNIV SCHOOL NIHON JURIDIC PER [JP]) 10 March 2004 (2004-03-10) * page 6, line 16 - page 9, line 3 * * figures 1, 2 *	1-12	
X	US 4 573 969 A (SCHLENSOG KLAUS [CH] ET AL) 4 March 1986 (1986-03-04) * column 5, lines 20-28 * * column 8, lines 10-64 * * figures 1, 2 *	1-12	
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~~The present search report has been drawn up for all claims~~

Place of search	Date of completion of the search	Examiner
The Hague	24 August 2011	Schlaug, Martin

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

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Application Number
EP 11 15 8960

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing claims for which payment was due.

☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due and for those claims for which claims fees have been paid, namely claim(s):

☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

☐ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.

☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:

☒ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

1-12

☐ The present supplementary European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims (Rule 164 (1) EPC).

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LACK OF UNITY OF INVENTION
SHEET B

Application Number
EP 11 15 8960

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1-12

A breast pump comprising an insert (claim 1-6), an insert (claim 7) and an insert kit (claim 8-12)
and further features relating to
the insert being interchangable

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2. claims: 13-15

A breast pump comprising a funnel (claim 13, 15) or an insert (claim 14, 15)
and further features relating to
a textured surface finish

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 11 15 8960

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

24-08-2011

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	COURTNEY B. FREDRICKSON
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-D788293-S	05-30-2017	ECKSTEIN et al.	
	002	US-D809646-S	02-06-2018	MASON et al.	
	003	US-D832995-S	11-06-2018	MASON et al.	
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	022	US-20210030934-A1	02-04-2021	ZHANG; Shu Ting	

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 4

Complete if Known	
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Attorney Docket Number	4944.0120006

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]–Number[4]–Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	WO-2016010524-A1	01-21-2016	HEWLETT PACKARD DEVELOPMENT CO [US]		☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 4

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First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	COURTNEY B. FREDRICKSON
Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author(in CAPITAL LETTERS),title of the article(when appropriate), title of the item (book,magazine,journal,serial,symposium,catalog,etc.),date,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
	001	4MD Medical, "Assembling Spctra Breast Pump Parts," YouTube [online], dated November13, 2016, URL: http://www.youtube.com/watch?v=ChV8xQfcBxU.	☐
	002	The Best Hands-Free Breast Pumps, posted at healthline.com, earliest date posted on 08/24/2020, [online], acquired on 10/30/2021, Available on internet. url:https://www.healthline.com/health/parenting/breast-feeding/best-hands-free-breast-pumps#Best-hands-free-breast-pumps (Year: 2020).	☐

Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	10/17/2022

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Sheet 4 of 4

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Application Number	17/181,057
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First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	COURTNEY B. FREDRICKSON
Attorney Docket Number	4944.0120006

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Anupma Sahay #78,704/	Date (YYYY-MM-DD)	2022-07-12
Name/Print	Anupma Sahay	Registration Number	78,704

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.B.F./

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	1	17/181057.app.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:05 PM
L2	128	((("O'TOOLE") near3 ("Jonathan")) OR (("ROLLO") near3 ("Adam")) OR (("CARR") near3 ("Andrew"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/12/31 01:05 PM
L3	8470	a61m1/06-069.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L5	2	("20170216505").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L6	8	("20130023821" "20070219486" "20160296682").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:14 PM
L7	2	("20140378895").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:16 PM
L8	2	("7824363").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU,	OR	ON	ON	2022/01/01 01:04 PM

			SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L9	126	("10881766" OR "10926011" OR "20040087898" OR "20090281482" OR "20100292636" OR "20120165729" OR "20140263611" OR "20160228625" OR "20180110900" OR "20210196873" OR "20210196874" OR "20210196875" OR "20210196876" OR "20210205511" OR "20210205512" OR "20210205513" OR "20210205514" OR "20210205515" OR "20210205516" OR "20210205517" OR "20210205518" OR "20210228789" OR "20210268158" OR "7666162" OR "8608685" OR "20070135761" OR "20070179439" OR "20090281485" OR "20110009824" OR "20160271305" OR "20160296682" OR "20160325031" OR "20170095599" OR "20170112983" OR "20180028733" OR "20180333523" OR "5542921" OR "7833190" OR "10039871" OR "20020193731" OR "20040056641" OR "20040074281" OR "20040267215" OR "20050219302" OR "20060122575" OR "20070051172" OR "20070051727" OR "20080177224" OR "20080262420" OR "20080275386" OR "20110004154" OR "20110196291" OR "20110274566" OR "20120277636" OR "20130023821" OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/01/12 05:14 PM

		"20140031744" OR "20140052056" OR "20140275857" OR "20140323962" OR "20140378895" OR "20150217036" OR "20150217037" OR "20150283311" OR "20160000980" OR "20160058928" OR "20160058929" OR "20160082165" OR "20160082166" OR "20160151551" OR "20160158424" OR "20160166745" OR "20160206794" OR "20160220743" OR "20160220745" OR "20160256617" OR "20160287767" OR "20160296681" OR "20160310650" OR "20170021068" OR "20170035951" OR "20170043065" OR "20170072117" OR "20170072118" OR "20170143879" OR "20170220753" OR "20180021490" OR "20180110906" OR "2849881" OR "4390024" OR "4535627" OR "5474683" OR "5941847" OR "5973770" OR "6045529" OR "6090065" OR "6227936" OR "6328709" OR "6358226" OR "6383163" OR "6440100" OR "6461324" OR "6547756" OR "6579258" OR "6663587" OR "6749582" OR "7048519" OR "7201735" OR "7312554" OR "7314400" OR "7662018" OR "7776008" OR "8057425" OR "8118772" OR					

		"8187227" OR "8262606" OR "8282596" OR "8376986" OR "8702646" OR "8801495" OR "8876760" OR "8926556" OR "9033913" OR "9173587" OR "9345274" OR "9539377" OR "D548831").pn.					
L10	45	9 AND (transparent)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/12 06:05 PM
L11	105	3 AND (batter$4) AND ((interface flange shield cup) WITH (clear transparent))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/13 02:07 PM
L12	382	3 AND (silicone WITH plastic)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 10:40 AM
L13	2	("20180333523").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 11:50 AM
L14	43	3 AND ((USB "universal service bus") WITH (charg$4 recharg$4))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:19 PM
L15	2	("20160220743").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD,	OR	ON	ON	2022/01/14 12:42 PM

			DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L16	5	("5542921").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:52 PM
L20	256	3 AND ((shield cup interface flange) WITH (siz$4) WITH different)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 01:23 PM
L21	2	("20120165729").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 01:31 PM
L22	2	("10881766").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:23 PM
L23	2	("10926011").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:38 PM
L24	12	("20080275386" "20140378895" "20130023821" "20180333523" "20160296682" "20070228059" "20120277636" "20160220743" "6227936" "20090281485" "20120165729"	(US-PGPUB; USPAT)	OR	ON	ON	2022/01/14 03:55 PM

		"5542921").pn.					
L25	267	3 AND (nipple WITH (chang$4 differ$4 adjust$4 dissimilar$4) WITH (size width))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/17 03:06 PM
L26	2	"44148977".fmid.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; JPO)	OR	ON	ON	2022/10/17 03:31 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

Equivalent of Form PTO/SB/08

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 2

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	2014/0288466 A1	09-25-2014	Alvarez et al.	
	US2	2017/0173233 A1	06-22-2017	Tanaka	
	US3	2017/0292509 A1	10-12-2017	Kurihara et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	FP1	JP 2007501673 A	02-01-2007	PLAYTEX PRODUCTS INC		X
	FP2	JP 2014529312 A	11-06-2014	MEDELA HOLDING AG		X
	FP3	JP 2016514516 A	05-23-2016	NAIA HEALTH INC		X
	FP4	JP 2017509379 A	04-06-2017	NAIA HEALTH INC		X

Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	10/17/2022

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.B.F./

Equivalent of Form PTO/SB/08

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Sheet 2 of 2

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First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Anupma Sahay #78,704/	Date (YYYY-MM-DD)	2022-09-16
Name/Print	Anupma Sahay	Registration Number	78,704

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

19027878.1

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.B.F./

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 2

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	US2	2017/0173233 A1	06-22-2017	Tanaka	
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	FP2	JP 2014529312 A	11-06-2014	MEDELA HOLDING AG		X
	FP3	JP 2016514516 A	05-23-2016	NAIA HEALTH INC		X
	FP4	JP 2017509379 A	04-06-2017	NAIA HEALTH INC		X

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO				Complete if Known	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	17/181,057
				Filing Date	February 22, 2021
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				Art Unit	3783
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Sheet	2	of	2	Attorney Docket Number	4944.0120006

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Signature	/Anupma Sahay #78,704/	Date (YYYY-MM-DD)	2022-09-16
Name/Print	Anupma Sahay	Registration Number	78,704

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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(43)公表日　平成19年2月1日(2007.2.1)

(51)Int.Cl.		F I		テーマコード（参考）
A61M 1/06	(2006.01)	A61M 1/06		4C077

審査請求 未請求　予備審査請求 未請求　（全 40 頁）

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(86)(22)出願日	平成16年8月5日 (2004.8.5)
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(32)優先日	平成15年8月8日 (2003.8.8)
(33)優先権主張国	米国(US)

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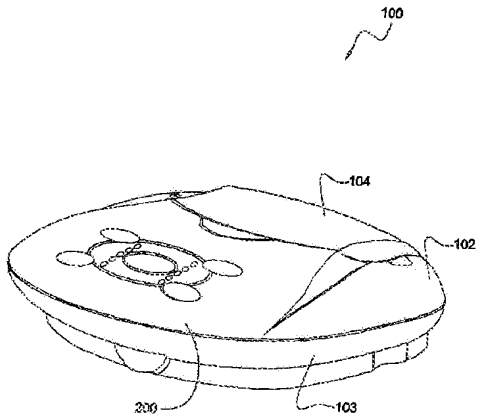
弁理士　蔵田　昌俊

最終頁に続く

(54)【発明の名称】搾乳ポンプシステム

(57)【要約】
【課題】搾乳ポンプシステム
【解決手段】母乳を得る搾乳ポンプシステムが提供されている。そのシステムは、母乳からの空気の流れを密閉するように分離して、女性の乳房に印加される陽圧と負圧との両方に単一の空気チューブを使用する。搾乳ポンプは、圧力を生成するピストン／シリンダ装置を有することが可能であり、これにより、使用者が吸引力とサイクル時間とを制御することを可能にする。
【選択図】　図１



【特許請求の範囲】
【請求項１】
圧力源と流体連絡し、乳首を有する乳房から母乳を絞り出すように構成された乳房カップであって、この乳房カップは、
乳房を受容して、前記圧力源と流体連絡するフードを備え、このフードは、負圧工程の間乳首への負の力を生成し、この負の力は、横方向成分と軸方向成分とを有し、前記横方向成分は、前記軸方向成分よりも大きい、乳房カップ。
【請求項２】
前記フードに動作的に接続されたバリア部材をさらに備え、このバリア部材は、前記負圧工程の間、前記負の力の前記軸方向成分を減少させる、請求項１に記載の乳房カップ。
【請求項３】
前記フードは、ハウジングと、このハウジングにシール状態で取着された柔軟なインサートと、前記ハウジングと前記柔軟なインサートとの間に形成された排気容積部とを備え、この排気容積部は、前記圧力源と流体連絡する、請求項１に記載の乳房カップ。
【請求項４】
前記排気容積部は、前記乳房が前記フードに受容されるとき前記乳首をほぼ包囲する、請求項３に記載の乳房カップ。
【請求項５】
前記柔軟なインサートは、前記圧力源と流体連絡する空気袋を備え、前記排気容積部は、少なくとも部分的に前記空気袋によって規定され、前記空気袋および前記排気容積部は、前記負圧工程の間、前記乳首への前記負の力を形成するように収縮する、請求項３に記載の乳房カップ。
【請求項６】
前記空気袋にほぼ隣接して配置されたバリア部材をさらに備え、このバリア部材により、前記乳房が前記空気袋に接触することが防止される、請求項５に記載の乳房カップ。
【請求項７】
前記柔軟なインサートは、前記乳房を受容する内側容積部を規定し、前記バリア部材は、円筒形状を有し、前記内側容積部中に配置されている、請求項６に記載の乳房カップ。
【請求項８】
前記柔軟なインサートは、これの上に形成されたマッサージ突起を持つじょうご形状を有する、請求項３に記載の乳房カップ。
【請求項９】
前記マッサージ突起は、星形状を有する、請求項８に記載の乳房カップ。
【請求項１０】
真空源に接続され、乳首を有する乳房から母乳を絞り出すように構成された乳房カップであって、この乳房カップは、
前記真空源と流体連絡する乳房受容部材を備え、この乳房受容部材は、負圧工程の間、前記乳首に負圧を印加し、前記乳首を横方向に沿って広げさせる、乳房カップ。
【請求項１１】
前記負圧により、前記乳首が軸方向に沿って伸びる以上に横方向に沿って乳首を広げさせる、請求項１０に記載の乳房カップ。
【請求項１２】
前記負圧は、平均横方向成分と平均軸方向成分とを有し、前記負圧工程の間、前記平均横方向成分は、前記平均軸方向成分よりも大きい、請求項１０に記載の乳房カップ。
【請求項１３】
前記乳房受容部材に動作的に接続されたバリア部材をさらに備え、このバリア部材は、前記負圧工程の間、前記軸方向に沿う前記乳首の伸張を減少させる、請求項１０に記載の乳房カップ。
【請求項１４】
前記乳房受容部材は、ハウジングと、このハウジングにシール状態で取着された柔軟な

インサートと、前記ハウジングと前記柔軟なインサートとの間に形成された排気容積部とを備え、この排気容積部は、前記真空源と流体連絡する、請求項１０に記載の乳房カップ。

【請求項１５】

前記排気容積部は、前記乳房が前記乳房受容部材に受容されるとき、前記乳首をほぼ包囲する、請求項１４に記載の乳房カップ。

【請求項１６】

前記柔軟なインサートは、前記真空源と流体連絡する空気袋を備え、前記排気容積部は、少なくとも部分的にこの空気袋によって規定され、前記空気袋および前記排気容積部は、前記負圧工程の間、前記乳首への負の力を形成するように収縮する、請求項１４に記載の乳房カップ。

【請求項１７】

前記空気袋にほぼ隣接して配置されたバリア部材をさらに備え、このバリア部材により、前記乳房が前記空気袋に接触することが防止されている、請求項１６に記載の乳房カップ。

【請求項１８】

前記柔軟なインサートは、前記乳房を受容する内側容積部を規定し、前記バリア部材は、円筒形状を有し、前記内側容積部に配置されている、請求項１７に記載の乳房カップ。

【請求項１９】

前記柔軟なインサートは、これの中に形成されているマッサージ突起を持つじょうご形状を有する、請求項１４に記載の乳房カップ。

【請求項２０】

乳首を有する乳房から母乳を絞り出す搾乳ポンプシステムであって、このシステムは、

圧力源と、

前記乳房を受容して、この圧力源と流体連絡し、負圧工程の間、前記乳首への負の力を生成し、前記負の力は、前記横方向成分と軸方向成分とを有し、前記横方向成分は、前記軸方向成分よりも大きい、乳房カップと、

を備える、搾乳ポンプシステム。

【請求項２１】

前記乳房カップに動作的に接続されたバリア部材をさらに備え、このバリア部材は、前記負圧工程の間、前記負の力の前記軸方向成分を減少させる、請求項２０に記載の搾乳ポンプシステム。

【請求項２２】

前記乳房カップは、ハウジングと、前記ハウジングにシール状態で取着された柔軟なインサートと、前記ハウジングと前記柔軟なインサートとの間に形成された排気容積部とを備え、この排気容積部は、前記圧力源と流体連絡する、請求項２０に記載の搾乳ポンプシステム。

【請求項２３】

前記排気容積部は、前記乳房が前記乳房カップに受容されたとき前記乳首をほぼ包囲する、請求項２２に記載の搾乳ポンプシステム。

【請求項２４】

前記柔軟なインサートは、前記圧力源と流体連絡する空気袋を備え、前記排気容積部は、少なくとも部分的に前記空気袋によって規定され、前記空気袋および前記排気容積部は、前記負圧工程の間、前記乳首への前記負の力を形成するように収縮する、請求項２２に記載の搾乳ポンプシステム。

【請求項２５】

前記空気袋にほぼ隣接して配置されたバリア部材をさらに備え、このバリア部材により、前記乳房が前記空気袋に接触することが防止されている、請求項２４に記載の搾乳ポンプシステム。

【請求項２６】

前記柔軟なインサートは、これの中に形成されたマッサージ突起を持つじょうご形状を有する、請求項２２に記載の搾乳ポンプシステム。

【請求項２７】

乳首を有する乳房から母乳を絞り出す搾乳ポンプシステムであって、このシステムは、

真空源と、

前記真空源と流体連絡し、負圧工程の間、乳首に負圧を印加し、前記乳首を横方向に沿って広げさせる乳房受容部材と、

を備える、搾乳ポンプシステム。

【請求項２８】

前記負圧により、前記乳首が軸方向に沿って伸びる以上に横方向に沿って乳首を広げさせる、請求項２７に記載の搾乳ポンプシステム。

【請求項２９】

前記負圧は、平均横方向成分と平均軸方向成分とを有し、前記平均横方向成分は、前記負圧工程の間、前記平均軸方向成分よりも大きい、請求項２７に記載の搾乳ポンプシステム。

【請求項３０】

前記乳房受容部材に動作的に接続されたバリア部材をさらに備え、このバリア部材は、前記負圧工程の間、前記軸方向に沿う前記乳首の伸張を減少させる、請求項２７に記載の搾乳ポンプシステム。

【請求項３１】

前記乳房受容部材は、ハウジングと、このハウジングにシール状態で取着された柔軟なインサートと、前記ハウジングと前記柔軟なインサートとの間に形成された排気容積部と、この排気容積部および前記真空源と流体連絡する空気用オリフィスとを備える、請求項２７に記載の搾乳ポンプシステム。

【請求項３２】

前記排気容積部は、前記乳房が前記乳房受容部材に受容されたとき前記乳首をほぼ包囲する、請求項３１に記載の搾乳ポンプシステム。

【請求項３３】

前記柔軟なインサートは、前記真空源と流体連絡する空気袋を備え、前記排気容積部は、少なくとも部分的にこの空気袋によって規定され、前記空気袋および前記排気容積部は、前記負圧工程の間、前記乳首への負の力を形成するように収縮する、請求項３１に記載の搾乳ポンプシステム。

【請求項３４】

前記空気袋にほぼ隣接して配置されたバリア部材をさらに備え、このバリア部材により、前記乳房が前記空気袋に接触することが防止されている、請求項３３に記載の搾乳ポンプシステム。

【請求項３５】

前記柔軟なインサートは、前記乳房を受容する内側容積部を規定し、前記バリア部材は、円筒形状を有し、前記内側容積部内に配置されている、請求項３４に記載の搾乳ポンプシステム。

【請求項３６】

前記柔軟なインサートは、これの上に形成されたマッサージ突起を持つじょうご形状を有する、請求項３１に記載の搾乳ポンプシステム。

【請求項３７】

前記真空源は、シリンダ内に移動可能に配置されたピストンである、請求項２７に記載の搾乳ポンプシステム。

【請求項３８】

前記ピストンに動作的に接続された可逆モータをさらに備える、請求項３７に記載の搾乳ポンプシステム。

【請求項３９】

第１の歯を有するラックと、第２の歯を有するギヤとをさらに備え、前記ラックは、前記ピストンに接続され、前記ギヤは、前記可逆モータに動作的に接続され、前記第１の歯は、前記第２の歯と係合して、前記シリンダ内でピストンを往復移動させる、請求項３８に記載の搾乳ポンプシステム。

【請求項４０】

前記シリンダは、第１の直径と空気穴とを有し、この空気穴は、第２の直径を有して、大気と流体連絡し、前記第１の直径は、前記第２の直径よりもかなり大きい、請求項３７に記載の搾乳ポンプシステム。

【請求項４１】

前記可逆モータに動作的に接続されたコントローラをさらに備え、このコントローラは、前記ピストンが前記シリンダに対して進んだ移動量を測定し、前記コントローラは、前記移動量に基づき前記モータを逆転させる、請求項３８に記載の搾乳ポンプシステム。

【請求項４２】

前記可逆モータに動作的に接続されたコントローラをさらに備え、前記モータは、可変速であり、前記コントローラは、前記乳房に前記負圧を印加する所望のサイクル時間に基づき前記速度を調節する、請求項３８に記載の搾乳ポンプシステム。

【請求項４３】

乳房から母乳を絞り出す圧力源と共に使用する搾乳ポンプキットであって、このキットは、

ホルダと、

乳房を受容する複数のフードとを備え、これら複数のフードの各々は、前記乳房から前記母乳を絞り出すために前記圧力源と前記ホルダとに選択的に係合可能であり、前記複数のフードの少なくとも１つは、前記複数のフードの他のものに比べて異なるサイズまたは異なる形状を有する、

搾乳ポンプキット。

【請求項４４】

前記複数のフードの各々は、ハウジングと、このハウジングにシール状態で取着された柔軟なインサートと、前記ハウジングと前記柔軟なインサートとの間に形成されて、前記圧力源と流体連絡する排気容積部とを備える、請求項４３に記載の搾乳ポンプキット。

【請求項４５】

前記複数のフードの前記少なくとも１つの前記ハウジングと前記柔軟なインサートとは、前記複数のフードの前記他のものの前記ハウジングと前記柔軟なインサートとに比べて、異なるサイズまたは異なる形状を有する、請求項４４に記載の搾乳ポンプキット。

【請求項４６】

前記複数のフードの前記少なくとも１つの前記ハウジングは、前記複数のフードの前記他のものの前記ハウジングに比べて異なるサイズまたは異なる形状を有する、請求項４４に記載の搾乳ポンプキット。

【請求項４７】

前記複数のフードの前記少なくとも１つの前記柔軟なインサートは、前記複数のフードの前記他のものの前記柔軟なインサートに比べて異なるサイズまたは異なる形状を有する、請求項４４に記載の搾乳ポンプキット。

【請求項４８】

容器をさらに備え、前記ホルダは、この容器と選択的に係合可能である、請求項４３に記載の搾乳ポンプキット。

【請求項４９】

前記ホルダは、複数の異なるサイズの容器に選択的に係合するために複数の係合構造を有する、請求項４８に記載の搾乳ポンプキット。

【請求項５０】

前記複数のフードの前記少なくとも１つの前記柔軟なインサートは、第１のマッサージ突起を有し、前記複数のフードの前記他のものの前記柔軟なインサートは、第２のマッサ

ージ突起を有し、前記第１のマッサージ突起および第２のマッサージ突起は、異なるサイズまたは異なる形状を有する、請求項４７に記載の搾乳ポンプキット。

【請求項５１】

乳房から母乳を絞り出す搾乳ポンプシステムであって、このシステムは、

圧力を生成するポンプと、

前記乳房を受容する複数のフードとを備え、これらフードの各々は、前記乳房から前記母乳を絞り出す前記ポンプに選択的に、流動的に接続可能であり、前記複数のフードの少なくとも１つは、前記複数のフードの他のものに比べて異なるサイズまたは異なる形状を有する、

搾乳ポンプシステム。

【請求項５２】

前記複数のフードの各々と選択的に係合可能なホルダをさらに備える、請求項５１に記載のシステム。

【請求項５３】

前記複数のフードの各々は、ハウジングと、このハウジングにシール状態で取着された柔軟なインサートと、前記ハウジングと前記柔軟なインサートとの間に形成されて、前記ポンプと流体連絡する排気容積部とを備える、請求項５１に記載のシステム。

【請求項５４】

前記複数のフードの前記少なくとも１つの前記ハウジングおよび前記柔軟なインサートは、前記複数のフードの前記他のものの前記ハウジングおよび前記柔軟なインサートに比べて、異なるサイズまたは異なる形状を有する、請求項５３に記載のシステム。

【請求項５５】

前記複数のフードの前記少なくとも１つの前記ハウジングは、前記複数のフードの前記他のものの前記ハウジングに比べて異なるサイズまたは異なる形状を有する、請求項５３に記載のシステム。

【請求項５６】

前記複数のフードの前記少なくとも１つの前記柔軟なインサートは、前記複数のフードの前記他のものの前記柔軟なインサートに比べて異なるサイズまたは異なる形状を有する、請求項５３に記載のシステム。

【請求項５７】

容器をさらに備え、前記ホルダは、この容器と選択的に係合可能である、請求項５２に記載のシステム。

【請求項５８】

前記ホルダは、複数の異なるサイズの容器に選択的に係合するために複数の係合構造を有する、請求項５７に記載のシステム。

【請求項５９】

前記複数のフードの前記少なくとも１つの前記柔軟なインサートは、第１のマッサージ突起を有し、前記複数のフードの前記他のものの前記柔軟なインサートは、第２のマッサージ突起を有し、前記第１のマッサージ突起と第２のマッサージ突起とは、異なるサイズまたは異なる形状を有する、請求項５６に記載のシステム。

【請求項６０】

乳房から母乳を絞り出す搾乳ポンプであって、このポンプは、

圧力工程の間、圧力を生成する移動可能な構造体を有し、この移動可能な構造体は、可変圧力または可変サイクル時間を有する、圧力源と、

この圧力源に動作的に接続されたコントローラとを備え、このコントローラは、前記移動可能な構造体によって進められた移動量に基づき前記圧力を調整する、または、前記移動可能な構造体の速度に基づき前記可変サイクル時間を調整し、また、このコントローラは、進められた前記移動量または前記速度のほぼリアルタイムなモニタリングを行う、

搾乳ポンプ。

【請求項６１】

前記コントローラは、前記圧力対可変サイクル時間の非正弦波信号に基づき前記圧力サイクルを調整できる、請求項６０に記載のポンプ。

【請求項６２】

乳房から母乳を絞り出す搾乳ポンプシステムであって、

圧力を生成する排気容積部と空気穴とを有する圧力源と、

前記乳房を受容し、前記圧力を前記乳房に印加するように前記圧力源と流体連絡する乳房カップとを備え、前記空気穴は、所定の直径を有し、また、この空気穴は、大気と前記排気容積部と流体連絡し、前記直径は、約０．１５ｍｍから０．７５ｍｍの間である、

搾乳ポンプシステム。

【請求項６３】

前記直径は、約０．２５ｍｍから０．５ｍｍの間である、請求項６２に記載のシステム。

【請求項６４】

前記直径は、約０．３ｍｍである、請求項６２に記載のシステム。

【請求項６５】

乳房から母乳を絞り出す方法であって、

真空工程の間、圧力源から前記乳房に負圧を印加することと、

マッサージ工程の間、前記圧力源から前記乳房に陽圧を印加することと、

前記真空工程の間、前記圧力源に大気から空気を供給することと、

を備える、方法。

【請求項６６】

前記真空工程の間、前記圧力源に大気から空気を供給する前記ステップは、前記圧力源および前記大気と流体連絡する空気穴を設けることを備え、前記空気穴は、約０．１５ｍｍから０．７５ｍｍの間の直径を有する、請求項６５に記載の方法。

【請求項６７】

乳首を有する乳房から母乳を絞り出す方法であって、

少なくとも前記乳首の一部に負圧を印加し、前記乳首を横方向に沿って広げさせることを備える、方法。

【請求項６８】

前記負圧により、前記乳首が軸方向に沿って伸びる以上に前記横方向に沿って前記乳首を広げさせる、請求項６７に記載の方法。

【請求項６９】

前記負圧は、負圧工程の間、平均横方向成分と平均軸方向成分とを有し、前記平均横方向成分は、前記平均軸方向成分よりも大きい、請求項６７に記載の方法。

【請求項７０】

乳房から母乳を絞り出す方法であって、

前記乳房に圧力を印加することと、

コントローラで前記圧力のほぼリアルタイムなモニタリングおよび制御を行うことと、

を備える、方法。

【請求項７１】

前記圧力は、移動可能な構造体の可変圧力または前記移動可能な構造体の可変サイクル時間に基づき幾分制御され、前記コントローラは、前記移動可能な構造体によって進められる移動量に基づき前記圧力を調整する、または、前記移動可能な構造体の速度に基づき前記可変サイクル時間を調整し、前記コントローラは、進められた前記移動量または前記速度のほぼリアルタイムなモニタリングを行う、請求項７０に記載の方法。

【請求項７２】

前記コントローラは、前記圧力対可変サイクル時間の非正弦波信号に基づき前記圧力を調整する、請求項７０に記載の方法。

【請求項７３】

圧力を供給するポンプであって、

容積部を規定し、圧力排出装置を有するハウジングと、
前記容積部内に前記圧力を生成するように前記ハウジングに動作的に接続されたアクチュエータと、
前記ハウジングに接続されたインサートとを備え、このインサートは、インサートを通るように配置されている穴を有し、この穴は、前記容積部と大気との間の流体連絡をもたらす、
ポンプ。
【請求項７４】
前記ハウジングは、第１の材料でできており、前記インサートは第２の材料でできている、請求項７３に記載のポンプ。
【請求項７５】
前記ハウジングは、プラスチックでできており、前記インサートは金属でできている、請求項７４に記載のポンプ。
【請求項７６】
前記ハウジングは、シリンダであり、前記アクチュエータは、ピストンである、請求項７３に記載のポンプ。
【請求項７７】
前記シリンダは、オリフィスを有し、前記インサートは、このオリフィス内に配置されている、請求項７６に記載のポンプ。
【請求項７８】
前記インサートは、前記オリフィス内にプレス嵌合されている、請求項７７に記載のポンプ。
【請求項７９】
前記インサートは、複数のインサートであり、前記複数のインサートの各々は、前記シリンダと選択的に係合可能である、請求項７６に記載のポンプ。
【請求項８０】
前記インサートは、複数のインサートであり、前記複数のインサートの各々は、前記オリフィスと選択的に係合可能である、請求項７７に記載のポンプ。
【請求項８１】
第１の容器と第２の容器と流体連絡して乳房に当てる乳房カップであって、前記第１の容器および第２の容器は、異なる直径を持つ開口を有し、乳房カップは、
前記乳房を受容するじょうご形体と、
前記じょうご形体に接続され、ベースを有するハウジングとを備え、前記ベースは、周方向壁と、開口を規定するために前記周方向壁から内方に延出するフランジと、第１のねじ山と、第２のねじ山とを有し、
前記第１のねじ山は、第１の直径と第１のピッチとを有し、これら第１の直径および前記第１のピッチは、前記第１の容器との選択的係合を可能にし、前記第２のねじ山は、第２の直径と第２のピッチとを有し、これら第２の直径および前記第２のピッチは、前記第２の容器との選択的係合を可能にし、前記第１のねじ山と第２のねじ山とは、前記ベースに沿って同軸を有するように配置されている、乳房カップ。
【請求項８２】
前記第１のピッチは、前記第２のピッチに等しい、請求項８１に記載の乳房カップ。
【請求項８３】
前記第１のねじ山は、前記フランジから延出し、前記第２のねじ山は、前記周方向壁に配置されている、請求項８１に記載の乳房カップ。
【請求項８４】
前記じょうご形体は、前記ハウジングから選択的に除去可能である、請求項８１に記載の乳房カップ。
【請求項８５】
第１の容器および第２の容器を哺乳瓶の乳首に係合する、哺乳瓶の乳首リングであって

、これら第１の容器および第２の容器は、異なる直径を持つ開口を有し、この哺乳瓶の乳首リングは、
周方向壁と、開口を規定するために前記周方向壁から内方に延出するフランジと、第１のねじ山と、第２のねじ山とを有する、本体を備え、
前記第１のねじ山は、第１の直径と第１のピッチとを有し、これら第１の直径および前記第１のピッチは、前記第１の容器との選択的係合を可能にし、前記第２のねじ山は、第２の直径と前記第２のピッチとを有し、これら第２の直径および前記第２のピッチは、前記第２の容器との選択的係合を可能にし、前記第１のねじ山と前記第２のねじ山とは、前記本体に沿って同軸を有するように配置されている、哺乳瓶の乳首リング。
【請求項８６】
前記第１のピッチは、前記第２のピッチに等しい、請求項８５に記載の哺乳瓶の乳首リング。
【請求項８７】
前記第１のねじ山は、前記フランジから延出し、前記第２のねじ山は、前記周方向壁に配置されている、請求項８５に記載の哺乳瓶の乳首リング。
【請求項８８】
第１の容器と第２の容器とに係合するキャップであって、これら第１の容器および第２の容器は、異なる直径を持つ開口を有し、このキャップは、
周方向壁と、前記周方向壁に接続された頂部壁と、第１のねじ山と、第２のねじ山とを有する、本体を備え、
前記第１のねじ山は、第１の直径と第１のピッチとを有し、これら第１の直径および前記第１のピッチは、前記第１の容器との選択的係合を可能にし、前記第２のねじ山は、第２の直径と第２のピッチとを有し、これら第２の直径および前記第２のピッチは、前記第２の容器との選択的係合を可能にし、前記第１のねじ山と前記第２のねじ山とは、前記本体に沿って同軸を有するように配置されている、キャップ。
【請求項８９】
前記第１のピッチは、前記第２のピッチに等しい、請求項８８に記載のキャップ。
【請求項９０】
前記第１のねじ山は、前記フランジから延出し、前記第２のねじ山は、前記周方向壁に配置されている、請求項８８に記載のキャップ。
【発明の詳細な説明】
【技術分野】
【０００１】
本発明は、母乳を得る装置および方法に関する。より詳細には、本発明は、母乳を絞り出すために乳房に陽圧または負圧を印加可能な搾乳ポンプシステムに関する。
【背景技術】
【０００２】
手動および自動の両方で、母乳を得る搾乳ポンプシステムは、技術上周知である。従来のシステムは、乳房に当てられる乳房フードまたはカップに管を介して送られる、負圧または真空を生成するために真空源を使用する。この従来の装置および方法は、母乳を絞り出すために乳房に負圧を使用する。
【０００３】
上述のシステムは、母乳の絞り出しを誘発するために、負圧として真空源だけを乳房に印加するという欠点をもつ。その上、上述の従来のシステムは、乳首に軸方向に負圧または負の力を印加するという欠点をもち、母乳の絞り出しに不快で、かつ、不十分な軸方向での乳首の伸張および膨張という結果になる。
【発明の開示】
【発明が解決しようとする課題】
【０００４】
本発明の目的は、母乳を絞り出すために陽圧または負圧を乳房に印加可能な、母乳を絞

り出す搾乳ポンプシステムを提供することである。

【０００５】

本発明の別の目的は、単一の源から陽圧と負圧とを供給する上述のシステムを提供することである。

【０００６】

本発明のさらに別の目的は、乳房に印加される陽圧と負圧との制御を容易にする上述のシステムを提供することである。

【０００７】

本発明のさらなる別の目的は、乳汁を絞り出すために、乳首を広げる上述のシステムを提供することである。

【０００８】

本発明の別の目的は、乳首の軸方向の伸張または膨張を減少する上述のシステムを提供することである。

【０００９】

本発明の別のさらなる目的は、軸方向成分に比べてより大きい横方向成分を有する、負の力または負圧勾配を乳首に印加することである。

【００１０】

本発明のさらに別の目的は、異なるサイズおよび／または形状の互換性のある乳房フードを持つキットを提供することによって、異なるサイズおよび／または形状の乳房を収容することである。

【００１１】

本発明のさらに別の目的は、リアルタイムで圧力源を実質的にモニタして、制御することである。

【００１２】

本発明の以上および他の目的および利点は、乳房を受容するフードを有し、圧力源と流体連絡する乳房カップによってもたらされる。フードは、負圧工程の間、乳首への負の力を生成する。負の力は、横方向成分と軸方向成分とを有する。横方向成分は、軸方向成分よりも大きい。

【課題を解決するための手段】

【００１３】

本発明は、真空源と流体連絡する乳房受容部材を有する、乳房カップを含む。乳房受容部材は、負圧工程の間乳首に負圧を印加し、乳首を横方向に沿って広げさせる。

【００１４】

本発明は、圧力源と、乳房を受容する乳房カップとを有する、搾乳ポンプシステムを含む。乳房カップは、圧力源と流体連絡する。乳房カップは、負圧工程の間乳首への負の力を生成する。負の力は、横方向成分と軸方向成分とを有する。横方向成分は軸方向成分よりも大きい。

【００１５】

本発明は、真空源と、その真空源と流体連絡する乳房受容部材とを有する、搾乳ポンプシステムを含む。乳房受容部材は、負圧工程の間乳首に負圧を印加し、乳首を横方向に沿って広げさせる。

【００１６】

本発明は、ホルダと乳房を受容する複数のフードとを有する、搾乳ポンプキットを含む。複数のフードの各々は、ホルダと乳房から母乳を絞り出すための圧力源とに、選択的に係合可能である。複数のフードの少なくとも１つは、複数のフードの他のものに比べて異なるサイズまたは異なる形状を有する。

【００１７】

本発明は、圧力を生成するポンプと、乳房を受容する複数のフードとを有する、搾乳ポンプシステムを含む。複数のフードの各々は、乳房から母乳を絞り出すポンプに選択的に、流動的に接続可能である。複数のフードの少なくとも１つは、複数のフードの他のもの

に比べて異なるサイズまたは異なる形状を有する。

【００１８】

本発明は、圧力工程の間圧力を生成する移動可能な構造体を持つ圧力源を有する搾乳ポンプを含む。移動可能な構造体は、可変圧力または可変サイクル時間とを有する。ポンプは、さらに、圧力源に動作的に接続されるコントローラを有する。コントローラは、移動可能な構造体によって進められる移動量に基づき圧力を調整する、または、移動可能な構造体の速度に基づき可変サイクル時間を調整する。コントローラは、進められる移動量または速度のほぼリアルタイムなモニタリングを行う。

【００１９】

本発明は、圧力を生成する排気容積部を持つ圧力源と、空気穴とを有する搾乳ポンプシステムを含む。システムは、乳房を受容し、圧力を乳房に印加する圧力源と流体連絡する乳房カップをさらに有する。空気穴は、直径を有し、大気と排気容積部と流体連絡する。空気穴の直径は、約０．１５ｍｍから０．７５ｍｍとの間である。

【００２０】

本発明は、真空工程の間圧力源から乳房に負圧を印加することと、マッサージ工程の間圧力源から乳房に陽圧を印加することと、真空工程の間圧力源に大気から空気を供給することと、の各ステップを有する、乳房から母乳を絞り出す方法を含む。

【００２１】

本発明は、少なくとも乳首の部分に負圧を印加し、乳首を横方向に沿って広げさせるステップを有する、乳房から母乳を絞り出す方法を含む。

【００２２】

本発明は、乳房に圧力を印加することと、コントローラで前記圧力のほぼリアルタイムなモニタリングおよび制御を行うことと、の各ステップとを有する、乳房から母乳を絞り出す方法を含む。

【００２３】

本発明は、ハウジングと、アクチュエータと、インサートとを有する、圧力を供給するポンプを含む。ハウジングは、容積部を規定し、圧力排出装置を有する。アクチュエータは、容積部内に圧力を生成するハウジングに動作的に接続されている。インサートは、ハウジングに接続されている。インサートは、それを通って配置されている穴を有する。穴は、容積部と大気との間の流体連絡をもたらす。

【００２４】

本発明は、異なる直径を持つ開口を有する第１の容器と第２の容器と流体連絡して乳房に当てる乳房カップを含む。乳房カップは、乳房を受容するじょうご形体と、そのじょうご形体に接続されているハウジングとを有する。じょうご形体は、ベースを有する。ベースは、周方向壁と、開口を規定するために周方向壁から内方に延出するフランジと、第１のねじ山と、第２のねじ山とを有する。第１のねじ山は、第１の直径と第１のピッチとを有する。第１の直径および第１のピッチは、第１の容器との選択的係合を可能にする。第２のねじ山は、第２の直径と第２のピッチとを有する。第２の直径および第２のピッチは、第２の容器との選択的係合を可能にする。第１のねじ山および第２のねじ山は、ベースに沿って同軸を有するように配置されている。

【００２５】

本発明は、異なる直径を持つ開口を有する第１の容器および第２の容器を哺乳瓶の乳首に係合する、哺乳瓶の乳首リングを含む。哺乳瓶の乳首リングは、周方向壁と、開口を規定するためにその周方向壁から内方に延出するフランジと、第１のねじ山と、第２のねじ山とを有する、本体を有する。第１のねじ山は、第１の直径と第１のピッチとを有する。第１の直径および第１のピッチは、第１の容器との選択的係合を可能にする。第２のねじ山は、第２の直径と第２のピッチとを有する。第２の直径および第２のピッチは、第２の容器との選択的係合を可能にする。第１のねじ山および第２のねじ山は、本体に沿って同軸を有するように配置されている。

【００２６】

本発明は、異なる直径を持つ開口を有する第１の容器および第２の容器と係合するキャップを含む。キャップは、周方向壁と、その周方向壁に接続されている頂部壁と、第１のねじ山と、第２のねじ山とを持つ、本体を有する。第１のねじ山は、第１の直径と第１のピッチとを有する。第１の直径および第１のピッチは、第１の容器との選択的係合を可能にする。第２のねじ山は、第２の直径と第２のピッチとを有する。第２の直径および第２のピッチは、第２の容器との選択的係合を可能にする。第１のねじ山および第２のねじ山は、本体に沿って同軸を有するように配置されている。

【００２７】

第１のピッチは、第２のピッチに等しくてよい。第１のねじ山は、フランジから延出可能である。第２のねじ山は、周方向壁に配置可能である。じょうご形体は、ハウジングから選択的に除去可能である。

【００２８】

ハウジングは第１の材料であってよく、インサートは第２の材料であってよい。ハウジングはプラスチックであってよく、インサートは金属であってよい。ハウジングはシリンダであってよく、アクチュエータはピストンであってよい。シリンダはオリフィスであってよく、インサートはそのオリフィス内に配置可能である。インサートは、オリフィス内にプレス嵌合可能である。インサートは、複数のインサートであり、複数のインサートの各々は、シリンダと選択的に係合可能である。

【００２９】

乳房カップは、さらに、フードに動作的に接続されているバリア部材を有し、そのバリア部材は、負圧工程の間負の力の軸方向成分を減少する。フードは、ハウジングと、そのハウジングに密閉固定されている柔軟なインサートと、ハウジングと柔軟なインサートとの間に形成されている排気容積部とを有することが可能であり、その排気容積部は、圧力源と流体連絡する。排気容積部は、乳房がフードに受容されるとき乳首をほぼ包囲可能である。柔軟なインサートは、圧力源と流体連絡する空気袋を有することが可能であり、排気容積部は、少なくとも部分的にその空気袋によって規定されている。空気袋および排気容積部は、負圧工程の間乳首への負の力を形成するように収縮させることが可能である。

【００３０】

乳房カップは、さらに、空気袋にほぼ隣接して配置されているバリア部材を有し、それによって、乳房が空気袋に接触することを防止する。柔軟なインサートは、乳房を受容する内側容積部を規定することが可能であり、バリア部材は、円筒形状を有し、内側容積部に配置可能である。柔軟なインサートは、これの上に形成されたマッサージ突起を持つじょうご形状を有することが可能である。マッサージ突起は、星形状を有する。

【００３１】

乳房カップに生成される負圧により、乳首が軸方向に沿って伸びる以上に横方向に沿って沿って乳首を広げさせることが可能である。負圧は、平均横方向成分と平均軸方向成分とを有することが可能であり、負圧工程の間、平均横方向成分は、平均軸方向成分よりも大きい。バリア部材は、乳房受容部材に動作的に接続可能であり、負圧工程の間軸方向に沿う乳首の伸張を減少することが可能である。乳房受容部材は、ハウジングと、そのハウジングに密閉固定されている柔軟なインサートと、ハウジングと柔軟なインサートとの間に形成されている排気容積部とを有することが可能であり、その排気容積部は、真空源と流体連絡する。

【００３２】

真空源または圧力源は、シリンダ内に移動可能に配置されているピストンであってよい。システムは、そのピストンに動作的に接続されている可逆モータを有することが可能である。システムは、さらに、第１の歯を有するラックと、第２の歯を有するギヤを有することが可能である。ラックは、ピストンに接続可能であり、ギヤは、可逆モータに動作的に接続可能である。第１の歯は、第２の歯と係合可能であり、シリンダ内でピストンを往復移動させる。シリンダは、第１の直径と空気穴とを有することが可能である。空気穴は、第２の直径を有して、大気と流体連絡することが可能である。シリンダの第１の直径は

、空気穴の第２の直径よりもかなり大きくてよい。

【００３３】

システムは、可逆モータに動作的に接続されているコントローラを有することが可能である。コントローラは、ピストンがシリンダに対して進んだ移動量を測定することが可能である。コントローラは、少なくとも部分的にその移動量に基づきモータを逆転させることが可能である。システムは、さらに、可変速度を持つモータを有することが可能である。コントローラは、乳房に負圧を印加する所望のサイクル時間に基づき速度を調節することが可能である。コントローラは、圧力対可変サイクル時間の非正弦波信号に基づき圧力サイクルを調整することが可能である。

【００３４】

キットの複数のフードの各々は、ハウジングと、そのハウジングに密閉固定されている柔軟なインサートと、ハウジングと柔軟なインサートとの間に形成されて、圧力源と流体連絡する排気容積部とを有することが可能である。複数のフードのうち少なくとも１つのハウジングおよび／または柔軟なインサートは、ハウジングおよび／または複数のフードのうち他のものの柔軟なインサートに比べて、異なるサイズまたは異なる形状を有することが可能である。キットは、さらに、容器を有することが可能であり、ホルダは、その容器と選択的に係合可能である。ホルダは、複数の異なるサイズの容器に選択的に係合するために複数の係合構造を有することが可能である。複数のフードのうち少なくとも１つの柔軟なインサートは、第１のマッサージ突起を有することが可能であり、複数のフードのうち他のものの柔軟なインサートは、第２のマッサージ突起を有することが可能である。第１のマッサージ突起および第２のマッサージ突起は、異なるサイズまたは異なる形状を有することが可能である。

【００３５】

本発明のこれ以外の、さらなる目的、利点および特徴は、以下を参照することにより理解されるであろう。

【発明を実施するための最良の形態】

【００３６】

図面、特に、図１と図２とを参照すると、全体として参照符号１００で表わされている本発明の搾乳ポンプが示されている。この搾乳ポンプ１００は、図１１に示されている乳房カップ４００と共に、本発明の搾乳ポンプシステムの重要構成要素を形成している。搾乳ポンプ１００は、組立ユニットを形成するように構成されている頂部ハウジング１０２と底部ハウジング１０３とを有する。

【００３７】

図１から図３を参照すると、頂部ハウジング１０２は、平坦な前部面２００と区画ドア１０４を有する貯蔵区画２１０とを持つ、ほぼ楕円の形状を有する。ドア１０４は、搾乳ポンプ１００をシステムの他の構成要素に接続する空気管または導管３５０を貯蔵するために、選択的に密閉可能な貯蔵区画２１０を形成するように、頂部ハウジング１０２にヒンジ式に接続されることが好ましく、このことについては、以下により詳細に論じる。

【００３８】

面２００は、ＬＥＤカバー１０６を有するボタンパッド１０５を受容することができる。パッド１０５は、搾乳ポンプ１００を制御するために消費者によって使用される。底部ハウジング１０３は、搾乳ポンプの様々な構成要素を確実に収容することが可能であり、ラックギヤ１０９と、ラックギヤに係合可能なピニオンギヤ１１０と、ピストン１１２と、ピストンを受容可能なシリンダ１１３と、ピニオンギヤが取り付けられるシャフト１２６を有するモータ１２５とを含む。ある程度この設計により、搾乳ポンプ１００は、低騒音のポンプ吸い出しをもたらす。搾乳ポンプ１００は、例えば、プラスチックなどのあらゆる剛性材料で作られることが可能である。

【００３９】

図３から図７を参照すると、搾乳ポンプ１００は、母乳を得るために陽圧と負圧との両方を生成するためにピストン１１２とシリンダ１１３とを利用している。このピストン１

１２は、これに固定されているラックギヤ１０９によって駆動される。ピストン１１２は、第１のヘッド３０００と第２のヘッド３１００とを持つほぼ円筒の形状を有する。第１のヘッド３０００および第２のヘッド３１００は、各々、中に形成されている環状チャネル３０２０、３１２０を有することが好ましい。チャネル３０２０、３１２０は、各々、第１のヘッド３０００と第２のヘッド３１００との外側周辺に沿って配置されている。チャネル３０２０、３１２０は、第１のヘッド３０００と第２のヘッド３１００との外側周辺に沿って中心に位置されていることが好ましい。チャネル３０２０、３１２０内に着座されているのは、各々に、密閉部材３０５０、３１５０である。密閉部材３０５０、３１５０は、Ｏ－リングガスケットであることが好ましい。密閉部材３０５０、３１５０は、チャネル３０２０とチャネル３１２０との深さまたは高さよりも大きい直径または幅を有する。密閉部材３０５０、３１５０は、第１のヘッド３０００と第２のヘッド３１００の外側周辺を越えて延在し、ピストン１１２がシリンダ内を往復して駆動されるときシリンダ１１３の内部表面１３０との密閉係合を形成している。

【００４０】

複数の密閉部材、すなわち、ピストン１１２へのＯ－リングガスケット３０５０とＯ－リングガスケット３１５０との使用により、ダブル密閉をもたらし、陽圧と負圧とを生成する効果を増大する。この実施形態が、２つの独立した密閉表面を生成するために２つの密閉部材を使用するのに対して、かなり多数の密閉部材が、ピストン１１２をシリンダ１１３と密閉するかなり多数の密閉表面を生成するのに使用可能である。加えて、この実施形態が、Ｏ－リング密閉ガスケット３０５０、３１５０を有するピストン１１２を使用するのに対して、別の密閉構造が、ピストンとシリンダ１１３との間に使用可能である。

【００４１】

ラックギヤ１０９は、歯１１００を有するピニオンギヤ１１０と係合する歯１０９０を有する。ピニオンギヤ１１０は、好ましくは、シャフト１２６によってモータ１２５に機能的に接続されている。モータ１２５が始動されるとき、シャフト１２６およびピニオンギヤ１１０は、回転する。ラック１０９の歯１０９０およびピニオン１１０の歯１１００は、噛み合い、モータ１２５とシャフト１２６との相互の回転運動を、両方向に単一軸に沿う相互の長手方向運動に変換する。

【００４２】

ラックギヤ１０９は、ピストン１１２内に形成されている凹部３２００と係合する第１の端部１０９５を有することが好ましい。凹部３２００は、ピストン１１２において中心に位置されることが好ましい。ラックギヤ１０９の第１の端部１０９５は、ピストン１１２の凹部３２００とのスナップ嵌合係合または摩擦嵌合係合を有することが好ましい。各々に、第１の端部１０９５および凹部３２００に形成されているデテント構造１０９６、３２９６があることが好ましい。これにより、これら構成要素の製造を容易にし、さらに、ラックギヤ１０９に対してピストン１１２に必要とされる場合がある、わずかなピボットのような動きをもたらす。

【００４３】

ピストンの別の方法の実施形態が図８に示され、全体として参照符号８１１２で表わされている。ピストン８１１２は、前縁８１２０と後縁８１２１とを持つほぼＶ字の形状を有する。前縁８１２０および後縁８１２１は、ピストン８１１２がシリンダ内を往復して駆動されるとき、シリンダ１１３の内部表面１１３０に密閉係合している。複数の縁、すなわち、シリンダ１１３の内部表面１１３０に密閉係合するピストン８１１２の前縁８１２０と追従縁８１２１の使用により、ダブル密閉をもたらし、陽圧と負圧とを生成する効果を増大する。

【００４４】

図３から図７を参照すると、モータ１２５は、可変速度であることが好ましい。これにより、使用者が乳房のポンプ吸い出しのサイクル時間を制御して変えることを可能にする。搾乳ポンプ１００は、さらに、振動を減少して、底部ハウジング１０３にモータ１２５を固定するために、モータカバー１０７とベアリング１０８とを有する。

【００４５】
陽圧および負圧は、シリンダ１１３の排気量を変更することによって変えられることが可能である。この実施形態では、これは、光電子または光センサシステムの使用によって行われる。光センサシステムは、２つ以上の光センサ１２１と位置スイッチ１２４とを有する。光センサ１２１は、ラックギヤが往復して移動するとき、ラックギヤ１０９の開口５０の数をカウントする。したがって、使用者は、ラックギヤ１０９が進む移動量を制御することが可能であり、相応じて、シリンダ１１３内の排気量を制御することが可能である。例えば、ホイール上のスロットをカウントするコード化したホイール、ベルトの歯のカウント、これ自体の回転をカウントするロータリーエンコーダ、または、ホール効果センサなどの、別の排気量または移動量モニタがさらに使用可能である。

【００４６】
ピストン１１２がシリンダ１１３の前に適切に移動することを確実にするために、光センサシステムは、さらに、シリンダの前に位置されることが好ましい、カウンタ用スタータとして機能する位置スイッチ１２４を含む。別の方法として、この位置スイッチは、光センサ１２１によって探知可能な異なるサイズまたは形状を有する開口５０であってよい。

【００４７】
ラックギヤ１０９は、さらに、それに取り付けられる安全メカニズムを有することが可能である。光センサ１２１は、ラックギヤ１０９が後方に移動するとき開口５０を読み取り続ける。なんらかの理由のために、ラックギヤ１０９がターゲットを見失い、はるか遠くに移動する場合、安全装置が、位置スイッチを起動する。ラックギヤ１０９が後方に移動する間に位置スイッチが起動されるとき、ソフトウェアが、再度前方に移動して、位置決め位置に戻るように、そのシステムを起動することが可能である。

【００４８】
搾乳ポンプ１００は、ラックギヤ１０９全体にわたり位置決めされているガイドカバー１１１を有する。ガイドカバー１１１は、ラックギヤ１０９の相互の動きをガイドして、消振することによって、搾乳ポンプに安全性を追加する。ガイドカバー１１１は、さらに、光センサ１２１と開口５０との整列不良のリスクを減少することによって、光センサシステムに精度をもたらす。

【００４９】
光センサシステムおよびモータ１２５は、ＰＣまたは回路基板１２０に接続されることが好ましい。したがって、陽圧および負圧の量に応じて変換するピストン１１２の移動量、およびサイクル時間に応じて変換するピストン速度は、電子的に制御される。

【００５０】
図１５から図１９を参照すると、本発明の駆動システムの好ましい実施形態が示され、全体として参照符号１５００で表わされている。駆動システム１５００は、図１から図７の搾乳ポンプ１００と共に使用可能であり、シリンダ１１３とのピストン１１２の線形の相互の動きをもたらす。

【００５１】
駆動システム１５００は、中に組み込まれるギヤ減速を有するラックおよびピニオン駆動のためのベルト駆動システムである。駆動システム１５００は、第１の駆動ホイールまたはプーリ１５１０と、第１の駆動ホイール１５１０に固定されている第２のギヤ、駆動ホイールまたはプーリ１５２０と、第３のギヤ、駆動ホイールまたはプーリ４５３０と、第３のギヤに固定されているピニオンギヤ１５４０とを有する。

【００５２】
第１の駆動ホイール１５１０は、第１のベルト１５５０によってモータ駆動シャフト１２６に動作的に接続されている。好ましい実施形態では、第１のベルト１５５０は、歯形のないベルトである。第１のベルト１５５０は、弾力性または柔軟性を有することがより好ましい。柔軟性または弾力性のあるベルト１５５０の使用により、駆動シャフト１２６と第１の駆動ホイール１５１０との間の確実な接続をもたらし、さらに、騒音と振動とを

減少する。駆動シャフト１２６および第１の駆動ホイール１５１０は、円滑な外側表面を有し、これの上に第１のベルト１５５０は固定されている。

【００５３】

第１の駆動ホイール１５１０は、第１の同軸シャフト１５１５によって第２のギヤ１５２０に動作的に接続されている。好ましい実施形態では、第１のシャフト１５１５は、対向する第１のベアリング１５１７間に回転可能に取り付けられる。しかしながら、別の方法の回転可能な取付構成または固定構造も使用可能である。騒音と振動とを減少するために、モータシャフト１２６および第１の駆動ホイール１５１０は、金属で作られる。第１の駆動ホイール１５１０および第２のギヤ１５２０は、モータシャフト１２６とピニオンギヤ１５４０との間のギヤ減速を部分的にもたらす異なる直径を有する。

【００５４】

第２のギヤ１５２０は、第２のベルト１５７０によって第３のギヤ１５３０に動作的に接続されている。第２のベルト１５７０は、第２のギヤ１５２０と第３のギヤ１５３０との周辺に沿って形成されている歯１５８０と噛み合う、歯１５７５を有することが好ましい。第２のギヤ１５２０および第３のギヤ１５３０は、モータシャフト１２６とピニオンギヤ１５４０との間にギヤ減速を部分的にもたらす異なる直径を有する。駆動システム１５００は、さらに、第２のベルト１５７０に引張りをもたらす引張りプーリ１５８０を有することが可能である。

【００５５】

第３のギヤ１５３０は、第２の同軸シャフト１５３５によってピニオンギヤ１５４０に動作的に接続されている。好ましい実施形態では、第２のシャフト１５３５は、対向する第２のベアリング１５３７間に回転可能に取り付けられる。しかしながら、別の方法の回転可能な取り付け構成または固定構造も使用可能である。第３のギヤ１５３０は、第２のシャフト１５３５に沿うピニオンギヤ１５４０と一体化して成形されることが好ましい。

【００５６】

ピニオンギヤ１５４０は、ラックギヤ１０９の歯１０９０と係合する歯１５４５を有する。モータ１２５が始動されるとき、シャフト１２６の回転運動は、両方向にラックギヤ１０９の単一軸に沿う相互の長手方向運動に変換される。駆動システム１５００は、第１のベルト１５５０と、第２のベルト１５７０と、第１の駆動ホイールまたはギヤ１５１０と、第２の駆動ホイールまたはギヤ１５２０と、第３の駆動ホイールまたはギヤ１５３０との使用を介して、モータシャフト１２６とピニオンギヤ１５４０との間の動きの所望の割合、すなわち、ギヤ減速をもたらすことができる。

【００５７】

歯形のないベルト１５５０と歯形ベルト１５７０との組合せの使用により、騒音と振動とを減少すると同時に、搾乳ポンプ１００のための所望の速度と圧力とで、必要な往復の線形運動をもたらすことができる確実で、丈夫な駆動システム１５００を維持する。

【００５８】

図２０から図２６を参照すると、本発明の駆動システムの別の方法の実施形態が示され、全体として参照符号４５００で表わされている。駆動システム４５００は、図１から図７の搾乳ポンプ１００と共に使用可能であり、シリンダ１１３とのピストン１１２の線形の相互の動きをもたらす。

【００５９】

駆動システム４５００は、中に組み込まれるギヤ減速を有するベルト駆動システムである。駆動システム４５００は、第１のギヤ、駆動ホイール、またはプーリ４５１０と、第１のギヤに固定されている第２のギヤ、駆動ホイールまたはプーリ４５２０と、第３のギヤ、駆動ホイールまたはプーリ４５３０と、第３のギヤに固定されているピニオンギヤ４５４０とを有する。

【００６０】

第１のギヤ４５１０は、第１のベルト４５５０によってモータ駆動シャフト１２６に動作的に接続されている。好ましい実施形態では、第１のベルト４５５０は複数のベルトで

あり、３つのベルトであることがより好ましい。第１のベルト４５５０は、歯形のないベルトであることが好ましい。第１のベルト４５５０は、弾力性または柔軟性を有するＯ－リングであることがより好ましい。例えば、Ｏ－リングなどの柔軟な、または弾力性のあるベルト４５５０の使用により、駆動シャフト１２６と第１のギヤ４５１０との間の確実な接続をもたらし、さらに、騒音と振動とを減少する。駆動シャフト１２６および第１のギヤ４５１０は、各々に、中に形成されている環状のチャネル４５５５、４５６０を有する。環状のチャネル４５５５、４５６０は、第１のベルト４５５０を適所に保持するのを助け、駆動システム４５００のアセンブリを容易にするガイドである。

【００６１】

第１のギヤ４５１０は、第１の同軸シャフト４５１５によって第２のギヤ４５２０に動作的に接続されている。この別の方法の実施形態では、第１のシャフト４５１５は、対向する第１のベアリング４５１７間に回転可能に取り付けられる。しかしながら、別の方法の回転可能な取付構成または固定構造も使用可能である。騒音と振動とを減少するために、モータシャフト１２６および第１のギヤ４５１０は、金属で作られる。第１のギヤ４５１０および第２のギヤ４５２０は、モータシャフト１２６とピニオンギヤ４５４０との間にギヤ減速を部分的にもたらす異なる直径を有する。

【００６２】

第２のギヤ４５２０は、第２のベルト４５７０によって第３のギヤ４５３０に動作的に接続されている。この第２のベルト４５７０は、第２のギヤ４５２０と第３のギヤ４５３０との周辺に沿って形成されている歯４５８０と噛み合っている、歯４５７５を有することが好ましい。第２のギヤ４５２０および第３のギヤ４５３０は、モータシャフト１２６とピニオンギヤ４５４０との間にギヤ減速を部分的にもたらす異なる直径を有する。駆動システム４５００は、さらに、第２のベルト４５７０に引張りをもたらす引張りプーリ４５８０を有することが可能である。

【００６３】

第３のギヤ４５３０は、第２の同軸シャフト４５３５によってピニオンギヤ４５４０に動作的に接続されている。この別の方法の実施形態では、第２のシャフト４５３５は、対向する第２のベアリング４５３７間に回転可能に取り付けられる。しかしながら、別の方法の回転可能な取り付け構成または固定構造も使用可能である。第３のギヤ４５３０は、第２のシャフト４５３５に沿うピニオンギヤ４５４０と一体化して成形されることが好ましい。

【００６４】

ピニオンギヤ４５４０は、ラックギヤ１０９の歯１０９０と係合する歯４５４５を有する。モータ１２５が始動されるとき、シャフト１２６の回転運動は、両方向にラックギヤ１０９の単一軸に沿う相互の長手方向運動に変換される。駆動システム４５００は、第１のベルト４５５０と、第２のベルト４５７０と、第１のギヤ４５１０と、第２のギヤ４５２０と、第３のギヤ４５３０との使用を介して、モータシャフト１２６とピニオンギヤ４５４０との間の動きの所望の割合、すなわち、ギヤ減速をもたらすことができる。

【００６５】

歯形のないＯ－リングベルト４５５０と歯形ベルト４５７０との組合せの使用により、騒音と振動とを減少すると同時に、搾乳ポンプ１００のための所望の速度と圧力とで、必要な往復の線形運動をもたらすことができる、確実で丈夫な駆動システム４５００を維持する。

【００６６】

上記に説明されている駆動システム１５００、４５００の実施形態は、ギヤ減速のためにベルトを利用する。しかしながら、別の方法の実施形態は、搾乳ポンプ１００を駆動するラックおよびピニオンギヤ装置に伝達される所望の割合にギヤ装置を減速する、ギヤボックスを使用することが可能である。

【００６７】

図３から図９を参照すると、シリンダ１１３は、乳房カップ４００に陽圧と負圧とを供

給する供給コネクタ１１５に固定されている供給チューブ１１６を有する。供給コネクタは、貯蔵区画２１０に配置されている出口２１５を有することが好ましい。空気管３５０は、出口２１５に固定され、さらに、乳房カップ４００に固定可能である。貯蔵区画２１０は、ポンプ吸い出し操作の間、開口または閉鎖可能である。シリンダ１１３は、約１．５ｉｎ．Ｈｇに設定されることが好ましい圧力リリーフバルブ２０００（図９に図示）と流体連絡する。

【００６８】

圧力リリーフバルブ２０００は、取り入れ口２０１０と排気装置２０５０とを有する。取り入れ口２０１０は、シリンダ１１３と流体連絡し、排気装置２０５０は、管３５０によって、乳房カップ４００と流体連絡する。圧力リリーフバルブ２０００は、取り入れ口２０１０と排気装置２０５０と流体連絡するリリーフ排気装置２１００を有する。リリーフ排気装置２１００は、ほぼ管状であり、リリーフアセンブリ２２００に固定されている。

【００６９】

リリーフアセンブリ２２００は、柔軟なインサート２２１０と、付勢部材２２２０と、保持部材２２３０とを有する。柔軟なインサート２２１０は、リリーフ排気装置２１００の内部表面と密閉係合し、空気がリリーフ排気装置を通って抜け出ることを防止する。インサート２２１０は、付勢部材２２２０と噛み合う固定部材２２１５を有する。この実施形態では、固定部材２２１５は、付勢部材２２２０の内側容積部に受容される十字形構造である。付勢部材２２２０は、スプリングであることが好ましい。付勢部材２２２０は、コイルスプリングであることがより好ましい。保持部材２２３０は、リリーフ排気装置２１００の外側表面に位置決めされている対応する１対の係合突出部２１０５と係合する、対向する保持アーム２２３５を有するキャップ状構造である。インサート２２１０およびスプリング２２２０は、キャップ２２３０によってリリーフ排気装置２１００の内側容積部に保持されている。

【００７０】

スプリング２２２０は、圧力リリーフバルブ２０００のリリーフ圧力に等しい付勢強度または抵抗を有する。陽圧が、この実施形態では約１．５ｉｎ．Ｈｇに設定されることが好ましい、リリーフ圧力を超えるとき、インサート２２１０の内部表面に生成される力が、スプリング２２２０の付勢力を圧倒し、インサートはキャップ２２３０の方へ向い、リリーフ排気装置２１００の内側容積部の外側に移動する。空気は、圧力リリーフバルブの陽圧がスプリング２２２０の付勢強度未満に減少するまで、リリーフ排気装置２１００を通って圧力リリーフバルブ２０００を抜け出て、その時にインサート２２１０は、リリーフ排気装置の内側容積部内に戻って移動し、リリーフ排気装置の内部表面に密閉係合する。

【００７１】

さらに、図３２を参照すると、圧力リリーフバルブ２０００は、インサート２２１１と付勢部材２２２１とを含む好ましいリリーフアセンブリ２２０１と共に示されている。リリーフアセンブリ２２０１は、上記に説明されているように、リリーフアセンブリ２２００のインサート２２１０とスプリング２２２０と同様に機能する。インサート２２１１は、ボールであり、付勢部材２２２１は、シリンダ形状を有する発泡体である。リリーフアセンブリ２２０１は、ボール２２１１がリリーフ排気装置２１００内でいっそう容易に組立られるのが利点である。加えて、発泡体シリンダ２２２１は、これがボール２２１１と容易に噛み合い、不変のスプリング稼働力をもたらすのでいっそう不変である。加えて、別の方法の圧力リリーフバルブが使用されることが可能であり、それは、「マッサージ強度」、すなわち、使用者の乳房への陽圧の量が制御可能であるように調節可能である。

【００７２】

図３に示されている回路基板１２０により、使用者がいくつかのレベルの速度といくつかのレベルの吸引力をプログラムすることを可能にする。この実施形態では、速度（サイクル時間）は、約４５サイクル／分（ｃｐｍ）から約７５ｃｐｍの範囲にわたる。本発明

は、速度範囲内でかなり多数の速度レベルの事前設定プログラミングを行う。レベルの数は、約２つから約８つのレベルであることが好ましい。使用者は、速度範囲内で５つのレベルの速度をプログラムすることが可能であることがより好ましい。本発明は、さらに、使用者による速度レベルのプログラミングも想定している。

【００７３】

単一の乳房カップ４００および図１５から図２１に示されている好ましい駆動システム１５００と共に使用する吸引力範囲は、約３ｉｎ．Ｈｇから約１０ｉｎ．Ｈｇであり、２つの乳房カップのためには、約３ｉｎ．Ｈｇから約８ｉｎ．Ｈｇである。単一の乳房カップ４００および図３および図４に示されているギヤボックスシステムと共に使用する吸引力範囲は、約３ｉｎ．Ｈｇから約９ｉｎ．Ｈｇであり、２つの乳房カップのためには、約３ｉｎ．Ｈｇから約８ｉｎ．Ｈｇである。本発明は、吸引力範囲内でかなり多数の吸引レベルの事前設定プログラミングを行う。レベルの数は、約２つから約８つのレベルであることが好ましい。使用者は、吸引力範囲内で５つのレベルの吸引をプログラムすることが可能であることがより好ましい。本発明は、さらに、使用者による吸引レベルのプログラミングも想定している。

【００７４】

コンピュータソフトウェアは、さらに、陽圧および負圧の量を制御するのに使用可能である。これにより、陽圧および負圧の量が、使用者用に個人化され、さらに、効率を最大にするために、ポンプ吸い出しプロセスの期間全体にわたり変えられることを可能にする。

【００７５】

搾乳ポンプ１００は、ギヤモータ１２５、ラックおよびピニオンセット１０９、１１０およびピストンシステム１１２、１１３と共に、ソフトウェア駆動型回路基板１２０によって制御されることが好ましい。ソフトウェアおよびシステムは、最大の柔軟性をもたらすように、そして、圧力曲線または「波」の変更を容易にするように設計される。ソフトウェアが、モータ１２５の速度と、ピストン１１２がシリンダ１１３内で進む移動量とを制御するので、このことは実現可能である。ピストン１１２の移動量は、圧力レベルに関連する。ソフトウェアで、速度と圧力レベルとを制御することによって、圧力曲線または「波」は、制御可能である。

【００７６】

乳児の吸引力に類似するまたは母にもっとも心地よい特定の「波」または圧力曲線であるという決定が行われると、その場合、所望の波は、タイミング（モータ速度とピストンの移動量）を変更することによって得ることが可能である。ソフトウェアの使用を介して、使用者が、使用者のための心地よさを最大にするように、長期にわたり特定の圧力曲線とその圧力曲線の変化にメモリを適用する能力を有する。

【００７７】

この実施形態では、正弦波が、搾乳ポンプ１００の制御に使用されている。これは、もっとも心地よい圧力曲線が、使用者に挟んで締め付ける感触を与える鋭い圧力の高低がなく、正弦波に類似する圧力を徐々に増加したり減少したりするものであるという推定に基づく。ピストン１１２の往復運動は、所望の正弦波に似ている。しかしながら、鋭い圧力の頂点を回避するために、ピストン１１２のタイミングは、これらの高い点でスローダウンされ、圧力は、その波の最大および最小吸引力ポイントで時間の期間の間一定に保持される。これにより、使用者にいっそう心地よい安定した正弦波を有する圧力曲線という結果になる。

【００７８】

別の方法の波も、上述の波が母によって望ましいと決定される場合、圧力曲線に使用可能である。例えば、母が鋭い頂点を持つ「鋸歯」圧力曲線を好む場合、ピストン１１２のタイミングは、単純に往復サイクルに変更されることが可能であり、ピストン１１２が方向を変更するときの一時停止を最小にする。さらに、例えば、母が、「矩形曲線」を好む場合、ピストン１１２のタイミングは、ピストンが方向を変更しようとするときピストン

の位置を保持し、次に、迅速に下方に傾斜をつけて、これが上方に戻る傾斜をつける前に再度これの位置を保持するように変更可能である。これにより、「矩形曲線」波を生成することになる。

【００７９】

ソフトウェア制御の使用により、波または圧力曲線の多数の選択をもたらす。これにより、さらに、その柔軟性が１つの搾乳ポンプ１００でのより大きい選択を変更または提供することを可能にする。対照的に、最新のポンプは、圧力曲線波を変更する柔軟性を可能にしないという欠点を有する。搾乳ポンプ１００により、圧力と速度とのサイクル間制御が可能になる。好ましい実施形態では、これは、ピストン１１２とシリンダ１１３とを組み込む線形システムに動作的に接続されている可逆可変速度モータ１２５の使用を介して行われる。したがって、最新の装置は、繰り返して特定の正弦波圧力曲線を表面上使用することが可能であるのに対して、搾乳ポンプ１００は、あらゆるタイプの波を使用して、サイクルの間その波を変更する能力を有する。

【００８０】

本発明の制御システムおよびソフトウェアは、閉ループ制御システムまたはサイクル間リアルタイム調節をもたらす。したがって、進められるピストンの移動量および速度などの制御変数のリアルタイムなモニタリングが生じる。モータおよび他の構成要素が老化して、摩耗するとき、閉ループ制御システムは、使用者によって求められる精密なサイクル時間と圧力とを与えるために、上述の有害な変化の原因となる。リアルタイムなモニタリングおよび制御により、トルクの変化にもかかわらず、単一のおよび２つのカップのポンプ吸い出しの両方のために効果的に等しい速度レベルを供給する。

【００８１】

シリンダ１１３は、圧力差穴７５を有する。圧力差穴７５は、シリンダ１１３の底部面８０に沿って位置されていることが好ましい。圧力差穴７５は、排気装置穴１０１３および供給チューブ１１６よりも実質的に小さく、それを通して、空気は、陽圧と負圧とを生成するために流動する。圧力差穴７５は、負圧の量と比べると、陽圧の量の変化をもたらす。圧力差穴７５は、真空工程の終りに、「損失した」空気を供給するために、高い範囲の真空に効力がある。陽圧工程時、少量の空気が圧力差穴７５を通してリリースされるが、空気は、圧力のレベルが高くなるとき、負圧工程の間に再導入される。

【００８２】

図３３を参照すると、圧力差インサート７６の好ましい実施形態を持つシリンダ１１３が示されている。圧力差穴７５は、圧力差インサート７６を通して配置されている。インサート７６は、次に、シリンダの壁を通して配置されているシリンダ穴７７を通ってシリンダ１１３に接続されている。インサート７６は、シリンダ穴７７にプレス嵌合されることが好ましい。しかしながら、例えば、ねじまたは接着剤などの別の方法の接続方法も使用可能である。圧力差インサート７６は、きわめて小さい許容差内の精密な直径を持つ圧力差穴７５の機械加工を可能にする、機械加工金属部品である。

【００８３】

インサート７６の使用により、プラスチック部分に穴を成形する、または穴をあけることのいずれかにおいて、精度がかなり欠如するため、シリンダ１１３の壁を通して直接圧力差穴７５を配置することが、より有利である。加えて、圧力差インサート７６は、シリンダの穴７７を通して選択的に挿入されることが可能であり、そのために、複数のサイズの異なる圧力差穴７５を有する複数のインサートが使用可能である。圧力差穴７５のために異なる直径を設けることによって、ポンプによって生成される吸引レベルが変えられることが可能である。

【００８４】

圧力差穴７５により、搾乳ポンプ１００の使用の間長期にわたり損失される空気を、負圧工程の間に再生することを可能にし、そのために、陽圧は、長期にわたり正確に維持可能である。搾乳ポンプ１００のテストの間、予期しない重大な結果が、圧力差穴７５の異なるサイズの直径の使用から生じた。約０．１５ｍｍから約０．７５ｍｍとの間の直径を

有する圧力差穴７５が、所望の負圧をもたらす間の長期にわたり精密な陽圧を維持したということが発見された。シリンダ１１３の容量は、１２６ｃｍ^{3}であった。圧力差穴７５は、約０．２５ｍｍから約０．５ｍｍの間の直径を有することが好ましく、直径が約０．３ｍｍであることが最も好ましい。

【００８５】

図１０を参照すると、シリンダ１１３は、ゼロドラフトシリンダとして形成されている。ピストン１１２の外径は、シリンダの内部で空気を移動させるために、シリンダ１１３の内径ｄとの密閉を生成し、乳房への真空と圧力を生成する。搾乳ポンプ１００は、ピストン１１２に対する妨害または抵抗を最小にしながら、適切な密閉を生成するために、シリンダの全長を通して不変の内径ｄを有するシリンダ１１３を必要とする。典型的な射出成形部品は、シリンダ１１３の一様でない内径ｄを生成するドラフト角度を必要とする。

【００８６】

シリンダ１１３は、一様な内径ｄを設けるゼロドラフトシリンダとして成形されることが好ましく、単一の部品に成形されることがより好ましい。図１０に示されているように、シリンダ１１３は、一体形のプラスチック射出成形部品である。２つの部分からなるシリンダまたは機械加工シリンダは、単一の部品のゼロドラフトシリンダ１１３が克服する欠点を有する。２つの部品からなるシリンダは、端部キャップに取り付けられる押出し加工チューブを必要とし、２つの部品は、溶接を使用して、または、接着剤を使用して接合されている。機械加工部品は、一般に金属チューブである。ゼロドラフトの一体形シリンダ１１３に対する利点の１つは、これが射出成形可能であることである。

【００８７】

図３から図１０を参照すると、ボタンパッド１０５が、搾乳ポンプ１００用ユーザインターフェースまたは制御メカニズムである。ボタンパッド１０５は、吸引と速度とのレベルを増大または減少する、１対の正のキーおよび負のキーを有する。パッド１０５は、さらに、オン／オフスイッチを含む。

【００８８】

シリンダ１１３内のピストン１１２の相互の往復運動により、搾乳ポンプ１００は、単一のホースまたは管３５０を通して、女性の乳房に陽圧と負圧との両方を供給する。この実施形態が、陽圧と負圧とを生成するのにピストン／シリンダメカニズムを使用するのに対して、別の方法の膨張可能な容積部または圧力源もまた、使用できる。上述の別の方法の実施形態は、よりわずかな部品を必要とするベローメカニズムまたはダイヤフラムを含む。

【００８９】

図１１と図１２とを参照すると、本発明の乳房カップ、フードまたは乳房受容部材４００が示されている。乳房カップ４００は、空気用オリフィス５６０と、柔軟なインサート６００と、ホルダ７００とを有する、ハウジング５００を有する。ハウジング５００は、剛性構造であり、柔軟なインサート６００は、柔軟な構造である。ハウジング５００は、ハウジングとインサートとの間に排気容積部５１０を形成するために、インサート６００と密閉係合するように構成されている。じょうご状形状のインサート６００は、乳房を受容するために内側容積部６５５を設ける。空気用オリフィス５６０は、排気容積部５１０と流体連絡している。

【００９０】

搾乳ポンプ１００は、空気用オリフィス５６０に接続されて、シリンダ１１３と流体連絡する空気管３５０によって、乳房カップ４００と流体連絡して配置されている。搾乳ポンプは、乳房カップ４００に陽圧と負圧との両方を供給する。搾乳ポンプ１００によって生成される陽圧および負圧は、空気用オリフィス５６０を介して排気容積部５１０の内外に空気を流動させる。乳房カップ４００に供給される陽圧および負圧は、柔軟なインサート６００、特に、排気容積部５１０を膨張および収縮させて、往復する正の力と負の力とを使用者の乳房に印加する。

【００９１】

排気容積部５１０の排気と、ハウジング５００へのインサート６００のかなりのへこみとによって生成される負圧により、乳房カップ４００は、本質的に中に組み込まれる最大吸引レベルを有する。真空源から直接乳首に真空をもたらす、したがって、過剰吸引に対して損傷を受けやすい最新の装置とは違って、乳房カップ４００は、排気容積部５１０に基づき最大負圧をもたらすことだけが可能である。すべての空気が排気容積部５１０から排気されると、乳房カップ４００は、乳房に印加される負圧または負の力をもはや増大しないことが好ましい。搾乳ポンプ１００および乳房カップ４００は、空気用オリフィス５６０に接続されている単一の空気管３５０を介して、使用者の乳房に陽圧と負圧とを印加することができる。

【００９２】

排気容積部５１０内に設定される容量は、２２立方センチメートルから５２立方センチメートルの間であることが好ましく、３２立方センチメートルから４２立方センチメートルの間であることがより好ましい。膨張可能で、収縮可能な排気容積部５１０は、使用者の乳房に印加可能である負圧の量に上限を設け、それは、さらに、搾乳ポンプ１００の使用における安全な機構としての役割を果たす。加えて、インサート６００とハウジング５００との密閉係合は、使用者の乳房と搾乳ポンプ１００との間にバリアを設け、少しの母乳も空気管３５０または搾乳ポンプに入らないようにする。インサート６００は、さらに、マッサージ部材６３４を含むことが可能である。マッサージ部材６３４は、星形状を有し、これは、乳房への付加的なマッサージ作用をもたらす。別の形状が、さらに、マッサージ部材６３４に使用可能である。

【００９３】

図２７から図２９を参照すると、乳房カップ４００は、乳房１について部分断面で示されている。乳房１は、乳輪３を持つ乳首２と、乳腺５によって供給される乳湖またはダクト４とを有する。乳房カップ４００は、インサート６００の空気袋６８５とホルダ７００の管状部材７３５とを有する。空気袋６８５は、排気容積部５１０を部分的に規定する。空気が空気袋６８５と排気容積部５１０とから排出され、そのために、インサート６００がハウジング５００の方へ向って、および、ハウジング５００に対抗して引張られるとき、負圧、真空または負の力は、乳房１に印加される。

【００９４】

管状部材７３５は、空気袋６８５にほぼ隣接して配置されて、インサート６００を部分的に延通する。管状部材７３５は、乳房１と空気袋６８５との間の剛性バリアであり、乳房が空気袋と接触して突き当ることを防止し、それにより、それらの膨張と収縮との量を減少する、したがって、乳房に印加される往復圧力を減少する。

【００９５】

乳房１への乳房カップ４００の位置決めは、排気容積部５１０によってほぼ包囲される乳首２と、乳輪３と、乳ダクト４という結果になる。排気容積部によってほぼ包囲される乳首２、および乳輪３の前部で空気袋６８５に隣接する剛性のバリアを生成するための管状部材７３５の使用は、図２９に表わされているように、負圧工程またはサイクルの間の排気容積部５１０内の空気排出時、乳首２に印加される負圧勾配、真空または負の力１０という結果になる。負圧勾配または力１０は、軸方向成分または軸方向Ａよりも大きい横方向成分または横方向Ｌを有する。負圧勾配または力１０およびより大きい横方向成分Ｌにより、乳首２を軸方向以上に横方向に引張らさせるまたは吸引させ、それは、乳ダクト４から母乳を搾り出させるのにかなり大きい効果があることを示した。負圧勾配または力１０は、さらに、軸方向Ａに沿って乳首を軸方向に伸張または膨張するのに相反して乳首２を幾分広げることにより、使用者にとっていっそう心地よく、授乳の間の乳児の吸引に近いことを示した。

【００９６】

排気容積部５１０は、ハウジングがインサート６００に固定されているハウジング５００の前縁にほとんど延入し、それにより、横方向成分Ｌに沿って乳首２の横方向吸引と横方向の動きとを生じる負圧工程またはサイクルの間、負圧勾配または力１０を生成するの

に役に立つ。図２９に示されているように、負圧勾配、真空またはカ１０は、乳輪３の外側周辺を越えて延在し、負圧工程またはサイクルの間それにほぼ横方向に印加され、それにより、さらに、軸方向成分Ａと比べてより大きい横方向成分Ｌで乳首２への力を生成するのに役立ち、したがって、乳首を広げる。

【００９７】

管状部材７３５の位置決めは、負圧工程またはサイクルの間、乳首２からまたは乳首２の前部で軸方向に負圧勾配またはカ１０を減少する手助けをし、それにより、乳首の軸方向膨張に関連する不快感を減少する。管状部材７３５は、管状部材壁に沿って形成されている開口（図示せず）を有する。負圧工程の間に管状部材７３５の方へ引張られる柔らかい乳房１に対して、開口により、乳首２の末端部への負圧の印加または真空が可能になる。

【００９８】

図３０と図３１とを参照すると、真空ライン２１を介して真空源に接続される最新の乳房カップ２０が示されている。最新の乳房カップ２０は、乳房１に係合することが可能なフード２２と、そのフードに取り付けられる円筒形延長部２３とを有する。円筒形延長部２３は、真空ライン２１と収集部材２４とに流体連絡する。真空または負圧は、真空ラインから、円筒形延長部２３を介して、乳輪２に供給される。分離壁２７により、外観上、母乳が真空ライン２１に入ることを防止する。円筒形延長部２３内の空気の排出により、図３１に表わされているように、負圧工程の間、負圧勾配またはカ３０を生成する。

【００９９】

負圧勾配またはカ３０は、負圧工程の間、横方向成分Ｌと比べてより大きい軸方向成分Ａを有し、乳首２を横方向以上に軸方向に引張らさせるまたは吸引させ、それは、乳ダクトから母乳を搾り出させるのにかなり効果のないことを示した。負圧工程の間、横方向成分Ｌと比べてより大きい軸方向成分Ａを有する負圧勾配またはカ３０は、さらに、使用者にとって不快であることを示した。真空または負圧は、負圧工程またはサイクルの間、乳首２からまたは乳首２の前部で軸方向に供給され、それにより、乳首の軸方向伸張と膨張に関連する不快感を生じる。

【０１００】

乳房カップ４００は、負圧工程またはサイクルの間、乳首２に負圧勾配、真空またはカ１０を印加する排気容積部５１０を部分的に規定する、柔軟なインサート６００を使用すると同時に、本発明は、負圧勾配、真空またはカ１０を生成する他の設計と構成との使用を意図している。負圧工程またはサイクルの間、軸方向成分Ａに沿う乳首の伸張または膨張に相反して、横方向成分Ｌに沿って乳首をより大きく広げさせる乳房カップ４００のための別の方法の設計が、本発明によって意図されている。さらに、負圧工程の間、平均軸方向成分Ａよりも大きい平均横方向成分Ｌを有する負の力を乳首２に印加する乳房カップ４００のための別の方法の設計が、本発明によって意図されている。さらに、負圧工程の間、平均軸方向成分Ａよりも大きい平均横方向成分Ｌを有する負圧勾配または真空を乳首２に印加する乳房カップ４００のための別の方法の設計が本発明によって意図されている。

【０１０１】

好ましい実施形態は、乳房カップ４００に圧力を供給するモータ付きポンプ１００の使用を説明すると同時に、本発明は、乳房カップ４００に固定されるポンプ吸い出しメカニズムを含む、乳房カップ４００と共に使用する手動ポンプの使用を意図する。加えて、本発明は、乳首２の末端端部または前部に印加される負圧、真空または負の力を減少する、および／または、横方向成分Ｌに比べて、乳首２に印加される負圧、真空または負の力の軸方向成分Ａを減少する、他のバリア構造、設計または方法を意図する。

【０１０２】

本発明は、使用者が搾乳ポンプ１００にだけではなく乳房カップ４００に、陽圧または負圧の量を別の方法で選択的に制御できるように、排気容積部５１０と流体連絡するバルブまたは他の周知のリリースメカニズム（図示せず）の使用を意図する。乳房カップ４０

０のバルブまたはリリースメカニズムは、さらに、使用者にとって不快である場合、安全な機構としての迅速なリリースメカニズムでよい。バルブまたはリリースメカニズムは、さらに、陽圧または負圧だけが乳房カップ４００で生成されることを選択的に可能にするために使用できる。

【０１０３】

容易に組立可能である３つの独立した部品、すなわち、ハウジング５００と、インサート６００と、ホルダ７００の使用による乳房カップ４００のモジュール性により、本発明が可変サイズと形状との乳房を収容するためにキットを含むことを可能にする。キットは、複数の異なるサイズのハウジング５００およびインサート６００と、異なる形状のハウジング５００およびインサート６００とを含み、異なるサイズの乳房と異なる形状の乳房とを収容する。複数の異なるハウジング５００およびインサート６００は、すべて、ホルダ７００に組立可能であり、搾乳ポンプ１００に接続可能である。ハウジング５００とインサート６００とのサイズの変化の一例は、ハウジングとインサートとの端から端までの内径と外径と、ハウジングとインサートとの全長とを含む。ハウジング５００とインサート６００との形状の変化の一例は、テーパ角度を変えることと、ハウジングとインサートとの前縁の円形形状を変更することとを含む。加えて、本発明のモジュール性および互換性により、異なるインサート６００への異なる形状またはサイズのマッサージ部材、あるいは突起６３４の使用を可能にする。

【０１０４】

本発明は、さらに、搾乳ポンプ１００と共に使用する複数の異なる乳房カップ４００を形成するために、ハウジング５００とホルダ７００とにすべて組立可能である、複数の異なるサイズまたは形状のインサート６００を含むキットを意図する。複数の異なるサイズのインサート６００は、異なるサイズの乳房を収容するために、さらに、排気容積部５１０を変更するために使用可能である。複数の異なる形状のインサート６００は、異なる形状の乳房を収容するために、また、例えば、インサートに形成される異なるマッサージ部材６３４などの異なるマッサージ効果を乳房に供給するために使用可能である。いくつかの別の方法のインサート６００の例示は、２００２年１２月２７日に出願された米国特許同時係属出願第１０／３３１，１８３号にいっそう完全に説明され、これの開示は、全体が参照してここに組み込まれる。

【０１０５】

搾乳ポンプシステムの好ましい実施形態は、使用者の乳房から流体分離する排気容積部５１０を有する乳房カップ４００を使用するのに対して、別の方法の乳房カップは、さらに、搾乳ポンプ１００と共に使用可能である。本発明の搾乳ポンプシステムの唯一の特徴は、例えば、本発明の制御システムまたはラックおよびピニオン駆動メカニズムなどの他のタイプの乳房カップと共に使用可能である。

【０１０６】

図３４を参照すると、本発明の乳房カップの別の方法の実施形態が示され、全体として参照符号５４００で表わされている。乳房カップ５４００は、インサート６００と共に使用可能である。乳房カップ５４００は、円筒形状ホルダ５７００に接続されているじょうご形状ハウジング５５００を有する。ホルダ５７００は、ハンドル５７２５と、圧力オリフィス５７５０と、圧力調節器５７７５とを有する。ハンドル５７２５は、人間工学に基づき輪郭付けされ、異なる保持角度をもたらす波状形状５７３０を有する。ハンドル５７２５は、じょうご形体５５００から対向する側のホルダ５７００に沿って配置されている。ハンドル５７２５は、握ることを容易にする材料で作られる、またはカバーされることが好ましい。ハンドル５７２５は、ポンプ吸い出しプロセスの間、使用者の手を和らげるように、様々なテクスチャ、突起および／または浮き出し加工を含む。

【０１０７】

圧力オリフィス５７５０は、搾乳ポンプ１００と流体連絡して乳房カップ５４００を配置するために、管３５０に取り付け可能である。圧力調節器５７７５は、圧力オリフィス５７５０と流体連絡し、使用者が搾乳ポンプ１００で調節を行う必要なく、乳房カップ５

４００で圧力を調節することを可能にする。この実施形態では、圧力調節器５７７５はダイアルであるが、別の方法のアクチュエータも使用可能である。

【０１０８】

図３５を参照すると、本発明の乳房カップの別の方法の実施形態が示され、全体として参照符号６４００で表わされている。乳房カップ６４００は、インサート６００と共に使用可能である。乳房カップ６４００は、ホルダ６７００に接続されているじょうご形体６５００を有する。ホルダ６７００は、ハンドル部分６７２５、６７２６と、圧力オリフィス６７５０と、圧力調節器６７７５とを有する。ハンドル部分６７２５、６７２６は、ホルダ６７００の両側に配置され、ホルダの握りを容易にする。ハンドル部分６７２５、６７２６は、握ることを容易にする材料で作られる、またはカバーされることが好ましい。ハンドル部分６７２５、６７２６は、ポンプ吸い出しプロセスの間、使用者の手を和らげるように、様々なテクスチャ、突起および／または浮き出し加工を含む。

【０１０９】

図１２に戻って参照すると、乳房カップ４００のホルダ７００は、第１のセットのねじ山７０１と、第２セットのねじ山７０２とを設ける。第１のねじ山７０１および第２のねじ山７０２は、異なる直径を有し、授乳と乳房ポンプ吸い出しに使用される２つの標準サイズのボトルまたはホルダ、すなわち、再利用可能な容器と使い捨て容器にフィットするようなサイズに作られる。第１のねじ山７０１および第２のねじ山７０２は、同じピッチを有し、同軸に整列されている。成形加工プロセスの間、これにより、スチール型枠コアがホルダ７００からねじを抜いて外されることが可能になる。

【０１１０】

図示されている実施形態は、乳房カップ４００に２つのねじ山、すなわち、第１のねじ山７０１と第２のねじ山７０２を示すのに対して、本発明は、例えば、哺乳瓶の乳首リングまたはキャップなどのホルダまたはボトルの使用を必要とする、他の乳児ケア製品への２つのねじ山の使用を意図する。図３６および図３７を参照すると、哺乳瓶の乳首リングが示され、全体として参照符号７０００で表わされている。哺乳瓶の乳首リング７０００は、開口７２５０を規定する内方に延長するフランジ７２００を持つ、周方向壁７１００を有する。哺乳瓶の乳首リング７０００は、上述の２つのねじ山、すなわち、第１のセットのねじ山７０１と第２のセットのねじ山７０２とを有する。哺乳瓶の乳首リング７０００は、第１のねじ山７０１によって再利用可能な容器か、または、第２のねじ山７０２によって使い捨て可能な容器かのいずれかと、哺乳瓶の乳首７５００との係合をもたらす。第１のねじ山７０１は、フランジ７２００から下方に延出し、第２のねじ山７０２は、周方向壁７１００に沿って形成されることが好ましい。

【０１１１】

図３８と図３９とを参照すると、キャップが示され、全体として参照符号８０００で表わされている。キャップ８０００は、頂部壁８２００に接続されている周方向壁８１００を有する。キャップ８０００は、さらに、上述の２つのねじ山、すなわち、第１のセットのねじ山７０１と第２のセットのねじ山７０２とを有する。キャップ８０００は、第１のねじ山７０１によって再利用可能な容器か、または、第２のねじ山７０２によって使い捨て可能な容器の、いずれかとの密閉をもたらす。第１のねじ山７０１は、頂部壁８２００から下方に延出し、第２のねじ山７０２は、周方向壁８１００に沿って形成されることが好ましい。

【０１１２】

図１３を参照すると、Ｔ－コネクタ３００は、三角形状バルブであり、それにより、使用者が、第１のオリフィス３１０と第２のオリフィス３２０との使用により、単一の乳房カップ４００か、または、２つの乳房カップかのいずれかを使用することを可能にする。搾乳ポンプ１００は、入口３３０で空気管３５０を介してｔ－コネクタ３００に接続されている。ｔ－コネクタ３００の単一の割りバルブ構成は、ダブルポンプ吸い出しに必要な管３５０の量を最小にする。Ｔ－コネクタ３００は、単一のポンプ吸い出しが望まれる場合、第１のオリフィス３１０か、または第２のオリフィス３２０かのいずれかを閉鎖する

、プラグ３４０を有する。プラグ３４０は、第１のオリフィス３１０または第２のオリフィス３２０との係合を容易にするために、ｔ－コネクタ３００の外側表面に係留されることが好ましい。

【０１１３】

図１４を参照すると、本発明の搾乳ポンプシステムにより母乳を絞り出す方法が示されている。使用者は、ステップ８００のように、搾乳ポンプ１００を「オン」にして搾乳ポンプ吸い出し操作を開始する。これにより、動力が搾乳ポンプ１００に供給される（ステップ８１０）。使用者は、次に、ステップ８２０のように、所望のサイクル時間と吸引レベルとを入力する。好ましい実施形態では、使用者は、選択するための５つのサイクル時間と吸引レベルとを有する。サイクル時間および吸引レベルは、ボタンパッド１０５を使用して入力される。

【０１１４】

ステップ８３０で、ＰＣボード１２０は、サイクル時間と吸引とに対する使用者の入力レベルに応じて、モータ速度とターゲットピストンの移動量とを設定する。サイクル時間および吸引レベルは、次に、ステップ８４０のように、使用者に表示される。この実施形態では、サイクル時間および吸引レベルは、レベルに対応する照明された光の数を持つ光２２５によって示される。ステップ８５０で、モータ１２５は始動され、ピストン１１２をシリンダ１１３の底部１７５の方へ向って移動させる。これにより、空気管３５０によって乳房カップ４００に供給される陽圧を生成する。

【０１１５】

ステップ８５５で、ＰＣボードは、それがピストン１１２との接触によって起動されたかどうかを決定するために、ホームスイッチをモニタする。ステップ８６０で、ホームスイッチが起動されたかどうかが決定される。ホームスイッチが起動された場合、ステップ８７０のようにそれはリセットされる。ステップ８８０で、モータ１２５は、次に逆転にされ、ピストン１１２をシリンダ１１３の頂部１８０の方へ向って移動させる。これにより、空気管３５０によって乳房カップ４００に供給される負圧を生成する。本発明の搾乳ポンプシステムの利点の１つは、同じ空気管３５０を介して陽圧と負圧との両方を供給することである。これにより洗浄を減少し、使用者の操作を簡素化する。

【０１１６】

使用者によって入力されるような吸引の適当な量を与えるために、光センサ１２１が、ステップ８９０のように、ラックの開口５０の数をカウントする。ステップ９００で、ＰＣボード１２０は、カウントされたラックの開口５０の数が、使用者によって入力されるようにターゲットのピストンの移動量と同等であるかどうかを決定する。ステップ９１０で、搾乳ポンプ１００が「オン」のままであるかどうかが決定される。搾乳ポンプ１００が止められた場合、ポンプ吸い出し操作は、ステップ９１５のように終了する。

【０１１７】

ステップ９２０で、使用者は新しいサイクル時間または吸引レベルを入力したかどうかが決定される。新しいサイクル時間または吸引レベルが入力された場合、ＰＣボード１２０は、サイクル時間と吸引力に対する使用者の入力レベルに応じてモータ速度とターゲットのピストン移動量とを設定し、ステップ８３０に逆戻りして、上述のステップを繰り返す。使用者が新しいサイクル時間または吸引レベルを入力しなかった場合、モータは再度逆転にされ、ピストン１１２をシリンダ１１３の底部１７５の方へ向って移動させる。これにより、空気管３５０によって乳房カップ４００に供給される陽圧を生成する。このプロセスにより、搾乳ポンプ１００は、搾乳ポンプが止められるまで、乳房カップ４００に陽圧と、次に負圧とを供給し続ける（ステップ９１０）。

【０１１８】

本発明の搾乳ポンプシステムは、かなり多数の構成要素を含み、使用者が旅行するときなどの遠い位置で使用可能である。様々な構成要素は、使いやすいようにバッグシステム内に配置可能である。上述のバッグシステムと上述のシステムの構成要素との一例は、２００２年１２月２７日に出願された、同一所有の米国特許同時係属出願第１０／３３１，

１３０号に開示され、これの開示は、参照してここに組み込まれる。

【０１１９】

本発明は、それの好ましい形態を特に参照して説明されてきたが、様々な変更および修正が、添付の特許請求の範囲に定義されているような本発明の精神と範囲とから逸脱することなく行われることは明らかである。

【図面の簡単な説明】

【０１２０】

【図１】本発明の搾乳ポンプシステムの搾乳ポンプの正面斜視図である。

【図２】開いた状態における、図１の搾乳ポンプの正面斜視図である。

【図３】図１の搾乳ポンプの分解斜視図である。

【図４】カバーのない図１の搾乳ポンプの平面図である。

【図５】本発明のピストンおよびシリンダの分解斜視図である。

【図６】図５のピストンおよびシリンダの一部分の分解側面図である。

【図７】図５のピストンの正面斜視図である。

【図８】本発明のピストンの別の方法の実施形態の分解斜視図である。

【図９】図１のシステムの圧力リリーフバルブの分解斜視図である。

【図１０】図５のシリンダの断面平面図である。

【図１１】本発明の乳房カップの正面斜視図である。

【図１２】図１１の乳房カップの側面断面図である。

【図１３】本発明のＴ－コネクタの背面斜視図である。

【図１４】図１と図１１とのシステムによる、乳房をポンプで吸い出す方法を示すフローチャートである。

【図１５】本発明の搾乳ポンプシステムのための搾乳ポンプの好ましい実施形態の平面斜視図である。

【図１６】図１５の搾乳ポンプの平面図である。

【図１７】図１５の搾乳ポンプの駆動システムの平面斜視図である。

【図１８】図１７の駆動システムの側面斜視図である。

【図１９】部分的に組立された、図１５の駆動システムのギヤ減速システムの部分の平面斜視図である。

【図２０】本発明の搾乳ポンプシステムのための搾乳ポンプの、別の方法の実施形態の平面斜視図である。

【図２１】図２０の搾乳ポンプの平面図である。

【図２２】図２０の搾乳ポンプの駆動システムの平面斜視図である。

【図２３】図２０の駆動システムの側面斜視図である。

【図２４】図２０の駆動システムのモータの平面斜視図である。

【図２５】部分的に組立された、図２０の駆動システムのギヤ減速システムの部分の平面斜視図である。

【図２６】部分的に組立された、図２０の駆動システムのギヤ減速システムの平面斜視図である。

【図２７】乳房と共に示した、図１１の乳房カップの部分断面側面図である。

【図２８】負圧工程前に乳房に当てられる、図２７の乳房カップの部分断面側面図である。

【図２９】乳房への負圧勾配または力の表示を示す、負圧工程の間の図２７の乳房カップと乳房の分解断面図である。

【図３０】負圧工程前に乳房に当てられる、従来技術の乳房カップの断面側面図である。

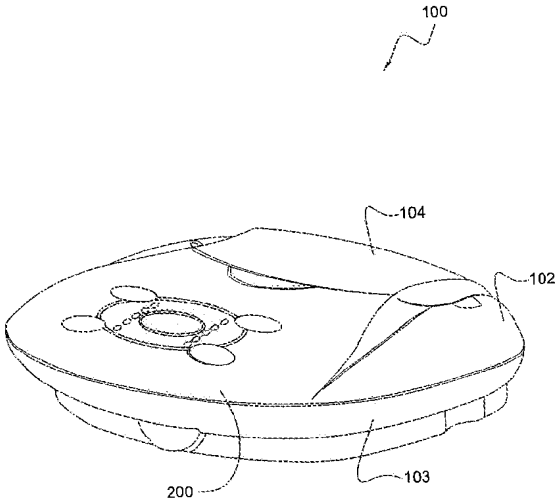
【図３１】乳房への負圧勾配または力の表示を示す、負圧工程の間の図３０の従来技術の乳房カップと乳房の分解断面図である。

【図３２】リリーフアセンブリの別の実施形態を持つ、図９の圧力リリーフバルブの分解斜視図である。

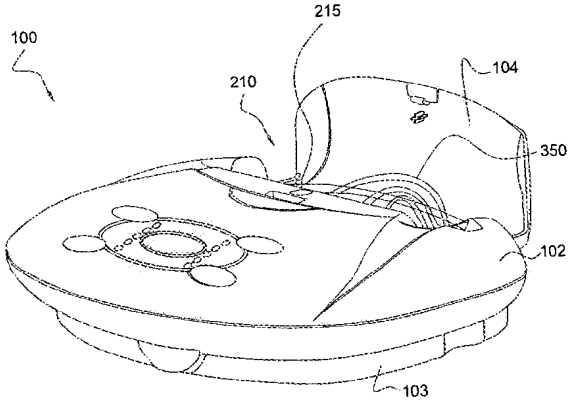
【図３３】圧力差穴の別の実施形態を持つ図５のシリンダの斜視図である。

【図３４】本発明の乳房カップの別の方法の実施形態である。
【図３５】本発明の乳房カップのもう１つの別の方法の実施形態である。
【図３６】本発明の哺乳瓶の乳首を持つ哺乳瓶の乳首リングの底面斜視図である。
【図３７】図３６の哺乳瓶の乳首リングと哺乳瓶の乳首との側面断面図である。
【図３８】本発明のキャップの底面斜視図である。
【図３９】図３８のキャップの側面断面図である。

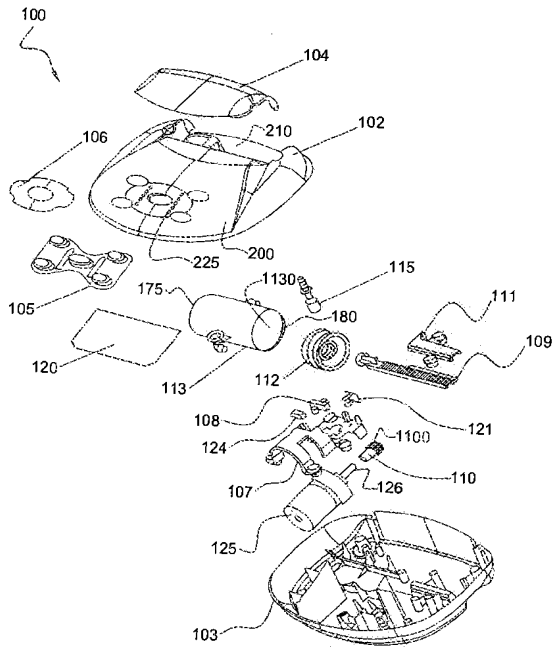
【図１】



【図２】



【図３】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112
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121
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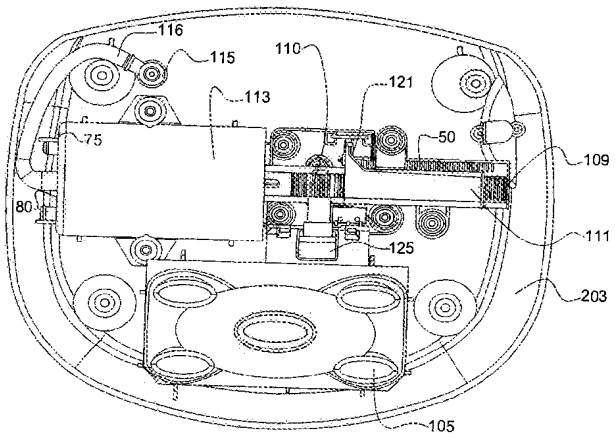
125
103

【図４】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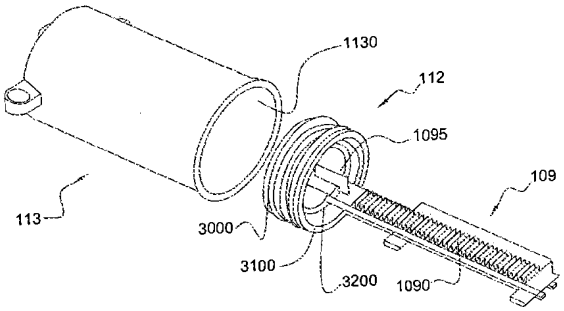
105

【図５】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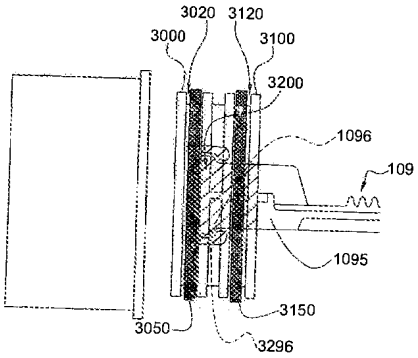
【図６】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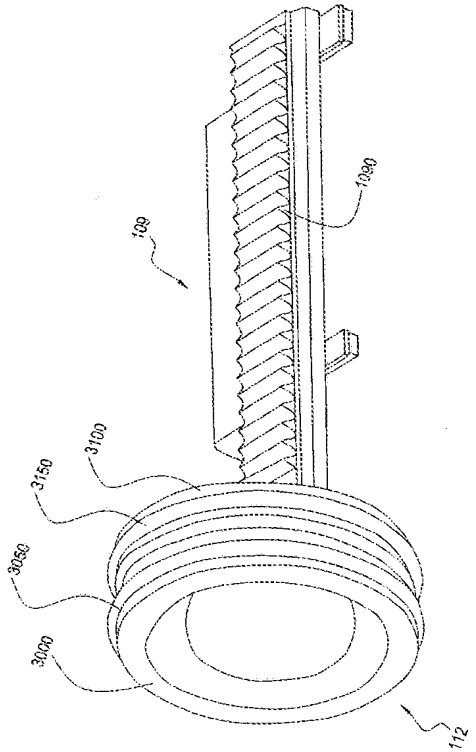
【図７】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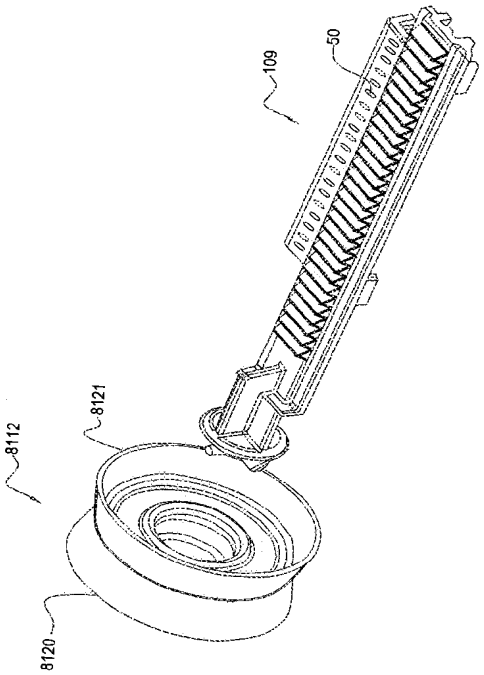
【図８】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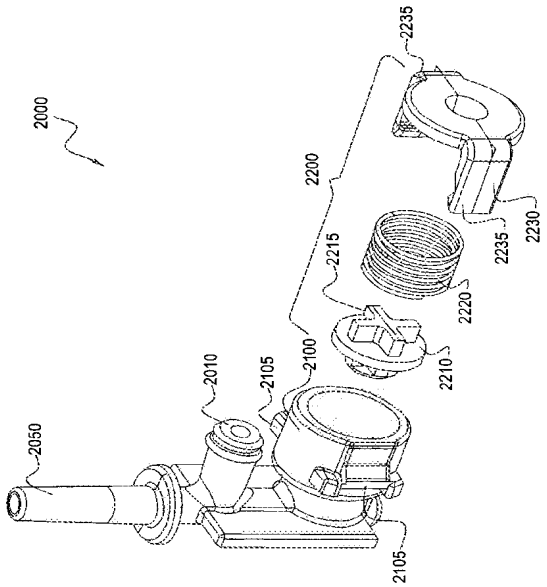
【図９】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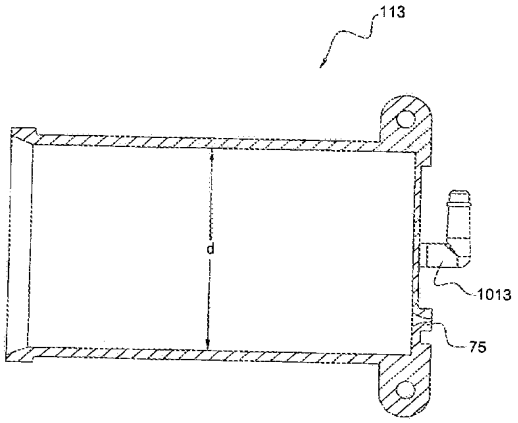
【図１０】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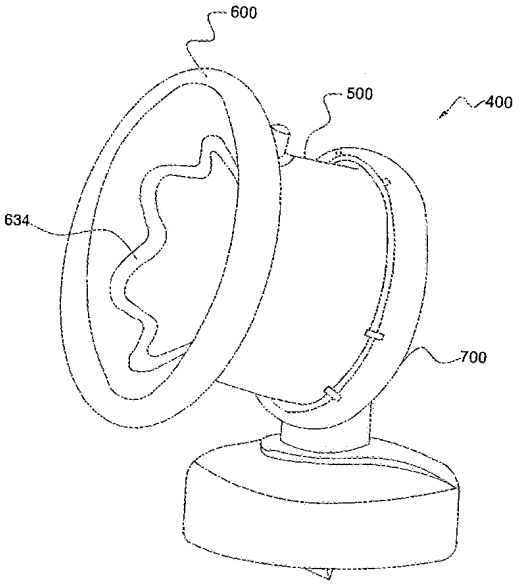
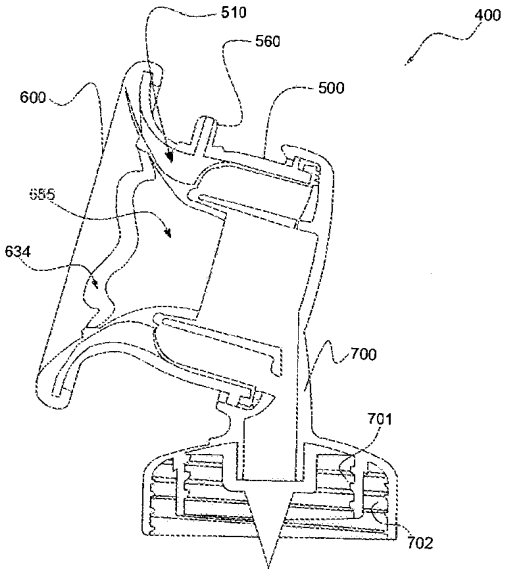
【図１１】



【図１２】



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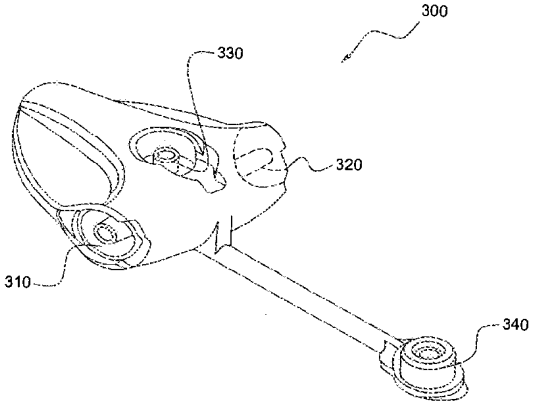

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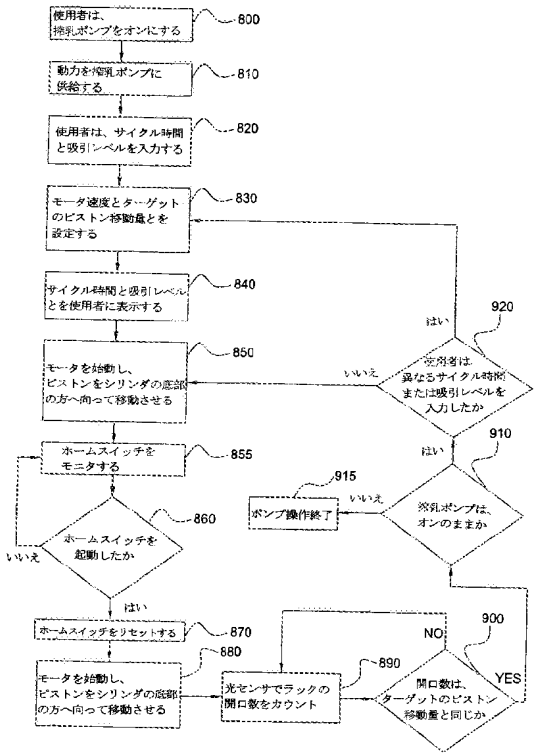

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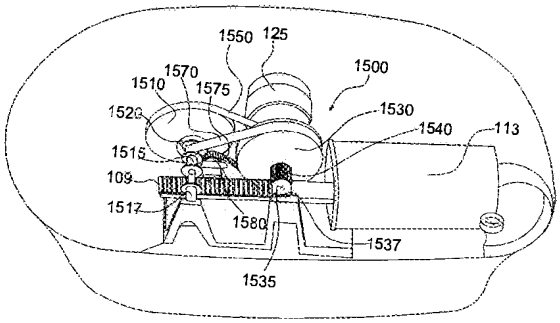

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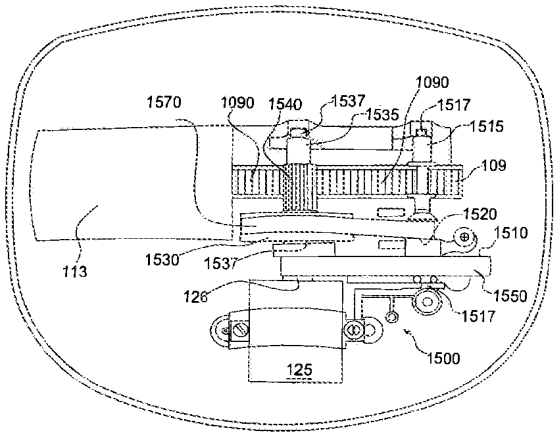

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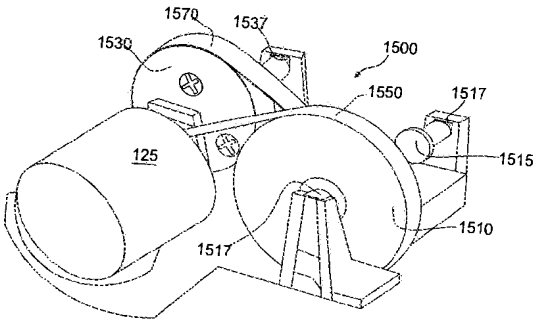

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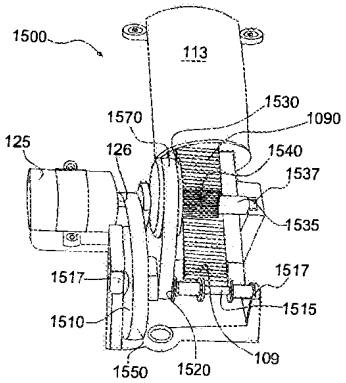

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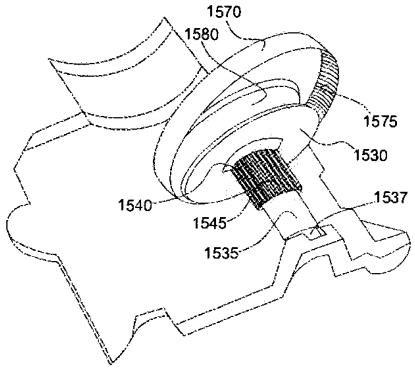

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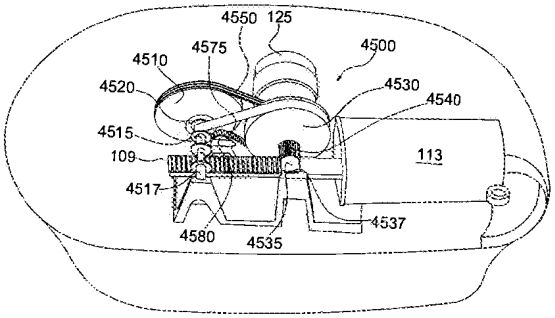

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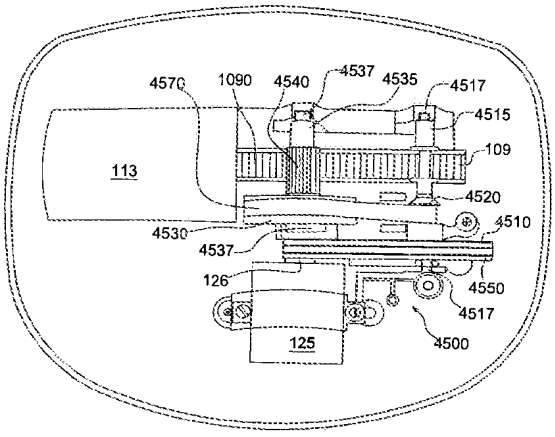

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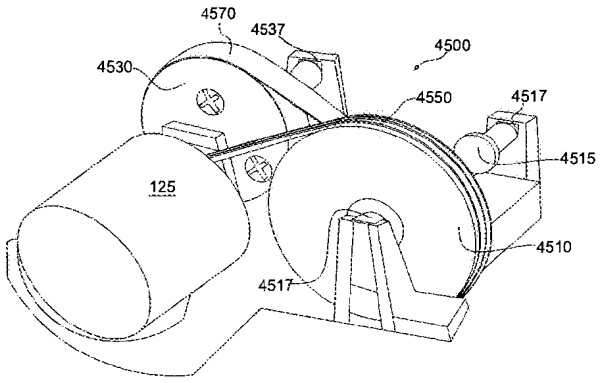

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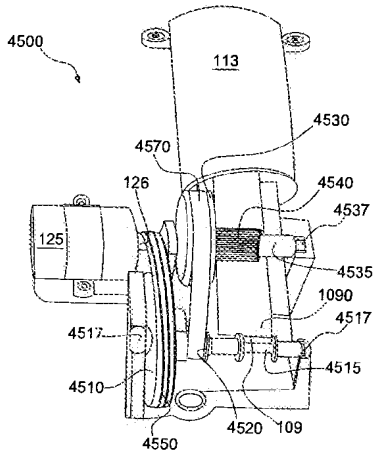

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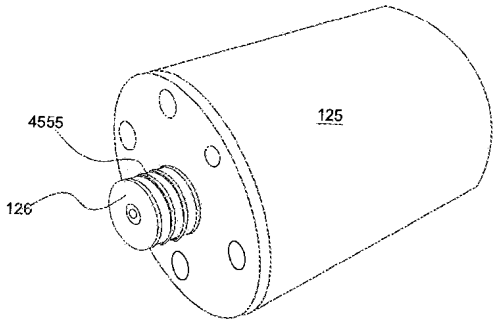

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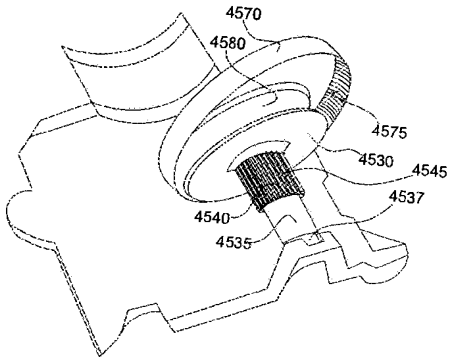

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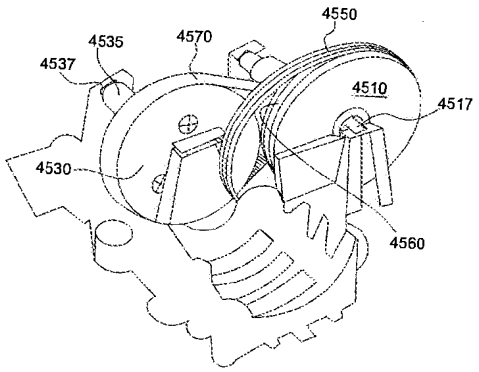

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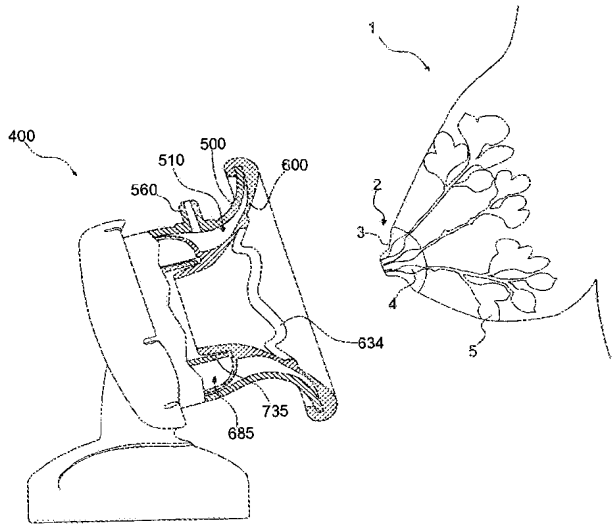

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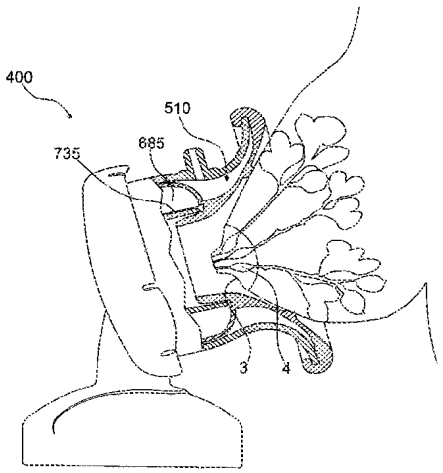

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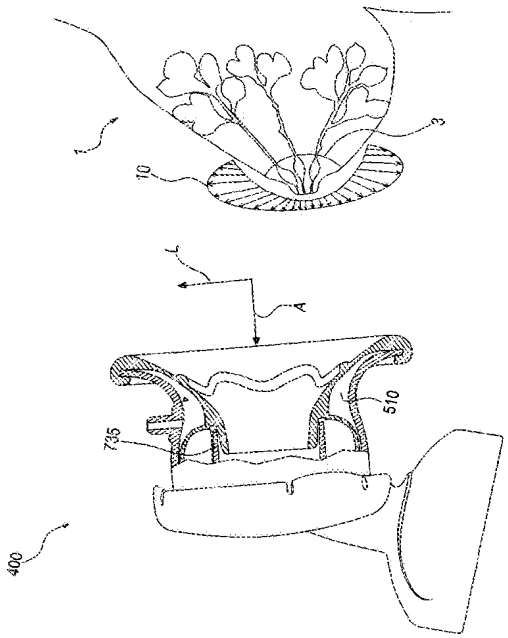

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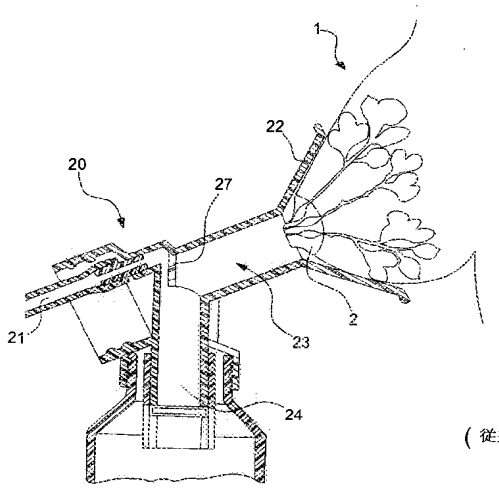

（従来技術）

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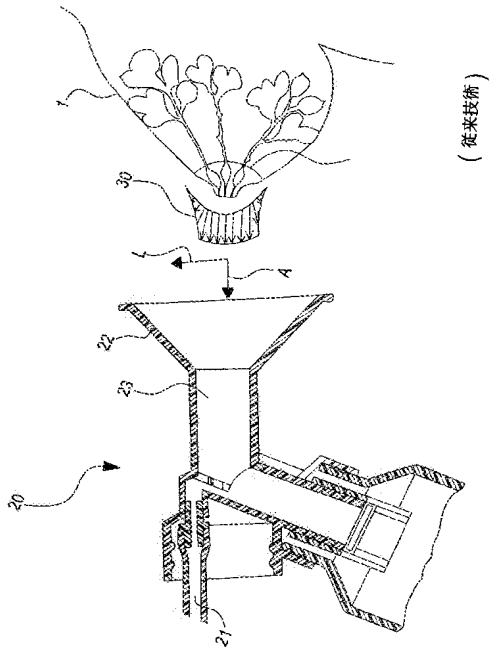

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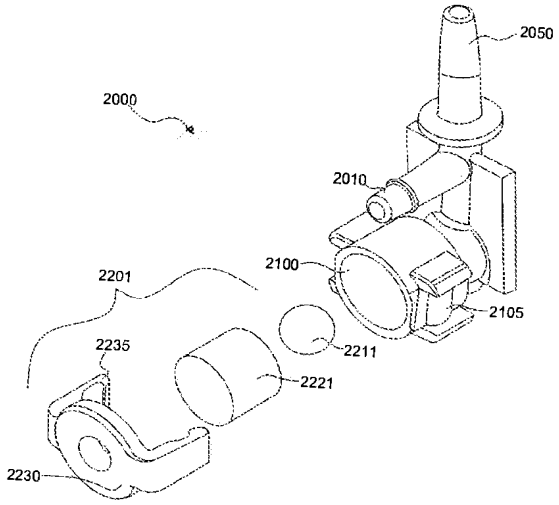

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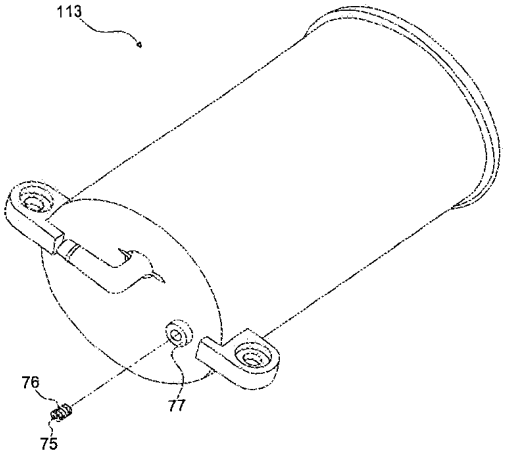

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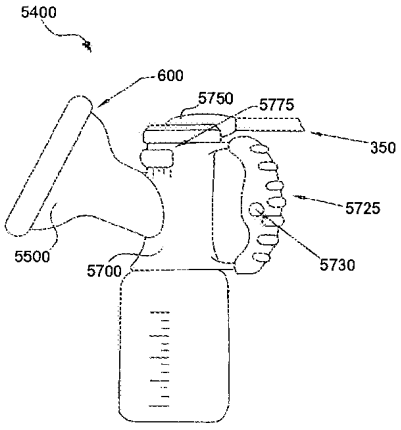

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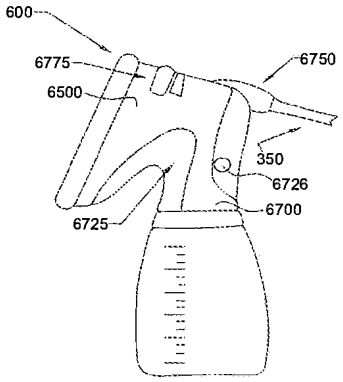

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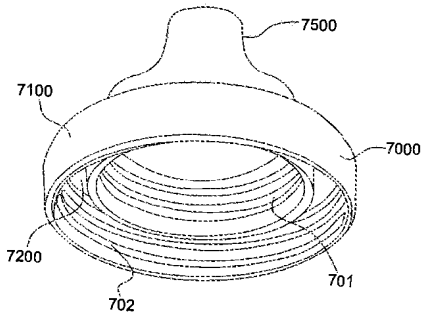

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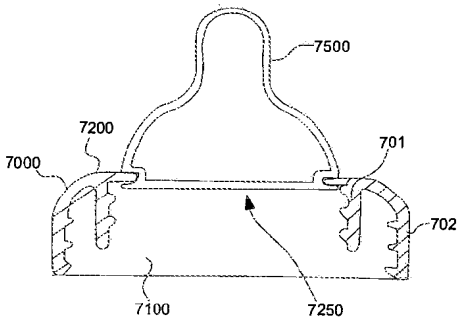

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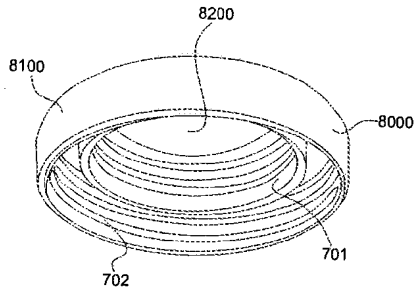

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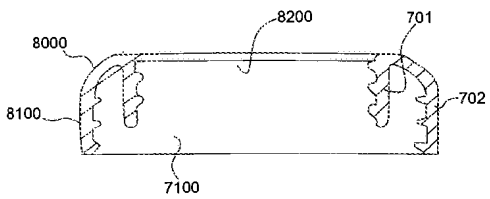

【国際調査報告】

60601030063

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/25285

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61M 1/06
US CL : 604/74
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 604/74

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
None

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
None

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2002/0198489 A1 (SILVER) 26 December 2002 (26.12.2002), see Para. 0007.	65, 66
A		1-64, 70-90
A	US 5,049,126 A (LARSSON) 17 September 1991 (17.09.1991), see entire document.	1-90
Y	US 2003/0149398 A1 (RENZ et al.) 07 August 2003 (07.08.2003), see Para. 0008.	65, 66
A		1-64, 67-90

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of the actual completion of the international search
30 October 2005 (30.10.2005)

Date of mailing of the international search report
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Ｆターム(参考) 4C077 AA22 DD10 DD19 PP07

Patents JP2007501673

Milking pump system

Abstract

translated from Japanese

A milking pump system is provided that obtains breast milk. The system uses a single air tube for both positive and negative pressure applied to a woman's breast, separating the air flow from breast milk to seal it. The milking pump can have a piston / cylinder device that generates pressure, thereby allowing the user to control the suction force and cycle time.
[Selection] Figure 1

Images (39)

Classifications

- A61M1/066 Inserts therefor

View 11 more classifications

JP2007501673A

Japan

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Other languages: Japanese

Inventor: レンズ、チャールズ・ジェイ、, ロブソン、デイビッド, ウォ、マルコ, カムプ、クリストファー, ベトリー、アイダン, ペレイラ、マイケル

Worldwide applications

2003 US 2004 JP AU GB WO CA

Application JP2006523234A events

2003-08-08 Priority to US10/637,979

2004-08-05 Application filed by プレイテックス プロダクツ インコーポレーテッド

2004-08-05 Priority to PCT/US2004/025285

2007-02-01 Publication of JP2007501673A

Status Pending

Info: Patent citations (101), Cited by (49), Similar documents, Priority and Related Applications

External links: Espacenet, Global Dossier, Discuss

Claims (90)

Hide Dependent translated from Japanese

A breast cup in fluid communication with a pressure source and configured to squeeze breast milk from a breast having a nipple,
A hood that receives the breast and is in fluid communication with the pressure source, the hood generates a negative force on the nipple during the negative pressure process, the negative force comprising a lateral component and an axial component. A breast cup, wherein the lateral component is greater than the axial component. The breast cup according to claim 1, further comprising a barrier member operatively connected to the hood, wherein the barrier member reduces the axial component of the negative force during the negative pressure step The hood includes a housing, a flexible insert attached to the housing in a sealed state, and an exhaust volume formed between the housing and the flexible insert. The breast cup of claim 1, in fluid communication with a pressure source. The breast cup according to claim 3, wherein the exhaust volume substantially surrounds the nipple when the breast is received in the hood. The flexible insert includes an air bag in fluid communication with the pressure source, the exhaust volume is at least partially defined by the air bag, and the air bag and the exhaust volume are in the negative pressure process. 4. A breast cup according to claim 3, wherein the breast cup contracts to form the negative force on the nipple during a period of time. The breast cup according to claim 5, further comprising a barrier member disposed substantially adjacent to the bladder, wherein the barrier member prevents the breast from contacting the bladder The breast cup according to claim 6, wherein the flexible insert defines an inner volume that receives the breast, and the barrier member has a cylindrical shape and is disposed in the inner volume. 4. A breast cup according to claim 3, wherein the flexible insert has a funnel shape with massage protrusions formed thereon The breast cup according to claim 8, wherein the massage protrusion has a star shape. A breast cup connected to a vacuum source and configured to squeeze breast milk from a breast having a nipple,
A breast cup comprising a breast receiving member in fluid communication with the vacuum source, wherein the breast receiving member applies a negative pressure to the nipple during a negative pressure process, causing the nipple to spread laterally. The breast cup according to claim 10, wherein the negative pressure causes the nipple to expand along the lateral direction more than the nipple extends along the axial direction. The breast cup according to claim 10, wherein the negative pressure has an average lateral component and an average axial component, and the average lateral component is greater than the average axial component during the negative pressure step. . The breast cup of claim 10, further comprising a barrier member operatively connected to the breast receiving member, the barrier member reducing extension of the nipple along the axial direction during the negative pressure process. . The breast receiving member comprises a housing, a flexible insert sealed to the housing, and an exhaust volume formed between the housing and the flexible insert, the exhaust volume being The breast cup of claim 10, in fluid communication with the vacuum source. The breast cup according to claim 14, wherein the exhaust volume substantially surrounds the nipple when the breast is received in the breast receiving member. The flexible insert includes an air bag in fluid communication with the vacuum source, the exhaust volume being at least partially defined by the air bag, the air bag and the exhaust volume being in the negative pressure step. 15. A breast cup according to claim 14, wherein the breast cup contracts to create a negative force on the nipple during the period. The breast cup according to claim 16, further comprising a barrier member disposed substantially adjacent to the bladder, wherein the barrier member prevents the breast from contacting the bladder. The breast cup of claim 17, wherein the flexible insert defines an inner volume that receives the breast, and the barrier member has a cylindrical shape and is disposed in the inner volume. 18. A breast cup according to claim 14, wherein the flexible insert has a funnel shape with a massage projection formed therein. A milking pump system that squeezes breast milk from a breast with a nipple,
A pressure source;
Receives the breast and is in fluid communication with the pressure source and generates a negative force on the nipple during a negative pressure process, the negative force having the lateral component and the axial component. The lateral component is larger than the axial component and the breast cup;
A milking pump system. 21. The milking pump system of claim 20, further comprising a barrier member operatively connected to the breast cup, wherein the barrier member

reduces the axial component of the negative force during the negative pressure step. . The breast cup includes a housing, a flexible insert sealed to the housing, and an exhaust volume formed between the housing and the flexible insert. 21. A milking pump system according to claim 20, in fluid communication with the pressure source. 24. The milking pump system of claim 22, wherein the exhaust volume substantially surrounds the nipple when the breast is received in the breast cup. The flexible insert includes an air bag in fluid communication with the pressure source, the exhaust volume is at least partially defined by the air bag, and the air bag and the exhaust volume are in the negative pressure process. 23. A milking pump system according to claim 22, wherein the milking pump system contracts to create the negative force on the nipple during a period of time. 25. The milking pump system according to claim 24, further comprising a barrier member disposed substantially adjacent to the bladder, wherein the barrier member prevents the breast from contacting the bladder. 24. The milking pump system according to claim 22, wherein the flexible insert has a funnel shape with massage protrusions formed therein. A milking pump system that squeezes breast milk from a breast with a nipple,

A vacuum source;

A breast receiving member that is in fluid communication with the vacuum source, applies a negative pressure to the nipple during a negative pressure process, and causes the nipple to spread laterally,

A milking pump system. 26. The milking pump system according to claim 27, wherein the negative pressure causes the nipple to expand along the lateral direction more than the nipple extends along the axial direction. 28. The milking pump according to claim 27, wherein the negative pressure has an average lateral component and an average axial component, the average lateral component being greater than the average axial component during the negative pressure process. system. 28. The milking pump of claim 27, further comprising a barrier member operatively connected to the breast receiving member, the barrier member reducing extension of the nipple along the axial direction during the negative pressure process. system. The breast receiving member includes a housing, a flexible insert sealed in the housing, an exhaust volume formed between the housing and the flexible insert, the exhaust volume and the vacuum. 28. The milking pump system of claim 27, comprising an air orifice in fluid communication with the source. 32. The milking pump system of claim 31, wherein the exhaust volume substantially surrounds the nipple when the breast is received by the breast receiving member. The flexible insert includes an air bag in fluid communication with the vacuum source, the exhaust volume being at least partially defined by the air bag, the air bag and the exhaust volume being in the negative pressure step. 32. The milking pump system of claim 31, wherein the milking pump system contracts to create a negative force on the nipple during a period of time. 34. The milking pump system of claim 33, further comprising a barrier member disposed substantially adjacent to the bladder, wherein the barrier member prevents the breast from contacting the bladder. 35. The milking pump system of claim 34, wherein the flexible insert defines an inner volume that receives the breast, and the barrier member has a cylindrical shape and is disposed within the inner volume. 32. The milking pump system according to claim 31, wherein the flexible insert has a funnel shape with massage protrusions formed thereon. 28. The milking pump system according to claim 27, wherein the vacuum source is a piston movably disposed in a cylinder. 38. The milking pump system of claim 37, further comprising a reversible motor operatively connected to the piston. A rack having first teeth; and a gear having second teeth; the rack is connected to the piston, the gear is operatively connected to the reversible motor, and the first teeth 40. The milking pump system of claim 38, wherein the pump engages the second tooth to reciprocate a piston within the cylinder. The cylinder has a first diameter and an air hole, the air hole having a second diameter and in fluid communication with the atmosphere, wherein the first diameter is greater than the second diameter. 38. The milking pump system of claim 37, wherein the milking pump system is substantially large. A controller operably connected to the reversible motor, wherein the controller measures the amount of movement of the piston relative to the cylinder, the controller reverses the motor based on the amount of movement; 40. A milking pump system according to claim 38. A controller operably connected to the reversible motor, wherein the motor is variable speed and the controller adjusts the speed based on a desired cycle time to apply the negative pressure to the breast. Item 39. A milking pump system according to Item 38. A milking pump kit for use with a pressure source that squeezes breast milk from the breast,

A holder,

A plurality of hoods for receiving breasts, each of the plurality of hoods being selectively engageable with the pressure source and the holder to squeeze the breast milk from the breasts; At least one has a different size or a different shape compared to the others of the plurality of hoods,

Milking pump kit. Each of the plurality of hoods includes a housing, a flexible insert sealed to the housing, and an exhaust volume formed between the housing and the flexible insert and in fluid communication with the pressure source. The milking pump kit according to claim 43, comprising a portion. The at least one housing and the flexible insert of the plurality of hoods have a different size or shape compared to the housing and the flexible insert of the other of the plurality of hoods. 44. A milking pump kit according to 44. 45. The milking pump kit of claim 44, wherein the at least one housing of the plurality of hoods has a different size or a different shape than the housings of the other of the plurality of hoods. 45. The milking pump kit of claim 44, wherein the at least one flexible insert of the plurality of hoods has a different size or a different shape than the flexible inserts of the other of the plurality of hoods. 44. The milking pump kit of claim 43, further comprising a container, wherein the holder is selectively engageable with the container. 49. The milking pump kit of claim 48, wherein the holder has a plurality of engagement structures for selectively engaging a plurality of different sized containers. The at least one flexible insert of the plurality of hoods has a first massage protrusion, the flexible insert of the other of the plurality of hoods has a second massage protrusion, and the first 48. The milking pump kit of claim 47, wherein the one massage protrusion and the second massage protrusion have different sizes or different shapes. A milking pump system that squeezes breast milk from the breast,

A pump for generating pressure;

A plurality of hoods for receiving the breasts, each of the hoods being selectively fluidly connectable to the pump for squeezing the breast milk from the breast, wherein at least one of the plurality of hoods is Having a different size or different shape compared to the others of the plurality of hoods,

Milking pump system. 52. The system of claim 51, further comprising a holder that is selectively engageable with each of the plurality of hoods. Each of the plurality of hoods includes a housing, a flexible insert sealed to the housing, and an exhaust volume formed between the housing and the flexible insert and in fluid communication with the pump. 52. The system of claim 51, comprising: 54. The at least one housing and the flexible insert of the plurality of hoods have a different size or shape compared to the housing and the flexible insert of the other of the plurality of hoods. The described system. 54. The system of claim 53, wherein the at least one housing of the plurality of hoods has a different size or shape compared to the housing of the other of the plurality of hoods. 54. The system of claim 53, wherein the at least one flexible insert of the plurality of hoods has a different size or shape compared to the flexible insert of the other of the plurality of hoods. 53. The system of claim 52, further comprising a container, wherein the holder is selectively engageable with the container. 58. The system of claim 57, wherein the holder has a plurality of engagement structures for selectively engaging a plurality of different sized containers. The at least one flexible insert of the plurality of hoods has a first massage protrusion, the flexible insert of the other of the plurality of hoods has a second massage protrusion, and the first 57. The system of claim 56, wherein the first massage protrusion and the second massage protrusion have different sizes or different shapes. A milking pump that squeezes breast milk from the breast,

A pressure source having a movable structure for generating pressure during the pressure process, the movable structure having a variable pressure or a variable cycle time, and

A controller operatively connected to the pressure source, wherein the controller adjusts the pressure based on the amount of movement advanced by the movable structure, or adjusts the speed of the movable structure. Adjusts the variable cycle time based on, and the controller also provides near real-time monitoring of the amount of travel or the speed advanced;

Milking pump. 61. The pump of claim 60, wherein the controller is capable of adjusting the pressure cycle based on a non-sinusoidal signal of the pressure versus variable cycle time. A milking pump system that squeezes breast milk from the breast,

A pressure source having an exhaust volume and an air hole for generating pressure;

A breast cup in fluid communication with the pressure source to receive the breast and apply the pressure to the breast, the air hole having a predetermined diameter, and in fluid communication with the exhaust volume, the diameter being between about 0.15 mm and 0.75 mm;

Milking pump system. 64. The system of claim 62, wherein the diameter is between about 0.25 mm and 0.5 mm. 64. The system of claim 62, wherein the diameter is about 0.3 mm. A method of squeezing breast milk from the breast,

Applying a negative pressure to the breast from a pressure source during the vacuum process;

Applying a positive pressure from the pressure source to the breast during a massage process,

Supplying air from the atmosphere to the pressure source during the vacuum process;

A method comprising: During the vacuum process, the step of supplying air from the atmosphere to the pressure source comprises providing an air hole in fluid communication

with the pressure source and the atmosphere, wherein the air hole is between about 0.15 mm and. 66. The method of claim 65, having a diameter between 75 mm. A method of extracting breast milk from a breast having a nipple,

Applying a negative pressure to at least a portion of the nipple and causing the nipple to spread laterally. 68. The method of claim 67, wherein the negative pressure causes the nipple to expand along the transverse direction more than the nipple extends along the axial direction. 68. The method of claim 67, wherein the negative pressure has an average lateral component and an average axial component during a negative pressure step, the average lateral component being greater than the average axial component. A method of squeezing breast milk from the breast,

Applying pressure to the breast,

Performing near real-time monitoring and control of the pressure with a controller;

A method comprising: The pressure is controlled somewhat based on the variable pressure of the movable structure or the variable cycle time of the movable structure, and the controller adjusts the pressure based on the amount of movement advanced by the movable structure. 71. The method of claim 70, wherein the controller adjusts or adjusts the variable cycle time based on the speed of the movable structure, and the controller provides near real-time monitoring of the amount of travel or the speed advanced. Method. 71. The method of claim 70, wherein the controller adjusts the pressure based on the pressure versus variable cycle time non-sinusoidal signal. A pump for supplying pressure,

A housing defining a volume and having a pressure exhaust device;

An actuator operatively connected to the housing to generate the pressure in the volume;

An insert connected to the housing, the insert having a hole disposed through the insert, the hole providing fluid communication between the volume and the atmosphere; pump. 74. The pump of claim 73, wherein the housing is made of a first material and the insert is made of a second material. 75. A pump according to claim 74, wherein the housing is made of plastic and the insert is made of metal. 74. The pump according to claim 73, wherein the housing is a cylinder and the actuator is a piston. 77. The pump of claim 76, wherein the cylinder has an orifice and the insert is disposed within the orifice. 78. The pump of claim 77, wherein the insert is press fit within the orifice. 77. The pump of claim 76, wherein the insert is a plurality of inserts, each of the plurality of inserts being selectively engageable with the cylinder. 78. The pump of claim 77, wherein the insert is a plurality of inserts, and each of the plurality of inserts is selectively engageable with the orifice. A breast cup that is in fluid communication with a first container and a second container and applied to a breast, wherein the first container and the second container have openings with different diameters,

A funnel shape for receiving the breast;

A housing connected to the funnel shape and having a base, the base including a circumferential wall, a flange extending inwardly from the circumferential wall to define an opening, and a first thread A second thread,

The first thread has a first diameter and a first pitch, the first diameter and the first pitch enabling selective engagement with the first container; The second thread has a second diameter and a second pitch, the second diameter and the second pitch allowing selective engagement with the second container; The breast cup, wherein the first thread and the second thread are arranged to be coaxial along the base. 82. The breast cup according to claim 81, wherein the first pitch is equal to the second pitch. 82. The breast cup of claim 81, wherein the first thread extends from the flange and the second thread is disposed on the circumferential wall. 82. The breast cup of claim 81, wherein the funnel feature is selectively removable from the housing. A baby bottle nipple ring that engages a first container and a second container with a baby bottle nipple, the first container and the second container having openings with different diameters, The nipple ring of the baby bottle

A body having a circumferential wall, a flange extending inwardly from the circumferential wall to define an opening, a first thread, and a second thread;

The first thread has a first diameter and a first pitch, the first diameter and the first pitch enabling selective engagement with the first container; The second thread has a second diameter and the second pitch, and the second diameter and the second pitch enable selective engagement with the second container. The baby bottle nipple ring, wherein the first thread and the second thread are arranged to be coaxial along the body. 86. The baby bottle nipple ring according to claim 85, wherein the first pitch is equal to the second pitch. 86. The baby bottle nipple ring according to claim 85, wherein the first thread extends from the flange and the second thread is disposed on the circumferential wall. A cap that engages a first container and a second container, the first container and the second container having openings with different diameters;

A body having a circumferential wall, a top wall connected to the circumferential wall, a first thread, and a second thread;

The first thread has a first diameter and a first pitch, the first diameter and the first pitch enabling selective engagement with the first container; The second thread has a second diameter and a second pitch, the second diameter and the second pitch allowing selective engagement with the second container; The first screw thread and the second screw thread are arranged so as to have a coaxial line along the main body. 90. A cap according to claim 86, wherein the first pitch is equal to the second pitch. The cap of claim 86, wherein the first thread extends from the flange and the second thread is disposed on the circumferential wall.

Description

translated from Japanese

The present invention relates to an apparatus and method for obtaining breast milk. More particularly, the present invention relates to a milking pump system that can apply positive or negative pressure to the breast to squeeze breast milk.

Milking pump systems that obtain breast milk, both manually and automatically, are well known in the art. Conventional systems use a vacuum source to create a negative pressure or vacuum that is sent through a tube to a breast hood or cup that is applied to the breast. This conventional apparatus and method uses negative pressure on the breast to squeeze breast milk.

The system described above has the disadvantage that only a vacuum source is applied to the breast as a negative pressure in order to induce milk extraction. In addition, the conventional systems described above have the disadvantage of applying a negative pressure or force in the axial direction to the nipple, uncomfortable with milk squeezing, and insufficient nipple stretching and expansion in the axial direction. Result.

It is an object of the present invention to provide a milking pump system for squeezing breast milk that can apply positive or negative pressure to the breast to squeeze the breast milk.

Another object of the present invention is to provide a system as described above that supplies positive and negative pressure from a single source.

Yet another object of the present invention is to provide a system as described above that facilitates control of positive and negative pressure applied to the breast.

Yet another object of the present invention is to provide a system as described above for spreading the nipple to squeeze milk.

Another object of the present invention is to provide a system as described above that reduces the axial extension or expansion of the nipple.

Another further object of the present invention is to apply a negative force or negative pressure gradient to the nipple that has a greater lateral component compared to the axial component.

Yet another object of the present invention is to accommodate breasts of different sizes and / or shapes by providing a kit with compatible breast hoods of different sizes and / or shapes.

Yet another object of the present invention is to substantially monitor and control the pressure source in real time.

These and other objects and advantages of the present invention are provided by a breast cup having a hood for receiving a breast and in fluid communication with a pressure source. The hood generates a negative force on the nipple during the negative pressure process. The negative force has a lateral component and an axial component. The lateral component is larger than the axial component.

The present invention includes a breast cup having a breast receiving member in fluid communication with a vacuum source. The breast receiving member applies a negative pressure to the nipple during the negative pressure process, causing the nipple to spread laterally.

The present invention includes a milking pump system having a pressure source and a breast cup that receives a breast. The breast cup is in fluid communication with a pressure source. The breast cup generates a negative force on the nipple during the negative pressure process. The negative force has a lateral component and an axial component. The lateral component is larger than the axial component.

The present invention includes a milking pump system having a vacuum source and a breast receiving member in fluid communication with the vacuum source. The breast receiving member applies a negative pressure to the nipple during the negative pressure process, causing the nipple to spread laterally.

The present invention includes a milking pump kit having a holder and a plurality of hoods for receiving breasts. Each of the plurality of hoods is selectively engageable with a holder and a pressure source for squeezing breast milk from the breast. At least one of the plurality of hoods has a different size or shape compared to the others of the plurality of hoods.

The present invention includes a milking pump system having a pump for generating pressure and a plurality of hoods for receiving breasts. Each of the plurality of hoods can be selectively fluidly connected to a pump that squeezes breast milk from the breast. At least one of the plurality of hoods has a different size or shape compared to the others of the plurality of hoods.

The present invention includes a milking pump having a pressure source with a movable structure that generates pressure during the pressure process. The movable structure has a variable pressure or variable cycle time. The pump further has a controller operatively connected to the pressure source. The controller adjusts the pressure based on the amount of movement advanced by the movable structure, or adjusts the variable cycle time based on the speed of the movable structure. The controller provides near real-time monitoring of the amount of travel or speed being advanced

The present invention includes a milking pump system having a pressure source having an exhaust volume for generating pressure and an air hole. The system further includes a breast cup that receives the breast and is in fluid communication with a pressure source that applies pressure to the breast. The air holes have a diameter and are in fluid communication with the atmosphere and the exhaust volume. The diameter of the air hole is between about 0.15 mm and 0.75 mm.

The present invention applies negative pressure from the pressure source to the breast during the vacuum process, applies positive pressure from the pressure source to the breast during the massage process, and supplies air from the atmosphere to the pressure source during the vacuum process. And squeezing breast milk from the breast.

The present invention includes a method of squeezing breast milk from a breast, comprising applying a negative pressure to at least a portion of the nipple to cause the nipple to spread laterally.

The present invention includes a method of squeezing breast milk from a breast, comprising the steps of applying pressure to the breast and performing near real-time monitoring and control of the pressure with a controller.

The present invention includes a pump for supplying pressure having a housing, an actuator, and an insert. The housing defines a volume and has a pressure exhaust device. The actuator is operatively connected to a housing that generates pressure within the volume. The insert is connected to the housing. The insert has a hole disposed therethrough. The hole provides fluid communication between the volume and the atmosphere.

The present invention includes a breast cup that is in fluid communication with a first container and a second container that have openings with different diameters and applied to the breast. The breast cup has a funnel shape that receives the breast and a housing connected to the funnel shape. The funnel shape has a base. The base has a circumferential wall, a flange extending inwardly from the circumferential wall to define an opening, a first thread, and a second thread. The first thread has a first diameter and a first pitch. The first diameter and the first pitch allow selective engagement with the first container. The second thread has a second diameter and a second pitch. The second diameter and the second pitch allow selective engagement with the second container. The first thread and the second thread are arranged so as to be coaxial along the base.

The present invention includes a baby bottle nipple ring that engages a first container and a second container having openings with different diameters to the baby bottle nipple. A nipple ring of a baby bottle has a body having a circumferential wall, a flange extending inwardly from the circumferential wall to define an opening, a first thread, and a second thread. Have. The first thread has a first diameter and a first pitch. The first diameter and the first pitch allow selective engagement with the first container. The second thread has a second diameter and a second pitch. The second diameter and the second pitch allow selective engagement with the second container. The first thread and the second thread are arranged to have a coaxial axis along the body.

The present invention includes a cap that engages a first container and a second container having openings with different diameters. The cap has a body having a circumferential wall, a top wall connected to the circumferential wall, a first thread, and a second thread. The first thread has a first diameter and a first pitch. The first diameter and the first pitch allow selective engagement with the first container. The second thread has a second diameter and a second pitch. The second diameter and the second pitch allow selective engagement with the second container. The first thread and the second thread are arranged to have a coaxial axis along the body.

The first pitch may be equal to the second pitch. The first thread can extend from the flange. The second thread can be disposed on the circumferential wall. The funnel shape can be selectively removed from the housing.

The housing may be a first material and the insert may be a second material. The housing may be plastic and the insert may be metal. The housing may be a cylinder and the actuator may be a piston. The cylinder can be an orifice and the insert can be disposed within the orifice. The insert can be press fit into the orifice. The insert is a plurality of inserts, and each of the plurality of inserts is selectively engageable with the cylinder.

The breast cup further has a barrier member that is operatively connected to the hood, which reduces the axial component of negative forces during the negative pressure process. The hood can have a housing, a flexible insert hermetically secured to the housing, and an exhaust volume formed between the housing and the flexible insert, the exhaust volume being in fluid communication with the pressure source. The exhaust volume can substantially surround the nipple when the breast is received in the hood. The flexible insert may have a bladder in fluid communication with the pressure source, with the exhaust volume being at least partially defined by the bladder. The bladder and the exhaust volume can be contracted to create a negative force on the nipple during the negative pressure process.

The breast cup further has a barrier member disposed substantially adjacent to the bladder, thereby preventing the breast from contacting the bladder. The flexible insert can define an inner volume that receives the breast, and the barrier member has a cylindrical shape and can be disposed in the inner volume. The flexible insert can have a funnel shape with massage protrusions formed thereon. The massage protrusion has a star shape.

The negative pressure generated in the breast cup can cause the nipple to spread along the lateral direction more than the nipple extends along the axial direction. The negative pressure can have an average lateral component and an average axial component, and during the negative pressure process, the average lateral component is greater than the average axial component. The barrier member can be operatively connected to the breast receiving member and can reduce nipple extension along the

axial direction during the negative pressure process. The breast receiving member may have a housing, a flexible insert hermetically secured to the housing, and an exhaust volume formed between the housing and the flexible insert. Is in fluid communication with a vacuum source.

The vacuum source or pressure source may be a piston movably disposed in the cylinder. The system can have a reversible motor operatively connected to its piston. The system can further include a rack having first teeth and a gear having second teeth. The rack can be connected to the piston, and the gear can be operably connected to the reversible motor. The first tooth is engageable with the second tooth and causes the piston to reciprocate within the cylinder. The cylinder can have a first diameter and an air hole. The air holes have a second diameter and can be in fluid communication with the atmosphere. The first diameter of the cylinder may be significantly larger than the second diameter of the air holes.

The system can have a controller operatively connected to the reversible motor. The controller can measure the amount of movement that the piston has advanced relative to the cylinder. The controller can reverse the motor based at least in part on the amount of movement. The system can further have a motor with variable speed. The controller can adjust the speed based on the desired cycle time for applying negative pressure to the breast. The controller can adjust the pressure cycle based on a non-sinusoidal signal of pressure versus variable cycle time.

Each of the plurality of hoods of the kit includes a housing, a flexible insert hermetically secured to the housing, and an exhaust volume formed between the housing and the flexible insert and in fluid communication with the pressure source. It is possible. The at least one housing and / or the flexible insert of the plurality of hoods can have a different size or a different shape compared to the flexible insert of the other of the housing and / or the plurality of hoods. The kit can further include a container, and the holder is selectively engageable with the container. The holder can have a plurality of engagement structures for selectively engaging a plurality of different sized containers. At least one flexible insert of the plurality of hoods can have a first massage protrusion, and a flexible insert of the other of the plurality of hoods can have a second massage protrusion. is there. The first massage protrusion and the second massage protrusion can have different sizes or different shapes.

Other and further objects, advantages and features of the present invention will be understood by reference to the following.

With reference to the figures, and in particular with reference to FIGS. 1 and 2, there is shown a milking pump of the present invention, generally designated by the reference numeral 100. This milking pump 100, together with the breast cup 400 shown in FIG. 11, forms an important component of the milking pump system of the present invention. The milking pump 100 has a top housing 102 and a bottom housing 103 that are configured to form an assembly unit.

With reference to FIGS. 1-3, the top housing 102 has a generally oval shape with a flat front surface 200 and a storage compartment 210 having a compartment door 104. The door 104 is hinged to the top housing 102 to form a selectively sealable storage compartment 210 for storing an air tube or conduit 350 that connects the milking pump 100 to other components of the system. This is preferably connected and will be discussed in more detail below.

The surface 200 can receive a button pad 105 having an LED cover 106. Pad 105 is used by the consumer to control milking pump 100. The bottom housing 103 can reliably accommodate various components of the milking pump, and includes a rack gear 109, a pinion gear 110 that can be engaged with the rack gear, a piston 112, and a cylinder 113 that can receive the piston. And a motor 125 having a shaft 126 to which a pinion gear is attached. To some extent this design allows milking pump 100 to provide low noise pumping. The milking pump 100 can be made of any rigid material such as, for example, plastic.

Referring to FIGS. 3-7, the milking pump 100 utilizes a piston 112 and a cylinder 113 to generate both positive and negative pressure to obtain breast milk. The piston 112 is driven by a rack gear 109 fixed thereto. The piston 112 has a substantially cylindrical shape having a first head 3000 and a second head 3100. The first head 3000 and the second head 3100 preferably each have an annular channel 3020, 3120 formed therein. The channels 3020 and 3120 are arranged along the outer periphery of the first head 3000 and the second head 3100, respectively. The channels 3020 and 3120 are preferably located at the center along the outer periphery of the first head 3000 and the second head 3100. Seated within channels 3020, 3120 are sealing members 3050, 3150, respectively. The sealing members 3050 and 3150 are preferably O-ring gaskets. Sealing members 3050, 3150 have a diameter or width that is greater than the depth or height of channel 3020 and channel 3120. The sealing members 3050 and 3150 extend beyond the outer periphery of the first head 3000 and the second head 3100 and seal with the inner surface 130 of the cylinder 113 when the piston 112 is driven back and forth within the cylinder. Engagement is formed.

The use of multiple sealing members, i.e., O-ring gasket 3050 and O-ring gasket 3150 on piston 112, provides a double seal and increases the effectiveness of generating positive and negative pressure. Whereas this embodiment uses two sealing members to generate two independent sealing surfaces, a significant number of sealing members generate a significant number of sealing surfaces that seal the piston 112 with the cylinder 113. Can be used to In addition, while this embodiment uses a piston 112 having O-ring sealing gaskets 3050, 3150, other sealing structures can be used between the piston and cylinder 113.

Rack gear 109 has teeth 1090 that engage with pinion gear 110 having teeth 1100. Pinion gear 110 is preferably operatively connected to motor 125 by shaft 126. When the motor 125 is started, the shaft 126 and the pinion gear 110 rotate. The teeth 1090 of the rack 109 and the teeth 1100 of the pinion 110 mesh and convert the mutual rotational movement of the motor 125 and the shaft 126 into a mutual longitudinal movement along a single axis in both directions.

The rack gear 109 preferably has a first end 1095 that engages a recess 3200 formed in the piston 112. The recess 3200 is preferably located at the center of the piston 112. The first end 1095 of the rack gear 109 preferably has a snap fit engagement or a friction fit engagement with the recess 3200 of the piston 112. Each preferably has a detent structure 1096, 3296 formed in the first end 1095 and recess 3200. This facilitates the manufacture of these components and provides a slight pivot-like movement that may be required for the piston 112 relative to the rack gear 109.

Another method embodiment of the piston is shown in FIG. 8 and is generally designated 8112. The piston 8112 has a substantially V shape with a leading edge 8120 and a trailing edge 8121. The leading edge 8120 and the trailing edge 8121 are in sealing engagement with the inner surface 1130 of the cylinder 113 when the piston 8112 is driven back and forth within the cylinder. The use of multiple edges, ie, the leading edge 8120 and trailing edge 8121 of the piston 8112 that sealingly engage the inner surface 1130 of the cylinder 113 provides a double seal and increases the effect of generating positive and negative pressure.

Referring to FIGS. 3-7, the motor 125 is preferably variable speed. This allows the user to control and change the cycle time for breast pumping. The milking pump 100 further includes a motor cover 107 and a bearing 108 to reduce vibration and secure the motor 125 to the bottom housing 103.

The positive pressure and the negative pressure can be changed by changing the displacement of the cylinder 113. In this embodiment, this is done by use of an optoelectronic or photosensor system. The optical sensor system includes two or more optical sensors 121 and a position switch 124. The optical sensor 121 counts the number of openings 50 of the rack gear 109 when the rack gear moves back and forth. Therefore, the user can control the amount of movement of the rack gear 109, and can control the exhaust amount in the cylinder 113 correspondingly. Additional displacement or displacement monitors can be used, for example, a coded wheel that counts slots on the wheel, a belt tooth count, a rotary encoder that counts its own rotation, or a Hall effect sensor It is.

To ensure that the piston 112 moves properly in front of the cylinder 113, the photosensor system further includes a position switch 124 that functions as a counter starter, preferably located in front of the cylinder. Alternatively, the position switch may be an aperture 50 having a different size or shape that can be detected by the optical sensor 121.

The rack gear 109 can further have a safety mechanism attached to it. The optical sensor 121 continues to read the opening 50 when the rack gear 109 moves backward. If for some reason the rack gear 109 loses sight of the target and moves far away, the safety device activates the position switch. When the position switch is

activated while the rack gear 109 moves backward, the system can be activated so that the software moves forward again and returns to the positioning position.

The milking pump 100 has a guide cover 111 positioned over the entire rack gear 109. The guide cover 111 adds safety to the milking pump by guiding the mutual movement of the rack gear 109 and vibrating it. The guide cover 111 further provides accuracy to the optical sensor system by reducing the risk of misalignment between the optical sensor 121 and the opening 50.

The optical sensor system and motor 125 are preferably connected to a PC or circuit board 120. Therefore, the moving amount of the piston 112 to be converted according to the positive pressure and the negative pressure and the piston speed to be converted according to the cycle time are electronically controlled.

Referring to FIGS. 15-19, a preferred embodiment of the drive system of the present invention is shown and designated generally by the reference numeral 1500. The drive system 1500 can be used with the milking pump 100 of FIGS. 1-7 and provides linear reciprocal movement of the piston 112 with the cylinder 113.

Drive system 1500 is a belt drive system for rack and pinion drive with gear reduction incorporated therein. The drive system 1500 includes a first drive wheel or pulley 1510, a second gear, drive wheel or pulley 1520 fixed to the first drive wheel 1510, a third gear, drive wheel or pulley 4530, And a pinion gear 1540 fixed to the third gear.

First drive wheel 1510 is operatively connected to motor drive shaft 126 by a first belt 1550. In a preferred embodiment, the first belt 1550 is a toothless belt. More preferably, the first belt 1550 has elasticity or flexibility. The use of a flexible or elastic belt 1550 provides a secure connection between the drive shaft 126 and the first drive wheel 1510, and further reduces noise and vibration. The drive shaft 126 and the first drive wheel 1510 have a smooth outer surface on which the first belt 1550 is fixed.

First drive wheel 1510 is operatively connected to second gear 1520 by first coaxial shaft 1515. In a preferred embodiment, the first shaft 1515 is rotatably mounted between opposing first bearings 1517. However, other methods of rotatable mounting arrangements or fixing structures can also be used. To reduce noise and vibration, the motor shaft 126 and the first drive wheel 1510 are made of metal. First drive wheel 1510 and second gear 1520 have different diameters that provide in part a gear reduction between motor shaft 126 and pinion gear 1540.

Second gear 1520 is operatively connected to third gear 1530 by second belt 1570. Second belt 1570 preferably has teeth 1575 that mesh with teeth 1580 formed along the periphery of second gear 1520 and third gear 1530. Second gear 1520 and third gear 1530 have different diameters that partially provide gear reduction between motor shaft 126 and pinion gear 1540. The drive system 1500 can further include a tension pulley 1580 that provides tension to the second belt 1570.

Third gear 1530 is operatively connected to pinion gear 1540 by a second coaxial shaft 1535. In a preferred embodiment, the second shaft 1535 is rotatably mounted between opposing second bearings 1537. However, other methods of rotatable mounting arrangements or securing structures can also be used. The third gear 1530 is preferably molded integrally with the pinion gear 1540 along the second shaft 1535.

Pinion gear 1540 has teeth 1545 that engage with teeth 1090 of rack gear 109. When the motor 125 is started, the rotational movement of the shaft 126 is converted into mutual longitudinal movement along a single axis of the rack gear 109 in both directions. The drive system 1500 uses a first belt 1550, a second belt 1570, a first drive wheel or gear 1510, a second drive wheel or gear 1520, and a third drive wheel or gear 1530. , The desired rate of movement between the motor shaft 126 and the pinion gear 1540 can be provided, ie, gear reduction.

The use of the combination of the toothless belt 1550 and the tooth profile belt 1570 can reduce noise and vibration while providing the required reciprocating linear motion at the desired speed and pressure for the milking pump 100. Maintain a secure and rugged drive system 1500.

Referring to FIGS. 20-26, another method embodiment of the drive system of the present invention is shown and generally designated by reference numeral 4500. The drive system 4500 can be used with the milking pump 100 of FIGS. 1-7 and provides linear reciprocal movement of the piston 112 with the cylinder 113.

The drive system 4500 is a belt drive system having a gear reduction incorporated therein. The drive system 4500 includes a first gear, drive wheel or pulley 4510, a second gear, drive wheel or pulley 4520 fixed to the first gear, and a third gear, drive wheel or pulley 4530. And a pinion gear 4540 fixed to the third gear.

First gear 4510 is operatively connected to motor drive shaft 126 by a first belt 4550. In a preferred embodiment, the first belt 4550 is a plurality of belts, more preferably three belts. The first belt 4550 is preferably a belt without a tooth profile. More preferably, the first belt 4550 is an O-ring having elasticity or flexibility. For example, the use of a flexible or elastic belt 4550 such as an O-ring provides a secure connection between the drive shaft 126 and the first gear 4510, and further reduces noise and vibration. Drive shaft 126 and first gear 4510 each have an annular channel 4555, 4560 formed therein. The annular channels 4555, 4560 are guides that help hold the first belt 4550 in place and facilitate assembly of the drive system 4500.

First gear 4510 is operatively connected to second gear 4520 by a first coaxial shaft 4515. In this alternative method embodiment, the first shaft 4515 is rotatably mounted between opposing first bearings 4517. However, other methods of rotatable mounting arrangements or fixing structures can also be used. To reduce noise and vibration, the motor shaft 126 and the first gear 4510 are made of metal. First gear 4510 and second gear 4520 have different diameters that partially provide gear reduction between motor shaft 126 and pinion gear 4540.

Second gear 4520 is operatively connected to third gear 4530 by second belt 4570. The second belt 4570 preferably has teeth 4575 that mesh with teeth 4580 formed along the periphery of the second gear 4520 and the third gear 4530. Second gear 4520 and third gear 4530 have different diameters that partially provide gear reduction between motor shaft 126 and pinion gear 4540. The drive system 4500 can further include a tension pulley 4580 that provides tension to the second belt 4570.

Third gear 4530 is operatively connected to pinion gear 4540 by second coaxial shaft 4535. In this alternative method embodiment, the second shaft 4535 is rotatably mounted between opposing second bearings 4537. However, other methods of rotatable mounting arrangements or securing structures can also be used. Third gear 4530 is preferably molded integrally with pinion gear 4540 along second shaft 4535.

Pinion gear 4540 has teeth 4545 that engage with teeth 1090 of rack gear 109. When the motor 125 is started, the rotational movement of the shaft 126 is converted into mutual longitudinal movement along a single axis of the rack gear 109 in both directions. Drive system 4500 includes motor shaft 126 and pinion gears through the use of first belt 4550, second belt 4570, first gear 4510, second gear 4520, and third gear 4530. A desired rate of movement between 4540, ie gear reduction, can be provided.

Use of a combination of O-ring belt 4550 without tooth profile and tooth profile belt 4570 reduces noise and vibration while providing the required reciprocating linear motion at the desired speed and pressure for milking pump 100. Maintain a secure and robust drive system 4500 that can.

The embodiments of the drive systems 1500, 4500 described above utilize a belt for gear reduction. However, another method embodiment may use a gearbox that decelerates the gearing to a desired rate that is transmitted to the rack and pinion gearing that drives the milking pump 100.

Referring to FIGS. 3 to 9, the cylinder 113 has a supply tube 116 fixed to a supply connector 115 that supplies positive and negative pressure to the breast cup 400. The supply connector preferably has an outlet 215 located in the storage compartment 210. The air tube 350 is fixed to the outlet 215 and can be fixed to the breast cup 400.

The storage compartment 210 can be opened or closed during the pumping operation. The cylinder 113 is about 1.5 in. In fluid communication with a pressure relief valve 2000 (shown in FIG. 9), which is preferably set to Hg.

The pressure relief valve 2000 has an intake port 2010 and an exhaust device 2050. The intake 2010 is in fluid communication with the cylinder 113, and the exhaust device 2050 is in fluid communication with the breast cup 400 via a tube 350. Pressure relief valve 2000 has a relief exhaust device 2100 in fluid communication with intake 2010 and exhaust device 2050. The relief exhaust device 2100 is substantially tubular and is fixed to the relief assembly 2200.

The relief assembly 2200 includes a flexible insert 2210, a biasing member 2220, and a holding member 2230. The flexible insert 2210 is in sealing engagement with the internal surface of the relief exhaust device 2100 and prevents air from escaping through the relief exhaust device. The insert 2210 has a fixing member 2215 that meshes with the biasing member 2220. In this embodiment, the securing member 2215 is a cruciform structure that is received in the inner volume of the biasing member 2220. The biasing member 2220 is preferably a spring. The urging member 2220 is more preferably a coil spring. The retention member 2230 is a cap-like structure having opposing retention arms 2235 that engage a corresponding pair of engagement protrusions 2105 positioned on the outer surface of the relief exhaust device 2100. The insert 2210 and the spring 2220 are held in the inner volume portion of the relief exhaust device 2100 by a cap 2230.

The spring 2220 has a biasing strength or resistance equal to the relief pressure of the pressure relief valve 2000. Positive pressure is about 1.5 in. In this embodiment. When the relief pressure is exceeded, which is preferably set to Hg, the force generated on the inner surface of the insert 2210 overwhelms the biasing force of the spring 2220, the insert faces toward the cap 2230, and the relief exhaust system 2100 Move outside the inner volume. Air exits the pressure relief valve 2000 through the relief exhaust device 2100 until the positive pressure of the pressure relief valve decreases below the biasing strength of the spring 2220, at which time the insert 2210 is within the inner volume of the relief exhaust device. Move back into a sealing engagement with the internal surface of the relief exhaust.

Further, referring to FIG. 32, the pressure relief valve 2000 is shown with a preferred relief assembly 2201 that includes an insert 2211 and a biasing member 2221. Relief assembly 2201 functions similarly to insert 2210 and spring 2220 of relief assembly 2200, as described above. The insert 2211 is a ball, and the biasing member 2221 is a foam having a cylinder shape. The relief assembly 2201 has the advantage that the ball 2211 is more easily assembled within the relief exhaust device 2100. In addition, the foam cylinder 2221 is more invariant because it easily engages the ball 2211 and provides a constant spring actuation force. In addition, another method of pressure relief valve can be used, which can be adjusted so that the "massage intensity", ie the amount of positive pressure on the user's breast, is controllable .

The circuit board 120 shown in FIG. 3 allows the user to program several levels of speed and several levels of suction. In this embodiment, the rate (cycle time) ranges from about 45 cycles / minute (cpm) to about 75 cpm. The present invention provides for a number of speed level preset programming within a speed range. The number of levels is preferably from about 2 to about 8 levels. More preferably, the user can program five levels of speed within the speed range. The present invention further contemplates speed level programming by the user.

The suction force range for use with a single breast cup 400 and the preferred drive system 1500 shown in FIGS. 15-21 is about 3 in. About 10 in. From Hg. Hg and for the two breast cups about 3 in. About 8 in. From Hg. Hg. The suction range for use with the single breast cup 400 and the gearbox system shown in FIGS. 3 and 4 is about 3 in. About 9 in. From Hg. Hg and for the two breast cups about 3 in. About 8 in. From Hg. Hg. The present invention provides for a number of pre-set programming of suction levels within the suction force range. The number of levels is preferably from about 2 to about 8 levels. More preferably, the user can program five levels of suction within the suction force range. The present invention further contemplates suction level programming by the user.

Computer software can also be used to control the amount of positive and negative pressure. This allows the amount of positive and negative pressure to be personalized for the user and further changed throughout the duration of the pumping process to maximize efficiency.

Milking pump 100 is preferably controlled by software driven circuit board 120 along with gear motor 125, rack and pinion sets 109, 110 and piston systems 112, 113. The software and system are designed to provide maximum flexibility and to facilitate pressure curve or "wave" changes. This is feasible because the software controls the speed of the motor 125 and the amount that the piston 112 travels in the cylinder 113. The amount of movement of the piston 112 is related to the pressure level. By controlling the speed and pressure level with software, the pressure curve or "wave" can be controlled.

When a determination is made that the specific "wave" or pressure curve is similar to the infant's suction force or most comfortable to the mother, then the desired wave changes timing (motor speed and piston travel). Can be obtained. Through the use of software, the user has the ability to apply memory to a specific pressure curve and changes in that pressure curve over time to maximize comfort for the user.

In this embodiment, a sine wave is used to control the milking pump 100. This is based on the assumption that the most comfortable pressure curve does not have a sharp pressure level that gives the user a feeling of tightening and gradually increases or decreases the pressure similar to a sine wave. The reciprocating motion of the piston 112 is similar to the desired sine wave. However, to avoid sharp pressure peaks, the piston 112 timing is slowed down at these high points, and the pressure is held constant for a period of time at the maximum and minimum suction points of the wave. . This results in a pressure curve with a stable sine wave that is more comfortable for the user.

Another method of waves can also be used for the pressure curve if the above waves are determined by the mother to be desirable. For example, if the mother prefers a "sawtooth" pressure curve with a sharp apex, the timing of the piston 112 can simply be changed to a reciprocating cycle, minimizing the pause when the piston 112 changes direction. To. Further, for example, if the mother prefers a "rectangular curve", the timing of the piston 112 will hold the position of the piston as the piston attempts to change direction, and then quickly ramp down, it can be changed to hold this position again before applying an upward tilt. This will generate a "rectangular curve" wave

Use of software control results in a large selection of wave or pressure curves. This further allows that flexibility to change or provide a greater choice with one milking pump 100. In contrast, modern pumps have the disadvantage of not allowing the flexibility to change the pressure curve wave. The milking pump 100 allows control between cycles of pressure and speed. In the preferred embodiment, this is done through the use of a reversible variable speed motor 125 operatively connected to a linear system that incorporates a piston 112 and a cylinder 113. Thus, modern devices can repeatedly use a specific sinusoidal pressure curve on the surface, whereas the milking pump 100 uses any type of wave and uses that wave during the cycle. Has the ability to change.

The control system and software of the present invention provides a closed loop control system or real-time adjustment between cycles. Therefore, real-time monitoring of control variables such as the amount and speed of movement of the piston to be advanced occurs. As motors and other components age and wear, the closed loop control system is responsible for the detrimental changes described above to provide the precise cycle time and pressure required by the user. Real-time monitoring and control provides effectively equal speed levels for both single and two cup pump pumps despite torque changes.

The cylinder 113 has a pressure differential hole 75. The pressure differential hole 75 is preferably located along the bottom surface 80 of the cylinder 113. The pressure differential hole 75 is substantially smaller than the exhaust device hole 1013 and the supply tube 116, through which air flows to generate positive and negative pressure. The pressure differential hole 75 changes the amount of positive pressure compared to the amount of negative pressure. The pressure differential hole 75 is effective over a high range of vacuum to provide "lost" air at the end of the vacuum process. During the positive pressure process, a small amount of air is released through the pressure differential hole 75, but air is reintroduced during the negative pressure process when the pressure level increases.

Referring to FIG. 33, a cylinder 113 with a preferred embodiment of the pressure differential insert 76 is shown. The pressure differential hole 75 is disposed through the pressure differential insert 76. The insert 76 is then connected to the cylinder 113 through a cylinder hole 77 located through the cylinder wall. The insert 76 is preferably press-fitted into the cylinder hole 77. However, other methods of connection such as, for example, screws or adhesives can also be used. The pressure differential insert 76 is a machined metal part that allows machining of the pressure differential hole 75 with a precise diameter within very small tolerances.

It is more advantageous to place the pressure differential hole 75 directly through the wall of the cylinder 113 because of the considerable lack of accuracy in either molding or drilling the hole in the plastic part by using the insert 76, is there. In addition, the pressure differential insert 76 can be selectively inserted through a hole 77 in the cylinder, and therefore a plurality of inserts having a plurality of different pressure differential holes 75 can be used. By providing different diameters for the pressure differential hole 75, the suction level generated by the pump can be varied.

The pressure differential hole 75 allows air lost over time during use of the milking pump 100 to be regenerated during the negative pressure process, so that the positive pressure can be accurately maintained over time. During testing of the milking pump 100, unexpected and significant results resulted from the use of different sized diameters of the pressure differential hole 75. It was discovered that the pressure differential hole 75 having a diameter between about 0.15 mm and about 0.75 mm maintained a precise positive pressure over time while providing the desired negative pressure. The capacity of the cylinder 113 was 126 cm^3. The pressure differential hole 75 preferably has a diameter between about 0.25 mm and about 0.5 mm, and most preferably has a diameter of about 0.3 mm.

Referring to FIG. 10, the cylinder 113 is formed as a zero draft cylinder. The outer diameter of the piston 112 creates a seal with the inner diameter d of the cylinder 113 to move air inside the cylinder, creating a vacuum and pressure on the breast. The milking pump 100 requires a cylinder 113 with a constant inner diameter d through the entire length of the cylinder in order to create a proper seal while minimizing obstruction or resistance to the piston 112. A typical injection molded part requires a draft angle that produces a non-uniform inner diameter d of the cylinder 113.

The cylinder 113 is preferably formed as a zero draft cylinder having a uniform inner diameter d, and more preferably formed into a single part. As shown in FIG. 10, the cylinder 113 is an integral plastic injection molded part. Two-part cylinders or machining cylinders have the disadvantages that a single part zero draft cylinder 113 overcomes. A two-part cylinder requires an extruded tube that is attached to the end cap, and the two parts are joined using welding or using an adhesive. The machined part is typically a metal tube. One advantage over the zero draft integral cylinder 113 is that it can be injection molded.

Referring to FIGS. 3-10, the button pad 105 is the user interface or control mechanism for the milking pump 100. The button pad 105 has a pair of positive and negative keys that increase or decrease the level of suction and speed. Pad 105 further includes an on / off switch.

Due to the reciprocal movement of the piston 112 within the cylinder 113, the milking pump 100 supplies both positive and negative pressure to the female breast through a single hose or tube 350. While this embodiment uses a piston / cylinder mechanism to generate positive and negative pressure, another method of inflatable volume or pressure source can also be used. Another method embodiment described above includes a bellows mechanism or diaphragm that requires fewer parts.

Referring to FIGS. 11 and 12, a breast cup, hood or breast receiving member 400 of the present invention is shown. The breast cup 400 has a housing 500 having an air orifice 560, a flexible insert 600 and a holder 700. The housing 500 is a rigid structure, and the flexible insert 600 is a flexible structure. The housing 500 is configured to sealingly engage the insert 600 to form an exhaust volume 510 between the housing and the insert. Funnel-shaped insert 600 provides an inner volume 655 for receiving the breast. Air orifice 560 is in fluid communication with exhaust volume 510.

Milking pump 100 is placed in fluid communication with breast cup 400 by an air tube 350 connected to air orifice 560 and in fluid communication with cylinder 113. The milking pump supplies both positive and negative pressure to the breast cup 400. The positive pressure and negative pressure generated by the milking pump 100 cause air to flow into and out of the exhaust volume 510 through the air orifice 560. The positive and negative pressure supplied to the breast cup 400 expands and contracts the flexible insert 600, particularly the exhaust volume 510, to apply reciprocating positive and negative forces to the user's breast. .

Due to the negative pressure created by the exhaust of the exhaust volume 510 and the significant indentation of the insert 600 into the housing 500, the breast cup 400 has a maximum suction level that is inherently incorporated therein. Unlike modern devices that provide vacuum directly from the vacuum source to the nipple, and therefore are susceptible to damage from over-suction, the breast cup 400 can only provide maximum negative pressure based on the exhaust volume 510, is there. When all air is exhausted from the exhaust volume 510, the breast cup 400 preferably no longer increases the negative pressure or negative force applied to the breast. Milking pump 100 and breast cup 400 can apply positive and negative pressure to the user's breast via a single air tube 350 connected to air orifice 560.

The capacity set in the exhaust volume 510 is preferably between 22 cubic centimeters and 52 cubic centimeters, and more preferably between 32 cubic centimeters and 42 cubic centimeters. The inflatable and retractable exhaust volume 510 places an upper limit on the amount of negative pressure that can be applied to the user's breast, which further serves as a safe mechanism in the use of the milking pump 100. In addition, the hermetic engagement of the insert 600 and the housing 500 provides a barrier between the user's breast and the milking pump 100 to prevent any breast milk from entering the air tube 350 or the milking pump. The insert 600 can further include a massage member 634. The massage member 634 has a star shape, which provides an additional massage action to the breast. Other shapes can also be used for the massage member 634.

With reference to FIGS. 27 to 29, the breast cup 400 is shown in partial cross-section with respect to the breast 1. The breast 1 has a nipple 2 with a areola 3 and a milk lake or duct 4 supplied by a mammary gland 5. The breast cup 400 has an air bag 685 of the insert 600 and a tubular member 735 of the holder 700. The air bag 685 partially defines the exhaust volume 510. When air is exhausted from the bladder 685 and the exhaust volume 510 so that the insert 600 is pulled toward the housing 500 and against the housing 500, negative pressure, vacuum or negative force is , Applied to the breast 1.

Tubular member 735 is disposed substantially adjacent to bladder 685 and partially extends through insert 600. Tubular member 735 is a rigid barrier between breast 1 and bladder 685 that prevents the breast from bumping into contact with the bladder, thereby reducing the amount of their expansion and contraction. Thus, the reciprocating pressure applied to the breast is reduced.

The positioning of the breast cup 400 on the breast 1 results in the nipple 2, the areola 3, and the milk duct 4 that are substantially surrounded by the exhaust volume 510. The use of a tubular member 735 to create a rigid barrier adjacent the bladder 685 at the front of the nipple 2 and the areola 3 that is substantially surrounded by the exhaust volume, as illustrated in FIG. When exhausting air in the exhaust volume 510 during the negative pressure process or cycle, this results in a negative pressure gradient, vacuum or negative force 10 applied to the nipple 2. The negative pressure gradient or force 10 has a lateral component or lateral direction L that is greater than the axial component or axial direction A. The negative pressure gradient or force 10 and the larger lateral component L cause the nipple 2 to be pulled or sucked laterally beyond the axial direction, which has a considerable effect on milking the milk duct 4. Showed that. The negative pressure gradient or force 10 is also more comfortable for the user by extending the nipple 2 somewhat in contradistinction to the axial extension or expansion of the nipple along the axial direction A. It was shown to be close to aspiration.

The exhaust volume 510 extends almost at the front edge of the housing 500 where the housing is fixed to the insert 600, thereby causing lateral suction and lateral movement of the nipple 2 along the lateral component L. Helps generate a negative pressure gradient or force 10 during the negative pressure process or cycle. As shown in FIG. 29, a negative pressure gradient, vacuum or force 10 extends beyond the outer periphery of the areola 3 and is applied substantially laterally thereto during

the negative pressure process or cycle, thereby Furthermore, it helps to generate a force on the nipple 2 with a greater lateral component L compared to the axial component A, thus spreading the nipple.

The positioning of the tubular member 735 helps to reduce the negative pressure gradient or force 10 axially from the nipple 2 or at the front of the nipple 2 during the negative pressure process or cycle, thereby reducing the axial expansion of the nipple. Reduce associated discomfort. Tubular member 735 has an opening (not shown) formed along the tubular member wall. For a soft breast 1 that is pulled towards the tubular member 735 during the negative pressure process, the opening allows for the application of a negative pressure or vacuum to the distal end of the nipple 2.

Referring to FIGS. 30 and 31, a modern breast cup 20 connected to a vacuum source via a vacuum line 21 is shown. A modern breast cup 20 has a hood 22 capable of engaging the breast 1 and a cylindrical extension 23 attached to the hood. Cylindrical extension 23 is in fluid communication with vacuum line 21 and collection member 24. Vacuum or negative pressure is supplied from the vacuum line to the areola 2 via the cylindrical extension 23. The separation wall 27 prevents the breast milk from entering the vacuum line 21 in appearance. The discharge of air in the cylindrical extension 23 generates a negative pressure gradient or force 30 during the negative pressure process, as shown in FIG.

The negative pressure gradient or force 30 has a larger axial component A compared to the lateral component L during the negative pressure process, causing the nipple 2 to be pulled or sucked axially more than laterally, It has been shown to be ineffective at pumping breast milk from the milk duct. During the negative pressure process, a negative pressure gradient or force 30 having a larger axial component A compared to the lateral component L has also been shown to be uncomfortable for the user. Vacuum or negative pressure is supplied axially from the nipple 2 or at the front of the nipple 2 during the negative pressure process or cycle, thereby creating discomfort associated with the axial extension and expansion of the nipple

While the breast cup 400 uses a flexible insert 600 that partially defines an exhaust volume 510 that applies a negative pressure gradient, vacuum or force 10 to the nipple 2 during a negative pressure process or cycle, the present invention simultaneously intended for use with negative pressure gradients, vacuum or other designs and configurations that generate force 10. Another method design for the breast cup 400 that causes the nipple to expand more widely along the transverse component L, as opposed to stretching or expanding the nipple along the axial component A during the negative pressure process or cycle, intended by the present invention. Furthermore, another method design for the breast cup 400 is contemplated by the present invention that applies a negative force to the nipple 2 having a mean lateral component L greater than the mean axial component A during the negative pressure process. ing. Furthermore, the design of another method for the breast cup 400 for applying a negative pressure gradient or vacuum to the nipple 2 with a mean lateral component L greater than the mean axial component A during the negative pressure process is contemplated by the present invention. Has been.

While the preferred embodiment describes the use of a motorized pump 100 that supplies pressure to the breast cup 400, the present invention provides for a manual pump for use with the breast cup 400 that includes a pump suction mechanism that is secured to the breast cup 400. Intended for use. In addition, the present invention reduces the negative pressure, vacuum or negative force applied to the distal end or front of the nipple 2 and / or is applied to the nipple 2 relative to the transverse component L. Other barrier structures, designs, or methods that reduce the axial component A of negative pressure, vacuum, or negative force are contemplated.

The present invention provides a valve or other that is in fluid communication with the exhaust volume 510 so that the user can selectively control the amount of positive or negative pressure in the breast cup 400 as well as in the milking pump 100. Is intended to use a known release mechanism (not shown). The valve or release mechanism of the breast cup 400 may also be a quick release mechanism as a safe mechanism if it is uncomfortable for the user. The valve or release mechanism can also be used to selectively allow only positive or negative pressure to be generated in the breast cup 400.

Due to the modularity of the breast cup 400 through the use of three independent parts that can be easily assembled: the housing 500, the insert 600, and the holder 700, the present invention accommodates a breast of variable size and shape. Allows to include kits. The kit includes a plurality of different sized housings 500 and inserts 600 and different shaped housings 500 and inserts 600 to accommodate different sized and differently shaped breasts. A plurality of different housings 500 and inserts 600 can all be assembled to the holder 700 and connected to the milking pump 100. An example of a change in size between the housing 500 and the insert 600 includes the inner and outer diameters of the housing and the insert from end to end, and the total length of the housing and the insert. An example of a change in shape between the housing 500 and the insert 600 includes changing the taper angle and changing the circular shape of the leading edge of the housing and insert. In addition, the modularity and interchangeability of the present invention allows the use of differently shaped or sized massage members or protrusions 634 on different inserts 600.

The present invention further includes a kit that includes a plurality of different sized or shaped inserts 600 that can all be assembled into the housing 500 and holder 700 to form a plurality of different breast cups 400 for use with the milking pump 100. Intended. A plurality of different sized inserts 600 can be used to accommodate different sized breasts and also to modify the exhaust volume 510. A plurality of differently shaped inserts 600 can be used to accommodate differently shaped breasts and to provide different massage effects to the breast, such as, for example, different massage members 634 formed on the inserts. An illustration of several alternative method inserts 600 is more fully described in US Patent Application No. 10 / 331,183, filed December 27, 2002, the disclosure of which is hereby incorporated by reference in its entirety And incorporated here.

The preferred embodiment of the milking pump system uses a breast cup 400 having an exhaust volume 510 that fluidly separates from the user's breast, whereas another method breast cup can also be used with the milking pump 100. It is. The only features of the milking pump system of the present invention can be used with other types of breast cups such as, for example, the control system of the present invention or rack and pinion drive mechanisms.

Referring to FIG. 34, another method embodiment of the breast cup of the present invention is shown and generally designated by the reference numeral 5400. The breast cup 5400 can be used with the insert 600. The breast cup 5400 has a funnel-shaped housing 5500 that is connected to a cylindrical holder 5700. Holder 5700 has a handle 5725, a pressure orifice 5750, and a pressure regulator 5775. The handle 5725 is ergonomically contoured and has a wavy shape 5730 that provides different holding angles. The handle 5725 is disposed along the holder 5700 on the side facing away from the funnel shape 5500. The handle 5725 is preferably made of or covered with a material that facilitates gripping. The handle 5725 includes various textures, protrusions and / or relief processes to ease the user's hands during the pumping process.

A pressure orifice 5750 can be attached to the tube 350 to place the breast cup 5400 in fluid communication with the milking pump 100. The pressure regulator 5775 is in fluid communication with the pressure orifice 5750 and allows the user to adjust the pressure at the breast cup 5400 without having to make adjustments at the milking pump 100. In this embodiment, the pressure regulator 5775 is a dial, but other methods of actuators can be used.

Referring to FIG. 35, another method embodiment of the breast cup of the present invention is shown and generally designated by reference numeral 6400. The breast cup 6400 can be used with the insert 600. The breast cup 6400 has a funnel shape 6500 connected to a holder 6700. Holder 6700 has handle portions 6725, 6726, a pressure orifice 6750, and a pressure regulator 6775. Handle portions 6725, 6726 are disposed on either side of the holder 6700 to facilitate gripping of the holder. The handle portions 6725, 6726 are preferably made of or covered with a material that facilitates gripping. The handle portions 6725, 6726 include various textures, protrusions and / or relief processes to ease the user's hands during the pumping process.

Referring back to FIG. 12, the holder 700 of the breast cup 400 provides a first set of threads 701 and a second set of threads 702. The first thread 701 and the second thread 702 have different diameters and are in two standard sized bottles or holders used for breastfeeding and breast pumping; reusable containers and disposable

containers. Made to fit size. The first thread 701 and the second thread 702 have the same pitch and are coaxially aligned. During the molding process, this allows the steel formwork core to be unscrewed from the holder 700.

While the illustrated embodiment shows two threads on the breast cup 400, a first thread 701 and a second thread 702, the present invention is, for example, a nipple ring in a baby bottle Or the use of two threads on other infant care products that require the use of a holder or bottle such as a cap. 36 and 37, a baby bottle nipple ring is shown and generally designated by the reference numeral 7000. The baby bottle nipple ring 7000 has a circumferential wall 7100 with an inwardly extending flange 7200 defining an opening 7250. The baby bottle nipple ring 7000 has the two threads described above: a first set of threads 701 and a second set of threads 702. The baby bottle nipple ring 7000 engages the baby bottle nipple 7500 with either a container reusable by the first thread 701 or a container disposable by the second thread 702. Bring. The first thread 701 preferably extends downward from the flange 7200 and the second thread 702 is formed along the circumferential wall 7100.

Referring to FIGS. 38 and 39, the cap is shown and is generally designated by the reference numeral 8000. The cap 8000 has a circumferential wall 8100 that is connected to the top wall 8200. The cap 8000 further has two threads as described above: a first set of threads 701 and a second set of threads 702. Cap 8000 provides a seal with either a reusable container with first thread 701 or a disposable container with second thread 702. The first thread 701 preferably extends downward from the top wall 8200 and the second thread 702 is formed along the circumferential wall 8100.

Referring to FIG. 13, the T-connector 300 is a triangular valve that allows the user to use either the single breast cup 400 or the first orifice 310 and the second orifice 320, or it makes it possible to use either of the two breast cups. The milking pump 100 is connected to the t-connector 300 via an air pipe 350 at an inlet 330. The single split valve configuration of the t-connector 300 minimizes the amount of tubing 350 required for double pump suction. The T-connector 300 has a plug 340 that closes either the first orifice 310 or the second orifice 320 if a single pump suction is desired. Plug 340 is preferably anchored to the outer surface of t-connector 300 to facilitate engagement with first orifice 310 or second orifice 320.

Referring to FIG. 14, a method of squeezing breast milk with the milking pump system of the present invention is shown. As shown in step 800, the user turns on the milking pump 100 and starts the milking pump sucking operation. Thereby, power is supplied to the milking pump 100 (step 810). The user then enters the desired cycle time and suction level as in step 820. In a preferred embodiment, the user has five cycle times to select and a suction level. The cycle time and suction level are entered using the button pad 105.

In step 830, the PC board 120 sets the motor speed and the amount of movement of the target piston according to the user input level for the cycle time and suction The cycle time and suction level are then displayed to the user, as in step 840. In this embodiment, the cycle time and suction level are indicated by light 225 with the number of illuminated lights corresponding to the level. At step 850, the motor 125 is started and moves the piston 112 toward the bottom 175 of the cylinder 113. Thereby, a positive pressure supplied to the breast cup 400 by the air tube 350 is generated.

In step 855, the PC board monitors the home switch to determine if it was activated by contact with the piston 112. At step 860, it is determined whether the home switch has been activated. If the home switch is activated, it is reset as in step 870. At step 880, the motor 125 is then reversed to move the piston 112 toward the top 180 of the cylinder 113. Thereby, a negative pressure supplied to the breast cup 400 by the air tube 350 is generated. One advantage of the milking pump system of the present invention is that it supplies both positive and negative pressure through the same air tube 350. This reduces cleaning and simplifies user operation.

In order to provide an appropriate amount of suction as input by the user, the optical sensor 121 counts the number of rack openings 50 as in step 890. In step 900, the PC board 120 determines whether the counted number of rack openings 50 is equal to the amount of movement of the target piston as entered by the user. At step 910, it is determined whether milking pump 100 remains "on". If the milking pump 100 is stopped, the pump suction operation ends as in step 915.

At step 920, it is determined whether the user has entered a new cycle time or suction level. When a new cycle time or suction level is input, the PC board 120 sets the motor speed and the target piston movement amount according to the user input level with respect to the cycle time and the suction force, and returns to step 830. Repeat the above steps. If the user does not enter a new cycle time or suction level, the motor is reversed again, causing the piston 112 to move toward the bottom 175 of the cylinder 113. Thereby, a positive pressure supplied to the breast cup 400 by the air tube 350 is generated. This process causes milking pump 100 to continue supplying positive and then negative pressure to breast cup 400 until the milking pump is turned off (step 910).

The milking pump system of the present invention includes a significant number of components and can be used at a remote location, such as when a user travels. Various components can be placed in the bag system for ease of use. An example of the bag system described above and the components of the system described above is disclosed in co-owned US patent application Ser. No. 10 / 331,130 filed on Dec. 27, 2002, the disclosure of which is , incorporated herein by reference.

Although the invention has been described with particular reference to preferred forms thereof, various changes and modifications can be departed from the spirit and scope of the invention as defined in the appended claims. Obviously it will be done.

It is a front perspective view of the milking pump of the milking pump system of this invention. FIG. 2 is a front perspective view of the milking pump of FIG. 1 in an open state. It is a disassembled perspective view of the milking pump of FIG. It is a top view of the milking pump of FIG. 1 without a cover. It is a disassembled perspective view of the piston and cylinder of this invention. FIG. 6 is an exploded side view of a portion of the piston and cylinder of FIG. 5. It is a front perspective view of the piston of FIG. FIG. 6 is an exploded perspective view of another piston method embodiment of the present invention. FIG. 2 is an exploded perspective view of a pressure relief valve of the system of FIG. FIG. 6 is a cross-sectional plan view of the cylinder of FIG. 5. It is a front perspective view of the breast cup of the present invention. FIG. 12 is a side cross-sectional view of the breast cup of FIG. 11. It is a back perspective view of the T-connector of the present invention. 12 is a flow chart illustrating a method of pumping a breast according to the system of FIGS. 1 and 11. It is a top perspective view of a preferred embodiment of a milking pump for the milking pump system of the present invention. it is a top view of the milking pump of FIG. It is a top perspective view of the drive system of the milking pump of FIG. FIG. 18 is a side perspective view of the drive system of FIG. 17. FIG. 16 is a top perspective view of a portion of the gear reduction system portion of the drive system of FIG. 15 partially assembled. FIG. 6 is a top perspective view of another method embodiment of a milking pump for the milking pump system of the present invention. it is a top view of the milking pump of FIG. It is a top perspective view of the drive system of the milking pump of FIG. FIG. 21 is a side perspective view of the drive system of FIG. 20. It is a top perspective view of the motor of the drive system of FIG. FIG. 21 is a top perspective view of a portion of the gear reduction system portion of the drive system of FIG. 20 partially assembled. FIG. 21 is a top perspective view of the gear reduction system of the drive system of FIG. 20 partially assembled. FIG. 12 is a partial cross-sectional side view of the breast cup of FIG. 11 shown with a breast. FIG. 28 is a partial cross-sectional side view of the breast cup of FIG. 27 applied to the breast prior to the negative pressure process. FIG. 28 is an exploded cross-sectional view of the breast cup and breast of FIG. 27 during a negative pressure process showing a display of negative pressure gradient or force on the breast. 1 is a cross-sectional side view of a prior art breast cup applied to a breast prior to a negative pressure process. FIG. FIG. 31 is an exploded cross-sectional view of the prior art breast cup and breast of FIG. 30 during a negative pressure process showing a negative pressure gradient or force display on the breast. FIG. 10 is an exploded perspective view of the pressure relief valve of FIG. 9 with another embodiment of a relief assembly. FIG. 6 is a perspective view of the cylinder of FIG. 5 with another embodiment of a pressure differential hole. 3 is another method embodiment of the breast cup of the present invention. Figure 5 is another alternative method embodiment of the breast cup of the present invention. It is a bottom perspective view of the nipple ring of the baby bottle having the nipple of the baby bottle of the present invention. It is side surface sectional drawing of the teat ring of the baby bottle of FIG. 36, and the teat of a baby bottle. It is a bottom perspective view of the cap of the present invention. It is side surface sectional drawing of the cap of FIG.

Patent Citations (101)

Publication number	Priority date	Publication date	Assignee	Title
Family To Family Citations				
US11135A *		1854-06-20		Breas
US2160651A *	1936-12-03	1939-05-30	Laval Separator Co De	Pulsator for milking machines
US2419795A *	1945-07-11	1947-04-29	Paul W Saunders	Breast pump
US2584435A *	1946-11-30	1952-02-05	Norman B Doerr	Baby supply cabinet
NL73732C *	1948-10-08			
US3382867A *	1965-03-22	1968-05-14	Ruby L. Reaves	Body portion developing device with combined vacuum and vibrating means
US3741161A *	1971-06-03	1973-06-26	Z Zhuk	Milking apparatus for milking lactiferous animals
US3738363A *	1972-01-17	1973-06-12	F Lunas	Breast pump
US3977405A *	1975-04-07	1976-08-31	Shozaburo Yanase	Breast pump
US4041904A *	1976-05-14	1977-08-16	The De Laval Separator Company	Pneumatic pulsator for teat cups
US4249481A *	1977-02-22	1981-02-10	Adams Frank H	Milking apparatus and method
US4263912A *	1977-06-08	1981-04-28	Adams Frank H	Milking apparatus and method
US4323067A *	1977-06-20	1982-04-06	Adams Frank H	Combination breast pump and gavage feeding apparatus and method
US4251015S *	1978-02-17	1979-02-06	Cone Richard E	Breast pump
US4281445A *	1979-07-05	1981-08-04	Datafile Limited	Apparatus and method for replacement of file folders having fasteners
US4311141A *	1980-03-13	1982-01-19	Diamond Arthur D	Breast pump
US4857051A *	1980-09-05	1989-08-15	Isg/Ag	Breastpump
US4501585A *	1982-08-23	1985-02-26	Friedman Laura L	Mother's milk harvesting and collection device
EP0116186B1 *	1983-01-11	1986-07-23	Ameda Ag	A manually operated breast pump
US4607596A *	1983-05-11	1986-08-26	Whittlestone Walter G	Milking methods and apparatus
USD283782S *	1983-10-03	1986-05-06	Medela, Inc.	Breast pump
US4754776A *	1984-01-24	1988-07-05	Mckee James E	Pneumatic control valves with diaphragm actuators and modular body structure
CH662949A5 *	1984-03-14	1987-11-13	Ameda Ag	Breast pump for sucking breast milk.
DE3419613C2 *	1984-05-25	1992-09-24	Kaweco Gmbh, 7257 Ditzingen, De	
US4680028A *	1984-07-02	1987-07-14	Lact-Assist, Incorporated	Flexible breast receptor for breast pump
GB8422861D0 *	1984-09-11	1984-10-17	Avent Medical Ltd	Single handed breast pump
JPS6294170A *	1985-10-21	1987-04-30	Pigeon Kk	Milking device
US4761160A *	1986-01-23	1988-08-02	Vermillion Richard E	Human milk retrieval system
AT64310T *	1986-02-28	1991-06-15	Ameda Ag	INSERT FOR CHEST PUMPS.
US4740196A *	1986-07-24	1988-04-26	Powell Margaret D	Nursing apparatus
US4796758A *	1987-09-02	1989-01-10	David Hauk	Assembly for storage, transportation and chilling of expressed human milk
US5007899A *	1988-02-29	1991-04-16	Isg/Ag	Drive unit adapted for use with manual piston pump

US5039500S *	1988-04-11	1990-07-24	Spalding & Evenflo Companies, Inc.	Breast pump
US4892517A *	1988-04-11	1990-01-09	Spalding & Evenflo Companies, Inc.	Breast pump
US4950236A *	1988-10-21	1990-08-21	Aurora Search Ltd.	Breast pump adapter for filling infant nursers having disposable liners
US4929229A *	1988-11-30	1990-05-29	Isg/Ag	Breastpump having improved valve mechanism
CH676795A5 *	1989-03-01	1991-03-15	Ameda Ag	
US5049126A *	1990-02-16	1991-09-17	Isg/Ag	Breast pump with nipple stimulating insert
US5100406A *	1990-11-01	1992-03-31	Graham-Field, Inc	Silicone breast pump insert
US5178095A *	1991-06-13	1993-01-12	Dec International, Inc.	Milking system with positive pressure on thin liner
US5295957A *	1991-12-23	1994-03-22	Pigeon Co., Ltd.	Breast pump having a pressure adjusting mechanism
US5308321A *	1992-05-05	1994-05-03	Castro Donna J	Retainer assisted by vacuum expansion system
USD346209S *	1992-05-19	1994-03-15	Palo Alto Design Group, Inc.	Breast pump
US5304129A *	1993-07-12	1994-04-19	Forgach Suzanne E	Pivotable foot operated breast pump
US5415632A *	1994-01-10	1995-05-16	Playskool, Inc.	Breast pump
US5476490A *	1994-05-10	1995-12-19	Medela, Inc.	Heating pad
US5542921A *	1994-11-04	1996-08-06	Gerber Products Company	Electric breast pump
USD372975S *	1994-11-04	1996-08-20	Gerber Products Company	Electric breast pump
US5514166A *	1995-01-20	1996-05-07	Medela, Inc.	Device and method for supporting a breast shield and related pump equipment
GB9502995D0 *	1995-02-16	1995-04-05	Cannon Rubber Ltd	Breast pump insert
US5601531A *	1995-02-16	1997-02-11	Medela, Incorporated	Breast pump assembly and method of using same
GB2299027B *	1995-03-24	1999-02-17	Cannon Rubber Ltd	Diaphragm breast pump
US6093168A *	1995-06-08	2000-07-25	Omw, Inc.	Breast pump attachment to a household vacuum cleaner
US5776098A *	1995-08-03	1998-07-07	Medela, Incorporated	Diaphragm pump and pump mounted in a carrying case useful in breast pumping
US6257847B1 *	1995-08-03	2001-07-10	Medela, Inc.	Diaphragm pump and pump for double-breast pumping
US5616126A *	1995-08-28	1997-04-01	Jelks; Casandra N.	Apparatus for simultaneously pumping milk from the right and left breast of a nursing mother
US5871456A *	1995-09-15	1999-02-16	Armstrong; Edie C.	Apparatus and method for correcting flat, inverted or retracting nipples of varying sizes
CH690956A5 *	1995-10-03	2001-03-15	Trimed Ag	Regeleinrichtung, particularly for a Muttermilchabsaugeinrichtung.
US6379327B2 *	1995-10-06	2002-04-30	Ellen F. Lundy	Hands-free portable breast pump system
US5720722A *	1996-01-11	1998-02-24	Medela, Incorporated	Connector for use in single and double breast pumping and breast pump using same
USD420443S *	1996-02-08	2000-02-08	Jex Company Limited	Breast pump
DE19611788C2 *	1996-03-12	1999-11-11	Francotyp Postalia Gmbh	Arrangement for folding sheets
US5902267A *	1996-08-09	1999-05-11	Medo; Elena M.	Breast pump system using wall vacuum source
US6110140A *	1996-09-17	2000-08-29	Medela, Inc.	Manual breastmilk pump
NO307079B1 *	1996-11-12	2000-02-07	Tone Nordvik	Breast device
USD408528S *	1996-12-13	1999-04-20	Blue Ribbon Plastic Factory Co., Ltd.	Breast pump
DE19652232A1 *	1996-12-16	1998-06-18	Nueesch Logistik	Breast breast pump and valve therefor
DE19700545A1 *	1997-01-10	1998-07-16	Nueesch Logistik	Breast pump
AT288769T *	1997-02-26	2005-02-15	Medela Ag	DEVICE FOR SUCTION OF LIQUIDS

US6109100A *	1997-09-03	2000-08-29	Buckley; Scott F.	Pressure-or flow-sensitive feeding monitor
DE19747842A1 *	1997-10-30	1999-05-06	Nuesch Logistik	Pump for mother's milk with breast body
US6213840B1 *	1997-12-03	2001-04-10	Bonnifant Heeja Han	Hands-free breast pump supporting bra and system
US5941847A *	1998-02-06	1999-08-24	Medela Holding Ag	Breast shield with vacuum isolation element
US6338163B1 *	1998-05-04	2002-05-07	Patricia Ann Kelly	Electric breast pump designed to simulate infant suckling
US6050432A *	1998-06-09	2000-04-18	Koehnke; Diane Lynn	Sealable slip-in baby bottle liner
US6090065A *	1998-07-06	2000-07-18	Evenflo Company, Inc.	Self-cycling breast pump
GB2340755B *	1998-08-24	2002-09-25	Cannon Rubber Ltd	Breast pump insert
US6418598B *	1998-11-20	2000-01-04	Jauch Shelly M	Breast pump
US6387072B1 *	1998-12-10	2002-05-14	Medela Holding Ag	Breastpump with universal hood base and interchangeable suction hoods
US6471660B1 *	1999-01-21	2002-10-29	Chandice Covington	Method and apparatus for measuring factors in mammary fluids
US6210360B1 *	1999-05-26	2001-04-03	Carl Cheung Tung Kong	Fluid displacement pumps
US20010016708A1 *	1999-05-26	2001-08-23	Kong Carl Cheung Tung	Fluid displacement pumps
US6706012B2 *	2000-06-12	2004-03-16	L. Jason Clute	Apparatus for expressing milk
US6227936B1 *	1999-09-20	2001-05-08	Amelia Mendoza	Hands free pumping and nursing bra
US6547756B1 *	1999-12-10	2003-04-15	Medela Holding Ag	Programmable breastpump
US6808517B2 *	1999-12-10	2004-10-26	Medela Holding Ag	Suction sequences for a breastpump
US6328882B1 *	2000-03-07	2001-12-11	Bbtresor inc.	Disposable sterile bag, e.g. for breast milk
US6585686B2 *	2000-05-04	2003-07-01	Medela Holding Ag	Method of collecting fluid with a breastpump membrane
US6440100B1 *	2000-05-31	2002-08-27	John Gilbert Prentiss	Concealed apparatus for hands free breast milk pumping and storage
USD446300S1 *	2000-06-02	2001-08-07	Kaweee Gmbh	Breast pump
US6358226B1 *	2000-06-21	2002-03-19	Audrey M. Ryan	Lactation apparatus
USD446852S1 *	2000-07-13	2001-08-21	Gerber Products Company	Breast pump funnel with insert
US6338164B1 *	2000-09-26	2002-05-07	Gerber Products Company	Massaging breast pump and funnel therefor
AU2716302A *	2000-11-13	2002-05-21	Atossa Healthcare Inc	Methods and devices for collecting, handling and processing mammary fluid samples for evaluating breast diseases, including cancer
US6423030B1 *	2000-11-27	2002-07-23	Medela Holding Ag	Lubricated breastshield
DE10059710A1 *	2000-12-01	2002-06-06	Nuesch Engineering Remetschwi	Breast milk pump arrangement as well as control device, distribution valve and pump therefor
US6886994B2 *	2001-05-30	2005-03-15	Neomatrix, Llc	Noninvasive intraductal fluid diagnostic screen
US20030073951A1 *	2001-05-30	2003-04-17	Morton Kevin B.	Disposable patient interface for intraductal fluid aspiration system
US6663587B2 *	2001-06-22	2003-12-16	Medela Holding Ag	Breastshield with multi-pressure and expansible chamber construction, related breastpump and method
IL162730D0 *	2001-12-27	2005-11-20	Playtex Products Inc	Breast cup
US20040024352A1 *	2001-12-27	2004-02-05	Playtex Products, Inc.	Breast pump system

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JP2010525899A *	2007-05-04	2010-07-29	ウィスパーウエア，インク．	Hands-free milking machine with balanced reciprocating drive
JP2012511324A *	2008-12-12	2012-05-24	ユーニンクレッカフィリップスエレクトロニクスエヌヴィ	Automatic head for milking machine
JP2013102867A *	2011-11-11	2013-05-30	Pigeon Corp	Breast pump and mechanical unit for the same
WO2017082400A1 *	2015-11-13	2017-05-18	ピジョン株式会社	Breast pump
JP2020523179A *	2017-06-15	2020-08-06	チアロテクノロジーリミテッドChiaroTechnology limited	Milking system
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US6749582B2 *	2002-04-30	2004-06-15	The First Years Inc.	Pumping breast milk
GB0224986D0	2002-10-28	2002-12-04	Smith & Nephew	Apparatus
US7776008B2 *	2003-08-08	2010-08-17	Playtex Products, Inc.	Manual breast pump
US11298465B2	2003-10-28	2022-04-12	Smith & Nephew Plc	Apparatus and method for wound cleansing with actives
US20050154348A1 *	2004-01-08	2005-07-14	Daniel Lantz	Breast pump
US8529548B2	2004-04-27	2013-09-10	Smith & Nephew Plc	Wound treatment apparatus and method
US7753894B2 *	2004-04-27	2010-07-13	Smith & Nephew Plc	Wound cleansing apparatus with stress
US10413644B2	2004-04-27	2019-09-17	Smith & Nephew Plc	Wound treatment apparatus and method
GB0409446D0	2004-04-28	2004-06-02	Smith & Nephew	Apparatus
US7396339B2	2004-04-30	2008-07-08	The First Years Inc.	Pumping breast milk
US7806855B2	2006-04-11	2010-10-05	Playtex Products, Inc.	Manual breast pump
US9162016B2	2006-09-22	2015-10-20	Medela Holding Ag	Breastpump with irregular milk expression sequences
DE102006056321B4 *	2006-11-24	2013-01-17	Mapa Gmbh	Manual breast pump
US8377016B2	2007-01-10	2013-02-19	Wake Forest University Health Sciences	Apparatus and method for wound treatment employing periodic sub-atmospheric pressure
US8070716B2	2007-04-11	2011-12-06	Medela Holding Ag	Method and apparatus for minimum negative pressure control, particularly for breastpump with breastshield pressure control system
US8070716B2	2007-04-11	2011-12-06	Medela Holding Ag	Method and apparatus for minimum negative pressure control, particularly for a breastpump with breastshield pressure control system
RU2489993C2	2007-10-10	2013-08-20	Уэйк Форест Юниверсити Хелс Сайенсиз	Device and method of treating spinal cord tissue
US8366692B2	2008-01-08	2013-02-05	Richard Scott Weston	Sustained variable negative pressure wound treatment and method of controlling same
AU2009223037A1	2008-03-12	2009-09-17	Smith & Nephew Plc	Negative pressure dressing and method of using same
EP2313008B1	2008-07-18	2017-04-12	Wake Forest University Health Sciences	Apparatus for cardiac tissue modulation by topical application of vacuum to minimize cell death and damage
WO2010054174A1 *	2008-11-07	2010-05-14	Simplisse, Inc.	Breast pump
US8398584B2	2009-01-16	2013-03-19	Learning Curve Brands, Inc.	Breast pump and method of use
CN201375699Y *	2009-02-15	2010-01-06	郭永峰	Piston type breast pump
CN201469749U *	2009-06-16	2010-05-19	郭永峰	Suction device of piston-type breast pump
GB0912229D0	2009-07-14	2009-08-26	Jackel Int Ltd	A breast pump
EP2324868A1 *	2009-07-28	2011-05-25	Koninklijke Philips Electronics N.V.	Flexible drive for breast pump
EP2606816A1	2011-12-22	2013-06-26	Koninklijke Philips Electronics N.V.	A method and system for providing an indication as to the amount of milk remaining in a breast during lactation
BR112015021286A2	2013-03-05	2017-07-18	Koninklijke Philips Nv	breast interface for a breast pump, breast pump, lining support

				structure for use on a breast interface, and breast for use on a breast interface
US10207082B2	2013-03-14	2019-02-19	Medela Holding Ag	Small-volume collection for a breastpump system
RU2015152082A3	2013-05-10	2018-03-21		
CA2955605A1 *	2014-07-22	2016-01-28	John Y. Chang	Breast pump system and methods
SG10201911394QA	2014-07-22	2020-02-27	Exploramed Nc7 inc	Breast pump system and methods
WO2016014488A1 *	2014-07-22	2016-01-28	Exploramed Nc7, Llc	Breast pump system and methods
WO2016014483A1	2014-07-22	2016-01-28	Exploramed Nc7, Llc	Breast pump system and methods
US10039871B2 *	2015-04-14	2018-08-07	Asha M. Pollen	Milk repellent breast pump
AU2016258207B2	2015-05-07	2020-10-15	Jared Miller	Breast pump system
USD809646S1 *	2016-02-10	2018-02-06	Exploramed Nc7, Inc.	Breast pump
EP3461513A1 *	2017-09-27	2019-04-03	Koninklijke Philips N.V.	Pump device, comprising a pump and a housing accommodating the pump
USD882061S1 *	2018-02-09	2020-04-21	Ningbo YouHe Electric Technology Co., Ltd	Breast pump
USD954933S1 *	2018-06-01	2022-06-14	Chiaro Technology Limited	Breast pump accessory
JP1662265S *	2019-08-01	2020-06-22		
EP3789053A1	2019-09-03	2021-03-10	Koninklijke Philips N.V	Electric breast pump

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JP5290135B2	2013-09-18	Milking pump equipment
JP4831984B2	2010-06-16	Chest pump system
JP3744570B2	2006-02-15	Milking machine
US6257847B1	2001-07-10	Diaphragm pump and pump for double-breast pumping
RU2449811C2	2012-05-10	Breast pump with synchronised diaphragm and pressure control system in pumping cycle
JP2005514116A5	2006-02-16	
JP6403575B2	2018-10-10	Milking machine
GB2435617A	2007-09-05	Breast pump
GB2435618A	2007-09-05	Breast cup
JPH07136245A	1995-05-30	Milker
JP3698218B2	2005-09-21	Milking machine
JPH06292720A	1994-10-21	Electric milking machine
AU744212B2	2002-02-21	Diaphragm pump useful in breast pumping
KR200296860Y1	2002-12-02	Pressure controller for a milking machine

Priority And Related Applications

Priority Applications (2)

Application	Priority date	Filing date	Title
US10/637,979	2002-12-27	2003-08-08	Breast pump system
PCT/US2004/025285	2003-08-08	2004-08-05	Breast pump system

Concepts

machine-extracted

Download Filter table

Name	Image	Sections	Count	Query match
Breast		claims,abstract,description	223	0.000
Milk, Human		claims,abstract,description	31	0.000
human milk		claims,abstract,description	31	0.000
Nipples		claims,description	92	0.000
method		claims,description	54	0.000
communication		claims,description	45	0.000
fluid		claims,description	45	0.000
Urinary Bladder		claims,description	18	0.000
reversible		claims,description	8	0.000
material		claims,description	7	0.000
metal		claims,description	6	0.000
pressing		claims,description	2	0.000

Show all concepts from the description section

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(19)日本国特許庁(JP)　(12)公表特許公報(A)　(11)特許出願公表番号
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(51)Int.Cl.	F I	テーマコード（参考）
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(33)優先権主張国	スイス(CH)

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最終頁に続く

(54)【発明の名称】乳房シールドユニット

(57)【要約】
ヒトの母乳を搾り出すための乳房シールドユニットが、ヒトの乳頭を受容するための受容部（１０）と、前記乳頭に負圧を印加するための負圧室（４０）と、前記負圧室（４０）に負圧を発生させるための膜（３）とを有し、前記受容部（１０）はこの負圧室（４０）に開いている。前記膜（３）は１枚又は複数枚に設計され、少なくとも部分的に前記受容部（１０）を取り囲む。この乳房シールドユニットは、乳房に近接する領域での媒体の分離を可能にする。これは小型で洗浄が容易であり、特にハンズフリーの乳房シールドユニットとしての使用に適している。
【選択図】図３

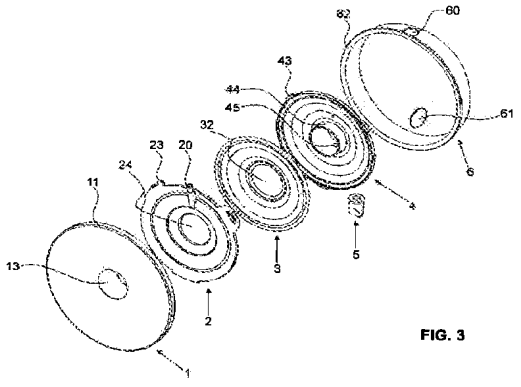

FIG. 3

【特許請求の範囲】
【請求項１】
ヒトの母乳を搾り出すための乳房シールドユニットであって、
ヒトの乳頭を受容するための受容部（１０）と、
前記乳頭に負圧を印加するための　　負圧室（４０）と、
前記負圧室（４０）に負圧を発生させるための膜（３）と、
を有し、前記受容部（１０）は前記負圧室（４０）に開口する乳房シールドユニットにおいて、
前記膜（３）が１枚又は複数枚に設計され、少なくとも部分的に前記受容部（１０）を取り囲むことを特徴とする、乳房シールドユニット。
【請求項２】
ヒトの母乳を搾り出すための乳房シールドユニットであって、
乳頭を受容するための受容部（１０）と、
前記乳頭に負圧を印加するための　　負圧室（４０）と、
前記負圧室（４０）に負圧を発生させるための膜（３）と、
を有し、前記受容部（１０）は中心軸（Ａ）を画定し、前記負圧室（４０）に開口する乳房シールドユニットにおいて、
前記中心軸（Ａ）の延長方向に見て、前記膜（３）が前記負圧室（４０）の前記乳頭に面する側に配置されることを特徴とする、乳房シールドユニット。
【請求項３】
ヒトの母乳を搾り出すための乳房シールドユニットであって、
母親の乳房の乳頭を受容するための受容部（１０）と、
前記乳頭に負圧を印加するための　　負圧室（４０）と、
前記負圧室（４０）をミルク収集容器（７、７’）に接続するためのミルクポート（４５）と、
前記負圧室（４０）に負圧を発生させるための膜（３）と、
を有し、前記受容部（１０）は中心軸（Ａ）を画定し、前記負圧室（４０）に開口する乳房シールドユニットにおいて、
前記中心軸（Ａ）の延長方向に見て、前記膜（３）が前記ミルクポート（４５）の前記母親の乳房に面する側に配置されることを特徴とする、乳房シールドユニット。
【請求項４】
前記膜（３）が円又は部分的円の形状の開口部を取り囲む、請求項１～３のいずれか１項に記載の乳房シールドユニット。
【請求項５】
前記膜（３）が１枚に形成され、円環形状であることを特徴とする、請求項４に記載の乳房シールドユニット。
【請求項６】
前記膜（３）が少なくとも２つの個別のパーツ（３’、３’’、３’’’）を有し、組み立てられた状態の前記個別のパーツ（３’、３’’、３’’’）が円又は部分的円を包囲する、請求項４に記載の乳房シールドユニット。
【請求項７】
乳房側膜ハウジング部（２）と乳房から遠い膜ハウジング部（４）を有し、これらの膜ハウジング部（２、４）が共通の膜ハウジングを形成し、前記膜（３）がこれらの２つの膜ハウジング部（２、４）の間に移動可能に保持される、請求項１～６のいずれか１項に記載の乳房シールドユニット。
【請求項８】
前記膜（３）が静止位置で円錐台形状である、請求項１～７のいずれか１項に記載の乳房シールドユニット。
【請求項９】
母親の乳房に置くための乳房接触面（１）を有し、この乳房接触面（１）を前記膜（３

）を包囲するハウジングシェル（６）に固定させることができる、請求項１～８のいずれか１項に記載の乳房シールドユニット。
【請求項１０】
前記乳房接触面（１）が前記乳頭を受容するための円錐台形状又は円筒形状の第一のスタブ（１０）を有し、この第一のスタブ（１０）を前記負圧室（４０）の第二のスタブ（４４）に接続させることができ、この第一のスタブ（１０）と前記第二のスタブ（４４）が前記受容部を形成する、請求項９に記載の乳房シールドユニット。
【請求項１１】
前記乳房シールドユニットに一体化されたミルク収集容器（７’）を有し、前記ミルク収集容器（７’）が前記乳房シールドユニットの残りの部分に取り外し可能に配置される、請求項１～１０のいずれか１項に記載の乳房シールドユニット。
【請求項１２】
真空ポンプ（８、８１）に接続させることができる真空ポート（２０）を有し、前記膜（３）が前記真空ポート（２０）を前記負圧室（４０）から分離する、請求項１～１１のいずれか１項に記載の乳房シールドユニット。
【請求項１３】
前記膜（３）が、前記真空ポート（２０）に通じる第一の出口（２２）と、前記負圧室（４０）に通じる第二の出口（４２）を有するポンプ室（４６）に配置される、請求項１２に記載の乳房シールドユニット。
【請求項１４】
請求項１２又は１３に記載の乳房シールドユニットと、真空ライン（８０）と、真空ポンプ（８、８１）とを備える乳房ポンプであって、前記真空ライン（８０）が前記真空ポート（２０）を前記真空ポンプ（８、８１）に接続する、乳房ポンプ。
【請求項１５】
前記乳房ポンプユニットがハウジングシェル（６）を有し、このハウジングシェル（６）が前記膜（３）を包囲し、このハウジングシェル（６）の中に前記真空ポンプ（８１）が配置される、請求項１４に記載の乳房ポンプ。
【発明の詳細な説明】
【技術分野】
【０００１】
本発明は、請求項１、２、３のいずれかのプリアンブルに記載の乳房シールドユニット及び請求項１４のプリアンブルに記載の乳房ポンプに関する。
【背景技術】
【０００２】
ヒトの母乳を搾り出すための装置は良く知られている。手動又は電動の真空ポンプが直接又は真空ラインを介して乳房シールドに接続され、この乳房シールドが乳頭を含む母親の乳房の一部を受容するために使用される。
【０００３】
特許文献１は、真空ポンプと、真空ラインと、ベースと、このベース上に固定させることができる漏斗状の硬い乳房シールドを備える乳房ポンプを開示する。真空ラインは真空ポンプをベースに接続する。真空ラインと真空ポンプを汚染から保護するために、大表面の膜形状のバリアがベースに配置される。この膜はポンプ室に配置され、その中で、ポンプユニットによって発生させられた負圧が膜の反対側に伝達される。
【０００４】
特許文献２は同様にベース部を備えた乳房ポンプを記載し、ベース部に漏斗状の硬い乳房シールドと、真空ポンプに接続するための真空ラインと、ミルク収集容器とを接続することができる。ベース部は同様に真空ラインを保護するために膜を有する。
【０００５】
特許文献３と特許文献４は、いわゆるハンズフリーの乳房ポンプを開示し、ブラジャーの下に装着することができる。乳房接触面が母親の乳房の上に密着して置かれ、同時に真

空ポンプの膜としての役割を果たす。即ち、真空ポンプのポンプ室が柔らかい乳房接触面と母親の乳房との間に形成される。

【０００６】

特許文献５は別のハンズフリーの乳房ポンプを開示する。ここでは、小型の乳房シールドがブラジャーの中に配置される。この乳房シールドから、真空ラインが真空ポンプユニットに通じ、ミルクラインがミルク収集容器に通じる。真空ポンプユニットとミルク収集容器はストラップに配置され、母親はこのストラップをウエストに巻き付ける。

【０００７】

特許文献６では、ミルクを収集するための柔軟な袋を硬い乳房シールドに固定して、これら両方をブラジャーに装着する。乳房シールドの上部領域の中に開いている真空ラインが、ストラップにつけられた真空ポンプにつながっている。

【０００８】

特許文献７もまた、ハンズフリーの乳房ポンプを開示する。ここでも、真空ラインは乳房シールドから真空ポンプへつなげられる。このラインは同時にミルクラインとして使用される。

【０００９】

特許文献８は硬い乳房シールドのための支持装置に関し、この支持装置はブラジャーに固定させることができる。

【００１０】

特許文献９は母乳の自然流出を捕えるように設計された乳房シールドを開示する。乳房シールドは柔らかい乳房接触面と、これに接続されたキャップとを有し、ミルクはこのキャップ内に流れ込むことができる。

【００１１】

特許文献１０はヒトの母乳を搾り出すための乳房ポンプを開示し、真空ラインは同時にミルクラインとして使用され、隔膜真空ポンプの膜は媒体分離器としての役目を果たす。

【先行技術文献】

【特許文献】

【００１２】

【特許文献１】国際公開第２００８／０５７２１８号
【特許文献２】国際公開第２０１１／０３７８４１号
【特許文献３】米国特許第７２２３２５５号明細書
【特許文献４】国際公開第２００８／１３７６７８号
【特許文献５】米国特許第６３７９３２７号明細書
【特許文献６】米国特許出願公開第２００８／０２６２４２０号明細書
【特許文献７】米国特許第６４４０１００号明細書
【特許文献８】米国特許出願公開第２００８／００３９７８１号明細書
【特許文献９】米国特許第４２７０５３８号明細書
【特許文献１０】国際公開第２０１１／０３５４４８号

【発明の概要】

【発明が解決しようとする課題】

【００１３】

本発明の目的は、ヒトの母乳を搾り出すための改良された装置を創造することである。

【課題を解決するための手段】

【００１４】

この目的は、請求項１、２、３の特徴を備える乳房シールドユニットによって、及び、請求項１４の特徴を備える乳房ポンプによって達成される。

【００１５】

ヒトの母乳を搾り出すための本発明による乳房シールドユニットは、ヒトの乳頭を受容するための受容部と、乳頭に負圧を印加するための負圧室と、負圧室に負圧を発生させるための膜とを有し、受容部は負圧室に開口している。

【００１６】
本発明によれば、膜は１枚又は複数枚に設計され、少なくとも部分的に受容部を取り囲む。
【００１７】
或いは又は加えて、膜は、受容部の中心軸の延長方向に見て、負圧室の乳頭に面する側に配置される。この位置の指示は、膜が負圧室を乳頭から分離することを意味するのではなく、先行技術で公知のように、膜が中心軸の方向において、負圧室よりも乳頭から遠くに配置されないことを意味する。この負圧室と膜の配置により、コンパクトな乳房シールドユニットの形成が可能となる。
【００１８】
また、或いは又は加えて、本発明による乳房シールドユニットは、負圧室をミルク収集容器に接続するためのミルクポートを有する。負圧室内に負圧を発生させるための膜は、受容部の中心軸の延長方向に見て、このミルクポートの母親の乳房に面する側に配置される。ここでもまた、この位置の指示は、上記の段落で述べたことを再び意味する。前の例と同様の利点がここでもまた達成される。
【００１９】
本発明による乳房シールドユニットは、膜のこの特別な配置のおかげで、非常に小型でコンパクトにすることができる。それでもなお、大表面の膜を使用することができるので、ミルクの搾り出しに必要な負圧を乳房シールドの領域で発生させることを確実にするのに、膜の小さなストロークで十分である。死容積が最小に抑えられる、即ち、乳頭の領域にある負圧室の容積が小さいため、ストロークの必要量もまた低減される。
【００２０】
膜の直径が大きいこともまた、装置の組み立てと、さらに洗浄も容易にする。媒体の分離、即ち、空気又は真空とミルクとの分離もまた膜の大表面により最適に確保される。
【００２１】
膜は１枚又は複数枚に設計することができる。円又は部分的円の形状の開口部を含むことが好ましい。この開口部は中央に配置されることが好ましい。好ましい実施形態では、受容部は開口部を貫通する。
【００２２】
好ましい実施形態では、膜は１枚に形成され、円環形状である。この膜は製造が容易であり、組み立てが容易であり、洗浄が容易であるという利点を有する。また、大きな表面を有する。
【００２３】
別の好ましい実施形態では、膜は少なくとも２つの個別のパーツ、好ましくは３つの個別のパーツから構成される。これらの個別のパーツは、組み立てられた状態では、円又は部分的円を囲む。この実施形態は、乳房シールドユニットの残りの部分の設計を膜の円環形状に合わせる必要がなく、代わりに膜のパーツをユニットの形状に合わせることができるという利点を有する。ポンプ室を膜の分割に応じて分割してもよく、又は連続したポンプ室として設計してもよい。個々の膜パーツは同一の設計にしてもよいし、又は異なる形状と大きさにしてもよい。
【００２４】
別の好ましい実施形態では、単一の膜パーツのみが存在し、その片側に、部分的円形状の凹部を有する。組み立てられた状態では、この凹部は受容部に割り当てられ、受容部がこの凹部を貫通することが好ましい。この凹部と反対側の膜の縁も同様に湾曲していることが好ましい。例えば、膜は腎臓形であってもよい。
【００２５】
その静止位置、即ち、負圧が印加されない状況では、１枚からなる円環状の膜は、母親の乳房の形状に最適に適合させられるように円錐台形状にすることが好ましい。複数枚からなる膜のパーツ及び部分的円として形成された１枚からなる膜は、このような円錐台のパーツとして設計されることが好ましい。膜は柔軟な可撓性材料、特にシリコーンで製造

される。６０ショアＡの硬度が好ましい。

【００２６】

膜は膜ハウジング内で移動可能の保持されることが好ましい。この目的のために、例えば、膜はその縁に膜ハウジングの対応する台座部に保持される周囲ビードを有する。

【００２７】

膜ハウジングは複数の部分、特に、乳房側の部分と乳房から遠い部分の２つの部分からなることが好ましい。

【００２８】

好ましい実施形態では、本発明による乳房シールドユニットは、母親の乳房に置くための乳房接触面を有し、この乳房接触面は膜を包囲するハウジングシェルに固定させることができる。ハウジングシェルは、乳房から遠い膜ハウジング部によって、又はこの膜ハウジング部を同様に包囲する部分によって形成することができる。乳房接触面が通常使用される乳房シールドの代わりとなることが好ましい。

【００２９】

好ましい実施形態では、乳房接触面は柔軟な材料、特にシリコーンで製造される。硬度が５０ショアＡであることが好ましい。

【００３０】

好ましい実施形態では、乳房接触面は、乳頭を受容するための円錐台形又は円筒形の第一のスタブ（ｓｔｕｂ）を有し、この第一のスタブは負圧室の第二のスタブに接続させることができ、この第一のスタブと第二のスタブが受容部を形成する。乳房シールドが通常乳輪のみに、場合により隣接組織にも接触するように、円錐台形部は非常に短く、大きな開口角と大きな表面をもつように設計されることが好ましい。

【００３１】

乳房接触面は膜とは別のパーツにすることができ、又はこの膜と一体に接続させることができる。

【００３２】

膜ハウジングは好ましくはハウジングシェルに対して移動可能に保持される。好ましくは、そこに配置させた膜で膜懸架を形成し、これらをこのハウジングシェル内に移動可能に配置する。これは、乳房接触面が使用中に変形した場合、膜ハウジングは変形せず、従ってポンプ室と負圧室、即ち、死容積はその容積に関して変化しないという利点を有する。これにより使用中に均一なポンプ出力が確保される。

【００３３】

本発明による乳房シールドユニットはハンズフリーユニットとして設計でき、ブラジャーの下に装着することができる。好ましい実施形態では、ミルク収集容器をユニットのハウジングに一体化させる、又は、そこに直接連結させることができる。或いは又は加えて、手動制御又はモーター駆動の真空ポンプをハウジングに一体化させる、又はそこに直接接続させることができる。モーター駆動の真空ポンプを使用する場合、電源をハウジングに一体化させる、又はそこに直接接続させることもまた好ましい。

【００３４】

別の好ましい実施形態では、乳房シールドユニットは外部ラインを介してミルク収集容器及び／又は外部真空源に接続される。

【００３５】

その他の実施形態は、従属請求項に記載される。

【図面の簡単な説明】

【００３６】

【図１】図１は、本発明による乳房シールドユニットを備える乳房ポンプの概略図である。

【図２】図２は、図１の乳房ポンプの第二の斜視図である。

【図３】図３は、図１の乳房シールドユニットの分解図である。

【図４】図４は、母親の乳房の上に置かれてミルクポートが開いている場合の図１の乳房

シールドユニットの長手方向断面を示す。
【図５】図５は、ミルクポートが閉じている図４の乳房シールドユニットを示す。
【図６】図６は、本発明による乳房シールドユニットの第二の実施形態の分解図である。
【図７】図７は、本発明による乳房シールドユニットの第三の実施形態の分解図である。
【図８】図８は、組み立てた状態の図７の乳房シールドユニットを示す。
【図９】図９は、乳房シールドユニット、一体化されたミルク収集容器、一体化された真空ポンプを備える本発明による乳房ポンプの斜視図である。
【図１０】図１０は、カバーを外した図９の乳房ポンプを示す。
【図１１】図１１は、図９の乳房ポンプの分解図である。
【発明を実施するための形態】
【００３７】
本発明の好ましい実施形態を、図を参照して以下に説明するが、これらの図は、説明のためだけのものであって、本発明を限定するものと解釈されるべきではない。同一のパーツには同一の参照符号を付している。
【００３８】
図１～５は、本発明による乳房シールドユニット９の第一の実施形態を示す。
【００３９】
乳房シールドユニット９は、ヒトの母親の乳房に置くための乳房接触面１とシェル６を有し、シェル６に乳房接触面１が取り外し可能に固定される。乳房接触面１は好ましくは円形であり、周囲固定用リップ１１がシェル６の周囲固定用フランジ６２を取り囲む。
【００４０】
乳房接触面１は柔軟な弾性材料、特にシリコーンで製造され、母親の乳房の形状に一致する。乳房接触面１は開口部１３を有し、これは円錐台形又は円筒形のスタブ１０で取り囲まれる。この開口部１３は、乳房接触面１の中央に配置されることが好ましい。
【００４１】
シェル６はドーム形又は半球形であることが好ましい。一体であり、剛性であることが好ましい。通常、プラスチック製である。
【００４２】
図１～５の例示的実施形態では、シェル６は第一の貫通開口６０を有し、これを通って真空ライン８０、ここではシリコーンホースが、乳房シールドユニットの対応するポートに接続される。接続は解除可能であることが好ましい。この真空ライン８０は外部吸引ポンプユニット８につながり、このユニットには真空ポンプが配置される。これはモーター駆動の真空ポンプであることが好ましい。真空ポンプは電源に接続して作動させる（ｍａｉｎｓ－ｏｐｅｒａｔｅｄ）ことができる。加えて又は或いは、電源を吸引ポンプユニットに一体化させてもよい。吸引ポンプユニット８は通常、制御要素と表示部８４を有する。
【００４３】
シェル６には第二の貫通開口６１が設けられる。ミルクライン７０の第一の端部は、ここでも同様にシリコーンホースであり、この貫通開口６１を通って乳房ポンプユニット９のミルクポートに解除可能に接続させることができる。ミルクライン７０の他方の端部は外部のミルク収集容器７に解除可能に接続される。
【００４４】
本発明による乳房シールドユニット９の個々のパーツは、図３に明確に見られる。既に説明した乳房接触面１は、第一の外壁を形成し、シェル６は、ユニット９の反対側の第二の外壁を形成する。これらの間に、乳房側膜ハウジング部２と、膜３と、乳房から遠い膜ハウジング部４と、逆止め弁５、ここではダックビル弁（ｄｕｃｋｂｉｌｌ　ｖａｌｖｅ）とが配置される。
【００４５】
２つの膜ハウジング部２、４は、好ましくは硬い材料、特にプラスチックで製造される。これらはそれぞれ、好ましくは一体に形成される。膜３は好ましくは可撓性材料、特に

シリコーンで製造される。好ましい硬度は６０ショアＡである。

【００４６】

個々のパーツは、逆止め弁５を除いて、円形であることが好ましい。乳房接触面１、乳房側膜ハウジング部２及び膜３は好ましくは、互いに位置合わせされて本ケースでは中央に配置された開口部１３、２４、３２を有する。乳房から遠い膜ハウジング部４はスタブ４４を有し、このスタブ４４はこれらの開口部１３、２４、３２と位置合わせされる。

【００４７】

乳房に近い膜ハウジング部２はその外周に複数の、本ケースでは３つの、角度を付けた固定用小穴２３を有する。これらの固定用小穴２３は、乳房から遠い膜ハウジング部４の対応する固定用突起４３の上にかぶせることができる。このようにして、挿入された膜３と組み合わせて、密封された環状のポンプ室４６を備えた閉じた膜ハウジング部２、４が形成される。膜３はこのポンプ室４６に移動可能に保持される。

【００４８】

組み立てられたこの状態は図４及び５で明確に見られる。好ましくは隆起部３３が設けられた１枚からなる環状膜３は、外側及び内側固定用ビード３０、３１を有し、これらのビードは対応する台座部に保持され、適所に固定されて密封作用を有する。これらの台座部は、結合された２つのハウジング部２、４によって形成される。膜３の領域では、２つのハウジング部２、４がポンプ側開口部２２と乳房側開口部４２を有する環状のポンプ室４６を形成する。

【００４９】

ポンプ側開口部２２は、ポート２０に終わる真空チャネル２１を経由して、真空ライン８０に通じる。乳房側開口部４２は接続チャネル４１を経由して負圧室４０に通じる。この負圧室４０は乳房から遠い膜ハウジング部４によって境界が決められ、乳房接触面１の方向に開いている。負圧室４０はミルクポート４５を有し、これは負圧室４０の、接続チャネル４１から遠い端部に配置されることが好ましい。逆止め弁５はこのミルクポート４５に配置される。大気圧に対して真空室４０が過圧になると、逆止め弁５が開き、ミルクライン７０への接続が確立される。真空室４０が負圧になると、逆止め弁５が閉じて、ミルクライン７０への接続が遮断される。逆止め弁５はミルクポート４５又はミルクライン７０に固定的に接続させることができる。

【００５０】

真空室４０は、その開いた領域でスタブ４４に合流する。乳房接触面１のスタブ１０はこのスタブ４４の上にかぶせられる。このスタブ１０はこの目的のために環状の受け溝１００を有する。

【００５１】

ここに見られるように、乳房接触面１は、わずかに漏斗状になった構造のベース部１２と、そこに一体に形成されたスタブ１０を有することが好ましい。このスタブは中心軸Ａを画定する。図４及び５では、乳房接触面１は、乳頭Ｂがスタブ１０とスタブ４４によって形成される受容部内に突出するように、ヒトの母親の乳房上に置かれている。このようにして、負圧室４０のこの開口部は密閉される。

【００５２】

ここで、脈動真空圧又は周波数と強度が変化する真空圧が吸引ポンプユニット８によって発生させられ、真空ライン８０を通ってポンプ室４６に移送されると、膜３はポンプ側開口部２２に引き寄せられてポンプ側開口部２２を閉じる。この状況は図５に示される。膜３の移動によって、負圧がポンプ室４６に、従って、負圧室４０に発生させられる。図５の矢印で表されるように、ミルクが母親の乳房から搾り出される。負圧室４０は少なくとも部分的に母乳で満たされる。

【００５３】

今度は、真空チャネル２１に印加された負圧が乳房ポンプによって発生させられた吸引周期に応じて低減される、又は大気圧までさらに下げられると、膜３は乳房側開口部４２に引き寄せられて乳房側開口部４２を閉じ、従って、ポンプ側開口部２２を解放する。こ

のようにして、負圧室４０内の圧力が上昇し、逆止め弁５が開く。搾り出されたミルクはミルクライン７０を通って流出することができる。この状況は図４に見られる。

【００５４】

膜３もまた、吸引ポンプユニット８によって発生させられた負圧のリズムで動き、従って、負圧室４０へとそのリズムと真空レベルを伝達する。膜３の比較的大きな表面と負圧室４０の小容量のおかげで、ミルクを搾り出すのに必要な負圧を乳頭Ｂの領域内で発生させることを確実にするのに、比較的小さなストロークで十分である。

【００５５】

図６は第二の例示的実施形態を示す。これは、第一の例示的実施形態と基本的に同じパーツを有する。しかし、膜３は複数枚である。ここでは、３つの膜パーツ３’、３’’、３’’’が存在し、これらは膜ハウジング部２、４の対応する台座部に保持され、ここでもまた、ポンプ室内でポンプ側開口部と乳房側開口部の間を行ったり来たり移動することができる。膜パーツ３’、３’’、３’’’は円形の開口部を包囲し、そこを乳房接触面１のスタブ１０と乳房から遠い膜ハウジング部４のスタブ４４がまたしても貫通する。

【００５６】

図７と８は、第三の例示的実施形態を示す。ここでは、膜３は再び１枚に設計されているが、リングの一部の領域のみを形成する。これもまた腎臓形であってもよい。これは２つの前述のスタブ１０、４４を一部だけ包囲する。これに応じて、膜ハウジング部２、４も同様に部分的円の形状の横断面のみを有する。乳房から遠い膜ハウジング部４では、当然ながら断面が丸く、全体に閉じたジャケットを有するスタブ４４が、この部分的円に一体に形成される。シェル６は、乳房から遠い膜ハウジング部４がよく見えるように、図８では透明の形状で示されている。

【００５７】

図９～１１は別の例示的実施形態を示し、乳房シールドユニットは一体化された吸引ポンプユニット８’を備えた完全な乳房ポンプとして設計されている。乳房接触面１、膜ハウジング部２、４及び膜３は図１～５の実施形態に対応する。しかし、図６～８の実施形態をこのようなポンプに使用することも可能である。

【００５８】

しかし、ドーム形のシェル６の代わりに、ここではシェルリング６’が存在する。シェルリング６’はここでもまた剛性で、特にプラスチック製である。シェルリング６’は、乳房接触面１を固定するための周囲固定用フランジ６２を備える開口部を有する。その後面、即ち、乳房とは反対の方向を向く面は、カバー６’’によって部分的に閉じられる。真空ポンプ８１を中に保持するポンプ台座部８２が、このカバー６’’に一体に形成される。電源はこの真空ポンプ８１に一体化されることが好ましい。真空ポンプ８１は、電気モーターによって作動される、公知のタイプのダイヤフラム真空ポンプであることが好ましい。

【００５９】

真空ポンプ８１を起動させるための制御要素８４はカバー６’’の外側に存在する。さらに、乳房ポンプユニットは対応する制御系を備え、この制御系によって、使用者が制御要素８４を介して入力したコマンドが真空ポンプに伝達される。この制御系はハウジング内に別に配置させてもよく、又は、真空ポンプ８１に一体化させてもよい。

【００６０】

ミルク収集容器７’はカバー６’’に隣接する下部領域に配置される。これはカバー６’’と同様にプラスチック製であることが好ましい。係止突起７１はこのミルク収集容器７’に一体に形成され、シェルリング６’の対応する窪み（図示せず）に係合することができる。このようにして、ミルク収集容器７’はシェルリング６’に解除可能に接続される。さらに、ミルク収集容器７’は一体化された弁（図示せず）を備える連結部７２を有し、この弁は乳房から遠い膜ハウジング部４のミルクポート４５に差し込むことができ、搾り出されたミルクは負圧室４０からミルク収集容器７’の内部に流出することができる。この弁は上述の実施形態の逆止め弁５に相当する。目盛り形状の充填レベル指示器７３

がミルク収集容器７’上に存在することが好ましい。ミルク収集容器７’は、その全体が透明又は部分的に透明であるか、或いは、目盛り７３の領域に透明又は部分的に透明の窓を有する。

【００６１】

本発明による乳房シールドユニットは、乳房に近接する領域での媒体の分離を可能とする。これは小型で洗浄が容易であり、特に、ブラジャーに装着することができるハンズフリーの乳房ポンプユニットとしての使用に適している。

【符号の説明】

【００６２】

１ 乳房接触面
１０ スタブ
１００ 受け溝
１１ 固定用リップ
１２ ベース部
１３ 中央開口部
２ 乳房側膜ハウジング部
２０ ポート
２１ 真空チャネル
２２ ポンプ側開口部
２３ 固定用小穴
２４ 中央開口部
３ 膜
３’、３’’、３’’’ 膜パーツ
３０ 外側固定用ビード
３１ 内側固定用ビード
３２ 中央開口部
３３ 隆起部
４ 乳房から遠い膜ハウジング部
４０ 負圧室
４１ 接続チャネル
４２ 乳房側開口部
４３ 固定用突起
４４ スタブ
４５ ミルクポート
４６ ポンプ室
５ 逆止め弁
６ シェル
６’ シェルリング
６’’ カバー
６０ 第一の貫通開口
６１ 第二の貫通開口
６２ 固定用フランジ
７、７’ ミルク収集容器
７０ ミルクライン
７１ 係止突起
７２ 連結部
７３ 充填レベル指示器
８、８’ 吸引ポンプユニット
８０ 真空ライン
８１ 真空ポンプ

８２　　ポンプ台座部
８３　　ねじ穴
８４　　制御要素／表示部
９　　乳房シールドユニット
Ａ　　中心軸
Ｂ　　乳頭

【図１】

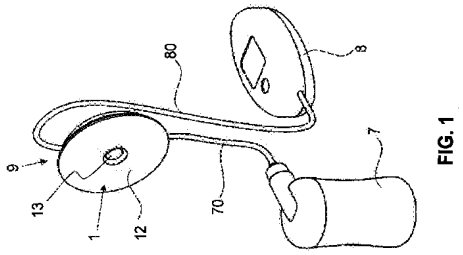

FIG. 1

【図２】

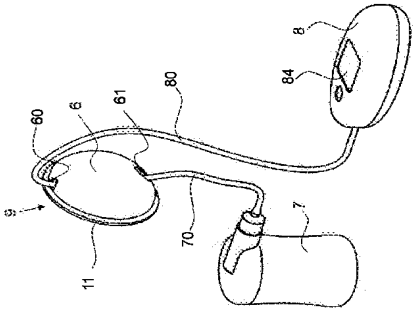

FIG. 2

【図３】

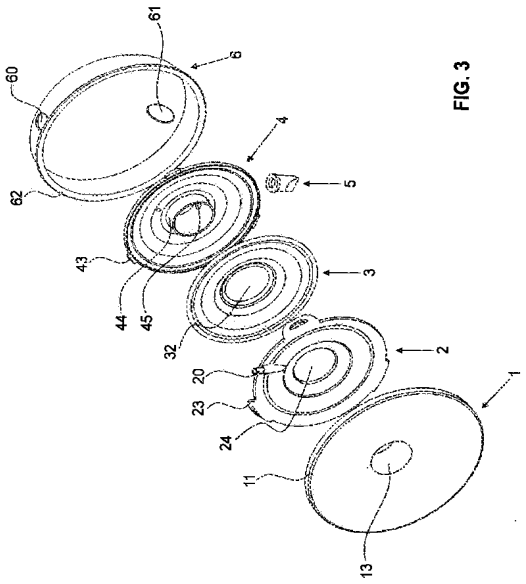

FIG. 3

【図４】

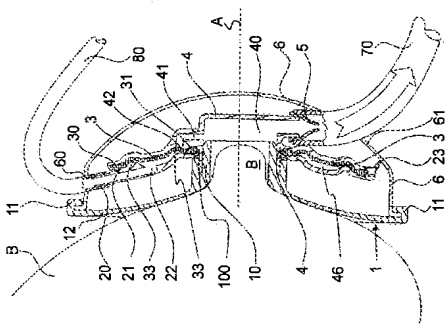

FIG. 4

【図５】

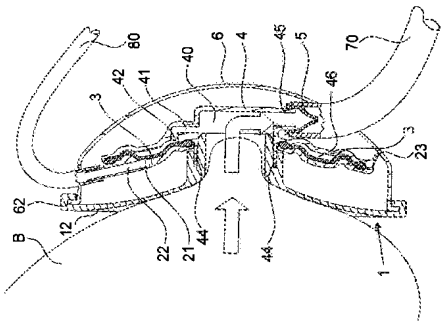

FIG. 5

【図６】

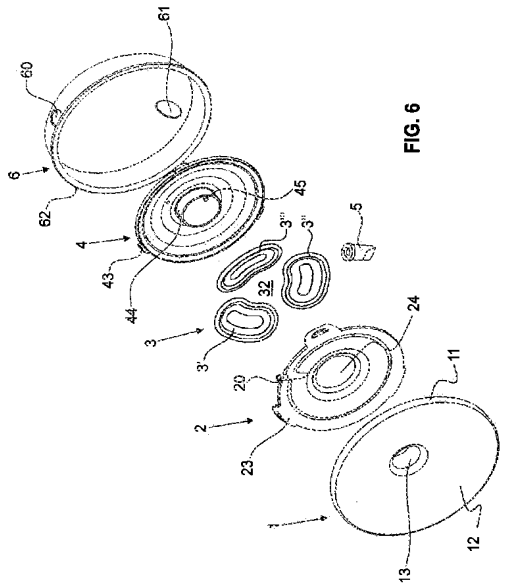

FIG. 6

【図７】

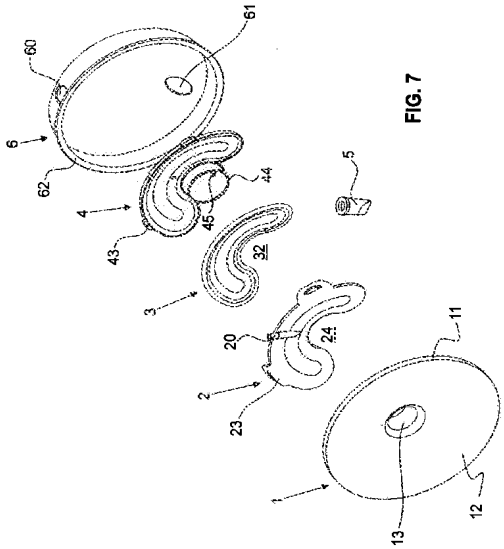

FIG. 7

【図８】

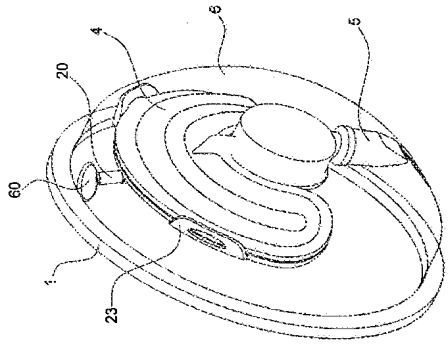

FIG. 8

【図９】

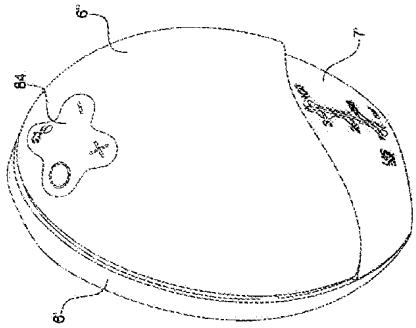

FIG. 9

【図１０】

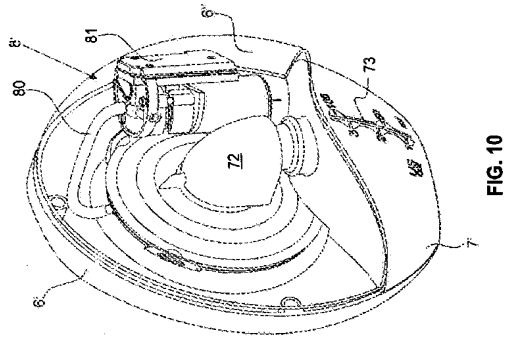

FIG. 10

【図１１】

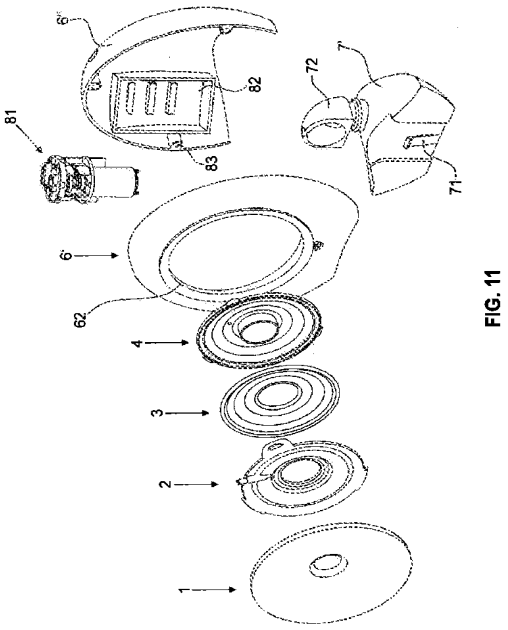

FIG. 11

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No
PCT/CH2012/000164

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/06
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/071466 A1 (SILVER BRIAN H [US] ET AL) 24 March 2011 (2011-03-24) cited in the application abstract; figures 14,15 paragraphs [0092] - [0098]	1-5,7-11
X	US 6 461 324 B1 (SCHLENSOG KLAUS [CH]) 8 October 2002 (2002-10-08) abstract; figure 1 column 4, line 40 - column 5, line 19	2-6, 8-10, 12-15
X	EP 2 138 197 A1 (TRIMED AG [LI]) 30 December 2009 (2009-12-30) abstract; figure 3 paragraphs [0015] - [0017]	1,4-6,8, 9

-/--

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
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"O" document referring to an oral disclosure, use, exhibition or other means
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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 September 2012	01/10/2012

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Kaden, Malte

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/CH2012/000164

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2008/262420 A1 (DAO STELLA [US] ET AL) 23 October 2008 (2008-10-23) abstract; figures paragraphs [0023] - [0028] -----	11

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/CH2012/000164

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011071466 A1	24-03-2011	AU 2010300011 A1	08-03-2012
		AU 2010300058 A1	03-05-2012
		CN 102596280 A	18-07-2012
		CN 102665783 A	12-09-2012
		EP 2480264 A1	01-08-2012
		EP 2480265 A1	01-08-2012
		KR 20120074279 A	05-07-2012
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		SG 179094 A1	27-04-2012
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		WO 2011035447 A1	31-03-2011
		WO 2011035448 A1	31-03-2011
		WO 2011037841 A2	31-03-2011
US 6461324 B1	08-10-2002	AU 3328799 A	20-09-1999
		US 6461324 B1	08-10-2002
		WO 9944650 A1	10-09-1999
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		EP 2138197 A1	30-12-2009
US 2008262420 A1	23-10-2008	NONE	

Form PCT/ISA/210 (patent family annex) (April 2005)

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/CH2012/000164

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
INV. A61M1/06
ADD.

Nach der Internationalen Patentklassifikation (IPC) oder nach der nationalen Klassifikation und der IPC

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
A61M

Recherchierte, aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
EPO-Internal

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	US 2011/071466 A1 (SILVER BRIAN H [US] ET AL) 24. März 2011 (2011-03-24) in der Anmeldung erwähnt Zusammenfassung; Abbildungen 14,15 Absätze [0092] - [0098]	1-5,7-11
X	US 6 461 324 B1 (SCHLENSOG KLAUS [CH]) 8. Oktober 2002 (2002-10-08) Zusammenfassung; Abbildung 1 Spalte 4, Zeile 40 - Spalte 5, Zeile 19	2-6, 8-10, 12-15
X	EP 2 138 197 A1 (TRIMED AG [LI]) 30. Dezember 2009 (2009-12-30) Zusammenfassung; Abbildung 3 Absätze [0015] - [0017]	1,4-6,8, 9

-/--

[X] Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen [X] Siehe Anhang Patentfamilie

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Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
24. September 2012	01/10/2012

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Kaden, Malte

Formblatt PCT/ISA/210 (Blatt 2) (April 2005)

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/CH2012/000164

C. (Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	US 2008/262420 A1 (DAO STELLA [US] ET AL) 23. Oktober 2008 (2008-10-23) Zusammenfassung; Abbildungen Absätze [0023] - [0028] -----	11

Formblatt PCT/ISA/210 (Fortsetzung von Blatt 2) (April 2005)

Seite 2 von 2

INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationales Aktenzeichen
PCT/CH2012/000164

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
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		AU 2010300058 A1	03-05-2012
		CN 102596280 A	18-07-2012
		CN 102665783 A	12-09-2012
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		KR 20120074279 A	05-07-2012
		KR 20120074296 A	05-07-2012
		SG 179094 A1	27-04-2012
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		TW 201121592 A	01-07-2011
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		TW 201127426 A	16-08-2011
		US 2011071466 A1	24-03-2011
		WO 2011035447 A1	31-03-2011
		WO 2011035448 A1	31-03-2011
		WO 2011037841 A2	31-03-2011
US 6461324 B1	08-10-2002	AU 3328799 A	20-09-1999
		US 6461324 B1	08-10-2002
		WO 9944650 A1	10-09-1999
EP 2138197 A1	30-12-2009	AT 492308 T	15-01-2011
		EP 2138197 A1	30-12-2009
US 2008262420 A1	23-10-2008	KEINE	

Formblatt PCT/ISA/210 (Anhang Patentfamilie) (April 2005)

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(81)指定国 AP(BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), EA(AM, AZ, BY, KG, KZ, RU, TJ, TM), EP(AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OA(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG), AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA

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Ｆターム(参考) 4C077 AA22 DD01 DD11 KK15 KK17 KK23 KK25

Patents JP2014529312

Breast shield unit

Abstract

translated from Japanese

A breast shield unit for expressing human breast milk includes a receiving part (10) for receiving a human nipple, a negative pressure chamber (40) for applying a negative pressure to the nipple, and the negative pressure chamber (40) has a membrane (3) for generating a negative pressure, and the receiving part (10) is open to the negative pressure chamber (40). The membrane (3) is designed as one or more and at least partly surrounds the receiving part (10). This breast shield unit allows the separation of media in the area close to the breast. This is small and easy to clean, and is particularly suitable for use as a hands-free breast shield unit. [Selection] Figure 3

Images (11)

Classifications

- A61M1/06 Milking pumps

View 3 more classifications

JP2014529312A

Japan

Download PDF Find Prior Art Similar

Other languages: Japanese

Inventor: ハリール ガマル, ハリール ガマル, フィッシャー ルネ, フィッシャー ルネ, シュランジェ アンドレ, シュランジェ アンドレ

Worldwide applications

2011 ~~CH~~ 2012 ~~US BR~~ AU PL EP WO CN KR RU MY JP TW 2014 IL

Application JP2014520487A events

2011-07-18 Priority to CH1201/11

2012-07-12 Application filed by メデラ ホールディング アーゲー, メデラ ホールディング アーゲー

2014-11-06 Publication of JP2014529312A

2017-01-18 Application granted

2017-01-18 Publication of JP6062937B2

2020-10-09 First worldwide family litigation filed

Status Active

2032-07-12 Anticipated expiration

Show all events

Info: Patent citations (22), Cited by (30), Legal events, Similar documents, Priority and Related Applications

External links: Espacenet, Global Dossier, Discuss

Claims (15)

Hide Dependent

translated from Japanese

A breast shield unit for milking human breast milk,
A receiving portion (10) for receiving a human teat;
A negative pressure chamber (40) for applying negative pressure to the nipple;
A membrane (3) for generating a negative pressure in the negative pressure chamber (40),
A breast shield unit that opens into the negative pressure chamber (40);
Breast shield unit, characterized in that the membrane (3) is designed in one or more and at least partly surrounds the receiving part (10). A breast shield unit for milking human breast milk,
A receiving portion (10) for receiving the nipple;
A negative pressure chamber (40) for applying negative pressure to the nipple,
A membrane (3) for generating a negative pressure in the negative pressure chamber (40);
A breast shield unit, wherein the receptacle (10) defines a central axis (A) and opens into the negative pressure chamber (40);
A breast shield unit characterized in that the membrane (3) is arranged on the side of the negative pressure chamber (40) facing the nipple as viewed in the direction of extension of the central axis (A). A breast shield unit for milking human breast milk,
A receiving part (10) for receiving the mother's breast nipple;
A negative pressure chamber (40) for applying negative pressure to the nipple;
A milk port (45) for connecting the negative pressure chamber (40) to a milk collection container (7, 7 ');
A membrane (3) for generating a negative pressure in the negative pressure chamber (40);
A breast shield unit, wherein the receptacle ('10) defines a central axis (A) and opens into the negative pressure chamber (40);
Breast shield unit, characterized in that the membrane (3) is arranged on the side of the milk port (45) facing the mother's breast when viewed in the direction of extension of the central axis (A). Breast shield unit according to any of the preceding claims, wherein the membrane (3) surrounds an opening in the shape of a circle or a partial circle. Breast shield unit according to claim 4, characterized in that the membrane (3) is formed in one piece and has an annular shape The membrane (3) has at least two individual parts (3 ', 3 ", 3 ' '), and the assembled individual parts (3 ', 3 ", 3 ' ') 5. The breast shield unit according to claim 4, wherein) surrounds a circle or a partial circle. It has a breast membrane housing part (2) and a membrane housing part (4) far from the breast. These membrane housing parts (2, 4) form a common membrane housing, and the membrane (3) is the 2 Breast shield unit according to any one of the preceding claims, which is movably held between two membrane housing parts (2, 4). Breast shield unit according to any one of the

preceding claims, wherein the membrane (3) is frustoconical in a rest position. 9. A breast contact surface (1) for placing on a mother's breast, the breast contact surface (1) being fixable to a housing shell (6) surrounding the membrane (3). The breast shield unit according to any one of the above. The breast contact surface (1) has a frustoconical or cylindrical first stub (10) for receiving the teat, and this first stub (10) is connected to the negative pressure chamber (40). Breast shield unit according to claim 9, which can be connected to a second stub (44), the first stub (10) and the second stub (44) forming the receptacle. 11. A milk collection container (7 ') integrated into the breast shield unit, wherein the milk collection container (7 ') is removably disposed on the rest of the breast shield unit. The breast shield unit according to any one of the above. A vacuum port (20) that can be connected to a vacuum pump (8, 81), wherein the membrane (3) separates the vacuum port (20) from the negative pressure chamber (40). The breast shield unit according to any one of 11. The membrane (3) is disposed in a pump chamber (46) having a first outlet (22) leading to the vacuum port (20) and a second outlet (42) leading to the negative pressure chamber (40). The breast shield unit according to claim 12. A breast pump comprising a breast shield unit according to claim 12 or 13, a vacuum line (80), and a vacuum pump (8, 81), wherein the vacuum line (80) connects the vacuum port (20). Breast pump connected to the vacuum pump (8, 81). The breast pump unit has a housing shell (6), which surrounds the membrane (3), in which the vacuum pump (81) is arranged; The breast pump according to claim 14.

Description

translated from Japanese

The present invention relates to a breast shield unit according to any one of the preambles of claims 1, 2, and 3 and a breast pump according to the preamble of claim 14.

Devices for expressing human breast milk are well known. A manual or motorized vacuum pump is connected to the breast shield, either directly or through a vacuum line, and this breast shield is used to receive a portion of the mother's breast, including the nipple.

Patent document 1 discloses a breast pump including a vacuum pump, a vacuum line, a base, and a funnel-shaped hard breast shield that can be fixed on the base. The vacuum line connects the vacuum pump to the base. In order to protect the vacuum line and the vacuum pump from contamination, a large surface membrane shaped barrier is placed on the base. This membrane is placed in the pump chamber, in which the negative pressure generated by the pump unit is transmitted to the opposite side of the membrane.

Patent document 2 similarly describes the breast pump provided with the base part, and can connect the funnel-like hard breast shield, the vacuum line for connecting to the vacuum pump, and the milk collection container to the base part. The base part also has a membrane to protect the vacuum line.

Patent Documents 3 and 4 disclose so-called hands-free breast pumps that can be mounted under a brassiere. The breast contact surface is placed in close contact with the mother's breast and at the same time serves as a membrane for the vacuum pump. That is, the pump chamber of the vacuum pump is formed between the soft breast contact surface and the mother's breast.

U.S. Pat. No. 6,057,077 discloses another hands-free breast pump. Here, a small breast shield is placed in the brassiere. From this breast shield, a vacuum line leads to the vacuum pump unit and a milk line leads to the milk collection container. The vacuum pump unit and milk collection container are placed on a strap, and the mother wraps the strap around the waist.

In Patent Document 6, a flexible bag for collecting milk is fixed to a hard breast shield, and both are attached to a brassiere. An open vacuum line in the upper area of the breast shield leads to a vacuum pump attached to the strap.

U.S. Patent No. 6,099,077 also discloses a hands-free breast pump. Again, the vacuum line is connected from the breast shield to the vacuum pump. This line is simultaneously used as a milk line.

Patent document 8 relates to a support device for a hard breast shield, which can be fixed to a brassiere.

U.S. Patent No. 6,099,077 discloses a breast shield designed to catch natural spillage of breast milk. The breast shield has a soft breast contact surface and a cap connected thereto, so that milk can flow into the cap.

U.S. Pat. No. 6,057,077 discloses a breast pump for expressing human breast milk, the vacuum line being used simultaneously as a milk line, and the membrane of the diaphragm vacuum pump serves as a media separator.

International Publication No. 2008/057218 International Publication No. 2011/037841 US Pat. No. 7,223,255 International Publication No. 2008/137678 US Pat. No. 6,379,327 US Patent Application Publication No. 2008/0262420 US Pat. No. 6,440,100 US Patent Application Publication No. 2008/0039781 US Pat. No. 4,270,538 International Publication No. 2011/035448

The object of the present invention is to create an improved device for expressing human breast milk.

This object is achieved by a breast shield unit comprising the features of claims 1, 2, 3 and by a breast pump comprising the features of claim 14.

Breast shield unit according to the present invention for milking human breast milk generates a receiving part for receiving a human nipple, a negative pressure chamber for applying negative pressure to the nipple, and a negative pressure in the negative pressure chamber And the receiving part is open to the negative pressure chamber.

According to the invention, the membrane is designed as one or more and at least partly surrounds the receiving part.

Alternatively or additionally, the membrane is arranged on the side of the negative pressure chamber facing the nipple as viewed in the direction of extension of the central axis of the receiving part. This position indication does not mean that the membrane separates the negative pressure chamber from the nipple, but as is known in the prior art, the membrane is located farther from the nipple than the negative pressure chamber in the direction of the central axis. Means not. The arrangement of the negative pressure chamber and the membrane makes it possible to form a compact breast shield unit.

Alternatively or additionally, the breast shield unit according to the invention has a milk port for connecting the negative pressure chamber to the milk collection container. A membrane for generating a negative pressure in the negative pressure chamber is arranged on the side of the milk port facing the mother's breast as viewed in the direction of extension of the central axis of the receiving part. Again, this position indication means again what was said in the paragraph above. Similar advantages as in the previous example are also achieved here.

The breast shield unit according to the invention can be very small and compact thanks to this special arrangement of membranes. Nevertheless, because a large surface membrane can be used, a small stroke of the membrane is sufficient to ensure that the negative pressure required for milking is generated in the area of the breast shield. Since the dead volume is minimized, i.e. the volume of the negative pressure chamber in the area of the teat is small, the required stroke is also reduced.

The large membrane diameter also facilitates assembly and further cleaning of the device. The separation of the medium, i.e. the separation of air or vacuum and milk, is also optimally ensured by the large surface of the membrane.

The film can be designed as one sheet or a plurality of sheets. It preferably includes an opening in the shape of a circle or a partial circle. This opening is preferably arranged in the center. In a preferred embodiment, the receptacle passes through the opening.

In a preferred embodiment, the membrane is formed in one piece and has an annular shape. This membrane has the advantage of being easy to manufacture, easy to assemble and easy to clean. It also has a large surface.

In another preferred embodiment, the membrane is composed of at least two individual parts, preferably three individual parts. These individual parts, when assembled, enclose a circle or a partial circle. This embodiment has the advantage that the design of the rest of the breast shield unit need not be matched to the toroidal shape of the membrane, but instead the membrane parts can be matched to the shape of the unit. The pump chamber may be divided according to the membrane division, or may be designed as a continuous pump chamber. Individual membrane parts may have the same design, or different shapes and sizes.

In another preferred embodiment, there is only a single membrane part with a partially circular recess on one side. In the assembled state, it is preferred that this recess is assigned to a receiving part, and that the receiving part passes through this recess. It is preferable that the edge of the film on the side opposite to the concave portion is similarly curved. For example, the membrane may be kidney-shaped.

In its rest position, i.e., when no negative pressure is applied, the single toroidal membrane is preferably frustoconical so as to be optimally adapted to the shape of the mother's breast. A plurality of membrane parts and a single membrane formed as a partial circle are preferably designed as such a truncated cone part. The membrane is made of a soft flexible material, in particular silicone. A hardness of 50 Shore A is preferred.

The membrane is preferably held movable within the membrane housing. For this purpose, for example, the membrane has a peripheral bead at its edge which is held in a corresponding pedestal of the membrane housing.

The membrane housing preferably comprises a plurality of parts, in particular two parts, a part on the breast side and a part far from the breast.

In a preferred embodiment, a breast shield unit according to the present invention has a breast contact surface for placement on the mother's breast, which can be secured to a housing shell surrounding the membrane. The housing shell can be formed by a membrane housing part remote from the breast or by a part that also surrounds the membrane housing part. The breast contact surface is preferably an alternative to the commonly used breast shield.

In a preferred embodiment, the breast contact surface is made of a flexible material, particularly silicone. The hardness is preferably 50 Shore A.

In a preferred embodiment, the breast contacting surface has a frustoconical or cylindrical first stub for receiving the teat, which first stub is connected to the second stub of the negative pressure chamber. The first stub and the second stub form a receptacle. The frustoconical part is preferably designed to be very short, with a large opening angle and a large surface, so that the breast shield is usually in contact with the areola only and possibly also with adjacent tissue.

The breast contact surface can be a separate part from the membrane, or it can be integrally connected to the membrane.

The membrane housing is preferably held movably with respect to the housing shell. Preferably, a membrane suspension is formed from the membrane disposed therein and is movably disposed within the housing shell. This has the advantage that if the breast contact surface deforms in use, the membrane housing will not deform, and therefore the pump chamber and negative pressure chamber, ie the dead volume, will not change with respect to its volume. This ensures a uniform pump output during use.

The breast shield unit according to the invention can be designed as a hands-free unit and can be mounted under a brassiere. In a preferred embodiment, the milk collection container can be integrated into the unit housing or directly connected thereto. Alternatively or additionally, a manually controlled or motor driven vacuum pump can be integrated into the housing or directly connected thereto. If a motor driven vacuum pump is used, it is also preferred that the power source be integrated into the housing or directly connected thereto.

In another preferred embodiment, the breast shield unit is connected to a milk collection container and / or an external vacuum source via an external line.

Other embodiments are set forth in the dependent claims.

FIG. 1 is a schematic view of a breast pump comprising a breast shield unit according to the present invention. FIG. 2 is a second perspective view of the breast pump of FIG. FIG. 3 is an exploded view of the breast shield unit of FIG. 4 shows a longitudinal section of the breast shield unit of FIG. 1 when placed on the mother's breast and the milk port is open. FIG. 5 shows the breast shield unit of FIG. 4 with the milk port closed. FIG. 6 is an exploded view of a second embodiment of the breast shield unit according to the present invention. FIG. 7 is an exploded view of a third embodiment of a breast shield unit according to the present invention. FIG. 8 shows the breast shield unit of FIG. 7 in an assembled state. FIG. 9 is a perspective view of a breast pump according to the present invention comprising a breast shield unit, an integrated milk collection container, and an integrated vacuum pump. FIG. 10 shows the breast pump of FIG. 9 with the cover removed. FIG. 11 is an exploded view of the breast pump of FIG.

Preferred embodiments of the invention are described below with reference to the figures, which are for illustration purposes only and are not to be construed as limiting the invention. The same parts have the same reference numerals.

1 to 5 show a first embodiment of a breast shield unit 9 according to the invention.

The breast shield unit 9 has a breast contact surface 1 and a shell 6 to be placed on the breast of a human mother, and the breast contact surface 1 is detachably fixed to the shell 6. The breast contact surface 1 is preferably circular and the perimeter fixing lip 11 surrounds the perimeter fixing flange 62 of the shell 6.

The breast contact surface 1 is made of a flexible elastic material, in particular silicone, and matches the shape of the mother's breast. The breast contact surface 1 has an opening 13 that is surrounded by a frustoconical or cylindrical stub 10. The opening 13 is preferably arranged at the center of the breast contact surface 1.

The shell 6 is preferably dome-shaped or hemispherical. It is preferably integral and rigid. Usually made of plastic.

In the exemplary embodiment of FIGS. 1-5, the shell 6 has a first through opening 60, through which a vacuum line 80, here a silicone hose, is connected to a corresponding port of the breast shield unit. The connection is preferably releasable. This vacuum line 80 is connected to an external suction pump unit 8, in which a vacuum pump is arranged. This is preferably a motor driven vacuum pump. The vacuum pump can be mains-operated by connecting to a power source. In addition or alternatively, the power source may be integrated into the suction pump unit. The suction pump unit 8 usually has a control element and a display part 84.

The shell 6 is provided with a second through opening 61. The first end of the milk line 70 is again a silicone hose and can be releasably connected to the milk port of the breast pump unit 9 through this through opening 61. The other end of the milk line 70 is releasably connected to an external milk collection container 7.

The individual parts of the breast shield unit 9 according to the invention can be clearly seen in FIG. The breast contact surface 1 already described forms a first outer wall and the shell 6 forms a second outer wall on the opposite side of the unit 9. Between these are the breast-side membrane housing part 2, the membrane 3, the

membrane housing part 4 remote from the breast, and a check valve 5, here a duckbill valve.

The two membrane housing parts 2, 4 are preferably made of a hard material, in particular plastic. Each of these is preferably integrally formed. The membrane 3 is preferably made of a flexible material, in particular silicone. A preferred hardness is 60 Shore A.

The individual parts are preferably circular except for the check valve 5. The breast contact surface 1, the breast side membrane housing part 2 and the membrane 3 preferably have openings 13, 24, 32 aligned with each other and centrally arranged in this case. The membrane housing part 4 remote from the breast has stubs 44 which are aligned with these openings 13, 24, 32.

The membrane housing part 2 close to the breast has a plurality of angled fixing holes 23 on the outer periphery thereof, in this case, three. These fixing holes 23 can be placed on the corresponding fixing protrusions 43 of the membrane housing part 4 far from the breast. In this way, in combination with the inserted membrane 3, closed membrane housing parts 2, 4 with a sealed annular pump chamber 46 are formed. The membrane 3 is movably held in the pump chamber 46.

This assembled state is clearly seen in FIGS. Preferably, the single annular membrane 3 provided with a raised portion 33 has outer and inner fixing beads 30, 31 which are held by corresponding pedestals and fixed in place for sealing action. Have These pedestals are formed by two housing parts 2, 4 joined together. In the region of the membrane 3, the two housing parts 2, 4 form an annular pump chamber 46 having a pump side opening 22 and a breast side opening 42.

The pump side opening 22 leads to the vacuum line 80 via the vacuum channel 21 ending at the port 20. The breast opening 42 communicates with the negative pressure chamber 40 via the connection channel 41. The negative pressure chamber 40 is delimited by the membrane housing part 4 far from the breast and opens in the direction of the breast contact surface 1. The negative pressure chamber 40 has a milk port 45 which is preferably arranged at the end of the negative pressure chamber 40 remote from the connection channel 41. The check valve 5 is arranged in this milk port 45. When the vacuum chamber 40 is overpressured relative to atmospheric pressure, the check valve 5 opens and a connection to the milk line 70 is established. When the vacuum chamber 40 becomes negative pressure, the check valve 5 is closed and the connection to the milk line 70 is cut off. The check valve 5 can be fixedly connected to the milk port 45 or the milk line 70.

The vacuum chamber 40 joins the stub 44 in the open area. The stub 10 of the breast contact surface 1 is placed on the stub 44. The stub 10 has an annular receiving groove 100 for this purpose.

As can be seen, the breast contact surface 1 preferably has a base portion 12 with a slightly funnel-like structure and a stub 10 formed integrally therewith. This stub defines a central axis A. 4 and 5, the breast contact surface 1 is placed on the breast of a human mother so that the teat B protrudes into the receptacle formed by the stub 10 and stub 44. In this way, this opening of the negative pressure chamber 40 is sealed.

Here, when a pulsating vacuum pressure or a vacuum pressure changing in frequency and intensity is generated by the suction pump unit 8 and transferred to the pump chamber 46 through the vacuum line 80, the membrane 3 is attracted to the pump side opening 22. Then, the pump side opening 22 is closed. This situation is shown in FIG. Due to the movement of the membrane 3, a negative pressure is generated in the pump chamber 46 and thus in the negative pressure chamber 40. As represented by the arrow in FIG. 5, milk is squeezed out of the mother's breast. The negative pressure chamber 40 is at least partially filled with breast milk.

This time, when the negative pressure applied to the vacuum channel 21 is reduced according to the suction cycle generated by the breast pump, or further reduced to atmospheric pressure, the membrane 3 is attracted to the breast side opening 42. The breast side opening 42 is closed, thus releasing the pump side opening 22. In this way, the pressure in the negative pressure chamber 40 increases and the check valve 5 opens. The milk that has been expressed can flow through the milk line 70. This situation can be seen in FIG.

The membrane 3 also moves with a negative pressure rhythm generated by the suction pump unit 8 and thus transmits that rhythm and vacuum level to the negative pressure chamber 40. Thanks to the relatively large surface of the membrane 3 and the small volume of the negative pressure chamber 40, a relatively small stroke is ensured in order to ensure that the negative pressure required to express the milk is generated in the area of the teat B. is enough.

FIG. 6 shows a second exemplary embodiment. This has essentially the same parts as the first exemplary embodiment. However, there are a plurality of films 3. Here, there are three membrane parts 3 ', 3 ", 3' ", which are held on corresponding pedestals of the membrane housing parts 2, 4 and again here the pump side opening in the pump chamber And back and forth between the breast opening. The membrane parts 3 ', 3 ", 3" surround a circular opening through which the stub 10 of the breast contact surface 1 and the stub 44 of the membrane housing part 4 remote from the breast penetrate again.

7 and 8 show a third exemplary embodiment. Here, the film 3 is again designed as a single sheet, but only a partial region of the ring is formed. This may also be in kidney form. This only partially encloses the two aforementioned stubs 10,44. Correspondingly, the membrane housing parts 2, 4 likewise have only a partial circular cross section. In the membrane housing part 4 remote from the breast, of course, a stub 44 having a rounded cross section and a closed jacket is integrally formed in this partial circle. The shell 6 is shown in a transparent shape in FIG. 8 so that the membrane housing part 4 far from the breast can be seen well.

9-11 illustrate another exemplary embodiment, where the breast shield unit is designed as a complete breast pump with an integrated suction pump unit 8 '. The breast contact surface 1, membrane housing parts 2, 4 and membrane 3 correspond to the embodiment of FIGS. However, the embodiments of FIGS. 6-8 can also be used with such a pump.

However, instead of the dome-shaped shell 6, a shell ring 6 'is present here. The shell ring 6 'is again rigid, in particular made of plastic. The shell ring 6 ' has an opening provided with a peripheral fixing flange 62 for fixing the breast contact surface 1. The rear face, ie the face facing away from the breast, is partially closed by the cover 6 ". A pump base 82 for holding the vacuum pump 81 therein is formed integrally with the cover 6 ". The power source is preferably integrated with the vacuum pump 81. The vacuum pump 81 is preferably a known type of diaphragm vacuum pump operated by an electric motor.

A control element 84 for activating the vacuum pump 81 is present outside the cover 6 ". In addition, the breast pump unit has a corresponding control system by which commands entered by the user via the control element 84 are transmitted to the vacuum pump. This control system may be separately arranged in the housing, or may be integrated with the vacuum pump 81.

The milk collection container 7 'is arranged in the lower region adjacent to the cover 6 ". This is preferably made of plastic like the cover 6 ". The locking protrusion 71 is formed integrally with the milk collection container 7 'and can engage with a corresponding recess (not shown) in the shell ring 6'. In this way, the milk collection container 7 'is releasably connected to the shell ring 6'. Furthermore, the milk collection container 7 'has a connection 72 with an integrated valve (not shown), which can be inserted into the milk port 45 of the membrane housing part 4 remote from the breast and squeezed out. The milk can flow out of the negative pressure chamber 40 into the milk collection container 7 '. This valve corresponds to the check valve 5 of the above-described embodiment. A scale-shaped filling level indicator 73 is preferably present on the milk collection container 7 '. The milk collection container 7 ' is entirely or partially transparent, or has a transparent or partially transparent window in the area of the scale 73.

The breast shield unit according to the present invention allows the separation of media in the area close to the breast. It is small and easy to clean, and is particularly suitable for use as a hands-free breast pump unit that can be mounted on a brassiere.

1 breast contact surface 10 stub 100 receiving groove 11 fixing lip 12 base portion 13 central opening 2 breast side membrane housing portion 20 port 21 vacuum channel 22 pump side opening 23 fixing small hole 24 central opening 3 membrane 3 ', 3 " 3 "Membrane part 30 Outside fixing bead 31 inner fixing bead 32 Central opening 33 Raised part 4 Membrane housing part 40 far from the breast Negative pressure chamber 41 Connection channel 42 Breast side opening 43 Fixing protrusion 44 Stub 45 Milk port 46 Pump chamber 5 Check valve 6 Shell 6 'Shell ring 6 "Cover 60 First through opening 61 Second through opening 62 Fixing flange 7, 7' Milk collection container 70 Milk line 71 Locked Projection 72 Connecting portion 73 Filling level indicator 8, 8 'Suction pump unit 80 Vacuum line 81 Vacuum pump 82 Pump base 83 Screw hole 8 Control element / display unit 9 breastshield unit A central axis B papilla

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Priority And Related Applications

Priority Applications (3)

Application	Priority date	Filing date	Title
CH1201/11		2011-07-18	
CH01201/11A	2011-07-18	2011-07-18	Breastshield unit
PCT/CH2012/000164	2011-07-18	2012-07-12	Breastshield unit

Legal Events

Date	Code	Title	Description
2015-06-11	A621	Written request for application examination	**Free format text**: JAPANESE INTERMEDIATE CODE: A621 **Effective date**: 20150511
2016-03-14	A977	Report on retrieval	**Free format text**: JAPANESE INTERMEDIATE CODE: A971007 **Effective date**: 20160311
2016-03-15	A131	Notification of reasons for refusal	**Free format text**: JAPANESE INTERMEDIATE CODE: A131 **Effective date**: 20160315
2016-06-15	A521	Request for written amendment filed	**Free format text**: JAPANESE INTERMEDIATE CODE: A523 **Effective date**: 20160615
2016-11-09	TRDD	Decision of grant or rejection written	
2016-11-22	A01	Written decision to grant a patent or to grant a registration (utility model)	**Free format text**: JAPANESE INTERMEDIATE CODE: A01 **Effective date**: 20161122
2016-12-22	A61	First payment of annual fees (during grant procedure)	**Free format text**: JAPANESE INTERMEDIATE CODE: A61 **Effective date**: 20161215
2016-12-22	R150	Certificate of patent or registration of utility model	**Ref document number**: 6062937 **Country of ref document**: JP **Free format text**: JAPANESE INTERMEDIATE CODE: R150
2019-12-17	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2020-12-17	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2021-12-16	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250

Concepts

machine-extracted

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Name	Image	Sections	Count	Query match
Breast		title,claims,abstract,description	154	0.000
membrane		claims,abstract,description	101	0.000
Nipples		claims,abstract,description	20	0.000
human milk		claims,abstract,description	10	0.000
Milk		claims,description	48	0.000
milk		claims,description	48	0.000
milk		claims,description	48	0.000
separation method		abstract,description	4	0.000
easy-to-clean		abstract,description	3	0.000

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最終頁に続く

(54)【発明の名称】ヒトの母乳の圧出および定量化のための方法、装置、およびシステム

(57)【要約】
母乳の圧出および採取のための装置は、作動可能なアセンブリと、胸部インターフェースと、チューブとを含む。胸部インターフェースは、胸部を受ける大きさであり、胸部に対し流体密封シールを形成する。胸部インターフェースは、胸部インターフェースの少なくとも一部に設けられた変形可能部材を含む。変形可能部材は、作動可能なアセンブリの作動に応じて変形し、胸部に真空圧をかけて乳を圧出させる。チューブは、作動可能なアセンブリを胸部インターフェースに操作可能に結合する。

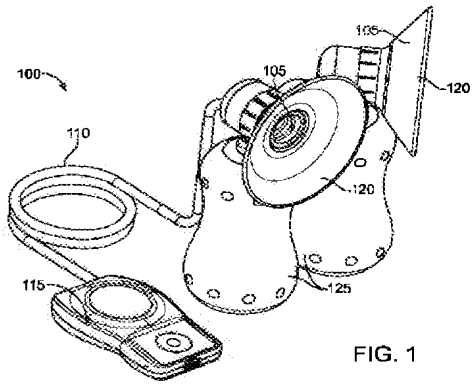

FIG. 1

【特許請求の範囲】
【請求項１】
母乳の圧出および採取のための装置であって、前記装置は、
作動可能なアセンブリと、
胸部インターフェースであって、前記胸部インターフェースは、胸部に係合し、これに対し流体密封を行う大きさであり、前記胸部インターフェースは、その少なくとも一部内に配置された可動部材を有する、胸部インターフェースと、
前記作動可能なアセンブリを前記胸部インターフェースに操作可能に結合するチューブと、
を備え、
前記可動部材は、前記作動可能なアセンブリの作動に応じて動作し、それによって前記胸部インターフェース内に真空を形成し、前記胸部に前記真空を適用してそこから乳を圧出させる、装置。
【請求項２】
前記作動可能なアセンブリは、ピストンまたはポンプを備える、請求項１に記載の装置。
【請求項３】
前記作動可能なアセンブリは、一対のピストンまたは一対のポンプを備える、請求項１に記載の装置。
【請求項４】
前記作動可能なアセンブリの作動は、前記チューブ内にある流体を移動させる、請求項１に記載の装置。
【請求項５】
前記可動部材は、柔軟膜を備える、請求項１に記載の装置。
【請求項６】
前記柔軟膜は、膨張・収縮するように構成された波形領域を有する、請求項５に記載の装置。
【請求項７】
前記柔軟膜は、前記作動可能なアセンブリの作動に応じて変形し、前記作動可能なアセンブリの作動が前記チューブ内に収められた流体を移動させる、請求項５に記載の装置。
【請求項８】
前記可動部材は、変形可能部材を備える、請求項１に記載の装置。
【請求項９】
前記胸部インターフェースは、前記胸部に係合し、前記胸部に対して流体密封を形成する弾力性があり馴染みやすいフランジを備える、請求項１に記載の装置。
【請求項１０】
流体は、前記チューブ内に配置される、請求項１に記載の装置。
【請求項１１】
前記流体は、非圧縮性流体である、請求項１０に記載の装置。
【請求項１２】
引張要素は、前記チューブ内に配置される、請求項１に記載の装置。
【請求項１３】
前記引張要素は、ロープ、ワイヤ、またはケーブルを備える、請求項１２に記載の装置。
【請求項１４】
前記引張要素は、前記可動部材および前記作動可能なアセンブリと操作可能に結合される、請求項１２に記載の装置。
【請求項１５】
前記作動可能なアセンブリと操作可能に結合され、前記作動可能なアセンブリを作動させるように構成された駆動機構をさらに備える、請求項１に記載の装置。

【請求項１６】
前記駆動機構は、電気機械装置である、請求項１５に記載の装置。
【請求項１７】
前記駆動機構は、モータを備える、請求項１５に記載の装置。
【請求項１８】
前記駆動機構は、前記作動可能なアセンブリに解放自在に結合される、請求項１５に記載の装置。
【請求項１９】
前記胸部インターフェースは、出口弁を備え、前記出口弁は、前記圧出した母乳の流れを採取容器内に向けて制御するように構成された、請求項１に記載の装置。
【請求項２０】
前記出口弁は、前記変形可能部材が変形されたときには前記出口弁を通して前記圧出した母乳が流れないようにし、前記変形可能部材が非変形形状のときには前記出口弁を通して前記圧出した母乳が流れるようにすることによって前記流れを制御する、請求項１９に記載の装置。
【請求項２１】
前記出口弁は、前記変形可能部材内に一体的に形成される、請求項１９に記載の装置。
【請求項２２】
第２の胸部インターフェースであって、前記第２の胸部インターフェースは、第２の胸部に係合し、これに対し流体密封を行う大きさであり、前記第２の胸部インターフェースは、その少なくとも一部内に配置された可動部材を有する、第２の胸部インターフェースと、
前記作動可能なアセンブリを前記第２の胸部インターフェースに操作可能に結合する第２のチューブと、
をさらに備え、
前記可動部材は、前記作動可能なアセンブリの作動に応じて変形し、それによって前記第２の胸部インターフェース内に真空を形成し、前記第２の胸部に真空を適用してそこから乳を圧出させる、請求項１に記載の装置。
【請求項２３】
第２の作動可能なアセンブリと、
第２の胸部インターフェースであって、前記第２の胸部インターフェースは、第２の胸部に係合し、これに対し流体密封を行う大きさであり、前記第２の胸部インターフェースは、その少なくとも一部内に配置された可動部材を有する、第２の胸部インターフェースと、
前記第２の作動可能なアセンブリを前記第２の胸部インターフェースに操作可能に結合する第２のチューブと、
をさらに備え、
前記可動部材は、前記作動可能なアセンブリまたは前記第２の作動可能なアセンブリの作動に応じて変形し、それによって前記第２の胸部インターフェース内に真空を形成し、前記第２の胸部に前記真空を適用してそこから乳を圧出させる、請求項１に記載の装置。
【請求項２４】
前記作動可能なアセンブリの作動を制御するためのコントローラを有する筐体をさらに備える、請求項１に記載の装置。
【請求項２５】
母乳産出情報の計算および表示を制御し、他の装置との通信を制御するためのコントローラを有する筐体をさらに備える、請求項１に記載の装置。
【請求項２６】
母乳の圧出および採取のための前記装置に電力を提供する電源を有する筐体をさらに備える、請求項１に記載の装置。
【請求項２７】

前記作動可能なアセンブリを作動させるための駆動用機構を有する筐体をさらに備える、請求項１に記載の装置。
【請求項２８】
前記胸部インターフェースと流体的に結合された採取容器をさらに備える、請求項１に記載の装置。
【請求項２９】
前記胸部インターフェースに隣接するセンサをさらに備え、前記センサは、そこを流れる乳の少なくとも１つの側面を感知するように構成される、請求項１に記載の装置。
【請求項３０】
前記乳の圧出に関するデータを表示するための表示ユニットをさらに備える、請求項１に記載の装置。
【請求項３１】
母乳の圧出および採取のためのシステムであって、請求項１に記載の装置を備えるシステム。
【請求項３２】
患者に圧力または真空を適用するための装置であって、前記装置は、
作動可能なアセンブリと、
標的組織インターフェースであって、前記標的組織インターフェースは、標的組織に係合し、これに対し流体密封を行う大きさであり、前記標的組織インターフェースは、その少なくとも一部内に配置された変形可能部材を有する、標的組織インターフェースと、
前記作動可能なアセンブリを前記標的組織インターフェースに操作可能に結合するチューブと、
を備え、
前記変形可能部材は、前記作動可能なアセンブリの作動に応じて変形し、それによって標的組織インターフェース内に真空または圧力を形成し、前記標的組織に前記真空または圧力を適用する、装置。
【請求項３３】
母乳を圧出させ採取する方法であって、前記方法は、
少なくとも１つの胸部インターフェースと、前記少なくとも１つの胸部インターフェースに操作可能に結合された少なくとも１つの作動可能なアセンブリとを有する胸部圧出および採取装置を提供するステップであって、前記胸部インターフェースは、変形可能部材を含む、ステップと、
胸部を前記胸部インターフェースに係合させて流体密封するステップと、
前記作動可能なアセンブリを作動させるステップと、
前記作動可能なアセンブリの作動に応じて変形可能部材を変形させ、それによって真空を形成し前記胸部に適用するステップと、
前記胸部から乳を圧出させて採取するステップと、
を含む、方法。
【請求項３４】
前記係合ステップが、前記胸部インターフェース上の弾力性があり馴染みやすいフランジを前記胸部に係合させ、それによって前記胸部インターフェースと前記胸部との間に流体密封を形成するステップを含む、請求項３３に記載の方法。
【請求項３５】
前記作動可能なアセンブリは、流体を移動させる、請求項３３に記載の方法。
【請求項３６】
前記流体は、前記作動可能なアセンブリおよび前記変形可能部材に流体的に結合されたチューブ内に配置される、請求項３５に記載の方法。
【請求項３７】
前記作動可能なアセンブリを作動させるステップは、ピストンを動作させるステップを含む、請求項３３に記載の方法。

【請求項３８】
前記作動可能なアセンブリを作動させるステップは、前記チューブ内に配置された引張要素に張力を適用するステップを含む、請求項３３に記載の方法。
【請求項３９】
軸荷重吸収部材は、前記引張要素の周囲に同心円状に配置され、前記方法が、前記引張要素の反力を吸収するステップをさらに含む、請求項３８に記載の方法。
【請求項４０】
前記作動可能なアセンブリを、それと操作可能に結合された駆動機構から解放するステップをさらに含む、請求項３３に記載の方法。
【請求項４１】
前記作動ステップと、前記変形ステップと、前記圧出ステップとを繰り返すステップをさらに含む、請求項３３に記載の方法。
【請求項４２】
前記圧出された乳の産出を定量するステップをさらに含む、請求項３３に記載の方法。
【請求項４３】
前記圧出された乳の１つまたはそれより多い側面を定量するステップをさらに含む、請求項３３に記載の方法。
【請求項４４】
前記母乳の圧出に関するデータを前記胸部圧出および採取装置と計算機との間で伝送するステップをさらに含む、請求項３３に記載の方法。
【請求項４５】
前記モバイル装置は、スマートフォンを含む、請求項４４に記載の方法。
【請求項４６】
前記データをディスプレイに表示するステップをさらに含む、請求項４４に記載の方法。
【請求項４７】
前記圧出された乳の採取容器への流れを、前記胸部圧出および採取装置に流体的に結合された弁で制御するステップをさらに含む、請求項３３に記載の方法。
【請求項４８】
流れを制御するステップは、前記変形可能部材が未変形の時には前記弁を開け、前記変形可能部材が変形されたときには前記弁を閉めるステップを含む、請求項４７に記載の方法。
【請求項４９】
前記圧出した母乳の流れを、前記胸部インターフェースに流体的に結合されたセンサで感知するステップをさらに含む、請求項３３に記載の方法。
【請求項５０】
前記胸部圧出および採取装置は、第２の胸部インターフェースと、前記第２の胸部インターフェースに操作可能に結合された第２の作動可能なアセンブリとをさらに備え、前記第２の胸部インターフェースは、変形可能部材を含み、前記方法は、
第２の胸部を前記第２の胸部インターフェースに係合させて流体密封させるステップと、
前記第２の作動可能なアセンブリを作動させるステップと、
前記第２の胸部インターフェース内の前記変形可能部材を前記第２の作動可能なアセンブリの作動に応じて変形させ、それによって前記第２の胸部に真空を形成し適用するステップと、
前記第２の胸部から乳を圧出させて採取するステップと、
をさらに含む、請求項３３に記載の方法。
【請求項５１】
両方の胸部から乳を圧出させ採取するステップは、同時に起こる、請求項５０に記載の方法。

【請求項５２】
乳を圧出させ採取するステップは、両方の胸部の間を交互に繰り返す、請求項５０に記載の方法。
【請求項５３】
差圧を患者に適用する方法であって、前記方法は、
インターフェースと、差圧装置に操作可能に結合された作動可能なアセンブリと、を有する差圧装置を提供するステップであって、前記インターフェースは、変形可能部材を備える、ステップと、
前記インターフェースを前記患者上の標的領域に係合させ、流体的に密封するステップと、
前記作動可能なアセンブリを作動させるステップと、
前記変形可能部材を前記作動可能なアセンブリの作動に応じて変形させ、それによって正圧または真空を形成し、前記正圧または前記真空を前記標的領域に適用するステップと、
を含む、方法。
【請求項５４】
前記変形可能部材を変形させるステップは、前記標的領域に適用される正圧を形成し、前記標的領域が、口または鼻を含み、それによって前記患者が睡眠している間の無呼吸状態を低減または解消する、請求項５３に記載の方法。
【請求項５５】
前記柔軟膜を変形させるステップは、前記標的領域に適用される真空を形成し、前記標的領域は、体液貯蔵器官を含み、それによって、そこから前記体液を圧出させるステップを含む、請求項５３に記載の方法。

【発明の詳細な説明】
【技術分野】
【０００１】
（関連出願）
本願は、２０１３年３月２４日に出願された、米国仮特許出願第６１／８０４，７２２号（代理人管理番号第４４３９６－７０２．１０１号）、２０１３年９月１７日に出願された、米国仮特許出願第６１／８７９，０５５号（代理人管理番号第４４３９６－７０３．１０２号）、２０１４年３月２０日に出願された、米国特許出願第１４／２２１，１１３号（代理人管理番号第４４９３６－７０３．２０１号）の利益を主張するものであり、これらの全内容は、参照により本明細書中に援用される。
【０００２】
本発明は、概して、医療装置および方法に関し、より具体的には、ヒトの母乳の圧出および採取のための装置および方法に関する。
【０００３】
本明細書で開示される例示的実施形態は、好ましくは、母乳の圧出を対象とするが、当業者は、これが限定を意図するものではなく、本明細書で開示される装置、システム、および方法が差圧の適用を必要とする他の治療法にも用いられ得ることを認識するであろう。
【０００４】
胸部ポンプは、母親が自らの子供と離れていても授乳を続けられるように母乳を採取するため一般に用いられている。今のところ、胸部ポンプには、２種類の基本型、すなわち、小型ではあるが非効率的で使用の疲れを生じる手動措置と、効率的ではあるが大きくかさばる電動装置とがある。このため、母乳の圧出および採取のために小型で非常に効率的な改良された胸部ポンプを提供することが望ましいであろう。乳産出の定量化やモバイル装置との通信等の追加的な特徴は、ユーザの利便性を高める上でさらに望ましい。これら

の目的の少なくともいくつかは、以下に開示される装置および方法によって満足されるであろう。

【背景技術】

【０００５】

以下の米国特許は、ヒトの母乳の圧出および採取に関する。米国特許第６，６７３，０３６号（特許文献１）、第６，７４９，５８２号（特許文献２）、第６，８４０，９１８号（特許文献３）、第６，８８７，２１０号（特許文献４）、第７，８７５，０００号（特許文献５）、第８，１１８，７７２号（特許文献６）、および第８，２１６，１７９号（特許文献７）。

【先行技術文献】

【特許文献】

【０００６】

【特許文献１】米国特許第６，６７３，０３６号明細書
【特許文献２】米国特許第６，７４９，５８２号明細書
【特許文献３】米国特許第６，８４０，９１８号明細書
【特許文献４】米国特許第６，８８７，２１０号明細書
【特許文献５】米国特許第７，８７５，０００号明細書
【特許文献６】米国特許第８，１１８，７７２号明細書
【特許文献７】米国特許第８，２１６，１７９号明細書

【発明の概要】

【発明が解決しようとする課題】

【０００７】

本発明は、概して、医療装置、システム、および方法に関し、より具体的には、ヒトの母乳の圧出および採取のための装置、システム、および方法に関する。

【課題を解決するための手段】

【０００８】

本発明の第１の側面では、母乳の圧出および採取のための装置が、作動可能なアセンブリと、胸部インターフェースと、チューブとを備える。胸部インターフェースは、胸部と係合し、それを流体密封する大きさになっている。胸部インターフェースはまた、その少なくとも一部内に配置された可動部材を含む。可動部材は、作動可能なアセンブリの作動に応じて動作し、それによって胸部インターフェースに真空を形成し、真空を胸部に適用し、そこから乳を圧出させる。チューブは、作動可能なアセンブリと、胸部インターフェースとに、操作可能に結合されている。

【０００９】

作動可能なアセンブリは、ピストンもしくはポンプ、または一対のピストンもしくは一対のポンプを備えてもよい。作動可能なアセンブリの作動は、チューブ内に配置された流体を移動させ得る。

【００１０】

可動部材は、柔軟膜を備え得る。柔軟膜は、膨張し収縮するように構成された波形領域を有してもよい。柔軟膜は、作動可能なアセンブリの作動に応じて変形し、作動可能なアセンブリの作動が、チューブに含まれる流体を移動させ得る。可動部材は、変形可能部材を備えてもよい。

【００１１】

胸部インターフェースは、胸部に係合して流体密封を形成する弾力性があり馴染みやすいフランジを備えてもよい。

【００１２】

流体が、チューブ内に配置されてもよい。流体は、水や油等の非圧縮性流体であり得る。他の実施形態では、チューブ内に、引張要素が配置されてもよい。引張要素は、ロープ、ワイヤ、またはケーブルを含み得る。引張要素は、可動部材および作動可能なアセンブリに操作可能に結合され、引張要素の反荷重を吸収する軸方向圧縮要素と同心円状に配置

されてもよい。

【００１３】

本装置は、作動可能なアセンブリに操作可能に結合され、作動可能なアセンブリを作動させるように構成された駆動機構を備えてもよい。駆動機構は、モータ等の電気機械装置を含み得る。駆動機構は、作動可能なアセンブリに解放自在に結合され得る。

【００１４】

胸部インターフェースは、圧出した母乳の採取容器内への流れを制御するように構成された出口弁を備えてもよい。出口弁は、変形可能部材が変形されたときには、圧出された乳が弁を通して流れることを防ぎ、変形可能部材が非変形形状にあるときは、圧出した母乳が弁を通して流れることを可能にすることによって、流れを制御し得る。出口弁は、変形可能部材内に一体的に形成され得る。

【００１５】

本装置は、第２の作動可能なアセンブリと、第２の胸部インターフェースと、第２のチューブとをさらに備えてもよい。第２の胸部インターフェースは、第２の胸部と係合し、それに対し流体密封する大きさになり得る。第２の胸部インターフェースは、少なくともその一部内に配置された可動部材を有し得、可動部材は、作動可能なアセンブリまたは随意の第２の作動可能なアセンブリのいずれかによる作動に応じて変形し、それによって第２の胸部インターフェース内に真空を形成し、これを第２の胸部に適用し、そこから乳を圧出させてもよい。第２のチューブは、第２の作動可能なアセンブリおよび第２の胸部インターフェースに操作可能に結合され得る。

【００１６】

本装置は、作動可能なアセンブリの作動を制御するためのコントローラを有する筐体をさらに備えてよい。コントローラは、母乳産出情報の計算および表示を制御し得、またコントローラは、他の装置との通信も制御し得る。筐体内に電源を配置し、電源が、乳の圧出および採取のための装置に電力を提供し得る。筐体は、その内部に配置され、作動可能なアセンブリを作動させるための駆動用機構を有し得る。

【００１７】

本装置は、胸部インターフェースと流体的に結合された採取容器をさらに備えてよい。本装置はまた、胸部インターフェースに隣接し、そこを過ぎる乳通過のある側面を測定するように構成されたセンサを備えてもよい。本装置はまた、乳の圧出に関するデータを表示する表示ユニットを備えてもよい。母乳の圧出および採取のためのシステムは、これまで上に記された装置を含み得る。これらの構成要素はいずれも、他の構成要素とは別個であってもよく、もしくはこれらは、筐体またはペンダント内に配置され得る。

【００１８】

本発明の別の側面では、患者に圧力または真空を適用するための装置が、作動可能なアセンブリと、標的組織インターフェースと、チューブとを備える。標的組織インターフェースは、好ましくは、標的組織と係合しそれに対し流体密封する大きさになっている。標的組織インターフェースは、その少なくとも一部内に配置された変形可能部材を有し、変形可能部材は、作動可能なアセンブリの作動に応じて変形する。これが、標的組織インターフェース内に真空または圧力を形成し、真空または圧力を標的組織に適用する。チューブは、作動可能なアセンブリおよび標的組織インターフェースに操作可能に結合される。

【００１９】

本発明のさらに別の側面では、母乳を圧出させ、採取するための方法が、胸部インターフェースと、胸部インターフェースに操作可能に結合された作動可能なアセンブリとを有する胸部圧出および採取装置を提供するステップを含む。胸部インターフェースは、変形可能部材を備える。本方法はまた、胸部を胸部インターフェースと係合させ流体密封するステップと、作動可能なアセンブリを作動させるステップとを含む。本方法はまた、作動可能なアセンブリの作動に応じて変形可能部材を変形させるステップを含み、それによって真空を胸部に形成し適用して、胸部から乳を圧出させて採取するステップを含む。

【００２０】

係合ステップは、胸部インターフェース上の弾力性があり馴染みやすいフランジを胸部と係合させ、それによって胸部インターフェースと胸部との間に流体密封を形成するステップを含んでもよい。

【００２１】

作動可能なアセンブリを作動させると、流体が移動し得る。作動可能なアセンブリおよび変形可能部材と流体的に結合されたチューブ内に流体を配置してもよい。作動可能なアセンブリを作動させるステップは、ピストンを動作させること、またはチューブ内に配置された引張要素に張力を適用することを含んでもよい。本方法は、作動可能なアセンブリを、それと操作可能に結合された駆動機構から解放することをさらに含み得る。

【００２２】

本方法は、作動、変形、および圧出のステップを繰り返すことをさらに含んでよい。本方法は、圧出された乳の産出を定量するステップと、胸部圧出および採取装置とモバイル装置との間で、母乳の圧出に関するデータを伝送するステップをさらに含み得る。モバイル装置は、スマートフォン、タブレット、または計算機であり得る。データは、ディスプレイに表示され得る。本方法はまた、圧出された乳の採取容器への流れを、胸部圧出および採取装置に流体的に結合された弁によって制御するステップを含み得る。流れを制御するステップは、変形可能部材が未変形のときに弁を開き、変形可能部材が変形したときに弁を閉じることを含み得る。また母乳の側面は、胸部インターフェースに流体的に、または別様に結合されたセンサで感知してもよい。

【００２３】

胸部圧出および採取装置は、第２の胸部インターフェースと、第２の胸部インターフェースに操作可能に結合された第２の作動可能なアセンブリとをさらに備えてもよい。第２の胸部インターフェースは、変形可能部材を備え得る。本方法は、第２の胸部を第２の胸部インターフェースと係合させ流体密封するステップと、第１または第２の作動可能なアセンブリを作動させるステップとをさらに含み得る。本方法はまた、第２の胸部インターフェース内の変形可能部材を第２の作動可能なアセンブリの作動に応じて変形させ、それによって第２の胸部に真空を形成して適用し、第２の胸部から乳を圧出させ採取するステップを含み得る。両方の胸部からの乳の圧出と採取は、両方の胸部で同時に行なってもよく、または交互に行ってもよい。

【００２４】

本発明のさらに別の側面では、患者に差圧を適用する方法が、インターフェースを有する差圧装置と、差圧装置に操作可能に結合された作動可能なアセンブリとを提供することを含む。インターフェースは変形可能部材を備え、本方法は、インターフェースを患者上の標的領域と係合させ流体密封し、作動可能なアセンブリを作動させるステップをさらに含む。本方法はまた、作動可能なアセンブリの作動に応じて変形可能部材を変形させ、それによって正圧または真空を形成し、標的領域に正圧または真空を適用するステップを含む。いずれの構成要素も他の構成要素から切り離してよく、またはこれらを筐体もしくはペンダント内に配置してもよい。

【００２５】

変形可能部材を変形させるステップは、標的領域に適用される正圧を形成し得る。標的領域は、口または鼻を含み、正圧の適用が、患者の睡眠時の無呼吸または同様な障害を低減または解消し得る。柔軟膜を変形させるステップは、標的領域に適用される真空を形成し得る。標的領域は、体液貯蔵器官を含み、そのようにして、真空が、貯蔵器官からの体液の圧出を引き起こす。

【００２６】

これらおよび他の実施形態は、添付図面に関連する以下の記述により詳細に記される。

（参照による組み込み）

【００２７】

本明細書で述べられる全ての出版物、特許、および特許出願は、個々の出版物、特許、および特許出願が具体的かつ個々に参照によって組み込まれるのと同程度に参照によって本

明細書に組み込まれる。
【図面の簡単な説明】
【００２８】
本発明の新規の特徴は、具体性をもって添付の請求項に示される。本発明の特徴および利点のより深い理解は、本発明の原理が活用された例証的実施形態を示す以下の詳細な記述および付随の図面の参照によって得られるであろう。
【図１】図１は、ポンプ装置の例示的実施形態の斜視図である。
【図２】図２は、ポンプ装置の例示的実施形態の斜視図である。
【図３】図３は、ポンプ装置の例示的実施形態の断面である。
【図４】図４は、駆動機構に結合された作動可能なアセンブリの例示的実施形態を図示する。
【図５Ａ】図５Ａ－５Ｂは、ペンダントユニットに結合された作動可能なアセンブリの例示的実施形態を図示する。
【図５Ｂ】図５Ａ－５Ｂは、ペンダントユニットに結合された作動可能なアセンブリの例示的実施形態を図示する。
【図６】図６は、胸部インターフェースの例示的実施形態の断面図である。
【図７】図７は、胸部インターフェースの別の例示的実施形態の断面図である。
【図８Ａ】図８Ａは、開位置にある一体化された弁の例示的実施形態の断面図である。
【図８Ｂ】図８Ｂは、閉位置にある一体化された弁の例示的実施形態の断面図である。
【図９Ａ】図９Ａは、胸部インターフェース内に一体化されたセンサの例示的実施形態の断面図である。
【図９Ｂ】図９Ｂは、胸部インターフェース内に一体化されたセンサの別の例示的実施形態の断面図である。
【図１０】図１０は、ペンダントユニットおよびモバイル装置の例示的実施形態を図示する。
【図１１】図１１は、モバイル装置と通信中のペンダントユニットの例示的実施形態を図示する。
【図１２】図１２は、機械的変形可能部材のついた胸部インターフェースの例示的実施形態の断面図である。
【図１３】図１３は、機械的変形可能部材用の機械的駆動機の例示的実施形態の断面図である。
【図１４】図１４は、商用装置と比較した例示的実施形態のポンプ性能を図示するグラフである。
【図１５】図１５は、商用装置と比較した例示的実施形態のポンプ効率を図示するグラフである。
【発明を実施するための形態】
【００２９】
開示された装置および方法の具体的な実施形態を、図面を参照しつつ以下に記述する。いかなる詳細な記述も、特定の構成要素、特徴、またはステップが本発明にとって絶対必要であることを示唆することを意図しない。当業者は、様々な特徴またはステップが、互いに置き換え、または組み合わせされ得ることを理解するであろう。
【００３０】
本発明は、母乳の圧出および採取に関連して記述される。しかしながら、当業者は、それが限定を意図するものではなく、本明細書で開示される装置および方法が、睡眠時無呼吸の治療および／または他の遠隔圧力ニーズ等、圧力差の形成と伝達を必要とする他の用途にも使用し得ることを理解するであろう。
【００３１】
図１は、本発明の例示的実施形態を図示する。ポンプ装置１００は、胸部インターフェース１０５と、チューブ１１０と、チューブ１１０を通して胸部インターフェース１０５に操作可能に結合されたコントローラまたはペンダントユニット１１５とを含む。胸部イ

ンターフェース１０５は、胸部と係合し、それに対し流体密封を形成する弾力性があり馴染みやすいフランジ１２０と、採取容器１２５とを含む。本装置は、随意に、単一の胸部インターフェースのみを有してもよい。ペンダントユニット１１５は、ポンプ装置１００の電源および駆動用機構を収容し、また、ポンプ装置１００の制御、乳産出の定量化、他の装置との通信等、様々な機能のためのハードウェアを含む。チューブ１１０は、機械的なエネルギー入力等の好適なエネルギー入力を、ペンダントユニット１１５から胸部インターフェース１０５までの長い距離にわたって伝達する。胸部インターフェース１０５は、エネルギー入力を胸部に対する真空圧力に効率よく変換し、採取容器１２５内への乳の圧出を引き起こす。

【００３２】

当業者は、本例示的実施形態の構成要素および特徴が、以下に示すいずれの本発明の実施形態の構成要素および特徴とも組み合わせ、または代替ができることを理解するであろう。同様に、本明細書で開示される他の実施形態の構成要素および特徴は、互いに代替または組み合わされ得る。

（液圧ポンプ装置）

【００３３】

液圧システムは、必要とされるポンプ力を減らすことができ、そのため、ポンプ効率を維持しながらポンプ装置のサイズを減らすことができる。好適な実施形態では、ポンプ装置が、液圧ポンプ装置を利用して、乳の圧出および採取のため、胸部に対する圧力差を発生させることができる。

【００３４】

例示的液圧ポンプ装置が、図２および３に示される。図２は、チューブ１６５によって胸部インターフェース１６０に流体的に結合された注射器１５５を有するポンプ装置１５０を図示する。注射器１５５は、三方弁１７０を通してチューブ１６５に結合される。胸部インターフェース１６０は、出口ポート１７５を含む。注射器１５５は、チューブ１６５内に含まれる流体１８０を、胸部インターフェース１６０内に収容された柔軟な部材に向けて、またはこれから離れるように駆動し、胸部からの乳の圧出に必要な圧力差を作り出す。

【００３５】

図３は、ポンプ装置２００の別の実施形態を図示する。作動可能なアセンブリ２０５は、アセンブリ筐体２１０と、駆動要素２１５と、ラジアルシール２２０と、シャフト２２２と、を含む。駆動要素２１５は、シャフト２２２を通してペンダントユニット１１５等のペンダントユニットに操作可能に結合される。チューブ２２５は、流体２３０を含み、作動可能なアセンブリ２０５および胸部インターフェース２３５に流体的に結合される。胸部インターフェース２３５は、インターフェース筐体２４０と、柔軟膜２４５と、貯蔵器２５０と、密封要素２５５と、圧出領域２６０と、排出ポート２６５とから成る。密封要素２５５は、変形可能部分２７０を含む。排出ポート２６５は、採取容器２７５に結合され、フラップ弁２８０を含む。

【００３６】

作動可能なアセンブリ２０５は、たわみ管路であり得るチューブ内２２５に含まれる流体２３０を移動させる。流体２３０は、胸部インターフェース２３５内の貯蔵器２５０内を占め、柔軟膜２４５と結合される。柔軟膜２４５は、流体２３０から密封要素２５５の変形可能部分２７０に真空圧力を伝達する。胸部が密封要素２５５によって胸部インターフェース２３５と係合し流体的に密封されたとき、作動可能な要素２１５の移動が、柔軟膜２４５および変形可能部分２７０を通して、胸部に対する実質的な真空圧力を作り出し、その結果、圧出領域２６０中への母乳の圧出が引き起こされる。圧出された乳は、排出ポート２６５を通して採取容器２７５中に排出される。排出ポート２６５は、フラップ弁２８０を持つ構成になっており、圧出領域２６０内の真空圧力を維持しながら乳の通路を確保する。

【００３７】

液圧ポンプ装置の流体は、非圧縮性流体等、任意の好適な流体とすることができる。多くの実施形態では、非圧縮性流体は、水または油であり得る。代わりに、流体は、空気等、任意の好適な気体とすることができる。液圧システム用の好適な非圧縮性流体およびガスは、当業者に知られている。

【００３８】

当業者は、液圧ポンプ装置のいずれの例示的実施形態の構成要素および特徴が、本明細書に記載される本発明のいずれの例示的実施形態の構成要素および特徴とも組み合わせ、または置き換えができることを理解するであろう。

（作動機構）

【００３９】

当業者に知られる多くの作動機構が、作動可能なアセンブリ２０５に利用されることができる。作動可能なアセンブリ２０５は、ピストンアセンブリ、ダイアフラムポンプ等のポンプ、または任意の他の好適な作動機構とすることができる。作動可能なアセンブリ２０５の最適な構成は、真空要件、サイズ、電力、およびポンプ装置２００のその他の必要性、ならびに粘度、生体適合性、および流体寿命要件等の流体２３０の特性等、多くの要因によって異なり得る。

【００４０】

図３は、作動可能なアセンブリ２０５がピストンアセンブリで、駆動要素２１５がピストンである例示的実施形態を図示する。作動可能なアセンブリ２０５は、流体２３０の不要な滲出を防ぎ、流体２３０の駆動を可能にするようにアセンブリ筐体２１０に対して密封を行うＯリング等のラジアルシール２２０を含む。

【００４１】

図４は、一対のピストン３０５を含む作動可能なアセンブリ３００の別の例示的実施形態を図示する。

【００４２】

好適な実施形態では、作動可能なアセンブリが、ペンダントユニット１１５内の駆動機構等、好適な駆動機構によって動く駆動要素を含む。多くの駆動機構が当業者に知られている。例えば、駆動要素２１５等の駆動要素は、モータによって電気機械的に作動されてもよく、レバー等の好適なユーザー・オペレータインターフェースによって手動で作動されてもよい。当業者に知られる様々な駆動モードが用いられることができる。特に、本明細書に記載されるような例示的液圧ポンプ装置の実施は、液圧システムにより低減された力の要件により、直接駆動やソレノイド等の好適な駆動モードの使用を可能にする。

【００４３】

図４の例示的実施形態を参照すると、ピストン３０５は、クランクシャフト３１５へのカップリング３１０を含む。クランクシャフト３１５は、ベルト駆動３２５を通してモータ３２０に操作可能に結合されている。クランクシャフト３１５は、両方の胸部に同時に真空圧力を適用するように一対のピストン３０５を同じストロークタイミングで駆動するが、この特徴は、乳の産出増大に望ましい。代わりに、クランクシャフト３１５は、交互またはオフセットストロークサイクル等の任意の好適なストロークタイミングで一対のピストン３０５を駆動できる。

【００４４】

駆動機構は、局部電池またはＡＣアダプタ等の任意の好適な電源で動かすことができる。駆動機構は、ペンダントユニット１１５内に配置された内臓電子装置等のハードウェアにより制御することができる。

【００４５】

図５は、解放自在なカップリング３５５を含む作動可能なアセンブリ３５０の例示的実施形態を図示する。好ましくは、作動可能なアセンブリ３５０が、ペンダントユニット３６０と、そこに収納される駆動機構とに解放自在に結合される。カップリングは、機械的カップリング、または当業者に公知の任意の好適な簡易脱着機構であり得る。解放自在に結合された設計は、構成の柔軟性とポンプ装置の使用とを可能にする。例えば、使い心地

は、様々な胸部サイズと適合する異なる大きさの胸部インターフェースによって改良され得る。加えて、この特徴は、取り換え可能な胸部インターフェースとともに一般のポンプ装置の使用を可能にし、病原体の拡散リスクを低減する。さらに、解放自在カップリングは、ポンプ装置の個々の部品の容易な交換を可能にする。

【００４６】

当業者は、作動機構のいずれの例示的実施形態の構成要素および特徴も、本明細書に記述されるような本発明のいずれの実施形態の構成要素および特徴と組み合わせまたは代替できることを理解するであろう。

（柔軟膜）

【００４７】

図３に示される実施形態等、多くの実施形態において、柔軟膜２４５は、胸部インターフェース２３５内に位置し、少なくともその一部を覆うように配置されており、インターフェース筐体２４０と柔軟膜２４５との間に貯蔵器２５０を形成する。好ましくは、柔軟膜２４５は、流体２３０が作動可能なアセンブリ２０５によって貯蔵器２５０から移動されたときに形成される負圧にさらされたとき、実質的に変形する。柔軟膜２４５の変形量は、多くの要因（例えば、壁厚、ゴム硬さ、表面積）によって制御することができ、ポンプ装置（例えば、ポンプ電力、真空要件）に基づいて最適化できる。

【００４８】

図６は、特定の厚さとゴム硬さとを有する例示的柔軟膜３７０を図示する。

【００４９】

図７は、表面積を増大させる波形の特徴３８０が付いた柔軟膜３７５の別の実施形態を図示する。

【００５０】

柔軟膜に好適な材料は、当業者に知られている。多くの実施形態では、柔軟膜は、シリコーン、ＰＥＢＡＸ等のポリエーテルブロックアミド、およびネオプレン等のポリクロロプレン等の結合流体からの圧力にさらされたとき、膨張および収縮するように設計された材料で作ることができる。代わりに、柔軟膜は、ステンレス鋼、ニチノール、硬質ポリマー、または硬質エラストマー等の実質的剛体材料から作られ得る。これらの実施形態では、剛体材料が、材料の降伏点を超えない柔軟膜の実質的な変形を可能にする応力および／またはひずみ分散要素とともに設計されるであろう。

【００５１】

図８Ａおよび８Ｂは、出口弁４０５が柔軟膜４１０に一体化され、圧出された乳の流れを、出口ポート４１５を通して制御する胸部インターフェース４００の好適な実施形態を図示する。出口弁４０５は、図８Ａに示されるように、柔軟膜４１０が緩和されたときに開かれて流体の流れを可能にし、また、図８Ｂに示されるように、柔軟膜４１０が変形されたときに閉じられて流体の流れを阻止する。出口弁４０５は、抽出の間には圧出領域４２０に実質的な真空圧力が存在できるようにする一方、ポンプストロークの休止状態の間は、乳が排出できるようにする。多くの従来型胸部ポンプバルブは、圧力差のみで機能する一方、出口弁４０５は、好ましくは、柔軟膜４１０の機械的動きにも機能するように構成されることができる。一体化された出口弁４０５に、本明細書に記載されるような機械的機能を組み込むことで、真空形成の間、胸部インターフェース４００の密封が改良され得る。さらに、出口弁４０５のように、柔軟膜４１０内に一体的に形成された出口弁を使用すると、洗浄すべき部品の数が減る。

【００５２】

当業者は、柔軟膜のいずれの例示的実施形態の構成要素および特徴が、本明細書に記述されるような本発明のいずれの実施形態の構成要素および特徴とも組み合わせまたは代替できることを理解するであろう。

（乳採取および定量化システム）

【００５３】

図３を参照すると、圧出された乳は、柔軟膜２４５内の出口ポート２６５を通して採取

容器２７５中に排出される。採取容器２７５は、ビンや袋等の任意の好適な容器であり得る。多くの実施形態で、採取容器２７５は、柔軟膜２４５に、取り外し可能に結合されている。採取容器２７５は、延長配管等の任意の好適な装置を介して、直接または離れて結合されることができる。

【００５４】

多くの場合、乳産出の量等、乳圧出および採取に関する様々なデータを追跡することが望まれ得る。現在のところ、乳産出の追跡は、手動測定と記録管理によって一般に行われている。本明細書に記載される本装置の例示的実施形態は、改良された利便性、効率、および精度のため、乳産出を自動測定し追跡するデジタルに基づく手段を提供し得る。

【００５５】

図９Ａおよび９Ｂは、１つまたはそれより多い一体化されたセンサ４５５の付いた胸部インターフェース４５０の例示的実施形態を図示する。センサ４５５は、好ましくは、フラップ弁４６０内に位置されるが、出口弁４６５または流体の流れを監視するのに好適な任意の他の場所に位置されてもよい。好適な実施形態では、少なくとも１つのセンサ４５５が、流体の流れによって開かれる弁に一体化され、弁が開いている延べ時間を検知する。センサ信号は、流体の流れを定量するように問い合わられ得る。好適なセンサは、加速度計、ホール効果センサ、およびフォトダイオード／ＬＥＤセンサ等が当業者に知られている。胸部インターフェースは、乳産出を定量する単一センサまたは多重センサを含むことができる。

【００５６】

図１０は、乳圧出データがディスプレイスクリーン５０５に表示されたペンダントユニット５００の例示的実施形態を図示する。多くの実施形態では、ペンダントユニット５００は、乳圧出に関するデータを採取し、処理し、貯蔵し、表示する。好ましくは、ペンダントユニット５００は、モバイルフォン５１０等の第２の装置にデータを伝送することができる。

【００５７】

図１１は、ペンダントユニット５００とモバイルフォン５１０との間のデータ伝送５１５を図示する。装置間の通信およびデータ伝送の好適な方法は、Ｂｌｕｅｔｏｏｔｈ（登録商標）や近距離無線通信等が当業者に知られている。

【００５８】

例示的実施形態では、ペンダントユニット５００が、モバイルフォン５１０と通信し、圧出体積、持続時間、および日付等の乳圧出データを伝送する。モバイルフォン５１０は、圧出データを採取して集計し、それを対話式フォーマットで表示するモバイルアプリケーションを含む。好ましくは、モバイルアプリケーションは、ライフスタイルの選択、食生活、乳産出増大のための方略等の情報をユーザがオーバーレイできるようにする追加的な特徴を含み、このような情報と乳産出統計との比較を容易にする。加えて、ペンダントユニット５００が、ポンプの使用回数に関する情報をモバイルフォン５１０に送り、モバイルアプリケーションが、ポンプ動作がいつ起こるかを識別し、所望のポンプ動作回数にリマインダを設定できるようにすることができる。このようなリマインダは、ポンプセッションの忘れ防止に役立ち、その結果、乳腺炎等の合併症の発生率を低減することができる。

【００５９】

当業者は、乳採取および定量化システムのいずれの例示的実施形態の構成要素および特徴が、本明細書に記述されるような本発明のいずれの実施形態の構成要素および特徴とも組み合わせまたは代替できることを理解するであろう。

（機械的ポンプ装置）

【００６０】

図１２は、柔軟膜の代わりに機械的変形可能部材６０５が用いられ得る、胸部インターフェース６００の代替的実施形態を図示する。機械的変形可能部材６０５は、本明細書に記載の柔軟膜に用いられるのと同様な手法で構成されることができる。機械的変形可能部

材６０５は、引張要素６１０に結合される。ある場合には、引張要素６１０は、軸荷重吸収部材６１５内に配置される。軸荷重吸収部材６１５は、チューブ６２０内に配置される。好ましくは、引張要素６１０が、軸荷重吸収部材６１５内に同心円状に配置され、軸荷重吸収部材６１５が、チューブ６２０内に同心円状に配置される。引張要素６１０の代替的構成では、軸荷重吸収部材６１５およびチューブ６２０を使用することもできる。

【００６１】

図１３は、作動可能なアセンブリ６３０のアセンブリ筐体６３５内の駆動要素６２５に結合された引張要素６１０を図示する。駆動要素６２５は、シャフト６４０を介して、ペンダントユニット内に収納された駆動機構等の駆動機構に操作可能に結合される。チューブ６２０内の軸荷重吸収部材６１５は、アセンブリ筐体６３５に固定的に結合される。駆動要素６２５の移動が、引張要素６１０を通して機械的変形部材６０５に張力を伝達し、胸部に対し真空圧力を形成する。

【００６２】

引張要素６１０は、ワイヤ、コイル、またはロープ等の任意の好適な装置であることができ、また金属、ポリマー、またはエラストマー等の任意の好適な材料で作られることができる。軸荷重吸収部材６１５は、金属やポリマー等、軸方向に剛い任意の好適な材料で作られることができ、チューブやコイル等、軸方向に剛い任意の好適な形状で構成されることができる。

【００６３】

当業者は、機械的ポンプ装置のいずれの例示的実施形態の構成要素および特徴も、本明細書に記述されるような本発明のいずれの実施形態の構成要素および特徴と組み合わせまたは代替できることを理解するであろう。

（実験データ）

【００６４】

図１４および１５は、商用の胸部ポンプ装置および本発明の例示的実施形態から得られた実験的ポンプ動作のデータを図示する。例示的実施形態は、ポンプ動作に非圧縮性流体を用い、４ｃｃの最大液圧流体体積を有し、一方、商用装置は、空気ポンプ動作を用い、１１４ｃｃの最大体積を有した。

【００６５】

図１４は、１行程あたりに発生される真空圧力で定量されたポンプ性能のグラフを図示する。例示的実施形態については、ポンプによって移動された流体体積の１ｃｃ、２ｃｃ、３ｃｃ、および４ｃｃについて圧力測定を行い、行程番号は体積ｃｃに対応する。商用装置については、ポンプによって移動された流体体積の４６ｃｃ、５７ｃｃ、６８ｃｃ、８０ｃｃ、９１ｃｃ、１０３ｃｃ、および１１４ｃｃをそれぞれ代表する真空調整ゲージに沿った７つの等間隔位置の１つにポンプを設定して測定が行われ、行程番号が位置番号に対応する。曲線７００は、例示的実施形態に対応し、曲線７０５は、商用装置に対応する。例示的実施形態は、商用装置に比べ移動体積あたりにより高レベルな真空圧力を発生させ、最高真空圧力は、それぞれ、－２４０．５ｍｍＨｇおよび－１７７．９ｍｍＨｇであった。

【００６６】

図１５は、流体移動の最大体積当たりの最大真空圧力で測定されたポンプ効率のグラフを図示し、棒７１０は、例示的実施形態に対応し、棒７１５は、商用装置に対応する。例示的実施形態は、商用装置に比べて４２倍のポンプ効率増加を実証し、効率は、それぞれ、－７１．１ｍｍＨｇ／ｃｃおよび－１．７ｍｍＨｇ／ｃｃであった。

【００６７】

本発明の好適な実施形態が、本明細書に示され記述されたが、このような実施形態が、例としてのみ提示されることは当業者にとって当然である。多くの変形、変更、および代替が、本発明から逸脱することなく当業者に想起されることであろう。本明細書に記載された本発明の実施形態への様々な代替が、本発明の実施に使われ得るものと理解されるべきである。以下の請求項は、本発明の範囲を画定することを意図したもので、これら請求

項の範囲内にある方法、構成、およびそれらの均等物は、それによって包含されることを意図する。

【図１】

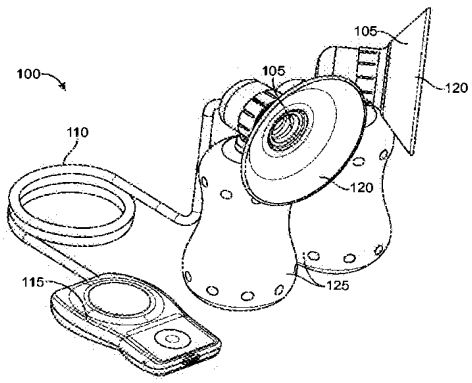

FIG. 1

【図２】

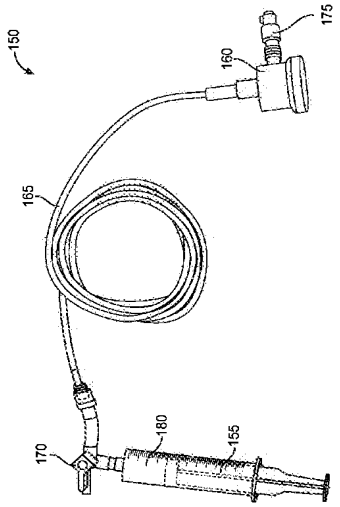

FIG. 2

【図３】

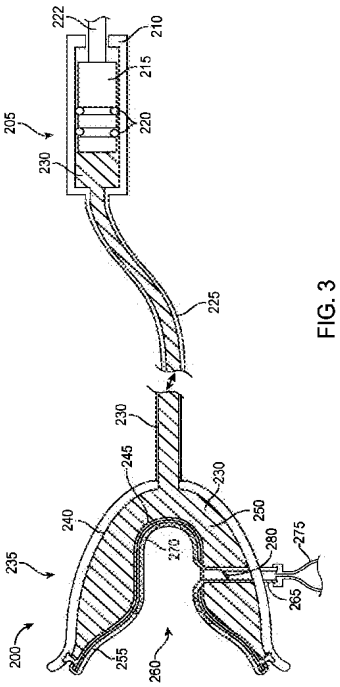

FIG. 3

【図４】

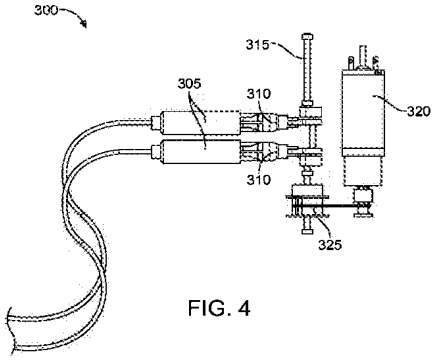

FIG. 4

【図５Ａ】

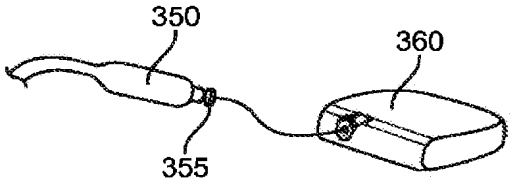

FIG. 5A

【図５Ｂ】

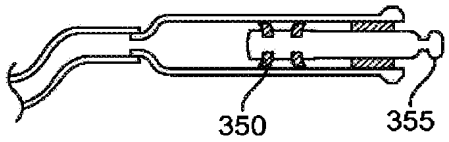

FIG. 5B

【図６】

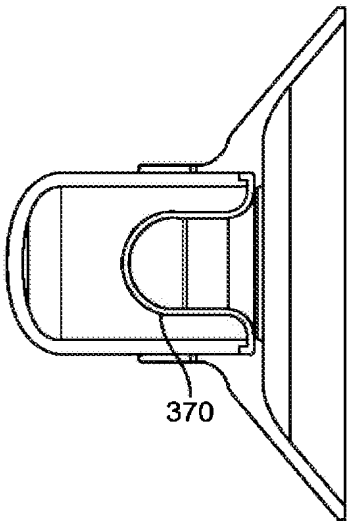

FIG. 6

【図７】

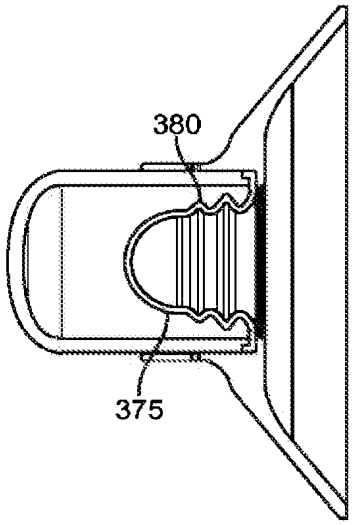

FIG. 7

【図８Ａ】

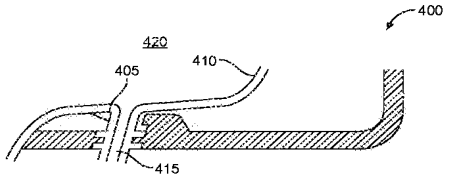

FIG. 8A

【図８Ｂ】

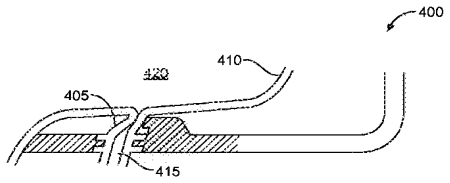

FIG. 8B

【図９Ａ】

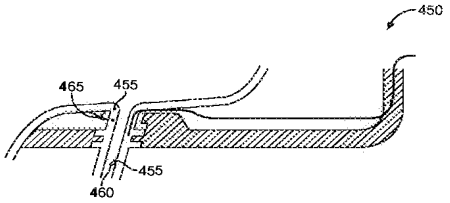

FIG. 9A

【図９Ｂ】

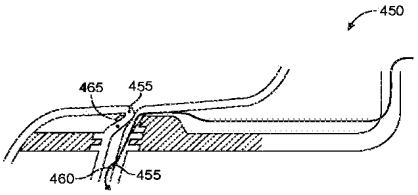

FIG. 9B

【図１０】

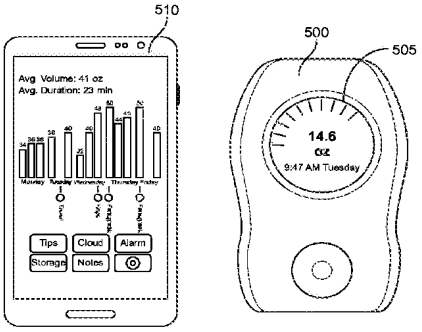

FIG. 10

【図１１】

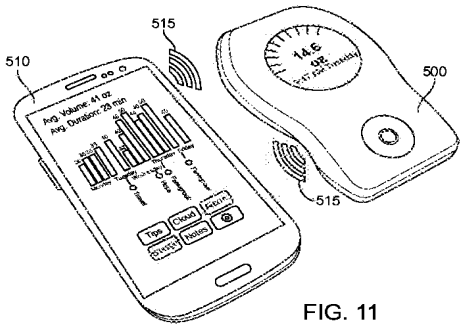

FIG. 11

【図１２】

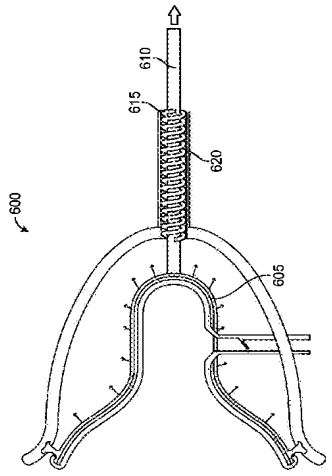

FIG. 12

【図１３】

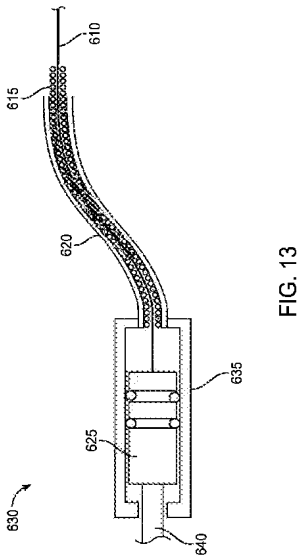

FIG. 13

【図１４】

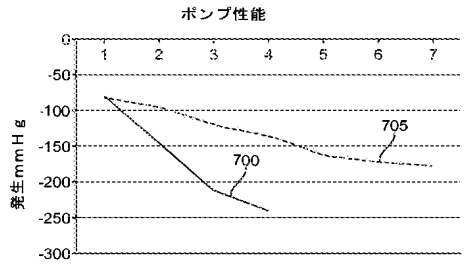

FIG. 14

【図１５】

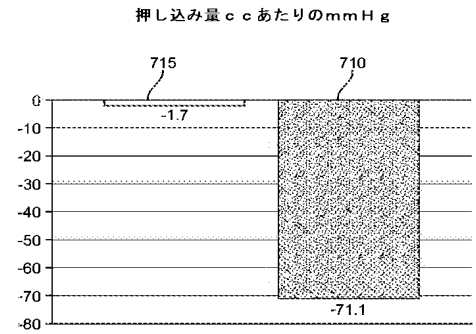

FIG. 15

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/031510

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 1/06 (2014.01)
USPC - 604/74
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A41C 3/04; A61J 9/00, 11/00; A61M 1/06 (2014.01)
USPC - 215/11.1; 450/36, 37; 606/73, 74

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61M 1/06, 1/062, 1/064, 1/066 (2014.07)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Orbit, Google Patents, Google Scholar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/0316493 A1 (SCHLIENGER et al) 13 December 2012 (13.12.2012) entire document	1, 2, 4, 5, 7-11, 15-17, 19, 20, 26-28, 31-36, 41, 47, 48, 53, 55
Y		3, 6, 12-14, 18, 21-25, 29, 30, 37-40, 42-46, 49-52, 54
Y	WO 2012/014135 A1 (BOSMAN et al) 02 February 2012 (02.02.2012) entire document	3, 37
Y	US 2003/0153869 A1 (YTTEBORG) 14 August 2003 (14.08.2003) entire document	6
Y	US 2006/0106334 A1 (JORDAN et al) 18 May 2006 (18.05.2006) enire document	12-14, 38, 39
Y	US 5,007,899 A (LARSSON) 16 April 1991 (16.041991) entire document	18, 40
Y	US 2003/0191433 A1 (PRENTISS) 09 October 2003 (09.10.2003) entire document	21
Y	US 6,997,897 B1 (SILVER et al) 14 February 2006 (15.02.2006) entire document	22-24, 50-52
Y	US 2008/0039741 A1 (SHEMESH et al) 14 February 2008 (14.02.2008) entire document	25, 29, 30, 42-46,49
Y	US 2012/004603 A1 (HARARI et al) 05 January 2012 (05.01.2012) entire document	45
Y	US 2012/0325219 A1 (SMITH) 27 December 2012 (27.12.2012) entire document	54

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"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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Date of the actual completion of the international search
13 August 2014

Date of mailing of the international search report
02 SEP 2014

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Ｆターム(参考) 4C077 AA22 DD01

Patents JP2016514516

Methods, apparatus, and systems for expression and quantification of human breast milk

Abstract

translated from Japanese

The apparatus for breast milk expression and collection includes an operable assembly, a breast interface, and a tube. The chest interface is sized to receive the chest and forms a fluid tight seal with the chest. The chest interface includes a deformable member provided on at least a portion of the chest interface. The deformable member deforms in response to actuation of the actuatable assembly and applies vacuum pressure to the breast to squeeze out the milk. The tube operably couples the actuatable assembly to the chest interface.

Images (18)

FIG. 5A

Classifications

- A61M1/064 Suction cups

View 6 more classifications

JP2016514516A

Japan

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Other languages: Japanese

Inventor: ジェフリー ピー. アルバレス, ジェフリー ピー. アルバレス, ジャニカ ピー. アルバレス, ジャニカ ピー. アルバレス, ジャンリッドフォース, ジャンリッドフォース.

Worldwide applications

2014 US WO CN AU BR JP EP 2017 BR

Application JP2016504391A events

2013-03-24 Priority to US201361804722P

2014-03-21 Application filed by ナヤ ヘルス, インコーポレイテッド, ナヤ ヘルス, インコーポレイテッド

2016-05-23 Publication of JP2016514516A

2017-04-27 Publication of JP2016514516A5

Status Pending

Show all events

Info: Patent citations (55), Cited by (31), Legal events, Similar documents, Priority and Related Applications

External links: Espacenet, Global Dossier, Discuss

Claims (55)

Hide Dependent

translated from Japanese

A device for the expression and collection of breast milk, said device comprising.
An operable assembly.
A chest interface, wherein the chest interface is sized to engage and fluid seal against the chest, the chest interface having a movable member disposed within at least a portion thereof, and ,
A tube operably coupling the actuatable assembly to the chest interface;
With
The movable member operates in response to actuation of the actuatable assembly, thereby creating a vacuum in the breast interface and applying the vacuum to the breast to pump milk therefrom. The apparatus of claim 1, wherein the actuatable assembly comprises a piston or a pump. The apparatus of claim 1, wherein the actuatable assembly comprises a pair of pistons or a pair of pumps. The apparatus of claim 1, wherein actuation of the actuatable assembly moves fluid within the tube. The apparatus of claim 1, wherein the movable member comprises a flexible membrane. The apparatus of claim 5, wherein the flexible membrane has a corrugated region configured to expand and contract. The apparatus of claim 5, wherein the flexible membrane deforms in response to actuation of the actuatable assembly, and actuation of the actuatable assembly moves fluid contained within the tube. The apparatus of claim 1, wherein the movable member comprises a deformable member. The apparatus of claim 1, wherein the chest interface comprises a resilient and familiar flange that engages the chest and forms a fluid tight seal with the chest. The apparatus of claim 1, wherein fluid is disposed within the tube. The apparatus of claim 10, wherein the fluid is an incompressible fluid. The apparatus of claim 1, wherein a tension element is disposed within the tube. The apparatus of claim 12, wherein the tensioning element comprises a rope, wire, or cable. The apparatus of claim 12, wherein the tensioning element is operably coupled to the movable member and the actuatable assembly The apparatus of claim 1, further comprising a drive mechanism operably coupled to the actuatable assembly and configured to actuate the actuatable assembly. The apparatus of claim 15, wherein the drive mechanism is an electromechanical device. The apparatus of claim 15, wherein the drive mechanism comprises a motor. The apparatus of claim 15, wherein the drive mechanism is releasably coupled to the actuatable assembly. The apparatus of claim 1, wherein the breast interface comprises an outlet valve, the outlet valve configured to control the flow of the pumped breast milk into a collection container. The outlet valve prevents the pumped milk from flowing through the outlet valve when the deformable member is deformed, and the pumped breast milk flows through the outlet valve when the deformable member is in a non-deformed shape. 20. The apparatus of claim 19, wherein the flow is controlled by: The apparatus of claim 19, wherein the outlet valve is integrally formed within the deformable member. A second chest interface, wherein the second chest interface is sized to engage and fluid seal against the second chest, the second chest interface being within at least a portion of the second chest interface; A second chest interface having a movable member disposed on the
A second tube operably coupling the actuatable assembly to the second chest interface;
Further comprising
The movable member deforms in response to actuation of the actuatable assembly, thereby creating a vacuum in the second chest interface and applying vacuum to the second chest to pump milk therefrom. The apparatus of claim 1. A second operable assembly;
A second chest interface, wherein the second chest interface is sized to engage and fluid seal against the second chest, the second chest interface being within at least a portion

of the second chest interface; A second chest interface having a movable member disposed on the
A second tube operably coupling the second actuatable assembly to the second chest interface;
Further comprising
The movable member deforms in response to actuation of the actuatable assembly or the second actuatable assembly, thereby creating a vacuum in the second chest interface, and the vacuum on the second chest. The apparatus of claim 1 wherein said device is applied to express milk therefrom. The apparatus of claim 1, further comprising a housing having a controller for controlling operation of the actuatable assembly. The apparatus according to claim 1, further comprising a housing having a controller for controlling calculation and display of breast milk production information and controlling communication with other apparatuses. The apparatus of claim 1, further comprising a housing having a power supply that provides power to the apparatus for milking and collecting milk. The apparatus of claim 1, further comprising a housing having a drive mechanism for actuating the actuatable assembly. The apparatus of claim 1, further comprising a collection container fluidly coupled to the chest interface. The apparatus of claim 1, further comprising a sensor adjacent to the breast interface, wherein the sensor is configured to sense at least one side of milk flowing therethrough. The apparatus of claim 1, further comprising a display unit for displaying data relating to the milk expression. A system for milking and collecting milk comprising the apparatus according to claim 1. A device for applying pressure or vacuum to a patient, the device comprising:
An operable assembly;
A target tissue interface, wherein the target tissue interface is sized to engage and fluid seal against the target tissue, the target tissue interface including a deformable member disposed within at least a portion thereof. Having a target tissue interface;
A tube operably coupling the actuatable assembly to the target tissue interface;
With
The apparatus wherein the deformable member deforms in response to actuation of the actuatable assembly, thereby creating a vacuum or pressure in a target tissue interface and applying the vacuum or pressure to the target tissue. A method for extracting and collecting breast milk, the method comprising:
Providing a chest expression and collection device having at least one chest interface and at least one actuable assembly operably coupled to the at least one chest interface, the chest interface comprising: including a possible member; and
Engaging the chest with the chest interface to fluid-tight;
Actuating the actuatable assembly;
Deforming the deformable member in response to actuation of the actuatable assembly, thereby creating a vacuum and applying it to the chest;
Extracting milk from the chest and collecting it;
Including a method. 34. The engaging step includes engaging a resilient and familiar flange on the chest interface to the chest, thereby forming a fluid seal between the chest interface and the chest. The method described in 1. 34. The method of claim 33, wherein the actuatable assembly moves fluid. 36. The method of claim 35, wherein the fluid is disposed in a tube fluidly coupled to the actuatable assembly and the deformable member. 34. The method of claim 33, wherein actuating the actuatable assembly includes actuating a piston. 34. The method of claim 33, wherein actuating the actuatable assembly comprises applying tension to a tensioning element disposed within the tube. 39. The method of claim 38, wherein an axial load absorbing member is disposed concentrically around the tension element, and the method further comprises absorbing a reaction force of the tension element. 34. The method of claim 33, further comprising releasing the actuatable assembly from a drive mechanism operably coupled thereto. 34. The method of claim 33, further comprising the step of repeating the actuating step, the deforming step, and the extruding step. 34. The method of claim 33, further comprising quantifying the production of the expressed milk. 34. The method of claim 33, further comprising quantifying one or more aspects of the pumped milk. 34. The method of claim 33, further comprising the step of transmitting data relating to the breast milk expression between the breast expression and collection device and a computer. 45. The method of claim 44, wherein the mobile device comprises a smartphone. 45. The method of claim 44, further comprising displaying the data on a display. 34. The method of claim 33, further comprising controlling the flow of the pumped milk to a collection container with a valve fluidly coupled to the chest pumping and collection device. 48. The method of claim 47, wherein controlling the flow comprises opening the valve when the deformable member is undeformed and closing the valve when the deformable member is deformed. 34. The method of claim 33, further comprising sensing the pumped breast milk flow with a sensor fluidly coupled to the breast interface. The chest expression and collection device further comprises a second chest interface and a second actuable assembly operably coupled to the second chest interface, the second chest interface being deformed
Comprising a possible member, the method comprising:
Engaging a second chest with the second chest interface to fluid-tight;
Activating the second actuatable assembly;
Deforming the deformable member in the second chest interface in response to actuation of the second actuatable assembly, thereby creating and applying a vacuum to the second chest;
Extracting and extracting milk from the second breast;
34. The method of claim 33, further comprising: 51. The method of claim 50, wherein the steps of pumping and collecting milk from both breasts occur simultaneously. 51. The method of claim 50, wherein the step of pumping and collecting the milk alternates between both breasts. A method of applying a differential pressure to a patient, the method comprising:
Providing a differential pressure device having an interface and an actuatable assembly operably coupled to the differential pressure device, the interface comprising a deformable member,
Engaging the interface with a target area on the patient and fluidly sealing;
Actuating the actuatable assembly;
Deforming the deformable member in response to actuation of the actuatable assembly, thereby creating a positive pressure or vacuum, and applying the positive pressure or the vacuum to the target area;
Including a method. The step of deforming the deformable member creates a positive pressure applied to the target area, the target area including the mouth or nose, thereby reducing apnea conditions while the patient is sleeping. 54. The method of claim 53, wherein the method resolves. 54. The step of deforming the flexible membrane forms a vacuum applied to the target area, the target area including a body fluid storage organ, thereby squeezing out the body fluid therefrom. The method described in 1.

Description

translated from Japanese

(Related application)
The present application was filed on March 24, 2013, US Provisional Patent Application No. 61 / 804,722 (attorney management number 44396-702101), filed on September 17, 2013, US Provisional Patent Application No. 61 / 879,055 (Agent Management No. 44396-703.102), US Patent Application No. 14 / 221,113 (Agent Management) filed on March 20, 2014 No. 44936-703.201), the entire contents of which are hereby incorporated by reference.

The present invention relates generally to medical devices and methods, and more specifically to devices and methods for the expression and collection of human breast milk.

The exemplary embodiments disclosed herein are preferably directed to breast milk expression, although those of ordinary skill in the art are not intended to be limiting, and the devices, systems, it will be appreciated that and the method can be used for other therapies that require the application of differential pressure.

Chest pumps are commonly used to collect breast milk so that mothers can continue breastfeeding even when they are separated from their children. At present, there are two basic types of chest pumps: manual measures that are small but inefficient and tired of use, and efficient but bulky electric devices. Thus, it would be desirable to provide an improved chest pump that is small and very efficient for milking and collecting milk. Additional features such as quantification of milk production and communication with mobile devices are more desirable to enhance user convenience. At least some of these objectives will be met by the apparatus and methods disclosed below.

The following US patents relate to the expression and collection of human breast milk. US Pat. No. 6,673,036 (Patent Document 1), 6,749,582 (Patent Document 2), 6,840,918 (Patent Document 3), 6,887,210 (Patent) Document 4), 7,875,000 (Patent Document 5), 8,118,772 (Patent Document 6), and 8,216,179 (Patent Document 7).

US Pat. No. 6,673,036 US Pat. No. 6,749,582 US Pat. No. 6,840,918 US Pat. No. 6,887,210 US Pat. No. 7,875,000 US Pat. No. 8,118,772 US Pat. No. 8,216,179

The present invention relates generally to medical devices, systems, and methods, and more specifically to devices, systems, and methods for the expression and collection of human breast milk.

In a first aspect of the present invention, an apparatus for breast milk expression and collection comprises an actuable assembly, a breast interface, and a tube. The chest interface is sized to engage and fluid-tighten the chest. The chest interface also includes a movable member disposed within at least a portion thereof. The movable member operates in response to actuation of the actuatable assembly, thereby creating a vacuum at the chest interface, applying the vacuum to the chest and pumping milk therefrom. The tube is operably coupled to the actuatable assembly and the chest interface.

The actuatable assembly may comprise a piston or pump, or a pair of pistons or a pair of pumps. Actuation of the actuatable assembly may move fluid disposed within the tube.

The movable member may comprise a flexible membrane. The flexible membrane may have a corrugated region configured to expand and contract. The flexible membrane deforms in response to actuation of the actuatable assembly, and actuation of the actuatable assembly can move the fluid contained in the tube. The movable member may comprise a deformable member.

The chest interface may include a resilient and familiar flange that engages the chest to form a fluid seal.

A fluid may be placed in the tube. The fluid may be an incompressible fluid such as water or oil. In other embodiments, tension elements may be disposed within the tube. The tensioning element can include a rope, wire, or cable. The tensioning element may be operably coupled to the movable member and the actuatable assembly and arranged concentrically with an axial compression element that absorbs the counterload of the tensioning element.

The apparatus may comprise a drive mechanism operably coupled to the actuatable assembly and configured to actuate the actuatable assembly. The drive mechanism may include an electromechanical device such as a motor. The drive mechanism can be releasably coupled to the actuatable assembly.

The breast interface may comprise an outlet valve configured to control the flow of pumped breast milk into the collection container. The outlet valve prevents pumped milk from flowing through the valve when the deformable member is deformed, and allows pumped milk to flow through the valve when the deformable member is in an undeformed shape. By doing so, the flow can be controlled. The outlet valve can be integrally formed in the deformable member.

The apparatus may further comprise a second actuatable assembly, a second chest interface, and a second tube. The second chest interface may be sized to engage and fluid-tightly engage the second chest. The second chest interface may have a movable member disposed within at least a portion thereof, the movable member deforming in response to actuation by either the actuatable assembly or the optional second actuatable assembly. , Thereby creating a vacuum in the second breast interface, which may be applied to the second breast and pumping milk therefrom. The second tube can be operably coupled to the second actuatable assembly and the second chest interface.

The apparatus may further comprise a housing having a controller for controlling the operation of the operable assembly. The controller may control the calculation and display of breast milk production information, and the controller may also control communication with other devices. A power source may be placed within the housing, and the power source may provide power to a device for milking and collecting milk. The housing may have a drive mechanism disposed therein for operating the actuatable assembly.

The apparatus may further comprise a collection container fluidly coupled to the chest interface. The device may also include a sensor configured to measure the side of the breast interface adjacent and past the breast interface. The apparatus may also include a display unit that displays data relating to milk expression. A system for

milk expression and collection can include the devices previously described above. Any of these components may be separate from the other components or they may be placed in a housing or pendant.

In another aspect of the invention, an apparatus for applying pressure or vacuum to a patient comprises an actuatable assembly, a target tissue interface, and a tube. The target tissue interface is preferably sized to engage and fluid seal against the target tissue. The target tissue interface has a deformable member disposed within at least a portion thereof, the deformable member deforming in response to actuation of the actuatable assembly. This creates a vacuum or pressure within the target tissue interface and applies the vacuum or pressure to the target tissue. The tube is operably coupled to the actuatable assembly and the target tissue interface.

In yet another aspect of the invention, a method for expressing and collecting breast milk provides a chest expression and collection device having a chest interface and an operable assembly operably coupled to the chest interface. Including the steps of: The chest interface includes a deformable member. The method also includes engaging and fluid-sealing the chest with the chest interface and actuating the actuatable assembly. The method also includes the step of deforming the deformable member in response to actuation of the actuatable assembly, thereby forming and applying a vacuum to the chest to squeeze and collect milk from the chest.

The engaging step may include engaging a resilient and familiar flange on the chest interface with the chest, thereby creating a fluid seal between the chest interface and the chest.

Actuating the actuatable assembly can move fluid. The fluid may be disposed in a tube fluidly coupled to the actuatable assembly and the deformable member. Actuating the actuatable assembly may include actuating the piston or applying tension to a tensioning element disposed within the tube. The method may further include releasing the actuatable assembly from a drive mechanism operably coupled thereto.

The method may further comprise repeating the steps of actuation, deformation and extrusion. The method may further comprise the steps of quantifying the production of the expressed milk and transmitting data relating to the expression of the breast milk between the chest expression and collection device and the mobile device. The mobile device can be a smartphone, a tablet, or a calculator. The data can be displayed on a display. The method may also include controlling the flow of pumped milk to the collection container by a valve fluidly coupled to the chest pumping and collection device. Controlling the flow may include opening the valve when the deformable member is undeformed and closing the valve when the deformable member is deformed. The side of the breast milk may also be sensed with a sensor fluidly or otherwise coupled to the breast interface.

The chest expression and collection device may further comprise a second chest interface and a second actuatable assembly operably coupled to the second chest interface. The second chest interface may comprise a deformable member. The method may further include engaging and fluid-sealing the second chest with the second chest interface and activating the first or second actuatable assembly. The method also deforms the deformable member in the second chest interface in response to actuation of the second actuatable assembly, thereby creating a vacuum in the second chest and applying the second chest From which milk may be expressed and collected. The expression and collection of milk from both breasts may be performed simultaneously on both breasts or alternately.

In yet another aspect of the invention, a method of applying differential pressure to a patient includes providing a differential pressure device having an interface and an actuable assembly operably coupled to the differential pressure device. The interface includes a deformable member, and the method further includes engaging the interface with a target region on the patient to fluid seal and actuate the actuatable assembly. The method also includes deforming the deformable member in response to actuation of the actuatable assembly, thereby creating a positive pressure or vacuum, and applying the positive pressure or vacuum to the target area. Either component may be separated from the other components, or they may be placed in a housing or pendant.

The step of deforming the deformable member may create a positive pressure applied to the target area. The target area includes the mouth or nose, and application of positive pressure may reduce or eliminate apnea or similar disturbances during patient sleep. The step of deforming the flexible membrane can create a vacuum applied to the target area. The target area includes a fluid storage organ, so that a vacuum causes the fluid to be pumped out of the storage organ.

These and other embodiments are described in more detail in the following description with reference to the accompanying drawings.
(Incorporation by reference)

All publications, patents, and patent applications mentioned herein are hereby incorporated by reference to the same extent as if each individual publication, patent, and patent application were specifically and individually incorporated by reference. It is.

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. 1 is a perspective view of an exemplary embodiment of a pump device. FIG. 2 is a perspective view of an exemplary embodiment of a pump device. FIG. 3 is a cross section of an exemplary embodiment of a pump device. FIG. 4 illustrates an exemplary embodiment of an actuatable assembly coupled to a drive mechanism. 5A-5B illustrate an exemplary embodiment of an actuatable assembly coupled to a pendant unit. 5A-5B illustrate an exemplary embodiment of an actuatable assembly coupled to a pendant unit. FIG. 6 is a cross-sectional view of an exemplary embodiment of a chest interface. FIG. 7 is a cross-sectional view of another exemplary embodiment of a chest interface. FIG. 8A is a cross-sectional view of an exemplary embodiment of an integrated valve in an open position. FIG. 8B is a cross-sectional view of an exemplary embodiment of an integrated valve in a closed position. FIG. 9A is a cross-sectional view of an exemplary embodiment of a sensor integrated within a chest interface. FIG. 9B is a cross-sectional view of another exemplary embodiment of a sensor integrated within a chest interface. FIG. 10 illustrates an exemplary embodiment of a pendant unit and mobile device. FIG. 11 illustrates an exemplary embodiment of a pendant unit in communication with a mobile device. FIG. 12 is a cross-sectional view of an exemplary embodiment of a chest interface with a mechanically deformable member. FIG. 13 is a cross-sectional view of an exemplary embodiment of a mechanical drive for a mechanically deformable member. FIG. 14 is a graph illustrating the pump performance of an exemplary embodiment compared to a commercial device. FIG. 15 is a graph illustrating the pump efficiency of an exemplary embodiment compared to a commercial device.

Specific embodiments of the disclosed apparatus and method are described below with reference to the drawings. Any detailed description is not intended to imply that a particular component, feature, or step is absolutely necessary for the present invention. Those skilled in the art will appreciate that various features or steps may be substituted for or combined with each other.

The present invention will be described in the context of milk expression and collection. However, those skilled in the art are not intended to limit it, and the devices and methods disclosed herein may create and communicate pressure differentials, such as sleep apnea treatment and / or other remote pressure needs. It will be understood that it can be used for other applications that require.

FIG. 1 illustrates an exemplary embodiment of the present invention. The pump device 100 includes a chest interface 105, a tube 110, and a controller or pendant unit 115 operably coupled to the chest interface 105 through the tube 110. The chest interface 105 includes a resilient and familiar flange 120 that engages the chest and forms a fluid seal thereto, and a collection container 125. The device may optionally have only a single chest interface. The pendant unit 115 houses a power source and a driving mechanism for the pump device 100, and includes hardware for various functions such as control of the pump device 100, quantification of milk production, communication with other devices, and the like. The tube 110 transmits a suitable energy input, such as a mechanical energy input, over a long distance from the pendant unit 115 to the chest interface 105. The breast interface 105 efficiently converts the energy input into vacuum pressure on the breast, causing milk to be pumped into the collection container 125.

Those skilled in the art will appreciate that the components and features of the present exemplary embodiment can be combined or substituted with the components and features of any of the embodiments of the present invention described below. Similarly, the components and features of other embodiments disclosed herein may be substituted or combined with each other.
(Hydraulic pump device)

The hydraulic system can reduce the pump power required, and thus reduce the size of the pump device while maintaining pump efficiency. In a preferred embodiment, the pump device can utilize a hydraulic pump device to generate a pressure differential across the breast for milk extraction and collection.

An exemplary hydraulic pump device is shown in FIGS. FIG. 2 illustrates a pump device 150 having a syringe 155 fluidly coupled to the chest interface 160 by a tube 165. Syringe 155 is coupled to tube 165 through three-way valve 170. Chest interface 160 includes an outlet port 175. The syringe 155 drives the fluid 180 contained in the tube 165 toward or away from the flexible member housed in the chest interface 160 to create the pressure differential required for pumping milk from the chest. produce.

FIG. 3 illustrates another embodiment of the pump device 200. The actuatable assembly 205 includes an assembly housing 210, a drive element 215, a radial seal 220, and a shaft 222. The drive element 215 is operably coupled to a pendant unit such as the pendant unit 115 through the shaft 222. Tube 225 contains fluid 230 and is fluidly coupled to actuatable assembly 205 and chest interface 235. The chest interface 235 comprises an interface housing 240, a flexible membrane 245, a reservoir 250, a sealing element 255, a pressure area 260, and a discharge port 265. The sealing element 255 includes a deformable portion 270. The discharge port 265 is coupled to the collection container 275 and includes a flap valve 280.

Actuable assembly 205 moves fluid 230 contained within tube 225, which can be a flexible conduit. The fluid 230 occupies the reservoir 250 in the chest interface 235 and is coupled to the flexible membrane 245. The flexible membrane 245 transmits vacuum pressure from the fluid 230 to the deformable portion 270 of the sealing element 255. When the chest is engaged and fluidly sealed with the chest interface 235 by the sealing element 255, movement of the actuatable element 215 creates a substantial vacuum pressure on the chest through the flexible membrane 245 and the deformable portion 270; As a result, the milk is pumped into the pumping area 260.

The pumped milk is discharged into the collection container 275 through the discharge port 265. The discharge port 265 is configured to have a flap valve 280 and secures a milk passage while maintaining the vacuum pressure in the pumping region 260.

The fluid of the hydraulic pump device can be any suitable fluid, such as an incompressible fluid. In many embodiments, the incompressible fluid can be water or oil. Alternatively, the fluid can be any suitable gas, such as air. Suitable incompressible fluids and gases for hydraulic systems are known to those skilled in the art.

Those skilled in the art will be able to combine or replace the components and features of any exemplary embodiment of the hydraulic pump apparatus with the components and features of any exemplary embodiment of the invention described herein. Will understand.
(Operating mechanism)

Many actuation mechanisms known to those skilled in the art can be utilized for actuatable assembly 205. The actuatable assembly 205 can be a piston assembly, a pump such as a diaphragm pump, or any other suitable actuation mechanism. The optimal configuration of the actuatable assembly 205 depends on a number of factors, such as vacuum requirements, size, power, and other needs of the pump device 200, and the characteristics of the fluid 230 such as viscosity, biocompatibility, and fluid life requirements. May vary.

FIG. 3 illustrates an exemplary embodiment where the actuatable assembly 205 is a piston assembly and the drive element 215 is a piston. The actuatable assembly 205 includes a radial seal 220, such as an O-ring, that seals against the assembly housing 210 to prevent unwanted exudation of the fluid 230 and allow the fluid 230 to be driven.

FIG. 4 illustrates another exemplary embodiment of an actuatable assembly 300 that includes a pair of pistons 305.

In a preferred embodiment, the actuatable assembly includes a drive element that is moved by a suitable drive mechanism, such as a drive mechanism in pendant unit 115. Many drive mechanisms are known to those skilled in the art. For example, a drive element such as drive element 215 may be electromechanically actuated by a motor or manually actuated by a suitable user-operator interface such as a lever. Various drive modes known to those skilled in the art can be used. In particular, the implementation of an exemplary hydraulic pump device as described herein allows for the use of a suitable drive mode such as direct drive or solenoids due to the reduced force requirements of the hydraulic system.

With reference to the exemplary embodiment of FIG. 4, piston 305 includes a coupling 310 to crankshaft 315. Crankshaft 315 is operably coupled to motor 320 through belt drive 325. Crankshaft 315 drives a pair of pistons 305 with the same stroke timing to apply vacuum pressure to both breasts simultaneously, a feature that is desirable for increased milk production. Instead, the crankshaft 315 can drive the pair of pistons 305 at any suitable stroke timing, such as alternating or offset stroke cycles.

The drive mechanism can be powered by any suitable power source such as a local battery or an AC adapter. The drive mechanism can be controlled by hardware such as a built-in electronic device arranged in the pendant unit 115.

FIG. 5 illustrates an exemplary embodiment of an actuatable assembly 350 that includes a releasable coupling 355. Preferably, the actuatable assembly 350 is releasably coupled to the pendant unit 360 and the drive mechanism housed therein. The coupling can be a mechanical coupling or any suitable simple desorption mechanism known to those skilled in the art. The releasably coupled design allows for configuration flexibility and use of the pump device. For example, comfort can be improved by different sized breast interfaces that are compatible with various breast sizes. In addition, this feature allows the use of a common pump device with a replaceable chest interface, reducing the risk of pathogen spread. Furthermore, the releasable coupling allows easy replacement of the individual parts of the pump device.

Those skilled in the art will appreciate that the components and features of any exemplary embodiment of the actuation mechanism can be combined or replaced with the components and features of any embodiment of the invention as described herein. I will.
(Flexible membrane)

In many embodiments, such as the embodiment shown in FIG. 3, the flexible membrane 245 is located within the chest interface 235 and is disposed to cover at least a portion thereof, and the interface housing 240, the flexible membrane 245, 8etween which the reservoir 250 is formed. Preferably, the flexible membrane 245 substantially deforms when exposed to the negative pressure created when the fluid 230 is moved from the reservoir 250 by the actuable assembly 205. The amount of deformation of the flexible membrane 245 can be controlled by a number of factors (eg, wall thickness, rubber hardness, surface area) and can be optimized based on the pump device (eg, pump power, vacuum requirements).

FIG. 6 illustrates an exemplary flexible membrane 370 having a specific thickness and rubber hardness.

FIG. 7 illustrates another embodiment of a flexible membrane 375 with corrugated features 380 that increase surface area.

Suitable materials for the flexible membrane are known to those skilled in the art. In many embodiments, the flexible membrane is a material designed to expand and contract when exposed to pressure from a binding fluid such as silicone, polyether block amides such as PEBAX, and polychloroprene such as neoprene. Can be made. Alternatively, the flexible membrane can be made from a substantially rigid material such as stainless steel, nitinol, a rigid polymer, or a rigid elastomer. In these embodiments, the rigid material will be designed with stress and / or strain distribution elements that allow substantial deformation of the flexible membrane that does not exceed the yield point of the material.

FIGS. 8A and 8B illustrate a preferred embodiment of a chest interface 400 in which an outlet valve 405 is integrated into the flexible membrane 410 and controls the flow of pumped milk through the outlet port 415. The outlet valve 405 is opened when the flexible membrane 410 is relaxed, as shown in FIG. 8A, and when the flexible membrane 410 is deformed, as shown in FIG. 8B. Closed to prevent fluid flow. Outlet valve 405 allows substantial vacuum pressure to be present in pumping area 420 during extraction while allowing milk to be drained during the rest of the pump stroke. While many conventional chest pump valves function only with pressure differentials, the outlet valve 405 can preferably be configured to function also with mechanical movement of the flexible membrane 410. Incorporating a mechanical function as described herein into the integrated outlet valve 405 can improve the sealing of the chest interface 400 during vacuum formation. Furthermore, the use of an outlet valve integrally formed in the flexible membrane 410, such as the outlet valve 405, reduces the number of parts to be cleaned.

Those skilled in the art will appreciate that the components and features of any exemplary embodiment of the flexible membrane can be combined or replaced with the components and features of any embodiment of the invention as described herein. I will.
(Milk collection and quantification system)

Referring to FIG. 3, the pumped milk is discharged into the collection container 275 through the outlet port 265 in the flexible membrane 245. The collection container 275 can be any suitable container such as a bottle or bag. In many embodiments, collection container 275 is removably coupled to flexible membrane 245. The collection vessel 275 can be coupled directly or remotely via any suitable device such as an extension line.

In many cases, it may be desirable to track various data related to milk expression and collection, such as the amount of milk production. Currently, tracking milk production is commonly done by manual measurement and record keeping. The exemplary embodiments of the apparatus described herein may provide a digital-based

means for automatically measuring and tracking milk production for improved convenience, efficiency, and accuracy

9A and 9B illustrate an exemplary embodiment of a chest interface 450 with one or more integrated sensors 455. The sensor 455 is preferably located within the flap valve 460, but may be located at the outlet valve 465 or any other location suitable for monitoring fluid flow. In a preferred embodiment, at least one sensor 455 is integrated into a valve that is opened by fluid flow to detect the total time that the valve is open. The sensor signal can be queried to quantify the fluid flow. Suitable sensors are known to those skilled in the art, such as accelerometers, Hall effect sensors, and photodiode / LED sensors. The chest interface can include a single sensor or multiple sensors that quantify milk production.

FIG. 10 illustrates an exemplary embodiment of a pendant unit 500 with milk expression data displayed on the display screen 505. In many embodiments, the pendant unit 500 collects, processes, stores, and displays data regarding milk expression. Preferably, the pendant unit 500 can transmit data to a second device such as the mobile phone 510.

FIG. 11 illustrates data transmission 515 between the pendant unit 500 and the mobile phone 510. Bluetooth (registered trademark), near field communication, and the like are known to those skilled in the art as suitable methods for communication and data transmission between devices.

In the exemplary embodiment, pendant unit 500 communicates with mobile phone 510 and transmits milk expression data such as expression volume, duration, and date. The mobile phone 510 includes a mobile application that collects and aggregates the compressed data and displays it in an interactive format. Preferably, the mobile application includes additional features that allow the user to overlay information such as lifestyle choices, dietary habits, strategies for increasing milk production, and the like. Make comparisons easier. In addition, the pendant unit 500 may send information about the number of times the pump is used to the mobile phone 510 so that the mobile application can identify when pumping occurs and set a reminder for the desired number of pumping operations. it can. Such a reminder helps prevent forgetting of the pump session, and as a result, can reduce the incidence of complications such as mastitis.

One of ordinary skill in the art can combine or substitute the components and features of any exemplary embodiment of the milking and quantification system with the components and features of any embodiment of the invention as described herein. Will understand.
(Mechanical pump device)

FIG. 12 illustrates an alternative embodiment of a chest interface 600 where a mechanically deformable member 605 can be used instead of a flexible membrane. The mechanically deformable member 605 can be configured in a manner similar to that used for the flexible membrane described herein. Mechanically deformable member 605 is coupled to tensioning element 610. In some cases, the tension element 610 is disposed within the axial load absorbing member 615. The axial load absorbing member 615 is disposed in the tube 620. Preferably, the tension element 610 is concentrically disposed within the axial load absorbing member 615 and the axial load absorbing member 615 is concentrically disposed within the tube 620. In an alternative configuration of the tension element 610, an axial load absorbing member 615 and a tube 620 can be used.

FIG. 13 illustrates tensioning element 610 coupled to drive element 625 in assembly housing 635 of actuatable assembly 630. Drive element 625 is operably coupled to a drive mechanism, such as a drive mechanism housed within the pendant unit, via shaft 640. An axial load absorbing member 615 within the tube 620 is fixedly coupled to the assembly housing 635. Movement of the drive element 625 transmits tension through the tension element 610 to the mechanical deformation member 605 and creates a vacuum pressure on the chest.

The tensile element 610 can be any suitable device such as a wire, coil, or rope, and can be made of any suitable material such as a metal, polymer, or elastomer. The axial load absorbing member 615 can be made of any suitable material that is rigid in the axial direction, such as metal or polymer, and can be configured in any suitable shape that is rigid in the axial direction, such as a tube or coil. it can.

Those skilled in the art will appreciate that the components and features of any exemplary embodiment of the mechanical pumping device can be combined or replaced with the components and features of any embodiment of the present invention as described herein. Will do.
(Experimental data)

14 and 15 illustrate experimental pumping data obtained from a commercial chest pumping device and an exemplary embodiment of the present invention. The exemplary embodiment used an incompressible fluid for pump operation and had a maximum hydraulic fluid volume of 4 cc, while the commercial device used an air pump operation and had a maximum volume of 114 cc.

FIG. 14 illustrates a graph of pump performance quantified by the vacuum pressure generated per stroke. For the exemplary embodiment, pressure measurements are made for 1 cc, 2 cc, 3 cc, and 4 cc of the fluid volume moved by the pump, with the stroke number corresponding to the volume cc. For commercial equipment, set the pump to one of seven equally spaced positions along the vacuum adjustment gauges representing 46cc, 57cc, 68cc, 80cc, 91cc, 103cc, and 114cc, respectively, of the fluid volume moved by the pump. The measurement is performed and the stroke number corresponds to the position number. Curve 700 corresponds to an exemplary embodiment and curve 705 corresponds to a commercial device. The exemplary embodiment generated a higher level of vacuum pressure per moving volume compared to commercial equipment, with the highest vacuum pressures being -240.5 mmHg and -177.9 mmHg, respectively.

FIG. 15 illustrates a graph of pump efficiency measured at maximum vacuum pressure per maximum volume of fluid transfer, with bar 710 corresponding to an exemplary embodiment and bar 715 corresponding to a commercial device. The exemplary embodiment demonstrated a 42-fold increase in pump efficiency compared to commercial equipment, with efficiencies of -71.1 mmHg / cc and -1.7 mmHg / cc, respectively.

While preferred embodiments of the present invention have been shown and described herein, it will be appreciated by those skilled in the art that such embodiments are presented by way of example only. Many variations, modifications, and alternatives will occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein can be used to practice the invention. The following claims are intended to define the scope of the invention, and the methods, configurations, and equivalents within the scope of these claims are intended to be encompassed thereby.

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JP2011507577A *	2007-12-21	2011-03-10	コーニンクレッカ フィリップス エレクトロニクス エヌ ヴィ	Milking machine to express milk from the chest

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Priority And Related Applications

Priority Applications (7)

Application	Priority date	Filing date	Title
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US201361879055P	2013-09-17	2013-09-17	*US Provisional Application*
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US14/221,113		2014-03-20	
PCT/US2014/031510	2013-03-24	2014-03-21	Method, apparatus, and system for expression and quantification of human breast milk

Legal Events

Date	Code	Title	Description
2017-03-21	A521	Written amendment	**Free format text**: JAPANESE INTERMEDIATE CODE: A523 **Effective date**: 20170321
2017-03-21	A621	Written request for application examination	**Free format text**: JAPANESE INTERMEDIATE CODE: A621 **Effective date**: 20170321
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2018-02-26	A131	Notification of reasons for refusal	**Free format text**: JAPANESE INTERMEDIATE CODE: A131 **Effective date**: 20180226
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2018-10-18	A02	Decision of refusal	**Free format text**: JAPANESE INTERMEDIATE CODE: A02 **Effective date**: 20181018

Concepts

machine-extracted

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human milk		title,claims,abstract,description	20	0.000
quantification		title,description	5	0.000
chest		claims,abstract,description	125	0.000
fluid		claims,abstract,description	54	0.000
Milk		claims,abstract,description	52	0.000
milk		claims,abstract,description	52	0.000
milk		claims,abstract,description	52	0.000
Breast		claims,abstract,description	26	0.000
Milk, Human		claims,abstract,description	16	0.000
response		claims,abstract,description	16	0.000
membrane		claims,description	33	0.000
pumping		claims,description	15	0.000
tissues		claims,description	15	0.000
manufacturing process		claims,description	12	0.000
coupling		claims,description	9	0.000
coupling process		claims,description	9	0.000
coupling reaction		claims,description	9	0.000
controlling effect		claims,description	8	0.000
sealing		claims,description	8	0.000

communication	claims,description	7	0.000
organs	claims,description	3	0.000
rope	claims,description	3	0.000
storage	claims,description	3	0.000
Apnea	claims,description	2	0.000
Apnoea	claims,description	2	0.000
Nose	claims,description	2	0.000
activating	claims,description	2	0.000
pressing	claims,description	2	0.000
Body Fluids	claims	2	0.000
body fluid	claims	2	0.000
chemical reaction	claims	1	0.000

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最終頁に続く

(54)【発明の名称】ヒト母乳の搾乳のための方法、装置およびシステム

(57)【要約】
母乳の搾乳のためのシステム、方法、およびデバイスが、提供される。一側面では、システムは、乳房に係合するように構成されるインターフェースと、インターフェースに動作可能に結合される作動アセンブリとを有する、搾乳装置を含む。作動アセンブリの作動は、インターフェースに、減圧圧力を乳房に対して印加させ、乳房から母乳を搾乳させる。システムはまた、データ接続を介して搾乳装置と通信するように構成される、コンピューティングデバイスを含む。

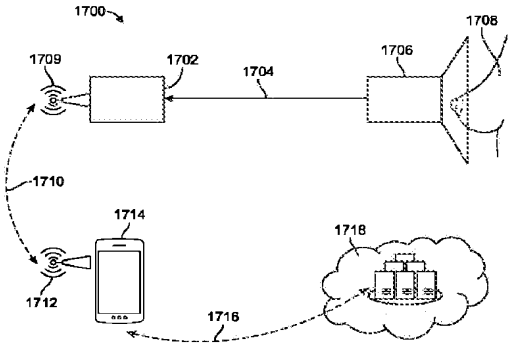

FIG. 17

【特許請求の範囲】
【請求項１】
乳房からの母乳の搾乳のためのシステムであって、
乳房に係合するように構成されるインターフェースと、前記インターフェースに動作可能に結合される作動アセンブリとを備える、搾乳装置であって、前記作動アセンブリの作動は、前記インターフェースに、減圧圧力を前記乳房に対して印加させ、そこから母乳を搾乳させる、搾乳装置と、
データ接続を介して前記搾乳装置と通信するように構成される、コンピューティングデバイスと、
を備える、システム。
【請求項２】
前記インターフェースは、前記乳房に対して流体的にシールするように構成される、請求項１に記載のシステム。
【請求項３】
前記データ接続は、無線通信、近距離通信、およびＵＳＢケーブルのうちの１つまたはそれを上回るものを利用し、前記搾乳装置の少なくとも一部と前記コンピューティングデバイスとの間でデータを伝送する、請求項１に記載のシステム。
【請求項４】
前記コンピューティングデバイスは、スマートフォン、タブレット、およびパーソナルコンピュータから選択される、請求項１に記載のシステム。
【請求項５】
前記搾乳装置はさらに、母乳の搾乳の１つまたはそれを上回る特性を示す測定データを生成するように構成される、感知ユニットを備える、請求項１に記載のシステム。
【請求項６】
前記測定データは、前記データ接続を介して前記コンピューティングデバイスに伝送される、請求項５に記載のシステム。
【請求項７】
前記コンピューティングデバイスは、前記測定データを分析するように構成される、アプリケーションを備える、請求項６に記載のシステム。
【請求項８】
前記コンピューティングデバイスは、前記測定データをサーバに伝送する、請求項６に記載のシステム。
【請求項９】
前記搾乳装置はさらに、前記測定データを分析し、それによって、分析結果を生成するように構成される、処理ユニットを備える、請求項５に記載のシステム。
【請求項１０】
前記搾乳装置はさらに、前記分析結果をユーザに表示するように構成される、ディスプレイユニットを備える、請求項９に記載のシステム。
【請求項１１】
前記分析結果は、グラフ、チャート、または表に表示される、請求項１０に記載のシステム。
【請求項１２】
前記分析結果は、前記データ接続を介して前記コンピューティングデバイスに伝送される、請求項９に記載のシステム。
【請求項１３】
前記コンピューティングデバイスは、前記分析結果をユーザに表示する、請求項１２に記載のシステム。
【請求項１４】
前記コンピューティングデバイスは、前記データ接続を介して、前記搾乳装置の少なくとも１つの機能性を制御する、請求項１に記載のシステム。

【請求項１５】
前記機能性は、前記搾乳装置の電力、前記搾乳装置によって印加される減圧圧力、および前記搾乳装置の１分あたりのサイクルのうちの１つまたはそれを上回るものを含む、請求項１４に記載のシステム。
【請求項１６】
母乳を搾乳するようにユーザにリマインドする通知は、前記データ接続を介して前記コンピューティングデバイスに伝送される、請求項１に記載のシステム。
【請求項１７】
母乳を搾乳するようにユーザにリマインドする通知は、前記データ接続を介して、前記搾乳装置の少なくとも一部に伝送される、請求項１に記載のシステム。
【請求項１８】
ファームウェア更新が、前記データ接続を介して、前記搾乳装置の少なくとも一部に伝送される、請求項１に記載のシステム。
【請求項１９】
前記コンピューティングデバイスは、ネットワークを介してサーバと通信する通信モジュールを備える、請求項１に記載のシステム。
【請求項２０】
母乳を搾乳するようにユーザにリマインドする通知は、前記サーバから前記コンピューティングデバイスに伝送される、請求項１９に記載のシステム。
【請求項２１】
前記コンピューティングデバイスは、携帯電話番号と関連付けられた携帯電話を備え、前記通知は、ショートメッセージサービス（ＳＭＳ）によって、前記ネットワークを介して前記携帯電話番号に伝送される、請求項２０に記載のシステム。
【請求項２２】
乳房からの母乳の搾乳を測定するための方法であって、
インターフェースと、前記インターフェースに動作可能に結合される作動アセンブリと、感知ユニットとを備える、母乳搾乳装置を提供するステップと、
前記インターフェースと乳房を係合するステップと、
前記作動アセンブリを作動させ、それによって、前記インターフェースに、減圧圧力を前記乳房に対して印加させるステップと、
前記乳房から母乳を搾乳するステップと、
前記感知ユニットを使用して、母乳の搾乳の特性を測定し、それによって、測定データを生成するステップと、
データ接続を介して、前記測定データを前記感知ユニットからコンピューティングデバイスに伝送するステップと、
を含む、方法。
【請求項２３】
前記測定データを前記コンピューティングデバイスの１つまたはそれを上回るデータ記憶内に記憶するステップをさらに含む、請求項２２に記載の方法。
【請求項２４】
前記コンピューティングデバイスのアプリケーションを介して前記測定データを分析し、分析結果を生成するステップをさらに含む、請求項２２に記載の方法。
【請求項２５】
前記コンピューティングデバイスを介して前記分析結果をユーザに表示するステップをさらに含む、請求項２４に記載の方法。
【請求項２６】
前記分析結果は、グラフ、チャート、または表に表示される、請求項２５に記載の方法。
【請求項２７】
乳房からの母乳の搾乳を制御するための方法であって、

インターフェースと、前記インターフェースに動作可能に結合される作動アセンブリとを備える、母乳搾乳装置を提供するステップと、
前記インターフェースと乳房を係合するステップと、
データ接続を介して、制御信号をコンピューティングデバイスから受信するステップと、
前記制御信号に基づいて、前記作動アセンブリを作動させ、それによって、前記インターフェースに、減圧圧力を前記乳房に対して印加させるステップと、
前記乳房から母乳を搾乳するステップと、
を含む、方法。
【請求項２８】
乳房からの母乳の搾乳のための装置であって、
乳房に係合するように構成されるインターフェースと、
前記インターフェースに動作可能に結合される作動アセンブリであって、前記作動アセンブリの作動は、前記インターフェースに、減圧圧力を前記乳房に対して印加させ、そこから母乳を搾乳させる、作動アセンブリと、
ネットワークを介してサーバと通信する通信モジュールと、
を備える、装置。
【請求項２９】
前記インターフェースは、前記乳房に対して流体的にシールするように構成される、請求項２８に記載の装置。
【請求項３０】
前記ネットワークは、インターネットネットワークを備える、請求項２８に記載の装置。
【請求項３１】
母乳の搾乳の１つまたはそれを上回る特性を示す測定データを生成するように構成される、感知ユニットをさらに備える、請求項２８に記載の装置。
【請求項３２】
前記測定データは、前記ネットワークを介して前記サーバに伝送される、請求項３１に記載の装置。
【請求項３３】
前記サーバは、前記測定データを分析するように構成される、アプリケーションを備える、請求項３２に記載の装置。
【請求項３４】
前記測定データを分析し、それによって、分析結果を生成するように構成される、処理ユニットをさらに備える、請求項３１に記載の装置。
【請求項３５】
前記分析結果をユーザに表示するように構成される、ディスプレイユニットをさらに備える、請求項３４に記載の装置。
【請求項３６】
前記分析結果は、前記ネットワークを介して前記サーバに伝送される、請求項３４に記載の装置。
【請求項３７】
前記分析結果は、前記サーバと通信するコンピューティングデバイス上に表示される、請求項３６に記載の装置。
【請求項３８】
前記作動アセンブリの少なくとも１つの機能性は、前記ネットワークを介して、前記サーバ上のアプリケーションによって制御される、請求項２８に記載の装置。
【請求項３９】
前記機能性は、前記作動アセンブリの電力、前記作動アセンブリによって印加される減圧圧力、および前記作動アセンブリの１分あたりのサイクルのうちの１つまたはそれを上

回るものを含む、請求項３８に記載の装置。
【請求項４０】
母乳を搾乳するようにユーザにリマインドする通知は、前記ネットワークを介して電子メールアドレスに伝送される、請求項２８に記載の装置。
【請求項４１】
母乳を搾乳するようにユーザにリマインドする通知は、ショートメッセージサービス（ＳＭＳ）によって、前記ネットワークを介して携帯電話番号に伝送される、請求項２８に記載の装置。
【請求項４２】
前記通知は、ＳＭＳによって、前記サーバから前記携帯電話番号と関連付けられたスマートフォンに伝送される、請求項４１に記載の装置。
【請求項４３】
母乳を搾乳するようにユーザにリマインドする通知は、前記ネットワークを介して前記通信モジュールに伝送される、請求項２８に記載の装置。
【請求項４４】
ファームウェア更新が、前記ネットワークを介して前記通信モジュールに伝送される、請求項２８に記載の装置。
【請求項４５】
乳房からの母乳の搾乳を測定するための方法であって、
インターフェースと、前記インターフェースに動作可能に結合される作動アセンブリと、感知ユニットとを備える、母乳搾乳装置を提供するステップと、
前記インターフェースと乳房を係合するステップと、
前記作動アセンブリを作動させ、それによって、前記インターフェースに、減圧圧力を前記乳房に対して印加させるステップと、
前記乳房から母乳を搾乳するステップと、
前記感知ユニットを使用して、母乳の搾乳の特性を測定し、それによって、測定データを生成するステップと、
ネットワークを介して前記測定データをサーバに伝送するステップと、
を含む、方法。
【請求項４６】
前記サーバは、分散型コンピューティングサーバである、請求項４５に記載の方法。
【請求項４７】
前記母乳の搾乳の特性は、前記母乳が前記インターフェースから前記インターフェースと流体連通する収集リザーバに移動するにつれて、前記感知ユニットによって測定される、請求項４５に記載の方法。
【請求項４８】
前記測定データを前記サーバと関連付けられた１つまたはそれを上回るデータ記憶内に記憶するステップをさらに含む、請求項４５に記載の方法。
【請求項４９】
前記サーバ上のアプリケーションを介して前記測定データを分析し、分析結果を生成するステップをさらに含む、請求項４５に記載の方法。
【請求項５０】
前記分析結果を前記サーバからコンピューティングデバイスに伝送するステップと、
前記コンピューティングデバイスを介して前記分析結果をユーザに表示するステップと、
をさらに含む、請求項４９に記載の方法。
【請求項５１】
乳房からの母乳の搾乳を遠隔制御するための方法であって、
インターフェースと、前記インターフェースに動作可能に結合される作動アセンブリとを備える、母乳搾乳装置を提供するステップと、
前記インターフェースと乳房を係合するステップと、

ネットワークを介して、制御信号をサーバから受信するステップと、
前記制御信号に基づいて、前記作動アセンブリを作動させ、それによって、前記インターフェースに、減圧圧力を前記乳房に対して印加させるステップと、
前記乳房から母乳を搾乳するステップと、
を含む、方法。
【請求項５２】
乳房からの流体の搾乳を測定するための装置であって、
乳房に係合するように構成されるインターフェースと、
前記インターフェースに動作可能に結合されるであって、前記作動アセンブリの作動は、前記インターフェースに、減圧圧力を前記乳房に対して印加させ、そこから流体を搾乳させる、作動アセンブリと、
前記乳房から搾乳された流体の体積を示す測定データを生成するように構成される、感知ユニットと、
を備える、装置。
【請求項５３】
前記インターフェースは、前記乳房に対して流体的にシールするように構成される、請求項５２に記載の装置。
【請求項５４】
前記流体は、母乳および初母乳のうちの１つまたはそれを上回るものである、請求項５２に記載の装置。
【請求項５５】
前記測定データは、前記搾乳された流体の時間の単位あたりの体積を示す、請求項５２に記載の装置。
【請求項５６】
前記作動アセンブリは、ポンプを備え、前記測定データは、前記搾乳された流体の前記ポンプのストロークあたりの体積を示す、請求項５２に記載の装置。
【請求項５７】
前記作動アセンブリは、ポンプを備え、前記測定データは、前記搾乳された流体のポンプ電力サイクルあたりの体積を示す、請求項５２に記載の装置。
【請求項５８】
前記インターフェースは、前記搾乳された流体の通過を可能にする弁を備え、前記感知ユニットは、前記弁の運動を測定する加速度計を備える、請求項５２に記載の装置。
【請求項５９】
前記測定データは、前記弁の運動に基づいて生成される、請求項５８に記載の装置。
【請求項６０】
第２の乳房に係合するように構成される、第２のインターフェースをさらに備え、前記作動アセンブリの作動は、減圧圧力を前記乳房および前記第２の乳房に対して交互に印加させ、そこから交互に流体を搾乳させ、前記第２のインターフェースは、前記第２の乳房から搾乳された流体の通過を可能にする第２の弁を備え、前記感知ユニットは、前記第２の弁の運動を測定する第２の加速度計を備える、請求項５８に記載の装置。
【請求項６１】
前記感知ユニットは、前記加速度計および前記第２の加速度計の両方によって検出された運動に基づいて、ユーザ運動を判定する、請求項６０に記載の装置。
【請求項６２】
前記ユーザ運動は、前記第１の弁または第２の弁のうちの少なくとも１つの運動を判定するとき、前記加速度計または前記第２の加速度計のうちの少なくとも１つによって検出される運動から減算される、請求項６１に記載の装置。
【請求項６３】
前記インターフェースは、前記搾乳された流体の通過を可能にする弁を備え、前記感知ユニットは、前記インターフェースに結合される第１の加速度計と、前記弁に結合される

第２の加速度計とを備える、請求項５２に記載の装置。
【請求項６４】
前記第１の加速度計は、前記インターフェースの運動を測定するように構成される、請求項６３に記載の装置。
【請求項６５】
前記第２の加速度計は、前記弁の運動を測定するように構成される、請求項６３に記載の装置。
【請求項６６】
前記測定データは、前記インターフェースの運動および前記弁の運動に基づいて生成される、請求項６３に記載の装置。
【請求項６７】
前記感知ユニットは、前記第１の加速度計によって検出される運動に基づいて、背景運動を判定する、請求項６３に記載の装置。
【請求項６８】
前記背景運動は、前記弁の運動を判定するとき、前記第２の加速度計によって検出される運動から減算される、請求項６７に記載の装置。
【請求項６９】
前記インターフェースは、前記搾乳された流体を収集するように構成されるリザーバに結合され、前記感知ユニットは、前記リザーバに結合され、前記リザーバは、前記感知ユニットと通信する処理ユニットを備え、前記処理ユニットは、前記感知ユニットによって生成される測定データを受信するように構成される、請求項５２に記載の装置。
【請求項７０】
前記処理ユニットは、データ接続を介して前記測定データをコンピューティングデバイスに伝送するように構成される、通信モジュールを備える、請求項６９に記載の装置。
【請求項７１】
前記処理ユニットは、ネットワークを介して前記測定データをサーバに伝送するように構成される、通信モジュールを備える、請求項６９に記載の装置。
【請求項７２】
前記感知ユニットは、ビーム遮断センサの１つまたはそれを上回るセンサ構成要素の近傍の前記搾乳された流体の通過を検出するように構成される、ビーム遮断センサを備える、請求項５２に記載の装置。
【請求項７３】
前記測定データは、前記搾乳された流体が前記センサ構成要素間を通過する時間の長さに基づいて生成される、請求項７２に記載の装置。
【請求項７４】
前記インターフェースは、前記搾乳された流体の通過を可能にする弁を備え、前記感知ユニットは、前記弁を通して通過する前記搾乳された流体の液滴を計数するように構成される、電荷結合素子（ＣＣＤ）を備える、請求項５２に記載の装置。
【請求項７５】
前記測定データは、前記液滴の１つまたはそれを上回るＣＣＤ画像に基づいて生成される、請求項７４に記載の装置。
【請求項７６】
前記インターフェースは、前記搾乳された流体の通過を可能にする管を備え、前記感知ユニットは、前記管内に含まれる前記搾乳された流体を感知するように構成される、容量センサを備える、請求項５２に記載の装置。
【請求項７７】
前記インターフェースは、前記搾乳された流体を収集するように構成されるリザーバに結合され、前記感知ユニットは、前記リザーバ内に含まれる前記搾乳された流体の体積を測定するように構成される、容量センサを備える、請求項５２に記載の装置。
【請求項７８】

前記感知ユニットは、前記搾乳された流体の体積を測定するように構成される、歪みゲージを備える、請求項５２に記載の装置。
【請求項７９】
前記インターフェースは、前記搾乳された流体の通過を可能にする弁を備え、前記歪みゲージは、前記弁に結合され、前記弁の経時的変位を判定するように構成される、請求項７８に記載の装置。
【請求項８０】
前記インターフェースは、前記搾乳された流体を収集するように構成されるリザーバに結合され、前記歪みゲージは、前記リザーバに結合され、前記リザーバ内に含まれる前記搾乳された流体の体積を測定するように構成される、請求項７８に記載の装置。
【請求項８１】
前記リザーバは、蛇腹要素を有する底部内部表面を備え、前記蛇腹要素は、前記搾乳された流体によって前記底部内部表面上にかかる負荷の前記底部内部表面による吸収を最小限にするように構成される、請求項８０に記載の装置。
【請求項８２】
前記感知ユニットは、前記インターフェースに結合され、前記搾乳された流体の１つまたはそれを上回る画像を捕捉するように構成される、カメラを備える、請求項５２に記載の装置。
【請求項８３】
前記１つまたはそれを上回る画像を分析し、前記搾乳された流体の体積を判定するように構成される、処理ユニットをさらに備える、請求項８２に記載の装置。
【請求項８４】
前記１つまたはそれを上回る画像は、前記１つまたはそれを上回る画像を分析し、前記搾乳された流体の体積を判定するように構成されるコンピューティングデバイスに伝送される、請求項８２に記載の装置。
【請求項８５】
前記コンピューティングデバイスは、スマートフォンである、請求項８４に記載の装置。
【請求項８６】
前記カメラは、モバイル装置上に据え付けられる、請求項８２に記載の装置。
【請求項８７】
処理ユニットと、
前記作動アセンブリに動作可能に結合され、その少なくとも１つの機能性を制御する、制御ユニットと、
をさらに備え、前記測定データの少なくともサブセットは、フィードバックとして、前記処理ユニットおよび前記制御ユニットのうちの少なくとも１つに伝送される、請求項５２に記載の装置。
【請求項８８】
前記作動アセンブリは、ポンプを備え、前記フィードバックは、前記ポンプの減圧ストロークを調節し、最適流体搾乳を維持するために使用される、請求項８７に記載の装置。
【請求項８９】
前記作動アセンブリは、ポンプを備え、前記フィードバックは、前記ポンプの１分あたりのサイクルを調節し、最適流体搾乳を維持するために使用される、請求項８７に記載の装置。
【請求項９０】
乳房から搾乳された流体の体積を測定するための方法であって、
インターフェースと、前記インターフェースに動作可能に結合される作動アセンブリと、感知ユニットとを備える、乳房流体搾乳装置を提供するステップと、
前記インターフェースと乳房を係合するステップと、
前記作動アセンブリを作動させ、それによって、前記インターフェースに、減圧圧力を

前記乳房に対して印加させるステップと、
前記乳房から流体を搾乳するステップと、
前記感知ユニットを介して、前記搾乳された流体の体積を示す測定データを生成するステップと、
を含む、方法。
【請求項９１】
前記測定データの少なくともサブセットに基づいて、前記作動アセンブリの作動パラメータを変更するステップと、
前記変更された作動パラメータに基づいて、前記作動アセンブリを作動させるステップと、
をさらに含む、請求項９０に記載の方法。
【発明の詳細な説明】
【技術分野】
【０００１】
（相互参照）
本出願は、２０１４年２月７日に出願された米国仮特許出願番号第６１／９３７，０２７号［代理人書類番号４４９３６－７０４．１０１］の非仮出願であって、この仮出願の利益を主張しており、この仮出願の全体の内容は本明細書中に参考として援用される。
【０００２】
本願の主題は、２０１４年３月２０日に出願された米国特許出願第１４／２２１，１１３号［代理人書類番号４４９３６－７０３．２０１］、２０１４年７月７日に出願された米国仮特許出願番号第６２／０２１，６０１号［代理人書類番号４４９３６－７０５．１０１］、２０１４年７月７日に出願された米国仮特許出願番号第６２／０２１，５９７号［代理人書類番号４４９３６－７０６．１０１］、２０１４年７月２３日に出願された米国仮特許出願番号第６２／０２８，２１９号［代理人書類番号４４９３６－７０８．１０１］、および２０１４年９月１９日に出願された米国仮特許出願番号第６２／０５２，９４１号［代理人書類番号４４９３６－７０９．１０１］に関連し、これら出願の全体の内容は、参考として本明細書中に援用される。
【０００３】
（発明の背景）
（１．発明の分野）
本発明は、概して、医療デバイスおよび方法に関し、より具体的には、ヒトの母乳の搾乳および採取のためのデバイスおよび方法に関する。
【背景技術】
【０００４】
乳房ポンプは、母親が自らの子供と離れていても授乳を続けられるように母乳を採取するため一般に用いられている。今のところ、乳房ポンプには、２種類の基本型、すなわち、小型ではあるが非効率的で使用するために疲れを生じる手動デバイスと、効率的ではあるが大きくかさばる電動デバイスとがある。このため、母乳の搾乳および採取のために小型で非常に効率的な改良された乳房ポンプを提供することが望ましいであろう。母乳産出量の定量化、母乳特性評価、およびモバイルデバイスとの通信等の追加的な特徴は、ユーザの利便性を高める上でさらに望ましい。これらの目的の少なくともいくつかは、以下に開示されるデバイスおよび方法によって満足される。
【０００５】
（２．背景技術の記載）
以下の米国特許は、ヒトの母乳の搾乳および採取に関する。米国特許第６，６７３，０３６号、第６，７４９，５８２号、第６，８４０，９１８号、第６，８８７，２１０号、第７，８７５，０００号、第８，１１８，７７２号、および第８，２１６，１７９号。
【先行技術文献】
【特許文献】

【０００６】
【特許文献１】米国特許第６，６７３，０３６号明細書
【特許文献２】米国特許第６，７４９，５８２号明細書
【特許文献３】米国特許第６，８４０，９１８号明細書
【特許文献４】米国特許第６，８８７，２１０号明細書
【特許文献５】米国特許第７，８７５，０００号明細書
【特許文献６】米国特許第８，１１８，７７２号明細書
【特許文献７】米国特許第８，２１６，１７９号明細書
【発明の概要】
【０００７】
（発明の要旨）
本発明は、概して、医療デバイスおよび方法に関し、より具体的には、ヒトの母乳の搾乳ならびに採取のためのデバイスおよび方法に関する。
【０００８】
本発明の第１の側面では、乳房からの母乳の搾乳のためのシステムが、提供される。本システムは、乳房に係合するように構成されるインターフェースと、インターフェースに動作可能に結合される作動アセンブリとを有する、搾乳装置を備えてもよい。作動アセンブリの作動は、インターフェースに、減圧圧力を乳房に対して印加させ、乳房から母乳を搾乳させることができる。本システムはさらに、データ接続を介して搾乳装置と通信するように構成される、コンピューティングデバイスを備える。
【０００９】
多くの実施形態では、乳房は、ヒト乳房である。インターフェースは、乳房に対して流体的にシールするように構成されることができる。
【００１０】
多くの実施形態では、データ接続は、無線通信、近距離通信、またはＵＳＢケーブルを利用し、搾乳装置の少なくとも一部とコンピューティングデバイスとの間でデータを伝送する。コンピューティングデバイスは、スマートフォン、タブレット、またはパーソナルコンピュータであってもよい。
【００１１】
多くの実施形態では、搾乳装置はさらに、母乳の搾乳の１つまたはそれを上回る特性を示す測定データを生成するように構成される、感知ユニットを含む。測定データは、データ接続を介してコンピューティングデバイスに伝送されることができる。コンピューティングデバイスは、測定データを分析するように構成される、アプリケーションを含むことができる。コンピューティングデバイスは、測定データをサーバに伝送することができる。搾乳装置はさらに、測定データを分析し、分析結果を生成するように構成される、処理ユニットと、分析結果をユーザに表示するように構成される、ディスプレイユニットとを含むことができる。分析結果は、グラフ、チャート、または表に表示されることができる。分析結果は、データ接続を介してコンピューティングデバイスに伝送されることができ、コンピューティングデバイスは、分析結果をユーザに表示することができる。
【００１２】
多くの実施形態では、コンピューティングデバイスは、データ接続を介して搾乳装置の少なくとも１つの機能性を制御することができる。機能性は、搾乳装置の電力、搾乳装置によって印加される減圧圧力、または搾乳装置の１分あたりのサイクルのうちの１つまたはそれを上回るものを備えることができる。
【００１３】
多くの実施形態では、母乳を搾乳するようにユーザにリマインドする通知は、データ接続を介してコンピューティングデバイスに伝送されてもよい。通知は、データ接続を介して、搾乳装置の少なくとも一部に伝送されることができる。ファームウェア更新が、データ接続を介して、搾乳装置の少なくとも一部に伝送されることができる。
【００１４】

多くの実施形態では、コンピューティングデバイスは、ネットワークを介してサーバと通信する通信モジュールを備えることができる。母乳を搾乳するようにユーザにリマインドする通知は、サーバからコンピューティングデバイスに伝送されてもよい。コンピューティングデバイスは、携帯電話番号と関連付けられた携帯電話を備えてもよく、通知は、ショートメッセージサービス（ＳＭＳ）によって、ネットワークを介して携帯電話番号に伝送されてもよい。

【００１５】

本発明の別の側面では、乳房からの母乳の搾乳を測定するための方法が、提供される。本方法は、インターフェースと、インターフェースに動作可能に結合される作動アセンブリと、感知ユニットとを有する、母乳搾乳装置を提供するステップを含む。本方法はさらに、インターフェースと乳房を係合するステップと、作動アセンブリを作動させ、それによって、インターフェースに、減圧圧力を乳房に対して印加させるステップとを含む。本方法はさらに、乳房から母乳を搾乳するステップを含む。本方法はさらに、測定データを生成するために、感知ユニットを使用して、母乳の搾乳の特性を測定するステップを含んでもよい。測定データは、データ接続を介して、感知ユニットからコンピューティングデバイスに伝送されてもよい。

【００１６】

多くの実施形態では、測定データは、コンピューティングデバイスの１つまたはそれを上回るデータ記憶内に記憶されてもよい。測定データは、コンピューティングデバイスのアプリケーションを介して分析され、分析結果を生成することができ、分析結果は、コンピューティングデバイスを介してユーザに表示されることができる。分析結果は、グラフ、チャート、表、または任意の他の視覚的、聴覚的、もしくは触知的インジケータに表示されることができる。

【００１７】

本発明の別の側面では、乳房からの母乳の搾乳を制御するための方法が、提供される。本方法は、インターフェースと、インターフェースに動作可能に結合される作動アセンブリとを有する、母乳搾乳装置を提供するステップを含む。本方法はさらに、インターフェースと乳房を係合するステップを含む。制御信号は、データ接続を介して、コンピューティングデバイスから受信されてもよい。本方法はさらに、制御信号に基づいて、作動アセンブリを作動させ、インターフェースに、減圧圧力を乳房に対して印加させるステップを含んでもよい。本方法はさらに、乳房から母乳を搾乳するステップを含む。

【００１８】

本発明の別の側面では、乳房からの母乳の搾乳のための装置が、提供される。本装置は、乳房に係合するように構成されるインターフェースと、インターフェースに動作可能に結合される作動アセンブリとを備える。作動アセンブリの作動は、インターフェースに、減圧圧力を乳房に対して印加させ、乳房から母乳を搾乳させることができる。本装置はまた、ネットワークを介してサーバと通信する通信モジュールを含むことができる。

【００１９】

多くの実施形態では、ネットワークは、インターネットネットワークを含む。本装置はさらに、母乳の搾乳の１つまたはそれを上回る特性を示す測定データを生成するように構成される、感知ユニットを含むことができ、測定データは、ネットワークを介してサーバに伝送されることができる。サーバは、測定データを分析するように構成される、アプリケーションを含むことができる。

【００２０】

多くの実施形態では、本装置はさらに、測定データを分析し、分析結果を生成するように構成される、処理ユニットと、分析結果をユーザに表示するように構成される、ディスプレイユニットとを含む。分析結果は、ネットワークを介してサーバに伝送されることができる。分析結果は、サーバと通信するコンピューティングデバイス上に表示されることができる。

【００２１】

多くの実施形態では、作動アセンブリの少なくとも１つの機能性は、ネットワークを介して、サーバ上のアプリケーションによって制御される。機能性は、作動アセンブリの電力、作動アセンブリによって印加される減圧圧力、または作動アセンブリの１分あたりのサイクルを含むことができる。

【００２２】

多くの実施形態では、母乳を搾乳するようにユーザにリマインドする通知は、ネットワークを介して電子メールアドレスに伝送されてもよい。母乳を搾乳するようにユーザにリマインドする通知は、サーバから携帯電話番号と関連付けられたスマートフォンへのＳＭＳ等、ショートメッセージサービス（ＳＭＳ）によって、ネットワークを介して携帯電話番号に伝送されることができる。母乳を搾乳するようにユーザにリマインドする通知は、ネットワークを介して通信モジュールに伝送されることができる。ファームウェア更新は、ネットワークを介して通信モジュールに伝送されることができる。

【００２３】

別の側面では、本発明は、乳房からの母乳の搾乳を測定するための方法を提供する。本方法は、インターフェースと、インターフェースに動作可能に結合される作動アセンブリと、感知ユニットとを含む、母乳搾乳装置を提供するステップを含む。インターフェースは、乳房と係合されてもよい。作動アセンブリは、作動され、インターフェースに、減圧圧力を乳房に対して印加させることができる。母乳は、乳房から搾乳される。感知ユニットは、母乳の搾乳の特性を測定し、測定データを生成するために使用されてもよい。測定データは、ネットワークを介してサーバに伝送されてもよい。

【００２４】

多くの実施形態では、サーバは、分散型コンピューティングサーバである。母乳の搾乳の特性は、母乳がインターフェースからインターフェースと流体連通する収集リザーバに移動するにつれて、感知ユニットによって測定されることができる。測定データは、サーバと関連付けられた１つまたはそれを上回るデータ記憶内に記憶されることができる。測定データは、サーバ上のアプリケーションを介して分析され、分析結果を生成することができる。分析結果は、サーバからコンピューティングデバイスに伝送され、コンピューティングデバイスを介してユーザに表示されることができる。

【００２５】

本発明の別の側面では、乳房からの母乳の搾乳を遠隔制御するための方法が、提供される。本方法は、インターフェースと、インターフェースに動作可能に結合される作動アセンブリとを備える、母乳搾乳装置を提供するステップを含む。インターフェースは、乳房と係合されてもよい。制御信号が、ネットワークを介してサーバから受信されることができる。作動アセンブリは、制御信号に基づいて作動され、インターフェースに、減圧圧力を乳房に対して印加させてもよい。母乳は、乳房から搾乳されてもよい。

【００２６】

本発明の別の側面では、乳房からの流体の搾乳を測定するための装置が、提供される。本装置は、乳房に係合するように構成されるインターフェースと、インターフェースに動作可能に結合される作動アセンブリとを含む。作動アセンブリの作動は、インターフェースに、減圧圧力を乳房に対して印加させ、乳房から母乳を搾乳させる。本装置は、乳房から搾乳された流体の体積を示す測定データを生成するように構成される、感知ユニットを含む。

【００２７】

多くの実施形態では、乳房は、ヒト乳房である。インターフェースは、乳房に対して流体的にシールするように構成されることができる。流体は、母乳または初母乳であることができる。測定データは、搾乳された流体の単位時間あたりの体積、ポンプのストロークあたりの体積、またはポンプ電力サイクルあたりの体積を示すことができる。

【００２８】

多くの実施形態では、インターフェースは、搾乳された流体の通過を可能にする弁を含み、感知ユニットは、弁の運動を測定する加速度計を備える。測定データは、弁の運動に

基づいて生成されることができる。

【００２９】

多くの実施形態では、本装置はさらに、第２の乳房に係合するように構成される、第２のインターフェースを含むことができる。作動アセンブリの作動は、減圧圧力を乳房および第２の乳房に対して交互に印加させ、交互に乳房から流体を搾乳させてもよい。第２のインターフェースは、第２の乳房から搾乳された流体の通過を可能にする第２の弁を含むことができ、感知ユニットは、第２の弁の位置を測定する第２の加速度計を含むことができる。感知ユニットは、加速度計および第２の加速度計の両方によって検出された運動に基づいて、ユーザ運動を判定することができる。ユーザ運動は、第１の弁または第２の弁のうちの少なくとも１つの位置を判定するとき、加速度計または第２の加速度計のうちの少なくとも１つによって検出される運動から減算されることができる。

【００３０】

多くの実施形態では、インターフェースは、インターフェース筐体と、搾乳された流体の通過を可能にする弁とを備えてもよい。感知ユニットは、インターフェース筐体に結合される第１の加速度計と、弁に結合される第２の加速度計とを備えてもよい。第１の加速度計は、インターフェース筐体の位置を測定するように構成されてもよい。第２の加速度計は、弁の位置を測定するように構成されてもよい。測定データは、インターフェース筐体の位置および弁の位置に基づいて、生成されてもよい。感知ユニットは、第１の加速度計によって検出される運動に基づいて、背景運動を判定することができる。背景運動は、弁の位置を判定するとき、第２の加速度計によって検出される運動から減算されてもよい。

【００３１】

多くの実施形態では、インターフェースは、搾乳された流体を収集するように構成されるリザーバに結合されてもよい。感知ユニットは、リザーバに結合されてもよい。リザーバは、感知ユニットと通信する処理ユニットを備えてもよく、処理ユニットは、感知ユニットによって生成される測定データを受信するように構成されてもよい。処理ユニットはさらに、データ接続を介して測定データをコンピューティングデバイスに伝送するように構成される、通信モジュールを備えてもよい。処理ユニットの通信モジュールは、ネットワークを介して測定データをサーバに伝送するように構成されてもよい。

【００３２】

多くの実施形態では、感知ユニットは、ビーム遮断センサの１つまたはそれを上回るセンサ構成要素の近傍の搾乳された流体の通過を検出するように構成される、ビーム遮断センサを含む。測定データは、搾乳された流体がセンサ構成要素間を通過する時間の長さに基づいて生成されることができる。

【００３３】

多くの実施形態では、インターフェースは、搾乳された流体の通過を可能にする弁を含み、感知ユニットは、弁を通して通過する搾乳された流体の液滴を計数するように構成される、電荷結合素子（ＣＣＤ）を含む。測定データは、液滴の１つまたはそれを上回るＣＣＤ画像に基づいて生成されることができる。

【００３４】

多くの実施形態では、インターフェースは、搾乳された流体の通過を可能にする管を含み、感知ユニットは、管内に含まれる搾乳された流体を感知するように構成される、容量センサを含む。インターフェースは、搾乳された流体を収集するように構成されるリザーバに結合されることができ、感知ユニットは、リザーバ内に含まれる搾乳された流体の体積を測定するように構成される、容量センサを含むことができる。

【００３５】

多くの実施形態では、感知ユニットは、搾乳された流体の体積を測定するように構成される、歪みゲージを含む。インターフェースは、搾乳された流体の通過を可能にする弁を含むことができ、歪みゲージは、弁に結合され、弁の経時的変位を判定するように構成されることができる。インターフェースは、搾乳された流体を収集するように構成されるリ

ザーバに結合されることができ、歪みゲージは、リザーバに結合され、リザーバ内に含まれる搾乳された流体の体積を測定するように構成されることができる。リザーバは、蛇腹要素を有する底部内部表面を備えてもよい。蛇腹要素は、搾乳された流体によって底部内部表面にかかる負荷の底部内部表面による吸収を最小限にするように構成されることができる。

【００３６】

多くの実施形態では、感知ユニットは、インターフェースに結合され、搾乳された流体の１つまたはそれを上回る画像を捕捉するように構成される、カメラを含む。本装置はさらに、１つまたはそれを上回る画像を分析し、搾乳された流体の体積または搾乳された流体の他の特性を判定するように構成される、処理ユニットを含むことができる。１つまたはそれを上回る画像は、１つまたはそれを上回る画像を分析し、搾乳された流体の体積を判定するように構成されるコンピューティングデバイスに伝送されることができる。コンピューティングデバイスは、スマートフォンであることができる。カメラは、モバイルデバイス上に据え付けられることができる。

【００３７】

多くの実施形態では、本装置はさらに、処理ユニットと、作動アセンブリに動作可能に結合され、作動アセンブリの少なくとも１つの機能性を制御する、制御ユニットとを備える。測定データの少なくともサブセットは、フィードバックとして、処理ユニットおよび制御ユニットのうちの少なくとも１つに伝送されてもよい。作動アセンブリは、ポンプを含むことができ、フィードバックは、ポンプの減圧ストロークまたはポンプの１分あたりのサイクルを調節し、最適流体搾乳を維持するために使用されることができる。

【００３８】

本発明の別の側面では、乳房から搾乳された流体の体積を測定するための方法が、提供される。本方法は、インターフェースと、インターフェースに動作可能に結合される作動アセンブリと、感知ユニットとを含む、乳房流体搾乳装置を提供するステップを含む。インターフェースは、乳房と係合される。作動アセンブリは、作動され、インターフェースに、減圧圧力を乳房に対して印加させる。流体は、乳房から搾乳される。搾乳された流体の体積を示す測定データは、感知ユニットを介して生成される。

【００３９】

多くの実施形態では、本方法はさらに、測定データの少なくともサブセットに基づいて、作動アセンブリの作動パラメータを変更するステップを含む。作動アセンブリは、変更された作動パラメータに基づいて作動される。

【００４０】

本発明の他の目的および特徴は、明細書、請求項、および添付の図の精査によって明白となる。

【００４１】

（参照による引用）

本明細書に記載される全ての刊行物、特許、および特許出願は、各個々の刊行物、特許、または特許出願が、具体的かつ個々に、参照することによって組み込まれることが示される場合と同程度まで、参照することによって本明細書に組み込まれる。

【００４２】

本発明の新規の特徴は、具体性をもって添付の請求項に示される。本発明の特徴および利点のより深い理解は、本発明の原理が活用された例証的実施形態を示す以下の詳細な記述および付随の図面の参照によって得られ得る。

【図面の簡単な説明】

【００４３】

【図１】図１は、実施形態による、ポンプデバイスの斜視図である。

【図２】図２は、実施形態による、水圧ポンプデバイスの斜視図である。

【図３】図３は、実施形態による、水圧ポンプデバイスの断面図である。

【図４】図４は、実施形態による、駆動機構に結合される作動アセンブリを図示する。

【図５】図５Ａ－５Ｂは、実施形態による、コントローラに結合される作動アセンブリを図示する。
【図６】図６は、実施形態による、乳房インターフェースの断面図である。
【図７】図７は、実施形態による、別の乳房インターフェースの断面図である。
【図８】図８Ａは、実施形態による、開位置にある、可撓性膜内に統合される弁の断面図である。図８Ｂは、実施形態による、閉位置にある、可撓性膜内に統合される弁の断面図である。
【図９】図９は、実施形態による、機械的変形可能部材を伴う乳房インターフェースの断面図である。
【図１０】図１０は、実施形態による、機械的変形可能部材のための機械的駆動装置の断面図である。
【図１１Ａ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｂ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｃ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｄ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｅ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｆ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｇ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｈ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｉ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｊ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｋ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｌ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｍ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｎ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｏ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｐ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｑ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１２】図１２は、実施形態による、コントローラおよびモバイルデバイスを図示する。
【図１３】図１３は、実施形態による、コントローラとモバイルデバイスとの間の短距離通信を図示する。
【図１４】図１４は、実施形態による、コンピューティングデバイスおよびサーバと通信

するポンプデバイスの概略図である。
【図１５】図１５は、実施形態による、市販のデバイスと比較した例示的ポンプデバイスのポンプの性能を図示するグラフである。
【図１６】図１６は、実施形態による、市販のデバイスと比較した例示的ポンプデバイスのポンプ効率を図示するグラフである。
【図１７】図１７は、母乳の搾乳のためのシステムの概略図を図示する。
【図１８】図１８は、母乳の搾乳のためのシステムの別の例示的実施形態を図示する。
【図１９】図１９Ａ－１９Ｃは、コンピューティングデバイス上の例示的ディスプレイを図示する。
【図２０】図２０Ａ－２０Ｂは、母乳搾乳システム内の例示的ディスプレイを図示する。
【図２１】図２１は、母乳搾乳デバイスを制御するためのフィードバック制御ループの使用を図示する。
【図２２】図２２は、二重搾乳システムを図示する。
【発明を実施するための形態】
【００４４】
（発明の詳細な説明）
開示されたシステム、デバイス、および方法の具体的な実施形態を、ここで、図面を参照しつつ以下に記述する。いかなる詳細な記述も、任意の特定の構成要素、特徴、またはステップが本発明にとって必須であることを示唆することを意図しない。本発明は、主に、母乳に関するが、母乳の搾乳および採取の本明細書における任意の説明はまた、初母乳等の乳房から搾乳される他のタイプの流体にも適用されることができる。さらに、開示される実施形態は、他の用途、特に、睡眠時無呼吸の治療および／または他の遠隔圧力ニーズ等、圧力差の形成と伝達を含む用途において使用されてもよい。
【００４５】
本発明のシステム、デバイス、および方法は、ヒトの母乳等の母乳の搾乳ならびに採取のための改良されたポンプデバイスを提供する。既存のデバイスと対照的に、本明細書に説明される機構は、より小型かつより効率的な電気ポンプデバイスの開発を可能にし、それによって、利便性および使用の容易性を向上させる。加えて、本明細書に開示される例示的実施形態の少なくともいくつかは、母乳の搾乳の特性を測定するためのセンサを組み込む。得られたデータは、例えば、ポンプ効率を改善し、かつ母乳の搾乳に関連する情報および／または分析をユーザに提供するためのフィードバックとして、使用されることができる。さらに、好適な実施形態では、データは、ポンプデバイスと通信する別のデバイスに伝送され、それによって、母乳の搾乳の制御、表示、および／または分析が、遠隔で行われることを可能にすることができる。
【００４６】
図１は、本発明の例示的実施形態を図示する。ポンプデバイス１００は、（「搾乳装置」としても知られる）は、乳房インターフェース１０５と、管１１０と、管１１０を通して乳房インターフェース１０５に動作可能に結合される、コントローラ１１５（「ペンダントユニット」とも称される場合がある）とを含む。乳房インターフェース１０５は、乳房に係合し、それに対して流体シールを形成するための弾性かつ整合的なフランジ１２０と、採取容器１２５とを含む。コントローラ１１５は、本明細書にさらに詳細に説明されるように、電源およびポンプデバイス１００の駆動機構を格納し、また、ポンプデバイス１００の制御、母乳産出量の定量化、他のデバイスとの通信等、種々の機能のためのハードウェアを含む。管１１０は、機械的なエネルギー入力等の好適なエネルギー入力を、コントローラ１１５から乳房インターフェース１０５までの長い距離にわたって伝達する。乳房インターフェース１０５は、エネルギー入力を乳房に対する減圧圧力に高度に効率的な様式で変換し、採取容器１２５の中への母乳の搾乳をもたらす。デバイス１００はさらに、本明細書にさらに詳細に説明されるように、収集された流体の種々の特性を追跡するように構成される、１つまたはそれを上回るセンサを備えてもよい。電力が、コントローラ１１５もしくは別の電力源への接続を介して、１つまたはそれを上回るセンサに提供さ

れてもよい。１つまたはそれを上回るセンサが、乳房インターフェース１０５もしくは採取容器１２５の１つまたはそれを上回る部分に結合される実施形態では、センサはさらに、センサとコントローラとの間で信号を伝送するように構成される１つまたはそれを上回る通信ラインを介して、コントローラ１１５に結合されてもよい。

【００４７】

水圧（油圧）ポンプデバイス

水圧システムは、必要とされるポンプ力を低減させることができ、したがって、高ポンプ効率を維持しながらポンプデバイスのサイズを低減させることができる。好適な実施形態では、ポンプデバイスは、水圧ポンプシステムを利用して、母乳の搾乳および採取のため、乳房に対する圧力差を発生させることができる。

【００４８】

例示的水圧ポンプデバイスが、図２および３に示される。図２は、管１６５によって乳房インターフェース１６０に流体的に結合された注射器１５５を有する、ポンプデバイス１５０を図示する。注射器１５５は、三方弁１７０を通して管１６５に結合される。乳房インターフェース１６０は、出口ポート１７５を含む。注射器１５５は、管１６５内に含まれる流体１８０を、乳房インターフェース１６０内に格納された可撓性部材に向けて駆動し、乳房からの母乳の搾乳に必要な圧力差を生成する。

【００４９】

図３は、ポンプデバイス２００の別の実施形態を図示する。作動アセンブリ２０５は、アセンブリ筐体２１０と、駆動要素２１５と、シール２２０と、シャフト２２２とを含む。駆動要素２１５は、シャフト２２２を通してコントローラ１１５等のコントローラに動作可能に結合される。管２２５は、流体２３０を含み、作動アセンブリ２０５および乳房インターフェース２３５に流体的に結合される。乳房インターフェース２３５は、インターフェース筐体２４０と、可撓性膜２４５と、リザーバ２５０と、シール要素２５５と、搾乳面積２６０と、排出ポート２６５とから成る。シール要素２５５は、変形可能部分２７０を含む。代替として、可撓性膜２４５は、変形可能部分２７０を有するシール要素２５５を備えてもよく、可撓性膜２４５は、乳房インターフェース２３５の中に係合される乳房に対して流体的にシールすることによって、シール要素として機能するように構成される。排出ポート２６５は、採取容器２７５に結合され、フラップ弁２８０を含む。

【００５０】

作動アセンブリ２０５は、可撓性ラインであり得る、管内２２５に含有まれる流体２３０を変位させる。流体２３０は、乳房インターフェース２３５内のリザーバ２５０を占有し、可撓性膜２４５と結合される。好ましくは、可撓性膜２４５、シール要素２５５、およびインターフェース筐体２４０間の結合は、流体２３０が、リザーバ２５０内に含まれ、搾乳面積２６０の中に浸潤することができないような液密結合である。可撓性膜２４５は、流体２３０からシール要素２５５の変形可能部分２７０に減圧圧力を伝達する。乳房がシール要素２５５によって乳房インターフェース２３５の中に係合され、それと流体的にシールされると、作動要素２１５の変位が、可撓性膜２４５および変形可能部分２７０を通して、乳房に対する実質的な減圧圧力を生成し、その結果、搾乳面積２６０中への母乳の搾乳をもたらす。代替として、可撓性膜２４５は、可撓性膜２４５が、乳房インターフェース２３５の中に係合される乳房に対して流体シールを形成し、減圧圧力を流体２３０から可撓性膜２４５の変形可能部分に伝達するように、変形可能部分２７０を有するシール要素２５５を備えてもよい。搾乳された母乳は、排出ポート２６５を通して採取容器２７５中に排出される。排出ポート２６５は、フラップ弁２８０とともに構成され、搾乳面積２６０内の減圧圧力を維持しながら、母乳の通過をもたらす。採取容器２７５は、瓶またはバッグ等の任意の好適な容器であることができる。多くの実施形態では、採取容器２７５は、可撓性膜２４５に取り外し可能に結合される。採取容器２７５は、直接または延在管類等の任意の好適なデバイスを介して遠隔で、結合されることができる。好ましくは、採取容器は、ポンプデバイス２００の他の構成要素から迅速に分断されることができる（例えば、母乳貯蔵、清浄等のため）。

【００５１】
水圧ポンプデバイスの流体は、非圧縮性流体等、任意の好適な流体であることができる。多くの実施形態では、非圧縮性流体は、水または油等の液体であることができる。多くの実施形態では、流体は、ポンプデバイスによって流体に付与される減圧圧力が、流体の脱ガスをもたらさないような特性を有する流体であることができる。代替として、流体は、空気等の任意の好適なガスであることができる。水圧システムと併用するために好適な任意の液体またはガスが、本明細書に説明される水圧ポンプデバイスのために使用されることができる。

【００５２】
作動機構
当業者に公知の多くの作動機構が、作動アセンブリ２０５のために利用されることができる。作動アセンブリ２０５は、ピストンアセンブリ、ダイアフラムポンプ等のポンプ、または任意の他の好適な作動機構とすることができる。作動アセンブリ２０５の最適な構成は、減圧要件、サイズ、電力、およびポンプデバイス２００のその他の必要性、ならびに粘度、生体適合性、および流体寿命要件等の流体２３０の特性等、多くの要因に依存し得る。

【００５３】
図３は、作動アセンブリ２０５がピストンアセンブリであって、駆動要素２１５がピストンである、例示的実施形態を図示する。作動アセンブリ２０５は、Ｏリング、回転ダイヤフラムシール、またはワイパシール等のシール２２０を含み、流体２３０の望ましくない滲出を防止し、流体２３０の駆動を可能にするようにアセンブリ筐体２１０に対してシールする。

【００５４】
図４は、一対のピストン３０５を含む、作動アセンブリ３００の別の例示的実施形態を図示する。

【００５５】
好適な実施形態では、作動アセンブリは、コントローラ１１５内の駆動機構等、好適な駆動機構によって動力供給される駆動要素を含む。多くの駆動機構が、当業者に公知である。例えば、駆動要素２１５等の駆動要素は、モータによって電気機械的に作動されてもよく、レバー等の好適なユーザ作動式インターフェースによって手動で作動されてもよい。当業者に公知の種々の駆動モードが、使用されることができる。特に、本明細書に記載されるような例示的水圧ポンプデバイスの実装は、水圧システムの低減された力要件により、直接駆動およびソレノイド等の好適な駆動様式の使用を可能にする。

【００５６】
ここで図４の例示的実施形態を参照すると、ピストン３０５は、クランクシャフト３１５へのカップリング３１０を含む。クランクシャフト３１５は、ベルト駆動３２５を通してモータ３２０に動作可能に結合される。クランクシャフト３１５は、両方の乳房に同時に減圧圧力を印加するように一対のピストン３０５を同じストロークタイミングで駆動するが、この特徴は、母乳の産出増大に望ましい。代替として、クランクシャフト３１５は、交互またはオフセットストロークサイクル等の任意の好適なストロークタイミングで一対のピストン３０５を駆動することができる。交互またはオフセットストロークサイクルは、モータ３２０の電力要件を低減させる利点を有し得る。

【００５７】
駆動機構は、局部電池またはＡＣアダプタ等の任意の好適な電源によって給電されることができる。駆動機構は、コントローラ１１５内に配置された内蔵電子装置等のハードウェアによって制御されることができる。

【００５８】
図２２は、交互ポンプシステム２２００の別の実施形態を図示する。システム２２００は、標的組織、ここでは、乳房２２２０に一致するようなサイズおよび形状にされるインターフェース２２１２を伴う、二重搾乳デバイスを含む。リザーバ２２１４は、搾乳デバ

イスに螺合または別様に結合される。水圧ライン２２１０は、各搾乳デバイスを、ピストンチャンバ内の油等の非圧縮性流体と、作動可能ピストン２２０６とを有する、水圧ピストンアセンブリ２２０４に流体的に結合する。一方の水圧ライン２２１０は、水圧ピストンの高圧側２２０８に結合され、他方の水圧ラインは、ピストンの低圧側２２０８に結合される。モータ２２０２が、ピストン２２０６を作動させる。したがって、動作時、ピストンが作動されるにつれて、高圧側は、搾乳デバイスの一方内には、より高い圧力を、他方の搾乳デバイス内には、低い圧力を生成する。より低い圧力の搾乳デバイスは、減圧をもたらし、母乳の搾乳を生じさせる一方、高圧側は、母乳を搾乳しない。次いで、ピストンが、そのストロークの端部に到達し、反対方向に往復運動するにつれて、高圧側および低圧側は、反転され、それによって、反対側に母乳の搾乳を生じさせ、元の側には搾乳を生じさせない。本プロセスは、母乳が、交互方式において収集されることを可能にする。本システムにおける搾乳デバイス、リザーバは、本開示のいずれかに開示される構成要素のいずれかであってもよい。

【００５９】

図５Ａ－５Ｂは、取り外し可能カップリング３５５を含む、作動アセンブリ３５０の例示的実施形態を図示する。図５Ａは、取り外し可能カップリング３５５を介して結合される、作動アセンブリ３５０およびコントローラ３６０の等角図である。図５Ｂは、取り外し可能カップリング３５５を備える、作動アセンブリ３５０の断面図である。好ましくは、作動アセンブリ３５０は、コントローラ３６０およびその中に格納される駆動機構に取り外し可能に結合される。カップリングは、機械的カップリングまたは当業者に公知の任意の好適な迅速脱着機構であり得る。取り外し可能に結合された設計は、ポンプデバイスの構成および使用の柔軟性を可能にする。例えば、ユーザの使い心地は、種々の乳房サイズとの適合性のために、異なるサイズの乳房インターフェースを通して改良され得る。加えて、本特徴は、一般のポンプデバイスが、取り換え可能な乳房インターフェースと併用されることを可能にし、したがって、病原体の拡散リスクを低減させる。さらに、取り外し可能カップリングは、ポンプデバイスの個々のパーツの容易な交換を可能にする。

【００６０】

可撓性膜

図３に示される実施形態等、多くの実施形態において、可撓性膜２４５は、乳房インターフェース２３５内に位置し、少なくともその一部を覆うように配置され、インターフェース筐体２４０と可撓性膜２４５との間にリザーバ２５０を形成する。好ましくは、可撓性膜２４５は、流体２３０が作動アセンブリ２０５によってリザーバ２５０から変位されたときに形成される負圧に曝されると、実質的に変形する。可撓性膜２４５の変形量は、多くの要因（例えば、壁厚、デュロメータ、表面積）によって制御することができ、ポンプデバイス（例えば、ポンプ電力、減圧要件）に基づいて最適化することができる。

【００６１】

図６は、特定の厚さとデュロメータとを有する、例示的可撓性膜３７０を図示する。

【００６２】

図７は、表面積増加のためのひだのついた特徴３８０を伴う、可撓性膜３７５の別の実施形態を図示する。

【００６３】

可撓性膜に好適な材料は、当業者に公知である。多くの実施形態では、可撓性膜は、シリコーン、ＰＥＢＡＸ等のポリエーテルブロックアミド、およびネオプレン等のポリクロロプレン等の結合流体からの圧力に曝されると、膨張および収縮するように設計された材料から作製されることができる。代替として、可撓性膜は、ステンレス鋼、ニチノール、高デュロメータのポリマー、または高デュロメータのエラストマー等の実質的に剛性の材料から作製されることができる。これらの実施形態では、剛性の材料は、材料の降伏点を超えない可撓性膜の実質的な変形を可能にする応力および／または歪み分散要素とともに設計されるであろう。

【００６４】

図８Ａおよび８Ｂは、出口弁４０５が可撓性膜４１０の中に統合され、搾乳された母乳の流れを出口ポート４１５を通して制御する、乳房インターフェース４００の好適な実施形態を図示する。出口弁４０５は、図８Ａに示されるように、可撓性膜４１０が弛緩されたときに開放され、流体の流れを可能にし、また、図８Ｂに示されるように、可撓性膜４１０が変形されたときに閉鎖され、流体の流れを防止する。出口弁４０５は、抽出の間は、搾乳面積４２０に実質的な減圧圧力が存在するようにする一方、ポンプストロークの休止相の間は、母乳が排出することを可能にする。多くの従来型乳房ポンプ弁は、圧力差のみで機能する一方、出口弁４０５は、好ましくは、可撓性膜４１０の機械的移動にも機能するように構成されることができる。統合された出口弁４０５に、本明細書に記載されるような機械的機能性を組み込むことで、減圧形成の間、乳房インターフェース４００のシールを改良することができる。さらに、出口弁４０５等の可撓性膜４１０内における一体的に形成された出口弁の実装は、洗浄されるべきパーツの数を低減させる。

【００６５】

機械的ポンプデバイス

図９は、可撓性膜の代わりに機械的変形可能部材６０５が使用され得る、乳房インターフェース６００の代替的実施形態を図示する。機械的変形可能部材６０５は、本明細書に記載の可撓性膜のために使用されるものと類似技法から構成されることができる。機械的変形可能部材６０５は、引張要素６１０に結合される。ある場合には、引張要素６１０は、軸荷重吸収部材６１５内に配置される。軸荷重吸収部材６１５は、管６２０内に配置される。好ましくは、引張要素６１０が、軸荷重吸収部材６１５内に同心円状に配置され、軸荷重吸収部材６１５が、管６２０内に同心円状に配置される。引張要素６１０の代替的構成では、軸荷重吸収部材６１５および管６２０もまた、使用されることができる。

【００６６】

図１０は、アセンブリ筐体６３５内の作動アセンブリ６３０の駆動要素６２５に結合される引張要素６１０を図示する。駆動要素６２５は、シャフト６４０を通して、コントローラ内に格納された駆動機構等の駆動機構に動作可能に結合される。管６２０内の軸荷重吸収部材６１５は、アセンブリ筐体６３５に固定して結合される。駆動要素６２５の変位は、引張要素６１０を通して機械的変形部材６０５に張力を伝達し、減圧圧力を乳房に対して生成する。駆動要素６２５は、本明細書に前述される実施形態等の好適な駆動機構によって作動されることができる。

【００６７】

引張要素６１０は、ワイヤ、コイル、管、編組、ロープ、または任意のそれらの組み合わせ等の任意の好適なデバイスであることができる。例えば、引張要素６１０は、その周囲に配置されるステンレス鋼編組を伴う、小型ニチノールワイヤであることができる。引張要素６１０は、金属、ポリマー、またはエラストマー等、高い引張強度を有する多くの好適な材料から作製されることができる。軸荷重吸収部材６１５は、金属またはポリマー等、軸方向に合成の任意の好適な材料から作製されることができ、管またはコイル等、軸方向に合成の任意の好適な幾何学形状に構成されることができる。

【００６８】

流体収集および定量化システム

多くの事例では、母乳産出量の量（例えば、体積、重量）、搾乳頻度（例えば、時間、日付）、および／または搾乳持続時間等、母乳の搾乳ならびに収集等の収集された流体の種々の特性を測定および追跡することが望ましくあり得る。既存のアプローチでは、母乳産出の追跡は、一般に、手動測定および記録付けによって遂行される。本明細書に説明されるデバイスの例示的実施形態は、改良された利便性、効率、および正確度のために、デジタルベースの手段を提供し、母乳産出を自動的に測定および追跡してもよい。例えば、センサが、搾乳された母乳の体積を測定するために使用されることができる。好適な実施形態では、体積は、単位時間あたりの体積、ポンプストローク（例えば、作動アセンブリのストローク）あたりの体積、またはポンプ電力サイクル（例えば、作動アセンブリの電力サイクル）あたりの体積として測定されることができる。

【００６９】
例示的実施形態では、本明細書に説明されるポンプデバイスは、搾乳された母乳の体積等、母乳の搾乳の１つまたはそれを上回る特性を示す測定データを生成するために、１つまたはそれを上回るセンサを含む。体積の測定に関する本明細書における任意の説明はまた、他の特性の測定にも適用されることができ、その逆も同様である。加速度計、ホール効果センサ、およびフォトダイオード／ＬＥＤセンサ、ＣＣＤセンサ、カメラ、および他の撮像デバイス、容量センサ、歪みゲージ等の任意の好適なタイプのセンサが、使用されることができ、そのようなセンサは、任意の数および組み合わせにおいて使用されることができる。センサは、乳房インターフェース上またはその近傍等、乳房からの流体流れを監視するために好適な任意の場所（例えば、搾乳面積２６０、排出ポート２６５、採取容器２７５）に位置付けられることができる。母乳が、一対の乳房インターフェースを介して、一対の乳房から同時に搾乳される実施形態では、センサは、乳房インターフェースの両方の上もしくはその近傍、または乳房インターフェースの一方のみの上もしくはその近傍に位置することができる。センサは、ポンプデバイスと一体的に形成されるか、またはそれに恒久的に添着されてもよい。代替として、センサは、別個に提供され、使用に先立って、ポンプデバイスに結合されてもよい。

【００７０】
図１１Ａおよび１１Ｂは、弁統合式センサ４５５を伴う、乳房インターフェース４５０の例示的実施形態を図示する。センサ４５５は、好ましくは、フラップ弁４６０等の弁内に位置するが、また、流体流れによって開放される出口弁４６５または任意の他の弁（例えば、採取容器上またはその近傍）内に位置してもよい。例示的実施形態では、センサ４５５は、弁が開放される時間の長さ等、弁の位置および／または運動を測定する加速度計を含み、得られた測定データは、流体流れを定量化するために照会されることができる。好ましくは、乳房インターフェース４５０は、一対の乳房から母乳を並行して搾乳するために（例えば、同時に、交互に、または連続して）、第２の同じ乳房インターフェースと併用される。一対の加速度計が、各インターフェース内の対応する弁の位置および／または運動を検出するために使用されることができる。いくつかの事例では、ユーザの移動は、加速度計に、弁運動として誤って解釈される運動信号を生成させ得る。故に、好適な実施形態では、好適なアプローチが、ユーザの運動から生じる信号と、弁の運動によって生成される信号とを区別するために使用される。例えば、ポンプデバイスは、対応する弁もまた、交互に開放されるように、各乳房から交互に母乳を搾乳するように構成されることができる。その結果、両方の加速度計から同時に検出される運動は、弁運動からではなく、ユーザ運動から生じたものと見なされることができる。ユーザ運動は、弁運動を得るために、加速度計によって得られる総運動信号から減算され、それによって、各弁の位置を判定することができる。代替として、または組み合わせて、センサ４５５は、一式の弁加速度計に加え、一式の背景運動加速度計を備えてもよく、背景運動加速度計は、本明細書にさらに詳細に説明されるように、ユーザの運動を含む背景運動を測定するように構成される。背景運動加速度計によって測定される背景運動は、単離された弁運動を得るために、弁加速度計によって測定される運動から減算されてもよい。

【００７１】
図１１Ｃは、加速度計４７０を伴う実施形態をより明確に図示する。加速度計４７０は、乳房インターフェース４７４（本明細書では、遠位アセンブリとも称される場合がある）を有する、搾乳デバイス４７２の出力上の弁４７６に結合される。弁４７６は、フラップ弁、ダックビル弁、または同等物であってもよい。搾乳デバイスおよび乳房インターフェースは、本明細書に開示される実施形態のいずれかであってもよい。母乳４６８が搾乳されるにつれて、それは、デバイスの出力に収集される。十分な流体が収集されると、フラップ弁４７０は、開放し、母乳４６８は、リザーバ４６２の中に排出され、層４６４をその中に収集する。リザーバ４６２は、好ましくは、それが容易に取り付けられ、かつ取り外され得るように、搾乳デバイス４７２に螺合接続される。弁４７６の移動は、加速度計４７０を使用して追跡される。加速度計からのデータは、次いで、本明細書に開示され

る方法または手段のいずれかを使用して、処理、伝送、または表示される。

【００７２】

図１１Ｌ－１１Ｎは、背景運動加速度計４７３および弁運動加速度計４７８を有する、例示的実施形態を図示する。図１１Ｌは、例示的実施形態の等角図である。図１１Ｍは、例示的実施形態の側面断面図である。背景運動加速度計４７３は、乳房インターフェース２３５の一部、例えば、乳房インターフェースの筐体２４０に結合されてもよい。弁運動加速度計４７８は、弁４７１に結合されてもよく、弁４７１は、フラップ弁、ダックビル弁、または搾乳された母乳４６８によって付与される圧力もしくは重量に応答して開放するように構成される、任意の他の弁であってもよい。背景運動加速度計４７３および弁運動加速度計４７８は、電力ライン４８２を通して、電源、例えば、コントローラ１１５に結合されてもよい。背景運動加速度計４７３および弁運動加速度計４７８はさらに、通信ライン４８０を通して、コントローラ１１５等のポンプ制御ユニットの処理デバイスまたは通信モジュールに結合されてもよい。代替として、または組み合わせて、加速度計は、乳房インターフェースまたはリザーバの一部上に配置される通信モジュールに結合されてもよく、通信モジュールは、コントローラまたはコンピューティングデバイスと無線通信するように構成される。電力ライン４８２および通信ライン４８０は、１つまたはそれを上回るワイヤを備えてもよく、可撓性管類１１０の異なるチャネルまたは同一チャネル４８４内に配置され、乳房インターフェース２３５をポンプデバイスの作動アセンブリに結合してもよい。背景運動加速度計４７３は、電力ライン４８２および通信ライン４８０に近接して位置付けられるように、筐体２４０の表面上に配置されてもよい。同様に、弁運動加速度計４７８は、電力ラインおよび通信ラインに近接して位置付けられるように、弁４７１の表面上に配置されてもよい。弁４７１は、その上に配置される弁加速度計４７８が電力および通信ラインに近接して位置付けられることができるような構成に配列されてもよい。好ましくは、背景運動加速度計４７３は、加速度計によって生成される位置データの一貫性を最適化するように、その感知軸を弁加速度計４７１の軸に整合される場所および配向に配置されてもよい。

【００７３】

図１１Ｍに示されるように、搾乳された母乳４６８は、乳房インターフェース２３５の搾乳面積２６０に進入し、続いて、採取容器に結合される排出ポート２６５に進入することができる。母乳４６８の流体流れは、弁４７１に対して圧力を生成し、弁４７１を開放させることができる。例えば、弁４７１は、構成４８６まで矢印４８５によって示される方向に変位されてもよい。弁４７１の移動は、弁運動加速度計４７８によって追跡されてもよい。弁運動加速度計４７８は、多くの場合、弁の運動４７１に加え、ユーザ運動等の弁の運動４７１と関連しない背景運動を測定し得る。背景運動に対して弁運動加速度計４７８の測定を正規化するために、背景運動加速度計４７３は、弁の運動４７１と関連しないデバイスの背景運動を測定するように、空間内のポンプデバイスの全体的移動を追跡するように構成されることができる。加速度計４７３および４７８によって生成されるデータは、通信ライン４８０を介してポンプ制御ユニットの通信モジュールに伝送されてもよく、通信モジュールは、データ分析および／または表示のために、データをポンプ制御ユニットまたは別のコンピューティングデバイスのいずれかの処理デバイスに伝送するように構成されてもよい。代替として、または組み合わせて、加速度計によって生成されるデータは、乳房インターフェースまたはリザーバの一部と統合される通信モジュールを介して、無線で伝送されてもよい。

【００７４】

図１１Ｎは、背景運動加速度計４７３および弁運動加速度計４７８によって生成される運動信号の例示的グラフを示す。グラフに示されるように、弁運動加速度計４７８によって生成される弁信号４８７は、背景運動加速度計４７３によって生成される背景信号４８８と異なる。測定された弁運動への背景運動の寄与を除外または最小限にするために、背景信号４８８は、弁信号４８７から減算され、正規化された弁信号４８９を生成してもよい。

【００７５】
他の例示的実施形態では、本明細書に説明されるポンプデバイスは、ポンプデバイス内の好適な場所（例えば、弁、出口ポート、または流体通過を可能にする他の構成要素内もしくはその近傍）に据え付けられる、１つまたはそれを上回るビーム遮断センサ（例えば、赤外線ベース、レーザベース等）を利用することができる。ビーム遮断センサは、複数のセンサ構成要素を含むことができ、構成要素のうちの１つまたはそれを上回るものの間またはその近傍の流体の通過を検出するように構成されることができる。好ましくは、センサは、ビームエミッタとビーム検出器との間を通過することによって、搾乳された流体がビームを遮断すると、信号を生成するように構成されることができる。得られた信号は、搾乳された流体の体積を示す測定データを生成するために使用されることができる。例えば、測定データは、流体がセンサ構成要素間またはその近傍を通過する時間の長さに基づくことができる。

【００７６】
図１１Ｄは、ビーム遮断センサ４７７を採用する、母乳搾乳デバイスの例示的実施形態を図示する。搾乳デバイス４７２は、乳房インターフェース４７４と、リザーバ４６２とを含む。リザーバは、搾乳デバイス４６６に螺合または別様に結合される。本明細書に開示される搾乳デバイス、インターフェース、リザーバ等の例示的実施形態のいずれも、本例示的システムにおいて使用されてもよい。ビーム遮断センサ４７７は、搾乳デバイスの出力に隣接して配置され、したがって、母乳の液滴４６８が、搾乳デバイス出口からリザーバ４６２の中に排出されるにつれて、光ビーム４７７ａを遮断し、搾乳された流体の測定を可能にする。流体は、リザーバ４６２内の層４６４に収集される。センサからのデータは、次いで、本明細書に開示される方法のいずれかを使用して、処理、伝送、または別様に表示されることができる。

【００７７】
別の例示的実施形態では、本明細書に説明されるポンプデバイスは、電荷結合素子（ＣＣＤ）、相補型金属－酸化物－半導体（ＣＭＯＳ）内のアクティブピクセルセンサ、またはカメラ等の、搾乳体積を定量化するために、流体の画像を捕捉するための１つまたはそれを上回る画像センサを含むことができる。画像センサは、ポンプデバイスの好適な部分と統合されるか、またはそこに結合されてもよい。逆に言えば、画像センサは、スマートフォンまたは他のモバイルデバイス等、ポンプデバイスと別個の別のデバイス上に位置することができる。例示的実施形態では、乳房インターフェースは、本明細書に前述されるように、搾乳された流体の通過を可能にする弁を含み、好適な画像センサが、弁を通して通過する流体の画像を捕捉するために、弁上またはその近傍に位置付けられる。好ましくは、画像センサは、流体体積を判定するために、画像データを分析する（例えば、好適な画像分析アルゴリズムを使用して）ように構成される、処理ユニットに動作可能に結合される。例えば、画像センサは、流体の液滴の画像を捕捉するために使用されることができ、画像は、液滴の数を計数するために分析されることができる。いくつかの事例では、画像データは、以下にさらに詳細に説明されるように、分析のために、コンピューティングデバイス（例えば、スマートフォン）に伝送されることができる。

【００７８】
図１１Ｅは、搾乳デバイスの出口に隣接するＣＣＤまたはＣＭＯＳデバイス４７９を有する、例示的実施形態を図示する。搾乳デバイス４７２は、インターフェース４７４と、リザーバ４６２とを含み、いずれも、本明細書に開示される実施形態のいずれかであってもよい。母乳４６８が搾乳されるにつれて、それは、前述のように、流体を検出し、その定量化を可能にする、ＣＣＤまたはＣＭＯＳ４７９を越えて搾乳デバイスの出口を通過する。母乳４６８は、次いで、リザーバ４６２内の層４６４に蓄積される。デバイス４７９からのデータは、次いで、本明細書に開示される方法のいずれかを使用して、処理、伝送、または別様に表示されてもよい。

【００７９】
図１１Ｆは、リザーバの画像を使用して、搾乳された母乳を特性評価する、例示的実施

形態を図示する。いったん母乳４６８が、リザーバ４６２内に収集されると、リザーバは、随意に、搾乳デバイスから取り外されてもよい。写真を分析し、搾乳された母乳の量を判定し、随意に、搾乳された母乳についての他の詳細を提供するための好適なアプリケーションを有する、携帯電話が、次いで、リザーバの写真４６３ａを撮影するために使用されてもよい。データは、本明細書に開示される方法のいずれかを使用して、処理、伝送、または別様に表示される。

【００８０】

図１１Ｇは、光センサシステムの代替実施形態を図示する。母乳４６８が、搾乳され、リザーバ４６２内に収集された後、ポンプ制御ユニット４６５内のカメラが、リザーバ内の母乳の画像を得て、量または他の特性のために、それを分析するために使用されてもよい。ポンプ制御４６５は、本願のいずれかに説明されるポンプ制御のいずれかであってもよく、データは、本明細書に開示される方法のいずれかを使用して、処理、伝送、または表示されてもよい。

【００８１】

いくつかの例示的実施形態では、本明細書に説明されるポンプデバイスは、流体体積を測定するために、１つまたはそれを上回る容量センサを採用することができる。容量センサは、収集リザーバおよび／または乳房インターフェース内に含まれる流体等、ポンプデバイスの任意の好適な部分（例えば、搾乳面積２６０、弁、出口ポート、または管等のインターフェースからの流体の通過を可能にする構成要素）内に含まれる流体の体積を検出するように構成されることができる。

【００８２】

図１１Ｈ－１１Ｉは、容量センサを使用する、搾乳デバイスの例示的実施形態を図示する。搾乳デバイス４７２は、本明細書に開示される搾乳デバイスのいずれかであってもよく、同様に、本明細書に開示されるインターフェースのいずれかであり得る、インターフェース４７４を有する。リザーバ４６２は、搾乳デバイスに螺合４６６または別様に結合され、リザーバは、本明細書に説明されるリザーバのいずれかであってもよい。母乳４６８が、搾乳され、搾乳デバイスの出口に収集されるにつれて、それは、容量センサ４７５を通して通過し、これは、次いで、流体体積を測定することが可能となる。図１１Ｉは、図１１Ｈにおける実施形態に類似するが、主な差異は、容量センサ４７５ａが、搾乳デバイスの出口内ではなく、底部近傍のリザーバ４６２内に配置されることである。いずれの実施形態におけるセンサからのデータも、次いで、本明細書に説明される技法のいずれかを使用して、処理、伝送、または表示されてもよい。

【００８３】

他の例示的実施形態では、１つまたはそれを上回る歪みゲージが、搾乳された流体の体積を測定するために使用されることができる。歪みゲージは、ポンプデバイス内の任意の好適な位置に据え付けられることができる。例えば、歪みゲージは、フラップ弁（または搾乳された流体の通過を可能にする任意の他の弁）に結合され、弁の経時的変位に基づいて、体積を判定するように構成されることができる。代替として、または加えて、歪みゲージは、収集リザーバに結合され、リザーバ内に含まれる搾乳された流体の体積を測定するように構成されることができる。

【００８４】

図１１Ｊは、歪みゲージの例示的実施形態を図示する。搾乳デバイス４７２は、インターフェース４７４と、そこに螺合または別様に結合される４６６、リザーバ４６２とを含む。本システムの任意の部分は、本明細書のいずれかに説明される構成要素のいずれかであってもよい。母乳が搾乳される４６８につれて、それは、搾乳デバイスの出口内に蓄積する。最終的に、蓄積された母乳の重量は、弁４７６を作動および開放させるために十分である。歪みゲージ４８１は、フラップ弁に結合され、本センサは、次いで、弁の移動に関するデータを収集するために使用され、したがって、これは、収集された流体に相関する。流体は、リザーバ４６２内の層４６４に蓄積する。センサからのデータは、次いで、本明細書に開示される方法のいずれかを使用して、処理、伝送、または表示される。

【００８５】
図１１Ｋは、歪みゲージの代替実施形態を図示する。本実施形態は、概して、前述の実施形態と同一形態をとるが、主な差異は、収集された流体層４６４が、収集された流体の重量に耐える、プレート４８３上に配置されることである。したがって、重量が増加または減少するにつれて、プレート４８３下に配置される歪みゲージ４８１ａが、重量変化を検出し、これは、収集された流体体積に相関されることができる。センサからのデータは、次いで、本明細書に開示される方法のいずれかに従って、処理、伝送、または表示される。

【００８６】
図１１Ｏ－１１Ｑは、統合処理ユニットを備える、歪みゲージまたは力感応抵抗器（ＦＳＲ）の例示的実施形態を図示する。図１１Ｏは、実施形態の断面図である。歪みゲージ４９０は、搾乳された母乳４６８の負荷４６９を歪みゲージまたはＦＳＲ４９０のセンサ面積上に配置するような構成において、リザーバ４６２または本明細書に説明される任意のリザーバ等のリザーバの底部の中に統合されてもよい。歪みゲージ４９０は、それにかかる圧縮力に基づいてその抵抗を調節する、小型の力感応抵抗器を備えてもよい。負荷４６９に対する歪みゲージ４９０の感度を最大限にするために、リザーバ４６２の底部内部表面４９１は、負荷が歪みゲージに伝達されるにつれて、負荷４６９の吸収を最小限にするように設計されてもよい。例えば、底部内部表面４９１は、蛇腹要素４９２を備え、表面４９１を伸展させることによって、表面４９１が上下に移動することを可能にし、それによって、負荷４６９の吸収を最小限にしてもよい。好ましくは、リザーバ４６２は、内蔵タイプの電子機器を備え、歪みゲージ４９０を使用して生成されるデータを収集、処理、および通信する。図１１Ｏにおける実施形態の分解図である、図１１Ｐに示されるように、歪みゲージ４９０は、支持体４９３上に搭載され、処理ユニット４９４に結合されてもよい。電力が、バッテリまたはケーブルもしくはパッドコネクタ等の直接接触接続を介して、または好ましくは、誘導充電システムを介して、処理ユニット４９４に供給されてもよい。誘導充電システムは、処理ユニットに結合されるバッテリ４９５と、バッテリに結合され、当技術分野において公知の誘導充電方法を使用して充電され得る、無線充電器４９６とを備えてもよい。図１１Ｑは、処理ユニット４９４の詳細図である。処理ユニット４９４は、マイクロコントローラ４９４ａ、通信モジュール４９４ｂ、歪みゲージ接続４９４ｃ、電力接続４９４ｄ、およびタイマ４９４ｅのうちの１つまたはそれを上回るものを格納する、印刷回路基板（ＰＣＢ）を備えてもよい。処理ユニット４９４は、信号を歪みゲージ４９０から歪みゲージ接続４９４ｃを通して受信してもよく、信号は、マイクロコントローラ４９４ａに伝送されてもよい。マイクロコントローラ４９４ａは、歪みゲージ４９０から受信された信号を収集および処理するための命令を備える、非一過性コンピュータ可読媒体を備えてもよい。マイクロコントローラ４９４ａはさらに、収集および／または処理された信号を通信モジュール４９４ｂに伝送するための命令を備えてもよい。通信モジュール４９４ｂは、例えば、Ｂｌｕｅ　Ｔｏｏｔｈモジュール等の無線送信機／受信機を備えてもよい。通信モジュール４９４ｂは、データ分析および／または表示のために、歪みゲージデータを搾乳デバイスのポンプ制御ユニットまたは携帯電話等の別のコンピューティングデバイスに伝送するように構成されてもよい。

【００８７】
図１１Ｏ－１１Ｑの実施形態の統合処理ユニットはまた、本明細書に説明される任意の他のセンサと好適に組み合わせられてもよい。説明されるような統合センサおよび処理ユニットを有するリザーバを伴う、搾乳デバイスは、母乳産出の管理および監視の自動化に役立ち、したがって、母乳産出に関連する記録を手動で維持する必要性を低減させることができる。例えば、説明されるような歪みゲージシステムは、産生された母乳の量を監視し、自動的に、データを処理し、ユーザが情報に容易にアクセスし得る、コンピューティングデバイスに送信することができる。そのようなシステムは、ユーザにとって利便性を大幅に改善し、また、手動記録維持に関連する人的エラーを低減させるのに役立つことができる。

【００８８】
例示的実施形態では、センサによって収集された測定データの一部または全部は、流体搾乳を最適化するために、ポンプデバイスにフィードバックされることができる。好ましくは、フィードバックは、作動アセンブリの１つまたはそれを上回る機能性を制御するように構成される、ポンプデバイスの処理ユニットおよび／または制御ユニット（例えば、コントローラ１１５内に位置する好適なハードウェア）に伝送されることができる。フィードバックに基づいて、処理ユニットは、最適流体搾乳を達成および／または維持するために、作動アセンブリの作動パラメータへの変更を判定することができる。例えば、フィードバックは、ポンプ、ピストンアセンブリ、または任意の他の好適な作動アセンブリの減圧ストロークまたは１分あたりのサイクルへの調節を判定するために使用されることができる。

【００８９】
図２１は、フィードバック制御を伴う、例示的搾乳システムを図示する。システムは、好ましくは、コントローラおよびプロセッサ２１０４ならびにデバイスを作動させるためのモータ２１０２を含む、ポンプユニット２１００と、標的生体構造、ここでは、乳房２１１２と噛合するようなサイズおよび形状にされる、遠位アセンブリ２１１０とを含む。本例示的システムにおける要素のいずれも、他の例示的実施形態における本明細書にいずれかに開示される構成要素のいずれかであってもよい。本実施形態では、搾乳デバイス２１１０内の搾乳された母乳を監視する、センサからのフィードバック２１０６は、遠位アセンブリ（インターフェースを伴う搾乳デバイス）からコントローラおよびプロセッサ２１０４に伝送される。データは、処理され、本情報は、搾乳デバイスの作動を増加または減少させる命令をモータ２１０２に提供するために使用され、次いで、これは、通信２１０８によって、搾乳デバイスまたは遠位アセンブリ２１１０に返信される。フィードバック情報はまた、搾乳デバイスの１分あたりのストロークまたはサイクル数を変更するための命令をモータ２０１２に提供するために使用されてもよい。本明細書における実施形態のいずれも、そのようなフィードバックループを含んでもよい。

【００９０】
図１２は、ディスプレイ画面５０５を含むポンプデバイスのためのコントローラ５００の例示的実施形態を図示する。コントローラ５００は、本明細書に説明される母乳の搾乳データならびに搾乳データの処理から得られた分析結果を収集、処理、および記憶するために好適なハードウェアを含むことができる。好適な実施形態では、本情報は、ディスプレイ画面５０５を介してポンプデバイスのユーザに表示される。さらに、図１３に示されるように、情報はまた、以下にさらに詳細に説明されるように、コントローラ５００から伝送され、モバイルデバイス５１０等の別個のコンピューティングデバイス上に表示されることができる。情報は、グラフ、チャート、表、画像、または異なる色の１つもしくはそれを上回る光等の他の視覚的要素を含む、任意の好適な形式で提示されることができる。代替として、または組み合わせて、情報は、聴覚的インジケータを介して提供されてもよい。情報は、静的または動的である（例えば、リアルタイムで更新される等）形式で提示されてもよい。加えて、コントローラ５００は、ボタン５１５、ならびにキーボード、ジョイスティック、タッチスクリーン、スイッチ、またはノブ、もしくはそれらの好適な組み合わせ等、ユーザが表示される情報と相互作用することを可能にする入力デバイスを含むことができる。

【００９１】
コンピューティングデバイスとの通信
本明細書に開示される実施形態のいずれかでは、本明細書に説明されるポンプデバイスは、１つまたはそれを上回るコンピューティングデバイスおよび／またはサーバ等、別のエンティティと通信するように構成されることができる。例示的コンピューティングデバイスとして、パーソナルコンピュータ、ラップトップ、タブレット、およびモバイルデバイス（例えば、スマートフォン、携帯電話）が挙げられる。本明細書に説明されるサーバは、物理的ハードウェア、仮想化コンピューティングリソース（例えば、仮想機械）、ま

たは任意の好適なそれらの組み合わせを横断して実装されることができる。好適な実施形態では、サーバは、公共および／または私的分散型コンピューティングリソースの任意の好適な組み合わせを利用する、分散型コンピューティングサーバ（クラウドサーバとしても知られる）である。コンピューティングデバイスおよび／またはサーバは、ポンプデバイスに近接近してもよく（短距離通信）、またはポンプデバイスから遠隔に据え付けられてもよい（長距離通信）。コンピューティングデバイスとポンプデバイスとの間の通信に関する本明細書における任意の説明はまた、サーバとポンプデバイスおよびその逆との間の通信にも適用されることができる。

【００９２】

図１３は、ポンプデバイスのコントローラ５００とモバイルデバイス５１０との間の短距離通信５１５を図示する。通信５１５は、以下に説明されるように、無線通信方法を利用することができる。多くの実施形態では、コントローラ５００およびモバイルデバイス５１０はまた、長距離通信可能である。

【００９３】

図１４は、コンピューティングデバイス８０５およびサーバ８１０と通信する、ポンプデバイス８００の概略図である。ポンプデバイス８００は、１つまたはそれを上回る乳房インターフェース８１５と、作動アセンブリ８２０と、感知ユニット８２５と、通信モジュール８３５とを含む。好ましくは、通信モジュール８３０は、ポンプデバイスのコントローラ（例えば、コントローラ５００）内の好適なハードウェアを横断して実装される。ポンプデバイス８００は、通信モジュール８３０を介して、コンピューティングデバイス８０５およびサーバ８１０と通信することができる。多くの実施形態では、通信モジュール８３０は、第１および第２のデータ接続８３５、８４０を介して、コンピューティングデバイス８０５およびサーバ８１０に通信可能に結合される。さらに、サーバ８１０は、第３のデータ接続８４５を介して、コンピューティングデバイス８０５に通信可能に結合され得る。ポンプデバイス８００は、本明細書ではコンピューティングデバイス８０５およびサーバ８１０と直接通信するように描写されるが、他の構成もまた、可能性として考えられる。例えば、ポンプデバイス８００は、コンピューティングデバイス８０５を介して、サーバ８１０と間接的に通信するか、または逆も同様であってもよい。逆に、サーバ８１０は、コンピューティングデバイス８０５を介して、ポンプデバイス８００と間接的に通信してもよく、コンピューティングデバイス８０５は、サーバ８１０を介して、ポンプデバイス８００と通信してもよい。ポンプデバイス８００、コンピューティングデバイス８０５、またはサーバ８１０間の通信に関する本明細書における任意の説明は、これらのエンティティ間の直接通信ならびに間接通信に適用されることができる。

【００９４】

データ接続８３５、８４０、および８４５は、ポンプデバイス８００、コンピューティングデバイス８０５、およびサーバ８１０間でデータを伝送するための好適な任意の通信方法を利用することができる。そのような通信方法は、有線通信（例えば、ワイヤ、ＵＳＢケーブル等のケーブル、光ファイバ）および／または無線通信（Ｂｌｕｅｔｏｏｔｈ（登録商標）、ＷｉＦｉ、近距離通信）を含むことができる。多くの実施形態では、データは、ローカルエリアネットワーク（ＬＡＮ）、広域ネットワーク（ＷＡＮ）、電気通信ネットワーク、インターネット、またはそれらの好適な組み合わせ等、１つまたはそれを上回るネットワークを経由して伝送されることができる。

【００９５】

例示的実施形態では、ポンプデバイス８００は、母乳の搾乳データをコンピューティングデバイス８０５またはサーバ８１０（直接もしくは間接的に）に伝送する。母乳の搾乳データは、本明細書に前述されるように、ポンプデバイス８００の感知ユニット８２５によって生成される測定データを含むことができる。多くの実施形態では、ポンプデバイス８００は、測定データを分析し（例えば、好適な内蔵ハードウェアおよび／またはソフトウェアを使用して）、分析結果をコンピューティングデバイス８０５またはサーバ８１０に伝送する。代替として、測定データは、１つまたはそれを上回るアプリケーションを使

用して等、コンピューティングデバイス８０５またはサーバ８１０によって分析されることができる。コンピューティングデバイス８０５またはサーバ８１０は、測定データおよび／または分析結果の記憶のために、データ記憶と関連付けられてもよい。

【００９６】

（コンピューティングデバイス８０５またはサーバ８１０の）アプリケーションはまた、本明細書に前述されるように、測定データおよび／または分析結果を収集ならびに集積し、好適な形式（例えば、チャート、表、グラフ、画像等）において、それらをユーザに表示することができる。好ましくは、アプリケーションは、そのような情報と母乳産出統計の比較を促進するために、ユーザが、母乳産出を増加させるため生活様式選択肢、食事、および方略等の情報をオーバーレイすることを可能にする、付加的特徴を含む。本明細書に説明される分析および表示機能性は、単一エンティティまたはエンティティの任意の好適な組み合わせによって行われてもよい。例えば、多くの実施形態では、データ分析は、サーバ８１０によって実施され、分析結果が、ユーザへの表示のために、ポンプデバイス８００またはコンピューティングデバイス８０５に伝送されることができる。

【００９７】

加えて、コンピューティングデバイス８０５またはサーバ８１０は、電力、印加される減圧圧力（インターフェース８１５を介して）、または１分あたりのサイクル等、ポンプデバイス８００またはその一部（例えば、作動アセンブリ８２０）の少なくとも１つの機能性を制御するように構成される、アプリケーションを含むことができる。例えば、通信モジュール８３０は、コンピューティングデバイス８０５および／またはサーバ８１０からの制御信号を受信し、制御信号を作動アセンブリ８２０に伝送し、所望の作動をもたらすことができる。好適な実施形態では、制御信号は、本明細書に前述されるように、感知ユニット８２５によって提供される測定データに基づいて、そのようなフィードバックとしてポンプデバイス８００によって提供されるフィードバックを使用して生成されることができる。加えて、コンピューティングデバイス８０５またはサーバ８１０は、ポンプ性能を経時的に改善および最適化するために、ポンプデバイス８００の制御に関する機械学習技法を実装してもよい。

【００９８】

さらに、ポンプデバイス８００、コンピューティングデバイス８０５、および／またはサーバ８１０は、母乳を搾乳するようにユーザにリマインドする通知を提供するように構成されることができる。そのような通知は、ポンプセッションの逸失を回避するのに役立ち、したがって、乳腺炎等の関連付けられた合併症の発生を低減させることができる。通知は、以前のポンプセッションの搾乳頻度および／またはタイミングに関するデータ等、以前に収集された母乳の搾乳データに基づいて、かつユーザ選好に基づいて、生成されることができる。好ましくは、通知機能性は、コンピューティングデバイス８０５またはサーバ８１０上で起動する好適なアプリケーション内に含まれる。例えば、ポンプデバイス８００は、アプリケーションが、ポンプ圧送が生じたときを識別し、所望のポンプ時間にリマインダを識別し得るように、ポンプの使用時間についての情報をコンピューティングデバイス８０５またはサーバ８１０に送信することができる。

【００９９】

通知は、任意の好適な方法を使用して、そして任意の好適な形式において提供されることができる。例えば、通知は、コンピューティングデバイス８０５またはサーバ８１０によって生成され、ポンプデバイス８００（例えば、通信モジュール８３０）に伝送され、ユーザに表示される（例えば、ディスプレイ画面５０５等のポンプデバイス８００のディスプレイ上に）ことができる。逆に、通知は、ポンプデバイス８００によって生成され、コンピューティングデバイス８０５および／またはサーバ８１０に伝送されることができる。多くの実施形態では、通知は、コンピューティングデバイス８０５によって、ユーザに表示される。代替として、ポンプデバイス８００、コンピューティングデバイス８０５、および／またはサーバ８１０は、他の方法を使用して、通知をユーザに提供することができる。例えば、通知は、電子メールアドレスに、ショートメッセージサービス（ＳＭＳ

）を介して携帯電話番号と関連付けられたスマートフォンもしくは他のモバイル装置に、またはユーザによってアクセス可能なウェブページに送信されることができる。

【０１００】

他のタイプのデータもまた、ポンプデバイス８００、コンピューティングデバイス８０５、および／またはサーバ８１０間で伝送されることができる。例えば、多くの実施形態では、ポンプデバイス８００の１つまたはそれを上回る構成要素のためのファームウェア更新が、コンピューティングデバイス８０５および／またはサーバ８１０からポンプデバイス８００に伝送されることができる。

【０１０１】

図１７は、母乳の搾乳または他の流体を監視するためのシステムの別の例示的実施形態を図示する。システム１７００は、ポンプユニット１７０２と、遠位アセンブリ１７０６（本明細書では、インターフェースとも称される場合がある）と、無線通信送信機および受信機１７０９、１７１２と、コンピューティングデバイス１７１４と、遠隔サーバ１７１８とを含む。ポンプユニット１７０２は、本明細書に説明されるか、または当技術分野において公知のポンプユニットのいずれかであってもよく、遠位アセンブリ１７０８はまた、それらの本明細書に説明されるか、または当技術分野において公知のもののいずれかであってもよい。遠位アセンブリ１７０６は、好ましくは、本例示的実施形態では、乳房１７０８である、標的生体構造に一致するようなサイズおよび形状にされる。ポンプユニット１７０２は、遠位アセンブリ１７０６を作動させ１７０４、本明細書に開示される作動機構のいずれかを使用して、乳房１７０８からの母乳の搾乳を生じさせる。送信機１７０９は、好ましくは、ポンプユニット上に、またはそこに隣接して配置され、データ１７１０をポンプユニットからコンピューティングデバイス１７１４上の受信機１７１２に伝送するように構成される。データは、本明細書に開示されるもの等の当技術分野において公知の方法を使用して、無線で伝送されてもよい。代替実施形態では、ＵＳＢケーブルを用いて等、有線接続が、ポンプ１７０２およびコンピューティングデバイス１７１４をともに動作可能に結合するために使用されてもよい。コンピューティングデバイスは、スマートフォン、タブレット、パーソナルコンピュータ、またはポンプユニット１７０２から伝送されたデータを表示することができる、任意の他の電子コンピューティングデバイスであってもよい。コンピューティングデバイスはまた、情報をポンプユニットに返信し、遠位アセンブリの動作の制御に役立ててもよい。コンピューティングデバイス１７１４はまた、データを記憶または表示し得る、遠隔サーバ１７１８と通信１７１６してもよい。遠隔サービス１７１８へのアクセスは、インターネットまたは当技術分野において公知の他の手段によって行われてもよく、したがって、クラウドベースのデータが、インターネットアクセスを用いて、任意の他のデバイスから容易にアクセスされ得る。

【０１０２】

図１８は、母乳の搾乳のためのシステム１８００の別の例示的実施形態を図示する。本実施形態では、システム１８００は、ポンプユニット１８０２と、遠位アセンブリ１８０６と、クラウドベースまたは遠隔サーバ１８１２とを含む。ポンプユニット１８０２は、本明細書に開示されるポンプのいずれかであってもよく、乳房１８０８等の標的に一致するようなサイズおよび形状にされる、遠位アセンブリ１８０６と動作可能に結合される。遠位アセンブリは、本明細書に説明される遠位アセンブリのいずれかであってもよい。ポンプユニット１８０２は、本明細書に開示される機構のいずれかを使用して、遠位アセンブリを作動１８０４させ、乳房１８０８からの母乳の搾乳を生じさせる。ポンプユニット１８０２はまた、ポンプデータ１８１０を、本実施形態では、クラウドベースのサーバである、遠隔サーバ１８１２に伝送するための送信機および受信機１８０９を含む。したがって、データは、インターネットを介して、遠隔サービスに伝送され、インターネットを介して、ポンプ１８０２または任意の他のコンピューティングデバイスによって、クラウドベースのサーバからアクセスされてもよい。好ましくは、クラウドベースのサーバとの通信は、無線通信によって行われる。

【０１０３】

図１９Ａ－１９Ｃは、例示的コンピューティングデバイスディスプレイ１９０４を図示する。例えば、図１９Ａは、携帯電話１９０２上の例示的ディスプレイを図示し、母乳産出、最後のポンプセッションの時間、目標達成のグラフィック、およびユーザの流体消費を図示するグラフィックを図式的に図示する。加えて、ディスプレイ１９０４はまた、母乳産出の量に基づいて、ユーザ奨励またはユーザフィードバックを提供してもよい。図１９Ｂは、図１９Ａにおけるディスプレイ１９０４の拡大図である。図１９Ｃは、ディスプレイ１９０４が、タッチスクリーンが作動される（例えば、画面をスワイプまたはタッチすることによって）ときに示し得る、付加的情報を図示する。例えば、搾乳された母乳の体積が、ディスプレイの「最終ポンプセッション」区分が選択された後に示される。一部または全部のアイテムは、同様に図１９Ｃに示されるように、拡張されてもよい。付加的情報、またはいくつかの状況では、より少ない情報が、所望に応じて表示されてもよい。

【０１０４】

図２０Ａ－２０Ｂは、母乳搾乳システムにおいて使用され得る、他の例示的ディスプレイを図示する。例えば、図２０Ａは、本明細書に開示されるコンピューティングデバイスのいずれか上にあって、本明細書に説明されるポンプユニットのいずれかと動作可能に結合される、例示的ディスプレイ２００２である。ディスプレイは、その同一期間の間の搾乳セッションの平均持続時間とともに、任意の期間にわたって搾乳された母乳の平均体積を示してもよい。グラフィック（例えば、棒グラフ、円グラフ、ｘ－ｙプロット等）が、ここでは、月曜日から金曜日までの数日の経過にわたる個々のセッションの間に搾乳された体積を示すために使用されてもよい。ディスプレイは、ユーザが、例えば、セッションが旅行に起因して省略される場合、逸失したセッションが考慮され得るように、ディスプレイに注釈を付けることを可能にしてもよく、ディスプレイは、その期間の間の旅行を示してもよい。ここでは、ホップまたはフェヌグリークである、ある食品または栄養補助剤が摂取されたとき等、他の注釈もまた、付けられてもよい。これは、ユーザが、搾乳された母乳サンプルが、食品または栄養補助剤の消費に対して得られたときを思い出させることを可能にする。ディスプレイは、アドバイスを求める、クラウドにアクセスする、アラームを設定する、メモをとる、データを記憶する、またはシステム選好を確立するため等の他の機能ボタンを有してもよい。図２０Ａ－２０Ｂにおけるコンピューティングデバイスとポンプユニットとの間の通信は、図１３に関連して前述でより完全に論じられている。

【０１０５】

図２０Ｂは、システム内のコンピューティングデバイス上にあり得るか、またはより好ましくは、本明細書に開示されるポンプのいずれか上にある、例示的ディスプレイ２００４を図示する。ディスプレイ２００４は、ダッシュボード式ゲージに類似し、搾乳および収集された流体の体積およびその時間を示す。他の情報もまた、表示されてもよい。

【０１０６】

実験データ

図１５および１６は、市販の乳房ポンプデバイスおよび本発明の例示的実施形態から得られた実験的ポンプ動作のデータを図示する。例示的実施形態は、ポンプ圧送のために非圧縮性流体を利用し、４ｃｃの最大水圧流体体積を有する一方、市販のデバイスは、ポンプ圧送のために空気を利用し、１１４ｃｃの最大体積を有した。

【０１０７】

図１５は、１行程あたり生成される減圧圧力によって定量化された際のポンプ性能のグラフを図示する。例示的実施形態に関しては、ポンプによって変位された流体体積の１ｃｃ、２ｃｃ、３ｃｃ、および４ｃｃに対して圧力測定が行われ、行程番号は、体積ｃｃに対応する。市販のデバイスに関しては、それぞれ、ポンプによって変位された流体体積の４６ｃｃ、５７ｃｃ、６８ｃｃ、８０ｃｃ、９１ｃｃ、１０３ｃｃ、および１１４ｃｃを表す減圧調整ゲージに沿った７つの等間隔で増分された位置の１つに設定されたポンプを用いて測定が行われ、行程番号は、位置番号に対応する。曲線７００は、例示的実施形態に対応し、曲線７０５は、市販のデバイスに対応する。例示的実施形態は、市販のデバイ

スと比較して、変位体積あたりより高レベルの減圧圧力を生成し、最高減圧圧力は、それぞれ、－２４０．５ｍｍＨｇおよび－１７７．９ｍｍＨｇであった。

【０１０８】

図１６は、変位された流体の最大体積あたりの最大減圧圧力によって測定されたポンプ効率のグラフを図示し、バー７１０は、例示的実施形態に対応し、バー７１５は、市販のデバイスに対応する。例示的実施形態は、市販のデバイスと比較して、４２倍のポンプ効率増加を実証し、効率は、それぞれ、－７１．１ｍｍＨｇ／ｃｃおよび－１．７ｍｍＨｇ／ｃｃであった。

【０１０９】

本明細書に説明される種々の技法は、記憶媒体およびコンピュータ可読媒体上に記憶可能であって、コンピュータシステムの１つまたはそれを上回るプロセッサによって実行可能なコードを使用して、部分的または完全に実装されてもよい。コードまたはコードの一部を含む記憶媒体およびコンピュータ可読媒体は、ＲＡＭ、ＲＯＭ、ＥＥＰＲＯＭ、フラッシュメモリまたは他のメモリ技術、ＣＤ－ＲＯＭ、デジタル多用途ディスク（ＤＶＤ）または他の光学記憶、磁気カセット、磁気テープ、磁気ディスク記憶または他の磁気記憶デバイス、ソリッドステートドライブ（ＳＳＤ）または他の固体ソリッドステート記憶デバイス、もしくは所望の情報を記憶するために使用されることができ、かつシステムデバイスによってアクセスされることができる、任意の他の媒体を含む、コンピュータ可読命令、データ構造、プログラムモジュール、または他のデータ等の情報の記憶および／または伝送のための任意の方法または技術において実装される、限定ではないが、揮発性および不揮発性、取り外し可能および取り外し不可能な媒体等の記憶媒体および通信媒体を含む、当技術分野において公知のまたは使用される任意の適切な媒体を含むことができる。本明細書に提供される開示および教示に基づいて、当業者は、種々の実施形態を実装する他のやり方および／または方法を理解し得る。

【０１１０】

本発明の異なる側面は、個々に、集合的に、または相互に組み合わせて、認識され得ることを理解されたい。本明細書に説明される実施形態のいずれかの好適な要素または特徴は、任意の他の実施形態の要素または特徴と組み合わせられる、もしくはそれと置換されることができる。

【０１１１】

本発明の好適な実施形態が、本明細書に示され記述されたが、このような実施形態が、例としてのみ提示されることは当業者にとって当然である。多くの変形、変更、および代替が、今や、本発明から逸脱することなく当業者に想起され得る。本明細書に記載された本発明の実施形態への種々の代替が、本発明の実施に使われ得るものと理解されるべきである。以下の請求項は、本発明の範囲を画定することを意図したもので、これら請求項の範囲内にある方法、構成、およびそれらの均等物は、それによって包含されることが意図される。

【図１】

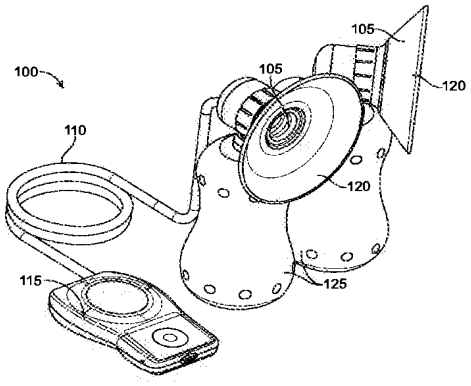

FIG. 1

【図２】

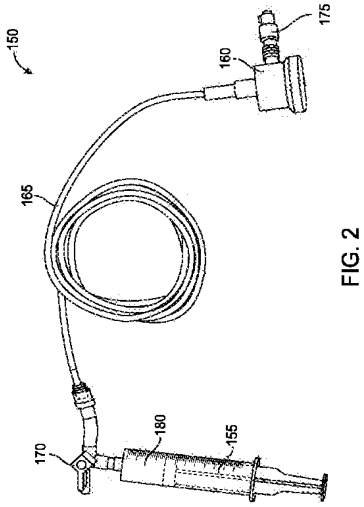

FIG. 2

【図３】

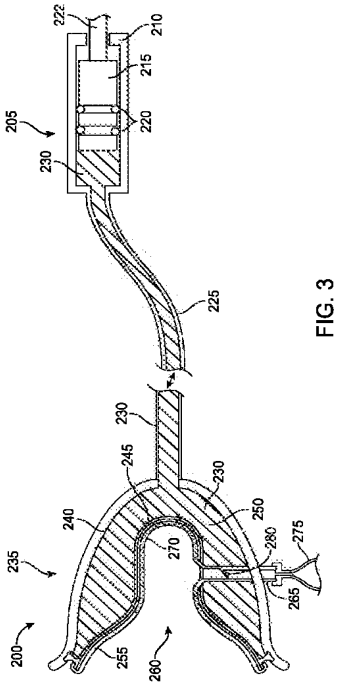

FIG. 3

【図４】

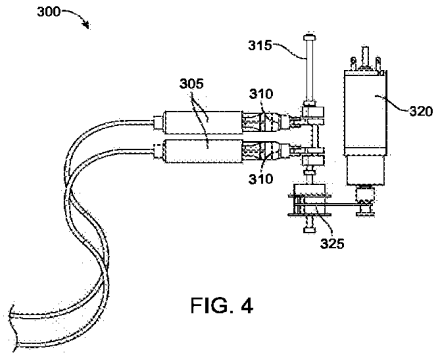

FIG. 4

【図５Ａ】

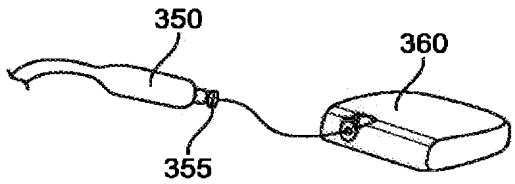

FIG. 5A

【図５Ｂ】

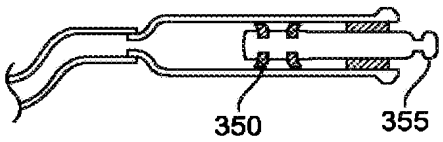

FIG. 5B

【図６】

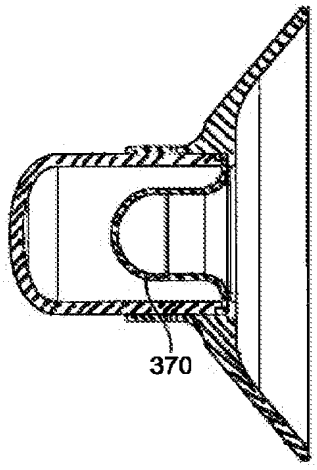

FIG. 6

【図７】

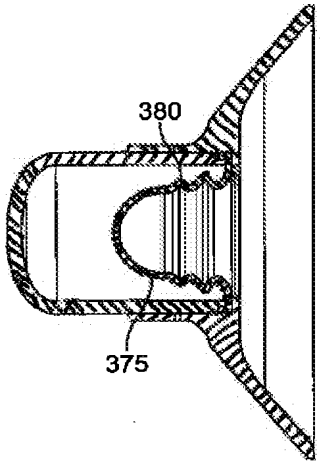

FIG. 7

【図８Ａ】

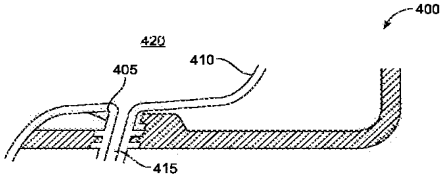

FIG. 8A

【図８Ｂ】

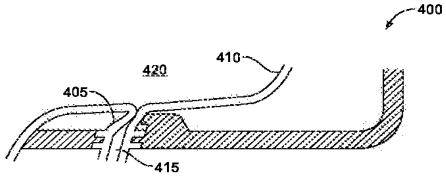

FIG. 8B

【図９】

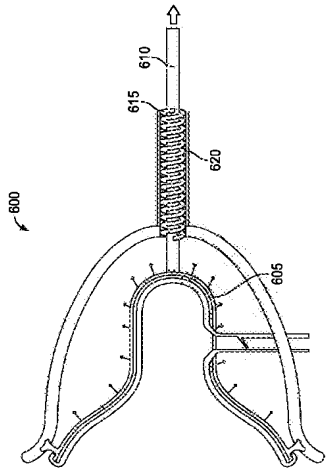

FIG. 9

【図１０】

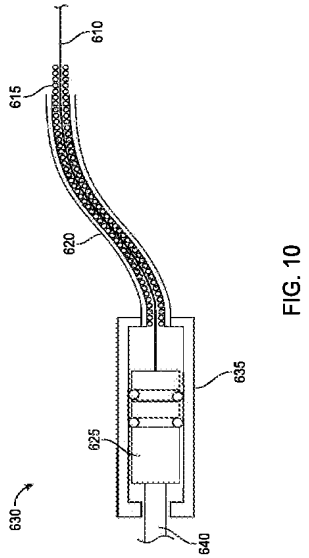

FIG. 10

【図１１Ａ】

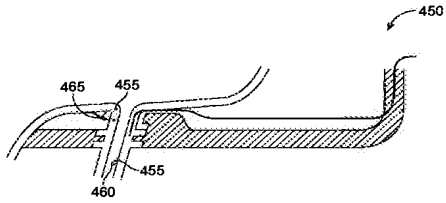

FIG. 11A

【図１１Ｂ】

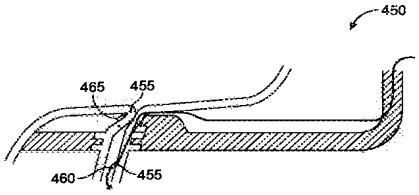

FIG. 11B

【図１１Ｃ】

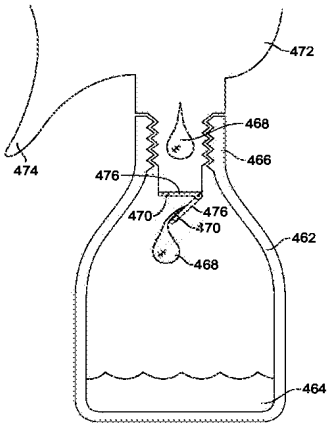

FIG. 11C

【図１１Ｄ】

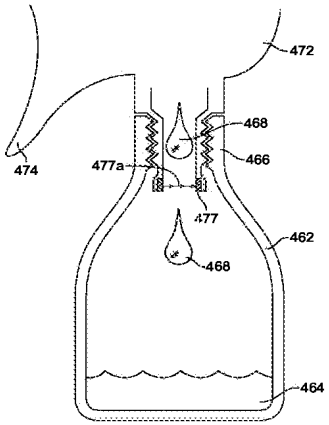

FIG. 11D

【図１１Ｅ】

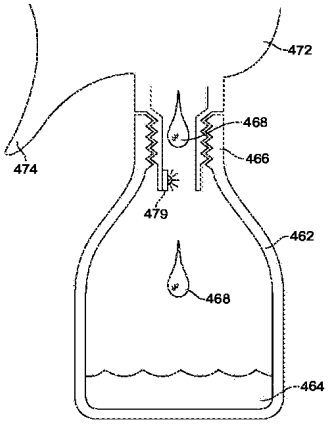

FIG. 11E

【図１１Ｆ】

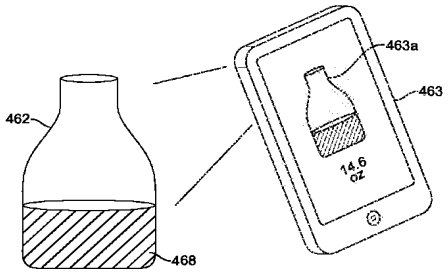

FIG. 11F

【図１１Ｇ】

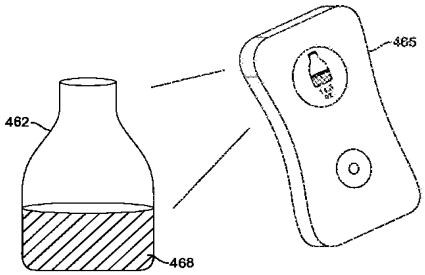

FIG. 11G

【図１１Ｈ】

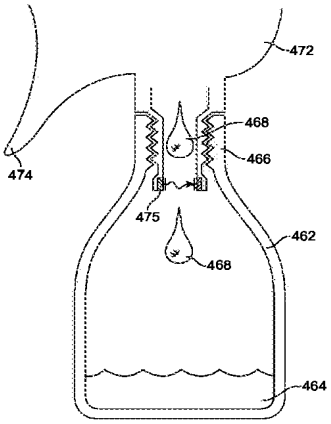

FIG. 11H

【図１１Ｉ】

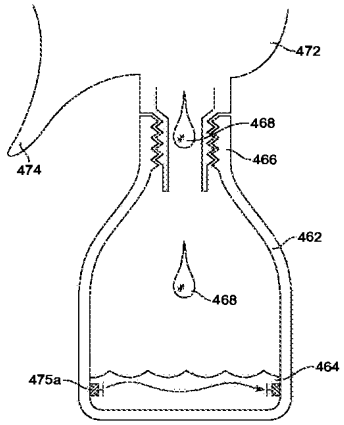

FIG. 11I

【図１１Ｊ】

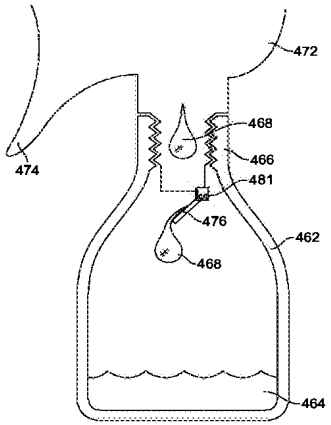

FIG. 11J

【図１１Ｋ】

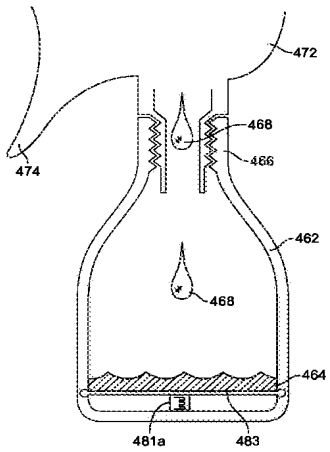

FIG. 11K

【図１１Ｌ】

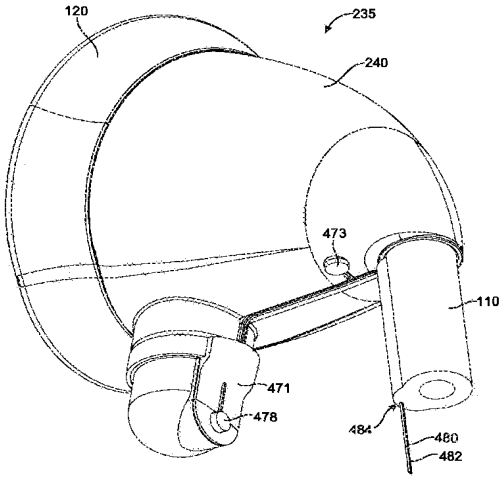

FIG. 11L

【図１１Ｍ】

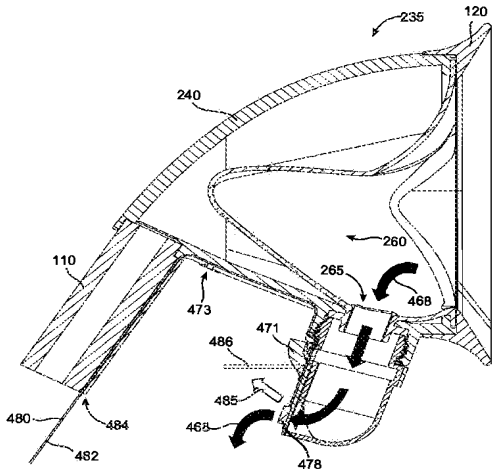

FIG. 11M

【図１１Ｎ】

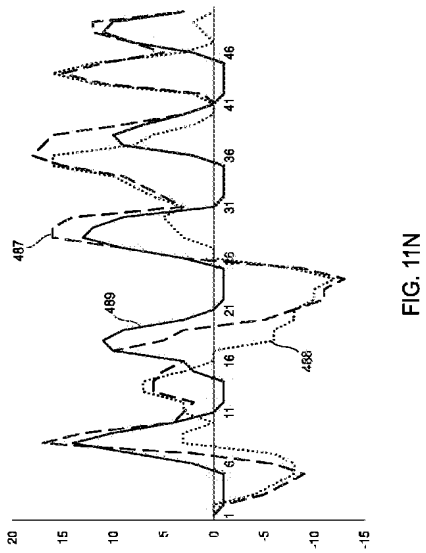

FIG. 11N

【図１１Ｏ】

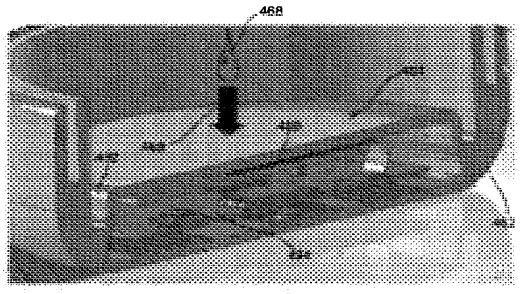

FIG. 11O

【図１１Ｐ】

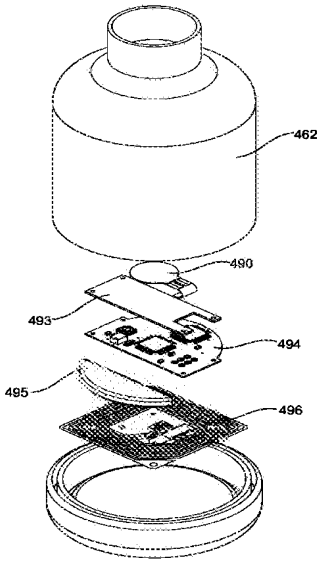

FIG. 11P

【図１１Ｑ】

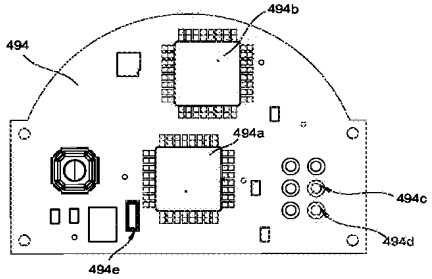

FIG. 11Q

【図１２】

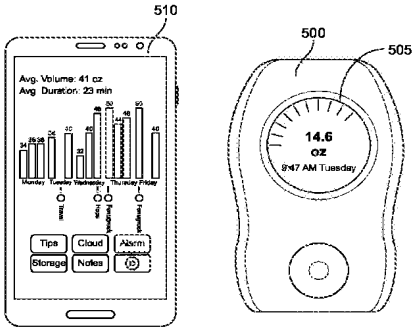

FIG. 12

【図１３】

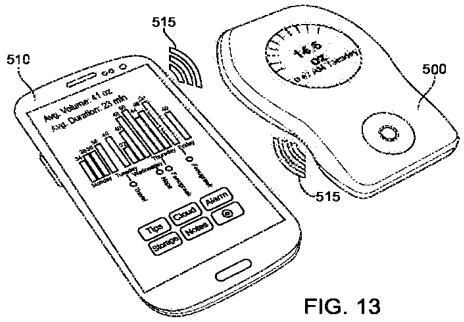

FIG. 13

【図１４】

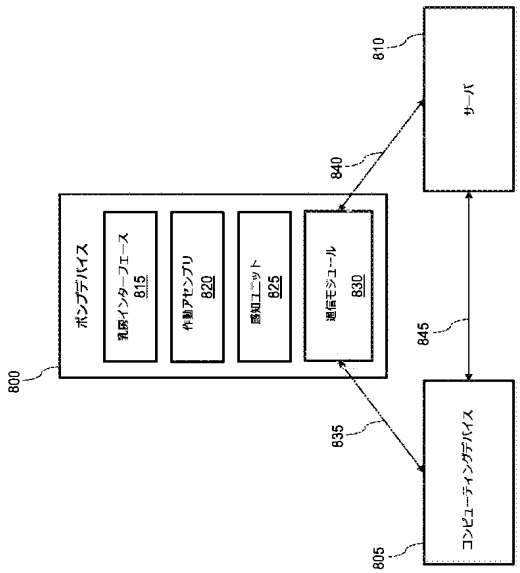

FIG. 14

【図１５】

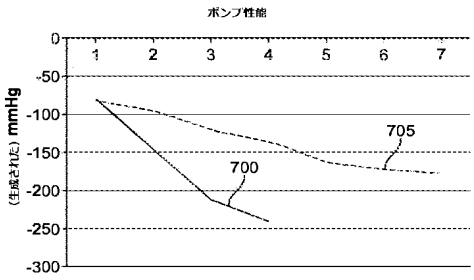

FIG. 15

【図１６】

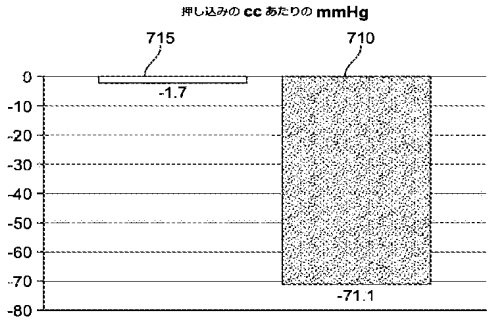

FIG. 16

【図１７】

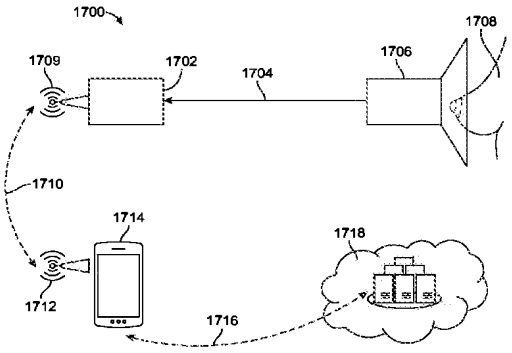

FIG. 17

【図１８】

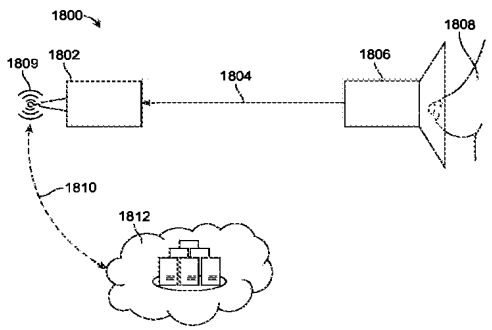

FIG. 18

【図１９Ａ】

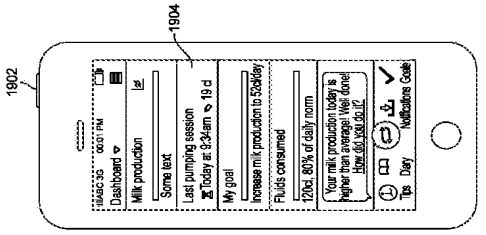

FIG. 19A

【図１９Ｂ】

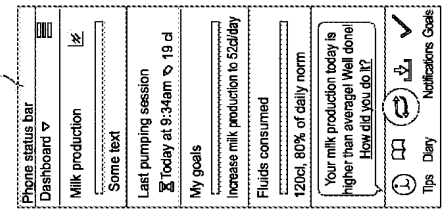

FIG. 19B

【図１９Ｃ】

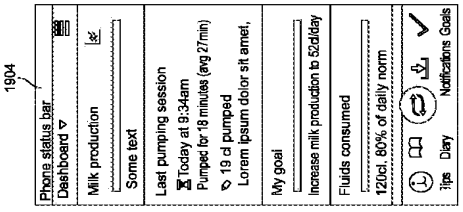

FIG. 19C

【図２０Ａ】

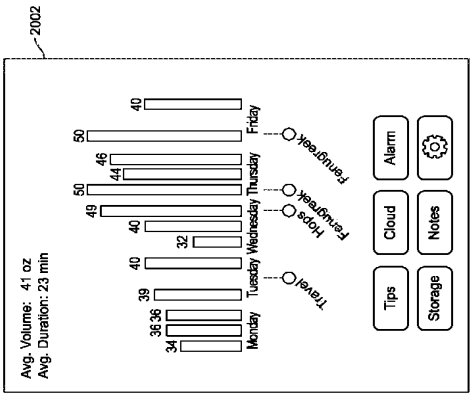

FIG. 20A

【図２０Ｂ】

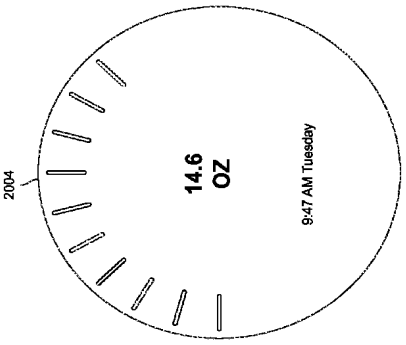

FIG. 20B

【図２１】

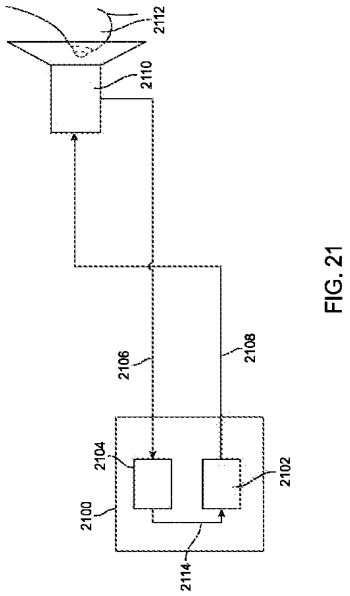

FIG. 21

【図２２】

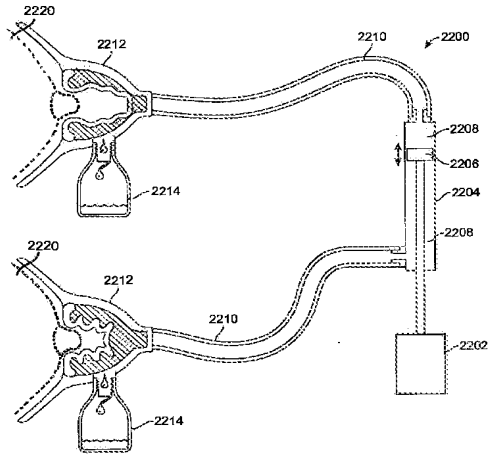

FIG. 22

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US15/14901

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A01J 5/00, 5/007; A61M 1/06 (2015.01)
CPC - A01J 5/047; A61M 1/06
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8): A01J 5/00, 5/007; A61M 1/06 (2015.01)
CPC: A01J 5/047; A61M 1/06; USPC: 119/14.02; 604/74, 346

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatSeer (US, EP, WO, JP, DE, GB, CN, FR, KR, ES, AU, IN, CA, INPADOC Data); Google; Google Scholar; Google Patent; ProQuest; Medline/PubMed. Search terms: Breast*, Milk*, Mammar* W5 Pump*, Express*, Vacuum*, Draw*, Computer*, Processor*, CPU, Microprocess*, Data*, Internet*, Server*, Informat*, Network*, Wireless*, Near, Field, USB, Connect*, Communicat*, Transfer*, SMS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X – Y	US 6547756 B1 (GRETER, A, et al.) April 15, 2003; abstract; figure 1; column 2, lines 24-37; column 5, lines 46-57; column 7, lines 53-56; column 8, lines 8-11; column 9, lines 39-55; claims 8,20, 25, 28-31	1, 3-8, 14, 15, 19, 22-24, 28, 30-33, 38, 39, 45, 48, 49 2, 9-13, 16-18, 20, 21, 25, 26, 29, 34-37, 40-44, 46, 47, 50
Y	US 2010/0121266 A1 (BRYAN, RG et al.) May 13, 2010; figure 2; paragraph [0070]	2, 29
Y	US 2007/0209595 A1 (UMEGARD, A, et al.) September. 13, 2007; paragraphs [0016], [0023]-[0024]; claim 10	9-13, 25, 26, 34-37, 46, 47, 50
Y	WO 00/41744 A1 (TAGGART MEDO) July 20, 2000; page 2, lines 10-21; page 11, lines 28-31; page 12, lines 1-2; claims 1, 7	16, 17, 20, 43
Y	WO 2013/070063 A1 (LELY PATENT N.V.) May 16, 2013; page 6, fourth paragraph	18, 44
Y	US 2013/0125821 A1 (GIBBS, RN et al.) May 23, 2013; paragraphs [0053], [0054]	20, 21, 40-42
A	US 2010/0284251 A1 (CHANG, S) November 11, 2010; abstract; paragraph [0004]	1-26, 28-50

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 April 2015 (30.04.2015)	08 JUL 2015
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US15/14901

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: Claims 1-26 and 28-50 are directed toward a method, system and apparatus for measuring milk expression from a breast.

Group II: Claims 27 and 51 are directed toward a method for controlling and remotely controlling expression of milk from a breast comprising receiving a control signal from a server via a network.

Group III: Claims 52-91 are directed toward an apparatus and method for measuring the volume of fluid expressed from a breast, comprising: a sensing unit configured to generate measurement data indicative of volume of expressed fluid from the breast.

-***-Continued Within the Extra Sheet-***-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-26, 28-50

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (January 2015)

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/US15/14901

Continuation of Box No. III - Observations where unity of invention is lacking:

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Group I include transmitting the measurement data from the sensing unit to a computing device via a data connection, which are not present in Groups II-III; the special technical features of Group II include receiving a control signal from a computing device via a data connection, which are not present in Groups I and III; the special technical features of Group III include generating, via the sensing unit, measurement data indicative of volume of the expressed fluid, which are not present in Groups I-II.

The common technical features of Groups I, II and III are an apparatus, system and method relating to expression of fluid/milk from a breast, comprising: providing a breast fluid expression apparatus comprising an interface, an actuation assembly operably coupled to the interface, and a sensing unit; engaging the interface with a breast; actuating the actuation assembly, thereby causing the interface to apply vacuum pressure against the breast; expressing fluid from the breast.

These common technical features are disclosed by US 6,547,756 B1 to Greter et al. (hereinafter 'Greter'). Greter discloses an apparatus, system and method relating to expression of fluid/milk from a breast (breastpump which can be programmed to generate a plurality of differing milk expression sequences; abstract), comprising: providing a breast fluid expression apparatus comprising an interface (breastpump with breastshield; claim 1), an actuation assembly operably coupled to the interface (programmable controller having an interface for the inputting of programs; figures 9-10; claim 1), and a sensing unit (sensing mechanism 78 uses a toothed wheel 78a mounted to the shaft 29 of motor 28, which is registered by counter 78b; signals generated by the counter 78b are processed by the cpu of the breastpump; column 7, lines 1-4); engaging the interface with a breast (a breastshield having a portion within which a woman's breast is received for the expression of milk; claim 1); actuating the actuation assembly, thereby causing the interface to apply vacuum pressure against the breast (a source of vacuum in communication with said breastshield; claim 11); expressing fluid from the breast (claim 1).

Since the common technical features are previously disclosed by the Greter reference, the common features are not special and so Groups I, II and III lack unity.

Form PCT/ISA/210 (patent family annex) (January 2015)

フロントページの続き

(81)指定国 AP(BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), EA(AM, AZ, BY, KG, KZ, RU, TJ, TM), EP(AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OA(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG), AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US

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GD03 GD15 GD21 JA11 JA34

Patents jP 2017509379 A

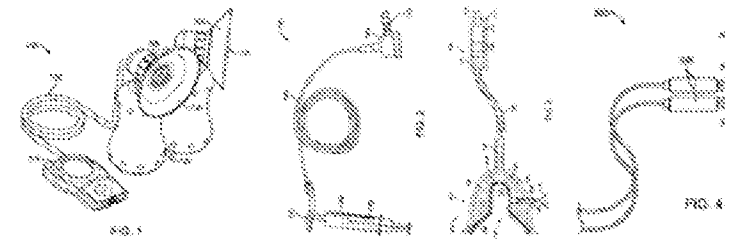
Method, apparatus and system for milking human breast milk

Abstract

translated from Japanese

Systems, methods, and devices for milking milk are provided. In one aspect, the system includes a milking device having an interface configured to engage the breast and an actuation assembly operably coupled to the interface. Actuation of the actuating assembly causes the interface to apply reduced pressure to the breast and milk the breast from the breast. The system also includes a computing device configured to communicate with the milking device via a data connection.

Images (43)



Classifications

A61M1/06 Milking pumps

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JP2017509379A

Japan

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Other languages: Japanese

Inventor: ジェフリー ビー, アルバレス, , ジェフリー ビー, アルバレス, , ジャニカ ビー, アルバレス, , ジャニカ ビー, アルバレス, , アレックス ゴールデンバーク, , アレックス ゴールデンバーク, , グレッグ スターラー, , グレッグ スターラー,

Worldwide applications

2015 CA ~~AU~~ EP WO JP CN CA
2018 ~~AU~~

Application JP2016550177A events

2014-02-07	Priority to US201461937027P
2014-02-07	Priority to US61/937,027
2015-02-06	Application filed by ナヤ ヘルス, インコーポレイテッド, ナヤ ヘルス, インコーポレイテッド
2015-02-06	Priority to PCT/US2015/014901
2017-04-06	Publication of JP2017509379A
Status	Pending

Info: Patent citations (12), Cited by (14), Similar documents, Priority and Related Applications

External links: Espacenet, Global Dossier, Discuss

Claims (91)

Hide Dependent
translated from Japanese

A system for milking breast milk from the breast,
A milking device comprising an interface configured to engage a breast and an actuation assembly operably coupled to the interface, the actuation of the actuation assembly applying a reduced pressure to the interface A milking device for applying to and milking the milk from there,
A computing device configured to communicate with the milking device via a data connection;
A system comprising: The system of claim 1, wherein the interface is configured to fluidly seal against the breast. The data connection utilizes one or more of wireless communication, near field communication, and USB cable to transmit data between at least a portion of the milking device and the computing device; The system of claim 1. The system of claim 1, wherein the computing device is selected from a smartphone, a tablet, and a personal computer. The system of claim 1, wherein the milking device further comprises a sensing unit configured to generate measurement data indicative of one or more characteristics of breast milking. The system of claim 5, wherein the measurement data is transmitted to the computing device via the data connection. The system of claim 6, wherein the computing device comprises an application configured to analyze the measurement data. The system of claim 6, wherein the computing device transmits the measurement data to a server. The system of claim 5, wherein the milking device further comprises a processing unit configured to analyze the measurement data and thereby generate an analysis result. The system of claim 9, wherein the milking device further comprises a display unit configured to display the analysis results to a user. The system according to claim 10, wherein the analysis result is displayed in a graph, a chart, or a table. The system of claim 9, wherein the analysis result is transmitted to the computing device via the data connection. The system of claim 12, wherein the computing device displays the analysis results to a user. The system of claim 1, wherein the computing device controls at least one functionality of the milking device via the data connection. 15. The functionality of claim 14, wherein the functionality includes one or more of: a power of the milking device, a reduced pressure applied by the milking device, and a cycle per minute of the milking device. system. The system of claim 1, wherein a notification to remind a user to milk breast milk is transmitted to the computing device via the data connection. The system of claim 1, wherein a notification to remind a user to milk breast milk is transmitted to at least a portion of the milking device via the data connection. The system of claim 1, wherein firmware updates are transmitted to at least a portion of the milking device via the data connection. The system of claim 1, wherein the computing device comprises a communication module that communicates with a server over a network. The system of claim 19, wherein a notification to remind a user to milk breast milk is transmitted from the server to the computing device. 21. The computing device of claim 20, wherein the computing device comprises a mobile phone associated with a mobile phone number, and the notification is transmitted to the mobile phone number over the network by a short message service (SMS). system. A method for measuring milking of breast milk from a breast,
Providing a breast milking device comprising an interface, an actuation assembly operably coupled to the interface, and a sensing unit;
Engaging the breast with the interface;
Activating the actuation assembly, thereby causing the interface to apply a reduced pressure to the breast;
Milking breast milk from the breast;

Using said sensing unit to measure milking characteristics of breast milk, thereby generating measurement data;
Transmitting the measurement data from the sensing unit to a computing device via a data connection;
Including the method. 23. The method of claim 22, further comprising storing the measurement data in one or more data stores of the computing device. 23. The method of claim 22, further comprising analyzing the measurement data via the computing device application and generating an analysis result. 25. The method of claim 24, further comprising displaying the analysis results to a user via the computing device. 26. The method of claim 25, wherein the analysis results are displayed in a graph, chart or table. A method for controlling milking of breast milk from a breast,
Providing a breast milking device comprising an interface and an actuation assembly operably coupled to the interface;
Engaging the breast with the interface;
Receiving a control signal from a computing device via a data connection;
Activating the actuation assembly based on the control signal, thereby causing the interface to apply a reduced pressure to the breast;
Milking breast milk from the breast;
Including the method. A device for milking breast milk from the breast,
An interface configured to engage the breast;
An actuating assembly operably coupled to the interface, wherein actuating the actuating assembly causes the interface to apply a reduced pressure to the breast and milk milk therefrom;
A communication module for communicating with a server via a network;
An apparatus comprising: 30. The apparatus of claim 28, wherein the interface is configured to fluidly seal against the breast. 30. The apparatus of claim 28, wherein the network comprises an internet network. 30. The apparatus of claim 28, further comprising a sensing unit configured to generate measurement data indicative of one or more characteristics of breast milking. 32. The apparatus of claim 31, wherein the measurement data is transmitted to the server via the network. 35. The apparatus of claim 32, wherein the server comprises an application configured to analyze the measurement data. 32. The apparatus of claim 31, further comprising a processing unit configured to analyze the measurement data and thereby generate an analysis result. 35. The apparatus of claim 34, further comprising a display unit configured to display the analysis results to a user. The apparatus according to claim 34, wherein the analysis result is transmitted to the server via the network. 37. The apparatus of claim 36, wherein the analysis result is displayed on a computing device that communicates with the server. 30. The apparatus of claim 28, wherein at least one functionality of the actuation assembly is controlled by an application on the server via the network. 39. The functionality of claim 38, wherein the functionality includes one or more of: power of the actuation assembly, reduced pressure applied by the actuation assembly, and cycles per minute of the actuation assembly. apparatus. 30. The apparatus of claim 28, wherein a notification to remind a user to milk breast milk is transmitted to an email address via the network. 30. The apparatus of claim 28, wherein a notification to remind a user to milk breast milk is transmitted to the mobile phone number via the network by a short message service (SMS). 42. The apparatus of claim 41, wherein the notification is transmitted by SMS from the server to a smartphone associated with the mobile phone number. 29. The apparatus of claim 28, wherein a notification to remind a user to milk breast milk is transmitted to the communication module via the network. 30. The apparatus of claim 28, wherein firmware updates are transmitted to the communication module over the network. A method for measuring milking of breast milk from a breast,
Providing a breast milking device comprising an interface, an actuation assembly operably coupled to the interface, and a sensing unit;
Engaging the breast with the interface;
Activating the actuation assembly, thereby causing the interface to apply a reduced pressure to the breast;
Milking breast milk from the breast;
Using said sensing unit to measure milking characteristics of breast milk, thereby generating measurement data;
Transmitting the measurement data to a server via a network;

Including the method. 46. The method of claim 45, wherein the server is a distributed computing server. 46. The method of claim 45, wherein the milking characteristics of the breast milk are measured by the sensing unit as the breast milk moves from the interface to a collection reservoir in fluid communication with the interface. 46. The method of claim 45, further comprising storing the measurement data in one or more data stores associated with the server. 46. The method of claim 45, further comprising analyzing the measurement data via an application on the server and generating an analysis result. Transmitting the analysis result from the server to a computing device;

Displaying the analysis results to a user via the computing device;

50. The method of claim 49, further comprising: A method for remotely controlling milking of breast milk from a breast,

Providing a breast milking device comprising an interface and an actuation assembly operably coupled to the interface;

Engaging the breast with the interface;

Receiving a control signal from a server via a network;

Activating the actuation assembly based on the control signal, thereby causing the interface to apply a reduced pressure to the breast;

Milking breast milk from the breast;

Including the method. A device for measuring the milking of fluid from the breast,

An interface configured to engage the breast;

An actuating assembly operatively coupled to the interface, wherein actuating the actuating assembly causes the interface to apply a reduced pressure to the breast and milk fluid therefrom;

A sensing unit configured to generate measurement data indicative of the volume of fluid pumped from the breast;

An apparatus comprising: 53. The apparatus of claim 52, wherein the interface is configured to fluidly seal against the breast. 53. The apparatus of claim 52, wherein the fluid is one or more of breast milk and colostrum. 53. The apparatus of claim 52, wherein the measurement data indicates a volume per unit of time of the milked fluid. 53. The apparatus of claim 52, wherein the actuation assembly comprises a pump and the measurement data indicates a volume per stroke of the pumped fluid. 53. The apparatus of claim 52, wherein the actuation assembly comprises a pump and the measurement data indicates the volume per pump power cycle of the milked fluid. 53. The apparatus of claim 52, wherein the interface comprises a valve that allows passage of the milked fluid and the sensing unit comprises an accelerometer that measures movement of the valve. 59. The apparatus of claim 58, wherein the measurement data is generated based on movement of the valve. A second interface configured to engage a second breast, wherein actuation of the actuation assembly causes reduced pressure to be applied alternately to the breast and the second breast; Alternately milking the fluid, the second interface comprises a second valve that allows the passage of fluid pumped from the second breast, and the sensing unit controls the movement of the second valve. 59. The apparatus of claim 58, comprising a second accelerometer to measure. 61. The apparatus of claim 60, wherein the sensing unit determines user movement based on movement detected by both the accelerometer and the second accelerometer. The user movement is subtracted from movement detected by at least one of the accelerometer or the second accelerometer when determining movement of at least one of the first valve or second valve. 62. The apparatus of claim 61, wherein: The interface includes a valve that allows passage of the milked fluid, and the sensing unit includes a first accelerometer coupled to the interface and a second accelerometer coupled to the valve. 54. The apparatus of claim 52, comprising. 64. The apparatus of claim 63, wherein the first accelerometer is configured to measure movement of the interface. 64. The apparatus of claim 63, wherein the second accelerometer is configured to measure movement of the valve. 64. The apparatus of claim 63, wherein the measurement data is generated based on movement of the interface and movement of the valve. 64. The apparatus of claim 63, wherein the sensing unit determines background motion based on motion detected by the first accelerometer. 68. The apparatus of claim 67, wherein the background motion is subtracted from motion detected by the second accelerometer when determining motion of the valve.

The interface is coupled to a reservoir configured to collect the milked fluid, the sensing unit is coupled to the reservoir, the reservoir comprising a processing unit in communication with the sensing unit; 53. The apparatus of claim 52, wherein the unit is configured to receive measurement data generated by the sensing unit. 70. The apparatus of claim 69, wherein the processing unit comprises a communication module configured to transmit the measurement data to a computing device via a data connection. 70. The apparatus of claim 69, wherein the processing unit comprises a communication module configured to transmit the measurement data to a server over a network. 53. The apparatus of claim 52, wherein the sensing unit comprises a beam block sensor configured to detect the passage of the milked fluid in the vicinity of one or more sensor components of the beam block sensor. . 73. The apparatus of claim 72, wherein the measurement data is generated based on a length of time that the milked fluid passes between the sensor components. The interface includes a valve that allows passage of the milked fluid, and the sensing unit is configured to count droplets of the milked fluid that pass through the valve. 53. The apparatus of claim 52, comprising a CCD). 75. The apparatus of claim 74, wherein the measurement data is generated based on one or more CCD images of the droplet. The interface comprises a tube that allows passage of the milked fluid, and the sensing unit comprises a capacitive sensor configured to sense the milked fluid contained within the tube. 52. The apparatus according to 52. The interface is coupled to a reservoir configured to collect the milked fluid, and the sensing unit is configured to measure a volume of the milked fluid contained within the reservoir 54. The apparatus of claim 52, comprising a sensor. 53. The apparatus of claim 52, wherein the sensing unit comprises a strain gauge configured to measure a volume of the milked fluid. 80. The interface of claim 78, wherein the interface comprises a valve that allows passage of the milked fluid, and the strain gauge is coupled to the valve and configured to determine displacement of the valve over time. Equipment. The interface is coupled to a reservoir configured to collect the milked fluid, and the strain gauge is coupled to the reservoir to measure the volume of the milked fluid contained within the reservoir. 80. The apparatus of claim 78, wherein the apparatus is configured as follows. The reservoir includes a bottom inner surface having a bellows element, the bellows element configured to minimize absorption by the bottom inner surface of a load applied on the bottom inner surface by the milked fluid. The apparatus of claim 80. 53. The apparatus of claim 52, wherein the sensing unit comprises a camera coupled to the interface and configured to capture one or more images of the milked fluid. 84. The apparatus of claim 82, further comprising a processing unit configured to analyze the one or more images and determine a volume of the milked fluid. 83. The one or more images are transmitted to a computing device configured to analyze the one or more images and determine a volume of the milked fluid. Equipment. The apparatus of claim 84, wherein the computing device is a smartphone. The apparatus of claim 82, wherein the camera is mounted on a mobile device. A processing unit;

A control unit operably coupled to the actuation assembly and controlling at least one functionality thereof;

53. The apparatus of claim 52, wherein at least a subset of the measurement data is transmitted as feedback to at least one of the processing unit and the control unit. 88. The apparatus of claim 87, wherein the actuation assembly comprises a pump and the feedback is used to adjust the pump's vacuum stroke and maintain optimal fluid milking. 88. The apparatus of claim 87, wherein the actuating assembly comprises a pump and the feedback is used to regulate a cycle per minute of the pump and maintain optimal fluid milking. A method for measuring the volume of fluid pumped from a breast, comprising:

Providing a breast fluid milking device comprising an interface, an actuation assembly operably coupled to the interface, and a sensing unit;

Engaging the breast with the interface;

Activating the actuation assembly, thereby causing the interface to apply a reduced pressure to the breast;

Milking fluid from the breast;

Generating measurement data indicative of the volume of the milked fluid via the sensing unit;

Including the method. Changing operating parameters of the operating assembly based on at least a subset of the measurement data;

Activating the actuation assembly based on the altered actuation parameter;

92. The method of claim 90, further comprising:

Description

translated from Japanese

(Cross-reference)
This application is a non-provisional application of US Provisional Patent Application No. 61 / 937,027 [Attorney Document No. 44936-704.101] filed on Feb. 7, 2014, and the benefit of this provisional application. The entire contents of this provisional application are incorporated herein by reference.

The subject matter of this application is US Patent Application No. 14 / 221,113 filed on March 20, 2014 [Attorney Document No. 44936-703.201], and US Provisional Patent filed on July 7, 2014. Application No. 62 / 021,601 [Attorney Document No. 44936-705.101], US Provisional Patent Application No. 62 / 021,597 filed July 7, 2014 [Attorney Document No. 44936- 706.101], US Provisional Patent Application No. 62 / 028,219 filed July 23, 2014 [Attorney Document Number 44936-708.101], and filed September 19, 2014 No. 62 / 052,941 [Attorney Document No. 44936-709.101], the entire contents of these applications are hereby incorporated by reference. It is use.

(Background of the Invention)
(1. Field of the Invention)
The present invention relates generally to medical devices and methods, and more particularly to devices and methods for milking and collecting human breast milk.

Breast pumps are commonly used to collect breast milk so that mothers can continue breastfeeding even when they are separated from their children. Currently, there are two basic types of breast pumps: small but inefficient and manual devices that cause fatigue due to use, and efficient but bulky electric devices. For this reason, it would be desirable to provide an improved breast pump that is small and very efficient for milking and collecting milk. Additional features such as quantifying breast milk output, evaluating breast milk characteristics, and communicating with mobile devices are further desirable to enhance user convenience. At least some of these objectives will be met by the devices and methods disclosed below.

(2. Description of background art)
The following US patents relate to milking and collection of human breast milk. U.S. Patent Nos. 6,673,036, 6,749,582, 6,840,918, 6,887,210, 7,875,000, 8,118,772, And No. 8,216,179.

US Pat. No. 6,673,036 US Pat. No. 6,749,582 US Pat. No. 6,840,918 US Pat. No. 6,887,210 US Pat. No. 7,875,000 US Pat. No. 8,118,772 US Pat. No. 8,216,179

(Summary of the Invention)
The present invention relates generally to medical devices and methods, and more specifically to devices and methods for milking and collecting human breast milk.

In a first aspect of the invention, a system for milking breast milk from a breast is provided. The system may comprise a milking device having an interface configured to engage the breast and an actuation assembly operably coupled to the interface. Actuation of the actuating assembly can cause the interface to apply reduced pressure to the breast and milk milk from the breast. The system further comprises a computing device configured to communicate with the milking device via a data connection.

In many embodiments, the breast is a human breast. The interface can be configured to fluidly seal against the breast.

In many embodiments, the data connection utilizes wireless communication, near field communication, or a USB cable to transmit data between at least a portion of the milking device and the computing device. The computing device may be a smartphone, tablet, or personal computer.

In many embodiments, the milking device further includes a sensing unit configured to generate measurement data indicative of one or more characteristics of breast milking. Measurement data can be transmitted to a computing device via a data connection. The computing device can include an application configured to analyze the measurement data. The computing device can transmit the measurement data to the server. The milking device can further include a processing unit configured to analyze the measurement data and generate an analysis result, and a display unit configured to display the analysis result to a user. The analysis results can be displayed in a graph, chart or table. The analysis results can be transmitted to the computing device via the data connection, and the computing device can display the analysis results to the user.

In many embodiments, the computing device can control at least one functionality of the milking device via a data connection. The functionality may comprise one or more of milking machine power, reduced pressure applied by the milking machine, or a cycle per minute of the milking machine.

In many embodiments, a notification to remind the user to milk the milk may be transmitted to the computing device via the data connection. The notification can be transmitted to at least a portion of the milking device via a data connection. Firmware updates can be transmitted to at least a portion of the milking device via a data connection.

In many embodiments, the computing device can comprise a communication module that communicates with a server over a network. A notification to remind the user to milk the milk may be transmitted from the server to the computing device. The computing device may comprise a mobile phone associated with the mobile phone number and the notification may be transmitted over the network to the mobile phone number by a short message service (SMS).

In another aspect of the present invention, a method for measuring milking of breast milk from the breast is provided. The method includes providing a breast milking apparatus having an interface, an actuation assembly operably coupled to the interface, and a sensing unit. The method further includes engaging the interface and the breast and activating the actuation assembly, thereby causing the interface to apply reduced pressure to the breast. The method further includes milking breast milk from the breast. The method may further include measuring the milking characteristics of the breast milk using the sensing unit to generate measurement data. Measurement data may be transmitted from the sensing unit to the computing device via a data connection.

In many embodiments, the measurement data may be stored in one or more data stores of the computing device. The measurement data can be analyzed via an application on the computing device and an analysis result can be generated, and the analysis result can be displayed to the user via the computing device. The analysis results can be displayed in a graph, chart, table, or any other visual, audible, or tactile indicator.

In another aspect of the invention, a method for controlling milking of breast milk from a breast is provided. The method includes providing a breast milking device having an interface and an actuation assembly operably coupled to the interface. The method further includes engaging the interface and the breast. The control signal may be received from the computing device via a data connection. The method may further include activating the actuation assembly based on the control signal and causing the interface to apply a reduced pressure to the breast. The method further includes milking breast milk from the breast.

In another aspect of the invention, an apparatus for milking breast milk from a breast is provided. The apparatus includes an interface configured to engage the breast and an actuation assembly operably coupled to the interface. Actuation of the actuating assembly can cause the interface to apply reduced pressure to the breast and milk milk from the breast. The apparatus can also include a communication module that communicates with the server over a network.

In many embodiments, the network includes an Internet network. The apparatus can further include a sensing unit configured to generate measurement data indicative of one or more characteristics of breast milking, wherein the measurement data is transmitted to a server via a network. be able to. The server can include an application configured to analyze the measurement data.

In many embodiments, the apparatus further includes a processing unit configured to analyze the measurement data and generate an analysis result, and a display unit configured to display the analysis result to a user. . The analysis result can be transmitted to the server via the network. The analysis results can be displayed on a computing device that communicates with the server.

In many embodiments, at least one functionality of the actuation assembly is controlled by an application on the server via a network. Functionality can include the power of the actuation assembly, the reduced pressure applied by the actuation assembly, or the cycles per minute of the actuation assembly.

In many embodiments, a notification to remind the user to milk the milk may be transmitted over the network to an email address. A reminder to the user to milk the milk can be transmitted to the mobile phone number over the network by a short message service (SMS), such as SMS from the server to the smartphone associated with the mobile phone number. . A notification to remind the user to milk the milk can be transmitted to the communication module via the network. The firmware update can be transmitted to the communication module via the network.

In another aspect, the present invention provides a method for measuring milking of breast milk from a breast. The method includes providing a breast milking device that includes an interface, an actuation assembly operably coupled to the interface, and a sensing unit. The interface may be engaged with the breast. The actuation assembly can be actuated to cause the interface to apply a reduced pressure to the breast. Breast milk is milked from the breast. The sensing unit may be used to measure milking characteristics of milk and generate measurement data. The measurement data may be transmitted to the server via the network.

In many embodiments, the server is a distributed computing server. The characteristics of breast milking can be measured by the sensing unit as the milk moves from the interface to a collection reservoir in fluid communication with the interface. The measurement data can be stored in one or more data stores associated with the server. The measurement data can be analyzed through an application on the server and an analysis result can be generated. The analysis results can be transmitted from the server to the computing device and displayed to the user via the computing device.

In another aspect of the invention, a method for remotely controlling milking of breast milk from a breast is provided. The method includes providing a breast milking device comprising an interface and an actuation assembly operably coupled to the interface. The interface may be engaged with the breast. A control signal can be received from the server via the network. The actuation assembly may be actuated based on the control signal and cause the interface to apply a reduced pressure to the breast. Breast milk may be milked from the breast.

In another aspect of the invention, an apparatus for measuring fluid milking from a breast is provided. The apparatus includes an interface configured to engage the breast and an actuation assembly operably coupled to the interface. Actuation of the actuating assembly causes the interface to apply reduced pressure to the breast and milk the breast from the breast. The apparatus includes a sensing unit configured to generate measurement data indicative of a volume of fluid pumped from the breast.

In many embodiments, the breast is a human breast. The interface can be configured to fluidly seal against the breast. The fluid can be breast milk or colostrum. The measurement data can indicate the volume per unit time of the milked fluid, the volume per pump stroke, or the volume per pump power cycle.

In many embodiments, the interface includes a valve that allows passage of milked fluid, and the sensing unit comprises an accelerometer that measures the movement of the valve. Measurement data can be generated based on valve motion.

In many embodiments, the apparatus can further include a second interface configured to engage the second breast. Actuation of the actuating assembly may alternately apply reduced pressure to the breast and the second breast to alternately pump fluid from the breast. The second interface can include a second valve that allows passage of fluid pumped from the second breast, and the sensing unit includes a second accelerometer that measures the position of the second valve. Can be included. The sensing unit can determine user movement based on movement detected by both the accelerometer and the second accelerometer. The user motion may be subtracted from the motion detected by at least one of the accelerometer or the second accelerometer when determining the position of at least one of the first valve or the second valve. it can.

In many embodiments, the interface may comprise an interface housing and a valve that allows passage of milked fluid. The sensing unit may comprise a first accelerometer coupled to the interface housing and a second accelerometer coupled to the valve. The first accelerometer may be configured to measure the position of the interface housing. The second accelerometer may be configured to measure the position of the valve. Measurement data may be generated based on the position of the interface housing and the position of the valve. The sensing unit can determine the background motion based on the motion detected by the first accelerometer. The background motion may be subtracted from the motion detected by the second accelerometer when determining the position of the valve.

In many embodiments, the interface may be coupled to a reservoir configured to collect milked fluid. The sensing unit may be coupled to the reservoir. The reservoir may comprise a processing unit in communication with the sensing unit, and the processing unit may be configured to receive measurement data generated by the sensing unit. The processing unit may further comprise a communication module configured to transmit the measurement data to the computing device via the data connection. The communication module of the processing unit may be configured to transmit measurement data to the server via a network.

In many embodiments, the sensing unit includes a beam block sensor configured to detect the passage of milked fluid in the vicinity of one or more sensor components of the beam block sensor. The measurement data can be generated based on the length of time that the milked fluid passes between the sensor components.

In many embodiments, the interface includes a valve that allows passage of milked fluid, and the sensing unit is configured to count milked fluid droplets passing through the valve. (CCD).

Measurement data can be generated based on one or more CCD images of the droplet.

In many embodiments, the interface includes a tube that allows passage of milked fluid and the sensing unit includes a capacitive sensor configured to sense the milked fluid contained within the tube. The interface can be coupled to a reservoir configured to collect milked fluid, and the sensing unit is configured to measure the volume of milked fluid contained in the reservoir Can be included.

In many embodiments, the sensing unit includes a strain gauge configured to measure the volume of milked fluid. The interface can include a valve that allows passage of milked fluid, and a strain gauge can be coupled to the valve and configured to determine displacement of the valve over time. The interface can be coupled to a reservoir configured to collect milked fluid, and a strain gauge is coupled to the reservoir and configured to measure the volume of milked fluid contained within the reservoir Can be done. The reservoir may comprise a bottom inner surface having a bellows element. The bellows element can be configured to minimize absorption by the bottom inner surface of the load applied to the bottom inner surface by the milked fluid.

In many embodiments, the sensing unit includes a camera coupled to the interface and configured to capture one or more images of the milked fluid. The apparatus can further include a processing unit configured to analyze one or more images and determine a volume of milked fluid or other characteristics of the milked fluid. The one or more images can be transmitted to a computing device configured to analyze the one or more images and determine the volume of the milked fluid. The computing device can be a smartphone. The camera can be installed on a mobile device.

In many embodiments, the apparatus further comprises a processing unit and a control unit operably coupled to the actuation assembly and controlling at least one functionality of the actuation assembly. At least a subset of the measurement data may be transmitted as feedback to at least one of the processing unit and the control unit. The actuation assembly can include a pump and feedback can be used to adjust the pump's vacuum stroke or pump's cycle per minute to maintain optimal fluid milking.

In another aspect of the invention, a method for measuring the volume of fluid pumped from a breast is provided. The method includes providing a breast fluid milking device that includes an interface, an actuation assembly operably coupled to the interface, and a sensing unit. The interface is engaged with the breast. The actuation assembly is actuated, causing the interface to apply a reduced pressure to the breast. The fluid is milked from the breast. Measurement data indicative of the volume of the milked fluid is generated via the sensing unit.

In many embodiments, the method further includes altering the operating parameters of the operating assembly based on at least a subset of the measurement data. The actuation assembly is actuated based on the altered actuation parameter.

Other objects and features of the invention will become apparent upon review of the specification, claims and appended drawings.

(Quoted by reference)
All publications, patents, and patent applications mentioned in this specification are intended to indicate that each individual publication, patent, or patent application is specifically and individually indicated to be incorporated by reference. To the same extent, it is incorporated herein by reference.

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention may be obtained by reference

to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. 1 is a perspective view of a pump device according to an embodiment. FIG. 2 is a perspective view of a hydraulic pump device, according to an embodiment. FIG. 3 is a cross-sectional view of a hydraulic pump device according to an embodiment. FIG. 4 illustrates an actuation assembly coupled to a drive mechanism, according to an embodiment. 5A-5B illustrate an actuation assembly coupled to a controller, according to an embodiment. FIG. 6 is a cross-sectional view of a breast interface, according to an embodiment. FIG. 7 is a cross-sectional view of another breast interface, according to an embodiment. FIG. 8A is a cross-sectional view of a valve integrated into a flexible membrane in an open position, according to an embodiment. FIG. 8B is a cross-sectional view of a valve integrated into a flexible membrane in a closed position, according to an embodiment. FIG. 9 is a cross-sectional view of a breast interface with a mechanically deformable member, according to an embodiment. FIG. 10 is a cross-sectional view of a mechanical drive for a mechanically deformable member, according to an embodiment. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. FIG. 12 illustrates a controller and mobile device according to an embodiment. FIG. 13 illustrates short range communication between a controller and a mobile device, according to an embodiment. FIG. 14 is a schematic diagram of a pump device in communication with a computing device and a server, according to an embodiment. FIG. 15 is a graph illustrating the pump performance of an exemplary pump device compared to a commercially available device, according to an embodiment. FIG. 16 is a graph illustrating the pump efficiency of an exemplary pump device compared to a commercially available device, according to an embodiment. FIG. 17 illustrates a schematic diagram of a system for milking milk. FIG. 18 illustrates another exemplary embodiment of a system for milking breast milk. 19A-19C illustrate exemplary displays on a computing device. 20A-20B illustrate exemplary displays within a breast milking system. FIG. 21 illustrates the use of a feedback control loop to control a breast milking device. FIG. 22 illustrates a double milking system.

(Detailed description of the invention)
Specific embodiments of the disclosed systems, devices, and methods will now be described below with reference to the drawings. Any detailed description is not intended to suggest that any particular component, feature, or step is essential to the invention. Although the present invention is primarily concerned with breast milk, any description herein of milking and collection of milk can also be applied to other types of fluids that are milked from the breast, such as colostrum. Furthermore, the disclosed embodiments may be used in other applications, particularly in applications involving pressure differential formation and transmission, such as sleep apnea treatment and / or other remote pressure needs.

The systems, devices, and methods of the present invention provide an improved pump device for milking and collecting breast milk, such as human breast milk. In contrast to existing devices, the mechanisms described herein allow for the development of smaller and more efficient electric pump devices, thereby improving convenience and ease of use. In addition, at least some of the exemplary embodiments disclosed herein incorporate sensors for measuring milking characteristics of breast milk. The obtained data can be used, for example, as feedback to improve pump efficiency and provide users with information and / or analysis related to milking milk. Further, in a preferred embodiment, the data is transmitted to another device that communicates with the pump device, thereby allowing control, display and / or analysis of milking of the milk to be performed remotely. Can do.

FIG. 1 illustrates an exemplary embodiment of the present invention. The pump device 100 (also known as a "milking device") is also referred to as a controller 115 (also referred to as a "pendant unit") that is operatively coupled to the breast interface 105 through the breast interface 105, the tube 110, and the tube 110. May be included). The breast interface 105 includes a resilient and conforming flange 120 for engaging the breast and forming a fluid seal thereto, and a collection container 125. The controller 115 stores the power supply and the drive mechanism of the pump device 100, as described in further detail herein, and also controls the pump device 100, quantifies breast milk output, and communicates with other devices. Etc., including hardware for various functions. Tube 110 transmits a suitable energy input, such as a mechanical energy input, over a long distance from controller 115 to breast interface 105. The breast interface 105 converts the energy input to reduced pressure on the breast in a highly efficient manner, resulting in milking the milk into the collection container 125. The device 100 may further comprise one or more sensors configured to track various properties of the collected fluid, as described in further detail herein. Power may be provided to one or more sensors via a connection to the controller 115 or another power source. In embodiments in which one or more sensors are coupled to one or more portions of breast interface 105 or collection container 125, the sensors are further configured to transmit signals between the sensors and the controller. May be coupled to the controller 115 via one or more communication lines.

Hydraulic (Hydraulic) Pump Device The hydraulic system can reduce the required pumping force and thus reduce the size of the pump device while maintaining high pump efficiency. In a preferred embodiment, the pump device can utilize a hydraulic pump system to generate a pressure differential with respect to the breast for milking and collection of breast milk.

An exemplary hydraulic pump device is shown in FIGS. FIG. 2 illustrates a pump device 150 having a syringe 155 fluidly coupled to the breast interface 160 by a tube 165. Syringe 155 is coupled to tube 165 through three-way valve 170. The breast interface 160 includes an outlet port 175. The syringe 155 drives the fluid 180 contained in the tube 165 toward a flexible member stored in the breast interface 160 to generate the pressure differential required for milking the breast milk from the breast.

FIG. 3 illustrates another embodiment of the pump device 200. Actuation assembly 205 includes an assembly housing 210, a drive element 215, a seal 220, and a shaft 222. Drive element 215 is operatively coupled to a controller, such as controller 115, through shaft 222. Tube 225 contains fluid 230 and is fluidly coupled to actuation assembly 205 and breast interface 235. The breast interface 235 comprises an interface housing 240, a flexible membrane 245, a reservoir 250, a sealing element 255, a milking area 260, and a discharge port 265. Seal element 255 includes a deformable portion 270. Alternatively, the flexible membrane 245 may comprise a sealing element 255 having a deformable portion 270 that is fluidly sealed against the breast engaged in the breast interface 235. By doing so, it is configured to function as a sealing element. The discharge port 265 is coupled to the collection container 275 and includes a flap valve 280.

Actuating assembly 205 displaces fluid 230 contained within tube 225, which can be a flexible line. Fluid 230 occupies reservoir 250 in breast interface 235 and is coupled with flexible membrane 245. Preferably, the coupling between the flexible membrane 245, the sealing element 255, and the interface housing 240 is a liquid tight coupling such that the fluid 230 is contained within the reservoir 250 and cannot infiltrate into the milking area 260. it is. The flexible membrane 245 transmits reduced pressure from the fluid 230 to the deformable portion 270 of the sealing element 255. When the breast is engaged into the breast interface 235 by the sealing element 255 and fluidly sealed therewith, the displacement of the actuating element 215 causes a substantial vacuum to the breast through the flexible membrane 245 and the deformable portion 270. Pressure is generated, resulting in milking of the milk into the milking area 260. Alternatively, the flexible membrane 245 forms a fluid seal against the breast with which the flexible membrane 245 is engaged in the breast interface 235 and deforms the flexible membrane 245 from the fluid 230 with reduced pressure. A sealing element 255 having a deformable portion 270 may be provided to communicate to the possible portion. Milked milk is discharged into the collection container 275 through the discharge port 265. The discharge port 265 is configured with a flap valve 280 and provides passage of breast milk while maintaining a reduced pressure within the milking area 260. The collection container 275 can be any suitable container such as a bottle or bag. In many embodiments, the collection container 275 is removably coupled to the flexible membrane 245. Collection vessel 275 can be coupled directly or remotely via any suitable device, such as extended tubing. Preferably, the collection container can be quickly disconnected from other components of the pump device 200 (eg, for breast milk storage, cleaning, etc.).

The fluid of the hydraulic pump device can be any suitable fluid, such as an incompressible fluid. In many embodiments, the incompressible fluid can be a liquid such as water or oil. In many embodiments, the fluid can be a fluid having properties such that the reduced pressure applied to the fluid by the pump device does not result in degassing of the fluid. Alternatively, the fluid can be any suitable gas, such as air. Any liquid or gas suitable for use with the hydraulic system can be used for the hydraulic pump device described herein.

Actuation Mechanisms Many actuation mechanisms known to those skilled in the art can be utilized for actuation assembly 205. The actuation assembly 205 can be a piston assembly, a pump such as a diaphragm pump, or any other suitable actuation mechanism. The optimal configuration of the actuating assembly 205 depends on many factors, such as decompression requirements, size, power, and other needs of the pump device 200, and the characteristics of the fluid 230 such as viscosity, biocompatibility, and fluid life requirements Can do.

FIG. 3 illustrates an exemplary embodiment where the actuation assembly 205 is a piston assembly and the drive element 215 is a piston. Actuating assembly 205 includes a seal 220, such as an O-ring, rotating diaphragm seal, or wiper seal, to seal against assembly housing 210 to prevent undesired exudation of fluid 230 and allow fluid 230 to be driven. .

FIG. 4 illustrates another exemplary embodiment of an actuation assembly 300 that includes a pair of pistons 305.

In a preferred embodiment, the actuation assembly includes a drive element that is powered by a suitable drive mechanism, such as a drive mechanism in controller 115. Many drive mechanisms are known to those skilled in the art. For example, a drive element, such as drive element 215, may be electromechanically actuated by a motor or manually actuated by a suitable user-actuated interface such as a lever. Various drive modes known to those skilled in the art can be used. In particular, the implementation of an exemplary hydraulic pump device as described herein allows the use of suitable

drive modes such as direct drive and solenoids due to the reduced force requirements of the hydraulic system.

Referring now to the exemplary embodiment of FIG. 4, the piston 305 includes a coupling 310 to the crankshaft 315. Crankshaft 315 is operably coupled to motor 320 through belt drive 325. Crankshaft 315 drives a pair of pistons 305 at the same stroke timing so as to apply reduced pressure to both breasts simultaneously, a feature that is desirable for increased milk production. Alternatively, the crankshaft 315 can drive the pair of pistons 305 at any suitable stroke timing, such as alternating or offset stroke cycles. Alternate or offset stroke cycles can have the advantage of reducing the power requirements of the motor 320.

The drive mechanism can be powered by any suitable power source such as a local battery or an AC adapter. The drive mechanism can be controlled by hardware such as a built-in electronic device arranged in the controller 115.

FIG. 22 illustrates another embodiment of an alternating pump system 2200. System 2200 includes a dual milking device with an interface 2212 that is sized and shaped to match a target tissue, here a breast 2220. Reservoir 2214 is threaded or otherwise coupled to the milking device. A hydraulic line 2210 fluidly couples each milking device to a hydraulic piston assembly 2204 having an incompressible fluid, such as oil in the piston chamber, and an actuatable piston 2206. One hydraulic line 2210 is coupled to the high pressure side 2208 of the hydraulic piston, and the other hydraulic line is coupled to the low pressure side 2208 of the piston. A motor 2202 activates the piston 2206. Thus, in operation, as the piston is actuated, the high pressure side generates a higher pressure in one of the milking devices and a lower pressure in the other milking device. Lower pressure milking devices result in reduced pressure and cause milking of the milk, while the high pressure side does not milk the milk. Then, as the piston reaches the end of its stroke and reciprocates in the opposite direction, the high and low pressure sides are reversed, thereby producing milking on the opposite side and the original side Does not cause milking. This process allows breast milk to be collected in an alternating fashion. The milking device, reservoir in the system may be any of the components disclosed in any of the present disclosure.

5A-5B illustrate an exemplary embodiment of an actuation assembly 350 that includes a removable coupling 355. FIG. 5A is an isometric view of the actuation assembly 350 and controller 360 coupled via a removable coupling 355. FIG. 5B is a cross-sectional view of actuation assembly 350 with removable coupling 355. Preferably, the actuation assembly 350 is removably coupled to the controller 360 and the drive mechanism stored therein. The coupling can be a mechanical coupling or any suitable rapid desorption mechanism known to those skilled in the art. The releasably coupled design allows flexibility in configuration and use of the pump device. For example, the user experience can be improved through different sized breast interfaces for compatibility with different breast sizes. In addition, this feature allows a common pump device to be used in conjunction with a replaceable breast interface, thus reducing the risk of pathogen spread. Furthermore, the removable coupling allows for easy replacement of individual parts of the pump device.

Flexible Membrane In many embodiments, such as the embodiment shown in FIG. 3, the flexible membrane 245 is located within the breast interface 235 and disposed to cover at least a portion thereof, and the interface housing 240 and A reservoir 250 is formed between the flexible membrane 245. Preferably, the flexible membrane 245 substantially deforms when exposed to negative pressure formed when the fluid 230 is displaced from the reservoir 250 by the actuation assembly 205. The amount of deformation of the flexible membrane 245 can be controlled by a number of factors (eg,

wall thickness, durometer, surface area) and can be optimized based on the pump device (eg, pump power, decompression requirements). .

FIG. 6 illustrates an exemplary flexible membrane 370 having a specific thickness and durometer.

FIG. 7 illustrates another embodiment of a flexible membrane 375 with pleated features 380 for increased surface area.

Suitable materials for the flexible membrane are known to those skilled in the art. In many embodiments, the flexible membrane is designed to expand and contract when exposed to pressure from binding fluids such as silicone, polyether block amides such as PEBAX, and polychloroprene such as neoprene. It can be made from a material. Alternatively, the flexible membrane can be made from a substantially rigid material, such as stainless steel, nitinol, a high durometer polymer, or a high durometer elastomer. In these embodiments, the rigid material will be designed with stress and / or strain distribution elements that allow substantial deformation of the flexible membrane that does not exceed the yield point of the material.

FIGS. 8A and 8B illustrate a preferred embodiment of a breast interface 400 in which an outlet valve 405 is integrated into the flexible membrane 410 to control the flow of milked breast milk through the outlet port 415. The outlet valve 405 is opened when the flexible membrane 410 is relaxed, as shown in FIG. 8A, allowing fluid flow, and as shown in FIG. 8B, the flexible membrane 410 is Closed when deformed to prevent fluid flow. The outlet valve 405 allows substantial vacuum pressure to be present in the milking area 420 during extraction while allowing breast milk to drain during the rest phase of the pump stroke. While many conventional breast pump valves function only with pressure differentials, the outlet valve 405 can preferably be configured to function also for mechanical movement of the flexible membrane 410. Incorporating mechanical functionality as described herein into the integrated outlet valve 405 can improve the seal of the breast interface 400 during decompression formation. Furthermore, the integrally formed outlet valve implementation within the flexible membrane 410, such as the outlet valve 405, reduces the number of parts to be cleaned.

Mechanical Pump Device FIG. 9 illustrates an alternative embodiment of a breast interface 600 where a mechanically deformable member 605 can be used instead of a flexible membrane. The mechanically deformable member 605 can be constructed from techniques similar to those used for the flexible membranes described herein. Mechanically deformable member 605 is coupled to tensioning element 610. In some cases, the tension element 610 is disposed within the axial load absorbing member 615. The axial load absorbing member 615 is disposed in the tube 620. Preferably, the tension element 610 is concentrically disposed within the axial load absorbing member 615 and the axial load absorbing member 615 is concentrically disposed within the tube 620. In an alternative configuration of the tensioning element 610, an axial load absorbing member 615 and a tube 620 can also be used.

FIG. 10 illustrates a tensioning element 610 that is coupled to the drive element 625 of the actuation assembly 630 in the assembly housing 635. Drive element 625 is operably coupled through shaft 640 to a drive mechanism, such as a drive mechanism stored in the controller. The axial load absorbing member 615 in the tube 620 is fixedly coupled to the assembly housing 635. The displacement of the drive element 625 transmits tension through the tension element 610 to the mechanical deformation member 605 and generates a reduced pressure against the breast. The drive element 625 can be actuated by a suitable drive mechanism such as the embodiments previously described herein.

The tensioning element 610 can be any suitable device such as a wire, coil, tube, braid, rope, or any combination thereof. For example, the tension element 610 can be a miniature nitinol wire with a

stainless steel braid placed around it. The tensile element 610 can be made from a number of suitable materials having a high tensile strength, such as a metal, polymer, or elastomer. The axial load absorbing member 615 can be made from any suitable material that is axially synthetic, such as metal or polymer, and is configured in any suitable geometric shape that is axially synthetic, such as a tube or coil. Can.

Fluid collection and quantification systems In many cases, collection such as milk production and collection, such as the amount of milk production (eg, volume, weight), frequency of milking (eg, time, date), and / or milking duration It may be desirable to measure and track various properties of the treated fluid. In existing approaches, tracking milk production is typically accomplished by manual measurement and recording. The exemplary embodiments of the devices described herein provide digital-based means for improved convenience, efficiency, and accuracy, and can automatically measure and track breast milk production. Good. For example, a sensor can be used to measure the volume of milked milk. In preferred embodiments, the volume is measured as volume per unit time, volume per pump stroke (eg, stroke of the actuation assembly), or volume per pump power cycle (eg, power cycle of the actuation assembly). Can do.

In an exemplary embodiment, the pump device described herein may use one or more measurement data to generate one or more characteristics of breast milking, such as the volume of milk pumped. Including more sensors. Any description herein relating to measuring volume can also be applied to measuring other properties, and vice versa. Any suitable type of sensor can be used, such as accelerometers, Hall effect sensors, and photodiode / LED sensors, CCD sensors, cameras, and other imaging devices, capacitive sensors, strain gauges, etc. The sensors can be used in any number and combination. The sensor can be located at any location suitable for monitoring fluid flow from the breast, such as on or near the breast interface (eg, milking area 260, drain port 265, collection container 275). In embodiments where breast milk is milked simultaneously from a pair of breasts via a pair of breast interfaces, the sensor is located on or near both breast interfaces or only one of the breast interfaces. be able to. The sensor may be integrally formed with the pump device or permanently attached thereto. Alternatively, the sensor may be provided separately and coupled to the pump device prior to use.

FIGS. 11A and 11B illustrate an exemplary embodiment of a breast interface 450 with a valve integrated sensor 455. Sensor 455 is preferably located in a valve, such as flap valve 460, but is also located in outlet valve 465 or any other valve (eg, on or near the collection vessel) that is opened by fluid flow. May be. In the exemplary embodiment, sensor 455 includes an accelerometer that measures valve position and / or movement, such as the length of time that the valve is opened, and the resulting measurement data is for quantifying fluid flow. Can be queried. Preferably, breast interface 450 is used in conjunction with a second identical breast interface to milk milk from a pair of breasts in parallel (eg, simultaneously, alternately or sequentially). A pair of accelerometers can be used to detect the position and / or movement of the corresponding valve in each interface. In some cases, the user's movement may cause the accelerometer to generate a motion signal that is misinterpreted as a valve motion. Thus, in a preferred embodiment, a preferred approach is used to distinguish between signals resulting from user movement and signals generated by valve movement. For example, the pump device can be configured to milk milk alternately from each breast so that the corresponding valves are also opened alternately. As a result, motion detected simultaneously from both accelerometers can be considered to have resulted from user motion, not from valve motion. User motion can be subtracted from the total motion signal obtained by the accelerometer to obtain valve motion, thereby determining the position of each valve. Alternatively or in combination, the sensor 455 may comprise a set of background motion accelerometers in addition to the set of valve accelerometers, the background motion accelerometer, as described in further detail herein. It is

configured to measure background motion including user motion. The background motion measured by the background motion accelerometer may be subtracted from the motion measured by the valve accelerometer to obtain an isolated valve motion.

FIG. 11C more clearly illustrates an embodiment with an accelerometer 470. The accelerometer 470 is coupled to a valve 476 on the output of the milking device 472 having a breast interface 474 (which may also be referred to herein as a distal assembly). Valve 476 may be a flap valve, a duckbill valve, or the like. The milking device and the breast interface may be any of the embodiments disclosed herein. As breast milk 468 is milked, it is collected at the output of the device. When sufficient fluid is collected, the flap valve 470 opens and the breast milk 468 is drained into the reservoir 462 and collects the layer 464 therein. The reservoir 462 is preferably threadably connected to the milking device 472 so that it can be easily installed and removed. The movement of valve 476 is tracked using accelerometer 470. Data from the accelerometer is then processed, transmitted, or displayed using any of the methods or means disclosed herein.

FIGS. 11L-11N illustrate an exemplary embodiment having a background motion accelerometer 473 and a valve motion accelerometer 478. FIG. 11L is an isometric view of an exemplary embodiment. FIG. 11M is a side cross-sectional view of an exemplary embodiment. The background motion accelerometer 473 may be coupled to a portion of the breast interface 235, for example, the housing 240 of the breast interface. The valve accelerometer 478 may be coupled to a valve 471 that is configured to open in response to pressure or weight applied by a flap valve, duckbill valve, or milked breast milk 468. Any other valve may be used. Background motion accelerometer 473 and valve motion accelerometer 478 may be coupled to a power source, eg, controller 115, through power line 482. The background motion accelerometer 473 and the valve motion accelerometer 478 may further be coupled via a communication line 480 to a processing device or communication module of a pump control unit, such as the controller 115. Alternatively or in combination, the accelerometer may be coupled to a communication module disposed on a portion of the breast interface or reservoir, the communication module configured to communicate wirelessly with a controller or computing device. . The power line 482 and the communication line 480 may comprise one or more wires and are located in different channels or the same channel 484 of the flexible tubing 110 to connect the breast interface 235 to the actuation assembly of the pump device. May be combined. The background motion accelerometer 473 may be disposed on the surface of the housing 240 so as to be positioned in proximity to the power line 482 and the communication line 480. Similarly, the valve motion accelerometer 478 may be placed on the surface of the valve 471 so as to be positioned proximate to the power line and communication line. The valve 471 may be arranged in a configuration such that a valve accelerometer 478 disposed thereon can be positioned in proximity to the power and communication lines. Preferably, the background motion accelerometer 473 may be placed in a location and orientation whose sensing axis is aligned with the axis of the valve accelerometer 471 so as to optimize the consistency of the position data generated by the accelerometer. Good.

As shown in FIG. 11M, the milked milk 468 can enter the milking area 260 of the breast interface 235 and subsequently enter the drain port 265 coupled to the collection container. The fluid flow of breast milk 468 can generate pressure on the valve 471 and cause the valve 471 to open. For example, valve 471 may be displaced in the direction indicated by arrow 485 up to configuration 486. The movement of the valve 471 may be tracked by the valve motion accelerometer 478. Valve motion accelerometer 478 can often measure background motion that is not associated with valve motion 471, such as user motion, in addition to valve motion 471. In order to normalize the measurement of the valve motion accelerometer 478 relative to the background motion, the background motion accelerometer 473 measures the overall pump device in space to measure the background motion of the device unrelated to the valve motion 471. Can be configured to track global movement. Data generated by

accelerometers 473 and 478 may be transmitted via communication line 480 to the communication module of the pump control unit, which communicates the data to the pump control unit for data analysis and / or display. Or it may be configured to transmit to any processing device of another computing device. Alternatively, or in combination, the data generated by the accelerometer may be transmitted wirelessly via a communication module that is integrated with a portion of the breast interface or reservoir.

FIG. 11N shows an exemplary graph of the motion signal generated by the background motion accelerometer 473 and the valve motion accelerometer 478. As shown in the graph, the valve signal 487 generated by the valve motion accelerometer 478 is different from the background signal 488 generated by the background motion accelerometer 473. To exclude or minimize the background motion contribution to the measured valve motion, the background signal 488 may be subtracted from the valve signal 487 to produce a normalized valve signal 489.

In other exemplary embodiments, the pump device described herein is in a suitable location within the pump device (eg, within or near a valve, outlet port, or other component that allows fluid passage). One or more beam block sensors (eg, infrared-based, laser-based, etc.) installed in The beam block sensor can include a plurality of sensor components and can be configured to detect the passage of fluid between or near one or more of the components. Preferably, the sensor can be configured to generate a signal when the milked fluid blocks the beam by passing between the beam emitter and the beam detector. The resulting signal can be used to generate measurement data indicative of the volume of the milked fluid. For example, the measurement data can be based on the length of time that the fluid passes between or near sensor components.

FIG. 11D illustrates an exemplary embodiment of a breast milking device that employs a beam block sensor 477. Milking device 472 includes a breast interface 474 and a reservoir 462. The reservoir is threaded or otherwise coupled to the milking device 466. Any of the exemplary embodiments disclosed herein, such as milking devices, interfaces, reservoirs, etc., may be used in the exemplary system. The beam block sensor 477 is positioned adjacent to the output of the milking device, thus blocking and milking the light beam 477a as the milk droplet 468 is discharged from the milking device outlet into the reservoir 462. Allows fluid measurement. Fluid is collected in layer 464 within reservoir 462. Data from the sensor can then be processed, transmitted, or otherwise displayed using any of the methods disclosed herein.

In another exemplary embodiment, the pump device described herein is a milking volume, such as a charge coupled device (CCD), an active pixel sensor in a complementary metal-oxide-semiconductor (CMOS), or a camera. Can be included to include one or more image sensors for capturing an image of the fluid. The image sensor may be integrated with or coupled to a suitable part of the pump device. Conversely, the image sensor can be located on another device separate from the pump device, such as a smartphone or other mobile device. In an exemplary embodiment, the breast interface includes a valve that allows passage of milked fluid, as previously described herein, and a suitable image sensor captures an image of the fluid passing through the valve. Therefore, it is positioned on or near the valve. Preferably, the image sensor is operably coupled to a processing unit configured to analyze the image data (eg, using a suitable image analysis algorithm) to determine fluid volume. For example, an image sensor can be used to capture an image of a fluid droplet, and the image can be analyzed to count the number of droplets. In some instances, the image data can be transmitted to a computing device (eg, a smartphone) for analysis, as described in further detail below.

FIG. 11E illustrates an exemplary embodiment having a CCD or CMOS device 479 adjacent to the exit of the milking device. Milking device 472 includes an interface 474 and a reservoir 462, any of which may be any of the embodiments disclosed herein. As breast milk 468 is milked, it passes through the outlet of the milking device beyond the CCD or CMOS 479, which detects fluid and allows its quantification as described above. Breast milk 468 then accumulates in layer 464 within reservoir 462. Data from device 479 may then be processed, transmitted, or otherwise displayed using any of the methods disclosed herein.

FIG. 11F illustrates an exemplary embodiment of characterizing milked breast milk using an image of the reservoir. Once breast milk 468 is collected in reservoir 462, the reservoir may optionally be removed from the milking device. A cell phone with a suitable application to analyze the photos, determine the amount of milked milk, and optionally provide other details about the milked milk, then take a photo 463a of the reservoir May be used to The data is processed, transmitted, or otherwise displayed using any of the methods disclosed herein.

FIG. 11G illustrates an alternative embodiment of the optical sensor system. After breast milk 468 is milked and collected in reservoir 462, a camera in pump control unit 465 obtains an image of breast milk in the reservoir and analyzes it for volume or other characteristics May be used. The pump control 465 may be any of the pump controls described herein, and the data is processed, transmitted, or displayed using any of the methods disclosed herein. May be.

In some exemplary embodiments, the pump devices described herein can employ one or more capacitive sensors to measure fluid volume. The capacitive sensor allows passage of fluid from any suitable part of the pump device, such as fluid contained within the collection reservoir and / or breast interface (eg, milking area 260, valve, outlet port, or tubing interface) The volume of fluid contained within the component.

11H-11I illustrate an exemplary embodiment of a milking device using a capacitive sensor. The milking device 472 may be any of the milking devices disclosed herein and similarly has an interface 474, which may be any of the interfaces disclosed herein. Reservoir 462 is threaded 466 or otherwise coupled to the milking device, and the reservoir may be any of the reservoirs described herein. As breast milk 468 is milked and collected at the outlet of the milking device, it passes through the volume sensor 475, which then allows the fluid volume to be measured. FIG. 11I is similar to the embodiment in FIG. 11H, but the main difference is that the capacitive sensor 475a is located in the reservoir 462 near the bottom rather than in the outlet of the milking device. Data from the sensor in any embodiment may then be processed, transmitted, or displayed using any of the techniques described herein.

In other exemplary embodiments, one or more strain gauges can be used to measure the volume of the milked fluid. The strain gauge can be installed at any suitable location within the pump device. For example, the strain gauge may be coupled to a flap valve (or any other valve that allows passage of milked fluid) and configured to determine volume based on the displacement of the valve over time. it can. Alternatively or additionally, a strain gauge can be coupled to the collection reservoir and configured to measure the volume of milked fluid contained within the reservoir.

FIG. 11J illustrates an exemplary embodiment of a strain gauge. The milking device 472 includes an interface 474, a thread 466 or otherwise coupled thereto 466, a reservoir 462. Any part of the system may be any of the components described elsewhere herein. As the milk is milked 468, it accumulates in the outlet of the milking device. Ultimately, the accumulated breast milk weight is sufficient to activate and open valve 476. A strain gauge 481 is coupled to the flap valve and the sensor is then used to collect data regarding the movement of the valve, thus it correlates with the collected fluid.

Fluid accumulates in layer 464 within reservoir 462. Data from the sensor is then processed, transmitted, or displayed using any of the methods disclosed herein.

FIG. 11K illustrates an alternative embodiment of a strain gauge. This embodiment generally takes the same form as the previous embodiment, the main difference being that the collected fluid layer 464 is placed on a plate 483 that bears the weight of the collected fluid. . Thus, as the weight increases or decreases, the strain gauge 481a disposed under the plate 483 detects the weight change, which can be correlated to the collected fluid volume. Data from the sensor is then processed, transmitted, or displayed according to any of the methods disclosed herein.

FIGS. 11O-11Q illustrate an exemplary embodiment of a strain gauge or force sensitive resistor (FSR) comprising an integrated processing unit. FIG. 11O is a cross-sectional view of the embodiment. The strain gauge 490 is located in the bottom of the reservoir, such as the reservoir 462 or any reservoir described herein, in a configuration that places the load 469 of the milked milk 468 on the sensor area of the strain gauge or FSR 490. May be integrated. The strain gauge 490 may include a small force sensitive resistor that adjusts its resistance based on the compressive force applied thereto. To maximize the sensitivity of the strain gauge 490 to the load 469, the bottom inner surface 491 of the reservoir 462 may be designed to minimize the absorption of the load 469 as the load is transmitted to the strain gauge. Good. For example, the bottom inner surface 491 may comprise a bellows element 492, allowing the surface 491 to move up and down by extending the surface 491, thereby minimizing the absorption of the load 469. Preferably, reservoir 462 comprises a self-contained electronic device that collects, processes, and communicates data generated using strain gauge 490. A strain gauge 490 may be mounted on the support 493 and coupled to the processing unit 494, as shown in FIG. 11P, which is an exploded view of the embodiment in FIG. Power may be supplied to the processing unit 494 via a direct contact connection such as a battery or cable or pad connector, or preferably via an inductive charging system. The inductive charging system may include a battery 495 coupled to the processing unit and a wireless charger 496 coupled to the battery and may be charged using inductive charging methods known in the art. FIG. 11Q is a detailed view of the processing unit 494. The processing unit 494 may comprise a printed circuit board (PCB) that stores one or more of the microcontroller 494a, the communication module 494b, the strain gauge connection 494c, the power connection 494d, and the timer 494e. . The processing unit 494 may receive a signal from the strain gauge 490 through the strain gauge connection 494c and the signal may be transmitted to the microcontroller 494a. The microcontroller 494a may comprise a non-transitory computer readable medium comprising instructions for collecting and processing signals received from the strain gauge 490. The microcontroller 494a may further comprise instructions for transmitting the collected and / or processed signals to the communication module 494b. The communication module 494b may include a wireless transmitter / receiver such as a Blue Tooth module, for example. Communication module 494b may be configured to transmit strain gauge data to another computing device, such as a pump control unit of a milking device or a mobile phone, for data analysis and / or display.

The integrated processing unit of the embodiment of FIGS. 11O-11Q may also be suitably combined with any other sensor described herein. A milking device with a reservoir with an integrated sensor and processing unit as described helps to automate the management and monitoring of breast milk production, thus reducing the need to manually maintain records related to breast milk production Can do. For example, a strain gauge system as described can monitor the amount of milk produced and automatically process the data and send it to a computing device where the user can easily access the information. . Such a system can greatly improve the convenience for the user and can help reduce human errors associated with manual record keeping.

In an exemplary embodiment, some or all of the measurement data collected by the sensor can be fed back to the pump device to optimize fluid milking. Preferably, the feedback is a processing unit and / or control unit (eg, suitable hardware located within controller 115) of the pump device configured to control one or more functionalities of the actuation assembly. Can be transmitted. Based on the feedback, the processing unit can determine changes to the operating parameters of the operating assembly to achieve and / or maintain optimal fluid milking. For example, the feedback can be used to determine the adjustment of the pump, piston assembly, or any other suitable actuation assembly to a reduced pressure stroke or cycle per minute.

FIG. 21 illustrates an exemplary milking system with feedback control. The system is preferably sized and shaped to mate with a pump unit 2100 and a target anatomy, here a breast 2112, including a controller and processor 2104 and a motor 2102 for operating the device. Assembly 2110. Any of the elements in the present exemplary system may be any of the components disclosed elsewhere herein in other exemplary embodiments. In this embodiment, feedback 2106 from a sensor that monitors milked milk in the milking device 2110 is transmitted from the distal assembly (milking device with interface) to the controller and processor 2104. The data is processed and this information is used to provide instructions to the motor 2102 to increase or decrease the operation of the milking device, which is then sent back to the milking device or distal assembly 2110 via communication 2108. The The feedback information may also be used to provide instructions to the motor 2012 to change the number of strokes or cycles per minute of the milking device. Any of the embodiments herein may include such a feedback loop.

FIG. 12 illustrates an exemplary embodiment of a controller 500 for a pump device that includes a display screen 505. The controller 500 may include suitable hardware for collecting, processing, and storing milking data as described herein, and analysis results obtained from processing the milking data. In the preferred embodiment, this information is displayed to the user of the pump device via display screen 505. Further, as shown in FIG. 13, information can also be transmitted from the controller 500 and displayed on a separate computing device, such as the mobile device 510, as described in more detail below. Information can be presented in any suitable form, including graphs, charts, tables, images, or other visual elements such as one or more lights of different colors. Alternatively or in combination, the information may be provided via an audible indicator. Information may be presented in a form that is static or dynamic (eg, updated in real time, etc.). In addition, the controller 500 includes buttons 515 and input devices that allow a user to interact with displayed information, such as a keyboard, joystick, touch screen, switch, or knob, or a suitable combination thereof. be able to.

Communicating with a computing device In any of the embodiments disclosed herein, the pump device described herein can communicate with another entity, such as one or more computing devices and / or servers. Can be configured to communicate. Exemplary computing devices include personal computers, laptops, tablets, and mobile devices (eg, smartphones, cell phones). The servers described herein can be implemented across physical hardware, virtualized computing resources (eg, virtual machines), or any suitable combination thereof. In a preferred embodiment, the server is a distributed computing server (also known as a cloud server) that utilizes any suitable combination of public and / or private distributed computing resources. The computing device and / or server may be in close proximity to the pump device (short range communication) or may be remotely located from the pump device (long range communication). Any description herein relating to communication between a computing device and a pump device can also be applied to communication between a server and a pump device and vice versa.

FIG. 13 illustrates short range communication 515 between the controller 500 of the pump device and the mobile device 510. The communication 515 can use a wireless communication method as will be described below. In many embodiments, the controller 500 and mobile device 510 are also capable of long-range communication.

FIG. 14 is a schematic diagram of a pump device 800 in communication with a computing device 805 and a server 810. The pump device 800 includes one or more breast interfaces 815, an actuation assembly 820, a sensing unit 825, and a communication module 835. Preferably, the communication module 830 is implemented across suitable hardware in the controller (eg, controller 500) of the pump device. The pump device 800 can communicate with the computing device 805 and the server 810 via the communication module 830. In many embodiments, the communication module 830 is communicatively coupled to the computing device 805 and the server 810 via first and second data connections 835, 840. Further, server 810 may be communicatively coupled to computing device 805 via third data connection 845. Although the pump device 800 is depicted herein as communicating directly with the computing device 805 and the server 810, other configurations are also possible. For example, pump device 800 may communicate indirectly with server 810 via computing device 805, or vice versa. Conversely, server 810 may communicate indirectly with pump device 800 via computing device 805, and computing device 805 may communicate with pump device 800 via server 810. Any description herein regarding communication between pump device 800, computing device 805, or server 810 can be applied to direct communication as well as indirect communication between these entities.

Data connections 835, 840, and 845 can utilize any suitable communication method for transmitting data between pump device 800, computing device 805, and server 810. Such communication methods may include wired communication (eg, wire, cable such as USB cable, optical fiber) and / or wireless communication (Bluetooth®, WiFi, near field communication). In many embodiments, data is transmitted over one or more networks, such as a local area network (LAN), a wide area network (WAN), a telecommunications network, the Internet, or a suitable combination thereof. be able to.

In the exemplary embodiment, pump device 800 transmits milking data for breast milk to computing device 805 or server 810 (directly or indirectly). Breast milking data may include measurement data generated by the sensing unit 825 of the pump device 800, as previously described herein. In many embodiments, the pump device 800 analyzes the measurement data (eg, using suitable built-in hardware and / or software) and transmits the analysis results to the computing device 805 or server 810. Alternatively, the measurement data can be analyzed by computing device 805 or server 810, such as using one or more applications. A computing device 805 or server 810 may be associated with data storage for storage of measurement data and / or analysis results.

The application (of computing device 805 or server 810) also collects and aggregates measurement data and / or analysis results, as described earlier in this specification, in a suitable format (eg, chart, table, graph, image). Etc.) can be displayed to the user. Preferably, the application allows the user to overlay information such as lifestyle choices, meals, and strategies to increase breast milk output to facilitate comparison of such information with milk output statistics. , Including additional features. The analysis and display functionality described herein may be performed by a single entity or any suitable combination of entities. For example, in many embodiments, data analysis can be performed by server 810 and the analysis results can be transmitted to pump device 800 or computing device 805 for display to the user.

In addition, the computing device 805 or server 810 may be configured to power the pump device 800 or a portion thereof (eg, the actuation assembly 820), such as power, applied reduced pressure

(via the interface 815), or cycles per minute. An application configured to control at least one functionality can be included. For example, the communication module 830 can receive control signals from the computing device 805 and / or the server 810 and transmit the control signals to the actuation assembly 820 to effect the desired actuation. In a preferred embodiment, the control signal is based on the measurement data provided by the sensing unit 825, using feedback provided by the pump device 800 as such feedback, as previously described herein. Can be generated. In addition, the computing device 805 or server 810 may implement machine learning techniques for controlling the pump device 800 to improve and optimize pump performance over time.

Further, the pump device 800, the computing device 805, and / or the server 810 can be configured to provide a reminder to the user to milk the breast milk. Such notifications can help avoid loss of pump sessions and thus reduce the occurrence of associated complications such as mastitis. The notification may be generated based on previously collected milking data for breast milk, such as data regarding milking frequency and / or timing of previous pump sessions, and based on user preferences. Preferably, the notification functionality is included in a suitable application that runs on computing device 805 or server 810. For example, the pump device 800 sends information about the pump usage time to the computing device 805 or server 810 so that the application can identify when the pumping has occurred and identify the reminder at the desired pump time. can do.

Notifications can be provided using any suitable method and in any suitable form. For example, the notification is generated by computing device 805 or server 810 and transmitted to pump device 800 (eg, communication module 830) and displayed to the user (eg, on the display of pump device 800 such as display screen 505).)be able to. Conversely, the notification can be generated by pump device 800 and transmitted to computing device 805 and / or server 810. In many embodiments, the notification is displayed to the user by the computing device 805. Alternatively, pump device 800, computing device 805, and / or server 810 can use other methods to provide notifications to the user. For example, the notification can be sent to an email address, via a short message service (SMS) to a smartphone or other mobile device associated with a mobile phone number, or to a web page accessible by the user.

Other types of data can also be transmitted between pump device 800, computing device 805, and / or server 810. For example, in many embodiments, firmware updates for one or more components of pump device 800 can be transmitted from computing device 805 and / or server 810 to pump device 800.

FIG. 17 illustrates another exemplary embodiment of a system for monitoring milking or other fluids of breast milk. The system 1700 includes a pump unit 1702, a distal assembly 1706 (sometimes referred to herein as an interface), a wireless communication transmitter and receiver 1709, 1712, a computing device 1714, a remote server. 1718. The pump unit 1702 may be any of the pump units described herein or known in the art, and the distal assembly 1708 may also be described herein. Or any of those known in the art. Distal assembly 1706 is preferably sized and shaped to match the target anatomy, which in this exemplary embodiment is breast 1708. Pump unit 1702 operates distal assembly 1706 1704 to produce milk from breast 1708 using any of the activation mechanisms disclosed herein. The transmitter 1709 is preferably disposed on or adjacent to the pump unit and is configured to transmit data 1710 from the pump unit to a receiver 1712 on the computing device 1714. Data may be transmitted wirelessly using methods known in the art, such as those disclosed herein. In an alternative embodiment, a wired connection, such as with a USB cable, may be used to operably couple pump 1702 and computing device 1714 together. The computing device may be a smartphone, tablet, personal computer, or any other electronic computing device that can display data transmitted from the pump unit 1702. The computing device may also send information back to the

pump unit to help control the operation of the distal assembly. Computing device 1714 may also communicate 1716 with remote server 1718, which may store or display data. Access to remote service 1718 may be by the Internet or other means known in the art, so that cloud-based data can be easily accessed from any other device using internet access. obtain.

FIG. 18 illustrates another exemplary embodiment of a system 1800 for milking milk. In this embodiment, system 1800 includes a pump unit 1802, a distal assembly 1806, and a cloud-based or remote server 1812. The pump unit 1802 can be any of the pumps disclosed herein and is operably coupled to a distal assembly 1806 that is sized and shaped to match a target, such as a breast 1808. . The distal assembly may be any of the distal assemblies described herein. Pump unit 1802 activates the distal assembly 1804 using any of the mechanisms disclosed herein to produce milk from breast 1808. Pump unit 1802 also includes a transmitter and receiver 1809 for transmitting pump data 1810 to remote server 1812, which in this embodiment is a cloud-based server. Thus, data may be transmitted to a remote service via the internet and accessed from a cloud-based server via the internet by pump 1802 or any other computing device. Preferably, communication with the cloud-based server is performed by wireless communication.

19A-19C illustrate an exemplary computing device display 1904. FIG. For example, FIG. 19A illustrates an exemplary display on the mobile phone 1902 and schematically illustrates breast milk production, time of the last pump session, goal achievement graphics, and graphics illustrating user fluid consumption. In addition, display 1904 may also provide user incentives or user feedback based on the amount of milk production. FIG. 19B is an enlarged view of the display 1904 in FIG. 19A. FIG. 19C illustrates additional information that the display 1904 may show when the touch screen is activated (eg, by swiping or touching the screen). For example, the milked milk volume is shown after the "Final Pump Session" section of the display is selected. Some or all items may be expanded as shown in FIG. 19C as well. Additional information, or in some situations, less information may be displayed as desired.

20A-20B illustrate another exemplary display that may be used in a breast milking system. For example, FIG. 20A is an exemplary display 2002 on any of the computing devices disclosed herein and operably coupled with any of the pump units described herein. The display may show the average volume of breast milk milked over any period, along with the average duration of the milking session during that same period. Graphics (eg, bar charts, pie charts, xy plots, etc.) may be used here to show the milked volume during individual sessions over the course of several days from Monday to Friday. The display may allow the user to annotate the display so that a lost session may be considered if, for example, the session is omitted due to travel, the display may be May indicate a trip. Other annotations may also be added here, such as when a food or nutritional supplement is taken, which is hops or fenugreek. This allows the user to remind when a milked milk sample is obtained for consumption of food or nutritional supplements. The display may have other function buttons such as seeking advice, accessing the cloud, setting an alarm, taking notes, storing data, or establishing system preferences. Communication between the computing device and the pump unit in FIGS. 20A-20B is discussed more fully above with respect to FIG.

FIG. 20B illustrates an exemplary display 2004 that may be on a computing device in the system or, more preferably, on any of the pumps disclosed herein. The display 2004 is similar to a dashboard gauge and shows the volume and time of the milked and collected fluid. Other information may also be displayed.

Experimental Data FIGS. 15 and 16 illustrate experimental pump operation data obtained from a commercial breast pump device and an exemplary embodiment of the present invention. The

exemplary embodiment utilizes an incompressible fluid for pumping and has a maximum hydraulic fluid volume of 4 cc, while commercially available devices utilize air for pumping and have a maximum volume of 114 cc. did.

FIG. 15 illustrates a graph of pump performance as quantified by the reduced pressure generated per stroke. For the exemplary embodiment, pressure measurements are made on fluid volumes 1 cc, 2 cc, 3 cc, and 4 cc displaced by the pump, and the stroke number corresponds to volume cc. For commercially available devices, one of seven equally spaced positions along the vacuum adjustment gauge representing 46 cc, 57 cc, 68 cc, 80 cc, 91 cc, 103 cc, and 114 cc of the fluid volume displaced by the pump, respectively. Measurement is performed using a pump set to, and the stroke number corresponds to the position number. Curve 700 corresponds to an exemplary embodiment and curve 705 corresponds to a commercially available device. The exemplary embodiment produced higher levels of reduced pressure per displacement volume compared to commercially available devices, with the highest reduced pressure being -240.5 mmHg and -177.9 mmHg, respectively.

FIG. 16 illustrates a graph of pump efficiency as measured by maximum reduced pressure per maximum volume of displaced fluid, with bar 710 corresponding to an exemplary embodiment and bar 715 corresponding to a commercially available device. . The exemplary embodiment demonstrated a 42-fold increase in pump efficiency compared to commercially available devices, with efficiencies of −71.1 mmHg / cc and −1.7 mmHg / cc, respectively.

The various techniques described herein may be partially or fully performed using code that can be stored on storage media and computer-readable media and that can be executed by one or more processors of a computer system. May be implemented. Storage media and computer readable media containing code or part of code include: RAM, ROM, EEPROM, flash memory or other memory technology, CD-ROM, digital versatile disc (DVD) or other optical storage, magnetic cassette, Magnetic tape, magnetic disk storage or other magnetic storage device, solid state drive (SSD) or other solid state storage device, or can be used to store desired information and accessed by system devices Implemented in any method or technique for storing and / or transmitting information such as computer readable instructions, data structures, program modules, or other data, including any other medium Not volatile and non-volatile Nonvolatile, including storage media and communication media, such as removable and non-removable media, may include any suitable medium that is known or used in the art. Based on the disclosure and teachings provided herein, one of ordinary skill in the art may appreciate other ways and / or methods to implement various embodiments.

It should be understood that different aspects of the present invention may be recognized individually, collectively, or in combination with each other. Any suitable element or feature of the embodiments described herein can be combined with or substituted for the element or feature of any other embodiment.

While preferred embodiments of the present invention have been shown and described herein, it will be appreciated by those skilled in the art that such embodiments are presented by way of example only. Many variations, modifications, and alternatives can now be devised by those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein can be used to practice the invention. The following claims are intended to define the scope of the invention, and the methods, configurations, and equivalents within the scope of these claims are intended to be encompassed thereby.

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WO2016014488A1	2014-07-22	2016-01-28	Exploramed Nc7, Llc	Breast pump system and methods
WO2016014483A1	2014-07-22	2016-01-28	Exploramed Nc7, Llc	Breast pump system and methods
AU2015292839B2	2014-07-22	2019-09-12	Willow Innovations, Inc.	Breast pump system and methods
SG11201700862VA	2014-08-11	2017-03-30	Joelle K Barral	Synchronizing breast pumping with infant feeding
WO2016044368A1	2014-09-16	2016-03-24	Exploramed Nc7, Inc.	Systems, devices and methods for assessing milk volume expressed from a breast
CN105148341A *	2015-08-25	2015-12-16	陈俊波	Time-division pumping mode of double-side breast pump
EP3393540B1	2015-12-23	2019-11-20	Koninklijke Philips N.V.	Breast pump, method and computer program
WO2017139437A1	2016-02-10	2017-08-17	Exploramed Nc7, Inc.	Breast pump assembly and methods
EP3299043A1 *	2016-09-22	2018-03-28	Medela Holding AG	Breast hood unit

WO2022173352A1 *	2021-02-11	2022-08-18	Delaval Holding Ab	A method of controlling a milking arrangement, and a milking arrangement

* Cited by examiner, † Cited by third party, ‡ Family to family citation

Similar Documents

Publication	Publication Date	Title
JP2017509379A	2017-04-06	Method, apparatus and system for milking human breast milk
US20150283311A1	2015-10-08	Method, apparatus, and system for expression of human breast milk
JP6728220B2	2020-07-22	Improved milking system with detection, feedback and connectivity
JP2016514516A	2016-05-23	Methods, apparatus, and systems for expression and quantification of human breast milk
US20200061265A1	2020-02-27	Breast pump assembly with remote interface
US20160296681A1	2016-10-13	Fluid measurement accessory for breast pumps
WO2008150633A3	2009-02-19	Wireless monitor for a personal medical device system
RU2729444C2	2020-08-06	Breast pump, a method for determining the amount of expressed milk and an information carrier with a program recorded thereon for realizing the method
TWI559254B	2016-11-21	Tele-care management systems and methods for peritoneal dialysis
US20210060220A1	2021-03-04	Breast pump assembly with customized and variable functionality
EP3517148A1	2019-07-31	Breast status determination
AU2020203701A1	2020-06-25	Pump apparatus and methods for expression of human breast milk
US20220203001A1	2022-06-30	Smart connected breast pump
JP2022100769A	2022-07-06	Completely closed perfusate delivery system and completely closed perfusate circulation system

Priority And Related Applications

Priority Applications (3)

Application	Priority date	Filing date	Title
US201461937027P	2014-02-07	2014-02-07	*US Provisional Application*
US61/937,027		2014-02-07	
PCT/US2015/014901	2014-02-07	2015-02-06	Methods, apparatus, and system for expression of human breast milk

Concepts

machine-extracted

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Name	Image	Sections	Count	Query match
human milk		title,claims,description	76	0.000
Breast		claims,abstract,description	176	0.000
Milk		claims,abstract,description	61	0.000
milk		claims,abstract,description	56	0.000
milk		claims,abstract,description	56	0.000
fluid		claims,description	156	0.000
measurement		claims,description	75	0.000
Milk, Human		claims,description	71	0.000
communication		claims,description	67	0.000
analytical method		claims,description	38	0.000
activating		claims,description	8	0.000
controlling effect		claims,description	7	0.000
displacement reaction		claims,description	6	0.000
absorption reaction		claims,description	4	0.000
Colostrum		claims,description	3	0.000
colostrum		claims,description	3	0.000

Show all concepts from the description section

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Electronic Patent Application Fee Transmittal

Application Number:	17181057
Filing Date:	22-Feb-2021
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Filer:	Anupma Sahay/Renee Bennett
Attorney Docket Number:	4944.0120006

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	130	130
		Total in USD ($)		**130**

Electronic Acknowledgement Receipt

EFS ID:	46632776
Application Number:	17181057
International Application Number:	
Confirmation Number:	4690
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	26111
Filer:	Anupma Sahay/Renee Bennett
Filer Authorized By:	Anupma Sahay
Attorney Docket Number:	4944.0120006
Receipt Date:	16-SEP-2022
Filing Date:	22-FEB-2021
Time Stamp:	16:47:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$130
RAM confirmation Number	E20229FG48081468
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	2022-09-16-IDS_Transmittal_4944-0120006.PDF	222882 ca8762094b02f19f8b1610652a757453f74573dd	no	1
Warnings:					
Information:					
2	Transmittal Letter	2022-09-16-IDS-Pleading-4944-0120006.pdf	103253 eef2733232d207cc198e6e2607a9f40da811aeed	no	2
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	2022-09-16-IDS-SB08a-4944-0120006.pdf	171431 e11f4562794d91d0166c7a52dc98a57164dbb021	no	2
Warnings:					
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4	Foreign Reference	FP1_JP2007501673A.PDF	1047933 ded1cff23953f063a92ff6b940b429861238b620	no	56
Warnings:					
Information:					
5	Foreign Reference	FP2_JP2014529312A.PDF	502800 85aca051c5292465ee8a0d28fda804d31c2603d6	no	28
Warnings:					
Information:					
6	Foreign Reference	FP3_JP2016514516A.PDF	568791 5010bc4d9e8d89fbde11360d405db7b6a01ab5ff	no	32
Warnings:					

Information:					
7	Foreign Reference	FP4_JP2017509379A.PDF	1442845 4361e48dfc0bfc140b4793248b976d2904431915	no	73
Warnings:					
Information:					
8	Fee Worksheet (SB06)	fee-info.pdf	37817 19fe2b8f34f4292f0b320c70487211c3a02e3d65	no	2
Warnings:					
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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/21 (07-09)
Approved for use through 12/31/2020. OMB 0651-0031
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☑ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☑ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

Copies of cited documents FP1-FP4.

Remarks

The Office may charge any fee deficiency for any submission made with this transmittal to Deposit Account No. 19-0036.

Online Payment Authorization for $130.00 to cover the IDS fee

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Anupma Sahay #78,704/		
Printed name	Anupma Sahay		
Date	September 16, 2022	Reg. No.	78,704

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: CHIARO TECHNOLOGY LIMITED	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, COURTNEY B
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Supplemental Information Disclosure Statement

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

Listed on accompanying IDS Form PTO/SB/08a or its equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Applicant has listed publication dates on the attached IDS Form based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

Filing under 37 C.F.R. § 1.97(c). This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on

the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application.

The required fee is provided through online credit card payment authorization in the amount of **$130.00** in payment of the fee under 37 C.F.R. § 1.17(p).

Copies of documents **FP1-FP4** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2)(ii), no copies of the U.S. patent application publications cited as documents **US1-US3** on the attached IDS Form are submitted.

It is expected that the examiner will review the prosecution and cited art in the parent Application No. 16/009,547, filed June 15, 2018 (now U.S. Patent No. 10,926,011) in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Anupma Sahay #78,704/

Anupma Sahay
Attorney for Applicant
Registration No. 78,704

Date: September 16, 2022

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(202) 371-2600

19027893.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: Chiaro Technology Limited	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, Courtney B.
Filed: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Amendment and Reply Under 37 C.F.R. § 1.111

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

In reply to the Office Action dated January 26, 2022, Applicant submits the following amendment and remarks.

If extensions of time are necessary to prevent abandonment of this application, then they are petitioned for under 37 C.F.R. § 1.136(a). Any additional fees required to continue prosecution or appeal of this application (including issue fee, fees for net addition of claims or forwarding to appeal) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently amended) A breast pump device ~~that is configured as a self-contained, in-bra wearable device,~~ comprising:

a self-contained, in-bra wearable device comprising:

~~(i)~~ a housing comprising: ~~that includes~~

~~(a)~~ a battery, and

~~(b)~~ a pump configured to generate ~~generating~~ negative air pressure;

~~(ii)~~ a breast shield of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing, the breast shield comprising ~~made up of~~ a breast flange and a nipple tunnel comprising a side wall and a front end, wherein ~~in which~~ the breast shield is transparent or optically clear; and

~~(iii)~~ a milk container ~~that is~~ configured to be attached to and removed from the housing,

wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast.

2. (Canceled)

3. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast shield is rigid.

4. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast shield is a dishwasher safe, plastic breast shield.

5. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast shield is configured to be attached using magnets to the housing.

6. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast.

7. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast shield is configured to present[[s]], in use, a single continuous surface to a nipple and a breast.

8. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which the breast shield integrates~~ the breast flange and the nipple tunnel are integrally formed ~~as a single item~~.

9. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast shield is configured to be generally symmetrical about a center-line ~~centre-line~~ running from a top to a bottom of the breast shield when positioned upright for normal use.

10. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast shield is configured to slide into the housing with a single push action.

11. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast shield is configured to slide out from the housing, together with a membrane that is configured to prevent[[s]] milk from flowing into the pump.

12. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the milk container is rigid.

13. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the milk container is an optically clear, dishwasher safe, plastic milk container.

14. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein the ~~in which~~ milk container is configured to attach[[es]] to a lower part of the housing and forms a base of the breast pump device.

15. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the milk container is configured to magnetically attach to the housing.

16. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the nipple tunnel comprises ~~includes~~ guide lines running parallel along one or more sides of the nipple tunnel.

17. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the nipple tunnel comprises ~~includes~~ an air hole or passage, and wherein the pump is configured to transfer[[s]] negative air pressure into the nipple tunnel via the air hole or passage.

18. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the nipple tunnel comprises ~~includes~~ on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container.

19. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the pump comprises ~~includes~~ one or more piezo air pumps.

20. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the housing further comprises ~~includes~~ a Universal Serial Bus (USB) charging socket.

21. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the housing comprises ~~includes~~ a left or right breast selector or toggle switch that, when selected

for a particular pumping session, is configured to send[[s]] data to a connected application configured to track pumping sessions, to indicate whether that particular session is associated with a left or a right breast.

22. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the housing is configured to be shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra.

23. (Canceled).

24. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast pump device is configured to deliver a maximum suction of approximately 240_mmHg.

25. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast pump device comprises ~~includes~~ a sensor that is configured to directly measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container.

26. (Canceled)

27. (Canceled)

28. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the pump is configured to deliver[[s]] in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

29. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the pump is a lightweight air pump that enables a total mass of the breast pump device, unfilled with milk, to be less than 250 gm.

30. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast pump device is configured to make ~~makes~~ less than 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

31. (Currently amended) A kit, comprising:

the breast pump device of claim ~~Claim~~ 1; and

the plurality of interchangeable breast shields.

32. (Currently amended) The kit of claim ~~Claim~~ 31, wherein each of the plurality of interchangeable breast shields comprises ~~includes~~ fit lines in a nipple tunnel of that breast shield that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel.

33. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein the battery is a rechargeable battery, and wherein the housing further comprises: ~~includes (c)~~

a power charging circuit configured to control ~~for controlling~~ the charging of the rechargeable battery, and

~~(d)~~ control electronics configured to be powered by the rechargeable battery.

34. (New) The breast pump device of claim 1, wherein length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same.

Remarks

Upon entry of the foregoing amendment, claims 1, 3–22, 24–25, and 28–34 are pending in the application. Claim 1 is an independent claim. Claims 1, 3–22, 24–25, and 28–34 are amended. Claim 2 is canceled without prejudice or disclaimer. New claim 34 is added. These changes do not introduce any new matter, and Applicant respectfully requests their entry.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Office reconsider and withdraw all outstanding objections and rejections.

Allowable Subject Matter

The Office indicates claim 28 is allowable over the prior art of record excepting the double patenting rejection of the same. (Office Action dated January 26, 2022, p. 53.) Applicant appreciates the Office's indication that claim 28 would be allowable if the double patenting rejection is overcome. (*Id.*) For at least the reasons discussed below, all pending claims are allowable over the cited art.

Claim Objections

The Office objects to claims 14, 28, and 29 because of alleged informalities. (*Id.*, 2.) Without acquiescing to the propriety of the objections and in an effort to expedite prosecution, Applicant amends claims 14, 28, and 29 to recite "the milk container," recite "the pump is configured to deliver," and to end in a period, respectively. Accordingly, Applicant asks the Office to withdraw the objections to claims 14, 28, and 29.

Rejections under 35 U.S.C. § 103

The Office rejects claim 1 under 35 U.S.C. § 103 as allegedly obvious over U.S. Publication No. 2008/0275386 to Myers in view of U.S. Publication No. 2014/0378895 to Barack. (*Id.*, 4.) The Office also rejects claim 1 under 35 U.S.C. § 103 as allegedly obvious over U.S. Publication No. 2013/0023821 to Khalil *et al.* in view of Myers and Barack. (*Id.*, 8.)

Without acquiescing to the propriety of the rejection and in an effort to expedite prosecution, Applicant amends claim 1. For at least the reasons discussed below, Khalil, Myers, and Barack,

alone or in combination, do not disclose or suggest the features of claim 1, and do not render obvious claim 1 or its dependents.

Independent Claim 1

Claim 1 recites, in part, "wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast." The Office acknowledges that Myers and Khalil do not teach or disclose "the breast shield being of a plurality of interchangeable breast shields each having a different size." (*Id.*, 5, 9.) Instead, the Office relies on Barack as allegedly teaching "interchangeable breast shields each having a different size." (*Id.* (citing Barack, ¶[0054]).) However, Barack's limited disclosure simply states that says that one breast shield with one tunnel size may be switched with another breast shield with another tunnel size. (Barack, ¶[0054].) Barack fails to disclose or suggest how the tunnel sizes are different, let alone that the tunnel sizes provide "a different spacing of a nipple from the side wall of the nipple tunnel," as claimed.

Accordingly, Khalil, Myers, and Barack, alone or in combination, fail to disclose or suggest "wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast" and do not render claim 1 obvious. Applicant asks the Office to withdraw the § 103 rejections of claim 1.

Dependent Claims

The Office rejects claims 2–3, 6–8, 10, 11, 14, 16–18, 22, 24, and 31 under 35 U.S.C. § 103 as allegedly obvious over Myers in view of Barack. (Office Action dated January 26, 2022, p. 4.) Claim 2 is canceled rendering its rejection moot. Claims 3, 6–8, 10–11, 14, 16–18, 22, 24, and 31 depend from and add features to claim 1. Accordingly, claims 3, 6–8, 10–11, 14, 16–18, 22, 24, and 31 are allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claims 3, 6–8, 10–11, 14, 16–18, 22, 24, and 31.

The Office rejects claim 4 under 35 U.S.C. § 103 as allegedly obvious over Myers in view of Barack, as applied to claim 1 above, and further in view of U.S. Publication No. 2016/0296682 to

Phillips *et al.*, as evidenced by U.S. Publication No. 2005/0228342 to Yuen. (*Id.*, 7.) Claim 4 depends from and adds features to independent claim 1. Phillips and Yuen do not overcome the deficiencies discussed above. Accordingly, claim 4 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 4.

The Office rejects claims 2, 6–10, 14, 17, 18, 20–22, and 31 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and Barack. (*Id.*, 8.) Claim 2 is canceled rendering its rejection moot. Claims 6–10, 14, 17, 18, 20–22, and 31 depend from and add features to claim 1. Accordingly, claims 6–10, 14, 17, 18, 20–22, and 31 are allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claims 6–10, 14, 17, 18, 20–22, and 31.

The Office rejects claim 5 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of U.S. Publication No. 2018/0333523 to Chang. (*Id.*, 13.) Claim 5 depends from and adds features to independent claim 1. Chang does not overcome the deficiencies discussed above. Accordingly, claim 5 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 5.

The Office rejects claims 12 and 13 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Phillips. (*Id.*, 13.) Claims 12–13 depend from and add features to independent claim 1. Phillips does not overcome the deficiencies discussed above. Accordingly, claims 12–13 are allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claims 12–13.

The Office rejects claim 15 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of U.S. Publication No. 2007/0228059 to Karsan. (*Id.*, 15.) Claim 15 depends from and adds features to independent claim 1. Karsan does not overcome the deficiencies discussed above. Accordingly, claim 15 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 15.

The Office rejects claim 19 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of U.S. Publication No. 2012/0277636 to Blondheim *et al.* (*Id.*, 16.) Claim 19 depends from and adds features to independent claim 1. Blondheim does not overcome the deficiencies discussed above. Accordingly, claim 19 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 19.

The Office rejects claim 25 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of U.S. Publication No. 2016/0220743 to Guthrie *et al.* (*Id.*) Claim 25 depends from and adds features to independent claim 1. Guthrie does not overcome the deficiencies discussed above. Accordingly, claim 25 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 25.

The Office rejects claim 29 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of U.S. Patent No. 6,227,936 to Mendoza. (*Id.*, 17.) Claim 29 depends from and adds features to independent claim 1. Mendoza does not overcome the deficiencies discussed above. Accordingly, claim 29 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 29.

The Office rejects claim 30 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, in further view of U.S. Publication No. 2009/0281485 to Baker *et al.* (*Id.*, 18.) Claim 30 depends from and adds features to independent claim 1. Baker does not overcome the deficiencies discussed above. Accordingly, claim 30 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 30.

The Office rejects claim 32 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and in further view of Barack, as applied to claim 31 above, in further view of U.S. Publication No. 2012/0165729 to Cudworth. (*Id.*, 18.) Claim 32 depends from and adds features to independent claim 1. Cudworth does not overcome the deficiencies discussed above. Accordingly, claim 32 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 32.

The Office rejects claim 33 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, in further view of U.S. Patent No. 5,542,921 to Meyers *et al.* (*Id.*, 19.) Claim 33 depends from and adds features to independent claim 1. Meyers does not overcome the deficiencies discussed above. Accordingly, claim 33 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 33.

Double Patenting Rejections

The Office rejects claims 1–22, 24, 25, and 29–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of U.S. Patent No. 10,881,766 in view of Khalil, Myers, and Barack. (*Id.*, 21.) The Office rejects claims 1–22, 24, 25, and 28–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of U.S. Patent No. 10,926,011 in view of Khalil, Myers, and Barack. (*Id.*, 23.) The Office provisionally rejects claims 1–22, 24, 25, and 28–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,050. (*Id.*, 26.) The Office provisionally rejects claims 1–22, 24, 25, and 29–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,079. (*Id.*, 29.) The Office provisionally rejects claims 1–22, 24, 25, and 28–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,109. (*Id.*, 30.) The Office provisionally rejects claims 1–22, 24, 25, and 28–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,150. (*Id.*, 32.) The Office provisionally rejects claims 1–22, 24, 25, and 28–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,179. (*Id.*, 34.) The Office provisionally rejects claims 1–22, 24, 25, and 29–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,216. (*Id.*, 36.) The Office provisionally rejects claims 1–22, 24, 25, and 29–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,259. (*Id.*, 38.) The Office provisionally rejects claims 1–22, 24, 25, and 28–33 on the ground of nonstatutory double patenting as allegedly obvious over claims 1 and 31 of copending U.S. Application No. 17/203,292. (*Id.*, 39.) The Office provisionally rejects claims 1–22, 24, 25, and 28–33 on the ground

of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,313. (*Id.*, 41.) The Office provisionally rejects claims 1–22, 24, 25, and 29–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,327. (*Id.*, 43.) The Office provisionally rejects claims 1–22, 24, 25, and 29–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,355. (*Id.*, 45.) The Office provisionally rejects claims 1–22, 24, 25, and 29–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,384. (*Id.*, 47.) The Office provisionally rejects claims 1–22, 24, 25, and 29–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,397. (*Id.*, 49.) The Office provisionally rejects claims 1–22, 24, 25, and 29–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,418. (*Id.*, 51.)

Application Nos. 17/203,109, 17/203,259, and 17/203,313 issued rendering the rejections with respect to these applications moot. Additionally, Applicant respectfully requests that the remaining currently asserted double patenting rejections be held in abeyance until the claimed subject matter is otherwise deemed allowable. After analyzing the final allowed claim scope, Applicant will consider filing a terminal disclaimer if necessary to overcome any obviousness-type double patenting rejections.

New Claim

New claim 34 is added. Claim 34 depends from and adds features to independent claim 1. Accordingly, claim 34 is allowable for at least the same reasons as claim 1.

Conclusion

All grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Office reconsider and withdraw them. A complete reply has been made to the outstanding Office Action. As such, the present application is in condition for allowance. If the Office believes, for any reason, that personal communication will expedite prosecution of this application, the Office is asked to telephone the undersigned at the number provided. Applicant respectfully requests prompt and favorable consideration of this amendment and reply.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Anupma Sahay #78,704/

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Attorney for Applicant
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Date: July 12, 2022

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18100718.1

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	4944.0120006
	Application Number	17/181,057
Title of Invention	BREAST PUMP SYSTEM	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Inventor Information:

Inventor 1 Legal Name				
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Postal Code	EC1N 8LE	**Country**	GB

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	4944.0120006
	Application Number	17/181,057
Title of Invention	BREAST PUMP SYSTEM	

City	London	**State/Province**	
Postal Code	EC1N 8LE	**Country**	GB

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Anupma Sahay #78,704/			**Date (YYYY-MM-DD)**	2022-07-12
First Name	Anupma	**Last Name**	Sahay	**Registration Number**	78,704

18467276.1

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	COURTNEY B. FREDRICKSON
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-D788293-S	05-30-2017	ECKSTEIN et al.	
	002	US-D809646-S	02-06-2018	MASON et al.	
	003	US-D832995-S	11-06-2018	MASON et al.	
	004	US-D888225-S	06-23-2020	ASKEM et al.	
	005	US-7641629-B2	01-05-2010	YUEN; Yat Keung William	
	006	US-10398816-B2	09-03-2019	CHANG et al.	
	007	US-10625005-B2	04-21-2020	CHANG et al.	
	008	US-20040127845-A1	07-01-2004	RENZ; Charles J. et al.	
	009	US-20070219486-A1	09-20-2007	MYERS; Kenneth E. et al.	
	010	US-20120021068-A1	01-26-2012	BARNESS; Itzhak et al.	
	011	US-20120035951-A1	02-09-2012	GOETZ; Steven M. et al.	
	012	US-20120043065-A1	02-23-2012	RANNE; Pasi et al.	
	013	US-20120072117-A1	03-22-2012	LODDOCH; Alexander et al.	
	014	US-20120072118-A1	03-22-2012	MANN; Tobias	
	015	US-20120095599-A1	04-19-2012	PAK; H. Ali et al.	
	016	US-20120143879-A1	06-07-2012	STOITSEV; Todor	
	017	US-20120220753-A1	08-30-2012	GERA; Lajos et al.	
	018	US-20150212036-A1	07-30-2015	JIN; Jian et al.	
	019	US-20150212037-A1	07-30-2015	OKAZAKI; Satoshi et al.	
	020	US-20170216505-A1	08-03-2017	KIM; Sang Ha	
	021	US-20180361040-A1	12-20-2018	O'TOOLE; Jonathan et al.	
	022	US-20210030934-A1	02-04-2021	ZHANG; Shu Ting	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 4

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	COURTNEY B. FREDRICKSON
Attorney Docket Number	4944.0120006

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]–Number[4]–Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	WO-2016010524-A1	01-21-2016	HEWLETT PACKARD DEVELOPMENT CO [US]		☐

Examiner Signature		Date Considered	

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Substitute for form 1449/PTO	Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)	Application Number	17/181,057
	Filing Date	02-22-2021
	First Named Inventor	O'TOOLE; Jonathan
	Art Unit	3783
	Examiner Name	COURTNEY B. FREDRICKSON
Sheet 3 of 4	Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author(in CAPITAL LETTERS),title of the article(when appropriate), title of the item (book,magazine,journal,serial,symposium,catalog,etc.),date,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
	001	4MD Medical, "Assembling Spctra Breast Pump Parts," YouTube [online], dated November13, 2016, URL: http://www.youtube.com/watch?v=ChV8xQfcBxU.	☐
	002	The Best Hands-Free Breast Pumps, posted at healthline.com, earliest date posted on 08/24/2020, [online], acquired on 10/30/2021, Available on internet. url:https://www.healthline.com/health/parenting/breast-feeding/best-hands-free-breast-pumps#Best-hands-free-breast-pumps (Year: 2020).	☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	17/181,057
				Filing Date	02-22-2021
				First Named Inventor	O'TOOLE; Jonathan
				Art Unit	3783
				Examiner Name	COURTNEY B. FREDRICKSON
Sheet	4	of	4	Attorney Docket Number	4944.0120006

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Anupma Sahay #78,704/	Date (YYYY-MM-DD)	2022-07-12
Name/Print	Anupma Sahay	Registration Number	78,704

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to the identity of the inventor (Rule 4.17(i))*

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

— *with international search report (Art. 21(3))*

(54) Title: VIRTUAL KEYBOARD

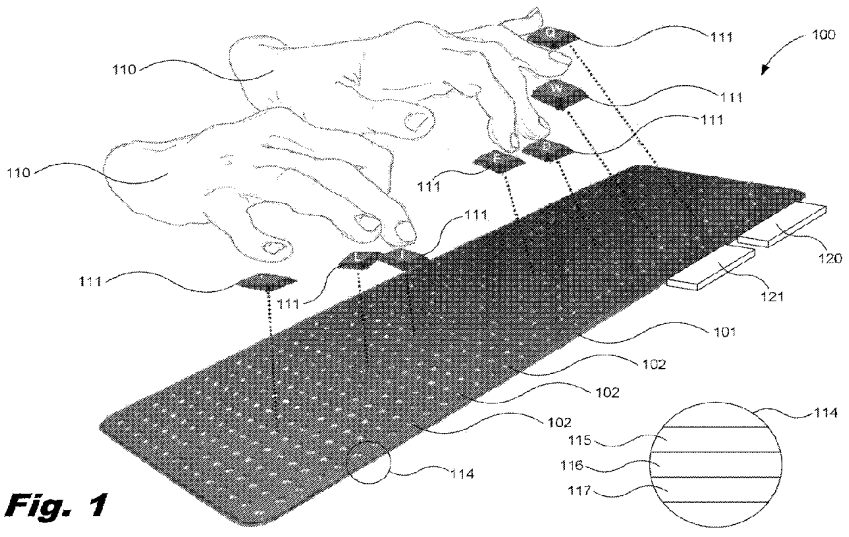

Fig. 1

(57) Abstract: A virtual keyboard includes a pad, a number of motion sensors coupled to the pad to detect the presence of a user's hands over the pad, a processor, and a memory. The memory includes executable code that, when executed by the processor calibrates the virtual keyboard based on a number of criteria of the user's hand upon detection of the user's hands by the motion sensors, in which the criteria comprises the user's unique keyboard profile.

WO 2016/010524 A1

VIRTUAL KEYBOARD

BACKGROUND

[0001] Computer keyboards are typewriter-style devices that use an arrangement of buttons or keys with a number of alphanumeric characters, graphemes, symbols, and other types of characters printed or engraved on the buttons or keys. The buttons and keys act as mechanical levers or electronic switches that cause input of a character to a computing device or otherwise control a computing device to which the keyboard is communicatively coupled. Keyboards, however, are bulky and are not easily mobile. Keyboards also contain mechanical parts that are easily broken. In addition, a user of a keyboard must strike the buttons or keys as they are laid out on the keyboard with no ability to fit the layout of the keyboard to a user. Even if customized keyboards were produced, such customized keyboards would be disadvantageous in shared computing environments such as workshops and call centers were several individuals may use the same keyboard. Further, keyboards provide no form of user authentication to secure and protect data on an associated computing device from unauthorized access. Still further, keyboards increase the potential to suffer from injuries or illnesses such as carpal tunnel syndrome or other repetitive strain injury and illness due to the extensive spread of bacteria.

BRIEF DESCRIPTION OF THE DRAWINGS

[0002] The accompanying drawings illustrate various examples of the principles described herein and are a part of the specification. The illustrated

examples are given merely for illustration, and do not limit the scope of the claims.

[0003] Fig. 1 is a perspective view of the virtual keyboard, according to one example of the principles described herein.

[0004] Fig. 2 is a block diagram of a virtual input computing system for processing data obtained from the virtual keyboard of Fig. 1, according to one example of the principles described herein.

[0005] Fig. 3 is a flowchart showing a method of calibrating the virtual keyboard, according to one example of the principles described herein.

[0006] Fig. 4 is a flowchart showing a method of processing signals from the virtual keyboard, according to one example of the principles described herein.

[0007] Fig. 5 is a flowchart showing a method of processing authentication signals from the virtual keyboard, according to one example of the principles described herein.

[0008] Throughout the drawings, identical reference numbers designate similar, but not necessarily identical, elements.

DETAILED DESCRIPTION

[0009] The present systems and methods provide a virtual keyboard that detects user's hands over the virtual keyboard and maps a number of virtual input keys to the user's hands and builds a unique keyboard profile for authentication purposes and character entry. The virtual keyboard is communicatively coupled to a computing device to provide for data input to the computing device control the computing device to which the virtual keyboard is communicatively coupled. The virtual keyboard comprises a pad, a number of motion sensors coupled to the pad to detect the presence of a user's hands over the pad, and a tracking system to track hand and finger movements of the user's hand. In this manner, the user does not touch any hardware device when utilizing the virtual keyboard. Detection of the user's hands by the motion sensors activates the tracking system. The tracking system comprises a

number of wave detectors to detect wavelengths reflected off the user's hands. The wave detectors may, for example, detect electromagnetic wavelengths or acoustical frequencies. The virtual keyboard may be calibrated to a user's hand positioning, hand size, or any other criteria to define a keyboard profile unique to that user. This keyboard profile may be used to identify the user as well as provide a number of security and access controls.

[0010] As used in the present specification and in the appended claims, the term "a number of" or similar language is meant to be understood broadly as any positive number comprising 1 to infinity; zero not being a number, but the absence of a number.

[0011] In the following description, for purposes of explanation, numerous specific details are set forth in order to provide a thorough understanding of the present systems and methods. It will be apparent, however, to one skilled in the art that the present apparatus, systems, and methods may be practiced without these specific details. Reference in the specification to "an example" or similar language means that a particular feature, structure, or characteristic described in connection with that example is included as described, but may not be included in other examples.

[0012] Fig. 1 is a perspective view of the virtual keyboard (100), according to one example of the principles described herein. The user's hands and fingers (110) are depicted in Fig. 1 above the pad (101). A number of keys (111) are depicted in Fig. 1 to depict how movements of the user's hands and fingers (110) over an area of the pad (101) virtually activate the input of a character or otherwise control a computing device to which the pad (101) is communicatively coupled much like activation of keys (111) of a non-virtual keyboard function.

[0013] The pad (101) may be shaped or sized approximately similar to a non-virtual keyboard. In another example, the pad (101) may be larger or smaller than a non-virtual keyboard. A number of sensing devices (102) are included in the pad (101) to detect the presence of the user's hands and fingers (110) over the pad (101), to track the hand and finger movements of the user's hands and fingers (110), and to detect tissue density of the user's hands and

fingers (110), to detect palm and fingerprints of the user's hands and fingers (110), and to create and store a keyboard profile of a user, among other functions as will be described in more detail below.

[0014] The sensing devices (102) may be located along the surface of the pad (101) as depicted in Fig. 1 in a pattern to provide homogeneous and uniform coverage along the surface of the pad (101). The sensing devices (102) are depicted as bumps along the surface of the pad (101). In one example, the sensing devices (102) may be any type of sensor device that can detect the presence of the user's hands and fingers (110) over the pad (101), track the hand and finger movements of the user's hands and fingers (110), and/or detect a keyboard profile of a user, among other functions. The sensing devices (102) may be, for example, video-based devices that capture video data for processing in the manner described herein, image-based devices that capture image data for processing in the manner described herein, electromagnetic-based devices that use electromagnetic waves and light detectors such as, for example, photodiodes to detect movement, acoustic-based devices such as an ultrasonic-based device that produce acoustical waves and detect the acoustical frequencies reflected from an object, backscatter x-ray devices to detect radiation reflected from the hands and fingers (110), or other types of motion and tracking devices.

[0015] As to the ultrasonic-based device, this type of device may detect the position and motion of the user's hands and fingers (110), as well as the tissue density of the user's hands and fingers (110) for authentication and security purposes. As to the electromagnetic-based devices, this type of device may use light-emitting diodes (LEDs), lasers, infrared light emitters, or other types of electromagnetic wave propagation devices.

[0016] In one example, the sensing devices (102) may be protected by a layer of flexible material such as, for example, silicone that allows the pad (101) to be rolled up or folded for storage and mobility. In one example as depicted in the call-out circle (114), the pad (101) may comprise a top layer (115) of silicone, a middle layer (116) in which the sensor devices (102) and associated wiring are disposed, and a bottom layer (117) of silicone. Although the top layer

(115) and bottom layer (117) are described as being made of silicone, any other insulating, flexible material may be used to house the array of sensor devices (102) and associated wiring.

[0017] The pad (101) may further include a communication module (120) to provide communication with a computing device with which the pad (101) interacts with to manipulate the operation of the computing device. In one example, the communication module (120) may be a wired or wireless communication device. The types of communication utilized by the communication module (120) may include, for example, any communication type that supports any Open Systems Interconnection (OSI) model standardized communication type, any communication type that supports any Institute of Electrical and Electronics Engineers (IEEE) standardized communication type, BLUETOOTH communication types developed by the Bluetooth Special Interest Group, Ethernet communication types, WI-FI communication types as defined by the Wi-Fi Alliance, near field communication types, infrared communication types, among many other types of communications and their respective types of networks, or combinations thereof. The communication module (120) may be embedded within the pad (101) or communicatively coupled to the pad (101) as depicted in Fig. 1.

[0018] A power source (121) may also be coupled to the pad (101) to provide electrical power to the pad (101). The power module may provide AC or DC power to the pad. In the example of an AC power source, the power source (121) may be coupled to a wall outlet, the computing device with which the virtual keyboard (100) communicates, or other AC power supply. In the example of a DC power source, the power source may comprise a battery, a rechargeable battery, or other type of DC power supply. The power source (121) may also be a solar panel that directly powers the virtual keyboard (100) or indirectly powers the virtual keyboard (100) through charging a battery, for example.

[0019] In one example, the pad (101) of the virtual keyboard (100) may be built into or installed in a user's desk, a wall, the dashboard of a car, or other fixture.

[0020] Fig. 2 is a block diagram of a virtual input computing system (200) for processing data obtained from the virtual keyboard (100) of Fig. 1, according to one example of the principles described herein. The virtual input computing system (200) may be incorporated into the pad (101) of the virtual keyboard (100), may be a coupled to the virtual keyboard (100), may be a standalone computing device, or may be incorporated into a computing device to which the virtual keyboard (100) is communicatively coupled. In the example where the virtual input computing system (200) is incorporated into a computing device to which the virtual keyboard (100) is communicatively coupled, the various computing elements and resources provided by the virtual input computing system (200) may be part of the computing device, and the modules comprising executable program code used in the implementation of the virtual keyboard (100) and its associated functions may be stored within a data storage device of the computing device.

[0021] The virtual input computing system (200) may be utilized in any data processing scenario including, stand-alone hardware, mobile applications, through a computing network, or combinations thereof. Further, the virtual input computing system (200) may be used in a computing network, a public cloud network, a private cloud network, a hybrid cloud network, other forms of networks, or combinations thereof. In one example, the methods provided by the virtual input computing system (200) are provided as a service over a network by, for example, a third party. In this example, the service may comprise, for example, the following: a Software as a Service (SaaS) hosting a number of applications; a Platform as a Service (PaaS) hosting a computing platform comprising, for example, operating systems, hardware, and storage, among others; an Infrastructure as a Service (IaaS) hosting equipment such as, for example, servers, storage components, network, and components, among others; application program interface (API) as a service (APIaaS), other forms of network services, or combinations thereof. The present systems may be implemented on one or multiple hardware platforms, in which the modules in the system can be executed on one or across multiple platforms. Such modules can run on various forms of cloud technologies and hybrid cloud technologies or

offered as a SaaS (Software as a service) that can be implemented on or off the cloud. In another example, the methods provided by the virtual input computing system (200) are executed by a local administrator.

[0022] To achieve its desired functionality, the virtual input computing system (200) comprises various hardware components. Among these hardware components may be a number of processors (201), a number of data storage devices (202), a number of peripheral device adapters (203), and a number of network adapters (204). These hardware components may be interconnected through the use of a number of busses and/or network connections. In one example, the processor (201), data storage device (202), peripheral device adapters (203), and a network adapter (204) may be communicatively coupled via a bus (205).

[0023] The processor (201) may include the hardware architecture to retrieve executable code from the data storage device (202) and execute the executable code. The executable code may, when executed by the processor (201), cause the processor (101) to implement at least the functionality of detect the presence of the user's hands and fingers (110) over the pad (101), track the hand and finger movements of the user's hands and fingers (110), detect a keyboard profile of a user, and provide security and access controls to a computing device to which the virtual keyboard (100) is coupled among other functions according to the methods of the present specification described herein. In the course of executing code, the processor (201) may receive input from and provide output to a number of the remaining hardware units.

[0024] The data storage device (202) may store data such as executable program code that is executed by the processor (201) or other processing device. As will be discussed, the data storage device (202) may specifically store computer code representing a number of applications that the processor (201) executes to implement at least the functionality described herein.

[0025] The data storage device (202) may include various types of memory modules, including volatile and nonvolatile memory. For example, the data storage device (202) of the present example includes Random Access Memory (RAM) (206), Read Only Memory (ROM) (207), and Hard Disk Drive

(HDD) memory (208). Many other types of memory may also be utilized, and the present specification contemplates the use of many varying type(s) of memory in the data storage device (202) as may suit a particular application of the principles described herein. In certain examples, different types of memory in the data storage device (202) may be used for different data storage needs. For example, in certain examples the processor (201) may boot from Read Only Memory (ROM) (207), maintain nonvolatile storage in the Hard Disk Drive (HDD) memory (208), and execute program code stored in Random Access Memory (RAM) (206).

[0026] The data storage device (202) may comprise a computer readable medium, a computer readable storage medium, or a non-transitory computer readable medium, among others. For example, the data storage device (202) may be, but not limited to, an electronic, magnetic, optical, electromagnetic, infrared, or semiconductor system, apparatus, or device, or any suitable combination of the foregoing. More specific examples of the computer readable storage medium may include, for example, the following: an electrical connection having a number of wires, a portable computer diskette, a hard disk, a random access memory (RAM), a read-only memory (ROM), an erasable programmable read-only memory (EPROM or Flash memory), a portable compact disc read-only memory (CD-ROM), an optical storage device, a magnetic storage device, or any suitable combination of the foregoing. In the context of this document, a computer readable storage medium may be any tangible medium that can contain, or store computer usable program code for use by or in connection with an instruction execution system, apparatus, or device. In another example, a computer readable storage medium may be any non-transitory medium that can contain, or store a program for use by or in connection with an instruction execution system, apparatus, or device.

[0027] The hardware adapters (203, 204) in the virtual input computing system (200) enable the processor (201) to interface with various other hardware elements, external and internal to the virtual input computing system (200). For example, the peripheral device adapters (203) may provide an interface to input/output devices, such as, for example, display device (209), a

mouse, or a non-virtual keyboard in addition to the virtual keyboard (100). The peripheral device adapters (203) may also provide access to other external devices such as an external storage device, a number of network devices such as, for example, servers, switches, and routers, client devices, other types of computing devices, and combinations thereof.

[0028] The display device (209) may be provided to allow a user of the virtual input computing system (200) to interact with and implement the functionality of the virtual input computing system (200). In one example, an image of a keyboard (250) may be presented to a user of the virtual keyboard (100) on the display device (209). In this example, the user may input data through the user of the virtual keyboard (100), and the processor (201) may execute code to display to the user keystrokes associated with the hand movements of the user on the keyboard (250) displayed on the display device (209). The peripheral device adapters (203) may also create an interface between the processor (101) and the display device (109), a printer, or other media output devices.

[0029] In another example, the display device (209) may display the image of the keyboard (250) on the pad (101). In one example, the image of the keyboard (250) may be displayed on the pad (102) using a projection system to project the image of the keyboard (250) on the pad (101). In another example, a keyboard (250) may not be displayed on the pad (101).

[0030] In another example, the image of the keyboard (250) may be displayed on the pad (102) using a number of LEDs embedded within the pad (101). In this example, the LEDs light up to create a pattern in the pad. In one example, the pattern may be the pattern of a keyboard as arranged within a non-virtual keyboard. In another example, the pattern, although arranged similarly to a non-virtual keyboard, may be sized to fit the user's hand sizes, typing patterns, hand positioning during typing various keystrokes or keystroke combinations, or any hand positioning detected by the virtual keyboard (100) from an initial hand position through any subsequent hand position, keystroke or keystroke combination. Thus, in this example, the image of the keyboard as outlined on the pad (101) through lighting of the LEDs may look significantly

different from the tight and inline layout of a non-virtual keyboard and will fit to a user's distinct hand posturing, hand positioning, and keystroke style.

[0031] In still another example, the image of the keyboard (250) may be displayed on the pad (102) using a number of laser devices embedded within the pad (101) or that project light onto the pad (101). In this example, the laser devices function in a manner similar to the above-described LEDs. In one example, the display of the keyboard (250) on the display device (209) or the pad (101) as described above may be performed only during a keyboard profile calibration and learning phase as will be described in more detail below in order to assist a user in visualizing placement of keystrokes and help with typing while the user's keystrokes are being learned.

[0032] The network adapter (204) may provide an interface to other computing devices within, for example, a network, thereby enabling the transmission of data between the virtual input computing system (200) and other devices located within the network. In an example where the virtual input computing system (200) is incorporated into a computing device to which the virtual keyboard (100) is communicatively coupled, the network adapter (204) provides network connectivity with the virtual keyboard (100).

[0033] The virtual input computing system (200) may, when executed by the processor (101), display the number of graphical user interfaces (GUIs) on the display device (109) associated with the executable program code representing the number of applications stored on the data storage device (102). The GUIs may include aspects of the executable code including the displayed keyboard (250) described above. The GUIs may display, for example, a real time indication of which keys are being selected by a user of the virtual keyboard by presenting those keys in an activated state to the user on the GUI displayed on the display device (209). Examples of display devices (209) include a computer screen, a laptop screen, a mobile device screen, a personal digital assistant (PDA) screen, a tablet screen, and a touch screen, among other display devices (106).

[0034] The virtual input computing system (200) further comprises a number of modules used in the implementation of the virtual keyboard (100).

The various modules within the virtual input computing system (200) comprise executable program code that may be executed separately. In this example, the various modules may be stored as separate computer program products. In another example, the various modules within the virtual input computing system (200) may be combined within a number of computer program products; each computer program product comprising a number of the modules.

[0035] The virtual input computing system (200) may include a gesture calibration and learning module (210) to, when executed by the processor (201), calibrate user interactions with the virtual keyboard (100) and learn gestures used by the user in attempting to input data using the virtual keyboard (100). The a gesture calibration and learning module (210) may prompt a user to perform an initial calibration procedure in which the user is requested to demonstrate a number of keystrokes for detection by the pad (101). For example, the user may be prompted to demonstrate a home row hand gesture where the user places his or her hands above the pad (101) and positions his or her fingers as if the user were placing his or her hands and fingers on a home row of a keyboard. This provides the virtual input computing system (200) with data representing a home row position of the user and orients the home row keys and the remainder of the keys on the virtual keyboard (100) with respect to the home row gesture.

[0036] The gesture calibration and learning module (210) may also request a user to demonstrate a number of individual keystrokes. For example, the gesture calibration and learning module (210) may request a user to demonstrate keystrokes associated with each of the characters displayed on a keyboard or the keyboard (250) displayed on the display device (209). The gesture calibration and learning module (210) may also request a user to demonstrate a number of combination keystrokes where the user is requested to demonstrate instances where the user would simultaneously press two or more keys on a keyboard. For example, the "shift" key along with the "a" key to produce a capital "A." In this manner, the gesture calibration and learning module (210) may calibrate the virtual keyboard (100) for the user. The calibration is unique to that particular user. The gesture calibration and learning

module (210) may also learn a user's distinct hand posturing, hand positioning, and keystroke styles from the outset of that user utilizing the virtual keyboard (100) and throughout the user's use of the virtual keyboard (100). In this manner, the virtual keyboard adapts to the user's potentially changing hand posturing, hand positioning, and keystroke styles.

[0037] The gesture calibration and learning module (210) may perform calibration and learning techniques for a number of users of a particular virtual keyboard (100). This is advantageous in situations where a number of individuals have access to a particular computing device via the virtual keyboard (100) such as, for example, in a classroom setting where may groups of students utilize a set of computing devices. In one example, the gesture calibration and learning module (210) may begin calibration and learning for a particular user once the user logs onto a computing device coupled to the virtual keyboard (100). Thus, each user that logs into the computing device may be prompted to initiate a calibration and learning sequence to prepare and continue to fine-tune each user's individual and unique keyboard profile. Calibration and learning processes will be described in more detail below.

[0038] In one example, the gesture calibration and learning module (210) identifies an initial interaction by the user with the virtual keyboard (100) when the user interacts with any number of sensing devices (102) within the pad (101). The sensing devices (102) of the pad (101) may detect the initial interaction by the user and the gesture calibration and learning module (210) may identify that initial interaction as the position from which the user's keyboard profile is mapped. Thus, if a user presents his or her hands and fingers (110) on a left portion of the pad (101), then the virtual keyboard (100) and gesture calibration and learning module (210) maps the virtual keyboard (100) around the user's hands and fingers (110) from the left portion of the pad (101). In one example, the pad (101) may be larger than a non-virtual keyboard to accommodate for the possibility of this type of off-center initiation.

[0039] The virtual input computing system (200) may include a data input processing module (220) to, when executed by the processor (201), process a number of keystrokes a user performs on the virtual keyboard (100). The data

input processing module (220) receives input data from the virtual keyboard (100), and identifies a number of the inputs or a series of the inputs as being associated with keystrokes based on the calibrated and learned gestures obtained by the calibration and learning module (210). The data input processing module (220) may submit the identified inputs to a computing device to which the virtual keyboard (100) is coupled for controlling the computing device according to the identified inputs and commands.

[0040] The data input processing module (220) of the virtual input computing system (200) may also provide feedback to the user of the virtual keyboard (100). In one example, feedback may be provided to the user as the user types on the virtual keyboard (100). The feedback may be provided in the form of haptic feedback, audio feedback, visual feedback, or other types of feedback that indicate to the user that keystrokes are being made. In the example of haptic feedback, the pad (101) may include a rumble device to provide a tactile response when the user touches a certain portion of the pad (101) if the user were to touch the pad (101) during typing.

[0041] In the example of audio feedback, a speaker or other audio device may provide an audible noise when the user makes a keystroke in the space above the pad (101). In this example, the audible noise may mimic the sound of a key on a non-virtual keyboard being pressed, or make any other noise to indicate to the user that their keystrokes are being received by the virtual keyboard (100) and interpreted by the computing device to which the virtual keyboard (100) is coupled.

[0042] In the example of visual feedback, the computing device to which the virtual keyboard (100) is coupled may display the a keyboard (250) as described above, and provide feedback to the user that the display device (209) may indicate that keystrokes are being received by the virtual keyboard (100) and interpreted by the computing device to which the virtual keyboard (100) is coupled by changing an aspect of the displayed keyboard (250) such as lighting or filling in a key corresponding to the user's keystrokes.

[0043] A keyboard profile module (230) may also be included within the virtual input computing system (200) to, when executed by the processor (201),

identify, refine, amend or build on an individual user's unique keyboard profile. As described above, the user's unique keyboard profile may include information regarding the user's distinct hand posturing, hand positioning, and keystroke style. The keyboard profile module (230) may store each user's keyboard profile in memory such as the data storage device (202) or another data storage associated with the virtual keyboard (100).

[0044] The virtual input computing system (200) may include a security module (240) to, when executed by the processor (201), provide security to a computing device to which the virtual keyboard (100) is communicatively coupled. The security module (240) may detect an initial presence of a user's hands and fingers (110) over the pad (101) and within the detection range of the sensor devices (102). Once the user's hands and fingers (110) are detected, the security module (240) analyzes the user's hand posturing, hand positioning, keystroke style, the tissue density of the user's hands and fingers, the user's palm and fingerprints, other aspects of the movement and characteristics of the user's hands and fingers (110), and combinations thereof. Based on this analysis, the security module (240) compares these collected aspects of the user's hands and fingers (110) with keyboard profiles stored in memory. If the collected aspects of the user's hands and fingers (110) match a keyboard profile stored in memory, then the user is allowed access to the computing resources of the computing device to which the virtual keyboard (100) is communicatively coupled.

[0045] The security module (240) may also lock out a subsequent individual who attempts to gain access to the computing device while a first user is utilizing the virtual keyboard (110) and the computing device. For example, if a first user is logged onto the computing device and walks away from the computing device, the subsequent user's hand posturing, hand positioning, keystroke style, the tissue density of the subsequent user's hands and fingers, the subsequent user's palm and fingerprints, other aspects of the movement and characteristics of the subsequent user's hands and fingers (110) will not be recognized as the first user's keyboard profile and/or will not be recognized as a keyboard profile stored in memory. In this scenario, the virtual keyboard (100)

and the computing device will lock up or otherwise deny access. Once the first user who is authorized to access the computing device via the virtual keyboard (100) once again place his or her hands and fingers (110) over the pad (101) and within the detection range of the sensor devices (102) to compares the first user's collected aspects of the user's hands and fingers (110) with keyboard profiles stored in memory and provides access to the first user. Thus, the security module (240) detects an unauthorized keyboard profile, locks the computing device, and prompts a user to authenticate his or herself.

[0046] The modules described above (210, 220, 230, 240) may utilize a number of technologies to detect and track movement of the user's hands and fingers (110) above or within the vicinity of the pad (101). In one example, the modules (210, 220, 230, 240) may use motion tracking hardware and software developed and distributed by Leap Motion, Inc.

[0047] Software and drivers associated with the modules (210, 220, 230, 240) may be obtained from a network using the network adaptor (204), from a disk, or any other source. More details in connection with the calibration and learning module (210), the data input processing module (220), the keyboard profile module (230), and the a security module (240) will now be described in more detail in connection with Figs. 3 through 5.

[0048] Fig. 3 is a flowchart showing a method (300) of calibrating the virtual keyboard (100), according to one example of the principles described herein. The method of Fig. 3 may include determining (block 301), with the processor (201) executing the gesture calibration and learning module (210), whether the user's hands are detected. This determination (block 301) may be a condition by which waking the virtual keyboard and/or the computing device is achieved. If the user the user's hands are not detected (block 301, determination NO), then the method (300) loops back to determining (block 301) whether the user's hands are detected. If the user's hands are detected (block 301, determination YES), then the processor (201) executing the gesture calibration and learning module (210), determines (block 302) whether the user is a new user of the virtual keyboard (100). If the user is a new user of the virtual keyboard (100) (block 302, determination YES), then the processor (201)

executing the gesture calibration and learning module (210), performs (block 303) an initial calibration of the user's hand posturing, hand positioning, and keystroke style.

[0049] For example, at block 303, the gesture calibration and learning module (210) may prompt a user to demonstrate a home row hand gesture where the user places his or her hands above the pad (101) and positions his or her fingers as if the user were placing his or her hands and fingers on a home row of a keyboard as described above. This provides the virtual input computing system (200) with data representing a home row position of the user and orients the home row keys and the remainder of the keys on the virtual keyboard (100) with respect to the home row gesture. The gesture calibration and learning module (210) may also prompt a user to demonstrate a number of individual keystrokes and a number of combination keystrokes as described above.

[0050] The gesture calibration and learning module (210) may also learn a user's distinct hand posturing, hand positioning, and keystroke styles from the outset of that user utilizing the virtual keyboard (100) and throughout the user's use of the virtual keyboard (100). In this manner, the virtual keyboard adapts to the user's potentially changing hand posturing, hand positioning, and keystroke styles.

[0051] The gesture calibration and learning module (210) may perform calibration and learning techniques for a number of users of a particular virtual keyboard (100). This is advantageous in situations where a number of individuals have access to a particular computing device via the virtual keyboard (100) such as, for example, in a classroom setting where may groups of students utilize a set of computing devices. In one example, the gesture calibration and learning module (210) may begin calibration and learning for a particular user once the user logs onto a computing device coupled to the virtual keyboard (100). Thus, each user that logs into the computing device may be prompted to initiate a calibration and learning sequence to prepare and continue to fine-tune each user's individual and unique keyboard profile. Calibration and learning processes will be described in more detail below.

[0052] The gesture calibration and learning module (210) and keyboard profile module (230), when executed by the processor, may store (block 304) the calibration from block 303 as the user's keyboard profile. The user's keyboard profile may be data representing the detected hand posturing, hand positioning, and keystroke styles, among other aspects of the user's hand movements as detected by the sensing devices (102) of the pad (101). The user's keyboard profile may be stored in the memory located at the virtual keyboard (100), in the data storage device (202) of the virtual input computing system (200), or another storage device accessible by the processor (201), the virtual keyboard (100) or other processing device for use in execution of the various functions of the present systems and methods.

[0053] If the user is a not new user of the virtual keyboard (100) (block 302, determination NO), or after performing an initial calibration (block 303), then the gesture calibration and learning module (210) may determine (block 305) if the user's keyboard profile should be updated. A number of aspects of the user's hand posturing, hand positioning, and keystroke style may change through time as the user becomes more comfortable using the virtual keyboard (100). A number of criteria may indicate that a user's keyboard profile should be updated including, for example, changes in initial home row positioning, changes in keystrokes or keystroke combinations, or other nuanced changes in the user's hand posturing, hand positioning, and keystroke style. Further, the user's keyboard profile may be updated upon identification by the sensing devices (102) that an injury such as a loss of a portion of the user's hand or the loss of a finger has cause the user accommodate in order to make keystrokes or present a particular hand position. Thus, the gesture calibration and learning module (210) continues to learn the user's hand posturing, hand positioning, and keystroke style by performing (block 303) subsequent learning of the user's keyboard profile if it is determined that the user's keyboard profile should be updated (block 305, determination YES).

[0054] The method (300) loops back to blocks 305 and 306 as long as it is determined that the user's keyboard profile should be updated (block 305, determination YES). The method may terminate if it is determined that the

user's keyboard profile should not be updated (block 305, determination NO). In this manner, the user's keyboard profile may be initially created and continually updated to accommodate the user's changing hand posturing, hand positioning, and keystroke style.

[0055] Fig. 4 is a flowchart showing a method (400) of processing signals from the virtual keyboard (100), according to one example of the principles described herein. The method of Fig. 4 may include determining (block 401), with the processor (201) executing the data input processing module (220), whether the user's hands are detected. If the user the user's hands are not detected (block 401, determination NO), then the method (400) loops back to determining (block 401) whether the user's hands are detected. Again, this determination (block 401) may be a condition by which waking the virtual keyboard and/or the computing device is achieved. If the user's hands are detected (block 401, determination YES), then the processor (201), executing the data input processing module (220), determines keystroke identity based on the user's keyboard profile identified in Fig. 3. The keystroke identity identifies the how the user's hand posturing, hand positioning, and keystroke style correlate with input to the computing device to which the virtual keyboard is communicatively coupled.

[0056] Using the keystroke identity, the data input processing module (220), when executed by the processor (201), instructs (block 403) the computing device to process data in accordance with the keystroke identity. In this manner, the user's input at the virtual keyboard (100) is translated into computer readable instructions that are consumed by the computing device in order to perform the tasks the user wishes the computing device to perform such as, for example, typing in a word processing application, or any other application of user input from a keyboard.

[0057] The method may continue by determining (block 404) whether the user is inputting data though the virtual keyboard (100). If the user is still utilizing the virtual keyboard (100), then those keystrokes should be identified and translated into computer readable instructions for consumption by the computing device in order to perform the tasks the user wishes the computing

device to perform. Thus, if the user is inputting data though the virtual keyboard (100), then the method (400) of Fig. 4 may loop back to block 402 for processing as described above. If the user is not inputting data though the virtual keyboard (100), then the method (400) may terminate.

[0058] Fig. 5 is a flowchart showing a method (500) of processing authentication signals from the virtual keyboard (100), according to one example of the principles described herein. As described above, the virtual keyboard (100) may be used to permit access to individuals who are permitted to use a computing device to which the virtual keyboard (100) is communicatively coupled, while denying access to others who are not permitted. The method of Fig. 5 may include determining (block 501), with the processor (201) executing the security module (240), whether the user's hands are detected. Again, this determination (block 501) may be a condition by which waking the virtual keyboard and/or the computing device is achieved. If the user the user's hands are not detected (block 501, determination NO), then the method (500) loops back to determining (block 501) whether the user's hands are detected. If the user's hands are detected (block 501, determination YES), then the processor (201) executing the security module (240), identifies (block 402) an initial hand characteristics of the user attempting to access the computing device via the virtual keyboard (100).

[0059] The method (500) of Fig. 5 may continue by the processor (201) executing the security module (240) to determine (block 503) if the initial hand characteristics match a number of hand characteristics defined by a keystroke identity such as the keystroke identity defined and stored at blocks 303 and 304 of Fig. 3. In one example, the initial hand characteristics may be compared to the keystroke identity of an individual currently logged into the computing device. In this example, a user who is authorized to access the computer, but is not the current user of the computer may still be denied access. In another example, the processor (201) may compare the initial hand characteristics to the keystroke identity of a number of users. If the initial hand characteristics match hand characteristics defined by a keystroke identity (block 503, determination YES), then access to the computing device may be allowed. The method (500)

may loop back to block 501 to ensure that every time a user's hands are detected, that this security measure may be performed. The hand characteristics compared at block 503 may include, hand movements, hand sizes, hand posturing, hand positioning, and keystroke style, tissue density of the user's hands and fingers (110), palm prints, fingerprints, among many other characteristics of the user's hands and fingers as detected by the sensing devices (102), or combinations thereof.

[0060] If, however, the initial hand posture does not match a hand posture defined by a keystroke identity (block 503, determination NO), then the processor (201), executing the security module (240) may deny access (block 505) to the computing device. Denying access to the computing device may include, for example, not registering input from the virtual keyboard (100), locking the computing device, shutting down the computing device, alerting a valid user or an administrator of an unauthorized access to the computing device, requesting the accessing user for additional credentials such as a password or fingerprint identification, other security measures, or combinations thereof. The method (500) of Fig. 5 may terminate, and may be initiated once again when a user's hands are detected at block 501.

[0061] In this manner, the virtual keyboard (100) may be used to provide access control and security to any computing device. These computing devices may include, for example, desktop computers, laptop computers, tablet computers, mobile phone devices, as well as objects or devices that user computing devices such as vehicles, automated teller machines (ATMs), buildings, musical instruments such as keyboards, checkout stands at retail stores, among many other devices and objects.

[0062] Aspects of the present system and method are described herein with reference to flowchart illustrations and/or block diagrams of methods, apparatus (systems) and computer program products according to examples of the principles described herein. Each block of the flowchart illustrations and block diagrams, and combinations of blocks in the flowchart illustrations and block diagrams, may be implemented by computer usable program code. The computer usable program code may be provided to a processor of a general

purpose computer, special purpose computer, or other programmable data processing apparatus to produce a machine, such that the computer usable program code, when executed via, for example, the processor (201) of the virtual input computing system (200) or other programmable data processing apparatus, implement the functions or acts specified in the flowchart and/or block diagram block or blocks. In one example, the computer usable program code may be embodied within a computer readable storage medium; the computer readable storage medium being part of the computer program product. In one example, the computer readable storage medium is a non-transitory computer readable medium.

[0063] The specification and figures describe a virtual keyboard. The virtual keyboard includes a pad, a number of motion sensors coupled to the pad to detect the presence of a user's hands over the pad, and a tracking system to track hand and finger movements of the user's hand. A computing device for processing input from a virtual keyboard is also described. The computing device includes a processor and a memory. The memory includes executable code that, when executed by the processor initiates a tracking system to track hand and finger movements of the user's hand, in response to receiving data from a number of motion sensors coupled to a pad of the virtual keyboard to detect the presence of a user's hands over the pad. The executable code also calibrates the virtual keyboard based on a number of criteria of the user's hand.

[0064] This virtual keyboard may have a number of advantages, including: (1) the virtual keyboard is easy to store by rolling it up, folding it, or laying it on top of a computing device for storage; (2) due to its virtual aspects, a user need not come in physical contact with his or her fingers or hands to operate the virtual keyboard; (3) the virtual keyboard conforms to a user's hand positions and learns from the user's usage patterns to increase comfort and utility; and (4) the virtual keyboard provides increased security to a computing device to which the virtual keyboard is communicatively coupled, among many other advantages.

[0065] The preceding description has been presented to illustrate and describe examples of the principles described. This description is not intended

to be exhaustive or to limit these principles to any precise form disclosed. Many modifications and variations are possible in light of the above teaching.

CLAIMS

WHAT IS CLAIMED IS:

1. A virtual keyboard comprising:

a pad;

a number of motion sensors coupled to the pad to detect the presence of a user's hands over the pad;

a processor; and

a memory, the memory comprising executable code that, when executed by the processor:

calibrates the virtual keyboard based on a number of criteria of the user's hand upon detection of the user's hands by the motion sensors,

in which the criteria comprises the user's unique keyboard profile.

2. The virtual keyboard of claim 1, in which detection of the user's hands by the motion sensors activates the tracking system.

3. The virtual keyboard of claim 1, in which the tracking system comprises a number of wave detectors to detect wavelengths reflected off the user's hands.

4. The virtual keyboard of claim 1, in which the pad is dimensioned to approximate the size of a keyboard.

5. The virtual keyboard of claim 1, further comprising a tracking system to track hand and finger movements of the user's hand.

6. The virtual keyboard of claim 1, in which the user's unique keyboard profile comprises hand position, hand size, hand posturing, keystroke style, or combinations thereof.

7. The virtual keyboard of claim 1, further comprising

a processor; and

a memory, the memory comprising executable code that, when executed by the processor:

builds a hand position profile; and

authenticates the user based on the hand position profile.

8. The virtual keyboard of claim 7, in which access to a computing device to which the pad is communicatively coupled is denied if the hand position profile is not recognized.

9. A computing device for processing input from a virtual keyboard, comprising:

a processor; and

a memory, the memory comprising executable code that, when executed by the processor:

initiates a tracking system to track hand and finger movements of the user's hand in response to receiving data from a number of motion sensors coupled to a pad of the virtual keyboard to detect the presence of a user's hands over the pad; and

calibrates the virtual keyboard based on a number of criteria of the user's hand, the criteria comprising the user's unique keyboard profile,

in which the user's unique keyboard profile comprises hand position, hand size, hand posturing, keystroke style, or combinations thereof.

10. The computing device of claim 9, in which the memory further comprises executable code that, when executed by the processor:

builds a hand position profile; and

authenticates the user based on the hand position profile.

11. The computing device of claim 9, in which the virtual keyboard comprises:

a pad;

a number of motion sensors coupled to the pad to detect the presence of a user's hands over the pad; and

a tracking system to track hand and finger movements of the user's hand.

12. The computing device of claim 9, further comprising:

a display system, in which a number of keys of a keyboard are displayed on the pad using the display system.

13. A computer program product for dynamically learning a user's unique keyboard profile in association with a virtual keyboard, the computer program product comprising:

a computer readable storage medium comprising computer usable program code embodied therewith, the computer usable program code comprising:

computer usable program code to, when executed by a processor, with a number of motion sensors coupled to a pad, detect a user's hands above the pad;

computer usable program code to, when executed by a processor, with a number of lasers, track movements of the hands; and

computer usable program code to, when executed by a processor, based on information transmitted from the motion sensors and the lasers, build a hand position profile for the user.

14. The computer program product of claim 13, further comprising computer usable program code to, when executed by a processor, identify the user as a user authorized to access a computing device to which the pad is communicatively coupled using the hand position profile.

15. The computer program product of claim 14, further comprising computer usable program code to, when executed by a processor, restrict access to computing resources of the computing device if the hand position profile of the individual does not match an authorized hand position profile.

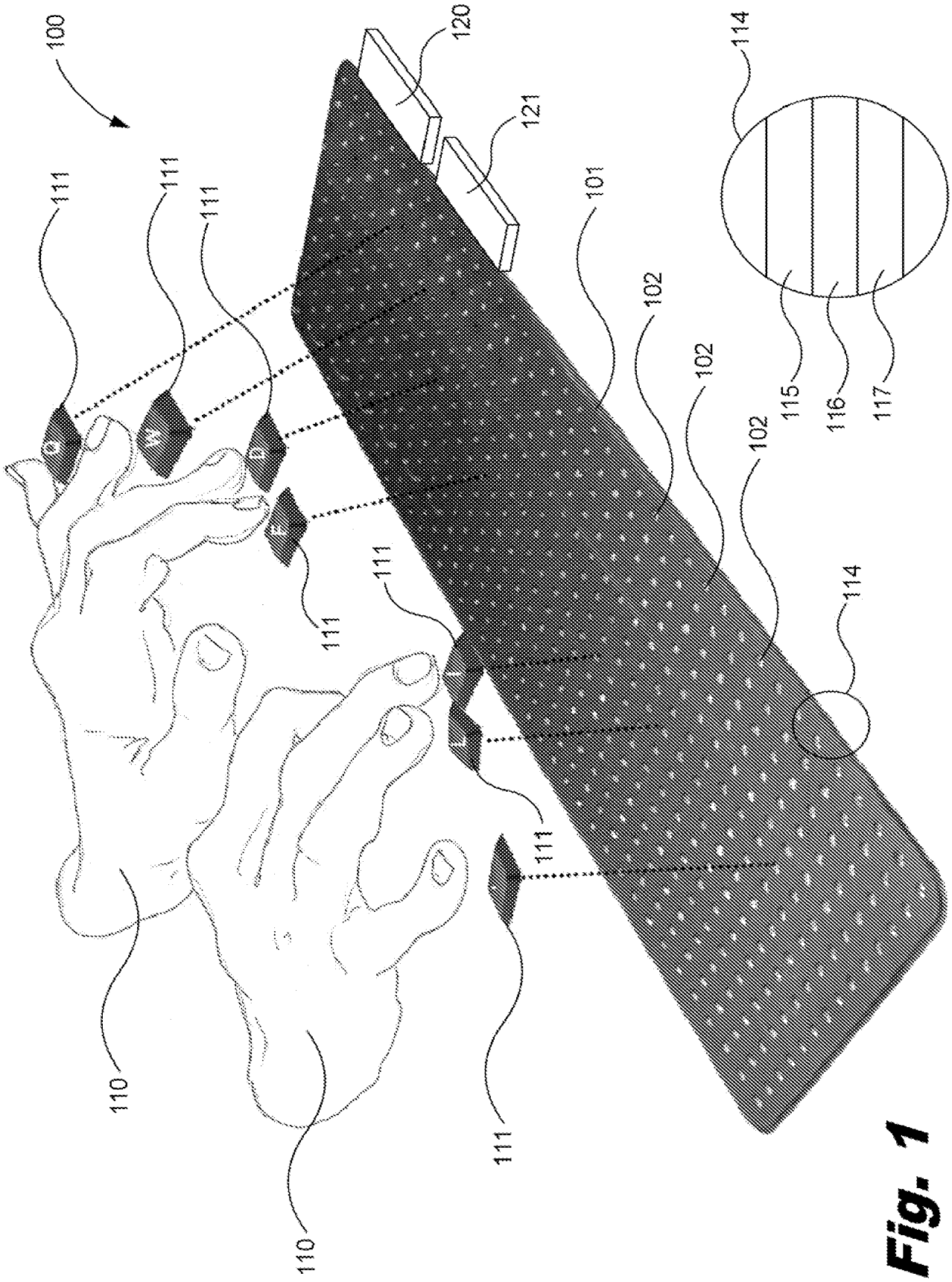
100
120
121
114
111
111
111
101
102
102
102
115
116
117
111
111
114
111
110
110
111

Fig. 1

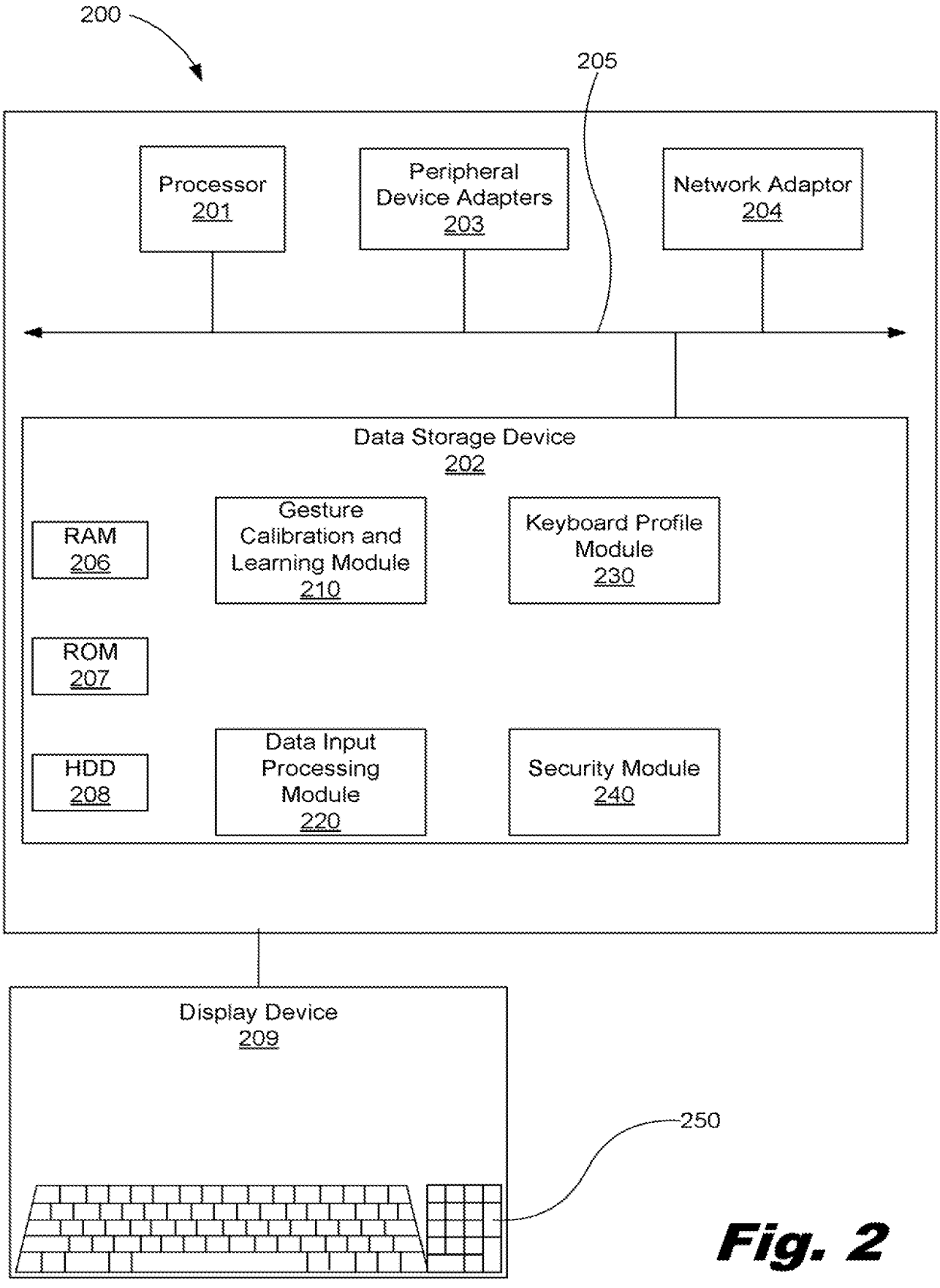
200
205
Processor
201
Peripheral
Device Adapters
203
Network Adaptor
204
Data Storage Device
202
RAM
206
Gesture
Calibration and
Learning Module
210
Keyboard Profile
Module
230
ROM
207
HDD
208
Data Input
Processing
Module
220
Security Module
240
Display Device
209
250

Fig. 2

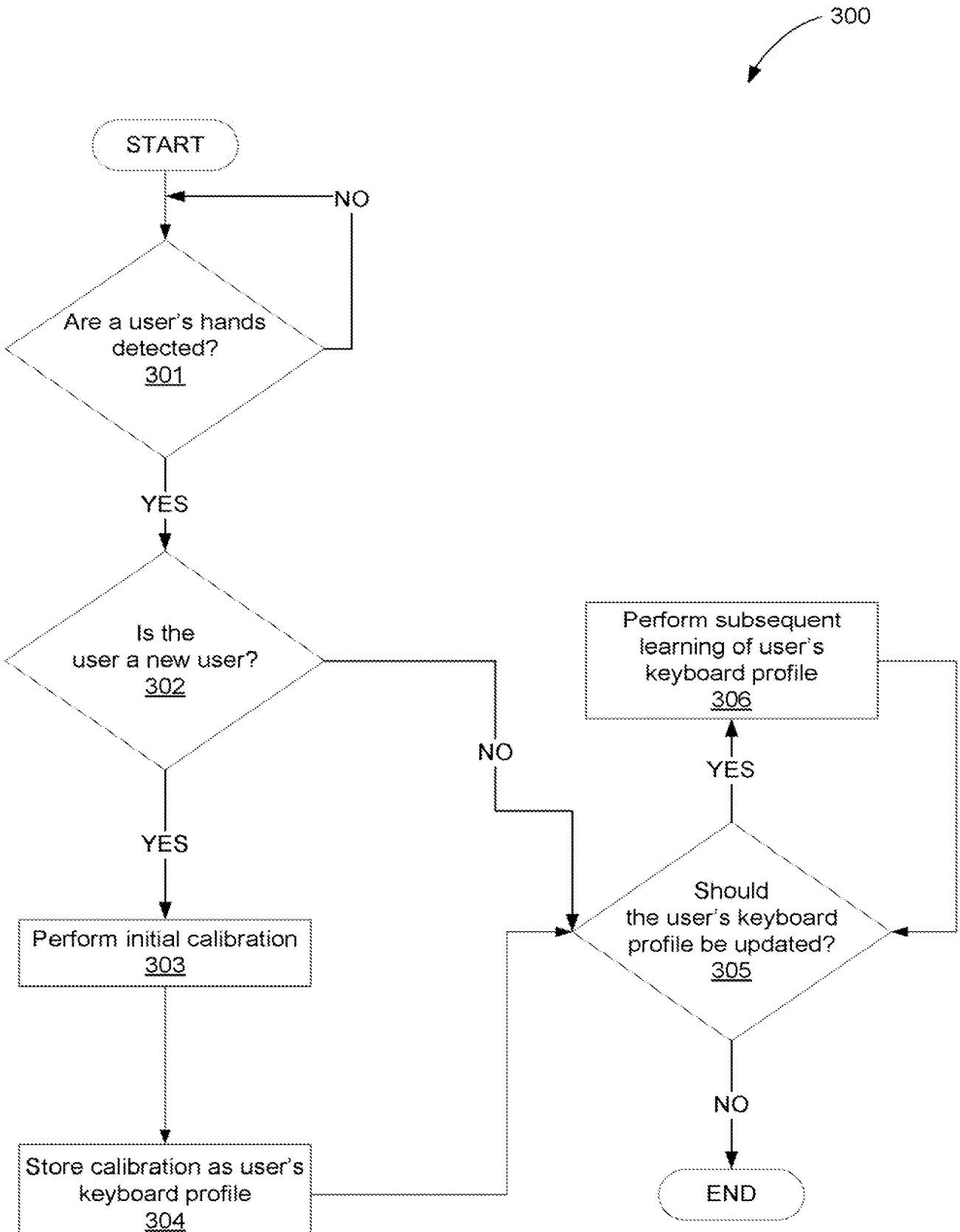
300
START
NO
Are a user's hands detected?
301
YES
Is the user a new user?
302
NO
YES
Perform initial calibration
303
Store calibration as user's keyboard profile
304
Perform subsequent learning of user's keyboard profile
306
YES
Should the user's keyboard profile be updated?
305
NO
END

Fig. 3

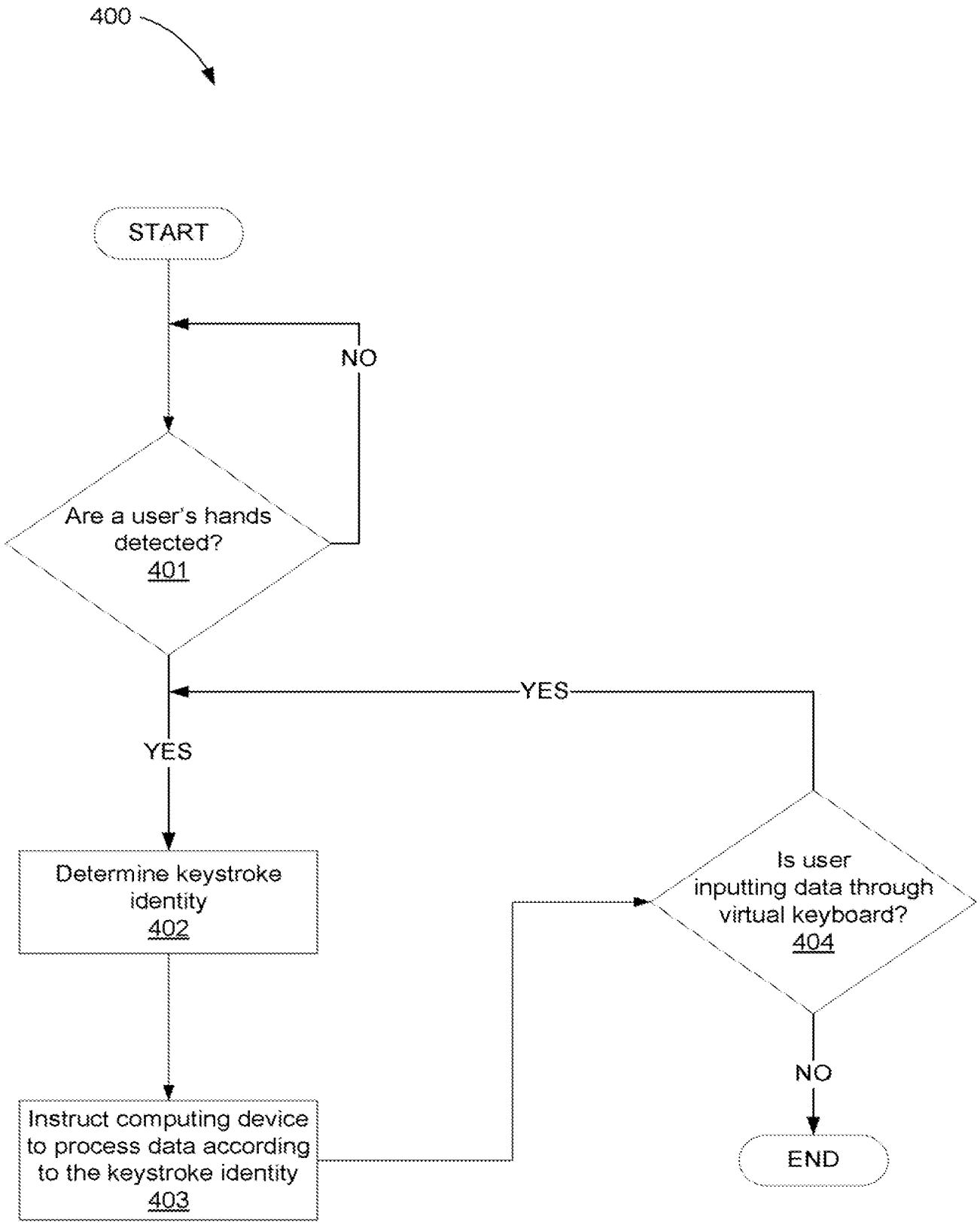
400
START
NO
Are a user's hands detected?
401
YES
YES
Determine keystroke identity
402
Instruct computing device to process data according to the keystroke identity
403
Is user inputting data through virtual keyboard?
404
NO
END

Fig. 4

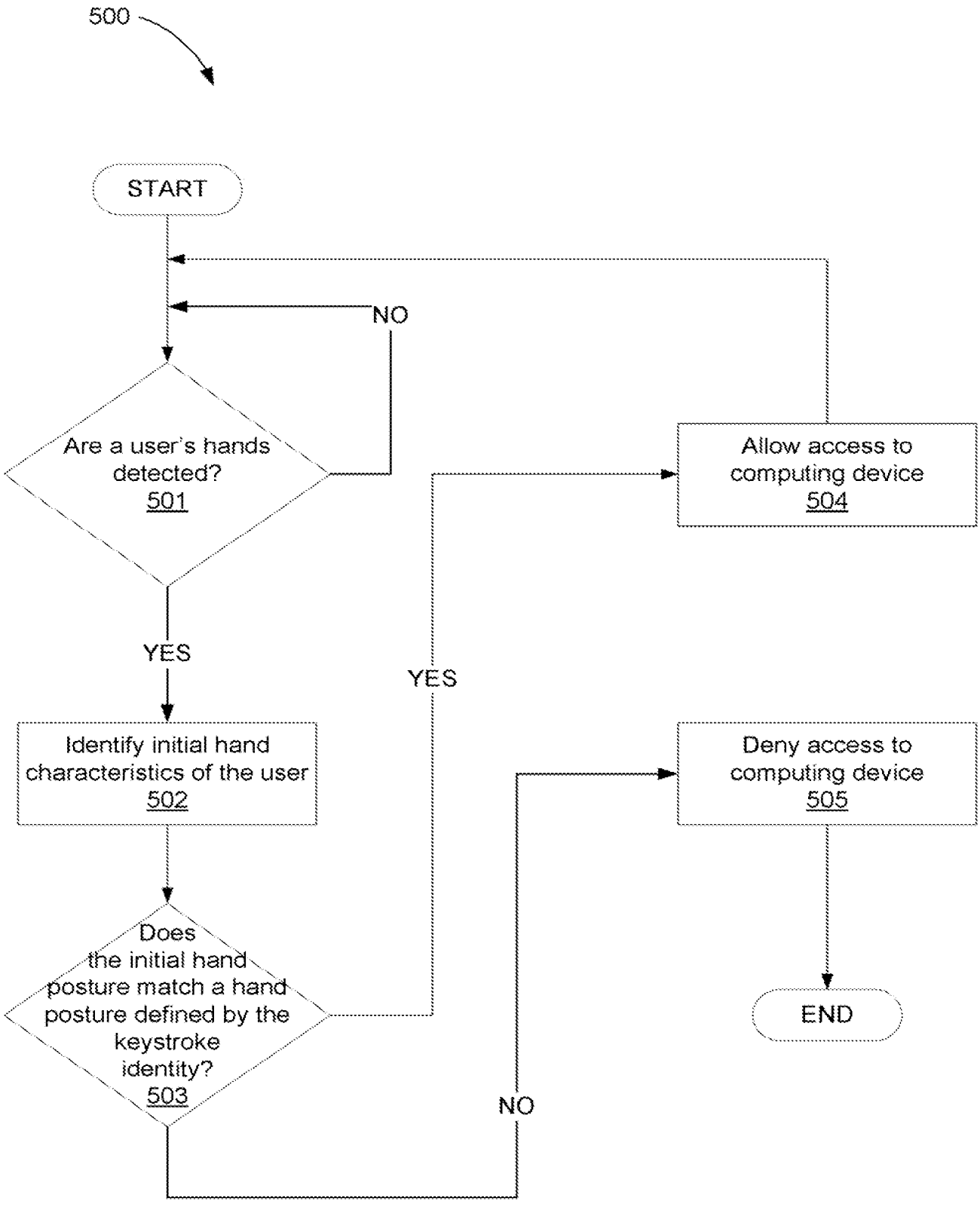
500
START
Are a user's hands detected? 501
NO
YES
Identify initial hand characteristics of the user 502
Does the initial hand posture match a hand posture defined by the keystroke identity? 503
YES
NO
Allow access to computing device 504
Deny access to computing device 505
END

Fig. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/046715

A. CLASSIFICATION OF SUBJECT MATTER

G06F 3/02(2006.01)i, G06F 3/048(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
G06F 3/02; G06F 3/048; H04M 1/24; G06F 3/041; G09G 5/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & keywords: virtual keyboard, sensor, detect, hand, user, profile, and similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012-0260207 A1 (ANTON TRESKUNOV et al.) 11 October 2012 See paragraphs 7, 27-52; claims 4, 16, 29; and figures 1-6B.	1-6,9-13
Y		7-8,14-15
Y	US 2013-0109369 A1 (BABAK FORUTANPOUR et al.) 02 May 2013 See paragraphs 73-74; and figure 7.	7-8,14-15
A	US 2013-0127729 A1 (TIMOTHY J. MOSBY et al.) 23 May 2013 See paragraphs 27-43; and figures 1-4.	1-15
A	US 2009-0303200 A1 (JOEL GRAD) 10 December 2009 See paragraphs 47-63; and figures 2-7.	1-15
A	US 2005-0225538 A1 (WILHELMUS VERHAEGH) 13 October 2005 See paragraphs 18-32; and figures 1-4.	1-15

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 February 2015 (25.02.2015)	**25 February 2015 (25.02.2015)**

Name and mailing address of the ISA/KR
International Application Division
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701,
Republic of Korea
Facsimile No. ++82 42 472 3473

Authorized officer
BYUN, Sung Cheal
Telephone No. +82-42-481-8262

Form PCT/ISA/210 (second sheet) (January 2015)

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2012-0260207 A1	11/10/2012	KR 10-2012-0114139 A	16/10/2012
US 2013-0109369 A1	02/05/2013	CN 103931163 A	16/07/2014
		EP 2772044 A1	03/09/2014
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US 2009-0303200 A1	10/12/2009	CN 101634932 A	27/01/2010
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		WO 2004-006080 A2	15/01/2004
		WO 2004-006080 A3	02/09/2004

Electronic Patent Application Fee Transmittal

Application Number:	17181057
Filing Date:	22-Feb-2021
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Filer:	Anupma Sahay/Tierra Brown
Attorney Docket Number:	4944.0120006

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 3 months with $0 paid	2253	1	740	740
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	130	130
		Total in USD ($)		**870**

Electronic Acknowledgement Receipt

EFS ID:	46171157
Application Number:	17181057
International Application Number:	
Confirmation Number:	4690
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	26111
Filer:	Anupma Sahay/Tierra Brown
Filer Authorized By:	Anupma Sahay
Attorney Docket Number:	4944.0120006
Receipt Date:	12-JUL-2022
Filing Date:	22-FEB-2021
Time Stamp:	16:33:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$870
RAM confirmation Number	E20227BG33514836
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	2022-07-12-Transmittal-Form-4944-0120006.PDF	220103 d3d040249e346affb1793345a77a30bbcc757178	no	1
Warnings:					
Information:					
2	Extension of Time	2022-07-12-EOT-4944-0120006.PDF	167612 bf684690e0a81d6bdb7e27c6a30d0c71b470cdb1	no	1
Warnings:					
Information:					
3		2022-07-12-Amendment-Reply-111-4944-0120006.PDF	150019 10890028d3f5c8bb27aefdf6e44e814bfd2d215b	yes	13

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment/Request for Reconsideration-After Non-Final Rejection	1	1
Claims	2	6
Applicant Arguments/Remarks Made in an Amendment	7	13

Warnings:					
Information:					
4	Application Data Sheet	2022-07-12-Marked-Up-ADS-4944-0120006.PDF	110254 cea4233788a433b504fbb0d08aefa20091e71e79	no	2
Warnings:					
Information:					

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5	Information Disclosure Statement (IDS) Form (SB08)	2022-07-12-IDS-Form-SB08a-4944-0120006.PDF	121895 f932f16bcfad204fa3c9892721473715d3df5027	no	4
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
6	Non Patent Literature	NPL1_4MD-Medical-4944-0120006.PDF	435766 40a5e5c20aba66962094 8e4f8130a31cbc0611dd	no	3
Warnings:					
Information:					
7	Non Patent Literature	NPL2_Best-Hands-Free-Breast-Pumps-4944-0120006.PDF	858447 1f513f3e5a82aeacd71f1eee85427355bb3d864c	no	11
Warnings:					
Information:					
8	Foreign Reference	FP1_WO2016010524A1-4944-0120006.PDF	2679431 2cc0f68f12b62c66f40c29d3a44a697615b59710	no	34
Warnings:					
Information:					
9	Fee Worksheet (SB06)	fee-info.pdf	40606 02fc0ff0b27370e65a3d7a9aedb2a90547d59de8	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	4784133		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/21 (07-09)
Approved for use through 12/31/2020. OMB 0651-0031
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDRICKSON, Courtney B.
Attorney Docket Number	4944.0120006

ENCLOSURES (*Check all that apply*)

- ☐ Fee Transmittal Form
- ☑ Fee Attached
- ☑ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☑ Extension of Time Request
- ☐ Express Abandonment Request
- ☑ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

Marked-Up Application Data Sheet; FP1; NPL1-NPL2

Remarks

Online Credit Card Authorization for $870.00 to cover:

$130.00 - Information Disclosure Statement Fee;
$740.00 - 3 Month Extension of Time Fee

The Office may charge any fee deficiency for any submission made with this transmittal to Deposit Account 19-0036.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Anupma Sahay #78,704/		
Printed name	Anupma Sahay		
Date	July 12, 2022	Reg. No.	78,704

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional): 4944.0120006

Application Number: 17/181,057

Filed: February 22, 2021

For: BREAST PUMP SYSTEM

Art Unit: 3783

Examiner: FREDRICKSON, Courtney B.

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	Micro Entity Fee	
☐ One month (37 CFR 1.17(a)(1))	$220	$110	$55	$
☐ Two months (37 CFR 1.17(a)(2))	$640	$320	$160	$
☑ Three months (37 CFR 1.17(a)(3))	$1,480	$740	$370	$ 740.00
☐ Four months (37 CFR 1.17(a)(4))	$2,320	$1,160	$580	$
☐ Five months (37 CFR 1.17(a)(5))	$3,160	$1,580	$790	$

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 19-0036.

☑ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant.

☑ attorney or agent of record. Registration number 78,704.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/Anupma Sahay #78,704/
Signature

July 12, 2022
Date

Anupma Sahay
Typed or printed name

(202) 371-2600
Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☑ * Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/181,057	02/22/2021	Jonathan O'TOOLE	ELVI-002/06US

CONFIRMATION NO. 4690

POWER OF ATTORNEY NOTICE

58249
COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004

OC000000131861528

Date Mailed: 02/17/2022

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/11/2022.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/tnguyen/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006

CONFIRMATION NO. 4690

POA ACCEPTANCE LETTER

26111
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

OC000000131861557

Date Mailed: 02/17/2022

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/11/2022.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/tnguyen/

PTO/AIA/82A (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Title	BREAST PUMP SYSTEM
Art Unit	3783
Examiner Name	Courtney B. FREDRICKSON
Attorney Docket Number	4944.0120006

SIGNATURE of Applicant or Patent Practitioner

Signature	/Anupma Sahay #78,704/	Date (Optional)	
Name	Anupma Sahay	Registration Number	78,704
Title (if Applicant is a juristic entity)	Attorney for Applicant		
Applicant Name (if Applicant is a juristic entity)	Chiaro Technology Limited		

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ *Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/AIA/82B (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 26111

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

CHIARO TECHNOLOGY LIMITED

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	/Hannah Brunskill/	Date (Optional)	8 December 2021
Name	Hannah Brunskill		
Title	Head of Legal		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	44977990
Application Number:	17181057
International Application Number:	
Confirmation Number:	4690
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	58249
Filer:	Anupma Sahay/Rolonda Lee
Filer Authorized By:	Anupma Sahay
Attorney Docket Number:	ELVI-002/06US
Receipt Date:	11-FEB-2022
Filing Date:	22-FEB-2021
Time Stamp:	17:56:02
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	2022-02-11-Transmittal-Form-4944-0120006.pdf	1287494 d725f03d80fa6bab0960448fdd84cce8ad30d36e	no	2

Warnings:

Information:					
2	Authorization for Extension of Time all replies	2022-02-11-EOT-Authorization-4944-0120006.pdf	97945 5a79c260d0beb35644b7d6278f18c0531f4390aa	no	1
Warnings:					
Information:					
3	Power of Attorney	2022-02-11-POA-82A-4944-0120006.pdf	514012 43965031c9a62c01effef034e091baca721ab214	no	1
Warnings:					
Information:					
4	Power of Attorney	2022-02-11-POA-82B-4944-0120006.pdf	511087 f8a9fa77ddb50636ad50d2b6e5e926a62169a6dd	no	1
Warnings:					
Information:					
		Total Files Size (in bytes):	2410538		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/21 (07-09)
Approved for use through 12/31/2020. OMB 0651-0031
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	Courtney B. FREDRICKSON
Attorney Docket Number	4944.0120006

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☑ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

Authorization under 37 CFR 1.136(a)(3)

Remarks

The Office may charge any fee deficiency for any submission made with this transmittal to Deposit Account 19-0036.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Anupma Sahay #78,704/		
Printed name	Anupma Sahay		
Date	February 11, 2022	Reg. No.	78,704

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: Chiaro Technology Limited	Art Unit: 3783
Application No.: 17/181,057	Examiner: Courtney B. FREDRICKSON
Filing Date: 02/22/2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Authorization to Treat a Reply as Incorporating an Extension of Time Under 37 C.F.R. § 1.136(a)(3)

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

The U.S. Patent and Trademark Office is hereby authorized to treat any concurrent or future reply that requires a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. The U.S. Patent and Trademark Office is hereby authorized to charge all required extension of time fees to our Deposit Account No. 19-0036, if such fees are not otherwise provided for in such reply.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Anupma Sahay #78,704/

Anupma Sahay
Attorney for Applicant
Registration No. 78,704

Date: February 11, 2022

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

18011752_1

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/181,057	02/22/2021	Jonathan O'TOOLE	ELVI-002/06US	4690

58249 7590 01/26/2022

COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004

EXAMINER	
FREDRICKSON, COURTNEY B	

ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
01/26/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

zIPPatentDocketingMailboxUS@cooley.com

Office Action Summary	Application No. 17/181,057	Applicant(s) O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	Art Unit 3783	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 17December2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-22,24-25 and 28-33 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-22,24-25 and 28-33 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 22February2021 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☑ All b)☐ Some** c)☐ None of the:

1.☑ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

The information disclosure statement (IDS) submitted is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Amendment

This office action is responsive to the Preliminary amendment filed on December 17, 2021. As directed by the amendment: claims 1, 2, 4-9, 13-16, 18-22, 24, 25, 28-30 have been amended, claims 23, 26, and 27 have been cancelled, and claims 31-33 have been added. Thus, claims 1-22, 24, 25, and 28-33 are presently pending in this application.

Claim Objections

Claims 14, 28, and 29 are objected to because of the following informalities:

Regarding claim 14, the claim should be amended to recite "in which the milk container" in line 1 to correct for grammar.

Regarding claim 28, it is recommended to amend the claim to recite that "the pump is configured to deliver in excess…" to clarify that the feature is a functional aspect of the pump.

Claim 29 should end in a period.

Appropriate correction is required.

Claim Interpretation

The preamble in claim 1 recites "A breast pump device that is configured as a self-contained, in-bra wearable device". The examiner notes that this limitation gives life and meaning to the claim since it sets forth structural limitations to the overall breast pump device. For examination purposes, the term "self-contained, in-bra wearable device' is interpreted to mean "complete, or having all that is needed, in itself' and is capable of being worn in a bra. Applicant's disclosure appears to support this interpretation in fig. 1 of the Drawings which shows a fully complete breast pump device which is capable of being worn in a bra due to the device being self-contained.

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 6-8, 10, 11, 14, 16-18, 22, 24, and 31 is/are rejected under 35 U.S.C. 103 as being unpatentable over Myers (US 20080275386) and in further view of Barack (US 20140378895).

Regarding claim 1, Myers discloses a breast pump device that is configured as a self-contained, in-bra wearable device (breast pump 10 in fig. 1), comprising:

(i) a housing (outer housing 16 in fig. 1) that includes (a) a battery (AA battery 51 in fig. 10), and (b) a pump generating negative air pressure (motor 54 in fig. 10);

(ii) a breast shield (breast cup 16 in fig. 1) being configured to slide in and out of the housing (paragraph 58 discloses that the cup “clicks” into place within the housing; paragraph 42 discloses the breast cup being removable), the breast shield made up of a breast flange (outer flange area 50 in fig. 5) and a nipple tunnel (nipple tunnel 46 in fig. 5), in which the breast shield is transparent or optically clear (paragraph 65); and

(iii) a milk container that is configured to be attached to and removed from the housing (collection bag 28 is shown to be operatively attached to the housing and is physically engaged to the bottom portion of the housing).

However, Myers does not teach or disclose the breast shield being of a plurality of interchangeable breast shields each having a different size.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield of modified Khalil to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

Regarding claim 2, in the modified device of Myers, Barack discloses the plurality of interchangeable breast shields each provide a different spacing of a nipple from side walls of the nipple tunnel when that breast shield has been placed onto a breast (paragraph 54).

Regarding claim 3, in the modified device of Myers, Myers discloses the breast shield is rigid (paragraph 47 discloses the nipple tunnel, which is part of the breast shield, is rigid).

Regarding claim 6, in the modified device of Myers, Myers discloses the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast (the shield of Myers is

functionally capable of being rotated smoothly around a nipple since the claim does not require that the shield be fully latched onto the nipple for this rotation to occur).

Regarding claim 7, in the modified device of Myers, Myers discloses the breast shield presents, in use, a single continuous surface to a nipple and a breast (fig. 9A/B shows a singular inner surface which would extend from the nipple to the breast).

Regarding claim 8, in the modified device of Myers, Myers discloses the breast shield integrates the breast flange and the nipple tunnel as a single item (fig. 5 shows a singular item).

Regarding claim 10, in the modified device of Myers, Myers discloses the breast shield is configured to slide into the housing with a single push action (paragraph 58 discloses the shield can click into place).

Regarding claim 11, in the modified device of Myers, Myers discloses the breast shield is configured to slide out from the housing, together with a membrane that prevents milk from flowing into the pump (flange top 36 in fig. 9A).

Regarding claim 14, in the modified device of Myers, Myers discloses milk container attaches to a lower part of the housing (fig. 1 shows a part of the collection bag attached to the bottom part of the housing 16) and forms a base of the breast pump device (fig. 1).

Regarding claim 16, in the modified device of Myers, Myers discloses the nipple tunnel includes guide lines running parallel along one or more sides of the nipple tunnel (detent tabs 52a/b in fig. 15 are shown to be extending in a parallel to the width direction of the nipple tunnel sides).

Regarding claim 17, in the modified device of Myers, Myers discloses the nipple tunnel includes an air hole or passage (24 in fig. 9A), and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage (paragraph 52).

Regarding claim 18, in the modified device of Myers, Myers discloses the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container (outlet 24 in fig. 9A).

Regarding claim 22, in the modified device of Myers, Myers discloses the housing is shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra (fig. 1; paragraph 40).

Regarding claim 24, in the modified device of Myers, Myers discloses the breast pump device is configured to deliver a maximum suction of approximately 240 mmHg (paragraph 72).

Regarding claim 31, modified Myers teaches a kit comprising the breast pump device of claim 1 (see discussion above); and the plurality of interchangeable breast shields (paragraph 54 of Barack).

Claim 4 is/are rejected under 35 U.S.C. 103 as being unpatentable over Myers in view of Barack, as applied to claim 1 above, and further in view of Phillips (US 20160296682), as evidenced by Yuen (US 20050228342).

Regarding claim 4, modified Myers teaches all of the claimed limitations set forth in claim 1, as discussed above. Myers further teaches the breast shield is made from plastic (paragraph 40 discloses the breast cup being made from silicone, which is a type of plastic, as evidenced by Yuen in paragraph 24). However, modified Myers does not teach or disclose breast shield is dishwasher safe.

Phillips teaches a breast pump device (fig. 1) comprising a breast shield (110 in fig. 1). Phillips further teaches that the shield can be washed in a dishwasher (paragraph 60). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield of modified Myers to be dishwasher safe for the purpose of enabling the shield to be cleaned in the dishwasher for reuse, as taught by Phillips (paragraph 60).

Claims 1, 2, 6-10, 14, 17, 18, 20-22, and 31 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil (US 20130023821) in view of Myers (US 20080275386) and in further view of Barack (US 20140378895).

Regarding claim 1, Khalil discloses a breast pump device that is configured as a self-contained, in-bra wearable device (figs. 9-11), comprising:

(i) a housing (6' and 6" form a housing as shown in fig. 9) that includes (a) a power source (paragraph 32 discloses the power source integrated into the housing), and (b) a pump generating negative air pressure (vacuum pump 81 in fig. 10);

(ii) a breast shield (breast interface 1 in fig. 11) being configured to slide in and out of the housing (breast interface 1 is configured to slide in/out from the housing by attaching/detaching the lip 11 to the flange 62 of the housing as shown in fig. 4), the breast shield made up of a breast flange (base part 12 in fig. 4) and a nipple tunnel (stub 10 in fig. 4); and

(iii) a milk container that is configured to be attached to and removed from the housing (milk collection container 7' in fig. 11; paragraph 69 discloses the container being releasably connected to the housing part 6').

However, Khalil does not teach or disclose the power source being a battery and the breast shield being of a plurality of interchangeable breast shields each having a different size and each breast shield being transparent or optically clear.

Myers teaches a similar breast pump system (fig. 1) having a housing (outer housing 16 in fig. 1) which comprises a battery (battery 52 in fig. 10) and a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing to include a battery, as taught by Myers, for the purpose of providing power to the device and to have made the breast shield transparent to enable a user to view the condition of a nipple (paragraph 65).

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield of modified Khalil to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

Regarding claim 2, in the modified device of Khalil, Barack discloses the plurality of interchangeable breast shields each provide a different spacing of a nipple

from side walls of the nipple tunnel when that breast shield has been placed onto a breast (paragraph 54).

Regarding claim 6, in the modified device of Khalil, Khalil discloses the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast (the shield of Khalil is functionally capable of being rotated smoothly around a nipple since the claim does not require that the shield be fully latched onto the nipple for this rotation to occur).

Regarding claim 7, in the modified device of Khalil, Khalil discloses the breast shield presents, in use, a single continuous surface to a nipple and a breast (fig. 11).

Regarding claim 8, in the modified device of Khalil, Khalil discloses the breast shield integrates the breast flange and the nipple tunnel as a single item (fig. 11).

Regarding claim 9, in the modified device of Khalil, Khalil discloses the breast shield is generally symmetrical about a centre-line running from a top to a bottom of the breast shield when positioned upright for normal use (fig. 11).

Regarding claim 10, in the modified device of Khalil, Khalil discloses the breast shield is configured to slide into the housing with a single push action (the shield of Khalil is functionally capable of being pushed into the housing so that the nipple tunnel is located in the housing).

Regarding claim 14, in the modified device of Khalil, Khalil discloses milk container attaches to a lower part of the housing and forms a base of the breast pump device (fig. 9).

Regarding claim 17, in the modified device of Khalil, Khalil discloses the nipple tunnel includes an air hole or passage (opening 13 in fig. 3), and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage (figs. 4 and 5).

Regarding claim 18, in the modified device of Khalil, Khalil discloses the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container (opening 13 in fig. 3 is considered to be on a "lower" surface of the nipple tunnel since "lower" is not further defined; see fig. 5).

Regarding claim 20, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the housing further includes a Universal Serial Bus (USB) charging socket.

As discussed above, Barack is directed towards a breast pump device (fig. 1) which comprises a housing which houses a pump (fig. 1 shows a pump 20 which would necessarily have some sort of housing since it is disclosed to have a USB port and a user interface). Barack further teaches a USB charging socket (USB port 34 in fig. 1; paragraph 45). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing of modified Khalil to include the USB charging socket, as taught by Khalil, for the purpose of enabling the device to interface with an external memory (paragraph 45).

Regarding claim 21, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the housing includes a left or right breast selector or toggle switch, that, when selected for a particular pumping session, sends data to a connected application configured to track

pumping sessions, to indicate whether that particular session is associated with a left or a right breast.

Barack teaches a breast pump device (fig. 1) which has a control electronics (controller 22 in fig. 1) and a control interface (user interface 30 in fig. 1) that is user selectable to indicate or record if milk is being expressed from the left or right breast (paragraph 43) and that, when selected for a particular pumping session, sends data to a connected application, running on a device, such as a smartphone, that tracks pumping sessions, to indicate whether that session is associated with the left or the right breast (paragraph 46 discloses transmitting via transceiver the parameters that have been entered at the user interface 30 to a remove device; paragraph 43 discloses that one parameter entered at the user interface is which breast is selected).

Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing of modified Khalil to include a left or right breast selector or toggle switch, that, when selected for a particular pumping session, sends data to a connected application configured to track pumping sessions, to indicate whether that particular session is associated with a left or a right breast, as taught by Barack. This modification would enable a user to track which parameters are best suited for each breast to optimize pumping, as taught by Barack (paragraphs 8 and 43).

Regarding claim 22, in the modified device of Khalil, Khalil discloses the housing is shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra (fig. 9).

Regarding claim 31, modified Khalil teaches a kit comprising the breast pump device of claim 1 (see discussion above); and the plurality of interchangeable breast shields (paragraph 54 of Barack).

Claim 5 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Chang (US 20180333523).

Regarding claim 5, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast shield is configured to attach using magnets to the housing.

Chang teaches a substantially similar self-contained breast pump system (breast pump system 10 in fig. 1A) having a breast shield (flange 14 in fig. 1A) attached to a housing (housing 12 in fig. 1A) and configured to attach to the housing using one or more magnets (paragraph 108 discloses the shield uses magnets 118 attached to the shield to determine if the shield is properly attached to the housing). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield of modified Khalil to be configured to attach using magnets to the housing since Chang teaches this configuration provides a safeguard such that the system will not operate unless all components are fully connected (paragraph 108).

Claims 12 and 13 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Phillips (US 20160296682).

Regarding claim 12, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Although it appears based on fig. 11 of Khalil that the container would be rigid, modified Khalil does not explicitly teach or disclose this limitation.

Phillips teaches a breast pump system (fig. 1) comprising a milk collection container ("collection container" 120 in fig. 1) which is substantially rigid (paragraph 57 discloses the container being made from Tritan; pg. 21 of Applicant's specification discloses that Tritan is a polycarbonate material, which is a known rigid material). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the container of modified Khalil to be made of Tritan for the purpose of enabling the container to maintain its strength when a vacuum is applied, as taught by Phillips (paragraph 57).

Regarding claim 13, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses the milk container is an optically clear, plastic container (paragraph 69 discloses the container is made of plastic like cover 6" and is transparent in its entirety). However, Khalil does not explicitly teach or disclose the milk container is dishwasher safe.

Phillips teaches a breast pump system (fig. 1) comprising a milk collection container ("collection container" 120 in fig. 1) which is dishwasher safe (paragraph 57 discloses the container being made from Tritan; pg. 21, lines 13-18 of Applicant's specification discloses that Tritan a dishwasher safe material). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the container of modified Khalil to be made of Tritan for the

purpose of enabling the container to maintain its strength when a vacuum is applied, as taught by Phillips (paragraph 57).

Claim 15 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Karsan (US 20070228059).

Regarding claim 15, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the milk container is configured to magnetically attach to the housing.

Khalil teaches that the milk container latches to the housing by a locking lug (paragraph 69 discloses a locking lug formed on the container latches engages into a corresponding recess). Karsan teaches a container (1 in fig. 1) having a case (2 in fig. 3) and a base (fig. 3) which are releasably held together (paragraph 51 discloses the connection being releasable) via a latch mechanism (5 and 6 in fig. 3). Karsan further teaches that the latching mechanism is embodied as a lug and recess (5 and 6, respectively in fig. 3; paragraph 65) but may alternatively be embodied as a magnetic means so that the two components may be magnetically latched (paragraph 65).

In Applicant's invention, Applicant uses the magnets to removably secure the milk container to the housing. Thus, Karsan is reasonably pertinent to the problem faced by the inventor since Karsan teaches using magnets as a removable latching connection between two components. As Karsan teaches that the magnetic means (paragraph 65) are functional equivalents to a locking lug and recess (paragraph 65), it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have substituted the locking lug/recess configuration of Khalil with

the magnetic means, as taught by Karsan. The substitution would have resulted in providing an equivalent secure attachment of the milk container to the housing.

Claim 19 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Blondheim (US 20120277636).

Regarding claim 19, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the pump comprises one or more piezo air pumps.

Blondheim is directed towards a breast pump device (fig. 1) which comprises an air pump (66 in fig. 6). Blondheim further teaches that the air pump can be a piezoelectric pump (paragraph 36). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the pump of modified Khalil to be a piezoelectric pump, as taught by Blondheim for the purpose of rendering the pump small in size (paragraph 36).

Claim 25 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Guthrie (US 20160220743).

Regarding claim 25, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast pump device includes a sensor that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container.

Guthrie is directed towards a breast pump device comprising a sensor (detector 607 in fig. 6B) that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container (paragraph 63 discloses that the emitter 606 and the detector 607 operate to detect light reflecting off the opaque surface of the milk). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the device to include a sensor that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container, as taught by Guthrie, for the purpose of measuring volume of milk pumped (paragraph 54).

Claim 29 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Mendoza (US 6227936).

Regarding claim 29, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the pump is a lightweight air pump that enables the total mass of the breast pump system, unfilled with milk, to be less than 250gm.

Mendoza teaches a bra which is designed to support a breast pump to allow the mother's hands to remain free (1:8-12). Mendoza further discloses that the bra must be able to support up to 8 ounces when the pump is full (1:58-62). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed

invention to have modified the system of modified Khalil to be a lightweight air pump that enables the total weight of the system, unfilled with milk, to be less than 250gm, as taught by Mendoza since Mendoza teaches that a lightweight system is crucial for enabling the system to be supported by a bra.

Claim 30 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, in further view of Baker (US 20090281485).

Regarding claim 30, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast pump device makes less than 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

Baker is directed towards a device for removing fluid from a body (fig. 6) using a vacuum pump embodied as a motor (motor 9 in fig. 6; paragraph 243). Baker further teaches that the device makes less than 20 decibel of noise at full power (paragraph 121) by sound proofing the walls of the housing and by adding a counter balance to the motor (paragraph 144). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the device of modified Khalil to have the device make less than 20 dB of noise during maximum power for the purpose of making the device for discrete and comfortable for the user and others around the user.

Claim 32 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 31 above, in further view of Cudworth (US 20120165729).

Regarding claim 32, modified Khalil teaches all of the claimed limitations set forth in claim 31, as discussed above, but does not teach or disclose each of the plurality of interchangeable breast shields includes fit lines in a nipple tunnel of that breast shield that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel.

Cudworth teaches a breast pump system (fig. 1) having a shield (attachment 1) having a flange (cup 2 in fig. 2) and a nipple tunnel (cylindrical portion 3 in fig. 1). Cudworth further teaches the nipple tunnel includes fit lines in a nipple tunnel of that breast shield that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel (grooves 12 in fig. 1 are functionally capable of serving as "fit lines" to assist a user in determining if the breast shield is correctly sized and since the claimed fit lines are not further structurally defined). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of Khalil to include the claimed fit lines, as taught by Cudworth, for the purpose of providing a massaging pressure on the breast to help stimulate milk production (paragraph 30).

Claim 33 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, in further view of Meyers (US 5542921).

Regarding claim 33, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further teaches control electronics ("control

elements and a display" in paragraph 51) which would be powered by the battery (the power source of Khalil is understood to power the device).

However, Khalil does not teach or disclose the battery to be rechargeable and the housing further including a power charging circuit for controlling the charging of the rechargeable battery.

Meyers is directed to a breast pump device (fig. 1) comprising a battery configured to be recharged (9:50-52 discloses recharging the batteries) and a power charging circuit for controlling the charging of the rechargeable battery ("circuit" in 9:50-52). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the battery of modified Khalil to be rechargeable and to have incorporated a power charging circuit for controlling the charging of the rechargeable battery, as taught by Meyers to enable the batteries to be reused.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-22, 24, 25, 29-33 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10881766 in view of Khalil, Myers, Barack, and the teachings below (see table).

Regarding claim 1, claim 1 of the issued patent claims all of the claimed limitations of instant claim 1 except the device being a self-contained, in-bra device having a breast shield being substantially rigid and formed from dishwasher safe plastic.

Khalil teaches a breast pump device (fig. 10) configured as a self-contained, in-bra wearable device (fig. 10; paragraph 70). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the reference claim to be a self-contained, in-bra wearable device, as taught by Khalil, for the purpose of enabling the device to be a small and hands-free (paragraph 70).

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65).

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may

change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5	8	
6		Myers and Khalil teach this limitation above.
7	7	
8	27	
9		Khalil teaches this limitation above.
10	8	
11		Myers teaches this limitation above.
12		Philips teaches this limitation above.
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.
15	2	
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19	18	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25	26	
29		Mendoza teaches this limitation above.
30		Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

Claims 1-22, 24, 25, and 28-33 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10926011 in view of Khalil, Myers, and Barack, and the teachings below (see table).

Regarding claim 1, claim 1 of the issued patent claims all of the limitations in instant claim 1 except claim 1 does not claim a self-contained device, the housing having a battery, the breast shield having a breast flange and nipple tunnel and being substantially rigid and formed of an optically clear, dishwasher safe plastic and being configured to slide into the housing and the milk container being configured for attachment and removal from the housing.

Khalil teaches a breast pump device (fig. 10) configured as a self-contained, in-bra wearable device (fig. 10; paragraph 70) having a breast shield (1 in fig. 11) having a flange (12in fig. 6) and a nipple tunnel (13 in fig. 6) and a milk container (7' in fig. 11)configured to be attached and removed from the housing (paragraph 69). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the reference claim to be a self-contained, in-bra wearable device having a breast shield with a flange and nipple tunnel and a milk container configured to be attached and removed from the housing, as taught by Khalil, for the purpose of enabling the device to be a small and hands-free (paragraph 70). The modification of the breast shield would enable the shield to interface with the breast and receive the nipple and the modification of the milk container would enable the milk to be collected after expression.

Myers teaches a self-contained, in bra breast pump (fig. 1) which comprises a breast shield (18 in fig. 2) having a flange (48 in fig. 5) and nipple tunnel (46 in fig. 5) and a housing (16 in fig. 2) for housing a pump (56 in fig. 10) and a battery for powering the pump (52 in fig. 10). Myers further teaches that the breast shield is optically clear (paragraph 65). Therefore, it would have been obvious to one of ordinary skill before

the effective filing date of the claimed invention to have modified the shield to be optically clear for the purpose of allowing a user to visualize the placement of the breast and nipple and to have modified the housing to include a battery, as taught by Myers, for the purpose of providing power to the device.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6		Myers and Khalil teach this limitation above.
7	30	
8		Myers and Khalil teach this limitation above.
9		Khalil teaches this limitation above.
10	14	
11		Myers teaches this limitation above.
12	12	
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.

15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19	1	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25	19	
28	9	
29	28	
30	10	
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

Claims 1-22, 24, 25, 28-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203050 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph

65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	6	
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	7	
7	8	
8	9	
9	11	
10		Myers and Khalil teach this limitation above.
11		Myers teaches this limitation above.
12		Philips teaches this limitation above.
13		Philips teaches this limitation above.
14	20	
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.

19	2	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22	21	
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
28	4	
29	4	
30	5	
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203079 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph

65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6		Myers and Khalil teach this limitation above.
7		Myers and Khalil teach this limitation above.
8		Myers and Khalil teach this limitation above.
9		Khalil teaches this limitation above.
10		Myers and Khalil teach this limitation above.
11		Myers teaches this limitation above.
12		Philips teaches this limitation above.
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.

19		Blondheim teaches this limitation above.
20		Barack teaches this limitation above.
21	1	
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
29		Mendoza teaches this limitation above.
30		Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33	31	

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 28-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203109 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	20	
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	21	
7	22	
8	22	
9		Khalil teaches this limitation above.
10		Myers and Khalil teach this limitation above.
11	23	
12	29	
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19	6	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.

24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
28	18	
29		Mendoza teaches this limitation above.
30	19	
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 28-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203150 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each

having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

This is a provisional nonstatutory double patenting rejection.

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	2	
4		Philips teaches this limitation above.
5	1	
6	3	
7	4	
8	6	
9	7	
10		Myers and Khalil teach this limitation above.
11	8	
12	15	
13		Philips teaches this limitation above.
14	16	
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18	23	
19	28	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22	17	

24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
28	29	
29	29	
30	30	Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

Claims 1-22, 24, 25, 28-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203179 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several

breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	10	
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	11	
7	12	
8	13	
9	15	
10		Myers and Khalil teach this limitation above.
11	16	
12	2	
13		Philips teaches this limitation above.
14	3	
15	1	
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18	23	
19	28	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
28	29	
29	29	
30	30	

31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203216 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of

ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6		Myers and Khalil teach this limitation above.
7		Myers and Khalil teach this limitation above.
8		Myers and Khalil teach this limitation above.
9		Khalil teaches this limitation above.
10		Myers and Khalil teach this limitation above.
11		Myers teaches this limitation above.
12		Philips teaches this limitation above.
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19		Blondheim teaches this limitation above.
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25	1	
29		Mendoza teaches this limitation above.
30		Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33	31	

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203259 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may

change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6		Myers and Khalil teach this limitation above.
7		Myers and Khalil teach this limitation above.
8		Myers and Khalil teach this limitation above.
9		Khalil teaches this limitation above.
10		Myers and Khalil teach this limitation above.
11		Myers teaches this limitation above.
12	22	
13		Philips teaches this limitation above.
14	23	
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19	28	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25	13	
29	29	
30		Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33	31	

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 28-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 and 31 of copending Application No. 17/203292 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching

1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	3	
7	4	
8	5	
9	7	
10		Myers and Khalil teach this limitation above.
11		Myers teaches this limitation above.
12	12	
13		Philips teaches this limitation above.
14	16	
15		Karsan teaches this limitation above.
16	1	
17		Myers and Khalil teach this limitation above.
18	23	
19	28	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24	32	
25		Guthrie teaches this limitation above.
28	29	
29	29	
30	30	
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 28-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203313 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or

optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	16	
4		Philips teaches this limitation above.

5		Chang teaches this limitation above.
6	17	
7	18	
8	18	
9	19	
10		Myers and Khalil teach this limitation above.
11	20	
12	27	
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19	1	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
28	13	
29	14	
30	15	
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203327 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
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6	3	
7	4	

8	4	
9	7	
10		Myers and Khalil teach this limitation above.
11	8	
12	15	
13		Philips teaches this limitation above.
14	16	
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18	23	
19		Blondheim teaches this limitation above.
20	1	
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
29		Mendoza teaches this limitation above.
30		Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203355 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses

the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

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16	1	
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18		Myers and Khalil teach this limitation above.
19	28	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
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25		Guthrie teaches this limitation above.
28		
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33	32	

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203384 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast

shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

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8		Myers and Khalil teach this limitation above.
9		Khalil teaches this limitation above.
10		Myers and Khalil teach this limitation above.
11		Myers teaches this limitation above.
12		Philips teaches this limitation above.
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17		Myers and Khalil teach this limitation above.
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21		Barack teaches this limitation above.
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This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203397in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

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32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203418 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

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24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
29	30	
30	31	
31		Barack teaches this limitation above.

32		Cudworth teaches this limitation above.
33	32	

This is a provisional nonstatutory double patenting rejection.

Allowable Subject Matter

Except for the double patenting rejection above, **claim 28** would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not teach or suggest the pump delivers the claimed stall pressure and free air flow.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COURTNEY FREDRICKSON whose telephone number is (571)270-7481. The examiner can normally be reached Monday-Friday (9 AM - 5 PM EST).

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NATHAN PRICE can be reached on 571-270-5421. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/COURTNEY B FREDRICKSON/
Examiner, Art Unit 3783

/NATHAN R PRICE/
Supervisory Patent Examiner, Art Unit 3783

Notice of References Cited	Application/Control No. 17/181,057	Applicant(s)/Patent Under Reexamination O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	Art Unit 3783	Page 1 of 1

U.S. PATENT DOCUMENTS

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*	C	US-20070228059-A1	10-2007	Karsan; Chettan	B65D43/16	220/824
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*	I	US-20140378895-A1	12-2014	Barack; Doron	A61M1/06	604/74
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*	K	US-20160296682-A1	10-2016	Phillips; Andrew Luke	A61J13/00	1/1
*	L	US-20180333523-A1	11-2018	Chang; John	A61M1/06	1/1
	M					

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
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Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

CPC - Searched*		
Symbol	Date	Examiner
a61m1/06-069	01/12/2022	cbf

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
see SEARCH history	01/12/2022	cbf
searched inventors in PALM and SEARCH	01/12/2022	cbf
consulted child search history	01/12/2022	cbf

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/12/2022								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
	7	✓								
	8	✓								
	9	✓								
	10	✓								
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	26	-								
	27	-								
	28	✓								
	29	✓								
	30	✓								
	31	✓								
	32	✓								
	33	✓								

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	
First Named Inventor	Jonathan O'Toole
Art Unit	
Examiner Name	
Attorney Docket Number	373499.00049

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	25	20160000980	A1	2016-01-07	ALVAREZ, et al.	
	26	20160058928	A1	2016-03-03	NOWROOZI, et al.	
	27	20160058929	A1	2016-03-03	MEDVEDEV, et al.	
	28	20160082165	A1	2016-03-24	ALVAREZ, et al.	
	29	20160082166	A1	2016-03-24	GUTHRIE, et al.	
	30	20160151551	A1	2016-06-02	FELBER	
	31	20160158424	A1	2016-06-09	CHEN, et al.	
	32	20160166745	A1	2016-06-16	AALDERS	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	Jonathan O'Toole
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

	33	20160206794	A1	2016-07-21	MAKOWER, et al.	
	34	20160220743	A1	2016-08-04	GUTHRIE, et al.	
	35	20160220745	A1	2016-08-04	GUTHRIE, et al.	
	36	20160256617	A1	2016-09-08	HANSEN	
	37	20160287767	A1	2016-10-06	SIMMONS, et al.	
	38	20160296681	A1	2016-10-13	GASKIN, et al.	
	39	20160310650	A1	2016-10-27	MAKOWER, et al.	
	40	20170021068	A1	2017-01-26	GASKIN, et al.	
	41	20170035951	A1	2017-02-09	TANAKA	
	42	20170043065	A1	2017-02-16	TAKEUCHI	
	43	20170072117	A1	2017-03-16	KURIHARA, et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Attorney Docket Number	373499.00049

	44	20170072118	A1	2017-03-16	MAKOWER, et al.	
	45	20170143879	A1	2017-05-25	OKAGUCHI	
	46	20170220753	A1	2017-08-03	GUTHRIE, et al.	
	47	20180021490	A1	2018-01-25	CHANG, et al.	
	48	20180110906	A1	2018-04-26	BARACK	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	3311982	DE	C2	1983-10-13	BATTELLE MEMORIAL INSTITUTE		
	2	9503280	EP	A2	1992-02-08	PIERBURG GMBH		
	3	9420158	WO	A1	1994-09-15	DEKA PRODUCTS LIMITED PARTNERSHIP		
	4	19750620	DE	A1	1999-06-02	SIEMENS AG, 80333 MUENCHEN, DE		

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	Application Number	
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	First Named Inventor	Jonathan O'Toole
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	Examiner Name	
	Attorney Docket Number	373499.00049

	5	1586340	EP	A2	2005-10-19	SEA PROFIT (HONG KONG) LIMITED		
	6	2005114116	WO	A1	2005-12-01	LANE, JOHN, DENNIS; ESPARZA, JOSEPH, LUIS; NICHOLS		
	7	2005114113	WO	A3	2006-03-02	ACCU-GAUGE LIMITED		
	8	1430918	EP	B1	2008-05-14	MEDELA HOLDING AG		
	9	2344380	RU	C1	2009-01-20	GOSUDARSTVENNOE OBRAZOVATEL'NOE UCHREZHDENIE VYSSH		
	10	2009134271	WO	A1	2009-11-05	UTC POWER CORPORATION		
	11	2473022	GB	B	2011-12-14			
	12	2441367	RU	C2	2012-02-10	OBSHCHESTVO S OGRANICHENNOJ OTVETSTVENNOST'JU "NAU		
	13	2436277	EP	A1	2012-04-04	DREW, LORNA		
	14	2210628	EP	B1	2013-02-13	MEDELA HOLDING AG		
	15	2499248	GB	B	2014-04-02	ELIZABETH MORANA		

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	Examiner Name	
	Attorney Docket Number	373499.00049

	16	1404393	EP	B1	2014-12-24	MEDELA HOLDING AG		
	17	2015081459	WO	A1	2015-06-11	CHEN, JUNBO		
	18	2015116749	WO	A1	2015-08-06	CORNING INCORPORATED		
	19	2015120321	WO	A1	2015-08-13	NAIA HEALTH, INC.		
	20	2015150225	WO	A1	2015-10-08	KONINKLIJKE PHILIPS N.V.		
	21	2015174330	WO	A1	2015-11-19	MURATA MANUFACTURING CO., LTD.		
	22	2016002606	WO	A1	2016-01-07	MURATA MANUFACTURING CO., LTD.		
	23	2016006494	WO	A1	2016-01-14	MURATA MANUFACTURING CO., LTD.		
	24	2016006496	WO	A1	2016-01-14	MURATA MANUFACTURING CO., LTD.		
	25	2016007560	WO	A1	2016-01-14	NAYA HEALTH, INC.		
	26	2016010524	JP	A	2016-01-21	MURATA MFG CO LTD		

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	First Named Inventor	Jonathan O'Toole
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

	27	2016014469	WO	A1	2016-01-28	EXPLORAMED NC7, LLC		
	28	2016014488	WO	A1	2016-01-28	EXPLORAMED NC7, LLC		
	29	105288759	CN	A	2016-02-03	SHANGHAI NORMAL UNIVERSITY		
	30	2016024558	WO	A1	2016-02-18	MURATA MANUFACTURING CO., LTD.		
	31	2016039083	WO	A1	2016-03-17	MURATA MANUFACTURING CO., LTD.		
	32	2016104673	WO	A1	2016-06-30	MURATA MANUFACTURING CO., LTD.		
	33	2077868	EP	B1	2016-07-27	MEDELA HOLDING AG		
	34	2016164853	WO	A1	2016-10-13	NAYA HEALTH, INC.		
	35	1263487	EP	B2	2016-11-23	MEDELA HOLDING AG		
	36	2017061349	WO	A1	2017-04-13	MURATA MANUFACTURING CO., LTD.		
	37	2017108555	WO	A1	2017-06-29	KONINKLIJKE PHILIPS N.V.		

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	Application Number	
	Filing Date	
	First Named Inventor	Jonathan O'Toole
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

	38	2017139480	WO	A1	2017-08-17	EXPLORAMED NC7, INC.		

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Whisper Wear Hands-Free Breast Pump, Model: WWPMP01, User Guide, pps. 1-20, Distributed with product at least as early as 2007 (see https://web.archive.org/web/20070621162539/http://www.whisperwear.com/pump_single.html)	

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Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	01/12/2022

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	
First Named Inventor	Jonathan O'Toole
Art Unit	
Examiner Name	
Attorney Docket Number	373499.00049

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

✓ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Mark D. Simpson/	Date (YYYY-MM-DD)	2021-02-22
Name/Print	Mark D Simpson	Registration Number	32942

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17181057
Filing Date	2021-02-22
First Named Inventor	Jonathan O'Toole
Art Unit	3783
Examiner Name	
Attorney Docket Number	373499.00049

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5542921	A	1996-08-06	MEYERS, et al.	
	2	7833190	B1	2010-11-16	HALL	

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	1	20070135761	A1	2007-06-14	CHENG, et al.	
	2	20070179439	A1	2007-08-02	VOGELIN, et al.	
	3	20090281485	A1	2009-11-12	BAKER, et al.	
	4	20110009824	A1	2011-01-13	YODFAT, et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17181057
	Filing Date	2021-02-22
	First Named Inventor	Jonathan O'Toole
	Art Unit	3783
	Examiner Name	
	Attorney Docket Number	373499.00049

	5	20160271305	A1	2016-09-22	KURIHARA, et al.	
	6	20160296682	A1	2016-10-13	PHILLIPS, et al.	
	7	20160325031	A1	2016-11-10	MILLER, et al.	
	8	20170095599	A1	2017-04-06	KONDO, et al.	
	9	20170112983	A1	2017-04-27	THORNE, et al.	
	10	20180028733	A1	2018-02-01	RIGERT, et al.	
	11	20180333523	A1	2018-11-22	CHANG, et al.	

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Filing Date	2021-02-22
First Named Inventor	Jonathan O'Toole
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	17181057
Filing Date	2021-02-22
First Named Inventor	Jonathan O'Toole
Art Unit	3783
Examiner Name	
Attorney Docket Number	373499.00049

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Signature	/Mark D. Simpson/	Date (YYYY-MM-DD)	2021-09-05
Name/Print	Mark D. Simpson	Registration Number	32942

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L1	1	17/181057.app.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:05 PM
L2	128	((("O'TOOLE") near3 ("Jonathan")) OR (("ROLLO") near3 ("Adam")) OR (("CARR") near3 ("Andrew"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/12/31 01:05 PM
L3	8470	a61m1/06-069.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L5	2	("20170216505").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L6	8	("20130023821" "20070219486" "20160296682").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:14 PM
L7	2	("20140378895").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:16 PM
L8	2	("7824363").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU,	OR	ON	ON	2022/01/01 01:04 PM

			SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

Bibliographic Data

Application No: 17/181,057

Foreign Priority claimed: (•) Yes ( ) No

35 USC 119 (a-d) conditions met: [✓] Yes [ ] No [ ] Met After Allowance

Verified and Acknowledged: /COURTNEY B FREDRICKSON/ Examiner's Signature | Initials

Title: BREAST PUMP SYSTEM

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
02/22/2021	604	3783	ELVI-002/06US
RULE			

APPLICANTS

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INVENTORS

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Adam ROLLO, London, UNITED KINGDOM

Andrew CARR, London, UNITED KINGDOM

CONTINUING DATA

This application is a CON of 16009547 06/15/2018 PAT 10926011

FOREIGN APPLICATIONS

UNITED KINGDOM GB1709566.2 06/15/2017

UNITED KINGDOM GB1709561.3 06/15/2017

UNITED KINGDOM GB1709564.7 06/15/2017

UNITED KINGDOM GB1809036.5 06/01/2018

IF REQUIRED, FOREIGN LICENSE GRANTED**

03/02/2021

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UNITED KINGDOM

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Washington, DC 20004

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$1,540

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 2

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	Courtney B. FREDRICKSON
Attorney Docket Number	ELVI-002/06US 339454-2025

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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	4.	10,926,011 B2	02-23-2021	O'Toole et al.	
	5.	2004/0087898 A1	05-06-2004	Weniger	
	6.	2009/0281482 A1	11-12-2009	Baker et al.	
	7.	2010/0292636 A1	11-18-2010	Renz et al.	
	8.	2012/0165729 A1	06-28-2012	Cudworth	
	9.	2014/0263611 A1	09-18-2014	Bauer	
	10.	2016/0228625 A1	08-11-2016	Holtz et al.	
	11.	2018/0110900 A1	04-26-2018	Barack	
	12.	2021/0196873 A1	07-01-2021	O'Toole et al.	
	13.	2021/0196876 A1	07-01-2021	O'Toole et al.	
	14.	2021/0196874 A1	07-01-2021	O'Toole et al.	
	15.	2021/0196875 A1	07-01-2021	O'Toole et al.	
	16.	2021/0205511 A1	07-08-2021	O'Toole et al.	
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	18.	2021/0205513 A1	07-08-2021	O'Toole et al.	
	19.	2021/0205514 A1	07-08-2021	O'Toole et al.	
	20.	2021/0205515 A1	07-08-2021	O'Toole et al.	
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	22.	2021/0205517 A1	07-08-2021	O'Toole et al.	
	23.	2021/0205518 A1	07-08-2021	O'Toole et al.	
	24.	2021/0228789 A1	07-29-2021	O'Toole et al.	
	25.	2021/0268158 A1	09-02-2021	O'Toole et al.	

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	27.	EP 0503280 A2	02-08-1992	Pierburg GmbH		
	28.	GB 2435617 B	03-05-2008	Playtex Products Inc.		
	29.	WO 2005/079441 A2	09-01-2005	Childrens Hospital Medical Center		

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Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	01/12/2022

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	3.	10,881,766 B2	01-05-2021	O'Toole et al.	
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	6.	2009/0281482 A1	11-12-2009	Baker et al.	
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	9.	2014/0263611 A1	09-18-2014	Bauer	
	10.	2016/0228625 A1	08-11-2016	Holtz et al.	
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	28.	GB 2435617 B	03-05-2008	Playtex Products Inc.		
	29.	WO 2005/079441 A2	09-01-2005	Childrens Hospital Medical Center		

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	32.	GB Search Report, dated Nov. 29, 2017, issued in priority GB Application No. GB1709564.7.	
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Bibliographic data

Title:	Breast pump
Pub/Pat no:	CN101549180A
Pub/Issue Date:	2009-10-07
Inventor(s):	MITSUO TASHIRO[JP]| SHINICHI KATAOKA[JP]|TASHIRO MITSUO |KATAOKA SHINICHI
Applicant(s):	PIGEON CORP[JP]
Classification:	A61M1/06AI
Application number:	CN200910134014 2009-04-03
Priority number:	JP20080098492 2008-04-04;

Abstract of CN101549180A

A breast pump can be configured to be capable of easily attaching/detaching a primary side serving as a sealed space which is in communication with a milking space and allows the passage of breast milk, with a secondary side in which a case is connected with a pressure changing apparatus 51. The breast pump can include a breast pump main body 21 connected to the pressure changing apparatus by a conduit, wherein a milking part is disposed so as to liquid-tightly separate a sealed space (or a space that is in fluid communication with the sealed space), and the pressure changing apparatus from each other. A pressure transmission part 30 for transmitting pressure changed by the pressure changing apparatus can be provided. The pressure transmission part can include a deformable part 32 where a volume in the sealed space can be deformed by a pressure fluctuation generated by the pressure changing apparatus. A case 31 can accommodate the deformable part and be connected with the pressure changing apparatus at one end, and the other end of the case can include attachment structure 33 for communicably attaching/detaching the case with the portion of the milking part that forms the sealed space.

[19] 中华人民共和国国家知识产权局

[51] Int. Cl.
A61M 1/06 (2006.01)

[12] 发明专利申请公布说明书

[21] 申请号 200910134014.1

[43] 公开日 2009 年 10 月 7 日

[11] 公开号 CN 101549180A

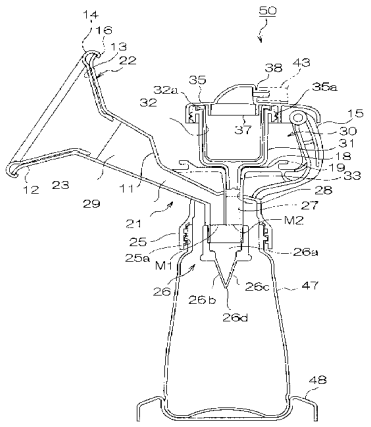
[22] 申请日 2009.4.3
[21] 申请号 200910134014.1
[30] 优先权
[32] 2008. 4. 4 [33] JP [31] 2008 - 098492
[71] 申请人 贝亲株式会社
地址 日本东京都
[72] 发明人 田代光雄 片冈信一
[74] 专利代理机构 北京市金杜律师事务所
代理人 陈 伟
权利要求书 2 页 说明书 16 页 附图 9 页

[54] 发明名称

吸奶器

[57] 摘要

本发明提供一种吸奶器，能够容易地对与吸奶空间连通的母乳所通过的密闭空间即一次侧和与压力改变机构连接的壳体所存在的一侧即二次侧进行装拆。吸奶器具有吸奶器主体(21)和压力改变机构(51)，吸奶部具有用于传递通过所述压力改变机构被改变的压力的压力传递部(30)，该压力传递部将密闭空间或与其连通的空间和所述压力改变机构液密地分离。所述压力传递部具有：变形部(32)，该变形部使所述密闭空间或与该密闭空间连通的空间内所占的体积或容积因所述压力改变机构所产生的压力变化而变形；壳体(31)，用于收容该变形部，并且一端与所述压力改变机构侧连接，在该壳体的另一端，具有用于以能够连通的方式对该壳体内和所述密闭空间进行装拆的装拆机构(33)。



1. 一种吸奶器，具有：与使用者的乳房抵接的大致圆锥状的吸奶部；包含所述吸奶部、以连通的方式与瓶进行装拆的吸奶器主体；与所述吸奶部连接，交替地产生负压状态以及比该负压状态压力高的至少大气压状态的压力改变机构，其特征在于，

具有用于传递通过所述压力改变机构被改变的压力的压力传递部，该压力传递部被配置成，当所述吸奶部进行吸奶时，将因抵接使用者的乳房而形成的密闭空间或与该密闭空间连通的空间和所述压力改变机构液密地分离，

所述压力传递部具有：变形部，该变形部使所述密闭空间或与该密闭空间连通的空间内所占的体积或容积因所述压力改变机构所产生的压力变化而变形；壳体，用于收容该变形部，并且一端与所述压力改变机构侧连接，

在该壳体的另一端，具有用于以能够连通的方式对该壳体内和所述密闭空间进行装拆的装拆机构。

2. 如权利要求 1 所述的吸奶器，其特征在于，所述壳体是在内部收容了所述变形部的筒状体，在该筒状体上具有作为所述装拆机构的、从与所述另一端对应的端部突出的管状突出部，而在所述密闭空间中，具有在该空间内延伸的筒状连接部，使所述筒状连接部的内径比所述壳体侧的所述管状突出部的外径稍大，由此，将所述管状突出部插入所述筒状连接部，成为所述壳体和所述密闭空间被气密接合的结构。

3. 如权利要求 2 所述的吸奶器，其特征在于，所述壳体的所述管状突出部的周边为平坦的底部，在所述吸奶器主体的所述筒状连接部的开口周边形成有平坦的接触面部，将所述管状突出部插入所述筒状连接部，将所述壳体的所述平坦的底部推入至与所述平坦的接触面部抵接的位置，由此，成为所述壳体和所述密闭空间气密接合的结构。

4. 如权利要求 3 所述的吸奶器，其特征在于，所述筒状连接部以在将所述吸奶器主体载置在所述瓶上的状态下、向瓶下方大致垂直延伸的方式形成，并且，所述管状突出部向前端逐渐变细。

5. 如权利要求 1～4 的任一项所述的吸奶器，其特征在于，具有盖部件，该盖部件将收纳所述变形部的所述壳体的一端侧覆盖，并且，与作为所述压力改变机构的负压形成机构连接的管相对于该盖部件装拆，所述盖部件具有卡定机构，在所述壳体和所述密闭空间被接合的状态下，所述卡定机构用于在将所述盖部件安装在所述壳体的一端侧的位置上，将该盖部件相对于所述吸奶器主体的所述密闭空间侧进行卡定。

6. 如权利要求 5 所述的吸奶器，其特征在于，所述卡定机构设置在所述盖部件的周缘部，该卡定机构相对于从所述吸奶器主体侧向上方突出的支承机构被卡定。

7. 如权利要求 5 所述的吸奶器，其特征在于，使从所述盖部件的周缘部延伸的卡定机构相对于在所述吸奶器主体的所述筒状连接部的开口周边所设置的接触面部的周缘部进行卡定。

吸奶器

技术领域

本发明涉及用于吸取母乳的吸奶器的改进。

背景技术

供母亲等吸取母乳使用的吸奶器，例如具有用于与乳房抵接的喇叭部、和用于在因乳房抵接该喇叭部而形成的空间中产生负压的泵等的负压形成机构。被吸引到负压空间的母乳流入瓶等中而被贮存，负压形成空间和所述泵通过连接机构连接（参照专利文献1）。

在这样的吸奶器中，被收容在设置于所述连接机构的外壳中的阀体根据母乳液面的上升而可动，从而阻塞向负压形成机构即所述泵侧的开口。由此，能够防止母乳回流到负压形成机构即泵侧，并能够防止机械结构生锈及被污染。另外，即使在负压形成机构不是由泵等的机械构造构成、而是由杆等的手动机构构成的情况下，也能够避免因母乳回流到该杆等而沾污使用者的手等不良情况。

但是，在这样的吸奶器中，设置在所述连接机构上的、将所述负压空间和所述泵侧连通的开口，是会因阀体的动作而被阻塞的构造。

因此，负压空间和泵侧无法成为始终完全地液密分离的构造，即使阀体将所述开口阻塞，也存在着母乳本身以及随负压成为雾状的母乳等从微小的间隙回流到泵侧的危险。

因此，可能会造成泵的机械部分污损、杂菌繁殖，在手动的负压形成机构中也同样存在着污损和不卫生的问题。

因此，本申请中提出了专利文献2所示的吸奶器。

该吸奶器中具有压力传递部，该压力传递部被配置成，当吸奶部进行吸奶时，能够将因与使用者的乳房抵接而形成的密闭空间、

或与该密闭空间连通的空间和所述压力改变机构液密地分离，该压力传递部用于传递被所述压力改变机构改变了的压力，所述压力传递部具有变形部，该变形部在所述密闭空间或与该密闭空间连通的空间内所占的体积或容积因所述压力改变机构的动作而变化。

因此，由于压力传递部将形成于所述吸奶部的所述密闭空间和泵等的压力改变机构完全液密分离，因而能够有效地防止吸取出的母乳从所述密闭空间侧回流到所述压力改变机构。其结果是，能够有效地防止压力改变机构侧接触母乳而产生腐蚀和破损，或是被污染成为不卫生的状态。

专利文献 1：日本特开平 11-226117

专利文献 2：日本特开 2006-102220

但是，在专利文献 2 的吸奶器中，虽然能够实现将与吸奶空间连通的母乳所通过的密闭空间即一次侧和与压力改变机构连接的壳体所存在的一侧即二次侧液密分离的结构，但它们在构造上是相互结合的构造。

因此，在搬运时、收纳时等，一次侧的构造和二次侧的构造是结合的，因而产生了操作、清洁时等不方便的另外的问题。

发明内容

因此，本发明的目的在于提供一种吸奶器，能够容易地对与吸奶空间连通的母乳所通过的密闭空间即一次侧和与压力改变机构连接的壳体所存在的一侧即二次侧进行装拆，并能够使清洁等的操作变得极其容易。

上述目的在第一发明中是通过如下所述的吸奶器实现的，吸奶器具有：与使用者的乳房抵接的大致圆锥状的吸奶部；包含所述吸奶部、以连通的方式与瓶进行装拆的吸奶器主体；与所述吸奶部连接，交替地产生负压状态以及比该负压状态压力高的至少大气压状态的压力改变机构，其中，具有用于传递通过所述压力改变机构被改变的压力的压力传递部，该压力传递部被配置成，当所述吸奶部

进行吸奶时，将因抵接使用者的乳房而形成的密闭空间或与该密闭空间连通的空间和所述压力改变机构液密地分离，所述压力传递部具有：变形部，该变形部使所述密闭空间或与该密闭空间连通的空间内所占的体积或容积因所述压力改变机构所产生的压力变化而变形；壳体，用于收容该变形部，并且一端与所述压力改变机构侧连接，在该壳体的另一端，具有用于以能够连通的方式对该壳体内和所述密闭空间进行装拆的装拆机构。

根据第一发明的结构，所述压力传递机构通过壳体内收容的所述变形部的体积变化使所述密闭空间的内压变化，由此，改变对抵接于所述吸奶部的乳房的吸引压。

而且，因此，由于所述压力传递部将形成于所述吸奶部的所述密闭空间和泵等的压力改变机构完全地分离，因而能够有效地防止吸取出的母乳从所述密闭空间侧回流到所述压力改变机构。因此，能够有效地防止压力改变机构侧与母乳接触发生腐蚀、破损而被污染成为不卫生的状态。

而且，所述压力传递部具有一端与所述压力改变机构侧连接的壳体，在该壳体的另一端具有用于将该壳体内和所述密闭空间以能够连通的方式进行装拆的装拆机构。因此，例如，能够容易地将收容有变形部的壳体装拆，与密闭空间侧分离，不仅便于携带、移动，尤其在清洗时等，能够容易地仅对需要频繁清洗的一次侧即密闭空间侧进行分离、清洗。

第二发明在第一发明的结构的基础上，所述壳体是在内部收容了所述变形部的筒状体，在该筒状体上具有作为所述装拆机构的、从与所述另一端对应的端部突出的管状突出部，而在所述密闭空间中，具有在该空间内延伸的筒状连接部，使所述筒状连接部的内径比所述壳体侧的所述管状突出部的外径稍大，由此，将所述管状突出部插入所述筒状连接部，成为所述壳体和所述密闭空间被气密接合的结构。

根据第二发明的结构，在所述密闭空间中设置有筒状连接部，

由于该筒状连接部具有比壳体侧的管状突出部的外径稍大的内径，所以通过仅将该管状突出部插入筒状连接部这一简单的操作，就能够将压力改变机构侧和密闭空间侧连接。

第三发明在第二发明的结构的基础上，所述壳体的所述管状突出部的周边为平坦的底部，在所述吸奶器主体的所述筒状连接部的开口周边形成有平坦的接触面部，将所述管状突出部插入所述筒状连接部，将所述壳体的所述平坦的底部推入至与所述平坦的接触面部抵接的位置，由此，成为所述壳体和所述密闭空间气密接合的结构。

根据第三发明的结构，所述壳体的所述管状突出部的周边为平坦的底部，在所述吸奶器主体的所述筒状连接部的开口周边形成有平坦的接触面部，只要将所述管状突出部插入所述筒状连接部、将所述壳体的所述平坦的底部压入到与所述平坦的接触面部抵接的位置，便能够极其容易地将所述壳体和所述密闭空间接合。

第四发明在第三发明的结构的基础上，所述筒状连接部以在将所述吸奶器主体载置在所述瓶上的状态下、向瓶下方大致垂直延伸的方式形成，并且，所述管状突出部向前端逐渐变细。

根据第四发明的结构，只要将管状突出部向下插入筒状连接部，由于前端细而插入容易，并且当插入得较深时，随着该管状突出部的外径扩大，该管状突出部能够与筒状连接部的内表面紧密地接触、实现嵌合，能够极其容易地接合。

第五发明在第一～第四任意一个发明的结构的基础上，具有盖部件，该盖部件将收纳所述变形部的所述壳体的一端侧覆盖，并且，与作为所述压力改变机构的负压形成机构连接的管相对于该盖部件装拆，所述盖部件具有卡定机构，在所述壳体和所述密闭空间被接合的状态下，所述卡定机构用于在将所述盖部件安装在所述壳体的一端侧的位置上，将该盖部件相对于所述吸奶器主体的所述密闭空间侧进行卡定。

根据第五发明的结构，所述盖部件具有所述卡定机构，由此，

能够使壳体相对于密闭空间侧的接合状态不会轻易脱落。

第六发明在第五发明的结构的基础上，所述卡定机构设置在所述盖部件的周缘部，该卡定机构相对于从所述吸奶器主体侧向上方突出的支承机构被卡定。

根据第六发明的结构，卡定机构设置在所述盖部件的周缘部，由于该卡定机构是相对于从所述吸奶器主体侧向上方突出的支承机构被卡定的结构，因此，在与所述管状突出部和筒状连接部的接合位置不同的位置进行所述卡定机构的卡定，能够更稳定地维持接合状态。

第七发明在第五发明的结构的基础上，使从所述盖部件的周缘部延伸的卡定机构相对于在所述吸奶器主体的所述筒状连接部的开口周边所设置的接触面部的周缘部进行卡定。

根据第七发明的结构，由于能够利用在吸奶器主体的所述筒状连接部的开口周边所设置的接触面部来卡定盖部件，因而不需要在吸奶器主体侧形成用于卡定的特别的机构，另外，还能够相应地谋求小型化。

（发明的效果）

如上所述，根据本发明，能够提供一种吸奶器，能够容易地对与吸奶空间连通的母乳所通过的密闭空间即一次侧和与压力改变机构连接的壳体所存在的一侧即二次侧进行装拆，并能够使清洁等的操作变得极其容易。

附图说明

图 1 是本发明的第一实施方式的吸奶器的概略立体图。

图 2 是图 1 的吸奶器的吸奶单元的概略剖视图。

图 3 是图 1 的吸奶器的盖部件的概略立体图。

图 4 是图 1 的吸奶器的电机部的分解立体图。

图 5 是图 1 的吸奶器的活塞部的分解立体图。

图 6 是图 1 的吸奶器的压力调整部的分解立体图。

图 7 是图 1 的吸奶器的变形例一的说明图。

图 8 是图 1 的吸奶器的变形例二的说明图。

图 9 是本发明的第二实施方式的吸奶器的主要部位的图。

（附图标记的说明）

15...支承机构，20...吸奶器，21...（吸奶器）主体，22...吸奶部，23...通气路，28...筒状连接部，29...密闭空间，30...压力传递部，31...壳体，32...变形部（件），33...（装拆机构）管状突出部，35...盖部件，50...吸奶单元，51...泵单元

具体实施方式

以下，参照附图详细说明本发明的优选实施方式。

另外，由于以下所述的实施方式是本发明的优选具体例，因而在技术方面附加了优选的各种限定，但只要在以下的说明中没有特别限定本发明的主旨的记载，本发明的范围就不限于这些实施方式。

图 1 是表示本发明的实施方式的吸奶器的结构的概略立体图。

图 1 表示吸奶器 20 的整体，在图中，吸奶器 20 具有吸奶单元 50 和通过管 43 与该吸奶单元 50 连接的作为压力改变机构的泵单元 51。

首先，对吸奶单元 50 进行说明。

图 2 是吸奶单元 50 的概略剖视图，在图 1 以及图 2 中，吸奶单元 50 具有吸奶器主体 21（以下称为“主体”），该吸奶器主体 21 能够相对于用于贮存吸取出的母乳的容器即瓶 47 装拆。

主体 21 例如其整体由较轻的、牢固的合成树脂材料成形，例如，由聚碳酸酯、聚环烯烃、聚醚砜、聚酰胺、聚丙烯等形成。

如图 2 所示，主体 21 具有与用于贮存吸取出的母乳的瓶 47 进行装拆的装拆部 25。装拆部 25 是例如扁平的筒状部分，在内侧具有内螺纹部 25a，该内螺纹部 25a 与形成在瓶 47 的瓶口周围的外螺纹部螺合。此外，瓶 47 可以是吸奶器 20 的专用品，也可以使用能与装拆部 25 配合的哺乳瓶等瓶体。此外，瓶 47 被载置在支承台 48 上。

在图 2 中，在主体 21 的装拆部 25 的上部，设置有以斜向倾斜的状态向外敞开的圆锥状或喇叭状的吸奶部 22。

该吸奶部 22 具有：构成通气路 23 的稍微扩开的开放通路 11；一体设置在开放通路 11 的前端侧的、大幅扩开成喇叭状的开放前端部 12。它们由与主体 21 相同的材料成形，具有较高的刚性，不易变形。

另外，在开放前端部 12 的内侧，设置有形状与开放前端部 12 大致相同的筒状的吸奶口变形部件 13。吸奶口变形部件 13 能够相对于开放前端部 12 装拆。该吸奶口变形部件 13 由硅橡胶、人造橡胶、天然橡胶等弹性体形成。

另外，在吸奶口变形部件 13 的开放前端部 12，以覆盖其全周的方式设有凸状刺激部 14。

在密闭空间的负压升高时，凸状刺激部 14 与乳房抵接、提高乳房与密闭空间的密闭性，并且，推压乳房、随着吸奶的进行给予良性刺激，发挥按摩的效果。

吸奶部 22 的通气路 23 作为通气以及吸取出的母乳的通路，是向斜上方逐渐扩大的筒状，其下端侧向下方弯折并朝向瓶 47 侧。

另外，吸奶部 22 的通气路 23 的开口 M1 位于主体 21 与瓶 47 之间的装拆部 25 的内侧，并安装有小室阀 26。与通气路 23 邻接地设置有另一个通气路 27。

通气路 27 的下端开口 M2 如图所示地在小室阀 26 中与通气路 23 连通，通气路 27 的上端向上方延伸并与压力传递部 30 的壳体 31 下端连通。

因此，由吸奶部 22 的内侧和通气路 23、通气路 27 形成在吸奶时形成吸引母乳的负压的密闭空间 29。

如图 2 所示，上述小室阀 26 是整体由硅橡胶、人造橡胶、天然橡胶等弹性体形成的帽状的形态，图 2 的两侧壁 26b、26c 是向下端幅宽逐渐相互接近地形成的弹性体的倾斜壁。在两侧壁 26b、26c 的接近的下端，设置有狭缝 26d，吸取的母乳在小室 26a 中贮存到规定

量时，伴随其重量和如下所述的负压解除时的压力的变化，两侧壁26b、26c的前端侧打开，狭缝26d开放，母乳流入瓶47内。另外，通过在倾斜壁的下端形成狭缝26d，能够发挥防止负压时瓶47内的空气进入小室26a的空气阀的功能。

主体21的通气路27的上部与后述的筒状连接部28一体形成，在其上部，沿着该筒状连接部28的开口的周边部形成有接触面部18。该接触面部18是当装拆后述的壳体31时进行抵接、配置的部分，是呈适于容纳该壳体31的底面的形态的平坦或略呈凹状的皿状的部分，在其外缘形成有凸缘部19。

而且，在与主体21的吸奶部22外伸的部位相反的一侧，形成有向上方突出的支承机构15。在本实施方式中，支承机构15是例如从上述接触面部18的侧方的位置向上方延伸的部分，是以支柱状或臂状起立的突出体。支承机构15的上端到达图2的壳体31的上端附近。相对于该支承机构15，通过如下述那样支承壳体31的盖部件35，从而经由该盖部件35稳定地支承壳体31。

图3是表示壳体31的从下方观察的概略立体图，图3（a）是将盖部件35安装在壳体31上的状态，图3（b）是分解立体图。

压力传递部30的壳体31在该情况下例如是纵向长的圆筒体，其内部空间也是纵向长的空间，并收容有变形部。变形部在本实施方式中是与壳体31分体的独立部件，作为能够相对于壳体31装拆的变形部件32而构成。

变形部件32由不透气的薄材料形成，具有柔软的性质，能够容易地变形。

尤其，在本实施方式中，如图2以及图3所示，变形部件32是以与由硬质的合成树脂的成形品等形成的圆筒壳体即壳体31的内侧空间内接的形状形成的、一端开口而另一端被封闭的有底圆筒形的变形部件，例如是由硅橡胶、人造橡胶、天然橡胶等的弹性体、以极其柔软、不会因反复伸缩的变形而产生断裂等情况的材料形成的。

如图2以及图3所示，变形部件32在其上端的开口周缘部一体

地具有凸缘部 32a，该凸缘部 32a 载置、抵接在壳体 31 的上端开口的周缘部上。

在壳体 31 的上端开口的外缘部，形成有外螺纹部等的装拆机构 34，通过螺纹旋入盖部件 35 的下侧内周 35a 等方法，盖部件 35 能够相对于壳体 31 装拆（参照图 2）。

在盖部件 35 的内侧，在其下端设置有较低地向下方突出的肋 37。

由此，在盖部件 35 通过螺纹旋入而相对于壳体 31 完成安装的图 2 的状态下，由于该变形部件 32 的凸缘部 32a 以紧密接触的方式被夹在壳体 31 的开口周缘部的上表面与盖部件 35 的下表面之间，因而变形部件 32 的内侧成为气密的状态。

而且，在盖部件 35 的上端，在本实施方式的情况下，具有向横向略微突出的安装部 38，通过将其插入图 1 所示的可挠性的管 43 的端部，能够与该管 43 实现装拆，在图 2 的状态下，管 43 经由盖部件 35 与变形部件 32 的内侧空间连通。因此，该空间经由管 43 成为与后述的压力改变机构连通的二次侧的空间。

该二次侧的空间通过变形部件 32 与一次侧的空间即密闭空间 29 液密地分离，该一次侧的空间包括经由从图 2 的吸奶部 22 的通气路 23 连续的小室 26a 而连通的通气路 27、以及经由后述的装拆机构 33 连接的壳体 31 的内部。也就是说，以气体或液体都完全不会漏出的方式气密且液密地实现密封。

而且，如图 2 以及图 3 所示，在壳体 31 的下端，平坦的底部 39 的中央部较细地向下方垂直突出，形成有内部为空洞的筒状的作为上述装拆机构的管状突出部 33。该管状突出部 33 优选随着趋向前端其外径逐渐变细。

与此相应地，在图 2 所说明的主体 21 的接触面部 18 的中心附近，形成有筒状连接部 28。如图所示，该筒状连接部 28 向瓶 47 垂直地延伸并与小室 26a 连通。而且，通过使筒状连接部 28 的内径比壳体 31 的管状突出部 33 的外径略大，当该管状突出部 33 被插入时，

筒状连接部 28 的内径与其以紧密接触的方式外接，在该状态下能够保持气密状态。

图 2 表示了如上述这样、将管状突出部 33 嵌入筒状连接部 28 中的状态，另外，在盖部件 35 被安装到壳体 31 上的状态下，盖部件 35 的卡定机构 36 卡定于支承机构 15，从而稳定地维持壳体 31 的安装状态。

即，盖部件 35 的外周缘部横向延长，形成由收容支承机构 15 的上端的凹部等构成的卡定机构 36。

由此，在通过螺纹旋入等方法将盖部件 35 安装在收容了变形部件 32 的壳体 31 的上端的状态下，与将该壳体 31 的管状突出部 33 嵌入筒状连接部 28 同时地，通过使支承机构 15 的前端收容到盖部件 35 的卡定机构 36 中，由此，不但能够简单地进行安装，还能够通过安装部和卡定部这两点进行支承，从而稳定地保持安装状态。

以下说明作为压力改变机构的泵单元 51。

图 1 中表示了泵单元 51 的概略立体图。

如图 1 所说明的那样，泵单元 51 通过可挠性的管 43 与吸奶单元 50 连接。泵单元 51 作为真空泵，当后述的开关被打开时，能够将吸奶单元 50 的二次侧的空间即压力传递部 30 的壳体 31 内以及与其连通的空间吸成负压。在此情况下，根据后述的构造，能够以脉动状态实现负压形成。即，能够进行如下的脉动压力变动：使压力变动而连续地进行从负压状态至少到大气压状态的变动。

在图 1 中，在泵单元 51 的箱体 52 上露出有：将泵单元 51 的驱动打开、关闭的开关（按钮）54；用于调整负压形成过程中的脉动的周期的循环按钮 55；用于调整负压压力的旋钮 53。另外，在泵单元 52 上还安装有可挠性的管 43。

参照图 4 至图 6。

在泵单元 51 的箱体 52 的内侧，收容有电机部 70、气缸部 60、压力调整部 90 等。

电机部 70 具有电机 72 和该电机 72 的电机轴结合于其上的齿轮

单元 73。电机 72 在本实施方式中使用直流电机。

齿轮单元 73 中，延伸有使电机轴的旋转适当减速而进行传递的驱动轴 74，该驱动轴 74 与偏心凸轮 63 连接。偏心凸轮 63 的凸轮轴与气缸部 60 的活塞杆连接，驱动轴 74 的旋转运动被转换成活塞杆的往复运动。

即，气缸部 60 具有气缸 62，在该气缸 62 内，以能够进退的方式插入活塞杆 67。在活塞杆 67 的活塞头上安装有其间夹有垫片 66 的两个活塞环 64a、64b，利用固定板 65 将其用螺丝固定。

在气缸 62 内部，连通有吸引管 85、排气管 86、压力调整管 87。由此，通过活塞杆 67 进行往复运动，借助规定的阀驱动，在气缸 62 内形成负压，该负压经由吸引管 85 进行传递。

在此，通过适当地选择活塞环 64a、64b 的材质，能够降低活塞杆 67 在气缸 62 内的滑动阻力，减少电力损耗，能够谋求节能化，并能够提高密封性。

因此，这些活塞环 64a、64b 优选由特氟隆（注册商标）、尼龙、聚甲醛等耐热性较好且滑动阻力低的材料形成，具有比气缸内径稍大的外径，并形成有活塞鳍片，随着活塞杆 67 的往复运动，该活塞鳍片与气缸 62 的内壁接触的凸缘状的外缘部能够变形。

为了谋求活塞杆 67 在气缸 62 内的滑动阻力的降低、并使密封性良好，作为活塞环 64a、64b 的材质，可以选择特氟隆（注册商标）。

但是，由于特氟隆（注册商标）无法在模具内成形，因而存在着制造成本升高的缺点。

因此，在本实施方式中，以聚甲醛的成形品来形成这些活塞环 64a、64b。由此，能够降低活塞杆 67 在气缸 62 内的滑动阻力，减少电力损耗，能够谋求节能化，并且能够提高密封性，还能够实现制造成本的降低。

排气管 86 与排气阀连接。吸引管 85 经由管安装口如图 1 所示从箱体 52 露出，与可挠性的管 43 连接，从而与吸奶单元 50 的盖部件 35 连接。压力调整管 87 与压力调整部 90 连接。

在箱体 52 内收纳有控制电路基板，该控制电路基板例如被固定支承在收纳单元中，该控制电路基板控制泵单元 51 的驱动，并连接有泵单元 51 的打开关闭开关（按钮）54 和用于调整负压形成中的脉动周期的循环按钮 55 等。

压力调整部 90 与气缸部 60 的气缸 62 连通，具有零件的收纳壳体 91。在该收纳壳体 91 内具有板 92，为了调整气缸 62 内的负压，该板 92 具有直径大的负压调整用孔和直径小的负压调整用孔。通过使该板 92 旋转来进行板 92 的这些孔的切换。板 92 通过衬垫 93 和垫块 94 被固定在按钮 53 上。

本实施方式的吸奶器 20 如上所述地构成，在图 1 中，操作泵单元 51 打开关闭开关按钮 54，起动该泵单元 51 时，电机 72 旋转，驱动轴 74 经由齿轮单元 73 旋转，该旋转运动经由偏心凸轮 63 被转换成气缸 62 内的活塞杆 67 的往复运动。通过活塞杆的往复运动，气缸 62 内形成的负压脉动变化，经由吸引管 85 以及可挠性的管 43 被传递到图示的吸奶单元 50 的压力传递部 30。

由此，在图 2 中，壳体 31 内的变形部件 32 内部的气压降低。因此，在壳体 31 内，由于与变形部件 32 的外侧的空间之间的气压差，变形部件 32 的内部空间以被压溃的方式变形，其底部上升、接近盖部件 35 侧。即，由于变形部 32 在壳体 31 内大幅度地减小体积，所以与变形部件 32 的外侧的壳体 31 的空间连通的密闭空间 29 内，气压大幅度地减小。

即，由于在密闭空间 29 内负压增大，因而母乳被从乳房吸引，被吸取出的母乳通过通气路 23 内，流入小室 26a。而且，此时，伴随着压力差，吸奶口变形部件 13 的凸状刺激部 14 向乳房侧变形，推压乳房进行刺激，因而能够进一步促进母乳的分泌。

接着，当基于泵单元 51 的气缸杆 67 的往复动作，负压状态被解除时，再次如图 2 所示地，变形部件 32 以恢复其形态的方式变位。由此，在壳体 31 内，当由于变形部件 32 使体积增大而使密闭空间内的气压升高时，母乳的吸引压降低。

通过重复进行以上动作，作为压力改变机构的泵单元 51 的动作通过压力传递部 30 的变形部件 32 的动作被传递至密闭空间 29，从而密闭空间 29 的负压被增减，由此，实现与婴儿的哺乳动作接近的状态，能够使吸取出的母乳贮存在瓶 47 中。

另外，在此，在上述动作中，当经由管 43 作用负压时，变形部件 32 以向盖部件 35 侧贴靠的方式收缩变形。此时，虽然收缩变形了的变形部件 32 欲贴靠盖部件 35 侧，但由于肋 37 的存在，能够阻止其完全地贴靠。

而且，压力传递部 30 具有上端经由盖部件 35 与泵单元 51 连接的壳体 31，在该壳体 31 的下端具有装拆机构 33，该装拆机构 33 用于将该壳体 31 内和密闭空间 29 以能够连通的方式装拆。由此，例如，能够容易地对收容有变形部件 32 的壳体 31 进行装拆，并能够使其与密闭空间 29 侧分离，不仅便于携带、移动，尤其在清洗时等，能够容易地仅对需要频繁清洗的一次侧即密闭空间 29 侧进行分离、清洗。

这样，能够容易地对与吸奶空间连通的母乳所通过的密闭空间 29 即一次侧和与压力改变机构即泵单元 51 侧连接的壳体 31 的侧即二次侧进行装拆，能够使清扫等的操作变得极其容易。

另外，由于压力传递部 30 将形成于吸奶部 22 的密闭空间和泵等的压力改变机构完全液密且气密地分离，所以能够有效地防止滞留在密闭空间侧即小室 26a 等的母乳或成为雾状的母乳回流到泵单元 51。因此，能够有效地防止泵单元 51 等的压力改变机构侧接触到母乳而发生腐蚀、破损以及被污染成为不卫生的状态。

另外，在本实施方式中，壳体 31 是内部收容有变形部件 32 的筒状体，在该筒状体上具有作为装拆机构的管状突出部 33。

而且，在密闭空间 29 中，具有在该密闭空间 29 内延伸的筒状连接部 28，通过使筒状连接部 28 的内径比管状突出部 33 的外径稍大，从而成为将管状突出部 33 插入筒状连接部 28、壳体 31 和密闭空间 29 气密地接合的结构。

由此，通过仅将管状突出部 33 插入筒状连接部 28 这一简单的操作，就能够将泵单元 51 侧和密闭空间 29 侧连接。

而且，如上所述，壳体 31 的管状突出部 33 的周边为平坦的底部，在主体 21 的筒状连接部 28 的开口周边形成有平坦的接触面部 18。因此，只要将管状突出部 33 插入筒状连接部 28、将壳体 31 的平坦的底部压入到与平坦的接触面部 18 抵接的位置，便能够极其容易地以气密状态将壳体 31 和密闭空间 29 接合。

而且，上述筒状连接部 28 是如图 2 所示、在载置瓶 47 的状态下向瓶 47 下方大致垂直延伸而形成的，管状突出部 33 以向前端逐渐变细的方式形成。

因此，只通过将管状突出部 33 向下插入筒状连接部 28，由于前端细而插入容易，并且当插入得较深时，随着该管状突出部 33 的外径扩大，该管状突出部 33 能够与筒状连接部 28 的内表面紧密地接触、实现嵌合，能够极其容易地接合。

而且，在本实施方式中，具有盖部件 35，该盖部件 35 覆盖收纳变形部 32 的壳体 31 的上端侧，并且，与作为压力改变机构的负压形成机构即管单元 51 连接的管 43 能够相对于该盖部件 35 装拆。

而且，在壳体 31 和密闭空间 29 被接合的状态下，在将盖部件 35 安装到壳体 31 的上端侧的位置上，具有用于将盖部件 35 相对于主体 21 的密闭空间 29 侧进行卡定的卡定机构 36，因此，壳体 31 的相对于密闭空间 29 侧的接合状态被稳定地支承，不会轻易脱落。

而且，在本实施方式中，图 3 的卡定机构 36 设置在盖部件 35 的周缘部上。该卡定机构 36 是如图 2 所说明的那样、相对于从主体 21 侧向上方突出的支承机构 15 被卡定的结构。

由此，在与管状突出部 33 和筒状连接部 28 的接合位置不同的位置进行该卡定，能够更稳定地维持接合状态。

图 7 及图 8 表示设置在盖部件上的卡定机构的变形例。

图 7 表示第一变形例，盖部件的结构与图 3 的情况稍有不同。

在该例中，盖部件 35-1 的外缘具有向下方延长的一对脚片 36-1、

36-1，该脚片 36-1、36-1 能够根据规定的弹性向相互接近、远离的方向变形。在各脚片 36-1、36-1 的下端附近形成有钩状的卡定部 45、45。

因此，如图 7 的下部所示，当使盖部件 35-1 相对于壳体 31 从上方下降进行覆盖时，各脚片 36-1、36-1 与接触面部 18 的凸缘部 19 接触，通过略微打开各脚片 36-1、36-1 便能够越过凸缘部 19 的外缘，该凸缘部 19 进入各脚片 36-1、36-1 的卡定部 45、45 而被卡定。

图 8 表示第二变形例，盖部件的结构与图 3 的情况稍有不同。

在该例中，在盖部件 35-2 上不仅形成有与图 3 的盖部件 35 相同的卡定机构 36，而且其相反侧的端部外缘向下方延长，形成有脚片 36-2。在该脚片 36-2 的下端部形成有钩状的卡定部 46。

由此，盖部件 35-2 通过卡定部 46 在卡定在凸缘部 19 上的同时，相对于支承机构 15 也被卡定。

这样，根据各变形例，在与管状突出部和筒状连接部的接合位置不同的位置，通过卡定机构实现卡定，能够更稳定地维持接合状态。不仅如此，由于能够利用主体 21 的筒状连接部的开口周边所设置的接触面部 18 卡定盖部件，因而不需要在主体 21 侧形成用于卡定的特别的机构，另外，还能够相应地谋求小型化。

图 9 表示第二实施方式的主要部位，图示的结构以外的结构与第一实施方式相同，因此以下以不同点为中心进行说明。

在图 9（a）中，壳体 31 能够相对于吸奶单元 50-1 的主体 21 装拆。该壳体 31 的下端部如图 9（b）所示，成为在径向上鼓出的凸缘状的卡定机构 41。

即，该卡定机构 41 具有鼓出成凸缘状的周缘向下方弯折且其前端趋向内侧的阶梯部 41b，接触面部 18 的凸缘部 19 的前端能够卡定在该阶梯部上。

如图 9（a）所示，在卡定机构 41 上，沿其圆周方向形成有多个狭缝 41a，由此，该卡定机构 41 能够弹性变形，通过如图 9（b）所示那样嵌入接触面部 18 的凸缘部 19，能够容易地变形、装拆。

本实施方式如上所述地构成，不仅能够发挥与第一实施方式相同的作用效果，即使不使用图 2 那样的支承机构 15，也能够形成用于维持壳体 31 的接合状态的卡定机构。

因此，即使省略图 2 那样的支承机构 15，也能够得到与第一实施方式同等的接合稳定性。

此外，本发明不限于上述实施方式。

例如，壳体 31 中收容的变形部件可以与壳体一体地构成，成为作为其一部分的“变形部”。

变形部不仅可以是有底圆筒体，也可以使用折皱构造等各种形态。

装拆机构即管状突出部 33 可以适当地改变成与实施方式不同的形状、构造。

此外，上述各实施方式、变形例的个别结构可以根据需要省略，或与未说明的其他结构进行组合。

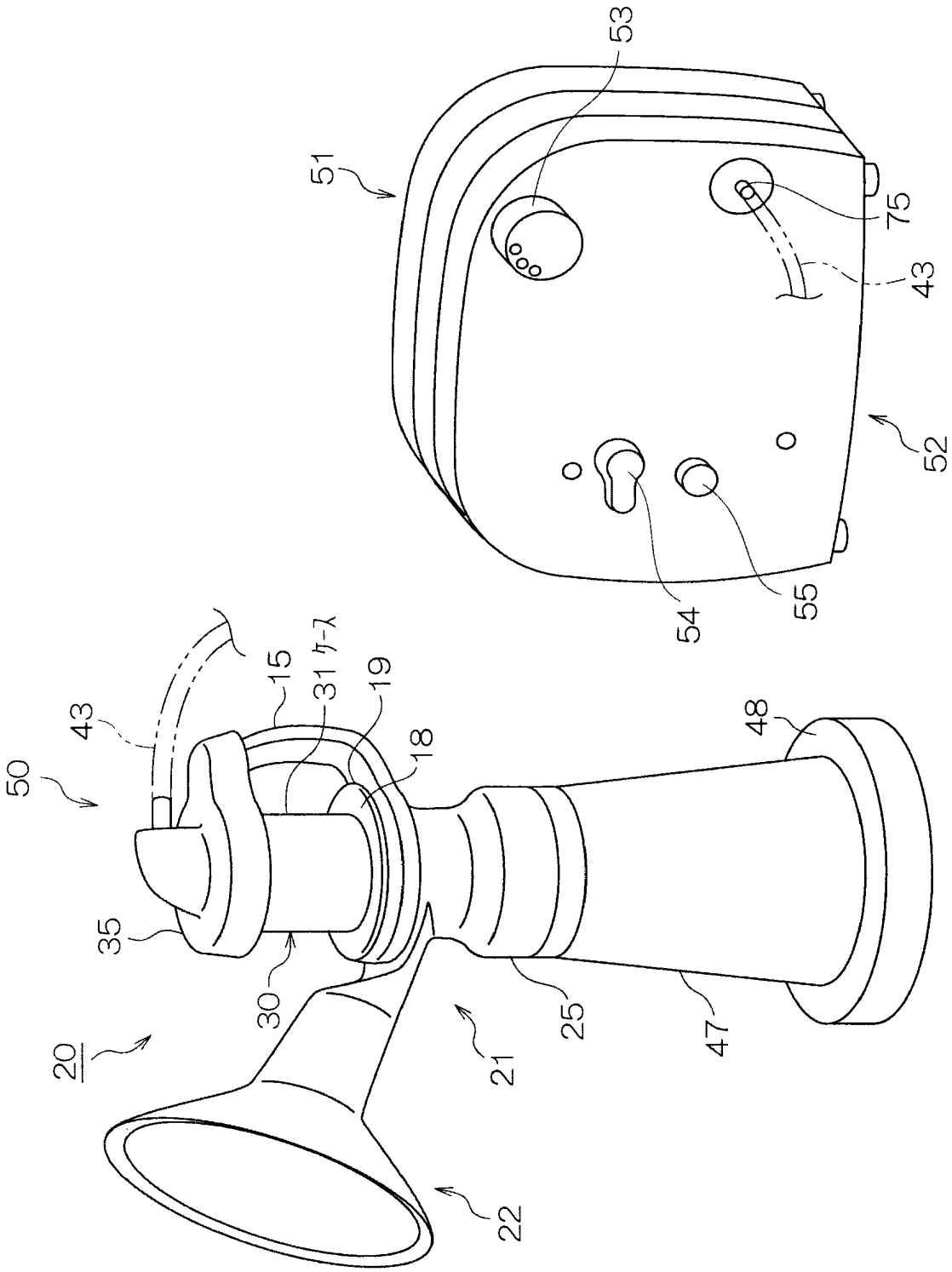
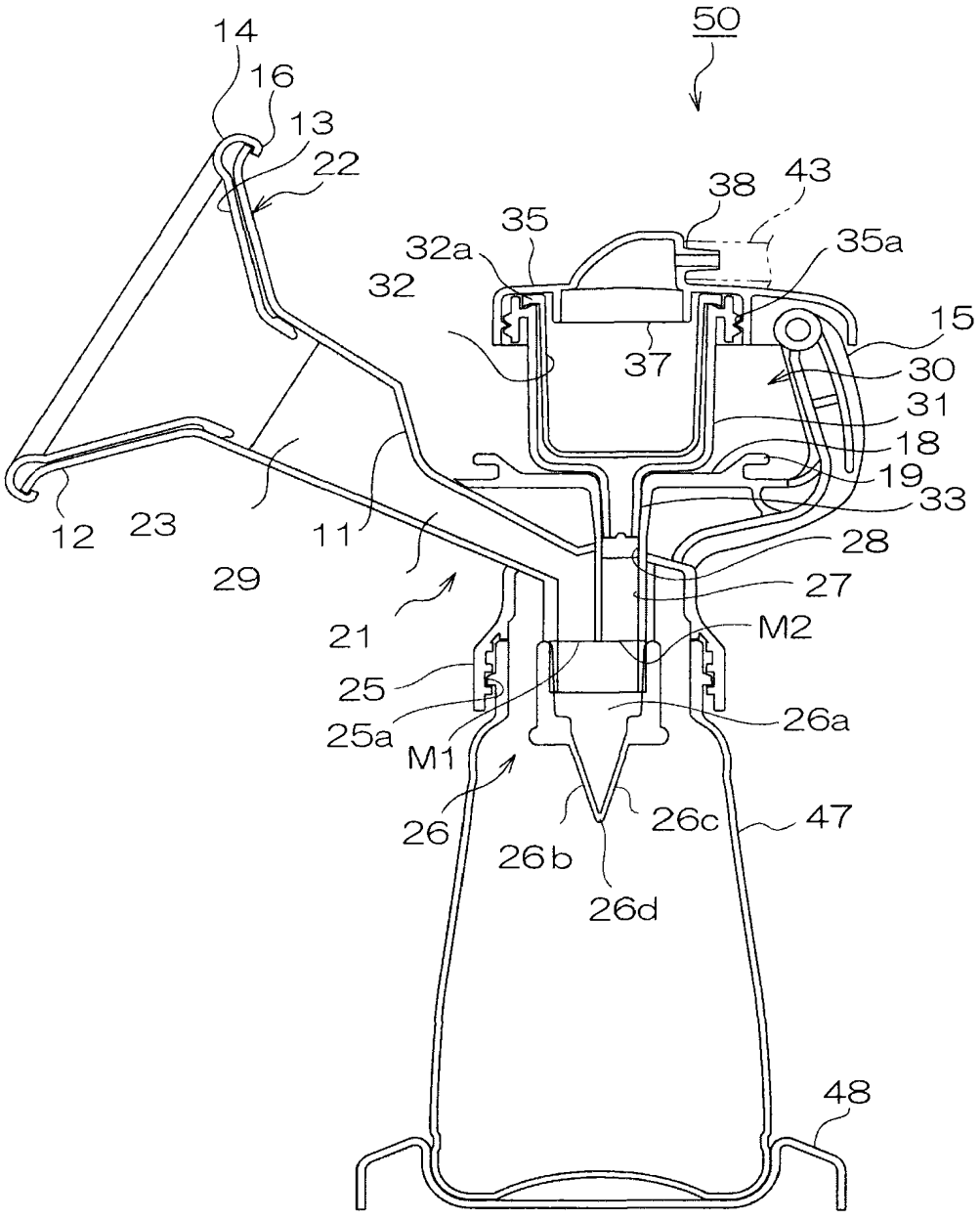


图 1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12
23
11
28
29
27
21
M2
25
26a
25a
M1
26
26c
47
26b
26d
48

图 2

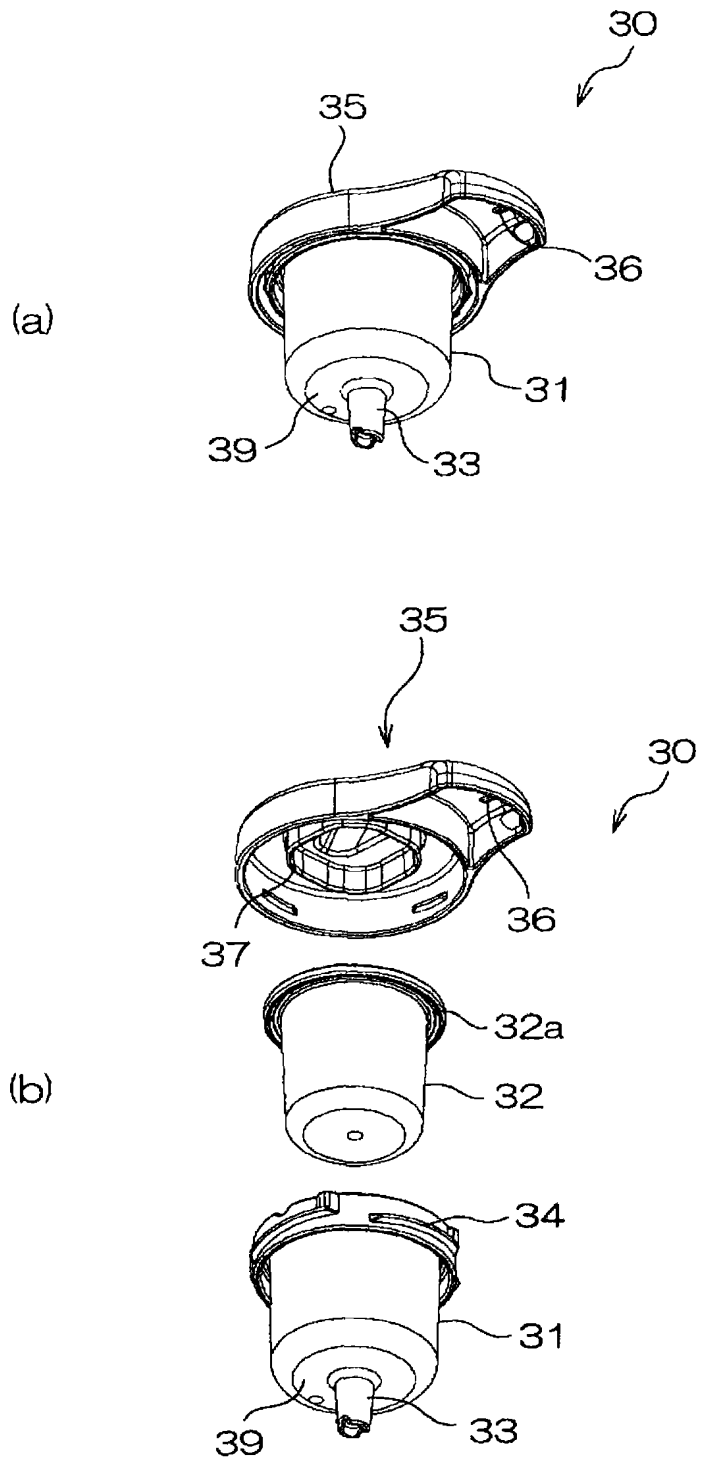


图 3

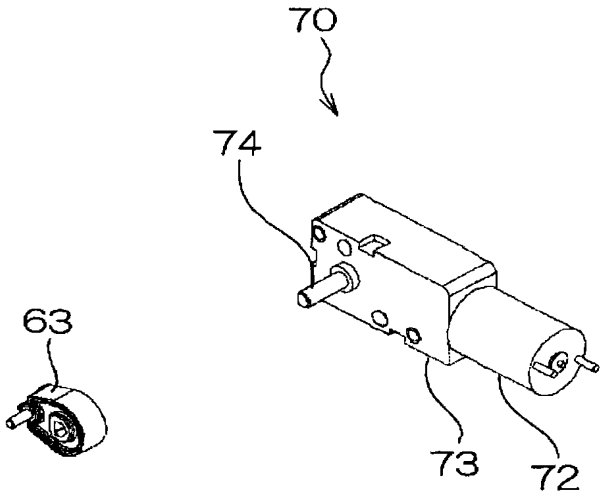


图 4

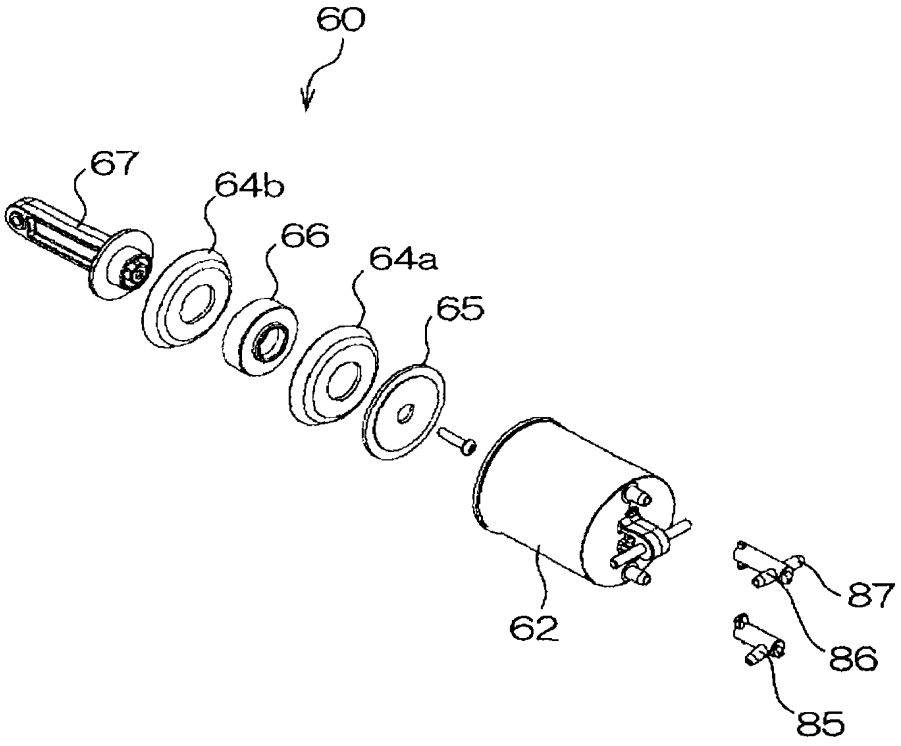


图 5

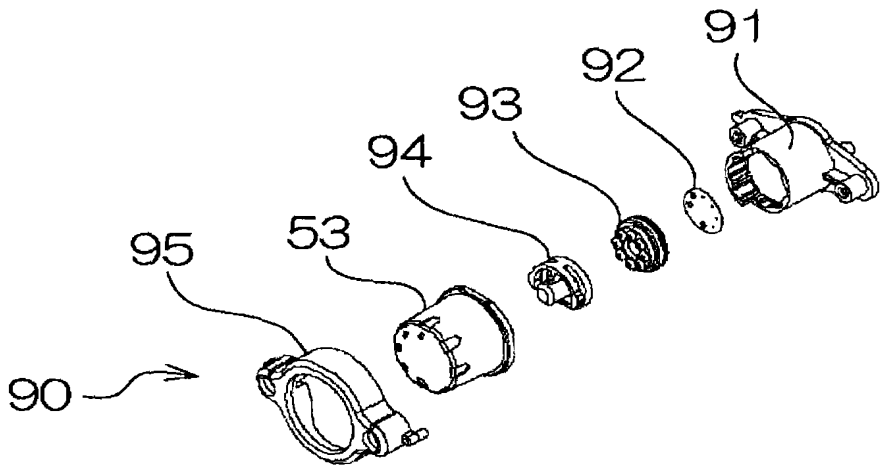


图 6

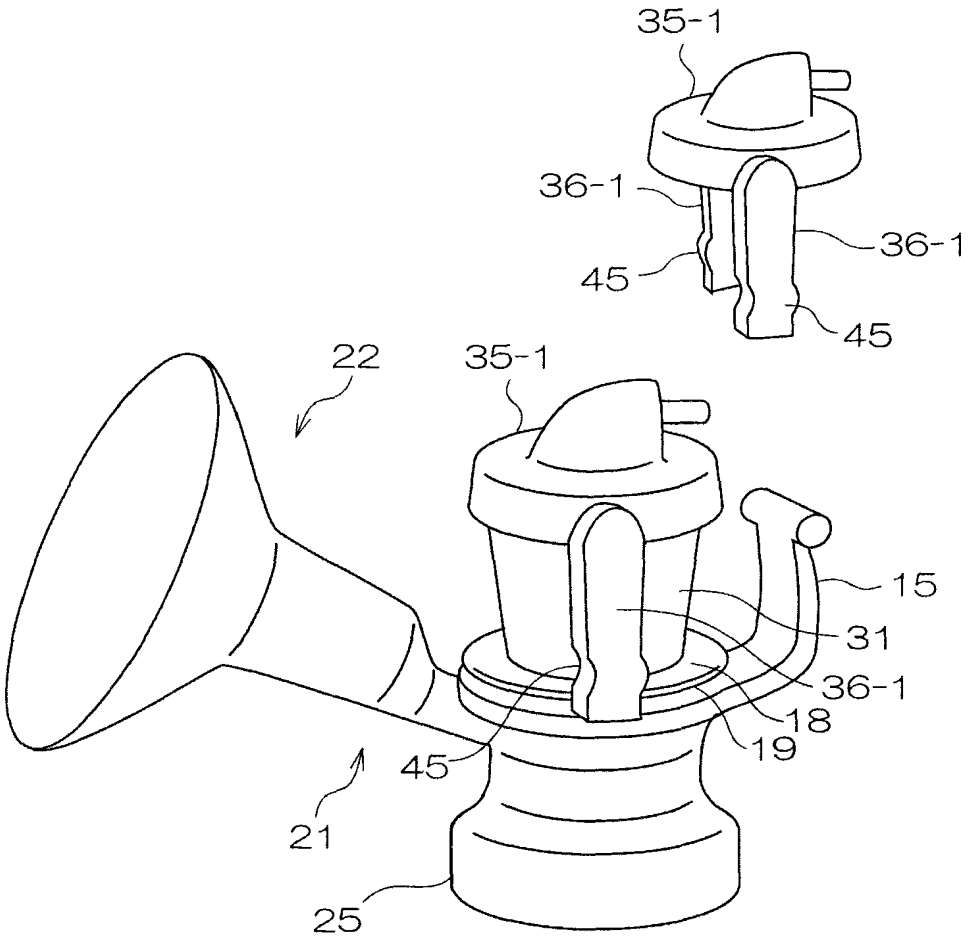


图 7

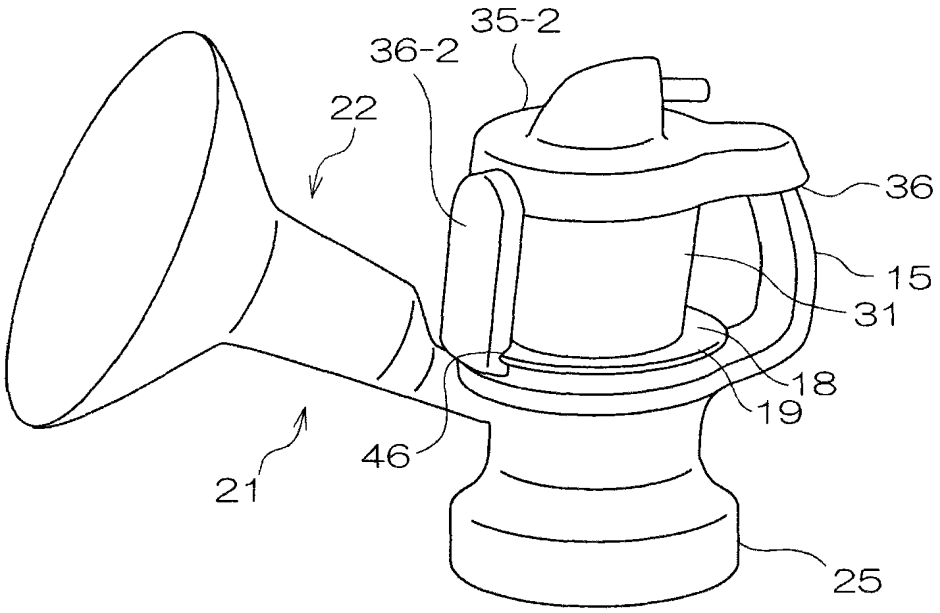
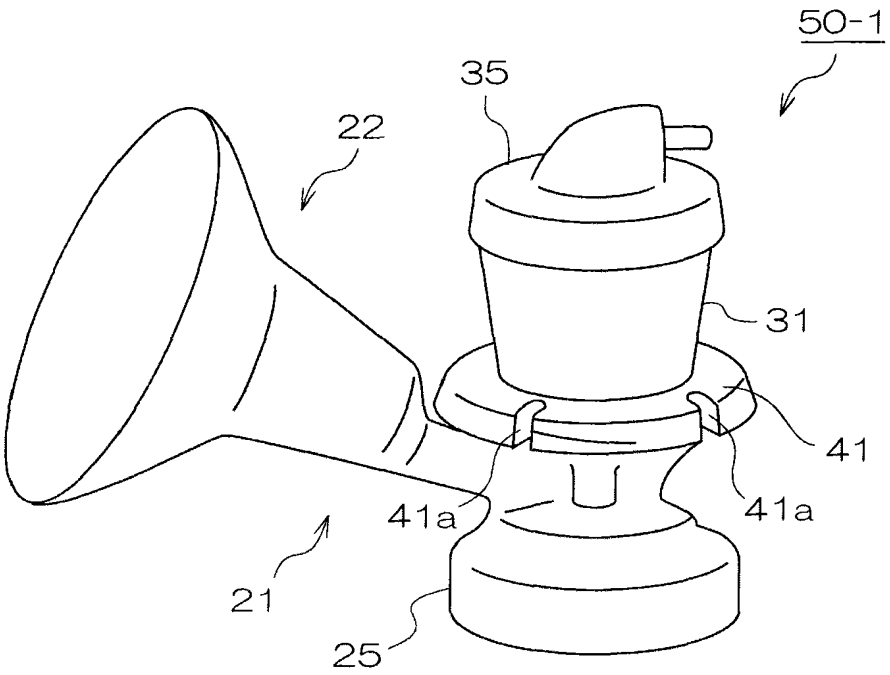


图 8

(a)



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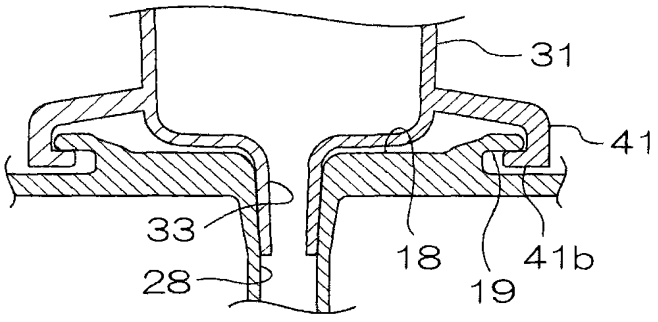

图 9

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INT CL **A61M**
Other
ONLINE: WPI, EPODOC
updated as appropriate

Additional Fields
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INT CL **A61M**
Other
ONLINE: WPI, EPODOC

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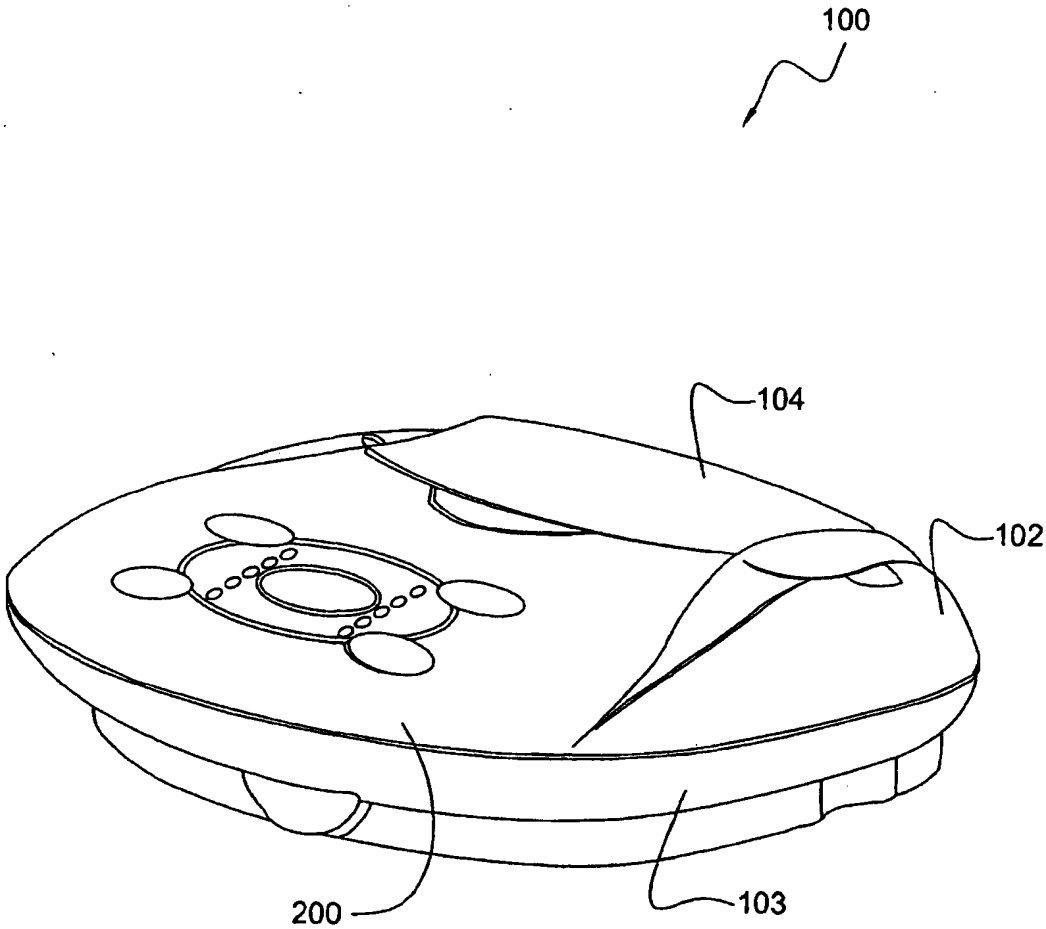


Fig. 1

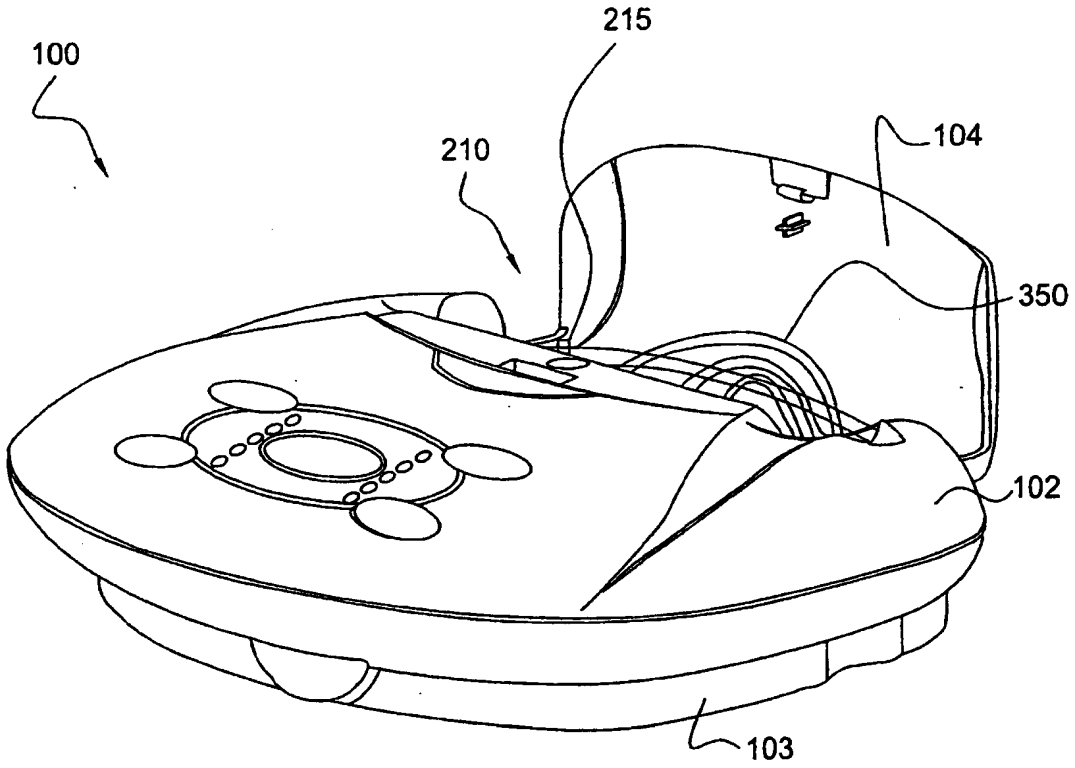
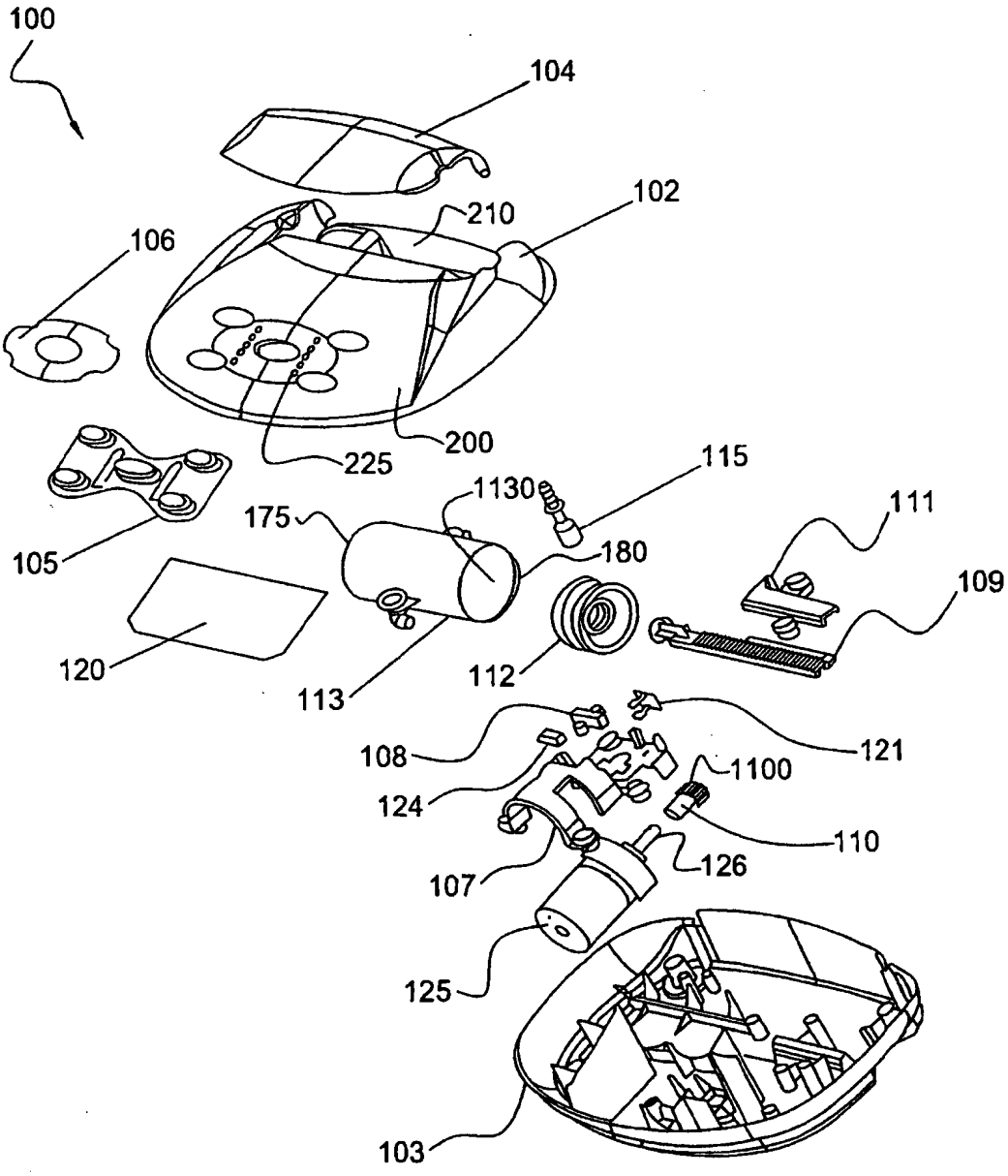


Fig. 2


100
104
102
210
106
200
225
115
1130
175
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180
105
109
120
112
113
108
121
1100
124
110
126
107
125
103

Fig. 3

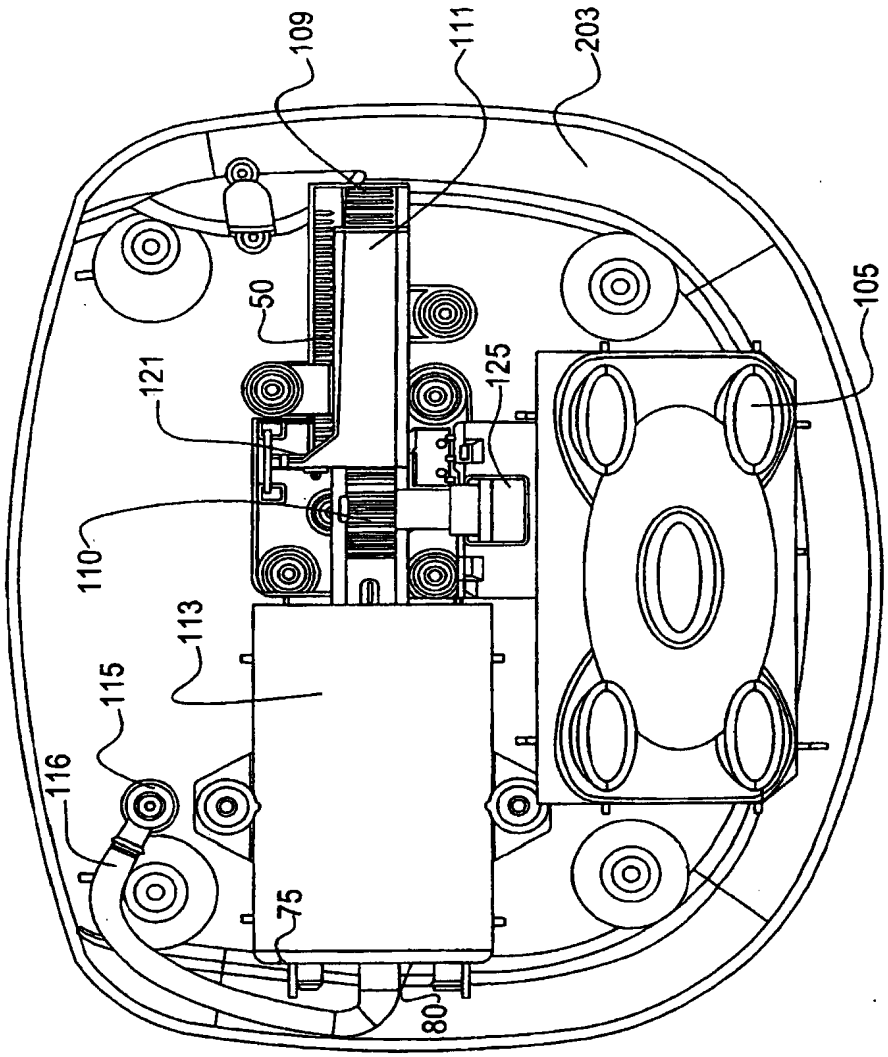


Fig. 4

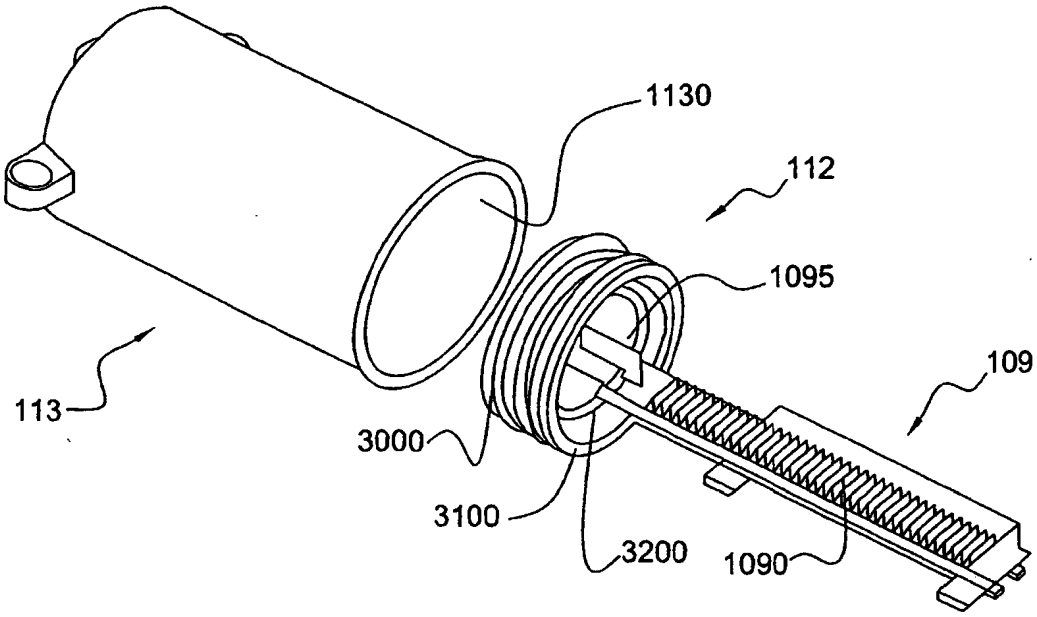

1130
112
1095
109
113
3000
3100
3200
1090

Fig. 5

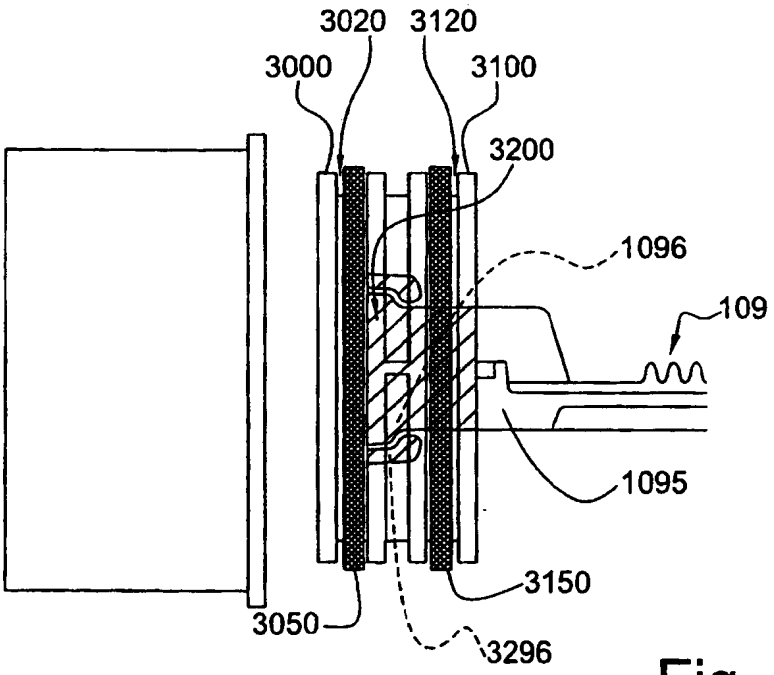

3020
3120
3000
3100
3200
1096
109
1095
3150
3050
3296

Fig. 6

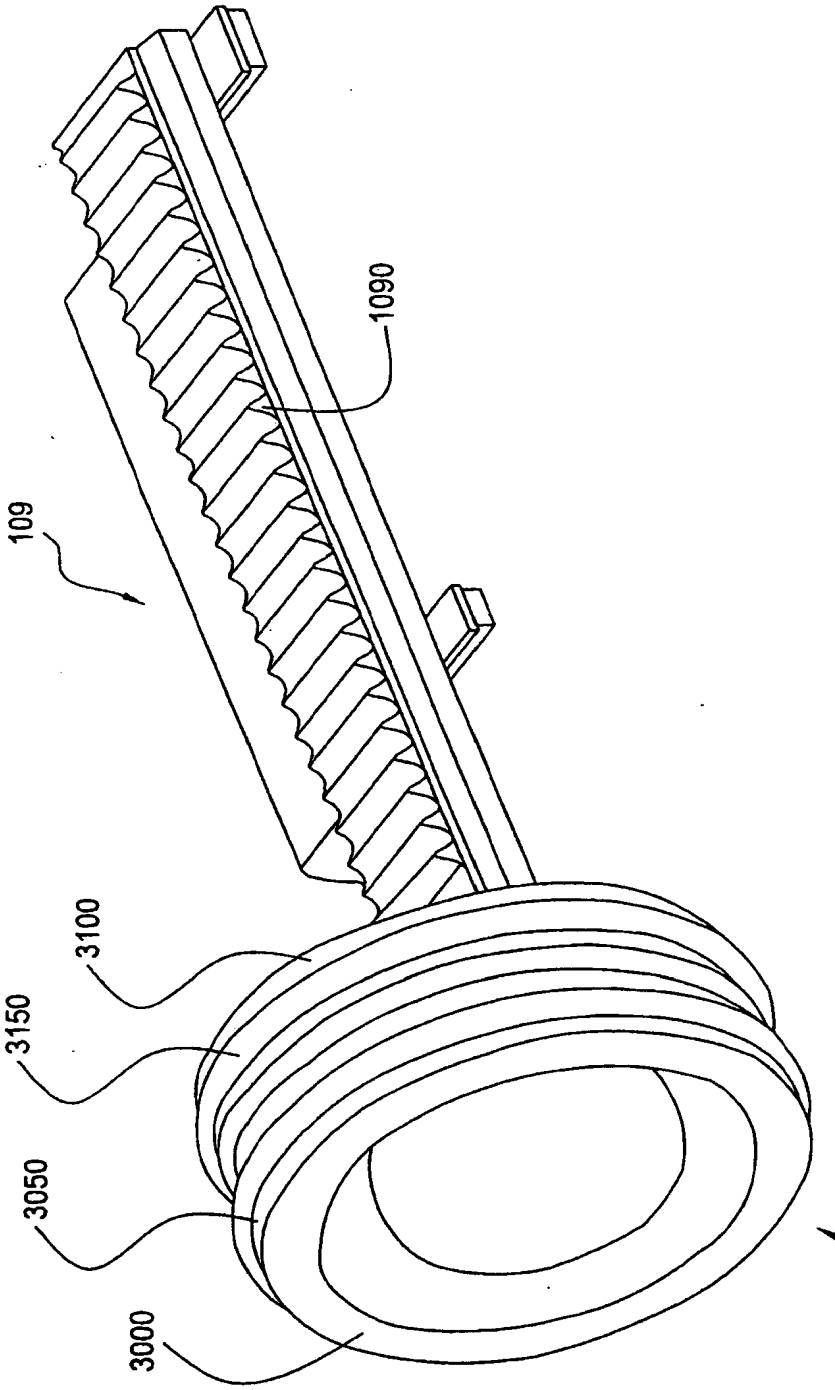


Fig. 7

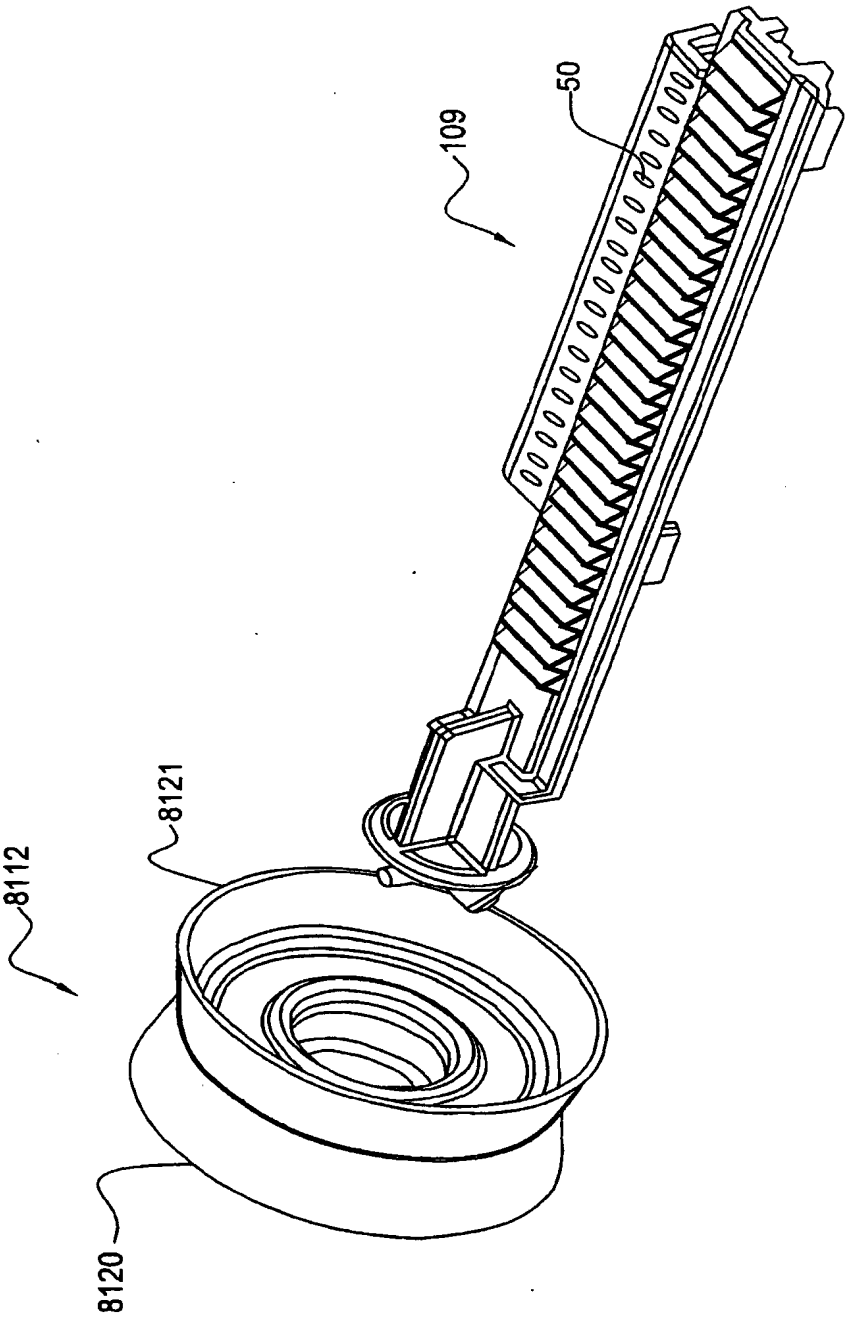
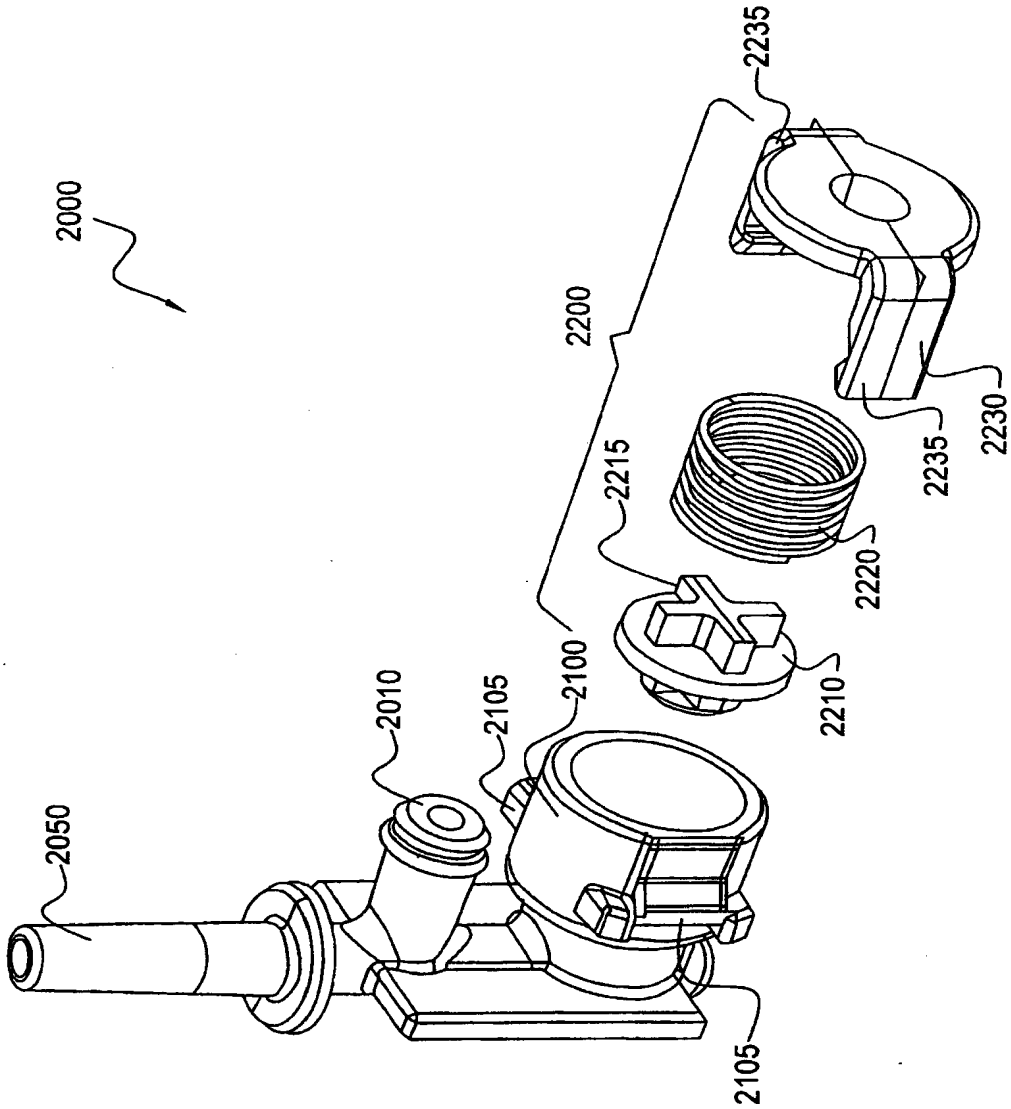


Fig. 8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2050
2010
2105
2100
2105
2200
2215
2210
2220
2235
2230
2235

Fig. 9

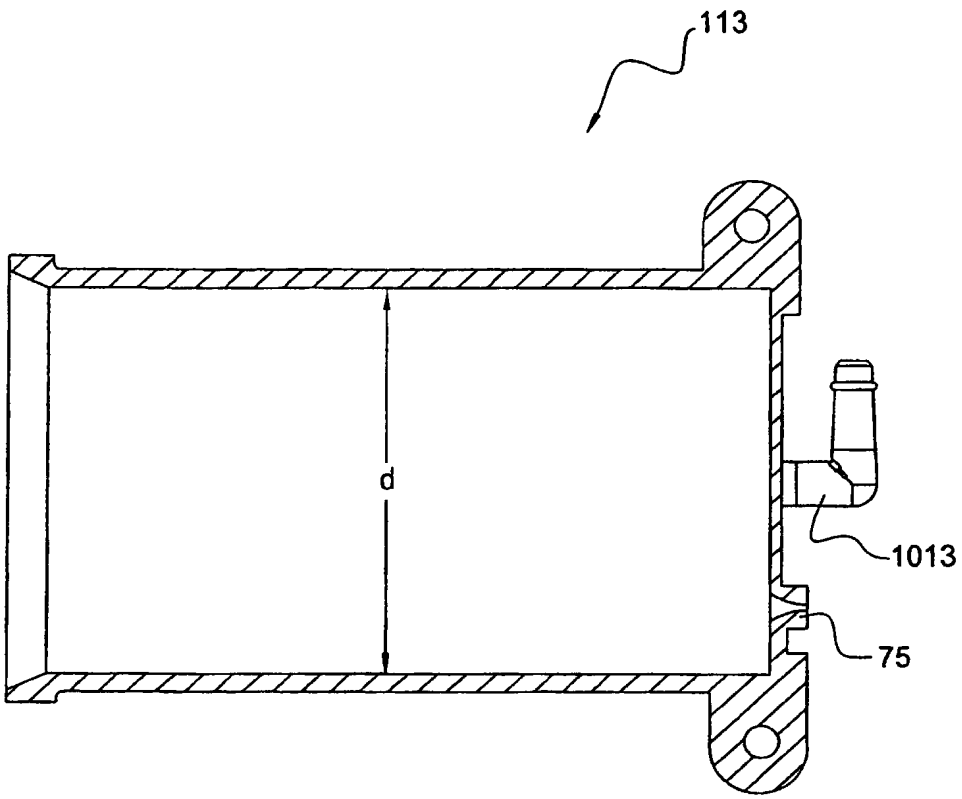


Fig. 10

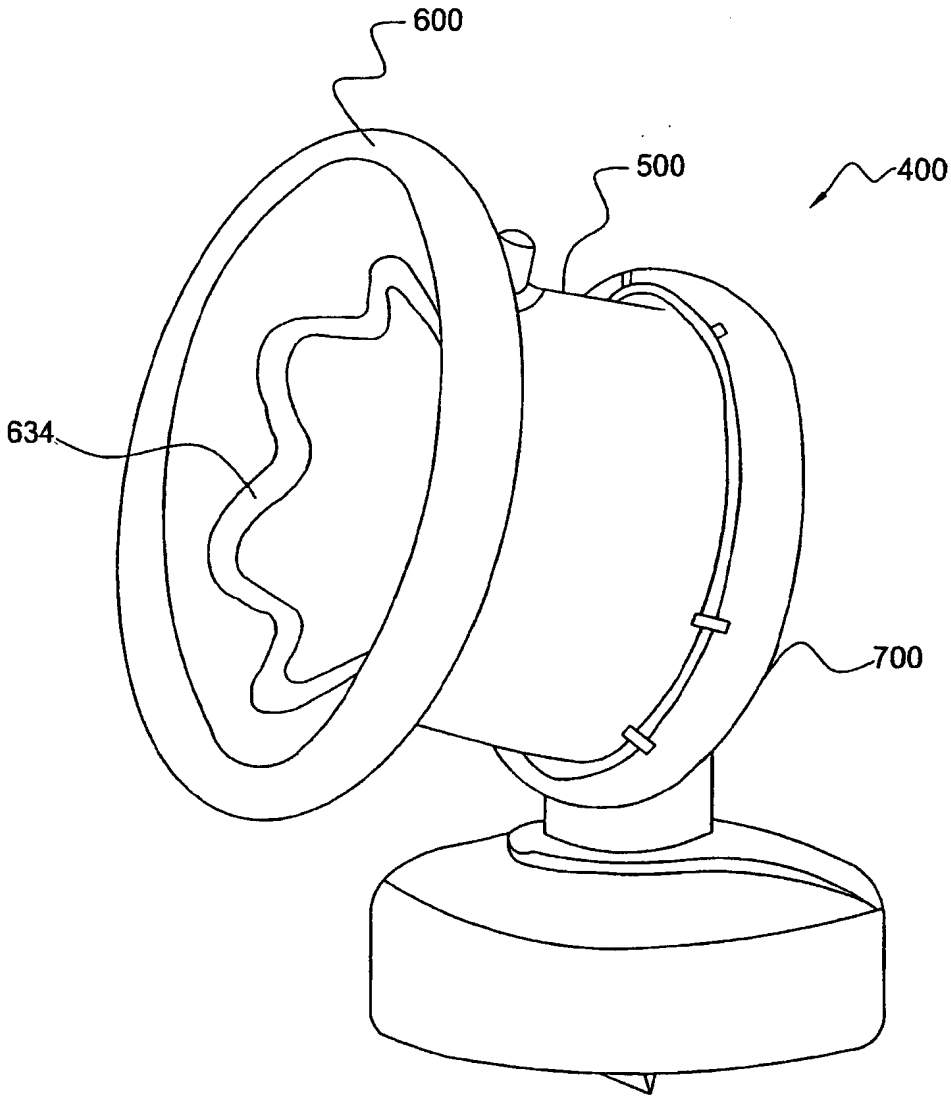


Fig. 11

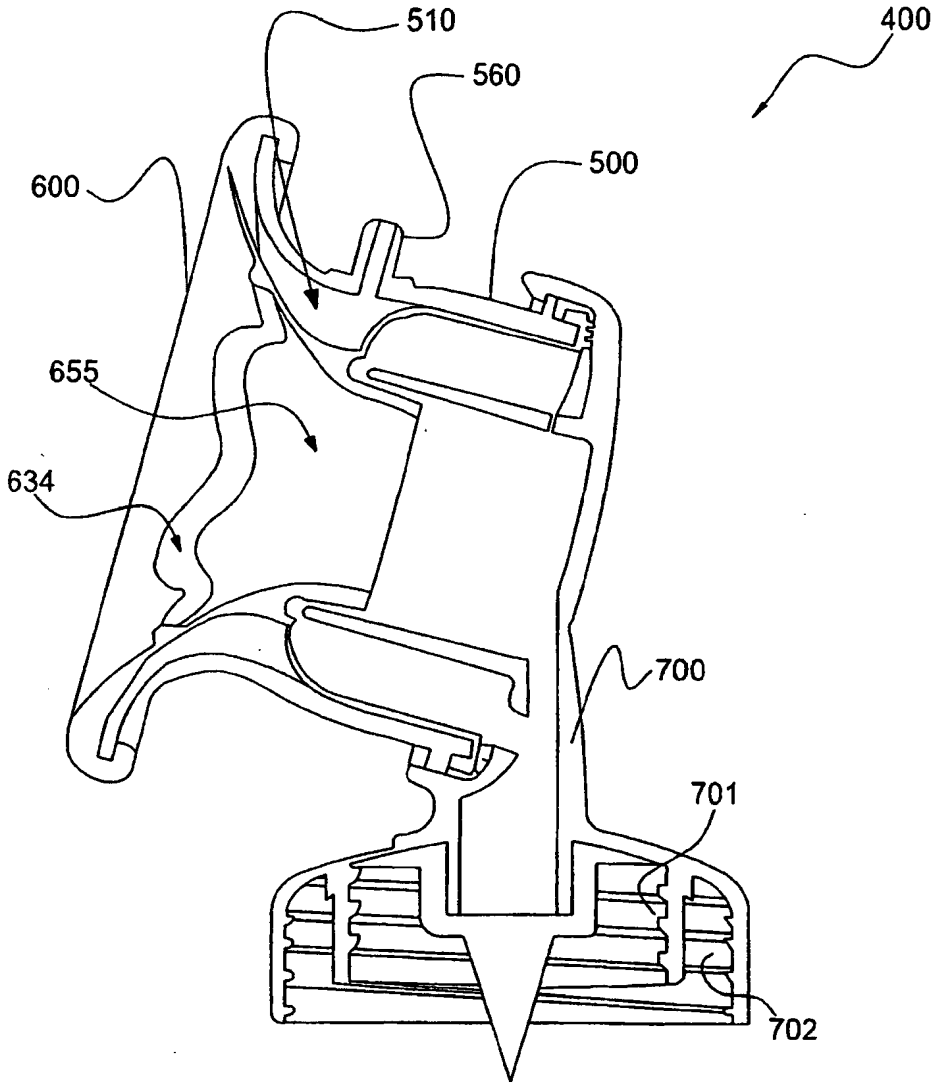


Fig. 12

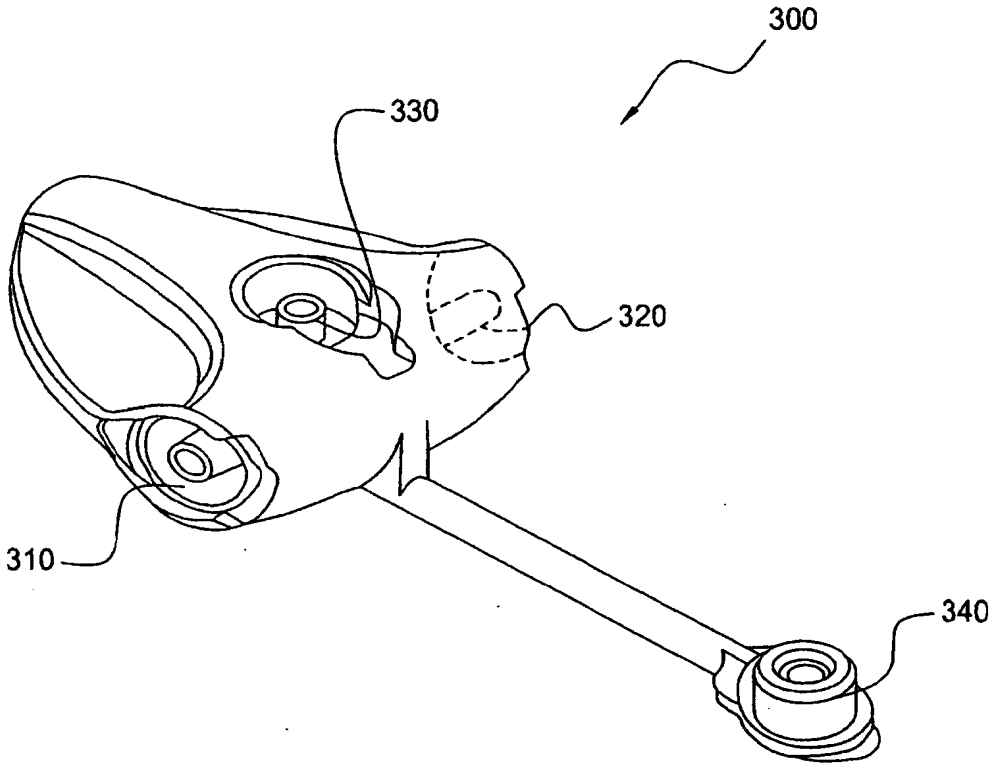


Fig. 13

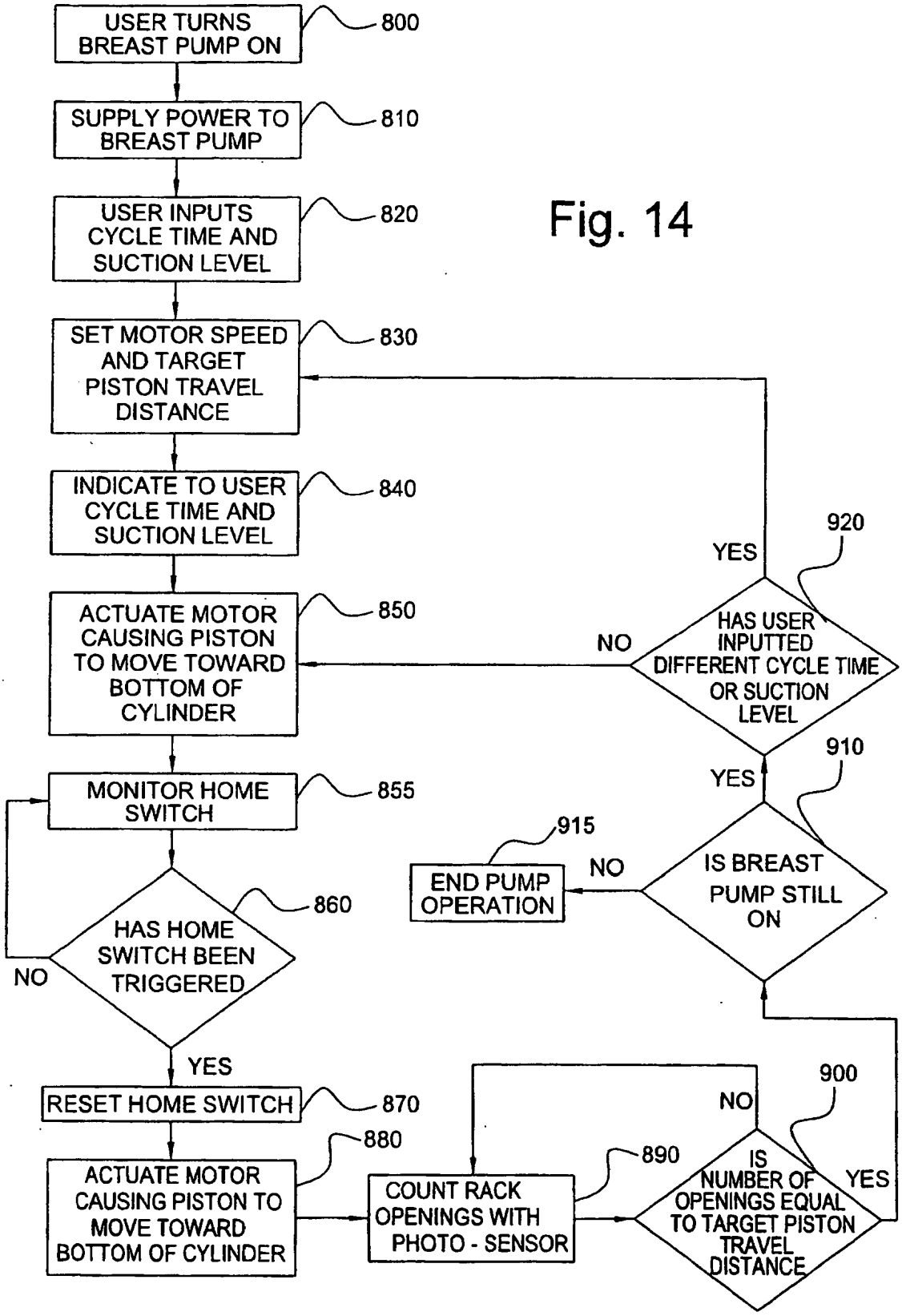

USER TURNS BREAST PUMP ON
800
SUPPLY POWER TO BREAST PUMP
810
USER INPUTS CYCLE TIME AND SUCTION LEVEL
820
SET MOTOR SPEED AND TARGET PISTON TRAVEL DISTANCE
830
INDICATE TO USER CYCLE TIME AND SUCTION LEVEL
840
ACTUATE MOTOR CAUSING PISTON TO MOVE TOWARD BOTTOM OF CYLINDER
850
MONITOR HOME SWITCH
855
HAS HOME SWITCH BEEN TRIGGERED
860
NO
YES
RESET HOME SWITCH
870
ACTUATE MOTOR CAUSING PISTON TO MOVE TOWARD BOTTOM OF CYLINDER
880
COUNT RACK OPENINGS WITH PHOTO - SENSOR
890
IS NUMBER OF OPENINGS EQUAL TO TARGET PISTON TRAVEL DISTANCE
900
NO
YES
IS BREAST PUMP STILL ON
910
NO
END PUMP OPERATION
915
HAS USER INPUTTED DIFFERENT CYCLE TIME OR SUCTION LEVEL
920
NO
YES

Fig. 14

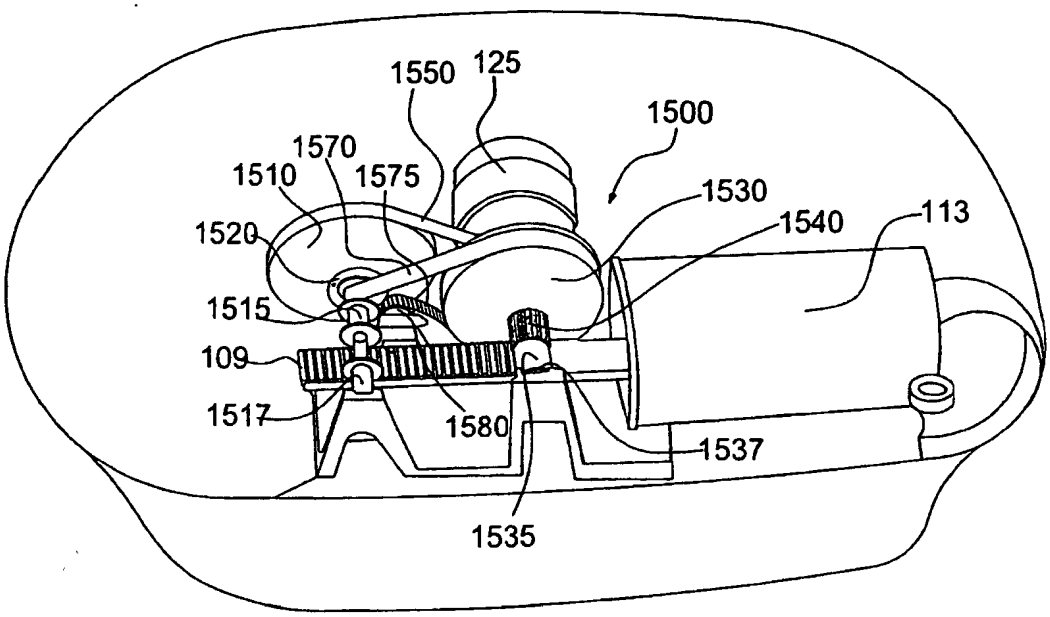

1550
125
1500
1570
1510
1575
1530
1520
1540
113
1515
109
1517
1580
1537
1535

Fig. 15

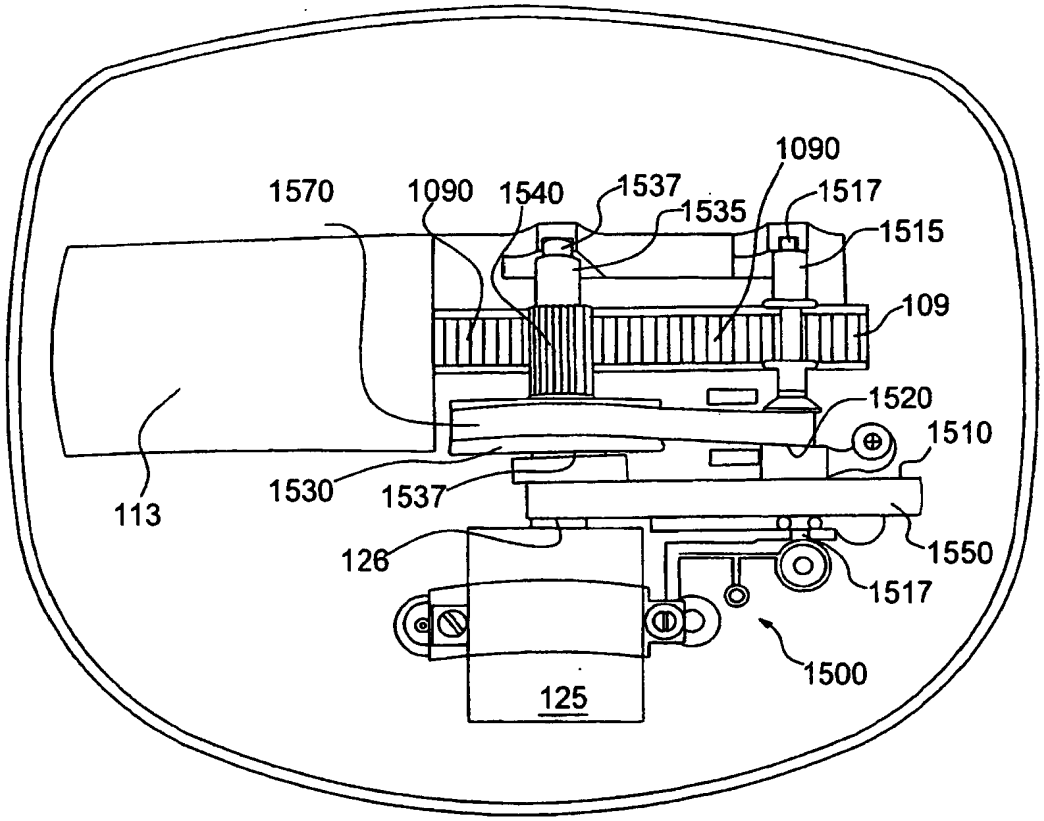

1090
1570
1090
1540
1537
1535
1517
1515
109
1520
1510
113
1530
1537
126
1550
1517
1500
125

Fig. 16

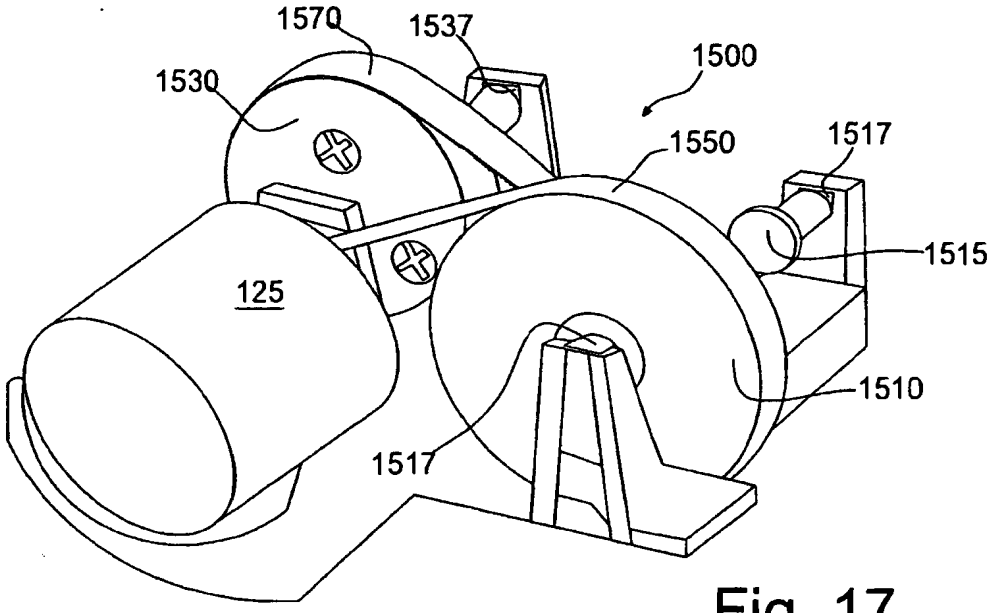
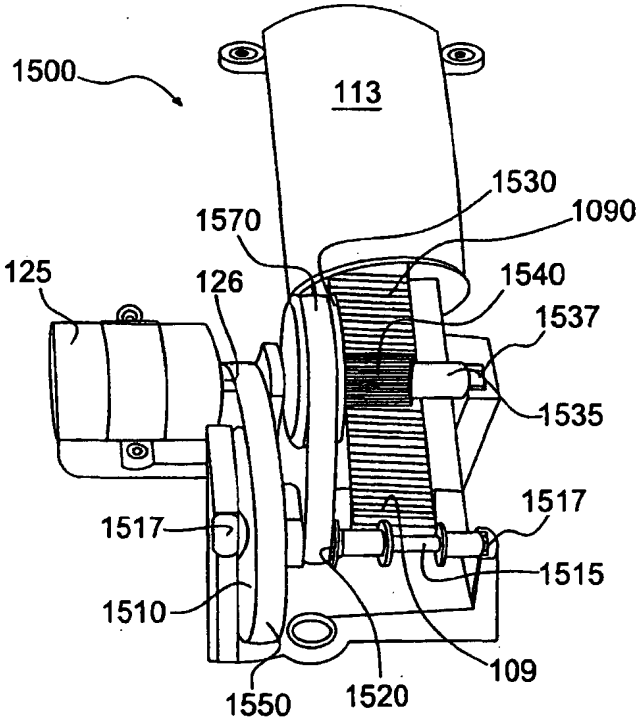

1570
1537
1530
1500
1550
1517
1515
125
1510
1517

Fig. 17


1500
113
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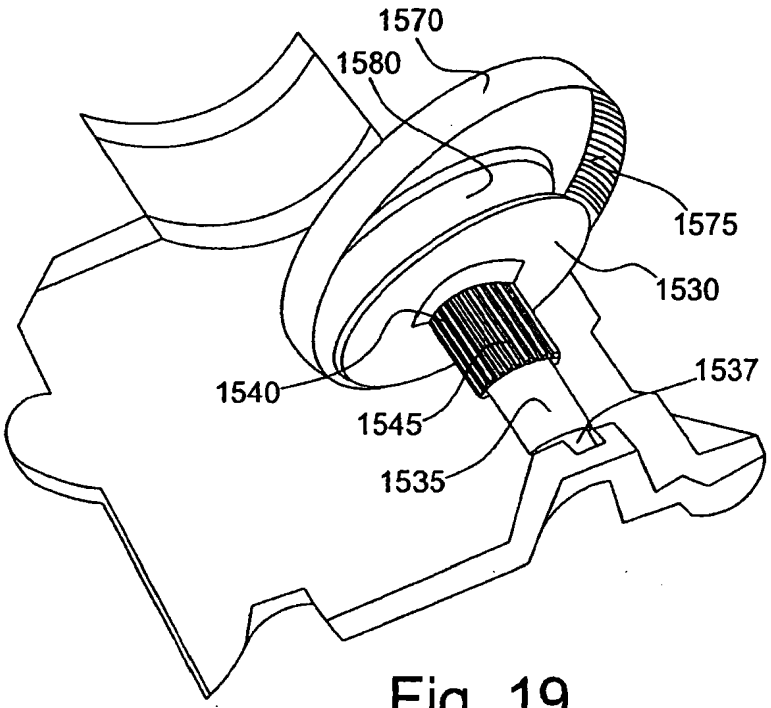
1090
1570
125
126
1540
1537
1535
1517
1517
1515
1510
109
1550
1520

Fig. 18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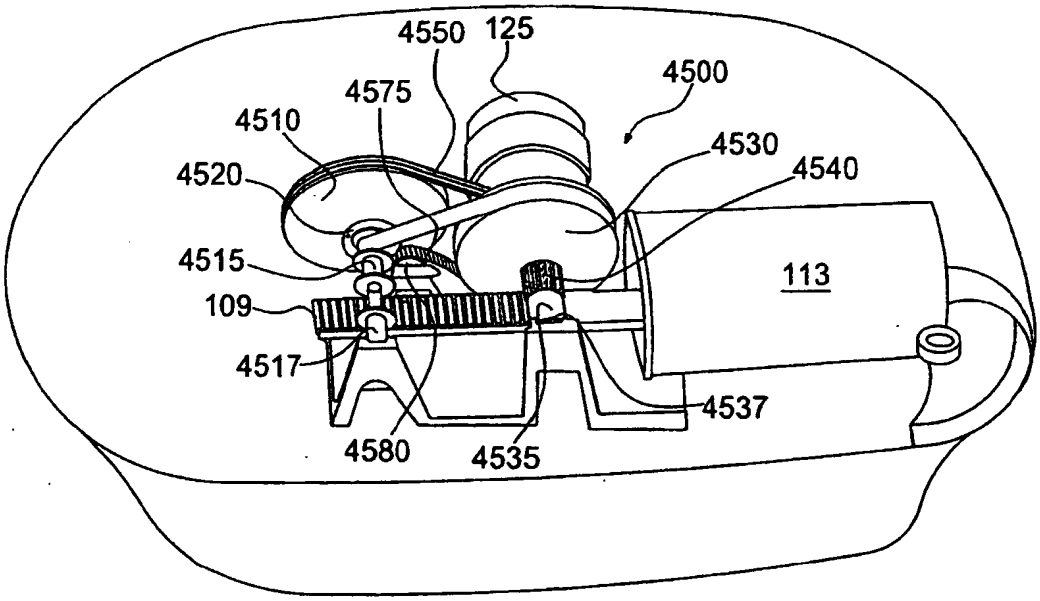
1580
1575
1530
1537
1540
1545
1535

Fig. 19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125
4500
4575
4510
4530
4520
4540
4515
113
109
4517
4537
4580
4535

Fig. 20

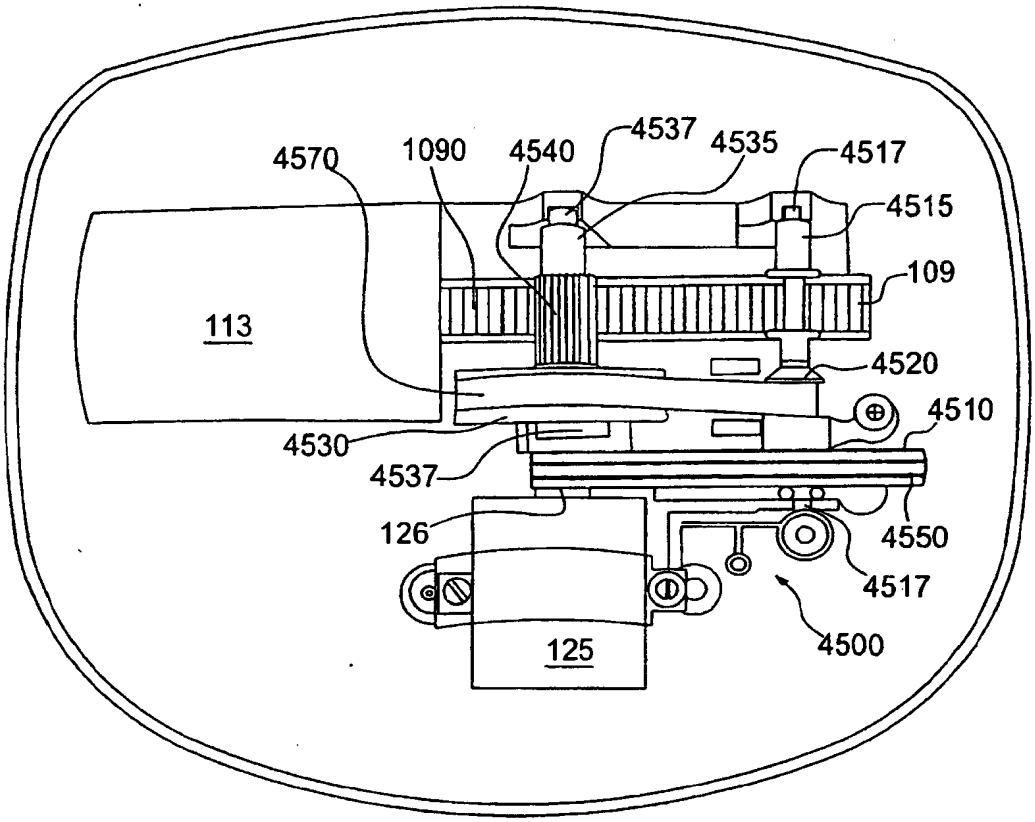

4570
1090
4540
4537
4535
4517
4515
109
113
4520
4510
4530
4537
126
4550
4517
4500
125

Fig. 21

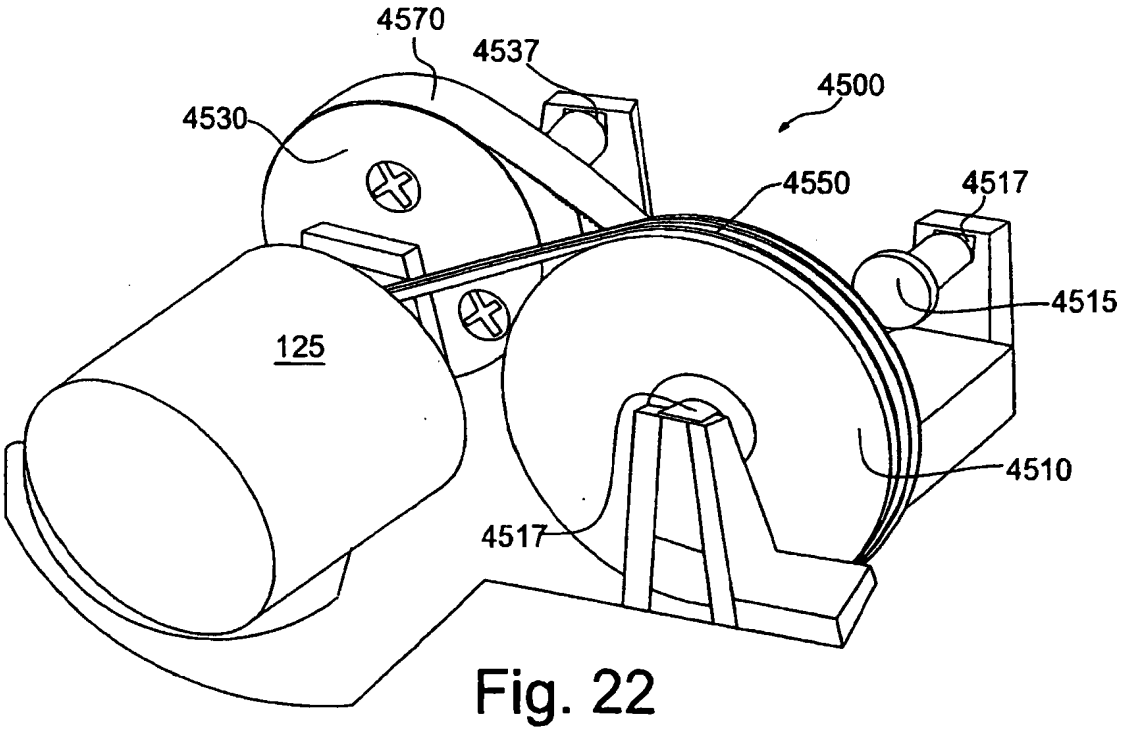

4570
4537
4500
4530
4550
4517
4515
125
4510
4517

Fig. 22

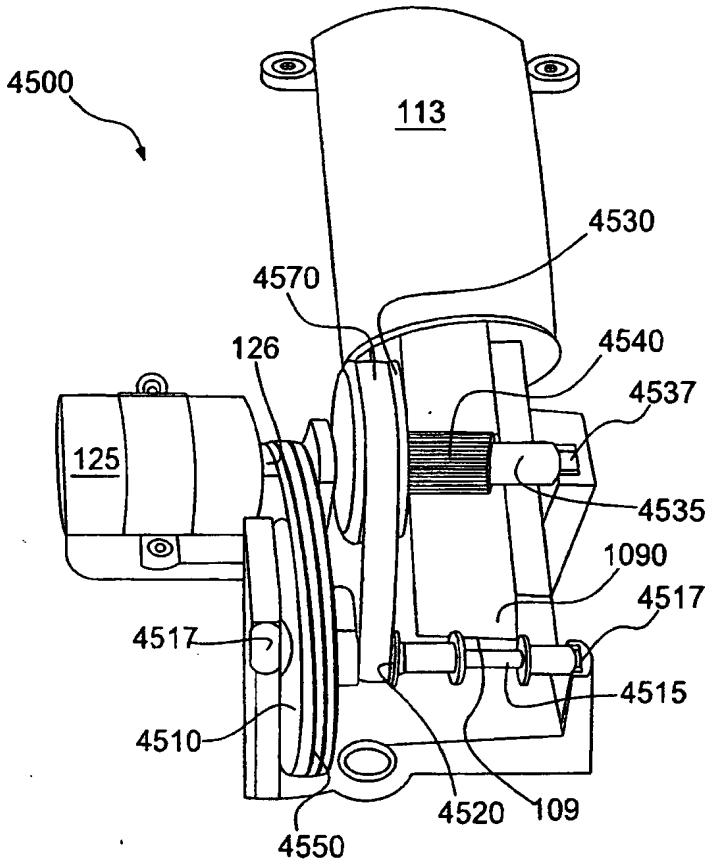

4500
113
4530
4570
126
4540
4537
125
4535
1090
4517
4517
4515
4510
4520
109
4550

Fig. 23

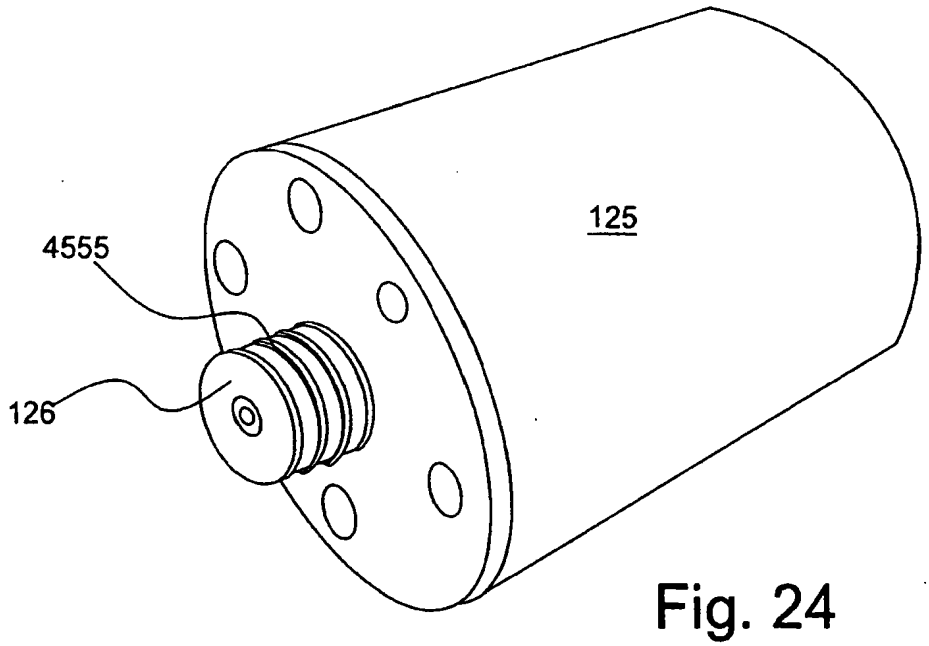

125
4555
126

Fig. 24

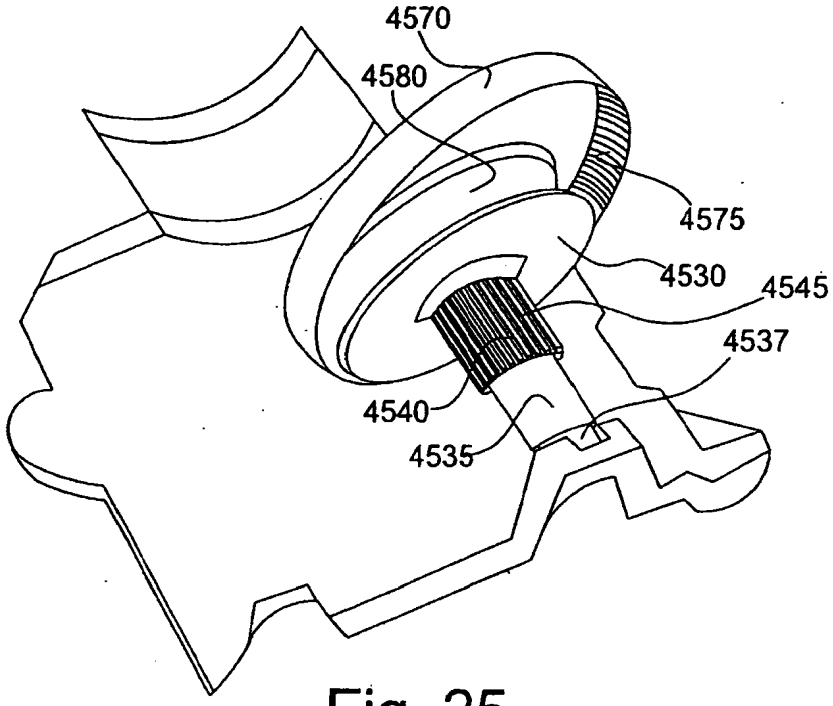

4570
4580
4575
4530
4545
4537
4540
4535

Fig. 25

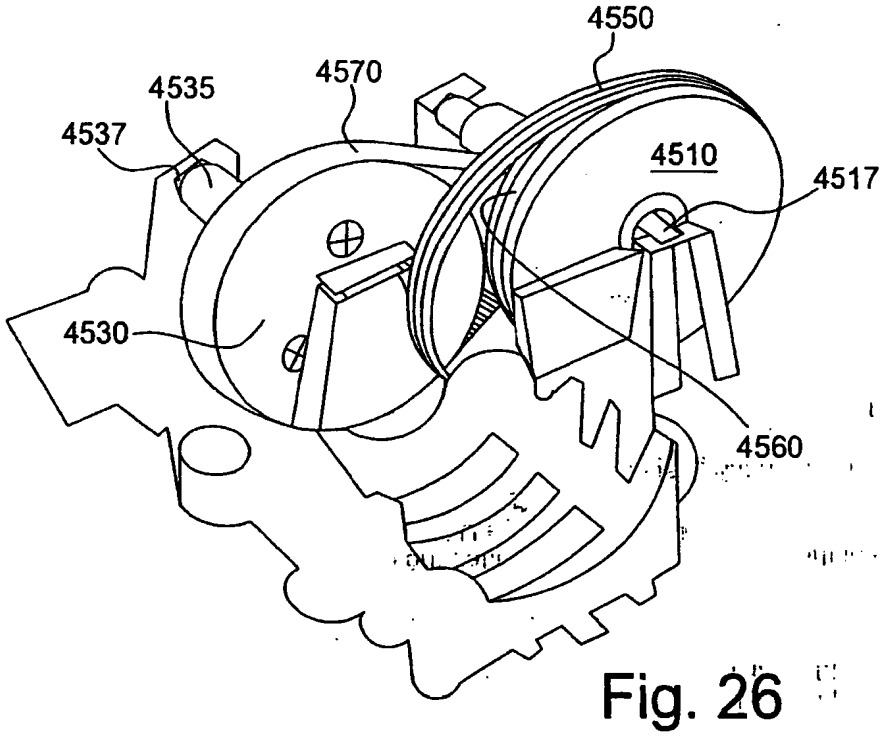

4550
4570
4535
4537
4510
4517
4530
4560

Fig. 26

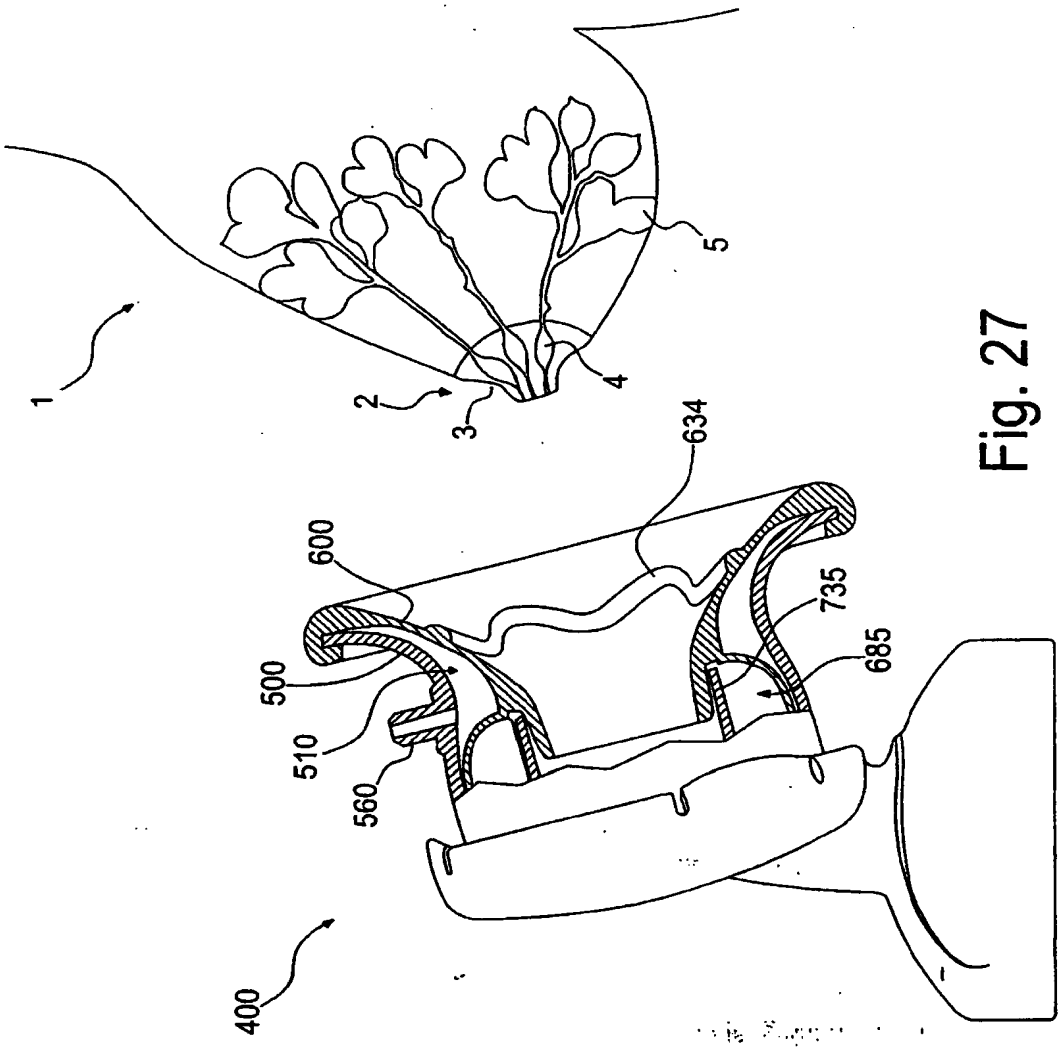


Fig. 27

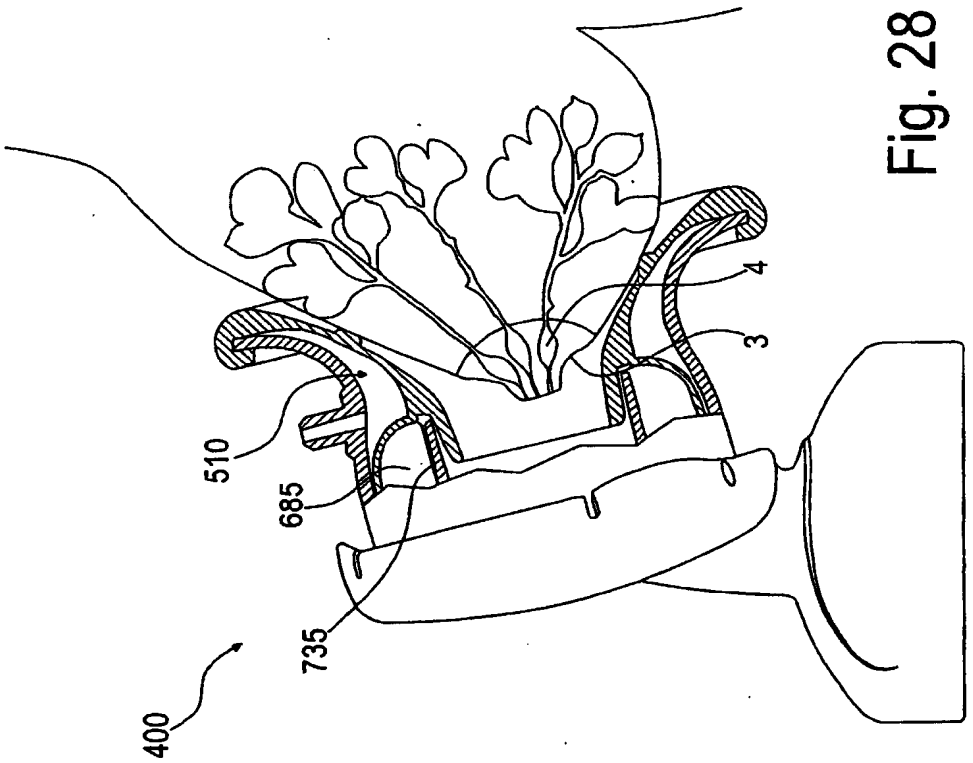


Fig. 28

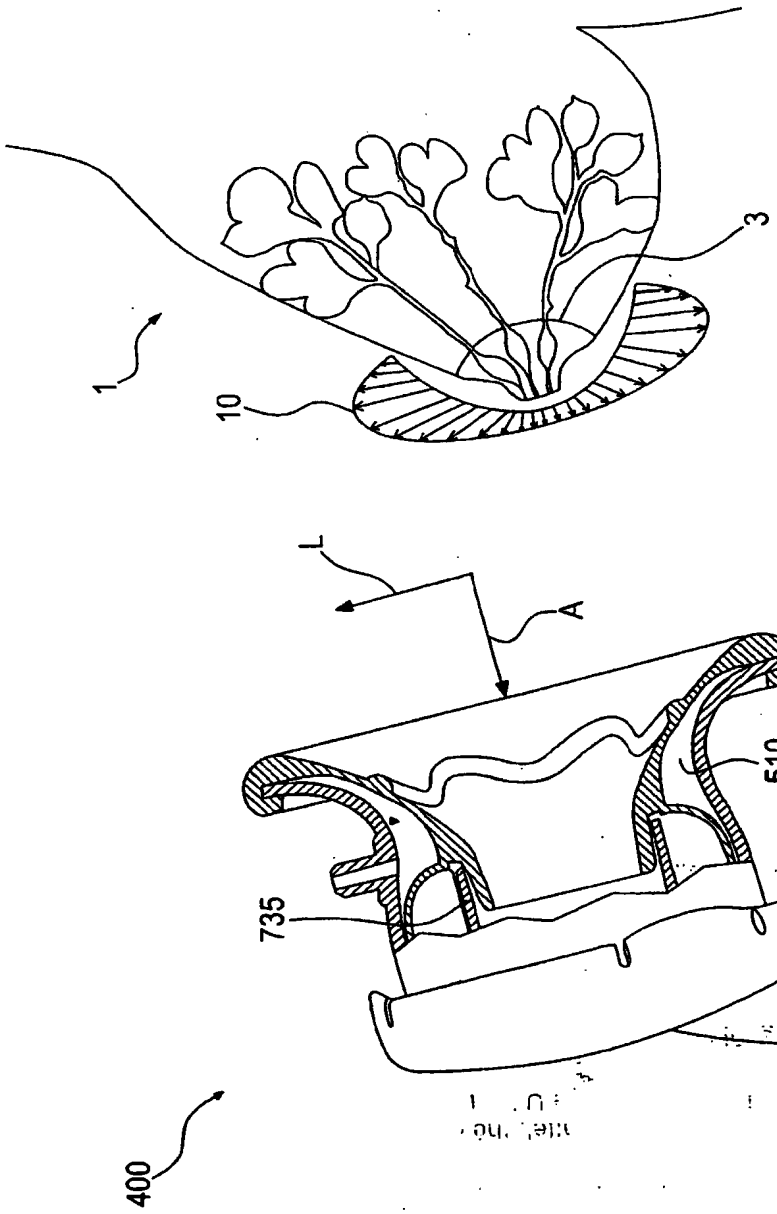


Fig. 29

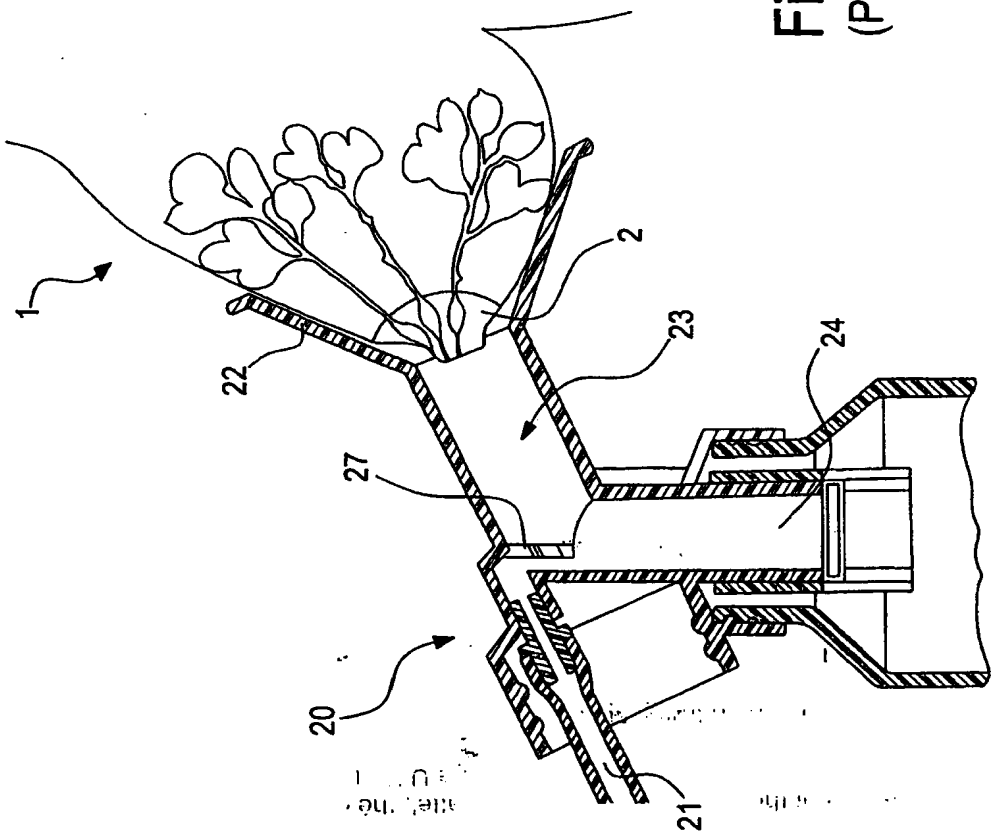


Fig. 30
(Prior Art)

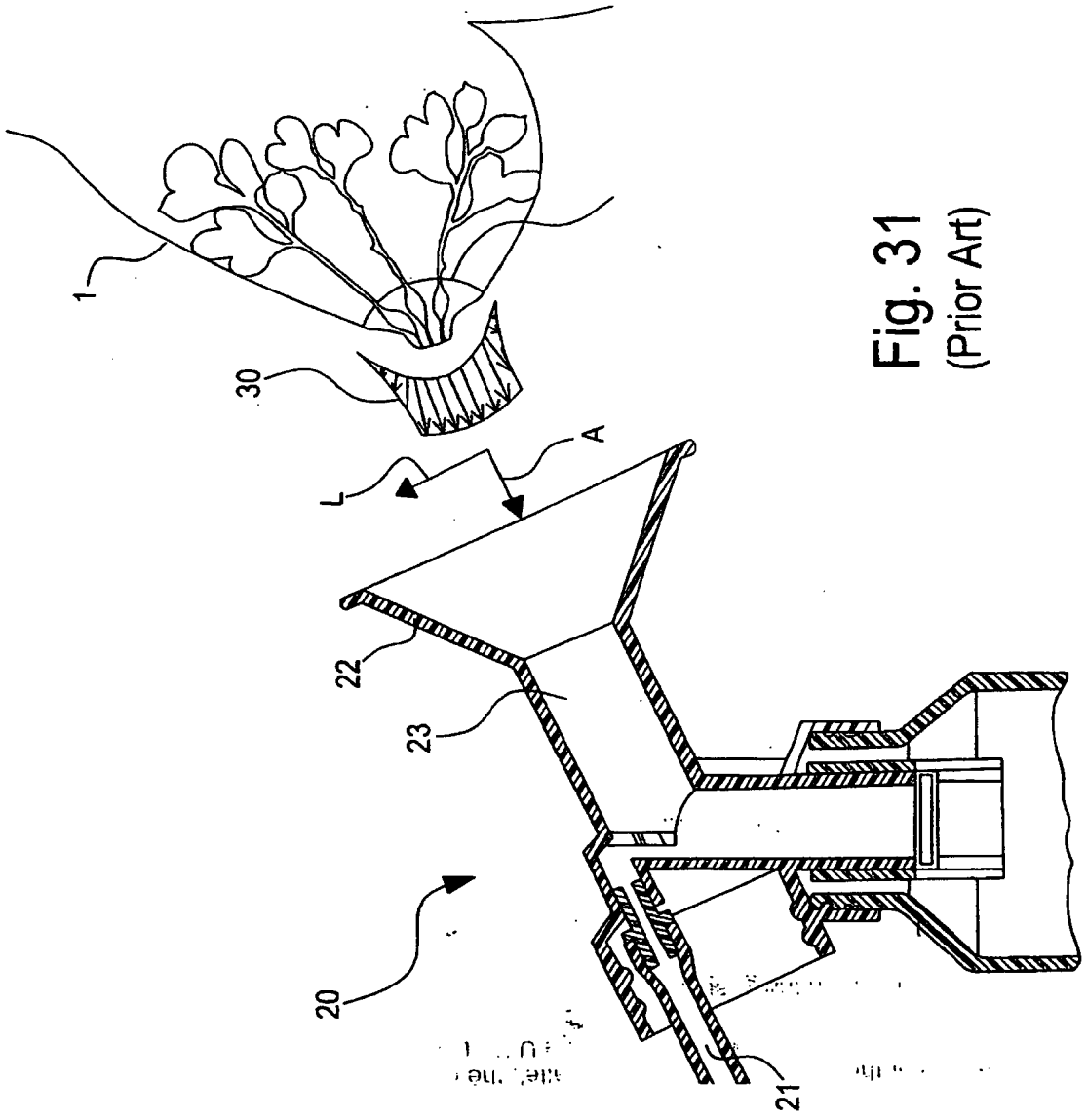


Fig. 31
(Prior Art)

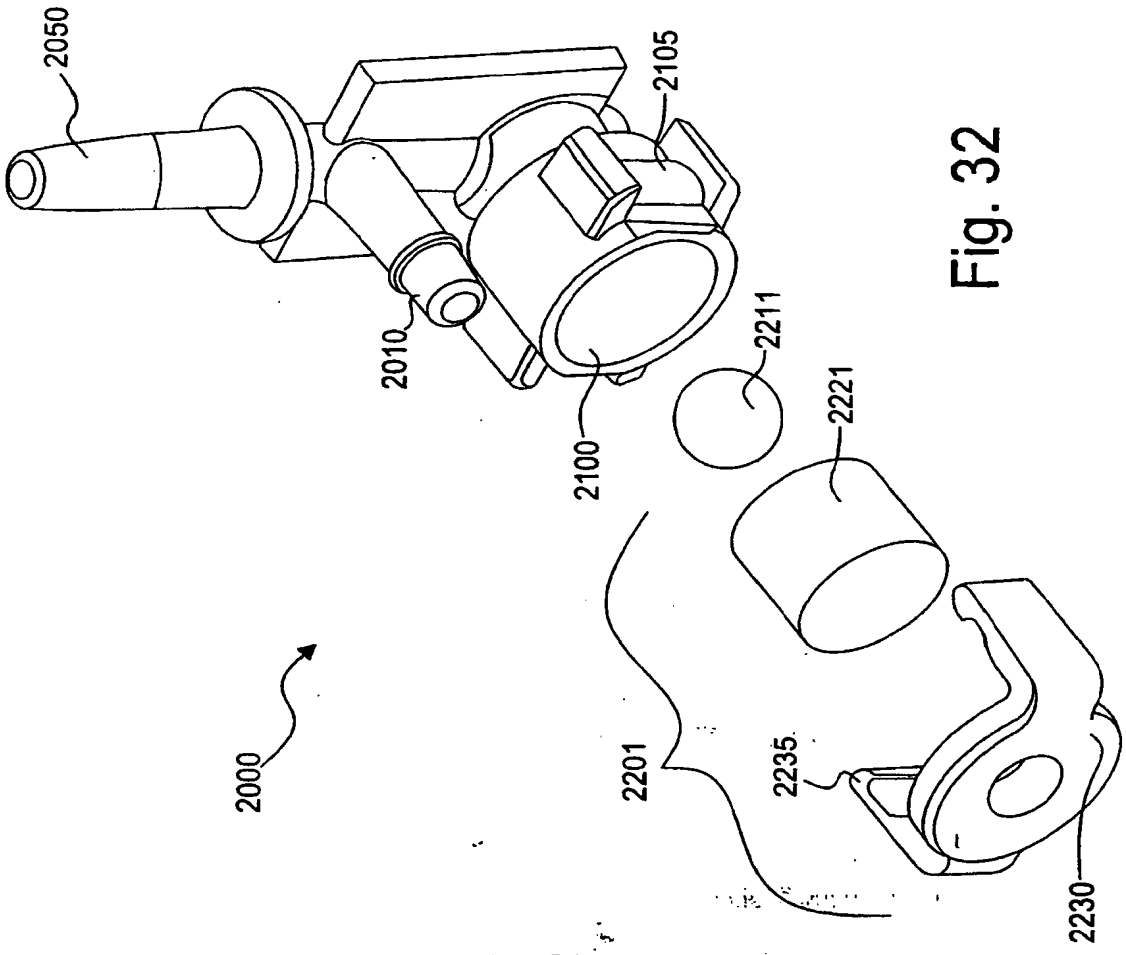


Fig. 32

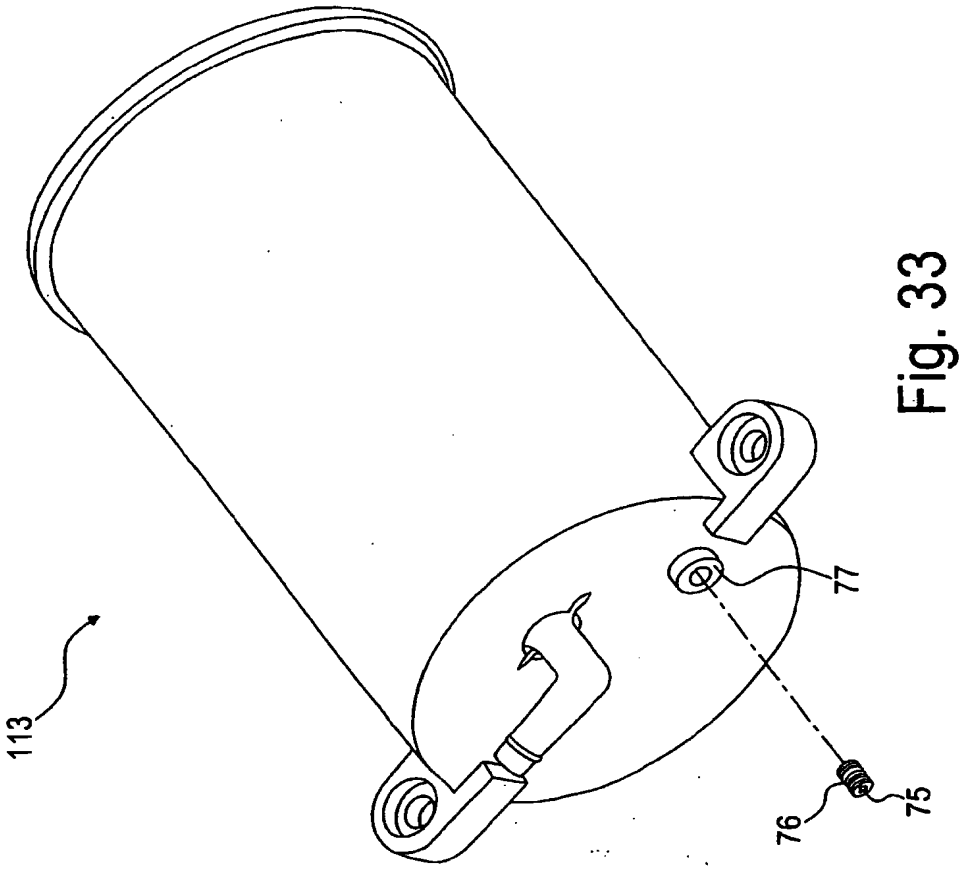
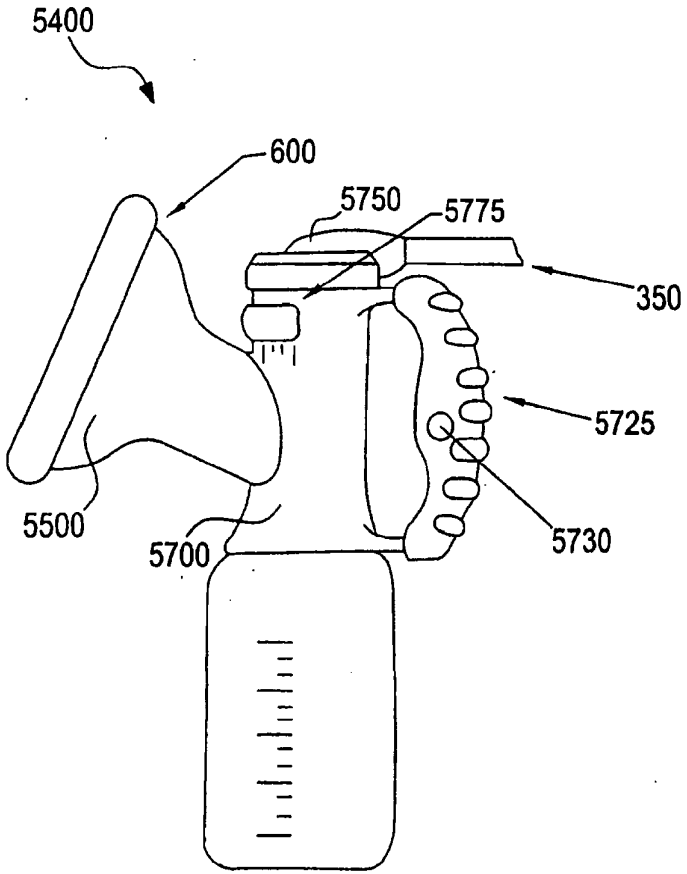


Fig. 33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600
5750
5775
350
5725
5500
5700
5730

Fig. 34

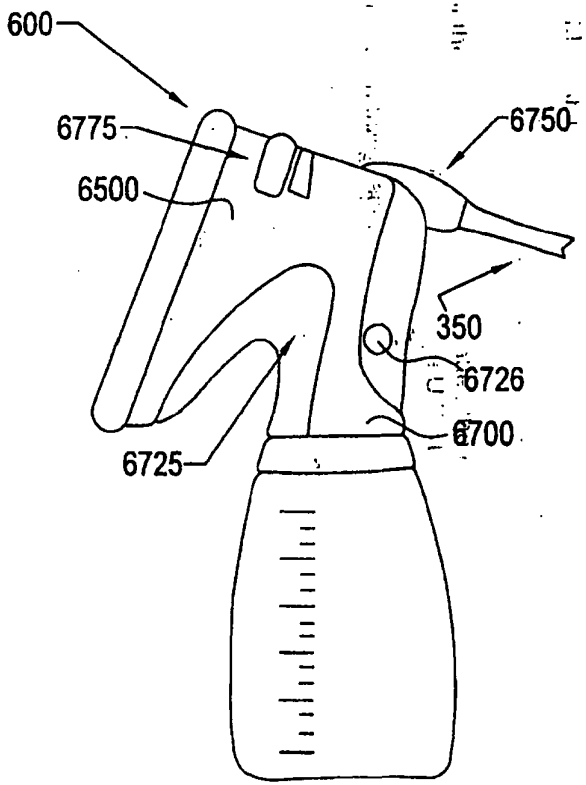
600
6775
6750
6500
350
6726
6700
6725

Fig. 35

Fig. 36

Fig. 37

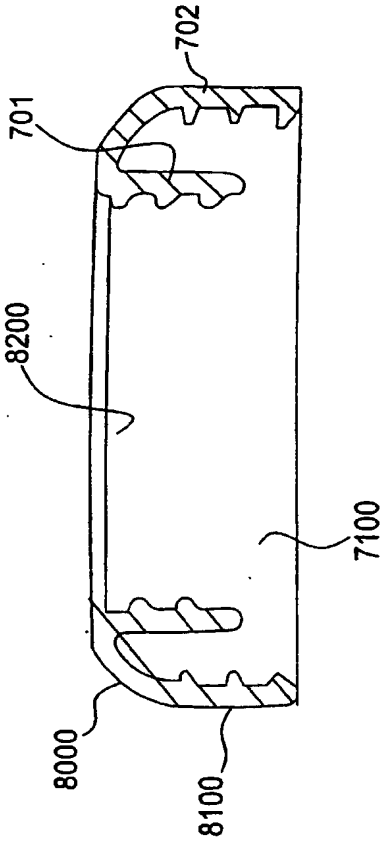

Fig. 39

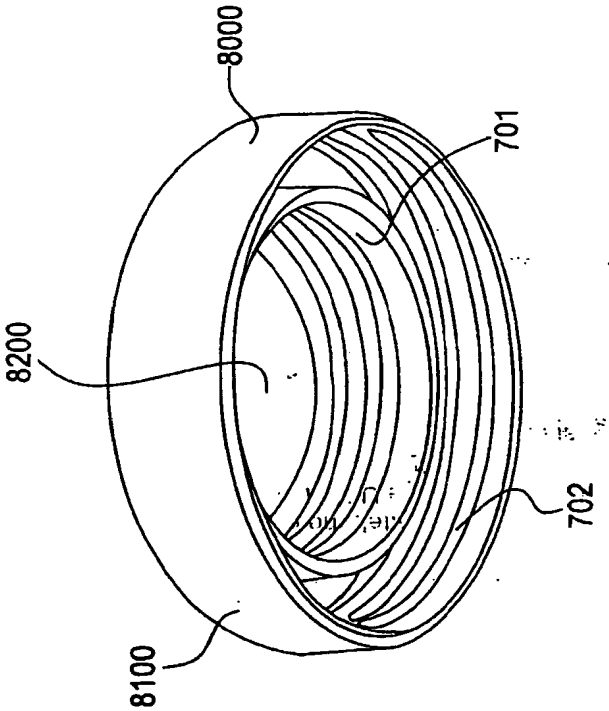

Fig. 38

BREAST PUMP

BACKGROUND OF THE INVENTION

The present invention relates to apparatus and methods for obtaining breast milk. More particularly, the present invention relates to a breast pump that can apply a variable pressure to a breast to express breast milk and to a method effecting the same.

Breast pump systems for obtaining breast milk, both manually and automatically, are known in the art. Conventional systems use a vacuum source to generate a negative pressure or vacuum that is transmitted through tubing to a breast hood or cup that is placed on the breast. This conventional device and method uses a negative pressure on the breast to express the breast milk.

Such systems suffer from the drawback of applying only a vacuum source as negative pressure to the breast to induce the expression of breast milk. Moreover, such conventional systems suffer from the drawback of applying the negative pressure or force axially to the nipple, resulting in elongation and distention of the nipple in an axial direction that is both uncomfortable and inefficient for the expression of breast milk.

SUMMARY OF THE INVENTION

It is an object of the present invention to substantially monitor and control the pressure source of a breast pump in real-time.

It is an object of the present invention to provide a breast pump system for expressing milk that can apply a positive pressure or a negative pressure to a breast to express the milk.

It is another object of the present invention to provide such a system that supplies the positive and negative pressure from a single source.

It is still another object of the present invention to provide such a system that facilitates control of the positive and negative pressure applied to the breast.

It is yet another object of the present invention to provide such a system that widens the nipple to express milk.

It is a further object of the present invention to provide such a system that reduces axial elongation or distention of the nipple.

It is another further object of the present invention to apply a negative force or negative pressure gradient to the nipple that has a greater lateral component than axial component.

It is yet a further object of the present invention to accommodate breasts of differing size and/or shape by providing a kit with interchangeable breast hoods of differing size and/or shape.

These and other objects and advantages are provided by a breast cup having a hood for receiving the breast and in fluid communication with a pressure source. The hood creates a negative force on the nipple during a negative pressure stroke. The negative force has a lateral component and an axial component. The lateral component is greater than the axial component.

The present invention includes a breast pump for expressing breast milk from a breast, the pump comprising a pressure source with a movable structure for generating

pressure during a pressure stroke. The movable structure has a variable pressure volume or variable cycle time. The pump also has a controller operably connected to the pressure source. The controller regulates the pressure volume based upon a distance traveled by the movable structure and regulates the variable cycle time based upon a speed of the movable structure. The controller provides substantially real-time monitoring of the distance traveled and the speed.

Preferably, the controller regulates the pressure cycle based on a non-sinusoidal wave signal of the pressure versus variable cycle time.

A method of expressing breast milk from a breast is described having the steps of applying a pressure to the breast; and performing substantially real-time monitoring and controlling of the pressure with a controller. Said pressure may be controlled in part based on a variable pressure volume of a movable structure or a variable cycle time of said movable structure. As before, the controller regulates the pressure volume based upon a distance traveled by the movable structure or regulates the variable cycle time based upon a speed of the movable structure and the controller provides substantially real-time monitoring of the distance traveled or the speed.

Preferably, the controller regulates the pressure cycle based on a non-sinusoidal wave signal of the pressure versus a cycle time.

There is disclosed a breast cup having a breast receiving member in fluid communication with a vacuum source. The breast receiving member applies a negative pressure to the nipple during a negative pressure stroke causing the nipple to widen along a lateral direction.

Described is a breast pump system having a pressure source and a breast cup for receiving the breast. The breast cup is in fluid communication with the pressure source.

The breast cup creates a negative force on the nipple during a negative pressure stroke. The negative force has a lateral component and an axial component. The lateral component is greater than the axial component.

A breast pump system is also disclosed having a vacuum source and a breast receiving member that is in fluid communication with the vacuum source. The breast receiving member applies a negative pressure to the nipple during a negative pressure stroke causing the nipple to widen along a lateral direction.

Additionally disclosed is a breast pump kit having a holder and a plurality of hoods for receiving the breast. Each of the plurality of hoods are selectively engageable to the holder and a pressure source for expressing the breast milk from the breast. At least one of the plurality of hoods has a different size or a different shape than another of the plurality of hoods.

There is described a breast pump system having a pump generating pressure and a plurality of hoods for receiving the breast. Each of the plurality of hoods are selectively fluidly connectable to the pump for expressing the breast milk from the breast. At least one of the plurality of hoods has a different size or a different shape than another of the plurality of hoods.

A breast pump system is disclosed having a pressure source with an evacuation volume for generating a pressure and an air hole. The system also has a breast cup for receiving the breast and in fluid communication with the pressure source for applying the pressure to the breast. The air hole has a diameter and is in fluid communication with the atmosphere and the evacuation volume. The diameter of the air hole is between about 0.15 mm to 0.75 mm.

A method describes expressing breast milk from a breast having the steps of applying a negative pressure to the breast from a pressure source during a vacuum stroke; applying a positive pressure to the breast from the pressure source during a massage stroke; and providing air from the atmosphere to the pressure source during the vacuum stroke.

There is also a method disclosing the expression of breast milk from a breast having the step of applying a negative pressure on at least a portion of the nipple causing the nipple to widen along a lateral direction.

A pump for providing pressure is described which has a housing, an actuator and an insert. The housing defines a volume and has a pressure exhaust. The actuator is operably connected to the housing for producing the pressure in the volume. The insert is connected to the housing. The insert has a hole disposed therethrough. The hole provides fluid communication between the volume and atmosphere.

A breast cup is disclosed for placing a breast in fluid communication with a first container and a second container that have openings with different diameters. The breast cup has a funnel for receiving the breast and a housing connected to the funnel. The funnel has a base. The base has a circumferential wall, a flange extending inwardly from the circumferential wall to define an opening, first threads, and second threads. The first threads have a first diameter and a first pitch. The first diameter and the first pitch allow for selective engagement with the first container. The second threads have a second diameter and a second pitch. The second diameter and the second pitch allow for selective engagement with the second container. The first threads and the second threads are concentrically disposed along the base.

There is also described a nipple ring for engaging a nipple with a first container and a second container that have openings with different diameters. The nipple ring has a

body having a circumferential wall, a flange extending inwardly from the circumferential wall to define an opening, first threads, and second threads. The first threads have a first diameter and a first pitch. The first diameter and the first pitch allow for selective engagement with the first container. The second threads have a second diameter and a second pitch. The second diameter and the second pitch allow for selective engagement with the second container. The first threads and the second threads are concentrically disposed along the body.

Also disclosed is a cap for engaging with a first container and a second container that have openings with different diameters. The cap has a body with a circumferential wall, a top wall connected to the circumferential wall, first threads, and second threads. The first threads have a first diameter and a first pitch. The first diameter and the first pitch allow for selective engagement with the first container. The second threads have a second diameter and a second pitch. The second diameter and the second pitch allow for selective engagement with the second container. The first threads and the second threads are concentrically disposed along the body.

The first pitch can be equal to the second pitch. The first threads can extend from the flange. The second threads can be disposed on the circumferential wall. The funnel can be selectively removable from the housing.

The housing can be a first material and the insert can be a second material. The housing can be plastic and the insert can be metal. The housing can be a cylinder and the actuator can be a piston. The cylinder can be an orifice and the insert can be disposed in the orifice. The insert can be press fit into the orifice. The insert can be a plurality of inserts, and each of the plurality of inserts can be selectively engageable with the cylinder.

The breast cup can also have a barrier member operably connected to the hood, wherein the barrier member reduces the axial component of the negative force during the

negative pressure stroke. The hood can have a housing, a flexible insert sealingly secured to the housing, and a displacement volume formed between the housing and the flexible insert, wherein the displacement volume is in fluid communication with the pressure source. The displacement volume can substantially surround the nipple when the breast is received in the hood. The flexible insert can have a bladder in fluid communication with the pressure source with the displacement volume being defined at least partially by the bladder. The bladder and the displacement volume can contract to form the negative force on the nipple during the negative pressure stroke.

The breast cup can also have a barrier member disposed substantially adjacent to the bladder, thereby preventing the breast from contacting the bladder. The flexible insert can define an inner volume for receiving the breast, and the barrier member can have a cylindrical shape and be disposed in the inner volume. The flexible insert can have a funnel shape with a massaging projection formed thereon. The massaging projection can have a star-like shape.

The negative pressure created at the breast cup can cause the nipple to widen along a lateral direction more than the nipple elongates along an axial direction. The negative pressure can have an average lateral component and an average axial component, wherein during the negative pressure stroke the average lateral component is greater than the average axial component. The barrier member can be operably connected to the breast receiving member, and can reduce elongation of the nipple along the axial direction during the negative pressure stroke. The breast receiving member can have a housing, a flexible insert sealingly secured to the housing, and a displacement volume formed between the housing and the flexible insert, wherein the displacement volume is in fluid communication with the vacuum source.

The vacuum or pressure source can be a piston movably disposed in a cylinder. The system can have a reversible motor operably connected to the piston. The system can

also have a rack having first teeth and a gear having second teeth. The rack can be connected to the piston and the gear can be operably connected to the reversible motor. The first teeth can engage with the second teeth to reciprocally move the piston in the cylinder. The cylinder can have a first diameter and an air hole. The air hole can have a second diameter and be in fluid communication with the atmosphere. The first diameter of the cylinder can be significantly larger than the second diameter of the air hole.

The system can have a controller operably connected to the reversible motor. The controller can determine a distance that the piston has traveled relative to the cylinder. The controller can reverse the motor based at least in part upon that distance. The system can also have a motor with variable speed. The controller can adjust the speed based upon a desired cycle time for applying the negative pressure to the breast. The controller can regulate the pressure cycle based on a non-sinusoidal wave signal of pressure versus variable cycle time.

Each of the plurality of hoods of the kit can have a housing, a flexible insert sealingly secured to the housing, and a displacement volume formed between the housing and the flexible insert and in fluid communication with the pressure source. The housing and/or the flexible insert of the at least one of the plurality of hoods can have a different size or a different shape than the housing and/or the flexible insert of the another of the plurality of hoods. The kit can also have a container, wherein the holder is selectively engageable with the container. The holder can have a plurality of engagement structures for selectively engaging a plurality of different sized containers. The flexible insert of the at least one of the plurality of hoods can have a first massaging projection, and the flexible insert of the another of the plurality of hoods can have a second massaging projection. The first and second massaging projections can have a different size or a different shape.

BRIEF DESCRIPTION OF THE DRAWINGS

Other and further objects, advantages and features of the present invention will be understood by reference to the following:

Fig. 1 is a front perspective view of a breast pump of the breast pump system of the present invention;

Fig. 2 is a front perspective view of the breast pump of Fig. 1 in an opened position;

Fig. 3 is an exploded perspective view of the breast pump of Fig. 1;

Fig. 4 is a top view of the breast pump of Fig. 1 without the cover;

Fig. 5 is an exploded perspective view of a piston and cylinder of the present invention;

Fig. 6 is an exploded side view of a portion of the piston and cylinder of Fig. 5;

Fig. 7 is a front perspective view of the piston of Fig. 5;

Fig. 8 is an exploded perspective view of an alternative embodiment of the piston;

Fig. 9 is an exploded perspective view of a pressure relief valve of the system of Fig. 1;

Fig. 10 is a cross-sectional plan view of the cylinder of Fig. 5;

Fig. 11 is a front perspective view of a breast cup;

Fig. 12 is a side cross-sectional view of the breast cup of Fig. 11;

Fig. 13 is a rear perspective view of a T-connector;

Fig. 14 is a flow chart depicting a method for pumping a breast according to the system of Figs. 1 and 11;

Fig. 15 is a top perspective view of a preferred embodiment of breast pump for the breast pump system of the present invention;

Fig. 16 is a top view of the breast pump of Fig. 15;

Fig. 17 is a top perspective view of the drive system of the breast pump of Fig. 15;

Fig. 18 is a side perspective view of the drive system of Fig. 17;

Fig. 19 is a top perspective view of a portion of the gear reduction system of the drive system of Fig. 15, partially assembled;

Fig. 20 is a top perspective view of an alternative embodiment of breast pump for the breast pump system of the present invention;

Fig. 21 is a top view of the breast pump of Fig. 20;

Fig. 22 is a top perspective view of the drive system of the breast pump of Fig. 20;

Fig. 23 is a side perspective view of the drive system of Fig. 20;

Fig. 24 is a top perspective view of the motor of the drive system of Fig. 20;

Fig. 25 is a top perspective view of a portion of the gear reduction system of the drive system of Fig. 20, partially assembled;

Fig. 26 is a top perspective view of the gear reduction system of the drive system of Fig. 20, partially assembled;

Fig. 27 is a partial cross-sectional side view of the breast cup of Fig. 11 with a breast;

Fig. 28 is a partial cross-sectional side view of the breast cup of Fig. 27 applied to the breast prior to the negative pressure stroke;

Fig. 29 is an exploded cross-sectional view of the breast cup and breast of Fig. 27 during the negative pressure stroke showing a representation of the negative pressure gradient or force on the breast;

Fig. 30 is a cross-sectional side view of a prior art breast cup applied to a breast prior to the negative pressure stroke;

Fig. 31 is an exploded cross-sectional view of the prior art breast cup and breast of Fig. 30 during the negative pressure stroke showing a representation of the negative pressure gradient or force on the breast;

Fig. 32 is an exploded perspective view of the pressure relief valve of Fig. 9 with another embodiment of a relief assembly;

Fig. 33 is a perspective view of the cylinder of Fig. 5 with another embodiment of the pressure differential hole;

Fig. 34 is an alternative embodiment of a breast cup;

Fig. 35 is another alternative embodiment of a breast cup;

Fig. 36 is a bottom perspective view of a nipple ring with a nipple;

Fig. 37 is a side cross-sectional view of the nipple ring and nipple of Fig. 36;

Fig. 38 is a bottom perspective view of a cap; and

Fig. 39 is a side cross-sectional view of the cap of Fig. 38.

DESCRIPTION OF THE INVENTION

Referring to the drawings and, in particular, Figs. 1 and 2, there is shown a breast pump of the present invention generally represented by reference numeral 100. Breast pump 100, along with breast cup 400 shown in Fig. 11, form the major components of the breast pump system of the present invention. Breast pump 100 has a top housing 102 and a bottom housing 103 that are adapted to form an assembled unit.

Referring to Figs. 1 through 3, top housing 102 has a substantially ellipsoidal shape with a flat front face 200 and a storage compartment 210 having a compartment door 104. Preferably, door 104 is hingedly connected to top housing 102 to form a selectively sealable storage compartment 210 for storing air tubing or conduit 350 that connects breast pump 100 to the other components of the system, which will be discussed later in greater detail.

Face 200 can receive a button pad 105 having an LED cover 106. Pad 105 is used by the consumer to control breast pump 100. Bottom housing 103 can securely house the various components of the breast pump, which include a rack gear 109, a pinion gear 110 that can engage the rack gear, a piston 112, a cylinder 113 that can receive the piston, and a motor 125 having a shaft 126 upon which the pinion gear is mounted. Due in part to this design, breast pump 100 provides pumping with low noise. Breast pump 100 can be made of any rigid material, such as, for example, plastic.

Referring to Figs. 3 through 7, breast pump 100 utilizes piston 112 and cylinder 113 to create both a positive pressure and a negative pressure for obtaining breast milk. Piston 112 is driven by rack gear 109, which is affixed thereto. Piston 112 has a substantially cylindrical-shape with a first head 3000 and a second head 3100. First and second heads 3000, 3100 preferably have annular channels 3020, 3120 formed therein, respectively. Channels 3020, 3120 are disposed along the outer circumference of first and second heads 3000, 3100, respectively. Preferably, channels 3020, 3120 are centrally located along the outer circumference of first head 3000 and second head 3100. Seated in channels 3020, 3120 are sealing members 3050, 3150, respectively. Preferably, sealing members 3050, 3150 are o-ring gaskets. Sealing members 3050, 3150 have a diameter or width that is larger than the depth or height of channel 3020 and channel 3120. Sealing members 3050, 3150 extend beyond the outer circumference of first head 3000 and second head 3100 forming a sealing engagement with an inner surface 1130 of cylinder 113 as piston 112 is driven back and forth in the cylinder.

The use of multiple sealing members, i.e., o-ring gasket 3050 and o-ring gasket 3150 on piston 112, provide a double sealing to increase the efficiency of creating the positive pressure and negative pressure. While this embodiment uses two sealing members to create two separate sealing surfaces, any number of sealing members can be used to create any number of sealing surfaces for sealing piston 112 with cylinder 113.

Additionally, while this embodiment uses piston 112 having o-ring sealing gaskets 3050, 3150, alternative sealing structures can be used between the piston and cylinder 113.

Rack gear 109 has teeth 1090 that engage with pinion gear 110 having teeth 1100. Pinion gear 110 is operatively connected to motor 125, preferably via shaft 126. When motor 125 is activated, shaft 126 and pinion gear 110 rotate. Teeth 1090 on rack 109 and teeth 1100 on pinion 110 mesh and translate the reciprocal rotational motion of motor 125 and shaft 126 into a reciprocal longitudinal motion along a single axis in both directions.

Preferably, rack gear 109 has a first end 1095 that engages with a recess 3200 formed in piston 112. Recess 3200 is preferably centrally located in piston 112. First end 1095 of rack gear 109 preferably has a snap fit or friction fit engagement with recess 3200 of piston 112. Preferably, there are detent structures 1096, 3296 formed on first end 1095 and recess 3200, respectively. This facilitates production of these components and also provides for any slight pivotal movement that may be required of piston 112 with respect to rack gear 109.

An alternative embodiment of a piston is shown in Fig. 8 and generally represented by reference numeral 8112. Piston 8112 has a substantially V-shape with a leading edge 8120 and a trailing edge 8121. Leading edge 8120 and trailing edge 8121 sealingly engage an inner surface 1130 of cylinder 113 as piston 8112 is driven back and forth in the cylinder. The use of multiple edges, i.e., leading edge 8120 and following edge 8121, on piston 8112 that sealingly engage inner surface 1130 of cylinder 113, provide a double sealing to increase the efficiency of creating the positive pressure and negative pressure.

Referring to Figs. 3 through 7, motor 125 is preferably variable speed. This allows a user to control and vary the cycle time of the pumping of the breast. Breast

pump 100 further has a motor cover 107 and a bearing 108 to reduce vibration and to secure motor 125 to bottom housing 103.

The positive and negative pressures can be varied by changing the displacement of air volume in cylinder 113. In this embodiment, this is done by use of a photoelectric or photo-sensor system. The photo-sensor system has two or more photo-sensors 121 and a position switch 124. The photo-sensors 121 count the number of openings 50 on rack gear 109, as the rack gear moves back and forth. Thus, a user can control the distance that rack gear 109 travels and correspondingly control the air volume displacement in cylinder 113. Alternative displacement or distance monitors can also be used, such as, for example a coded wheel for counting the slots on the wheel; counting of the belt teeth; rotary encoder which counts its own revolutions; or a hall effect sensor.

To ensure that piston 112 is properly moving to the front of cylinder 113, the photo-sensor system further includes position switch 124, preferably located at the front of the cylinder, which acts as a starter for the counter. Alternatively, the position switch can be an opening 50 having a different size or shape that is detectable by photo-sensor 121.

Rack gear 109 can also have a safety mechanism attached thereto. Photo-sensor 121 will be reading openings 50 as rack gear 109 moves backwards. If for some reason rack gear 109 misses its target and moves too far, the safety will trigger the position switch. When the position switch is triggered while rack gear 109 is moving backwards, the software can trigger the system to move forward again and return to the position position.

Breast pump 100 has a guide cover 111 positioned over rack gear 109. Guide cover 111 provides added stability to the breast pump by guiding and vibration dampening the reciprocal movement of rack gear 109. Guide cover 111 also provides

accuracy to the photo-sensor system by reducing the risk of misalignment of photo-sensors 121 and openings 50.

The photo-sensor system and motor 125 are preferably connected to a PC or circuit board 120. Thus, the distance piston 112 travels, which translates to the amount of positive and negative pressure, and the piston speed, which translates to the cycle time, are electronically controlled.

Referring to Figs. 15 through 19, a preferred embodiment of a drive system is shown and generally represented by reference numeral 1500. Drive system 1500 is usable with breast pump 100 of Figs. 1 through 7 to provide the linear reciprocal movement of piston 112 with cylinder 113.

Drive system 1500 is a belt drive system for a rack and pinion drive having gear reduction incorporated therein. Drive system 1500 has a first drive wheel or pulley 1510; a second gear, drive wheel or pulley 1520 secured to the first drive wheel 1510; a third gear, drive wheel or pulley 4530; and a pinion gear 1540 secured to the third gear.

First drive wheel 1510 is operably connected to motor drive shaft 126 by a first belt 1550. In the preferred embodiment, first belt 1550 is a non-toothed belt. More preferably, first belt 1550 has resiliency or flexibility. The use of flexible or resilient belt 1550 provides a secure connection between drive shaft 126 and first drive wheel 1510 and also reduces noise and vibration. Drive shaft 126 and first drive wheel 1510 have smooth outer surfaces upon which the first belt 1550 is secured.

First drive wheel 1510 is operably connected to second gear 1520 by a first co-axial shaft 1515. In the preferred embodiment, first shaft 1515 is rotatably mounted between opposing first bearings 1517. However, alternative rotatable mounting arrangements or securing structures could also be used. To reduce noise and vibration,

motor shaft 126 and first drive wheel 1510 are made of metal. First drive wheel 1510 and second gear 1520 have different diameters that partially provide for gear reduction between motor shaft 126 and pinion gear 1540.

Second gear 1520 is operably connected to third gear 1530 by a second belt 1570. Preferably, second belt 1570 has teeth 1575 that mesh with teeth 1580 formed along the circumference of second gear 1520 and third gear 1530. Second and third gears 1520, 1530 have different diameters that partially provide for gear reduction between motor shaft 126 and pinion gear 1540. Drive system 1500 can also have a tension pulley 1580 that provides tension to second belt 1570.

Third gear 1530 is operably connected to pinion gear 1540 by a second co-axial shaft 1535. In the preferred embodiment, second shaft 1535 is rotatably mounted between opposing second bearings 1537. However, alternative rotatable mounting arrangements or securing structures could also be used. Preferably, third gear 1530 is integrally molded with pinion gear 1540 along second shaft 1535.

Pinion gear 1540 has teeth 1545 that engage with teeth 1090 of rack gear 109. When motor 125 is activated, the rotational motion of shaft 126 is translated into a reciprocal longitudinal motion along a single axis of rack gear 109 in both directions. Drive system 1500, through use of first and second belts 1550, 1570 and first, second and third drive wheels or gears 1510, 1520, 1530, is able to provide a desired ratio of movement between motor shaft 126 and pinion gear 1540, i.e., gear reduction.

The use of a combination of the non-toothed belt 1550 and the toothed belt 1570 reduces noise and vibration, while maintaining a secure, sturdy drive system 1500 that is able to provide the necessary back and forth linear motion at the desired speeds and pressure for breast pump 100.

Referring to Figs. 20 through 26, an alternative embodiment of a drive system is shown and generally represented by reference numeral 4500. Drive system 4500 is also usable with breast pump 100 of Figs. 1 through 7 to provide the linear reciprocal movement of piston 112 with cylinder 113.

Drive system 4500 is a belt drive system having gear reduction incorporated therein. Drive system 4500 has a first gear, drive wheel or pulley 4510; a second gear, drive wheel or pulley 4520 secured to the first gear; a third gear, drive wheel or pulley 4530; and a pinion gear 4540 secured to the third gear.

First gear 4510 is operably connected to motor drive shaft 126 by a first belt 4550. In the preferred embodiment, first belt 4550 is a plurality of belts, and more preferably, three belts. First belts 4550 are preferably non-toothed belts. More preferably, first belts 4550 are o-rings having resiliency or flexibility. The use of flexible or resilient belts 4550, such as, for example, o-rings, provides a secure connection between drive shaft 126 and first gear 4510, and also reduces noise and vibration. Drive shaft 126 and first gear 4510 have annular channels 4555, 4560, formed therein, respectively. Annular channels 4555, 4560 are guides that assist in holding first belts 4550 in place and facilitate assembly of drive system 4500.

First gear 4510 is operably connected to second gear 4520 by a first co-axial shaft 4515. In this alternative embodiment, first shaft 4515 is rotatably mounted between opposing first bearings 4517. However, alternative rotatable mounting arrangements or securing structures could also be used. To reduce noise and vibration, motor shaft 126 and first gear 4510 are made of metal. First and second gears 4510, 4520 have different diameters that partially provide for gear reduction between motor shaft 126 and pinion gear 4540.

Second gear 4520 is operably connected to third gear 4530 by a second belt 4570. Preferably, second belt 4570 has teeth 4575 that mesh with teeth 4580 formed along the circumference of second gear 4520 and third gear 4530. Second and third gears 4520, 4530 have different diameters that partially provide for gear reduction between motor shaft 126 and pinion gear 4540. Drive system 4500 can also have a tension pulley 4580 that provides tension to second belt 4570.

Third gear 4530 is operably connected to pinion gear 4540 by a second co-axial shaft 4535. In this alternative embodiment, second shaft 4535 is rotatably mounted between opposing second bearings 4537. However, alternative rotatable mounting arrangements or securing structures could also be used. Preferably, third gear 4530 is integrally molded with pinion gear 4540 along second shaft 4535.

Pinion gear 4540 has teeth 4545 that engage with teeth 1090 of rack gear 109. When motor 125 is activated, the rotational motion of shaft 126 is translated into a reciprocal longitudinal motion along a single axis of rack gear 109 in both directions. Drive system 4500, through use of first and second belts 4550, 4570 and first, second and third gears 4510, 4520, 4530, is able to provide a desired ratio of movement between motor shaft 126 and pinion gear 4540, i.e., gear reduction.

The use of a combination of the non-toothed o-ring belts 4550 and the toothed belt 4570 reduces noise and vibration, while maintaining a secure, sturdy drive system 4500 that is able to provide the necessary back and forth linear motion at the desired speeds and pressure for breast pump 100.

The embodiments of the drive systems 1500 and 4500 described above utilize belts for gear reduction. However, alternative embodiments can use a gear-box that reduces the gearing to the desired ratio that is transferred to the rack and pinion gearing that drives breast pump 100.

Referring back to Figs. 3 through 9, cylinder 113 has a supply tube 116 that is secured to a supply connector 115 for supplying the positive and negative pressure to breast cup 400. Preferably, supply connector has an outlet 215 disposed in storage compartment 210. Air tubing 350 can be secured to outlet 215 and also secured to breast cup 400. Storage compartment 210 can be opened or closed during the pumping operation. Cylinder 113 is in fluid communication with a pressure relief valve 2000 (shown in Fig. 9) that is preferably set at about 1.5 in. Hg.

Pressure relief valve 2000 has an intake 2010 and an exhaust 2050. Intake 2010 is in fluid communication with cylinder 113 and exhaust 2050 is in fluid communication with breast cup 400, by tubing 350. Pressure relief valve 2000 has a relief exhaust 2100 that is in fluid communication with intake 2010 and exhaust 2050. Relief exhaust 2100 is substantially tubular and is secured to a relief assembly 2200.

Relief assembly 2200 has a flexible insert 2210, a biasing member 2220 and a retaining member 2230. Flexible insert 2210 sealing engages with the inner surface of relief exhaust 2100 to prevent air from exiting through the relief exhaust. Insert 2210 has a securing member 2215 that mates with biasing member 2200. In this embodiment, securing member 2215 is a cross-shaped structure that is received in the inner volume of biasing member 2200. Preferably, biasing member 2220 is a spring. More preferably, biasing member 2220 is a coil spring. Retaining member 2230 is a cap-like structure having opposing retaining arms 2235 that engage with a corresponding pair of engaging protrusions 2105 positioned on the outer surface of relief exhaust 2100. Insert 2210 and spring 2220 are held in the inner volume of relief exhaust 2100 by cap 2230.

Spring 2220 has a biasing strength or resistance that is equal to the relief pressure of relief pressure valve 2000. When a positive pressure exceeds the relief pressure, which in this embodiment is preferably set at about 1.5 in. Hg, the force created on the inner

surface of insert 2210 overcomes the biasing force of spring 2220 and the insert moves toward cap 2230 and outside of the inner volume of relief exhaust 2100. Air exits pressure relief valve 2000 through relief exhaust 2100 until the positive pressure in the pressure relief valve decreases below the biasing strength of spring 2220, at which time insert 2210 moves back in the inner volume of the relief exhaust, sealingly engaging the inner surfaces of the relief exhaust.

Referring also to Fig. 32, pressure relief valve 2000 is shown with a preferred relief assembly 2201 that includes an insert 2211 and a biasing member 2221. Relief assembly 2201 functions similarly to the insert 2210 and the spring 2220 of relief assembly 2200, as described above. Insert 2211 is a ball and biasing member 2221 is foam having a cylindrical shape. Relief assembly 2201 is advantageous because the ball 2211 is more easily assembled in relief exhaust 2100. Additionally, the foam cylinder 2221 is more consistent because it easily mates with the ball 2211 and provides a consistent spring actuation force. Additionally, alternative pressure relief valves can be used which are adjustable so that the "massage strength", i.e., the amount of positive pressure on the user's breast, can be controlled.

Circuit board 120, shown in Fig. 3, allows a user to program several levels of speed and several levels of suction. In this embodiment, the speed (cycle time) ranges from about 45 cycles/minute (cpm) to about 75 cpm. The embodiment provides for pre-set programming of a number of speed levels within the speed range. Preferably, the number of levels can be from about two to about eight levels. More preferably, the user can program five levels of speeds within the speed range. The embodiment also envisions programming of the speed levels by the user.

The suction range for use with a single breast cup 400 and the preferred drive system 1500 shown in Figs. 15 through 21, is from about 3 in. Hg to about 10 in. Hg, and from about 3 in. Hg to about 8 in. Hg for two breast cups. The suction range for use with

a single breast cup 400 and the gear box system shown in Figs. 3 and 4 is from about 3 in. Hg to about 9 in. Hg, and from about 3 in. Hg to about 8 in. Hg for two breast cups. The embodiment provides for pre-set programming of a number of suction levels within the suction range. Preferably, the number of levels can be from about two to about eight levels. More preferably, the user can program five levels of suction within the suction range. The present invention also envisions programming of the suction levels by the user.

Computer software can also be used to control the amount of positive and negative pressure. This allows the amounts of positive and negative pressure to be personalized for the user and also varied over the duration of the pumping process to maximize efficiency.

Breast pump 100 is preferably controlled by a software-driven circuit board 120, along with a gear motor 125, a rack and pinion set 109, 110, and a piston system 112, 113. The software and system are designed to provide maximum flexibility and to facilitate changing of the pressure curve or "wave." This is feasible because the software controls the speed of motor 120 and the distance that piston 112 will travel in cylinder 113. The distance piston 112 travels relates to the pressure levels. By controlling speed and pressure levels with software, the pressure curve or "wave" can be controlled.

Once a determination is made that there is a specific "wave" or pressure curve that is similar to the sucking of an infant or most comfortable to the mother, then the desired wave can be obtained by changing the timing (motor speed and piston distance). Through use of software, a user has the ability to apply memory to a particular pressure curve and the variation of that pressure curve over time so as to maximize the comfort for the user.

In this embodiment, a sine wave is used for the control of breast pump 100. This is based on the assumption that the most comfortable pressure curve would be one that

increases and decreases in pressure gradually, similar to a sine wave, without sharp pressure peaks and valleys providing a pinching feeling on the user. The back and forth motion of piston 112 approximates the desired sine wave. However, to avoid sharp pressure peaks, the timing of piston 112 is slowed down at these peaks, and the pressure is held constant for a duration of time at the maximum and minimum suction points on the wave. This results in a pressure curve having a steady sine wave that is more comfortable to the user.

Alternative waves can also be used for the pressure curve, if such a wave is determined to be desirable by the mother. For example, if a mother prefers a "saw tooth" pressure curve with sharp peaks, the timing of piston 112 can be changed to simply cycle back and forth, minimizing the pause when piston 112 changes direction. Also, for example, if a mother prefers a "square curve", the timing of piston 112 can be changed to hold the piston position when the piston is ready to change direction, and then quickly ramp down and hold its position again before it ramps back up. This will create a "square curve" wave.

Use of software control provides for numerous choices of waves or pressure curves. This further allows the flexibility to change or offer greater choice with one breast pump 100. In contrast, contemporary pumps have the drawback of not allowing the flexibility of changing pressure curve waves. Breast Pump 100 allows for inter-cycle control of the pressure and speed. In the preferred embodiment, this is done through use of a reversible, variable speed motor 125 operably connected to a linear system incorporating piston 112 and cylinder 113. Thus, contemporary devices could seemingly use a particular sinusoidal pressure curve repeatedly, while the breast pump 100 has the ability to use any type of wave and to change the wave during the cycle.

The control system and software provide for a closed-loop control system or inter-cycle real-time adjustment. Thus, real-time monitoring of the control variables occurs,

such as piston distance traveled and speed. As the motor and other components age and wear, the closed-loop control system accounts for such detrimental changes to provide accurate cycle time and pressure sought by the user. The real-time monitoring and control provides effectively equal speed levels for both single and double cup pumping even with the changes in torque.

Cylinder 113 has a pressure differential hole 75. Preferably, pressure differential hole 75 is located along bottom face 80 of cylinder 113. Pressure differential hole 75 is substantially smaller than exhaust hole 1013 and supply tube 116 through which the air flows for generating the positive and negative pressure. Pressure differential hole 75 provides a variance in the amount of positive pressure as compared to the amount of negative pressure. Pressure differential hole 75 is effective for the higher ranges of vacuum to provide the "lost" air at the end of the vacuum stroke. On the positive pressure stroke, a small amount of air will be released through pressure differential hole 75 but the air will be reintroduced during the negative pressure stroke when the level of pressure is higher.

Referring to Fig. 33, cylinder 113 is shown with a preferred embodiment of a pressure differential insert 76. Pressure differential hole 75 is disposed through pressure differential insert 76. Insert 76 is then connected to cylinder 113 through a cylinder hole 77 disposed through the wall of the cylinder. Insert 76 is preferably press fit into cylinder hole 77. However, alternative connection methods can also be used, such as, for example, threads or adhesive. Pressure differential insert 76 is a machined metal piece that allows for the machining of pressure differential hole 75 with a precise diameter within very small tolerances.

The use of insert 76 is advantageous over disposing pressure differential hole 75 directly through the wall of cylinder 113 because of the significant lack of precision in either molding the hole or drilling the hole through a plastic part. Additionally, pressure

differential insert 76 can be selectively inserted through cylinder hole 77 so that a plurality of inserts having a plurality of differently sized pressure differential holes 75 can be used. By providing for different diameters for pressure differential hole 75, the suction levels produced by the pump can be altered.

Pressure differential hole 75 allows for reclaiming of the air during the negative pressure stroke that is lost over time during use of breast pump 100 so that the positive pressure can be accurately maintained over time. During testing of breast pump 100, unexpected and significant results occurred from the use of differently sized diameters of pressure differential hole 75. It was discovered that a pressure differential hole 75 having a diameter of between about 0.15 mm to about 0.75 mm maintained an accurate positive pressure over time while providing the desired negative pressure. The volume of cylinder 113 was 126 cm^3. Preferably, pressure differential hole 75 has a diameter of between about 0.25 mm to about 0.5 mm, and most preferably the diameter is about 0.3 mm.

Referring to Fig. 10, cylinder 113 is formed as a zero- draft cylinder. The outer diameter of piston 112 creates a seal with the inner diameter d of cylinder 113 to move the volume of air inside the cylinder, creating vacuum and pressure on the breast. Breast pump 100 requires a cylinder 113 that has a consistent inner diameter d through the entire length of the cylinder to create an appropriate seal while minimizing interference or resistance to piston 112. Typical injection molded parts require a draft angle that would create a non-uniform inner diameter d of cylinder 113.

Cylinder 113 is preferably molded as a zero-draft cylinder that provides a uniform inner diameter d and more preferably, molded in a single piece. As shown in Fig. 10, cylinder 113 is a one piece, plastic injection molded part. A two-part cylinder or a machined-cylinder have drawbacks which the single piece, zero draft cylinder 113 overcomes. The two-part cylinder requires an extruded tube attached to an end cap, with the two parts joined using a weld or using an adhesive. The machined part is typically a

metal tube. One of the advantages to the zero-draft, one-piece cylinder 113 is that it is injection moldable.

Referring to Figs. 3 through 10, button pad 105 is the user interface or control mechanism for breast pump 100. Button pad 105 has a pair of positive and negative keys for increasing or decreasing the level of suction and speed. Pad 105 further includes an on/off switch.

Due to the reciprocal back and forth motion of piston 112 in cylinder 113, breast pump 100 supplies both a positive pressure and a negative pressure to a woman's breast through a single hose or tubing 350. While this embodiment uses a piston/cylinder mechanism to create positive and negative pressure, alternative expandable volumes or pressure sources can also be used. Such alternative embodiments include a bellows mechanism or a diaphragm that would require fewer parts.

Referring to Figs. 11 and 12, breast Cup, hood, or breast receiving member 400 is shown. Breast cup 400 has a housing 500 having an air orifice 560, a flexible insert 600, and a holder 700. Housing 500 is a rigid structure and flexible insert 600 is a flexible structure. Housing 500 is adapted for sealing engagement with insert 600 to form a displacement volume 510 between the housing and the insert. The funnel-like shape of insert 600 provides for an inner volume 655 for receiving of the breast. Air orifice 560 is in fluid communication with displacement volume 510.

Breast pump 100 is placed in fluid communication with breast cup 400 via air tubing 350 that is connected to air orifice 560 and in fluid communication with cylinder 113. Breast pump supplies both a positive and negative pressure to breast cup 400. The positive and negative pressure created by breast pump 100 causes air to flow through air orifice 560 into and out of displacement volume 510. The positive and negative pressure supplied to breast cup 400 causes flexible insert 600 and, in particular, displacement

volume 510 to expand and contract to apply reciprocating positive and negative forces on the user's breast.

Due to the negative pressure being created by evacuation of displacement volume 510 and the substantial collapsing of insert 600 upon housing 500, breast cup 400 has a maximum suction level inherently incorporated therein. Unlike contemporary devices that provide vacuum directly to the nipple from the vacuum source and are thus vulnerable to over-sucking, breast cup 400 can only provide a maximum negative pressure based upon the displacement volume 510. Once all of the air is evacuated from displacement volume 510, breast cup 400 preferably no longer increases the negative pressure or force applied to the breast. Breast pump 100 and breast cup 400 are able to apply both a positive and a negative pressure to a user's breast through a single air tubing 350, which is connected to air orifice 560.

The volume disposed in displacement volume 510 is preferably between 22 to 52 cubic centimeters, and more preferably between 32 to 42 cubic centimeters. The expandable and contractible displacement volume 510 provides an upper limit to the amount of negative pressure that can be applied to a user's breast, which can further serve as a safety feature in use of breast pump 100. Additionally, the sealing engagement of insert 600 and housing 500 provides a barrier between the user's breast and breast pump 100 to prevent any breast milk from entering air tubing 350 or the breast pump. Insert 600 can also include a massaging member 634. Massaging member 634 has a star-like shape, which provides additional massaging action to the breast. Alternative shapes can also be used for massaging member 634.

Referring to Figs. 27 through 29, breast cup 400 is shown in partial cross-section with a breast 1. The breast 1 has a nipple 2 with an areola 3, and milk lakes or ducts 4, which are supplied by milk glands 5. Breast cup 400 has bladders 685 on insert 600 and tubular member 735 on holder 700. Bladders 685 partially define displacement volume

510. When air is evacuated from the bladders 685 and the displacement volume 510 such that insert 600 is pulled toward and against housing 500, then the negative pressure, vacuum or negative force is applied to breast 1.

Tubular member 735 is disposed substantially adjacent to bladders 685 and extends partially through insert 600. Tubular member 735 is a rigid barrier between the breast 1 and bladders 685 to prevent the breast from making contact with and impinging the bladders, which would reduce the amount of their inflation and deflation, and thus reduce the reciprocating pressure applied to the breast.

Positioning of the breast cup 400 on the breast 1, results in the nipple 2, areola 3 and milk ducts 4 being substantially surrounded by displacement volume 510. Nipple 2 being substantially surrounded by the displacement volume and the use of tubular member 735 to create a rigid barrier in front of areola 3 and adjacent to bladders 685, results in a negative pressure gradient, vacuum or negative force 10 being applied to nipple 2 upon evacuation of the air in displacement volume 510 during the negative pressure stroke or cycle, as represented in Fig. 29. The negative pressure gradient or force 10 has a lateral component or direction L that is greater than an axial component or direction A. The negative pressure gradient or force 10 and the larger lateral component L causes the nipple 2 to be pulled or sucked laterally more than axially, which has been shown to be significantly more efficient at causing expression of breast milk from the milk ducts 4. The negative pressure gradient or force 10 has also been shown to be more comfortable for the user and more like the sucking of a baby during breast-feeding, due in part to the widening of the nipple 2 as opposed to axially elongating or distending the nipple along axial direction A.

Displacement volume 510 extends almost to the leading edge of housing 500 where the housing is secured to insert 600, which assists in creating the negative pressure gradient or force 10 during the negative pressure stroke or cycle that causes lateral

sucking and lateral movement of the nipple 2 along the lateral component L. As shown in Fig. 29, the negative pressure gradient, vacuum or force 10 extends beyond the outer circumference of the areola 3 and is substantially laterally applied thereto during the negative pressure stroke or cycle, which further assists in creating a force on the nipple 2 with a greater lateral component L than axial component A and thus a widening of the nipple.

The positioning of tubular member 735 helps reduce the negative pressure gradient or force 10 axially from or in front of, the nipple 2 during the negative pressure stroke or cycle, which reduces discomfort associated with axial distention of the nipple. Tubular member 735 has an opening (not shown) formed along the tubular member wall. For softer breasts 1, which are pulled into the tubular member 735 during the negative pressure stroke, the opening allows application of the negative pressure or vacuum to the distal end of the nipple 2.

Referring to Figs. 30 through 31, a contemporary breast cup 20 is shown which is connected to a vacuum source through a vacuum line 21. The contemporary breast cup 20 has a hood 22 that can engage the breast 1 and a cylindrical extension 23 attached to the hood. The cylindrical extension 23 is in fluid communication with the vacuum line 21 and a collection member 24. The vacuum or negative pressure is supplied from the vacuum line through the cylindrical extension 23 and to the areola 2. A separation wall 27 seemingly prevents the breast milk from entering the vacuum line 21. The evacuation of the air in cylindrical extension 23 creates a negative pressure gradient or force 30 during the negative pressure stroke, as represented in Fig. 31.

The negative pressure gradient or force 30 has a greater axial component A than lateral component L during the negative pressure stroke, causing the nipple 2 to be pulled or sucked axially more than laterally, which has been shown to be significantly less efficient at causing expression of breast milk from the milk ducts. The negative pressure

gradient or force 30 having a greater axial component A than lateral component L during the negative pressure stroke, has also been shown to be uncomfortable for the user. The vacuum or negative pressure is supplied axially from or in front of, nipple 2 during the negative pressure stroke or cycle, which causes discomfort associated with axial elongation and distention of the nipple.

While breast cup 400 uses a flexible insert 600 partially defining a displacement volume 510 that applies the negative pressure gradient, vacuum or force 10 to the nipple 2 during the negative pressure stroke or cycle, the embodiment contemplates the use of other designs and arrangements that create the negative pressure gradient, vacuum or force 10. Alternative designs for breast cup 400 that cause greater widening of the nipple along the lateral component L as opposed to elongation or distention of the nipple along the axial component A during the negative pressure stroke or cycle are contemplated. Also, alternative designs for breast cup 400 that apply a negative force to nipple 2 during the negative pressure stroke having an average lateral component L that is greater than the average axial component A are contemplated. Further, alternative designs for breast cup 400 that apply a negative pressure gradient or vacuum to nipple 2 during the negative pressure stroke having an average lateral component L that is greater than the average axial component A are contemplated.

While the preferred embodiment describes the use of a motorized pump 100 that supplies the pressure to breast cup 400, the use of manual pumps for use with breast cup 400 is contemplated, including pumping mechanisms that are affixed to breast cup 400. Additionally, other barrier structures, designs or methods are contemplated which reduce the negative pressure, vacuum or negative force applied to the distal end or front of nipple 2, and/or reduce the axial component A of the negative pressure, vacuum or negative force applied to the nipple 2, as compared to the lateral component L.

It is contemplated that a valve or other known release mechanism (not shown) in fluid communication with displacement volume 510 could be used so that a user could alternatively selectively control the amount of positive or negative pressure at the breast cup 400 rather than only at the breast pump 100. The valve or release mechanism on the breast cup 400 could also be a quick release mechanism as a safety feature in the event of discomfort to the user. The valve or release mechanism could also be used to selectively allow only positive or negative pressure to be generated at the breast cup 400.

The modularity of breast cup 400 through use of three separate pieces that can be easily assembled, i.e., housing 500, insert 600 and holder 700, allows a kit to accommodate breasts of varying sizes and shapes. The kit can include a plurality of differently sized housings 500 and inserts 600, as well as differently shaped housings 500 and inserts 600, to accommodate different sized breasts and different shaped breasts. The plurality of different housings 500 and inserts 600 can all be assembled to holder 700 and can be connected to breast pump 100. An example of the variation in sizes of housings 500 and inserts 600 includes the inner and outer diameters throughout the housings and inserts, as well as the length of the housings and inserts. An example of the variation in shapes of housings 500 and inserts 600 includes varying the taper angle, as well as changing the circular shape of the leading edge of the housing and insert. Additionally, the modularity and interchangeability allows for the use of different shaped or sized massaging members or projections 634 on different inserts 600.

A kit containing a plurality of differently sized or shaped inserts 600 that can all be assembled to housing 500 and holder 700, to form a plurality of different breast cups 400 for use with breast pump 100 is also contemplated. The plurality of differently sized inserts 600 can be used to accommodate different sized breasts and also to change the displacement volume 510. The plurality of differently shaped inserts 600 can be used to accommodate differently shaped breasts, as well as to provide different massaging effects to the breasts, such as, for example, different massaging members 634 formed on the

insert. Examples of some alternative inserts 600 are described more fully in copending U.S. Published Patent No. 20030149398, filed December 27, 2002, the disclosure of which has been incorporated by reference herein in its entirety.

While the preferred embodiment of the breast pump system uses breast cup 400 having a displacement volume 510 in fluid isolation from the user's breast, alternative breast cups can also be used with breast pump 100. The unique features of the breast pump system can be used with other types of breast cups, such as, for example, the control system or the rack and pinion driving mechanism.

Referring to Fig. 34, an alternative embodiment of the breast cup is shown and generally represented by reference numeral 5400. Breast cup 5400 is usable with insert 600. Breast cup 5400 has a funnel shaped housing 5500 that is connected to a cylindrically-shaped holder 5700. Holder 5700 has a handle 5725, a pressure orifice 5750, and a pressure adjuster 5775. Handle 5725 is ergonomically contoured and has a wave-like shape 5730 that provides for different holding angles. Handle 5725 is disposed along holder 5700 on the opposing side from funnel 5500. Handle 5725 is preferably made of, or covered by, a material that facilitates gripping. Handle 5725 can include various textures, projections and/or embossments to sooth the users hand during the pumping process.

Pressure orifice 5750 can be attached to tubing 350 to place breast cup 5400 in fluid communication with breast pump 100. Pressure adjuster 5775 is in fluid communication with pressure orifice 5750 and allows a user to adjust the pressure at the breast cup 5400 without having to make an adjustment at the breast pump 100. In this embodiment, pressure adjuster 5775 is a dial but alternative actuators can also be used.

Referring to Fig. 35, another alternative embodiment of the breast cup is shown and generally represented by reference numeral 6400. Breast cup 6400 is usable with

insert 600. Breast cup 6400 has a funnel 6500 that is connected to a holder 6700. Holder 6700 has handle portions 6725, 6726, a pressure orifice 6750, and a pressure adjuster 6775. Handle portions 6725, 6726 are disposed on opposing sides of holder 6700 and facilitate grasping of the holder. Handle portions 6725, 6726 are preferably made of, or covered by, a material that facilitates gripping. Handle portions 6725, 6726 can include various textures, projections and/or embossments to sooth the users hand during the pumping process.

Referring back to Fig. 12, holder 700 of breast cup 400 provides a first set of threads 701 and a second set of threads 702. First and second threads 701, 702 have different diameters and are sized to fit the two standard sized bottles or holders that are used with infant feeding and breast pumping, i.e., reusable containers and disposable containers. The first and second threads 701, 702 have the same pitch and are concentrically aligned. During the molding process, this allows the steel mold core to be unscrewed from holder 700.

While the embodiment illustrated shows the dual threads, i.e., first and second threads 701, 702 on breast cup 400, the use of the dual threads on other infant care products that require the use of a holder or bottle, such as, for example, a nipple ring or a cap is contemplated. Referring to Figs. 36 and 37, a nipple ring is shown and generally represented by reference numeral 7000. Nipple ring 7000 has a circumferential wall 7100 with an inwardly extending flange 7200 defining an opening 7250. Nipple ring 7000 has the dual threads described above, i.e., a first set of threads 701 and a second set of threads 702. The nipple ring 7000 provides for engagement of nipple 7500 with either reusable containers by way of first threads 701 or disposable containers by way of second threads 702. Preferably, first threads 701 downwardly extend from flange 7200 and second threads 702 are formed along circumferential wall 7100.

Referring to Figs. 38 and 39, a cap is shown and generally represented by reference numeral 8000. Cap 8000 has a circumferential wall 8100 connected to a top wall 8200. Cap 8000 also has the dual threads described above, i.e., a first set of threads 701 and a second set of threads 702. The cap 8000 provides sealing of either reusable containers by way of first threads 701 or disposable containers by way of second threads 702. Preferably, first threads 701 downwardly extend from top wall 8200 and second threads 702 are formed along circumferential wall 8100.

Referring to Fig. 13, T-connector 300 is a triangular shaped valve that allows a user to utilize either a single breast cup 400 or two breast cups through use of a first orifice 310 and a second orifice 320. Breast pump 100 is connected to t-connector 300 through air tubing 350 at inlet 330. The single split valve configuration of t-connector 300 minimizes the amount of tubing 350 necessary for double pumping. T-connector 300 has a plug 340 for closing off either of first or second orifices 310, 320 if single pumping is desired. Preferably, plug 340 is tethered to an outer surface of t-connector 300 to facilitate engagement with first or second orifices 310, 320.

Referring to Fig. 14, a method of expressing breast milk according to the breast pump system, is shown. The user commences the breast pumping operation by turning breast pump 100 "on," as in step 800. This causes power to be supplied to breast pump 100 (step 810). The user then inputs the cycle time and suction level that is desired, as in step 820. In the preferred embodiment, the user has five cycle times and suction levels from which to choose. The cycle time and suction level is inputted by use of button pad 105.

In step 830, PC board 120 sets the motor speed and target piston travel distance according to the user's inputted levels for cycle time and suction. The cycle time and suction level are then displayed to the user, as in step 840. In this embodiment, the cycle time and suction level are indicated by lights 225 with the number of illuminated lights

corresponding to the level. In step 850, motor 125 is actuated causing piston 112 to move toward bottom 175 of cylinder 113. This creates a positive pressure that is supplied to breast cup 400 by air tubing 350.

In step 855, the PC Board monitors the home switch to determine whether it has been triggered by contact with piston 112. In step 860, it is determined whether the home switch has been triggered. If the home switch has been triggered then it is reset as in step 870. In step 880, motor 125 is then reversed causing piston 112 to move toward top 180 of cylinder 113. This creates a negative pressure that is supplied to breast cup 400 by air tubing 350. One of the advantages of the breast pump system is that is supplies both a positive pressure and a negative pressure through the same air tubing 350. This reduces cleaning and simplifies the operation for a user.

To provide the proper amount of suction as inputted by the user, photo-sensors 121 count the number of rack openings 50, as in step 890. In step 900, PC board 120 determines if the number of rack openings 50 that have been counted is the equivalent of the target piston travel distance as inputted by the user. In step 910, it is determined whether breast pump 100 is still "on." If breast pump 100 has been shut off then the pumping operation ends, as in step 915.

In step 920, it is determined whether the user has inputted a new cycle time or suction level. If a new cycle time or suction level has been inputted, then PC Board 120 sets the motor speed and target piston travel distance according to the user's inputted levels for cycle time and suction, reverting back to step 830 and repeating the above described steps. If the user has not inputted a new cycle time or suction level then the motor is again reversed causing piston 112 to move toward bottom 175 of cylinder 113. This creates a positive pressure that is supplied to breast cup 400 by air tubing 350. The process continues with breast pump 100 supplying positive pressure and then negative pressure to breast cup 400 until the breast pump is shut off (step 910).

The breast pump system includes a number of components and can be used in remote locations, such as when a user is traveling. The various components can be disposed within a bag system for ease of use. An example of such a bag system, as well as the components of such a system, is disclosed in the co-pending and commonly owned U.S. Published Patent No. 20030149398, filed December 27, 2002, the disclosure of which is incorporated herein by reference.

The present invention having been thus described with particular reference to the preferred forms thereof, it will be obvious that changes may be made therein without departing from the scope of the present invention as defined in the appended claims.

WHAT IS CLAIMED IS:

1. A breast pump for expressing breast milk from a breast, the pump comprising:

a pressure source having a movable structure for generating pressure during a pressure stroke, said movable structure having a variable pressure volume or variable cycle time; and

a controller operably connected to said pressure source,

wherein said controller regulates said pressure volume based upon a distance traveled by said movable structure and regulates said variable cycle time based upon a speed of said movable structure, and wherein said controller provides substantially real-time monitoring of said distance traveled and said speed.

2. The pump of Claim 1, wherein said controller can regulate said pressure cycle based upon a non-sinusoidal wave signal of said pressure versus said variable cycle time.

3. The pump of Claim 2, wherein said non-sinusoidal wave signal comprises a square curve wave signal.

4. The pump of Claim 1, wherein said controller can regulate said pressure cycle based upon a sine wave signal of said pressure versus said variable cycle time.

5. The pump of Claim 1, wherein said pressure comprises both a positive pressure and a negative pressure.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
ElviePumpPCT		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/GB2018/051659	15 June 2018 (15-06-2018)	15 June 2017 (15-06-2017)
Applicant		
CHIARO TECHNOLOGY LIMITED		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 9 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language,** the international search was carried out on the basis of:
      ☒ the international application in the language in which it was filed
      ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (See Box No. II)

3. ☒ **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**
   ☒ the text is approved as submitted by the applicant
   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
   ☒ the text is approved as submitted by the applicant
   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**
   a. the figure of the **drawings** to be published with the abstract is Figure No. 1
      ☒ as suggested by the applicant
      ☐ as selected by this Authority, because the applicant failed to suggest a figure
      ☐ as selected by this Authority, because this figure better characterizes the invention
   b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2018/051659

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 31-72(completely); 73-158(partially)
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-6, 11-14, 108-119(completely); 158(partially)

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2018/051659

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/06
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M F04B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JP 2016 010524 A (MURATA MANUFACTURING CO) 21 January 2016 (2016-01-21) abstract figures 1-5,8	1-6, 11-14, 108-119, 158
X	US 2013/023821 A1 (KHALIL GAMAL [CH] ET AL) 24 January 2013 (2013-01-24) cited in the application page 3, paragraph 51-53 page 4, paragraph 66 - paragraph 69 figures 3-5,9-11	1-6, 11-14, 108-119, 158

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 September 2018	04/12/2018

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Kempeneers, Johanna

2

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2017/095599 A1 (KONDO DAISUKE [JP] ET AL) 6 April 2017 (2017-04-06) page 3, paragraph 55 - paragraph 57 page 7, paragraph 146 - page 8, paragraph 175 figures 1,15,16	1,2,4-6, 108, 112-114, 158
A	US 2016/271305 A1 (KURIHARA KIYOSHI [JP] ET AL) 22 September 2016 (2016-09-22) page 3, paragraph 51 - paragraph 56 page 4, paragraph 61 page 6, paragraph 91 - paragraph 93 figures 1,2,6	1,2,14, 118,158

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2018/051659

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
JP 2016010524 A	21-01-2016	NONE	
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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-6, 11-14, 108-119(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the piezo air-pump; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump.

1.1. claims: 2(completely); 158(partially)

A wearable breast pump system as in claim 1, configured as a self-contained wearable device with an internal rechargeable battery; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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2. claims: 7-10, 120-127(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the diaphragm.

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3. claims: 15, 27, 28, 30, 87-95(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the milk container; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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4. claims: 16, 29, 73-86(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the breast shield; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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5. claims: 17-19, 21, 23, 128-157(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features related to flow measurement and indication; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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6. claims: 22(completely); 158(partially)

A wearable breast pump system as in claim 1, in which the centre of gravity with an empty milk container attached to te housing is at or below (i) the half-way height line of the housing or (ii) the horizontal line passing through a nipple tunnel or filling point on a breast shield (so that

the device that is not top-heavy for a woman using the pump); A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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7. claims: 24(completely); 158(partially)

A wearable breast pump system as in claim 1, including a data sub-system that collects and provides data to a connected device or remote application or remote sensor; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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8. claims: 20, 25, 26, 96-107(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the pump (control); A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 31-72(completely); 73-158(partially)

The present application contains 158 claims, of which 44 are independent.

There is no clear distinction between several of the 44 independent claims because of overlapping scope. Various independent claims directed to subject-matter that does not (completely) overlap do not meet the requirements of unity of invention (Rule 13 PCT).

According to what can be understood from the description, it seems that a protection is sought after for several a spects of a breast pump system:

- wearability (including a housing shaped at least in part to fit inside a bra)
- technical features of the breast shield
- technical features of the milk container
- technical features of the pump and its control to improve user comfort
- the pump is specifically a piezo air-pump (possibly two piezo air-pumps in series or in parallel), and details thereof
- a separate deformable diaphragm to generate negative air pressure inside the breast shield, the diaphragm as such separating the (piezo) air-pump from the breast shield such that the (piezo) air-pump forms part of a closed loop system
- a flow measurement and milk volume indication means

The 44 independent claims are either directed to one of the above aspects, or to what appears to be an aleatory mix and match of two or several of these aspects.

Moreover, from the 114 dependent claims, 85 claims are dependent on any of the 41 independent claims directed to a "system" (as well as on any of the other dependent claims). They too are directed to one of the above aspects, or to what appears to be an aleatory mix and match of two or several of these aspects.

There are thus so many claims, and they are drafted in such a way that the claims as a whole are not in compliance with the provisions of clarity and conciseness of Article 6 PCT, as it is particularly burdensome for a skilled person to establish the subject-matter for which protection is sought.

The non-compliance with the s ubstantive provisions is to such an extent, that the search was performed taking into consideration the non-compliance in determining the extent of the search (PCT Guidelines 9.19 and 9.25).

The search was based on the subject-matter that is expected to be claimed later in the procedure, and the corresponding independent claim 1. Moreover, independent claim 158, directed to a method of expressing and collecting milk, comprising the step of using a system as defined in claim 1, has also been searched. Independent claims 31-72 and independent claim 158 when referring to any of the independent

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

claims 31-72 were not searched. Claims 73-157 when being dependent on any of claims 31-72 were also not searched.
Since the claims dependent on
claim 1 are not complying with unity of invention (Rule 13 PCT) (see non unity reasoning), the extent of the search was further limited to the technical features as claimed in claim 1 in combination with the first and second invention for which protection is sought, namely dependent claim 2 and the dependent claims further specifying details concerning the piezo air-pump (claims 3-6, 11-14, 108-119).

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

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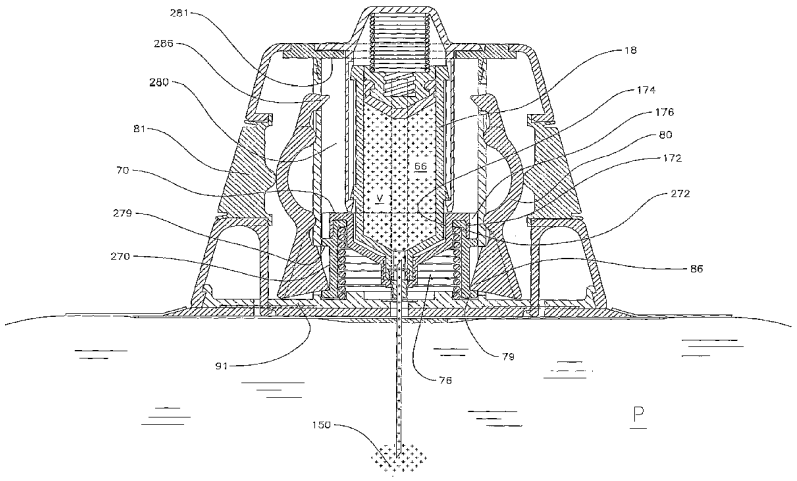
[Continued on next page]

(54) Title: INJECTION DEVICE FOR ADMINISTERING A VACCINE



(57) Abstract: A manually-powered injection device that self-administers a painless injection. The injection device provides a method for substantially painless injections of vaccine and other medication into a patient that does not require the use of an anesthetic, that does not require the medical personnel to spend a substantial amount of time performing the injection procedure, that is relatively simple and inexpensive to perform and operate, and that provides a relatively high degree of safety for both the medical personnel and for the patient. The injection needle can have an outside diameter greater than 0.10 mm and less than about 0.38 mm. The vaccine or other medicament can be injected painlessly through the needle and into the patient at a substantially constant volumetric flow rate of about 0.05 μL/s to about 50 μL/s, typically over a 3- to 5-minute period of time. The injection device is configured for easy handling, and is manuallypowered by the use of the hand or fingers of the medical technician, patient or other person.

WO 2005/079441 A2

Declaration under Rule 4.17:

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INJECTION DEVICE FOR ADMINISTERING A VACCINE

BACKGROUND OF THE INVENTION

[0001] The present invention relates to the injection of vaccines and other medication and, more particularly, to an injection device that can be used in a method for administering vaccine injections painlessly for a patient.

[0002] Conventional medical injection devices for injecting medication into the muscle or tissue of a patient typically comprise some form of a manual hypodermic syringe. Generally speaking, a hypodermic syringe consists of a cylindrical barrel having a chamber that provides a reservoir for a liquid medication, a distal end adapted to be connected to a hollow hypodermic needle and for placing one end of the needle into flow communication with the medication contained within the chamber, and a proximal end adapted for receiving a stopper and plunger assembly. The stopper and plunger assembly includes a stopper effective for moving along the barrel chamber and an elongated plunger effective for causing movement of the stopper. The needle of the hypodermic syringe is manually inserted into the patient through the skin. The stopper is moved along the barrel chamber by applying axial force to the plunger, thereby forcing the liquid medication out of the barrel chamber, through the hypodermic needle and into the muscle or tissue of the patient.

[0003] Receiving an injection by such a conventional device can be a very traumatic experience, particularly for a child. The child's fears, and that of the child's parent, can become a significant medical problem if it leads to the child not receiving a required vaccination. These fears are predominately caused by pain that is associated with injections given by conventional injection devices and methods.

[0004] We have found that the pain associated with an injection is related to the size of the needle and the flow rate at which the medication is injected. It has been found that the amount of pain or discomfort experienced by a patient increases as the outside diameter of the needle increases. It is believed that high flow rates of medication injection (e.g., about 0.5-2 ml per second) into the patient can tear internal tissue and cause pain. The tearing of tissue is caused by the build-up of excessive pressure within the tissue when the surrounding tissue is unable to quickly absorb the injected medication.

[0005] While the injection of a medication at a relatively slow flow rate is more comfortable for the patient, the increased amount of time the syringe remains in the hand of the medical personnel can make the technique tiring for such personnel as well as the patient. In addition, small vibrations or disturbances of the needle caused by movement of the medical personnel or the patient can result in pain to the patient. It is known that the fluctuation of flow rate of the injection of medication being delivered by a hand-held syringe can vary greatly. It is extremely difficult, if not impossible, to deliver a steady, very slow flow of medication from a hand-operated syringe (the human thumb depressing the syringe plunger) over an extended amount of time.

[0006] It has also been found that the sight of the hypodermic needle by itself is often enough to cause many patients to become anxious and tense. This reaction in turn may cause the patient's muscles to become tight and hard, making needle penetration even more difficult and painful.

[0007] A number of methods and devices have been developed for reducing or eliminating the pain and discomfort associated with medical injections. One such method includes the application of a topical anesthetic to the injection site on the patient's skin prior to the injection, which itself can be painful. While this method has reduced some of the discomfort associated with injections, the topical anesthetic does not substantially penetrate the skin into the deeper skin and muscle tissue, and can take significant time (up to 45 minutes) to show effects. Substantial pain and discomfort with intramuscular injections can remain.

[0008] Another technique for reducing the pain and discomfort associated with medical injections includes the step of injecting an anesthetic at the site of the injection using a fine gauge needle, then inserting the larger medication hypodermic needle through the anesthetized skin to inject the medication at a constant and slow flow rate intramuscularly at the desired depth. Unfortunately, injecting an anesthetic into a patient can be painful, and is not always desirable, and the technique is relatively expensive and impractical for many routine injection procedures.

[0009] In addition to reducing pain or discomfort to the patient, safety has also become a principal concern to medical personnel. Special precautions must be taken to avoid accidental needle sticks that could place a user at serious risk because of the danger from fluid borne pathogens. Despite the taking of special precautions, there still remains the possibility of an accidental needle contact and attendant injury.

Accordingly, medical injection devices should operate to minimize the possibility of injury caused by accidental needle sticks.

[0010] In recent years, increased emphasis has been placed on establishing treatment protocols aimed at providing a patient as well as medical personnel with greater freedom of movement. To this end, there is a great deal of interest in the development of light weight and easy-to-use portable injection devices.

[0011] Accordingly, a need exists for substantially painless method and an apparatus for performing the method of injecting medication into a patient that does not require the use of an anesthetic, that does not require the medical personnel to spend a substantial amount of time performing a particular procedure, that is relatively simple, portable and inexpensive to perform and operate, that permits the patient a relatively high degree of movement during the injection, and that provides a relatively high degree of safety for both the medical personnel and for the patient.

SUMMARY OF THE INVENTION

[0012] The present invention relates to an injection device that is manually-powered and configured for self-administering painlessly an injectable liquid composition, such as a vaccine or medicament. The device can be used in a method for providing a substantially painless injection of the injectable liquid composition to a patient that does not require the use of an anesthetic, that does not require the medical personnel to spend a substantial amount of time performing the injection procedure, that is relatively simple and inexpensive to prepare and operate, and that provides a relatively high degree of safety for both the medical personnel and for the patient.

[0013] The present invention further relates to a manually-powered injection device for self-administering painlessly an inter-muscular injection of an injectable liquid composition contained within a reservoir, comprising a) a housing having a base for semi-permanent attachment to the skin of a patient, b) an injection needle disposed substantially perpendicular to the base and within the housing, the needle having an injection end, and configured for axial movement manually between a first position wherein the injection end is within the housing and a second position wherein the injection end extends outwardly from the base to a distance sufficient for intramuscular insertion thereof, the injection needle having an outside diameter greater than 0.10 mm and less than about 0.38 mm, c) a means for retaining a reservoir for containing an

injectable liquid composition, d) a means for providing liquid communication between the retained reservoir and the injection needle, e) a means for injecting the injectable liquid composition from the retained reservoir through the needle.

[0014] The present invention also relates to a manually-powered injection device for self-administering painlessly an inter-muscular injection of an injectable liquid composition, comprising a) a housing having a base for semi-permanent attachment to the skin of a patient, b) an injection needle disposed substantially perpendicular to the base and within the housing, the needle having an injection end, and configured for axial movement manually between a first position wherein the injection end is within the housing and a second position wherein the injection end extends outwardly from the base to a distance sufficient for intramuscular insertion thereof, the injection needle having an outside diameter greater than 0.10 mm and less than about 0.38 mm, c) a reservoir for containing the injectable liquid composition, d) a means for liquid communication between the reservoir and the injection needle, and e) a means for injecting the injectable liquid composition from the reservoir to the needle.

[0015] The present invention also provides an improved cartridge for use in a self-administering injection device, that comprises separate and spaced-apart filling and dispensing ports, and which allows a dispensing plunger to ascend within the cartridge during the injection in a direction toward the filling port. This can provide a visual signal when the distal end of the plunger approaches the filling end of the cartridge, at the completion of the liquid composition injection.

[0016] In typical embodiments of the present invention, the needle is affixed to a needle carriage that is configured for axial movement between a first position associated with the first position of the injection needle, and a second position associated with the second position of the injection needle, in response to the manual force applied by the person. Upon manual insertion of the needle, a needle insertion securement secures the carriage in the second position the liquid composition is injected. The device is typically employs a manually-powered spring that is compressed during the manual needle insertion, which exerts pressure upon the injectable liquid composition within the retained reservoir. The needle carriage and the reservoir comprise cooperating threads that can engage and retain the reservoir within the carriage, and which can cause penetration of a penetrable membrane in the reservoir by the inlet end of the injection needle to establish liquid communication there between. At the end of the injection

cycle, a needle retracting means can be activated, typically manually, to retract the injection needle, whereby the injection end of the needle is retracted from its second position in the body to a third position wherein the injection end of the needle is within the housing. The needle retracting means can employ a disengagement means configured to disengage the needle insertion securement from the needle carriage, and a power means configured to bias the needle carriage to the third position. An implement, such as a plunger or stem, can be used in place of the finger or hand to apply the manual insertion force to the needle carriage. The device can also comprises a separable base, a base securement means configured for separable securement of the separable base to the housing, and a base separation means configured for separation of the separable base from the housing, wherein the separable base comprising an adhesive for attachment thereof to the skin of the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Figure 1 shows a cross-sectioned elevation view of a housing of a manually-powered painless injection device of the present invention in an extracted position, taken through line 1-1 of the housing shown in Figure 4.

[0018] Figure 2 shows the cross-sectioned elevation view of Figure 1 of the housing in an inserted position.

[0019] Figure 3 shows a cross-sectioned elevation view of the housing shown in Figure 4, taken through line 3-3 of Figure 4.

[0020] Figure 3A shows a detailed cross-sectional view of the housing of Figure 3.

[0021] Figure 4 shows a top plan view of the housing of the manually-powered painless injection device.

[0022] Figure 5 shows a cross-sectioned elevation view of the housing of Figure 4, taken through line 5-5.

[0023] Figure 6 shows a cross-sectioned elevation view of the housing of Figure 4 taken through line 6-6.

[0024] Figure 7 shows a cross-sectioned plan view of the housing of Figure 1, taken through line 7-7.

[0025] Figure 8 shows a cross-sectioned plan view of the housing of Figure 1, taken through line 8-8.

[0026] Figure 9 shows an exploded cross-sectioned elevation view of the elements of the housing of Figure 1.

[0027] Figure 10 shows a cross-sectioned elevation view of a syringe cartridge of a manually-powered painless injection device of the present invention in an extended position, taken through line 10-10 of the syringe cartridge shown in Figure 12.

[0028] Figure 11 shows a cross-sectioned elevation view of the syringe cartridge in an extended position, taken through line 11-11 of Figure 12.

[0029] Figure 12 shows a plan view of the syringe cartridge of Figure 10.

[0030] Figure 13 shows a detailed cross-sectional elevation view of the syringe cartridge of Figure 10.

[0031] Figure 14 shows another detailed cross-sectional elevation view of the syringe cartridge of Figure 10.

[0032] Figure 15 shows a plan view of the syringe cartridge shown in Figure 14.

[0033] Figure 16 shows a cross-sectioned plan view of the syringe cartridge of Figure 11.

[0034] Figure 17 shows a bottom plan view of the syringe cartridge of Figure 11.

[0035] Figure 18 shows an exploded cross-sectioned elevation view of the elements of the syringe cartridge of Figure 10.

[0036] Figure 19 shows a cross-sectioned elevation view of the syringe cartridge of Figure 10 containing an injectable liquid composition in a pressurized position.

[0037] Figure 20 shows a cross-sectioned elevation view of the housing and a separable base assembly prior to its attachment to the housing, and of a syringe cartridge prior to its installation into the housing.

[0038] Figure 21 shows the housing and syringe cartridge of Figure 20, with the housing being affixed to a patient's skin.

[0039] Figure 22 shows the syringe cartridge being installed into the housing of Figure 21.

[0040] Figure 23 shows the syringe cartridge being force into an inserted position within the housing.

[0041] Figure 24 shows the syringe cartridge in the inserted position within the housing, injecting the liquid composition.

[0042] Figure 25 shows the syringe cartridge in the inserted position within the housing, at the completion of the liquid composition injection.

[0043] Figure 26 shows the syringe cartridge in the inserted position within the housing of Figure 25, being manipulated to retract the needle.

[0044] Figure 27 shows the syringe cartridge and housing of Figure 26, with the needle retracted.

[0045] Figure 28 shows the housing and the syringe cartridge of Figure 27 being removed from the separable base that remains attached to the patient.

[0046] Figure 29 shows a top plan view of another embodiment of the invention, of a device having a housing that can accommodate two syringe cartridges.

[0047] Figure 30 shows an elevation view of the device of Figure 29.

[0048] Figure 31 shows a cross-sectioned elevation view of the dual-syringe device of Figure 29 taken through line 31-31.

[0049] Figure 32 shows a separable base assembly having an adhesive flap for use in attaching the device of the present invention to the skin of a patient.

[0050] Figure 33 shows a cross-sectioned elevation view of the separable base assembly of Figure 32 through lines 33-33.

[0051] Figure 34 shows a detailed cross-sectioned elevation view of the separable base assembly of Figure 33.

[0052] Figure 35 shows another detailed cross-sectioned elevation view of the separable base assembly of Figure 33.

[0053] Figure 36 shows a cross-sectional plan view of a base shown in Figure 22 through lines 36-36, which has been modified to provide blocking plate that is in a deployment position to allow needle deployment.

[0054] Figure 37 shows a cross-sectional elevation view of the base of Figure 36.

[0055] Figure 38 shows a cross-sectional plan view of the base of Figure 36, which is in a blocking position to prevent needle deployment.

[0056] Figure 39 shows a cross-sectioned elevation view of an alternative embodiment of the device having an improved means for establishing liquid communication between the injection needle and the reservoir.

[0057] Figure 39A shows a detailed cross-sectional view of the device of Figure 39.

[0058] Figure 40 shows cross-sectioned elevation view of an alternative embodiment of a syringe cartridge in a first configuration.

[0059] Figure 41 shows the syringe cartridge of Figure 40 is a second configuration.

[0060] Figure 42 shows cross-sectioned elevation view of an alternative embodiment of the injection device having a means for selectively restraining the axial movement of the needle carriage.

[0061] Figure 42A shows a detailed cross-sectional view of the device of Figure 42.

[0062] Figure 43 shows cross-sectioned elevation view of another alternative embodiment of a syringe cartridge.

[0063] Figure 44 shows cross-sectioned elevation view of an alternative embodiment of the device having a needle retracting means.

DETAILED DESCRIPTION OF INVENTION

Definitions:

[0064] As used herein, "patient" means a mammal, including a person, including a child or infant, or an animal, typically a mammal, on which the device is attached, and into whom the device injects an injectable liquid composition.

[0065] As used herein, unless specified otherwise, the phrase "manually powered" means that the power provided to the device of the present invention to at least insert the injection needle into the patient's body is provided manually by a person, including a medical technician (a nurse, doctor, or other person who can administer the injection) or a patient, by manipulating the injection device with the hands or fingers, or by manipulating an appropriate implement that interacts with the device.

[0066] As used herein, unless specified otherwise, the term "self-administering" describes the ability of the device of the present invention to be held or to hold itself in a position attached to the skin of a patient by a securement means, without requiring a medical technician, the patient, or other person, to hold the device, during the time that an injectable liquid composition contained within the device is injected into the patient through the injection needle.

[0067] As used herein, unless specified otherwise, the term "upward" means in a direction or oriented away from the patient's skin or the base of the device; the term "downward" means in a direction or oriented toward the patient's skin or the base of the device; the term "inward" means in a direction or oriented toward the centerline of the device, typically the needle; and the term "outward" means in a direction or oriented away from the centerline of the device.

[0068] The manually-powered, self-administering injection device of the present invention typically comprises a housing, an injection needle, a reservoir for containing an injectable liquid composition, such as a vaccine or a medicament, and a plurality of elements associated with and at least semi-permanently attached to the housing. The other associated elements can also include the various means of providing power or energy for the functional operations of the device, such as the insertion and retraction of the injection needle, and the pumping or injecting of vaccine to the injection needle. Typically, these associated elements are contained within the confines of the housing, although these elements can also partially confront or penetrate through the outer surface of the housing.

[0069] In the course of administering most injections of vaccines and other medicaments, the injection can be advantageously administered intramuscularly (that is, into the muscle). The injection is made with an injection needle that is configured for insertion through the outer layer of the patient's skin, and more typically into the muscle tissue of the patient. Typically, the depth of insertion is at least about 5 mm, and typically up to about 35 mm or more, more typically from about 10 mm to about 25 mm, and even more typically from about 15 mm to about 20 mm. For a young child or infant, the depth of insertion is typically from about 10 mm to about 25 mm, more typically from about 12 mm to about 15 mm. Alternatively, some injections can be administered intradermally, or into other internal organs or the general body cavity of the patient.

[0070] Painless injections can be achieved when the size or diameter of the injection needle is minimized, typically by using a needle of gauge size 28 or small (typically up to gauge size 33), and when the injectable liquid composition, such as a vaccine or other medicament, is injected at a volumetric flow rate significantly lower than that of a conventional injection made by hand, typically less than about 50 microliter per second (μL/s) and more typically about 1-4 μL/s. To achieve such low flow rates when administering a typical injection dose of between 0.5 ml to about 1.0 ml, an injection time of about 3 to 5 minutes may be needed. Typically, the human hand, using a conventional syringe, can not accurately or reproducibly control the flow rate within a range that ensures a painless injection. Furthermore, the desired slower injection rate of the medicament would require that the medical technician (or the patient) hold the conventional syringe carefully in place against the skin of the patient, and that the

patient not move the limb or body part that is the site of the injection while the injection is being administered. The present invention overcomes these problems by providing a self-administering device that remains in position on the skin of the patient at the injection site, and administers the injection of the injectable liquid composition, without requiring a medical technician or patient to hold the injecting device in its place by hand, and without requiring that the patient remain still and not move while the injection is being administered. These problems are particularly troublesome when the patient is an infant or young child.

The manually-powered device of the invention is intended to be attached semi-permanently to the skin of the patient before, during or after the injection. The device is typically configured to be attached to the upper arm or to the thigh area, providing access to the larger skeletal muscles (the deltoids and the quadriceps) for intramuscular injection. The attachment is preferably semi-permanent, whereby the device can be removed reasonably easily from the skin. The device is configured to attach to the body of the patient so that it does not move or migrate along the surface of the skin after attachment. In many situations, an adhesive attachment is sufficient. Alternative attachment means can include strapping, such as with a buckle strap or with a "hook and loop" attachment means commonly referred to as "Velcro", or cuffing, as with a sphygmomanometer cuff. In an other alternative embodiment, a portion of the device, such as a bandage associated with the device or a portion of the base of the housing, can be configured to remain affixed to the patient's skin after the housing of the device has been removed.

[0071] A typical adhesive for securing the device directly to the skin is a pressure sensitive adhesive (PSA). The direct-attaching PSA and the base where the PSA is affixed are typically configured whereby the PSA adheres to the device more strongly than the PSA adheres to the skin. The PSA is typically permanently affixed to the device, such that no PSA will remain adhered to the skin of the patient when the device, or at least the housing portion of the device, is removed from the skin. The PSA is also selected for a secure though releasable affixment to the skin. These criteria ensure that the device, or at least the bandage or base portion of the device, can be securely affixed to the skin for the vaccination procedure, and can be safely and efficiently removed from the skin thereafter.

[0072] Typically, the manually-powered device having a skin-attaching PSA will also include a release member, such as a release paper or film, which overlies the adhesive on its skin-contacting side. After the release member is peeled from the PSA, the exposed adhesive layer can be placed against the patient's skin to attach the device thereto.

[0073] A main objective for initiating the development of the present injection was effecting a painless injection of injectable liquid compositions. While pain can be a relative experience, typically the painless device of the present invention will, after having been secured to the skin of the patient, effect the insertion of the injection needle and injection of the injectable liquid composition into the body without a sensation or feeling of pain, and more typically without any sensation or feeling whatsoever. In other words, the patient in most circumstances will have no sensation that the device has inserted a needle into the body, or that the injectable liquid compositions is or has been injected into the body, except perhaps visually observing the device or touching the device with a hand, or feeling the attachment of the device to the outside of the skin.

[0074] Typically the manually-powered device is configured to complete the vaccination or injection of medicament into the patient utilizing a source of power or energy that is external to the device itself. The source of power can be provided by a person, such as a medical technician (a nurse, doctor, or other person who can administer the injection) or the patient, typically by manually (or bodily) manipulating the injection device with the hands or fingers, or by using an appropriate implement, as hereinafter described. The self-administering feature of the device and method of the invention enables injection of injectable liquid compositions without requiring medical personnel to hold the device against the skin of the patient during the time that the injectable liquid composition is in liquid communication with the needle, and is being pumped from the device into the patient. The use of the device that self-administers an injection allows medical personnel to perform other tasks while the injection proceeds. The device also allows the patient to have freedom of movement for the minutes of time that the injection proceeds. Typically, the source of power for arming the manually-powered device from its unarmed configuration comprises a manual power. This can be the use of the hands or fingers of a technician or an adult patient to manipulate the device or elements thereof with force. The manipulating force can also be applied using an implement, such as a key, push rod, or other inanimate object. The manually-applied

kinetic force is stored by a power means within the device as potential energy, which can, upon subsequent activation, power one or more of the functions of the device. Typically, the external force used for the needle insertion function can also be used to store potential energy within the device, such as in a compressed spring or other biased resilient member. The external force can also be stored as electrical power or pneumatic power.

[0075] Typically, the device is manufactured and shipped to a use center, such as a clinic or hospital, with the needle insertion function in a first unarmed configuration. The unarmed configuration provides that the injection needle, which in its first position has it's the distal end or tip of the injection needle wholly within the housing, can not be intentionally or accidentally extended to a second position wherein the injection tip extends through the base of the device and outside of the device. In the unarmed configuration, there is typically no potential energy source, such as a compressed wire spring, available to the needle insertion means for spontaneous insertion of the needle. The unarmed condition can also be termed a fail-safe position, since, in this configuration, even a malfunction of the device will no allow the needle to extend from the housing. By contrast, if the needle insertion means is armed, then the device has potential energy stored on board, such as in a compressed, extended or torsioned spring, or other power means for insertion of the needle. If this armed device is activated, such as when an actuation button is depressed, the potential energy of the power means is released as kinetic energy that can move the needle insertion means from its first position to its second, extended position. If the device is shipped, stored, or handled in an armed configuration, there is a risk of an inadvertent, or even an intentional, activation of the needle insertion means. Consequently, the shipment and handling of the manually-powered device of the present invention in an unarmed configuration can avoid both an intentional and accidental needle sticks prior to its use in administering an injectable liquid composition. This improves the safety and security of the device during, storage, and pre-injection handling. In this configuration, at least the needle extension function (also called the insertion function when the needle tip extends into the skin of the patient) is unarmed.

[0076] Other functions, such as the pumping or injection means (for passing the injectable liquid composition through the injection needle) and the needle retracting means (to withdraw the needle from its second position in the body, back toward its first

position in the housing) can be configured for shipment and storage as either armed or unarmed. Preferably, the power means for the pumping means has an unarmed configuration, to avoid an accidental activation of the pumping of injectable liquid composition from the reservoir, which could prematurely empty the reservoir and render the device useless. Likewise, any needle retracting means is preferably shipped and stored in an unarmed configuration, to avoid the possibility of an unintentional or accidental activation, which in some embodiments may make the opposing needle insertion function inoperable, where the needle retraction is irreversible.

[0077] The power means can be used to provide energy to one or more of the elements of the device, such as insertion and retraction of the injection needle, or pumping of the medicament. Two or more power means can be used to provide energy for different elements, such as where the injection needle is moved from one position to another by a first power means, and an injectable liquid composition is pumped from a reservoir to the injection needle by a different, second power means.

[0078] The device can be at least partially self-controlled, wherein at least one of the elements of the device can initiate operation automatically in response to the operation of another element.

[0079] The typical device of the present invention has a housing comprising a base for placement against the skin of a patient, for attachment of the device. The base can have a contoured surface that generally conforms to the shape of the body (typically, the arm or leg), to maintain the base surface in optimum confronting relationship with the skin. For example, the base of the device can have a slightly concave surface, which arches inwardly toward the interior of the housing.

[0080] The housing is typically made of a thermoplastic material that is light and inexpensive to manufacture, such as by molding, and yet is durable and resilient to gross deformation or breakage. A typical plastic material can include polyethylene, polypropylene and polycarbonate. The housing can be designed with a shape that is both aesthetically pleasing and functional, for example, to allow insertion of the reservoir, to allow activation of one or more of the elements, such as the injection needle and liquid communication means, and other elements of the device. The housing can be made as a single part or as a plurality of parts configured to associate and secure together in both either static or moving relation to one another.

[0081] The housing also provides a visual enclosure for the injection needle that keeps the needle out of sight of the patient at all times during the injection procedure. This can reduce or eliminate the patient's apprehension or fear caused by the sight of a needle, thereby reducing the tendency of the patient's muscles to tighten and harden, which can make needle penetration more difficult and painful for the patient.

[0082] The housing also provides a physical enclosure for the injection needle that helps to avoid accidental needle stick, particularly after an injection, which could place a user at serious risk from fluid-borne pathogens. The device can be configured for use only once (unless completely disassembled and retrofitted), thereby minimizing the likelihood of reuse of a contaminated hypodermic needle. The device can also advantageously be configured wherein some parts or assemblies, such as the housing and it associated elements, can be reused.

[0083] The housing can also be configured to receive and secure the needle and optionally the reservoir of injectable liquid composition as a modular insert into the housing body. The housing can include two or more parts, at least one of which is movable relative to another, which can be configured into an open position wherein either the needle or the reservoir, or both, can be inserted into the body of the housing, or a closed position wherein the needle and/or reservoir are not accessible or retrievable from within the housing. The movable part can be a door or a panel that is movable to provide an access port into the housing. The door or panel can be hinged or removably affixed to the housing, or can be slidable away from the access port.

[0084] The injection needle of the device provides for liquid communication of the injectable liquid composition passing from the reservoir and through other liquid communication means of the device, into the body tissue of the patient, from where the injectable liquid composition can dissipate into the surrounding tissue and throughout the body. The injection needle should be shaped and configured to provide painless insertion and painless injection of the injectable liquid composition. Generally an injection needle having a smooth circular outer surface and an outer diameter D of about 0.36 mm (28 gauge needle) and less can be inserted painlessly through the skin of a patient. For small children, infants and patients having more sensitive skin, an outer diameter D of about 0.30 mm (30 gauge needle) and less (31 gauge to 33 gauge), will typically ensure painless needle insertion.

[0085] Typically the injection needle is configured to be substantially linear or straight, from its distal end or tip, toward the opposed inlet opening. The needle can be configured to be linear completely to its inlet end, or can be configured with a bent or curved portion near the inlet opening.

[0086] The needle size should be sufficiently large to allow passage of the required volume of liquid medicament into the body within a period of time that is suitable to avoid causing pain. For a typical medicament volume of about 0.5 ml to about 1.0 ml, a substantially painless to completely painless injection can be achieved over an injection period of from about 1 minute to about 10 minutes, more typically from about 3 minutes to about 5 minutes. The volumetric flow rate is at least about 0.05 microliter per second (μL/s), and up to about 50 μL/s. Typically, the volumetric flow rate is about 0.5 μL/s to about 20 μL/s, and more typically about 1 μL/s to about 4 μL/s. The injection needle should be sufficiently durable and axially rigid to avoid bending or breaking when inserted into the skin and muscle. Typically, a needle having an outer diameter of from about 0.10 mm (about 36 gauge), more typically of from about 0.23 mm (32 gauge), up to about 0.36 mm (28 gauge), is sufficiently painless, durable, and liquid conductive.

[0087] It is also within the practice of the device and method of the present invention to inject medicament volumes of greater than about 1.0 ml, and to deliver the injection over time periods greater than 10 minutes.

[0088] Typically, the injection needle is pre-installed into the injection device during its manufacture, prior to its distribution to the facility or site where the injection shall occur. Although the device can be configured for installation of the injection needle at the use facility, the small, fine size of the injection needle may make it difficult for a medical technician or patient to manipulate it into position within the device. Likewise, after a vaccination, the injection needle and the housing or assembly thereof into which the needle is secured, can be disposed of in accordance with health and safety regulations and guidelines.

[0089] The injectable liquid composition is typically contained within the cavity of the reservoir, and flows from the reservoir to the injection needle during injection. The reservoir is typically positioned within the housing although the structure of the reservoir can also form a portion of the outer surface of the housing. The reservoir can have a rigid structure having a fixed volume with a moveable member, such as a plunger that defines a variable volume cavity. The reservoir can also have a flexible

structure where its volume can decrease as its content of injectable liquid composition is removed there from. Typical materials for use in making the reservoir include natural and synthetic rubber, polyolefin, and other elastomeric plastics. The selection of the structure and material of construction of the reservoir will depend in part on the specific means of pumping the medicament from the reservoir to the injection needle. Selection of the material of the reservoir should also be chemically stable with the injectable liquid composition. In another typical embodiment, the reservoir can be affixed to the injection needle as part of a injectable liquid composition product, for assembly into the device. A reservoir will generally have a volume sufficient to contain about 0.1 ml to about 10 ml, typically about 0.1 ml to about 3 ml, of medicament. In a more typical embodiment, the reservoir would hold about 0.5 ml to about 1.0 ml of medicament.

[0090] The reservoir comprises an outlet port that is in liquid communication with, or can be brought into liquid communication with, the injection needle. The reservoir outlet can be temporarily sealed, such as with a penetrable membrane that can provide an air-tight and leak-proof seal over the outlet opening of the reservoir during manufacture, shipment and storage of the filled reservoir, and that can provide a self-sealing, leak-proof joint when pierced by the inlet end of the needle or a separate piercing conduit at the time of the injection. A typical reservoir membrane comprises natural or synthetic rubber or a thermoplastic material. Alternatively, a wall of the reservoir can be adapted to allow penetration thereof by the piercing conduit, such as the inlet end of a needle.

[0091] A typical embodiment of a reservoir comprises a reservoir body having a cavity that has been pre-filled with the injectable liquid composition and sealed. The pre-filled reservoir can be assembled into the device during manufacture. In this case, the device is labeled to identify the particular injectable liquid composition that is contained therein.

[0092] More typically, pre-filled reservoir will be configured for installation or insertion into the housing of the injection device at the facility or site where the injection will occur. The technician would typically remove the reservoir from a storage area, such as a refrigerator, and insert it into position within the housing of the device. An identity label associated with the reservoir can be provided that is conveniently transferred to the patient's records.

[0093] Alternatively, a device can have secured within an empty reservoir can be filled by medical personnel with the appropriate quantity and type of medicament, prior to injection. Typically, this embodiment of the reservoir comprises a liquid flow valve that has a self-closing, self-sealing opening to the cavity of the reservoir. The flow valve can be a one-way flow valve, also referred to as a check valve. The liquid composition flow valve is typically an elastomeric or rubber material.

[0094] One type of one-way flow valve is a flapper or so-called duckbill valve (available from MiniValve International Yellow Springs, OH) that allows flow of liquid in one direction, but which self-seals in response to liquid flow or pressure in the opposite direction. Another type of one-way flow valve is a cylindrical member having a slit opening formed axially there through, through which a hypodermic needle of a syringe is inserted to inject a desired dose of the liquid composition into the cavity of the reservoir. When withdrawn, the slit opening closes and seals. When the device is used by medical personnel as supplied from a manufacturer with the reservoir securely inserted within the housing, the device can have a companion flow valve in communication with the reservoir flow valve that is disposed in the outer surface of the housing, or otherwise accessible to the medial personnel. The liquid composition flow value can be inserted into a bore formed in the sidewall of the reservoir that is slightly smaller in diameter than the flow valve.

[0095] If the reservoir is configured so that a portion of the reservoir is integral with the housing, then a single flow valve can be used, with an inlet accessible to the medical technician and an outlet into the cavity of the reservoir. Alternatively, the device can be configured with a second liquid composition flow valve positioned in the housing, disposed adjacent to and aligned with the first flow valve disposed in the reservoir.

[0096] An important requirement of the liquid communication means is to ensure that the liquid composition can flow from the reservoir to the injection needle regardless of the specific orientation of the device. Typically, the attachment of the device to the skin of the patient can position the reservoir and the injection needle into a variety of relative spatial orientations that can sometimes require the liquid composition to flow upward against gravity, or that can position the outlet of the reservoir in an upward position, opposite the pool of liquid composition disposed in the reservoir.

[0097] Consequently, a preferred configuration of the reservoir and liquid communication means provides that the outlet of the reservoir is maintained in

communication with the remaining liquid composition in the reservoir. A typical configuration comprises a collapsible reservoir comprising an outlet that maintains liquid communication with any residual liquid composition present in the reservoir. This reservoir has an upper flexible wall that can be conformed to the volume of the liquid remaining therein. The reservoir typically contains little or no air or gas when filled with the supply of liquid composition and during its displacement and injection operation. Thus, the reservoir collapses to become essentially empty, terminating delivery. In like manner, when a non-flexible material is used for a reservoir, such as a conventional tube-with-plunger syringe, the displacement of the plunger empties the reservoir, which terminates delivery.

[0098] The housing can also comprise an outer support structure that confines and protects the reservoir from outside elements that might puncture it, and which can define the initial shape of the reservoir.

[0099] The reservoir can also be constructed of an elastomeric material that can be expanded in volume when filled with the liquid composition, and holds the liquid composition under pressure. After puncture by a piercing conduit, such as the inlet end of the injection needle or an intermediate member that is in liquid communication, such as via tube, with the injection needle, the expanded reservoir can contract to reduce the effective volume of the reservoir as liquid composition is pumped there from. One or more of the walls of the reservoir can be made of an elastomeric material, while other walls or surfaces are made of other elastic or inelastic rubber or plastic material.

[0100] The reservoir can also comprise an adaptable structure having a means of varying its effective volume, such as a piston-plunger construction or an accordion construction, as in a bellows. In the embodiments described herein, a self-contained reservoir can be replaced with a more conventional syringe and plunger for storing and injecting the liquid composition to the injection needle.

[0101] Non-limiting examples of a reservoir of the present invention are those described in US Patent 5,527,288 (element 10), US Patent 5,704,520 (element 12), and US Patent 5,858,001 (elements 16 and 17), all such publications incorporated herein by reference.

[0102] A first embodiment of the invention is shown in Figures 1-3, 3A, and 4-28. The device includes a housing, shown in Figs. 1-3, 3A, and 4-9, and a cylindrical syringe cartridge shown in Figs. 10-19. The use and operation of the device for

manually self-administering a painless injection is illustrated in Figs. 20-28. A device having a housing for retaining a plurality of cylindrical syringe cartridges is shown in Figures 29-31. Figures 32-25 show a separable base and means for attaching the device to a patient's skin.

[0103] Figures 1-8 show an assembled housing 10 in various views and aspects. Figure 1 shows the housing 10 having an outer body 11, a needle carriage 70, a means for retaining a reservoir for an injectable liquid composition, and a base 12 for placement of the device against the skin of a patient. The carriage 70 is configured for movement along an axial centerline 100 in a direction perpendicular to the base 12. The cylindrical carriage has a cylindrical recess 71 having a tapered bottom 78, that opens to a connector portion 73 having internal female threads, which provide the at least a portion of the retaining means for the reservoir, described below. A needle 40 lies along the centerline 100 and is disposed through the axial center of a needle hub 72 that is secured to the connector 73. The inlet 42 end of the needle 40 extends within the connector portion 73 sufficiently below the opening in the tapered bottom 78 to prevent the sticking of a finger that may probe the recess. A retracting spring 76 is positioned about the centerline 100, having one end disposed within an annular groove 74 in the underside of carriage 70, and the other end disposed around an annular flange 94 projecting up from the base 12. The needle 40 extends downward from the lower end of the needle hub 72 toward the base 12. The needle is completely within the housing when the carriage 70 when in the first retracted position shown in Figure 1.

[0104] As will become more evident, the retracting spring 76 disposed as shown in Figs. 1, 3, and 20 should have an amount of pre-tensioning or compression that is sufficient to completely retract the carriage 70 back to the top of the housing 10 when the needle 40 is retracted from the body.

[0105] In a second inserted position, shown in Fig. 2, the carriage 70 has moved axially toward a position proximate to the base 12 of the device, and the needle 40 extends downwardly and out through the opening 13 in the base. The guide wall 14 comprises an inwardly-projecting, axially-oriented guide, shown as elongated rib 19, that registers along its length with an axially-oriented peripheral groove 77 in the outer wall 75 of the carriage 70, shown in Figure 3, to prevent the carriage 70 from rotating within the guide wall 14. A retainer heel 86 is biased inward from an opening in the cylindrical guide wall 14. As the carriage 70 passes down the guide wall 14, the heel

86 is temporarily biased outward, allowing the carriage to pass. The retracting spring 76 is compressed between the underside of the carriage 70 and the base 12. When the carriage arrives at the fully inserted position shown in Fig. 2, the lower end flange 79 of the carriage has cleared past the heel 86, which returns to its inwardly-biased position, where it can secure the carriage 70 and the needle 40 in the inserted position, and secures the retracting spring 76 in a compressed state. The heel 86 is part of a release arm 80, described herein after.

[0106] Figure 4 shows a plan view of the housing 10 in its first retracted position, with selected cross-sectional views taken as Figures 1, 3, 5, and 6 to illustrate certain elements of the housing. Figures 7 and 8 are sectional views of the housing in Figure 1. An exploded view of the elements of the housing 10 is shown in Fig. 9.

[0107] Figs. 10 and 11 are sectional views of the syringe cartridge 18 taken through perpendicular section lines 10-10 and 11-11 of Fig. 12. Figs. 13-17 provide additional detailed views of the syringe cartridge 18 shown in Figures 10 and 11. Figure 18 shows an exploded view of the elements of the syringe cartridge 18.

[0108] The syringe cartridge 18 shown in Figures 10 and 11 comprises a syringe assembly 20 and a telescoping pressurizing assembly 30, configured as a reservoir having liquid cavity 66 for the injectable liquid composition. The syringe cartridge 18 is configured to be associated with and retained within the housing 10 of the device. In the illustrated embodiment, the cylindrical recess 71 of the needle carriage 70 provides the means for retaining the reservoir of injectable liquid composition, embodied by the syringe cartridge 18. The syringe assembly 20 comprises a syringe body comprising a cylindrical wall 21 that has an open upper end 25 and a tapering base 22 that has, at the lower end, an externally-threaded syringe port 64 having an aperture 23. A cylindrical plunger 24 can be inserted through the opening in the upper end 25 for engagement with the inner surface of the wall 21. The space between the plunger 24 and the syringe body in Fig. 10 defines the reservoir cavity 66. The respective threads of the syringe port 64 of the syringe cartridge and of connector portion 73 of the needle carriage cooperate and engage when the syringe cartridge is placed into the needle carriage and rotated, which secures or locks the syringe cartridge into its retained position within the needle carriage. The cooperating threads also provide liquid communication between the injection needle and the reservoir of the syringe cartridge, as the inlet 42 end of the

needle advances and penetrates a membrane 65 of the membrane plug 67 disposed in the opening of the syringe port 64 (see Figure 14).

[0109] The plunger 24 is typically a flexible, resilient rubber material that can form an effective liquid seal about its periphery with the sidewall 21 of the syringe. The plunger 24 is secured around a rigid plunger plug 26 to maintain its cylindrical shape. As can be seen in greater detail in called-out Fig. 13, the inner surface of the syringe wall 21 has, at its upper end, a slight inwardly-extending rim 38 that can engage the upper end of the outer wall 43 of the plunger 24, which can prevent the plunger 24 from incidentally withdrawing from and falling out of the upper opening of the syringe wall 21. Nevertheless, the plunger wall 43 is sufficiently flexible to be inserted into or extracted out of the syringe opening by force. The threaded bore in the plunger plug 26 is provided for attachment of a stem (not shown) having a mating thread so that the plug 26 and the plunger 24 secured thereto can be manipulated into and out of the syringe opening, and along the length of the syringe.

[0110] The telescoping pressurizing assembly 30 comprises a cylindrical body 31 that is closed at an upper end 34 and has an opening 32 at the opposed lower end. The lower edge of the cylindrical body 31 has a pair of opposed mechanical engaging means shown as inwardly-extending ribs 36 that can engage an outwardly-extending rim 28 disposed on the upper end 25 of the syringe wall 21, to secure the pressurizing assembly 30 to the upper end 25 of the syringe assembly 20 in a first extended position, as shown in Figs. 10 and 13. A pressurizing spring 33 is restrained within the body 31 between an annular groove 35 at the closed end 34, and an annular groove 27 in the plunger plug 26. When the pressurizing assembly 30 is in the extended position shown in Figure 10, the pressurizing spring 33 is typically under minimal compression. Nevertheless, this amount of pre-tensioning or compression of the spring 33 should be sufficient to maintain an adequate rate of flow of liquid composition from the cavity 66 at the end of the injection term, as shown in Fig. 25. Figure 11 shows the same syringe cartridge as in Fig. 10, but with the plunger 24 and the pressurizing spring 33 extended to the bottom of the syringe body 21. In this configuration, a medical technician can fill the syringe assembly. The upper pressurizing assembly 30 and the membrane plug 67 are first removed. Then, using a threaded stem (not shown), the plunger can be pulled upward to draw in injectable liquid composition through the aperture 23. The membrane plug 67 and the upper assembly 30 can then be reinstalled.

[0111] The wall 31 of the pressurizing assembly 30 is configure to telescope axially over the outside of the syringe wall 21 to a second pressurizing position (shown in Figure 19) where the ribs 36 can engage a second set of outwardly-extending rims 29 disposed near the lower end of the syringe wall 21, also shown in Figure 10. This causes the closed upper end 34 of the pressurizing body 31 to compress fully the pressurizing spring 33 against the plunger plug 26, which causes the plunger 24 to move to the bottom 22 of the syringe 21 when no liquid is contained in the cavity 66 of the syringe. The engagement of the ribs 36 with the lower rims 29 retains cylindrical body 31 in the fully pressurized configuration. When the cavity 66 of syringe 21 contains a volume of injectable liquid composition, such as vaccine V as shown in Figure 19, the manual depressing of the syringe cartridge causes the compression of the pressurizing spring 33. The engagement of ribs 36 with rims 29 restrains the compressed pressurizing spring 33, and retains the potential energy within the compressed spring 33 as a means for injecting the liquid composition from the retainer. The manually-powered, compressed spring 33 exerts a downward force upon the plunger 24, which exerts pressure upon the liquid composition in the cavity 66. When the cavity 66 is put into liquid communication with the needle, the pressurized liquid composition can flow out of the cavity 66 under pressure. The pressurizing spring 33 is configured and designed to maintain a relatively constant force, resulting in a relatively constant pressure and liquid composition flow rate through the needle throughout the injection process.

[0112] Optionally, the device 1 of the present invention can comprise a separable base 92, from which the housing 10 can be removed at any time, particularly and advantageously after completion of the injection. The separable base 92 is typically configured for separable securement to the base 12 of the housing by a base securement means, and typically provides the skin-contacting surface of the device 1. A base separation means provides selective separation of the separable base 92 from the device. Figs. 2, 27 and 28 illustrate an embodiment of a separable base 92, as embodied in a separable attachment assembly 93 that removably associates with the base 12 of the housing 10.

[0113] The base securement means can comprise a mechanical engagement, such as a catch 89 formed on a distal end of a release finger 88 that depends downward from a portion of the housing body 11. The distal end of the finger 88 extends through an

opening 95 in an inner base member 91 shown in Fig. 2. The finger 88 further extends through an opening 98 in the removable base 92 when the removable base 92 is positioned against the base 12 of the housing. The finger 88 is configured to bias the catch 89 toward and into engagement with a latch 96 formed in the separable base 92, shown in Figure 27. The separable base 92 remains affixed to the housing of the device provided that the catch 89 remains engaged with the latch 96.

[0114] The base separation means for separating the separable base 92 from the permanent housing base 12 can comprise a mechanically-biased member associated with the housing 10 that is configured for manipulation that forces to disengage the base securement means, specifically in the illustrated embodiment by moving the catch 89 out of engagement with the latch 96. In Figure 27, after the needle 40 and carriage 70 have been retracted, the person can depress the release button 81 even further, thereby causing a toe 87 on a release arm 80 to pivot into engagement with the release finger 88, and to bias the catch 89 out of engagement with latch 96. With the catch 89 disengaged from latch 96, and with the needle 40 fully retracted, the housing can be safely and easily separated from the separable base 92 for post-injection inspection, and for disposal.

[0115] The separable base further comprises a means for attachment to the skin of the patient. Typically, the means for attachment comprises an adhesive means adhered to the skin-contacting surface of the separable base.

[0116] While the figures and associated description describe the separation of the separable base from the housing while the device is attached to the skin of a patient, it can be understood that the separable base can also be removed from the housing while the device is free from attachment to the body.

[0117] In a method of using the device of the invention, a device 1 is provided as shown in Figure 20 comprising a housing 10 having an optional separable attachment assembly 93 comprising a separable case 92, and a syringe cartridge 18. The three members are shown separated to illustrate, that prior to use as an assembled product, the components can be separated and visually inspected.

[0118] The separable attachment assembly 93 can be attached manually to the base 12 of the housing 10 as previously described. Prior to attachment of the device to a person, a release paper 111 that covers the separable base 92 and adhesive flaps 112, is peeled away and disposed of.

[0119] As shown in Fig. 21, the separable attachment assembly 93 of the housing 10 can be attached to an area of the patient's skin on the upper arm or leg of the patient P, designated as the injection site, secured by the adhesive on the underside of the adhesive flap 112 that extends outward from the periphery of the separable base 92.

[0120] After attachment of the device to the skin, a seal 105 is removed that covers the opening to the carriage recess 71 to protect the inlet end 42 of the needle 40 from contamination, as shown in Figures 21 and 22. The syringe cartridge 18 is then inserted into the recess 71 of the carriage 70. The threaded syringe port 64 engages the threaded connector 73, so that manual axial rotation of the syringe cartridge 18 mates the respective threads and secures the syringe cartridge 18 to the carriage 70. As that occurs, a membrane 65 disposed in the opening of the syringe port 64 (see Figure 14) is penetrated by the inlet 42 end of the needle, which establishes liquid communication with the syringe cavity 66. A pair of tabs 45 extending out from the top of the pressurizing body 31 provides a grip for manually rotating the syringe cartridge 18 into the carriage 70. Relative axial rotation between the syringe assembly 20 and the pressurizing assembly 30 is prevented by disposing the outwardly-extending rims 28 of the syringe wall 21 into longitudinal grooves 37 formed in the inner surface of the pressurizing body 31.

[0121] In an alternative method, the syringe cartridge 18 can be provided in its pressurized configuration, as shown in Figure 19, just after the technician has compressed the telescoping pressurizing assembly 30 down onto the syringe assembly 20, and just prior to insertion of the cartridge 18 into the carriage 70, shown in Fig. 22. When the technician inserts the pressurized cartridge 18 into the recess 17 of the carriage 70, and rotates or twists the cartridge 18 to establish liquid communication between the reservoir cavity 66 and the needle 40, liquid composition may begin to flow from the syringe cavity and into and through the needle 40.

[0122] The device can also be configured to prevent rotation and removal of the modular syringe from its position in fluid communication with the needle, once the carriage 70 has been moved to and secured in the injection position. The tabs 45 extending from the closed end 34 of the pressurizing assembly 30 nest within the oblong recess 17 in the top of the housing 10 to inhibit finger access to the assembly, and to prevent manual rotation and removal of the syringe cartridge 18 in the injection

position. This prevents an unwanted exposure of a needle that is penetrating the skin from being open at its inlet 42 end to the atmosphere.

[0123] As shown in Figure 23, the needle 40 is then inserted into the patient by manual force downward on the syringe cartridge 18 to move it into the housing 10 and toward the base 12, thereby inserting the injection needle 40 into the body and initiating the injection. The pressing downward of the syringe cartridge 18 has also compressed the retracting spring 76. Fully manually pressing the syringe cartridge 18 downward causes the carriage 70 to be retained in a second position associated with the second injection position of the injection needle. A needle insertion securement, such as the retainer heel 86 shown in Figure 24, is configured to retain the needle carriage, and the injection needle, in the second, inserted position while the liquid composition is injected. Under the relatively constant force of the pressurizing spring 33, the vaccine V is slowly though constantly expressed out of the syringe cavity 66 and into the targeted body tissue 150. The size of the needle 40 and the force factor of the pressurizing spring 33 can be configured and designed to cause the liquid composition to flow under pressure through the needle within a target volumetric flow rate, to complete the injection within a prescribed period of time.

[0124] At the end of the injection term, shown in Figure 25, the plunger 24 has moved under the force of spring 33 to the bottom 22 of the syringe, and has collapsed the reservoir cavity 66 and driven substantially all of the vaccine out of the syringe cartridge 18.

[0125] An alternative method of inserting the needle 40 can employ the syringe cartridge 18 itself as an implement or plunger for depressing the needle cartridge to its inserted position, without having the needle inlet 42 penetrate the membrane 65 to the syringe cavity and placing the needle into liquid communication with the cavity. The syringe port 64 of syringe cartridge 18 can be rested against the bottom of the carriage 70, as shown by the left-side syringe in Figure 31, and pressed downward without having engaged the threads, or having only partially engaged the threads, of needle hub 72 and connector 73. Alternatively, the syringe port 64 and the connector 73 can be configured to provide a first position wherein the threads partial engage without establishing liquid communication between the needle and the cavity (that is, without rupturing the membrane 65), and a second position wherein the threads further engage

and establish liquid communication by penetration of the membrane by the inlet end of the needle.

[0126] Once the injection has been completed, or at any time during the vaccination, the needle can be retracted from its second or inserted position by activating a needle retracting means. The needle retracting means can comprise a disengagement means that is configured to disengage the needle insertion securement, and a power means configured to bias the needle, and the needle carriage, to respective third positions where the injection end of the needle is disposed within the housing. In the illustrated embodiment of Figure 26, the disengagement means comprises one or more release arms 80 and one or more release buttons 81. The release arm 80 comprises an upper end 82 shown as a ball having an inward flat surface that is secured within a socket 15 formed in the main body 11. The release arm 80 also comprises a pivot 83 that resides in a detent in the outside of the guide wall 14, and a resilient, flexible elbow portion 84 intermediate the ball end 82 and the pivot 83. A lateral bar 85 on the inside of the release button 81 is disposed proximate the elbow 84. In response to an inwardly-directed force on the button 81 that moves the button inward, as shown in Fig. 26, bar 85 causes the release arm 80 to flex inwardly at the elbow 84, causing heel 86 to pivot outwardly and out of engagement with the carriage lower flange 79. As shown in Figure 27, the power means comprises a compressed retracting spring 76 that had been manually disposed into a compressed configuration when the needle was manually inserted, and biases the needle toward a third position. With the needle carriage 70 unsecured by the needle insertion securement, retainer heel 86, the compressed retracting spring 76 can drive the carriage 70 upward from the base 12, and retract the distal end of the needle, needle tip 41, completely out of the body of the patient P and into the third position where the needle tip is within the housing 10. As described earlier, the retracting spring 76 should be disposed within the housing 10 with an amount of pre-tensioning or compression that is sufficient to completely retract the carriage 70 back to the top of the housing 10, so that the needle 40 will be retracted completely back into the housing.

[0127] The needle insertion securement and the disengagement means can function through or comprise the same element of the device (like the release arm 80 which functions to both secure the carriage and to disengage the securement), or can employ distinct elements.

[0128] After retraction of the needle 40, the syringe cartridge 18 can be grasped and removed by oppositely rotating the cartridge to disengage the threaded connection of the cartridge with the carriage. The cartridge assembly 18 can be inspected to confirm that all the liquid composition from the syringe cavity 66 had been injected, and then is disposed. If for any reason a significant amount of the liquid composition remained in the syringe, the syringe cartridge 18 can be reinserted into the carriage 70 and again rotated into liquid communication with the inlet of the needle 40, and the carriage and needle reinserted into the patient to complete the injection.

[0129] The illustrated embodiment shown in Figures 5, 25 and 27 shows that the release button 81 can have a generally cylindrical shape. The button can have a main inner wall 104 and an annular outer wall 101 having an annular periphery that is slightly larger than the annular opening 102 in the housing body 11 in which the button is disposed. The flared outer wall 101 resist movement of the button 81 into the opening 102 until a manual force is applied that is sufficient to bias inward the outer wall 101. As the button 81 is depressed, it biases elbow 84 of the release arm 80. When the force on the button 81 is released, the resilient elbow 84 will spring back against, and move, button 80 outward to its original position. The button 81 can also provided with a small aperture in its face, through which a small hooked implement can be inserted to pull out the button if it should become lodged inwardly.

[0130] In an alternative embodiment of the device, the means for establishing liquid communication can comprise a separate piercing conduit for establishing liquid communication with the reservoir, and which is in liquid communication with the injection needle. Fig. 39 shows a carriage 70 having a connector portion 73 that comprises a piercing needle 120 configured to penetrate a seal or membrane in the syringe cartridge 18 (not shown), and which is in liquid communication with the inlet end 42 of the injection needle 40. Fig. 39A shows in more detail a needle hub 72 positioned within a recessed bore in the end of the connector portion 73. The inlet end 42 of the needle 40 is flared so that the injection needle is retained within the needle hub 72. A conduit hub 121 is securely positioned over the needle hub and retains the piercing needle 120 in position. The distal end 122 of the piercing needle 120 is typically sharpened or pointed to facilitate penetration of the liquid seal or membrane. The piercing needle 120 is typically of a smaller gauge (larger diameter) than the injection needle to ensure penetration of the liquid membrane without crimping or

bending. Alternatively, the injection needle 40 can be made with an integral piercing conduit at the inlet end 42 that has a larger diameter and thickness than the skin-inserted portion of the needle.

[0131] Another alternative embodiment of the device can comprise the syringe cartridge shown in Fig. 40. The syringe cartridge 218 illustrated comprises a body having a cylindrical wall 221, a tapered base portion 222 having an aperture 223, and an upper closed end 234. The syringe cartridge 218 also comprises a plunger 224 that is configured for axial movement along the length of the cylinder wall 221. Figure 40 illustrates the plunger 224 both at a first position prior to filling of the cartridge reservoir with liquid composition, and at the end of the injection when the last amount of liquid composition has been evaluated from the cavity 66. A pressurizing spring 233 is disposed within the cartridge between the plunger 224 and the closed end 234, and is typically pre-tensioned to maintain a minimal force upon the plunger 224 when the plunger is in the first position. The cartridge 218 also comprises an outlet connector 264, comprising a one-way flow valve 267, illustrated as a duckbill valve having confronting flaps 268a and 268b.

[0132] The syringe cartridge 218 shown in Fig. 40 is in its configuration prior to filling. The medical technician or patient can draw the injectable liquid composition from a source, such as a glass vial, into a standard syringe (not shown) fitted with an outlet connector, such as a threaded female luer connector, that can be secured to the outlet 264 of the cartridge 218. After sealably connecting the supply syringe to the outlet port 264 of the cartridge 218, the person depresses the stem of the supply syringe plunger, causing the liquid composition to flow under pressure through the one-way valve 267 and into the cartridge. The pressurized composition moves the plunger 224 toward the closed end 234 and forms the reservoir of liquid composition V within the cavity 66. The pressurized composition also compresses the pressurizing spring 233 back toward the closed end 234. When the force applied to the plunger stem of the supply syringe is released, the pressurized liquid composition within the cavity 66 collapses and closes the one-way valve 267, as shown in Fig. 41. The one-way valve 267 can be positioned so that the inlet end 42 of the needle or the piercing needle 120 can penetrate the flappers 268 sufficiently to establish liquid communication. The filled cartridge 218 can then be inserted into the housing as described herein before.

[0133] In another alternative embodiment of the invention of a dual-port syringe cartridge 318. The dual-port cartridge has a first port 323 at a first end of the cartridge, configured for filling the cartridge with liquid composition V, and a second opposed port 364 at a second end of the cartridge, configured for dispensing the liquid composition from the reservoir to the injection needle 40. The cartridge 318 comprises a plunger 324 disposed in the cartridge for movement toward the first end for dispensing the liquid composition from the cavity 66. The plunger 324 is associated with a liquid dispensing means shown as pressurizing spring 333 for maintaining pressure upon the composition V within the cavity 66 to cause the liquid composition to flow from the cavity. The pressurizing spring it typically pre-tensioned to ensure sufficient force is exerted through the entire length of the plunger travel to maintain adequate liquid flow through the injection needle.

[0134] The cartridge 318 comprises a means to establish liquid communication between the first or filling end of the cartridge, and the second or dispensing end of the cartridge. This liquid communication means can comprise a flow channel 341 in liquid communication between the distal end of the cavity 66 and the dispensing end 364 of the cartridge. In the illustrated embodiment, an tube 342 having the flow channel 341 is secured to the second end 322 of the cartridge, and extends to a distal end 343 that terminates proximate the inlet port 323. The dip tube 342 is preferably aligned along the axial centerline of the cartridge. In the illustrated embodiment, the plunger 324 is configured with an orifice through its longitudinal centerline, and forms an annular liquid seal 326 with the outside surface of the dip tube 342 and a peripheral seal 325 with the inside of the cylindrical wall.

[0135] The filling port 323 can be fitted with a one-way valve 357 and filled as described above. As the reservoir is filled under pressure, the pressurizing spring 333 compresses toward the dispensing end 322. The one-way valve 357 seals inlet port 323 to prevent leakage of the pressurized liquid V within the cavity 66. The membrane seal 367 seals the outlet port 364 and maintains the cavity of the filled cartridge 318 under pressure. The filled cartridge can then be inserted into the housing of a device as described herein. An optional cap 334 can be secured to the filling port 323 after filling to prevent curious fingers form pulling on the cartridge during injection.

[0136] The illustrated cartridge 318 in Fig. 43 provides distinct features that can be advantageous. The cartridge has separate and spaced-apart filling and dispensing ports,

which can allow the cartridge to be filled after it has been positioned and secured to the device. This avoids the need to handle the cartridge after it has been filled. The filling port 323 is typically oriented toward the top of the device. The configuration of the cartridge also provides for the dispensing plunger to ascend within the syringe during the injection in a direction other than downward and toward the base of the device. When the plunger has completed the dispensing of the composition V and has voided the cavity 66, the patient or medical technician will be able to see the distal end of the plunger proximate to the filling end 352 of the cartridge, which serves as a convenient visual signal that the injection is nearing completion or has been completed.

[0137] To assist in installing the separable attachment assembly 93 to the housing of the device, the lower surface of the housing base 12 can optionally be provided with a wide indent 97 surrounding the opening 95 in the inner base 91, and the separable base 92 can be provided with a raised flange 94 that registers with the indent 97, as shown in Fig. 20. Pressing upward on this area assists engaging the catch 89 onto the latch 96 of the separable base 92.

[0138] A top plan view of a typical separable base assembly 93 is shown in Fig. 32, with a sectional view Fig. 33 taken through line 33-33, and detailed sectional views shown in Figures 34-35. The adhesive flap 112 extends outwardly from the periphery of the separable base 92, and is covered on its slower surface with the release paper 111. The adhesive flap 112 comprises a first film layer 114 that is affixed on its upper surface to cover the skin-facing surface of the separable base 92, and extends outward from the peripheral circumference of the base 92. The flap 112 has a PSA on its lower surface (not shown) for attachment to the skin. Flap 112 also comprises a second film layer 115 that is shaped as a ring with an inner circular edge 116 and an outer edge 117. The inner edge 116 extends inwardly and is affixed, typically with PSA, to the upper surface of the separable base 92 inboard of its circumferential edge. The second film layer 115 extends outwardly from the separable base 92, to overlap the first film layer 114 to its periphery, and there beyond to its outer edge 117. Typically, the adhesive flap layers 114 and 115 can be made of a flexible plastic film, and can be optionally vapor permeable or breathable.

[0139] Alternatively, the second film layer 114 can be eliminated, and the underside of the separable base 92 can have a coating of PSA for direct-contact adhesion to the skin.

Optionally a gauze bandage 113 can be secured to the underside of the separable base 92 over the opening 13, as shown in Fig. 35.

[0140] In an alternative embodiment, the base separating means can comprise other mechanical securements, an adhesive securement, and a magnetic securement of the separable bas to the housing of the device. The other mechanical securements could include a mechanical "hook-and-loop" device that can include Velcro®, a hasp, a frangible joint, and a threaded joint). The magnetic securement can comprise a first magnetic member proximate the upwardly-facing surface of the separable base; and a second magnetic member proximate to the base portion and inside of the housing; wherein first magnet member and the second magnetic member have a magnetic attraction that secures the removable base to the housing, and wherein the removable base can be manually separated from the base portion of the housing by a manually-applied force that overcomes the force of the magnetic attraction.

[0141] The separable base provides a means for obtaining a secure attachment of the housing of the device to the patient's skin, by providing for outwardly-extending adhesive flaps that are securely affixed to the relatively rigid structure of the separable base. In most circumstances, the separable base that remains behind on the skin of the patient is well tolerated by the patient, and can be removed at any time, since most vaccinations, particularly with very small needle diameters, leave little wounding of the skin

[0142] The separable base 92 can also be removed for pre-injection inspection of the device, by fully depressing the release button 81, prior to installing the reservoir or the initiating needle insertion. The inner base 91, or a portion thereof, can be made of a transparent thermoplastic material to allow a visual inspection of the needle and the internal assembly prior to use. The separable base 92 can then be easily reaffixed.

As shown in Figure 28, after completing the injection, the syringe cartridge 18 can be removed from the attached housing 10, before the housing is removed from the separable base 92; or, the housing 10 with the syringe cartridge 18 attached can be removed from the separable base 92 as a unit, and then the syringe cartridge can be removed.

[0143] The device can also comprise a means for preventing deployment of the needle through the opening in the base of the housing, particularly after the needle has been inside the skin and body of a person. A typical deployment prevention means for

preventing needle deployment comprises a sliding or rotating plate disposed in the base that can moved between a first position where the needle opening in the base is not covered by the plate, and a second position wherein the plate covers the opening. In the embodiment illustrated in Figs. 36-38, a rotating plate 131 is disposed in an annular recess 130 on the annular flange 94 of the inner base 91. The recess 130 and plate 131 have a center that is positioned off the centerline 100 passing through needle 40, though they overlap the needle opening 13 in the base 12. The plate 131 has an opening 136 disposed between the center of the plate 131 and its periphery. The plate 131 can rotate between a first deployment position shown in Figs. 36 and 37 wherein the plate opening 136 registers with and leaves exposed the opening 13, and a second blocking position shown in Fig. 38 wherein the plate 131 covers the opening 13, and prevents deployment of the needle 40. The plate is movable between the first and second positions by a knob 132 that is attached to the plate by a stem 133. The stem is disposed within arc-shaped stem slot 134. The knob 132 moves along a knob recess 135 formed in the inner surface of the removable base 92, and that lies below the knob slot 134. The knob retains the plate in position, and can be manipulated by finger to move the plate between its first and second positions. Prior to injection, the technician can remove the removable base plate and manipulate the knob 132 to move the plate 131 to its deployment position. After the device is removed from the skin following the injection, and the device has been removed from the separable base 92, the exposed knob 132 can be manipulated to move the plate 131 to its blocking position. This physically closes the opening 13 to ensure that the needle 40 can not be redeployed accidentally and cause an undesired stick.

[0144] In a further embodiment of the present invention, a device can have a plurality of injection needles and reservoirs disposed within the housing. The device can provide for injecting at least two injectable liquid compositions to a patient. Figs. 29 and 30 show a top plan view and an elevation view of a device 1 for injecting at least two liquid compositions from separate reservoirs contained in the housing. As shown in Figure 31, the device 1 can comprise a housing 10 and base 12 for two needle carriages 70a and 70b and two injection needles 40a and 40b, which can be configured to be separately and independently manipulated for insertion, injection and retraction, as described herein above.

[0145] Alternatively, the two needle carriages and needles can be configured for simultaneous insertion, injection, and retraction using shared elements, including a shared, unitary dual-recess needle carriage, and a dual unitary pressurizing assembly.

[0146] If only one injectable liquid composition will be administered, there is a potential for the patient, during the injection procedure, to pick at and possibly poke a finger though the seal 105 that is initially positioned over the cavity recess 71. To prevent this, the seal 105 can be affixed to a cylindrical member 106 that partly supports the underside of the seal 105 layer, as shown in Figure 3A. Alternatively, the seal can be removed and replaced with a "dummy" plunger that has the upper appearance of the active syringe cartridge, but which fits securely in the opening in the housing above the carriage to block any attempt to depress the carriage.

[0147] Another alternative embodiment of the device can comprise a means for selectively positioning and optionally securing the needle carriage 70 to respective positions that either prevent or enable its movement in the axial direction within the housing. This embodiment also is an alternative deployment prevention means. Fig. 42 illustrates this embodiment in the context of the dual-needle device. Each of the carriages 70a and 70b in Fig. 42 are shown in their first axial position, disposed within the carriage passageway 280 proximate the upper end 281. This is also the position in which the syringe cartridge 18 is inserted into or removed from the needle carriage 70. In the first axial position, the carriage can be rotated between a first rotational position wherein the carriage is restrained from movement in the axial direction, and a second rotational position wherein the carriage can move in the axial direction.

[0148] Looking first at the carriage 70a on the left side of the device, which is in the axially restrained configuration, the vertically-oriented guide rib 19 projects outward from the cylindrical wall 14. The toe 79 of the carriage is positioned within a notch 119 formed in the guide rib 19, allowing the carriage to rotate, but preventing the carriage from moving downward axially so long as the toe 19 is disposed within notch 119. The cooperation of the toe 79 of the carriage disposed within the notch 119 of the guide rib 19 provides a means for restraining the movement of the carriage in the axial direction.

[0149] The carriage 70b on the right side of the device is shown in the axially un-restrained configuration. In this configuration, the carriage 70b has been rotated (typically in the clockwise direction) to a position where the gap 179 in the toe 79 registers with the notch 119 in the guide rib 19, which allows the carriage 70b to move

axially toward its second axial position proximate the base of the housing. As the carriage 70b first begins to descend, the gap 179 in the toe 79 slides along the guide rib 19, preventing the carriage from rotating after it has moved axially out of the first axial position.

[0150] The carriage can also comprise a means for registering the rotation of the carriage in a direction that corresponds with either the axially restrained configuration (typically, counter-clockwise direction in the plan view shown in Fig. 29) or with the axially un-restricted configuration (typically clockwise). In the illustrated embodiment, a stop lug 180 is provided to assist registering the gap 179 with the notch 119, by limiting the rotation of the carriage. At the appropriate configuration, a stop lug 80 will engage the upper end 219 of the guide rib 19. The stop lug 180 is shown as a downwardly-extending projection from the outer wall 75 of the carriage 70, over a portion of the wall-contacting periphery of the carriage. As viewed in Fig. 42A, in the top-right of carriage 70b, a first end of the stop lug 180 is engaging the upper end 219 of the guide rib 19 from behind the guide rib, when the carriage is rotated in the clockwise direction. Conversely, as shown in Fig. 42, the stop lug 180 (which is not shown since it is out of the page in front of the section line), a second end of the stop lug 180 is engaging the upper end 219 of the guide rib 19 from in front the guide rib, when the carriage is rotated in the counter-clockwise direction.

[0151] Fig. 44 shows an alternative embodiment of a device having a needle retracting means that comprises a pre-tensioned retracting spring that is associated with a separate member for retracting the needle. As illustrated in Fig. 44, the retracting means comprises an auxiliary retracting carriage 270. The retracting carriage 270 is configured for movement within the housing between a first secured position, shown in Fig. 44 where the retracting carriage is disposed proximate the base 91, and a second position where the retracting carriage is disposed proximate the upper end 281 of the carriage passageway 280. In the first position, the retracting spring 76 is in a fully compressed position, restrained by the retracting carriage 270, the toe 79 of which is restrained by the lower heels 86 of the release arms 80. As described above, when buttons 81 are depressed, heels 86 bias outwardly and out of engagement with toe 79, allowing the retracting spring 76 to move the unrestrained retracting carriage 270 toward and to its second position. It can be understood that depressing of the buttons 81 also bias the upper heels 286 to pivot or move outwardly. The force factor of the

retracting spring 270 can be sufficient to cause the upper toe 279 of the retracting carriage 270 to pass over the upper heels 286 of the release arms 80 and into its second position proximate upper end 281 in the carriage passageway (not shown). Upon releasing of the pressing force upon buttons 81, the upper heels 286 return and are placed into an interference position that can prevent the retracting carriage 270 from being moved axially in a direction back toward its first position shown in Fig. 44. It can also be understood that the retracting carriage 270 can be moved from its second position proximate the upper end 281, to its first position, by sufficiently depressing buttons 81 to release the upper toe 279 from engagement with the upper heels 286, and manually pushing the retracting carriage 270 (and compressing the retracting spring 76) toward the base 91.

[0152] It can also be understood that the needle carriage 70 can move within the carriage passageway 280 separately from the retracting carriage 270. The needle carriage 70 is typically positioned in its first position adjacent the upper end 281 of the carriage passageway 280 (such as shown in Fig. 22) for attachment of the syringe cartridge 18. In this position, the needle carriage can be restrained temporarily from axial movement (the needle carriage's axially restrained configuration, as described in the aforementioned embodiment and illustrated by the left-hand carriage 70a of Fig. 42). Alternatively, the needle carriage can be biased toward its first position by a second mechanical spring (not shown). At the same time, the retracting carriage 270 is typically in its pre-tensioned position shown in Fig. 44, adjacent the base 91. After the syringe cartridge 18 containing the liquid composition V has been secured in place to the needle carriage 70, also as shown in Fig. 22, the needle carriage bearing the injection needle 40 can be rotated from its axially restrained configuration into the axially un-restrained configuration (also described above and illustrated by the right-hand carriage 70b of Fig. 42).

[0153] From its axially un-restrained configuration, the needle carriage 70 can be moved to its second position shown in Fig. 44 by manually pressing downward on the inserted syringe cartridge 18. The annular outer wall of the needle carriage 70 can have cut-out grooves 176 that align axially with the upper heels 286 when the carriage is in the axially un-restrained configuration, to allow free passage of the carriage past the upper heels 286. The needle carriage 70 can have an annular recess formed between the inner wall 174 and the outer annular wall 172. The respective carriages can become

engaged and frictionally coupled together when the upper rim 272 of the retracting carriage 270 is nested within the annular recess of the needle carriage 70, but can be separated by hand. The frictional coupling of the needle carriage 70 to the restrained retracting carriage 270 assists in holding the inserted injection needle 40 within the injection site, as shown in Fig. 44.

[0154] A further embodiment of the invention can comprise a means of indicating the extent of liquid composition dispensed from the reservoir. The indication means can comprise a visual means that allows personnel to actually view the remaining contents of the reservoir. An embodiment of a visual indication means can comprise a transparent section positioned in a portion of the housing adjacent the reservoir, to view the reservoir. Alternatively, the housing can comprise a door or panel that can be opened to permit inspection. Further, the reservoir can be provided with a corresponding transparent portion to permit the medical personnel to see the medication contained within the reservoir. The transparent portion can include a portion of the base or a portion of the housing, or both. The transparent portion can be a small area relative to the total surface area of the housing body, or can be a significant portion of the housing body surface. In a typical embodiment, the transparent portion is positioned on one side of the housing body that, when applied to the patient's arm, can face away for the patient's line of sight. This allows the medical technician to see through the transparent portion, but provides no indication to the patient, typically a small child, that the inside of the device contains something interesting that might arouse the patient's curiosity.

[0155] The indication means can also comprise a signal means that signals the end or the approaching end of medicament dispensing. A signal means can comprise a mechanical or electrical switch that is activated by the plunger member as the last remaining contents of the reservoir is dispensed. The signal can be a flag, a pop-out tab, an illuminated light, or any other well known signal.

[0156] Another embodiment of the invention can comprise a covering or disguise configured for attachment or placement over the injection device either to provide the device with a pleasurable impression, or to direct the patient's attention away from the device. The covering can be formed as a cartoon character, a zoo animal, or the like. In this way, much of the patient's fear that might be caused by the sight of the device can be alleviated.

[0157] In another embodiment of the invention, the housing of the device can be colored coded or have a colored indicator or marking that identifies the particular type or quantity of medication contained within the reservoir. For example, for one certain medication the outer casing may be blue in color. The device can also display various warnings, such as a precaution to avoid needle stick and possible side effects to the medication. The device can also comprise a removable label comprising information about the liquid composition to be administered (such as the type of vaccine or medicament, the manufacturer and lot number, and volume), which can be placed into a medical record or patient chart.

[0158] Another embodiment of the invention, shown in the figures, is an improved injection device for self-administering an injection that does not provide the patient with any convenient fingerhold to grasp the device for jostling or removing the device from the skin during the injection procedure. A preferred design of the device will include an outer surface that has not sharp edges or deep groove with which the patient can get a fingerhold. Preferably, the housing and the base are constructed of a thermoplastic material that has a non-grip or non-sticky surface, and is preferably a resilient material that can flex but not deform in shape. A matte finish on the outside surface can make the housing difficult to grasp, except when properly grasped by a medical technician by its release buttons. Typically, the indentures and grooves in the housing, and including the base, have a breadth not greater than 3 mm, more typically not greater than 1 mm. Typically, external edges can be rounded, maintaining an edge radius of about at least 1 mm, more typically of about at least 3 mm.

[0159] While specific embodiments of the apparatus and method of the present invention have been described, it will be apparent to those skilled in the art that various modifications thereto can be made without departing from the spirit and scope of the present invention as defined in the appended claims.

We claim:

1. A manually-powered injection device for painless inter-muscular injection of an injectable liquid composition from with a reservoir, comprising:

a) a housing having a base for semi-permanent attachment to the skin of a patient,

b) an injection needle disposed substantially perpendicular to the base and within the housing, the needle having an injection end, and configured for axial movement manually between a first position wherein the injection end is within the housing and a second position wherein the injection end extends outwardly from the base to a distance sufficient for intramuscular insertion thereof, the injection needle having an outside diameter greater than 0.10 mm and less than about 0.38 mm,

c) a means for retaining a reservoir containing an injectable liquid composition,

d) a means for providing liquid communication between the retained reservoir and the injection needle, and

e) a means for injecting the injectable liquid composition from the retained reservoir through the needle.

2. The injection device of Claim 1 wherein the means for injecting is a manually-powered spring that is configured to exert pressure upon the injectable liquid composition within the retained reservoir.

3. The injection device of Claim 1, further comprising a needle insertion securement configured to retain the inserted needle in its second position while injecting the liquid composition.

4. The injection device of Claim 3 further comprising a means for retracting the injection needle, whereby the injection end of the needle can be retracted from its second position to a third position wherein the injection end of the needle is within the housing.

5. The injection device of Claim 3 further comprising a needle carriage to which the injection needle is affixed, the needle carriage being configured for axial movement

between a first position associated with the first position of the injection needle, and a second position associated with the second position of the injection needle, in response to a manual force applied by a person.

6. The injection device according to Claim 5 further comprising an implement for use in applying the manual force to the needle carriage.

7. The injection device according to Claim 5 wherein the needle insertion securement is configured to retain the needle carriage in its second position.

8. The injection device according to Claim 7, further comprising a retracting means comprising a disengagement means configured to disengage the needle insertion securement from the needle carriage, and a power means configured to bias the needle carriage to a third position that is associated with a third position of the injection needle wherein the injection end of the needle is within the housing.

9. The injection device according to Claim 1 wherein the device further comprises a separable base, a base securement means configured for separable securement of the separable base to the housing, and a base separation means configured for separation of the separable base from the housing, wherein the separable base comprising an adhesive for attachment thereof to the skin of the patient.

10. A manually-powered injection device for painless inter-muscular injection of an injectable liquid composition, comprising:

a) a housing having a base for semi-permanent attachment to the skin of a patient,

b) an injection needle disposed substantially perpendicular to the base and within the housing, the needle having an injection end, and configured for axial movement manually between a first position wherein the injection end is within the housing and a second position wherein the injection end extends outwardly from the base to a distance sufficient for intramuscular insertion thereof, the injection needle having an outside diameter greater than 0.10 mm and less than about 0.38 mm,

c) a reservoir containing an injectable liquid composition,

d) a means for liquid communication between the reservoir and the injection needle, and

e) a means for injecting the liquid composition from the reservoir to the injection end of the needle.

11. The injection device of Claim 10 wherein the means for injecting is a manually-powered spring that is configured to exert pressure upon the injectable liquid composition within the retained reservoir.

12. The injection device of Claim 10, further comprising a needle insertion securement configured to retain the inserted needle in its second position while injecting the liquid composition.

13. The injection device of Claim 12 further comprising a means for retracting the injection needle, whereby the injection end of the needle can be retracted from its second position to a third position wherein the injection end of the needle is within the housing.

14. The injection device of Claim 12 further comprising a needle carriage to which the injection needle is affixed, the needle carriage being configured for axial movement between a first position associated with the first position of the injection needle, and a second position associated with the second position of the injection needle, in response to a manual force applied by a person.

15. The injection device according to Claim 14 further comprising an implement for use in applying the manual force to the needle carriage.

16. The injection device according to Claim 14 wherein the needle insertion securement is configured to retain the needle carriage in its second position.

17. The injection device according to Claim 16, further comprising a retracting means comprising a disengagement means configured to disengage the needle insertion securement from the needle carriage, and a power means configured to bias the needle

carriage to a third position that is associated with a third position of the injection needle wherein the injection end of the needle is within the housing.

18. The injection device according to Claim 14 wherein the needle carriage comprises threads, and the reservoir comprises cooperating threads that can engage and retain the threads of the reservoir.

19. The injection device according to Claim 18 wherein the reservoir comprises a penetrable membrane, wherein when the cooperating threads of the reservoir and the needle carriage are engaged, a piercing conduit in liquid communication with the injection needlecan penetrate the penetrable membrane to establish liquid communication between the reservoir and the injection needle.

20. The injection device according to Claim 10 wherein the device further comprises a separable base, a base securement means configured for separable securement of the separable base to the housing, and a base separation means configured for separation of the separable base from the housing, wherein the separable base comprising an adhesive for attachment thereof to the skin of the patient.

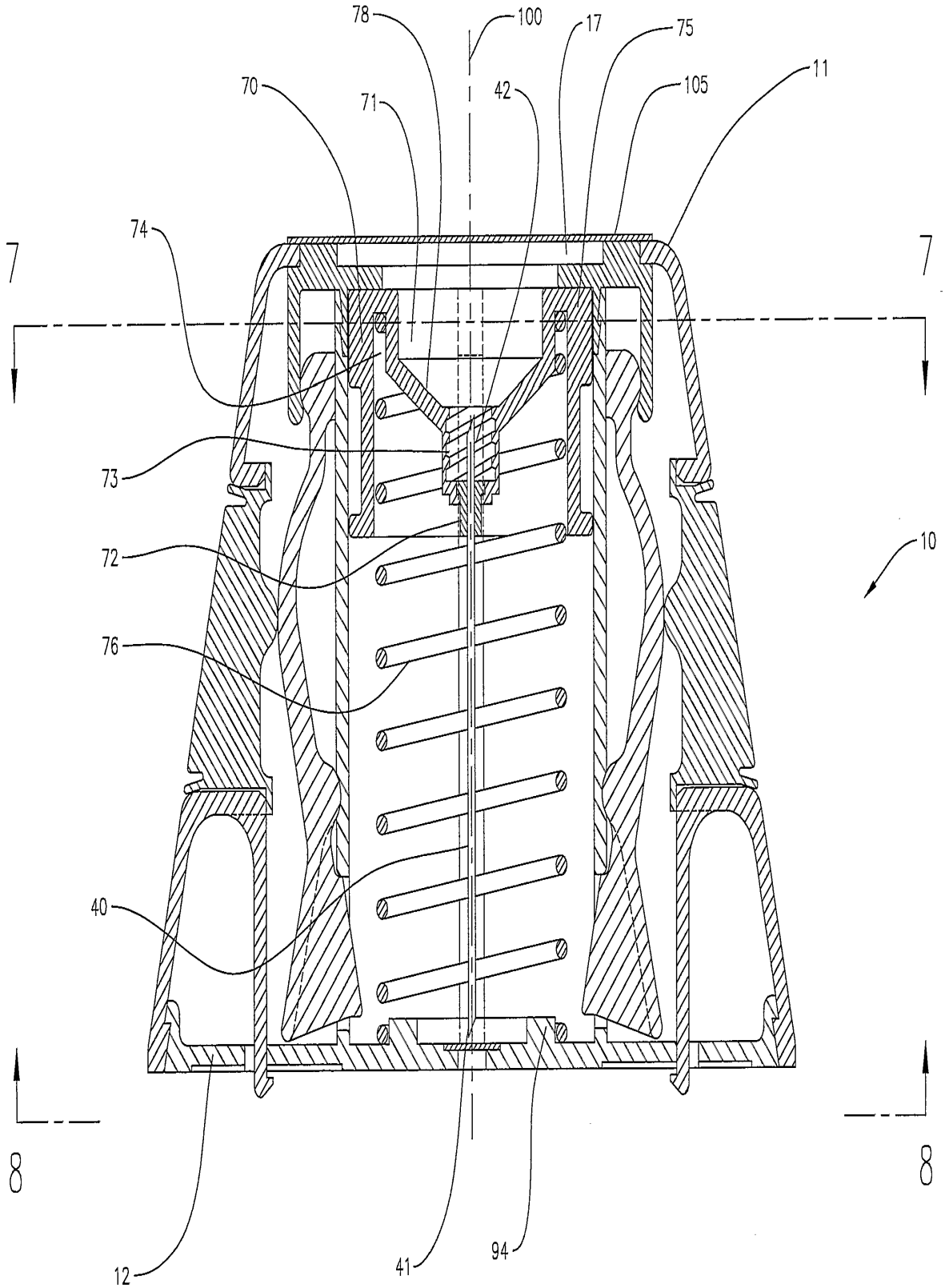


Fig. 1

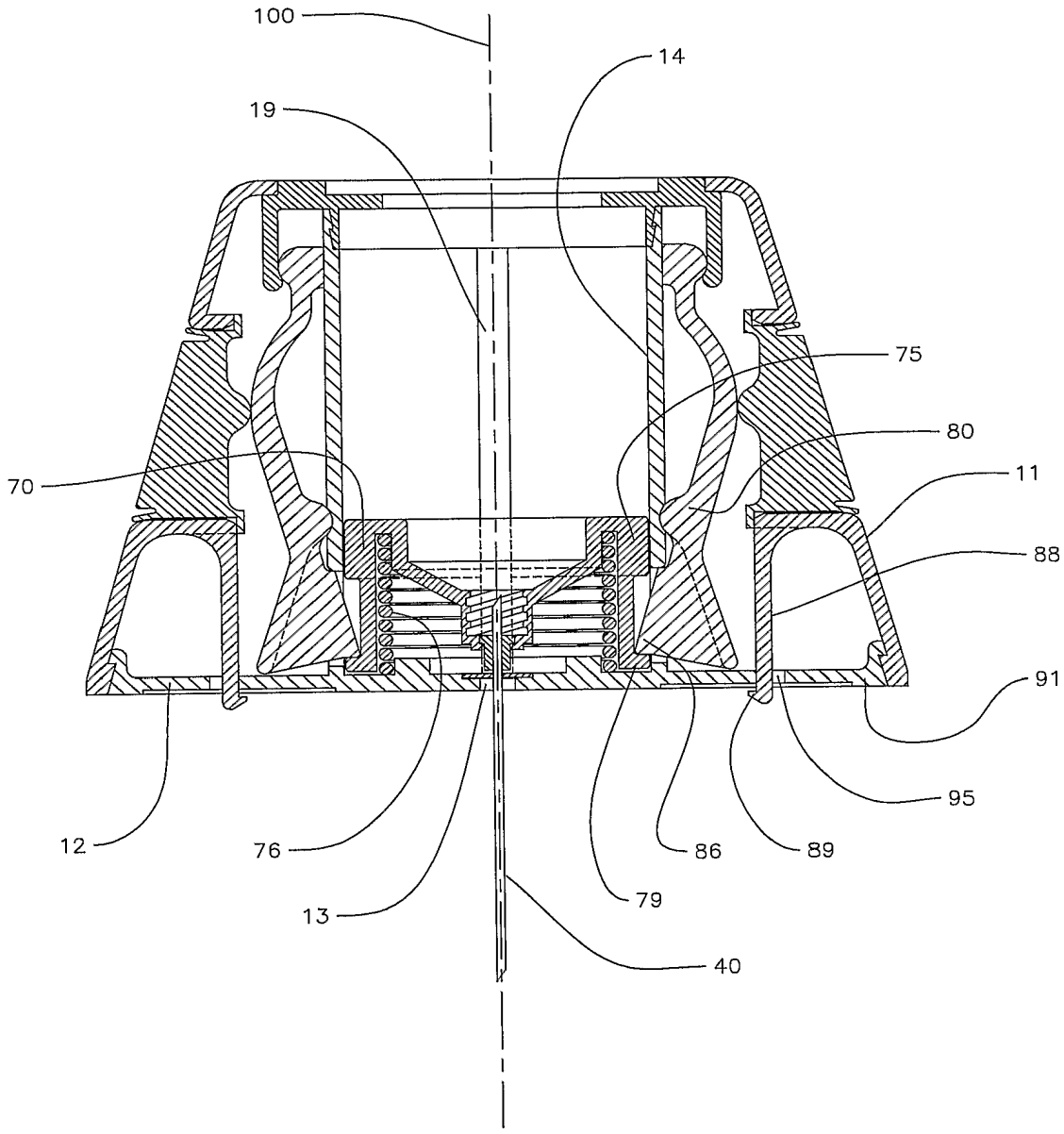


Fig. 2

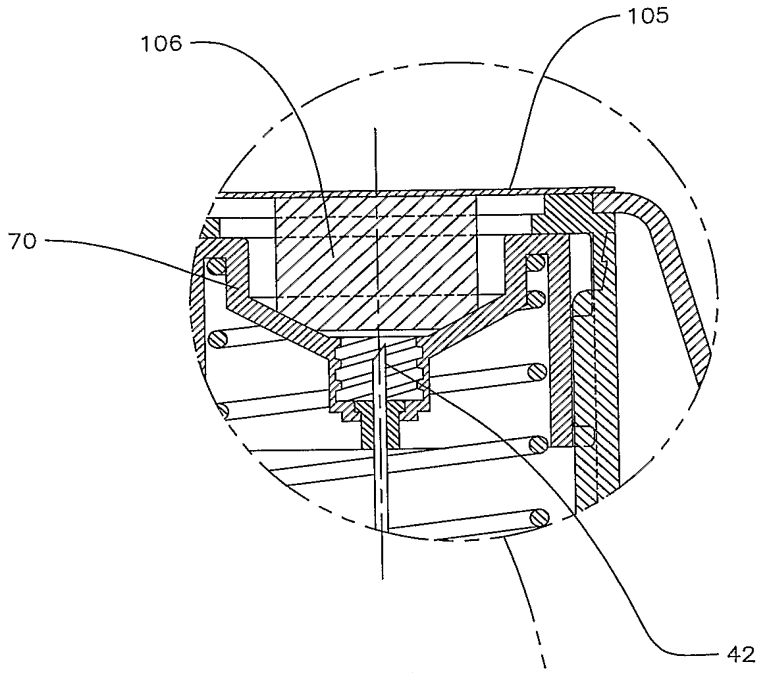


Fig. 3A

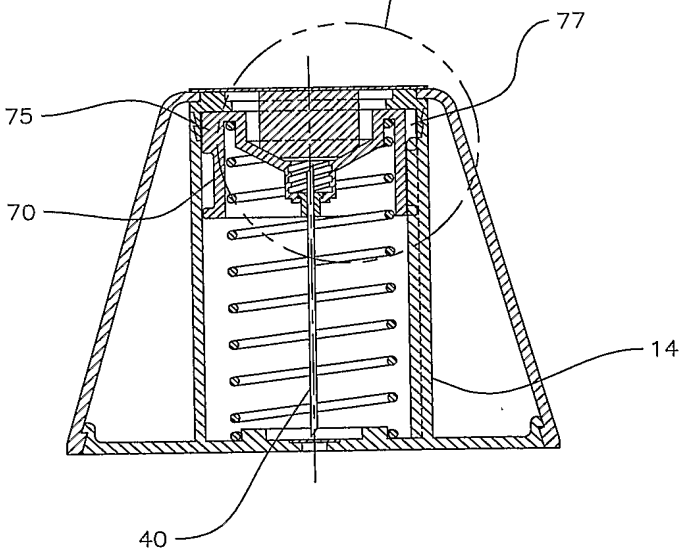
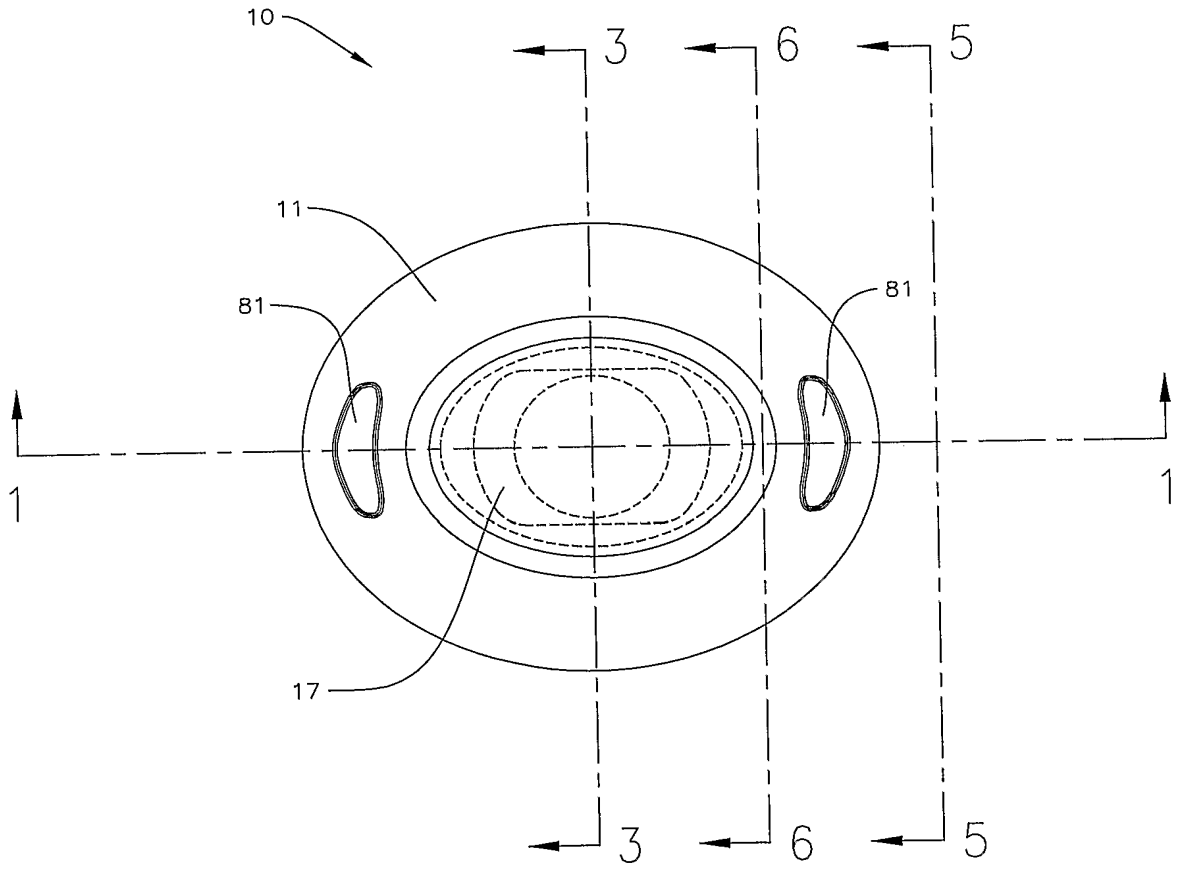


Fig. 3



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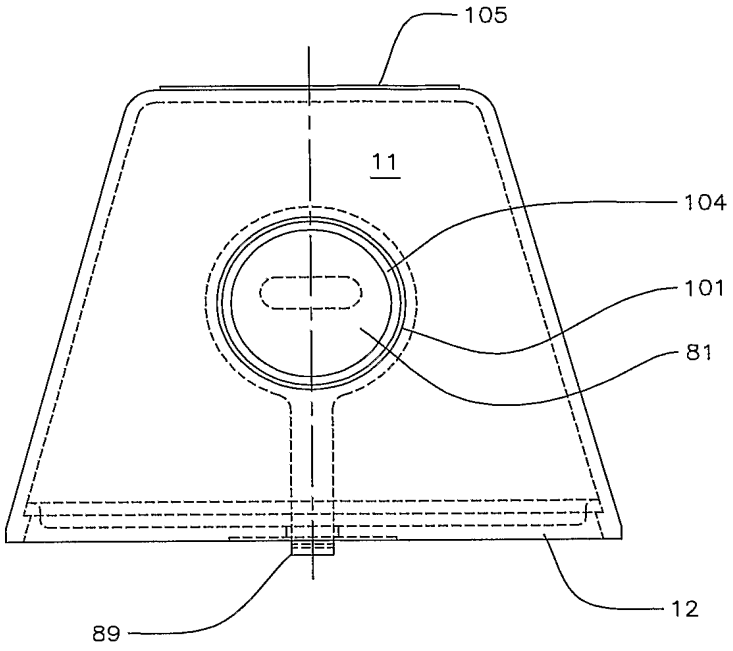

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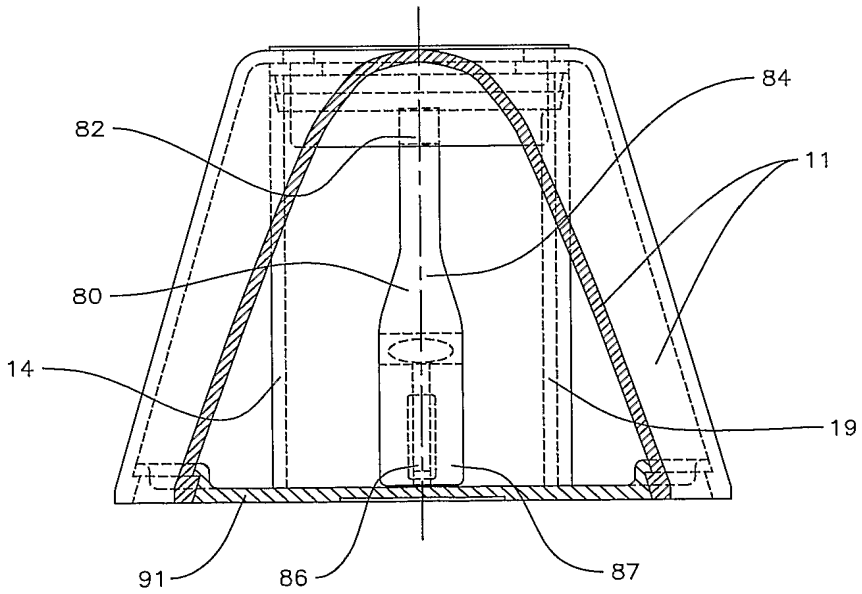

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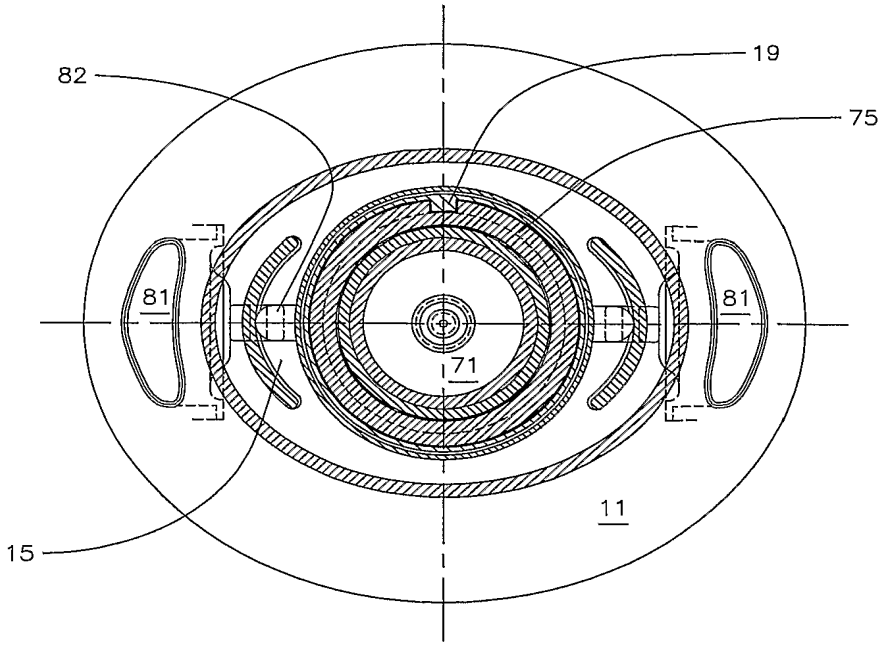

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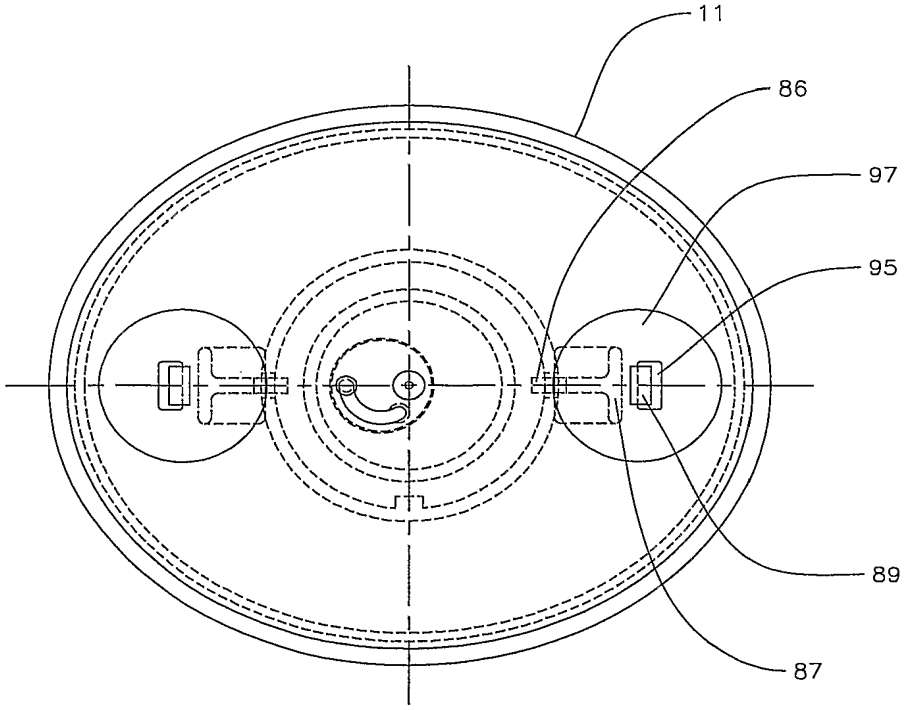

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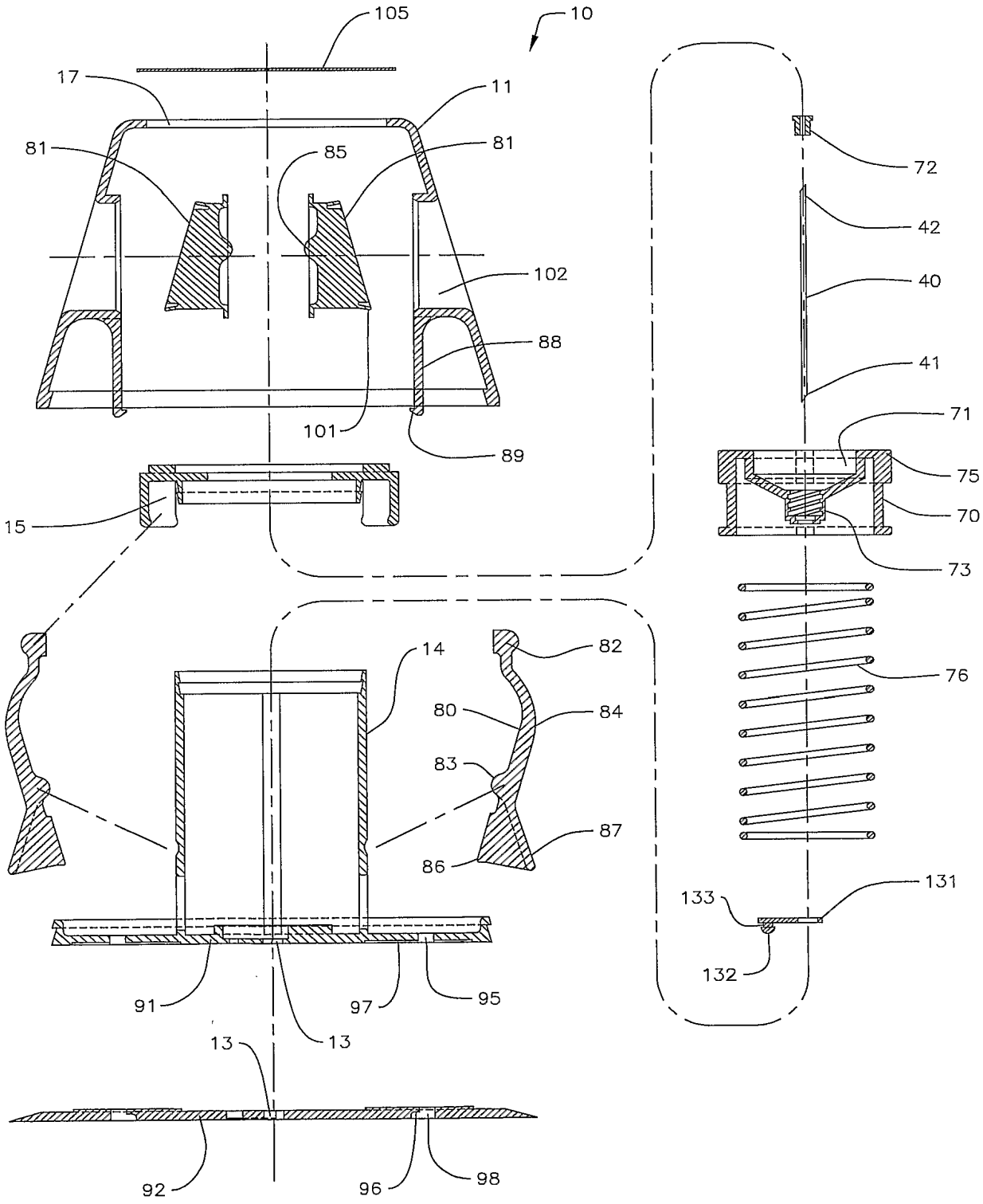
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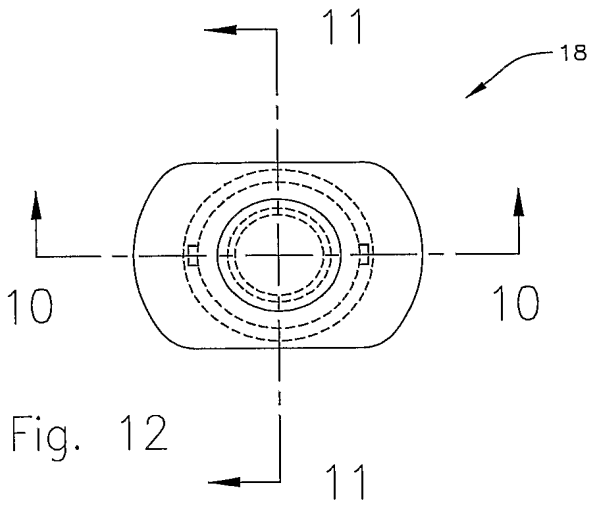
Fig. 9



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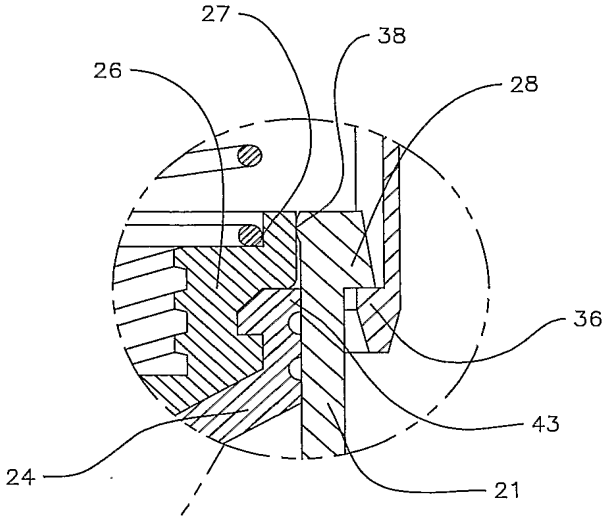
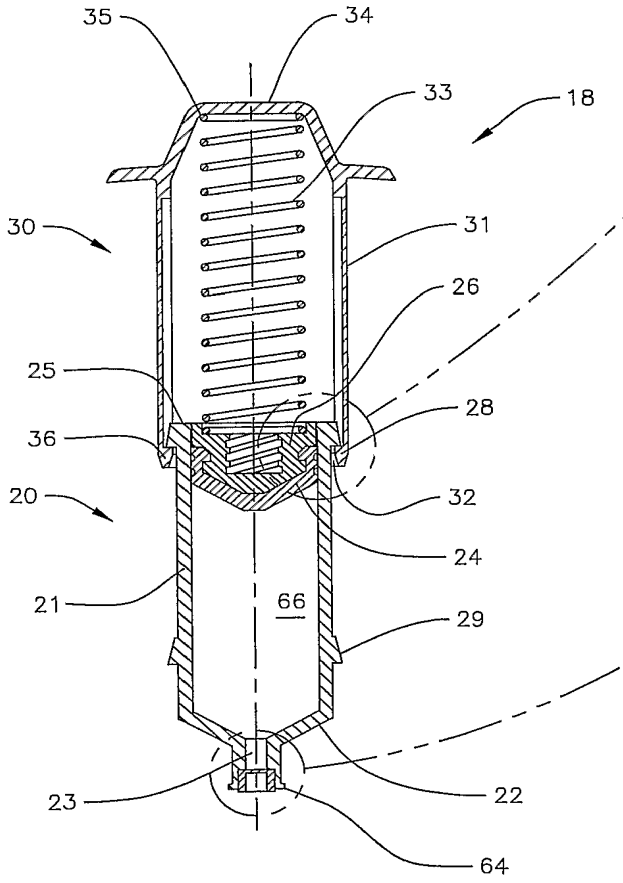


Fig. 13



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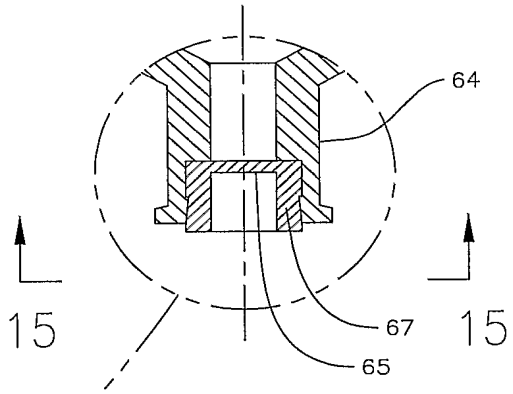

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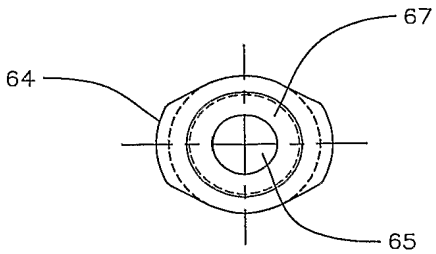

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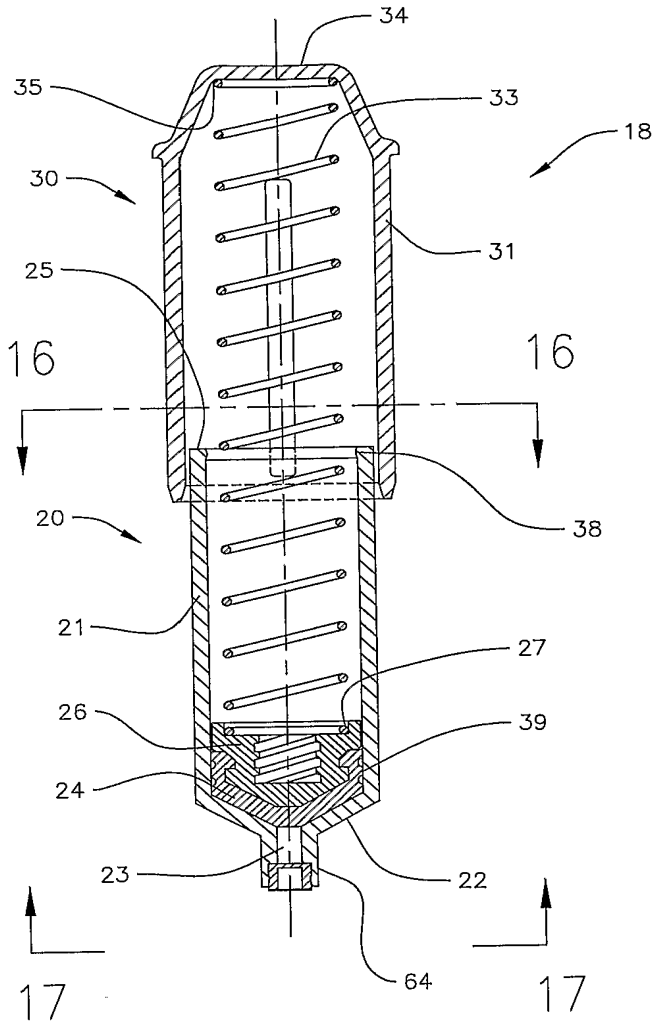

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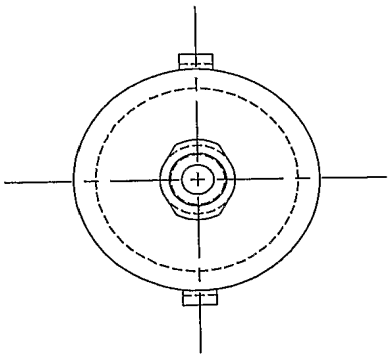

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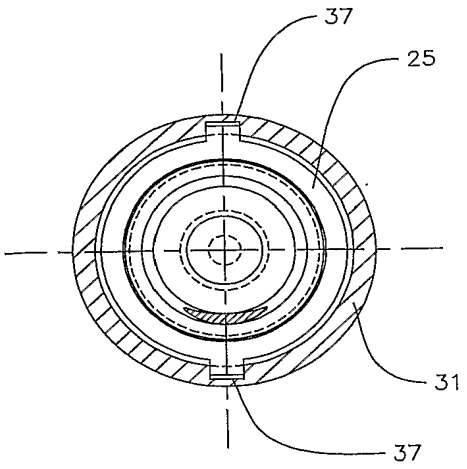

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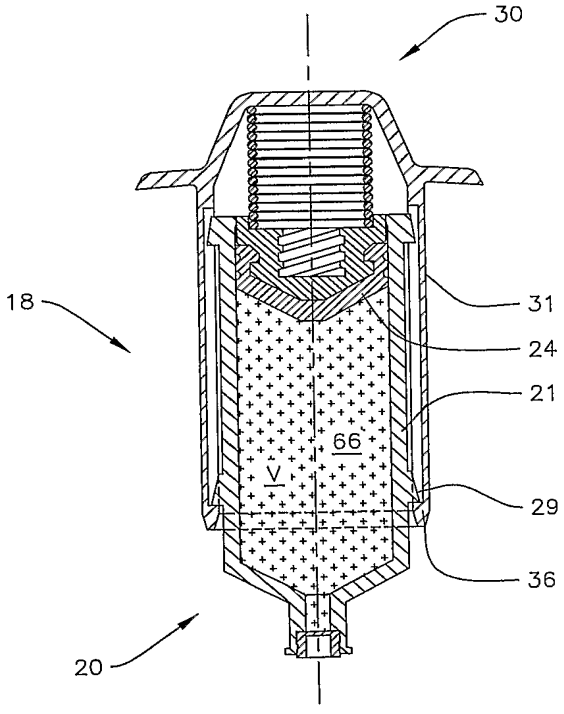

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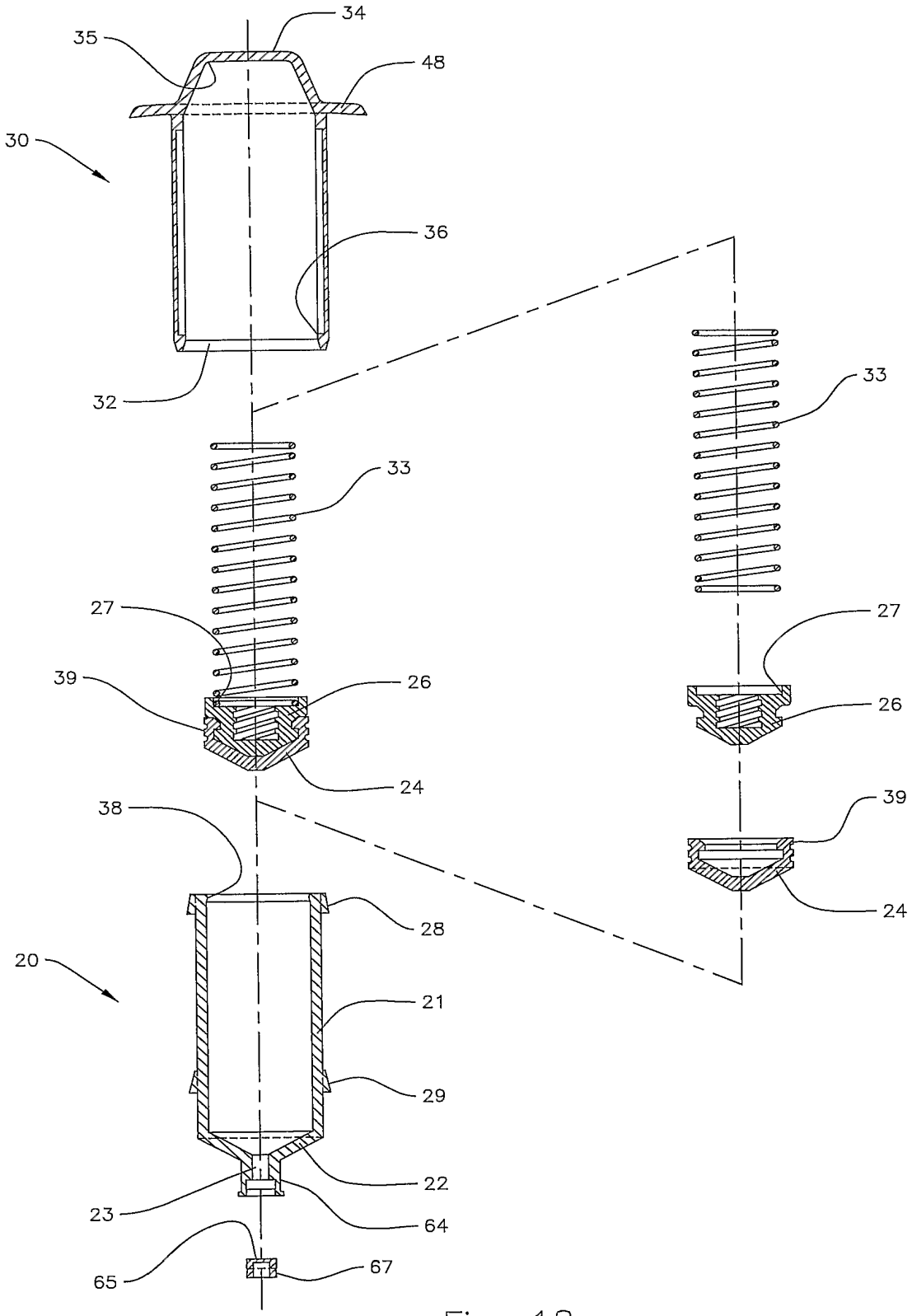
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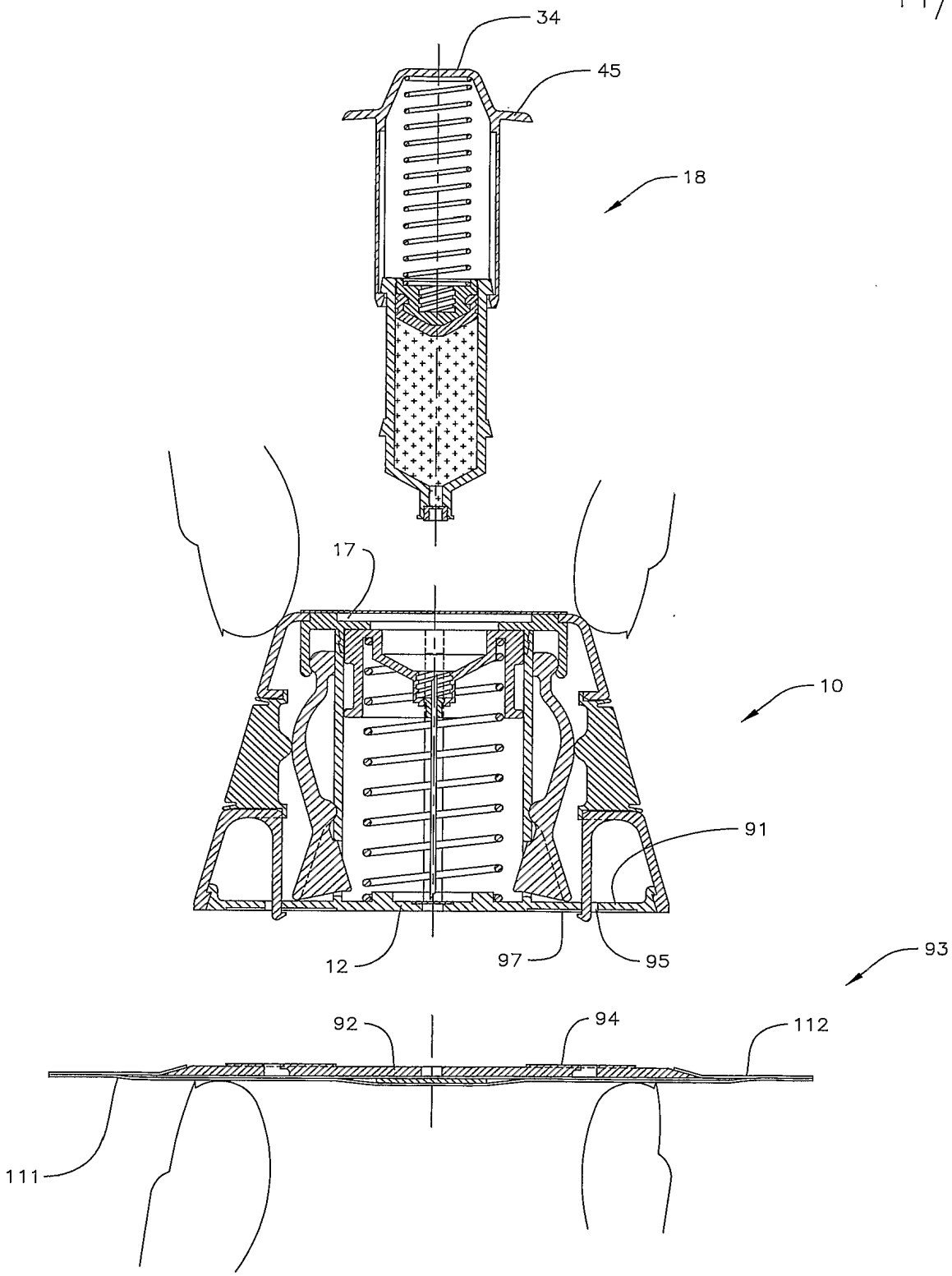
Fig. 18



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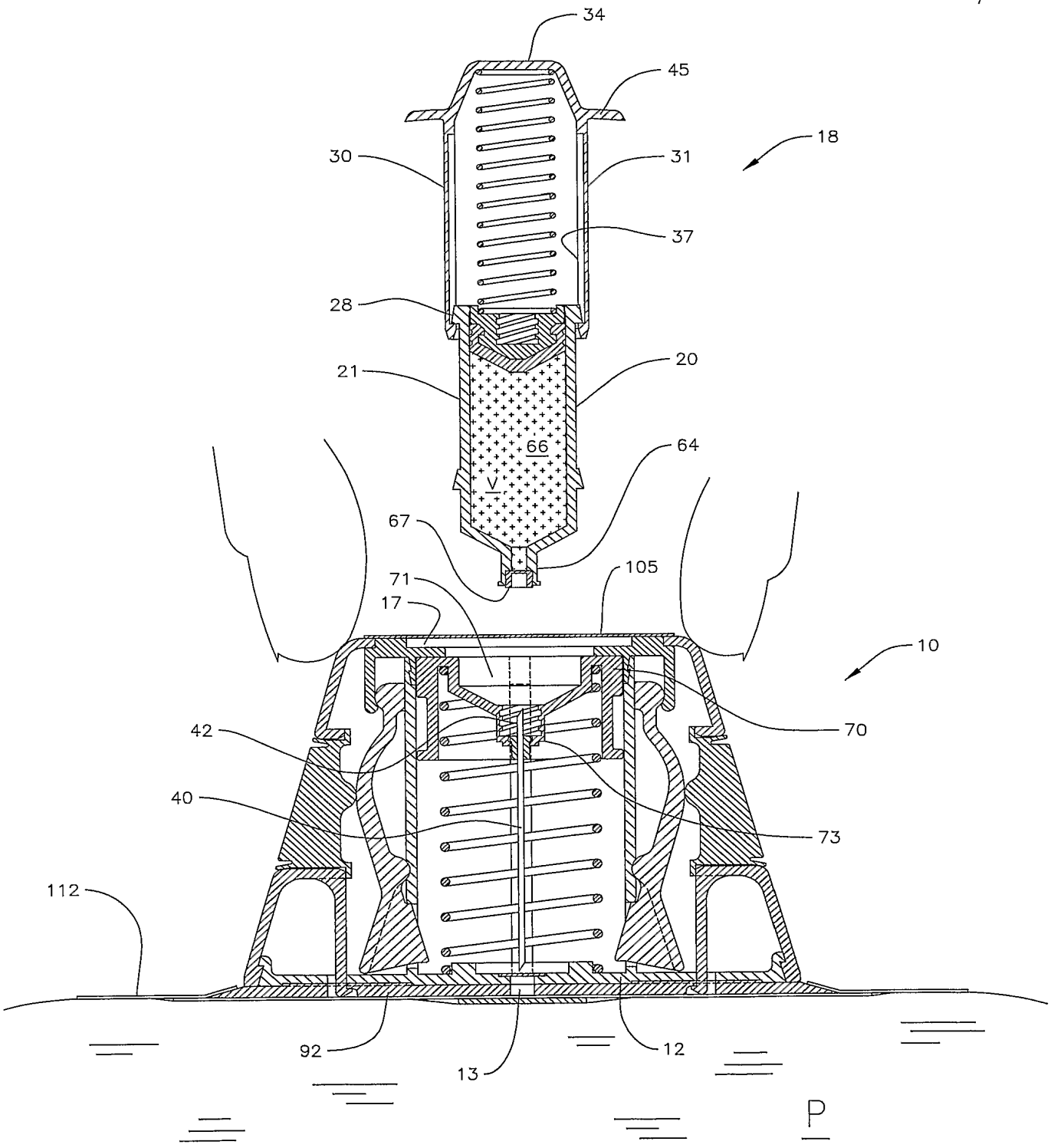
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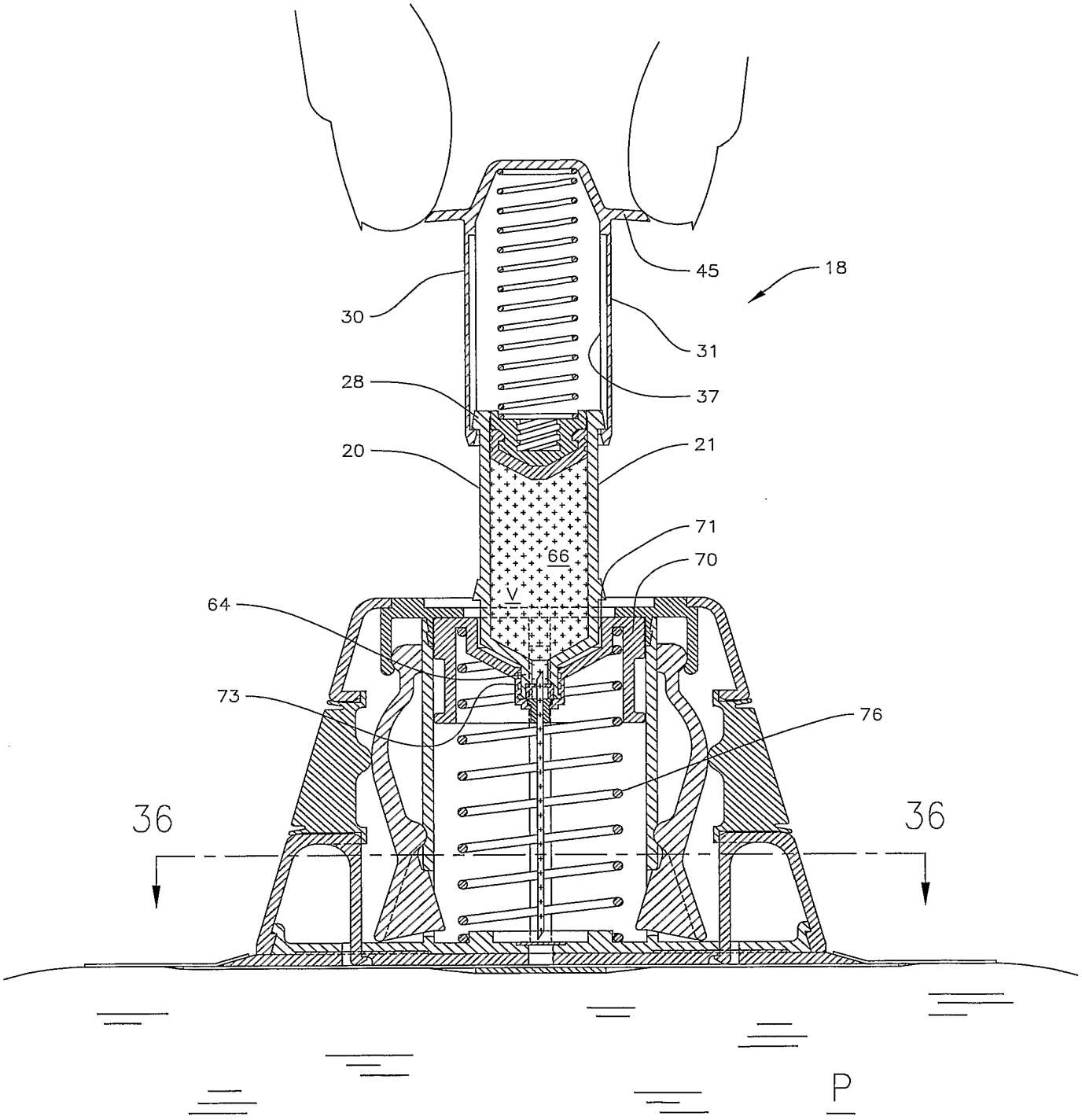
Fig. 21



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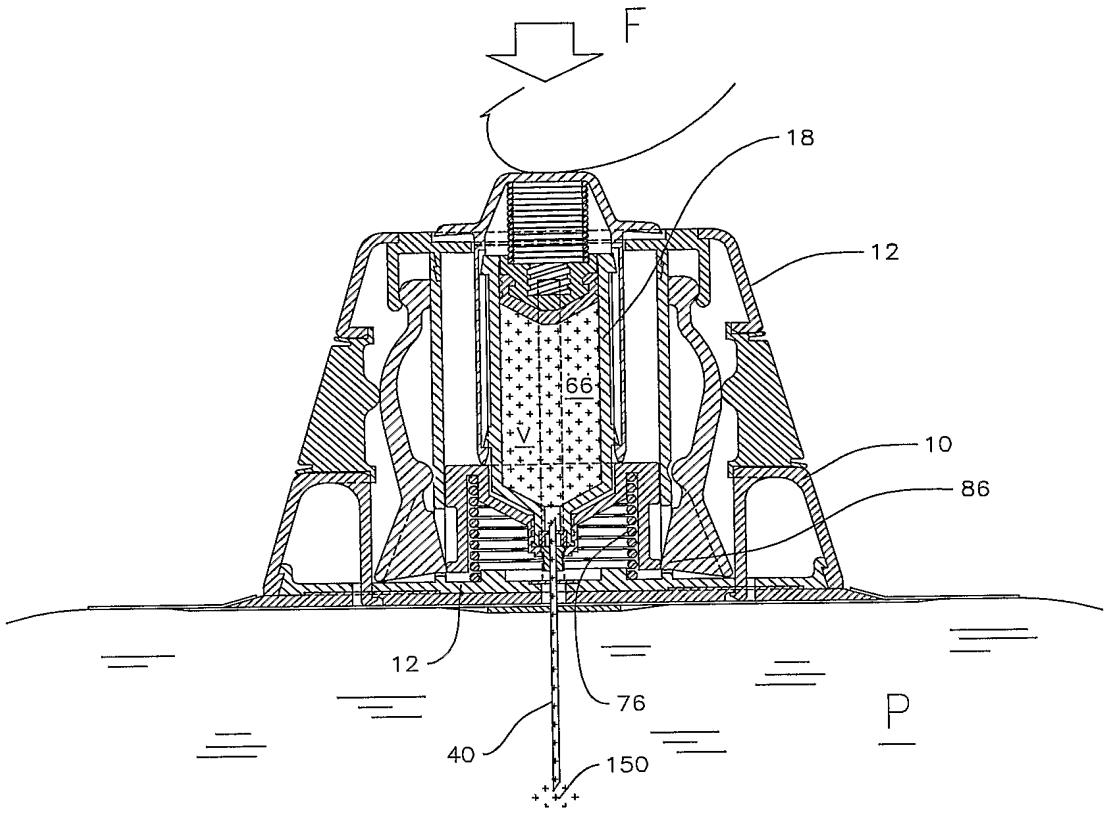

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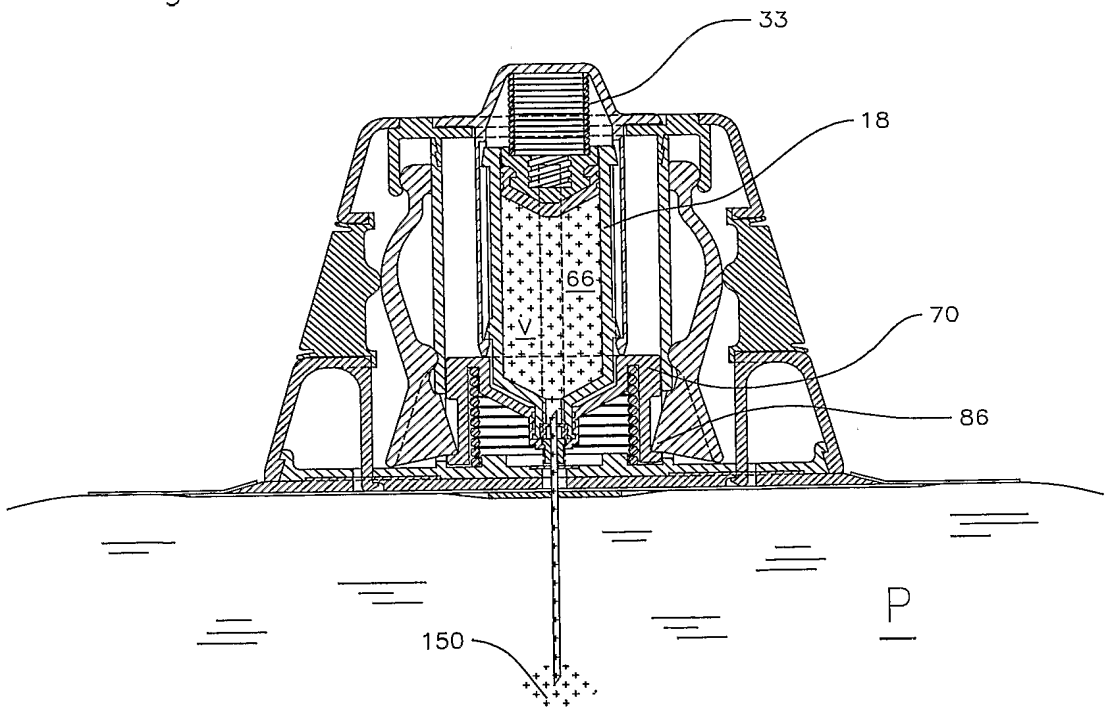

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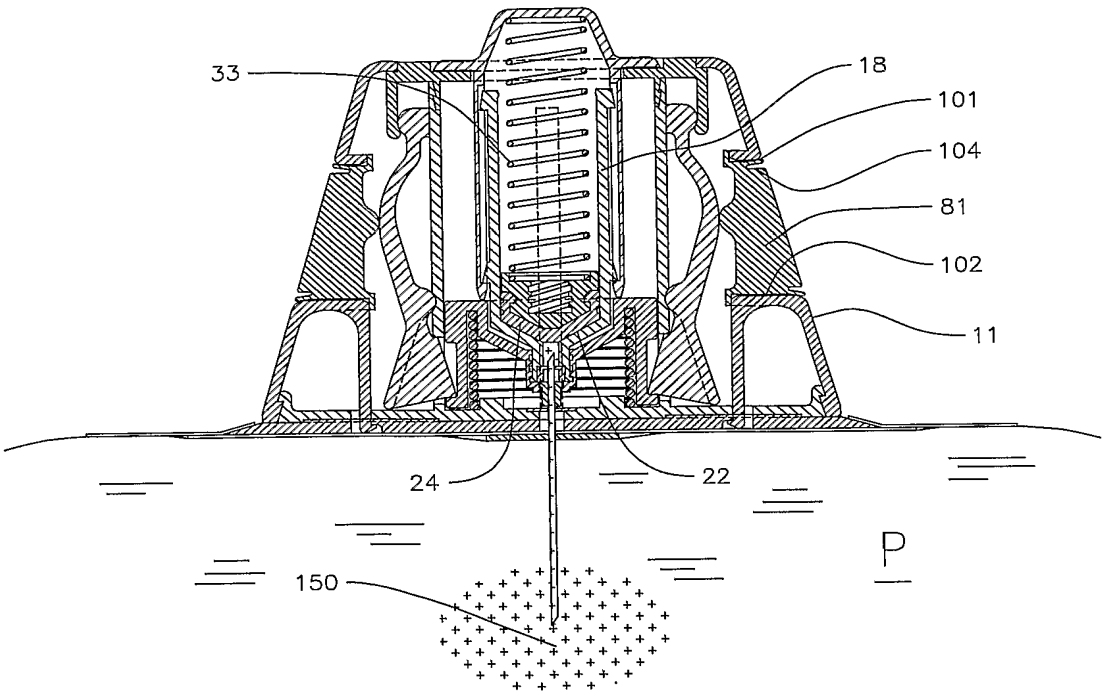
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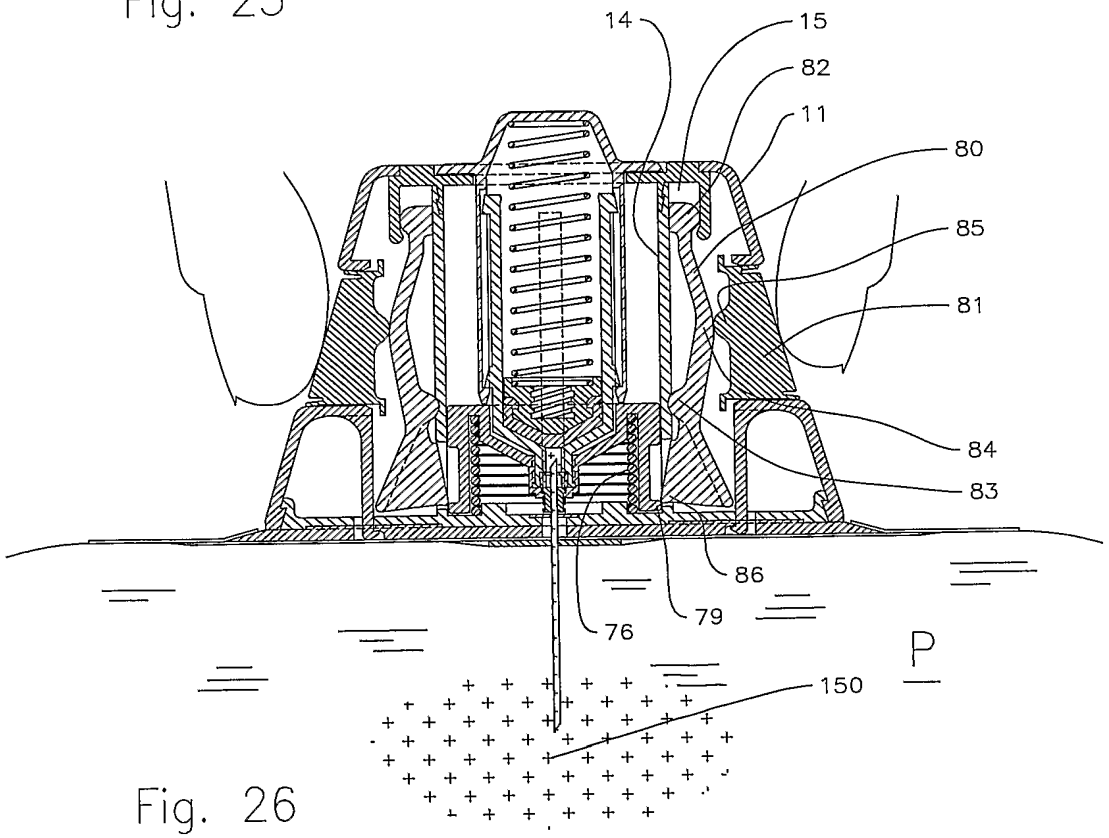
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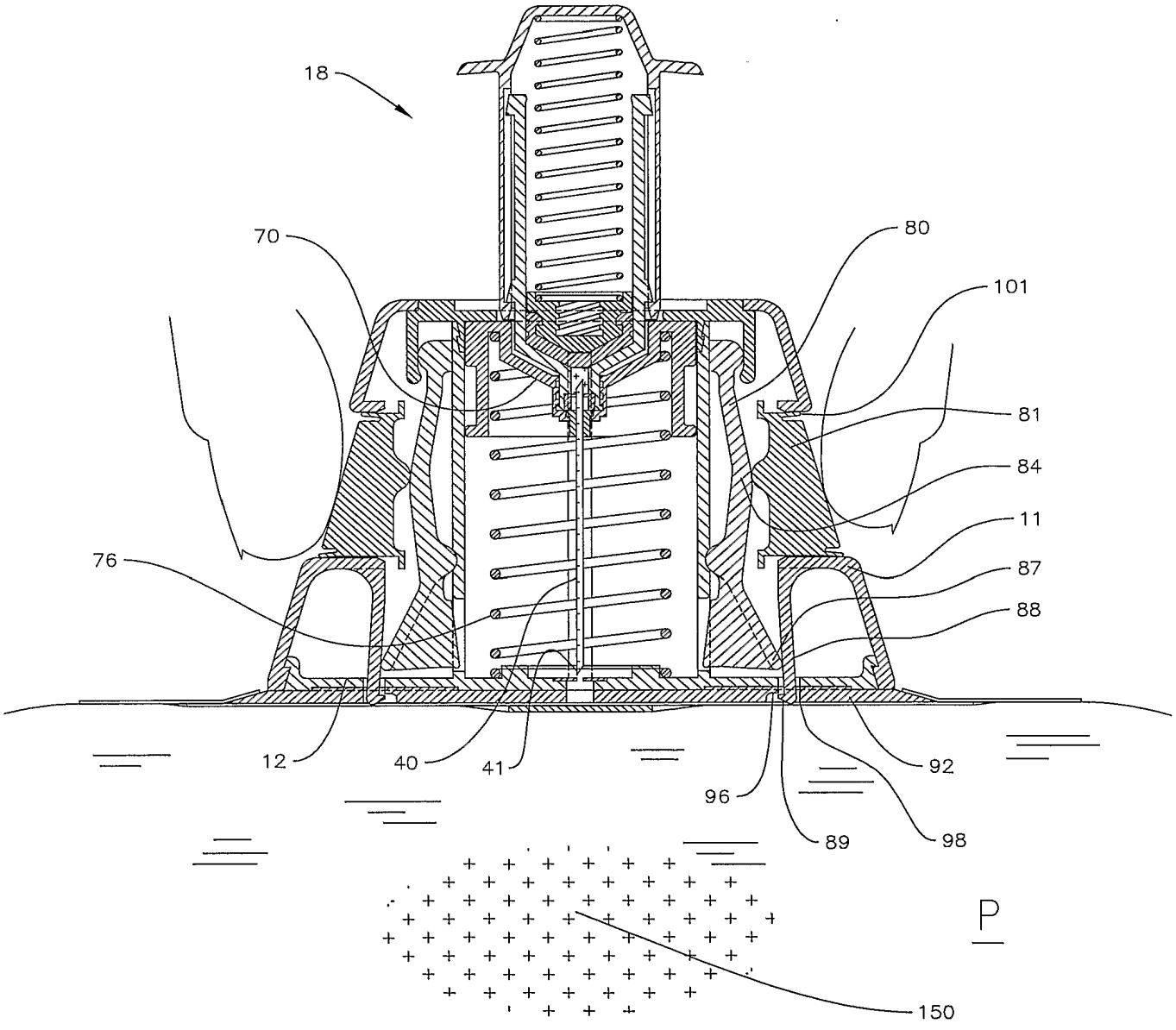
Fig. 26



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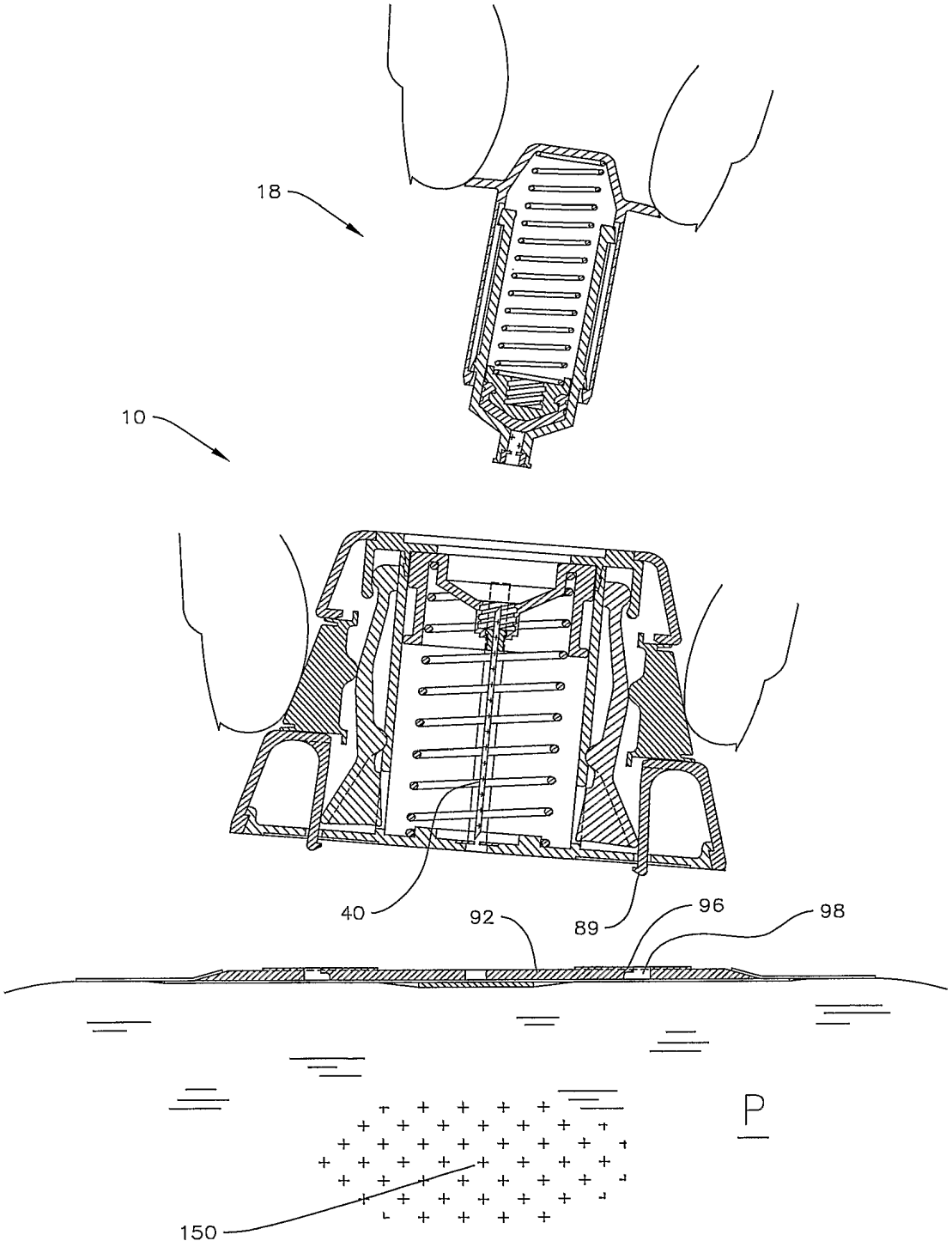

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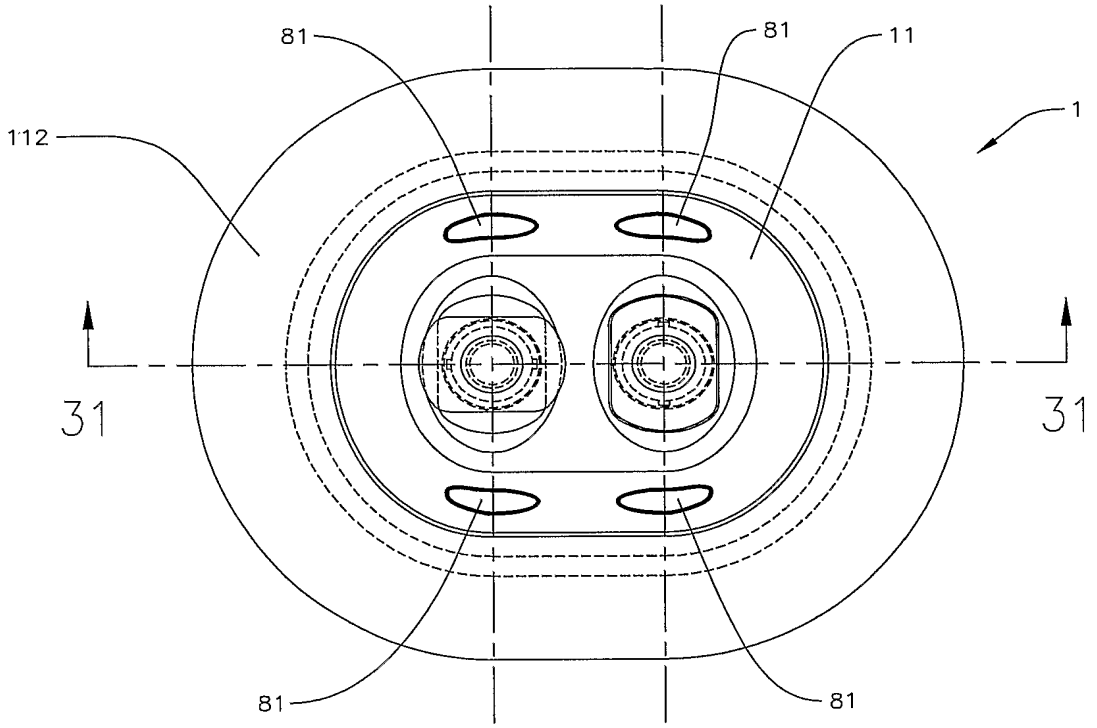

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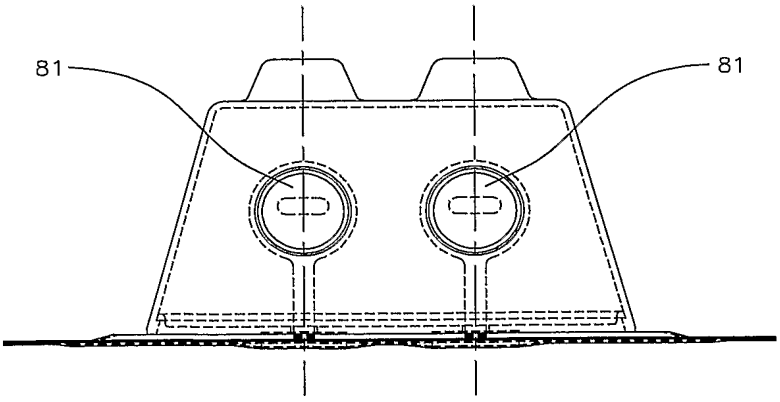

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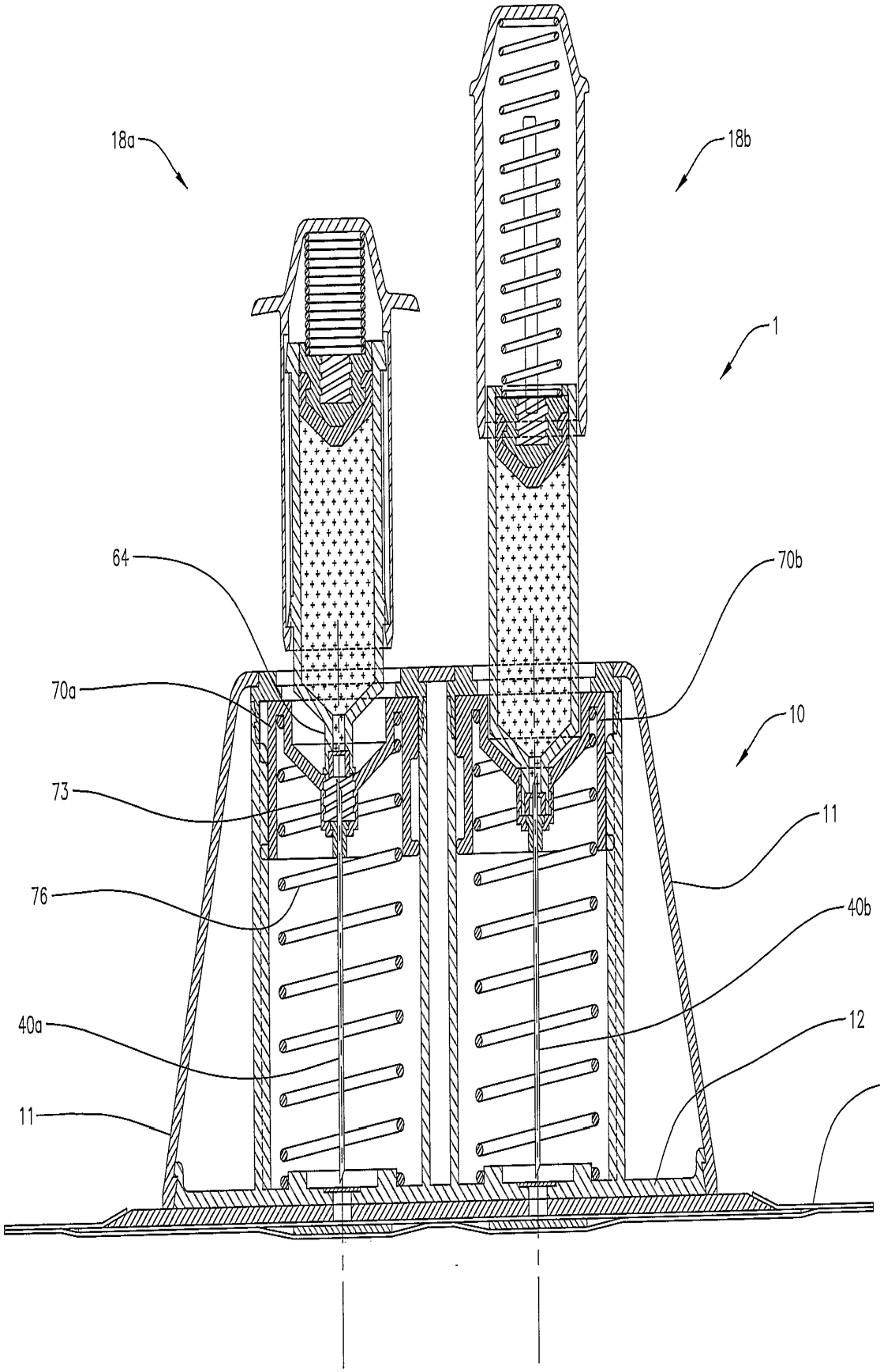

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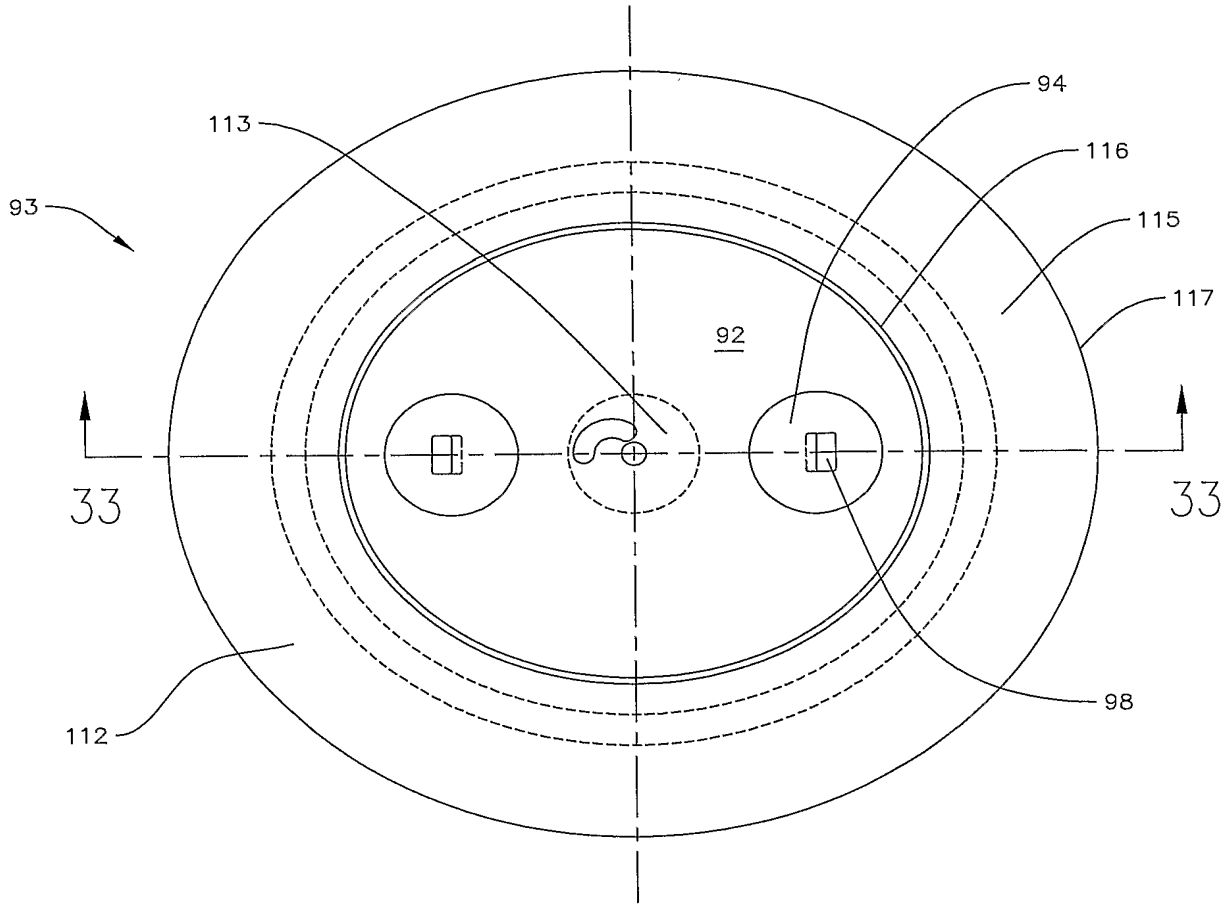

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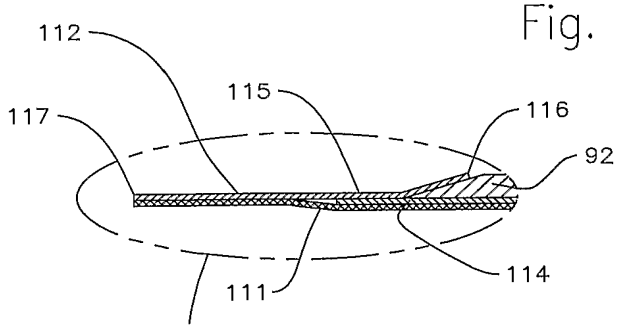

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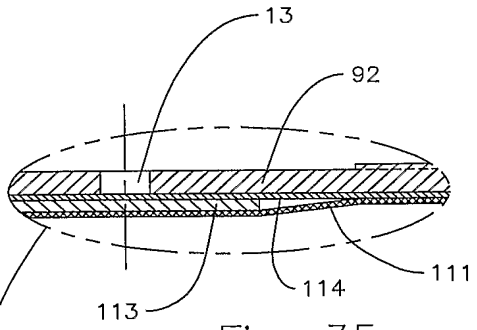

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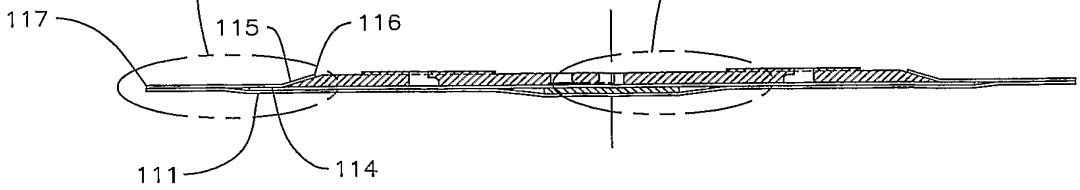

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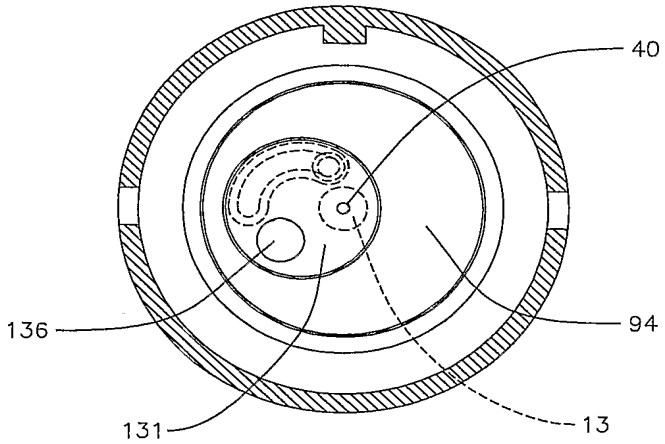

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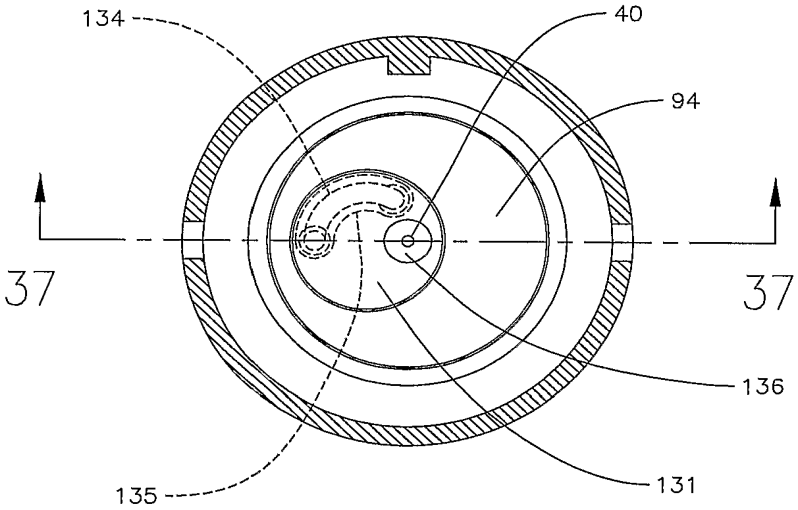

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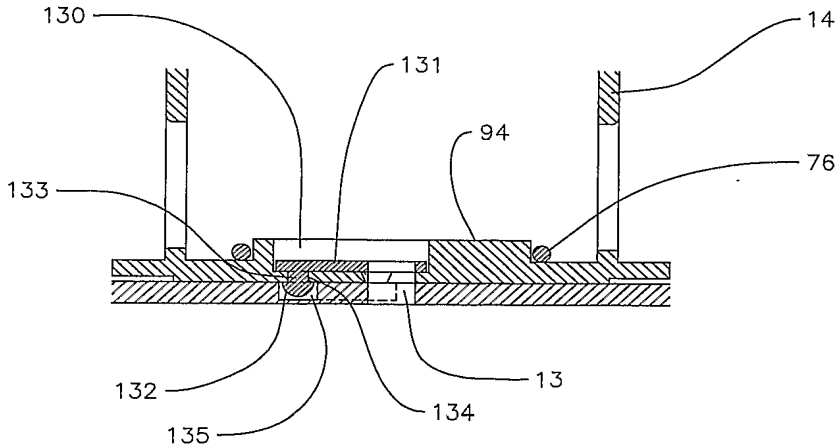

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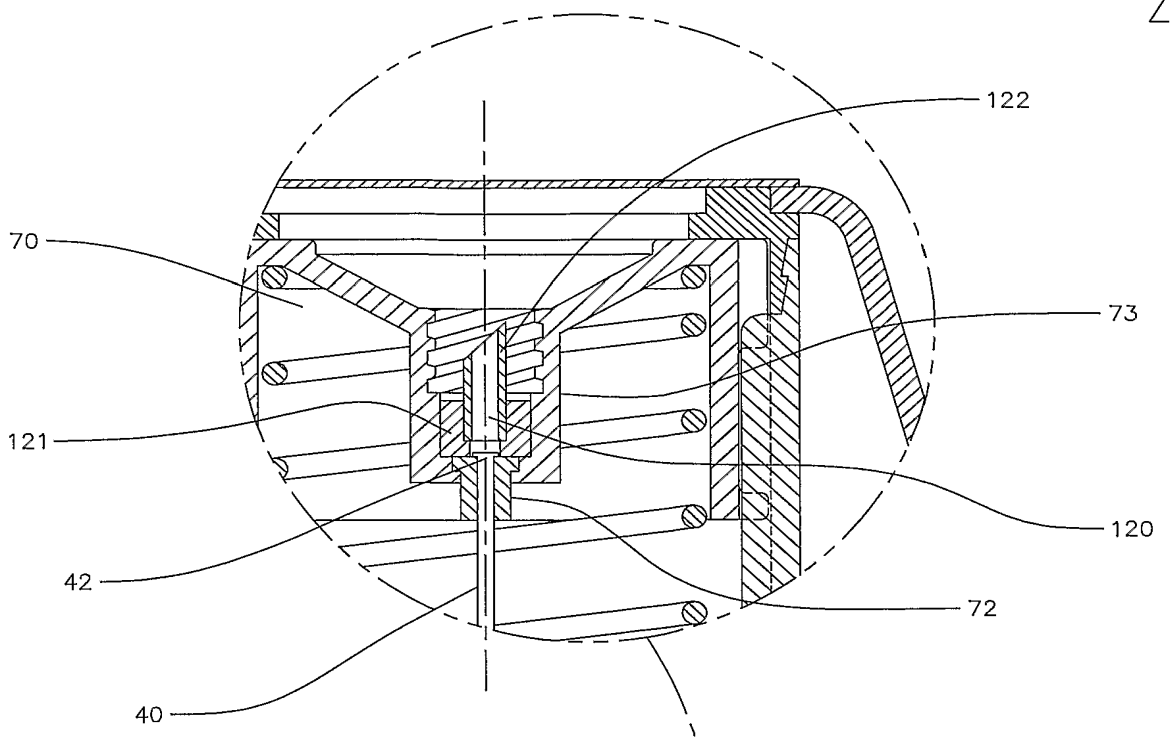

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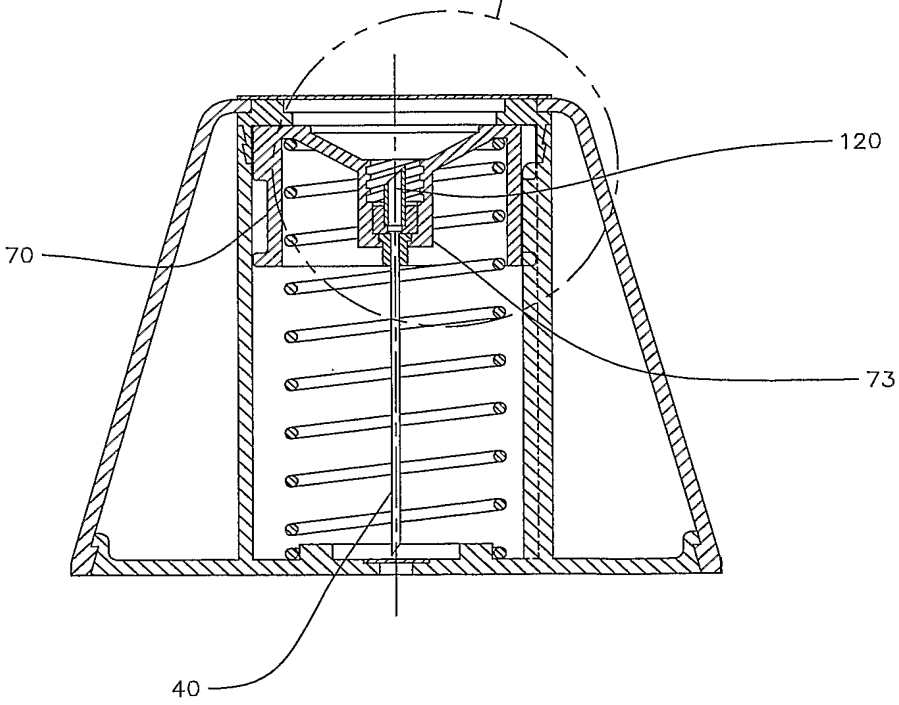

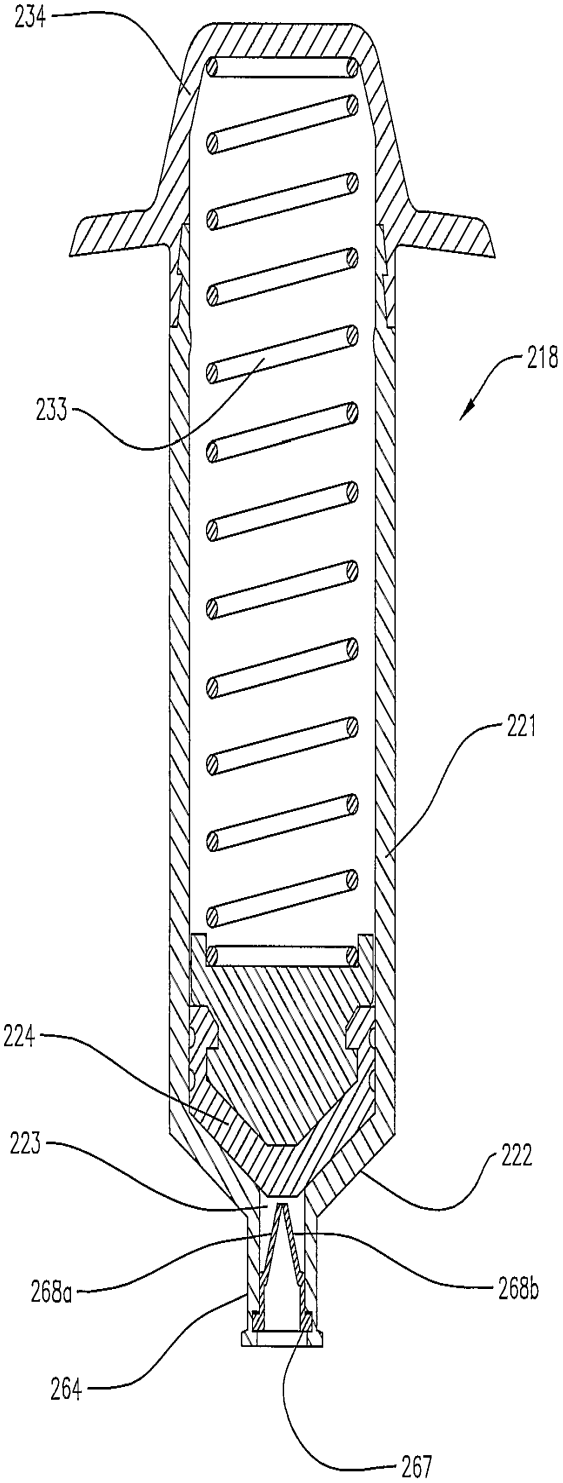
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Fig. 40

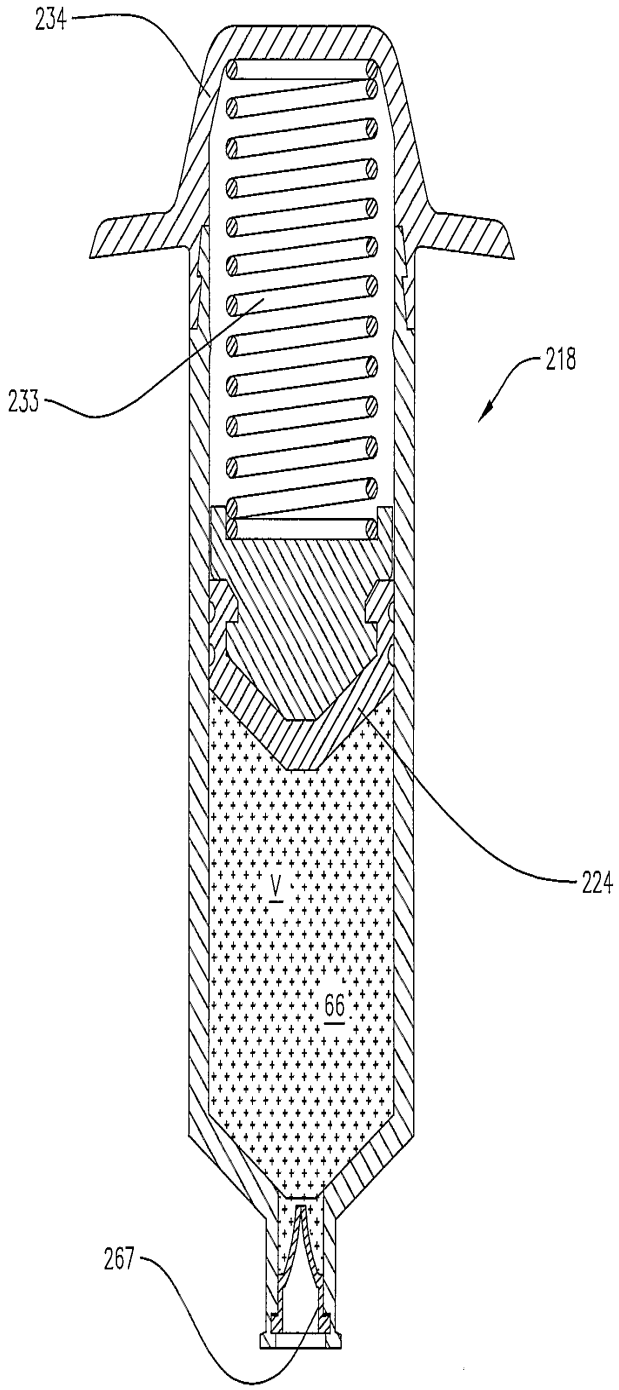
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Fig. 41

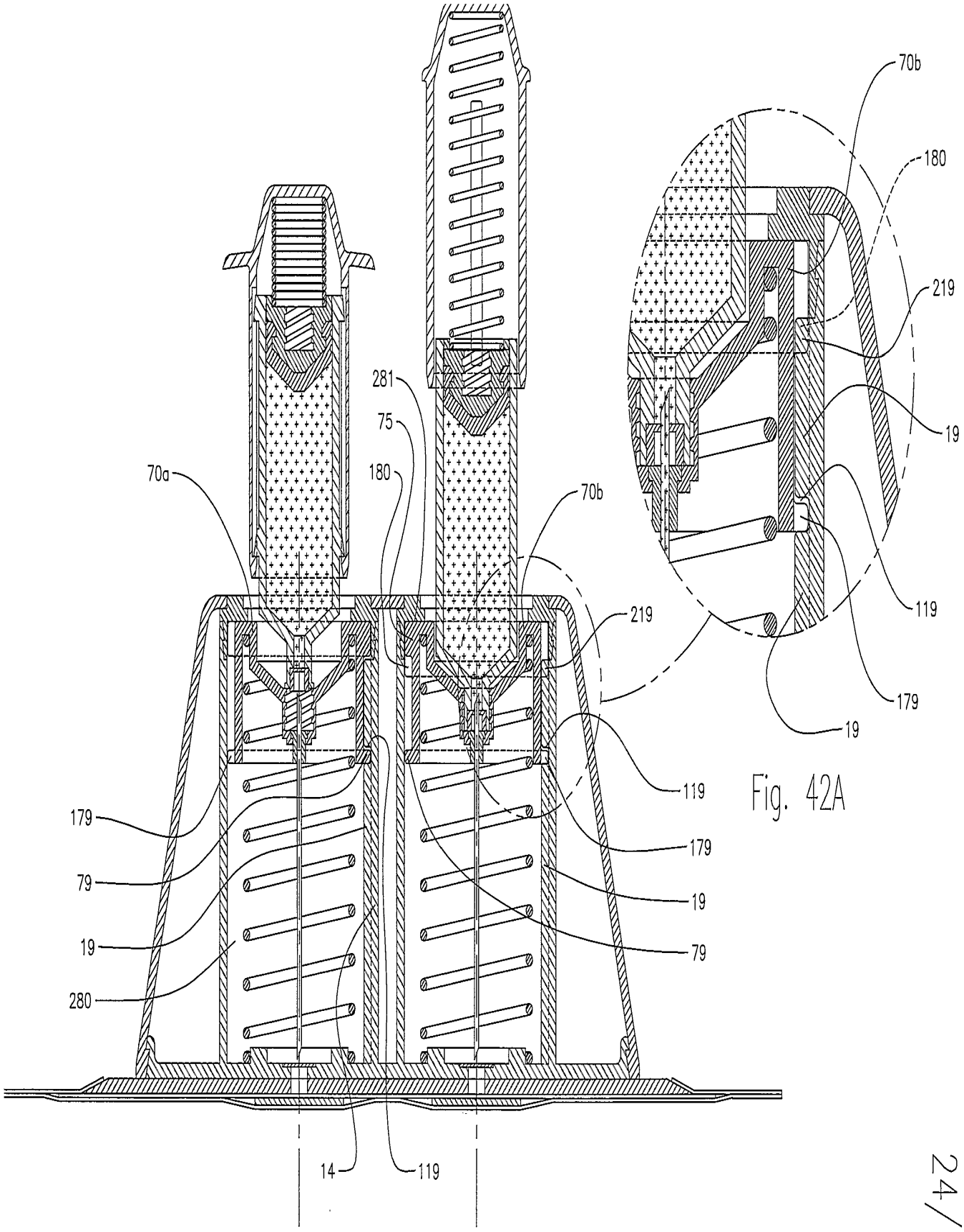
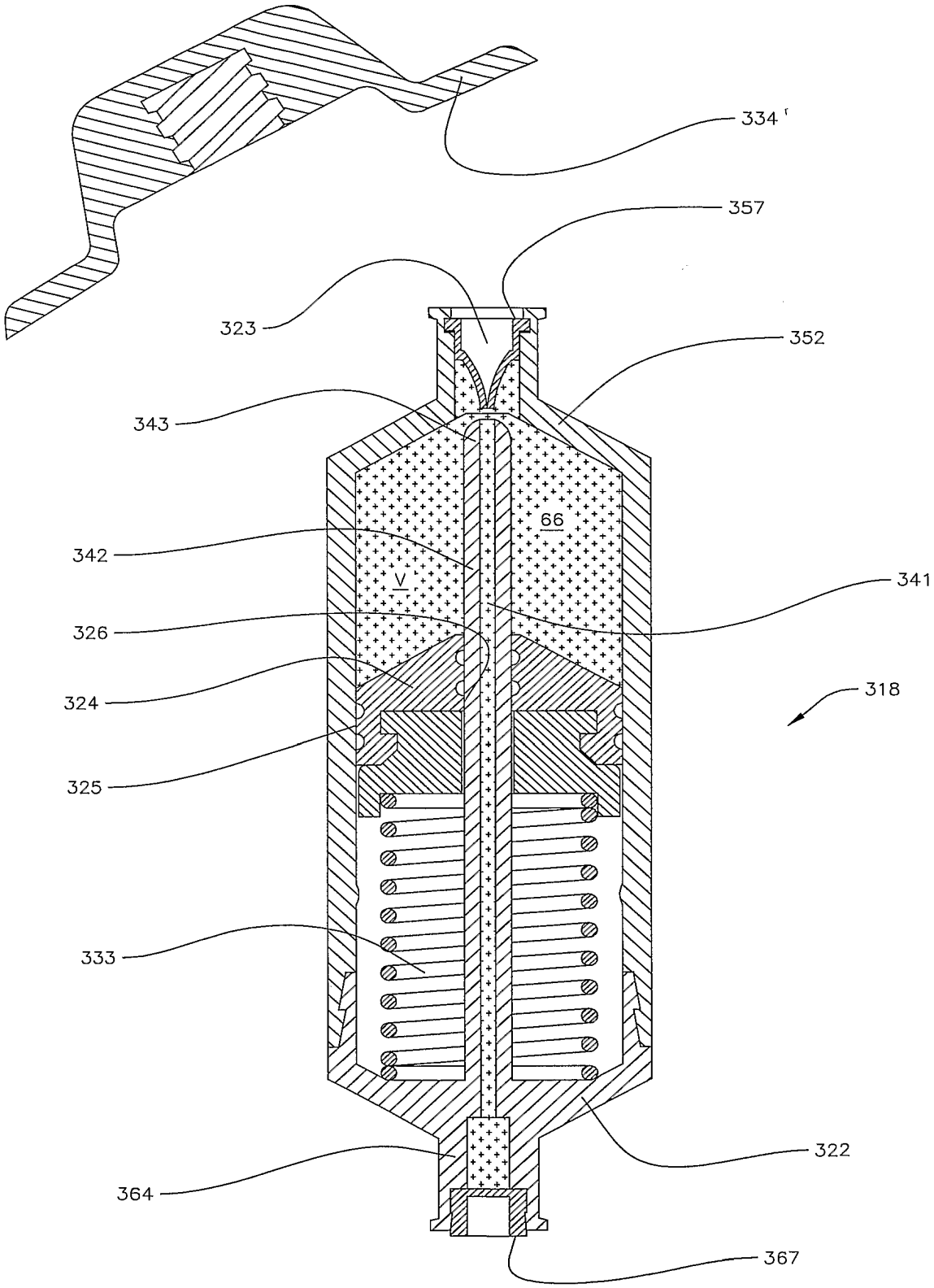


Fig. 42

Fig. 42A



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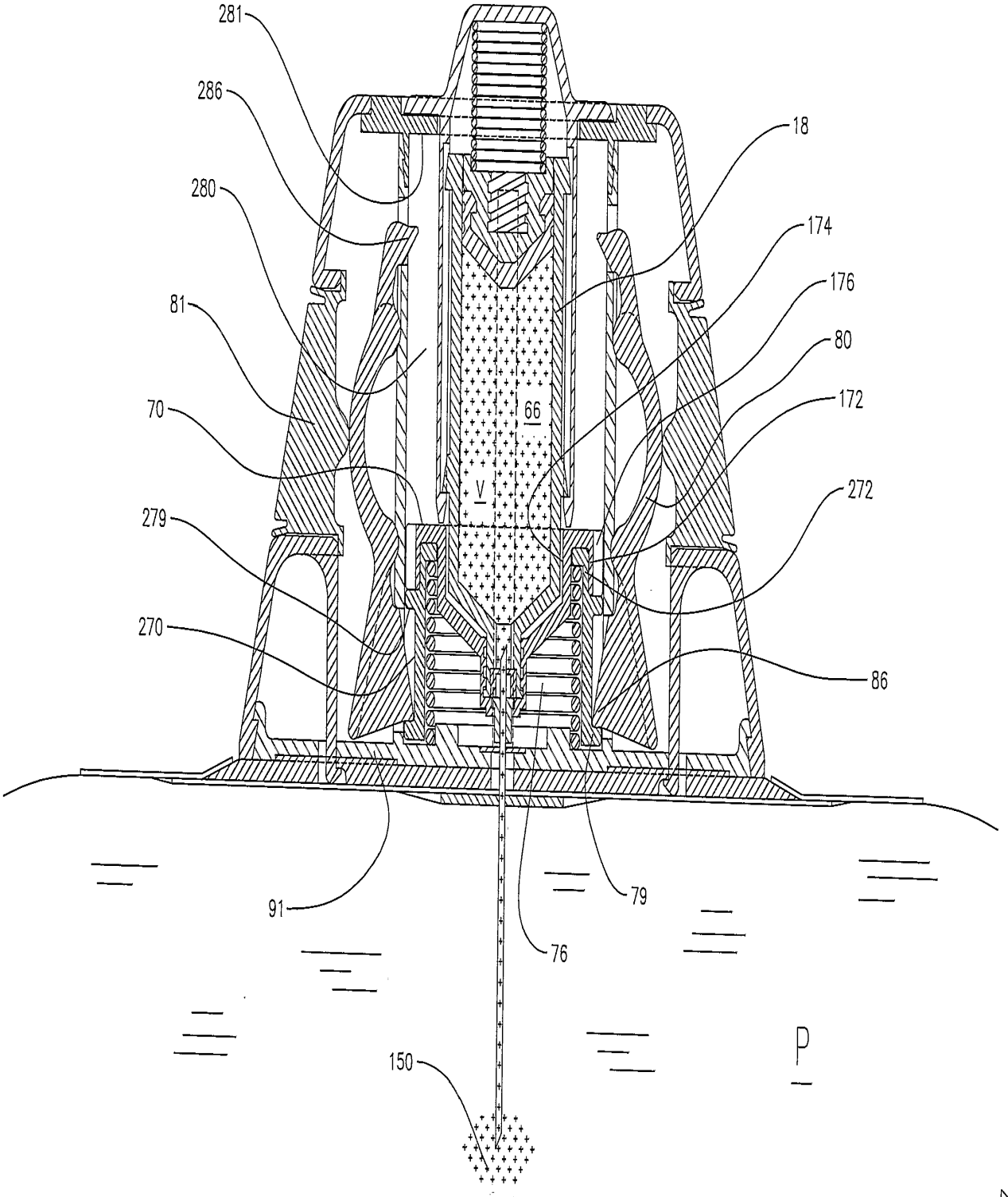
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Fig. 44

Electronic Acknowledgement Receipt

EFS ID:	44551001
Application Number:	17181057
International Application Number:	
Confirmation Number:	4690
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	58249
Filer:	Kassity L. Mai/Donna Doyle
Filer Authorized By:	Kassity L. Mai
Attorney Docket Number:	ELVI-002/06US
Receipt Date:	17-DEC-2021
Filing Date:	22-FEB-2021
Time Stamp:	18:41:20
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		ELVI_002_06US_Preliminary_Amendment.pdf	140479 949ea1289cd835f3ad42a4577092106ea29b755b	yes	7

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Claims	2	6
	Applicant Arguments/Remarks Made in an Amendment	7	7

Warnings:					
Information:					
2	Transmittal Letter	ELVI-002-06US_IDS_Transmittal.pdf	121422 8ccdd4991c96e1104e84665ec4c9e788ff70bf52	no	5
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3	Information Disclosure Statement (IDS) Form (SB08)	ELVI-002_06US_SB08.pdf	198710 93ee84ef4b3b6e1dd6a95df4f599b3d720561dba	no	2
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Information:					
6	Other Reference-Patent/App/Search documents	002-04WO_ISR.pdf	309414 d00a7d0b55be23742a16f08f55945a2aa00c3979	no	9
Warnings:					
Information:					

7	Foreign Reference	WO2005079441A2.pdf	3510260 39d881c285fcb2a70a4f5ef12d44bf42845c7d56	no	69

Warnings:	
Information:	
Total Files Size (in bytes):	7516126

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Docket No.: ELVI-002/06US 339454-2025
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Jonathan O'TOOLE	Confirmation No.:	4690
Application No.:	17/181,057	Group Art Unit:	3783
Filed:	February 22, 2021	Examiner:	C. B. Fredrickson

For: BREAST PUMP SYSTEM

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Prior to examination of the above-identified application, please amend the above-captioned application as follows:

Amendments to the Claims are reflected on the listing of the claims which begins on page 2 of this paper.

Remarks begin on page 7 of this paper.

IN THE CLAIMS:

Set forth below in ascending order, with status identifiers, is a complete listing of all claims currently under examination. Changes to any amended claims are indicated by [[double brackets]], ~~strikethrough~~ and/or underlining. This listing also reflects any cancellation and/or addition of claims.

1. (Currently Amended) A breast pump device that is configured as a self-contained, in-bra wearable device, comprising ~~and includes~~:

(i) a housing that includes (a) a ~~rechargeable~~ battery, and (b) ~~control electronics; (c)~~ a pump generating negative air pressure;

(ii) a breast shield of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing, the breast shield made up of a breast flange and a nipple tunnel ~~and that is configured to be slid in and out of the housing~~, in which the breast shield is transparent or optically clear ~~and comes in several different sizes, each of which are configured to slide in and out of the same housing~~; and

(iii) a milk container that is configured to be attached to and removed from the housing ~~device~~.

2. (Currently Amended) The kit of Claim 31~~breast pump device of Claim 1~~, in which the plurality of interchangeable breast shields ~~different sizes of the breast shield~~ each provide a different spacing of [[the]]a nipple from side walls of the nipple tunnel[[,]] when [[the]]that breast shield has been placed onto a breast.

3. (Original) The breast pump device of Claim 1, in which the breast shield is rigid.

4. (Currently Amended) The breast pump device of Claim 1, in which the breast shield is a ~~an optically clear,~~ dishwasher safe, plastic ~~polycarbonate~~ breast shield.

5. (Currently Amended) The breast pump device of Claim 1, in which the breast shield is configured to attach ~~attaches~~ using magnets to the housing.

6. (Currently Amended) The breast pump device of Claim 1, in which the breast shield is configured to rotate smoothly around [[the]]a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto [[the]]a breast.

7. (Currently Amended) The breast pump device of Claim 1, in which the breast shield presents, in use, a single continuous surface to [[the]]a nipple and a breast.

8. (Currently Amended) The breast pump device of Claim 1, in which the breast shield integrates the breast flange and the nipple tunnel as a single item.

9. (Currently Amended) The breast pump device of Claim 1, in which the breast shield is generally symmetrical about a centre-line running from [[the]]a top to [[the]]a bottom of the breast shield when positioned upright for normal use.

10. (Original) The breast pump device of Claim 1, in which the breast shield is configured to slide into the housing with a single push action.

11. (Original) The breast pump device of Claim 1, in which the breast shield is configured to slide out from the housing, together with a membrane that prevents milk from flowing into the pump.

12. (Original) The breast pump device of Claim 1, in which the milk container is rigid.

13. (Currently Amended) The breast pump device of Claim 1, in which the milk container is an optically clear, dishwasher safe, plastic ~~polycarbonate~~ milk container.

14. (Currently Amended) The breast pump device of Claim 1, in which milk container attaches to a lower part of the housing and forms [[the]]a base of the breast pump device.

15. (Currently Amended) The breast pump device of Claim 1, in which the milk container is configured to magnetically attach ~~attaches~~ to the housing.

16. (Currently Amended) The breast pump device of Claim 1, in which the nipple tunnel includes guide lines running parallel ~~to the~~ along one or more sides of the nipple tunnel.

17. (Original) The breast pump device of Claim 1, in which the nipple tunnel includes an air hole or passage, and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage.

18. (Currently Amended) The breast pump device of Claim 1, in which the nipple tunnel includes on [[its]]a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container.

19. (Currently Amended) The breast pump device of Claim 1, in which the pump ~~the housing~~ includes one or more piezo air pumps.

20. (Currently Amended) The breast pump device of Claim 1, in which the housing further includes a Universal Serial Bus (USB) charging socket.

21. (Currently Amended) The breast pump device of Claim 1, in which the housing includes a left or right breast selector or toggle switch ~~on the housing,~~ that, when selected for a particular pumping session ~~sessions~~, sends data to a connected [[app]]application configured to track ~~that tracks~~ pumping sessions, to indicate whether that particular session is associated with [[the]]a left or [[the]]a right breast.

22. (Currently Amended) The breast pump device of Claim 1, in which the housing is shaped to fit inside a bra by having an outer surface that is curved to fit [[the]] contours of a bra.

23. (Canceled) .

24. (Currently Amended) The breast pump device of Claim 1, in which the breast pump device is configured to deliver a maximum suction of approximately 240 mmHg.

25. (Currently Amended) The breast pump device of Claim 1, in which the breast pump device includes a sensor that is configured to directly ~~measures the~~ measure a level of [[the]] milk in the milk container by measuring [[the]]an intensity of light reflected from [[the]]a surface of the milk stored in the milk container.

26. (Canceled)

27. (Canceled)

28. (Currently Amended) The breast pump device of Claim 1, in which the pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

29. (Currently Amended) The breast pump device of Claim 1, in which the pump is a lightweight air pump that enables [[the]]a total mass of the breast pump device, unfilled with milk, to be less than 250 gm

30. (Currently Amended) The breast pump device of Claim 1, in which the breast pump device makes less than 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

31. (New) A kit, comprising:

the breast pump device of Claim 1; and

the plurality of interchangeable breast shields.

32. (New) The kit of Claim 31, wherein each of the plurality of interchangeable breast shields includes fit lines in a nipple tunnel of that breast shield that are configured to enable a user to

visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel.

33. (New) The breast pump device of Claim 1, wherein the battery is a rechargeable battery, and the housing further includes (c) a power charging circuit for controlling the charging of the rechargeable battery, and (d) control electronics powered by the rechargeable battery.

REMARKS

Entry and consideration of the foregoing amendments is respectfully requested. The above-noted amendments are supported by the application as originally filed and do not introduce any new matter.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

Dated: December 17, 2021

Respectfully submitted,
COOLEY LLP

By: /Kassity L. Mai/
Kassity L. Mai
Reg. No. 68,774
C. Scott Talbot
Reg. No. 34,262

USPTO CUSTOMER NO. 58249

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Tel: (202) 842-7853
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Docket No.: ELVI-002/06US 339454-2025
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Jonathan O'TOOLE	Confirmation No.:	4690
Application No.:	17/181,057	Group Art Unit:	3783
Filed:	February 22, 2021	Examiner:	Courtney B. FREDRICKSON

For: BREAST PUMP SYSTEM

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.56, 1.97, AND 1.98

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98. It is respectfully requested that the information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

[x] Pursuant to 37 C.F.R. §1.98, a copy of each non-US patent document except for cite nos. 26, 28, 29 and 33 cited on the attached Form used in lieu of PTO/SB/08 is enclosed.

[x] No copies of the foreign patent, foreign patent application, or non-patent literature publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98(d) except for cite nos. 26, 28, 29 and 33 because the publications were previously cited by or submitted to the Office in prior Application Serial No(s). 16/009,547 to which the above-identified application claims priority under 35 U.S.C. §120.

[x] No copies of any U.S. patents or U.S. patent application publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98.

[] Publication(s) listed on the attached Form used in lieu of PTO/SB/08 were cited in a foreign search or examination report corresponding to application serial no. and mailed on .

[] Enclosed is a copy of a non-English publication(s) _____ Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).

[] Enclosed is a copy of a non-English publication(s) _____ English language publication _____ (copy enclosed) claims priority from this non-English publication.

[] Enclosed is an explanation of non-English publication(s) _____ for which an English translation is not available.

[] Enclosed is an English translation of non-English publication(s) _____ cited on the attached Form used in lieu of PTO/SB/08.

[] Enclosed is an English language Abstract of non-English publication(s) _____ cited on the attached Form used in lieu of PTO/SB/08.

[] Enclosed is a copy of pending patent Application No. _____.

[x] In accordance with **37 C.F.R. §1.97(b)**, no additional fee for submission of this Information Disclosure Statement is required, as it is filed within any one of the following time periods:

[] within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);

[] within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;

[x] before the mailing date of a first Office action on the merits; or

[] before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

[] In accordance with **37 C.F.R. §1.97(c)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of any of the following: a final action under 37 C.F.R. §1.113; a notice of allowance under 37 C.F.R. §1.311; or an action that otherwise closes prosecution in this application.

In accordance with 37 C.F.R. §1.97(c) also enclosed is:

[] Fee under 37 C.F.R. §1.17(p) in the amount of $260.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $130.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $65.00; or

[] Statement as specified in 37 C.F.R. §1.97(e):

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] This Information Disclosure Statement is filed after payment of the issue fee, but before issuance of the patent under the Quick Path Information Disclosure Statement pilot program.

In accordance with the Quick Path Information Disclosure Statement pilot program also enclosed is:

[] Fee under 37 C.F.R. §1.17(p) in the amount of $260.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $130.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $65.00;

and

[] Statement as specified in 37 C.F.R. §1.97(e):

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. §1.97(d)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(c), but with or before the payment of the issue fee.

In accordance with 37 C.F.R. §1.97(d) also enclosed is:

[] Fee under 37 C.F.R. §1.17(p) in the amount of $260.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $130.00; or

[] Fee under 37 C.F.R. §1.17(p) in the amount of $65.00;

and

[] Statement as specified in 37 C.F.R. §1.97(e):

- [] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or
- [] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. § 1.704(d)**, Applicant notes that to our knowledge each item of information contained in the information disclosure statement:

- [] was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.
- [] is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

In accordance with 37 C.F.R. § 1.97(g), this Information Disclosure Statement shall not be construed as to mean that a search has been made.

In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be material to patentability as defined by 37 C.F.R § 1.56(b).

Remarks

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form used in lieu of PTO/SB/08 to the undersigned.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Applicant believes no fee is due with this response.

Dated: December 17, 2021

Respectfully submitted,
COOLEY LLP

Electronic signature: /Kassity L. Mai/
Kassity L. Mai
Reg. No. 68,774
C. Scott Talbot
Reg. No. 34,262

USPTO CUSTOMER NO. 58249

COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue NW, Suite 700
Washington, DC 20004

Tel: (202) 842-7853
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PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/181,057	Filing Date 02/22/2021	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $240 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	12/17/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 29	Minus	** 30	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $240 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/LISA R EPPS/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/181,057	02/22/2021	Jonathan O'TOOLE	373499.00049

CONFIRMATION NO. 4690

POWER OF ATTORNEY NOTICE

78905
Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

OC000000128525873

Date Mailed: 09/21/2021

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 09/16/2021.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/ttran/

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Alexandria, Virginia 22313-1450
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/181,057	02/22/2021	Jonathan O'TOOLE	ELVI-002/06US

CONFIRMATION NO. 4690

POA ACCEPTANCE LETTER

58249
COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004

OC000000128525909

Date Mailed: 09/21/2021

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 09/16/2021.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/ttran/

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
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If the TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Title	BREAST PUMP SYSTEM
Art Unit	3783
Examiner Name	Courtney B. Fredrickson
Attorney Docket Number	ELVI-002/06US

SIGNATURE of Applicant or Patent Practitioner

Signature	/Kassity L. Mai/	Date (Optional)	September 16, 2021
Name	Kassity L. Mai	Registration Number	68,774
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ *Total of 1 forms are submitted.

256907869 v1

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

[X] I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 58249

OR

[ ] I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

[X] The address associated with the above-mentioned Customer Number

OR

[ ] The address associated with Customer Number:

OR

[ ] Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Chiaro Technology Limited

[ ] Inventor or Joint Inventor (title not required below)

[ ] Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

[X] Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

[ ] Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	Hannah Brunskill	Date (Optional)	September 13, 2021
Name	Hannah Brunskill		
Title	Head of Legal		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

[X] Total of 1 forms are submitted.

Electronic Acknowledgement Receipt

EFS ID:	43786749
Application Number:	17181057
International Application Number:	
Confirmation Number:	4690
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	78905
Filer:	Kassity L. Mai/Julie Chandler
Filer Authorized By:	Kassity L. Mai
Attorney Docket Number:	373499.00049
Receipt Date:	16-SEP-2021
Filing Date:	22-FEB-2021
Time Stamp:	16:52:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	ELVI_002_06US_Power_Of_attorney.pdf	119126 c86d0c5919fa87119748a8b379a058ebcaaa8ab2	no	2

Warnings:

Information:	
Total Files Size (in bytes):	119126

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17181057
Filing Date	2021-02-22
First Named Inventor	Jonathan O'Toole
Art Unit	3783
Examiner Name	
Attorney Docket Number	373499.00049

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5542921	A	1996-08-06	MEYERS, et al.	
	2	7833190	B1	2010-11-16	HALL	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20070135761	A1	2007-06-14	CHENG, et al.	
	2	20070179439	A1	2007-08-02	VOGELIN, et al.	
	3	20090281485	A1	2009-11-12	BAKER, et al.	
	4	20110009824	A1	2011-01-13	YODFAT, et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17181057
	Filing Date	2021-02-22
	First Named Inventor	Jonathan O'Toole
	Art Unit	3783
	Examiner Name	
	Attorney Docket Number	373499.00049

	5	20160271305	A1	2016-09-22	KURIHARA, et al.	
	6	20160296682	A1	2016-10-13	PHILLIPS, et al.	
	7	20160325031	A1	2016-11-10	MILLER, et al.	
	8	20170095599	A1	2017-04-06	KONDO, et al.	
	9	20170112983	A1	2017-04-27	THORNE, et al.	
	10	20180028733	A1	2018-02-01	RIGERT, et al.	
	11	20180333523	A1	2018-11-22	CHANG, et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							

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NON-PATENT LITERATURE DOCUMENTS Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17181057
	Filing Date	2021-02-22
	First Named Inventor	Jonathan O'Toole
	Art Unit	3783
	Examiner Name	
	Attorney Docket Number	373499.00049

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17181057
	Filing Date	2021-02-22
	First Named Inventor	Jonathan O'Toole
	Art Unit	3783
	Examiner Name	
	Attorney Docket Number	373499.00049

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

✓ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Mark D. Simpson/	Date (YYYY-MM-DD)	2021-09-05
Name/Print	Mark D. Simpson	Registration Number	32942

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	43688914
Application Number:	17181057
International Application Number:	
Confirmation Number:	4690
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	78905
Filer:	Mark D. Simpson/Lynn White
Filer Authorized By:	Mark D. Simpson
Attorney Docket Number:	373499.00049
Receipt Date:	05-SEP-2021
Filing Date:	22-FEB-2021
Time Stamp:	19:42:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	38945165_1.PDF	1035283 f7c2571aacda3d7b74c7754f87b8c232447ba959	no	5

Warnings:

Information:	
Total Files Size (in bytes):	1035283

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New Applications Under 35 U.S.C. 111

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National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/181,057	02/22/2021	Jonathan O'TOOLE	373499.00049

CONFIRMATION NO. 4690

78905
Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

PUBLICATION NOTICE

Title:BREAST PUMP SYSTEM

Publication No.US-2021-0170080-A1
Publication Date:06/10/2021

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently https://portal.uspto.gov/pair/PublicPair. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
17/181,057	02/22/2021	3783	1540	373499.00049	30	1

CONFIRMATION NO. 4690

FILING RECEIPT

78905
Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

OC000000123774298

Date Mailed: 03/03/2021

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Jonathan O'TOOLE, London, UNITED KINGDOM;
Adam ROLLO, London, UNITED KINGDOM;
Andrew CARR, London, UNITED KINGDOM;

Applicant(s)

CHIARO TECHNOLOGY LIMITED, London, UNITED KINGDOM;

Power of Attorney: The patent practitioners associated with Customer Number 78905

Domestic Priority data as claimed by applicant

This application is a CON of 16/009,547 06/15/2018 PAT 10926011

Foreign Applications (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.)
UNITED KINGDOM 1709561.3 06/15/2017 Access Code Provided
UNITED KINGDOM 1709564.7 06/15/2017 Access Code Provided
UNITED KINGDOM 1709566.2 06/15/2017 Access Code Provided
UNITED KINGDOM 1809036.5 06/01/2018 Access Code Provided

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

Request to Retrieve - This application either claims priority to one or more applications filed in an intellectual property Office that participates in the Priority Document Exchange (PDX) program or contains a proper **Request to Retrieve Electronic Priority Application(s)** (PTO/SB/38 or its equivalent). Consequently, the USPTO will attempt to electronically retrieve these priority documents.

If Required, Foreign Filing License Granted: 03/02/2021

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/181,057**

Projected Publication Date: 06/10/2021

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

BREAST PUMP SYSTEM

Preliminary Class

604

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign

patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 17/181,057

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	80		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	350		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	400		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	30 minus 20 =	* 10	x 50 =	500	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	x 240 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			210			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	1540		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
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Application number GB 1709566.2

1.	Your reference	**MJD/P153992GB00**
2.	Full name, address and postcode of the applicant or of each applicant	**CHIARO TECHNOLOGY LIMITED** **Second Floor 63-66 Hatton Garden** **London EC1N 8LE** **Greater London** **United Kingdom**
	Patents ADP number *(if you know it)*	**11287869002**
3.	Title of the invention	**BREAST PUMP**
4.	Name of your agent *(if you have one)*	**Boult Wade Tennant**
	"Address for service" to which all correspondence should be sent. This may be in the European Economic area or Channel Islands (see warning note below) *(including the postcode)*	**Boult Wade Tennant** **Verulam Gardens** **70, Gray's Inn Road** **London WC1X 8BT** **United Kingdom**
	Patents ADP number *(if you know it)*	**42001**
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Country	Application number	Date of filing	PDAS Access Code

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   Description: **20**

   Claim*(s)*: **6**

   Abstract: **n/a**

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    Signature: **/DRAPER, Martyn John/** Date: **15 Jun 2017**

12. Name, e-mail address, telephone, fax and/or mobile number, if any, of a contact point for the applicant

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BREAST PUMP

BACKGROUND

A breast pump is a mechanical device that extracts milk from the breasts of a lactating woman.

The typical breast pump design is as shown in WO 96/25187 A1. A large suction generating device is provided, which is freestanding. This is attached by air lines to one or two breast shields which engage with the user's breasts. A pressure cycle is applied from the suction generating device, via the air lines, to the breast shields. This generates a pressure cycle on the user's breasts to simulate the suction generated by a feeding child. The suction generating device is a large component that connects to mains power to operate the pumps therein.

Milk collection bottles are provided to store the expressed breast milk. In the system of WO 96/36298 A1 separate bottles are provided attached to each breast shield. However, in alternative embodiments there may be a single bottle with tubing connecting the breast shields thereto. For a mother to use this somewhat discretely, such as in an office environment, specialised bras must be used. In particular, breast-pumping bras which have a central slit, for the spout of the breast shield to extend through are typically used. The breast shield is held within the bra, with the suction generating device and milk bottle outside the bra.

The fundamental breast pump system has not been significantly altered from this, with minor technical improvements being the main developments.

However, these systems present a number of significant disadvantages. As the suction generating device is a large freestanding unit connected to the mains power, the user may feel tethered to the wall. The devices also require a specific user posture and undressing to function normally. This is obviously difficult for a user to do discretely, such as in an office setting.

Fully integrated wearable breast pumps have begun to enter the market, such as US 2016 206794 A1. In such pumps, the suction source, power supply and milk container are locally provided, without the need for bulky external components or connections. Such devices can be provided with a substantially breast shaped profile so as to fit within a

user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations.

In US 2016 206794 A1, the breast pump has an offset shape favouring the lower half of the pump, and requires complex collapsible bag systems as milk collection devices. This is to force the pump to fit within the user's existing bras.

As the collection bag systems are collapsible, it will be very difficult for a user to extract all of their milk from the bag due to the small cut opening and capillary action between the bonded plastic sheets. This waste can be disheartening for the user as this is food for their child. The bags are also not re-usable, so the user is required to purchase and maintain a stock of these. As well as presenting a recurring cost, if the user runs out of stock they are unable to use the product until more bags are purchased.

Furthermore, as a result of the collapsible bags, a complex pumping arrangement is necessary. In particular, the breast shield connects to a tube which is provided with a plurality of compression units which "step" the expressed milk through the tube to the collection bag. This uses the breast milk as a hydraulic fluid to generate suction on the breast. In order to carry this out, a complex sequenced pulsing arrangement must be implemented.

In addition to these systems being particularly complex and wasteful, a relatively small bag must be used. In US 2016 206794, approximately 110 ml (4 fluid ounces) of milk can be collected before the bag must be changed. While this may be sufficient for some users, others may produce much more milk in a session.

A further integrated wearable breast pump is shown in US 2013 0023821 A1. In the third embodiment in this document, an integral breast pump is provided including a motor driven vacuum pump and power source. An annular (or punctured disc) membrane is provided, with the flow path of the milk going through the centre of the annulus. The membrane is housed in separate housing components and is sealed at its inner and outer edges. The breast shield has a small protrusion to engage with these housing components. However, the design of this breast pump results in a number of problems. The use of an annular membrane, with the fluid flow path running through the opening of the annulus is undesirable as it results in a large and bulky device.

There is therefore a need for improved integrated breast pump systems.

SUMMARY OF THE INVENTION

A breast pump according to a first embodiment of the present invention is provided according to claim 1. This breast pump is for wearing inside a bra, and comprises: a breast shield for engagement with the user's breast; a housing for receiving at least a portion of the breast shield; a pump inside the housing for generating a negative pressure in the breast shield; a battery inside the housing for powering the pump; a detachable rigid milk collection container attachable, in use, to a lower face of the housing and being in connected to the breast shield for collecting milk expressed by the user, with a milk-flow pathway defined from an opening in the breast shield to the milk collection container; and a barrier, the pump acting on one side of the barrier to generate a pressure on the opposite, milk-flow side of the barrier, the barrier having an outer periphery, wherein: the shield, housing, pump, battery and container are provided as a unit with a convex outer surface contoured to fit in a bra; and the milk-flow pathway extends past the outer periphery of the barrier.

This breast pump allows discrete wearing and use, which can fit within a user's bra. The milk-flow path extending past the outer periphery of the barrier allows for a simpler and more robust design, without the milk-flow pathway extending through the barrier. This provides increased interior space and functionality of the device.

A breast pump according to a second embodiment of the present invention is provided according to claim 2. The breast pump is for wearing inside a bra, the breast pump comprising: a breast shield for engagement with the user's breast; a housing for receiving at least a portion of the breast shield; a pump inside the housing for generating a negative pressure in the breast shield; a battery inside the housing for powering the pump; a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user with a milk-flow pathway defined from an opening in the breast shield to the milk collection container, wherein: the shield, housing, pump, battery and container are provided as a unit with a convex outer surface contoured to fit in a bra; and the breast shield comprises a shield flange for engaging the user's breast, and an elongate spout aligned with the opening and extending away from the user's breast, the spout being substantially aligned, in use, with the user's nipple and areolae; the spout comprising a first opening for depositing milk into

the collection container and a second opening for transferring pressure generated by the pump to the user's nipple, the shield flange and spout being detachable from the housing together.

This breast pump allows discrete wearing and use, which can fit within a user's bra. The shield flange and spout being detachable together helps further simplify the design, and reduce the number of components which must be removed for cleaning and sterilisation.

A breast pump according to a third embodiment of the present invention is provided according to claim 3. This breast pump is for wearing inside a bra, and comprises: a breast shield for engagement with the user's breast; a housing for receiving at least a portion of the breast shield; a piezo pump inside the housing for generating a negative pressure in the breast shield; a battery inside the housing for powering the pump; a detachable milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user with a milk-flow pathway defined from an opening in the breast shield to the milk collection container, wherein the shield, housing, pump, battery and container are provided as a unit with a convex outer surface contoured to fit in a bra.

This breast pump allows discrete wearing and use, which can fit within a user's bra. The piezo pump is ideally suited for this environment as it is low noise and high strength with a compact size.

The breast shield of embodiments 1 or 3 may further comprise a shield flange for engaging the user's breast, and an elongate spout aligned with the opening and extending away from the user's breast, the spout being substantially aligned, in use, with the user's nipple and areolae; the spout comprising a first opening for depositing milk into the collection container and a second opening for transferring pressure generated by the pump to the user's nipple.

The shield flange and spout may be detachable from the housing together. Preferably, the spout will be integral with the breast shield. This helps to simplify the design and reduce the number of components which must be removed for cleaning and sterilisation.

The breast shield cup may extend over a majority of the inner surface of the unit, preferably the breast shield extends over 80% of the inner surface of the unit. This reduces the risk of milk contacting a part of the device which cannot be easily sterilised. This also helps to disperse the pressure applied to the user's breast across a larger area. Additionally, by covering the majority of the inner surface, the breast shield is the only component which contact's the wearer's breast. This leaves fewer surfaces which require thorough cleaning.

The spout may connect directly to the container. By reducing the distance covered by the milk, the device is reduced in size and complexity of small intermediate portions.

The spout may comprise an opening directly above the milk collection container. By reducing the distance covered by the milk, the device is reduced in size and complexity of small intermediate portions.

The breast pump of the second or third embodiments may further comprise a barrier mounted in the breast pump, the pump acting on one side of the barrier to generate a pressure on the opposite, milk-flow, side of the barrier.

Preferably, the barrier has an outer periphery and the milk-flow pathway extends past the outer periphery of the barrier. This allows for a simpler and more robust design, without the milk-flow pathway extending through the barrier.

Preferably the milk-flow pathway extends beneath the barrier. This provides an added benefit of having gravity tend the milk away from the barrier.

Preferably the milk-flow pathway does not pass through the barrier. This results in a simpler and smaller barrier design.

Preferably, the barrier is mounted on a housing on the breast shield. More preferably, the housing is integral with the breast shield. This further helps increase the ease of cleaning and sterilisation as all of the components on the "dirty" side can be removed.

Preferably, the barrier is not an annulus.

The barrier may provide a seal to isolate the pump from the milk-flow side of the barrier. This helps to avoid the milk becoming contaminated from the “dirty” airflow side.

Preferably, the only seal is around an outer edge of the barrier. This is a simple design as only a single seal needs to be formed and maintained. Having multiple seals, such as for an annular membrane, introduces additional complexity and potential failure points.

Preferably, the barrier is a diaphragm.

Preferably, the diaphragm is a continuous membrane which is devoid of any openings or holes. This provides a larger effective “working” area of the diaphragm (i.e. the area of the surface in contact with the pneumatic gasses) than an annular membrane and hence the membrane may be smaller to have the same working area.

The breast pump may further comprise a pressure sensor in pneumatic connection with the piezo pump. This allows the output of the pump to be determined.

Preferably, the width of the breast pump is less than 110 mm.

Preferably, the height of the breast pump is less than 180 mm.

Preferably, the plane to plane depth of the breast pump less than 100 mm.

Preferably, in use, the breast pump extends from the user’s breasts by between 3 to 4 cup sizes as per the European standard EN 13402.

Preferably, the milk container has a volume of greater than 120 ml. More preferably, the milk container has a volume of greater than 140 ml.

Preferably, the milk container has a volume of less than 150 ml.

The milk container and housing may form a substantially continuous outer surface of the breast pump. This helps ensure that the breast pump in use fits within a conventional bra system discretely.

The milk container may be at least partially transparent on the outer surface of the breast pump. This allows the level of milk within the container to be easily observed even while pumping.

The milk container may be provided with a spout. This makes it easier for the end user to pour the collected milk into other containers for use or storage.

The milk container may be provided with attachment means for attaching a teat to the container. This allows the milk container to be used directly as a drinking vessel for a child.

The breast shield may be removable. This allows the shield to be easily washed and sterilised.

The milk collection container may be formed of at least two rigid sections which are connectable. This allows simple cleaning of the container for re-use.

The breast pump may further comprise a one-way valve between an inner surface of the breast shield, for engaging with the breast in use, and the milk container.

The one-way valve may be located in an opening to the container.

The pump of the first or second embodiments may be a piezo pump.

The breast shield may be detachable from the breast pump.

The breast pump of the may further comprise a single pole, double throw pneumatic valve, wherein: the pole is in pneumatic connection with the pump and pressure sensor; one of the throws is in pneumatic connection with a dead-end.

The breast pump may further comprise: a first non-return valve between the milk-flow side of the diaphragm and the breast shield, configured to allow only a negative pressure to be applied to the breast shield by the pump; a second non-return valve between the milk-flow side of the diaphragm and the milk collection container configured to allow only a positive pressure to be applied to the milk collection container by the pump; and a pressure sensor in pneumatic connection with the pressure-generation side of the diaphragm.

A method of estimating the pressure applied by a breast pump according to an aspect of the present invention is provided according to claim 42, comprising the steps of: providing a breast pump according to the third embodiment; selecting a pressure cycle from a pre-defined list of pressure cycles; applying pressure with the pump to stimulate milk expression; reading the output of the pressure sensor; and adjusting the applied pressure of the pump to match the pressure profile selected. This allows for repeatable application of force to the breast, even as the pump performance degrades.

Preferably the method further comprises the steps of: approximating the elasticity and extension of the diaphragm at the relevant pressure; and calculating an estimated applied pressure based upon the output of the pressure sensor and the approximated elasticity and extension of the diaphragm.

A method of estimating the milk collected by a breast pump according to an aspect of the present invention is provided according to claim 44, comprising the steps of: providing a breast pump according to claim 33; generating a positive pressure with the pump; transmitting the positive pressure via the diaphragm and second non-return valve to only the milk collection container; measuring the increase in pressure by the pressure sensor in pneumatic connection with the diaphragm; estimating the volume of milk inside the milk collection container based upon the rate of increase of pressure. In this manner, the volume of milk can be estimated remotely.

DESCRIPTION OF THE FIGURES

The invention will now be described with respect to the Figures in which:

Figure 1 is a front view of an assembled breast pump;

Figure 2 is a rear view of the assembled breast pump of Figure 1;

Figure 3 is a front view of a partially disassembled breast pump;

Figure 4 is a rear view of the partially disassembled breast pump of Figure 3;

Figure 5 is a front view of a further partially disassembled breast pump;

Figure 6 is a rear view of the further partially disassembled breast pump of Figure 5;

Figure 7 is a front view of the breast pump of Figure 1, with the outer shell translucent for ease of explanation;

Figure 8 is a further front view of the breast pump of Figure 1, with the front of the outer shell removed for ease of explanation;

Figure 9 is a schematic view of a spout for a breast shield;

Figure 10 is a schematic of a pneumatic system for a breast pump;

Figure 11 is a schematic of an alternative pneumatic system for a breast pump;

Figure 12 is a schematic of a further alternative pneumatic system for a breast pump; and

Figure 13 is a graph depicting measured pressure in the breast pump system of Figure 12 over time.

DETAILED DESCRIPTION

Figure 1 is a front view of a breast pump 100 according to the present invention. The breast pump 100 comprises a housing 1 and a milk collection container (or bottle) 3. The milk collection container 3 is attached to a lower face 1A of the housing 1. While the breast pump 100 may be arranged to be used with one of the right or the left breast specifically, it is preferred the breast pump 100 can be used with either breast without modification. To this end, the outer surfaces of the breast pump 100 are preferably substantially symmetrical

The breast pump 100 is further provided with a user interface 5. This may take the form of a touchscreen and/or physical buttons. In particular, this may include buttons, sliders, any form of display, lights, or any other componentry necessary to control and indicate use of the breast pump 100. Such functions might include turning the breast pump 100 on, specifying which breast is being pumped, or increasing the peak pump pressure. Alternatively, the information provided through the user interface 5 might also be conveyed through haptic feedback, such as device vibration, driven from a miniature vibration motor within the pump housing 1.

In the particular embodiment of the Figures, the user interface 5 comprises power button 5A for turning the pump on and off. The user interface 5 further comprises pump up

button 5B and pump down button 5C. These buttons adjust the pressure generated by the pump and hence applied to the user's breast. In preferable embodiments, the pump up button 5B is physically larger than the pump down button 5C. A play/pause button 5D is provided for the user to interrupt the pumping process without turning the device on and off.

The user interface 5 further comprises a breast toggle button 5E for the user to toggle a display of which breast is being pumped. This may be used for data collection, which is discussed in more detail later, or for the user to keep track of which breast has most recently been pumped. In particular, there may be a pair of LEDs, one to the left of the toggle button 5E and one to the right. When the user is pumping the left breast, the LED to the right of the toggle button 5E will illuminate, so that when the user looks down at the toggle it is the leftmost LED from their point of view that is illuminated. When the user then wishes to switch to the right breast, the toggle button can be pressed and the LED to the left of the toggle button 5E will illuminate.

As depicted in Figure 1, the housing 1 and milk collection container 3 form a substantially continuous outer surface, with a generally convex shape. This shape roughly conforms with the shape of a breast. This allows the breast pump 100 to fit within the cup of a user's bra. The milk collection container 3 is retained in attachment with the housing 3 by means of a latch system, which is released by button 2.

The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting an additional 2 cm difference. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc. In preferred embodiments, the breast pump 100 of the present invention corresponds to an increase of between 3 or 4 cup sizes of the user according to EN 13402.

A plane-to-plane depth of the breast pump can also be defined. This is defined as the distance between two parallel planes, the first of which is aligned with the innermost point of the breast pump 100, and the second of which is aligned with the outermost point of the breast pump 100. This distance is preferably less than 100 mm.

Figure 2 is a rear view of the breast pump 100 of Figure 1. The inner surface of the housing 1 and milk collection container 3 are shown, along with a breast shield 7. The

housing 1, milk collection container 3 and breast shield 7 form the three major sub-components of the breast pump 100. In use, these sub-components clip together to provide the functioning breast pump 100. The breast shield 7 is designed to engage with the user's breast, and comprises a concave inner flange 7A which contacts the breast. To allow the breast pump 100 to be used on either of the user's breasts, the breast shield 7 is preferably substantially symmetrical on its inner flange 7A.

The inner flange 7A is substantially oval-shaped. While the inner flange 7A is concave, it is relatively shallow such that it substantially fits the body form of the user's breast. In particular, when measured side-on the inner-most point of the flange 7A and the outer-most point may be separated by less than 25 mm. By having a relatively shallow concave surface, the forces applied can be spread out over more surface area of the breast. The flatter form also allows easier and more accurate location of the user's nipple. In particular, the flange 7A of the breast shield 7 may extend over the majority of the inner surface of the housing 1 and milk collection container 3. Preferably, it may extend over 80% of this surface.

The breast shield 7 substantially aligns with the outer edge 1B of the housing 1. The milk collection container 3 may be provided with an arcuate groove for receiving a lower part of the breast shield 7. This is best shown in later Figures. In the assembled arrangement of Figures 1 and 2, the inner surface of the breast pump 100 is substantially continuous.

The breast shield 7 further comprises a spout 9 extending from an opening 7B in the breast shield 7. In preferable embodiments the spout 9 is integral with the breast shield 7. However, it is appreciated that separate removable/interchangeable spouts may be used. The opening 7B is aligned with the user's nipple and areola in use. The breast shield 7 forms an at least partial seal with the rest of the user's breast around this portion. This spout 9 defines a milk-flow path from the inner surface of the breast shield 7A, through the spout 9 and into the milk collection container 3. The spout 9 is preferably quite short in order to minimise the length of the milk-flow path in order to minimise losses. In particular, the spout 9 may extend less than 70 mm from its start to end, more preferably less than 50 mm,

Figures 3 and 4 are of a partially disassembled breast pump 100 of the present invention. In these Figures, the breast shield 7 has been disengaged from the housing 1 and milk collection bottle 3. As shown in Figure 4, the housing 1 comprises a slot 11 for receiving the spout 9 of the breast shield 7. The breast shield 7 is held in place by means of a clip 15 engaging with a slot 17 in the housing 1. While this clip 15 is shown at the top of the breast shield 7, it may be placed at any suitable point on the shield 7, with the slot 17 in a corresponding location. The spout 9 of the breast shield 7, is provided with a protrusion 9A on its lower surface. This protrusion 9A is configured to engage with the milk collection bottle 3.

The breast pump 100 further comprises a barrier for transferring the pressure from the pump to the milk-collection side of the system. In the depicted example, this is flexible diaphragm 13. However, it is appreciated that the barrier could be any other suitable component such as a filter or an air transmissive material.

The diaphragm 13 is arranged so that the milk-flow pathway extends past the outer periphery of the diaphragm 13. This means that the milk-flow pathway does not extend through the diaphragm 13. In particular, the milk-flow pathway is beneath the diaphragm 13. However, is appreciated that the diaphragm 13 may be offset in any direction with respect to the milk-flow pathway provided that the milk-flow pathway does not extend through the diaphragm 13.

Preferably, the diaphragm 13 is a continuous membrane, devoid of any openings.

The diaphragm 13 is held in a diaphragm housing 19, which is formed in two parts. The first half 19A of the diaphragm housing 19 is provided on the outer surface of the breast shield 7, above the spout 9 and hence the milk-flow pathway. In preferred embodiments, the first half 19A of the diaphragm housing 19 is integral with the breast shield. The second half 19B of the diaphragm housing is provided in a recessed portion of the housing 1. The diaphragm 13 seals in this diaphragm housing 19 around its outer edge, to form a watertight and airtight seal. Preferably, the seal around the outer edge of the diaphragm 13 is the only seal of the diaphragm 13. This is beneficial over systems with annular diaphragms which must seal at an inner edge as well. Having the diaphragm 13 mounted in the breast pump 100 in this manner ensures that it is easily accessible for

cleaning and replacement. It also ensures that the breast shield 7 and diaphragm 13 are the only components which need to be removed from the pump 100 for cleaning.

Figures 5 and 6 show a breast pump 100 according to the present invention in a further disassembled state. In addition to the breast shield 7 and diaphragm 13 being removed, the milk collection container 3 has been unclipped.

Preferably, the milk collection container 3 is a substantially rigid component. This ensures that expressed milk does not get wasted therein, while also enhancing re-usability. In some embodiments, the milk collection container 3 may be formed of three sections: a front bottle potion, a rear bottle potion, and a cap. These three sections may clip together to form the milk collection container 3. This three part system is easy to empty, easily cleanable, and easily re-usable.

However, in the preferred embodiments the milk bottle 3 is a single integral part with a cap 35. The milk collection container 3 has a capacity of approximately 5 fluid ounces (148 ml).

To achieve this, the milk collection container 3 preferably has a depth in a direction extending away from the breast in use, of between 50 to 80 mm, more preferably between 60 mm to 70 mm, and most preferably between 65 mm to 68 mm.

The milk collection container 3 further preferably has a height, extending in the direction from the bottom of the container 3 in use to the cap 35, of between 40 mm to 60 mm, more preferably between 45 mm to 55 mm, and most preferably between 48 mm to 52 mm.

Further preferably, the milk collection container has a length, extending from the leftmost point to the rightmost point of the container 3 in use, of between 100 mm to 120 mm, more preferably between 105 mm to 115 mm, and most preferably between 107 mm to 110 mm.

This cap 35 is provided with a one-way valve 37, through which milk can flow. This valve 37 prevents milk from spilling from the bottle once it has been collected. In addition, the valve 37 automatically seals completely unless engaged to the breast shield 7. This

ensures that when the pump 100 is dismantled immediately after pumping, no milk is lost from the collection bottle 3. It can be appreciated that this one-way valve 37 might also be placed on the breast shield 7 rather than in this bottle cap 35. The cap 35 may screw into the milk collection bottle 3. In particular, it may be provided with a threaded connection or a bayonet and slot arrangement.

In certain embodiments, a teat may be provided to attach to the annular protrusion 31A to allow the container 3 to be used directly as a bottle. Alternatively, or in addition, a spout may be provided to attach to the protrusion 31A for ease of pouring.

Figures 7 and 8 show front views of a breast pump 100 according to the present invention. The outer-surface of the housing 1 has been drawn translucent to show the components inside. The control circuitry 71 for the breast pump 100 is shown in these figures. The control circuitry in the present embodiment comprises four separate printed circuit boards, but it is appreciated that any other suitable arrangement may be used.

The control circuitry may include sensing apparatus for determining the level of milk in the container 3. The control circuitry may further comprise a wireless transmission device for communicating over a wireless protocol (such as Bluetooth) with an external device. This may be the user's phone, and information about the pumping may be sent to this device. In embodiments where the user interface 5 comprises a breast toggle button 5E, information on which breast has been selected by the user may also be transmitted with the pumping information. This allows the external device to separate pumping data for the left and right breasts.

There should also be charging means within the control circuitry 71 for charging the battery 81. While an external socket, cable or contact point may be required for charging, a form of wireless charging may instead be used such as inductive or resonance charging. In the Figures, charging port 6 is shown for charging the battery 81. This port 6 may be located anywhere appropriate on the housing 1.

Figure 8 shows the location of the battery 81 and the pumps 83A, 83B mounted in series inside the housing 1. While the depicted embodiment shows two pumps 83A, 83B it is appreciated that the present invention may have a single pump.

Preferably, an air filter 86 is provided at the output to the pumps 83A, 83B.In preferable embodiments, the pumps 83A, 83B are piezoelectric pumps (or piezo pump). A suitable piezo pump is manufactured by TTP Ventus, which can deliver in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free flow.

The rear side of the second half of the diaphragm housing 19B in the housing 1 is provided with a pneumatic connection spout. The pumps 83A, 83B are pneumatically connected with this connection spout.

Operation of the breast pump 100 will not be described. Once the breast pump 100 is activated and a pumping cycle is begun, the pumps 83A, 83B generates a negative pressure which is transmitted via the connection spout 85 to a first side of the diaphragm 13 in the diaphragm housing 19. This side of the diaphragm 13 is denoted the pumping side 13B of the diaphragm 13.

The diaphragm 13 transmits this negative pressure to its opposite side (denoted the milk-flow side 13A). This negative pressure is transferred from the first side of the diaphragm housing 19A to the opening 7B of the breast shield 7 via the spout 9. This acts to apply the pressure cycle to the breast of the user, in order to express milk. The milk is then drawn through the spout 9, through the one way valve 37 and into the milk collection container 3. The negative pressure is then released, and periodically reapplied in a manner to imitate the sucking of a child.

While the depicted embodiment of the breast pump 100 is provided with two pumps, the following schematics will be described with a single pump 83. It is understood that the single pump 83 could be replaced by two separate pumps 83A, 83B as above.

Figure 9 depicts a schematic of a further embodiment of a spout 9 for a breast pump 100. The spout 9 is provided with an antechamber 91 and a separation chamber 93. A protrusion 95 extends from the walls of the spout 9 to provide a tortuous air-liquid labyrinth path through the spout 9. In the separation chamber 93 there are two opening 97, 99. An air opening 97 is provided in an upper surface 93A of the separation chamber 93. This upper surface 93 is provided transverse to the direction of the spout 9. This opening 97 connects to the first side of the diaphragm housing 19A and is the source of the negative pressure. This airflow opening 97 also provides a route for air to flow as shown

with arrow 96. It is appreciated that the tortuous pathway is not necessary and that a spout 9 without such a pathway will work.

The other opening 99 is a milk opening 99. The milk opening 99 is provided on a lower surface 93B of the separation chamber 93 and connects in use to the container 3. After flowing through the tortuous spout 9 pathway, the milk is encouraged to flow through this opening 99 into the container 3. This is further aided by the transverse nature of the upper surface 93A.

In this manner, expressed milk is kept away from the diaphragm 13. As such, the breast pump 100 can be separated into a "clean" air-flow side comprising the pump 83, the connection spout 85 and the pumping side 13B of the diaphragm 13 and a "dirty" milk-flow side comprising the breast shield 7, the milk collection container 3 and the milk-flow side 13A of the diaphragm 13. This ensures that all of the "dirty" components are easily detachable for cleaning, maintenance and replacement. Additionally, the milk is kept "clean" by ensuring it does not contact the mechanical components.

While the present embodiment discusses the generation of negative pressure with the pump 83, it will be appreciated that positive pressure may instead be generated.

While the embodiments described herein use a diaphragm 13, any suitable structure to transmit pressure while isolating either side of the system may be used.

Figure 10 shows a schematic of a basic pneumatic system 200 for a breast pump 100. In the system 200 milk expressed into the breast shield 7 is directed through the breast shield spout 9 through the torturous air-liquid labyrinth interface 95. The milk is directed through the non-return valve 37 to the collection container 3. This side of the system forms the "dirty" side 201.

The rest of the pneumatic system 200 forms the "clean" side 202 and is separated from contact with milk. This is achieved by way of a flexible diaphragm 13 which forms a seal between the two sides of the system. The diaphragm 13 has a milk-flow side 13A and an air-flow side 13B.

The “clean” side 202 of the system 200 is a closed system. This side 202 may contain a pressure sensor 101 in pneumatic connection with the diaphragm 13 and the pump 83. Preferably, the pump 83 is a piezoelectric pump (or piezo pump). Due to their low noise, strength and compact size, piezoelectric pumps are ideally suited to the embodiment of a small, wearable breast pump. The pump 83 has an output 83A for generating pressure, and an exhaust to the atmosphere 83B. In a first phase of the expression cycle, the pump 83 gradually applies negative pressure to clean half of the closed system 202 behind the diaphragm 13. This causes the diaphragm 13 to extend away from the breast, and thus the diaphragm 13 conveys a decrease in pressure into the breast shield 7. The reduced pressure encourages milk expression from the breast, which is directed through the tortuous labyrinth system 95 and the one-way valve 37 to the collection bottle 3.

While in the depicted embodiment the exhaust 83B is not used, it may be used for functions including, but not limited to, cooling of electrical components, inflation of the bottle to determine milk volume (discussed further later) or inflation of a massage bladder against the breast. This massage bladder may be used to help mechanically encourage milk expression.

The “clean” side 202 further comprises a two-way solenoid valve 103 connected to a filtered air inlet 105 and the pump 83. Alternatively, the filter could be fitted on the pump line 83A. If the filter is fitted here, all intake air is filtered but the performance of the pump may drop. After the negative pressure has been applied to the user’s breast, air is bled into the system 202 through the valve 103 in a second phase of the expression cycle. In this embodiment, the air filter 105 is affixed to this inlet to protect the delicate components from degradation. In particular, in embodiments with piezoelectric components these are particularly sensitive.

The second phase of the expression cycle and associated switching of valve 103 is actioned once a predefined pressure threshold has been reached. The pressure is detected by a pressure sensor 101.

In certain embodiments, if the elasticity and extension of the diaphragm 13 may be approximated mathematically at different pressures, the pressure measured by sensor 101 can be used to infer the pressures exposed to the nipple on the opposite side of the diaphragm 13.

Figure 11 shows an alternative pneumatic system 300. The core architecture of this system is the same as the system shown in Figure 10.

In this system 300, the closed loop 202 is restricted with an additional three way solenoidal valve 111. This valve 111 allows the diaphragm 13 to be selectively isolated from the rest of the closed loop 202. This additional three way valve 111 is located between the diaphragm 13 and the pump 83. The pressure sensor 101 is on the pump 83 side of the three way valve 111. The three way valve 111 is a single pole double throw (SPDT) valve, with the diaphragm 13 connected to one of the throws 111B. The pump 83 is connected to the pole 111A. The final throw 111C is connected to a dead-end 113. This dead-end 113 may either be a simple closed pipe, or any component(s) that does not allow the flow of air into the system 202. This could include, for example, an arrangement of one-way valves.

In this system 300, therefore, the pump 83 has the option of applying negative pressure directly to the pressure sensor 101. This allows repeated testing of the pump in order to calibrate pump systems, or to diagnose issues with the pump in what is called a dead end stop test. This is achieved by throwing the valve to connect the pump 83 to the dead end 113. The pump 83 then pulls directly against the dead end 113 and the reduction of pressure within the system can be detected by the pressure sensor 101.

Using this function, material fatigue of the pump 83 can be assessed directly. Principally, this knowledge can be used to ensure user experience is not altered, despite the changing output of the pump 83 as it degrades over time. For example, the pump cycle may be changed to drive longer or operate under increased voltage to ensure the same pressures are met. This is particularly relevant for piezo pumps where the output may vary significantly.

Figure 12 shows a schematic for a system 400 for a breast pump 100 which can estimate the volume of milk collected in the collection container 3 from data collected on the “clean” airflow part 202 of the system 400.

The pump 83 is connected to the circuit via two bleed valves 126, 128. The first bleed valve 126 is arranged to function when the pump 83 applies a negative pressure. As

such, this valve 126 is connected to a “bleed in” 127, for supplying atmospheric air to the system 202.

The second bleed valve 128 is arranged to function when the pump 83 applies a positive pressure. As such, this valve 128 is connected to a “bleed out” 129 for bleeding air in the system 202 to the atmosphere.

During a milking pump cycle, the pump 83 applies negative pressure on the “clean” side 13B of the diaphragm 13 which causes its extension towards the pump 83. This increases the volume of the space on the “dirty” side 13B of the diaphragm 13. This conveys the decrease in pressure to the breast to encourage expression of milk. A set of three non-return valves 121, 123, 125 ensure that this decrease in pressure is applied only to the breast (via the breast shield 7) and not the milk collection container 3.

To measure the volume of milk collected in the container 3, the pump 83 is used instead to apply positive pressure to the diaphragm 13. The diaphragm 13 is forced to extend away from the pump 83 and conveys the pressure increase to the “dirty side” 201 of the system 400. The three non-return valves 121, 123, 125 ensure that this increase in pressure is exclusively conveyed to the milk collection container 13.

The resulting pressure increase is monitored behind the diaphragm 13 from the “clean” side 202 by a pressure sensor 101. Preferably, the pressure sensor 101 is a piezoelectric pressure sensor (piezo pressure sensor). The rate at which the pump 83 (at constant strength) is able to increase the pressure in the system 400 is a function of the volume of air that remains in the milk collection container 3. As air is many times more compressible than liquid, the rate at which pressure increases in the system 400 can be expressed as an approximate function of the volume of milk held in the collection container 3.

Thus by increasing the pressure in this fashion, the rate of pressure increase can be determined, from which the volume of milk held in the container 3 is calculable.

The inventor has proved this method for estimating milk volume. Figure 13 shows repeated milking and volume measurement cycles as the collection container 3 is filled. To determine the rate of pressure increase the pump 83 was run for a fixed time. As pumping

proceeds and the volume of air reduces in the system 400, the pump 83 is able to achieve a higher pressure. Each milking cycle is represented by a positive pressure spike 41. There is a clear upwards trend 43 in magnitude of positive pressures achieved as the collection container 3 is filled.

In this manner, an estimate can be obtained for the volume of milk in the container 3 based upon the measured pressures.

Figure 13 also shows a dead end stop pump test 45 as described above. The negative spike 45 shows the application of negative pressure directly to the pressure sensor 101.

CLAIMS:

1. A breast pump for wearing inside a bra, the breast pump comprising:

a breast shield for engagement with the user's breast;

a housing for receiving at least a portion of the breast shield;

a pump inside the housing for generating a negative pressure in the breast shield;

a battery inside the housing for powering the pump;

a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user with a milk-flow pathway defined from an opening in the breast shield to the milk collection container; and

a barrier, the pump acting on one side of the barrier to generate a pressure on the opposite, milk-flow, side of the barrier, the barrier having an outer periphery,

wherein:

the shield, housing, pump, battery and container are provided as a unit with a convex outer surface contoured to fit in a bra; and

the milk-flow pathway extends past the outer periphery of the barrier.

2. A breast pump for wearing inside a bra, the breast pump comprising:

a breast shield for engagement with the user's breast;

a housing for receiving at least a portion of the breast shield;

a pump inside the housing for generating a negative pressure in the breast shield;

a battery inside the housing for powering the pump;

a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user with a milk-flow pathway defined from an opening in the breast shield to the milk collection container,

wherein:

the shield, housing, pump, battery and container are provided as a unit with a convex outer surface contoured to fit in a bra; and

the breast shield comprises a shield flange for engaging the user's breast, and an elongate spout aligned with the opening and extending away from the user's breast, the spout being substantially aligned, in use, with the user's nipple and areolae; the spout comprising a first opening for depositing milk into the collection container and a second opening for transferring pressure generated by the pump to the user's nipple, the shield flange and spout being detachable from the housing together.

3. A breast pump for wearing inside a bra, the breast pump comprising:

a breast shield for engagement with the user's breast;

a housing for receiving at least a portion of the breast shield;

a piezo pump inside the housing for generating a negative pressure in the breast shield;

a battery inside the housing for powering the pump;

a detachable milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user with a milk-flow pathway defined from an opening in the breast shield to the milk collection container,

wherein the shield, housing, pump, battery and container are provided as a unit with a convex outer surface contoured to fit in a bra.

4. The breast pump according to claim 1 or 3 wherein the breast shield comprises a shield flange for engaging the user's breast, and an elongate spout aligned with the opneing extending away from the user's breast, the spout being substantially aligned, in use, with the user's nipple and areolae; the spout comprising a first opening for depositing milk into the collection container and a second opening for transferring pressure generated by the pump to the user's nipple.

5. The breast pump of claim 4, wherein the shield flange and spout are detachable from the housing together

6. The breast pump of claim 2, 4 or 5, wherein the spout is integral with the breast shield.

7. The breast pump according to claim 2 or 4 to 6, wherein the breast shield cup extends over a majority of the inner surface of the unit.

8. The breast pump of claim 7, wherein the breast shield extends over 80% of the inner surface of the unit.

9. The breast pump of any of claims 2 or 4 to 8, wherein the spout connects directly to the container.

10. The breast pump of any of claims 2 or 4 to 9, wherein the spout comprises an outflow opening for depositing milk directly above the milk collection container.

11. The breast pump of any of claims 2 or 3, and claims 4 to 10 when dependent upon claims 2 or 3, further comprising a barrier, the pump acting on one side of the barrier to generate a pressure on the opposite, milk-flow, side of the barrier.

12. The breast pump of claim 10, wherein the barrier has an outer periphery and the milk-flow pathway extends past the outer periphery of the barrier.

13. The breast pump of any of claims 2, 11 or 12, wherein the milk-flow pathway is beneath the barrier.

14. The breast pump of any of claims 2 or 11 to 13, wherein the milk-flow pathway does not pass through the barrier.

15. The breast pump of any of claims 2 or 11 to 14, wherein the barrier is mounted in a housing on the breast shield.

16. The breast pump of claim 15, wherein the housing is integral with the breast shield.

17. The breast pump of any of claims 2 or 11 to 16, wherein the barrier is not an annulus.

18. The breast pump of any of claims 2 or 11 to 17, wherein the barrier provides a seal to isolate the pump from the milk-flow side of the barrier.

19. The breast pump of claim 18, wherein the only seal is around an outer edge of the barrier.

20. The breast pump of any of claims 2 or 11 to 19, wherein the barrier is a diaphragm.

21. The breast pump of claim 20, wherein the diaphragm is a continuous membrane which is devoid of any openings or holes.

22. The breast pump according to any preceding claim, further comprising a pressure sensor in pneumatic connection with the pump.

23. The breast pump of any preceding claim, wherein the width of the breast pump is less than 110 mm.

24. The breast pump of any preceding claim, wherein the height of the breast pump is less than 180 mm.

25. The breast pump of any preceding claim, wherein the plane to plane depth of the breast pump is less than 100 mm.

26. The breast pump of any preceding claim, wherein, in use, the breast pump extends from the user's breasts by 3 to 4 cup sizes as per the European standard EN 13402.

27. The breast pump of any preceding claim, wherein the milk container has a volume of greater than 120 ml.

28. The breast pump of claim 27, wherein the milk container has a volume of greater than 140 ml.

29. The breast pump of claim 27 or 28, wherein the milk container has a volume of less than 150 ml.

30. The breast pump of any preceding claim, wherein the milk container and housing form a substantially continuous outer surface of the breast pump.

31. The breast pump of any preceding claim, wherein the milk container is at least partially transparent on the outer surface of the breast pump.

32. The breast pump of any preceding claim, wherein the milk container is provided with a spout.

33. The breast pump of any preceding claim, wherein the milk container is provided with attachment means for attaching a teat to the container.

34. The breast pump of any preceding claim, wherein the breast shield is removable.

35. The breast pump of any preceding claim, wherein the milk collection container is formed of at least two rigid sections which are connectable.

36. The breast pump of any preceding claim, further comprising a one-way valve between an inner surface of the breast shield, for engaging with the breast in use, and the milk container.

37. The breast pump of claim 36, wherein the one-way valve is located in an opening to the container.

38. The breast pump of claim 1 or 2, wherein the pump is a piezo pump.

39. The breast pump of any of any preceding claim, wherein the breast shield is detachable from the breast pump.

40. The breast pump of any of claims 22 or 23 to 39 when dependent upon claim 22, further comprising a single pole, double throw pneumatic valve, wherein:

the pole is in pneumatic connection with the pump and pressure sensor;

one of the throws is in pneumatic connection with the diaphragm; and

the other throw is in pneumatic connection with a dead-end.

41. The breast pump of any of claim22 or 23 to 40 when dependent upon claim 22, further comprising:

a first non-return valve between the milk-flow side of the diaphragm and the breast shield, configured to allow only a negative pressure to be applied to the breast shield by the pump;

a second non-return valve between the milk-flow side of the diaphragm and the milk collection container configured to allow only a positive pressure to be applied to the milk collection container by the pump; and

a pressure sensor in pneumatic connection with the pressure-generation side of the diaphragm.

42. A method of estimating the pressure applied by a breast pump according to claim 40, comprising the steps of:

providing a breast pump according to claim 40;

selecting a pressure cycle from a pre-defined list of pressure cycles;

applying pressure with the pump to stimulate milk expression;

reading the output of the pressure sensor;

adjusting the applied pressure of the pump to match the pressure profile selected by the user.

43. The method of claim 42, further comprising:

approximating the elasticity and extension of the diaphragm at the relevant pressure; and

calculating an estimated applied pressure based upon the output of the pressure sensor and the approximated elasticity and extension of the diaphragm.

44. A method of estimating the milk collected by a breast pump according to claim 41, comprising the steps of:

providing a breast pump according to claim 41;

generating a positive pressure with the pump;

transmitting the positive pressure via the diaphragm and second non-return valve to only the milk collection container;

measuring the increase in pressure by the pressure sensor in pneumatic connection with the diaphragm;

estimating the volume of milk inside the milk collection container based upon the rate of increase of pressure.

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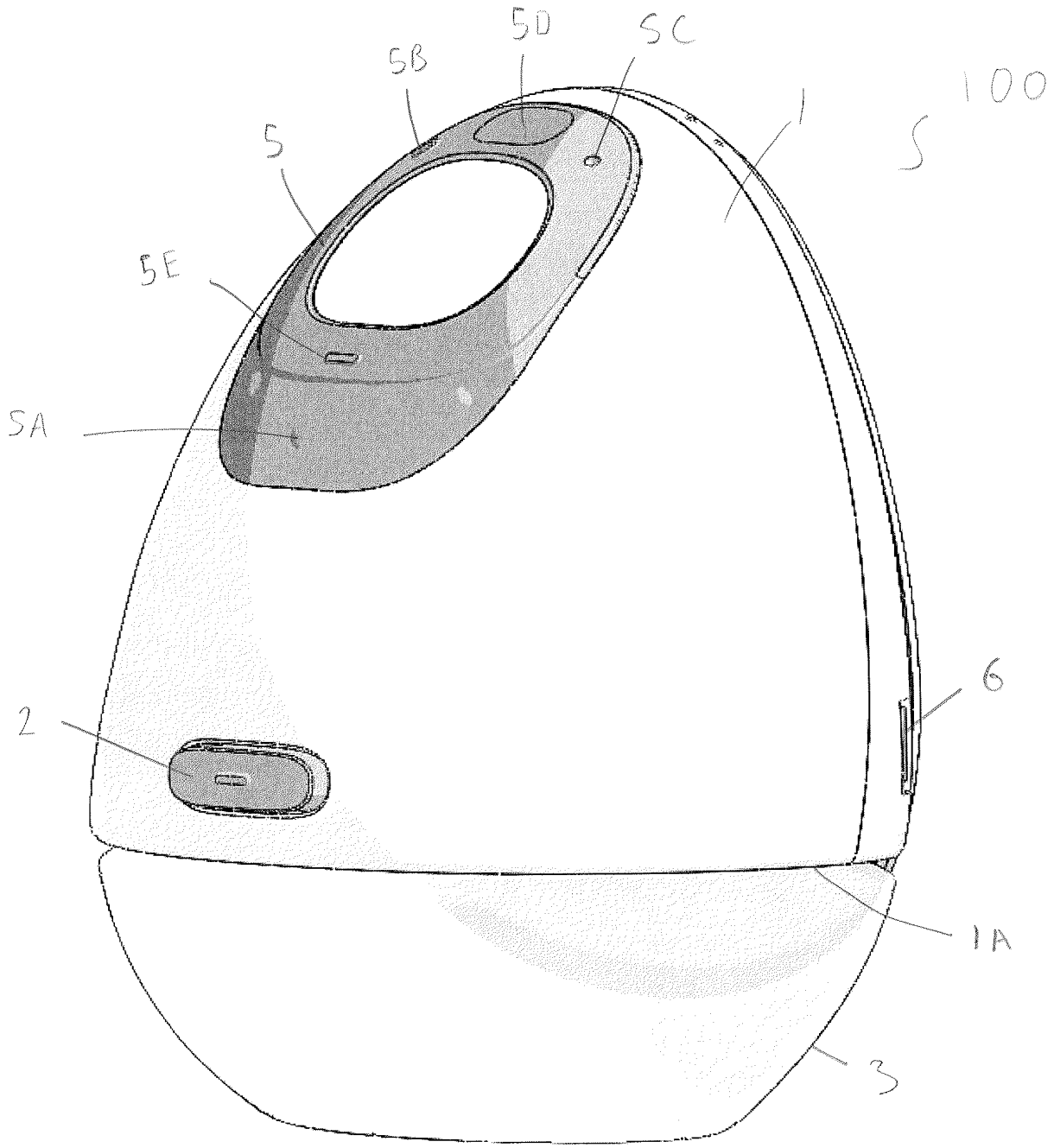

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Fig 2

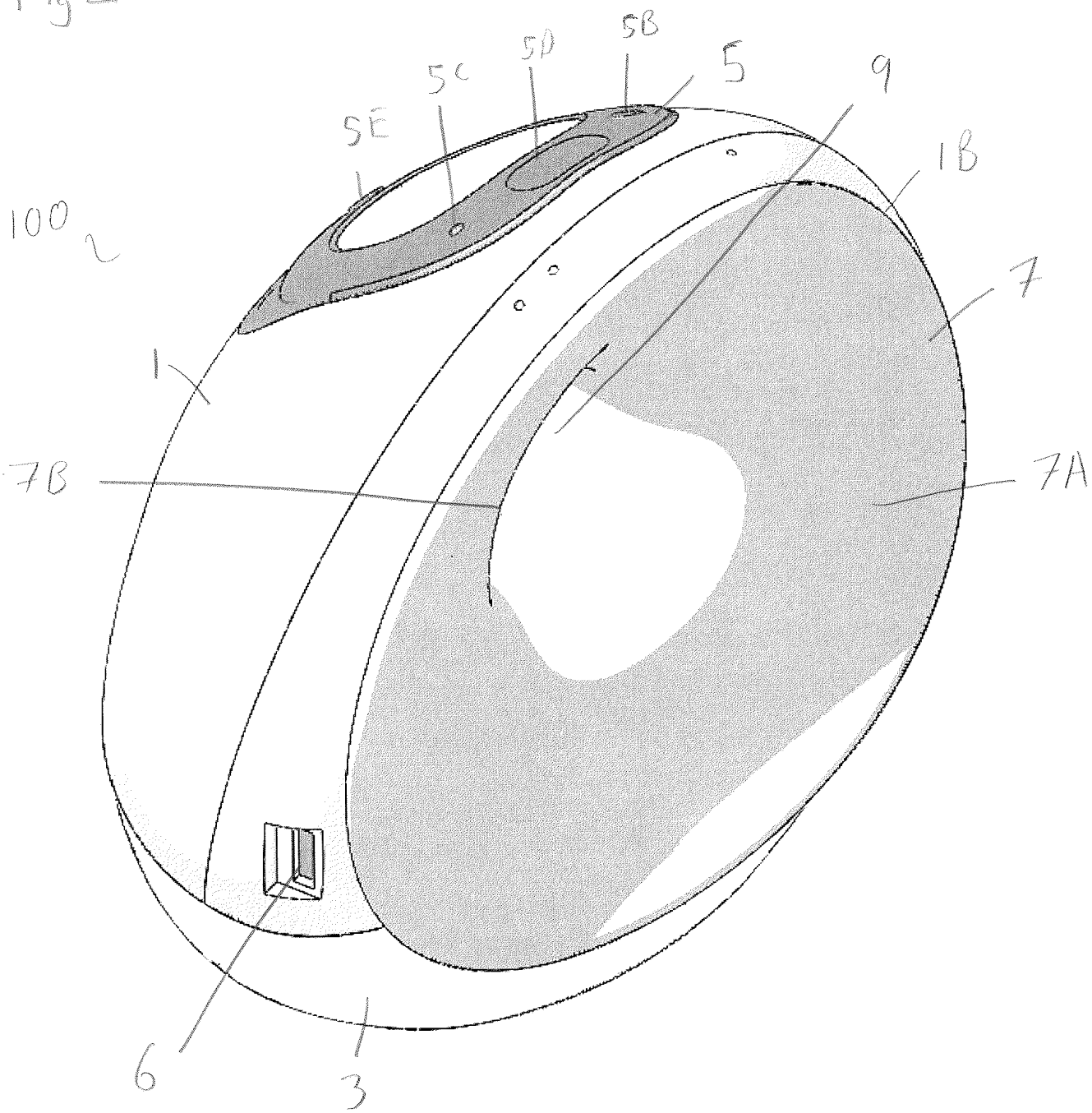

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Fig. 3

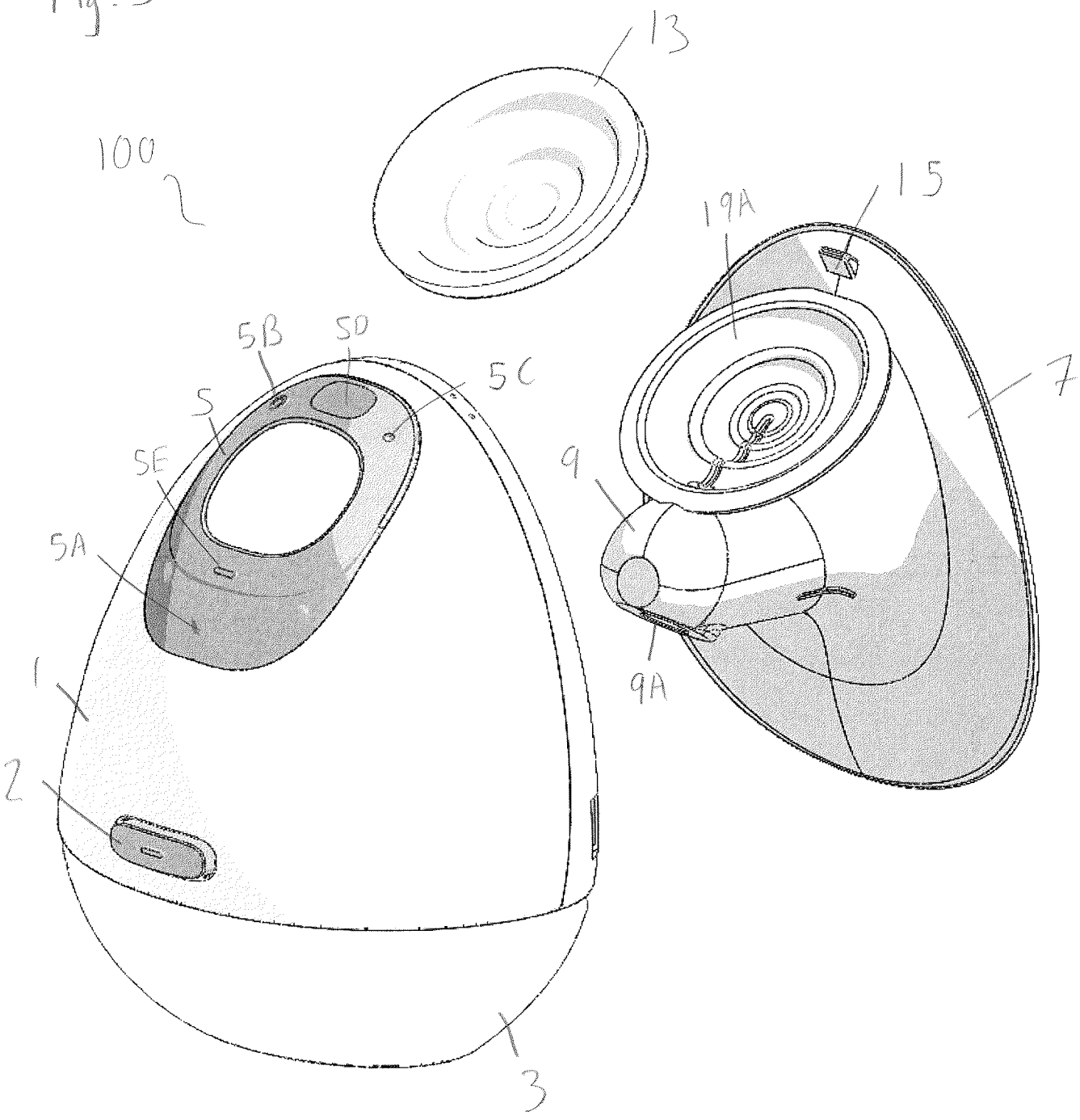

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Fig 4

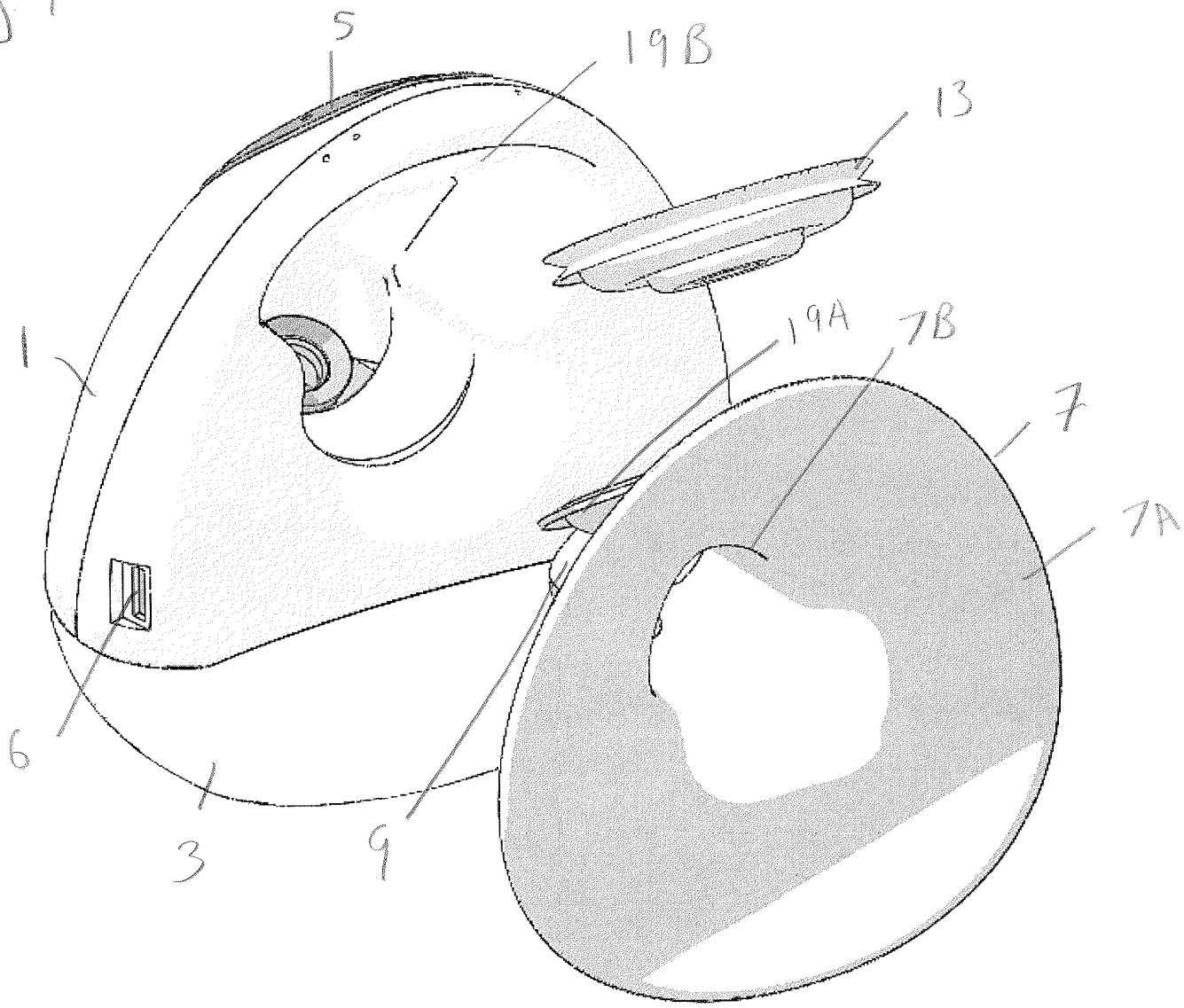

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Fig. 5

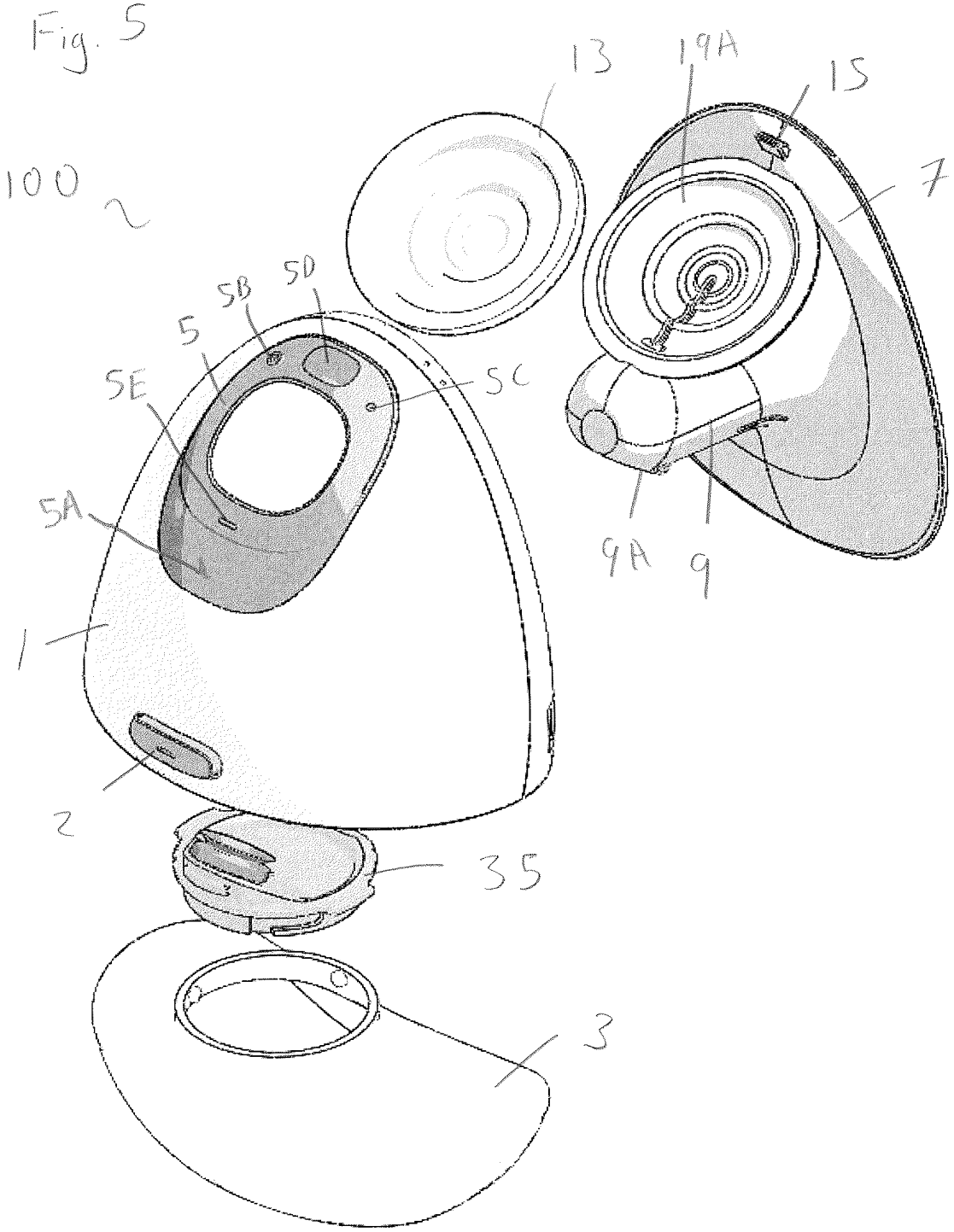

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Fig. 6

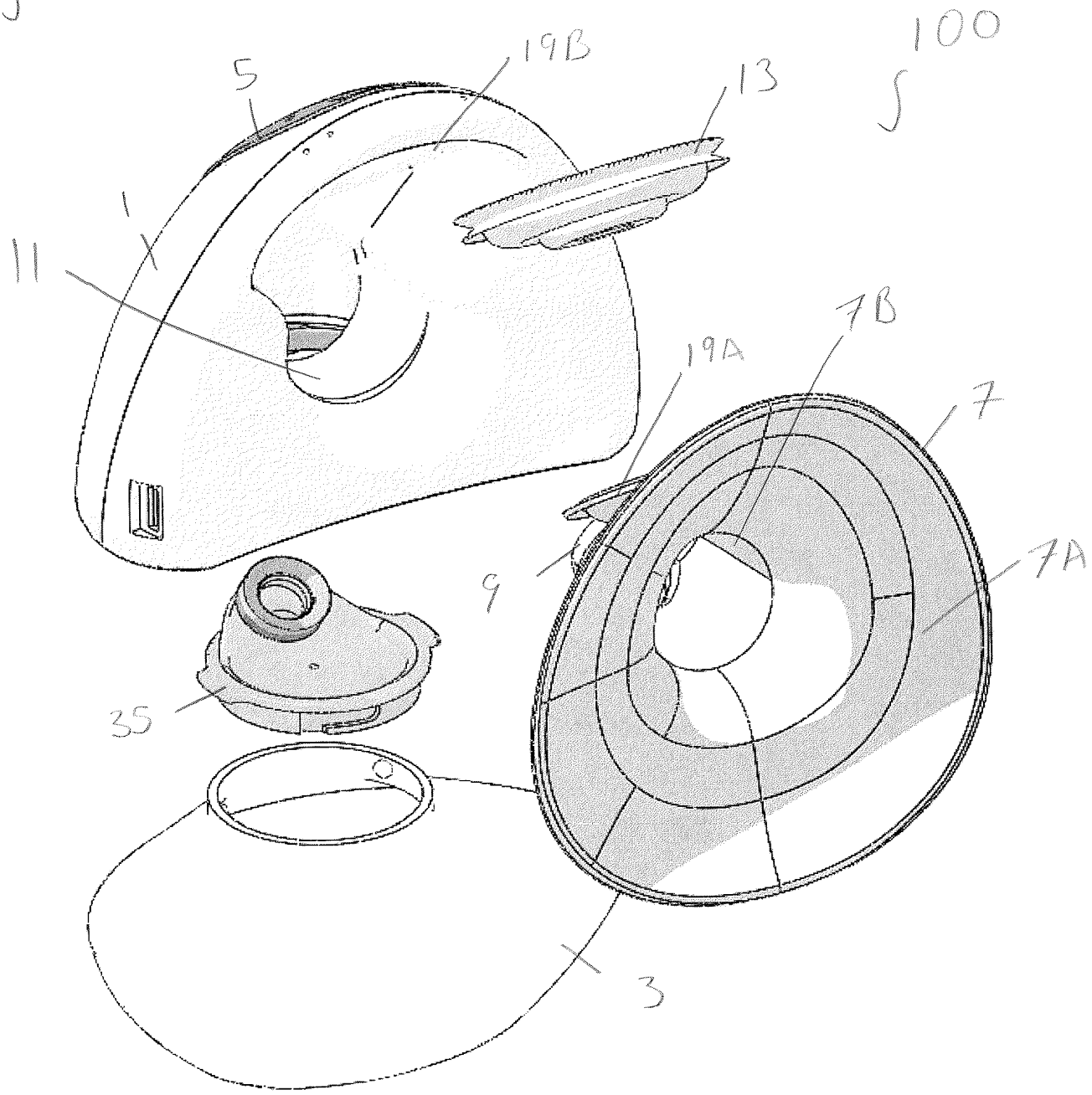

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Fig 7

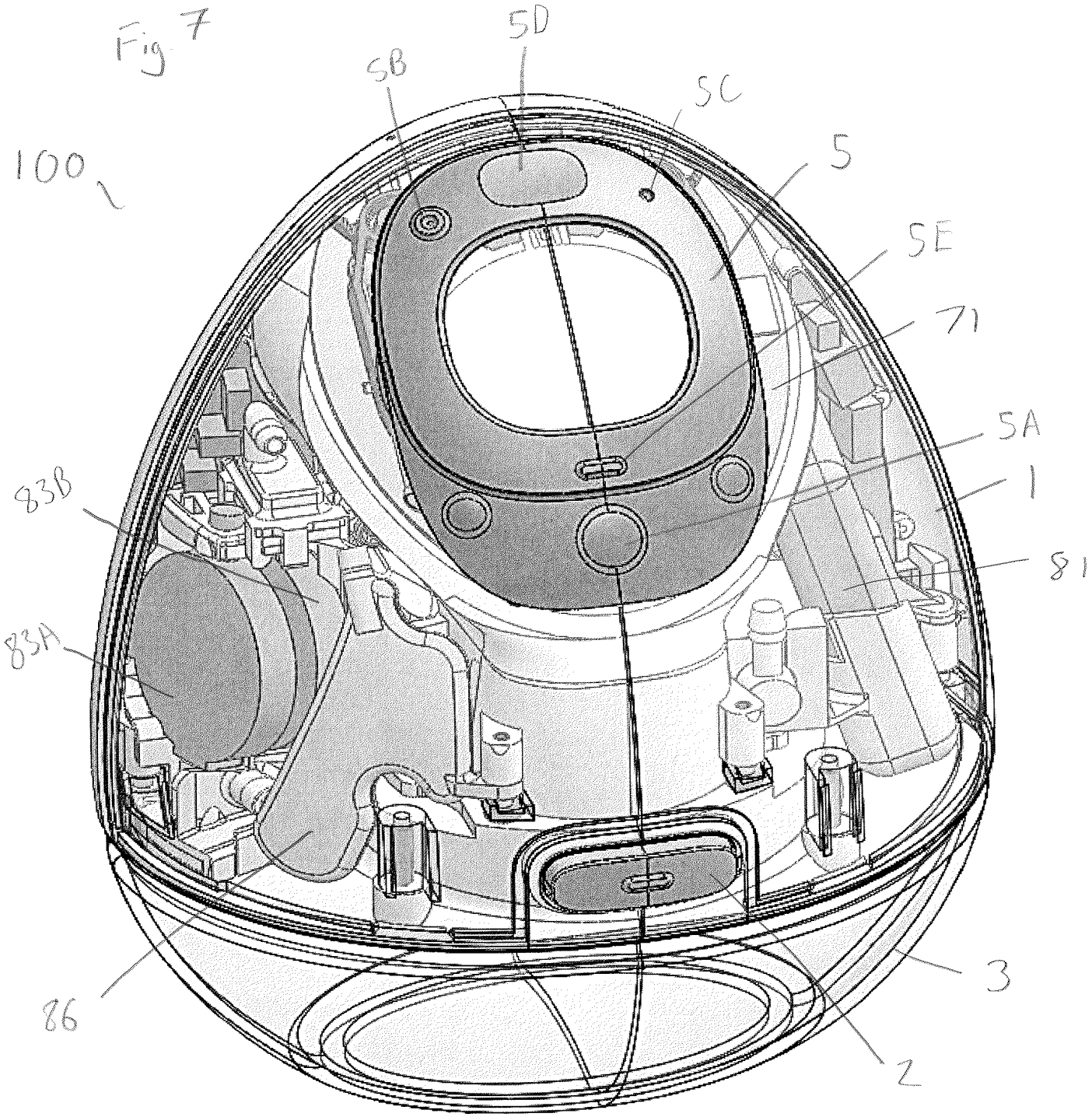

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Fig. 8

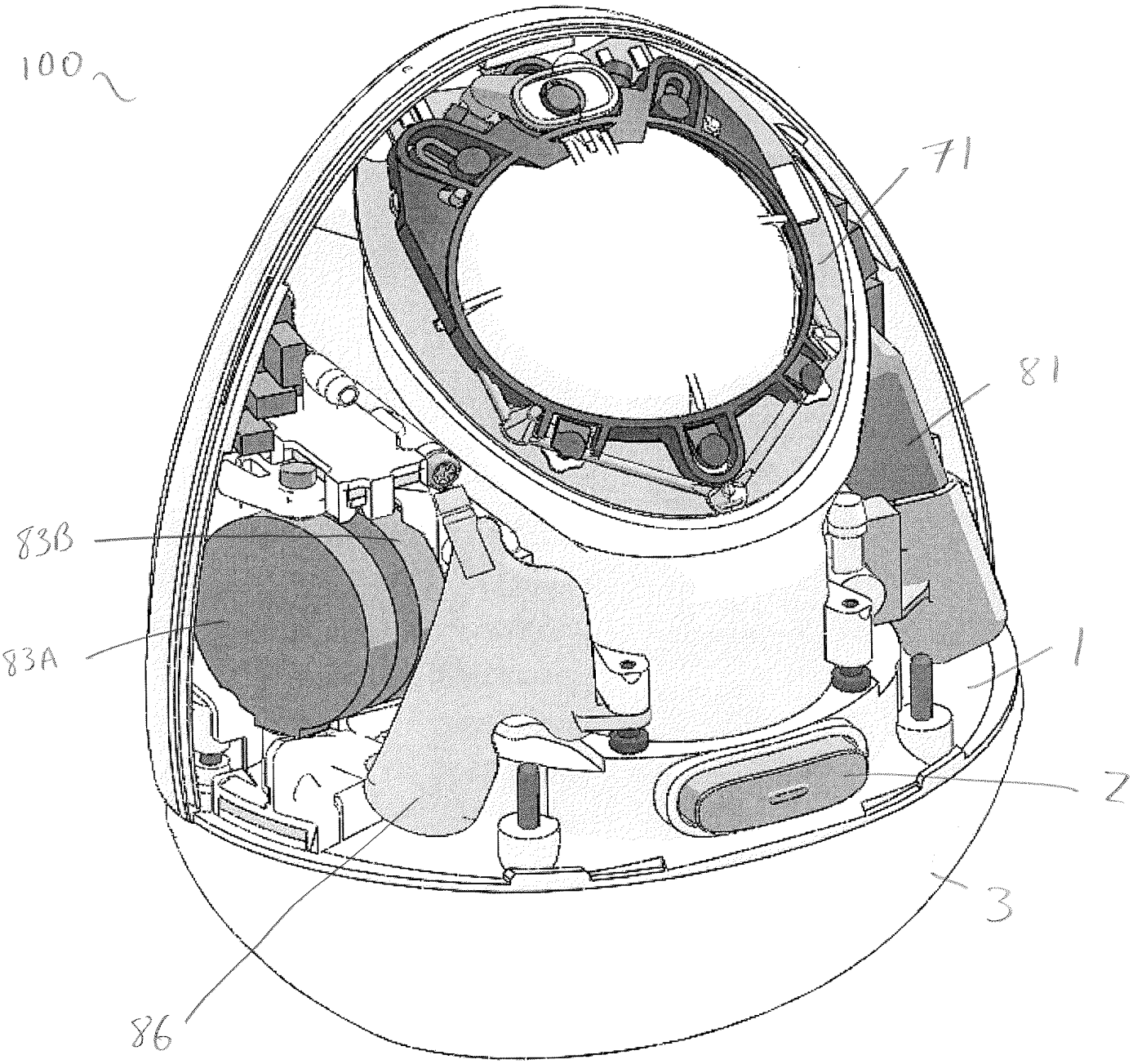

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Fig 9

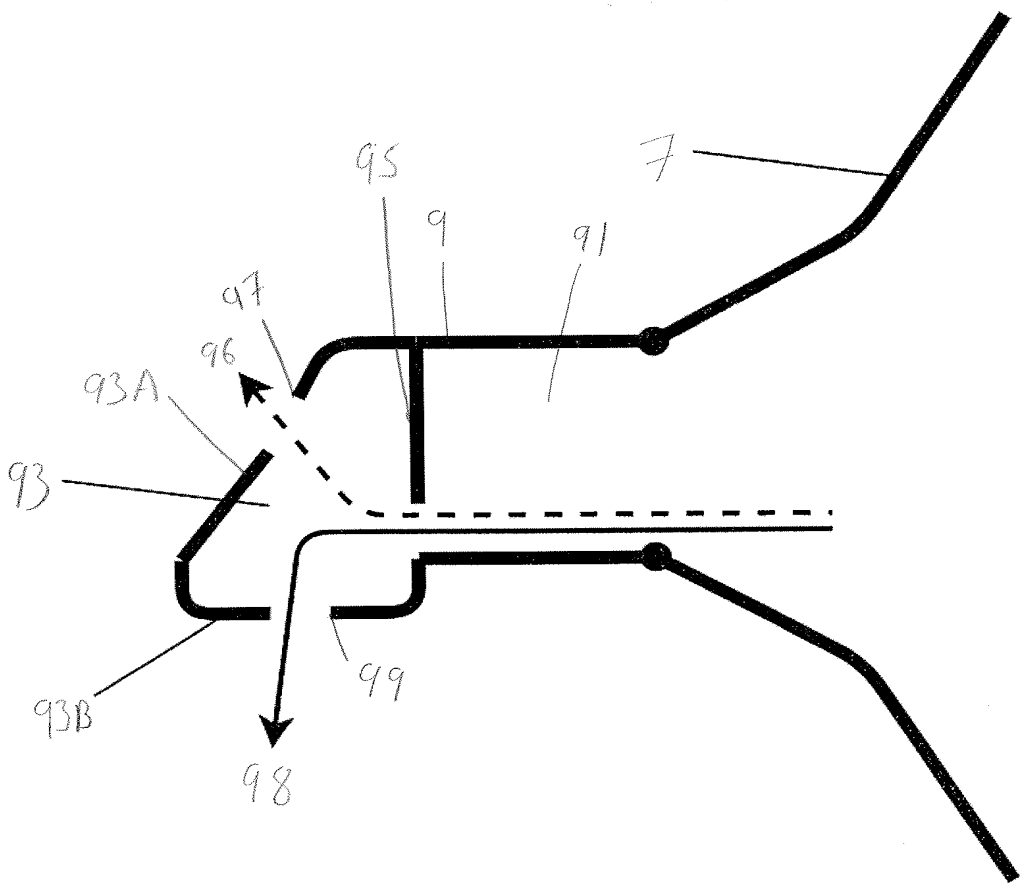

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Fig. 10

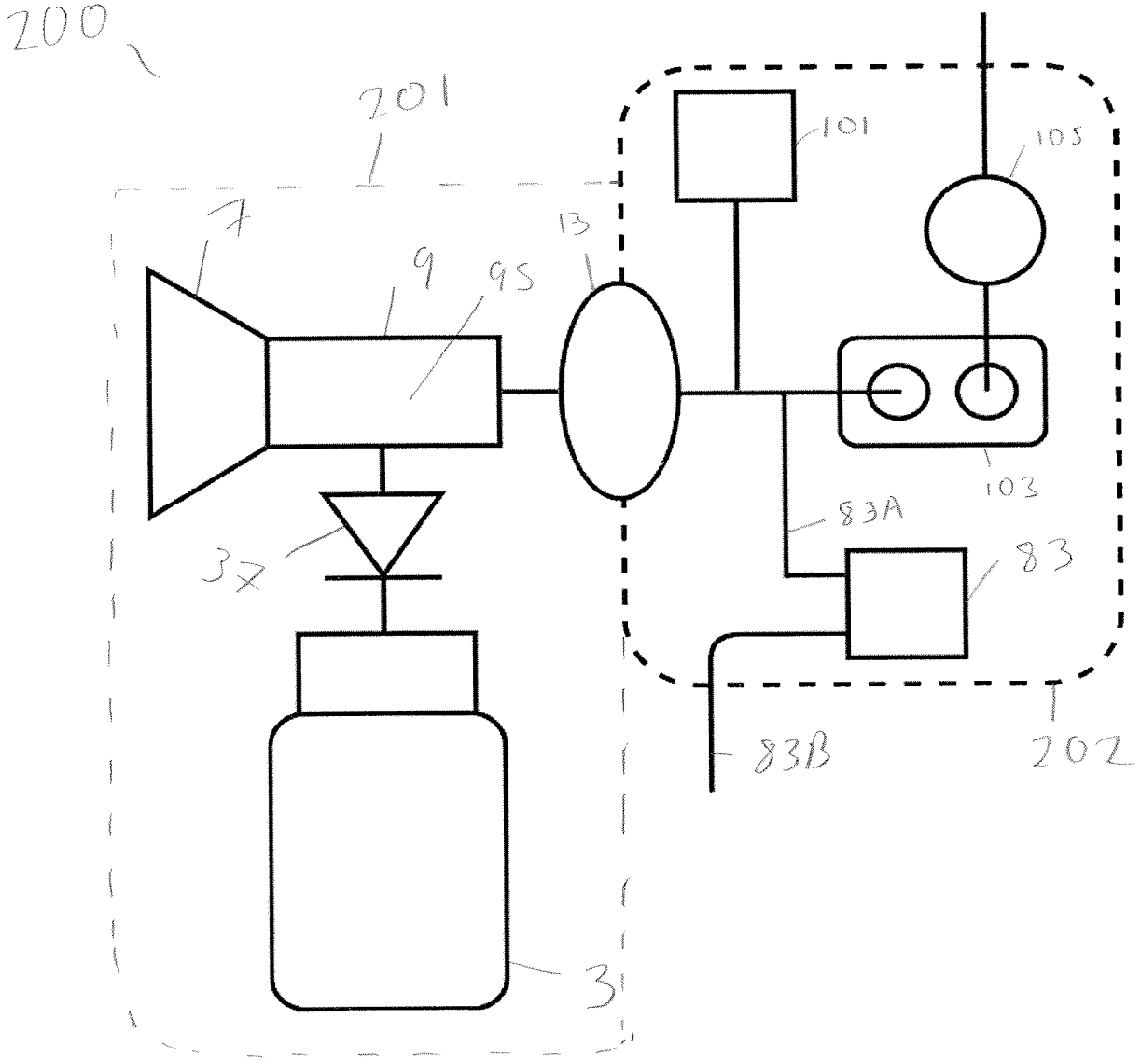

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Fig 11

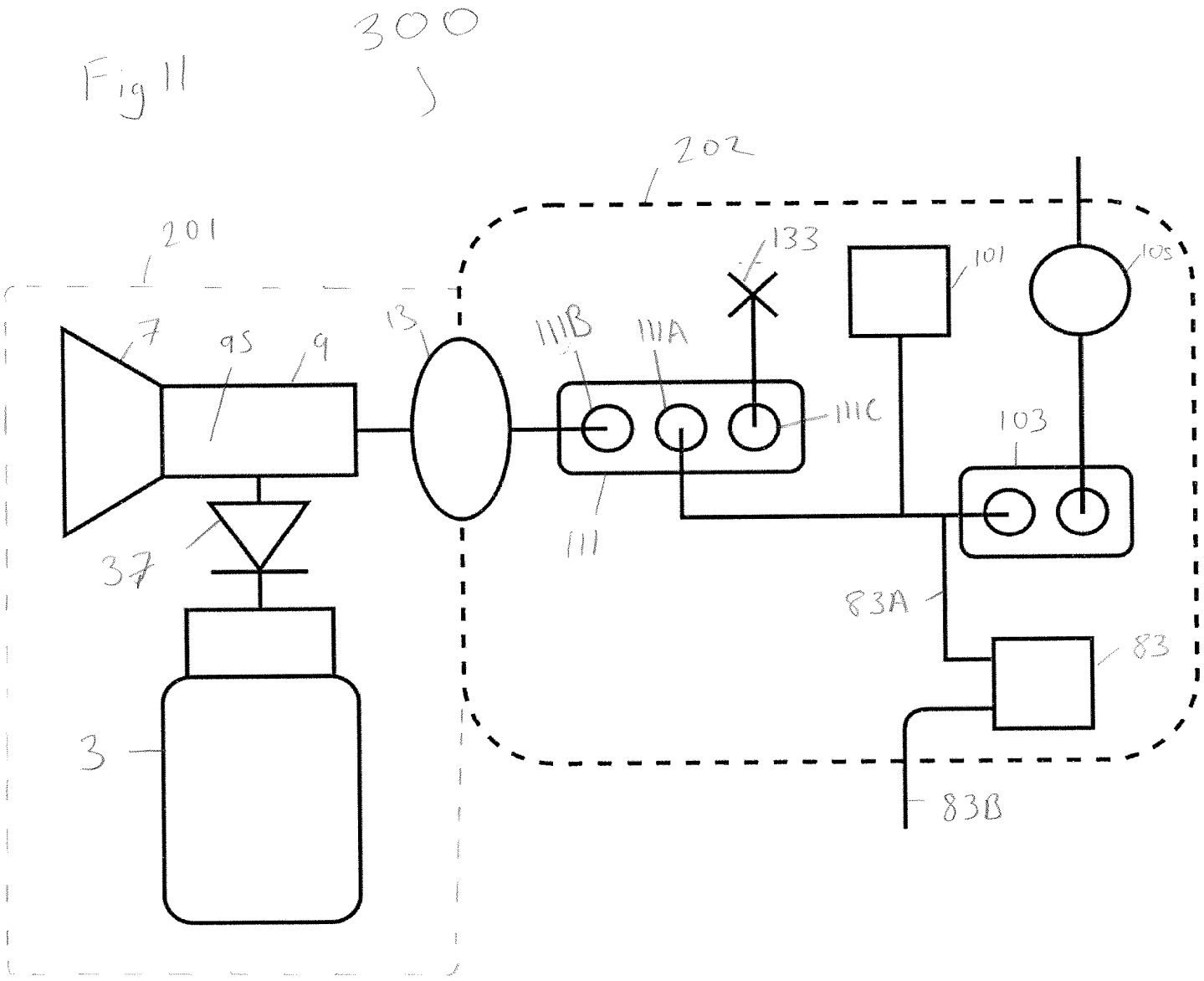

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Fig. 12

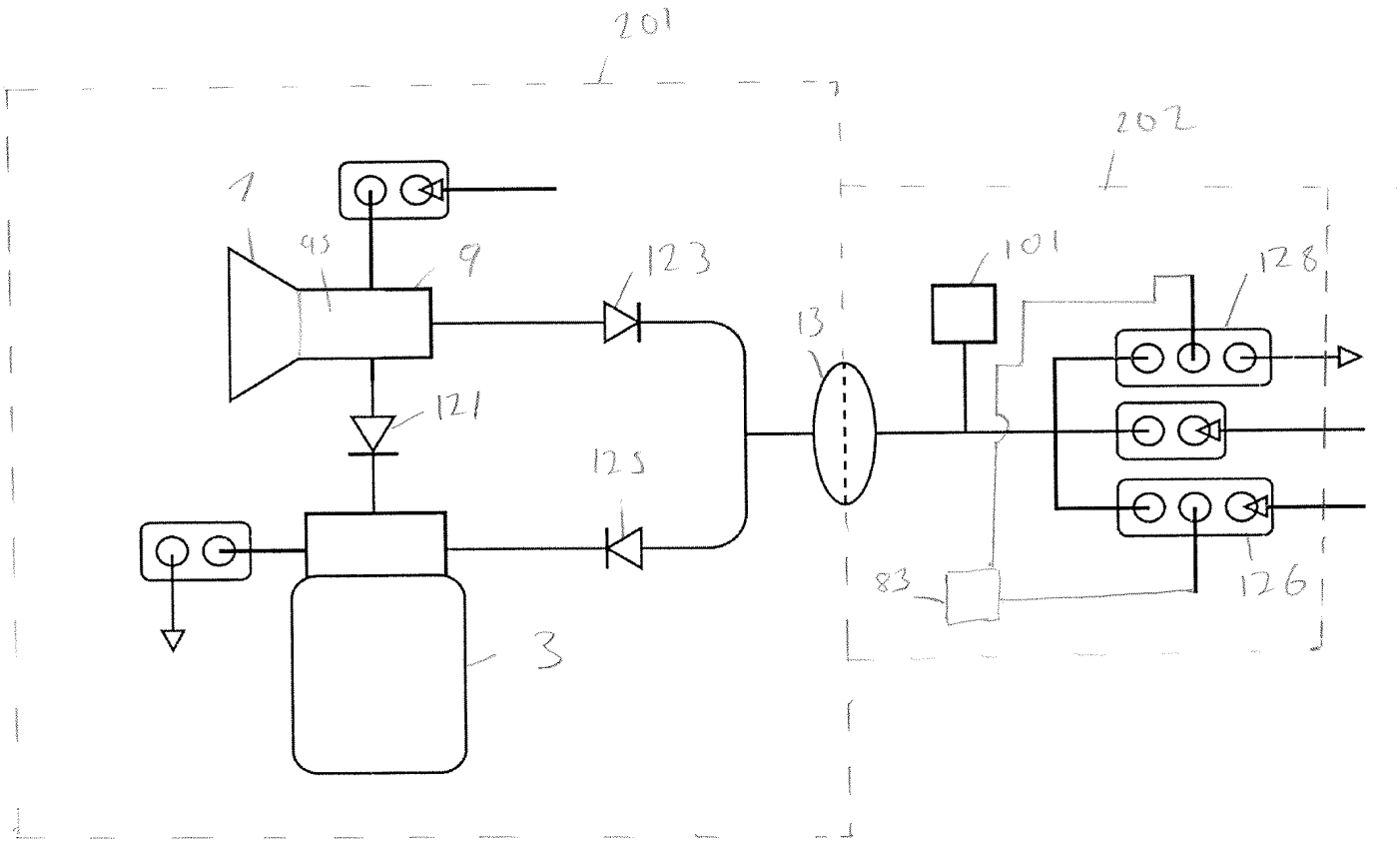

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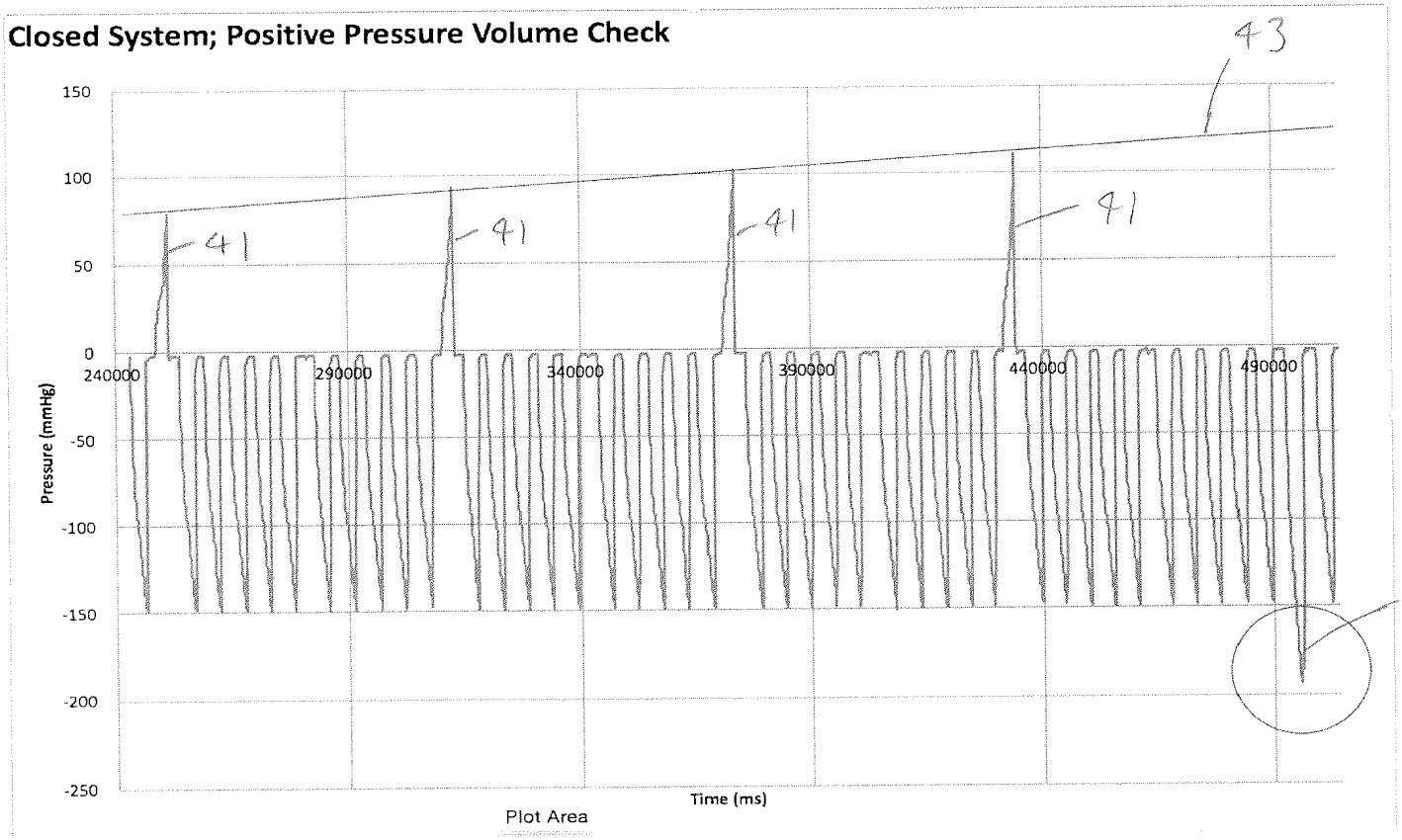
Fig 13



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Signed A HAYES

Dated 07 June 2018

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Concept House
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Newport
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NP10 8QQ

Application number GB1809036.5

1.	Your reference	**Elvie Pump (UK)**
2.	Full name, address and postcode of the applicant or of each applicant	**CHIARO TECHNOLOGY LIMITED** **63 - 66 Hatton Garden** **London EC1N 8LE** **United Kingdom**
	Patents ADP number *(if you know it)*	11287869002
3.	Title of the invention	**Breast pump system**
4.	Name of your agent *(if you have one)* "Address for service" to which all correspondence should be sent. This may be in the European Economic area or Channel Islands (see warning note below) *(including the postcode)*	**Langley, Mr Peter** **Origin Limited** **Twisden Works** **Twisden Road** **London NW5 1DN** **United Kingdom**
	Patents ADP number *(if you know it)*	11436136001 ~~**09541046001**~~
5.	Priority declaration: Are you claiming priority from one or more earlier-filed patent applications? If so, please give details of the application(s)	

Country	Application number	Date of filing	PDAS Access Code

6.	Divisionals etc: Is this application a divisional application, or being made following resolution of an entitlement dispute about an earlier application. If so, please give the application number and filing date of the earlier application	Number of earlier UK application	Date of filing *(day / month / year)*
7.	Inventorship: (Inventors must be individuals not companies) Are all the applicants named above also inventors?	**No**	
8.	Are you paying the application fee with this form?	**No**	

9. Accompanying documents: please enter the number of pages of each item accompanying this form.

Continuation sheets of this form

Description:	**121**
Claim*(s)*:	**n/a**
Abstract:	**n/a**
Drawing*(s)*:	**44**

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10. If you are also filing any of the following, state how many against each item.

Priority documents:	**0**
Statement of inventorship and right to grant of a patent (Patents Form 7):	**0**
Request for search (Patents Form 9A):	**0**
Request for substantive examination (Patents Form 10):	**0**
Any other documents (please specify):	**PDAS Registration Form**

11. I/We request the grant of a patent on the basis of this application.

Date: **01 Jun 2018**

12. Name, e-mail address, telephone, fax and/or mobile number, if any, of a contact point for the applicant

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BREAST PUMP SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

The field of the invention relates to a breast pump system; one implementation of the system is a wearable, electrically powered breast pump system for extracting milk from a mother.

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2. Description of the Prior Art

The specification of the present disclosure is broad and deep. We will now describe the prior art in relation to key aspects of the present disclosure.

Prior art related to breast pump systems

A breast pump system is a mechanical or electro-mechanical device that extracts milk from the breasts of a lactating woman.

A typical breast pump design is as shown in WO 96/25187 A1. A large suction generating device is provided, which is freestanding. This is attached by air lines to one or two breast shields which engage with the user's breasts. A pressure cycle is applied from the suction generating device, via the air lines, to the breast shields. This generates a pressure cycle on the user's breasts to simulate the suction generated by a feeding child.

The suction generating device is a large component that connects to mains power to operate the pumps therein. Milk collection bottles are provided to store the expressed

breast milk. In the system of WO 96/36298 A1 separate bottles are provided attached to each breast shield. A single bottle with tubing connecting to each breast shield may also be used. But for a mother to use this discretely, such as in an office environment, specialised bras must be used. In particular, breast-pumping bras which have a central slit, for the nipple tunnel of the breast shield to extend through, are typically used. The breast shield is held within the bra, with the suction generating device and milk bottle outside the bra.

The fundamental breast pump system has not significantly evolved from this approach, only minor technical improvements have been made.

However, these systems present a number of significant disadvantages. As the suction generating device is a large freestanding unit connected to mains power, the user may feel tethered to the wall. The known devices typically also require a specific user posture and undressing to function normally. This is obviously difficult for a user to do discretely, such as in an office setting. The known devices are also typically noisy, uncomfortable, and hard to clean.

Fully integrated wearable breast pump systems have begun to enter the market, such as described in US 2016 0206794 A1. In such pump systems, the suction source, power supply and milk container are contained in a single, wearable device; there is no need for bulky external components or connections. Such devices can be provided with a substantially breast shaped convex profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations. The internal breast shield is naturally convex to fit over a breast.

In US 2016 0206794 A1, when viewed from the front, the breast pump device has a 'tear-drop' rounded shape, fuller at its base than at its top. But it uses collapsible bags as milk collection devices. As the collection bag systems are collapsible, it can be difficult for a user to extract all of their milk from the bag, due to the small cut opening that is needed and the capillary action between the bonded plastic sheets that form the bag. This waste can be disheartening for the user, as this is food for their child. The bags are also not re-usable, so the user is required to purchase and maintain a stock of these. As well as presenting a recurring cost, if the user runs out of stock they are unable to use the

product until more bags are purchased.

Furthermore, as a result of the collapsible bags, a complex and somewhat noisy pumping arrangement is necessary. In particular, the breast shield connects to a tube which is provided with compression units which "step" the expressed milk through the tube to the collection bag. This uses the breast milk as a hydraulic fluid to generate suction on the breast. In order to carry this out, a complex sequenced pulsing arrangement must be implemented.

In addition to these systems being particularly complex and wasteful, only a relatively small bag can be used. In US 2016 206794, approximately 110 ml (4 fluid ounces) of milk can be collected before the bag must be changed. While this may be sufficient for some users, others may produce much more milk in a session.

A further integrated wearable breast pump system is shown in US 2013 0023821 A1. In the third embodiment in this document, the breast pump system includes a motor driven vacuum pump and power source. An annular (or punctured disc) membrane is provided, with the flow path of the milk going through the centre of the annulus. The membrane is housed in separate housing and is sealed at its inner and outer edges. The breast shield has a small protrusion to engage with these housing components. However, the design of this breast pump system results in a number of problems. The use of an annular membrane, with the fluid flow path running through the opening of the annulus is undesirable as it results in a large and bulky device. There is therefore a need for improved integrated breast pump systems.

Prior Art related to liquid measurement systems

In the context of breast pump systems, it is useful to measure the quantity of expressed milk. One way to do this is to have a clear container for the breast pump, through which the level of expressed milk inside the container can be seen. However, viewing the milk bottle is not always possible, for example in a breast pump that collects milk while being worn inside a maternity bra.

An existing apparatus for detecting the level of liquid inside a container of a breast pump is that disclosed in US 2016/296681. In this apparatus, a sensing mechanism is provided

at the top of a container, which detects droplets of liquid, specifically breast milk, entering the container. By detecting these droplets entering the container, the apparatus can determine the quantity of liquid which enters the container. In this apparatus, an accurate indication of the level of liquid in the container is reliant on the sensing mechanism being able to accurately record every droplet entering the container.

Particularly at times when liquid enters the container at a high flow rate, this accuracy cannot be guaranteed, leading to significant cumulative errors. An accurate indication of the level of liquid in the container in this apparatus is also reliant on the sensing mechanism always being on during the pumping process, so that power consumption of the sensing mechanism is correspondingly high.

In view of the above, there is the need for an improved way to determine the level of liquid inside a container connected to a breast pump.

Prior Art related to bra clips

Many specialised bras (or brassieres) exist for maternity use and that facilitate nursing and/or breast pumping for milk collection, without the need to remove the bra itself. In a traditional nursing bra, this is achieved with the use of an at least partially detachable cup, which can be unhooked for feeding and/or pumping.

Further specialised bras are known which are provided with cut-out portions or slits which substantially align with the wearer's areola and nipple. Traditional breast pump systems comprise an elongate breast shield which extends away from the breast towards an external bottle and source of suction. The breast shield is arranged to extend through the cut-out portion or slit, with the collection bottle and pumping apparatus placed outside of the bra. These systems require the user to remove or unbutton any over-garments, and are uncomfortable when not pumping.

Integrated, wearable breast pump systems have begun to enter the market, such as previously noted US 2016 0206794 A1. In such pumps, the suction source, power supply and milk container are all in a single, wearable device, as noted above, without the need for bulky external components or connections. Such devices can be provided with a substantially breast shaped profile so as to fit within a user's bra for discrete pumping, as

well as pumping on-the-go without any tethers to electrical sockets or collection stations.

Maternity (or nursing) bras such as disclosed in US 4,390,024 A have partially detachable cups, with several hooks provided along the bra strap for attaching the cups to the strap. The cups can then be attached to different hooks in order to adjust the bra strap length. However, these attachment points are fixed. Additionally, this bra has been designed to accommodate the change in breast size before and after the feeding/pumping process. It is not designed to accommodate a breast pump. Accordingly, there is a need for a better system to accommodate integrated wearable breast pumps.

SUMMARY OF THE INVENTION

The invention is a wearable breast pump system including: a housing shaped at least in part to fit inside a bra and including a pumping mechanism; a breast shield; a rigid or non-collapsible milk container; and in which the breast pump system includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and the rigid, non-collapsible milk container.

BRIEF DESCRIPTION OF THE FIGURES

Aspects of the invention will now be described, by way of example(s), with reference to the following Figures, which each show features of various implementations of the invention including optional features that may be utilised:

Figure 1 is a front view of an assembled breast pump system.

Figure 2 is a rear view of the assembled breast pump system of Figure 1.

Figure 3 is a front view of a partially disassembled breast pump system.

Figure 4 is a rear view of the partially disassembled breast pump system of Figure 3.

Figure 5 is a front view of a further partially disassembled breast pump system.

Figure 6 is a rear view of the further partially disassembled breast pump system of Figure 5.

Figure 7 is a front view of the breast pump system of Figure 1, with the outer shell translucent for ease of explanation.

Figure 8 is a further front view of the breast pump system of Figure 1, with the front of the outer shell removed for ease of explanation.

Figure 9 is a schematic view of a nipple tunnel for a breast shield.

Figure 10 is a schematic of a pneumatic system for a breast pump system.

Figure 11 is a schematic of an alternative pneumatic system for a breast pump system.

Figure 12 is a schematic of a further alternative pneumatic system for a breast pump system.

Figure 13 is a graph depicting measured pressure in the breast pump system of Figure 12 over time.

Figure 14 shows schematics for breast shield sizing and nipple alignment.

Figure 15 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 16 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 17 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 18 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 19 shows a screenshot of an application running on a device connected to the

breast pump system.

Figure 20 shows a screenshot of an application running on a connected device.

Figure 21 shows a screenshot of an application running on a connected device.

Figure 22 shows a screenshot of an application running on a connected device.

Figure 23 shows a screenshot of an application running on a connected device.

Figure 24 shows a screenshot of an application running on a connected device.

Figure 25 shows a screenshot of an application running on a connected device.

Figure 26 shows a diagram of a breast pump sensor network,

Figure 27 shows a sectional view of a device being used to determine the level of liquid in a container;

Figure 28 shows a sectional view of the device and the container from Figure 27 being used at a different orientation.

Figure 29 shows a sectional view of the device and the container from Figure 27 being used whilst undergoing acceleration.

Figure 30 shows a sectional view of the device from Figure 27 being used as part of a breast pump assembly.

Figure 31 shows a sectional view of a device connected between a container and its lid, and which is operable to determine the level of liquid inside the container.

Figure 32 depicts a prior art design for a maternity bra;

Figure 33 depicts a clip and clasp being fitted to a maternity bra.

Figure 34 depicts an alternative clip for adjustment of a maternity bra.

Figure 35 depicts the alternative clip of Figure 34.

Figure 36 depicts an alternative clip for adjustment of a maternity bra.

Figure 37 depicts an alternative clip for adjustment of a maternity bra.

Figure 38 depicts an alternative clip for adjustment of a maternity bra.

Figure 39 depicts adjustment of the maternity bra of Figure 37.

Figure 40 shows a configuration with two piezo pumps mounted in series.

Figure 41 shows a configuration of two piezo pumps mounted in parallel.

Figure 42 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in series and mounted in parallel respectively.

Figure 43 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration.

Figure 44 shows a figure of a pump including two piezo pumps in which each piezo pump is connected to a heat sink.

DETAILED DESCRIPTION

We will now describe an implementation of the invention, called the Elvie™ pump, in the following sections:

Section A: The Elvie™ Breast Pump System

Section B: An IR System

Section C: A Bra Clip

Section D: Piezo Pumps and Wearable Devices

Section A: The Elvie™ Breast Pump System

1. Elvie™ Breast Pump System Overview

An implementation of the invention, called the Elvie™ pump, is a breast pump system that is, at least in part, wearable inside a bra. The breast pump system comprises a breast shield for engagement with the user's breast, a housing for receiving at least a portion of the breast shield and a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user, with a milk-flow pathway defined from an opening in the breast shield to the milk collection container. The housing inside also includes a pump for generating a negative pressure in the breast shield, as well as battery and control electronics Unlike other wearable breast pumps, the only parts of the system that come into contact with milk in normal use are the breast shield and the milk container; milk only flows through the breast shield and then directly into the milk container. Milk does not flow through any parts of the housing at all, for maximum hygiene and ease of cleaning.

With reference to Figure 1 and Figure 2, the assembled breast pump system 100 includes a housing 1 shaped to substantially fit inside a bra. The housing 1 includes one or more pumps and a rechargeable battery. The breast pump system includes two parts that are directly connected to the housing 1: the breast shield 7 and a milk container 3. The breast shield 7 and the milk container 3 are directly removable or attachable from the housing 1 in normal use or during normal dis-assembly (most clearly shown in Figure 5). All other parts that are user-removable in normal use or during normal dis-assembly are attached to either the breast shield 7 or the milk container 3. The breast shield 7 and milk container 3 may be removed or attached for example using a one click or one press action or a push button or any other release mechanism. Audible and/or haptic feedbacks confirm that the pump is properly assembled.

The modularity of the breast pump allows for easy assembly, disassembly and replacement of different parts such as the breast shield and milk collection container. This also allows for different parts of the pump to be easily washed and/or sterilised. The breast shield and bottle assembly, both of which are in contact with milk during

pumping, may therefore be efficiently and easily cleaned; these are the only two items that need to be cleaned; in particular, the housing does not need to be cleaned.

The housing 1, breast shield 7 that is holding a flexible diaphragm, and milk container 3 attach together to provide a closed-loop pneumatic system powered by piezoelectric pumps located in the housing 1. This system then applies negative pressure directly to the nipple, forms an airtight seal around the areola, and provides a short path for expressed milk to collect in an ergonomically shaped milk container 3.

The different parts of the breast shield system are also configured to automatically self-seal under negative pressure for convenience of assembly and disassembly and to reduce the risk of milk spillage. Self-sealing refers to the ability of sealing itself automatically or without the application of adhesive, glue, or moisture (such as for example a self-sealing automobile tire or self-sealing envelopes). Hence once the breast pump system is assembled it self-seals under its assembled condition without the need to force seals into interference fits to create sealed chambers. A degree of interference fitting is usual however, but is not the predominating attachment mechanism. Self-sealing enables simple components to be assembled together with a light push: for example, the diaphragm just needs to be placed lightly against the diaphragm housing; it will self-seal properly and sufficiently when the air-pump applies sufficient negative air-pressure. The diaphragm itself self-seals against the housing when the breast shield is pushed into the housing. Likewise, the breast shield self-seals against the milk container when the milk container is pushed up to engage the housing. This leads to simple and fast assembly and dis-assembly, making it quick and easy to set the device up for use, and to clean the device after a session.

Self-sealing has a broad meaning and may also relate to any, wholly or partly self-energising seals. It may also cover any interference seals, such as a press seal or a friction seal, which are achieved by friction after two parts are pushed together.

Whilst one particular embodiment of the invention's design and a specific form of each of the parts of the breast pump system is detailed below, it can be appreciated that the overall description is not restrictive, but an illustration of topology and function that the design will embody, whilst not necessary employing this exact form or number of

discrete parts.

The breast pump system 100 comprises a housing 1 and a milk collection container (or bottle) 3. The housing 1 (including the one or more pumps and a battery) and the container 3 are provided as a unit with a convex outer surface contoured to fit inside a bra. The milk collection container 3 is attached to a lower face 1A of the housing 1 and forms an integral part of the housing when connected, such that it can be held comfortably inside a bra. While the breast pump 100 may be arranged to be used with just the right or the left breast specifically, the breast pump 100 is preferably used with both breasts, without modification. To this end, the outer surfaces of the breast pump 100 are preferably substantially symmetrical.

Preferably, the width of the complete breast pump device (housing 1 and milk container 3) is less than 110 mm and the height of the complete breast pump device is less than 180 mm.

Overall, the breast pump system 100 gives discrete and comfortable wear and use. The system weighs about 224 grams when the milk container is empty, making it relatively lighter as compared to current solutions; lightness has been a key design goal from the start, and has been achieved through a lightweight piezo pump system and engineering design focussed on minimising the number of components.

The breast pump system 100 is small enough to be at least in part held within any bra without the need to use a specialized bra, such as a maternity bra or a sports bra. The rear surface of the breast pump is also concave so that it may sit comfortably against the breast. The weight of the system has also been distributed to ensure that the breast pump is not top heavy, ensuring comfort and reliable suction against the breast. The centre of gravity of the pump system is, when the container is empty, substantially at or below the horizontal line that passes through the filling point on the breast shield, so that the device does not feel top-heavy to a person while using the pump.

Preferably, when the container is empty, the centre of gravity is substantially at or below the half-way height line of the housing so that the device does not feel top-heavy to a user using the pump.

The centre of gravity of the breast pump, as depicted by Figure 1, is at around 60mm high on the centreline from the base of the breast pump when the milk container is empty. During normal use, and as the milk container gradually receives milk, the centre of gravity lowers, which increases the stability of the pump inside the bra. It reduces to around 40mm high on the centreline from the base of the breast pump when the milk container is full.

The centre of gravity of the breast pump is at about 5.85mm below the centre of the nipple tunnel when the milk container is empty, and reduced to about 23.60mm below the centre of the nipple tunnel when the milk container is full. Generalising, the centre of gravity should be at least 2mm below the centre of the nipple tunnel when the container is empty.

The breast pump 100 is further provided with a user interface 5. This may take the form of a touchscreen and/or physical buttons. In particular, this may include buttons, sliders, any form of display, lights, or any other componentry necessary to control and indicate use of the breast pump 100. Such functions might include turning the breast pump 100 on or off, specifying which breast is being pumped, increasing or decreasing the peak pump pressure. Alternatively, the information provided through the user interface 5 might also be conveyed through haptic feedback, such as device vibration, driven from a miniature vibration motor within the pump housing 1.

In the particular embodiment of the Figures, the user interface 5 comprises power button 5A for turning the pump on and off. The user interface 5 further comprises pump up button 5B and pump down button 5C. These buttons adjust the pressure generated by the pump and hence the vacuum pressure applied to the user's breast. In preferable embodiments, the pump up button 5B could be physically larger than the pump down button 5C. A play/pause button 5D is provided for the user to interrupt the pumping process without turning the device off.

The user interface 5 further comprises a breast toggle button 5E for the user to toggle a display of which breast is being pumped. This may be used for data collection, e.g. via an application running on a connected smartphone; the app sends data to a remote server, where data analysis is undertaken (as discussed in more detail later), or for the user to keep track of which breast has most recently been pumped. In particular, there may be a

pair of LEDs, one to the left of the toggle button 5E and one to the right. When the user is pumping the left breast, the LED to the right of the toggle button 5E will illuminate, so that when the user looks down at the toggle it is the rightmost LED from their point of view that is illuminated. When the user then wishes to switch to the right breast, the toggle button can be pressed and the LED to the left of the toggle button 5E, when the user looks down will illuminate. The connected application can automatically track and allocate how much milk has been expressed, and when, by each breast.

The breast pump system also comprises an illuminated control panel, in which the level of illumination can be controlled at night or when stipulated by the user. A day time mode, and a less bright night time mode that are suitable to the user, are available. The control of the illumination level is either implemented in hardware within the breast pump system itself or in software within a connected device application used in combination with the breast pump system.

As depicted in Figure 1, the housing 1 and milk collection container 3 form a substantially continuous outer surface, with a generally convex shape. This shape roughly conforms with the shape of a 'tear-drop' shaped breast. This allows the breast pump 100 to substantially fit within the cup of a user's bra. The milk collection container 3 is retained in attachment with the housing 1 by means of a latch system, which is released by a one-click release mechanism such as a push button 2 or any other one-handed release mechanism. An audible and/or haptic feedback may also be used to confirm that the milk collection container 3 has been properly assembled.

The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting an additional 2 cm difference. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc. In preferred embodiments, the breast pump 100 of the present invention corresponds to an increase of between 3 or 4 cup sizes of the user according to EN 13402.

A plane-to-plane depth of the breast pump can also be defined. This is defined as the distance between two parallel planes, the first of which is aligned with the innermost

point of the breast pump 100, and the second of which is aligned with the outermost point of the breast pump 100. This distance is preferably less than 100 mm.

Figure 2 is a rear view of the breast pump 100 of Figure 1. The inner surface of the housing 1 and milk collection container 3 are shown, along with a breast shield 7. The housing 1, milk collection container 3 and breast shield 7 form the three major subcomponents of the breast pump system 100. In use, these sub-components clip together to provide the functioning breast pump system 100. The breast shield 7 is designed to engage with the user's breast, and comprises a concave inner flange 7A which contacts the breast. To allow the breast pump 100 to be used on either of the user's breasts, the breast shield 7 is preferably substantially symmetrical on its inner flange 7A.

The inner flange 7A is substantially oval-shaped. While the inner flange 7A is concave, it is relatively shallow such that it substantially fits the body form of the user's breast. In particular, when measured side-on the inner-most point of the flange 7A and the outer-most point may be separated by less than 25 mm. By having a relatively shallow concave surface, the forces applied can be spread out over more surface area of the breast. The flatter form also allows easier and more accurate location of the user's nipple. In particular, the flange 7A of the breast shield 7 may extend over the majority of the inner surface of the housing 1 and milk collection container 3. Preferably, it may extend over 80% of this surface. By covering the majority of the inner surface, the breast shield is the only component which contact's the wearer's breast. This leaves fewer surfaces which require thorough cleaning as it reduces the risk of milk contacting a part of the device which cannot be easily sterilized. Additionally, this also helps to disperse the pressure applied to the user's breast across a larger area.

The breast shield 7 substantially aligns with the outer edge 1B of the housing 1. The milk collection container 3 may be provided with an arcuate groove for receiving a lower part of the breast shield 7. This is best shown in later Figures. In the assembled arrangement of Figures 1 and 2, the inner surface of the breast pump 100 is substantially continuous.

The breast shield 7 comprises a shield flange for engaging the user's breast, and an elongate nipple tunnel 9) aligned with the opening and extending away from the user's

breast. Breast shield nipple tunnel 9 extends from a curved section 7B in the breast shield 7. In preferable embodiments the nipple tunnel 9 is integral with the breast shield 7. However, it is appreciated that separate removable/interchangeable nipple tunnels may be used. Curved section 7B is positioned over the user's nipple and areola in use. The breast shield 7 forms an at least partial seal with the rest of the user's breast around this portion, under the negative air pressure created by an air-pressure pump.

This breast shield nipple tunnel 9 defines a milk-flow path from the inner surface of the breast shield 7A, through the breast shield nipple tunnel 9 and into the milk collection container 3. The breast shield nipple tunnel 9 is preferably quite short in order to minimise the length of the milk-flow path in order to minimise losses. By reducing the distance covered by the milk, the device is also reduced in size and complexity of small intermediate portions. In particular, the breast shield nipple tunnel 9 may extend less than 70 mm from its start to end, more preferably less than 50 mm. In use, the nipple tunnel 9 is substantially aligned with the user's nipple and areolae. The nipple tunnel comprises a first opening 9A for depositing milk into the collection container and a second opening 19A for transferring negative air pressure generated by the pump to the user's nipple.

The shield flange 7A and nipple tunnel 9 may be detachable from the housing 1 together. The shield flange 7A and nipple tunnel 9 being detachable together helps further simplify the design, and reduce the number of components which must be removed for cleaning and sterilization. However, preferably, the nipple tunnel 9 will be integral with the breast shield 7, in order to simplify the design and reduce the number of components which must be removed for cleaning and sterilisation.

Figures 3 and 4 are of a partially disassembled breast pump 100 of the present invention. In these Figures, the breast shield 7 has been disengaged from the housing 1 and milk collection bottle 3. As shown in Figure 4, the housing 1 comprises a region or slot 11 for receiving the breast shield nipple tunnel 9 of the breast shield 7. The breast shield is held in place thanks to a pair of channels (9B) included in the nipple tunnel 9, each channel including a small indent. When pushing the housing 1 onto the breast shield 7, which has been placed over the breast, ridges in the housing (9C) engage with the channels, guiding the housing into position; a small, spring plunger, such as ball bearing in each

ridge facilitates movement of the housing on to the nipple tunnel 9. The ball bearings locate into the indent to secure the housing on to the nipple tunnel with a light clicking sound. In this way, the user can with one hand place and position the breast shield 7 onto her breast and with her other hand, position and secure the housing 1 on to the breast shield 7. The breast shield 7 can be readily separated from the housing 1 since the ball bearing latch only lightly secures the breast shield 7 to the housing 1.

Alternatively, the breast shield 7 may also be held in place by means of a clip engaging with a slot located on the housing. The clip may be placed at any suitable point on the shield 7, with the slot in a corresponding location.

The breast shield nipple tunnel 9 of the breast shield 7 is provided with an opening 9A on its lower surface through which expressed milk flows. This opening 9A is configured to engage with the milk collection bottle 3.

The breast pump 100 further comprises a barrier or diaphragm for transferring the pressure from the pump to the milk-collection side of the system. In the depicted example, this includes flexible rubber diaphragm 13 seated into diaphragm housing 19A. The barrier could be any other suitable component such as a filter or an air transmissive material. Diaphragm housing 19A includes a small air hole into the nipple tunnel 9 to transfer negative air pressure into nipple tunnel 9 and hence to impose a sucking action on the nipple placed in the nipple tunnel 9.

Hence, the air pump acts on one side of the barrier or diaphragm 13 to generate a negative air pressure on the opposite, milk-flow side of the barrier. The barrier has an outer periphery or surface, i.e. the surface of diaphragm housing 19A that faces towards the breast, and the milk-flow pathway extends underneath the outer periphery or surface of the barrier or diaphragm housing 19A. The milk-flow path extending under the outer periphery or surface of the barrier 19A allows for a simpler and more robust design, without the milk-flow pathway extending through the barrier. This provides increased interior space and functionality for the device.

As noted, the milk-flow pathway extends beneath or under the barrier 13 or surface of diaphragm housing 19A. This provides an added benefit of having gravity move the milk down and away from the barrier.

Preferably the milk-flow pathway does not pass through the barrier 32. This results in a simpler and smaller barrier design.

As noted, the diaphragm 13 is mounted on diaphragm housing 19A that is integral to the breast shield. This further helps increase the ease of cleaning and sterilisation as all of the components on the "milk" flow side can be removed.

The barrier 13 may also provide a seal to isolate the air pump from the milk-flow side of the barrier. This helps to avoid the milk becoming contaminated from the airflow or pumping side (i.e. the non-milk-flow side).

Alternatively, the only seal is around an outer edge of the barrier 13. This is a simple design as only a single seal needs to be formed and maintained. Having multiple seals, such as for an annular membrane, introduces additional complexity and potential failure points.

As illustrated in Figures 3 and 4, the barrier may include a flexible diaphragm 13 formed by a continuous circular disc shaped membrane which is devoid of any openings or holes. This provides a larger effective "working" area of the diaphragm (i.e. the area of the surface in contact with the pneumatic gasses) than an annular membrane and hence the membrane may be smaller in diameter to have the same working area.

The diaphragm 13 is arranged so that the milk-flow pathway extends below and past the outer surface or periphery of the diaphragm 13. This means that the milk-flow pathway does not extend through the diaphragm 13. In particular, the milk-flow pathway is beneath the diaphragm 13. However, the diaphragm 13 may be offset in any direction with respect to the milk-flow pathway, provided that the milk-flow pathway does not extend through the diaphragm 13.

Preferably, the diaphragm 13 is a continuous membrane, devoid of any openings. The diaphragm 13 is held in a diaphragm housing 19, which is formed in two parts. The first half 19A of the diaphragm housing 19 is provided on the outer surface of the breast shield 7, above the breast shield nipple tunnel 9 and hence the milk-flow pathway. In

preferred embodiments, the first half 19A of the diaphragm housing 19 is integral with the breast shield. The second half 19B of the diaphragm housing is provided in a recessed portion of the housing 1. The diaphragm 13 self-seals in this diaphragm housing 19 around its outer edge, to form a watertight and airtight seal. Preferably, the self-seal around the outer edge of the diaphragm 13 is the only seal of the diaphragm 13. This is beneficial over systems with annular diaphragms which must seal at an inner edge as well. Having the diaphragm 13 mounted in the breast pump 100 in this manner ensures that it is easily accessible for cleaning and replacement. It also ensures that the breast shield 7 and diaphragm 13 are the only components which need to be removed from the pump 100 for cleaning. Because the diaphragm 13 self-seals under vacuum pressure, it is easily removed for cleaning when the device is turned off.

Figures 5 and 6 show a breast pump 100 according to the present invention in a further disassembled state. In addition to the breast shield 7 and diaphragm 13 being removed, the milk collection container 3 has been unclipped. Preferably, the milk collection container 3 is a substantially rigid component. This ensures that expressed milk does not get wasted, while also enhancing re-usability. In some embodiments, the milk collection container 3 may be formed of three sections: a front bottle potion, a rear bottle potion, and a cap. These three sections may clip together to form the milk collection container 3. This three-part system is easy to empty, easily cleanable since it can be dis-assembled, and easily re-usable. The milk collection container or milk bottle may be formed of at least two rigid sections which are connectable. This allows simple cleaning of the container for re-use. Alternatively, the container may be a single container made using a blow moulding construction, with a large opening to facilitate cleaning. This large opening is then closed with a cap with an integral spout 35 or 'sealing plate' (which is bayonet-mounted and hence more easily cleaned than a threaded mount spout). A flexible rubber valve 37 (or 'sealing plate seal') is mounted onto the cap or spout 35 and includes a rubber duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump; this ensures that negative air-pressure does not need to be applied to the milk container and hence adds to the efficiency of the system. The flexible valve 37 self-seals against opening 9A in nipple tunnel 9. Because it self-seals under vacuum pressure, it automatically releases when the system is off, making it easy to remove the milk container.

Preferably, the milk collection container resides entirely below the milk flow path defined by the breast shield when the breast pump system 100 is positioned for normal use, hence ensuring fast and reliable milk collection.

The milk collection container 3 has a capacity of approximately 5 fluid ounces (148 ml). Preferably, the milk collection container has a volume of greater than 120 ml. More preferably, the milk collection container has a volume of greater than 140 ml. To achieve this, the milk collection container 3 preferably has a depth in a direction extending away from the breast in use, of between 50 to 80 mm, more preferably between 60 mm to 70 mm, and most preferably between 65 mm to 68 mm.

The milk collection container 3 further preferably has a height, extending in the direction from the bottom of the container 3 in use to the cap or spout or sealing plate 35, of between 40 mm to 60 mm, more preferably between 45 mm to 55 mm, and most preferably between 48 mm to 52 mm. The cap 35 may screw into the milk collection bottle 3. In particular, it may be provided with a threaded connection or a bayonet and slot arrangement.

Further preferably, the milk collection container has a length, extending from the leftmost point to the rightmost point of the container 3 in use, of between 100 mm to 120 30 mm, more preferably between 105 mm to 115 mm, and most preferably between 107 mm to 110 mm.

This cap 35 is provided with a one-way valve 37, through which milk can flow only into the bottle. This valve 37 prevents milk from spilling from the bottle once it has been collected. In addition, the valve 37 automatically seals completely unless engaged to the breast shield 7. This ensures that when the pump 100 is dismantled immediately after pumping, no milk is lost from the collection bottle 3. It can be appreciated that this one-way valve 37 might also be placed on the breast shield 7 rather than in this bottle cap 35.

Alternatively, the milk bottle 3 may form a single integral part with a cap 35. Cap 35 may include an integral milk pouring spout.

In certain embodiments, a teat may be provided to attach to the annular protrusion 31A

or attach to the spout that is integral with cap 35, to allow the container 3 to be used directly as a bottle. This allows the milk container to be used directly as a drinking vessel for a child. The milk collection container may also be shaped with broad shoulders such that it can be adapted as a drinking bottle that a baby can easily hold.

Alternatively, or in addition, a spout may be provided to attach to the protrusion 31A for ease of pouring. A cap may also be provided to attach to the protrusion 31A in order to seal the milk collection bottle 3 for easy storage.

The pouring spout, drinking spout, teat or cap may also be integral to the milk collection container.

Further, the removable milk collection container or bottle includes a clear or transparent wall or section to show the amount of milk collected. Additionally, measurement markings (3A) may also be present on the surface of the container. This allows the level of milk within the container to be easily observed, even while pumping. The milk collection container or bottle may for example be made using an optically clear, dishwasher safe polycarbonate material such as Tritan™.

The milk collection container or bottle may include a memory or a removable tag, such as a tag including an NFC chip, that is programmed to store the date and time it was filled with milk, using data from the breast pump system or a connected device such as a smartphone. The container therefore includes wireless connectivity and connects to a companion app. The companion app then tracks the status of multiple milk collection containers or bottles to select an appropriate container or bottle for feeding. The tag of the bottle may also be programmed to store the expiry date of the milk as well as the quantity of the milk stored.

Figures 7 and 8 show front views of a breast pump system 100. The outer-surface of the housing 1 has been drawn translucent to show the components inside. The control circuitry 71 for the breast pump 100 is shown in these figures. The control circuitry in the present embodiment comprises four separate printed circuit boards, but it is appreciated that any other suitable arrangement may be used.

The control circuitry may include sensing apparatus for determining the level of milk in the container 3. The control circuitry may further comprise a wireless transmission device for communicating over a wireless protocol (such as Bluetooth) with an external device. This may be the user's phone, and information about the pumping may be sent to this device. In embodiments where the user interface comprises a breast toggle button 5E, information on which breast has been selected by the user may also be transmitted with the pumping information. This allows the external device to separately track and record pumping and milk expression data for the left and right breasts.

There should also be a power charging means within the control circuitry 71 for charging the battery 81. While an external socket, cable or contact point may be required for charging, a form of wireless charging may instead be used such as inductive or resonance charging. In the Figures, charging port 6 is shown for charging the battery 81. This port 6 may be located anywhere appropriate on the housing 1.

Figure 8 shows the location of the battery 81 and the pumps 83A, 83B mounted in series inside the housing 1. While the depicted embodiment shows two pumps 83A, 83B it is appreciated that the present invention may have a single pump. Preferably, an air filter 86 is provided at the output to the pumps 83A, 83B. In preferable embodiments, the pumps 83A, 83B are piezoelectric air pumps (or piezo pumps), which operate nearly silently and with minimal vibrations. A suitable piezo pump is manufactured by TTP Ventus, which can deliver in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free flow. The rear side of the second half of the diaphragm housing 19B in the housing 1 is provided with a pneumatic connection spout. The pumps 83A, 83B are pneumatically connected with this connection spout.

Operation of the breast pump 100 will now be described. Once the breast pump 100 is activated and a pumping cycle is begun, the pumps 83A, 83B generates a negative air pressure which is transmitted via an air channel to a first side of the diaphragm 13 mounted on the diaphragm housing 19A. This side of the diaphragm 13 is denoted the pumping side 13B of the diaphragm 13.

The diaphragm 13 transmits this negative air pressure to its opposite side (denoted the milk-flow side 13A). This negative pressure is transferred through a small opening in the

diaphragm housing 19A to the breast shield nipple tunnel 9 and the curved opening 7B of the breast shield 7 that contacts the breast. This acts to apply the pressure cycle to the breast of the user, in order to express milk. The milk is then drawn through the nipple tunnel 9, to the one way valve 37 that remains closed whilst negative pressure is applied. When the negative air pressure is released, the valve 37 opens and milk flows under gravity past the valve 37 and into milk container 3. Negative air pressure is periodically (e.g. cyclically, every few seconds) applied to deliver pre-set pressure profiles such as profiles that imitate the sucking of a child.

While the depicted embodiment of the breast pump 100 is provided with two pumps, the following schematics will be described with a single pump 83. It is understood that the single pump 83 could be replaced by two separate piezo air-pumps 83A, 83B as above.

Figure 9 depicts a schematic of a further embodiment of a breast shield nipple tunnel 9 for a breast pump 100. The breast shield nipple tunnel 9 is provided with an antechamber 91 and a separation chamber 93. A protrusion 95 extends from the walls of the breast shield nipple tunnel 9 to provide a tortuous air-liquid labyrinth path through the breast shield nipple tunnel 9. In the separation chamber 93 there are two opening 97, 99. An air opening 97 is provided in an upper surface 93A of the separation chamber 93. This upper surface 93 is provided transverse to the direction of the breast shield nipple tunnel 9. This opening 97 connects to the first side of the diaphragm housing 19A and is the source of the negative pressure. This airflow opening 97 also provides a route for air to flow as shown with arrow 96. It is appreciated that the tortuous pathway is not necessary and that a breast shield nipple tunnel 9 without such a pathway will work.

The other opening 99 is a milk opening 99. The milk opening 99 is provided on a lower surface 93B of the separation chamber 93 and connects in use to the container 3. After flowing through the tortuous breast shield nipple tunnel 9 pathway, the milk is encouraged to flow through this opening 99 into the container 3. This is further aided by the transverse nature of the upper surface 93A. In this manner, expressed milk is kept away from the diaphragm 13. As such, the breast pump 100 can be separated into a "air" side comprising the pump 83, the connection spout 85 and the pumping side 13B of the diaphragm 13 and a "milk-flow" side comprising the breast shield 7, the milk collection container 3 and the milk-flow side 13A of the diaphragm 13. This ensures that all of the

"milk-flow" components are easily detachable for cleaning, maintenance and replacement. Additionally, the milk is kept clean by ensuring it does not contact the mechanical components. While the present embodiment discusses the generation of negative pressure with the pump 83, it will be appreciated that positive pressure may instead be generated.

While the embodiments described herein use a diaphragm 13, any suitable structure to transmit air pressure while isolating either side of the system may be used.

The breast pump may further comprise a pressure sensor in pneumatic connection with the piezo pump. This allows the output of the pump to be determined.

Figure 10 shows a schematic of a basic pneumatic system 200 for a breast pump 100. In the system 200 milk expressed into the breast shield 7 is directed through the breast shield nipple tunnel 9 through the torturous air-liquid labyrinth interface 95. The milk is directed through the non-return valve 37 to the collection container 3. This side of the system forms the "milk-flow" side 201.

The rest of the pneumatic system 200 forms the air side 202 and is separated from contact with milk. This is achieved by way of a flexible diaphragm 13 which forms a seal between the two sides of the system. The diaphragm 13 has a milk-flow side 13A and an air side or pumping side 13B.

The air side 202 of the system 200 is a closed system. This air side 202 may contain a pressure sensor 101 in pneumatic connection with the diaphragm 13 and the pump 83. Preferably, the pump 83 is a piezoelectric pump (or piezo pump). Due to their low noise, strength and compact size, piezoelectric pumps are ideally suited to the embodiment of a small, wearable breast pump. The pump 83 has an output 83A for generating pressure, and an exhaust to the atmosphere 83B. In a first phase of the expression cycle, the pump 83 gradually applies negative pressure to half of the closed system 202 behind the diaphragm 13. This causes the diaphragm 13 to extend away from the breast, and thus the diaphragm 13 conveys a decrease in pressure into the breast shield 7. The reduced pressure encourages milk expression from the breast, which is directed through the tortuous labyrinth system 95 and the one-way valve 37 to the collection bottle 3.

While in the depicted embodiment the air exhaust 83B is not used, it may be used for functions including, but not limited to, cooling of electrical components, inflation of the bottle to determine milk volume (discussed further later) or inflation of a massage bladder or liner against the breast. This massage bladder may be used to help mechanically encourage milk expression. More than one massage bladder may be inflated regularly or sequentially to massage one or more parts of the breast. Alternatively, the air pump may be used to provide warm air to one or more chambers configured to apply warmth to one or more parts of the breast to encourage let-down.

The air side 202 further comprises a two-way solenoid valve 103 connected to a filtered air inlet 105 and the pump 83. Alternatively, the filter could be fitted on the pump line 83A. If the filter is fitted here, all intake air is filtered but the performance of the pump may drop. After the negative pressure has been applied to the user's breast, air is bled into the system 202 through the valve 103 in a second phase of the expression cycle. In this embodiment, the air filter 105 is affixed to this inlet to protect the delicate components from degradation. In particular, in embodiments with piezoelectric components, these are particularly sensitive.

The second phase of the expression cycle and associated switching of valve 103 is actioned once a predefined pressure threshold has been reached. The pressure is detected by a pressure sensor 101.

In certain embodiments, if the elasticity and extension of the diaphragm 13 may be approximated mathematically at different pressures, the pressure measured by sensor 101 can be used to infer the pressures exposed to the nipple on the opposite side of the diaphragm 13. Figure 11 shows an alternative pneumatic system 300. The core architecture of this system is the same as the system shown in Figure 10.

In this system 300, the closed loop 202 is restricted with an additional three way solenoid valve 111. This valve 111 allows the diaphragm 13 to be selectively isolated from the rest of the closed loop 202. This additional three way valve 111 is located between the diaphragm 13 and the pump 83. The pressure sensor 101 is on the pump 83 side of the three way valve 111. The three way valve 111 is a single pole double throw (SPDT) valve,

wherein: the pole 111A is in pneumatic connection with the pump 83 and pressure sensor; one of the throws 11 is in pneumatic connection with the diaphragm 13; and the other throw 111C is in pneumatic connection with a dead-end 113. This dead-end 113 may either be a simple closed pipe, or any component(s) that does not allow the flow of air into the system 202. This could include, for example, an arrangement of one-way valves.

In this system 300, therefore, the pump 83 has the option of applying negative pressure directly to the pressure sensor 101. This allows repeated testing of the pump in order to calibrate pump systems, or to diagnose issues with the pump in what is called a dead end stop test. This is achieved by throwing the valve to connect the pump 83 to the dead end 113. The pump 83 then pulls directly against the dead end 113 and the reduction of pressure within the system can be detected by the pressure sensor 101.

The pressure sensor detects when pressure is delivered and is then able to measure the output of the pumping mechanism. The results of the pressure sensor are then sent to an external database for analysis such as a cloud database, or are fed back to an on-board microcontroller that is located inside the housing of the breast pump system.

Based on the pressure sensor measurements, the breast pump system is able to dynamically tune the operation of the pumping mechanism (i.e. the duty or pump cycle, duration of a pumping session, the voltage applied to the pumping mechanism, the peak negative air pressure) in order to ensure a consistent pressure performance across different breast pump systems.

In addition, the breast pump system, using the pressure sensor measurements, is able to determine if the pump is working correctly, within tolerance levels. Material fatigue of the pump is therefore directly assessed by the breast pump system. Hence, if the output of the pumping mechanism degrades over time, the breast pump system can tune the pumping mechanism operation accordingly. As an example, the breast pump system may increase the duration of a pumping session or the voltage applied to the pumping mechanism to ensure the expected pressures are met.

This ensures that the user experience is not altered, despite the changing output of the pump as it degrades over time. This is particularly relevant for piezo pumps where the output of the pump may vary significantly.

The microcontroller can also be programmed to deliver pre-set pressure profiles. The pressure profiles may correspond to, but not necessarily, any suction patterns that would mimic the sucking pattern of an infant. The patterns could mimic for example the sucking pattern of a breastfed infant during a post birth period or at a later period in lactation.

The profiles can also be manually adjusted by the user using a control interface on the housing of the breast pump system or on an application running on a connected device.

Additionally, the user is able to manually indicate the level of comfort that they are experiencing when they are using the system. This can be done using a touch or voice-based interface on the housing of the breast pump system itself or on an application running on a connected device.

The system stores the user-indicated comfort levels together with associated parameters of the pumping system. The pressure profiles may then be fine scaled in order to provide the optimum comfort level for a particular user.

The profiles or any of the pumping parameters may be calculated in order to correlate with maximum milk expression rate or quantity.

The pressure profiles or any of the pumping parameters may also be dynamically adjusted depending on the real time milk expression rate or quantity of milk collected. The pressure profiles or any of the pumping parameters may also be dynamically adjusted when the start of milk let-down has been detected.

Additionally, the system is also able to learn which parameters improve the breast pump system efficiency. The system is able to calculate or identify the parameters of the pumping mechanism that correlate with the quickest start of milk let-down or the highest volume of milk collected for a certain time period. The optimum comfort level for a particular user may also be taken into account.

Figure 12 shows a schematic for a system 400 for a breast pump 100 which can estimate the volume of milk collected in the collection container 3 from data collected on the air-side part 202 of the system 400.

The pump 83 is connected to the circuit via two bleed valves 126, 128. The first bleed valve 126 is arranged to function when the pump 83 applies a negative pressure. As such, this valve 126 is connected to a "bleed in" 127, for supplying atmospheric air to the system 202.

The second bleed valve 128 is arranged to function when the pump 83 applies a positive pressure. As such, this valve 128 is connected to a "bleed out" 129 for bleeding air in the system 202 to the atmosphere.

Although Section C describes the preferred embodiment for measuring or inferring the volume of milk collected in the milk collection container using IR sensors, an alternative method for measuring or inferring the volume of milk collected in the milk collection container using pressure sensors is described also below.

During a milking pump cycle, the pump 83 applies negative pressure on the air side 13B of the diaphragm 13 which causes its extension towards the pump 83. This increases the volume of the space on the milk side 13B of the diaphragm 13. This conveys the decrease in pressure to the breast to encourage expression of milk. A set of three non-return valves 121, 123, 125 ensure that this decrease in pressure is applied only to the breast (via the breast shield 7) and not the milk collection container 3. To measure the volume of milk collected in the container 3, the pump 83 is used instead to apply positive pressure to the diaphragm 13. The diaphragm 13 is forced to extend away from the pump 83 and conveys the pressure increase to the milk side 201 of the system 400. The three non-return valves 121, 123, 125 ensure that this increase in pressure is exclusively conveyed to the milk collection container 13.

The breast pump may further comprise: a first non-return valve between the milk flow side of the diaphragm and the breast shield, configured to allow only a negative pressure to be applied to the breast shield by the pump; a second non-return valve between the milk-flow side of the diaphragm and the milk collection container configured to allow only a positive pressure to be applied to the milk collection container by the pump; and a pressure sensor in pneumatic connection with the pressure-generation side of the diaphragm.

The resulting pressure increase is monitored behind the diaphragm 13 from the air-side 202 by a pressure sensor 101. Preferably, the pressure sensor 101 is a piezoelectric pressure sensor (piezo pressure sensor). The rate at which the pump 83 (at constant strength) is able to increase the pressure in the system 400 is a function of the volume of air that remains in the milk collection container 3. As air is many times more compressible than liquid, the rate at which pressure increases in the system 400 can be expressed as an approximate function of the volume of milk held in the collection container 3.

Thus by increasing the pressure in this fashion, the rate of pressure increase can be determined, from which the volume of milk held in the container 3 is calculable. Figure 13 shows repeated milking and volume measurement cycles as the collection container 3 is filled. To determine the rate of pressure increase the pump 83 was run for a fixed time. As pumping proceeds and the volume of air reduces in the system 400, the pump 83 is able to achieve a higher pressure. Each milking cycle is represented by a positive pressure spike 41. There is a clear upwards trend 43 in magnitude of positive pressures achieved as the collection container 3 is filled.

A method of estimating the pressure applied by a breast pump may comprise the steps of: selecting a pressure cycle from a pre-defined list of pressure cycles; applying pressure with the pump to stimulate milk expression; reading the output of the pressure sensor; and adjusting the applied pressure of the pump to match the pressure profile selected. This allows for repeatable application of force to the breast, even as the pump performance degrades.

Preferably the method further comprises the steps of: approximating the elasticity and extension of the diaphragm at the relevant pressure; and calculating an estimated applied pressure based upon the output of the pressure sensor and the approximated elasticity and extension of the diaphragm.

Alternatively, a method of estimating the milk collected by a breast pump may comprise the steps of: generating a positive pressure with the pump; transmitting the positive pressure via the diaphragm and second non-return valve to only the milk collection

container; measuring the increase in pressure by the pressure sensor in pneumatic connection with the diaphragm; estimating the volume of milk inside the milk collection container based upon the rate of increase of pressure. In this manner, the volume of milk can be estimated remotely.

In this manner, an estimate can be obtained for the volume of milk in the container 3 based upon the measured pressures.

Figure 13 also shows a dead end stop pump test 45 as described above. The negative spike shows the application of negative pressure directly to the pressure sensor 101.

2. Breast shield sizing and nipple alignment

The correct sizing of the breast shield and the alignment of the nipple in the breast shield are key for an efficient and comfortable use of the breast pump. However breast shape, size as well as nipple size and position on the breast vary from one person to another and one breast from another. In addition, women's bodies often change during the pumping life cycle and consequently breast shield sizing may also need to be changed. Therefore, a number of breast shield sizes are available. Guide lines for correct nipple alignment are also provided.

With reference to Figure 14, three breast shield sizes are shown (A1, B1, C1). The substantially clear breast shield gives an unobstructed view of the breast and allows a user to easily confirm that she has the appropriate sized shield for her breast.

In order to determine the correct breast shield size and nipple alignment, the breast shield and the diaphragm are detached from the housing and placed on the breast with the sizing symbol facing upwards (with the diaphragm positioned below the nipple) and the nipple aligned in the centre of the fit lines (as shown in A2, B2, C2). The transparent breast shield allows the user to observe the nipple while adjusting the position of the breast shield in order to align the nipple correctly near the centre of the breast shield nipple tunnel. Prior to using the pump, the nipple is aligned correctly, and the breast shield is pushed into place ensuring the seal is correctly positioned on the breast shield. The fit lines should be directly aligned with the outside of the nipple. The correct

alignment is illustrated B2.

When the nipple is correctly aligned, the user then rotates the breast shield in order for the diaphragm to be positioned on top of the nipple. The user may then quickly assemble the rest of the breast pump (i.e. the housing and the milk container) on the breast shield via a one-click attachment mechanism confirming correct engagement, which may be performed one-handed. Nipple alignment may therefore be easily maintained. Audio and/or haptic feedback may also be provided to further confirm correct engagement.

3. Connected Device Application

Figures 15 to 20 show examples of screenshots of a connected device application that may be used in conjunction with the breast pump system as described above. The interface shown here is an example only and the same data may be presented via any conceivable means including animated graphics, device notifications, audio or text descriptions.

Figure 15 shows a homepage of the application with different functions provided to the user which can be accessed either directly while pumping or at a later time in order for example: to review pump settings or the history of previous pumping sessions.

Figure 16 shows a status page with details of remaining battery life, pumping time elapsed and volume of milk inside the milk container.

Figure 17 shows screenshots of a control page, in which a user is able to control different pump parameters for a single breast pump (A) or two breast pumps (B). The user may press on the play button to either start, pause, or resume a pumping activity. The user may also directly increase or decrease the rate of expression using the (+) or (-) buttons. When only one breast is being pumped (A), the user may also indicate if it is either the right or left breast that is being pumped. The user may also control the pump peak pressure or alternatively may switch between different pre-programmed pressure profiles such as one mimicking the sucking pattern of a baby during expression or stimulation cycle.

Figure 18 shows a page providing a summary of the last recorded pumping session.

Figure 19 shows a page providing a history of previous pumping sessions. The user may scroll down through the page and visualize the data related to specific pumping sessions as a function of time.

The application is also capable of providing notifications relating to pumping. Figure 20 shows a screenshot of the application, in which a user is provided a notification when the milk collection bottle is full. Other generated notifications may include warnings about battery life, Bluetooth connection status or any other wireless communication status, status of miss-assembly, excessive movement or lack of expression.

Figure 21 shows a further example with a screenshot of an application running on a connected device. The page shows the pumping status when a user is using a double pump mode of operation with a pump on each breast. The user is able to manually control each pump individually and may start, stop or change a pumping cycle, increase or decrease each pump peak pressure, or switch between different pre-program pressure profiles such as one mimicking the sucking pattern of a baby during an expression or stimulation cycle. The application also notifies the user when a milk collection container is nearly full as shown in Figure 22.

Figure 23 shows a status page with an alert notifying the user that the milk collection container of the pump on the right breast is full. A message is displayed that the pump session has paused and that the milk collection container should be changed or emptied before resuming pumping.

With reference to Figure 24, when the left and right pump are stopped or paused, the application displays the elapsed time since the start of each session (right and left), the total volume of milk collected in each bottle.

With reference to Figure 25, a page summarising the last session (with a double pump mode) is displayed.

In addition to the data provided to the user, and their interactions with the application, the app will also hold data that the user does not interact with. For example, this may include data associated with pump diagnostics. In addition to all functions and sources of

data discussed above, the application may itself generate metadata associated with its use or inputs, notes or files uploaded by the user. All data handled within the mobile application can be periodically transferred to a cloud database for analysis. An alternative embodiment of the breast pump system may include direct contact between the database and the pump, so that pumping data may be conveyed directly, without the use of a smartphone application.

In addition to providing data to the cloud, the application may also provide a platform to receive data including for example firmware updates.

4. Breast pump data analysis

The discreet, wearable and fully integrated breast pump may offer live expression monitoring and intelligent feedback to the user in order to provide recommendations for improving pump efficiency or performance, user comfort or other pumping/sensing variables, and to enable the user to understand what variables correlate to good milk flow.

Examples of variables automatically collected by the device are: time of day, pump speed, pressure level setting, measured pressure, pressure cycle or duty cycle, voltage supplied to pumps, flow rate, volume of milk, tilt,, temperature, events such as when let-down happens, when a session is finished. The user can also input the following variables: what side they have pump with (left or right or both), and the comfort level.

This is in part possible because the live milk volume measurement system functions reliably (as discussed in Section B). The breast pump system includes a measurement sub system including IR sensors that measures or infers milk flow into the milk container, and that enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. The generated data may then be distributed to a connected device and/or to a cloud server for analysis in order to provide several useful functions.

Figure 26 illustrates an outline of a smart breast pump system network which includes the breast pump system (100) in communication with a peripheral mobile device and application (270) and several cloud-based databases (268, 273). The breast pump system

(100) includes several sensors (262). Sensor data refers to a broad definition including data generated from any sensor or any other analogue/digital reading directly from the motherboard or any other component. However, within the embodiment detailed, these measurements include one or more of the following, but not limited to: milk volume measurements, temperature sensor readings, skin temperature sensing, pressure sensor readings, accelerometer data and user inputs through any physical device interface.

The device also contains a number of actuators, including, but not restricted to: piezoelectric pump(s), solenoid valve(s), IREDs and an LED display. Sensors and actuators within the device are coordinated by the CPU (263). In addition, any interactions, and data from these components, may be stored in memory (264).

Further to these components, the device also contains a communication chip, such as a Bluetooth chip (265) which can be used to communicate wirelessly with connected devices such as a peripheral mobile device (270). Through this connection any sensor data (267) generated in the breast pump can be sent to the connected device. This user data, along with any other metadata generated from a connected device app, can be provided to an online database which aggregates all user data (273). In addition, the communication chip will also allow the sending of user control data / firmware updates from the connected device to the breast pump system (266).

Raw data (271) collected from the measurement sub-system including sensors (262) may be analysed on a cloud database and the analysed data may be stored on the cloud (272). Through inferences provided by the analysed data, firmware updates (269) may be developed. These can be provided for download to the pump through, for example, an online firmware repository or bundled with the companion app in the connected device app store (268).

In addition, it should be appreciated that despite the sophistication of the proposed breast pump network, the breast pump still retains complete functionality without wireless integration into this network. Relevant data may be stored in the device's memory (264) which may then be later uploaded to the peripheral portion of the system when a connection is established, the connection could be via USB cable or wireless.

The measurement sub-system may analyse one or more of the following:

- the quantity of the liquid in the container above its base;
- the height of the liquid in the container above its base;
- the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.

Based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase, a haptic and/or visual indicator indicates if the pump is operating correctly to pump milk. For example, the visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.

The visual indicator may provide:

- an estimation of the flow rate;
- an estimation of the fill rate;
- an indication of how much of the container has been filled.

As a further example, an accelerometer may infer the amount of movement or tilt angle during a pumping session. If the tilt angle excesses a threshold, the system warns or alerts the user of an imminent spillage, or provides the user with an alert to change position. Alternatively, the system may also stop pumping to prevent spillage, and once the tilt angle reduces below the threshold, pumping may resume automatically. By sensing the movement or title angle during a pumping session, the system may also derive the user's activity such as walking, standing or lying.

Many variables can affect milk expression and data analysis of these multiple variables can help mothers to achieve efficient pumping regimes and improve the overall user experience.

Therefore, the measurement sub-system measures or infers milk flow into the milk container and enables a user to understand what variables (e.g. time of day, pump setting) correlates to good milk flow. The amount of milk expressed over one or more sessions is recorded as well as additional metrics such as: time of day, pump setting, length of a single pumping session, vacuum level, cycle times, comfort, liquids consumed by the mother. Live data or feedback is then provided to the user to ensure the breast pump is

being used properly and to support the user in understanding the variables that would correspond to the specific individual optimum use of the breast pump.

Furthermore, live data can be used to automatically and intelligently affect specific pumping parameters in order to produce the most efficient pumping session. For example, if the rate of expression increases, the milking cycle might be adjusted accordingly to achieve a more efficient, or more comfortable pumping cycle.

The measurement sub-system also enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. Collected metrics are transferred through wireless connections between the pump, a connected device or app and a cloud database. Additionally, the application can also connect to other apps residing on the connected device, such as fitness app or social media app or any other apps. Further metrics may also include the behaviour or specific usage of the user associated with the connected device while using the pump (detection of vision and/or audio cues, internet usage, application usage, calls, text message).

Different aspects of pumping can be automatically changed based on dynamic sensor feedback within the breast pump device. The data analysis system is able to access real-time data of pumping sessions and may be used to perform one or more of the following functions, but not limited to:

- indicate whether the milk is flowing or not flowing,
- measure or infer the quantity and/or height of the liquid in the container above its base,
- give recommendations to the mother for optimal metrics for optimal milk flow,
- give recommendations to the mother for optimal metrics for weaning,
- give recommendations to the mother for optimal metrics for increasing milk supply (e.g. power pumping),
- give recommendations to the mother for optimal metrics if an optimal session start time or a complete session has been missed,
- automatically set metrics for the pumping mechanism, such as length of a single pumping session, vacuum level, cycle times.
- automatically stop pumping when the milk container is full,
- automatically adjust one or more pumping parameters to achieve an optimum

pumping session,

- automatically adjust one or more pumping parameters to achieve a comfortable pumping session,
- automatically change the pumping cycle from a programmed cycle to another different programmed cycle, such as from a stimulation cycle to an expression cycle.

In addition, sensor feedback might be used to improve the physical function of the breast pump system itself. For example, an array of piezoelectric pumps may be dynamically adjusted in response to their operating temperatures so as to optimise the total life of the component whist maintaining peak pressures.

Many additional embodiments may be described for these simple feedback systems, yet the premise remains: real-time sensor feedback is used to automatically and dynamically adjust actuator function. Each feedback program may feasibly include any number and combination of data sources and affect any arrangement of actuators.

The data generated can also be used to generate large datasets of pumping parameters, user metadata and associated expression rates, therefore allowing the analysis of trends and the construction of associations or correlations that can be used to improve pumping efficiency, efficacy or any function related to effective milk expression. The analysis of large user datasets may yield useful general associations between pumping parameters and expression data, which may be used to construct additional feedback systems to include on firmware updates.

Multiple data sources can be interpreted simultaneously and several different changes to pumping might be actuated to increase pumping efficiency, user experience or optimize pump performance.

Collected metrics may be anonymised and exported for sharing to other apps, community or social media platforms on the connected device, or to an external products and services, such as community or social media platform. By contrasting the performance of different users in the context of associated metadata, users may be grouped into discrete 'Pumper profiles' or communities, which may then be used to

recommend, or action the most appropriate selection of intelligent feedback systems to encourage efficient expression. For example, a higher peak pressure may be recommended for women who tend to move more whilst pumping, so as to achieve more efficient expression.

5

SECTION B: IR SYSTEM

This section describes the milk detecting system used in the Elvie™ pump.

With reference to Figures 27 and 28, there is shown a device 270 for use in detecting the level of liquid inside a container 275. The device 270 is formed of a housing 271 in which is located a sensing assembly 272 comprising a series of optical emitters 273 (an array of three optical emitters is used on one implementation) which are relative to, and each located at a distance from, an optical receiver 274. In operation of the device as will be described, each optical emitter 273 is operable to emit radiation which is received by the optical receiver 274. In an embodiment of the invention, the series of optical emitters are each located equidistant from the optical receiver 274.

The optical emitters 273 and the optical receiver 274 from the sensing assembly 272 are located in a portion 276 of the device 270 which faces the container 275 when the device is connected to the container 275. The portion 276 of the device 270 containing the optical emitters 273 and the optical receiver 274 comprises a window 277 of material which is transparent to optical radiation. In this way, each of the optical emitters 273 and the optical receiver 274 have a line of sight through the window 277 into the container 275 when the device 270 is connected thereto.

A controller 278 comprising a CPU 279 and a memory 280 is provided in the device 270 for controlling the operation of the sensing assembly 272. An accelerometer 281 is also provided in the housing 271, which is operatively connected to the controller 278. Operation of the device 270 when connected to the container 275 will now be described.

In a principal mode of operation, to determine the level L of liquid inside the container 275, the controller 278 instructs the optical emitters 273 to each emit radiation towards the surface of the liquid inside the container 275 at a given intensity. The optical receiver 274 receives the reflected radiation from each optical emitter 273 via the surface of the liquid and each of these intensities is recorded by the controller.

For each operation of the sensing assembly 272, the controller 278 records the intensities of radiation emitted by each of the optical emitters 273 as intensities IE1; IE2…IEn

(where n is the total number of optical emitters), and records the intensities of radiation received by the optical receiver 274 from each of the optical emitters 273 as received intensities IR1; IR2…IRn.

By comparing the emitted radiation intensities IE1; IE2…IEn with the received radiation intensities IR1; IR2…IRn, the controller 278 calculates a series of intensity ratios IE1:IR1; IE2:IR2…IEn:IRn, which are then used to determine the level of the liquid inside the container. At the most basic level, if the intensity ratio of IE1:IR1 is the same as IE2:IR2, given the optical emitters 273 are equidistant from the optical receiver 274, this indicates that the level of the liquid inside the container is parallel to the top of the bottle, as shown in Figure 27. In contrast, if these two intensity ratios are different, this indicates that the liquid level is at a different angle, such as that shown in Figure 28.

To accurately determine the level and the quantity of liquid inside the container 275, the controller 278 processes the recorded intensity ratios using a database located in the memory 280. The database contains an individual record for each container which is operable to connect with the device 270. Each record from the database contains a look-up table of information, which contains expected intensity ratios (IE1:IR1 and IE2:IR2) for the container 275 when filled at different orientations, and with different quantities of liquid.

By comparing the information from the look-up table with the recorded intensity ratios, the controller 278 calculates the level and quantity of liquid inside the container 275 and stores this information in the memory 280.

In situations where a container 275 to the device 270 contains no stored record in the database, the sensing assembly 272 can be used in a calibration mode to create a new record. In the calibration mode, the sensing assembly 272 is operated as the container is filled from empty, and as it is positioned at different orientations. At each point during the calibration mode, the controller 278 calculates the recorded intensity ratios (IE1:IR1 and IE2:IR2) and stores them in the record relating to the container 275. For each set of recorded intensity ratios, the user includes information in the record relating to the orientation and fill level of liquid inside of the container 275.

To improve the accuracy of the results obtained by the device 270 during its use, the controller 278 when recording each intensity ratio also records a parameter from the accelerometer 281 relating to the acceleration experienced by the device 270. For each recorded acceleration parameter, the controller 278 determines whether the parameter 278 exceeds a predetermined threshold acceleration parameter stored in the memory 280. The predetermined threshold is indicative of an excessive acceleration, which causes sloshing of liquid inside the container 275 connected to the device 270. In the event of a recorded acceleration parameter exceeding the predetermined threshold acceleration parameter, the controller 278 flags the recorded intensity ratios associated with the recorded acceleration parameter as being unreliable (due to sloshing).

Even without the use of the accelerometer 281, the controller 278 is nonetheless operable to determine whether a set of recorded intensity ratios occur during a period of excess acceleration. In this regard, for each set of intensity ratios recorded at a given time, the controller 278 checks whether any of these intensity ratios is of a predetermined order of magnitude different than the remaining recorded intensity ratios from the set. In the event that the controller 278 determines that this is the case, this indicates that the liquid inside the container has 'sloshed' as a result of the excess acceleration, as shown in Figure 29. In this event, the controller 278 flags the set of recorded intensity ratios as being unreliable.

It will be appreciated that instead of recording the relative intensities of radiation emitted by the optical emitters 273 with the radiation received by the optical emitter 274, the controller 278 could instead record the time taken for radiation emitted by each of the optical emitters 273 to be received by the optical receiver 274. In this arrangement, the look up table would instead contain time periods as opposed to intensity ratios.

In terms of the applications for the device 270, it will be appreciated that the device can be used in a wide variety of applications. One possible application is the use of the device 270 to determine the level of liquid located within a container 275, such as a baby bottle, used as part of a breast pump assembly. In this arrangement, the device 270 is associated with a breast pump 301 which assists with the expression of milk from a breast. The breast pump may be located in the housing 271 of the device 270 as shown in Figure 30, or it may be realisably connected to the housing 271.

Either way, the device 270 would be connectable to the container 275 such that milk expressed by the breast pump can pass from the pump via a channel 302 into the container 275.

The breast pump may be any type of breast pump system including any shapes of milk container or bottle and may comprise a pump module for pumping milk from a breast. The pump module being contained within the housing may comprise: a coupling, a container attachable to the housing via the coupling to receive milk from the pump, a sensing assembly within the housing and comprising at least one optical emitter operable to emit optical radiation towards the surface of the body of milk held in the container when the housing is connected to the container, an optical receiver for receiving the reflected radiation from the surface of the milk, and a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the milk inside the container based on the reflected radiation received by the optical receiver.

By determining the level of milk inside the container based on reflected radiation from the surface of the milk in the container, there is no need to monitor the individual droplets of milk entering the container, such that the sensing assembly can avoid errors associated with measuring these droplets. For example, because we take multiple reflection-based measurements once the container is filled, we can generate an average measurement that that is more accurate than a single measurement. But with systems that rely in counting individual droplets, that is not possible – further, systemic errors (e.g. not counting droplets below a certain size) will accumulate over time and render the overall results unreliable. Furthermore, by not needing to measure these droplets, the sensing assembly from the breast pump need not always be on during the pumping process, which saves power.

When at least two optical emitters are used, the sensing assembly from the breast pump may determine the level of milk inside the container more accurately and irrespective of the orientation of the liquid level inside the container.

Each optical emitter may be equidistant from the optical receiver in order for the

controller to easily calculate the level of the milk inside the container based on the reflected radiation originating from each optical emitter. The signals from the optical receiver preferably comprise information relating to the intensity of the radiation received by the optical receiver.

Each optical emitter may be operable to emit radiation at a different wavelength, or at a different time, than the other optical emitters. In this way, the controller can more easily process the signals from the optical receiver, and more easily distinguish between the radiation emitted by each of the optical emitters.

The optical emitter may emit radiation in the visible range of wavelengths. Alternatively, it may be UV or IR light. The emitted wavelength may be for example between 10nm and 1mm.

The sensing assembly may also comprise at least one accelerometer electrically connected to the controller. The controller may be configured to record an accelerometer parameter from the accelerometer and determine whether the accelerometer parameter exceeds a predetermined threshold. The predetermined threshold may be indicative of an excessive acceleration, which might cause sloshing of milk inside any container connected to the breast pump.

Another application for the device 270 is as a collar for detecting the level/quantity of liquid in a container 275, such as a baby bottle, via its lid 310. An example of the device 270 being used as such a collar is shown in Figure 31. In this arrangement, the device 270 is located between the container 275 and the lid 310, and comprises a first end 311 having a first coupling 312 for attaching the collar to the lid 310. The device comprises a second end 313 having a second coupling 314 for attaching the device 270 to the container 275. The second coupling may be a screw thread, shown in Figure 31, on the inside surface of the container 275. In this way, the distinctive bottom inside surface can be used by the sensing assembly 272 to more easily calibrate itself to the container 275 on which the distinctive bottom inside surface is located. The distinctive bottom may also be used to help identify which container 275 the device is connected to, and thus which record should be used from the database when the device 270 is used.

To further improve the accuracy of the sensing assembly 272, the controller 278 may also be configured to use the recorded information from the accelerometer 281, in situations where the record acceleration is below the predetermined threshold acceleration parameter, to calculate a more accurate liquid level and/or quantity of liquid located inside the container which is compensated for acceleration.

In one particular arrangement, the controller 278 may poll the accelerometer 281 prior to each operation of the sensing assembly 272 to verify that the device 270 is not currently undergoing excessive acceleration. In the event of the controller 278 determining excessive acceleration in the device 270, the controller 278 would continually re-poll the accelerometer, and not operate the sensing assembly 272, until the parameter from the accelerometer is determined as being below the predetermined threshold acceleration parameter stored in the memory 280.

It will also be appreciated that for each container record stored in the database, the container record may comprise a plurality of look up tables, wherein each look up table is associated with a particular liquid used in the container, and wherein each look up table contains its own set of intensity ratios. In this way, the device 270 can more accurately determine the level/quantity of different liquids used in a particular container 275.

As described herein, the sensing assembly 272 has been described as having a plurality of optical emitters 273. It will be appreciated however that the sensing assembly could operate using a single optical emitter 273 and plurality of optical receivers 274. In this arrangement, each record from the database would contain a plurality of ratios relating to the emitted radiation from the optical emitter 273 as received by each of the optical receivers 274. In use of the device 270, the controller 278 would then similarly record the emitted radiation from the optical emitter 273 as received by each of the optical receivers 274. In an alternate arrangement, there may be provided a plurality of optical emitters 273 and a plurality of optical receivers 274, wherein each optical emitter 273 is associated with a respective optical receiver 274. In its simplest arrangement, the sensing assembly 272 may comprise a single optical emitter 273 and a single optical receiver 274.

In certain configurations, the optical emitters 273 may together emit radiation having the same wavelength. In other configurations, the optical emitters 273 may each emit

radiation having a different wavelength. In this latter configuration, the optical receiver 274 would then be able to determine which optical emitter 273 is associated with any given received radiation, based on the wavelength of the received radiation.

The optical emitters 273 may also each emit radiation at different times, such to allow the controller 278 to more easily process the signals from the optical receiver 274, and more easily distinguish between the radiation emitted by each of the optical emitters 273.

In relation to the electrical connection between the controller 278 and the sensing assembly 272, it will be appreciated this electrical connection may be either a wired/wireless connection as required.

Although not shown in the Figures, the device 270 herein described is preferably powered by a battery or some other power source located in the device 270. In other embodiments, the device 270 may be powered using mains electricity.

In one configuration, it is also envisaged that rather than the controller 278 comparing the information from the look-up table with the recorded intensity ratios to calculate the level and quantity of liquid inside the container 275, the controller 278 could instead process the recorded intensity ratios through a liquid-level equation stored in the memory 280. In this configuration, the liquid-level equation could be a generalised equation covering a family of different containers, or could be an equation specific to a container having a given shape and/or type of liquid inside.

It will also be appreciated that in some applications of the device 270, the device could be used to detect the level of a solid, as opposed to a liquid, in a container. As used herein, the terms 'optical emitter' and 'optical receiver' are intended to cover sensors which can emit radiation in or close to the optical wavelength. Any type of radiation at or close to the optical wavelength is suitable provided that it does not have any harmful effects. The exact wavelength is not important in the context of the invention. Such sensors thus include those which can emit visible radiation (such as radiation having wavelengths in the region of 400nm-700nm), and/or those which can emit IR radiation (such as radiation having wavelengths in the region of 700nm-1mm and/or those which can emit UV radiation (such as radiation having wavelengths in the region of 10nm to

400nm).

Existing prior art for such a sensor module is the apparatus disclosed in RU2441367. In this apparatus, the container is an industrially sized milk tank, which only includes a single laser mounted at the top of the tank. Whilst this apparatus is suited for large-sized containers, which do not move in use, the apparatus is less-suited for applications where the container moves in use, or where the liquid level inside the container is non perpendicular to the laser beam shone into the container. In contrast, the sensor module described above can be used in a variety of different applications, is conveniently located within a housing, and which by virtue of it having at least two optical emitters, can determine the level of liquid even inside containers of irregular shapes, and which can determine the level of liquid inside a container irrespective of the orientation of the liquid level inside the container.

Further to the embodiments of the fluid measurement system in different contexts, it can be appreciated that different functions entirely may be possible using the same component structure. For example, it is known that certain molecules within breast milk absorb specific wavelengths of light at characteristic propensities. Whilst the proposed system uses multiplexed IREDs at the same wavelengths to perform proximity measurements, the same array of IREDs may instead be used to emit several different wavelengths of light and determine their absorption upon reflection. If appropriately calibrated, the system may be able to report on the presence or concentration of specific compounds in the expressed milk, such as fat, lactose or protein content.

In addition to this embodiment, it is feasible that the system might be applied to monitor the change in volume of any other container of liquid, given there is sufficient reflection of IR off its surface. These embodiments might include for example: liquid vessel measurement such as for protein shakes, cement or paint, or volume measurements within a sealed beer keg.

SECTION C: BRA CLIP

This section describes a bra clip that forms an accessory to the Elvie™ pump.

It relates to a system allowing a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump. As such, the user does not need a specialised adjustable bra; instead the present system works with all conventional maternity bras. The user also does not have to purchase any larger bras to wear while pumping.

As shown in Figure 32, a typical maternity bra 320 comprises a support structure made up of shoulder straps 321 which support the bra 320 on the wearer's shoulders, and a bra band 322 for extending around a user's ribcage, comprising two wings 323 and a central panel or bridge 324. The straps 321 are typically provided with adjustment mechanisms 325 for varying the length of the straps 321 to fit the bra 320 to the wearer. At the outermost end of each wing, an attachment region 326 is provided. Typically, hooks 327 and loops 328 are provided for securing the bra 320 at the user's back. However, any other suitable attachment mechanism may be used. Alternatively, the attachment region 326 may be provided at the front of the bra 320 in the bridge region 324, with a continuous wing 323 extending continuously around the wearer's back. Typically, a number of sets of loops 328 are provided to allow for variation in the tightness of the bra 320 on the wearer. While shown as having a separation in Figure 32, the wings 323 and bridge 324 may form a single continuous piece in certain designs. Likewise, while shown with a distinct separation in Figure 32, the shoulder straps 321 and the wings 323 may likewise form a single continuous piece.

The maternity bra 320 is further provided with two breast-supporting cups 329 attached to the support structure. The cups 329 define a cup size, which defines the difference in protrusion of the cups 329 from the band 322. The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting a 2 cm difference between the protrusion of the cups 329 from the band 322. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes

of S, M, L, XL, etc.

The cups 329 may be stitched to the bra band 321. At least one of the cups 329, is in detachable attachment with the corresponding strap 321. In particular, this is achieved at attachment point 330 where a hook 331 attached to the bra strap 321 engages with a clasp 331 attached to the cup 329. The hook 331 and the bra strap adjuster 325 are set such that in the closed position, the cup size of the bra 320 fits the wearer's breasts.

In Figure 32, the left cup 329 is shown attached to its attachment point 330, which the right cup 329 is unattached. In this manner, the wearer is able to detach the cup 329 to expose their breast for feeding or for breast pumping. Once this is completed, the cup 329 is reattached and the maternity bra 320 continues to function as a normal bra.

While in the depicted embodiments, a hook 331 is shown on the bra strap 321 and a clasp 332 is shown on the cup 329, it is appreciated that the provision of these may be reversed, or that alternative attachment mechanisms may be used.

A maternity bra therefore may comprise a support structure comprising shoulder straps and a bra band and a first and a second cup each attached to the support structure to provide a first cup size, at least one cup being at least partially detachable from the support structure at an attachment point.

In other embodiments, the detachable attachment point 330 may be provided at a different location, such as at the attachment between the bra band 322 and the cup 329. The mechanism for such an attachment point is the same as described above.

A clip has been designed such that it is configured to be attached to the support structure at a position away from the attachment point. This results in the original attachment point being usable, with the clip providing an alternative attachment point to give, in effect, an adjusted cup size.

Alternatively, the clip may also be attachable to the support structure at a plurality of non-discrete positions. This ensures essentially infinite adjustment of the clip position such that the perfect position for the user can be found.

The clip can also extend between an unextended and an extended state, and can attach to the support structure at the attachment point; the first cup size is providable when the at least partially detachable cup is attached to the clip when the clip is an unextended state; the second cup size is providable when the at least partially detachable cup is attached to the clip when the clip is in an extended state. An extendable clip like this allows quick switching between the two states in use.

Figure 33 depict a clip 335 according to the present invention, along with a clasp 332 shown in isolation from the bra cup 329 it is normally attached to. The clip comprises a first engagement mechanism and at least one second engagement mechanism(s). The clip is attachable in a releasable manner to the support structure at a first position via the first engagement mechanism and attachable in a releasable manner to one of the partially detachable cups via the second engagement mechanism to provide a second cup size different to the first cup size. The clip 335 is provided with a material pathway 336 which receives a portion of the bra strap 321. In the particular embodiment of these Figures, the clip 335 is substantially U-shaped, with a narrowing profile towards its open end. However, it is appreciated that any other suitable shape with a material pathway may be used, such as an S-shape or E-shape. The clip 335 is designed to be attached to the bra strap 321 in a releasable manner, with the slot 336 acting as a support engaging mechanism. The releasable manner means that the clip 335 may be simply removed from the bra 320 without causing any damage to the functioning of the bra 320. To enhance the ease of attachment, the clip 335 may be provided with outwardly extending wings 204 which help direct the bra strap 321 into the clip 335. The clip 335 is further provided with a hook 220 acting as a cup engaging mechanism which can engage with the clasp 332.

Figure 33 (c) shows the clip 335 being attached to a bra strap 321 in order to provide a second attachment point 337 for the clasp 332 to attach to, and hence to provide a second cup size for the bra 320. In this particular embodiment, the clip 335 is attached in a portion of strap 321A below the original attachment point 330 and hence the second attachment point 337 is likewise below the original attachment point. This results in a second cup size larger than the first cup size. In preferred embodiments, as shown in these Figures, the clip 335 engages with the support structure in a direction transverse to

the direction in which it engages with the cup.

Figure 33 (d) and (e) show how a wearer is able to move between the first and second cup sizes. In 33(d), the cup 329 is attached at the first attachment point 330 to provide a first cup size. The wearer then disengages the clasp 332 from the hook 331 at the hook 338 at the second engagement point 239. In this manner, the wearer is easily able to transition between the two cup sizes.

Figures 34 and 35 show an alternative design for a clip 340. This clip 340 is substantially "E-shaped", with a back portion 341 and first, second and 5 third prongs 342A, 342B, 342C extending transverse from this back portion 341. The three prongs 342A, 342B, 342C are spaced apart along the length of the back portion 341. The first and third prongs 342A, 342C are provided with attachment clips 343A, 343B.

These attachment clips 343A, 343B can engage with the clasp 332 of a bra to provide the second cup size. Depending upon the orientation of the clip 300, one or the other of the attachment clips 343A, 343B will be used to attach the clasp 332 of the bra. By providing these clips 343A, 343B on both of the first and the third prongs 342A, 342C the clip is easily reversible so it can be used on either side of the bra. Preferably the clip 340 is also symmetrical, to aid the reversibility of the clip 340.

Figure 35 shows the clip 340 attached to a bra. As can be seen, the first and third prongs 342A, 342C extend on the front side of the bra strap, with the second prong 342B extending on the rear side of the bra strap. In this manner, the clip 340 is attached to the strap. In preferable embodiments, a grip-enhancing member 344 such as a number of projections and/or roughened patches can be provided on the second prong 342B in order to strengthen this grip.

In alternative embodiments, the attachment clip could be provided on the second, centremost prong 342B. In such an arrangement, the centremost prong 342B would be on the outside of the bra, with the first and third prongs 342A, 342C on the inside.

The provision of the attachable clip allows maternity bras already owned by the wearer to be quickly transformed into bras with quick switchable double cup size options.

This allows the use of integrated wearable breast pumps which increase the user's required cup size. This allows more design freedom for the breast pump in terms of size and shape, while still allowing the user to discretely pump with the pump held within their bra. By allowing conversion of the user's existing maternity bras, they are not forced to purchase specially designed bras to wear with the pump. The bra is hence normally at the first engagement point 330 when the breast pump device is not being used. As shown in Figure 33, the clasp 332 is then engaged by the user to discretely switch between the two configurations, and the user then inserts the pump without any complex adjustment or removal of clothing.

Preferably, the clip will be relatively unobtrusive in size and shape and hence can be left in place when the bra is first put on and used when necessary. To this end, the clip is preferably machine washable without significant damage or degradation.

In some embodiments, the clip may be switchable between positions for engaging with each cup so that a single clip may be used on either side of the bra. To achieve this, the clip is preferably reversible. This may provide the user with a visual indication of which breast has produced milk most recently so switching can take place.

In a preferred embodiment, the first engagement mechanism engages with the support structure in a first direction and the second engagement mechanism engages with the cup in a second direction transverse to the first direction. This increases ease of attachment as with this structure the sideways engagement of the clip to the support structure ensures that the second attachment mechanism is correctly orientated for the cup.

The second engagement mechanism may be one or more of a hook or a snap or a clip. This ensures easy interfacing with the traditional hook and clasp systems already provided on maternity bras.

Preferably the clip further comprises two distinct second engagement mechanisms which can be used interchangeably dependent upon the orientation of the clip. This makes the clip easier to use as it can be quickly switched between each bra strap, and the user does not have to worry which way up to put the clip on.

Preferably, the clip comprises a material pathway with an opening for receiving a portion of the support structure as the first engagement mechanism for securing the clip to the bra. This ensures a quick and simple method for attaching the clip to the bra. In particular, the clip may substantially U-shaped, and the material pathway is between the arms of the U.

Preferably, the clip comprises three prongs extending from a central support, the three prongs arranged as a central prong and two outer prongs so as to receive the support structure on one side of the central prong and on the opposite side of each respective outer prong, at least one prong being provided with the second engagement mechanism. This ensures a strong attachment to the bra and a simple design.

Preferably, both outer prongs are each provided with a respective second engagement mechanism. This ensures that the clip is reversible for easier attachment to the bra.

A method of adjusting the cup size of a maternity bra is provided according to the present invention, comprising: providing a maternity bra comprising: a support structure comprising shoulder straps and a bra band; and a first and second cup each attached to the support structure to provide a first cup size, the at least one cup being detachable from the support structure at an attachment point, providing a clip comprising first and section engagement mechanisms, attaching the first engagement mechanism of the clip in a releasable manner to a first position of the support structure of the maternity bra, attaching one of the detachable cup to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

This clip and method allow a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump.

Preferably, the method further comprises the step of inserting a breast pump into the detachable cup. The adjustment of the size of the bra allows the bra to support the breast pump against the user's breast for comfort and ease.

Preferably, the method further comprises the steps of: detaching the first engagement mechanism of the clip from the first position support structure of the maternity bra; attaching the first engagement mechanism of the clip in a releasable manner to a second position of the support structure of the maternity bra; and attaching the other of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size. This allows the user to use a single clip on either of the cups.

An alternative embodiment may be provided, with an extendable clip 360 as shown in Figure 36. In such an embodiment the clip is attached to the hook 331 on the strap 321 in a releasable manner, with the clasp 332 attached to an expandable portion of the clip. The clip is then able to expand between an unexpanded state where the clasp 332 is held in substantially the same position as the first attachment point 330 to provide the first cup size, and an expanded state, where the clasp 332 is held in a second position away from the first attachment point 330 to provide the second cup size.

For example, an elongate clip with first and second opposite ends may be provided. A first attachment point for attaching to the hook 331 is provided at the first end, and a second attachment point for attaching to the clasp 332 is provided at the second end. The elongate clip is hinged between the two ends, such that the clip can be folded between an elongate configuration to a closed configuration where the second end touches the first end. A clasp can be provided on the clip to hold the second end in this closed configuration. Thus, in the closed position the clasp 332 is held in substantially the same location as the first attachment point 330 to provide the first cup size, and in the open position the clasp is held away from the first attachment point 330 to provide the second cup size.

Other extendable clip embodiments are also possible, for example sliding clips or elastic clips.

Additional embodiments of a maternity bra adjuster are provided in Figures 37 and 38. The alternative proposed solution is a small adapter device, which comprises a first portion 370 including a clasp 373 and a second portion 372 including a hook 374, in which the first and second portions are separated by a small distance 371 in order to

provide two different adjustable sizes. The first portion includes a clasp 373 that is designed to attach to the hook on the bra strap 321. It may also include a top hook 375 positioned underneath the clasp, and a clip 376 on the rear side. The second portion includes a bottom hook 372.

The clasp 332 that is present on the cup 329 of the maternity bra, may then either engage with the top hook (321) to provide a first cup size, and engage with the bottom hook (332) to provide a second cup size that is different from the first cup size, as illustrated in Figure 39. The user may then discretely switch between a non pumping position, provided by the first cup size, and a second pumping position without any complex adjustment or removal of clothing needed, while using a wearable breast pump system (100).

The first portion and second portion may be made of plastic and may be separated by a stretchy material such as elastic or elastomeric material. The first portion may also include a clip on the rear side, the purpose of which is to allow the user to leave the clip attached to the bra for an extended time period.

Section D: Use of Piezo Pump in Wearables

As described in Section A, the breast pump system includes a piezo air pump, resulting in a fully wearable system that delivers a quiet, comfortable and discreet operation in normal use. This section gives further information on the piezo air pump.

In comparison with other pumps of comparable strength, piezo pumps are smaller, lighter and quieter. In operation, the Elvie breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise; tests indicate that it makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

Piezo pumps also have lower current draw, allowing for increased battery life. A piezo pump is therefore ideally suited for wearable devices with its low noise, high strength and compact size. Further, as shown in the breast pump system of Figures 7 and 8, more than one piezo pump may be used.

Whilst a breast pump system is largely described in previous sections, the use of piezo mounted either in series or in parallel can also be implemented in any medical wearable devices or any wearable device. The piezo pump may pump air as well as any liquid.

With reference to Figure 40, a diagram illustrating a configuration of two piezo pumps mounted in series is shown.

With reference to Figure 41, a diagram illustrating a configuration of two piezo pumps mounted in parallel is shown.

With reference to Figure 42, the air pressure generated as a function of time by two piezo pumps mounted in series and two piezo pumps mounted in parallel are compared. In this example, the parallel configuration produces higher flow rate and achieves -100mmHg negative air pressure faster than the series configuration. In comparison, the series configuration produces lower flow rate and takes slightly longer to reach 100mmHg. However, the parallel configuration cannot achieve as high as a vacuum as the series configuration and plateaus at -140mmHg. In comparison, the series

configuration is able to generate about -240mmHg.

A dual configuration is also implemented in which more than one piezo pump is configured such that they can easily switch between a parallel mode and a series mode. This dual configuration would suit wearable devices that would need to achieve either lower or higher pressure faster.

Figure 43 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration. In this dual configuration, the piezo pumps first start with a parallel mode in order to benefit from faster flow rate, and then switch to a series mode (as indicated by the switch-over point) when stronger vacuums are required, enabling to save up to 500ms on cycle time with elastic loads.

Additionally, a piezo pump may be used in combination with a heat sink in order to efficiently manage the heat produced by the wearable pump. This configuration may be used to ensure that the wearable device can be worn comfortably. The heat sink or heat sinks are configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin (especially prolonged contact for greater than 1 minute) are no more than 48°C and preferably no more than 43°C.

The heat sink may store the heat produced by a piezo pump in order to help diverting the heat produced to another location. This not only ensures that the wearable system can be worn comfortably, but also increases the lifetime of a piezo pump.

Figure 44 shows a picture of a wearable breast pump housing including multiple piezo pumps (440). The breast pump system is wearable and the housing is shaped at least in part to fit inside a bra. By applying a voltage to the piezo pumps, the pressure provided by the pumps increase. The generation of higher pressure by the piezo pumps also means higher heat produced that needs to be managed. Each piezo pump is therefore connected to a heat sink (441), such as a thin sheet of copper. The heat sink has a long thermal path length that diverts the heat away from the piezo pump.

The use of a heat sink in combination with a piezo pump is particularly relevant when the wearable device is worn directly or near the body, and where the management of heat induced by the piezo pump is crucial.

A wearable device including a piezo pump may therefore include a thermal cut out, and may allow for excess heat to be diverted to a specific location. The heat sink may be connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere. For example, the wearable system is a breast pump system and the heat sink stores heat, which can then be diverted to warm the breast shield of the breast pump system.

Use cases application include but are not limited to:

- Wound therapy;
- High degree burns;
- Sleep apnoea;
- Deep vein thrombosis;
- Sports injury.

APPENDIX: SUMMARY OF KEY FEATURES

In this section, we summarise the various features implemented in the Elvie™ pump system. We organize these features into six broad categories:

A. Elvie Breast Pump: General Usability Feature Cluster

B. Elvie Piezo Air Pump Feature Cluster

C. Elvie Milk Container Feature Cluster

D. Elvie IR System Feature Cluster

E. Elvie Bra Clip Feature Cluster

F. Other Features, outside the breast pump context

Drilling down, we now list the features for each category:

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is wearable and includes only two parts that are removable from the pump main housing in normal use.

Feature 2 Elvie is wearable and includes a clear breast shield giving an unobstructed view of the breast for easy nipple alignment.

Feature 3 Elvie is wearable and includes a clear breast shield with nipple guides for easy breast shield sizing.

Feature 4 Elvie is wearable and includes a breast shield that audibly attaches to the housing.

Feature 5 Elvie is wearable and includes a breast shield that attaches to the housing with a single push.

Feature 6 Elvie is wearable and not top heavy, to ensure comfort and reliable suction against the breast.

Feature 7 Elvie is wearable and has a Night Mode for convenience.

Feature 8 Elvie is wearable and includes a haptic or visual indicator showing when milk is flowing or not flowing well.

Feature 9 Elvie is wearable and collects data to enable the mother to understand what variables (e.g. time of day, pump speed etc.) correlate to good milk-flow.

Feature 10 Elvie is wearable and collects data that can be exported to social media.

Feature 11 Elvie is wearable and has a smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 12 A smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 13 Elvie is wearable and includes a sensor to infer the amount of movement or tilt angle during normal use.

Feature 14 Elvie includes a control to toggle between expressing milk from the left breast and the right breast.

Feature 15 Elvie includes a pressure sensor.

Feature 16 Elvie includes a microcontroller to enable fine tuning between pre-set pressure profiles.

Feature 17 Elvie enables a user to set the comfort level they are experiencing.

Feature 18 Elvie includes a microcontroller to dynamically and automatically alter pump operational parameters.

Feature 19 Elvie automatically learns the optimal conditions for let-down.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is wearable and has a piezo air-pump for quiet operation.

Feature 21 Elvie has a piezo air-pump and self-sealing diaphragm

Feature 22 Elvie uses more than one piezo air pump in series.

Feature 23 Elvie is wearable and has a piezo air-pump, a breast shield and a diaphragm that fits directly onto the breast shield.

Feature 24 Elvie is wearable and has a piezo air-pump for quiet operation and a re-useable, rigid milk container for convenience.

Feature 25 Elvie has a piezo-pump for quiet operation and is a connected device.

Feature 26 Elvie uses a piezo in combination with a heat sink that manages the heat produced by the pump.

Feature 27 Elvie is wearable and gently massages a mother's breast using small bladders inflated by air from its negative pressure air-pump.

Feature 28 Elvie is wearable and gently warms a mother's breast using small chambers inflated by warm air from its negative pressure air-pump.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is wearable and includes a re-useable, rigid milk container that forms the lower part of the pump, to fit inside a bra comfortably.

Feature 30 Elvie is wearable and includes a milk container that latches to the housing with a simple push to latch action.

Feature 31 Elvie is wearable and includes a removable milk container with an integral milk pouring spout for convenience.

Feature 32 Elvie is wearable and includes a removable milk container below the milk flow path defined by a breast shield for fast and reliable milk collection.

Feature 33 Elvie is wearable and includes a breast shield and removable milk container of optically clear, dishwasher safe plastic for ease of use and cleaning.

Feature 34 Elvie is wearable and includes various components that self-seal under negative air pressure, for convenience of assembly and disassembly.

Feature 35 Elvie is wearable and includes a spout at the front edge of the milk container for easy pouring.

Feature 36 Elvie is wearable and includes a milk container that is shaped with broad shoulders and that can be adapted as a drinking bottle that baby can easily hold.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the quantity of milk in the container for fast and reliable feedback.

Feature 38 The separate IR puck for liquid quantity measurement.

Feature 39 The separate IR puck combined with liquid tilt angle measurement.

E. Bra Clip Feature

Feature 40 Bra Adjuster.

F. Other Features that can sit outside the breast pump context

Feature 41 Wearable device using more than one piezo pump connected in series or in parallel.

Feature 42 Wearable medical device using a piezo pump and a heat sink attached together.

We define these features in terms of the device; methods or process steps which correspond to these features or implement the functional requirements of a feature are also covered.

We'll now explore each feature 1 – 41 in depth. Note that each feature can be combined with any other feature; any sub-features described as 'optional' can be combined with any other feature or sub-feature.

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is wearable and includes only two parts that are removable from the pump main housing in normal use

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a rigid or non-collapsible milk container;

and in which the breast pump system includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and the rigid, non-collapsible milk container.

Optional:

- The only parts of the system that come into contact with milk in normal use are the breast shield and the milk container.
- Milk only flows through the breast shield and then directly into the milk container.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings, in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- No other parts are removable from the breast shield, apart from the flexible diaphragm.
- The milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.
- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

- No other parts are removable from the milk container, apart from the cap and the valve.
- All parts that are user-removable in normal use are attached to either the breast shield or the milk container.
- Audible or haptic feedback confirms the pump system is properly assembled for normal use with the milk container locked to the housing and the breast shield locked to the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 2 Elvie is wearable and includes a clear breast shield giving an unobstructed view of the breast for easy nipple alignment

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel, shaped to receive a nipple, providing to the mother placing the breast shield onto her breast a clear and unobstructed view of the nipple when positioned inside the nipple tunnel, to facilitate correct nipple alignment.

Optional:

- The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is completely out, of or separated from, the housing.
- The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is partially out of, or partially separated from, the housing.
- Entire breast shield is substantially transparent.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.

- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

Feature 3 Elvie is wearable and includes a clear breast shield with nipple guides for easy breast shield sizing

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel shaped to receive a nipple, the nipple tunnel including guide lines that define the correct spacing of the nipple from the side walls of the nipple tunnel.

Optional:

- The guide lines run generally parallel to the sides of the nipple placed within the nipple tunnel.
- Breast shield is selected by the user from a set of different sizes of breast shield to give the correct spacing.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers in the housing locate into small indents in the breast shield.

- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 4 Elvie is wearable and includes a breast shield that audibly attaches to the housing.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield that is attachable to the housing with a mechanism that latches with an audible click when the breast shield is slid on to or against the housing with sufficient force.

Optional:

- The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.

- Breast shield is removable from the housing with an audible click when the breast shield is pulled away from the housing with sufficient force.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.

- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 5 Elvie is wearable and includes a breast shield that attaches to the housing with a single push

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield configured to attach to the housing with a single, sliding push action.

Optional:

- The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.
- The single push action overcomes a latching resistance.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into a nipple tunnel in the breast shield to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield when the breast shield has been placed onto a breast using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b)

transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

- The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.
- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

Feature 6 Elvie is wearable and not top heavy, to ensure comfort and reliable suction against the breast

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism

(b) and a breast shield;

(c) a milk container;

and in which the centre of gravity of the pump system is, when the milk container is empty, substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through a nipple tunnel or filling point on a breast shield, so that the device is not top-heavy for a woman using the pump.

Optional:

- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- In which the centre of gravity only moves lower during use as the milk container gradually receives milk, which increases the stability of the pump inside the bra.
- In which milk only passes downwards when moving to the milk container, passing through the nipple tunnel and then through an opening in the lower surface of the nipple tunnel directly into the milk container, or components that are attached to the milk container.
- System is configured so that its centre of gravity is no more than 60mm up from the base of the milk container also below the top of the user's bra cup.
- In which the pumping mechanism and the power supply for that mechanism are positioned within the housing to provide a sufficiently low centre of gravity.
- In which the pumping mechanism is one or more piezo air pumps, and the low weight of the piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.
- In which the pumping mechanism is one or more piezo air pumps, and the small size of the piezo air pumps enables the components in the housing to be arranged so that the centre of gravity is substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.
- In which the pumping mechanism is one or more piezo air pumps, and the low weight of the battery or batteries needed to power that piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of

the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.

- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 7 Elvie is wearable and has a Night Mode for convenience

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) an illuminated control panel;

(c) a control system that reduces or adjusts the level or colour of illumination of the control panel at night or when stipulated by the user.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Control system is implemented in hardware in the pump itself using a 'night mode' button.
- Control system is implemented in software within a connected device app running on the user's smartphone.
- Control system is linked to the illumination level on a connected device app., so that when the connected app is in 'night mode', the illuminated control panel is also in 'night mode', with a lower level of illumination, and when the illuminated control panel on the housing is in 'night mode', then the connected app is also in 'night mode'.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast. The pumping mechanism is one or more piezo air pumps, selected for quiet operation.

Feature 8 Elvie is wearable and includes a haptic or visual indicator showing when milk is flowing or not flowing well

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a milk container that is configured to be concealed within a bra and is hence not visible to the mother in normal use;

(c) a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

Optional:

- A haptic and/or visual indicator indicates if the pump is operating correctly to pump milk, based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase
- The visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.
- The haptic and/or visual indicator provides an indication of an estimation of the flow rate.
- The visual indicator provides a colour-coded indication of an estimation of the flow rate.
- The visual indicator provides an indication of how much of the container has been filled.
- The visual indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.
- The haptic indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.
- A sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect

light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

- Sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- A sub-system measures or infers the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.
- A haptic and/or visual indicator indicates if the amount of milk in the milk container has reached a preset quantity or level.
- A haptic and/or visual indicator indicates if there is too much movement of the breast pump system for viable operation.
- Milk container is attached to the lower part of the housing and forms the base of the breast pump system.
- Milk container is made of transparent material.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 9 **Elvie is wearable and collects data to enable the mother to understand what variables (e.g. time of day, pump speed etc.) correlate to good milk-flow**

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a measurement sub-system that measures or infers milk flow into the milk container;

and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- User-defined requirement is to enhance or increase milk-flow.
- User-defined requirement is to reduce milk-flow.
- The data analysis system analyses data such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system determines metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.
- The data analysis system determines metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.
- Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.
- measurement sub-system measures or infers the quantity and/or the height of the liquid in the container above its base.
- Measurement sub-system measures or infers angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.
- Data analysis system gives recommended metrics for improving milk flow
- Data analysis system gives recommended metrics for weaning.
- Data analysis system gives recommended metrics for increasing milk supply (e.g. power pumping).
- Data analysis system gives recommended metrics if an optimal session start time or a complete session has been missed.

- Data analysis system leads to automatic setting of metrics for the pumping mechanism, such as pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session.
- Data analysis system enables sharing across large numbers of connected devices or apps information that in turn optimizes the milk pumping or milk weaning efficacy of the breast pump.
- Metrics include the specific usage of the connected device by a woman while using the pump (for example by the detection of vision and/or audio cues).
- The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- The measurement sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the measurement sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 10 Elvie is wearable and collects data that can be exported to social media.

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a data sub-system that collects and provides data to a connected device or remote application or remote server;

(d) and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.
- The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.
- Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.
- The social media or community function or platform organizes the collected data into different profiles.
- The social media or community function or platform enables a user to select a matching profile from a set of potential profiles.
- each profile is associated with a specific kind of milk expression profile, and provides information or advice that is specifically relevant to each milk expression profile.
- Information or advice includes advice on how to increase milk expression by varying parameters, such as time of milk expression, frequency of a milk

expression session, pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session and any other parameter that can be varied by a mother to help her achieve her milk expression goals.

- The application is connected to other applications residing on the connected device, such as a fitness app.
- The collected data includes data received from other connected apps.
- The collected data is anonymised before it is shared.
- The sub-system includes a wi-fi connectivity component for direct connectivity to a remote server.
- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 11 Elvie is wearable and has a smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh

A breast pump system including a pumping mechanism and a milk container and including:

(a) a housing including the pumping mechanism;

(b) a milk container;

(c) and in which the milk container or any associated part, such as a lid, includes a memory or tag that is automatically programmed to store the time and/or date it was filled with milk.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Memory or tag is programmed to store the quantity of milk in the milk container.
- Memory or tag stores the milk expiry date.

- Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.
- System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.
- Clock is in the housing.
- Clock is in the milk container.
- Milk container includes a display that shows the time and/or date it was filled with milk.
- Milk container includes a display that shows the quantity of milk that it was last filled with milk.
- Milk container includes a display that shows whether the left or right breast was used to fill the milk container.
- Memory or tag is connected to a data communications sub-system.
- Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone, and have the time and/or date that container was filled with milk, displayed on the reader device.
- Reader device shows the time and/or date a specific milk container was filled with milk.
- Reader device shows the quantity of milk that a specific milk container was last filled with.
- Reader device shows the time and/or date and/or quantity that each of several different milk containers were filled with.
- Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.
- A sub-system measures or infers milk flow into the milk container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/Tr the height of the liquid in the container.
- The sub-system is in the housing.
- Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 12 A smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

A smart bottle or container that includes or is associated with a memory or a tag that is programmed to store the date and time it is filled using data from a pump or a connected device, such as a smartphone.

Optional:

- The container includes wireless connectivity and connects to a companion app.
- The memory or tag includes an NFC chip and is read using a NFC reader.
- The memory or tag stores also an expiry date.
- Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.
- The memory or tag stores also the quantity of milk stored.
- System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.
- Clock is in the housing.
- Clock is in the container.
- Milk container includes a display that shows the time and/or date it was filled with milk.
- Milk container includes a display that shows the quantity of milk that it was last filled with milk.

- Milk container includes a display that shows whether the left or right breast was used to fill the milk contained.
- Milk container includes a display that shows the expiry date.
- memory or tag is connected to a data communications sub-system.
- Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone.
- Reader device shows the time and/or date a specific milk container was filled with milk.
- Reader device shows the quantity of milk that a specific milk container was last filled with.
- Reader device shows the time and/or date and/or quantity that each of several different containers were filled with.
- Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.
- Reader device shows the expiry date.
- Container includes wireless connectivity and connects to a companion application.
- An application tracks status of one or more smart containers and enables a user to select an appropriate smart container for a feeding session.
- The pump is wearable.
- The pump is in a housing shaped to fit inside a bra and the container is a milk container that is connected to the housing and is positioned to form the base of the housing.
- Container is used for liquids other than milk.

Feature 13 Elvie is wearable and includes a sensor to infer the amount of movement or tilt angle during normal use.

A breast pump system including:

(a) a housing;

(b) a milk container;

(c) the housing including a sensor, such as an accelerometer, that measures or determines the movement and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by warning or alerting the mother of a potential imminent spillage (e.g. from milk flowing back out of a breast shield) using an audio, or visual or haptic alert, or a combination of audio, haptic and visual alerts.
- If the tilt angle of the housing exceeds a threshold, then the system automatically adjusts the operation of the system by stopping the pump to prevent spillage.
- When the tilt angle of the housing reduces below the threshold, the system automatically adjusts the operation of the system by causing pumping to resume automatically.
- If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by providing the mother with an alert to change position.
- The container includes an optically clear region.
- There are one or more light emitters and detectors positioned in the base of the housing, the light emitters and receivers operating as part of a sub-system that measures or infers the tilt angle of the milk in the container.
- The sub-system measures the quantity of liquid in the milk container and also takes the measured tilt angle of the housing into account.
- If the tilt angle is above a certain threshold, the system ignores the quantity of liquid measured.
- The sub-system derives or infers the mother's activity, such as walking, standing or lying activities, from the sensor.
- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

- Sub-system stores a time-stamped record of movement and/or tilt angles of the housing in association with milk flow data.
- System includes a breast shield that attaches to the housing.
- System includes a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 14 Elvie includes a control to toggle between recording whether milk is being expressed from the left breast and the right breast.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a control interface that the user can select to indicate or record if milk is being expressed from the left or the right breast.

Optional:

- Control interface is a physical interface on the housing.
- Control interface is a single button on the housing.
- Control interface is from an application running on a device, such as a smartphone or smart ring.
- Visual indicators on the housing indicate whether the breast pump system is being set up the left or the right breast.
- The visual indicator for the left breast is on the right-hand side of the housing, when viewed from the front; and the visual indicator for the right breast is on the left-hand side of the housing, when viewed from the front.
- The housing includes a button labeled to indicate the left breast and a button labeled to indicate the right breast, that are respectively illuminated to indicate from which breast the milk is being expressed.
- Breast pump system is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 15 Elvie includes a pressure sensor.

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) an air pressure sensor configured to measure the negative pressure delivered by the negative air-pressure mechanism and (iii) a measurement sub-system that measures or infers milk flow or milk volume.

Optional:

- The system also includes a control sub-system that combines or relates the air-pressure measurements with the milk flow or milk volume measurements
- The control sub-system automatically adjusts the negative air-pressure to give the optimal milk flow or milk volume.
- The control sub-system automatically adjusts the negative air-pressure during a pumping session to give the optimal milk flow or milk volume within comfort constraints defined by the user.
- The air pressure sensor detects pressure created by the pumping mechanism.
- Sensor is a piezo air pressure sensor
- Air pressure sensor measures the negative air pressure during a normal milk expression session.
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that it deliver consistent performance over time.
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that different pumping mechanisms in different breast pump systems all deliver consistent performance
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to determine if the pumping mechanism is working correctly, within tolerance levels.
- The operation of the pumping mechanism is varied by altering the duty or pump cycle.
- The operation of the pumping mechanism is varied by altering the voltage applied to the pumping mechanism.
- Pumping mechanism is a piezo air pump.

- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 16 Elvie includes a microcontroller to enable fine tuning between pre-set pressure profiles

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to cause the pumping mechanism to deliver various pre-set pressure profiles and to permit the user to manually vary the pressure to a value or values that are in-between the values available from a pre-set pressure profile.

Optional:

- The user manually varies the pressure using a control interface on a housing of the breast pump system
- The user manually varies the pressure using a control interface on an application running on a wireless device such as a smartphone that is wirelessly connected to the breast pump system.
- The user manually varies the pressure by altering a control parameter of the pumping mechanism.
- The user manually varies the pressure by altering the duty cycle or timing of the

pumping mechanism.

- The user manually varies the pressure by altering the voltage applied to the pumping mechanism.
- The system includes an air pressure sensor configured to measure the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Pressure profile defines one or more maximum negative air pressure levels.
- Pressure profile defines one or more maximum negative air pressure levels, each for a pre-set time.
- Pressure profile defines one or more cycle time.
- Pressure profile defines peak flow rate.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 17 Elvie enables a user to set the comfort level they are experiencing

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to control the pumping mechanism and to permit the user to manually indicate the level of comfort that they are experiencing when the system is in use.

Optional:

- The user manually indicates the level of comfort that they are experiencing using a touch or voice-based interface on a housing of the breast pump system
- The user manually indicate the level of comfort that they are experiencing using a touch or voice-based interface on an application running on a wireless device, such as a smartphone, that is wirelessly connected to the breast pump system.
- The system stores user-indicated comfort levels together with associated parameters of the pumping system.
- The system is a connected device and a remote server stores user-indicated comfort levels together with associated parameters of the pumping system.
- The parameters of the pumping system include one or more of: pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System automatically varies parameters of the pumping system and then enables the user to indicate which parameters are acceptable.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the

intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 18 Elvie includes a microcontroller to dynamically and automatically alter pump operational parameters

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to automatically change one or more parameters of the pumping mechanism, and to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

Optional:

- The milk expression data includes one or more of the following: milk expression rate or quantity; comfort; optimal pumping mode; optimal pumping mode given remaining battery power.
- The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters.
- The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters if the comfort experienced by the user when those parameters are used is above a threshold.
- The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user.
- The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user and enables the user to manually select those parameters if they are acceptable.
- Parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.

- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 19 Elvie automatically learns the optimal conditions for let-down

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to dynamically change one or more parameters of the pumping mechanism, and to automatically detect the start of milk let-down.

Optional:

- The microcontroller is programmed to dynamically change one or more parameters of the pumping mechanism, to enable it to learn or optimize the parameters relating to milk let-down.
- The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down.
- The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and uses that set of parameters if the comfort experienced by the user when those

parameters are used is above a threshold or are otherwise acceptable to the user.

- The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down to the user.
- The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and enables the user to manually select those parameters if they are acceptable.
- parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is wearable and has a piezo air-pump for quiet operation

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a separate, deformable diaphragm to generate negative air pressure.

Optional:

- The deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- Deformable diaphragm is removably mounted against a part of a breast shield.
- Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.
- Deformable diaphragm is not physically connected to the piezo air-pump.
- Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield
- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 25gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise. The piezo pump is fed by air that passes through an air filter.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 21 Elvie has a piezo air-pump and self-sealing diaphragm

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a physically separate, deformable, self-sealing diaphragm, to generate negative air pressure.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement .
- The closed system is separated from a 'milk' side by the flexible diaphragm.
- Deformable diaphragm is removably mounted against a part of a breast shield.
- Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.
- Deformable diaphragm is not physically connected to the piezo air-pump.
- Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield.
- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the

diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- The piezo pump is fed by air that passes through an air filter.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 22 Elvie uses more than one piezo air pump in series

A breast pump system including:

(a) a housing;

(b) multiple piezo air-pumps in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure; in which the multiple piezo air-pumps can be operated at different times in series-connected and in parallel-connected modes.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Parallel connected mode is used during a first part of a pumping cycle to reach a defined negative air pressure more quickly than series connected mode would, and then the system switches to a series connected mode to reach a greater negative air pressure than series connected mode can reach.
- An actuator switches the system from parallel-connected piezo pump mode to series-connected piezo pump mode.

- Each piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- Each piezo air pump weighs less than 10 gm, and may weigh less than 6gm..
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- Each piezo pump is fed by air that passes through an air filter.
- Each piezo air pump forms part of a closed or closed loop system.
- Each piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- The piezo-air pumps are a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

Feature 23 Elvie is wearable and has a piezo air-pump, a breast shield and a diaphragm that fits directly onto the breast shield

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a breast shield that attaches to the housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm that fits directly onto the breast shield.

Optional:

- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Deformable diaphragm is removable from the diaphragm housing for cleaning.

- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- Piezo air pump is position at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum. power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.The piezo pump is fed by air that passes through an air filter.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Feature 24 Elvie is wearable and has a piezo air-pump for quiet operation and a re-useable, rigid milk container for convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing;

(c) and a re-useable, rigid or non-collapsible milk container that when connected to the housing forms an integral part of the housing and that is also removable from the housing.

Optional:

- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The closed system is separated from a 'milk' side by a flexible diaphragm.

- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- The deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.

Feature 25 Elvie has a piezo-pump for quiet operation and is a connected device

A breast pump system including

(a) a housing;

(b) a piezo air-pump in the housing;

(c) a milk container;

(d) a data connectivity module that enables data collection relating to the operation of the piezo air-pump and transmission of that data to a data analysis system.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Transmission is to an application running on a connected device such as a smartphone, or a server, or the cloud.
- The data collection and transmission relates to any other operational data of the system.
- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- A sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with the data connectivity module.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level,

peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.

- The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.

Feature 26 Elvie uses a piezo in combination with a heat sink that manages the heat produced by the pump.

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure;

(c) a heat sink to manage the heat produced by the piezo-air pump to ensure it can be worn comfortably.

Optional:

- The heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48°C and preferably no more than 43°C.
- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Heat sink is connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere.
- Heat sink warms a breast shield.
- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.

- There are two or more piezo air pumps, each connected to its own or a shared heat sink.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- The deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 25g.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

Feature 27 Elvie is wearable and gently massages a mother's breast using small bladders inflated by air from its negative pressure air-pump

A breast pump system including:

(a) a housing;

(b) an air-pump in the housing that drives a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides air to regularly or sequentially inflate one or more air bladders or liners that are configured to massage one or more parts of the breast.

Optional:

- Air-pump is a piezo pump.
- Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- Bladders or liners are formed in a breast shield that attaches to the housing.

Feature 28 Elvie is wearable and gently warms a mother's breast using small chambers inflated by warm air from its negative pressure air-pump

A breast pump system including:

(a) a housing;

(b) an air-pump, such as a piezo pump, in the housing that drive a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides warm air to regularly or sequentially inflate one or more air chambers that are configured to apply warmth to one or more parts of the breast.

Optional:

- Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- The air chamber is a deformable diaphragm positioned on a breast shield that attaches to the housing.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is wearable and includes a re-useable, rigid milk container that forms the lower part of the pump, to fit inside a bra comfortably

A wearable breast pump system configured including:

(a) a housing shaped at least in part with a curved surface to fit inside a bra and including a pumping mechanism;

(b) and a re-useable rigid or non-collapsible milk container that when connected to the housing forms an integral, lower part of the housing, with a surface shaped to continue the curved shape of the housing, so that the pump system can be held comfortably inside the bra.

Optional:

- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is attached to the housing with a push action.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture, spout or lid that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a

breast shield, and milk flows under gravity through the opening into the milk container.

- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump mechanism to ensure that negative air-pressure is not applied to the milk container.
- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 30 Elvie is wearable and includes a milk container that latches to the housing with a simple push to latch action

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that is attachable to the housing with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

Optional:

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Milk container, when connected to the housing, forms an integral, lower part of the housing and that is removable from the housing with a release mechanism that can be operated with one hand.

- Mechanism that releasably attaches or latches is a mechanical or magnetic mechanism.
- Mechanical mechanism includes flanges on the top of the milk container, or the sealing plate that seals the opening to the milk contained, that engage with and move past a surface to occupy a latched position over that surface when the milk container is pressed against the housing to lock into the housing.
- The housing includes a button that when pressed releases the milk container from the housing by flexing the surface away from the flanges so that the flanges no longer engage with and latch against the surface.
- Mechanism that attaches or latches the milk container into position does so with an audible click.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing by releasing the latch and moving the housing off the milk container.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.

- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 31 Elvie is wearable and includes a removable milk container with an integral milk pouring spout for convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a re-useable milk container that is connected to the housing with a surface shaped to continue the curved or breast-like shape of the pump, so that the pump can be held comfortably inside a bra and where the milk container includes a pouring spout for pouring milk.

Optional:

- Spout is integral to the milk container.
- Spout is integral to a removable lid to the milk container.
- Spout is positioned at or close to the front edge of the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.

- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 32 Elvie is wearable and includes a removable milk container below the milk flow path defined by a breast shield for fast and reliable milk collection

A wearable breast pump system including:

(a) a housing including a pumping mechanism, the housing being shaped at least in part to fit inside a bra;

(b) and a breast shield including a nipple tunnel shaped to receive a nipple, and including an opening that defines the start of a milk flow path;

(c) a re-useable milk container that when connected to the housing is positioned entirely below the opening or the milk flow path, when the breast pump is positioned or oriented for normal use.

Optional:

- The milk container includes an aperture that sits directly underneath the opening in the nipple tunnel in the breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- Milk flows from the opening directly into the milk container.
- Milk flows from the opening directly into the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against the opening in the breast shield, and milk flows under gravity through the opening into the milk container.
- Milk flows from the opening directly onto a valve that is attached to the milk container, the valve closing whilst there is sufficient negative air pressure in the volume of air between the valve and the breast shield opening, and then opening to release the milk into the container when the air pressure rises sufficiently.
- Milk flows from the opening directly onto a valve that is attached to a spout, that is in turn attached to the milk container.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the milk container cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container, and milk flows towards and is retained by the duck bill valve whilst the valve is closed, and flows past the valve into the milk container when the negative air pressure is released and the valve opens.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 33 Elvie is wearable and includes a breast shield and removable milk container of optically clear, dishwasher safe plastic for ease of use and cleaning

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) and a breast shield defining a region shaped to receive a nipple, the region defining the start of a milk flow path;

(c) a re-useable, rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the breast shield and the milk container are made substantially of an optically clear, dishwasher safe material.

Optional:

- The material is a polycarbonate material, such as Tritan™.

- breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield operates with a flexible diaphragm that flexes when negative air pressure is applied to it by an air pump system in the housing, and transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 34 Elvie is wearable and includes various components that self-seal under negative air pressure, for convenience of assembly and disassembly

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including an air pumping mechanism;

(b) a breast shield;

(c) a diaphragm that flexes in response to changes in air pressure caused by the air pumping mechanism and that seals to the breast shield;

(d) a re-useable milk container that seals to the breast shield;

and in which either or both of the diaphragm and the re-useable milk container substantially self-seal under the negative air pressure provided by the pumping mechanism.

Optional:

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a

breast shield, and milk flows under gravity through the opening into the milk container.

- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.
- The 1 way valve is attached to the milk container, or a lid or spout of the milk container with an interference fit and is readily removed in normal use for separate cleaning.
- The diaphragm partly or wholly self-seals to the breast shield under the negative air pressure provided by the pumping mechanism.
- The diaphragm partly or wholly self-seals to the housing under the negative air pressure provided by the pumping mechanism.
- The diaphragm is attached to the diaphragm housing using elastomeric or rubber latches and is readily removed in normal use for separate cleaning.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.

- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 35 Elvie is wearable and includes a spout at the front edge of the milk container for easy pouring

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that forms an integral part of the housing;

(c) a re-useable pouring spout that is positioned at or close to the front edge of the milk container.

Optional:

- Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigeratable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.
- Spout is integral to a removable lid to the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- By placing the spout at or close to the front edge of the milk container, the milk container fully empties more readily than where the spout is placed in the middle of the lid of a milk container.
- The spout sits generally under an opening in the breast shield spout or nipple tunnel through which expressed milk flows.
- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Feature 36 Elvie is wearable and includes a milk container that is shaped with broad shoulders and that can be adapted as a drinking bottle that baby can easily hold

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a milk container that is removable from the housing and is shaped or configured to also serve as a drinking bottle that is readily held by a baby because it is wider than it is tall.

Optional:

- Teat is attachable directly to the milk container.
- Pouring or drinking spout is integral to the milk container.
- The shoulders are at least 2cm in width, and the neck is no more than 1 cm in height, to enable a baby to readily grip and hold the container when feeding from the milk in the container.
- Spout/teat/straw resides near the edge of the container's rim.
- Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigertable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.
- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals

against the conduit under the negative air pressure provided by the pumping mechanism.

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Spout is integral to the milk container.
- Spout is integral to a removable lid to the milk container.
- Spout is positioned at or close to the front edge of the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the quantity of milk in the container for fast and reliable feedback

A system for milk volume determination, for use as part of a breast pump, or breast milk collecting device, including:

(a) a re-useable rigid or non-collapsible milk container;
(b) at least one light emitter, configured to direct radiation towards the surface of the milk;
(c) at least one light detector, configured to detect reflected radiation from the surface of the milk;

wherein the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container.

Optional:

The wearable breast pump system includes:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield;

(c) a re-useable rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the top of the container includes an optically clear region that is aligned below one or more light emitters positioned in the base of the housing.

- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

- The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.
- Where the quantity or level exceeds a threshold, then the pumping mechanism automatically changes mode, e.g. from a stimulation mode to an expression mode.
- Where the quantity or level exceeds a threshold, then the pumping mechanism automatically stops.
- Milk-flow data is captured and stored.
- If milk-flow falls below a threshold, then a notification is provided to the mother.

Feature 38 The separate IR puck for liquid quantity measurement

A liquid-level measuring system for measuring the quantity of liquid in a container for a breast pump; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to detect light from the light emitters that has been reflected from the liquid;

(c) a sub-system that infers, measures or calculates the quantity in the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

- The quantity of milk is measured as milk enters the container or as milk is removed from the container.
- Measured property includes the reflected light intensity

Feature 39 The separate IR puck combined with liquid tilt angle measurement

A liquid-level measuring system for measuring the tilt angle of liquid in a container; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to measure properties of the light reflected from the liquid;

(c) a sub-system including an accelerometer that infers, measures or calculates the tilt angle of the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

- Measured property includes the reflected light intensity
- The quantity of liquid is measured as liquid enters the container or as liquid is removed from the container.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.

Generally applicable optional features

- Weight of the entire unit, unfilled, is under 250g and preferably 214g.
- Silver based bactericide is used on all parts that are not steam or heat sterilized in normal cleaning.
- Housing includes a rechargeable battery.
- System is self-contained.
- System is a closed loop system.
- Breast pump system is a self-contained, wearable device that includes an integral rechargeable battery, control electronics, and one or more air pumps operating as a closed system, driving a flexible diaphragm that in turn delivers negative air-pressure to the breast, to cause milk to be expressed.
- Housing has a generally rounded or convex front surface and has a generally tear-drop shape when seen from the front.

E. Bra Clip Feature Cluster

Feature 40 Bra Adjuster

A bra adjuster for a nursing or maternity bra, the nursing or maternity bra including a bra cup with a flap that can be undone to expose the nipple, and the flap attaching to the shoulder strap using a clasp, hook or other fastener attached to the flap, and a corresponding fastener attached to the shoulder strap;

and in which the bra adjuster is attachable at one end to the fastener attached to the flap, and at its other end to the fastener attached to the shoulder strap, and hence increases the effective bra cup size sufficiently to accommodate a wearable breast pump, and is also detachable from the flap and shoulder strap.

Optional:

- Bra adjuster is retained in position on the bra during normal wearing of the bra, even when the flap is attached directly to the shoulder strap, and is used to increases the effective bra cup size only when the wearable breast pump is used.
- Bra adjuster is extensible or elastic.
- Bra adjuster is of a fixed length.
- Bra adjuster includes a clip that the user can slide onto the bra strap to secure the bra adjuster in position.
- Bra adjuster is machine-washing washable.

F. Other Features that can sit outside the breast pump context

Feature 41 Wearable device using more than one piezo pump connected in series or in parallel

A wearable device including multiple piezo pumps mounted together either in series or in parallel.

Optional:

- The wearable device is a medical wearable device.
- The piezo pumps air or any liquid etc.
- The system can switch between a parallel mode and a series mode to arrive to lower or higher pressure quicker.

Feature 42 Wearable medical device using a piezo pump and a heat sink attached together.

A wearable medical device including a piezo pump and a heat sink attached together.

Optional

- The wearable device uses more than one piezo pump connected in series.
- The wearable device uses more than one piezo pump connected in parallel.
- Each piezo pump is connected to its own heat sink, or to a common heat sink.
- The or each heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48°C and preferably no more than 43°C
- The wearable device includes a thermal cut out.
- Excess heat is diverted to a specific location on the device that is selected to not be in prolonged contact with the skin of the user, in normal use.
- Use cases application:
    - Wound therapy
    - High degree burns
    - Sleep apnea
    - Deep vein thrombosis
    - Sports injury.
- Wearable medical device is powered/charged via USB.

Note

It is to be understood that the above-referenced arrangements are only illustrative of the application for the principles of the present invention. Numerous modifications and alternative arrangements can be devised without departing from the spirit and scope of

the present invention. While the present invention has been shown in the drawings and fully described above with particularity and detail in connection with what is presently deemed to be the most practical and preferred example(s) of the invention, it will be apparent to those of ordinary skill in the art that numerous modifications can be made without departing from the principles and concepts of the invention as set forth herein.

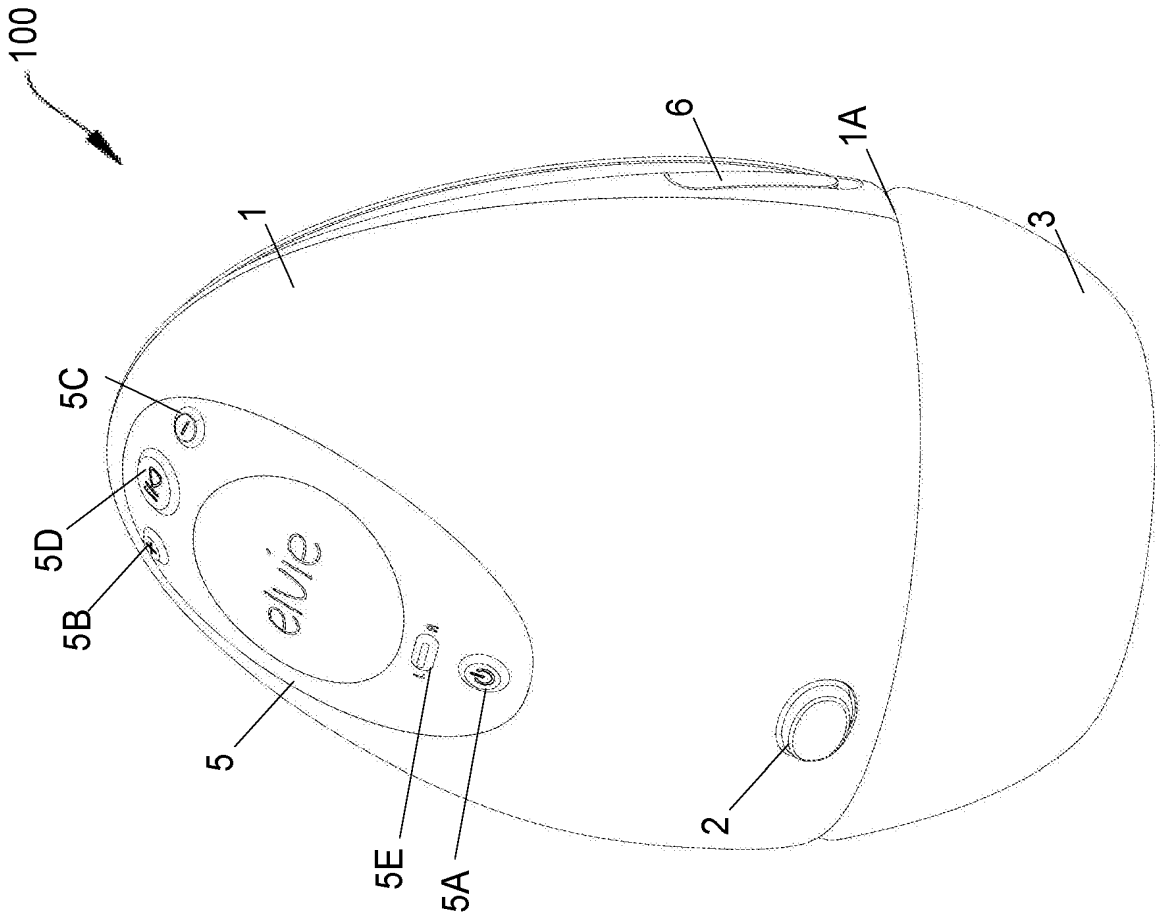


FIGURE 1

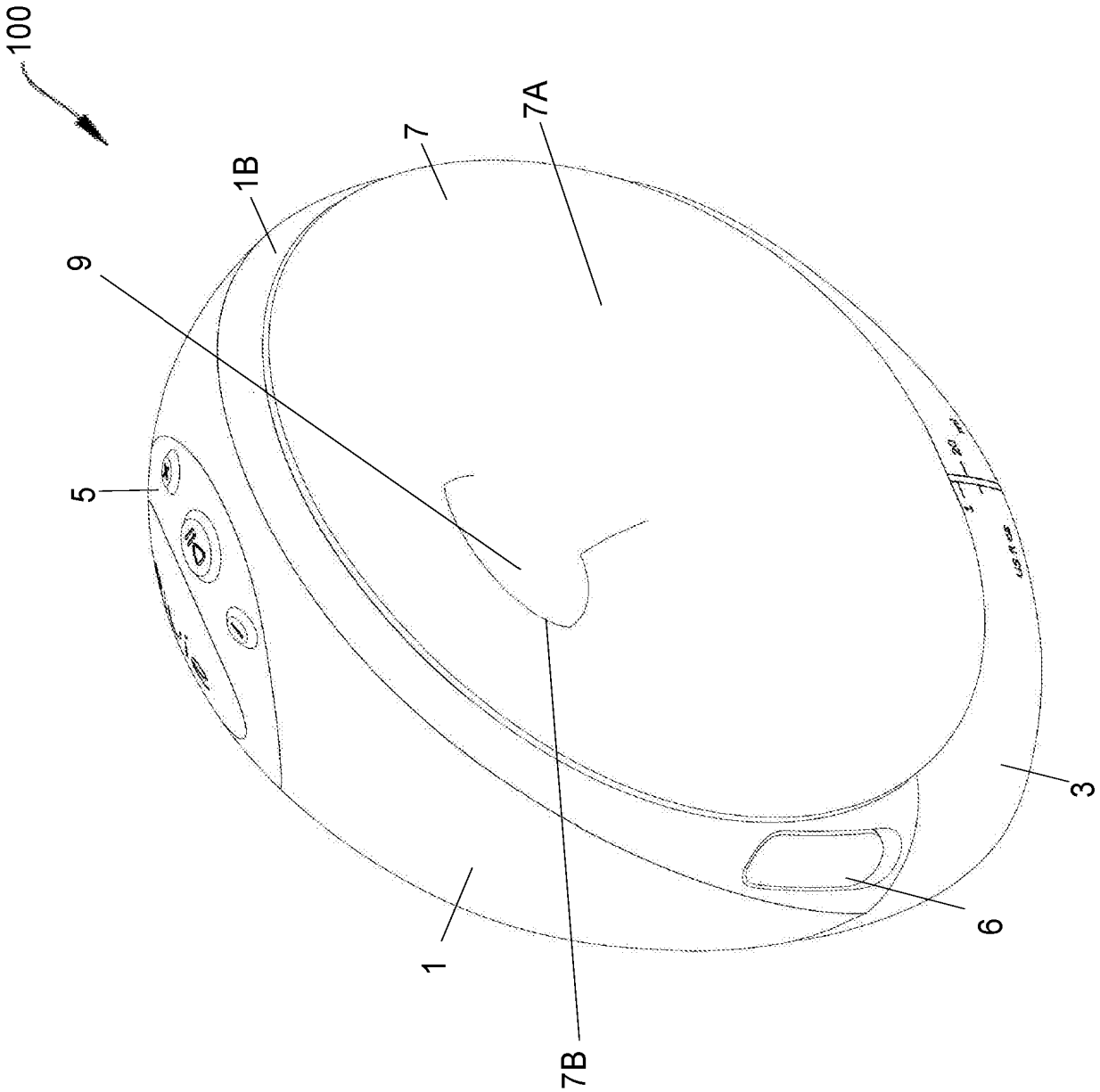


FIGURE 2

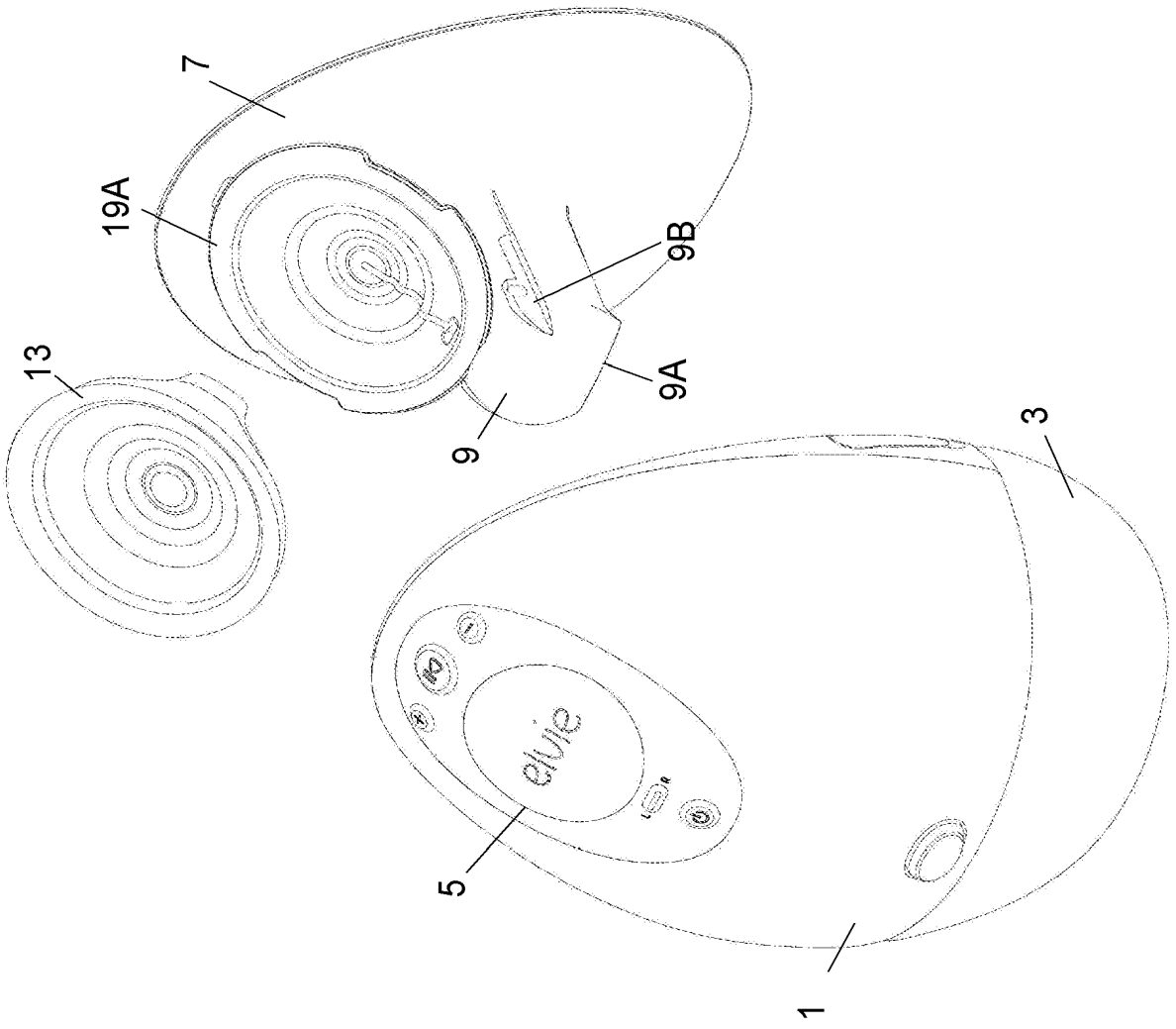


FIGURE 3

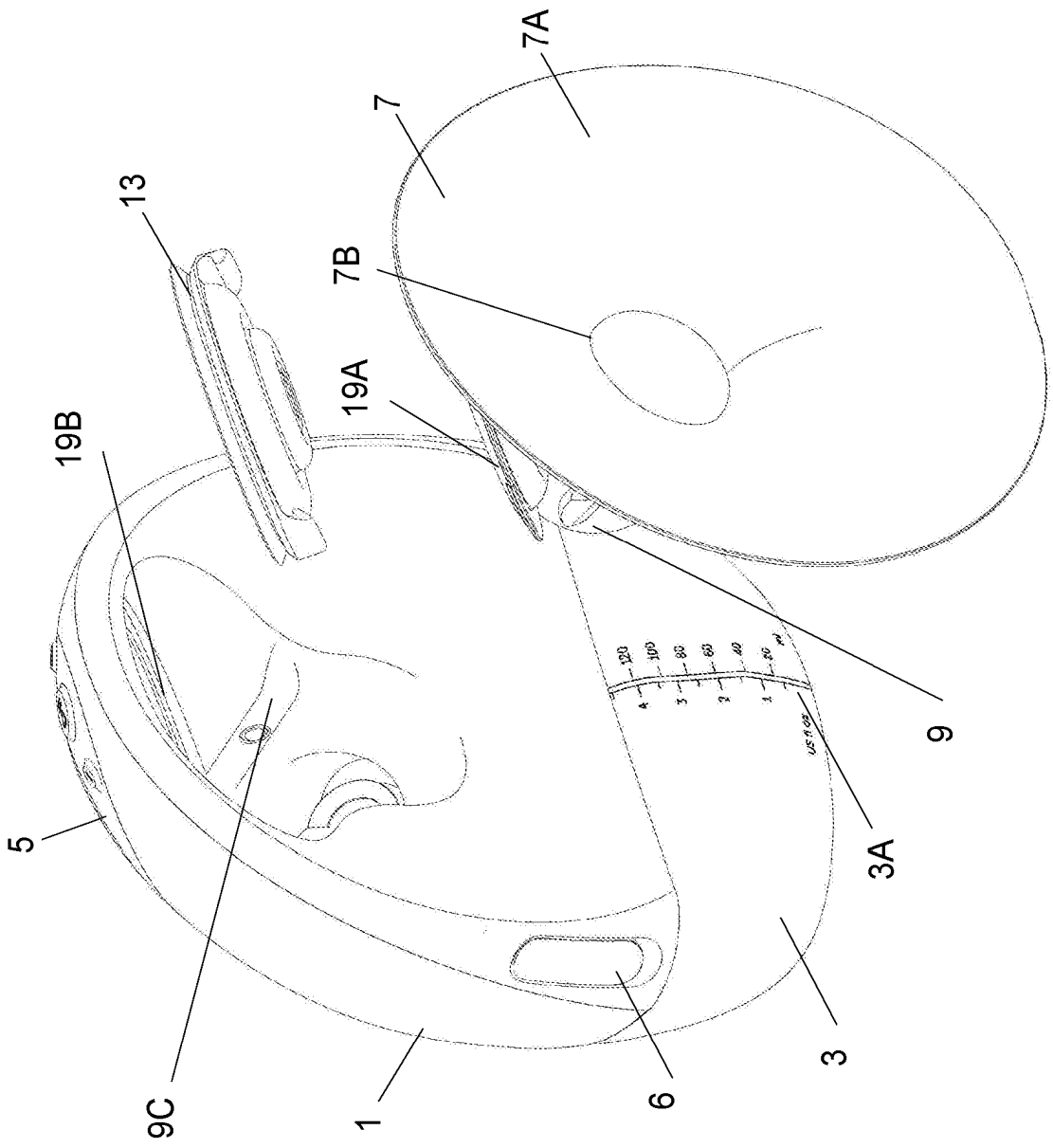


FIGURE 4

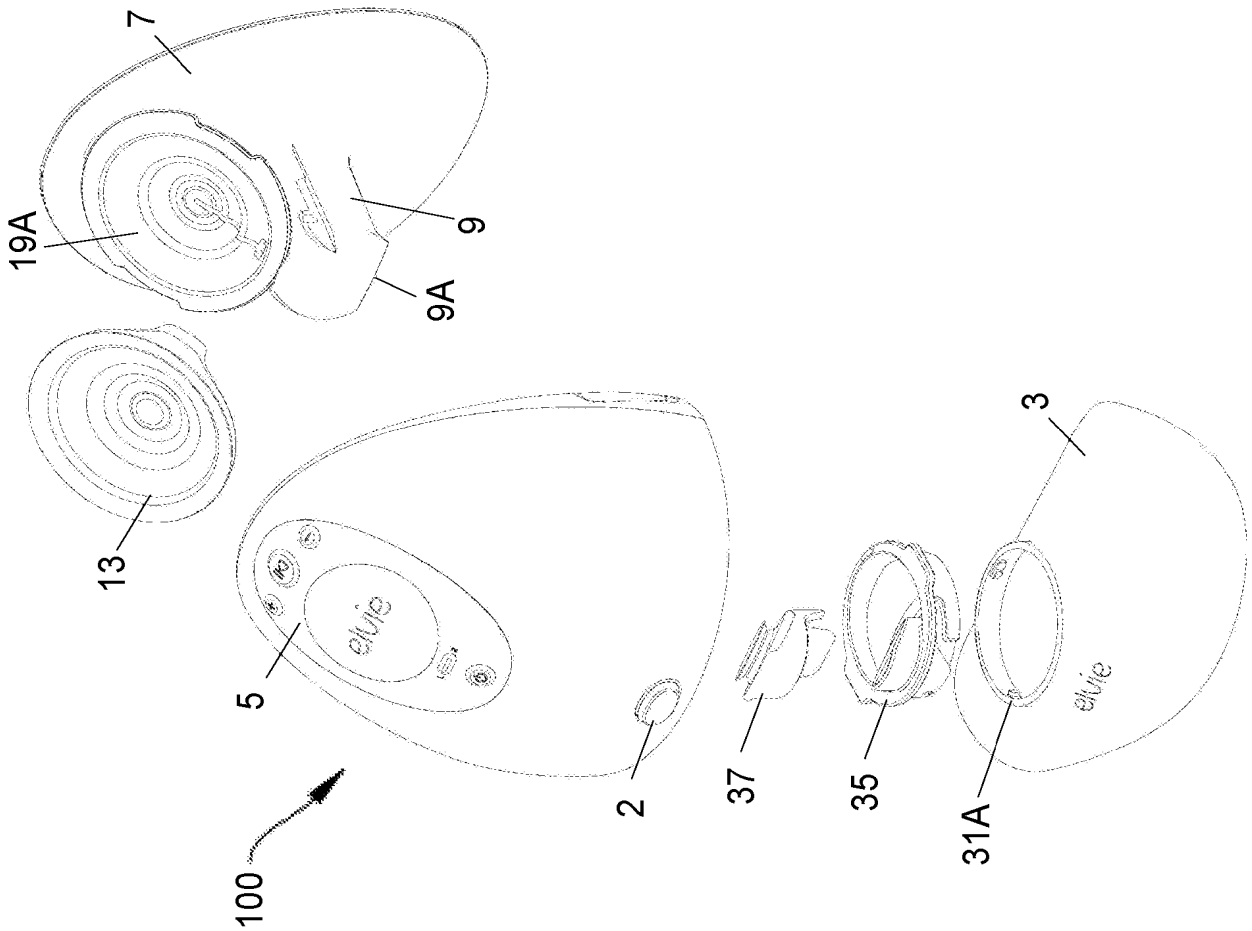


FIGURE 5

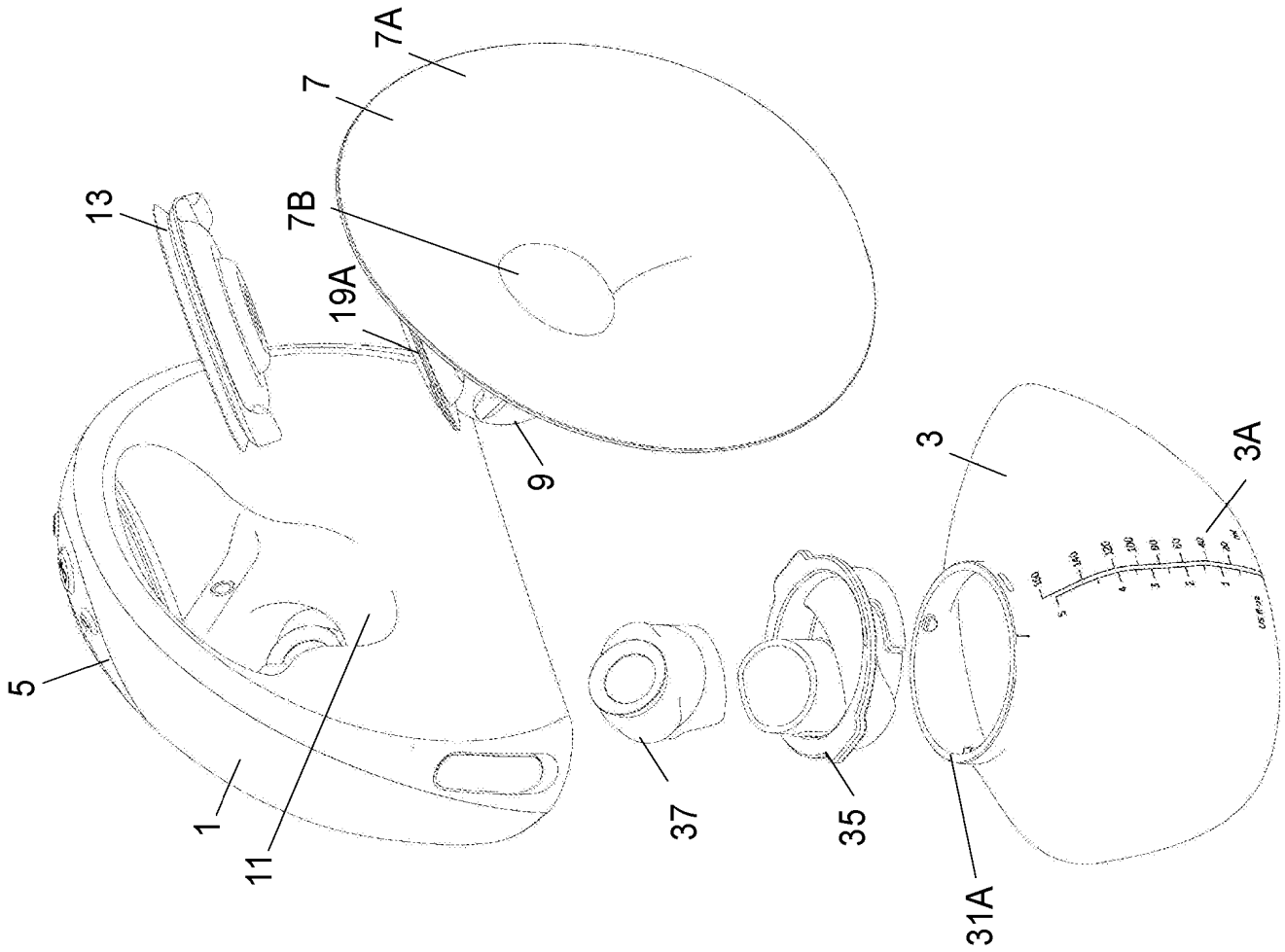


FIGURE 6

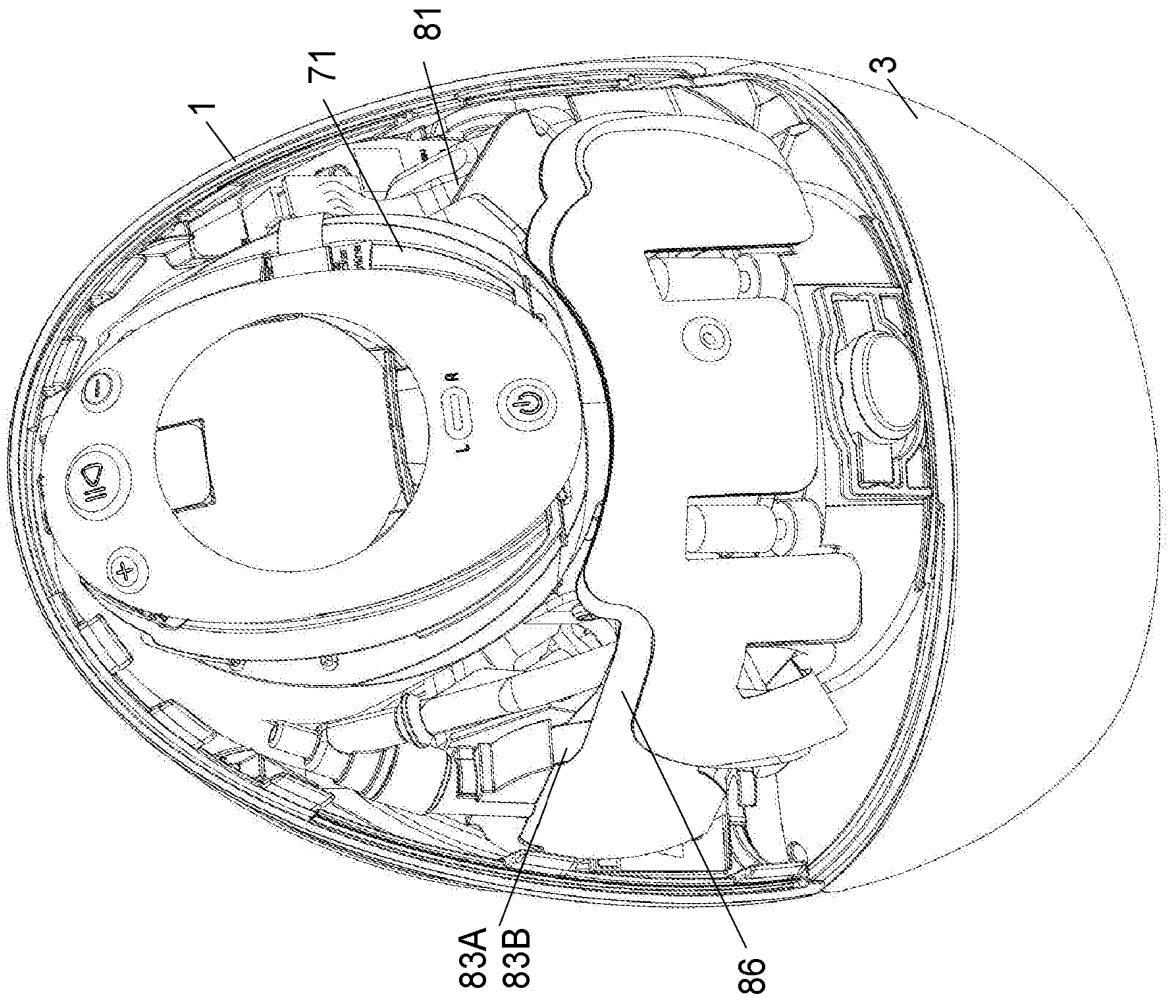


FIGURE 7

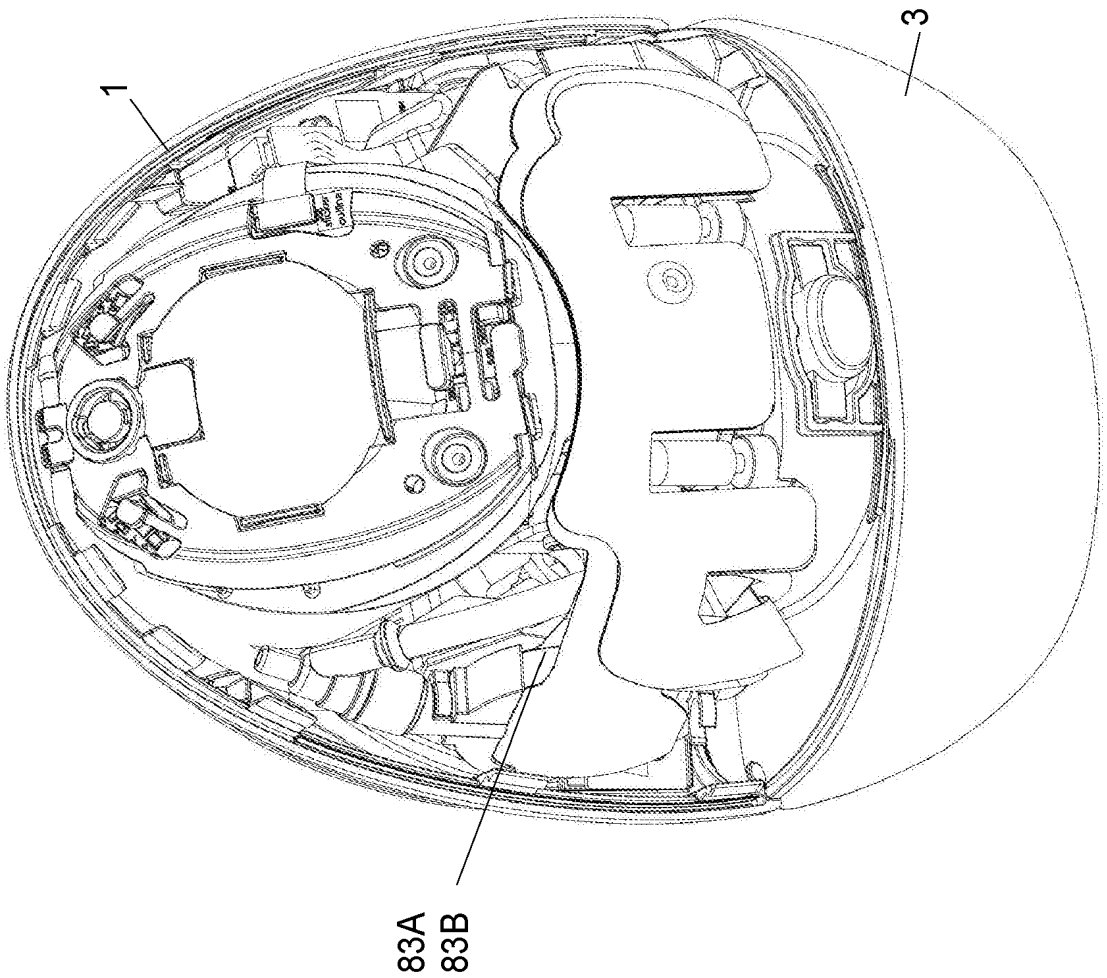


FIGURE 8

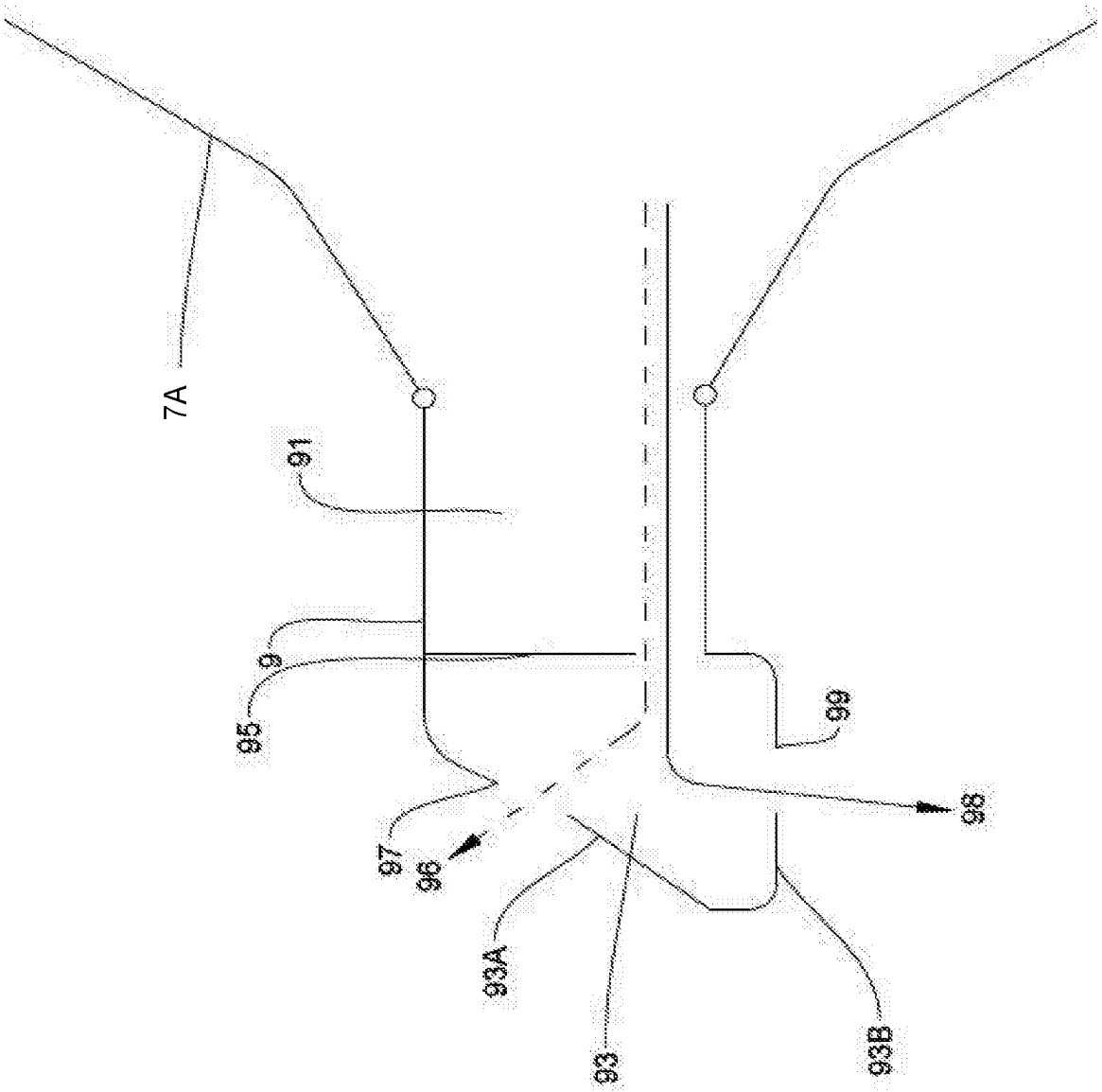


FIGURE 9

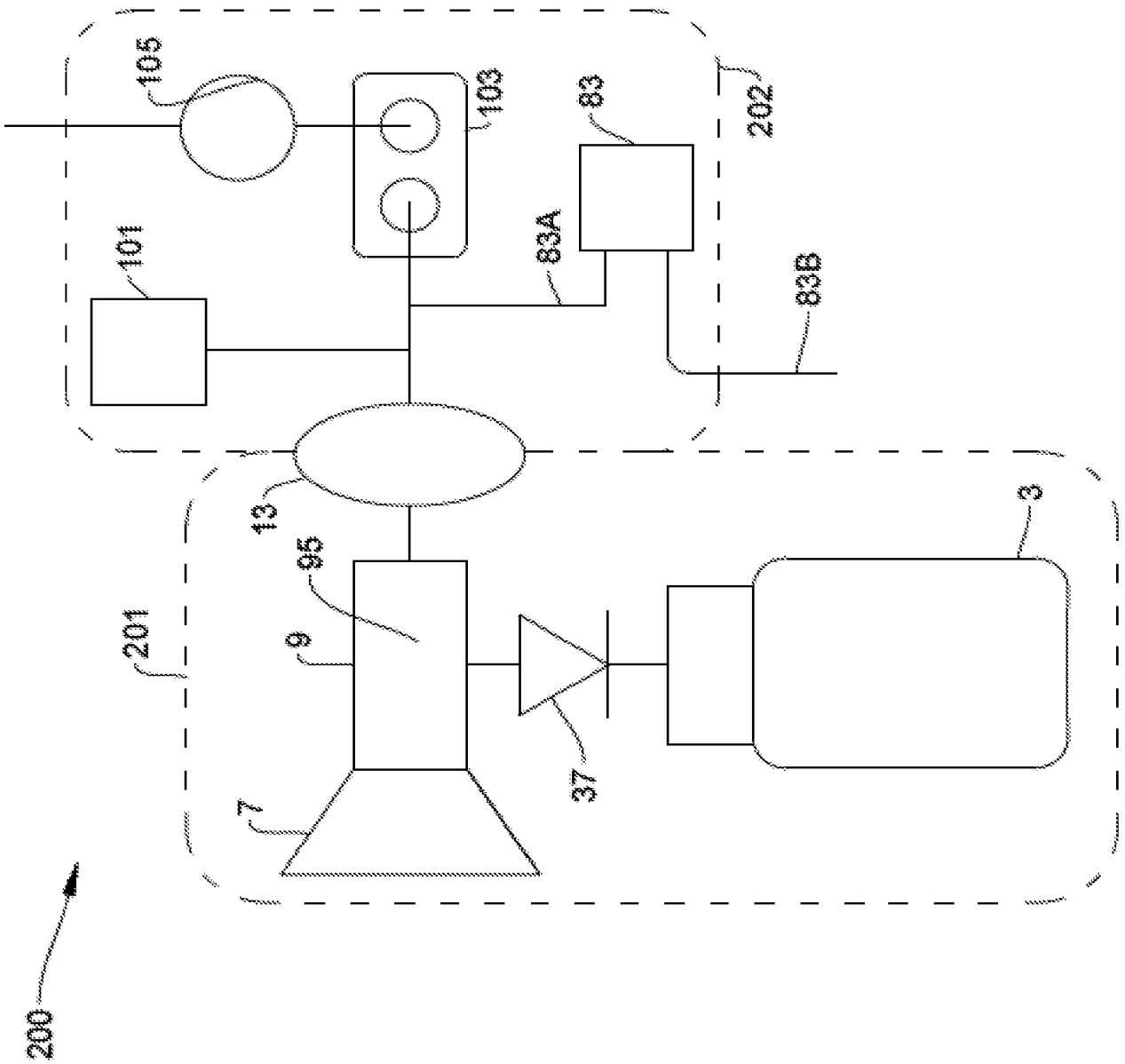


FIGURE 10

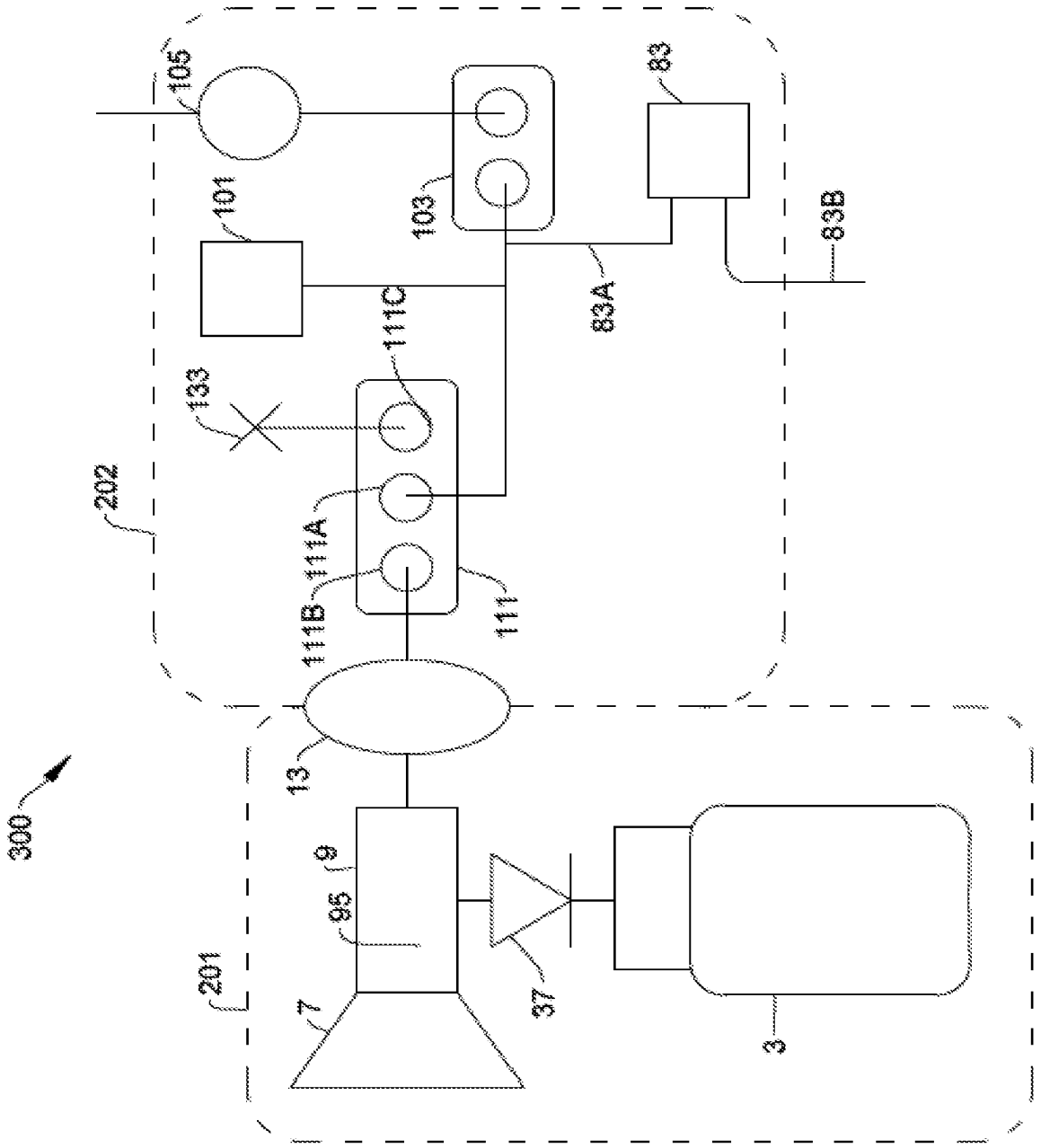

300
105
101
103
83
83B
83A
111C
133
202
111A
111B
111
13
9
95
201
7
37
3

FIGURE 11

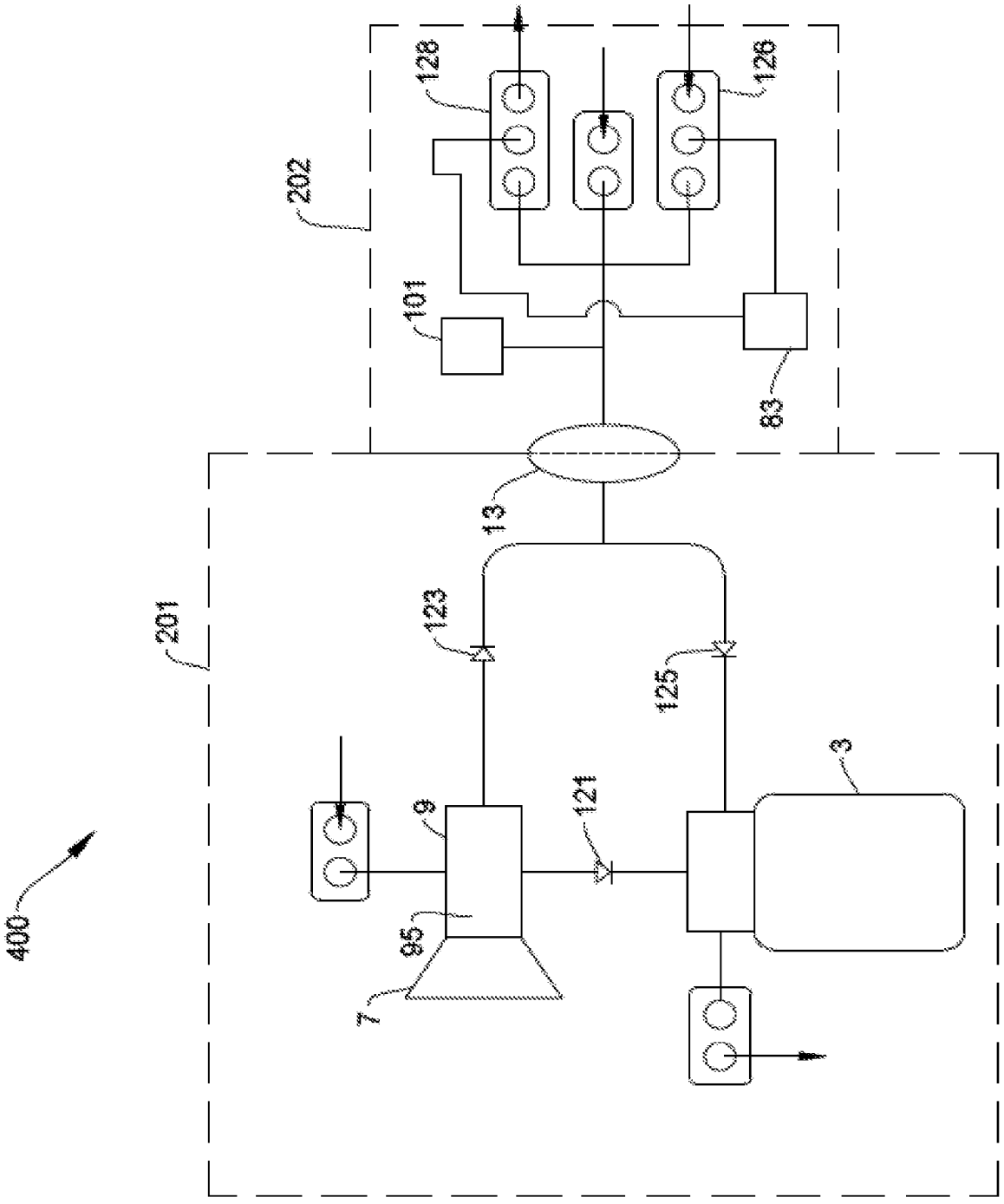


FIGURE 12

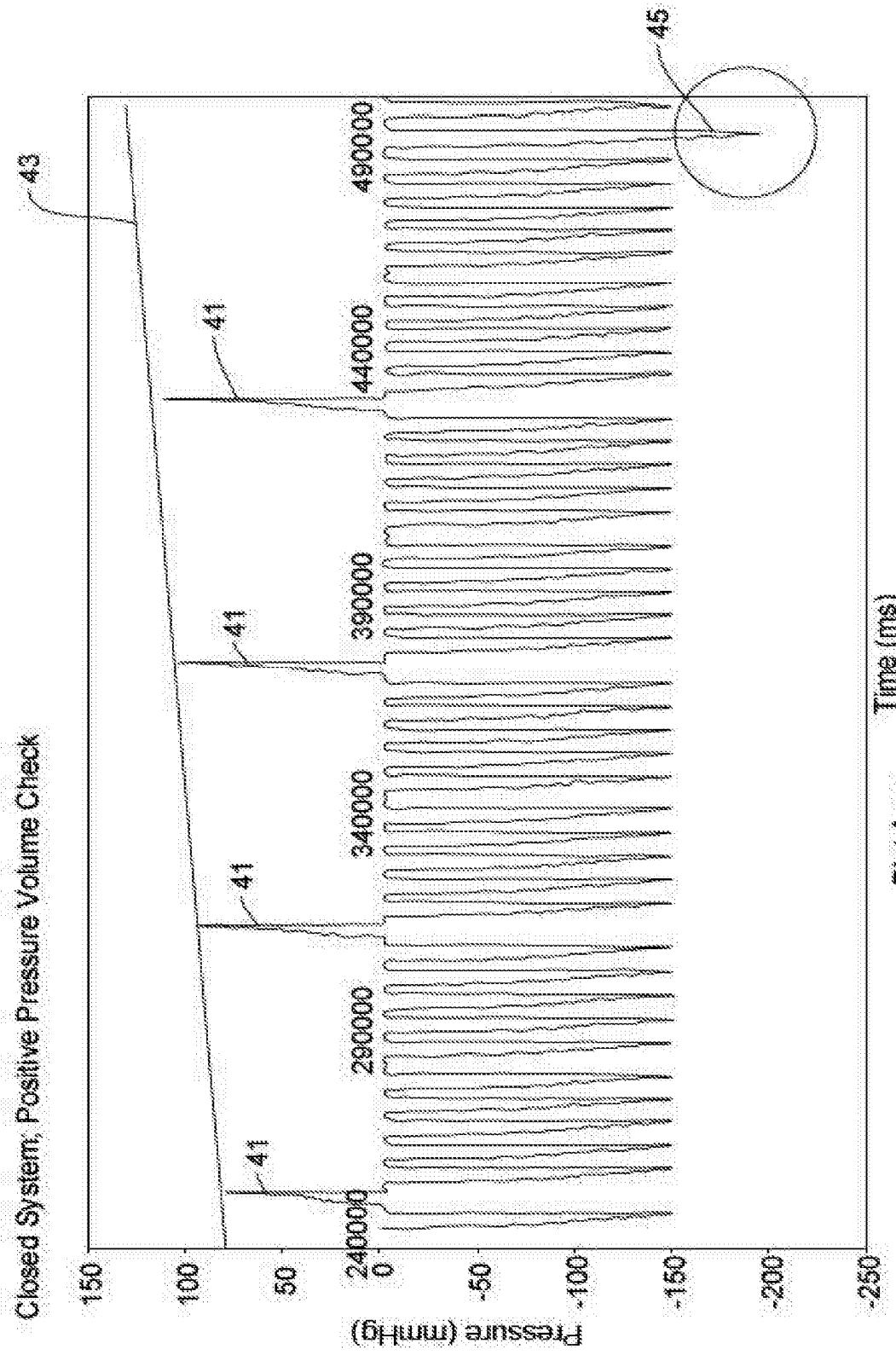

Closed System; Positive Pressure Volume Check
43
41
41
41
41
45
240000
290000
340000
390000
440000
490000
150
100
50
0
-50
-100
-150
-200
-250
Pressure (mmHg)
Time (ms)
Plot Area

FIGURE 13

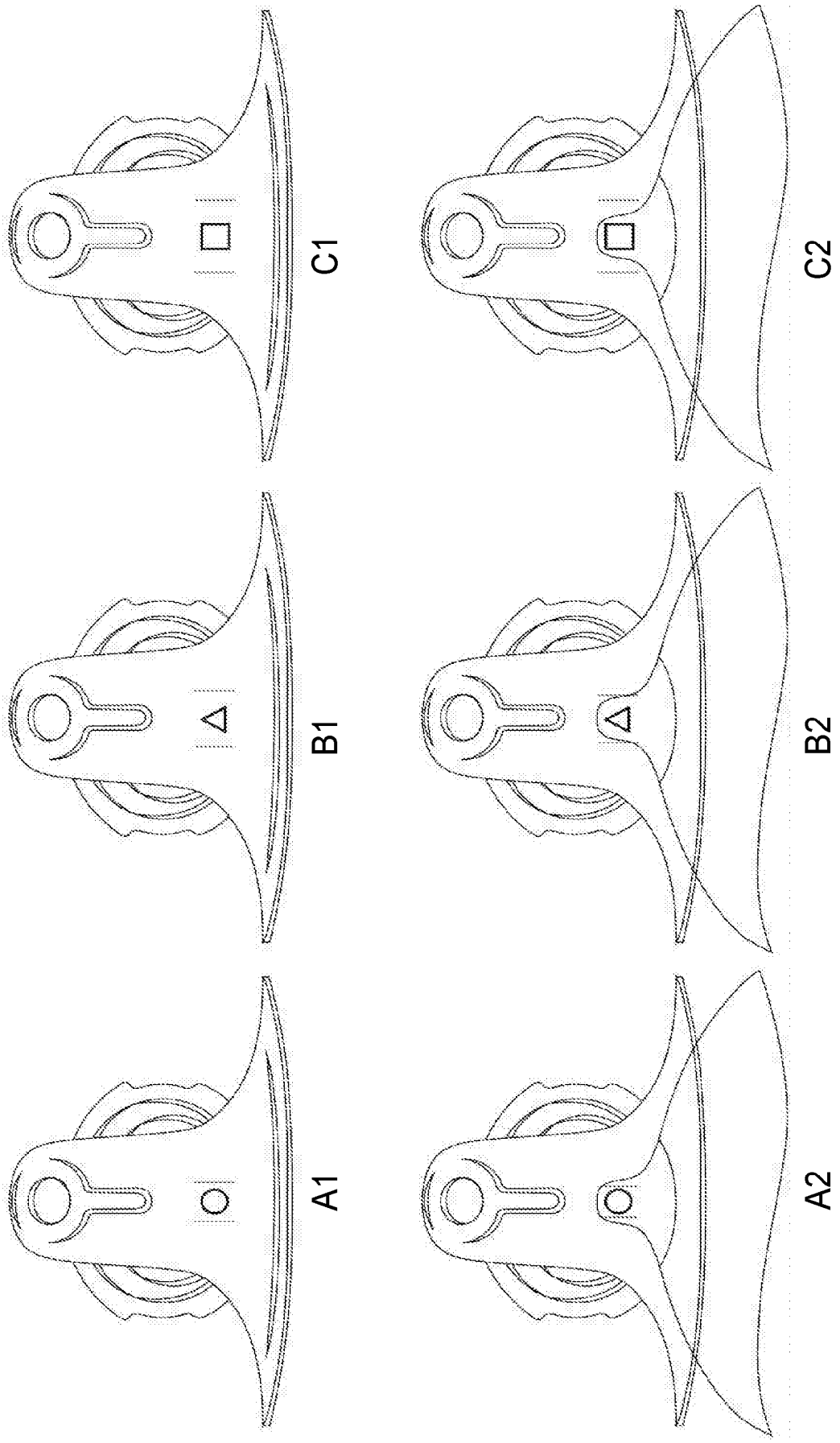


FIGURE 14

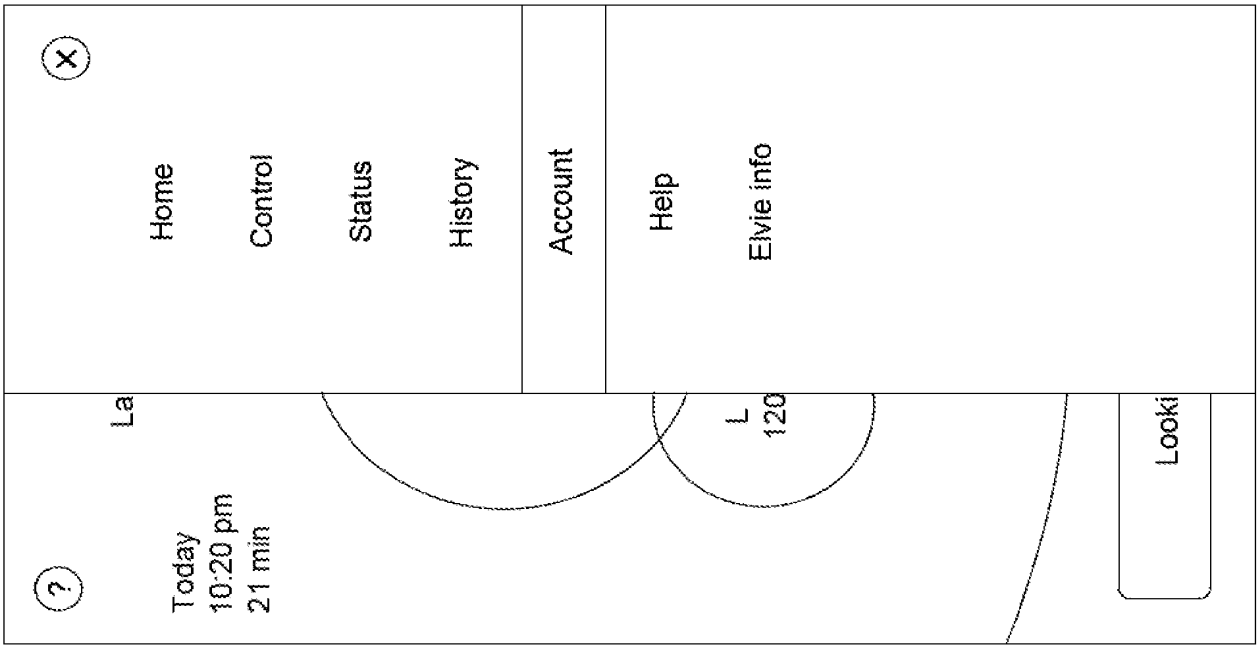

Home
Control
Status
History
Account
Help
Elvie info
Today
10:20 pm
21 min
Looki

FIGURE 15

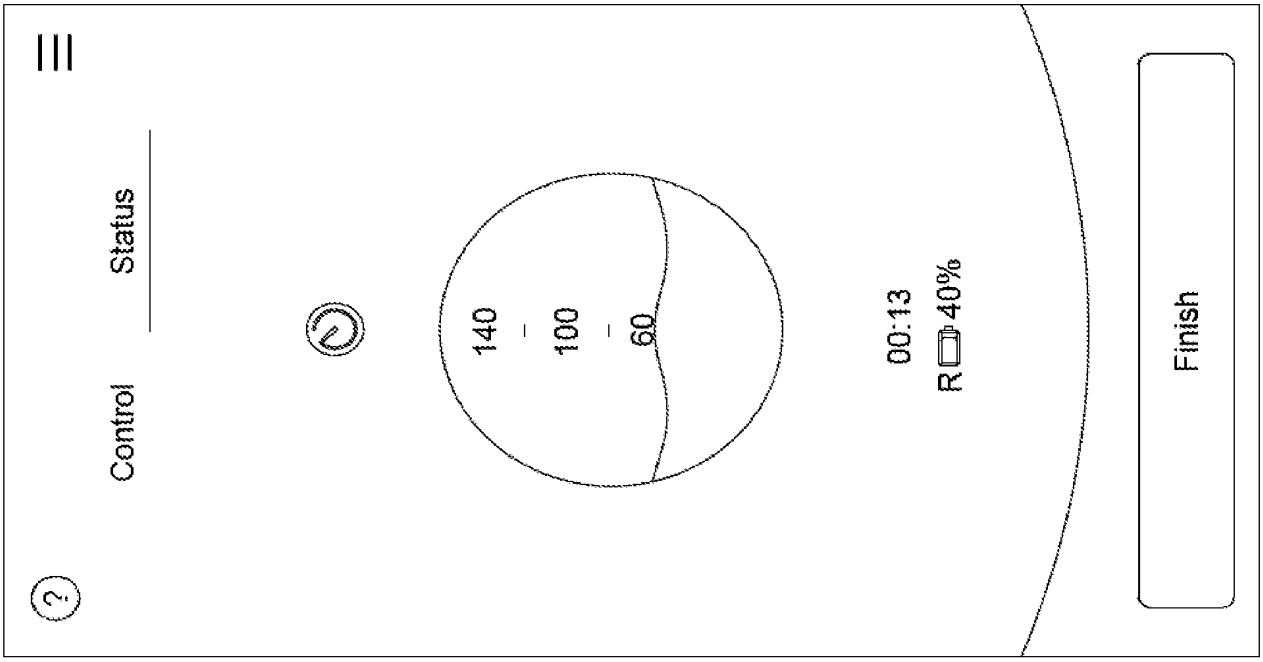
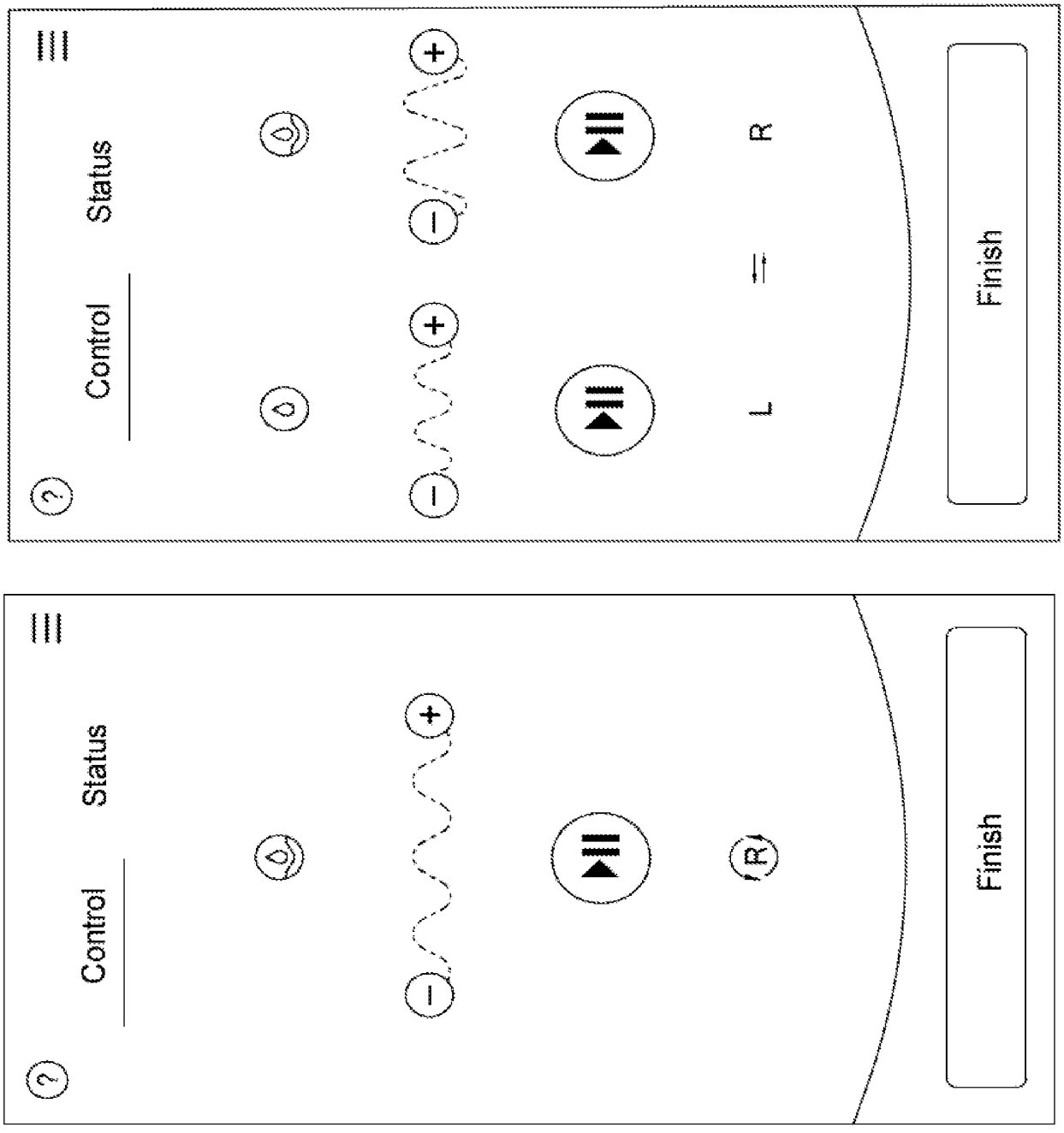


FIGURE 16



A B

FIGURE 17

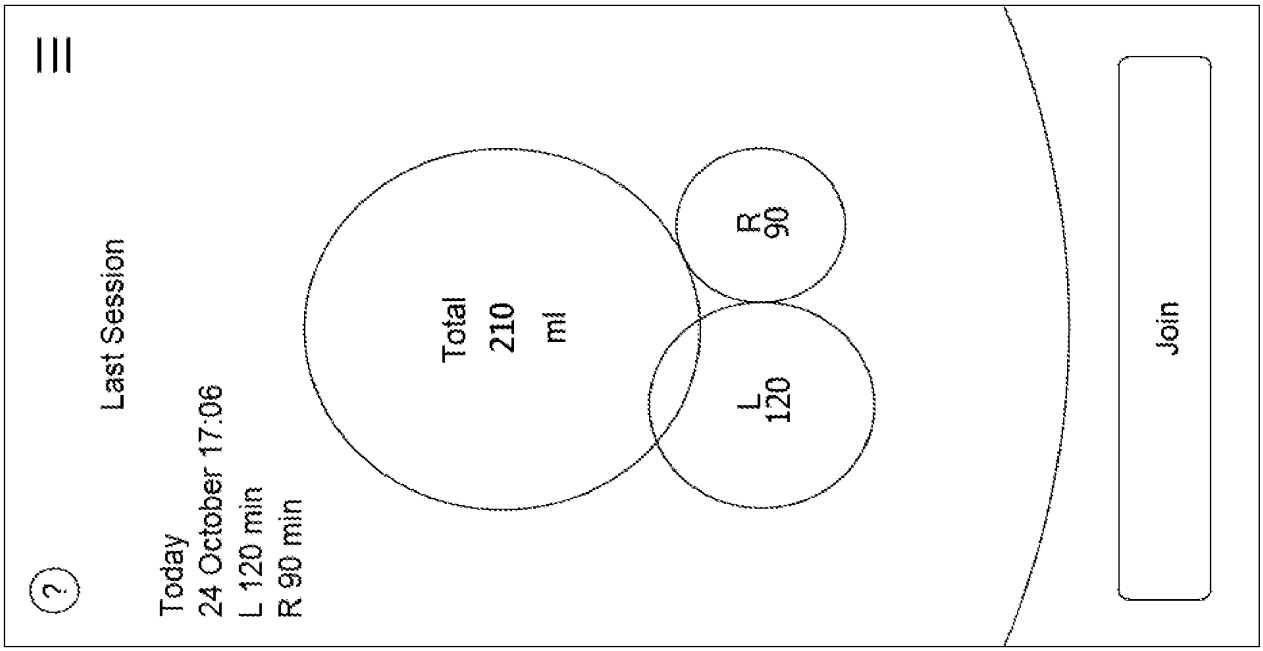

Last Session
Today
24 October 17:06
L 120 min
R 90 min
Total
210
ml
L
120
R
90
Join

FIGURE 18

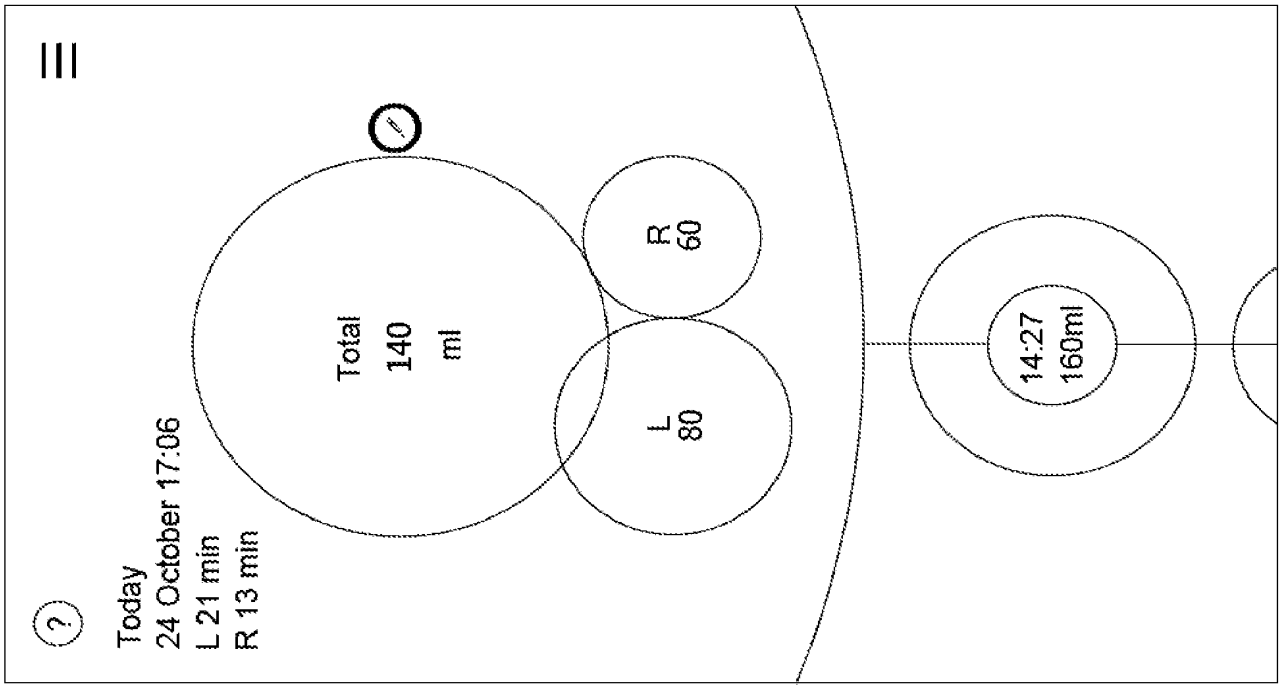

Today
24 October 17:06
L 21 min
R 13 min
Total
140
ml
L
80
R
60
14:27
160ml

FIGURE 19

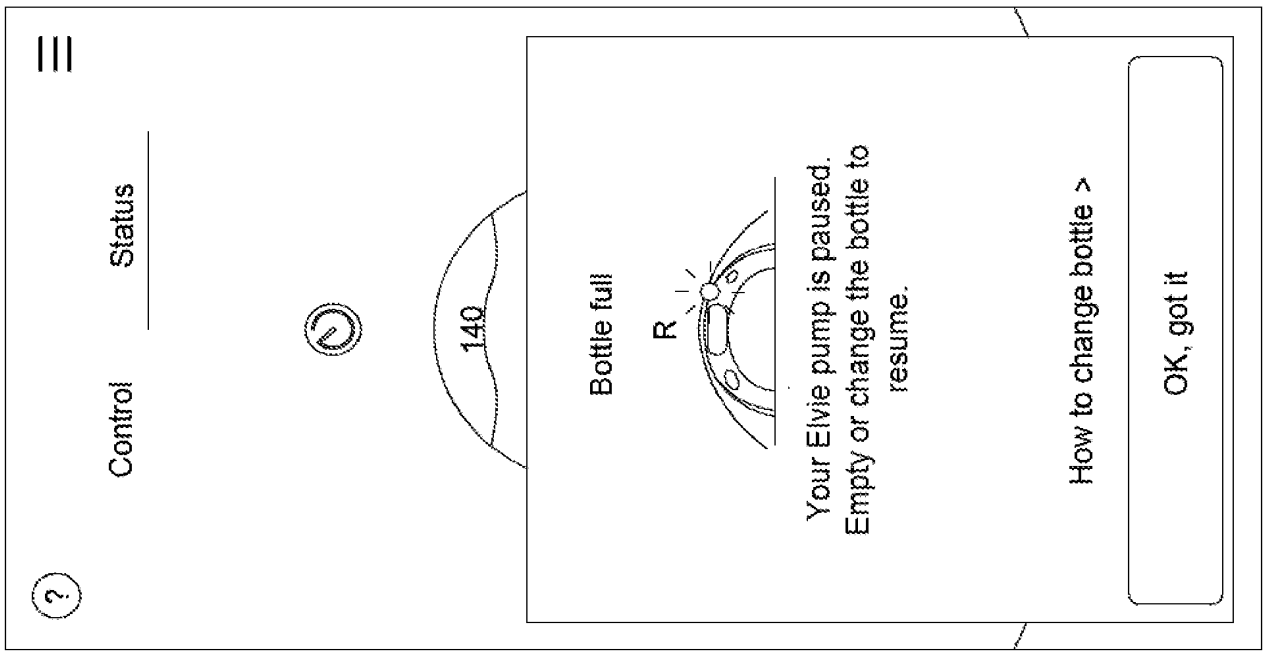

Control
Status
140
Bottle full
R
Your Elvie pump is paused.
Empty or change the bottle to
resume.
How to change bottle >
OK, got it

FIGURE 20

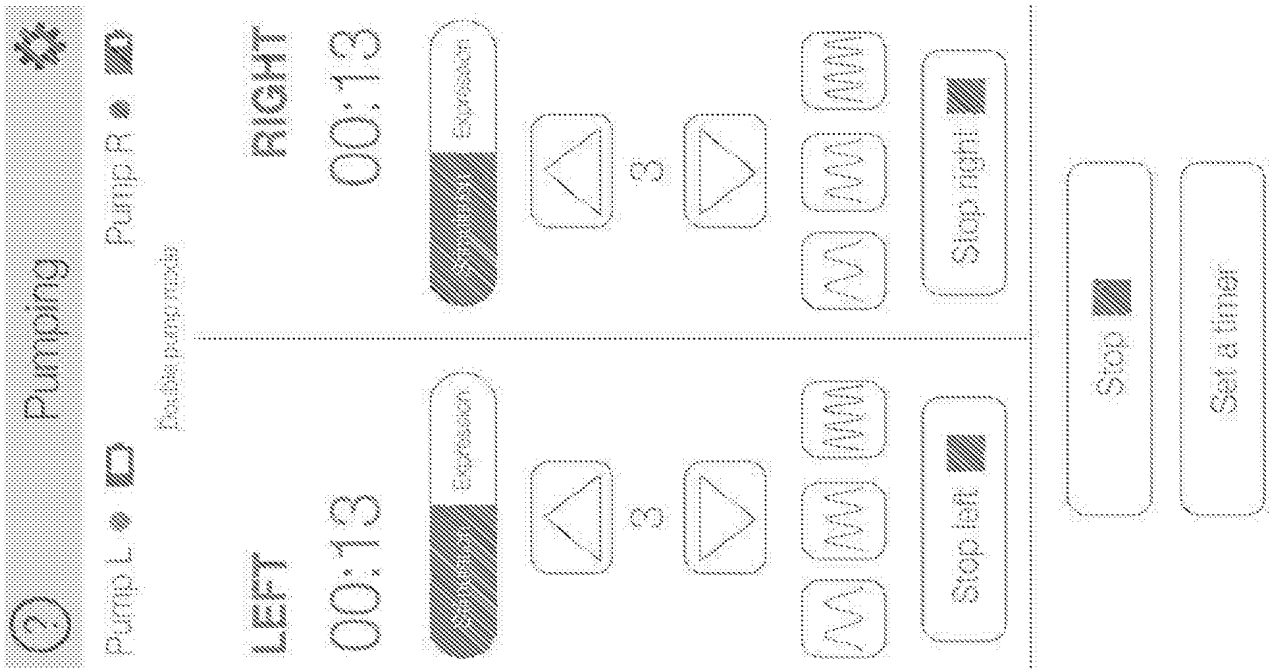

Pumping
Pump L
Pump R
Double pump mode
LEFT
00:13
Expansion
RIGHT
00:13
Expansion
Stop left
Stop right
Stop
Set a timer

FIGURE 21

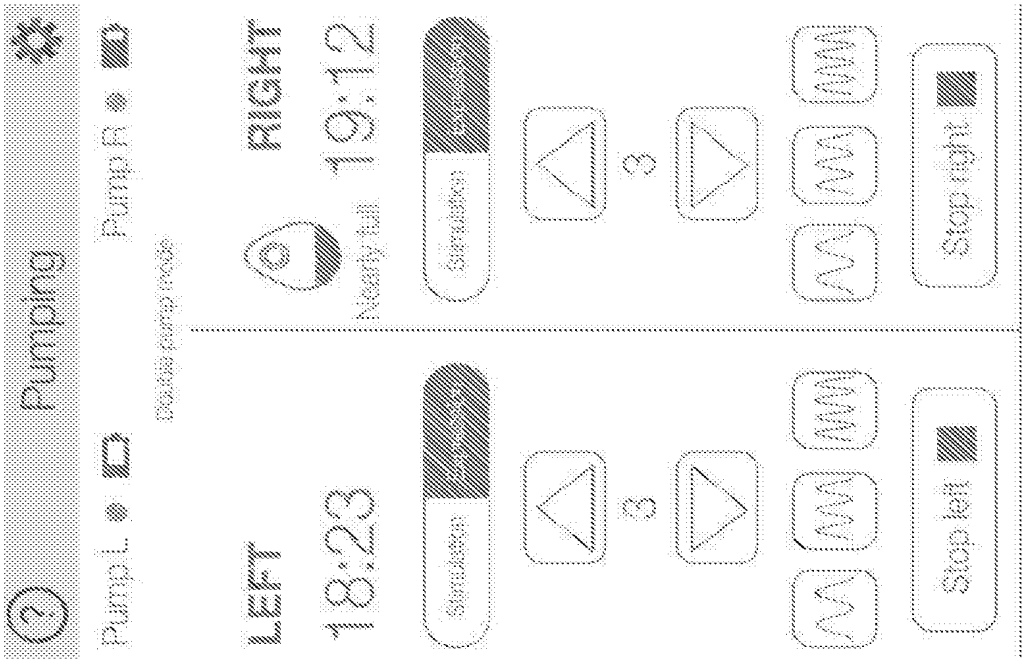

Pumping
Pump L
Pump R
Double pump mode
LEFT
18:23
Stimulation
RIGHT
19:12
Nearly full
Stimulation
Stop left
Stop right
Stop
Set a timer

FIGURE 22

Pumping
Pump L
Pump R
Pump R: bottle full
Pump paused.
Change or empty the bottle before resuming pumping.
OK
Stop
Settings

FIGURE 23

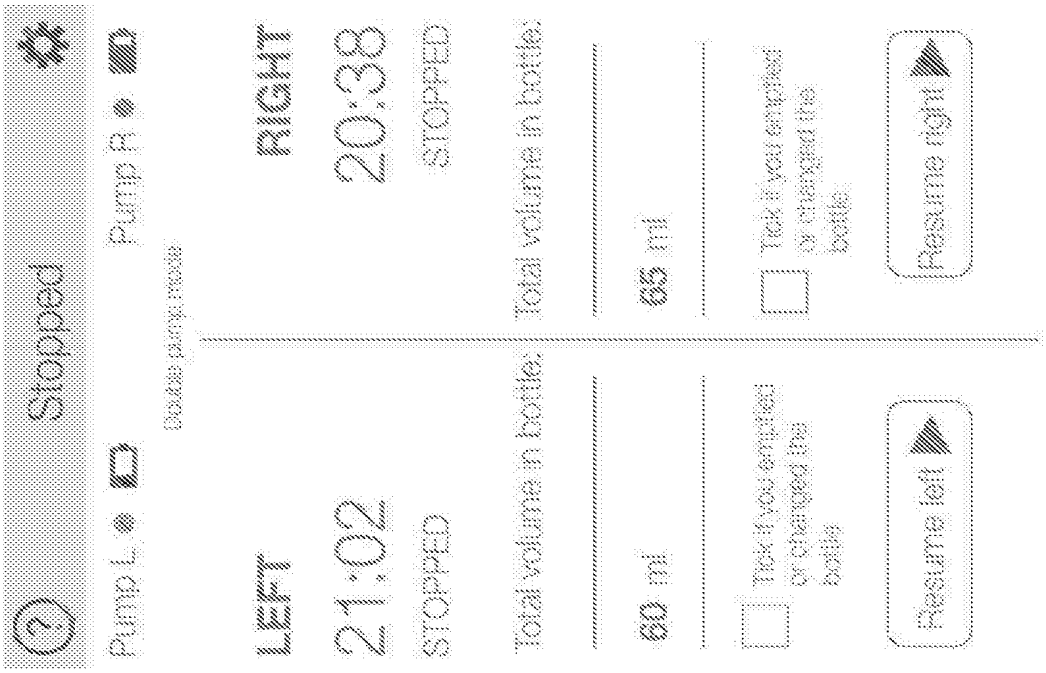

Stopped
Pump L
Pump R
Delete pump volume
LEFT
21:02
STOPPED
RIGHT
20:38
STOPPED
Total volume in bottle:
60 ml
Tick if you emptied or changed the bottle
Resume left
Total volume in bottle:
65 ml
Tick if you emptied or changed the bottle
Resume right
Resume
End session

FIGURE 24

PUMP
Pump L
25/5
Pump R
Double-pump mode
LAST SESSION
Start time: 3.50pm today
Total volume: 125ml
LEFT
20mins 13s
60ml
RIGHT
18mins 10s
65ml
Full history >
NEW SESSION
Start

FIGURE 25

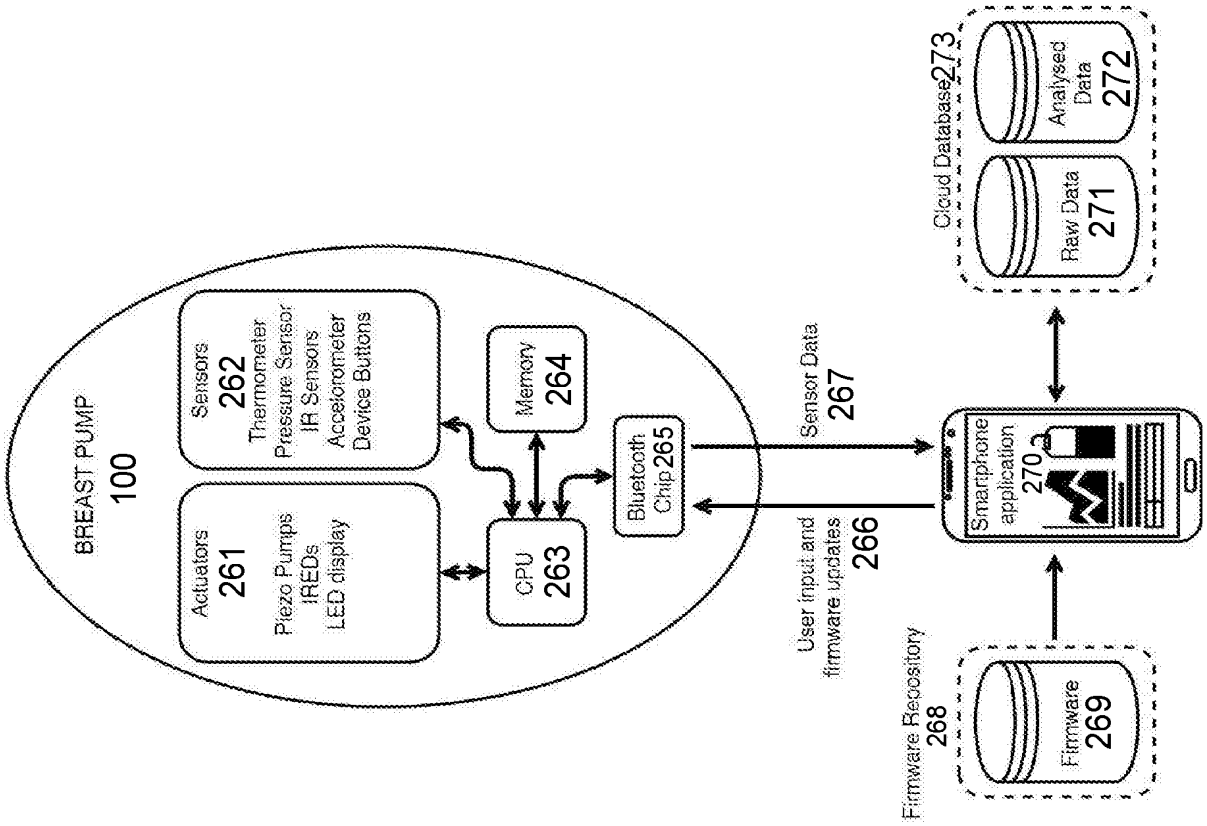

BREAST PUMP
100
Actuators
261
Piezo Pumps
IREDs
LED display
Sensors
262
Thermometer
Pressure Sensor
IR Sensors
Accelorometer
Device Buttons
CPU
263
Memory
264
Bluetooth
Chip 265
Sensor Data
267
User input and
firmware updates
266
Smartphone
application
270
Cloud Database 273
Raw Data
271
Analysed
Data
272
Firmware Repository
268
Firmware
269

FIGURE 26

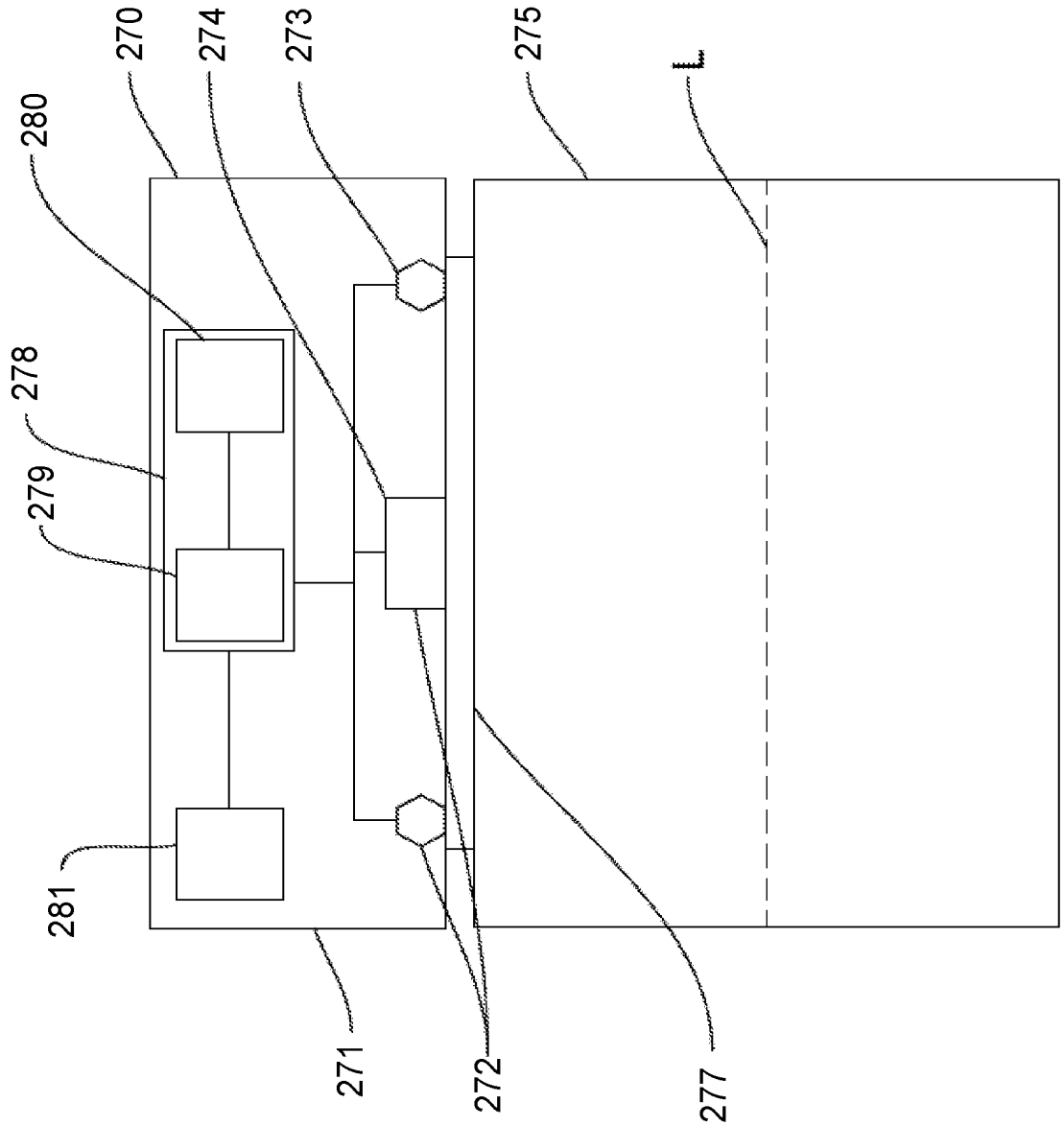


FIGURE 27

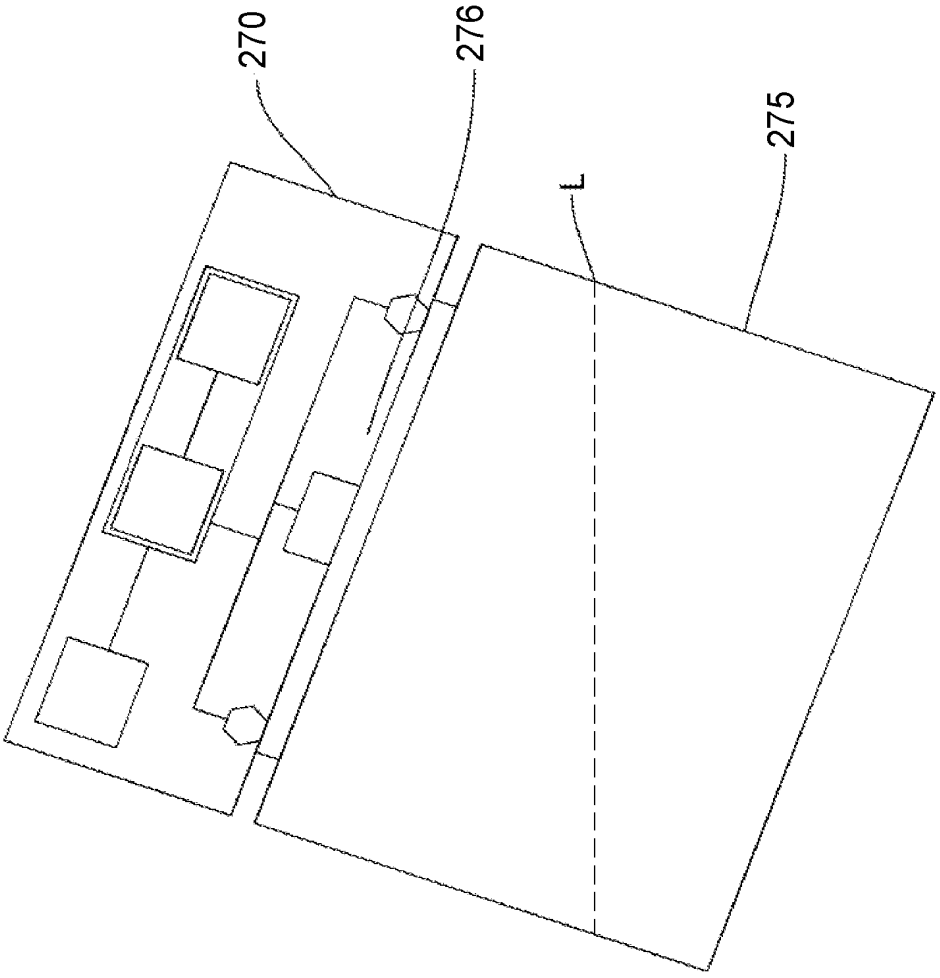


FIGURE 28

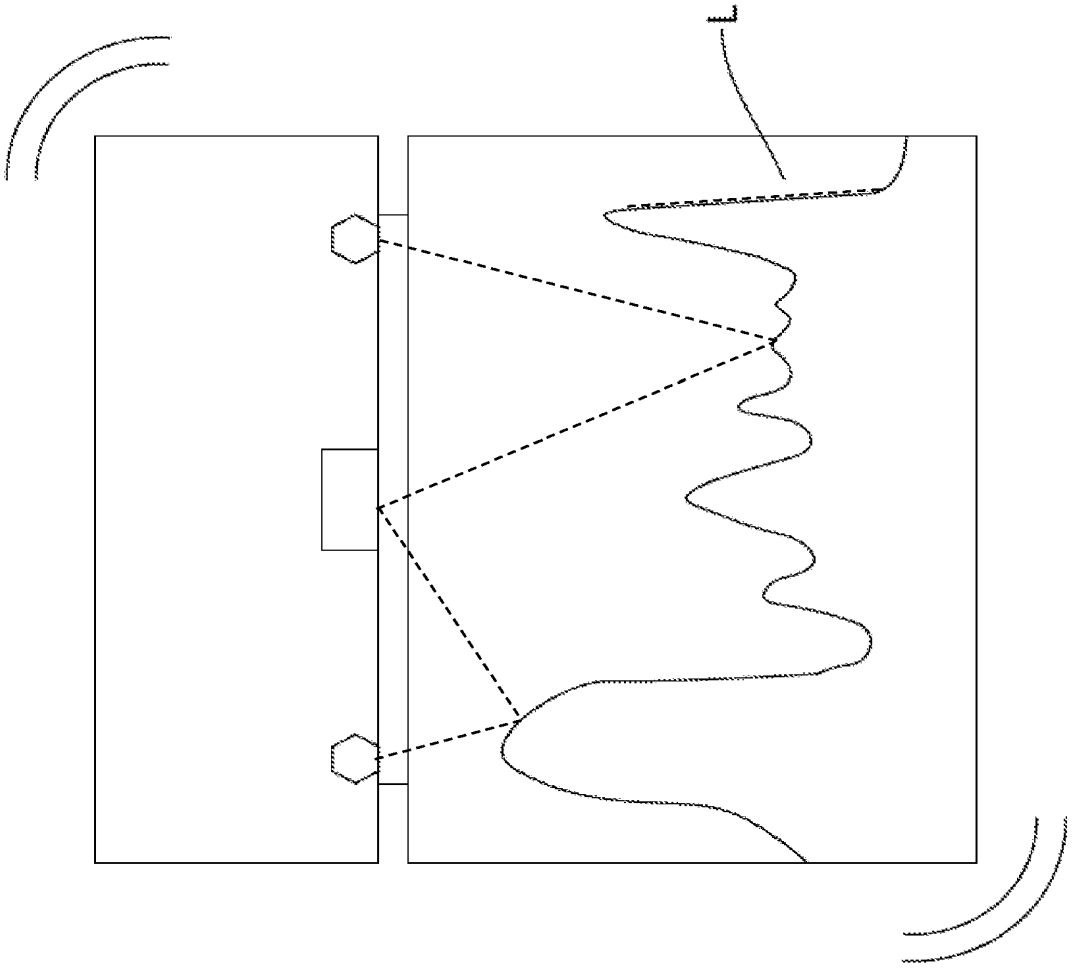


FIGURE 29

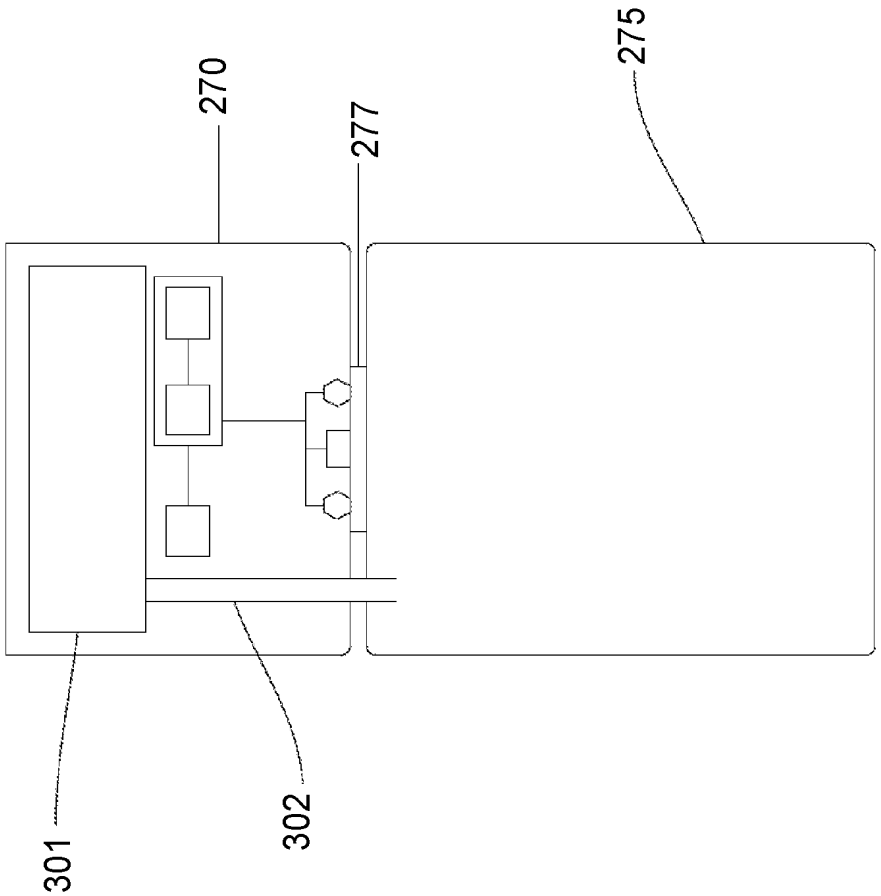


FIGURE 30

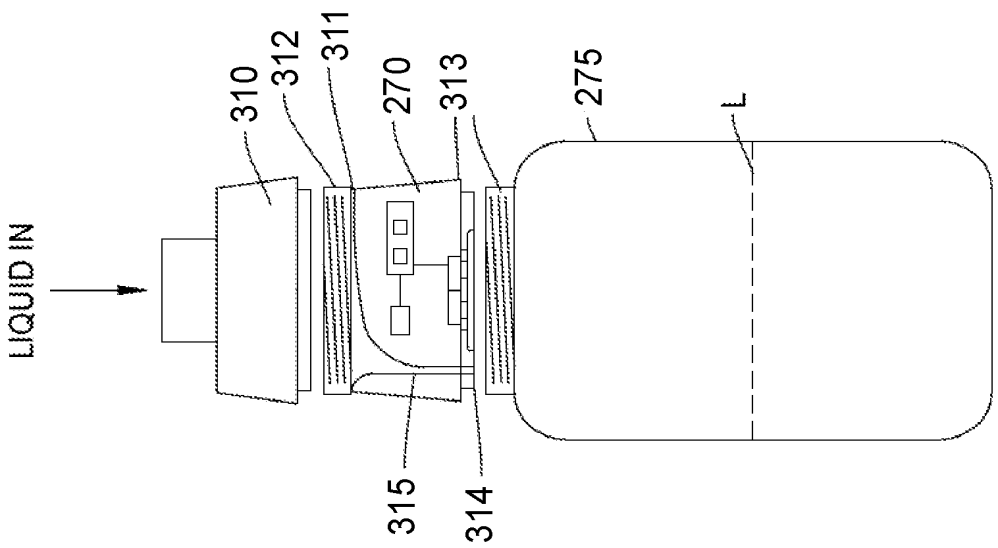


FIGURE 31

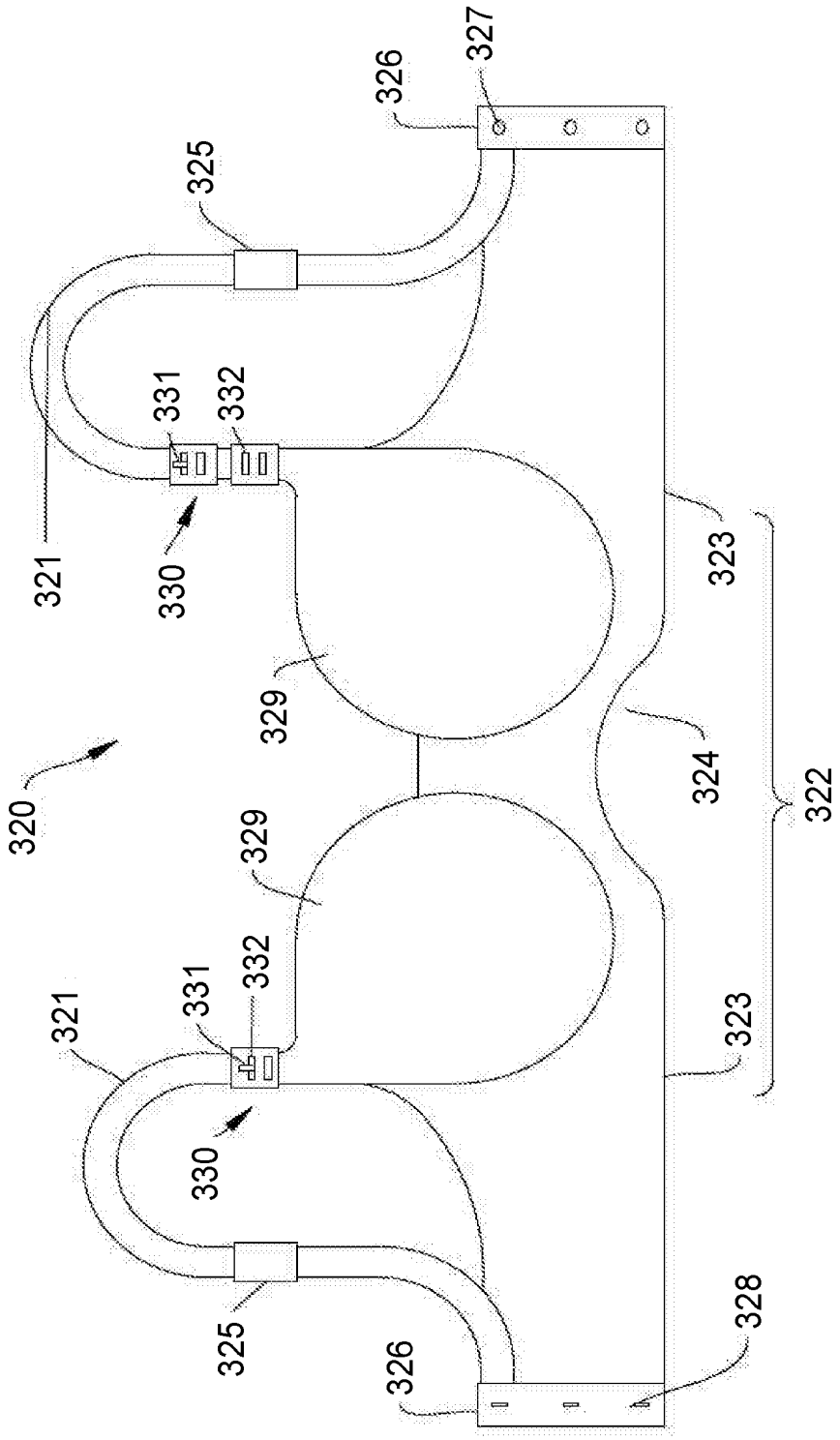


FIGURE 32

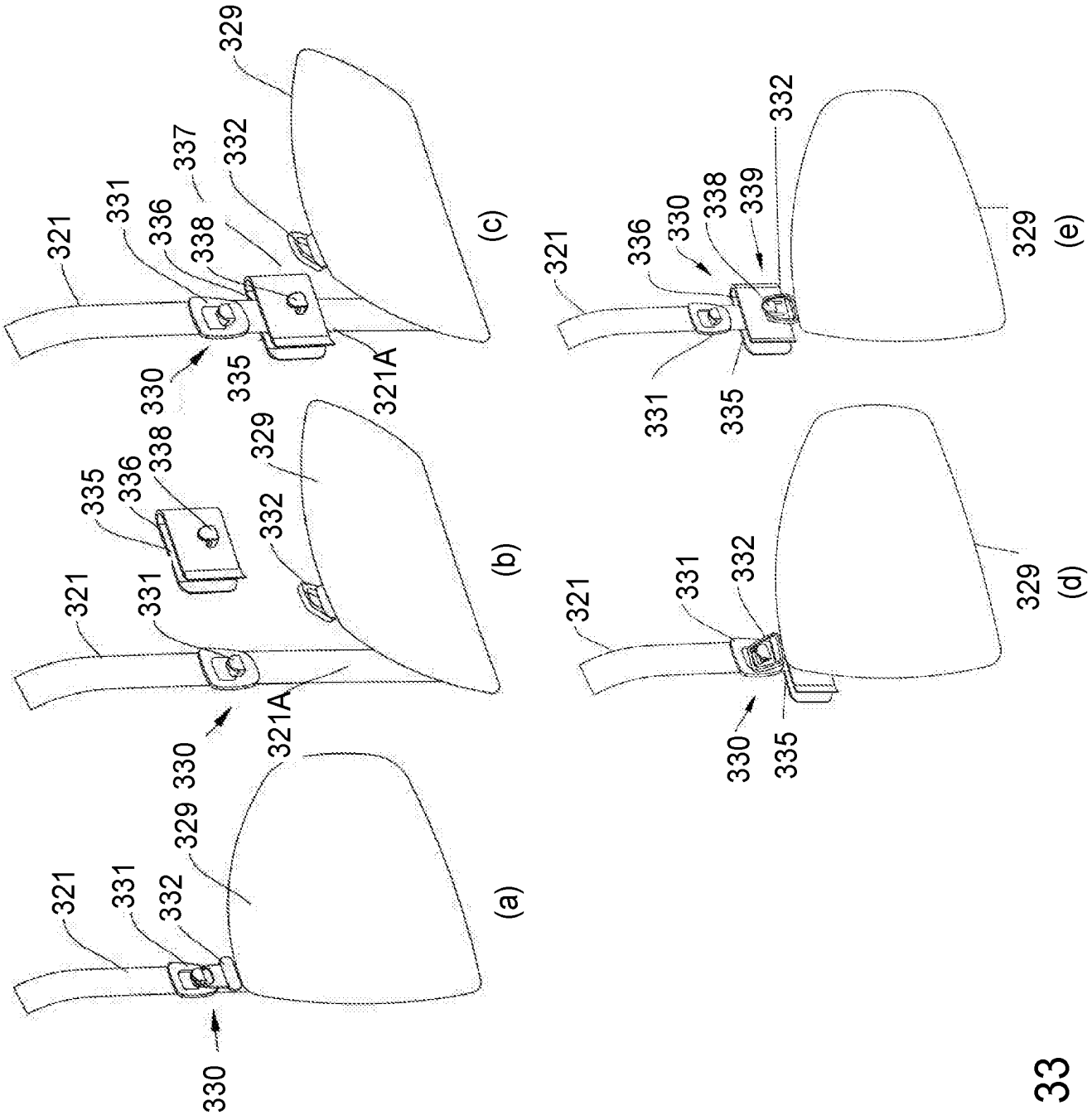

321
331
332
329
330
(a)
321
331
335
336
338
329
332
330
321A
(b)
321
331
336
338
337
332
329
330
335
321A
(c)
321
331
336
330
338
339
332
329
(e)
321
331
332
329
330
335
(d)

FIGURE 33

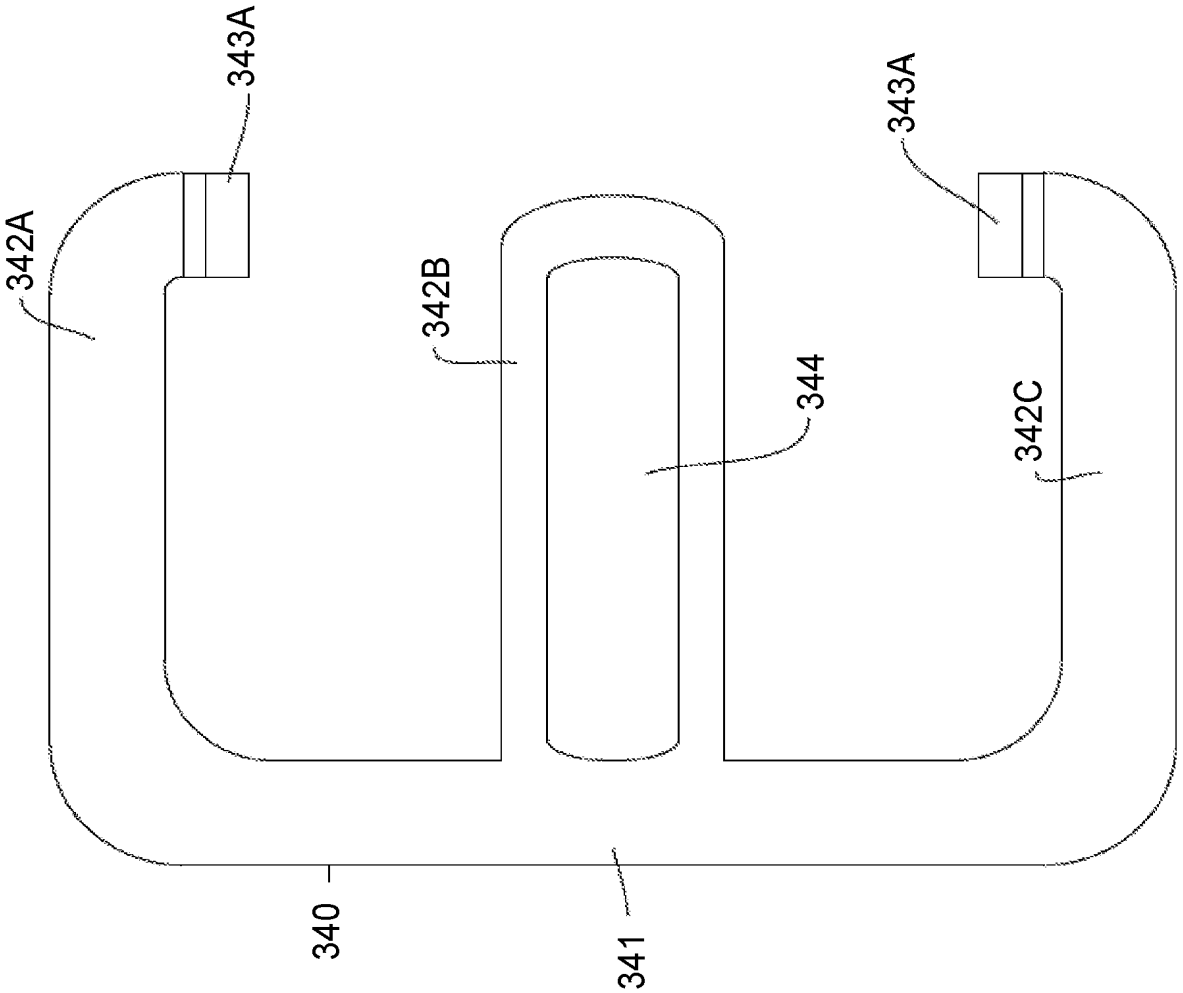


FIGURE 34

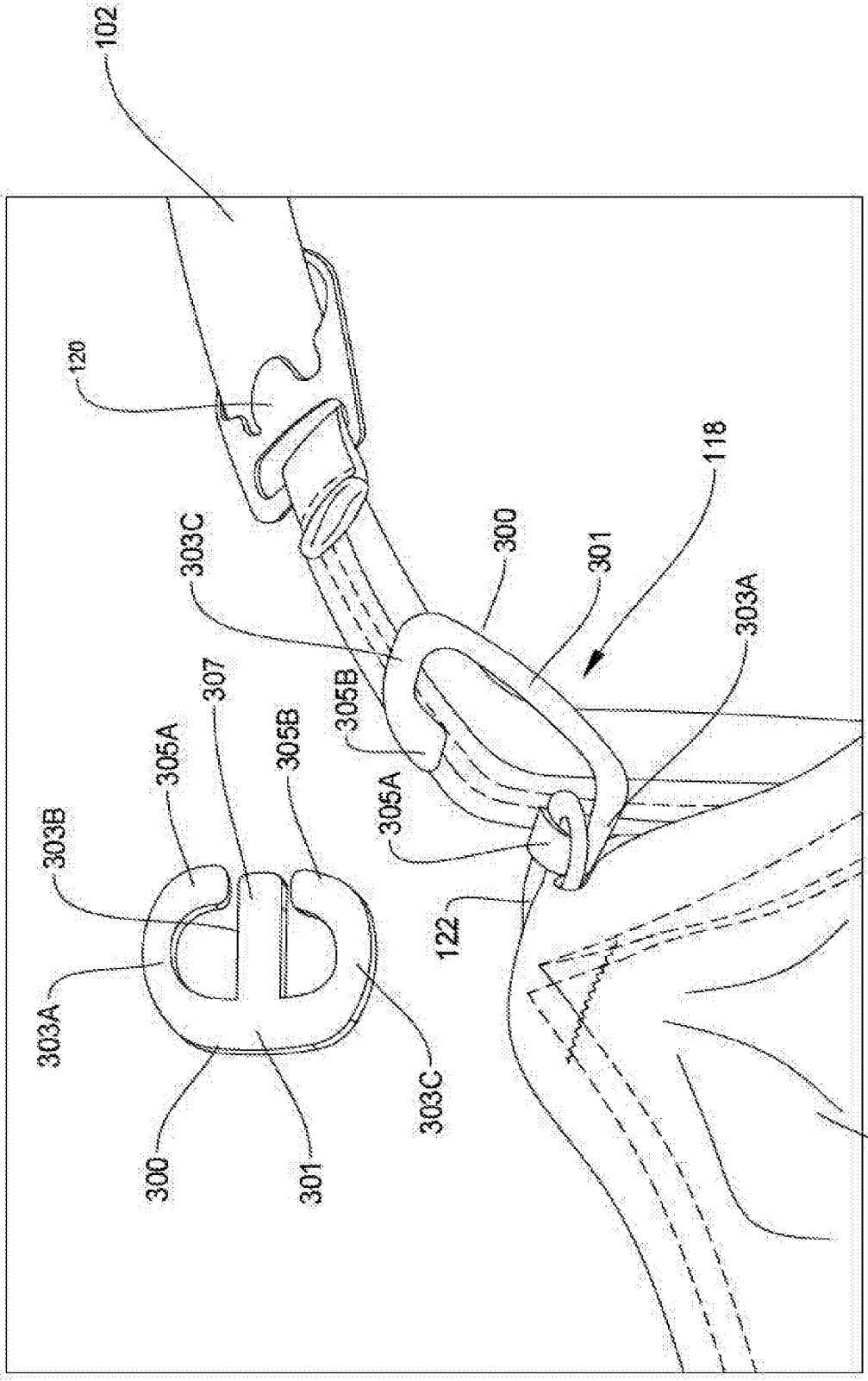

102
120
303C
300
301
118
303A
307
305B
305A
305A
305B
303B
303A
122
303C
300
301
116

FIGURE 35

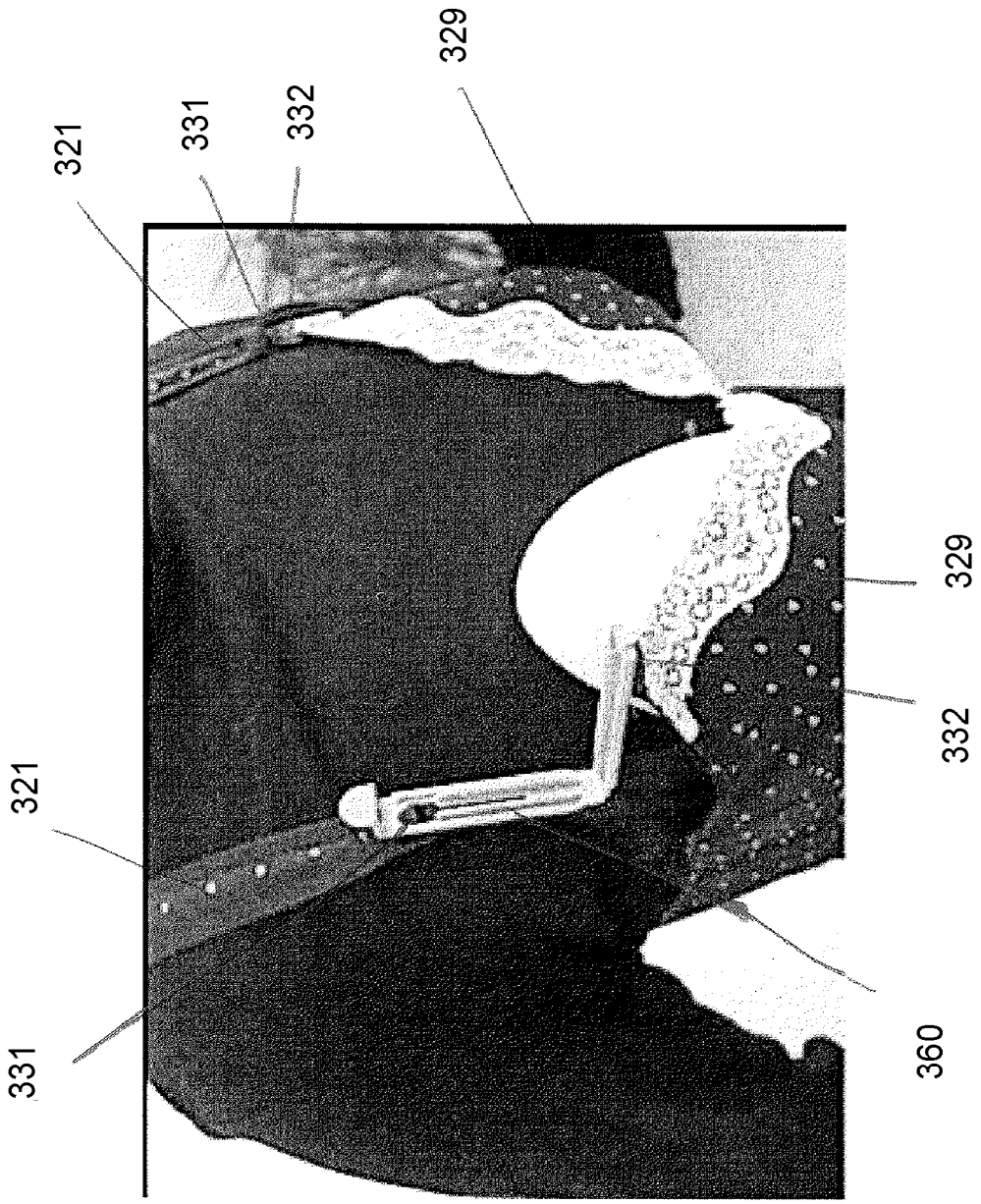


FIGURE 36

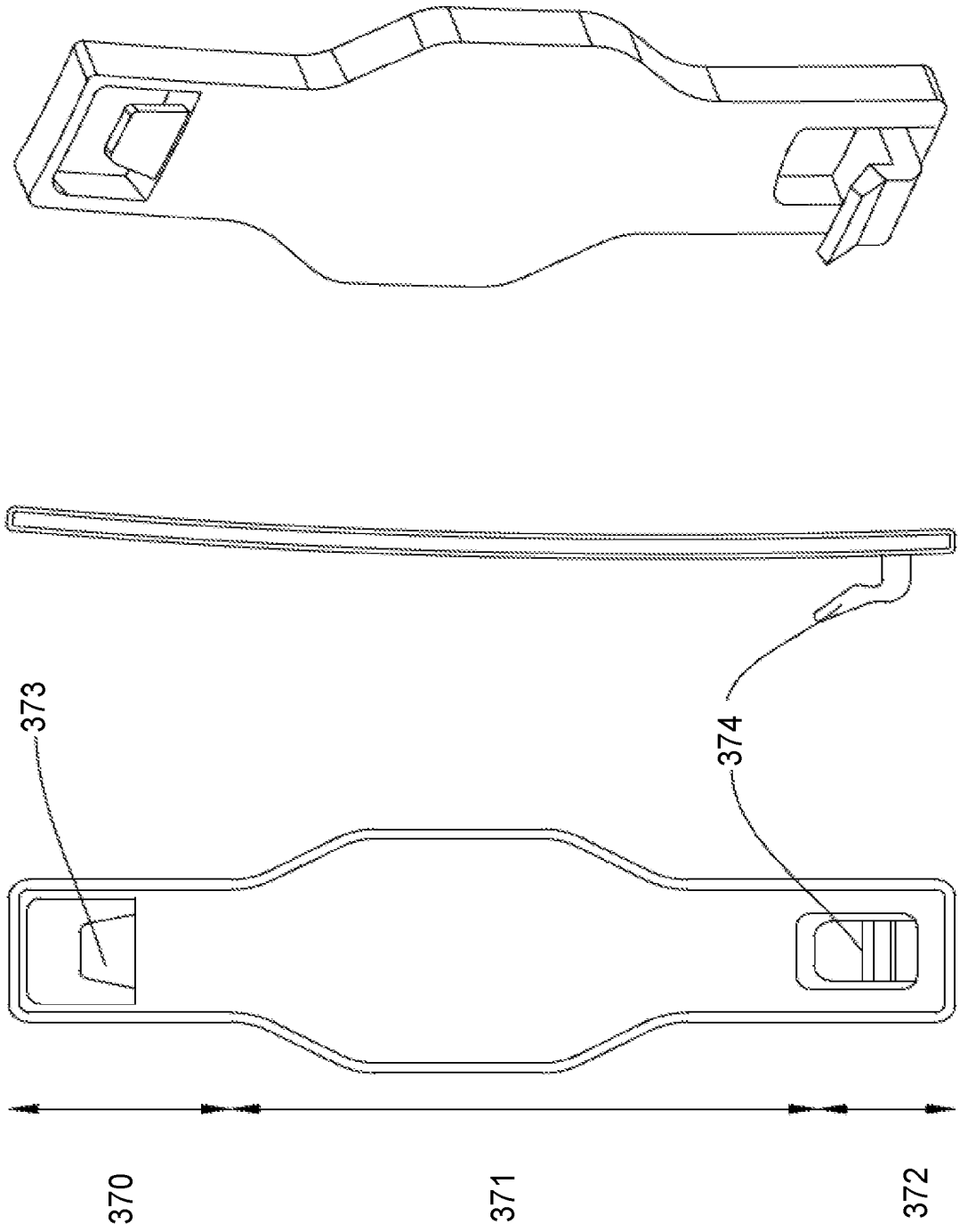


FIGURE 37

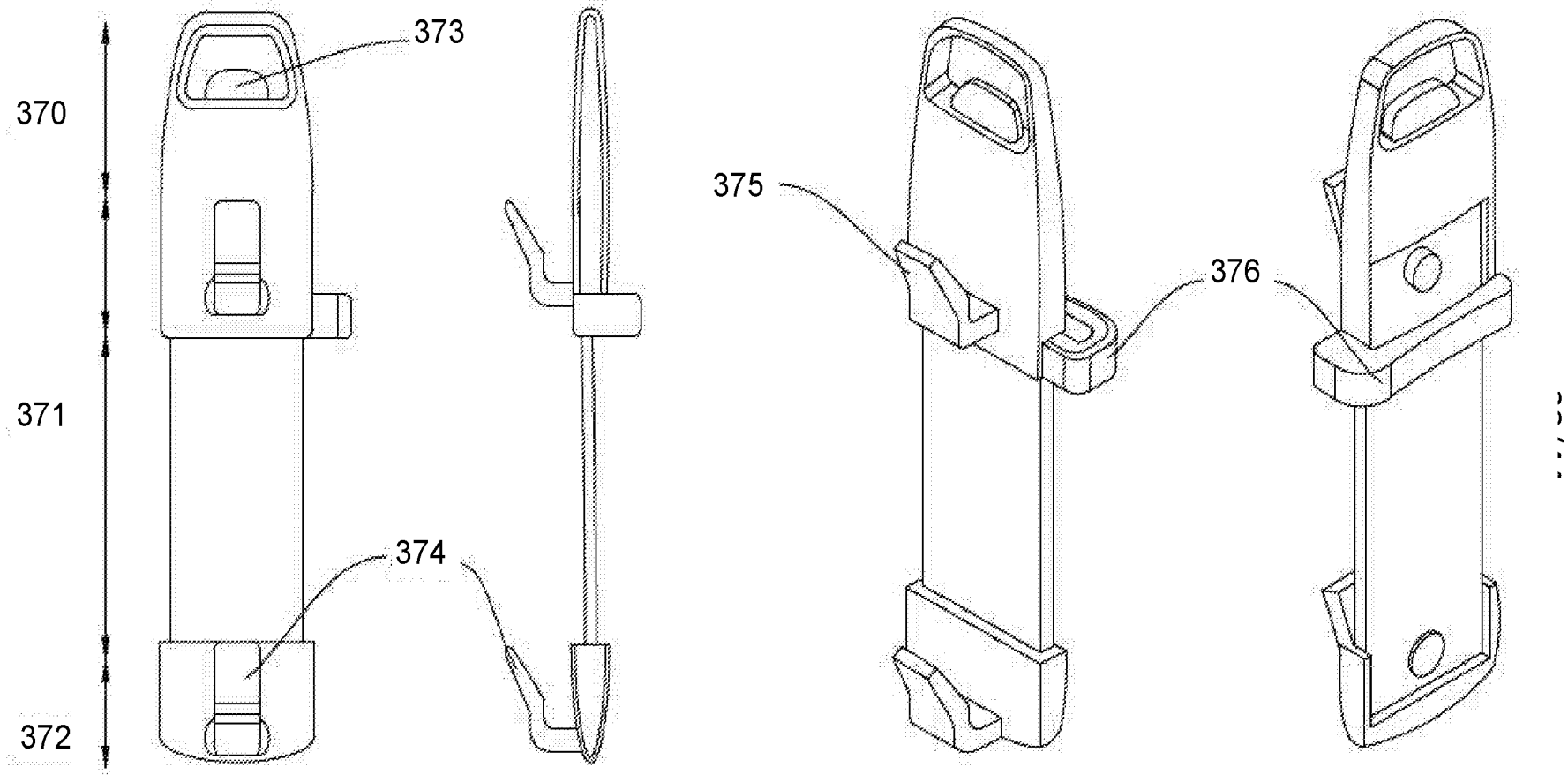


FIGURE 38

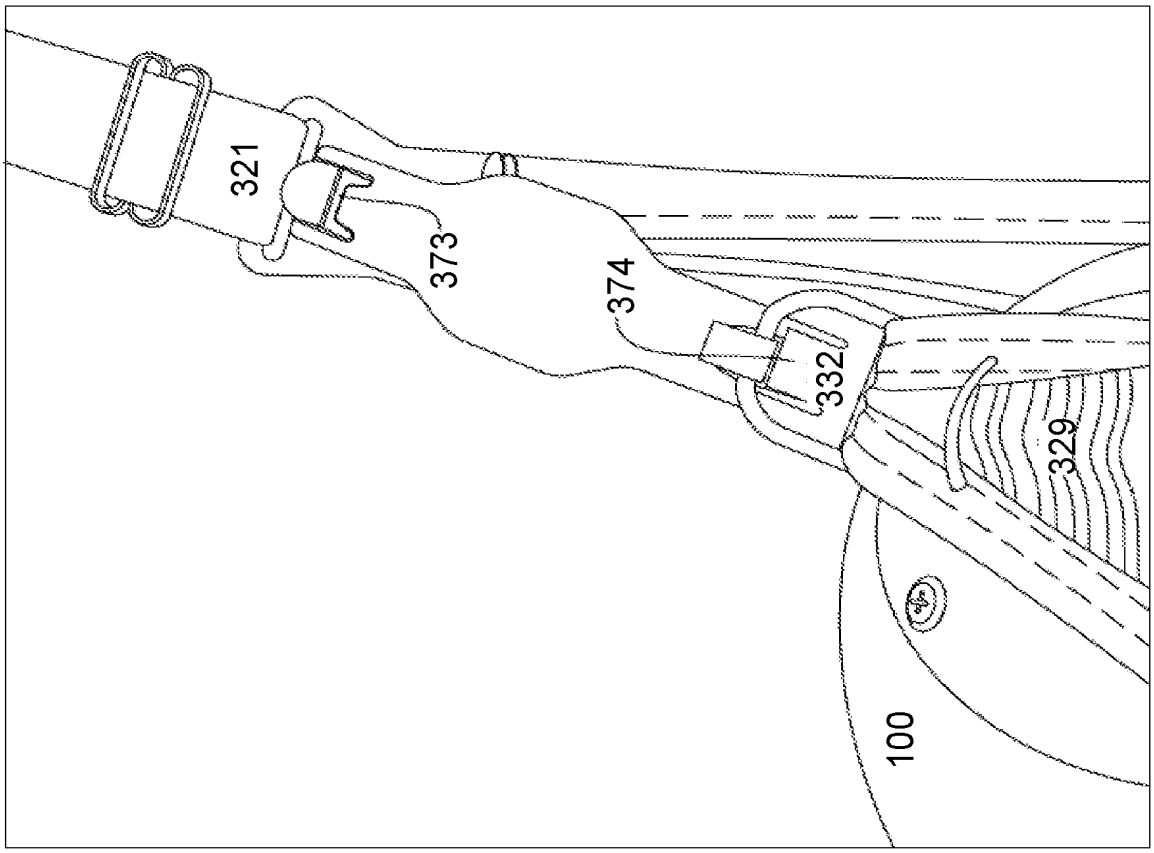


FIGURE 39

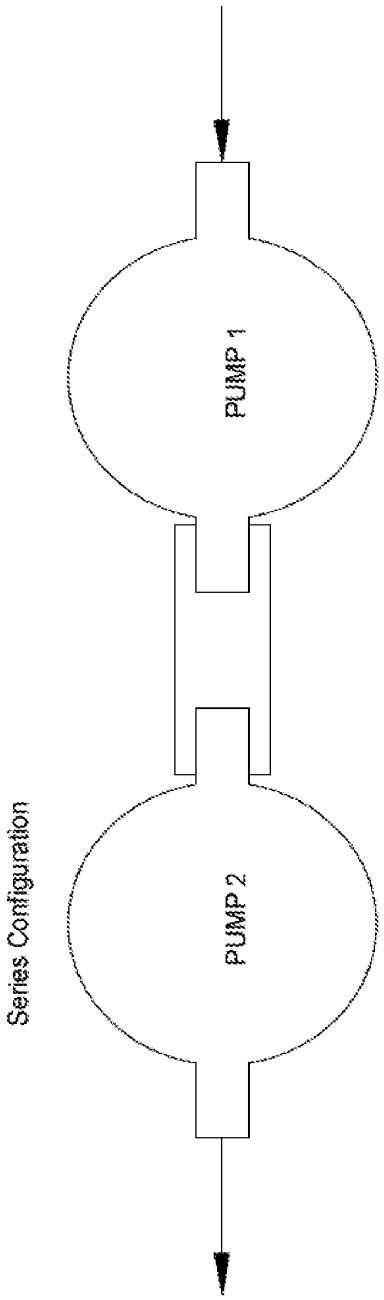


FIGURE 40

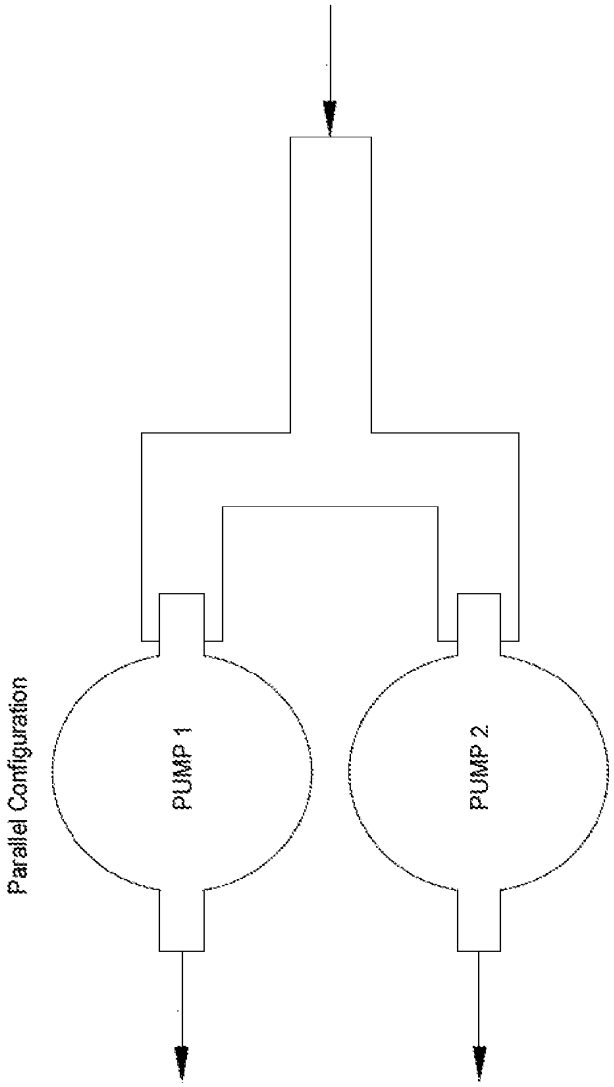


FIGURE 41

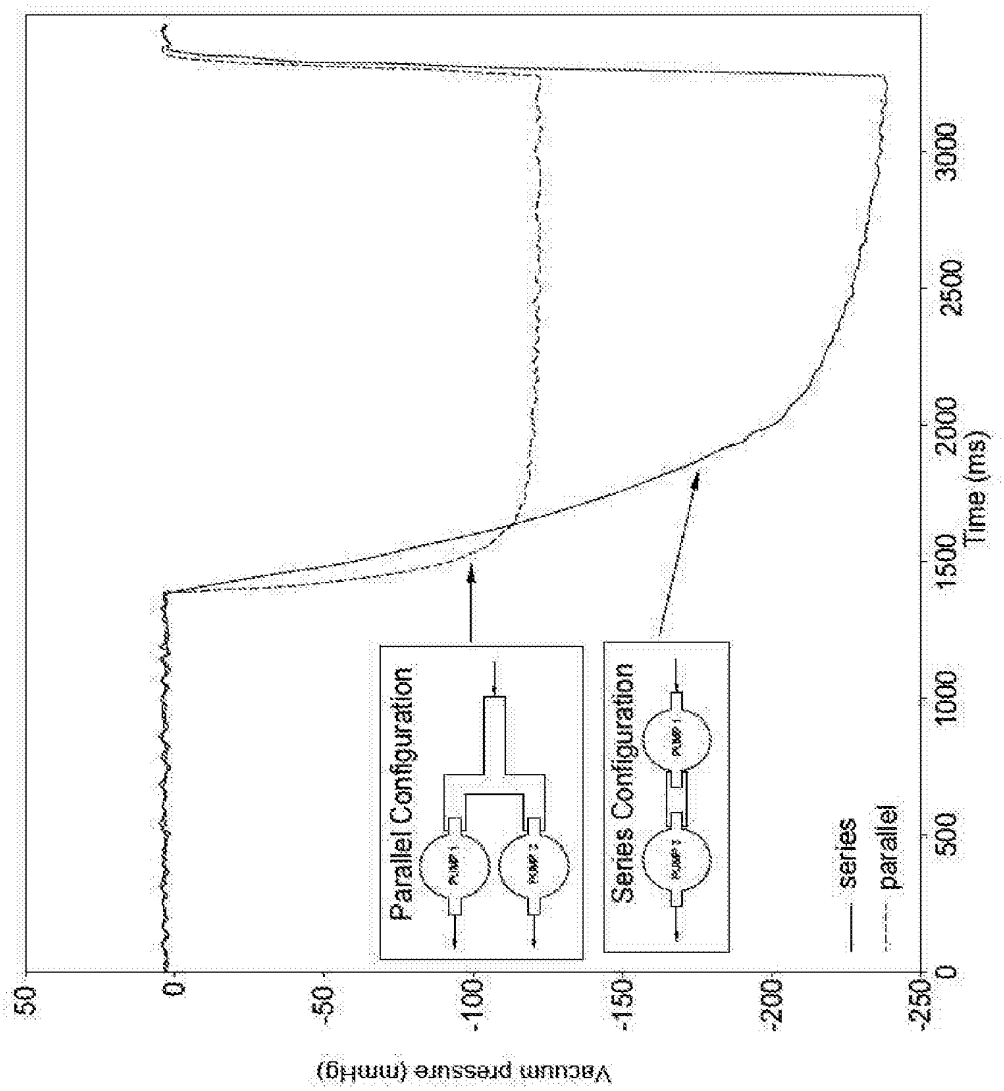

Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
Parallel Configuration
Series Configuration
series
parallel

FIGURE 42

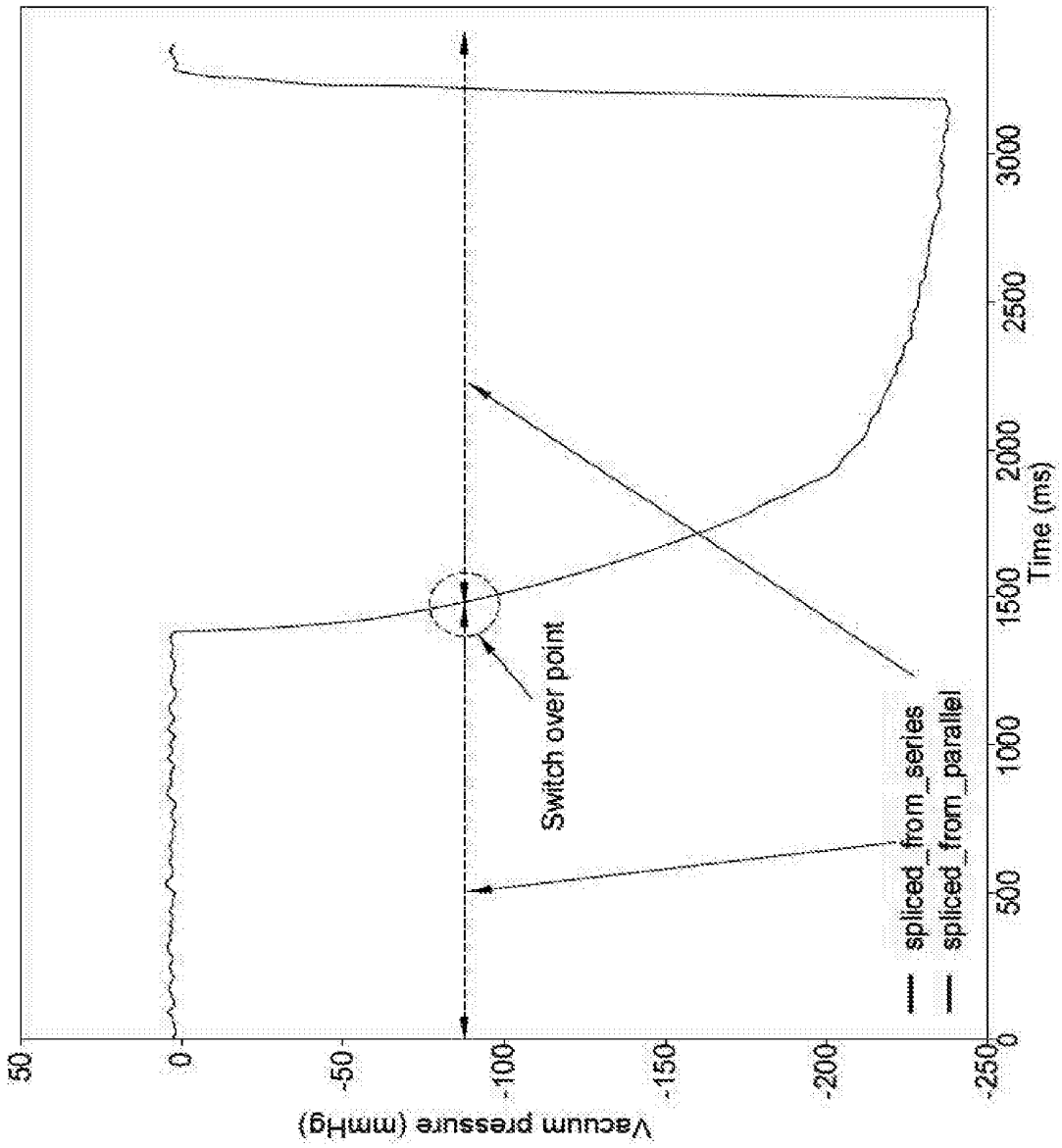

Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
Switch over point
spliced_from_series
spliced_from_parallel

FIGURE 43

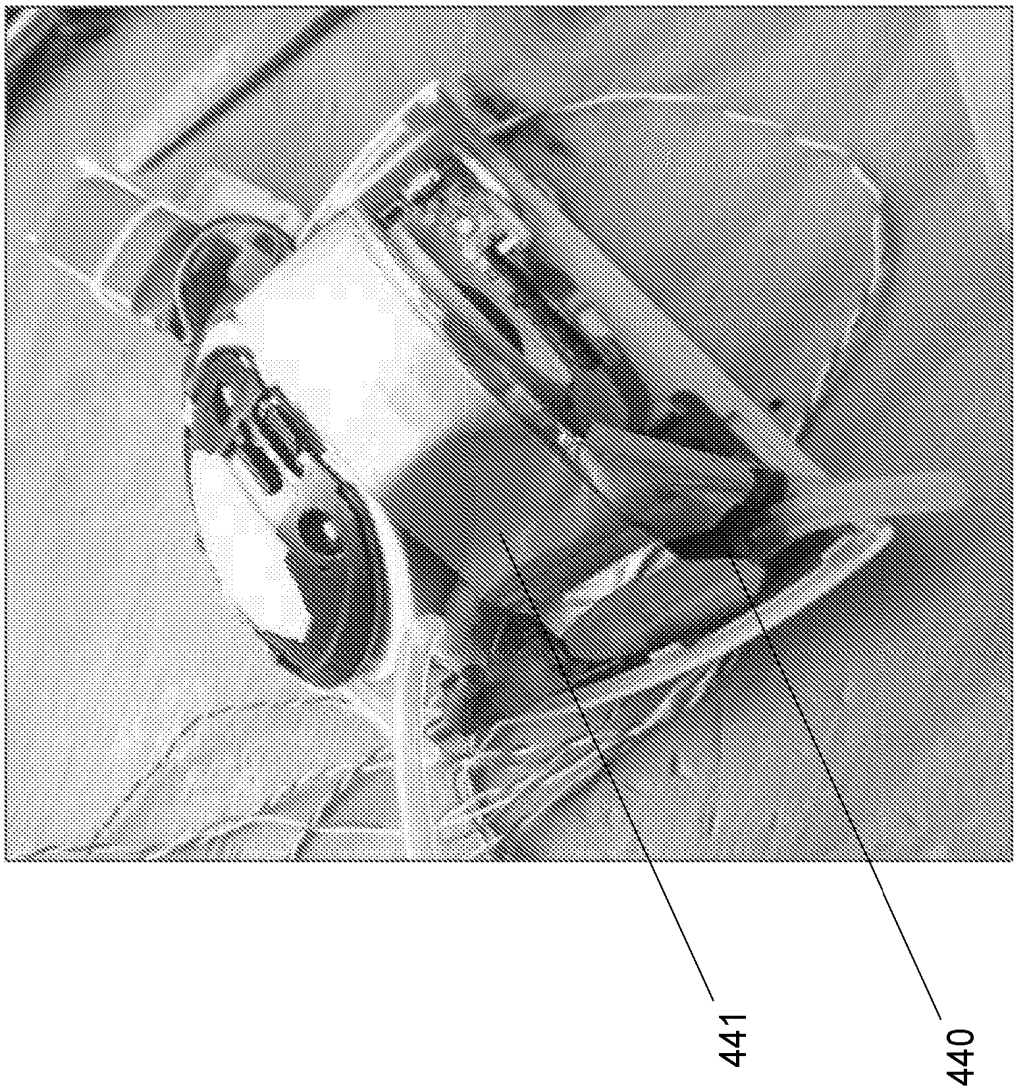


FIGURE 44

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Dated 19 June 2017

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Concept House
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South Wales
NP10 8QQ

Application number GB 1709561.3

1.	Your reference	**MJD/P153994GB00**
2.	Full name, address and postcode of the applicant or of each applicant	**CHIARO TECHNOLOGY LIMITED** **Second Floor 63-66 Hatton Garden** **London EC1N 8LE** **Greater London** **United Kingdom**
	Patents ADP number *(if you know it)*	**11287869002**
3.	Title of the invention	**BRA CLIP**
4.	Name of your agent *(if you have one)*	**Boult Wade Tennant**
	"Address for service" to which all correspondence should be sent. This may be in the European Economic area or Channel Islands (see warning note below) *(including the postcode)*	**Boult Wade Tennant** **Verulam Gardens** **70, Gray's Inn Road** **London WC1X 8BT** **United Kingdom**
	Patents ADP number *(if you know it)*	**42001**

5. Priority declaration: Are you claiming priority from one or more earlier-filed patent applications? If so, please give details of the application(s)

Country	Application number	Date of filing	PDAS Access Code

6.	Divisionals etc: Is this application a divisional application, or being made following resolution of an entitlement dispute about an earlier application. If so, please give the application number and filing date of the earlier application	Number of earlier UK application	Date of filing *(day / month / year)*
7.	Inventorship: (Inventors must be individuals not companies) Are all the applicants named above also inventors?	**No**	
8.	Are you paying the application fee with this form?	**Yes**	

9. Accompanying documents: please enter the number of pages of each item accompanying this form.

Continuation sheets of this form

Description:	**9**
Claim*(s)*:	**3**
Abstract:	**n/a**
Drawing*(s)*:	**7**

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10. If you are also filing any of the following, state how many against each item.

Priority documents:	**0**
Statement of inventorship and right to grant of a patent (Patents Form 7):	**1**
Request for search (Patents Form 9A):	**1**
Request for a substantive examination (Patents Form 10):	**0**
Any other documents (please specify):	**PDAS Registration Form**

11. I/We request the grant of a patent on the basis of this application.

Signature: **/DRAPER, Martyn John/** Date: **15 Jun 2017**

12. Name, e-mail address, telephone, fax and/or mobile number, if any, of a contact point for the applicant

DRAPER, Mr Martyn
Email: boult@boult.com
Telephone: 020 7430 7500
Fax: 020 7430 7600

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BRA CLIP

BACKGROUND

Many specialised bras (or brassieres) exist for maternity that facilitate nursing and/or breast pumping for milk collection without the need to remove the bra itself. In a traditional nursing bra, this is achieved with the use of an at least partially detachable cup, which can be unhooked for feeding and/or pumping.

Further specialised bras are known which are provided with cut-out portions or slits which substantially align with the wearer's areola and nipple. Traditional breast pumps comprise an elongate breast shield which extends away from the breast towards an external bottle and source of suction. The breast shield is arranged to extend through the cut-out portion or slit, with the collection bottle and pumping apparatus connected thereto outside of the bra. These require the user to remove or unbutton any over-garments, and are uncomfortable for use when not pumping.

Integrated wearable breast pumps have begun to enter the market, such as US 2016 206794 A1. In such pumps, the suction source, power supply and milk container are locally provided, without the need for bulky external components or connections. Such devices can be provided with a substantially breast shaped profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations.

In US 2016 206794 A1, the applicant has appreciated that the added size of the breast pump means that the combination of the user's breast and the breast pump may no longer fit within the user's regular bra. This is particularly relevant as over-compression of the user's breast will result in the closing of the user's milk ducts and hence reduced expression. To address this, the breast pump of US 2016 206794 A1 has an offset shape favouring the lower half of the pump, and requires complex collapsible bag systems as milk collection devices. This is to force the pump to fit within the user's existing bras. This works by breast milk leaving the breast and enters the bag, and the breast shrinking in a corresponding volume to the expansion of the bag. The inventors consider that this is unlikely to be a perfect 1 to 1 transfer of volume, and hence the compression on the breast may increase as the collapsible bags fill.

In addition to these systems being particularly complex and wasteful, a relatively smaller bag must be used. In US 2016 206794, approximately 110 ml (4 fluid ounces) of milk can be collected before the bag must be changed. While this may be sufficient for some users, others may produce much more milk in a session. Additionally, even this small increase in cup size may make bras less comfortable for the user.

It is our understanding that in the product which has been brought to market based on the disclosure of US 2016 206794 does increase the effective cup size of the wearer by around 2 cup sizes based upon European standard EN 13402 which is discussed later.

Maternity (or nursing) bras such as disclosed in US 4,390,024 A have partially detachable cups, with a plurality of attaching means provided along the bra strap for attaching the cups to the strap. The cup can then be attached to different points in order to adjust the support provided. However, these attachment points are fixed. Additionally, this bra has been designed to accommodate the change in breast size before and after the feeding/pumping process. It is not designed to accommodate a breast pump.

Accordingly, there is a need for a better system to accommodate integrated wearable breast pumps.

SUMMARY OF THE INVENTION

A maternity bra system is provided according to the present invention comprising: a maternity bra comprising: a support structure comprising shoulder straps and a bra band; and a first and a second cup each attached to the support structure to provide a first cup size, at least one cup being at least partially detachable from the support structure at an attachment point, the system further comprising: a clip comprising a first engagement mechanism and at least one second engagement mechanism(s), the clip being attachable in a releasable manner to the support structure at a first position via the first engagement mechanism and attachable in a releasable manner to one of the partially detachable cups via the second engagement mechanism to provide a second cup size different to the first cup size.

This system allows a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump. As such, the user does not need a specialised adjustable bra; instead the present

system works with all conventional maternity bras. The user also does not have to purchase any larger bras to wear while pumping.

The clip may be configured to be attached to the support structure at a position away from the attachment point. This results in the original attachment point being usable, with the clip providing an alternative attachment point for the adjusted cup size.

The clip may be attachable to the support structure at a plurality of non-discrete positions. This ensures essentially infinite adjustment of the clip position such that the perfect position for the user can be found.

The clip may be extendable between an unextended and an extended state, and attaches to the support structure at the attachment point; the first cup size is providable when the at least partially detachable cup is attached to the clip when the clip is an unextended state; the second cup size is providable when the at least partially detachable cup is attached to the clip when the clip is in an extended state.

An extendable clip like this allows quick switching between the two states in use.

Preferably, the attachment point is on at least one of the shoulder straps. Again this matches the standard system used in most maternity bras.

A clip is provided for use in the system described above according to the present invention. The clip comprising first and section engagement mechanisms and being releasably attachable to a support structure of a maternity bra with the first engagement mechanism and an at least partially detachable cup of a maternity bra with the second engagement mechanism to provide a second cup size which is different to a first cup size providable when the cup is attached to the support structure of the bra at an attachment point.

In a preferred embodiment, the first engagement mechanism engages with the support structure in a first direction and the second engagement mechanism engages with the cup in a second direction transverse to the first direction. This increases ease of attachment as with this structure the sideways engagement of the clip to the support

structure ensures that the second attachment mechanism is correctly orientated for the cup.

The second engagement mechanism may be one or more of a hook or a snap or a clip. This ensures easy interfacing with the traditional hook and clasp systems already provided on maternity bras.

Preferably the clip further comprises two distinct second engagement mechanisms which can be used interchangeably dependent upon the orientation of the clip. This makes the clip easier to use as it can be quickly switched between each bra strap, and the user does not have to worry which way up to put the clip on.

Preferably, the clip comprises a material pathway with an opening for receiving a portion of the support structure as the first engagement mechanism for securing the clip to the bra. This ensures a quick and simple method for attaching the clip to the bra. In particular, the clip may substantially U-shaped, and the material pathway is between the arms of the U.

Preferably, the clip comprises three prongs extending from a central support, the three prongs arranged as a central prong and two outer prongs so as to receive the support structure on one side of the central prong and on the opposite side of each respective outer prong, at least one prong being provided with the second engagement mechanism. This ensures a strong attachment to the bra and a simple design.

Preferably, both outer prongs are each provided with a respective second engagement mechanism. This ensures that the clip is reversible for easier attachment to the bra.

A method of adjusting the cup size of a maternity bra is provided according to the present invention, comprising: providing a maternity bra comprising: a support structure comprising shoulder straps and a bra band; and a first and second cup each attached to the support structure to provide a first cup size, the at least one cup being detachable from the support structure at an attachment point, providing a clip comprising first and section engagement mechanisms, attaching the first engagement mechanism of the clip in a releasable manner to a first position of the support structure of the maternity bra, attaching one of the detachable cup to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

This clip and method allow a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump.

Preferably, the method further comprises the step of inserting a breast pump into the detachable cup. The adjustment of the size of the bra allows the bra to support the breast pump against the user's breast for comfort and ease.

Preferably, the method further comprises the steps of: detaching the first engagement mechanism of the clip from the first position support structure of the maternity bra; attaching the first engagement mechanism of the clip in a releasable manner to a second position of the support structure of the maternity bra; and attaching the other of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size. This allows the user to use a single clip on either of the cups.

DESCRIPTION OF THE FIGURES

The following invention will be described with reference to the following Figures in which:

Figure 1 depicts a prior art design for a maternity bra;

Figures 2A and 2B depict a clip and clasp according to the present invention;

Figures 3A, 3B and 3C depict the clip of Figures 2A and 2B being fitted to a maternity bra according to the present invention;

Figures 4A and 4B depict adjustment of the maternity bra of Figures 3A, 3B and 3C according to the present invention;

Figure 5 depicts an alternative clip for adjustment of a maternity bra according to the present invention;

Figure 6 depicts the alternative clip of Figure 5; and

Figure 7 depicts an alternative clip for adjustment of a maternity bra according to the present invention.

DETAILED DESCRIPTION

As shown in Figure 1, a typical maternity bra 100 comprises a support structure made up of shoulder straps 102 which support the bra 100 on the wearer's shoulders, and a bra band 104 for extending around a user's ribcage, comprising two wings 106 and a

central panel or bridge 108. The straps 102 are typically provided with adjustment mechanisms 103 for varying the length of the straps 102 to fit the bra 100 to the wearer.

At the outermost end of each wing, an attachment region 110 is provided. Typically, hooks 112 and loops 114 are provided for securing the bra 100 at the user's back. However, any other suitable attachment mechanism may be used. Alternatively, the attachment region 110 may be provided at the front of the bra 100 in the bridge region 108, with a continuous wing 106 extending continuously around the wearer's back. Typically, a number of sets of loops 114 are provided to allow for variation in the tightness of the bra 100 on the wearer.

While shown as having a separation in Figure 1, the wings 106 and bridge 108 may form a single continuous piece in certain designs. Likewise, while shown with a distinct separation in Figure 1, the shoulder straps 102 and the wings 106 may likewise form a single continuous piece.

The maternity bra 100 is further provided with two breast-supporting cups 116 attached to the support structure. The cups 116 define a cup size, which defines the difference in protrusion of the cups 116 from the band 104. The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting a 2 cm difference between the protrusion of the cups 116 from the band 104. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc.

The cups 116 may be stitched to the bra band 102. At least one of the cups 116, is in detachable attachment with the corresponding strap 102. In particular, this is achieved at attachment point 118 where a hook 120 attached to the bra strap 102 engages with a clasp 122 attached to the cup 116. The hook 120 and the bra strap adjuster 103 are set such that in the closed position, the cup size of the bra 100 fits the wearer's breasts. In Figure 1, the left cup 116 is shown attached to its attachment point 118, which the right cup 116 is unattached. In this manner, the wearer is able to detach the cup 116 to expose their breast for feeding or for breast pumping. Once this is completed, the cup 116 is reattached and the maternity bra 100 continues to function as a normal bra.

While in the depicted embodiments, a hook 120 is shown on the bra strap 102 and a clasp 122 is shown on the cup 116, it is appreciated that the provision of these may be reversed, or that alternative attachment mechanisms may be used.

In other embodiments, the detachable attachment point 118 may be provided at a different location, such as at the attachment between the bra band 104 and the cup 116. The mechanism for such an attachment point is the same as described above.

Figure 2A and 2B depict a clip 200 according to the present invention, along with a clasp 122 shown in isolation from the bra cup 116 it is normally attached to. The clip 200 is provided with a material pathway 203 which receives a portion of the bra strap 102. In the particular embodiment of these Figures, the clip 200 is substantially U-shaped, with a narrowing profile towards its open end 202. However, it is appreciated that any other suitable shape with a material pathway may be used, such as an S-shape or E-shape. The clip 200 is designed to be attached to the bra strap 102 in a releasable manner, with the slot 203 acting as a support engaging mechanism. The releasable manner means that the clip 200 may be simply removed from the bra 100 without causing any damage to the functioning of the bra 100. To enhance the ease of attachment, the clip 200 may be provided with outwardly extending wings 204 which help direct the bra strap 102 into the clip 200. The clip 200 is further provided with a hook 220 acting as a cup engaging mechanism which can engage with the clasp 122.

Figures 3A, 3B and 3C show the clip 200 being attached to a bra strap 102 in order to provide a second attachment point 228 for the clasp 122 to attach to, and hence to provide a second cup size for the bra 100. In this particular embodiment, the clip 200 is attached in a portion of strap 102A below the original attachment point 118 and hence the second attachment point 228 is likewise below the original attachment point. This results in a second cup size larger than the first cup size. In preferred embodiments, as shown in these Figures, the clip 200 engages with the support structure in a direction transverse to the direction in which it engages with the cup.

Figures 4A and 4B show how a wearer is able to move between the first and second cup sizes. In Figure 4A, the cup 116 is attached at the first attachment point 118 to provide a first cup size. The wearer then disengages the clasp 122 from the hook 120 at the first engagement point 118. As shown in Figure 4B, the clasp 122 is then engaged with

the hook 220 at the second engagement point 218. In this manner, the wearer is easily able to transition between the two cup sizes.

Figures 5 and 6 show an alternative design for a clip 300. This clip 300 is substantially "E-shaped", with a back portion 301 and first, second and third prongs 303A, 303B, 303C extending transverse from this back portion 301. The three prongs 303A, 303B, 303C are spaced apart along the length of the back portion 301. The first and third prongs 303A, 303C are provided with attachment clips 305A, 305B.

These attachment clips 305A, 305B are engageable with the clasp 122 of a bra to provide the second cup size. Depending upon the orientation of the clip 300, one or the other of the attachment clips 305A, 305B will be used to attach the clasp 122 of the bra. By providing these clips 305A, 305B on both of the first and the third prongs 303A, 303C the clip is easily reversible so it can be used on either side of the bra. Preferably the clip 300 is also symmetrical, to aid the reversibility of the clip 300.

Figure 6 shows the clip 300 attached to a bra. As can be seen, the first and third prongs 303A, 303C extend on the front side of the bra strap, with the second prong 303B extending on the rear side of the bra strap. In this manner, the clip 300 is attached to the strap. In preferably embodiments, a grip-enhancing member 307 such as a number of projections and/or roughened patches can be provided on the second prong 303B in order to strengthen this grip.

In alternative embodiments, the attachment clip could be provided on the second, centremost prong 303B. In such an arrangement, the centremost prong 303B would be on the outside of the bra, with the first and third prongs 303A, 303C on the inside.

The provision of the attachable clip allows maternity bras already owned by the wearer to be quickly transformed into bras with quick switchable double cup size options. This allows the use of integrated wearable breast pumps which increase the user's cup size. This allows more design freedom for the breast pump in terms of size and shape, while still allowing the user to discretely pump with the pump held within their bra. By allowing conversion of the user's existing maternity bras, they are not forced to purchase specially designed bras to wear with the pump. As such, the present invention allows a

user to discretely switch between the two configurations, and insert the pump without any complex adjustment or removal of clothing.

Preferably, the clip will be relatively unobtrusive in size and shape and hence can be left in place when the bra is first put on and used when necessary. To this end, the clip is preferably machine washable without significant damage or degradation.

In some embodiments, the clip may be switchable between positions for engaging with each cup so that a single clip may be used on either side of the bra. To achieve this, the clip is preferably reversible. This may provide the user with a visual indication of which breast has produced milk most recently so switching can take place.

An alternative embodiment may be provided, with an extendable clip as shown in Figure 7. In such an embodiment the clip is attached to the hook 120 on the strap 102 in a releasable manner, with the clasp 122 attached to an expandable portion of the clip. The clip is then able to expand between an unexpanded state where the clasp 122 is held in substantially the same position as the first attachment point 118 to provide the first cup size, and an expanded state, where the clasp 122 is held in a second position away from the first attachment point 118 to provide the second cup size.

For example, an elongate clip with first and second opposite ends may be provided. A first attachment point for attaching to the hook 120 is provided at the first end, and a second attachment point for attaching to the clasp 122 is provided at the second end. The elongate clip is hinged between the two ends, such that the clip can be folded between an elongate configuration to a closed configuration where the second end touches the first end. A clasp can be provided on the clip to hold the second end in this closed configuration. Thus, in the closed position the clasp 122 is held in substantially the same location as the first attachment point 118 to provide the first cup size, and in the open position the clasp is held away from the first attachment point 118 to provide the second cup size.

Other extendable clip embodiments are also possible, for example sliding clips or elastic clips.

CLAIMS:

1. A maternity bra system comprising:

a maternity bra comprising:

a support structure comprising shoulder straps and a bra band; and

a first and a second cup each attached to the support structure to provide a first cup size, at least one cup being detachable from the support structure at an attachment point,

the system further comprising:

a clip comprising a first engagement mechanism and at least one second engagement mechanism(s), the clip being attachable in a releasable manner to the support structure at a first position via the first engagement mechanism and attachable in a releasable manner to one of the detachable cups via the second engagement mechanism to provide a second cup size different to the first cup size.

2. The maternity bra system of claim 1, wherein the clip is configured to be attached to the support structure at a position away from the attachment point.

3. The maternity bra system of claim 2, wherein the clip is attachable to the support structure at a plurality of non-discrete positions.

4. The maternity bra system of claim 1, wherein:

the clip is extendable between an unextended and an extended state, and attaches to the support structure at the attachment point;

the first cup size is providable when the at least partially detachable cup is attached to the clip when the clip is an unextended state;

the second cup size is providable when the at least partially detachable cup is attached to the clip when the clip is in an extended state.

5. The maternity bra system of any preceding claim, wherein the attachment point is on at least one of the shoulder straps.

6. The maternity bra system of any preceding claim, wherein the second cup size is larger than the first cup size.

7. A clip for use in a system according to any preceding claim, the clip comprising first and section engagement mechanisms and being attachable in a releasable manner to a support structure of a maternity bra with the first engagement mechanism and an at least partially detachable cup of a maternity bra with the second engagement mechanism to provide a second cup size which is different to a first cup size providable when the cup is attached to the support structure of the bra at an attachment point.

8. The maternity bra system or clip of any preceding claim, wherein the first engagement mechanism engages with the support structure in a first direction and the second engagement mechanism engages with the cup in a second direction transverse to the first direction.

9. The maternity bra system of clip of any preceding claim, wherein the second engagement mechanism is one or more of a hook or a snap or a clip.

10. The maternity bra system or clip of any preceding claim, wherein the clip further comprises two distinct second engagement mechanisms which can be used interchangeably dependent upon the orientation of the clip.

11. The maternity bra system or clip of any preceding claim, wherein the clip comprises a material pathway with an opening for receiving a portion of the support structure as the first engagement mechanism for securing the clip to the bra.

12. The maternity bra system or clip of claim 11, wherein the clip is substantially U-shaped, and the material pathway is between the arms of the U.

13. The maternity bra system or clip of any of claims 1 to 11, wherein the clip comprises three prongs extending from a central support, the three prongs arranged as a central prong and two outer prongs so as to receive the support structure on one side of the central prong and on the opposite side of each respective outer prong, at least one prong being provided with the second engagement mechanism.

14. The maternity bra system or clip of claim 13, wherein both outer prongs are each provided with a respective second engagement mechanism.

15. A method of adjusting the cup size of a maternity bra, comprising:

providing a maternity bra comprising:

a support structure comprising shoulder straps and a bra band; and

a first and second cup each attached to the support structure to provide a first cup size, at least one cup being detachable from the support structure at an attachment point,

providing a clip comprising first and section engagement mechanisms;

attaching the first engagement mechanism of the clip in a releasable manner to a first position of the support structure of the maternity bra;

attaching one of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

16. The method of claim 15, further comprising the step of inserting a breast pump into the one of the detachable cup.

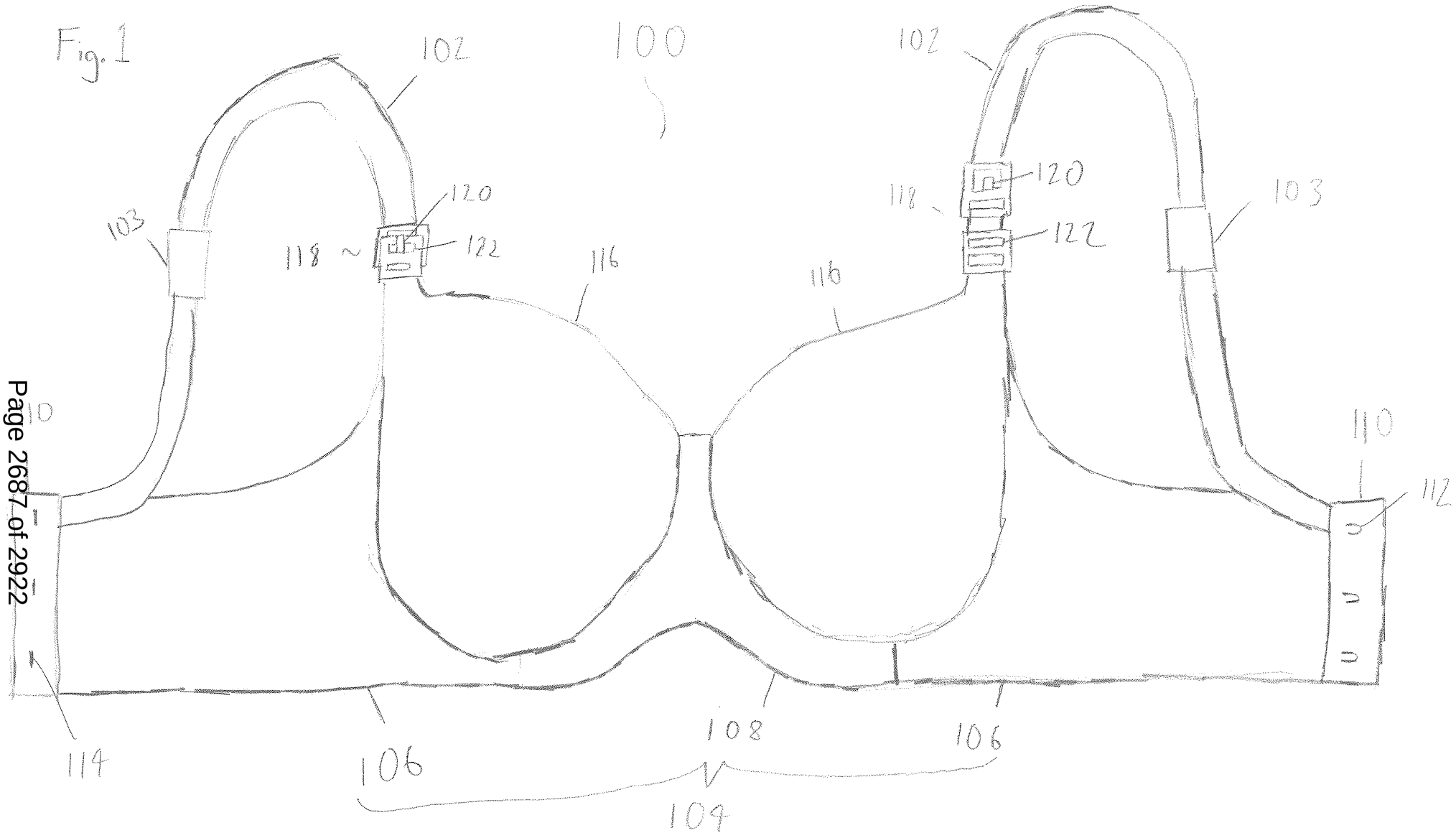
17. The method of claim 15 or 16, further comprising the steps of:

detaching the first engagement mechanism of the clip from the first position support structure of the maternity bra;

attaching the first engagement mechanism of the clip in a releasable manner to a second position of the support structure of the maternity bra; and

attaching the other of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

Fig. 1



PRIOR ART

Page 2687 of 2922

Fig. 2A

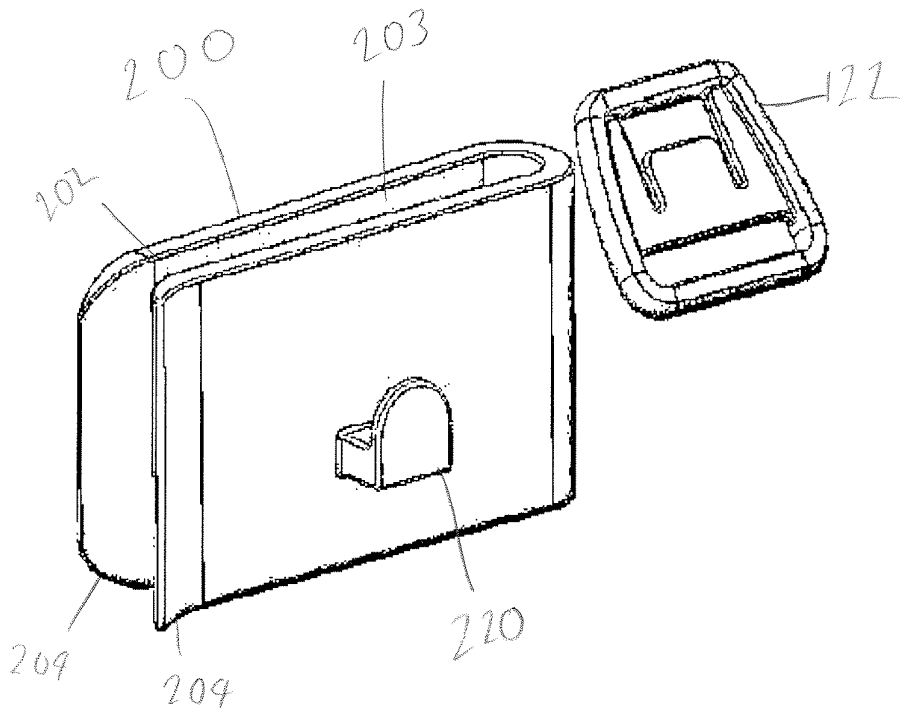


Fig 2B

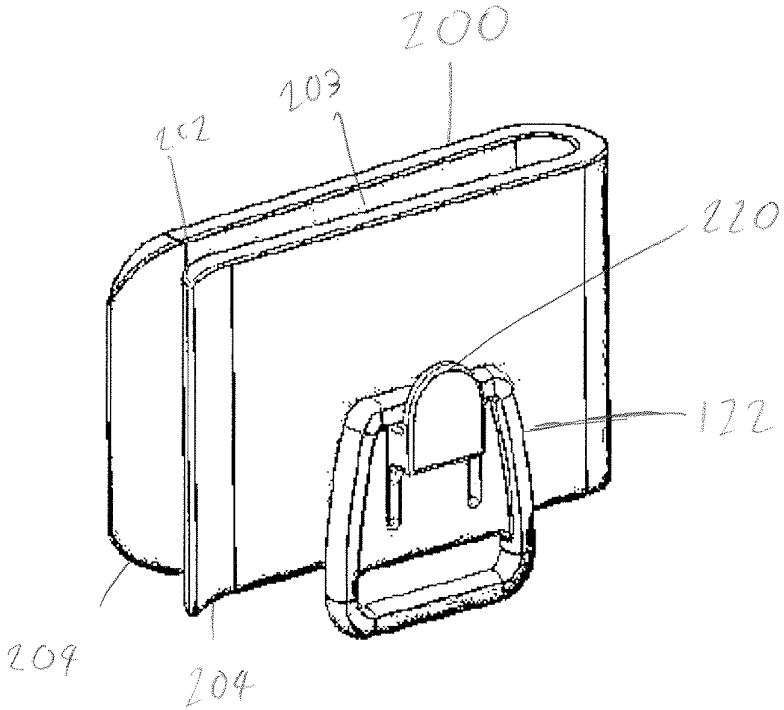


Fig. 3A

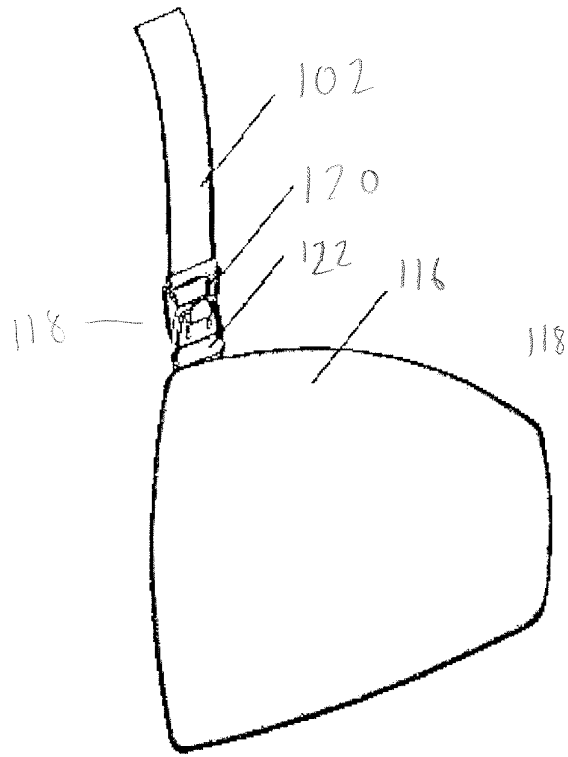


Fig. 3B

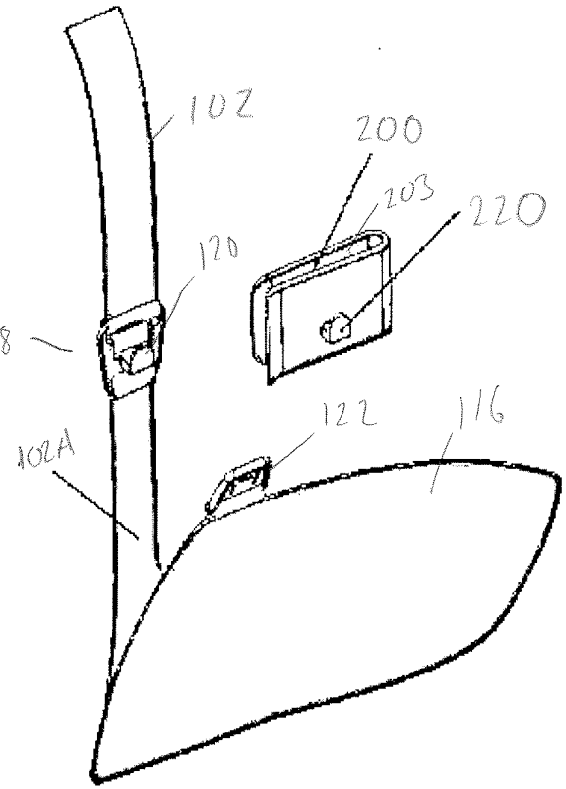


Fig. 3C

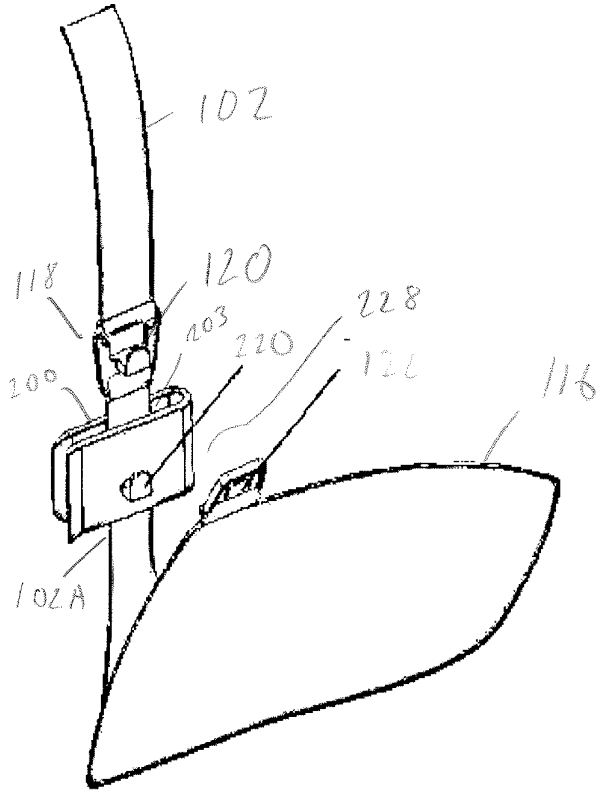


Fig. 4A

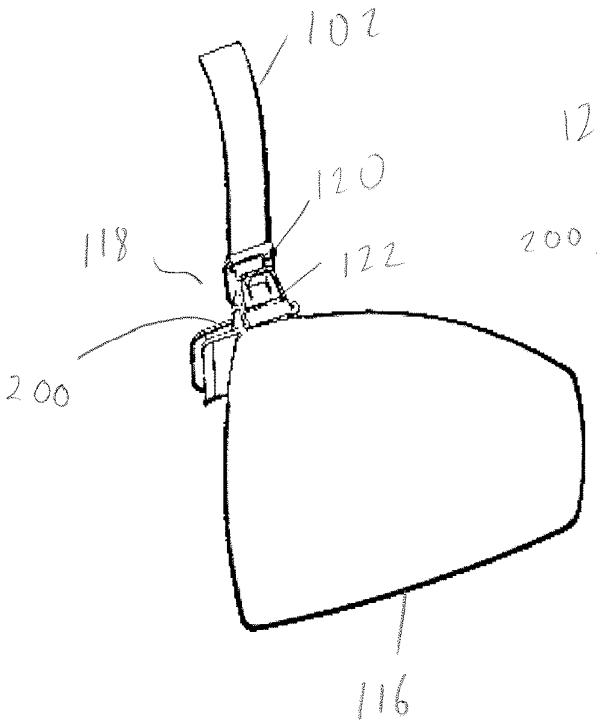
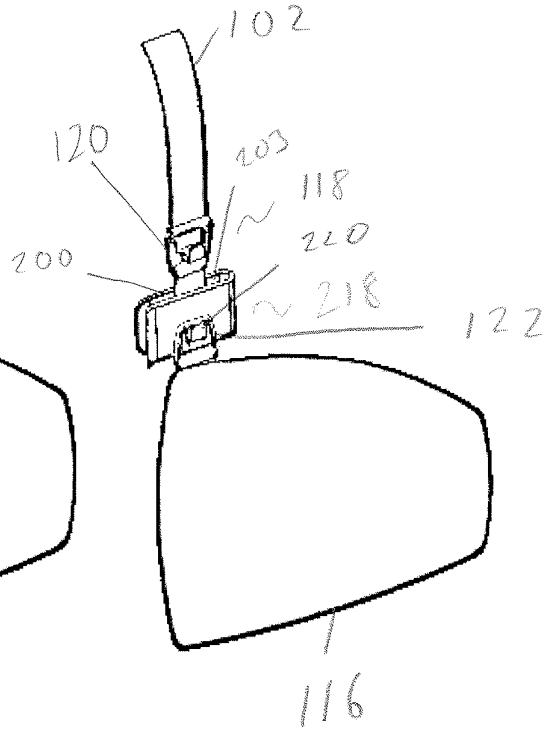


Fig. 4B



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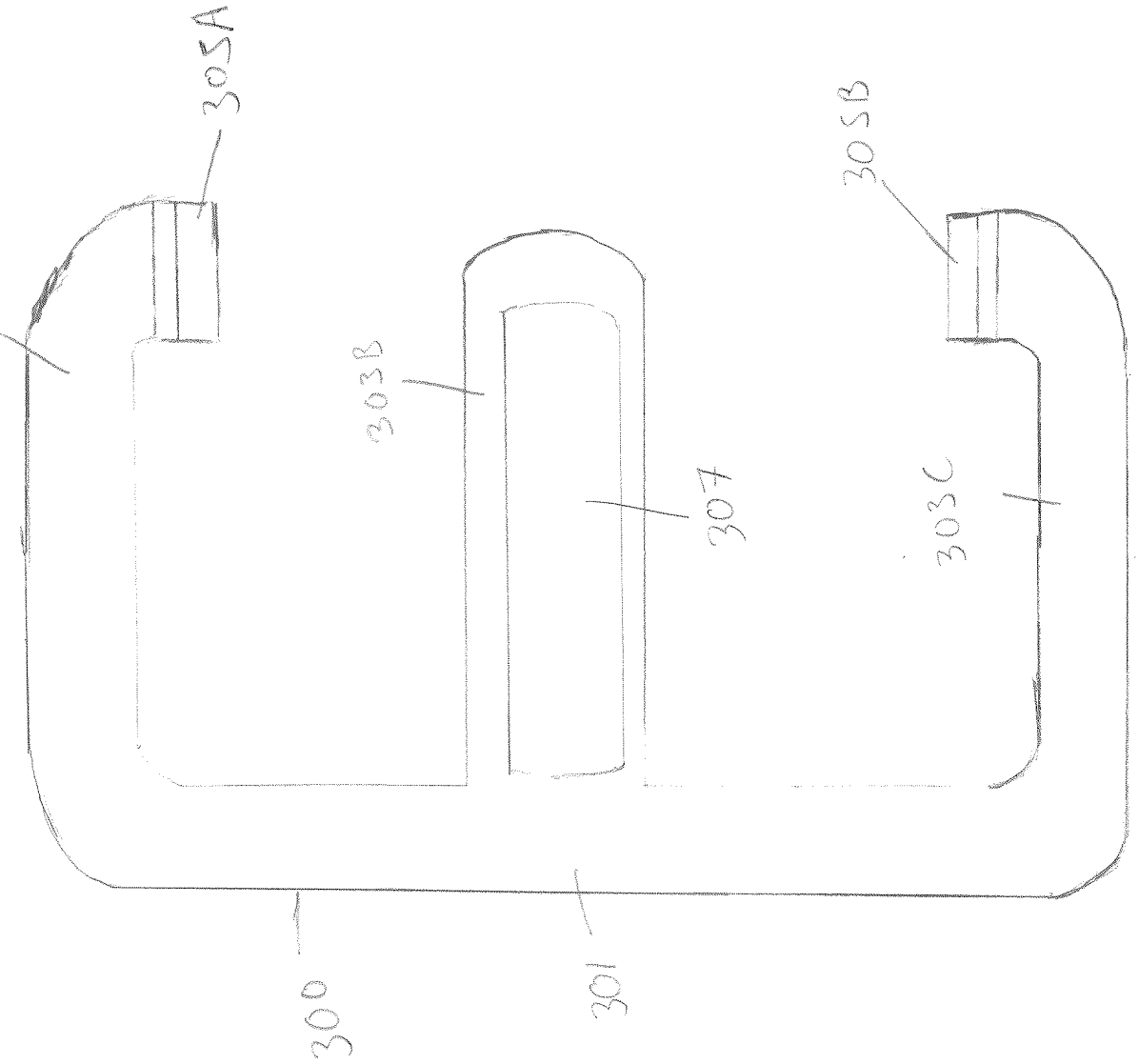
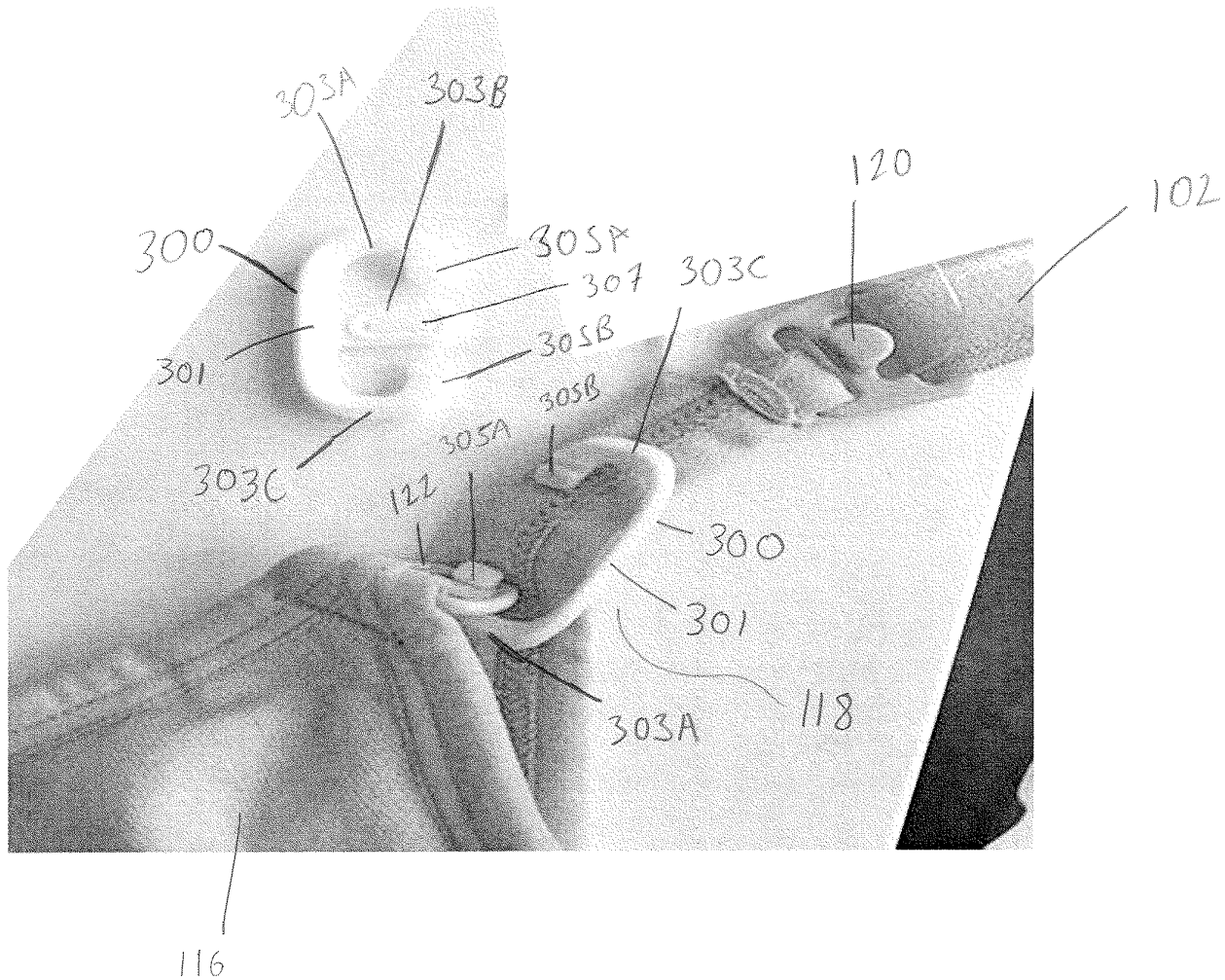


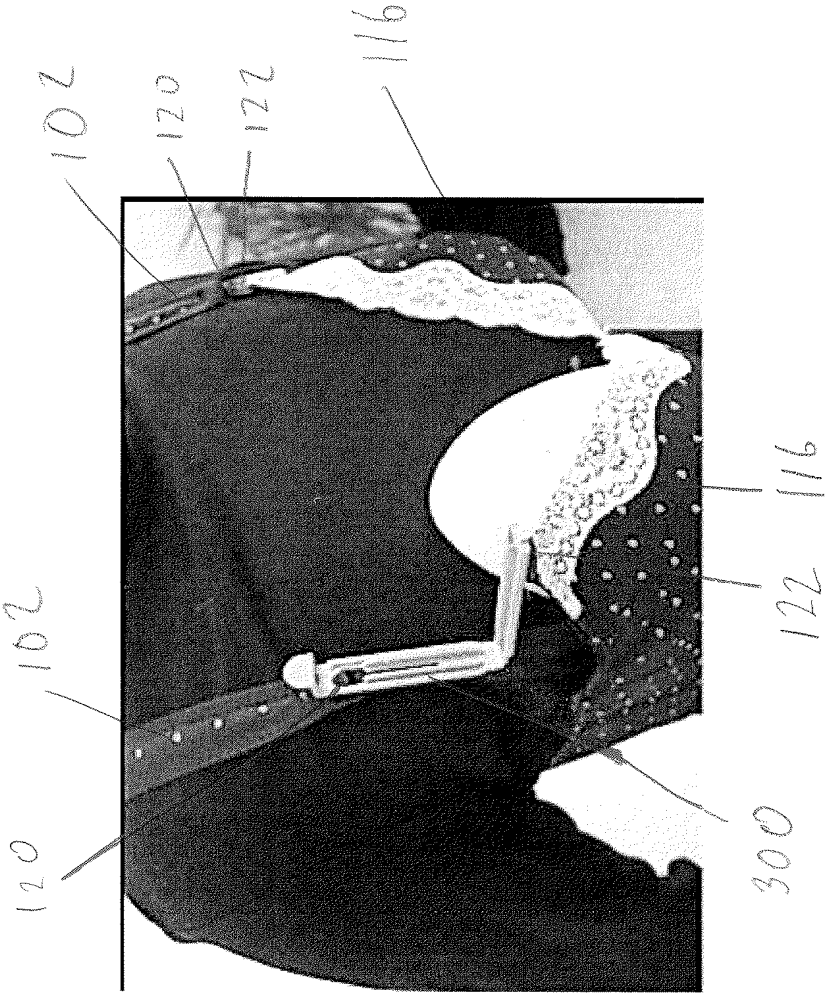
FIG 5

Fig. 6


303A
303B
300
305A
307
303C
120
102
301
305B
305B
305A
303C
122
300
301
118
303A
116

7/7

Fig 7



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Application number GB 1709564.7

1.	Your reference	**MJD/P153993GB00**
2.	Full name, address and postcode of the applicant or of each applicant	**CHIARO TECHNOLOGY LIMITED** **Second Floor 63-66 Hatton Garden** **London EC1N 8LE** **Greater London** **United Kingdom**
	Patents ADP number *(if you know it)*	**11287869002**
3.	Title of the invention	**A LIQUID LEVEL MEASUREMENT SYSTEM**
4.	Name of your agent *(if you have one)*	**Boult Wade Tennant**
	"Address for service" to which all correspondence should be sent. This may be in the European Economic area or Channel Islands (see warning note below) *(including the postcode)*	**Boult Wade Tennant** **Verulam Gardens** **70, Gray's Inn Road** **London WC1X 8BT** **United Kingdom**
	Patents ADP number *(if you know it)*	**42001**
5.	Priority declaration: Are you claiming priority from one or more earlier-filed patent applications? If so, please give details of the application(s)	

Country	Application number	Date of filing	PDAS Access Code

6.	Divisionals etc: Is this application a divisional application, or being made following resolution of an entitlement dispute about an earlier application. If so, please give the application number and filing date of the earlier application	Number of earlier UK application	Date of filing *(day / month / year)*
7.	Inventorship: (Inventors must be individuals not companies) Are all the applicants named above also inventors?	**No**	
8.	Are you paying the application fee with this form?	**Yes**	

9. Accompanying documents: please enter the number of pages of each item accompanying this form.

   Continuation sheets of this form

   Description: **12**

   Claim*(s)*: **3**

   Abstract: **n/a**

   Drawing*(s)*: **4**

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10. If you are also filing any of the following, state how many against each item.

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    Statement of inventorship and right to grant of a patent (Patents Form 7): **1**

    Request for search (Patents Form 9A): **1**

    Request for a substantive examination (Patents Form 10): **0**

    Any other documents (please specify): **PDAS Registration Form**

11. I/We request the grant of a patent on the basis of this application.

    Signature: **/DRAPER, Martyn John/** Date: **15 Jun 2017**

12. Name, e-mail address, telephone, fax and/or mobile number, if any, of a contact point for the applicant

    DRAPER, Mr Martyn
    Email: boult@boult.com
    Telephone: 020 7430 7500
    Fax: 020 7430 7600

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A LIQUID LEVEL MEASUREMENT SYSTEM

BACKGROUND

The present invention relates to a sensing mechanism for detecting the level of liquid in a container. In a particular arrangement, the present invention relates to such a sensing mechanism when used along with a breast pump.

In the context of breast pumps, it is useful to measure the quantity of expressed milk. One way to do this is to have a clear container affixed to the breast pump, through which the level of expressed milk inside the container can be visibly determined. However, such visual determinations are not always possible, for example in a breast pump that collects milk while being worn inside a maternity bra.

An existing apparatus for detecting the level of liquid inside a container of a breast pump is that disclosed in US 2016/296681. In this apparatus, a sensing mechanism is provided at the top of a container, which measures droplets of liquid, specifically breast milk, entering the container. By measuring the properties of these droplets entering the container, the apparatus can determine the quantity of liquid which enters the container. In this apparatus, an accurate indication of the level of liquid in the container is reliant on the sensing mechanism being able to accurately record every droplet entering the container. Particularly at times when large flow rates of liquid enter the container, this accuracy cannot be guaranteed leading to significant cumulative errors. An accurate indication of the level of liquid in the container in this apparatus is also reliant on the sensing mechanism always being on during the pumping process, so that power consumption of the sensing mechanism is correspondingly high.

In view of the above, there is the need for an improved way to determine the level of liquid inside a container connected to a breast pump.

SUMMARY OF THE INVENTION

According to a first aspect of the present invention, there is provided a breast pump comprising:

a pump module for pumping milk from a breast, the pump module being contained within a housing comprising a coupling;

a container attachable to the housing via the coupling to receive milk from the pump;

a sensing assembly within the housing and comprising at least one optical emitter operable to emit optical radiation towards the surface of the body of milk held in the container when the housing is connected to the container, and an optical receiver for receiving the reflected radiation from the surface of the milk; and

a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the milk inside the container based on the reflected radiation received by the optical receiver.

By determining the level of milk inside the container based on reflected radiation from the surface of the milk in the container, there is no need to monitor the individual droplets of milk entering the container, such that the sensing assembly can avoid errors associated with measuring these droplets. Furthermore, by not needing to measure these droplets, the sensing assembly from the breast pump need not always be on during the pumping process.

Preferably, the at least one optical emitter comprises at least two optical emitters. In this way, the sensing assembly from the breast pump can determine the level of milk inside the container more accurately and irrespective of the orientation of the liquid level inside the container.

Preferably, each optical emitter is equidistant from the optical receiver. In this way, the controller can more easily calculate the level of the milk inside the container based on the reflected radiation originating from each optical emitter.

Each optical emitter may be operable to emit radiation at a different wavelength, or at a different time, than the other optical emitters. In this way, the controller can more easily process the signals from the optical receiver, and more easily distinguish between the radiation emitted by each of the optical emitters.

Preferably, the optical emitter may emit radiation in the visible range of wavelengths. Alternatively it may be UV or IR light. The emitted wavelength is preferably between 10nm and 1mm.

The signals from the optical receiver preferably comprise information relating to the intensity of the radiation received by the optical receiver.

Preferably, the sensing assembly comprises at least one accelerometer electrically connected to the controller. In one embodiment, the controller may be configured to record an accelerometer parameter from the accelerometer, and determine whether the accelerometer parameter exceeds a predetermined threshold. The predetermined threshold may be indicative of an excessive acceleration, which might cause sloshing of milk inside any container connected to the breast pump.

In some cases, the coupling may be a screw thread.

Preferably, the breast pump is sized to be similar to that of a female breast. On this basis, the breast pump is preferably no longer than 20cm in any given linear direction; more preferably no longer than 18cm in any given linear direction; and even more preferably no longer than 15cm in any given linear direction.

The breast pump may contain any suitable power source, such as a battery. The power source is preferably located in the housing.

In some cases, the container may comprise a window through which optical radiation can pass, wherein when the container is connected to the housing, radiation is operable to pass between the optical emitters/receiver and the inside of the container via the window. In other cases, the container may be made entirely of a material through which the optical radiation can pass.

When the container is connected to the housing, each optical emitter and the optical receiver are preferably located adjacent to the container, to ensure reliable transmission of radiation between the device and the container.

In this case, the portion of the container adjacent to each optical emitter and the optical receiver preferably comprises a surface inside the container which comprises at least one channel and/or feature for directing milk away from each optical emitter and/or the optical receiver. In this way the formation of milk on this surface, which would cause erroneous signals from the optical receiver, can be inhibited.

To further inhibit the formation of milk in the vicinity of each optical emitter/receiver, the portion of the container adjacent to each optical emitter and the optical receiver may comprise a surface inside the container which comprises an oleophobic and/or hydrophobic coating.

Preferably, the container has a volumetric capacity of no more than 200ml. These volumetric capacities are particularly relevant when the container is a baby bottle.

It will be appreciated that the sensing assembly from the above breast pump has applications in other fields. Thus according to a second aspect of the present invention, there is provided a sensor module operable to be connected with a container for holding liquid, and suitable for use in detecting the level of liquid inside the container, the sensor module comprising:

a housing having a coupling for attachment to the top of the container;

a sensing assembly within the housing and comprising at least two optical emitters operable to emit optical radiation towards the surface of the body of liquid held in the container when the housing is connected to the container, and an optical receiver for receiving the reflected radiation from the surface of the liquid; and

a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the liquid inside the container based on the reflected radiation received by the optical receiver.

Existing prior art for such a sensor module is the apparatus disclosed in RU2441367. In this apparatus, the container is an industrially sized milk tank, which only includes a single laser mounted at the top of the tank. Whilst this apparatus is suited for large-sized containers, which do not move in use, the apparatus is less-suited for applications where the container moves in use, or where the liquid level inside the container is non-perpendicular to the laser beam shone into the container. In contrast, the sensor module described above can be used in a variety of different applications, is conveniently located within a housing, and which by virtue of it having at least two optical emitters, can determine the level of liquid even inside containers of irregular shapes, and which can determine the level of liquid inside a container irrespective of the orientation of the liquid level inside the container.

Although not fully recited herein, it will be appreciated that the sensor module according to the second aspect of the invention may include any or all of the optional features described in relation to the breast pump from the first aspect of the present invention.

According to a third aspect of the present invention, there is provided a collar incorporating the sensor module according to the second aspect of the invention, wherein the collar comprises a first end having the coupling, and a second end having a second coupling for attaching the collar to a lid of the container.

In the above case, the second coupling may be a screw thread.

According to fourth aspect of the present invention, there is provided a lid attachable to a container, wherein the lid comprises the sensor module according to the second aspect of the invention.

DESCRIPTION OF THE FIGURES

Figure 1A shows a sectional view of a device being used to determine the level of liquid in a container; and

Figure 1B shows a sectional view of the device and the container from Figure 1A being used at a different orientation.

Figure 2 shows a sectional view of the device and the container from Figure 1A being used whilst undergoing acceleration.

Figure 3 shows a sectional view of the device from Figure 1A being used as part of a breast pump assembly.

Figure 4 shows a sectional view of a device connected between a container and its lid, and which is operable to determine the level of liquid inside the container.

DETAILED DESCRIPTION

With reference to Figures 1A and 1B, there is shown a device 10 for use in detecting the level of liquid inside a container 100.

The device 10 is formed of a housing 12 in which is located a sensing assembly 14 comprising a series of optical emitters 16 which are angled relative to, and each located equidistant from, an optical receiver 18. In operation of the device as will be described, each optical emitter 16 is operable to emit radiation which is received by the optical receiver 18.

The optical emitters 16 and the optical receiver 18 from the sensing assembly 14 are located in a portion 20 of the device 10 which faces the container 100 when the device 10 is connected to the container 100. The portion 20 of the device 10 containing the optical emitters 16 and the optical receiver 18 comprises a window 22 of material which is transparent to optical radiation. In this way, each of the optical emitters 16 and the optical receiver 18 have a line of sight through the window 22 into the container 100 when the device 10 is connected thereto.

A controller 30 comprising a CPU 32 and a memory 34 is provided in the device 10 for controlling the operation of the sensing assembly 14. An accelerometer 36 is also provided in the housing 10, which is operatively connected to the controller 30.

Operation of the device 10 when connected to the container 100 will now be described.

In a principal mode of operation, to determine the level L of liquid inside the container 100, the controller 30 instructs the optical emitters 16 to each emit radiation towards the surface of the liquid inside the container 100 at a given intensity. The optical receiver 18 receives the reflected radiation from each optical emitter 16 via the surface of the liquid and each of these intensities is recorded by the controller.

For each operation of the sensing assembly 14, the controller 30 records the intensities of radiation emitted by each of the optical emitters 16 as intensities IE_1; $IE_{2...}IE_n$ (where n is the total number of optical emitters), and records the intensities of radiation received by the optical receiver 18 from each of the optical emitters 16 as received intensities IR_1; $IR_{2...}IR_n$.

By comparing the emitted radiation intensities IE_1; $IE_{2...}IE_n$ with the received radiation intensities IR_1; $IR_{2...}IR_n$, the controller 30 calculates a series of intensity ratios IE_1:IR_1; IE_2:IR_2…IE_n:IR_n, which are then used to determine the level of the liquid inside the container. At the most basic level, if the intensity ratio of IE_1:IR_1 is the same as IE_2:IR_2,

given the optical emitters 16 are equidistant from the optical receiver 18, this indicates that the level of the liquid inside the container is parallel to the top of the bottle, as shown in Figure 1A. In contrast, if these two intensity ratios are different, this indicates that the liquid level is at a different angle, such as that shown in Figure 1B.

To accurately determine the level and the quantity of liquid inside the container 100, the controller 30 processes the recorded intensity ratios using a database located in the memory 34. The database contains an individual record for each container which is operable to connect with the device 10. Each record from the database contains a look-up table of information, which contains expected intensity ratios (IE_1:IR_1 and IE_2:IR_2) for the container 100 when filled at different orientations, and with different quantities of liquid.

By comparing the information from the look-up table with the recorded intensity ratios, the controller 30 calculates the level and quantity of liquid inside the container 100 and stores this information in the memory 34.

In situations where a container 100 to the device 10 contains no stored record in the database, the sensing assembly 14 can be used in a calibration mode to create a new record. In the calibration mode, the sensing assembly 14 is operated as the container is filled, and as it is located at different orientations. At each point during the calibration mode, the controller 30 calculates the recorded intensity ratios (IE_1:IR_1 and IE_2:IR_2) and stores them in the record relating to the container 100. For each set of recorded intensity ratios, the user includes information in the record relating to the orientation and fill level of liquid inside of the container 100.

To improve the accuracy of the results obtained by the device 10 during its use, the controller 30 when recording each intensity ratio also records a parameter from the accelerometer 36 relating to the acceleration experienced by the device 10. For each recorded acceleration parameter, the controller 30 determines whether the parameter exceeds a predetermined threshold acceleration parameter stored in the memory 34. The predetermined threshold is indicative of an excessive acceleration, which causes sloshing of liquid inside the container 100 connected to the device 10. In the event of a recorded acceleration parameter exceeding the predetermined threshold acceleration parameter, the controller 30 flags the recorded intensity ratios associated with the recorded acceleration parameter as being unreliable (due to sloshing).

Even without the use of the accelerometer 36, the controller 30 is nonetheless operable to determine whether a set of recorded intensity ratios occur during a period of excess acceleration. In this regard, for each set of intensity ratios recorded at a given time, the controller 30 checks whether any of these intensity ratios is of a predetermined order of magnitude different than the remaining recorded intensity ratios from the set. In the event that the controller 30 determines that this is the case, this indicates that the liquid inside the container has 'sloshed' as a result of the excess acceleration, as shown in Figure 2. In this event, the controller 30 flags the set of recorded intensity ratios as being unreliable.

It will be appreciated that instead of recording the relative intensities of radiation emitted by the optical emitters 16 with the radiation received by the optical emitter 18, the controller 30 could instead record the time taken for radiation emitted by each of the optical emitters 16 to be received by the optical receiver 18. In this arrangement, the look up table would instead contain time periods as opposed to intensity ratios.

In terms of the applications for the device 10, it will be appreciated that the device can be used in a wide variety of applications.

One possible application is the use of the device 10 to determine the level of liquid located within a container 100, such as a baby bottle, used as part of a breast pump assembly. In this arrangement, the device 10 is associated with a breast pump 200 which assists with the expression of milk from a breast. The breast pump may be located in the housing 12 of the device 10 as shown in Figure 3, or it may be realisably connected to the housing 12. Either way, the device 10 would be connectable to the container 100 such that milk expressed by the breast pump can pass from the pump via a channel 202 into the container 100.

Another application for the device 10 is as a collar for detecting the level/quantity of liquid in a container 100, such as a baby bottle, via its lid 102. An example of the device 10 being used as such a collar is shown in Figure 4. In this arrangement, the device 10 is located between the container 100 and the lid 102, and comprises a first end 42 having a first coupling 44 for attaching the collar to the lid 102. The device comprises a second end 46 having a second coupling 48 for attaching the device 10 to the container 100. In Figure 4,

the first and second couplings are shown as screw threads which engage with respective screw heads on the lid 102 and the container 100.

To allow the device 10 to pass liquid from the lid 102 to the container 100, the device comprises a channel 50 passing from the first end 42 to the second end 46.

In a further application, the device 10 may be integrated into the lid 102 of a container 100. In this application, the device 10 has a similar configuration to that shown in Figure 4, except that the first end 42 is covered and has no coupling 44.

It will be appreciated the device may be connected to a wide variety of different containers 100. In some applications, the container 100 may be a baby bottle, or a drinks bottle.

In certain applications, the container 100 connected to the device 10 may have a volumetric capacity of no more than 500ml, less than 400ml, less than 300ml, and/or less than 200ml. These volumetric capacities are particularly relevant when the container is a baby bottle/drink bottle.

It will also be appreciated that the container 100 connected to the device 10 may comprise an inside surface which comprises an oleophobic and/or hydrophobic coating. In this way, the container 100 is easy to clean between uses. When such a coating is applied to the portion of the container 100 which is adjacent to the optical emitters 16 and the optical receiver 18 from the device 10, this coating also helps prevent liquid from forming in front of these emitters/receiver, which might cause erroneous signals to be recorded by the optical receiver 18 from the sensing assembly 14.

To further reduce such erroneous signals, the portion of the container adjacent to the optical emitters and the optical receiver may comprise a surface inside the container having at least one channel and/or feature for directing liquid away from the optical emitters and/or the optical receiver.

To improve the accuracy of the sensing assembly 14, the container 100 may be made opaque to prevent ambient radiation outside the container 100 from reaching the optical receiver 18. Other possibilities to improve the accuracy to the accuracy of the sensing assembly 14 include the provision of a distinctive pattern/colour/texture on the bottom

inside surface of the container 100. In this way, the distinctive bottom inside surface can be used by the sensing assembly 14 to more easily calibrate itself to the container 100 on which the distinctive bottom inside surface is located. The distinctive bottom may also be used to help identify which container 100 the device is connected to, and thus which record should be used from the database when the device 10 is used.

To further improve the accuracy of the sensing assembly 14, the controller 30 may also be configured to use the recorded information from the accelerometer 36, in situations where the record acceleration is below the predetermined threshold acceleration parameter, to calculate a more accurate liquid level and/or quantity of liquid located inside the container which is compensated for acceleration.

In one particular arrangement, the controller 30 may poll the accelerometer 36 prior to each operation of the sensing assembly 14 to verify that the device 10 is not currently undergoing excessive acceleration. In the event of the controller 30 determining excessive acceleration in the device 10, the controller 30 would continually re-poll the accelerometer, and not operate the sensing assembly 14, until the parameter from the accelerometer is determined as being below the predetermined threshold acceleration parameter stored in the memory 34.

It will also be appreciated that for each container record stored in the database, the container record may comprise a plurality of look up tables, wherein each look up table is associated with a particular liquid used in the container, and wherein each look up table contains its own set of intensity ratios. In this way, the device 10 can more accurately determine the level/quantity of different liquids used in a particular container 100.

As described herein, the sensing assembly 14 has been described as having a plurality of optical emitters 16. It will be appreciated however that the sensing assembly could operate using a single optical emitter 16 and plurality of optical receivers 18. In this arrangement, each record from the database would contain a plurality of ratios relating to the emitted radiation from the optical emitter 16 as received by each of the optical receivers 18. In use of the device 10, the controller 30 would then similarly record the emitted radiation from the optical emitter 16 as received by each of the optical receivers 18. In an alternate arrangement, there may be provided a plurality of optical emitters 16 and a plurality of optical receivers 18, wherein each optical emitter 16 is associated with a respective optical

receiver 18. In its simplest arrangement, the sensing assembly 14 may comprise a single optical emitter 16 and a single optical receiver 18.

In certain configurations, the optical emitters 16 may together emit radiation having the same wavelength. In other configurations, the optical emitters 16 may each emit radiation having a different wavelength. In this latter configuration, the optical receiver 18 would then be able to determine which optical emitter 16 is associated with any given received radiation, based on the wavelength of the received radiation.

The optical emitters 16 may also each emit radiation at different times, such to allow the controller 30 to more easily process the signals from the optical receiver 18, and more easily distinguish between the radiation emitted by each of the optical emitters 16.

In relation to the electrical connection between the controller 30 and the sensing assembly 14, it will be appreciated this electrical connection may be either a wired/wireless connection as required.

Although not shown in the Figures, the device 10 herein described is preferably powered by a battery or some other power source located in the device 10. In other embodiments, the device 10 may be powered using mains electricity.

In one configuration, it is also envisaged that rather than the controller 30 comparing the information from the look-up table with the recorded intensity ratios to calculate the level and quantity of liquid inside the container 100, the controller 30 could instead process the recorded intensity ratios through a liquid-level equation stored in the memory 34. In this configuration, the liquid-level equation could be a generalised equation covering a family of different containers, or could be an equation specific to a container having a given shape and/or type of liquid inside.

It will also be appreciated that in some applications of the device 10, the device could be used to detect the level of a solid, as opposed to a liquid, in a container.

As used herein, the terms ‘optical emitter’ and ‘optical receiver’ are intended to cover sensors which can emit radiation in or close to the optical wavelength. Any type of radiation at or close to the optical wavelength is suitable provided that it does not have any harmful

effects. The exact wavelength is not important in the context of the invention. Such sensors thus include those which can emit visible radiation (such as radiation having wavelengths in the region of 400nm-700nm), and/or those which can emit IR radiation (such as radiation having wavelengths in the region of 700nm-1mm and/or those which can emit UV radiation (such as radiation having wavelengths in the region of 10nm to 400nm).

CLAIMS:

1. A breast pump comprising:

a pump module for pumping milk from a breast, the pump module being contained within a housing comprising a coupling;

a container attachable to the housing via the coupling to receive milk from the pump;

a sensing assembly within the housing and comprising at least one optical emitter operable to emit optical radiation towards the surface of the body of milk held in the container when the housing is connected to the container, and an optical receiver for receiving the reflected radiation from the surface of the milk; and

a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the milk inside the container based on the reflected radiation received by the optical receiver.

2. A breast pump according to claim 1, wherein the at least one optical emitter comprises at least two optical emitters.

3. A breast pump according to claim 2, wherein each optical emitter is equidistant from the optical receiver.

4. A breast pump according to claim 2 or 3, wherein each optical emitter is operable to emit radiation at a different wavelength, or at a different time, than the other optical emitters.

5. A breast pump according to any preceding claim, wherein each optical emitter is an IR optical emitter, and the optical receiver is an IR optical receiver.

6. A breast pump according to any preceding claim, wherein the signals from the optical receiver comprise information relating to the intensity of the radiation received by the optical receiver.

7. A breast pump according to any preceding claim, wherein the sensing assembly comprises at least one accelerometer electrically connected to the controller.

8. A breast pump according to any preceding claim, wherein the coupling is a screw thread.

9. A breast pump according to any preceding claim, wherein the breast pump is no longer than 20cm in any given linear direction.

10. A breast pump according to any preceding claim, wherein the breast pump contains a power source.

11. A breast pump according to any preceding claim, wherein the container comprises a window through which optical radiation can pass, wherein when the container is connected to the housing, radiation is operable to pass between each optical emitter/receiver and the inside of the container via the window.

12. A breast pump according to any preceding claim, wherein when the container is connected to the housing, each optical emitter and the optical receiver are located adjacent to the container.

13. A breast pump according to claim 12, wherein the portion of the container adjacent to each optical emitter and the optical receiver comprises a surface inside the container which comprises at least one channel and/or feature for directing milk away from each optical emitter and/or the optical receiver.

14. A breast pump according to claim 12 or 13, wherein the portion of the container adjacent to each optical emitter and the optical receiver comprises a surface inside the container which comprises an oleophobic and/or hydrophobic coating.

15. A breast pump according to any preceding claim, wherein the container has a volumetric capacity of no more than 200ml.

16. A sensor module operable to be connected with a container for holding liquid, and suitable for use in detecting the level of liquid inside the container, the sensor module comprising:

a housing having a coupling for attachment to the top of the container;

a sensing assembly within the housing and comprising at least two optical emitters operable to emit optical radiation towards the surface of the body of liquid held in the container when the housing is connected to the container, and an optical receiver for receiving the reflected radiation from the surface of the liquid; and

a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the liquid inside the container based on the reflected radiation received by the optical receiver.

17. A collar incorporating the sensor module according to claim 16, wherein the collar comprises a first end having the coupling, and a second end having a second coupling for attaching the collar to a lid of the container.

18. A collar according to claim 17, wherein the second coupling is a screw thread.

19. A lid attachable to a container, wherein the lid comprises the sensor module according to claim 16.

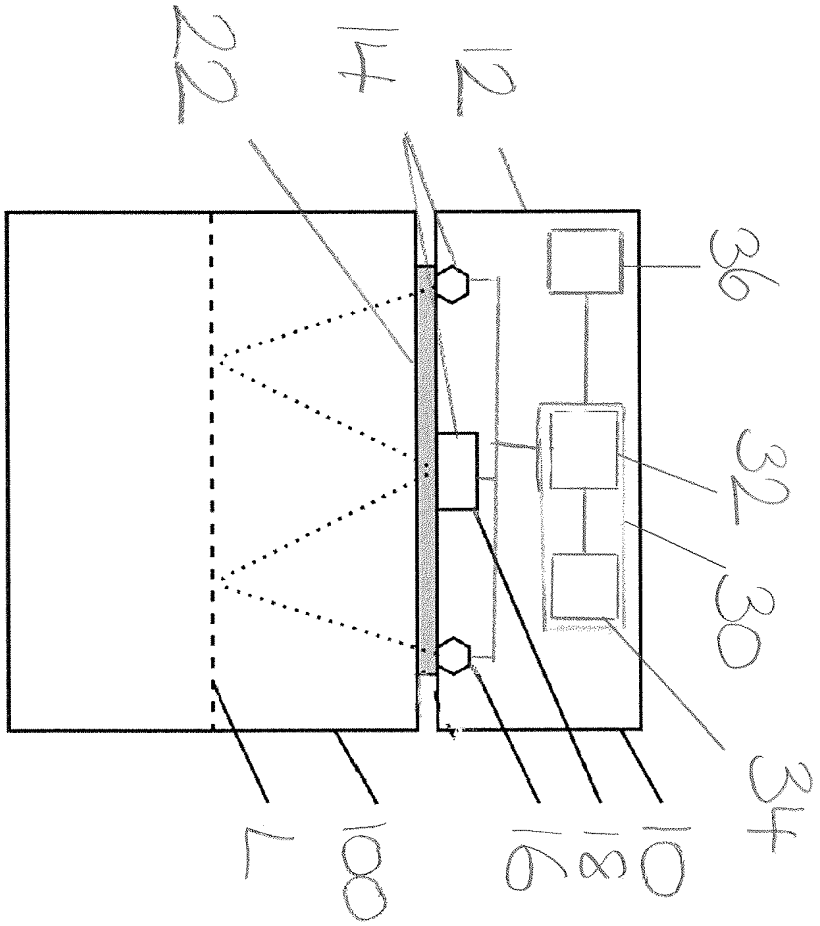

FIG 1A

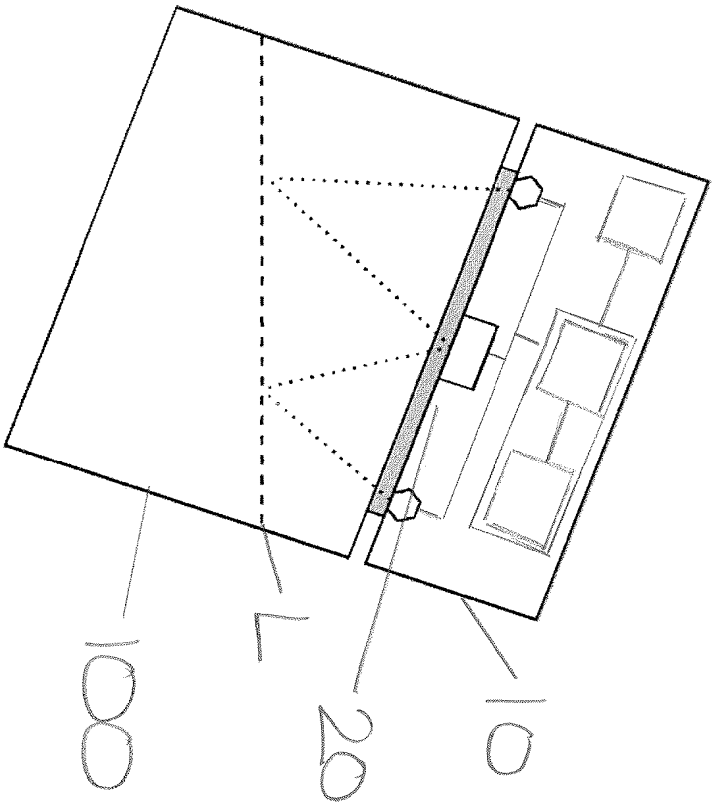

FIG 1B

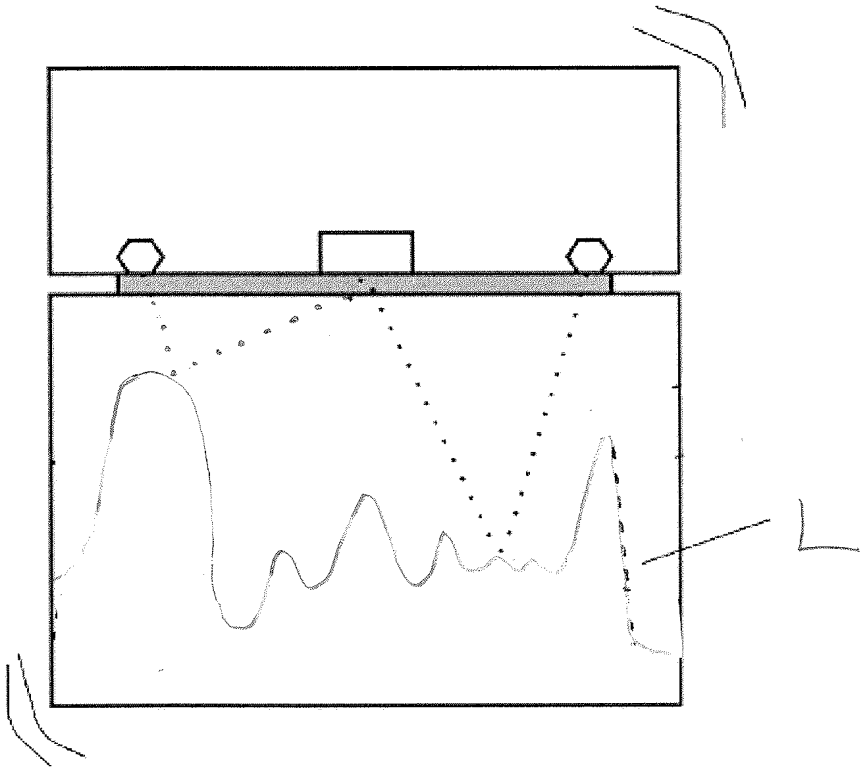

FIG 2

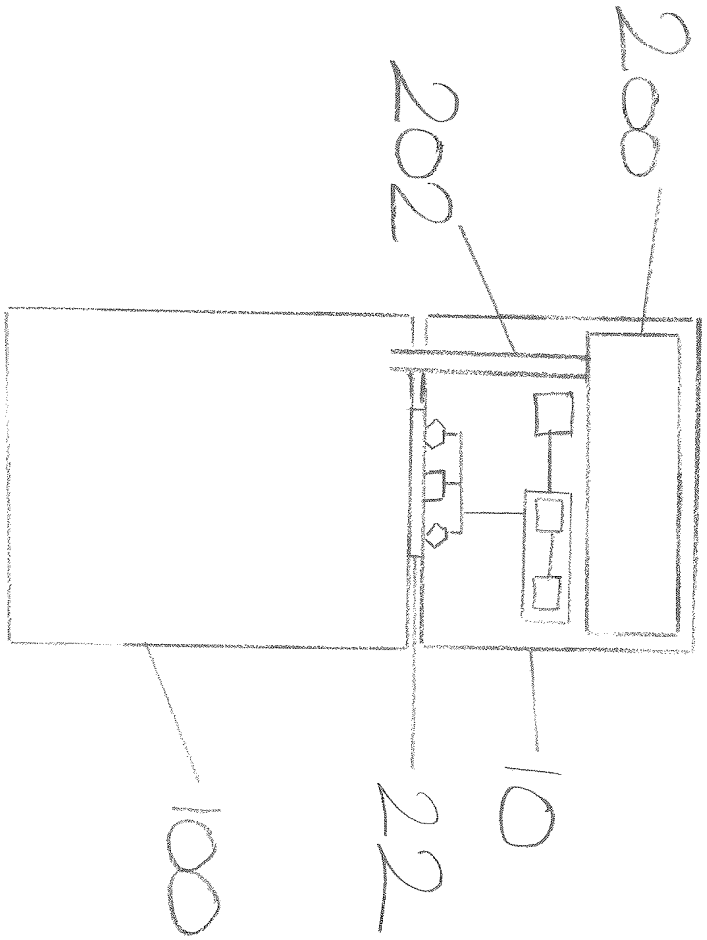

Fig 3

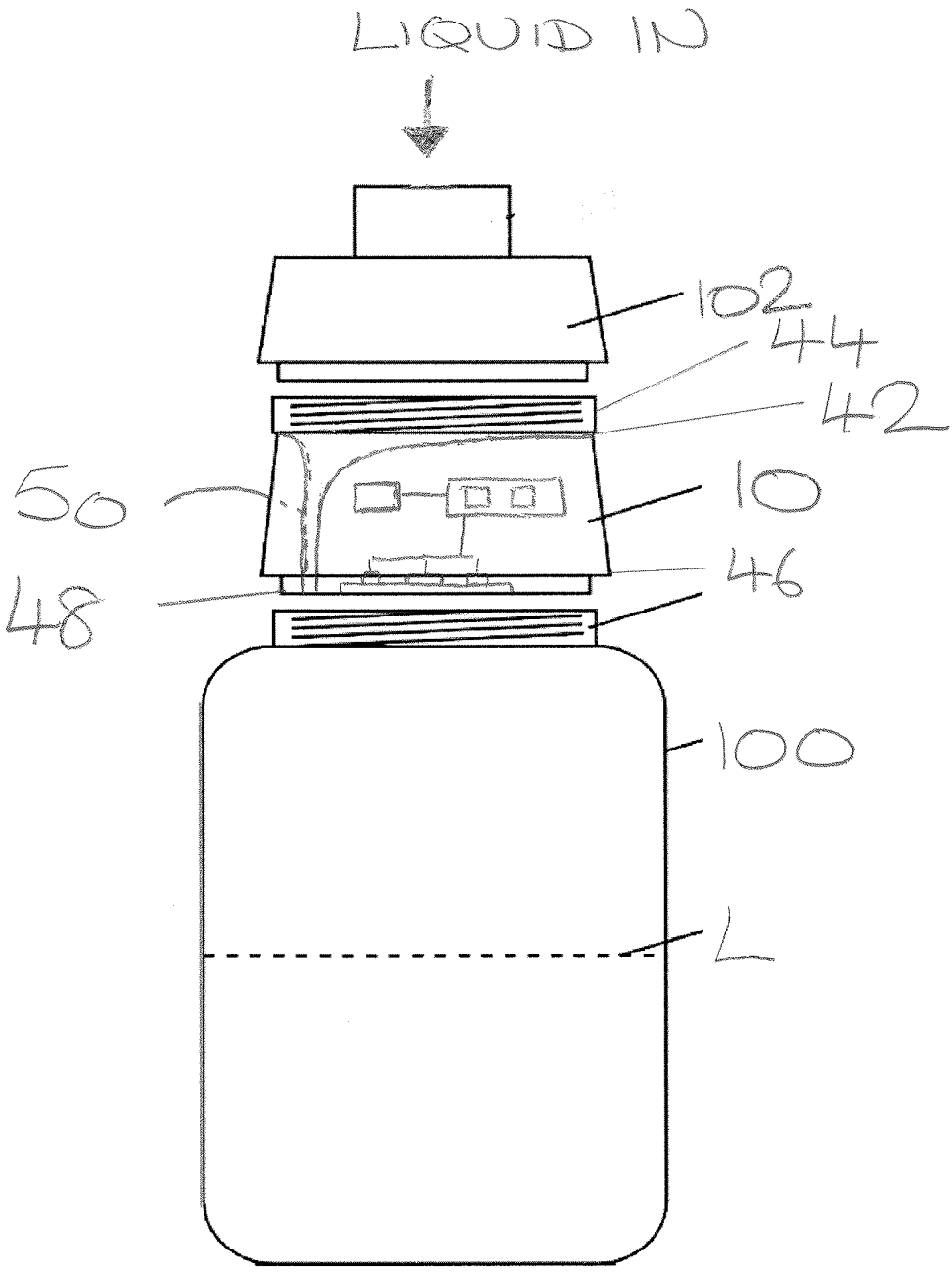

FIG 4.

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I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

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☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 78905

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I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

CHIARO TECHNOLOGY LIMITED

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	18 JULY 2018
Name	ANDREA ZITNA		
Title	CHIEF REVENUE OFFICER		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ Total of 1 forms are submitted.

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	BREAST PUMP SYSTEM

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 16/009,547 filed on 15 June 2018.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

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LEGAL NAME OF INVENTOR

Inventor: Jonathan O'TOOLE

Date (Optional): _____

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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LEGAL NAME OF INVENTOR

Inventor: Adam ROLLO Date (Optional): _____

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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LEGAL NAME OF INVENTOR

Inventor: Andrew CARR Date (Optional): _____

Signature: _____

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PATENT **Docket No. 373499.00049**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INVENTORS:	**Jonathan O'TOOLE et al.**	Confirmation No.
APPLICATION NO.	**TBD**	
FILED:	**Herewith**	Examiner:
CASE NO.	**373499.00049**	Group Art Unit:
TITLE:	**BREAST PUMP SYSTEM**	

FILED ELECTRONICALLY ON February 22, 2021

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUBMISSION OF INFORMATION DISCLOSURE
STATEMENT UNDER 37 CFR §§1.97 AND 1.98

Sir:

Submitted herewith for the above-identified application is an Information Disclosure Statement under 37 CFR §§1.97 and 1.98. Pursuant to 37 CFR §1.98(d)(1), Applicant has not provided copies of the foreign patent and non-patent literature cited in the accompanying Information Disclosure Statement ("IDS"), since copies of these publications were submitted in IDS's filed on June 15, 2018; December 7, 2018; or November 3, 2020, in parent Application No. 16/009,547, of which the present application is a continuation.

The Examiner is requested to initial a copy of the enclosed Form PTO-1449 and return a copy to applicant.

Respectfully submitted

February 22, 2021
Date

/Mark D. Simpson/
Mark D. Simpson, Esquire
Registration No. 32,942

SAUL EWING ARNSTEIN & LEHR LLP
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1500 Market Street, 38th Floor
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Application Number	
Filing Date	
First Named Inventor	Jonathan O'Toole
Art Unit	
Examiner Name	
Attorney Docket Number	373499.00049

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	1	2849881	A	1958-09-02	ANDERSON	
	2	4390024	A	1983-06-28	WILLIAMS	
	3	4535627	A	1985-08-20	PROST, et al.	
	4	5474683	A	1995-12-12	BRYANT, et al.	
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	8	6090065	A	2000-07-18	GILES	

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	Filing Date	
	First Named Inventor	Jonathan O'Toole
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

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	10	6328709	B1	2001-12-11	HUNG, et al.	
	11	6358226	B1	2002-03-19	RYAN	
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	19	7048519	B2	2006-05-23	FONG, et al.	

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	Filing Date	
	First Named Inventor	Jonathan O'Toole
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

	20	7201735	B2	2007-04-10	ATKIN, et al.	
	21	D548831	S	2007-08-14	CHARLEZ	
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	Filing Date	
	First Named Inventor	Jonathan O'Toole
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	Examiner Name	
	Attorney Docket Number	373499.00049

	31	8376986	B2	2013-02-19	VAN, et al.	
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	40	10039871	B2	2018-08-07	POLLEN, et al.	

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	Examiner Name	
	Attorney Docket Number	373499.00049

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020193731	A1	2002-12-19	MYERS, et al.	
	2	20040056641	A1	2004-03-25	MYERS, et al.	
	3	20040074281	A1	2004-04-22	LOBDELL, et al.	
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	First Named Inventor	Jonathan O'Toole
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

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	12	20110004154	A1	2011-01-06	VAN, et al.	
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	21	20140378895	A1	2014-12-25	BARACK	

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	Filing Date	
	First Named Inventor	Jonathan O'Toole
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

	22	20150217036	A1	2015-08-06	POLLEN, et al.	
	23	20150217037	A1	2015-08-06	POLLEN, et al.	
	24	20150283311	A1	2015-10-08	ALVAREZ, et al.	
	25	20160000980	A1	2016-01-07	ALVAREZ, et al.	
	26	20160058928	A1	2016-03-03	NOWROOZI, et al.	
	27	20160058929	A1	2016-03-03	MEDVEDEV, et al.	
	28	20160082165	A1	2016-03-24	ALVAREZ, et al.	
	29	20160082166	A1	2016-03-24	GUTHRIE, et al.	
	30	20160151551	A1	2016-06-02	FELBER	
	31	20160158424	A1	2016-06-09	CHEN, et al.	
	32	20160166745	A1	2016-06-16	AALDERS	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	Jonathan O'Toole
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

	33	20160206794	A1	2016-07-21	MAKOWER, et al.	
	34	20160220743	A1	2016-08-04	GUTHRIE, et al.	
	35	20160220745	A1	2016-08-04	GUTHRIE, et al.	
	36	20160256617	A1	2016-09-08	HANSEN	
	37	20160287767	A1	2016-10-06	SIMMONS, et al.	
	38	20160296681	A1	2016-10-13	GASKIN, et al.	
	39	20160310650	A1	2016-10-27	MAKOWER, et al.	
	40	20170021068	A1	2017-01-26	GASKIN, et al.	
	41	20170035951	A1	2017-02-09	TANAKA	
	42	20170043065	A1	2017-02-16	TAKEUCHI	
	43	20170072117	A1	2017-03-16	KURIHARA, et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
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	First Named Inventor	Jonathan O'Toole
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

	44	20170072118	A1	2017-03-16	MAKOWER, et al.	
	45	20170143879	A1	2017-05-25	OKAGUCHI	
	46	20170220753	A1	2017-08-03	GUTHRIE, et al.	
	47	20180021490	A1	2018-01-25	CHANG, et al.	
	48	20180110906	A1	2018-04-26	BARACK	

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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	3311982	DE	C2	1983-10-13	BATTELLE MEMORIAL INSTITUTE		
	2	9503280	EP	A2	1992-02-08	PIERBURG GMBH		
	3	9420158	WO	A1	1994-09-15	DEKA PRODUCTS LIMITED PARTNERSHIP		
	4	19750620	DE	A1	1999-06-02	SIEMENS AG, 80333 MUENCHEN, DE		

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	Jonathan O'Toole
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

	5	1586340	EP	A2	2005-10-19	SEA PROFIT (HONG KONG) LIMITED		
	6	2005114116	WO	A1	2005-12-01	LANE, JOHN, DENNIS; ESPARZA, JOSEPH, LUIS; NICHOLS		
	7	2005114113	WO	A3	2006-03-02	ACCU-GAUGE LIMITED		
	8	1430918	EP	B1	2008-05-14	MEDELA HOLDING AG		
	9	2344380	RU	C1	2009-01-20	GOSUDARSTVENNOE OBRAZOVATEL'NOE UCHREZHDENIE VYSSH		
	10	2009134271	WO	A1	2009-11-05	UTC POWER CORPORATION		
	11	2473022	GB	B	2011-12-14			
	12	2441367	RU	C2	2012-02-10	OBSHCHESTVO S OGRANICHENNOJ OTVETSTVENNOST'JU "NAU		
	13	2436277	EP	A1	2012-04-04	DREW, LORNA		
	14	2210628	EP	B1	2013-02-13	MEDELA HOLDING AG		
	15	2499248	GB	B	2014-04-02	ELIZABETH MORANA		

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	Jonathan O'Toole
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

	16	1404393	EP	B1	2014-12-24	MEDELA HOLDING AG		
	17	2015081459	WO	A1	2015-06-11	CHEN, JUNBO		
	18	2015116749	WO	A1	2015-08-06	CORNING INCORPORATED		
	19	2015120321	WO	A1	2015-08-13	NAIA HEALTH, INC.		
	20	2015150225	WO	A1	2015-10-08	KONINKLIJKE PHILIPS N.V.		
	21	2015174330	WO	A1	2015-11-19	MURATA MANUFACTURING CO., LTD.		
	22	2016002606	WO	A1	2016-01-07	MURATA MANUFACTURING CO., LTD.		
	23	2016006494	WO	A1	2016-01-14	MURATA MANUFACTURING CO., LTD.		
	24	2016006496	WO	A1	2016-01-14	MURATA MANUFACTURING CO., LTD.		
	25	2016007560	WO	A1	2016-01-14	NAYA HEALTH, INC.		
	26	2016010524	JP	A	2016-01-21	MURATA MFG CO LTD		

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	Jonathan O'Toole
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

	27	2016014469	WO	A1	2016-01-28	EXPLORAMED NC7, LLC		
	28	2016014488	WO	A1	2016-01-28	EXPLORAMED NC7, LLC		
	29	105288759	CN	A	2016-02-03	SHANGHAI NORMAL UNIVERSITY		
	30	2016024558	WO	A1	2016-02-18	MURATA MANUFACTURING CO., LTD.		
	31	2016039083	WO	A1	2016-03-17	MURATA MANUFACTURING CO., LTD.		
	32	2016104673	WO	A1	2016-06-30	MURATA MANUFACTURING CO., LTD.		
	33	2077868	EP	B1	2016-07-27	MEDELA HOLDING AG		
	34	2016164853	WO	A1	2016-10-13	NAYA HEALTH, INC.		
	35	1263487	EP	B2	2016-11-23	MEDELA HOLDING AG		
	36	2017061349	WO	A1	2017-04-13	MURATA MANUFACTURING CO., LTD.		
	37	2017108555	WO	A1	2017-06-29	KONINKLIJKE PHILIPS N.V.		

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	Jonathan O'Toole
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

	38	2017139480	WO	A1	2017-08-17	EXPLORAMED NC7, INC.		

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Whisper Wear Hands-Free Breast Pump, Model: WWPMP01, User Guide, pps. 1-20, Distributed with product at least as early as 2007 (see https://web.archive.org/web/20070621162539/http://www.whisperwear.com/pump_single.html)	

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	Jonathan O'Toole
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

✓ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Mark D. Simpson/	Date (YYYY-MM-DD)	2021-02-22
Name/Print	Mark D Simpson	Registration Number	32942

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Filer:	Mark D. Simpson/Lynn White
Attorney Docket Number:	373499.00049

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	80	80
UTILITY SEARCH FEE	2111	1	350	350
UTILITY EXAMINATION FEE	2311	1	400	400
Pages:				
UTILITY APPL SIZE FEE PER 50 SHEETS >100	2081	1	210	210
Claims:				
CLAIMS IN EXCESS OF 20	2202	10	50	500
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1540**

Electronic Acknowledgement Receipt

EFS ID:	41980268
Application Number:	17181057
International Application Number:	
Confirmation Number:	4690
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	78905
Filer:	Mark D. Simpson/Lynn White
Filer Authorized By:	Mark D. Simpson
Attorney Docket Number:	373499.00049
Receipt Date:	22-FEB-2021
Filing Date:	
Time Stamp:	11:50:41
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$1540
RAM confirmation Number	E20212LB51264897
Deposit Account	504364
Authorized User	Lynn White

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	38100216_1.PDF	1840898 e18d5b636885ae687cdded5ad7ebb66abebb9982	no	9
Warnings:					
Information:					
2		38102084_1.PDF	439142 2b118aabea10baabd2f13e20ff86170a6c16a544	yes	127

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Abstract	127	127
	Claims	122	126
	Specification	1	121

Warnings:					
Information:					
3	Drawings-other than black and white line drawings	38100202_1.PDF	7248994 dd8a02bde993a389fd699c5d98244e20a84d91cd	no	44
Warnings:					
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4		38100214_1.PDF	236689 25e4ff64342b479b953e8a937054b7c94bfca5f4	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**

	Power of Attorney		4		4
	Oath or Declaration filed		1		3
Warnings:					
Information:					
5	Transmittal Letter	38102041_1.PDF	95914 ebd8d3ceb20517464b70d30c0f34916230cd9a65	no	1
Warnings:					
Information:					
6	Information Disclosure Statement (IDS) Form (SB08)	38100228_1.PDF	1043546 c571836125d6d166fa35653984d73323480d172	no	15
Warnings:					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	38319 fc50b9ebe01f7e6d704f97e531e411f95b06881d	no	2
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		Total Files Size (in bytes):	10943502		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/AIA/14 (02-18)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00049
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jonathan		O'TOOLE	

Residence Information (Select One) US Residency ● Non US Residency Active US Military Service

City	London	Country of Residence i	GB

Mailing Address of Inventor:

Address 1	c/o Chiaro Technology Limited
Address 2	63-66 Hatton Garden
City	London
State/Province	
Postal Code	EC1N 8LE
Country i	GB

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Adam		ROLLO	

Residence Information (Select One) US Residency ◉ Non US Residency Active US Military Service

City	London	Country of Residence i	GB

Mailing Address of Inventor:

Address 1	c/o Chiaro Technology Limited
Address 2	63-66 Hatton Garden
City	London
State/Province	
Postal Code	EC1N 8LE
Country i	GB

Inventor 3 Remove

Legal Name

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00049
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

Prefix	Given Name	Middle Name	Family Name	Suffix
	Andrew		CARR	

Residence Information (Select One) US Residency ◉ Non US Residency Active US Military Service

City	London	Country of Residence i	GB

Mailing Address of Inventor:

Address 1	c/o Chiaro Technology Limited		
Address 2	63-66 Hatton Garden		
City	London	State/Province	
Postal Code	EC1N 8LE	Country i	GB

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	78905		
Email Address	patents@saul.com	Add Email	Remove Email

Application Information:

Title of the Invention	BREAST PUMP SYSTEM		
Attorney Docket Number	373499.00049	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	44	Suggested Figure for Publication (if any)	1

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country i

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00049
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	◯ Limited Recognition (37 CFR 11.9)
Customer Number	78905		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	16009547	2018-06-15

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00049
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)
1709561.3	GB	2017-06-15	1DE1
1709564.7	GB	2017-06-15	B3B5
1709566.2	GB	2017-06-15	D6F6
1809036.5	GB	2018-06-01	D82C

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00049
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00049
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Title of Invention	BREAST PUMP SYSTEM	

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Signature	/Mark D. Simpson/			Date (YYYY-MM-DD)	2021-02-22
First Name	Mark D.	Last Name	Simpson	Registration Number	32942

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	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

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ABSTRACT

The invention is a wearable breast pump system including a housing shaped at least in part to fit inside a bra and a piezo air-pump. The piezo air-pump is fitted in the housing and forms part of a closed loop system that drives a separate, deformable diaphragm to generate negative air pressure. The diaphragm is removably mounted on a breast shield.

CLAIMS

1. A breast pump device that is configured as a self-contained, in-bra wearable device, and includes:

(i) a housing that includes (a) a rechargeable battery, (b) control electronics; (c) a pump generating negative air pressure;

(ii) a breast shield made up of a breast flange and a nipple tunnel and that is configured to be slid in and out of the housing, in which the breast shield is transparent or optically clear and comes in several different sizes, each of which are configured to slide in and out of the same housing; and

(iii) a milk container that is configured to be attached to and removed from the device.

2. The breast pump device of Claim 1, in which the different sizes of the breast shield each provide a different spacing of the nipple from side walls of the nipple tunnel, when the breast shield has been placed onto a breast.

3. The breast pump device of Claim 1, in which the breast shield is rigid.

4. The breast pump device of Claim 1, in which the breast shield is an optically clear, dishwasher safe polycarbonate breast shield.

5. The breast pump device of Claim 1, in which the breast shield attaches using magnets to the housing.

6. The breast pump device of Claim 1, in which the breast shield is configured to rotate smoothly around the nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto the breast.

7. The breast pump device of Claim 1, in which the breast shield presents in use a single continuous surface to the nipple and breast.

8. The breast pump device of Claim 1, in which the breast integrates the breast flange and nipple tunnel as a single item.

9. The breast pump device of Claim 1, in which the breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

10. The breast pump device of Claim 1, in which the breast shield is configured to slide into the housing with a single push action.

11. The breast pump device of Claim 1, in which the breast shield is configured to slide out from the housing, together with a membrane that prevents milk from flowing into the pump.

12. The breast pump device of Claim 1, in which the milk container is rigid.

13. The breast pump device of Claim 1, in which the milk container is an optically clear, dishwasher safe polycarbonate milk container.

14. The breast pump device of Claim 1, in which milk container attaches to a lower part of the housing and forms the base of the device.

15. The breast pump device of Claim 1, in which milk container magnetically attaches to the housing.

16. The breast pump device of Claim 1, in which the nipple tunnel includes guide lines running parallel to the sides of the nipple tunnel.

17. The breast pump device of Claim 1, in which the nipple tunnel includes an air hole or passage, and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage.

18. The breast pump device of Claim 1, in which the nipple tunnel includes on its lower surface an opening through which expressed milk flows into the milk container.

19. The breast pump device of Claim 1, in which the housing includes one or more piezo air pumps.

20. The breast pump device of Claim 1, in which the housing includes a USB charging socket.

21. The breast pump device of Claim 1, in which the housing includes a left or right breast selector or toggle switch on the housing, that when selected for a

particular pumping sessions, sends data to a connected app that tracks pumping sessions, to indicate whether that session is associated with the left or the right breast.

22. The breast pump device of Claim 1, in which the housing is shaped to fit inside a bra by having an outer surface that is curved to fit the contours of a bra.

23. The breast pump device of Claim 1, in which the housing is configured to slide in and out of the several different sized breast shields, when the breast shield has been placed onto a breast.

24. The breast pump device of Claim 1, in which the device is configured to deliver a maximum suction of approximately 240mmHg.

25. The breast pump device of Claim 1, in which the device includes a sensor that directly measures the level of the milk in the milk container by measuring the intensity of light reflected from the surface of the milk stored in the container.

26. The breast pump device of Claim 1, in which the includes a tilt sensor system that automatically alerts the mother and/or stops pumping if the tilt angle of the breast pump device exceeds a threshold so that milk spillage is imminent.

27. The breast pump device of Claim 1, in which the includes a left or right breast selector or toggle switch on the housing, that when selected for a particular pumping sessions, sends data to a connected app that tracks pumping sessions, to indicate whether that session is associated with the left or the right breast.

28. The breast pump device of Claim 1, in which the pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

29. The breast pump device of Claim 1, in which the pump is a lightweight air pump that enables the total mass of the breast pump device, unfilled with milk, to be less than 250gm

30. The breast pump device of Claim 1, in which the device makes less than 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

BREAST PUMP SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This is a continuation of U.S. Application No. 16/009,547, filed on June 15, 2018, which is based on, and claims priority to, GB Application No. 1709561.3, filed June 15, 2017; GB Application No. 1709564.7, filed on June 15, 2017; GB Application No. 1709566.2, filed on June 15, 2017; and GB Application No. 1809036.5, filed on June 1, 2018, the entire contents of each of which being fully incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The field of the invention relates to a breast pump system; one implementation of the system is a wearable, electrically powered breast pump system for extracting milk from a mother.

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2. Description of the Prior Art

The specification of the present disclosure is broad and deep. We will now describe the prior art in relation to key aspects of the present disclosure.

Prior art related to breast pump systems

A breast pump system is a mechanical or electro-mechanical device that extracts milk from the breasts of a lactating woman.

A typical breast pump design is as shown in WO 96/25187 A1. A large suction generating device is provided, which is freestanding. This is attached by air lines to one or two breast shields which engage with the user's breasts. A pressure cycle is applied

from the suction generating device, via the air lines, to the breast shields. This generates a pressure cycle on the user's breasts to simulate the suction generated by a feeding child.

The suction generating device is a large component that connects to mains power to operate the pumps therein. Milk collection bottles are provided to store the expressed breast milk. In the system of WO 96/36298 A1 separate bottles are provided attached to each breast shield. A single bottle with tubing connecting to each breast shield may also be used. But for a mother to use this discretely, such as in an office environment, specialised bras must be used. In particular, breast-pumping bras which have a central slit, for the nipple tunnel of the breast shield to extend through, are typically used. The breast shield is held within the bra, with the suction generating device and milk bottle outside the bra.

The fundamental breast pump system has not significantly evolved from this approach, only minor technical improvements have been made.

However, these systems present a number of significant disadvantages. As the suction generating device is a large freestanding unit connected to mains power, the user may feel tethered to the wall. The known devices typically also require a specific user posture and undressing to function normally. This is obviously difficult for a user to do discretely, such as in an office setting. The known devices are also typically noisy, uncomfortable, and hard to clean.

Fully integrated wearable breast pump systems have begun to enter the market, such as described in US 2016 0206794 A1. In such pump systems, the suction source, power supply and milk container are contained in a single, wearable device; there is no need for bulky external components or connections. Such devices can be provided with a substantially breast shaped convex profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations. The internal breast shield is naturally convex to fit over a breast.

In US 2016 0206794 A1, when viewed from the front, the breast pump device has a 'tear-drop' rounded shape, fuller at its base than at its top. But it uses collapsible bags as milk collection devices. As the collection bag systems are collapsible, it can be difficult

for a user to extract all of their milk from the bag, due to the small cut opening that is needed and the capillary action between the bonded plastic sheets that form the bag. This waste can be disheartening for the user, as this is food for their child. The bags are also not re-usable, so the user is required to purchase and maintain a stock of these. As well as presenting a recurring cost, if the user runs out of stock they are unable to use the product until more bags are purchased.

Furthermore, as a result of the collapsible bags, a complex and somewhat noisy pumping arrangement is necessary. In particular, the breast shield connects to a tube which is provided with compression units which "step" the expressed milk through the tube to the collection bag. This uses the breast milk as a hydraulic fluid to generate suction on the breast. In order to carry this out, a complex sequenced pulsing arrangement must be implemented.

In addition to these systems being particularly complex and wasteful, only a relatively small bag can be used. In US 2016 206794, approximately 110 ml (4 fluid ounces) of milk can be collected before the bag must be changed. While this may be sufficient for some users, others may produce much more milk in a session.

A further integrated wearable breast pump system is shown in US 2013 0023821 A1. In the third embodiment in this document, the breast pump system includes a motor driven vacuum pump and power source. An annular (or punctured disc) membrane is provided, with the flow path of the milk going through the centre of the annulus. The membrane is housed in separate housing and is sealed at its inner and outer edges. The breast shield has a small protrusion to engage with these housing components. However, the design of this breast pump system results in a number of problems. The use of an annular membrane, with the fluid flow path running through the opening of the annulus is undesirable as it results in a large and bulky device. There is therefore a need for improved integrated breast pump systems.

Prior Art related to liquid measurement systems

In the context of breast pump systems, it is useful to measure the quantity of expressed milk. One way to do this is to have a clear container for the breast pump, through which the level of expressed milk inside the container can be seen. However, viewing the milk

bottle is not always possible, for example in a breast pump that collects milk while being worn inside a maternity bra.

An existing apparatus for detecting the level of liquid inside a container of a breast pump is that disclosed in US 2016/296681. In this apparatus, a sensing mechanism is provided at the top of a container, which detects droplets of liquid, specifically breast milk, entering the container. By detecting these droplets entering the container, the apparatus can determine the quantity of liquid which enters the container. In this apparatus, an accurate indication of the level of liquid in the container is reliant on the sensing mechanism being able to accurately record every droplet entering the container.

Particularly at times when liquid enters the container at a high flow rate, this accuracy cannot be guaranteed, leading to significant cumulative errors. An accurate indication of the level of liquid in the container in this apparatus is also reliant on the sensing mechanism always being on during the pumping process, so that power consumption of the sensing mechanism is correspondingly high.

In view of the above, there is the need for an improved way to determine the level of liquid inside a container connected to a breast pump.

Prior Art related to bra clips

Many specialised bras (or brassieres) exist for maternity use and that facilitate nursing and/or breast pumping for milk collection, without the need to remove the bra itself. In a traditional nursing bra, this is achieved with the use of an at least partially detachable cup, which can be unhooked for feeding and/or pumping.

Further specialised bras are known which are provided with cut-out portions or slits which substantially align with the wearer's areola and nipple. Traditional breast pump systems comprise an elongate breast shield which extends away from the breast towards an external bottle and source of suction. The breast shield is arranged to extend through the cut-out portion or slit, with the collection bottle and pumping apparatus placed outside of the bra. These systems require the user to remove or unbutton any over-garments, and are uncomfortable when not pumping.

Integrated, wearable breast pump systems have begun to enter the market, such as previously noted US 2016 0206794 A1. In such pumps, the suction source, power supply and milk container are all in a single, wearable device, as noted above, without the need for bulky external components or connections. Such devices can be provided with a substantially breast shaped profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations.

Maternity (or nursing) bras such as disclosed in US 4,390,024 A have partially detachable cups, with several hooks provided along the bra strap for attaching the cups to the strap. The cups can then be attached to different hooks in order to adjust the bra strap length. However, these attachment points are fixed. Additionally, this bra has been designed to accommodate the change in breast size before and after the feeding/pumping process. It is not designed to accommodate a breast pump. Accordingly, there is a need for a better system to accommodate integrated wearable breast pumps.

SUMMARY OF THE INVENTION

The invention is a wearable breast pump system including: a housing shaped at least in part to fit inside a bra; a piezo air-pump fitted in the housing and forming part of a closed loop system that drives a separate, deformable diaphragm to generate negative air pressure, that diaphragm being removably mounted on a breast shield.

BRIEF DESCRIPTION OF THE FIGURES

Aspects of the invention will now be described, by way of example(s), with reference to the following Figures, which each show features of various implementations of the invention including optional features that may be utilised:

Figure 1 is a front view of an assembled breast pump system.

Figure 2 is a rear view of the assembled breast pump system of Figure 1.

Figure 3 is a front view of a partially disassembled breast pump system.

Figure 4 is a rear view of the partially disassembled breast pump system of Figure 3.

Figure 5 is a front view of a further partially disassembled breast pump system.

Figure 6 is a rear view of the further partially disassembled breast pump system of Figure 5.

Figure 7 is a front view of the breast pump system of Figure 1, with the outer shell translucent for ease of explanation.

Figure 8 is a further front view of the breast pump system of Figure 1, with the front of the outer shell removed for ease of explanation.

Figure 9 is a schematic view of a nipple tunnel for a breast shield.

Figure 10 is a schematic of a pneumatic system for a breast pump system.

Figure 11 is a schematic of an alternative pneumatic system for a breast pump system.

Figure 12 is a schematic of a further alternative pneumatic system for a breast pump system.

Figure 13 is a graph depicting measured pressure in the breast pump system of Figure 12 over time.

Figure 14 shows schematics for breast shield sizing and nipple alignment.

Figure 15 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 16 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 17 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 18 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 19 shows a screenshot of an application running on a device connected to the

breast pump system.

Figure 20 shows a screenshot of an application running on a connected device.

Figure 21 shows a screenshot of an application running on a connected device.

Figure 22 shows a screenshot of an application running on a connected device.

Figure 23 shows a screenshot of an application running on a connected device.

Figure 24 shows a screenshot of an application running on a connected device.

Figure 25 shows a screenshot of an application running on a connected device.

Figure 26 shows a diagram of a breast pump sensor network,

Figure 27 shows a sectional view of a device being used to determine the level of liquid in a container;

Figure 28 shows a sectional view of the device and the container from Figure 27 being used at a different orientation.

Figure 29 shows a sectional view of the device and the container from Figure 27 being used whilst undergoing acceleration.

Figure 30 shows a sectional view of the device from Figure 27 being used as part of a breast pump assembly.

Figure 31 shows a sectional view of a device connected between a container and its lid, and which is operable to determine the level of liquid inside the container.

Figure 32 depicts a prior art design for a maternity bra;

Figure 33 depicts a clip and clasp being fitted to a maternity bra.

Figure 34 depicts an alternative clip for adjustment of a maternity bra.

Figure 35 depicts the alternative clip of Figure 34.

Figure 36 depicts an alternative clip for adjustment of a maternity bra.

Figure 37 depicts an alternative clip for adjustment of a maternity bra.

Figure 38 depicts an alternative clip for adjustment of a maternity bra.

Figure 39 depicts adjustment of the maternity bra of Figure 37.

Figure 40 shows a configuration with two piezo pumps mounted in series.

Figure 41 shows a configuration of two piezo pumps mounted in parallel.

Figure 42 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in series and mounted in parallel respectively.

Figure 43 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration.

Figure 44 shows a figure of a pump including two piezo pumps in which each piezo pump is connected to a heat sink.

DETAILED DESCRIPTION

We will now describe an implementation of the invention, called the Elvie™ pump, in the following sections:

Section A: The Elvie™ Breast Pump System

Section B: An IR System

Section C: A Bra Clip

Section D: Piezo Pumps and Wearable Devices

Section A: The Elvie™ Breast Pump System

1. Elvie™ Breast Pump System Overview

An implementation of the invention, called the Elvie™ pump, is a breast pump system that is, at least in part, wearable inside a bra. The breast pump system comprises a breast shield for engagement with the user's breast, a housing for receiving at least a portion of the breast shield and a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user, with a milk-flow pathway defined from an opening in the breast shield to the milk collection container. The housing inside also includes a pump for generating a negative pressure in the breast shield, as well as battery and control electronics Unlike other wearable breast pumps, the only parts of the system that come into contact with milk in normal use are the breast shield and the milk container; milk only flows through the breast shield and then directly into the milk container. Milk does not flow through any parts of the housing at all, for maximum hygiene and ease of cleaning.

With reference to Figure 1 and Figure 2, the assembled breast pump system 100 includes a housing 1 shaped to substantially fit inside a bra. The housing 1 includes one or more pumps and a rechargeable battery. The breast pump system includes two parts that are directly connected to the housing 1: the breast shield 7 and a milk container 3. The breast shield 7 and the milk container 3 are directly removable or attachable from the housing 1 in normal use or during normal dis-assembly (most clearly shown in Figure 5). All other parts that are user-removable in normal use or during normal dis-assembly are attached to either the breast shield 7 or the milk container 3. The breast shield 7 and milk container 3 may be removed or attached for example using a one click or one press action or a push button or any other release mechanism. Audible and/or haptic feedbacks confirm that the pump is properly assembled.

The modularity of the breast pump allows for easy assembly, disassembly and replacement of different parts such as the breast shield and milk collection container. This also allows for different parts of the pump to be easily washed and/or sterilised. The breast shield and bottle assembly, both of which are in contact with milk during

pumping, may therefore be efficiently and easily cleaned; these are the only two items that need to be cleaned; in particular, the housing does not need to be cleaned.

The housing 1, breast shield 7 that is holding a flexible diaphragm, and milk container 3 attach together to provide a closed-loop pneumatic system powered by piezoelectric pumps located in the housing 1. This system then applies negative pressure directly to the nipple, forms an airtight seal around the areola, and provides a short path for expressed milk to collect in an ergonomically shaped milk container 3.

The different parts of the breast shield system are also configured to automatically self-seal under negative pressure for convenience of assembly and disassembly and to reduce the risk of milk spillage. Self-sealing refers to the ability of sealing itself automatically or without the application of adhesive, glue, or moisture (such as for example a self-sealing automobile tire or self-sealing envelopes). Hence once the breast pump system is assembled it self-seals under its assembled condition without the need to force seals into interference fits to create sealed chambers. A degree of interference fitting is usual however, but is not the predominating attachment mechanism. Self-sealing enables simple components to be assembled together with a light push: for example, the diaphragm just needs to be placed lightly against the diaphragm housing; it will self-seal properly and sufficiently when the air-pump applies sufficient negative air-pressure. The diaphragm itself self-seals against the housing when the breast shield is pushed into the housing. Likewise, the breast shield self-seals against the milk container when the milk container is pushed up to engage the housing. This leads to simple and fast assembly and dis-assembly, making it quick and easy to set the device up for use, and to clean the device after a session.

Self-sealing has a broad meaning and may also relate to any, wholly or partly self-energising seals. It may also cover any interference seals, such as a press seal or a friction seal, which are achieved by friction after two parts are pushed together.

Whilst one particular embodiment of the invention's design and a specific form of each of the parts of the breast pump system is detailed below, it can be appreciated that the overall description is not restrictive, but an illustration of topology and function that the design will embody, whilst not necessary employing this exact form or number of

discrete parts.

The breast pump system 100 comprises a housing 1 and a milk collection container (or bottle) 3. The housing 1 (including the one or more pumps and a battery) and the container 3 are provided as a unit with a convex outer surface contoured to fit inside a bra. The milk collection container 3 is attached to a lower face 1A of the housing 1 and forms an integral part of the housing when connected, such that it can be held comfortably inside a bra. While the breast pump 100 may be arranged to be used with just the right or the left breast specifically, the breast pump 100 is preferably used with both breasts, without modification. To this end, the outer surfaces of the breast pump 100 are preferably substantially symmetrical.

Preferably, the width of the complete breast pump device (housing 1 and milk container 3) is less than 110 mm and the height of the complete breast pump device is less than 180 mm.

Overall, the breast pump system 100 gives discrete and comfortable wear and use. The system weighs about 224 grams when the milk container is empty, making it relatively lighter as compared to current solutions; lightness has been a key design goal from the start, and has been achieved through a lightweight piezo pump system and engineering design focussed on minimising the number of components.

The breast pump system 100 is small enough to be at least in part held within any bra without the need to use a specialized bra, such as a maternity bra or a sports bra. The rear surface of the breast pump is also concave so that it may sit comfortably against the breast. The weight of the system has also been distributed to ensure that the breast pump is not top heavy, ensuring comfort and reliable suction against the breast. The centre of gravity of the pump system is, when the container is empty, substantially at or below the horizontal line that passes through the filling point on the breast shield, so that the device does not feel top-heavy to a person while using the pump.

Preferably, when the container is empty, the centre of gravity is substantially at or below the half-way height line of the housing so that the device does not feel top-heavy to a user using the pump.

The centre of gravity of the breast pump, as depicted by Figure 1, is at around 60mm high on the centreline from the base of the breast pump when the milk container is empty. During normal use, and as the milk container gradually receives milk, the centre of gravity lowers, which increases the stability of the pump inside the bra. It reduces to around 40mm high on the centreline from the base of the breast pump when the milk container is full.

The centre of gravity of the breast pump is at about 5.85mm below the centre of the nipple tunnel when the milk container is empty, and reduced to about 23.60mm below the centre of the nipple tunnel when the milk container is full. Generalising, the centre of gravity should be at least 2mm below the centre of the nipple tunnel when the container is empty.

The breast pump 100 is further provided with a user interface 5. This may take the form of a touchscreen and/or physical buttons. In particular, this may include buttons, sliders, any form of display, lights, or any other componentry necessary to control and indicate use of the breast pump 100. Such functions might include turning the breast pump 100 on or off, specifying which breast is being pumped, increasing or decreasing the peak pump pressure. Alternatively, the information provided through the user interface 5 might also be conveyed through haptic feedback, such as device vibration, driven from a miniature vibration motor within the pump housing 1.

In the particular embodiment of the Figures, the user interface 5 comprises power button 5A for turning the pump on and off. The user interface 5 further comprises pump up button 5B and pump down button 5C. These buttons adjust the pressure generated by the pump and hence the vacuum pressure applied to the user's breast. In preferable embodiments, the pump up button 5B could be physically larger than the pump down button 5C. A play/pause button 5D is provided for the user to interrupt the pumping process without turning the device off.

The user interface 5 further comprises a breast toggle button 5E for the user to toggle a display of which breast is being pumped. This may be used for data collection, e.g. via an application running on a connected smartphone; the app sends data to a remote server, where data analysis is undertaken (as discussed in more detail later), or for the user to keep track of which breast has most recently been pumped. In particular, there may be a

pair of LEDs, one to the left of the toggle button 5E and one to the right. When the user is pumping the left breast, the LED to the right of the toggle button 5E will illuminate, so that when the user looks down at the toggle it is the rightmost LED from their point of view that is illuminated. When the user then wishes to switch to the right breast, the toggle button can be pressed and the LED to the left of the toggle button 5E, when the user looks down will illuminate. The connected application can automatically track and allocate how much milk has been expressed, and when, by each breast.

The breast pump system also comprises an illuminated control panel, in which the level of illumination can be controlled at night or when stipulated by the user. A day time mode, and a less bright night time mode that are suitable to the user, are available. The control of the illumination level is either implemented in hardware within the breast pump system itself or in software within a connected device application used in combination with the breast pump system.

As depicted in Figure 1, the housing 1 and milk collection container 3 form a substantially continuous outer surface, with a generally convex shape. This shape roughly conforms with the shape of a 'tear-drop' shaped breast. This allows the breast pump 100 to substantially fit within the cup of a user's bra. The milk collection container 3 is retained in attachment with the housing 1 by means of a latch system, which is released by a one-click release mechanism such as a push button 2 or any other one-handed release mechanism. An audible and/or haptic feedback may also be used to confirm that the milk collection container 3 has been properly assembled.

The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting an additional 2 cm difference. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc. In preferred embodiments, the breast pump 100 of the present invention corresponds to an increase of between 3 or 4 cup sizes of the user according to EN 13402.

A plane-to-plane depth of the breast pump can also be defined. This is defined as the distance between two parallel planes, the first of which is aligned with the innermost

point of the breast pump 100, and the second of which is aligned with the outermost point of the breast pump 100. This distance is preferably less than 100 mm.

Figure 2 is a rear view of the breast pump 100 of Figure 1. The inner surface of the housing 1 and milk collection container 3 are shown, along with a breast shield 7. The housing 1, milk collection container 3 and breast shield 7 form the three major subcomponents of the breast pump system 100. In use, these sub-components clip together to provide the functioning breast pump system 100. The breast shield 7 is designed to engage with the user's breast, and comprises a concave inner flange 7A which contacts the breast. To allow the breast pump 100 to be used on either of the user's breasts, the breast shield 7 is preferably substantially symmetrical on its inner flange 7A.

The inner flange 7A is substantially oval-shaped. While the inner flange 7A is concave, it is relatively shallow such that it substantially fits the body form of the user's breast. In particular, when measured side-on the inner-most point of the flange 7A and the outer-most point may be separated by less than 25 mm. By having a relatively shallow concave surface, the forces applied can be spread out over more surface area of the breast. The flatter form also allows easier and more accurate location of the user's nipple. In particular, the flange 7A of the breast shield 7 may extend over the majority of the inner surface of the housing 1 and milk collection container 3. Preferably, it may extend over 80% of this surface. By covering the majority of the inner surface, the breast shield is the only component which contact's the wearer's breast. This leaves fewer surfaces which require thorough cleaning as it reduces the risk of milk contacting a part of the device which cannot be easily sterilized. Additionally, this also helps to disperse the pressure applied to the user's breast across a larger area.

The breast shield 7 substantially aligns with the outer edge 1B of the housing 1. The milk collection container 3 may be provided with an arcuate groove for receiving a lower part of the breast shield 7. This is best shown in later Figures. In the assembled arrangement of Figures 1 and 2, the inner surface of the breast pump 100 is substantially continuous.

The breast shield 7 comprises a shield flange for engaging the user's breast, and an elongate nipple tunnel 9) aligned with the opening and extending away from the user's

breast. Breast shield nipple tunnel 9 extends from a curved section 7B in the breast shield 7. In preferable embodiments the nipple tunnel 9 is integral with the breast shield 7. However, it is appreciated that separate removable/interchangeable nipple tunnels may be used. Curved section 7B is positioned over the user's nipple and areola in use. The breast shield 7 forms an at least partial seal with the rest of the user's breast around this portion, under the negative air pressure created by an air-pressure pump.

This breast shield nipple tunnel 9 defines a milk-flow path from the inner surface of the breast shield 7A, through the breast shield nipple tunnel 9 and into the milk collection container 3. The breast shield nipple tunnel 9 is preferably quite short in order to minimise the length of the milk-flow path in order to minimise losses. By reducing the distance covered by the milk, the device is also reduced in size and complexity of small intermediate portions. In particular, the breast shield nipple tunnel 9 may extend less than 70 mm from its start to end, more preferably less than 50 mm. In use, the nipple tunnel 9 is substantially aligned with the user's nipple and areolae. The nipple tunnel comprises a first opening 9A for depositing milk into the collection container and a second opening 19A for transferring negative air pressure generated by the pump to the user's nipple.

The shield flange 7A and nipple tunnel 9 may be detachable from the housing 1 together. The shield flange 7A and nipple tunnel 9 being detachable together helps further simplify the design, and reduce the number of components which must be removed for cleaning and sterilization. However, preferably, the nipple tunnel 9 will be integral with the breast shield 7, in order to simplify the design and reduce the number of components which must be removed for cleaning and sterilisation.

Figures 3 and 4 are of a partially disassembled breast pump 100 of the present invention. In these Figures, the breast shield 7 has been disengaged from the housing 1 and milk collection bottle 3. As shown in Figure 4, the housing 1 comprises a region or slot 11 for receiving the breast shield nipple tunnel 9 of the breast shield 7. The breast shield is held in place thanks to a pair of channels (9B) included in the nipple tunnel 9, each channel including a small indent. When pushing the housing 1 onto the breast shield 7, which has been placed over the breast, ridges in the housing (9C) engage with the channels, guiding the housing into position; a small, spring plunger, such as ball bearing in each

ridge facilitates movement of the housing on to the nipple tunnel 9. The ball bearings locate into the indent to secure the housing on to the nipple tunnel with a light clicking sound. In this way, the user can with one hand place and position the breast shield 7 onto her breast and with her other hand, position and secure the housing 1 on to the breast shield 7. The breast shield 7 can be readily separated from the housing 1 since the ball bearing latch only lightly secures the breast shield 7 to the housing 1.

Alternatively, the breast shield 7 may also be held in place by means of a clip engaging with a slot located on the housing. The clip may be placed at any suitable point on the shield 7, with the slot in a corresponding location.

The breast shield nipple tunnel 9 of the breast shield 7 is provided with an opening 9A on its lower surface through which expressed milk flows. This opening 9A is configured to engage with the milk collection bottle 3.

The breast pump 100 further comprises a barrier or diaphragm for transferring the pressure from the pump to the milk-collection side of the system. In the depicted example, this includes flexible rubber diaphragm 13 seated into diaphragm housing 19A. The barrier could be any other suitable component such as a filter or an air transmissive material. Diaphragm housing 19A includes a small air hole into the nipple tunnel 9 to transfer negative air pressure into nipple tunnel 9 and hence to impose a sucking action on the nipple placed in the nipple tunnel 9.

Hence, the air pump acts on one side of the barrier or diaphragm 13 to generate a negative air pressure on the opposite, milk-flow side of the barrier. The barrier has an outer periphery or surface, i.e. the surface of diaphragm housing 19A that faces towards the breast, and the milk-flow pathway extends underneath the outer periphery or surface of the barrier or diaphragm housing 19A. The milk-flow path extending under the outer periphery or surface of the barrier 19A allows for a simpler and more robust design, without the milk-flow pathway extending through the barrier. This provides increased interior space and functionality for the device.

As noted, the milk-flow pathway extends beneath or under the barrier 13 or surface of diaphragm housing 19A. This provides an added benefit of having gravity move the milk down and away from the barrier.

Preferably the milk-flow pathway does not pass through the barrier 32. This results in a simpler and smaller barrier design.

As noted, the diaphragm 13 is mounted on diaphragm housing 19A that is integral to the breast shield. This further helps increase the ease of cleaning and sterilisation as all of the components on the "milk" flow side can be removed.

The barrier 13 may also provide a seal to isolate the air pump from the milk-flow side of the barrier. This helps to avoid the milk becoming contaminated from the airflow or pumping side (i.e. the non-milk-flow side).

Alternatively, the only seal is around an outer edge of the barrier 13. This is a simple design as only a single seal needs to be formed and maintained. Having multiple seals, such as for an annular membrane, introduces additional complexity and potential failure points.

As illustrated in Figures 3 and 4, the barrier may include a flexible diaphragm 13 formed by a continuous circular disc shaped membrane which is devoid of any openings or holes. This provides a larger effective "working" area of the diaphragm (i.e. the area of the surface in contact with the pneumatic gasses) than an annular membrane and hence the membrane may be smaller in diameter to have the same working area.

The diaphragm 13 is arranged so that the milk-flow pathway extends below and past the outer surface or periphery of the diaphragm 13. This means that the milk-flow pathway does not extend through the diaphragm 13. In particular, the milk-flow pathway is beneath the diaphragm 13. However, the diaphragm 13 may be offset in any direction with respect to the milk-flow pathway, provided that the milk-flow pathway does not extend through the diaphragm 13.

Preferably, the diaphragm 13 is a continuous membrane, devoid of any openings. The diaphragm 13 is held in a diaphragm housing 19, which is formed in two parts. The first half 19A of the diaphragm housing 19 is provided on the outer surface of the breast shield 7, above the breast shield nipple tunnel 9 and hence the milk-flow pathway. In

preferred embodiments, the first half 19A of the diaphragm housing 19 is integral with the breast shield. The second half 19B of the diaphragm housing is provided in a recessed portion of the housing 1. The diaphragm 13 self-seals in this diaphragm housing 19 around its outer edge, to form a watertight and airtight seal. Preferably, the self-seal around the outer edge of the diaphragm 13 is the only seal of the diaphragm 13. This is beneficial over systems with annular diaphragms which must seal at an inner edge as well. Having the diaphragm 13 mounted in the breast pump 100 in this manner ensures that it is easily accessible for cleaning and replacement. It also ensures that the breast shield 7 and diaphragm 13 are the only components which need to be removed from the pump 100 for cleaning. Because the diaphragm 13 self-seals under vacuum pressure, it is easily removed for cleaning when the device is turned off.

Figures 5 and 6 show a breast pump 100 according to the present invention in a further disassembled state. In addition to the breast shield 7 and diaphragm 13 being removed, the milk collection container 3 has been unclipped. Preferably, the milk collection container 3 is a substantially rigid component. This ensures that expressed milk does not get wasted, while also enhancing re-usability. In some embodiments, the milk collection container 3 may be formed of three sections: a front bottle potion, a rear bottle potion, and a cap. These three sections may clip together to form the milk collection container 3. This three-part system is easy to empty, easily cleanable since it can be dis-assembled, and easily re-usable. The milk collection container or milk bottle may be formed of at least two rigid sections which are connectable. This allows simple cleaning of the container for re-use. Alternatively, the container may be a single container made using a blow moulding construction, with a large opening to facilitate cleaning. This large opening is then closed with a cap with an integral spout 35 or 'sealing plate' (which is bayonet-mounted and hence more easily cleaned than a threaded mount spout). A flexible rubber valve 37 (or 'sealing plate seal') is mounted onto the cap or spout 35 and includes a rubber duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump; this ensures that negative air-pressure does not need to be applied to the milk container and hence adds to the efficiency of the system. The flexible valve 37 self-seals against opening 9A in nipple tunnel 9. Because it self-seals under vacuum pressure, it automatically releases when the system is off, making it easy to remove the milk container.

Preferably, the milk collection container resides entirely below the milk flow path defined by the breast shield when the breast pump system 100 is positioned for normal use, hence ensuring fast and reliable milk collection.

The milk collection container 3 has a capacity of approximately 5 fluid ounces (148 ml). Preferably, the milk collection container has a volume of greater than 120 ml. More preferably, the milk collection container has a volume of greater than 140 ml. To achieve this, the milk collection container 3 preferably has a depth in a direction extending away from the breast in use, of between 50 to 80 mm, more preferably between 60 mm to 70 mm, and most preferably between 65 mm to 68 mm.

The milk collection container 3 further preferably has a height, extending in the direction from the bottom of the container 3 in use to the cap or spout or sealing plate 35, of between 40 mm to 60 mm, more preferably between 45 mm to 55 mm, and most preferably between 48 mm to 52 mm. The cap 35 may screw into the milk collection bottle 3. In particular, it may be provided with a threaded connection or a bayonet and slot arrangement.

Further preferably, the milk collection container has a length, extending from the leftmost point to the rightmost point of the container 3 in use, of between 100 mm to 120 30 mm, more preferably between 105 mm to 115 mm, and most preferably between 107 mm to 110 mm.

This cap 35 is provided with a one-way valve 37, through which milk can flow only into the bottle. This valve 37 prevents milk from spilling from the bottle once it has been collected. In addition, the valve 37 automatically seals completely unless engaged to the breast shield 7. This ensures that when the pump 100 is dismantled immediately after pumping, no milk is lost from the collection bottle 3. It can be appreciated that this one-way valve 37 might also be placed on the breast shield 7 rather than in this bottle cap 35.

Alternatively, the milk bottle 3 may form a single integral part with a cap 35. Cap 35 may include an integral milk pouring spout.

In certain embodiments, a teat may be provided to attach to the annular protrusion 31A

or attach to the spout that is integral with cap 35, to allow the container 3 to be used directly as a bottle. This allows the milk container to be used directly as a drinking vessel for a child. The milk collection container may also be shaped with broad shoulders such that it can be adapted as a drinking bottle that a baby can easily hold.

Alternatively, or in addition, a spout may be provided to attach to the protrusion 31A for ease of pouring. A cap may also be provided to attach to the protrusion 31A in order to seal the milk collection bottle 3 for easy storage.

The pouring spout, drinking spout, teat or cap may also be integral to the milk collection container.

Further, the removable milk collection container or bottle includes a clear or transparent wall or section to show the amount of milk collected. Additionally, measurement markings (3A) may also be present on the surface of the container. This allows the level of milk within the container to be easily observed, even while pumping. The milk collection container or bottle may for example be made using an optically clear, dishwasher safe polycarbonate material such as Tritan™.

The milk collection container or bottle may include a memory or a removable tag, such as a tag including an NFC chip, that is programmed to store the date and time it was filled with milk, using data from the breast pump system or a connected device such as a smartphone. The container therefore includes wireless connectivity and connects to a companion app. The companion app then tracks the status of multiple milk collection containers or bottles to select an appropriate container or bottle for feeding. The tag of the bottle may also be programmed to store the expiry date of the milk as well as the quantity of the milk stored.

Figures 7 and 8 show front views of a breast pump system 100. The outer-surface of the housing 1 has been drawn translucent to show the components inside. The control circuitry 71 for the breast pump 100 is shown in these figures. The control circuitry in the present embodiment comprises four separate printed circuit boards, but it is appreciated that any other suitable arrangement may be used.

The control circuitry may include sensing apparatus for determining the level of milk in the container 3. The control circuitry may further comprise a wireless transmission device for communicating over a wireless protocol (such as Bluetooth) with an external device. This may be the user's phone, and information about the pumping may be sent to this device. In embodiments where the user interface comprises a breast toggle button 5E, information on which breast has been selected by the user may also be transmitted with the pumping information. This allows the external device to separately track and record pumping and milk expression data for the left and right breasts.

There should also be a power charging means within the control circuitry 71 for charging the battery 81. While an external socket, cable or contact point may be required for charging, a form of wireless charging may instead be used such as inductive or resonance charging. In the Figures, charging port 6 is shown for charging the battery 81. This port 6 may be located anywhere appropriate on the housing 1.

Figure 8 shows the location of the battery 81 and the pumps 83A, 83B mounted in series inside the housing 1. While the depicted embodiment shows two pumps 83A, 83B it is appreciated that the present invention may have a single pump. Preferably, an air filter 86 is provided at the output to the pumps 83A, 83B. In preferable embodiments, the pumps 83A, 83B are piezoelectric air pumps (or piezo pumps), which operate nearly silently and with minimal vibrations. A suitable piezo pump is manufactured by TTP Ventus, which can deliver in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free flow. The rear side of the second half of the diaphragm housing 19B in the housing 1 is provided with a pneumatic connection spout. The pumps 83A, 83B are pneumatically connected with this connection spout.

Operation of the breast pump 100 will now be described. Once the breast pump 100 is activated and a pumping cycle is begun, the pumps 83A, 83B generates a negative air pressure which is transmitted via an air channel to a first side of the diaphragm 13 mounted on the diaphragm housing 19A. This side of the diaphragm 13 is denoted the pumping side 13B of the diaphragm 13.

The diaphragm 13 transmits this negative air pressure to its opposite side (denoted the milk-flow side 13A). This negative pressure is transferred through a small opening in the

diaphragm housing 19A to the breast shield nipple tunnel 9 and the curved opening 7B of the breast shield 7 that contacts the breast. This acts to apply the pressure cycle to the breast of the user, in order to express milk. The milk is then drawn through the nipple tunnel 9, to the one way valve 37 that remains closed whilst negative pressure is applied. When the negative air pressure is released, the valve 37 opens and milk flows under gravity past the valve 37 and into milk container 3. Negative air pressure is periodically (e.g. cyclically, every few seconds) applied to deliver pre-set pressure profiles such as profiles that imitate the sucking of a child.

While the depicted embodiment of the breast pump 100 is provided with two pumps, the following schematics will be described with a single pump 83. It is understood that the single pump 83 could be replaced by two separate piezo air-pumps 83A, 83B as above.

Figure 9 depicts a schematic of a further embodiment of a breast shield nipple tunnel 9 for a breast pump 100. The breast shield nipple tunnel 9 is provided with an antechamber 91 and a separation chamber 93. A protrusion 95 extends from the walls of the breast shield nipple tunnel 9 to provide a tortuous air-liquid labyrinth path through the breast shield nipple tunnel 9. In the separation chamber 93 there are two opening 97, 99. An air opening 97 is provided in an upper surface 93A of the separation chamber 93. This upper surface 93 is provided transverse to the direction of the breast shield nipple tunnel 9. This opening 97 connects to the first side of the diaphragm housing 19A and is the source of the negative pressure. This airflow opening 97 also provides a route for air to flow as shown with arrow 96. It is appreciated that the tortuous pathway is not necessary and that a breast shield nipple tunnel 9 without such a pathway will work.

The other opening 99 is a milk opening 99. The milk opening 99 is provided on a lower surface 93B of the separation chamber 93 and connects in use to the container 3. After flowing through the tortuous breast shield nipple tunnel 9 pathway, the milk is encouraged to flow through this opening 99 into the container 3. This is further aided by the transverse nature of the upper surface 93A. In this manner, expressed milk is kept away from the diaphragm 13. As such, the breast pump 100 can be separated into a "air" side comprising the pump 83, the connection spout 85 and the pumping side 13B of the diaphragm 13 and a "milk-flow" side comprising the breast shield 7, the milk collection container 3 and the milk-flow side 13A of the diaphragm 13. This ensures that all of the

"milk-flow" components are easily detachable for cleaning, maintenance and replacement. Additionally, the milk is kept clean by ensuring it does not contact the mechanical components. While the present embodiment discusses the generation of negative pressure with the pump 83, it will be appreciated that positive pressure may instead be generated.

While the embodiments described herein use a diaphragm 13, any suitable structure to transmit air pressure while isolating either side of the system may be used.

The breast pump may further comprise a pressure sensor in pneumatic connection with the piezo pump. This allows the output of the pump to be determined.

Figure 10 shows a schematic of a basic pneumatic system 200 for a breast pump 100. In the system 200 milk expressed into the breast shield 7 is directed through the breast shield nipple tunnel 9 through the torturous air-liquid labyrinth interface 95. The milk is directed through the non-return valve 37 to the collection container 3. This side of the system forms the "milk-flow" side 201.

The rest of the pneumatic system 200 forms the air side 202 and is separated from contact with milk. This is achieved by way of a flexible diaphragm 13 which forms a seal between the two sides of the system. The diaphragm 13 has a milk-flow side 13A and an air side or pumping side 13B.

The air side 202 of the system 200 is a closed system. This air side 202 may contain a pressure sensor 101 in pneumatic connection with the diaphragm 13 and the pump 83. Preferably, the pump 83 is a piezoelectric pump (or piezo pump). Due to their low noise, strength and compact size, piezoelectric pumps are ideally suited to the embodiment of a small, wearable breast pump. The pump 83 has an output 83A for generating pressure, and an exhaust to the atmosphere 83B. In a first phase of the expression cycle, the pump 83 gradually applies negative pressure to half of the closed system 202 behind the diaphragm 13. This causes the diaphragm 13 to extend away from the breast, and thus the diaphragm 13 conveys a decrease in pressure into the breast shield 7. The reduced pressure encourages milk expression from the breast, which is directed through the tortuous labyrinth system 95 and the one-way valve 37 to the collection bottle 3.

While in the depicted embodiment the air exhaust 83B is not used, it may be used for functions including, but not limited to, cooling of electrical components, inflation of the bottle to determine milk volume (discussed further later) or inflation of a massage bladder or liner against the breast. This massage bladder may be used to help mechanically encourage milk expression. More than one massage bladder may be inflated regularly or sequentially to massage one or more parts of the breast. Alternatively, the air pump may be used to provide warm air to one or more chambers configured to apply warmth to one or more parts of the breast to encourage let-down.

The air side 202 further comprises a two-way solenoid valve 103 connected to a filtered air inlet 105 and the pump 83. Alternatively, the filter could be fitted on the pump line 83A. If the filter is fitted here, all intake air is filtered but the performance of the pump may drop. After the negative pressure has been applied to the user's breast, air is bled into the system 202 through the valve 103 in a second phase of the expression cycle. In this embodiment, the air filter 105 is affixed to this inlet to protect the delicate components from degradation. In particular, in embodiments with piezoelectric components, these are particularly sensitive.

The second phase of the expression cycle and associated switching of valve 103 is actioned once a predefined pressure threshold has been reached. The pressure is detected by a pressure sensor 101.

In certain embodiments, if the elasticity and extension of the diaphragm 13 may be approximated mathematically at different pressures, the pressure measured by sensor 101 can be used to infer the pressures exposed to the nipple on the opposite side of the diaphragm 13. Figure 11 shows an alternative pneumatic system 300. The core architecture of this system is the same as the system shown in Figure 10.

In this system 300, the closed loop 202 is restricted with an additional three way solenoid valve 111. This valve 111 allows the diaphragm 13 to be selectively isolated from the rest of the closed loop 202. This additional three way valve 111 is located between the diaphragm 13 and the pump 83. The pressure sensor 101 is on the pump 83 side of the three way valve 111. The three way valve 111 is a single pole double throw (SPDT) valve,

wherein: the pole 111A is in pneumatic connection with the pump 83 and pressure sensor; one of the throws 11 is in pneumatic connection with the diaphragm 13; and the other throw 111C is in pneumatic connection with a dead-end 113. This dead-end 113 may either be a simple closed pipe, or any component(s) that does not allow the flow of air into the system 202. This could include, for example, an arrangement of one-way valves.

In this system 300, therefore, the pump 83 has the option of applying negative pressure directly to the pressure sensor 101. This allows repeated testing of the pump in order to calibrate pump systems, or to diagnose issues with the pump in what is called a dead end stop test. This is achieved by throwing the valve to connect the pump 83 to the dead end 113. The pump 83 then pulls directly against the dead end 113 and the reduction of pressure within the system can be detected by the pressure sensor 101.

The pressure sensor detects when pressure is delivered and is then able to measure the output of the pumping mechanism. The results of the pressure sensor are then sent to an external database for analysis such as a cloud database, or are fed back to an on-board microcontroller that is located inside the housing of the breast pump system.

Based on the pressure sensor measurements, the breast pump system is able to dynamically tune the operation of the pumping mechanism (i.e. the duty or pump cycle, duration of a pumping session, the voltage applied to the pumping mechanism, the peak negative air pressure) in order to ensure a consistent pressure performance across different breast pump systems.

In addition, the breast pump system, using the pressure sensor measurements, is able to determine if the pump is working correctly, within tolerance levels. Material fatigue of the pump is therefore directly assessed by the breast pump system. Hence, if the output of the pumping mechanism degrades over time, the breast pump system can tune the pumping mechanism operation accordingly. As an example, the breast pump system may increase the duration of a pumping session or the voltage applied to the pumping mechanism to ensure the expected pressures are met.

This ensures that the user experience is not altered, despite the changing output of the pump as it degrades over time. This is particularly relevant for piezo pumps where the output of the pump may vary significantly.

The microcontroller can also be programmed to deliver pre-set pressure profiles. The pressure profiles may correspond to, but not necessarily, any suction patterns that would mimic the sucking pattern of an infant. The patterns could mimic for example the sucking pattern of a breastfed infant during a post birth period or at a later period in lactation.

The profiles can also be manually adjusted by the user using a control interface on the housing of the breast pump system or on an application running on a connected device.

Additionally, the user is able to manually indicate the level of comfort that they are experiencing when they are using the system. This can be done using a touch or voice-based interface on the housing of the breast pump system itself or on an application running on a connected device.

The system stores the user-indicated comfort levels together with associated parameters of the pumping system. The pressure profiles may then be fine scaled in order to provide the optimum comfort level for a particular user.

The profiles or any of the pumping parameters may be calculated in order to correlate with maximum milk expression rate or quantity.

The pressure profiles or any of the pumping parameters may also be dynamically adjusted depending on the real time milk expression rate or quantity of milk collected. The pressure profiles or any of the pumping parameters may also be dynamically adjusted when the start of milk let-down has been detected.

Additionally, the system is also able to learn which parameters improve the breast pump system efficiency. The system is able to calculate or identify the parameters of the pumping mechanism that correlate with the quickest start of milk let-down or the highest volume of milk collected for a certain time period. The optimum comfort level for a particular user may also be taken into account.

Figure 12 shows a schematic for a system 400 for a breast pump 100 which can estimate the volume of milk collected in the collection container 3 from data collected on the air-side part 202 of the system 400.

The pump 83 is connected to the circuit via two bleed valves 126, 128. The first bleed valve 126 is arranged to function when the pump 83 applies a negative pressure. As such, this valve 126 is connected to a "bleed in" 127, for supplying atmospheric air to the system 202.

The second bleed valve 128 is arranged to function when the pump 83 applies a positive pressure. As such, this valve 128 is connected to a "bleed out" 129 for bleeding air in the system 202 to the atmosphere.

Although Section C describes the preferred embodiment for measuring or inferring the volume of milk collected in the milk collection container using IR sensors, an alternative method for measuring or inferring the volume of milk collected in the milk collection container using pressure sensors is described also below.

During a milking pump cycle, the pump 83 applies negative pressure on the air side 13B of the diaphragm 13 which causes its extension towards the pump 83. This increases the volume of the space on the milk side 13B of the diaphragm 13. This conveys the decrease in pressure to the breast to encourage expression of milk. A set of three non-return valves 121, 123, 125 ensure that this decrease in pressure is applied only to the breast (via the breast shield 7) and not the milk collection container 3. To measure the volume of milk collected in the container 3, the pump 83 is used instead to apply positive pressure to the diaphragm 13. The diaphragm 13 is forced to extend away from the pump 83 and conveys the pressure increase to the milk side 201 of the system 400. The three non-return valves 121, 123, 125 ensure that this increase in pressure is exclusively conveyed to the milk collection container 13.

The breast pump may further comprise: a first non-return valve between the milk flow side of the diaphragm and the breast shield, configured to allow only a negative pressure to be applied to the breast shield by the pump; a second non-return valve between the milk-flow side of the diaphragm and the milk collection container configured to allow only a positive pressure to be applied to the milk collection container by the pump; and a pressure sensor in pneumatic connection with the pressure-generation side of the diaphragm.

The resulting pressure increase is monitored behind the diaphragm 13 from the air-side 202 by a pressure sensor 101. Preferably, the pressure sensor 101 is a piezoelectric pressure sensor (piezo pressure sensor). The rate at which the pump 83 (at constant strength) is able to increase the pressure in the system 400 is a function of the volume of air that remains in the milk collection container 3. As air is many times more compressible than liquid, the rate at which pressure increases in the system 400 can be expressed as an approximate function of the volume of milk held in the collection container 3.

Thus by increasing the pressure in this fashion, the rate of pressure increase can be determined, from which the volume of milk held in the container 3 is calculable. Figure 13 shows repeated milking and volume measurement cycles as the collection container 3 is filled. To determine the rate of pressure increase the pump 83 was run for a fixed time. As pumping proceeds and the volume of air reduces in the system 400, the pump 83 is able to achieve a higher pressure. Each milking cycle is represented by a positive pressure spike 41. There is a clear upwards trend 43 in magnitude of positive pressures achieved as the collection container 3 is filled.

A method of estimating the pressure applied by a breast pump may comprise the steps of: selecting a pressure cycle from a pre-defined list of pressure cycles; applying pressure with the pump to stimulate milk expression; reading the output of the pressure sensor; and adjusting the applied pressure of the pump to match the pressure profile selected. This allows for repeatable application of force to the breast, even as the pump performance degrades.

Preferably the method further comprises the steps of: approximating the elasticity and extension of the diaphragm at the relevant pressure; and calculating an estimated applied pressure based upon the output of the pressure sensor and the approximated elasticity and extension of the diaphragm.

Alternatively, a method of estimating the milk collected by a breast pump may comprise the steps of: generating a positive pressure with the pump; transmitting the positive pressure via the diaphragm and second non-return valve to only the milk collection

container; measuring the increase in pressure by the pressure sensor in pneumatic connection with the diaphragm; estimating the volume of milk inside the milk collection container based upon the rate of increase of pressure. In this manner, the volume of milk can be estimated remotely.

In this manner, an estimate can be obtained for the volume of milk in the container 3 based upon the measured pressures.

Figure 13 also shows a dead end stop pump test 45 as described above. The negative spike shows the application of negative pressure directly to the pressure sensor 101.

2. Breast shield sizing and nipple alignment

The correct sizing of the breast shield and the alignment of the nipple in the breast shield are key for an efficient and comfortable use of the breast pump. However breast shape, size as well as nipple size and position on the breast vary from one person to another and one breast from another. In addition, women's bodies often change during the pumping life cycle and consequently breast shield sizing may also need to be changed. Therefore, a number of breast shield sizes are available. Guide lines for correct nipple alignment are also provided.

With reference to Figure 14, three breast shield sizes are shown (A1, B1, C1). The substantially clear breast shield gives an unobstructed view of the breast and allows a user to easily confirm that she has the appropriate sized shield for her breast.

In order to determine the correct breast shield size and nipple alignment, the breast shield and the diaphragm are detached from the housing and placed on the breast with the sizing symbol facing upwards (with the diaphragm positioned below the nipple) and the nipple aligned in the centre of the fit lines (as shown in A2, B2, C2). The transparent breast shield allows the user to observe the nipple while adjusting the position of the breast shield in order to align the nipple correctly near the centre of the breast shield nipple tunnel. Prior to using the pump, the nipple is aligned correctly, and the breast shield is pushed into place ensuring the seal is correctly positioned on the breast shield. The fit lines should be directly aligned with the outside of the nipple. The correct

alignment is illustrated B2.

When the nipple is correctly aligned, the user then rotates the breast shield in order for the diaphragm to be positioned on top of the nipple. The user may then quickly assemble the rest of the breast pump (i.e. the housing and the milk container) on the breast shield via a one-click attachment mechanism confirming correct engagement, which may be performed one-handed. Nipple alignment may therefore be easily maintained. Audio and/or haptic feedback may also be provided to further confirm correct engagement.

3. Connected Device Application

Figures 15 to 20 show examples of screenshots of a connected device application that may be used in conjunction with the breast pump system as described above. The interface shown here is an example only and the same data may be presented via any conceivable means including animated graphics, device notifications, audio or text descriptions.

Figure 15 shows a homepage of the application with different functions provided to the user which can be accessed either directly while pumping or at a later time in order for example: to review pump settings or the history of previous pumping sessions.

Figure 16 shows a status page with details of remaining battery life, pumping time elapsed and volume of milk inside the milk container.

Figure 17 shows screenshots of a control page, in which a user is able to control different pump parameters for a single breast pump (A) or two breast pumps (B). The user may press on the play button to either start, pause, or resume a pumping activity. The user may also directly increase or decrease the rate of expression using the (+) or (-) buttons. When only one breast is being pumped (A), the user may also indicate if it is either the right or left breast that is being pumped. The user may also control the pump peak pressure or alternatively may switch between different pre-programmed pressure profiles such as one mimicking the sucking pattern of a baby during expression or stimulation cycle.

Figure 18 shows a page providing a summary of the last recorded pumping session.

Figure 19 shows a page providing a history of previous pumping sessions. The user may scroll down through the page and visualize the data related to specific pumping sessions as a function of time.

The application is also capable of providing notifications relating to pumping. Figure 20 shows a screenshot of the application, in which a user is provided a notification when the milk collection bottle is full. Other generated notifications may include warnings about battery life, Bluetooth connection status or any other wireless communication status, status of miss-assembly, excessive movement or lack of expression.

Figure 21 shows a further example with a screenshot of an application running on a connected device. The page shows the pumping status when a user is using a double pump mode of operation with a pump on each breast. The user is able to manually control each pump individually and may start, stop or change a pumping cycle, increase or decrease each pump peak pressure, or switch between different pre-program pressure profiles such as one mimicking the sucking pattern of a baby during an expression or stimulation cycle. The application also notifies the user when a milk collection container is nearly full as shown in Figure 22.

Figure 23 shows a status page with an alert notifying the user that the milk collection container of the pump on the right breast is full. A message is displayed that the pump session has paused and that the milk collection container should be changed or emptied before resuming pumping.

With reference to Figure 24, when the left and right pump are stopped or paused, the application displays the elapsed time since the start of each session (right and left), the total volume of milk collected in each bottle.

With reference to Figure 25, a page summarising the last session (with a double pump mode) is displayed.

In addition to the data provided to the user, and their interactions with the application, the app will also hold data that the user does not interact with. For example, this may include data associated with pump diagnostics. In addition to all functions and sources of

data discussed above, the application may itself generate metadata associated with its use or inputs, notes or files uploaded by the user. All data handled within the mobile application can be periodically transferred to a cloud database for analysis. An alternative embodiment of the breast pump system may include direct contact between the database and the pump, so that pumping data may be conveyed directly, without the use of a smartphone application.

In addition to providing data to the cloud, the application may also provide a platform to receive data including for example firmware updates.

4. Breast pump data analysis

The discreet, wearable and fully integrated breast pump may offer live expression monitoring and intelligent feedback to the user in order to provide recommendations for improving pump efficiency or performance, user comfort or other pumping/sensing variables, and to enable the user to understand what variables correlate to good milk flow.

Examples of variables automatically collected by the device are: time of day, pump speed, pressure level setting, measured pressure, pressure cycle or duty cycle, voltage supplied to pumps, flow rate, volume of milk, tilt,, temperature, events such as when let-down happens, when a session is finished. The user can also input the following variables: what side they have pump with (left or right or both), and the comfort level.

This is in part possible because the live milk volume measurement system functions reliably (as discussed in Section B). The breast pump system includes a measurement sub system including IR sensors that measures or infers milk flow into the milk container, and that enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. The generated data may then be distributed to a connected device and/or to a cloud server for analysis in order to provide several useful functions.

Figure 26 illustrates an outline of a smart breast pump system network which includes the breast pump system (100) in communication with a peripheral mobile device and application (270) and several cloud-based databases (268, 273). The breast pump system

(100) includes several sensors (262). Sensor data refers to a broad definition including data generated from any sensor or any other analogue/digital reading directly from the motherboard or any other component. However, within the embodiment detailed, these measurements include one or more of the following, but not limited to: milk volume measurements, temperature sensor readings, skin temperature sensing, pressure sensor readings, accelerometer data and user inputs through any physical device interface.

The device also contains a number of actuators, including, but not restricted to: piezoelectric pump(s), solenoid valve(s), IREDs and an LED display. Sensors and actuators within the device are coordinated by the CPU (263). In addition, any interactions, and data from these components, may be stored in memory (264).

Further to these components, the device also contains a communication chip, such as a Bluetooth chip (265) which can be used to communicate wirelessly with connected devices such as a peripheral mobile device (270). Through this connection any sensor data (267) generated in the breast pump can be sent to the connected device. This user data, along with any other metadata generated from a connected device app, can be provided to an online database which aggregates all user data (273). In addition, the communication chip will also allow the sending of user control data / firmware updates from the connected device to the breast pump system (266).

Raw data (271) collected from the measurement sub-system including sensors (262) may be analysed on a cloud database and the analysed data may be stored on the cloud (272). Through inferences provided by the analysed data, firmware updates (269) may be developed. These can be provided for download to the pump through, for example, an online firmware repository or bundled with the companion app in the connected device app store (268).

In addition, it should be appreciated that despite the sophistication of the proposed breast pump network, the breast pump still retains complete functionality without wireless integration into this network. Relevant data may be stored in the device's memory (264) which may then be later uploaded to the peripheral portion of the system when a connection is established, the connection could be via USB cable or wireless.

The measurement sub-system may analyse one or more of the following:

- the quantity of the liquid in the container above its base;
- the height of the liquid in the container above its base;
- the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.

Based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase, a haptic and/or visual indicator indicates if the pump is operating correctly to pump milk. For example, the visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.

The visual indicator may provide:

- an estimation of the flow rate;
- an estimation of the fill rate;
- an indication of how much of the container has been filled.

As a further example, an accelerometer may infer the amount of movement or tilt angle during a pumping session. If the tilt angle excesses a threshold, the system warns or alerts the user of an imminent spillage, or provides the user with an alert to change position. Alternatively, the system may also stop pumping to prevent spillage, and once the tilt angle reduces below the threshold, pumping may resume automatically. By sensing the movement or title angle during a pumping session, the system may also derive the user's activity such as walking, standing or lying.

Many variables can affect milk expression and data analysis of these multiple variables can help mothers to achieve efficient pumping regimes and improve the overall user experience.

Therefore, the measurement sub-system measures or infers milk flow into the milk container and enables a user to understand what variables (e.g. time of day, pump setting) correlates to good milk flow. The amount of milk expressed over one or more sessions is recorded as well as additional metrics such as: time of day, pump setting, length of a single pumping session, vacuum level, cycle times, comfort, liquids consumed by the mother. Live data or feedback is then provided to the user to ensure the breast pump is

being used properly and to support the user in understanding the variables that would correspond to the specific individual optimum use of the breast pump.

Furthermore, live data can be used to automatically and intelligently affect specific pumping parameters in order to produce the most efficient pumping session. For example, if the rate of expression increases, the milking cycle might be adjusted accordingly to achieve a more efficient, or more comfortable pumping cycle.

The measurement sub-system also enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. Collected metrics are transferred through wireless connections between the pump, a connected device or app and a cloud database. Additionally, the application can also connect to other apps residing on the connected device, such as fitness app or social media app or any other apps. Further metrics may also include the behaviour or specific usage of the user associated with the connected device while using the pump (detection of vision and/or audio cues, internet usage, application usage, calls, text message).

Different aspects of pumping can be automatically changed based on dynamic sensor feedback within the breast pump device. The data analysis system is able to access real-time data of pumping sessions and may be used to perform one or more of the following functions, but not limited to:

- indicate whether the milk is flowing or not flowing,
- measure or infer the quantity and/or height of the liquid in the container above its base,
- give recommendations to the mother for optimal metrics for optimal milk flow,
- give recommendations to the mother for optimal metrics for weaning,
- give recommendations to the mother for optimal metrics for increasing milk supply (e.g. power pumping),
- give recommendations to the mother for optimal metrics if an optimal session start time or a complete session has been missed,
- automatically set metrics for the pumping mechanism, such as length of a single pumping session, vacuum level, cycle times.
- automatically stop pumping when the milk container is full,
- automatically adjust one or more pumping parameters to achieve an optimum

pumping session,

- automatically adjust one or more pumping parameters to achieve a comfortable pumping session,
- automatically change the pumping cycle from a programmed cycle to another different programmed cycle, such as from a stimulation cycle to an expression cycle.

In addition, sensor feedback might be used to improve the physical function of the breast pump system itself. For example, an array of piezoelectric pumps may be dynamically adjusted in response to their operating temperatures so as to optimise the total life of the component whist maintaining peak pressures.

Many additional embodiments may be described for these simple feedback systems, yet the premise remains: real-time sensor feedback is used to automatically and dynamically adjust actuator function. Each feedback program may feasibly include any number and combination of data sources and affect any arrangement of actuators.

The data generated can also be used to generate large datasets of pumping parameters, user metadata and associated expression rates, therefore allowing the analysis of trends and the construction of associations or correlations that can be used to improve pumping efficiency, efficacy or any function related to effective milk expression. The analysis of large user datasets may yield useful general associations between pumping parameters and expression data, which may be used to construct additional feedback systems to include on firmware updates.

Multiple data sources can be interpreted simultaneously and several different changes to pumping might be actuated to increase pumping efficiency, user experience or optimize pump performance.

Collected metrics may be anonymised and exported for sharing to other apps, community or social media platforms on the connected device, or to an external products and services, such as community or social media platform. By contrasting the performance of different users in the context of associated metadata, users may be grouped into discrete 'Pumper profiles' or communities, which may then be used to

recommend, or action the most appropriate selection of intelligent feedback systems to encourage efficient expression. For example, a higher peak pressure may be recommended for women who tend to move more whilst pumping, so as to achieve more efficient expression.

5

SECTION B: IR SYSTEM

This section describes the milk detecting system used in the Elvie™ pump.

With reference to Figures 27 and 28, there is shown a device 270 for use in detecting the level of liquid inside a container 275. The device 270 is formed of a housing 271 in which is located a sensing assembly 272 comprising a series of optical emitters 273 (an array of three optical emitters is used on one implementation) which are relative to, and each located at a distance from, an optical receiver 274. In operation of the device as will be described, each optical emitter 273 is operable to emit radiation which is received by the optical receiver 274. In an embodiment of the invention, the series of optical emitters are each located equidistant from the optical receiver 274.

The optical emitters 273 and the optical receiver 274 from the sensing assembly 272 are located in a portion 276 of the device 270 which faces the container 275 when the device is connected to the container 275. The portion 276 of the device 270 containing the optical emitters 273 and the optical receiver 274 comprises a window 277 of material which is transparent to optical radiation. In this way, each of the optical emitters 273 and the optical receiver 274 have a line of sight through the window 277 into the container 275 when the device 270 is connected thereto.

A controller 278 comprising a CPU 279 and a memory 280 is provided in the device 270 for controlling the operation of the sensing assembly 272. An accelerometer 281 is also provided in the housing 271, which is operatively connected to the controller 278. Operation of the device 270 when connected to the container 275 will now be described.

In a principal mode of operation, to determine the level L of liquid inside the container 275, the controller 278 instructs the optical emitters 273 to each emit radiation towards the surface of the liquid inside the container 275 at a given intensity. The optical receiver 274 receives the reflected radiation from each optical emitter 273 via the surface of the liquid and each of these intensities is recorded by the controller.

For each operation of the sensing assembly 272, the controller 278 records the intensities of radiation emitted by each of the optical emitters 273 as intensities IE1; IE2…IEn

(where n is the total number of optical emitters), and records the intensities of radiation received by the optical receiver 274 from each of the optical emitters 273 as received intensities IR1; IR2…IRn.

By comparing the emitted radiation intensities IE1; IE2…IEn with the received radiation intensities IR1; IR2…IRn, the controller 278 calculates a series of intensity ratios IE1:IR1; IE2:IR2…IEn:IRn, which are then used to determine the level of the liquid inside the container. At the most basic level, if the intensity ratio of IE1:IR1 is the same as IE2:IR2, given the optical emitters 273 are equidistant from the optical receiver 274, this indicates that the level of the liquid inside the container is parallel to the top of the bottle, as shown in Figure 27. In contrast, if these two intensity ratios are different, this indicates that the liquid level is at a different angle, such as that shown in Figure 28.

To accurately determine the level and the quantity of liquid inside the container 275, the controller 278 processes the recorded intensity ratios using a database located in the memory 280. The database contains an individual record for each container which is operable to connect with the device 270. Each record from the database contains a look-up table of information, which contains expected intensity ratios (IE1:IR1 and IE2:IR2) for the container 275 when filled at different orientations, and with different quantities of liquid.

By comparing the information from the look-up table with the recorded intensity ratios, the controller 278 calculates the level and quantity of liquid inside the container 275 and stores this information in the memory 280.

In situations where a container 275 to the device 270 contains no stored record in the database, the sensing assembly 272 can be used in a calibration mode to create a new record. In the calibration mode, the sensing assembly 272 is operated as the container is filled from empty, and as it is positioned at different orientations. At each point during the calibration mode, the controller 278 calculates the recorded intensity ratios (IE1:IR1 and IE2:IR2) and stores them in the record relating to the container 275. For each set of recorded intensity ratios, the user includes information in the record relating to the orientation and fill level of liquid inside of the container 275.

To improve the accuracy of the results obtained by the device 270 during its use, the controller 278 when recording each intensity ratio also records a parameter from the accelerometer 281 relating to the acceleration experienced by the device 270. For each recorded acceleration parameter, the controller 278 determines whether the parameter 278 exceeds a predetermined threshold acceleration parameter stored in the memory 280. The predetermined threshold is indicative of an excessive acceleration, which causes sloshing of liquid inside the container 275 connected to the device 270. In the event of a recorded acceleration parameter exceeding the predetermined threshold acceleration parameter, the controller 278 flags the recorded intensity ratios associated with the recorded acceleration parameter as being unreliable (due to sloshing).

Even without the use of the accelerometer 281, the controller 278 is nonetheless operable to determine whether a set of recorded intensity ratios occur during a period of excess acceleration. In this regard, for each set of intensity ratios recorded at a given time, the controller 278 checks whether any of these intensity ratios is of a predetermined order of magnitude different than the remaining recorded intensity ratios from the set. In the event that the controller 278 determines that this is the case, this indicates that the liquid inside the container has 'sloshed' as a result of the excess acceleration, as shown in Figure 29. In this event, the controller 278 flags the set of recorded intensity ratios as being unreliable.

It will be appreciated that instead of recording the relative intensities of radiation emitted by the optical emitters 273 with the radiation received by the optical emitter 274, the controller 278 could instead record the time taken for radiation emitted by each of the optical emitters 273 to be received by the optical receiver 274. In this arrangement, the look up table would instead contain time periods as opposed to intensity ratios.

In terms of the applications for the device 270, it will be appreciated that the device can be used in a wide variety of applications. One possible application is the use of the device 270 to determine the level of liquid located within a container 275, such as a baby bottle, used as part of a breast pump assembly. In this arrangement, the device 270 is associated with a breast pump 301 which assists with the expression of milk from a breast. The breast pump may be located in the housing 271 of the device 270 as shown in Figure 30, or it may be realisably connected to the housing 271.

Either way, the device 270 would be connectable to the container 275 such that milk expressed by the breast pump can pass from the pump via a channel 302 into the container 275.

The breast pump may be any type of breast pump system including any shapes of milk container or bottle and may comprise a pump module for pumping milk from a breast. The pump module being contained within the housing may comprise: a coupling, a container attachable to the housing via the coupling to receive milk from the pump, a sensing assembly within the housing and comprising at least one optical emitter operable to emit optical radiation towards the surface of the body of milk held in the container when the housing is connected to the container, an optical receiver for receiving the reflected radiation from the surface of the milk, and a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the milk inside the container based on the reflected radiation received by the optical receiver.

By determining the level of milk inside the container based on reflected radiation from the surface of the milk in the container, there is no need to monitor the individual droplets of milk entering the container, such that the sensing assembly can avoid errors associated with measuring these droplets. For example, because we take multiple reflection-based measurements once the container is filled, we can generate an average measurement that that is more accurate than a single measurement. But with systems that rely in counting individual droplets, that is not possible – further, systemic errors (e.g. not counting droplets below a certain size) will accumulate over time and render the overall results unreliable. Furthermore, by not needing to measure these droplets, the sensing assembly from the breast pump need not always be on during the pumping process, which saves power.

When at least two optical emitters are used, the sensing assembly from the breast pump may determine the level of milk inside the container more accurately and irrespective of the orientation of the liquid level inside the container.

Each optical emitter may be equidistant from the optical receiver in order for the

controller to easily calculate the level of the milk inside the container based on the reflected radiation originating from each optical emitter. The signals from the optical receiver preferably comprise information relating to the intensity of the radiation received by the optical receiver.

Each optical emitter may be operable to emit radiation at a different wavelength, or at a different time, than the other optical emitters. In this way, the controller can more easily process the signals from the optical receiver, and more easily distinguish between the radiation emitted by each of the optical emitters.

The optical emitter may emit radiation in the visible range of wavelengths. Alternatively, it may be UV or IR light. The emitted wavelength may be for example between 10nm and 1mm.

The sensing assembly may also comprise at least one accelerometer electrically connected to the controller. The controller may be configured to record an accelerometer parameter from the accelerometer and determine whether the accelerometer parameter exceeds a predetermined threshold. The predetermined threshold may be indicative of an excessive acceleration, which might cause sloshing of milk inside any container connected to the breast pump.

Another application for the device 270 is as a collar for detecting the level/quantity of liquid in a container 275, such as a baby bottle, via its lid 310. An example of the device 270 being used as such a collar is shown in Figure 31. In this arrangement, the device 270 is located between the container 275 and the lid 310, and comprises a first end 311 having a first coupling 312 for attaching the collar to the lid 310. The device comprises a second end 313 having a second coupling 314 for attaching the device 270 to the container 275. The second coupling may be a screw thread, shown in Figure 31, on the inside surface of the container 275. In this way, the distinctive bottom inside surface can be used by the sensing assembly 272 to more easily calibrate itself to the container 275 on which the distinctive bottom inside surface is located. The distinctive bottom may also be used to help identify which container 275 the device is connected to, and thus which record should be used from the database when the device 270 is used.

To further improve the accuracy of the sensing assembly 272, the controller 278 may also be configured to use the recorded information from the accelerometer 281, in situations where the record acceleration is below the predetermined threshold acceleration parameter, to calculate a more accurate liquid level and/or quantity of liquid located inside the container which is compensated for acceleration.

In one particular arrangement, the controller 278 may poll the accelerometer 281 prior to each operation of the sensing assembly 272 to verify that the device 270 is not currently undergoing excessive acceleration. In the event of the controller 278 determining excessive acceleration in the device 270, the controller 278 would continually re-poll the accelerometer, and not operate the sensing assembly 272, until the parameter from the accelerometer is determined as being below the predetermined threshold acceleration parameter stored in the memory 280.

It will also be appreciated that for each container record stored in the database, the container record may comprise a plurality of look up tables, wherein each look up table is associated with a particular liquid used in the container, and wherein each look up table contains its own set of intensity ratios. In this way, the device 270 can more accurately determine the level/quantity of different liquids used in a particular container 275.

As described herein, the sensing assembly 272 has been described as having a plurality of optical emitters 273. It will be appreciated however that the sensing assembly could operate using a single optical emitter 273 and plurality of optical receivers 274. In this arrangement, each record from the database would contain a plurality of ratios relating to the emitted radiation from the optical emitter 273 as received by each of the optical receivers 274. In use of the device 270, the controller 278 would then similarly record the emitted radiation from the optical emitter 273 as received by each of the optical receivers 274. In an alternate arrangement, there may be provided a plurality of optical emitters 273 and a plurality of optical receivers 274, wherein each optical emitter 273 is associated with a respective optical receiver 274. In its simplest arrangement, the sensing assembly 272 may comprise a single optical emitter 273 and a single optical receiver 274.

In certain configurations, the optical emitters 273 may together emit radiation having the same wavelength. In other configurations, the optical emitters 273 may each emit

radiation having a different wavelength. In this latter configuration, the optical receiver 274 would then be able to determine which optical emitter 273 is associated with any given received radiation, based on the wavelength of the received radiation.

The optical emitters 273 may also each emit radiation at different times, such to allow the controller 278 to more easily process the signals from the optical receiver 274, and more easily distinguish between the radiation emitted by each of the optical emitters 273.

In relation to the electrical connection between the controller 278 and the sensing assembly 272, it will be appreciated this electrical connection may be either a wired/wireless connection as required.

Although not shown in the Figures, the device 270 herein described is preferably powered by a battery or some other power source located in the device 270. In other embodiments, the device 270 may be powered using mains electricity.

In one configuration, it is also envisaged that rather than the controller 278 comparing the information from the look-up table with the recorded intensity ratios to calculate the level and quantity of liquid inside the container 275, the controller 278 could instead process the recorded intensity ratios through a liquid-level equation stored in the memory 280. In this configuration, the liquid-level equation could be a generalised equation covering a family of different containers, or could be an equation specific to a container having a given shape and/or type of liquid inside.

It will also be appreciated that in some applications of the device 270, the device could be used to detect the level of a solid, as opposed to a liquid, in a container. As used herein, the terms 'optical emitter' and 'optical receiver' are intended to cover sensors which can emit radiation in or close to the optical wavelength. Any type of radiation at or close to the optical wavelength is suitable provided that it does not have any harmful effects. The exact wavelength is not important in the context of the invention. Such sensors thus include those which can emit visible radiation (such as radiation having wavelengths in the region of 400nm-700nm), and/or those which can emit IR radiation (such as radiation having wavelengths in the region of 700nm-1mm and/or those which can emit UV radiation (such as radiation having wavelengths in the region of 10nm to

400nm).

Existing prior art for such a sensor module is the apparatus disclosed in RU2441367. In this apparatus, the container is an industrially sized milk tank, which only includes a single laser mounted at the top of the tank. Whilst this apparatus is suited for large-sized containers, which do not move in use, the apparatus is less-suited for applications where the container moves in use, or where the liquid level inside the container is non perpendicular to the laser beam shone into the container. In contrast, the sensor module described above can be used in a variety of different applications, is conveniently located within a housing, and which by virtue of it having at least two optical emitters, can determine the level of liquid even inside containers of irregular shapes, and which can determine the level of liquid inside a container irrespective of the orientation of the liquid level inside the container.

Further to the embodiments of the fluid measurement system in different contexts, it can be appreciated that different functions entirely may be possible using the same component structure. For example, it is known that certain molecules within breast milk absorb specific wavelengths of light at characteristic propensities. Whilst the proposed system uses multiplexed IREDs at the same wavelengths to perform proximity measurements, the same array of IREDs may instead be used to emit several different wavelengths of light and determine their absorption upon reflection. If appropriately calibrated, the system may be able to report on the presence or concentration of specific compounds in the expressed milk, such as fat, lactose or protein content.

In addition to this embodiment, it is feasible that the system might be applied to monitor the change in volume of any other container of liquid, given there is sufficient reflection of IR off its surface. These embodiments might include for example: liquid vessel measurement such as for protein shakes, cement or paint, or volume measurements within a sealed beer keg.

SECTION C: BRA CLIP

This section describes a bra clip that forms an accessory to the Elvie™ pump.

It relates to a system allowing a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump. As such, the user does not need a specialised adjustable bra; instead the present system works with all conventional maternity bras. The user also does not have to purchase any larger bras to wear while pumping.

As shown in Figure 32, a typical maternity bra 320 comprises a support structure made up of shoulder straps 321 which support the bra 320 on the wearer's shoulders, and a bra band 322 for extending around a user's ribcage, comprising two wings 323 and a central panel or bridge 324. The straps 321 are typically provided with adjustment mechanisms 325 for varying the length of the straps 321 to fit the bra 320 to the wearer. At the outermost end of each wing, an attachment region 326 is provided. Typically, hooks 327 and loops 328 are provided for securing the bra 320 at the user's back. However, any other suitable attachment mechanism may be used. Alternatively, the attachment region 326 may be provided at the front of the bra 320 in the bridge region 324, with a continuous wing 323 extending continuously around the wearer's back. Typically, a number of sets of loops 328 are provided to allow for variation in the tightness of the bra 320 on the wearer. While shown as having a separation in Figure 32, the wings 323 and bridge 324 may form a single continuous piece in certain designs. Likewise, while shown with a distinct separation in Figure 32, the shoulder straps 321 and the wings 323 may likewise form a single continuous piece.

The maternity bra 320 is further provided with two breast-supporting cups 329 attached to the support structure. The cups 329 define a cup size, which defines the difference in protrusion of the cups 329 from the band 322. The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting a 2 cm difference between the protrusion of the cups 329 from the band 322. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes

of S, M, L, XL, etc.

The cups 329 may be stitched to the bra band 321. At least one of the cups 329, is in detachable attachment with the corresponding strap 321. In particular, this is achieved at attachment point 330 where a hook 331 attached to the bra strap 321 engages with a clasp 331 attached to the cup 329. The hook 331 and the bra strap adjuster 325 are set such that in the closed position, the cup size of the bra 320 fits the wearer's breasts.

In Figure 32, the left cup 329 is shown attached to its attachment point 330, which the right cup 329 is unattached. In this manner, the wearer is able to detach the cup 329 to expose their breast for feeding or for breast pumping. Once this is completed, the cup 329 is reattached and the maternity bra 320 continues to function as a normal bra.

While in the depicted embodiments, a hook 331 is shown on the bra strap 321 and a clasp 332 is shown on the cup 329, it is appreciated that the provision of these may be reversed, or that alternative attachment mechanisms may be used.

A maternity bra therefore may comprise a support structure comprising shoulder straps and a bra band and a first and a second cup each attached to the support structure to provide a first cup size, at least one cup being at least partially detachable from the support structure at an attachment point.

In other embodiments, the detachable attachment point 330 may be provided at a different location, such as at the attachment between the bra band 322 and the cup 329. The mechanism for such an attachment point is the same as described above.

A clip has been designed such that it is configured to be attached to the support structure at a position away from the attachment point. This results in the original attachment point being usable, with the clip providing an alternative attachment point to give, in effect, an adjusted cup size.

Alternatively, the clip may also be attachable to the support structure at a plurality of non-discrete positions. This ensures essentially infinite adjustment of the clip position such that the perfect position for the user can be found.

The clip can also extend between an unextended and an extended state, and can attach to the support structure at the attachment point; the first cup size is providable when the at least partially detachable cup is attached to the clip when the clip is an unextended state; the second cup size is providable when the at least partially detachable cup is attached to the clip when the clip is in an extended state. An extendable clip like this allows quick switching between the two states in use.

Figure 33 depict a clip 335 according to the present invention, along with a clasp 332 shown in isolation from the bra cup 329 it is normally attached to. The clip comprises a first engagement mechanism and at least one second engagement mechanism(s). The clip is attachable in a releasable manner to the support structure at a first position via the first engagement mechanism and attachable in a releasable manner to one of the partially detachable cups via the second engagement mechanism to provide a second cup size different to the first cup size. The clip 335 is provided with a material pathway 336 which receives a portion of the bra strap 321. In the particular embodiment of these Figures, the clip 335 is substantially U-shaped, with a narrowing profile towards its open end. However, it is appreciated that any other suitable shape with a material pathway may be used, such as an S-shape or E-shape. The clip 335 is designed to be attached to the bra strap 321 in a releasable manner, with the slot 336 acting as a support engaging mechanism. The releasable manner means that the clip 335 may be simply removed from the bra 320 without causing any damage to the functioning of the bra 320. To enhance the ease of attachment, the clip 335 may be provided with outwardly extending wings 204 which help direct the bra strap 321 into the clip 335. The clip 335 is further provided with a hook 220 acting as a cup engaging mechanism which can engage with the clasp 332.

Figure 33 (c) shows the clip 335 being attached to a bra strap 321 in order to provide a second attachment point 337 for the clasp 332 to attach to, and hence to provide a second cup size for the bra 320. In this particular embodiment, the clip 335 is attached in a portion of strap 321A below the original attachment point 330 and hence the second attachment point 337 is likewise below the original attachment point. This results in a second cup size larger than the first cup size. In preferred embodiments, as shown in these Figures, the clip 335 engages with the support structure in a direction transverse to

the direction in which it engages with the cup.

Figure 33 (d) and (e) show how a wearer is able to move between the first and second cup sizes. In 33(d), the cup 329 is attached at the first attachment point 330 to provide a first cup size. The wearer then disengages the clasp 332 from the hook 331 at the hook 338 at the second engagement point 239. In this manner, the wearer is easily able to transition between the two cup sizes.

Figures 34 and 35 show an alternative design for a clip 340. This clip 340 is substantially "E-shaped", with a back portion 341 and first, second and 5 third prongs 342A, 342B, 342C extending transverse from this back portion 341. The three prongs 342A, 342B, 342C are spaced apart along the length of the back portion 341. The first and third prongs 342A, 342C are provided with attachment clips 343A, 343B.

These attachment clips 343A, 343B can engage with the clasp 332 of a bra to provide the second cup size. Depending upon the orientation of the clip 300, one or the other of the attachment clips 343A, 343B will be used to attach the clasp 332 of the bra. By providing these clips 343A, 343B on both of the first and the third prongs 342A, 342C the clip is easily reversible so it can be used on either side of the bra. Preferably the clip 340 is also symmetrical, to aid the reversibility of the clip 340.

Figure 35 shows the clip 340 attached to a bra. As can be seen, the first and third prongs 342A, 342C extend on the front side of the bra strap, with the second prong 342B extending on the rear side of the bra strap. In this manner, the clip 340 is attached to the strap. In preferable embodiments, a grip-enhancing member 344 such as a number of projections and/or roughened patches can be provided on the second prong 342B in order to strengthen this grip.

In alternative embodiments, the attachment clip could be provided on the second, centremost prong 342B. In such an arrangement, the centremost prong 342B would be on the outside of the bra, with the first and third prongs 342A, 342C on the inside.

The provision of the attachable clip allows maternity bras already owned by the wearer to be quickly transformed into bras with quick switchable double cup size options.

This allows the use of integrated wearable breast pumps which increase the user's required cup size. This allows more design freedom for the breast pump in terms of size and shape, while still allowing the user to discretely pump with the pump held within their bra. By allowing conversion of the user's existing maternity bras, they are not forced to purchase specially designed bras to wear with the pump. The bra is hence normally at the first engagement point 330 when the breast pump device is not being used. As shown in Figure 33, the clasp 332 is then engaged by the user to discretely switch between the two configurations, and the user then inserts the pump without any complex adjustment or removal of clothing.

Preferably, the clip will be relatively unobtrusive in size and shape and hence can be left in place when the bra is first put on and used when necessary. To this end, the clip is preferably machine washable without significant damage or degradation.

In some embodiments, the clip may be switchable between positions for engaging with each cup so that a single clip may be used on either side of the bra. To achieve this, the clip is preferably reversible. This may provide the user with a visual indication of which breast has produced milk most recently so switching can take place.

In a preferred embodiment, the first engagement mechanism engages with the support structure in a first direction and the second engagement mechanism engages with the cup in a second direction transverse to the first direction. This increases ease of attachment as with this structure the sideways engagement of the clip to the support structure ensures that the second attachment mechanism is correctly orientated for the cup.

The second engagement mechanism may be one or more of a hook or a snap or a clip. This ensures easy interfacing with the traditional hook and clasp systems already provided on maternity bras.

Preferably the clip further comprises two distinct second engagement mechanisms which can be used interchangeably dependent upon the orientation of the clip. This makes the clip easier to use as it can be quickly switched between each bra strap, and the user does not have to worry which way up to put the clip on.

Preferably, the clip comprises a material pathway with an opening for receiving a portion of the support structure as the first engagement mechanism for securing the clip to the bra. This ensures a quick and simple method for attaching the clip to the bra. In particular, the clip may substantially U-shaped, and the material pathway is between the arms of the U.

Preferably, the clip comprises three prongs extending from a central support, the three prongs arranged as a central prong and two outer prongs so as to receive the support structure on one side of the central prong and on the opposite side of each respective outer prong, at least one prong being provided with the second engagement mechanism. This ensures a strong attachment to the bra and a simple design.

Preferably, both outer prongs are each provided with a respective second engagement mechanism. This ensures that the clip is reversible for easier attachment to the bra.

A method of adjusting the cup size of a maternity bra is provided according to the present invention, comprising: providing a maternity bra comprising: a support structure comprising shoulder straps and a bra band; and a first and second cup each attached to the support structure to provide a first cup size, the at least one cup being detachable from the support structure at an attachment point, providing a clip comprising first and section engagement mechanisms, attaching the first engagement mechanism of the clip in a releasable manner to a first position of the support structure of the maternity bra, attaching one of the detachable cup to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

This clip and method allow a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump.

Preferably, the method further comprises the step of inserting a breast pump into the detachable cup. The adjustment of the size of the bra allows the bra to support the breast pump against the user's breast for comfort and ease.

Preferably, the method further comprises the steps of: detaching the first engagement mechanism of the clip from the first position support structure of the maternity bra; attaching the first engagement mechanism of the clip in a releasable manner to a second position of the support structure of the maternity bra; and attaching the other of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size. This allows the user to use a single clip on either of the cups.

An alternative embodiment may be provided, with an extendable clip 360 as shown in Figure 36. In such an embodiment the clip is attached to the hook 331 on the strap 321 in a releasable manner, with the clasp 332 attached to an expandable portion of the clip. The clip is then able to expand between an unexpanded state where the clasp 332 is held in substantially the same position as the first attachment point 330 to provide the first cup size, and an expanded state, where the clasp 332 is held in a second position away from the first attachment point 330 to provide the second cup size.

For example, an elongate clip with first and second opposite ends may be provided. A first attachment point for attaching to the hook 331 is provided at the first end, and a second attachment point for attaching to the clasp 332 is provided at the second end. The elongate clip is hinged between the two ends, such that the clip can be folded between an elongate configuration to a closed configuration where the second end touches the first end. A clasp can be provided on the clip to hold the second end in this closed configuration. Thus, in the closed position the clasp 332 is held in substantially the same location as the first attachment point 330 to provide the first cup size, and in the open position the clasp is held away from the first attachment point 330 to provide the second cup size.

Other extendable clip embodiments are also possible, for example sliding clips or elastic clips.

Additional embodiments of a maternity bra adjuster are provided in Figures 37 and 38. The alternative proposed solution is a small adapter device, which comprises a first portion 370 including a clasp 373 and a second portion 372 including a hook 374, in which the first and second portions are separated by a small distance 371 in order to

provide two different adjustable sizes. The first portion includes a clasp 373 that is designed to attach to the hook on the bra strap 321. It may also include a top hook 375 positioned underneath the clasp, and a clip 376 on the rear side. The second portion includes a bottom hook 372.

The clasp 332 that is present on the cup 329 of the maternity bra, may then either engage with the top hook (321) to provide a first cup size, and engage with the bottom hook (332) to provide a second cup size that is different from the first cup size, as illustrated in Figure 39. The user may then discretely switch between a non pumping position, provided by the first cup size, and a second pumping position without any complex adjustment or removal of clothing needed, while using a wearable breast pump system (100).

The first portion and second portion may be made of plastic and may be separated by a stretchy material such as elastic or elastomeric material. The first portion may also include a clip on the rear side, the purpose of which is to allow the user to leave the clip attached to the bra for an extended time period.

Section D: Use of Piezo Pump in Wearables

As described in Section A, the breast pump system includes a piezo air pump, resulting in a fully wearable system that delivers a quiet, comfortable and discreet operation in normal use. This section gives further information on the piezo air pump.

In comparison with other pumps of comparable strength, piezo pumps are smaller, lighter and quieter.

Each individual Piezo pump weighs approximately 6gm and may, with material and design improvements, weigh less than 6gm.

In operation, the Elvie breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise; tests indicate that it makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

Piezo pumps also have lower current draw, allowing for increased battery life. A piezo pump is therefore ideally suited for wearable devices with its low noise, high strength and compact size. Further, as shown in the breast pump system of Figures 7 and 8, more than one piezo pump may be used.

Whilst a breast pump system is largely described in previous sections, the use of piezo mounted either in series or in parallel can also be implemented in any medical wearable devices or any wearable device. The piezo pump may pump air as well as any liquid.

With reference to Figure 40, a diagram illustrating a configuration of two piezo pumps mounted in series is shown.

With reference to Figure 41, a diagram illustrating a configuration of two piezo pumps mounted in parallel is shown.

With reference to Figure 42, the air pressure generated as a function of time by two piezo pumps mounted in series and two piezo pumps mounted in parallel are compared. In

this example, the parallel configuration produces higher flow rate and achieves -100mmHg negative air pressure faster than the series configuration. In comparison, the series configuration produces lower flow rate and takes slightly longer to reach 100mmHg. However, the parallel configuration cannot achieve as high as a vacuum as the series configuration and plateaus at -140mmHg. In comparison, the series configuration is able to generate about -240mmHg.

A dual configuration is also implemented in which more than one piezo pump is configured such that they can easily switch between a parallel mode and a series mode. This dual configuration would suit wearable devices that would need to achieve either lower or higher pressure faster.

Figure 43 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration. In this dual configuration, the piezo pumps first start with a parallel mode in order to benefit from faster flow rate, and then switch to a series mode (as indicated by the switch-over point) when stronger vacuums are required, enabling to save up to 500ms on cycle time with elastic loads.

Additionally, a piezo pump may be used in combination with a heat sink in order to efficiently manage the heat produced by the wearable pump. This configuration may be used to ensure that the wearable device can be worn comfortably. The heat sink or heat sinks are configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin (especially prolonged contact for greater than 1 minute) are no more than 48°C and preferably no more than 43°C.

The heat sink may store the heat produced by a piezo pump in order to help diverting the heat produced to another location. This not only ensures that the wearable system can be worn comfortably, but also increases the lifetime of a piezo pump.

Figure 44 shows a picture of a wearable breast pump housing including multiple piezo pumps (440). The breast pump system is wearable and the housing is shaped at least in part to fit inside a bra. By applying a voltage to the piezo pumps, the pressure provided by the pumps increase. The generation of higher pressure by the piezo pumps also means higher heat produced that needs to be managed. Each piezo pump is therefore

connected to a heat sink (441), such as a thin sheet of copper. The heat sink has a long thermal path length that diverts the heat away from the piezo pump.

The use of a heat sink in combination with a piezo pump is particularly relevant when the wearable device is worn directly or near the body, and where the management of heat induced by the piezo pump is crucial.

A wearable device including a piezo pump may therefore include a thermal cut out, and may allow for excess heat to be diverted to a specific location. The heat sink may be connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere. For example, the wearable system is a breast pump system and the heat sink stores heat, which can then be diverted to warm the breast shield of the breast pump system.

Use cases application include but are not limited to:

- Wound therapy;
- High degree burns;
- Sleep apnoea;
- Deep vein thrombosis;
- Sports injury.

APPENDIX: SUMMARY OF KEY FEATURES

In this section, we summarise the various features implemented in the Elvie™ pump system. We organize these features into six broad categories:

A. Elvie Breast Pump: General Usability Feature Cluster

B. Elvie Piezo Air Pump Feature Cluster

C. Elvie Milk Container Feature Cluster

D. Elvie IR System Feature Cluster

E. Elvie Bra Clip Feature Cluster

F. Other Features, outside the breast pump context

Drilling down, we now list the features for each category:

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is wearable and includes only two parts that are removable from the pump main housing in normal use.

Feature 2 Elvie is wearable and includes a clear breast shield giving an unobstructed view of the breast for easy nipple alignment.

Feature 3 Elvie is wearable and includes a clear breast shield with nipple guides for easy breast shield sizing.

Feature 4 Elvie is wearable and includes a breast shield that audibly attaches to the housing.

Feature 5 Elvie is wearable and includes a breast shield that attaches to the housing with a single push.

Feature 6 Elvie is wearable and not top heavy, to ensure comfort and reliable suction against the breast.

Feature 7 Elvie is wearable and has a Night Mode for convenience.

Feature 8 Elvie is wearable and includes a haptic or visual indicator showing when milk is flowing or not flowing well.

Feature 9 Elvie is wearable and collects data to enable the mother to understand what variables (e.g. time of day, pump speed etc.) correlate to good milk-flow.

Feature 10 Elvie is wearable and collects data that can be exported to social media.

Feature 11 Elvie is wearable and has a smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 12 A smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 13 Elvie is wearable and includes a sensor to infer the amount of movement or tilt angle during normal use.

Feature 14 Elvie includes a control to toggle between expressing milk from the left breast and the right breast.

Feature 15 Elvie includes a pressure sensor.

Feature 16 Elvie includes a microcontroller to enable fine tuning between pre-set pressure profiles.

Feature 17 Elvie enables a user to set the comfort level they are experiencing.

Feature 18 Elvie includes a microcontroller to dynamically and automatically alter pump operational parameters.

Feature 19 Elvie automatically learns the optimal conditions for let-down.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is wearable and has a piezo air-pump for quiet operation.

Feature 21 Elvie has a piezo air-pump and self-sealing diaphragm

Feature 22 Elvie uses more than one piezo air pump in series.

Feature 23 Elvie is wearable and has a piezo air-pump, a breast shield and a diaphragm that fits directly onto the breast shield.

Feature 24 Elvie is wearable and has a piezo air-pump for quiet operation and a re-useable, rigid milk container for convenience.

Feature 25 Elvie has a piezo-pump for quiet operation and is a connected device.

Feature 26 Elvie uses a piezo in combination with a heat sink that manages the heat produced by the pump.

Feature 27 Elvie is wearable and gently massages a mother's breast using small bladders inflated by air from its negative pressure air-pump.

Feature 28 Elvie is wearable and gently warms a mother's breast using small chambers inflated by warm air from its negative pressure air-pump.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is wearable and includes a re-useable, rigid milk container that forms the lower part of the pump, to fit inside a bra comfortably.

Feature 30 Elvie is wearable and includes a milk container that latches to the housing with a simple push to latch action.

Feature 31 Elvie is wearable and includes a removable milk container with an integral milk pouring spout for convenience.

Feature 32 Elvie is wearable and includes a removable milk container below the milk flow path defined by a breast shield for fast and reliable milk collection.

Feature 33 Elvie is wearable and includes a breast shield and removable milk container of optically clear, dishwasher safe plastic for ease of use and cleaning.

Feature 34 Elvie is wearable and includes various components that self-seal under negative air pressure, for convenience of assembly and disassembly.

Feature 35 Elvie is wearable and includes a spout at the front edge of the milk container for easy pouring.

Feature 36 Elvie is wearable and includes a milk container that is shaped with broad shoulders and that can be adapted as a drinking bottle that baby can easily hold.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the quantity of milk in the container for fast and reliable feedback.

Feature 38 The separate IR puck for liquid quantity measurement.

Feature 39 The separate IR puck combined with liquid tilt angle measurement.

E. Bra Clip Feature

Feature 40 Bra Adjuster.

F. Other Features that can sit outside the breast pump context

Feature 41 Wearable device using more than one piezo pump connected in series or in parallel.

Feature 42 Wearable medical device using a piezo pump and a heat sink attached together.

We define these features in terms of the device; methods or process steps which correspond to these features or implement the functional requirements of a feature are also covered.

We'll now explore each feature 1 – 42 in depth. Note that each feature can be combined with any other feature; any sub-features described as 'optional' can be combined with any other feature or sub-feature.

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is wearable and includes only two parts that are removable from the pump main housing in normal use

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a rigid or non-collapsible milk container;

and in which the breast pump system includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and the rigid, non-collapsible milk container.

Optional:

- The only parts of the system that come into contact with milk in normal use are the breast shield and the milk container.
- Milk only flows through the breast shield and then directly into the milk container.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings, in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- No other parts are removable from the breast shield, apart from the flexible diaphragm.
- The milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.
- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

- No other parts are removable from the milk container, apart from the cap and the valve.
- All parts that are user-removable in normal use are attached to either the breast shield or the milk container.
- Audible or haptic feedback confirms the pump system is properly assembled for normal use with the milk container locked to the housing and the breast shield locked to the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 2 Elvie is wearable and includes a clear breast shield giving an unobstructed view of the breast for easy nipple alignment

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel, shaped to receive a nipple, providing to the mother placing the breast shield onto her breast a clear and unobstructed view of the nipple when positioned inside the nipple tunnel, to facilitate correct nipple alignment.

Optional:

- The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is completely out, of or separated from, the housing.
- The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is partially out of, or partially separated from, the housing.
- Entire breast shield is substantially transparent.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

- A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.

- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.

- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

Feature 3 Elvie is wearable and includes a clear breast shield with nipple guides for easy breast shield sizing

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel shaped to receive a nipple, the nipple tunnel including guide lines that define the correct spacing of the nipple from the side walls of the nipple tunnel.

Optional:

- The guide lines run generally parallel to the sides of the nipple placed within the nipple tunnel.
- Breast shield is selected by the user from a set of different sizes of breast shield to give the correct spacing.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers in the housing locate into small indents in the breast shield.

- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 4 Elvie is wearable and includes a breast shield that audibly attaches to the housing.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield that is attachable to the housing with a mechanism that latches with an audible click when the breast shield is slid on to or against the housing with sufficient force.

Optional:

- The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.

- Breast shield is removable from the housing with an audible click when the breast shield is pulled away from the housing with sufficient force.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.

- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 5 Elvie is wearable and includes a breast shield that attaches to the housing with a single push

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield configured to attach to the housing with a single, sliding push action.

Optional:

- The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.
- The single push action overcomes a latching resistance.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into a nipple tunnel in the breast shield to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield when the breast shield has been placed onto a breast using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b)

transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

- The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.
- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

Feature 6 Elvie is wearable and not top heavy, to ensure comfort and reliable suction against the breast

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism

(b) and a breast shield;

(c) a milk container;

and in which the centre of gravity of the pump system is, when the milk container is empty, substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through a nipple tunnel or filling point on a breast shield, so that the device is not top-heavy for a woman using the pump.

Optional:

- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- In which the centre of gravity only moves lower during use as the milk container gradually receives milk, which increases the stability of the pump inside the bra.
- In which milk only passes downwards when moving to the milk container, passing through the nipple tunnel and then through an opening in the lower surface of the nipple tunnel directly into the milk container, or components that are attached to the milk container.
- System is configured so that its centre of gravity is no more than 60mm up from the base of the milk container also below the top of the user's bra cup.
- In which the pumping mechanism and the power supply for that mechanism are positioned within the housing to provide a sufficiently low centre of gravity.
- In which the pumping mechanism is one or more piezo air pumps, and the low weight of the piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.
- In which the pumping mechanism is one or more piezo air pumps, and the small size of the piezo air pumps enables the components in the housing to be arranged so that the centre of gravity is substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.
- In which the pumping mechanism is one or more piezo air pumps, and the low weight of the battery or batteries needed to power that piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of

the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.

- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 7 Elvie is wearable and has a Night Mode for convenience

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) an illuminated control panel;

(c) a control system that reduces or adjusts the level or colour of illumination of the control panel at night or when stipulated by the user.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Control system is implemented in hardware in the pump itself using a 'night mode' button.
- Control system is implemented in software within a connected device app running on the user's smartphone.
- Control system is linked to the illumination level on a connected device app., so that when the connected app is in 'night mode', the illuminated control panel is also in 'night mode', with a lower level of illumination, and when the illuminated control panel on the housing is in 'night mode', then the connected app is also in 'night mode'.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast. The pumping mechanism is one or more piezo air pumps, selected for quiet operation.

Feature 8 Elvie is wearable and includes a haptic or visual indicator showing when milk is flowing or not flowing well

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a milk container that is configured to be concealed within a bra and is hence not visible to the mother in normal use;

(c) a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

Optional:

- A haptic and/or visual indicator indicates if the pump is operating correctly to pump milk, based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase
- The visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.
- The haptic and/or visual indicator provides an indication of an estimation of the flow rate.
- The visual indicator provides a colour-coded indication of an estimation of the flow rate.
- The visual indicator provides an indication of how much of the container has been filled.
- The visual indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.
- The haptic indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.
- A sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect

light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

- Sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- A sub-system measures or infers the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.
- A haptic and/or visual indicator indicates if the amount of milk in the milk container has reached a preset quantity or level.
- A haptic and/or visual indicator indicates if there is too much movement of the breast pump system for viable operation.
- Milk container is attached to the lower part of the housing and forms the base of the breast pump system.
- Milk container is made of transparent material.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 9 **Elvie is wearable and collects data to enable the mother to understand what variables (e.g. time of day, pump speed etc.) correlate to good milk-flow**

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a measurement sub-system that measures or infers milk flow into the milk container;

and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- User-defined requirement is to enhance or increase milk-flow.
- User-defined requirement is to reduce milk-flow.
- The data analysis system analyses data such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system determines metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.
- The data analysis system determines metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.
- Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.
- measurement sub-system measures or infers the quantity and/or the height of the liquid in the container above its base.
- Measurement sub-system measures or infers angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.
- Data analysis system gives recommended metrics for improving milk flow
- Data analysis system gives recommended metrics for weaning.
- Data analysis system gives recommended metrics for increasing milk supply (e.g. power pumping).
- Data analysis system gives recommended metrics if an optimal session start time or a complete session has been missed.

- Data analysis system leads to automatic setting of metrics for the pumping mechanism, such as pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session.
- Data analysis system enables sharing across large numbers of connected devices or apps information that in turn optimizes the milk pumping or milk weaning efficacy of the breast pump.
- Metrics include the specific usage of the connected device by a woman while using the pump (for example by the detection of vision and/or audio cues).
- The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- The measurement sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the measurement sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 10 Elvie is wearable and collects data that can be exported to social media.

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a data sub-system that collects and provides data to a connected device or remote application or remote server;

(d) and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.
- The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.
- Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.
- The social media or community function or platform organizes the collected data into different profiles.
- The social media or community function or platform enables a user to select a matching profile from a set of potential profiles.
- each profile is associated with a specific kind of milk expression profile, and provides information or advice that is specifically relevant to each milk expression profile.
- Information or advice includes advice on how to increase milk expression by varying parameters, such as time of milk expression, frequency of a milk

expression session, pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session and any other parameter that can be varied by a mother to help her achieve her milk expression goals.

- The application is connected to other applications residing on the connected device, such as a fitness app.
- The collected data includes data received from other connected apps.
- The collected data is anonymised before it is shared.
- The sub-system includes a wi-fi connectivity component for direct connectivity to a remote server.
- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 11 Elvie is wearable and has a smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh

A breast pump system including a pumping mechanism and a milk container and including:

(a) a housing including the pumping mechanism;

(b) a milk container;

(c) and in which the milk container or any associated part, such as a lid, includes a memory or tag that is automatically programmed to store the time and/or date it was filled with milk.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Memory or tag is programmed to store the quantity of milk in the milk container.
- Memory or tag stores the milk expiry date.

- Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.
- System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.
- Clock is in the housing.
- Clock is in the milk container.
- Milk container includes a display that shows the time and/or date it was filled with milk.
- Milk container includes a display that shows the quantity of milk that it was last filled with milk.
- Milk container includes a display that shows whether the left or right breast was used to fill the milk container.
- Memory or tag is connected to a data communications sub-system.
- Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone, and have the time and/or date that container was filled with milk, displayed on the reader device.
- Reader device shows the time and/or date a specific milk container was filled with milk.
- Reader device shows the quantity of milk that a specific milk container was last filled with.
- Reader device shows the time and/or date and/or quantity that each of several different milk containers were filled with.
- Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.
- A sub-system measures or infers milk flow into the milk container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/Tr the height of the liquid in the container.
- The sub-system is in the housing.
- Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 12 A smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

A smart bottle or container that includes or is associated with a memory or a tag that is programmed to store the date and time it is filled using data from a pump or a connected device, such as a smartphone.

Optional:

- The container includes wireless connectivity and connects to a companion app.
- The memory or tag includes an NFC chip and is read using a NFC reader.
- The memory or tag stores also an expiry date.
- Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.
- The memory or tag stores also the quantity of milk stored.
- System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.
- Clock is in the housing.
- Clock is in the container.
- Milk container includes a display that shows the time and/or date it was filled with milk.
- Milk container includes a display that shows the quantity of milk that it was last filled with milk.

- Milk container includes a display that shows whether the left or right breast was used to fill the milk contained.
- Milk container includes a display that shows the expiry date.
- memory or tag is connected to a data communications sub-system.
- Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone.
- Reader device shows the time and/or date a specific milk container was filled with milk.
- Reader device shows the quantity of milk that a specific milk container was last filled with.
- Reader device shows the time and/or date and/or quantity that each of several different containers were filled with.
- Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.
- Reader device shows the expiry date.
- Container includes wireless connectivity and connects to a companion application.
- An application tracks status of one or more smart containers and enables a user to select an appropriate smart container for a feeding session.
- The pump is wearable.
- The pump is in a housing shaped to fit inside a bra and the container is a milk container that is connected to the housing and is positioned to form the base of the housing.
- Container is used for liquids other than milk.

Feature 13 Elvie is wearable and includes a sensor to infer the amount of movement or tilt angle during normal use.

A breast pump system including:

(a) a housing;

(b) a milk container;

(c) the housing including a sensor, such as an accelerometer, that measures or determines the movement and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by warning or alerting the mother of a potential imminent spillage (e.g. from milk flowing back out of a breast shield) using an audio, or visual or haptic alert, or a combination of audio, haptic and visual alerts.
- If the tilt angle of the housing exceeds a threshold, then the system automatically adjusts the operation of the system by stopping the pump to prevent spillage.
- When the tilt angle of the housing reduces below the threshold, the system automatically adjusts the operation of the system by causing pumping to resume automatically.
- If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by providing the mother with an alert to change position.
- The container includes an optically clear region.
- There are one or more light emitters and detectors positioned in the base of the housing, the light emitters and receivers operating as part of a sub-system that measures or infers the tilt angle of the milk in the container.
- The sub-system measures the quantity of liquid in the milk container and also takes the measured tilt angle of the housing into account.
- If the tilt angle is above a certain threshold, the system ignores the quantity of liquid measured.
- The sub-system derives or infers the mother's activity, such as walking, standing or lying activities, from the sensor.
- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

- Sub-system stores a time-stamped record of movement and/or tilt angles of the housing in association with milk flow data.
- System includes a breast shield that attaches to the housing.
- System includes a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 14 Elvie includes a control to toggle between recording whether milk is being expressed from the left breast and the right breast.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a control interface that the user can select to indicate or record if milk is being expressed from the left or the right breast.

Optional:

- Control interface is a physical interface on the housing.
- Control interface is a single button on the housing.
- Control interface is from an application running on a device, such as a smartphone or smart ring.
- Visual indicators on the housing indicate whether the breast pump system is being set up the left or the right breast.
- The visual indicator for the left breast is on the right-hand side of the housing, when viewed from the front; and the visual indicator for the right breast is on the left-hand side of the housing, when viewed from the front.
- The housing includes a button labeled to indicate the left breast and a button labeled to indicate the right breast, that are respectively illuminated to indicate from which breast the milk is being expressed.
- Breast pump system is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 15 Elvie includes a pressure sensor.

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) an air pressure sensor configured to measure the negative pressure delivered by the negative air-pressure mechanism and (iii) a measurement sub-system that measures or infers milk flow or milk volume.

Optional:

- The system also includes a control sub-system that combines or relates the air-pressure measurements with the milk flow or milk volume measurements
- The control sub-system automatically adjusts the negative air-pressure to give the optimal milk flow or milk volume.
- The control sub-system automatically adjusts the negative air-pressure during a pumping session to give the optimal milk flow or milk volume within comfort constraints defined by the user.
- The air pressure sensor detects pressure created by the pumping mechanism.
- Sensor is a piezo air pressure sensor
- Air pressure sensor measures the negative air pressure during a normal milk expression session.
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that it deliver consistent performance over time.
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that different pumping mechanisms in different breast pump systems all deliver consistent performance
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to determine if the pumping mechanism is working correctly, within tolerance levels.
- The operation of the pumping mechanism is varied by altering the duty or pump cycle.
- The operation of the pumping mechanism is varied by altering the voltage applied to the pumping mechanism.
- Pumping mechanism is a piezo air pump.

- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 16 Elvie includes a microcontroller to enable fine tuning between pre-set pressure profiles

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to cause the pumping mechanism to deliver various pre-set pressure profiles and to permit the user to manually vary the pressure to a value or values that are in-between the values available from a pre-set pressure profile.

Optional:

- The user manually varies the pressure using a control interface on a housing of the breast pump system
- The user manually varies the pressure using a control interface on an application running on a wireless device such as a smartphone that is wirelessly connected to the breast pump system.
- The user manually varies the pressure by altering a control parameter of the pumping mechanism.
- The user manually varies the pressure by altering the duty cycle or timing of the

pumping mechanism.

- The user manually varies the pressure by altering the voltage applied to the pumping mechanism.
- The system includes an air pressure sensor configured to measure the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Pressure profile defines one or more maximum negative air pressure levels.
- Pressure profile defines one or more maximum negative air pressure levels, each for a pre-set time.
- Pressure profile defines one or more cycle time.
- Pressure profile defines peak flow rate.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 17 Elvie enables a user to set the comfort level they are experiencing

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to control the pumping mechanism and to permit the user to manually indicate the level of comfort that they are experiencing when the system is in use.

Optional:

- The user manually indicates the level of comfort that they are experiencing using a touch or voice-based interface on a housing of the breast pump system
- The user manually indicate the level of comfort that they are experiencing using a touch or voice-based interface on an application running on a wireless device, such as a smartphone, that is wirelessly connected to the breast pump system.
- The system stores user-indicated comfort levels together with associated parameters of the pumping system.
- The system is a connected device and a remote server stores user-indicated comfort levels together with associated parameters of the pumping system.
- The parameters of the pumping system include one or more of: pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System automatically varies parameters of the pumping system and then enables the user to indicate which parameters are acceptable.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the

intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 18 Elvie includes a microcontroller to dynamically and automatically alter pump operational parameters

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to automatically change one or more parameters of the pumping mechanism, and to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

Optional:

- The milk expression data includes one or more of the following: milk expression rate or quantity; comfort; optimal pumping mode; optimal pumping mode given remaining battery power.
- The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters.
- The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters if the comfort experienced by the user when those parameters are used is above a threshold.
- The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user.
- The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user and enables the user to manually select those parameters if they are acceptable.
- Parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.

- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 19 Elvie automatically learns the optimal conditions for let-down

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to dynamically change one or more parameters of the pumping mechanism, and to automatically detect the start of milk let-down.

Optional:

- The microcontroller is programmed to dynamically change one or more parameters of the pumping mechanism, to enable it to learn or optimize the parameters relating to milk let-down.
- The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down.
- The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and uses that set of parameters if the comfort experienced by the user when those

parameters are used is above a threshold or are otherwise acceptable to the user.

- The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down to the user.
- The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and enables the user to manually select those parameters if they are acceptable.
- parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is wearable and has a piezo air-pump for quiet operation

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a separate, deformable diaphragm to generate negative air pressure.

Optional:

- The deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- Deformable diaphragm is removably mounted against a part of a breast shield.
- Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.
- Deformable diaphragm is not physically connected to the piezo air-pump.
- Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield
- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

- The piezo pump is fed by air that passes through an air filter.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 21 Elvie has a piezo air-pump and self-sealing diaphragm

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a physically separate, deformable, self-sealing diaphragm, to generate negative air pressure.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement .
- The closed system is separated from a 'milk' side by the flexible diaphragm.
- Deformable diaphragm is removably mounted against a part of a breast shield.
- Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.
- Deformable diaphragm is not physically connected to the piezo air-pump.
- Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield.
- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing,

and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- The piezo pump is fed by air that passes through an air filter.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 22 Elvie uses more than one piezo air pump in series

A breast pump system including:

(a) a housing;

(b) multiple piezo air-pumps in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure; in which the multiple piezo air-pumps can be operated at different times in series-connected and in parallel-connected modes.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Parallel connected mode is used during a first part of a pumping cycle to reach a defined negative air pressure more quickly than series connected mode would, and then the system switches to a series connected mode to reach a greater negative air pressure than series connected mode can reach.
- An actuator switches the system from parallel-connected piezo pump mode to series-connected piezo pump mode.

- Each piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- Each piezo air pump weighs less than 10 gm, and may weigh less than 6gm..
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- Each piezo pump is fed by air that passes through an air filter.
- Each piezo air pump forms part of a closed or closed loop system.
- Each piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- The piezo-air pumps are a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

Feature 23 Elvie is wearable and has a piezo air-pump, a breast shield and a diaphragm that fits directly onto the breast shield

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a breast shield that attaches to the housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm that fits directly onto the breast shield.

Optional:

- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Deformable diaphragm is removable from the diaphragm housing for cleaning.

- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- Piezo air pump is position at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum. power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.The piezo pump is fed by air that passes through an air filter.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Feature 24 Elvie is wearable and has a piezo air-pump for quiet operation and a re-useable, rigid milk container for convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing;

(c) and a re-useable, rigid or non-collapsible milk container that when connected to the housing forms an integral part of the housing and that is also removable from the housing.

Optional:

- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The closed system is separated from a 'milk' side by a flexible diaphragm.

- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- The deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.

Feature 25 Elvie has a piezo-pump for quiet operation and is a connected device

A breast pump system including

(a) a housing;

(b) a piezo air-pump in the housing;

(c) a milk container;

(d) a data connectivity module that enables data collection relating to the operation of the piezo air-pump and transmission of that data to a data analysis system.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Transmission is to an application running on a connected device such as a smartphone, or a server, or the cloud.
- The data collection and transmission relates to any other operational data of the system.
- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- A sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with the data connectivity module.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level,

peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.

- The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.

Feature 26 Elvie uses a piezo in combination with a heat sink that manages the heat produced by the pump.

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure;

(c) a heat sink to manage the heat produced by the piezo-air pump to ensure it can be worn comfortably.

Optional:

- The heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48°C and preferably no more than 43°C.
- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Heat sink is connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere.
- Heat sink warms a breast shield.
- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.

- There are two or more piezo air pumps, each connected to its own or a shared heat sink.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- The deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

Feature 27 Elvie is wearable and gently massages a mother's breast using small bladders inflated by air from its negative pressure air-pump

A breast pump system including:

(a) a housing;

(b) an air-pump in the housing that drives a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides air to regularly or sequentially inflate one or more air bladders or liners that are configured to massage one or more parts of the breast.

Optional:

- Air-pump is a piezo pump.
- Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- Bladders or liners are formed in a breast shield that attaches to the housing.

Feature 28 Elvie is wearable and gently warms a mother's breast using small chambers inflated by warm air from its negative pressure air-pump

A breast pump system including:

(a) a housing;

(b) an air-pump, such as a piezo pump, in the housing that drive a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides warm air to regularly or sequentially inflate one or more air chambers that are configured to apply warmth to one or more parts of the breast.

Optional:

- Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- The air chamber is a deformable diaphragm positioned on a breast shield that attaches to the housing.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is wearable and includes a re-useable, rigid milk container that forms the lower part of the pump, to fit inside a bra comfortably

A wearable breast pump system configured including:

(a) a housing shaped at least in part with a curved surface to fit inside a bra and including a pumping mechanism;

(b) and a re-useable rigid or non-collapsible milk container that when connected to the housing forms an integral, lower part of the housing, with a surface shaped to continue the curved shape of the housing, so that the pump system can be held comfortably inside the bra.

Optional:

- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is attached to the housing with a push action.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture, spout or lid that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a

breast shield, and milk flows under gravity through the opening into the milk container.

- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump mechanism to ensure that negative air-pressure is not applied to the milk container.
- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 30 Elvie is wearable and includes a milk container that latches to the housing with a simple push to latch action

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that is attachable to the housing with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

Optional:

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Milk container, when connected to the housing, forms an integral, lower part of the housing and that is removable from the housing with a release mechanism that can be operated with one hand.

- Mechanism that releasably attaches or latches is a mechanical or magnetic mechanism.
- Mechanical mechanism includes flanges on the top of the milk container, or the sealing plate that seals the opening to the milk contained, that engage with and move past a surface to occupy a latched position over that surface when the milk container is pressed against the housing to lock into the housing.
- The housing includes a button that when pressed releases the milk container from the housing by flexing the surface away from the flanges so that the flanges no longer engage with and latch against the surface.
- Mechanism that attaches or latches the milk container into position does so with an audible click.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing by releasing the latch and moving the housing off the milk container.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.

- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 31 Elvie is wearable and includes a removable milk container with an integral milk pouring spout for convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a re-useable milk container that is connected to the housing with a surface shaped to continue the curved or breast-like shape of the pump, so that the pump can be held comfortably inside a bra and where the milk container includes a pouring spout for pouring milk.

Optional:

- Spout is integral to the milk container.
- Spout is integral to a removable lid to the milk container.
- Spout is positioned at or close to the front edge of the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.

- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 32 Elvie is wearable and includes a removable milk container below the milk flow path defined by a breast shield for fast and reliable milk collection

A wearable breast pump system including:

(a) a housing including a pumping mechanism, the housing being shaped at least in part to fit inside a bra;

(b) and a breast shield including a nipple tunnel shaped to receive a nipple, and including an opening that defines the start of a milk flow path;

(c) a re-useable milk container that when connected to the housing is positioned entirely below the opening or the milk flow path, when the breast pump is positioned or oriented for normal use.

Optional:

- The milk container includes an aperture that sits directly underneath the opening in the nipple tunnel in the breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- Milk flows from the opening directly into the milk container.
- Milk flows from the opening directly into the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against the opening in the breast shield, and milk flows under gravity through the opening into the milk container.
- Milk flows from the opening directly onto a valve that is attached to the milk container, the valve closing whilst there is sufficient negative air pressure in the volume of air between the valve and the breast shield opening, and then opening to release the milk into the container when the air pressure rises sufficiently.
- Milk flows from the opening directly onto a valve that is attached to a spout, that is in turn attached to the milk container.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the milk container cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container, and milk flows towards and is retained by the duck bill valve whilst the valve is closed, and flows past the valve into the milk container when the negative air pressure is released and the valve opens.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 33 Elvie is wearable and includes a breast shield and removable milk container of optically clear, dishwasher safe plastic for ease of use and cleaning

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) and a breast shield defining a region shaped to receive a nipple, the region defining the start of a milk flow path;

(c) a re-useable, rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the breast shield and the milk container are made substantially of an optically clear, dishwasher safe material.

Optional:

- The material is a polycarbonate material, such as Tritan™.

- breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield operates with a flexible diaphragm that flexes when negative air pressure is applied to it by an air pump system in the housing, and transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 34 Elvie is wearable and includes various components that self-seal under negative air pressure, for convenience of assembly and disassembly

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including an air pumping mechanism;

(b) a breast shield;

(c) a diaphragm that flexes in response to changes in air pressure caused by the air pumping mechanism and that seals to the breast shield;

(d) a re-useable milk container that seals to the breast shield;

and in which either or both of the diaphragm and the re-useable milk container substantially self-seal under the negative air pressure provided by the pumping mechanism.

Optional:

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a

breast shield, and milk flows under gravity through the opening into the milk container.

- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.
- The 1 way valve is attached to the milk container, or a lid or spout of the milk container with an interference fit and is readily removed in normal use for separate cleaning.
- The diaphragm partly or wholly self-seals to the breast shield under the negative air pressure provided by the pumping mechanism.
- The diaphragm partly or wholly self-seals to the housing under the negative air pressure provided by the pumping mechanism.
- The diaphragm is attached to the diaphragm housing using elastomeric or rubber latches and is readily removed in normal use for separate cleaning.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.

- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 35 Elvie is wearable and includes a spout at the front edge of the milk container for easy pouring

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that forms an integral part of the housing;

(c) a re-useable pouring spout that is positioned at or close to the front edge of the milk container.

Optional:

- Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigeratable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.
- Spout is integral to a removable lid to the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- By placing the spout at or close to the front edge of the milk container, the milk container fully empties more readily than where the spout is placed in the middle of the lid of a milk container.
- The spout sits generally under an opening in the breast shield spout or nipple tunnel through which expressed milk flows.
- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Feature 36 Elvie is wearable and includes a milk container that is shaped with broad shoulders and that can be adapted as a drinking bottle that baby can easily hold

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a milk container that is removable from the housing and is shaped or configured to also serve as a drinking bottle that is readily held by a baby because it is wider than it is tall.

Optional:

- Teat is attachable directly to the milk container.
- Pouring or drinking spout is integral to the milk container.
- The shoulders are at least 2cm in width, and the neck is no more than 1 cm in height, to enable a baby to readily grip and hold the container when feeding from the milk in the container.
- Spout/teat/straw resides near the edge of the container's rim.
- Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigertable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.
- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals

against the conduit under the negative air pressure provided by the pumping mechanism.

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Spout is integral to the milk container.
- Spout is integral to a removable lid to the milk container.
- Spout is positioned at or close to the front edge of the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the quantity of milk in the container for fast and reliable feedback

A system for milk volume determination, for use as part of a breast pump, or breast milk collecting device, including:

(a) a re-useable rigid or non-collapsible milk container;
(b) at least one light emitter, configured to direct radiation towards the surface of the milk;
(c) at least one light detector, configured to detect reflected radiation from the surface of the milk;

wherein the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container.

Optional:

The wearable breast pump system includes:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield;

(c) a re-useable rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the top of the container includes an optically clear region that is aligned below one or more light emitters positioned in the base of the housing.

- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

- The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.
- Where the quantity or level exceeds a threshold, then the pumping mechanism automatically changes mode, e.g. from a stimulation mode to an expression mode.
- Where the quantity or level exceeds a threshold, then the pumping mechanism automatically stops.
- Milk-flow data is captured and stored.
- If milk-flow falls below a threshold, then a notification is provided to the mother.

Feature 38 The separate IR puck for liquid quantity measurement

A liquid-level measuring system for measuring the quantity of liquid in a container for a breast pump; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to detect light from the light emitters that has been reflected from the liquid;

(c) a sub-system that infers, measures or calculates the quantity in the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

- The quantity of milk is measured as milk enters the container or as milk is removed from the container.
- Measured property includes the reflected light intensity

Feature 39 The separate IR puck combined with liquid tilt angle measurement

A liquid-level measuring system for measuring the tilt angle of liquid in a container; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to measure properties of the light reflected from the liquid;

(c) a sub-system including an accelerometer that infers, measures or calculates the tilt angle of the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

- Measured property includes the reflected light intensity
- The quantity of liquid is measured as liquid enters the container or as liquid is removed from the container.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.

Generally applicable optional features

- Weight of the entire unit, unfilled, is under 250g and preferably 214g.
- Silver based bactericide is used on all parts that are not steam or heat sterilized in normal cleaning.
- Housing includes a rechargeable battery.
- System is self-contained.
- System is a closed loop system.
- Breast pump system is a self-contained, wearable device that includes an integral rechargeable battery, control electronics, and one or more air pumps operating as a closed system, driving a flexible diaphragm that in turn delivers negative air-pressure to the breast, to cause milk to be expressed.
- Housing has a generally rounded or convex front surface and has a generally tear-drop shape when seen from the front.

E. Bra Clip Feature Cluster

Feature 40 Bra Adjuster

A bra adjuster for a nursing or maternity bra, the nursing or maternity bra including a bra cup with a flap that can be undone to expose the nipple, and the flap attaching to the shoulder strap using a clasp, hook or other fastener attached to the flap, and a corresponding fastener attached to the shoulder strap;

and in which the bra adjuster is attachable at one end to the fastener attached to the flap, and at its other end to the fastener attached to the shoulder strap, and hence increases the effective bra cup size sufficiently to accommodate a wearable breast pump, and is also detachable from the flap and shoulder strap.

Optional:

- Bra adjuster is retained in position on the bra during normal wearing of the bra, even when the flap is attached directly to the shoulder strap, and is used to increases the effective bra cup size only when the wearable breast pump is used.
- Bra adjuster is extensible or elastic.
- Bra adjuster is of a fixed length.
- Bra adjuster includes a clip that the user can slide onto the bra strap to secure the bra adjuster in position.
- Bra adjuster is machine-washing washable.

F. Other Features that can sit outside the breast pump context

Feature 41 Wearable device using more than one piezo pump connected in series or in parallel

A wearable device including multiple piezo pumps mounted together either in series or in parallel.

Optional:

- The wearable device is a medical wearable device.
- The piezo pumps air or any liquid etc.
- The system can switch between a parallel mode and a series mode to arrive to lower or higher pressure quicker.

Feature 42 Wearable medical device using a piezo pump and a heat sink attached together.

A wearable medical device including a piezo pump and a heat sink attached together.

Optional

- The wearable device uses more than one piezo pump connected in series.
- The wearable device uses more than one piezo pump connected in parallel.
- Each piezo pump is connected to its own heat sink, or to a common heat sink.
- The or each heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48°C and preferably no more than 43°C
- The wearable device includes a thermal cut out.
- Excess heat is diverted to a specific location on the device that is selected to not be in prolonged contact with the skin of the user, in normal use.
- Use cases application:
    - Wound therapy
    - High degree burns
    - Sleep apnea
    - Deep vein thrombosis
    - Sports injury.
- Wearable medical device is powered/charged via USB.

Note

It is to be understood that the above-referenced arrangements are only illustrative of the application for the principles of the present invention. Numerous modifications and alternative arrangements can be devised without departing from the spirit and scope of

the present invention. While the present invention has been shown in the drawings and fully described above with particularity and detail in connection with what is presently deemed to be the most practical and preferred example(s) of the invention, it will be apparent to those of ordinary skill in the art that numerous modifications can be made without departing from the principles and concepts of the invention as set forth herein.

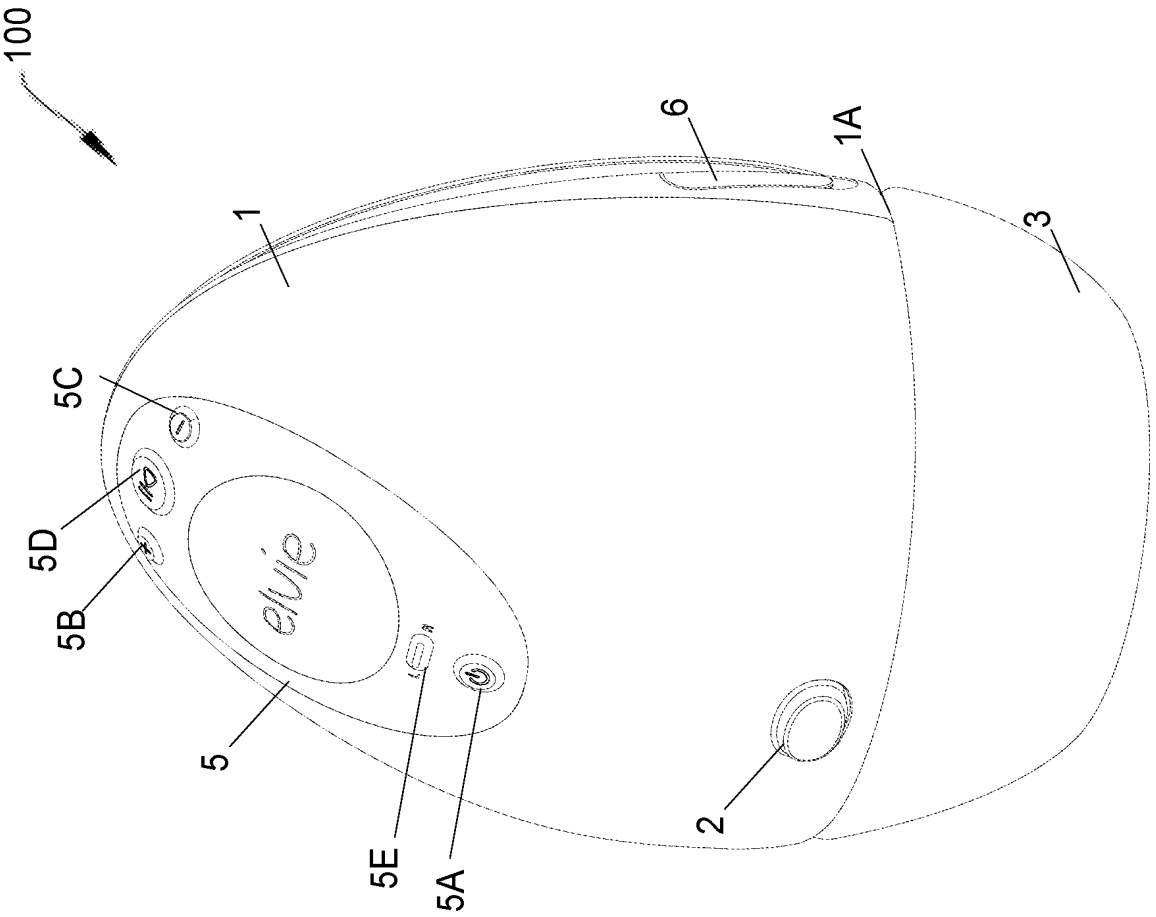

FIGURE 1

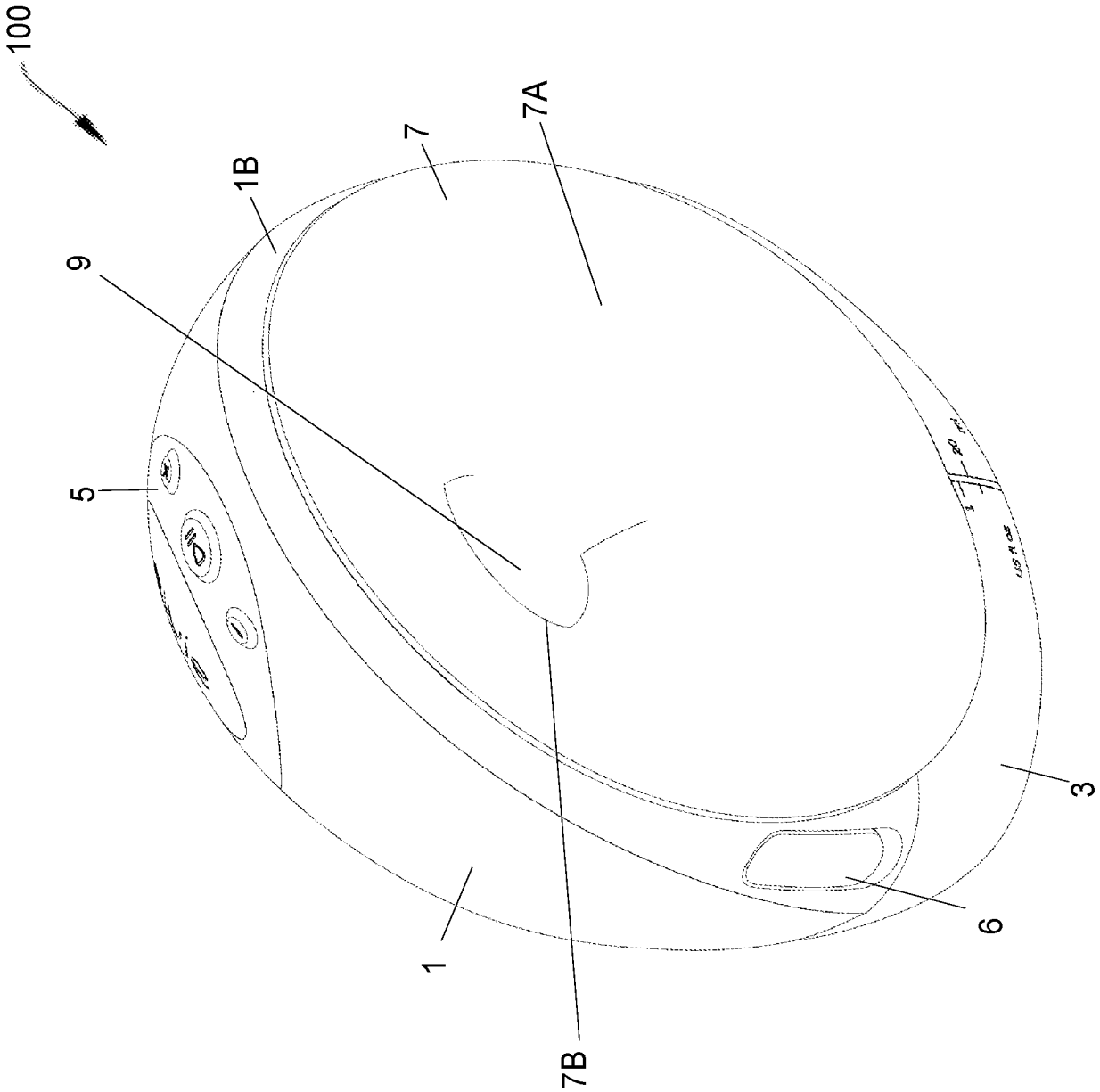

FIGURE 2

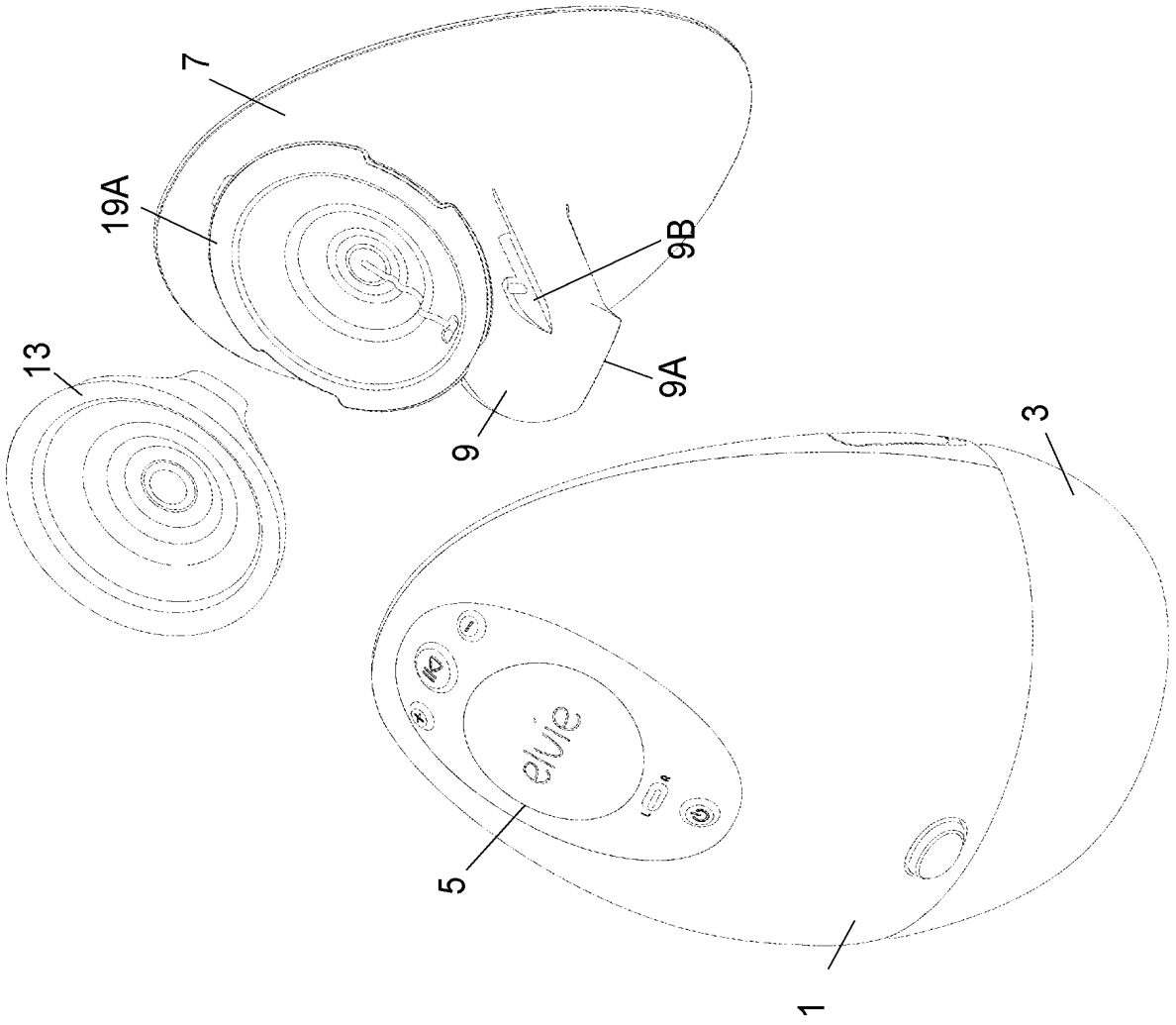

FIGURE 3

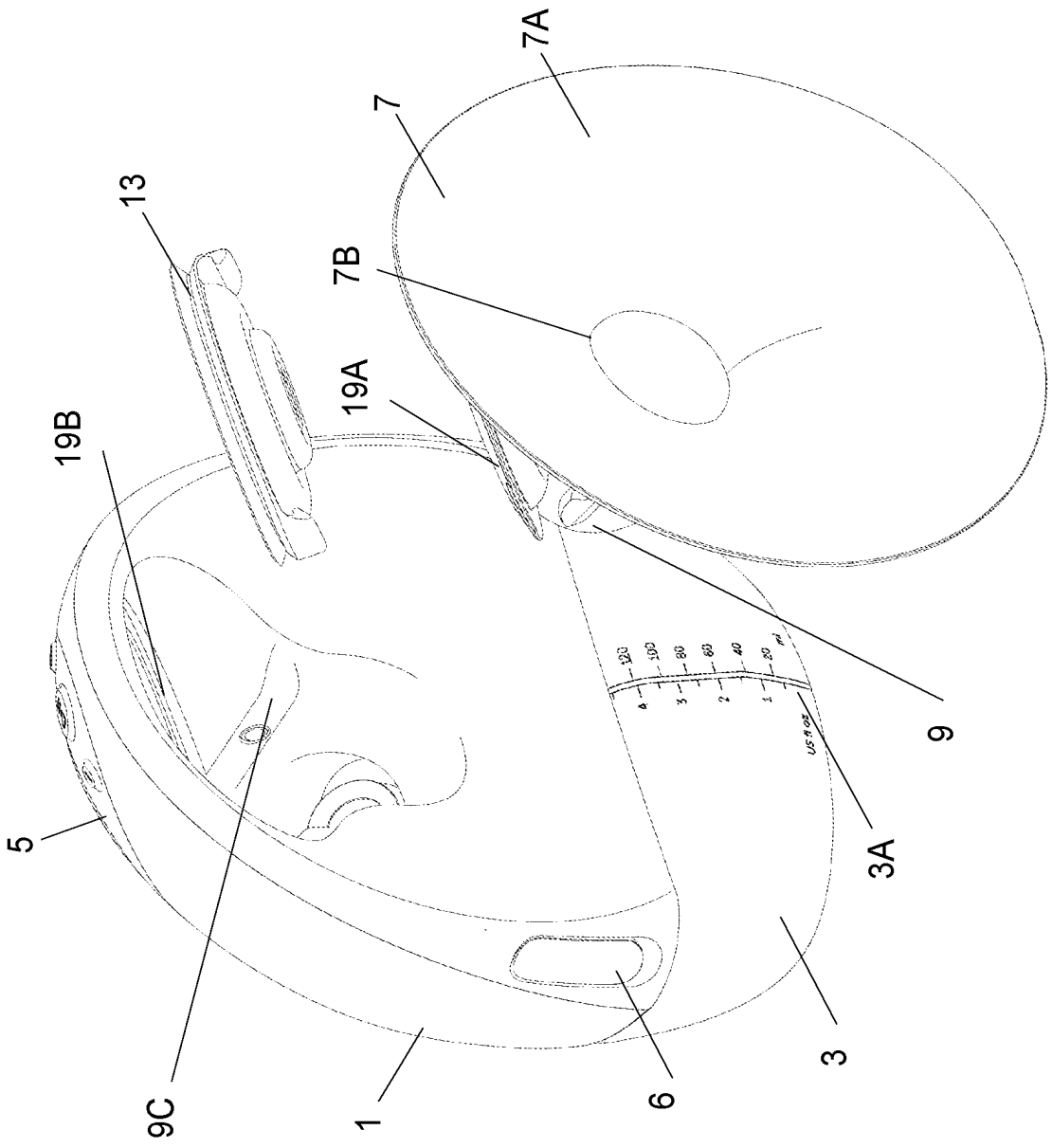

FIGURE 4

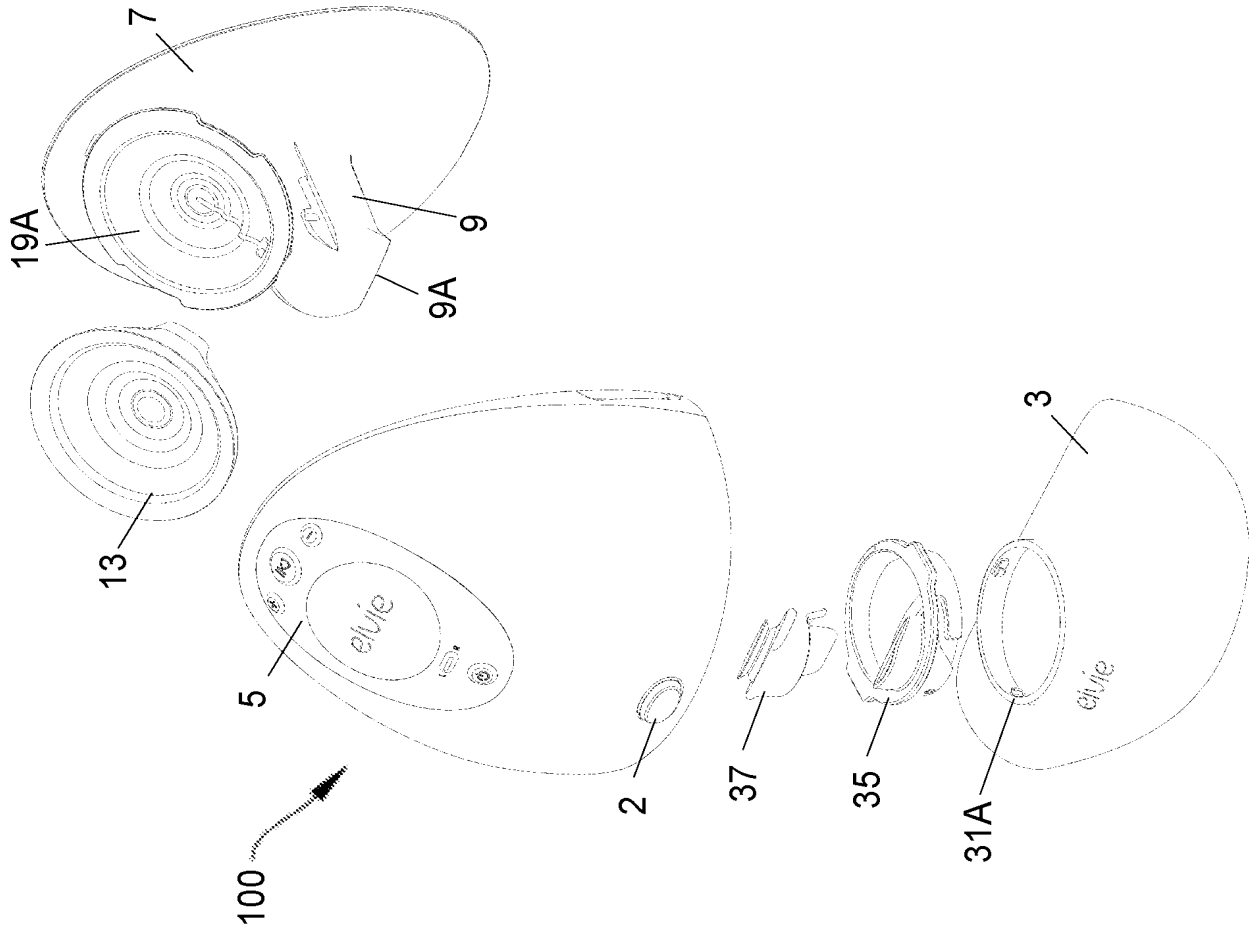

FIGURE 5

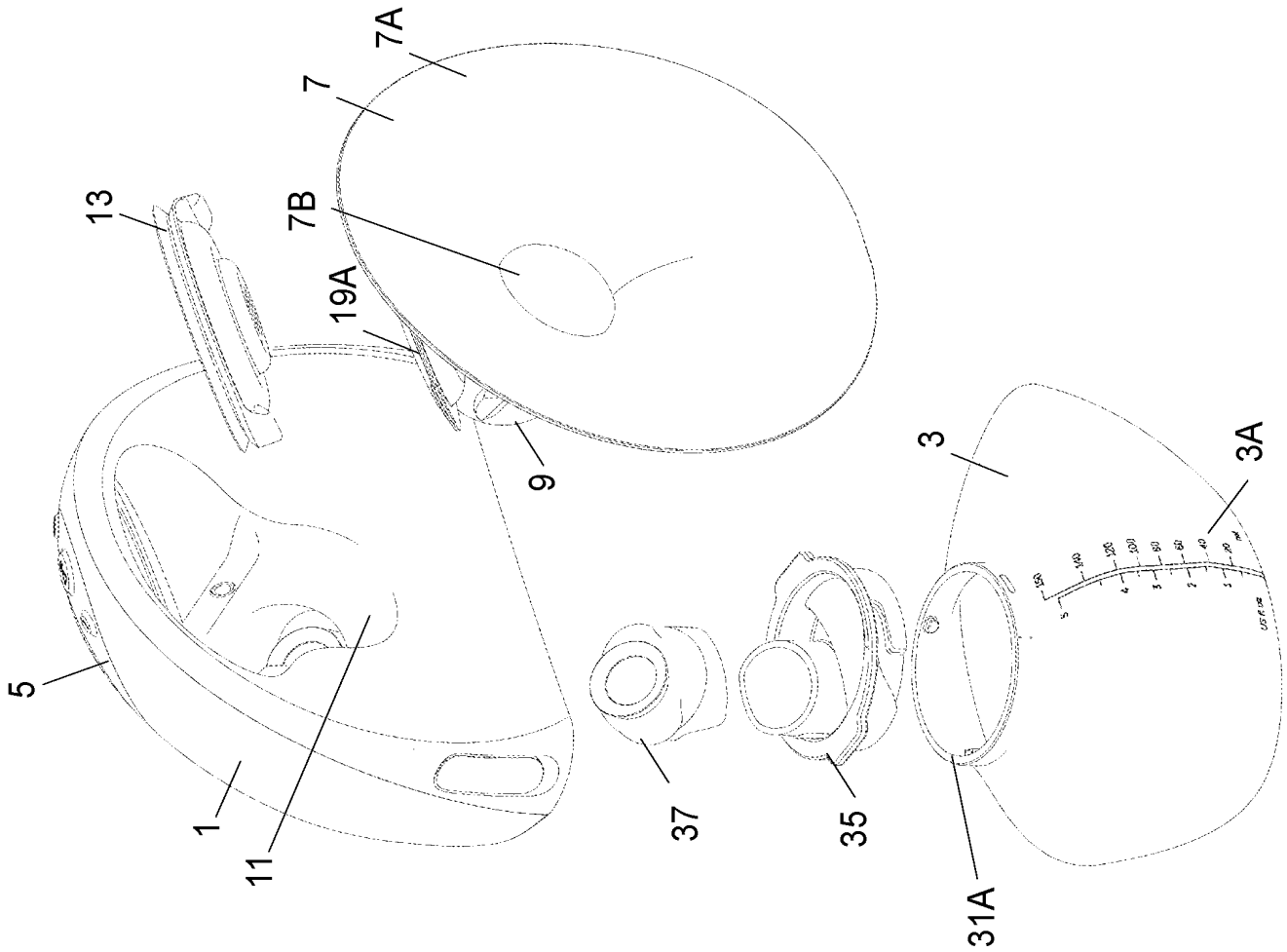

FIGURE 6

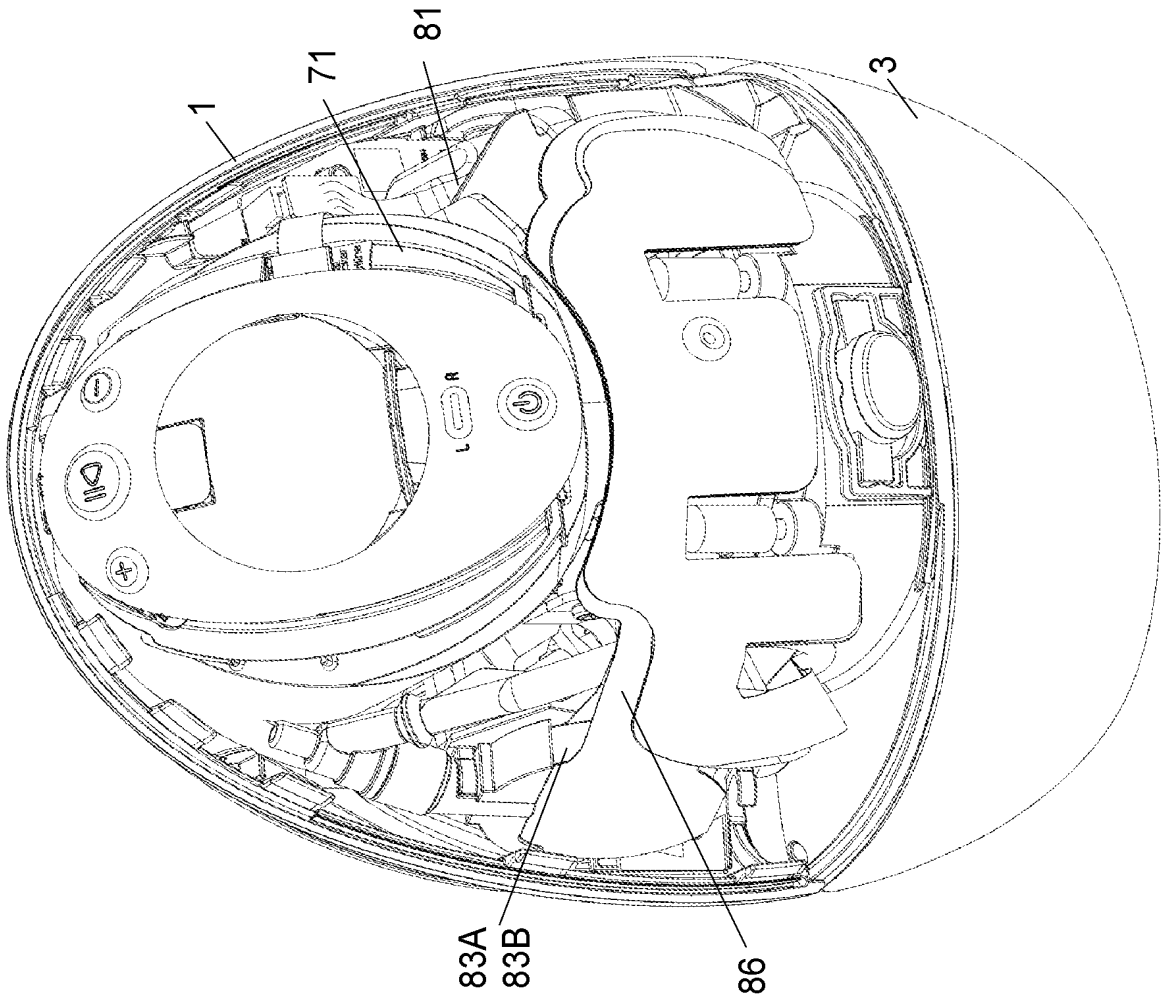

FIGURE 7

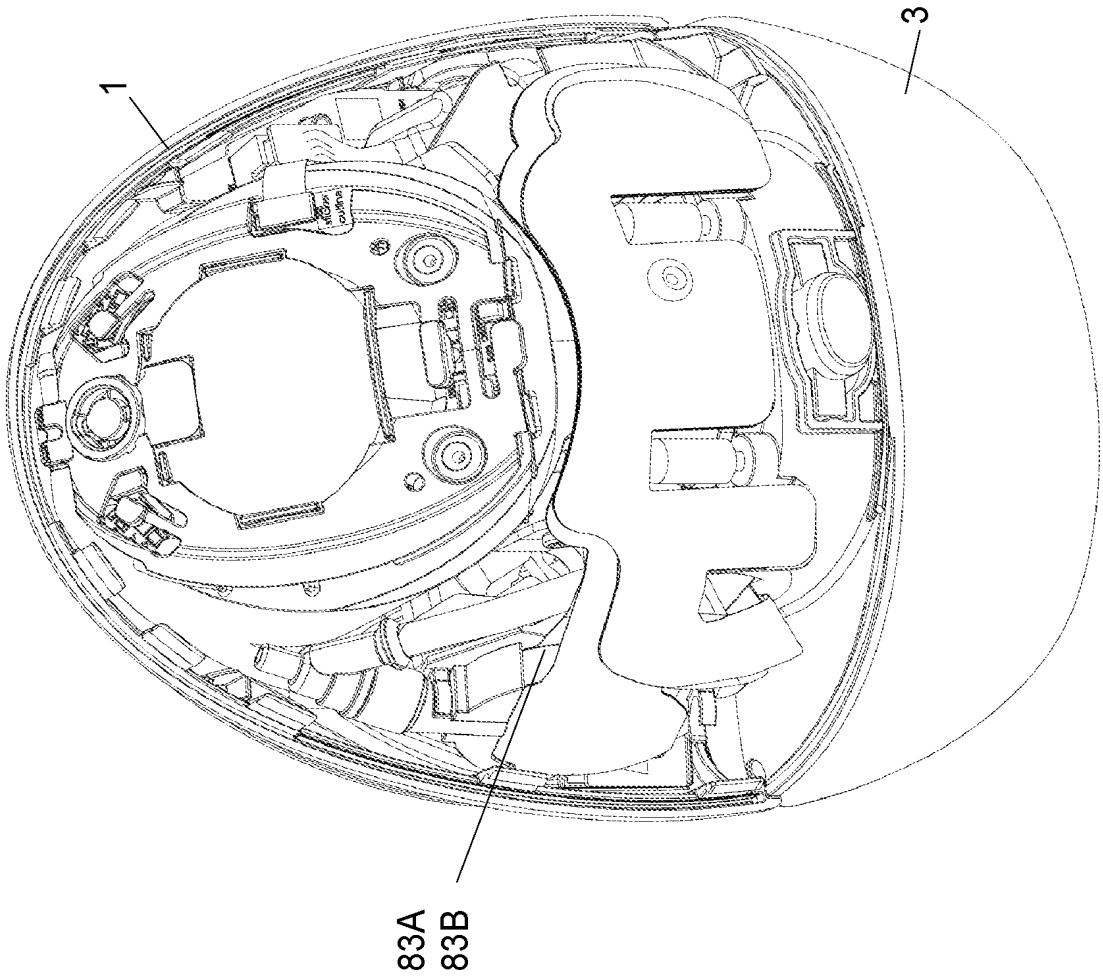

FIGURE 8

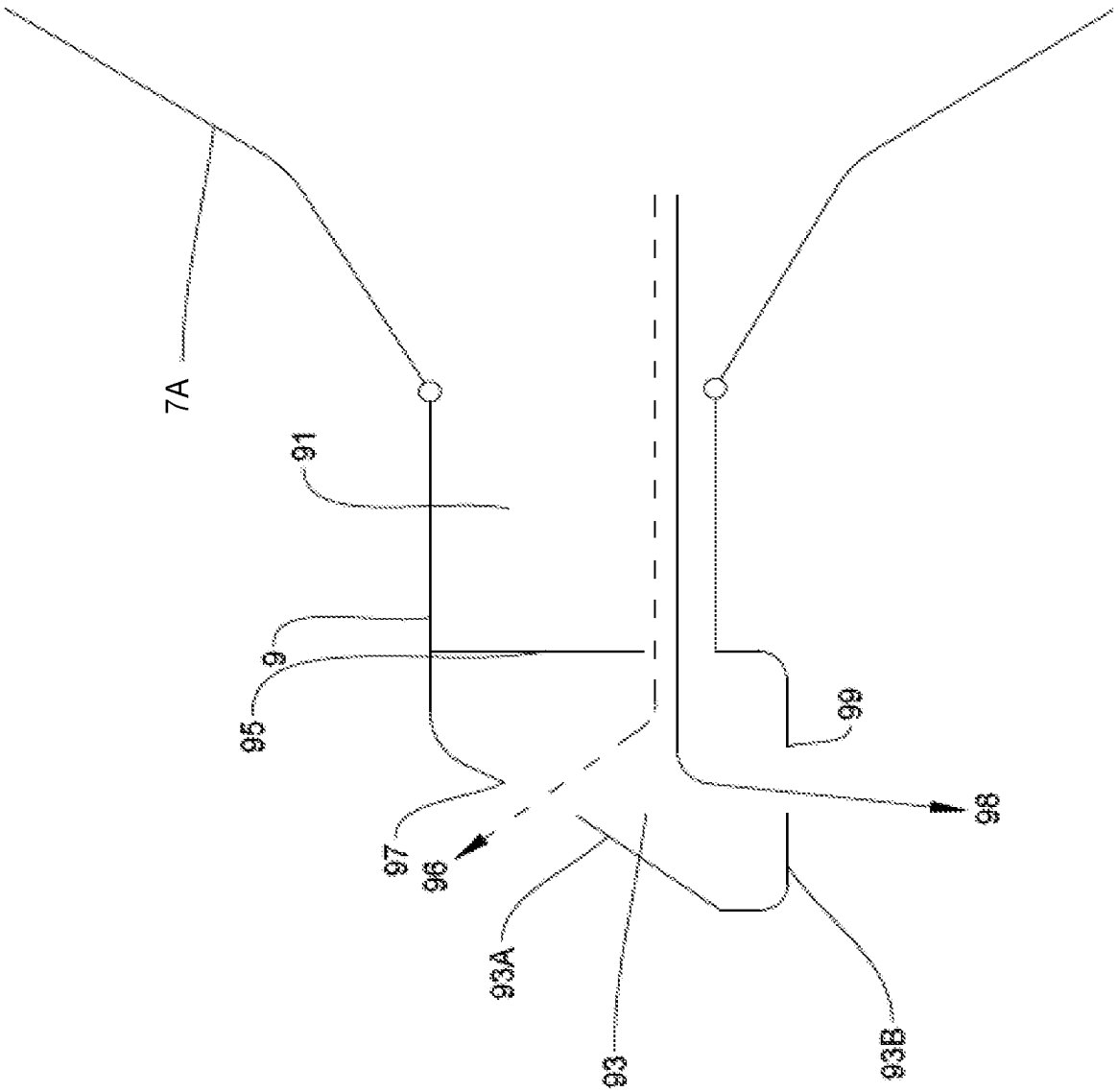

FIGURE 9

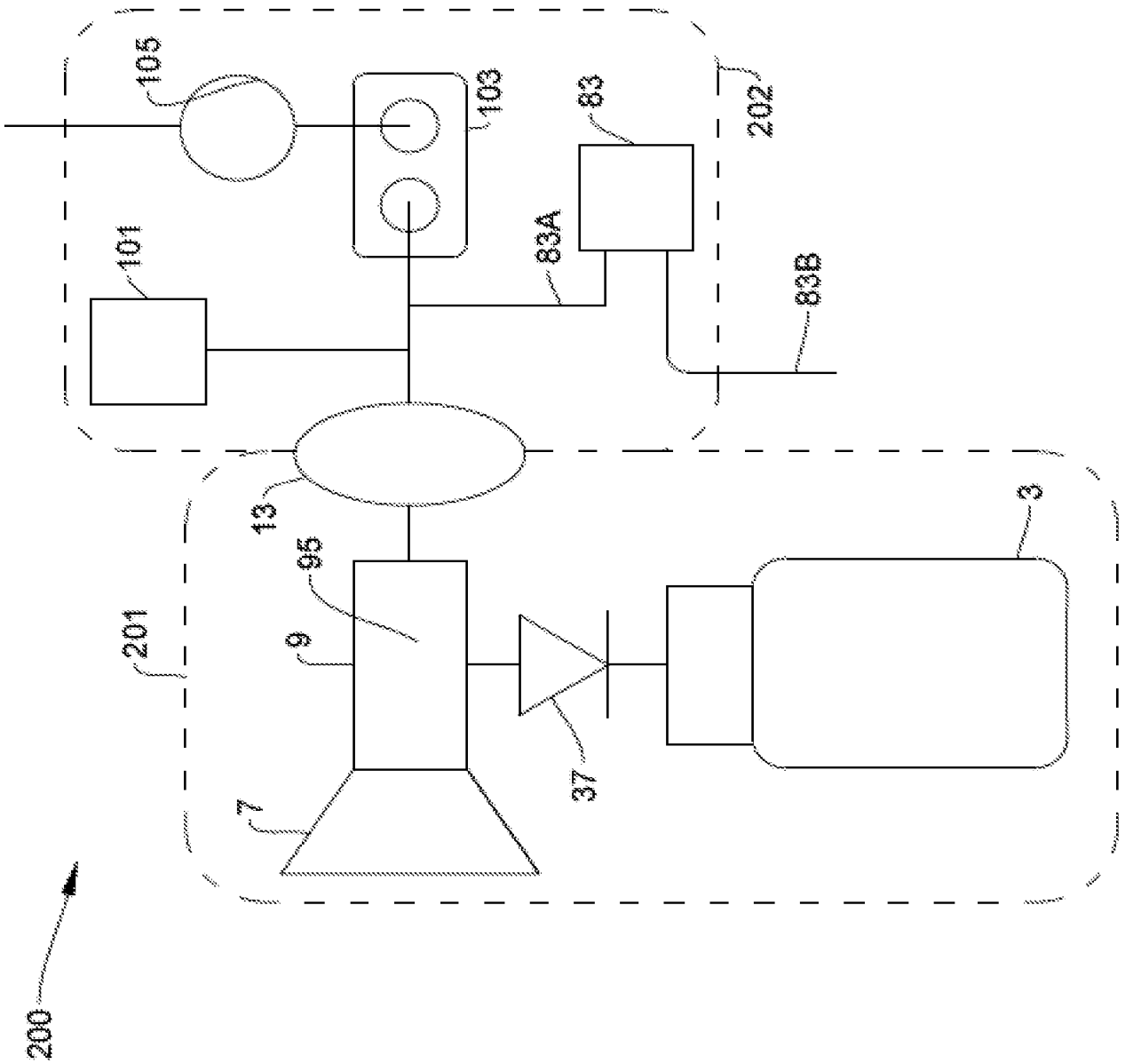

FIGURE 10

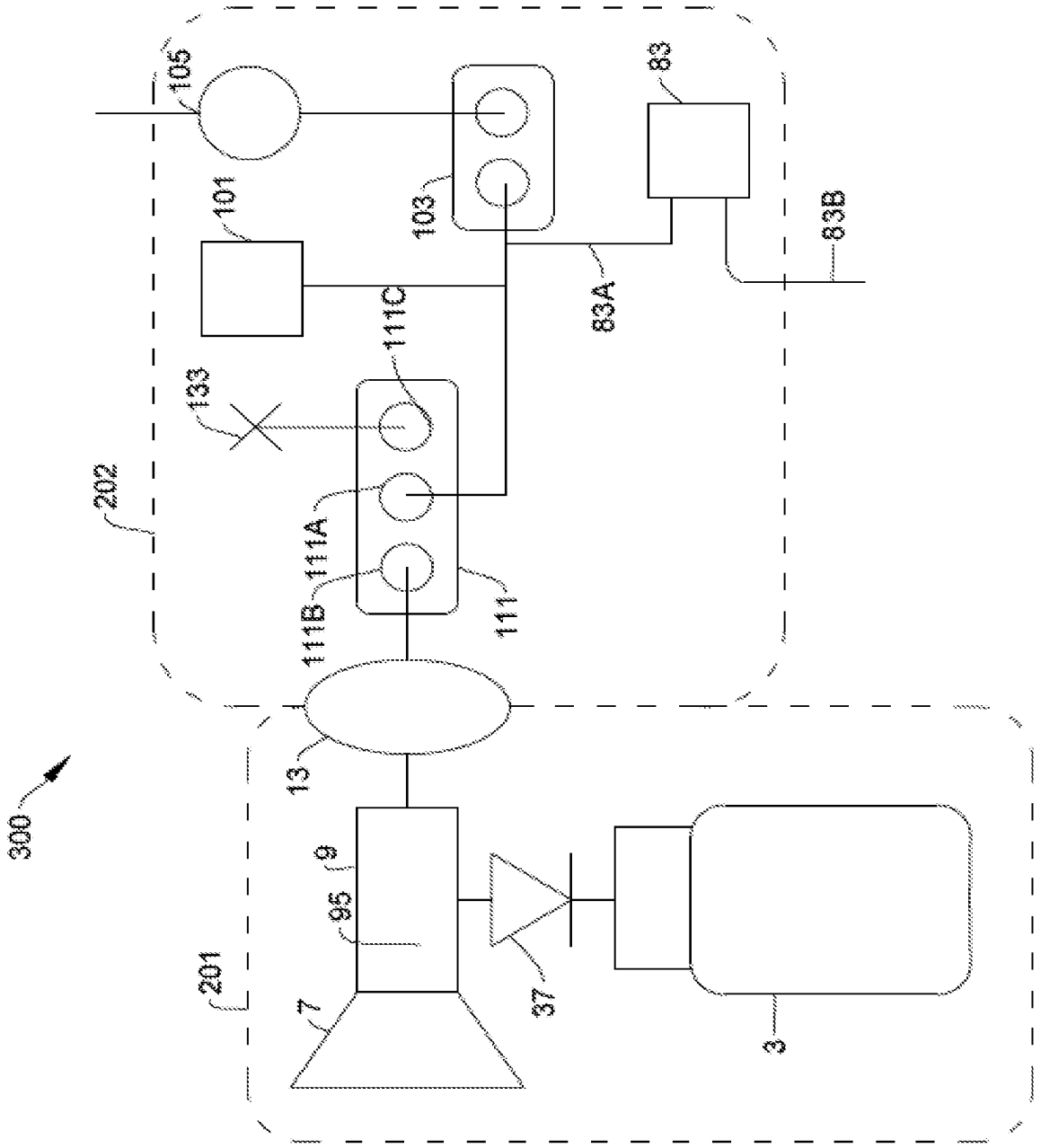
300
105
101
103
83
83B
83A
111C
133
202
111A
111B
111
13
9
95
201
7
37
3

FIGURE 11

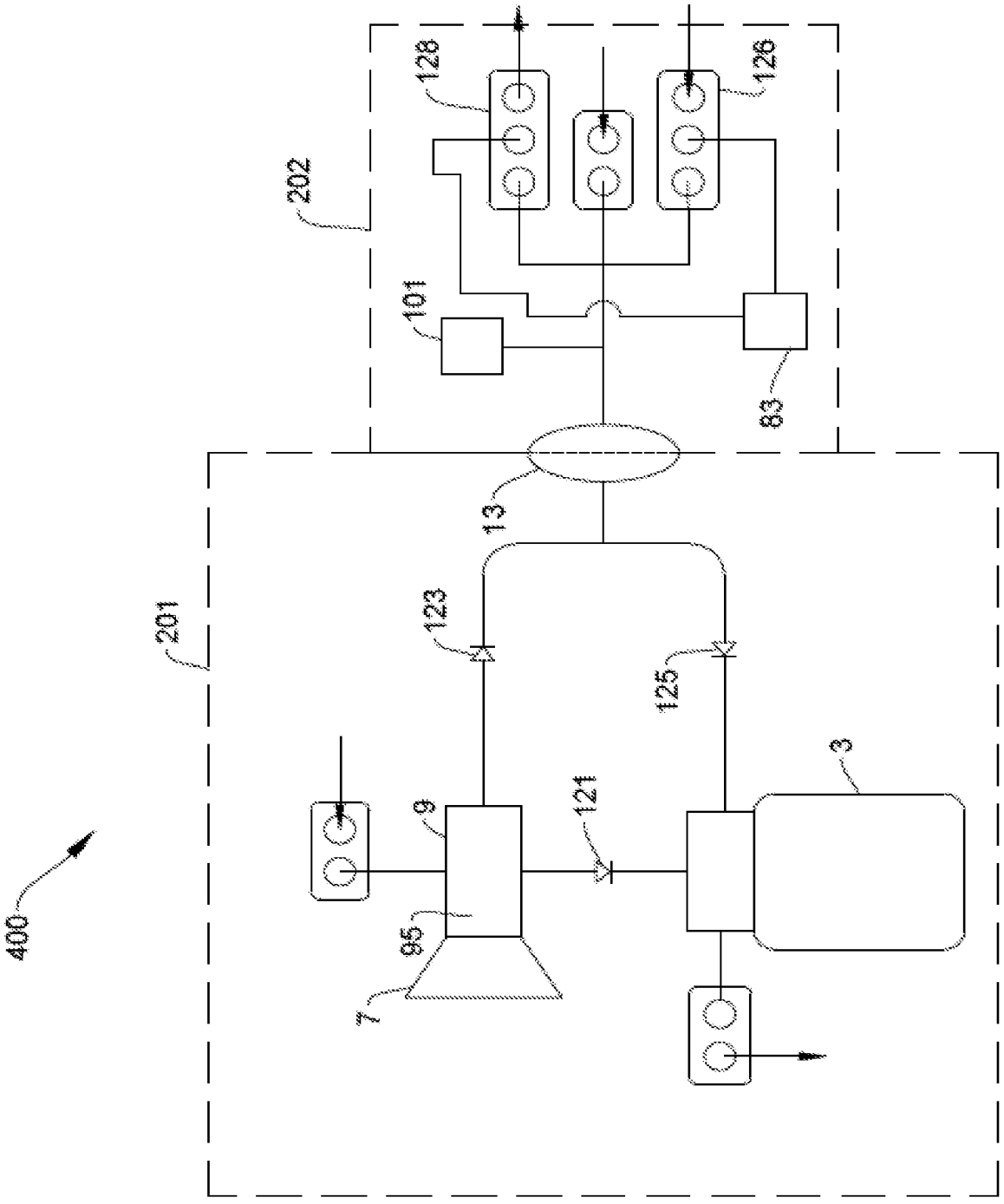

FIGURE 12

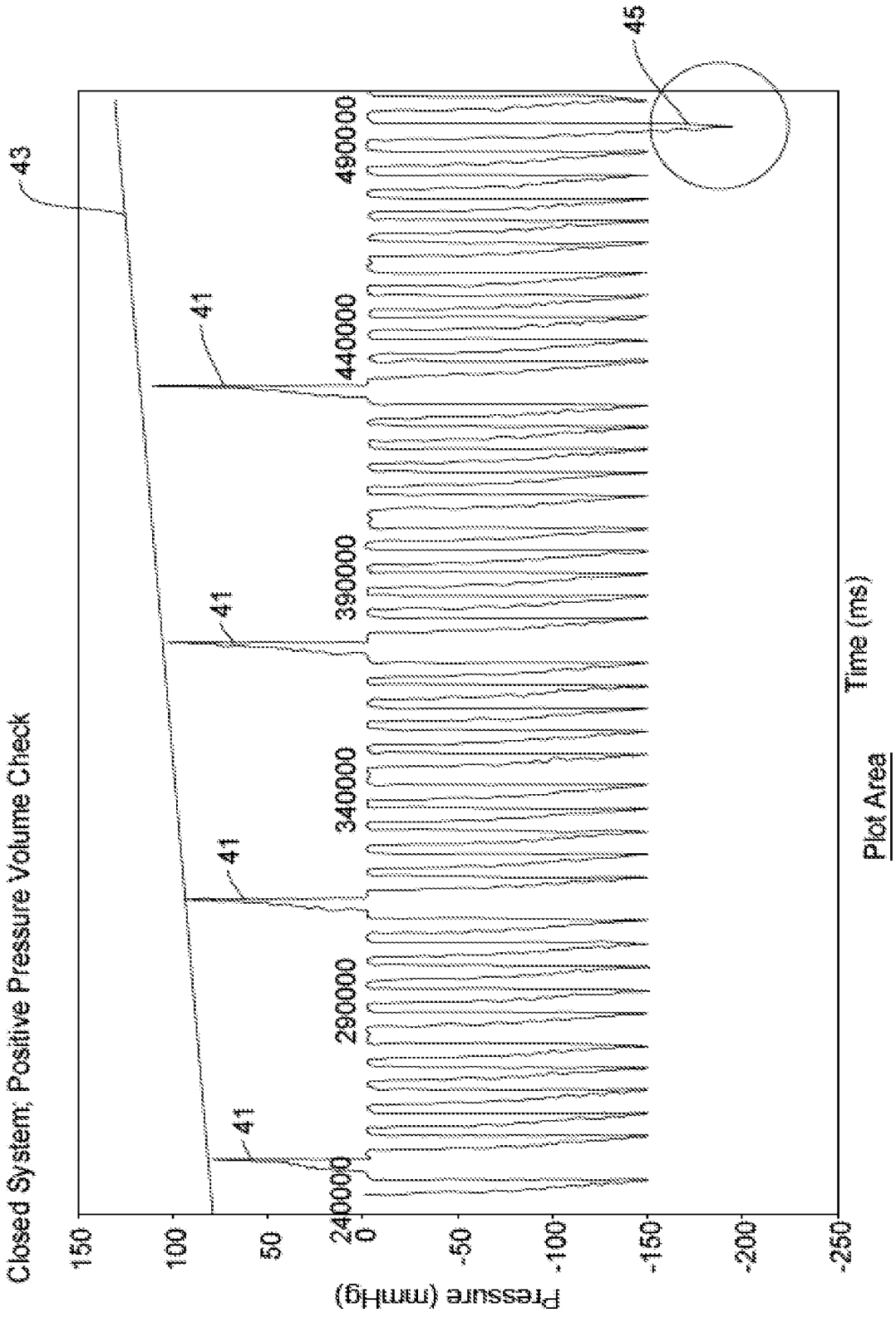
Closed System; Positive Pressure Volume Check
43
45
41
41
41
41
41
240000
290000
340000
390000
440000
490000
150
100
50
0
-50
-100
-150
-200
-250
Pressure (mmHg)
Time (ms)
Plot Area

FIGURE 13

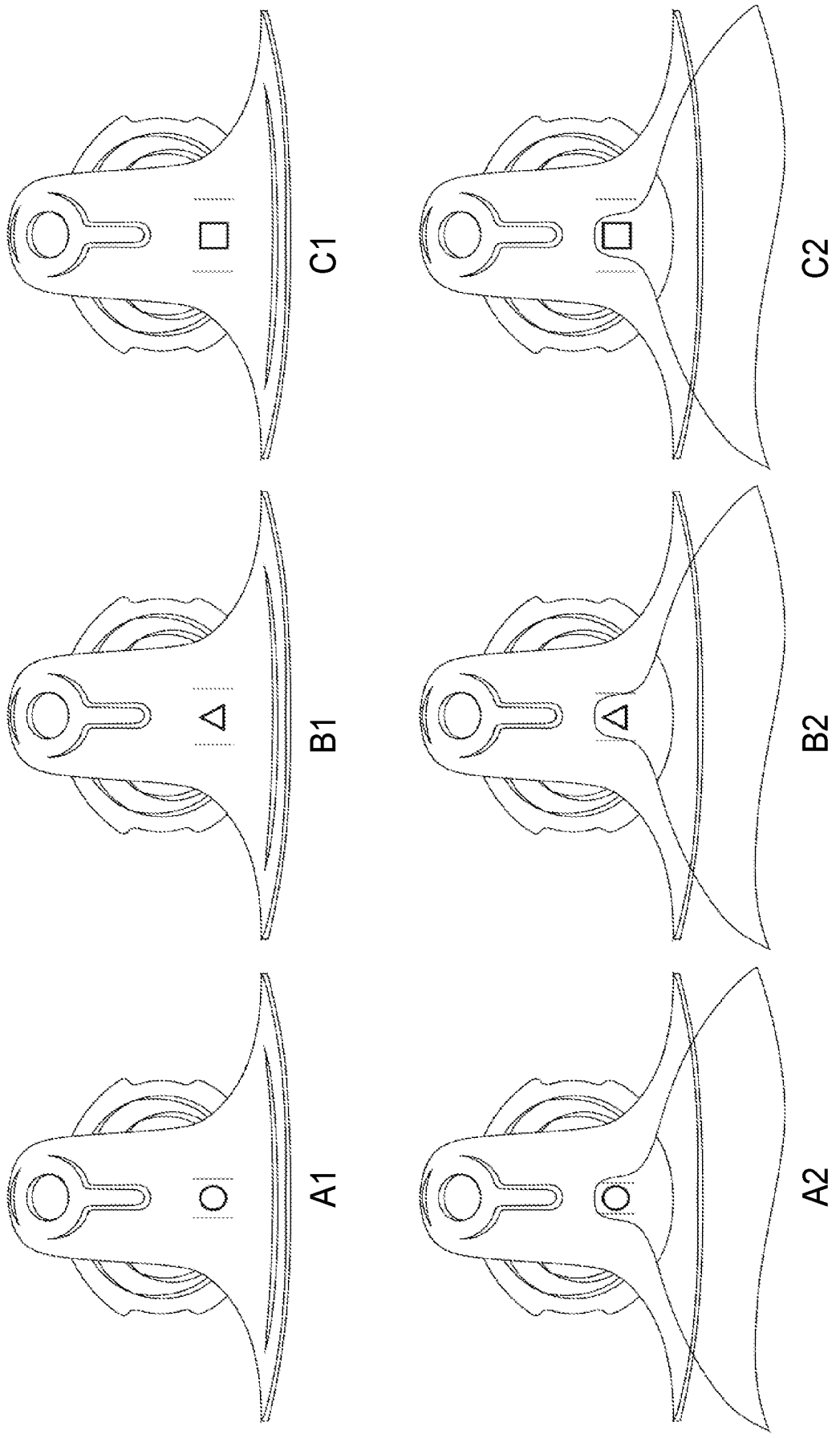

FIGURE 14

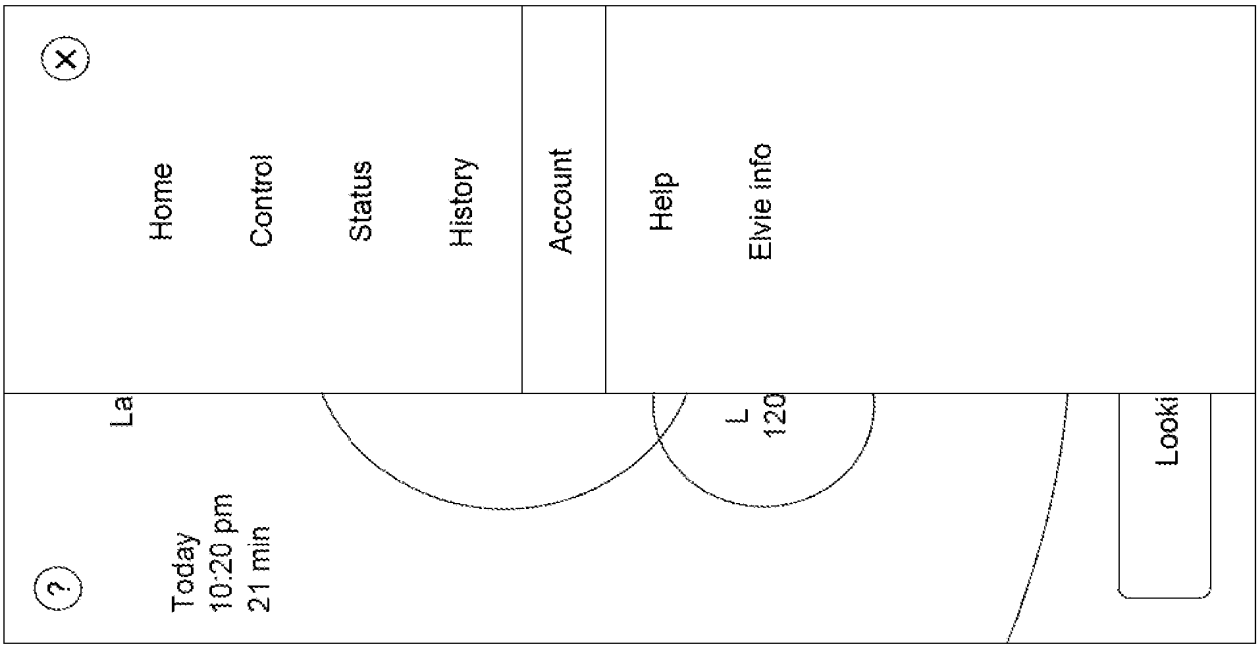
Home
Control
Status
History
Account
Help
Elvie info
Today
10:20 pm
21 min
Looki

FIGURE 15

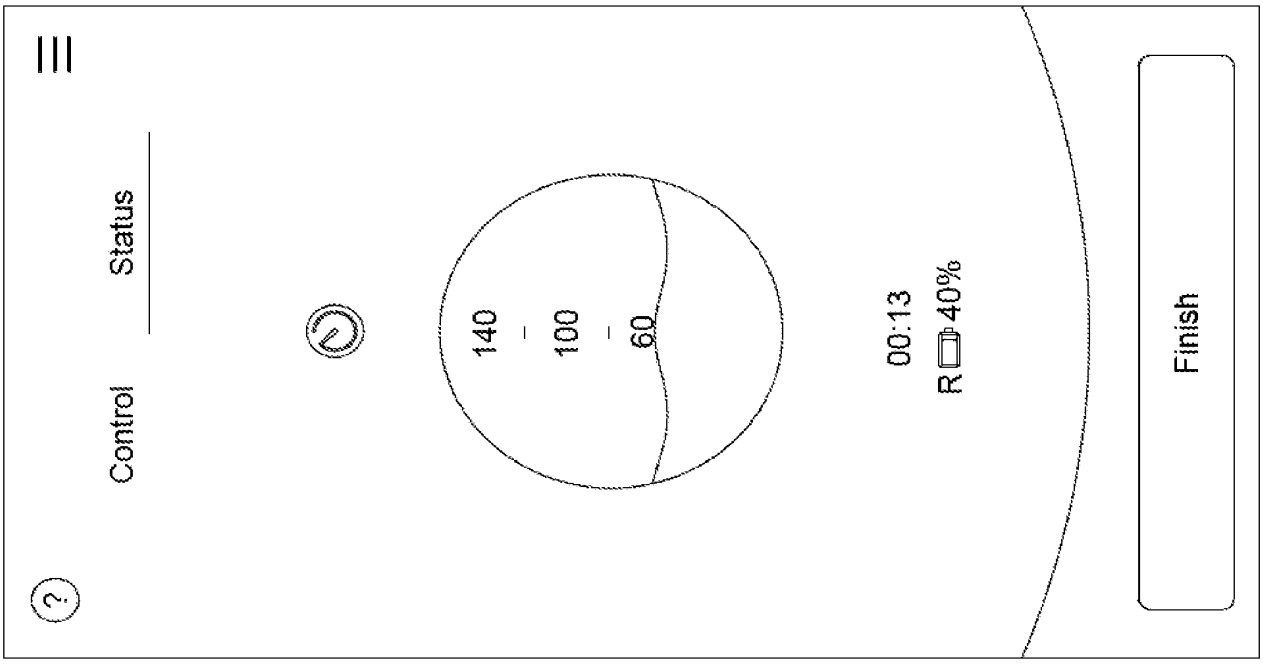

FIGURE 16

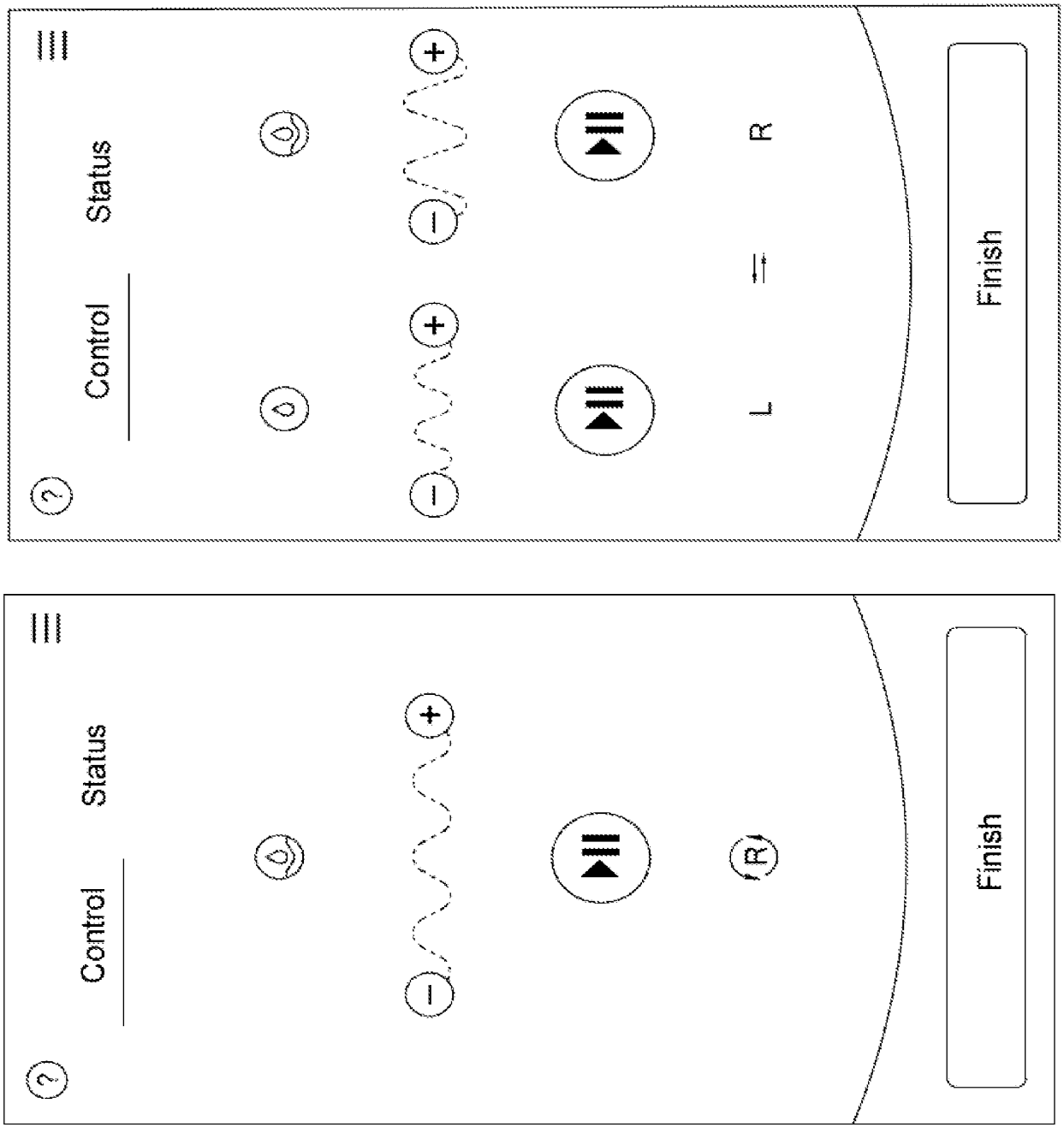

FIGURE 17

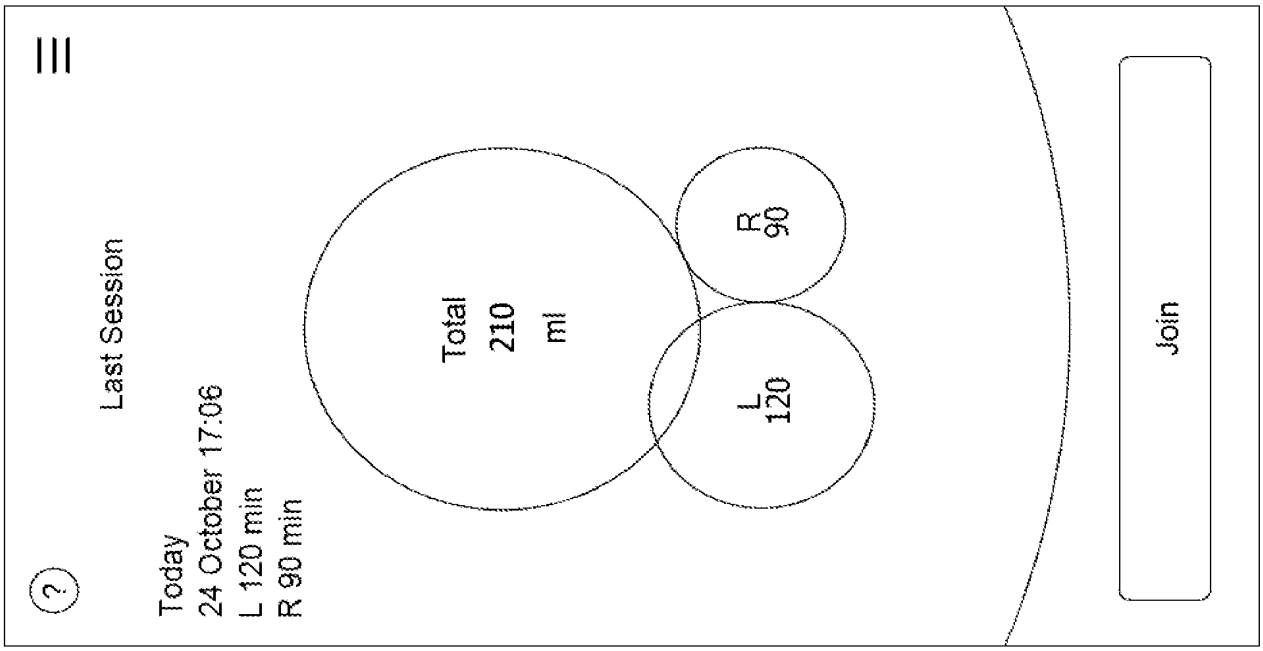
Last Session
Today
24 October 17:06
L 120 min
R 90 min
Total
210
ml
L
120
R
90
Join

FIGURE 18

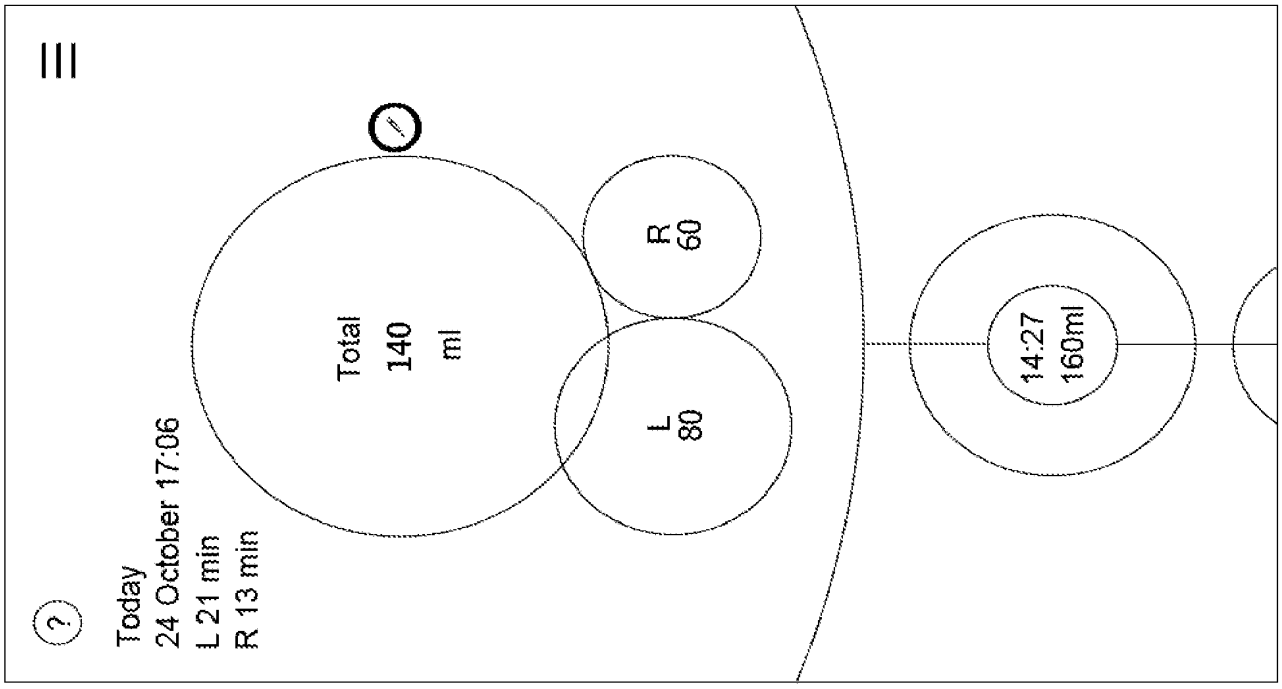
Today
24 October 17:06
L 21 min
R 13 min
Total
140
ml
L
80
R
60
14:27
160ml

FIGURE 19

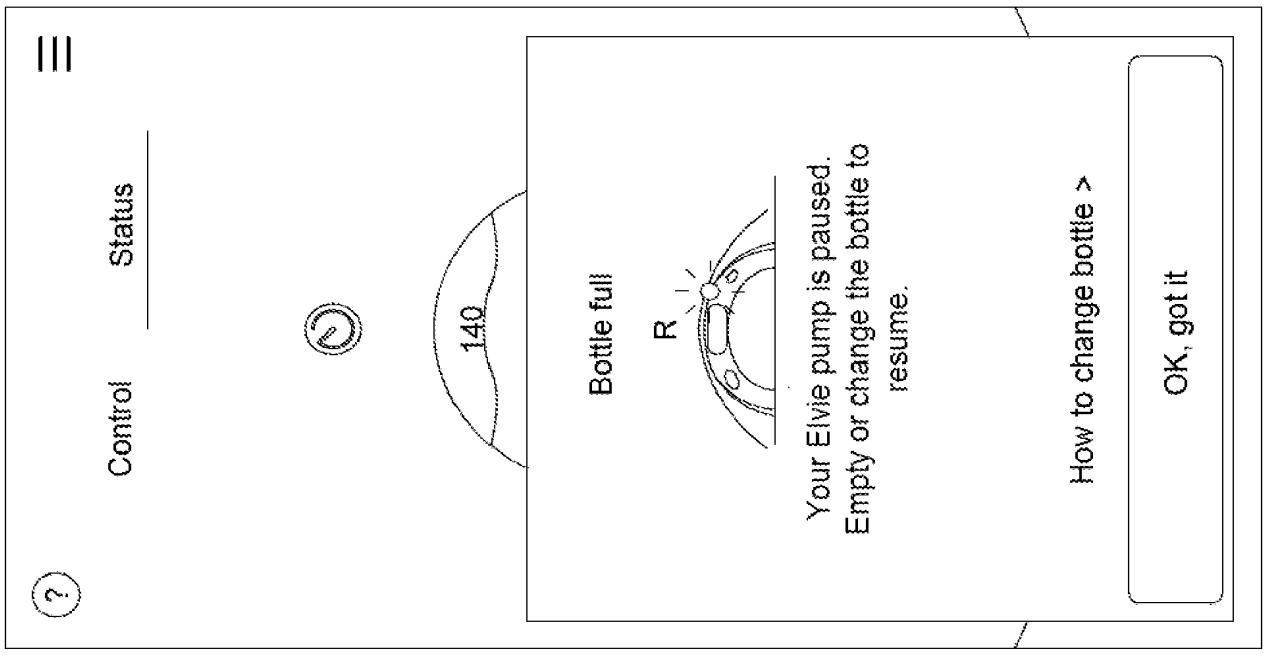
Control
Status
140
Bottle full
R
Your Elvie pump is paused.
Empty or change the bottle to
resume.
How to change bottle >
OK, got it

FIGURE 20

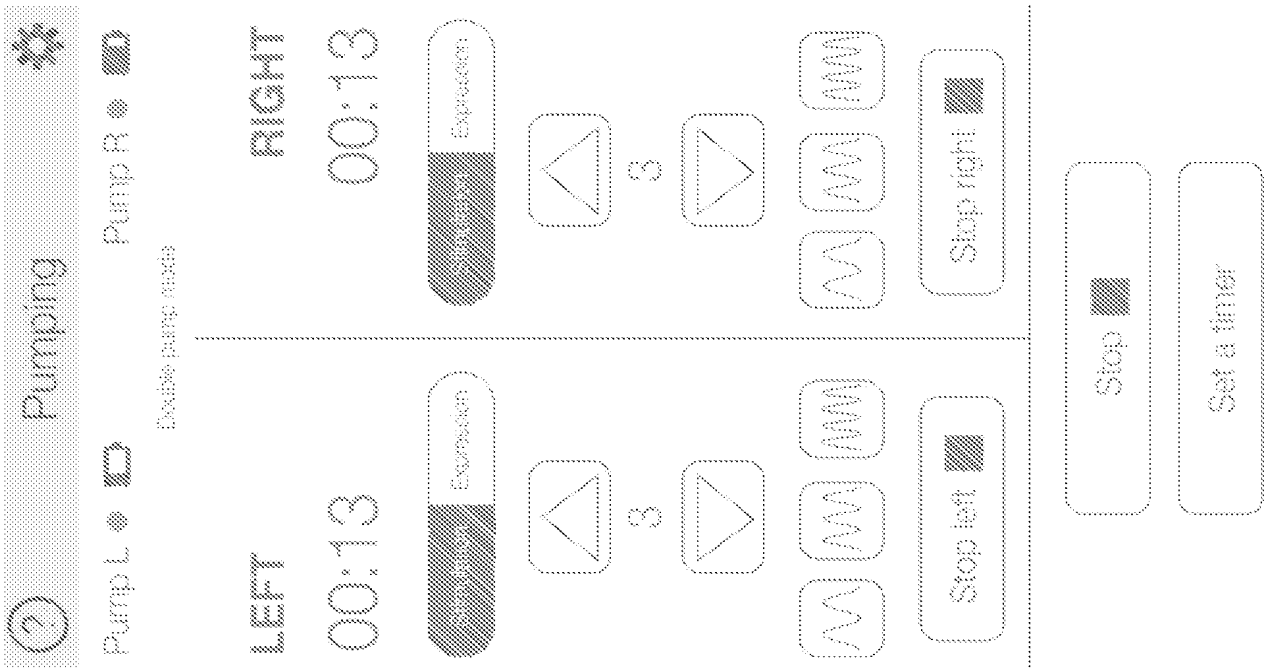
Pumping
Pump L
Pump R
Double tuning rates
LEFT
00:13
Expansion
RIGHT
00:13
Expansion
Stop left
Stop right
Stop
Set a timer

FIGURE 21

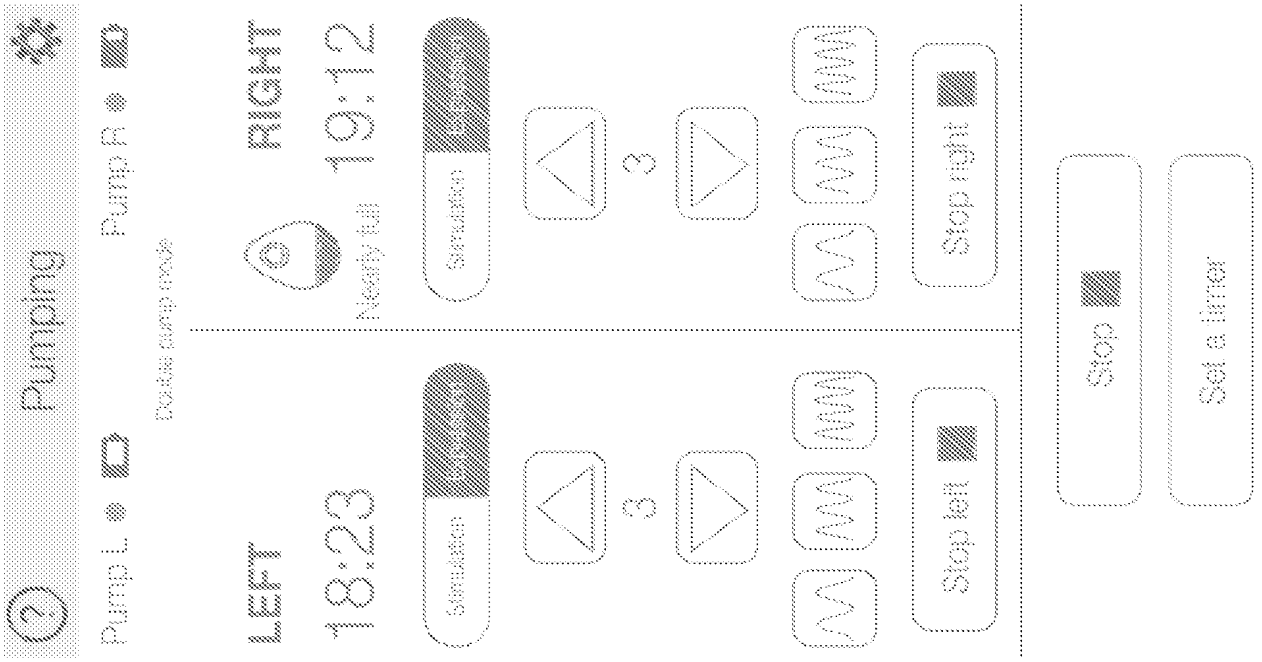
Pumping
Pump L
Pump R
Double pump mode
LEFT
18:23
Stimulation
3
Stop left
RIGHT
19:12
Nearly full
Stimulation
3
Stop right
Stop
Set a timer

FIGURE 22

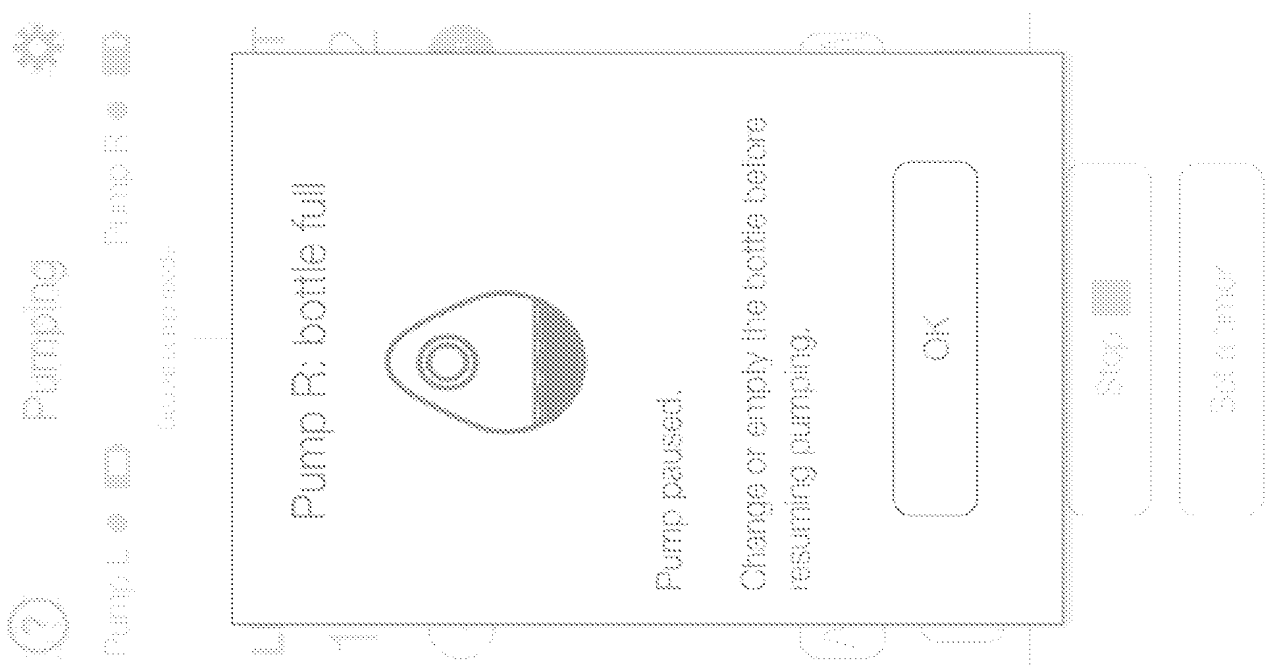
Pumping
Pump L
Pump R
Pump R: bottle full
Pump paused.
Change or empty the bottle before resuming pumping.
OK
Stop
Set a timer

FIGURE 23

Stopped
Pump L
Pump R
Double pump mode
LEFT
21:02
STOPPED
RIGHT
20:38
STOPPED
Total volume in bottle
60 ml
Tick if you emptied the previous bottle
Total volume in bottle
65 ml
Tick if you emptied the previous bottle
Resume left
Resume right
Resume
End session

FIGURE 24

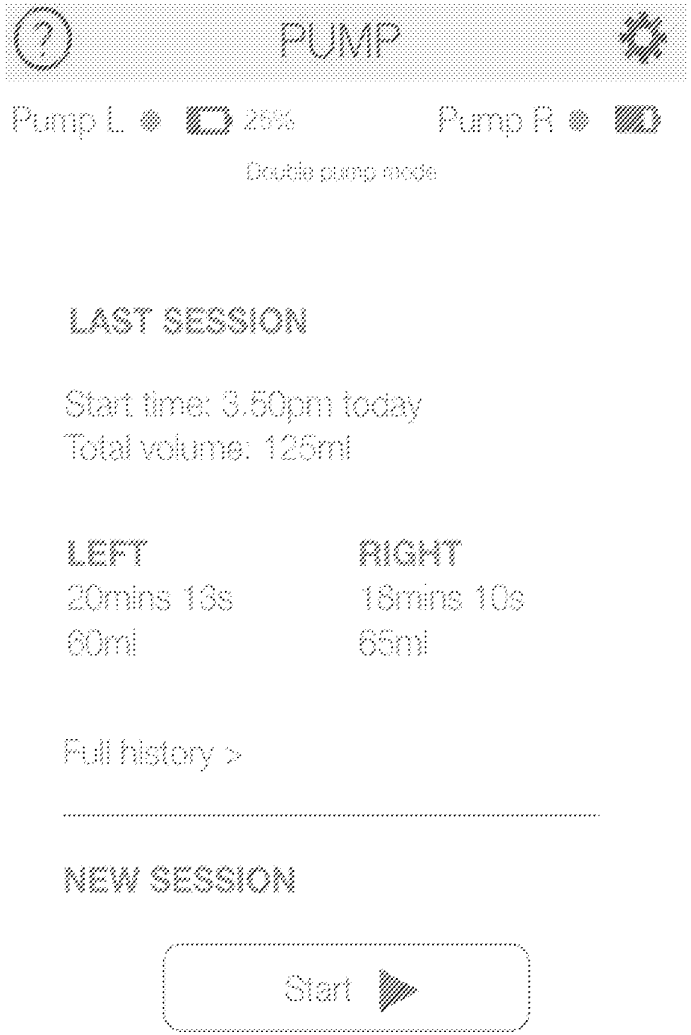
PUMP
Pump L 25%
Pump R
Double pump mode
LAST SESSION
Start time: 3.50pm today
Total volume: 125ml
LEFT
20mins 13s
80ml
RIGHT
18mins 10s
65ml
Full history >
NEW SESSION
Start

FIGURE 25

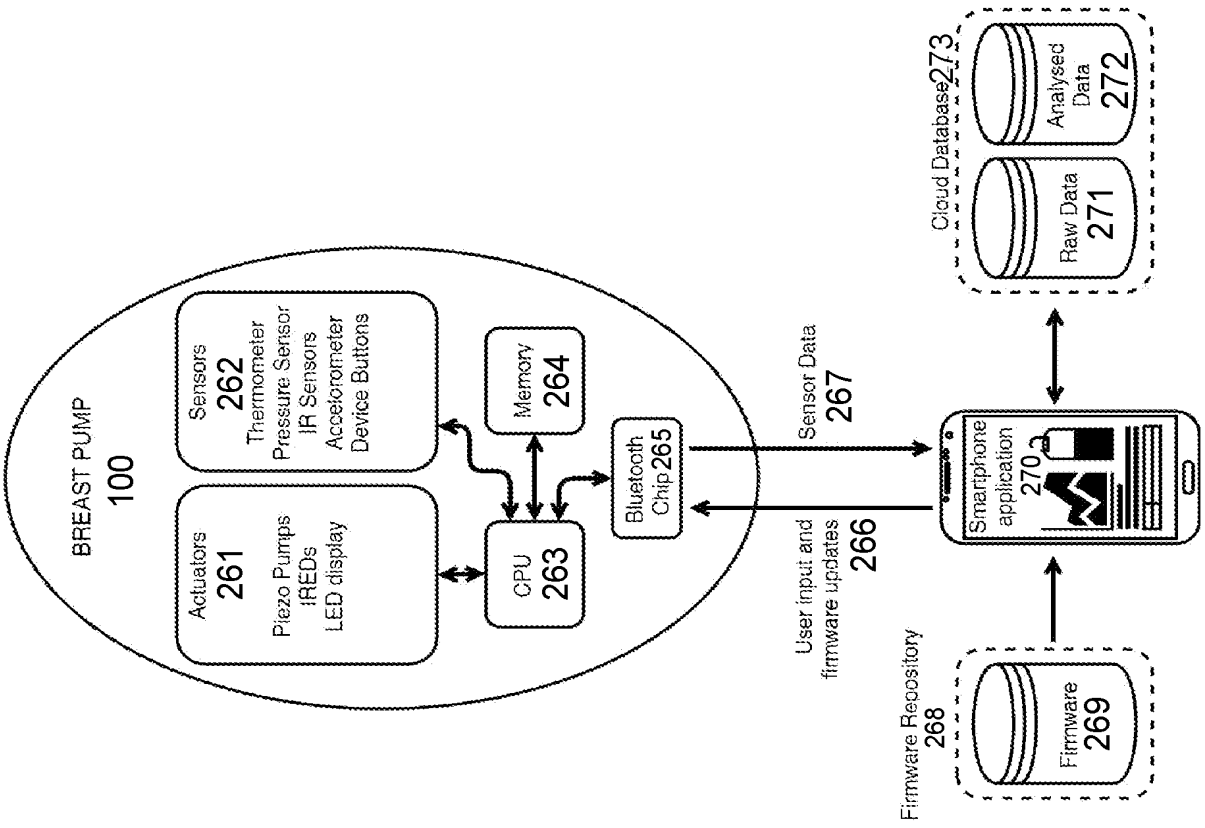
BREAST PUMP
100
Actuators
261
Piezo Pumps
fREDs
LED display
Sensors
262
Thermometer
Pressure Sensor
IR Sensors
Accelorometer
Device Buttons
CPU
263
Memory
264
Bluetooth
Chip 265
Sensor Data
267
User input and
firmware updates
266
Smartphone
application
270
Cloud Database 273
Raw Data
271
Analysed
Data
272
Firmware Repository
268
Firmware
269

FIGURE 26

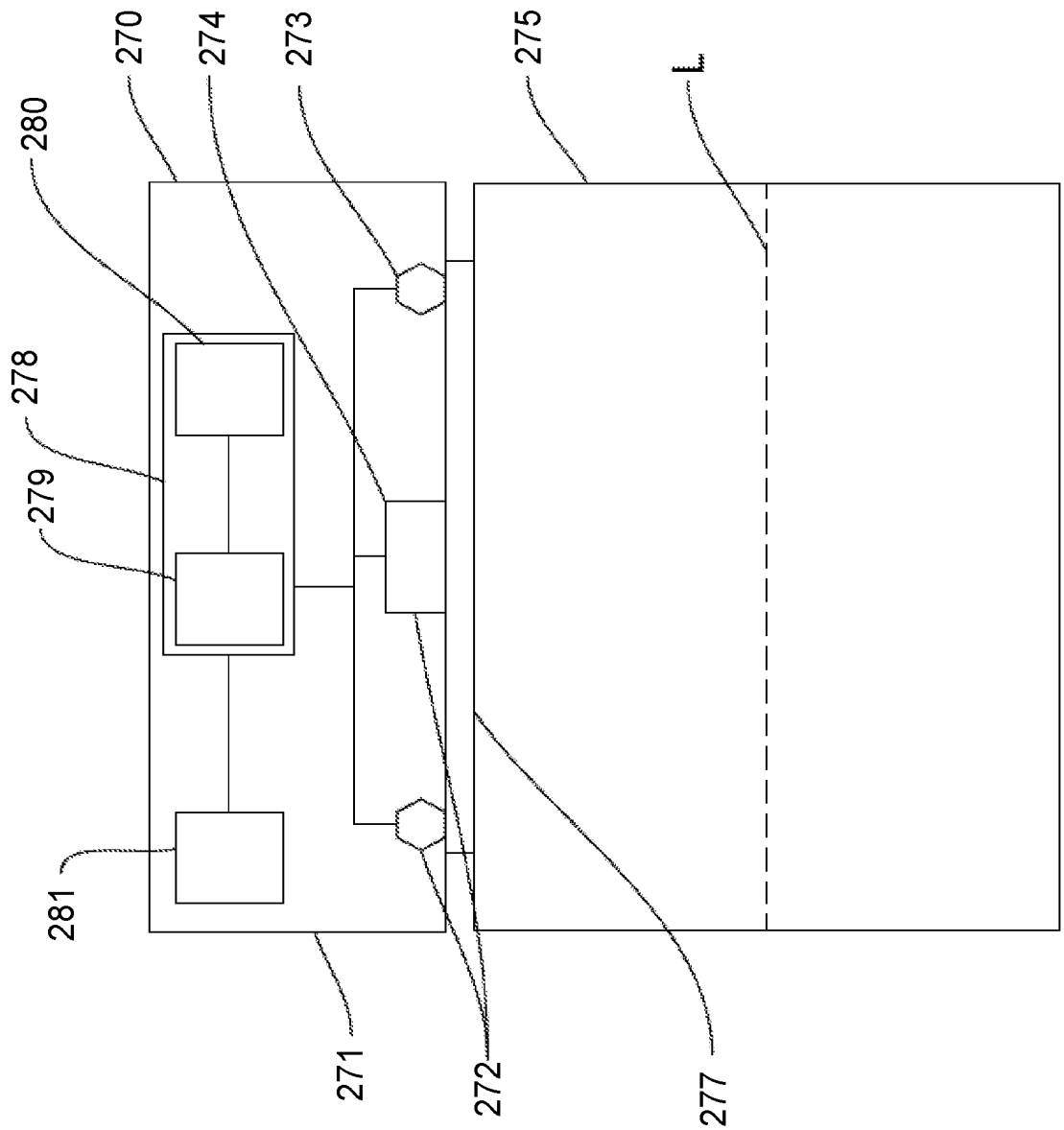

FIGURE 27

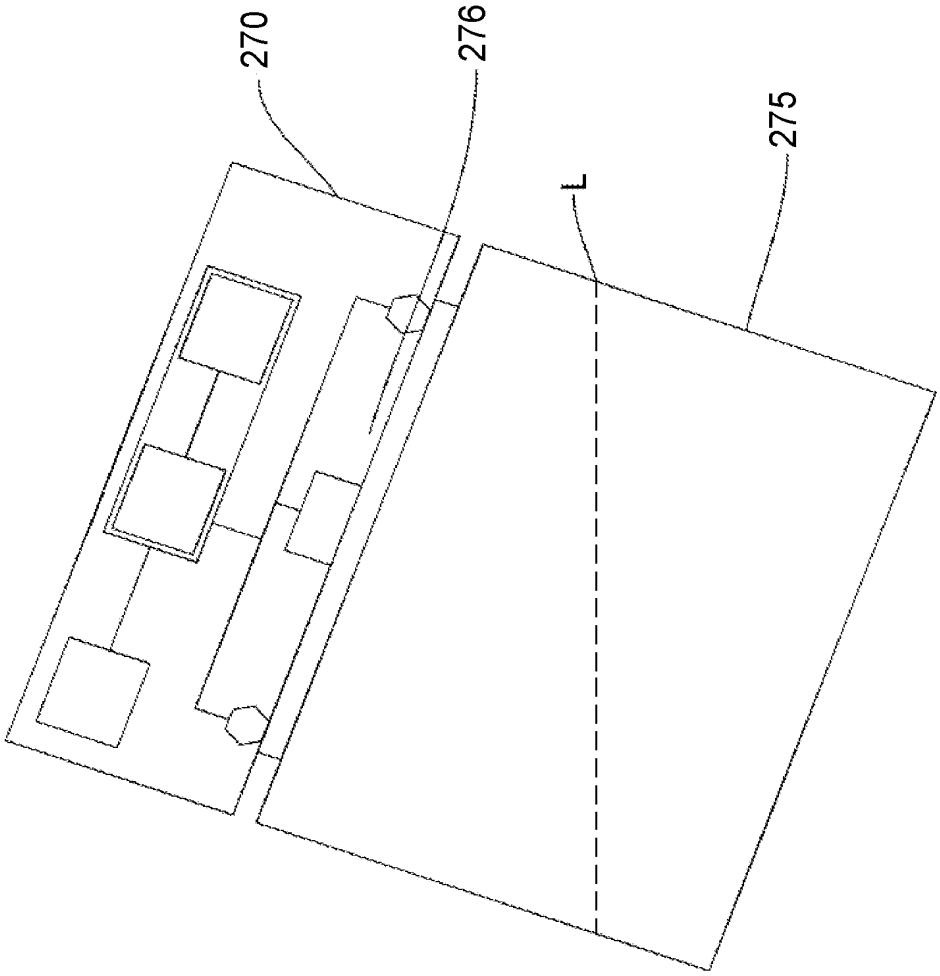

FIGURE 28

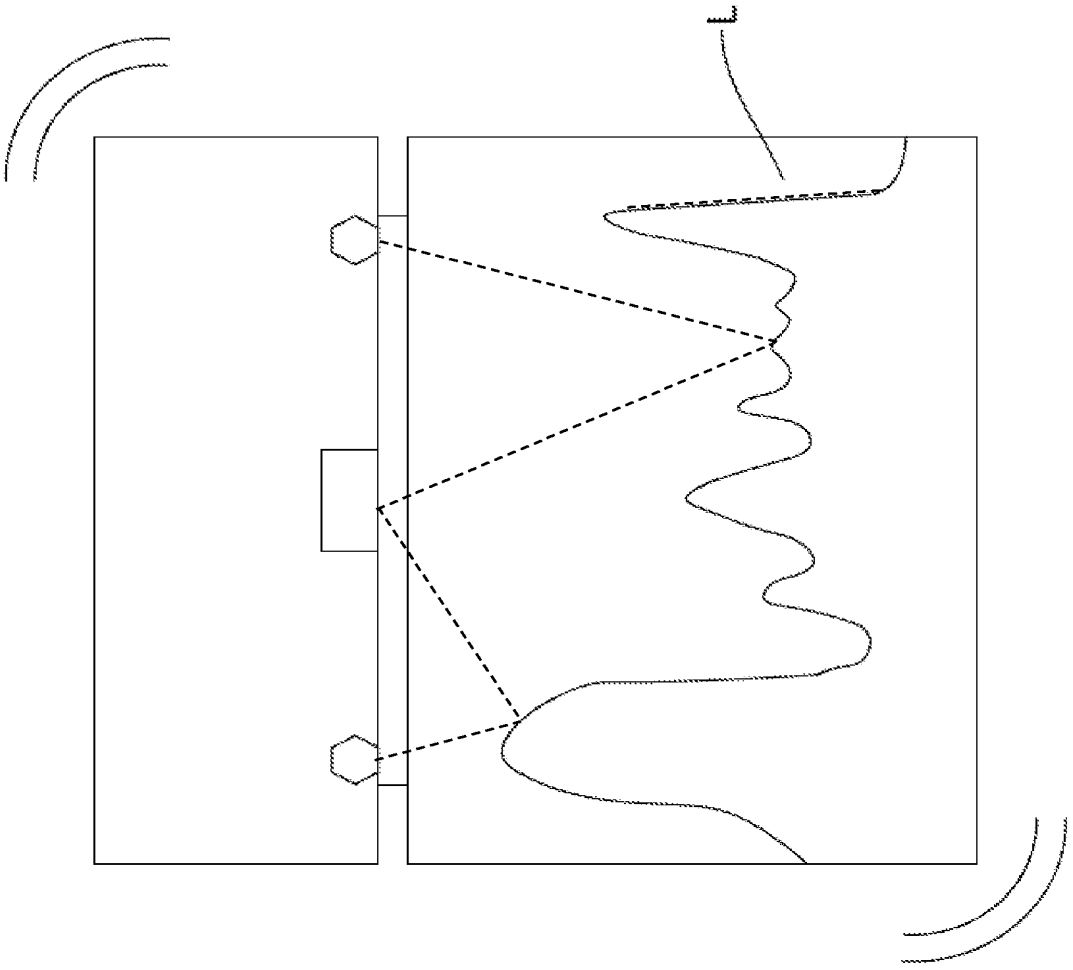

FIGURE 29

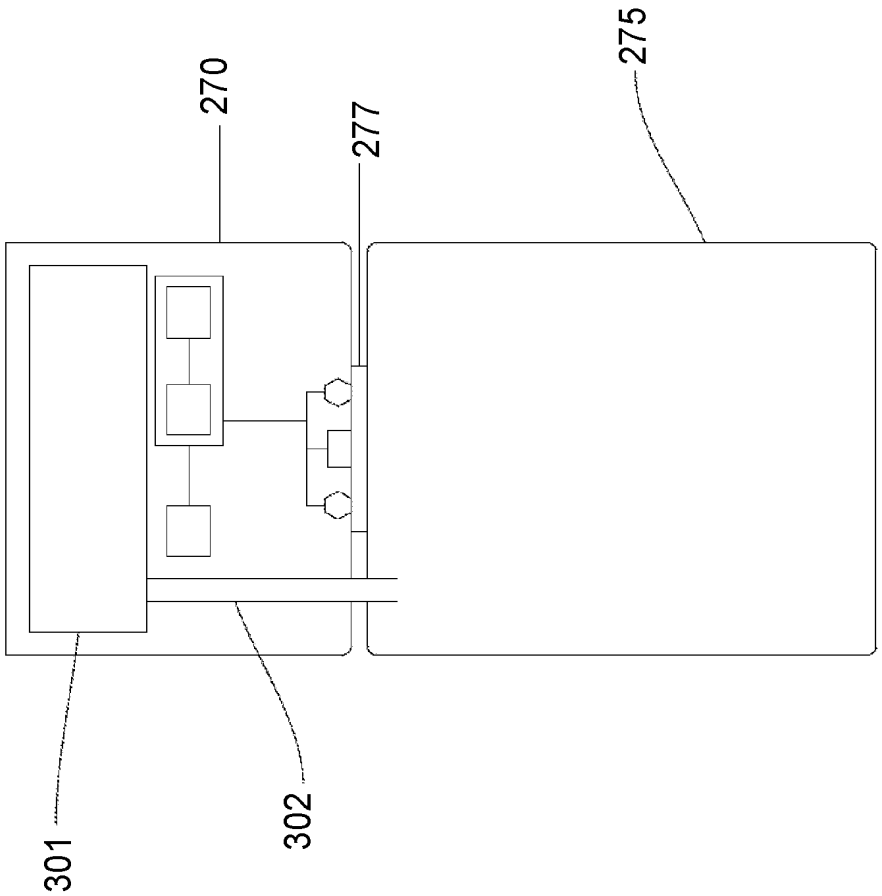

FIGURE 30

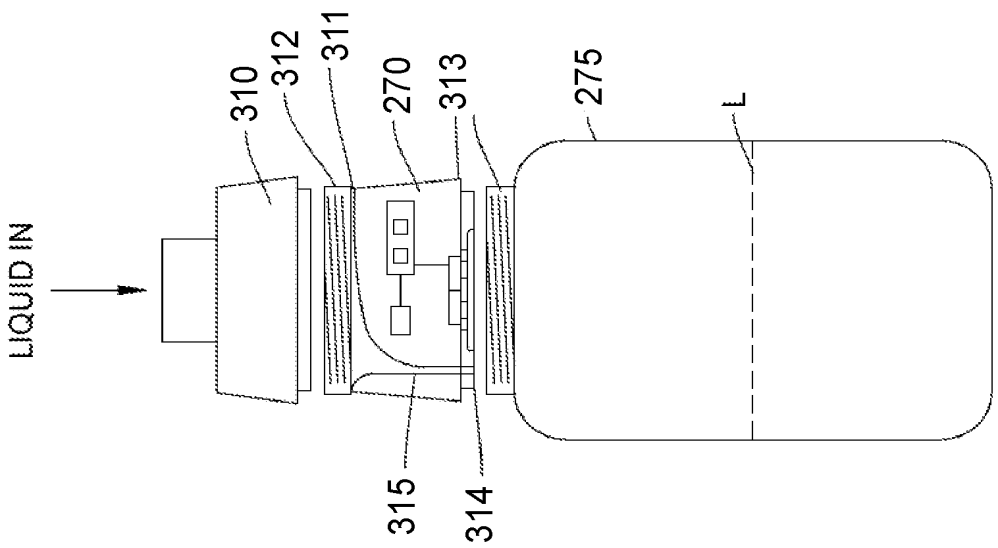

FIGURE 31

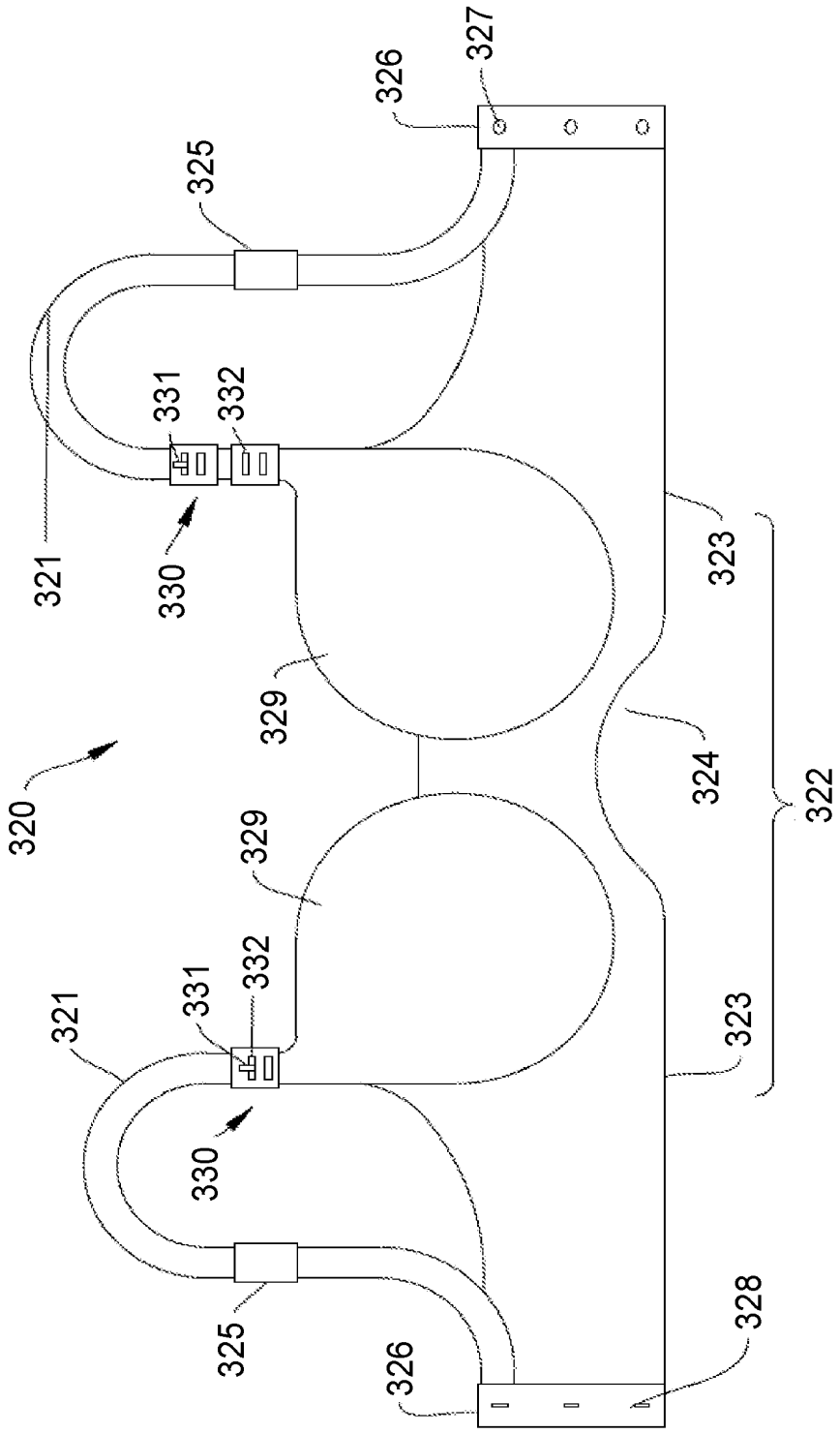

FIGURE 32

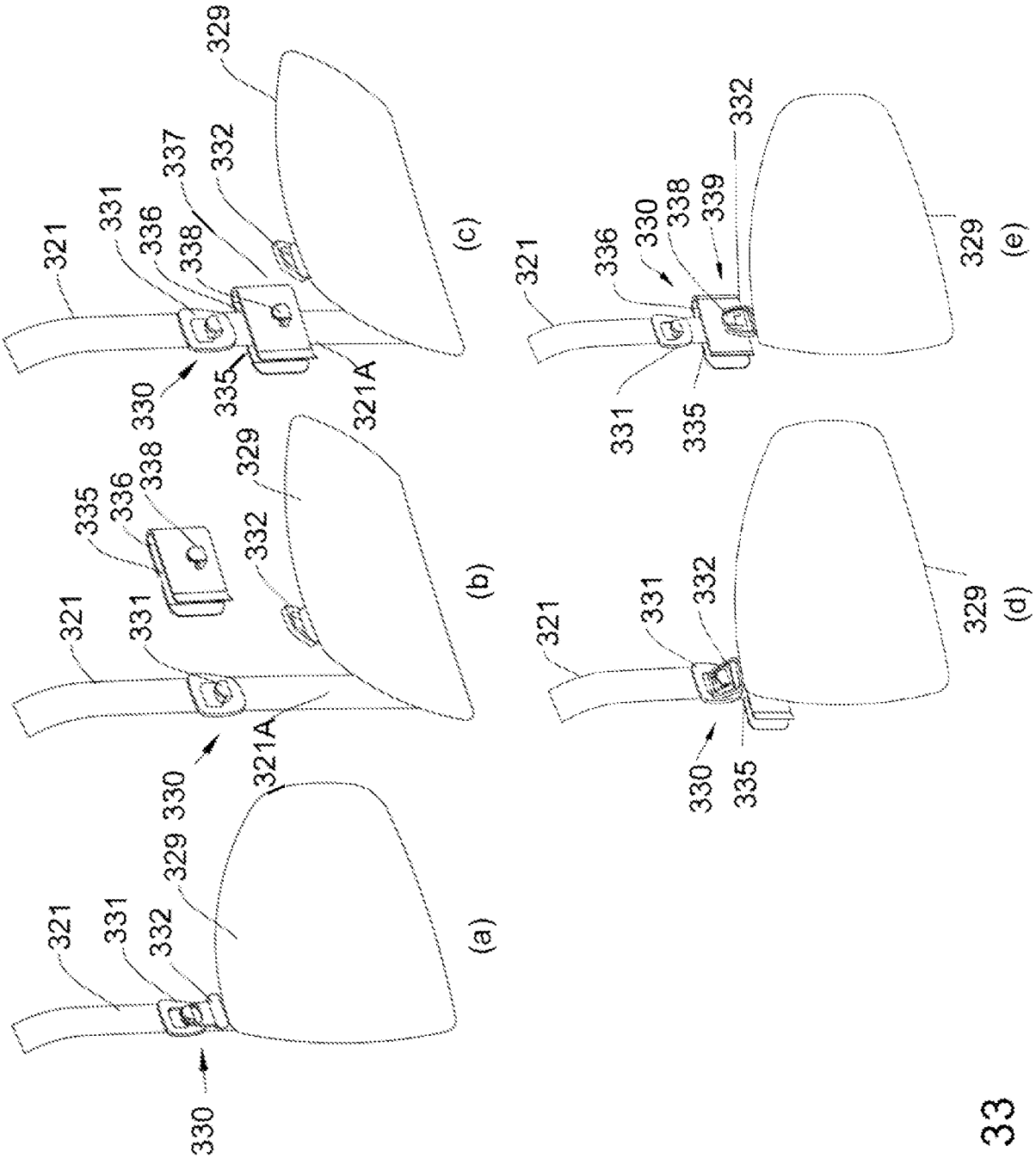

FIGURE 33

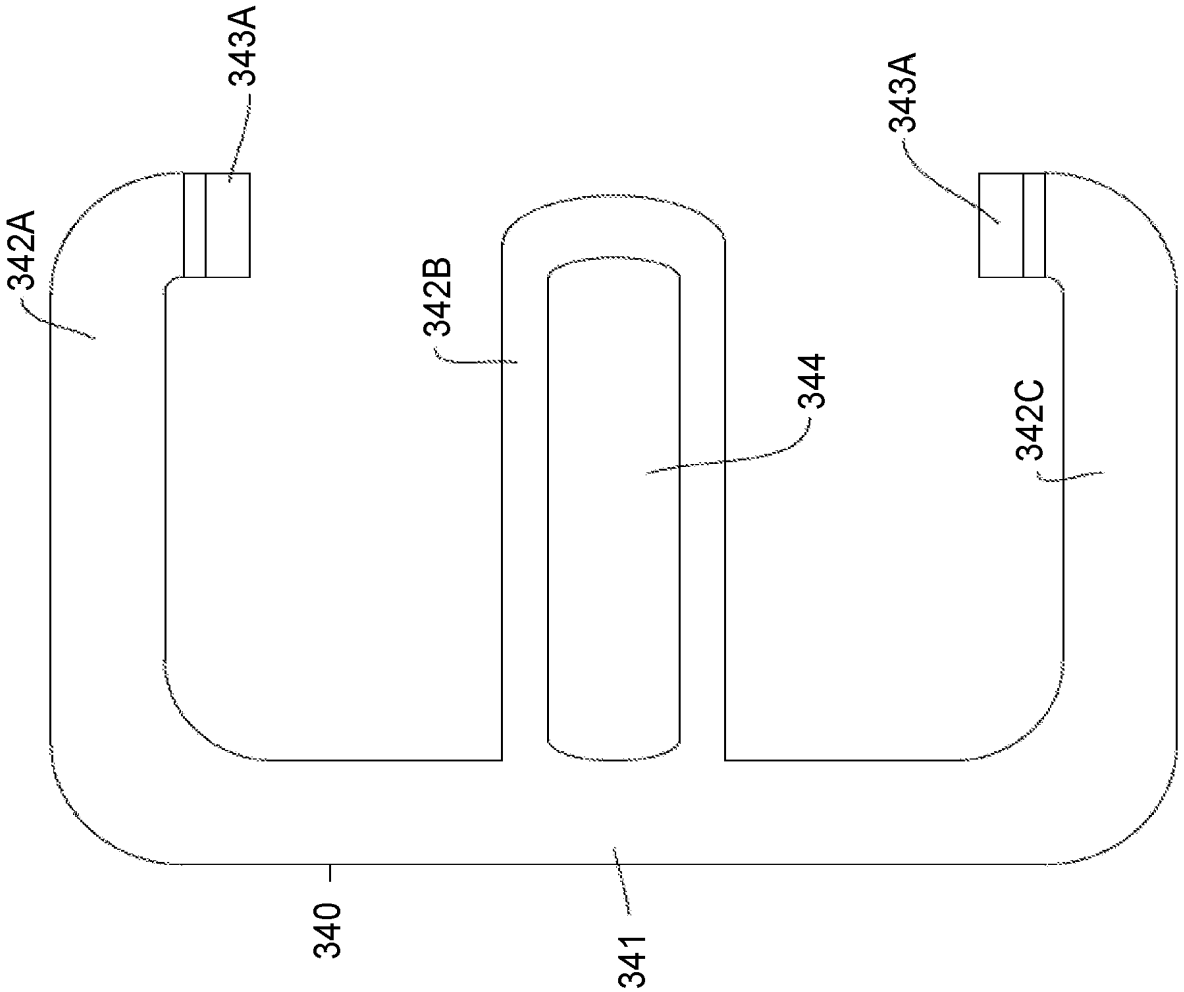

FIGURE 34

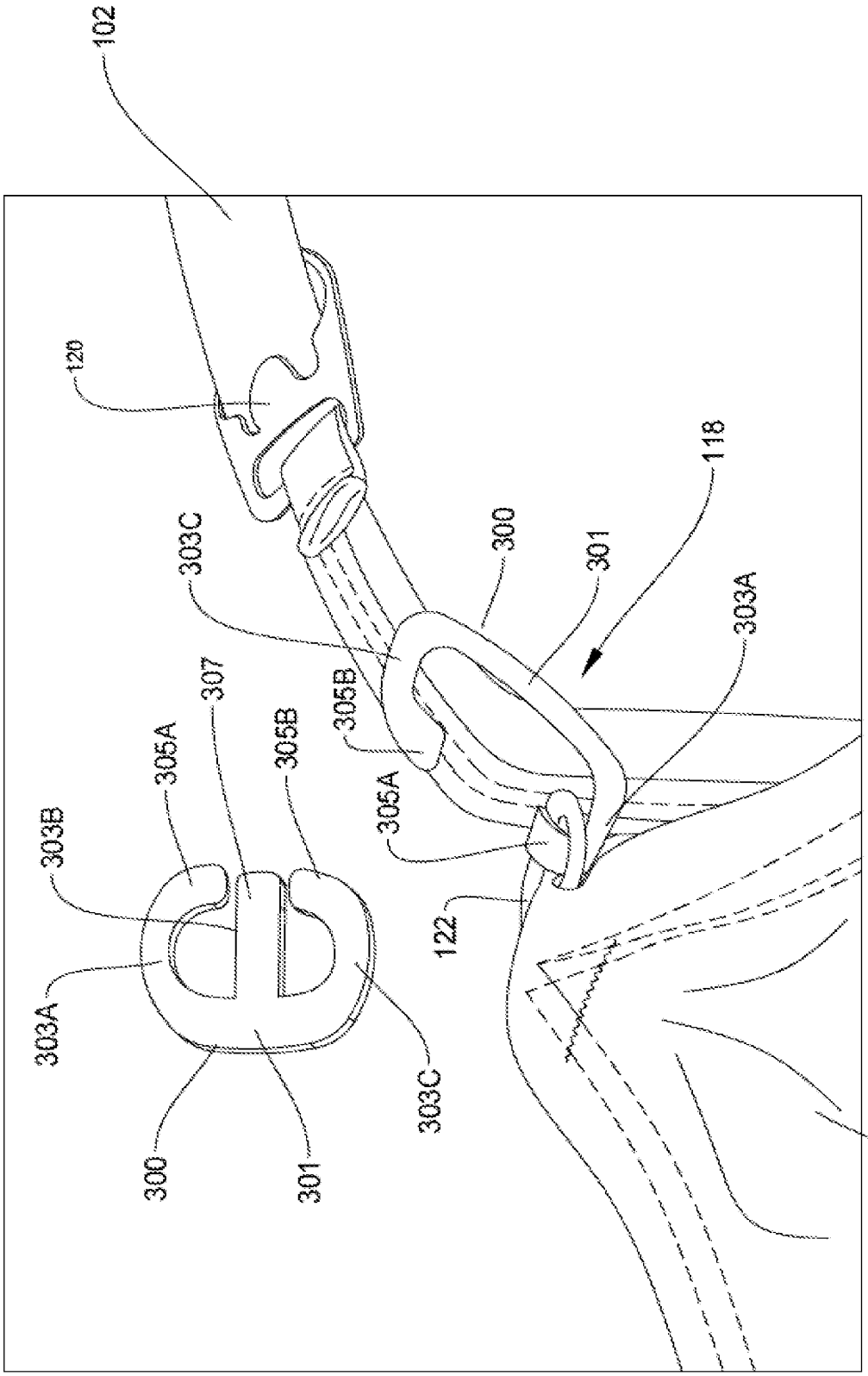
102
120
118
300
301
303C
303A
305B
307
305A
305B
305A
303B
122
303A
303C
300
301
116

FIGURE 35

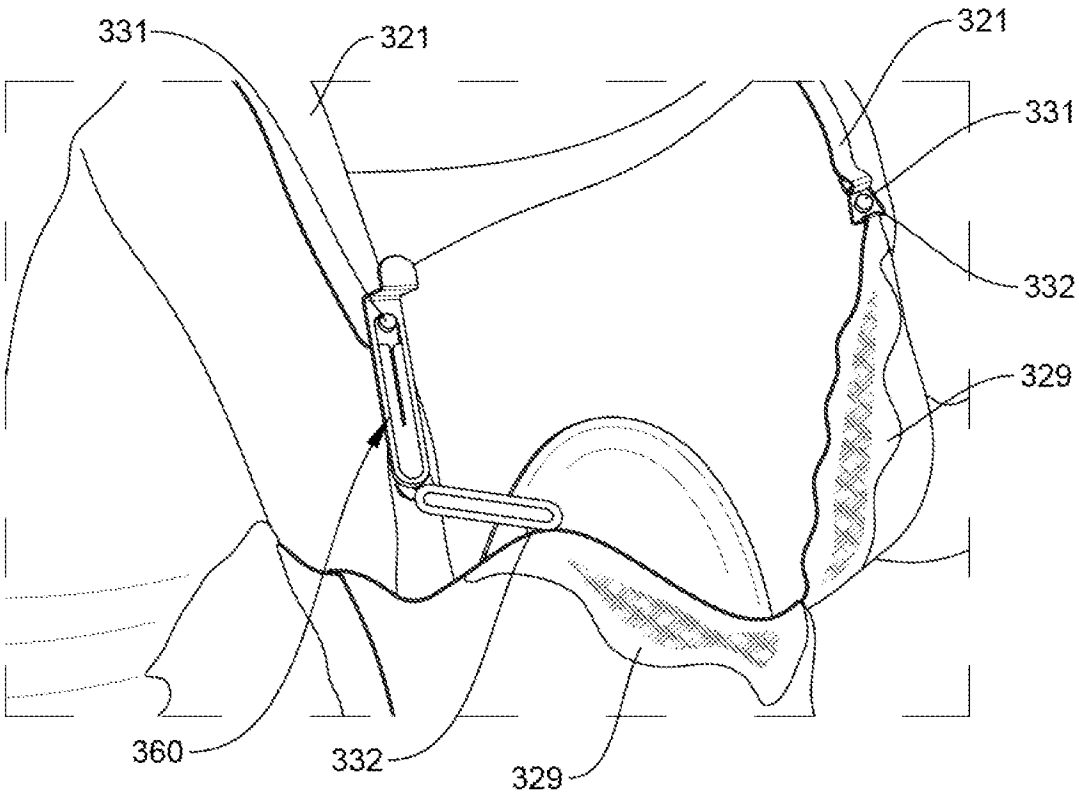

FIGURE 36

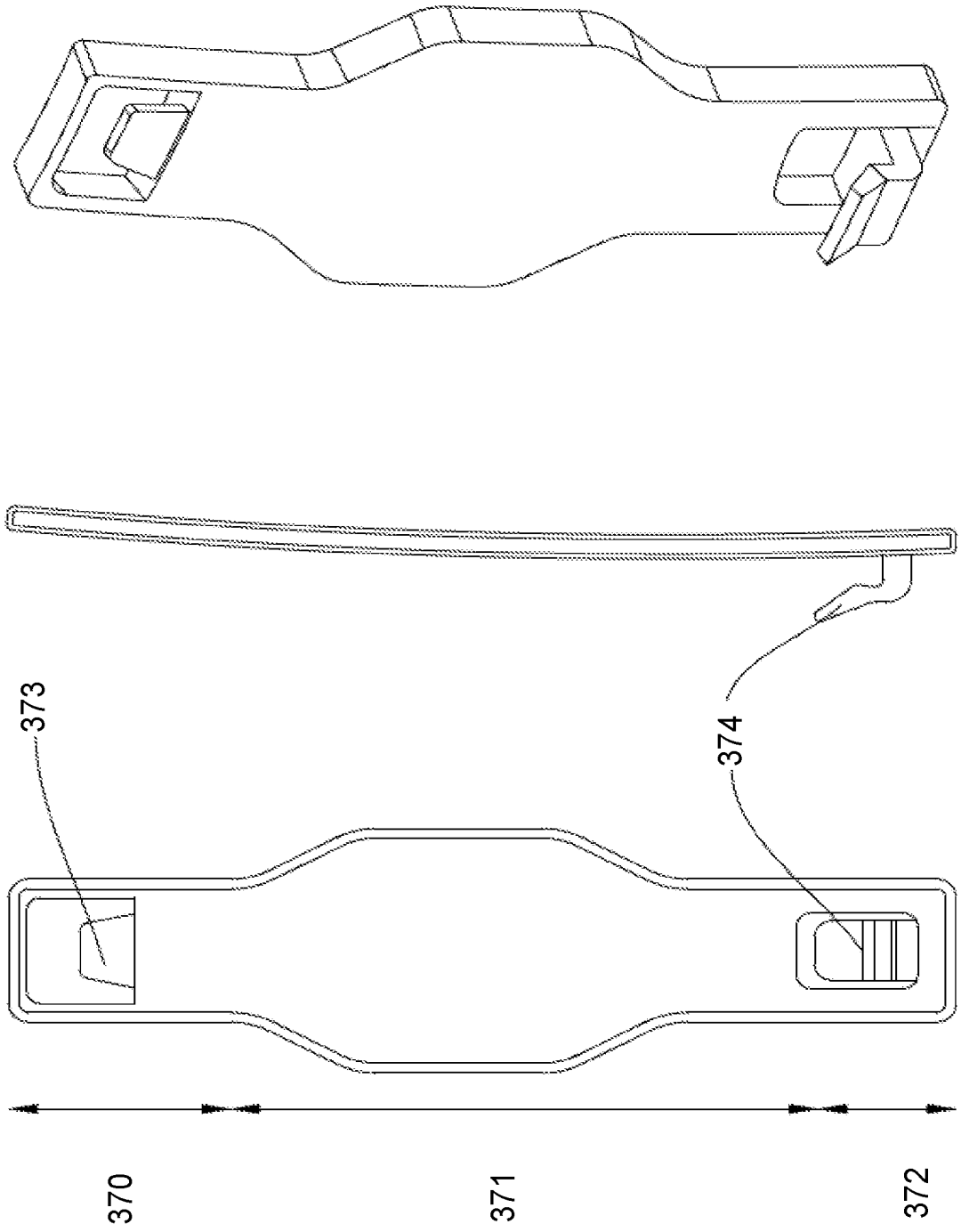

FIGURE 37

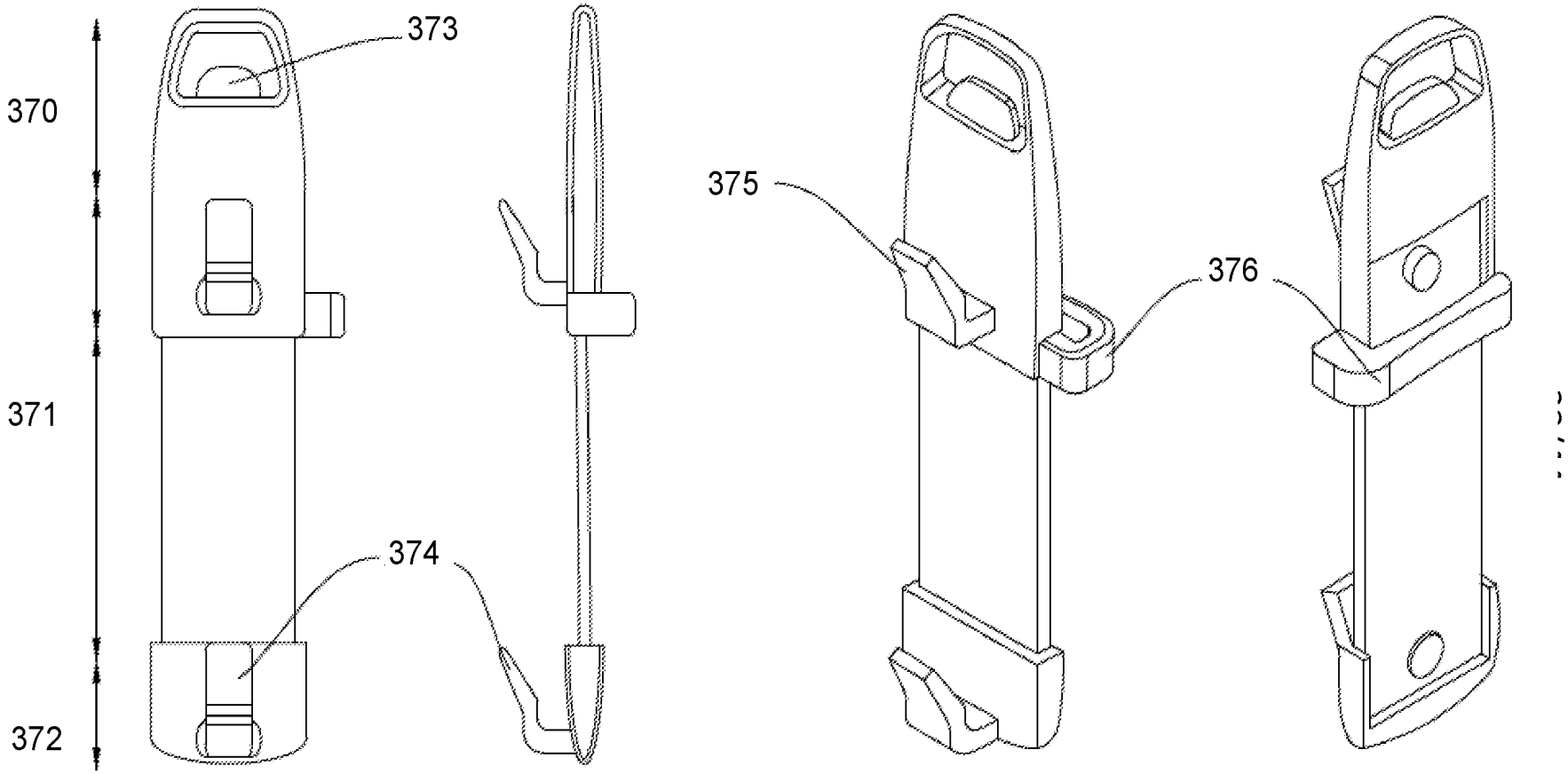

FIGURE 38

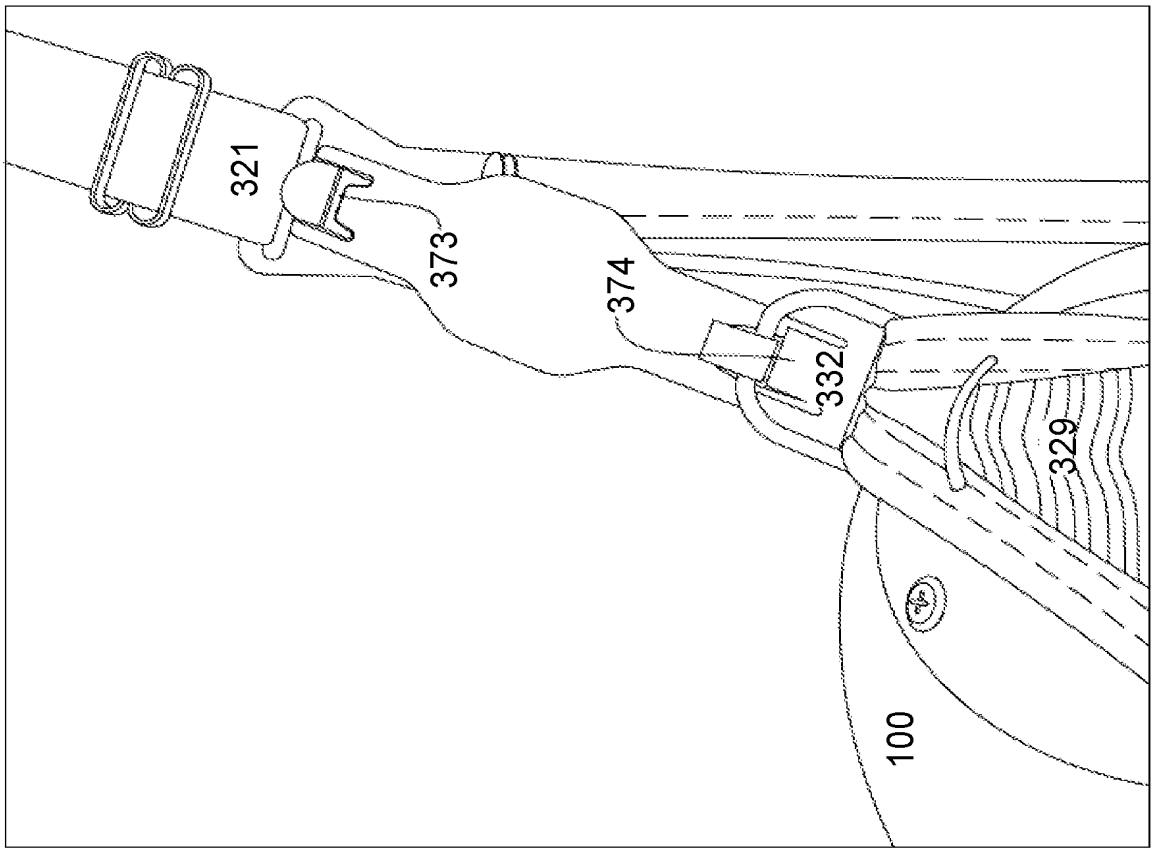

FIGURE 39

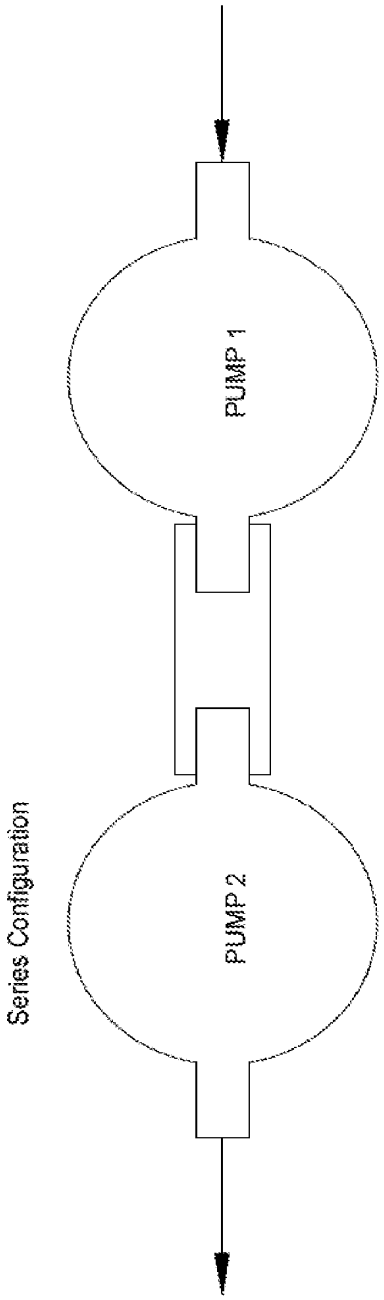

FIGURE 40

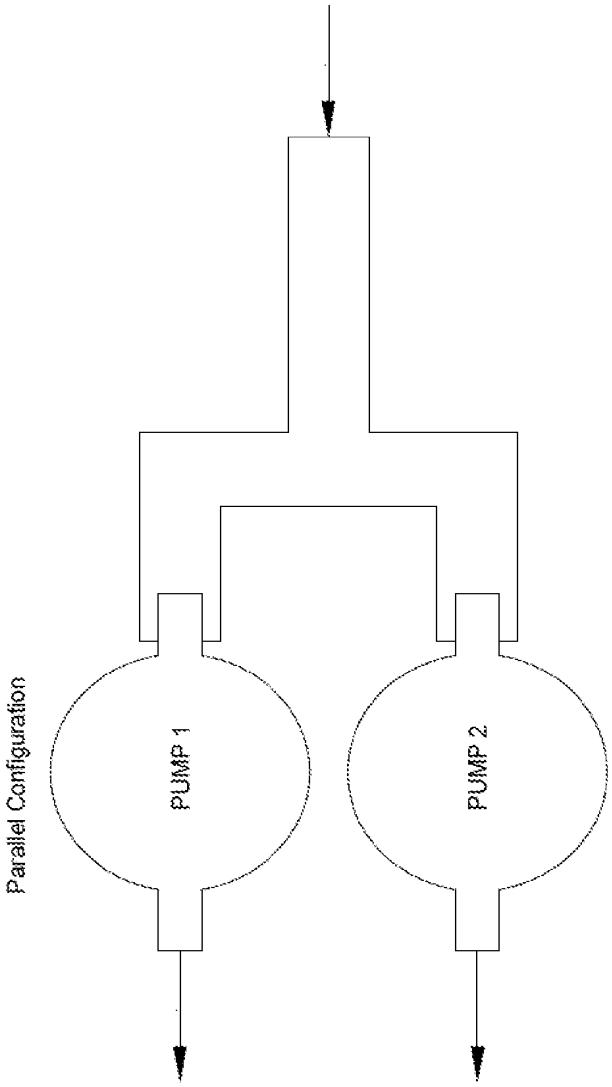

FIGURE 41

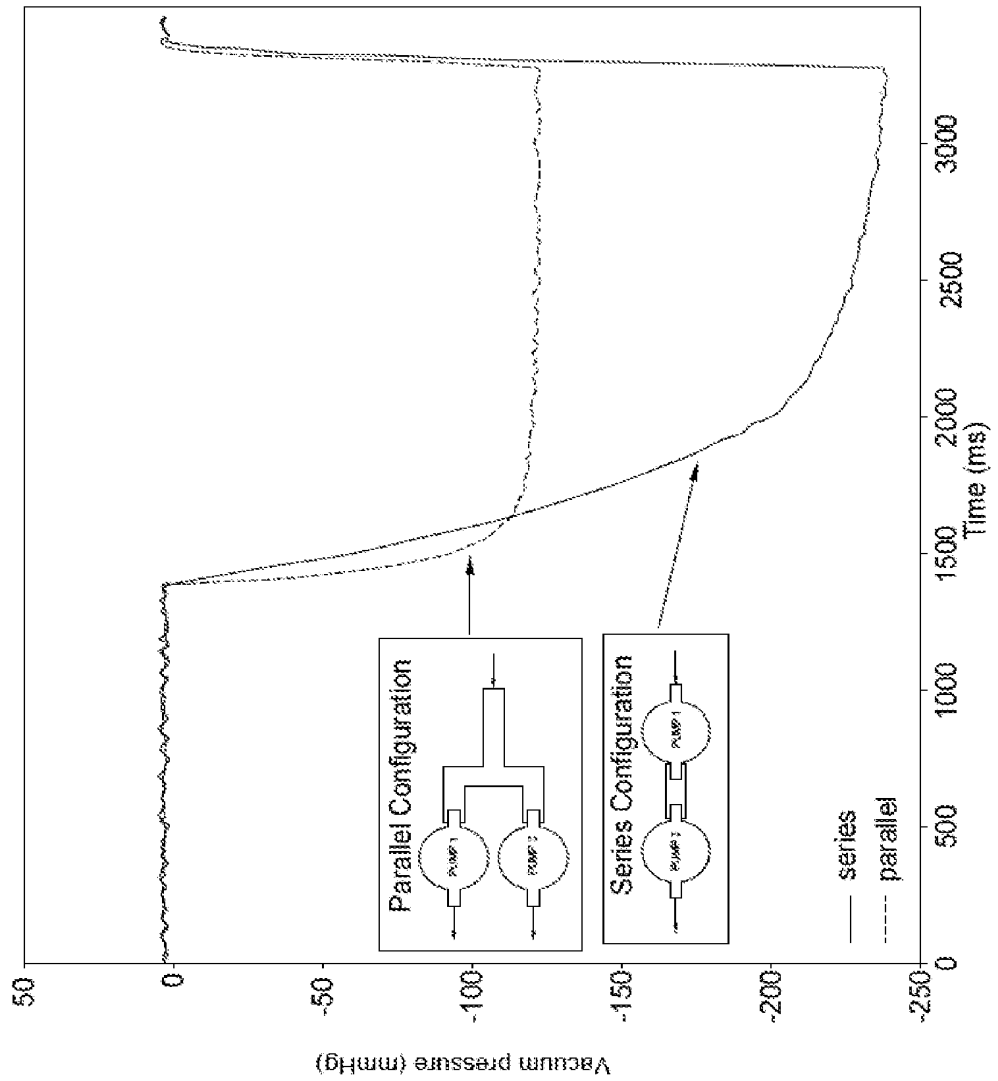
Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
series
parallel
Parallel Configuration
Series Configuration

FIGURE 42

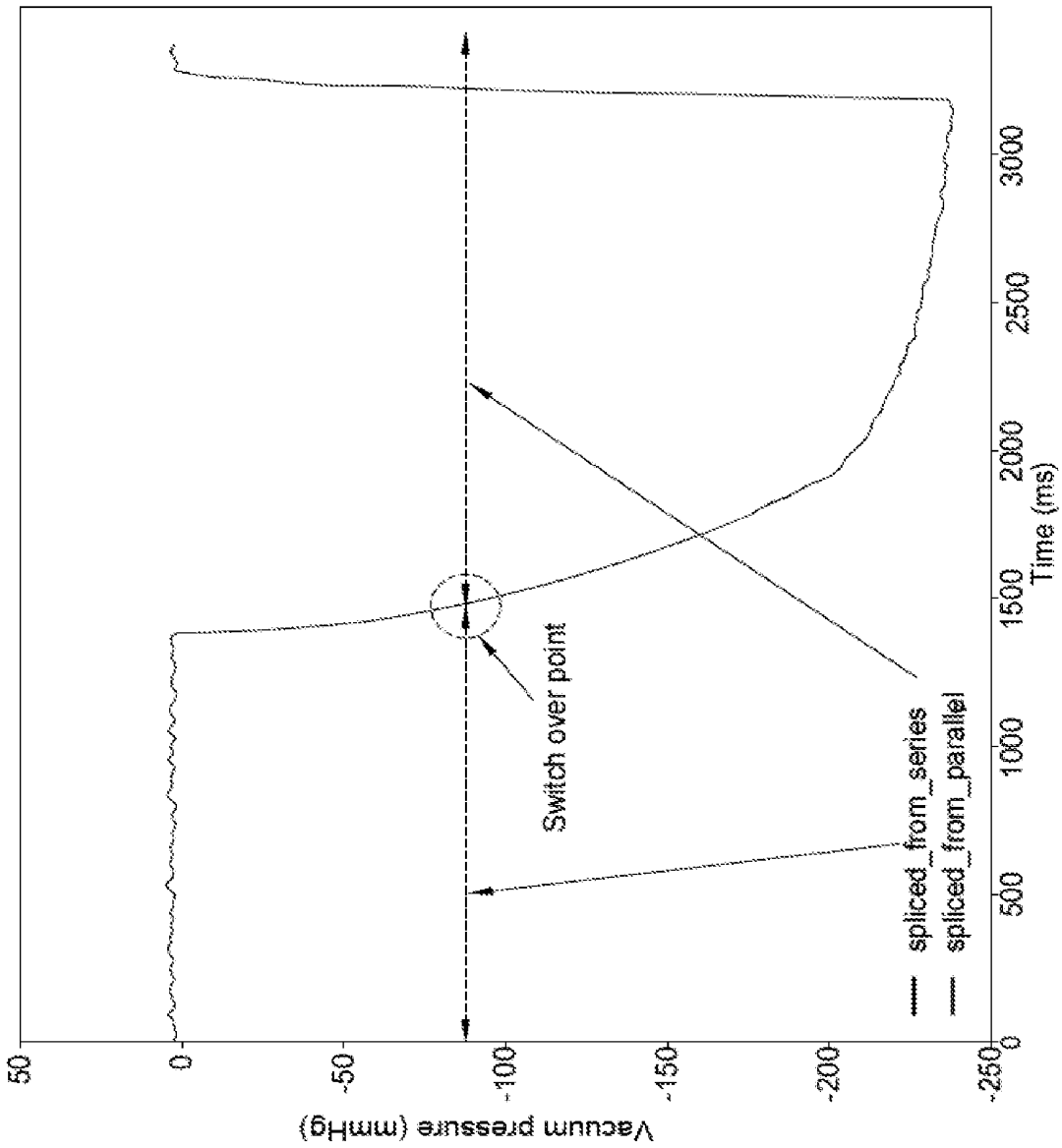
Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
Switch over point
spliced_from_series
spliced_from_parallel

FIGURE 43

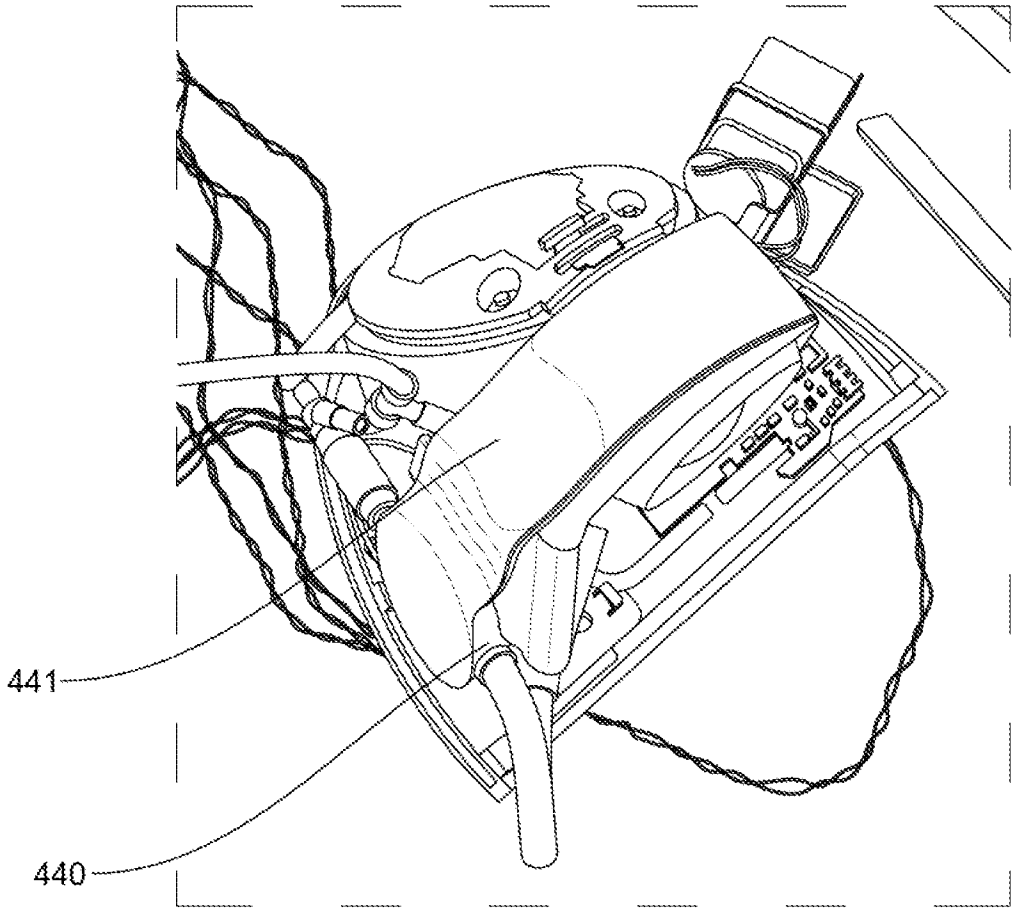

FIGURE 44

SCORE Placeholder Sheet for IFW Content

Application Number: 17181057 Document Date: 02/22/2021

The presence of this form in the IFW record indicates that the following document type was received in electronic format on the date identified above. This content is stored in the SCORE database.

Since this was an electronic submission, there is no physical artifact folder, no artifact folder is recorded in PALM, and no paper documents or physical media exist. The TIFF images in the IFW record were created from the original documents that are stored in SCORE.

- Drawing

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Form Revision Date: March 1, 2019