that are between 9 and 19 cm in length (e.g., 9 x 9 cm for a 15 x 15 cm dressing, 14 x 14 cm for a 20 x 20 cm dressing, or 19 x 19 cm for a 25 x 25 cm dressing).

[0139] The dressing can contain anti-microbial e.g. nanocrystalline silver agents on the wound contact layer and/or silver sulphur diazine in the absorbent layer. These may be used separately or together. These respectively kill micro-organisms in the wound and micro-organisms in the absorption matrix. As a still further option other active components, for example, pain suppressants, such as ibuprofen, may be included. Also agents which enhance cell activity, such as growth factors or that inhibit enzymes, such as matrix metalloproteinase inhibitors, such as tissue inhibitors of metalloproteinase (TIMPS) or zinc chelators could be utilized. As a still further option odor trapping elements such as activated carbon, cyclodextrine, zeolite or the like may be included in the absorbent layer or as a still further layer above the filter layer.

[0140] Whilst some embodiments of the present invention have so far been described in which the transmission layer is formed as a 3D knit layer, e.g., two layers spaced apart by a monofilament layer, it will be appreciated that some embodiments of the present invention are not restricted to the use of such a material. In some embodiments, as an alternative to such a 3D knit material, one or more layers of a wide variety of materials could be utilized. In each case, according to embodiments of the present invention, the openings presented by layers of the transmission layer are wider and wider as one moves away from the side of the dressing which, in use will be located proximate to the wound. In some embodiments, the transmission layer may be provided by multiple layers of open celled foam. In some embodiments, the foam is reticulated open cell foam. The foam can be hydrophilic or able to wick aqueous based fluids. The pore size in each layer is selected so that in the foam layer most proximate to the wound side in use the pores have a smallest size. If only one further foam layer is utilized that includes pore sizes which are greater than the pore sizes of the first layer. This helps avoid solid particulate being trapped in the lower layer which thus helps maintain the lower layer in an open configuration in which it is thus able to transmit air throughout the dressing. In some embodiments, two, three, four or more foam layers may be included. The foam layers may be integrally formed, for example, by selecting a foam having a large pore size and then repeatedly dipping this to a lesser and lesser extent into material which will clog the pores or alternatively, the transmission layer formed by the

multiple foam layers may be provided by laminating different types of foam in a layered arrangement or by securing such layers of foam in place in a known manner.

[0141] Figures 7A-7D illustrate the use of an embodiment of a TNP wound treatment system being used to treat a wound site on a patient. Figure 7A shows a wound site W being cleaned and prepared for treatment. Here, the healthy skin surrounding the wound site W is preferably cleaned and excess hair removed or shaved. The wound site W may also be irrigated with sterile saline solution if necessary. Optionally, a skin protectant may be applied to the skin surrounding the wound site W. If necessary, a wound packing material, such as foam or gauze, may be placed in the wound site W. This may be preferable if the wound site W is a deeper wound.

[0142] After the skin surrounding the wound site W has been prepared, the cover 151 can be removed from the first packaging element 150 to provide access to the components. The dressing 102 can be removed from the packaging 150 and, as illustrated in Figure 7B, be positioned and placed over the wound site W. The wound dressing 102 can be placed with the wound contact layer of the dressing 102 over and/or in contact with the wound site W. In some embodiments, an adhesive layer can be provided on a lower surface of the wound contact layer, which may in some cases be protected by an optional release layer to be removed prior to placement of the wound dressing 102 over the wound site W. The dressing 102 can be positioned such that the port 108 is in a raised position with respect to the remainder of the dressing 102 so as to avoid fluid pooling around the port 108. In some embodiments, the dressing 102 is positioned so that the port 108 is not directly overlying the wound, and is level with or at a higher point than the wound. To help ensure adequate sealing for TNP, the edges of the dressing 102 can be smoothed over to avoid creases or folds. The dressing and the adhesive formed thereon can be configured such that the dressing can be lifted away from the skin or wound and repositioned to remove creases and folds, or to simply reposition the dressing over the wound, or for other reasons, without sacrificing the performance of the adhesive. The tubing 106 can be connected to the dressing 102 either before or after placement of the dressing 102 over the wound.

[0143] Thereafter, the pump assembly 104 can be removed from the packaging 150 and connected to the tubing 106, as illustrated in Figure 7C. The batteries 142 can be removed from the packaging 150 and installed in the pump assembly 104 either before or

after the pump is attached to the conduit 106. The pump assembly 104 can be configured to apply negative pressure to the wound site via the dressing 102, and typically through the tubing or conduit 106. In some embodiments, a connector may be used to join the conduit 106 to the dressing 102 and to the pump assembly 104. Upon the application of negative pressure with the pump assembly 104, the dressing 102 may in some embodiments partially collapse and present a wrinkled appearance as a result of the evacuation of some or all of the air underneath the dressing 102. In some embodiments, the pump assembly 104 may be configured to detect if any leaks are present in the dressing 102, such as at the interface between the dressing 102 and the skin surrounding the wound site W. Should a leak be found, such leak is preferably remedied prior to continuing treatment. The leak can be remedied by repositioning the dressing 102, smoothing out wrinkles or folds in the dressing, or by applying fixation strips 148 around the periphery of the dressing 102.

[0144] Turning to Figure 7D, as mentioned, fixation strips 148 can be attached around the peripheral edges of the dressing 102 or otherwise. Such fixation strips 148 can be advantageous in some situations so as to provide additional sealing against the skin of the patient surrounding the wound site W. For example, the sealing or fixation strips 148 can provide additional sealing for when a patient is more mobile. In some cases, the fixation strips 148 may be used prior to activation of the pump assembly 104, particularly if the dressing 102 is placed over a difficult to reach or contoured area. In some embodiments, the dressing kit 100 can be provided with up to five sealing strips.

[0145] Treatment of the wound site W preferably continues until the wound has reached a desired level of healing. In some embodiments, it may be desirable to replace the dressing 102 after a certain time period has elapsed, or if the dressing is full of wound fluids. During such changes, the pump assembly 104 may be kept, with just the dressing 102 being changed.

[0146] Figures 8A – 20H are top isometric, bottom isometric, top plane, bottom plane, front, back, first side, and second side views, respectively, of embodiments of packaging elements that can be used with any of the embodiments of the wound dressing apparatuses disclosed herein, including a variety of differently sized wound dressing apparatuses. Any of the embodiments of the packaging elements illustrated in Figures 8A – 20H or otherwise disclosed in this application can have any of the same features, materials, or

other details of any of the other packaging elements disclosed herein, including first packaging element 150 discussed above.

[0147] The packaging element 300 illustrated in Figures 8A-8H is configured to support a dressing that has an approximate 10 cm x 20 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 310 illustrated in Figures 9A-9H is configured to support a dressing that has an approximate 10 cm x 20 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 320 illustrated in Figures 10A-10H is configured to support a dressing that has an approximate 10 cm x 30 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 330 illustrated in Figures 11A-11H is configured to support a dressing that has an approximate 10 cm x 30 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 300 illustrated in Figures 12A-12H is configured to support a dressing that has an approximate 10 cm x 40 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 350 illustrated in Figures 13A-13H is configured to support a dressing that has an approximate 10 cm x 40 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 360 illustrated in Figures 14A-14H is configured to support a dressing that has an approximate 15 cm x 15 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 365 illustrated in Figures 14I-14P is configured to support a dressing that has an approximate 15 cm x 15 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein.

[0148] The packaging element 370 illustrated in Figures 15A-15H is configured to support a dressing that has an approximate 15 cm x 20 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 380 illustrated in Figures 16A-16H is configured to support a dressing that has an approximate 15 cm x 20 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 390 illustrated in Figures 17A-17H is configured to support a dressing that has an approximate 20 cm x 20 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 395

illustrated in Figures 17I-17P is configured to support a dressing that has an approximate 20 cm x 20 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 400 illustrated in Figures 18A-18H is configured to support a dressing that has an approximate 15 cm x 30 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 405 illustrated in Figures 18I-18P is configured to support a dressing that has an approximate 15 cm x 30 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 410 illustrated in Figures 19A-19H is configured to support a dressing that has an approximate 25 cm x 25 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein. The packaging element 420 illustrated in Figures 20A-20H is configured to support a dressing that has an approximate 25 cm x 25 cm size, and/or one or more of the other components of any TNP therapy kits disclosed herein.

[0149] Figure 21 illustrates a pump assembly 1000 according to some embodiments. Any of the embodiments of the pump assembly 1000 disclosed herein can have any of the same or similar components, features, materials, sizes, configurations, and other details of any other pump assembly embodiments disclosed or incorporated by reference herein, including the embodiment of the pump assembly 104 described above. Preferably, the pump assembly 1000 can be miniaturized and portable, although larger conventional portable or non-portable (e.g., wall suction) pumps can also be used. The pump assembly 1000 can include a switch or a button 1002, illustrated as a play/pause button located on the exterior of the housing of the pump assembly. As is explained below, the button 1002 can be configured to stop, pause, and/or restart therapy. Although illustrated as a press button 1002, other types of switches or buttons can be included, such as a touchpad, touch screen, keyboard, and so on.

[0150] The pump assembly can further include a connector 1050 (for connecting a conduit, e.g., conduit 106), and three LED indicators 1062, 1064, and 1066. As is illustrated, LED indicator 1062 (e.g., OK indicator) can be configured to indicate normal/abnormal operation of the system. For example, an active (e.g., lit) indicator 1062 can represent normal operation. LED indicator 1064 (e.g., dressing indicator) can be configured to indicate a leak in the system. For example, an active (e.g., lit) indicator 1064 can represent a leak. LED

indicator 1066 (e.g., battery indicator) can be configured to indicate the remaining capacity or life of a power source (e.g., batteries). For example, an active (e.g., lit) indicator 1066 can represent a low capacity. In some embodiments, the indicators 1062, 1064, and 1066 can be of a different color, two different colors (e.g., two indicators can share the same color), or same color. Although the pump assembly preferably includes three LED indicators and a push play/pause button, other configurations, locations, and types of indicators, alarms, and switches can alternatively be used. In some embodiments, the pump assembly 1000 can include visual, audible, tactile, and other types of indicators or alarms configured to signal to the user various operating conditions. Such conditions include system on/off, standby, pause, normal operation, dressing problem, leak, error, and the like. The indicators can include speakers, displays, light sources, etc., and/or combinations thereof.

[0151] Figure 22 illustrates a cross-sectional view showing the interior of the pump assembly 1000 according to some embodiments. As is illustrated, a housing 1020 can enclose the pump assembly. A one-way flow valve 1030 can be configured to maintain a level of negative pressure when the source of negative pressure is not active (e.g., prevent leaks) and prevent fluids and/or exudate aspirated or removed from the wound from entering the pump assembly via the connector 1050. A control board 1040, such as a printed circuit board assembly (PCBA), can be configured to mechanically support and electrically connect various electrical/electronic components, which are described below. The PCBA can be single-sided or double-sided. A negative pressure source 1090, such as pump, can aspirate fluid and/or exudate from a wound. In any of the embodiments disclosed herein, the negative pressure source 1090 can have any of the same components, features, limitations, or other details of any of other negative pressure source embodiment disclosed herein, including without limitation the pump 232 disclosed above. Various pumps can be used for the negative pressure source, including peristaltic pumps, piston pumps, rotary vane pumps, liquid ring pumps, scroll pumps, diaphragm pumps, piezoelectric pumps (e.g., a diaphragm pump operated by a piezoelectric transducer), etc, or combinations thereof. Although the pump assembly preferably includes a miniature, low noise, low power pump, any suitable pump can alternatively be used. The pump assembly 1000 includes indicators 1060 (e.g., LEDs), a pressure sensor 1070 for monitoring pressure in the system, such as pressure under the dressing, and a battery cover 1080 configured to provide access to a battery compartment

1100. Although the pump assembly is preferably powered by two standard, disposable alkaline batteries (e.g., 2 AA batteries), any type of power source, including rechargeable batteries and external power, can alternatively be used.

[0152] Figure 23 illustrates a system schematic of the pump assembly 1000 according to some embodiments. The pump assembly includes a press button 1002, a control board 1040, and indicators 1060. The pump assembly 1000 can be powered by a battery cell 1130. The pump assembly also includes a pump 1090, such as a diaphragm pump powered by an electric motor 1092, and a pressure sensor 1070. An inlet 1120 can be configured to connect the pump assembly 1000 to a dressing, for example, via a conduit. The inlet 1120 can be connected to a one-way valve 1030, which can be configured to help maintain a level of negative pressure when the source of negative pressure is not active, avoid leaks, and prevent fluids and/or exudate aspirated or removed from the wound from entering the pump assembly 1000. The pump 1090 can also be connected to an outlet 1110. In some embodiments, the outlet 1110 can be configured to vent air to the atmosphere. In some embodiments, a filter (not shown) can be interposed between the outlet and the atmosphere. The filter can be a bacterial filter, odor filter, etc. or any combination thereof.

[0153] Figure 24 illustrates an electrical component schematic of the pump assembly 1000 according to some embodiments. Module 1140, which can be a control board (e.g., PCBA), can include an input/output (I/O) module 1150, controller 1160, and memory 1170. In some embodiments, module 1140 can include additional electric/electronic components, for example, fuse or fuses. The controller 1160 can be a microcontroller, processor, microprocessor, etc. or any combination thereof. For example, the controller 1160 can be of STM8L MCU family type from ST Microelectronics, such as STM8L 151G4U6, or of MC9S08QE4/8 series type from Freescale, such as MC9S08QE4CWJ. Preferably, the controller 1160 is a low power or ultra low power device, but other types of devices can alternatively be used. Memory 1170 can include one or more of volatile and/or nonvolatile memory modules, such as one or more of read-only memory (ROM), write once read many memory (WORM), random access memory (e.g.., SRAM,. DRAM. SDRAM, DDR, etc.), solid-state memory, flash memory, magnetic storage, etc. or any combination thereof. Memory 1170 can be configured to store program code or instructions (executed by the controller), system parameters, operational data, user data, etc. or any combination thereof.

[0154] The I/O module 1150 can be configured to function as an interface between the controller 1160 and other system components that provide and/or are responsive to electromagnetic signals. In other words, the I/O module 1150 can be configured to allow the controller 1160 to monitor the operation of the system and to control other components of the system. In some embodiments, as is illustrated, the I/O module 1150 can be in electromagnetic communication with a button 1002, indicators 1060, pressure sensor 1070, power source 1130, and source of negative pressure 1090. The I/O module can comprise an interface or multiple interfaces configured to communicate with various components. The interface can include standard and/or non-standard ports, such as serial ports, parallel ports, bus interfaces, etc. or any combination thereof.

[0155] In some embodiments, the pump assembly 1000 can be configured to control the operation of system. For example, the pump assembly 1000 can be configured to provide a suitable balance between uninterrupted delivery of therapy and/or avoidance of inconveniencing the user by, for example, frequently or needlessly pausing or suspending therapy and a desire to conserve power, limit noise and vibration generated by the negative pressure source, etc. Figure 25 illustrates a top level state diagram 1200 of operation of the pump assembly according to some embodiments. In some embodiments, the controller 1140 can be configured to implement the flow of the state diagram 1200. As is illustrated in Figure 25, the operation of the pump assembly can, in some embodiments, be grouped into four general state categories: inactive/initialization (states 1206 and 1202), active 1210, operational 1250, and end of life (state 1214). As is illustrated in Figures 25 and 26, state categories 1210 and 1250 each comprises multiple states and transitions between states.

[0156] In some embodiments, so long as the power source is not connected, removed (as is illustrated by the transition 1204), or the pump assembly has not been activated (e.g., by pulling an activation strip, triggering the switch, or the like), the pump assembly remains in state 1206. While remaining in this state, the pump assembly can remain inactive. When the power source is connected and/or the pump assembly has been activated for a first time, the pump assembly transitions to state 1202, where power on self test(s) (POST) can be performed. Power on self test(s) can include performing various checks to ensure proper functionality of the system, such as testing the memory 1170 (e.g., performing a check, such as a cyclic redundancy check, of the program code to determine its

integrity, testing the random access memory, etc.), reading the pressure sensor 1070 to determine whether the pressure values are within suitable limits, reading the remaining capacity or life of the power source (e.g., battery voltage, current, etc.) to determine whether it is within suitable limits, testing the negative pressure source, and the like. As is illustrated, indicators 1060 (e.g., LEDs) can be configured to indicate to the user (e.g., by blinking or flashing once) that the pump assembly is undergoing POST test(s).

[0157] In some embodiments, if one or more of POST test(s) fail, the pump assembly can transition to non-recoverable error state 1214. While in this state, the pump assembly can deactivate therapy, and the indicators 1060 can be configured and indicate to the user that an error was encountered. In some embodiments, all indicators can be configured to remain active. Based on the severity of error, in some embodiments, the pump assembly can be configured to recover from the error and continue operation (or transition to the non-recoverable error state 1214). As is illustrated, the pump assembly can transition to state 1214 upon encountering a fatal error during operation. Fatal errors can include program memory errors, program code errors (e.g., encountering an invalid variable value), controller operation errors (e.g., watchdog timer expires without being reset by the controller 1160), component failure (e.g., inoperative negative pressure source, inoperative pressure sensor 1070, etc.), and any combination thereof.

[0158] When POST test(s) pass, in some embodiments, the pump assembly can transition to a manually paused state 1216. As is illustrated, this transition can be indicated to the user by deactivating one of indicators 1060 (e.g., battery indicator 1066). When the pump assembly transitions into and remains in the manually paused state 1216, the user can be provided an indication, such as by deactivating indicators 1062 (OK indicator) and 1064 (dressing indicator). In some embodiments, therapy can be suspended while the pump assembly remains in the manually paused state 1216. For example, the source of negative pressure (e.g., pump 1090) can be deactivated (or turned off). In some embodiments, indication can be provided by deactivating the source of negative pressure.

[0159] In some embodiments, the pump assembly can be configured to make a transition 1224 from the manually paused state 1216 to the operational state category 1250 (where the pump assembly is configured to deliver therapy) in response to receiving a signal from the switch. For example, the user can press a button to start, suspend, and/or restart

therapy. In some embodiments, the pump assembly can be configured to monitor the duration of time the pump assembly remains in the manually paused state 1216. This can be accomplished, for example, by maintaining a timer (in firmware, software, hardware or any combination thereof), which can be reset and started when the pump assembly transitions into the manually paused state 1216. The pump assembly can be configured to automatically make the transition 1224 from the manually paused state 1216 to the operational state category 1250 when the time duration exceeds a threshold. In some embodiments, such threshold can be a preset value, such as between 1 minute or less and 1 hour or more. In some embodiments, the threshold can be set or changed by the user. In some embodiments, the threshold can be varied based on various operating conditions or on any combination thereof. For example, as the pump assembly nears the end of life (as is explained below), the threshold can be decreased. In some embodiments, the user can pause therapy by activating the switch (e.g., pressing the button), thereby causing the pump assembly to make a transition 1222 from the operational state category 1250 to the manually paused state 1216. In some embodiments, the pump assembly can be configured so that the user can only pause therapy, whereas disconnecting the power source (e.g., removing batteries) stops therapy.

[0160] In some embodiments, the pump assembly can be configured to include a paused state 1218. When the pump assembly transitions into and remains in the paused state 1218, the user can be provided an indication. For example, the pump assembly can be configured to deactivate the OK indicator 1062 and cause the dressing indicator 1064 to flash or blink. In some embodiments, therapy can be suspended while the pump assembly remains in the manually paused state 1216. For example, the source of negative pressure (e.g., pump 1090) can be deactivated (or turned off), which provides the indication to the user that the pump assembly is in the paused state 1218. As is explained below, in some embodiments, the pump assembly can be configured to transition from the operational state category 1250 into the paused state 1218 when a number of retry cycles exceeds a retry limit (transition 1228) or when duty cycle is determined to exceed a duty cycle limit (transition 1230). In some embodiments, transitions 1228 and 1230 can reflect the presence of a leak in the system.

[0161] In some embodiments, the pump assembly can be configured to make a transition 1226 from the paused state 1218 to the operational state category 1250 (where the

pump assembly is configured to activate the pump to deliver therapy) in response to receiving a signal from the switch (e.g., the user pressing a button to restart therapy). In some embodiments, the pump assembly can be configured to monitor the duration of time the pump assembly remains in the paused state 1218. For example, this can be accomplished by maintaining a timer (in firmware, software, hardware or any combination thereof), which can be reset and started when the pump assembly transitions into the paused state 1218. The pump assembly can be configured to automatically make the transition 1226 from the paused state 1218 to the operational state category 1250 when the time duration exceeds a threshold. The threshold can be the same or different than the threshold of the manually paused state 1216 described above. In some embodiments, the threshold can be a preset value, such as between 1 minute or less and 1 hour or more. In some embodiments, the threshold can be set or changed by the user. In some embodiments, the threshold can be varied based on various operating conditions or on any combination thereof. For example, as the pump assembly nears the end of life (as is explained below), the threshold can be decreased.

[0162] In some embodiments, the pump assembly includes both the manually paused state 1216 and the paused state 1218 in order to differentiate between various causes for pausing therapy. Such ability to differentiate can allow the pump assembly to provide the user with an indication of a particular cause for pausing therapy (e.g., manually paused state 1216 and paused state 1218 can provide different indications). For example, therapy can be paused due to the user manually pressing the button, in which case the pump assembly can make the transition 1222 from the operational state category 1250 to the manually paused state 1216. As another example, therapy can be paused due to detecting a leak, in which case the pump assembly can make the transition 1228 and/or 1230 from the operational state category 1250 to the paused state 1218. In some embodiments, the pump assembly can be configured to include one state indicating a suspension or pause in the delivery of therapy or more than two such states.

[0163] In some embodiments, the pump assembly can be configured to monitor the remaining capacity or life of the power source (e.g., by periodically reading or sampling the battery voltage, current, etc.). The pump assembly can be configured to indicate to the user the remaining capacity. For example, if the power source is determined to have a normal remaining capacity (e.g., as a result of comparison to a threshold, such as 2.7V, 2.6V, 2.5V,

etc.), the battery indicator 1066 can be deactivated. If the power source is determined to have low remaining capacity, the pump assembly can be configured to provide an indication to the user by, for example, causing the battery indicator 1066 to blink or flash, as is illustrated by the transition 1220. In some embodiments, the battery indicator 1066 can be configured to be blinking or flashing intermittently or continuously regardless of the state the pump assembly is in or only in particular states.

[0164] In some embodiments, when the remaining capacity of the power source is determined to be at or near a critical level (e.g., as a result of comparison to a threshold, such as 2.4V, 2.3V, 2.2V, etc.), the pump assembly can be configured to transition into a battery critical state 1212. In some embodiments, the pump assembly can be configured to remain in this state until the capacity of the power source is increased, such as by replacing or recharging the power source. The pump assembly can be configured to deactivate therapy while remaining in the battery critical state 1212. In addition, as is illustrated, the pump assembly can be configured to indicate to the user that the power source is at or near the critical level by, for example, deactivating all indicators.

[0165] In some embodiments, the pump assembly can be configured to provide therapy for a predetermined period of time, such as approximately 1 day, 2-10 days, etc. following a first activation. In some embodiments, such period of time can be a preset value, changed by the user, and/or varied based on various operating conditions or on any combination thereof. The pump assembly can be disposed upon the expiration of such period of time. In some embodiments, the first activation can be reflected by a transition into the active state category 1210, by pulling the activation strip (e.g., transition into state 1202), etc. Once the pump assembly has been activated, the pump assembly can be configured to monitor the duration it has remained active. In some embodiments, the pump assembly can be configured to monitor the cumulative duration of remaining in the active state category 1210. This can be accomplished, for example, by maintaining a timer (in firmware, software, hardware or any combination thereof), that reflects such duration.

[0166] When the duration reaches or exceeds a threshold (e.g., 7 days), the pump assembly can be configured to transition to an end of life (EOL) state 1240. The pump assembly can be configured to deactivate therapy while remaining in state 1240 and to indicate to the user that end of pump assembly' usable life has been reached. For example,

the pump assembly can be configured to deactivate all indicators and/or deactivate the button. In some embodiments, when the pump assembly is disposable, transitioning to the end of life state 1240 means that the pump assembly can be disposed of. The pump assembly can be configured to disable reactivation of the pump assembly once the end of life has been reached. For example, the pump assembly can be configured to not allow reactivation even if the power source is disconnected and reconnected later, which can be accomplished by storing an indication, value, flag, etc. in the read only memory.

[0167] Figure 26 illustrates the operational flow in state category 1250 of the pump assembly 1000 according to some embodiments. The pump assembly can be configured to deliver therapy, monitor leaks in the system, provide indication(s) to the user, and the like. As is explained below, in some embodiments, the pump assembly can be configured to deliver therapy by initially attempting to establish a first desired negative pressure level (e.g., negative pressure between -5 mmHg or less and -200 mmHg or more, such as -100 mmHg) under the dressing 1010. In some embodiments, the first desired negative pressure level can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. Once the first desired negative pressure level is established under the dressing 1010, the pump assembly can be configured to deactivate the source of negative pressure (e.g., pump). When negative pressure under the dressing 1010 decreases (i.e., gravitates toward standard atmospheric pressure) due to leaks in the system, the pump assembly can be configured to restore negative pressure under the dressing by activating the pump to establish a second desired negative pressure level under the dressing (e.g., negative pressure between -5 mmHg or less and -200 mmHg or more, such as -100 mmHg). In some embodiments, the second desired negative pressure level can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. In some embodiments, the first and second desired negative pressure levels can be the same. In some embodiments, the first and second desired negative pressure levels can be different, that is, the second negative pressure level can be less than the first negative pressure level or vice versa.

[0168] In some embodiments, the pump assembly can transition from the manually paused state 1216 and/or paused state 1218 to state 1252. As is explained above, this transition can be caused by the user pressing the button to start/restart therapy and/or

upon expiration of duration of time, such as 1 hour. The pump assembly can be configured to immediately transition to an initial pump down (IPD) state 1260, where the pump can be activated to establish the first desired negative pressure level under the dressing 1010. In some embodiments, the pump can be activated if the pressure level under the dressing is above (less than) the first desired negative pressure level. Activating the source of negative pressure to establish the first desired negative pressure level under the dressing 1010 can be referred to herein as the "initial pump down." The pump assembly can be configured to indicate to the user that it is performing the initial pump down by, for example, causing the OK indicator 1062 to blink or flash and deactivating the dressing indicator 1064. In some embodiments, the indication can be provided by, for example, activating the source of negative pressure. The pump assembly can be configured to measure the level of pressure under the dressing 1010 by reading or sampling the sensor 1070.

[0169] In some embodiments, the pump assembly can be configured to monitor the duration of time the pump assembly remains in the IPD state 1260. This can be accomplished, for example, by maintaining a timer (in firmware, software, hardware or any combination thereof), which can be reset and started when the pump assembly transitions into the IPD state 1260. In some embodiments, in order to conserve power, limit the noise and/or vibration generated by the pump, etc., the pump assembly can be configured to suspend the initial pump down operation for a period of time and, later, retry the initial pump down. This functionality can, for example, conserve battery power and allow transient and/or non-transient leaks to become resolved without user intervention or allow the user to fix the leak (e.g., straighten the dressing, fix the seal, check the connection or connections, etc.).

[0170] In some embodiments, when the duration of time for remaining in the IPD state 1260 equals or exceeds a threshold (e.g., 30 seconds), the pump assembly can be configured to make the transition 1264 to state 1266. In some embodiments, the threshold can be a preset value, such as between 5 seconds or lower and 5 minutes or higher. In some embodiments, the threshold can be set or changed by the user. In some embodiments, the threshold can be varied based on various operating conditions or on any combination thereof. In some embodiments, the pump assembly can be configured to deactivate the pump when making the transition 1264. The pump assembly can be configured to monitor a number attempts (e.g., by maintaining a counter which can be reset in state 1252 and updated in wait

state 1270) made to establish the first desired negative pressure under the dressing 1010. In some embodiments, the pump assembly can be configured to provide a limited or maximum number of IPD retry attempts in order, for example, to conserve power. Preferably, the pump assembly can be configured to provide a limited number of consecutive IPD retry attempts, although the pump assembly can be configured to provide a limited number of non-consecutive IPD retry attempts or a mix of consecutive and non-consecutive IPD retry attempts. The threshold for IPD retry attempts can be 1, 2, 3, 4, 5, and so on. In some embodiments, the threshold can be a preset value. In some embodiments, the threshold can be set or changed by the user. In some embodiments, the threshold can be varied based on various operating conditions or on any combination thereof.

[0171] In some embodiments, the pump assembly can be configured to determine in state 1266 whether the number of IPD retry attempts made is equal to or exceeds the threshold (e.g., 1 retry attempt). In case the number of IPD retry attempts made is equal or exceeds the threshold, the pump assembly can be configured to make the transition 1228a to the paused state 1218, where therapy is paused or suspended as is described above. Otherwise, the pump assembly can be configured to make the transition 1268 to the wait state 1270. In some embodiments, the pump assembly can be configured to deactivate the source of negative pressure in state 1266, which can provide an indication to the user that the pump assembly transitioned to state 1266.

[0172] In some embodiments, the pump assembly can be configured to deactivate the pump in the wait state 1270, thereby pausing therapy for a period of time (e.g., between 1 second or less and 1 minute or more, such as 15 seconds). This can be accomplished, for example, by maintaining a timer (in firmware, software, hardware or any combination thereof), which can be reset and started when the pump assembly transitions into the wait state 1270. This period of time in the wait state 1270 can be preset or variable (e.g., automatically or by the user). In some embodiments, the period of time can be varied based on various operating conditions or on any combination thereof. The period of time the pump assembly remains in the wait state 1270 can be decreased or increased (e.g., multiplied by a factor between 0.1 or less and 4.0 or more, such as 2), on each transition into the wait state 1270. The period of time can be decreased or increased on each successive transition into the wait state 1270. The period of time can be decreased or increased until it equals or passes a

threshold (e.g., between 1 second or less and 5 minutes or more, such as 4 minutes). In addition, the period of time can be reset to an initial value upon transition to a monitor pressure state 1280, transition to the manually paused state 1216, transition to the paused state 1218, etc.

[0173] In some embodiments, the pump assembly can be configured to indicate to the user that the pump assembly is in the wait state 1270. For example, the pump assembly can be configured to cause the OK indicator 1062 to flash or blink and deactivate the dressing indicator 1064. In some embodiments, deactivating the pump can provide indication that the pump assembly is in the wait state 1270. Upon expiration of the period of time in the wait state, the pump assembly can be configured to make the transition 1272 from the wait state 1270 to the IPD state 1260, where the pump assembly can attempt to establish the first desired negative pressure level under the dressing 1010. In some embodiments, the pump assembly can be configured to ensure that the negative pressure level under the dressing remains above a certain safety level. For example, the pump assembly can be configured to maintain the negative pressure level under the dressing 1010 above a safety level between -150 mmHg or less and -250 mmHg or more, such as -225 mmHg.

[0174] In some embodiments, when the first desired negative pressure level under the dressing 1010 has been established, the pump assembly can be configured to make the transition 1276 to a monitor state 1280. The pump assembly can be configured to reset the number of IPD retry attempts when making the transition 1276. The pump assembly can be configured to indicate the transition to the monitor state 1280 to the user by, for example, causing the OK indicator 1062 to blink or flash and deactivating the dressing indicator 1064. While remaining in the monitor state 1280, the pump assembly can be configured to deactivate the pump (which can provide an indication to the user that the pump assembly is in the monitor state 1280) and periodically or continuously monitor the level of pressure under the dressing 1010. The pump assembly can be configured to measure the level of pressure under the dressing 1010 by reading or sampling the sensor 1070.

[0175] In some embodiments, the pump assembly can be configured to determine whether, for example, due to leaks in the system, the level of negative pressure under the dressing 1010 decreases to reach and/or pass (e.g., become less than) a threshold. The threshold can be selected from the range between -10 mmHg or less and -100 mmHg or

more, such as -60 mmHg. In some embodiments, the threshold can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. If the threshold is determined to be reached or passed, the pump assembly can be configured to restore the level of negative pressure under the dressing 1010. In some embodiments, the pump assembly can be configured to reestablish the first desired negative pressure level or establish another, different negative pressure level. This can be accomplished by making the transition 1282 to a maintenance pump down (MPD) state 1290.

[0176] In some embodiments, the pump assembly can be configured to activate the pump to establish the desired level of negative pressure under the dressing 1010 (e.g., the first desired level) while the pump assembly remains in the MPD state 1290. The pump assembly can be configured to provide an indication to the user, for example, by causing the OK indicator 1062 to blink or flash and deactivating the dressing indicator 1064. In some embodiments, the pump assembly activating the source of negative pressure can provide an indication to the user that the pump assembly transitioned to state 1290. In some embodiments, the pump assembly can be configured to generate less noise and vibration when the pump is activated in the MPD state 1290 than when the pump is activated in the IPD state 1264. For example, the difference in the noise level can be between 1 dB or less and 30 dB or more, such as approximately 7 dB, approximately 20 dB, etc. As another example, the difference in the noise level can be between 30 dB or less to 80 dB or more, such as approximately 45 dB, approximately 50 dB, approximately 65 dB, etc.

[0177] In some embodiments, the pump assembly can be configured to monitor the duration of time it remains in the MPD state 1290. This can be accomplished, for example, by maintaining a timer (in firmware, software, hardware or any combination thereof), which can be reset and started when the pump assembly makes the transition 1282 into the MPD state 1290. In some embodiments, in order to conserve power, limit the noise and/or vibration generated by the pump, etc., the pump assembly can be configured to suspend the maintenance pump down operation for a period of time and, later, retry the initial pump down and/or maintenance pump down. This functionality can, for example, conserve battery power and allow transient and/or non-transient leaks to become resolved without user intervention or allow the user to fix the leak (e.g., straighten the dressing, fix the seal, check the connection or connections, etc.).

[0178] In some embodiments, when the duration of time in the MPD state 1290 equals or exceeds a threshold (e.g., a value between 5 seconds or lower and 5 minutes or higher, such as 10 seconds) and the pressure level under the dressing 1010 has not reached the desired negative pressure level, the pump assembly can be configured to make the transition 1292 to state 1294. The threshold can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. In some embodiments, the pump assembly can be configured to deactivate the pump when making the transition 1292, which can provide an indication to the user that the pump assembly is making the transition. The pump assembly can be configured to monitor a number of MPD attempts (e.g., by maintaining a counter which can be reset in the state 1252 and/or when making the transition 1228b and updated when making the transition 1296) made to establish the desired negative pressure under the dressing 1010. In some embodiments, the pump assembly can be configured to provide a limited or maximum number of MPD retry attempts (e.g., to conserve power). Preferably, the pump assembly can be configured to provide a limited number of consecutive MPD retry attempts, although the pump assembly can be configured to provide a limited number of non-consecutive MPD retry attempts or a mix of consecutive and non-consecutive retry attempts. The threshold for MPD retry attempts can be 1, 2, 3, 4, 5, and so on. In some embodiments, the threshold can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. The pump assembly can be configured to set the number of IPD and MPD retry attempts to the same or different value. The pump assembly can be configured to determine in state 1294 whether the number of MPD retry attempts made is equal to or exceeds the threshold (e.g., 3 retry attempts). In case the number of MPD retry attempts made is equal or exceeds the threshold, the pump assembly can be configured to make the transition 1228b to the paused state 1218, where therapy is paused or suspended as is described above. Otherwise, the pump assembly can be configured to make the transition 1296 to the wait state 1270, where therapy is paused or suspended as is described above. Alternatively, the pump assembly can be configured to make the transition to the IPD state 1260 or MPD state 1290.

[0179] In some embodiments, the pump assembly can be configured to make the transition 1284 to the monitor state 1280 if the level of pressure under the dressing reaches or

exceeds (e.g., become greater than) the desired negative pressure level. The pump assembly can also be configured to reset the number of MPD retry attempts when making the transition 1284.

[0180] In some embodiments, the pump assembly can be configured to monitor the duty cycle of the source of negative pressure (e.g., pump). The pump assembly can be configured to monitor the duty cycle periodically and/or continuously. Duty cycle measurements can reflect various operating conditions of the system, such as presence and/or severity of leaks, rate of flow of fluid (e.g., air, liquid and/or solid exudate, etc.) aspirated from wound, and so on. For example, duty cycle measurements can indicate presence of a high leak, and the pump assembly can be configured to indicate this condition and/or temporarily suspend or pause operation of the pump in order to conserve power. This functionality can, for example, conserve battery power and allow transient and/or non-transient leaks to become resolved without user intervention or allow the user to fix the leak (e.g., straighten the dressing, fix the seal, check the connection or connections, etc.).

[0181] In some embodiments, the pump assembly can be configured to periodically monitor the duty cycle, such as once between every 10 seconds or less and 5 minutes or more. In some embodiments, the pump assembly can be configured to monitor the duty cycle once per minute. This can be accomplished by maintaining a timer (in firmware, software, hardware or any combination thereof), which can be set to expire every minute (e.g., as is indicated by an interrupt or via polling) and can be restarted (e.g., by clearing an interrupt). In some embodiments, the time interval for measuring the duty cycle can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. In some embodiments, the pump assembly can be configured to monitor the duty cycle when the pump assembly is in the operational state category 1250 (i.e., any of states 1260, 1266, 1270, 1280, 1290, 1294 and/or any transitions between any of the states), as the pump assembly is configured to activate the pump in this state category. In some embodiments, the pump assembly can be configured to monitor the duty cycle when the pump assembly is in a particular state and/or state transition or subset of states and/or state transitions of the operational state category 1250. In some embodiments, the pump assembly can be configured to monitor the duty cycle when the pump assembly is in a particular state and/or state transition, subset of states and/or state transitions, or all states

and/or state transitions of the active state category 1210 or any combination of any states and/or state transitions disclosed herein. As is illustrated in Figure 26, the pump assembly can make the transition 1302 from any of states 1260, 1266, 1270, 1280, 1290, 1294 and/or transitions between any of the states to state 1300, where the pump assembly determines the duty cycle of the pump during the elapsed minute. The duty cycle can be determined according to the equation:

[0182] DC = t / T, (2)

[0183] where DC is the duty cycle, t is the duration that the source of negative pressure is active, and T is the total time under consideration. In case of monitoring the duty cycle once per minute (i.e., T = 60 seconds), the duty cycle can be expressed (e.g., in percent) as:

[0184] DC = (Pump run time during the elapsed minute / 60) * 100% (3)

[0185] In order to determine the duty cycle, the pump assembly can be configured to monitor the duration of time that the pump has been active (e.g., the pump run time) and/or inactive.

[0186] In some embodiments, the pump assembly can be configured to compare the determined duty cycle to a duty cycle threshold, which can be selected from the range between 1% or less and 50% or more. The comparison can, for example, indicate presence of a leak in the system. In other words, if the pump is remains active over a period of time so that the duty cycle threshold is reached or exceeded, the pump may be working hard to overcome the leak. In such cases, the pump assembly can be configured to suspend or pause the delivery of therapy. The pump assembly can be configured to provide an indication to the user that the pump is working hard (e.g., duty cycle exceeds the duty cycle threshold) by, for example, deactivating the source of negative pressure. In some embodiments, the duty cycle threshold can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. As is illustrated in Figure 26, the pump assembly can be configured to compare the determined duty cycle to the duty cycle threshold (e.g., 9%). The pump assembly can be configured to monitor the number of duty cycles that exceed the threshold by, for example, maintaining and updating an overload counter, which can be reset when the pump assembly transitions from state 1252 to the IPD state 1260.

[0187] In some embodiments, the pump assembly can be configured to update the overload counter in state 1300. If the determined duty cycle does not exceed the duty cycle threshold, the pump assembly can decrement the overload counter. In some embodiments, the minimum value of overload counter can be set to zero, that is the overload counter cannot become negative. Conversely, if the determined duty cycle is equal to or exceeds the duty cycle threshold, the pump assembly can increment the overload counter.

[0188] In some embodiments, the pump assembly can be configured to monitor a total or aggregate number of duty cycles that equal to or exceed the duty cycle threshold. This approach can help to smooth or average the duty cycle variation in order to, for example, prevent one or several erratic cycles that may be caused by a transient leak from interrupting therapy. In some embodiments, the pump assembly can be configured to monitor consecutive or non-consecutive duty cycles exceeding the duty cycle threshold. In some embodiments, the threshold can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. If the number of duty cycles that exceed the duty cycle threshold is determined to exceed an overload threshold (e.g., a number between 1 and 60 or more, such as 30), the pump assembly can be configured to make the transition 1230 to the paused state 1216, where therapy is suspended or paused as is described above. In some embodiments, the pump assembly can be configured to deactivate the source of negative pressure, which can provide an indication to the user that the pump is working hard (e.g., duty cycle exceeds the overload threshold). If the number of duty cycles that exceed the duty cycle threshold is not determined to exceed the overload threshold, the pump assembly can be configured to make the transition 1304 and remain in the operational state category 1250. In some embodiments, the pump assembly can be configured to return to the same state and/or transition between states from which the pump assembly made the transition 1302. In some embodiments, the pump assembly can be configured to transition to a different state and/or transition between states.

[0189] In some embodiments the pump assembly is further configured to suspend or pause therapy if the user presses the button 1002 while the pump assembly is in the operational state category 1250. In some embodiments, the pump assembly can be configured to transition to the manually paused state 1216.

[0190] Figure 27 illustrates another state diagram of operation of the pump assembly 1000 according to some embodiments. In some embodiments, the controller 1140 can be configured to implement the flow of the state diagram 1400. In some embodiments, the flow 1400 can be largely similar to the flow illustrated in Figures 25-26. State 1402 corresponds to state 1202, state 1406 corresponds to state 1260, state category 1410 corresponds to state category 1210, state 1414 corresponds to state 1214, state 1416 corresponds to state 1216, state 1418 corresponds to state 1218, transition 1420 corresponds to transition 1220, transition 1422 corresponds to transition 1222, transition 1424 corresponds to the transition 1224, transition 1426 corresponds to transition 1226, and state 1440 corresponds to state 1240. In addition, state category 1450 corresponds to state category 1250, state 1460 corresponds to state 1260, transition 1464 corresponds to transition 1264, state 1466 corresponds to transition 1266, transition 1468 corresponds to transition 1268, transition 1428a corresponds to transition 1228a, state 1470 corresponds to state 1270, and transition 1472 corresponds to transition 1272. Further, transition 1476 corresponds to transition 1276, state 1480 corresponds to state 1280, transition 1482 corresponds to transition 1282, state 1490 corresponds to state 1290, transition 1492 corresponds to transition 1292, state 1494 corresponds to state 1294, transition 1496 corresponds to transition 1296, and transition 1428b corresponds to transition 1228b.

[0191] In some embodiments, the pump assembly can be configured to monitor the duty cycle after a desired negative pressure level is established under the dressing 1010 in the MPD state 1490. In some embodiments, the pump assembly can also take into account the duration of time that the pump has been active while the pump assembly remains in the IPD state 1460. As is illustrated, the device can be configured to make the transition 1484 from the MPD state 1490. Transition 1484 can be similar to the transition 1284, but instead of transitioning directly to the IPD state 1480, the pump assembly can be configured to monitor the duty cycle in state 1500. In some embodiments, the pump assembly can be configured to monitor the duty cycle during a cumulative period of time that the pump assembly has remained in the monitor state 1480 and MPD state 1490. In some embodiments, the pump assembly can be configured to monitor the duty cycle over the cumulative period of time during the immediately preceding or previous monitor and MPD cycles. For example, immediately before transitioning to state 1500 the pump assembly

could have remained in the MPD state 1490 for time duration X (during which the pump was active). In addition, assuming that immediately before transitioning to the MPD state 1490, the pump assembly remained in the monitor state 1480 for a time duration Y (during which the pump was not active), the duty cycle (DC) can be expressed (e.g., in percent) as:

[0192] $DC = 100\% * [X / (X + Y)]$. (4)

[0193] In order to determine the duty cycle, the pump assembly can be configured to monitor the duration of time that the pump has been active and/or inactive.

[0194] In some embodiments, the pump assembly can be configured to compare the determined duty cycle to a duty cycle threshold (e.g., 9%), as is described above. In some embodiments, the threshold can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. If the duty cycle is determined to be below the threshold, the pump assembly can be configured to make the transition 1502 to the monitor state 1480. Conversely, if the duty cycle is determined to be equal to or exceed the threshold, the pump assembly can be configured to make the transition 1504 to state 1506. In some embodiments, the pump assembly can provide an indication that the duty cycle exceeds the threshold by, for example, deactivating the pump.

[0195] In some embodiments, the pump assembly can be configured to monitor a total or aggregate time over which the duty cycle is equal to or exceeds the threshold. This approach can help to smooth or average the duty cycle variation in order to, for example, prevent one or several erratic cycles that may be caused by a transient leak from interrupting therapy. Monitoring can be accomplished by maintaining a timer (in firmware, software, hardware or any combination thereof), which can be restarted (e.g., on the transition 1476) and updated (e.g., in state 1506). In some embodiments, the pump assembly can be configured to determine whether the duty cycle equals to or exceeds the threshold over a certain aggregate period of time, which can be compared to an aggregate duration threshold. The threshold can be selected from a range between 5 minutes or less and 2 hours or more, such as 30 minutes. In some embodiments, the threshold can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. If the aggregate period of time equals to or exceeds the threshold, the pump assembly can be configured to make the transition 1508 to the paused state 1418, where the pump assembly can be configured to suspend or pause the delivery of therapy. In

some embodiments, the pump assembly can indicate this transition to the user by, for example, deactivating the pump. Conversely, if the aggregate period of time is determined to be less than the threshold, the pump assembly can be configured to make the transition 1510 to the monitor state 1480. The pump assembly can be configured to indicate the transition 1510 to the user by, for example, causing the OK indicator 1062 to blink or flash and deactivating the dressing indicator 1064.

[0196] Figure 28 illustrates a graph 1600 depicting a duty cycle determination for the pump assembly 1000 according to some embodiments. The x-axis represents time and the y-axis represents pressure. In some embodiments, the pump assembly can be configured to establish a negative pressure level of -100 mmHg under the dressing 1010, as is represented by position 1606. For example, this can be performed during the initial pump down in state 1260. The pump assembly can be configured to monitor the level of negative pressure under the dressing 1010. For example, this can be performed in the monitor state 1280. As is illustrated, the pump assembly can monitor pressure over the period of time a, as represented by interval 1602. The level of negative pressure under the dressing 1010 can decay over time (e.g., due to leaks in the system), as is illustrated by line 1620.

[0197] In some embodiments, the pump assembly can be configured to restore or reestablish the negative pressure level under the dressing 1010 when that pressure decays to reach or pass a threshold of approximately -70 mmHg, as is represented by position 1608. In some embodiments, the pump assembly can be configured to activate the pump, as is illustrated by line 1622. For example, this can be performed by transitioning to the maintenance pump down state 1290. As is illustrated, the pump assembly can activate the pump for a time duration b (1604) until the negative pressure level of -100 mmHg is reestablished under the dressing 1010. The pump assembly can be configured to deactivate the pump when the level of pressure under the dressing 1010 reaches -100 mmHg at position 1610. For example, this can be performed by transition to the monitor state 1280. The duty cycle (DC) over the period illustrated in 1600 (i.e., a + b) can be expressed (e.g., in percent) as:

[0198] $DC = 100\% * [b / (a + b)]$. (5)

[0199] Figure 29 illustrates a non-limiting example of a normal (e.g., no leak or low leak) operation 1700 of some embodiments of the pump assembly 1000. The pump

assembly can be configured to establish a desired level of negative pressure under the dressing 1010, as is illustrated in box 1702. The pump assembly can be configured such that, if the level of pressure under the dressing 1010 rises above a desired level (e.g., first set point value, such as –70 mmHg), the source of negative pressure (e.g., a pump) will be activated and will start operating to reduce the level of pressure under the dressing 1010 to the desired value. For example, the desired value can be approximately within the interval between the first and second set point value or approximately the second set point value (e.g., -100 mmHg). In some embodiments, this can be accomplished in the initial pump down state 1260.

[0200] In some embodiments, when the level of pressure under the dressing 1010 reaches the desired value, the pump assembly can be configured to deactivate the pump and monitor the level of pressure under the dressing, as is illustrated in box 1704. For example, this can be accomplished in the monitor state 1280. The pump assembly can be configured to periodically or continuously monitor the level of pressure under the dressing 1010 by, for example, reading or sampling the sensor 1070. Based on the monitored pressure, the pump assembly can determine in box 1706 whether the pump needs to be activated or restarted to reestablish the desired level of negative pressure under the dressing 1010. If the monitored pressure is determined to be low (e.g., less than or less than or equal to the first set point value), the pump assembly can be configured to activate the pump, as is illustrated in box 1708. For example, this can be accomplished by transitioning to the MPD state 1290. Conversely, if the monitored level of pressure is not determined to be low (e.g., greater than or greater than or equal to the first set point value), the pump assembly can be configured to continue monitoring the level of pressure under the dressing 1010. During this operational flow, the pump assembly can be configured to indicate to the user that it is operating normally. As is illustrated in 1060a, the pump assembly can activate or cause to blink or flash the OK indicator 1062, which is depicted as 1062a. In addition, the pump assembly can deactivate the dressing indicator 1064 and the battery indicator 1066, which are depicted as 1064a and 1066a respectively.

[0201] Figure 30 illustrates a non-limiting example of operation 1800 of some embodiments of the pump assembly 1000 in presence of a high leak. As is described above in connection with Figure 29, the pump assembly can be configured to establish a desired

level of negative pressure under the dressing 1010, as is illustrated in box 1802. In some embodiments, when the level of pressure under the dressing 1010 reaches the desired value, the pump assembly can be configured to deactivate the pump and monitor the level of pressure under the dressing, as is illustrated in box 1804. The pump assembly can be configured to periodically or continuously monitor the level of pressure under the dressing 1010 by, for example, reading or sampling the sensor 1070. Based on the monitored level of pressure, the pump assembly can determine whether the pump needs to be activated or restarted to reestablish the desired level of negative pressure under the dressing 1010. If the monitored level of pressure is determined to be low (e.g., less than or less than or equal to the first set point value), the pump assembly can be configured to activate the pump, as is illustrated in box 1808. Once the desired level of pressure has been reestablished under the dressing 1010, the pump assembly can recommence monitoring the level of negative pressure under the dressing (e.g., transition to the monitor state 1280).

[0202] In some embodiments, due to presence of a leak or leaks in the system, the pump assembly 1010 can be configured to carry out multiple cycles of monitoring and reactivating the pump. During this operational flow, the pump assembly can be configured to indicate to the user that the pump assembly is operating normally. As is illustrated in 1060b, the pump assembly can activate or cause to blink or flash the OK indicator 1062, which is depicted as 1062b. In addition, the pump assembly can deactivate the dressing indicator 1064 and the battery indicator 1066, which are depicted as 1064b and 1066b respectively. The pump assembly can be configured to continuously or periodically determine whether the pump is pumping too often, as is illustrated in box 1810. As is illustrated, in some embodiments, the pump assembly can be configured to use the duty cycle as a proxy for determining whether the pump is pumping too often. For example, the pump assembly can be configured to determine whether the pump is "working hard," that is determine whether the pump is on for more than a threshold duration, such as 9% of the total therapy time. In other words, the pump assembly can be configured to determine whether the duty cycle of the pump reaches or exceeds the duty cycle threshold.

[0203] In some embodiments, the pump assembly can be configured to suspend or pause operation of the pump if the pump is determined to be working hard over a duration of time (e.g., the pump is on for more than about 2 hours a day, or is on for more than a

predetermined amount of time), even if the desired level of negative pressure (e.g., second set point value) has been established. As is illustrated in box 1812, the pump assembly can be configured to determine whether the pump is working hard for a duration of 30 minutes or more. For example, the pump assembly can be configured to determine whether duty cycle (or cycles) monitored over the past 30 minutes exceed the duty cycle threshold. For example, the pump assembly can determine whether the pump has been on for about 2 minutes and 42 seconds or longer over the last 30 minutes, which corresponds to 9% duty cycle threshold.

[0204] In some embodiments, the pump assembly can be configured to pause or suspend therapy if the pump is determined to be working hard, as is illustrated in box 1814. The pump assembly can be further configured to turn a "Leak alarm" indicator on. As is illustrated in 1060c, the pump assembly can activate or cause to blink or flash the dressing indicator 1064, which is depicted as 1064b, and deactivate the OK indicator 1062 and the battery indicator 1066, which are depicted as 1062c and 1066c respectively. To restart the therapy, the user may need to straighten the dressing, to fix the leak, and/or to activate the pump once again. In some embodiments, the pump can be activated again by pressing the start or operating button on the pump, because of a timeout, etc.

[0205] In the case of a leak or leaks being present in the dressing, in some embodiments, the pump assembly 1000 can be programmed or otherwise configured to suspend or pause therapy if the second set point value is not reached after a predetermined amount of operating time of the pump. For example, in some embodiments, if the pump has been running continuously for X minutes and the second set point pressure value has not been reached, the pump assembly can activate an alarm which can comprise an LED indicator, a "leak detected" LED indicator 1064, or other alarm, and pause the therapy. In some embodiments, the predetermined amount of time can be approximately 5% of the total planned duration of the negative pressure therapy for the system, or from approximately 3% or less to approximately 15% or more of the total planned duration of the negative pressure therapy for the system. In some embodiments, the predetermined amount of time can be approximately 9 minutes, or from approximately 4 minutes or less to approximately 40 minutes or more, or from approximately 6 minutes to approximately 10 minutes.

[0206] Figure 31 illustrates a non-limiting example of operation 1900 of some embodiments of the pump assembly 1000 in presence of a very high leak. As is described

above in connection with Figure 29, the pump assembly can be configured to establish a desired level of negative pressure under the dressing 1010, as is illustrated in box 1902. In some embodiments, when the level of pressure under the dressing 1010 reaches the desired value, the pump assembly can be configured to deactivate the pump and monitor the level of pressure under the dressing, as is illustrated in box 1904. The pump assembly can be configured to periodically or continuously monitor the level of pressure under the dressing 1010 by, for example, reading or sampling the sensor 1070. Based on the monitored level of pressure, the pump assembly can determine whether the pump needs to be activated or restarted to reestablish the desired level of negative pressure under the dressing 1010. If the monitored level of pressure is determined to be low (e.g., less than or less than or equal to the first set point value), the pump assembly can be configured to activate the pump, as is illustrated in box 1908. During this operational flow, the pump assembly can be configured to indicate to the user that the pump assembly is operating normally. As is illustrated in 1060d, the pump assembly can activate or cause to blink or flash the OK indicator 1062, which is depicted as 1062d. In addition, the pump assembly can deactivate the dressing indicator 1064 and the battery indicator 1066, which are depicted as 1064d and 1066d respectively.

[0207] In some embodiments, due to a leak or leaks (e.g., a leak that has a relatively very high flow rate), the pump assembly may not be able to reach a desired negative pressure level and/or the second set point value under the dressing 1010. If after a predetermined amount of operating time, the desired negative pressure level is not reached under the dressing, the pump assembly can be configured to suspend or pause the pump, as is illustrated in box 1914. For example, this can be accomplished by transitioning to the wait state 1270. In some embodiments, the predetermined amount of pump operating time can be 10 seconds (as is illustrated in Figure 31). In some embodiments, the predetermined amount of pump operating time can be from approximately 5 seconds or less to approximately 60 seconds or more.

[0208] In some embodiments, the pump assembly can be configured to provide a limited number of retry cycles before pausing or suspending therapy. As illustrated in boxes 1920, 1922, and 1924, the pump assembly can be configured to go through three retry cycles before suspending or pausing therapy (1914) and/or activating an alarm, such as the "Leak

alarm." Some embodiments of the pump assembly can go through two retry cycles, four retry cycles, etc. before pausing therapy and/or activating an alarm. As is illustrated in 1060e, the pump assembly can activate or cause to blink or flash the dressing indicator 1064, which is depicted as 1064e, and deactivate the OK indicator 1062 and the battery indicator 1066, which are depicted as 1062e and 1066e respectively.

[0209] Figure 32 illustrates a non-limiting example of operation 2000 of some embodiments of the pump assembly 1000 in presence of an extremely high leak. The pump assembly can be configured to quickly go into a therapy pause or suspend mode to avoid wasting the batteries trying to cope with a high flow rate leak. As is illustrated in box 2001, the pump assembly can be turned on, which can be accomplished, for example, by transitioning into the operational state category 1250. As is described above in connection with Figure 29, the pump assembly can be configured to establish a desired level of negative pressure under the dressing 1010, as is illustrated in box 2002.

[0210] In some embodiments, if the leak is extremely high, such as when the pump is turned on but not yet connected to the dressing or not properly connected to the dressing, the pump assembly can be configured to operate for a predetermined amount of time while attempting to draw the pressure under the dressing 1010 to a desired negative pressure level. (e.g., approximately the second set point value or a value within the interval between the first and second set point values). The pump assembly can be configured to suspend or pause therapy upon expiration of the predetermined amount of time. For example, this can be accomplished by transitioning to the wait state 1270. As is illustrated, the pump assembly can be configured to operate the pump for 30 seconds. If during this period of time the pressure under the dressing 1010 has not been drawn to the desired negative pressure, the pump assembly can go into a timeout mode 2020 for another predetermined amount of time (e.g., for 15 seconds, as illustrated in Figure 32). During this operational flow, the pump assembly can be configured to indicate to the user that the pump assembly is operating normally. As is illustrated in 1060f, the pump assembly can activate or cause to blink or flash the OK indicator 1062, which is depicted as 1062f. In addition, the pump assembly can deactivate the dressing indicator 1064 and the battery indicator 1066, which are depicted as 1064f and 1066f respectively.

[0211] In some embodiments, the pump assembly can be configured to provide a limited number of retry cycles for establishing the desired level of negative pressure under the dressing 1010. As is illustrated, after the first trial (or any number of additional trials), the pump assembly can be configured to establish or reestablish the desired negative pressure level under the dressing, as is illustrated in box 2002. In some embodiments, as is illustrated in box 2014, if the pump assembly operates for another predetermined amount of time without drawing the pressure under the dressing 1010 to the desired level (e.g., approximately the second set point value or to a value within the interval between the first and second set point values) after a first attempt, the pump assembly can be configured to suspend or pause therapy without retrying the pump down. The pump assembly can be configured to remain in the suspended or paused state until the pump assembly is reactivated (e.g., due to a timeout, due to the user pressing the button, etc.) The pump assembly can be configured to activate an alarm in this state. During this operational flow, the pump assembly can be configured to indicate to the user that a leak or leaks are present. As is illustrated in 1060g, the pump assembly can activate or cause to blink or flash the dressing indicator 1064, which is depicted as 1064g, and deactivate the OK indicator 1062 and the battery indicator 1066, which are depicted as 1062g and 1066g respectively.

[0212] Throughout the description and claims of this specification, the words "comprise" and "contain" and variations of the words, for example "comprising" and "comprises", mean "including but not limited to", and is they are not intended to (and does not) exclude other moieties, additives, components, integers or steps.

[0213] Throughout the description and claims of this specification, the singular encompasses the plural unless the context otherwise requires. In particular, where the indefinite article is used, the specification is to be understood as contemplating plurality as well as singularity, unless the context requires otherwise. Further, in some embodiments, the term approximately is meant to refer to values within 10% of the stated values, unless otherwise stated herein.

[0214] Any value of a threshold, limit, duration, timeout, retry count, etc. provided herein is not intended to be absolute and, thereby, can be approximate. In addition, any threshold, limit, duration, timeout, retry count, etc. provided herein can be fixed or varied either automatically or by the user. Furthermore, as is used herein relative terminology such

as exceeds, greater than, less than, etc. in relation to a reference value is intended to also encompass being equal to the reference value. For example, exceeding a reference value that is positive can encompass being equal to or greater than the reference value.

[0215] Features, integers, characteristics, compounds, chemical moieties or groups described in conjunction with a particular aspect, embodiment, or example are to be understood to be applicable to any other aspect, embodiment or example described herein unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive. The protection is not restricted to the details of any foregoing embodiments. The protection extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

[0216] While certain embodiments have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of protection. Indeed, the novel methods and systems described herein may be embodied in a variety of other forms. Furthermore, various omissions, substitutions and changes in the form of the methods and systems described herein may be made. Those skilled in the art will appreciate that in some embodiments, the actual steps taken in the processes illustrated and/or disclosed may differ from those shown in the figures. Depending on the embodiment, certain of the steps described above may be removed, others may be added. Accordingly, the scope of the present disclosure is intended to be defined only by reference to the appended claims. The accompanying claims and their equivalents are intended to cover such forms or modifications as would fall within the scope and spirit of the protection. For example, the various components illustrated in the figures may be implemented as software and/or firmware on a processor, controller, ASIC, FPGA, and/or dedicated hardware. Furthermore, the features and attributes of the specific embodiments disclosed above may be combined in different ways to form additional embodiments, all of which fall within the scope of the present disclosure. Although the present disclosure provides certain preferred embodiments and applications, other embodiments that are apparent to those of ordinary skill in the art,

including embodiments which do not provide all of the features and advantages set forth herein, are also within the scope of this disclosure. Accordingly, the scope of the present disclosure is intended to be defined only by reference to the appended claims.

WHAT IS CLAIMED IS:

1. A pump assembly for reduced pressure wound therapy, comprising:

a housing;

a pump supported within or by the housing, the pump comprising:

a motor;

an inlet and an outlet;

a first valve configured to control a flow of a fluid through the inlet; and

a second valve configured to control a flow of a fluid through the outlet;

a flow pathway through the pump assembly; and

a one-way flow valve in fluid communication with the pump, the one-way flow valve being configured to substantially prevent a flow of gas through the flow pathway in a direction of flow away from the pump.

2. The pump assembly of Claim 1, wherein the pump assembly is canisterless.

3. The pump assembly of any one of the previous claims, further comprising a controller supported within or by the housing, the controller being configured to control an operation of the pump.

4. The pump assembly of any one of the previous claims, further comprising a pressure sensor in communication with the flow pathway.

5. The pump assembly of any one of the previous claims, further comprising only one switch or button supported by the housing, the at least one switch or button being accessible to a user and being in communication with the controller.

6. The pump assembly of any one of the previous claims, wherein the first valve and the second valve leak at a rate of approximately 0.1 mL/min and 10 mL/min at nominal working pressures.

7. The pump assembly of any one of the previous claims, wherein the pump assembly has been sterilized such that at least an inside and an outside of the housing, the flow pathway, the first and second valves, and the pump have been sterilized.

8. The pump assembly of any one of the previous claims, further comprising one or more LED lights supported by the housing.

9. The pump assembly of any one of the previous claims, wherein the pump assembly comprises one or more batteries and weighs between 80 and 90 grams, including the weight of the one or more batteries.

10. The pump assembly of any one of the previous claims, wherein an outside surface of the pump assembly defines a volume of between 60 and 80 cubic centimeters.

11. A negative pressure therapy kit, comprising:

the pump assembly of any one of the previous claims;

a dressing;

a conduit coupleable with the dressing and the pump assembly and configured to provide a fluid pathway of reduced pressure to the dressing;

one or more batteries; and

a first packaging element and a second packaging element configured to be removably coupled with the first packaging element, at least one of the first and second packaging elements having recesses for receiving the pump assembly, the dressing, the conduit, and the one or more batteries.

12. The negative pressure therapy kit of Claim 11, wherein the negative pressure kit is sterile, having been sterilized after the pump assembly, the dressing, the conduit, and the one or more batteries have been supported inside at least one of the first packaging element and the second packaging element.

13. The negative pressure therapy kit of any one of Claims 11-12, further comprising one or more adhesive sealing strips.

14. The negative pressure therapy kit of any one of Claims 11-13, wherein the one or more batteries are supported outside the housing.

15. The negative pressure therapy kit of any one of Claims 11-14, wherein the negative pressure therapy kit is sterilized with ethylene oxide.

16. The negative pressure therapy kit of any one of Claims 11-15, wherein the dressing comprises:

a transmission layer;

an absorbent layer for absorbing wound exudate, the absorbent layer overlying the transmission layer; and

a cover layer overlying the absorbent layer and comprising an orifice therethrough.

17. The negative pressure therapy kit of any one of Claims 11-16, wherein the dressing comprises a suction port for applying negative pressure to the dressing for the application of topical negative pressure at a wound site.

18. The negative pressure therapy kit of Claim 17, wherein the suction port comprises a connector portion for connecting the suction port to the pump assembly and a sealing surface for sealing the suction port to the cover layer of the dressing.

19. The negative pressure therapy kit of any one of Claims 11-18, wherein the dressing comprises a liquid impermeable gas permeable filter element arranged to prevent a liquid from entering the connector portion.

20. The negative pressure therapy kit of any one of Claims 11-19, wherein the first packaging element comprises PETG.

21. A negative pressure therapy system, comprising:

the pump assembly of any one of Claims 1-10; and

a dressing.

22. The negative pressure therapy kit of Claim 21, wherein a wound facing surface of the dressing is at least partially covered by a silicone based adhesive configured to create a low leak rate seal with skin surrounding the wound.

23. A method of treating a wound with negative pressure, comprising:

providing a dressing;

applying the dressing over the wound so as to create a substantially fluid tight seal over the wound; and

delivering negative pressure to the wound through the dressing using the pump assembly of any one of Claims 1-10.

24. The method of treating a wound with negative pressure of Claim 23, wherein applying the dressing over the wound so as to create a substantially fluid tight seal over the wound and delivering negative pressure to the wound through the dressing using the pump assembly of any one of Claims 1-10 is performed in an operating room.

25. A negative pressure therapy kit for reduced pressure wound therapy, comprising:

a pump assembly comprising:

a housing;

a pump supported within the housing, comprising:

a pump motor;

an inlet and an outlet;

at least one valve configured to control a flow of fluid through at least one of the inlet and the outlet; and

a flow pathway through at least the inlet, the outlet, and the at least one valve;

a controller supported within or by the housing, the controller being configured to control an operation of the pump and the valve; and

at least one switch or button supported by the housing, the at least one switch or button being in communication with the controller and being accessible to a user so as to permit a user to control one or more modes of operation of the pump;

a dressing configured to form a substantially fluid tight seal over a wound;

a conduit coupleable with the dressing and the pump assembly and configured to provide a substantially or completely enclosed fluid flow pathway from the pump assembly to the dressing; and

a first packaging element for packaging the pump assembly, the one or more batteries, the dressing, and the conduit;

wherein the negative pressure therapy kit has been sterilized such that at least an inside and an outside of the housing, the at least one valve, the pump, the controller, and the at least one switch or button have been sterilized.

26. The negative pressure therapy kit of Claim 25, further comprising one or more adhesive sealing strips.

27. The negative pressure therapy kit of any one of Claims 21-26, further comprising one or more batteries configured to provide a source of power to at least the pump and the controller.

28. The negative pressure therapy kit of Claim 27, further comprising a second packaging element configured to couple with the first packaging element, wherein the first packaging element has a plurality of recesses for receiving one or more of the pump assembly, the one or more batteries, the dressing, the conduit, and one or more adhesive sealing strips.

29. The negative pressure therapy kit of Claim 28, wherein the second packaging element is permeable to a sterilization gas and impermeable to bacteria.

30. The negative pressure therapy kit of any one of Claims 25-29, wherein the first packaging element supports the one or more batteries so that the one or more batteries are supported outside the housing during sterilization of the negative pressure therapy kit.

31. The negative pressure therapy kit of any one of Claims 25-30, wherein the pump is a diaphragm pump, a rotary diaphragm pump, or a piezoelectric pump.

32. The negative pressure therapy kit of any one of Claims 25-31, wherein the negative pressure therapy kit is sterilized with ethylene oxide.

33. The negative pressure therapy kit of any one of Claims 25-32, wherein the at least one valve is configured to permit a flow of sterilization gas through the at least one valve during the sterilization process.

34. The negative pressure therapy kit of any one of Claims 25-33, wherein the pump assembly further comprises a flow manifold, the flow manifold being in fluid communication with a pressure sensor, the pump, and at least one of a conduit or a connector for a conduit.

35. The negative pressure therapy kit of Claim 34, further comprising a one-way flow valve supported by the manifold.

36. The negative pressure therapy kit of any one of Claims 25-35, comprising a one-way flow valve positioned between the pump and the dressing, the one-way flow valve being configured to substantially prevent the flow of gas through the one-way flow valve in a direction of flow from the pump toward the dressing.

37. The negative pressure therapy kit of Claim 36, wherein the one-way flow valve is supported within the housing.

38. The negative pressure therapy kit of any one of Claims 25-37, further comprising a pressure sensor configured to monitor a level of pressure of a gas within a fluid flow pathway between the pump and the dressing or within the pump assembly.

39. The negative pressure therapy kit of any one of Claims 25-38, wherein one end of the conduit is connected to the dressing when packaged in the first packaging element.

40. The negative pressure therapy kit of any one of Claims 25-39, wherein the conduit comprises a first end and a second end, the first end being connected or connectable to the dressing and the second end comprising a connector configured to couple with the housing.

41. The negative pressure therapy kit of any one of Claims 25-40, wherein the housing is not sealed.

42. The negative pressure therapy kit of any one of Claims 25-41, wherein the pump assembly does not comprise a canister.

43. The negative pressure therapy kit of any one of Claims 25-42, further comprising an open foam layer surrounding at least a portion of the pump to reduce the noise and vibration produced by the pump.

44. The negative pressure therapy kit of any one of Claims 25-43, wherein the dressing comprises:

a transmission layer;

an absorbent layer for absorbing wound exudate, the absorbent layer overlying the transmission layer;

a cover layer overlying the absorbent layer;

a suction port for receiving an end portion of a conduit; and

a liquid impermeable gas permeable filter element arranged to prevent a liquid from passing through the suction port.

45. The negative pressure therapy kit of any one of Claims 25-44, wherein the pump assembly comprises a battery compartment supported by or formed within the housing.

46. The negative pressure therapy kit of any one of Claims 25-45, wherein the negative pressure therapy kit comprises a wound dressing having a silicone based adhesive configured to create a low leak rate seal with skin surrounding the wound, and wherein the

pump assembly weighs between 70 and 90 grams, including the weight of the one or more batteries.

47. The negative pressure therapy kit of any one of Claims 25-46, wherein the pump assembly weighs between 70 and 90 grams, including the weight of the one or more batteries.

48. The negative pressure therapy kit of any one of Claims 25-47, wherein an outside surface of the pump assembly defines a volume of from approximately 3 cubic inches to approximately 5 cubic inches.

49. The negative pressure therapy kit of any one of Claims 25-48, wherein the negative pressure therapy kit is configured such that the dressing must be removed from the first packaging element before the sealing strips can be removed from the first packaging element.

50. A negative pressure therapy kit for reduced pressure wound therapy, comprising:

a pump assembly comprising a pump having a flow rate of approximately 350 milliliters per minute or less; and

a dressing comprising a cover layer, the dressing having a wound contact surface that is covered with a silicone based adhesive.

51. The negative pressure therapy kit of Claim 50, wherein the pump assembly comprises a one-way flow valve in fluid communication with the pump, the one-way flow valve being configured to substantially prevent a flow of gas through the flow path in a direction of flow away from the pump.

52. The negative pressure therapy kit of any one of Claims 50-51, wherein the dressing comprises a transmission layer comprising a 3D knitted or fabric material configured to remain open upon application of negative pressure to the dressing.

53. The negative pressure therapy kit of any one of Claims 50-52, wherein the dressing comprises an absorbent layer for absorbing wound exudate, the absorbent layer overlying the transmission layer.

54. The negative pressure therapy kit of any one of Claims 50-53, wherein the dressing comprises a cover layer overlying the absorbent layer and comprising an orifice, wherein the cover layer is moisture vapor permeable.

55. The negative pressure therapy kit of any one of Claims 50-54, wherein the dressing comprises a suction port for applying negative pressure to the dressing for the application of topical negative pressure at a wound site, the suction port comprising a connector portion for connecting the suction port to the pump assembly and a sealing surface for sealing the suction port to the cover layer of the dressing.

56. The negative pressure therapy kit of any one of Claims 50-55, wherein the dressing comprises a liquid impermeable gas permeable filter element arranged to prevent a liquid from entering the connector portion.

57. The negative pressure therapy kit of any one of Claims 50-56, wherein the pump assembly is canisterless.

58. The negative pressure therapy kit of any one of Claims 50-57, further comprising a controller supported within or by a housing of the pump assembly, the controller being configured to control an operation of the pump.

59. The negative pressure therapy kit of any one of Claims 50-58, further comprising a pressure sensor in communication with a flow pathway through the pump assembly.

60. The negative pressure therapy kit of any one of Claims 50-59, further comprising at least one switch or button supported by a housing of the pump assembly, the at least one switch or button being accessible to a user and being in communication with the controller.

61. The negative pressure therapy kit of any one of Claims 50-60, further comprising a battery compartment supported by the pump assembly.

62. The negative pressure therapy kit of any one of Claims 50-61, wherein the pump assembly has been sterilized following the assembly of the pump assembly such that at least an inside and an outside of the pump assembly has been sterilized.

63. The negative pressure therapy kit of any one of Claims 50-62, wherein the pump assembly has one or more LED lights.

64. The negative pressure therapy kit of any one of Claims 50-63, wherein the pump assembly comprises one or more batteries and weighs between 80 and 90 grams, including the weight of the one or more batteries.

65. The negative pressure therapy kit of any one of Claims 50-64, wherein an outside surface of the pump assembly defines a volume of between 60 and 80 cubic centimeters.

66. A canisterless pump assembly for reduced pressure wound therapy, comprising:

a housing; and

a pump supported within or by the housing, the pump comprising:

a motor;

an inlet and an outlet;

a first valve configured to control a flow of a fluid through the inlet; and

a second valve configured to control a flow of a fluid through the outlet;

wherein:

the pump assembly is canisterless; and

the first and second valves each has a leakage rate of between approximately 5 mL/min and approximately 10 mL/min at nominal working pressures.

67. The pump assembly of Claim 66, wherein the pump assembly comprises a one-way flow valve in fluid communication with the pump, the one-way flow valve being configured to substantially prevent a flow of gas through the flow path in a direction of flow away from the pump.

68. The pump assembly of any one of Claims 66-67, further comprising a controller supported within or by the housing, the controller being configured to control an operation of the pump.

69. The pump assembly of any one of Claims 66-68, further comprising a pressure sensor in communication with the flow pathway through the pump assembly.

70. The pump assembly of any one of Claims 66-69, further comprising at least one switch or button supported by the housing, the at least one switch or button being accessible to a user and being in communication with the controller.

71. The pump assembly of any one of Claims 66-70, further comprising a battery compartment supported by or formed within the housing.

72. The pump assembly of any one of Claims 66-71, wherein the pump assembly has been sterilized following the assembly of the pump assembly such that at least an inside and an outside of the housing, the flow pathway, the one or more valves, and the pump have been sterilized.

73. The pump assembly of any one of Claims 66-72, further comprising one or more LED lights supported by the housing.

74. The pump assembly of any one of Claims 66-73, wherein the pump assembly comprises one or more batteries and weighs between 80 and 90 grams, including the weight of the one or more batteries.

75. The pump assembly of any one of Claims 66-74, wherein an outside surface of the pump assembly defines a volume of between 60 and 80 cubic centimeters.

76. A sterile pump kit, comprising:

the pump assembly of any one of Claims 66-75;

a dressing;

a conduit coupleable with the dressing and the pump assembly and configured to provide a fluid pathway of reduced pressure to the dressing;

one or more batteries; and

a first packaging element and a second packaging element configured to be removably coupled with the first packaging element, at least one of the first and second packaging elements having recesses for receiving the pump assembly, a dressing, a conduit coupleable with the dressing and the pump assembly and configured to provide a fluid pathway of reduced pressure to the dressing;

wherein the sterile pump kit has been sterilized after the pump assembly, the dressing, the conduit, and the one or more batteries have been supported inside at least one of the first packaging element and the second packaging element.

77. The sterile pump kit of Claim 76, wherein the pump assembly, the dressing, the conduit, and the one or more batteries are supported within at least one of the first packaging element and the second packaging element before the pump assembly, the dressing, the conduit, or the one or more batteries are sterilized.

78. The sterile pump kit of any one of Claims 76-77, further comprising one or more adhesive sealing strips.

79. The sterile pump kit of any one of Claims 76-78, wherein the one or more batteries are supported outside the housing.

80. The sterile pump kit of any one of Claims 76-79, wherein the sterile pump kit is sterilized with ethylene oxide.

81. The sterile pump kit of any one of Claims 76-80, wherein the dressing comprises:

a transmission layer;

an absorbent layer for absorbing wound exudate, the absorbent layer overlying the transmission layer; and

a cover layer overlying the absorbent layer.

82. The sterile pump kit of any one of Claims 76-81, wherein the dressing comprises a suction port for applying negative pressure to the dressing for the application of topical negative pressure at a wound site.

83. The sterile pump kit of Claim 82, wherein the suction port comprises a connector portion for connecting the suction port to the pump assembly and a sealing surface for sealing the suction port to the cover layer of the dressing.

84. The sterile pump kit of any one of Claims 76-83, wherein the dressing comprises a liquid impermeable gas permeable filter element arranged to prevent a liquid from entering the connector portion.

85. The sterile pump kit of any one of Claims 76-84, wherein the first packaging element comprises PETG.

86. A method for initiating treatment of a wound in an operating room, comprising:

applying a sterile dressing over a wound so as to create a substantially fluid tight seal over the wound;

coupling a sterile pump assembly to dressing via a sterile conduit; and

reducing a level of pressure between the dressing and the wound in an operating room by activating the pump assembly in the operating room.

87. The method of Claim 86, further comprising applying one or more sealing strips over at least one peripheral edge of the dressing so as to improve the seal between the dressing and skin surrounding the wound.

88. The method of any one of Claims 86-87, further comprising removing one or more batteries from a first packaging element and installing the one or more batteries in the pump assembly.

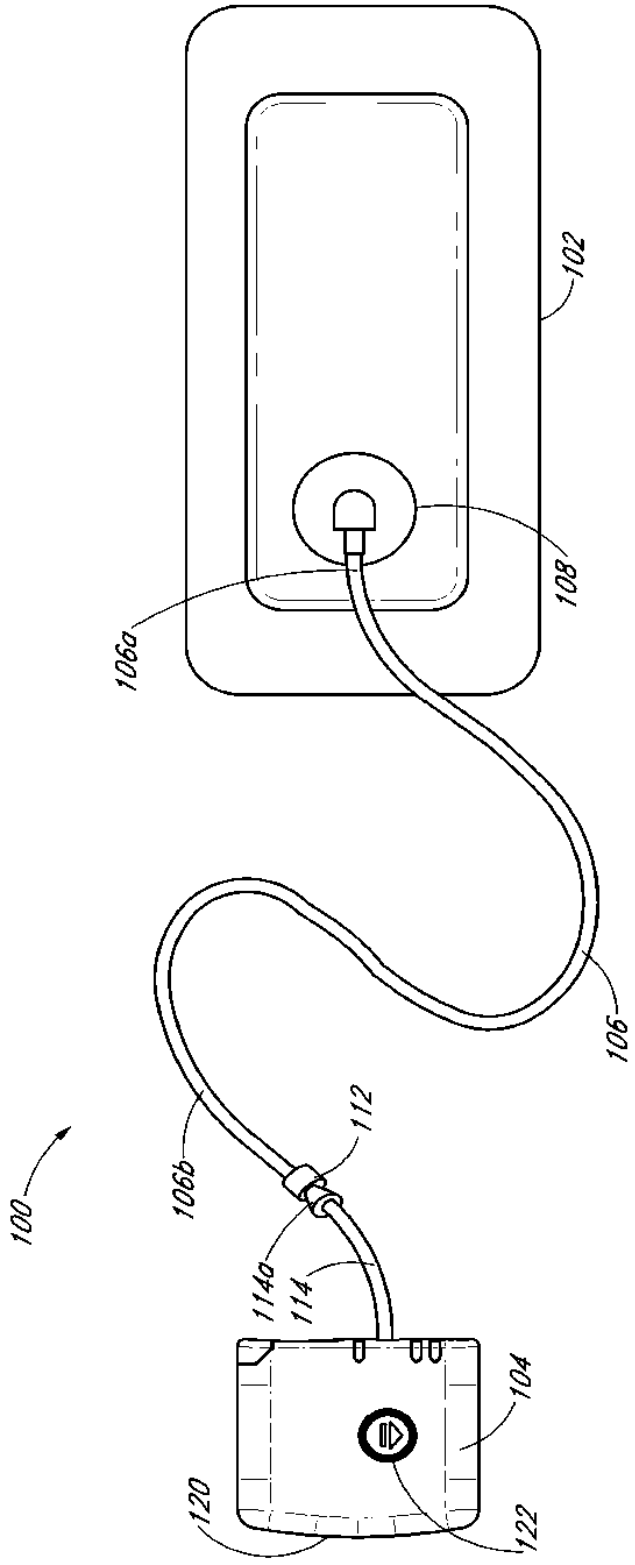


FIG. 1

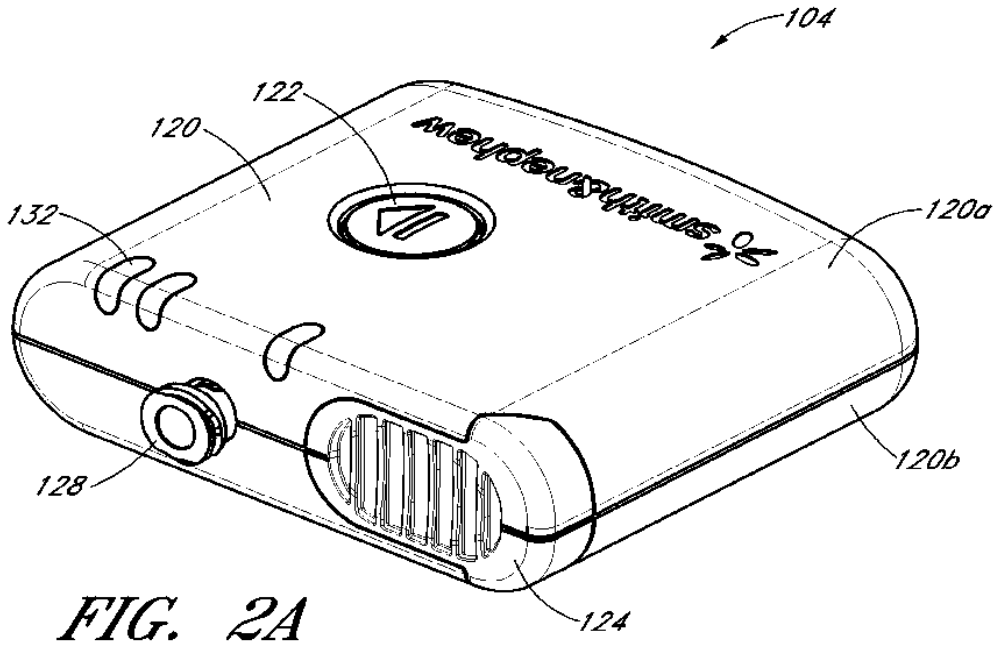


FIG. 2A

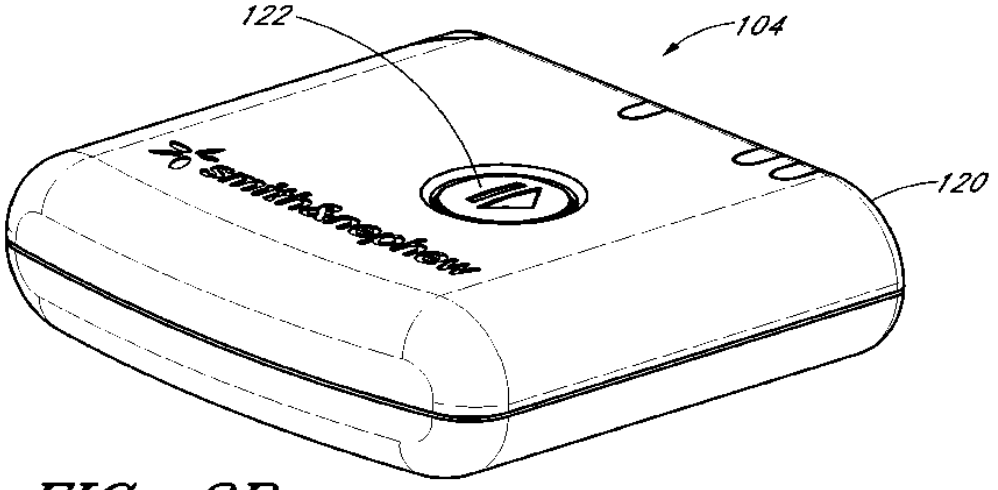


FIG. 2B

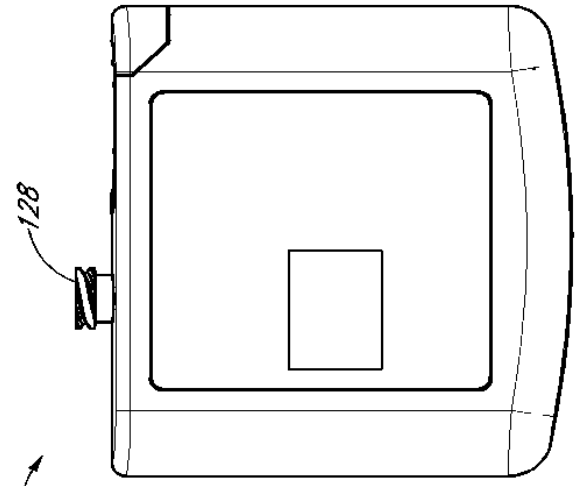


FIG. 2E

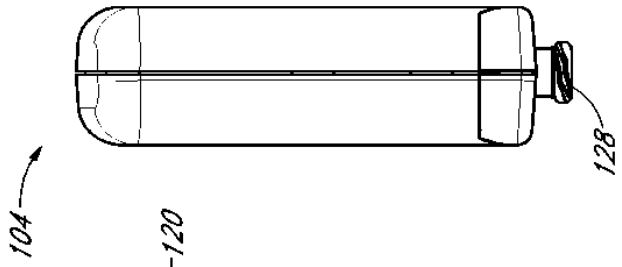


FIG. 2D

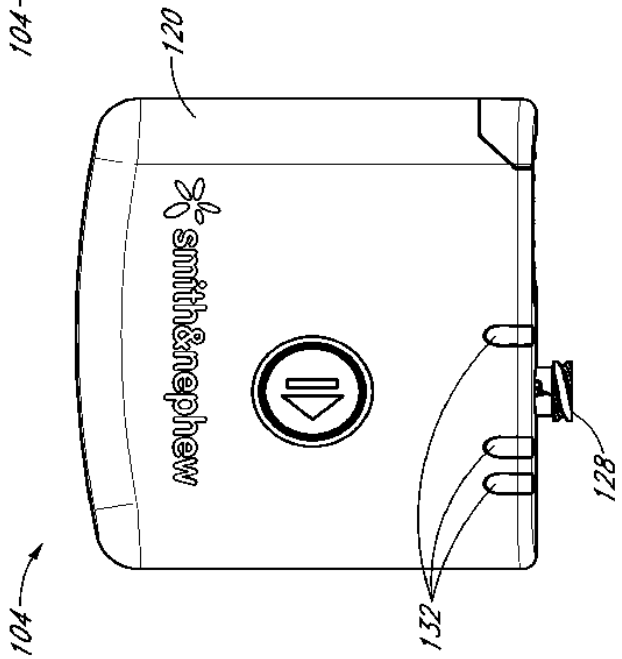


FIG. 2C

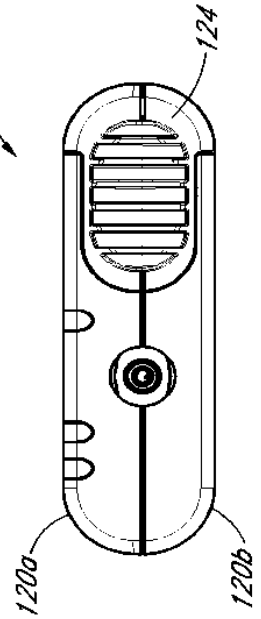


FIG. 2F

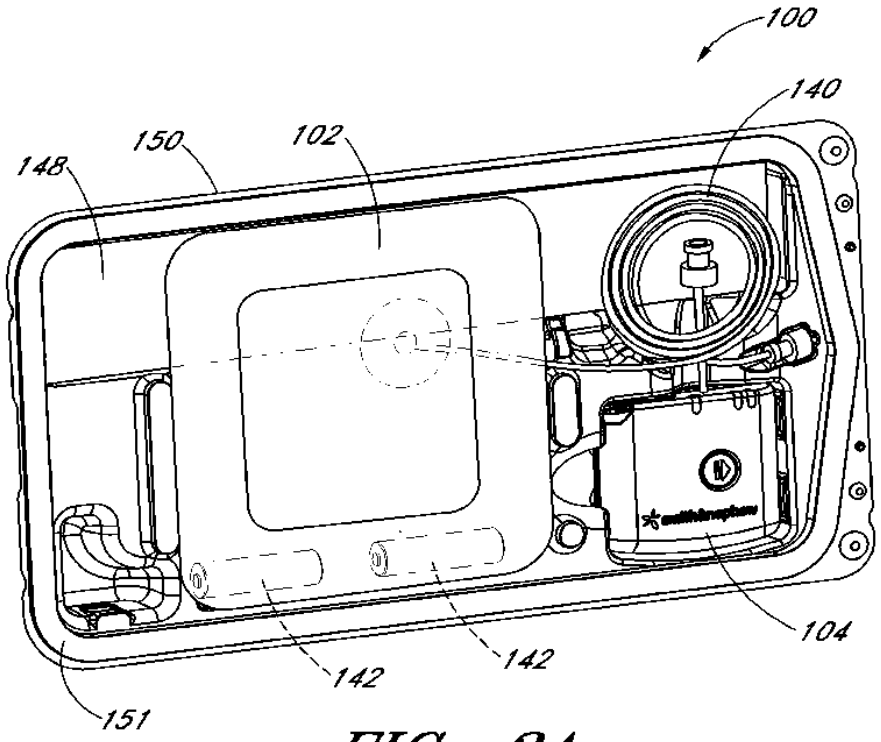


FIG. 3A

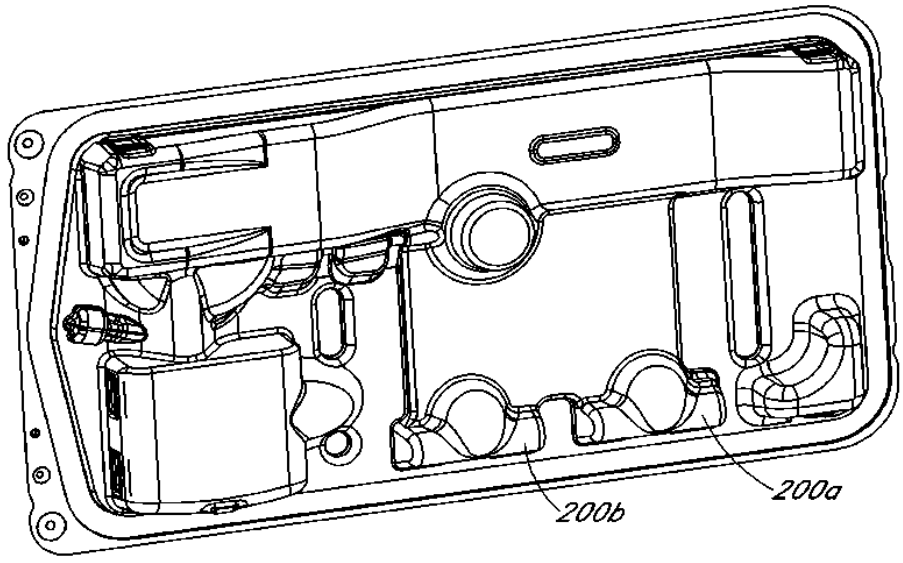


FIG. 3B

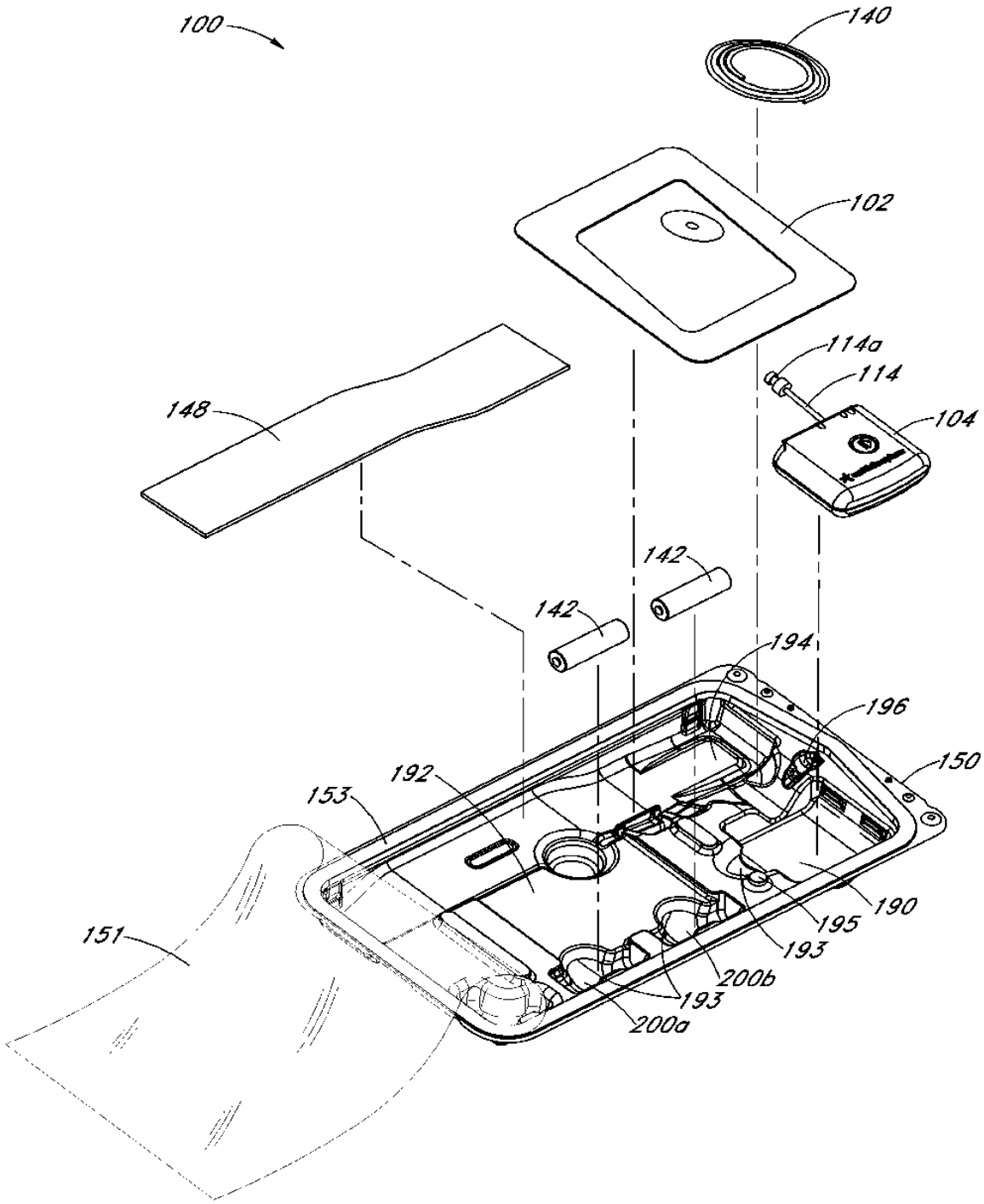

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200b
193
200a

FIG. 3C

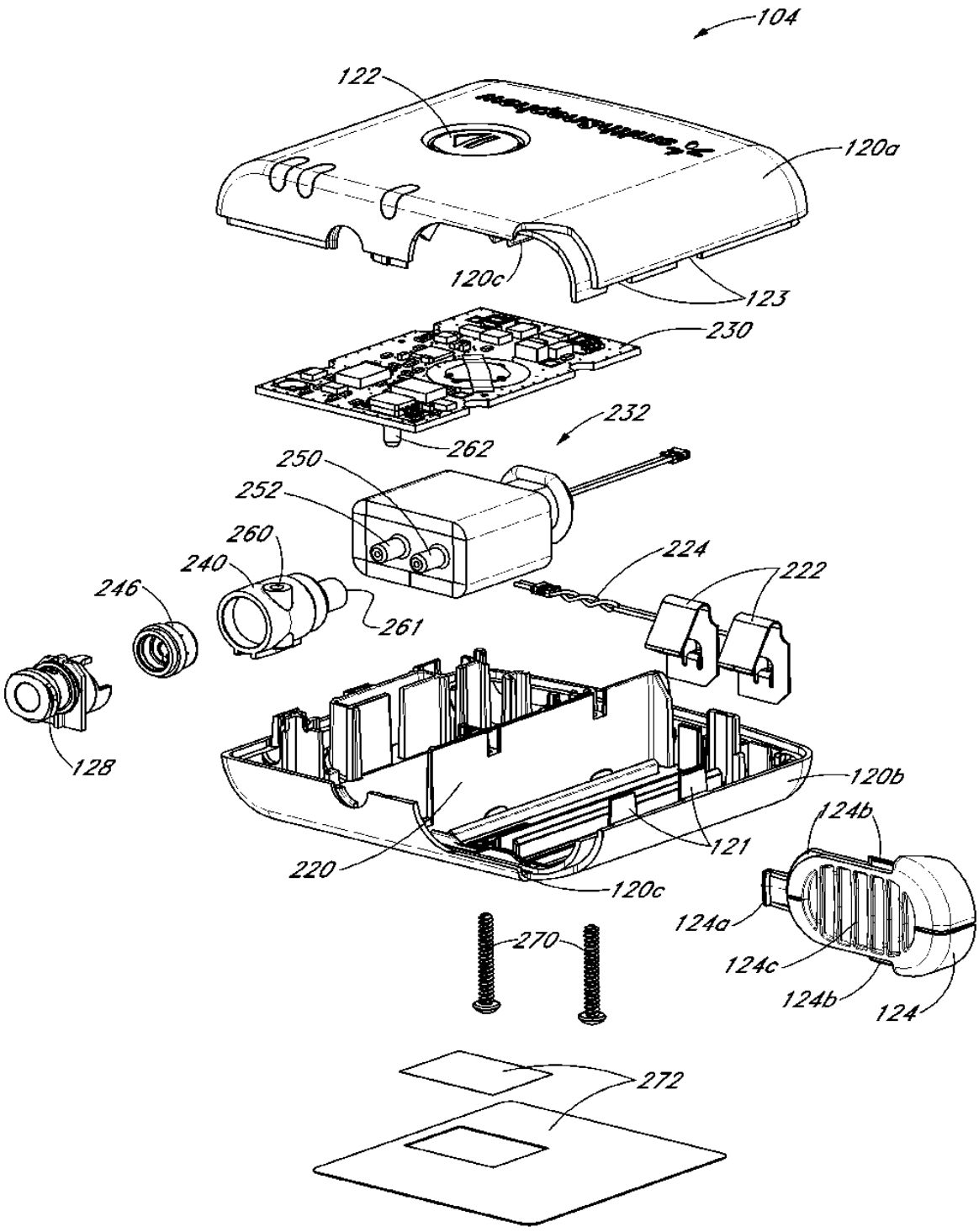

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FIG. 4A

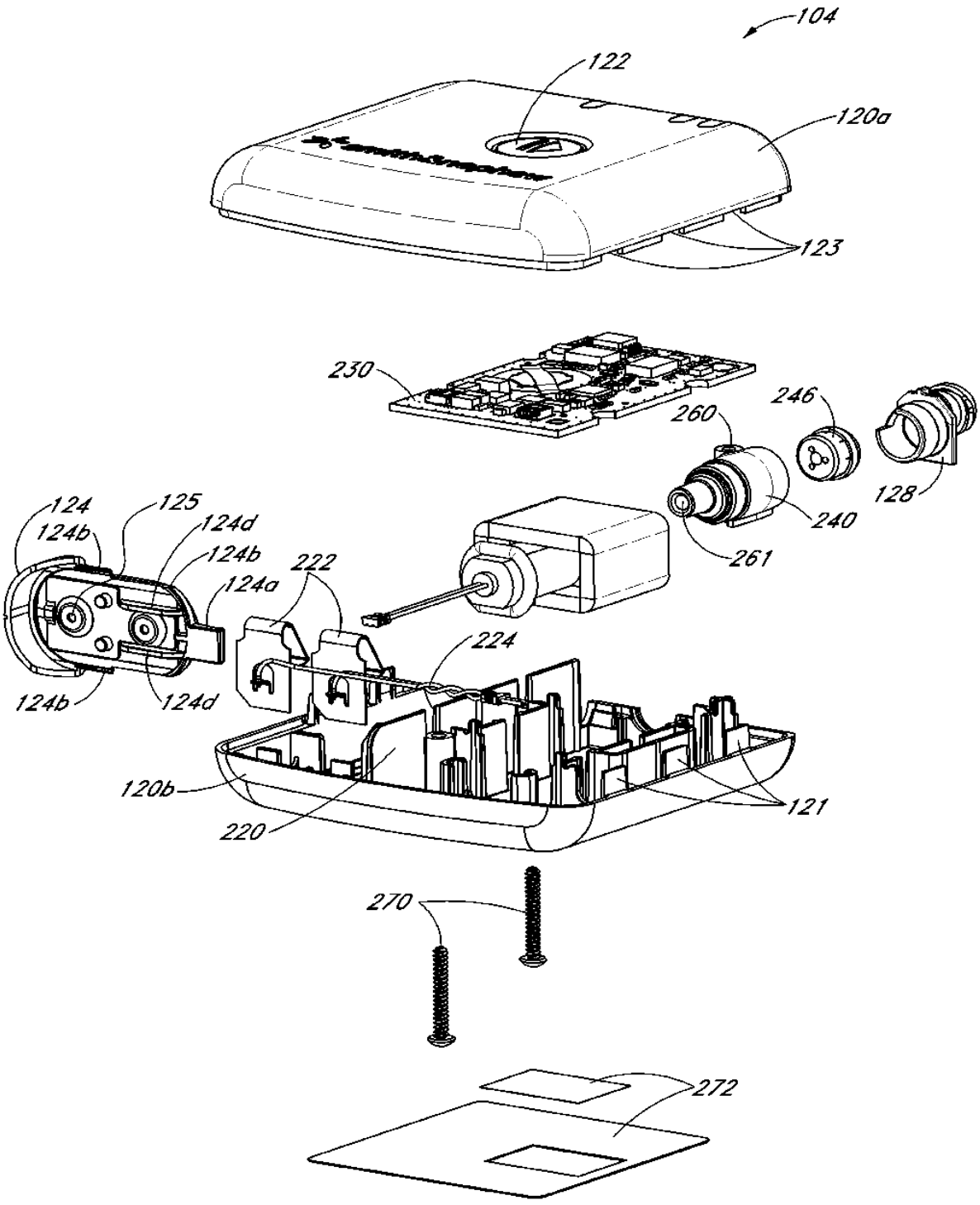

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220
270
272

FIG. 4B

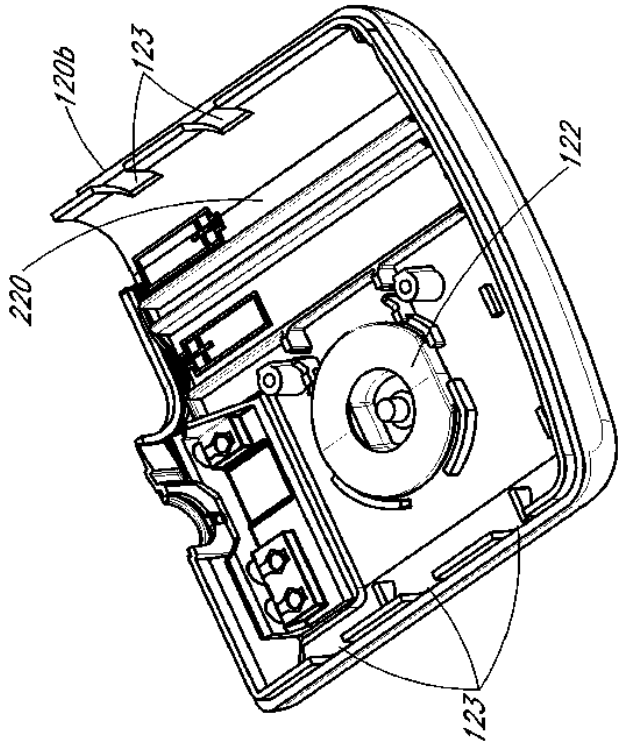


FIG. 5B

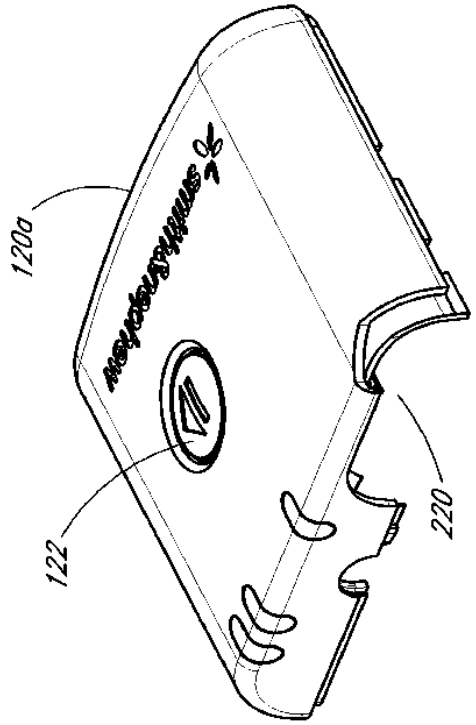


FIG. 5A

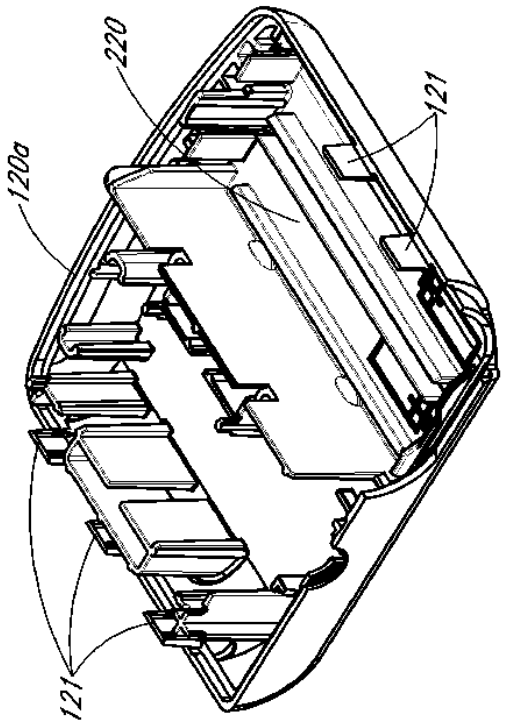


FIG. 6B

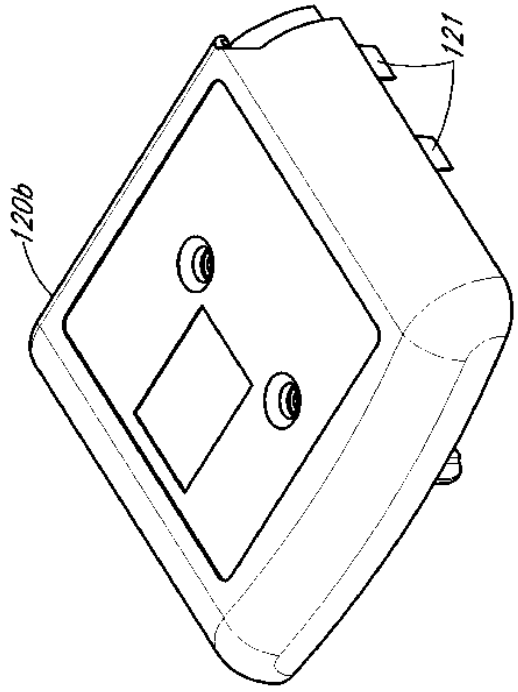


FIG. 6A

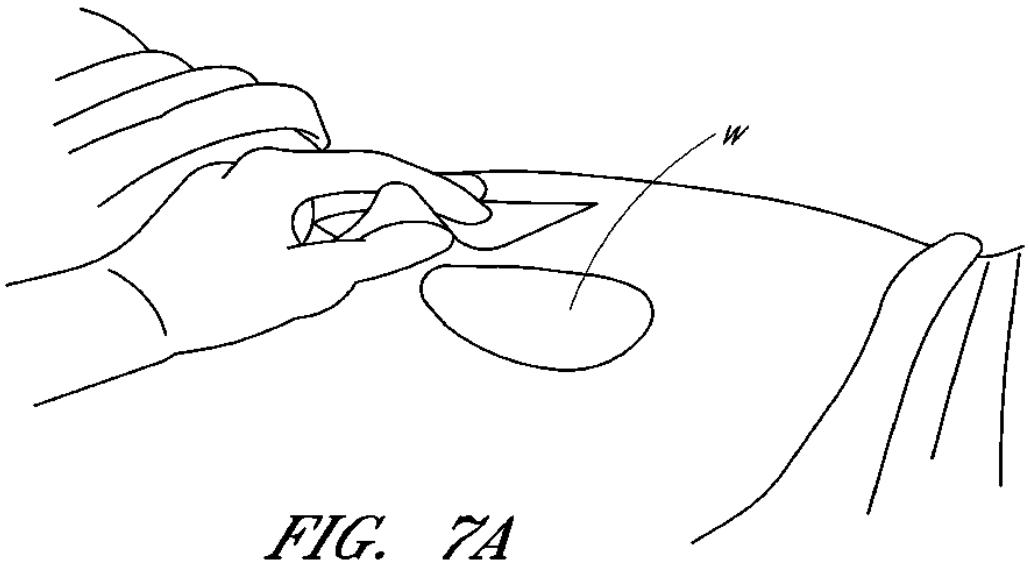


FIG. 7A

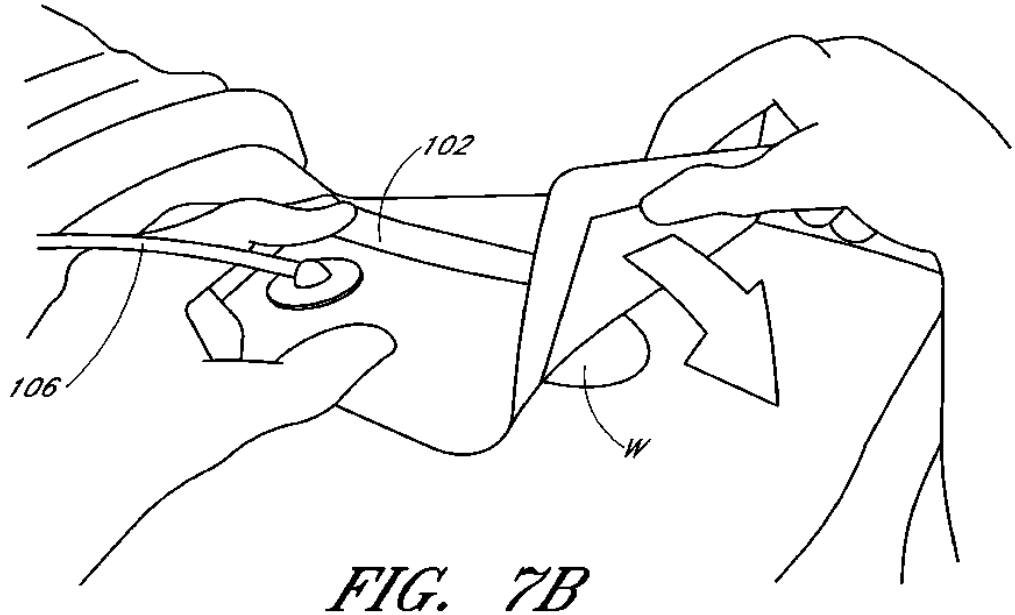


FIG. 7B

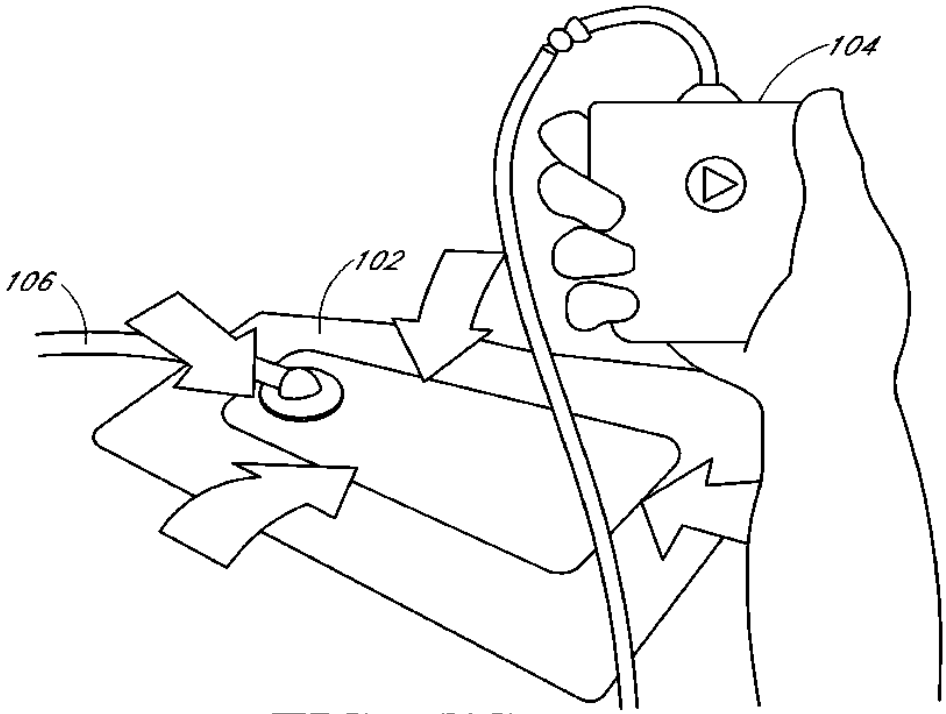


FIG. 7C

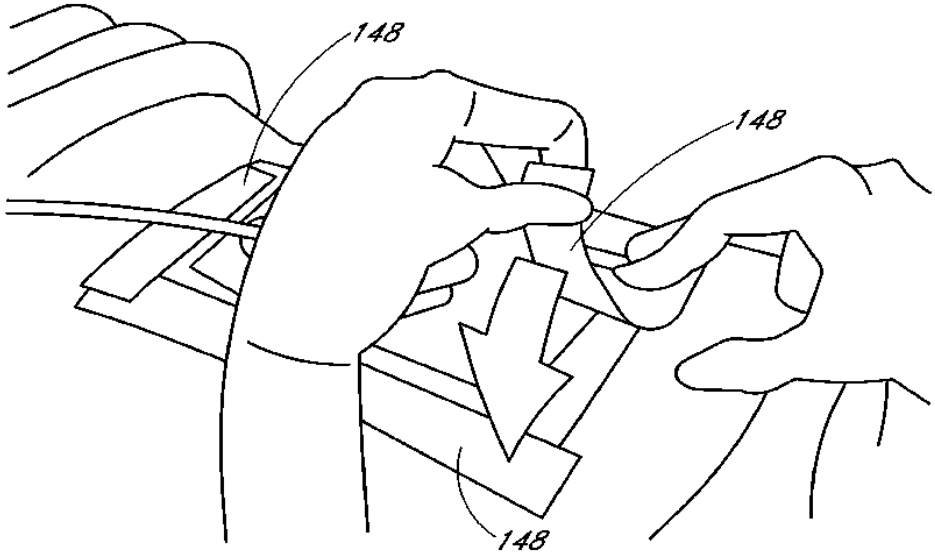


FIG. 7D

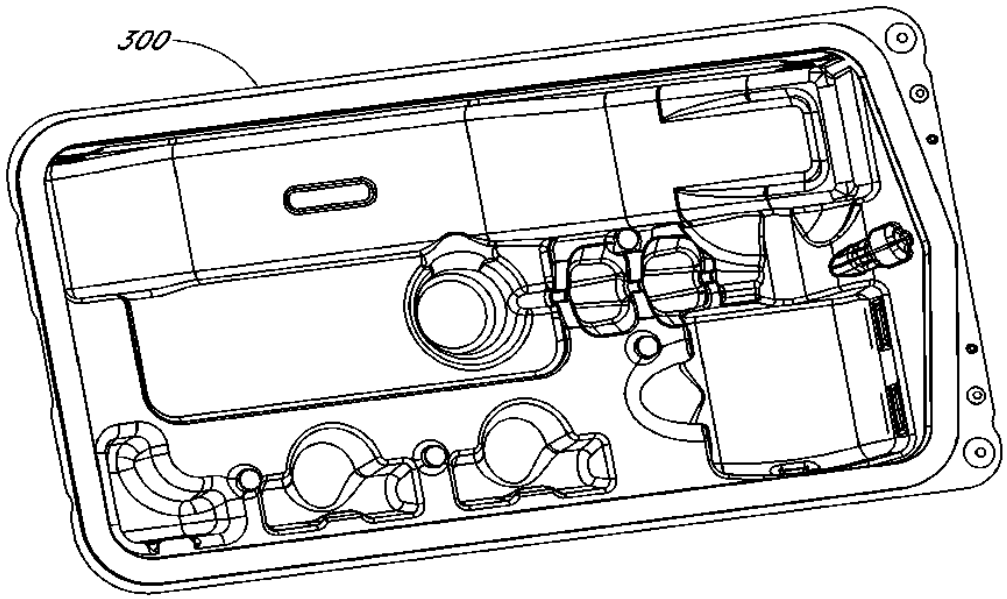


FIG. 8A

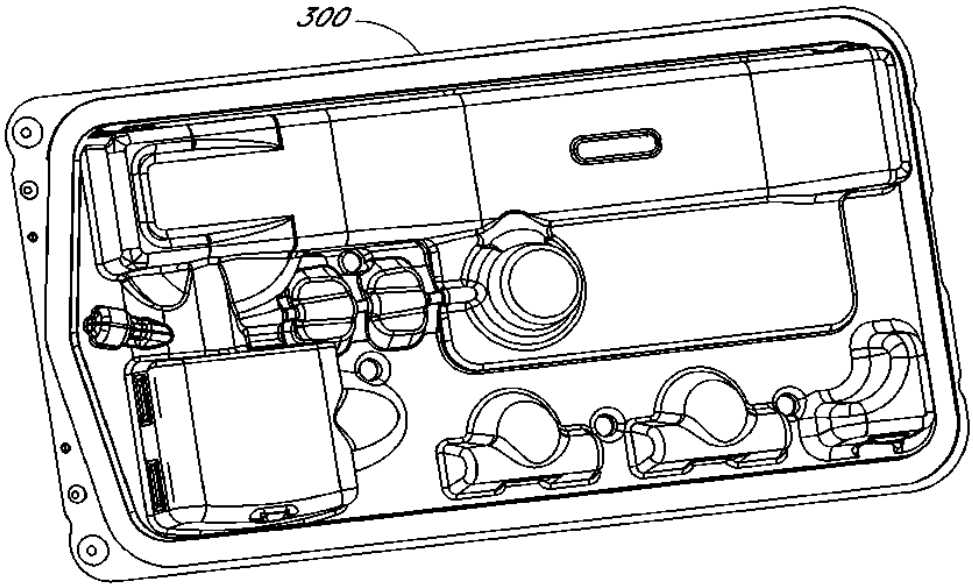


FIG. 8B

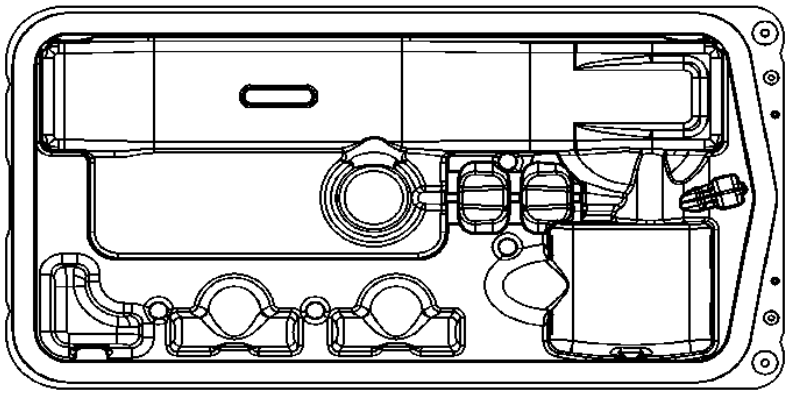


FIG. 8C

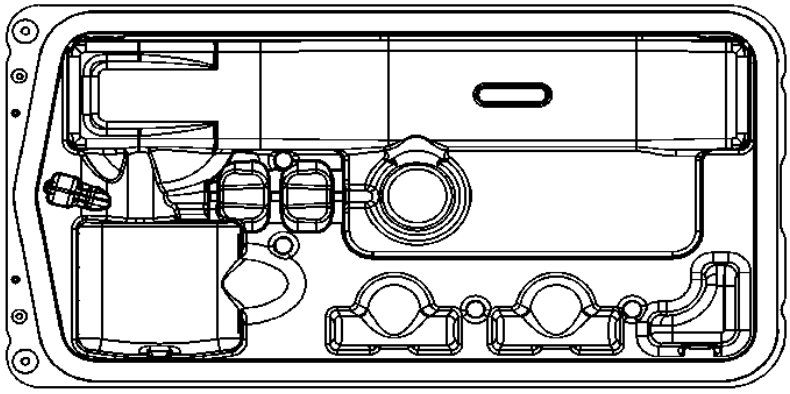


FIG. 8D



FIG. 8E

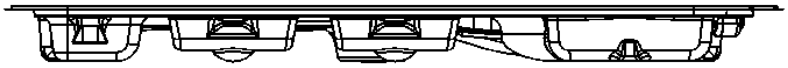


FIG. 8F



FIG. 8G

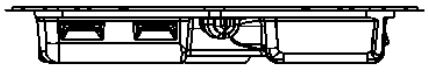


FIG. 8H

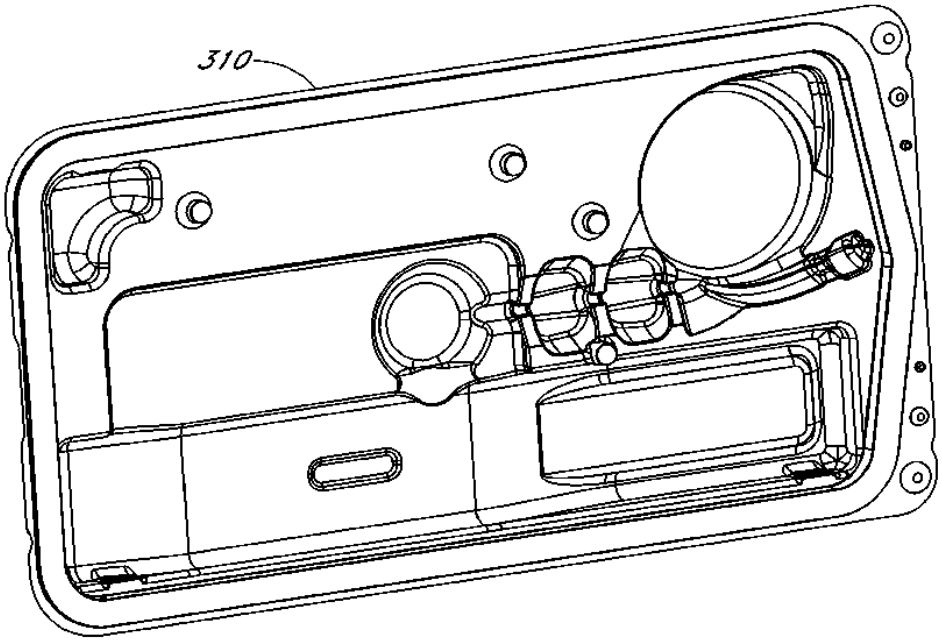


FIG. 9A

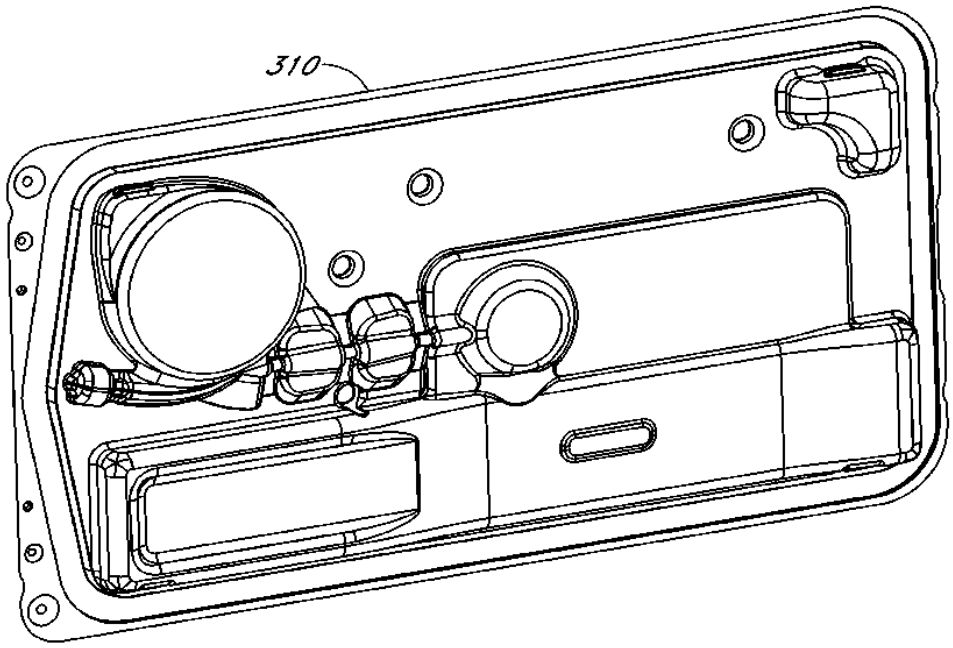


FIG. 9B

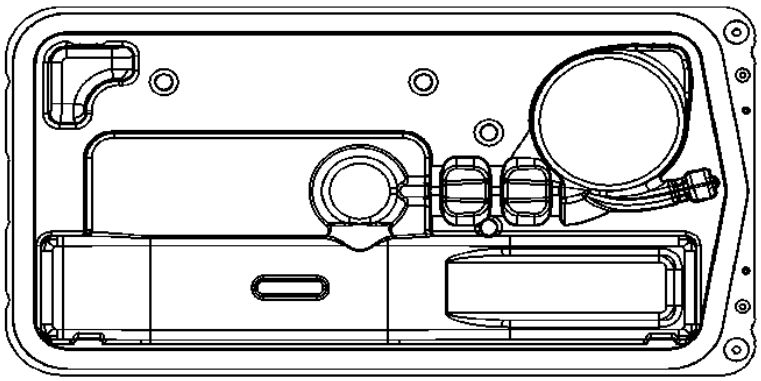


FIG. 9C

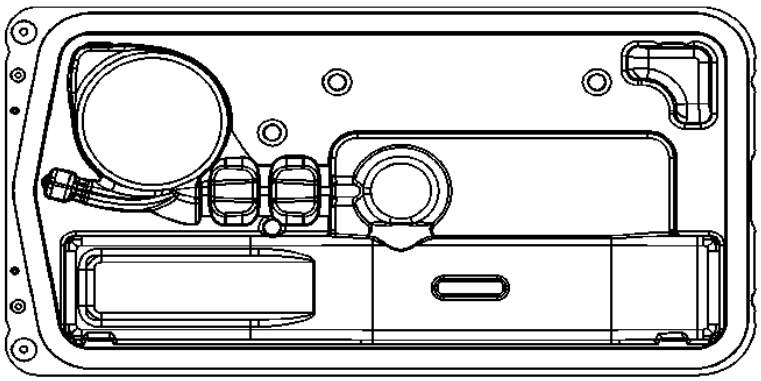


FIG. 9D



FIG. 9E



FIG. 9F



FIG. 9G



FIG. 9H

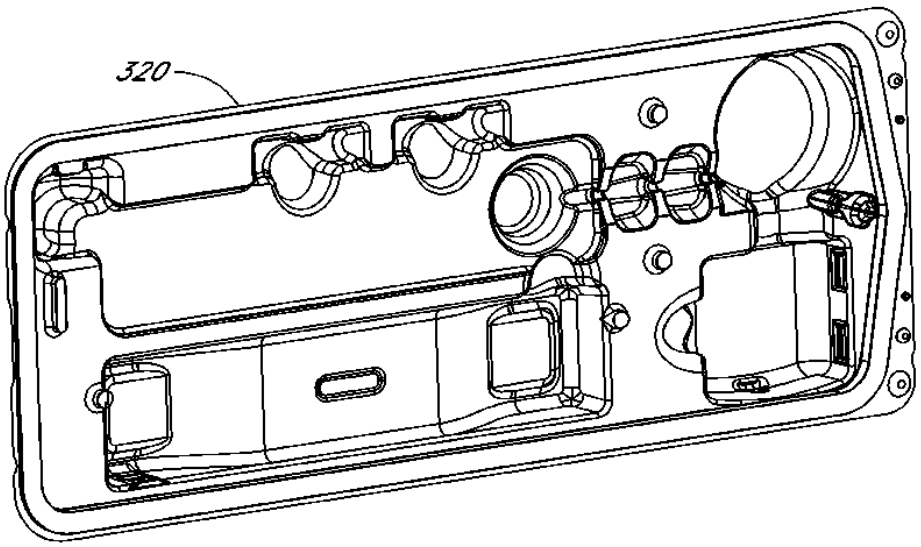


FIG. 10A

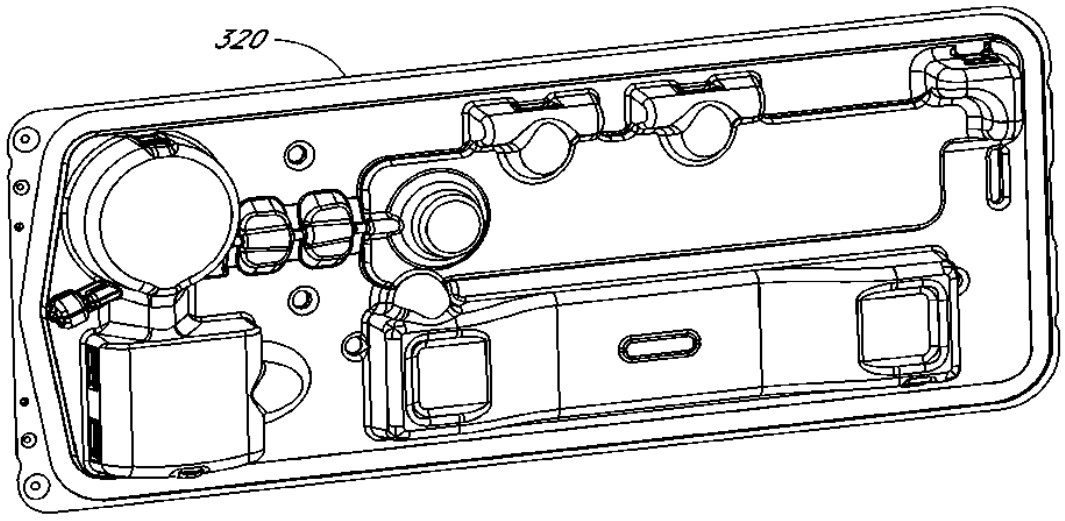


FIG. 10B

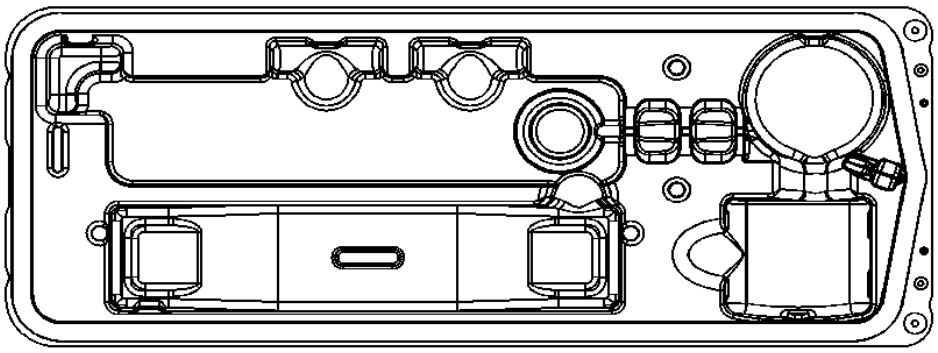


FIG. 10C

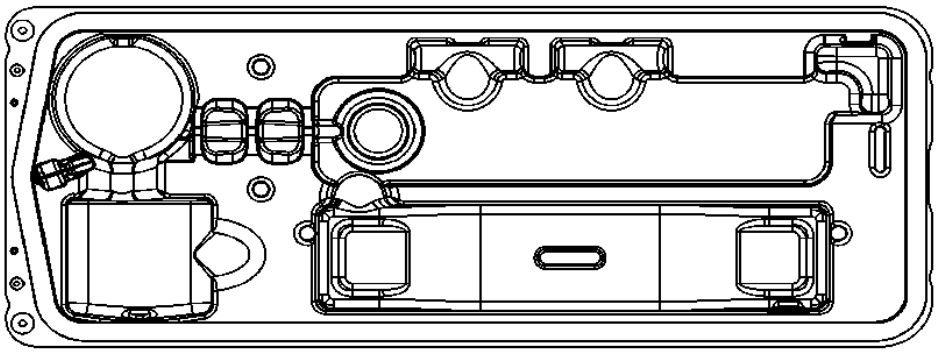


FIG. 10D



FIG. 10E



FIG. 10F



FIG. 10G



FIG. 10H

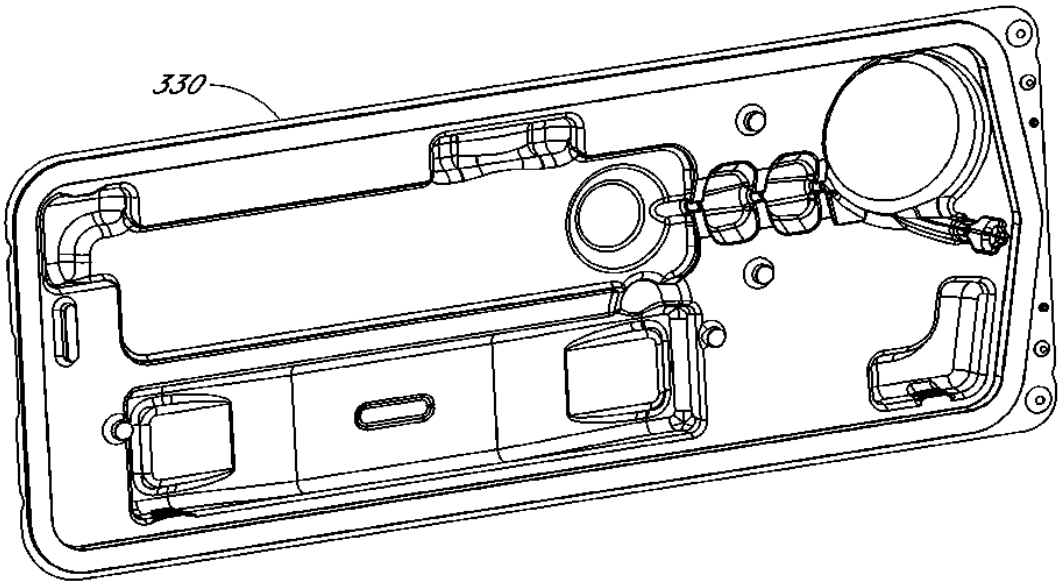


FIG. 11A

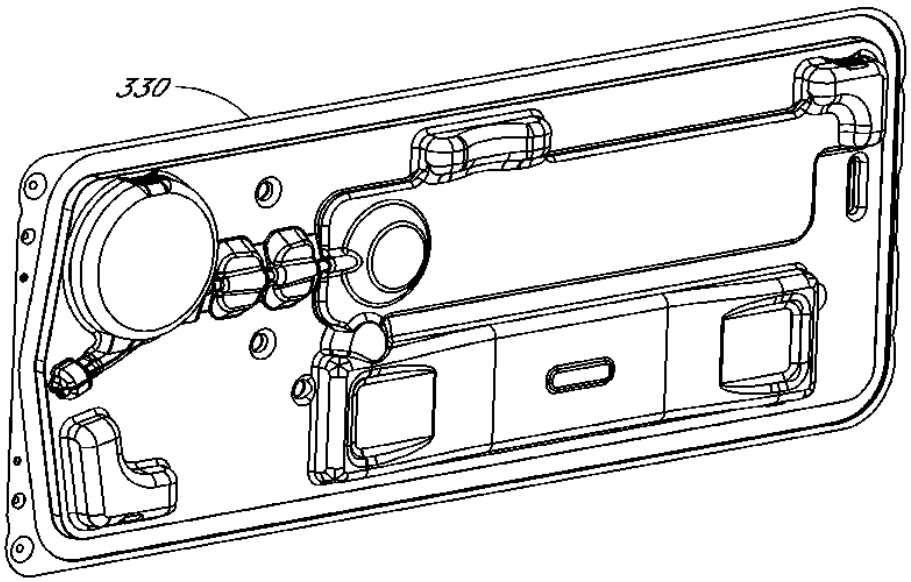


FIG. 11B

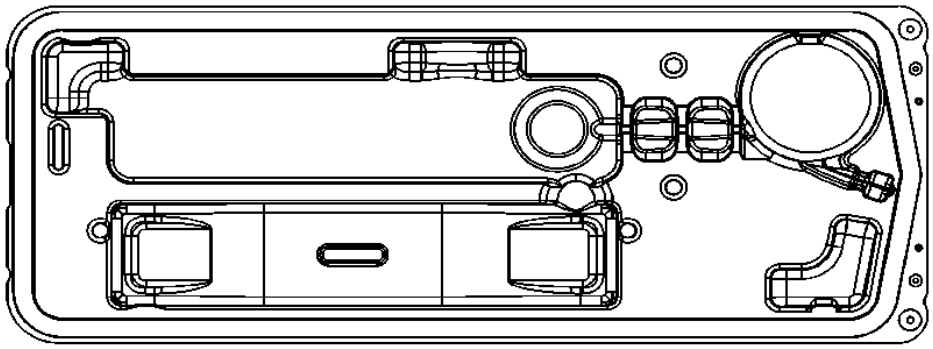


FIG. 11C

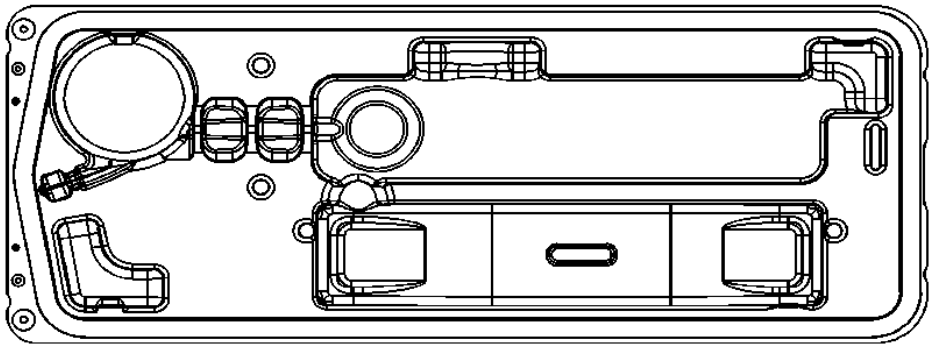


FIG. 11D



FIG. 11E



FIG. 11F



FIG. 11G

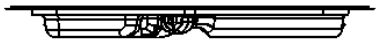


FIG. 11H

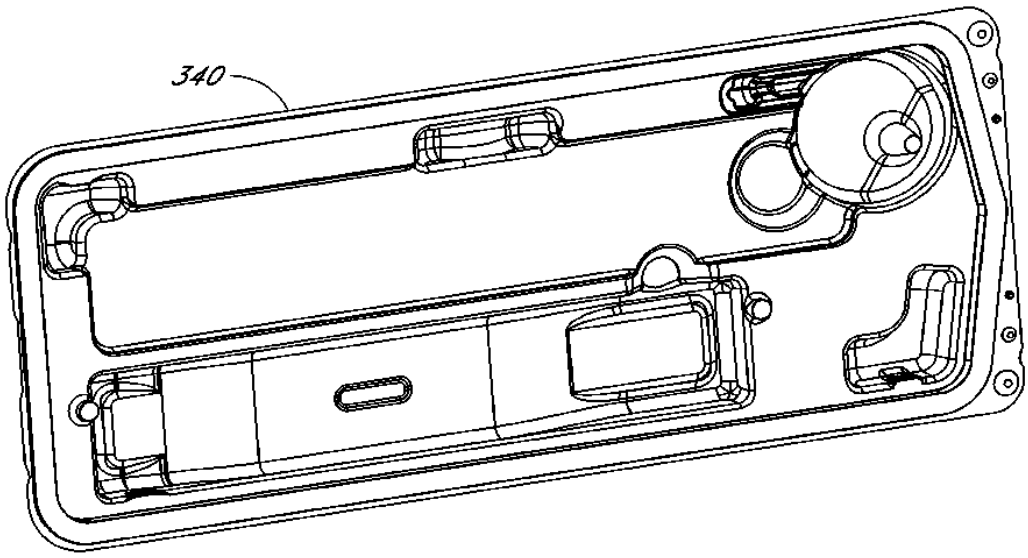


FIG. 12A

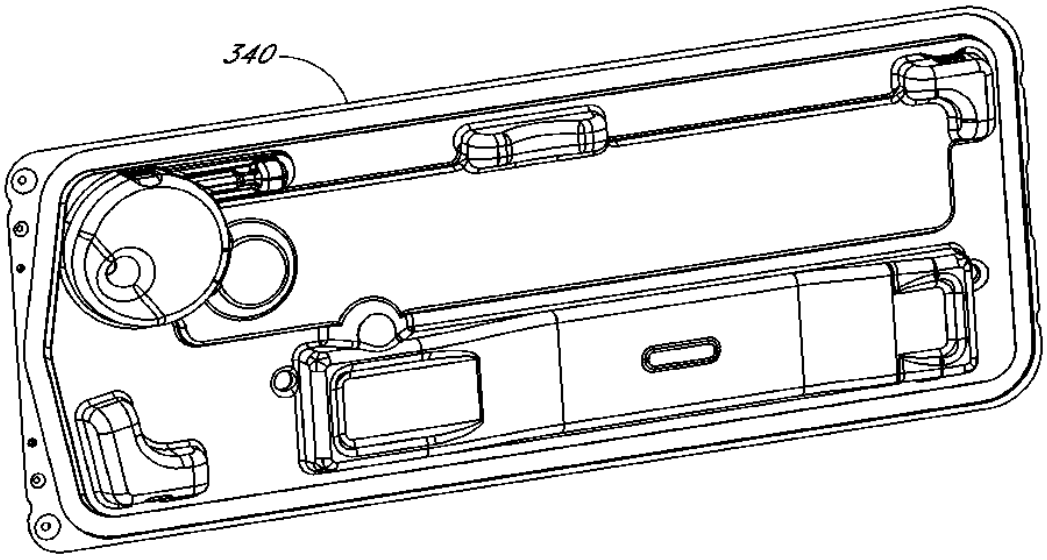


FIG. 12B

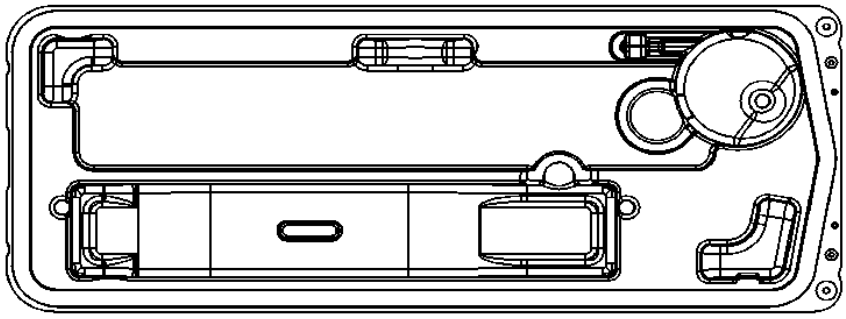


FIG. 12C

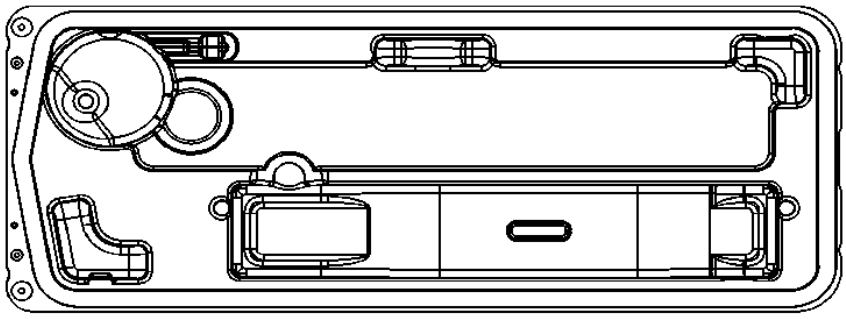


FIG. 12D



FIG. 12E



FIG. 12F



FIG. 12G

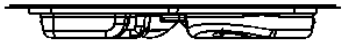


FIG. 12H

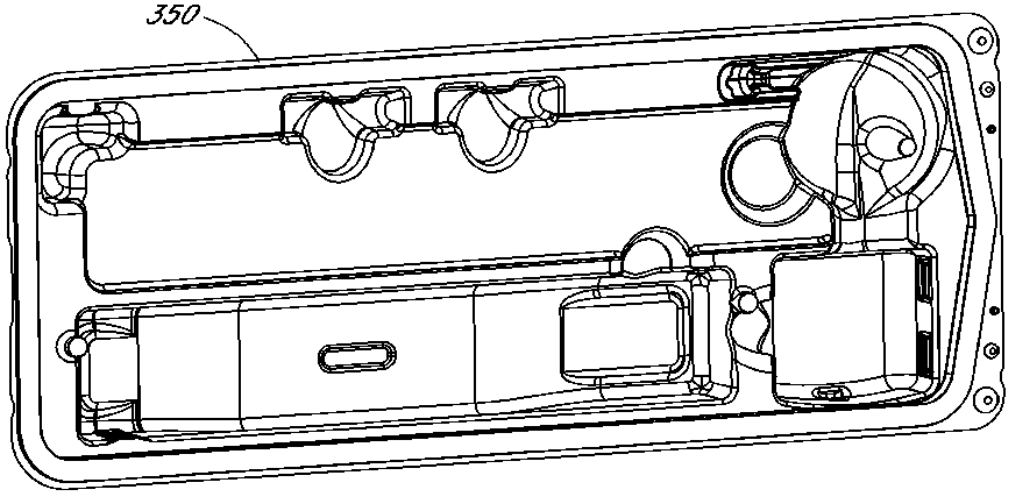


FIG. 13A

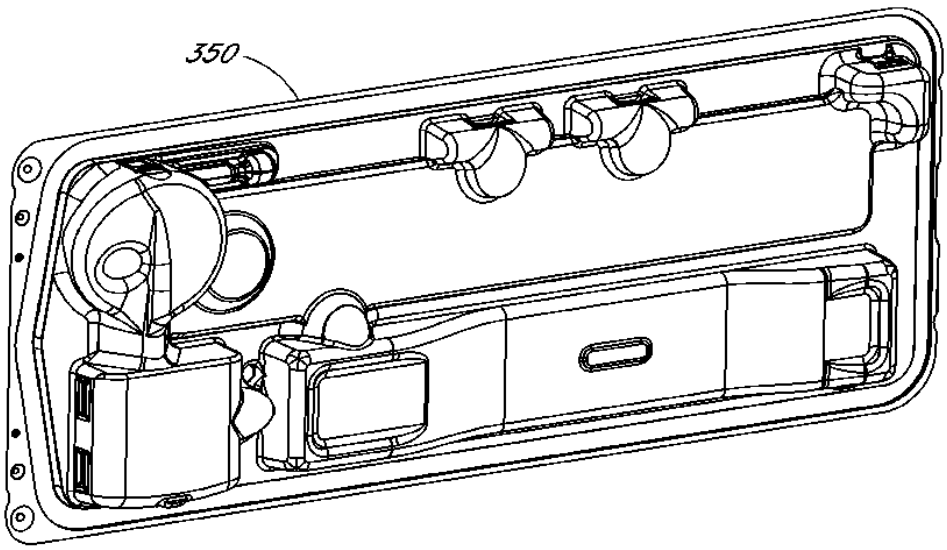


FIG. 13B

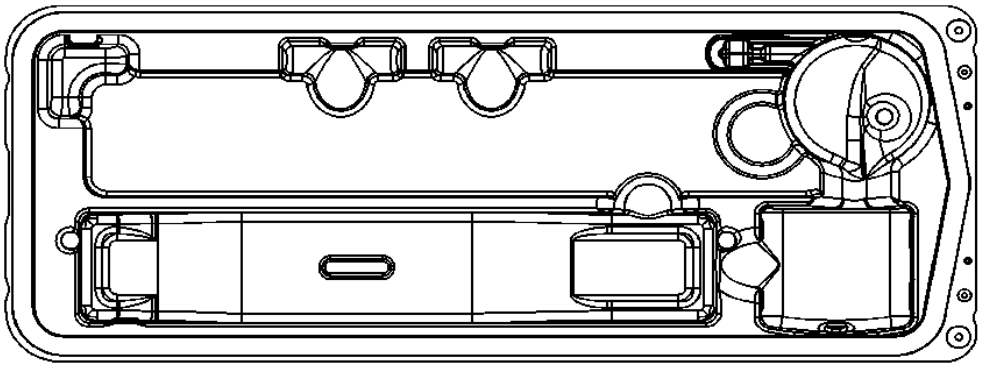


FIG. 13C

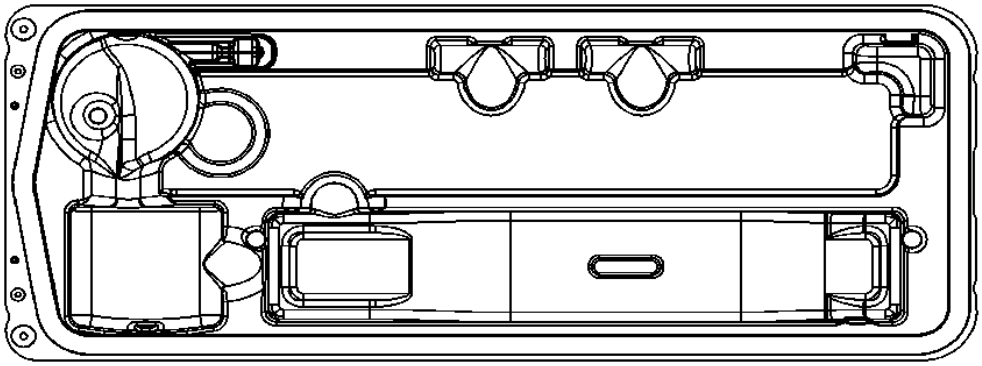


FIG. 13D



FIG. 13E



FIG. 13F

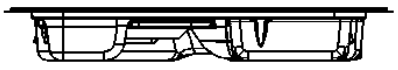


FIG. 13G

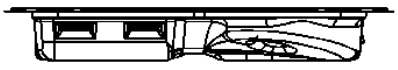


FIG. 13H

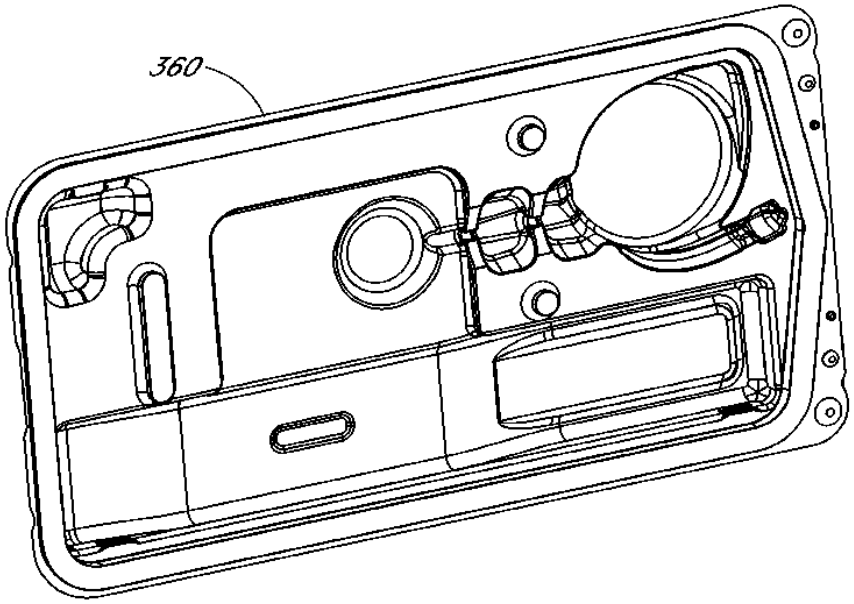


FIG. 14A

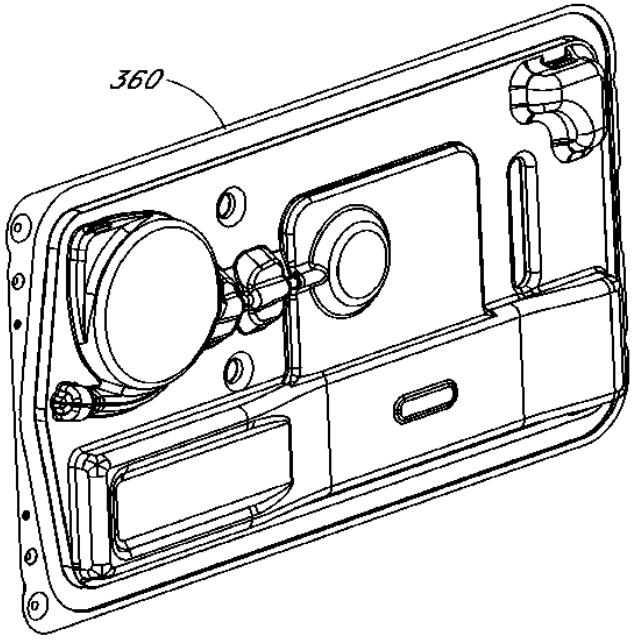


FIG. 14B

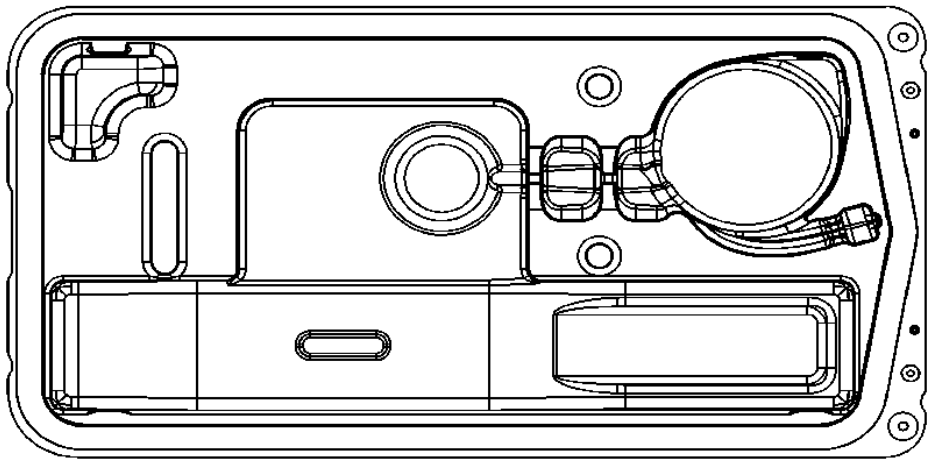


FIG. 14C

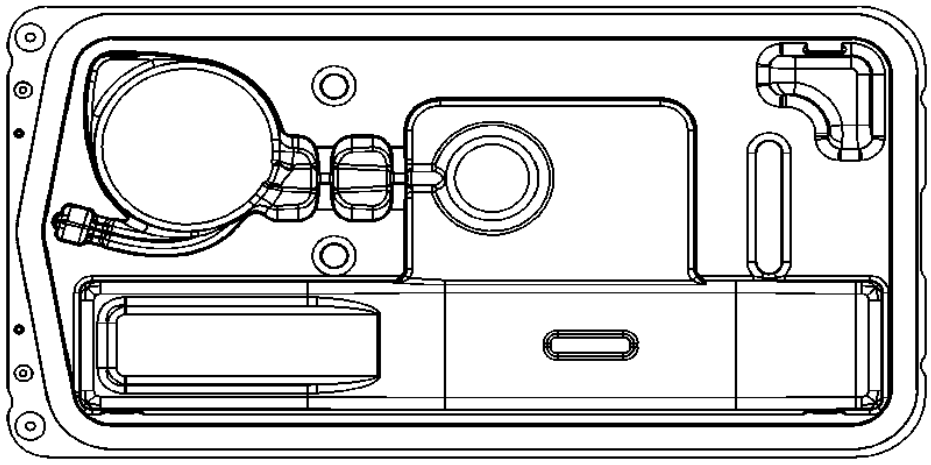


FIG. 14D



FIG. 14E

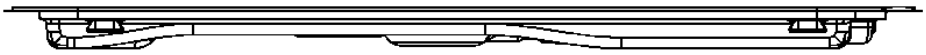


FIG. 14F

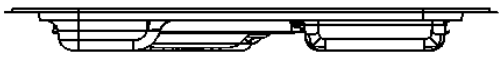


FIG. 14G



FIG. 14H

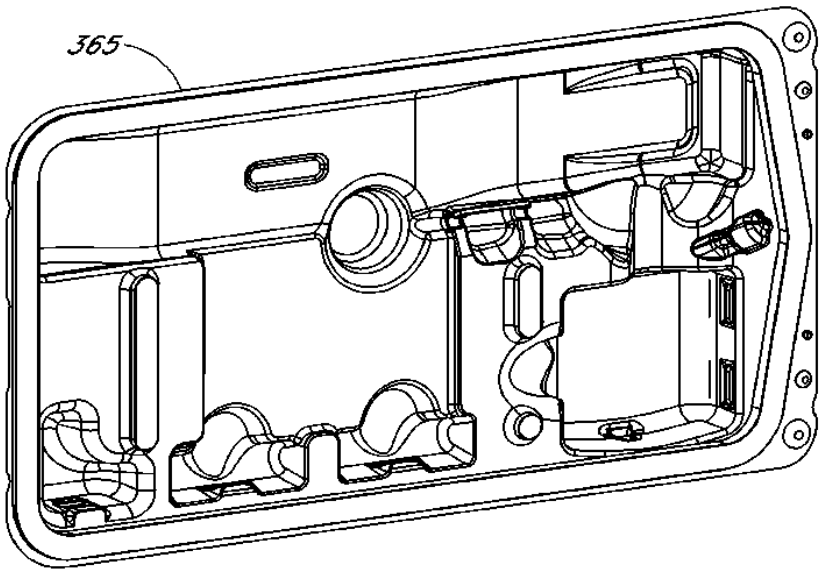


FIG. 14I

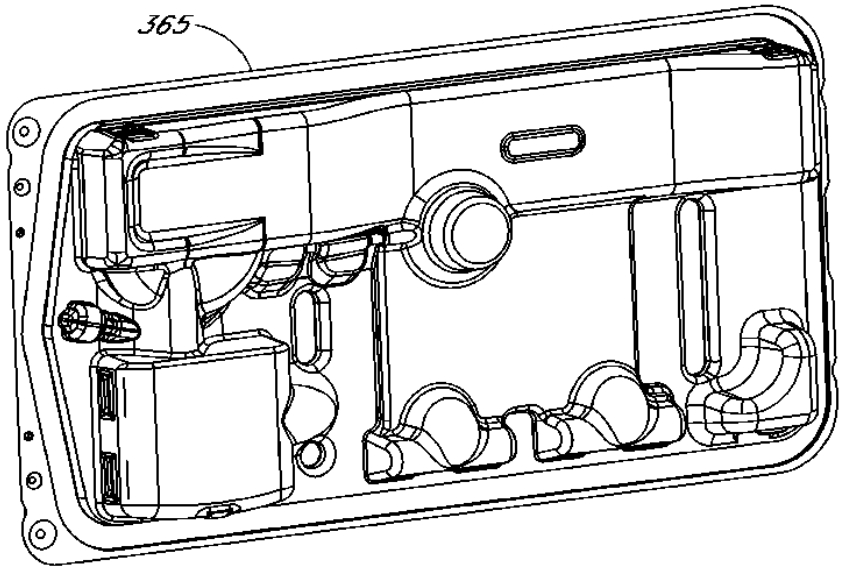


FIG. 14J

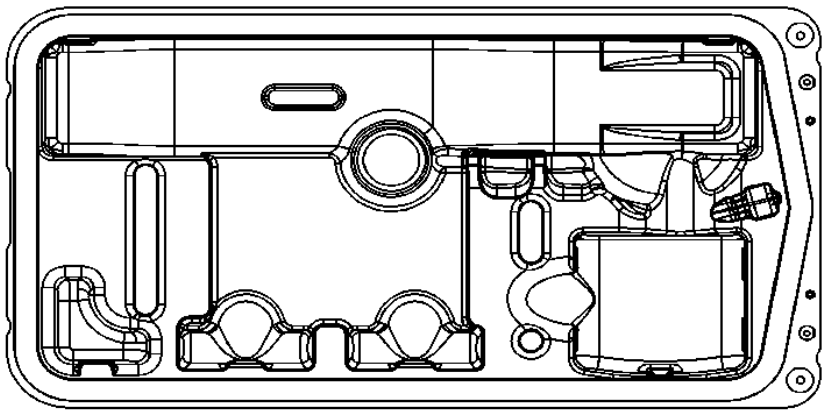


FIG. 14K

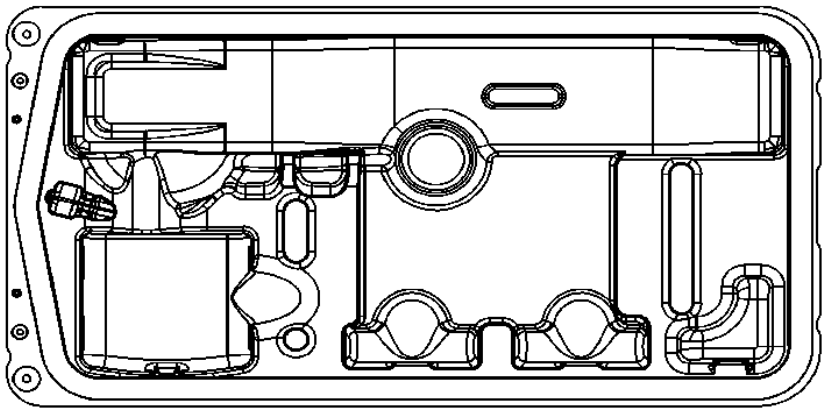


FIG. 14L



FIG. 14M

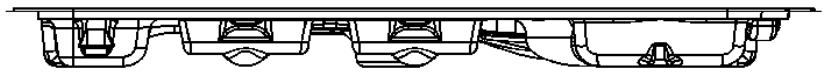


FIG. 14N

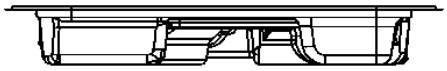


FIG. 140

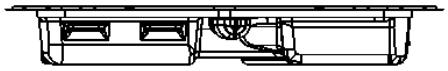


FIG. 14P

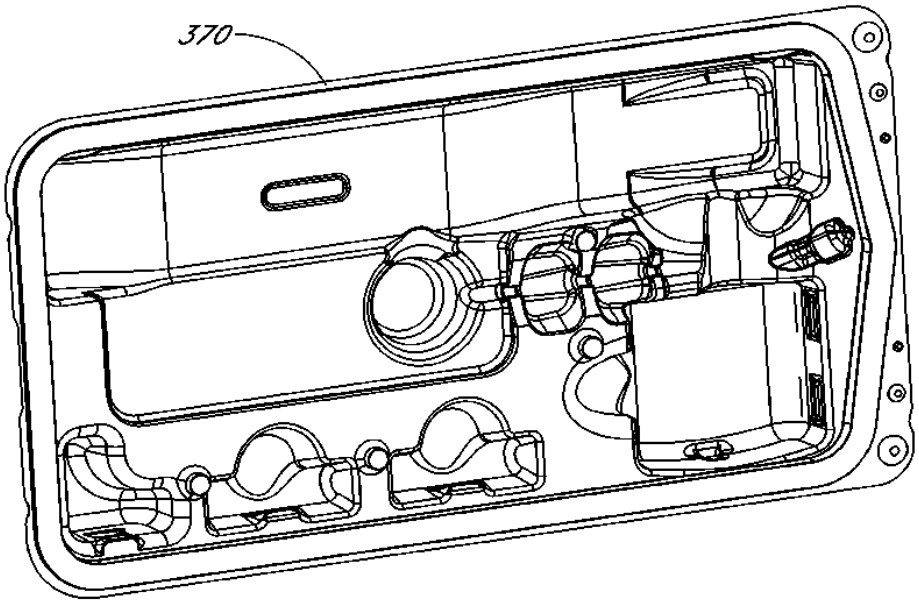


FIG. 15A

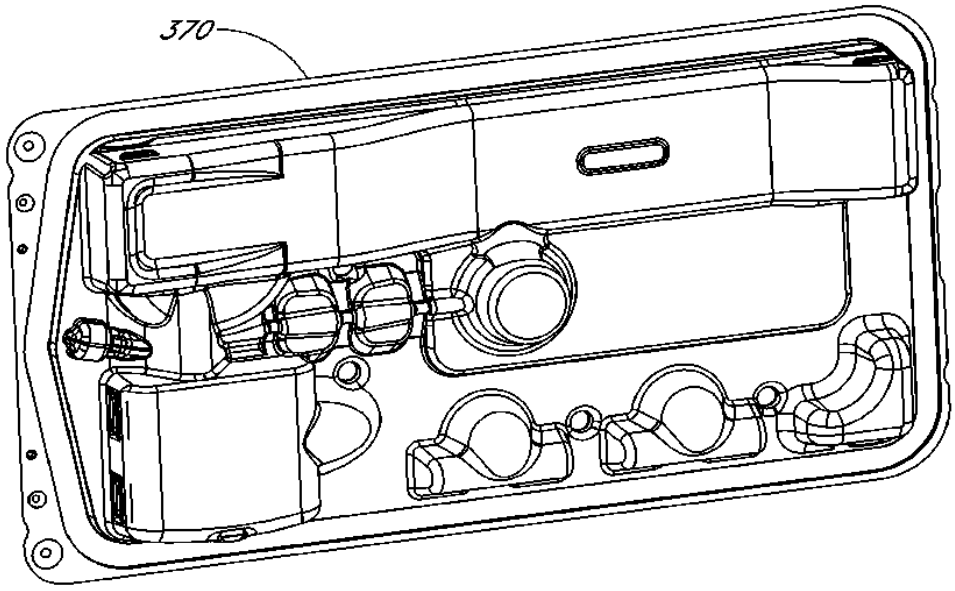


FIG. 15B

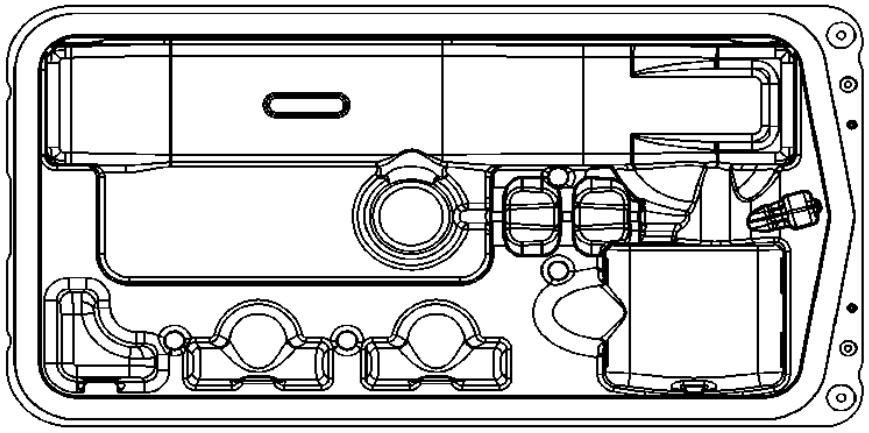


FIG. 15C

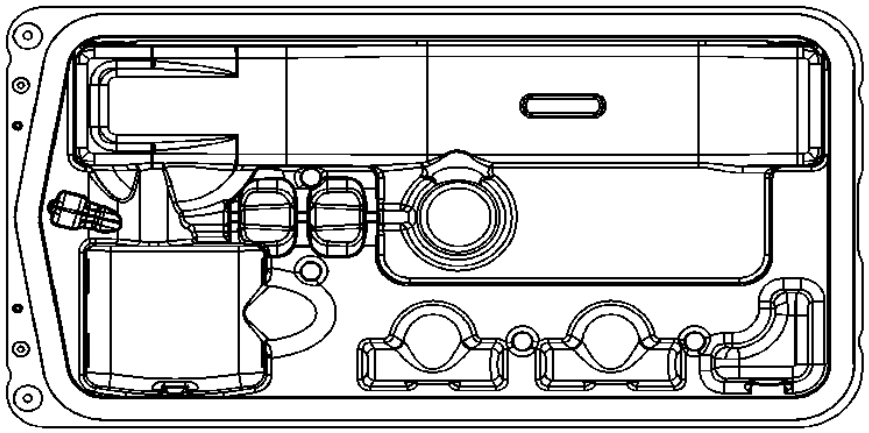


FIG. 15D



FIG. 15E

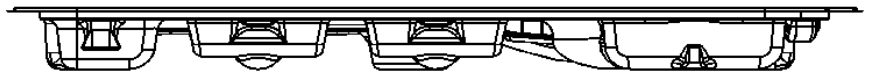


FIG. 15F



FIG. 15G

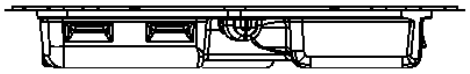


FIG. 15H

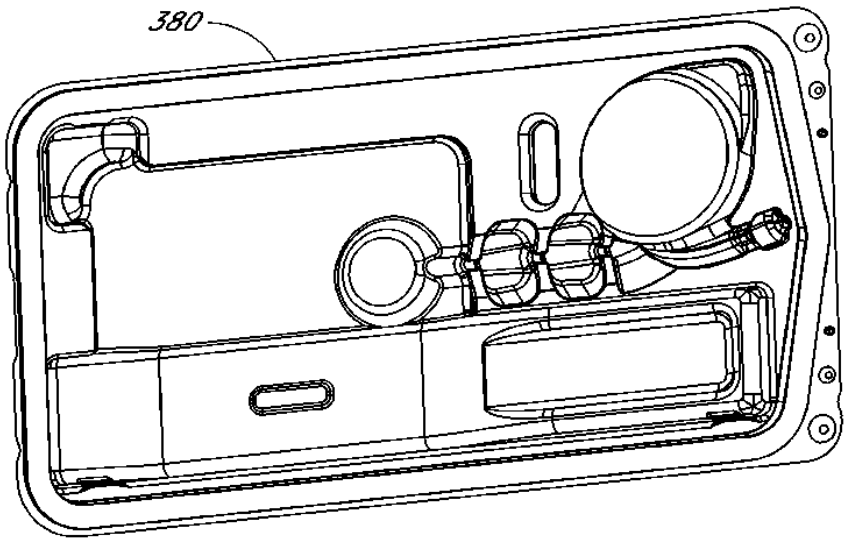


FIG. 16A

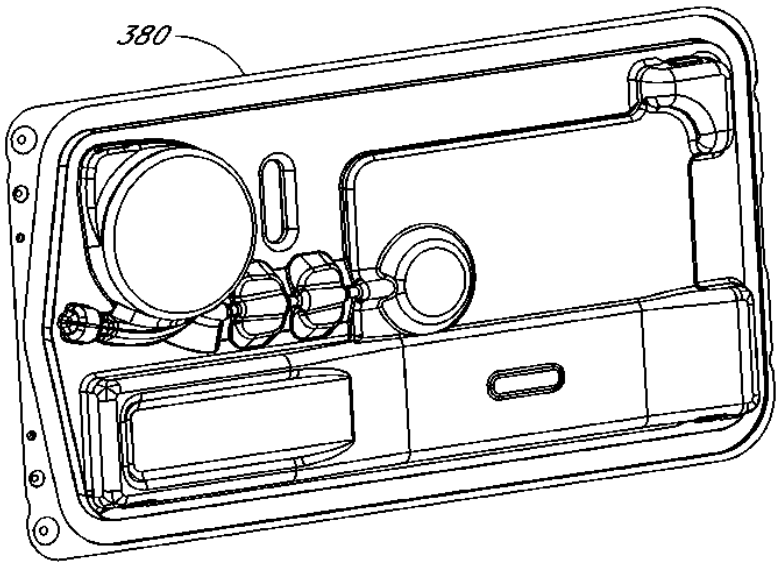


FIG. 16B

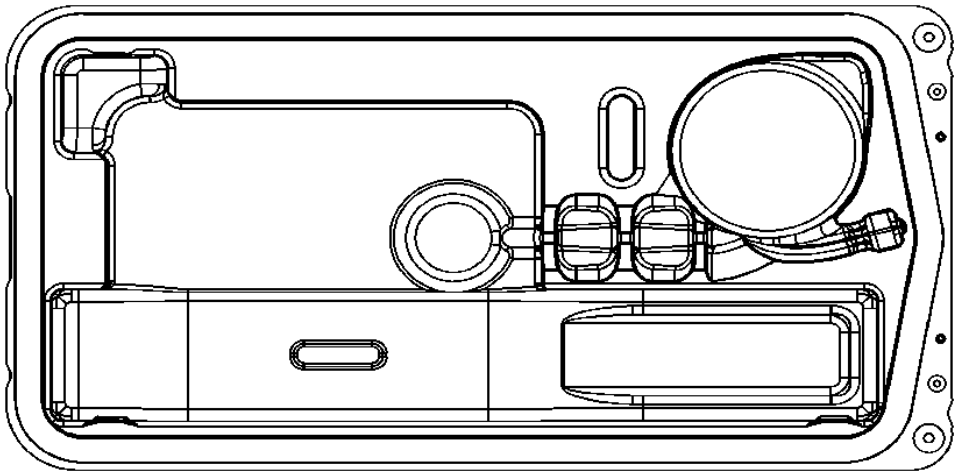


FIG. 16C

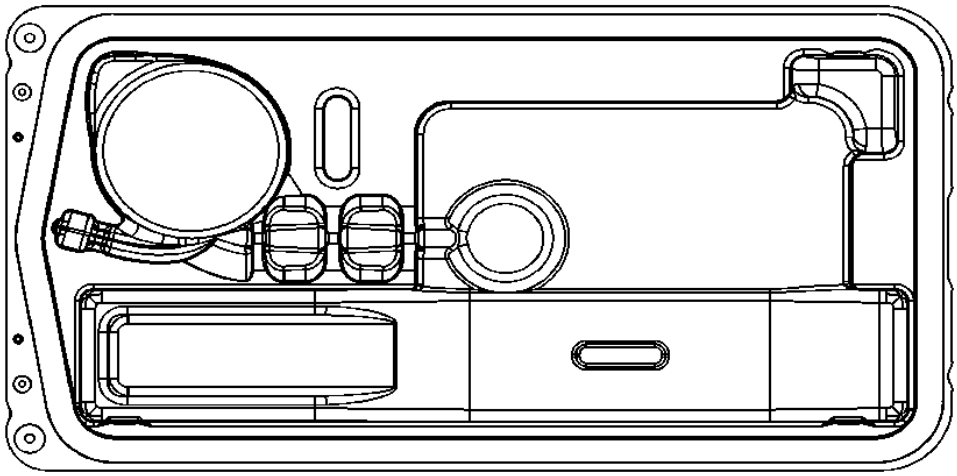


FIG. 16D



FIG. 16E



FIG. 16F



FIG. 16G



FIG. 16H

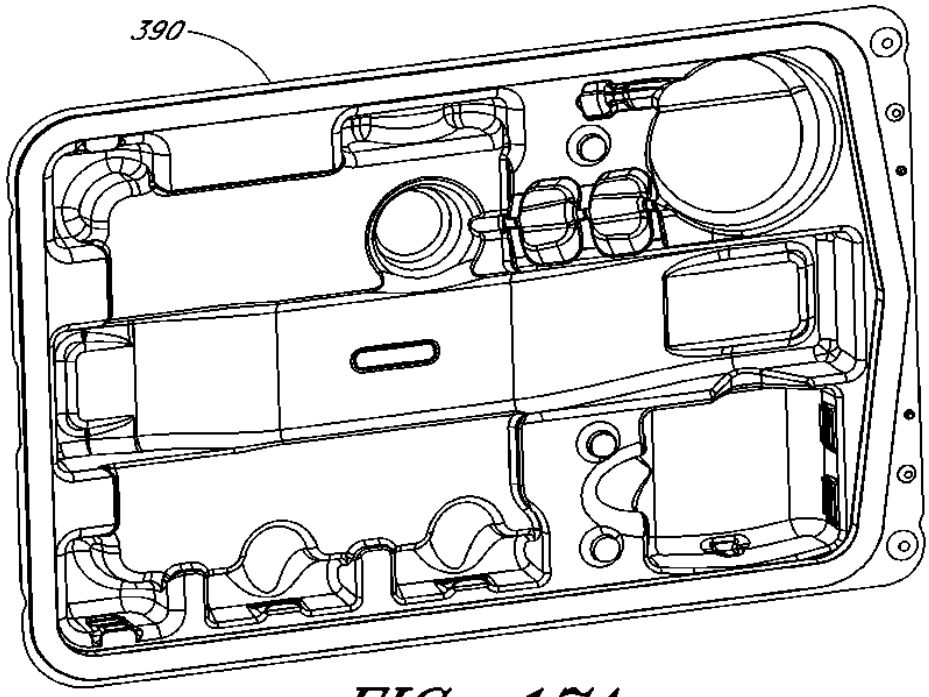


FIG. 17A

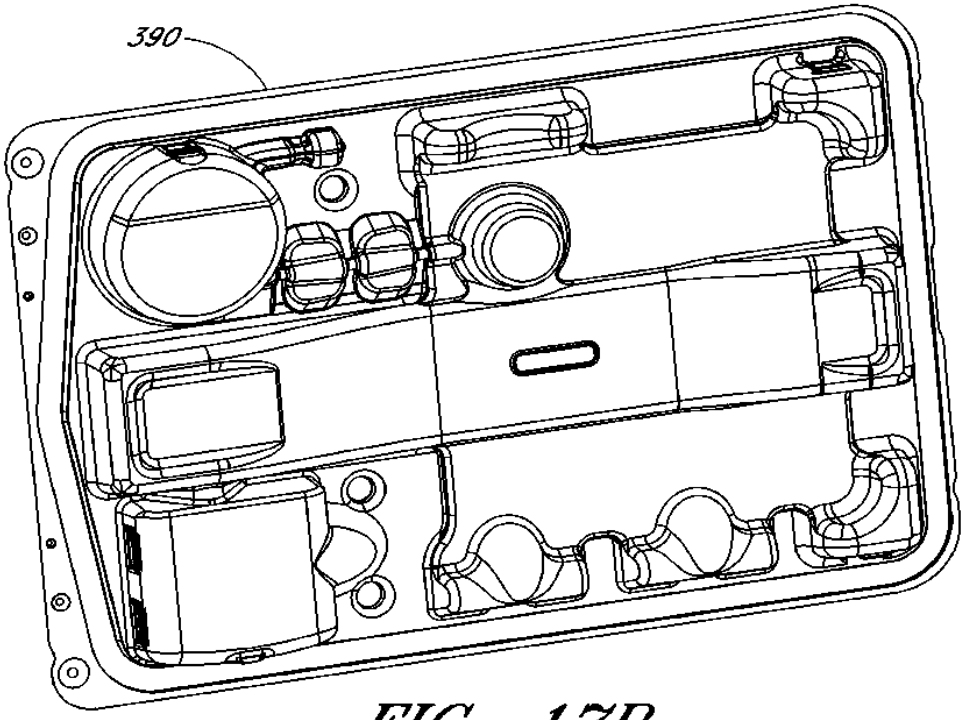


FIG. 17B

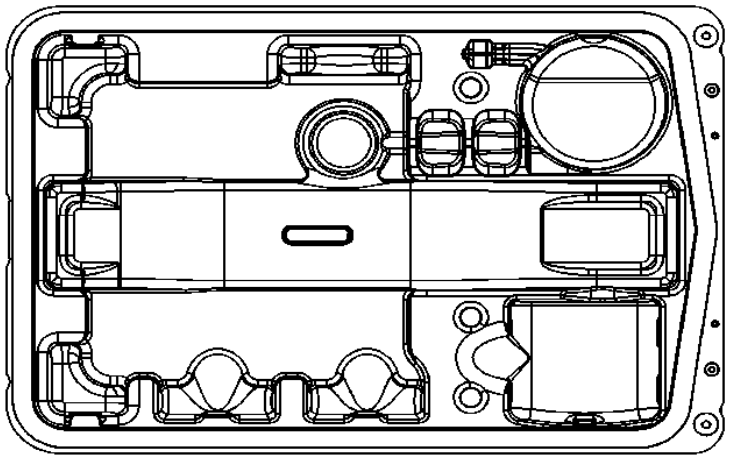


FIG. 17C

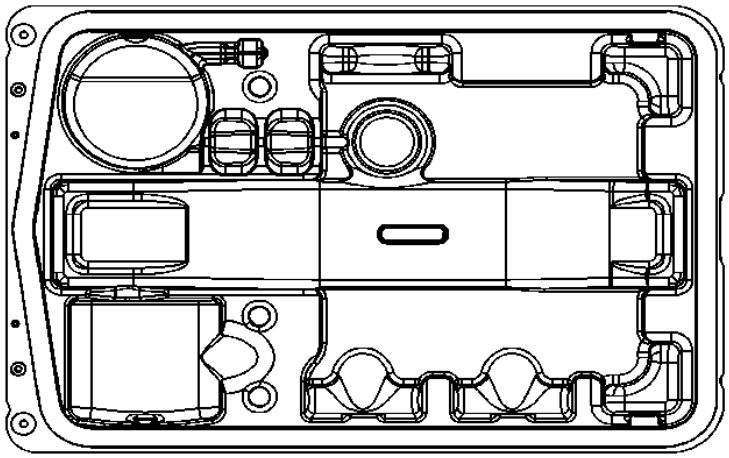


FIG. 17D



FIG. 17E

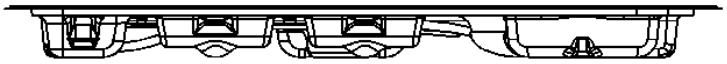


FIG. 17F



FIG. 17G



FIG. 17H

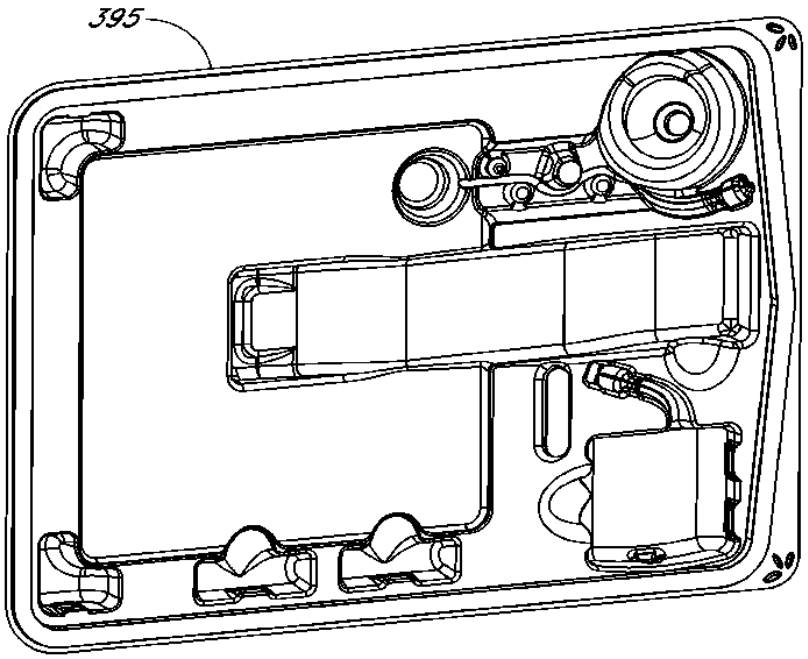


FIG. 17I

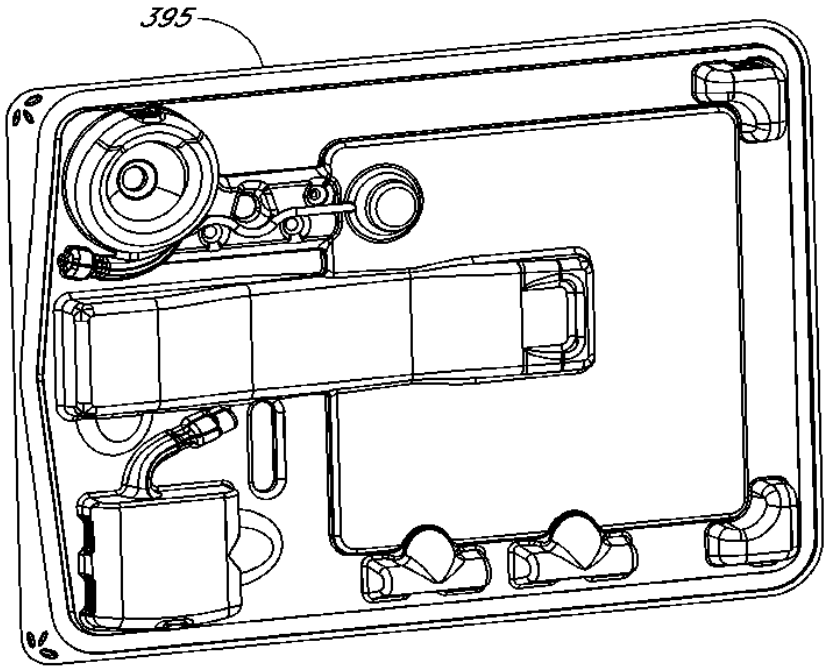


FIG. 17J

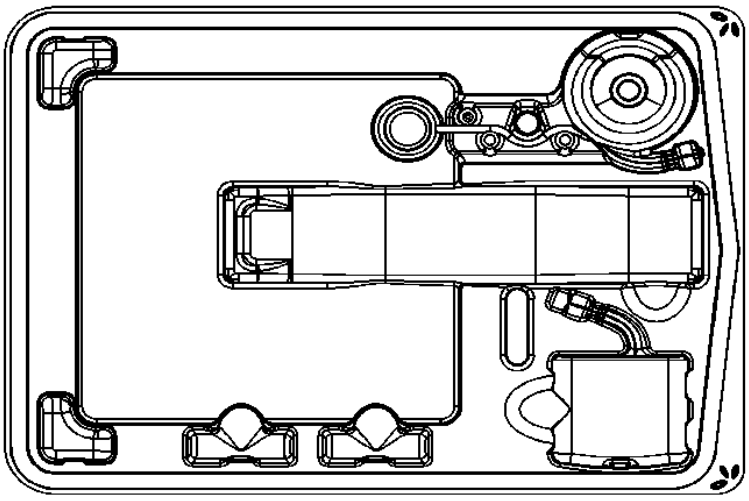


FIG. 17K

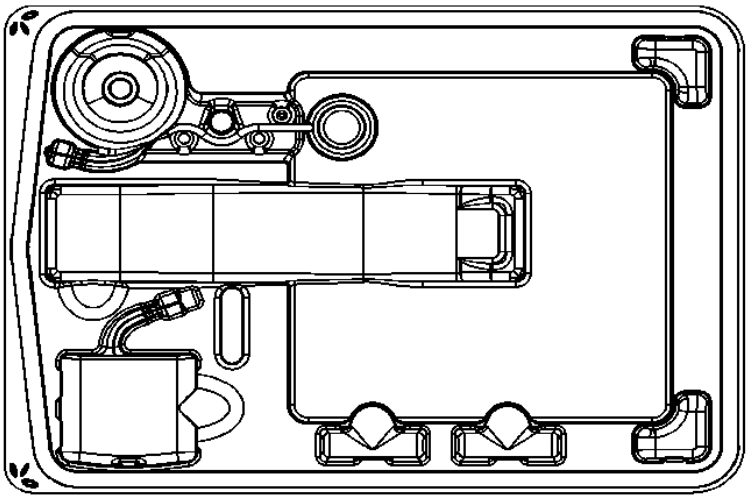


FIG. 17L



FIG. 17M



FIG. 17N



FIG. 17O



FIG. 17P

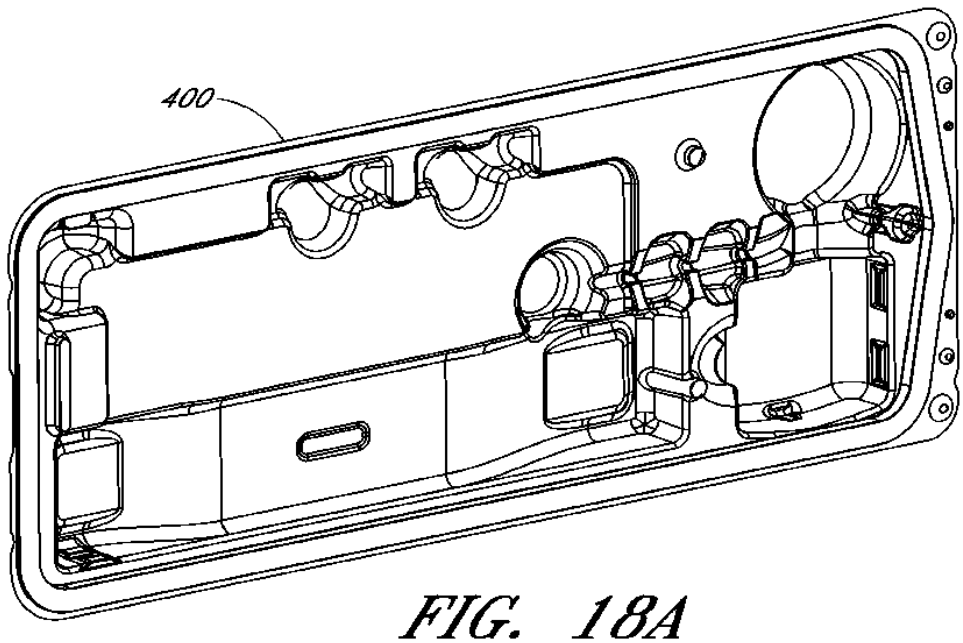


FIG. 18A

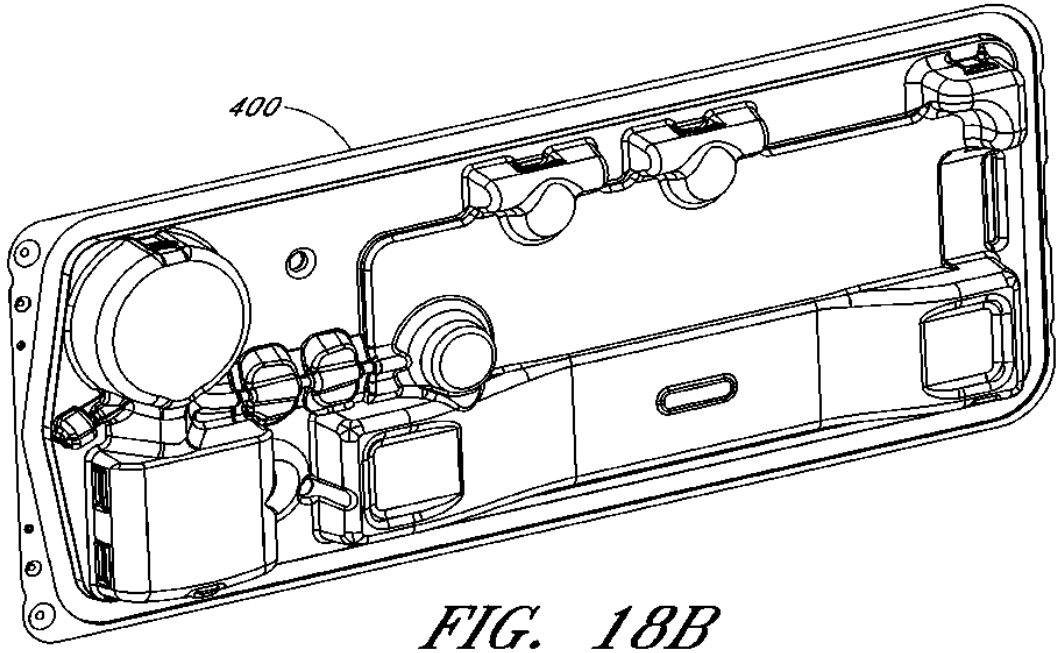


FIG. 18B

3

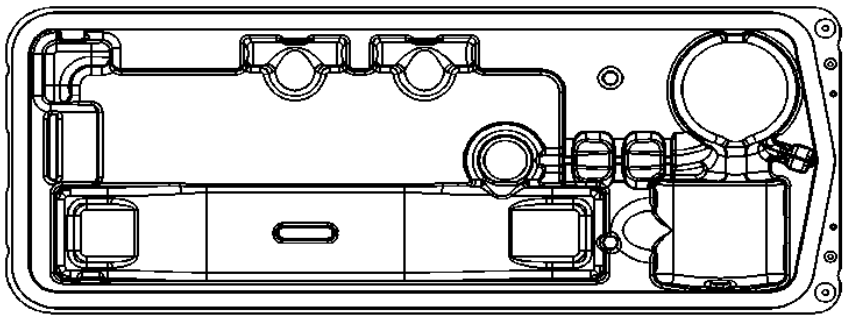


FIG. 18C

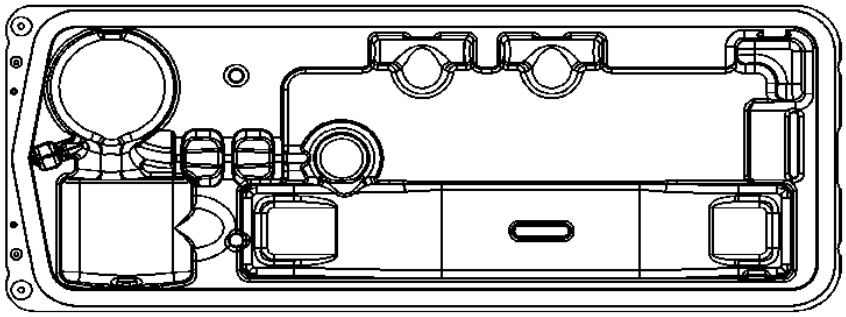


FIG. 18D



FIG. 18E



FIG. 18F



FIG. 18G



FIG. 18H

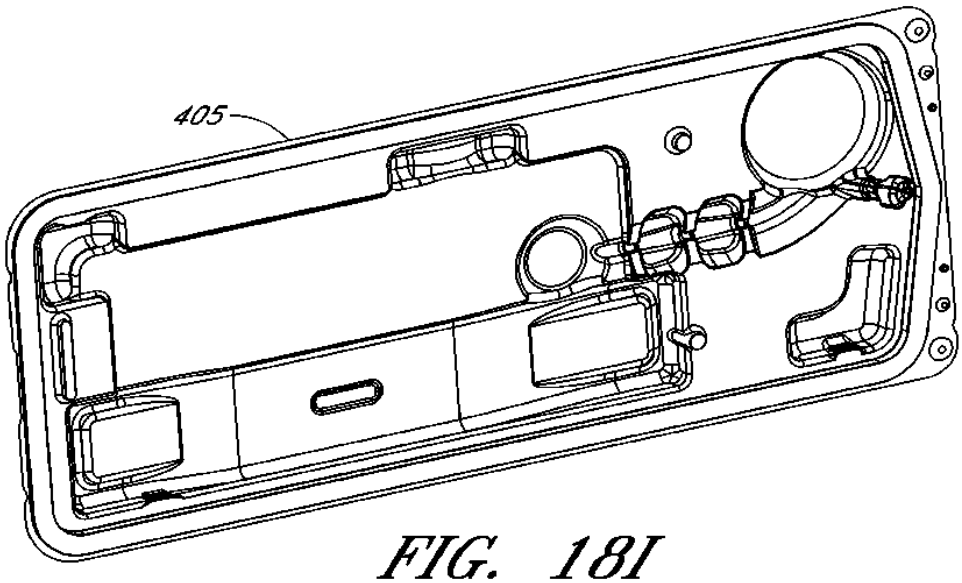


FIG. 18I

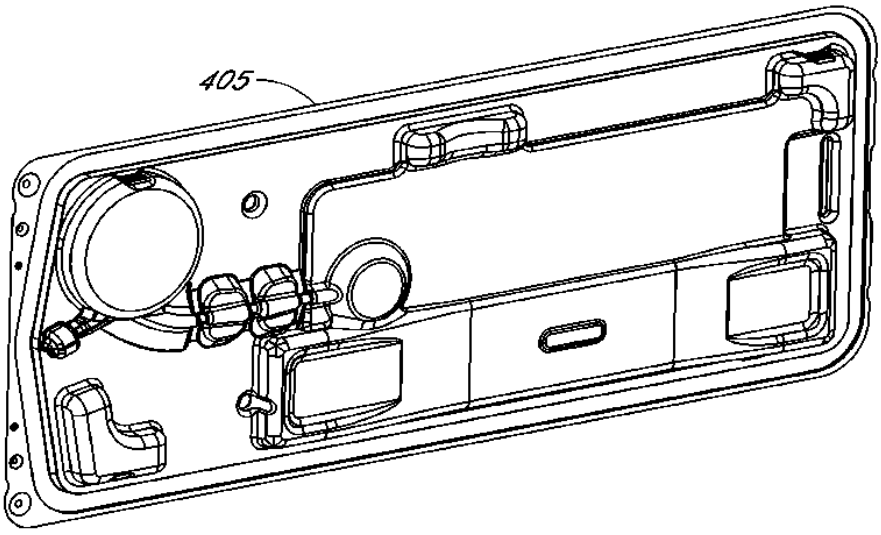


FIG. 18J

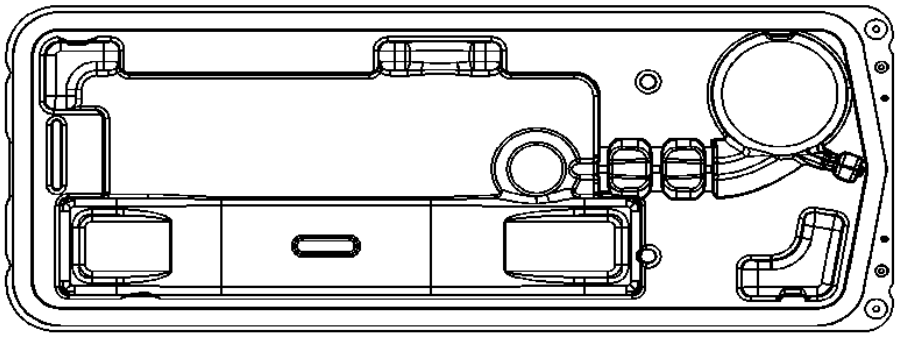


FIG. 18K

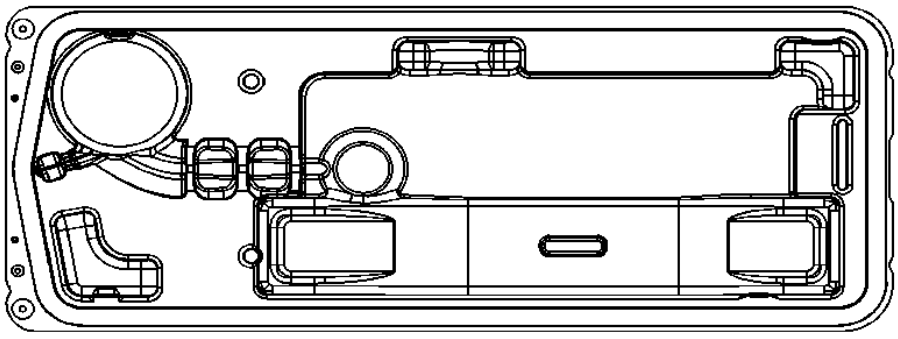


FIG. 18L



FIG. 18M

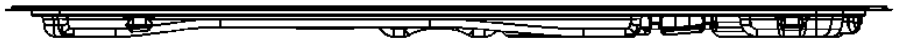


FIG. 18N



FIG. 180



FIG. 18P

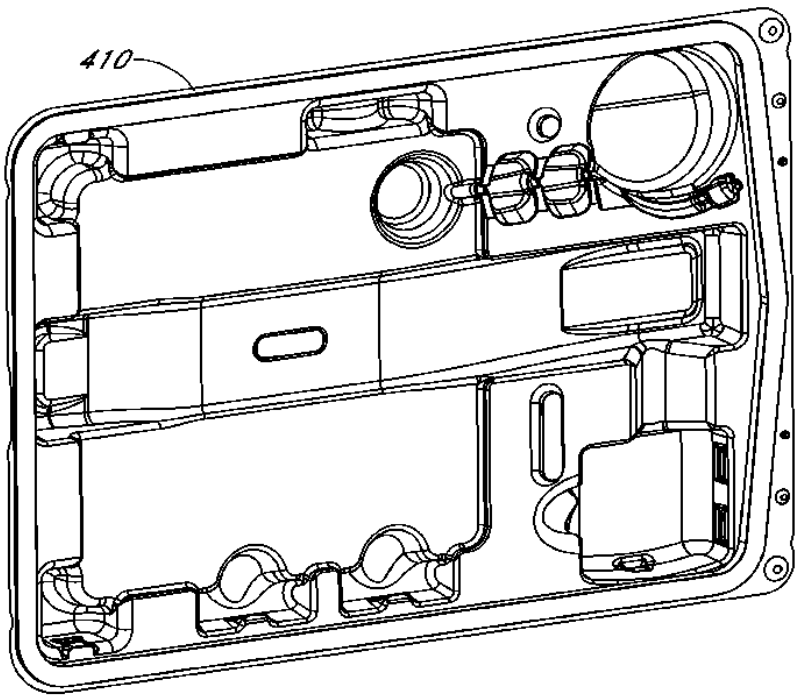


FIG. 19A

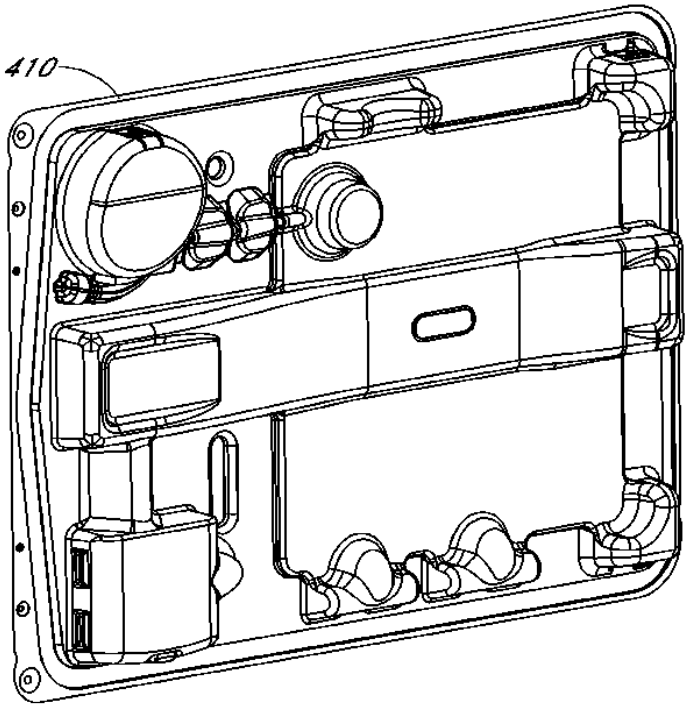


FIG. 19B

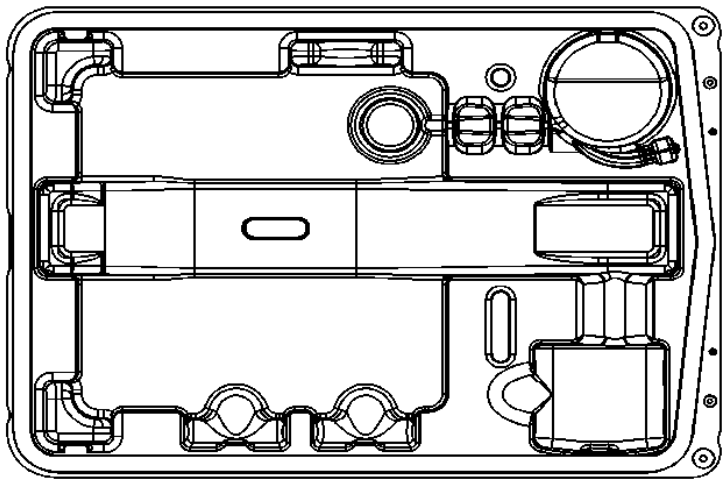


FIG. 19C

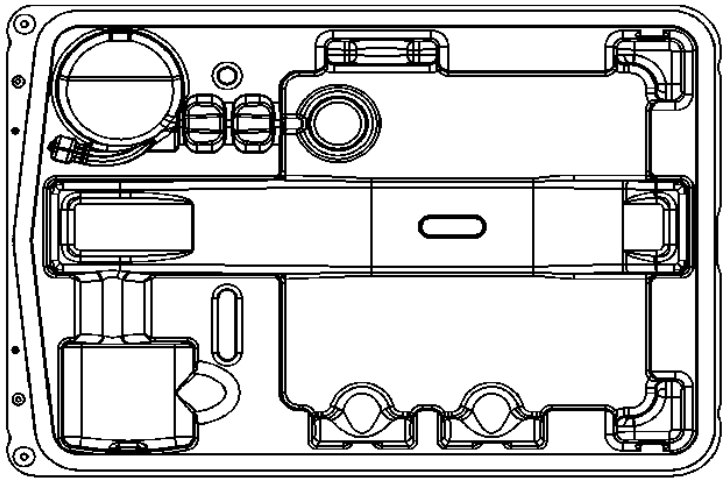


FIG. 19D



FIG. 19E



FIG. 19F

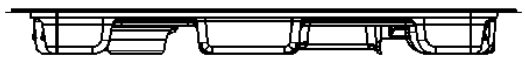


FIG. 19G

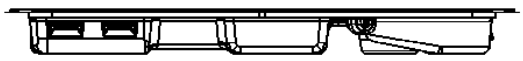


FIG. 19H

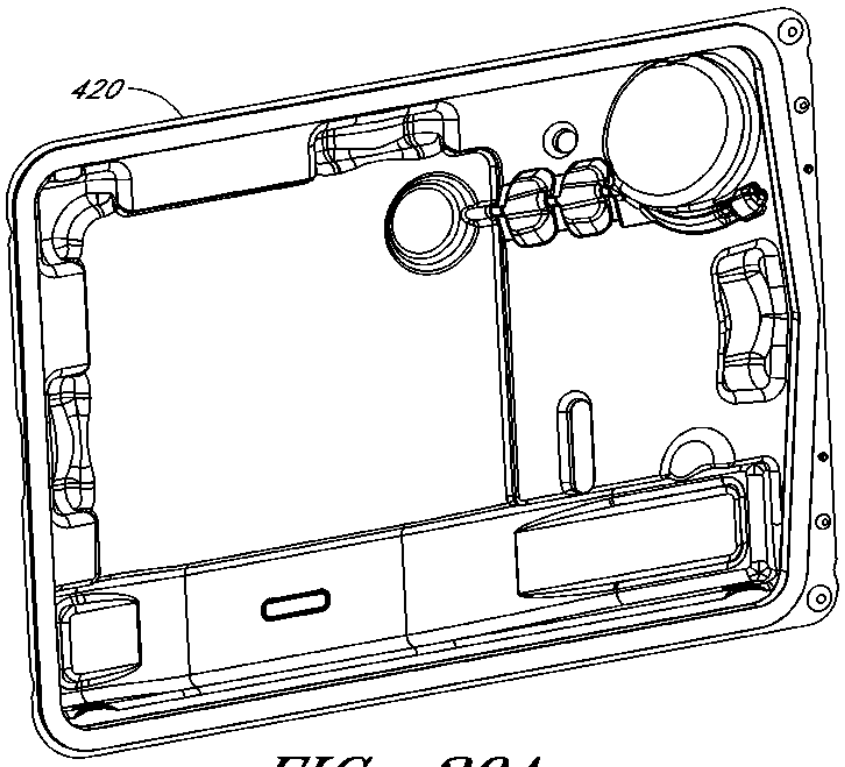


FIG. 20A

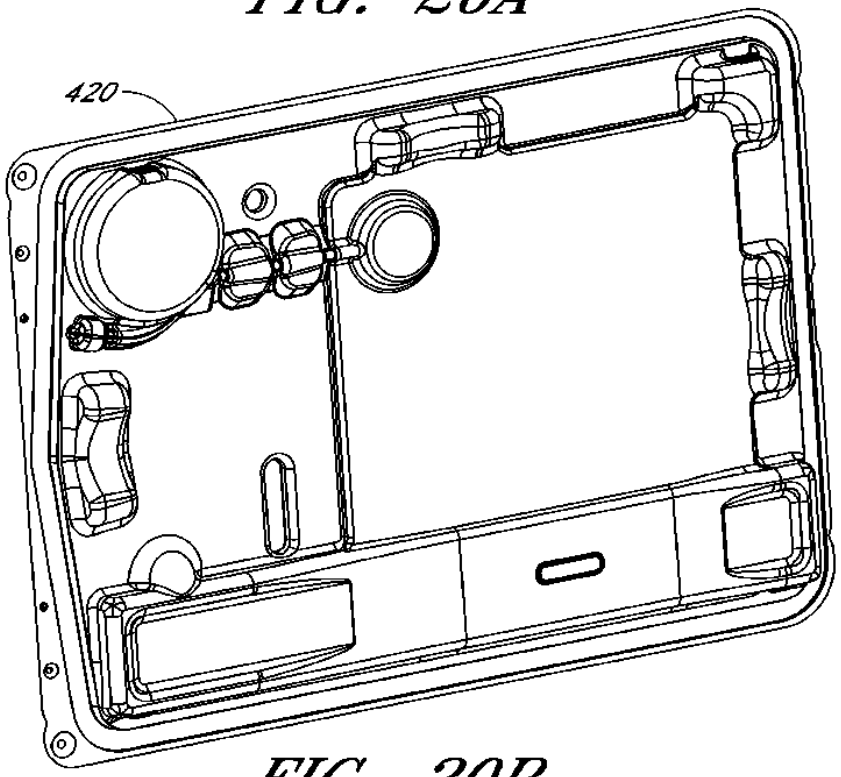


FIG. 20B

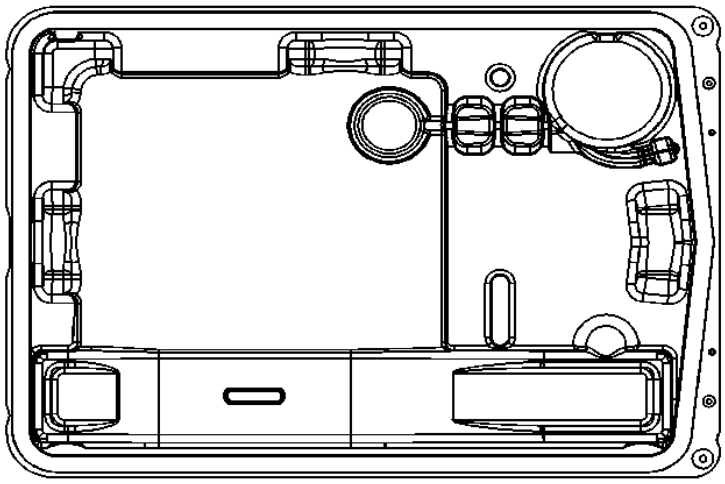


FIG. 20C

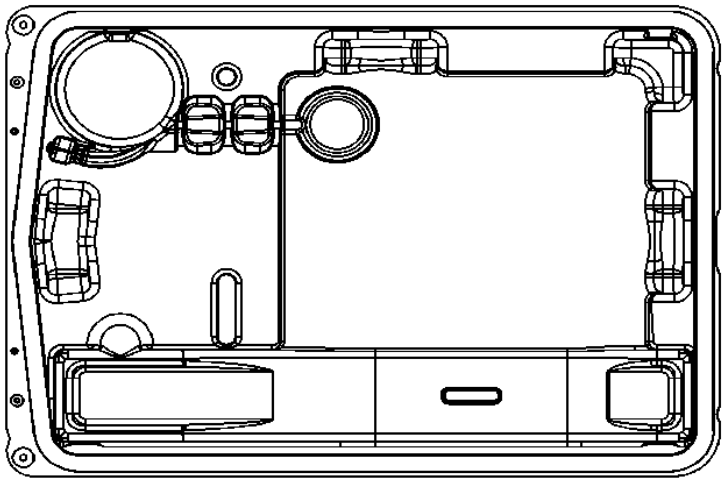


FIG. 20D



FIG. 20E

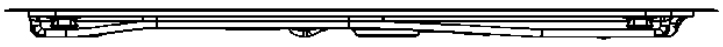


FIG. 20F



FIG. 20G
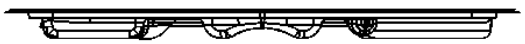


FIG. 20H

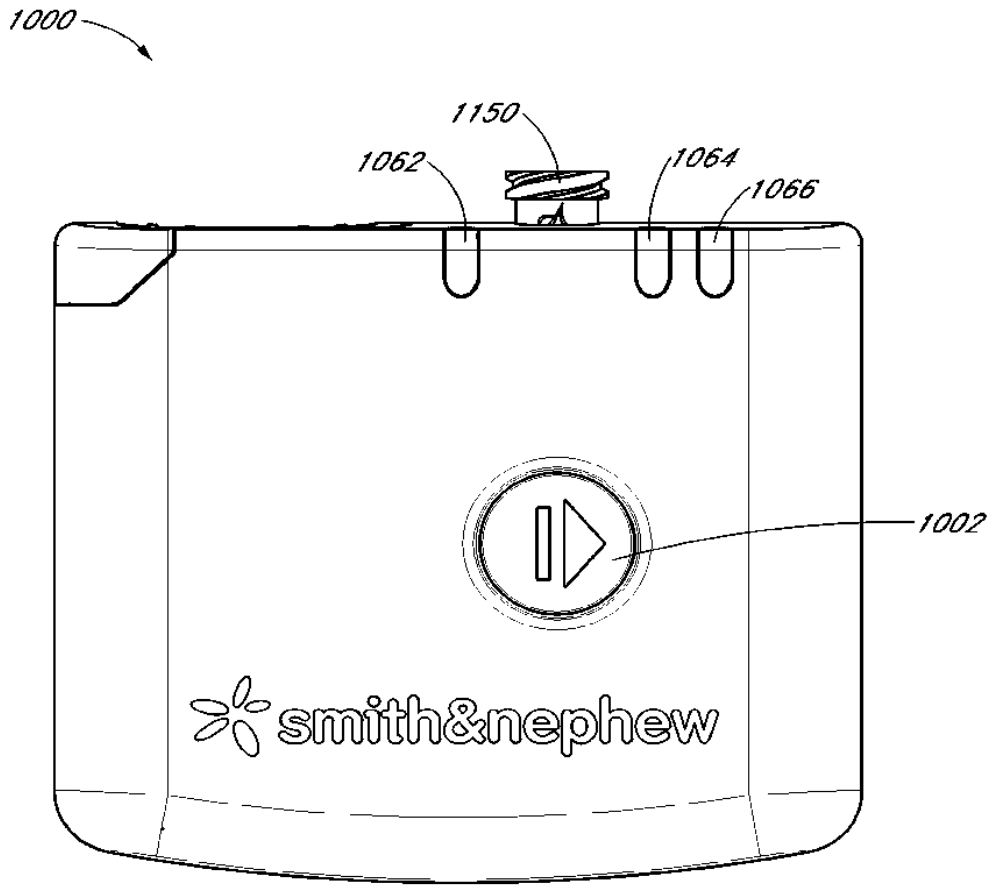


FIG. 21

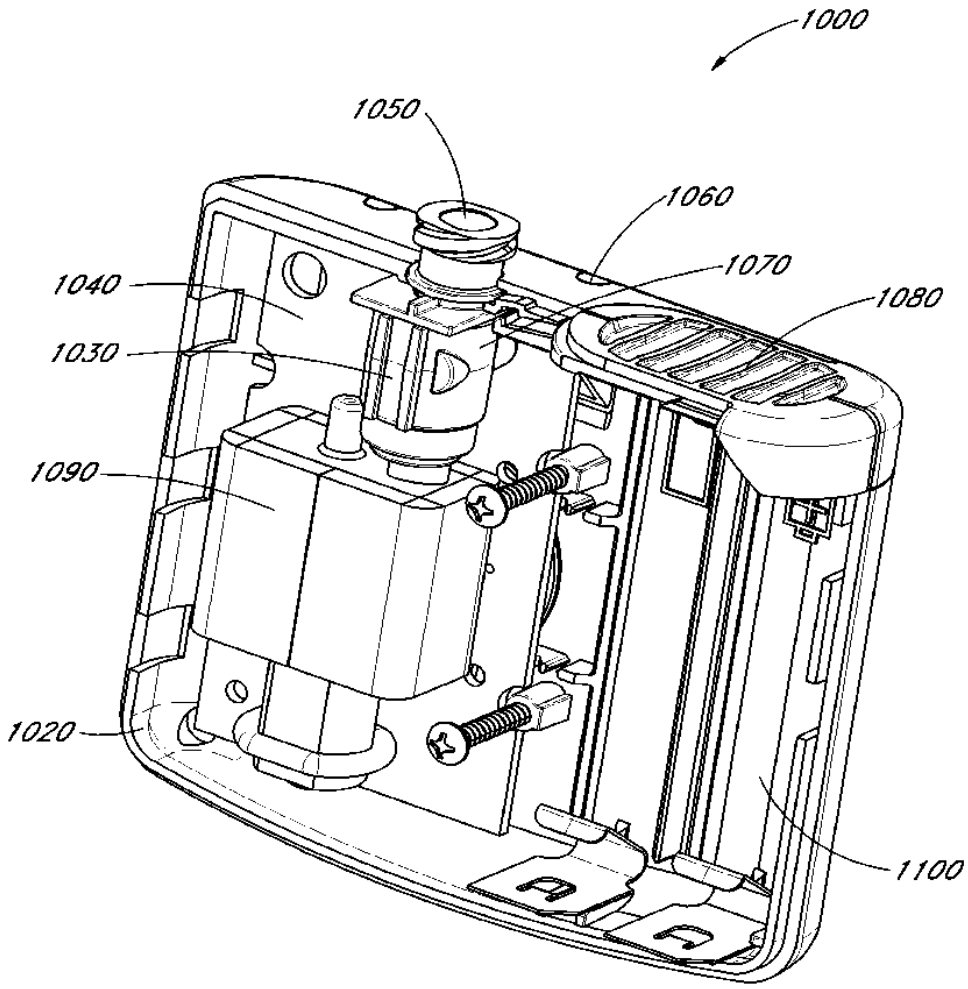


FIG. 22

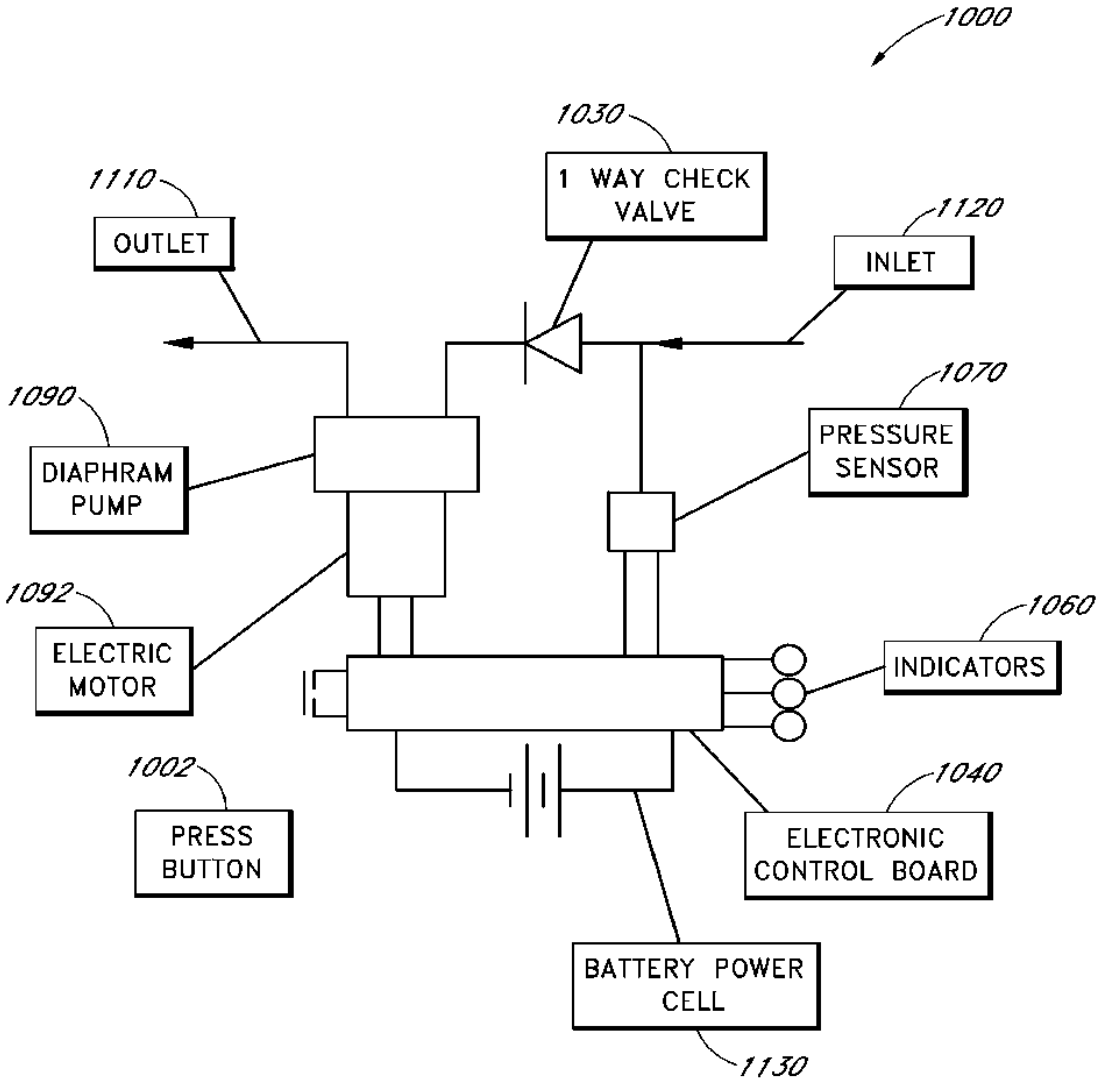

1000
1030
1 WAY CHECK VALVE
1110
OUTLET
1120
INLET
1090
DIAPHRAM PUMP
1070
PRESSURE SENSOR
1092
ELECTRIC MOTOR
1060
INDICATORS
1002
PRESS BUTTON
1040
ELECTRONIC CONTROL BOARD
BATTERY POWER CELL
1130

FIG. 23

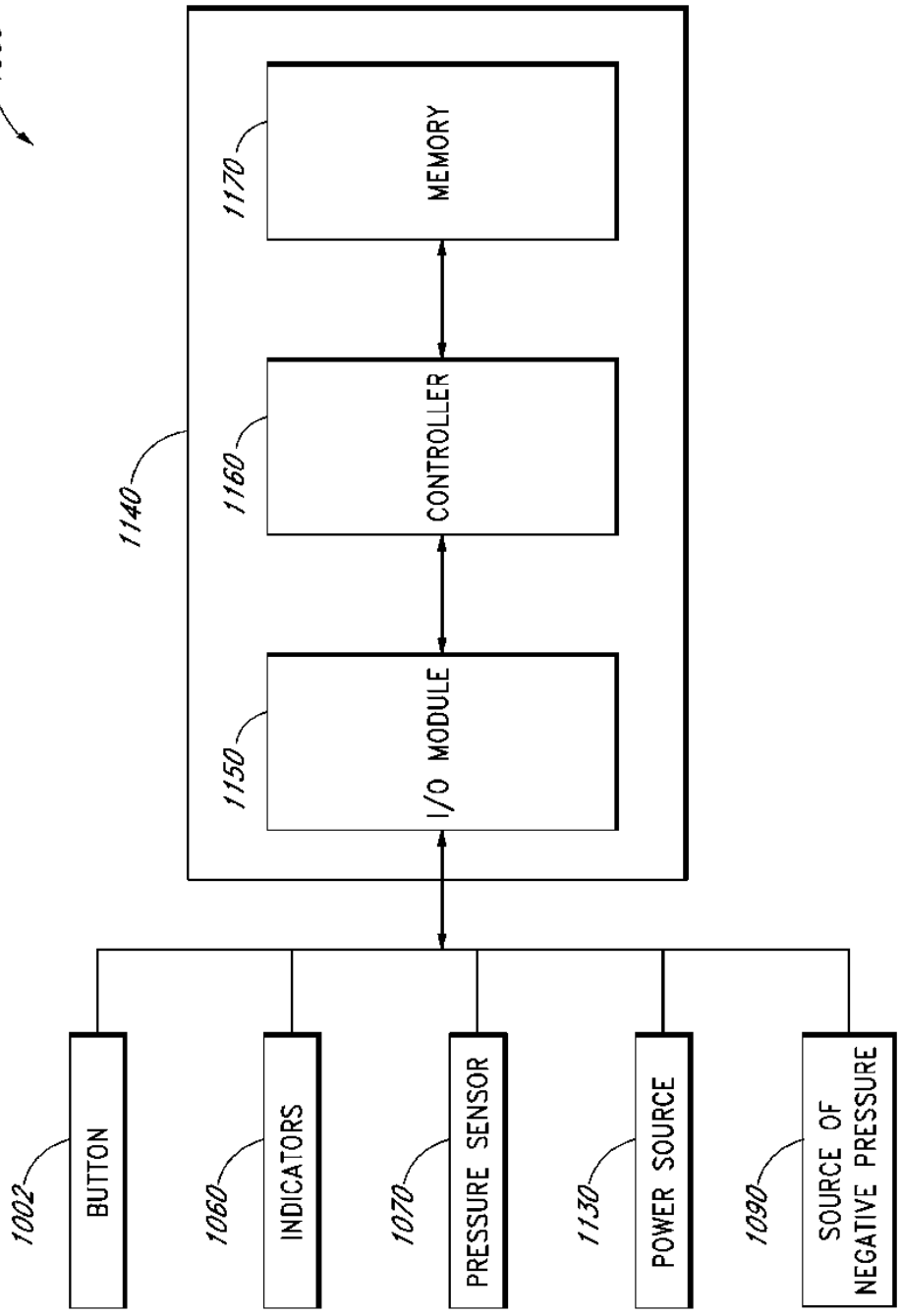

1000
1140
1170
MEMORY
1160
CONTROLLER
1150
I/O MODULE
1002
BUTTON
1060
INDICATORS
1070
PRESSURE SENSOR
1130
POWER SOURCE
1090
SOURCE OF NEGATIVE PRESSURE

FIG. 24

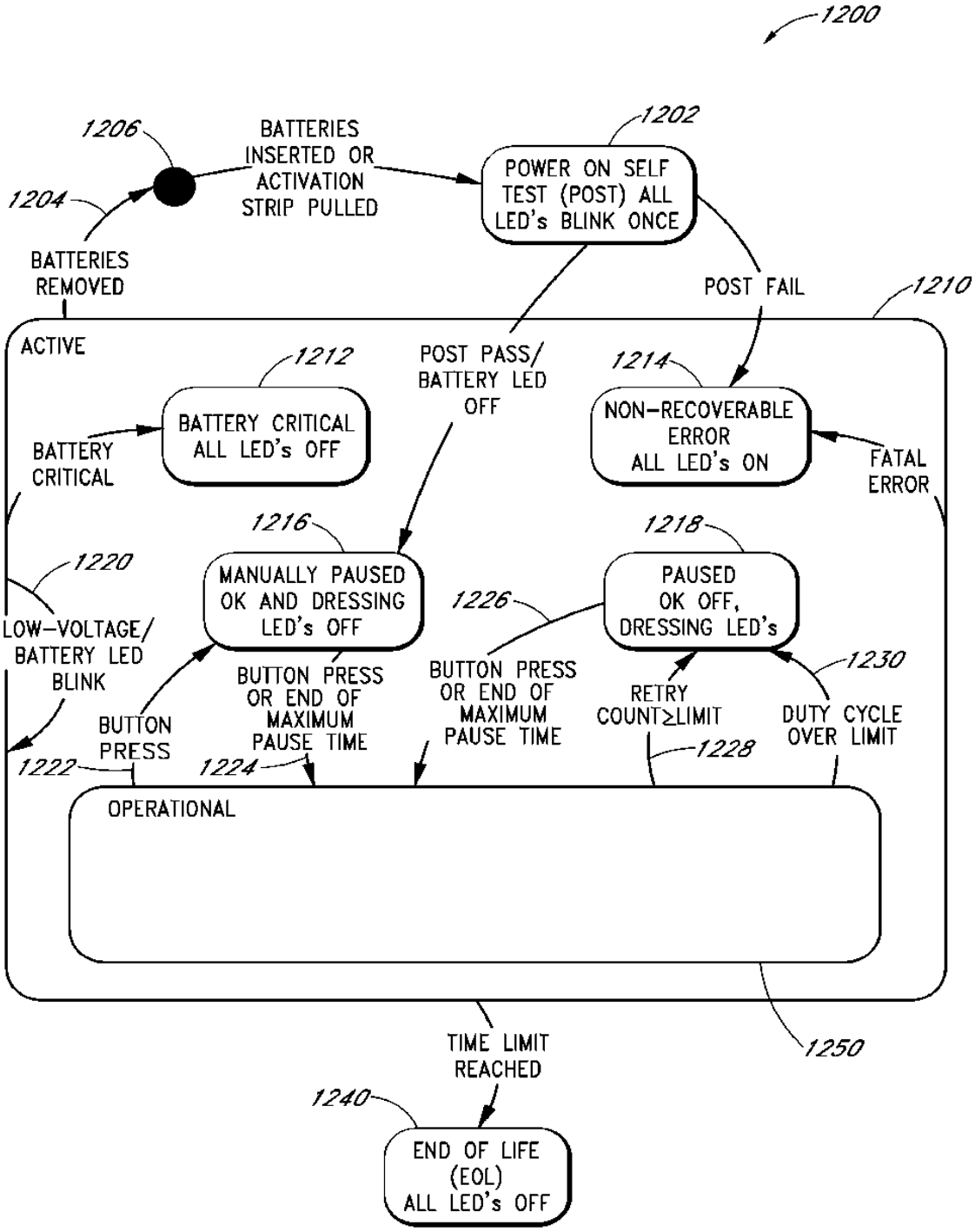

1200
1206
BATTERIES INSERTED OR ACTIVATION STRIP PULLED
1202
POWER ON SELF TEST (POST) ALL LED's BLINK ONCE
1204
BATTERIES REMOVED
POST FAIL
1210
ACTIVE
1212
BATTERY CRITICAL ALL LED's OFF
POST PASS/ BATTERY LED OFF
1214
NON-RECOVERABLE ERROR ALL LED's ON
BATTERY CRITICAL
FATAL ERROR
1216
MANUALLY PAUSED OK AND DRESSING LED's OFF
1218
PAUSED OK OFF, DRESSING LED's
1220
LOW-VOLTAGE/ BATTERY LED BLINK
1226
BUTTON PRESS OR END OF MAXIMUM PAUSE TIME
1230
RETRY COUNT≥LIMIT
DUTY CYCLE OVER LIMIT
BUTTON PRESS
BUTTON PRESS OR END OF MAXIMUM PAUSE TIME
1222
1224
1228
OPERATIONAL
1250
TIME LIMIT REACHED
1240
END OF LIFE (EOL) ALL LED's OFF

FIG. 25

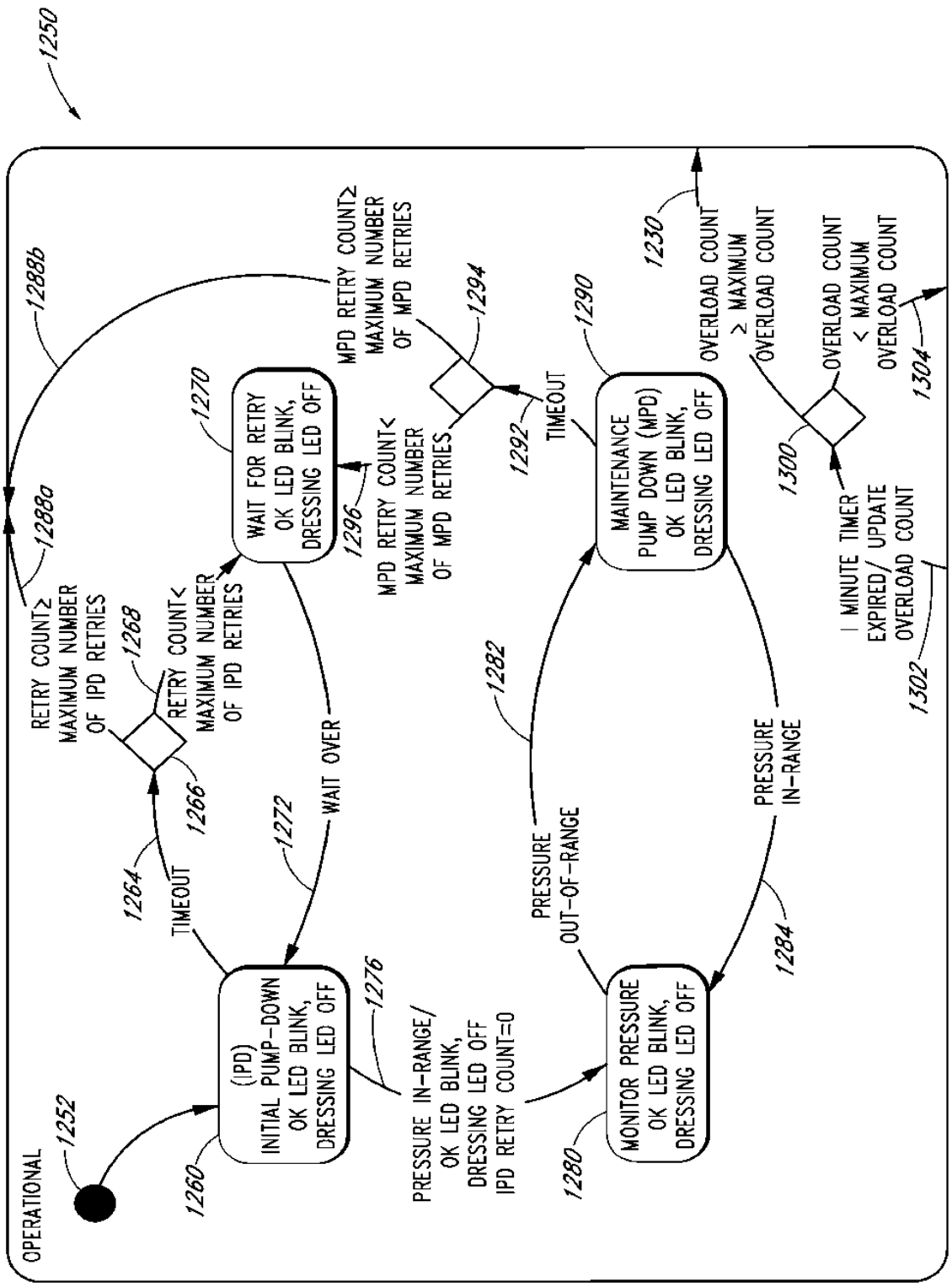

1250
OPERATIONAL
1252
(IPD)
INITIAL PUMP-DOWN
OK LED BLINK,
DRESSING LED OFF
1260
1276
PRESSURE IN-RANGE/
OK LED BLINK,
DRESSING LED OFF
IPD RETRY COUNT=0
1264
TIMEOUT
1266
RETRY COUNT≥
MAXIMUM NUMBER
OF IPD RETRIES
1268
RETRY COUNT<
MAXIMUM NUMBER
OF IPD RETRIES
1272
WAIT OVER
1270
WAIT FOR RETRY
OK LED BLINK,
DRESSING LED OFF
1296
MPD RETRY COUNT<
MAXIMUM NUMBER
OF MPD RETRIES
1294
MPD RETRY COUNT≥
MAXIMUM NUMBER
OF MPD RETRIES
1292
TIMEOUT
1290
MAINTENANCE
PUMP DOWN (MPD)
OK LED BLINK,
DRESSING LED OFF
1230
OVERLOAD COUNT
≥ MAXIMUM
OVERLOAD COUNT
1300
1 MINUTE TIMER
EXPIRED/ UPDATE
OVERLOAD COUNT
1302
OVERLOAD COUNT
< MAXIMUM
OVERLOAD COUNT
1304
1282
PRESSURE
OUT-OF-RANGE
1284
PRESSURE
IN-RANGE
1280
MONITOR PRESSURE
OK LED BLINK,
DRESSING LED OFF
12880
12886

FIG. 26

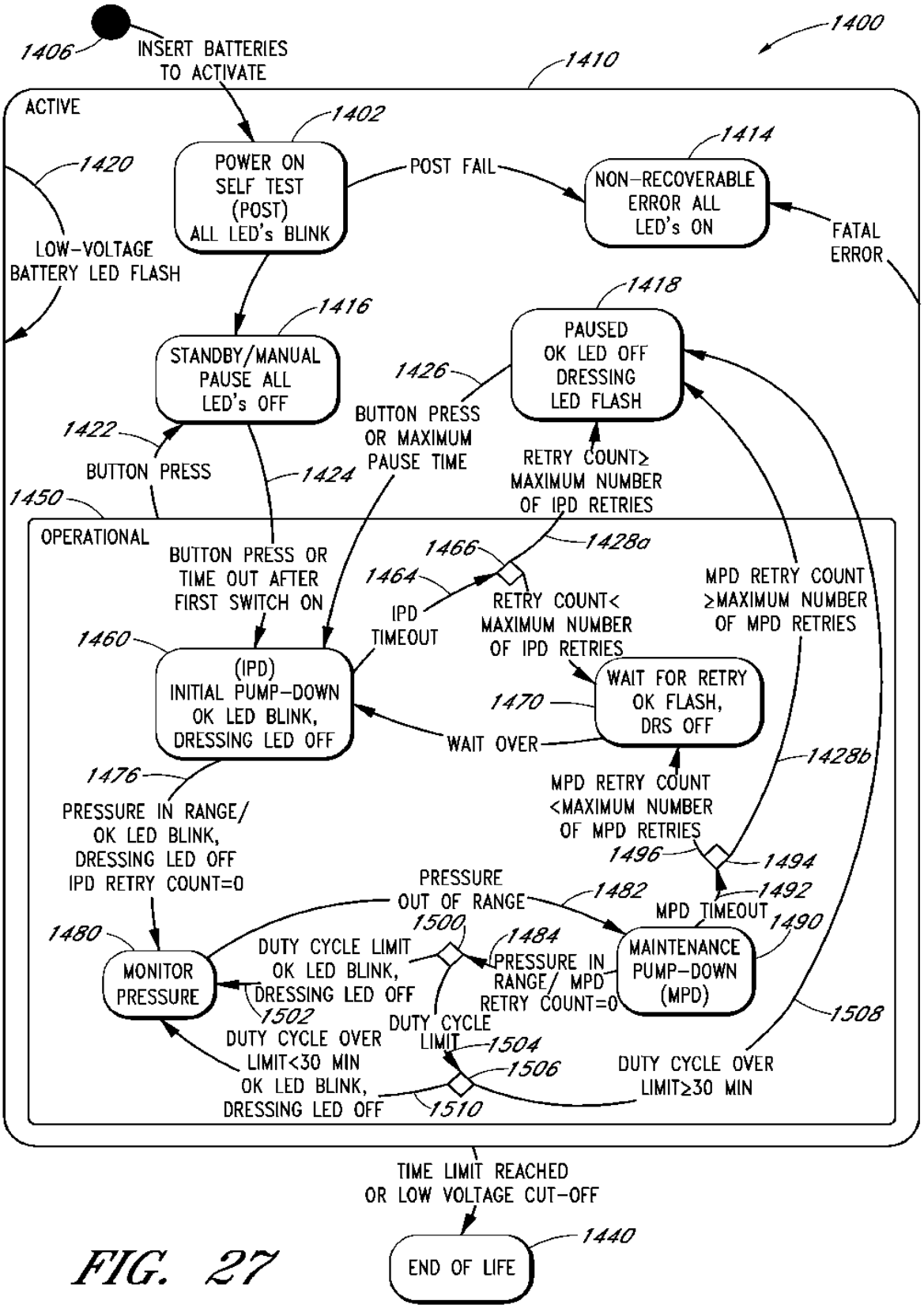

1406
INSERT BATTERIES TO ACTIVATE
1400
1410
ACTIVE
1402
POWER ON SELF TEST (POST) ALL LED's BLINK
POST FAIL
1414
NON-RECOVERABLE ERROR ALL LED's ON
FATAL ERROR
1420
LOW-VOLTAGE BATTERY LED FLASH
1416
STANDBY/MANUAL PAUSE ALL LED's OFF
1418
PAUSED OK LED OFF DRESSING LED FLASH
1426
BUTTON PRESS OR MAXIMUM PAUSE TIME
1422
BUTTON PRESS
1424
RETRY COUNT≥ MAXIMUM NUMBER OF IPD RETRIES
1450
OPERATIONAL
BUTTON PRESS OR TIME OUT AFTER FIRST SWITCH ON
1466
1428a
1464
IPD TIMEOUT
RETRY COUNT< MAXIMUM NUMBER OF IPD RETRIES
MPD RETRY COUNT ≥MAXIMUM NUMBER OF MPD RETRIES
1460
(IPD) INITIAL PUMP-DOWN OK LED BLINK, DRESSING LED OFF
1470
WAIT FOR RETRY OK FLASH, DRS OFF
WAIT OVER
1428b
1476
PRESSURE IN RANGE/ OK LED BLINK, DRESSING LED OFF IPD RETRY COUNT=0
MPD RETRY COUNT <MAXIMUM NUMBER OF MPD RETRIES
1496
1494
PRESSURE OUT OF RANGE
1482
1492
MPD TIMEOUT
1490
1500
1480
DUTY CYCLE LIMIT OK LED BLINK, DRESSING LED OFF
1484
PRESSURE IN RANGE/ MPD RETRY COUNT=0
MAINTENANCE PUMP-DOWN (MPD)
MONITOR PRESSURE
1502
1508
DUTY CYCLE LIMIT
1504
DUTY CYCLE OVER LIMIT<30 MIN OK LED BLINK, DRESSING LED OFF
1506
DUTY CYCLE OVER LIMIT≥30 MIN
1510
TIME LIMIT REACHED OR LOW VOLTAGE CUT-OFF
1440
END OF LIFE

FIG. 27

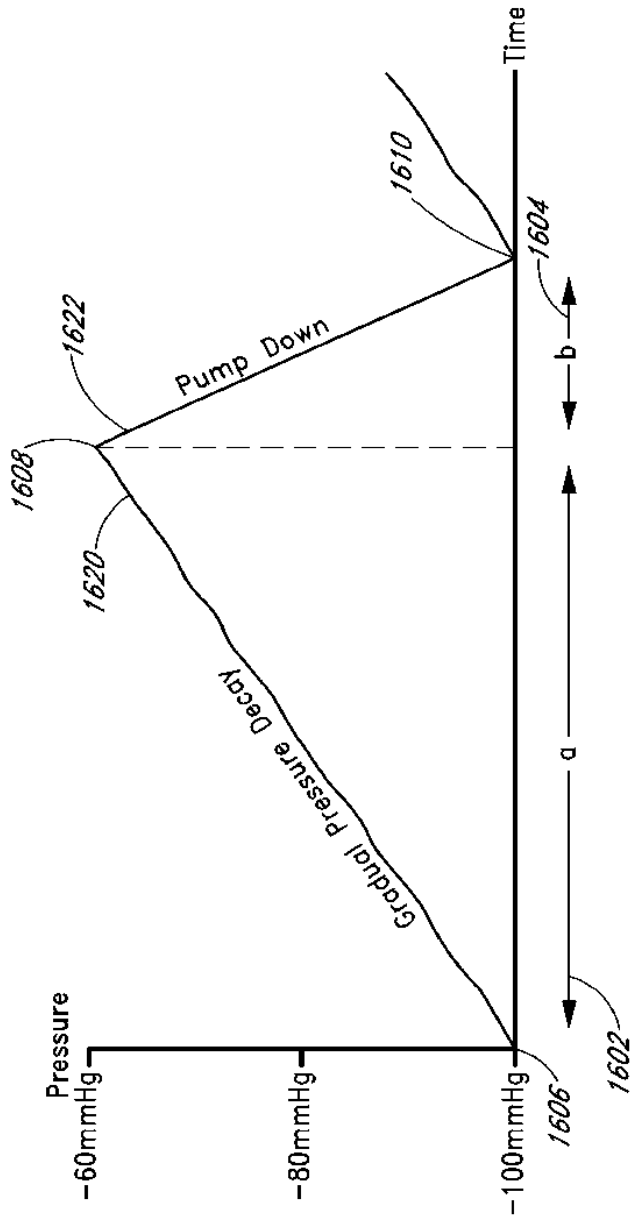

1600
Time
1610
1604
b
1622
Pump Down
1608
1620
Gradual Pressure Decay
a
Pressure
-60mmHg
-80mmHg
-100mmHg
1606
1602

FIG. 28

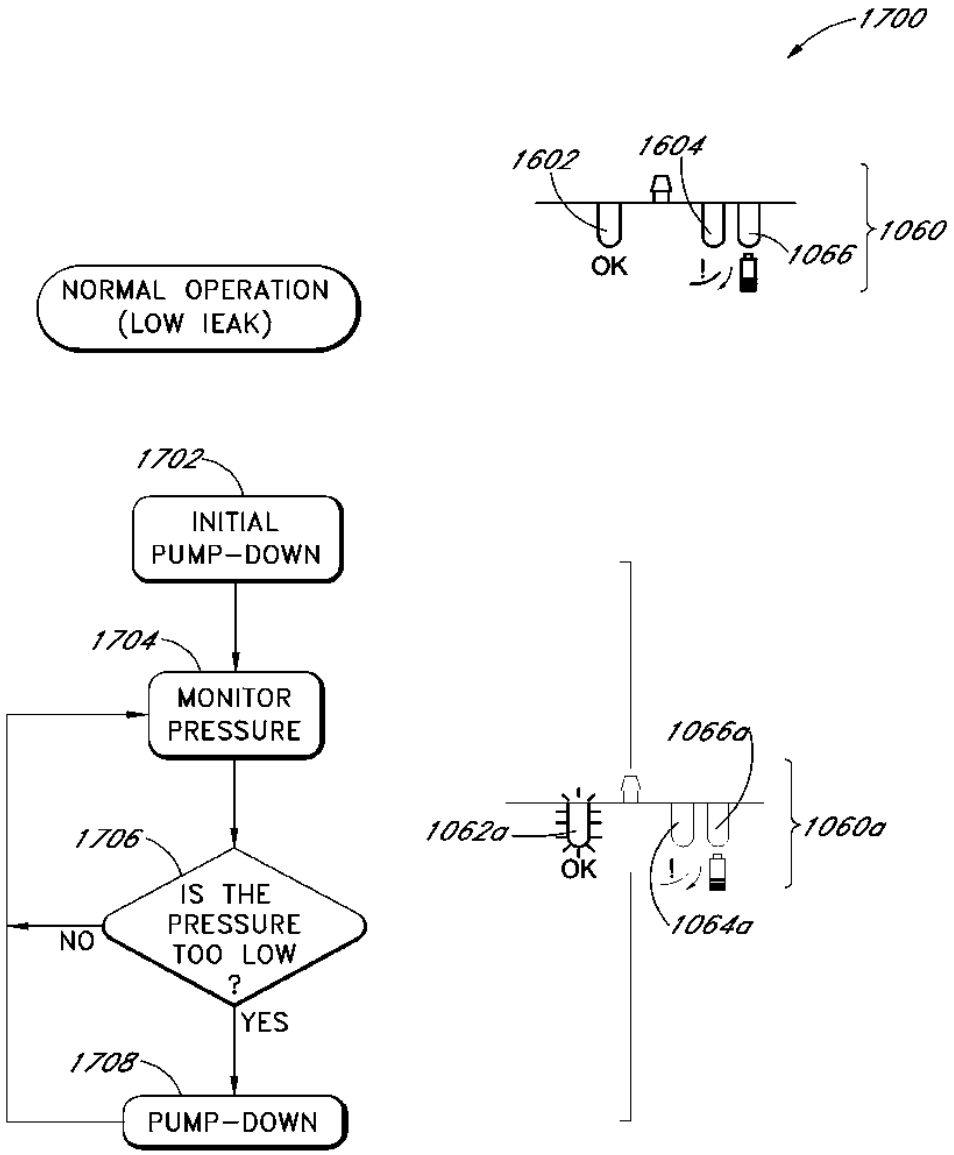
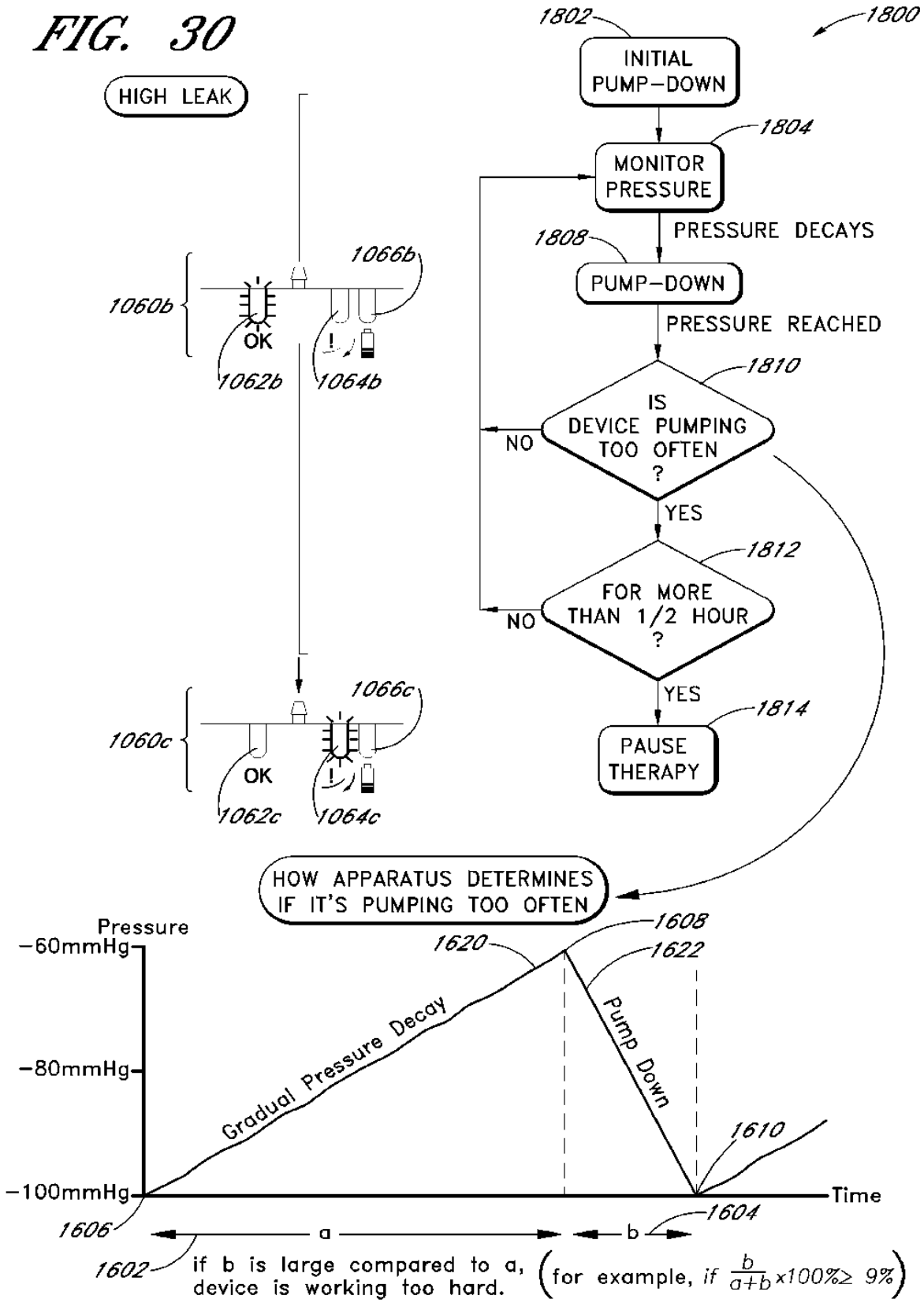

1700
1602
1604
1066
1060
OK
NORMAL OPERATION
(LOW IEAK)
1702
INITIAL
PUMP-DOWN
1704
MONITOR
PRESSURE
1706
IS THE
PRESSURE
TOO LOW
?
NO
YES
1708
PUMP-DOWN
1066a
1062a
1060a
OK
1064a

FIG. 29

FIG. 30


HIGH LEAK
1060b
1066b
OK
1062b
1064b
1060c
1066c
OK
1062c
1064c
1800
1802
INITIAL PUMP-DOWN
1804
MONITOR PRESSURE
PRESSURE DECAYS
1808
PUMP-DOWN
PRESSURE REACHED
1810
IS DEVICE PUMPING TOO OFTEN ?
NO
YES
1812
FOR MORE THAN 1/2 HOUR ?
NO
YES
1814
PAUSE THERAPY
HOW APPARATUS DETERMINES IF IT'S PUMPING TOO OFTEN
Pressure
-60mmHg
-80mmHg
-100mmHg
1608
1620
1622
Gradual Pressure Decay
Pump Down
1610
Time
1606
1604
a
b
1602
if b is large compared to a, device is working too hard.
(for example, if $\frac{b}{a+b} \times 100\% \geq 9\%$)

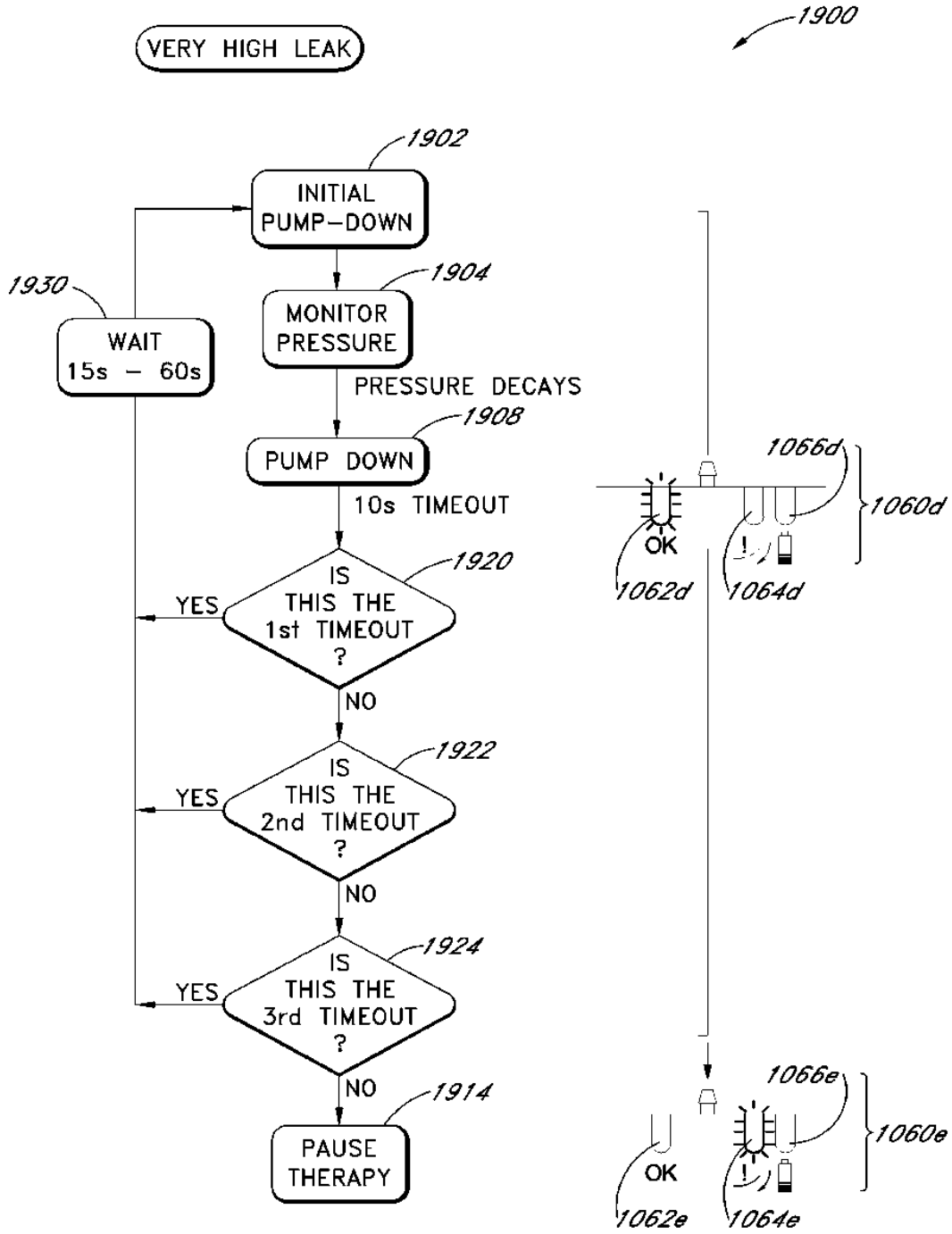

1900
VERY HIGH LEAK
1902
INITIAL PUMP–DOWN
1904
MONITOR PRESSURE
1930
WAIT 15s – 60s
PRESSURE DECAYS
1908
PUMP DOWN
10s TIMEOUT
1920
IS THIS THE 1st TIMEOUT ?
YES
NO
1922
IS THIS THE 2nd TIMEOUT ?
YES
NO
1924
IS THIS THE 3rd TIMEOUT ?
YES
NO
1914
PAUSE THERAPY
1066d
1060d
OK
1062d
1064d
1066e
1060e
OK
1062e
1064e

FIG. 31

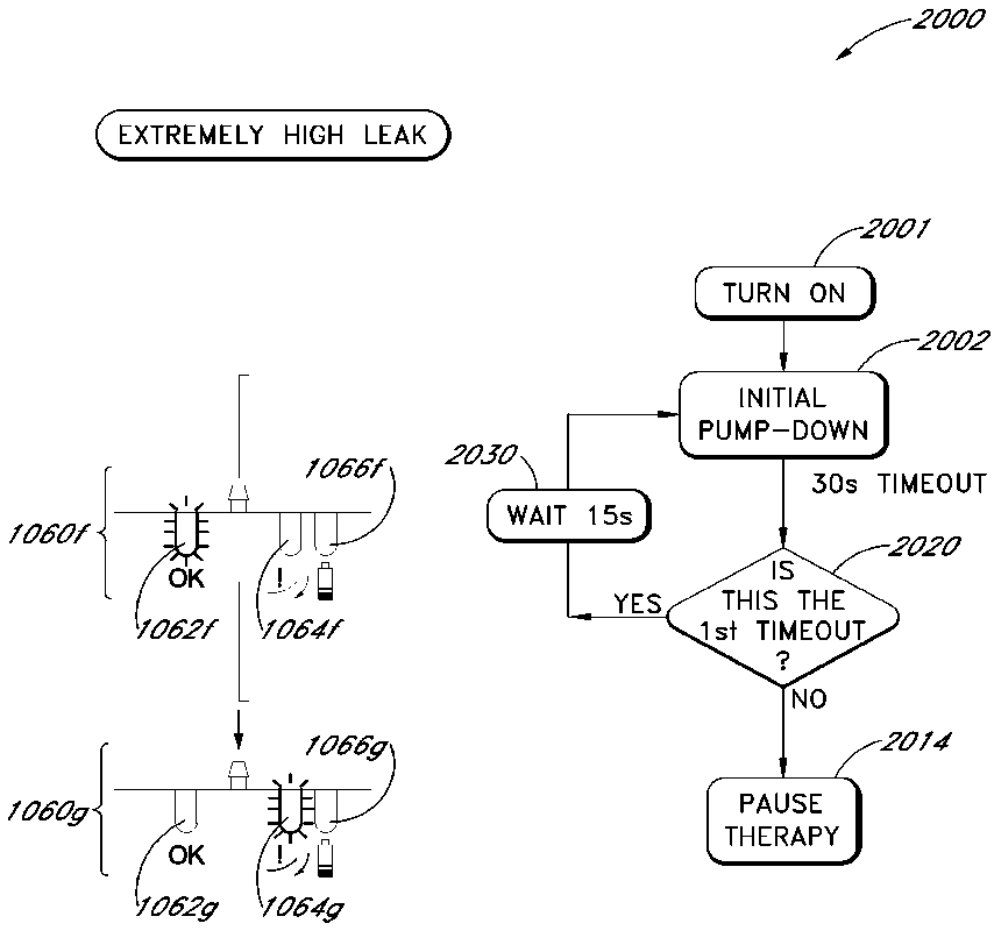

2000
EXTREMELY HIGH LEAK
1060f
1066f
OK
1062f
1064f
1060g
1066g
OK
1062g
1064g
2001
TURN ON
2002
INITIAL PUMP-DOWN
30s TIMEOUT
2030
WAIT 15s
2020
IS THIS THE 1st TIMEOUT ?
YES
NO
2014
PAUSE THERAPY

FIG. 32

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/002943

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61L2/00 A61M1/00
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M A61L F04B F04C F04D

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/125004 A1 (SHEN TE-YANG [TW] ET AL) 14 May 2009 (2009-05-14) paragraphs [0001], [0025], [0029] - [0030], [0035]; claim 4; figures 2,4	1-10,21, 22
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-/--

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

[X] See patent family annex

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 December 2012	28/01/2013

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

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/002943

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/057307 A1 (HILL ROM SERVICES INC [US]; LOCKWOOD JEFFREY S [US]; PETROSENKO ROBERT) 17 July 2003 (2003-07-17) page 15, line 32 - page 16, line 56; figures 1,4	11-20
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INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/002943

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2007/219532 A1 (KARPOWICZ JOHN [US] ET AL) 20 September 2007 (2007-09-20) paragraph [0055]	66

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2011/002943

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

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

1. [X] Claims Nos.: 23, 24, 86-88
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

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

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

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

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

see additional sheet

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

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

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

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

Remark on Protest

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

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

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-10, 21, 22

   A pump assembly comprising: a pump having a first valve at the inlet and second valve at the outlet; a flow path; a one-way flow valve configured to substantially prevent a flow of gas through the flow path away from the pump.

   ---

2. claims: 11-20

   A pump assembly as in the first group of claims additionally comprising a dressing, one or more batteries and a first and second packaging element.

   ---

3. claims: 25-49

   A negative pressure therapy kit comprising a pump assembly comprising: a pump having at least one valve configured to control the flow through at least one of the inlet and the outlet; a controller; at least one switch button in communication with the controller; a first packaging element.

   ---

4. claims: 50-65

   A negative pressure therapy kit comprising: a pump assembly having a flow rate of approx. 350 ml/min or less; a dressing with a cover layer and a wound contact layer covered with a silicone based adhesive.

   ---

5. claims: 66-88

   A canisterless pump assembly comprising; a pump having a first and second valve controlling the flow at the inlet and outlet respectively, wherein the leakage rate of the valves is between approx. 5-10 ml/min at nominal working pressure.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 23, 24, 86-88

Claims 23-24 refer to a method for treatment of the human or animal body by therapy, which is against Rule 39.1(iv) PCT and Rule 67.1(iv). The reason is that they include the step of delivering negative pressure to a wound. Claims 86-88 refer to a method for treatment of the human or animal body by therapy, which is against Rule 39.1(iv) PCT and Rule 67.1(iv). The reason is that they include the step applying a sterile dressing over a wound and reducing a level of pressure between the dressing and the wound.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2011/002943

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International application No
PCT/IB2011/002943

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Form PCT/ISA/210 (patent family annex) (April 2005)

(19)日本国特許庁(JP)　(12)公表特許公報(A)　(11)特許出願公表番号
特表2014-532498
(P2014-532498A)
(43)公表日　平成26年12月8日(2014.12.8)

(51)Int.Cl.		F I			テーマコード（参考）
A61M 1/00	(2006.01)	A61M	1/00	500	4C077
A61M 27/00	(2006.01)	A61M	27/00		4C167
A61F 13/00	(2006.01)	A61F	13/00	301Z	

審査請求 未請求　予備審査請求 未請求　（全 97 頁）

(21)出願番号　特願2014-539415 (P2014-539415)
(86)(22)出願日　平成23年11月2日 (2011.11.2)
(85)翻訳文提出日　平成26年6月18日 (2014.6.18)
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(87)国際公開番号　WO2013/064852
(87)国際公開日　平成25年5月10日 (2013.5.10)

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(74)代理人　100110364
弁理士　実広 信哉

最終頁に続く

(54)【発明の名称】減圧治療装置及びその使用方法

(57)【要約】
幾つかの実施形態は、ハウジングと、ポンプを通る流路と、流路と連通する１つ又は複数の弁と、ハウジング内で又はハウジングによって支持されるポンプと、ポンプと流体連通する一方向フロー弁とを備える減圧創傷治療用のポンプアセンブリを備える。ポンプアセンブリは、ポンプを通る流路と連通する圧力センサ、及びハウジングによって支持される少なくとも１つのスイッチ又はボタンを有することができ、少なくとも１つスイッチ又はボタンがユーザにとってアクセス可能であり、コントローラと連通している。一方向フロー弁は、ポンプから離れるフロー方向で一方向フロー弁を通ってガスが流れるのを実質的に防ぐように構成することができる。ポンプアセンブリは、ハウジング内で又はハウジングによって支持され、ポンプの動作を制御するように構成されているコントローラを有することができる。ポンプは、ハウジングの内部及び外部、流路、１つ又は複数の弁、ポンプ、コントローラ、電池区画、及び少なくとも１つのスイッチ又はボタンが滅菌されたものであるようにポンプの組み立てに続いて滅菌される。

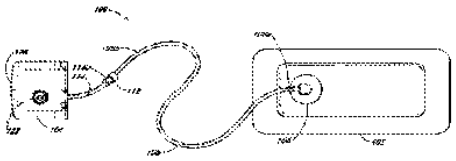


FIG. 1

【特許請求の範囲】
【請求項１】
ハウジングと、
前記ハウジング内で又はハウジングによって支持されるポンプとを備える減圧創傷治療用のポンプアセンブリにおいて、前記ポンプが、
モータと、
入口及び出口と、
前記入口を通る流体のフローを制御するように構成された第１の弁と、
前記出口を通る流体のフローを制御するように構成された第２の弁と、
前記ポンプアセンブリを通る流路と、
前記ポンプと流体連通し、前記ポンプから離れるフロー方向で前記流路を通ってガスが流れるのを実質的に防ぐように構成されている一方向フロー弁と
を備える、ポンプアセンブリ。
【請求項２】
前記ポンプアセンブリが無容器型である、請求項１に記載のポンプアセンブリ。
【請求項３】
前記ハウジング内で又は前記ハウジングによって支持されるコントローラであって、前記ポンプの動作を制御するように構成されているコントローラをさらに備える、請求項１又は２に記載のポンプアセンブリ。
【請求項４】
前記流路と連通している圧力センサをさらに備える、請求項１から３のいずれか一項に記載のポンプアセンブリ。
【請求項５】
前記ハウジングによって支持される１つのみのスイッチ又はボタンをさらに備え、前記少なくとも１つのスイッチ又はボタンがユーザにとってアクセス可能であり、コントローラと連通していることができる、請求項１から４のいずれか一項に記載のポンプアセンブリ。
【請求項６】
前記第１の弁及び前記第２の弁が、公称の動作圧力で約０．１ｍＬ／分及び１０ｍＬ／分の速度で漏れる、請求項、請求項１から５のいずれか一項に記載のポンプアセンブリ。
【請求項７】
前記ポンプアセンブリが、前記ハウジングの少なくとも内部及び外部、前記流路、前記第１及び第２の弁、及び前記ポンプが滅菌されたものであるように滅菌される、請求項１から６のいずれか一項に記載のポンプアセンブリ。
【請求項８】
前記ハウジングによって支持される１つ又は複数のＬＥＤライトをさらに備える、請求項１から７のいずれか一項に記載のポンプアセンブリ。
【請求項９】
前記ポンプアセンブリが１つ又は複数の電池を備え、前記１つ又は複数の電池の重量を含めて８０ｇと９０ｇの間の重量である、請求項１から８のいずれか一項に記載のポンプアセンブリ。
【請求項１０】
前記ポンプアセンブリの外表面が６０立方センチメートルと８０立方センチメートルの間の体積を画成する、請求項１から９のいずれか一項に記載のポンプアセンブリ。
【請求項１１】
陰圧治療キットであって、
請求項１から１０のいずれか一項に記載の前記ポンプアセンブリと、
包帯と、
前記包帯及び前記ポンプアセンブリと連結可能であり、前記包帯までの減圧の流体経路を提供するように構成された導管と、

１つ又は複数の電池と、
第１のパッケージング要素、及び前記第１のパッケージング要素と取外し可能に連結されるように構成された第２のパッケージング要素であって、前記第１及び第２のパッケージング要素の少なくとも一方は、前記ポンプアセンブリと、前記包帯と、前記導管と、前記１つ又は複数の電池とを受け入れるための陥凹部を有する第１及び第２のパッケージング要素と
を備える陰圧治療キット。
【請求項１２】
前記陰圧治療キットが、滅菌性であり、前記ポンプアセンブリ、前記包帯、前記導管、及び前記１つ又は複数の電池を、前記第１のパッケージング要素及び前記第２のパッケージング要素の少なくとも一方の内部で支持した後に滅菌される、請求項１１に記載の陰圧治療キット。
【請求項１３】
１つ又は複数の接着剤シールストリップをさらに備える、請求項１１又は１２に記載の陰圧治療キット。
【請求項１４】
前記１つ又は複数の電池が、前記ハウジングの外部で支持される、請求項１１から１３のいずれか一項に記載の陰圧治療キット。
【請求項１５】
前記陰圧治療キットが酸化エチレンによって滅菌される、請求項１１から１４のいずれか一項に記載の陰圧治療キット。
【請求項１６】
前記包帯が、
透過層と、
創傷浸出物を吸収するための吸収性層であって、前記透過層を覆う吸収性層と、
前記吸収性層を覆い、そこを通るオリフィスを備えるカバー層と
を備える、請求項１１から１５のいずれか一項に記載の陰圧治療キット。
【請求項１７】
前記包帯が、創傷部位に局所陰圧を加えるために前記包帯に陰圧を加えるための吸気ポートを備える、請求項１１から１６のいずれか一項に記載の陰圧治療キット。
【請求項１８】
前記吸気ポートが、前記吸気ポートを前記ポンプアセンブリに接続するためのコネクタ部分、及び前記吸気ポートを前記包帯のカバー層にシールするためのシール面を備える、請求項１７に記載の陰圧治療キット。
【請求項１９】
前記包帯が、液体がコネクタ部分に入るのを防ぐようになされた液体不透過性ガス透過性フィルタ要素を備える、請求項１１から１８のいずれか一項に記載の陰圧治療キット。
【請求項２０】
前記第１のパッケージング要素がＰＥＴＧを備える、請求項１１から１９のいずれか一項に記載の陰圧治療キット。
【請求項２１】
陰圧治療システムであって、
請求項１から１０のいずれか一項に記載の前記ポンプアセンブリと、
包帯と
を備える陰圧治療システム。
【請求項２２】
前記包帯の創傷に向く面が、前記創傷を取り囲む皮膚と漏れ量の少ないシールを形成するように構成されたシリコーン系接着剤によって少なくとも部分的に覆われている、請求項２１に記載の陰圧治療キット。
【請求項２３】

陰圧を用いて創傷を治療する方法であって、
包帯を用意するステップと、
前記創傷の上に実質的に液密のシールを形成するように前記創傷の上に前記包帯を当てるステップと、
請求項１から１０のいずれか一項に記載の前記ポンプアセンブリを使用して前記包帯を通して前記創傷に陰圧を送達するステップと
を含む方法。
【請求項２４】
創傷の上に実質的に液密のシールを形成するように前記創傷の上に包帯を当てるステップ、及び請求項１から１０のいずれか一項に記載の前記ポンプアセンブリを使用して前記包帯を通して創傷に陰圧を送達するステップが、手術ルームで行われる、請求項２３に記載の陰圧を用いて創傷を治療する方法。
【請求項２５】
ポンプアセンブリであって、
ハウジングと、
ポンプモータ、
入口及び出口、
前記入口及び前記出口のうちの少なくとも１つを通して流体のフローを制御するように構成された少なくとも１つの弁、及び
少なくとも前記入口、前記出口、及び前記少なくとも１つの弁を通る流路
を備えるハウジング内で支持されるポンプと、
前記ハウジング内で又は前記ハウジングによって支持されるコントローラであって、前記ポンプ及び前記弁の動作を制御するように構成されているコントローラと、
少なくとも１つのスイッチ又はボタンであって、前記ハウジングで支持され、前記コントローラと連通し、ユーザがポンプの１つ又は複数の動作モードを制御できるように、ユーザにとってアクセス可能である少なくとも１つのスイッチ又はボタンと
を備えるポンプアセンブリと、
創傷の上に実質的に液密のシールを形成するように構成された包帯と、
前記包帯及び前記ポンプアセンブリと連結可能であり、前記ポンプアセンブリから前記包帯までの実質的に又は完全に包囲された流体流路を設けるように構成された導管と、
前記ポンプアセンブリ、前記１つ又は複数の電池、前記包帯、及び前記導管をパッケージングするための第１のパッケージング要素と
を備える、減圧創傷治療用の陰圧治療キットにおいて、
前記陰圧治療キットが、前記ハウジングの少なくとも内部及び外部、前記少なくとも１つの弁、前記ポンプ、前記コントローラ、及び前記少なくとも１つのスイッチ又はボタンが滅菌されたものであるように滅菌される、減圧創傷治療用の陰圧治療キット。
【請求項２６】
１つ又は複数の接着剤シールストリップをさらに備える、請求項２５に記載の陰圧治療キット。
【請求項２７】
動力を少なくとも前記ポンプ及びコントローラに供給するように構成された１つ又は複数の電池をさらに備える、請求項２１から２６のいずれか一項に記載の陰圧治療キット。
【請求項２８】
第１のパッケージング要素と連結するように構成された第２のパッケージング要素をさらに備え、前記第１のパッケージング要素が、前記ポンプアセンブリ、前記１つ又は複数の電池、前記包帯、導管、及び１つ又は複数の接着剤シールストリップのうちの１つ又は複数を受け入れるための複数の陥凹部を有する、請求項２７に記載の陰圧治療キット。
【請求項２９】
前記第２のパッケージング要素が、滅菌ガスに対して透過性であり、細菌に対して不透過性である、請求項２８に記載の陰圧治療キット。

【請求項３０】
第１のパッケージング要素が前記１つ又は複数の電池を支持し、それによって前記陰圧治療キットの滅菌処理中に前記１つ又は複数の電池が前記ハウジングの外部で支持される、請求項２５から２９のいずれか一項に記載の陰圧治療キット。
【請求項３１】
前記ポンプが、ダイヤフラムポンプ、回転ダイヤフラムポンプ、又は圧電ポンプである、請求項２５から３０のいずれか一項に記載の陰圧治療キット。
【請求項３２】
前記陰圧治療キットが酸化エチレンによって滅菌される、請求項２５から３１のいずれか一項に記載の陰圧治療キット。
【請求項３３】
前記少なくとも１つの弁が、滅菌プロセスの際に前記少なくとも１つの弁を通る滅菌ガスのフローを可能にするように構成された、請求項２５から３２のいずれか一項に記載の陰圧治療キット。
【請求項３４】
前記ポンプアセンブリが、フローマニホルドをさらに備え、前記フローマニホルドが、圧力センサ、前記ポンプ、及び導管、導管用コネクタのうちの少なくとも１つと流体連通している、請求項２５から３３のいずれか一項に記載の陰圧治療キット。
【請求項３５】
マニホルドによって支持された一方向フロー弁をさらに備える、請求項３４に記載の陰圧治療キット。
【請求項３６】
前記ポンプと前記包帯の間に位置付けられた一方向フロー弁を備え、前記一方向フロー弁が、前記ポンプから前記包帯に向かうフロー方向で前記一方向フロー弁を通るガスの前記フローを実質的に防ぐように構成されている、請求項２５から３５のいずれか一項に記載の陰圧治療キット。
【請求項３７】
前記一方向フロー弁が、前記ハウジング内で支持される、請求項３６に記載の陰圧治療キット。
【請求項３８】
前記ポンプと前記包帯の間、又は前記ポンプアセンブリ内で流体流路内のガスの圧力レベルを監視するように構成された圧力センサをさらに備える、請求項２５から３７のいずれか一項に記載の陰圧治療キット。
【請求項３９】
第１のパッケージング要素にパッケージングされた場合に導管の一方の端部が前記包帯に接続される、請求項２５から３８のいずれか一項に記載の陰圧治療キット。
【請求項４０】
導管が第１の端部及び第２の端部を備え、前記第１の端部が前記包帯に接続され、又は接続可能であり、前記第２の端部が前記ハウジングと連結するように構成されたコネクタを備える、請求項２５から３９のいずれか一項に記載の陰圧治療キット。
【請求項４１】
前記ハウジングがシールされない、請求項２５から４０のいずれか一項に記載の陰圧治療キット。
【請求項４２】
前記ポンプアセンブリが容器を備えない、請求項２５から４１のいずれか一項に記載の陰圧治療キット。
【請求項４３】
前記ポンプによって生成される雑音及び振動を低減するため前記ポンプの少なくとも一部分を取り囲む、解放した発泡体層をさらに備える、請求項２５から４２のいずれか一項に記載の陰圧治療キット。

【請求項４４】
前記包帯が、
透過層と、
創傷浸出物を吸収するための吸収性層であって、前記透過層を覆う吸収性層と、
前記吸収性層を覆うカバー層と、
導管の端部を受け入れるための吸気ポートと、
液体が前記吸気ポートを通過するのを防ぐようになされた液体不透過性ガス透過性フィルタ要素と
を備える、請求項２５から４３のいずれか一項に記載の陰圧治療キット。
【請求項４５】
前記ポンプアセンブリが、前記ハウジングにより支持され、又は前記ハウジング内に形成された電池区画を備える、請求項２５から４４のいずれか一項に記載の陰圧治療キット。
【請求項４６】
前記陰圧治療キットが、創傷を取り囲む皮膚と漏れ量の少ないシールを形成するように構成されたシリコーン系接着剤を有する創傷包帯を備え、前記ポンプアセンブリが前記１つ又は複数の電池の重量を含めて７０ｇと９０ｇの間の重量である、請求項２５から４５のいずれか一項に記載の陰圧治療キット。
【請求項４７】
前記ポンプアセンブリが、前記１つ又は複数の電池の重量を含めて７０ｇと９０ｇの間の重量である、請求項２５から４６のいずれか一項に記載の陰圧治療キット。
【請求項４８】
前記ポンプアセンブリの外表面が、約３立方インチ（４９．１６立方センチメートル）から約５立方インチ（８１．９４立方センチメートル）の体積を画成する、請求項２５から４７のいずれか一項に記載の陰圧治療キット。
【請求項４９】
前記陰圧治療キットが、シールストリップを第１のパッケージング要素から除去できる前に、前記包帯を前記第１のパッケージング要素から除去しなければならないように構成される、請求項２５から４８のいずれか一項に記載の陰圧治療キット。
【請求項５０】
約３５０ｍＬ／分以下の流量を有するポンプを備えるポンプアセンブリと、
カバー層を備える包帯であって、シリコーン系接着剤によって覆われている創傷接触面を有する包帯と
を備える、減圧創傷治療用の陰圧治療キット。
【請求項５１】
前記ポンプアセンブリが前記ポンプと流体連通している一方向フロー弁を備え、前記一方向フロー弁が前記ポンプから離れるフロー方向で流路を通ってガスが流れるのを実質的に防ぐように構成されている、請求項５０に記載された陰圧治療キット。
【請求項５２】
前記包帯が、前記包帯に陰圧を加えたときに開いたままであるように構成された３Ｄ編成材料又は布地材料を備える透過層を備える、請求項５０又は５１に記載の陰圧治療キット。
【請求項５３】
前記包帯が創傷浸出物を吸収するための吸収性層を備え、前記吸収性層が透過層を覆う、請求項５０から５２のいずれか一項に記載の陰圧治療キット。
【請求項５４】
前記包帯が、吸収性層を覆うカバー層を備え、オリフィスを備え、前記カバー層が水蒸気透過性である、吸収性層が透過層を覆う、請求項５０から５３のいずれか一項に記載の陰圧治療キット。
【請求項５５】

前記包帯が、創傷部位に局所陰圧を加えるために、陰圧を前記包帯に加えるための吸気ポートを備え、前記吸気ポートが、前記吸気ポートを前記ポンプアセンブリに接続するためのコネクタ部分、及び前記吸気ポートを前記包帯の前記カバー層にシールするためのシール面を備える、請求項５０から５４のいずれか一項に記載の陰圧治療キット。

【請求項５６】

前記包帯が、液体がコネクタ部分に入るのを防ぐようになされた液体不透過性ガス透過性フィルタ要素を備える、請求項５０から５５のいずれか一項に記載の陰圧治療キット。

【請求項５７】

前記ポンプアセンブリが無容器型である、請求項５０から５６のいずれか一項に記載の陰圧治療キット。

【請求項５８】

前記ポンプアセンブリのハウジング内で又は前記ポンプアセンブリのハウジングによって支持されるコントローラであって、前記ポンプの動作を制御するように構成されているコントローラをさらに備える、請求項５０から５７のいずれか一項に記載の陰圧治療キット。

【請求項５９】

前記ポンプアセンブリを通る流路と連通している圧力センサをさらに備える、請求項５０から５８のいずれか一項に記載の陰圧治療キット。

【請求項６０】

前記ポンプアセンブリのハウジングによって支持される少なくとも１つのスイッチ又はボタンをさらに備え、前記少なくとも１つスイッチ又はボタンがユーザにとってアクセス可能であり、コントローラと連通していることができる、請求項５０から５９のいずれか一項に記載の陰圧治療キット。

【請求項６１】

前記ポンプアセンブリにより支持された電池区画をさらに備える、請求項５０から６０のいずれか一項に記載の陰圧治療キット。

【請求項６２】

前記ポンプアセンブリの少なくとも内部及び外部が滅菌されているように、前記ポンプアセンブリが、前記ポンプアセンブリの組み立てに続いて滅菌される、請求項５０から６１のいずれか一項に記載の陰圧治療キット。

【請求項６３】

前記ポンプアセンブリが１つ又は複数のＬＥＤライトを有する、請求項５０から６２のいずれか一項に記載の陰圧治療キット。

【請求項６４】

前記ポンプアセンブリが、１つ又は複数の電池を備え、前記１つ又は複数の電池の重量を含めて８０ｇと９０ｇの間の重量である、請求項５０から６３のいずれか一項に記載の陰圧治療キット。

【請求項６５】

前記ポンプアセンブリの外表面が６０立方センチメートルと８０立方センチメートルの間の体積を画成する、請求項５０から６４のいずれか一項に記載の陰圧治療キット。

【請求項６６】

減圧創傷治療用の無容器型ポンプアセンブリであって、

ハウジングと、

ハウジング内で又はハウジングによって支持されるポンプとを備えるポンプアセンブリにおいて、前記ポンプが、

モータと、

入口及び出口と、

前記入口を通る流体のフローを制御するように構成された第１の弁と、

前記出口を通る流体のフローを制御するように構成された第２の弁と

を備える容器型ポンプアセンブリにおいて、

前記ポンプアセンブリが無容器型であり、
前記第１及び第２の弁が、それぞれ公称の動作圧力で約５Ｌ／分と約１０Ｌ／分の間の漏れ速度を有する、容器型ポンプアセンブリ。
【請求項６７】
前記ポンプアセンブリが前記ポンプと流体連通している一方向フロー弁を備え、前記一方向フロー弁が前記ポンプから離れるフロー方向で流路を通ってガスが流れるのを実質的に防ぐように構成された、請求項６６に記載のポンプアセンブリ。
【請求項６８】
前記ハウジング内で又は前記ハウジングによって支持されるコントローラであって、前記ポンプの動作を制御するように構成されているコントローラをさらに備える、請求項６６又は６７に記載のポンプアセンブリ。
【請求項６９】
前記ポンプアセンブリを通る流路と連通している圧力センサをさらに備える、請求項６６から６８のいずれか一項に記載のポンプアセンブリ。
【請求項７０】
前記ハウジングによって支持される少なくとも１つのスイッチ又はボタンをさらに備え、前記少なくとも１つスイッチ又はボタンがユーザにとってアクセス可能であり、コントローラと連通していることができる、請求項６６から６９のいずれか一項に記載のポンプアセンブリ。
【請求項７１】
前記ハウジングにより支持され、又は前記ハウジング内に形成された電池区画をさらに備える、請求項６６から７０のいずれか一項に記載のポンプアセンブリ。
【請求項７２】
前記ハウジングの少なくとも内部及び外部、流路、前記１つ又は複数の弁、及び前記ポンプが滅菌されたものであるように、前記ポンプアセンブリの組み立てに続いて滅菌される、請求項６６から７１のいずれか一項に記載のポンプアセンブリ。
【請求項７３】
前記ハウジングによって支持される１つ又は複数のＬＥＤライトをさらに備える、請求項６６から７２のいずれか一項に記載のポンプアセンブリ。
【請求項７４】
前記ポンプアセンブリが１つ又は複数の電池を備え、前記１つ又は複数の電池の重量を含めて８０ｇ及び９０ｇの重量である、請求項６６から７３のいずれか一項に記載のポンプアセンブリ。
【請求項７５】
前記ポンプアセンブリの外表面が６０立方センチメートルと８０立方センチメートルの間の体積を画成する、請求項６６から７４のいずれか一項に記載のポンプアセンブリ。
【請求項７６】
滅菌ポンプキットであって、
請求項６６から７５のいずれか一項に記載の前記ポンプアセンブリと、
包帯と、
前記包帯及び前記ポンプアセンブリと連結可能であり、前記包帯までの減圧の流体経路を提供するように構成された導管と、
１つ又は複数の電池と、
第１のパッケージング要素、及び前記第１のパッケージング要素と取外し可能に連結されるように構成された第２のパッケージング要素であって、前記第１及び第２のパッケージング要素の少なくとも一方は、前記ポンプアセンブリと、包帯と、前記包帯及び前記ポンプアセンブリと連結可能であり、前記包帯までの減圧の流体経路を提供するように構成された前記導管とを受け入れるための陥凹部を有する滅菌ポンプキットにおいて、
前記滅菌ポンプキットが、前記ポンプアセンブリ、前記包帯、前記導管、及び前記１つ又は複数の電池が、前記第１のパッケージング要素及び前記第２のパッケージング要素の

少なくとも一方の内部で支持された後に滅菌される、滅菌ポンプキット。
【請求項７７】
前記ポンプアセンブリ、前記包帯、前記導管、及び前記１つ又は複数の電池が滅菌される前に、前記ポンプアセンブリ、前記包帯、前記導管、及び前記１つ又は複数の電池が、前記第１のパッケージング要素及び前記第２のパッケージング要素の少なくとも一方の内部で支持される、請求項７６に記載の滅菌ポンプキット。
【請求項７８】
１つ又は複数の接着剤シールストリップをさらに備える、請求項７６又は７７に記載の滅菌ポンプキット。
【請求項７９】
前記１つ又は複数の電池が、前記ハウジングの外表面で支持される、請求項７６から７８のいずれか一項に記載の滅菌ポンプキット。
【請求項８０】
前記滅菌ポンプキットが酸化エチレンによって滅菌される、請求項７６から７９のいずれか一項に記載の滅菌ポンプキット。
【請求項８１】
前記包帯が、
透過層と、
創傷浸出物を吸収するための吸収性層であって、前記吸収性層が前記透過層を覆う吸収性層と、
前記吸収性層を覆うカバー層と
を備える請求項７６から８０のいずれか一項に記載の滅菌ポンプキット。
【請求項８２】
前記包帯が、創傷部位に局所陰圧を加えるために前記包帯に陰圧を加えるための吸気ポートを備える、請求項７６から８１のいずれか一項に記載の滅菌ポンプキット。
【請求項８３】
前記吸気ポートが、前記吸気ポートを前記ポンプアセンブリに接続するためのコネクタ部分、及び前記吸気ポートを前記包帯のカバー層にシールするためのシール面を備える、請求項８２に記載の滅菌ポンプキット。
【請求項８４】
前記包帯が、液体がコネクタ部分に入るのを防ぐようになされた液体不透過性ガス透過性フィルタ要素を備える、請求項７６から８３のいずれか一項に記載の滅菌ポンプキット。
【請求項８５】
前記第１のパッケージング要素がＰＥＴＧを備える、請求項７６から８４のいずれか一項に記載の滅菌ポンプキット。
【請求項８６】
手術ルームにおいて創傷の治療を開始するための方法であって、
創傷の上に滅菌包帯を当てて、前記創傷の上に実質的に液密のシールを作り出すステップと、
滅菌導管を介して滅菌ポンプアセンブリを包帯に連結するステップと、前記手術ルームで前記滅菌ポンプアセンブリを動作させることによって手術ルームで前記包帯と前記創傷との間の圧力レベルを低減するステップと
を含む、方法。
【請求項８７】
少なくとも１つの前記包帯の外周縁部の上に１つ又は複数のシールストリップを当てて、前記包帯と前記創傷を取り囲む皮膚の間の前記シールを改善するためのステップをさらに含む、請求項８６に記載の方法。
【請求項８８】
１つ又は複数の電池を第１のパッケージング要素から取り出すステップと、前記１つ又

は複数の電池を前記滅菌ポンプアセンブリに取り付けるステップをさらに含む、請求項８６又は８７に記載の方法。

【発明の詳細な説明】

【技術分野】

【０００１】

［参照による組込み］

本出願は、２０１１年４月２１日出願の（ＷＯＵＮＤ ＤＲＥＳＳＩＮＧ ＡＮＤ ＭＥＴＨＯＤ ＯＦ ＵＳＥという名称の）米国特許出願第１３／０９２，０４２号、２００８年５月２１日出願の（ＡＮＴＩＭＩＣＲＯＢＩＡＬ ＢＩＧＵＡＮＩＤＥ ＭＥＴＡＬ ＣＯＭＰＬＥＸＥＳという名称の）米国特許出願第１１／９２２，８９４号、２０１１年７月２６日出願の（ＭＥＴＨＯＤＳ ＡＮＤ ＡＰＰＡＲＡＴＵＳＥＳ ＦＯＲ ＤＥＴＥＣＴＩＮＧ ＬＥＡＫＳ ＡＮＤ ＣＯＮＴＲＯＬＬＩＮＧ ＰＵＭＰ ＯＰＥＲＡＴＩＯＮ ＩＮ Ａ ＮＥＧＡＴＩＶＥ ＰＲＥＳＳＵＲＥ ＷＯＵＮＤ ＴＨＥＲＡＰＹ ＳＹＳＴＥＭという名称の）米国特許仮出願第６１／５１１，９５０号、２０１１年４月２１日出願の（ＷＯＵＮＤ ＤＲＥＳＳＩＮＧという名称の）ＰＣＴ特許出願第ＰＣＴ／ＧＢ １１／０００６２２号、２０１１年４月２１日出願の（ＷＯＵＮＤ ＰＲＯＴＥＣＴＩＯＮという名称の）ＰＣＴ特許出願第ＰＣＴ／ＧＢ １１／０００６２１号、２０１１年４月２１日出願の（ＷＯＵＮＤ ＤＲＥＳＳＩＮＧという名称の）ＰＣＴ特許出願第ＰＣＴ／ＧＢ １１／０００６２５号、２０１１年４月２１日出願の（ＭＵＬＴＩ ＰＯＲＴ ＤＲＥＳＳＩＮＧという名称の）ＰＣＴ特許出願第ＰＣＴ／ＧＢ １１／０００６２６号、２０１１年４月２１日出願の（ＳＵＣＴＩＯＮ ＰＯＲＴという名称の）ＰＣＴ特許出願第ＰＣＴ／ＧＢ １１／０００６２８号、２０１１年９月１６日出願の（ＰＲＥＳＳＵＲＥ ＣＯＮＴＲＯＬ ＡＰＰＡＲＡＴＵＳという名称の）ＰＣＴ特許出願第ＰＣＴ／ＧＢ １１／０５１７４５号を参照によって組み込む。各及びすべての上記の特許出願は、その全体が参照によって本明細書に組み込まれ、本開示の一部分を成す。さらに、２０１１年１１月２日出願の「ＳＹＳＴＥＭＳ ＡＮＤ ＭＥＴＨＯＤＳ ＦＯＲ ＣＯＮＴＲＯＬＬＩＮＧ ＯＰＥＲＡＴＩＯＮ ＯＦ Ａ ＲＥＤＵＣＥＤ ＰＲＥＳＳＵＲＥ ＴＨＥＲＡＰＹ ＳＹＳＴＥＭ」という名称の同時係属中の特許出願第１３／ＸＸＸ，ＸＸＸ号（代理人整理番号ＳＭＮＰＨ．１９５Ａ）、及び２０１１年１１月２日出願の「ＳＹＳＴＥＭＳ ＡＮＤ ＭＥＴＨＯＤＳ ＦＯＲ ＣＯＮＴＲＯＬＬＩＮＧ ＯＰＥＲＡＴＩＯＮ ＯＦ Ａ ＲＥＤＵＣＥＤ ＰＲＥＳＳＵＲＥ ＴＨＥＲＡＰＹ ＳＹＳＴＥＭ」という名称の同時係属中のＰＣＴ特許出願第ＰＣＴ／ＵＳ１１／ＸＸＸ，ＸＸＸ号（代理人整理番号ＳＭＮＰＨ．１９４ＷＯ）もその全体があたかも本明細書に明記したごとく参照によって本明細書に組み込まれる。

【０００２】

本明細書に開示する実施形態は、局所陰圧（ＴＮＰ）療法を用いて創傷を包帯で処置し、治療するための方法及び装置に関する。例えば、ただし非限定的に、本明細書に開示する幾つかの実施形態は、ポンプキットから与えられる減圧を用いて創傷を治療することに関する。必須ではないが、ポンプキットの幾つかの実施形態は滅菌性とすることができる。別の非限定例として、本明細書に開示する幾つかの実施形態は、ＴＮＰシステムの動作を制御するための装置及び方法に関する。

【背景技術】

【０００３】

ヒト又は動物の治癒プロセスに役立つ、多くの異なるタイプの創傷包帯が知られている。これらの異なるタイプの創傷包帯としては、多くの異なるタイプの材料及び層、例えばガーゼ、パッド、フォームパッド、又は多層創傷包帯が挙げられる。局所陰圧（「ＴＮＰ」）療法は、真空補助閉鎖療法、陰圧創傷療法、又は減圧創傷療法と呼ばれることがあるが、創傷の治癒速度を改善するための有益な機序として広く認識されている。かかる療法は、切開創、開放創、及び腹部創など、広範囲の創傷に適用可能である。

【０００４】

ＴＮＰ療法は、組織浮腫を軽減し、血流を促進し、肉芽組織の形成を刺激し、過剰な浸出物を除去することによって、創傷の閉鎖及び治癒を支援し、また細菌負荷を、ひいては創傷に対する感染を低減し得る。さらに、ＴＮＰ療法は、創傷の外部障害（ｏｕｔｓｉｄｅ　ｄｉｓｔｕｒｂａｎｃｅ）をより少なくすることができ、より迅速な治癒を推進する。

【先行技術文献】
【特許文献】
【０００５】
【特許文献１】米国特許第７５５００３４号明細書
【特許文献２】米国特許出願公開第２０１１／１８６７６５号明細書
【特許文献３】米国特許出願第１３／０９２０４２号明細書
【特許文献４】英国特許出願第１０１５６５６．０号明細書
【特許文献５】英国特許出願第１００６９８６．２号明細書
【特許文献６】英国特許出願第１００６９８３．９号明細書
【特許文献７】英国特許出願第１００６９８５．４号明細書
【特許文献８】英国特許出願第１００６９８８．８号明細書
【特許文献９】英国特許出願第１００８３４７．５号明細書
【特許文献１０】米国特許出願第１１／９２２８９４号明細書
【特許文献１１】米国特許第７５２４３１５号明細書
【特許文献１２】米国特許第７７０８７２４号明細書
【特許文献１３】米国特許第７９０９８０５号明細書
【特許文献１４】米国特許出願公開第２００５／０２６１６４２号明細書
【特許文献１５】米国特許出願公開第２００７／０１６７９２６号明細書
【特許文献１６】米国特許出願公開第２００９／００１２４８３号明細書
【特許文献１７】米国特許出願公開第２００９／０２５４０５４号明細書
【特許文献１８】米国特許出願公開第２０１０／０１６０８７９号明細書
【特許文献１９】米国特許出願公開第２０１０／０１６０８８０号明細書
【特許文献２０】米国特許出願公開第２０１０／０１７４２５１号明細書
【特許文献２１】米国特許出願公開第２０１０／０２７４２０７号明細書
【特許文献２２】米国特許出願公開第２０１０／０２９８７９３号明細書
【特許文献２３】米国特許出願公開第２０１１／０００９８３８号明細書
【特許文献２４】米国特許出願公開第２０１１／００２８９１８号明細書
【特許文献２５】米国特許出願公開第２０１１／００５４４２１号明細書
【特許文献２６】米国特許出願公開第２０１１／００５４４２３号明細書
【特許文献２７】米国特許出願第１２／９４１３９０号明細書
【特許文献２８】米国特許出願第２９／３８９７８２号明細書
【特許文献２９】米国特許出願第２９／３８９７８３号明細書
【発明の概要】
【課題を解決するための手段】
【０００６】
本明細書に開示する幾つかの実施形態は、減圧創傷治療用のポンプアセンブリに関し、このポンプアセンブリは、ハウジングと、ハウジング内で又はハウジングによって支持されるポンプと、ポンプアセンブリを通る流路と、ポンプと流体連通しておりハウジングによって支持される一方向フロー弁とを備える。一方向フロー弁の幾つかの実施形態は、ポンプから離れるフロー方向で流路を通ってガスが流れるのを実質的に防ぐように構成することができる。ポンプは、モータと、入口及び出口と、ポンプによって支持され、入口を通る流体のフローを制御するように構成された第１の弁と、ポンプによって支持され、出口を通る流体のフローを制御するように構成された第２の弁とを有することができる。
【０００７】
本明細書に開示する幾つかの実施形態は、減圧創傷治療用のポンプアセンブリに関し、

このポンプアセンブリは、ハウジングと、ハウジング内で又はハウジングによって支持されるポンプと、ポンプと流体連通している一方向フロー弁と、ポンプアセンブリを通る流路とを備える。一方向フロー弁は、ポンプから離れるフロー方向で流路を通ってガスが流れるのを実質的に防ぐように構成することができる。ポンプは、モータと、入口と、出口とを備えることができる。本明細書に開示するポンプの実施形態のいずれにおいても、必須ではないものの、ポンプは、入口を通る流体のフローを制御するように構成された第１の弁と、出口を通る流体のフローを制御するように構成された第２の弁とを有することもできる。本明細書に開示する幾つかのポンプの実施形態は、オリフィス又は他の機構もしくは構成要素を使用して、ポンプを通る流体のフロー又は流量を制御することができる。

【０００８】

本明細書に開示する幾つかの実施形態は、減圧創傷治療用の陰圧治療キットに関し、この陰圧治療キットは、ハウジングと、ハウジング内で支持されるポンプと、ハウジング内で又はハウジングによって支持されるコントローラと、ハウジングによって支持される少なくとも１つのスイッチ又はボタンとを備えるポンプアセンブリを備える。本明細書全体に亘って使用されるとき、「幾つかの実施形態」又は「幾つかの実施形態では」という語句は、本明細書に記載されるか、例証されるか、参照により組み込まれるか、又は別の形で開示される任意の実施形態を指すことを意味する。少なくとも１つのスイッチ又はボタンは、コントローラと連通していることができ、ユーザがポンプの１つ又は複数の動作モードを制御できるように、ユーザにとってアクセス可能であることができる。幾つかの実施形態では、必須ではないものの、陰圧治療キットは、創傷の上に実質的に液密のシールを形成するように構成された包帯と、包帯及びポンプアセンブリと連結可能であって、ポンプアセンブリから包帯までの実質的に又は完全に包囲された流体流路を設けるように構成された導管と、ポンプアセンブリ、１つ又は複数の電池、包帯、及び導管をパッケージングするための第１のパッケージング要素とを備えることができる。幾つかの実施形態では、コントローラは、ポンプ及び弁の動作を制御するように構成することができる。陰圧治療キットの幾つかの実施形態は、陰圧治療キットが滅菌されたものであるように構成することができる。陰圧治療キットは、ハウジングの少なくとも内部及び外部、少なくとも１つの弁、ポンプ、コントローラ、ならびに少なくとも１つのスイッチ又はボタンが滅菌されたものであるように、滅菌することができる。幾つかの実施形態では、ポンプは、ポンプモータと、入口及び出口と、入口及び出口の少なくとも一方を通る流体のフローを制御するように構成された少なくとも１つの弁と、少なくとも入口、出口、及び少なくとも１つの弁を通る流路とを有することができる。

【０００９】

本明細書に開示する幾つかの実施形態は、減圧ポンプを用いた創傷の減圧治療に関する。本明細書に開示するポンプの実施形態は、滅菌することを必須としない。しかし、減圧ポンプを使用前に滅菌し、ポンプ及び／又は包帯もしくはポンプのキットの構成要素を滅菌状態で提供することによって、デバイスの滅菌性が求められる手術ルーム（手術室とも呼ばれる）又は他の任意の場所でポンプを使用するのを可能にすることができる。例示的且つ非限定的な幾つかの実施形態は、手術ルームで使用することができる、滅菌ポンプと、滅菌包帯と、包帯及びポンプに接続可能な滅菌導管とを備える、滅菌ポンプキットを対象とする。

【００１０】

本明細書に開示する幾つかの実施形態は、減圧創傷治療用の陰圧治療キットに関し、この陰圧治療キットは、約３５０ｍＬ／分以下の流量を有するポンプと、カバー層を備える包帯とを備える。包帯は、シリコーン系接着剤で覆われた創傷接触面を有することができる。

【００１１】

本明細書に開示する幾つかの実施形態は、減圧創傷治療用の無容器ポンプ（ｃａｎｉｓｔｅｒｌｅｓｓ　ｐｕｍｐ）に関し、この無容器ポンプは、ハウジングと、ポンプを通る流路と、流路と連通している１つ又は複数の弁と、ハウジング内で又はハウジングによっ

て支持される、無容器型のポンプとを備える。本明細書に開示する幾つかの実施形態は、減圧創傷治療用の無容器ポンプアセンブリに関し、この無容器ポンプアセンブリは、ハウジングと、ハウジング内で又はハウジングによって支持されるポンプとを備える。ポンプは、モータと、入口及び出口と、ポンプによって支持され、入口を通る流体のフローを制御するように構成された第１の弁と、ポンプによって支持され、出口を通る流体のフローを制御するように構成された第２の弁とを有することができる。ポンプ又はポンプアセンブリは無容器型であることができる。さらに、本明細書に開示するすべての実施形態に関して必須ではないが、第１及び第２の弁はそれぞれ、公称動作圧力で、かつ／又は公称滅菌圧力の間、約０．１ｍＬ／分～約１０ｍＬ／分の漏れ速度を、あるいは公称動作圧力で、０．１ｍＬ／分以下～５ｍＬ／分以上の間、又は１ｍＬ／分以下～３ｍＬ／分以上の間、又は上記範囲のいずれかにおける任意の２つの値の間の漏れ速度を有することができる。幾つかの実施形態では、漏れ速度は、公称動作圧力で、かつ／又は公称滅菌圧力の間、約０．４ｍＬ／分～０．７ｍＬ／分であることができる。

【００１２】

ポンプアセンブリの幾つかの実施形態は、非限定的に、特許文献１及び／又は特許文献２に開示されている圧電ポンプなどの、圧電ポンプを有することができる。幾つかの圧電ポンプは、ポンプが停止中のとき、ポンプを通る流量が２００ｍＬ／分程度の多量であることができるように、弁機能を実施するためのオリフィスを有することができる。したがって、幾つかの実施形態では、ポンプ速度が約３００ｍＬ／分又は３２０ｍＬ／分又はその他の高い速度であることができる場合、第１及び第２の弁（オリフィスであり得る）はそれぞれ、約２００ｍＬ／分以下の漏れ速度を有することができる。

【００１３】

本明細書に開示する幾つかの実施形態は、滅菌ポンプキットに関し、この滅菌ポンプキットは、本明細書に開示するポンプの実施形態のいずれかと、包帯と、包帯及び滅菌ポンプと連結可能であって、包帯までの減圧の流体経路を提供するように構成された導管と、１つ又は複数の電池と、第１のパッケージング要素及び第１のパッケージング要素と取外し可能に連結されるように構成された第２のパッケージング要素とを備える。幾つかの実施形態では、第１及び第２のパッケージング要素の少なくとも一方は、滅菌ポンプと、包帯と、包帯及び滅菌ポンプと連結可能であって、包帯までの減圧の流体経路を提供するように構成された導管とを受け入れるための、陥凹部を有することができる。滅菌ポンプキットは、ポンプ、包帯、導管、及び１つ又は複数の電池を、第１のパッケージング要素及び第２のパッケージング要素の少なくとも一方の内部で支持した後に、滅菌することができる。

【００１４】

本明細書に開示する幾つかの実施形態は、手術ルームにおいて創傷の治療を開始するための方法に関し、この方法は、創傷の上に滅菌包帯を当てて、創傷の上に実質的に液密のシールを作り出すステップと、滅菌導管を介して滅菌ポンプを包帯に連結するステップと、手術ルームでポンプを動作させることによって手術ルームで包帯と創傷との間の圧力レベルを低減するステップとを含む。

【００１５】

本明細書に開示する幾つかの実施形態は、陰圧創傷治療システムの動作を制御するための装置及び方法に関する。特に、ただし非限定的に、本明細書に開示する実施形態は、陰圧治療装置及び包帯、ならびにかかる陰圧治療システムを動作させるための方法及びアルゴリズムに関する。幾つかの実施形態では、必須ではないものの、装置は、創傷の上に配置されるとともに、創傷の上に実質的に流体不透過性のシールを作り出すように構成された包帯を備えることができる。装置は、包帯に連結されるように構成された陰圧源を備えることができる。装置は、陰圧源を動作させ、陰圧源のデューティサイクルを監視し、デューティサイクルがデューティサイクル閾値を超えたか否かを判定するように構成された、コントローラをさらに備えることができる。幾つかの実施形態では、コントローラは、複数の連続した均等な持続時間に亘って陰圧源の複数のデューティサイクルを監視し、複

数のデューティサイクルのうちのあるデューティサイクルがデューティサイクル閾値を超えたか否かを判定するように構成することができる。デューティサイクルは、所定の期間の間、又は複数の連続した均等な持続時間のうちのある持続時間の間、陰圧源が活性である時間量を反映することができる。

【００１６】

幾つかの実施形態では、コントローラは、デューティサイクルの数がデューティサイクル閾値を超えたか、またその数が過負荷閾値を超えたか否かを判定するように構成することができる。幾つかの実施形態では、コントローラは、複数のデューティサイクルのうち一組のデューティサイクルがデューティサイクル閾値を超えたか否かを判定し、その組におけるデューティサイクルの数が過負荷閾値を超えたか否かを判定するように構成することができる。コントローラは、デューティサイクル閾値を超えるデューティサイクルの数が連続的であるか否かを判定するように構成することができる。幾つかの実施形態では、過負荷閾値は３０デューティサイクルを含むことができ、期間もしくは持続時間は１分を含むことができ、かつ／又はデューティサイクル閾値は９％を含むことができる。幾つかの実施形態では、コントローラは、デューティサイクル又は複数のデューティサイクルを継続的に監視するように構成することができる。

【００１７】

装置の幾つかの実施形態は、所定の期間の間、陰圧源を一時停止するように構成されたスイッチを備え、コントローラは、その期間が経過すると陰圧源を再始動させるように構成することができる。期間は可変であることができる。幾つかの実施形態では、装置は、外表面を含むハウジングに包囲することができ、スイッチは、ハウジングの外表面上に配置されたボタンを含むことができる。

【００１８】

装置の幾つかの実施形態は、動作状態の指示を提供するように構成されたコントローラを備える。動作状態は、デュ―ティサイクルがデュ―ティサイクル閾値を超えていることの判定を含むことができ、指示は、陰圧源を動作停止してシールの漏れを指示することを含むことができる。幾つかの実施形態では、動作状態は、陰圧源が一時停止されているか否かを含み、コントローラは、陰圧源が活動状態であるときの第１の指示と、陰圧源が一時停止されているときの第２の指示とを提供するように構成することができ、その場合、第２の指示は第１の指示とは異なる。

【００１９】

幾つかの実施形態では、コントロ―ラは、包帯の下に所望の陰圧レベルを発生させるように試みるため、陰圧源を動作させるように構成することができ、また、第１の時間間隔が経過したときに、包帯の下の圧力レベルが所望の陰圧レベルに達していない場合、コントローラは、第２の時間間隔の間、陰圧源を動作停止することができる。第２の時間間隔が経過すると、コントローラは、包帯の下に所望の陰圧レベルを発生させるように試みるため、陰圧源を動作させることができる。コントロ―ラは、包帯の下の圧力レベルが所望の陰圧レベルに達していなかった回数に基づいて、第２の時間間隔を変更するように構成することができる。例えば、コントローラは、結果として得られる値が第２の間隔閾値を超えないという条件で、第２の時間間隔を二倍にするように構成することができる。装置は、包帯の下の圧力を感知し、感知した圧力をコントローラに通信するように構成されたセンサを備えることができる。

【００２０】

幾つかの実施形態では、コントローラは、包帯の下の圧力レベルが所望の陰圧レベルに達していると、陰圧源を動作停止し、包帯の下の圧力レベルが陰圧閾値を上回ると、陰圧源を動作させるように構成することができ、その際、所望の陰圧レベルは陰圧閾値よりも負性の圧力に相当する。

【００２１】

幾つかの実施形態では、陰圧源は、創傷の上に包帯を位置付けて、創傷の上に実質的に流体不透過性のシ―ルを作り出し、陰圧源から包帯に陰圧を送達し、陰圧源のデュ―ティ

サイクルを監視し、デューティサイクルがデューティサイクル閾値を超えていると判定された場合に指示を提供することによって、動作させることができる。デューティサイクルは、１分につき一回など、所定の期間の間に陰圧源が活動状態である時間量を反映することができる。

【００２２】

装置の幾つかの実施形態は、最初の動作以降の合計経過時間を監視し、合計経過時間が寿命閾値に達すると、陰圧源の動作を不能にするように構成することができる。寿命閾値は、例えば７日間を含むことができる。

【００２３】

幾つかの実施形態では、創傷に陰圧を加えるための装置は、創傷の上に配置されて、創傷の上に実質的に流体不透過性のシールを作り出すように構成された包帯と、包帯に連結されるように構成された陰圧源と、陰圧源を動作させ、陰圧源のデューティサイクルを監視し、デューティサイクルがデューティサイクル閾値を超えた場合に、指示を提供するように構成されたコントローラとを備える。

【００２４】

幾つかの実施形態では、装置は、創傷の上に配置されて、創傷の上に実質的に流体不透過性のシールを作り出すように構成された包帯と、包帯に連結するように構成されたポンプと、所定の期間の間、ポンプを一時停止するように構成されたスイッチと、その期間が経過するとポンプを再始動するように構成されたコントローラとを備える。期間は可変であることができる。装置の幾つかの実施形態は、モータによって動作する小型のダイヤフラムポンプ、又は圧電変換器によって動作する小型のダイヤフラムポンプを含む。幾つかの実施形態では、ポンプは、小型のピストンポンプ及び小型のダイヤフラムポンプを含むことができる。

【００２５】

幾つかの実施形態は、陰圧源（例えば、陰圧ポンプ）を動作させる方法を開示し、方法は、包帯を創傷の上に位置付けて、創傷の上に実質的に流体不透過性のシールを作り出すステップと、ポンプから包帯に陰圧を送達するステップと、所定の期間の間、ポンプを一時停止するステップと、その期間が経過するとポンプを再始動するステップとを含む。期間は可変であることができる。

【００２６】

幾つかの実施形態では、陰圧ポンプは、創傷の上に包帯を位置付けて、創傷の上に実質的に流体不透過性のシールを作り出し、陰圧ポンプを使用して創傷から流体を吸引し、ポンプの活動レベルを測定し、ポンプの活動レベルを閾値と比較し、活動レベルが閾値を超えている場合に、指示を提供することによって動作させることができる。活動レベルの測定は、ポンプのデューティサイクルの判定、（例えば、流量計を使用することによる）創傷から吸引される流体の流量の判定、圧力センサを使用した包帯の下の圧力変化率の測定など、又はそれらの組合せを含むことができる。

【００２７】

幾つかの実施形態は、陰圧ポンプを動作させる方法を開示し、この方法は、創傷の上に包帯を位置付けて、創傷の上に実質的に流体不透過性のシールを作り出すステップと、包帯の下の圧力を第１の陰圧設定値に近付けるため、ポンプから包帯に陰圧を送達するステップと、包帯の下の陰圧レベルが第２の陰圧設定値よりも高くなった場合に、包帯の下の圧力を第１の陰圧設定値に近付けるため、ポンプを動作させるステップと、ポンプが動作している時間量を監視するステップと、時間量が所定の時間量を超えた場合に、指示を提供するステップとを含む。方法は、所定の期間に亘ってポンプが動作していた時間量を判定するステップと、時間量が期間の９％を超えた場合に、指示を提供するステップとをさらに含むことができる。幾つかの実施形態では、指示を提供するステップは、所定の期間に亘ってポンプが動作していた時間量を判定するステップをさらに含む。幾つかの実施形態では、指示を提供するステップは、アラームを動作させるステップをさらに含む。

【００２８】

幾つかの実施形態では、装置は、陰圧源を動作させて、陰圧創傷治療用包帯の下の圧力を、第１の陰圧設定値と第２の陰圧設定値との間の値、又は第２の陰圧設定値の値にほぼ等しい値など、所望の陰圧値に近付けるように構成することができる。包帯の下の圧力レベルを測定することができる。装置は、包帯の下の圧力が閾値の上まで減少（例えば、第１の陰圧設定値の値まで減少）した場合に、陰圧源を動作させて、包帯の下の圧力を第２の所望の陰圧レベル（例えば、第２の陰圧設定値の値）に近付けるように構成することができる。陰圧源が例えば継続的に動作していた時間量を、監視することができる。包帯の下にほぼ第２の所望の陰圧レベル（例えば、第２の陰圧設定値の値）を確立することなく、陰圧源が所定の時間量の間、動作していた場合、陰圧源の動作を一時停止又は中断することができる。

【００２９】

幾つかの実施形態は、陰圧源を動作させる方法を開示し、この方法は、包帯を創傷の上に位置付けて、創傷の上に実質的に流体不透過性のシールを作り出すステップと、陰圧源から包帯に陰圧を送達するステップとを含む。陰圧源から包帯に陰圧を送達するステップは、包帯の下に所望の陰圧レベルを発生させるように試みるため、陰圧源を動作させるとともに、第１の動作カウントを更新するステップと、第１の時間間隔が経過したときに、包帯の下の陰圧が所望の陰圧レベルに達していなかった場合、第１の動作カウントが第１の再試行閾値未満であるという条件で、第２の時間間隔の間、陰圧源を動作停止するステップと、第１の動作カウントが第１の再試行閾値以上である場合、第３の時間間隔の間、陰圧源を動作停止し、第１の動作カウントをリセットするとともに、第３の時間間隔が経過したときに、包帯の下に所望の陰圧レベルを発生させるように試みるため、陰圧源を動作させるステップと、第２の時間間隔が経過したときに、包帯の下に所望の陰圧レベルを発生させるように試みるため、陰圧源を動作させるとともに、第１の動作カウントを更新するステップと、包帯の下の陰圧が所望の陰圧レベルに達していると、陰圧源を動作停止し、第１の動作カウントをリセットするとともに、包帯の下の陰圧を監視するステップと、包帯の下の陰圧が陰圧閾値を上回ると、陰圧源を動作させ、第２の動作カウントを更新するステップであって、所望の陰圧レベルが陰圧閾値よりも負性の圧力に相当する、更新するステップと、第４の時間間隔が経過する前に包帯の下の陰圧が所望の陰圧レベルに達した場合に、陰圧源を動作停止し、包帯の下の陰圧を監視するとともに、第２の動作カウントをリセットするステップと、第４の時間間隔が経過したときに、包帯の下の陰圧が所望の陰圧レベルに達していなかった場合、第２の動作カウントが第２の再試行閾値未満であるという条件で、第２の時間間隔の間、陰圧源を動作停止するステップと、第２の動作カウントが第２の再試行閾値以上である場合、第３の時間間隔の間、陰圧源を動作停止し、第２の動作カウントをリセットするとともに、第３の時間間隔が経過したときに、包帯の下に所望の陰圧レベルを発生させるように試みるため、陰圧源を動作させ、第１の動作カウントを更新するステップと、陰圧源のデューティサイクルを継続的に監視するステップと、デューティサイクル閾値を超えるデューティサイクルの数を追跡するステップと、デューティサイクル閾値を超えるデューティサイクルの数が過負荷閾値を超えると、第３の時間間隔の持続時間の間、陰圧源を動作停止するステップとを含む。

【００３０】

本発明の実施形態について、添付図面を参照して、単なる例証として以下に記載する。

【図面の簡単な説明】

【００３１】

【図１】ポンプ、包帯、及び導管を備える減圧創傷治療装置の一実施形態を示す図である。

【図２Ａ】図１に示されるポンプの実施形態を示す図である。

【図２Ｂ】図１に示されるポンプの実施形態を示す図である。

【図２Ｃ】図１に示されるポンプの実施形態を示す図である。

【図２Ｄ】図１に示されるポンプの実施形態を示す図である。

【図２Ｅ】図１に示されるポンプの実施形態を示す図である。

【図２Ｆ】図１に示されるポンプの実施形態を示す図である。
【図３Ａ】第１のパッケージング要素内で支持されている、包帯、ポンプ、導管、２つの電池、及び１つ又は複数のシールストリップを備える、創傷包帯キットの一実施形態を示す図である。
【図３Ｂ】図３Ａの創傷包帯キットの実施形態を示す下面等角図である。
【図３Ｃ】図３Ａの創傷包帯キットの実施形態を示す分解組立図である。
【図４Ａ】図１のポンプの実施形態を示す第１の分解組立図である。
【図４Ｂ】図１のポンプの実施形態を示す第２の分解組立図である。
【図５Ａ】第１のハウジング部材を示す第１の図である。
【図５Ｂ】第１のハウジング部材を示す第２の図である。
【図６Ａ】第２のハウジング部材を示す第１の図である。
【図６Ｂ】第２のハウジング部材を示す第２の図である。
【図７Ａ】患者の創傷部位を治療するのに使用されているＴＮＰ創傷治療システムの一実施形態の使用を示す図である。
【図７Ｂ】患者の創傷部位を治療するのに使用されているＴＮＰ創傷治療システムの一実施形態の使用を示す図である。
【図７Ｃ】患者の創傷部位を治療するのに使用されているＴＮＰ創傷治療システムの一実施形態の使用を示す図である。
【図７Ｄ】患者の創傷部位を治療するのに使用されているＴＮＰ創傷治療システムの一実施形態の使用を示す図である。
【図８Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図８Ｂ】図８Ａの実施形態の下面等角図である。
【図８Ｃ】図８Ａの実施形態の上面図である。
【図８Ｄ】図８Ａの実施形態の下面図である。
【図８Ｅ】図８Ａの実施形態の前面図である。
【図８Ｆ】図８Ａの実施形態の後面図である。
【図８Ｇ】図８Ａの実施形態の第１の側面図である。
【図８Ｈ】図８Ａの実施形態の第２の側面図である。
【図９Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図９Ｂ】図９Ａの実施形態の下面等角図である。
【図９Ｃ】図９Ａの実施形態の上面図である。
【図９Ｄ】図９Ａの実施形態の下面図である。
【図９Ｅ】図９Ａの実施形態の前面図である。
【図９Ｆ】図９Ａの実施形態の後面図である。
【図９Ｇ】図９Ａの実施形態の第１の側面図である。
【図９Ｈ】図９Ａの実施形態の第２の側面図である。
【図１０Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１０Ｂ】図１０Ａの実施形態の下面等角図である。
【図１０Ｃ】図１０Ａの実施形態の上面図である。
【図１０Ｄ】図１０Ａの実施形態の下面図である。
【図１０Ｅ】図１０Ａの実施形態の前面図である。
【図１０Ｆ】図１０Ａの実施形態の後面図である。
【図１０Ｇ】図１０Ａの実施形態の第１の側面図である。
【図１０Ｈ】図１０Ａの実施形態の第２の側面図である。

【図１１Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１１Ｂ】図１１Ａの実施形態の下面等角図である。
【図１１Ｃ】図１１Ａの実施形態の上面図である。
【図１１Ｄ】図１１Ａの実施形態の下面図である。
【図１１Ｅ】図１１Ａの実施形態の前面図である。
【図１１Ｆ】図１１Ａの実施形態の後面図である。
【図１１Ｇ】図１１Ａの実施形態の第１の側面図である。
【図１１Ｈ】図１１Ａの実施形態の第２の側面図である。
【図１２Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１２Ｂ】図１２Ａの実施形態の下面等角図である。
【図１２Ｃ】図１２Ａの実施形態の上面図である。
【図１２Ｄ】図１２Ａの実施形態の下面図である。
【図１２Ｅ】図１２Ａの実施形態の前面図である。
【図１２Ｆ】図１２Ａの実施形態の後面図である。
【図１２Ｇ】図１２Ａの実施形態の第１の側面図である。
【図１２Ｈ】図１２Ａの実施形態の第２の側面図である。
【図１３Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１３Ｂ】図１３Ａの実施形態の下面等角図である。
【図１３Ｃ】図１３Ａの実施形態の上面図である。
【図１３Ｄ】図１３Ａの実施形態の下面図である。
【図１３Ｅ】図１３Ａの実施形態の前面図である。
【図１３Ｆ】図１３Ａの実施形態の後面図である。
【図１３Ｇ】図１３Ａの実施形態の第１の側面図である。
【図１３Ｈ】図１３Ａの実施形態の第２の側面図である。
【図１４Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１４Ｂ】図１４Ａの実施形態の下面等角図である。
【図１４Ｃ】図１４Ａの実施形態の上面図である。
【図１４Ｄ】図１４Ａの実施形態の下面図である。
【図１４Ｅ】図１４Ａの実施形態の前面図である。
【図１４Ｆ】図１４Ａの実施形態の後面図である。
【図１４Ｇ】図１４Ａの実施形態の第１の側面図である。
【図１４Ｈ】図１４Ａの実施形態の第２の側面図である。
【図１４Ｉ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１４Ｊ】図１４Ｉの実施形態の下面等角図である。
【図１４Ｋ】図１４Ｉの実施形態の上面図である。
【図１４Ｌ】図１４Ｉの実施形態の下面図である。
【図１４Ｍ】図１４Ｉの実施形態の前面図である。
【図１４Ｎ】図１４Ｉの実施形態の後面図である。
【図１４Ｏ】図１４Ｉの実施形態の第１の側面図である。
【図１４Ｐ】図１４Ｉの実施形態の第２の側面図である。

【図１５Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１５Ｂ】図１５Ａの実施形態の下面等角図である。
【図１５Ｃ】図１５Ａの実施形態の上面図である。
【図１５Ｄ】図１５Ａの実施形態の下面図である。
【図１５Ｅ】図１５Ａの実施形態の前面図である。
【図１５Ｆ】図１５Ａの実施形態の後面図である。
【図１５Ｇ】図１５Ａの実施形態の第１の側面図である。
【図１５Ｈ】図１５Ａの実施形態の第２の側面図である。
【図１６Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１６Ｂ】図１６Ａの実施形態の下面等角図である。
【図１６Ｃ】図１６Ａの実施形態の上面図である。
【図１６Ｄ】図１６Ａの実施形態の下面図である。
【図１６Ｅ】図１６Ａの実施形態の前面図である。
【図１６Ｆ】図１６Ａの実施形態の後面図である。
【図１６Ｇ】図１６Ａの実施形態の第１の側面図である。
【図１６Ｈ】図１６Ａの実施形態の第２の側面図である。
【図１７Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１７Ｂ】図１７Ａの実施形態の下面等角図である。
【図１７Ｃ】図１７Ａの実施形態の上面図である。
【図１７Ｄ】図１７Ａの実施形態の下面図である。
【図１７Ｅ】図１７Ａの実施形態の前面図である。
【図１７Ｆ】図１７Ａの実施形態の後面図である。
【図１７Ｇ】図１７Ａの実施形態の第１の側面図である。
【図１７Ｈ】図１７Ａの実施形態の第２の側面図である。
【図１７Ｉ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１７Ｊ】図１７Ｉの実施形態の下面等角図である。
【図１７Ｋ】図１７Ｉの実施形態の上面図である。
【図１７Ｌ】図１７Ｉの実施形態の下面図である。
【図１７Ｍ】図１７Ｉの実施形態の前面図である。
【図１７Ｎ】図１７Ｉの実施形態の後面図である。
【図１７Ｏ】図１７Ｉの実施形態の第１の側面図である。
【図１７Ｐ】図１７Ｉの実施形態の第２の側面図である。
【図１８Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１８Ｂ】図１８Ａの実施形態の下面等角図である。
【図１８Ｃ】図１８Ａの実施形態の上面図である。
【図１８Ｄ】図１８Ａの実施形態の下面図である。
【図１８Ｅ】図１８Ａの実施形態の前面図である。
【図１８Ｆ】図１８Ａの実施形態の後面図である。
【図１８Ｇ】図１８Ａの実施形態の第１の側面図である。
【図１８Ｈ】図１８Ａの実施形態の第２の側面図である。

【図１８１】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１８Ｊ】図１８Ｉの実施形態の下面等角図である。
【図１８Ｋ】図１８Ｉの実施形態の上面図である。
【図１８Ｌ】図１８Ｉの実施形態の下面図である。
【図１８Ｍ】図１８Ｉの実施形態の前面図である。
【図１８Ｎ】図１８Ｉの実施形態の後面図である。
【図１８Ｏ】図１８Ｉの実施形態の第１の側面図である。
【図１８Ｐ】図１８Ｉの実施形態の第２の側面図である。
【図１９Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図１９Ｂ】図１９Ａの実施形態の下面等角図である。
【図１９Ｃ】図１９Ａの実施形態の上面図である。
【図１９Ｄ】図１９Ａの実施形態の下面図である。
【図１９Ｅ】図１９Ａの実施形態の前面図である。
【図１９Ｆ】図１９Ａの実施形態の後面図である。
【図１９Ｇ】図１９Ａの実施形態の第１の側面図である。
【図１９Ｈ】図１９Ａの実施形態の第２の側面図である。
【図２０Ａ】あるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図である。
【図２０Ｂ】図２０Ａの実施形態の下面等角図である。
【図２０Ｃ】図２０Ａの実施形態の上面図である。
【図２０Ｄ】図２０Ａの実施形態の下面図である。
【図２０Ｅ】図２０Ａの実施形態の前面図である。
【図２０Ｆ】図２０Ａの実施形態の後面図である。
【図２０Ｇ】図２０Ａの実施形態の第１の側面図である。
【図２０Ｈ】図２０Ａの実施形態の第２の側面図である。
【図２１】幾つかの実施形態によるポンプアセンブリを示す図である。
【図２２】幾つかの実施形態によるポンプアセンブリの内部を示す断面図である。
【図２３】幾つかの実施形態によるポンプアセンブリのシステム概略図である。
【図２４】幾つかの実施形態によるポンプアセンブリの電気的構成要素の概略図である。
【図２５】幾つかの実施形態によるポンプアセンブリの動作を示す上位状態図である。
【図２６】幾つかの実施形態によるポンプアセンブリの動作を示す動作状態図である。
【図２７】幾つかの実施形態によるポンプアセンブリの動作を示す別の状態図である。
【図２８】幾つかの実施形態によるポンプアセンブリに対するデューティサイクルの判定を示すグラフである。
【図２９】幾つかの実施形態による少量の漏れが存在する状態でのポンプアセンブリの動作を示す図である。
【図３０】幾つかの実施形態による多量の漏れが存在する状態でのポンプアセンブリの動作を示す図である。
【図３１】幾つかの実施形態による非常に多量の漏れが存在する状態でのポンプアセンブリの動作を示す図である。
【図３２】幾つかの実施形態による極めて多量の漏れが存在する状態でのポンプアセンブリの動作を示す図である。
【発明を実施するための形態】
【００３２】
図面中、類似の参照番号は類似の部分を指す。

【００３３】
本明細書に開示する実施形態は、減圧を用いて創傷を治療する装置及び方法に関する。本明細書で使用するとき、－Ｘ　ｍｍＨｇなどの減圧又は陰圧レベルは、７６０ｍｍＨｇ（又は、１気圧、２９．９３水銀柱インチ、１０１．３２５ｋＰａ、１４．６９６ｐｓｉなど）に相当する標準大気圧未満の圧力レベルを表す。したがって、－Ｘ　ｍｍＨｇの陰圧値は、７６０ｍｍＨｇよりもＸ　ｍｍＨｇ低い絶対圧力、又は換言すれば（７６０－Ｘ）ｍｍＨｇの絶対圧力を反映する。それに加えて、Ｘ　ｍｍＨｇよりも「低い」又は「小さい」陰圧は、大気圧により近い圧力に相当する（例えば、－４０ｍｍＨｇは－６０ｍｍＨｇよりも低い）。－Ｘ　ｍｍＨｇよりも「高い」又は「大きい」陰圧は、大気圧からより遠い圧力に相当する（例えば、－８０ｍｍＨｇは－６０ｍｍＨｇよりも高い）。

【００３４】
実施形態のいくつかは、ポンプ及び／又はポンプと包帯のキットを備える。幾つかの実施形態は、病院、手術ルーム、又は手術室への納入前、又はかかるデバイスを使用する医療従事者への納入前に滅菌されているポンプ及び／又はポンプと包帯のキットを対象とし、したがって、滅菌ポンプ及び／又は滅菌ポンプ／包帯キットは、外科処置もしくは手術処置の直後に使用することができる。これの１つの利点は、減圧ポンプが動作中であること、及び可能な限り最も早い時点で減圧療法が開始されていることを知って、外科医は患者を手術ルームから解放することができる点である。外科処置又は他の処置の直後に包帯キットを当てることのさらなる利点は、そうすることによって、普通なら病棟で必要とされることがある感染の機会を、後の包帯交換を排除することによって低減できる点である。換言すれば、手術室で包帯（ポンプではなく）が当てられ、その後に漏れ又は包帯に関する他の問題などの事態が見つかるそのような患者に関しては、患者が手術室から解放された後に、包帯を再配置され、交換され、又は別の形がなされるために取り外す必要がある場合、患者の創傷は、手術室の外で包帯が再配置され、交換され、又は別の形がなされるときに、感染リスクに暴露されることがある。しかし、本明細書に開示する実施形態を用いると、患者が手術室にいる間にポンプが使用され試験された場合、包帯は除去され、再配置され、又は別の形がなされることが必要なこともある包帯に関するあらゆる問題を、滅菌された手術ルーム環境で取り扱うことができ、それによって、病原菌、細菌、又は他の汚染物質に暴露されるリスクが大幅に低減又は排除される。さらに、従来のポンプが一旦病院に受け入れられた後でそれを病院側で滅菌することは一般的に不可能であり、したがって、病院は、ポンプを滅菌バッグに入れるという手段を取ることがあるが、この方策によって手術ルームの滅菌野を危険に晒すリスクがあり、特に一旦デバイスをオンにすると、ポンプ内部にあることがある病原菌、細菌、又は他の汚染物質がポンプの動作によって放出される。

【００３５】
幾つかの実施形態では、ポンプを、ポンプの構成要素全体にわたる滅菌ガスへの完全な暴露及びその浸透に適したものにする、機構、構成要素、及び他の特性を有する、ガス滅菌に適したものであるように構成することができる。例えば、非限定的に、ポンプ内の流体経路全体を滅菌ガスに暴露することができるように、十分な滅菌ガスのフローを流すことを可能にする、１つ又は複数のポンプ弁が選択又は構成されている。より詳細に後述するように、幾つかの実施形態では、ポンプは、非限定的に、戦略的に位置付けられた一方向フロー弁など、ポンプアセンブリ内の流路を通る漏れを低減することによってポンプの効率を改善することができる、ポンプ内の他の弁を補完する他の構成要素を有することができる。

【００３６】
それに加えて、提供された場合、滅菌ポンプ／包帯キットもまた、ガス滅菌に適したものであるように設計し構成することができる。後述するように、滅菌ポンプ／包帯キットは、ポンプアセンブリを含む、滅菌ポンプ／包帯キットを備える構成要素がすべて、滅菌前に少なくとも第１のパッケージング要素にともにパッケージングされて、構成要素をすべてともに滅菌できるように構成することができる。さらに、後述するように、滅菌ポン

プ／包帯キットを備える構成要素は、構成要素の少なくともいくつかを予め定義された順序で除去することができるようにパッケージング内で配列することができるので、外科医又は医療従事者が組み立て、包帯を患者に当てることがより簡単になる。

【００３７】

手術室で創傷の治療を始められることには、非限定的に、創傷が滅菌状態及び環境にある状態で、創傷の上に実質的にシールされたバリアを提供し、それによって細菌又は他の汚染物質が創傷に入り込むのを阻害もしくは防止することを含む、多数の利益がある。それに加えて、可能な限り最も早い段階で減圧治療を開始することも、創傷の治癒にとって有利である。

【００３８】

それに加えて、特許文献３、特許文献４、特許文献５、特許文献６、特許文献７、特許文献８、及び特許文献９に開示されているものなど、本明細書に開示するか又は参照により組み込まれている実施形態は、改善された創傷包帯の構成要素を備える。かかる開示のすべての実施形態、構成要素、機構、及び他の詳細は、本開示の一部を成すものとして参照により本明細書に組み込まれているとともに、本明細書に開示する実施形態の構成要素、機構、及び他の詳細のいずれかの代わりに、又はそれらと組み合わせて使用することができる。例えば、幾つかの実施形態では、創傷包帯は、例えば患者の動きによって創傷包帯に掛かる圧縮力又は剪断力が、治癒途中の創傷を傷つけるのを防ぐ助けとなる、緩衝材として作用するように構成することができる。創傷包帯の実施形態は、創傷部位から除去された創傷浸出物を回収し格納する廃棄物容器として作用してもよく、また、ＴＮＰ療法が適用されている間、創傷部位を覆う創傷包帯における固形物の蓄積の管理に関する。さらに、本明細書に開示する実施形態は、創傷包帯に陰圧を加えるための方法及び吸気ポート、ならびに吸気ポート及び創傷包帯を製造する方法に関する。

【００３９】

さらに、本明細書に開示する幾つかの実施形態は、陰圧治療装置及び包帯を含むシステム、ならびに陰圧治療用包帯とともに使用される、かかる陰圧治療装置を動作させるための方法及びアルゴリズムを対象とする。幾つかの実施形態では、陰圧治療装置は、特に陰圧を創傷に提供するように構成された、ポンプアセンブリを備える。本明細書に開示するポンプアセンブリの幾つかの実施形態は、ポンプアセンブリの動作を制御するように構成された新規で独創的な制御論理を含む。例えば、幾つかの実施形態は、システムにおける１つ又は複数の漏れの存在ならびに／又は深刻度、創傷から吸引された流体（例えば、空気、液体、及び／もしくは固体浸出物など）の流量など、様々な動作状態の監視ならびに検出に応答して、ポンプアセンブリの動作を制御するように構成された、新規で独創的な制御論理を含む。幾つかの実施形態では、制御論理は、システムにおける１つ又は複数の漏れ（例えば、ポンプと流体連通している包帯における１つ又は複数の漏れ、創傷の上の包帯によって作り出されるシールにおける１つ又は複数の漏れなど）を検出するとともに、かかる１つ又は複数の漏れが検出されたときのポンプアセンブリの動作を制御するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、少なくとも正常な又は少量の漏れ（例えば、相対的に低い流量を有する漏れ）、多量の漏れ（例えば、相対的に高い流量を有する漏れ）、及び非常に多量の漏れ（例えば、相対的に非常に高い流量を有する漏れ）の間で区別するように構成することができる。幾つかの実施形態はさらに、上記の漏れと極めて多量の漏れとの間で区別するように構成することができる。

【００４０】

幾つかの実施形態では、ポンプアセンブリは、電池電源などの電源によって動力供給される、小型の使い捨てポンプなどの陰圧源を備えることができる。ポンプアセンブリは、約１日間、２～１０日間など、所定の期間の間、治療を提供するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、かかる期間の間、中断されない治療を提供するように求められる場合がある。幾つかの実施形態では、ポンプアセンブリは、最初の動作後の所定の期間（例えば、７日間）で、それ自体を動作停止するように構成することができる。本明細書に開示するアルゴリズム又は論理は、ポンプアセンブリをより

効率的に動作させ、電力を、例えば非限定的に電池電力を節約する助けとすることができる。

【００４１】

幾つかの実施形態では、ポンプアセンブリは、陰圧源（例えば、ポンプ）のデューティサイクルを監視するように構成することができる。本明細書で使用するとき、「デューティサイクル」は、所定の期間に亘って陰圧源が活動状態であるか又は稼働している時間量を反映する。換言すれば、デューティサイクルは、検討中の合計時間の一部として、陰圧源が活動状態にある時間を反映する。これは、次式のように数学的に表すことができる。

【００４２】

ＤＣ＝ｔ／Ｔ　　（１）

【００４３】

式中、ＤＣはデューティサイクル、ｔは陰圧源が活動状態である持続時間、Ｔは検討中の合計時間である。デューティサイクルは、絶対値（例えば、Ｘ秒）、割合（例えば、１／Ｘ）、百分率（例えば、Ｘ％）などとして測定することができる。例えば、１分の期間に亘って、陰圧源が６秒間オンであり（すなわち、動作している）、５４秒間オフである（すなわち、動作していない）場合、デューティサイクルは、６秒、１／１０、１０％などとして表すことができる。

【００４４】

幾つかの実施形態では、ポンプアセンブリは、陰圧源のデューティサイクルを監視するように構成されたコントローラを含むことができる。デューティサイクル測定は、陰圧源の活動レベルを反映することができる。例えば、デューティサイクルは、陰圧源が正常に動作している、酷使されている、極めて酷使されているなどを指示することができる。さらに、周期的なデューティサイクル測定などのデューティサイクル測定は、システムにおける漏れの存在ならびに／又は深刻度、創傷から吸引された流体（例えば、空気、液体、及び／もしくは固体浸出物など）の流量など、様々な動作状態を反映することができる。デューティサイクル測定に基づいて、測定されたデューティサイクルを閾値の組（例えば、較正で決定される）と比較することなどによって、コントローラは、様々なシステム要件にしたがって、システムの動作を制御するアルゴリズムもしくは論理を実行し、かつ／又はそれらを実行するようにプログラムすることができる。例えば、デューティサイクル測定は、システムにおける多量の漏れの存在を指示することができ、この条件をユーザ（例えば、患者、介護者、医師など）に対して指示し、かつ／又は電力を節約するために陰圧源の動作を一時的に保留又は一時停止するように、コントローラをプログラムすることができる。

【００４５】

幾つかの実施形態では、システムは、他の任意の適切な手段によって流量を監視するように構成することができる。ポンプアセンブリは、流量計（例えば、機械的、圧力ベース、光学、質量、熱質量、電磁、音波、超音波、レーザー、ドップラーなど）、風速計、圧力変換器又はセンサ、電磁センサ（例えば、ホールセンサなど、ポンプ速度を測定するように構成されたセンサ）、電磁測定（例えば、ポンプの電流及び／もしくは電力の引込みを測定する、電源の電流及び／もしくは電力のドレインを測定する、電源の残容量を測定するなど）、あるいはそれらの任意の組合せを使用するように構成することができる。監視された流量に基づいて、流量を閾値の組（例えば、較正で決定される）と比較することなどによって、コントローラは、様々なシステム要件にしたがって、システムの動作を制御するアルゴリズムもしくは論理を実行し、かつ／又はそれらを実行するようにプログラムすることができる。例えば、コントローラは、圧力センサから周期的な測定値を得るか、又はポンプモータから周期的なフィードバックを得るように構成することができる。圧力センサは、包帯の下の圧力を測定することができる。コントローラは、例えば、圧力勾配、圧力変化率、及び／又は圧力減少率を判定することによって、流量を判定することができる。例えば、正の圧力勾配（例えば、増加するもの）は、閾値と関連して増加する流量（例えば、漏れ）を反映することができ、コントローラは、この条件をユーザに対して

指示するようにプログラムすることができる。

【００４６】

幾つかの実施形態では、創傷の治療のためのシステムを提供することができる。包帯は、創傷の周りに（例えば、包帯の下に）実質的にシール又は閉止された空間を作り出すことができ、ポンプアセンブリは、この空間における圧力レベルを周期的もしくは継続的に測定又は監視することができる、センサを有することができる。ポンプアセンブリ又はそのコントローラは、第１の陰圧設定値限界と少なくとも第２の陰圧設定値限界との間で、空間（例えば、包帯の下）の圧力レベルを制御するように構成することができる。幾つかの実施形態では、第１の陰圧設定値限界は、約－７０ｍｍＨｇ、又は約－６０ｍｍＨｇ以下～約－８０ｍｍＨｇ以上の間であることができる。幾つかの実施形態では、第２の陰圧設定値限界は、約－９０ｍｍＨｇ、又は約－８０ｍｍＨｇ以下～約－１００ｍｍＨｇ以上の間であることができる。

【００４７】

幾つかの実施形態では、システムは「再試行」の機能性及び／又は論理を含むように構成することができる。ポンプアセンブリは、包帯の下の陰圧レベル（創腔の陰圧レベルに相当する場合がある）を監視し、監視したレベルを所望の陰圧レベル（例えば、第１の陰圧設定値、第２の陰圧設定値など）と比較し、特定の時間間隔の間に所望の陰圧レベルに達していない場合は治療を保留又は一時停止するように構成することができる。治療の保留又は一時停止に続いて、ポンプアセンブリは、治療を再開し（例えば、陰圧源を再始動し）、包帯の下に所望の陰圧レベルを再度発生させるように試みるように構成することができる。再試行の機能性は、例えば、電池電力を節約し、ユーザの介在なしに過渡的及び／又は非過渡的な漏れを解決できるようにするか、あるいはユーザが漏れを直す（例えば、包帯を真っ直ぐにする、シールを直す、１つ又は複数の接続を確認するなど）ことができるようにすることができる。幾つかの実施形態では、コントローラは、再試行の機能性及び／もしくは論理を実行し、かつ／又はそれらを実行するようにプログラムすることができる。

【００４８】

幾つかの実施形態では、システムは、ポンプアセンブリのハウジングの外部、又はユーザがアクセスすることができる他の任意の適切な場所に配置されたスイッチ、ボタンなどを介して、「稼働／一時停止」の機能性及び／又は論理を提供するように構成することができる。稼働／一時停止の機能性によって、ユーザが治療を保留及び／又は再開する（例えば、ポンプを一時停止及び／又は再始動する）のを可能にすることができる。ポンプアセンブリは、特定の所定の又は可変の一時停止間隔にしたがって、治療を自動的に再開するように構成することができる。ポンプアセンブリは、かかる間隔が経過すると治療を自動的に再開し、かつ／又はかかる間隔が経過したことをユーザに指示するように構成することができる。

【００４９】

幾つかの実施形態では、システムは、動作状態を反映して、ユーザに対して表示、アラームなどを提供するように構成することができる。システムは、ユーザに対して様々な動作状態を信号で通知するように構成された、視覚、聴覚、触覚、及び他のタイプのインジケータならびに／又はアラームを含むことができる。かかる状態は、システムのオン／オフ、スタンバイ、一時停止、通常動作、包帯の問題、漏れ、エラーなどを含む。インジケータならびに／あるいはアラームは、スピーカー、ディスプレイ、光源など、及び／又はそれらの組合せを含むことができる。例えば、指示は、陰圧源を動作させるか又は動作停止すること、陰圧源によって発生する陰圧レベルを軽減すること、陰圧源によって使用される電力量を低下させることなど、あるいはそれらの任意の組合せによって、提供することができる。

【００５０】

図１は、ポンプアセンブリ１０４と組み合わせて創傷包帯１０２を備える、減圧創傷治療装置１００の一実施形態を示す。本明細書に開示する装置の実施形態のいずれにおいて

も、図１に示される実施形態のように、ポンプアセンブリは無容器ポンプアセンブリ（ポンプアセンブリが浸出物又は液体の回収容器を有さないことを意味する）であることができる。しかし、本明細書に開示するポンプの実施形態のいずれも、容器を含む又は支持するように構成することができる。それに加えて、本明細書に開示する装置の実施形態のいずれにおいても、ポンプアセンブリの実施形態のいずれかを包帯に装着する、もしくは包帯に隣接して装着するか、又は包帯によって支持する、もしくは包帯に隣接して支持することができる。包帯１０２は、参照によりその開示を本明細書に組み込み本開示の一部と成す特許文献３により詳細に記載されているように、創傷（図示せず）の上に配置されてもよく、次に導管１０６が包帯１０２に接続されてもよい。包帯１０２又は本明細書に開示する他の任意の包帯は、特許文献３に開示されている包帯の実施形態のいずれかにおける材料、サイズ、構成要素、又は他の詳細のいずれかを有することができ、該出願のかかる実施形態及び例証の全体を、本開示の一部を成すものとして参照により本明細書に組み込まれている。導管１０６又は本明細書に開示する他の任意の導管は、ポリウレタン、ＰＶＣ、ナイロン、ポリエチレン、シリコーン、又は他の任意の適切な材料から形成することができる。

【００５１】

包帯１０２の幾つかの実施形態は、導管１０６の端部（例えば、導管１０６の第１の端部１０６ａ）を受け入れるように構成されたポート１０８を有することができるが、かかるポート１０８は必須ではない。幾つかの実施形態では、導管は、別の形で包帯１０２の中及び／又は下を通って、包帯１０２と創傷との間の空間に陰圧源を供給し、それによってかかる空間における所望の陰圧レベルを維持することができる。装置１００の幾つかの実施形態は、導管１０６の第１の端部１０６ａがポート１０８に予め取り付けられるように構成することができる。導管１０６は、ポンプアセンブリ１０４と包帯１０２との間に少なくとも実質的にシールされた流体流路を提供し、それによって、ポンプアセンブリ１０４によって提供される陰圧を包帯１０２に供給するように構成された、任意の適切な物品であることができる。

【００５２】

包帯１０２は、すべての創傷包帯要素（ポート１０８を含む）が予め取り付けられ、単一の単位体へと統合された、単一の物品として提供することができる。次に、創傷包帯１０２は、導管１０６を介してポンプアセンブリ１０４などの陰圧源に接続されてもよい。幾つかの実施形態では、必須ではないものの、ポンプアセンブリ１０４は小型化され可搬型であることができるが、ＥＺ　ＣＡＲＥ（商標）ポンプなどのより大型の従来のポンプも、包帯１０２と共に使用することができる。

【００５３】

本発明の実施形態は、概して、局所陰圧（「ＴＮＰ」）治療システムで使用するのに適用可能であることが理解されるであろう。簡潔には、陰圧創傷療法は、組織浮腫を軽減し、血流及び肉芽組織の形成を促進し、かつ／又は過剰な浸出物を除去することによって、多くの形態の「難治性」創傷の閉鎖及び治癒を支援するとともに、細菌負荷（及び、ひいては感染のリスク）を低減することができる。それに加えて、療法によって創傷の障害をより少なくすることができ、より迅速な治癒に結び付く。ＴＮＰ治療システムはまた、流体を除去することによって、かつ閉鎖の並置位置にある組織を安定化させるのを助けることによって、外科的に閉鎖された創傷の治癒を支援することができる。ＴＮＰ療法のさらなる有益な使用は、過剰な流体を除去することが重要であり、組織の生存度を担保するために移植片が組織に近接していることが求められる、移植片及びフラップにおいて見出すことができる。

【００５４】

創傷包帯１０２は、治療すべき創傷部位の上に配置することができる。包帯１０２は、実質的にシールされた腔又はエンクロージャを創傷部位の上に形成することができる。本明細書全体を通して、創傷に関して言及することが認識されるであろう。この意味で、創傷という用語は広く解釈され、皮膚が断裂、切開、もしくは穿孔される、又は外傷によっ

て挫傷が引き起こされる開放創及び閉鎖創、あるいは患者の皮膚における他の任意の表層もしくは他の部分の状態又は欠陥、あるいは減圧治療によって利益を得る他のものを包含することを理解されたい。したがって、創傷は、流体が生成されることもされないこともある、組織の任意の損傷領域として広く定義される。かかる創傷の例としては、急性創傷、慢性創傷、外科的切開及び他の切開、亜急性創傷及び裂開創傷、外傷性創傷、フラップ及び皮膚移植片、裂傷、擦傷、挫傷、火傷、糖尿病性潰瘍、褥瘡性潰瘍、ストーマ、術創、外傷性濃瘍及び静脈性潰瘍などが挙げられるが、それらに限定されない。幾つかの実施形態では、本明細書に開示するＴＮＰシステムの構成要素は、少量の創傷浸出物を浸出する切開創傷に特に適したものであり得る。

【００５５】

装置の幾つかの実施形態は、浸出物容器を使用することなく動作するように設計されている。包帯１０２は、余剰の流体を蒸発させることができるように、高い水蒸気透過性を有するフィルムを有するように構成することができ、創傷浸出物を安全に吸収するように、超吸収性材料を中に含めることができる。装置の幾つかの実施形態は、使い捨ての治療用に設計されており、最大約７～１１日間の使用後に環境に優しい形で廃棄することができる。ポンプは、所望の日数後に、例えば７日後に治療を自動的に終了し、ポンプのさらなる動作が不可能であるようにプログラムすることができる。幾つかの実施形態は、より長い使用又は繰返しの使用向けに設計され、浸出物容器を支持するように構成することができる。

【００５６】

装置１００は、種々の異なるモデル又はバージョンで製造することができ、その際、広範囲の創傷サイズに適応するように包帯１０２のサイズを変更することができる。例えば、以下のサイズの包帯１０２及び創傷パッド（すなわち、図１に図示されない吸収性要素）を有する装置１００を作ることができる。

【００５７】

【表１】

おおよその包帯サイズ	おおよその創傷パッドサイズ
10cm×30cm(4in×11.75in)	5cm×20cm(2in×8in)
15cm×15cm(6in×6in)	10cm×10cm(4in×4in)
15cm×20cm(6in×8in)	10cm×15cm(4in×6in)
10cm×20cm(4in×8in)	5cm×10cm(2in×4in)
20cm×20cm(8in×8in)	15cm×15cm(6in×6in)

【００５８】

オーバーレイ又は包帯の幾つかの実施形態は、オーバーレイ層を通る空気流及び細菌又は他の汚染物質のフローに対して実質的に不浸透性である一方で、蒸気の通過に対しては浸透性であることができる。

【００５９】

幾つかの実施形態では、創傷部位を創傷充填材で部分的に又は完全に充填するのが好ましいことがある。この創傷充填材は任意選択であるが、特定の創傷、例えばより深い創傷において望ましいことがある。創傷充填材は、創傷包帯１０２に加えて使用することができる。創傷充填材は、概して、多孔質で適合性のある材料、例えば発泡体（網状発泡体を含む）、及びガーゼを含むことができる。好ましくは、創傷充填材は、任意の空の空間を充填するように、創傷部位に嵌合するようにサイズ決めされるか、又は形作られる。次に、創傷包帯１０２を、創傷部位及び創傷部位を覆う創傷充填材の上に配置することができる。創傷充填材が使用されるとき、一旦創傷包帯１０２が創傷部位の上でシールされると、ＴＮＰが創傷包帯１０２を通して、かつ創傷充填材を通して、ポンプから創傷部位へと伝達される。この陰圧は、創傷浸出物及び他の流体又は分泌物を創傷部位から遠ざける。

【００６０】

幾つかの実施形態では、管材１０６は、管材１０６の第２の端部１０６ｂに位置付けられたコネクタ１１２を有することができる。コネクタ１１２は、嵌合するコネクタ１１４ａを短い長さの導管１１４と連通させ、コネクタをポンプハウジング（より詳細に後述する）によって支持させるか、又は別の形で、ポンプアセンブリ１０４から突出する短い長さの導管１１４と連結するように構成することができる。管材１１４の長さは、幾つかの実施形態では、約０．５５インチ（１４ｍｍ）、又は約０．５～約５インチ（１２．７～１２７ｍｍ）であることができる。短い長さの導管又は管材１１４は、患者がポンプ及びコネクタ１１２の上に横たわるか又は別の形でその上にいるときの不快感を減少させることができる。管材１０６をポンプアセンブリ１０４から迅速かつ簡単に除去できるように、ポンプアセンブリ１０４及び管材１０６を構成することによって、必要であれば包帯又はポンプを交換するプロセスを容易にし、あるいは改善することができる。本明細書に開示するポンプの実施形態のいずれも、管材とポンプとの間に、本明細書に開示する接続構成のいずれかを有するように構成することができる。

【００６１】

幾つかの実施形態では、図示される実施形態のように、ポンプアセンブリ１０４は、ユーザの身体上又はユーザの衣服内で支持するのに十分に小さく可搬型のサイズのものであることができる。例えば、ポンプアセンブリ１０４は、接着性の医療用テープを使用するか又は別の形で、包帯１０２に隣接して、もしくは包帯１０２上に、又は別の形で、ヒトの皮膚の快適な場所に取り付けられるようにサイズ決めすることができる。さらに、ポンプアセンブリ１０４は、ヒトのズボン又はシャツのポケットに収まるようにサイズ決めすることができ、あるいは、吊りひも、ポーチ、又は他の適切なデバイスもしくは物品を使用して、ヒトの身体に繋ぎとめることができる。

【００６２】

幾つかの実施形態では、ポンプアセンブリ１０４は、１つ又は複数の電池（例えば、２つの電池）によって電力供給することができ、電池の重量を含めて、約８４ｇ、又は９０ｇ未満の重量であることができる。幾つかの実施形態では、ポンプアセンブリ１０４は、任意の所望の数の電池を有することができ、約８０ｇ～約９０ｇ、又は約７５ｇ～約１００ｇ、又は上記範囲内の任意の値の間の重量であることができる。例えば、ポンプアセンブリ１０４の重量及び／又はサイズは、電池のサイズ及び／又は重量を（例えば、単４電池以下のサイズに）、あるいはポンプのサイズ及び／又は重量を低減することによって、低減することができる。

【００６３】

さらに、ポンプアセンブリ１０４の幾つかの実施形態は、ポンプの外表面によって画成される総体積が、約５．６立方インチ（約９２．５ｃｍ^3）、又は５．６立方インチ（９２．５ｃｍ^3）以下、又は７５ｃｍ^{3}以下～１１５ｃｍ^{3}以上の間、又は８５ｃｍ^3～１００ｃｍ^{3}であるようにサイズ決めすることができる。それに加えて、ポンプアセンブリ１０４は、当業者には知られている技術を使用して、約４０ｃｍ^3、又は４０ｃｍ^{3}以下、又は３０ｃｍ^{3}以下～６０ｃｍ^{3}以上の間の範囲のサイズまでさらに小型化することができる。ポンプアセンブリ１０４の幾つかの実施形態は、２立方インチ（３２．８ｃｍ^3）以下～６．５立方インチ（１０６．５ｃｍ^3）以上の間、又は約４立方インチ（６５．５ｃｍ^3）～約６立方インチ（９８．３ｃｍ^3）、又は上記範囲内の任意の値の間の総体積を有するようにサイズ決めすることができる。

【００６４】

ポンプアセンブリ１０４は、約７．２ｃｍ×約６．４ｃｍ×約２．１ｃｍ（もしくは、７．２ｃｍ×６．４ｃｍ×２．１ｃｍ）の全外形サイズ、又は約８．５ｃｍ×約８．５ｃｍ×約３ｃｍの最大値を有することができる。それに加えて、ポンプアセンブリ１０４は、約５．５ｃｍ×約４．８ｃｍ×約１．５ｃｍ（もしくは、５．５ｃｍ×４．８ｃｍ×１．５ｃｍ）の全外形サイズを有することができる。上述したように、ポンプアセンブリ１０４のサイズ及び重量は、本明細書に開示する実施形態のように、ユーザが着用又は携行するのにより快適になり、それによって移動性の向上がもたらされるように、最適化する

ことができる。

【００６５】

本開示の幾つかの実施形態に関する陰圧範囲は、約－８０ｍｍＨｇ、又は約－２０ｍｍＨｇ～－２００ｍｍＨｇであることができる。これらの圧力は、正常な周囲気圧に対する相対値であり、つまり、実用的用語では、－２００ｍｍＨｇは約５６０ｍｍＨｇであることに留意されたい。幾つかの実施形態では、圧力範囲は約－４０ｍｍＨｇ～－１５０ｍｍＨｇであることができる。あるいは、－７５ｍｍＨｇ以下、－８０ｍｍＨｇ以下、又は８０ｍｍＨｇ超過の圧力範囲を使用することができる。また、他の実施形態では、－７５ｍｍＨｇ未満の圧力範囲を使用することができる。あるいは、約－１００ｍｍＨｇ超過、又はさらには１５０ｍｍＨｇの圧力範囲を、装置１００によって供給することができる。ポンプアセンブリ１０４の動作に関する他の詳細は、特許文献３に記載されており、該特許文献のかかる実施形態、構成、詳細、及び例証の全体を、本開示の一部を成すものとして参照により本明細書に組み込まれている。

【００６６】

図２Ａ～図２Ｆは、図１に示されるポンプアセンブリ１０４の実施形態の様々な図である。図３Ａは、第１のパッケージング要素１５０内で支持されている、包帯１０２（本明細書に開示するか又は参照により組み込まれている包帯の実施形態のいずれかであることができる）と、ポンプアセンブリ１０４と、導管１４０と、１つ又は複数の電池１４２（２つが図示されている）と、１つ又は複数のシールストリップ１４８とを備える、創傷包帯キット１００の一実施形態を示す。図３Ｂは、図３Ａの創傷包帯キット１００の実施形態の下面等角図、図３Ｃは、図３Ａの創傷包帯キット１００の実施形態の分解組立図である。

【００６７】

図２Ａ～図３Ｃを参照すると、ポンプアセンブリ１０４は、第１のハウジング部材１２０ａ及び第２のハウジング部材１２０ｂを備えるハウジング１２０と、制御ボタン１２２（スイッチもしくは他の類似の構成要素であることもできる）と、電池カバー１２４と、コネクタ１２８と、ＬＥＤライトであることができる１つ又は複数のライトとを有することができる。幾つかの実施形態では、ポンプアセンブリ１０４は、２つ以上のボタン１２２を有することができ、３つ以上のライト１３２を有することができる。ライト１３２は、正常のもしくは適切な動作状態、ポンプの故障、ポンプに供給される電力もしくは電源異常、電池の状態もしくは電圧レベル、包帯もしくは流路内の漏れの検出、吸気の阻害、又は他の任意の類似のもしくは適切な状態、あるいはそれらの組合せをユーザに警告することを含む、ポンプアセンブリ１０４の様々な動作状態及び／又は故障状態をユーザに警告するように構成することができる。

【００６８】

ハウジング１２０は、二酸化エチレンなどの滅菌ガスがハウジング内に侵入し、それによって、通常の滅菌プロセスの間、ポンプアセンブリ１０４の内部構成要素が滅菌ガスに暴露されるように構成することができる。一般的に、ポンプは、空気又は他の任意のガスを実質的に排気してあるチャンバ内で滅菌ガスに暴露されるので、滅菌ガスは、ポンプハウジング１２０内に、かつポンプアセンブリ１０４内の他の空間及びチャンバ内に引き込まれる。例えば、ポンプハウジング１２０の幾つかの実施形態は、滅菌ガスが通過することができる、コネクタ１２８を取り囲むシールされていない間隙を有することができる。また、幾つかの実施形態では、間にシールを使用することなく、第１のハウジング部材１２０ａを第２のハウジング部材１２０ｂに接合することができる。

【００６９】

滅菌プロセスに関しては、幾つかの実施形態では、滅菌される構成要素を、とりわけ、任意の順序で、次のステップに晒すことができる。構成要素は、約１５分～１時間１５分の間、約７０ｍＢａｒＡ（又は６７ｍＢａｒＡ～８０ｍＢａｒＡ）まで排気される、チャンバ又はコンテナ内に配置することができる。構成要素はまた、不活性希釈、蒸気圧もしくは調節、又は窒素サイクルに晒すことができ、その後にさらなる排気サイクルを続ける

ことができる。酸化エチレン又は他の任意の適切な滅菌ガスを、約４８２ｍＢａｒＡ（又は約４６７ｍＢａｒＡ～約５００ｍＢａｒＡ）の圧力設定値で、チャンバ又はコンテナに導入することができる。構成要素は、約４６℃（又は約４２℃～４９℃）、又は６０℃以下の温度で、滅菌ガスに暴露することができる。構成要素は、約１０分間（短サイクル）もしくは約１時間（長サイクル）、又は約９分～約１１分間（短サイクル）、又は約５９分～約１時間（長サイクル）、又はそれ以上、滅菌ガスに暴露することができる。構成要素又はチャンバは、窒素及び／もしくは空気で洗い流し、かつ／又はその後に脱気することができる。

【００７０】

ポンプアセンブリ１０４は、１つ又は複数の電池１４２によって電力供給することができる。電池１４２は、二酸化エチレン及び／又は他の滅菌ガスに暴露するのに適している、塩化リチウム又は他の任意の適切な電池であることができる。電池１４２は、１つ又は複数のパッケージング要素内で支持したとき、滅菌プロセス中に滅菌ガスもしくは爆発性ガスの存在下で爆発を引き起こす場合がある、電気火花が起こる可能性を最小限に抑えるか又は排除するように、ポンプハウジング１２０の外部で支持することができる。それに加えて、複数の電池１４２がある場合、滅菌プロセス中の、又は別の使用前における、電池の何らかの電力損失又は火花発生を防ぐため、パッケージング内で電池を離隔するか又は別の形で分離することができる。

【００７１】

図３Ａを参照すると、電池１４２及び１つ又は複数のシールストリップ１４８を包帯１０２の下方に位置付けることができるので、電池１４２を除去する前に包帯１０２を第１のパッケージング要素１５０から除去しなければならず、それによって、包帯キット１００の構成要素をパッケージング１５０から除去する、かつ／又は患者に当てるか、もしくは装置１００を備える他の構成要素に組み合わせる順序が提示される。

【００７２】

幾つかの実施形態では、導管１４０の両端が自由であるか、又は別の形で装置１００の他の構成要素から分断されて、滅菌ガスに対する導管１４０の内表面の暴露が改善され、かつ／又は滅菌ガスに対する管材の完全な暴露が担保されるように、導管１４０をパッケージング１５０内で位置付けることができる。導管１４０の端部は、第１のパッケージング要素１５０に形成された陥凹部内で支持することができる。

【００７３】

第１のパッケージング要素１５０は、ポンプアセンブリ１０４を受け入れる陥凹部１９０、包帯１０２を受け入れる陥凹部１９２、１つ又は複数のシールストリップ１４８及び／又は導管１４０を受け入れる陥凹部１９４、導管１１４及び／又はコネクタ１１４ａ（存在する場合）を受け入れる陥凹部１９６、ならびに電池１４２のための離隔した陥凹部２００ａ及び２００ｂを含む、装置１００の構成要素を受け入れ支持するように構成された１つ又は複数の陥凹部を有することができる。電池を離隔することによって、酸化エチレンの潜在的に可燃性の性質により、滅菌処置中に爆発するリスクを低減又は排除することができる。

【００７４】

幾つかの実施形態では、第１のパッケージング要素１５０は、包帯キットの処理又は運搬中、電池、ポンプ、及び／又は他の構成要素を適所で保持するのに十分に剛性及び／又は堅牢性である、材料又は材料の組合せから作ることができる。例えば、第１のパッケージング要素１５０の幾つかの実施形態は、約１５Ｇ～約２５Ｇ、又は１Ｇ～４０Ｇ、又は１Ｇ～２０Ｇ、又は２５Ｇ～４０Ｇの加速に耐えるのに十分な、電池、ポンプ、又は他の構成要素などの構成要素の圧縮嵌めもしくは締まり嵌めをもたらすように構成することができる。第１のパッケージング要素１５０の幾つかの実施形態は、パッケージングの短絡もしくは溶融／磨耗に結び付く可能性があり、結果としてパッケージングの損傷もしくは細菌の進入につながる、構成要素の移動又はずれを防ぐのに十分である一方で、ユーザがかかる構成要素を必要なときにパッケージングから除去できることを妨害しないように、

ポンプ、電池、管材（管材のピンチ又は陥凹部を含む）、及び他の構成要素をしっかり保持するように構成することができる。

【００７５】

それに加えて、図示されるように、第１のパッケージング要素１５０は、手袋をはめた手及びはめていない手の両方で、外科医又はユーザがアクセスし、装置１００の様々な構成要素を除去するのを容易にするように、サイズ決めされ構成された溝又は陥凹部１９３を有することができる。さらに、隆起又は突起１９５を第１のパッケージング要素１５０に形成して、パッケージング及びキットの構成要素に対する付加的な支持及び保護を提供することができる。第１のパッケージング要素１５０は、Ｎｅｌｉｐａｋ Ｃｕｓｔｏｍ Ｔｈｅｒｍｏｆｏｒｍｅｄ Ｐｒｏｄｕｃｔｓによって提供される、再生利用可能な未使用のＰＥＴＧを青色に染色した０．８０ Ｅａｓｔｍａｎ ６７６３医療用グレードを含む、滅菌することができる任意の適切な材料から作ることができる。パッケージング要素１５０は、ＥＡＳＴＡＲ（商標）、Ｃｈｅｍｉｃａｌ ＰｒｏｄｕｃｔのＥＡＳＴＡＲコポリエステル樹脂から押し出し、熱成形することができる。例えば、押出しシート又はフィルムであり得る原料を、高温下での真空及び染色ツール上への圧迫を使用して、熱成形することができる。第１のパッケージング要素１５０に適した他の材料としては、ポリカーボネート、ＰＶＣ、又は他の任意の適切な樹脂もしくはプラスチック材料が挙げられる。幾つかの実施形態では、第１のパッケージング要素は、０．８ｍｍ（もしくは約０．８）の厚さ、又は０．８ｍｍ以下、もしくは１．０ｍｍ以下、もしくは約０．７ｍｍ～１．２ｍｍの厚さを有する材料（プレート、シート、フィルムなどを含む）から作ることができる。

【００７６】

ガス透過性のカバー１５１（本明細書では、第２のパッケージング要素とも呼ばれる）は、第１のパッケージング要素１５０の上にシール可能に位置付けて、包帯キット１００の内容物に対する細菌及び汚染物質のバリアを提供することができる。例えば、ＴＹＶＥＫ（商標）、紙、又は他の任意の適切な材料のシート状の層もしくはフィルムを、第１のパッケージング要素１５０の周縁部分１５３にシールすることができる。カバー１５１は、滅菌ガスに対して透過性であるが、細菌及び他の汚染物質に対してはバリアを提供する、ＴＹＶＥＫを含む任意の適切な材料から作ることができる。カバー１５１は、不透明、透明、又は半透明であることができる。

【００７７】

カバー１５１は、包帯キットの構成要素をすべて中で組み立てた後に、第１のパッケージング要素１５０とシール可能に連結することができる。その後、第１のパッケージング要素１５０、カバー１５１、及び包帯キットの構成要素を、滅菌ガスがバッグに入り包帯キットの構成要素を滅菌できるように、バッグに形成された開口部の上でＴＹＶＥＫ又は他の滅菌ガス透過性の材料パッチを有するシールされた不透過性のバッグ内に位置付けることができる。

【００７８】

図４Ａ及び図４Ｂは、第２のハウジング部材１２０ｂから分離された第１のハウジング部材１２０ａを示す、図１のポンプアセンブリ１０４の実施形態の第１及び第２の分解組立図である。図５Ａ及び図５Ｂは、第１のハウジング部材１２０ａの第１及び第２の図である。図６Ａ及び図６Ｂは、第２のハウジング部材１２０ｂの第１及び第２の図である。図４Ａ～図６Ｂを参照すると、ポンプアセンブリ１０４の幾つかの実施形態は、ハウジング１２０内で支持される、又はハウジング１２０内に形成される電池区画２２０を有することができる。１つ又は複数の電池接点２２２は、電池区画２２０内で支持することができる。１つ又は複数の電線２２４は、電池接点２２２をポンプ２３２及び／又は制御盤２３０に接続することができる。ポンプアセンブリ１０４は、組み立て中にポンプが暴露されるか又はポンプが受け取る可能性がある、汚染もしくはバイオバーデンのリスクを低減するため、クリーンルーム内で組み立てることができる。

【００７９】

幾つかの実施形態では、ポンプ２３２は、モータと、入口ポート又はコネクタ２５０と、出口ポート２５２とを備えることができる。ポンプ２３２は、１つ又は複数の弁を中に有することができる。例えば、第１の弁は、入口ポート２５０に隣接してポンプ２３２内に位置付けることができる。それに加えて、第２の弁は、出口ポート２５２に隣接してポンプ２３２内に位置付けることができる。ポンプ２３２は、入口ポート２５０を通り、第１及び第２の弁を通り、出口ポート２５２を出る流路を画成することができる。

【００８０】

幾つかの実施形態では、電池接点２２２は、極性保護を有するように構成することもできる。例えば、電池接点１２５に隣接した１つ又は複数の突出部１２４ｄと同様に、電池接点２２２の１つ又は複数は、電池接点２２２と、正しくない向きで電池区画に挿入された電池の正しくない側との接触を阻害するため、接点に隣接したプラスチック又は他の突出部（図示せず）を有することができる。例えば、１つ又は複数の突出部は、標準的な円筒形電池の負極が、１つ又は複数の突出部に隣接した電池接点２２２に接触するのを防ぐ一方で、かかる電池の正極が電池接点２２２に接触するのを可能にするように、サイズ決めし構成することができる。概して、この構成を用いて、電池は概して、電池を電池区画２２０に正しい向きで挿入した場合にのみ接点２２２と接触することができ、それによってポンプアセンブリ１０４に極性保護がもたらされる。突出部は、好ましくは非導電性材料から作られる。別の方法として、又はそれに加えて、制御盤２３０を、極性保護の機構又は構成要素を有するように構成することができる。それに加えて、制御盤２３０は、過電力状態又はサージ電力状態に対する保護のため、１つ又は複数のヒューズを有することができる。

【００８１】

ポンプアセンブリ１０４は、ポンプアセンブリ１０４内の流体流路と連通している、フローマニホルド２４０及び一方向フロー弁２４６を有することができる。一方向フロー弁２４６（逆止め弁とも呼ばれる）は、シリコーン、あるいは非限定的に、ポリウレタン、バイトン、ニトリルゴム、ネオプレン、テフロン（登録商標）、及び他の適切な材料を含む他の任意の適切なエラストマー材料又は軟質材から作られた、ダイヤフラム弁であることができる。一方向フロー弁に対する他の適切な弁は、例えば非限定的に、アンブレラ弁、玉弁、リード弁、ダックビル弁である。幾つかの実施形態では、一方向フロー弁２４６の漏れ速度は約０．０５ｍＬ／分であることができる。幾つかの実施形態では、一方向フロー弁２４６は、ポンプ２３２内に、又はポンプ２３２内に位置付けられた弁の１つの代わりに位置付けることができる。

【００８２】

マニホルド２４０及び／又は一方向フロー弁２４６は、コネクタ１２８と連通していることができる。幾つかの実施形態では、一方向フロー弁２４６はマニホルド２４０内で支持することができ、マニホルド２４０は、ポンプ２３２の入口ポートもしくはコネクタ２５０と実質的にシール可能に連結するか、又は別の形でハウジング１２０内で支持して、入口ポートもしくはコネクタ２５０と流体連通するようにすることができる。例えば、図４Ａ及び図４Ｂを参照すると、マニホルド２４０は、入口コネクタ２５０がマニホルド２４０に形成された開口部２６１内に受け入れられるように、ポンプ２３２とともに組み立てることができる。空気及び／又は他のガスは、出口ポートもしくはコネクタ２５２を通してポンプ２３２を出ることができる。滅菌中、ポンプ２３２は、滅菌ガスがポンプ２３２の内部空間又はチャンバに侵入して、ポンプ２３２全体（内部及び外部の両方）が滅菌されていることを担保することができるように構成することができる。１つ又は複数の弁（アンブレラ弁もしくは他の任意の適切な弁であり得る）を、ポンプ２３２内に位置付けることができる。例えば、非限定的に、１つ又は複数の弁を、入口ポート２５０及び出口ポート２５２それぞれに隣接して位置付けて、ポンプ２３２内で支持することができる。

【００８３】

最適な滅菌のため、幾つかの実施形態では、滅菌ガスをゆっくり導入して、弁を通る滅菌ガスのフローを最適化するとともに、滅菌ガスによる圧力が弁を完全に閉止するのを防

ぐことができる。上述したように、弁（第１及び第２の弁など）は、ある程度漏れ性であるように構成し、それによって滅菌ガスのフローが弁を超えて先に進んでポンプ２３２の内部構成要素を滅菌できるようにすることができる。例えば、弁は、公称のもしくは一般的な動作圧力で（すなわち、導管内の流体の公称動作圧力で）、又は公称のもしくは一般的な滅菌圧力で、０．１ｍＬ／分～１０ｍＬ／分以上の速度でそこを通る流体の漏れ流量（すなわち、弁が閉止位置にあるときに弁を通る流量）を可能にすることができる。幾つかの構成では、２つの弁の間、又は弁と一方向弁との間にある流路の部分は、流路又はポンプアセンブリ１０４を滅菌するのに最も難しい部分であり得る。

【００８４】

ポンプアセンブリの幾つかの実施形態は、圧電ポンプを有することができる。本明細書に開示する幾つかの圧電ポンプ又は他のポンプは、ポンプが停止中のとき、ポンプを通る流量が２００ｍＬ／分程度の多量であることができるように、弁機能を実施するオリフィスを有するか、あるいはオリフィスを有するように構成することができる。したがって、幾つかの実施形態では、ポンプ速度が約３００ｍＬ／分又は３２０ｍＬ／分又はその他の高い速度であることができる場合、第１及び第２の弁（オリフィスであり得る）はそれぞれ、約２００ｍＬ／分以下の漏れ速度を有することができる。

【００８５】

ポンプ２３２は、非限定的に、回転ダイヤフラムポンプもしくは他のダイヤフラムポンプ、圧電ポンプ、蠕動ポンプ、ピストンポンプ、回転翼ポンプ、液封ポンプ（ｌｉｑｕｉｄ　ｒｉｎｇ　ｐｕｍｐ）、スクロールポンプ、圧電変換器によって動作するダイヤフラムポンプ、又は他の任意の適切なポンプもしくはマイクロポンプ、あるいは上記のものの任意の組合せなど、任意の適切なタイプのものであることができる。ポンプ２３２は、例えば、Ｋｏｇｅ　ＥｌｅｃｔｒｏｎｉｃｓのＫＰＶ８Ａ－３Ａポンプなどの、標準的な既製の真空ポンプであることができる。ポンプ２３２は、ＫＮＦダイヤフラムポンプ又は任意の適切なＫＮＦポンプであることもできる。

【００８６】

ポンプの幾つかの実施形態は、約１０ｇ、又は約６ｇ～１５ｇ、又は上記範囲内の任意の値と値の間のような軽量であることができる。ポンプ２３２は、約５００ｍＬ／分、又は約３００ｍＬ／分以下～約６００ｍＬ／分以上の間、又は約４００ｍＬ／分～約５００ｍＬ／分の間、又は上記範囲内の任意の値の間のポンプ容量を有することができる。幾つかの実施形態では、ポンプアセンブリ１０４は２つ以上のポンプ２３２を備えることができる。例えば、ポンプアセンブリ１０４は、創傷のオーバーレイと創傷との間の空間の迅速なドローダウンをもたらすように構成された、高い流量を有する第１のポンプと、最初のドローダウン後に創傷のオーバーレイと創傷との間の空間の減圧レベルを維持するように構成された、第２のより少ない容量のポンプとを有することができる。幾つかの実施形態では、ポンプ流量は、約１５ｍＬ／分に設定することができる、漏れアラームの流量の約２０倍であることができる。

【００８７】

上述したように、コネクタ１２８は、管材１０６の端部と連結された噛合するねじ山付きのコネクタを螺合可能に受け入れることができる、ねじ山付きのコネクタ（図示されるようなもの）であることができる。ねじ山付きのコネクタ１２８は、医療従事者が標準的なルアーコネクタ（静脈ラインからのコネクタなど）を不用意に取り付けるのを防ぐため、他の医療用コネクタと比較して標準的ではないサイズのものであってもよい。

【００８８】

あるいは、図示されないが、コネクタ１２８は、管材１０６の端部上における別個の噛合するコネクタを省略できるように、管材をその上にシール可能に受け入れるように構成された、標準的な管材コネクタ（ニップルコネクタなど）であることができる。

【００８９】

マニホルド２４０は、圧力モニタの導管又はコネクタ２６２を受け入れるように構成することができる、別個のポート２６０を有することができる。圧力モニタは、制御盤２３

０によって支持することができ、流体流路内の圧力レベルを監視するように構成することができる。圧力モニタは、モータ２３２を保護して予め定義された閾値圧力を超過しないように構成することができる。幾つかの実施形態では、圧力モニタは１７５＋／－５０ｍｍＨｇを超過しないように較正することができる。幾つかの実施形態では、圧力モニタは２３５ｍｍＨｇを超過しないように較正することができる。圧力モニタは、圧力の読取り値が所定の値に達した場合にモータに対する電力を停止するように構成することができ、圧力レベルが所定の値を、又は第１の所定の値よりも高いもしくは低い場合がある第２の所定の値を下回ると、電力を再開するように構成することができる。それに加えて、ポンプアセンブリ１０４は、かかる過圧を防ぐようにプログラムすることができる。ポンプアセンブリ１０４は、ソフトウェアが過圧を防ぐ主要機構を提供するように構成することができ、圧力モニタが過圧保護のバックアップを提供することができる。

【００９０】

ポンプ２３２は、ポンプ２３２によって生成される雑音及び振動を低減するため、ポンプ２３２の外表面の周りに少なくとも部分的に巻き付けられる、連続気泡発泡体又は他の材料の層を有することができる。これらの構成要素はすべて、任意の適切な締結具２７０（例えば、一対のねじ）でともに固定することができる、第１及び第２のポンプハウジング部材１２０ａ、１２０ｂ内で支持することができる。１つ又は複数のラベル２７２を、ハウジング１２０の外表面に付着させることができる。それに加えて、幾つかの実施形態では、ポンプ２３２は、ポンプ２３２によって支持されるか、又はポンプの１つ又は複数の外表面に隣接して位置付けられる、１つ又は複数の重り、クッション、発泡体（粘弾性発泡体など）、プラスチック（ＡＢＳ、ポリウレタン、ウレタンなど）、あるいは他のパッド、パネル、シート、又はセグメントを有することができる。幾つかの実施形態は、質量ベースの、又は柔軟な制振材料を有することができる。かかる構成要素又は材料（図示せず）は、ポンプによって生成される振動を減衰し、かつ／又は雑音を弱めることができる。

【００９１】

例えば、１つ又は複数の重り（鋼、金属、もしくは他の任意の適切な材料から作られる）を、ポンプ２３２又は本明細書に開示する他の任意のポンプの実施形態の外表面で支持するか、あるいはそれに取り付けることができる。鋼製重りは、約１．８ｇ、３．８ｇ、もしくは５．８ｇ、又は１ｇ～１０ｇ以上、もしくは１．５ｇ～６ｇの重量であることができる。２つ以上の重りを、ポンプ２３２又は本明細書に開示する他の任意のポンプの実施形態の外表面で支持するか、あるいはそれに取り付けることができる。それぞれ約１．８ｇ、３．８ｇ、もしくは５．８ｇ、又は１ｇ～１０ｇ以上、もしくは１．５ｇ～６ｇの重量である２つの鋼製重りを、ポンプ２３２の外表面に取り付けることができる。２つのプレートをそれぞれ、モータ２３２の対向面に、又は別の形で位置付けることができる。幾つかの実施形態では、それぞれ約１．８ｇ、３．８ｇ、もしくは５．８ｇ、又は１ｇ～１０ｇ以上、もしくは１．５ｇ～６ｇの重量である４つの鋼製重りを、ポンプ２３２の外表面に取り付けることができる。プレートは、２つのプレートがモータ２３２の２つの対向面それぞれに位置付けられるように、又は別の形で配列することができる。幾つかの実施形態では、例えば非限定的に、ポンプ２３２の側面及び上面を含む、ポンプ２３２の３つ以上の面に隣接して重りを位置付けることができる。

【００９２】

図４Ａを参照すると、電池カバー１２４は、電池カバー１２４が閉止位置にあるときに不用意に開くのを阻害するため、ハウジング１２０の噛合する機構と係合するように構成することができる、ラッチ又はタブ部材１２４ａを有することができる。それに加えて、電池カバー１２４を開閉することができる容易さを促進するため、ガイド又は突出部１２４ｂを電池カバー１２４に形成することができる。ガイド１２４ｂは、ハウジング１２０に形成された噛合するガイド又はチャネル１２０ｃを係合することができる。電池カバー１２４は、一本の指で使用するために、把持面を有するように構成することができる。例えば、非限定的に、複数の窪み１２４ｃを電池カバー１２４の表面に形成して、ユーザの

指又は他の物体と電池カバー１２４との間の把持を向上させ、電池カバー１２４の開閉を容易にすることができる。

【００９３】

図４Ｂを参照すると、電池カバー１２４は、２つの電池間の接続を提供するように構成された、１つ又は複数の電池接点又は端子１２５をその上で支持することができる。電池カバー１２４は、電池接点１２５に隣接した１つ又は複数の突出部１２４ｄをさらに支持することができる。１つ又は複数の突出部１２４ｄは、標準的な円筒形電池の負極が、１つ又は複数の突出部１２４ｄに隣接した電池接点１２５に接触するのを防ぐ一方で、かかる電池の正極が電池接点１２５に接触するのを可能にするように、サイズ決めし構成することができる。この構成を用いて、電池は概して、電池を電池区画２２０に正しい向きで挿入した場合にのみ接点１２５と接触することができ、それによってポンプアセンブリ１０４に極性保護がもたらされる。

【００９４】

図４Ａ及び図４Ｂを参照すると、ハウジング１２０は、ハウジングの２つの部材１２０ａ、１２０ｂの間の接続を改善するため、１つ又は複数のタブ１２１と、タブ１２１を受け入れるように構成された窪み又はチャネル１２３とを有することができる。タブ１２１及び窪み１２３は、ハウジング１２０の縁部をともにより良好に保持して、ハウジング１２０の強度を改善するとともに、ハウジングの２つの部材１２０ａ、１２０ｂの間の接続をよりきつくすることができる。制御盤２３０は、同様の機構を用いてハウジング１２０に組み合わせることができる。

【００９５】

本明細書に全体が記載されているものとして参照により本明細書にその開示を組み込まれている、特許文献３に記載されているように、本明細書に開示する創傷包帯１０２の実施形態のいずれかの下面は、任意の創傷接触層を有することができる。本明細書に開示する包帯の実施形態のいずれも、創傷接触層を有さずに作ることができる。創傷接触層は、例えば、ホットピンプロセス（ｈｏｔ　ｐｉｎ　ｐｒｏｃｅｓｓ）、レーザーアブレーションプロセス、超音波プロセスによって、又は他の何らかの手法で多孔性もしくは有孔にすることができる、あるいは別の方法で液体及びガス透過性にすることができる、ポリウレタン層又はポリエチレン層又は他の可撓性層であることができる。貫通孔によって、液体及び／又はガスが層を通って流れることを可能にすることができる。創傷接触層は、創傷包帯の別の材料内への組織の内成長を防ぐ助けとなり得る。

【００９６】

貫通孔は、この要件を満たすのに十分な小ささであるが、依然として流体を通すことができるようにサイズ決めすることができる。例えば、０．０２５ｍｍ～１．２ｍｍの範囲のサイズを有するスリット又は穴として形成された貫通孔は、創傷包帯内への組織の内成長を防ぐ助けとなるのに十分な小ささである一方で、創傷浸出物が包帯に流入するのを可能にするものと見なされる。創傷接触層は、創傷包帯全体をともに保持する助けとなるとともに、創傷における陰圧を維持するため、吸収性パッドの周りに気密シールを作り出す助けとなる。創傷接触層は、任意の下側及び上側の接着剤層（図示せず）の担体としても作用する。例えば、下側の感圧性接着剤層を創傷包帯の下面１０１に提供することができ、その一方で、上側の感圧性接着剤層を創傷接触層の上面１０３に提供することができる。シリコーン、ホットメルト、ヒドロコロイド、もしくはアクリル系の接着剤、又は他のかかる接着剤であることができる感圧性接着剤は、創傷接触層の両面に、又は任意選択で創傷接触層の選択された一面に形成するか、もしくはいずれの面にも形成しないことができる。下側の感圧性接着剤層が利用される場合、このことは、創傷包帯を創傷部位の周りで皮膚に接着する助けとなる。

【００９７】

上述したように、本明細書に開示するか又は参照により組み込まれている包帯キットで使用される、任意の包帯の実施形態は、接着剤で覆われた下面（例えば、創傷接触面）を有することができる。幾つかの実施形態では、上述したように、接着剤は、例えばポリシ

ロキサン又はポリオルガノシロキサンを含むシリコーン接着剤、あるいは他のポリマー性の感圧性シリコーン接着剤であることができる。例えば、ポリジメチルシロキサンなどを使用することができる。接着剤配合物は、流延（ｃａｓｔｉｎｇ）又は塗り広げる（ｓｐｒｅａｄｉｎｇ）に続いて最終重合ステップが行われるように、触媒との二液混合物として塗り広げ流延することができる、アルキルペンダントシロキサンの混合物であってもよい。幾つかの実施形態では、包帯層は、押出しＥＵ３０ポリウレタン透明フィルム（２７～３７ｇｓｍ）の対向面上にコーティングされた、無孔のシリコーン接着剤コーティング（コート重量は公称１３０ｇｓｍ）及び十分に流延されたアクリル接着剤（２７～３７ｇｓｍ）を有することができる。かかる配置の幾つかの実施形態の水蒸気透過性は、約３６７ｇｍ$^{-2}$／２４時間～約４０５ｇｍ$^{-2}$／２４時間、又は平均水蒸気透過性３８２ｇｍ$^{-2}$／２４時間であることができる。

【００９８】

本明細書に開示する包帯の実施形態に適したシリコーン接着剤層の幾つかの実施形態又は配置は、約３５０ｇｍ$^{-2}$／２４時間～約４１０ｇｍ$^{-2}$／２４時間の水蒸気透過率を有することができる。適切には、本明細書に開示する包帯の実施形態に適したシリコーン接着剤層の幾つかの実施形態又は配置の平均水蒸気透過性は、約３８０ｇｍ$^{-2}$／２４時間であることができる。本明細書に開示する包帯の実施形態のいくつかは、Ｗａｃｋｅｒ ｓｉｌｒｅｓ ＰＳＡ ４５感圧性接着剤が上にコーティングされたものであることができる。

【００９９】

それに加えて、本明細書に開示する包帯の実施形態のいずれも、包帯に組み込まれた、又は包帯の１つ又は複数の表面にコーティングされた、抗菌剤又は抗菌物質を有することができる。例えば、非限定的に、本明細書に開示する任意の包帯の実施形態の創傷接触層は、非限定的に、本開示の一部を成すものとして参照により本明細書に組み込まれている、２００８年５月２１日に出願された特許文献１０（「ＡＮＴＩＭＩＣＲＯＢＩＡＬ ＢＩＧＵＡＮＩＤＥ ＭＥＴＡＬ ＣＯＭＰＬＥＸＥＳ」という名称）に開示されているものなどの、ナノ結晶質の銀剤、銀塩、銅塩、又は金塩、ＰＨＭＢ、クロロヘキサジン、過酸化物、次亜塩素酸、あるいはその中又は上の他の漂白剤を有することができる。さらに、本明細書に開示する任意の包帯の実施形態の吸収性層は、銀硫黄ジアジン、あるいはその中もしくは上の上述した物質又は活性剤のいずれかを有することができる。これらは、別個に又は併せて使用されてもよい。これらはそれぞれ、創傷の中の微生物及び吸収マトリックスの中の微生物を排除することができる。さらなる他の選択肢として、他の活性成分、例えばイブプロフェンなどの痛み抑制剤又は治癒薬を、包帯に組み込むことができる。また、成長因子などの細胞活性を向上させる薬剤、又はメタロプロテイナーゼの組織阻害剤（ＴＩＭＰＳ）などのマトリックスメタロプロテイナーゼ阻害剤もしくは亜鉛キレート剤など、酵素を阻害する薬剤を包帯に組み込むことができる。活性炭、シクロデキストリン、ゼオライトなどの臭気捕集要素も、包帯の吸収性層又は他の部分もしくは構成要素に、あるいはフィルタ層の上に含めることができる。

【０１００】

多孔質材料の層は、創傷接触層の上に配置することができる。この多孔質層、つまり透過層によって、液体及びガスを含む流体を創傷部位から離して創傷包帯の上層へと透過させることが可能になる。特に、透過層は、吸収性層がかなりの量の浸出物を吸収しているときであっても、開放空気チャネルを維持して創傷範囲の上に陰圧を伝達できることを担保することができる。層は、上述したような陰圧創傷治療の間、加えられる一般的な圧力下で、開いたままであるべきであり、それによって、創傷部位全体に均等化された陰圧が見込まれる。層は、三次元構造を有する材料で形成することができる。例えば、編成もしくは織成したスペーサ布地（ｓｐａｃｅｒ ｆａｂｒｉｃ）（例えば、Ｂａｌｔｅｘ ７９７０横編みポリエステル）、又は不織布を使用することができる。他の材料を利用することができ、かかる材料の例は、参照により本明細書に組み込まれているとともに本開示の一部を成す、特許文献３に記載されている。

【０１０１】
幾つかの実施形態では、透過層は３Ｄポリエステルスペーサ布地層を有することができる。この層は、８４／１４４テクスチャードポリエステルである上層（すなわち、使用中は創傷床から遠位側にある層）と、１００デニールのフラットポリエステルであることができる下層（すなわち、使用中は創傷床に近接して位置する層）と、これら２つの層の間に挟まれて形成される、編成ポリエステルビスコース、セルロースなどのモノフィラメント繊維によって画成される領域である、第３の層とを有することができる。他の適切な材料、及び繊維の他の線形的な質量密度を使用することができる。

【０１０２】
離隔した層におけるフィラメント計数の間のこの差分は、透過層を横切る水分フローを制御する助けとなる。特に、最上層のフィラメント計数をより多くすることによって、すなわち、最下層で使用される糸よりも多数のフィラメントを有する糸で最上層を作ることによって、液体は、最下層よりも最上層に沿ってウィッキングされる傾向がある。使用の際、この差分により、液体が創傷床から離れるように吸い出され、包帯の中央領域に吸い込まれる傾向になり、そこで、吸収性層が液体を閉じ込めるか、又はそれ自体が液体を、蒸散させることができるカバー層に向かって前方にウィッキングする助けとなる。

【０１０３】
好ましくは、透過層を横切る（すなわち、上側スペーサ層と下側スペーサ層との間に形成されるチャネル領域に垂直な）液体のフローを改善するため、３Ｄ布地はドライクリーニング剤（ペルクロロエチレンなどであるが、それに限定されない）で処理されて、透過層の親水性を妨げることがある、以前は使用されていた鉱物油、油脂、及び／又はワックスなどの任意の工業製品を除去する助けとなる。幾つかの実施形態では、親水性薬剤（Ｒｕｄｏｌｐｈ Ｇｒｏｕｐから入手可能なＦｅｒａｎ Ｉｃｅ ３０ｇ／Ｌなどであるがそれに限定されない）で３Ｄスペーサ布地が洗浄される、追加の製造ステップを続いて行うことができる。このプロセスステップは、材料上の表面張力が低く、水などの液体が３Ｄ編地に接触するとすぐに布地に入ることができる程度であることを担保する助けとなる。これは、任意の浸出物の液体障害成分（ｌｉｑｕｉｄ ｉｎｓｕｌｔ ｃｏｍｐｏｎｅｎｔ）のフローを制御するのにも役立つ。

【０１０４】
やはり、特許文献３により詳細に記載されているように、吸水性材料層を透過層の上に設けることができる。発泡体又は不織布の天然もしくは合成材料であることができ、任意選択で超吸収性材料を含む又は超吸収性材料とすることができる、吸収性材料は、流体、特に創傷部位から除去された液体のリザーバを形成し、カバー層に向かってそれらの流体を吸い取る。吸収性層の材料は、創傷包帯に回収された液体が飛び散るように流れるのを防ぐことができる。吸収性層はまた、流体が創傷部位から吸い出され、吸収性層全体に亘って蓄積されるように、ウィッキング作用を介して層全体に流体を分配させる助けとなり得る。これは、吸収性層の範囲における凝集を防ぐことに役立つ。吸収材料の容量は、陰圧が加えられたときの創傷の浸出物流量を管理するのに十分でなければならない。使用の際、吸収性層は陰圧を受けるので、吸収性層の材料は、かかる状況下で液体を吸収するように選ばれる。陰圧下で液体を吸収することができる多数の材料、例えば超吸収性材料が存在する。吸収性層は、ＡＬＬＥＶＹＮ（商標）発泡体、Ｆｒｅｕｄｅｎｂｅｒｇ １１４－２２４－４、及び／又はＣｈｅｍ－Ｐｏｓｉｔｅ（商標）１１Ｃ－４５０、あるいは他の任意の適切な材料から製造することができる。

【０１０５】
幾つかの実施形態では、吸収性層は、乾燥粒子の形態の超吸収性材料が全体的に分散されている、不織布セルロース繊維の層であることができる。セルロース繊維を使用することで、包帯によって吸収された液体を迅速かつ均一に分配する助けとなる高速ウィッキング要素が導入される。複数のストランド状繊維を並置することは、液体を分配する助けとなる繊維状パッドにおける強力な毛管作用に結び付く。このように、超吸収性材料に液体が効率的に供給される。さらに、吸収性層の領域にはすべて、液体がもたらされる。

【０１０６】
ウィッキング作用はまた、包帯の蒸散速度を増加させるのに役立つように、液体を上側カバー層と接触させるのを支援する。ウィッキング作用はまた、浸出物が低速であるか又は停止したときに、液体を創傷床に向かって下方に送達するのを支援する。この送達プロセスは、透過層及び下側の創傷床領域を湿潤状態で維持する助けとなり、それが包帯内での痂皮形成（阻害に結び付き得る）を防ぐ助けとなるとともに、創傷治癒に対して最適化された環境を維持する助けとなる。
【０１０７】
幾つかの実施形態では、吸収性層はエアレイド材料であることができる。熱融着性繊維を任意選択で使用して、パッドの構造をともに保持するのを支援することができる。超吸収性粒子を使用するのではなく、又はそれを使用するのに加えて、本発明の幾つかの実施形態による超吸収性繊維を利用することができることが認識されるであろう。適切な材料の一例は、米国のＥｍｅｒｇｉｎｇ　Ｔｅｃｈｎｏｌｏｇｉｅｓ　Ｉｎｃ　（ＥＴｉ）から入手可能な製品Ｃｈｅｍ－Ｐｏｓｉｔｅ（商標）１１Ｃである。
【０１０８】
任意選択で、吸収性層は、合成の安定した繊維及び／又は二成分の安定した繊維及び／又は天然の安定した繊維及び／又は超吸収性繊維を含むことができる。吸収性層中の繊維は、ラテックス結合又は熱結合又は水素結合又は任意の結合技術の組合せ又は他の固定機構によって、互いに固定することができる。幾つかの実施形態では、吸収性層は、吸収性層内で超吸収性粒子を閉じ込めるように動作する繊維によって形成される。これにより、吸収性層の外部に、かつ下にある創傷床に向かって超吸収性粒子が移動しないことを担保する助けとなる。このことは特に有用であるが、それは、陰圧が加えられると、吸収性パッドが下向きに潰れる傾向があり、この作用によって超吸収性粒子状物質が、吸収性層の繊維構造によって閉じ込められていなかった場合に、創傷床に向かう方向へと押し込まれるためである。
【０１０９】
吸収性層は複数の繊維の層を含むことができる。好ましくは、繊維はストランド状であり、セルロース、ポリエステル、ビスコースなどで作られる。好ましくは、乾燥した吸収性粒子が、準備ができている吸収性層全体に亘って分配される。幾つかの実施形態では、吸収性層は、セルロース繊維のパッドと複数の超吸収性粒子とを含む。追加の実施形態では、吸収性層は、ランダムに向きを付けられたセルロール繊維の不織布層である。
【０１１０】
超吸収性粒子／繊維は、例えば、ポリアクリル酸ナトリウムもしくはカルボメトキシセルロース材料など、又は液体中における自身の重量の何倍も吸収することができる任意の材料とすることができる。幾つかの実施形態では、材料は、０．９％重量食塩水自体の重量の５倍を超えて吸収することができる。幾つかの実施形態では、材料は、０．９％重量食塩水自体の重量の１５倍を超えて吸収することができる。幾つかの実施形態では、材料は、０．９％重量食塩水自体の重量の２０倍を超えて吸収することができる。好ましくは、材料は、０．９％重量食塩水自体の重量の３０倍を超えて吸収することができる。吸収性層は、吸引ポートの下になるように配置された１つ又は複数の通し穴を有することができる。
【０１１１】
包帯１０２は、ガス不透過性であるが水蒸気透過性である、創傷包帯の幅を横切って延在するカバー層を有することができる。カバー層は、例えばポリウレタンフィルム（例えば、Ｅｌａｓｔｏｌｌａｎ　ＳＰ９１０９）、又は一面に感圧性接着剤を有する他の任意の適切な材料であることができ、実質的にガス不透過性であり、それによって実質的にシールされたエンクロージャが創傷の上に作られる。このように、有効なチャンバがカバー層と創傷部位との間に作られて、陰圧を確立することができる。カバー層は、包帯の周面の周りの境界領域で創傷接触層にシールすることができ、例えば接着又は溶接技術によって、境界範囲を通って空気が引き込まれないことが担保される。カバー層は、外部の細菌

汚染から創傷を保護することができ（細菌バリア）、創傷浸出物からの液体が層を通って移行し、フィルムの外表面から蒸発することを可能にしている。カバー層は、ポリウレタンフィルムと、フィルム上に流延された接着剤パターンとを有することができる。ポリウレタンフィルムは水蒸気透過性であり、湿潤したときの水透過率が増加する材料から製造されてもよい。

【０１１２】

陰圧を包帯１０２に加えることができるように、カバーフィルムにオリフィスを設けることができる。上述したように、幾つかの実施形態では、吸引ポート１０８は、オリフィスの上のカバーフィルム上にシールすることができ、それによってオリフィスを通して陰圧を伝達することができる。ポートは、アクリル、シアノアクリレート、エポキシ、ＵＶ硬化性、又はホットメルト接着剤などの接着剤を使用して、カバーフィルムに接着されシールされてもよい。ポート１０８は、軟質ポリマー、例えば、ショアＡスケールで３０～９０の硬さを有する、ポリエチレン、ポリ塩化ビニル、シリコーン、又はポリウレタンから形成することができる。

【０１１３】

包帯１０２は、液体に対しては不透過性であるが、ガスに対しては透過性であるフィルタ要素を有することができる。フィルタ要素は、液体が創傷包帯から逃げるのを実質的に防ぐか又は阻害する液体バリアとして、ならびに臭気バリアとして作用することができる。フィルタ要素はまた、細菌バリアとして機能してもよい。幾つかの実施形態では、フィルタ要素の孔径は約０．２μｍであることができる。フィルタ要素のフィルタ材料に適した材料としては、ＭＭＴ範囲から延伸された０．２ミクロンのＧｏｒｅ（商標）ＰＴＦＥ、ＰＡＬＬ　Ｖｅｒｓａｐｏｒｅ（商標）２００Ｒ、及びＤｏｎａｌｄｓｏｎ（商標）ＴＸ６６２８が挙げられる。このようにして、フィルタ要素によって、オリフィスを通してガスを排出することができる。しかし、液体、微粒子、及び病原菌は包帯に含まれている。フィルタに関する他の詳細は、米国特許出願第１３／０９２，０４２号に開示されており、参照により本明細書に組み込まれている。

【０１１４】

本明細書に記載するような創傷包帯１０２ならびにその製造方法及び使用方法はまた、次の特許及び特許出願に記載されている特徴、構成、及び材料を組み込んでもよく、それらのそれぞれは、本開示の一部を成すものとして、その全体が参照により本明細書に組み込まれている。特許文献１１、特許文献１２、及び特許文献１３、特許文献１４、特許文献１５、特許文献１６、特許文献１７、特許文献１８、特許文献１９、特許文献２０、特許文献２１、特許文献２２、特許文献２３、特許文献２４、特許文献２５、及び特許文献２６、ならびに２０１０年１１月８日に出願された特許文献２７、２０１１年４月１５日に出願された特許文献２８、及び２０１１年４月１５日に出願された特許文献２９。これらの参照により組み込まれる特許及び特許出願から、本開示に記載するものに類似した構成要素の特徴、構成、材料、及び製造又は使用の方法が、本出願の実施形態へと代用され、追加され、又は実装されてもよい。

【０１１５】

動作の際、創傷包帯１０２は、創腔を形成する創傷部位の上にシールされる。ポンプアセンブリ１０４は、包帯１０２に対する陰圧源を提供する。流体は、創傷接触層の下にある創傷部位から創傷包帯を通ってオリフィスに向かって吸い取られる。流体は透過層を通ってオリフィスに向かって移動する。流体が透過層を通って引かれるのにつれて、創傷浸出物が吸収性層に吸収される。

【０１１６】

創傷包帯の全体形状は、正方形、卵形、長方形、又は別の形であることができる。包帯は丸角領域を有することができる。本発明の他の実施形態による創傷包帯は、正方形、円形、又は楕円形の包帯など、異なるように形作ることができることが認識されるであろう。

【０１１７】

創傷包帯１０２の所望のサイズは、それが使用される創傷のサイズ及びタイプに基づいて選択することができる。幾つかの実施形態では、創傷包帯１０２は、その長軸で２０～４０ｃｍの間、その短軸で１０～２５ｃｍの間の寸法であることができる。例えば、上述したように、約１０×２０ｃｍ、１０×３０ｃｍ、１０×４０ｃｍ、１５×２０ｃｍ、及び１５×３０ｃｍのサイズで包帯を提供することができる。

【０１１８】

幾つかの実施形態では、創傷包帯１０２は、１５～２５ｃｍの間の寸法の辺を有する正方形の包帯（例えば１５×１５ｃｍ、２０×２０ｃｍ、及び２５×２５ｃｍ）であることができる。吸収性層は包帯全体よりも小さい面積を有することができ、幾つかの実施形態では、包帯１０２全体よりも、ともに約３～１０ｃｍ短い、より好ましくは約５ｃｍ短い、長さ及び幅を有してもよい。幾つかの長方形の実施形態では、吸収性層は、その長軸で約１０～３５ｃｍ、その短軸で５～１０ｃｍの間の寸法であってもよい。例えば、吸収性層は、５．６×１５ｃｍ又は５×１０ｃｍ（１０×２０ｃｍの包帯の場合）、５．６×２５ｃｍ又は５×２０ｃｍ（１０×３０ｃｍの包帯の場合）、５．６×３５ｃｍ又は５×３０ｃｍ（１０×４０ｃｍの包帯の場合）、１０×１５ｃｍ（１５×２０ｃｍの包帯の場合）、及び１０×２５ｃｍ（１５×３０ｃｍの包帯の場合）のサイズで提供することができる。幾つかの正方形の実施形態では、吸収性層は、１０～２０ｃｍの間の長さの辺を有してもよい（例えば、１５×１５ｃｍの包帯の場合は１０×１０ｃｍ、２０×２０ｃｍの包帯の場合は１５×１５ｃｍ、又は２５×２５ｃｍの包帯の場合は２０×２０ｃｍ）。透過層は吸収性層よりも小さいサイズのものであることができ、幾つかの実施形態では、吸収性層よりも、ともに約０．５～２ｃｍ短い、より好ましくは約１ｃｍ短い、長さ及び幅を有することができる。幾つかの長方形の実施形態では、透過層は、その長軸で９～３４ｃｍの間、その短軸で３～５ｃｍの間の寸法であってもよい。例えば、透過層は、４．６×１４ｃｍ又は４×９ｃｍ（１０×２０ｃｍの包帯の場合）、４．６×２４ｃｍ又は４×１９ｃｍ（１０×３０ｃｍの包帯の場合）、４．６×３４ｃｍ又は４×２９ｃｍ（１０×４０ｃｍの包帯の場合）、９×１４ｃｍ（１５×２０ｃｍの包帯の場合）、及び９×２４ｃｍ（１５×３０ｃｍの包帯の場合）のサイズで提供されてもよい。幾つかの正方形の実施形態では、透過層には、９～１９ｃｍの間の長さの辺を有してもよい（例えば、１５×１５ｃｍの包帯の場合は９×９ｃｍ、２０×２０ｃｍの包帯の場合は１４×１４ｃｍ、又は２５×２５ｃｍの包帯の場合は１９×１９ｃｍ）。

【０１１９】

包帯は、抗菌物質を、例えば、創傷接触層上のナノ結晶質の銀剤及び／又は吸収性層内の銀硫黄ジアジンを含むことができる。これらは、別個に又は共に使用されてもよい。これらはそれぞれ、創傷中の微生物を、かつ吸収マトリックス中の微生物を殺す。さらなる他の選択肢として、他の有効成分、例えばイブプロフェンなどの痛み抑制剤が含まれてもよい。また、成長因子などの細胞活性を向上させる薬剤、又はメタロプロテイナーゼの組織阻害剤（ＴＩＭＰＳ）などのマトリックスメタロプロテイナーゼ阻害剤もしくは亜鉛キレート剤など、酵素を阻害する薬剤を利用することができる。さらなる他の選択肢として、活性炭、シクロデキストリン、ゼオライトなどの臭気捕集要素が、吸収性層に、又はフィルタ層の上のさらなる別の層として含まれてもよい。

【０１２０】

透過層が３Ｄ編成層として、例えばモノフィラメント層によって離隔された２つの層として形成される本発明の幾つかの実施形態についてここまで記載してきたが、本発明の幾つかの実施形態はかかる材料を使用することに制約されないことが認識されるであろう。幾つかの実施形態では、かかる３Ｄ編成材料の代替物として、種々の材料の１つ又は複数の層を利用することができる。いずれも場合も、本発明の実施形態によれば、透過層の複数層によって示される開口部は、使用中は創傷に近接して配置されるであろう包帯の側面から離れる方向に移動するのにしたがって広くなっていく。幾つかの実施形態では、透過層は連続気泡発泡体の複数層によって提供されてもよい。幾つかの実施形態では、発泡体は網状連続気泡発泡体である。発泡体は、親水性であることができ、又は水性系の流体を

ウィッキングすることができる。各層の孔径は、発泡体層中において、使用中に最も創傷部位に近接する孔が最も小さい径を有するように選択される。１つのさらなる発泡体層のみが利用される場合、それは第１の層の孔径よりも大きい孔径を含む。このことが、固体粒子が下層に捕捉されるのを回避する助けとなり、それが結果として、下層を開いた構成で維持する助けとなり、その構成によって包帯を空気が透過することができる。幾つかの実施形態では、２つ、３つ、４つ、又はそれ以上の発泡体層が含まれてもよい。発泡体層は、例えば、大きな孔径を有する発泡体を選択し、これを孔を詰まらせる材料に浸漬する程度を徐々に減らしながら繰り返し浸漬することによって一体的に形成されてもよく、あるいは、複数の発泡体層によって形成される透過層は、異なるタイプの発泡体を層状の配列で積層するか、又はかかる発泡体の層を既知のやり方で適所に固定することによって提供されてもよい。

【０１２１】

図７Ａ～図７Ｄは、患者の創傷部位を治療するのに使用されているＴＮＰ創傷治療システムの一実施形態の使用を示す図である。図７Ａは、創傷部位Ｗが清浄にされ、治療のために準備されていることを示す。ここでは、創傷部位Ｗを取り囲む健康な皮膚は、好ましくは清浄にされ、余分な毛は除去又は剃毛される。必要であれば、創傷部位Ｗも滅菌生理食塩水で灌注されてもよい。任意選択で、皮膚保護薬が創傷部位Ｗを取り囲む皮膚に塗布されてもよい。必要であれば、発泡体又はガーゼなどの創傷充填材が創傷部位Ｗに配置されてもよい。これは、創傷部位Ｗがより深い創傷である場合に好ましいことがある。

【０１２２】

創傷部位Ｗを取り囲む皮膚が準備された後、カバー１５１を第１のパッケージング要素１５０から取り出して、構成要素に対するアクセスを提供することができる。包帯１０２は、パッケージング１５０から取り出すことができ、図７Ｂに示されるように、創傷部位Ｗの上に位置付け、配置することができる。創傷包帯１０２は、包帯１０２の創傷接触層が創傷部位Ｗの上にあるように、かつ／又はそこと接触するように配置することができる。幾つかの実施形態では、接着剤層を創傷接触層の下面に提供することができ、それは、場合によっては、創傷包帯１０２を創傷部位Ｗの上に配置するのに先立って除去される任意の剥離層によって保護されていてもよい。包帯１０２は、ポート１０８が包帯１０２の残りの部分に対して隆起した位置にあってポート１０８の周りに流体が貯留するのを回避するようにして、位置付けることができる。幾つかの実施形態では、包帯１０２は、ポート１０８が創傷の上に直接重なり合わず、創傷と同じ高さか又はそれよりも上にあるようにして位置付けられる。ＴＮＰに対して適切なシールを担保する助けとするため、包帯１０２の縁部を平滑にして、たたみ目又は折り目を回避することができる。包帯及びその上に形成される接着剤は、接着剤の性能を犠牲にすることなく、包帯を皮膚又は創傷から離れる方向に持ち上げ、位置付けし直してたたみ目及び折り目を除去するか、又は他の理由で単に包帯を創傷の上で位置付けし直すことができるように構成することができる。管材１０６は、包帯１０２を創傷の上に配置する前又は配置した後のどちらかに、包帯１０２に接続することができる。

【０１２３】

その後、図７Ｃに示されるように、ポンプアセンブリ１０４をパッケージング１５０から取り出し、管材１０６に接続することができる。電池１４２をパッケージング１５０から取り出し、ポンプを導管１０６に取り付ける前又は後のどちらかに、ポンプアセンブリ１０４に設置することができる。ポンプアセンブリ１０４は、包帯１０２を介して、一般的には管材又は導管１０６を通して、創傷部位に陰圧を加えるように構成される。幾つかの実施形態では、導管１０６を包帯１０２に、かつポンプアセンブリ１０４に接合するのにコネクタが使用されてもよい。ポンプアセンブリ１０４によって陰圧を加える際、包帯１０２は、幾つかの実施形態では、包帯１０２の下にある空気の一部又はすべてを排気した結果として、部分的に潰れ、しわが寄った外観を示してもよい。幾つかの実施形態では、ポンプアセンブリ１０４は、包帯１０２と創傷部位Ｗを取り囲む皮膚との間の接合部分などで、包帯１０２に何らかの漏れがあった場合にそれを検出するように構成されてもよ

い。漏れが見つかった場合、かかる漏れは好ましくは治療を継続する前に修正される。漏れは、包帯１０２を位置付けし直すか、包帯のしわもしくは折り目を伸ばすか、又は包帯１０２の外周の周りに固定用ストリップ１４８を当てることによって修正することができる。

【０１２４】

図７Ｄに移ると、上述したように、固定用ストリップ１４８を包帯１０２の外周縁部の周りに、又は別の方法で取り付けることができる。かかる固定用ストリップ１４８は、創傷部位Ｗを取り囲む患者の皮膚に対して追加のシールを提供するために、幾つかの状況で有利であり得る。例えば、シール又は固定用ストリップ１４８は、患者の動きがより活発なときに追加のシールを提供することができる。場合によっては、固定用ストリップ１４８は、特に包帯１０２が手の届きにくい、又は起伏のある範囲の上に配置される場合に、ポンプアセンブリ１０４を動作させる前に使用されてもよい。幾つかの実施形態では、包帯キット１００は５つ以下のシールストリップを備えることができる。

【０１２５】

創傷部位Ｗの治療は、好ましくは、創傷が所望の治癒レベルに達するまで継続する。幾つかの実施形態では、特定の期間が経過した後に、又は包帯が創傷流体でいっぱいになった場合に、包帯１０２を交換するのが望ましいことがある。そのような交換の間、ポンプアセンブリ１０４は保持され、包帯１０２のみが交換されてもよい。

【０１２６】

図８Ａ～図２０Ｈはそれぞれ、様々な異なるサイズの創傷包帯装置を含む、本明細書に開示する創傷包帯装置の実施形態のいずれかとともに使用することができる、パッケージング要素の実施形態の上面等角図、下面等角図、上面図、下面図、前面図、後面図、第１の側面図、及び第２の側面図である。図８Ａ～図２０Ｈに示される、又は別の形で本出願に開示するパッケージング要素の実施形態のいずれも、上述した第１のパッケージング要素１５０を含む、本明細書に開示する他のパッケージング要素のいずれかと同じ特徴、材料、又は他の詳細のいずれかを有することができる。

【０１２７】

図８Ａ～図８Ｈに示されるパッケージング要素３００は、約１０ｃｍ×２０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図９Ａ～図９Ｈに示されるパッケージング要素３１０は、約１０ｃｍ×２０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１０Ａ～図１０Ｈに示されるパッケージング要素３２０は、約１０ｃｍ×３０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１１Ａ～図１１Ｈに示されるパッケージング要素３３０は、約１０ｃｍ×３０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１２Ａ～図１２Ｈに示されるパッケージング要素３４０は、約１０ｃｍ×４０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１３Ａ～図１３Ｈに示されるパッケージング要素３５０は、約１０ｃｍ×４０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１４Ａ～図１４Ｈに示されるパッケージング要素３６０は、約１５ｃｍ×１５ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１４Ｉ～図１４Ｐに示されるパッケージング要素３６５は、約１５ｃｍ×１５ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。

【０１２８】

図１５Ａ～図１５Ｈに示されるパッケージング要素３７０は、約１５ｃｍ×２０ｃｍの

サイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１６Ａ～図１６Ｈに示されるパッケージング要素３８０は、約１５ｃｍ×２０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１７Ａ～図１７Ｈに示されるパッケージング要素３９０は、約２０ｃｍ×２０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１７Ｉ～図１７Ｐに示されるパッケージング要素３９５は、約２０ｃｍ×２０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１８Ａ～図１８Ｈに示されるパッケージング要素４００は、約１５ｃｍ×３０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１８Ｉ～図１８Ｐに示されるパッケージング要素４０５は、約１５ｃｍ×３０ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図１９Ａ～図１９Ｈに示されるパッケージング要素４１０は、約２５ｃｍ×２５ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。図２０Ａ～図２０Ｈに示されるパッケージング要素４２０は、約２５ｃｍ×２５ｃｍのサイズを有する包帯、及び／又は本明細書に開示する任意のＴＮＰ治療キットの他の構成要素の１つ又は複数を支持するように構成される。

【０１２９】

図２１は、幾つかの実施形態によるポンプアセンブリ１０００を示す。本明細書に開示するポンプアセンブリ１０００の実施形態のいずれも、上述したポンプアセンブリ１０４の実施形態を含む、本明細書に開示するか又は本明細書に参照により組み込まれている他の任意のポンプアセンブリの実施形態と同じもしくは類似の構成要素、特徴、材料、サイズ、構成、及び他の詳細のいずれかを有することができる。好ましくは、ポンプアセンブリ１０００は小型化され可搬型であることができるが、より大きな従来の可搬型又は非可搬型（例えば、壁面吸込み）のポンプも使用することができる。ポンプアセンブリ１０００は、ポンプアセンブリのハウジングの外部に位置する稼働／一時停止ボタンとして図示される、スイッチ又はボタン１００２を含むことができる。後述するように、ボタン１００２は、治療を停止、一時停止、及び／又は再開させるように構成することができる。押しボタン１００２として図示されているが、タッチパッド、タッチスクリーン、キーボードなど、他のタイプのスイッチ又はボタンを含むことができる。

【０１３０】

ポンプアセンブリは、コネクタ１０５０（導管を、例えば導管１０６を接続するためのもの）と、３つのＬＥＤインジケータ１０６２、１０６４、及び１０６６とをさらに含むことができる。図示されるように、ＬＥＤインジケータ１０６２（例えば、ＯＫインジケータ）は、システムの正常／異常動作を指示するように構成することができる。例えば、活動状態の（例えば、点灯している）インジケータ１０６２は、正常動作を表すことができる。ＬＥＤインジケータ１０６４（例えば、包帯インジケータ）は、システムの漏れを指示するように構成することができる。例えば、活動状態の（例えば、点灯している）インジケータ１０６４は、漏れを表すことができる。ＬＥＤインジケータ１０６６（例えば、電池インジケータ）は、電源（例えば、電池）の残容量又は寿命を指示するように構成することができる。例えば、活動状態の（例えば、点灯している）インジケータ１０６６は、低容量を表すことができる。幾つかの実施形態では、インジケータ１０６２、１０６４、及び１０６６は、異なる色、２つの異なる色（例えば、２つのインジケータが同じ色を共有することができる）、又は同じ色であることができる。ポンプアセンブリは、好ましくは３つのＬＥＤインジケータ及び１つの稼働／一時停止押しボタンを含むが、他の構成、場所、及びタイプのインジケータ、アラーム、ならびにスイッチを代わりに使用することができる。幾つかの実施形態では、ポンプアセンブリ１０００は、ユーザに対して様

々な動作状態を信号で通知するように構成された、視覚、聴覚、触覚、及び他のタイプのインジケータ又はアラームを含むことができる。そのような状態は、システムのオン／オフ、スタンバイ、一時停止、正常動作、包帯の問題、漏れ、エラーなどを含む。インジケータは、スピーカー、ディスプレイ、光源など、及び／又はそれらの組合せを含むことができる。

【０１３１】

図２２は、幾つかの実施形態によるポンプアセンブリ１０００の内部を示す断面図を示す。図示されるように、ハウジング１０２０はポンプアセンブリを包囲することができる。一方向フロー弁１０３０は、陰圧源が活動状態でないときに陰圧レベルを維持し（例えば、漏れを防ぎ）、創傷から吸引もしくは除去された流体及び／又は浸出物が、コネクタ１０５０を介してポンプアセンブリに入るのを防ぐように構成することができる。プリント回路基板アセンブリ（ＰＣＢＡ）などの制御盤１０４０は、後述する様々な電気的／電子的構成要素を機械的に支持し、電気的に接続するように構成することができる。ＰＣＢＡは片面又は両面であることができる。ポンプなどの陰圧源１０９０は、流体及び／又は浸出物を創傷から吸引することができる。本明細書に開示する実施形態のいずれかにおいて、陰圧源１０９０は、上述したポンプ２３２を非限定的に含む、本明細書に開示する他の陰圧源の実施形態のいずれかと同じ構成要素、特徴、限定、又は他の詳細のいずれかを有することができる。蠕動ポンプ、ピストンポンプ、回転翼ポンプ、液封ポンプ、スクロールポンプ、ダイヤフラムポンプ、圧電ポンプ（例えば、圧電変換器によって動作するダイヤフラムポンプ）など、又はそれらの組合せを含む、様々なポンプを陰圧源に使用することができる。ポンプアセンブリは、好ましくは、小型の低雑音低電力ポンプを含むが、任意の適切なポンプを代わりに使用することができる。ポンプアセンブリ１０００は、インジケータ１０６０（例えば、ＬＥＤ）と、包帯の下の圧力など、システムの圧力を監視する圧力センサ１０７０と、電池区画１１００へのアクセスを提供するように構成された電池カバー１０８０とを含む。ポンプアセンブリは、好ましくは、２つの標準的な使い捨てアルカリ電池（例えば、２つの単三電池）によって電力供給されるが、充電式電池及び外部電力を含む、任意のタイプの電源を代わりに使用することができる。

【０１３２】

図２３は、幾つかの実施形態によるポンプアセンブリ１０００のシステム概略図を示す。ポンプアセンブリは、押しボタン１００２、制御盤１０４０、及びインジケータ１０６０を含む。ポンプアセンブリ１０００は、電池セル１１３０によって電力供給することができる。ポンプアセンブリはまた、電気モータ１０９２によって電力供給されるダイヤフラムポンプなどのポンプ１０９０と、圧力センサ１０７０とを含む。入口１１２０は、例えば導管を介して、ポンプアセンブリ１０００を包帯に接続するように構成することができる。入口１１２０は、一方向弁１０３０に接続することができ、陰圧源が活動状態でないときに陰圧レベルを維持するのを助け、漏れを回避し、創傷から吸引もしくは除去した流体及び／又は浸出物がポンプアセンブリ１０００に入るのを防ぐように構成することができる。ポンプ１０９０はまた、出口１１１０に接続することができる。幾つかの実施形態では、出口１１１０は、空気を雰囲気へと放出するように構成することができる。幾つかの実施形態では、フィルタ（図示せず）を出口と雰囲気との間に差し挟むことができる。フィルタは、細菌フィルタ、臭気フィルタなど、又はそれらの任意の組合せであることができる。

【０１３３】

図２４は、幾つかの実施形態によるポンプアセンブリ１０００の電気的構成要素の概略図を示す。制御盤（例えば、ＰＣＢＡ）であることができるモジュール１１４０は、入／出力（Ｉ／Ｏ）モジュール１１５０、コントローラ１１６０、及びメモリ１１７０を含むことができる。幾つかの実施形態では、モジュール１１４０は、追加の電気的／電子的構成要素、例えば１つ又は複数のヒューズを含むことができる。コントローラ１１６０は、マイクロコントローラ、プロセッサ、マイクロプロセッサなど、又はそれらの任意の組合せであることができる。例えば、コントローラ１１６０は、ＳＴＭ８Ｌ　１５１Ｇ４Ｕ６

など、ＳＴ　Ｍｉｃｒｏｅｌｅｃｔｒｏｎｉｃｓ製のＳＴＭ８Ｌ　ＭＣＵファミリータイプのもの、又はＭＣ９Ｓ０８ＱＥ４ＣＷＪなど、Ｆｒｅｅｓｃａｌｅ製のＭＣ９Ｓ０８ＱＥ４／８直列タイプのものであることができる。好ましくは、コントローラ１１６０は低電力又は超低電力デバイスであるが、他のタイプのデバイスを代わりに使用することができる。メモリ１１７０は、リードオンリーメモリ（ＲＯＭ）、ライトワンスリードメニーメモリ（ＷＯＲＭ）、ランダムアクセスメモリ（例えば、ＳＲＡＭ、ＤＲＡＭ、ＳＤＲＡＭ、ＤＤＲなど）、固体メモリ、フラッシュメモリ、磁気記憶装置など、又はそれらの任意の組合せの１つ又は複数など、揮発性及び／又は不揮発性メモリモジュールの１つ又は複数を含むことができる。メモリ１１７０は、プログラムコードもしくは命令（コントローラによって実行される）、システムパラメータ、動作データ、ユーザデータなど、又はそれらの任意の組合せを格納するように構成することができる。

【０１３４】

Ｉ／Ｏモジュール１１５０は、コントローラ１１６０と、電磁信号を提供する、かつ／又は電磁信号に応答する他のシステム構成要素との間のインターフェースとして機能するように構成することができる。換言すれば、Ｉ／Ｏモジュール１１５０は、コントローラ１１６０がシステムの動作を監視し、システムの他の構成要素を制御することが可能になるように構成することができる。幾つかの実施形態では、図示されるように、Ｉ／Ｏモジュール１１５０は、ボタン１００２、インジケータ１０６０、圧力センサ１０７０、電源１１３０、及び陰圧源１０９０と電磁気的に連通していることができる。Ｉ／Ｏモジュールは、様々な構成要素と通信するように構成されたインターフェース又は複数のインターフェースを備えることができる。インターフェースは、シリアルポート、パラレルポート、バスインターフェースなど、又はそれらの任意の組合せなどの、規格及び／又は規格外のポートを含むことができる。

【０１３５】

幾つかの実施形態では、ポンプアセンブリ１０００は、システムの動作を制御するように構成することができる。例えば、ポンプアセンブリ１０００は、中断されずに治療を送達すること、ならびに／あるいは例えば、頻繁にもしくは不必要に治療を一時停止又は延期することによって、ユーザに不便を掛けるのを回避すること、及び電力を節約し、陰圧源によって発生する雑音と振動を制限したいという要求の間の適切なバランスを提供するように構成することができる。図２５は、幾つかの実施形態によるポンプアセンブリの動作の上位状態図１２００を示す。幾つかの実施形態では、コントローラ１１４０は、状態図１２００のフローを実施するように構成することができる。図２５に示されるように、ポンプアセンブリの動作は、幾つかの実施形態では、非活動状態／初期設定（状態１２０６及び１２０２）、活動状態１２１０、動作中１２５０、ならびに寿命末期（状態１２１４）の４つの一般状態カテゴリーにグループ化することができる。図２５及び図２６に示されるように、状態カテゴリー１２１０及び１２５０はそれぞれ、複数の状態を含み、状態間で遷移する。

【０１３６】

幾つかの実施形態では、電源が接続されておらず、除去されている（遷移１２０４によって図示される）限り、又はポンプアセンブリを（例えば、動作ストリップを引っ張るか、スイッチを起動するなどによって）動作させていない限り、ポンプアセンブリは状態１２０６に留まる。この状態に留まっている間、ポンプアセンブリは非活動状態に留まっていることができる。電源が接続されると、かつ／又はポンプアセンブリを最初に動作させると、ポンプアセンブリは状態１２０２に遷移して、１つ又は複数の電源投入時自己診断（ＰＯＳＴ）を実施することができる。電源投入時自己診断（複数可）は、メモリ１１７０を検査すること（例えば、プログラムコードの周期的冗長検査などのチェックを実施してその保全性を判定する、ランダムアクセスメモリを検査するなど）、圧力センサ１０７０を読み取って圧力値が適切な限界内にあるか否か否かを判定すること、電源の残容量もしくは寿命（例えば、電池電圧、電流など）を読み取ってそれが適切な限界内にあるか否か否かを判定すること、及び陰圧源を検査することなど、システムの適正な機能性を担保

するために様々なチェックを実施することを含むことができる。図示されるように、インジケータ１０６０（例えば、ＬＥＤ）は、ポンプアセンブリがＰＯＳＴ検査（複数可）を受けていることをユーザに（例えば、一度明滅又は点滅させることによって）指示するように構成することができる。

【０１３７】

幾つかの実施形態では、ＰＯＳＴ検査（複数可）のうち１つ又は複数が不合格だった場合、ポンプアセンブリは回復不能なエラー状態１２１４に遷移することができる。この状態にある間、ポンプアセンブリは治療を動作停止することができ、インジケータ１０６０は、エラーに遭遇したことをユーザに指示するように構成することができる。幾つかの実施形態では、すべてのインジケータが活動状態に留まるように構成することができる。エラーの深刻度に基づいて、幾つかの実施形態では、ポンプアセンブリは、エラーから回復し、動作を継続する（又は回復不能なエラー状態１２１４に遷移する）ように構成することができる。図示されるように、ポンプアセンブリは、動作中に決定的エラーに遭遇すると、状態１２１４へと遷移することができる。決定的エラーは、プログラムメモリエラー、プログラムコードエラー（例えば、無効な変数値に遭遇する）、コントローラ動作エラー（例えば、コントローラ１１６０によってリセットされることなく、ウォッチドッグタイマーが終了する）、構成要素の故障（例えば、陰圧源の動作不能、圧力センサ１０７０の動作不能など）、及びそれらの任意の組合せを含むことができる。

【０１３８】

ＰＯＳＴ検査（複数可）に合格すると、幾つかの実施形態では、ポンプアセンブリは手動一時停止状態１２１６に遷移することができる。図示されるように、インジケータ１０６０（例えば、電池インジケータ１０６６）の１つを動作停止することによって、この遷移をユーザに指示することができる。ポンプアセンブリが手動一時停止状態１２１６に遷移し、そのまま留まっているとき、インジケータ１０６２（ＯＫインジケータ）及び１０６４（包帯インジケータ）を動作停止することなどによって、ユーザに指示を提供することができる。幾つかの実施形態では、ポンプアセンブリが手動一時停止状態１２１６に留まっている間、治療を延期することができる。例えば、陰圧源（例えば、ポンプ１０９０）を動作停止する（又はオフにする）ことができる。幾つかの実施形態では、指示は、陰圧源を動作停止することによって提供することができる。

【０１３９】

幾つかの実施形態では、ポンプアセンブリは、スイッチからの信号の受信に応答して、手動一時停止状態１２１６から動作状態カテゴリー１２５０への遷移１２２４を行うように構成することができる（ポンプアセンブリが治療を送達するように構成されている場合）。例えば、ユーザがボタンを押して、治療を開始、延期、及び／又は再開することができる。幾つかの実施形態では、ポンプアセンブリは、ポンプアセンブリが手動一時停止状態１２１６に留まっている持続時間を監視するように構成することができる。これは、例えば、ポンプアセンブリが手動一時停止状態１２１６に遷移するとリセットし開始することができる、（ファームウェア、ソフトウェア、ハードウェア、もしくはそれらの任意の組合せの）タイマーを維持することによって、達成することができる。ポンプアセンブリは、持続時間が閾値を超えたときに、手動一時停止状態１２１６から動作状態カテゴリー１２５０への遷移１２２４を自動的に行うように構成することができる。幾つかの実施形態では、かかる閾値は、１分以下～１時間以上の間などの設定値であることができる。幾つかの実施形態では、閾値をユーザによって設定又は変更することができる。幾つかの実施形態では、閾値は様々な動作状態又はそれらの任意の組合せに基づいて変えることができる。例えば、ポンプアセンブリが寿命末期に近付くにつれて（後述するように）、閾値を減少させることができる。幾つかの実施形態では、ユーザは、スイッチを動作させる（例えば、ボタンを押す）ことによって治療を一時停止することができ、それによって、ポンプアセンブリが動作状態カテゴリー１２５０から手動一時停止状態１２１６への遷移１２２２を行う。幾つかの実施形態では、ユーザが単に治療を一時停止することができるように、ポンプアセンブリを構成することができるが、電源を分断する（例えば、電池を除

去する）ことによって治療が停止する。

【０１４０】

幾つかの実施形態では、ポンプアセンブリは一時停止状態１２１８を含むように構成することができる。ポンプアセンブリが一時停止状態１２１８に遷移し、そこに留まっているとき、ユーザに指示を提供することができる。例えば、ポンプアセンブリは、ＯＫインジケータ１０６２を動作停止し、包帯インジケータ１０６４を点滅又は明滅させるように構成することができる。幾つかの実施形態では、ポンプアセンブリが手動一時停止状態１２１６に留まっている状態で治療を延期することができる。例えば、陰圧源（例えば、ポンプ１０９０）を動作停止する（又はオフにする）ことができ、それによって、ポンプアセンブリが一時停止状態１２１８にあるという指示がユーザに提供される。後述するように、幾つかの実施形態では、ポンプアセンブリは、再試行サイクルの回数が再試行限界を超えたとき（遷移１２２８）、又はデューティサイクルがデューティサイクル限界を超えたと判定されたとき（遷移１２３０）、動作状態カテゴリー１２５０から一時停止状態１２１８に遷移するように構成することができる。幾つかの実施形態では、遷移１２２８及び１２３０は、システムにおける漏れの存在を反映することができる。

【０１４１】

幾つかの実施形態では、ポンプアセンブリは、スイッチからの信号（例えば、ユーザがボタンを押して治療を再開させる）を受信したのに応答して、一時停止状態１２１８から動作状態カテゴリー１２５０（ポンプアセンブリがポンプを動作させて、治療を送達する）への遷移１２２６を行うように構成することができる。幾つかの実施形態では、ポンプアセンブリは、ポンプアセンブリが一時停止状態１２１８に留まっている持続時間を監視するように構成することができる。例えば、これは、ポンプアセンブリが一時停止状態１２１８に遷移するとリセットし開始することができる、（ファームウェア、ソフトウェア、ハードウェア、もしくはそれらの任意の組合せの）タイマーを維持することによって達成することができる。ポンプアセンブリは、持続時間が閾値を超えたときに、一時停止状態１２１８から動作状態カテゴリー１２５０への遷移１２２６を自動的に行うように構成することができる。閾値は、上述の手動一時停止状態１２１６の閾値と同じものであるか、又は異なるものであることができる。幾つかの実施形態では、閾値は、１分以下～１時間以上の間などの設定値であることができる。幾つかの実施形態では、閾値をユーザによって設定又は変更することができる。幾つかの実施形態では、閾値は様々な動作状態又はそれらの任意の組合せに基づいて変えることができる。例えば、ポンプアセンブリが寿命末期に近付くにつれて（後述するように）、閾値を減少させることができる。

【０１４２】

幾つかの実施形態では、ポンプアセンブリは、治療を一時停止する様々な原因を区別するため、手動一時停止状態１２１６及び一時停止状態１２１８の両方を含む。かかる区別の能力によって、ポンプアセンブリが、治療を一時停止するための特定の原因の指示をユーザに提供できるようにすることができる（例えば、手動一時停止状態１２１６及び一時停止状態１２１８は異なる指示を提供することができる）。例えば、治療は、ユーザが手動でボタンを押すことによって一時停止することができ、その場合、ポンプアセンブリは、動作状態カテゴリー１２５０から手動一時停止状態１２１６への遷移１２２２を行うことができる。別の例として、治療は、漏れを検出することによって一時停止することができ、その場合、ポンプアセンブリは、動作状態カテゴリー１２５０から一時停止状態１２１８への遷移１２２８及び／又は１２３０を行うことができる。幾つかの実施形態では、ポンプアセンブリは、治療の送達の延期もしくは一時停止を示す１つの状態、又は２つを超えるかかる状態を含むように構成することができる。

【０１４３】

幾つかの実施形態では、ポンプアセンブリは、電源の残容量又は寿命を（例えば、電池電圧、電流などを周期的に読み取るか、もしくはサンプリングすることによって）監視するように構成することができる。ポンプアセンブリは残容量をユーザに指示するように構成することができる。例えば、電源が正常な残容量（例えば、閾値と比較した結果として

、２．７Ｖ、２．６Ｖ、２．５Ｖなど）を有すると判定された場合、電池インジケータ１０６６を動作停止することができる。電源が低い残容量を有すると判定された場合、ポンプアセンブリは、例えば、遷移１２２０によって示されるように、電池インジケータ１０６６を明滅又は点滅させることによって、ユーザに指示を提供するように構成することができる。幾つかの実施形態では、電池インジケータ１０６６は、ポンプアセンブリがどの状態にあるか、又は特定の状態のみにあるかに係わらず、断続的もしくは継続的に明滅又は点滅するように構成することができる。

【０１４４】

幾つかの実施形態では、電源の残容量が臨界レベル又はその付近（例えば、閾値と比較した結果として、２．４Ｖ、２．３Ｖ、２．２Ｖなど）であると判定されると、ポンプアセンブリは、電池臨界状態１２１２に遷移するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、電源を交換又は再充電することなどによって電源容量が増加するまで、この状態に留まるように構成することができる。ポンプアセンブリは、電池臨界状態１２１２に留まっている間、治療を動作停止するように構成することができる。それに加えて、図示されるように、ポンプアセンブリは、例えばすべてのインジケータを動作停止することによって、電源が臨界レベル又はその付近にあることをユーザに指示するように構成することができる。

【０１４５】

幾つかの実施形態では、ポンプアセンブリは、第１の動作に続いて、約１日間、２～１０日間などの所定の期間、治療を提供するように構成することができる。幾つかの実施形態では、かかる期間は、ユーザによって変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる、設定値であることができる。ポンプアセンブリは、かかる期間が終了すると廃棄することができる。幾つかの実施形態では、第１の動作は、動作ストリップを引っ張ること（例えば、状態１２０２への遷移）などによって、活動状態カテゴリー１２１０への遷移によって反映することができる。一旦ポンプアセンブリが動作されると、ポンプアセンブリは、活動状態に留まっていた持続時間を監視するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、活動状態カテゴリー１２１０に留まっている累積持続時間を監視するように構成することができる。これは、例えば、かかる持続時間を反映する、（ファームウェア、ソフトウェア、ハードウェア、又はそれらの任意の組合せの）タイマーを維持することによって達成することができる。

【０１４６】

持続時間が閾値（例えば、７日間）に達するか、又はそれを超えると、ポンプアセンブリは寿命末期（ＥＯＬ）状態１２４０に遷移するように構成することができる。ポンプアセンブリは、状態１２４０に留まっている状態で治療を動作停止し、ポンプアセンブリの有効寿命の終わりに達したことをユーザに指示するように構成することができる。例えば、ポンプアセンブリは、すべてのインジケータを動作停止する、かつ／又はボタンを動作停止するように構成することができる。幾つかの実施形態では、ポンプアセンブリが使い捨てであるとき、寿命末期状態１２４０に遷移することは、ポンプアセンブリを廃棄できることを意味する。ポンプアセンブリは、一旦寿命末期に達すると、ポンプアセンブリを再び動作させることができないように構成することができる。例えば、ポンプアセンブリは、電源が分断され、その後再接続された場合であっても、再び動作させることができないように構成することができ、それは、指示、値、フラグなどをリードオンリーメモリに格納することによって達成することができる。

【０１４７】

図２６は、幾つかの実施形態によるポンプアセンブリ１０００の状態カテゴリー１２５０における動作フローを示す。ポンプアセンブリは、治療を送達し、システムの漏れを監視し、指示（複数可）をユーザに提供するなどのために構成することができる。後述するように、幾つかの実施形態では、ポンプアセンブリは、包帯１０１０の下で第１の所望の陰圧レベル（例えば、－１００ｍｍＨｇなど、－５ｍｍＨｇ以下～－２００ｍｍＨｇ以上

の間の陰圧）を確立することを最初に試みることによって、治療を送達するように構成することができる。幾つかの実施形態では、第１の所望の陰圧レベルは、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる、設定値であることができる。一旦第１の所望の陰圧レベルが包帯１０１０の下で確立されると、ポンプアセンブリは、陰圧源（例えば、ポンプ）を動作停止するように構成することができる。システムの漏れによって包帯１０１０の下の陰圧が減少する（すなわち、標準大気圧に向かって下降する）と、ポンプアセンブリは、ポンプを動作させて包帯の下の第２の所望の陰圧レベル（例えば、－１００ｍｍＨｇなど、－５ｍｍＨｇ以下～－２００ｍｍＨｇ以上の間の陰圧）を確立することによって、包帯の下の陰圧を回復するように構成することができる。幾つかの実施形態では、第２の所望の陰圧レベルは、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる、設定値であることができる。幾つかの実施形態では、第１及び第２の所望の陰圧レベルは同じであることができる。幾つかの実施形態では、第１及び第２の所望の陰圧レベルは異なることができ、すなわち、第２の陰圧レベルは第１の陰圧レベルよりも低いか、又はその逆であることができる。

【０１４８】

幾つかの実施形態では、ポンプアセンブリは、手動―時停止状態１２１６及び／又は―時停止状態１２１８から状態１２５２に遷移することができる。上述したように、この遷移は、ユーザがボタンを押して治療を開始／再開することによって、かつ／又は１時間などの持続時間が経過すると引き起こすことができる。ポンプアセンブリは、ポンプを動作させて包帯１０１０の下の第１の所望の陰圧レベルを確立することができる、初期ポンプダウン（ｉｎｉｔｉａｌ　ｐｕｍｐ　ｄｏｗｎ：ＩＰＤ）状態１２６０に即座に遷移するように構成することができる。幾つかの実施形態では、包帯の下の圧力レベルが第１の所望の陰圧レベルの上（未満）である場合、ポンプを動作させることができる。陰圧源を動作させて、包帯１０１０の下の第１の所望の陰圧レベルを確立することは、本明細書では、「初期ポンプダウン」と呼ぶことができる。ポンプアセンブリは、例えば、ＯＫインジケータ１０６２を明滅又は点滅させ、包帯インジケータ１０６４を動作停止することによって、初期ポンプダウンを実施していることをユーザに指示するように構成することができる。幾つかの実施形態では、例えば、陰圧源を動作させることによって、指示を提供することができる。ポンプアセンブリは、センサ１０７０を読み取るか又はサンプリングすることによって、包帯１０１０の下の圧力レベルを測定するように構成することができる。

【０１４９】

幾つかの実施形態では、ポンプアセンブリは、ポンプアセンブリがＩＰＤ状態１２６０に留まっている持続時間を監視するように構成することができる。これは、例えば、ポンプアセンブリがＩＰＤ状態１２６０へと遷移したときにリセットし開始することができる、（ファームウェア、ソフトウェア、ハードウェア、又はそれらの任意の組合せの）タイマーを維持することによって達成することができる。幾つかの実施形態では、電力の節約、ポンプによって発生する雑音及び／又は振動の制限などのために、ポンプアセンブリは、所定の期間の間、初期ポンプダウン動作を延期し、その後で初期ポンプダウンを再試行するように構成することができる。この機能性は、例えば、電池電力を節約し、ユーザの介在なしに過渡的及び／又は非過渡的な漏れを解決できるようにするか、あるいはユーザが漏れを直すこと（例えば、包帯を真っ直ぐにする、シールを直す、１つ又は複数の接続を確認するなど）ができるようにすることができる。

【０１５０】

幾つかの実施形態では、ＩＰＤ状態１２６０に留まっている持続時間が閾値（例えば、３０秒間）に等しいか又はそれを超えると、ポンプアセンブリは、状態１２６６への遷移１２６４を行うように構成することができる。幾つかの実施形態では、閾値は、５秒以下～５分以上の間などの設定値であることができる。幾つかの実施形態では、ユーザは閾値を設定又は変更することができる。幾つかの実施形態では、閾値は、様々な動作状態又は

それらの任意の組合せに基づいて変えることができる。幾つかの実施形態では、ポンプアセンブリは、遷移１２６４を行うときにポンプを動作停止するように構成することができる。ポンプアセンブリは、包帯１０１０の下の第１の所望の陰圧を確立するために行われる試みの回数を、（例えば、状態１２５２でリセットし、待機状態１２７０で更新することができるカウンタを維持することによって）監視するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、例えば電力を節約するために、限定数又は最大数のＩＰＤ再試行の試みを提供するように構成することができる。好ましくは、ポンプアセンブリは、限定数の連続的なＩＰＤ再試行の試みを提供するように構成することができるが、ポンプアセンブリは、限定数の連続的でないＩＰＤ再試行の試み、又は連続的及び連続的でないＩＰＤ再試行の試みの混合を提供するように構成することができる。ＩＰＤ再試行の試みの閾値は、１、２、３、４、５などであることができる。幾つかの実施形態では、閾値は設定値であることができる。幾つかの実施形態では、ユーザによって閾値を設定又は変更することができる。幾つかの実施形態では、閾値は、様々な動作状態又はそれらの任意の組合せに基づいて変えることができる。

【０１５１】

幾つかの実施形態では、ポンプアセンブリは、状態１２６６で、行われたＩＰＤ再試行の試みの回数が閾値（例えば、１回の再試行の試み）に等しいか又はそれを超えているか否か否かを判定するように構成することができる。行われたＩＰＤ再試行の試みの回数が閾値に等しいか又はそれを超えている場合、ポンプアセンブリは、上述したように治療が一時停止又は延期される、一時停止状態１２１８への遷移１２２８ａを行うように構成することができる。そうでなければ、ポンプアセンブリは、待機状態１２７０への遷移１２６８を行うように構成することができる。幾つかの実施形態では、ポンプアセンブリは、状態１２６６で陰圧源を動作停止するように構成することができ、それによって、ポンプアセンブリが状態１２６６に遷移したことの指示をユーザに提供することができる。

【０１５２】

幾つかの実施形態では、ポンプアセンブリは、待機状態１２７０のポンプを動作停止し、それによって治療を所定の期間の間（例えば、１５秒間など、１秒以下～１分以上の間）一時停止するように構成することができる。これは、例えば、ポンプアセンブリが待機状態１２７０へと遷移したときにリセットし開始することができる、（ファームウェア、ソフトウェア、ハードウェア、又はそれらの任意の組合せの）タイマーを維持することによって達成することができる。待機状態１２７０におけるこの期間は、プリセット又は変数（例えば、自動的、もしくはユーザによる）であることができる。幾つかの実施形態では、期間は、様々な動作状態又はそれらの任意の組合せに基づいて変えることができる。ポンプアセンブリが待機状態１２７０に留まっている期間は、待機状態１２７０への遷移のたびに、増加又は減少させる（例えば、２など、０．１以下～４．０以上の間の係数で乗算する）ことができる。期間は、待機状態１２７０への一連の遷移それぞれにおいて増加又は減少させることができる。期間は、閾値（例えば、４分など、１秒以下～５分以上の間）に等しくなるか又はそれを過ぎるまで、増加又は減少させることができる。それに加えて、期間は、監視圧力状態１２８０への遷移、手動一時停止状態１２１６への遷移、一時停止状態１２１８への遷移の際に、初期値にリセットすることができる。

【０１５３】

幾つかの実施形態では、ポンプアセンブリは、ポンプアセンブリが待機状態１２７０にあることをユーザに指示するように構成することができる。例えば、ポンプアセンブリは、ＯＫインジケータ１０６２を点滅又は明滅させ、包帯インジケータ１０６４を動作停止するように構成することができる。幾つかの実施形態では、ポンプの動作停止によって、ポンプアセンブリが待機状態１２７０にあるという指示を提供することができる。待機状態の期間が経過すると、ポンプアセンブリは、待機状態１２７０からＩＰＤ状態１２６０への遷移１２７２を行うように構成することができ、その際、ポンプアセンブリは、包帯１０１０の下の第１の所望の陰圧レベルを確立するように試みることができる。幾つかの実施形態では、ポンプアセンブリは、包帯の下の陰圧レベルが特定の安全レベルを上回っ

たまま留まることを担保するように構成することができる。例えば、ポンプアセンブリは、－２２５ｍｍＨｇなど、－１５０ｍｍＨｇ以下～－２５０ｍｍＨｇ以上の間の安全レベルを上回る、包帯１０１０の下の陰圧レベルを維持するように構成することができる。

【０１５４】

幾つかの実施形態では、包帯１０１０の下の第１の所望の陰圧レベルが確立されていると、ポンプアセンブリは、監視状態１２８０への遷移１２７６を行うように構成することができる。ポンプアセンブリは、遷移１２７６を行うときに、ＩＰＤ再試行の試みの回数をリセットするように構成することができる。ポンプアセンブリは、例えば、ＯＫインジケータ１０６２を明滅又は点滅させ、包帯インジケータ１０６４を動作停止することによって、監視状態１２８０への遷移をユーザに指示するように構成することができる。監視状態１２８０に留まっているまま、ポンプアセンブリは、ポンプを動作停止し（それによって、ポンプアセンブリが監視状態１２８０にあるという、ユーザに対する指示を提供することができる）、包帯１０１０の下の圧力レベルを周期的又は継続的に監視するように構成することができる。ポンプアセンブリは、センサ１０７０を読み取るか又はサンプリングすることによって、包帯１０１０の下の圧力レベルを測定するように構成することができる。

【０１５５】

幾つかの実施形態では、ポンプアセンブリは、例えばシステムの漏れによって、包帯１０１０の下の陰圧レベルが、閾値に達するか、かつ／又は閾値を過ぎる（例えば、閾値よりも低くなる）まで減少しているか否か否かを判定するように構成することができる。閾値は、－６０ｍｍＨｇなど、－１０ｍｍＨｇ以下～－１００ｍｍＨｇ以上の間の範囲から選択することができる。幾つかの実施形態では、閾値は、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる設定値であることができる。閾値に達したか又は閾値を過ぎたと判定された場合、ポンプアセンブリは、包帯１０１０の下の陰圧レベルを回復するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、第１の所望の陰圧レベルを再度確立するように、又は別の異なる陰圧レベルを確立するように構成することができる。これは、保守ポンプダウン（ｍａｉｎｔｅｎａｎｃｅ　ｐｕｍｐ　ｄｏｗｎ：ＭＰＤ）状態１２９０への遷移１２８２を行うことによって達成することができる。

【０１５６】

幾つかの実施形態では、ポンプアセンブリは、ポンプアセンブリがＭＰＤ状態１２９０に留まっている状態で、ポンプを動作させて、包帯１０１０の下の所望の陰圧レベル（例えば、第１の所望のレベル）を確立するように構成することができる。ポンプアセンブリは、例えば、ＯＫインジケータ１０６２を明滅又は点滅させ、包帯インジケータ１０６４を動作停止することによって、ユーザに対して指示を提供するように構成することができる。幾つかの実施形態では、陰圧源を動作させるポンプアセンブリは、ポンプアセンブリが状態１２９０に遷移したことの指示をユーザに提供することができる。幾つかの実施形態では、ポンプアセンブリは、ＩＰＤ状態１２６４でポンプを動作させたときよりも、ＭＰＤ状態１２９０でポンプを動作させたときの方が、発生する雑音及び振動が少ないように構成することができる。例えば、雑音レベルの差は、約７ｄＢ、約２０ｄＢなど、１ｄＢ以下～３０ｄＢ以上の間であることができる。別の例として、雑音レベルの差は、約４５ｄＢ、約５０ｄＢ、約６５ｄＢなど、３０ｄＢ以下～８０ｄＢ以上の間であることができる。

【０１５７】

幾つかの実施形態では、ポンプアセンブリは、ＭＰＤ状態１２９０に留まっている持続時間を監視するように構成することができる。これは、例えば、ポンプアセンブリがＭＰＤ状態１２９０への遷移１２８２を行うときにリセットし開始することができる、（ファームウェア、ソフトウェア、ハードウェア、又はそれらの任意の組合せの）タイマーを維持することによって達成することができる。幾つかの実施形態では、電力の節約、ポンプによって発生する雑音及び／又は振動の制限などのために、ポンプアセンブリは、所定の

期間の間、保守ポンプダウン動作を延期し、その後で初期ポンプダウン及び／又は保守ポンプダウンを再試行するように構成することができる。この機能性は、例えば、電池電力を節約し、ユーザの介在なしに過渡的及び／又は非過渡的な漏れを解決できるようにするか、あるいはユーザが漏れを直すこと（例えば、包帯を真っ直ぐにする、シールを直す、１つ又は複数の接続を確認するなど）ができるようにすることができる。

【０１５８】

幾つかの実施形態では、ＭＰＤ状態１２９０の持続時間が閾値（例えば、１０秒など、５秒以下～５分以上の間の値）に等しいか又はそれを超え、包帯１０１０の下の圧力レベルが所望の陰圧レベルに達していないとき、ポンプアセンブリは、状態１２９４への遷移１２９２を行うように構成することができる。閾値は、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる設定値であることができる。幾つかの実施形態では、ポンプアセンブリは、遷移１２９２を行うときにポンプを動作停止するように構成することができ、それによって、ポンプアセンブリが遷移を行っていることの指示をユーザに提供することができる。ポンプアセンブリは、包帯１０１０の下の所望の陰圧を確立するために行われるＭＰＤの試みの回数を、（例えば、状態１２５２で、かつ／又は遷移１２２８ｂを行うときにリセットし、遷移１２９６を行うときに更新することができるカウンタを維持することによって）監視するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、（例えば、電力を節約するために）限定数又は最大数のＭＰＤ再試行の試みを提供するように構成することができる。好ましくは、ポンプアセンブリは、限定数の連続的なＭＰＤ再試行の試みを提供するように構成することができるが、ポンプアセンブリは、限定数の連続的でないＭＰＤ再試行の試み、又は連続的及び連続的でない再試行の試みの混合を提供するように構成することができる。ＭＰＤ再試行の試みの閾値は、１、２、３、４、５などであることができる。幾つかの実施形態では、閾値は、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる設定値であることができる。ポンプアセンブリは、ＩＰＤ及びＭＰＤの再試行の試みの回数を、同じ値又は異なる値に設定するように構成することができる。ポンプアセンブリは、状態１２９４で、行われたＭＰＤ再試行の試みの回数が閾値（例えば、３回の再試行の試み）に等しいか又はそれを超えているか否か否かを判定するように構成することができる。行われたＭＰＤ再試行の試みの回数が閾値に等しいか又はそれを超えている場合、ポンプアセンブリは、上述したように治療が一時停止又は延期される、一時停止状態１２１８への遷移１２２８ｂを行うように構成することができる。そうでなければ、ポンプアセンブリは、上述したように治療が一時停止又は延期される、待機状態１２７０への遷移１２９６を行うように構成することができる。あるいは、ポンプアセンブリは、ＩＰＤ状態１２６０又はＭＰＤ状態１２９０に遷移するように構成することができる。

【０１５９】

幾つかの実施形態では、ポンプアセンブリは、包帯の下の圧力レベルが所望の陰圧レベルに達するか又はそれを超えた（例えば、それよりも大きくなった）場合、監視状態１２８０への遷移１２８４を行うように構成することができる。ポンプアセンブリはまた、遷移１２８４を行ったときに、ＭＰＤ再試行の試みの回数をリセットするように構成することができる。

【０１６０】

幾つかの実施形態では、ポンプアセンブリは、陰圧源（例えば、ポンプ）のデューティサイクルを監視するように構成することができる。ポンプアセンブリは、デューティサイクルを周期的にかつ／又は連続的に監視するように構成することができる。デューティサイクル測定は、漏れの存在ならびに／又は深刻度、創傷から吸引された流体（例えば、空気、液体、及び／もしくは固体浸出物など）の流量など、システムの様々な動作状態を反映することができる。例えば、デューティサイクル測定は多量の漏れの存在を指示することができ、ポンプアセンブリは、この状態を指示し、かつ／又は電力を節約するためにポンプの動作を一時的に延期もしくは一時停止するように構成することができる。この機能

性は、例えば、電池電力を節約し、ユーザの介在なしに過渡的及び／又は非過渡的な漏れを解決できるようにするか、あるいはユーザが漏れを直すこと（例えば、包帯を真っ直ぐにする、シールを直す、１つ又は複数の接続を確認するなど）ができるようにすることができる。

【０１６１】

幾つかの実施形態では、ポンプアセンブリは、毎１０秒以下～毎５分以上の間に一回など、周期的にデューティサイクルを監視するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、デューティサイクルを１分につき一回監視するように構成することができる。これは、（例えば、割込みによって、もしくはポーリングを介して示されるように）１分ごとに期限が来るように設定することができ、（例えば、割込みをクリアすることによって）再始動することができる、（ファームウェア、ソフトウェア、ハードウェア、又はそれらの組合せの）タイマーを維持することによって達成することができる。幾つかの実施形態では、デューティサイクルを測定する時間間隔は、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる設定値であることができる。幾つかの実施形態では、ポンプアセンブリは、動作状態カテゴリー１２５０（すなわち、状態１２６０、１２６６、１２７０、１２８０、１２９０、１２９４のいずれか、及び／又はいずれかの状態間のいずれかの遷移）にあるときにポンプを動作させるように構成されているので、この状態カテゴリーにあるときに、デューティサイクルを監視するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、ポンプアセンブリが、動作状態カテゴリー１２５０の特定の状態及び／又は状態遷移、あるいは状態及び／又は状態遷移の部分集合にあるときに、デューティサイクルを監視するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、ポンプアセンブリが、活動状態カテゴリー１２１０の特定の状態及び／もしくは状態遷移、状態及び／もしくは状態遷移の部分集合、又はすべての状態及び／もしくは状態遷移、あるいは本明細書に開示する任意の状態及び／又は状態遷移のいずれかの組合せにあるときに、デューティサイクルを監視するように構成することができる。図２６に示されるように、ポンプアセンブリは、状態１２６０、１２６６、１２７０、１２８０、１２９０、１２９４のいずれかからの遷移１３０２、及び／又は状態のいずれかから状態１３００への遷移を行うことができ、ここで、ポンプアセンブリは、経過した分の間のポンプのデューティサイクルを判定することができる。デューティサイクルは、次式にしたがって判定することができる。

【０１６２】

ＤＣ＝ｔ／Ｔ　　（２）

【０１６３】

式中、ＤＣはデューティサイクル、ｔは陰圧源が活動状態である持続時間、Ｔは検討中の合計時間である。デューティサイクルを１分につき一回監視する場合（すなわち、Ｔ＝６０秒）、デューティサイクルは次式のように（例えば、百分率で）表すことができる。

【０１６４】

ＤＣ＝（経過した分の間のポンプ稼働時間／６０）＊１００％　　（３）

【０１６５】

デューティサイクルを判定するために、ポンプアセンブリは、ポンプが活動状態（例えば、ポンプ稼働時間）及び／又は非活動状態であった持続時間を監視するように構成することができる。

【０１６６】

幾つかの実施形態では、ポンプアセンブリは、判定されたデューティサイクルを、１％以下～５０％以上の間の範囲から選択することができるデューティサイクル閾値と比較するように構成することができる。比較は、例えば、システムの漏れの存在を示すことができる。換言すれば、ポンプが、デューティサイクル閾値に達するか又は超えるような期間に亘って活動状態に留まっていた場合、ポンプは漏れを克服するために酷使されていることがある。かかる場合、ポンプアセンブリは、治療の送達を延期又は一時停止するように

構成することができる。ポンプアセンブリは、例えば、陰圧源を動作停止することによって、ポンプが酷使されている（例えば、デューティサイクルがデューティサイクル閾値を超えている）ことの指示をユーザに提供するように構成することができる。幾つかの実施形態では、デューティサイクル閾値は、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる設定値であることができる。図２６に示されるように、ポンプアセンブリは、判定されたデューティサイクルをデュ―ティサイクル閾値（例えば、９％）と比較するように構成することができる。ポンプアセンブリは、例えば、ポンプアセンブリが状態１２５２からＩＰＤ状態１２６０に遷移したときにリセットすることができる、過負荷カウンタを維持し更新することによって、閾値を超えるデューティサイクルの数を監視するように構成することができる。

【０１６７】

幾つかの実施形態では、ポンプアセンブリは、状態１３００において過負荷カウンタを更新するように構成することができる。判定されたデューティサイクルがデューティサイクル閾値を超えない場合、ポンプアセンブリは過負荷カウンタを減分することができる。幾つかの実施形態では、過負荷カウンタの最小値はゼロに設定することができ、すなわち過負荷カウンタが負になることはない。反対に、判定されたデューティサイクルがデューティサイクル閾値に等しいか又はそれを超える場合、ポンプアセンブリは過負荷カウンタを増分することができる。

【０１６８】

幾つかの実施形態では、ポンプアセンブリは、デューティサイクル閾値に等しいか又はそれを超えるデューティサイクルの合計数もしくは総数を監視するように構成することができる。この方策は、例えば、治療を中断することによる過渡的な漏れによって引き起こされることがある、１つ又は幾つかの不安定なサイクルを防ぐために、デューティサイクルの変動を平滑化又は平均化する助けとすることができる。幾つかの実施形態では、ポンプアセンブリは、デュ―ティサイクル閾値を超える連続的又は非連続的なデュ―ティサイクルを監視するように構成することができる。幾つかの実施形態では、閾値は、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる設定値であることができる。デューティサイクル閾値を超えるデューティサイクルの数が過負荷閾値（例えば、３０など、１～６０以上の間）を超えると判定された場合、ポンプアセンブリは、上述したように治療が延期又は一時停止される、一時停止状態１２１６への遷移１２３０を行うように構成することができる。幾つかの実施形態では、ポンプアセンブリは陰圧源を動作停止するように構成することができ、それによって、ポンプが酷使されている（例えば、デューティサイクルが過負荷閾値を超える）という指示をユーザに提供することができる。デューティサイクル閾値を超えるデューティサイクルの数が過負荷閾値を超えると判定されなかった場合、ポンプアセンブリは、遷移１３０４を行い、かつ動作状態カテゴリー１２５０に留まるように構成することができる。幾つかの実施形態では、ポンプアセンブリは、同じ状態に戻る、かつ／又はポンプアセンブリがそこから遷移１３０２を行った状態の間で遷移するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、異なる状態へ遷移する、かつ／又は状態間で遷移するように構成することができる。

【０１６９】

幾つかの実施形態では、ポンプアセンブリは、ポンプアセンブリが動作状態カテゴリー１２５０にある状態でユーザがボタン１００２を押した場合に、治療を延期又は一時停止するようにさらに構成される。幾つかの実施形態では、ポンプアセンブリは、手動一時停止状態１２１６に遷移するように構成することができる。

【０１７０】

図２７は、幾つかの実施形態によるポンプアセンブリ１０００の動作の別の状態図を示す。幾つかの実施形態では、コントローラ１１４０は、状態図１４００のフローを実施するように構成することができる。幾つかの実施形態では、フロー１４００は、概して図２５～図２６に示されるフロ―に類似していることができる。状態１４０２は状態１２０２

に相当し、状態１４０６は状態１２６０に相当し、状態カテゴリー１４１０は状態カテゴリー１２１０に相当し、状態１４１４は状態１２１４に相当し、状態１４１６は状態１２１６に相当し、状態１４１８は状態１２１８に相当し、遷移１４２０は遷移１２２０に相当し、遷移１４２２は遷移１２２２に相当し、遷移１４２４は遷移１２２４に相当し、遷移１４２６は遷移１２２６に相当し、かつ状態１４４０は状態１２４０に相当する。それに加えて、状態カテゴリー１４５０は状態カテゴリー１２５０に相当し、状態１４６０は状態１２６０に相当し、遷移１４６４は遷移１２６４に相当し、状態１４６６は遷移１２６６に相当し、遷移１４６８は遷移１２６８に相当し、遷移１４２８ａは遷移１２２８ａに相当し、状態１４７０は状態１２７０に相当し、かつ遷移１４７２は遷移１２７２に相当する。さらに、遷移１４７６は遷移１２７６に相当し、状態１４８０は状態１２８０に相当し、遷移１４８２は遷移１２８２に相当し、状態１４９０は状態１２９０に相当し、遷移１４９２は遷移１２９２に相当し、状態１４９４は状態１２９４に相当し、遷移１４９６は遷移１２９６に相当し、かつ遷移１４２８ｂは遷移１２２８ｂに相当する。

【０１７１】

幾つかの実施形態では、ポンプアセンブリは、ＭＰＤ状態１４９０において包帯１０１０の下で所望の陰圧レベルが確立された後、デューティサイクルを監視するように構成することができる。幾つかの実施形態では、ポンプアセンブリはまた、ポンプアセンブリがＩＰＤ状態１４６０に留まっているままポンプが活動状態であった持続時間を考慮に入れることができる。図示されるように、デバイスは、ＭＰＤ状態１４９０からの遷移１４８４を行うように構成することができる。遷移１４８４は遷移１２８４に類似したものであり得るが、ＩＰＤ状態１４８０に直接遷移する代わりに、ポンプアセンブリを、状態１５００のデューティサイクルを監視するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、ポンプアセンブリが監視状態１４８０及びＭＰＤ状態１４９０に留まっている累積期間の間、デューティサイクルを監視するように構成することができる。幾つかの実施形態では、ポンプアセンブリは、直前又は過去の監視及びＭＰＤサイクル中の累積期間に亘って、デューティサイクルを監視するように構成することができる。例えば、状態１５００に遷移する直前には、ポンプアセンブリは、持続時間Ｘ（その間ポンプが活動状態である）の間、ＭＰＤ状態１４９０に留まっていることができる。それに加えて、ＭＰＤ状態１４９０に遷移する直前に、ポンプアセンブリが持続時間Ｙ（その間、ポンプが非活動状態であった）の間、監視状態１４８０に留まっていたと仮定して、デューティサイクル（ＤＣ）を次式のように（例えば、百分率で）表すことができる。

【０１７２】

ＤＣ＝１００％＊［Ｘ／（Ｘ＋Ｙ）］　　（４）

【０１７３】

デューティサイクルを判定するために、ポンプアセンブリを、ポンプが活動状態及び／又は非活動状態であった持続時間を監視するように構成することができる。

【０１７４】

幾つかの実施形態では、ポンプアセンブリは、上述したように、判定されたデューティサイクルをデューティサイクル閾値（例えば、９％）と比較するように構成することができる。幾つかの実施形態では、閾値は、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる設定値であることができる。デューティサイクルが閾値未満であると判定された場合、ポンプアセンブリは、監視状態１４８０への遷移１５０２を行うように構成することができる。反対に、デューティサイクルが閾値に等しいか又はそれを超えると判定された場合、ポンプアセンブリは、状態１５０６への遷移１５０４を行うように構成することができる。幾つかの実施形態では、ポンプアセンブリは、例えばポンプを動作停止することによって、デューティサイクルが閾値を超えているという指示を提供することができる。

【０１７５】

幾つかの実施形態では、ポンプアセンブリは、デューティサイクルが閾値に等しいか又はそれを超える合計時間もしくは総時間を監視するように構成することができる。この方

策は、例えば、治療を中断することによる過渡的な漏れによって引き起こされることがある、１つ又は幾つかの不安定なサイクルを防ぐために、デューティサイクルの変動を平滑化又は平均化する助けとすることができる。監視は、再始動（例えば、遷移１４７６の際に）し更新（例えば、状態１５０６で）することができる、（ファームウェア、ソフトウェア、ハードウェア、又はそれらの任意の組合せの）タイマーを維持することによって達成することができる。幾つかの実施形態では、ポンプアセンブリは、総持続時間閾値と比較することができる特定の総期間に亘って、デューティサイクルが閾値に等しいか又はそれを超えるか否か否かを判定するように構成することができる。閾値は、３０分など、５分以下～２時間以上の間の範囲から選択することができる。幾つかの実施形態では、閾値は、ユーザによって設定もしくは変更される、かつ／又は様々な動作状態もしくはそれらの任意の組合せに基づいて変えられる設定値であることができる。総期間が閾値に等しいか又はそれを超える場合、ポンプアセンブリは、ポンプアセンブリが治療の送達を延期又は一時停止するように構成することができる、一時停止状態１４１８への遷移１５０８を行うように構成することができる。幾つかの実施形態では、ポンプアセンブリは、例えばポンプを動作停止することによって、この遷移をユーザに指示することができる。反対に、総期間が閾値未満であると判定された場合、ポンプアセンブリは、監視状態１４８０への遷移１５１０を行うように構成することができる。ポンプアセンブリは、例えば、ＯＫインジケータ１０６２を明滅又は点滅させ、包帯インジケータ１０６４を動作停止することによって、遷移１５１０をユーザに指示するように構成することができる。

【０１７６】

図２８は、幾つかの実施形態によるポンプアセンブリ１０００のためのデューティサイクル判定を示すグラフ１６００を示す。Ｘ軸は時間を表し、Ｙ軸は圧力を表す。幾つかの実施形態では、ポンプアセンブリは、位置１６０６によって表されるように、包帯１０１０の下の－１００ｍｍＨｇの陰圧レベルを確立するように構成することができる。例えば、これは、状態１２６０の初期ポンプダウン中に実施することができる。ポンプアセンブリは、包帯１０１０の下の陰圧レベルを監視するように構成することができる。例えば、これは監視状態１２８０において実施することができる。図示されるように、間隔１６０２によって表されるように、ポンプアセンブリは期間ａ全体に亘って圧力を監視することができる。包帯１０１０の下の陰圧レベルは、線１６２０によって示されるように、時間全体に亘って減少する（例えば、システムの漏れに起因する）ことができる。

【０１７７】

幾つかの実施形態では、ポンプアセンブリは、位置１６０８によって表されるように、圧力減少が約－７０ｍｍＨｇの閾値に達するか又はそれを過ぎると、包帯１０１０の下の陰圧レベルを回復するか又は再度確立するように構成することができる。幾つかの実施形態では、線１６２２によって示されるように、ポンプアセンブリはポンプを動作させるように構成することができる。例えば、これは、保守ポンプダウン状態１２９０に遷移することによって実施することができる。図示されるように、ポンプアセンブリは、－１００ｍｍＨｇの陰圧レベルが包帯１０１０の下で再度確立されるまで、持続時間ｂ（１６０４）に亘ってポンプを動作させることができる。ポンプアセンブリは、包帯１０１０の下の圧力レベルが位置１６１０において－１００ｍｍＨｇに達すると、ポンプを動作停止するように構成することができる。例えば、これは、監視状態１２８０に遷移することによって実施することができる。１６００で示される期間（すなわち、ａ＋ｂ）全体にわたるデューティサイクル（ＤＣ）は、次式のように（例えば、百分率で）表すことができる。

【０１７８】

ＤＣ＝１００％＊［ｂ／（ａ＋ｂ）］　　（５）

【０１７９】

図２９は、ポンプアセンブリ１０００の幾つかの実施形態の正常な（例えば、漏れがないかもしくは少量の漏れ）動作１７００の非限定例を示す。ポンプアセンブリは、ボックス１７０２に示されるように、包帯１０１０の下の所望の陰圧レベルを確立するように構成することができる。ポンプアセンブリは、包帯１０１０の下の圧力レベルが所望のレベ

ル（例えば、－７０ｍｍＨｇなどの第１の陰圧設定値の値）を超えて上昇した場合、陰圧源（例えば、ポンプ）が動作し、包帯１０１０の下の圧力レベルを所望の値まで低減する動作を開始するように構成することができる。例えば、所望の値は、ほぼ第１の陰圧設定値の値と第２の陰圧設定値の値との間の間隔内であることができ、又はほぼ第２の陰圧設定値の値（例えば、－１００ｍｍＨｇ）であることができる。幾つかの実施形態では、これは初期ポンプダウン状態１２６０において達成することができる。

【０１８０】

幾つかの実施形態では、包帯１０１０の下の圧力レベルが所望の値に達すると、ポンプアセンブリは、ボックス１７０４に示されるように、ポンプを動作停止し、包帯の下の圧力レベルを監視するように構成することができる。例えば、これは監視状態１２８０において達成することができる。ポンプアセンブリは、例えば、センサ１０７０を読み取るか又はサンプリングすることによって、包帯１０１０の下の圧力レベルを周期的又は継続的に監視するように構成することができる。監視された圧力に基づいて、ポンプアセンブリは、ボックス１７０６において、包帯１０１０の下の所望の陰圧レベルを再度確立するために、ポンプを動作又は再始動させる必要があるか否か否かを判定することができる。監視された圧力が低い（例えば、第１の陰圧設定値の値未満か、もしくはそれ以下）と判定された場合、ポンプアセンブリは、ボックス１７０８に示されるように、ポンプを動作させるように構成することができる。例えば、これは、ＭＰＤ状態１２９０に遷移することによって達成することができる。反対に、監視された圧力レベルが低くない（例えば、第１の陰圧設定値の値を超えるか、もしくはそれ以上）と判定された場合、ポンプアセンブリは、包帯１０１０の下の圧力レベルを監視し続けるように構成することができる。この動作フローの間、ポンプアセンブリは、正常に動作していることをユーザに指示するように構成することができる。１０６０ａに示されるように、ポンプアセンブリを動作させるか、又は１０６２ａとして示されるように、ＯＫインジケータ１０６２を明滅もしくは点滅させることができる。それに加えて、ポンプアセンブリは、１０６４ａ及び１０６６ａとしてそれぞれ示される、包帯インジケータ１０６４及び電池インジケータ１０６６を動作停止させることができる。

【０１８１】

図３０は、多量の漏れが存在する状態におけるポンプアセンブリ１０００の幾つかの実施形態の動作１８００の非限定例を示す。図２９に関して上述したように、ポンプアセンブリは、ボックス１８０２に示されるように、包帯１０１０の下の所望の陰圧レベルを確立するように構成することができる。幾つかの実施形態では、包帯１０１０の下の圧力レベルが所望の値に達すると、ポンプアセンブリは、ボックス１８０４に示されるように、ポンプを動作停止し、包帯の下の圧力レベルを監視するように構成することができる。ポンプアセンブリは、例えば、センサ１０７０を読み取るか又はサンプリングすることによって、包帯１０１０の下の圧力レベルを周期的又は継続的に監視するように構成することができる。監視された圧力レベルに基づいて、ポンプアセンブリは、包帯１０１０の下の所望の陰圧レベルを再度確立するために、ポンプを動作又は再始動させる必要があるか否か否かを判定することができる。監視された圧力レベルが低い（例えば、第１の陰圧設定値の値未満か、もしくはそれ以下）と判定された場合、ポンプアセンブリは、ボックス１８０８に示されるように、ポンプを動作させるように構成することができる。一旦所望の圧力レベルが包帯１０１０の下で再度確立されると、ポンプアセンブリは、包帯の下の陰圧レベルの監視を再び始める（例えば、監視状態１２８０に遷移する）ことができる。

【０１８２】

幾つかの実施形態では、システムにおける１つ又は複数の漏れの存在により、ポンプアセンブリ１０１０は、ポンプの監視及び再動作の複数サイクルを実施するように構成することができる。この動作フローの間、ポンプアセンブリは、ポンプアセンブリが正常に動作していることをユーザに指示するように構成することができる。１０６０ｂに示されるように、ポンプアセンブリを動作させるか、又は１０６２ｂとして示される、ＯＫインジケータ１０６２を明滅もしくは点滅させることができる。それに加えて、ポンプアセンブ

リは、１０６４ｂ及び１０６６ｂとしてそれぞれ示される、包帯インジケータ１０６４及び電池インジケータ１０６６を動作停止させることができる。ポンプアセンブリは、ボックス１８１０に示されるように、ポンプが頻繁に給送しすぎているか否かを継続的又は周期的に判定するように構成することができる。図示されるように、幾つかの実施形態では、ポンプアセンブリは、ポンプが頻繁に給送しすぎているか否かの判定の代用として、デューティサイクルを使用するように構成することができる。例えば、ポンプアセンブリは、ポンプが「酷使されている」か否か否かを判定するように構成することができ、それによって、合計治療時間の９％などの閾値持続時間を超える間、ポンプがオンであるか否かが判定される。換言すれば、ポンプアセンブリは、ポンプのデューティサイクルがデューティサイクル閾値に達するか又はそれを超えるか否か否かを判定するように構成することができる。

【０１８３】

幾つかの実施形態では、ポンプアセンブリは、ポンプがある持続時間に亘って酷使されている（例えば、ポンプが１日約２時間を超えてオンであるか、もしくは所定の時間量を超えてオンである）と判定された場合、所望の陰圧レベル（例えば、第２の陰圧設定値の値）が確立されている場合であっても、ポンプの動作を延期又は一時停止するように構成することができる。ボックス１８１２に示されるように、ポンプアセンブリは、ポンプが３０分以上の持続時間に亘って酷使されているか否か否かを判定するように構成することができる。例えば、ポンプアセンブリは、過去３０分間に亘って監視されたデューティサイクル（複数可）がデューティサイクル閾値を超えるか否か否かを判定するように構成することができる。例えば、ポンプアセンブリは、ポンプが直近の３０分間で約２分４２秒以上オンであったか否か否かを判定することができ、これは、９％のデューティサイクル閾値に相当する。

【０１８４】

幾つかの実施形態では、ポンプアセンブリは、ボックス１８１４に示されるように、ポンプが酷使されていると判定された場合、治療を一時停止又は延期するように構成することができる。ポンプアセンブリはさらに、「漏れアラーム」インジケータをオンにするように構成することができる。１０６０ｃに示されるように、ポンプアセンブリを動作させるか、又は１０６４ｂとして示される、包帯インジケータ１０６４を明滅又は点滅させ、１０６２ｃ及び１０６６ｃとしてそれぞれ示される、ＯＫインジケータ１０６２及び電池インジケータ１０６６を動作停止することができる。治療を再開するため、ユーザは、包帯を真っ直ぐにし、漏れを直し、かつ／又はポンプを再び動作させることが必要なことがある。幾つかの実施形態では、ポンプは、タイムアウトなどのため、ポンプ上のスタート又は動作ボタンを押すことによって、再び動作させることができる。

【０１８５】

１つ又は複数の漏れが包帯に存在している場合、幾つかの実施形態では、ポンプアセンブリ１０００は、所定のポンプの動作時間量の後に第２の陰圧設定値の値に達していない場合に、治療を延期もしくは一時停止するようにプログラムするか、又は別の形でそのように構成することができる。例えば、幾つかの実施形態では、ポンプがＸ分間継続的に稼働しており、第２の陰圧設定値の圧力値に達していない場合、ポンプアセンブリは、ＬＥＤインジケータ、「漏れ検出」ＬＥＤインジケータ１０６４、もしくは他のアラームを含むことができるアラームを動作させ、治療を一時停止することができる。幾つかの実施形態では、所定の時間量は、システムの陰圧治療の合計計画持続時間の約５％であるか、又はシステムの陰圧治療の合計計画持続時間の約３％以下～約１５％以上であることができる。幾つかの実施形態では、所定の時間量は、約９分、又は約４分以下～約４０分以上、又は約６分～約１０分であることができる。

【０１８６】

図３１は、非常に多量の漏れが存在する状態におけるポンプアセンブリ１０００の幾つかの実施形態の動作１９００の非限定例を示す。図２９に関して上述したように、ポンプアセンブリは、ボックス１９０２に示されるように、包帯１０１０の下の所望の陰圧レベ

ルを確立するように構成することができる。幾つかの実施形態では、包帯１０１０の下の圧力レベルが所望の値に達すると、ポンプアセンブリは、ボックス１９０４に示されるように、ポンプを動作停止し、包帯の下の圧力レベルを監視するように構成することができる。ポンプアセンブリは、例えば、センサ１０７０を読み取るか又はサンプリングすることによって、包帯１０１０の下の圧力レベルを周期的又は継続的に監視するように構成することができる。監視された圧力レベルに基づいて、ポンプアセンブリは、包帯１０１０の下の所望の陰圧レベルを再度確立するために、ポンプを動作又は再始動させる必要があるか否か否かを判定することができる。監視された圧力レベルが低い（例えば、第１の陰圧設定値の値未満か、もしくはそれ以下）と判定された場合、ポンプアセンブリは、ボックス１９０８に示されるように、ポンプを動作させるように構成することができる。この動作フローの間、ポンプアセンブリは、ポンプアセンブリが正常に動作していることをユーザに指示するように構成することができる。１０６０ｄに示されるように、ポンプアセンブリを動作させるか、又は１０６２ｄとして示される、ＯＫインジケータ１０６２を明滅もしくは点滅させることができる。それに加えて、ポンプアセンブリは、１０６４ｄ及び１０６６ｄとしてそれぞれ示される、包帯インジケータ１０６４及び電池インジケータ１０６６を動作停止させることができる。

【０１８７】

幾つかの実施形態では、１つ又は複数の漏れ（例えば、相対的に非常に高い流量を有する漏れ）により、ポンプアセンブリは、包帯１０１０の下の所望の陰圧レベル及び／又は第２の陰圧設定値の値に達することができないことがある。所定の動作時間量の後に、包帯の下の所望の陰圧レベルに達していない場合、ポンプアセンブリは、ボックス１９１４に示されるように、ポンプを延期又は一時停止するように構成することができる。例えば、これは待機状態１２７０に遷移することによって達成することができる。幾つかの実施形態では、所定のポンプ動作時間量は（図３１に示されるように）１０秒であることができる。幾つかの実施形態では、所定のポンプ動作時間量は、約５秒以下～約６０秒以上であることができる。

【０１８８】

幾つかの実施形態では、ポンプアセンブリは、治療を一時停止又は延期する前に、限定数の再試行サイクルを提供するように構成することができる。ボックス１９２０、１９２２、及び１９２４に示されるように、ポンプアセンブリは、治療を延期もしくは一時停止する（１９１４）前に、かつ／又は「漏れアラーム」などのアラームを動作させる前に、３回の再試行サイクルを経るように構成することができる。ポンプアセンブリの幾つかの実施形態は、治療の一時停止及び／又はアラームの動作の前に、２回の再試行サイクル、４回の再試行サイクルなどを経ることができる。１０６０ｅに示されるように、ポンプアセンブリを動作させるか、又は１０６４ｅとして示される、包帯インジケータ１０６４を明滅又は点滅させ、１０６２ｅ及び１０６６ｅとしてそれぞれ示される、ＯＫインジケータ１０６２及び電池インジケータ１０６６を動作停止することができる。

【０１８９】

図３２は、極めて多量の漏れが存在する状態におけるポンプアセンブリ１０００の幾つかの実施形態の動作２０００の非限定例を示す。ポンプアセンブリは、高い流量の漏れに対処しようとして電池を消耗するのを回避するため、治療の一時停止又は延期モードに迅速に入るように構成することができる。ボックス２００１に示されるように、ポンプアセンブリをオンにすることができ、それは例えば、動作状態カテゴリー１２５０へと遷移することによって達成することができる。図２９に関して上述したように、ポンプアセンブリは、ボックス２００２に示されるように、包帯１０１０の下の所望の陰圧レベルを確立するように構成することができる。

【０１９０】

幾つかの実施形態では、ポンプがオンにされたがまだ包帯に接続されていないか、もしくは包帯に適切に接続されていないときなど、漏れが極めて多量である場合、ポンプアセンブリは、包帯１０１０の下の圧力を所望の陰圧レベル（例えば、おおよそ第２の陰圧設

定値の値、もしくは第１及び第２の陰圧設定値の値の間の間隔内にある値）に近付けるように試みながら、所定の時間量の間、動作するように構成することができる。ポンプアセンブリは、所定の時間量が経過すると、治療を延期又は一時停止するように構成することができる。例えば、これは待機状態１２７０に遷移することによって達成することができる。図示されるように、ポンプアセンブリは、３０秒間ポンプを動作させるように構成することができる。この期間の間、包帯１０１０の下の圧力が所望の陰圧に近付けられていない場合、ポンプアセンブリは、別の所定の時間量（例えば、図３２に示されるように、１５秒間）の間、タイムアウトモード２０２０に入ることができる。この動作フローの間、ポンプアセンブリは、ポンプアセンブリが正常に動作していることをユーザに指示するように構成することができる。１０６０ｆに示されるように、ポンプアセンブリを動作させるか、１０６２ｆとして示されるＯＫインジケータ１０６２を明滅又は点滅させることができる。それに加えて、ポンプアセンブリは、１０６４ｆ及び１０６６ｆとしてそれぞれ示される、包帯インジケータ１０６４及び電池インジケータ１０６６を動作停止することができる。

【０１９１】

幾つかの実施形態では、ポンプアセンブリは、包帯１０１０の下の所望の陰圧レベルを確立するために、限定数の再試行サイクルを提供するように構成することができる。図示されるように、第１の試行（もしくは任意の数の追加の試行）の後、ポンプアセンブリは、ボックス２００２に示されるように、包帯の下の所望の陰圧レベルを確立又は再度確立するように構成することができる。幾つかの実施形態では、ボックス２０１４に示されるように、第１の試行後に包帯１０１０の下の圧力が所望のレベル（例えば、おおよそ第２の陰圧設定値の値、もしくは第１及び第２の陰圧設定値の値の間の間隔内にある値）に近付くことなく、ポンプアセンブリが別の所定の時間量の間、動作する場合、ポンプアセンブリは、ポンプダウンを再試行することなく治療を延期又は一時停止するように構成することができる。ポンプアセンブリは、ポンプアセンブリが（例えば、タイムアウトによって、ユーザがボタンを押すことによって）再動作されるまで、延期又は一時停止状態に留まるように構成することができる。ポンプアセンブリは、この状態でアラームを動作させるように構成することができる。この動作フローの間、ポンプアセンブリは、１つ又は複数の漏れが存在することをユーザに指示するように構成することができる。１０６０ｇに示されるように、ポンプアセンブリを動作させるか、又は１０６４ｇとして示される、包帯インジケータ１０６４を明滅又は点滅させ、１０６２ｇ及び１０６６ｇとしてそれぞれ示される、ＯＫインジケータ１０６２及び電池インジケータ１０６６を動作停止することができる。

【０１９２】

本明細書の説明及び請求項全体を通して、「備える（ｃｏｍｐｒｉｓｅ）」及び「含む（ｃｏｎｔａｉｎ）」という用語、ならびにその用語の変形、例えば「ｃｏｍｒｉｓｉｎｇ」及び「ｃｏｍｐｒｉｓｅｓ」は、「～を含むがそれに限定されない（ｉｎｃｌｕｄｉｎｇ　ｂｕｔ　ｎｏｔ　ｌｉｍｉｔｅｄ　ｔｏ）」ことを意味し、他の部分、追加物、構成要素、整数値、又はステップを除外することを意図しない（かつ除外しない）。

【０１９３】

本明細書の説明及び特許請求の範囲全体を通して、文脈において別の形で求められない限り、単数形は複数形を包含する。特に、不定冠詞が使用される場合、本明細書は、文脈において別の形で求められない限り、複数ならびに単数を企図するものとして理解されるべきである。さらに、幾つかの実施形態では、約という用語は、本明細書において別の形で提示されない限り、提示される値の１０％以内の値を指すことを意味する。

【０１９４】

本明細書に提供される、閾値、限界、持続時間、タイムアウト、再試行カウントなどの任意の値は、絶対値であることを意図せず、それにより、近似であることができる。それに加えて、本明細書に提供される、任意の閾値、限界、持続時間、タイムアウト、再試行カウントなどは、固定であるか、又は自動的にもしくはユーザによって変えることができ

る。さらに、本明細書で使用するとき、基準値に対して、～を超える、～よりも大きい、～よりも少ないなどの相対的な語は、基準値に等しいことも包含することが意図される。例えば、正である基準値を超えるということは、基準値に等しい、又はそれよりも大きいことを包含することができる。

【０１９５】

特定の態様、実施形態、又は例と併せて記載される特徴、整数値、特性、化合物、化学的部分、もしくは群は、不適合性でない限り、本明細書に記載される他の任意の態様、実施形態、又は例に適用可能であることが理解されるべきである。本明細書（任意の添付の請求項、要約書、及び図面を含む）に開示する特徴のすべて、ならびに／あるいは本明細書に開示する任意の方法又はプロセスのステップのすべては、かかる特徴及び／又はステップの少なくともいくつかが相互に排他的である組合せを除いて、任意の組合せで組み合わされてもよい。保護は、任意の上述の実施形態の詳細に限定されない。保護は、本明細書（任意の添付の特許請求の範囲、要約書、及び図面を含む）に開示する特徴の任意の新規なもの、もしくは任意の新規な組合せにまで、あるいは本明細書に開示する任意の方法又はプロセスのステップの任意の新規なもの、もしくは任意の新規な組合せにまで及ぶ。

【０１９６】

特定の実施形態について記載してきたが、これらの実施形態は単なる例示として提示してきたものであり、保護の範囲を限定しようとするものではない。実際には、本明細書に記載した新規な方法及びシステムは、様々な他の形態で具体化されてもよい。さらに、本明細書に記載した方法及びシステムの形態における、様々な省略、置換、及び変更が行われてもよい。当業者であれば、幾つかの実施形態では、図示及び／又は開示されるプロセスで行われる実際のステップは、図面に示されるものと異なっていることがあることを認識するであろう。実施形態に応じて、上述したステップの特定のものが除去されてもよく、他のものが追加されてもよい。したがって、本開示の範囲は、添付の特許請求の範囲を参照することによってのみ定義されるものとする。添付の特許請求の範囲及びそれらの等価物は、保護の範囲及び趣旨内にある形態又は修正を網羅するものとする。例えば、図面に示される様々な構成要素は、プロセッサにおけるソフトウェア及び／もしくはファームウェア、コントローラ、ＡＳＩＣ、ＦＰＧＡ、ならびに／又は専用ハードウェアとして実現されてもよい。さらに、上述した特定の実施形態の特徴及び属性は、追加の実施形態を形成するのに異なる手法で組み合わされてもよく、それらすべてが本開示の範囲内にある。本開示は、特定の好ましい実施形態及び用途を提供するが、本明細書に記載した特徴及び利点のすべては提供しない実施形態を含む、当業者には明白である他の実施形態も、本開示の範囲内にある。したがって、本開示の範囲は、添付の特許請求の範囲を参照することによってのみ定義されるものとする。

【符号の説明】

【０１９７】

１００　減圧創傷治療装置
１０２　創傷包帯
１０４　ポンプアセンブリ
１０６　導管
１０６ａ　第１の端部
１０６ｂ　第２の端部
１０８　ポート
１１２　コネクタ
１１４　導管
１１４ａ　コネクタ
１２０　ハウジング
１２０ａ　第１のハウジング部材
１２０ｂ　第２のハウジング部材
１２０ｃ　ガイド、チャネル

１２１　タブ
１２２　制御ボタン
１２３　窪み
１２４　電池カバー
１２４ａ　ラッチ、タブ部材
１２４ｂ　ガイド、突出部
１２４ｃ　窪み
１２４ｄ　突出部
１２５　電池接点
１２８　コネクタ
１３２　ライト
１４０　導管
１４２　電池
１４８　シールストリップ
１５０　第１のパッケージング要素
１５１　カバー
１５３　周縁部分
１９０、１９２、１９３、１９４、１９６、２００ａ、２００ｂ　陥凹部
１９５　隆起
２２０　電池区画
２２２　電池接点
２２４　電線
２３０　制御盤
２３２　ポンプ
２４０　マニホルド
２４６　一方向フロー弁
２５０　入口ポート
２５２　出口ポート
２６０　ポート
２６１　開口部
２６２　導管
２７０　締結具
２７２　ラベル
３００、３１０、３２０、３３０、３４０、３５０、３６０、３６５、３７０、３８０、３９０、３９５、４００、４０５、４１０、４２０　パッケージング要素
１０００　ポンプアセンブリ
１００２　ボタン
１０２０　ハウジング
１０３０　一方向フロー弁
１０４０　制御盤
１０５０　コネクタ
１０６０、１０６２、１０６４、１０６６　インジケータ
１０７０　圧力センサ
１０８０　電池カバー
１０９０　陰圧源
１０９２　電気モータ
１１００　電池区画
１１１０　出口
１１２０　入口
１１３０　電池セル、電源

１１４０　モジュール
１１５０　入／出力モジュール
１１６０　コントローラ
１１７０　メモリ

【図１】

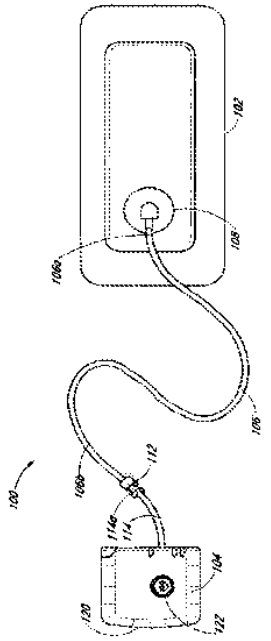


FIG. 1

【図２Ａ】

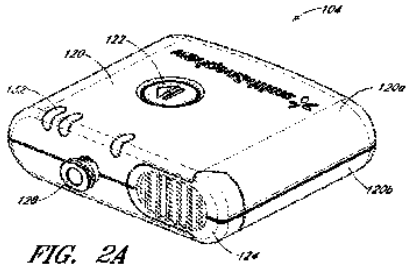


FIG. 2A

【図２Ｂ】

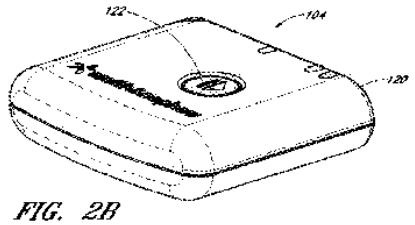


FIG. 2B

【図２Ｃ】

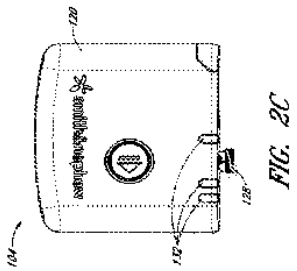


FIG. 2C

【図２Ｄ】

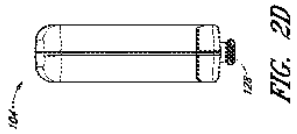


FIG. 2D

【図２Ｅ】

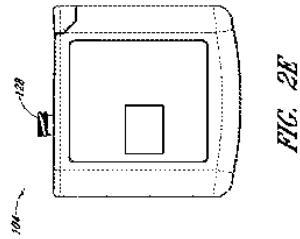


FIG. 2E

【図２Ｆ】

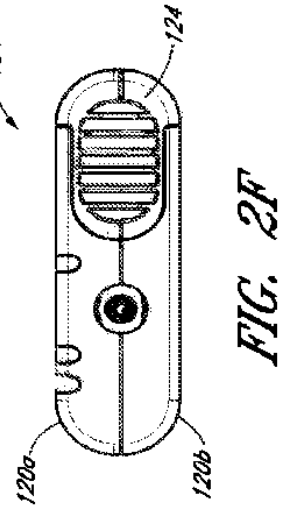


FIG. 2F

【図３Ａ】

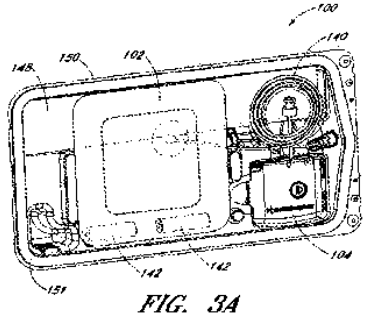


FIG. 3A

【図３Ｂ】

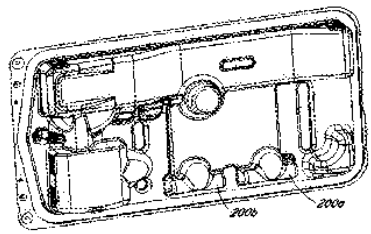


FIG. 3B

【図３Ｃ】

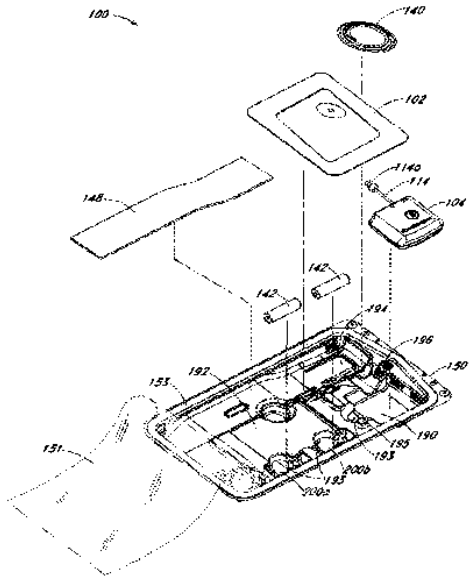


FIG. 3C

【図４Ａ】

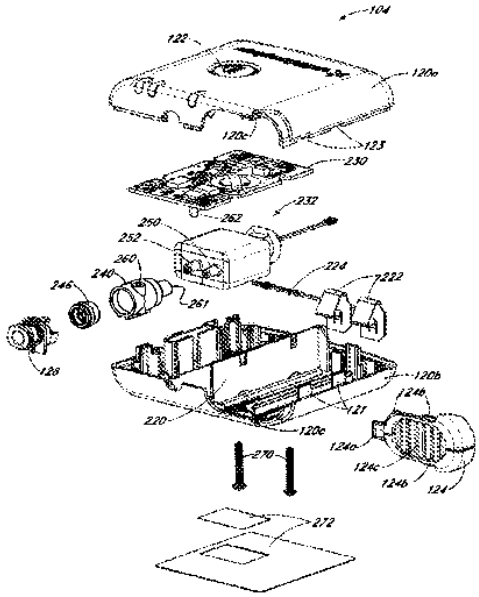


FIG. 4A

【図４Ｂ】

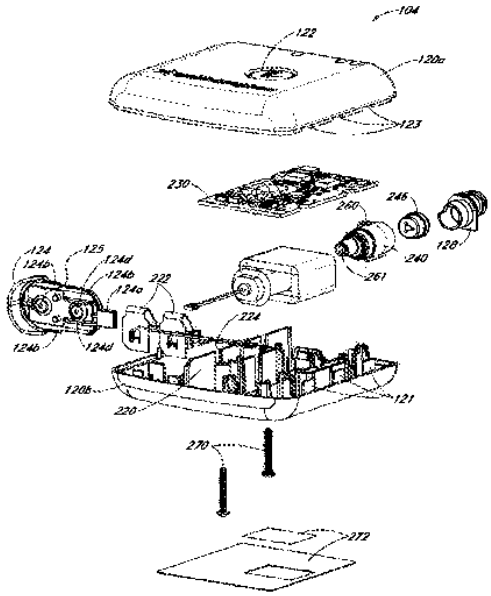


FIG. 4B

【図５Ａ】

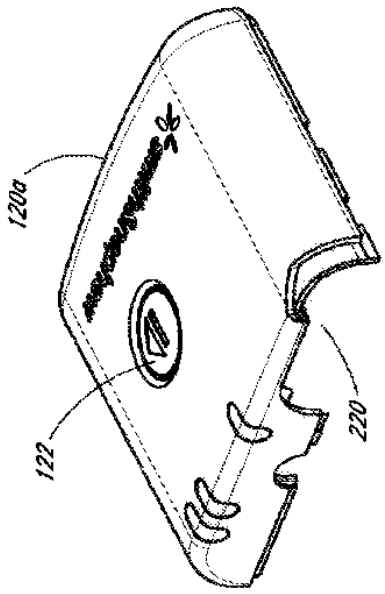


FIG. 5A

【図５Ｂ】

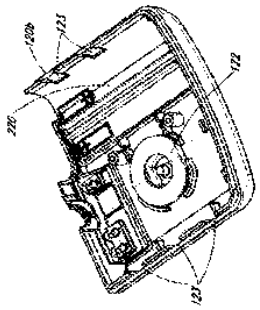


FIG. 5B

【図６Ａ】

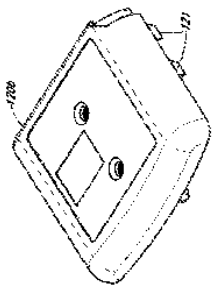


FIG. 6A

【図６Ｂ】

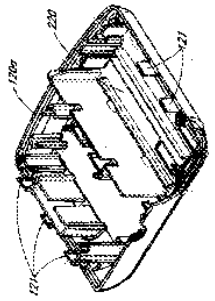


FIG. 6B

【図７Ａ】

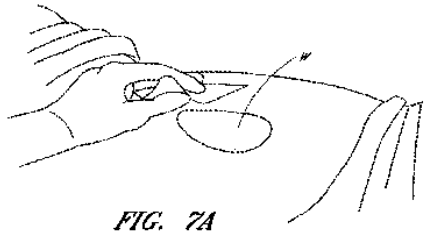


FIG. 7A

【図７Ｂ】

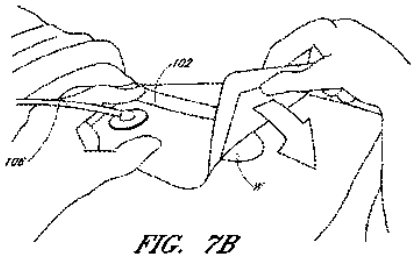


FIG. 7B

【図７Ｃ】

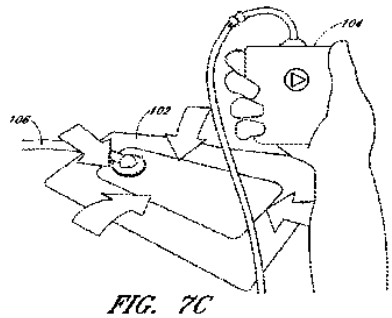


FIG. 7C

【図７Ｄ】

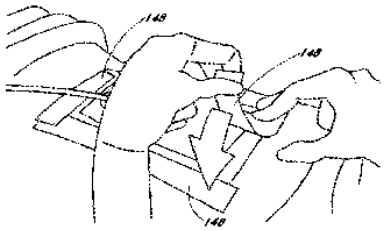


FIG. 7D

【図８Ｂ】

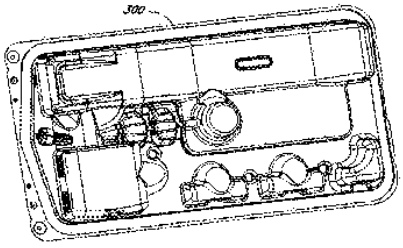


FIG. 8B

【図８Ａ】

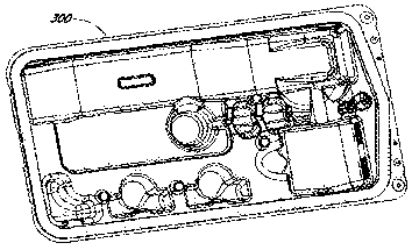


FIG. 8A

【図８Ｃ】

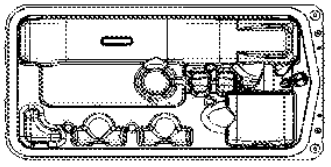


FIG. 8C

【図８Ｄ】

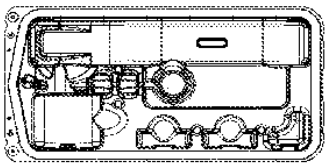


FIG. 8D

【図８Ｅ】

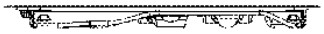


FIG. 8E

【図８Ｆ】



FIG. 8F

【図８Ｇ】

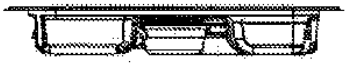


FIG. 8G

【図８Ｈ】



FIG. 8H

【図９Ａ】

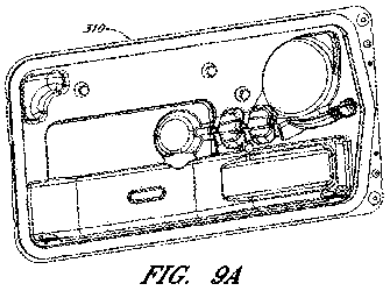


FIG. 9A

【図９Ｂ】

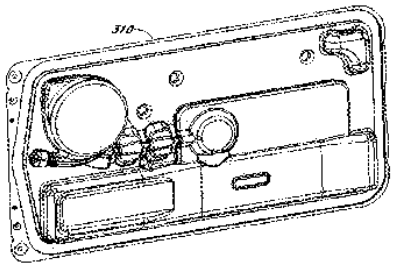


FIG. 9B

【図９Ｃ】

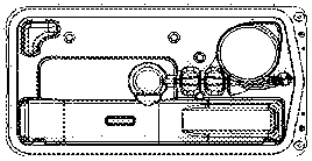


FIG. 9C

【図９Ｄ】

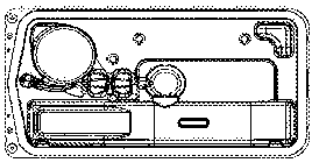


FIG. 9D

【図９Ｅ】

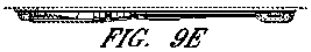


FIG. 9E

【図９Ｆ】



FIG. 9F

【図９Ｇ】



FIG. 9G

【図９Ｈ】



FIG. 9H

【図１０Ａ】

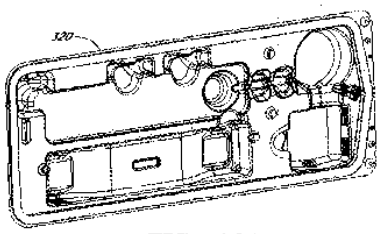


FIG. 10A

【図１０Ｂ】

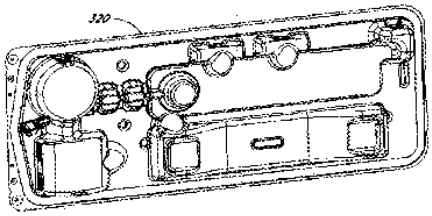


FIG. 10B

【図１０Ｃ】

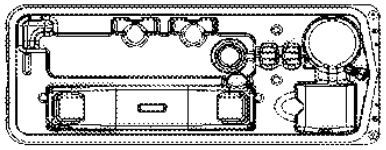


FIG. 10C

【図１０Ｄ】

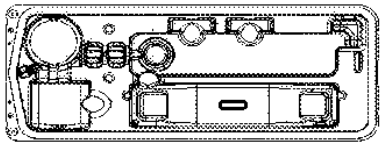


FIG. 10D

【図１０Ｅ】



FIG. 10E

【図１０Ｆ】



FIG. 10F

【図１０Ｇ】



FIG. 10G

【図１０Ｈ】



FIG. 10H

【図１１Ａ】

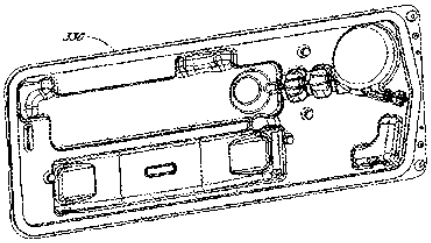


FIG. 11A

【図１１Ｂ】

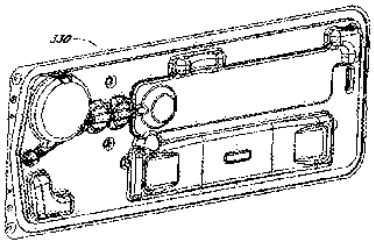


FIG. 11B

【図１１Ｃ】

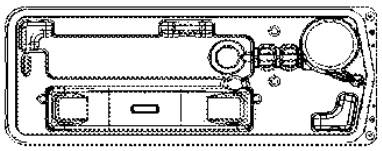


FIG. 11C

【図１１Ｄ】

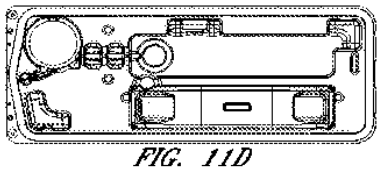


FIG. 11D

【図１１Ｅ】



FIG. 11E

【図１１Ｆ】

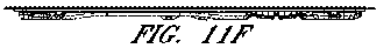


FIG. 11F

【図１１Ｇ】



FIG. 11G

【図１１Ｈ】



FIG. 11H

【図１２Ａ】

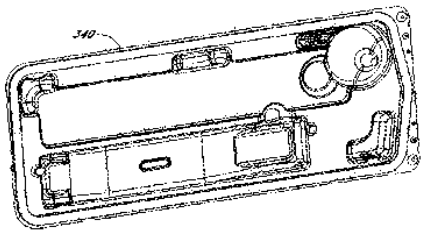


FIG. 12A

【図１２Ｂ】

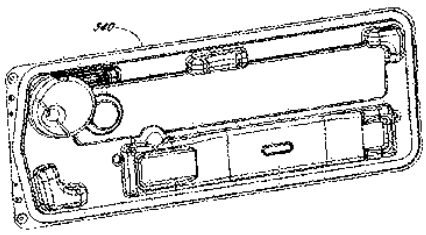


FIG. 12B

【図１２Ｃ】

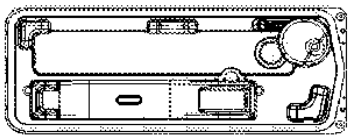


FIG. 12C

【図１２Ｄ】

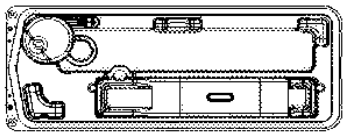


FIG. 12D

【図１２Ｅ】



FIG. 12E

【図１２Ｆ】



FIG. 12F

【図１２Ｇ】



FIG. 12G

【図１２Ｈ】



FIG. 12H

【図１３Ａ】

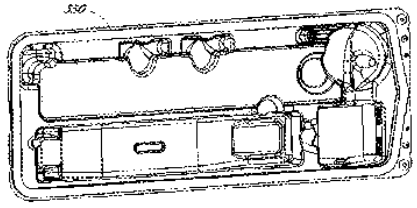


FIG. 13A

【図１３Ｂ】

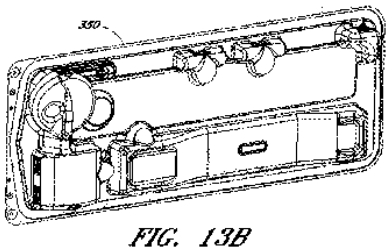


FIG. 13B

【図１３Ｃ】

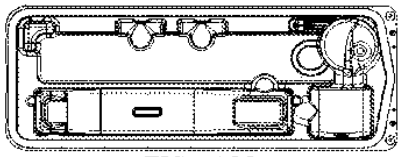


FIG. 13C

【図１３Ｄ】

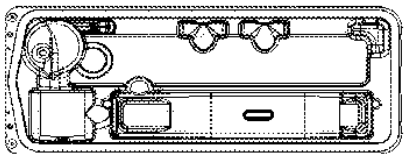


FIG. 13D

【図１３Ｅ】



FIG. 13E

【図１３Ｆ】



FIG. 13F

【図１３Ｇ】



FIG. 13G

【図１３Ｈ】



FIG. 13H

【図１４Ａ】

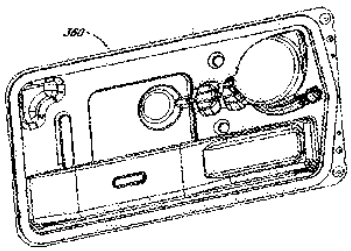


FIG. 14A

【図１４Ｂ】

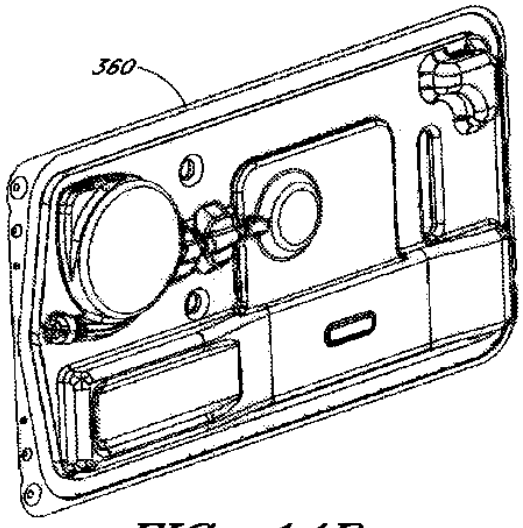


FIG. 14B

【図１４Ｃ】

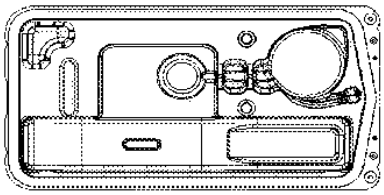


FIG. 14C

【図１４Ｄ】

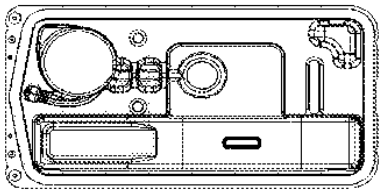


FIG. 14D

【図１４Ｅ】



FIG. 14E

【図１４Ｆ】

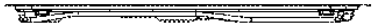


FIG. 14F

【図１４Ｇ】

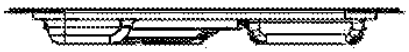


FIG. 14G

【図１４Ｈ】



FIG. 14H

【図１４Ｉ】

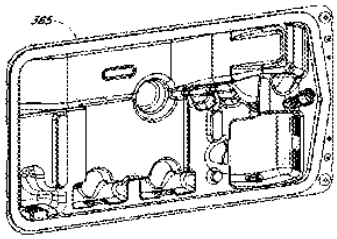


FIG. 14I

【図１４Ｊ】

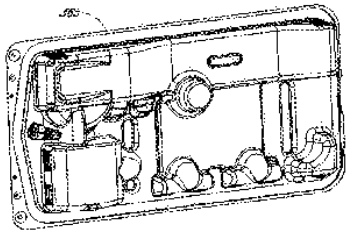


FIG. 14J

【図１４Ｋ】

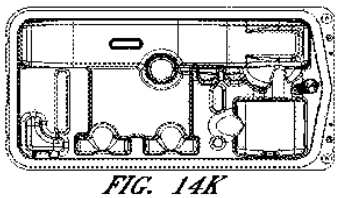


FIG. 14K

【図１４Ｌ】

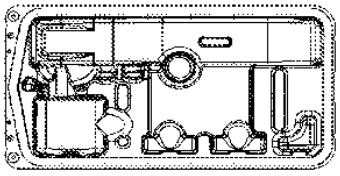


FIG. 14L

【図１４Ｍ】



FIG. 14M

【図１４Ｎ】



FIG. 14N

【図１４Ｏ】

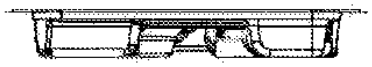


FIG. 140

【図１４Ｐ】



FIG. 14P

【図１５Ａ】

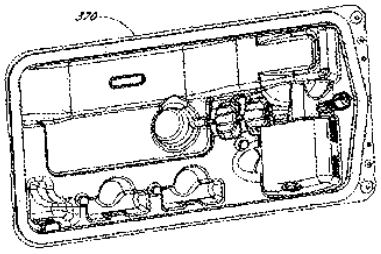


FIG. 15A

【図１５Ｂ】

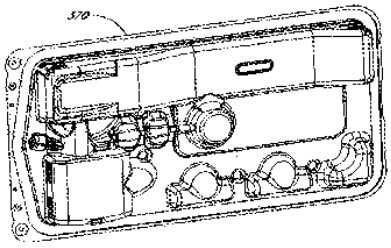


FIG. 15B

【図１５Ｃ】

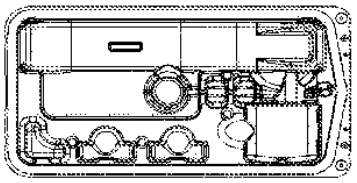


FIG. 15C

【図１５Ｄ】

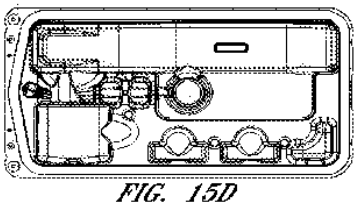


FIG. 15D

【図１５Ｅ】



FIG. 15E

【図１５Ｆ】



FIG. 15F

【図１５Ｇ】

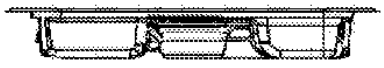


FIG. 15G

【図１５Ｈ】



FIG. 15H

【図１６Ａ】

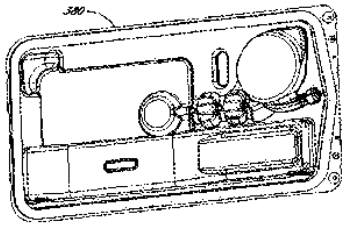


FIG. 16A

【図１６Ｂ】

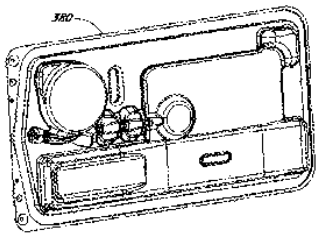


FIG. 16B

【図１６Ｃ】

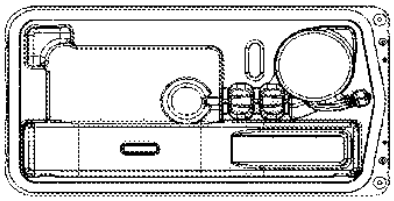


FIG. 16C

【図１６Ｄ】

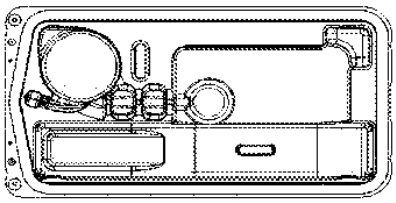


FIG. 16D

【図１６Ｅ】



FIG. 16E

【図１６Ｆ】



FIG. 16F

【図１６Ｇ】



FIG. 16G

【図１６Ｈ】



FIG. 16H

【図１７Ａ】

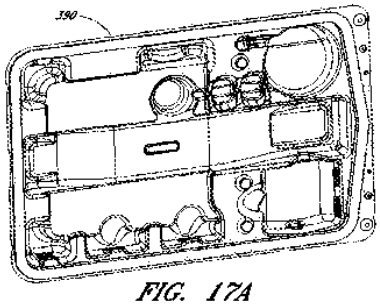


FIG. 17A

【図１７Ｂ】

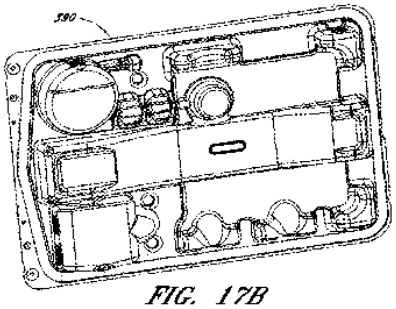


FIG. 17B

【図１７Ｃ】

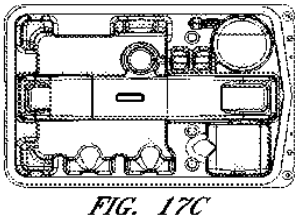


FIG. 17C

【図１７Ｄ】

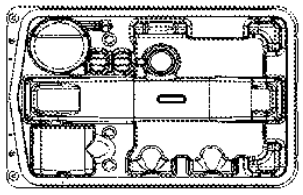


FIG. 17D

【図１７Ｅ】



FIG. 17E

【図１７Ｆ】



FIG. 17F

【図１７Ｇ】



FIG. 17G

【図１７Ｈ】



FIG. 17H

【図１７Ｉ】

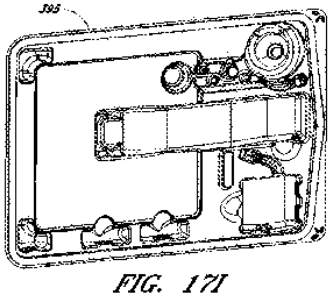


FIG. 17I

【図１７Ｊ】

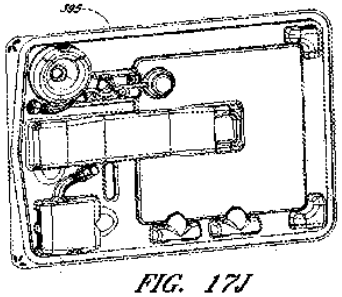


FIG. 17J

【図１７Ｋ】

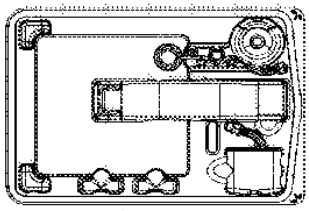


FIG. 17K

【図１７Ｌ】

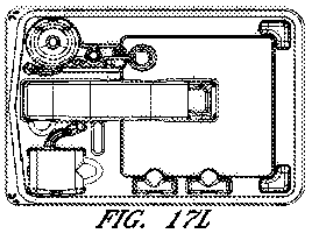


FIG. 17L

【図１７Ｍ】



FIG. 17M

【図１７Ｎ】



FIG. 17N

【図１７Ｏ】



FIG. 17O

【図１７Ｐ】



FIG. 17P

【図１８Ａ】

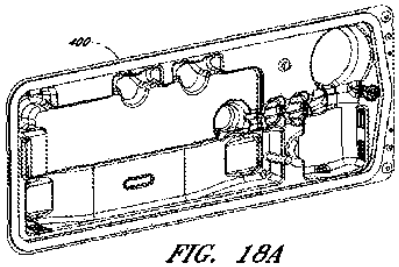


FIG. 18A

【図１８Ｂ】

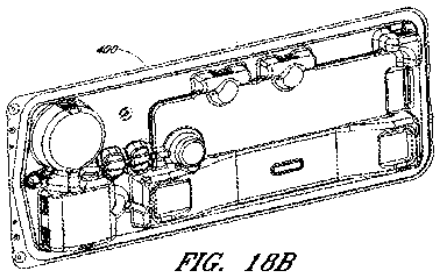


FIG. 18B

【図１８Ｃ】

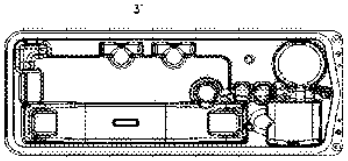


FIG. 18C

【図１８Ｄ】

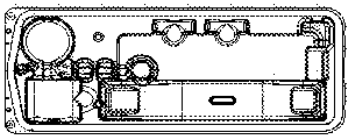


FIG. 18D

【図１８Ｅ】



FIG. 18E

【図１８Ｆ】



FIG. 18F

【図１８Ｇ】



FIG. 18G

【図１８Ｈ】



FIG. 18H

【図１８Ｉ】

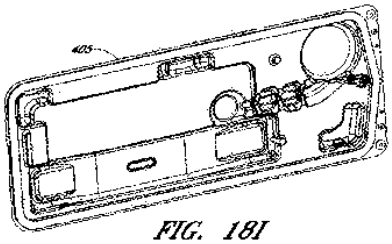


FIG. 18I

【図１８Ｊ】

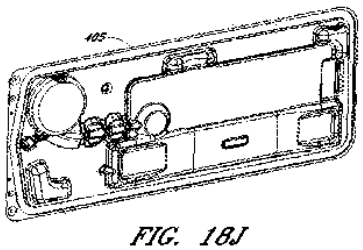


FIG. 18J

【図１８Ｋ】

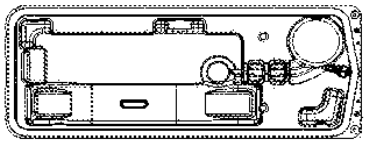


FIG. 18K

【図１８Ｌ】

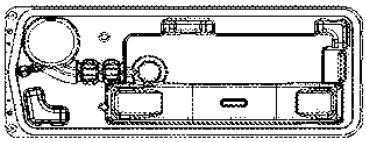


FIG. 18L

【図１８Ｍ】



FIG. 18M

【図１８Ｎ】

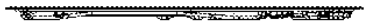


FIG. 18N

【図１８Ｏ】

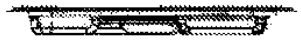


FIG. 180

【図１８Ｐ】



FIG. 18P

【図１９Ａ】

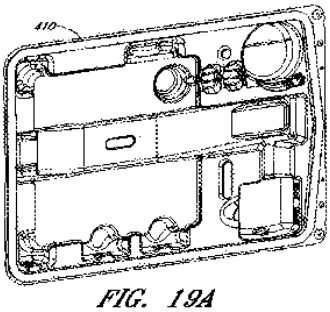


FIG. 19A

【図１９Ｂ】

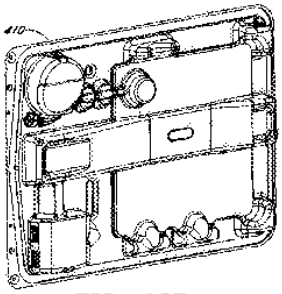


FIG. 19B

【図１９Ｃ】

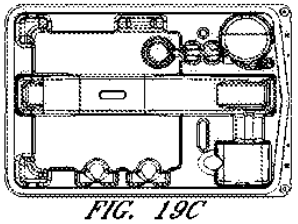


FIG. 19C

【図１９Ｄ】

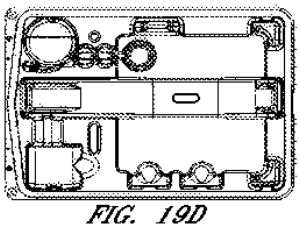


FIG. 19D

【図１９Ｅ】



FIG. 19E

【図１９Ｆ】



FIG. 19F

【図１９Ｇ】



FIG. 19G

【図１９Ｈ】



FIG. 19H

【図２０Ａ】

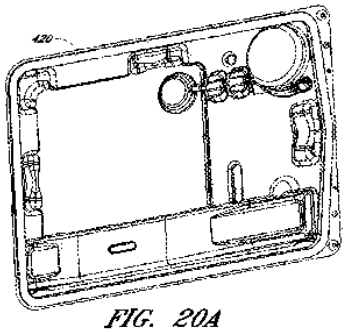


FIG. 20A

【図２０Ｂ】

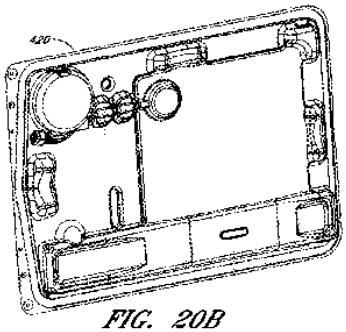


FIG. 20B

【図２０Ｃ】

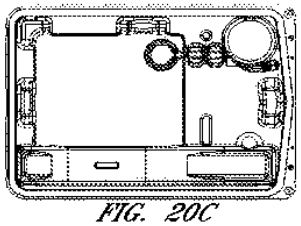


FIG. 20C

【図２０Ｄ】

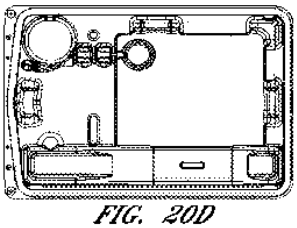


FIG. 20D

【図２０Ｅ】

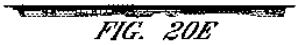


FIG. 20E

【図２０Ｆ】

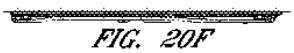


FIG. 20F

【図２０Ｇ】



FIG. 20G

【図２０Ｈ】



FIG. 20H

【図２１】

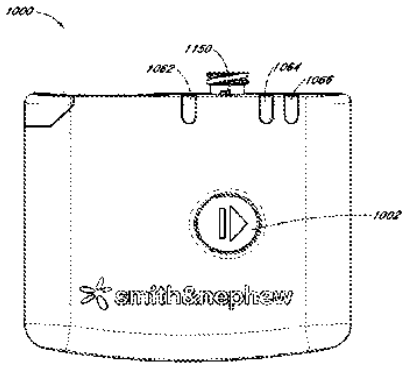


FIG. 21

【図２２】

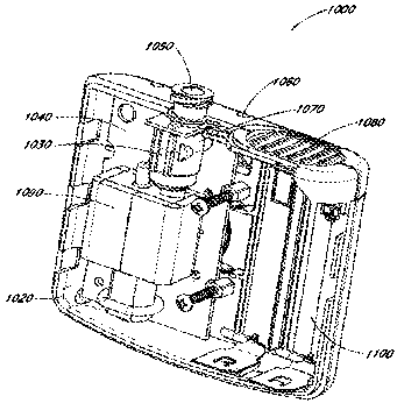


FIG. 22

【図２３】

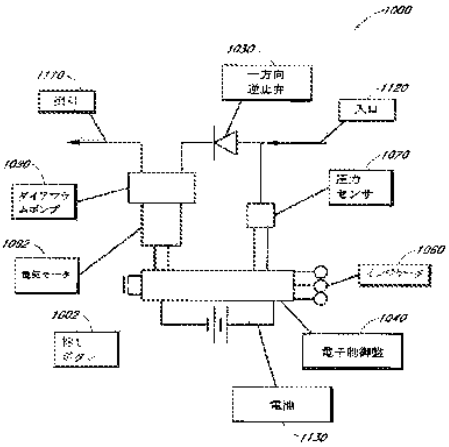


FIG. 23

【図２４】

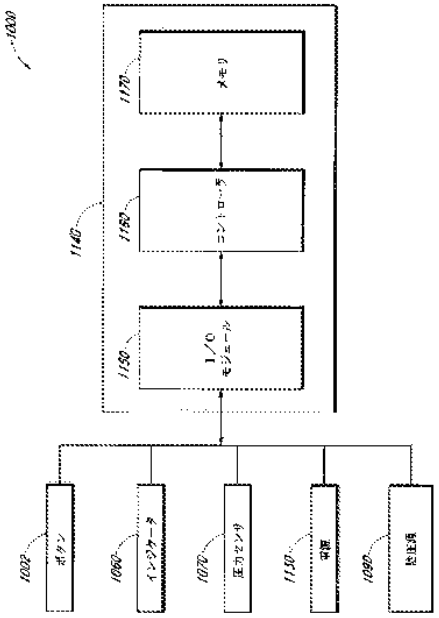


FIG. 24

【図２５】

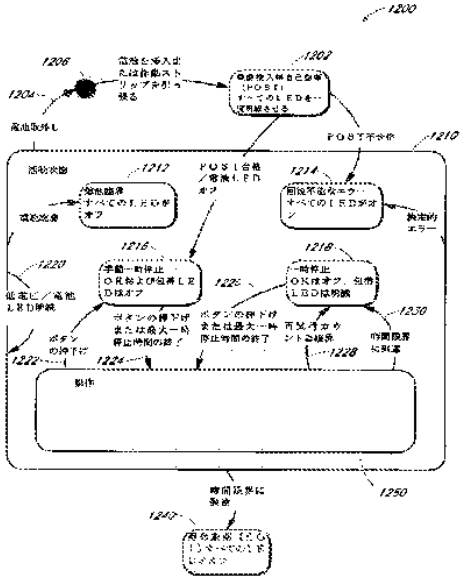


FIG. 25

【図２６】

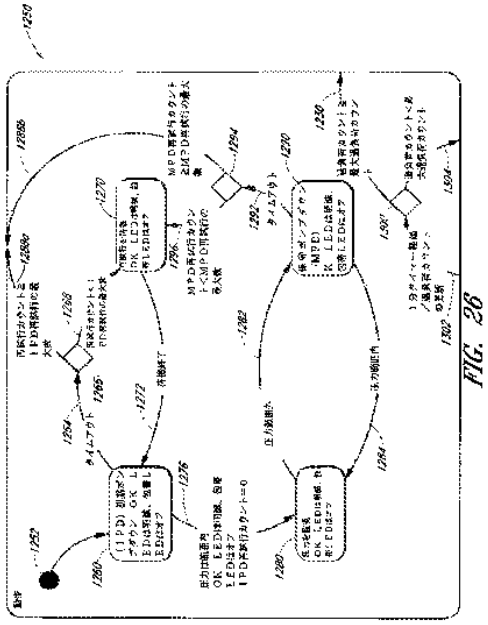


FIG. 26

【図２７】

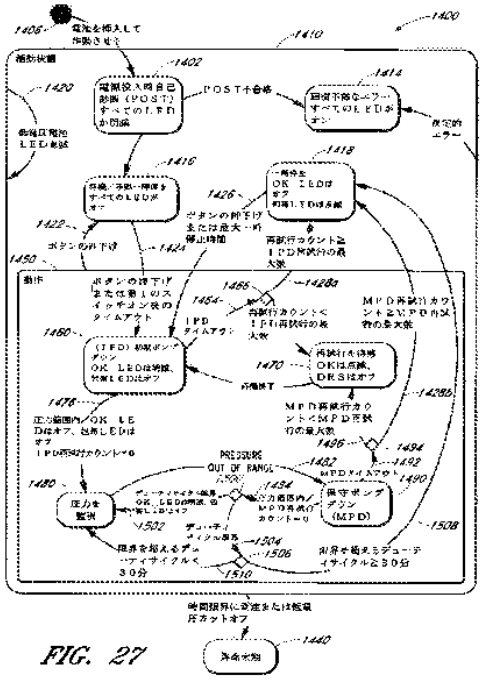


FIG. 27

【図２８】

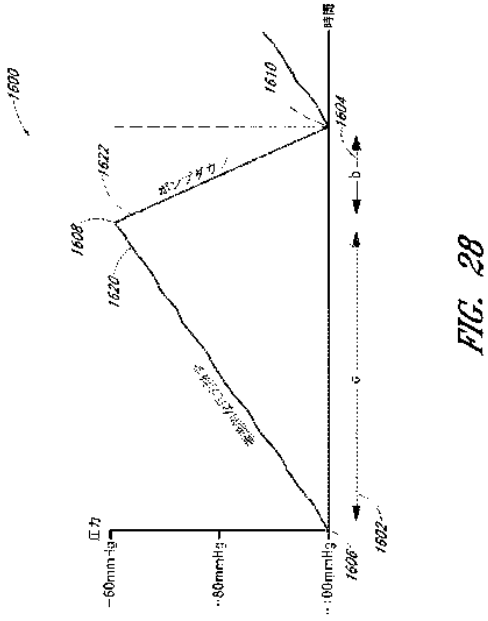


FIG. 28

【図２９】

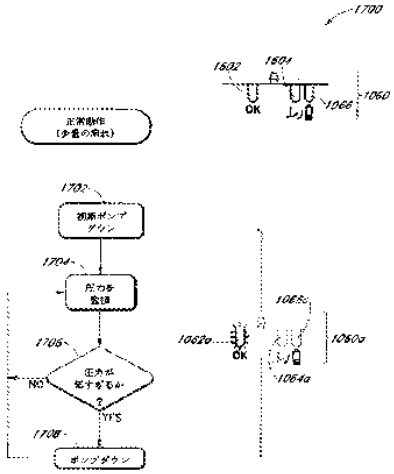


FIG. 29

【図３０】

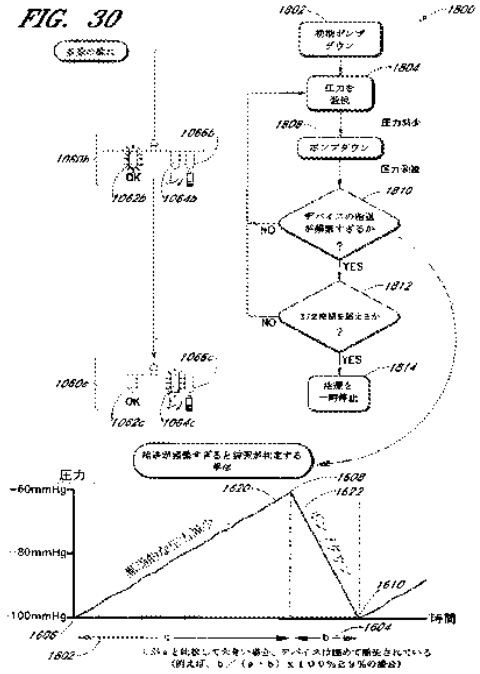


FIG. 30

【図３１】

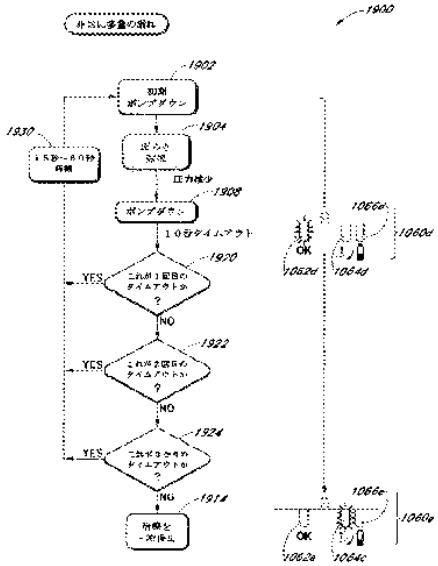


FIG. 31

【図３２】

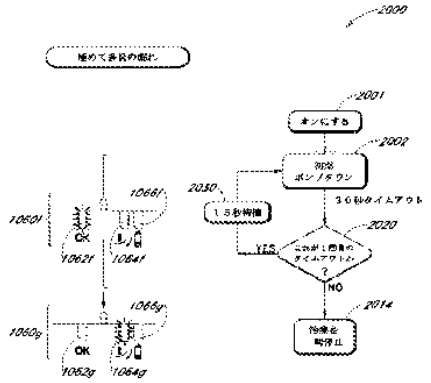


FIG. 32

【手続補正書】
【提出日】平成26年7月16日(2014.7.16)
【手続補正１】
【補正対象書類名】特許請求の範囲
【補正対象項目名】全文
【補正方法】変更
【補正の内容】
【特許請求の範囲】
【請求項１】
ハウジングと、
前記ハウジング内で又はハウジングによって支持されるポンプとを備える減圧創傷治療用のポンプアセンブリにおいて、前記ポンプが、
モータと、
入口及び出口と、
前記入口を通る流体のフローを制御するように構成された第１の弁と、
前記出口を通る流体のフローを制御するように構成された第２の弁と、
前記ポンプアセンブリを通る流路と、
前記ポンプと流体連通し、前記ポンプから離れるフロー方向で前記流路を通ってガスが流れるのを実質的に防ぐように構成されている一方向フロー弁と
を備える、ポンプアセンブリ。
【請求項２】
前記ポンプアセンブリが無容器型である、請求項１に記載のポンプアセンブリ。
【請求項３】
前記ハウジング内で又は前記ハウジングによって支持されるコントローラであって、前記ポンプの動作を制御するように構成されているコントローラをさらに備える、請求項１又は２に記載のポンプアセンブリ。
【請求項４】
前記流路と連通している圧力センサをさらに備える、請求項１から３のいずれか一項に記載のポンプアセンブリ。
【請求項５】
前記ハウジングによって支持される１つのみのスイッチ又はボタンをさらに備え、前記スイッチ又はボタンがユーザにとってアクセス可能であり、コントローラと連通していることができる、請求項１から４のいずれか一項に記載のポンプアセンブリ。
【請求項６】
前記第１の弁及び前記第２の弁が、公称の動作圧力で約０．１ｍＬ／分及び１０ｍＬ／分の速度で漏れる、請求項１から５のいずれか一項に記載のポンプアセンブリ。
【請求項７】
前記ポンプアセンブリが、前記ハウジングの少なくとも内部及び外部、前記流路、前記第１及び第２の弁、及び前記ポンプが滅菌されたものであるように滅菌される、請求項１から６のいずれか一項に記載のポンプアセンブリ。
【請求項８】
前記ハウジングによって支持される１つ又は複数のＬＥＤライトをさらに備える、請求項１から７のいずれか一項に記載のポンプアセンブリ。
【請求項９】
前記ポンプアセンブリが１つ又は複数の電池を備え、前記１つ又は複数の電池の重量を含めて８０ｇと９０ｇの間の重量である、請求項１から８のいずれか一項に記載のポンプアセンブリ。
【請求項１０】
前記ポンプアセンブリの外表面が６０立方センチメートルと８０立方センチメートルの間の体積を画成する、請求項１から９のいずれか一項に記載のポンプアセンブリ。

【請求項１１】
陰圧治療キットであって、
請求項１から１０のいずれか一項に記載の前記ポンプアセンブリと、
包帯と、
前記包帯及び前記ポンプアセンブリと連結可能であり、前記包帯までの減圧の流体経路を提供するように構成された導管と、
１つ又は複数の電池と、
第１のパッケージング要素、及び前記第１のパッケージング要素と取外し可能に連結されるように構成された第２のパッケージング要素であって、前記第１及び第２のパッケージング要素の少なくとも一方は、前記ポンプアセンブリと、前記包帯と、前記導管と、前記１つ又は複数の電池とを受け入れるための陥凹部を有する第１及び第２のパッケージング要素と
を備える陰圧治療キット。
【請求項１２】
前記陰圧治療キットが、滅菌性であり、前記ポンプアセンブリ、前記包帯、前記導管、及び前記１つ又は複数の電池を、前記第１のパッケージング要素及び前記第２のパッケージング要素の少なくとも一方の内部で支持した後に滅菌される、請求項１１に記載の陰圧治療キット。
【請求項１３】
１つ又は複数の接着剤シールストリップをさらに備える、請求項１１又は１２に記載の陰圧治療キット。
【請求項１４】
前記１つ又は複数の電池が、前記ハウジングの外部で支持される、請求項１１から１３のいずれか一項に記載の陰圧治療キット。
【請求項１５】
前記陰圧治療キットが酸化エチレンによって滅菌される、請求項１１から１４のいずれか一項に記載の陰圧治療キット。
【請求項１６】
前記包帯が、
透過層と、
創傷浸出物を吸収するための吸収性層であって、前記透過層を覆う吸収性層と、
前記吸収性層を覆い、そこを通るオリフィスを備えるカバー層と
を備える、請求項１１から１５のいずれか一項に記載の陰圧治療キット。
【請求項１７】
前記包帯が、創傷部位に局所陰圧を加えるために前記包帯に陰圧を加えるための吸気ポートを備える、請求項１１から１６のいずれか一項に記載の陰圧治療キット。
【請求項１８】
前記吸気ポートが、前記吸気ポートを前記ポンプアセンブリに接続するためのコネクタ部分、及び前記吸気ポートを前記包帯のカバー層にシールするためのシール面を備える、請求項１７に記載の陰圧治療キット。
【請求項１９】
前記包帯が、液体がコネクタ部分に入るのを防ぐようになされた液体不透過性ガス透過性フィルタ要素を備える、請求項１１から１８のいずれか一項に記載の陰圧治療キット。
【請求項２０】
前記第１のパッケージング要素がＰＥＴＧを備える、請求項１１から１９のいずれか一項に記載の陰圧治療キット。
【請求項２１】
陰圧治療システムであって、
請求項１から１０のいずれか一項に記載の前記ポンプアセンブリと、
包帯と

を備える陰圧治療システム。
【請求項２２】
前記包帯の創傷に向く面が、前記創傷を取り囲む皮膚と漏れ量の少ないシールを形成するように構成されたシリコーン系接着剤によって少なくとも部分的に覆われている、請求項２１に記載の陰圧治療キット。
【請求項２３】
陰圧を用いて創傷を治療する方法であって、
包帯を用意するステップと、
前記創傷の上に実質的に液密のシールを形成するように前記創傷の上に前記包帯を当てるステップと、
請求項１から１０のいずれか一項に記載の前記ポンプアセンブリを使用して前記包帯を通して前記創傷に陰圧を送達するステップと
を含む方法。
【請求項２４】
創傷の上に実質的に液密のシールを形成するように前記創傷の上に包帯を当てるステップ、及び請求項１から１０のいずれか一項に記載の前記ポンプアセンブリを使用して前記包帯を通して創傷に陰圧を送達するステップが、手術ルームで行われる、請求項２３に記載の陰圧を用いて創傷を治療する方法。
【請求項２５】
ポンプアセンブリであって、
ハウジングと、
ポンプモータ、
入口及び出口、
前記入口及び前記出口のうちの少なくとも１つを通して流体のフローを制御するように構成された少なくとも１つの弁、及び
少なくとも前記入口、前記出口、及び前記少なくとも１つの弁を通る流路
を備えるハウジング内で支持されるポンプと、
前記ハウジング内で又は前記ハウジングによって支持されるコントローラであって、前記ポンプ及び前記弁の動作を制御するように構成されているコントローラと、
少なくとも１つのスイッチ又はボタンであって、前記ハウジングで支持され、前記コントローラと連通し、ユーザがポンプの１つ又は複数の動作モードを制御できるように、ユーザにとってアクセス可能である少なくとも１つのスイッチ又はボタンと
を備えるポンプアセンブリと、
創傷の上に実質的に液密のシールを形成するように構成された包帯と、
前記包帯及び前記ポンプアセンブリと連結可能であり、前記ポンプアセンブリから前記包帯までの実質的に又は完全に包囲された流体流路を設けるように構成された導管と、
前記ポンプアセンブリ、前記１つ又は複数の電池、前記包帯、及び前記導管をパッケージングするための第１のパッケージング要素と
を備える、減圧創傷治療用の陰圧治療キットにおいて、
前記陰圧治療キットが、前記ハウジングの少なくとも内部及び外部、前記少なくとも１つの弁、前記ポンプ、前記コントローラ、及び前記少なくとも１つのスイッチ又はボタンが滅菌されたものであるように滅菌される、減圧創傷治療用の陰圧治療キット。
【請求項２６】
１つ又は複数の接着剤シールストリップをさらに備える、請求項２５に記載の陰圧治療キット。
【請求項２７】
動力を少なくとも前記ポンプ及びコントローラに供給するように構成された１つ又は複数の電池をさらに備える、請求項２１から２６のいずれか一項に記載の陰圧治療キット。
【請求項２８】
第１のパッケージング要素と連結するように構成された第２のパッケージング要素をさ

らに備え、前記第１のパッケージング要素が、前記ポンプアセンブリ、前記１つ又は複数の電池、前記包帯、導管、及び１つ又は複数の接着剤シールストリップのうちの１つ又は複数を受け入れるための複数の陥凹部を有する、請求項２７に記載の陰圧治療キット。

【請求項２９】

前記第２のパッケージング要素が、滅菌ガスに対して透過性であり、細菌に対して不透過性である、請求項２８に記載の陰圧治療キット。

【請求項３０】

第１のパッケージング要素が前記１つ又は複数の電池を支持し、それによって前記陰圧治療キットの滅菌処理中に前記１つ又は複数の電池が前記ハウジングの外部で支持される、請求項２５から２９のいずれか一項に記載の陰圧治療キット。

【請求項３１】

前記ポンプが、ダイヤフラムポンプ、回転ダイヤフラムポンプ、又は圧電ポンプである、請求項２５から３０のいずれか一項に記載の陰圧治療キット。

【請求項３２】

前記陰圧治療キットが酸化エチレンによって滅菌される、請求項２５から３１のいずれか一項に記載の陰圧治療キット。

【請求項３３】

前記少なくとも１つの弁が、滅菌プロセスの際に前記少なくとも１つの弁を通る滅菌ガスのフローを可能にするように構成された、請求項２５から３２のいずれか一項に記載の陰圧治療キット。

【請求項３４】

前記ポンプアセンブリが、フローマニホルドをさらに備え、前記フローマニホルドが、圧力センサ、前記ポンプ、及び導管、導管用コネクタのうちの少なくとも１つと流体連通している、請求項２５から３３のいずれか一項に記載の陰圧治療キット。

【請求項３５】

マニホルドによって支持された一方向フロー弁をさらに備える、請求項３４に記載の陰圧治療キット。

【請求項３６】

前記ポンプと前記包帯の間に位置付けられた一方向フロー弁を備え、前記一方向フロー弁が、前記ポンプから前記包帯に向かうフロー方向で前記一方向フロー弁を通るガスの前記フローを実質的に防ぐように構成されている、請求項２５から３５のいずれか一項に記載の陰圧治療キット。

【請求項３７】

前記一方向フロー弁が、前記ハウジング内で支持される、請求項３６に記載の陰圧治療キット。

【請求項３８】

前記ポンプと前記包帯の間、又は前記ポンプアセンブリ内で流体流路内のガスの圧力レベルを監視するように構成された圧力センサをさらに備える、請求項２５から３７のいずれか一項に記載の陰圧治療キット。

【請求項３９】

第１のパッケージング要素にパッケージングされた場合に導管の一方の端部が前記包帯に接続される、請求項２５から３８のいずれか一項に記載の陰圧治療キット。

【請求項４０】

導管が第１の端部及び第２の端部を備え、前記第１の端部が前記包帯に接続され、又は接続可能であり、前記第２の端部が前記ハウジングと連結するように構成されたコネクタを備える、請求項２５から３９のいずれか一項に記載の陰圧治療キット。

【請求項４１】

前記ハウジングがシールされない、請求項２５から４０のいずれか一項に記載の陰圧治療キット。

【請求項４２】

前記ポンプアセンブリが容器を備えない、請求項２５から４１のいずれか一項に記載の陰圧治療キット。
【請求項４３】
前記ポンプによって生成される雑音及び振動を低減するため前記ポンプの少なくとも一部分を取り囲む、解放した発泡体層をさらに備える、請求項２５から４２のいずれか一項に記載の陰圧治療キット。
【請求項４４】
前記包帯が、
透過層と、
創傷浸出物を吸収するための吸収性層であって、前記透過層を覆う吸収性層と、
前記吸収性層を覆うカバー層と、
導管の端部を受け入れるための吸気ポートと、
液体が前記吸気ポートを通過するのを防ぐようになされた液体不透過性ガス透過性フィルタ要素と
を備える、請求項２５から４３のいずれか一項に記載の陰圧治療キット。
【請求項４５】
前記ポンプアセンブリが、前記ハウジングにより支持され、又は前記ハウジング内に形成された電池区画を備える、請求項２５から４４のいずれか一項に記載の陰圧治療キット。
【請求項４６】
前記陰圧治療キットが、創傷を取り囲む皮膚と漏れ量の少ないシールを形成するように構成されたシリコーン系接着剤を有する創傷包帯を備え、前記ポンプアセンブリが前記１つ又は複数の電池の重量を含めて７０ｇと９０ｇの間の重量である、請求項２５から４５のいずれか一項に記載の陰圧治療キット。
【請求項４７】
前記ポンプアセンブリが、前記１つ又は複数の電池の重量を含めて７０ｇと９０ｇの間の重量である、請求項２５から４６のいずれか一項に記載の陰圧治療キット。
【請求項４８】
前記ポンプアセンブリの外表面が、約３立方インチ（４９．１６立方センチメートル）から約５立方インチ（８１．９４立方センチメートル）の体積を画成する、請求項２５から４７のいずれか一項に記載の陰圧治療キット。
【請求項４９】
前記陰圧治療キットが、シールストリップを第１のパッケージング要素から除去できる前に、前記包帯を前記第１のパッケージング要素から除去しなければならないように構成される、請求項２５から４８のいずれか一項に記載の陰圧治療キット。
【請求項５０】
約３５０ｍＬ／分以下の流量を有するポンプを備えるポンプアセンブリと、
カバー層を備える包帯であって、シリコーン系接着剤によって覆われている創傷接触面を有する包帯と
を備える、減圧創傷治療用の陰圧治療キット。
【請求項５１】
前記ポンプアセンブリが前記ポンプと流体連通している一方向フロー弁を備え、前記一方向フロー弁が前記ポンプから離れるフロー方向で流路を通ってガスが流れるのを実質的に防ぐように構成されている、請求項５０に記載された陰圧治療キット。
【請求項５２】
前記包帯が、前記包帯に陰圧を加えたときに開いたままであるように構成された３Ｄ編成材料又は布地材料を備える透過層を備える、請求項５０又は５１に記載の陰圧治療キット。
【請求項５３】
前記包帯が創傷浸出物を吸収するための吸収性層を備え、前記吸収性層が透過層を覆う

、請求項５０から５２のいずれか一項に記載の陰圧治療キット。
【請求項５４】
前記包帯が、吸収性層を覆うカバー層を備え、オリフィスを備え、前記カバー層が水蒸気透過性である、吸収性層が透過層を覆う、請求項５０から５３のいずれか一項に記載の陰圧治療キット。
【請求項５５】
前記包帯が、創傷部位に局所陰圧を加えるために、陰圧を前記包帯に加えるための吸気ポートを備え、前記吸気ポートが、前記吸気ポートを前記ポンプアセンブリに接続するためのコネクタ部分、及び前記吸気ポートを前記包帯の前記カバー層にシールするためのシール面を備える、請求項５０から５４のいずれか一項に記載の陰圧治療キット。
【請求項５６】
前記包帯が、液体がコネクタ部分に入るのを防ぐようになされた液体不透過性ガス透過性フィルタ要素を備える、請求項５０から５５のいずれか一項に記載の陰圧治療キット。
【請求項５７】
前記ポンプアセンブリが無容器型である、請求項５０から５６のいずれか一項に記載の陰圧治療キット。
【請求項５８】
前記ポンプアセンブリのハウジング内で又は前記ポンプアセンブリのハウジングによって支持されるコントローラであって、前記ポンプの動作を制御するように構成されているコントローラをさらに備える、請求項５０から５７のいずれか一項に記載の陰圧治療キット。
【請求項５９】
前記ポンプアセンブリを通る流路と連通している圧力センサをさらに備える、請求項５０から５８のいずれか一項に記載の陰圧治療キット。
【請求項６０】
前記ポンプアセンブリのハウジングによって支持される少なくとも１つのスイッチ又はボタンをさらに備え、前記少なくとも１つスイッチ又はボタンがユーザにとってアクセス可能であり、コントローラと連通していることができる、請求項５０から５９のいずれか一項に記載の陰圧治療キット。
【請求項６１】
前記ポンプアセンブリにより支持された電池区画をさらに備える、請求項５０から６０のいずれか一項に記載の陰圧治療キット。
【請求項６２】
前記ポンプアセンブリの少なくとも内部及び外部が滅菌されているように、前記ポンプアセンブリが、前記ポンプアセンブリの組み立てに続いて滅菌される、請求項５０から６１のいずれか一項に記載の陰圧治療キット。
【請求項６３】
前記ポンプアセンブリが１つ又は複数のＬＥＤライトを有する、請求項５０から６２のいずれか一項に記載の陰圧治療キット。
【請求項６４】
前記ポンプアセンブリが、１つ又は複数の電池を備え、前記１つ又は複数の電池の重量を含めて８０ｇと９０ｇの間の重量である、請求項５０から６３のいずれか一項に記載の陰圧治療キット。
【請求項６５】
前記ポンプアセンブリの外表面が６０立方センチメートルと８０立方センチメートルの間の体積を画成する、請求項５０から６４のいずれか一項に記載の陰圧治療キット。
【請求項６６】
減圧創傷治療用の無容器型ポンプアセンブリであって、
ハウジングと、
ハウジング内で又はハウジングによって支持されるポンプとを備えるポンプアセンブリ

において、前記ポンプが、
モータと、
入口及び出口と、
前記入口を通る流体のフローを制御するように構成された第１の弁と、
前記出口を通る流体のフロ―を制御するように構成された第２の弁と
を備える容器型ポンプアセンブリにおいて、
前記ポンプアセンブリが無容器型であり、
前記第１及び第２の弁が、それぞれ公称の動作圧力で約５Ｌ／分と約１０Ｌ／分の間の漏れ速度を有する、容器型ポンプアセンブリ。
【請求項６７】
前記ポンプアセンブリが前記ポンプと流体連通している一方向フロー弁を備え、前記一方向フロ―弁が前記ポンプから離れるフロ―方向で流路を通ってガスが流れるのを実質的に防ぐように構成された、請求項６６に記載のポンプアセンブリ。
【請求項６８】
前記ハウジング内で又は前記ハウジングによって支持されるコントローラであって、前記ポンプの動作を制御するように構成されているコントローラをさらに備える、請求項６６又は６７に記載のポンプアセンブリ。
【請求項６９】
前記ポンプアセンブリを通る流路と連通している圧力センサをさらに備える、請求項６６から６８のいずれか一項に記載のポンプアセンブリ。
【請求項７０】
前記ハウジングによって支持される少なくとも１つのスイッチ又はボタンをさらに備え、前記少なくとも１つスイッチ又はボタンがユーザにとってアクセス可能であり、コントローラと連通していることができる、請求項６６から６９のいずれか一項に記載のポンプアセンブリ。
【請求項７１】
前記ハウジングにより支持され、又は前記ハウジング内に形成された電池区画をさらに備える、請求項６６から７０のいずれか一項に記載のポンプアセンブリ。
【請求項７２】
前記ハウジングの少なくとも内部及び外部、流路、前記１つ又は複数の弁、及び前記ポンプが滅菌されたものであるように、前記ポンプアセンブリの組み立てに続いて滅菌される、請求項６６から７１のいずれか一項に記載のポンプアセンブリ。
【請求項７３】
前記ハウジングによって支持される１つ又は複数のＬＥＤライトをさらに備える、請求項６６から７２のいずれか一項に記載のポンプアセンブリ。
【請求項７４】
前記ポンプアセンブリが１つ又は複数の電池を備え、前記１つ又は複数の電池の重量を含めて８０ｇ及び９０ｇの重量である、請求項６６から７３のいずれか一項に記載のポンプアセンブリ。
【請求項７５】
前記ポンプアセンブリの外表面が６０立方センチメートルと８０立方センチメートルの間の体積を画成する、請求項６６から７４のいずれか一項に記載のポンプアセンブリ。
【請求項７６】
滅菌ポンプキットであって、
請求項６６から７５のいずれか一項に記載の前記ポンプアセンブリと、
包帯と、
前記包帯及び前記ポンプアセンブリと連結可能であり、前記包帯までの減圧の流体経路を提供するように構成された導管と、
１つ又は複数の電池と、
第１のパッケージング要素、及び前記第１のパッケージング要素と取外し可能に連結さ

れるように構成された第２のパッケージング要素であって、前記第１及び第２のパッケージング要素の少なくとも一方は、前記ポンプアセンブリと、包帯と、前記包帯及び前記ポンプアセンブリと連結可能であり、前記包帯までの減圧の流体経路を提供するように構成された前記導管とを受け入れるための陥凹部を有する滅菌ポンプキットにおいて、

前記滅菌ポンプキットが、前記ポンプアセンブリ、前記包帯、前記導管、及び前記１つ又は複数の電池が、前記第１のパッケージング要素及び前記第２のパッケージング要素の少なくとも一方の内部で支持された後に滅菌される、滅菌ポンプキット。

【請求項７７】

前記ポンプアセンブリ、前記包帯、前記導管、及び前記１つ又は複数の電池が滅菌される前に、前記ポンプアセンブリ、前記包帯、前記導管、及び前記１つ又は複数の電池が、前記第１のパッケージング要素及び前記第２のパッケージング要素の少なくとも一方の内部で支持される、請求項７６に記載の滅菌ポンプキット。

【請求項７８】

１つ又は複数の接着剤シールストリップをさらに備える、請求項７６又は７７に記載の滅菌ポンプキット。

【請求項７９】

前記１つ又は複数の電池が、前記ハウジングの外表面で支持される、請求項７６から７８のいずれか一項に記載の滅菌ポンプキット。

【請求項８０】

前記滅菌ポンプキットが酸化エチレンによって滅菌される、請求項７６から７９のいずれか一項に記載の滅菌ポンプキット。

【請求項８１】

前記包帯が、

透過層と、

創傷浸出物を吸収するための吸収性層であって、前記吸収性層が前記透過層を覆う吸収性層と、

前記吸収性層を覆うカバー層と

を備える請求項７６から８０のいずれか一項に記載の滅菌ポンプキット。

【請求項８２】

前記包帯が、創傷部位に局所陰圧を加えるために前記包帯に陰圧を加えるための吸気ポートを備える、請求項７６から８１のいずれか一項に記載の滅菌ポンプキット。

【請求項８３】

前記吸気ポートが、前記吸気ポートを前記ポンプアセンブリに接続するためのコネクタ部分、及び前記吸気ポートを前記包帯のカバー層にシールするためのシール面を備える、請求項８２に記載の滅菌ポンプキット。

【請求項８４】

前記包帯が、液体がコネクタ部分に入るのを防ぐようになされた液体不透過性ガス透過性フィルタ要素を備える、請求項７６から８３のいずれか一項に記載の滅菌ポンプキット。

【請求項８５】

前記第１のパッケージング要素がＰＥＴＧを備える、請求項７６から８４のいずれか一項に記載の滅菌ポンプキット。

【請求項８６】

手術ルームにおいて創傷の治療を開始するための方法であって、

創傷の上に滅菌包帯を当てて、前記創傷の上に実質的に液密のシールを作り出すステップと、

滅菌導管を介して滅菌ポンプアセンブリを包帯に連結するステップと、前記手術ルームで前記滅菌ポンプアセンブリを動作させることによって手術ルームで前記包帯と前記創傷との間の圧力レベルを低減するステップと

を含む、方法。

【請求項８７】
少なくとも１つの前記包帯の外周縁部の上に１つ又は複数のシールストリップを当てて、前記包帯と前記創傷を取り囲む皮膚の間の前記シールを改善するためのステップをさらに含む、請求項８６に記載の方法。
【請求項８８】
１つ又は複数の電池を第１のパッケージング要素から取り出すステップと、前記１つ又は複数の電池を前記滅菌ポンプアセンブリに取り付けるステップをさらに含む、請求項８６又は８７に記載の方法。

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/002943

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61L2/00 A61M1/00
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M A61L F04B F04C F04D

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/125004 A1 (SHEN TE-YANG [TW] ET AL) 14 May 2009 (2009-05-14) paragraphs [0001], [0025], [0029] - [0030], [0035]; claim 4; figures 2,4	1-10,21, 22
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[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 December 2012	28/01/2013

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

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/002943

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/057307 A1 (HILL ROM SERVICES INC [US]; LOCKWOOD JEFFREY S [US]; PETROSENKO ROBERT) 17 July 2003 (2003-07-17) page 15, line 32 - page 16, line 56; figures 1,4	11-20
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Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/002943

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2011/002943

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

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

1. [X] Claims Nos.: 23, 24, 86-88
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210

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

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

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

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

see additional sheet

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

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

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

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

Remark on Protest

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

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

[X] No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (April 2005)

International Application No. PCT/IB2011/002943

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-10, 21, 22

A pump assembly comprising: a pump having a first valve at the inlet and second valve at the outlet; a flow path; a one-way flow valve configured to substantially prevent a flow of gas through the flow path away from the pump.

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2. claims: 11-20

A pump assembly as in the first group of claims additionally comprising a dressing, one or more batteries and a first and second packaging element.

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3. claims: 25-49

A negative pressure therapy kit comprising a pump assembly comprising: a pump having at least one valve configured to control the flow through at least one of the inlet and the outlet; a controller; at least one switch button in communication with the controller; a first packaging element.

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4. claims: 50-65

A negative pressure therapy kit comprising: a pump assembly having a flow rate of approx. 350 ml/min or less; a dressing with a cover layer and a wound contact layer covered with a silicone based adhesive.

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5. claims: 66-88

A canisterless pump assembly comprising; a pump having a first and second valve controlling the flow at the inlet and outlet respectively, wherein the leakage rate of the valves is between approx. 5-10 ml/min at nominal working pressure.

International Application No. PCT/IB2011/002943

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 23, 24, 86-88

Claims 23-24 refer to a method for treatment of the human or animal body by therapy, which is against Rule 39.1(iv) PCT and Rule 67.1(iv). The reason is that they include the step of delivering negative pressure to a wound. Claims 86-88 refer to a method for treatment of the human or animal body by therapy, which is against Rule 39.1(iv) PCT and Rule 67.1(iv). The reason is that they include the step applying a sterile dressing over a wound and reducing a level of pressure between the dressing and the wound.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2011/002943

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International application No
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Ｆターム(参考) 4C077 AA15 DD02 DD25 EE04 GG03 HH07 HH13 JJ08 JJ13
4C167 AA40 BB23 BB33 BB40 BB42 BB62 CC01 DD10

Patents | JP 2014-532498 A

Decompression treatment device and method of using the same

Abstract

translated from Japanese

Some embodiments include a housing, a flow path through the pump, one or more valves in communication with the flow path, a pump in or supported by the housing, and a one-way flow in fluid communication with the pump. A reduced pressure wound therapy pump assembly comprising a valve. The pump assembly may have a pressure sensor in communication with the flow path through the pump, and at least one switch or button supported by the housing, at least one switch or button being accessible to the user and in communication with the controller. is doing. The one way flow valve can be configured to substantially prevent gas from flowing through the one-way flow valve in the flow direction away from the pump. The pump assembly can have a controller that is supported in or by the housing and configured to control the operation of the pump. The pump is sterilized following assembly of the pump such that the interior and exterior of the housing, flow path, one or more valves, pump, controller, battery compartment, and at least one switch or button are sterilized. The

Images (160)



Classifications

- A61M1/80 Suction pumps

View 12 more classifications

JP2014532498A

Japan

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Other languages: *Japanese*

Inventor: ロードン・キャスパル・アディー, ジョリー・アレン, ビクトリア・ヒードル, サラ・ジェニー・コリンソン, クリストファー・ジョン・クライヤー, エドワード・キーバリー・ハートウェル, ヨリダヘス・アン・ファイア・ジャニングス, デレック・ニコラース, ゼニック・ルイス・パトン

Current Assignee : Smith and Nephew PLC

Worldwide applications

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Application JP2014539415A events

2011-11-02	Application filed by Smith and Nephew PLC
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Status	Active
2031-11-02	Anticipated expiration

Info: Patent citations (70), Cited by (32), Legal events, Similar documents, Priority and Related Applications

External links: Espacenet, Global Dossier, Discuss

Claims (58)

Hide Dependent

translated from Japanese

A housing;
A reduced pressure wound therapy pump assembly comprising a pump supported in or by the housing, the pump comprising:
A motor,
An inlet and an outlet,
A first valve configured to control the flow of fluid through the inlet;
A second valve configured to control the flow of fluid through the outlet,
A flow path through the pump assembly;
A pump assembly comprising: a one-way flow valve in fluid communication with the pump and configured to substantially prevent gas from flowing through the flow path in a flow direction away from the pump. The pump assembly of claim 1, wherein the pump assembly is contactless. The pump assembly of claim 1 or 2, further comprising a controller supported within or by the housing, the controller configured to control operation of the pump. The pump assembly according to any one of claims 1 to 3, further comprising a pressure sensor in communication with the flow path. 5. The method of claim 1, further comprising only one switch or button supported by the housing, wherein the at least one switch or button is accessible to a user and can be in communication with a controller. The pump assembly according to claim 1. 6. The pump according to claim 1, wherein the first valve and the second valve leak at a rate of about 0.1 mL / min and 10 mL / min at nominal operating pressure. assembly. 7 The pump assembly of any of claims 1 to 6, wherein the pump assembly is sterilized such that at least the interior and exterior of the housing, the flow path, the first and second valves, and the pump are sterilized. The pump assembly according to claim 1. The pump assembly according to any one of the preceding claims, further comprising one or more LED lights supported by the housing. 9. A pump assembly according to any one of the preceding claims, wherein the pump assembly comprises one or more batteries and has a weight between 80g and 90g including the weight of the one or more batteries. . The pump assembly according to any one of the preceding claims, wherein the outer surface of the pump assembly defines a volume between 60 cubic centimeters and 80 cubic centimeters. A negative pressure treatment kit,
The pump assembly according to any one of claims 1 to 10,
Bandages,
A conduit connectable with the bandage and the pump assembly and configured to provide a reduced pressure fluid path to the bandage;

One or more batteries,

A first packaging element and a second packaging element configured to be removably coupled to the first packaging element, wherein at least one of the first and second packaging elements A negative pressure treatment kit comprising: the pump assembly, the bandage, the conduit, and first and second packaging elements having recesses for receiving the one or more batteries. The negative pressure treatment kit is sterile, and the pump assembly, the bandage, the conduit, and the one or more batteries are connected to at least one of the first packaging element and the second packaging element. The negative pressure treatment kit according to claim 11, which is sterilized after being supported inside. 13. The negative pressure treatment kit according to claim 11 or 12, further comprising one or more adhesive seal strips. The negative pressure treatment kit according to any one of claims 11 to 13, wherein the one or more batteries are supported outside the housing. 15. The negative pressure treatment kit according to any one of claims 11 to 14, wherein the negative pressure treatment kit is sterilized with ethylene oxide. The bandage is

A transmission layer,

An absorbent layer for absorbing wound exudate, the absorbent layer covering the permeable layer;

The negative pressure treatment kit according to any one of claims 11 to 15, further comprising a cover layer that covers the absorbent layer and includes an orifice passing therethrough. 17. The negative pressure treatment kit according to any one of claims 11 to 16, wherein the bandage comprises an inspiratory port for applying a negative pressure to the bandage to apply a local negative pressure to a wound site. 18. The negative pressure treatment kit of claim 17, wherein the intake port comprises a connector portion for connecting the intake port to the pump assembly, and a sealing surface for sealing the intake port to a cover layer of the bandage. . 19. A negative pressure treatment kit according to any one of claims 11 to 18, wherein the bandage comprises a liquid impermeable gas permeable filter element adapted to prevent liquid from entering the connector portion. 20. The negative pressure treatment kit according to any one of claims 11 to 19, wherein the first packaging element comprises PETG. A negative pressure treatment system,

The pump assembly according to any one of claims 1 to 10,

A negative pressure treatment system comprising a bandage. 23. The negative pressure of claim 21, wherein the wound-facing surface of the dressing is at least partially covered by a silicone adhesive configured to form a low-leakage seal with the skin surrounding the wound. Treatment kit. A method of treating a wound using negative pressure,

Preparing a bandage,

Applying the bandage over the wound to form a substantially fluid tight seal over the wound;

Delivering negative pressure through the bandage to the wound using the pump assembly according to any one of the preceding claims. 11. A bandage is applied over the wound to form a substantially fluid tight seal over the wound, and through the bandage using the pump assembly according to any one of claims 1-10. 24. A method of treating a wound using negative pressure according to claim 23, wherein delivering negative pressure to the wound is performed in an operating room. A pump assembly comprising:

A housing;

Pump motor,

Entrance and exit,

In a housing comprising at least one valve configured to control fluid flow through at least one of the inlet and the outlet, and a flow path through at least the inlet, the outlet, and the at least one valve. A pump supported by

A controller supported within or by the housing, the controller configured to control operation of the pump and the valve;

At least one switch or button supported by the housing, in communication with the controller, and accessible to the user so that the user can control one or more modes of operation of the pump, A pump assembly comprising a button;

A bandage configured to form a substantially fluid tight seal over the wound,

A conduit connectable with the bandage and the pump assembly and configured to provide a substantially or completely enclosed fluid flow path from the pump assembly to the bandage;

A negative pressure treatment kit for treating a reduced pressure wound comprising the pump assembly, the one or more batteries, the bandage, and a first packaging element for packaging the conduit,

The reduced pressure wound wherein the negative pressure treatment kit is sterilized such that at least the interior and exterior of the housing, the at least one valve, the pump, the controller, and the at least one switch or button are sterilized Negative pressure treatment kit for treatment. 26. The negative pressure treatment kit of claim 25, further comprising one or more adhesive seal strips. 27. A negative pressure therapy kit according to any one of claims 21 to 26, further comprising one or more batteries configured to supply power to at least the pump and controller. A second packaging element configured to be coupled to the first packaging element, the first packaging element comprising the pump assembly, the one or more batteries, the bandage, a conduit, 28. The negative pressure treatment kit of claim 27, and having a plurality of recesses for receiving one or more of the one or more adhesive seal strips. 29. The negative pressure treatment kit of claim 28, wherein the second packaging element is permeable to sterilizing gas and impermeable to bacteria. 26. A first packaging element supports the one or more batteries, whereby the one or more batteries are supported outside the housing during a sterilization process of the negative pressure treatment kit. 30. The negative pressure treatment kit according to any one of to 29. 31. The negative pressure treatment kit according to any one of claims 25 to 30, wherein the pump is a diaphragm pump, a rotary diaphragm pump, or a piezoelectric pump. 32. The negative pressure treatment kit according to any one of claims 25 to 31, wherein the negative pressure treatment kit is sterilized with ethylene oxide. 33. Negative pressure treatment kit according to any one of claims 25 to 32, wherein the at least one valve is configured to allow a flow of sterilization gas through the at least one valve during a sterilization process. . 34. The pump assembly of claim 25, further comprising a flow manifold, wherein the flow manifold is in fluid communication with at least one of a pressure sensor, the pump, and a conduit, a conduit connector. The negative pressure treatment kit according to 1. 35. The negative pressure therapy kit of claim 34, further comprising a one-way flow valve supported by a manifold. A one-way flow valve positioned between the pump and the bandage, wherein the one-way flow valve substantially passes the flow of gas through the one-way flow valve in a flow direction from the pump toward the bandage. 36. The negative pressure treatment kit according to any one of claims 25 to 35, configured to prevent. 37. The negative pressure therapy kit of claim 36, wherein the one-way flow valve is supported within the housing. 38. The pressure sensor of any one of claims 25 to 37, further comprising a pressure sensor configured to monitor a pressure level of a gas in a fluid flow path between the pump and the bandage or within the pump assembly. Negative pressure treatment kit. 39. A negative pressure treatment kit according to any one of claims 25 to 38, wherein one end of a conduit is connected to the bandage when packaged in a first packaging element. A conduit includes a first end and a second end, wherein the first end is connected to or connectable to the bandage, and the second end is configured to couple with the housing. 40. The negative pressure treatment kit according to any one of claims 25 to 39, further comprising a connected connector. 41. The negative pressure treatment kit according to any one of claims 25 to 40, wherein the housing is not sealed. 42. The negative pressure treatment kit according to any one of claims 25 to 41, wherein the pump assembly does not comprise a container. 43. The negative pressure treatment kit according to any one of claims 25 to 42, further comprising a released foam layer surrounding at least a portion of the pump to reduce noise and vibration generated by the pump. The bandage is

A transmission layer;

An absorbent layer for absorbing wound exudate, the absorbent layer covering the permeable layer;

A cover layer covering the absorbent layer,

An intake port for receiving the end of the conduit,

44. A negative pressure therapy kit according to any one of claims 25 to 43, comprising a liquid impermeable gas permeable filter element adapted to prevent liquid from passing through the intake port. 45. A negative pressure treatment kit according to any one of claims 25 to 44, wherein the pump assembly comprises a battery compartment supported by or formed within the housing. The negative pressure treatment kit includes a wound dressing having a silicone adhesive configured to form a low-leakage seal with the skin surrounding the wound, the pump assembly weighing the one or more batteries. 46. The negative pressure treatment kit according to any one of claims 25 to 45, wherein the weight is between 70 g and 90 g. 47. The negative pressure treatment kit according to any one of claims 25 to 46, wherein the pump assembly has a weight between 70 g and 90 g including the weight of the one or more batteries. 48. The shade of any one of claims 25 to 47, wherein the outer surface of the pump assembly defines a volume of about 3 cubic inches (49.16 cubic centimeters) to about 5 cubic inches (81.94 cubic centimeters). Pressure treatment kit. 49. The negative pressure treatment kit is configured such that the bandage must be removed from the first packaging element before a sealing strip can be removed from the first packaging element. The negative pressure treatment kit according

to any one of the above. A pump assembly comprising a pump having a flow rate of about 350 mL / min or less;
A negative pressure treatment kit for reduced-pressure wound treatment comprising a bandage comprising a cover layer and having a wound contact surface covered with a silicone adhesive. The pump assembly includes a one-way flow valve in fluid communication with the pump, the one-way flow valve configured to substantially prevent gas from flowing through the flow path in a flow direction away from the pump. The negative pressure treatment kit according to claim 50. 52. The negative pressure treatment kit of claim 50 or 51, wherein the bandage comprises a permeable layer comprising a 3D knitted or fabric material configured to remain open when negative pressure is applied to the bandage. 53. The negative pressure treatment kit according to any one of claims 50 to 52, wherein the dressing comprises an absorbent layer for absorbing wound exudate, and the absorbent layer covers a permeable layer. 54. The dressing according to any one of claims 50 to 53, wherein the bandage comprises a cover layer covering the absorbent layer, comprises an orifice, the cover layer is water vapor permeable, and the absorbent layer covers the permeable layer. Negative pressure treatment kit. The bandage includes an intake port for applying negative pressure to the bandage to apply a local negative pressure to the wound site, the intake port connecting a portion of the intake port to the pump assembly, and 55. The negative pressure treatment kit according to any one of claims 50 to 54, comprising a sealing surface for sealing the intake port to the cover layer of the bandage. 56. A negative pressure treatment kit according to any one of claims 50 to 55, wherein the dressing comprises a liquid impermeable gas permeable filter element adapted to prevent liquid from entering the connector portion. 57. The negative pressure treatment kit according to any one of claims 50 to 56, wherein the pump assembly is containerless. 58. The controller of any one of claims 50 to 57, further comprising a controller supported in or by the pump assembly housing, the controller configured to control operation of the pump. The negative pressure treatment kit according to 1 59. The negative pressure treatment kit according to any one of claims 50 to 58, further comprising a pressure sensor in communication with a flow path through the pump assembly. 60. The apparatus of claim 50-59, further comprising at least one switch or button supported by a housing of the pump assembly, wherein the at least one switch or button is accessible to a user and can be in communication with a controller. The negative pressure treatment kit according to any one of the above. 61. The negative pressure treatment kit according to any one of claims 50 to 60, further comprising a battery compartment supported by the pump assembly. 62. The negative pressure treatment kit according to any one of claims 50 to 61, wherein the pump assembly is sterilized subsequent to assembly of the pump assembly such that at least the interior and exterior of the pump assembly are sterilized. . 63. A negative pressure therapy kit according to any one of claims 50 to 62, wherein the pump assembly comprises one or more LED lights. 64. The shade according to any one of claims 50 to 63, wherein the pump assembly comprises one or more batteries and has a weight between 80 g and 90 g including the weight of the one or more batteries. Pressure treatment kit. 65. The negative pressure treatment kit according to any one of claims 50 to 64, wherein the outer surface of the pump assembly defines a volume between 60 cubic centimeters and 80 cubic centimeters. A containerless pump assembly for the treatment of vacuum wounds.
A housing;
A pump assembly comprising a pump supported in or by the housing, the pump comprising:
A motor,
An inlet and an outlet,
A first valve configured to control the flow of fluid through the inlet,
A container-type pump assembly comprising a second valve configured to control the flow of fluid through the outlet;
The pump assembly is containerless;
A container pump assembly, wherein the first and second valves each have a leak rate between about 5 L / min and about 10 L / min at nominal operating pressure. The pump assembly includes a one-way flow valve in fluid communication with the pump, the one-way flow valve configured to substantially prevent gas from flowing through the flow path in a flow direction away from the pump. 68. A pump assembly according to claim 66. 68. A pump assembly according to claim 66 or 67, further comprising a controller supported in or by the housing and configured to control operation of the pump. 69. A pump assembly according to any one of claims 66 to 68, further comprising a pressure sensor in communication with a flow path through the pump assembly. 70. Any one of claims 66 to 69, further comprising at least one switch or button supported by the housing, wherein the at least one switch or button is accessible to a user and can be in communication with a controller. The pump assembly according to item. 71. A pump assembly according to any one of claims 66 to 70, further comprising a battery compartment supported by or formed within the housing. 72. The sterilization following assembly of the pump assembly such that at least the interior and exterior of the housing, the flow path, the one or more valves, and the pump are sterilized. A pump assembly according to any one of the preceding claims. 73. A pump assembly according to any one of claims 66 to 72, further comprising one or more LED lights supported by the housing. 74. A pump assembly according to any one of claims 66 to 73, wherein the pump assembly comprises one or more batteries and weighs 80g and 90g including the weight of the one or more batteries. 75. A pump assembly according to any one of claims 66 to 74, wherein the outer surface of the pump assembly defines a volume between 60 cubic centimeters and 80 cubic centimeters. A sterilization pump kit,
76. The pump assembly according to any one of claims 66 to 75;
Bandages,
A conduit connectable with the bandage and the pump assembly and configured to provide a reduced pressure fluid path to the bandage;
One or more batteries,
A first packaging element and a second packaging element configured to be removably coupled to the first packaging element, wherein at least one of the first and second packaging elements Sterilization having a recess for receiving the pump assembly, the bandage, and the conduit connectable to the bandage and the pump assembly and configured to provide a reduced pressure fluid path to the bandage. In the pump kit,
The sterilization pump kit includes the pump assembly, the bandage, the conduit, and the one or more batteries supported within at least one of the first packaging element and the second packaging element. Sterile pump kit, which is sterilized later. Before the pump assembly, the bandage, the conduit, and the one or more batteries are sterilized, the pump assembly, the bandage, the conduit, and the one or more batteries are in the first package. 77. The sterilization pump kit of claim 76, supported within at least one of a packaging element and the second packaging element. 78. The sterilization pump kit of claim 76 or 77, further comprising one or more adhesive seal strips. 79. A sterilization pump kit according to any one of claims 76 to 78, wherein the one or more batteries are supported on an outer surface of the housing. 80. The sterilization pump kit according to any one of claims 76 to 79, wherein the sterilization pump kit is sterilized with ethylene oxide. The bandage is
A transmission layer;
An absorbent layer for absorbing wound exudate, wherein the absorbent layer covers the permeable layer,
The sterilization pump kit according to any one of claims 76 to 80, further comprising a cover layer that covers the absorbent layer. 82. A sterile pump kit according to any one of claims 76 to 81, wherein the bandage comprises an inhalation port for applying a negative pressure to the bandage to apply a local negative pressure to the wound site. 84. The sterilization pump kit of claim 82, wherein the intake port comprises a connector portion for connecting the intake port to the pump assembly, and a sealing surface for sealing the intake port to a cover layer of the bandage. 84. A sterilization pump kit according to any one of claims 76 to 83, wherein the bandage comprises a liquid impermeable gas permeable filter element adapted to prevent liquid from entering the connector portion. 85. A sterilization pump kit according to any one of claims 76 to 84, wherein the first packaging element comprises PETG. A method for initiating wound treatment in an operating room comprising:
Applying a sterile bandage over the wound to create a substantially fluid tight seal over the wound,
Coupling a sterilization pump assembly to the bandage via a sterilization conduit and reducing the pressure level between the bandage and the wound in the operating room by operating the sterilizing pump assembly in the operating room. Method. 87. The method of claim 86, further comprising applying one or more sealing strips on an outer peripheral edge of at least one of the bandages to improve the seal between the bandage and the skin surrounding the wound. The method described. 88. The method of claim 86 or 87, further comprising removing one or more batteries from the first packaging element and attaching the one or more batteries to the sterilization pump assembly.

Description translated from Japanese

[Incorporation by reference]
This application is filed on April 21, 2011, U.S. Patent Application No. 13 / 092,042 (named WOUND DRESSING AND METHOD OF USE), filed on May 21, 2008 (named

ANTIMICROBIAL METAL COMPLEXES).] US Patent Application No. 11 / 922,894, filed July 26, 2011 (METHODS AND APPARATUSES FOR DETECTING LEAKS AND CONTROLLING PUMP OPERATION IN A NEGATIVE PRESSURE WORLD 61) No. 950, filed April 21, 2011 (named WOUND DRESSING) PCT Patent Application No. PCT / GB 11/000622, PCT Patent Application No. PCT / GB 11/000621 (named WOUND PROTECTION) filed on April 21, 2011 (WOUND DRESSING) filed April 21, 2011 PCT Patent Application No. PCT / GB 11/000625, PCT Patent Application No. PCT / GB 11/000626, filed April 21, 2011, filed Apr. 21, 2011 (filed MULTIPORT DRESSING) PCT Patent Application No. PCT / GB 11/000628 (named SUCTION PORT), PCT Patent Application No. PCT / GB 11/05 filed September 16, 2011 (named PRESSURE CONTROL APPARATUS) The No. 745 incorporated by reference. Each and all of the above patent applications are hereby incorporated by reference in their entirety and form part of the present disclosure. Further, copending patent application No. 13 / XXX, XXX (Attorney Docket No. 5), filed on November 2, 2011, entitled "SYSTEMS AND METHODS FOR CONTROLLING OPERATION OF A REDUCED PRESURE THERAPY SYSTEM". And the copending PCT patent application No. PCT / US11 / XXX, XXX, XXX, entitled "SYSTEMS AND METHODS FOR CONTROLLING OPERATION OF A REDUCED PRESURE THERAPY SYSTEM", filed on November 2, 2011.) Is incorporated herein by reference in its entirety as if explicitly set forth herein.

Embodiments disclosed herein relate to methods and devices for bandaging and treating wounds using local negative pressure (TNP) therapy. For example, but without limitation, some embodiments disclosed herein relate to treating a wound using reduced pressure provided from a pump kit. Although not required, some embodiments of the pump kit can be sterile. As another non-limiting example, some embodiments disclosed herein relate to an apparatus and method for controlling the operation of a TNP system.

Many different types of wound dressings are known to help the human or animal healing process. These different types of wound dressings include many different types of materials and layers, such as gauze, pads, foam pads, or multilayer wound dressings. Local negative pressure ("TNP") therapy, sometimes referred to as vacuum assisted closure therapy, negative pressure wound therapy, or vacuum wound therapy, is widely recognized as a beneficial mechanism for improving wound healing rates. Yes. Such therapy is applicable to a wide range of wounds such as incisional wounds, open wounds, and abdominal wounds.

TNP therapy helps to close and heal wounds by reducing tissue edema, promoting blood flow, stimulating granulation tissue formation, removing excess exudates, and reducing bacterial load and thus wounds. Can reduce infection. Furthermore, TNP therapy can result in less outside disturbance of the wound and promotes faster healing.

US Pat. No. 7559034 US Patent Application Publication No. 2011/135765 US Patent Application No. 13/092042 UK patent application No. 1015666.0 UK Patent Application No. 1006986.2 UK Patent Application No. 1006983.9 UK Patent Application No. 1006985.4 UK Patent Application No. 1006988.8 UK Patent Application No. 1008347.5 Specification US Patent Application No. 11/922894 US Pat. No. 7,524,315 US Patent No. 7,708,724 US Pat. No. 7,909,805 US Patent Application Publication No. 2005/0261642 US Patent Application Publication No. 2007/0167926 US Patent Application Publication No. 2009/0012483 US Patent Application Publication No. 2009/0254054 US Patent Application Publication No. 2010/0160879 US Patent Application Publication No. 2010/0160880 US Patent Application Publication No. 2010/0174251 US Patent Application Publication No. 2010/0274207 US Patent Application Publication No. 2010/0298793 US Patent Application Publication No. 2011/0009838 US Patent Application Publication No. 2011/0028918 US Patent Application Publication No. 2011/0054421 US Patent Application Publication No. 2011/0054423 US patent application Ser. No. 12/941390 US Patent Application No. 29 / 389,782 U.S. Patent Application No. 29 / 389,783

Some embodiments disclosed herein relate to a reduced pressure wound therapy pump assembly that includes a housing, a pump within or supported by the housing, a flow path through the pump assembly, A one-way flow valve in fluid communication with the pump and supported by the housing. Some embodiments of the one-way flow valve can be configured to substantially prevent gas from flowing through the flow path in the flow direction away from the pump. The pump is supported by the motor, inlet and outlet, a first valve configured to control the flow of fluid through the inlet, and is supported by the pump and controls the flow of fluid through the outlet. And a second valve configured as described above.

Some embodiments disclosed herein relate to a pump assembly for reduced pressure wound therapy, wherein the pump assembly is in fluid communication with a housing, a pump within or supported by the housing, and a pump. A directional flow valve and a flow path through the pump assembly. The one-way flow valve can be configured to substantially prevent gas from flowing through the flow path in the flow direction away from the pump. The pump can include a motor, an inlet, and an outlet. Although not required in any of the pump embodiments disclosed herein, the pump has a first valve configured to control the flow of fluid through the inlet and the flow of fluid through the outlet. And a second valve configured to control. Some pump embodiments disclosed herein can use an orifice or other mechanism or component to control the flow or flow rate of fluid through the pump.

Some embodiments disclosed herein relate to a negative pressure treatment kit for reduced pressure wound therapy, the negative pressure treatment kit being supported within a housing, a pump supported within the housing, and within or by the housing. And a pump assembly comprising a controller and at least one switch or button supported by the housing. As used throughout this specification, the phrase "some embodiments" or "in some embodiments" is described herein, exemplified, or incorporated by reference. Or is meant to refer to any embodiment disclosed otherwise. At least one switch or button can be in communication with the controller and can be accessible to the user so that the user can control one or more modes of operation of the pump. In some embodiments, although not required, the negative pressure treatment kit is connectable with a bandage configured to form a substantially fluid tight seal over the wound, and the bandage and pump assembly. A conduit configured to provide a substantially or completely enclosed fluid flow path from the pump assembly to the bandage, and a first assembly for packaging the pump assembly, the one or more batteries, the bandage, and the conduit. 1 packaging element. In some embodiments, the controller can be configured to control the operation of the pump and valve. Some embodiments of negative pressure treatment kits can be configured such that the negative pressure treatment kit is sterilized. The negative pressure treatment kit can be sterilized such that at least the interior and exterior of the housing, at least one valve, pump, controller, and at least one switch or button are sterilized. In some embodiments, the pump includes a pump motor, an inlet and an outlet, at least one valve configured to control the flow of fluid through the inlet and / or the outlet, at least the inlet, the outlet, and And a flow path through the at least one valve.

Some embodiments disclosed herein relate to reduced pressure treatment of wounds using reduced pressure pumps. The pump embodiments disclosed herein do not require sterilization. However, by sterilizing the vacuum pump before use and providing the pump and / or bandage or pump kit components in a sterile state, the operating room (also referred to as the operating room) or other devices where sterility of the device is required It may be possible to use the pump at any location. Some exemplary and non-limiting embodiments are directed to a sterilization pump kit comprising a sterilization pump, a sterilization bandage, and a sterilization conduit connectable to the bandage and pump, which can be used in an operating room. To do.

Some embodiments disclosed herein relate to a negative pressure treatment kit for reduced pressure wound treatment, the negative pressure treatment kit comprising a pump having a flow rate of about 350 mL / min or less and a bandage comprising a cover layer. Prepare. The bandage can have a wound contact surface covered with a silicone adhesive.

Some embodiments disclosed herein relate to a containerless pump for treating a reduced pressure wound, the containerless pump being in communication with a housing, a flow path through the pump, and a flow path. One or more valves and a containerless pump supported in or by the housing. Some embodiments disclosed herein relate to a containerless pump assembly for reduced pressure wound therapy, the containerless pump assembly comprising a housing and a pump supported in or by the housing. The pump is supported by the motor, inlet and outlet, a first valve configured to control the flow of fluid through the inlet, and is supported by the pump and controls the flow of fluid through the outlet. And a second valve configured as described above. The pump or pump assembly can be containerless. Further, although not required for all embodiments disclosed herein, the first and second valves are each at a nominal operating pressure and / or during a nominal sterilization pressure from about 0.1 mL / min to about A leak rate of 10 mL / min, or at nominal operating pressure, between 0.1 mL / min and below to 5 mL / min or above, or between 1 mL

/ min and below to 3 mL / min or above, or any of the above ranges It can have a leak rate between the two values. In some embodiments, the leak rate can be about 0.4 mL / min to 0.7 mL / min at nominal operating pressure and / or during nominal sterilization pressure.

Some embodiments of the pump assembly may include a piezoelectric pump, such as, but not limited to, the piezoelectric pump disclosed in US Pat. Some piezoelectric pumps can have an orifice to perform the valve function so that when the pump is stopped, the flow rate through the pump can be as high as 200 mL / min. Thus, in some embodiments, the first and second valves (which can be orifices) are each about 200 mL when the pump rate can be about 300 mL / min or 320 mL / min or other high rate. Can have a leak rate of less than / minute.

Some embodiments disclosed herein relate to a sterilization pump kit, which can be coupled to any of the pump embodiments disclosed herein, a bandage, a bandage and a sterilization pump. A conduit configured to provide a reduced pressure fluid path to the bandage, the one or more batteries, and the first packaging element and the first packaging element to be removably coupled. A configured second packaging element. In some embodiments, at least one of the first and second packaging elements is connectable to a sterilization pump, a bandage, and the bandage and sterilization pump so as to provide a reduced pressure fluid path to the bandage. And a recess for receiving a conduit configured in the housing. The sterilization pump kit can be sterilized after the pump, bandage, conduit, and one or more batteries are supported within at least one of the first packaging element and the second packaging element.

Some embodiments disclosed herein relate to a method for initiating treatment of a wound in an operating room, the method comprising applying a sterile bandage over the wound and substantially liquid-tight over the wound. A sterilization pump connected to the bandage via a sterilization conduit, and reducing the pressure level between the bandage and the wound in the operating room by operating the pump in the operating room. .

Some embodiments disclosed herein relate to an apparatus and method for controlling the operation of a negative pressure wound treatment system. In particular, but not exclusively, embodiments disclosed herein relate to negative pressure therapy devices and bandages, and methods and algorithms for operating such negative pressure therapy systems. In some embodiments, although not required, the device can include a bandage disposed on the wound and configured to create a substantially fluid-impermeable seal over the wound. . The device can comprise a negative pressure source configured to be coupled to the bandage. The apparatus can further comprise a controller configured to operate the negative pressure source, monitor the duty cycle of the negative pressure source, and determine whether the duty cycle exceeds a duty cycle threshold. In some embodiments, the controller monitors multiple duty cycles of the negative pressure source over a plurality of consecutive equal durations, and whether one of the plurality of duty cycles exceeds a duty cycle threshold. It can be configured to determine whether or not. The duty cycle can reflect the amount of time that the negative pressure source is active for a predetermined period of time or for a duration of a plurality of consecutive equal durations.

In some embodiments, the controller can be configured to determine whether the number of duty cycles exceeds a duty cycle threshold and whether the number exceeds an overload threshold. In some embodiments, the controller determines whether a set of duty cycles out of a plurality of duty cycles exceeds a duty cycle threshold and whether the number of duty cycles in the set exceeds an overload threshold. Can be configured to determine. The controller can be configured to determine whether the number of duty cycles that exceed the duty cycle threshold is continuous. In some embodiments, the overload threshold can include 30 duty cycles, the duration or duration can include 1 minute, and / or the duty cycle threshold can include 9%. In some embodiments, the controller can be configured to continuously monitor the duty cycle or multiple duty cycles.

Some embodiments of the apparatus comprise a switch configured to pause the negative pressure source for a predetermined period of time, and the controller is configured to restart the negative pressure source when that period of time has elapsed, be able to. The period can be variable. In some embodiments, the device can be enclosed in a housing that includes an outer surface, and the switch can include a button disposed on the outer surface of the housing.

Some embodiments of the apparatus comprise a controller configured to provide an indication of operating conditions. The operating condition can include a determination that the duty cycle exceeds a duty cycle threshold, and the indication can include deactivating the negative pressure source to indicate a leak in the seal. In some embodiments, the operating state includes whether or not the negative pressure source is paused, and the controller is configured to provide a first indication when the negative pressure source is active and the negative pressure source is paused. And a second instruction when being provided, in which case the second instruction is different from the first instruction.

In some embodiments, the controller can be configured to operate a negative pressure source to attempt to generate a desired negative pressure level under the bandage, and the first time interval has elapsed. If the pressure level under the bandage does not reach the desired negative pressure level, the controller can deactivate the negative pressure source for the second time interval. When the second time interval has elapsed, the controller can operate the negative pressure source to attempt to generate the desired negative pressure level under the bandage. The controller can be configured to change the second time interval based on the number of times the pressure level under the bandage has not reached the desired negative pressure level. For example, the controller can be configured to double the second time interval provided that the resulting value does not exceed the second interval threshold. The apparatus can comprise a sensor configured to sense pressure under the bandage and communicate the sensed pressure to a controller.

In some embodiments, the controller deactivates the negative pressure source when the pressure level under the bandage reaches the desired negative pressure level, and when the pressure level under the bandage exceeds the negative pressure threshold, The negative pressure source can be configured to operate, wherein the desired negative pressure level corresponds to a pressure that is more negative than the negative pressure threshold.

In some embodiments, the negative pressure source positions the bandage over the wound, creates a substantially fluid impermeable seal over the wound, delivers negative pressure from the negative pressure source to the bandage, Operation can be performed by monitoring the duty cycle of the pressure source and providing an indication if it is determined that the duty cycle exceeds the duty cycle threshold. The duty cycle can reflect the amount of time that the negative pressure source is active during a predetermined period, such as once per minute.

Some embodiments of the device may be configured to monitor the total elapsed time since the first operation and disable the operation of the negative pressure source when the total elapsed time reaches a life threshold. The lifetime threshold can include, for example, 7 days.

In some embodiments, a device for applying negative pressure to a wound is disposed on the wound and configured to create a substantially fluid impermeable seal over the wound, A negative pressure source configured to be coupled to and configured to operate the negative pressure source, monitor the duty cycle of the negative pressure source, and provide an indication if the duty cycle exceeds the duty cycle threshold Controller.

In some embodiments, the device is configured to be disposed on the wound and configured to couple to the bandage configured to create a substantially fluid impermeable seal over the wound. A pump, a switch configured to temporarily stop the pump for a predetermined period, and a controller configured to restart the pump when the period elapses. The period can be variable. Some embodiments of the apparatus include a small diaphragm pump operated by a motor or a small diaphragm pump operated by a piezoelectric transducer. In some embodiments, the pump can include a small piston pump and a small diaphragm pump.

Some embodiments disclose a method of operating a negative pressure source (eg, a negative pressure pump), the method positioning a bandage over the wound and a substantially fluid impermeable seal over the wound, Generating negative pressure from the pump to the bandage, pausing the pump for a predetermined period of time, and restarting the pump when that period has elapsed. The period can be variable.

In some embodiments, the negative pressure pump positions the bandage over the wound to create a substantially fluid impermeable seal over the wound and uses the negative pressure pump to aspirate fluid from the wound. It can be operated by measuring the activity level of the pump, comparing the activity level of the pump with a threshold, and providing an indication if the activity level exceeds the threshold. Activity level measurements include determining the pump duty cycle, determining the flow rate of fluid drawn from the wound (eg, by using a flow meter), measuring the rate of pressure change under the bandage using a pressure sensor, etc. , Or a combination thereof.

Some embodiments disclose a method of operating a negative pressure pump, the method positioning a bandage over a wound to create a substantially fluid impermeable seal over the wound; Delivering a negative pressure from the pump to the bandage to bring the pressure below the first negative pressure set value, and when the negative pressure level under the bandage becomes higher than the second negative pressure set value . The step of operating the pump to monitor the pressure under the bandage close to the first negative pressure set value, the step of monitoring the amount of time the pump is operating, and the amount of time exceeds a predetermined amount of time Providing instructions. The method can further include determining an amount of time that the pump has been operating for a predetermined period of time, and providing an indication if the amount of time exceeds 9% of the period. In some embodiments, providing the instructions further includes determining an amount of time that the pump has been operating for a predetermined period of time. In some embodiments, providing the indication further comprises activating an alarm.

In some embodiments, the device operates a negative pressure source to increase the pressure under the negative pressure wound dressing to a value between the first negative pressure setting and the second negative pressure setting. Or a value that is substantially equal to the value of the second negative pressure set value, such as a value close to a desired negative pressure value. The pressure level under the bandage can be measured. When the pressure under the bandage decreases above a threshold (eg, decreases to the value of the first negative pressure setpoint), the device operates the negative pressure source to reduce the pressure under the bandage to the second It can be configured to approach a desired negative pressure level (for example, the value of the second negative pressure set value). The amount of time that the negative pressure source has been operating, for example, can be monitored. If the negative pressure source has been operating for a predetermined amount of time without establishing a second desired negative pressure level under the bandage (eg, the value of the second negative pressure setting), The operation of the pressure source can be paused or interrupted.

Some embodiments disclose a method of operating a negative pressure source, the method comprising positioning a bandage over the wound to create a substantially fluid impermeable seal over the wound; Delivering negative pressure from the pressure source to the bandage. Delivering negative pressure from the negative pressure source to the bandage, operating the negative pressure source and updating the first motion count to attempt to generate a desired negative pressure level under the bandage; If the negative pressure under the bandage has not reached the desired negative pressure level when the first time interval has elapsed, the first action count is less than the first retry threshold, Deactivating the negative pressure source for two time intervals, and deactivating the negative pressure source for a third time interval if the first operation count is greater than or equal to the first retry threshold, Activating a negative pressure source to reset the first operational count and attempt to generate a desired negative pressure level under the bandage when the third time interval has elapsed, When the time interval has passed, the desired under the bandage Activating the negative pressure source to attempt to generate a pressure level and updating the first operational count; and if the negative pressure under the bandage has reached the desired negative pressure level, the negative pressure source And monitoring the negative pressure under the bandage and operating the negative pressure source when the negative pressure under the bandage exceeds the negative pressure threshold, An update count, wherein the desired negative pressure level corresponds to a pressure that is more negative than the negative pressure threshold, and the negative pressure under the bandage before the fourth time interval elapses. When the pressure reaches the desired negative pressure level, the negative pressure source is deactivated, the negative pressure under the bandage is monitored, the second operation count is reset, and a fourth time interval has elapsed. When the negative pressure under the bandage is the desired negative pressure level If not, deactivating the negative pressure source for a second time interval, provided that the second motion count is less than the second retry threshold; If the retry threshold is greater than 2, the negative pressure source is deactivated during the third time interval, the second operation count is reset, and when the third time interval elapses. Operating the negative pressure source to update the first operation count, continuously monitoring the negative pressure source duty cycle, and a duty cycle threshold. Tracking the number of duty cycles exceeding, and deactivating the negative pressure source for the duration of the third time interval when the number of duty cycles exceeding the duty cycle threshold exceeds the overload threshold including the step of.

Embodiments of the present invention will now be described by way of example only with reference to the accompanying drawings.

1 illustrates one embodiment of a reduced pressure wound therapy apparatus that includes a pump, a bandage, and a conduit. FIG. It is a figure which shows embodiment of the pump shown by FIG. It is a figure which shows embodiment of the pump shown by FIG. It is a figure which shows embodiment of the pump shown by FIG. It is a figure which shows embodiment of the pump shown by FIG. It is a figure which shows embodiment of the pump shown by FIG. It is a figure which shows embodiment of the pump shown by FIG. FIG. 4 shows an embodiment of a wound dressing kit comprising a dressing, pump, conduit, two batteries, and one or more seal strips supported in a first packaging element. 3B is a bottom isometric view illustrating the embodiment of the wound dressing kit of FIG. 3A. FIG. 3B is an exploded view illustrating the embodiment of the wound dressing kit of FIG. 3A. FIG. FIG. 2 is a first exploded view showing an embodiment of the pump of FIG. 1. FIG. 3 is a second exploded view showing the embodiment of the pump of FIG. 1. It is the 1st figure showing the 1st housing member. It is a 2nd figure which shows a 1st housing member. It is a 1st figure which shows the 2nd housing member. It is the 2nd figure showing the 2nd housing member. FIG. 2 illustrates the use of one embodiment of a TNP wound treatment system being used to treat a patient's wound site. FIG. 2 illustrates the use of one embodiment of a TNP wound treatment system being used to treat a patient's wound site. FIG. 2 illustrates the use of one embodiment of a TNP wound treatment system being used to treat a patient's wound site. FIG. 2 illustrates the use of one embodiment of a TNP wound treatment system being used to treat a patient's wound site. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 8B is a bottom isometric view of the embodiment of FIG. 8A. FIG. 8B is a top view of the embodiment of FIG. 8A. FIG. 8B is a bottom view of the embodiment of FIG. 8A. FIG. 8B is a front view of the embodiment of FIG. 8A. FIG. 8B is a rear view of the embodiment of FIG. 8A. FIG. 8B is a first side view of the embodiment of FIG. 8A. FIG. 8B is a second side view of the embodiment of FIG. 8A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 9B is a bottom isometric view of the embodiment of FIG. 9A. FIG. 9B is a top view of the embodiment of FIG. 9A. FIG. 9B is a bottom view of the embodiment of FIG. 9A. FIG. 9B is a front view of the embodiment of FIG. 9A. FIG. 9B is a rear view of the embodiment of FIG. 9A. FIG. 9B is a first side view of the embodiment of FIG. 9A. FIG. 9B is a second side view of the embodiment of FIG. 9A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 10B is a bottom isometric view of the embodiment of FIG. 10A. FIG. 10B is a top view of the embodiment of FIG. 10A. FIG. 10B is a bottom view of the embodiment of FIG. 10A. FIG. 10B is a front view of the embodiment of FIG. 10A. FIG. 10B is a rear view of the embodiment of FIG. 10A. FIG. 10B is a first side view of the embodiment of FIG. 10A. FIG. 10B is a second side view of the embodiment of FIG. 10A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 11B is a bottom isometric view of the embodiment of FIG. 11A. FIG. 11B is a top view of the embodiment of FIG. 11A. FIG. 11B is a bottom view of the embodiment of FIG. 11A. FIG. 11B is a front view of the embodiment of FIG. 11A. FIG. 11B is a rear view of the embodiment of FIG. 11A. FIG. 11B is a first side view of the embodiment of FIG. 11A. FIG. 11B is a second side view of the embodiment of FIG. 11A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 12B is a bottom isometric view of the embodiment of FIG. 12A. FIG. 12B is a top view of the embodiment of FIG. 12A. FIG. 12B is a bottom view of the embodiment of FIG. 12A. FIG. 12B is a front view of the embodiment of FIG. 12A. FIG. 12B is a rear view of the embodiment of FIG. 12A. FIG. 12B is a first side view of the embodiment of FIG. 12A. FIG. 12B is a second side view of the embodiment of FIG. 12A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size

of the wound dressing device. FIG. FIG. 13B is a bottom isometric view of the embodiment of FIG. 13A. FIG. 13B is a top view of the embodiment of FIG. 13A. FIG. 13B is a bottom view of the embodiment of FIG. 13A. FIG. 13B is a front view of the embodiment of FIG. 13A. FIG. 13B is a rear view of the embodiment of FIG. 13A. FIG. 13B is a first side view of the embodiment of FIG. 13A. FIG. 13B is a second side view of the embodiment of FIG. 13A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 14B is a bottom isometric view of the embodiment of FIG. 14A. FIG. 14B is a top view of the embodiment of FIG. 14A. FIG. 14B is a bottom view of the embodiment of FIG. 14A. FIG. 14B is a front view of the embodiment of FIG. 14A. FIG. 14B is a rear view of the embodiment of FIG. 14A. FIG. 14B is a first side view of the embodiment of FIG. 14A. FIG. 14B is a second side view of the embodiment of FIG. 14A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 14D is a bottom isometric view of the embodiment of FIG. 14I. FIG. 14D is a top view of the embodiment of FIG. 14I. FIG. 14D is a bottom view of the embodiment of FIG. 14I. FIG. 14D is a front view of the embodiment of FIG. 14I. FIG. 14D is a rear view of the embodiment of FIG. 14I. FIG. 14D is a first side view of the embodiment of FIG. 14I. FIG. 14D is a second side view of the embodiment of FIG. 14I. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 15B is a bottom isometric view of the embodiment of FIG. 15A. FIG. 15B is a top view of the embodiment of FIG. 15A. FIG. 15B is a bottom view of the embodiment of FIG. 15A. FIG. 15B is a front view of the embodiment of FIG. 15A. FIG. 15B is a rear view of the embodiment of FIG. 15A. FIG. 15B is a first side view of the embodiment of FIG. 15A. FIG. 15B is a second side view of the embodiment of FIG. 15A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 16B is a bottom isometric view of the embodiment of FIG. 16A. FIG. 16B is a top view of the embodiment of FIG. 16A. FIG. 16B is a bottom view of the embodiment of FIG. 16A. FIG. 16B is a front view of the embodiment of FIG. 16A. FIG. 16B is a rear view of the embodiment of FIG. 16A. FIG. 16B is a first side view of the embodiment of FIG. 16A. FIG. 16B is a second side view of the embodiment of FIG. 16A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 17B is a bottom isometric view of the embodiment of FIG. 17A. FIG. 17B is a top view of the embodiment of FIG. 17A. FIG. 17B is a bottom view of the embodiment of FIG. 17A. FIG. 17B is a front view of the embodiment of FIG. 17A. FIG. 17B is a rear view of the embodiment of FIG. 17A. FIG. 17B is a first side view of the embodiment of FIG. 17A. FIG. 17B is a second side view of the embodiment of FIG. 17A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 17D is a bottom isometric view of the embodiment of FIG. 17I. FIG. 17D is a top view of the embodiment of FIG. 17I. FIG. 17D is a bottom view of the embodiment of FIG. 17I. FIG. 17D is a front view of the embodiment of FIG. 17I. FIG. 17D is a rear view of the embodiment of FIG. 17I. FIG. 17D is a first side view of the embodiment of FIG. 17I. FIG. 17D is a second side view of the embodiment of FIG. 17I. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 18B is a bottom isometric view of the embodiment of FIG. 18A. FIG. 18B is a top view of the embodiment of FIG. 18A. FIG. 18B is a bottom view of the embodiment of FIG. 18A. FIG. 18B is a front view of the embodiment of FIG. 18A. FIG. 18B is a rear view of the embodiment of FIG. 18A. FIG. 18B is a first side view of the embodiment of FIG. 18A. FIG. 18B is a second side view of the embodiment of FIG. 18A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 19 is a bottom isometric view of the embodiment of FIG. 18I. FIG. 191 is a top view of the embodiment of FIG. 18I. FIG. 191 is a bottom view of the embodiment of FIG. 18I. FIG. 191 is a front view of the embodiment of FIG. 18I. FIG. 218 is a rear view of the embodiment of FIG. 18I. FIG. 191 is a first side view of the embodiment of FIG. 18I. FIG. 218 is a second side view of the embodiment of FIG. 18I. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 19B is a bottom isometric view of the embodiment of FIG. 19A. FIG. 19B is a top view of the embodiment of FIG. 19A. FIG. 19B is a bottom view of the embodiment of FIG. 19A. FIG. 19B is a front view of the embodiment of FIG. 19A. FIG. 19B is a rear view of the embodiment of FIG. 19A. FIG. 19B is a first side view of the embodiment of FIG. 19A. FIG. 19B is a second side view of the embodiment of FIG. 19A. 1 is a top isometric view of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including one size of the wound dressing device. FIG. FIG. 20B is a bottom isometric view of the embodiment of FIG. 20A. FIG. 20B is a top view of the embodiment of FIG. 20A. FIG. 20B is a bottom view of the embodiment of FIG. 20A. FIG. 20B is a front view of the embodiment of FIG. 20A. FIG. 20B is a rear view of the embodiment of FIG. 20A. FIG. 20B is a first side view of the embodiment of FIG. 20A. FIG. 20B is a second side view of the embodiment of FIG. 20A. FIG. 2 illustrates a pump assembly according to some embodiments. FIG. 2 is a cross-sectional view showing the interior of a pump assembly according to some embodiments. 1 is a system schematic diagram of a pump assembly according to some embodiments. FIG. FIG. 2 is a schematic diagram of electrical components of a pump assembly according to some embodiments. FIG. 5 is a high-level state diagram illustrating operation of a pump assembly according to some embodiments. FIG. 5 is an operational state diagram illustrating operation of a pump assembly according to some embodiments. FIG. 5 is another state diagram illustrating operation of a pump assembly according to some embodiments. 5 is a graph illustrating determination of duty cycle for a pump assembly according to some embodiments. FIG. 6 illustrates operation of the pump assembly in the presence of a small amount of leakage according to some embodiments. FIG. 6 illustrates operation of the pump assembly in the presence of a large amount of leakage in accordance with some embodiments. FIG. 5 illustrates operation of the pump assembly in the presence of a very large amount of leakage in accordance with some embodiments. FIG. 6 illustrates operation of the pump assembly in the presence of a very large amount of leakage in accordance with some embodiments.

In the drawings, like reference numerals refer to like parts.

Embodiments disclosed herein relate to an apparatus and method for treating a wound using reduced pressure. As used herein, a reduced pressure or negative pressure level, such as -X mmHg, is less than standard atmospheric pressure corresponding to 760 mmHg (or 1 atmosphere, 29.93 inches of mercury, 101.325 kPa, 14.696 psi, etc.). Represents the pressure level. Thus, the negative pressure value of -X mmHg reflects an absolute pressure that is X mmHg lower than 760 mmHg, or in other words, an absolute pressure of (760-X) mmHg. In addition, a negative pressure "lower" or "smaller" than X mmHg corresponds to a pressure closer to atmospheric pressure (eg, -40 mmHg is lower than -60 mmHg). A negative pressure "higher" or "larger" than -X mmHg corresponds to a pressure farther from atmospheric pressure (eg, -80 mmHg is higher than -60 mmHg).

Some embodiments comprise a pump and / or pump and bandage kit. Some embodiments are directed to pumps and / or pump and bandage kits that have been sterilized prior to delivery to a hospital, operating room, or operating room, or to medical personnel using such devices. Thus, the sterile pump and / or sterile pump / bandage kit can be used immediately after a surgical or surgical procedure. One advantage of this is that the surgeon can release the patient from the operating room, knowing that the vacuum pump is in operation and that vacuum therapy has begun at the earliest possible time. is there. A further advantage of applying a bandage kit immediately after a surgical procedure or other procedure is to reduce the chance of infection that would otherwise be required in the ward by eliminating subsequent bandage changes. This is a possible point. In other words, for such patients where a bandage (not a pump) is applied in the operating room, after which circumstances such as leakage or other problems with the bandage are found, the bandage is removed after the patient is released from the operating room. If the patient's wound needs to be repositioned, replaced, or removed to be otherwise shaped, the patient's wound will be replaced when the bandage is repositioned, replaced, or otherwise shaped outside the operating room. May be exposed to the risk of infection. However, with the embodiments disclosed herein, if the pump is used and tested while the patient is in the operating room, the bandage needs to be removed, repositioned, or otherwise shaped Any problems with a bandage that can be handled can be handled in a sterile operating room environment, thereby greatly reducing or eliminating the risk of exposure to pathogens, bacteria, or other contaminants. In addition, once a conventional pump has been accepted by the hospital, it is generally impossible for the hospital to sterilize it, so the hospital may take steps to place the pump in a sterilization bag. This approach risks putting the sterilization field of the operating room at risk, especially once the device is turned on, pathogens, bacteria, or other contaminants that may be inside the pump are released by the operation of the pump.

In some embodiments, suitable for gas sterilization, with mechanisms, components, and other characteristics that make the pump suitable for complete exposure to and penetration of sterilization gas across the pump components. Can be configured to be. For example, without limitation, one or more pump valves are selected or configured to allow a flow of suff-cient sterilization gas to allow the entire fluid path in the pump to be exposed to sterilization gas. Has been. As described in more detail below, in some embodiments, the pump is pumped by reducing leakage through a flow path in the pump assembly, such as, but not limited to, a strategically positioned one-way flow valve. It can have other components that complement other valves in the pump that can improve the efficiency of the pump.

In addition, if provided, the sterilization pump / bandage kit can also be designed and configured to be suitable for gas sterilization. As described below, the sterilization pump / bandage kit includes all components comprising the sterilization pump / bandage kit, including the pump assembly, all packaged together in at least a first packaging element prior to sterilization. Both can be configured to be sterilizable. Further, as described below, the components comprising the sterile pump / bandage kit can be arranged in the packaging so that at least some of the components can be removed in a predefined order, so that the surgeon Or it is easier for the health care worker to assemble and apply the bandage to the patient

Initiating wound treatment in the operating room includes, but is not limited to, providing a substantially sealed barrier over the wound while the wound is in a sterile and environmental condition, thereby allowing bacteria or other There are a number of benefits, including inhibiting or preventing contaminants from entering the wound. In addition, it is also advantageous for wound healing to start decompression treatment at the earliest possible stage.

In addition, those disclosed in Patent Document 3, Patent Document 4, Patent Document 5, Patent Document 6, Patent Document 7, Patent Document 8, and Patent Document 9 are disclosed in this specification or by reference. The incorporated embodiment comprises an improved wound dressing component. All embodiments, components, features, and other details of such disclosure are incorporated herein by reference as part of this disclosure, and the configurations of the embodiments disclosed herein. It can be used in place of or in combination with any of the elements, mechanisms, and other details. For example, in some embodiments, the wound dressing is configured to act as a cushioning material that helps prevent compressive or shear forces applied to the wound dressing, eg, by patient movement, from damaging the healing wound. can do. Embodiments of the wound dressing may act as a waste container for collecting and storing wound exudate removed from the wound site, and solids in the wound dressing that covers the wound site while TNP therapy is being applied. It relates to management of material accumulation. Furthermore, embodiments disclosed herein relate to a method and an inspiratory port for applying negative pressure to a wound dressing, and a method of manufacturing an inspiratory port and a wound dressing.

Further, some embodiments disclosed herein provide a system including a negative pressure treatment device and a bandage, and a method and algorithm for operating such a negative pressure treatment device for use with a negative pressure treatment bandage. set to target. In some embodiments, the negative pressure therapy device comprises a pump assembly that is specifically configured to provide negative pressure to the wound. Some embodiments of the pump assembly disclosed herein include novel and original control logic configured to control the operation of the pump assembly. For example, some embodiments may include the presence and / or severity of one or more leaks in the system, the flow rate of fluid aspirated from the wound (eg, air, liquid, and / or solid exudate, etc.), etc. Includes novel and original control logic configured to control the operation of the pump assembly in response to monitoring and detection of various operating conditions. In some embodiments, the control logic may control one or more leaks in the system (eg, one or more leaks in the bandage in fluid communication with the pump, one in the seal created by the bandage over the wound, Or a plurality of leaks) and the operation of the pump assembly when such one or more leaks are detected. In some embodiments, the pump assembly has at least normal or low leakage (eg, leakage with a relatively low flow), high leakage (eg, leakage with a relatively high flow), and very It can be configured to distinguish between a large amount of leaks (eg, leaks having a relatively very high flow rate). Some embodiments can be further configured to distinguish between the above leakage and a very large amount of leakage.

In some embodiments, the pump assembly can include a negative pressure source, such as a small disposable pump, powered by a power source, such as a battery power source. The pump assembly can be configured to provide therapy for a predetermined period of time, such as about 1 day, 2-10 days. In some embodiments, the pump assembly may be required to provide uninterrupted treatment for such a period. In some embodiments, the pump assembly can be configured to deactivate itself for a predetermined period of time (eg, 7 days) after initial operation. The algorithms or logic disclosed herein can help the pump assembly to operate more efficiently and save power, such as but not limited to battery power.

In some embodiments, the pump assembly can be configured to monitor the duty cycle of the negative pressure source (eg, pump). As used herein, "duty cycle" reflects the amount of time that the negative pressure source is active or running over a predetermined period of time. In other words, the duty cycle reflects the time that the negative pressure source is active as part of the total time under consideration. This can be expressed mathematically as:

DC = t / T (1)

Where DC is the duty cycle, t is the duration that the negative pressure source is active, and T is the total time under consideration. The duty cycle can be measured as an absolute value (eg, X seconds), a percentage (eg, 1 / X), a percentage (eg, X%), and the like. For example, if the negative pressure source is on (ie, operating) for 6 seconds and off (ie, not operating) for 54 seconds over a period of 1 minute, the duty cycle is 6 seconds, 1/10, 10%, etc.

In some embodiments, the pump assembly can include a controller configured to monitor the duty cycle of the negative pressure source. The duty cycle measurement can reflect the activity level of the negative pressure source. For example, the duty cycle can indicate that the negative pressure source is operating normally, being overworked, being overworked, etc. In addition, duty cycle measurements, such as periodic duty cycle measurements, can include the presence and / or severity of leaks in the system, the flow rate of fluid aspirated from the wound (eg, air, liquid, and / or solid exudates), etc. Various operating states can be reflected. Based on the duty cycle measurement, such as by comparing the measured duty cycle with a set of thresholds (eg, determined by calibration), the controller can control the operation of the system according to various system requirements or Logic can be executed and / or programmed to execute them. For example, a duty cycle measurement can indicate the presence of a large amount of leakage in the system. To indicate this condition to a user (eg, patient, caregiver, doctor, etc.) and / or to save power. The controller can be programmed to temporarily suspend or pause the operation of the negative pressure source.

In some embodiments, the system can be configured to monitor the flow rate by any other suitable means. Pump assemblies can be flow meters (eg, mechanical, pressure-based, optical, mass, thermal mass, electromagnetic, sonic, ultrasonic, laser, Doppler, etc.), anemometers, pressure transducers or sensors, electromagnetic sensors (eg, halls) Sensors configured to measure pump speed, such as sensors), electromagnetic measurements (eg, measuring pump current and / or power draw, measuring power source current and / or power drain, remaining power source Etc.), or any combination thereof may be used. Based on the monitored flow rate, the controller executes algorithms or logic that controls the operation of the system according to various system requirements, such as by comparing the flow rate to a set of thresholds (eg, determined by calibration) And / or can be programmed to perform them. For example, the controller can be configured to obtain periodic measurements from a pressure sensor or to obtain periodic feedback from a pump motor. The pressure sensor can measure the pressure under the bandage. The controller can determine the flow rate, for example, by determining a pressure gradient, a rate of pressure change, and / or a rate of pressure decrease. For example, a positive pressure gradient (e.g., increasing) can reflect an increasing flow rate (e.g., leak) relative to a threshold, and the controller can be programmed to indicate this condition to the user can do.

In some embodiments, a system for the treatment of wounds can be provided. The bandage can create a substantially sealed or closed space around the wound (eg, under the bandage), and the pump assembly measures or monitors the pressure level in this space periodically or continuously. Can have a sensor. The pump assembly or its controller may be configured to control the pressure level in the space (eg, under the bandage) between the first negative pressure setpoint limit and at least the

second negative pressure setpoint limit. it can. In some embodiments, the first negative pressure setpoint limit can be between about −70 mmHg, or between about −60 mmHg and lower to about −80 mmHg and higher. In some embodiments, the second negative pressure setpoint limit can be between about −90 mmHg, or between about −80 mmHg and lower to about −100 mmHg and higher.

In some embodiments, the system may be configured to include "retry" functionality and / or logic. The pump assembly monitors the negative pressure level under the bandage (which may correspond to the negative pressure level of the wound cavity), and the monitored level is the desired negative pressure level (eg, the first negative pressure setting. The negative pressure setting value (eg, 2) may be configured to suspend or pause treatment if the desired negative pressure level has not been reached during a particular time interval. Following suspension or suspension of treatment, the pump assembly is configured to resume treatment (eg, restart the negative pressure source) and attempt to regenerate the desired negative pressure level under the bandage. be able to. Retry functionality can, for example, save battery power and allow transient and / or non-transient leaks to be resolved without user intervention, or the user can correct the leak (eg, straighten the bandage). , Repair seals, check one or more connections, etc.). In some embodiments, the controller may perform and / or be programmed to perform retry functionality and / or logic.

In some embodiments, the system "run / pause" via a switch, button, etc. located outside the housing of the pump assembly or in any other suitable location that the user can access. Can be configured to provide the functionality and / or logic. Operation / pause functionality may allow the user to hold and / or resume therapy (eg, pause and / or restart the pump). The pump assembly can be configured to automatically resume therapy according to certain predetermined or variable pause intervals. The pump assembly can be configured to automatically resume therapy when such an interval has elapsed and / or to indicate to the user that such interval has elapsed.

In some embodiments, the system can be configured to provide an indication, alarm, etc. to the user reflecting the operating state. The system can include visual, auditory, tactile, and other types of indicators and / or alarms configured to signal various operational states to the user. Such conditions include system on / off, standby, pause, normal operation, bandage problems, leaks, errors, etc. Indicators and / or alarms can include speakers, displays, light sources, etc., and / or combinations thereof. For example, the instructions may activate or deactivate the negative pressure source, reduce the negative pressure level generated by the negative pressure source, reduce the amount of power used by the negative pressure source, etc. Any combination can be provided.

FIG. 1 illustrates one embodiment of a reduced-pressure wound treatment apparatus 100 that includes a wound dressing 102 in combination with a pump assembly 104. In any of the apparatus embodiments disclosed herein, the pump assembly, as in the embodiment shown in FIG. 1, is a canisterless pump assembly (that the pump assembly does not have a leachable or liquid collection container. Meaning). However, any of the pump embodiments disclosed herein can be configured to include or support a container. In addition, in any of the device embodiments disclosed herein, any of the pump assembly embodiments are attached to, attached to, or supported by the bandage, or it can be supported adjacent to the bandage. The bandage 102 may be placed over a wound (not shown) as described in more detail in US Pat. No. 6,999,023, the disclosure of which is incorporated herein by reference and made a part of this disclosure. A conduit 106 may be connected to the bandage 102. The bandage 102 or any other bandage disclosed herein may have any of the materials, sizes, components, or other details in any of the bandage embodiments disclosed in US Pat. All such embodiments and illustrations of that application are hereby incorporated by reference as part of the present disclosure. The conduit 106 or any other conduit disclosed herein can be formed from polyurethane, PVC, nylon, polyethylene, silicone, or any other suitable material.

Although some embodiments of the bandage 102 may have a port 108 configured to receive the end of the conduit 106 (eg, the first end 106a of the conduit 106), such port 108 is not required. Absent. In some embodiments, the conduit otherwise passes through and / or below the bandage 102 to provide a source of negative pressure to the space between the bandage 102 and the wound, thereby providing a desired amount in such space. Negative pressure level can be maintained. Some embodiments of the device 100 can be configured such that the first end 106 a of the conduit 106 is pre-attached to the port 108. The conduit 106 is configured to provide an at least substantially sealed fluid flow path between the pump assembly 104 and the bandage 102, thereby supplying the bandage 102 with the negative pressure provided by the pump assembly 104. It can be any suitable article.

The dressing 102 can be provided as a single article with all wound dressing elements (including the port 108) pre-attached and integrated into a single unit. The wound dressing 102 may then be connected to a negative pressure source, such as the pump assembly 104, via a conduit 106. In some embodiments, although not required, the pump assembly 104 can be miniaturized and portable, but larger conventional pumps such as EZ CARE ™ pumps can also be used with the bandage 102. Can do.

It will be appreciated that embodiments of the present invention are generally applicable for use in local negative pressure ("TNP") treatment systems. Briefly, negative pressure wound therapy reduces the number of tissue edema, promotes blood flow and granulation tissue formation, and / or removes excess exudate, thereby reducing the number of forms of "refractory" wounds. Helps with closure and healing, and reduces bacterial load (and thus the risk of infection). In addition, the therapy can reduce wound damage and lead to faster healing. The TNP treatment system can also assist in the healing of surgically closed wounds by removing fluids and helping stabilize tissue in the closed apposition position. A further beneficial use of TNP therapy is found in grafts and flaps where it is important to remove excess fluid and the graft is required to be in close proximity to the tissue to ensure tissue viability. be able to.

The wound dressing 102 can be placed over the wound site to be treated. The bandage 102 can form a substantially sealed cavity or enclosure over the wound site. It will be appreciated that throughout this specification reference will be made to wounds. In this sense, the term wound is to be interpreted broadly. open and closed wounds where the skin is torn, incised or perforated, or caused by a trauma, or any other surface or other part of the patient's skin It should be understood to encompass other conditions or defects, or others that benefit from reduced pressure treatment. Thus, a wound is broadly defined as any damaged area of tissue in which fluid may or may not be generated. Examples of such wounds include acute wounds, chronic wounds, surgical incisions and other incisions, subacute wounds and dehiscence wounds, traumatic wounds, flaps and skin grafts, lacerations, abrasions, contusions, burns, diabetic ulcers , Pressure ulcers, stomas, surgical wounds, traumatic ulcers, venous ulcers and the like. In some embodiments, the components of the TNP system disclosed herein may be particularly suitable for an incision wound that exudes a small amount of wound exudate.

Some embodiments of the device are designed to operate without the use of a leachable container. The bandage 102 can be configured to have a film with high water vapor permeability so that excess fluid can evaporate, and the superabsorbent material can be placed inside to safely absorb wound exudate. Can be included. Some embodiments of the device are designed for disposable treatment and can be disposed of in an environmentally friendly manner after up to about 7-11 days of use. The pump can be programmed to automatically terminate therapy after a desired number of days, such as 7 days, and no further operation of the pump is possible. Some embodiments are designed for longer or repeated use and can be configured to support a leachable container.

The device 100 can be manufactured in a variety of different models or versions, where the bandage 102 can be resized to accommodate a wide range of wound sizes. For example, a device 100 can be made having a bandage 102 and wound pad (ie, an absorbent element not shown in FIG. 1) of the following size:

Some embodiments of the overlay or bandage are substantially impermeable to air flow and bacterial or other contaminant flows through the overlay layer while being permeable to vapor passage. Can be.

In some embodiments, it may be preferable to partially or completely fill the wound site with a wound filler. This wound filler is optional but may be desirable in certain wounds, such as deeper wounds. The wound filler can be used in addition to the wound dressing 102. Wound fillers can generally include porous and compatible materials such as foam (including reticulated foam) and gauze. Preferably, the wound filler is sized or shaped to fit into the wound site so as to fill any empty space. The wound dressing 102 can then be placed over the wound site and the wound filler covering the wound site. When a wound filler is used, once the wound dressing 102 is

sealed over the wound site, TNP is transferred from the pump to the wound site through the wound dressing 102 and through the wound filler. This negative pressure moves the wound exudate and other fluids or secretions away from the wound site.

In some embodiments, the tubing 106 can have a connector 112 positioned at the second end 106 b of the tubing 106. Connector 112 communicates with mating connector 114a with a short length of conduit 114 and allows the connector to be supported by a pump housing (discussed in more detail below) or otherwise protrudes from pump assembly 104 with a short length. Can be configured to couple with the conduit 114. The length of the tubing 114 may in some embodiments be about 0.55 inches (14 mm), or about 0.5 to about 5 inches (12.7 to 127 mm). The short length of conduit or tubing 114 can reduce discomfort when the patient is lying on or otherwise over the pump and connector 112. By configuring the pump assembly 104 and tubing 106 so that the tubing 106 can be quickly and easily removed from the pump assembly 104, the process of replacing the dressing or pump can be facilitated or improved if necessary. Any of the pump embodiments disclosed herein can be configured to have any of the connection configurations disclosed herein between the tubing and the pump.

In some embodiments, as in the illustrated embodiment, the pump assembly 104 can be of a portable size that is small enough to be supported on the user's body or in the user's clothing. For example, the pump assembly 104 may use an adhesive medical tape or otherwise, adjacent to or on the bandage 102 or otherwise in a comfortable place on the human skin. Can be sized to be attached. Further, the pump assembly 104 can be sized to fit in a human trouser or shirt pocket, or can be attached to the human body using a strap, pouch, or other suitable device or article. You can step

In some embodiments, the pump assembly 104 can be powered by one or more batteries (eg, two batteries) and weighs less than about 84 g, or 90 g, including the weight of the battery. be able to. In some embodiments, the pump assembly 104 can have any desired number of batteries, and has a weight between about 80 g to about 90 g, or about 75 g to about 100 g, or any value within the above range. Can be. For example, the weight and / or size of the pump assembly 104 may be reduced by reducing the size and / or weight of the battery (eg, to a size below the AAA battery) or by reducing the size and / or weight of the pump. Can do.

Further, some embodiments of the pump assembly 104 may have a total volume defined by the outer surface of the pump of about 5.6 cubic inches (about 92.5 cm^3), or 5.6 cubic inches (92.5 cm). $^{3)}$ or less, or 75 cm^3 or less ~ 115Cm ^{3} or more, or between 85cm ^{3} can be sized such that 100 cm^3. In addition, the pump assembly 104, those in the skill in the art using known techniques, to about 40 cm^3 or 40 cm ^{3} or less, or even smaller to a size ranging between 30 cm^3 or less ~ 60Cm ^{3} or more can do. Some embodiments of the pump assembly 104 may be between 2 cubic inches (32.8 cm^3) or less to 6.5 cubic inches (106.5 cm^3) or more, or from about 4 cubic inches (65.5 cm^3) to about It can be sized to have a total volume between 6 cubic inches (98.3 cm^3), or any value within the above range.

The pump assembly 104 has an overall outer size of about 7.2 cm × about 6.4 cm × about 2.1 cm (or 7.2 cm × 6.4 cm × 2.1 cm), or about 8.5 cm × about 8.5 cm ×. It can have a maximum value of about 3 cm. In addition, the pump assembly 104 can have a total outer size of about 5.5 cm × about 4.8 cm × about 1.5 cm (or 5.5 cm × 4.8 cm × 1.5 cm). As described above, the size and weight of the pump assembly 104 is more comfortable for a user to wear or carry, such as the embodiments disclosed herein, thereby providing improved mobility. Can be optimized.

The negative pressure range for some embodiments of the present disclosure can be about -80 mmHg, or about -20 mmHg to -200 mmHg. Note that these pressures are relative to normal ambient pressure, that is, in practical terms -200 mmHg is about 560 mmHg. In some embodiments, the pressure range can be about -40 mmHg to -150 mmHg. Alternatively, a pressure range of -75 mmHg or less, -80 mmHg or less, or greater than 80 mmHg can be used. In other embodiments, a pressure range of less than -75 mmHg can be used. Alternatively, a pressure range above about -160 mmHg or even 150 mmHg can be provided by the device 100. Other details regarding the operation of the pump assembly 104 are described in U.S. Patent No. 6,057,086, and such embodiments, configurations, details, and illustrations of that patent document are incorporated herein by reference as part of this disclosure. It is incorporated in the description.

2A-2F are various views of the embodiment of the pump assembly 104 shown in FIG. FIG. 3A shows a bandage 102 (which can be any of the bandage embodiments disclosed herein or incorporated by reference) supported within a first packaging element 150, 1 illustrates one embodiment of a wound dressing kit 100 comprising a pump assembly 104, a conduit 140, one or more batteries 142 (two are shown), and one or more seal strips 148. 3B is a bottom isometric view of the embodiment of the wound dressing kit 100 of FIG. 3A, and FIG. 3C is an exploded view of the embodiment of the wound dressing kit 100 of FIG. 3A.

Referring to FIGS. 2A-2C, the pump assembly 104 may be a housing 120 comprising a first housing member 120a and a second housing member 120b and a control button 122 (a switch or other similar component).), A battery cover 124, a connector 128, and one or more lights, which can be LED lights. In some embodiments, the pump assembly 104 can have more than one button 122 and can have more than two lights 132. Light 132 may be in a normal or proper operating condition, pump failure, power or power supply failure supplied to the pump, battery condition or voltage level, detection of leaks in bandages or flow paths, obstruction of inspiration, or other. It can be configured to alert the user to various operational and / or fault conditions of the pump assembly 104, including alerting the user to any similar or appropriate condition, or combination thereof.

The housing 120 can be configured such that a sterilizing gas, such as ethylene dioxide, enters the housing, thereby exposing the internal components of the pump assembly 104 to the sterilizing gas during the normal sterilization process. In general, since the pump is exposed to sterilization gas in a chamber that is substantially evacuated of air or any other gas, the sterilization gas is contained in the pump housing 120 and elsewhere in the pump assembly 104. Drawn into the space and chamber. For example, some embodiments of the pump housing 120 can have an unsealed gap surrounding the connector 128 through which sterilizing gas can pass. Also, in some embodiments, the first housing member 120a can be joined to the second housing member 120b without using a seal in between.

With respect to the sterilization process, in some embodiments, the components to be sterilized can be subjected to the next step, among other things, in any order. The component can be placed in a chamber or container that is evacuated to about 70 mBarA (or 67 mBarA to 80 mBarA) for about 15 minutes to 1 hour and 15 minutes. The component can also be exposed to inert dilution, vapor pressure or regulation, or a nitrogen cycle, followed by further exhaust cycles. Ethylene oxide or any other suitable sterilization gas can be introduced into the chamber or container at a pressure setting of about 462 mBarA (or about 457 mBarA to about 500 mBarA). The component can be exposed to sterile gas at a temperature of about 45 ° C. (or about 42 ° C. to 49 ° C.), or 60 ° C. or less. The component is about 10 minutes (short cycle) or about 1 hour (long cycle), or about 9 minutes to about 11 minutes (short cycle), or about 59 minutes to about 1 hour (long cycle), or more. Can be exposed to sterile gas. The component or chamber can be flushed with nitrogen and / or air and / or subsequently degassed.

The pump assembly 104 can be powered by one or more batteries 142. Battery 142 can be lithium chloride or any other suitable battery that is suitable for exposure to ethylene dioxide and / or other sterilizing gases. The battery 142, when supported in one or more packaging elements, minimizes the possibility of electrical sparks that may cause an explosion in the presence of sterilizing or explosive gases during the sterilization process. It can be supported outside of the pump housing 120 to eliminate or eliminate. In addition, if there are multiple batteries 142, separate or otherwise separate the batteries within the packaging to prevent any power loss or sparking of the battery during the sterilization process or prior to another use. Can be separated.

Referring to FIG. 3A, since the battery 142 and one or more seal strips 148 can be positioned below the bandage 102, the bandage 102 must be removed from the first packaging element 150 before the battery 142 is removed. The order in which the components of the bandage kit 100 are removed from the packaging 150 and / or applied to the patient or combined with other components comprising the device 100 must be presented.

In some embodiments, both ends of the conduit 140 are free or otherwise disconnected from other components of the device 100 to improve exposure of the inner surface of the conduit 140 to sterilizing gas, and / or Alternatively, the conduit 140 can be positioned within the packaging 150 such that complete exposure of the tubing

to sterilization gas is ensured. The end of the conduit 140 can be supported in a recess formed in the first packaging element 150.

The first packaging element 150 includes a recess 190 that receives the pump assembly 104, a recess 192 that receives the bandage 102, a recess 194 that receives one or more seal strips 146 and / or a conduit 140, a conduit 114 and / or One or more recesses configured to receive and support components of the device 100, including a recess 196 that receives the connector 114a (if present) and spaced recesses 200a and 200b for the battery 142. Can have. By separating the batteries, the potentially flammable nature of ethylene oxide can reduce or eliminate the risk of explosion during the sterilization procedure.

In some embodiments, the first packaging element 150 is sufficiently rigid and / or robust to hold the battery, pump, and / or other components in place during processing or transportation of the bandage kit. Can be made from materials or combinations of materials. For example, some embodiments of the first packaging element 150 include a battery, pump, sufficient to withstand about 150 to about 250, or 1G to 40G, or 1G to 20G, or 25G to 40G. Or it can be configured to provide a compression or interference fit of components such as other components. Some embodiments of the first packaging element 150 may lead to packaging shorts or melting / wearing, resulting in component movement or misalignment that leads to packaging damage or bacterial ingress. Pumps, batteries, tubing (including tubing pinches or recesses), and other configurations so as not to prevent users from being able to remove such components from packaging when needed, while being sufficient to prevent It can be configured to hold the element firmly

In addition, as shown, the first packaging element 150 can be accessed by a surgeon or user with both gloved and non-gloved hands to remove various components of the device 100. It may have a groove or recess 193 that is sized and configured to facilitate this. In addition, ridges or protrusions 195 can be formed in the first packaging element 150 to provide additional support and protection for the packaging and kit components. The first packaging element 150 is any suitable that can be sterilized, including 9.80 Eastman 6763 medical grade, blue-stained with recyclable unused PETG, provided by Nelipak Custom Thermoformed Products. Can be made from any material. The packaging element 150 can be extruded and thermoformed from EASTAR ™, Chemical Product's EASTAR copolyester resin. For example, the raw material, which can be an extruded sheet or film, can be thermoformed using a vacuum at elevated temperatures and pressing on a dyeing tool. Other materials suitable for the first packaging element 150 include polycarbonate, PVC, or any other suitable resin or plastic material. In some embodiments, the first packaging element is 0.8 mm (or about 0.8) thick, or 0.8 mm or less, or 1.0 mm or less, or about 0.7 mm to 1.2 mm. Can be made from materials having a thickness of (including plates, sheets, films, etc.).

A gas permeable cover 151 (also referred to herein as a second packaging element) is sealably positioned over the first packaging element 150 to provide bacteria and contaminants to the contents of the dressing kit 100. Barriers can be provided. For example, a sheet-like layer or film of TYVEK ™, paper, or any other suitable material can be sealed to the peripheral portion 153 of the first packaging element 150. The cover 151 can be made from any suitable material, including TYVEK, that is permeable to sterilization gases but provides a barrier against bacteria and other contaminants. The cover 151 can be opaque, transparent, or translucent.

The cover 151 can be sealably connected to the first packaging element 150 after all the components of the bandage kit have been assembled therein. Thereafter, the first packaging element 150, the cover 151, and the bandage kit components may be TYVEK or over the opening formed in the bag so that sterilization gas can enter the bag and sterilize the bandage kit components. It can be positioned in a sealed, impermeable bag with other sterile gas permeable material patches.

4A and 4B are first and second exploded views of the embodiment of the pump assembly 104 of FIG. 1 showing the first housing member 120a separated from the second housing member 120b. 5A and 5B are first and second views of the first housing member 120a. 6A and 6B are first and second views of the second housing member 120b. With reference to FIGS. 4A-5B, some embodiments of the pump assembly 104 can have a battery compartment 220 supported within or formed within the housing 120. One or more battery contacts 222 may be supported within battery compartment 220. One or more electrical wires 224 may connect battery contacts 222 to pump 232 and / or control board 230. The pump assembly 104 can be assembled in a clean room to reduce the risk of contamination or bioburden that the pump is exposed to or may receive during assembly.

In some embodiments, the pump 232 can include a motor, an inlet port or connector 250, and an outlet port 252. The pump 232 can have one or more valves therein. For example, the first valve can be positioned in the pump 232 adjacent to the inlet port 250. In addition, a second valve can be positioned in the pump 232 adjacent to the outlet port 252. The pump 232 can define a flow path through the inlet port 250, through the first and second valves, and out of the outlet port 252.

In some embodiments, the battery contacts 222 can also be configured with polarity protection. For example, as with the one or more protrusions 124d adjacent to the battery contact 125, one or more of the battery contacts 222 may include the battery contact 222 and an incorrect side of a battery inserted into the battery compartment in an incorrect orientation. In order to prevent contact with the plastic, it may have plastic or other protrusions (not shown) adjacent to the contacts. For example, the one or more protrusions prevent the negative electrode of a standard cylindrical battery from contacting the battery contact 222 adjacent to the one or more protrusions, while the positive electrode of such a battery is the battery contact. It can be sized and configured to allow contact with 222. Generally, using this configuration, the battery can generally contact the contacts 222 only when the battery is inserted into the battery compartment 220 in the correct orientation, thereby providing polarity protection to the pump assembly 104. The protrusion is preferably made from a non-conductive material. Alternatively, or in addition, the control panel 230 can be configured with a polarity protection mechanism or component. In addition, the control board 230 can have one or more fuses for protection against overpower or surge power conditions.

The pump assembly 104 can have a flow manifold 240 and a one-way flow valve 246 in communication with a fluid flow path within the pump assembly 104. The one-way flow valve 246 (also referred to as a check valve) may be silicone or any other suitable material including, but not limited to, polyurethane, viton, nitrile rubber, neoprene, Teflon, and other suitable materials. It can be a diaphragm valve made from a flexible elastomeric material or a soft material. Other suitable valves for one-way flow valves are, for example, without limitation, umbrella valves, ball valves, reed valves, duckbill valves. In some embodiments, the leak rate of the one-way flow valve 246 can be about 0.05 mL / min. In some embodiments, the one-way flow valve 246 can be positioned in the pump 232 or instead of one of the valves positioned in the pump 232.

Manifold 240 and / or one-way flow valve 246 can be in communication with connector 128. In some embodiments, the one-way flow valve 246 can be supported within the manifold 240, which can be substantially sealably coupled to the inlet port or connector 250 of the pump 232 or otherwise. Can be supported in the housing 120 to be in fluid communication with the inlet port or connector 250. For example, referring to FIGS. 4A and 4B, the manifold 240 can be assembled with the pump 232 such that the inlet connector 250 is received within an opening 261 formed in the manifold 240. Air and / or other gases can exit the pump 232 through an outlet port or connector 252. During sterilization, the pump 232 may be configured such that sterilization gas can enter the interior space or chamber of the pump 232 to ensure that the entire pump 232 (both internal and external) is sterilized. It can. One or more valves (which can be umbrella valves or any other suitable valve) can be positioned in the pump 232. For example, without limitation, one or more valves may be supported within pump 232, positioned adjacent to each of inlet port 250 and outlet port 252.

For optimal sterilization, in some embodiments, sterilization gas can be introduced slowly to optimize the flow of sterilization gas through the valve and prevent the pressure from the sterilization gas from completely closing the valve. It can. As described above, the valves (such as the first and second valves) are configured to be leaky to some extent so that the flow of sterilization gas proceeds past the valve to allow the internal components of the pump 232 to Can be sterilized. For example, the valve may be 0.1 mL / min to 10 mL / min or more at nominal or general operating pressure (ie, at the nominal operating pressure of the fluid in the conduit) or at nominal or general sterilization pressure. A leakage flow rate of fluid passing therethrough at a velocity (ie, a flow rate through the valve when the valve is in the closed position) can be allowed. In some configurations, the portion of the flow path between the two valves, or between the valve and the one-way valve, may be the most difficult part to sterilize the flow path or pump assembly 104.

Some embodiments of the pump assembly may have a piezoelectric pump. Some piezoelectric pumps or other pumps disclosed herein have an orifice that performs the valve function so that when the pump is stopped, the flow rate through the pump can be as high as 200 mL / min. Or have an orifice. Thus, in some embodiments, the first and second valves (which can be orifices) are each about 200 mL when the pump rate can be about 300 mL / min or 320 mL / min or other high rate. Can have a leak rate of less than / minute

The pump 232 includes, but is not limited to, a rotary diaphragm pump or other diaphragm pump, a piezoelectric pump, a peristaltic pump, a piston pump, a rotary blade pump, a liquid ring pump, a scroll pump, a diaphragm operated by a piezoelectric transducer. It can be of any suitable type, such as a pump, or any other suitable pump or micropump, or any combination of the above. Pump 232 can be a standard off-the-shelf vacuum pump, such as, for example, Koge Electronics' KPV8A-3A pump. Pump 232 can also be a KNF diaphragm pump or any suitable KNF pump.

Some embodiments of the pump can be lightweight, such as about 10 g, or about 5–15 g, or between any value within the above range. Pump 232 has a pump capacity of about 500 mL / min, or between about 300 mL / min or less to about 500 mL / min or more, or between about 400 mL / min to about 500 mL / min, or any value within the above range. Can have. In some embodiments, the pump assembly 104 can include more than one pump 232. For example, the pump assembly 104 may include a first pump with a high flow rate configured to provide rapid drawdown of the space between the wound overlay and the wound, and the wound overlay and wound after the initial drawdown. And a second lesser capacity pump configured to maintain a reduced pressure level of the space between them. In some embodiments, the pump flow rate can be about 20 times the leak alarm flow rate, which can be set to about 15 mL / min.

As described above, the connector 128 is a threaded connector (as shown) that can threadably receive a mating threaded connector coupled to the end of the tubing 106, be able to. The threaded connector 128 is of a non-standard size compared to other medical connectors to prevent medical personnel from inadvertently attaching standard luer connectors (such as connectors from a venous line). It may be a thing.

Alternatively, although not shown, the connector 128 is a standard tubing connector (nipple) configured to sealably receive tubing thereon so that a separate mating connector on the end of tubing 106 can be omitted. Connector etc.).

Manifold 240 may have a separate port 260 that may be configured to receive a pressure monitor conduit or connector 262. The pressure monitor can be supported by the control board 230 and can be configured to monitor the pressure level in the fluid flow path. The pressure monitor can be configured to protect the motor 232 so that a predefined threshold pressure is not exceeded. In some embodiments, the pressure monitor can be calibrated to not exceed 175 +/- 50 mmHg. In some embodiments, the pressure monitor can be calibrated to not exceed 235 mmHg. The pressure monitor can be configured to stop power to the motor when the pressure reading reaches a predetermined value, and the pressure level is higher than the predetermined value, or higher than the first predetermined value, or it may be configured to resume power when below a second predetermined value, which may be low. In addition, the pump assembly 104 can be programmed to prevent such overpressure. The pump assembly 104 can be configured such that the software provides a primary mechanism to prevent overpressure, and a pressure monitor can provide backup for overpressure protection.

The pump 232 can have a layer of open cell foam or other material that is at least partially wrapped around the outer surface of the pump 232 to reduce noise and vibration generated by the pump 232. All of these components can be supported within the first and second pump housing members 120a, 120b, which can be secured together with any suitable fastener 270 (eg, a pair of screws). One or more labels 272 can be attached to the outer surface of the housing 120. In addition, in some embodiments, the pump 232 is supported by the pump 232 or positioned adjacent to one or more outer surfaces of the pump, one or more weights, cushions, foams it can have a body (such as a viscoelastic foam), plastic (such as ABS, polyurethane, urethane), or other pad, panel, sheet, or segment. Some embodiments can have a mass-based or flexible damping material. Such components or materials (not shown) can damp vibrations generated by the pump and / or attenuate noise.

For example, one or more weights (made of steel, metal, or any other suitable material) are supported on the outer surface of pump 232 or any other pump embodiment disclosed herein. Or it can be attached to it. The steel weight can be about 1.8 g, 3.8 g, or 5.8 g, or 1 g to 10 g or more, or 1.5 g to 6 g. Two or more weights can be supported on or attached to the outer surface of pump 232 or any other pump embodiment disclosed herein. Two steel weights, each weighing about 1.8 g, 3.8 g, or 5.8 g, or 1 g to 10 g or more, or 1.5 g to 6 g, can be attached to the outer surface of the pump 232. Each of the two plates can be positioned on the opposite surface of the motor 232 or otherwise. In some embodiments, four steel weights weighing about 1.8 g, 3.8 g, or 5.8 g, or 1 g to 10 g or more, or 1.5 g to 6 g, respectively, are applied to the outer surface of the pump 232. Can be attached to. The plates can be arranged such that the two plates are positioned on each of the two opposing surfaces of the motor 232 or otherwise. In some embodiments, weights can be positioned adjacent to more than two surfaces of the pump 232, including, but not limited to, the sides and top surface of the pump 232, for example.

Referring to FIG. 4A, the battery cover 124 may be configured to engage the mating mechanism of the housing 120 to prevent inadvertent opening when the battery cover 124 is in the closed position. Or it can have the tab member 124a. In addition, a guide or protrusion 124b can be formed on the battery cover 124 to facilitate the ease with which the battery cover 124 can be opened and closed. The guide 124b can engage a mating guide or channel 120c formed in the housing 120. The battery cover 124 can be configured to have a gripping surface for use with a single finger. For example, without limitation, a plurality of depressions 124c are formed on the surface of the battery cover 124 to improve gripping between the user's finger or other object and the battery cover 124, and the battery cover 124 can be easily opened and closed. can do.

Referring to FIG. 4B, the battery cover 124 can support thereon one or more battery contacts or terminals 125 configured to provide a connection between two batteries. The battery cover 124 may further support one or more protrusions 124 d adjacent to the battery contact 125. The one or more protrusions 124d prevent the negative electrode of a standard cylindrical battery from contacting the battery contact 125 adjacent to the one or more protrusions 124c, while the positive electrode of such a battery is the battery contact. 125 can be sized and configured to allow contact. With this configuration, the battery can generally contact the contact 125 only when the battery is inserted into the battery compartment 220 in the correct orientation, thereby providing polarity protection to the pump assembly 104.

Referring to FIGS. 4A and 4B, the housing 120 may include one or more tabs 121 and recesses configured to receive the tabs 121 to improve the connection between the two members 120a, 120b of the Housing. Channel 123. The tabs 121 and indents 123 can better hold the edges of the housing 120 together to improve the strength of the housing 120 and make the connection between the two members 120a, 120b of the housing tighter. The control panel 230 can be combined with the housing 120 using a similar mechanism.

Of an embodiment of the wound dressing 102 disclosed herein, as described in US Pat. No. 5,637,097, the disclosure of which is incorporated herein by reference as if fully set forth herein. Either lower surface can have an optional wound contact layer. Any of the bandage embodiments disclosed herein can be made without a wound contact layer. The wound contact layer can be made porous or perforated, for example, by a hot pin process, a laser ablation process, an ultrasonic process, or in some other manner, or otherwise liquid and gas It can be a polyurethane layer or a polyethylene layer or other flexible layer, which can be permeable. Through holes may allow liquid and / or gas to flow through the layers. The wound contact layer can help prevent tissue ingrowth into another material of the wound dressing.

The through hole is small enough to meet this requirement, but can still be sized to allow fluid to pass through. For example, a through-hole formed as a slit or hole having a size in the range of 0.025 mm to 1.2 mm is small enough to help prevent tissue ingrowth into the wound dressing it is considered to allow wound exudate to flow into the bandage. The wound contact layer helps hold the entire wound dressing together and helps create a hermetic seal around the absorbent pad to maintain negative pressure in the wound. The wound contact layer also acts as a carrier for any lower and upper adhesive layers (not shown). For example, a lower pressure sensitive

adhesive layer can be provided on the lower surface 101 of the wound dressing, while an upper pressure sensitive adhesive layer can be provided on the upper surface 103 of the wound contact layer. The pressure sensitive adhesive, which can be a silicone, hot melt, hydrocolloid, or acrylic adhesive, or other such adhesive, is selected on both sides of the wound contact layer, or optionally on the wound contact layer, it can be formed on one side or not on any side. If the lower pressure sensitive adhesive layer is utilized, this helps adhere the wound dressing to the skin around the wound site.

As described above, any bandage embodiment used in the bandage kit disclosed herein or incorporated by reference has an adhesive-coated lower surface (eg, a wound contact surface), be able to. In some embodiments, as described above, the adhesive can be, for example, a silicone adhesive comprising polysiloxane or polyorganosiloxane, or other polymeric pressure sensitive silicone adhesive. For example, polydimethylsiloxane can be used. The adhesive blend is a mixture of alkyl pendant siloxanes that can be spread and cast as a two-part mixture with the catalyst so that the final polymerization step follows the casting or spreading. It may be. In some embodiments, the bandage layer is coated on the opposite side of an extruded EU30 polyurethane transparent film (27-37 gsm) with a non-porous silicone adhesive coating (coat weight nominally 130 gsm) and fully cast. Acrylic adhesive (27-37 gsm). The water vapor permeability of some embodiments of such an arrangement can be from about 367 gm $^{-2}$ / 24 hours to about 405 gm $^{-2}$ / 24 hours, or an average water vapor permeability of 382 gm $^{-2}$ / 24 hours.

Some embodiments or arrangements of silicone adhesive layers suitable for the bandage embodiments disclosed herein may have a water vapor transmission rate of about 350 gm $^{-2}$ / 24 hours to about 419 gm $^{-2}$ / 24 hours. It can. Suitably, the average water vapor permeability of some embodiments or arrangements of silicone adhesive layers suitable for the bandage embodiments disclosed herein can be about 380 gm $^{-2}$ / 24 hours. Some of the bandage embodiments disclosed herein may be coated with Wacker silres PSA 45 pressure sensitive adhesive

In addition, any of the bandage embodiments disclosed herein can have an antimicrobial agent or substance incorporated into the bandage or coated on one or more surfaces of the bandage. For example, without limitation, the wound contact layer of any bandage embodiment disclosed herein is incorporated herein by reference as part of, but not limited to, Nanocrystalline silver agent, silver salt, copper salt, or gold salt, such as those disclosed in Patent Document 10 (named "ANTIMPROBIAL BIGUANIDE METAL COMPLEX") filed on May 21, 2008, PHMB Chlorohexazine, peroxide, hypochlorous acid, or other bleaching agents in or on it. Further, the absorbent layer of any bandage embodiment disclosed herein can have silver sulfur diazine, or any of the above-described substances or activators in or thereon. These may be used separately or in combination. Each of these can eliminate microorganisms in the wound and microorganisms in the absorbent matrix. As yet another option, other active ingredients can be incorporated into the bandage, for example pain inhibitors or healing agents such as ibuprofen. Also, agents that inhibit cellular activity such as growth factors, or agents that inhibit enzymes such as matrix metalloproteinase inhibitors or zinc chelators such as metalloproteinase tissue inhibitors (TIMPS) can be incorporated into the dressing. Odor trapping elements such as activated carbon, cyclodextrin, zeolite, etc. may also be included in the absorbent layer or other part or component of the bandage or on the filter layer.

A layer of porous material can be disposed over the wound contact layer. This porous layer, i.e., the permeable layer, allows fluids including liquids and gases to permeate away from the wound site and into the upper layer of the wound dressing. In particular, the permeable layer can ensure that an open air channel can be maintained and negative pressure transmitted over the wound area, even when the absorbent layer is absorbing a significant amount of exudate. . The layer should remain open under the general pressure applied during negative pressure wound treatment as described above, thereby allowing a uniform negative pressure across the wound site. The layer can be formed of a material having a three-dimensional structure. For example, a knitted or woven spacer fabric (eg, Baltex 7970 weft knitted polyester) or a non-woven fabric can be used. Other materials can be utilized, and examples of such materials are described in US Pat. No. 6,957,028, which is incorporated herein by reference and forms part of the present disclosure.

In some embodiments, the transmission layer can have a 3D polyester spacer fabric layer. This layer has an upper layer that is 84/144 textured polyester (ie, a layer distal to the wound bed in use) and a lower layer that can be 100 denier flat polyester (ie, the wound bed in use). And a third layer, which is a region defined by monofilament fibers such as knitted polyester viscose and cellulose formed between the two layers. be able to. Other suitable materials and other linear mass densities of fibers can be used.

This difference between the filament counts in the separated layers helps to control the moisture flow across the permeation layer. In particular, by increasing the filament count of the top layer, i.e. making the top layer with yarns that have more filaments than the yarn used in the bottom layer, the liquid will flow along the top layer rather than the bottom layer. Tend to be wicked. In use, this difference tends to draw the liquid away from the wound bed and into the central area of the bandage, where the absorbent layer traps the liquid or itself transpirations the liquid. Helps to wick forward toward the cover layer that can be allowed to.

Preferably, the 3D fabric is a dry cleaning agent (such as perchloroethylene) to improve the flow of liquid across the permeable layer (ie, perpendicular to the channel region formed between the upper and lower spacer layers). With the aid of removing any previously used industrial products such as mineral oils, oils and / or waxes that may be treated with, but not limited to, the hydrophilicity of the permeable layer Become. In some embodiments, an additional manufacturing step can be followed in which the 3D spacer fabric is washed with a hydrophilic agent (such as but not limited to Feran Ice 30 g / L available from Rudolph Group) . This process step helps to ensure that the surface tension on the material is low and that a liquid such as water can enter the fabric as soon as it contacts the 3D knitted fabric. This also helps to control the flow of liquid insult components of any exudate.

Again, as described in more detail in U.S. Patent No. 6,058,930, a water absorbent material layer can be provided on the permeable layer. The absorbent material, which can be a natural or synthetic material of foam or non-woven fabric, optionally comprising or being a superabsorbent material, is a fluid, in particular a liquid removed from the wound site The reservoir and sucking these fluids towards the cover layer. The material of the absorbent layer can prevent the liquid collected in the wound dressing from flowing away. The absorbent layer can also help distribute the fluid throughout the layer via a wicking action so that fluid is drawn from the wound site and accumulates throughout the absorbent layer. This helps to prevent aggregation in the area of the absorbent layer. The volume of absorbent material must be sufficient to manage wound exudate flow when negative pressure is applied. In use, since the absorbent layer is subjected to negative pressure, the material of the absorbent layer is chosen to absorb the liquid under such circumstances. There are many materials that can absorb liquids under negative pressure, for example superabsorbent materials. The absorbent layer can be made from ALLEVYN ™ foam, Freudenberg 114-224-4, and / or Chem-Posite ™ 11C-450, or any other suitable material.

In some embodiments, the absorbent layer can be a layer of nonwoven cellulose fibers in which superabsorbent material in the form of dry particles is dispersed throughout. The use of cellulose fibers introduces a high speed wicking element that helps to quickly and uniformly distribute the liquid absorbed by the bandage. The juxtaposition of multiple strand-like fibers leads to a strong capillary action in the fibrous pad that helps to distribute the liquid. In this way, the liquid is efficiently supplied to the superabsorbent material. Furthermore, all areas of the absorbent layer are provided with liquid.

The wicking action also assists in contacting the liquid with the upper cover layer to help increase the transpiration rate of the bandage. The wicking action also assists in delivering fluid down toward the wound bed when the exudate is slow or stops. This delivery process helps maintain the permeable layer and the underlying wound bed area in a moist state, which helps to prevent scab formation (which can lead to inhibition) within the bandage, and against wound healing Helps maintain an optimized environment.

In some embodiments, the absorbent layer can be an airlaid material. Thermally fusible fibers can optionally be used to help hold the pad structure together. It will be appreciated that superabsorbent fibers according to some embodiments of the present invention can be utilized rather than or in addition to using superabsorbent particles. An example of a suitable material is the product Chem-Posit ™ 11C available from Emerging Technologies Inc (ETi), USA.

Optionally, the absorbent layer can comprise synthetic stable fibers and / or bicomponent stable fibers and / or natural stable fibers and / or superabsorbent fibers. The fibers in the absorbent layer can be secured together by latex bonding or thermal bonding or hydrogen bonding or any combination of bonding techniques or other fixing mechanisms. In some embodiments, the absorbent layer is formed by fibers that operate to confine superabsorbent particles within the absorbent layer. This helps to ensure that the superabsorbent particles do not move out of the absorbent layer and toward the underlying wound bed. This is particularly useful as it tends to collapse the absorbent pad downwards when negative pressure is applied, and this action traps the superabsorbent particulate matter by the fibrous structure of the absorbent layer. This is because if not, it is pushed in the direction toward the wound bed.

The absorbent layer can include a plurality of fiber layers. Preferably, the fibers are strands and are made of cellulose, polyester, viscose, and the like. Preferably, the dried absorbent particles are distributed throughout the ready absorbent layer. In some embodiments, the absorbent layer includes a pad of cellulose fibers and a plurality of superabsorbent particles. In additional embodiments, the absorbent layer is a randomly oriented nonwoven layer of cellulose fibers.

The superabsorbent particles / fibers can be, for example, sodium polyacrylate or carboxymethylcellulose materials, or any material that can absorb many times its own weight in the liquid. In some embodiments, the material can absorb more than 5 times the weight of 0.9% weight saline solution itself. In some embodiments, the material can absorb more than 15 times the weight of 0.9% weight saline solution itself. In some embodiments, the material can absorb more than 20 times the weight of 0.9% weight saline solution itself. Preferably, the material can absorb more than 30 times the weight of the 0.9% weight saline solution itself. The absorbent layer can have one or more through holes arranged to be under the suction port.

The dressing 102 can have a cover layer that extends across the width of the wound dressing that is gas impermeable but water vapor permeable. The cover layer can be, for example, a polyurethane film (eg, Elastollan SP9109), or any other suitable material having a pressure sensitive adhesive on one side, and is substantially gas impermeable, thereby substantially A sealed enclosure is made over the wound. In this way, an effective chamber can be created between the cover layer and the wound site to establish a negative pressure. The cover layer can be sealed to the wound contact layer at the boundary area around the circumference of the bandage, ensuring that no air is drawn through the boundary area, for example by gluing or welding techniques. The cover layer can protect the wound from external bacterial contamination (bacterial barrier), allowing liquid from the wound exudate to migrate through the layer and evaporate from the outer surface of the film. The cover layer can have a polyurethane film and an adhesive pattern cast on the film. Polyurethane films are water vapor permeable and may be made from materials that increase water permeability when wet.

An orifice can be provided in the cover film so that negative pressure can be applied to the bandage 102. As described above, in some embodiments, the suction port 108 can be sealed onto the cover film over the orifice, thereby transmitting negative pressure through the orifice. The port may be adhered and sealed to the cover film using an adhesive such as acrylic, cyanoacrylate, epoxy, UV curable, or hot melt adhesive. The port 108 can be formed from a soft polymer, such as polyethylene, polyvinyl chloride, silicone, or polyurethane having a hardness of 30-90 on the Shore A scale.

The bandage 102 may have a filter element that is impermeable to liquid but permeable to gas. The filter element can act as a liquid barrier that substantially prevents or inhibits liquid from escaping from the wound dressing, as well as an odor barrier. The filter element may also function as a bacterial barrier. In some embodiments, the pore size of the filter element can be about 0.2 μm. Suitable materials for the filter material of the filter element include 0.2 micron Gore ™ PTFE, PALL Versapore ™ 200R, and Donaldson ™ TX6628 stretched from the MMT range. In this way, gas can be discharged through the orifice by the filter element. However, liquids, particulates, and pathogens are included in the bandage. Other details regarding filters are disclosed in US patent application Ser. No. 13 / 092,042, which is incorporated herein by reference.

Wound dressings 102 as described herein and methods of making and using the same may also incorporate the features, configurations, and materials described in the following patents and patent applications, each of which is disclosed in this disclosure, which is incorporated herein by reference in its entirety. Patent Literature 11, Patent Literature 12, Patent Literature 13, Patent Literature 14, Patent Literature 15, Patent Literature 16, Patent Literature 17, Patent Literature 18, Patent Literature 19, Patent Literature 20, Patent Literature 21, Patent Literature 22, Patent Document 23, Patent Document 24, Patent Document 25, and Patent Document 26, Patent Document 27 filed on November 8, 2010, Patent Document 28 filed on April 15, 2011, and April 2011 Patent Document 29 filed on the 15th. From patents and patent applications incorporated by these references, the features, configurations, materials, and methods of manufacture or use of components similar to those described in this disclosure have been substituted and added to the embodiments of this application. Or may be implemented.

In operation, the wound dressing 102 is seated over the wound site forming the wound cavity. The pump assembly 104 provides a negative pressure source for the bandage 102. Fluid is drawn from the wound site beneath the wound contact layer, through the wound dressing, and toward the orifice. The fluid moves through the permeable layer toward the orifice. As fluid is drawn through the permeable layer, wound exudate is absorbed into the absorbent layer.

The overall shape of the wound dressing can be square, oval, rectangular, or another shape. The bandage can have a rounded corner area. It will be appreciated that wound dressings according to other embodiments of the present invention can be shaped differently, such as square, circular, or elliptical dressings.

The desired size of the wound dressing 102 can be selected based on the size and type of wound in which it is used. In some embodiments, the wound dressing 102 can be sized between 20-40 cm on its long axis and 10-25 cm on its short axis. For example, as described above, bandages can be provided in sizes of about 10 × 20 cm, 10 × 30 cm, 10 × 40 cm, 15 × 20 cm, and 15 × 30 cm.

In some embodiments, the wound dressing 102 can be a square dressing (eg, 15 × 15 cm, 20 × 20 cm, and 25 × 25 cm) with sides sized between 15 and 25 cm. The absorbent layer can have a smaller area than the entire bandage, and in some embodiments, have a length and width that are both about 3-10 cm shorter, more preferably about 5 cm shorter than the entire bandage 102. May be. In some rectangular embodiments, the absorbent layer may have a dimension between about 10-35 cm on its long axis and 5-10 cm on its short axis. For example, the absorbent layer is 5.6 × 15 cm or 5 × 10 cm (for a 10 × 20 cm bandage), 5.6 × 25 cm or 5 × 20 cm (for a 10 × 30 cm bandage), 5.6 × 35 cm Or 5 × 30 cm (for 10 × 40 cm bandages), 10 × 15 cm (for 15 × 20 cm bandages), and 10 × 25 cm (for 15 × 30 cm bandages). In some square embodiments, the absorbent layer may have sides between 10 and 20 cm long (eg, 10 × 10 cm for a 15 × 15 cm bandage, 20 × 20 cm bandage) In the case of a bandage of 15 × 15 cm or 25 × 25 cm). The transmission layer can be smaller in size than the absorbent layer, and in some embodiments, both about 0.5-2 cm shorter than the absorbent layer, more preferably about 1 cm shorter, Can have a width. In some rectangular embodiments, the transmission layer may be sized between 9-34 cm on its long axis and 3-5 cm on its short axis. For example, the transmission layer may be 4.6 × 14 cm or 4 × 9 cm (for a 10 × 20 cm bandage), 4.6 × 24 cm or 4 × 19 cm (for a 10 × 30 cm bandage), 4.6 × 34 cm or it may be provided in sizes of 4 × 29 cm (for 10 × 40 cm bandage), 9 × 14 cm (for 15 × 20 cm bandage), and 9 × 24 cm (for 15 × 30 cm bandage). In some square embodiments, the transmission layer may have sides between 9 and 19 cm long (eg, 9 × 9 cm for a 15 × 15 cm bandage, 20 × 20 cm bandage) In the case of 14 × 14 cm, or 19 × 19 cm in the case of a 25 × 25 cm bandage).

The dressing can include an antimicrobial substance, for example, a nanocrystalline silver agent on the wound contact layer and / or silver sulfur diazine in the absorbent layer. These may be used separately or together. Each of these kills microorganisms in the wound and microorganisms in the absorbent matrix. As yet another option, other active ingredients may be included, for example pain suppressors such as ibuprofen. In addition, agents that improve cellular activity such as growth factors, or agents that inhibit enzymes such as matrix metalloproteinase inhibitors or zinc chelators such as metalloproteinase tissue inhibitors (TIMPS) can be used. As yet another option, odor trapping elements such as activated carbon, cyclodextrin, zeolite, etc. may be included in the absorbent layer or as a further separate layer above the filter layer.

Although several embodiments of the present invention have been described so far in which the transmissive layer is formed as a 3D knitted layer, for example as two layers separated by a monofilament layer, some embodiments of the present invention provide such materials. It will be appreciated that it is not constrained to use. In some embodiments, one or more layers of various materials can be utilized as an alternative to such 3D knitted materials. In either case, according to embodiments of the present invention, the opening represented by the layers of the permeable layer moves away from the side of the bandage that would be placed close to the wound during use. It gets wider as you go. In some embodiments, the permeable layer may be provided by multiple layers of open cell foam. In some embodiments, the foam is a reticulated open cell foam. The foam can be hydrophilic or can wick aqueous based fluids. The pore size of each layer is selected so that the pores closest to the wound site in use in the foam layer have the smallest diameter. If only one additional foam layer is utilized, it includes a pore size that is larger than the pore size of the first layer. This helps avoid solid particles being trapped in the lower layer, which in turn helps to maintain the lower layer in an open configuration, which allows air to permeate the bandage. In some embodiments, two, three, four, or more foam layers may be included. The foam layer may be formed integrally by, for example, selecting a foam having a large pore diameter and repeatedly immersing it while gradually reducing the degree of immersing it in a material that clogs the pores, or a plurality of foam layers may be formed. The permeable layer formed by the foam layer may be provided by laminating different types of foam in a layered arrangement, or by fixing such foam layers in place in a known manner.

7A-7D illustrate the use of one embodiment of a TNP wound treatment system being used to treat a patient's wound site. FIG. 7A shows that the wound site W has been cleaned and is ready for treatment. Here, the healthy skin surrounding the wound site W is preferably cleaned and excess hair is removed or shaved. If necessary, the wound site W may also be irrigated with sterile saline. Optionally, a skin protectant may be applied to the skin surrounding the wound site W. If necessary, a wound filler such as foam or gauze may be placed at the wound site W. This may be preferred when the wound site W is a deeper wound.

After the skin surrounding the wound site W is prepared, the cover 151 can be removed from the first packaging element 150 to provide access to the components. The bandage 102 can be removed from the packaging 150 and can be positioned and placed over the wound site W as shown in FIG. 7B. The wound dressing 102 can be positioned such that the wound contact layer of the dressing 102 is above and / or in contact with the wound site W. In some embodiments, an adhesive layer can be provided on the underside of the wound contact layer, which may optionally be removed prior to placing the wound dressing 102 over the wound site W. It may be protected by a release layer. The bandage 102 may be positioned such that the port 108 is in a raised position relative to the rest of the bandage 102 and avoids fluid accumulation around the port 108. In some embodiments, the bandage 102 is positioned such that the port 108 does not directly overlap the wound, but is at or above the wound. To help ensure a proper seal against TNP, the edges of the bandage 102 can be smoothed to avoid folds or folds. The bandage and the adhesive formed thereon may be used to lift and reposition the bandage away from the skin or wound, without sacrificing the performance of the adhesive. For reasons it can simply be configured so that the bandage can be repositioned on the wound. Tubing 106 can be connected to bandage 102 either before or after placing bandage 102 over the wound.

The pump assembly 104 can then be removed from the packaging 150 and connected to the tubing 106, as shown in FIG. 7C. The battery 142 can be removed from the packaging 150 and installed in the pump assembly 104 either before or after the pump is attached to the conduit 106. The pump assembly 104 is configured to apply negative pressure to the wound site through the bandage 102, typically through tubing or conduit 106. In some embodiments, a connector may be used to join the conduit 106 to the bandage 102 and to the pump assembly 104. When applying negative pressure by the pump assembly 104, the bandage 102, in some embodiments, has a partially collapsed, wrinkled appearance as a result of exhausting some or all of the air under the bandage 102. May be shown. In some embodiments, the pump assembly 104 may be configured to detect any leaks in the bandage 102, such as at the junction between the bandage 102 and the skin surrounding the wound site W. Good. If a leak is found, it is preferably corrected before continuing treatment. Leakage can be corrected by repositioning the bandage 102, extending the wrinkles or folds of the bandage, or applying a fastening strip 148 around the circumference of the bandage 102.

Turning to FIG. 7D, the fixation strip 148 may be attached around the outer periphery of the bandage 102 or otherwise as described above. Such a fixation strip 148 may be advantageous in some situations to provide an additional seal against the patient's skin surrounding the wound site W. For example, the seal or anchoring strip 148 can provide an additional seal when patient movement is more active. In some cases, the fixation strip 148 may be used prior to operating the pump assembly 104, particularly when the bandage 102 is placed over an inaccessible or undulating area. In some embodiments, the bandage kit 100 can include no more than five seal strips.

Treatment of the wound site W is preferably continued until the wound reaches the desired level of healing. In some embodiments, it may be desirable to replace the bandage 102 after a certain period of time has elapsed or when the bandage is full of wound fluid. During such replacement, the pump assembly 104 may be retained and only the bandage 102 may be replaced.

8A-20H each illustrate a top surface of an embodiment of a packaging element that can be used with any of the wound dressing device embodiments disclosed herein, including a variety of differently sized wound dressing devices, etc. FIG. 4 is a square view, a bottom isometric view, a top view, a bottom view, a front view, a rear view, a first side view, and a second side view. Other packaging disclosed herein, wherein any of the packaging element embodiments shown in FIGS. 8A-20H or otherwise disclosed in the present application include the first packaging element 150 described above. It may have any of the same features, materials, or other details as any of the ring elements.

The packaging element 300 shown in FIGS. 8A-8H supports one or more bandages having a size of about 10 cm × 20 cm and / or other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 310 shown in FIGS. 9A-9H supports one or more bandages having a size of about 10 cm × 20 cm and / or other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 320 shown in FIGS. 10A-10H supports a dressing having a size of about 10 cm × 30 cm and / or one or more of the other components of any of the TNP treatment kits disclosed herein. Configured to do. The packaging element 330 shown in FIGS. 11A-11H supports a bandage having a size of about 10 cm × 30 cm and / or one or more of the other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 340 shown in FIGS. 12A-12H supports one or more of a bandage having a size of about 10 cm × 40 cm and / or other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 350 shown in FIGS. 13A-13H supports one or more of the bandages having a size of about 10 cm × 40 cm and / or other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 360 shown in FIGS. 14A-14H supports one or more bandages having a size of about 15 cm × 15 cm and / or other components of any of the TNP treatment kits disclosed herein. Configured to do. The packaging element 365 shown in FIGS. 14I-14P supports one or more of a bandage having a size of about 15 cm × 15 cm and / or other components of any TNP treatment kit disclosed herein. Configured to do

The packaging element 370 shown in FIGS. 15A-15H supports a bandage having a size of about 15 cm × 20 cm and / or one or more of the other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 380 shown in FIGS. 16A-16H supports one or more of a bandage having a size of about 15 cm × 20 cm and / or other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 390 shown in FIGS. 17A-17H supports one or more of a bandage having a size of about 20 cm × 20 cm and / or other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 395 shown in FIGS. 17I-17P supports a dressing having a size of about 20 cm × 20 cm and / or one or more of the other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 400 shown in FIGS. 18A-18H supports a dressing having a size of about 15 cm × 30 cm and / or one or more of the other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 405 shown in FIGS. 18I-18P supports a bandage having a size of about 15 cm × 30 cm and / or one or more of the other components of any TNP treatment kit disclosed herein. Configured to do. The packaging element 410 shown in FIGS. 19A-19H supports one or more bandages having a size of about 25 cm × 25 cm and / or other components of any TNP treatment kit disclosed herein. Configured to

de. The packaging element 420 shown in FIGS. 20A-20H supports one or more bandages having a size of about 25 cm × 25 cm and / or other components of any TNP treatment kit disclosed herein. Configured to de.

FIG. 21 illustrates a pump assembly 1000 according to some embodiments. Any of the embodiments of the pump assembly 1000 disclosed herein include any of the other pumps disclosed herein or incorporated herein by reference, including the embodiments of the pump assembly 194 described above. It may have any of the same or similar components, features, materials, sizes, configurations, and other details as the assembly embodiment. Preferably, the pump assembly 1000 can be miniaturized and portable, but larger conventional portable or non-portable (eg, wall suction) pumps can also be used. The pump assembly 1000 can include a switch or button 1002, illustrated as an enable / pause button located outside the housing of the pump assembly. As described below, button 1002 can be configured to stop, pause, and / or resume treatment. Although illustrated as push button 1002, other types of switches or buttons may be included, such as a touchpad, touch screen, keyboard, and the like.

The pump assembly can further include a connector 1050 (for connecting a conduit, eg, for connecting the conduit 1061 and three LED indicators 1062, 1064, and 1066. As shown, LED indicator 1062 (eg, an OK indicator) can be configured to indicate normal / abnormal operation of the system. For example, an active (eg, lit) indicator 1062 can represent normal operation. An LED indicator 1064 (eg, a bandage indicator) can be configured to indicate a leak in the system. For example, an active (eg, lit) indicator 1064 can represent a leak. The LED indicator 1066 (eg, battery indicator) can be configured to indicate the remaining capacity or life of the power source (eg, battery). For example, an active (eg, lit) indicator 1066 can represent a low capacity. In some embodiments, the indicators 1062, 1064, and 1066 can be different colors, two different colors (eg, two indicators can share the same color), or the same color. The pump assembly preferably includes three LED indicators and one on / off push button, but other configurations, locations, and types of indicators, alarms, and switches can be used instead. In some embodiments, the pump assembly 1000 can include visual, audible, tactile, and other types of indicators or alarms configured to signal various operating conditions to the user. . Such conditions include system on / off, standby, pause, normal operation, bandage problems, leaks, errors and the like. The indicator can include a speaker, a display, a light source, etc., and / or combinations thereof.

FIG. 22 illustrates a cross-sectional view illustrating the interior of a pump assembly 1000 according to some embodiments. As shown, the housing 1020 can enclose the pump assembly. The one-way flow valve 1030 maintains a negative pressure level when the negative pressure source is not active (eg, prevents leakage), and fluids and / or exudates that are aspirated or removed from the wound via the connector 1050 It can be configured to prevent entry into the pump assembly. A control board 1040, such as a printed circuit board assembly (PCBA), can be configured to mechanically support and electrically connect various electrical / electronic components described below. PCBA can be single-sided or double-sided. A negative pressure source 1090, such as a pump, can aspirate fluid and / or exudate from the wound. In any of the embodiments disclosed herein, negative pressure source 1090 is the same component as any of the other negative pressure source embodiments disclosed herein, including but not limited to pump 232 described above. , Features, limitations, or other details. Negative pressure sources for various pumps, including peristaltic pumps, piston pumps, rotor blade pumps, liquid ring pumps, scroll pumps, diaphragm pumps, piezoelectric pumps (eg, diaphragm pumps operated by piezoelectric transducers), etc., or combinations thereof Can be used for The pump assembly preferably includes a small, low noise, low power pump, although any suitable pump can be used instead. The pump assembly 1000 includes an indicator 1060 (eg, an LED), a pressure sensor 1070 that monitors system pressure, such as the pressure under the bandage, and a battery cover 1080 configured to provide access to the battery compartment 1100, including. The pump assembly is preferably powered by two standard disposable alkaline batteries (eg, two AA batteries), but uses any type of power source instead, including rechargeable batteries and external power be able to.

FIG. 23 shows a system schematic diagram of a pump assembly 1000 according to some embodiments. The pump assembly includes a push button 1002, a control panel 1040, and an indicator 1060. The pump assembly 1000 can be powered by the battery cell 1130. The pump assembly also includes a pump 1090 such as a diaphragm pump powered by an electric motor 1092 and a pressure sensor 1070. The inlet 1120 can be configured to connect the pump assembly 1000 to the bandage, eg, via a conduit. Inlet 1120 can be connected to a one-way valve 1030 to help maintain negative pressure levels when the negative pressure source is inactive, avoid leakage, and fluid and / or leaching that is aspirated or removed from the wound It can be configured to prevent objects from entering the pump assembly 1000. Pump 1090 can also be connected to outlet 1110. In some embodiments, the outlet 1110 can be configured to release air into the atmosphere. In some embodiments, a filter (not shown) can be sandwiched between the outlet and the atmosphere. The filter can be a bacterial filter, an odor filter, etc., or any combination thereof.

FIG. 24 shows a schematic diagram of the electrical components of a pump assembly 1000 according to some embodiments. Module 1140, which can be a control board (eg, PCBA), can include an input / output (I / O) module 1150, a controller 1160, and a memory 1170. In some embodiments, the module 1140 can include additional electrical / electronic components, such as one or more fuses. The controller 1160 can be a microcontroller, processor, microprocessor, etc., or any combination thereof. For example, the controller 1160 can be of the STM8L MCU family type from ST Microelectronics, such as STM8L 151G4U6, or the MC9S08QE4 / 8 series type from Freescale, such as MC9S08QE4CWJ. Preferably, the controller 1160 is a low power or ultra low power device, although other types of devices can be used instead. The memory 1170 may be a read only memory (ROM), a write once read many memory (WORM), a random access memory (eg, SRAM, DRAM, SDRAM, DDR, etc.), a solid state memory, a flash memory, a magnetic storage device, etc. One or more of volatile and / or nonvolatile memory modules may be included, such as one or more of any combination. The memory 1170 may be configured to store program code or instructions (executed by the controller), system parameters, operational data, user data, etc., or any combination thereof.

The I / O module 1150 may be configured to function as an interface between the controller 1160 and other system components that provide and / or respond to electromagnetic signals. In other words, the I / O module 1150 can be configured to allow the controller 1160 to monitor system operation and control other components of the system. In some embodiments, as shown, the I / O module 1150 can be in electromagnetic communication with a button 1002, an indicator 1060, a pressure sensor 1070, a power source 1130, and a negative pressure source 1090. An I / O module may comprise an interface or multiple interfaces configured to communicate with various components. Interfaces can include standard and / or non-standard ports, such as serial ports, parallel ports, bus interfaces, etc., or any combination thereof.

In some embodiments, the pump assembly 1000 can be configured to control the operation of the system. For example, the pump assembly 1000 delivers treatment without interruption and / or avoids inconvenience to the user, for example by frequently or unnecessarily suspending or postponing treatment, and it can be configured to conserve power and provide an appropriate balance between the desire to limit noise and vibration generated by the negative pressure source. FIG. 25 illustrates a high-level diagram 1200 of operation of a pump assembly according to some embodiments. In some embodiments, the controller 1140 can be configured to implement the flow of state diagram 1200. As shown in FIG. 25, the operation of the pump assembly is, in some embodiments, inactive / initialized (states 1206 and 1202), active state 1210, operating 1250, and end of life (state 1214). Can be grouped into four general state categories. As shown in FIG. 25 and FIG. 26, the state categories 1210 and 1250 each include a plurality of states and transition between the states.

In some embodiments, as long as the power source is not connected and removed (illustrated by transition 1204) or the pump assembly is operated (eg, by pulling on an operating strip or activating a switch, etc.) Unless otherwise, the pump assembly remains in state 1206. While remaining in this state, the pump assembly can remain inactive. When power is connected and / or when the pump assembly is first operated, the pump assembly may transition to state 1202 to perform one or more power-on self tests (POST). Power-on self-diagnosis (s) include inspecting the memory 1170 (eg, performing a check such as periodic redundancy check of program code to determine its integrity, inspecting random access memory, etc.) Reading the pressure sensor 1070 to determine whether or not the pressure value is within appropriate limits, reading the remaining capacity or life of the power source (eg, battery voltage, current, etc.) and making it within the appropriate limits It may include performing various checks to ensure proper functionality of the system, such as determining whether or not there is, and examining the negative pressure source. As shown, the indicator 1060 (eg, LED) may be configured to indicate to the user (eg, by blinking or blinking once) that the pump assembly is undergoing a POST test (s). Can do.

In some embodiments, the pump assembly can transition to an unrecoverable error state 1214 if one or more of the POST test (s) fail. While in this state, the pump assembly can be deactivated and the indicator 1060 can be configured to indicate to the user that an error has been encountered. In some embodiments, all indicators can be configured to remain active. Based on the severity of the error, in some embodiments, the pump assembly can be configured to recover from the error and continue operation (or transition to an unrecoverable error state 1214). As shown, the pump assembly may transition to state 1214 if it encounters a critical error during operation. Deterministic errors include program memory errors, program code errors (eg, encountering invalid variable values), controller operating errors (eg, watchdog timer expires without being reset by controller 1160), component Faults (eg, negative pressure source inoperability, pressure sensor 1070 inoperability, etc.) and any combination thereof may be included.

Upon passing the POST test (s), in some embodiments, the pump assembly can transition to a manual pause state 1216. As shown, this transition can be indicated to the user by deactivating one of the indicators 1060 (eg, battery indicator 1066). When the pump assembly transitions to the manual pause state 1216 and remains there, instructions can be provided to the user, such as by deactivating indicators 1062 (OK indicator) and 1064 (bandage indicator). In some embodiments, treatment can be postponed while the pump assembly remains in the manual pause state 1216. For example, a negative pressure source (eg, pump 1090) can be deactivated (or turned off). In some embodiments, the indication can be provided by deactivating the negative pressure source.

In some embodiments, the pump assembly can be configured to make a transition 1224 from a manual pause state 1216 to an operational state category 1250 in response to receiving a signal from the switch (the pump assembly is treated). If configured to deliver). For example, the user can press a button to start, postpone, and / or resume treatment. In some embodiments, the pump assembly can be configured to monitor the duration that the pump assembly remains in the manual pause state 1216. This can be accomplished, for example, by maintaining a timer (of firmware, software, hardware, or any combination thereof) that can be reset and started when the pump assembly transitions to the manual pause state 1216. Can do. The pump assembly can be configured to automatically make a transition 1224 from a manual pause state 1216 to an operational state category 1250 when the duration exceeds a threshold. In some embodiments, such a threshold can be a set value, such as between 1 minute or less and 1 hour or more. In some embodiments, the threshold can be set or changed by the user. In some embodiments, the threshold can be varied based on various operating conditions or any combination thereof. For example, the threshold can be decreased as the pump assembly approaches the end of life (as described below). In some embodiments, the user can pause therapy by actuating a switch (eg, pressing a button), which causes the pump assembly to move from an operational category 1250 to a manual suspended state 1216. Transition 1222 is performed. In some embodiments, the pump assembly can be configured so that the user can simply suspend treatment, but the treatment is stopped by disconnecting the power source (eg, removing the battery).

In some embodiments, the pump assembly can be configured to include a paused state 1218. An indication can be provided to the user when the pump assembly transitions to and remains in the paused state 1218. For example, the pump assembly can be configured to deactivate the OK indicator 1062 and blink or blink the bandage indicator 1064. In some embodiments, treatment can be postponed while the pump assembly remains in the manual pause state 1216. For example, a negative pressure source (eg, pump 1090) can be deactivated (or turned off), thereby providing the user with an indication that the pump assembly is in a paused state 1218. As will be described below, in some embodiments, the pump assembly may be configured when the number of retry cycles exceeds the retry limit (transition 1226) or when the duty cycle is determined to exceed the duty cycle limit (transition). 1230), and can be configured to transition from the operational state category 1250 to the paused state 1218. In some embodiments, transitions 1228 and 1230 may reflect the presence of a leak in the system.

In some embodiments, the pump assembly is responsive to receiving a signal from a switch (eg, a user pressing a button to resume therapy) from a paused state 1218 to an operational state category 1250 (where the pump assembly is The pump can be operated to transition 1226 to deliver therapy. In some embodiments, the pump assembly can be configured to monitor the duration that the pump assembly remains in the paused state 1218. For example, this can be accomplished by maintaining a timer (of firmware, software, hardware, or any combination thereof) that can be reset and started when the pump assembly transitions to a paused state 1218. . The pump assembly can be configured to automatically make a transition 1226 from the paused state 1218 to the operational state category 1250 when the duration exceeds a threshold. The threshold can be the same as or different from the threshold of the manual pause state 1216 described above. In some embodiments, the threshold can be a set value, such as between 1 minute or less and 1 hour or more. In some embodiments, the threshold can be set or changed by the user. In some embodiments, the threshold can be varied based on various operating conditions or any combination thereof. For example, the threshold can be decreased as the pump assembly approaches the end of life (as described below).

In some embodiments, the pump assembly includes both a manual pause state 1216 and a pause state 1218 to distinguish different causes of suspending treatment. Such discriminating ability may allow the pump assembly to provide the user with a specific cause indication for suspending therapy (eg, manual pause state 1216 and pause state 1218 may provide different indications). Can be provided). For example, therapy can be paused by a user manually pressing a button, in which case the pump assembly can make a transition 1222 from an operational state category 1250 to a manual pause state 1216. As another example, treatment can be paused by detecting a leak, in which case the pump assembly can make a transition 1228 and / or 1230 from an operational state category 1250 to a paused state 1218. . In some embodiments, the pump assembly can be configured to include one state that indicates a postponement or suspension of treatment delivery, or more than two such states.

In some embodiments, the pump assembly can be configured to monitor the remaining capacity or life of the power source (eg, by periodically reading or sampling battery voltage, current, etc.). The pump assembly can be configured to indicate the remaining capacity to the user. For example, when it is determined that the power supply has a normal remaining capacity (for example, 2.7 V, 2.6 V, 2.5 V, etc. as a result of comparison with a threshold), the battery indicator 1066 can be deactivated. If it is determined that the power source has a low remaining capacity, the pump assembly may be configured to provide instructions to the user, for example, by blinking or blinking the battery indicator 1066, as shown by transition 1220. it can. In some embodiments, the battery indicator 1066 can be configured to blink or blink intermittently or continuously, regardless of which state the pump assembly is in or only certain states. .

In some embodiments, once it is determined that the remaining capacity of the power source is at or near a critical level (e.g., 2.4V, 2.3V, 2.2V, etc. as compared to a threshold), the pump assembly Can be configured to transition to a battery critical state 1212. In some embodiments, the pump assembly can be configured to remain in this state until the power supply capacity is increased, such as by replacing or recharging the power supply. The pump assembly can be configured to deactivate the therapy while remaining in the battery critical state 1212. In addition, as shown, the pump assembly can be configured to indicate to the user that the power source is at or near a critical level. for example, by deactivating all indicators.

In some embodiments, the pump assembly can be configured to provide therapy for a predetermined period of time, such as about 1 day, 2-10 days, etc. following the first operation. In some embodiments, such time period can be a set value that is changed by the user and / or changed based on various operating conditions or any combination thereof. The pump assembly can be discarded at the end of such period. In some embodiments, the first motion can be reflected by a transition to the active state category 1210, such as by pulling the motion strip (eg, transition to state 1202). Once the pump assembly is operated, the pump assembly can be configured to monitor the duration that it has remained active. In some embodiments, the pump assembly can be configured to monitor the cumulative duration remaining in the activity category 1210. This can be accomplished, for example, by maintaining a timer (of firmware, software, hardware, or any combination thereof) that reflects such duration.

When the duration reaches or exceeds a threshold (eg, 7 days), the pump assembly may be configured to transition to an end of life (EOL) state 1240. The pump assembly may be configured to deactivate the therapy while remaining in state 1240 and indicate to the user that the end of the useful life of the pump assembly has been reached. For example, the pump assembly can be configured to deactivate all indicators and / or deactivate buttons. In some embodiments, when the pump

assembly is disposable, transitioning to the end of life state 1240 means that the pump assembly can be discarded. The pump assembly can be configured such that once the end of life is reached, the pump assembly cannot be operated again. For example, the pump assembly can be configured so that it cannot be operated again even if the power is disconnected and then reconnected, which stores instructions, values, flags, etc. in a read-only memory Can be achieved.

FIG. 26 illustrates an operational flow in the state category 1250 of the pump assembly 1000 according to some embodiments. The pump assembly can be configured to deliver therapy, monitor system leaks, provide instruction (s) to the user, and the like. As described below, in some embodiments, the pump assembly provides a first desired negative pressure level (e.g., a negative pressure between −5 mmHg or lower to −200 mmHg or higher, such as −100 mmHg) under the bandage 1010. The treatment can be configured to be delivered by first trying to establish, in some embodiments, the first desired negative pressure level may be a set value that is set or changed by the user and / or changed based on various operating conditions or any combination thereof, it can. Once the first desired negative pressure level is established under the bandage 1010, the pump assembly can be configured to deactivate the negative pressure source (eg, pump). When the negative pressure under the bandage 1010 decreases due to system leakage (i.e., decreases toward normal atmospheric pressure), the pump assembly operates the pump to provide a second desired negative pressure level under the bandage (For example, by establishing a negative pressure between −5 mmHg or less and −200 mmHg or more, such as −100 mmHg, it can be configured to recover the negative pressure under the bandage. In some embodiments, the second desired negative pressure level may be a set value that is set or changed by the user and / or changed based on various operating conditions or any combination thereof, it can. In some embodiments, the first and second desired negative pressure levels can be the same. In some embodiments, the first and second desired negative pressure levels can be different, i.e., the second negative pressure level is lower than the first negative pressure level or vice versa. Can do.

In some embodiments, the pump assembly can transition from manual pause state 1216 and / or pause state 1218 to state 1252. As described above, this transition can be caused by the user pressing a button to start / resume treatment and / or when a duration such as one hour has elapsed. The pump assembly is configured to immediately transition to an initial pump down (IPD) state 1260 where the pump can be operated to establish a first desired negative pressure level under the bandage 1010. be able to. In some embodiments, the pump can be operated when the pressure level under the bandage is above (less than) the first desired negative pressure level. Operating the negative pressure source to establish a first desired negative pressure level under the bandage 1010 may be referred to herein as "initial pump down". The pump assembly can be configured to indicate to the user that an initial pump down is being performed, for example, by blinking or blinking the OK indicator 1062 and deactivating the bandage indicator 1064. In some embodiments, the indication can be provided, for example, by operating a negative pressure source. The pump assembly can be configured to measure the pressure level under the bandage 1010 by reading or sampling the sensor 1070.

In some embodiments, the pump assembly can be configured to monitor the duration that the pump assembly remains in the IPD state 1260. This can be accomplished, for example, by maintaining a timer (of firmware, software, hardware, or any combination thereof) that can be reset and started when the pump assembly transitions to IPD state 1260. Can do. In some embodiments, to conserve power, limit noise and / or vibrations generated by the pump, etc., the pump assembly postpones the initial pump down operation for a predetermined period of time, after which the initial pump down is Can be configured to retry. This functionality, for example, saves battery power and allows transient and / or non-transient leaks to be resolved without user intervention, or allows the user to correct the leak (eg, straighten the bandage). , Repair seal, check one or more connections, etc.).

In some embodiments, the pump assembly may be configured to make a transition 1264 to state 1266 when the duration of stay in IPD state 1260 is equal to or exceeds a threshold (eg, 30 seconds). Can do. In some embodiments, the threshold can be a set value, such as between 5 seconds or less and 5 minutes or more. In some embodiments, the user can set or change the threshold. In some embodiments, the threshold can be varied based on various operating conditions or any combination thereof. In some embodiments, the pump assembly can be configured to deactivate the pump when performing transition 1264. The pump assembly maintains a counter that can be reset in state 1252 and updated in wait state 1270, for example, the number of attempts made to establish the first desired negative pressure under the bandage 1010. Can be configured to monitor). In some embodiments, the pump assembly can be configured to provide a limited or maximum number of IPD retry attempts, eg, to conserve power. Preferably, the pump assembly may be configured to provide a limited number of consecutive IPD retry attempts, but the pump assembly may be configured to provide a limited number of non-consecutive IPD retry attempts, or continuous and it can be configured to provide a mix of non-sequential IPD retry attempts. The threshold for IPD retry attempts may be 1, 2, 3, 4, 5, etc. In some embodiments, the threshold can be a set value. In some embodiments, the threshold can be set or changed by the user. In some embodiments, the threshold can be varied based on various operating conditions or any combination thereof.

In some embodiments, the pump assembly, in state 1266, determines whether the number of IPD retry attempts made is equal to or exceeds a threshold (eg, one retry attempt). Can be configured to determine. If the number of IPD retry attempts made is equal to or exceeds the threshold, the pump assembly makes transition 1228a to pause state 1218 where treatment is paused or postponed as described above. It can be constituted as follows. Otherwise, the pump assembly can be configured to make a transition 1268 to the standby state 1270. In some embodiments, the pump assembly can be configured to deactivate the negative pressure source at state 1266, thereby providing an indication to the user that the pump assembly has transitioned to state 1266. it can.

In some embodiments, the pump assembly deactivates the stand-by 1270 pump, thereby suspending the therapy for a predetermined period of time (eg, between 1 second and 1 minute, such as 15 seconds). It can be constituted as follows. This can be accomplished, for example, by maintaining a timer (of firmware, software, hardware, or any combination thereof) that can be reset and started when the pump assembly transitions to standby state 1270. Can do. This period in the wait state 1270 can be preset or variable (eg, automatically or by the user). In some embodiments, the time period can vary based on various operating conditions or any combination thereof. The period during which the pump assembly remains in the standby state 1270 is increased or decreased at each transition to the standby state 1270 (eg, multiplied by a factor between 0.1 and less than 4.0, such as 2, etc.). be able to The period can be increased or decreased in each series of transitions to the wait state 1270. The time period can be increased or decreased until it equals or exceeds a threshold (eg, between 1 second and 5 minutes or more, such as 4 minutes). In addition, the time period can be reset to an initial value upon transition to the monitored pressure state 1280, transition to the manual pause state 1216, and transition to the pause state 1218.

In some embodiments, the pump assembly can be configured to indicate to the user that the pump assembly is in a standby state 1270. For example, the pump assembly can be configured to blink or blink the OK indicator 1062 and deactivate the bandage indicator 1064. In some embodiments, shutting down the pump can provide an indication that the pump assembly is in a standby state 1270. Once the standby period has elapsed, the pump assembly can be configured to make a transition 1272 from the standby state 1270 to the IPD state 1260, wherein the pump assembly is configured with a first desired underneath bandage 1010. Attempts can be made to establish negative pressure levels. In some embodiments, the pump assembly can be configured to ensure that the negative pressure level under the bandage remains above a certain safety level. For example, the pump assembly can be configured to maintain a negative pressure level below the bandage 1010 that exceeds a safety level between −150 mmHg or lower to −250 mmHg or higher, such as −225 mmHg.

In some embodiments, the pump assembly can be configured to make a transition 1276 to the monitoring state 1280 once the first desired negative pressure level under the bandage 1010 has been established. The pump assembly may be configured to reset the number of IPD retry attempts when making transition 1276. The pump assembly may be configured to instruct the user to transition to the monitoring state 1280, for example, by blinking or blinking the OK indicator 1062 and deactivating the bandage indicator 1064. While remaining in the monitoring state 1280, the pump assembly deactivates the pump (thus providing an indication to the user that the pump assembly is in the monitoring state 1280) and the pressure level below the bandage 1010. Can be configured to be monitored periodically or continuously. The pump assembly can be configured to measure the pressure level under the bandage 1010 by reading or sampling the sensor 1070.

In some embodiments, the pump assembly decreases until the negative pressure level under the bandage 1010 reaches a threshold and / or exceeds (eg, falls below) the threshold, eg, due to a system leak. It can be configured to determine whether or not. The threshold value can be selected from a range between −10 mmHg or less and −100 mmHg or more, such as −60 mmHg. In some embodiments, the threshold value can be a set value that is set or changed by the user and / or changed based on various operating conditions or any combination thereof. If it is determined that the threshold has been reached or passed, the pump assembly can be configured to restore the negative pressure level under the bandage 1010. In some embodiments, the pump assembly can be configured to re-establish the first desired negative pressure level or to establish another different negative pressure level. This can be accomplished by making a transition 1282 to a maintenance pump down (MPD) state 1290.

In some embodiments, the pump assembly operates the pump with the pump assembly remaining in the MPD state 1290 to provide a desired negative pressure level under the bandage 1010 (eg, a first desired level). Can be configured to establish. The pump assembly can be configured to provide instructions to the user, for example, by blinking or blinking the OK indicator 1062 and deactivating the bandage indicator 1064. In some embodiments, the pump assembly that operates the negative pressure source can provide an indication to the user that the pump assembly has transitioned to state 1290. In some embodiments, the pump assembly may be configured to generate less noise and vibration when the pump is operated in the MPD state 1290 than when the pump is operated in the IPD state 1264. Can do. For example, the noise level difference can be between 1 dB or less and 30 dB or more, such as about 7 dB, about 20 dB. As another example, the noise level difference can be between 30 dB and 80 dB or more, such as about 45 dB, about 50 dB, about 65 dB, and the like.

In some embodiments, the pump assembly can be configured to monitor the duration that it remains in the MPD state 1290. This is accomplished, for example, by maintaining a timer (of firmware, software, hardware, or any combination thereof) that can be reset and started when the pump assembly makes a transition 1282 to MPD state 1290. can do. In some embodiments, the pump assembly postpones maintenance pump down operation for a predetermined period of time, such as to conserve power, limit noise and / or vibrations generated by the pump, and then the initial pump down. And / or may be configured to retry maintenance pump down. This functionality, for example, saves battery power and allows transient and / or non-transient leaks to be resolved without user intervention, or allows the user to correct the leak (eg, straighten the bandage). , Repair seal, check one or more connections, etc.).

In some embodiments, the duration of the MPD state 1290 is equal to or exceeds a threshold (eg, a value between 5 seconds and 5 minutes or more, such as 10 seconds) and the pressure level below the bandage 1010 is When the desired negative pressure level has not been reached, the pump assembly can be configured to make a transition 1292 to state 1294. The threshold can be a set value that is set or changed by the user and / or changed based on various operating states or any combination thereof. In some embodiments, the pump assembly can be configured to deactivate the pump when performing transition 1292, thereby providing the user with an indication that the pump assembly is performing the transition. Can do. The pump assembly resets the number of MPD attempts made to establish the desired negative pressure under the bandage 1010 (e.g., at state 1252 and / or when performing transition 1228b and performs transition 1296 it can be configured to monitor (by maintaining a counter that can sometimes be updated). In some embodiments, the pump assembly can be configured to provide a limited or maximum number of MPD retry attempts (eg, to conserve power). Preferably, the pump assembly can be configured to provide a limited number of consecutive MPD retry attempts, but the pump assembly can be configured to provide a limited number of non-consecutive MPD retry attempts, or continuous and it can be configured to provide a mixture of non-sequential retry attempts. The threshold for MPD retry attempts may be 1, 2, 3, 4, 5, etc. In some embodiments, the threshold value can be a set value that is set or changed by the user and / or changed based on various operating conditions or any combination thereof. The pump assembly can be configured to set the number of IPD and MPD retry attempts to the same or different values. The pump assembly is configured to determine, at state 1294, whether the number of MPD retry attempts made is equal to or exceeding a threshold (eg, 3 retry attempts). can do. If the number of MPD retry attempts made is equal to or exceeds the threshold, the pump assembly makes transition 1228b to pause state 1218 where treatment is paused or postponed as described above. It can be constituted as follows. Otherwise, the pump assembly can be configured to make a transition 1296 to a wait state 1270 where treatment is suspended or postponed as described above. Alternatively, the pump assembly can be configured to transition to IPD state 1260 or MPD state 1290.

In some embodiments, the pump assembly may transition 1284 to a monitoring state 1280 if the pressure level under the bandage reaches or exceeds (eg, becomes greater than) the desired negative pressure level. Can be configured. The pump assembly may also be configured to reset the number of MPD retry attempts when making transition 1284.

In some embodiments, the pump assembly can be configured to monitor the duty cycle of the negative pressure source (eg, pump). The pump assembly can be configured to monitor the duty cycle periodically and / or continuously. Duty cycle measurements may reflect various operating conditions of the system, such as the presence and / or severity of leaks, the flow rate of fluid aspirated from the wound (eg, air, liquid, and / or solid exudates). it can. For example, a duty cycle measurement can indicate the presence of a large amount of leakage, and the pump assembly can indicate this condition and / or temporarily postpone or pause pump operation to save power. Can be configured. This functionality, for example, saves battery power and allows transient and / or non-transient leaks to be resolved without user intervention, or allows the user to correct the leak (eg, straighten the bandage). , Repair seal, check one or more connections, etc.).

In some embodiments, the pump assembly can be configured to monitor the duty cycle periodically, such as once every 10 seconds or less to once every 5 minutes or more. In some embodiments, the pump assembly can be configured to monitor the duty cycle once per minute. This can be set to expire every minute (eg, as indicated by an interrupt or via polling) and restarted (eg, by clearing the interrupt) , (By firmware, software, hardware, or a combination thereof). In some embodiments, the time interval for measuring the duty cycle can be a set value that is set or changed by the user and / or changed based on various operating conditions or any combination thereof. In some embodiments, the pump assembly is in an operational state category 1250 (ie, any of states 1260, 1266, 1270, 1280, 1290, 1294, and / or any transition between any states). Since it is sometimes configured to operate the pump, it can be configured to monitor the duty cycle when in this state category. In some embodiments, the pump assembly monitors the duty cycle when the pump assembly is in a particular state and / or state transition, or a subset of states and / or state transitions, of the operational state category 1250. Can be configured. In some embodiments, the pump assembly is configured such that the pump assembly is a specific state and / or state transition of an active state category 1210, a subset of states and / or state transitions, or all states and / or state transitions, or The duty cycle may be configured to be monitored when in any combination of any states and / or state transitions disclosed herein. As shown in FIG. 26, the pump assembly may perform a transition 1302 from any of states 1260, 1266, 1270, 1280, 1290, 1294 and / or a transition from any of the states to state 1300. Here, the pump assembly can determine the duty cycle of the pump during the elapsed minutes. The duty cycle can be determined according to the following equation:

DC = t / T (2)

Where DC is the duty cycle, t is the duration that the negative pressure source is active, and T is the total time under consideration. If the duty cycle is monitored once per minute (ie, T = 60 seconds), the duty cycle can be expressed as (eg, as a percentage):

DC = (pump operating time during elapsed time / 60) * 100% (3)

To determine the duty cycle, the pump assembly can be configured to monitor the duration that the pump has been active (eg, pump run time) and / or inactive.

In some embodiments, the pump assembly can be configured to compare the determined duty cycle to a duty cycle threshold that can be selected from a range between 1% or less and 50% or more. The comparison can indicate the presence of a system leak, for example. In other words, if the pump remains active for a period of time that reaches or exceeds the duty cycle threshold, the pump may be overworked to overcome the leak. In such cases, the pump assembly can be configured to postpone or suspend delivery of therapy. The pump assembly may be configured to provide an indication to the user that the pump is overworked (eg, the duty cycle

exceeds a duty cycle threshold), for example, by deactivating the negative pressure source. it can. In some embodiments, the duty cycle threshold may be a set value that is set or changed by a user and / or that is changed based on various operating conditions or any combination thereof. As shown in FIG. 26, the pump assembly can be configured to compare the determined duty cycle to a duty cycle threshold (eg, 9%). The pump assembly is configured to monitor the number of duty cycles that exceed a threshold, for example, by maintaining and updating an overload counter that can be reset when the pump assembly transitions from state 1252 to IPD state 1260, can do.

In some embodiments, the pump assembly can be configured to update an overload counter in state 1300. If the determined duty cycle does not exceed the duty cycle threshold, the pump assembly can decrement the overload counter. In some embodiments, the minimum value of the overload counter can be set to zero, i.e., the overload counter never becomes negative. Conversely, if the determined duty cycle is equal to or exceeds the duty cycle threshold, the pump assembly can increment the overload counter.

In some embodiments, the pump assembly can be configured to monitor the total number or total number of duty cycles equal to or exceeding the duty cycle threshold. This strategy helps smooth or average duty cycle variations to prevent one or several unstable cycles that may be caused by, for example, transient leakage by interrupting therapy can do. In some embodiments, the pump assembly can be configured to monitor continuous or non-continuous duty cycles that exceed a duty cycle threshold. In some embodiments, the threshold value can be a set value that is set or changed by the user and / or changed based on various operating conditions or any combination thereof. If it is determined that the number of duty cycles that exceed the duty cycle threshold exceeds an overload threshold (e.g., between 1 and 60 or more, such as 30,), the pump assembly is postponed or suspended as described above. It can be configured to make a transition 1230 to the paused state 1216. In some embodiments, the pump assembly can be configured to deactivate the negative pressure source, thereby providing an indication to the user that the pump is overworked (eg, the duty cycle exceeds an overload threshold). Can be provided. If it is not determined that the number of duty cycles that exceed the duty cycle threshold exceeds the overload threshold, the pump assembly may be configured to make transition 1304 and remain in the operational state category 1250. In some embodiments, the pump assembly can be configured to return to the same state and / or transition between states from which the pump assembly has made transition 1302. In some embodiments, the pump assembly can be configured to transition to different states and / or transition between states.

In some embodiments, the pump assembly is further configured to postpone or pause treatment if the user presses button 1002 while the pump assembly is in the operational category 1250. In some embodiments, the pump assembly can be configured to transition to a manual pause state 1216.

FIG. 27 illustrates another state diagram of the operation of the pump assembly 1000 according to some embodiments. In some embodiments, the controller 1140 can be configured to implement the flow of state diagram 1400. In some embodiments, the flow 1400 can be generally similar to the flows shown in FIGS. State 1402 corresponds to state 1202, state 1406 corresponds to state 1250, state category 1410 corresponds to state category 1210, state 1414 corresponds to state 1214, state 1415 corresponds to state 1215, state 1418 Corresponding to state 1218, transition 1420 corresponds to transition 1220, transition 1422 corresponds to transition 1222, transition 1424 corresponds to transition 1224, transition 1426 corresponds to transition 1226, and state 1440 corresponds to state 1240. To do. In addition, state category 1450 corresponds to state category 1250, state 1460 corresponds to state 1260, transition 1464 corresponds to transition 1264, state 1466 corresponds to transition 1266, and transition 1468 corresponds to transition 1268. , Transition 1428a corresponds to transition 1228a, state 1470 corresponds to state 1270, and transition 1472 corresponds to transition 1272. Further, transition 1476 corresponds to transition 1276, state 1480 corresponds to state 1280, transition 1482 corresponds to transition 1282, state 1490 corresponds to state 1290, transition 1492 corresponds to transition 1292, state 1494 Corresponding to state 1294, transition 1496 corresponds to transition 1296, and transition 1428b corresponds to transition 1228b.

In some embodiments, the pump assembly can be configured to monitor the duty cycle after a desired negative pressure level is established under bandage 1010 in MPD state 1490. In some embodiments, the pump assembly can also take into account the duration that the pump was active while the pump assembly remained in the IPD state 1460. As shown, the device can be configured to make a transition 1484 from MPD state 1490. Transition 1484 may be similar to transition 1284, but instead of transitioning directly to IPD state 1460, the pump assembly may be configured to monitor the duty cycle of state 1500. In some embodiments, the pump assembly can be configured to monitor the duty cycle for the cumulative period during which the pump assembly remains in the monitoring state 1480 and the MPD state 1490. In some embodiments, the pump assembly may be configured to monitor the duty cycle over the previous or past monitoring and accumulation period during the MPD cycle. For example, just prior to transitioning to state 1500, the pump assembly may remain in MPD state 1490 for duration X (while the pump is active). In addition, just prior to transitioning to MPD state 1490, assuming that the pump assembly remained in monitoring state 1480 for duration Y (while the pump was inactive), the duty cycle (DC) Can be expressed as (for example, as a percentage):

DC = 100% * [X / (X + Y)] (4)

To determine the duty cycle, the pump assembly can be configured to monitor the duration that the pump has been active and / or inactive.

In some embodiments, the pump assembly can be configured to compare the determined duty cycle to a duty cycle threshold (eg, 9%), as described above. in some embodiments, the threshold value can be a set value that is set or changed by the user and / or changed based on various operating conditions or any combination thereof. If it is determined that the duty cycle is less than the threshold, the pump assembly may be configured to make a transition 1502 to the monitoring state 1480. Conversely, if it is determined that the duty cycle is equal to or exceeds the threshold, the pump assembly can be configured to make a transition 1504 to state 1506. In some embodiments, the pump assembly can provide an indication that the duty cycle exceeds a threshold, for example by deactivating the pump.

In some embodiments, the pump assembly can be configured to monitor the total time or total time for which the duty cycle is equal to or exceeds the threshold. This strategy helps smooth or average duty cycle variations to prevent one or several unstable cycles that may be caused by, for example, transient leakage by interrupting therapy, can do. Monitoring is by maintaining a timer (of firmware, software, hardware, or any combination thereof) that can be restarted (eg, during transition 1476) and updated (eg, in state 1506). Can be achieved. In some embodiments, the pump assembly is configured to determine whether the duty cycle is equal to or exceeds the threshold over a specific total period that can be compared to a total duration threshold. Can be configured. The threshold can be selected from a range between 5 minutes or less and 2 hours or more, such as 30 minutes. In some embodiments, the threshold value can be a set value that is set or changed by the user and / or changed based on various operating conditions or any combination thereof. If the total duration is equal to or exceeds the threshold, the pump assembly is configured to make a transition 1508 to a pause state 1418 that can be configured to postpone or pause the delivery of therapy, can do. In some embodiments, the pump assembly can indicate this transition to the user, for example, by deactivating the pump. Conversely, if it is determined that the total duration is less than the threshold, the pump assembly can be configured to make a transition 1510 to the monitoring state 1480. The pump assembly can be configured to indicate a transition 1510 to the user, for example, by blinking or blinking the OK indicator 1062 and deactivating the bandage indicator 1064.

FIG. 28 illustrates a graph 1600 illustrating duty cycle determination for a pump assembly 1000 according to some embodiments. The X axis represents time and the Y axis represents pressure. In some embodiments, the pump assembly can be configured to establish a negative pressure level of −100 mmHg below the bandage 1010, as represented by position 1606. For example, this can be done during the initial pump down of state 1260. The pump assembly can be configured to monitor the negative pressure level under the bandage 1010. For example, this can be implemented in the monitoring state 1280. As shown, the pump assembly can monitor pressure over time period a, as represented by interval 1602. The negative pressure level under the bandage 1010 can decrease over time (eg, due to system leakage), as indicated by line 1620.

In some embodiments, the pump assembly may restore the negative pressure level under the bandage 1010 when the pressure reduction reaches or exceeds a threshold of about −70 mmHg, as represented by position 1608, or it can be configured to re-establish. In some embodiments, the pump assembly can be configured to operate the pump, as indicated by line 1622. For example, this can be done by transitioning to the maintenance pump down state 1290. As shown, the pump assembly can operate the pump for a duration b (1604) until a negative pressure level of −100 mmHg is re-established under the bandage 1010. The pump assembly can be configured to shut down the pump when the pressure level below the bandage 1010 reaches −100 mmHg at position 1610. For example, this can be done by transitioning to a monitoring state 1280. The duty cycle (DC) over the time period indicated by 1600 (ie, a + b) can be expressed as (eg, as a percentage):

DC = 100% * [b / (a + b)] (5)

FIG. 29 illustrates a non-limiting example of normal (eg, no or small leak) operation 1700 of some embodiments of the pump assembly 1000. The pump assembly can be configured to establish a desired negative pressure level under the bandage 1010, as shown in box 1702. If the pressure level under the bandage 1010 rises above a desired level (eg, a first negative pressure setting value such as -75 mmHg), the pump assembly will operate a negative pressure source (eg, pump). The pressure level under the bandage 1010 can be configured to begin to reduce to a desired value. For example, the desired value can be approximately within the interval between the value of the first negative pressure set value and the value of the second negative pressure set value, or is approximately the value of the second negative pressure set value. (E.g., -100 mmHg). In some embodiments, this can be achieved in the initial pump down state 1260.

In some embodiments, when the pressure level below the bandage 1010 reaches a desired value, the pump assembly shuts down the pump and monitors the pressure level below the bandage, as shown in box 1704. Can be configured. For example, this can be achieved in the monitoring state 1280. The pump assembly can be configured to periodically or continuously monitor the pressure level under the bandage 1010, for example, by reading or sampling the sensor 1070. Based on the monitored pressure, the pump assembly determines whether the pump needs to be operated or restarted in box 1706 to re-establish the desired negative pressure level under the bandage 1010. can do. If it is determined that the monitored pressure is low (eg, less than or less than the first negative pressure setpoint value), the pump assembly is configured to operate the pump, as shown in box 1708. can do. For example, this can be achieved by transitioning to MPD state 1290. Conversely, if it is determined that the monitored pressure level is not low (eg, exceeds or exceeds the value of the first negative pressure setpoint), the pump assembly monitors the pressure level below the bandage 1010. Can be configured to continue. During this operational flow, the pump assembly can be configured to indicate to the user that it is operating normally. As shown at 1060a, the pump assembly can be operated, or the OK indicator 1062 can blink or blink, as shown as 1062a. In addition, the pump assembly can deactivate the bandage indicator 1064 and battery indicator 1066, shown as 1064a and 1066a, respectively.

FIG. 30 illustrates a non-limiting example of operation 1800 of some embodiments of the pump assembly 1000 in the presence of a large amount of leakage. As described above with respect to FIG. 29, the pump assembly may be configured to establish a desired negative pressure level under the bandage 1010, as shown in box 1802. In some embodiments, when the pressure level below the bandage 1010 reaches a desired value, the pump assembly may deactivate the pump and monitor the pressure level below the bandage, as shown in box 1804. Can be configured. The pump assembly can be configured to periodically or continuously monitor the pressure level under the bandage 1010, for example, by reading or sampling the sensor 1070. Based on the monitored pressure level, the pump assembly may determine whether the pump needs to be operated or restarted to re-establish the desired negative pressure level under the bandage 1010. it can. If it is determined that the monitored pressure level is low (eg, less than or equal to the first negative pressure setpoint value), the pump assembly is configured to operate the pump, as shown in box 1808. Can be configured. Once the desired pressure level is re-established under the bandage 1010, the pump assembly can begin monitoring the negative pressure level under the bandage again (eg, transition to the monitoring state 1280).

In some embodiments, due to the presence of one or more leaks in the system, the pump assembly 1010 can be configured to perform multiple cycles of pump monitoring and reactivation. During this operational flow, the pump assembly can be configured to indicate to the user that the pump assembly is operating normally. As shown at 1060b, the pump assembly can be operated, or an OK indicator 1062, shown as 1062b, can blink or blink. In addition, the pump assembly can deactivate the bandage indicator 1064 and battery indicator 1066, shown as 1064b and 1066b, respectively. The pump assembly may be configured to continuously or periodically determine whether the pump is delivering too often, as shown in box 1810. As shown, in some embodiments, the pump assembly can be configured to use a duty cycle as an alternative to determining whether the pump is delivering too often. For example, the pump assembly can be configured to determine whether or not the pump is "overworked", so that the pump can be used while exceeding a threshold duration, such as 9% of the total treatment time. It is determined whether it is on. In other words, the pump assembly can be configured to determine whether the pump duty cycle reaches or exceeds the duty cycle threshold.

In some embodiments, the pump assembly is overworked for a certain duration (eg, the pump is on for more than about 2 hours a day, or is on for more than a predetermined amount of time). If the desired negative pressure level (for example, the value of the second negative pressure set value) is established, the pump operation is postponed or paused. can do. As shown in box 1812, the pump assembly can be configured to determine whether the pump has been overworked for a duration of 30 minutes or more. For example, the pump assembly can be configured to determine whether the duty cycle (s) monitored over the past 30 minutes exceeds a duty cycle threshold. For example, the pump assembly can determine whether the pump has been on for about 2 minutes 42 seconds or more in the last 30 minutes, which corresponds to a 9% duty cycle threshold.

In some embodiments, the pump assembly can be configured to suspend or postpone therapy if it is determined that the pump is overworked, as shown in box 1814. The pump assembly may be further configured to turn on a "leak alarm" indicator. As shown at 1060c, operating the pump assembly or blinking or blinking the bandage indicator 1064, shown as 1064b, and deactivating the OK indicator 1062 and battery indicator 1066, shown as 1062c and 1066c, respectively. it can. In order to resume treatment, the user may need to straighten the bandage, correct the leak, and / or operate the pump again. In some embodiments, the pump can be run again by pressing a start or run button on the pump, such as due to a timeout.

If one or more leaks are present in the bandage, in some embodiments, the pump assembly 1000 does not reach the second negative pressure setpoint value after a predetermined amount of pump operating time. In addition, the treatment can be programmed to be postponed or suspended, or otherwise configured as such. For example, in some embodiments, if the pump has been running continuously for X minutes and the pressure value of the second negative pressure setpoint has not been reached, the pump assembly may include an LED indicator, a "leak detection" LED indicator. Alarms, which can include 1064, or other alarms, can be activated to pause treatment. In some embodiments, the predetermined amount of time is about 5% of the total planned duration of the negative pressure treatment of the system, or about 0% or less to about 15 of the total planned duration of the negative pressure treatment of the system. % Or more. In some embodiments, the predetermined amount of time can be about 9 minutes, or about 4 minutes or less to about 40 minutes or more, or about 6 minutes to about 10 minutes.

FIG. 31 illustrates a non-limiting example of operation 1900 of some embodiments of pump assembly 1000 in the presence of a very large amount of leakage. As described above with respect to FIG. 29, the pump assembly can be configured to establish a desired negative pressure level under the bandage 1010, as shown in box 1902. In some embodiments, when the pressure level below the bandage 1010 reaches a desired value, the pump assembly may deactivate the pump and monitor the pressure level below the bandage, as shown in box 1904. Can be configured. The pump assembly can be configured to periodically or continuously monitor the pressure level under the bandage 1010, for example, by reading or sampling the sensor 1070. Based on the monitored pressure level, the pump assembly may determine whether the pump needs to be operated or restarted to re-establish the desired negative pressure level under the bandage 1010. it can. If it is determined that the monitored pressure level is low (eg, less than or equal to the first negative pressure setpoint value), the pump assembly is configured to operate the pump, as shown in box 1908. Can be configured. During this operational flow, the pump assembly can be configured to indicate to the user that the pump assembly is operating normally. As shown at

1060d, the pump assembly can be operated, or the OK indicator 1062, shown as 1062d, can blink or blink. In addition, the pump assembly can deactivate the bandage indicator 1064 and battery indicator 1066, shown as 1064d and 1066d, respectively.

In some embodiments, one or more leaks (eg, leaks having a relatively very high flow rate) cause the pump assembly to have a desired negative pressure level and / or a second negative pressure under the bandage 1010. The pressure setpoint value may not be reached. If the desired negative pressure level under the bandage has not been reached after a predetermined amount of operating time, the pump assembly can be configured to postpone or pause the pump, as shown in box 1914. For example, this can be accomplished by transitioning to a wait state 1270. In some embodiments, the predetermined amount of pumping time can be 10 seconds (as shown in FIG. 31). In some embodiments, the predetermined amount of pumping time can be about 5 seconds or less to about 60 seconds or more.

In some embodiments, the pump assembly can be configured to provide a limited number of retry cycles before suspending or delaying treatment. As shown in boxes 1920, 1922, and 1924, the pump assembly may be reactivated three times before deferring or suspending treatment (1914) and / or before operating an alarm such as a "leak alarm". It can be configured to go through a trial cycle. Some embodiments of the pump assembly may go through two retry cycles, four retry cycles, etc. prior to treatment suspension and / or alarm action. As shown at 1060e, operating the pump assembly or blinking or blinking the bandage indicator 1064, shown as 1064e, and deactivating the OK indicator 1062 and battery indicator 1066, shown as 1062e and 1066e, respectively. it can

FIG. 32 illustrates a non-limiting example of operation 2000 of some embodiments of pump assembly 1000 in the presence of a very large amount of leakage. The pump assembly can be configured to quickly enter a suspend or postpone mode of treatment to avoid draining the battery in an attempt to deal with high flow leaks. As shown in box 2001, the pump assembly can be turned on, which can be accomplished, for example, by transitioning to operational state category 1250. As described above with respect to FIG. 29, the pump assembly can be configured to establish a desired negative pressure level under the bandage 1010, as shown in box 2002.

In some embodiments, if the leak is very high, such as when the pump is turned on but not yet connected to the bandage or is not properly connected to the bandage, the pump assembly may be Attempts to bring the lower pressure closer to the desired negative pressure level (eg, approximately the value of the second negative pressure setpoint, or a value that is within the interval between the first and second negative pressure setpoint values). However, it can be configured to operate for a predetermined amount of time. The pump assembly can be configured to postpone or pause treatment after a predetermined amount of time has elapsed. For example, this can be accomplished by transitioning to a wait state 1270. As shown, the pump assembly can be configured to operate the pump for 39 seconds. During this period, if the pressure under the bandage 1010 is not approaching the desired negative pressure, the pump assembly may be engaged for another predetermined amount of time (eg, 15 seconds as shown in FIG. 32). A timeout mode 2020 can be entered. During this operational flow, the pump assembly can be configured to indicate to the user that the pump assembly is operating normally. As shown at 1060f, the pump assembly can be operated or the OK indicator 1062 shown as 1062f can blink or blink. In addition, the pump assembly can deactivate the bandage indicator 1064 and battery indicator 1066, shown as 1064f and 1066f, respectively.

In some embodiments, the pump assembly can be configured to provide a limited number of retry cycles to establish a desired negative pressure level under the bandage 1010. As shown, after the first trial (or any number of additional trials), the pump assembly establishes or reestablishes the desired negative pressure level under the bandage, as shown in box 2002. It can be constituted as follows. In some embodiments, as shown in box 2014, after the first trial, the pressure under the bandage 1010 is at a desired level (eg, approximately the value of the second negative pressure setpoint, or the first and second values). If the pump assembly operates for another predetermined amount of time without approaching a value that is within the interval between the negative pressure setpoint values, the pump assembly is treated without retrying the pump down. Can be configured to be postponed or suspended. The pump assembly can be configured to remain in a postponed or paused state until the pump assembly is reactivated (eg, by a user pressing a button due to a timeout). The pump assembly can be configured to operate an alarm in this state. During this operational flow, the pump assembly can be configured to indicate to the user that one or more leaks are present. Operate the pump assembly or blink or blink the bandage indicator 1064, shown as 1064g, and deactivate the OK indicator 1062 and battery indicator 1066, shown as 1062g and 1066g, respectively, as shown at 1060g. It can.

Throughout the description and claims throughout this specification, the terms "comprise" and "contain", as well as variations of that term, eg, "comprising" and "comprises" include "but are not limited to". Means "including but not limited to" and is not intended (and not excluded) to exclude other parts, additions, components, integer values, or steps.

Throughout the description and claims, the singular includes the plural unless the context dictates otherwise. In particular, where indefinite articles are used, this specification should be understood as contemplating plural as well as singular unless the context requires otherwise. Further, in some embodiments, the term about is meant to refer to a value within 10% of the value presented, unless otherwise presented herein.

Any values provided herein, such as thresholds, limits, durations, timeouts, retry counts, etc. are not intended to be absolute values and can thus be approximate. In addition, any thresholds, limits, durations, timeouts, retry counts, etc. provided herein are fixed or can be changed automatically or by the user. Further, as used herein, relative terms such as greater than, greater than, less than, etc. with respect to a reference value are also intended to encompass being equal to the reference value. . For example, exceeding a reference value that is positive can encompass being equal to or greater than the reference value.

A feature, integer value, property, compound, chemical moiety, or group described in conjunction with a particular aspect, embodiment, or example is not incompatible with any other aspect described herein, it should be understood that it is applicable to the embodiments or examples. All of the features disclosed in this specification (including any appended claims, abstracts, and drawings) and / or all of the steps of any method or process disclosed in this specification are such features and / or Or it may be combined in any combination except combinations where at least some of the steps are mutually exclusive. Protection is not limited to the details of any of the above embodiments. Protection is disclosed to any novel or any novel combination of features disclosed herein (including any appended claims, abstracts, and drawings), or disclosed herein. Extends to any new or any new combination of steps of any method or process.

Although specific embodiments have been described, these embodiments have been presented by way of example only and are not intended to limit the scope of protection. Indeed, the novel methods and systems described herein may be embodied in various other forms. In addition, various omissions, substitutions, and changes may be made in the form of the methods and systems described herein. One skilled in the art will recognize that in some embodiments, the actual steps performed in the illustrated and / or disclosed process may differ from those shown in the drawings. Depending on the embodiment, certain of the above steps may be removed and others may be added. Accordingly, the scope of the present disclosure should be defined only by reference to the appended claims. The appended claims and their equivalents are intended to cover forms or modifications that fall within the scope and spirit of protection. For example, the various components shown in the drawings may be implemented as software and / or firmware in a processor, controller, ASIC, FPGA, and / or dedicated hardware. Moreover, the features and attributes of the specific embodiments described above may be combined in different ways to form additional embodiments, all of which are within the scope of this disclosure. While this disclosure provides certain preferred embodiments and applications, other embodiments that will be apparent to those skilled in the art are also disclosed, including embodiments that do not provide all of the features and advantages described herein. It is in the range. Accordingly, the scope of the present disclosure should be defined only by reference to the appended claims.

100 Depressurized Wound Treatment Device 102 Wound Dressing 104 Pump Assembly 106 Conduit 106a First End 106b Second End 108 Port 112 Connector 114 Conduit 114a Connector 120 Housing 120a First Housing Member 120b Second Housing Member 120c Guide, Channel 121 Tab 122 Control button 123 Depression 124 Battery cover 124a Latch, Tab member 124b Guide, Protrusion 124c Depression 124d Protrusion 125 Battery contact 126 Connector 132 Light 140 Conduit 142 Battery 148 Seal strip 150 First packaging element 151 Cover 153 Peripheral portion 190, 192, 193, 194, 196, 200a, 200b Recess 195 Raised 220 Battery compartment 222

Battery contact 224 Electric wire 230 Control panel 232 Pump 240 Manifold 246 One-way flow valve 250 Inlet port 252 Outlet port 260 Port 261 Opening 262 Conduit 270 Fastener 272 Label 300, 310, 320, 330, 340, 350, 360, 365, 370, 380, 390, 395, 400, 405, 410, 420 Packaging element 1000 Pump assembly 1002 Button 1020 Housing 1030 One-way flow valve 1040 Control panel 1050 Connector 1060, 1062, 1064, 1066 Indicator 1070 Pressure sensor 1080 Battery cover 1090 Negative pressure Source 1092 Electric motor 1100 Battery compartment 1110 Outlet 1120 Inlet 1130 Battery cell, power source 1140 Module 1150 Input / output module Lumpur 1160 controller 1170 memory

Patent Citations (70)

Publication number	Priority date	Publication date	Assignee	Title
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JP2009509695A *	2005-10-03	2009-03-12	ケーシーアイライセンシングインコーポレイテッド	Patient interface system and method applied from outside
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JP2012508621A *	2008-11-14	2012-04-12	ケーシーアイライセンシングインコーポレイテッド	Fluid sac, system, and method for accumulating fluid from a tissue site
JP2012509723A *	2008-11-25	2012-04-26	スパイラセュアインコーポレイテッド	Device for delivering reduced pressure to the body surface
JP2012523915A *	2009-04-14	2012-10-11	ケーシーアイライセンシングインコーポレイテッド	Reduced pressure treatment system and method using variable cover
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Family To Family Citations				
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Priority And Related Applications

Child Applications (1)

Application	Priority date	Filing date	Relation	Title
JP2016033770A	2016-03-01	2016-03-01	Division	Pressure reduction treatment device and use method thereof

Priority Applications (1)

Application	Priority date	Filing date	Title
PCT/IB2011/002943	2011-11-02	2011-11-02	Reduced pressure therapy apparatuses and methods of using same

Legal Events

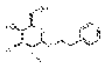
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2014-11-05	A521	Request for written amendment filed	**Free format text**: JAPANESE INTERMEDIATE CODE: A523 **Effective date**: 20141104
2014-11-05	A621	Written request for application examination	**Free format text**: JAPANESE INTERMEDIATE CODE: A621 **Effective date**: 20141104
2015-09-29	A131	Notification of reasons for refusal	**Free format text**: JAPANESE INTERMEDIATE CODE: A131 **Effective date**: 20150928
2015-10-01	A977	Report on retrieval	**Free format text**: JAPANESE INTERMEDIATE CODE: A971007 **Effective date**: 20150930
2015-12-25	A523	Request for written amendment filed	**Free format text**: JAPANESE INTERMEDIATE CODE: A523 **Effective date**: 20151225
2016-01-26	TRDD	Decision of grant or rejection written	
2016-02-02	A01	Written decision to grant a patent or to grant a registration (utility model)	**Free format text**: JAPANESE INTERMEDIATE CODE: A01 **Effective date**: 20160201
2016-03-10	A61	First payment of annual fees (during grant procedure)	**Free format text**: JAPANESE INTERMEDIATE CODE: A61 **Effective date**: 20160302
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2019-07-17	R350	Written notification of registration of transfer	**Free format text**: JAPANESE INTERMEDIATE CODE: R350
2020-02-28	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
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sterilization and disinfection	claims,description	63	0.000
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absorbent	claims,description	56	0.000
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polysiloxane	claims,description	14	0.000
water 	claims,description	11	0.000
biological transmission	claims,description	9	0.000
fabric	claims,description	7	0.000
Bacteria	claims,description	6	0.000
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coupling reaction	claims	1	0.000

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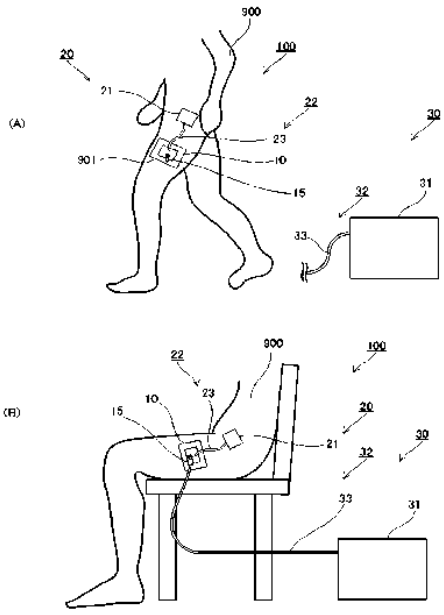
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添付公開書類:
— 国際調査報告（条約第 21 条(3)）

(54) Title: NEGATIVE-PRESSURE CLOSURE THERAPY DEVICE

(54) 発明の名称 : 陰圧閉鎖治療装置



(57) Abstract: Provided is a negative-pressure closure therapy device with which an adequate suction flow rate can be used to apply, when necessary, negative pressure to a closed space formed by a wound dressing and a wound area, even if a pump device is miniaturized. In this therapy device (100), a pump device (30) having a high suction flow rate is fitted to a wound dressing (10) at times of extraordinary use when a high suction flow rate is necessary, and air is sucked from a closed space (904) formed by a wound area (903) and the wound dressing (10). Accordingly, an adequate suction flow rate can be ensured at times of extraordinary use, even if a pump device (20) for everyday use is miniaturized and the suction flow rate of the pump device (20) is reduced. As a result, the pressure value of the closed space (904) can be reduced to a desired value more swiftly.

(57) 要約: ポンプ装置が小型化されても、必要なときに十分な吸引流量で創傷包帯及び創傷部位によって形成される閉鎖空間を陰圧にする陰圧閉鎖治療装置を提供する。 治療装置（１００）は、多くの吸引流量が必要な非日常使用時に、吸引流量が多いポンプ装置（３０）が、創傷包帯（１０）に装着されて、創傷部位（９０３）及び創傷包帯（１０）によって形成される閉鎖空間（９０４）から気体を吸引するため、日常的使用のためのポンプ装置（２０）が小型化されてポンプ装置（２０）の吸引流量が少なくなっても、非日常使用時に十分な吸引流量を確保することができる。その結果、閉鎖空間（９０４）の圧力値は、より早く所望値まで低下する。

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明　細　書

発明の名称 ： 陰圧閉鎖治療装置

技術分野

[0001] 本発明は、創傷部位の表面に陰圧をかけることにより、創傷部位の回復を促進させるための陰圧閉鎖治療装置に関する。

背景技術

[0002] 近年、創傷部位の表面に陰圧をかけることにより、創傷部位の回復を促進させる陰圧閉鎖治療が知られている。例えば、特許文献１には、創傷部位を覆う創傷包帯と、創傷包帯及び創傷部位によって形成される閉鎖空間から気体を吸引するポンプ装置と、を備える陰圧閉鎖治療装置が開示されている。特許文献１に記載の陰圧閉鎖治療装置は、ポンプ装置が閉鎖空間から気体を吸引することにより、当該閉鎖空間を陰圧にする。

[0003] また、特許文献１に記載の陰圧閉鎖治療装置では、ポンプ装置は、創傷部位の表面から滲み出た滲出液も吸引する。吸引された滲出液は、貯留部（収集キャニスタ）で貯留される。

[0004] 特許文献１に記載の陰圧閉鎖治療装置に限らず、利用者への装着を鑑みると、陰圧閉鎖治療装置のポンプ装置は、小型であることが望ましい。利用者は、ポンプ装置が小型であれば、例えばポンプ装置を携行して使用することができる。

先行技術文献

特許文献

[0005] 特許文献1：特開２０１３－２５５８２４号公報

発明の概要

発明が解決しようとする課題

[0006] しかしながら、ポンプ装置は、小型化されると、吸引を実現するポンプも小型化されるため吸引流量が低下してしまう。その結果、ポンプ装置の吸引流量は、当該ポンプ装置が小型化されると、閉鎖空間をより早く陰圧にする

ことが必要なときに、足りなくなる場合がある。

[0007] 同様に、滲出液を貯留する貯留部は、小型化されると、貯留容量が少なくなってしまう。その結果、貯留部の貯留容量は、当該貯留部が小型化されると、滲出液を多く貯留する必要があるときに、足りなくなる場合がある。

[0008] そこで、本発明の目的は、ポンプ装置が小型化されても、必要なときに十分な吸引流量で創傷包帯及び創傷部位によって形成される閉鎖空間を陰圧にする陰圧閉鎖治療装置を提供することにある。

課題を解決するための手段

[0009] 本発明の陰圧閉鎖治療装置は、主面の外周部が創傷部位の外周の皮膚表面に密着することで、該主面の中央部及び前記創傷部位の間に閉鎖空間を形成する創傷包帯と、前記創傷包帯に装着される第１流路と、前記閉鎖空間に前記第１流路を介して連通する第１吸引口と、を有する第１ポンプ装置と、前記創傷包帯に着脱自在に装着される第２流路と、前記閉鎖空間に前記第２流路を介して連通する第２吸引口と、を有する第２ポンプ装置と、を備える。

[0010] そして、前記第２ポンプ装置の吸引流量は、前記第１ポンプ装置の吸引流量より多く、前記第１ポンプ装置は、前記第１流路及び前記第１吸引口を介して前記閉鎖空間から流体を吸引し、前記第２ポンプ装置は、前記第２流路が前記創傷包帯に装着されているとき、前記第２流路及び前記第２吸引口を介して前記閉鎖空間から流体を吸引する。

[0011] 第１ポンプ装置の吸引流量が第２ポンプ装置の吸引流量より少ないため、第１ポンプ装置の吸引を実現するポンプは、第２ポンプ装置のポンプに比べて小型で済む。従って、第１ポンプ装置は第２ポンプ装置に比べて小型に実現可能である。

[0012] 例えば、利用者の日常的な使用のために第１ポンプ装置は駆動して閉鎖空間から流体を吸引し、利用者の非日常的な使用のために第２ポンプ装置を駆動して閉鎖空間から流体を吸引する。

[0013] 陰圧閉鎖治療装置の日常的な使用とは、閉鎖空間から吸引される流体の流量（吸引流量）が少なくてよいときの使用である。例えば、利用者は、既に

閉鎖空間が十分に陰圧になっているときに、陰圧閉鎖治療装置の日常的な使用として、第２流路を創傷包帯から取り外し、小型に実現可能な第１ポンプ装置を使用する。すなわち、利用者は、陰圧閉鎖治療装置の日常的な使用では、第２ポンプ装置を創傷包帯から取り外して、第１ポンプ装置のみを使用する。陰圧閉鎖治療装置の非日常的な使用とは、多くの吸引流量を必要とする使用である。例えば、利用者は、非日常的な使用として、創傷包帯を創傷部位に装着したばかりで、閉鎖空間をより早く陰圧にする必要があるときに、第２流路を創傷包帯に装着することにより、吸引流量が多い第２ポンプ装置を使用する。

[0014] 本発明の陰圧閉鎖治療装置は、多くの吸引流量が必要なときに、吸引流量が多い第２ポンプ装置が創傷包帯に装着されて、創傷部位及び創傷包帯によって形成される閉鎖空間から流体を吸引するため、利用者の日常的な使用のための第１ポンプ装置が小型化されても、必要なときに十分な吸引流量を確保して当該閉鎖空間を陰圧にすることができる。

[0015] また、前記第２流路が前記創傷包帯に装着されているとき、前記第１ポンプ装置及び前記第２ポンプ装置は、同時に駆動する態様であっても構わない。

[0016] これにより、陰圧閉鎖治療装置は、第２ポンプ装置の吸引流量が第１ポンプ装置の吸引流量を補助するため、必要なときにより多くの吸引流量を確保することができる。

[0017] また、本発明は、第２ポンプ装置の吸引流量が第１ポンプ装置より多いことに限らず、単に、前記第２流路が前記創傷包帯に装着されているとき、前記第１ポンプ装置及び前記第２ポンプ装置は、同時に駆動する態様であっても構わない。

[0018] 例えば、利用者は、第１ポンプ装置の吸引流量と第２ポンプ装置の吸引流量とが等しくても、非日常的使用時に第２ポンプ装置を補助的に使用する。

[0019] また、第１ポンプ装置は、前記第１流路の途中に設けられ、液体を貯留する第１貯留部を備え、第２ポンプ装置は、前記第２流路の途中に設けられ、

液体を貯留する第２貯留部を備え、前記第２貯留部の貯留容量は、前記第１貯留部の貯留容量より多くてもよい。

[0020] 第２貯留部は、第２流路が創傷包帯に着脱自在であるため、創傷包帯に着脱自在である。この構成では、陰圧閉鎖治療装置は、吸引流量が必要なときに、十分な吸引流量を確保するだけでなく、創傷部位からの滲出液を第２貯留部に貯留することにより、必要なときに十分な貯留容量を確保することもできる。

[0021] また、陰圧閉鎖治療装置は、前記創傷包帯に装着される第３流路と、前記第３流を介して前記閉鎖空間に連通し、前記創傷部位の洗浄用の洗浄液を貯留する第３貯留部と、を有する洗浄器具、を備えてもよい。

[0022] 洗浄液は、第３流路から閉鎖空間を介して第１流路及び第２流路へ順に流れることにより、創傷部位を洗浄する。この態様では、陰圧閉鎖治療装置は、洗浄液の流量が必要なときに第２ポンプ装置が駆動するため、第１ポンプ装置が小型化されても、十分な流量の洗浄液で閉鎖空間の創傷部位を洗浄することができる。

[0023] また、第１ポンプ装置を小型化するためには、以下のように構成するとよい。例えば、前記第１ポンプ装置は、圧電素子によって駆動するポンプ、を備える。

[0024] すなわち、第１ポンプ装置は、小型化のために、圧電ポンプを備えることが望ましい。圧電ポンプは、例えば、圧電素子と、当該圧電素子に接合される振動板と、を備える。圧電素子は、交番電圧が印加されると、主面の面方向に沿った伸縮を繰り返す。圧電素子は、主面の面方向に沿った伸縮を繰り返すと、接合された振動板を屈曲振動させる。圧電ポンプは、電磁ポンプ等に比べて小型化が容易である。また、圧電ポンプは、電磁ポンプ等に比べて振動が小さい点においても優れる。さらに、交番電圧の周波数を２０ｋＨｚ以上にすれば、振動板の振動音は、可聴周波数帯域外の２０ｋＨｚ以上となるため、利用者に聞こえにくくなる。

発明の効果

[0025] この発明の陰圧閉鎖治療装置は、吸引流量が必要なときに、第２ポンプ装置が創傷包帯に装着されて、創傷部位及び創傷包帯によって形成される閉鎖空間から流体を吸引するため、第１ポンプ装置が小型化されても、必要なときに十分な吸引流量を確保して当該閉鎖空間を陰圧にすることができる。

図面の簡単な説明

[0026] [図1]実施形態１に係る治療装置の上面側からの斜視図である。

[図2]実施形態１に係る治療装置の創傷包帯の装着時の側面断面図である。

[図3]実施形態１に係る治療装置の第１ポンプ装置の本体部の構成の一部を示すブロック図である。

[図4]（Ａ）は、実施形態１に係る治療装置の日常的な使用を説明するための図であり、（Ｂ）は、当該治療装置の非日常的な使用を説明するための図である。

[図5]実施形態１に係る治療装置の変形例に係る治療装置の非日常的な使用を説明するための図である。

[図6]実施形態２に係る治療装置の非日常的な使用を説明するための図である。

[図7]実施形態３に係る治療装置の創傷包帯の上面側からの斜視図である。

[図8]実施形態３に係る治療装置の非日常的な使用を説明するための図である。

発明を実施するための形態

[0027] 実施形態１に係る治療装置１００について、図１、図２、及び図３を用いて説明する。なお、図２は、治療装置１００の創傷包帯１０と生体内部９０２とを断面した図であるが、創傷包帯１０の断面のみを薄墨に示し、生体内部９０２を薄墨に示していない。また、図１及び図２において、高さ方向を上側とし、高さ方向と反対方向を下側とする。

[0028] 治療装置１００は、創傷部位の表面に陰圧をかけることにより、創傷部位の回復を促進する陰圧閉鎖治療のためのものである。

[0029] 図１に示すように、治療装置１００は、創傷包帯１０、ポンプ装置２０（

第１ポンプ装置に相当する。）、及びポンプ装置３０（第２ポンプ装置に相当する。）を備えている。

[0030] 図２に示すように、創傷包帯１０は、フィルム１１、吸収部材１７、ガーゼ１８、及び被覆部材１９を備えている。

[0031] フィルム１１は、液体及び気体の通過を防止する。吸収部材１７は、液体を吸収し、吸収した液体を保持する。吸収部材１７としては、例えば、綿、及び高給水性高分子が分散されてなるゲル、等が利用可能である。被覆部材１９は、液体を通過させる多孔質材料である。被覆部材１９としては、成形しやすいポリウレタンフォーム、等が利用可能である。

[0032] 図２に示す装着例では、ガーゼ１８は、創傷包帯１０の面方向（幅方向及び奥行方向）において、範囲９０３に示す創傷部位（以下、創傷部位９０３と称す。）より内側の創傷床９０５の表面に当接する。被覆部材１９は、創傷床９０５の形状に応じて成形された後、創傷床９０５を埋めるようにガーゼ１８より上側に配置されている。吸収部材１７は、被覆部材１９より上側に配置されている。フィルム１１は、吸収部材１７及び創傷部位９０３を上側から覆うように配置されている。具体的には、フィルム１１は、創傷包帯１０の平面視において、下面の外周部が、創傷部位９０３より外側の皮膚表面９０１に貼り付けられている。これにより、創傷包帯１０は、フィルム１１の中央部１２（外周部より内側の領域）と、創傷部位９０３と、の間に閉鎖空間９０４を形成している。

[0033] 図１に示すように、ポンプ装置２０は、本体部２１と、流路２２と、を備えている。流路２２の説明は後述する。

[0034] 図３に示すように、ポンプ装置２０の本体部２１は、圧電ポンプ２５、圧力センサ２６、及び制御部２７を備えている。圧電ポンプ２５、圧力センサ２６、及び制御部２７は、共通のＢＵＳに電気的に接続されている。なお、圧電ポンプ２５、圧力センサ２６、及び制御部２７は、本体部２１に備えられるバッテリからの電力供給によって動作する。

[0035] 圧電ポンプ２５は、第１主面及び第２主面を有する振動板と、当該振動板

の第１主面及び第２主面の少なくとも一方の主面に設けられる圧電素子（いずれも不図示）と、を備えている。当該圧電素子に交番電圧が印加されると、圧電素子は、主面方向に伸縮を繰り返す。振動板は、圧電素子の伸縮の繰り返しに伴って、屈曲振動する。圧電ポンプ２５は、振動板の屈曲振動を利用して、吸引口から吐出口へ気体を輸送する。

[0036] 圧電ポンプ２５は、電流と磁場とを利用した電磁ポンプ等に比べて、小型かつ低背である。ポンプ装置２０の本体部２１は、小型かつ低背である圧電ポンプ２５を備えることにより、利用者が携行しやすいように小型かつ薄型に実現されている。

[0037] また、圧電ポンプ２５の振動は、電磁ポンプ等の振動に比べて小さい。さらに、圧電ポンプ２５の圧電素子に印加される交番電圧を可聴周波数帯域より高い周波数（例えば２０ｋＨｚ以上）とすれば、圧電ポンプ２５の振動音は、利用者に聞こえにくくなる。

[0038] 圧力センサ２６は、圧電ポンプ２５の吸引口の圧力値を検出する。圧力センサ２６は、検出した圧力値に応じた検出信号を制御部２７に出力する。制御部２７は、圧力センサ２６からの検出信号に示す圧力値を用いて、圧電ポンプ２５の吸引口の圧力値が７５ｍｍＨｇから１２５ｍｍＨｇの範囲になるように、圧電ポンプ２５の駆動をフィードバック制御する。ただし、圧力センサ２６は、圧電ポンプ２５の吸引口に限らず、当該吸引口に連通する空間であれば、いずれの位置の圧力値を検出しても構わない。

[0039] 図１に戻り、ポンプ装置３０は、本体部３１と、流路３２と、を備えている。ポンプ装置３０の本体部３１は、例えば、電磁ポンプ（不図示）を備えている。電磁ポンプは、ポンプ装置２０の圧電ポンプ２５に比べて、大型である。従って、ポンプ装置３０の吸引流量（ｍｌ／ｓ）は、ポンプ装置３０の吸引を実現する電磁ポンプが圧電ポンプ２５より大型であるため、ポンプ装置２０の吸引流量よりも多くなっている。ただし、ポンプ装置３０は、電磁ポンプに代えて、例えば並列駆動する複数の圧電ポンプ２５を備えてもよい。

[0040] 次に、ポンプ装置２０の流路２２と、ポンプ装置３０の流路３２とについて説明する。図１及び図２に戻り、流路２２は、閉鎖空間９０４から圧電ポンプ２５の吸引口までである。流路２２の一部は、ゴム管２３の一端がフィルム１１の中央部１２に装着され、他端が本体部２１に装着されることによって、形成されている。

[0041] 流路３２は、閉鎖空間９０４から本体部３１の電磁ポンプの吸引口までである。流路３２の一部は、ゴム管３３の一端がフィルム１１の中央部１２に装着され、他端が本体部３１に装着されることによって、形成されている。

[0042] 流路３２について、より具体的には、創傷包帯１０は、図２に示すように、取付口１３を備えている。取付口１３は、フィルム１１の中央部１２に形成されている。取付口１３は、逆止弁１４と、ジョイント管１５とを備えている。逆止弁１４は、閉鎖空間９０４への流体の流れを防止する。ジョイント管１５は、例えば内径がゴム管３３の外径に略等しい。ゴム管３３の一端は、ジョイント管１５管に挿嵌されている。

[0043] ポンプ装置３０の流路３２は、ジョイント管１５に対するゴム管３３の挿抜によって、創傷包帯１０に着脱自在である。ただし、流路３２の創傷包帯１０への着脱は、ジョイント管１５を用いず、他の方法で実現されても構わない。

[0044] 治療装置１００は、圧電ポンプ２５の吸入口及びポンプ装置３０の電磁ポンプの吸入口に液体が流入することを防止するために、液体を通過させず、気体のみを通過させるフィルタ１６を２枚備えている。図２に示す例では、一方のフィルタ１６は、閉鎖空間９０４においてゴム管２３の口を覆うように配置され、他方のフィルタ１６は、閉鎖空間９０４において取付口１３を覆うように配置されている。

[0045] 次に、治療装置１００の使用について、図４（Ａ）及び図４（Ｂ）を用いて説明する。ここで、利用者９００による治療装置１００の日常的な使用とは、閉鎖空間９０４から吸引される流体の流量（以下、吸引流量と称す。）が少なくてよいときの使用とする。例えば、利用者９００は、創傷床９０５

の表面からの滲出液が少ないとき、治療装置１００を日常的に使用する。また、例えば、利用者９００は、既に創傷部位９０３の表面に十分に陰圧がかかっているときに、治療装置１００を日常的に使用する。

[0046] 利用者９００による治療装置１００の非日常的な使用とは、多くの吸引流量を必要とするときの使用とする。例えば、利用者９００は、創傷包帯１０が皮膚表面９０１に装着されたばかりで、閉鎖空間９０４をより早く陰圧にする必要があるときに、治療装置１００を非日常的に使用する。また、利用者９００は、創傷床９０５の表面からの滲出液が多いときに、治療装置１００を非日常的に使用する。

[0047] 図４（Ａ）に示すように、治療装置１００の日常使用では、ポンプ装置３０の流路３２は、ゴム管３３がジョイント管１５から挿去されることによって、創傷包帯１０から取り外される。治療装置１００の日常使用では、ポンプ装置２０は、圧電ポンプ２５を駆動させることにより、流路２２を介して閉鎖空間９０４から気体を吸引する。すると、閉鎖空間９０４の圧力値は、徐々に低下する。

[0048] 図４（Ｂ）に示すように、治療装置１００の非日常使用では、ポンプ装置３０の流路３２は、ゴム管３３がジョイント管１５に挿嵌されることによって、創傷包帯１０に装着される。治療装置１００の非日常使用では、ポンプ装置３０は、流路３２を介して閉鎖空間９０４から気体を吸引する。すると、閉鎖空間９０４の圧力値は、徐々に低下する。

[0049] なお、創傷床９０５からの滲出液は、陰圧側に配置される吸収部材１７へ流れ、吸収部材１７に吸収されて保持される。

[0050] 上述したように、ポンプ装置３０の吸引流量は、ポンプ装置２０の吸引流量より多い。閉鎖空間９０４が十分に陰圧（例えば圧力値が１００ｍｍＨｇ）となるまでの時間は、ポンプ装置２０及びポンプ装置３０の吸引流量に依存する。より多い吸引流量で閉鎖空間９０４から気体が吸引されると、閉鎖空間９０４の圧力値はより早く低下する。

[0051] 本実施形態に係る治療装置１００は、多くの吸引流量が必要な非日常使用

時に、吸引流量が多いポンプ装置３０が、創傷包帯１０に装着されて、創傷部位９０３及び創傷包帯１０によって形成される閉鎖空間９０４から気体を吸引するため、日常的使用のためのポンプ装置２０が小型化されてポンプ装置２０の吸引流量が少なくなっても、非日常使用時に十分な吸引流量を確保することができる。その結果、閉鎖空間９０４の圧力値は、より早く所望値まで低下する。

[0052] なお、治療装置１００では、非日常使用時に、ポンプ装置３０と、ポンプ装置２０と、は、同時に駆動してもよい。すなわち、ポンプ装置３０は、ポンプ装置２０の吸引流量を補助するように、ポンプ装置２０の駆動と同時に駆動してもよい。これにより、閉鎖空間９０４の圧力値はさらに早く所望値まで低下する。

[0053] また、治療装置１００は、１台のポンプ装置３０に限らず、２台以上のポンプ装置３０を備えてもよい。この場合、２台以上のポンプ装置３０は、非日常使用時にそれぞれ駆動する。さらに、２台以上のポンプ装置３０は、非日常使用時に、ポンプ装置２０の駆動と同時に駆動してもよい。

[0054] 上述の例では、非日常使用時に駆動するポンプ装置３０は、ポンプ装置２０よりも吸引流量が多かったが、非日常使用時に２台以上のポンプ装置が同時に駆動すれば、非日常使用時のみに駆動するポンプ装置の吸引流量は、日常使用時に駆動するポンプ装置の吸引流量と等しいか、又は、日常使用時に駆動するポンプ装置の吸引流量より少なくてもよい。

[0055] 例えば、図５の変形例に示すように、治療装置１００Ａは、ポンプ装置３０に代えて、ポンプ装置２０Ａを備えている。ポンプ装置２０Ａは、流路３２Ａ以外の各構成がポンプ装置２０と同じである。すなわち、ポンプ装置２０Ａの吸引流量は、ポンプ装置２０の吸引流量に等しい。流路３２Ａは、閉鎖空間９０４から、ポンプ装置２０Ａの本体部２１の圧電ポンプ２５の吸引口までである。この流路３２Ａの一部は、ゴム管３３Ａによって形成されている。ゴム管３３Ａの一端は、ジョイント管１５に挿抜自在である。

[0056] 利用者９００は、治療装置１００Ａの非日常使用時に、ゴム管３３Ａの一

端をジョイント管１５に挿嵌することにより、ポンプ装置２０Ａの流路３２Ａを創傷包帯１０に装着する。治療装置１００Ａは、ポンプ装置２０Ａの吸引流量がポンプ装置２０の吸引流量と等しくても、ポンプ装置２０の吸引流量をポンプ装置２０Ａの吸引流量で補助するため、非日常使用時に十分な吸引流量を確保することができる。

[0057] 次に、実施形態２に係る治療装置１００Ｂについて、図６を用いて説明する。上述の例では、創傷床９０５の表面からの滲出液を吸収して保持する吸収部材１７は、閉鎖空間９０４に配置されていたが、実施形態２に係る治療装置１００Ｂは、当該滲出液を貯留するキャニスタ２８（第１貯留部に相当する。）及びキャニスタ３４（第２貯留部に相当する。）を閉鎖空間９０４の外部に備えるものである。実施形態１と重複する構成の説明は省略する。

[0058] 図６に示すように、具体的には、治療装置１００Ｂは、創傷包帯１０Ｂと、ポンプ装置２０Ｂと、ポンプ装置３０Ｂと、を備えている。なお、図６は、滲出液の貯留を説明するためにキャニスタ３４のみを断面して示している。

[0059] 創傷包帯１０Ｂは、２枚のフィルタ１６を省略した点において、実施形態１に係る創傷包帯１０と相違する。

[0060] ポンプ装置２０Ｂは、本体部２１と、流路２２Ｂと、キャニスタ２８と、を備えている。流路２２Ｂは、途中にキャニスタ２８が設けられる点と、滲出液が流れる点と、について、実施形態１に係る流路２２と相違する。図６に示す例では、キャニスタ２８は、本体部２１の内部に配置されている。キャニスタ２８は、創傷床９０５からの滲出液を貯留する密閉容器である。キャニスタ２８は、流路２２Ｂの途中に設けられるため、圧電ポンプ２５が駆動すると、陰圧になる。なお、図示しないが、ポンプ装置２０Ｂは、圧電ポンプ２５の吸引口に滲出液が流入しないための構成（例えばフィルタ）を備えている。

[0061] ポンプ装置３０Ｂは、本体部３１と、流路３２Ｂと、キャニスタ３４と、を備えている。流路３２Ｂは、一部がゴム管３３Ｂ及びゴム管３６によって

形成される点と、途中にキャニスタ３４が設けられる点と、滲出液が流れる点と、において実施形態１に係る流路３２と相違する。図６に示す例では、キャニスタ３４は、本体部３１の外部に配置されている。キャニスタ３４は、創傷床９０５からの滲出液を貯留する密閉容器である。ゴム管３３Ｂは、一端がジョイント管１５に挿勘され、他端がキャニスタ３４に挿入されている。ゴム管３６は、一端がキャニスタ３４に挿入され、他端が本体部３１に装着されている。ゴム管３６の一端は、キャニスタ３４に輸送される滲出液３５がゴム管３６に流入しないように、例えば、キャニスタ３４の上部に挿入されている。

[0062] キャニスタ３４の滲出液の貯留容量は、キャニスタ２８の滲出液の貯留流量より多い。

[0063] キャニスタ３４は、本体部３１の外部に配置されているため、ゴム管３３Ｂ及びゴム管３６のキャニスタ３４からの挿去のみで、交換が可能である。

[0064] ポンプ装置２０Ｂが駆動して閉鎖空間９０４が陰圧になると、閉鎖空間９０４の滲出液は、流路２２Ｂの一部を介して、キャニスタ２８へ輸送される。キャニスタ２８は、輸送された滲出液を貯留する。

[0065] ポンプ装置３０Ｂが駆動して、閉鎖空間９０４が陰圧になると、閉鎖空間９０４の滲出液は、流路３２Ｂのうちゴム管３３Ｂを介して、キャニスタ３４へ輸送される。キャニスタ３４は、輸送された滲出液３５を貯留する。

[0066] 治療装置１００Ｂの日常使用では、ポンプ装置３０Ｂは、ゴム管３３Ｂがジョイント管１５から挿去されることによって、創傷包帯１０Ｂから取り外される。利用者９００の治療装置１００Ｂの非日常使用では、ポンプ装置３０Ｂは、ゴム管３３がジョイント管１５に挿嵌されることによって、創傷包帯１０Ｂに装着される。ポンプ装置３０Ｂが創傷包帯１０Ｂに装着されると、キャニスタ３４も、流路３２Ｂのうちゴム管３３Ｂを介して創傷包帯１０Ｂに装着される。

[0067] 本実施形態に係る治療装置１００Ｂは、必要なときに十分な吸引流量で閉鎖空間９０４を陰圧にすることができるだけでなく、多くの滲出液を貯留す

る必要があるときに、貯留容量が多いキャニスタ３４を備えるポンプ装置３０Ｂが創傷包帯１０Ｂに装着されるため、キャニスタ２８が小型化されてキャニスタ２８の貯留容量が少なくなっても、必要なときに多くの滲出液を貯留することができる。

[0068] なお、キャニスタ３４の貯留容量は、キャニスタ２８の貯留容量と等しいか、又はキャニスタ２８の貯留容量より少なくても構わない。キャニスタ３４の貯留容量がキャニスタ２８の貯留容量と等しいか、又はキャニスタ２８の貯留容量より少ない場合、ポンプ装置２０Ｂとポンプ装置３０Ｂとは、同時に駆動して、キャニスタ２８及びキャニスタ３４に滲出液を同時に貯留させる。

[0069] 次に、実施形態３に係る治療装置１００Ｃについて、図７及び図８を用いて説明する。治療装置１００Ｃは、洗浄液タンク４１の洗浄液を用いて、創傷部位９０３を洗浄するものである。

[0070] 治療装置１００Ｃは、創傷包帯１０Ｃ、及び洗浄器具４０を備える点において、実施形態３に係る治療装置１００Ｂと相違する。治療装置１００Ｂと重複する構成の説明は省略する。

[0071] 図７に示すように、創傷包帯１０Ｃは、中央部１２に取付口１３Ｃ及び取付口４４を備える点と、ゴム管２３の装着位置が異なる点と、において実施形態３に係る創傷包帯１０Ｂと相違する。取付口１３Ｃは、配置が異なる点について、実施形態３に係る取付口１３と相違する。より具体的には、取付口１３Ｃは、中央部１２において、幅方向の端部側に配置されている。ポンプ装置２０Ｂの流路２２Ｂの一部を形成するゴム管２３は、図７に示すように、中央部１２において、幅方向の端部側に装着されている。取付口４４は、中央部１２において、幅方向と反対方向の端部側に配置されている。取付口４４は、ジョイント管１５を備えている。

[0072] 取付口１３Ｃの位置、取付口４４の位置、ゴム管２３の中央部１２への装着位置は、上述の例に限らないが、創傷包帯１０Ｃの面方向（幅方向及び奥行方向）において、取付口４４は、取付口１３Ｃの位置及びゴム管２３の装

着位置から離れて配置されることが望ましい。

[0073] 図８に示すように、洗浄器具４０は、洗浄液タンク４１と、流路４２と、を備えている。流路４２は、洗浄液タンク４１から閉鎖空間９０４までである。流路４２の一部は、ゴム管４３によって形成されている。ゴム管４３は、一端が洗浄液タンク４１に装着され、他端がフィルム１１の中央部１２に装着されている。具体的には、ゴム管４３の他端は、図７に示すように、取付口４４のジョイント管１５に挿嵌されている。洗浄器具４０は、ゴム管４３の他端が取付口４４のジョイント管１５に挿抜自在であるため、創傷包帯１０Ｃに着脱自在である。

[0074] 利用者９００は、ポンプ装置３０Ｂを創傷包帯１０Ｃから取り外し、洗浄器具４０を創傷包帯１０Ｃに装着し、治療装置１００Ｃを日常的に使用する。ポンプ装置２０Ｂが駆動すると、洗浄液タンク４１の洗浄液は、流路４２を介して閉鎖空間９０４へ流入する。創傷部位９０３の表面は、閉鎖空間９０４に流入した洗浄液によって洗浄される。その後、洗浄液は、流路２２Ｂの一部を介してキャニスタ２８へ輸送される。キャニスタ２８は、創傷部位９０３の洗浄後の洗浄液を貯留する。

[0075] 利用者９００は、洗浄器具４０及びポンプ装置３０Ｂを創傷包帯１０Ｃに装着し、治療装置１００Ｃを非日常的に使用する。ポンプ装置３０Ｂが駆動すると、洗浄液タンク４１の洗浄液は、流路４２を介して閉鎖空間９０４へ流入する。創傷部位９０３の表面は、閉鎖空間９０４に流入した洗浄液によって洗浄される。その後、洗浄液は、流路３２Ｂのうちゴム管３３Ｂを介してキャニスタ３４へ輸送される。キャニスタ３４は、創傷部位９０３の洗浄後の洗浄液３７を貯留する。

[0076] 本実施形態に係る治療装置１００Ｃは、必要なときに十分な吸引流量で閉鎖空間９０４を陰圧にすることができるだけでなく、多くの洗浄液で創傷部位９０３を洗浄する必要があるときに吸引流量が多いポンプ装置３０Ｂが創傷包帯１０Ｂに装着されるため、ポンプ装置２０Ｂの吸引流量が少なくても必要なときに十分な流量で洗浄液を創傷部位９０３に送ることにより、創傷

部位９０３を多くの洗浄液で洗浄することができる。

[0077] また、治療装置１００Ｃは、洗浄後の洗浄液が多くなるときに、貯留容量が多いキャニスタ３４を備えるポンプ装置３０Ｂが創傷包帯１０Ｃに装着されるため、必要なときに洗浄後の洗浄液をより多く貯留することができる。

[0078] ただし、ポンプ装置３０Ｂの吸引流量は、ポンプ装置３０Ｂとポンプ装置２０Ｂとが同時に駆動すれば、ポンプ装置２０Ｂの吸引流量に等しいか、又はポンプ装置２０Ｂの吸引流量より少なくても構わない。

符号の説明

[0079] １０，１０Ｂ，１０Ｃ…創傷包帯

１１…フィルム

１２…中央部

１３，１３Ｃ…取付口

１４…逆止弁

１５…ジョイント管

１６…フィルタ

１７…吸収部材

１８…ガーゼ

１９…被覆部材

２０，２０Ａ，２０Ｂ…ポンプ装置

２１…本体部

２２，２２Ｂ…流路

２３…ゴム管

２５…圧電ポンプ

２６…圧力センサ

２７…制御部

２８…キャニスタ

３０，３０Ｂ…ポンプ装置

３１…本体部

３２，３２Ａ，３３Ｂ…流路

３３，３３Ａ，３３Ｂ…ゴム管

３４…キャニスタ

３５…滲出液

３６…ゴム管

３７…洗浄液

４０…洗浄器具

４１…洗浄液タンク

４２…流路

４３…ゴム管

４４…取付口

１００，１００Ａ，１００Ｂ，１００Ｃ，１００Ｄ…治療装置

請求の範囲

[請求項1] 主面の外周部が創傷部位の外周の皮膚表面に密着することで、該主面の中央部及び前記創傷部位の間に閉鎖空間を形成する創傷包帯と、

前記創傷包帯に装着される第１流路と、前記閉鎖空間に前記第１流路を介して連通する第１吸引口と、を有する第１ポンプ装置と、

前記創傷包帯に着脱自在に装着される第２流路と、前記閉鎖空間に前記第２流路を介して連通する第２吸引口と、を有する第２ポンプ装置と、

を備え、

前記第２ポンプ装置の吸引流量は、前記第１ポンプ装置の吸引流量より多く、

前記第１ポンプ装置は、前記第１流路及び前記第１吸引口を介して前記閉鎖空間から流体を吸引し、

前記第２ポンプ装置は、前記第２流路が前記創傷包帯に装着されているとき、前記第２流路及び前記第２吸引口を介して前記閉鎖空間から流体を吸引する、

陰圧閉鎖治療装置。

[請求項2] 前記第２流路が前記創傷包帯に装着されているとき、前記第１ポンプ装置及び前記第２ポンプ装置は、同時に駆動する、

請求項１に記載の陰圧閉鎖治療装置。

[請求項3] 主面の外周部が創傷部位の外周の皮膚表面に密着することで、該主面の中央部及び前記創傷部位の間に閉鎖空間を形成する創傷包帯と、

前記創傷包帯に装着される第１流路と、前記閉鎖空間に前記第１流路を介して連通する第１吸引口と、を有する第１ポンプ装置と、

前記創傷包帯に着脱自在に装着される第２流路と、前記閉鎖空間に前記第２流路を介して連通する第２吸引口と、を有する第２ポンプ装置と、

を備え、

前記第２流路が前記創傷包帯に装着されているとき、前記第１ポンプ装置及び前記第２ポンプ装置は、同時に駆動し、

前記第１ポンプ装置は、駆動すると、前記第１流路及び前記第１吸引口を介して前記閉鎖空間から流体を吸引し、

前記第２ポンプ装置は、駆動すると、前記第２流路及び前記第２吸引口を介して前記閉鎖空間から流体を吸引する、

陰圧閉鎖治療装置。

[請求項4] 第１ポンプ装置は、前記第１流路の途中に設けられ、液体を貯留する第１貯留部を備え、

第２ポンプ装置は、前記第２流路の途中に設けられ、液体を貯留する第２貯留部を備え、

前記第２貯留部の貯留容量は、前記第１貯留部の貯留容量より多い、

請求項１乃至請求項３のいずれかに記載の陰圧閉鎖治療装置。

[請求項5] 前記創傷包帯に装着される第３流路と、前記第３流路を介して前記閉鎖空間に連通し、前記創傷部位の洗浄用の洗浄液を貯留する第３貯留部と、を有する洗浄器具、を備える、

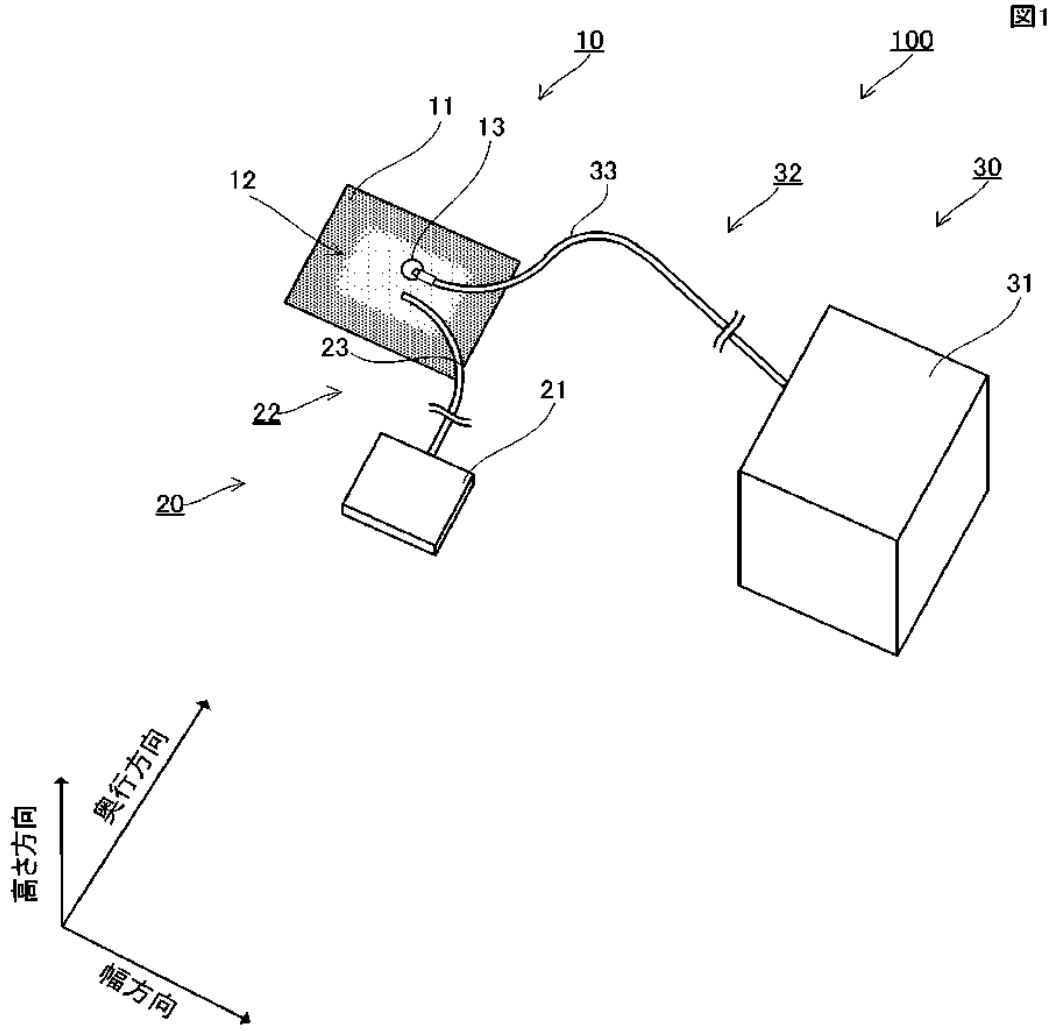
請求項４に記載の陰圧閉鎖治療装置。

[請求項6] 前記第１ポンプ装置は、圧電素子によって駆動するポンプ、を備える、

請求項１乃至請求項５のいずれかに記載の陰圧閉鎖治療装置。

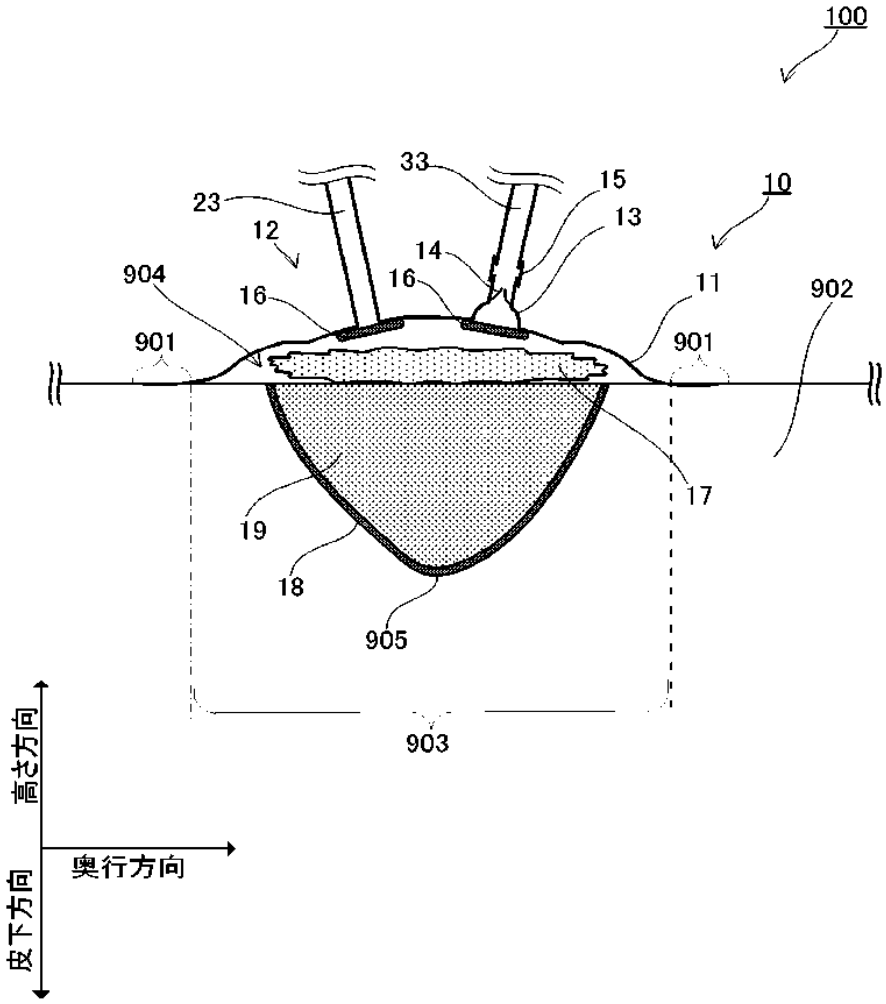
[図1]

図1



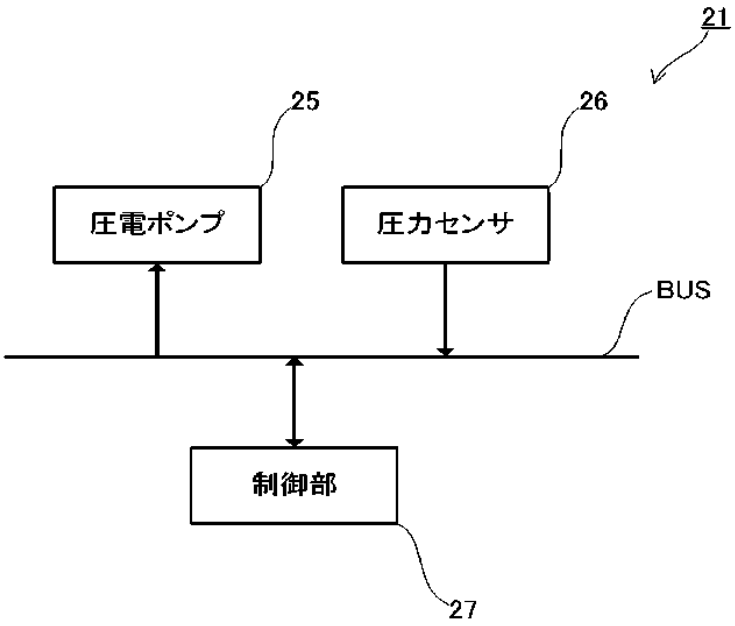
[図2]

図2


100
33
15
10
23
12
13
14
16
16
11
902
904
901
901
17
19
18
905
903
高さ方向
奥行方向
皮下方向

[図3]

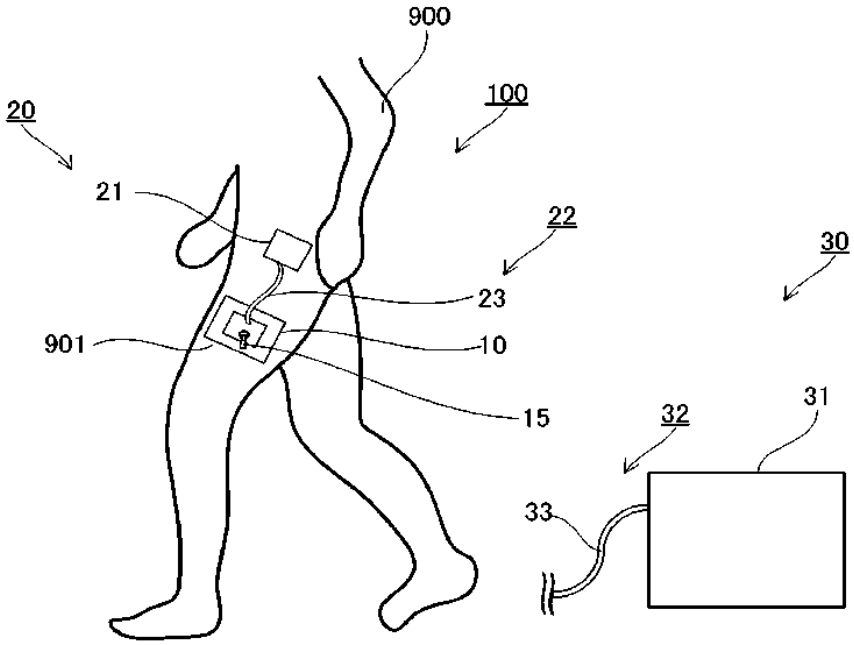
図3



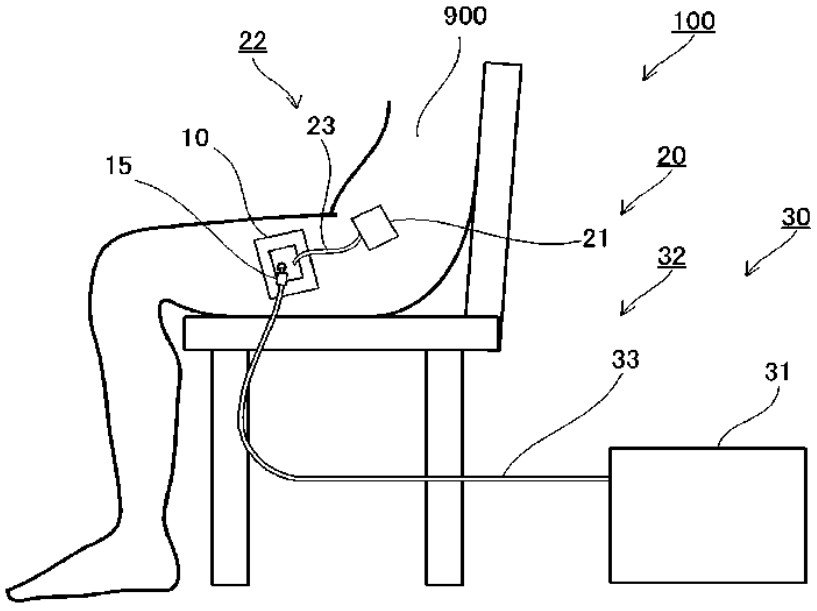
[図4]

図4

(A)

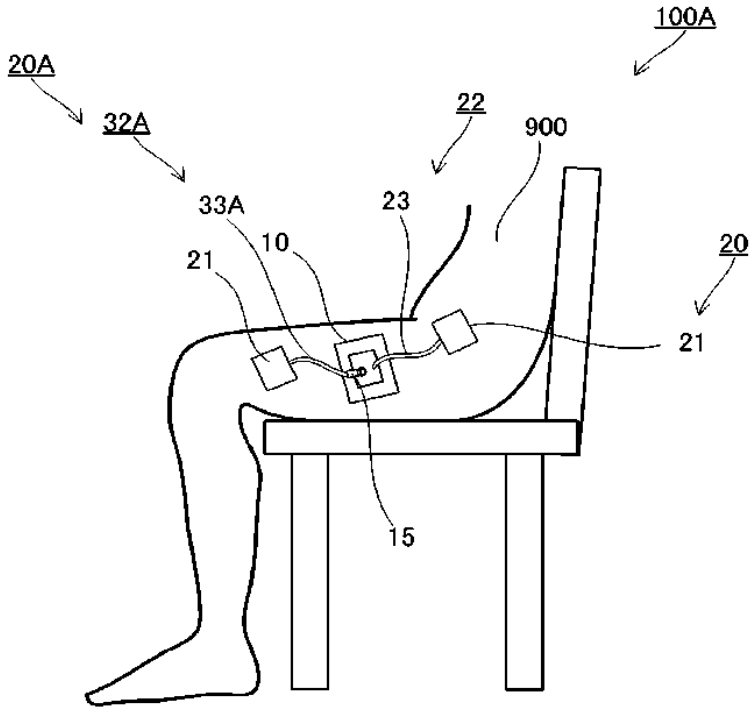

900
100
20
21
22
30
23
901
10
15
32
31
33

(B)


900
100
22
23
10
15
20
21
30
32
33
31

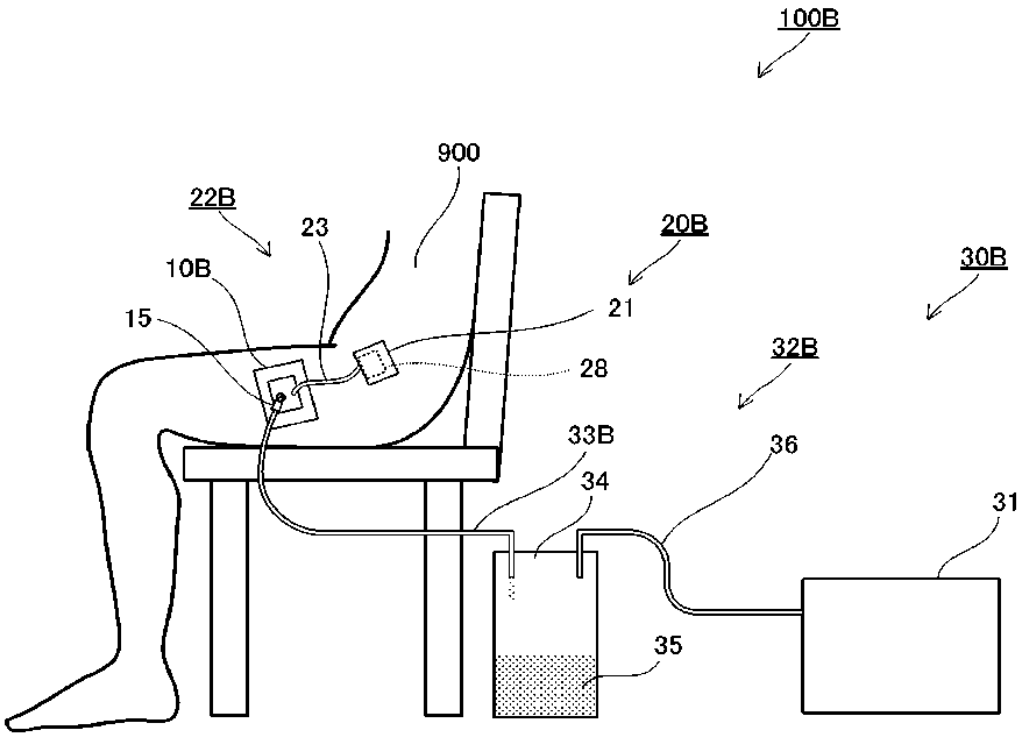
[図5]

図5


100A
20A
32A
22
900
33A
23
10
21
20
21
15

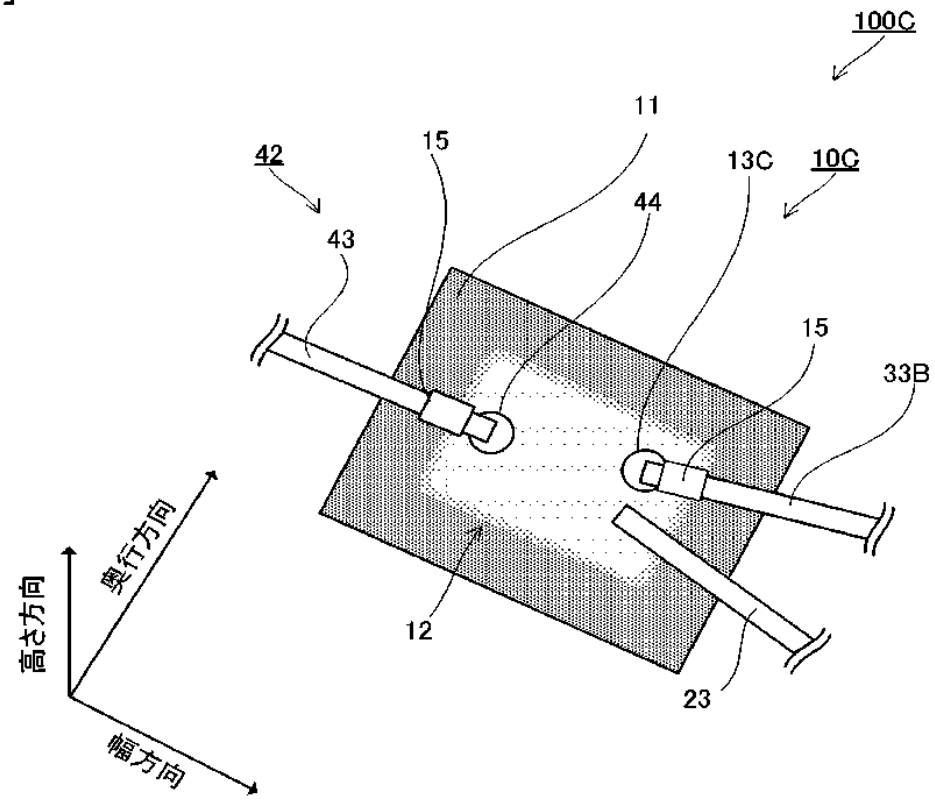
[図6]

図6


100B
900
22B
23
20B
30B
10B
15
21
28
32B
33B
36
34
31
35

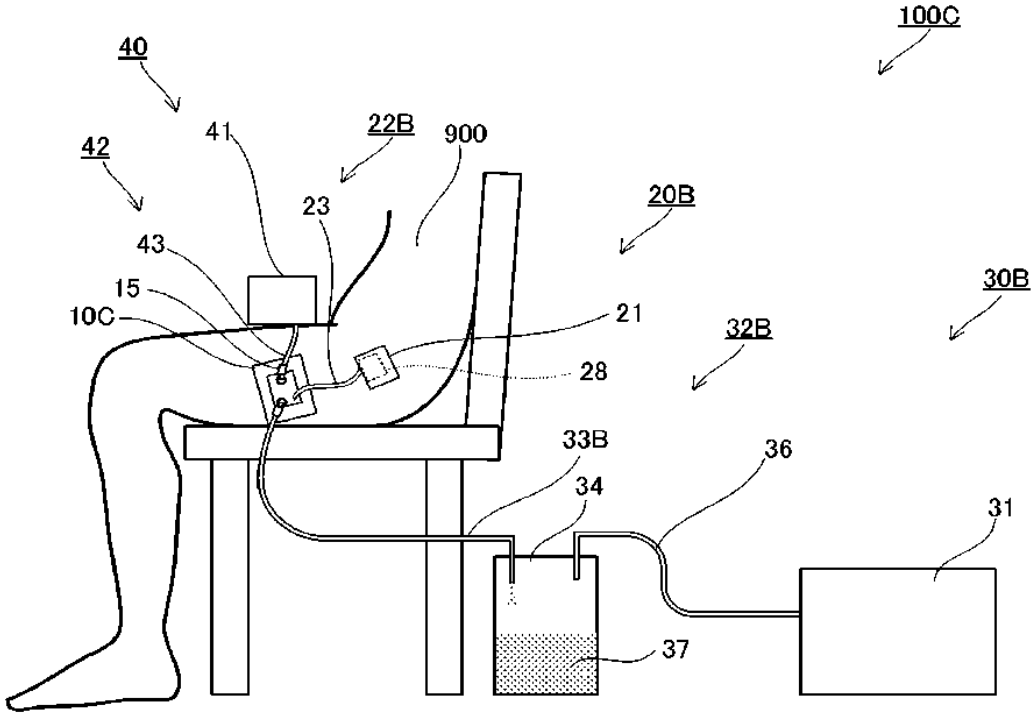
[図7]

図7


100C
11
15
42
13C
10C
44
43
15
33B
奥行方向
高さ方向
12
23
幅方向

[図8]

図8


100C
40
41
22B
900
42
23
20B
43
15
10C
21
30B
32B
28
33B
36
34
31
37

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2015/068284

A. CLASSIFICATION OF SUBJECT MATTER
A61M27/00(2006.01)i, *A61F13/00*(2006.01)i, *A61M1/00*(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M27/00, A61F13/00, A61M1/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Jitsuyo Shinan Koho 1922-1996 Jitsuyo Shinan Toroku Koho 1996-2015
Kokai Jitsuyo Shinan Koho 1971-2015 Toroku Jitsuyo Shinan Koho 1994-2015

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	JP 2011-512202 A (Spiracur Inc.), 21 April 2011 (21.04.2011), paragraphs [0043] to [0046], [0077] to [0080]; fig. 1, 11A to 12 & US 2010/0042021 A1 & WO 2009/103031 A1 & EP 2586470 A2 & CN 102006895 A	1-4 5-6
Y	JP 2012-90813 A (Gunze Ltd.), 17 May 2012 (17.05.2012), paragraphs [0020] to [0023]; fig. 1 to 2 (Family: none)	5-6
Y	JP 2012-525202 A (Mölnlycke Health Care AB), 22 October 2012 (22.10.2012), paragraph [0041]; fig. 1 to 2 & US 2012/0046625 A1 & WO 2010/126444 A1 & CN 102421464 A & KR 10-2012-0020103 A	6

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
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"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
03 September 2015 (03.09.15)	15 September 2015 (15.09.15)
Name and mailing address of the ISA/ Japan Patent Office 3-4-3, Kasumigaseki, Chiyoda-ku, Tokyo 100-8915, Japan	Authorized officer Telephone No.

Form PCT/ISA/210 (second sheet) (July 2009)

国際調査報告

国際出願番号　ＰＣＴ／ＪＰ２０１５／０６８２８４

Ａ．　発明の属する分野の分類（国際特許分類（ＩＰＣ））

Int.Cl.　A61M27/00(2006.01)i, A61F13/00(2006.01)i, A61M1/00(2006.01)i

Ｂ．　調査を行った分野

調査を行った最小限資料（国際特許分類（ＩＰＣ））

Int.Cl.　A61M27/00, A61F13/00, A61M1/00

最小限資料以外の資料で調査を行った分野に含まれるもの

日本国実用新案公報	１９２２－１９９６年
日本国公開実用新案公報	１９７１－２０１５年
日本国実用新案登録公報	１９９６－２０１５年
日本国登録実用新案公報	１９９４－２０１５年

国際調査で使用した電子データベース（データベースの名称、調査に使用した用語）

WPI

Ｃ．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
X Y	JP 2011-512202 A（スパイラキュア　インコーポレイテッド）2011.04.21, 段落［００４３］－［００４６］, ［００７７］－［００８０］, 第１，１１Ａ－１２図 & US 2010/0042021 A1 & WO 2009/103031 A1 & EP 2586470 A2 & CN 102006895 A	１－４ ５－６
Y	JP 2012-90813 A（グンゼ株式会社）2012.05.17, 段落［００２０］－［００２３］, 第１－２図（ファミリーなし）	５－６

☑　Ｃ欄の続きにも文献が列挙されている。

☐　パテントファミリーに関する別紙を参照。

＊　引用文献のカテゴリー

「Ａ」特に関連のある文献ではなく、一般的技術水準を示すもの

「Ｅ」国際出願日前の出願または特許であるが、国際出願日以後に公表されたもの

「Ｌ」優先権主張に疑義を提起する文献又は他の文献の発行日若しくは他の特別な理由を確立するために引用する文献（理由を付す）

「Ｏ」口頭による開示、使用、展示等に言及する文献

「Ｐ」国際出願日前で、かつ優先権の主張の基礎となる出願の日の後に公表された文献

「Ｔ」国際出願日又は優先日後に公表された文献であって出願と矛盾するものではなく、発明の原理又は理論の理解のために引用するもの

「Ｘ」特に関連のある文献であって、当該文献のみで発明の新規性又は進歩性がないと考えられるもの

「Ｙ」特に関連のある文献であって、当該文献と他の１以上の文献との、当業者にとって自明である組合せによって進歩性がないと考えられるもの

「＆」同一パテントファミリー文献

国際調査を完了した日 ０３．０９．２０１５	国際調査報告の発送日 １５．０９．２０１５
国際調査機関の名称及びあて先 日本国特許庁（ＩＳＡ／ＪＰ） 郵便番号１００－８９１５ 東京都千代田区霞が関三丁目４番３号	特許庁審査官（権限のある職員）　３Ｅ　９２４２ 田中　玲子 電話番号　０３－３５８１－１１０１　内線　３３４６

様式ＰＣＴ／ＩＳＡ／２１０（第２ページ）（２００９年７月）

Ｃ（続き）．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
Y	JP 2012-525202 A（メンリッケ・ヘルス・ケア・アーベー）2012.10.22, 段落［００４１］, 第１－２図 & US 2012/0046625 A1 & WO 2010/126414 A1 & CN 102421464 A & KR 10-2012-0020103 A	6

Patents | WO 2016/006458 A1

Negative-pressure closure therapy device

Abstract

Provided is a negative-pressure closure therapy device with which an adequate suction flow rate can be used to apply, when necessary, negative pressure to a closed space formed by a wound dressing and a wound area, even if a pump device is miniaturized. In this therapy device (100), a pump device (30) having a high suction flow rate is fitted to a wound dressing (10) at times of extraordinary use when a high suction flow rate is necessary, and air is sucked from a closed space (904) formed by a wound area (903) and the wound dressing (10). Accordingly, an adequate suction flow rate can be ensured at times of extraordinary use, even if a pump device (20) for everyday use is miniaturized and the suction flow rate of the pump device (20) is reduced. As a result, the pressure value of the closed space (904) can be reduced to a desired value more swiftly.

Images (8)



Classifications

- A61M1/74 Suction control

View 8 more classifications

WO2016006458A1
WIPO (PCT)

Other languages: French, Japanese

Inventor: [redacted]

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2015 JP WO 2017 US

Application PCT/JP2015/068284 events

2014-07-08 Priority to JP2014140147

2014-07-08 Priority to JP2014140147

2015-06-25 Application filed by [redacted]

2016-01-14 Publication of WO2016006458A1

Info: Patent citations (8), Cited by (10), Legal events, Similar documents, Priority and Related Applications

External links: Espacenet, Global Dossier, PatentScope, Discuss

Claims (6)

Hide Dependent

1. A wound dressing that forms a closed space between the central portion of the main surface and the wound site by allowing the outer periphery of the main surface to adhere to the skin surface of the outer periphery of the wound site;
A first pump device having a first flow path mounted on the wound dressing and a first suction port communicating with the closed space via the first flow path;
A second pump device having a second flow path detachably attached to the wound dressing, and a second suction port communicating with the closed space via the second flow path.
With
The suction flow rate of the second pump device is greater than the suction flow rate of the first pump device,
The first pump device sucks fluid from the closed space through the first flow path and the first suction port,
The second pump device sucks fluid from the enclosed space via the second channel and the second suction port when the second channel is attached to the wound dressing.
Negative pressure closure treatment device.

2. When the second channel is attached to the wound dressing, the first pump device and the second pump device are driven simultaneously.
The negative pressure closure treatment device according to claim 1.

3. A wound dressing that forms a closed space between the central portion of the main surface and the wound site by allowing the outer periphery of the main surface to adhere to the skin surface of the outer periphery of the wound site;
A first pump device having a first flow path mounted on the wound dressing and a first suction port communicating with the closed space via the first flow path;
A second pump device having a second flow path detachably attached to the wound dressing, and a second suction port communicating with the closed space via the second flow path.
With
When the second channel is attached to the wound dressing, the first pump device and the second pump device are driven simultaneously,
When the first pump device is driven, the first pump device sucks fluid from the closed space via the first flow path and the first suction port,
When the second pump device is driven, the second pump device sucks fluid from the closed space via the second flow path and the second suction port.
Negative pressure closure treatment device.

4. The first pump device includes a first reservoir that is provided in the middle of the first flow path and stores the liquid.
The second pump device includes a second reservoir that is provided in the middle of the second flow path and stores the liquid.
The storage capacity of the second storage part is greater than the storage capacity of the first storage part.
The negative pressure closure treatment device according to any one of claims 1 to 3.

5. A cleaning instrument comprising; a third flow path to be attached to the wound dressing; and a third storage section that communicates with the closed space via the third flow path and stores a cleaning liquid for cleaning the wound site; Comprising
The negative pressure closure treatment apparatus according to claim 4.

6. The first pump device includes a pump driven by a piezoelectric element.
The negative pressure closure treatment apparatus according to any one of claims 1 to 5.

Description

Negative pressure closure therapy device

The present invention relates to a negative pressure closure treatment device for promoting recovery of a wound site by applying a negative pressure to the surface of the wound site.

In recent years, negative pressure closure treatment that promotes recovery of a wound site by applying a negative pressure to the surface of the wound site is known. For example, Patent Document 1 discloses a negative pressure closed treatment device including a wound dressing that covers a wound site and a pump device that sucks gas from a closed space formed by the wound dressing and the wound site. In the negative pressure closed treatment device described in Patent Literature 1, the pump device draws gas from the closed space, thereby making the closed space have a negative pressure.

Also, in the negative pressure closure treatment device described in Patent Document 1, the pump device also sucks exudate that has exuded from the surface of the wound site. The sucked exudate is stored in a storage unit (collection canister).

In view of not only the negative pressure closure treatment device described in Patent Document 1 but also the user's wearing, it is desirable that the pump device of the negative pressure closure treatment device is small. If the pump device is small, the user can carry and use the pump device, for example.

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However, when the pump device is miniaturized, the pump for realizing suction is also miniaturized and the suction flow rate is reduced. As a result, the suction flow rate of the pump device may become insufficient when the pump device is miniaturized when it is necessary to make the closed space negative pressure earlier.

Similarly, when the reservoir for storing exudate is reduced in size, the storage capacity is reduced. As a result, the storage capacity of the storage part may become insufficient when the storage part is downsized when a large amount of exudate needs to be stored.

SUMMARY OF THE INVENTION Accordingly, an object of the present invention is to provide a negative pressure closed treatment device that makes a closed space formed by a wound dressing and a wound site negative pressure with a sufficient suction flow rate when necessary even if the pump device is downsized. There is.

The negative pressure closure treatment device of the present invention includes a wound dressing that forms a closed space between the central portion of the main surface and the wound site by bringing the outer peripheral portion of the main surface into close contact with the skin surface on the outer periphery of the wound site. A first pump device having a first flow path attached to the wound dressing, and a first suction port communicating with the closed space via the first flow path, and detachably attached to the wound dressing And a second pump device having a second suction port communicating with the closed space via the second flow path.

The suction flow rate of the second pump device is larger than the suction flow rate of the first pump device, and the first pump device draws fluid from the closed space via the first flow path and the first suction port. The second pump device sucks fluid from the closed space through the second channel and the second suction port when the second channel is attached to the wound dressing.

Since the suction flow rate of the first pump device is smaller than the suction flow rate of the second pump device, the pump realizing the suction of the first pump device can be smaller than the pump of the second pump device. Therefore, the first pump device can be realized smaller than the second pump device.

For example, the first pump device is driven to suck fluid from the enclosed space for daily use of the user, and the second pump device is driven to exit from the closed space for extraordinary use of the user. Aspirate fluid.

Daily use of the negative pressure closure treatment device is when the flow rate (suction flow rate) of the fluid sucked from the closed space may be small. For example, when the closed space is already sufficiently negative pressure, the user can remove the second flow path from the wound dressing and use the negative pressure closed treatment device as a daily use of the negative pressure closing treatment device. Use a pump device. That is, the user removes the second pump device from the wound dressing and uses only the first pump device in daily use of the negative pressure closure treatment device. Unusual use of negative pressure closure treatment devices is use that requires a large amount of suction flow. For example, the user may attach the second flow path to the wound dressing when it is just worn on the wound site for extraordinary use and the closed space needs to be negatively pressured earlier. Therefore, the second pump device having a large suction flow rate is used.

In the negative pressure closure treatment device of the present invention, when a large amount of suction flow is required, a second pump device having a high suction flow rate is attached to the wound dressing to draw fluid from the wound space and the closed space formed by the wound dressing. Even if the first pump device for daily use by the user is downsized, the closed space can be maintained at a negative pressure by securing a sufficient suction flow rate when necessary.

Further, when the second flow path is attached to the wound dressing, the first pump device and the second pump device may be driven simultaneously.

Thereby, since the suction flow rate of the second pump device assists the suction flow rate of the first pump device, the negative pressure closure treatment device can secure a larger suction flow rate when necessary.

Further, the present invention is not limited to the suction flow rate of the second pump device being higher than that of the first pump device, and simply when the second flow path is attached to the wound dressing, the first pump device and the The second pump device may be driven at the same time.

For example, even if the suction flow rate of the first pump device and the suction flow rate of the second pump device are equal, the user uses the second pump device as an auxiliary during non-daily use.

The first pump device includes a first storage section that is provided in the middle of the first flow path and stores the liquid, and the second pump device is provided in the middle of the second flow path to store the liquid. A storage capacity of the second storage section may be greater than a storage capacity of the first storage section.

The second reservoir is detachable from the wound dressing because the second channel is detachable from the wound dressing. In this configuration, the negative pressure closure treatment device not only ensures a sufficient suction flow rate when a suction flow rate is required, but also stores the exudate from the wound site in the second reservoir when necessary. A sufficient storage capacity can be secured.

Further, the negative pressure closure treatment device communicates with the closed space via the third flow path to be attached to the wound dressing and the third flow, and stores a cleaning liquid for cleaning the wound site. And a cleaning instrument having a portion.

The cleaning liquid flows from the third flow path to the first flow path and the second flow path through the closed space in order to clean the wound site. In this aspect, since the second pump device is driven when the flow rate of the irrigation liquid is necessary, the negative pressure closure treatment apparatus can be used to clean the wound site in the closed space with a sufficient amount of irrigation liquid even if the first pump device is downsized. Can be washed.

Also, in order to reduce the size of the first pump device, the following configuration is preferable. For example, the first pump device includes a pump driven by a piezoelectric element

That is, the first pump device desirably includes a piezoelectric pump for miniaturization. The piezoelectric pump includes, for example, a piezoelectric element and a diaphragm bonded to the piezoelectric element. When an alternating voltage is applied, the piezoelectric element repeatedly expands and contracts along the surface direction of the main surface. When the piezoelectric element repeatedly expands and contracts along the surface direction of the main surface, the bonded vibration plate bends and vibrates. Piezoelectric pumps can be easily downsized compared to electromagnetic pumps and the like. In addition, the piezoelectric pump is excellent in that the vibration is smaller than that of an electromagnetic pump or the like. Furthermore, if the frequency of the alternating voltage is set to 20 kHz or more, the vibration sound of the diaphragm becomes 20 kHz or more outside the audible frequency band, so that it is diff-cult for the user to hear.

The negative pressure closure treatment device of the present invention is configured such that when a suction flow rate is required, the second pump device is attached to the wound dressing to suck fluic from the closed space formed by the wound site and the wound dressing. Even if the pump device is reduced in size, a sufficient suction flow rate can be secured when necessary to make the closed space negative pressure.

It is a perspective view from the upper surface side of the treatment apparatus concerning Embodiment 1. FIG. It is side surface sectional drawing at the time of mounting | wearing of the wound dressing of the treatment apparatus which concerns on Embodiment 1. FIG. It is a block diagram which shows a part of structure of the main-body part of the 1st pump apparatus of the treatment apparatus which concerns on Embodiment 1. FIG. (A) is a figure for demonstrating the daily use of the treatment apparatus which concerns on Embodiment 1, (B) is a figure for demonstrating the unusual use of the said treatment apparatus. It is a figure for demonstrating the non-daily use of the treatment apparatus which concerns on the modification of the treatment apparatus which concerns on Embodiment 1. FIG. It is a figure for demonstrating the unusual use of the treatment apparatus which concerns on Embodiment 2. FIG. It is a perspective view from the upper surface side of the wound dressing of the treatment apparatus concerning Embodiment 3. It is a figure for demonstrating the non-daily use of the treatment apparatus which concerns on Embodiment 3. FIG.

The treatment apparatus 100 according to Embodiment 1 will be described with reference to FIGS. 1, 2, and 3. FIG. 2 is a cross-sectional view of the wound dressing 10 and the living body interior 902 of the treatment apparatus 100, but only the cross section of the wound dressing 10 is shown in light ink, and the living body interior 902 is not shown in light ink. 1 and 2, the height direction is the upper side, and the direction opposite to the height direction is the lower side.

The treatment device 100 is for negative pressure closure treatment that promotes recovery of the wound site by applying negative pressure to the surface of the wound site.

As shown in FIG. 1, the treatment device 100 includes a wound dressing 10, a pump device 20 (corresponding to a first pump device), and a pump device 30 (corresponding to a second pump device).

As shown in FIG. 2, the wound dressing 10 includes a film 11, an absorbent member 17, a gauze 18, and a covering member 19.

The film 11 prevents the passage of liquid and gas. The absorbing member 17 absorbs the liquid and holds the absorbed liquid. As the absorbent member 17, for example, cotton, a gel in which a high water supply polymer is dispersed, or the like can be used. The covering member 19 is a porous material that allows liquid to pass through. As the covering member 19, it is possible to use polyurethane foam that can be easily molded.

In the wearing example shown in FIG. 2, the gauze 18 is in the wound bed 905 inside the wound site (hereinafter referred to as the wound site 903) shown in the range 903 in the surface direction (width direction and depth direction) of the wound dressing 10. Contact the surface. The covering member 19 is formed in accordance with the shape of the wound bed 905 and then disposed above the gauze 18 so as to fill the wound bed 905. The absorbing member 17 is disposed above the covering member 19. The film 11 is arrange | positioned so that the absorption member 17 and the wound site | part 903 may be covered from the upper side. Specifically, in the film 11, the outer peripheral portion of the lower surface is attached to the skin surface 901 outside the wound site 903 in the plan view of the wound dressing 10. Thereby, the wound dressing 10 forms the closed space 904 between the center part 12 (area | region inside an outer peripheral part) of the film 11, and the wound site | part 903. FIG.

As shown in FIG. 1, the pump device 20 includes a main body 21 and a flow path 22. The description of the flow path 22 will be described later.

As shown in FIG. 3, the main body 21 of the pump device 20 includes a piezoelectric pump 25, a pressure sensor 26, and a control unit 27. The piezoelectric pump 25, the pressure sensor 26, and the control unit 27 are electrically connected to a common BUS. The piezoelectric pump 25, the pressure sensor 26, and the control unit 27 operate by supplying power from a battery provided in the main body unit 21.

The piezoelectric pump 25 includes a vibration plate having a first main surface and a second main surface, and a piezoelectric element (not shown) provided on at least one main surface of the first main surface and the second main surface of the vibration plate. And, When an alternating voltage is applied to the piezoelectric element, the piezoelectric element repeatedly expands and contracts in the main surface direction. The diaphragm vibrates flexibly with repeated expansion and contraction of the piezoelectric element. The piezoelectric pump 25 transports gas from the suction port to the discharge port using the bending vibration of the diaphragm.

The piezoelectric pump 25 is small and low-profile compared to an electromagnetic pump that uses an electric current and a magnetic field. The main body 21 of the pump device 20 includes a piezoelectric pump 25 having a small size and a low profile, so that it is small and thin so that the user can easily carry it.

Also, the vibration of the piezoelectric pump 25 is smaller than that of an electromagnetic pump or the like. Furthermore, if the alternating voltage applied to the piezoelectric element of the piezoelectric pump 25 is set to a frequency higher than the audible frequency band (for example, 20 kHz or more), the vibration sound of the piezoelectric pump 25 becomes difficult to be heard by the user.

The pressure sensor 26 detects the pressure value of the suction port of the piezoelectric pump 25. The pressure sensor 26 outputs a detection signal corresponding to the detected pressure value to the control unit 27. The control unit 27 feedback-controls the driving of the piezoelectric pump 25 using the pressure value indicated in the detection signal from the pressure sensor 26 so that the pressure value of the suction port of the piezoelectric pump 25 is in the range of 75 mmHg to 125 mmHg. However, the pressure sensor 26 is not limited to the suction port of the piezoelectric pump 25, and may detect the pressure value at any position as long as it is a space communicating with the suction port.

1, the pump device 30 includes a main body 31 and a flow path 32. The main body 31 of the pump device 30 includes, for example, an electromagnetic pump (not shown). The electromagnetic pump is larger than the piezoelectric pump 25 of the pump device 20. Therefore, the suction flow rate (ml / s) of the pump device 30 is larger than the suction flow rate of the pump device 20 because the electromagnetic pump that realizes the suction of the pump device 30 is larger than the piezoelectric pump 25. However, the pump device 30 may include, for example, a plurality of piezoelectric pumps 25 that are driven in parallel instead of the electromagnetic pump.

Next, the flow path 22 of the pump device 20 and the flow path 32 of the pump device 30 will be described. Returning to FIGS. 1 and 2, the flow path 22 extends from the closed space 904 to the suction port of the piezoelectric pump 25. A part of the flow path 22 is formed by attaching one end of the rubber tube 23 to the central portion 12 of the film 11 and attaching the other end to the main body portion 21.

The flow path 32 is from the closed space 904 to the suction port of the electromagnetic pump of the main body 31. A part of the flow path 32 is formed by attaching one end of the rubber tube 33 to the central portion 12 of the film 11 and attaching the other end to the main body portion 31.

More specifically, the wound dressing 10 is provided with the attachment port 13 as shown in FIG. The attachment port 13 is formed in the central portion 12 of the film 11. The attachment port 13 includes a check valve 14 and a joint pipe 15. The check valve 14 prevents fluid flow to the closed space 904. For example, the inner diameter of the joint pipe 15 is substantially equal to the outer diameter of the rubber pipe 33. One end of the rubber tube 33 is inserted into the joint tube 15 tube.

The flow path 32 of the pump device 30 is detachable from the wound dressing 10 by inserting and removing the rubber tube 33 with respect to the joint tube 15. However, the attachment / detachment of the flow path 32 to the wound dressing 10 may be realized by other methods without using the joint tube 15.

In order to prevent liquid from flowing into the suction port of the piezoelectric pump 25 and the suction port of the electromagnetic pump of the pump device 30, the treatment device 100 includes two filters 16 that allow only the gas to pass without passing the liquid. ing. In the example shown in FIG. 2, one filter 16 is disposed so as to cover the mouth of the rubber tube 23 in the closed space 904, and the other filter 16 is disposed so as to cover the attachment port 13 in the closed space 904. .

Next, the use of the treatment device 100 will be described with reference to FIGS. 4 (A) and 4 (B). Here, the daily use of the treatment device 100 by the user 900 is used when the flow rate of fluid sucked from the closed space 904 (hereinafter referred to as suction flow rate) may be small. For example, the user 900 uses the treatment apparatus 100 on a daily basis when there is little exudate from the surface of the wound bed 905. In addition, for example, the user 900 uses the treatment apparatus 100 on a daily basis when the surface of the wound site 903 is already sufficiently subjected to negative pressure.

The extraordinary use of the treatment device 100 by the user 900 is used when a large amount of suction flow is required. For example, the user 900 uses the treatment device 100 extraordinarily when the wound dressing 10 has just been attached to the skin surface 901 and the closed space 904 needs to be subjected to negative pressure earlier. Moreover, the user 900 uses the treatment apparatus 100 extraordinarily when there is much exudate from the surface of the wound bed 905

4A, in the daily use of the treatment device 100, the flow path 32 of the pump device 30 is removed from the wound dressing 10 by inserting the rubber tube 33 from the joint tube 15. In daily use of the treatment apparatus 100, the pump apparatus 20 sucks gas from the closed space 904 through the flow path 22 by driving the piezoelectric pump 25. Then, the pressure value in the closed space 904 gradually decreases.

As shown in FIG. 4B, in the non-daily use of the treatment device 100, the flow path 32 of the pump device 30 is attached to the wound dressing 10 by inserting the rubber tube 33 into the joint tube 15. . In extraordinary use of the treatment device 100, the pump device 30 sucks gas from the closed space 904 through the flow path 32. Then, the pressure value in the closed space 904 gradually decreases.

The exudate from the wound bed 905 flows to the absorption member 17 disposed on the negative pressure side, and is absorbed and held by the absorption member 17.

As described above, the suction flow rate of the pump device 30 is larger than the suction flow rate of the pump device 20. The time until the closed space 904 becomes sufficiently negative pressure (for example, the pressure value is 100 mmHg) depends on the suction flow rates of the pump device 20 and the pump device 30. When the gas is sucked from the closed space 904 with a larger suction flow rate, the pressure value in the closed space 904 decreases more quickly

The therapeutic device 100 according to the present embodiment is formed by the wound site 903 and the wound dressing 10 by attaching the pump device 30 having a large suction flow rate to the wound dressing 10 during non-daily use that requires a large amount of suction flow. Since the gas is sucked from the closed space 904, even if the pump device 20 for daily use is miniaturized and the suction flow rate of the pump device 20 decreases, a sufficient suction flow rate can be secured during non-daily use. . As a result, the pressure value of the closed space 904 decreases to a desired value more quickly.

In the treatment device 100, the pump device 30 and the pump device 20 may be driven simultaneously during non-daily use. That is, the pump device 30 may be driven simultaneously with the driving of the pump device 20 so as to assist the suction flow rate of the pump device 20. As a result, the pressure value in the closed space 904 is further reduced to a desired value.

Further, the treatment device 100 is not limited to one pump device 30 and may include two or more pump devices 30. In this case, the two or more pump devices 30 are each driven during non-daily use. Further, the two or more pump devices 30 may be driven simultaneously with the driving of the pump device 20 during non-daily use.

In the above example, the pump device 30 driven during non-daily use has a higher suction flow rate than the pump device 20, but if two or more pump devices are driven simultaneously during non-daily use, the pump device 30 can be used only during non-daily use. The suction flow rate of the pump device to be driven may be equal to or lower than the suction flow rate of the pump device to be driven during daily use.

For example, as shown in the modification of FIG. 5, the treatment device 100A includes a pump device 20A instead of the pump device 30. The configuration of the pump device 20A is the same as that of the pump device 20 except for the flow path 32A. That is, the suction flow rate of the pump device 20 </ b> A is equal to the suction flow rate of the pump device 20. The flow path 32A is from the closed space 904 to the suction port of the piezoelectric pump 25 of the main body 21 of the pump device 20A. A part of the flow path 32A is formed by a rubber tube 33A. One end of the rubber tube 33 </ b> A can be inserted into and removed from the joint tube 15.

The user 900 attaches the flow path 32A of the pump device 20A to the wound dressing 10 by inserting one end of the rubber tube 33A into the joint tube 15 when the treatment device 100A is not used everyday. Even if the suction flow rate of the pump device 20A is equal to the suction flow rate of the pump device 20, the treatment device 100A assists the suction flow rate of the pump device 20 with the suction flow rate of the pump device 20A. Can be secured

Next, the treatment apparatus 100B according to the second embodiment will be described with reference to FIG. In the above example, the absorbing member 17 that absorbs and holds exudate from the surface of the wound bed 905 is disposed in the closed space 904. However, the treatment device 100B according to the second embodiment stores the exudate. The canister 28 (corresponding to the first reservoir) and the canister 34 (corresponding to the second reservoir) are provided outside the closed space 904. The description of the same configuration as that of the first embodiment is omitted

As shown in FIG. 6, specifically, the treatment device 100B includes a wound dressing 10B, a pump device 20B, and a pump device 30B. FIG. 6 shows only the canister 34 in cross section in order to explain the storage of exudate.

The wound dressing 10B is different from the wound dressing 10 according to the first embodiment in that the two filters 16 are omitted.

The pump device 20B includes a main body 21, a flow path 22B, and a canister 28. The channel 22B is different from the channel 22 according to the first embodiment in that the canister 28 is provided in the middle and the exudate flows. In the example shown in FIG. 6, the canister 28 is disposed inside the main body 21. The canister 28

is a sealed container that stores exudate from the wound bed 905. Since the canister 28 is provided in the middle of the flow path 22B, when the piezoelectric pump 25 is driven, a negative pressure is generated. Although not shown, the pump device 20B has a configuration (for example, a filter) for preventing exudate from flowing into the suction port of the piezoelectric pump 25.

The pump device 30B includes a main body 31, a flow path 32B, and a canister 34. The flow path 32B is different from the flow path 32 according to the first embodiment in that a part thereof is formed by the rubber tube 33B and the rubber tube 36, a point where the canister 34 is provided in the middle, and a point where exudate flows. To do. In the example shown in FIG. 6, the canister 34 is disposed outside the main body 31. The canister 34 is a sealed container that stores exudate from the wound bed 905. The rubber tube 33B has one end inserted into the joint tube 15 and the other end inserted into the canister 34. The rubber tube 36 has one end inserted into the canister 34 and the other end attached to the main body 31. One end of the rubber tube 36 is inserted into, for example, the upper portion of the canister 34 so that the exudate 35 transported to the canister 34 does not flow into the rubber tube 36.

The storage capacity of the exudate in the canister 34 is larger than the storage flow rate of the exudate in the canister 28.

Since the canister 34 is disposed outside the main body 31, the canister 34 can be replaced only by inserting the rubber tube 33 </ b> B and the rubber tube 36 from the canister 34.

When the pump device 20B is driven and the closed space 904 becomes negative pressure, the exudate in the closed space 904 is transported to the canister 28 via a part of the flow path 22B. The canister 28 stores the transported exudate.

When the pump device 30B is driven and the closed space 904 becomes negative pressure, the exudate in the closed space 904 is transported to the canister 34 via the rubber tube 33B in the flow path 32B. The canister 34 stores the transported exudate 35.

In daily use of the treatment device 100B, the pump device 30B is removed from the wound dressing 10B by inserting the rubber tube 33B from the joint tube 15. In extraordinary use of the treatment device 100B of the user 900, the pump device 30B is attached to the wound dressing 10B by inserting the rubber tube 33 into the joint tube 15. When the pump device 30B is attached to the wound dressing 10B, the canister 34 is also attached to the wound dressing 10B via the rubber tube 33B in the channel 32B.

The treatment apparatus 100B according to the present embodiment can not only make the closed space 904 negative pressure with a sufficient suction flow rate when necessary, but also has a large storage capacity when it is necessary to store a large amount of exudate. Since the pump device 30B including the canister 34 is attached to the wound dressing 10B, even if the canister 28 is downsized and the storage capacity of the canister 28 is reduced, a large amount of exudate can be stored when necessary.

The storage capacity of the canister 34 may be equal to the storage capacity of the canister 28 or may be smaller than the storage capacity of the canister 28. When the storage capacity of the canister 34 is equal to or less than the storage capacity of the canister 28, the pump device 20 </ b> B and the pump device 30 </ b> B are driven at the same time, and exudate is simultaneously applied to the canister 28 and the canister 34. Store.

Next, a treatment apparatus 100C according to Embodiment 3 will be described with reference to FIGS. The treatment apparatus 100 </ b> C cleans the wound site 903 using the cleaning liquid in the cleaning liquid tank 41.

The treatment apparatus 100C is different from the treatment apparatus 100B according to the third embodiment in that the treatment apparatus 100C includes a wound dressing 10C and a cleaning instrument 40. A description of the same configuration as that of the treatment device 100B is omitted.

As shown in FIG. 7, the wound dressing 10 </ b> C is different from the wound dressing 10 </ b> B according to the third embodiment in that the attachment portion 13 </ b> C and the attachment port 44 are provided in the central portion 12 and the attachment position of the rubber tube 23 is different. To do. The mounting port 13C is different from the mounting port 13 according to the third embodiment in that the arrangement is different. More specifically, the attachment port 13 </ b> C is disposed on the end portion side in the width direction in the central portion 12. As shown in FIG. 7, the rubber tube 23 forming a part of the flow path 22B of the pump device 20B is attached to the end portion side in the width direction in the central portion 12. The attachment port 44 is disposed on the end portion side in the direction opposite to the width direction in the central portion 12. The attachment port 44 includes a joint pipe 15.

The position of the attachment port 13C, the position of the attachment port 44, and the attachment position of the rubber tube 23 to the central portion 12 are not limited to the above example, but in the surface direction (width direction and depth direction) of the wound dressing 10C, the attachment port 44 is preferably arranged away from the position of the attachment port 13 </ b> C and the mounting position of the rubber tube 23.

As shown in FIG. 8, the cleaning instrument 40 includes a cleaning liquid tank 41 and a flow path 42. The flow path 42 is from the cleaning liquid tank 41 to the closed space 904. A part of the flow path 42 is formed by a rubber tube 43. The rubber tube 43 has one end attached to the cleaning liquid tank 41 and the other end attached to the central portion 12 of the film 11. Specifically, the other end of the rubber tube 43 is inserted into the joint tube 15 of the attachment port 44 as shown in FIG. Since the other end of the rubber tube 43 can be inserted into and removed from the joint tube 15 of the attachment port 44, the cleaning device 40 is detachable from the wound dressing 10C.

User 900 removes pump device 30B from wound dressing 10C, attaches cleaning instrument 40 to wound dressing 10C, and uses treatment device 100C on a daily basis. When the pump device 20 </ b> B is driven, the cleaning liquid in the cleaning liquid tank 41 flows into the closed space 904 through the flow path 42. The surface of the wound site 903 is cleaned by the cleaning liquid that has flowed into the closed space 904. Thereafter, the cleaning liquid is transported to the canister 28 through a part of the flow path 22B. The canister 28 stores the cleaning liquid after cleaning the wound site 903.

User 900 attaches cleaning instrument 40 and pump device 30B to wound dressing 10C, and uses treatment device 100C on a non-daily basis. When the pump device 30 </ b> B is driven, the cleaning liquid in the cleaning liquid tank 41 flows into the closed space 904 through the flow path 42. The surface of the wound site 903 is cleaned by the cleaning liquid that has flowed into the closed space 904. Thereafter, the cleaning liquid is transported to the canister 34 through the rubber tube 33B in the flow path 32B. The canister 34 stores a cleaning liquid 37 after cleaning the wound site 903.

The treatment apparatus 100C according to the present embodiment can not only make the closed space 904 negative pressure with a sufficient suction flow rate when necessary, but also the suction flow rate when it is necessary to clean the wound site 903 with a large amount of cleaning liquid. Since the pump device 30B having a large amount is attached to the wound dressing 10B, even when the suction flow rate of the pump device 20B is small, the cleaning liquid is sent to the wound site 903 at a sufficient flow rate when necessary, so that a lot of cleaning liquid can be washed with.

In addition, when the cleaning liquid after cleaning increases, the treatment device 100C is mounted on the wound dressing 10C with the pump device 30B including the canister 34 having a large storage capacity, so that more cleaning liquid after cleaning is stored when necessary, can do.

However, the suction flow rate of the pump device 30B may be equal to or less than the suction flow rate of the pump device 20B as long as the pump device 30B and the pump device 20B are driven simultaneously.

DESCRIPTION OF SYMBOLS 10, 10B, 10C ... Wound dressing 11 ... Film 12 ... Center part 13, 13C ... Attachment part 14 ... Check valve 15 ... Joint pipe 16 ... Filter 17 ... Absorbing member 18 ... Gauze 19 ... Covering member 20, 20A, 20B ... Pump device 21... Main body portions 22 and 22 B .. Channel 23... Rubber tube 25. Piezoelectric pump 26. Pressure sensor 27... Control unit 28 ... Canisters 30 and 30 B. , 33A, 33B ... rubber tube 34 ... canister 35 ... exudate 36 ... rubber tube 37 ... cleaning solution 40 ... cleaning device 41 ... cleaning solution tank 42 ... flow path 43 ... rubber tube 44 ... mounting part 100, 100A, 100B, 100C, 100D ... treatment device

Patent Citations (8)

Publication number	Priority date	Publication date	Assignee	Title
JP2011512202A *	2008-02-14	2011-04-21	スパイラキュア インコーポレイテッド	Apparatus and method for treatment of damaged tissue
JP2012090813A *	2010-10-27	2012-05-17	Ounze Ltd	Negative pressure therapy device and control method thereof
JP2012526292A *	2009-04-30	2012-10-22	メンロケア ヘルス ケア ...	Apparatus and method for controlling negative pressure in a wound
Family To Family Citations				
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EP2782614B1 *	2011-11-23	2017-05-03	KCI Licensing, Inc.	Reduced pressure tissue treatment systems and methods having a reduced pressure dressing and associated valve

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JP6455515B2	2019-01-23	Negative pressure closure therapy device
JP6830869B2	2021-02-03	Negative pressure wound treatment device
US9155821B2	2015-10-13	Fluid collection canister including canister top with filter membrane and negative pressure wound therapy systems including same
JP6575573B2	2019-09-18	Inhaler
JP5208448B2	2013-06-11	Fluid collection canister including canister top surface with filter membrane and negative pressure wound therapy system including the same
JP5819391B2	2015-11-24	Sensor with electrical contact protection for use in a fluid collection canister and negative pressure wound therapy system including the same
US8257328B2	2012-09-04	Orientation independent canister for a negative pressure wound therapy device
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Priority And Related Applications

Child Applications (1)

Application	Priority date	Filing date	Relation	Title
US15/400,097	2014-07-08	2017-01-06	Continuation	Negative-pressure wound therapy apparatus

Priority Applications (2)

Application	Priority date	Filing date	Title
JP2014-140147		2014-07-08	
JP2014140147		2014-07-08	

Applications Claiming Priority (2)

Application	Filing date	Title
JP2015532869A	2015-06-25	Negative pressure closure therapy device
US15/400,097	2017-01-06	Negative-pressure wound therapy apparatus

Legal Events

Date	Code	Title	Description
2016-02-24	121	Ep: the epo has been informed by wipo that ep was designated in this application	**Ref document number**: 15819503 **Country of ref document**: EP **Kind code of ref document**: A1
2016-12-16	ENP	Entry into the national phase	**Ref document number**: 2016532869 **Country of ref document**: JP **Kind code of ref document**: A

2017-01-09	NENP	Non-entry into the national phase	**Ref country code:** DE
2017-08-02	122	Ep: pct application non-entry in european phase	**Ref document number:** 15819503 **Country of ref document:** EP **Kind code of ref document:** A1

Concepts

machine-extracted

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Name	Image	Sections	Count	Query match
therapeutic procedure		title,abstract	3	0.000
cleaning		claims,description	44	0.000
liquid		claims,description	35	0.000
fluid		claims,description	13	0.000
Skin		claims,description	5	0.000
everyday		abstract,description	2	0.000

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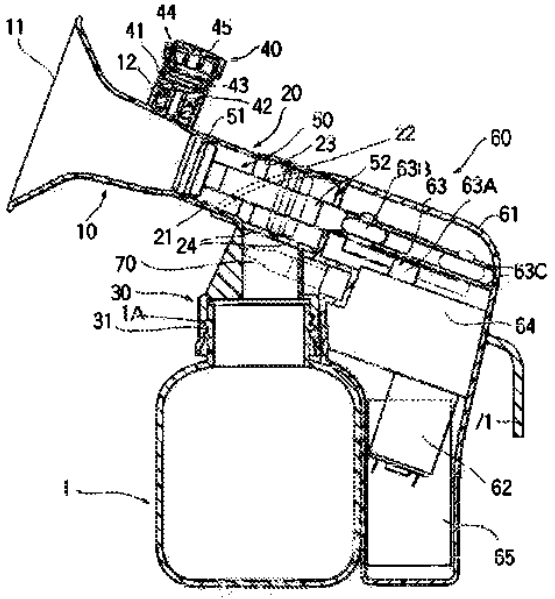
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最終頁に続く

(54)【発明の名称】　吸引圧脈動式搾乳器

(57)【要約】
【解決手段】　吸引圧脈動式搾乳器は、乳房覆い部と、シリンダ部と、シリンダ部内に挿着されたピストン部と、ピストン部をシリンダ部内のシリンダ空間内において往復動させて乳房覆い部内に脈動的に吸引圧を作り出すようにさせるための駆動部とを備え、シリンダ空間を定めるシリンダ部の内壁寸法は、乳房覆い部に近い側においては、ピストン部のピストン頭の外周を密着させて所定の長さの吸引部を与え、乳房覆い部から遠い側においては、ピストン部のピストン頭の外周との間に若干の隙間を与えて、吸引圧によって搾乳された乳を外部へと収集させるための乳収集部を与えるように選定されており、乳収集部に対応するシリンダ部の底部には、そこに収集された乳を外部へと送出しうるようにする穴部が形成されている。
【効果】　構造が非常に簡単で、小型とでき、消費電力も少なくてすみ、それだけコストを低減でき、しかも衛生状態を容易に保つことが可能である。



【特許請求の範囲】
【請求項１】　使用に際して乳房に対して装着され乳頭部を受け入れる開口部を有した乳房覆い部と、該乳房覆い部の前記開口部とは反対側において該乳房覆い部内と連通するシリンダ空間を定めるシリンダ部と、該シリンダ部内に挿着されたピストン部と、該ピストン部を前記シリンダ空間内において往復動させて前記乳房覆い部内に脈動的に吸引圧を作り出すようにさせるための駆動部とを備えており、前記シリンダ空間を定めるシリンダ部の内壁寸法は、前記乳房覆い部に近い側においては、前記ピストン部のピストン頭の外周を密着させて所定の長さの吸引部を与え、前記乳房覆い部から遠い側においては、前記ピストン部のピストン頭の外周との間に若干の隙間を与えて、前記吸引圧によって搾乳された乳を外部へと収集させるための乳収集部を与えるように選定されており、前記乳収集部に対応する前記シリンダ部の底部には、そこに収集された乳を外部へと送出しうるようにする穴部が形成されていることを特徴とする吸引圧脈動式搾乳器。
【請求項２】　前記シリンダ部の内壁には、前記吸引部と前記乳収集部との間の遷移部に対応する部分においてテーパ部が形成されている請求項１記載の吸引圧脈動式搾乳器。
【請求項３】　前記シリンダ部には、前記穴部を包囲する位置において、搾乳された乳を捕集するための乳捕集容器を接続するための容器接続手段が設けられている請求項１または２記載の吸引圧脈動式搾乳器。
【請求項４】　前記駆動部は、電気モータと、該電気モータの回転軸に接続され該回転軸の回転運動を前記シリンダ空間の軸方向にそう往復運動へと変換するためのクランク手段とを備えており、前記ピストン部のピストン軸は、前記クランク手段に連結されている請求項１または２または３記載の吸引圧脈動式搾乳器。
【請求項５】　前記乳房覆い部には、吸引圧調節手段が設けられている請求項１または２または３または４記載の吸引圧脈動式搾乳器。
【請求項６】　前記乳房覆い部と前記シリンダ部とは、第１の構成部分として一体的に形成されており、前記駆動部は、前記第１の構成部分に対して着脱自在な第２の構成部分として形成されたハウジングの内部に配置されている請求項１から５のうちのいずれかに記載の吸引圧脈動式搾乳器。
【請求項７】　前記ピストン部は、前記ハウジングが前記第１の構成部分から外されるときには、該ハウジングと共に前記シリンダ部から外されるようにされており、前記ピストン部の前記ピストン頭は、前記ピストン軸の先端部に対して着脱自在なものとされている請求項６記載の吸引圧脈動式搾乳器。
【請求項８】　前記ハウジングの内壁には、前記ピストン部の前記ピストン軸を直線的に往復動させるためのピストン軸ガイドが形成されている請求項６または７記載の吸引圧脈動式搾乳器。
【請求項９】　前記ハウジングには、前記第１の構成部分に対して固定するためのバックルが設けられている請求項６または７または８記載の吸引圧脈動式搾乳器。
【請求項１０】　前記バックルには、片手で把持しうるようにするグリップ部が設けられている請求項９記載の吸引圧脈動式搾乳器。
【発明の詳細な説明】
【０００１】
【発明の属する技術分野】本発明は、搾乳器に関するものであり、より詳細に述べるならば、新生児に後で飲ますことができるように貯蔵するために、母乳を乳房から抽出するための搾乳器に関するものである。
【０００２】
【従来の技術】この種の搾乳器は、乳房ポンプとも称されることがあり、代表的には、２つのタイプに分かれる。すなわち、モータによって駆動されるものと、手動のものとがある。この種の、いわゆる乳房ポンプは、モータ駆動のものでも手動のものでも、実際乳児が母乳を吸うのと同じ効果を出し易い等の理由から、往復動ピストンポンプを使用して脈動的に吸引圧を乳房に掛けることにより搾乳する吸引圧脈動式のものが主流である。
【０００３】このような吸引圧脈動式搾乳器の従来例としては、例えば、特開平１－３１７４４８号公報や米国特許第４９２９２２９号明細書に開示されたようなものがある。これら従来の吸引圧脈動式搾乳器は、使用に際して乳房に対して装着され乳頭部を受け入れる開口部を有した乳房覆い部と、この乳房覆い部の内部に連通して搾乳された乳を収集するための収集室部と、乳房覆い部の内部に吸引圧を作り出すための往復動ピストンポンプ部と、乳房覆い部と往復動ピストンポンプ部とを接続するための接続部とを、主として備えてなっている。
【０００４】収集室部には、往復動ピストンポンプ部によって乳房覆い部内に吸引圧を作り出す際には、収集室部の内部を外部に対して密閉するが、そこに収集された乳を外部へと送出するために収集室部内部を外部へと開放させるように作動するディスクが設けられている。また、乳房覆い部と収集室部との間で且つ往復動ピストンポンプ部への真空ラインの途中には、搾乳された乳が往復動ピストンポンプ部の方へ入り込んでしまわないようにするための分離壁等も設けられている。
【０００５】このような従来の吸引圧脈動式搾乳器によれば、収集室部に適当な容器を接続し、乳房覆い部を乳房の部分に装着して、往復動ピストンポンプ部を作動させれば、乳房覆い部内に脈動的に発生される負圧または真空のために、乳首および隣接部分が乳首覆い部内の狭い部分に吸引され引っ張られる。このような引っ張り作用は、乳児が吸引するように乳房をマッサージして圧縮し、母乳の抽出を生じさせる。乳首覆い部内に抽出され

た母乳は、収集室部へと導かれて、収集室部のディスクが外部への開放を許すときに、そこに接続された容器内へと捕集されるのである。

【０００６】

【発明が解決しようとする課題】しかしながら、このような従来の搾乳器は、乳房覆い部や収集室部等の内部構造が複雑で、それだけコスト高となっており、また、使用後の清掃も非常に難しく、衛生上の問題もあった。

【０００７】搾乳された母乳が、その後の使用のために容器へと捕集される前に、乳房覆い部の分離壁や収集室部のディスク等に接触するので、それだけ母乳の衛生状態を良好に保つのが難しい。

【０００８】また、分離壁を越えてピストンポンプ部へと流れ込んでしまった母乳は、廃棄するしかなく、それだけ、母乳の捕集率が低くなってしまう。

【０００９】ディスクに母乳がへばり付き易く、動作不良が生じ易い。また、母乳が捕集容器へと送出されるタイミングも不規則となり易い。

【００１０】ピストンポンプ部によって発生される吸引圧は、接続部および収集室部を通して乳房覆い部の内部へと及ぼされねばならないので、負圧空間が大きく、必要な吸引圧を発生させるためには、それだけ大きな動力が必要となる。したがって、ピストンポンプを電気モータにて駆動するような場合には、それだけ消費電力が大きくなってしまう。電池電源の場合には、特に、この点は重大な問題となる。

【００１１】本発明の目的は、前述したような従来の技術の問題点を解消しうるような吸引圧脈動式搾乳器を提供することである。

【００１２】

【課題を解決するための手段】本発明による吸引圧脈動式搾乳器は、使用に際して乳房に対して装着され乳頭部を受け入れる開口部を有した乳房覆い部と、該乳房覆い部の前記開口部とは反対側において該乳房覆い部内と連通するシリンダ空間を定めるシリンダ部と、該シリンダ部内に挿着されたピストン部と、該ピストン部を前記シリンダ空間内において往復動させて前記乳房覆い部内に脈動的に吸引圧を作り出すようにさせるための駆動部とを備えており、前記シリンダ空間を定めるシリンダ部の内壁寸法は、前記乳房覆い部に近い側においては、前記ピストン部のピストン頭の外周を密着させて所定の長さの吸引部を与え、前記乳房覆い部から遠い側においては、前記ピストン部のピストン頭の外周との間に若干の隙間を与えて、前記吸引圧によって搾乳された乳を外部へと収集させるための乳収集部を与えるように選定されており、前記乳収集部に対応する前記シリンダ部の底部には、そこに収集された乳を外部へと送出しうるようにする穴部が形成されていることを特徴とする。

【００１３】本発明の一つの実施の形態によれば、前記シリンダ部の内壁には、前記吸引部と前記乳収集部との間の遷移部に対応する部分においてテーパ部が形成されている。

【００１４】本発明の一つの実施例によれば、前記シリンダ部には、前記穴部を包囲する位置において、搾乳された乳を捕集するための乳捕集容器を接続するための容器接続手段が設けられている。

【００１５】本発明の一つの実施の形態によれば、前記駆動部は、電気モータと、該電気モータの回転軸に接続され該回転軸の回転運動を前記シリンダ空間の軸方向にそう往復運動へと変換するためのクランク手段とを備えており、前記ピストン部のピストン軸は、前記クランク手段に連結されている。

【００１６】本発明の別の実施の形態によれば、前記乳房覆い部には、吸引圧調節手段が設けられている。

【００１７】本発明のさらに別の実施の形態によれば、前記乳房覆い部と前記シリンダ部とは、第１の構成部分として一体的に形成されており、前記駆動部は、前記第１の構成部分に対して着脱自在な第２の構成部分として形成されたハウジングの内部に配置されている。

【００１８】本発明の一つの好ましい実施例によれば、前記ピストン部は、前記ハウジングが前記第１の構成部分から外されるときには、該ハウジングと共に前記シリンダ部から外されるようにされており、前記ピストン部の前記ピストン頭は、前記ピストン軸の先端部に対して着脱自在なものとされている。

【００１９】本発明の一つの好ましい実施例によれば、前記ハウジングの内壁には、前記ピストン部の前記ピストン軸を直線的に往復動させるためのピストン軸ガイドが形成されている。

【００２０】本発明の別の好ましい実施例によれば、前記ハウジングには、前記第１の構成部分に対して固定するためのバックルが設けられている。

【００２１】本発明の実施例によれば、前記バックルには、片手で把持しうるようにするグリップ部が設けられている。

【００２２】

【発明の実施の形態】次に、添付図面に基づいて、本発明の実施例について、本発明をより詳細に説明する。

【００２３】図１は、本発明の一実施例としての吸引圧脈動式搾乳器を、組立てた状態において乳捕集容器を接続した状態で示す概略断面図であり、図２は、図１の吸引圧脈動式搾乳器の幾つかの構成部分を分解した状態で示す概略断面図である。これら図１および図２に示されるように、この実施例の吸引圧脈動式搾乳器は、主として、使用に際して乳房に対して装着され乳頭部を受け入れる開口部１１を有した乳房覆い部１０と、乳房覆い部１０の開口部１１とは反対側において乳房覆い部１０内と連通するシリンダ空間を定めるシリンダ部２０と、シリンダ部２０内に挿着されたピストン部５０と、ピストン部５０をシリンダ空間内において往復動させて乳房覆

い部１０内に脈動的に吸引圧を作り出すようにさせるための駆動部６０とを備えている。

【００２４】この実施例においては、シリンダ空間を定めるシリンダ部２０の内壁寸法は、乳房覆い部１０に近い側においては、後述するようなピストン部５０のピストン頭５１の外周を密着させて所定の長さの吸引部２１を与え、乳房覆い部１０から遠い側においては、ピストン部５０のピストン頭５１の外周との間に若干の隙間を与えて、吸引圧によって搾乳された乳を外部へと収集させるための乳収集部２２を与えるように選定されている。そして、シリンダ部２０の内壁には、吸引部２１と乳収集部２２との間の遷移部に対応する部分においてテーパ部２３が形成されている。

【００２５】乳収集部２２に対応するシリンダ部２０の底部には、そこに収集された乳を外部へと送出しうるようにする穴部２４が形成されている。図３の部分横断面図によく示されているように、この実施例では、この穴部２４は、ピストン頭５１の最後退位置（図１において仮想線で示した位置）を境にして前に配置された１対のほぼ四角形状の前方穴２４Ａと、ピストン頭５１の最後退位置を境にして後に配置されたほぼ四角形状の後方中央穴２４Ｂおよびほぼ四半円形状の左右一対の後方側部穴２４Ｃとから形成されている。

【００２６】さらに、この実施例においては、シリンダ部２０には、穴部２４を包囲する位置において、搾乳された乳を捕集するための乳捕集容器１を接続するための容器接続部３０が設けられている。この容器接続部３０は、シリンダ部２０の乳収集部２２の底面部から下方へと延長するようにして、全体として円筒状に形成されている。そして、図１によく示されるように、この容器接続部３０の下端部の内周には、乳捕集容器１の口部のネジ部１Ａをねじ込むためのネジ部３１が形成されている。

【００２７】また、この実施例では、乳房覆い部１０には、吸引圧調節部４０を着脱自在に取り付けるための取付け部１２が形成されている。この取付け部１２は、乳覆い部１０の壁部に形成された通気穴１３を取り囲むようにして形成された二重の円筒壁で構成されている。吸引圧調節部４０の詳細構造および動作については、後述する。この実施例では、図２によく示されるように、取付け部１２を含む乳覆い部１０と、容器接続部３０を含むシリンダ部２０とは、第１の構成部分として、適当な材料、例えば、プラスチック材料にて一体的に成形されている。

【００２８】ピストン部５０は、この実施例では、ピストン頭５１と、このピストン頭５１を前端に着脱自在に取り付けうるようにしたピストン軸５２とからなっている。図２によく示されるように、ピストン軸５２の前端の軸中心には、雌ネジ穴５２Ａが形成されており、ピストン頭５１の後端軸に雄ネジ５１Ａが形成されており、雌ネジ穴５２Ａへ雄ネジ５１Ａをねじ込むことにより、ピストン頭５１をピストン軸５２に取り付け固定できるようになっている。

【００２９】駆動部６０は、この実施例では、乳覆い部１０、取付け部１２、シリンダ部２０および容器接続部３０を構成する第１の構成部分に対して着脱自在とされた第２の構成部分として形成されたハウジング６１を備えている。このハウジング６１も、適当な材料、例えば、プラスチック材料にて一体的に成形されている。そして、駆動部６０は、このハウジング６１内に配置された、電気モータ６２と、電気モータ６２の回転軸に接続され、この回転軸の回転運動をシリンダ空間の軸方向にそう往復運動へと変換するためのクランク機構６３とを備えている。この実施例では、電気モータ６２とクランク機構６３との間には、ギヤユニット６４が介在しており、ギヤユニット６４は、電気モータ６２の回転軸の回転速度を適当に変速して、クランク機構６３へ伝える。ハウジング６１内には、電気モータ６２を付勢するための電源としての電池を装着しうるようになった電池部６５も設けられている。勿論、ハウジング６１には、外部から、このような電池電源をオンオフしうる適当なスイッチ（図示していない）が設けられている。

【００３０】クランク機構６３は、この実施例においては、図４の部分横断面図によく示されているように、電気モータ６２の回転速度を変速して出力するギヤユニット６４の出力軸に接続されて回転されるクランクアーム６３Ａと、このクランクアーム６３Ａの自由端を遊動的に係合させた、ほぼＯ字状の移動子６３Ｂと、ハウジング６１の内壁にそって平行に形成された１対のピストン軸ガイド６３Ｃとからなっている。ピストン軸ガイド６３Ｃは、移動子６３Ｂの両側縁を挟み込むようにして、ピストン部５０のピストン軸５２を一層直線的に往復動させるように、移動子６３Ｂの移動を案内するものである。シリンダ部２０の軸方向にそう移動子６３Ｂの直線運動自体は、ハウジング６１の対向する平行内壁に、移動子６３Ｂの両側面が規制されることによって行われる。ピストン部５０のピストン軸５２の後端は、クランク機構６３の移動子６３Ｂの中心部に連結されている。

【００３１】さらにまた、この実施例では、ハウジング６１の周囲には、バックル７０が取付けられるようになっており、このバックル７０は、乳覆い部１０、取付け部１２、シリンダ部２０および容器接続部３０を構成する第１の構成部分に対して、第２の構成部分であるハウジング６０を、図１に示す如く組み付けたときに、容器接続部３０の外周に係合して、両者の組み付け状態を固定する作用を果たす。また、このバックル７０には、このように組み合わせられた搾乳器全体を片手で把持しうるようにするグリップ部７１が設けられている。

【００３２】次に、乳覆い部１０の取付け部１２に挿着される吸引圧調節部４０の詳細構造および動作につい

て、特に、図５および図６を参照して説明する。図５は、吸引圧調節部４０の分解部品配列斜視図であり、図６は、その吸引圧調節部４０のケースの構造の詳細を示すための一部破断斜視図である。この実施例における吸引圧調節部４０は、加圧開放弁としての機能も果たすものであり、図５によく示されるように、例えば、プラスチック材料にて形成されたケース４１と、例えば、金属の薄い板で形成されたプレート４２と、例えば、ゴム材料で形成されたクッション４３と、例えば、プラスチック材料で形成されたコマ４４と、例えば、プラスチック材料で形成された調節ツマミ４５とを備えている。

【００３３】先ず、ケース４１は、全体として円筒状に成形されたものであり、下端部は、図１によく示されるように、乳覆い部１０の取付け部１２に挿着しうる寸法とされている。その下端部の外周には、図６によく示されるように、Ｏリング４６を装着するための周囲溝４１Ａが設けられている。このＯリング４６は、ケース４１の下端部を取付け部１２へ挿着したときの密着性を高めるためのものである。ケース４１の上端部は、プレート４２、クッション４３およびコマ４４を収納しうる凹部を作り出しており、この凹部の底面部には、乳覆い部１０の通気穴１３と連通する貫通穴４１Ｂを有した底部溝４１Ｃが形成されている。また、この凹部の底面部には、プレート４２およびクッション４３を取り付け固定するための取付け溝４１Ｄおよび取付け柱４１Ｅが形成されている。

【００３４】プレート４２は、周囲の一個所に、比較的に大きな直径を有する圧力開放弁用の穴４２Ａと、この穴４２Ａの両側で複数個所に、比較的に直径の小さな圧力調整用の穴４２Ｂとが形成されている。これらの穴４２Ｂは、後述するようなピストン－シリンダの作用により、乳覆い部１０内に負圧が形成されようとするときに、外気を乳覆い部１０内へと吸い込めるようにして、その負圧の大きさを調整できるようにするものである。さらに、このプレート４２には、ケース４１の取付け柱４１Ｅを挿通させる取付け穴４２Ｃと、後述するクッション４３の取付け凸部４３Ｃを挿通させる挿通穴４２Ｄとが形成されている。

【００３５】クッション４３には、その中心部に、カンチレバー型の弁４３Ａが形成されており、周辺には、プレート４２に形成された穴４２Ｂのそれぞれと一致する位置に、圧力調整用の穴４３Ｂが形成されている。弁４３Ａは、プレート４２の圧力開放弁用の穴４２Ａを、常時は、閉じているが、後述するようなピストン－シリンダの作用により、乳覆い部１０内が加圧されようとするときには、その穴４２Ａを開放してその加圧力を開放させる作用をするものである。また、クッション４３の上面の穴４３Ｂの周辺部は、盛り上げられており、後述するコマ４４の下面とクッション４３の上面との間に空間が作り出されるようにしている。さらに、このクッション４３の下面には、プレート４２の挿通穴４２Ｄに挿通されて、さらに、ケース４１の取付け溝４１Ｄに嵌まり込みうる取付け凸部４３Ｃが設けられており、また、ケース４１の取付け柱４１Ｅの先端を受け入れる受入穴（図示していない）が設けられている。

【００３６】コマ４４は、調節ツマミ４５の下面内側に取付け固定される形状とされていて、その下面の外周の一部分に、圧力調整用の切欠き凹部４４Ａが形成されている。すなわち、クッション４３の上面にコマ４４の下面が接触した状態においては、そのコマ４４の下面の切欠き凹部４４Ａに対応する位置にある穴４３Ｂのみが外気を吸込みうるものとされるのである。一方、プレート４２の圧力開放弁用の穴４２Ａが弁４３Ａによって開放されたときには、前述したようなクッション４３の上面とコマ４４の下面との間に形成された空間を通して、圧力が開放されうるのである。

【００３７】調節ツマミ４５の下面の詳細は、図に現れていないが、コマ４４の上端部を取付け固定しうるような形状とされている。図１によく示されているように、この調節ツマミ４５は、ケース４１の上端に対して回転しうるように挿着されるような形状とされている。すなわち、調節ツマミ４５をケース４１に対して回転させると、コマ４４が一緒に回動させられることにより、その切欠き凹部４４Ａによって開放されるクッション４３の穴４３Ｂおよびプレート４２の穴４２Ｂの数が変化させられ、それにより、圧力調整を行えるようになっている。

【００３８】次に、前述したような構成を有する吸引圧脈動式搾乳器の全体的な動作について説明する。搾乳を行おうとするユーザは、先ず、図１に示すように、乳捕集容器１のネジ部１Ａを容器接続部３０のネジ部３１にねじ込むことにより、乳捕集容器１を組み付けると共に、ピストン部５０をシリンダ部２０内に挿着するようにして駆動部６０を乳覆い部１０に対して合体させて、バックル７０にてこの合体をロックする。

【００３９】それから、ユーザは、グリップ部７１を把持して、このようにして組み立てられた搾乳器の乳覆い部１０の開口部１１を通して、自身の乳房に対して乳覆い部１０を押し付けるようにして被せる。そして、吸引圧調節部４０の調節ツマミ４５を回動させて、吸引圧を所望値に設定する。その後、駆動部６０に設けられた電源スイッチ（図示していない）をオンに切り換える。

【００４０】すると、電気モータ６２が付勢されて、電気モータ６２の回転軸の回転により、ギヤユニット６４を介して、所定の回転速度にて、クランク機構６３のクランクアーム６３Ａが回転させられる。このようなクランクアーム６３Ａの回転により、移動子６３Ｂがハウジング６１の両側内壁およびピストン軸ガイド６３Ｃによって案内されて、図１および図４において実線で示した位置と仮想線で示した位置との間で往復動させられるよ

うになる。したがって、この移動子６３Ｂに接続されたピストン軸５２も往復動させられ、ピストン頭５１が、シリンダ部２０内において、図１に実線で示した位置と仮想線で示した位置との間で往復動させられる。

【００４１】このようなピストン頭５１のシリンダ部２０内での往復動作によって搾乳が行われるのであるが、次に、その動作の詳細について説明する。先ず、図１においてピストン頭５１は、仮想線で示す位置、すなわち、乳収集部２２の底部の穴部２４の前方穴２４Ａと、後方中央穴２４Ｂおよび後方側部穴２４Ｃとの間の位置にあると仮定する。この位置は、ピストン頭５１の最後退位置である。この位置からピストン頭５１が前方へと移動させられて、テーパ部２３を越えて、吸引部２１内へと入って行くとき、乳覆い部１０内の空気が圧縮され始めて、圧力が高まろうとする。しかし、乳覆い部１０内の空気は、その圧力の高まりにより、圧力調節部４０の弁４３Ａが開くことにより、通気穴１３および圧力開放弁用の穴４２Ａを通して外部へと逃がされる。したがって、ピストン頭５１は、シリンダ部２０の吸引部２１内へとスムーズに押し込まれうる。そして、ピストン頭５１は、図１において実線で示す位置、すなわち、最前進位置へと移動する。

【００４２】次いで、ピストン頭５１は、この最前進位置から後方へと移動させられ始める。すると、この吸引部２１においては、ピストン頭５１の外周はシリンダ部の内壁に密着しているので、乳覆い部１０内に吸引圧が生ぜしめられ始める。このような吸引圧により、乳覆い部１０に装着された乳房が絞られ、搾乳が行われ始める。このような搾乳作用は、ピストン頭５１が、吸引部２１と乳収集部２２との間の遷移部に相当するテーパ部２３へと後退するまで続けられる。ピストン頭５１がテーパ部２３を越えて後退すると、乳収集部２２では、ピストン頭５１の外周とシリンダ部２０の内壁との密着性が失われるので、それ以上の吸引圧の発生は停止させられる。そして、ピストン頭５１が仮想線で示す最後退位置に達すると、搾乳された乳は、開放された穴部２４の、主として、前方穴２４Ａを通して且つ容器接続部３０の内部を通して、そこに接続された容器１内へと落下して、そこに捕集される。ピストン頭５１の外周とシリンダ部２０の内壁との間の若干の隙間を通して、ピストン頭５１の後ろへと回り込んだ乳も、穴部２４の後方中央穴２４Ｂおよび後方側部穴２４Ｃを通して、容器１内に捕集できる。

【００４３】この最後退位置からピストン頭５１は、再び、前方へと移動させられて、前述したような動作が繰り返されることになる。こうして、乳覆い部１０内に装着された乳房には、脈動的に吸引圧が加えられて、実際に乳児が母乳を吸うのと同じような動作にて、搾乳が続けられることになる。ユーザは、このような搾乳動作中において、吸引圧に違和感を感ずる場合には、調節ツマミ４５を回動させて、その吸引圧を違和感のないものに調整することも可能である。

【００４４】このようにして適当量の搾乳がなされた後には、ユーザは、自分の乳房から搾乳器を外し、容器１を容器接続部３０から取り外して、容器１そのままで適当な場所に保管しておき、後に乳児に飲ますことができる。勿論、容器１から別の適当な容器へと搾乳された母乳を移して保管することも自由である。この搾乳器のその後の使用を衛生的なものとするために、使用後は、すぐに、乳覆い部１０、シリンダ部２０および容器接続部３０の第１の構成部分から、駆動部６０およびピストン部５０の第２の構成部分を取り外し、さらに、取付け部１２から圧力衝接部４０も取り外し、ピストン軸５２の先端からピストン頭５１も取り外して、各部分を清掃しておくとよい。

【００４５】なお、前述した実施例では、ピストン部の駆動源として電気モータを使用しているが、本発明は、これに限らず、例えば、ピストン部を手動にて動作させるようなものとすることもできる。

【００４６】

【発明の効果】乳覆い部に対してシリンダ部を直結した構成としたことにより、構造が非常に簡単となり、それだけコストの低減ができ、しかも、使用後の清掃も非常に簡単となり、衛生上の問題もない。

【００４７】搾乳された母乳は、その後の使用のために容器へと直接的に捕集され得るので、それだけ母乳の衛生状態を良好に保つのが容易である。

【００４８】搾乳された母乳は、シリンダ部の乳収集部２２の穴部２４を通してほとんどすべて容器へと捕集できるので、母乳の捕集率を高めることができる。

【００４９】搾乳された母乳の流路が非常に簡単な構造とされているので、母乳が構成部分にへばり付いてしまうようなことはなく、したがって、動作不良が生じたり、母乳が捕集容器へと送出されるタイミングが不規則とされてしまうようなことはない。

【００５０】ピストンポンプ部によって発生すべき吸引圧は、乳覆い部とシリンダ部の一部分である吸引部との内部だけですむので、負圧空間が最小限とされ、必要な吸引圧を発生させるために必要な動力は最小限ですみ、したがって、ピストンポンプを電気モータにて駆動するような場合には、それだけ消費電力が少なくてすむ。使用する電気モータも小型とすることができるので、それだけ搾乳器全体の大きさも小型とすることができる。

【００５１】一定周期の一定吸引圧で、より乳児が母乳を吸う感覚に近い搾乳が行える。

【００５２】乳覆い部に、吸引圧調節部と加圧開放弁とを共有化した加圧開放弁付調節部を設けることにより、簡単に搾乳しながら吸引圧を調節でき、違和感の伴わない搾乳を行わせることができる。

【００５３】この加圧開放弁付調節部は、乳覆い部に対

して着脱自在なものとしておくことにより、簡単な構造の乳覆い部の清掃が容易となる。

【００５４】搾乳された母乳を容器へと捕集するために乳収集部に設ける穴部の構成を工夫することにより、搾乳された母乳の捕集率をより高めることができる。

【図面の簡単な説明】

【図１】本発明の一実施例としての吸引圧脈動式搾乳器を、組立てた状態において乳捕集容器を接続した状態で示す概略断面図である。

【図２】図１の吸引圧脈動式搾乳器の幾つかの構成部分を分解した状態で示す概略断面図である。

【図３】図１の搾乳器の乳収集部の穴部の構成を詳細に示すための部分横断面図である。

【図４】図１の搾乳器のクランク機構の詳細を示すための部分横断面図である。

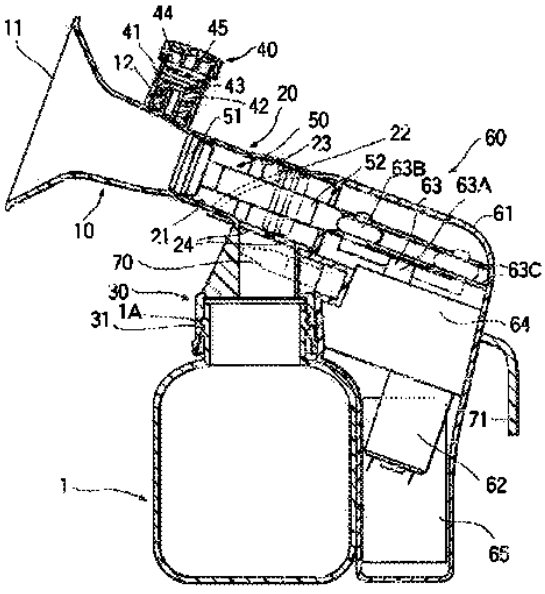
【図５】図１の搾乳器の吸引圧調節部４０の分解部品配列斜視図である。

【図６】図５の吸引圧調節部のケースの構造の詳細を示すための一部破断斜視図である。

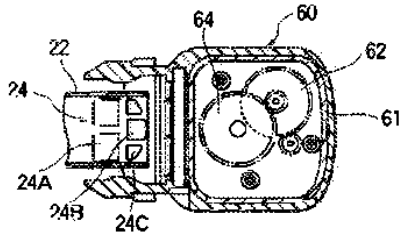
【符号の説明】

１　乳捕集容器
１０　乳覆い部
１１　開口部
２０　シリンダ部
２１　吸引部
２２　乳収集部
２３　テーパ部
２４　穴部
３０　容器接続部
４０　吸引圧調節部
５０　ピストン部
５１　ピストン頭
５２　ピストン軸
６０　駆動部
６１　ハウジング
６２　電気モータ
６３　クランク機構
６３Ａ　クランクアーム
６３Ｂ　移動子
６３Ｃ　ピストン軸ガイド
６４　ギヤユニット
６５　電池部

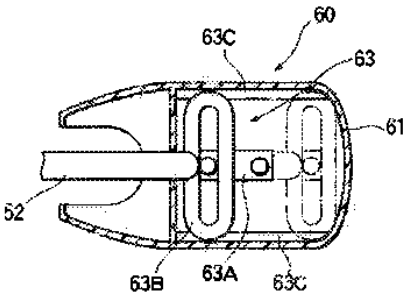
【図１】



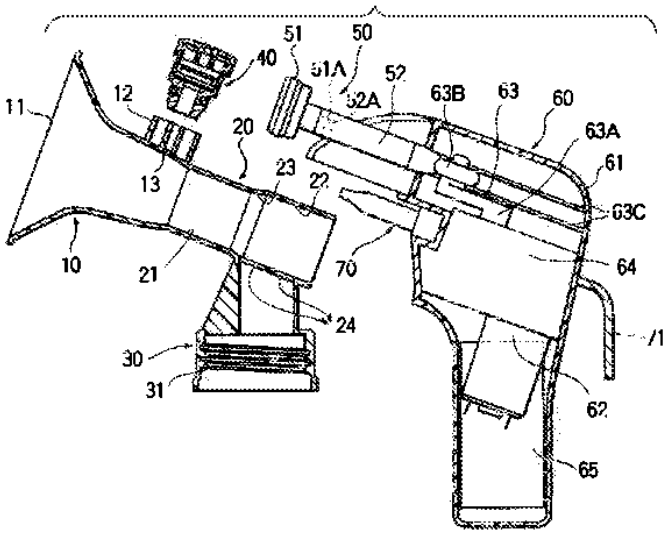
【図３】



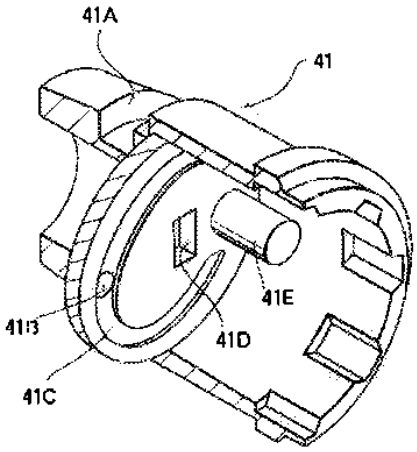
【図４】



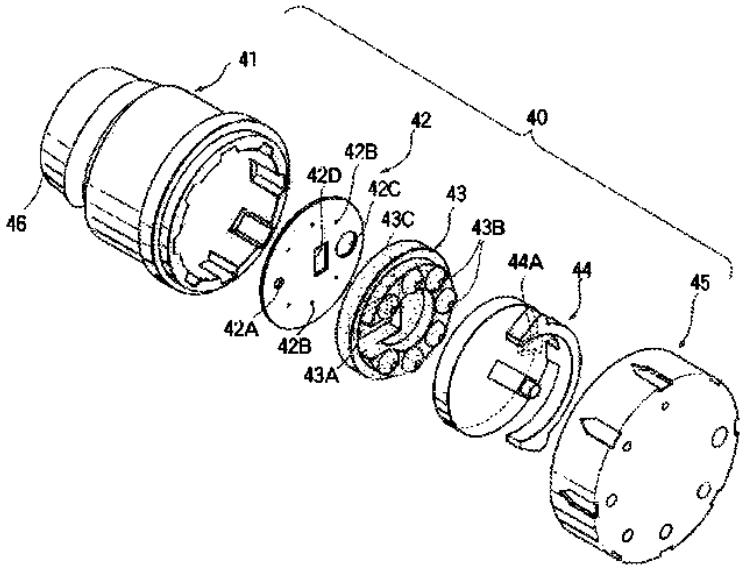
【図２】



【図６】



【図５】



フロントページの続き

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Pulsating suction force milking machine

Abstract

PROBLEM TO BE SOLVED: To provide a pulsating suction force milking machine which has simple structure, is small, of low power consumption, cost effective, and easily keeps good sanitary conditions. SOLUTION: This pulsating suction force milking machine is provided with a breast cover 10, cylinder 20, piston 50 installed in the cylinder 20, drive section 60 which reciprocates the piston 50 within the cylinder area in the cylinder 20 to make pulsating suction force in the udder cover 10. The inside wall size of the cylinder 20 defining the area of the cylinder is designed in such a manner that at the area near the udder cover 10, the circumference of the piston head 51 of the piston 50 is adhered to create a suction area 21 of a specified length, and at an area far from the udder cover 10, there is a clearance between the inside wall and the piston head 51 of the piston 50, and a milk collecting section 22 is made in which milk collected by suction force is guided to the outside, and at an area of the bottom of the cylinder 20 corresponding to the milk collecting section 22, an aperture 24 is made to feed collected milk to the outside.

Classifications

- A61M1/06 Milking pumps

JPH11178917A
Japan
Find Prior Art | Similar

Other languages: Japanese

Inventor: Hitoshi Tominaga, 斎 富永, Tadashi Kobota, 正 久保田, Kazuhiko Takano, 和彦 高野, Hiroyuki Uehara, 弘之 上原

Current Assignee : Hirose Electric Co Ltd, Pigeon Corp

Worldwide applications

1997 · 世

Application JP9356848A events

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Status • Expired - Fee Related

Info: Cited by (3), Legal events, Similar documents, Priority and Related Applications

External links: Espacenet, Global Dossier, Discuss

Claims (10)

Hide Dependent
Machine Translated from Japanese

[Claims] 1. A breast cover having an opening which is attached to a breast and receives a nipple in use, and a cylinder space which communicates with the inside of the breast cover at a side of the breast cover opposite to the opening. A cylinder portion to be defined, a piston portion inserted into the cylinder portion, and a drive portion for causing the piston portion to reciprocate in the cylinder space to generate pulsating suction pressure in the breast covering portion. The inner wall dimension of the cylinder portion that defines the cylinder space, on the side close to the breast covering portion, tightly contact the outer circumference of the piston head of the piston portion to provide a suction portion of a predetermined length, On the side far from the breast covering part, a slight clearance is provided between the piston part and the outer periphery of the piston head to collect milk pumped by the suction pressure to the outside. The bottom of the cylinder portion corresponding to the milk collecting unit is formed with a hole that allows the collected milk to be sent out to the outside. Pulsating breast pump with suction pressure. 2. A suction pressure pulsating breast pump according to claim 1, wherein a tapered portion is formed on an inner wall of said cylinder portion at a portion corresponding to a transition portion between said suction portion and said milk collecting portion. . 3. A cylinder connection means for connecting a milk collection container for collecting milked milk at a position surrounding the hole portion in the cylinder portion. Or the suction pulsation milking machine according to 2. 4. The driving unit includes an electric motor and crank means connected to a rotating shaft of the electric motor for converting a rotating motion of the rotating shaft into a reciprocating motion in an axial direction of the cylinder space. The suction pressure pulsation type breast pump according to claim 1, wherein a piston shaft of the piston portion is connected to the crank means. 5. The suction pulsation type breast pump according to claim 1, wherein said breast covering portion is provided with suction pressure adjusting means. 6. The breast covering part and the cylinder part,
The drive part is integrally formed as a first component, and the drive unit is disposed inside a housing formed as a second component detachable from the first component. A suction pressure pulsation milking machine according to any one of 1 to 5. 7. The piston portion is detached from the cylinder portion together with the housing when the housing is detached from the first component.
The suction pressure pulsating breast pump according to claim 6, wherein the piston head of the piston portion is detachable from a tip portion of the piston shaft. 8. The suction pressure pulsating breast pump according to claim 6, wherein a piston shaft guide for linearly reciprocating the piston shaft of the piston portion is formed on an inner wall of the housing. 9. The suction pressure pulsation type breast pump according to claim 6, wherein the housing is provided with a buckle for fixing to the first component. 10. The suction pressure pulsating breast pump according to claim 9, wherein the buckle is provided with a grip portion that can be gripped with one hand.

Description

Translated from Japanese

DETAILED DESCRIPTION OF THE INVENTION

[0001]

FIELD OF THE INVENTION The present invention relates to breast pumps and, more particularly, to a breast pump for extracting breast milk from the breast for storage in a newborn for later consumption. It is about a vessel.

[0002]

2. Description of the Related Art This type of breast pump is sometimes called a breast pump, and is typically divided into two types. That is, there are a type driven by a motor and a type driven manually. This kind of so-called breast pump, whether it is motor-driven or manual, has a pulsating suction pressure using a reciprocating piston pump, because it is easy to actually achieve the same effect as a baby sucking breast milk. The mainstream is the suction pressure pulsation type in which the milk is milked by hanging it on the breast.

[0003] Conventional examples of such a suction pressure pulsation type breast pump include those disclosed in, for example, Japanese Patent Application Laid-Open No 1-317448 and US Pat. No. 4,929,229. These conventional suction pressure pulsating breast pumps communicate with the breast cover having an opening that is attached to the breast and receives the nipple during use and collects the milk expressed by the inside of the breast cover. A reciprocating piston pump for generating suction pressure inside the breast cover, and a connection for connecting the breast cover and the reciprocating piston pump. ing.

When a suction pressure is created in the breast cover by the reciprocating piston pump in the collection chamber, the interior of the collection chamber is sealed from the outside, but the milk collected there is discharged to the outside. A disc is provided which operates to open the interior of the collection chamber to the outside in order to send out. Also, between the breast cover and the collection chamber and in the middle of the vacuum line to the reciprocating piston pump, milked milk is prevented from entering the reciprocating piston pump. Separation walls and the like are also provided.

According to such a conventional suction pressure pulsation type breast pump, an appropriate container is connected to the collection chamber, the breast cover is attached to the breast, and the reciprocating piston pump is operated. For example, the nipple and adjacent parts may be sucked and pulled into a narrow portion within the nipple cover due to the negative pressure or vacuum pulsatingly generated within the breast cover. Such a pulling action massages and compresses the breast so that the baby can suck, causing the extraction of breast milk. The breast milk extracted into the nipple cover is guided to the collection chamber, where it is collected into a container connected to the collection chamber when the disc is allowed to open to the outside.

[0006]

However, such a conventional breast pump has a complicated internal structure such as a breast cover portion and a collection room portion, which increases the cost, and also requires cleaning after use. It was very difficult and there were hygiene issues

Before the milked milk is collected in a container for subsequent use, it comes into contact with the separation wall of the breast cover, the disk of the collection chamber, and the like, so that the sanitary condition of the milk is improved accordingly. Difficult to keep in.

[0008] Further, the breast milk that has flowed into the piston pump section over the separation wall has to be discarded, and the collection rate of the breast milk is accordingly reduced.

[0009] Breast milk tends to stick to the disk, and malfunctions are likely to occur. In addition, the timing at which breast milk is delivered to the collection container tends to be irregular.

[0010] Since the suction pressure generated by the piston pump section must be applied to the inside of the breast covering section through the connection section and the collection chamber section, the negative pressure space is large, and in order to generate the required suction pressure. , So much power is needed. Therefore, when the piston pump is driven by the electric motor, the power consumption increases accordingly. This is a significant problem, especially in the case of battery power.

It is an object of the present invention to provide a suction pulsating breast pump which can solve the problems of the prior art as described above.

[0012]

SUMMARY OF THE INVENTION A suction pulsating breastpump according to the present invention is provided with a breast cover having an opening which is attached to the breast for use and receives a nipple, and the opening of the breast cover. On the opposite side, a cylinder part that defines a cylinder space communi-cating with the inside of the breast cover part, a piston part inserted in the cylinder part, and the piston part reciprocates in the cylinder space to enter the breast cover part. A drive unit for generating suction pressure in a pulsating manner, wherein an inner wall dimension of the cylinder unit that defines the cylinder space is, on a side close to the breast covering unit, an outer periphery of a piston head of the piston unit. To provide a suction portion of a predetermined length in close contact, and on the side far from the breast covering portion, to give a slight gap between the piston portion and the outer periphery of the piston head, it is selected so as to provide a milk collecting section for collecting milk expressed by drawing under pressure, and the bottom of the cylinder section corresponding to the milk collecting section is provided with milk collected there. A hole is formed so as to be capable of being sent to the outside.

According to one embodiment of the present invention, a tapered portion is formed on an inner wall of the cylinder portion at a portion corresponding to a transition portion between the suction portion and the milk collecting portion.

According to one embodiment of the present invention, the cylinder portion has a container connection for connecting a milk collecting container for collecting milked milk at a position surrounding the hole. Means are provided.

According to one embodiment of the present invention, the driving section is connected to an electric motor and a rotating shaft of the electric motor, so that the rotating motion of the rotating shaft is reciprocated in the axial direction of the cylinder space. And a crank means for converting the piston into a piston. The piston shaft of the piston portion is connected to the crank means.

According to another embodiment of the present invention, the breast cover is provided with suction pressure adjusting means.

According to yet another embodiment of the present invention,
The breast cover and the cylinder are integrally formed as a first component, and the driving unit is formed as a second component that is detachable from the first component. Located inside the housing.

According to one preferred embodiment of the present invention,
The piston portion is detached from the cylinder portion together with the housing when the housing is detached from the first component, and the piston head of the piston portion is provided at a tip end of the piston shaft. The part is detachable.

According to one preferred embodiment of the present invention,
A piston shaft guide for linearly reciprocating the piston shaft of the piston portion is formed on an inner wall of the housing.

According to another preferred embodiment of the present invention, the housing is provided with a buckle for fixing to the first component.

According to an embodiment of the present invention, the buckle is provided with a grip portion which can be gripped with one hand.

[0022]

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS Next, the present invention will be described in more detail with reference to the accompanying drawings.

FIG. 1 is a schematic sectional view showing a suction pulsation type breast pump as one embodiment of the present invention in a state where a milk collecting container is connected in an assembled state, and FIG. It is a schematic sectional drawing which shows some components of a suction pressure pulsation type breast pump in the disassembled state. As shown in FIGS. 1 and 2, the suction-pulsation-type breast pump of this embodiment mainly includes a breast covering part 10 having

an opening 11 which is attached to a breast in use and receives a nipple, A cylinder section 20 that defines a cylinder space communicating with the inside of the breast covering section 10 on the opposite side of the opening section 11 of the breast covering section 10, a piston section 50 inserted into the cylinder section 20, and the piston section 50. And a drive unit 60 for reciprocating within the breast cover 10 so as to generate pulsating suction pressure in the breast covering unit 10.

In this embodiment, the inner wall dimension of the cylinder portion 20 that defines the cylinder space is set to a predetermined value on the side close to the breast cover portion 10 by closely contacting the outer periphery of a piston head 51 of the piston portion 50 as described later. Length suction unit 21
On the side remote from the breast covering portion 10 to provide a slight gap between the piston portion 50 and the outer periphery of the piston head 51 to collect milk milked by suction pressure to the outside. The part 22 is selected to provide. Further, a tapered portion 23 is formed on the inner wall of the cylinder portion 20 at a portion corresponding to a transition portion between the suction portion 21 and the milk collecting portion 22.

A hole 24 is formed in the bottom of the cylinder 20 corresponding to the milk collecting unit 22 so that the milk collected there can be sent out. As shown in the partial cross-sectional view of FIG. 3, in this embodiment, the hole 24 is located at the most backward position of the piston head 51 (the position shown by the phantom line in FIG. 1). , A pair of substantially square front holes 24A, a substantially square rear central hole 24B disposed after the rearmost position of the piston head 51, and a pair of right and left rear sides substantially quadrant. 24C.

Further, in this embodiment, the cylinder connecting portion 30 is connected to the container connecting portion 30 for connecting the milk collecting container 1 for collecting milked milk at a position surrounding the hole portion 24. Is provided. This container connection part 30
Is formed in a cylindrical shape as a whole so as to extend downward from the bottom surface of the milk collecting part 22 of the cylinder part 20. As shown in FIG. 1, a screw portion 31 for screwing the screw portion 1 </ b> A at the mouth of the milk collecting container 1 is formed on the inner periphery of the lower end of the container connecting portion 30.

In this embodiment, an attachment portion 12 for detachably attaching the suction pressure adjusting portion 40 is formed in the breast covering portion 10. The mounting portion 12 is formed of a double cylindrical wall formed so as to surround a ventilation hole 13 formed in the wall of the milk covering portion 10. The detailed structure and operation of the suction pressure adjusting unit 40 will be described later. In this embodiment, as best shown in FIG. 2, the milk wrap 10 including the mounting portion 12 and the cylinder 20 including the container connection 30 are made of a suitable material such as a first component, for example, it is integrally formed of a plastic material.

In this embodiment, the piston section 50 comprises a piston head 51 and a piston shaft 52 so that the piston head 51 can be detachably attached to the front end. As shown in FIG. 2, a female screw hole 52 </ b> A is formed at the center of the front end of the piston shaft 52, and a male screw 51 </ b> A is formed at the rear end shaft of the piston head 51.
By screwing the male screw 51A into the female screw hole 52A,
The piston head 51 can be attached and fixed to a piston shaft 52.

In this embodiment, the drive unit 60 has a second structure which is detachably attached to the first components of the milk cover unit 10, the attachment unit 12, the cylinder unit 20, and the container connection unit 30. It has a housing 61 formed as a part. The housing 61 is also integrally formed of a suitable material, for example, a plastic material. The drive unit 60 is connected to an electric motor 62 and a rotating shaft of the electric motor 62 disposed in the housing 61, and converts the rotating motion of the rotating shaft into a reciprocating motion in the axial direction of the cylinder space. And a crank mechanism 63 for performing the operation. In this embodiment, a gear unit 64 is interposed between the electric motor 62 and the crank mechanism 63. The gear unit 64 appropriately changes the rotation speed of the rotating shaft of the electric motor 62, and Tell 63
A battery unit 6 in which a battery as a power source for energizing the electric motor 62 can be mounted is provided in the housing 61
6 is also provided. Of course, the housing 61 is provided with a suitable switch (not shown) that can turn on and off such a battery power supply from outside.

In this embodiment, the crank mechanism 63 is connected to an output shaft of a gear unit 64 for changing the rotation speed of the electric motor 62 and outputting the same, as is well shown in the partial cross-sectional view of FIG. A crank arm 63A which is rotated and rotated, a substantially O-shaped mover 63B in which a free end of the crank arm 63A is loosely engaged, and a pair formed in parallel along the inner wall of the housing 61. And a piston shaft guide 63C. Piston shaft guide 6
3C sandwiches both side edges of the mover 63B,
This guides the movement of the movable member 63B so that the piston shaft 52 of the piston portion 50 reciprocates more linearly. The linear movement itself of the moving member 63B in the axial direction of the cylinder portion 20 is performed by the opposing parallel inner walls of the housing 61 restricting both side surfaces of the moving member 63B. The rear end of the piston shaft 52 of the piston portion 50 is connected to the center of the moving member 63B of the crank mechanism 63.

Further, in this embodiment, a buckle 70 is mounted around the housing 61, and the buckle 70 is connected to the milk cover part 10, the mounting part 12, the cylinder part 20, and the container connecting part. When a housing 60 as a second component is assembled as shown in FIG. 1 with respect to the first component constituting the component 30, the housing 60 engages with the outer periphery of the container connection portion 30, and the two components are assembled. Serves to fix the In addition, the buckle 70 is provided with a grip portion 71 that enables the whole breast pump combined in this way to be gripped with one hand.

Next, the detailed structure and operation of the suction pressure adjusting section 40 inserted into the mounting section 12 of the milk covering section 10 will be described with reference to FIGS. 5 and 6. FIG.
6 is a perspective view of an exploded component arrangement of the suction pressure adjusting unit 40, and FIG. 6 is a partially cutaway perspective view showing details of the structure of the case of the suction pressure adjusting unit 40. The suction pressure adjusting unit 40 in this embodiment also functions as a pressure release valve, and as shown in FIG. 5, for example, a case 41 formed of a plastic material and a metal It includes a plate 42 formed of a thin plate, a cushion 43 formed of, for example, a rubber material, a top 44 formed of, for example, a plastic material, and an adjustment knob 45 formed of, for example, a plastic material. .

First, the case 41 is formed into a cylindrical shape as a whole, and the lower end portion is sized so as to be able to be inserted into the mounting portion 12 of the milk covering portion 10, as is well shown in FIG. ing. On the outer periphery of the lower end, as shown in FIG.
A is provided. The O-ring 46 is attached to the case 41
This is for improving the adhesiveness when the lower end of the base is inserted into the mounting portion 12. The upper end of the case 41 has a recess capable of accommodating the plate 42, the cushion 43, and the top 44, and the bottom of the recess has a milk cover 1
A bottom groove 41C having a through hole 41B communicating with the zero ventilation hole 13 is formed. Further, a mounting groove 41D and a mounting column 41E for mounting and fixing the plate 42 and the cushion 43 are formed on the bottom surface of the concave portion.

The plate 42 is provided with a pressure relief valve hole 42A having a relatively large diameter at one location and a pressure adjustment hole with a relatively small diameter at a plurality of locations on both sides of the hole 42A. 42B are formed. These holes 4
2B, when a negative pressure is to be formed in the milk cover 10 by the action of a piston cylinder as described later, so that outside air can be sucked into the milk cover 10 and
The magnitude of the negative pressure can be adjusted.
Further, the plate 42 has an attachment hole 42C through which the attachment column 41E of the case 41 is inserted, and an insertion hole 42D through which an attachment protrusion 43C of the cushion 43 described later is inserted
Are formed.

The cushion 43 has a cantilever type valve 43A formed at the center thereof, and a pressure adjusting hole 43B formed at a position corresponding to each of the holes 42B formed in the plate 42 at the periphery thereof. Are formed. Valve 4

3A normally closes the hole 42A for the pressure release valve of the plate 42, but when the inside of the milk covering part 10 is to be pressurized by the action of the piston-cylinder as described later, the hole is used. 42A is released to release the pressing force. The periphery of the hole 43 </ b> B on the upper surface of the cushion 43 is raised, so that a space is created between the lower surface of the top 44 and the upper surface of the cushion 43, which will be described later. Further, on the lower surface of the cushion 43, there is provided a mounting projection 43C which is inserted through the insertion hole 42D of the plate 42 and can be fitted into the mounting groove 41D of the case 41. A receiving hole (not shown) for receiving the tip of the column 41E is provided.

The top 44 has a shape fixed to the inside of the lower surface of the adjustment knob 45, and a notch concave portion 44A for pressure adjustment is formed in a part of the outer periphery of the lower surface. That is, when the lower surface of the top 44 is in contact with the upper surface of the cushion 43, only the hole 43B located at a position corresponding to the cutout recess 44A on the lower surface of the top 44 can suck outside air. On the other hand, when the pressure release valve hole 42A of the plate 42 is opened by the valve 43A, the pressure can be released through the space formed between the upper surface of the cushion 43 and the lower surface of the top 44 as described above. is there.

The details of the lower surface of the adjustment knob 45 are not shown in the figure, but are shaped so that the upper end of the top 44 can be attached and fixed. As best shown in FIG.
The adjustment knob 45 is shaped so as to be rotatable with respect to the upper end of the case 41. That is, when the adjustment knob 45 is rotated with respect to the case 41, the top 44 is rotated together, so that the number of the holes 43 </ b> B of the cushion 43 and the number of the holes 42 </ b> B of the plate 42 opened by the cutout recesses 44 </ b> A are reduced. It is varied so that a pressure adjustment can be made.

Next, the overall operation of the suction pressure pulsation type breast pump having the above-described configuration will be described. The user who wants to perform milking first attaches the milk collecting container 1 by screwing the screw portion 1A of the milk collecting container 1 into the screw portion 31 of the container connecting portion 30 as shown in FIG. The drive unit 60 is combined with the milk cover unit 10 by inserting the unit 50 into the cylinder unit 20,
This union is locked by the buckle 70.

Then, the user grasps the grip 71 and pushes the milk cover 10 against his / her breast through the opening 11 of the milk cover 10 of the breast pump assembled in this way. Cover. Then, the adjustment knob 45 of the suction pressure adjusting section 40 is turned to set the suction pressure to a desired value. Thereafter, a power switch (not shown) provided in the drive unit 60 is turned on.

Then, the electric motor 62 is energized, and the rotation of the rotating shaft of the electric motor 62 causes the gear unit 64 to rotate.
, The crank arm 63A of the crank mechanism 63 is rotated at a predetermined rotation speed. Due to the rotation of the crank arm 63A, the mover 63B is guided by the inner wall on both sides of the housing 61 and the piston shaft guide 63C, and moves between the position indicated by the solid line and the position indicated by the imaginary line in FIGS. To reciprocate. Therefore, the piston shaft 52 connected to the mover 63B is also reciprocated, and the piston head 51
The cylinder is reciprocated in the cylinder section 20 between a position indicated by a solid line and a position indicated by a virtual line in FIG.

The cylinder part 2 of the piston head 51 as described above
Milking is performed by reciprocating motion within 0,
Next, details of the operation will be described. First, in FIG. 1, the piston head 51 is located at a position indicated by an imaginary line, that is, a front hole 24 </ b> A of the hole 24 at the bottom of the milk collecting unit 22.
Assume that it is located between rear center hole 24B and rear side hole 24C. This position is the last retreat position of the piston head 51. From this position, when the piston head 51 is moved forward and crosses the taper portion 23 and enters the suction portion 21, the air in the milk cover portion 10 starts to be compressed, and the pressure increases. I do. However, the breast cover 10
The air inside is increased by the pressure control unit 40 due to the increase in the pressure.
When the valve 43A is opened, it escapes to the outside through the vent hole 13 and the hole 42A for the pressure release valve. Therefore, the piston head 51 is connected to the suction section 21 of the cylinder section 20.
It can be pushed in smoothly. Then, the piston head 51 moves to the position shown by the solid line in FIG. 1, that is, to the most advanced position

Next, the piston head 51 starts to be moved backward from the most advanced position. Then, in the suction section 21, since the outer periphery of the piston head 51 is in close contact with the inner wall of the cylinder section, suction pressure starts to be generated in the milk covering section 10. With such a suction pressure, the breast attached to the milk covering part 10 is squeezed, and milking starts. Such a milking action is continued until the piston head 51 retreats to the taper portion 23 corresponding to a transition portion between the suction portion 21 and the milk collection portion 22. When the piston head 51 retreats beyond the taper portion 23, the milk collecting unit 22 loses the adhesion between the outer periphery of the piston head 51 and the inner wall of the cylinder unit 20, so that further generation of suction pressure is stopped. . When the piston head 51 reaches the last retracted position indicated by the imaginary line, the milked milk is removed from the opened hole 24.
Mainly through the front hole 24A and the container connection 3
Through the interior of 0, it falls into the container 1 connected thereto and is collected there. The milk that has wrapped around the rear of the piston head 51 through a slight gap between the outer periphery of the piston head 51 and the inner wall of the cylinder portion 20 also passes through the rear central hole 24B and the rear side hole 24C of the hole portion 24, and the container. 1 can be collected.

From this last retreat position, the piston head 51 is moved forward again, and the above-described operation is repeated. Thus, the suction pressure is applied to the breast mounted in the milk cover part 10 in a pulsating manner, and the milking is continued by the same operation as the actual sucking of the breast milk by the infant. If the user feels uncomfortable with the suction pressure during such a milking operation, the user can also rotate the adjustment knob 45 to adjust the suction pressure to one that does not cause uncomfortable feeling.

After an appropriate amount of milking has been performed in this way, the user removes the breast pump from his / her breast, and
Can be detached from the container connection portion 30 and stored in an appropriate place with the container 1 as it is, so that it can be later consumed by an infant. Of course, it is free to transfer and store the milked milk from the container 1 to another suitable container. In order to make the subsequent use of this breast pump sanitary, immediately after use, the milking part 10, the cylinder part 20 and the first component part of the container connection part 30 are immediately replaced by the drive part 60 and the piston. It is preferable to remove the second component of the portion 50, further remove the pressure contact portion 40 from the mounting portion 12, and remove the piston head 51 from the tip of the piston shaft 52, and clean each portion.

In the above-described embodiment, the electric motor is used as the driving source of the piston portion.
However, the invention is not limited to this. For example, the piston unit may be manually operated.

[0046]

According to the construction in which the cylinder portion is directly connected to the milk cover portion, the structure becomes very simple, the cost can be reduced accordingly, and the cleaning after use becomes very simple, and the sanitary condition is improved. No problem

[0047] Milked milk can be collected directly into containers for subsequent use, so that it is easier to maintain good milk hygiene.

[0048] Almost all of the milk that has been milked can be collected in the container through the hole 24 of the milk collecting unit 22 of the cylinder unit, so that the collection rate of breast milk can be increased

Since the passage of the milked milk has a very simple structure, there is no possibility that the milk sticks to the constituent parts, so that malfunctions occur or the milk is collected. There is no irregularity in the timing of the delivery to the container.

Since the suction pressure to be generated by the piston pump section only needs to be inside the milk cover section and the suction section which is a part of the cylinder section, the negative pressure space is minimized and the necessary suction pressure is generated. Requires minimal power,
Therefore, when the piston pump is driven by the electric motor, the power consumption is reduced accordingly. Since the electric motor used can also be small, the overall size of the breast pump can be reduced accordingly.

With a constant suction pressure at a constant cycle, milking can be performed more like a baby sucking breast milk.

By providing a control unit with a pressure release valve that shares the suction pressure control unit and the pressure release valve in the milk cover unit,
The sucking pressure can be adjusted while milking easily, and milking without discomfort can be performed.

The adjusting section with the pressure release valve is detachable from the milk covering section, thereby facilitating cleaning of the milk covering section having a simple structure.

By devising the configuration of the hole provided in the milk collecting section for collecting the milked milk into the container, the collection rate of the milked milk can be further increased

[Brief description of the drawings]

FIG. 1 is a schematic cross-sectional view showing a suction pressure pulsation type breast pump as one embodiment of the present invention in a state where a milk collecting container is connected in an assembled state.

FIG. 2 is a schematic sectional view showing some components of the suction pressure pulsation type breast pump of FIG. 1 in an exploded state.

FIG. 3 is a partial cross-sectional view showing in detail a configuration of a hole of a milk collecting unit of the breast pump of FIG. 1.

FIG. 4 is a partial cross-sectional view showing details of a crank mechanism of the breast pump of FIG. 1;

FIG. 5 is an exploded perspective view of a disassembled component of a suction pressure adjusting unit 40 of the breast pump of FIG. 1;

FIG. 6 is a partially broken perspective view showing details of the structure of a case of a suction pressure adjusting unit in FIG. 5.

[Explanation of symbols]

DESCRIPTION OF SYMBOLS 1 Milk collection container 10 Milk covering part 11 Opening 20 Cylinder part 21 Suction part 22 Milk collecting part 23 Taper part 24 Hole part 30 Container connection part 40 Suction pressure adjustment part 50 Piston part 51 Piston head 52 Piston shaft 60 Drive part 61 Housing 62 Electric motor 63 Crank mechanism 63A Crank arm 63B Mover 63C Piston shaft guide 64 Gear unit 65 Battery unit

.....続き Continuing from the front page (72) Inventor Kazuhiko Takano 5-5-23 Osaki, Shinagawa-ku, Tokyo Hirose Electric Co., Ltd. (72) Inventor Hiroyuki Uehara 5-1-1 Kanda Toyama-cho, Chiyoda-ku, Tokyo Inside the corporation

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Family To Family Citations

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Priority And Related Applications

Priority Applications (1)

Application	Priority date	Filing date	Title
JP35684897A	1997-12-25	1997-12-25	Suction pressure pulsating breast pump

Applications Claiming Priority (1)

Application	Filing date	Title
JP35684897A	1997-12-25	Suction pressure pulsating breast pump

Legal Events

Date	Code	Title	Description
2004-12-09	A621	Written request for application examination	**Free format text:** JAPANESE INTERMEDIATE CODE: A621 **Effective date:** 20041208
2007-07-11	A977	Report on retrieval	**Free format text:** JAPANESE INTERMEDIATE CODE: A971007 **Effective date:** 20070711
2007-07-11	TRDD	Decision of grant or rejection written	
2007-07-24	A01	Written decision to grant a patent or to grant a registration (utility model)	**Free format text:** JAPANESE INTERMEDIATE CODE: A01 **Effective date:** 20070723
2007-08-02	A61	First payment of annual fees (during grant procedure)	**Free format text:** JAPANESE INTERMEDIATE CODE: A61 **Effective date:** 20070730
2007-08-03	R150	Certificate of patent or registration of utility model	**Free format text:** JAPANESE INTERMEDIATE CODE: R150
2007-08-06	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text:** PAYMENT UNTIL: 20100803 **Year of fee payment:** 3
2010-08-13	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text:** PAYMENT UNTIL: 20110803 **Year of fee payment:** 4
2010-08-13	R313	Request for change of ownership or part of ownership	**Free format text:** JAPANESE INTERMEDIATE CODE: R313117
2010-08-23	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text:** PAYMENT UNTIL: 20110803 **Year of fee payment:** 4
2010-08-23	R350	Written notification of registration of transfer	**Free format text:** JAPANESE INTERMEDIATE CODE: R350
2011-06-30	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text:** PAYMENT UNTIL: 20110803 **Year of fee payment:** 4
2011-07-05	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text:** PAYMENT UNTIL: 20120803 **Year of fee payment:** 5
2012-06-14	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text:** PAYMENT UNTIL: 20120803 **Year of fee payment:** 5
2012-06-19	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text:** PAYMENT UNTIL: 20130803

			Year of fee payment: 6
2013-06-18	R250	Receipt of annual fees	Free format text: JAPANESE INTERMEDIATE CODE: R250
2014-06-24	R250	Receipt of annual fees	Free format text: JAPANESE INTERMEDIATE CODE: R250
2015-06-11	R250	Receipt of annual fees	Free format text: JAPANESE INTERMEDIATE CODE: R250
2016-06-21	R250	Receipt of annual fees	Free format text: JAPANESE INTERMEDIATE CODE: R250
2017-06-03	LAPS	Cancellation because of no payment of annual fees	

Concepts

machine-extracted

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Name	Image	Sections	Count	Query match
Breast		claims,abstract,description	84	0.000
Milk		claims,abstract,description	77	0.000
milk		claims,abstract,description	77	0.000
milk		claims,abstract,description	77	0.000
corresponding		claims,abstract,description	10	0.000
Clearance		claims,abstract	2	0.000
clearance		claims,abstract	2	0.000
Nipples		claims,description	7	0.000

Show all concepts from the description section

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(19)日本国特許庁（ＪＰ）　(12) **公開特許公報**（Ａ）　(11)特許出願公開番号
特開2000－350527
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Ａ０１Ｊ　5/04		Ａ０１Ｊ　5/04	

審査請求　未請求　請求項の数５　ＯＬ　（全 11 頁）

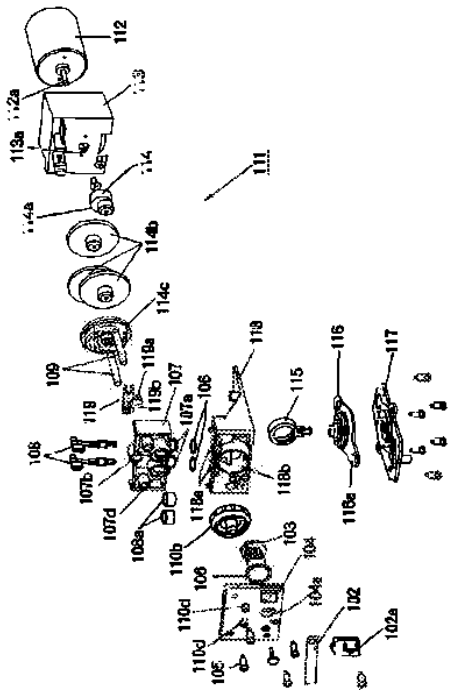
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(54)【発明の名称】　脈動搾乳器

(57)【要約】　（修正有）
【課題】　部品交換が容易で、使い勝手が良好な脈動搾乳器の提供。
【解決手段】　陰圧発生部１１６と、この陰圧発生部により、その内部が陰圧となる陰圧用空間部と、この陰圧用空間部と連結されて形成されている脈動用空間部と、を有する搾乳器本体と、使用者の乳房等に設置し、使用者の母乳を吸引、貯蔵する吸引貯蔵部と、を備える脈動搾乳器において、上記陰圧用空間部１１８と上記脈動用空間部１０７とが相互に分離可能に配置されていることを特徴とする脈動搾乳器。



【特許請求の範囲】
【請求項１】　陰圧発生部と、
この陰圧発生部により、その内部が陰圧となる陰圧用空間部と、
この陰圧用空間部と連結されて形成されている脈動用空間部と、を有する搾乳器本体と、
使用者の乳房等に設置し、使用者の母乳を吸引、貯蔵する吸引貯蔵部と、を備える脈動搾乳器において、
上記陰圧用空間部と上記脈動用空間部とが相互に分離可能に配置されていることを特徴とする脈動搾乳器。
【請求項２】　上記脈動用空間部には、上記陰圧用空間部と連結するための連結凸部が設けられ、この陰圧用空間部には、この脈動用空間部と連結するための連結凹部が設けられ、且つ、これら脈動用空間部と陰圧用空間部相互の連結を保持させるための保持部が設けられていることを特徴とする請求項１に記載の脈動搾乳器。
【請求項３】　上記吸引貯蔵部と上記搾乳器本体の間には、これらを接続するための接続部が設けられており、上記吸引貯蔵部の上記接続部側には、空気室が設けられており、この空気室の内部に凹凸部が形成されていることを特徴とする請求項１又は請求項２に記載の脈動搾乳器。
【請求項４】　上記吸引貯蔵部は、使用者の母乳を吸引するための吸引部と使用者の母乳を貯蔵するための貯蔵部を有しており、この貯蔵部には、この吸引部で吸引された使用者の母乳を上記貯蔵部へ移動させるための弁が設けられ、この弁の略中心部が、上記吸引部側に撓んで形成されていることを特徴とする請求項１乃至請求項３の何れかに記載の脈動搾乳器。
【請求項５】　上記搾乳器本体の両側及び上記吸引貯蔵部を載置可能に形成されているホルダ部には、このホルダ部をこの搾乳器本体に取付けるための係合部がそれぞれ備えられていることを特徴とする請求項１乃至請求項４の何れかに記載の脈動搾乳器。
【発明の詳細な説明】
【０００１】
【発明の属する技術分野】本発明は、使用者が母乳を搾乳する際に用いる搾乳器に関し、特に、間欠的に母乳の吸引を行う所謂、脈動搾乳器に関するものである。
【０００２】
【従来の技術】搾乳器には、大きく分けて、手動式搾乳器と電動式搾乳器がある。このうち、手動式搾乳器は、使用者が自己の手等でポンプを動かし、このポンプの力で搾乳を行うものである。一方、電動式搾乳器は、モータ等の力を用い、ダイヤフラム等を動作させ、一定の空間に陰圧を形成させるようになっている。この陰圧状態は、この空間と使用者の乳房と間の存在するようになっているため、母乳は吸引され、所定のボトル内に収容されるようになっている。この電動搾乳器の陰圧を発生させるポンプユニットとしては、例えば図２４に示すようなものがある。図２４に示すように、ポンプユニット１０は、モータ１１の動力が減速ギヤ１２、１２、１２、１２を介して伝わるようになっている。具体的には、先ず、モータ１１の軸には、図示しない偏心カムが装着されており、この偏心カムに図２５に示すコネクションロッド１３が係合するようになっている。このコネクションロッド１３は、ダイヤフラム裏板１５上に設けられているダイヤフラム１４と接続されている。
【０００３】このため、モータ１１の軸の回転が図で示す上下運動となり、ダイヤフラム１４を上下に動かすことになる。このダイヤフラムの弁１４ａは、図２５に示すシャーシ１６の陰圧空間部１６ａに設けられた孔と接続されている。したがって、ダイヤフラムの弁１４ａの動きによって、この陰圧空間部１６ａには、陰圧空間が形成されることになる。次に、上記陰圧空間部１６ａの上には、２つの脈動用空間部１６ｂ、１６ｂが、この陰圧空間部１６ａと一体に形成されている。そして、これら２つの脈動用空間部１６ｂ、１６ｂの低部には、それぞれ孔が設けられ、陰圧空間部１６ａとこの孔を介して連通して形成されている。これら２つの脈動用空間部１６ｂ、１６ｂには、図２５に示すコントロール軸１７、１７が、それぞれ上部の開口より挿入され、これらコントロール軸１７、１７の下端部には、図示しないコントロール弁が取り付けられることになる。このコントロール弁は、コントロール軸１７が図において下方向に移動すると、上記脈動用空間部１６ｂの低部に設けられた孔を塞ぎ、その下に設けられている陰圧空間部１６ａとの連通状態を遮断することになる。また、このコントロール弁が、コントロール軸１７が図において下方向に移動すると、この脈動用空間部１６ｂの上部の開口部を開口状態にすることになる。
【０００４】このような働きをするコントロール弁付きコントロール軸１７、１７は、図２５に示すシーソー１８と係合している。そして、このシーソー１８は、図２４に示す減速ギヤ１２、１２、１２、１２と歯合している図示しないコントロールギヤにより、揺動させられることになる。このシーソー１８の揺動により、上記2つのコントロール軸１７、１７は、交互に上下運動を行うことになる。ところで、上記２つの脈動用空間部１６ｂ、１６ｂは、図２４に示すノズル１９、１９と連通しており、このノズル１９、１９は、図示しない母乳収容用ボトルとホース等で接続されている。この母乳収容用ボトルには、使用者の乳房に密着させる碗状の母乳受け部が設けられている。このように構成される電動搾乳器のポンプユニット１０を動作させると、モータ１１の回転により、ダイヤフラム１４が動き、陰圧空間部１６ａを陰圧とする。一方、モータ１１の回転により、上記コントロールギヤが回転し、シーソー１８を揺動させ、２つのコントロール軸１７、１７を交互に上下動させることになる。このコントロール軸１７が下に動いた、一方

の脈動用空間部１６ｂは、陰圧空間部１６ａとの連通が遮断され、陰圧ではなく開放状態になる。また、コントロール軸１７が上に動いた、一方の脈動用空間部１６ｂは、陰圧状態となる。

【０００５】ここにおいて、上記母乳収容用ボトルを、ホースにて、一方のノズル１９（図２４参照）と接続させて、使用する場合、この母乳収容用ボトルと連通している脈動用空間部１６ｂは、一方のみであるため、一方のコントロール軸１７の上下動によって、陰圧状態と開放状態が繰り返えされることになる。これにより、連続的な吸引ではない、乳幼児が行う吸引に近い状態、すなわち脈動状態の吸引が可能となり、より効果的な搾乳ができることとなる。

【０００６】

【発明が解決しようとする課題】このような脈動搾乳器のモータユニット１０のシャーシ１６を形成する陰圧空間部１６ａと脈動用空間部１６ｂは、脈動搾乳器の吸引力となる陰圧を効果的に発生させるための重要な部品である。したがって、僅かな不具合がこれらの部品に発生しても、脈動搾乳器の吸引力に大きな影響を与えるため、不具合が生じた部品は取り替える必要があった。この不具合は、シャーシ１６の陰圧空間部１６ａ又は脈動用空間部１６ｂの何れか一方にのみ生じる場合が多いが、この場合でも、これら陰圧空間部１６ａと脈動空間部１６ｂが上述のように一体に形成されているため、シャーシ１６全体を取り替える必要がるという問題があった。

【０００７】本発明は、以上の点に鑑み、部品交換が容易で、使い勝手が良好な脈動搾乳器を提供することを目的とする。

【０００８】

【課題を解決するための手段】上記目的は、本発明によれば、陰圧発生部と、この陰圧発生部により、その内部が陰圧となる陰圧用空間部と、この陰圧用空間部と連結されて形成されている脈動用空間部と、を有する搾乳器本体と、使用者の乳房等に設置し、使用者の母乳を吸引、貯蔵する吸引貯蔵部と、を備える脈動搾乳器において、上記陰圧用空間部と上記脈動用空間部とが相互に分離可能に配置されていることを特徴とする脈動搾乳器により達成される。

【０００９】上記構成によれば、上記陰圧用空間部と上記脈動用空間部とが相互に分離可能に配置されているので、何れか一方のみを分離して交換することができる。

【００１０】好ましくは、請求項１の構成において、上記脈動用空間部には、上記陰圧用空間部と連結するための連結凸部が設けられ、この陰圧用空間部には、この脈動用空間部と連結するための連結凹部が設けられ、且つ、これら脈動用空間部と陰圧用空間部相互の連結を保持させるための保持部が設けられていることを特徴とする脈動搾乳器である。

【００１１】上記構成によれば、上記脈動用空間部には、上記陰圧用空間部と連結するための連結凸部が設けられ、この陰圧用空間部には、この脈動用空間部と連結するための連結凹部が設けられているので、これら連結凸部と連結凹部を組み合わせることで容易に脈動用空間部と陰圧用空間部を連結することができる。また、上記脈動用空間部と上記陰圧用空間部相互の連結を保持させるための保持部が設けられているので、脈動用空間部と陰圧用空間部との連結をより強固にすることができる。

【００１２】好ましくは、請求項１又は請求項２の構成において、上記吸引貯蔵部と上記搾乳器本体の間には、これらを接続するための接続部が設けられており、上記吸引貯蔵部の上記接続部側には、空気室が設けられており、この空気室の内部に凹凸部が形成されていることを特徴とする脈動搾乳器である。

【００１３】上記構成によれば、上記吸引貯蔵部の上記接続部側には、空気室が設けられているので、母乳が上記接続部へ流入するのを防ぐことができる。また、この空気室の内部に凹凸部が形成されているので、この空気室の内部面積が増加し、より母乳の水蒸気が、この空気室の内部に付着するので、母乳が上記接続部へ流入するのをより防ぐことができる。

【００１４】また、好ましくは、請求項１乃至請求項３の何れかの構成において、上記吸引貯蔵部は、使用者の母乳を吸引するための吸引部と使用者の母乳を貯蔵するための貯蔵部を有しており、この貯蔵部には、この吸引部で吸引された使用者の母乳を上記貯蔵部へ移動させるための弁が設けられ、この弁の略中心部が、上記吸引部側に撓んで形成されていることを特徴とする脈動搾乳器である。

【００１５】上記構成によれば、上記弁の略中心部が、上記吸引部側に撓んで形成されているので、この弁が閉じる方向に撓まされることになる。これにより陰圧状態がより確実になる。

【００１６】なお、好ましくは、請求項１乃至請求項４の何れかの構成において、上記搾乳器本体の両側及び上記吸引貯蔵部を載置可能に形成されているホルダ部には、このホルダ部をこの搾乳器本体に取付けるための係合部がそれぞれ備えられていることを特徴とする脈動搾乳器である。

【００１７】上記構成によれば、上記搾乳器本体の両側及び上記吸引貯蔵部を載置可能に形成されているホルダ部には、このホルダ部をこの搾乳器本体に取付けるための係合部がそれぞれ備えられているので、このホルダ部を上記搾乳器本体の両側又は片側に容易に取り付けることができる。

【００１８】

【発明の実施の形態】以下、この発明の好適な実施形態を図１乃至図２３を参照しながら、詳細に説明する。

尚、以下に述べる実施形態は、本発明の好適な具体例で

あるから、技術的に好ましい種々の限定が付されているが、本発明の範囲は、以下の説明において特に本発明を限定する旨の記載がない限り、これらの態様に限られるものではない。

【００１９】図１は、本発明の実施の形態に係る脈動搾乳器１００を示す図である。脈動搾乳器１００は、搾乳器本体であるポンプユニット１１０と、その両側に配置されているホルダ部であるボトルホルダ１２０、１２０を有している。また、脈動搾乳器１００は、吸引貯蔵部であるボトルユニット１３０、１３０を例えば２つ備えている。さらに、脈動搾乳器１００は、上記ボトルユニット１３０とポンプユニット１１０を接続するための接続部である吸気チューブ１４０、１４０が２本備えられている。また、上記ポンプユニット１１０の表面には、図１に示すように、電源スイッチ１１０ａと吸引圧調節ダイヤル１１０ｂが配置されている。図２は、上記ポンプユニット１１０とボトルホルダ１２０、１２０を、図１の裏側より見た図である。図２に示すように、ポンプユニット１１０には、吸気チューブ１４０、１４０を接続するためのノズル１１０ｄ、１１０ｄが例えば２つ設けられている。また、このポンプユニット１１０には、電源である例えば電池を収納するための電池収納部１１０ｃが設けられている。また、電源としてＡＣ電源を用いることもできる。この場合、図２に示すＡＣ電源用接続端子１１０ｅにＡＣ電源を接続して使用しすることになる。このポンプユニット１１０は、使用者である母親の母乳を吸引するための吸引圧を発生させるものであるため、以下、詳細に説明する。

【００２０】図３は、図１及び図２に示す上記ポンプユニット１１０のケーシングを外し、ポンプユニット１１０の中枢部であるポンプユニットの中枢部を示した図である。また、図４は、図３に示すポンプユニットの中枢部１１０を分解して示した分解斜視図である。図４に示すように、モータ１１２は、モータプレート１１３に収容されている。このとき、モータ１１２のモータ軸１１２ａは、モータプレート１１３のモータプレート孔１１３ａに挿入され、その先端に偏心カム１１４が取り付けられる。この偏心カム１１４の先端には、ギヤ１１４ａが設けられている。この偏心カム１１４は、陰圧発生部であるダイヤフラム１１６と接続されているコネクションロッド１１５と係合されている。また、このダイヤフラム１１６は、ダイヤフラム裏板１１７上に載置されるようになっている。なお、このコネクションロッド１１５は、陰圧用空間部であるシャーシ１１８に設けられている丸穴に挿入された状態で、偏心カム１１４と係合することとなる。

【００２１】一方、上記ギヤ１１４ａは、減速ギヤ１１４ｂと歯合し、さらに２枚の減速ギヤ１１４ｂ、１１４ｂが歯合状態で連なっている。さらに、この減速ギヤ１１４ｂと歯合されているのが、コントロールギヤ１１４ｃであり、このコントロールギヤ１１４ｃと係合しているのがシーソー１１９である。なお、上記減速ギヤ１１４ｂ、１１４ｂ、１１４ｂとコントロールギヤ１１４ｃは、ステンレス棒１０９、１０９により支持されている。また、上記シーソー１１９は、２つのコントロール軸１０８、１０８と係合されており、この２つのコントロール軸１０８、１０８は、脈動用空間部であるシーソーベース１０７の上部に設けられた開口部より下方向に挿入されることにより、ノズル用開口部１０７ｄ、１０７ｄ内に予め配置されているコントロール弁１０８ａ、１０８ａに取り付けられることになる。このシーソーベース１０７の下部には、上記シャーシ１１８と接続するための連結凸部であるシーソーベース連結部１０７ａが２個設けられている。このシーソーベース連結部１０７ａ、１０７ａにＯリング１０６が装着することになる。一方、シャーシ１１８の上部には、連結凹部であるシャーシ連結部１１８ａが２つ設けられている。したがって、このシャーシ連結部１１８ａ、１１８ａに上記シーソーベース連結部１０７ａ、１０７ａを挿入することで、シーソーベース１０７とシャーシ１１８は一体的に連結されることになる。このとき、シーソーベース連結部１０７ａ、１０７ａには、Ｏリング１０６が装着されているため、気密性を維持しつつ接続される。

【００２２】また、シャーシ１１８には、シャーシ開口部１１８ｂが設けられており、このシャーシ開口部１１８ｂに対応するように、図４に示すバルブ１０３及びＯリング１０６が配置されている。このバルブ１０３とＯリング１０６は、シャーシカバー１０４の吸引圧調節用孔１０４ａを介して図示しない留め具でリーフスプリング１０２に固定されている。そして、このシャーシカバー１０４には、吸引圧調整ダイヤル１１０ｂが配置されている。この吸引圧調整ダイヤル１１０ｂには、溝が設けられており、この溝に当接して配置されているのが調節ピン１０５である。この調節ピン１０５は、吸引圧調整ダイヤル１１０ｂの回転によって、図において左右方向に移動するようになっている。ところで、保持部であるシャーシカバー１０４は、シャーシ１１８に押しつけられ、固定されることになる。このとき、シャーシカバー１０４は、シャーシ１１８のみならずシーソーベース１０７をも押さえるように配置されるため、シーソーベース１０７とシャーシ１１８との連結状態がより強固になる。ところで、このシャーシカバー１０４には、板金製のリーフスプリング１０２が配置されている。このリーフスプリング１０２の一端部は、リーフスプリング押さえ１０２ａによって固定されている。しかし、このリーフスプリング１０２の他端部は、固定されておらず、リーフスプリング１０２自体の有する弾性によって、シャーシカバー１０４の表面に押しつけられている。また、このリーフスプリング１０２の他端部には、上述の調整ピン１０５の先端が当接しているため、この調整ピ

ン105の移動により、リーフスプリング102が移動し、これと接続されているバルブ103がシャーシ118のシャーシ開口部118bに対して移動することになる。

【0023】図4に示すポンプユニットの中枢部111は、以上のように構成されて、以下のように動作する。先ず、使用者が図1に示す電源スイッチ110aをON状態にすると、図2に示す電池収納部110cに収納されている電池を電源として、モータ112が回転を始める。このモータ112の回転により、偏心カム114が偏心状態で回転することになる。この偏心カム114は、ダイヤフラム116に接続されているコネクションロッド115と係合しているため、コネクションロッド115が上下運動することになる。この状態を示したのが、図5である。図5の矢印Aに示すように、ダイヤフラム116は上下運動を行い、これにより、矢印Bに示すような空気の流れが生じる。このときダイヤフラム116のダイヤフラム弁116aの近傍にあるダイヤフラム孔116bは、シャーシ118のダイヤフラム用連結孔118cと接続されているので、シャーシ118内に陰圧を発生させることになる。このダイヤフラム用連結孔118cを示したのが、図6である。図6は、シャーシ118の底面図を示した図である。図6に示すように、シャーシ118の底面にダイヤフラム用連結孔118cが設けられている。このダイヤフラム用連結孔118cは、図7に示すシャーシ118のシャーシ開口部118bの図において底部に設けられてるため、このシャーシ開口部118とダイヤフラム孔116bは、連通していることになる。

【0024】このシャーシ開口部118には、図7に示すようにシャーシ連結部118a、118aに繋がる部分か2つに分かれて形成されており、シャーシ118の平面図である図8を見ると、このシャーシ連結部118a、118aが開口状態になっているのが分かる。このように、シャーシ118は、シャーシ開口部118b、ダイヤフラム連結用孔118c及びシャーシ連結部118a、118a以外の部分は、閉空間となっている。そして、シャーシ開口部118bは、上述のように、シャーシカバー104で塞がれてしまうため、ダイヤフラム116によってシャーシ118の内部は、陰圧状態となる。このシャーシ118の陰圧状態は、上記シーソベース107のシーソベース連結部107a、107aを介して、シーソベース107の内部にも陰圧状態を惹起することとなる。ところで、上記モータ112が回転すると、偏心カム114以外に図4に示すギャ114aも回転を始め、このギヤ114aと歯合している減速ギヤ114bにより減速されることになる。そして、3枚目の減速ギヤ114bと歯合しているコントロールギヤ114cが回転を始めることとなる。このコントロールギヤ114cは、図4に示すように特有の溝が形成されており、この溝の一部にシーソー119が係合することとなる。

【0025】この状態を示したのが、図9である。図9に示すように、コントロールギヤ114cの下部の設けられた円弧状の溝部にシーソ119のシーソー凸部119aが係合することになる。このコントロールギヤ114cの円運動は、この溝部によりシーソー119の揺動に変化することになる。なお、このシーソー119の揺動の支点は、図4に示すシーソーの支点119bであり、このシーソーの支点119bは、シーソーベース107のシーソー受け部107bに挿入されることになる。また、このシーソー119には、図4に示す2つのコントロール軸108が取り付けられることになる。この状態を示したのが図10である。図10に示すように、2つのコントロール軸108、108は、シーソー119の両側にある切り欠き部に係合されることになる。また、このコントロール軸108、108は、上述のように、シーソーベース107内に挿入され、その下部にコントロール弁108a、108aが取付けられることになる。図11は、このシーソーベース107を示す正面図であり、図12は、シーソーベース107の平面図である。図12に示すようにシーソーベース107には、コントロール軸108を挿入するためのコントロール軸用孔107cが2つ形成されている。そして、このコントロール軸用孔107cは、図11に示すノズル用開口部107dと連通している。

【0026】しかし、これら2つのノズル用開口部107d、107d及び2つのコントロール軸用孔107c、107cは、相互に連通されておらず、それぞれが別々にシーソーベース連結部107a、107aと連通されている。このような、コントロール軸用孔107c、107c内にコントロール軸108、108は、それぞれ、配置される。この状態で、上記シーソー119が揺動運動を行うと、図10に示すようにコントロール軸108、108が交互に上下運動を行うことになる。このコントロール軸108が、下方向に動き、図11に示すノズル用開口部107d，107dの底部まで達すると、このコントロール軸108に付いているコントロール弁108aによりシーソー連結部107aが塞がれることになる。このとき、塞がれたシーソーベース107の内部空間には、上述のシャーシ118の陰圧状態が伝わらず、むしろシーソーベース107のコントロール軸用孔107cに生じるコントロール軸108との隙間によって大気開放状態となる。一方、コントロール軸108が、上方向に動くと、このコントロール軸108に付いているコントロール弁108aと、シーソー連結部107aの間に空間が生じると共に、このコントロール弁108aの上端がコントロール軸用孔107cの下端を塞ぐことになる。したがって、上述のシャーシ118内の陰圧状態が、このシーソーベース107内にも生じ

ることになる。このように陰圧状態と大気開放状態を、コントロール軸１０８、１０８の動きによって交互に生じさせることで、後述する脈動が生じることになる。

【００２７】ところで、このシーソーベース１０７に設けられた2つのノズル用開口部１０７ｄ、１０７ｄは、図4に示すようにシャーシカバーの１０４のノズル１１０ｄ、１１０ｄとそれぞれ対応して配置され、このノズル１１０ｄ、１１０ｄには、図1に示すように吸気チューブ１４０、１４０が接続されることになる。また、母親がシャーシ１１８の内部に生じている陰圧を調整するには、図4に示す吸引圧調整ダイヤル１１０ｂを、母親が操作することにより行う。すなわち、吸引圧調整ダイヤル１１０ｂは、具体的には、図１３に示すようになっている。図１３（１）に示すように、吸引圧調整ダイヤル１１０ｂには、螺旋状に厚みのことなる溝が設けられており、この溝に調整ピン１０５が当接するようになっている。この吸引圧調整ダイヤル１１０ｂは、図1に示すようにポンプユニット１１０の外部から母親が操作できるようになっている。そこで、母親がこの吸引圧調整ダイヤル１１０ｂを操作して、回すと調整ピン１０５が当接している吸引圧調整ダイヤル１１０ｂの溝の厚みが変化する。ここにおいて、例えば、溝の厚みが厚くなる場合、調整ピン１０５が図１３（２）のようにリーフスプリング１０２を押すことになる。このリーフスプリング１０２と図4に示すバルブ１０３とは、上述のように接続されているため、このバルブ１０３もシャーシ１１８のシャーシ開口部１１８ｂから離反する方向に動き、陰圧（吸引圧）は小となる。逆に、吸引圧調整ダイヤル１１０ｂの溝の厚みが薄くなれば、バルブ１０３は、シャーシ開口部１１８ｂの内部に押し込まれることになり、陰圧（吸引圧）は大となる。このようにして母親は、陰圧を調整することになる。

【００２８】以上のようにポンプユニット１１０は、構成され動作するが、このポンプユニット１１０と吸気チューブ１４０を介して接続されているボトルユニット１３０について以下、説明する。図１４は、ボトルユニット１３０の分解斜視図である。図示のようにボトルユニット１３０は、母親の母乳を吸引するための吸引部と、母乳を貯蔵するための貯蔵部とを有している。この吸引部を構成するものとしては、搾乳キャップ１３３、円板１３４、中栓１３５、円筒１３６及びブレストシールド１３７が挙げられる。このうち、ブレストシールド１３７は、その一部に母親が自己の乳房に装着させる部分である母乳受け部１３７ａを有している。この母乳受け部には、図示しない別体の滑り止め部を用いても良い。すなわち、母親の乳房に当接する部分に凹凸部が配置されるように滑り止め部を、母乳受け部の内面に装着する場合である。このブレストシールド１３７の断面は、図１５に示すようになっている。形成したをこのおり、その断面は、図１５に示すようになっている。すなわち、図１５に示すように、ブレストシールド１３７の内部では、母乳受け部１３７ａの内部空間と連通されており、図において上方及び下方に導くように形成されている。

【００２９】このブレストシールド１３７の上部の開口部１３７ｂには、図１４に示す円筒１３６と円板１３４を伴った中栓１３５が挿入されることになる。この中栓１３５等が挿入された状態を示すのが図１５のAの部分である。この中栓１３５等の構造を具体的に示したのが、図１６である。図１６に示すように、円板１３４の中心部に、円板孔１３４ａが設けられており、この円板孔１３４ａは、中栓１３５の中栓孔１３５ａ、１３５ａを介して、図１５のブレストシールド１３７内に連通している。また、中栓１３５の中栓本体１３５ｂは、図において上下方向に移動可能となっており、上方向に中栓本体１３５ｂが移動して、中栓１３５の中栓凸部１３５ｃ、１３５ｃが、円板１３４に当接すると、この移動が止まると共に、上記円板１３５の円板孔１３４ａと中栓本体１３５の中栓孔１３５ａとの間が連通状態でなくなることになる。また、この中栓１３５等の上には、図１４に示すように、空気室である搾乳口キャップ１３３が設けられている。この搾乳キャップ１３３の構造を示すのが、図１７である。図１７に示すように搾乳口キャップ１３３の上部には、図1に示す吸気チューブ１４０を接続するための吸気チューブ用孔１３３ａが設けられている。また、搾乳キャップ１３３の内周部１３３ｂには、凹凸部が設けられている。

【００３０】この凹凸部の形成は、例えば腐食加工により行う。この腐食加工は、搾乳キャップ１３３の内周部１３３ｂに、化学薬品を用いてエッチングし、不要部分を取り除く等して凹凸部を形成するものである。また、凹凸部を形成する他の方法としては、金型に砂等を吹き付けることにより、金型に傷を付けるブラスト処理の方法等もある。このように、その内周部１３３ｂに凹凸部を設けられた搾乳口キャップ１３３は、図１４に示すブレストシールド１３７に対して固定される。一方、母乳を貯蔵するための貯蔵部を構成するものとしては、図１４に示すボトル本体１３１、弁１３２及びチェックバルブ１３９等が挙げられる。このチェックバルブ１３９は、図１５に示すブレストシールド１３７の下端に差し込むように装着される。このチェックバルブ１３９の下端には、弁１３２が取り付けられている。この弁１３２は、図１８に示すように、可動片１３２ａが可動することにより弁１３２を閉状態にしたり、開状態にしたりするものである。また、図１９は、この弁１３２の断面を示した図である。図１９に示すように弁１３２の両側の上端部は、それ以外の部分と比べ肉厚に構成されている。このため、この弁１３２を、上記チェックバルブ１３９に取り付けると、上記肉厚の部分が外側に広がることになる。その結果、この弁１３２の略中心部である可動片１３２ａが、図において上方向に撓むこととなる。

そして、このように弁１３２の可動片１３２ａが上方に撓むと、この可動片１３２ａは、弁１３２を閉状態に保持する方向に配置されることになる。

【００３１】以上のように構成されているボトルユニット１３０の動作等を以下、説明する。先ず、図１に示すように、ポンプユニット１３０の搾乳口キャップ１３３に吸気チューブ１４０を取付ける。そして、２つのボトルユニット１３０のブレストシールド１３７、１３７の母乳受け部１３７ａ、１３７ａを、図２０に示すように、それぞれ使用者である母親の両方の乳房に密着させる。この状態で、ポンプユニット１１０の電源スイッチ１１０ａをＯＮ状態にすると、上述のように、ポンプユニットの中枢部１１１が動き出すことになる。このポンプユニットの中枢部１１１の動作により、ポンプユニット１１０の2つノズル１１０ｄ、１１０ｄは、交互に吸引と大気開放を繰り返すことになる。この２つノズル１１０ｄ、１１０ｄにおける吸引と大気開放は、吸気チューブ１４０、１４０を介してボトルユニット１３０、１３０に伝わることになる。すなわち、吸引状態の場合は、吸引圧が吸気チューブ１４０を通り、搾乳口キャップ１３０を介し、図１６に示す円板孔１３４ａを通り、中栓孔１３５ａを通って、図１５に示すブレストシールド１３７内に達することになる。

【００３２】ところで、このブレストシールド１３７の下端部には弁１３２を有するチェックバルブ１３９が設けられているため、この吸引圧によって、図１９の弁１３２の可動片１３２ａは図において上方に引っ張られることになり、これにより、弁１３２が閉状態に保持されることになる。このとき、たとえ吸引圧が若干、小さくても、弁１３２の可動片１３２ａが、上述のように上方に向かって撓んで保持されているため、可動片１３２ａが下方向に移動して、吸引圧を弱めてしまうことがない。このようにブレストシールド１３７の下端部は、弁１３２によって閉状態となっているため、ブレストシールド１３７内の吸引圧は、母乳受け部１３７ａに達し、そこに配置されている母親の乳房を吸引することになる。この吸引圧によって搾乳された母乳は、図１５に示す母乳受け部１３７ａに沿ってブレストシールド１３７内に流れ込み、チェックバルブ１３９を通り、弁１３２に達することになる。このとき、脈動により吸引が止まるのとほぼ同時に、母乳が弁１３２近傍で溜まると、その重みで弁１３２の可動片１３２ａが下方向に動き、母乳をボトル本体１３１内に落下させることになる。

【００３３】また、搾乳量が多く、母乳が自重でボトル本体１３１内に落下する前に、母乳がブレストシールド１３７内に溜まってしまう場合は、その溜まった母乳が図１６に示す円筒１３６を押し上げ、この円筒１３６の上昇で、中栓本体１３５ｂを押し上げ、中栓凸部１３５ｃが円板１３４に当たって、中栓本体１３５ｂより下方の空間との円板１３４より上方の空間の連通を遮断することになる。この遮断でポンプユニット１１０の吸引圧は、円板１３４部分と途切れるため、それ以上、ポンプユニット１１０側に母乳が移動することはなく、ポンプユニット１１０側へ母乳が流入することが防げることになる。このように、ポンプユニット１１０へ母乳が流入することが防ぐことで、ポンプユニット１１０の故障も防ぐことができる。また、この中栓１３５等の上には搾乳口キャップ１３３が配置され、この搾乳口キャップ１３３の内周部１３３ｂ（図１７参照）に凹凸部が設けられているため、この凹凸部によって表面積が増し吸着量が増すことにより、母乳の水蒸気等が保持され、ポンプユニット１１０へ水蒸気等が流れ込むのが有効に防止されることになる。さらに、搾乳口キャップ１３３の吸気チューブ用孔１３３ａが、図１７に示すように搾乳口キャップ１３３の上端に付いているため、より母乳の影響を受け難い位置となっている。

【００３４】一方、ポンプユニット１１０が大気開放と成っている場合は、ボトルユニット１３０において搾乳は、行われないことになる。このように、本実施の形態のポンプユニット１１０及びボトルユニット１３０等を用いれば、両方の乳房を同時に搾乳するすることができると共に、この搾乳は、吸引と大気開放を繰り返す所謂、脈動で行うことができる。また、ポンプユニット１１０のシャーシ１１８とシーソーベース１０７が分離可能に成っているため、いずれか一方が壊れても、他方のみを交換できるため、コストダウンが図れ、使い勝手が向上する。以上のようにポンプユニット１１０とボトルユニット１３０等を用いて搾乳を行った後、この２つのボトルユニット１３０、１３０を載置する場所として、ホルダ部であるボトルホルダ１２０が、図１に示すようにポンプユニット１１０の両側に設けられている。したがって、搾乳を終わった母親は、２つのボトルユニット１３０，１３０を、これらのボトルホルダ１２０、１２０に載置することができるようになっている。また、このボトルホルダ１２０、１２０は、ポンプユニット１１０に容易に取り付けられ、且つ、容易に取り外すことができるようになっている。具体的には、図２１に示すように、ポンプユニット１１０の両側にはボトルホルダ１２０を取り付けるための係合凸部１１０ｅ、１１０ｅが設けられている。この係合凸部１１０ｅは、図２２に示すように半楕円形を成している。

【００３５】一方、ボトルホルダ１２０には、図２３に示すように、この係合凸部１１０ｅに対応するようにボトルホルダ係合凹部１２０ａが設けられている。したがって、このボトルホルダ係合凹部１２０ａに、ポンプユニット１１０の係合凸部１１０ｅを差し込むことにより、ポンプユニット１１０にボトルホルダ１２０が取付けられることになる。また、使用者である母親が１つのボトルユニット１３０のみを使用する場合は、１つのボトルホルダ１２０をポンプユニット１１０の何れか一方

に取り付ければよく、脈動搾乳器１００を置いておくスペースが少なくて済む。

【００３６】

【発明の効果】以上述べたように、本発明によれば、部品交換が容易で、使い勝手が良好な脈動搾乳器を提供することができる。

【図面の簡単な説明】

【図１】本発明の実施の形態にかかる脈動搾乳器を示す概略斜視図である。

【図２】図１の脈動搾乳器のポンプユニット等を示す概略斜視図である。

【図３】ポンプユニットの中枢部を示す概略斜視図である。

【図４】図３のポンプユニットの中枢部の分解斜視図である。

【図５】図４のモータとダイヤフラムの関係を示す説明図である。

【図６】図４のシャーシの底面図である。

【図７】図４のシャーシの正面図である。

【図８】図４のシャーシの平面図である。

【図９】図４のコントロールギヤとシーソーとの関係を示す説明図である。

【図１０】図４のシーソーとコントロール軸との関係を示す説明図である。

【図１１】図４のシーソーベースの正面図である。

【図１２】図４のシーソーベースの平面図である。

【図１３】（１）吸引圧調整ダイヤルと調整ピンとの関係を示す説明図である。（２）吸引圧調整ダイヤルとリーフスプリングとの関係を示す説明図である。

【図１４】図１の脈動搾乳器のボトルユニットを示す分解斜視図である。

【図１５】図１４のブレストシールドを示す断面図である。

【図１６】図１４の円板、中栓、円筒を接続した状態を示す概略断面図である。

【図１７】図１４の搾乳口キャップを示す断面図である。

【図１８】図１４の弁を示す平面図である。

【図１９】図１４の弁を示す断面図である。

【図２０】母親が脈動搾乳器を使用している状態を示す図である。

【図２１】図１のポンプユニットと係合凸部との関係を示す平面図である。

【図２２】図２１のポンプユニットの側面図である。

【図２３】図１のポンプユニットとボトルホルダの係合状態を示す平面図である。

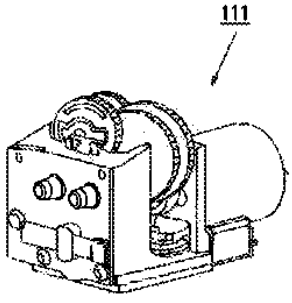
【図２４】従来のポンプユニットを示す斜視図である。

【図２５】図２４のポンプユニットの概略分解図である。

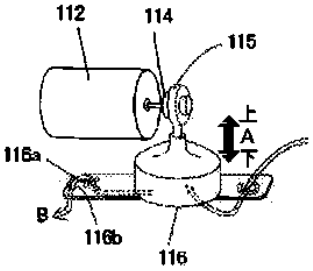
【符号の説明】

１００・・・脈動搾乳器、１０２・・リーフスプリング、１０３・・・バルブ、１０４・・・シャーシカバー、１０５・・・調節ピン、１０６・・・Ｏリング、１０７・・・シーソーベース、１０８・・・コントロール軸、１０９・・・ステンレス棒、１１０・・・ポンプユニット、１１２・・・モータ、１１３・・・モータプレート、１１４・・・偏心カム、１１５・・・コネクションロッド、１１６・・・ダイヤフラム、１１７・・・ダイタフラム裏板、１１８・・・シャーシ、１１９・・・シーソー、１２０・・・ボトルホルダ、１３０・・・ボトルユニット、１３１・・・ボトル本体、１３２・・・弁、１３３・・・搾乳口キャップ、１３４・・・円板、１３５・・・中栓、１３６・・・円筒、１３７・・・ブレストシールド、１３９・・・チェックバルブ

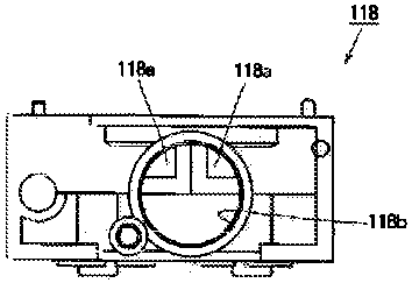
【図３】



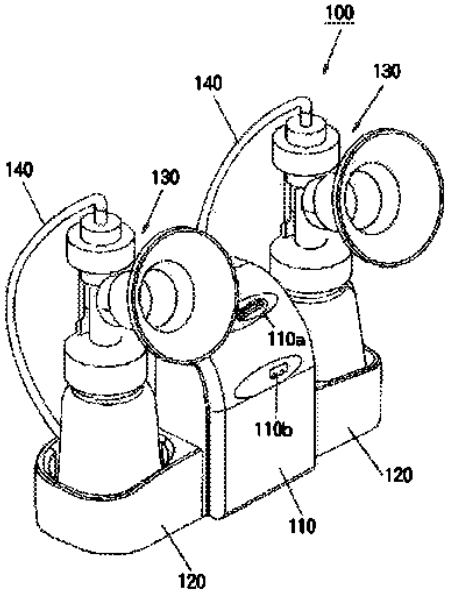
【図５】



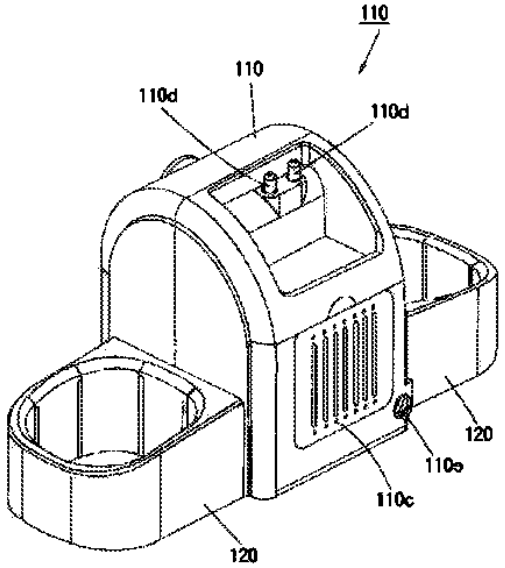
【図７】



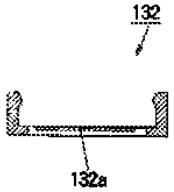
【図1】



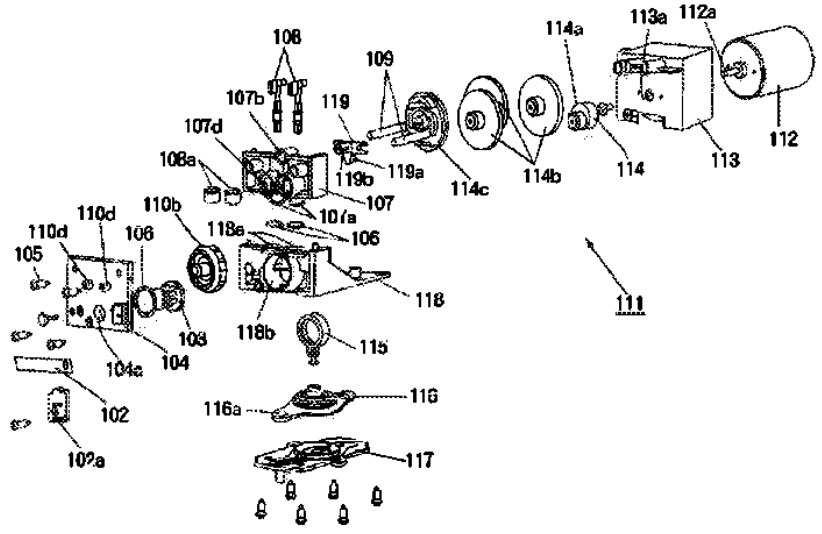
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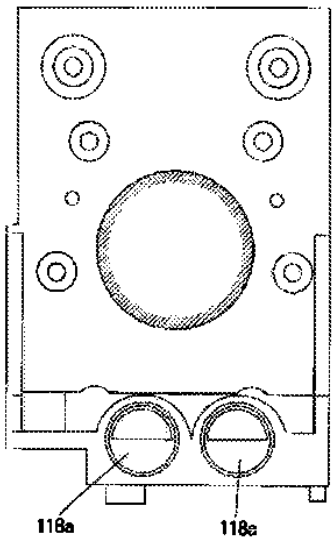
【図19】



【図4】

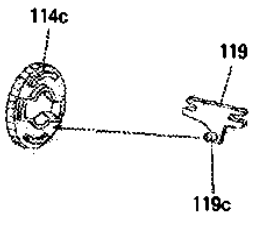


【図8】

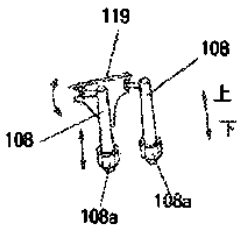


【図18】

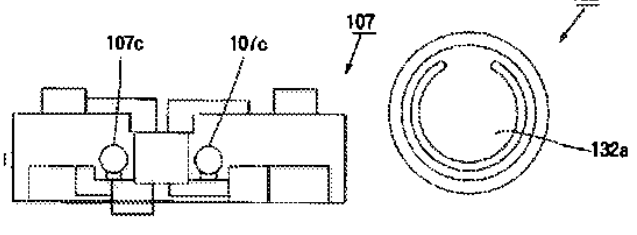
【図9】



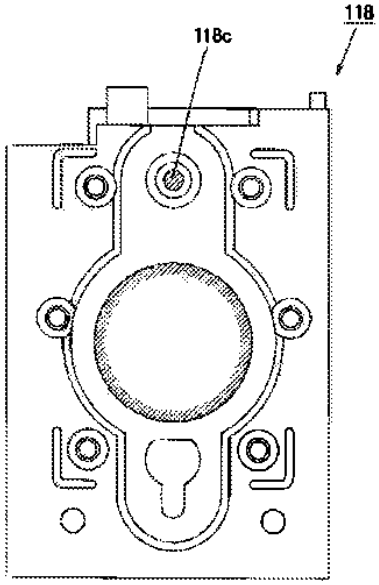
【図10】



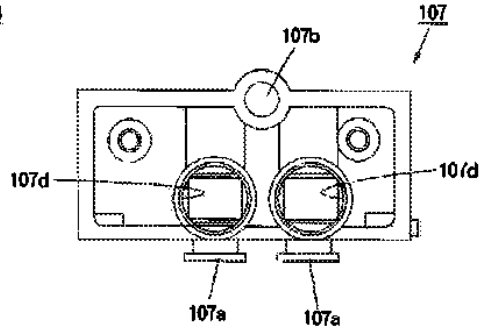
【図12】



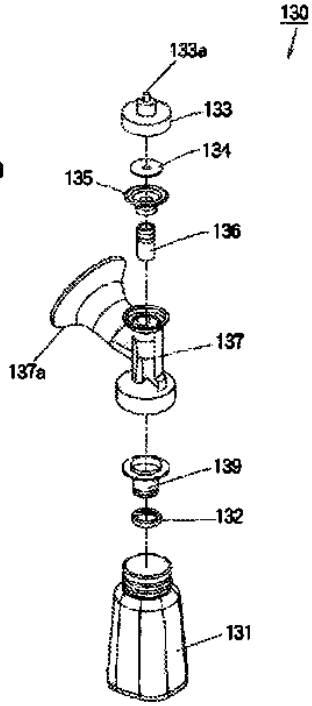
【図6】



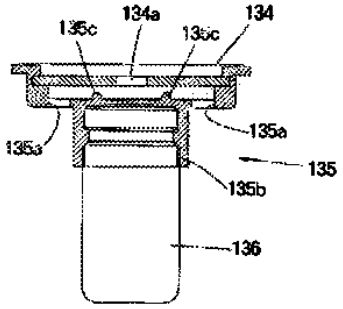
【図11】



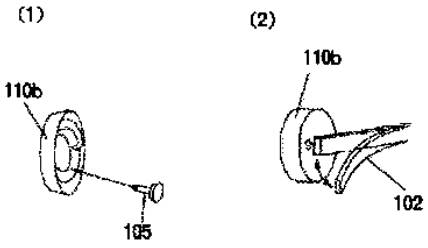
【図14】



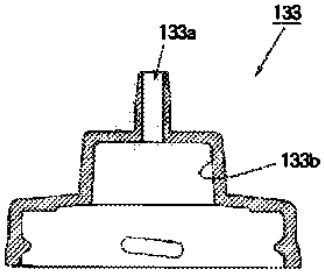
【図16】



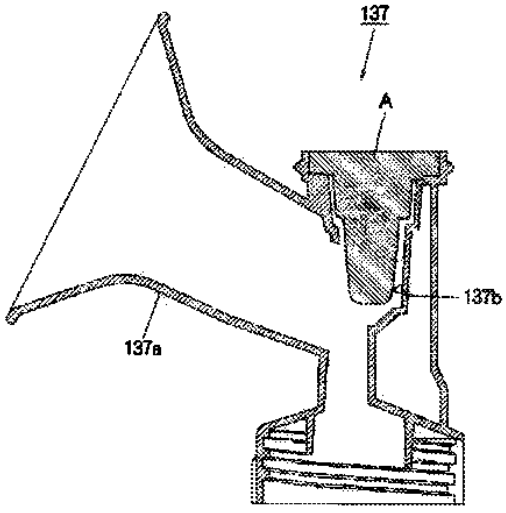
【図13】



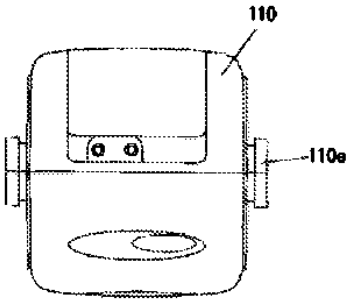
【図17】



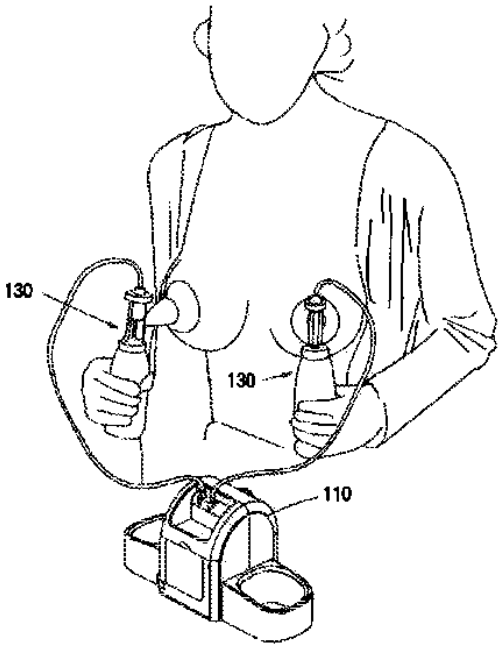
【図15】



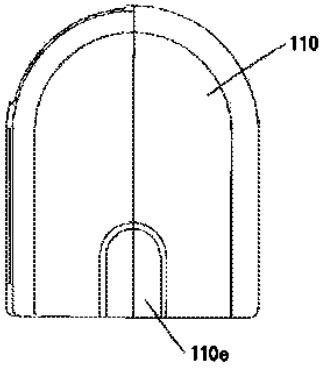
【図21】



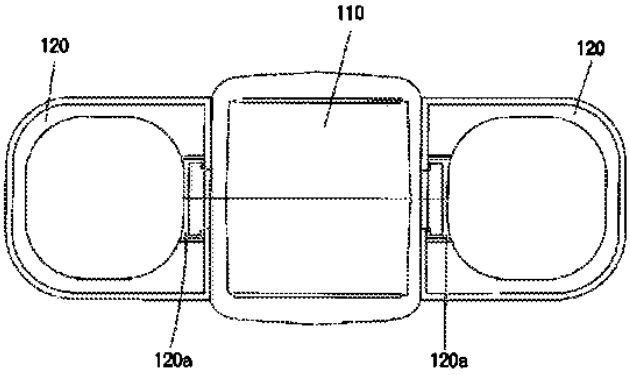
【図20】



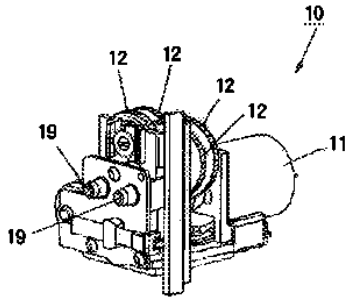
【図22】



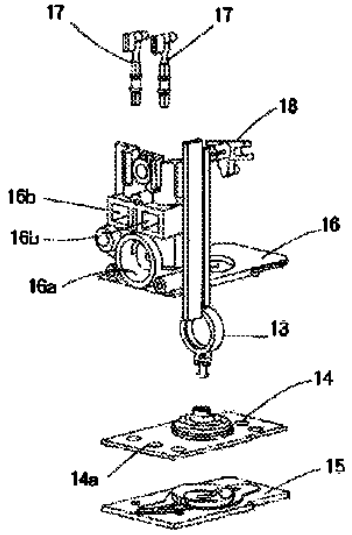
【図23】



【図24】



【図25】



Pulsating milking machine

Abstract

PROBLEM TO BE SOLVED: To provide a user-friendly pulsating milking machine capable of readily exchanging parts. SOLUTION: This pulsating milking machine is equipped with a pulsating milking machine body having a negative pressure-generating part 116, a space part 118 for negative pressure whose interior becomes negative pressure and a space part 107 for pulsation formed in coupling to the space part 118 for negative pressure and a sucking storage part installed in the breasts, etc., of users and used for sucking and storing mother milk of users. The pulsating milking machine teatmers being arranged so that the space part 118 for negative pressure and the space part 107 for pulsation are mutually separable

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Application JP11163044A events

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Claims (5)

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Translated from Japanese

[Claims] A negative pressure generating section; a negative pressure generating section in which the negative pressure is generated by the negative pressure generating section; a pulsating space formed by being connected to the negative pressure generating section; In a pulsating breast pump comprising: a breast pump body having: a suction storage unit that is installed on a user's breast or the like and sucks and stores the user's breast milk, wherein the negative pressure space portion and the pulsation space portion are A pulsating breast pump, which is arranged to be separable from each other. 2. The pulsation space portion is provided with a connection protrusion for connecting to the negative pressure space portion, and the connection recess portion for connecting to the pulsation space portion is provided in the negative pressure space portion. 2. The pulsating breast pump according to claim 1, further comprising a holding portion for holding the connection between the pulsating space portion and the negative pressure space portion. 3. A connection section for connecting the suction storage section and the breast pump body is provided between the suction storage section and the breast pump body.

The pulsating milking according to claim 1 or 2, wherein an air chamber is provided on the connection section side of the suction storage section, and an uneven portion is formed inside the air chamber. vessel. 4. The suction storage section has a suction section for sucking the breast milk of the user and a storage section for storing the breast milk of the user. A valve for moving the sucked user's breast milk to the storage unit is provided, and a substantially central portion of the valve is formed to bend toward the suction unit side Item 3

The pulsating breast pump according to any one of the above. 5. A holder formed on both sides of the breast pump main body and on which the suction storage section can be placed is provided with an engagement portion for attaching the holder to the breast pump main body. The pulsating breast pump according to any one of claims 1 to 4, wherein

Description

Translated from Japanese

DETAILED DESCRIPTION OF THE INVENTION

[0001]

BACKGROUND OF THE INVENTION 1. Field of the Invention The present invention relates to a breast pump used when a user expresses breast milk, and more particularly to a so-called pulsating breast pump for intermittently sucking breast milk.

[0002]

2. Description of the Related Art There are two main types of breast pumps: manual breast pumps and electric breast pumps. Of these, the manual breast pump is The user operates the pump with his / her own hand and milks with the power of the pump. On the other hand, the electric breast pump uses a force of a motor or the like to operate a diaphragm or the like to generate a negative pressure in a certain space. Since this negative pressure state exists between this space and the user's breast, breast milk is sucked and stored in a predetermined bottle. As a pump unit for generating a negative pressure of the electric breast pump, for example, there is one as shown in FIG. As shown in FIG.

9 means that the power of the motor 11 is the reduction gears 12, 12, 12,

12. Specifically, first, an eccentric cam (not shown) is mounted on the shaft of the motor 11, and the connection rod 13 shown in FIG. 25 is engaged with the eccentric cam. This connection rod 13 is connected to a diaphragm 14 provided on a diaphragm back plate 15.

[0003] As a result, the rotation of the shaft of the motor 11 causes a vertical movement as shown in the figure, and the diaphragm 14 is moved up and down. The valve 14a of the diaphragm is connected to a hole provided in the negative pressure space 15a of the chassis 15 shown in FIG. Therefore, the negative pressure space is formed in the negative pressure space 16a by the movement of the diaphragm valve 14a. Next, on the negative pressure space 16a, two pulsation spaces 16b, 16b are formed integrally with the negative pressure space 16a. Holes are provided in the lower portions of these two pulsation spaces 16b, 16b, respectively, and are formed so as to communicate with the negative pressure space 16a via the holes. These two pulsation spaces 1
The control shaft 17 shown in FIG.
The control shafts 17 are inserted through upper openings, and control valves (not shown) are attached to lower ends of the control shafts 17, 17, respectively. When the control shaft 17 moves downward in the figure, the control valve closes the hole provided in the lower part of the pulsation space 16b, and communicates with the negative pressure space 16a provided thereunder. Will be cut off. When the control shaft 17 moves downward in the figure, the control valve opens the upper opening of the pulsation space 16b

A control shaft 17 with a control valve having such a function is mounted on a seesaw 1 shown in FIG.
8 is engaged. And this seesaw 18 is shown in FIG.
The control gear (not shown) meshed with the reduction gears 12, 12, 12, 12 shown in FIG. The swing of the seesaw 18 causes the two control shafts 17 to alternately move up and down. By the way, the two pulsation spaces 16
The nozzles b and 16b communicate with the nozzles 19 and 19 shown in FIG. 24. The nozzles 19 and 19 are connected to a breast milk storage bottle (not shown) by a hose or the like. The breast milk storage bottle is provided with a bowl-shaped breast milk receiving portion that is in close contact with the breast of the user. When the pump unit 10 of the electric breast pump constructed as described above is operated, the diaphragm 14 moves by the rotation of the motor 11, and the negative pressure space 16a
is negative pressure. On the other hand, the rotation of the motor 11 causes the control gear to rotate, causing the seesaw 18 to swing.
The two control shafts 17, 17 are alternately moved up and down. The pulsation space 16b, in which the control shaft 17 has moved downward, is disconnected from the negative pressure space 16a and is opened instead of the negative pressure. In addition, one pulsation space 16b in which the control shaft 17 has moved upward
is in a negative pressure state.

[0005] Here, the bottle for storing breast milk is
When the hose is connected to one of the nozzles 19 (see FIG. 24) using a hose, only one of the pulsation spaces 16b communicates with the breast milk storage bottle. .
The negative pressure state and the open state are repeated. Thereby, it is possible to perform suction in a state that is not continuous suction but close to suction performed by an infant, that is, in a pulsating state, and more effective milking can be performed.

[0006]

The negative pressure space 16a and the pulsating space 16b forming the chassis 16 of the motor unit 10 of such a pulsating breast pump have a negative pressure acting as a suction force of the pulsating breast pump. It is an important part for generating the noise. Therefore, even if a slight defect occurs in these parts, it greatly affects the suction force of the pulsating breast pump, and the defective part has to be replaced. This problem often occurs only in one of the negative pressure space 16a and the pulsation space 16b of the chassis 16, but even in this case, the negative pressure space 16a and the pulsation space 16b are connected as described above. Since it is formed integrally, there is a problem that the entire chassis 16 needs to be replaced.

[0007] In view of the above, an object of the present invention is to provide a pulsating breast pump in which parts can be easily replaced and which is easy to use.

[0008]

SUMMARY OF THE INVENTION According to the present invention, there is provided a negative pressure generating section, a negative pressure generating section having a negative pressure inside the negative pressure generating section, and a negative pressure generating section. A pulsating breast pump comprising; a breast pump body having a pulsation space portion formed by being connected to a breast pump, and a suction storage section installed in a breast or the like of a user to suck and store the breast milk of the user. The pulsating breast pump is characterized in that the negative pressure space portion and the pulsation space portion are arranged so as to be separable from each other.

According to the above configuration, since the negative pressure space portion and the pulsation space portion are arranged so as to be separable from each other, only one of them can be separated and replaced.

Preferably, in the structure of the first aspect, the pulsation space is provided with a connecting projection for connecting to the negative pressure space, and the pulsation space is provided in the negative pressure space. A pulsating breast pump, characterized in that a coupling concave portion for coupling with the pulsating portion is provided, and a holding portion for holding the connection between the pulsating space portion and the negative pressure space portion is provided.

According to the above construction, the pulsation space is provided with a connection projection for connecting to the negative pressure space, and the negative pressure space is connected to the pulsation space. For this reason, the pulsation space and the negative pressure space can be easily connected by combining the connection protrusions and the connection recesses. In addition, since the holding portion for holding the connection between the pulsation space portion and the negative pressure space portion is provided, the connection between the pulsation space portion and the negative pressure space portion can be further strengthened.

Preferably, in the configuration of claim 1 or 2, between the suction storage unit and the breast pump body.
A connection part for connecting these is provided, and an air chamber is provided on the connection part side of the suction storage part, and an uneven part is formed inside the air chamber. Pulsating breast pump.

According to the above configuration, since the air chamber is provided on the connection portion side of the suction storage portion, it is possible to prevent breast milk from flowing into the connection portion. In addition, since an uneven portion is formed inside the air chamber, the internal area of the air chamber increases, and the water vapor of the milk adheres to the inside of the air chamber, so that the milk flows into the connection portion. Can be prevented.

Preferably, claims 1 to 3 are provided.
In any of the above configurations, the suction storage unit includes a suction unit for sucking the breast milk of the user and a storage unit for storing the breast milk of the user, and the storage unit includes the suction unit. A pulsating breast pump, characterized in that a valve is provided for moving the breast milk of the user sucked in the part to the storage part, and a substantially central part of the valve is bent toward the suction part side. It is

According to the above configuration, the substantially central portion of the valve is
Since the valve is bent toward the suction portion, the valve is bent in the closing direction. This ensures a negative pressure condition.

Preferably, claims 1 to 4 are provided.
In any one of the above configurations, the holder portions formed on both sides of the breast pump main body and the suction storage portion are provided with engaging portions for attaching the holder portion to the breast pump main body. A pulsating breast pump characterized in that it is used.

According to the above arrangement, the holder for mounting the suction storage section on both sides of the breast pump main body and the holder section on which the suction storage section can be placed is provided with an engaging section for attaching the holder section to the breast pump main body. Since each of them is provided, the holder can be easily attached to both sides or one side of the breast pump body.

[0018]

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS Preferred embodiments of the present invention will be described below in detail with reference to FIGS. The embodiment described below is a preferred specific example of the present invention, and thus various technically preferable limitations are added. However, the scope of the present invention particularly limits the present invention in the following description. The embodiment is not limited to these embodiments unless otherwise stated

FIG. 1 is a view showing a pulsating breast pump 100 according to an embodiment of the present invention. The pulsating breast pump 100 includes a pump unit 110 that is a breast pump body and bottle holders 120 and 120 that are holder units disposed on both sides thereof.
have. in addition, the pulsating breast pump 100 includes, for example, two bottle units 130, which are suction storage units. Further, the pulsating breast pump 100 is provided with two suction tubes 140, 140, which are connection portions for connecting the bottle unit 130 and the pump unit 110. Also, on the surface of the pump unit 110,
As shown in FIG. 1, a power switch 110a and a suction pressure adjustment dial 110b are arranged. FIG. 2 is a view of the pump unit 110 and the bottle holders 120, 120 viewed from the back side of FIG. As shown in FIG. 2, the pump unit 110 is provided with, for example, two nozzles 110d for connecting the intake tubes 140, 140. In addition, this pump unit 110 includes:
Battery storage unit 11 for storing a battery, for example, a power supply
0c is provided. Alternatively, an AC power supply can be used as the power supply. In this case, an AC power supply is connected to the AC power supply connection terminal 110e shown in FIG. 2 for use. Since the pump unit 110 generates a suction pressure for sucking the mother's milk as a user, the pump unit 110 will be described in detail below.

FIG. 3 shows a state in which the casing of the pump unit 110 shown in FIGS.
FIG. 5 is a view showing a central portion of a pump unit which is a central portion of the pump unit. FIG. 4 is an exploded perspective view showing the central part 110 of the pump unit shown in FIG. 3 in an exploded manner. As shown in FIG. 4, the motor 112 is accommodated in a motor plate 113. At this time, the motor shaft 11 of the motor 112
2a is the motor plate hole 11 of the motor plate 113;
8a, and the eccentric cam 114 is attached to the tip thereof. The tip of the eccentric cam 114 has a gear 114a
Is provided. The eccentric cam 114 is engaged with a connection rod 115 connected to a diaphragm 116 which is a negative pressure generating section. The diaphragm 116 is mounted on the diaphragm back plate 117. The connection rod 11
5 is engaged with the eccentric cam 114 in a state where it is inserted into a round hole provided in a chassis 118 which is a negative pressure space.

On the other hand, the gear 114a is
4b, and two reduction gears 114b, 114
b are connected in a meshing state. Furthermore, this reduction gear 1
14b is engaged with the control gear 114.
The seesaw 119 is engaged with the control gear 114c. The reduction gear 11
4b, 114b, 114b and control gear 114c
Are supported by stainless steel bars 109, 109. The seesaw 119 is engaged with two control shafts 108, 108. The two control shafts 108, 108 are lower than an opening provided on an upper portion of a seesaw base 107 which is a pulsating space. The nozzle openings 107d, 10c
7d, a control valve 106a previously arranged in
106a. Below the seesaw base 107, two seesaw base connecting portions 107a, which are connecting protrusions for connecting to the chassis 118, are provided. This seesaw base connecting part 107
The O-ring 106 is mounted on the a and 107a.
On the other hand, on the upper part of the chassis 118, two chassis connecting portions 118a, which are connecting concave portions, are provided. Therefore, the seesaw base 107 and the chassis 118 are integrally connected by inserting the seesaw base connecting portions 107a and 107a into the chassis connecting portions 118a and 118a. At this time, since the O-ring 106 is mounted on the seesaw base connecting portions 107a, 107a, they are connected while maintaining airtightness.

The chassis 118 is provided with a chassis opening 118b.
8b, the valves 103 and O shown in FIG.
A ring 106 is arranged. This valve 103 and O
The ring 106 is fixed to the leaf spring 102 with a fastener (not shown) via a suction pressure adjusting hole 104 a of the chassis cover 104. A suction pressure adjusting dial 110b is arranged on the chassis cover 104. The suction pressure adjustment dial 110b is provided with a groove, and the adjustment pin 105 is disposed in contact with the groove. The adjustment pin 105 is configured to move in the left and right direction in the figure by rotating the suction pressure adjustment dial 110b. By the way, the chassis cover 104 as the holding portion is pressed against the chassis 118 and fixed. At this time, since the chassis cover 104 is disposed so as to press not only the chassis 118 but also the seesaw base 107, the connection state between the seesaw base 107 and the chassis 118 is further strengthened. By the way, a leaf spring 102 made of sheet metal is arranged on the chassis cover 104. One end of the leaf spring 102 is fixed by a leaf spring retainer 102a. However, the other end of the leaf spring 102 is not fixed,
The leaf spring 102 is pressed against the surface of the chassis cover 104 by the elasticity of the leaf spring 102 itself. Further, since the tip of the above-described adjustment pin 105 is in contact with the other end of the leaf spring 102, the movement of the adjustment pin 105 causes the leaf spring 102 to move, and the valve 103 connected thereto. Is chassis 11
8 with respect to the chassis opening 118b.

The central part 111 of the pump unit shown in FIG
is configured as described above and operates as follows.
First, the user turns on the power switch 110a shown in FIG
In this state, the motor 112 starts to rotate using the battery housed in the battery housing 110c shown in FIG. 2 as a power source. The rotation of the motor 112 causes the eccentric cam 114 to rotate in an eccentric state. This eccentric cam 114
Is engaged with the connection rod 115 connected to the diaphragm 116, so that the connection rod 115 moves up and down. FIG. 5 shows this state. As shown by the arrow A in FIG. 5, the diaphragm 116 moves up and down, thereby generating a flow of air as shown by the arrow B. At this time, diaphragm 1
Since the diaphragm holes 116b near the 16 diaphragm valves 116a are connected to the diaphragm connection holes 118c of the chassis 118, a negative pressure is generated in the chassis 118. FIG. 6 shows the diaphragm connection hole 118c. FIG. 6 is a bottom view of the chassis 118. As shown in FIG. 6, the connecting hole 11 for the diaphragm is formed on the bottom of the chassis 118.
8c is provided. This diaphragm connection hole 11
8c is a chassis opening 1 of the chassis 118 shown in FIG.
18b, the chassis opening 118 and the diaphragm hole 116b communicate with each other.

As shown in FIG. 7, the chassis opening 118 is formed into two portions or two portions connected to the chassis connecting portions 118a, 118a. Referring to FIG. This chassis connecting portion 118
it can be seen that a and 118a are open. Thus, the chassis 118 has a chassis opening 118b,
Diaphragm connection hole 118c and chassis connection portion 11
Portions other than 8a and 118a are closed spaces. Then, since the chassis opening 118b is closed by the chassis cover 104 as described above, the inside of the

chassis 118 is brought into a negative pressure state by the diaphragm 116. The negative pressure state of the chassis 118 also causes a negative pressure state inside the seesaw base 107 via the seesaw base connecting portions 107a of the seesaw base 107. By the way, when the motor 112 rotates, the gear 114a shown in FIG. 4 starts rotating in addition to the eccentric cam 114, and the reduction gear 1 meshed with the gear 114a.
The speed is reduced by 14b. The control gear 11 meshed with the third reduction gear 114b
4c starts to rotate. The control gear 114c has a specific groove as shown in FIG. 4, and the seesaw 119 is engaged with a part of the groove.

FIG. 9 shows this state. FIG.
As shown in the figure, the seesaw convex portion 11 of the seesaw 119
9a will engage. This control gear 11
The circular motion of 4c is changed into swing of the seesaw 119 by the groove. The pivot of the seesaw 119 is a pivot 119b of the seesaw shown in FIG. 4, and the pivot 119b of the seesaw is
07 is inserted into the seesaw receiving portion 107b. Also, two control shafts 108 shown in FIG. 4 are attached to the seesaw 119. FIG. 10 shows this state. As shown in FIG. 10, the two control shafts 108, 108 will be engaged with cutouts on both sides of the seesaw 119. The control shafts 108, 108 are inserted into the seesaw base 107 as described above, and the control valves 108a, 108a are mounted below the control shafts. FIG. 11 is a front view showing the seesaw base 107, and FIG. 12 is a plan view of the seesaw base 107. As shown in FIG.
Are formed with two control shaft holes 107c into which the control shaft 108 is inserted. The control shaft hole 107c communicates with the nozzle opening 107d shown in FIG.

However, these two nozzle openings 10
7d, 107d and two control shaft holes 107
c and 107c are not communicated with each other, but each are separately communicated with the seesaw base coupling portions 107a and 107a. Such a control shaft hole 107
Control shafts 108 and 108 are arranged in c and 107c, respectively. In this state, the seesaw 119 is
When the rocking motion is performed, the control shafts 108 alternately move up and down as shown in FIG.
When the control shaft 108 moves downward and reaches the bottom of the nozzle openings 107d and 107d shown in FIG. 11, the seesaw connecting portion 107a is closed by the control valve 108a provided on the control shaft 108. Become. At this time, the closed seesaw base 10
In the internal space 7, the above-described negative pressure state of the chassis 118 is not transmitted, but rather, it is opened to the atmosphere due to a gap between the control shaft 108 and the control shaft hole 107 c of the seesaw base 107. On the other hand, control axis 1
When 08 moves upward, a space is created between the control valve 108a attached to the control shaft 108 and the seesaw connecting portion 107a, and the upper end of the control valve 108a closes the lower end of the control shaft hole 107c. Will be. Therefore, the above-described chassis 118
, A negative pressure condition will also occur in the seesaw base 107. Thus, the negative pressure state and the atmosphere open state
Pulsation, which will be described later, is caused by alternately causing the movement of the control shafts 108, 108.

By the way, the two nozzle openings 107d, 107d provided in the seesaw base 107 are
As shown in FIG. 4, the nozzle 11 of the chassis cover 104
0d and 110d, respectively, and intake tubes 140 and 140 are connected to the nozzles 110d and 110d as shown in FIG. In order for the mother to adjust the negative pressure generated inside the chassis 118, the mother operates the suction pressure adjustment dial 110b shown in FIG. 4 by operating the mother. That is, the suction pressure adjustment dial 110b is specifically configured as shown in FIG. As shown in FIG. 13A, the suction pressure adjusting dial 110b is provided with a spiral groove having a different thickness, and the adjusting pin 105 comes into contact with the groove. The suction pressure adjusting dial 110b can be operated by the mother from outside the pump unit 110 as shown in FIG. Therefore, when the mother operates and turns the suction pressure adjustment dial 110b, the thickness of the groove of the suction pressure adjustment dial 110b with which the adjustment pin 105 is in contact changes. Here, for example, when the thickness of the groove is increased, the adjustment pin 105 pushes the leaf spring 102 as shown in FIG. Since the leaf spring 102 and the valve 103 shown in FIG. 4 are connected as described above, the valve
103 is also connected to the chassis 11.
8 moves in a direction away from the chassis opening 118b,
The negative pressure (suction pressure) becomes small. Conversely, when the thickness of the groove of the suction pressure adjustment dial 110b is reduced, the valve 103 is pushed into the inside of the chassis opening 118b, and the negative pressure (suction pressure) increases. In this way, the mother adjusts the negative pressure.

As described above, the pump unit 110 is configured and operates, but the bottle unit 1 connected to the pump unit 110 via the suction tube 140 is operated.
30 will be described below. FIG. 14 is an exploded perspective view of the bottle unit 130. As shown, the bottle unit 130 has a suction unit for sucking mother's milk,
And a storage unit for storing breast milk. The suction unit includes a milking cap 133, a disk 134, an inner plug 135, a cylinder 136, and a breast shield 137. Among them,
breast shield 13
Numeral 7 has a breast milk receiving portion 137a, which is a part that the mother wears on her own breast. A separate non-slip portion (not shown) may be used for the breast milk receiving portion. That is, this is a case where the non-slip portion is mounted on the inner surface of the breast milk receiving portion so that the uneven portion is arranged in a portion that comes into contact with the mother's breast. The cross section of the breast shield 137 is shown in FIG.
As shown in FIG. The formed cage has a cross section as shown in FIG. That is, as shown in FIG. 15, inside the breast shield 137, the breast shield 137 communicates
with the internal space of the breast milk receiving portion 137a.
It is formed so as to guide upward and downward in the figure.

An opening 137b above the breast shield 137 has a cylinder 136 and a disc 134 shown in FIG.
is inserted. FIG. 15A shows a state in which the inner plug 135 and the like are inserted. FIG. 16 specifically shows the structure of the inner plug 135 and the like. As shown in FIG. 16, a disc hole 134a is provided at the center of the disc 134, and the disc hole 134a is used for the inner plug holes 135a and 135a of the inner plug 135.
Through the breast shield 137 of FIG. In addition, the inner plug main body 135b of the inner plug 135 is vertically movable in the drawing, and the inner plug main body
135b is moved upward, so that the inner plug convex portion 135 of the inner plug 135 is moved.
When c and 135c come into contact with the disk 134, this movement stops and the communication between the disk hole 134a of the disk 135 and the inner plug hole 135a of the inner plug main body 135 is stopped. Also, on the inner stopper 135 and the like, FIG
As shown in FIG. 4, a milking port cap 133 that is an air chamber is provided. FIG. 17 shows the structure of the milking cap 133. As shown in FIG. 17, an intake tube hole 133a for connecting the intake tube 140 shown in FIG. 1 is provided in the upper part of the milking opening cap 133. Further, an uneven portion is provided on the inner peripheral portion 133b of the milking cap 133.

The formation of the uneven portions is performed by, for example, corrosion processing. In this corrosion process, the inner peripheral portion 133b of the milking cap 133 is etched using a chemical to remove an unnecessary portion, thereby forming an uneven portion. Also,
As another method of forming the uneven portion, there is a blasting method of spraying sand or the like on the mold to damage the mold. In this way, the milking opening cap 133 having the concave and convex portions on the inner peripheral portion 133b is fixed to the breast shield 137 shown in FIG. On the other hand, what constitutes a storage unit for storing breast milk is shown in FIG.
4, a bottle 132, a valve 132, a check valve 139, and the like. This check valve 139
is mounted so as to be inserted into the lower end of the breast shield 137 shown in FIG. A valve 132 is attached to the lower end of the check valve 139. This valve 132
As shown in FIG. 18, the valve 132 is closed or opened by moving the movable piece 132a. FIG. 19 is a view showing a cross section of the valve 132. As shown in FIG.
19, the upper ends on both sides of the valve 132 are thicker than other portions. Therefore, this valve 132 is connected to the check valve 1
When attached to 39, the above-mentioned thick portion spreads outward. As a result, the movable piece 132a, which is a substantially central portion of the valve 132, is

bent upward in the drawing.
When the movable piece 132a of the valve 132 bends upward as described above, the movable piece 132a is arranged in a direction for holding the valve 132 in a closed state.

The operation and the like of the bottle unit 130 configured as described above will be described below. First, as shown in FIG.
Attach the intake tube 140 to. Then, the breast milk receiving portions 137a and 137a of the breast shields 137 and 137 of the two bottle units 130 are brought into close contact with both breasts of the mother as the user as shown in FIG. When the power switch 110a of the pump unit 110 is turned on in this state, the central part 111 of the pump unit starts to move as described above. Due to the operation of the central part 111 of the pump unit, the two nozzles 110d and 110d of the pump unit 110 alternately repeat suction and release to the atmosphere. These two nozzles 1
The suction and opening to the atmosphere at 10d and 110d are performed through the intake units 140 and 140, respectively.
30 will be transmitted. That is, in the case of the suction state, the suction pressure passes through the suction tube 140, passes through the milking mouth cap 130, passes through the disc hole 134a shown in FIG.
It passes through the inner stopper hole 135a and reaches the inside of the breast shield 137 shown in FIG.

At the lower end of the breast shield 137, a check valve 139 having a valve 132 is provided.
The movable piece 132a of the 32 will be pulled upward in the figure, whereby the valve 132 will be kept closed. At this time, even if the suction pressure is slightly small, since the movable piece 132a of the valve 132 is bent and held upward as described above, the movable piece 132a
Does not move downward to reduce the suction pressure. As described above, since the lower end of the breast shield 137 is closed by the valve 132, the suction pressure in the breast shield 137 reaches the breast milk receiving portion 137a,
The mother's breast placed there will be sucked. The breast milk milked by the suction pressure is moved along the breast shield 137 along the breast milk receiving portion 137a shown in FIG.
Through the check valve 139 and through the valve 132
Will be reached. At this time, when the sucking stops due to the pulsation and the breast milk accumulates in the vicinity of the valve 132, the movable piece 132a of the valve 132 moves downward by its weight, and the breast milk falls into the bottle main body 131

If the breast milk is accumulated in the breast shield 137 before the milk is dropped into the bottle main body 131 by its own weight due to a large amount of milk, the accumulated breast milk pushes up the cylinder 136 shown in FIG. By raising the cylinder 136, the inner plug main body 135b is pushed up, and the inner plug convex portion 135 is raised.
c hits the disk 134, thereby blocking communication between the space below the inner plug body 135b and the space above the disk 134. With this cutoff, the suction pressure of the pump unit 110 is interrupted at the disk 134 portion, so that the milk does not move to the pump unit 110 side any more, and it is possible to prevent the milk from flowing into the pump unit 110 side. . Thus, by preventing the breast milk from flowing into the pump unit 110, the failure of the pump unit 110 can be prevented. A milking mouth cap 133 is disposed on the inner plug 135 and the like.
Since the inner peripheral portion 133b (see FIG. 17) of 33 is provided with an uneven portion, the uneven surface portion increases the surface area and the amount of adsorption. Inflow will be effectively prevented. Furthermore, since the inlet tube hole 133a of the milking mouth cap 133 is provided at the upper end of the milking mouth cap 133 as shown in FIG. 17, the position is less affected by breast milk.

On the other hand, when the pump unit 110 is open to the atmosphere, milking is not performed in the bottle unit 130. Thus, by using the pump unit 110 and the bottle unit 130 of the present embodiment, both breasts can be milked at the same time, and this milking is performed by so-called pulsation that repeats suction and opening to the atmosphere. Can be. Pump unit 1
Since the ten chassis 118 and the seesaw base 167 are separable, if one of them is broken, only the other can be replaced, so that the cost can be reduced and the usability is improved. After performing milking using the pump unit 110 and the bottle unit 130 as described above, as a place where the two bottle units 130 and 130 are placed,
As shown in FIG. 1, bottle holders 120 serving as holder portions are provided on both sides of the pump unit 110. Thus, the mother who has finished milking will replace the two bottle units 130, 130 with these bottle holders 120, 12
0. In addition, the bottle holders 120, 120
9 and can be easily removed. More specifically, as shown in FIG.
20 are provided with engaging projections 110e, 110e. The engagement projection 110e has a semi-elliptical shape as shown in FIG.

On the other hand, as shown in FIG. 23, the bottle holder 120 is provided with a bottle holder engaging concave portion 120a corresponding to the engaging convex portion 110e. Therefore, the bottle holder 120 is attached to the pump unit 110 by inserting the engagement protrusion 110e of the pump unit 110 into the bottle holder engagement recess 120a. When the mother who is the user uses only one bottle unit 130, one bottle holder 120 may be attached to any one of the pump units 110, and the space where the pulsating breast pump 100 is placed is small. I'm done.

[0036]

As described above, according to the present invention, it is possible to provide a pulsating breast pump in which parts can be easily replaced and which is easy to use.

[Brief description of the drawings]

FIG. 1 is a schematic perspective view showing a pulsating breast pump according to an embodiment of the present invention.

FIG. 2 is a schematic perspective view showing a pump unit and the like of the pulsating breast pump of FIG. 1;

FIG. 3 is a schematic perspective view showing a central portion of a pump unit

FIG. 4 is an exploded perspective view of a central portion of the pump unit of FIG. 3;

FIG. 5 is an explanatory diagram showing a relationship between a motor and a diaphragm in FIG. 4,

FIG. 6 is a bottom view of the chassis of FIG. 4;

FIG. 7 is a front view of the chassis of FIG. 4;

FIG. 8 is a plan view of the chassis of FIG. 4;

FIG. 9 is an explanatory diagram showing the relationship between the control gear and the seesaw of FIG. 4;

FIG. 10 is an explanatory diagram showing a relationship between the seesaw of FIG. 4 and a control axis.

FIG. 11 is a front view of the seesaw base of FIG. 4;

FIG. 12 is a plan view of the seesaw base of FIG. 4;

FIG. 13 is an explanatory diagram showing a relationship between a suction pressure adjustment dial and an adjustment pin. (2) It is explanatory drawing which shows the relationship between a suction pressure adjustment dial and a leaf spring.

FIG. 14 is an exploded perspective view showing a bottle unit of the pulsating breast pump of FIG. 1;

FIG. 15 is a sectional view showing the breast shield of FIG. 14;

FIG. 16 is a schematic sectional view showing a state where the disk, inner plug, and cylinder of FIG. 14 are connected.

FIG. 17 is a sectional view showing the milking mouth cap of FIG. 14;

FIG. 18 is a plan view showing the valve of FIG.

FIG. 19 is a sectional view showing the valve of FIG. 14;

FIG. 20 is a diagram showing a state where the mother is using a pulsating breast pump.

FIG. 21 is a plan view showing the relationship between the pump unit of FIG. 1 and an engagement protrusion.

FIG. 22 is a side view of the pump unit of FIG. 21.

FIG. 23 is a plan view showing an engaged state between the pump unit and the bottle holder in FIG. 1;

FIG. 24 is a perspective view showing a conventional pump unit.

FIG. 25 is a schematic exploded view of the pump unit of FIG. 24;

[Explanation of symbols]

100: pulsating breast pump, 102: leaf spring, 103: valve, 104: chassis cover, 105: adjusting pin, 106: O-ring, 1
07: seesaw base, 108: control shaft, 109: stainless steel rod, 110: pump unit, 112: motor, 113: motor plate, 114: eccentric cam, 115 ..Connection rod, 116 ... diaphragm, 117 ... diaphragm back plate, 118 ... chassis, 119 ...
Seesaw, 120 ... bottle holder, 130 ... bottle unit, 131 ... bottle body, 132 ...
Valve 133: milking cap, 134: disk,
135: inside plug, 136: Cylindrical, 137: Breast shield, 139: Check valve

Similar Documents

Publication	Publication Date	Title
US4882464A	1989-11-28	Milking equipment
KR100611875B1	2006-08-11	Skin care device
KR1499814981	2006-12-10	Diaphragm breast pump
US4319570A	1982-03-16	Tracheal suction pump designed primarily for aspiration purposes
JP2001082226A	2001-03-27	Oil feeding device of linear compressor
JPH07312661A	1995-12-05	Fluid suction pump mechanism
JP2000360927A	2000-12-19	Pulsating milking machine
CN212631316U	2021-03-02	Milk bowl and breast pump for breast pump
US20210275278A1	2021-09-09	Dental irrigator water tank and dental irrigator
CN210177718U	2020-03-13	Pet drinking machine
CN111588927A	2020-08-28	Milk bowl and breast pump for breast pump
JP4697674B2	2011-06-08	pot
KR101070662B1	2011-10-06	Pparatus extracting mother's milk
JP2001269426A	2001-09-25	Milking device
KR101546037B1	2015-08-21	The Milker
KR20020038641	2002-06-01	Suction hose withdrawal device for drinking water suction means for gas mask
CN212577317U	2021-03-09	Oil cup for range hood and range hood applying same
CN211403390U	2020-08-21	Water purifier
CN216019624U	2021-12-07	Intelligent sterilizing household tooth washing device
CN112432498B	2022-09-23	Water intaking subassembly and purifier of purifier
CN211215720U	2020-08-11	Water intaking subassembly and purifier of purifier
JP2637909B2	1996-09-25	Milking machine
CN210728920U	2020-06-12	Built-in check valve of straw

CN212269811U	2020-08-11	Water purifier
CN112441696A	2022-08-30	Water purifier

Priority And Related Applications

Priority Applications (1)

Application	Priority date	Filing date	Title
JP16304499A	1999-06-09	1999-06-09	Pulsating breast pump

Applications Claiming Priority (1)

Application	Filing date	Title
JP16304499A	1999-06-09	Pulsating breast pump

Legal Events

Date	Code	Title	Description
2005-04-19	A621	Written request for application examination	**Free format text:** JAPANESE INTERMEDIATE CODE: A621 **Effective date:** 20050418
2006-04-13	A977	Report on retrieval	**Free format text:** JAPANESE INTERMEDIATE CODE: A971007 **Effective date:** 20060413
2006-04-19	A131	Notification of reasons for refusal	**Free format text:** JAPANESE INTERMEDIATE CODE: A131 **Effective date:** 20060418
2006-06-20	A523	Written amendment	**Free format text:** JAPANESE INTERMEDIATE CODE: A523 **Effective date:** 20060619
2006-07-06	TRDD	Decision of grant or rejection written	
2006-07-12	A01	Written decision to grant a patent or to grant a registration (utility model)	**Free format text:** JAPANESE INTERMEDIATE CODE: A01 **Effective date:** 20060711
2006-08-03	A61	First payment of annual fees (during grant procedure)	**Free format text:** JAPANESE INTERMEDIATE CODE: A61 **Effective date:** 20060727
2006-08-04	R150	Certificate of patent or registration of utility model	**Free format text:** JAPANESE INTERMEDIATE CODE: R150 **Ref document number:** 3836627 **Country of ref document:** JP **Free format text:** JAPANESE INTERMEDIATE CODE: R150
2009-04-02	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text:** PAYMENT UNTIL: 20090804 **Year of fee payment:** 3
2009-04-07	FPAY	Renewal fee payment (event date is renewal date of database)	**Free format text:** PAYMENT UNTIL: 20100804 **Year of fee payment:** 4
2009-04-07	R250	Receipt of annual fees	**Free format text:** JAPANESE INTERMEDIATE CODE: R250
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2011-05-31	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
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2012-06-26	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2013-08-13	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2014-07-29	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2015-08-04	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2016-08-02	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2017-08-08	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2018-07-10	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
2019-06-09	EXPY	Cancellation because of completion of term	

Concepts

machine-extracted

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Name	Image	Sections	Count	Query match
Breast		claims,abstract,description	77	0.000
human milk		claims,abstract,description	35	0.000
Milk, Human		claims,description	35	0.000
coupling		abstract,description	4	0.000
coupling process		abstract,description	4	0.000
coupling reaction		abstract,description	4	0.000
Feathers		abstract	1	0.000

Show all concepts from the description section

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[Continued on next page]

(54) Title: METHODS AND APPARATUS FOR TRANSFERRING PRESSURE DURING EXPRESSION OF HUMAN BREAST MILK

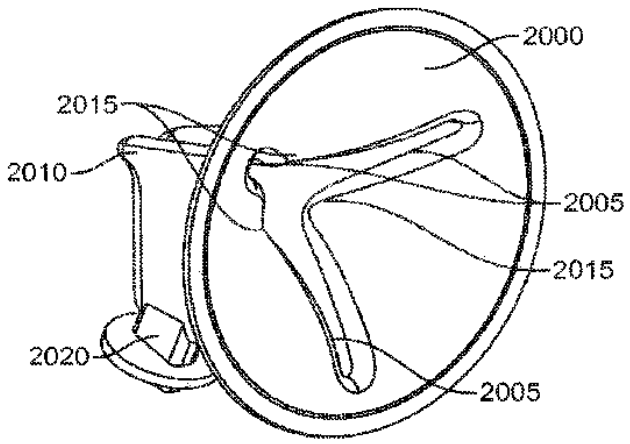


FIG. 20A

(57) Abstract: A device for expression and collection of breast milk includes an actuatable assembly and a breast interface. The breast interface is sized to receive a breast and form a fluid tight seal against the breast. The breast interface includes an expandable membrane disposed within at least a portion of the breast interface. The expandable membrane reversibly deforms in response to actuation of the actuatable assembly, thereby applying vacuum pressure at the breast to express milk. The expandable membrane comprises a plurality of expandable pleats which extend radially outward from a central longitudinal axis of the breast interface.

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METHODS AND APPARATUS FOR TRANSFERRING PRESSURE DURING EXPRESSION OF HUMAN BREAST MILK

CROSS-REFERENCE

[0001] This application claims the benefit of U.S. Provisional Application No. 62/021,597, filed July 7, 2014 [Attorney Docket No. 44936-706.101], the full disclosure of which is incorporated herein by reference.

[0002] This application is related to U.S. Patent Application No. 14/221,113, filed on March 20, 2014 [Attorney Docket No. 44936-703.201], U.S. Patent Application No. 14/616,557, filed on February 6, 2015 [Attorney Docket No. 44936-704.201], U.S. Provisional Application No. 62/021,601, filed on July 7, 2014 [Attorney Docket No. 44936-705.101], U.S. Provisional Application No. 62/021,604, filed July 7, 2014 [Attorney Docket No. 44936-707.101], and U.S. Provisional Application No. 62/028,219, filed on July 23, 2014 [Attorney Docket No. 44936-708.101], the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention. The present invention generally relates to medical devices and methods, and more particularly relates to devices and methods for expression and collection of human breast milk.

[0003] The exemplary embodiments disclosed herein are preferably directed at expression of breast milk, but one of skill in the art will appreciate that this is not intended to be limiting and that the devices, systems and methods disclosed herein may be used for other treatments requiring application of a differential pressure.

[0004] Breast pumps are commonly used to collect breast milk in order to allow mothers to continue breastfeeding while apart from their children. Currently, there are two primary types of breast pumps: manually-actuated devices, which are small, but inefficient and tiring to use; and electrically-powered devices, which are efficient, but large and bulky. Therefore, it would be desirable to provide improved breast pumps that are small and highly efficient for expression and collection of breast milk. Currently existing or proposed breast pumps also may employ membranes which help create negative pressure during expression of milk. These membranes may have unwanted motion during actuation and therefore improved membrane design is also desirable. At least some of these objectives will be satisfied by the devices and methods disclosed below.

2. Description of the Background Art. The following US patents are related to expression and collection of human breast milk: US Pat. Nos.: 6,673,036; 6,749,582; 6,840,918; 6,887,210; 7,875,000; 8,118,772; and 8,216,179.

SUMMARY OF THE INVENTION

[0005] The present invention generally relates to medical devices, systems and methods, and more particularly relates to devices, systems and methods for expression and collection of human breast milk.

[0006] In a first aspect, a device for expression of milk from a breast comprises an actuatable assembly and a breast interface sized to engage a breast and fluidly seal thereagainst. The breast interface comprises an expandable membrane disposed within at least a portion thereof, wherein the expandable membrane moves in response to actuation of the actuatable assembly, thereby applying vacuum pressure at the breast to express milk therefrom. The expandable membrane comprises a plurality of expandable pleats, each of the plurality of expandable pleats extending radially outward from a center of the expandable membrane.

[0007] The plurality of expandable pleats may be configured to expand radially outward or contract radially inward during acutation of the actuatable assembly. The device may further comprise a drain port disposed along a bottom portion of the expandable membrane, between pleats or in a section of the expandable membrane having no pleats. The drain port may be configured to remain in a substantially fixed longitudinal position during actuation of the actuatable assembly. Alternatively or in combination, the drain port may be disposed in a section of the expandable member having no pleats, such that the drain port is configured to remain in a substantially fixed radial position during actuation of the actuation assembly. The expandable membrane may further comprise a negative grade along a bottom portion thereof, configured to allow expressed milk to flow downhill into the drain port. The breast interface may further comprise a housing and a sealing member, the sealing member disposed around the drain port to secure the expandable membrane to the housing of the breast interface. The plurality of expandable pleats may be configured to converge at an apex, wherein the apex may be configured to remain in a substantially fixed position during actuation of the actuatable assembly.

[0008] The breast interface may further comprise a fluid reservoir operatively coupled to the actuatable assembly, wherein actuation of the actuatable assembly removes fluid from the fluid reservoir thereby expanding the expandable membrane, or wherein the actuation adds fluid to the fluid reservoir thereby contracting the expandable membrane. The actuatable assembly may be removably coupled to an actuatable assembly interface, the actuatable assembly interface

configured to operatively couple the actuatable assembly to the breast interface while maintaining physical separation between the actuatable assembly and the fluid. The actuatable assembly interface may comprise an interface membrane fluidly coupled to the fluid reservoir via an elongate tube. The interface membrane may be configured to operatively couple to an actuatable assembly membrane of the actuatable assembly, such that movement of the actuatable assembly membrane, affected by the actuation of the actuatable assembly, causes corresponding movement of the interface membrane, thereby causing movement of the fluid into or out of the fluid reservoir.

[0009] The actuatable assembly may comprise a one-way valve configured to allow air trapped between the actuatable assembly and the actuatable assembly interface to exit during actuation of the actuatable assembly. The actuatable assembly may comprise an alignment mechanism configured to couple the actuatable assembly with the actuatable assembly interface in a substantially fixed position and orientation. The actuatable assembly may be removably coupled to the actuatable assembly interface via one or more magnets. The one or more magnets may be configured to have a magnetic force greater than: (1) an exit force of air exiting a space between the actuatable assembly and the actuatable assembly interface via a one-way valve, and (2) a pull force generated by actuation of the actuatable assembly.

[0010] The breast interface may further comprise a housing, and the expandable membrane may comprise an enlarged edge configured to be disposed in a channel of the housing, so as to securely couple the expandable membrane to the housing. The breast interface may further comprise a flange comprising a resilient material that allows the breast interface to fluidly seal against the breast, wherein the breast interface further comprises a sealing member to seal the housing against the flange. The expandable membrane may be compressively fixed between the housing and the flange via an elastomeric pinch fixation to hold and seal the expandable membrane.

[0011] In another aspect, a method of expressing milk from a breast comprises engaging and fluidly sealing a breast interface with the breast, wherein the breast interface comprises an expandable membrane having a plurality of expandable pleats. The method further comprises actuating an actuatable assembly operatively coupled to the expandable membrane, thereby causing the plurality of expandable pleats to expand radially outward and apply vacuum pressure at the breast. The method further comprises expressing milk from the breast.

[0012] Actuation of the actuatable assembly may further cause the plurality of expandable pleats to contract radially inward, thereby returning the breast interface to atmospheric pressure or applying positive pressure at the breast interface, causing the expressed milk to drain into a collection vessel fluidly coupled to the breast interface. The plurality of expandable pleats may

apply a compressive force to a portion of the breast engaged with the plurality of expandable pleats, thereby facilitating expression of milk from the breast.

[0013] The breast interface may further comprise a drain port disposed along a bottom portion of the expandable membrane, wherein the drain port remains in a substantially fixed longitudinal position during actuation of the actuatable assembly. The method may further comprise collecting the expressed milk into a collection vessel fluidly coupled to the breast interface via the drain port, wherein the expandable membrane comprises a negative grade along a bottom portion of thereof to allow the expressed milk to flow downhill into the drain port.

[0014] The breast interface may further comprise a fluid reservoir fluidly coupled with the actuatable assembly, wherein actuation of the actuatable assembly removes fluid from the fluid reservoir thereby expanding the expandable membrane, or wherein the actuation adds fluid to the fluid reservoir thereby contracting the expandable membrane. The method may further comprise coupling the actuatable assembly to an actuatable assembly interface operatively coupled to the breast interface, thereby operatively coupling the actuatable assembly to the breast interface.

[0015] These and other embodiments are described in further detail in the following description related to the appended drawing figures.

INCORPORATION BY REFERENCE

[0016] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0018] Fig. 1 is a perspective view of an exemplary embodiment of a pumping device.

[0019] Fig. 2 is a perspective view of an exemplary embodiment of a pumping device.

[0020] Fig. 3 is a cross-section of an exemplary embodiment of a pumping device.

[0021] Fig. 4 illustrates an exemplary embodiment of an actuatable assembly coupled to a driving mechanism.

[0022] Figs. 5A-5B illustrate an exemplary embodiment of an actuatable assembly coupled to a pendant unit.

[0023] Fig. 6 is a cross-sectional view of an exemplary embodiment of a breast interface.

[0024] Fig. 7 is a cross-sectional view of another exemplary embodiment of a breast interface.

[0025] Fig. 8A is a cross-sectional view of an exemplary embodiment of an integrated valve in an open position.

[0026] Fig. 8B is a cross-sectional view of an exemplary embodiment of an integrated valve in a closed position.

[0027] Fig. 9A is a cross-sectional view of an exemplary embodiment of integrated sensors within a breast interface.

[0028] Fig. 9B is a cross-sectional view of another exemplary embodiment of integrated sensors within a breast interface.

[0029] Fig. 10 illustrates an exemplary embodiment of a pendant unit and a mobile device.

[0030] Fig. 11 illustrates an exemplary embodiment of a pendant unit in communication with a mobile device.

[0031] Fig. 12 is a cross-sectional view of an exemplary embodiment of a breast interface with a mechanical deformable member.

[0032] Fig. 13 is a cross-sectional view of an exemplary embodiment of a mechanical driver for a mechanical deformable member.

[0033] Fig. 14 is a graph illustrating the pump performance of an exemplary embodiment compared to a commercial device.

[0034] Fig. 15 is a graph illustrating the pumping efficiency of an exemplary embodiment compared to a commercial device.

[0035] Fig. 16 illustrates an exemplary embodiment of flexible radial bellows.

[0036] Fig. 17 illustrates a partial cross-section of a breast interface with the bellows in of Fig. 16.

[0037] Fig. 18 illustrates a cross-section of showing sealing of the breast interface and the radial bellows.

[0038] Fig. 19 illustrates a cross-section the bellows in Fig. 16.

[0039] Figs. 20A-20B illustrate another exemplary embodiment of an expandable membrane having radial pleats.

[0040] Fig. 21 is a cross-section of a breast interface comprising the expandable membrane illustrated in Figs. 20A-20B.

[0041] Fig. 22 is a cross-section of an exemplary embodiment of an expression device comprising an actuatable assembly interface.

[0042] Fig. 23 is a cross-section of an actuatable assembly coupled to an actuatable assembly interface as illustrated in Fig. 22.

DETAILED DESCRIPTION OF THE INVENTION

[0043] Specific embodiments of the disclosed devices and methods will now be described with reference to the drawings. Nothing in this detailed description is intended to imply that any particular component, feature, or step is essential to the invention. One of skill in the art will appreciate that various features or steps may be substituted or combined with one another.

[0044] The present invention will be described in relation to the expression and collection of breast milk. However, one of skill in the art will appreciate that this is not intended to be limiting, and the devices and methods disclosed herein may be used in other applications involving the creation and transmission of a pressure differential, such as in the treatment of sleep apnea and/or other remote pressure needs.

[0045] Fig. 1 illustrates an exemplary embodiment of the present invention. Pumping device 100 includes breast interfaces 105, a tube 110, and a controller or pendant unit 115 operatively coupled to breast interfaces 105 through tube 110. Breast interfaces 105 include resilient and conformable flanges 120, for engaging and creating a fluid seal against the breasts, and collection vessels 125. The device may optionally only have a single breast interface. Pendant unit 115 houses the power source and drive mechanism for pumping device 100, and also contains hardware for various functions, such as controlling pumping device 100, milk production quantification, and communication with other devices. Tube 110 transmits suitable energy inputs, such as mechanical energy inputs, from pendant unit 115 over a long distance to breast interfaces 105. Breast interfaces 105 convert the energy inputs into vacuum pressure against the breasts in a highly efficient manner, resulting in the expression of milk into collection vessels 125.

[0046] One of skill in the art will appreciate that components and features of this exemplary embodiment can be combined or substituted with components and features of any of the embodiments of the present invention as described below. Similarly, components and features of other embodiments disclosed herein may be substituted or combined with one another.

Hydraulic pumping device

[0047] Hydraulic or pneumatic systems can reduce pumping force requirements, and therefore also reduce the size of the pumping device, while maintaining high pumping efficiency. In a preferred embodiment, the pumping device can utilize a hydraulic or pneumatic pumping device to generate a pressure differential against the breast for the expression and collection of milk.

[0048] Exemplary hydraulic pumping devices are depicted in Figs. 2 and 3. Fig. 2 illustrates a pumping device 150 with a syringe 155 fluidly coupled to breast interface 160 by tube 165. Syringe 155 is coupled to tube 165 through a three-way valve 170. Breast interface 160 contains an exit port 175. The syringe 155 drives a fluid 180 contained within tube 165 against or away

from a flexible member contained within breast interface 160 to create the pressure differential necessary for milk expression from the breast.

[0049] Fig. 3 illustrates another embodiment of a pumping device 200. The actuatable assembly 205 includes an assembly housing 210, a driving element 215, radial seals 220, and a shaft 222. Driving element 215 is operatively coupled to a pendant unit, such as pendant unit 115, through shaft 222. The tube 225 contains a fluid 230 and is fluidly coupled to the actuatable assembly 205 and the breast interface 235. The breast interface 235 consists of an interface housing 240, a flexible membrane 245, a reservoir 250, a sealing element 255, an expression area 260, and a drain port 265. The sealing element 255 includes deformable portion 270. The drain port 265 is coupled to a collection vessel 275 and includes a flap valve 280.

[0050] Actuatable assembly 205 displaces fluid 230 contained within tube 225, which can be a flexible line. Fluid 230 occupies reservoir 250 within breast interface 235 and is coupled with flexible membrane 245. Flexible membrane 245 transmits vacuum pressure from fluid 230 to the deformable portion 270 of sealing element 255. When a breast is engaged into and fluidly sealed with breast interface 235 by sealing element 255, displacement of the actuatable element 215 produces substantial vacuum pressure against the breast through flexible membrane 245 and deformable portion 270, resulting in the expression of breast milk into expression area 260. The expressed milk drains through drain port 265 into collection vessel 275. Drain port 265 is configured with a flap valve 280 to provide passage of milk while maintaining vacuum pressure in expression area 260.

[0051] The fluid for the hydraulic pumping device can be any suitable fluid, such as an incompressible fluid. In many embodiments, the incompressible fluid can be water or oil. Alternatively, the fluid can be any suitable gas, such as air. Suitable incompressible fluids and gases for hydraulic systems are known to those of skill in the art.

[0052] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the hydraulic pumping device can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Actuation mechanism

[0053] Many actuation mechanisms known to those of skill in the art can be utilized for the actuatable assembly 205. Actuatable assembly 205 can be a piston assembly, a pump such as a diaphragm pump, or any other suitable actuation mechanism. The optimal configuration for actuatable assembly 205 can depend on a number of factors, such as: vacuum requirements; size, power, and other needs of the pumping device 200; and the properties of the fluid 230, such as viscosity, biocompatibility, and fluid life requirements.

[0054] Fig. 3 illustrates an exemplary embodiment in which actuatable assembly 205 is a piston assembly and driving element 215 is a piston. Actuatable assembly 205 includes radial seals 220, such as O-rings, sealing against assembly housing 210 to prevent undesired egress of fluid 230 and to enable driving of fluid 230.

[0055] Fig. 4 illustrates another exemplary embodiment of an actuatable assembly 300 including a pair of pistons 305.

[0056] In preferred embodiments, the actuatable assembly includes a driving element powered by a suitable driving mechanism, such as a driving mechanism residing in pendant unit 115. Many driving mechanisms are known to those of skill in the art. For instance, the driving element, such as driving element 215, may be actuated electromechanically by a motor, or manually by a suitable user-operated interface, such as a lever. Various drive modalities known to those of skill in the art can be used. In particular, implementation of the exemplary hydraulic pumping devices as described herein enables the use of suitable drive modalities such as direct drive and solenoids, owing to the reduced force requirements of hydraulic systems.

[0057] Referring now to the exemplary embodiment of Fig. 4, the pistons 305 include couplings 310 to a crankshaft 315. The crankshaft 315 is operatively coupled to a motor 320 through a belt drive 325. The crankshaft 315 drives the pair of pistons 305 with the same stroke timing in order to apply vacuum pressure against both breasts simultaneously, a feature desirable for increased milk production. Alternatively, the crankshaft 315 can drive the pair of pistons 305 with any suitable stroke timing, such as alternating or offset stroke cycles.

[0058] The driving mechanism can be powered by any suitable power source, such as a local battery or an AC adaptor. The driving mechanism can be controlled by hardware, such as onboard electronics located within pendant unit 115.

[0059] Fig. 5 illustrates an exemplary embodiment of an actuatable assembly 350 that includes releasable coupling 355. Preferably, actuatable assembly 350 is releasably coupled to a pendant unit 360 and the driving mechanism housed therein. The coupling can be a mechanical coupling or any suitable quick release mechanism known to those of skill in the art. The releasably coupled design allows for flexibility in the configuration and use of the pumping device. For instance, user comfort can be improved through the use of differently sized breast interfaces for compatibility with various breast sizes. Additionally, this feature enables a common pumping device to be used with interchangeable breast interfaces, thus reducing the risk of spreading pathogens. Furthermore, the releasable coupling enables easy replacement of individual parts of the pumping device.

[0060] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the actuation mechanism can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Flexible membrane

[0061] In many embodiments such as the embodiment depicted in Fig. 3, the flexible membrane 245 is located within breast interface 235 and disposed over at least portion thereof, forming reservoir 250 between the interface housing 240 and the flexible membrane 245. Preferably, the flexible membrane 245 deforms substantially when subject to the negative pressures created when the fluid 230 is displaced from reservoir 250 by actuatable assembly 205. The amount of deformation of the flexible membrane 245 can be controlled by many factors, (*e.g.*, wall thickness, durometer, surface area) and can be optimized based on the pumping device (*e.g.*, pump power, vacuum requirements).

[0062] Fig. 6 illustrates an exemplary flexible membrane 370 with a specified thickness and durometer.

[0063] Fig. 7 illustrates another embodiment of flexible membrane 375 with corrugated features 380 for increased surface area.

[0064] Suitable materials for the flexible membrane are known to those of skill in the art. In many embodiments, the flexible membrane can be made of a material designed to expand and contract when subject to pressures from the coupling fluid such as silicone, polyether block amides such as PEBAX, and polychloroprenes such as neoprene. Alternatively, the flexible membrane can be fabricated from a substantially rigid material, such as stainless steel, nitinol, high durometer polymer, or high durometer elastomer. In these embodiments, the rigid material would be designed with stress and/or strain distribution elements to enable the substantial deformation of the flexible membrane without surpassing the yield point of the material.

[0065] Figs. 8A and 8B illustrate preferred embodiments of a breast interface 400 in which an exit valve 405 is integrated into the flexible membrane 410 to control the flow of expressed milk through exit port 415. The exit valve 405 is opened to allow fluid flow when the flexible membrane 410 is relaxed, as shown in Fig. 8A, and is closed to prevent fluid flow when the flexible membrane 410 is deformed, as shown in Fig. 8B. The exit valve 405 enables substantial vacuum pressure to be present in expression area 420 during extraction, while allowing milk to drain during the rest phase of the pump stroke. While many conventional breast pump valves function on pressure differentials alone, the exit valve 405 can preferably be configured to also function on the mechanical movement of flexible membrane 410. Incorporation of an integrated exit valve 405 with mechanical functionality as described herein can improve the sealing of the breast interface 400 during vacuum creation. Furthermore, the implementation of an exit valve

integrally formed within the flexible membrane 410 such as exit valve 405 reduces the number of parts to be cleaned.

Radially Pleated Membrane

[0066] As discussed and best illustrated in Fig. 3, a drain port 265 and flap valve 280 may be coupled to the flexible membrane in order to allow milk to flow into collection vessel 275. Thus, as the flexible membrane is actuated and advanced and retracted, the drain portion 265 and flap valve 280 will typically also move forward and backward. This can cause unwanted stress on the junction between the drain port 265 and the membrane and the collection vessel 275 may also experience unwanted movement. Therefore, it may be desirable to isolate the drain port 265 and flap valve 280 from the membrane so that when the membrane is actuated, other portions of the device experience little or no unwanted motion.

[0067] Fig. 16 illustrates an exemplary embodiment of an expandable membrane that overcomes at least some of these challenges. The expandable membrane 1604 includes a plurality of expandable pleats 1606 that extend radially outward from the center of the expandable membrane. The pleats also have a longitudinal axis which runs substantially parallel to the longitudinal axis of the membrane, and the pleats extend around the circumference of the membrane. The spout or drain port 1602 is disposed along a bottom portion of the membrane in between pleats or in a section of the membrane having no pleats. Thus, actuation of the membrane will expand and contract the membrane radially outward and radially inward and axial motion along a longitudinal axis of the membrane will be minimized and substantially less than previous embodiments. Therefore, the spout or drain port 1602 will remain substantially stationary during actuation of membrane 1604, and the drain port will be substantially free of loads during expansion or contraction of the membrane.

[0068] Fig. 17 illustrates a cross-section of the breast interface which includes a flange 1708, the membrane 1604 with pleats 1606, output spout 1602 and housing 1712. The flange 1708 comprises a resilient material that allows the breast interface to be fluidly sealed against the breast. After collection, the expressed milk drains from output spout 1602 past valve 1716 into a collection vessel. A fluid reservoir 1710 is behind the membrane 1604 and fluid is pulled out to create a vacuum and pushed in to return to normal atmospheric pressure or to a positive pressure. The fluid is hydraulically displaced by movement of fluid in tubing 1714. Fluid movement in the tubing is actuated by any of the pumps or mechanisms disclosed in this specification. As previously discussed, a lower portion of the membrane does not substantially move in the axial direction, thereby holding the drain port or spout in a fixed axial position. This portion also may not move in the radial direction if there are no pleats in that section.

[0069] Fig. 18 is a close-up cross-sectional view of the interface between the membrane 1604 and the housing 1712. The expandable membrane may have enlarged edge 1806 that can be snapped or otherwise disposed in a channel in the housing 1712. An O-ring 1804 may be used to seal the housing against the flange 1708 (best seen in Fig. 17). Additionally the membrane may be pinched or compressively fixed between the housing and the flange using elastomeric pinch fixation 1808 to help hold and seal the membrane.

[0070] Fig. 19 is a cross-section of the expandable membrane 1604 with bellows or pleats 1606. Preferred embodiments include a negative grade 1902 that ensures that the expressed milk flows downhill into the drain port 1906. A housing seal 1904 may be positioned around the drain port to further secure the membrane and prevent leaks.

[0071] Figs. 20A and 20B illustrate another exemplary embodiment of an expandable membrane 2000 having radial pleats 2005. Fig. 20A is a view from the side of the membrane engaging the breast, while Fig. 20B is a view from of the side of the membrane engaging the breast interface housing. The expandable membrane 2000 comprises three expandable pleats 2005 extending radially outward from the center of the expandable membrane. The expandable pleats can be distributed evenly about the circumference of the membrane, for example at about 120 degrees away from one another as shown. The pleats comprise valleys 2015 that are configured to expand radially outwards when vacuum pressure is applied at the expandable membrane by an actuatable assembly operatively coupled to the breast interface. The valleys are further configured to contract radially inwards when the breast interface returns to normal atmospheric pressure, or when positive pressure is applied at the membrane. The pleats converge at the apex 2010, which can be configured to remain in a substantially fixed position during actuation of the actuatable assembly. The expandable membrane further comprises a drain port 2020, wherein milk expressed from the breast by the movement of the expandable membrane can drain through the drain port 2020 into a collection vessel. The drain port 2020 can be disposed at the base of the apex 2010, such that the drain port can remain in a substantially fixed position longitudinally and radially during actuation of the actuatable assembly.

[0072] Fig. 21 is a cross-section of a breast interface 2100 comprising the expandable membrane 2000 illustrated in Figs. 20A-20B. The breast interface 2100 comprises a housing 2105, within which the expandable membrane 2000 is disposed. The breast interface further comprises a flange 2110 configured to engage and fluidly seal against the breast, the flange often comprising a resilient material that can conform to the breast. The housing 2105 comprises a fluid reservoir 2115 disposed between the housing and the expandable membrane, wherein fluid can be added to or removed from the fluid reservoir in order to move the expandable membrane

and thereby generate pressure at the breast interface. The housing further comprises an outlet 2120 that can be coupled to a tube (not shown), wherein the tube is removably and operatively coupled to an actuatable assembly such as any of the pumps or actuatable mechanisms disclosed herein. The fluid in the fluid reservoir 2115 can be hydraulically displaced by movement of the fluid in the tubing when the actuatable assembly coupled to the tubing is actuated. When fluid is removed from the fluid reservoir, a vacuum is generated at the breast interface, causing the pleats of the expandable membrane 2000 to expand radially outwards such that the membrane moves in a direction away from the breast, and thereby apply vacuum pressure at the breast. The vacuum pressure and the movement of the membrane can cause breast tissue to be pulled into the membrane, and milk to be expressed from the breast. When fluid is added to the fluid reservoir, the pleats contract radially inwards such that the expandable membrane moves in a direction towards the breast. The contraction of the pleats can return the breast interface to normal atmospheric pressure and allow the expressed milk to drain through the drain port 2020, or apply positive pressure at the breast to force the expressed milk out through the drain port. Upon release of the vacuum pressure, the breast tissue that had been pulled into the membrane can be released and/or compressed, thereby facilitating the expression of milk from the breast.

Actuatable Assembly Interface

[0073] An actuatable assembly for a breast milk expression device as described herein can be configured to removably couple to a breast interface assembly, so as to keep the fluid carried in the transmission lines (such as the tubing described herein) and in the breast interface physically separate from the actuatable assembly. Such a physical separation between the actuatable assembly and the fluid in the breast interface can help prevent cross-contamination between the breast interface and the actuatable assembly. Further, the easy separation of various components of the expression device can facilitate the storage and maintenance of the device.

[0074] Fig. 22 is a cross-section of an exemplary embodiment of an expression device 2200 comprising an actuatable assembly interface 2300. The actuatable assembly interface 2300 can removably couple to the actuatable assembly 2205, so as to operatively couple the actuatable assembly to the breast interface 2210, while keeping the mechanisms of the actuatable assembly separate from the fluid 2220 in the tubing 2215 and in the breast interface 2210. When the actuatable assembly interface 2300 is coupled to the actuatable assembly 2205, the actuation of the actuatable assembly can cause the fluid 2220 to be pulled out of or pushed into the fluid reservoir of the breast interface, thereby causing an expandable membrane 2212 of the breast interface to apply pressure to the breast engaged into the breast interface.

[0075] Fig. 23 is a cross-section of an actuatable assembly 2205 coupled to an actuatable assembly interface 2300, as illustrated in Fig. 22. The actutable assembly interface 2300

comprises an actuatable assembly interface housing 2305 and an actuatable assembly interface membrane 2310 coupled thereto. The interface housing is configured to couple to tubing 2215, which is fluidly coupled to the fluid reservoir in the breast interface housing. The tubing 2215 is operatively coupled to the interface membrane 2310, such that movement of the interface membrane causes movement of the fluid 2220 carried by the tubing. The actuatable assembly 2205 comprises an actuatable assembly housing 2225 and an actuatable assembly membrane 2230 coupled thereto. The actuatable assembly membrane is operatively coupled to the driver mechanism 2235 of the actuatable assembly, such that actuation of the driver mechanism causes movement of the membrane 2230. The driver mechanism may comprise any pump mechanisms as described herein. For example, as shown in Fig. 23, the driver mechanism may comprise a piston assembly shown in Fig. 23, the piston configured to move in response to movement of the lead screw 2240 driven by a motor.

[0076] The actuatable assembly housing is configured to removably couple to the interface housing 2300, for example via one or more magnets 2315 as shown. The magnets may be embedded in the interface housing, the actuatable assembly housing, or both; accordingly, one or more of the interface housing and the actuatable assembly housing may comprise a metal material configured to be attracted to the magnets. The acutatable assembly may further comprise an alignment mechanism 2245, such as pins or screws configured to engage a portion of the actuatable assembly interface, in order to ensure correct alignment of the actuatable assembly with the actuatable assembly interface.

[0077] When the actuatable assembly and the actuatable assembly interface are coupled together, the actuatable assembly membrane 2230 and the interface membrane 2310 are brought into communication with one another. As the motor of the actuatable assembly is actuated, the driver mechanism 2235 pushes the membrane 2230 upward toward the interface membrane 2310, causing at least a portion of the air 2250 trapped between the two membranes to be pushed out via a one-way valve 2255 coupled to either the actuatable assembly or the interface. In order to ensure that the actuatable assembly interface does not separate from the actuatable assembly during coupling of the two members, the magnets 2315 may be configured to have a magnetic force that is greater than the exit force of air from the one-way valve.

[0078] Once the trapped air is pushed out through the valve outlet 2260, the interface membrane 2310 becomes operatively coupled to the actuatable assembly membrane 2230, such the interface membrane will follow the cyclical motions of the actuatable assembly membrane as the actuatable assembly is actuated. Movement of the interface membrane 2310 will cause corresponding movement of the fluid 2220 in the tubing 2215, causing fluid to be removed from or added to the fluid reservoir in the breast interface. In order to ensure that the actuatable

assembly interface does not separate from the actuatable assembly during actuation of the actuatable assembly, the magnets 2315 may be configured to have a magnetic force that is greater than the pull force of the actuatable assembly.

[0079] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the expandable membrane can be combined or substituted with components and features of any of the embodiments of the present invention as described herein. Additionally, one of skill in the art will appreciate that the expansion for either the radially expandable or axially expandable embodiments may also be in the form of deflection of material or stretching of material depending on geometry & construction.

Milk collection and quantification system

[0080] With reference to Fig. 3, expressed milk drains through exit port 265 in flexible membrane 245 into a collection vessel 275. Collection vessel 275 can be any suitable container, such as a bottle or a bag. In many embodiments, collection vessel 275 is removably coupled to flexible membrane 245. Collection vessel 275 can be coupled directly or remotely via any suitable device such as extension tubing.

[0081] In many instances, it can be desirable to track various data related to milk expression and collection, such as the amount of milk production. Currently, the tracking of milk production is commonly accomplished by manual measurements and record-keeping. Exemplary embodiments of the device described herein may provide digital-based means to automatically measure and track milk production for improved convenience, efficiency, and accuracy.

[0082] Figs. 9A and 9B illustrates exemplary embodiments of a breast interface 450 with one or more integrated sensors 455. Sensors 455 are preferably located in flap valve 460, but may also be located in exit valve 465, or any other suitable location for monitoring fluid flow. In a preferred embodiment, at least one sensor 455 is integrated into a valve that is opened by fluid flow and detects the length of time that the valve is opened. The sensor signal can be interrogated to quantify the fluid flow. Suitable sensors are known to those of skill in the art, such as accelerometers, Hall effect sensors, and photodiode/LED sensors. The breast interface can include a single sensor or multiple sensors to quantify milk production.

[0083] Fig. 10 illustrates an exemplary embodiment of pendant unit 500 in which milk expression data is shown on a display screen 505. In many embodiments, the pendant unit 500 collects, processes, stores, and displays data related to milk expression. Preferably, the pendant unit 500 can transmit the data to a second device, such as a mobile phone 510.

[0084] Fig. 11 illustrates data transmission 515 between pendant unit 500 and a mobile phone 510. Suitable methods for communication and data transmission between devices are known to those of skill in the art, such as Bluetooth or near field communication.

[0085] In exemplary embodiments, the pendant unit 500 communicates with a mobile phone 510 to transmit milk expression data, such as expression volume, duration, and date. The mobile phone 510 includes a mobile application to collect and aggregate the expression data and display it in an interactive format. Preferably, the mobile application includes additional features that allow the user to overlay information such as lifestyle choices, diet, and strategies for increasing milk production, in order to facilitate the comparison of such information with milk production statistics. Additionally, the pendant unit 500 can send information about the times of pump usage to the mobile phone 510 so that the mobile application can identify when pumping has occurred and set reminders at desired pumping times. Such reminders can help avoid missed pumping sessions, and thus reduce the incidence of associated complications such as mastitis.

[0086] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the milk collection and quantification system can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Mechanical pumping device

[0087] Fig. 12 illustrates an alternative embodiment of a breast interface 600 in which a mechanical deformable member 605 can be used in place of a flexible membrane. The mechanical deformable member 605 can be constructed from similar techniques as those used for the flexible membrane as described herein. The mechanical deformable member 605 is coupled to a tensile element 610. In some instances, tensile element 610 is disposed within an axial load absorbing member 615. The axial load absorbing member 615 is disposed within tube 620. Preferably, tensile element 610 is concentrically disposed within axial load absorbing member 615 and axial load absorbing member 615 is concentrically disposed within tube 620. Alternative arrangements of tensile element 610, axial load absorbing member 615, and tube 620 can also be used.

[0088] Fig. 13 illustrates the tensile element 610 coupled to driving element 625 of an actuatable assembly 630 within an assembly housing 635. Driving element 625 is operatively coupled to a driving mechanism, such as a driving mechanism housed within a pendant unit, through shaft 640. Axial load absorbing member 615 within tube 620 is fixedly coupled to the assembly housing 635. Displacement of the driving element 625 transmits tensile force through tensile element 610 to the mechanical deforming member 605 to create vacuum pressure against the breast.

[0089] The tensile element 610 can be any suitable device, such as a wire, coil, or rope, and can be made from any suitable material, such as metals, polymers, or elastomers. Axial load absorbing member 615 can be made from any suitable axially stiff materials, such as metals or polymers, and can be configured into any suitable axially stiff geometry, such as a tube or coil.

[0090] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the mechanical pumping device can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Experimental data

[0091] Figs. 14 and 15 illustrate experimental pumping data obtained from a commercial breast pump device and an exemplary embodiment of the present invention. The exemplary embodiment utilized an incompressible fluid for pumping and had a maximum hydraulic fluid volume of 4 cc, while the commercial device utilized air for pumping and had a maximum volume of 114 cc.

[0092] Fig. 14 illustrates a graph of the pump performance as quantified by vacuum pressure generated per run. For the exemplary embodiment, pressure measurements were taken for 1 cc, 2 cc, 3 cc, and 4 cc of fluid volume displaced by the pump, with the run number corresponding to the volume in cc. For the commercial device, measurements were taken with the pump set to one of seven equally incremented positions along the vacuum adjustment gauge representing 46 cc, 57 cc, 68 cc, 80 cc, 91 cc, 103 cc, and 114 cc of fluid volume displaced by the pump, respectively, with the run number corresponding to the position number. Curve 700 corresponds to the exemplary embodiment and curve 705 corresponds to the commercial device. The exemplary embodiment generated higher levels of vacuum pressure per displacement volume compared to the commercial device, with maximum vacuum pressures of -240.5 mmHg and -177.9 mmHg, respectively.

[0093] Fig. 15 illustrates a graph of the pump efficiency as measured by the maximum vacuum pressure per maximum volume of fluid displaced, with bar 710 corresponding to the exemplary embodiment and bar 715 corresponding to the commercial device. The exemplary embodiment demonstrated a 42-fold increase in pumping efficiency compared to the commercial device, with efficiencies of -71.1 mmHg/cc and -1.7 mmHg/cc, respectively.

[0094] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that

methods and structures within the scope of these claims and their equivalents be covered thereby.

CLAIMS

WHAT IS CLAIMED IS:

1. A device for expression of milk from a breast, said device comprising:

an actuatable assembly; and

a breast interface sized to engage a breast and fluidly seal thereagainst, the breast interface having an expandable membrane disposed within at least a portion thereof, wherein the expandable membrane moves in response to actuation of the actuatable assembly thereby applying vacuum pressure at the breast to express milk therefrom;

wherein the expandable membrane comprises a plurality of expandable pleats, each of the plurality of expandable pleats extending radially outward from a center of the expandable membrane.

2. The device of claim 1, wherein the plurality of expandable pleats is configured to expand radially outward or contract radially inward during acutation of the actuatable assembly.

3. A device as in any one of claims 1 or 2, further comprising a drain port disposed along a bottom portion of the expandable membrane, between pleats or in a section of the expandable membrane having no pleats.

4. The device of claim 3, wherein the drain port is configured to remain in a substantially fixed longitudinal position during actuation of the actuatable assembly.

5. A device as in any one of claims 3 or 4, where the drain port is disposed in a section of the expandable member having no pleats and is configured to remain in a substantially fixed radial position during actuation of the actuation assembly.

6. A device as in any one of claims 3, 4, or 5, wherein the expandable membrane comprises a negative grade along a bottom portion thereof, configured to allow expressed milk to flow downhill into the drain port.

7. A device as in any one of claims 3, 4, 5, or 6, wherein the breast interface further comprises a housing and a sealing member, the sealing member disposed around the drain port to secure the expandable membrane to the housing of the breast interface.

8. A device as in any one of the preceding claims, wherein the breast interface further comprises a fluid reservoir operatively coupled to the actuatable assembly, and wherein actuation of the actuatable assembly removes fluid from the fluid reservoir thereby expanding

the expandable membrane, or wherein the actuation adds fluid to the fluid reservoir thereby contracting the expandable membrane.

9. The device of claim 8, wherein the actuatable assembly is removably coupled to an actuatable assembly interface, the actuatable assembly interface configured to operatively couple the actuatable assembly to the breast interface while maintaining physical separation between the actuatable assembly and the fluid.

10. The device of claim 9, wherein the actuatable assembly interface comprises an interface membrane fluidly coupled to the fluid reservoir via an elongate tube, and wherein the interface membrane is configured to operatively couple to an actuatable assembly membrane of the actuatable assembly, such that movement of the actuatable assembly membrane, affected by the actuation of the actuatable assembly, causes corresponding movement of the interface membrane, thereby causing movement of the fluid into or out of the fluid reservoir.

11. A device as in any one of claims 9 or 10, wherein the actuatable assembly comprises a one-way valve configured to allow air trapped between the actuatable assembly and the actuatable assembly interface to exit during actuation of the actuatable assembly.

12. A device as in any one of claims 9, 10, or 11, wherein the actuatable assembly comprises an alignment mechanism configured to couple the actuatable assembly with the actuatable assembly interface in a substantially fixed position and orientation.

13. A device as in any one of claims 9, 10, 11, or 12, wherein the actuatable assembly is removably coupled to the actuatable assembly interface via one or more magnets.

14. The device of claim 13, wherein the one or more magnets are configured to have a magnetic force greater than: (1) an exit force of air exiting a space between the actuatable assembly and the actuatable assembly interface via a one-way valve, and (2) a pull force generated by actuation of the actuatable assembly.

15. A device as in any one of the preceding claims, wherein the breast interface further comprises a housing, and wherein the expandable membrane comprises an enlarged edge configured to be disposed in a channel of the housing so as to securely couple the expandable membrane to the housing.

16. A device as in any one of the preceding claims, wherein the breast interface further comprises a flange comprising a resilient material that allows the breast interface to

fluidly seal against the breast, and wherein the breast interface further comprises a sealing member to seal the housing against the flange.

17. A device as in any one of the preceding claims, wherein the expandable membrane is compressively fixed between the housing and the flange via an elastomeric pinch fixation to hold and seal the expandable membrane.

18. A device as in any one of the preceding claims, wherein the plurality of expandable pleats is configured to converge at an apex, and wherein the apex is configured to remain in a substantially fixed position during actuation of the actuatable assembly.

19. A method of expressing milk from a breast, said method comprising:

engaging and fluidly sealing a breast interface with the breast, wherein the breast interface comprises an expandable membrane having a plurality of expandable pleats;

actuating an actuatable assembly operatively coupled to the expandable membrane, thereby causing the plurality of expandable pleats to expand radially outward and apply vacuum pressure at the breast; and

expressing milk from the breast.

20. The method of claim 19, wherein actuation of the actuatable assembly further causes the plurality of expandable pleats to contract radially inward, thereby returning the breast interface to atmospheric pressure or applying positive pressure at the breast interface, causing the expressed milk to drain into a collection vessel fluidly coupled to the breast interface.

21. The method of claim 20, wherein the plurality of expandable pleats apply a compressive force to a portion of the breast engaged with the plurality of expandable pleats, thereby facilitating expression of milk from the breast.

22. A method as in any one of claims 19, 20, or 21, wherein the breast interface further comprises a drain port disposed along a bottom portion of the expandable membrane, and wherein the drain port remains in a substantially fixed longitudinal position during actuation of the actuatable assembly.

23. The method of claim 22, further comprising collecting the expressed milk into a collection vessel fluidly coupled to the breast interface via the drain port, wherein the expandable membrane comprises a negative grade along a bottom portion of thereof to allow the expressed milk to flow downhill into the drain port.

24. A method as in any one of claims 19, 20, 21, 22, or 23, wherein the breast interface further comprises a fluid reservoir fluidly coupled with the actuatable assembly, and wherein actuation of the actuatable assembly removes fluid from the fluid reservoir thereby expanding the expandable membrane, or wherein the actuation adds fluid to the fluid reservoir thereby contracting the expandable membrane.

25. A method as in any one of claims 19, 20, 21, 22, 23, or 24, further comprising coupling the actuatable assembly to an actuatable assembly interface operatively coupled to the breast interface, thereby operatively coupling the actuatable assembly to the breast interface.

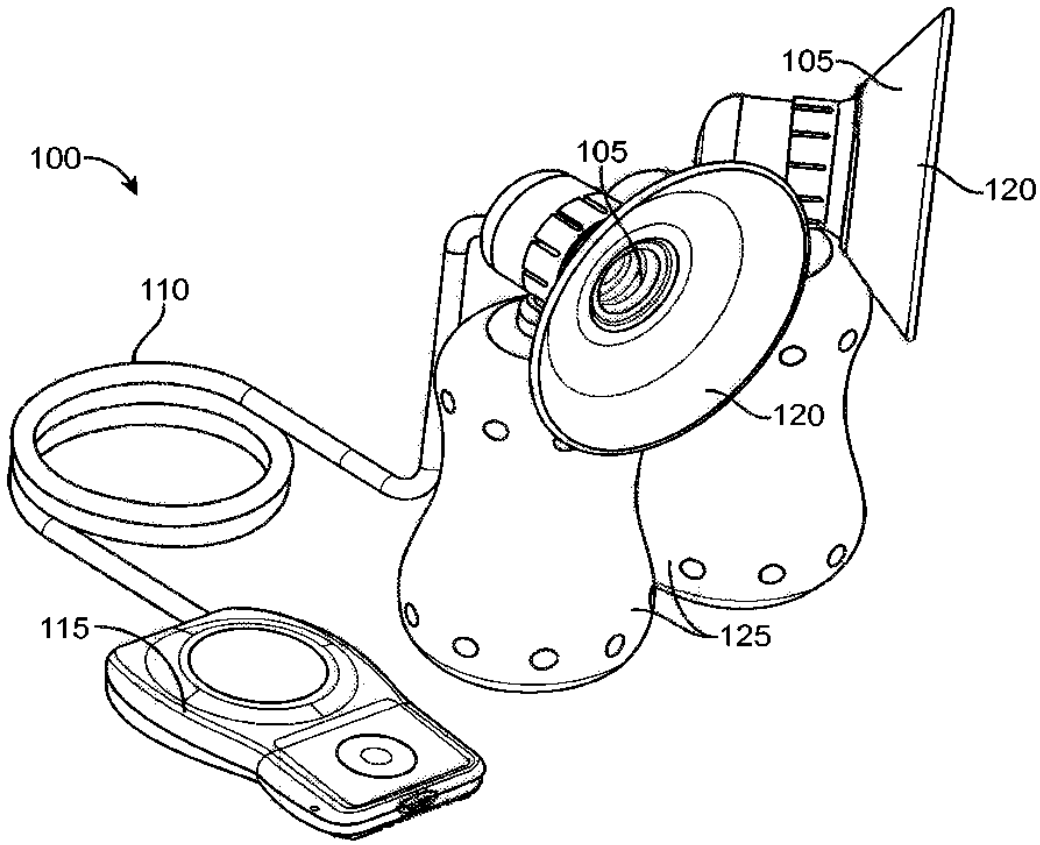


FIG. 1

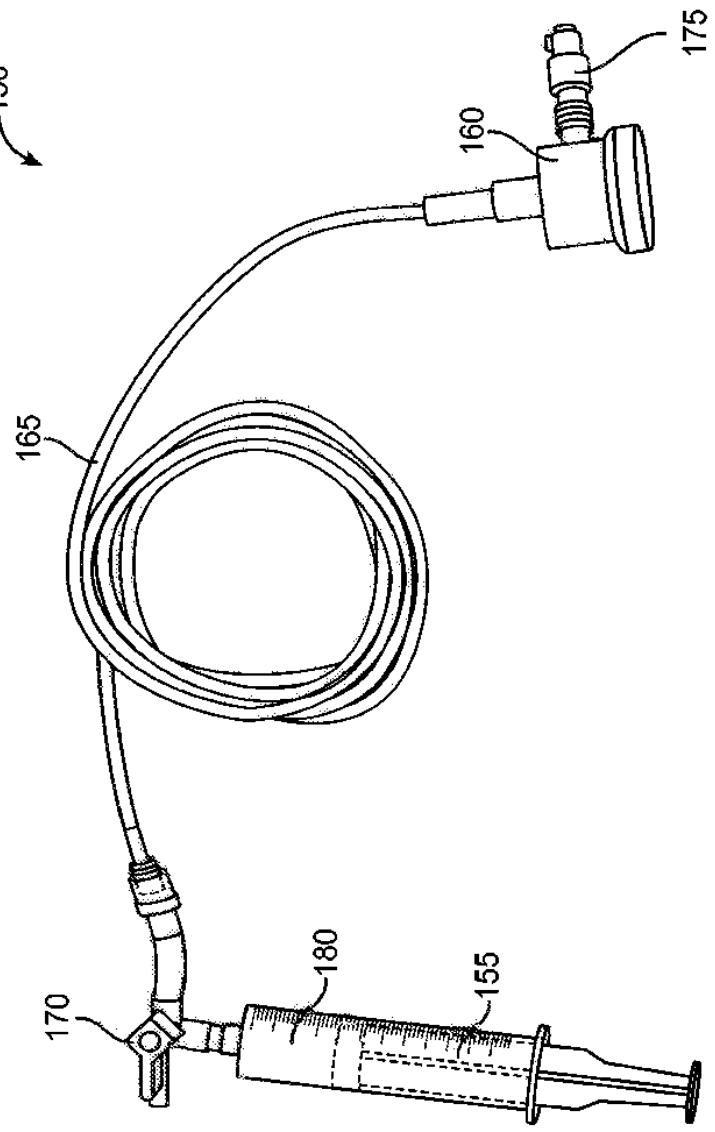


FIG. 2

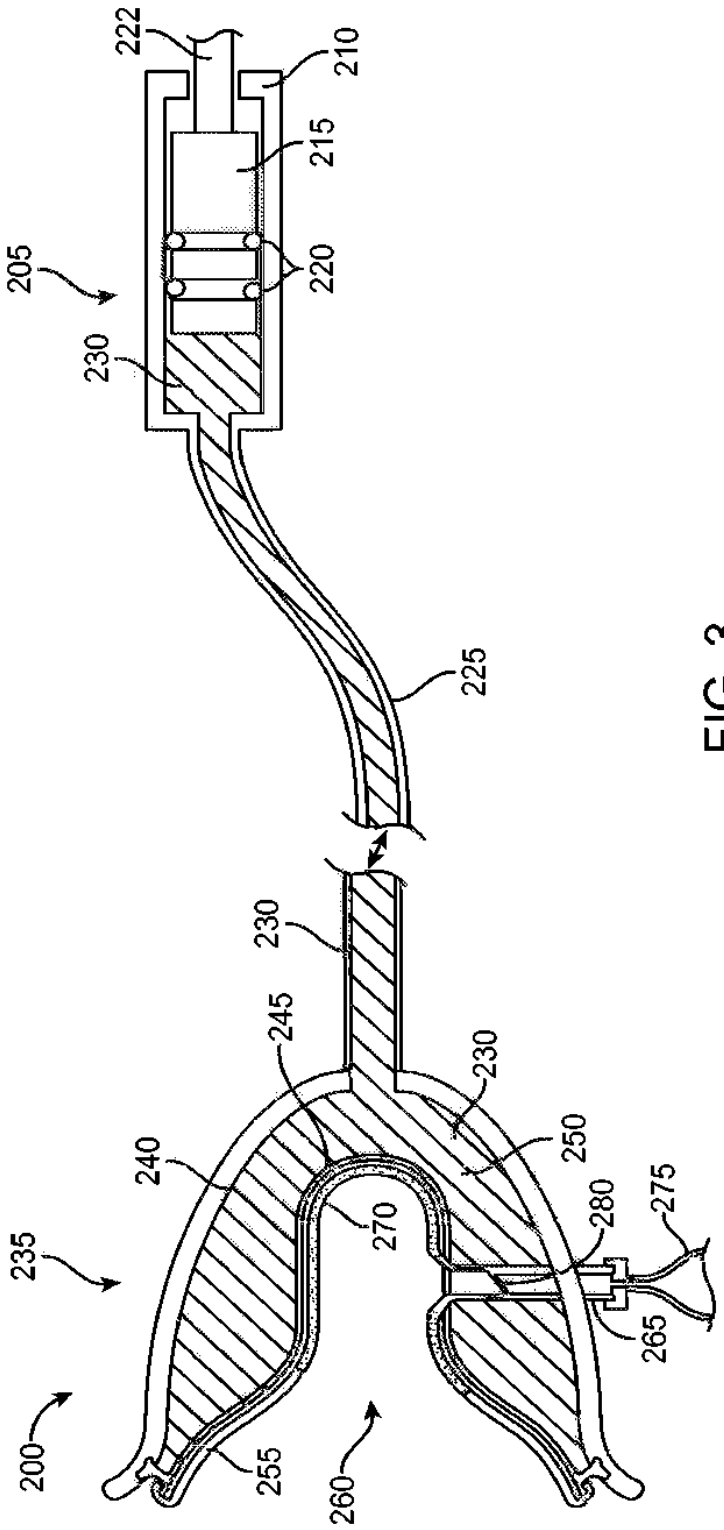

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FIG. 3

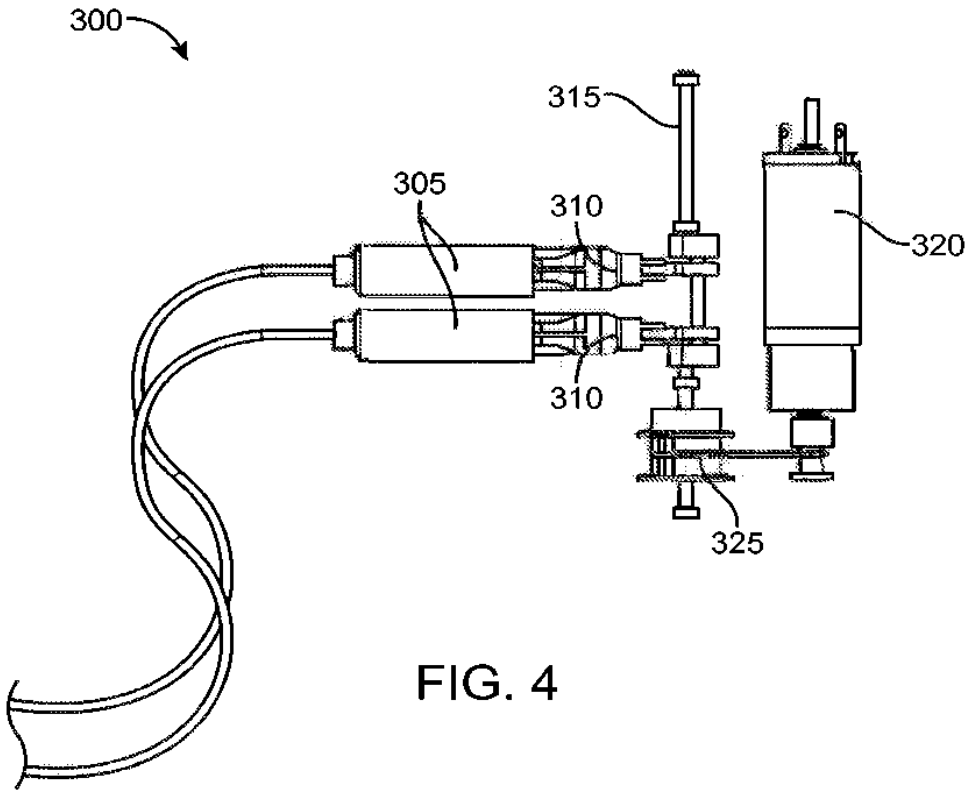


FIG. 4

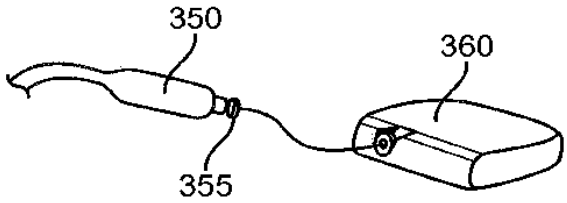


FIG. 5A

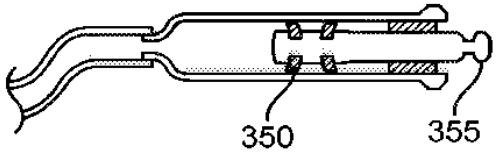


FIG. 5B

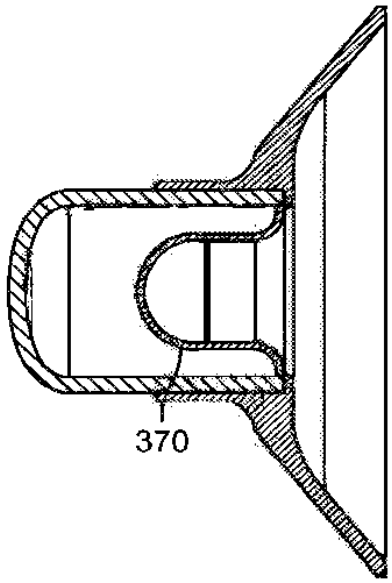


FIG. 6

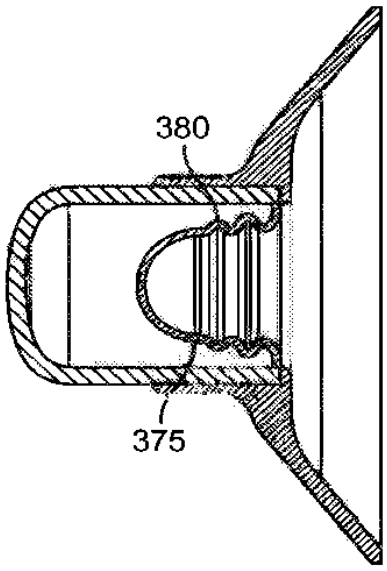


FIG. 7

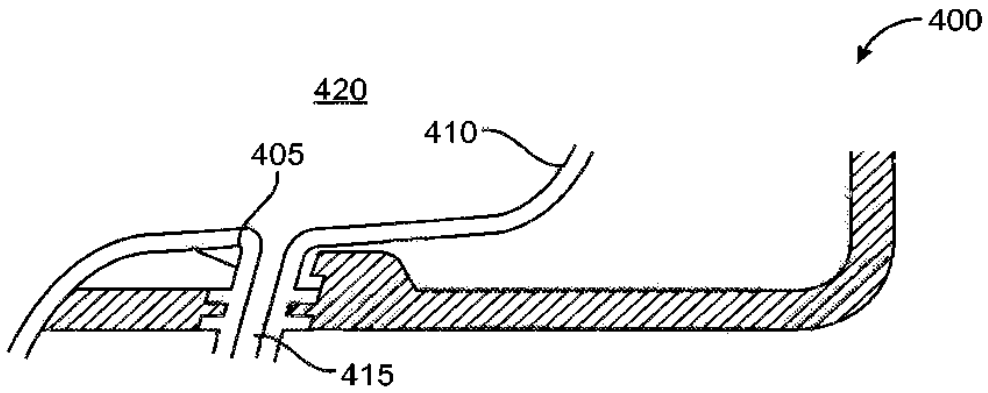


FIG. 8A

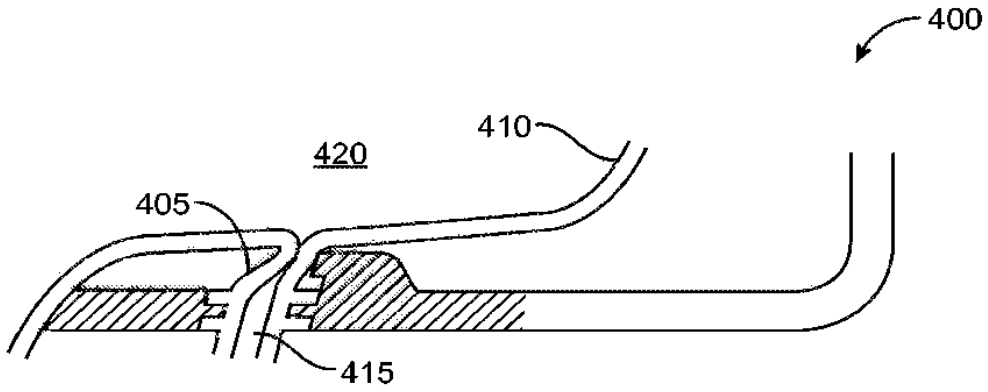


FIG. 8B

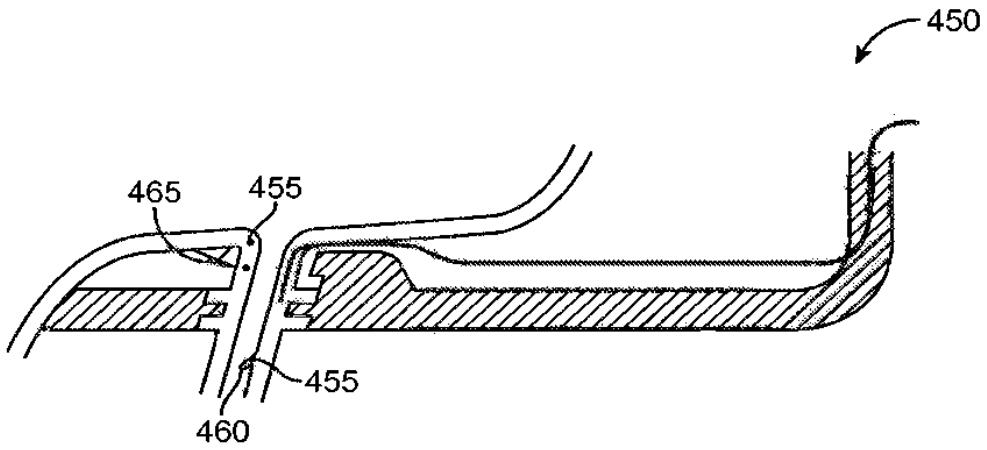


FIG. 9A

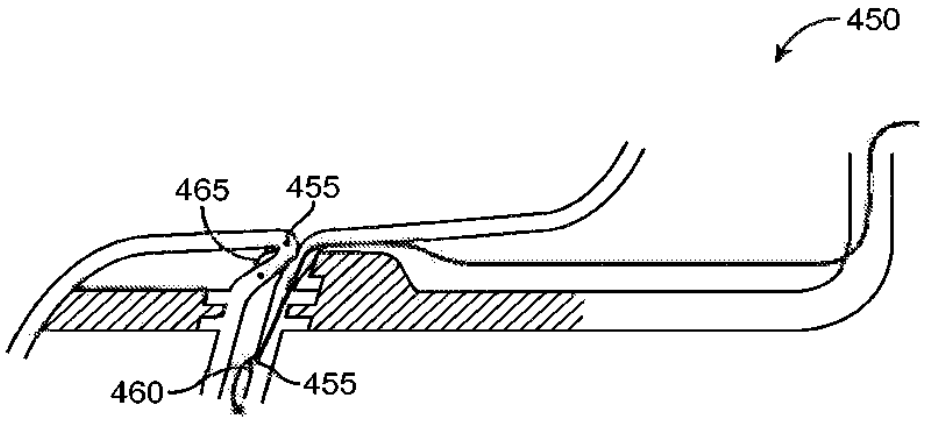


FIG. 9B

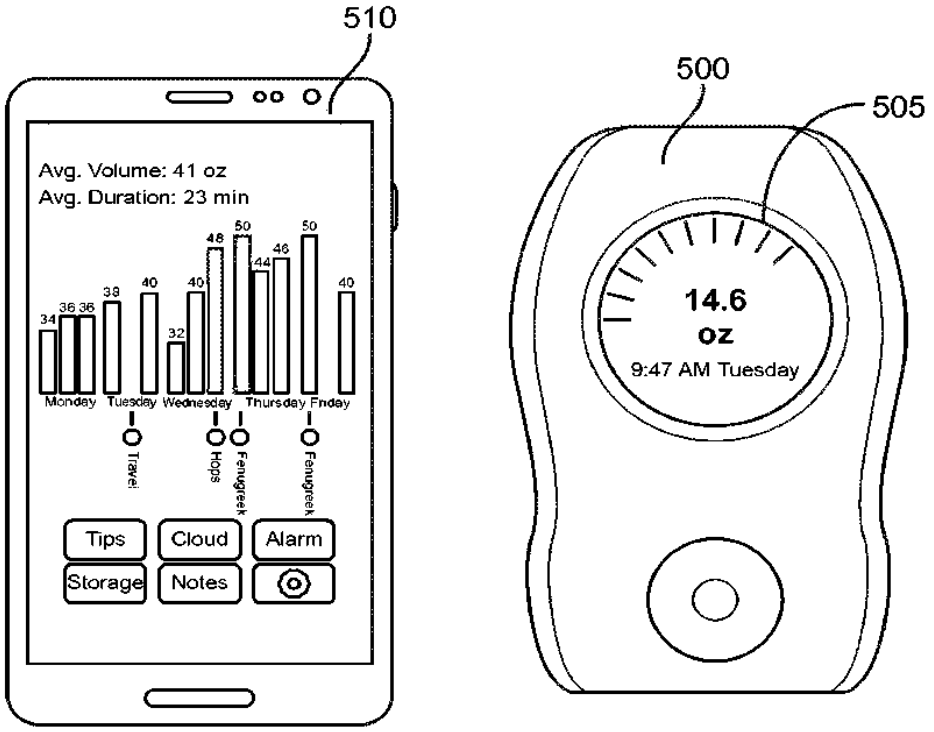

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500
505
Avg. Volume: 41 oz
Avg. Duration: 23 min
34
36
36
38
40
32
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50
44
46
50
40
Monday
Tuesday
Wednesday
Thursday
Friday
Travel
Hops
Fenugreek
Fenugreek
Tips
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Alarm
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Notes
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9:47 AM Tuesday

FIG. 10

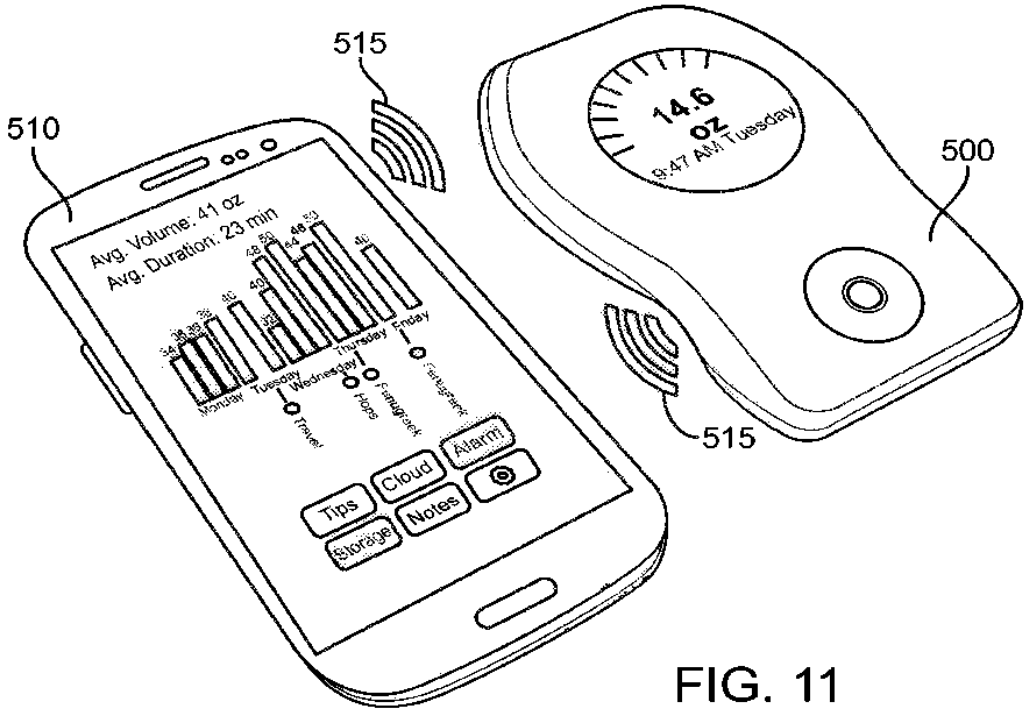

515
510
500
515
Avg. Volume: 41 oz
Avg. Duration: 23 min
Monday
Tuesday
Wednesday
Thursday
Friday
Travel
Hops
Fenugreek
Fenugreek
Tips
Cloud
Alarm
Storage
Notes
14.6
oz
9:47 AM Tuesday

FIG. 11

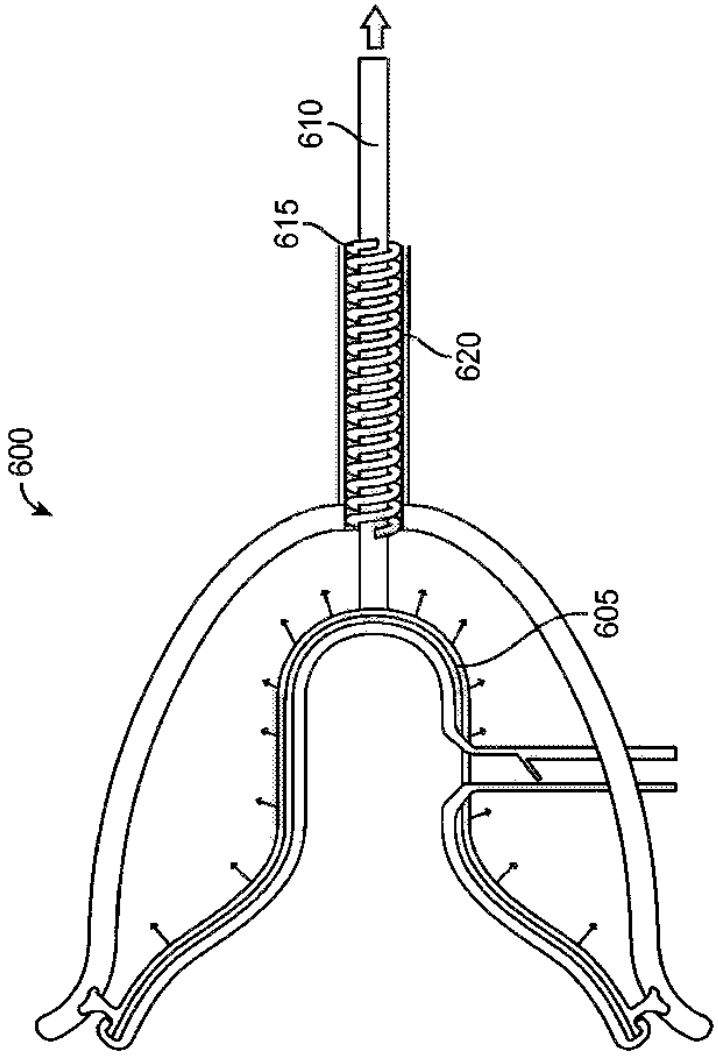


FIG. 12

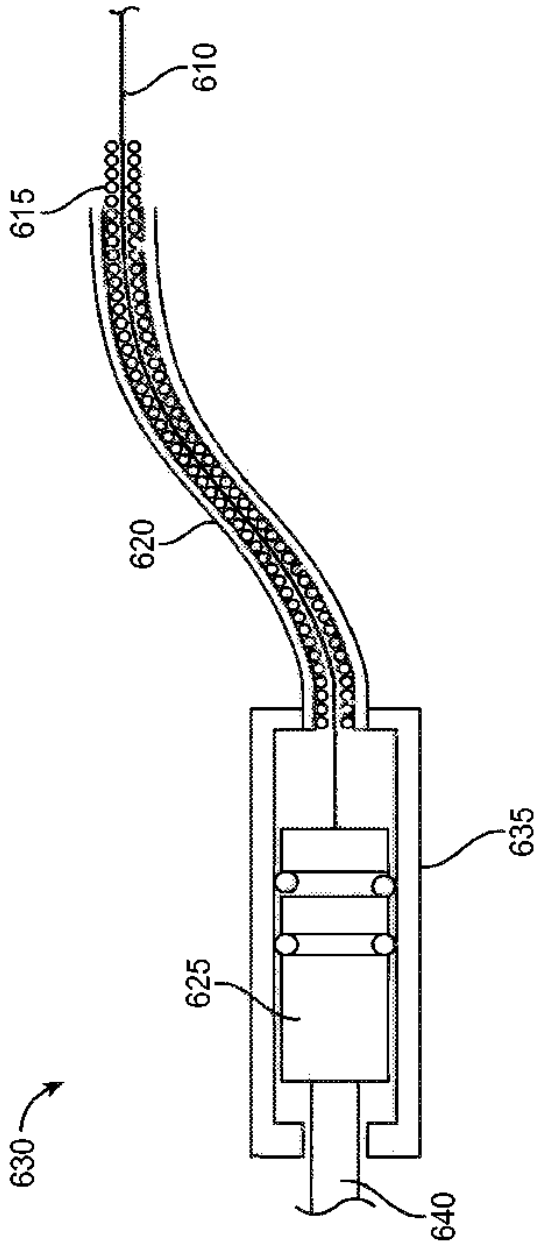


FIG. 13

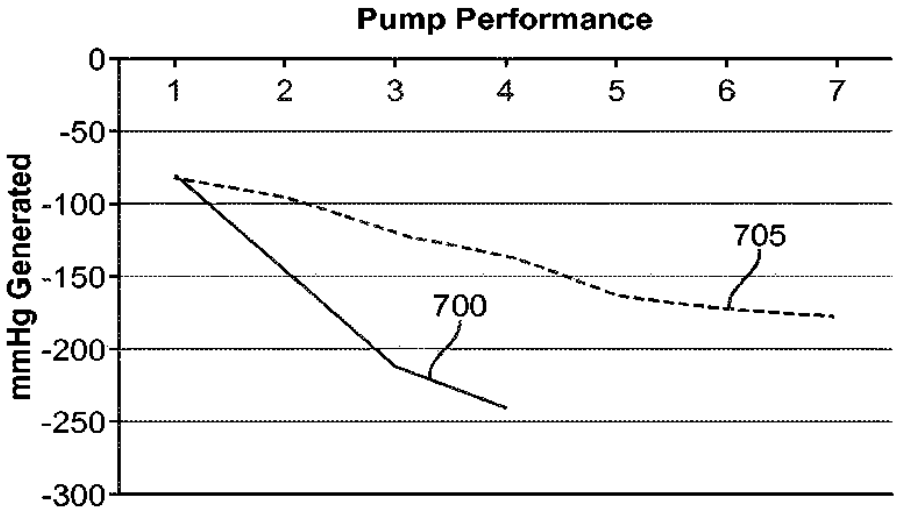

Pump Performance
0
-50
-100
-150
-200
-250
-300
mmHg Generated
1
2
3
4
5
6
7
705
700

FIG. 14

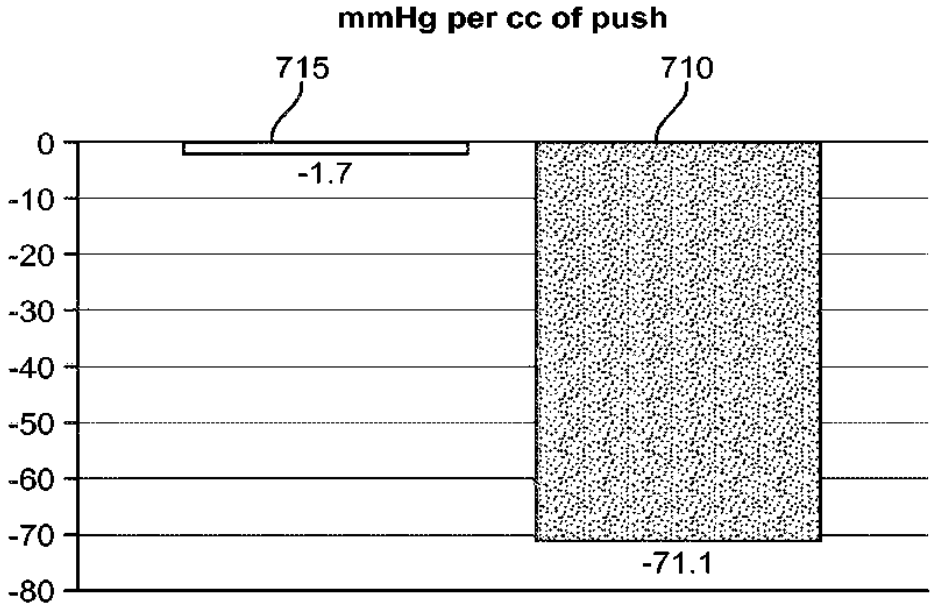


FIG. 15

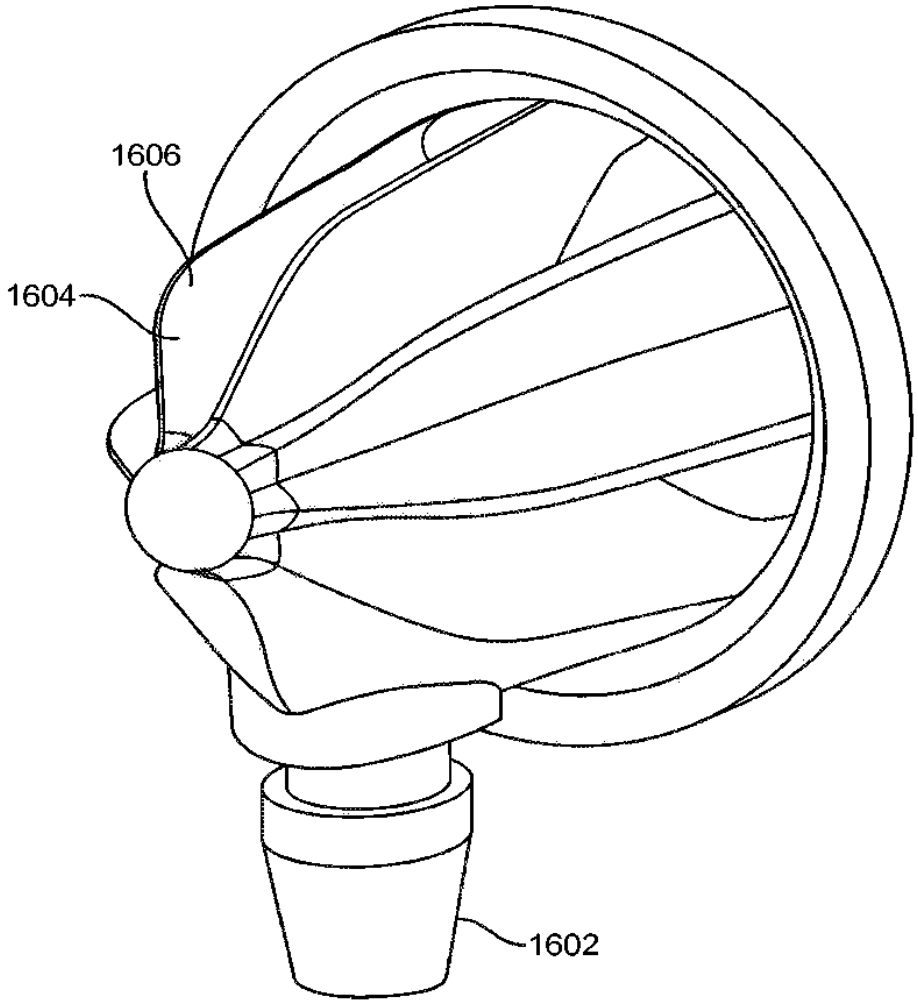


FIG. 16

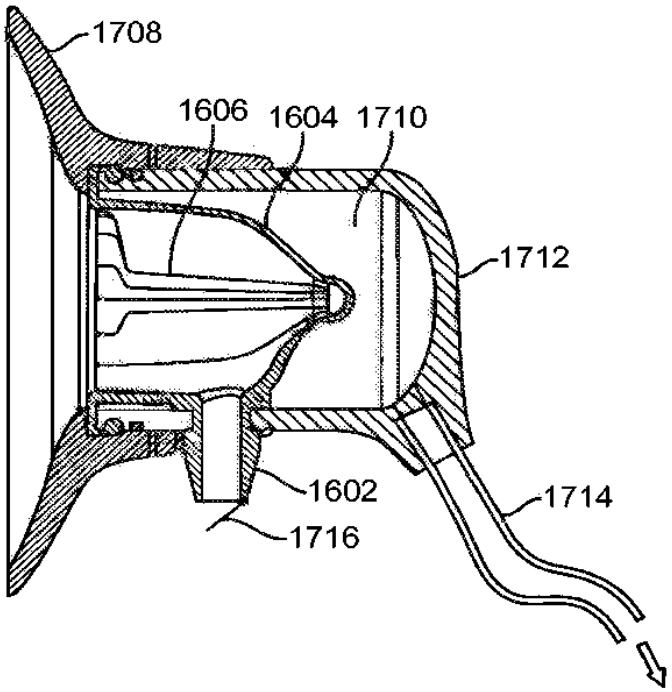

1708
1606
1604
1710
1712
1602
1714
1716

FIG. 17

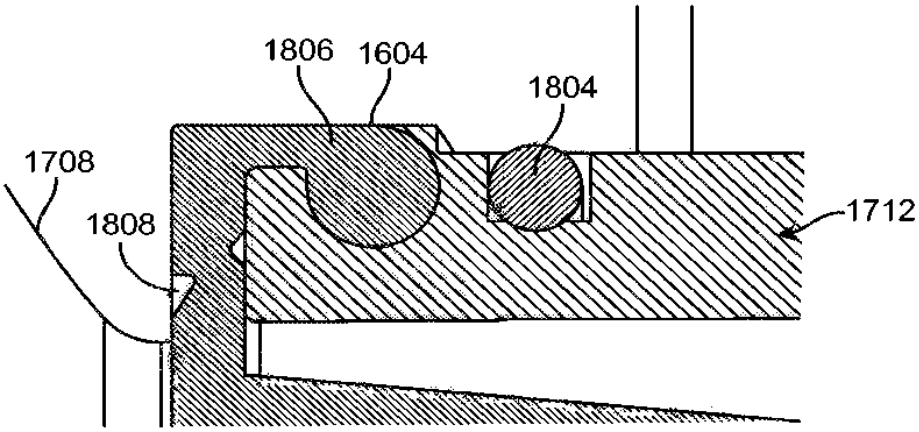

1806
1604
1804
1708
1808
1712

FIG. 18

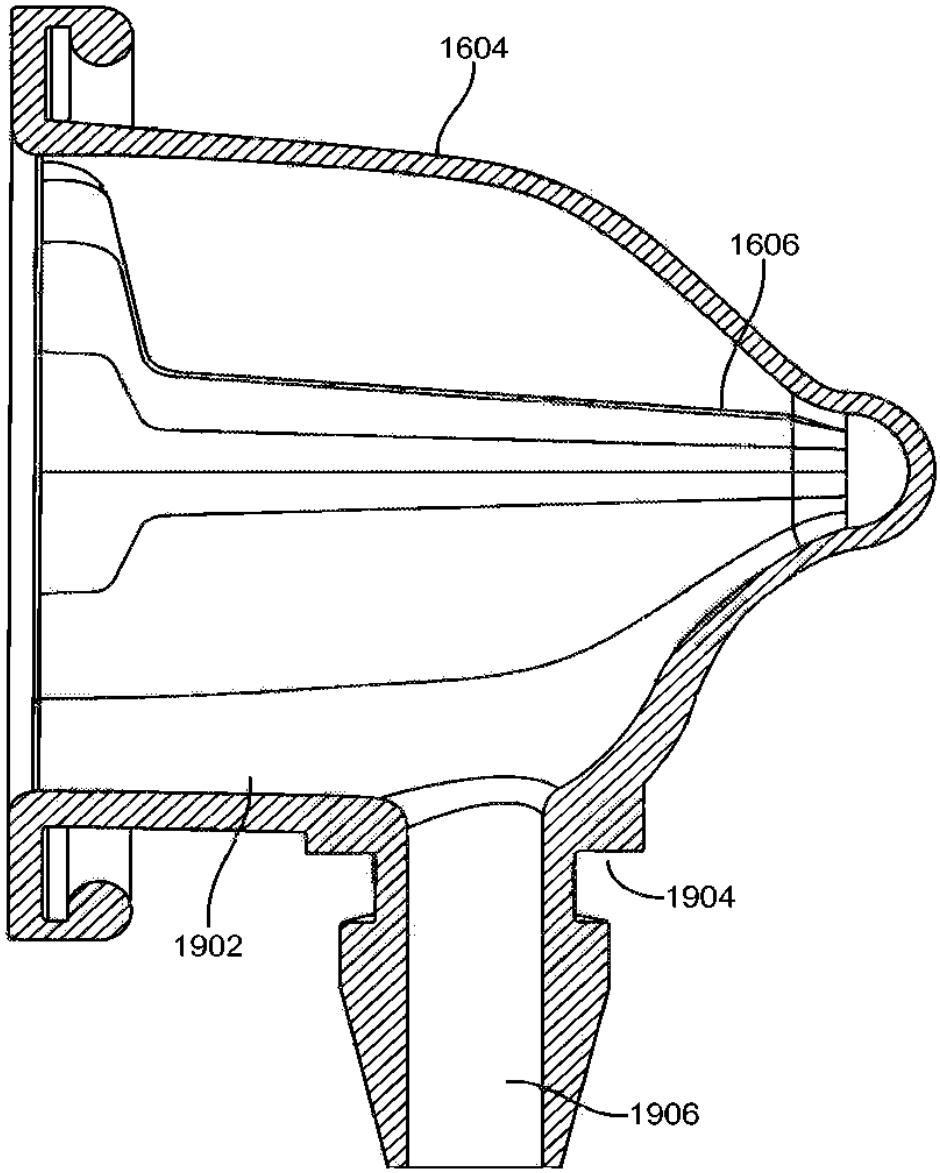


FIG. 19

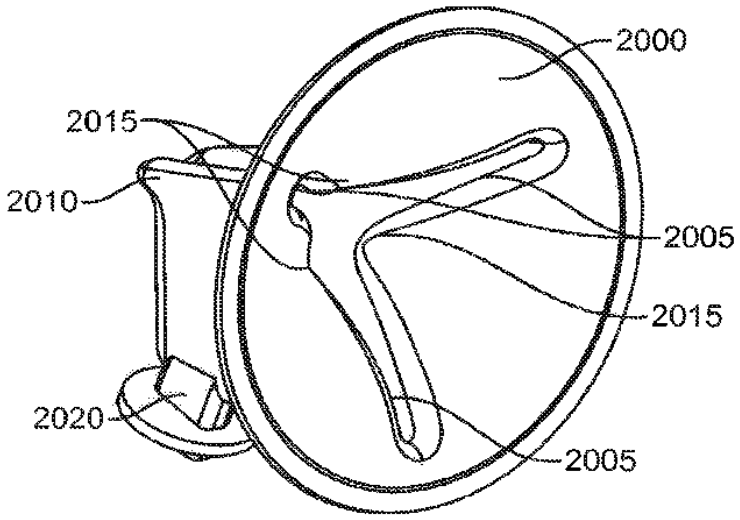


FIG. 20A

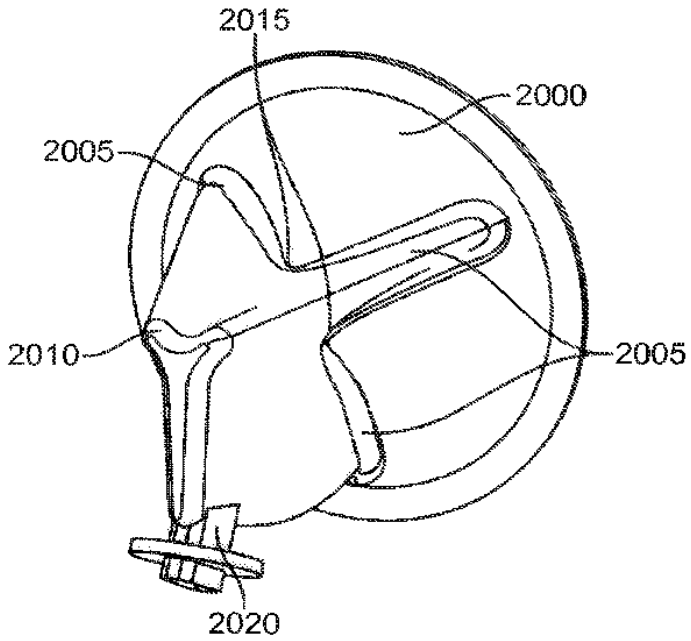


FIG. 20B

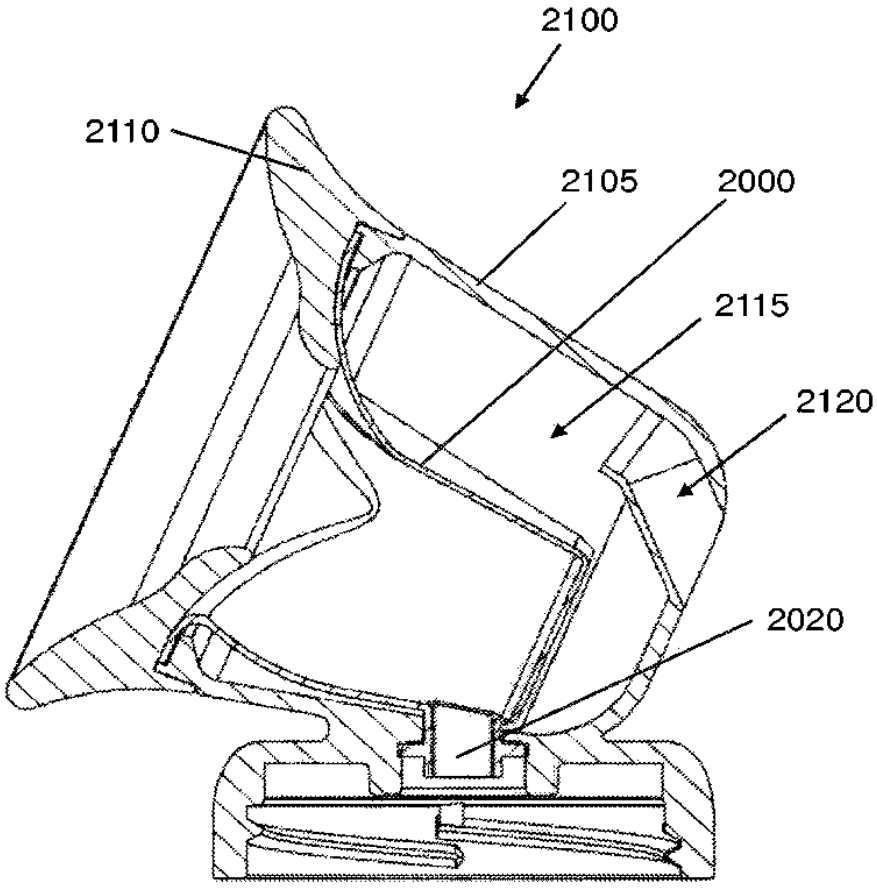


FIG. 21

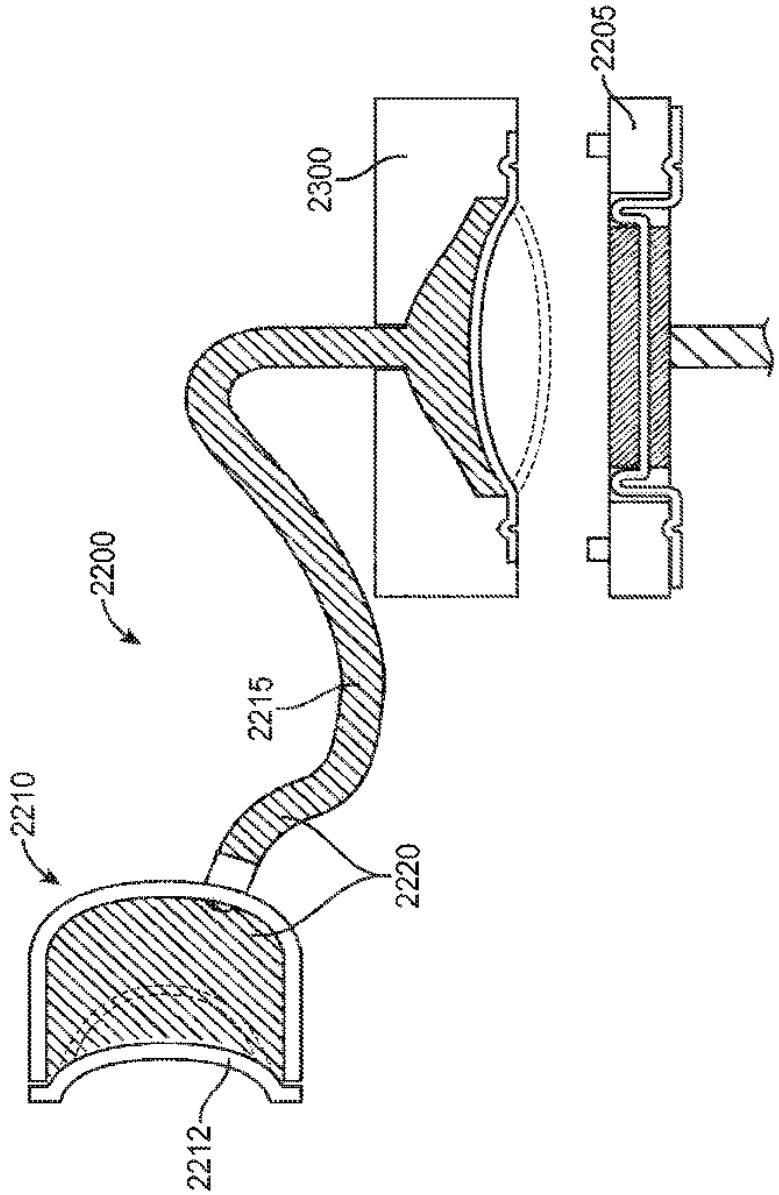


FIG. 22

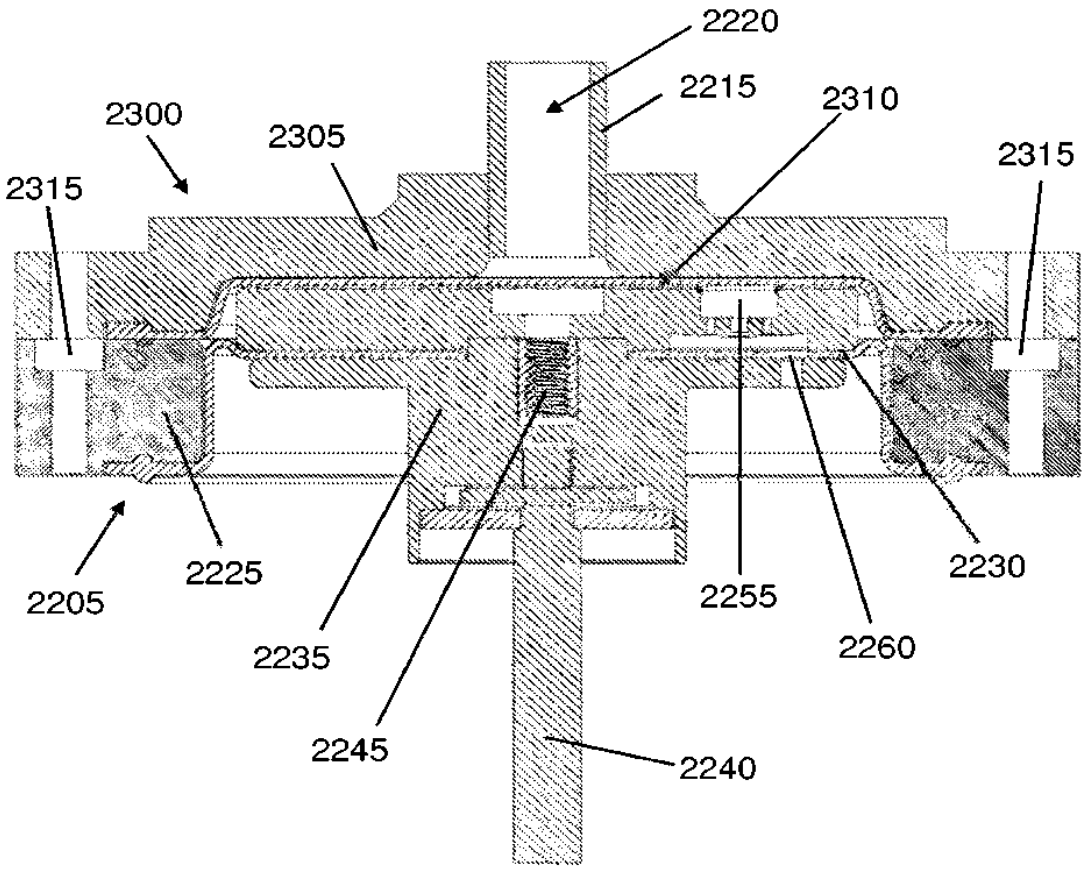

2220
2215
2310
2300
2305
2315
2315
2205
2225
2235
2245
2255
2260
2230
2240

FIG. 23

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/039453

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 1/06 (2015.01)
CPC - A61M 1/062 (2015.09)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61M 1/00, 1/06, 1/16 (2015.01)
CPC - A61M 1/0072, 1/062, 1/066 (2015.09)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 600/573; 604/73, 74
(keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Orbit, Google Patents, Google.
Search terms used: breast, milk, pleat, fold, crease, corrugate, bellows, membrane, diaphragh

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/0154348 A1 (LANTZ et al) 14 July 2005 (14.07.2005) entire document	1-4, 19-23
A	US 8,617,101 B2 (TACK) 31 December 2013 (31.12.2013) entire document	1-4, 19-23
A	US 2012/0004604 A1 (VAN DER KAMP et al) 05 January 2012 (05.01.2012) entire document	1-4, 19-23

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 September 2015	05 OCT 2015
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/039453

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

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

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

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

3. ☒ Claims Nos.: **5-18, 24, 25**
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

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

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

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

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

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

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WIPO | PCT

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PCT/US2015/044521

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10 August 2015 (10.08.2015)

(25) Filing Language: English

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(30) Priority Data:
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62/060,264 6 October 2014 (06.10.2014) US

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(74) Agents: **HUDAK, Jessica Anne** et al.; Hudak Consulting Group, LLC, 529 S. Murphy Avenue, Sunnyvale, California 94086 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) **Title**: SYNCHRONIZING BREAST PUMPING WITH INFANT FEEDING

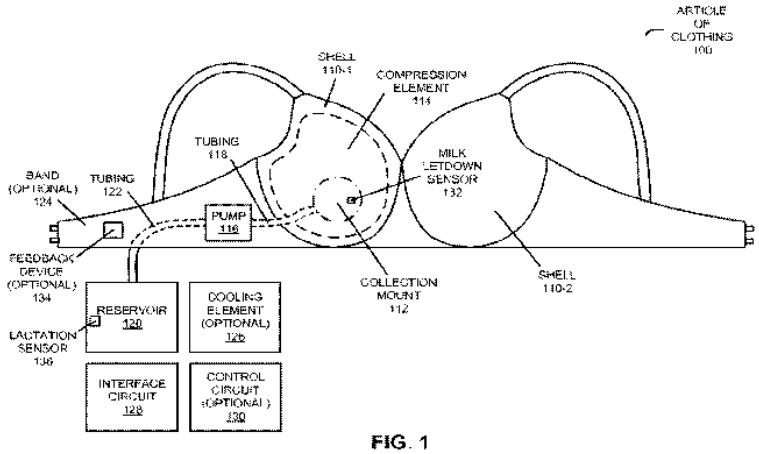


FIG. 1

(57) **Abstract**: A system for synchronizing one or more breast-pumping sessions of an individual (such as a mother) and milk consumption by a second individual (such as a baby or infant) is described. In particular, based on measurements of a volume of the collected milk as a function of time and received information specifying milk consumption by the second individual as a function of time, a control circuit may determine a need for milk. Then, the control circuit may provide feedback based on the determined need for milk that synchronizes the one or more breast-pumping sessions and the milk consumption. For example, the feedback may alert the individual to initiate a breast-pumping session and/or may provide a signal to a breast pump that initiates a breast-pumping session.

WO 2016/025405 A1

SYNCHRONIZING BREAST PUMPING WITH INFANT FEEDING

Inventors: Joëlle K. Barral, Venita Chandra, Mary K. Garrett, Jessica A. Hudak, Asha S. Nayak, Erika I. Palmer, Sandra Waugh Ruggles and Beverly T. Tang

CROSS REFERENCE TO RELATED APPLICATION

[001] This application claims priority under 35 U.S.C. § 119(e) to: U.S. Provisional Application Ser. No. 62/036,052, entitled "Breast Pump," by Joelle K. Barral, Venita Chandra, Mary K. Garrett, Asha S. Nayak, Erika I. Palmer, Sandra Waugh Ruggles and Beverly T. Tang, filed on August 11, 2014; and to U.S. Provisional Application Ser. No. 62/060,264, entitled "Systems and Methods for Managing Breast Pumping," by Joelle K. Barral, Venita Chandra, Jessica A. Hudak, Erika I. Palmer, Sandra Waugh Ruggles and Beverly T. Tang, Attorney Docket No. 0004-700.101, filed on October 6, 2014, the contents of both of which are herein incorporated by reference.

BACKGROUND

Field

[002] The described embodiments relate to an article of clothing that includes a breast pump and techniques for using the breast pump, including synchronizing one or more breast-pumping sessions of a woman with milk consumption by a baby or an infant.

Related Art

[003] Studies indicate that breast milk provides important vitamins and nutrients for babies. However, sometimes direct breastfeeding is not an option or may not desirable.

[004] Breast pumps make it possible for a mother to extract breast milk for her infant(s). In addition, breast pumps can help a mother continue lactating at regular intervals so that she does not lose the ability to generate milk during times when she is away from her

infant or when a baby may not be nursing. For example, premature infants or babies born with defects may be put in a neonatal intensive care unit (*NICU*) at a hospital, and therefore may not be able to nurse for a time. In these cases, a breast pump not only keeps a mother lactating, but may allow a baby in a *NICU*, who is able, to receive breast milk.

[005] However, there are challenges associated with existing breast pumps. In particular, many breast pumps are noisy, and can require regular cleaning and maintenance, which are time-consuming and expensive. Moreover, collecting milk, transferring it to a clean container, and then finding a place to store the milk can be time-consuming and frustrating. In addition, these actions often require a lot of attention or focus, which can be difficult for a mother with a newborn baby. For example, a mother may need to hold a pump or manually pump a device to extract milk. Then, the mother may need to switch breasts and repeat these operations, all while holding and encouraging their child.

[006] Furthermore, existing breast pumps often do not cause sufficient milk letdown, such that mothers may have to wait several minutes or even hours for another milk letdown. This problem may be compounded by the uncertainty it causes, because a mother may not know when her body is going to be ready to produce milk again. In some instances, the mother may have to put away the breast pump only to subsequently have to get it out right away because her milk is coming. The whole process can, therefore, become time-consuming and frustrating.

[007] Hence, there is a need for an improved breast pump and a technique for using a breast pump.

SUMMARY

[008] One group of described embodiments includes an article of clothing. This article of clothing includes a collection mount having an inner surface that mechanically couples to an areola of a breast of an individual, where the collection mount has an opening from the inner surface to an outer surface of the collection mount that is defined by an edge. Moreover, the article of clothing includes a compression element that surrounds at least a portion of the breast, and a pump mechanically coupled to the collection mount by tubing embedded in the article of clothing. During operation, the compression element applies a type of compression pattern at a location on the breast to facilitate lactation. In addition, the pump, in conjunction with the compression element, collects milk. Furthermore, the article of clothing includes a reservoir mechanically coupled to the pump by second tubing embedded in the article of clothing, which stores the collected milk.

[009] For example, during operation the pump may apply a pressure less than atmospheric pressure to a cavity between the areola and the inner surface of the collection mount. In particular, the compression element and the pump may apply time-varying compression to the breast and time-varying suction on the areola to collect the milk. Because of the type of compression pattern concurrently applied by the compression element, a maximum magnitude of the pressure applied by the pump may be less than a pain threshold of the individual. Note that the maximum magnitude of the pressure applied by the pump may be selectable.

[010] In some embodiments, the article of clothing includes: a band that attaches around a circumference of a torso of the individual; and shells, having inner surfaces, which are mechanically coupled to the band. The shells may support breasts of the individual. Moreover, the collection mount and the compression element may be included within a cavity defined by an inner surface of one of the shells. Note that a portion of the tubing may be included in cavities in the one of the shells. Furthermore, the article of clothing may include a cooling element that, during operation, reduces a temperature of the cavities to a temperature below room temperature. Additionally, a stiffness of outer surfaces of the shells may be greater than a stiffness of the internal surfaces of the shells.

[011] Note that the type of compression pattern may include: a circular pattern, a spiral pattern, a rhythmic pattern, a random pattern, a programmable pattern, and/or a localized pattern. Moreover, the type of compression pattern and the location may be selectable.

[012] Furthermore, the compression element may include channels. During operation, the compression element may generate the type of compression pattern using a gas and/or a liquid in the channels. Alternatively or additionally, the compression element may include bearings, and during operation the compression element may generate the type of compression pattern using the bearings.

[013] In some embodiments, during operation, the cooling element reduces a temperature of the reservoir to a temperature below room temperature.

[014] Moreover, the article of clothing may include an interface circuit, electrically coupled to the compression element and the pump, which communicates with an electronic device using wireless communication. During operation, the interface circuit may receive an activation command from the electronic device to turn on the compression element and the pump and/or may subsequently receive a deactivation command from the electronic device to turn off the compression element and the pump.

[015] Furthermore, the article of clothing may include a milk letdown sensor electrically coupled to the compression element and the pump. During operation, the milk letdown sensor may detect when the individual's milk has letdown, and may provide an activation signal to turn on the compression element and the pump. Alternatively or additionally, when the milk letdown sensor detects that the individual's milk has letdown, the milk letdown sensor may provide feedback to the individual.

[016] In some embodiments, the article of clothing includes a feedback device. During operation of the compression element and the pump, the feedback device may provide, to the individual, encouragement and/or feedback about milk collection.

[017] Moreover, the article of clothing may include a lactation sensor. During operation of the compression element and the pump, the lactation sensor may measure: a milk flow rate, and/or a volume of collected milk.

[018] Another embodiment provides a method for collecting milk from the breast using the article of clothing. During operation of the article of clothing, the compression element may compress the location on the breast to facilitate lactation using the type of compression pattern. Moreover, the pump mechanically coupled by tubing to the collection mount may apply suction to the areola of the breast. Next, the reservoir collects the milk based on the compression and the suction.

[019] A second group of described embodiments includes a system. This system includes: a breast pump, a lactation sensor, an interface circuit that communicates with a consumption sensor associated with a bottle, and a control circuit. During operation, the breast pump collects milk from an individual during one or more breast-pumping sessions. Moreover, the lactation sensor measures a volume of the collected milk as a function of time. Furthermore, the interface circuit receives information specifying milk consumption by a second individual (such as a baby) as a function of time. Additionally, the control circuit determines a need for milk based on a temporal pattern of the volume of the collected milk and a temporal pattern of the milk consumption, and provides feedback based on the determined need for milk that synchronizes the one or more breast-pumping sessions and the milk consumption.

[020] Note that the feedback may alert the individual to initiate a breast-pumping session. Alternatively or additionally, the feedback may include a signal to the breast pump that initiates a breast-pumping session.

[021] Moreover, the system may include a sensor. During operation, the sensor may measure: a vital sign of the individual as a function of time, a biomarker of the individual as a function of time, and/or an activity pattern of the individual as a function of time.

Alternatively or additionally, the vital-sign measurements, a biomarker of the individual as a function of time, and/or the activity pattern may be received by the interface circuit. Then, the control circuit may determine the need for milk based on: a temporal pattern of the vital sign, a temporal pattern of the biomarker, and/or a temporal pattern of the activity pattern.

[022] Furthermore, the interface circuit may receive additional information specifying: a vital sign of the second individual as a function of time, a biomarker of the second individual as a function of time, and/or an activity pattern of the second individual as a function of time. Then, the control circuit may determine the need for milk based on: a temporal pattern of the vital sign of the second individual, a temporal pattern of the biomarker of the second individual, and/or a temporal pattern of the activity pattern of the second individual.

[023] In some embodiments, the control circuit determines the need for milk based on a day of the week (and, more generally, a timestamp).

[024] Note that the received information may specify: a temperature of milk in the bottle, and/or a time duration since the milk in the bottle was collected. The control circuit may determine the need for milk based on: the temperature of the milk in the bottle, and/or the time duration.

[025] Moreover, the system may include memory that stores a program module with instructions for determining the need for milk and providing the feedback, and the control circuit may include a processor. During operation, the processor may execute the program module.

[026] Furthermore, the determining may be based on a supervised-learning model that relates the need for milk, the temporal pattern of the volume of the collected milk, and the temporal pattern of the milk consumption.

[027] Note that the feedback may maximize an average volume of the milk collected during a given breast-pumping session.

[028] Additionally, the system may include a feedback device. During a given breast-pumping session, the feedback device may provide, to the individual, encouragement about milk collection.

[029] Another embodiment provides a computer-program product for use with the *A/V* hub. This computer-program product includes instructions for at least some of the operations performed by the system.

[030] Another embodiment provides a method for synchronizing the one or more breast-pumping sessions of the individual and milk consumption by the second individual. This method includes at least some of the operations performed by the system.

[031] This Summary is provided merely for purposes of illustrating some exemplary embodiments, so as to provide a basic understanding of some aspects of the subject matter described herein. Accordingly, it will be appreciated that the above-described features are merely examples and should not be construed to narrow the scope or spirit of the subject matter described herein in any way. Other features, aspects, and advantages of the subject matter described herein will become apparent from the following Detailed Description, Figures, and Claims.

BRIEF DESCRIPTION OF THE FIGURES

[032] FIG. 1 is a block diagram illustrating an article of clothing in accordance with an embodiment of the present disclosure.

[033] FIG. 2 is a drawing illustrating a side view of a breast and a collection mount in accordance with an embodiment of the present disclosure.

[034] FIG. 3 is a block diagram illustrating a compression element for use in the article of clothing of FIG. 1 in accordance with an embodiment of the present disclosure.

[035] FIG. 4 is a drawing illustrating a front view of a breast and the compression element of FIG. 3 in accordance with an embodiment of the present disclosure.

[036] FIG. 5 is a flow diagram illustrating a method for collecting milk from a breast using an article of clothing in accordance with an embodiment of the present disclosure.

[037] FIG. 6 is a block diagram illustrating a system in accordance with an embodiment of the present disclosure.

[038] FIG. 7 is a block diagram illustrating a bottle with a consumption sensor in accordance with an embodiment of the present disclosure.

[039] FIG. 8 is a block diagram illustrating a user interface in an electronic device in the system of FIG. 6 in accordance with an embodiment of the present disclosure.

[040] FIG. 9 is a block diagram illustrating a user interface in an electronic device in the system of FIG. 6 in accordance with an embodiment of the present disclosure.

[041] FIG. 10 is a flow diagram illustrating a method for synchronizing one or more breast-pumping sessions of an individual and milk consumption by a second individual in accordance with an embodiment of the present disclosure.

[042] FIG. 11 is a block diagram illustrating an electronic device in accordance with an embodiment of the present disclosure.

[043] Note that like reference numerals refer to corresponding parts throughout the drawings. Moreover, multiple instances of the same part are designated by a common prefix separated from an instance number by a dash.

DETAILED DESCRIPTION

[044] One group of embodiments provides an article of clothing with an embedded breast pump. This breast pump combines a type of compression pattern at a location on a woman's breast with suction or vacuum to the areola or a region proximate to the nipple provided by a pump to collect milk. For example, the compression element may apply time-varying compression to the breast and the pump may provide time-varying suction on the areola to collect the milk. However, because the type of compression pattern is concurrently applied with the suction, the pressure applied by the pump may be reduced. In addition, to making mechanical breast feeding more comfortable, the pump may be smaller and less noisy. In conjunction with embedding the breast pump in the article of clothing, these features may allow women to collect milk discretely and at a time and place that is convenient for them (such as while at work).

[045] A second group of embodiments provides a system for synchronizing one or more breast-pumping sessions of an individual (such as a mother) and milk consumption by a second individual (such as a baby or infant). In particular, based on measurements of a volume of the collected milk as a function of time and received information specifying milk consumption by the second individual as a function of time, a control circuit may determine a need for milk. Then, the control circuit may provide feedback based on the determined need for milk that synchronizes the one or more breast-pumping sessions and the milk consumption. For example, the feedback may alert the individual to initiate a breast-pumping session and/or may provide a signal to a breast pump that initiates a breast-pumping session.

[046] By facilitating effective breast pumping, the article of clothing and the system may increase a mother's milk production. In addition, by making breast pumping easier and more discrete, the article of clothing and the system may reduce the time needed and the frustration associated with existing breast pumps, and may improve the user experience of the mother when using the breast pump. Consequently, the article of clothing and the system may encourage breast pumping, thereby allowing mothers to breast feed for a longer time, thereby providing health benefits for babies and infants.

[047] We now describe embodiments of the article of clothing. FIG. 1 presents a block diagram illustrating an article of clothing 100. This article of clothing includes a collection mount 112. As illustrated in FIG. 2, which presents a drawing illustrating a side view of a breast 200, collection mount 112 has an inner surface 210 that mechanically couples to (and makes a seal with) an areola of breast 200 of an individual (such as a mother and, more generally, a woman that is lactating), and collection mount 112 has an opening 212

from inner surface 210 to an outer surface 214 that is defined by an edge 216. For example, collection mount 112 may include: silicone, plastic and/or a composite material.

[048] Referring back to FIG. 1, article of clothing 100 includes a compression element 114 (which is described further below with reference to FIG. 3) that surrounds at least a portion of the breast, and a pump 116 mechanically coupled to collection mount 112 by tubing 118 embedded or included in article of clothing 100. Alternatively, pump 116 may be mechanically coupled to collection mount 112 without using tubing.

[049] During operation, compression element 114 applies a type of compression pattern at one or more locations on the breast to facilitate lactation. In addition, pump 116, in conjunction with compression element 114, collects milk. In particular, the milk may be collected and stored in reservoir 120 in article of clothing 100, which is mechanically coupled to pump 116 by tubing 122 that is included in or embedded in article of clothing 100.

[050] For example, during operation pump 116 may apply a pressure less than atmospheric pressure to a cavity 208 (defined by inner surface 210 and the individual's skin) between the areola and inner surface 210 of collection mount 112 via tubing 118 and opening 212. In particular, compression element 114 and pump 116 may apply time-varying compression to breast 200 (FIG. 2) and time-varying suction on the areola to collect the milk (such as a push-pull arrangement with alternating suction and massage). Because of the type of compression pattern concurrently applied by compression element 114, a maximum magnitude of the pressure applied by pump 116 may be less than that applied by pumps in existing breast pumps, such as a maximum magnitude of the pressure that is less than a pain threshold of the individual. (Thus, pump 116 may include: a roughing pump, an insulin pump, a portable pump, etc.) Furthermore, because of the type of compression pattern concurrently applied by compression element 114, a cyclic suction pattern applied by pump 116 may have a smaller fundamental frequency than that applied by pumps in existing breast pumps or may even be reduced to zero (*i.e.*, no cyclic component), thereby reducing the noise level and enhancing discretion during a pumping session. Note that the maximum magnitude of the pressure applied by pump 116 may be selectable by the individual via a knob or button in a physical control interface (which is sometimes referred to as an input/output or *I/O* interface). Alternatively, as described further below, the maximum magnitude of the pressure may be remotely selectable using an electronic device (such as a cellular telephone of the individual) via interface circuit 128. In some embodiments, during breast pumping, steady pressure and/or heat from a heating element (not shown) are applied to one or more locations on breast 200 (FIG. 2).

[051] Article of clothing 100 may include a wide variety of types of clothing, such

as a shirt, a jacket, a backpack, a vest, an undergarment (such as a corset, a brassiere or another breast-supporting article), etc. In some embodiments, article of clothing 100 includes: an optional band 124 that attaches around a circumference of a torso of the individual; and optional shells 110, which are mechanically coupled to optional band 124. These optional shells may support the breasts of the individual. Moreover, as shown in FIG. 2, collection mount 112 and compression element 114 may be included within a cavity 218 defined by an inner surface (such as inner surface 220-1) of at least one of optional shells 110 (such as optional shell 110-1). Note that a portion of tubing 122 may be included in cavity 218. In some embodiments, pump 116 is held in place by its own straps or another support material (such as body tape or another body adhesive).

[052] Furthermore, article of clothing 100 (FIG. 1) may include an optional cooling element 126 in FIG. 1 (such as a Peltier cooling device) that, during operation, reduces a temperature of cavities 208 and/or 218 to a temperature below room temperature (*i.e.*, that cools cavities 208 and/or 218). In some embodiments, during operation, optional cooling element 126 reduces a temperature of reservoir 120 (FIG. 1) to a temperature below room temperature (*i.e.*, that cools reservoir 120 in FIG. 1).

[053] Additionally, a stiffness of outer surfaces of optional shells 110 (such as outer surface 222-1) may be greater than a stiffness of the internal surfaces of optional shells 110 (such as inner surface 220-1). Thus, optional shells 110 may have a hard exterior (such as a hard plastic, a metal, a composite, etc.) that hides or masks mechanical motion associated with compression element 114 (and, more generally, the breast pumping) and the inner surface may be a softer material (such as a soft plastic, *e.g.*, a thermoplastic, silicone, a fabric, a foam, etc.). In some embodiments, optional shells 110 include breast-soothing elements, such as a gel pad. Alternatively, the outer surfaces of optional shells 110 may be made of a softer, conformable material (such as a thermoplastic or silicone) to mimic the outer shape of a natural breast, while the inner surface of optional shells 110 may be comprised of a hard cavity that holds the breasts in place and contains, hides, or masks the mechanical motion associated with compression element 114 (and, more generally, the breast pumping).

[054] As noted previously, article of clothing 100 may include an interface circuit 128, electrically coupled to compression element 114 and pump 116, which communicates with an electronic device (such as a cellular telephone of the individual) using wireless communication. During operation, interface circuit 128 may receive an activation command from the electronic device to turn on compression element 114 and/or pump 116. Subsequently, interface circuit 128 may receive a deactivation command from the electronic device to turn off compression element 114 and/or pump 116. A description of wireless

communication with article of clothing 100 (such as with optional electronic device 616) is described further below with reference to FIG. 6.

[055] Moreover, article of clothing 100 may include a milk letdown sensor 132 electrically coupled to compression element 114 and pump 116. During operation, milk letdown sensor 132 may detect when the individual's milk is ejected or has letdown, and may provide an activation signal to turn on compression element 114 and/or pump 116. (Similarly, when milk ejection or flow has stopped or dropped below a predefined threshold, milk letdown sensor 132 may subsequently provide a deactivation signal to turn off compression element 114 and/or pump 116.) For example, milk letdown sensor 132 may detect the presence of milk below the surface or proximate to the nipple of the breast, such as via an optical or an electrical or conductivity measurement. Alternatively or additionally, when milk letdown sensor 132 detects that the individual's milk has letdown, milk letdown sensor 132 may provide feedback to the individual. For example, article of clothing 100 may include an optional feedback device 134 that provides the feedback (such as a vibration motor, one or more speakers, etc.). In addition, during operation of compression element 114 and/or pump 116, optional feedback device 134 may provide, to the individual, encouragement and/or feedback about milk collection (such as how long the individual has been breast pumping and/or how much milk has been collected).

[056] Furthermore, article of clothing 100 may include a lactation sensor 136. During operation of compression element 114 and/or pump 116, lactation sensor 136 may measure: a milk flow rate, and/or a volume of collected milk (such as the volume in reservoir 120). For example, lactation sensor 136 may include: an optical sensor, a flow sensor, a level sensor, and/or a resistance sensor. Lactation sensor 136 may indicate that reservoir 120 is full and/or that the milk is due to be cooled and/or stored separately from article of clothing 100.

[057] In some embodiments, article of clothing 100 includes an optional control circuit 130 (such as a processor) that coordinates functions of article of clothing 100, such as conveying or providing: the activation command, the deactivation command, the activation signal, the deactivation command, the feedback, the encouragement, and/or communication via interface circuit 128 (such as measurements of the milk flow rate and/or the volume of collected milk).

[058] FIG. 3 presents a block diagram illustrating a compression element 114. This compression element may include channels 310 that, during operation, are used to generate the type of compression pattern. For example, compression element 114 may generate the type of compression pattern by selectively filling or emptying one or more of channels 310

using a gas and/or a liquid. Note that while radial channels 310 are shown in FIG. 3, in other embodiments different channel shapes and/or configurations are used. Moreover, note that compression element 114 may include a sleeve that can be wrapped around breast 200 (FIG. 2) to encompass a portion of breast 200 (FIG. 2), such as around a circumference of a portion of breast 200 (FIG. 2). Alternatively or additionally, compression element 114 may include bearings (such as ball bearings), and during operation compression element 114 may generate the type of compression pattern using the bearings.

[059] FIG. 4 presents a drawing illustrating a front view of breast 200 and compression element 114. By varying the compression at one or more locations on breast 200 as a function of time, compression element 114 may generate the type of compression pattern. Note that the type of compression pattern may include: a circular pattern around a circumference of breast 200, a spiral pattern around a circumference of breast 200 that moves from proximal to distal towards the areola, a rhythmic pattern (such as one that includes one or more fundamental frequencies), a random pattern (in terms of locations on breast 200, amplitude and/or frequencies), a massage pattern, a programmable pattern (which may be provided remotely via interface circuit 128 in FIG. 1 and/or which may be selected by the individual), and/or a localized pattern (such as a particular location on breast 200, such as proximate to the areola). Moreover, as noted previously, the type of compression pattern, an amplitude of the compression pattern and/or the location may be selectable by the individual.

[060] In an exemplary embodiment, reservoir 120 (FIG. 1) includes a disposable fabric reservoir or bag. Alternatively, another type of storage unit may be used, such as a bottle. Therefore, the reservoir may be used to deliver milk to a baby or an infant, thereby eliminating the need to transfer milk between a pumping container to a bottle or another delivery container. In some embodiments, a nipple and/or a lid is included or attached to the reservoir. The nipple and/or lid may be changed, thereby allowing the size to be changed and/or to adapt to the needs of the baby or the infant, such as if the baby is in the hospital.

[061] However, in other embodiments, the reservoir is fixed in the article of clothing. Moreover, the reservoir may include compartments, which may allow lids, nipples, cleaning tools, repair tools, paper towels, and other items to be safely housed together with the reservoir. Therefore, instead of one reservoir, there may be multiple reservoirs. For example, a 'popsicle holder' type of storage may be provided in which the milk is put into multiple reservoirs or containers. This approach may allow the milk to be given in smaller quantities, thereby preserving the remaining milk for a later time. In addition, multiple reservoirs may facilitate storage because it allows more flexibility in the amount of milk that remains with the individual and the quantity (and thus weight) of milk that gets stored

subsequent use. In some embodiments, the reservoir includes channels in the article of clothing. These channels may have different colors or labels that indicate a time when the milk was collected in a given channel and/or a temperature of the milk.

[062] Furthermore, the reservoir may have a wide variety of shapes, thereby allowing it to provide both function and fashion. For example, the reservoir may take on the form of a camelback vest that includes one or more small channels of a coolant interwoven with one or more channels of breast milk. In this way, the breast milk may be maintained at a relatively cool or constant temperature that is desired. Alternatively or additionally, a heat source may be used to achieve the desired temperature. Note that the channels may have a variety of shapes, such as oblong forms, cylinders or other forms. The channels may be removable, so that they can be cleaned and/or stored. This may also allow the article of clothing to be used for other purposes, such as hiking. Note that the coolant may include a liquid (such as water, oil or another liquid) and/or a gas with suitable thermodynamic properties. The pump element that is coupled to the reservoir may also provide a mechanism for 'self-cleaning' of the reservoir (such as a purge or steam-clean) to obviate the need for separate cleaning of the reservoir.

[063] While the preceding embodiments illustrated the article of clothing including the reservoir, in some embodiments off-body storage is used, such as: in a purse, a backpack, a fanny pack, high tops, thigh bag, an arm band, and/or a hat.

[064] In addition to detecting milk letdown, or measuring the milk flow rate or the volume of milk collected, the article of clothing may include a sensor that measures (or may receive information that specifies): the time elapsed since milk was last collected, breast temperature, another parameter related to the breast, etc. Note that the sensors in the article of clothing may be at one or more locations, *i.e.*, the sensors may be localized or distributed, within the article of clothing (such as on its associated components) and/or on the individual's body (on the breast or another area, such as the stomach, neck, arms, back, flank, etc.).

[065] Optional feedback device 134 (FIG. 1) may allow automated reminders to be provided to the individual, such as a reminder after a time interval since a last breast-pumping session has occurred. Reminders may be provided in a variety of forms, such as a physiological signal (such as a noise, a vibration, an audible message, etc.), and/or a message communicated to the electronic device (such as an email, a text, a phone alert, etc.).

[066] In some embodiments, the article of clothing includes passive and/or active components that reduce or mask the sound associated with operation of the article of clothing. For example, the article of clothing may include acoustic insulation (such as sound-

proof foam) and/or muffler. However, in other embodiments these components are external to the article of clothing. Moreover, active sound cancellation or sound masking may be used, such as a white-noise generator and a speaker.

[067] In order to encourage milk production and milk letdown, in some embodiments the article of clothing mechanically (such as by massaging or providing pressure to the nipple or a pressure point *e.g.*, GB21, or providing a small amount of fluid to the nipple), electrically and/or chemically stimulates a portion of the breast (such as the nipple). For example, a hormone or another stimulant may be provided that encourages milk letdown.

[068] Although article of clothing 100 in FIG. 1 is shown as including pump 116, in other embodiments pump 116 is separate from article of clothing 100. For example, pump 116 is remotely located, such as in a separate room. A pump case may be personalized to make it unique to the individual. For example, the pump case may include an electronic image or a photograph of a baby or an infant. This may provide a visual stimulus that helps promote breast-milk production. Furthermore, instead of using one pump, in alternating fashion, between breasts, there may two pumps (one for each breast). However, in some embodiments, a single pump may be used, and the breasts may be pumped sequentially. This configuration may provide a smaller form factor with reduced power consumption and noise.

[069] In some embodiments, a cleaning tool is provided with pump 116 (FIG. 1). For example, the cleaning tool may include a cleaning element attached to a heating device that steam cleans the pump and the associated tubing. Moreover, pump 116 may be plugged into the cleaning tool in order to be cleaned
and sterilized. This approach may eliminate the need for a user (such as the individual) to remove and reassemble components, or to scrub and dry the components. However, in some embodiments components in the article of clothing reduce or eliminate the need for cleaning. For example, a hard plastic (such as a thermoset plastic) and/or silver-coated materials may be used.

[070] We now describe a method for using the article of clothing. FIG. 5 presents a flow diagram illustrating a method 500 for collecting milk from a breast using an article of clothing, such as article of clothing 100 (FIG. 1). During operation of the article of clothing, a compression element may compress a location on the breast (operation 510) to facilitate lactation using a type of compression pattern. Moreover, a pump mechanically coupled by tubing to a collection mount in the article of clothing may apply suction to an areola of the breast (operation 512). Next, a reservoir in the article of clothing collects the milk (operation 514) based on the compression and the suction.

[071] In these ways, the article of clothing and the breast-pumping technique may allow a woman to breast pump when she wants to (such as at a time and place that is convenient, including while she is at work), and in an efficient and a discrete manner. Moreover, the article of clothing may reduce the woman's frustration and may improve her overall user experience while breast pumping. Consequently, the article of clothing may encourage breast pumping, with the commensurate health benefits for babies and infants.

[072] We now describe embodiments of the system, which may be used in conjunction with or separately from the article of clothing. FIG. 6 presents a block diagram illustrating a system 600. This system includes: a breast pump 612, lactation sensor 136, electronic device 610 that communicates with one or more electronic devices (such as optional consumption sensor 614 associated with optional bottle 700 in FIG. 7 and/or optional electronic device 616), and a control circuit 618. During operation, breast pump 612 collects milk from an individual during one or more breast-pumping sessions. Moreover, lactation sensor 136 measures a volume of the collected milk as a function of time. Furthermore, electronic device 610 receives information (*e.g.*, from optional consumption sensor 614 and/or optional electronic device 616) specifying milk consumption by a second individual (such as a baby or an infant) as a function of time. Additionally, control circuit 618 determines a need for milk based on a temporal pattern of the volume of the collected milk and a temporal pattern of the milk consumption, and provides feedback based on the determined need for milk that synchronizes the one or more breast-pumping sessions and the milk consumption.

[073] For example, the feedback may be provided using optional feedback device 134. Alternatively or additionally, as described further below with reference to FIGs. 8 and 9, the feedback may be provided to optional electronic device 616 (*e.g.*, for display on a user interface). Note that the feedback may alert the individual to initiate a breast-pumping session. (In addition, as noted previously, the feedback may provide encouragement to the individual while breast pumping, such as a summary of the amount of milk collected.) Alternatively or additionally, the feedback may include a signal to breast pump 612 that initiates a breast-pumping session without action by the individual (*e.g.*, automatically). In some embodiments, the individual can manually override a determination by control circuit 618 to initiate a breast-pumping session (*e.g.*, the individual may stop a breast-pumping session that occurs at an inopportune time, may reinitiate a previously stopped breast-pumping session, or may specify a predefined delay until starting a breast-pumping session).

[074] In some embodiments, control circuit 618 determines the need for milk based on one or more additional inputs. For example, system 600 may include an optional sensor

620. During operation, optional sensor 620 may measure: a vital sign of the individual as a function of time, a biomarker of the individual as a function of time, and/or an activity pattern of the individual as a function of time (such as a sleep pattern, an eating or dietary pattern, an exercise pattern, a sedentary pattern, etc.). For example, optional sensor 620 may measure: a pulse rate, a respiration rate, blood pressure, skin temperature, skin electrical conductivity, chemical analysis of a biological sample (such as sweat, saliva or blood), gene-expression analysis of a biological sample, ribonucleic-acid analysis of a biological sample and/or deoxyribonucleic-acid of a biological sample. The optional sensor may measure a wide variety of biomarkers, such as: an electroencephalogram signal, an electromyography signal, one or more electrolytes (*e.g.*, sodium, chloride, potassium, and/or calcium), one or more metabolites (*e.g.*, lactate, creatinine, glucose, and/or uric acid), and/or one or more small molecules (*e.g.*, an amino acid, a steroid or a hormone, cortisol, a protein, an interleukin, and/or a neuropeptides). Alternatively or additionally, the vital-sign measurements, the biomarker and/or the activity pattern may be received by electronic device 610. Similarly, electronic device 610 may receive additional information specifying: a vital sign of the second individual as a function of time, a biomarker of the second individual as a function of time, and/or an activity pattern of the second individual as a function of time. Then, control circuit 618 may determine the need for milk based on: a temporal pattern of the vital sign of the individual, a temporal pattern of the biomarker of the individual, a temporal pattern of the activity pattern of the individual, a temporal pattern of the vital sign of the second individual, a temporal pattern of the biomarker of the second individual, and/or a temporal pattern of the activity pattern of the second individual.

[075] Moreover, control circuit 618 may determine the need for milk based on a day of the week (and, more generally, a timestamp). For example, a woman's lactation may be different on the weekend than during the workweek. Furthermore, the information received by electronic device 610 may specify: a temperature of milk in optional bottle 700 (FIG. 7), and/or a time duration since the milk in optional bottle 700 (FIG. 7) was collected (which may indicate whether the milk is still usable). Control circuit 618 may, therefore, determine the need for milk based on: the temperature of the milk in optional bottle 700 (FIG. 7), and/or the time duration.

[076] Note that control circuit 618 may determine the need for milk using a supervised-learning model that relates the need for milk with one or more of the preceding inputs. For example, the supervised-learning model, which may be developed using a wide variety of supervised-learning techniques, may include: a neural network, LASSO (a regularized linear regression technique like ridge regression, but with L_1-norm regularization

of the coefficients), a decision tree (such as classification and regression trees, with or without gradient boosting), a support vector machine, a model developed using Bayesian statistical analysis, least-squares regression, logistic regression, a non-parametric multivariate analysis technique, etc. Moreover, the supervised-learning technique may include a linear or a non-linear kernel. In some embodiments, the supervised-learning model is determined using data from one or more other individuals, such as by using collaborative filtering.

[077] In addition to initiating a breast-feeding session when a need for milk is determined, control circuit 188 may initiate a breast-pumping session: after a predefined time interval since a previous breast-feeding session (such as one hour, two hours, three hours, etc.), according to a predefined schedule, according to user preferences (such as different time intervals during the day or at night, or for different days of the week) and/or randomly after a minimum time interval (such as one hour) since a previous breast-feeding session. For example, the predefined schedule may systematically increase the time interval between breast-pumping sessions, such as when an infant is being weaned off of breast milk.

[078] While preceding embodiments illustrated automated collection of data using sensors or receiving information from one or more electronic devices, in other embodiments at least some of the data used by control circuit 618 is entered manually using a user interface (such as a keyboard, a user-interface device, a user interface displayed on a touch-sensitive display, voice recognition, etc.). In some embodiments, at least some of the data used by control circuit 618 is automatically generated based on a time of a most-recent feeding and a predefined feeding schedule and/or predefined user feeding preferences (such as one or more time intervals between feedings).

[079] As noted previously, electronic device 610 and optional electronic device 616 may include radios that communicate packets or frames in accordance with one or more communication protocols, such as: an Institute of Electrical and Electronics Engineers (*IEEE*) 802.11 standard (which is sometimes referred to as 'Wi-Fi®,' from the Wi-Fi® Alliance of Austin, Texas), Bluetooth® (from the Bluetooth Special Interest Group of Kirkland, Washington), a cellular-telephone communication protocol, a near-field-communication standard or specification (from the NFC Forum of Wakefield, Massachusetts), and/or another type of wireless interface. For example, the cellular-telephone communication protocol may include or may be compatible with: a 2nd generation or mobile telecommunication technology, a 4rd generation of mobile telecommunications technology (such as a communication protocol that complies with the International Mobile Telecommunications-2000 specifications by the International Telecommunication Union of Geneva, Switzerland), a 4th generation of mobile telecommunications technology (such as a communication protocol

that complies with the International Mobile Telecommunications Advanced specification by the International Telecommunication Union of Geneva, Switzerland), and/or another cellular-telephone communication technique. In some embodiments, the communication protocol includes Long Term Evolution or *LTE*. However, a wide variety of communication protocols may be used. In addition, the communication may occur via a wide variety of frequency bands.

[080] As shown in FIG. 6, during operation electronic device 610 and optional electronic device 616 may wirelessly communicate while: transmitting advertising frames on wireless channels, detecting one another by scanning wireless channels, establishing connections (for example, by transmitting association requests), and/or transmitting and receiving packets or frames (which may include the association requests and/or additional information as payloads, such as commands, measurements, feedback, etc.).

[081] Moreover, as described further below with reference to FIG. 11, electronic device 610 and optional electronic device 616 may include subsystems, such as: a networking subsystem, a memory subsystem and a processor subsystem. In addition, electronic device 610 and optional electronic device 616 may include radios 622 in the networking subsystems (such as interface circuit 128 in FIG. 1). (Note that radios 622 may be instances of the same radio or may be different from each other.) More generally, electronic device 610 and optional electronic device 616 can include (or can be included within) any electronic devices with the networking subsystems that enable electronic device 610 and optional electronic device 616 to wirelessly communicate with each other. This wireless communication can comprise transmitting advertisements on wireless channels to enable electronic devices to make initial contact or detect each other, followed by exchanging subsequent data/management frames (such as association requests and responses) to establish a connection, configure security options (*e.g.*, Internet Protocol Security), transmit and receive packets or frames via the connection, etc.

[082] As can be seen in FIG. 1, wireless signals 624 (represented by a jagged line) are transmitted from radio 622-1 in optional electronic device 616. These wireless signals are received by electronic device 610. In particular, optional electronic device 616 may transmit packets. In turn, these packets may be received by a radio 622-2 in electronic device 610. This may allow optional electronic device 616 to communicate information to electronic device 610. While FIG. 1 illustrates optional electronic device 616 transmitting packets, note that optional electronic device 616 may also receive packets from electronic device 610.

[083] In the described embodiments, processing of a packet or frame in electronic device 610 includes: receiving wireless signals 624 with the packet or frame;

decoding/extracting the packet or frame from received wireless signals 624 to acquire the packet or frame; and processing the packet or frame to determine information contained in the packet or frame (such as the information or the additional information).

[084] Although we describe the network environment shown in FIG. 1 as an example, in alternative embodiments, different numbers or types of electronic devices may be present. For example, some embodiments comprise more or fewer electronic devices. As another example, in another embodiment, different electronic devices are transmitting and/or receiving packets or frames. While electronic device 610 and optional electronic device 616 are illustrated with a single instance of radios 622, in other embodiments electronic device 610 and optional electronic device 616 may include multiple radios.

[085] FIG. 7 presents a block diagram illustrating a bottle 700 with an optional consumption sensor 614. As noted previously, optional consumption sensor 614 may measure or determine absolute or relative milk consumption by the second individual, and may communicate this information to electronic device 610 (FIG. 6). For example, optional consumption sensor 614 may include: an accelerometer, a velocity sensor, a position sensor, an orientation sensor (such as a gyroscope), an optical sensor, a flow sensor, a level sensor, and/or a resistance sensor. In an exemplary embodiment, when bottle 700 is tipped back by at least 45°, optional consumption sensor 614 may indicate that the baby or infant is feeding, as well as a timestamp when the feeding started (and/or ended). Alternatively or additionally, removing bottle 700 from a refrigerator and/or heating bottle 700 may cause optional consumption sensor 614 to communicate that feeding is about to start.

[086] In some embodiments, the feedback is communicated to optional electronic device 616, and is then displayed on a user interface. This is shown in FIG. 8, which presents a block diagram illustrating a user interface 800 in optional electronic device 616 (FIG. 6). In particular, user interface 800 may include a woman's time-varying lactation cycle or pattern and a baby or infant's time-varying consumption cycle or pattern, along with an option to initiate a breast-pumping session by activating a virtual icon (*e.g.*, by touching a display screen within a strike area associated with the virtual icon). Alternatively or additionally, electronic device 616 (FIG. 6) may include a button or a knob that can be used to initiate a breast-pumping session. In general, information about the woman's lactation cycle and the baby or infant's consumption cycle may include: a graph, a table, a chart, summary statistics, etc.

[087] FIG. 9 presents a block diagram illustrating a user interface 900 in optional electronic device 616 (FIG. 6) that displays statistical information about collected milk, such as: temperature, amount or volume of milk (such as milk consumed, milk remaining, etc.),

how long the milk can be used for (or is expected to last) and a location where the milk is currently stored.

[088] Note that other information may be display to assist the individual. For example, the other information may include information about: a lactation consultant, a childcare provider, freezing suggestions, breast-pumping or breast-feeding education and/or a portal or link to a user community, a chat room or a social network. Furthermore, system 600 (FIG. 6) may use optional electronic device 616 (FIG. 6) to present advice to the individual based on what works best for them or other women, such as: positions, types of compression patterns, a likely or probable breast-pumping schedule (so the individual can plan their day), an estimate of the cost savings obtained by breast pumping (as opposed to buying an equivalent volume of formula), etc. Collectively, this information may provide encouragement and support to the individual.

[089] In an exemplary embodiment, the system includes sensors or uses sensor data that is received from other electronic devices for parameters such as: breast skin temperature, ambient temperature, pressure, humidity, position, etc. These measurements may be used in supervised or machine learning of the pumping technique. The system may learn and remember lessons from prior breast-pumping session and may cumulatively apply them to future sessions, so that the learning is 'across' and 'between' sessions, not just 'within' a session.

[090] The sensor data may include flow and/or volume sensing of expressed milk that occurs 'in-line' or 'at the level of the stream' as opposed to 'on-bottle.' This may allow the collected milk to be monitored even when the milk is collected in a non-rigid container as envisioned with a wearable device.

[091] In some embodiments, the reservoir is adaptable or a one-size fits all reservoir that can be used with any pump size. The reservoir may be wearable beyond pumping times, and may refrigerate milk while keeping the skin warm.

[092] The system may allow pumping automation to synchronization with the baby's feed times/durations (including knowing when the baby is feeding at a remote location) and is able to alert the mother (at a minimum) to pump or actually initiate pumping in synchronization with the baby's feedings. Thus, there may be one or more sensors on the baby or baby's bottle to synchronize with the pump via a network.

[093] Sound insulation or sound cancellation may be used with the breast pump so that it is less noisy.

[094] As noted previously, machine learning may be used with the sensor data, including determining what you want to sense, calculate, learn, and 'do' with the learning.

This may achieve faster let-down by monitoring a mother's breast (at pump) conditions (such as heat, humidity, temp, etc.) and also on her body (such as stress levels via wearables measuring heart rate, perspiration, activity, etc.) and/or provide stimulation (such as even music, messages, pictures via cellphone) to improve her mental state. In addition, the system may sense the response to off-the-shelf stimulation to determine what rate, rhythm, and intensity of suction intensifies let down and under what conditions.

[095] The system may incorporate breast massage with the wearable device and/or with machine learning. For example, the machine learning may determine the best massage pattern to optimize let down and shorten pump duration while increasing the milk extracted. Alternatively or additionally, pressure points, heat and/or vibration may be used to stimulate the breast.

[096] We now describe another method. FIG. 10 presents a flow diagram illustrating a method 1000 for synchronizing one or more breast-pumping sessions of an individual and milk consumption by a second individual, which may be performed using one or more electronic devices in a system, such as electronic device 610 in system 600 (FIG. 6). During operation, the system measures, using a lactation sensor, a volume of milk collected as a function of time (operation 1010) using a breast pump, where the breast pump collects the milk from the individual during the one or more breast-pumping sessions. For example, the measurements may be at discrete times or they may be performed continuously. Then, the system receives, from a consumption sensor associated with a bottle, information specifying the milk consumption as a function of time (operation 1012). Similarly, the milk consumption may be specified at discrete times or continuously. Moreover, the system determines a need for milk (operation 1014) based on a temporal pattern of the volume of the collected milk and a temporal pattern of the milk consumption. Next, the system provides feedback (operation 1016) based on the determined need for milk that synchronizes the one or more breast-pumping sessions and the milk consumption.

[097] In these ways, the system and the breast-pumping technique may allow women to breast pump in an efficient and effective manner. For example, by synchronizing supply and demand, and by taking into account temporal variations in a woman's milk production, the system may increase a mother's milk production. In particular, the system (such as the feedback provided during breast pumping) may maximize an average volume of the milk collected during a given breast-pumping session. Moreover, the system may reduce the woman's frustration and may improve her overall user experience while breast pumping. Consequently, the system may encourage breast pumping, with the commensurate health benefits for babies and infants.

[098] In some embodiments of methods 500 (FIG. 5) and/or 1000, there may be additional or fewer operations. Moreover, the order of the operations may be changed, and/or two or more operations may be combined into a single operation.

[099] We now describe embodiments of an electronic device. FIG. 11 presents a block diagram illustrating an electronic device 1100, such as one or more components in article of clothing 100 (FIG.1), electronic device 610 and/or optional electronic device 616. This electronic device includes processing subsystem 1110, memory subsystem 1112, and networking subsystem 1114. Processing subsystem 1110 includes one or more devices configured to perform computational operations. For example, processing subsystem 1110 can include one or more microprocessors, application-specific integrated circuits (*ASICs*), microcontrollers, programmable-logic devices, and/or one or more digital signal processors (*DSPs*). One or more of these components in processing subsystem are sometimes referred to as a 'control mechanism' or a 'control circuit' (such as control circuit 618 in FIG. 6).

[0100] Memory subsystem 1112 includes one or more devices for storing data and/or instructions for processing subsystem 1110 and networking subsystem 1114. For example, memory subsystem 1112 can include dynamic random access memory (*DRAM*), static random access memory (*SRAM*), and/or other types of memory. In some embodiments, instructions for processing subsystem 1110 in memory subsystem 1112 include: one or more program modules or sets of instructions (such as program module 1122 or operating system 1124), which may be executed by processing subsystem 1110. Note that the one or more computer programs may constitute a computer-program mechanism. Moreover, instructions in the various modules in memory subsystem 1112 may be implemented in: a high-level procedural language, an object-oriented programming language, and/or in an assembly or machine language. Furthermore, the programming language may be compiled or interpreted, *e.g.*, configurable or configured (which may be used interchangeably in this discussion), to be executed by processing subsystem 1110.

[0101] In addition, memory subsystem 1112 can include mechanisms for controlling access to the memory. In some embodiments, memory subsystem 1112 includes a memory hierarchy that comprises one or more caches coupled to a memory in electronic device 1100. In some of these embodiments, one or more of the caches is located in processing subsystem 1110.

[0102] In some embodiments, memory subsystem 1112 is coupled to one or more high-capacity mass-storage devices (not shown). For example, memory subsystem 1112 can be coupled to a magnetic or optical drive, a solid-state drive, or another type of mass-storage device. In these embodiments, memory subsystem 1112 can be used by electronic device

1100 as fast-access storage for often-used data, while the mass-storage device is used to store less frequently used data.

[0103] Networking subsystem 1114 includes one or more devices configured to couple to and communicate on a wired and/or wireless network (*i.e.*, to perform network operations), including: control logic 1116, interface circuit 1118 and associated antenna(s) 1120. (While FIG. 11 includes antenna(s) 1120, in some embodiments electronic device 1100 includes one or more nodes, such as node(s) 1108, *e.g.*, pads, which can be coupled to antenna(s) 1120. Thus, electronic device 1100 may or may not include antenna(s) 1120.) For example, networking subsystem 1114 can include a Bluetooth networking system, a cellular networking system (*e.g.*, a 3G/4G network such as *UMTS*, *LTE*, etc.), a universal serial bus (*USB*) networking system, an Institute of Electrical and Electronics Engineers (*IEEE*) 802.15 standard (such as ZigBee® from the ZigBee® Alliance of San Ramon, California), a networking system based on the standards described in *IEEE* 802.11 (*e.g.*, a Wi-Fi networking system), an Ethernet networking system, and/or another networking system. Note that the combination of interface circuit 1118 and at least one of antenna(s) 1120 may constitute a radio. In some embodiments, networking subsystem 1114 communicates with one or more electronic devices via a wired interface.

[0104] Networking subsystem 1114 includes processors, controllers, radios/antennas, sockets/plugs, and/or other devices used for coupling to, communicating on, and handling data and events for each supported networking system. Note that mechanisms used for coupling to, communicating on, and handling data and events on the network for each network system are sometimes collectively referred to as a 'network interface' for the network system. Moreover, in some embodiments a 'network' between the electronic devices does not yet exist. Therefore, electronic device 1100 may use the mechanisms in networking subsystem 1114 for performing simple wireless communication between the electronic devices, *e.g.*, transmitting advertising or beacon frames and/or scanning for advertising frames transmitted by other electronic devices as described previously.

[0105] Within electronic device 1100, processing subsystem 1110, memory subsystem 1112, and networking subsystem 1114 are coupled together using bus 1128. Bus 1128 may include an electrical, optical, and/or electro-optical connection that the subsystems can use to communicate commands and data among one another. Although only one bus 1128 is shown for clarity, different embodiments can include a different number or configuration of electrical, optical, and/or electro-optical connections among the subsystems.

[0106] In some embodiments, electronic device 1100 includes a display subsystem 1126 for displaying information on a display (such as the communication warning message),

which may include a display driver, an *I/O* controller and the display, such as a liquid-crystal display, a multi-touch touchscreen (which is sometimes referred to as a touch-sensitive display), etc.

[0107] Electronic device 1100 can be (or can be included in) any electronic device with at least one network interface. For example, electronic device 1100 can be (or can be included in): a desktop computer, a laptop computer, a subnotebook/netbook, a tablet computer, a smartphone, a cellular telephone, a smartwatch, a portable computing device, and/or another electronic device.

[0108] Although specific components are used to describe electronic device 1100, in alternative embodiments, different components and/or subsystems may be present in electronic device 1100. For example, electronic device 1100 may include one or more additional processing subsystems, memory subsystems, networking subsystems, display subsystems, one or more *I/O* interfaces and/or optional feedback subsystem 1130. Moreover, one or more of the subsystems may not be present in electronic device 1100. Furthermore, in some embodiments, electronic device 1100 may include one or more additional subsystems that are not shown in FIG. 11 (such as a power subsystem with a non-rechargeable or a rechargeable power source). Also, although separate subsystems are shown in FIG. 11, in some embodiments, some or all of a given subsystem or component can be integrated into one or more of the other subsystems or component(s) in electronic device 1100. For example, in some embodiments program module 1122 is included in operating system 1124. More generally, two or more components may be combined into a single component or a single electronic device.

[0109] Moreover, the circuits and components in electronic device 1100 may be implemented using any combination of analog and/or digital circuitry, including: bipolar, *PMOS* and/or *NMOS* gates or transistors. Furthermore, signals in these embodiments may include digital signals that have approximately discrete values and/or analog signals that have continuous values. Additionally, components and circuits may be single-ended or differential, and power supplies may be unipolar or bipolar.

[0110] An integrated circuit may implement some or all of the functionality of networking subsystem 1114, such as one or more radios. Moreover, the integrated circuit may include hardware and/or software mechanisms that are used for transmitting wireless signals from electronic device 1100 and receiving signals at electronic device 1100 from other electronic devices. Aside from the mechanisms herein described, radios are generally known in the art and hence are not described in detail. In general, networking subsystem 1114 and/or the integrated circuit can include any number of radios.

[0111] In some embodiments, networking subsystem 1114 and/or the integrated circuit include a configuration mechanism (such as one or more hardware and/or software mechanisms) that configures the radios to transmit and/or receive on a given channel (*e.g.*, a given carrier frequency). For example, in some embodiments, the configuration mechanism can be used to switch the radio from monitoring and/or transmitting on a given channel to monitoring and/or transmitting on a different channel. (Note that 'monitoring' as used herein comprises receiving signals from other electronic devices and possibly performing one or more processing operations on the received signals, *e.g.*, determining if the received signal comprises an advertising frame, etc.)

[0112] The described embodiments may be used in a variety of network interfaces. Furthermore, while some of the operations in the preceding embodiments were implemented in hardware or software, in general the operations in the preceding embodiments can be implemented in a wide variety of configurations and architectures. Therefore, some or all of the operations in the preceding embodiments may be performed in hardware, in software or both. For example, at least some of the operations in the breast-pumping technique may be implemented using program module 1122, operating system 1124 (such as drivers for interface circuit 1118) and/or in firmware in interface circuit 1118. Alternatively or additionally, at least some of the operations in the breast-pumping technique may be implemented in a physical layer, such as hardware in interface circuit 1118.

[0113] In the preceding description, we refer to 'some embodiments.' Note that 'some embodiments' describes a subset of all of the possible embodiments, but does not always specify the same subset of embodiments.

[0114] The foregoing description is intended to enable any person skilled in the art to make and use the disclosure, and is provided in the context of a particular application and its requirements. Moreover, the foregoing descriptions of embodiments of the present disclosure have been presented for purposes of illustration and description only. They are not intended to be exhaustive or to limit the present disclosure to the forms disclosed. Accordingly, many modifications and variations will be apparent to practitioners skilled in the art, and the general principles defined herein may be applied to other embodiments and applications without departing from the spirit and scope of the present disclosure. Additionally, the discussion of the preceding embodiments is not intended to limit the present disclosure. Thus, the present disclosure is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein.

What is Claimed is:

1. A system, comprising:

a breast pump that, during operation, collects milk from an individual during one or more breast-pumping sessions;

a lactation sensor that, during operation, measures a volume of the collected milk as a function of time;

an interface circuit that, during operation, communicates with a consumption sensor associated with a bottle, wherein the communication includes receiving information specifying milk consumption by a second individual as a function of time;

a control circuit, electrically coupled to the lactation sensor and the interface circuit, which, during operation, determines a need for milk based on a temporal pattern of the volume of the collected milk and a temporal pattern of the milk consumption, and provides feedback based on the determined need for milk that synchronizes the one or more breast-pumping sessions and the milk consumption.

2. The system of claim 1, wherein the feedback alerts the individual to initiate a breast-pumping session.

3. The system of claim 1, wherein the feedback includes a signal to the breast pump that initiates a breast-pumping session.

4. The system of claim 1, wherein the system further comprises a sensor, electrically coupled to the control circuit, which, during operation, measures one of: a vital sign of the individual as a function of time, a biomarker of the individual as a function of time, and an activity pattern of the individual as a function of time; and

wherein the control circuit determines the need for milk based on one of: a temporal pattern of the vital sign, a temporal pattern of the biomarker, and a temporal pattern of the activity pattern.

5. The system of claim 1, wherein, during operation, the interface circuit receives additional information specifying one of: a vital sign of the second individual as a function of time, a biomarker of the second individual as a function of time, and an activity pattern of the second individual as a function of time; and

wherein the control circuit determines the need for milk based on one of: a temporal pattern of the vital sign, a temporal pattern of the biomarker, and a temporal pattern of the activity pattern.

6. The system of claim 1, wherein the control circuit determines the need for milk based on a day of the week.

7. The system of claim 1, wherein the received information specifies one of: a temperature of milk in the bottle; and a time duration since the milk in the bottle was collected; and

wherein the control circuit determines the need for milk based on one of: the temperature of the milk in the bottle, and the time duration.

8. The system of claim 1, further comprising memory that stores a program module with instructions for determining the need for milk and providing the feedback; and

wherein control circuit includes a processor that, during operation, executes the program module.

9. The system of claim 1, wherein the determining is based on a supervised-learning model that relates the need for milk, the temporal pattern of the volume of the collected milk, and the temporal pattern of the milk consumption.

10. The system of claim 1, wherein the feedback maximizes an average volume of the milk collected during a given breast-pumping session.

11. The system of clothing of claim 1, further comprising a feedback device; and

wherein, during a given breast-pumping session, the feedback device provides to the individual encouragement about milk collection.

12. A computer-program product for use in conjunction with an electronic device, the computer-program product comprising a non-transitory computer-readable storage medium and a computer-program mechanism embedded therein to synchronize one or more breast-pumping sessions of an individual and milk consumption by a second individual, the computer-program mechanism including:

instructions for measuring, using a lactation sensor, a volume of milk collected as a function of time using a breast pump, wherein the breast pump collects the milk from the individual during the one or more breast-pumping sessions;

instructions for receiving, from a consumption sensor associated with a bottle, information specifying the milk consumption as a function of time;

instructions for determining a need for milk based on a temporal pattern of the volume of the collected milk and a temporal pattern of the milk consumption; and

instructions for providing feedback based on the determined need for milk that synchronizes the one or more breast-pumping sessions and the milk consumption.

13. The computer-program product of claim 12, wherein the feedback alerts the individual to initiate a breast-pumping session.

14. The computer-program product of claim 12, wherein the feedback includes a signal to the breast pump that initiates a breast-pumping session.

15. The computer-program product of claim 12, wherein the computer-program mechanism comprises instructions for measuring, using a sensor, one of: a vital sign of the individual as a function of time, a biomarker of the individual as a function of time, and an activity pattern of the individual as a function of time; and

wherein determining the need for milk is based on one of: a temporal pattern of the vital sign, a temporal pattern of the biomarker, and a temporal pattern of the activity pattern.

16. The computer-program product of claim 12, wherein the computer-program mechanism comprises instructions for receiving additional information specifying one of: a vital sign of the second individual as a function of time, a biomarker of the second individual as a function of time, and an activity pattern of the second individual as a function of time; and

wherein determining the need for milk is based on one of: a temporal pattern of the vital sign, a temporal pattern of the biomarker, and a temporal pattern of the activity pattern.

17. The computer-program product of claim 12, wherein determining the need for milk is based on a day of the week.

18. The computer-program product of claim 12, wherein the feedback maximizes an average volume of the milk collected during a given breast-pumping session.

19. The computer-program product of claim 12, wherein the computer-program mechanism comprises instructions for providing to the individual encouragement about the milk collection.

20. A method for synchronizing one or more breast-pumping sessions of an individual and milk consumption by a second individual, wherein the method comprises:

measuring, using a lactation sensor, a volume of milk collected as a function of time using a breast pump, wherein the breast pump collects the milk from the individual during the one or more breast-pumping sessions;

receiving, from a consumption sensor associated with a bottle, information specifying the milk consumption as a function of time;

determining a need for milk based on a temporal pattern of the volume of the collected milk and a temporal pattern of the milk consumption; and

providing feedback based on the determined need for milk that synchronizes the one or more breast-pumping sessions and the milk consumption.

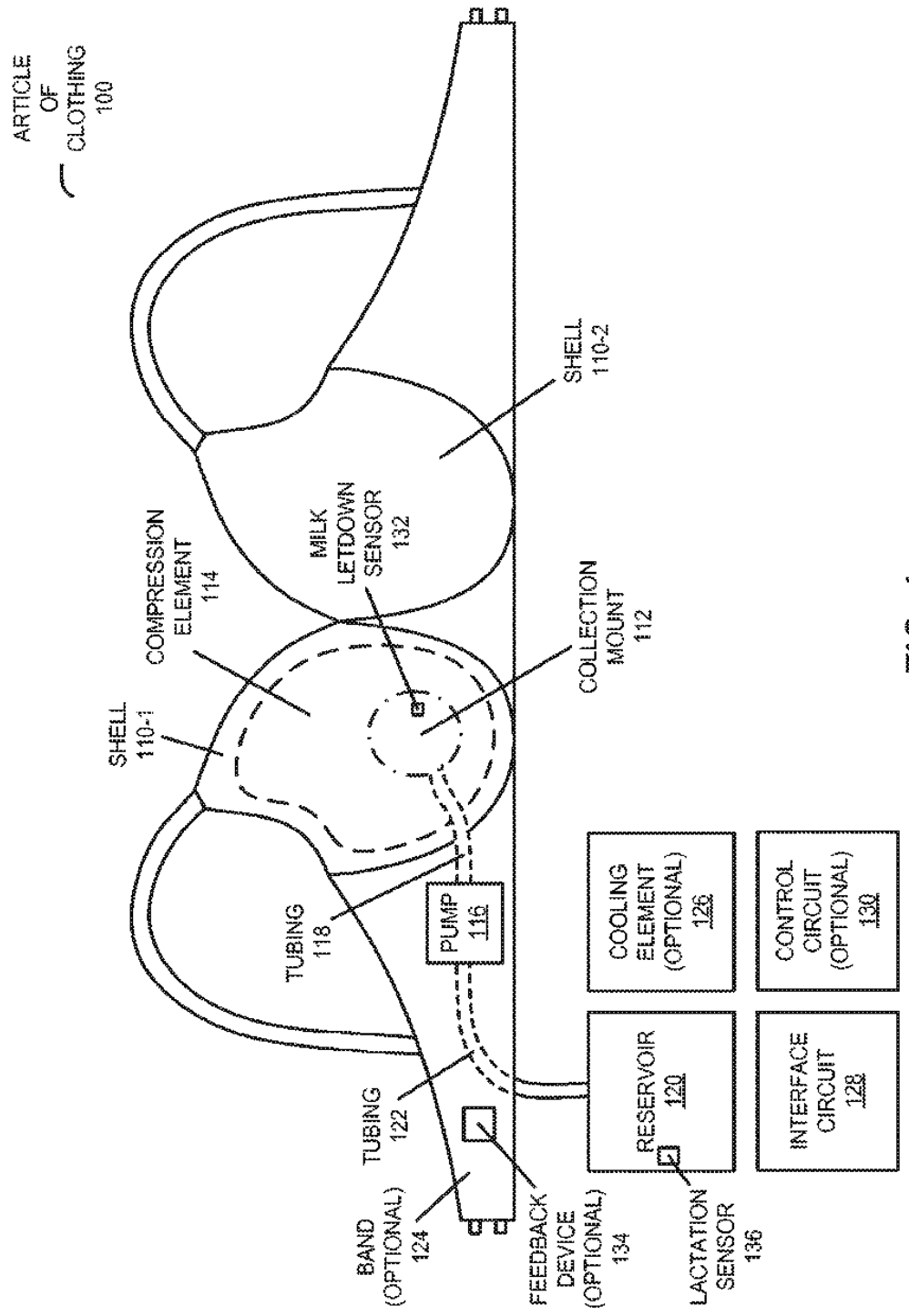

ARTICLE OF CLOTHING 100
SHELL 110-1
COMPRESSION ELEMENT 114
MILK LETDOWN SENSOR 132
SHELL 110-2
COLLECTION MOUNT 112
TUBING 118
PUMP 116
COOLING ELEMENT (OPTIONAL) 126
CONTROL CIRCUIT (OPTIONAL) 130
TUBING 122
RESERVOIR 120
INTERFACE CIRCUIT 128
BAND (OPTIONAL) 124
FEEDBACK DEVICE (OPTIONAL) 134
LACTATION SENSOR 136

FIG. 1

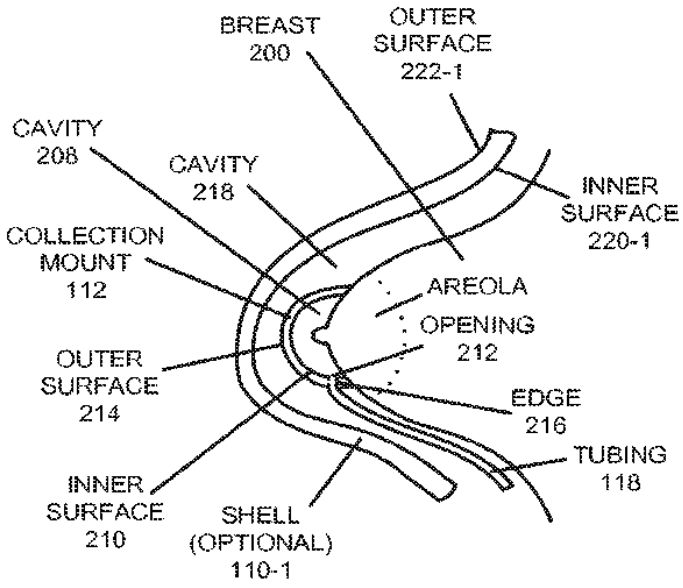

BREAST
200
OUTER
SURFACE
222-1
CAVITY
208
CAVITY
218
INNER
SURFACE
220-1
COLLECTION
MOUNT
112
AREOLA
OPENING
212
OUTER
SURFACE
214
EDGE
216
TUBING
118
INNER
SURFACE
210
SHELL
(OPTIONAL)
110-1

FIG. 2

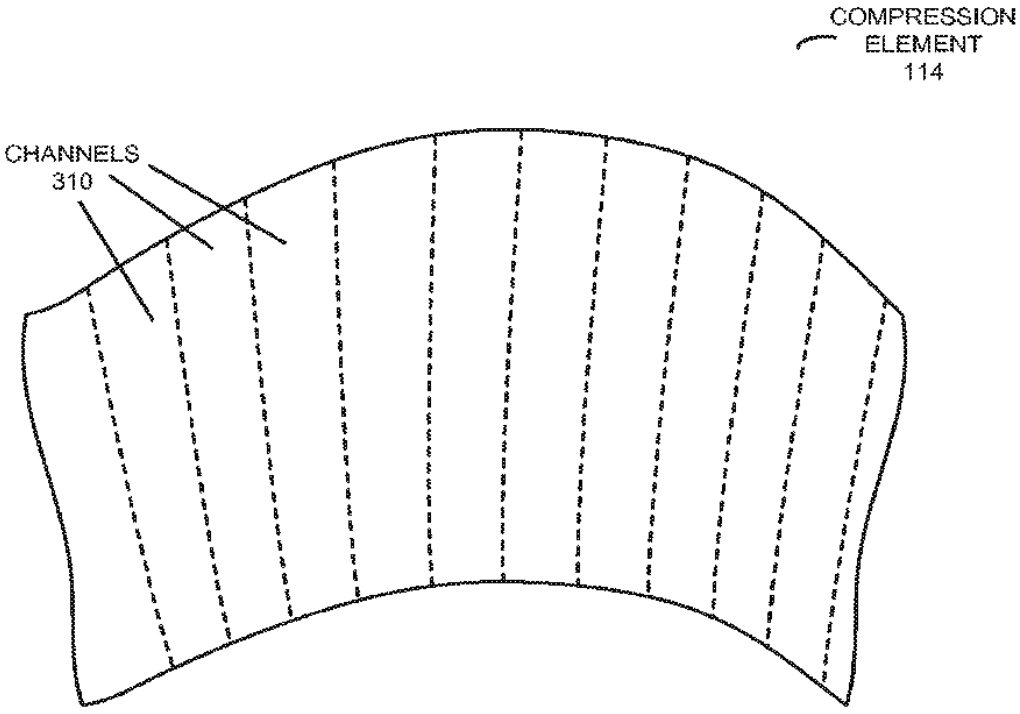


FIG. 3

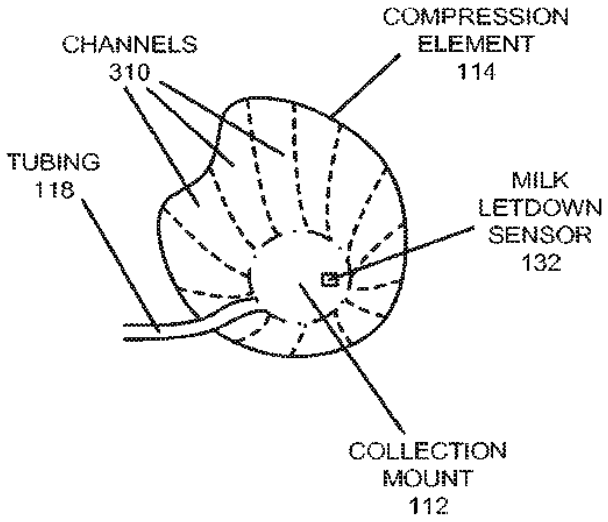

CHANNELS
310
COMPRESSION
ELEMENT
114
TUBING
118
MILK
LETDOWN
SENSOR
132
COLLECTION
MOUNT
112

FIG. 4

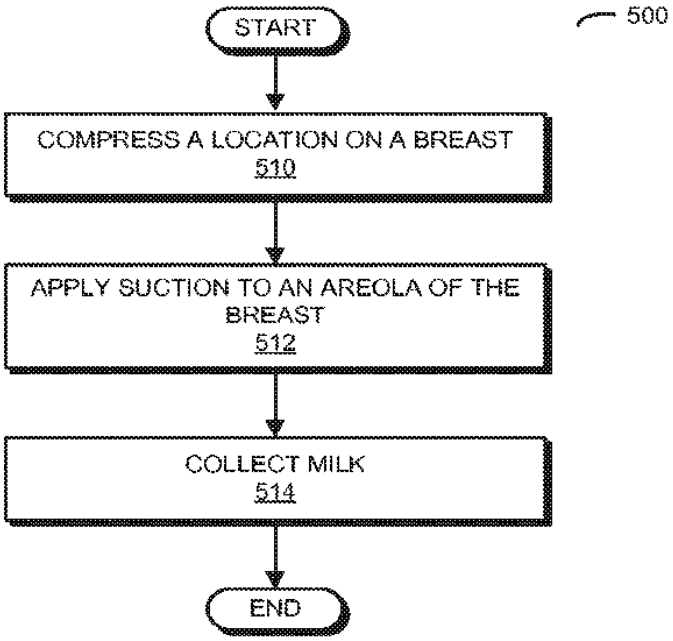

500
START
COMPRESS A LOCATION ON A BREAST
510
APPLY SUCTION TO AN AREOLA OF THE BREAST
512
COLLECT MILK
514
END

FIG. 5

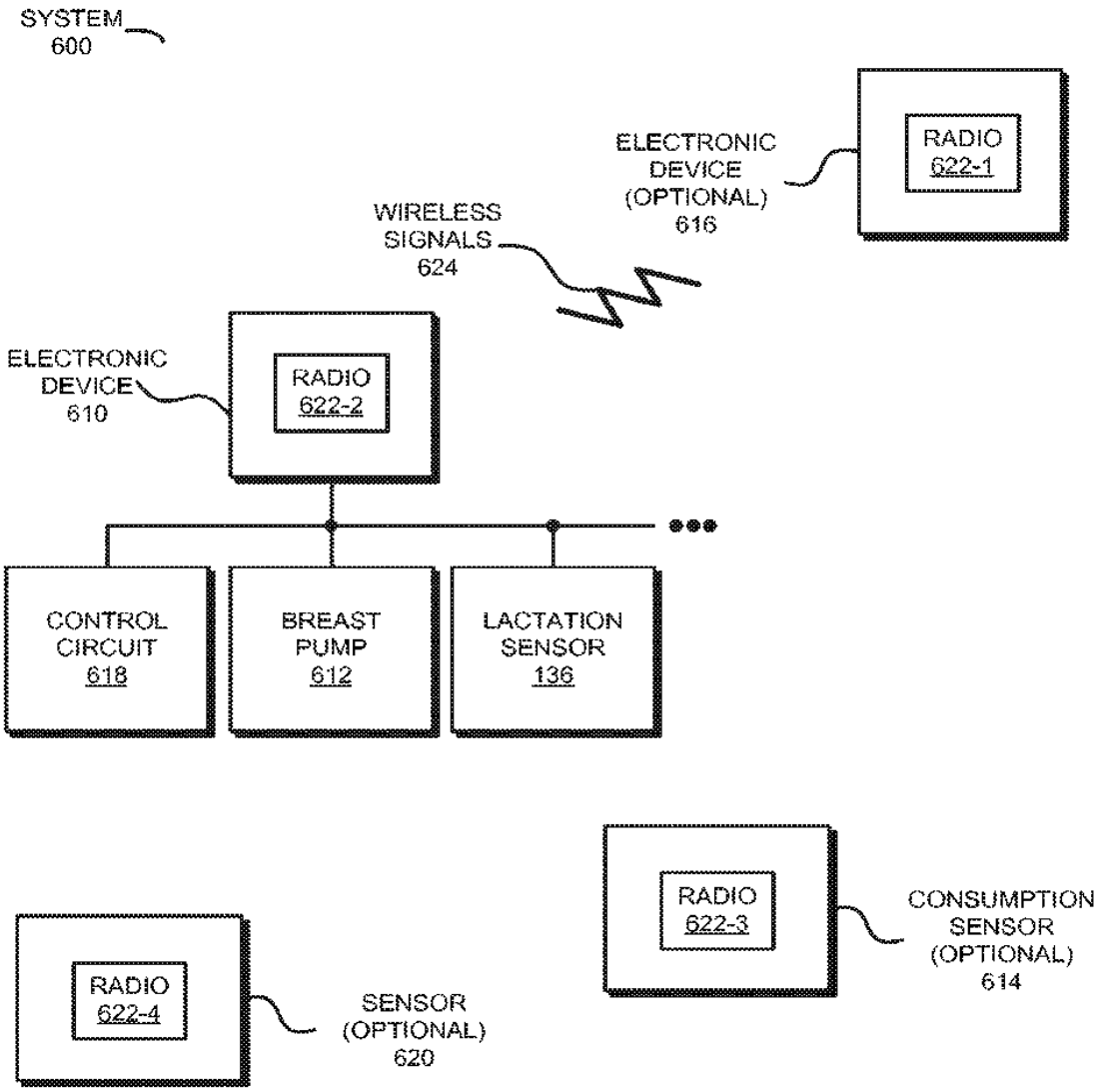

SYSTEM
600
ELECTRONIC
DEVICE
(OPTIONAL)
616
RADIO
622-1
WIRELESS
SIGNALS
624
ELECTRONIC
DEVICE
610
RADIO
622-2
CONTROL
CIRCUIT
618
BREAST
PUMP
612
LACTATION
SENSOR
136
RADIO
622-3
CONSUMPTION
SENSOR
(OPTIONAL)
614
RADIO
622-4
SENSOR
(OPTIONAL)
620

FIG. 6

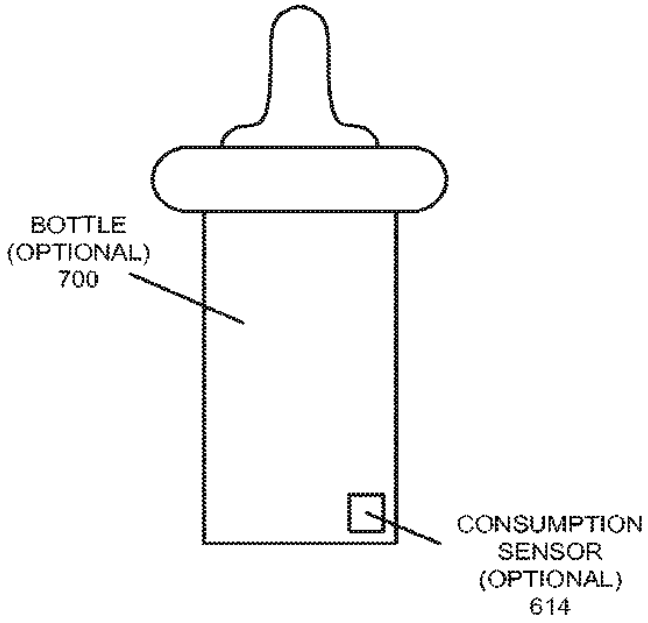


FIG. 7

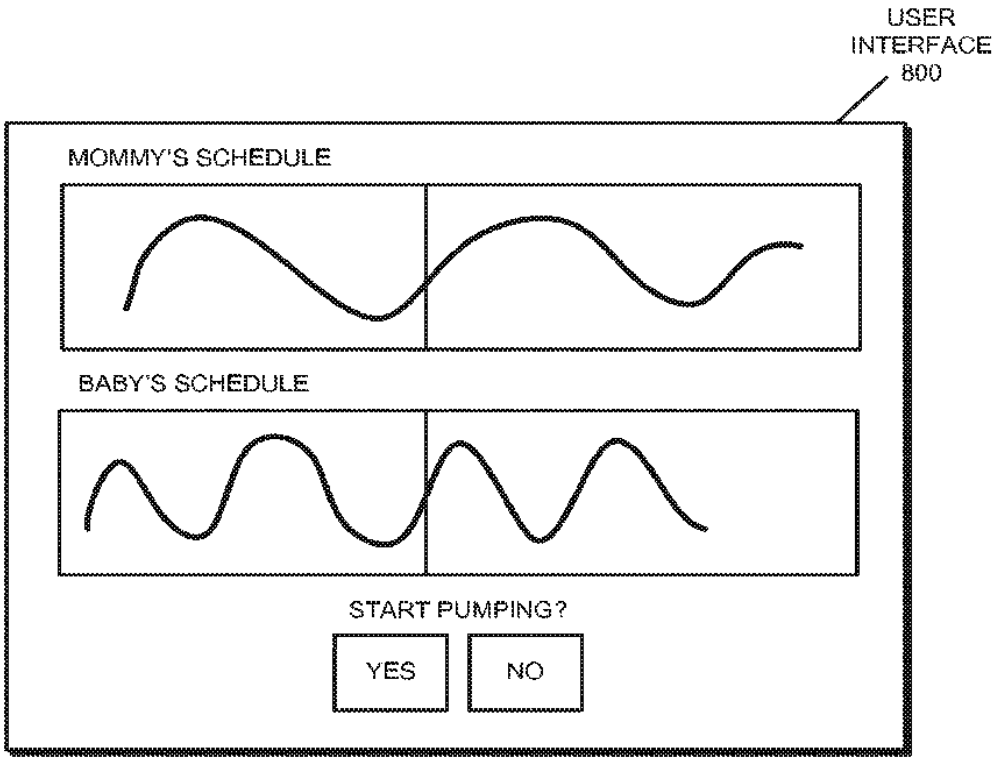

USER
INTERFACE
800
MOMMY'S SCHEDULE
BABY'S SCHEDULE
START PUMPING?
YES
NO

FIG. 8

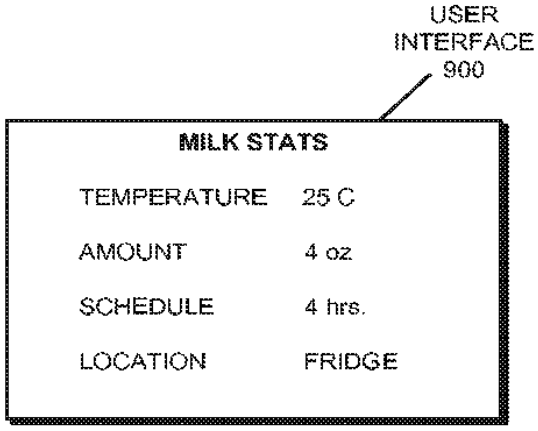

USER
INTERFACE
900
MILK STATS
TEMPERATURE 25 C
AMOUNT 4 oz
SCHEDULE 4 hrs.
LOCATION FRIDGE

FIG. 9

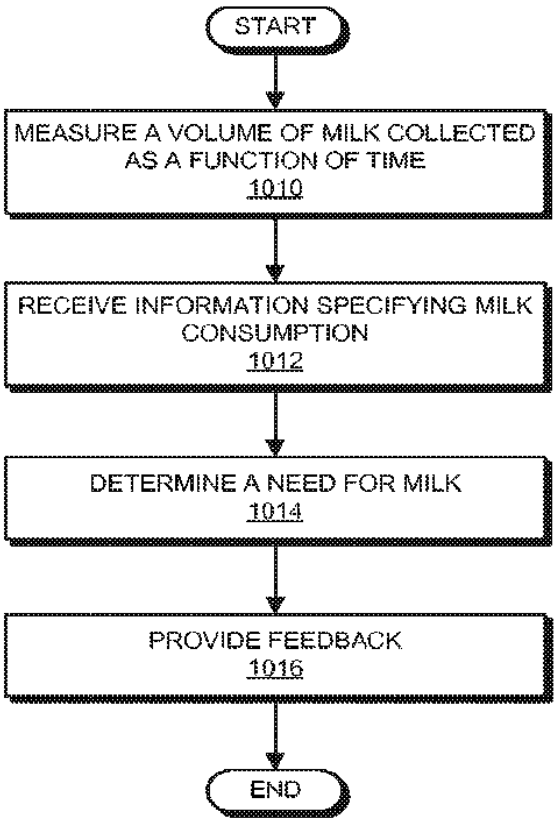

1000
START
MEASURE A VOLUME OF MILK COLLECTED AS A FUNCTION OF TIME
1010
RECEIVE INFORMATION SPECIFYING MILK CONSUMPTION
1012
DETERMINE A NEED FOR MILK
1014
PROVIDE FEEDBACK
1016
END

FIG. 10

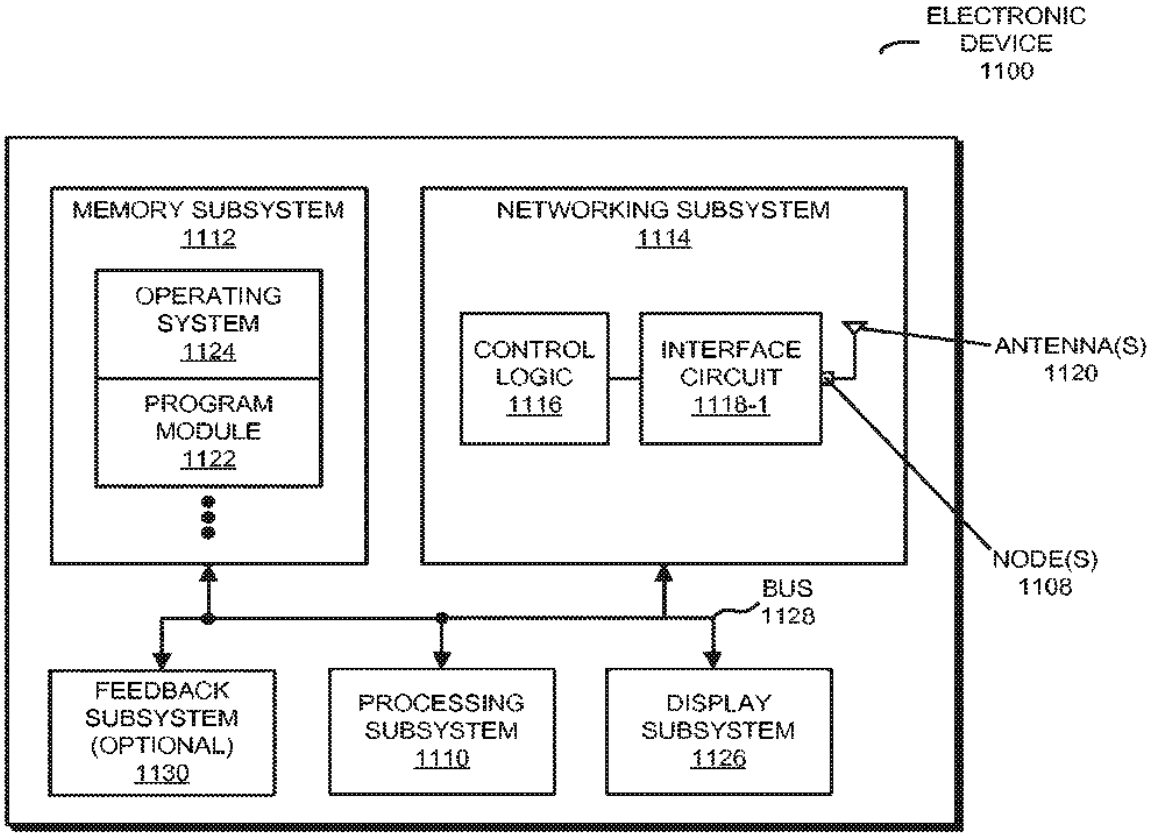

ELECTRONIC DEVICE 1100
MEMORY SUBSYSTEM 1112
OPERATING SYSTEM 1124
PROGRAM MODULE 1122
NETWORKING SUBSYSTEM 1114
CONTROL LOGIC 1116
INTERFACE CIRCUIT 1118-1
ANTENNA(S) 1120
NODE(S) 1108
BUS 1128
FEEDBACK SUBSYSTEM (OPTIONAL) 1130
PROCESSING SUBSYSTEM 1110
DISPLAY SUBSYSTEM 1126

FIG. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 15/44521

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 1/06 (2015.01)
CPC - A61M 1/06
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC (8) - A61M 1/06 (2015.01)
CPC - A61M 1/06

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61M 2001/064; A61M 2001/066 (See Keywords below)
USPC - 604/74, 235/375, 705/26.1, 705/26.2

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Thomsoninnovation.com; Patbase; Google Scholar; Google Patents; Gogole.com; Freepatentsonline; ProQuest Dialog
Search Terms: Breast pump, lactation, pattern, trend, consumption, volume, quantity, amount, collect, gather, activate, synchronize, need, requirement, temporal, time, session, milk, sensor, communicate, bottle, analysis, learn, etc.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2013/166462 A1 (GENADYNE BIOLTECHNOLOGIES), 07 November 2013 (07.11.2013), entire document, especially Abstract; page 1, ln 15-22; page 3, ln 7-18; page 13, ln 7 to page 14, ln 8	1-20
Y	WO 2013/187763 A1 (PATENTENTRANSFERIUM B.V.), 19 December 2013 (19.12.2013), entire document, especially Abstract; page 1, ln 10-20; page 8, ln 15-20; page 13, ln 25-35; page 14, ln 1-15	1-20
Y	US 2004/0186788 A1 (CZUCHRY, JR. et al.), 23 September 2004 (23.09.2004), entire document, especially Abstract; Para [0006], [0024], [0033]-[0036]	1-20
Y	US 2006/0278093 A1 (BIDERMAN et al.), 14 December 2006 (14.12.2006), entire document, especially Abstract; Para Para [0187]	5 and 16
A	US 2004/0122358 A1 (KENT et al.), 24 June 2004 (24.06.2004), entire document	1-20
A,P	US 2014/0263611 A1 (BAUER), 18 September 2014 (18.09.2014), entire document	1-20

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
09 October 2015 (09.10.2015)	23 NOV 2015
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

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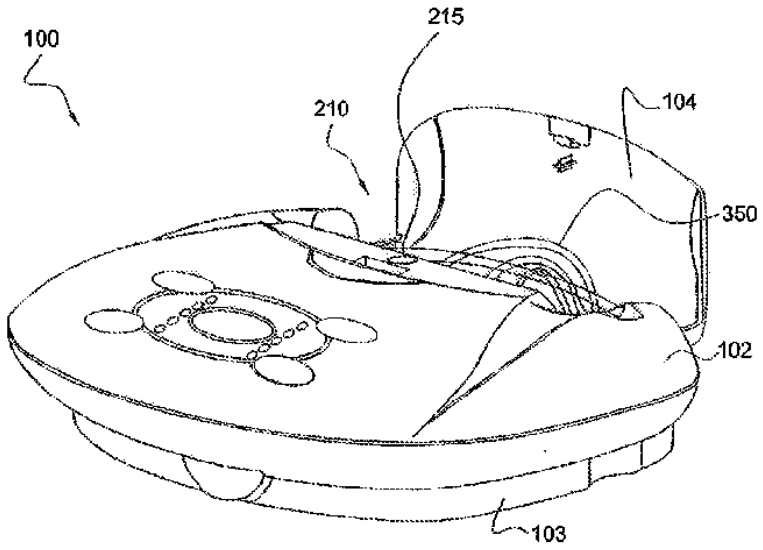
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(54) Title: BREAST PUMP SYSTEM



(57) Abstract: A breast pump system for obtaining breast milk is provided. The system sealingly separates the air flow from the breast milk and uses a single air tube for both positive pressure and negative pressure to be applied to a woman's breast. The breast pump can have a piston/cylinder device for generating pressure that allows a user to control suction and cycle time.

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BREAST PUMP SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to apparatus and methods for obtaining breast milk. More particularly, the present invention relates to a breast pump system that applies both a positive pressure and a negative pressure to a breast to express breast milk.

2. Description of the Related Art

Breast pump systems for obtaining breast milk, both manually and automatically, are known in the art. Conventional systems use a vacuum source to generate a negative pressure or vacuum that is transmitted through tubing to a breast hood or cup that is placed on the breast. This conventional device and method uses a negative pressure on the breast to express the breast milk. Such systems suffer from the drawback of applying only a vacuum source as negative pressure to the breast to induce the expression of breast milk.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a breast pump system for expressing milk that applies both a positive pressure and a negative pressure to a breast to express the milk.

It is another object of the present invention to provide such a system that supplies the positive and negative pressure from a single source.

It is still another object of the present invention to provide such a system that facilitates control of the positive and negative pressure applied to the breast.

These and other objects and advantages of the present invention are provided by a breast pump system having a pressure source for generating a positive pressure and a negative pressure, and a breast cup in fluid

communication with the pressure source, wherein the breast cup applies positive pressure and negative pressure to the breast.

The present invention also includes a breast pump system having a cylinder with a cylinder volume, a piston movably disposed in the cylinder, a motor operably connected to the piston to generate a pressure in the cylinder volume, and a breast cup in fluid communication with the cylinder volume, wherein the breast cup applies the pressure to the breast.

The present invention further includes a breast pump having a pressure source for generating a positive pressure and a negative pressure, and a controller operably connected to the pressure source, wherein the controller adjusts the positive and negative pressure and adjusts a cycle time between application of the positive and negative pressure to the breast.

The present invention additionally includes a breast pump having a pressure source for generating a pressure, and a controller operably connected to the pressure source, wherein the controller adjusts the pressure and adjusts a cycle time between application of the pressure to the breast. The controller also generates a wave signal in response to the pressure and the cycle time, and controls the pressure source in response to the wave signal.

The present invention includes a drive system for an expandable volume of a breast pump. The drive system has a motor having a first rotary output; a first gear system operably connected to the motor; and a second gear system operably connected to the first gear system and the expandable volume. The first gear system can have at least one belt. The second gear system has a rack gear and a pinion gear operably connected to the rack gear. The first gear system adjusts the rotary output provided to the second gear system to a second rotary output. The second gear system translates the second rotary output to a linear output.

The present invention includes a breast pump for supplying a pressure to a breast cup. The breast pump has an expandable volume in fluid

communication with the breast cup to supply the pressure; a motor having a first rotary output; a first gear system operably connected to the motor; and a second gear system operably connected to the first gear system and the expandable volume. The first gear system can have at least one belt. The second gear system has a rack gear and a pinion gear operably connected to the rack gear. The first gear system adjusts the rotary output provided to the second gear system to a second rotary output. The second gear system translates the second rotary output to a linear output.

The system can also have a channel and the breast cup can have an air orifice, wherein the channel is connected to the air orifice and the pressure source, and the pressure source supplies reciprocating air flow through the channel between the breast cup and the pressure source. The channel can be flexible tubing. The pressure source can be a piston movably disposed in a cylinder. There can be a motor, a rack having first teeth and a gear having second teeth. The rack is preferably connected to the piston, the gear is preferably operably connected to the motor, and the first teeth engage with the second teeth to reciprocally move the piston in the cylinder.

The piston can have a sealing member disposed between the piston and the cylinder. The sealing member can be an o-ring disposed on the piston. The piston can have a substantially cylindrical shape with a circumferential wall, and the sealing member can be a plurality of gaskets disposed on the circumferential wall. The piston can have a substantially cylindrical shape with a circumferential wall having a circumferential channel formed therein, and wherein the sealing member is at least partially disposed in the channel. The piston can have a v-shaped cross section with a leading edge and a trailing edge, and wherein the leading edge and the trailing edge form a sealing engagement with the cylinder.

The piston can be flexibly secured to the rack. The piston can have a recess and the rack can have a first end with an abutment formed therein, wherein the abutment is flexibly secured in the recess. The recess and the

first end can have detent structures. The cylinder can have a first diameter and an air hole, wherein the air hole has a second diameter and is in fluid communication with the atmosphere, and wherein the first diameter is significantly larger than the second diameter.

There can also be a controller operably connected to the motor, wherein the motor is reversible and the controller reverses the motor based upon a positive or negative pressure limit. There can be a controller operably connected to the motor, wherein the motor is a reversible motor, wherein the controller determines a distance that the piston has traveled relative to the cylinder and wherein the controller reverses the motor based upon the distance. There can be a photo-sensor that generates a signal in response to the distance, wherein the signal is transmitted to the controller, and wherein the controller reverses the motor in response to the signal.

The rack can have a plurality of openings formed therein, wherein the photo-sensor is operably aligned with the openings, and wherein the signal is generated based upon a count of the openings moving past the photo-sensor. There can also be a position switch, wherein the photo-sensor is operably aligned with the position switch to generate a position signal, wherein the position signal is transmitted to the controller, and wherein the controller resets the count in response to the position signal. There can be a controller operably connected to the motor, wherein the motor has variable speed, and the controller adjusts the speed based upon a desired cycle time for applying the positive or negative pressure to the breast. The controller can have a user interface, the desired cycle time can be inputted into the user interface, and the desired cycle time can be transmitted to the controller from the user interface.

There can be a controller having a user interface and operably connected to the pressure source, wherein the controller adjusts the positive or negative pressure generated by the pressure source in response to a signal transmitted from the user interface. There can also be a controller having a

user interface and operably connected to the pressure source, wherein the controller adjusts a cycle time for applying the positive or negative pressure to the breast in response to a signal transmitted to the controller from the user interface. There can be a controller that generates a wave signal in response to an amount of pressure and a cycle time between the positive and negative pressure, and controls the motor in response to the wave signal. There can be a user interface, wherein a desired wave signal is inputted into the user interface, the desired wave signal is transmitted to the controller from the user interface, and the controller adjusts the wave signal to correspond to the desired wave signal.

The cylinder can be in fluid communication with a pressure relief valve. The pressure relief valve can be adjustable. The pressure source can have a housing with a storage compartment formed therein, and wherein the flexible tubing is removably stored in the storage compartment. The housing can have an air outlet with a first end and a second end, wherein the first end is in fluid communication with the pressure source and the second end is disposed in the storage compartment.

There can be a t-connector having an inlet, a first outlet, a second outlet and a plug, wherein the inlet is in fluid communication with the first and second outlets, and wherein the plug is selectively sealingly engageable with the first outlet or the second outlet. The t-connector can have an outer surface and the plug is tethered to the outer surface. The controller can have a user interface, a desired level of the positive or negative pressure can be inputted into the user interface, and the controller can adjust the positive or negative pressure in response to a signal transmitted from the user interface.

The first gear system can have a first belt and a second belt. The first belt can be non-toothed and the second belt can be toothed. The first belt can be resilient. The first belt can be a plurality of belts. The first gear system can have a first pulley and a second pulley. The first pulley can have a first circumference and a first channel formed along the first circumference. The

second pulley can have a second circumference and a plurality of teeth formed along the second circumference. The first belt can be partially disposed in the first channel and the second belt can engages the plurality of teeth of the second pulley.

The motor can have a drive shaft with an annular channel formed therein. The first belt can be partially disposed in the annular channel. The second pulley can be secured to the pinion gear. The expandable volume can be a cylinder and a piston movable in the cylinder, with the rack gear secured to the piston. The rack gear can be flexibly secured to the piston. The cylinder can have a first diameter and an air hole. The air hole can have a second diameter and be in fluid communication with the atmosphere. The first diameter can be significantly larger than the second diameter.

BRIEF DESCRIPTION OF THE DRAWINGS

Other and further objects, advantages and features of the present invention will be understood by reference to the following:

Fig. 1 is a front perspective view of a breast pump of the breast pump system of the present invention;

Fig. 2 is a front perspective view of the breast pump of Fig. 1 in an opened position;

Fig. 3 is an exploded perspective view of the breast pump of Fig. 1;

Fig. 4 is a top view of the breast pump of Fig. 1 without the cover;

Fig. 5 is an exploded perspective view of a piston and cylinder of the present invention;

Fig. 6 is an exploded side view of a portion of the piston and cylinder of Fig. 5;

Fig. 7 is a front perspective view of the piston of Fig. 5;

Fig. 8 is an exploded perspective view of an alternative embodiment of the piston of the present invention;

Fig. 9 is an exploded perspective view of a pressure relief valve of the system of Fig. 1;

Fig. 10 is a cross-sectional plan view of the cylinder of Fig. 5;

Fig. 11 is a front perspective view of a breast cup of the present invention;

Fig. 12 is a side cross-sectional view of the breast cup of Fig. 11;

Fig. 13 is a rear perspective view of a T-connector of the present invention;

Fig. 14 is a flow chart depicting a method for pumping a breast according to the system of Figs. 1 and 11;

Fig. 15 is a top perspective view of a preferred embodiment of breast pump for the breast pump system of the present invention;

Fig. 16 is a top view of the breast pump of Fig. 15;

Fig. 17 is a top perspective view of the drive system of the breast pump of Fig. 15;

Fig. 18 is a side perspective view of the drive system of Fig. 17;

Fig. 19 is a top perspective view of a portion of the gear reduction system of the drive system of Fig. 15, partially assembled;

Fig. 20 is a top perspective view of an alternative embodiment of breast pump for the breast pump system of the present invention;

Fig. 21 is a top view of the breast pump of Fig. 20;

Fig. 22 is a top perspective view of the drive system of the breast pump of Fig. 20;

Fig. 23 is a side perspective view of the drive system of Fig. 20;

Fig. 24 is a top perspective view of the motor of the drive system of Fig. 20;

Fig. 25 is a top perspective view of a portion of the gear reduction system of the drive system of Fig. 20, partially assembled; and

Fig. 26 is a top perspective view of the gear reduction system of the drive system of Fig. 20, partially assembled.

DESCRIPTION OF THE INVENTION

Referring to the drawings and, in particular, Figs. 1 and 2, there is shown a breast pump of the present invention generally represented by reference numeral 100. Breast pump 100, along with breast cup 400 shown in Fig. 11, form the major components of the breast pump system of the present invention. Breast pump 100 has a top housing 102 and a bottom housing 103 that are adapted to form an assembled unit.

Referring to Figs. 1 through 3, top housing 102 has a substantially ellipsoidal shape with a flat front face 200 and a storage compartment 210 having a compartment door 104. Preferably, door 104 is hingedly connected to top housing 102 to form a selectively sealable storage compartment 210 for storing air tubing or conduit 350 that connects breast pump 100 to the other components of the system, which will be discussed later in greater detail.

Face 200 can receive a button pad 105 having an LED cover 106. Pad 105 is used by the consumer to control breast pump 100. Bottom housing 103 can securely house the various components of the breast pump, which include a rack gear 109, a pinion gear 110 that can engage the rack gear, a piston 112, a cylinder 113 that can receive the piston, and a motor 125 having a shaft 126 upon which the pinion gear is mounted. Due to this design, breast pump 100 provides pumping with low noise. Breast pump 100 can be made of any rigid material, such as, for example, plastic.

Referring to Figs. 3 through 7, breast pump 100 utilizes piston 112 and cylinder 113 to create both a positive pressure and a negative pressure for obtaining breast milk. Piston 112 is driven by rack gear 109, which is affixed thereto. Piston 112 has a substantially cylindrical-shape with a first head 3000 and a second head 3100. First and second heads 3000, 3100 preferably have annular channels 3020, 3120 formed therein, respectively. Channels 3020, 3120 are disposed along the outer circumference of first and second heads 3000, 3100, respectively. Preferably, channels 3020, 3120 are centrally located along the outer circumference of first head 3000 and second

head 3100. Seated in channels 3020, 3120 are sealing members 3050, 3150, respectively. Preferably, sealing members 3050, 3150 are o-ring gaskets. Sealing members 3050, 3150 have a diameter or width that is larger than the depth or height of channel 3020 and channel 3120. Sealing members 3050, 3150 extend beyond the outer circumference of first head 3000 and second head 3100 forming a sealing engagement with an inner surface 1130 of cylinder 113 as piston 112 is driven back and forth in the cylinder.

The use of multiple sealing members, i.e., o-ring gasket 3050 and o-ring gasket 3150 on piston 112, provide a double sealing to increase the efficiency of creating the positive pressure and negative pressure. While this embodiment uses two sealing members to create two separate sealing surfaces, any number of sealing members can be used to create any number of sealing surfaces for sealing piston 112 with cylinder 113. Additionally, while this embodiment uses piston 112 having o-ring sealing gaskets 3050, 3150, alternative sealing structures can be used between the piston and cylinder 113.

Rack gear 109 has teeth 1090 that engage with pinion gear 110 having teeth 1100. Pinion gear 110 is operatively connected to motor 125, preferably via shaft 126. When motor 125 is activated, shaft 126 and pinion gear 110 rotate. Teeth 1090 on rack 109 and teeth 1100 on pinion 110 mesh and translate the reciprocal rotational motion of motor 125 and shaft 126 into a reciprocal longitudinal motion along a single axis in both directions.

Preferably, rack gear 109 has a first end 1095 that engages with a recess 3200 formed in piston 112. Recess 3200 is preferably centrally located in piston 112. First end 1095 of rack gear 109 preferably has a snap fit or friction fit engagement with recess 3200 of piston 112. Preferably, there are detent structures 1096, 3296 formed on first end 1095 and recess 3200, respectively. This facilitates production of these components and also provides for any slight pivotal movement that may be required of piston 112 with respect to rack gear 109.

An alternative embodiment of a piston is shown in Fig. 8 and generally represented by reference numeral 8112. Piston 8112 has a substantially V-shape with a leading edge 8120 and a trailing edge 8121. Leading edge 8120 and trailing edge 8121 sealingly engage an inner surface 1130 of cylinder 113 as piston 8112 is driven back and forth in the cylinder. The use of multiple edges, i.e., leading edge 8120 and following edge 8121, on piston 8112 that sealingly engage inner surface 1130 of cylinder 113, provide a double sealing to increase the efficiency of creating the positive pressure and negative pressure.

Referring to Figs. 3 through 7, motor 125 is preferably variable speed. This allows a user to control and vary the cycle time of the pumping of the breast. Breast pump 100 further has a motor cover 107 and a bearing 108 to reduce vibration and to secure motor 125 to bottom housing 103.

The positive and negative pressures can be varied by changing the displacement of air volume in cylinder 113. In this embodiment, this is done by use of a photoelectric or photo-sensor system. The photo-sensor system has two or more photo-sensors 121 and a position switch 124. The photo-sensors 121 count the number of openings 50 on rack gear 109, as the rack gear moves back and forth. Thus, a user can control the distance that rack gear 109 travels and correspondingly control the air volume displacement in cylinder 113.

To ensure that piston 112 is properly moving to the front of cylinder 113, the photo-sensor system further includes position switch 124, preferably located at the front of the cylinder, which acts as a starter for the counter. Alternatively, the position switch can be an opening 50 having a different size or shape that is detectable by photo-sensor 121.

Rack gear 109 can also have a safety mechanism attached thereto. Photo-sensor 121 will be reading openings 50 as rack gear 109 moves backwards. If for some reason rack gear 109 misses its target and moves too far, the safety will trigger the position switch. When the position switch is

triggered while rack gear 109 is moving backwards, the software can trigger the system to move forward again and return to the position position.

Breast pump 100 has a guide cover 111 positioned over rack gear 109. Guide cover 111 provides added stability to the breast pump by guiding and vibration dampening the reciprocal movement of rack gear 109. Guide cover 111 also provides accuracy to the photo-sensor system by reducing the risk of misalignment of photo-sensors 121 and openings 50.

The photo-sensor system and motor 125 are preferably connected to a PC or circuit board 120. Thus, the distance piston 112 travels, which translates to the amount of positive and negative pressure, and the piston speed, which translates to the cycle time, are electronically controlled.

Referring to Figs. 15 through 19, a preferred embodiment of a drive system of the present invention is shown and generally represented by reference numeral 1500. Drive system 1500 is usable with breast pump 100 of Figs. 1 through 7 to provide the linear reciprocal movement of piston 112 with cylinder 113.

Drive system 1500 is a belt drive system for a rack and pinion drive having gear reduction incorporated therein. Drive system 1500 has a first drive wheel or pulley 1510; a second gear, drive wheel or pulley 1520 secured to the first drive wheel 1510; a third gear, drive wheel or pulley 4530; and a pinion gear 1540 secured to the third gear.

First drive wheel 1510 is operably connected to motor drive shaft 126 by a first belt 1550. In the preferred embodiment, first belt 1550 is a non-toothed belt. More preferably, first belt 1550 has resiliency or flexibility. The use of flexible or resilient belt 1550 provides a secure connection between drive shaft 126 and first drive wheel 1510 and also reduces noise and vibration. Drive shaft 126 and first drive wheel 1510 have smooth outer surfaces upon which the first belt 1550 is secured.

First drive wheel 1510 is operably connected to second gear 1520 by a first co-axial shaft 1515. In the preferred embodiment, first shaft 1515 is

rotatably mounted between opposing first bearings 1517. However, alternative rotatable mounting arrangements or securing structures could also be used. To reduce noise and vibration, motor shaft 126 and first drive wheel 1510 are made of metal. First drive wheel 1510 and second gear 1520 have different diameters that partially provide for gear reduction between motor shaft 126 and pinion gear 1540.

Second gear 1520 is operably connected to third gear 1530 by a second belt 1570. Preferably, second belt 1570 has teeth 1575 that mesh with teeth 1580 formed along the circumference of second gear 1520 and third gear 1530. Second and third gears 1520, 1530 have different diameters that partially provide for gear reduction between motor shaft 126 and pinion gear 1540. Drive system 1500 can also have a tension pulley 1580 that provides tension to second belt 1570.

Third gear 1530 is operably connected to pinion gear 1540 by a second co-axial shaft 1535. In the preferred embodiment, second shaft 1535 is rotatably mounted between opposing second bearings 1537. However, alternative rotatable mounting arrangements or securing structures could also be used. Preferably, third gear 1530 is integrally molded with pinion gear 1540 along second shaft 1535.

Pinion gear 1540 has teeth 1545 that engage with teeth 1090 of rack gear 109. When motor 125 is activated, the rotational motion of shaft 126 is translated into a reciprocal longitudinal motion along a single axis of rack gear 109 in both directions. Drive system 1500, through use of first and second belts 1550, 1570 and first, second and third drive wheels or gears 1510, 1520, 1530, is able to provide a desired ratio of movement between motor shaft 126 and pinion gear 1540, i.e., gear reduction.

The use of a combination of the non-toothed belt 1550 and the toothed belt 1570 reduces noise and vibration, while maintaining a secure, sturdy drive system 1500 that is able to provide the necessary back and forth linear motion at the desired speeds and pressure for breast pump 100.

Referring to Figs. 20 through 26, an alternative embodiment of a drive system of the present invention is shown and generally represented by reference numeral 4500. Drive system 4500 is also usable with breast pump 100 of Figs. 1 through 7 to provide the linear reciprocal movement of piston 112 with cylinder 113.

Drive system 4500 is a belt drive system having gear reduction incorporated therein. Drive system 4500 has a first gear, drive wheel or pulley 4510; a second gear, drive wheel or pulley 4520 secured to the first gear; a third gear, drive wheel or pulley 4530; and a pinion gear 4540 secured to the third gear.

First gear 4510 is operably connected to motor drive shaft 126 by a first belt 4550. In the preferred embodiment, first belt 4550 is a plurality of belts, and more preferably, three belts. First belts 4550 are preferably non-toothed belts. More preferably, first belts 4550 are o-rings having resiliency or flexibility. The use of flexible or resilient belts 4550, such as, for example, o-rings, provides a secure connection between drive shaft 126 and first gear 4510, and also reduces noise and vibration. Drive shaft 126 and first gear 4510 have annular channels 4555, 4560, formed therein, respectively. Annular channels 4555, 4560 are guides that assist in holding first belts 4550 in place and facilitate assembly of drive system 4500.

First gear 4510 is operably connected to second gear 4520 by a first co-axial shaft 4515. In this alternative embodiment, first shaft 4515 is rotatably mounted between opposing first bearings 4517. However, alternative rotatable mounting arrangements or securing structures could also be used. To reduce noise and vibration, motor shaft 126 and first gear 4510 are made of metal. First and second gears 4510, 4520 have different diameters that partially provide for gear reduction between motor shaft 126 and pinion gear 4540.

Second gear 4520 is operably connected to third gear 4530 by a second belt 4570. Preferably, second belt 4570 has teeth 4575 that mesh

with teeth 4580 formed along the circumference of second gear 4520 and third gear 4530. Second and third gears 4520, 4530 have different diameters that partially provide for gear reduction between motor shaft 126 and pinion gear 4540. Drive system 4500 can also have a tension pulley 4580 that provides tension to second belt 4570.

Third gear 4530 is operably connected to pinion gear 4540 by a second co-axial shaft 4535. In this alternative embodiment, second shaft 4535 is rotatably mounted between opposing second bearings 4537. However, alternative rotatable mounting arrangements or securing structures could also be used. Preferably, third gear 4530 is integrally molded with pinion gear 4540 along second shaft 4535.

Pinion gear 4540 has teeth 4545 that engage with teeth 1090 of rack gear 109. When motor 125 is activated, the rotational motion of shaft 126 is translated into a reciprocal longitudinal motion along a single axis of rack gear 109 in both directions. Drive system 4500, through use of first and second belts 4550, 4570 and first, second and third gears 4510, 4520, 4530, is able to provide a desired ratio of movement between motor shaft 126 and pinion gear 4540, i.e., gear reduction.

The use of a combination of the non-toothed o-ring belts 4550 and the toothed belt 4570 reduces noise and vibration, while maintaining a secure, sturdy drive system 4500 that is able to provide the necessary back and forth linear motion at the desired speeds and pressure for breast pump 100.

The embodiments of the drive systems 1500 and 4500 described above utilize belts for gear reduction. However, alternative embodiments can use a gear-box that reduces the gearing to the desired ratio that is transferred to the rack and pinion gearing that drives breast pump 100.

Referring back to Figs. 3 through 9, cylinder 113 has a supply tube 116 that is secured to a supply connector 115 for supplying the positive and negative pressure to breast cup 400. Preferably, supply connector has an outlet 215 disposed in storage compartment 210. Air tubing 350 can be

secured to outlet 215 and also secured to breast cup 400. Storage compartment 210 can be opened or closed during the pumping operation. Cylinder 113 is in fluid communication with a pressure relief valve 2000 (shown in Fig. 9) that is preferably set at about 1.5 in. Hg.

Pressure relief valve 2000 has an intake 2010 and an exhaust 2050. Intake 2010 is in fluid communication with cylinder 113 and exhaust 2050 is in fluid communication with breast cup 400, by tubing 350. Pressure relief valve 2000 has a relief exhaust 2100 that is in fluid communication with intake 2010 and exhaust 2050. Relief exhaust 2100 is substantially tubular and is secured to a relief assembly 2200.

Relief assembly 2200 has a flexible insert 2210, a biasing member 2220 and a retaining member 2230. Flexible insert 2210 sealing engages with the inner surface of relief exhaust 2100 to prevent air from exiting through the relief exhaust. Insert 2210 has a securing member 2215 that mates with biasing member 2200. In this embodiment, securing member 2215 is a cross-shaped structure that is received in the inner volume of biasing member 2200. Preferably, biasing member 2200 is a spring. More preferably, biasing member 2200 is a coil spring. Retaining member 2230 is a cap-like structure having opposing retaining arms 2235 that engage with a corresponding pair of engaging protrusions 2105 positioned on the outer surface of relief exhaust 2100. Insert 2210 and spring 2220 are held in the inner volume of relief exhaust 2100 by cap 2230.

Spring 2220 has a biasing strength or resistance that is equal to the relief pressure of relief pressure valve 2000. When a positive pressure exceeds the relief pressure, which in this embodiment is preferably set at about 1.5 in. Hg, the force created on the inner surface of insert 2210 overcomes the biasing force of spring 2220 and the insert moves toward cap 2230 and outside of the inner volume of relief exhaust 2100. Air exits pressure relief valve 2000 through relief exhaust 2100 until the positive pressure in the pressure relief valve decreases below the biasing strength of

spring 2220, at which time insert 2210 moves back in the inner volume of the relief exhaust, sealingly engaging the inner surfaces of the relief exhaust.

Alternatively, the pressure relief valve can be made adjustable so that the "massage strength", i.e., the amount of positive pressure on the user's breast, can be controlled. Circuit board 120, shown in Fig. 3, allows a user to program several levels of speed and several levels of suction.

In this embodiment, the speed (cycle time) ranges from about 45 cycles/minute (cpm) to about 75 cpm. The present invention provides for pre-set programming of a number of speed levels within the speed range. Preferably, the number of levels can be from about two to about eight levels. More preferably, the user can program five levels of speeds within the speed range. The present invention also envisions programming of the speed levels by the user.

The suction range for use with a single breast cup 400 and the preferred drive system 1500 shown in Figs. 15 through 21, is from about 3 in. Hg to about 10 in. Hg, and from about 3 in. Hg to about 8 in. Hg for two breast cups. The suction range for use with a single breast cup 400 and the gear box system shown in Figs. 3 and 4 is from about 3 in. Hg to about 9 in. Hg, and from about 3 in. Hg to about 8 in. Hg for two breast cups. The present invention provides for pre-set programming of a number of suction levels within the suction range. Preferably, the number of levels can be from about two to about eight levels. More preferably, the user can program five levels of suction within the suction range. The present invention also envisions programming of the suction levels by the user.

Computer software can also be used to control the amount of positive and negative pressure. This allows the amounts of positive and negative pressure to be personalized for the user and also varied over the duration of the pumping process to maximize efficiency.

Breast pump 100 is preferably controlled by a software-driven circuit board 120, along with a gear motor 125, a rack and pinion set 109, 110, and a

piston system 112, 113. The software and system are designed to provide maximum flexibility and to facilitate changing of the pressure curve or "wave." This is feasible because the software controls the speed of motor 120 and the distance that piston 112 will travel in cylinder 113. The distance piston 112 travels relates to the pressure levels. By controlling speed and pressure levels with software, the pressure curve or "wave" can be controlled.

Once a determination is made that there is a specific "wave" or pressure curve that is similar to the sucking of an infant or most comfortable to the mother, then the desired wave can be obtained by changing the timing (motor speed and piston distance). Through use of software, a user has the ability to apply memory to a particular pressure curve and the variation of that pressure curve over time so as to maximize the comfort for the user.

In this embodiment, a sine wave is used for the control of breast pump 100. This is based on the assumption that the most comfortable pressure curve would be one that increases and decreases in pressure gradually, similar to a sine wave, without sharp pressure peaks and valleys providing a pinching feeling on the user. The back and forth motion of piston 112 approximates the desired sine wave. However, to avoid sharp pressure peaks, the timing of piston 112 is slowed down at these peaks, and the pressure is held constant for a duration of time at the maximum and minimum suction points on the wave. This results in a pressure curve having a steady sine wave that is more comfortable to the user.

Alternative waves can also be used for the pressure curve if such a wave is determined to be desired by the mother. For example, if a mother prefers a "saw tooth" pressure curve with sharp peaks, the timing of piston 112 can be changed to simply cycle back and forth, minimizing the pause when piston 112 changes direction. Also, for example, if a mother prefers a "square curve", the timing of piston 112 can be changed to hold the piston position when the piston is ready to change direction, and then quickly ramp

down and hold its position again before it ramps back up. This will create a "square curve" wave.

Use of software control provides for numerous choices of waves or pressure curves. This further allows the flexibility to change or offer greater choice with one breast pump 100. In contrast, contemporary pumps have the drawback of not allowing the flexibility of changing pressure curve waves.

Cylinder 113 has a pressure differential hole 75. Preferably, pressure differential hole 75 is located along bottom face 80 of cylinder 113. Pressure differential hole 75 is substantially smaller than exhaust hole 1013 and supply tube 116 through which the air flows for generating the positive and negative pressure. Pressure differential hole 75 provides a variance in the amount of positive pressure as compared to the amount of negative pressure. Pressure differential hole 75 is effective for the higher ranges of vacuum to provide the "lost" air at the end of the vacuum stroke. On the positive pressure stroke, a small amount of air will be released through pressure differential hole 75 but the air will be reintroduced during the negative pressure stroke when the level of pressure is higher.

Referring to Fig. 10, cylinder 113 is formed as a zero- draft cylinder. The outer diameter of piston 112 creates a seal with the inner diameter d of cylinder 113 to move the volume of air inside the cylinder, creating vacuum and pressure on the breast. Breast pump 100 requires a cylinder 113 that has a consistent inner diameter d through the entire length of the cylinder to create an appropriate seal while minimizing interference or resistance to piston 112. Typical injection molded parts require a draft angle that would create a non-uniform inner diameter d of cylinder 113.

Cylinder 113 is preferably molded as a zero-draft cylinder that provides a uniform inner diameter d and more preferably, molded in a single piece. As shown in Fig. 10, cylinder 113 is a one piece, plastic injection molded part. A two-part cylinder or a machined-cylinder have drawbacks which the single piece, zero draft cylinder 133 overcomes. The two-part cylinder requires an

extruded tube attached to an end cap, with the two parts joined using a weld or using an adhesive. The machined part is typically a metal tube. One of the advantages to the zero-draft, one-piece cylinder 113 is that it is injection moldable.

Referring to Figs. 3 through 10, button pad 105 is the user interface or control mechanism for breast pump 100. Button pad 105 has a pair of positive and negative keys for increasing or decreasing the level of suction and speed. Pad 105 further includes an on/off switch.

Due to the reciprocal back and forth motion of piston 112 in cylinder 113, breast pump 100 supplies both a positive pressure and a negative pressure to a woman's breast through a single hose or tubing 350. While this embodiment uses a piston/cylinder mechanism to create positive and negative pressure, alternative expandable volumes or pressure sources can also be used. Such alternative embodiments include a bellows mechanism or a diaphragm that would require fewer parts.

Referring to Figs. 11 and 12, Breast Cup 400 of the present invention is shown. An example of breast cup 400 is disclosed in the co-pending and commonly owned U.S. Application Serial No. 10/331,183, filed December 27, 2002, the disclosure of which is incorporated herein by reference. Breast cup 400 has a housing 500 having an air orifice 560, a flexible insert 600, and a holder 700. Housing 500 is a rigid structure and flexible insert 600 is a flexible structure. Housing 500 is adapted for sealing engagement with insert 600 to form a displacement volume 510 between the housing and the insert. Air orifice 560 is in fluid communication with displacement volume 510.

Breast pump 100 is placed in fluid communication with breast cup 400 via air tubing 350 that is connected to air orifice 560 and in fluid communication with cylinder 113. Breast pump supplies both a positive and negative pressure to breast cup 400. The positive and negative pressure created by breast pump 100 causes air to flow through air orifice 560 into and out of displacement volume 510. The positive and negative pressure supplied

to breast cup 400 causes flexible insert 600 and, in particular, displacement volume 510 to expand and contract to apply reciprocating positive and negative forces on the user's breast.

Breast pump 100 and breast cup 400 are able to apply both a positive and a negative pressure to a user's breast through a single air tubing 350, which is connected to air orifice 560.

The volume disposed in displacement volume 510 is preferably between 22 to 52 cubic centimeters, and more preferably between 32 to 42 cubic centimeters. The expandable and contractible displacement volume 510 provides an upper limit to the amount of negative pressure that can be applied to a user's breast, which can further serve as a safety feature in use of breast pump 100. Additionally, the sealing engagement of insert 600 and housing 500 provides a barrier between the user's breast and breast pump 100 to prevent any breast milk from entering air tubing 350 or the breast pump.

While the preferred embodiment of the breast pump system uses breast cup 400 having a displacement volume 510 in fluid isolation from the user's breast, alternative breast cups can also be used with breast pump 100. The unique features of the breast pump system of the present invention can be used with other types of breast cups, such as, for example, the control system of the present invention or the rack and pinion driving mechanism.

Referring to Fig. 13, T-connector 300 is a triangular shaped valve that allows a user to utilize either a single breast cup 400 or two breast cups through use of a first orifice 310 and a second orifice 320. Breast pump 100 is connected to t-connector 300 through air tubing 350 at inlet 330. The single split valve configuration of t-connector 300 minimizes the amount of tubing 350 necessary for double pumping. T-connector 300 has a plug 340 for closing off either of first or second orifices 310, 320 if single pumping is desired. Preferably, plug 340 is tethered to an outer surface of t-connector 300 to facilitate engagement with first or second orifices 310, 320.

Referring to Fig. 14, a method of expressing breast milk according to the breast pump system of the present invention, is shown. The user commences the breast pumping operation by turning breast pump 100 "on," as in step 800. This causes power to be supplied to breast pump 100 (step 810). The user then inputs the cycle time and suction level that is desired, as in step 820. In the preferred embodiment, the user has five cycle times and suction levels from which to choose. The cycle time and suction level is inputted by use of button pad 105.

In step 830, PC board 120 sets the motor speed and target piston travel distance according to the user's inputted levels for cycle time and suction. The cycle time and suction level are then displayed to the user, as in step 840. In this embodiment, the cycle time and suction level are indicated by lights 225 with the number of illuminated lights corresponding to the level. In step 850, motor 125 is actuated causing piston 112 to move toward bottom 175 of cylinder 113. This creates a positive pressure that is supplied to breast cup 400 by air tubing 350.

In step 855, the PC Board monitors the home switch to determine whether it has been triggered by contact with piston 112. In step 860, it is determined whether the home switch has been triggered. If the home switch has been triggered then it is reset as in step 870. In step 880, motor 125 is then reversed causing piston 112 to move toward top 180 of cylinder 113. This creates a negative pressure that is supplied to breast cup 400 by air tubing 350. One of the advantages of the breast pump system of the present invention is that is supplies both a positive pressure and a negative pressure through the same air tubing 350. This reduces cleaning and simplifies the operation for a user.

To provide the proper amount of suction as inputted by the user, photo-sensors 121 count the number of rack openings 50, as in step 890. In step 900, PC board 120 determines if the number of rack openings 50 that have been counted is the equivalent of the target piston travel distance as inputted

by the user. In step 910, it is determined whether breast pump 100 is still "on." If breast pump 100 has been shut off then the pumping operation ends, as in step 915.

In step 920, it is determined whether the user has inputted a new cycle time or suction level. If a new cycle time or suction level has been inputted, then PC Board 120 sets the motor speed and target piston travel distance according to the user's inputted levels for cycle time and suction, reverting back to step 830 and repeating the above described steps. If the user has not inputted a new cycle time or suction level then the motor is again reversed causing piston 112 to move toward bottom 175 of cylinder 113. This creates a positive pressure that is supplied to breast cup 400 by air tubing 350. The process continues with breast pump 100 supplying positive pressure and then negative pressure to breast cup 400 until the breast pump is shut off (step 910).

The breast pump system of the present invention includes a number of components and can be used in remote locations, such as when a user is traveling. The various components can be disposed within a bag system for ease of use. An example of such a bag system, as well as the components of such a system, is disclosed in the co-pending and commonly owned U.S. Application Serial No. 10/331,130, filed December 27, 2002, the disclosure of which is incorporated herein by reference.

The present invention having been thus described with particular reference to the preferred forms thereof, it will be obvious that various changes and modifications may be made therein without departing from the spirit and scope of the present invention as defined in the appended claims.

WHAT IS CLAIMED IS:

1. A breast pump system for expressing breast milk from a breast, the system comprising:

a pressure source for generating a positive pressure and a negative pressure; and

a breast cup in fluid communication with said pressure source, wherein said breast cup applies said positive pressure and said negative pressure to said breast.

2. The system of claim 1, further comprising a channel, wherein said breast cup has an air orifice, wherein said channel is connected to said air orifice and said pressure source, and wherein said pressure source supplies reciprocating air flow through said channel between said breast cup and said pressure source.

3. The system of claim 2, wherein said channel is flexible tubing.

4. The system of claim 2, wherein said pressure source is a piston movably disposed in a cylinder.

5. The system of claim 4, further comprising a motor, a rack having first teeth and a gear having second teeth, wherein said rack is connected to said piston, said gear is operably connected to said motor, and said first teeth engage with said second teeth to reciprocally move said piston in said cylinder.

6. The system of claim 4, wherein said piston has a sealing member disposed between said piston and said cylinder.

7. The system of claim 6, wherein said sealing member is an o-ring disposed on said piston.

8. The system of claim 6, wherein said piston has a substantially cylindrical shape with a circumferential wall, and said sealing member is a plurality of gaskets disposed on said circumferential wall.

9. The system of claim 6, wherein said piston has a substantially cylindrical shape with a circumferential wall having a circumferential channel formed therein, and wherein said sealing member is at least partially disposed in said channel.

10. The system of claim 4, wherein said piston has a v-shaped cross section with a leading edge and a trailing edge, and wherein said leading edge and said trailing edge form a sealing engagement with said cylinder.

11. The system of claim 5, wherein said piston is flexibly secured to said rack.

12. The system of claim 11, wherein said piston has a recess and said rack has a first end with an abutment formed therein, and wherein said abutment is flexibly secured in said recess.

13. The system of claim 12, wherein said recess and said first end have detent structures.

14. The system of claim 5, wherein said cylinder has a first diameter and an air hole, wherein said air hole has a second diameter and is in fluid communication with said atmosphere, and wherein said first diameter is significantly larger than said second diameter.

15. The system of claim 5, further comprising a controller operably connected to said motor, wherein said motor is reversible and said controller reverses said motor based upon a positive or negative pressure limit.

16. The system of claim 5, further comprising a controller operably connected to said motor, wherein said motor is a reversible motor, wherein said controller determines a distance that said piston has traveled relative to said cylinder and wherein said controller reverses said motor based upon said distance.

17. The system of claim 16, further comprising a photo-sensor that generates a signal in response to said distance, wherein said signal is transmitted to said controller, and wherein said controller reverses said motor in response to said signal.

18. The system of claim 17, wherein said rack has a plurality of openings formed therein, wherein said photo-sensor is operably aligned with said openings, and wherein said signal is generated based upon a count of said openings moving past said photo-sensor.

19. The system of claim 18, further comprising a position switch, wherein said photo-sensor is operably aligned with said position switch to generate a position signal, wherein said position signal is transmitted to said controller, and wherein said controller resets said count in response to said position signal.

20. The system of claim 5, further comprising a controller operably connected to said motor, wherein said motor has variable speed, and said controller adjusts said speed based upon a desired cycle time for applying said positive or negative pressure to said breast.

25

21. The system of claim 20, wherein said controller has a user interface, said desired cycle time is inputted into said user interface, and said desired cycle time is transmitted to said controller from said user interface.

22. The system of claim 1, further comprising a controller having a user interface and operably connected to said pressure source, wherein said controller adjusts the positive or negative pressure generated by the pressure source in response to a signal transmitted from said user interface.

23. The system of claim 1, further comprising a controller having a user interface and operably connected to said pressure source, wherein said controller adjusts a cycle time for applying said positive or negative pressure to said breast in response to a signal transmitted to said controller from said user interface.

24. The system of claim 5, further comprising a controller that generates a wave signal in response to an amount of pressure and a cycle time between said positive and negative pressure, and controls said motor in response to said wave signal.

25. The system of claim 24, further comprising a user interface, wherein a desired wave signal is inputted into said user interface, said desired wave signal is transmitted to said controller from said user interface, and said controller adjusts said wave signal to correspond to said desired wave signal.

26. The system of claim 4, wherein said cylinder is in fluid communication with a pressure relief valve.

27. The system of claim 26, wherein said pressure relief valve is adjustable.

28. The system of claim 3, wherein said pressure source has a housing with a storage compartment formed therein, and wherein said flexible tubing is removably stored in said storage compartment.

29. The system of claim 28, wherein said housing has an air outlet with a first end and a second end, wherein said first end is in fluid communication with said pressure source and said second end is disposed in said storage compartment.

30. The system of claim 1, further comprising a t-connector having an inlet, a first outlet, a second outlet and a plug, wherein said inlet is in fluid communication with said first and second outlets, and wherein said plug is selectively sealingly engageable with said first outlet or said second outlet.

31. The system of claim 30, wherein said t-connector has an outer surface and said plug is tethered to said outer surface.

32. A breast pump system for expressing breast milk from a breast, the system comprising:

a cylinder having a cylinder volume;

a piston movably disposed in said cylinder;

a motor operably connected to said piston to generate a pressure in said cylinder volume; and

a breast cup in fluid communication with said cylinder volume, wherein said breast cup applies said pressure to said breast.

33. The system of claim 32, further comprising a channel, wherein said breast cup has an air orifice, wherein said channel is connected to said air orifice and said cylinder volume, and wherein said cylinder volume supplies reciprocating air flow through said channel.

34. The system of claim 33, wherein said channel is flexible tubing.

35. The system of claim 32, further comprising a rack having first teeth and a gear having second teeth, wherein said rack is connected to said piston, said gear is operably connected to said motor, and said first teeth engage with said second teeth to reciprocally move said piston in said cylinder.

36. The system of claim 32, wherein said piston has a sealing member disposed between said piston and said cylinder.

37. The system of claim 36, wherein said sealing member is an o-ring disposed on said piston.

38. The system of claim 36, wherein said piston has a substantially cylindrical shape with a circumferential wall, and said sealing member is a plurality of gaskets disposed on said circumferential wall.

39. The system of claim 36, wherein said piston has a substantially cylindrical shape with a circumferential wall having a circumferential channel formed therein, and wherein said sealing member is at least partially disposed in said channel.

40. The system of claim 32, wherein said piston has a v-shaped cross section with a leading edge and a trailing edge, and wherein said leading edge and said trailing edge form a sealing engagement with said cylinder.

41. The system of claim 35, wherein said piston is flexibly secured to said rack.

42. The system of claim 41, wherein said piston has a recess and said rack has a first end with an abutment formed therein, and wherein said abutment is flexibly secured in said recess.

43. The system of claim 42, wherein said recess and said first end have detent structures.

44. The system of claim 32, wherein said cylinder has a first diameter and an air hole, said air hole has a second diameter and is in fluid communication with said atmosphere, and said first diameter is significantly larger than said second diameter.

45. The system of claim 32, further comprising a controller operably connected to said motor, wherein said motor is reversible and said controller reverses said motor based upon a pressure limit.

46. The system of claim 35, further comprising a controller operably connected to said motor, wherein said motor is reversible, wherein said controller determines a distance that said piston has traveled relative to said cylinder and wherein said controller reverses said motor based upon said distance.

47. The system of claim 46, further comprising a photo-sensor that generates a signal in response to said distance, wherein said signal is transmitted to said controller.

48. The system of claim 47, wherein said rack has a plurality of openings formed therein, wherein said photo-sensor is operably aligned with said openings, and wherein said signal is generated based upon a count of said openings moving past said photo-sensor.

49. The system of claim 48, further comprising a position switch, wherein said photo-sensor is operably aligned with said position switch to generate a position signal, wherein said position signal is transmitted to said controller, and wherein said controller resets said count in response to said position signal.

50. The system of claim 32, further comprising a controller operably connected to said motor, wherein said motor is variable speed and said controller adjusts said speed based upon a desired cycle time for applying said pressure to said breast.

51. The system of claim 50, wherein said controller has a user interface, said desired cycle is inputted into said user interface, and said desired cycle time is transmitted to said controller from said user interface.

52. The system of claim 32, further comprising a controller having a user interface and operably connected to said motor, wherein said controller adjusts the pressure generated in said cylinder volume in response to a signal transmitted from said user interface.

53. The system of claim 32, further comprising a controller having a user interface and operably connected to said motor, wherein said controller adjusts a desired cycle time for applying said pressure to said breast in response to a signal transmitted to said controller from said user interface.

54. The system of claim 32, further comprising a controller that generates a wave signal in response to an amount of pressure and a cycle time for said pressure, and controls said motor in response to said wave signal.

55. The system of claim 54, further comprising a user interface, wherein a desired wave signal is inputted into said user interface, said desired wave signal is transmitted to said controller from said user interface, and wherein said controller adjusts said wave signal to correspond to said desired wave signal.

56. The system of claim 32, wherein said cylinder is in fluid communication with a pressure relief valve.

57. The system of claim 56, wherein said pressure relief valve is adjustable.

58. The system of claim 34, further comprising a housing having a storage compartment, wherein said motor, said piston and said cylinder are disposed in said housing, and wherein said flexible tubing is removably stored in said storage compartment.

59. The system of claim 58, wherein said housing has an air outlet with a first end and a second end, wherein said first end is in fluid communication with said cylinder volume and said second end is disposed in said storage compartment.

60. The system of claim 32, further comprising a t-connector having an inlet, a first outlet, a second outlet and a plug, wherein said inlet is in fluid communication with said first and second outlets, and wherein said plug is selectively sealingly engageable with said first outlet or said second outlet.

61. The system of claim 60, wherein said t-connector has an outer surface and said plug is tethered to said outer surface.

62. A breast pump for expressing breast milk from a breast, the pump comprising:

a pressure source for generating a positive pressure and a negative pressure; and

a controller operably connected to the pressure source, wherein said controller adjusts said positive and negative pressure and adjusts a cycle time between application of said positive and negative pressure to said breast.

63. The pump of claim 62, wherein said controller has a user interface, a desired cycle time is inputted into said user interface, said desired cycle time is transmitted to said controller from said user interface, and said controller adjusts said cycle time to correspond to said desired cycle time.

64. The pump of claim 62, wherein said controller has a user interface, a desired level of said positive or negative pressure is inputted into said user interface, and said controller adjusts said positive or negative pressure in response to a signal transmitted from said user interface.

65. The pump of claim 62, wherein said controller generates a wave signal in response to said pressure and said cycle time, and controls said pressure source in response to said wave signal.

66. The pump of claim 65, further comprising a user interface, wherein a desired wave signal is inputted into said user interface, said desired wave signal is transmitted to said controller from said user interface, and said controller adjusts said wave signal to correspond to said desired wave signal.

67. A breast pump for expressing breast milk from a breast, the pump comprising:

a pressure source for generating a pressure; and

a controller operably connected to the pressure source, wherein said controller adjusts said pressure and adjusts a cycle time between application of said pressure to said breast, and wherein said controller generates a wave signal in response to said pressure and said cycle time, and controls said pressure source in response to said wave signal.

68. The pump of claim 67, further comprising a user interface, wherein a desired wave signal is inputted into said user interface, said desired wave signal is transmitted to said controller from said user interface, and said controller adjusts said wave signal to correspond to said desired wave signal.

69. A drive system for an expandable volume of a breast pump, the system comprising:

a motor having a first rotary output;

a first gear system operably connected to said motor; and

a second gear system operably connected to said first gear system and the expandable volume, said second gear system having a rack gear and a pinion gear operably connected to said rack gear,

wherein said first rotary output is provided to said second gear system,

wherein said first gear system adjusts said first rotary output provided to said second gear system to a second rotary output, and

wherein said second gear system translates said second rotary output to a linear output.

70. The drive system of claim 69, wherein said first gear system has at least one belt.

71. The drive system of claim 70, wherein said at least one belt is a first belt and a second belt.

72. The drive system of claim 71, wherein said first belt is non-toothed and said second belt is toothed.

73. The drive system of claim 72, wherein said first belt is resilient.

74. The drive system of claim 73, wherein said first belt is a plurality of belts.

75. The drive system of claim 74, wherein said motor has a drive shaft with an annular channel formed therein, and wherein said first belt is partially disposed in said annular channel.

76. The drive system of claim 72, wherein said first gear system further comprises a first pulley and a second pulley, said first pulley having a first circumference and a first channel formed along said first circumference, said second pulley having a second circumference and a plurality of teeth formed along said second circumference, wherein said first belt is partially disposed in said first channel, and wherein said second belt engages said plurality of teeth of said second pulley.

77. The drive system of claim 76, wherein said second pulley is secured to said pinion gear.

78. A breast pump for supplying a pressure to a breast cup, said pump comprising:

an expandable volume in fluid communication with said breast cup to supply said pressure;

a motor having a first rotary output;

a first gear system operably connected to said motor; and

a second gear system operably connected to said first gear system and said expandable volume, said second gear system having a rack gear and a pinion gear operably connected to said rack gear,

wherein said first rotary output is provided to said second gear system,

wherein said first gear system adjusts said first rotary output provided to said second gear system to a second rotary output, and

wherein said second gear system translates said second rotary output to a linear output.

79. The drive system of claim 78, wherein said first gear system has at least one belt.

80. The drive system of claim 79, wherein said at least one belt is a first belt and a second belt.

81. The drive system of claim 80, wherein said first belt is non-toothed and said second belt is toothed.

82. The drive system of claim 81, wherein said first belt is resilient.

83. The drive system of claim 81, wherein said first belt is a plurality of belts.

84. The drive system of claim 83, wherein said motor has a drive shaft with an annular channel formed therein, and wherein said first belt is partially disposed in said annular channel.

85. The drive system of claim 81, wherein said first gear system further comprises a first pulley and a second pulley, said first pulley having a first circumference and a first channel formed along said first circumference,

said second pulley having a second circumference and a plurality of teeth formed along said second circumference, wherein said first belt is partially disposed in said first channel, and wherein said second belt engages said plurality of teeth of said second pulley.

86. The drive system of claim 85, wherein said second pulley is secured to said pinion gear.

87. The breast pump of claim 78, wherein said expandable volume comprises a cylinder and a piston movable in said cylinder, and wherein said rack gear is secured to said piston.

88. The breast pump of claim 87, wherein said rack gear is flexibly secured to said piston.

89. The breast pump of claim 87, wherein said cylinder has a first diameter and an air hole, said air hole has a second diameter and is in fluid communication with said atmosphere, and said first diameter is significantly larger than said second diameter.

90. The breast pump of claim 87, further comprising a controller operably connected to said motor, wherein said motor is reversible, wherein said controller determines a distance that said piston has traveled relative to said cylinder, and wherein said controller reverses said motor based upon said distance.

91. The breast pump of claim 78, further comprising a controller operably connected to said motor, wherein said motor is reversible and said controller reverses said motor based upon a pressure limit.

92. The breast pump of claim 78, further comprising a controller operably connected to said motor, wherein said motor is variable speed and said controller adjusts said speed based upon a desired cycle time for supplying said pressure to said breast cup.

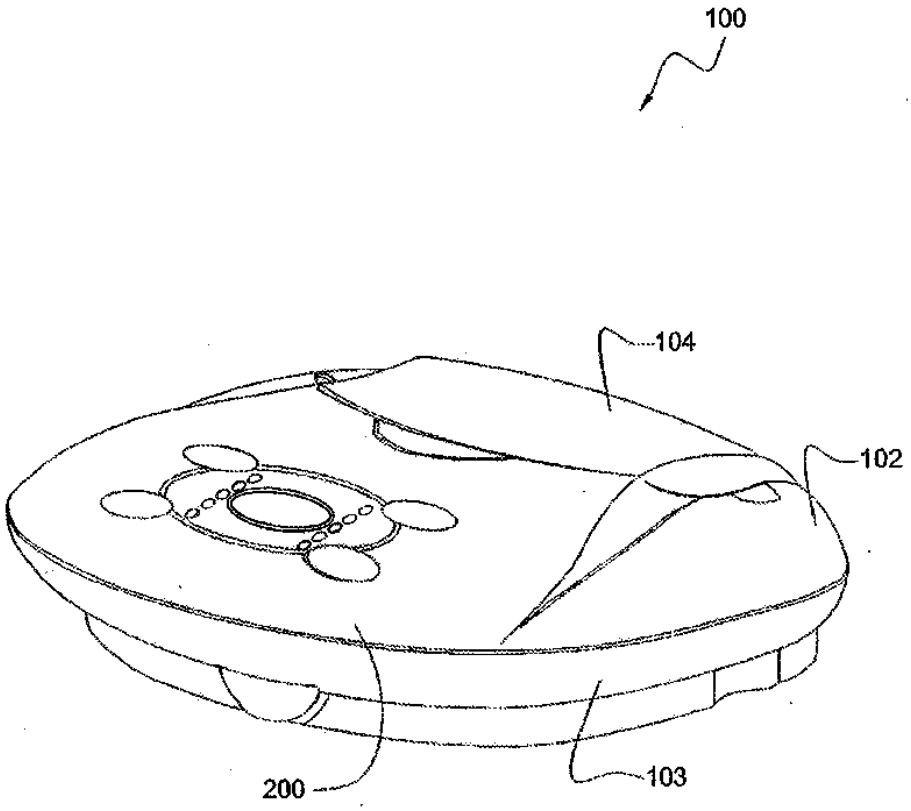


Fig. 1

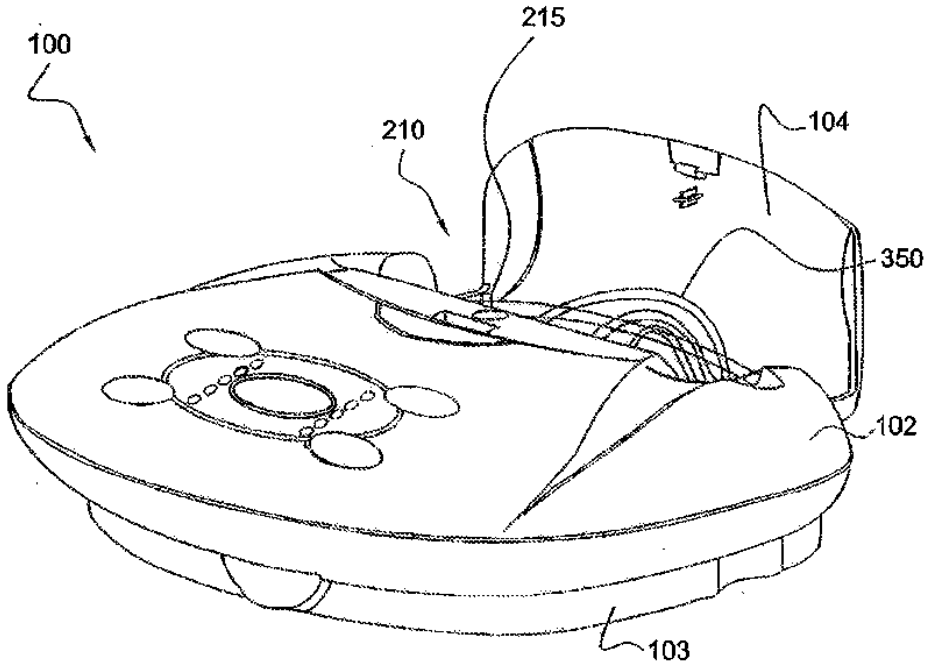


Fig. 2

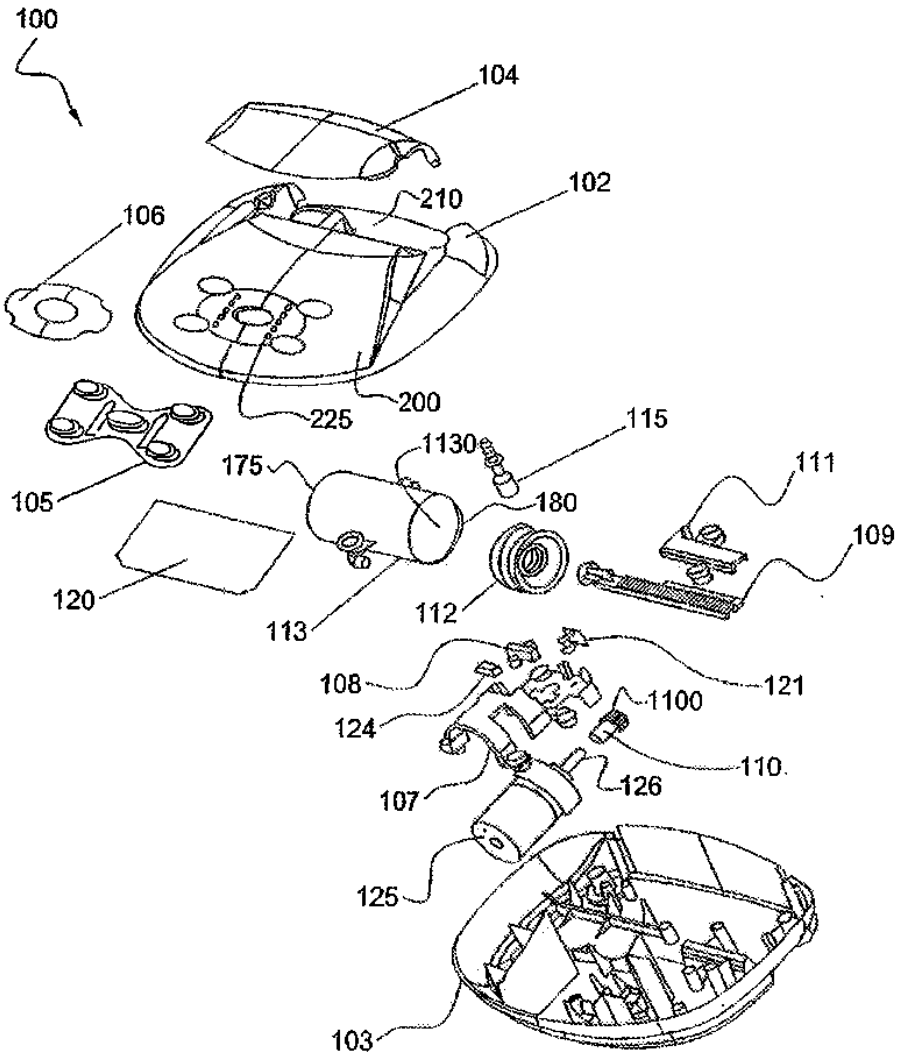

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107
125
103

Fig. 3

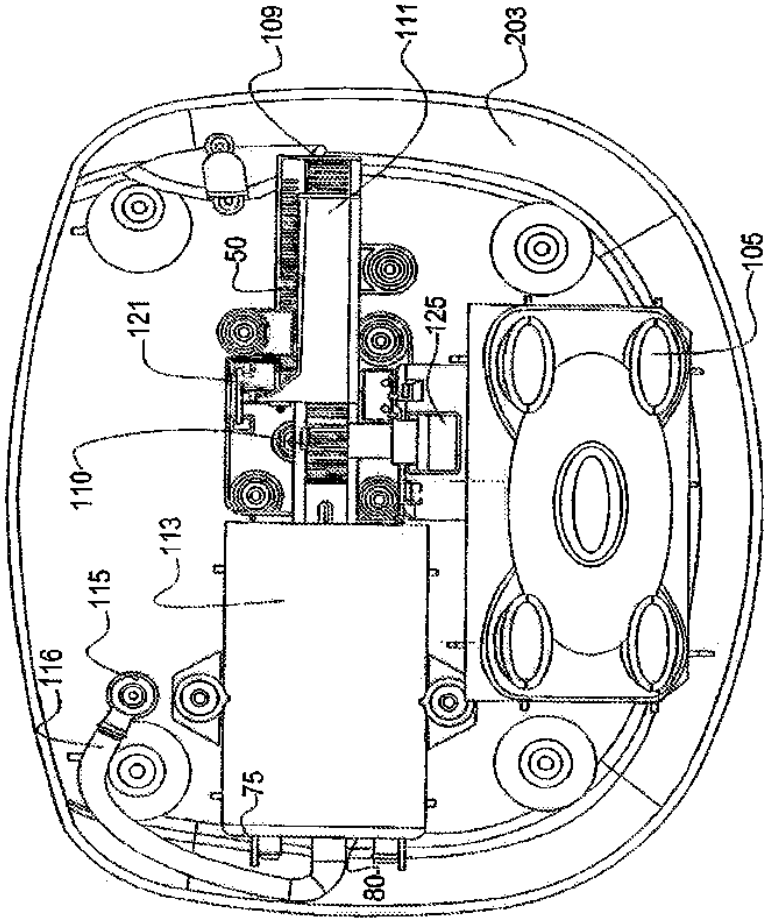


Fig. 4

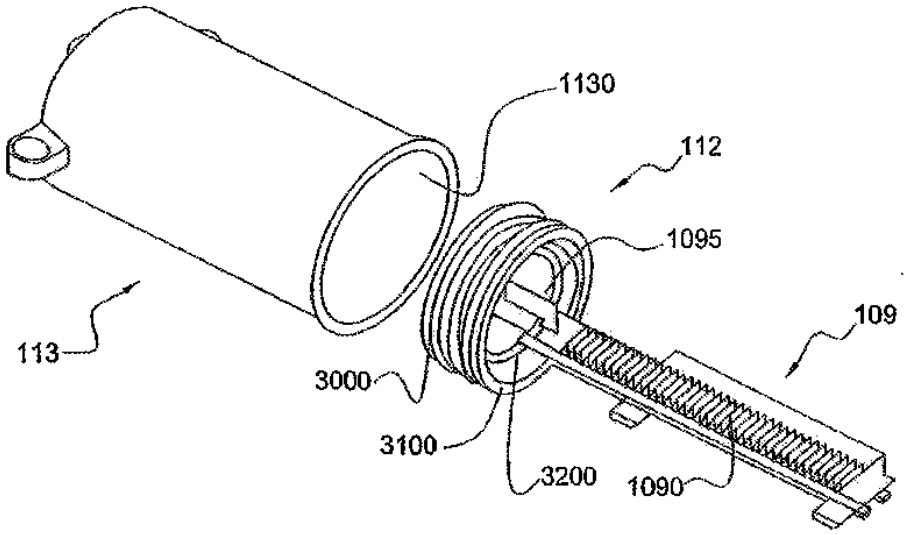

1130
112
1095
109
113
3000
3100
3200
1090

Fig. 5

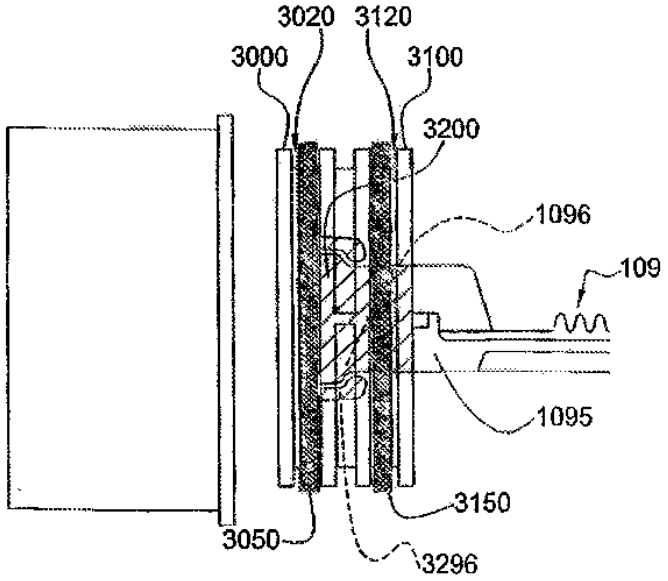

3020
3120
3000
3100
3200
1096
109
1095
3150
3050
3296

Fig. 6

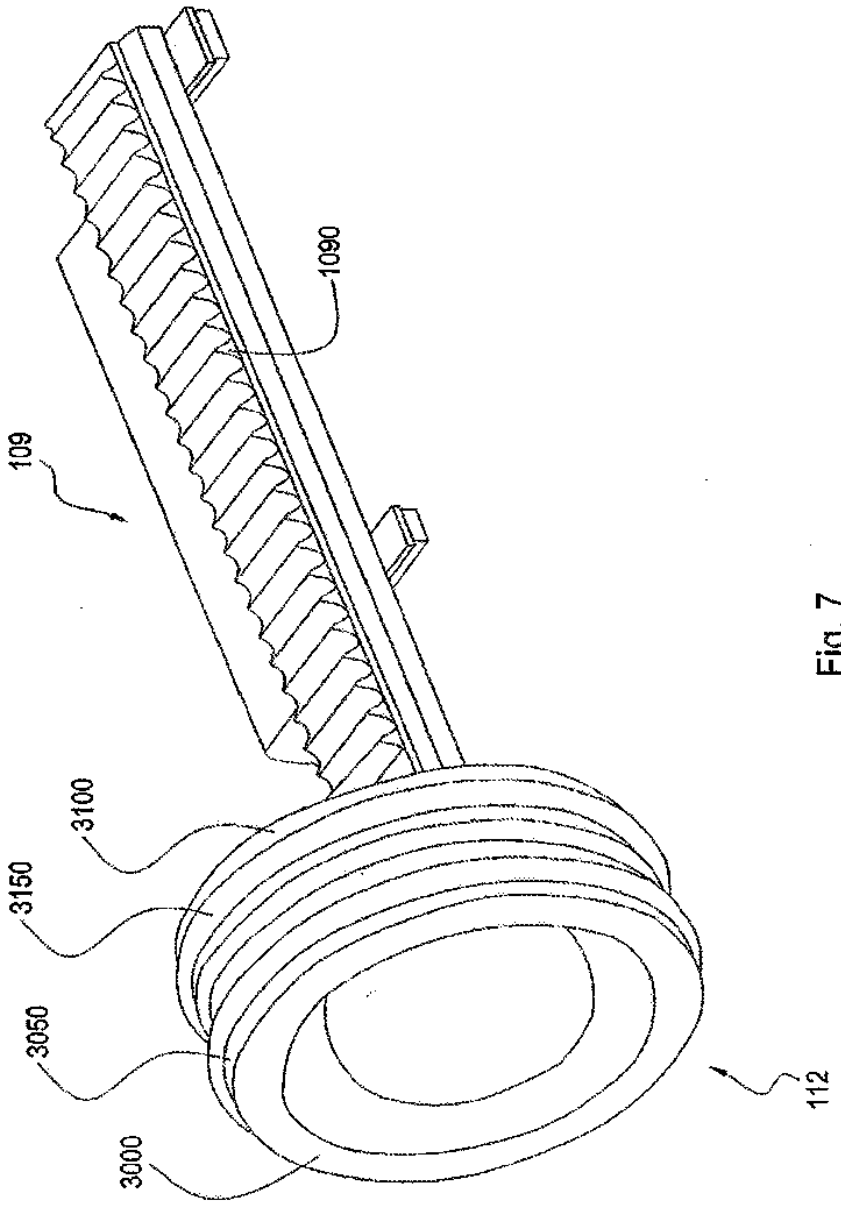


Fig. 7

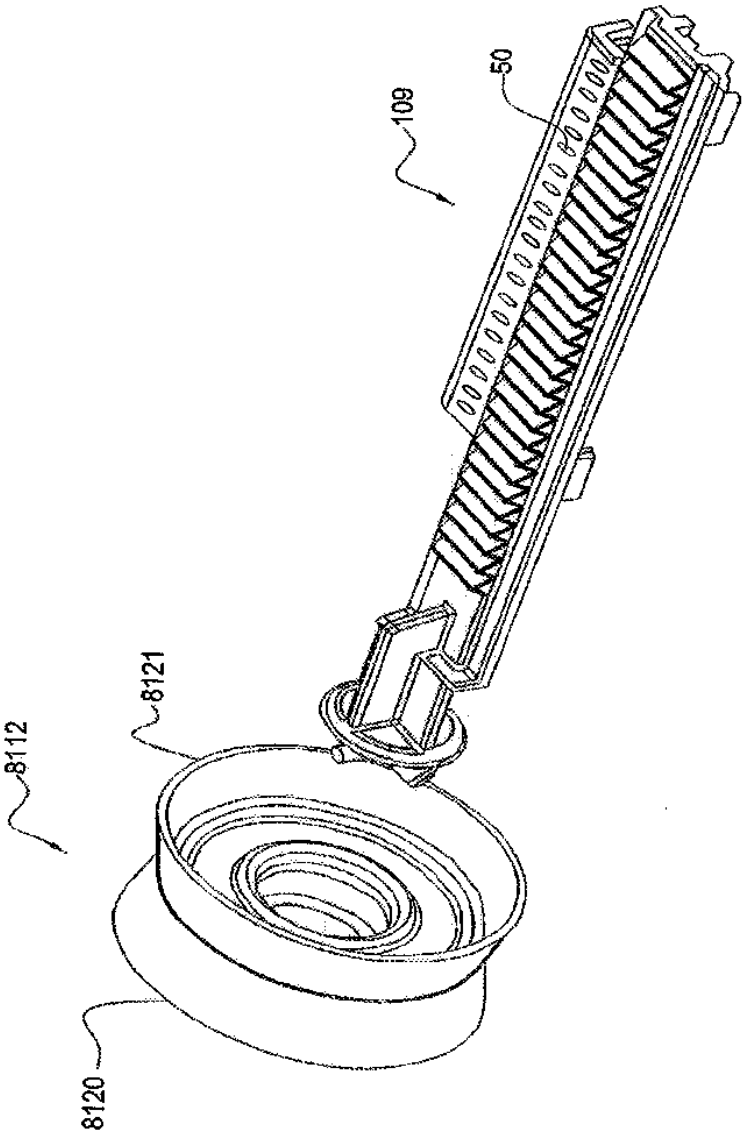


Fig. 8

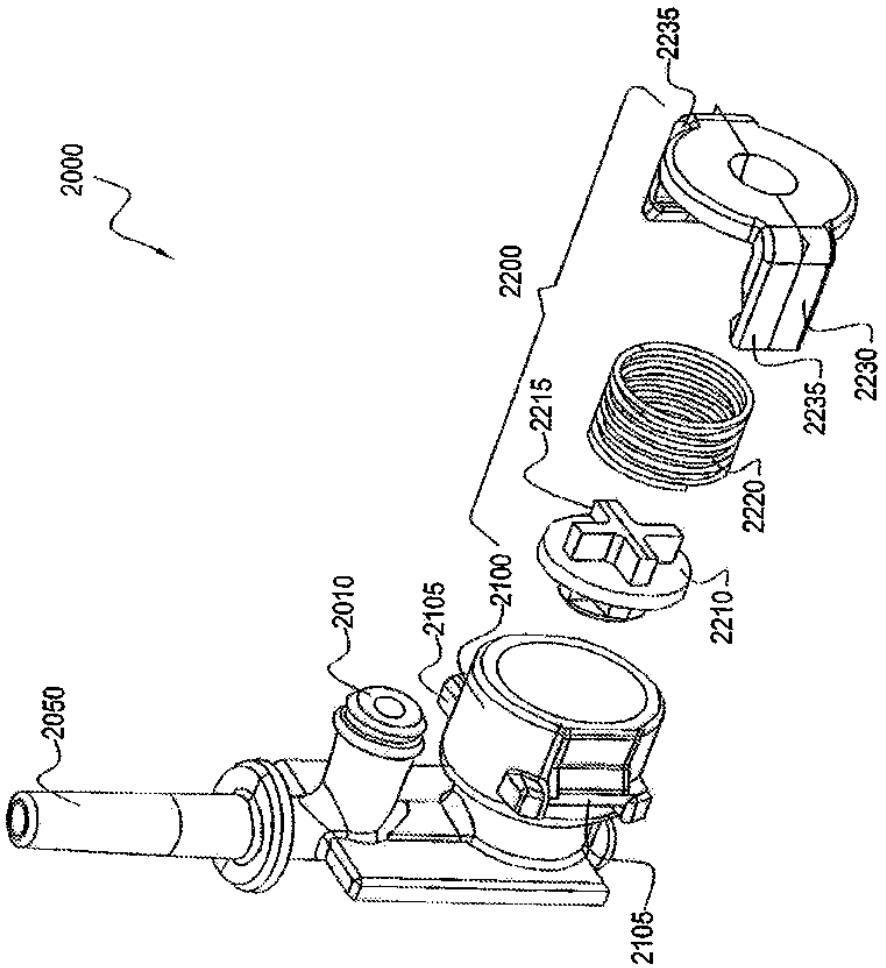

2000
2235
2200
2230
2235
2215
2220
2210
2100
2105
2010
2050
2105

Fig. 9

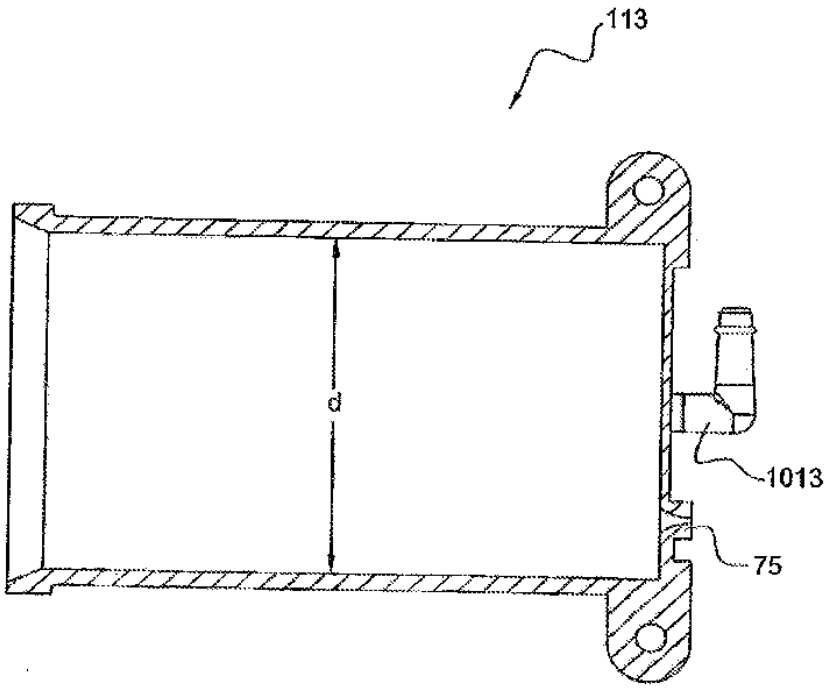


Fig. 10

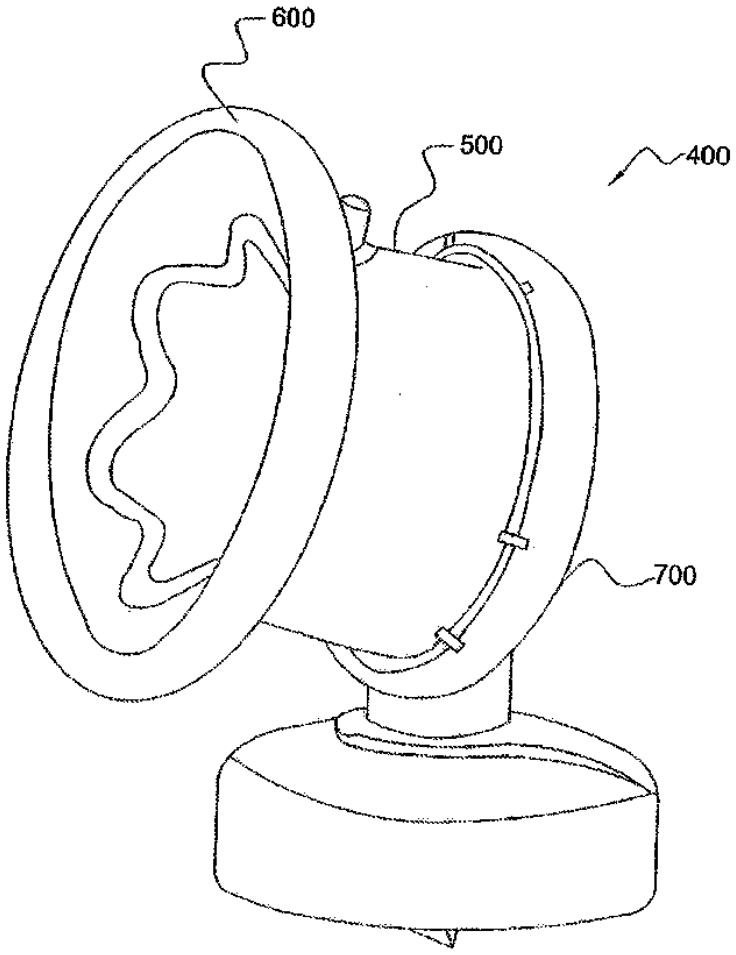


Fig. 11

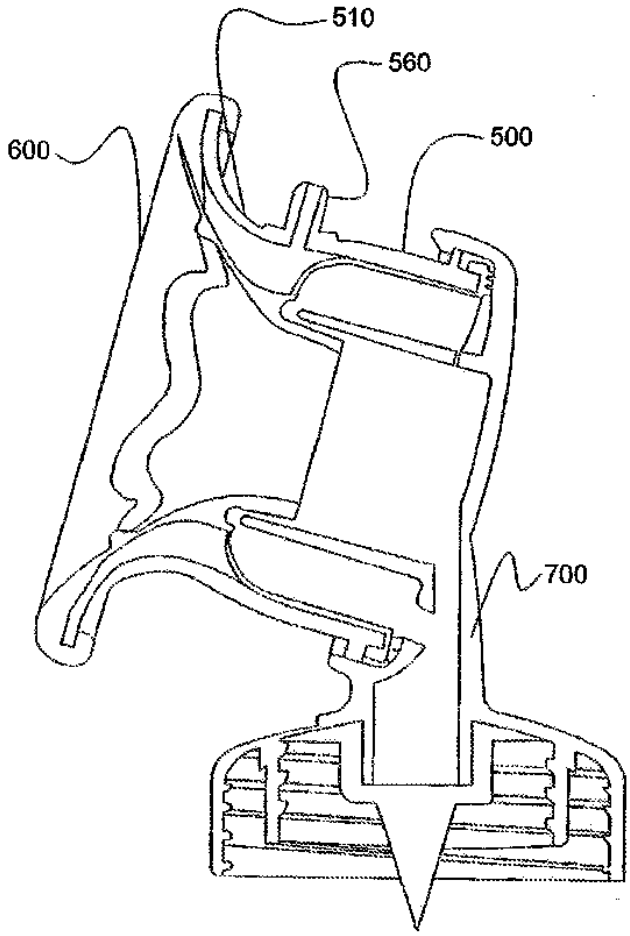


Fig. 12

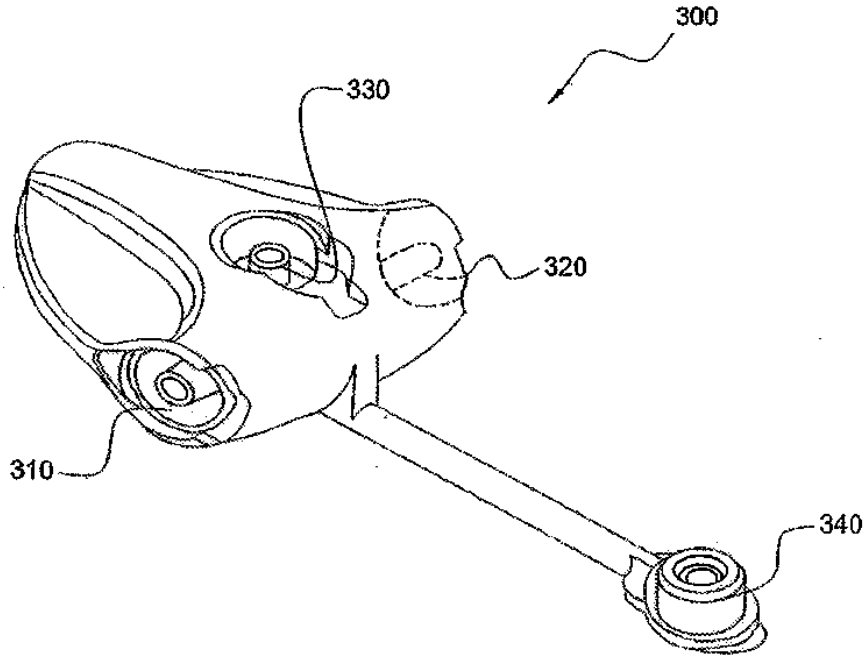


Fig. 13

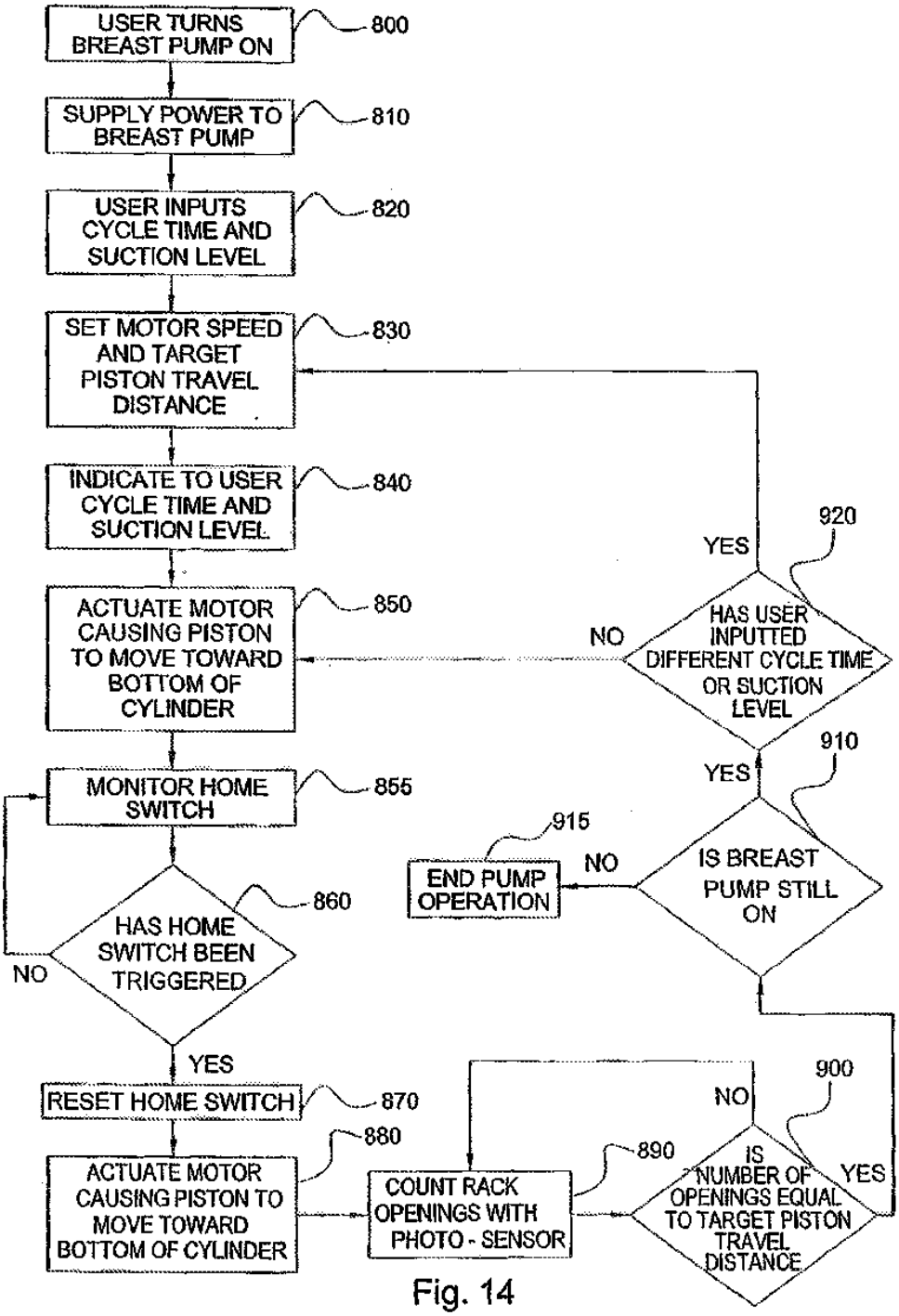

USER TURNS BREAST PUMP ON
800
SUPPLY POWER TO BREAST PUMP
810
USER INPUTS CYCLE TIME AND SUCTION LEVEL
820
SET MOTOR SPEED AND TARGET PISTON TRAVEL DISTANCE
830
INDICATE TO USER CYCLE TIME AND SUCTION LEVEL
840
ACTUATE MOTOR CAUSING PISTON TO MOVE TOWARD BOTTOM OF CYLINDER
850
MONITOR HOME SWITCH
855
HAS HOME SWITCH BEEN TRIGGERED
860
NO
YES
RESET HOME SWITCH
870
ACTUATE MOTOR CAUSING PISTON TO MOVE TOWARD BOTTOM OF CYLINDER
880
COUNT RACK OPENINGS WITH PHOTO - SENSOR
890
IS NUMBER OF OPENINGS EQUAL TO TARGET PISTON TRAVEL DISTANCE
900
NO
YES
HAS USER INPUTTED DIFFERENT CYCLE TIME OR SUCTION LEVEL
920
YES
NO
IS BREAST PUMP STILL ON
910
YES
END PUMP OPERATION
915
NO

Fig. 14

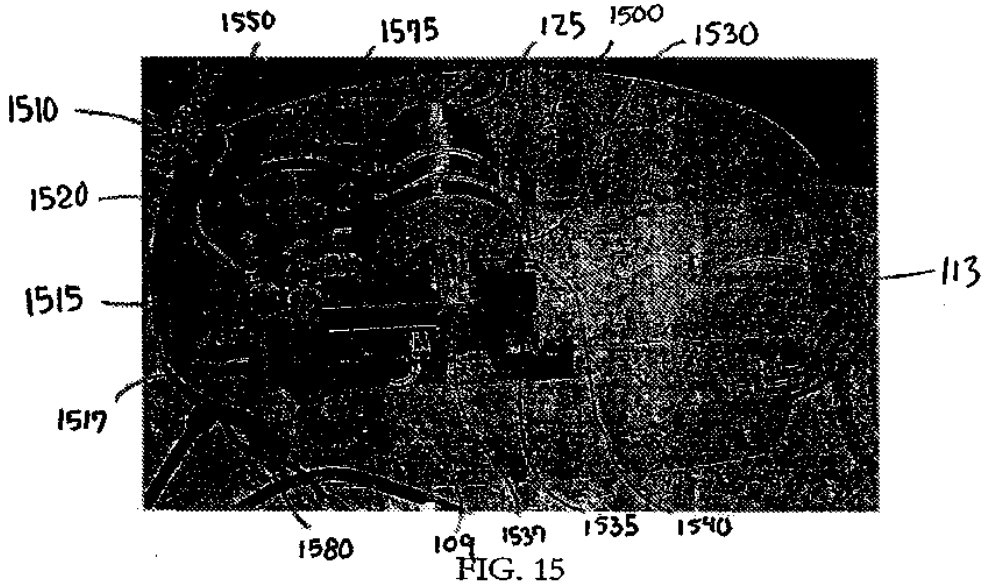

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FIG. 15

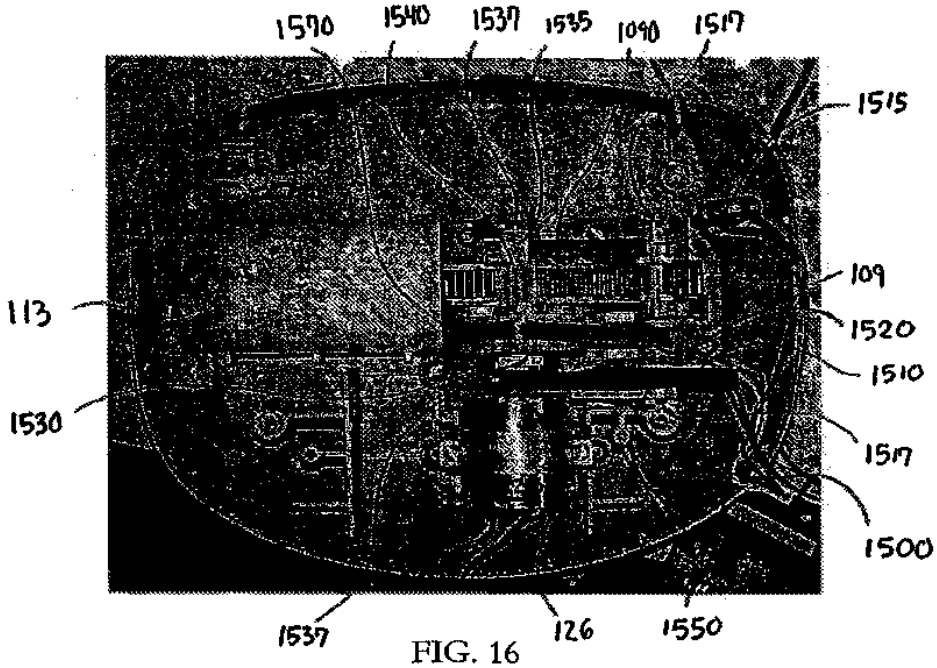

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FIG. 16

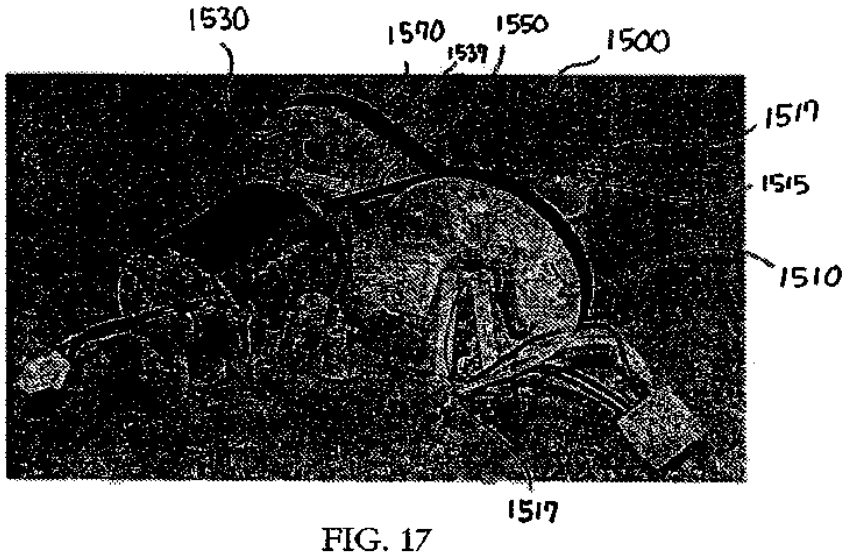

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FIG. 17

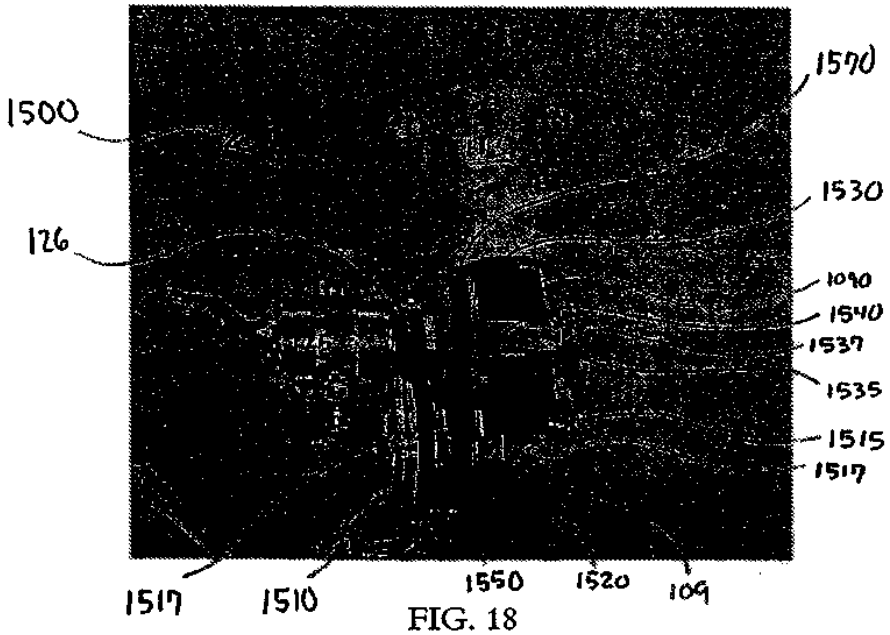

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FIG. 18

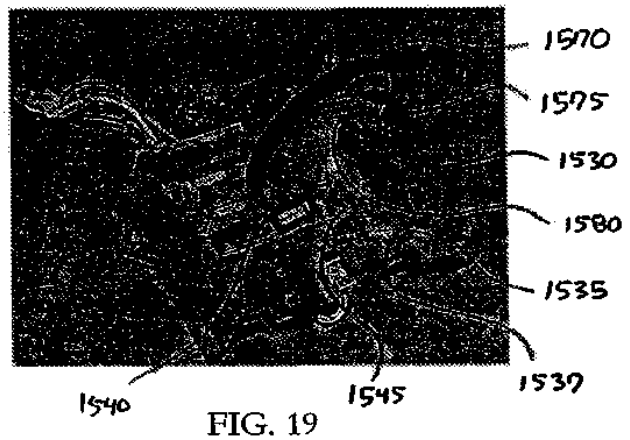

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FIG. 19

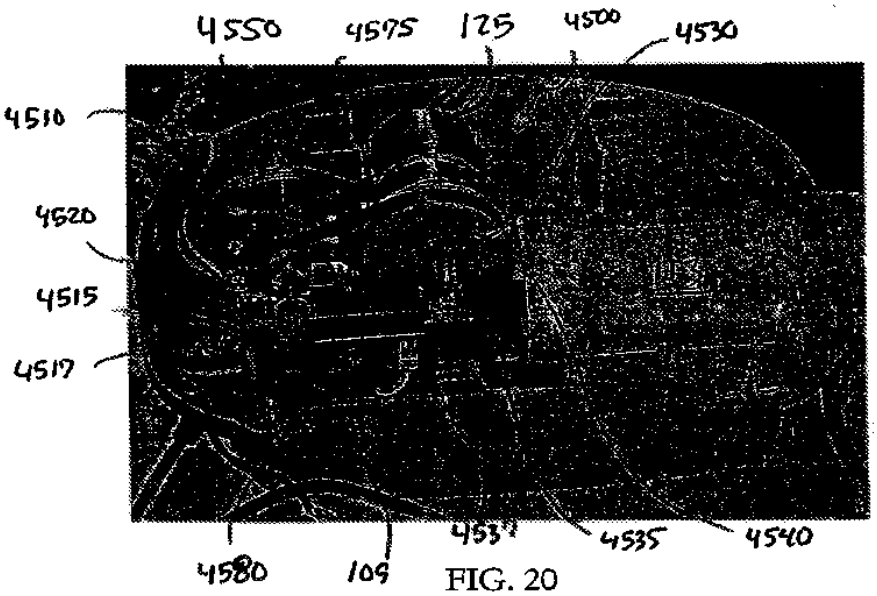

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FIG. 20

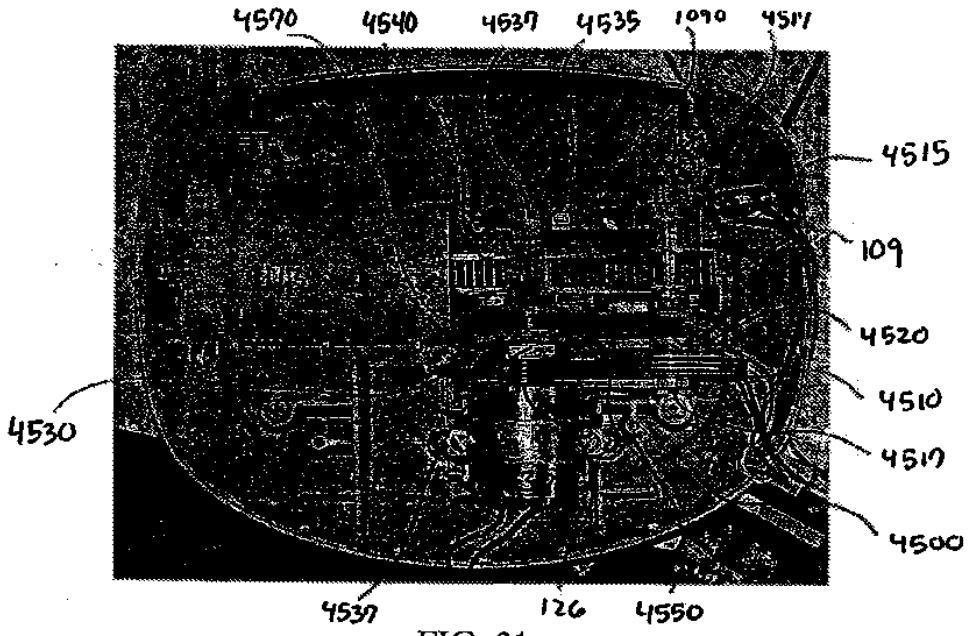

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FIG. 21

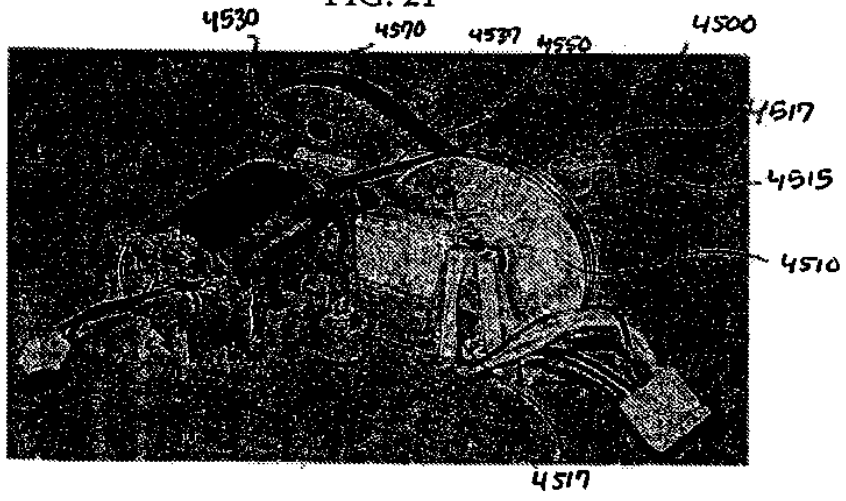

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FIG. 22

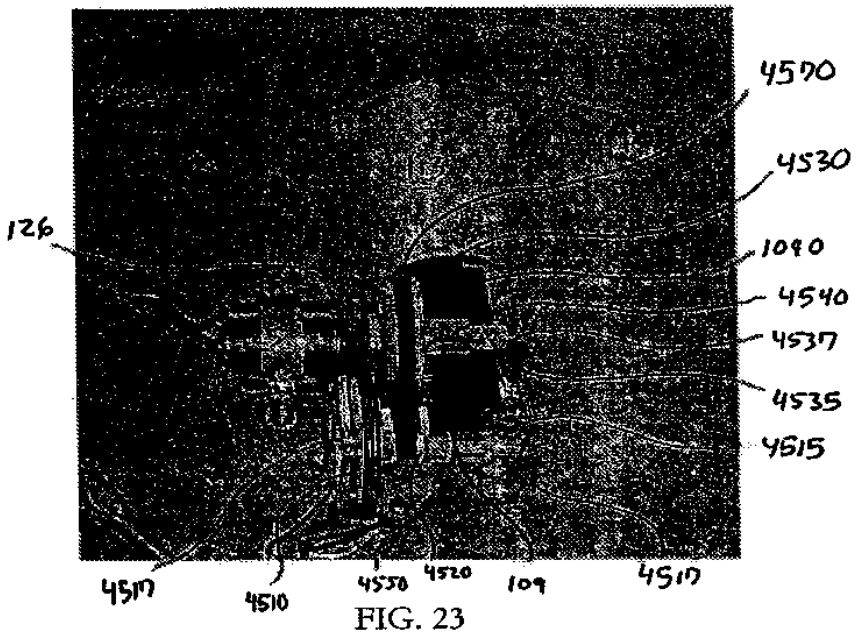

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FIG. 23

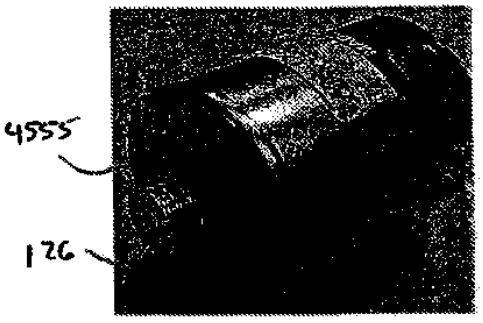

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FIG. 24

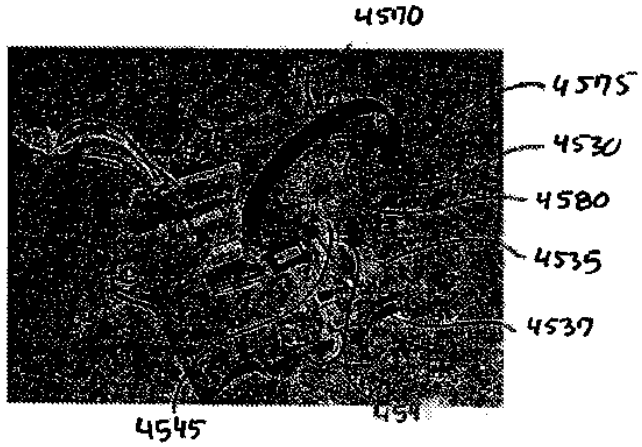

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FIG. 25

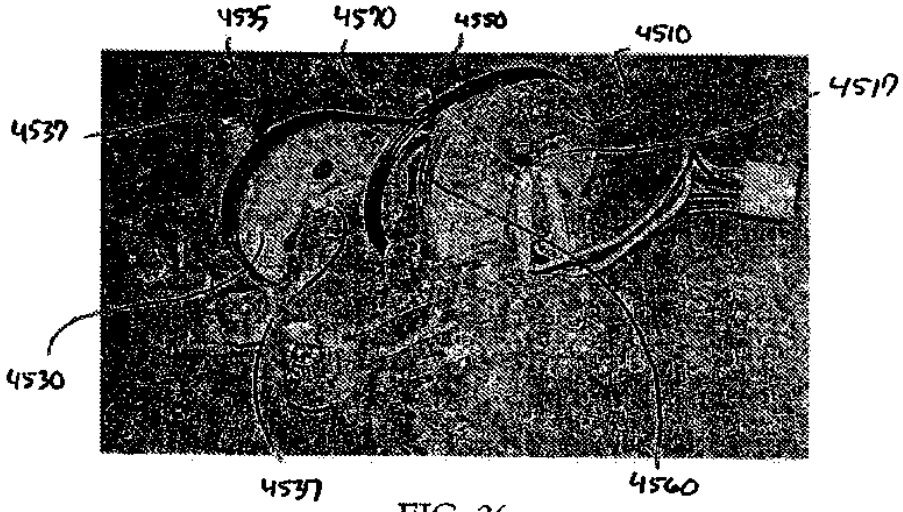

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FIG. 26

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ABSTRACT JP2016526396A

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13 The invention is an apparatus 1 for discharging a system 3, comprising a pump 5 suitable to be connected with said system 3 by a pump inlet 7, a pressure tank 11 and a directional control valve 13. , the pump 5 transports the medium from the system 3 and the pressure tank 11 to the external environment when the pressure tank 11 is connected to the pump inlet 7, and the directional control valve 13 is activated when predetermined criteria are met. , to a device arranged to switch the pressure tank 11 from the inlet 7 to the outlet 9 of the pump 5 . The invention further relates to a milking device 31 comprising an appliance 1 for emptying the system 3 and a receiving funnel 27 for receiving a female breast.

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(51)Int.Cl.		F I		テーマコード（参考）
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最終頁に続く

(54)【発明の名称】システムから排出するための機器及び方法

(57)【要約】
本発明は、システム３から排出するための機器１であって、ポンプ入口７によって前記システム３と接続されるのに適したポンプ５と、圧力タンク１１と、方向制御弁１３と、を有し、ポンプ５は、圧力タンク１１がポンプ入口７に接続されたときに、システム３及び圧力タンク１１から外部環境へと媒体を輸送し、方向制御弁１３は、所定の基準が満たされた場合に、ポンプ５の入口７から出口９へと圧力タンク１１を切り換えるよう構成された機器に関する。本発明は更に、システム３から排出するための機器１と、女性の胸部を受容するための受容漏斗２７と、を有する搾乳装置３１に関する。

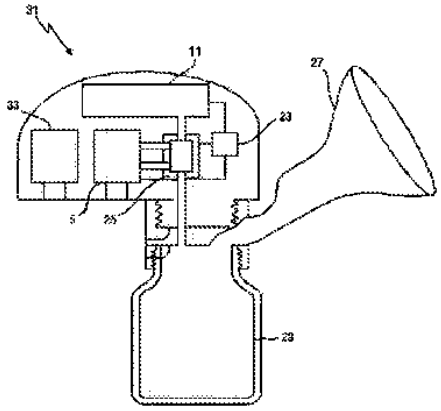


FIG.7

【特許請求の範囲】
【請求項１】
システムから排出するための機器であって、
ポンプ入口とポンプ出口との間の圧力の低下を生成するための、前記入口によって前記システムと接続されるのに適したポンプと、
かけられた圧力値を保持するための圧力タンクと、
前記ポンプ入口か又は前記ポンプ出口のいずれかに前記圧力タンクを切り換えるための方向制御弁と、
を有し、前記ポンプは、前記圧力タンクが前記ポンプ入口に接続されたときに、前記システム及び前記圧力タンクから外部環境へと媒体を輸送し、
前記方向制御弁は、所定の基準が満たされた場合に、前記ポンプ入口から前記ポンプ出口へと前記圧力タンクを切り換えるよう構成された機器。
【請求項２】
外部環境から前記ポンプ及び／又は前記圧力タンクへの流体の逆流を防ぐための、前記ポンプ出口と前記圧力タンクとの間に結合された一方弁を更に有する、請求項１に記載の機器。
【請求項３】
前記圧力タンクにおける圧力を決定するためのセンサを更に有する、請求項１に記載の機器。
【請求項４】
前記方向制御弁が、前記圧力タンクにおける圧力が所定の圧力閾値を下回ったときに、前記ポンプ入口から前記ポンプ出口へと前記圧力タンクを切り換えるよう構成された、請求項３に記載の機器。
【請求項５】
前記ポンプのスループットを決定するためのセンサを更に有する、請求項１に記載の機器。
【請求項６】
前記方向制御弁は、前記ポンプの前記スループットが所定のスループット閾値を超えたときに、前記ポンプ入口から前記ポンプ出口へと前記圧力タンクを切り換えるよう構成された、請求項５に記載の機器。
【請求項７】
前記システムから及び／又は前記圧力タンクから外部環境へと圧力を放出するための放出弁、及び／又は、前記圧力タンクから前記ポンプ出口への輸送される媒体の流量を制御するための流量制限器、を更に有する、請求項１に記載の機器。
【請求項８】
前記ポンプは、前記ポンプ入口から前記ポンプ出口へと、流体、特に気体を移動させるための、容積移送式ポンプである、請求項１に記載の機器。
【請求項９】
前記ポンプは、電動ポンプ、又は人間の手及び／又は足の動きによって駆動される機械式ポンプである、請求項１に記載の機器。
【請求項１０】
前記方向制御弁と前記一方弁とが、スマート弁に組み合わせられた、請求項２に記載の機器。
【請求項１１】
前記方向制御弁は、３つのポート及び２つの切り換え位置を持つ３／２弁である、請求項１に記載の機器。
【請求項１２】
前記方向制御弁は、電気的又は機械式に動作させられる弁である、請求項１に記載の機器。
【請求項１３】

前記ポンプ及び／又は前記方向制御弁を制御するためのコントローラを更に有する、請求項１に記載の機器。
【請求項１４】
請求項１に記載の機器と、女性の胸部を受容するための受容漏斗及び母乳を集めるための母乳槽を含むシステムと、を有する搾乳装置。
【請求項１５】
搾乳装置を制御するための方法であって、
システムにおける及び圧力タンクにおける圧力の低下を生成するためのポンプであって、前記圧力タンクがポンプ入口に接続されたときに、前記システム及び前記圧力タンクから外部環境へと媒体を輸送するポンプを構成するステップと、
所定の基準が満たされているか否かを決定するステップと、
前記所定の基準が満たされている場合、前記ポンプ入口からポンプ出口へと前記圧力タンクを切り換えるよう方向制御弁を構成するステップと、
を有する方法。
【発明の詳細な説明】
【技術分野】
【０００１】
本発明は、システムから排出するための機器、搾乳装置、及び搾乳装置を制御するための方法に関する。
【背景技術】
【０００２】
多くの用途において、種々の工業的、科学的及び医学的工程のため、（不完全な）真空を提供するための真空ポンプが必要とされる。これら種々の工程は、広範な種々のポンプタイプ及びポンピング原理に導く、種々の真空レベルを必要とする。真空ポンプの２つの主なパラメータは、達成可能流量及び達成可能真空レベル（即ち圧力レベル）である。いずれのポンピング原理も、特有の利点及び欠点を持ち、いずれの用途も、ポンプに対する特有の要件を持つ。通常、高いレベルの真空又は高い流量を提供することが可能なポンプは、大型であり、製造が難しいものである。従って、特定の用途のために真空ポンプを選択又は製造する際に、必要とされる流量、最高真空レベル、製造コスト、製造サイズ及びその他のパラメータの間に、妥協点が見出される必要がある。
【０００３】
真空ポンプのための一用途領域は、搾乳装置、即ち授乳中の女性の胸部から母乳を抽出するための装置の分野である。斯かる装置は通常、胸部から母乳を吸い出すため、女性の胸部に当てられる、（不完全な）真空をもたらすための真空ポンプを含む。国際特許出願公開WO2012/127405A1は、負圧を生成するよう動作可能な搾乳装置を開示している。搾乳装置によって実現され得る最大負圧は、使用される（不完全）真空ポンプが提供できる最大圧力値の関数である。高いレベルの真空が必要とされる場合には、通常は搾乳装置を大型化させ及び／又は製造するのが高価なものとしてしまう、異なるタイプのポンプが必要となる。
【０００４】
米国特許出願公開US2005/0283112A1において、搾乳器が開示されている。該装置は、胸部の乳頭上にフィットするよう適合された胸部シールドと、該胸部シールドに結合された流線と、を含む。該流線は、該流線を介して該胸部シールドに結合されたポンプを通して、空気が該流線を流れることを可能とするよう構成される。該ポンプは、ポンプ入口とポンプ出口とを含み、乳頭と該ポンプとの間に圧力降下を生成するよう動作可能であり、該圧力降下が、該流線における空気の圧力を低下させることによって該胸部シールドにおける吸引力を生成する。該流線と該ポンプとの間にブローバック弁が備えられ、該ブローバック弁は、弁ハウジングに配置された弁ピストンを持つ。該弁ハウジングは、該流線を介して該胸部シールドと連通する流線開口と、外部と該流線とを連通するよう構成された弁入口と、外部と該流線とを連通するよう構成された弁出口と、を含む。弁ピストンは、該

弁入口と該弁出口とを二者択一的に封止するよう構成される。

【０００５】

米国特許出願公開US2013/0165852A1においては、電気搾乳ポンプが開示されている。該ポンプは、電気モータと、該モータにより駆動されるポンプと、吸引カップと、吸引線における電気的に作動させられる第１の三方弁と、圧力線における電気的に作動させられる第２の三方弁と、電子制御システムと、を持ち、該電子制御システムが、スイッチの作動に依存して、電気モータを動作モード又はアイドリングモードに設定する。動作モードにおいては、電気モータがスイッチオンされ、ポンプの入口が第１の三方弁及びフロート弁を介して吸引カップに接続され、ポンプ出口が第２の三方弁を介して接続される、吸引フェーズを有するサイクルで、電気モータ並びに電気的に作動させられる第１及び第２の三方弁を動作させる。

【発明の概要】

【発明が解決しようとする課題】

【０００６】

本発明の目的は、コスト効率の良い製造及び小型の筐体における実装を可能としつつ、システムから排出し、適切な真空レベルを実現するための装置を提供することにある。本発明の更なる目的は、搾乳装置及び搾乳装置を制御するための方法を提供することにある。

【課題を解決するための手段】

【０００７】

本発明の第１の態様においては、システムから排出するための機器であって、ポンプ入口とポンプ出口との間の圧力の低下を生成するための、前記入口によって前記システムと接続されるのに適したポンプと、かけられた圧力値を保持するための圧力タンクと、前記ポンプ入口か又は前記ポンプ出口のいずれかに前記圧力タンクを切り換えるための方向制御弁と、を有し、前記ポンプは、前記圧力タンクが前記ポンプ入口に接続されたときに、前記システム及び前記圧力タンクから外部環境へと媒体を輸送し、前記方向制御弁は、所定の基準が満たされた場合に、前記ポンプ入口から前記ポンプ出口へと前記圧力タンクを切り換えるよう構成された機器が提供される。

【０００８】

本発明の更なる態様においては、以上に説明された機器と、女性の胸部を受容するための受容漏斗と母乳を集めるための母乳槽とを含むシステムと、を有する搾乳装置が提供される。

【０００９】

本発明の更に他の態様においては、搾乳装置を制御するための方法であって、システムにおける及び圧力タンクにおける圧力の低下を生成するためのポンプであって、前記圧力タンクがポンプ入口に接続されたときに、前記システム及び前記圧力タンクから外部環境へと媒体を輸送するポンプを構成するステップと、所定の基準が満たされているか否かを決定するステップと、前記所定の基準が満たされている場合、前記ポンプ入口からポンプ出口へと前記圧力タンクを切り換えるよう方向制御弁を構成するステップと、を有する方法が提供される。

【００１０】

本発明の好適な実施例は、従属請求項に定義される。請求される方法及び搾乳装置は、請求される機器及び従属請求項において定義されるものと同様の及び／又は同一の好適な実施例を持つことは理解されるべきである。

【００１１】

本発明による機器は、方向制御弁及び付加的な圧力タンクの利用によって、達成される真空レベルの増大を実現する。前記ポンプは、内側から外側へと媒体を輸送し、それによりこれらの間の圧力低下を生成する。輸送される媒体は、いずれの種類の流体即ち気体又は液体を含んでも良く、ポンプによってシステムから輸送されて出されるときに、該システムにおける圧力低下を引き起こす。ポンプの出口が外部環境と接続され、輸送される媒

体が外部環境へと放出される場合には、システム中の圧力は、外部環境の圧力に比べて低下する。

【００１２】

本発明によれば、該ポンプは、媒体をシステムから輸送するのみならず、圧力タンクに含まれる媒体をも輸送し、それによりシステム中の圧力及び圧力タンク中の圧力の両方が減少する。斯くして、該システム及び該圧力タンクの両方から、該ポンプによって吸い出されることとなる。

【００１３】

該圧力タンク（真空タンクとも呼ばれる）は、該タンクの内側及び外側において変化する圧力値にかかわらず変化しない一定値を提供することにより、かけられた（低）圧力値を保持することを可能とする。斯かる圧力タンクのとり得る実施例は、例えば、ポンプに接続されるべき単一の開口を備えた、剛性の気密な柔軟性のない金属体であっても良い。更に、本文脈においては、かけられた圧力値を保持するとは、例えば、圧力タンクから媒体を吸い出し、次いで圧力タンクの開口を閉じ又は封止し、圧力補償が実行される（例えばタンクを開いてタンク中の媒体を外部環境へと放出する又は外部環境からタンクへと媒体を通すことによって）まで該圧力タンク内の圧力を一定に保つことにより、圧力値をかける又は引き起こすことを指す。

【００１４】

圧力タンクから又は圧力タンクへと媒体をポンピングすることによって圧力タンク内の圧力を変化させる代わりに、圧力タンクを或る圧力レベル即ち圧力値に（受動的に）適合させ、次いで周囲の圧力が異なる領域に該タンクを輸送し、内部環境の圧力状態が保持されるようにすることも可能である。圧力タンクは、両方向に用いられることができ、即ち外部環境に対して低圧を保持することもできるし高圧を保持することもできる。

【００１５】

本発明によれば、圧力タンクは、方向制御弁によってポンプ入口又はポンプ出口に接続される。斯かる方向制御弁は、異なる経路への切り換えを可能とし、方向制御弁の設定に依存して、媒体が異なるポートへとガイドされることができる。本発明によれば、方向制御弁は特に、圧力タンクを、第１の設定においてポンプ入口に、第２の設定においてポンプ出口に切り換える機能を提供する。斯くして、圧力タンクの開口をポンプのいずれの側にも接続することが可能となる。

【００１６】

更に、本発明によれば、方向制御弁が、所定の基準が満たされたときに、斯かる切り換え手順、即ち圧力タンクをポンプの一方の側から他方へと切り換える手順を実行する。例えば、圧力タンクは最初にポンプ入口に接続され、システムからの媒体の吸い出し及び圧力タンクからの媒体の吸い出しを行わない。次いで、所定の基準が満たされるとすぐに、該圧力タンクはポンプ出口に接続される。この構成において、方向制御弁が第１の設定にある場合、ポンプはシステム及び圧力タンクから媒体を輸送して外部環境へと出す。次いで、方向制御弁を第２の設定へと切り換えた後には、媒体はポンプ入口において該システムから輸送され、ポンプ出口において圧力タンクへと輸送される。

【００１７】

本発明による機器の利点のひとつは、生成される圧力の低下又は全体的な低下が促進されることである。最初にポンプが、外部環境と該システム及び圧力タンクとの間に一定の圧力の低下を生成する。所定の基準が満たされるとすぐに、即ち圧力レベルがもう低下させられなくなると、方向制御弁によって該圧力タンクはポンプ出口に切り換えられる。切り換えの直後、このことはポンプ入口とポンプ出口における圧力の平衡に帰着する。次いで、ポンプ出口における圧力レベルが既に外部環境における圧力レベルよりも低い場合には、ポンプは外部環境に比べて該システムにおいて更に低い圧力を生成することができることを利用する。外部環境における圧力レベルとは独立して、該ポンプはポンプ入口とポンプ出口との間に圧力の低下を生成する。斯くして、ポンプ出口における圧力レベルが既に外部環境における圧力レベルよりも低い場合には、ポンプ入口における圧力レベルを更

に低下させることが可能となる。このことは、所定の基準が満たされたときに、ポンプ入口からポンプ出口へと圧力タンクを切り換えることができる方向制御弁によって、本発明により利用される。とりわけ、該ポンプの達成可能な圧力レベル又は真空レベルは、以上に概説されたように圧力タンクを切り換えることにより向上される。達成可能な真空レベル、即ち該ポンプを用いて生成されることができる最低圧力は、元の達成可能な真空レベルに比べて向上される。

【００１８】

本発明の第１の実施例においては、前記機器は更に、外部環境から前記ポンプ及び／又は前記圧力タンクへの流体の逆流を防ぐための、前記ポンプ出口と前記圧力タンクとの間に結合された一方弁を有する。一方弁は基本的に、媒体を或る方向には通すが、他の方向に媒体が通過することを防止するものである。本発明の第１の実施例によれば、該一方弁が、ポンプ出口に配置される。斯くして、圧力タンクが方向制御弁によってポンプ出口に接続されている場合であっても、外部環境から圧力タンク又はポンプへの輸送された媒体の逆流が防止される。最初に、圧力タンクがポンプ入口に接続されている限り、該一方弁は単に外部環境からポンプ出口を封止し、ポンプにより輸送された媒体が外部環境へと逃げることを可能とする。しかしながら、該一方弁の方向に反して、外部環境からポンプへと又は該システムへと媒体が逆流することはできない。次いで、以上に説明されたように、圧力タンクがポンプ入口からポンプ出口へと切り換えられるとすぐに、該一方弁は、外部環境から圧力タンクへ媒体が逆流することも防止する。この構成においては、ポンプ出口及び圧力タンクは、外部環境から一方向的に分離される。当該一方弁の利点のひとつは、外部環境における圧力に比べて圧力が保持されることができる点である。

【００１９】

本発明の更なる実施例によれば、前記機器は、前記圧力タンクにおける圧力を決定するためのセンサを有する。当該圧力センサは、例えば容量式、電磁式、圧電式又はピエゾ抵抗式の測定原理に基づくものであっても良く、該圧力タンク中の媒体又は流体の圧力についての情報を提供することができる。該センサは、該圧力タンクにおける絶対圧力についての情報を有するディジタルの補正された出力信号を提供するスマートセンサであっても良いし、又は該圧力タンクにおける圧力に依存した信号のアナログ値を提供するアナログセンサであっても良い。該センサにより生成された信号は、例えば該機器の特定のパラメータが、得られたセンサ信号に基づいて直接に構成される、閉ループ制御の使用を可能とすることによって、本発明による機器を制御することを可能とする。

【００２０】

当該センサの使用の一例は、本発明の他の実施例において更に詳細化され、前記方向制御弁が、前記圧力タンクにおける圧力が所定の圧力閾値を下回ったときに、前記ポンプ入口から前記ポンプ出口へと前記圧力タンクを切り換えるよう構成される。斯くして、以上に説明されたセンサにより決定される該圧力タンクにおける圧力は、ポンプ入口からポンプ出口への圧力タンクの切り換えがいつ実行されるべきかを決定するための基準として用いられる。特定の圧力閾値レベル即ち所定の閾値を定義することにより、該圧力タンクがポンプ入口に接続されている間、方向制御弁の構成が、該システムにおける圧力と同等である圧力タンクにおける現在の圧力と直接に関連付けられることができる。当該所定の閾値は、例えば達成可能な最大圧力差又は最大真空レベルといった、該ポンプの特性に依存して選択されても良い。選択された設定に依存して、本実施例の利点のひとつは、切り換え工程の制御が簡便となり、容易に実現され得ることである。

【００２１】

更に、本発明の他の実施例によれば、前記機器は、前記ポンプのスループットを決定するためのセンサを更に有する。斯かるスループットセンサは、例えば１つ又は複数の圧力センサ、熱流量計、力学的正変位計、又はその他のいずれかの流量センサ若しくは流量計として実現される流量センサであっても良い。当該流量センサは基本的に、以上に説明された圧力タンクにおける圧力を決定するためのセンサに代わるものとして用いられることができる。同等の機能が実現され得る。好適にも、ポンプのスループットを決定するため

の斯かるセンサの使用は、更なるユーザ入力の必要なく、切り換え手順を自動的に起動することを可能とする。

【００２２】

本発明の好適な実施例においては、前記方向制御弁は、前記スループットが所定のスループット閾値を超えたときに、前記ポンプ入口から前記ポンプ出口へと前記圧力タンクを切り換えるよう構成される。以上に説明されたように、ポンプのスループットを決定するための当該センサの測定値が評価され、得られたセンサ値が圧力タンクがポンプ入口からポンプ出口へと切り換えられるべきか否かを決定するための基準として用いられる。とりわけ、当該原理は、閾値即ち切り換えが実行されるべきスループット値が、ポンプの特性に基づいて決定される場合に、用いられても良い。当該閾値のとり得る設定のひとつは、該ポンプにより実現され得る最大スループットに対する特定の割合であっても良い。斯くして、ポンプが比較的低い効率で動作するとすぐに、圧力タンクが前記入口から前記出口へと切り換えられ、ポンプのスループットが増大させられる。最大の全圧低下が到達されるとすぐに、該センサは再び少ない流量のみを記録することとなる。

【００２３】

本発明の別の実施例においては、前記装置は更に、前記システムから及び／又は前記圧力タンクから外部環境へと圧力を放出するための放出弁を有する。幾つかの用途においては、意図される利用を継続するために、該システムから圧力又は特に真空を外部環境へと放出することが可能であることが必要となる。斯かる放出弁は、電気的に動作させられても良いし又は手動で動作させられても良く、単純なバタフライ弁又はその他のいずれのタイプの弁の形をとって実現されても良い。例えば圧力タンクが現在ポンプ出口に接続されている場合、当該放出弁の装着位置に依存して、該システム及び圧力タンクから又は該システムのみから圧力を放出することが可能となる。これにより該放出弁は好適にも、該システム又は圧力タンクと外部環境との間の圧力差の他にはいずれの外部入力をも必要とせずに、自動的に動作させられる。該放出弁はこのとき、ポンプの故障又は制御されない挙動の場合に、該システム又はタンクが過度に低い／高い圧力となることを防止する安全弁として機能することができる。例えば該排出システムが搾乳装置の母乳槽である場合、斯かる安全弁はユーザに害を及ぼすことを防止することができる。

【００２４】

本発明によるシステムから排出するための機器は更に、前記圧力タンクから前記ポンプ出口への輸送される媒体の流量を制御するための（任意に調節可能な）流量制限器を有する。斯かる流量制限器は、特に最大スループットの制限を可能とすることにより、より平滑な及び／又はなだらかなポンプ曲線を実現する。

【００２５】

本発明の好適な実施例においては、前記ポンプは、前記ポンプ入口から前記ポンプ出口へと、流体、特に気体を移動させるための、容積移送式真空ポンプである。当該ポンプは、本発明の別の実施例においては、電動ポンプか又は人間の手及び／又は足の動きによって動かされる機械式ポンプのいずれかであっても良い。用途に応じて、異なるタイプのポンプはそれぞれの利点及び欠点を持つ。とりわけ、気体が即ち気体分子がポンプ入口からポンプ出口へとポンピングされるべき場合には、容積移送式真空ポンプは有利である。斯かる容積移送式真空ポンプは、所与の容積の拡大に依存し、これにより該拡大させられた容積内の圧力が低下させられる。次いで、該容積の一部が分離され、再び拡大させられる。この手順は、数回繰り返されることにより真空のレベルを増大させても良く、気体をポンピングする際には容易に実装されることができる。このとき、主な関心事は、該ポンプが生成することができる真空レベル、即ち容積当たりに残る分子の最小の数である。斯かる容積移送式真空ポンプの利点のひとつは、単純な構成及び市場での入手可能性である。

【００２６】

どのポンピング原理が利用されるかにかかわらず、該機器に含まれるポンプは、例えばプロセッサ装置により制御されても良いし又は直接的なユーザインタフェースを提供しても良い、バッテリ又は電源により電力供給される電動ポンプであっても良い。代替として

は、該機器が、いずれの電気エネルギーも必要とはしないが、例えば人間の手及び／又は足の動きによる、手動の電力変換により電力供給を受けることができる、機械式ポンプを有することも可能である。斯かる機械式ポンプの可能性のひとつは、周期的に動かされ、例えば以上に説明された容積移送式原理のようなポンピング機構を動きに変換する、ハンドル部の使用である。機械式ポンプの利点は、バッテリの充電又はケーブル接続の利用を必要としない点を含む。また、故障のリスクや、例えば搾乳装置の場合にユーザを傷つけてしまリスクも軽減される。他方で、電動ポンプは、より使用が便利となり得る。

【００２７】

本発明の他の好適な実施例においては、方向制御弁と一方弁とがスマート弁へと組み合わせられる。斯かるスマート弁は、制御弁の機能と一方弁の機能とを１つの構成要素へと組み合わせる統合された部分であっても良い。２つの弁を１つの構成要素へと組み合わせることの利点は、構造的空間が削減され得る点である。更に、機器の構成要素の数が最小化されると、コストを低減することも可能となり得る。斯かるスマート弁は、更に放出弁を含んでも良く、これにより更に構成要素の数を削減しても良い。更に、安全弁の機能、即ち該機器のユーザ又は該機器自体の保護が、該スマート弁に組み込まれても良い。斯かるスマート弁は、完全に機械式に制御されても良く、圧力差及び機械的な利用に基づいて機能する、即ち特定の圧力差が材料を変形させ圧力を外部環境へと逃がすよう機能しても良い。該スマート弁はまた、圧力タンクとポンプとの間の流れを制御するための、調節可能な流量制限器を含んでも良い。

【００２８】

他の実施例においては、前記方向制御弁は、３つのポート及び２つの切り換え位置を持つ３／２弁である。斯かる３／２弁は基本的に、ポンプ入口からポンプ出口への圧力タンクの切り換えのために必要とされる機能を提供する、標準的な構成要素である。３／２弁の利点は、ポンプ入口からポンプ出口への圧力タンクの切り換えの機能が、単一の部品で実現され得る点である。ここでもまた、当該３／２弁は、圧力変化によって機械式に機能しても良いし、又は、例えばコントローラ装置によって若しくはユーザ入力によって起動される切り換え手順によって電気的に機能しても良い。

【００２９】

本発明の一実施例によれば、前記方向制御弁は、電気的に動作させられる弁であっても良いし、又は機械式に動作させられる弁であっても良い。該弁が電動弁である場合、ポンプを制御し切り換え工程を自動化するためにプロセッサを用いることが可能となる。代替としては、前記方向制御弁は、機械式に動作させられても良い。この場合には例えば、圧力が特定の閾値に到達するか又は超過するとすぐに、該方向制御弁の或る位置から他の位置への切り換えを起動するため、機械式の構成が用いられても良い。また、機械式の動作は、操作者が手動でポンプ入口からポンプ出口へと圧力タンクを切り換えることを可能とすることも予想され得る。

【００３０】

本発明の別の実施例においては、前記機器は更に、前記ポンプ及び／又は前記方向制御弁を制御するためのコントローラを有する。斯かるコントローラは、例えば所望の機能を実行するようプログラムされたマイクロコントローラ装置であっても良い。当該コントローラは、本発明による機器又は斯かる機器を有する装置における種々の弁、及び／又はその他の全ての構成要素及びその相互作用を制御するために用いられることができる。斯かるコントローラの利点のひとつは、搾乳装置における他の制御動作を実行するためにも用いられ得る点である。

【００３１】

本発明の更なる態様においては、以上に説明されたシステムから排出するための機器と、女性の胸部を受容するための受容漏斗及び母乳を集めるための母乳槽を含むシステムと、を有する搾乳装置が提供される。斯かる搾乳装置は、授乳中の女性の母乳を容器即ち母乳槽に集めるために用いられることができる。本発明の本態様によれば、システムから排出するための該機器は、女性の胸部に気密に接続された容器から排出する。当該容器は、

本発明による機器により生成された真空によって胸部から吸い出された授乳中の女性からの母乳を集めるための母乳槽として機能する。胸部に対する該容器の気密接続は通常、女性の胸部を収容するための、例えばプラスチック材料からつくられた、漏斗又は漏斗型の部分によって実現される。個々のユーザの要件に応じて、異なる形状の胸部を収容できるよう、交換可能な漏斗を用いることも可能である。

【００３２】

本発明の更に他の態様によれば、以上に説明された搾乳装置を制御するための方法が提供される。搾乳装置の設計に依存して、ポンプ、種々の弁及び／又は種々のセンサは、搾乳器を制御するための方法を実行する少なくとも１つのコントローラにより制御されても良い。斯かるコントローラは、必要な計算及び制御動作を実行するのに適したマイクロプロセッサ又はディジタル信号プロセッサであっても良い。該コントローラは、本発明による機器のそれぞれの弁、前記装置及び／又はセンサに接続されても良い。本発明による搾乳装置を制御するための方法は、決定された設定が、センサ値に直接に関連付けられる閉ループ制御に対応しても良いし、又はユーザフィードバックを含む開ループ制御に対応しても良い。斯かる方法の利点のひとつは、本発明による機器の又は搾乳装置の全ての機能が、適切に制御される及び／又は自動的に実行されることができる点である。種々の制御ステップを実行するために、ユーザ入力が必要ないか又は殆ど必要ない。

【００３３】

本発明のこれらの及び他の態様は、以下に説明される実施例を参照しながら説明され明らかとなるであろう。

【図面の簡単な説明】

【００３４】

【図１】本発明の第１の実施例の模式的な図を示す。

【図２】本発明により生成されるシステムにおける圧力減少の例を示す。

【図３】本発明の他の実施例の模式的な図を示す。

【図４】本発明の更なる実施例の模式的な図を示す。

【図５】本発明による機器の代替例の図を示す。

【図６】搾乳装置を制御するための方法を示す。

【図７】本発明の一態様による搾乳装置を示す。

【発明を実施するための形態】

【００３５】

図１において、本発明の第１の実施例によるシステムから排出するための機器１ａが模式的に示されている。機器１ａは、ポンプ入口７とポンプ出口９との間の圧力の減少をもたらすポンプであって、ポンプ入口７によってシステム３と接続された、ポンプ５を有する。ポンプ５は斯くして、ポンプ入口７からポンプ出口９へと媒体を輸送し、それにより圧力の減少をもたらす。機器１ａは更に、或る期間の間、かけられる圧力を保持することを可能とする、圧力タンク１１を有する。更に、ポンプ５の入口７か又は出口９へと圧力タンク１１を切り換えるための、方向制御弁１３が備えられる。本発明による機能を提供するため、即ちポンプ５のみを用いた場合と比べて高いレベルの真空を生成することを可能とするため、方向制御弁１３は、所定の基準が満たされたときに、ポンプ５の入口７から出口９へと圧力タンク１１を切り換えるよう構成される。それ故、方向制御弁１３は、媒体の吸入を可能とし、異なる構成に切り換えられることができる、異なる接続ポート即ち開口を提供する。

【００３６】

本発明の図示された実施例においては、方向制御弁１３は特に、３つのポートを持つ。これら３つのポートは、ポンプ入口７か又はポンプ出口９が圧力タンク１１に結合されるよう、切り換えられることができる。本文脈において、結合されるとは、方向制御弁１３の現在の設定に依存して、方向制御弁１３の或るポートから別のポートへと媒体が流れることができるよう接続されることを示す。当該切り換え機能を提供するため、方向制御弁は例えば、或る位置から別の位置へと機械式に又は電気的に動かされ、それにより或る経

路又は別の経路を通って媒体が流れることを可能とするスプールを円筒のなかに有する。

【００３７】

以上に概説されたように、本発明による機器は、ポンプ５のみを用いる場合と比べて、高いレベルの真空を実現することを可能とする。通常、ポンプ５は、該ポンプがポンプ入口７とポンプ出口９との間に生成することができる達成可能な最大の圧力低下によって特徴付けられる。斯くして、ポンプ５の出口９において既に低い圧力がかけられているとき、ポンプ５の入口における達成可能な圧力レベルは、ポンプ５の出口９が外部環境に直接に接続されている場合よりも高い。この挙動が、本発明により利用される。最初に、システム３及び圧力タンク１１の両方がポンプ５によって吸引され、システム３及び圧力タンク１１の両方において同じレベルの圧力（圧力レベル）が生成される。次いで、方向制御弁１３によって、圧力タンク１１がポンプ５の入口７からポンプ５の出口９へと切り換えられる。このことは、ポンプ５のみを用いる場合と比べて、システム３において更に高い真空レベル（低い圧力）を生成することを可能とする。

【００３８】

図２は、本発明による機器により生成される典型的な圧力低下を示す。圧力ｐは、時間ｔの関数として示されている。最初、システム３及び圧力タンク１１における圧力は、外部環境における圧力ｐ１と平衡状態にある。次いで、ｔ１においてポンプ５がスイッチオンされ、システム３及び圧力タンク１１の両方において圧力の低下をもたらす。特定の時点ｔ２において、この構成において達成可能な最高の真空レベルｐ２が到達される。ポンプ５の構成パラメータにより、ポンプ５はより高いレベルの真空（より低い圧力）を生成することはできない。所定の基準が満たされるとすぐに、方向制御弁１３が、圧力タンク１１をポンプ５の入口７から出口９へと切り換える。当該所定の基準は、例えば圧力閾値であっても良い。当該切り換えによって、該ポンプの入口７及び出口９における圧力レベルは一時的に再び平衡状態となる。ポンプ５はこのとき、システム３において更に高いレベルの真空（即ちより低い圧力）をもたらすことができる。しかしながら、この構成においても、システム３において特定の圧力値ｐ３が到達されると、ポンプ５は飽和状態となる。図２において、ｔ３においてポンプ５がスイッチオフされる及び／又は放出弁が開かれると、外部環境との圧力平衡に導かれる。

【００３９】

図３は、本発明による機器の別の実施例１ｂを示す。図１に示された機器１ａと比べると、ポンプ５の出口９及び圧力タンク１１に結合された一方弁１５が、更に備えられている。該一方弁１５は、輸送される媒体又はいずれかの種類の流体の、外部環境からポンプ５及び／又は圧力タンク１１への逆流を防ぐことができる。更に、圧力タンク１１のなかの圧力を決定するための第１のセンサ１７が示されている。該第１のセンサ１７は、圧力タンク１１における圧力が所定の閾値即ち圧力閾値を下回るとすぐに、ポンプ５の入口７から出口９への圧力タンク１１の切り換えを実行することを可能とする。また更に、図示される実施例は、ポンプ５のスループットを決定するための第２のセンサ１９を示している。当該第２のセンサ１９は、方向制御弁１３の切り換えを起動するため、センサ１７の代替として又はセンサ１７と組み合わせて用いられても良い。明瞭な可能性のひとつは、スループットセンサ１９によってスループットを決定し、連続して該スループットが所定の閾値を下回っているか否か、即ちポンプ５が少量の流体しか輸送しておらず、以上に説明されたような飽和状態にポンプ５が事実上あるか否かを決定することである。

【００４０】

図３は更に、システム３及び／又は圧力タンク１１から外部環境へと圧力を放出するための放出弁２１を示している。該放出弁２１は、リモートコントロールを可能とする制御接続部２２を有しても良い。

【００４１】

また更に、図３は、ポンプ５、方向制御弁１３、センサ１７及び１９を制御するための、並びに制御接続部２２を介して放出弁２１を制御するための、コントローラ２３を示している。本発明による機器の更なる実施例においては、コントローラ２３は、他のセンサ

又はその他の電子的に制御可能な構成要素をも制御しても良い。とりわけ、ポンプ５は、コントローラ２３により生成される特定の制御パルス又はその他の信号を必要とする、電動ポンプ又は機械式ポンプであっても良い。

【００４２】

該コントローラは、本発明の他の態様による搾乳装置の他の機能をも制御する、組み合わせられたコントローラであっても良く、これにより、ユーザフィードバックに応答して、吸引サイクル又はかけられる圧力の変動、信号若しくはユーザインタフェースに応じた機能の自動的な中断、又はその他の機能を可能としても良い。

【００４３】

本発明による機器の更に他の実施例１ｃが、図４に模式的に示されている。本実施例においては、機器１ｃは、方向制御弁１３、一方弁１５及び放出弁２１の機能を組み合わせた、スマート弁２５を有する。該スマート弁２５は、ポンプ５の入口７及び出口９、並びに圧力タンク１１に接続されている。種々の所望の機能を提供するためスマート弁２５を用いる主な利点のひとつは、複数の部品の代わりに１つの部品のみしか必要とされない点である。このことは、本発明による機器の、より安価な実装を可能とし得る。更に、斯かる統合された部品によって、故障率が低下させられ得る。スマート弁２５は更に、速度制御のための流量制限器を含んでも良い。

【００４４】

図５において、本発明による機器の実施例１ｄの更に他の模式的な図が示されている。方向制御弁１３は、種々の部分及びとり得る切り換え機能を強調するため、更に詳細化して示されている。斯かる３／２弁、即ち三方二位置方向制御弁は、ポンプ５の入口７から出口９へと圧力タンク１１を切り換えるための所望の機能を提供する。更に、本実施例においては、該方向制御弁とポンプ５の出口９との間に、調節可能な流量制限器２６が配置される。該調節可能な流量制限器は、特に最大スループットを調節可能に制限することにより、輸送される媒体の流量を制御することを可能とする。

【００４５】

本実施例においては、排出を実行されるべきシステム３は、漏斗２７及び母乳槽２９を有する。漏斗２７は、女性の胸部を収容する。ポンプ５により生成された不完全真空は次いで、該胸部にかけられ、母乳が搾出されることができる。該搾出された母乳は、槽２９に集められる。更に、外部環境から方向制御弁１３又はポンプ５への流体の逆流を防止するための一方弁１５が図示されている。とりわけ、本発明においては、ポンプ５は槽２９から空気を輸送して出し、該空気を一方弁１５を通して外部環境へと放出する。

【００４６】

図６において、本発明の一態様の実施例による搾乳装置を制御するための方法が示されている。斯かる方法は例えば、以上に説明された搾乳装置に含まれるコントローラにより実行されても良い。該コントローラは、より高い真空レベル（即ちより低い圧力）を達成するため、種々の構成要素（例えば弁、センサ、ポンプ又はその他）を制御しても良い。

【００４７】

図６に示された実施例によれば、ポンプは最初に、システム及び圧力タンクにおいて圧力の減少を生成するよう構成される（Ｓ１０）。ポンプのタイプ、及びコントローラへの接続のタイプに依存して、当該構成は特に、該ポンプの起動を含む。例えば該ポンプが異なるレベルで動作させられることができる場合には、当該構成はまた、適切なレベルを選択することを含んでも良い。次いで、所定の基準が満たされているか否かが決定される（Ｓ１２）。好適には、当該決定は、少なくとも１つのセンサ、特に圧力センサ又はスループットセンサから得られたセンサ値に基づく。従って、所定の基準が満たされているか否かの決定は、センサ（即ちスループットセンサ又は圧力センサ）からセンサ値を取得することを含む。このとき、該センサ値に基づいて、ことによるとユーザ入力とも組み合わせて、当該所定の基準が満たされているか否かが決定されても良い。本発明による搾乳器を制御するための方法は更に、該所定の基準が満たされている場合、ポンプの出口に圧力タンクを接続するよう、方向制御弁を切り換える（Ｓ１４）ことを有する（圧力タンクは最

初、ポンプの入口に接続されていた）。例えば該切り換えは、特定の閾値が該センサ値によって超過されたときに実行される。方向制御弁の切り換えは、必要な制御信号を接続ケーブルに送って、切り換え手順を起動することを示す。搾乳装置を制御するための該方法は更に、更なる弁（例えば方向制御弁及び／又は一方弁）及び装置（例えばポンプ）についての制御設定を決定し、該決定された制御設定に基づいてこれら弁及び装置を構成する（図示されていない）ことを有しても良い。ここでもまた、該構成は、必要な制御信号を接続ケーブルに送る（又は該信号を無線接続を介して送信する）ことを示す。該方法は、以上に概説されたように、閉ループ制御を表しても良いし、開ループ制御を表しても良い。

【００４８】

更に、本発明によるシステムから排出するための方法（図示されていない）は、システム及び圧力タンクにおける圧力の低下を生成すること、圧力タンクにおいてかけられている圧力値を保持すること、所定の基準が満たされたときに、ポンプ入口から出口へと圧力タンクを切り換えること、を有しても良い。

【００４９】

図７は、本発明の他の態様による搾乳装置３１を示す。受容漏斗２７は、女性の胸部を収容するような形状とされる。圧力低下、即ち不完全真空が胸部にかけられるとすぐに、母乳が搾出される。図７に示されるように、搾出された母乳は、槽２９に集められる。該槽は、スマート弁２５を通して該槽に接続されたポンプ５によって排出される。更に、圧力タンク１１及びコントローラ２３が含まれる。更に、種々の構成要素のために必要とされる電気エネルギーを供給するバッテリ３３が示されている。本実施例における図示されたスマート弁２５は、方向制御弁、一方弁及び放出弁の機能を包含している。該弁はまた、ポンプ５の故障の場合に、ユーザを損傷させることを防止する安全弁としても機能する。コントローラ２３は、スマート弁２５を制御し、圧力タンク１１のなかの圧力を測定し、ポンプ５を制御する。

【００５０】

図示されてはいないが、電動ポンプの代わりに機械式ポンプが用いられることも可能である。このことは、コントローラ２３が、ポンプ５に接続される必要がないことを意味する。機械式ポンプは通常、圧力の低下を生成するため、手動で力をかけるためのハンドル部を有する。更に、通常は、例えばユーザインタフェース（例えばボタン、タッチパッド、トラックボール又はその他の入力手段と組み合わせられた音響的、視覚的又は機械的なフィードバック手段）、電源（例えばバッテリ、太陽電池若しくはその他のエネルギー生成器、又は幹線電源接続器）、又は搾乳器の視覚的な知覚を改善するためのデザイン的要素のような、周辺装備（図示されていない）が備えられる。

【００５１】

ポンプの入口から出口への圧力タンクの切り換えの代わりに、或るポンプの出口が別のポンプの入口に直接に接続されるよう、複数のポンプを直列に接続することも可能である。このことは、真空レベルの向上も可能とする。

【００５２】

本発明は図面及び以上の記述において説明され記載されたが、斯かる説明及び記載は説明するもの又は例示的なものであり、限定するものではないとみなされるべきである。本発明は、開示された実施例に限定されるものではない。図面、説明及び添付される請求項を読むことにより、請求される本発明を実施化する当業者によって、開示された実施例に対する他の変形が理解され実行され得る。

【００５３】

請求項において、「有する（comprising）」なる語は他の要素又はステップを除外するものではなく、「１つの（a又はan）」なる不定冠詞は複数を除外するものではない。単一のプロセッサ又はその他のユニットが、請求項に列記された幾つかのアイテムの機能を実行しても良い。特定の手段が相互に異なる従属請求項に列挙されているという単なる事実は、これら手段の組み合わせが有利に利用されることができないことを示すものではな

い。

【００５４】

請求項におけるいずれの参照記号も、請求の範囲を限定するものとして解釈されるべきではない。

【図１】

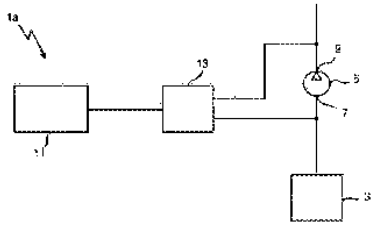


FIG.1

【図２】

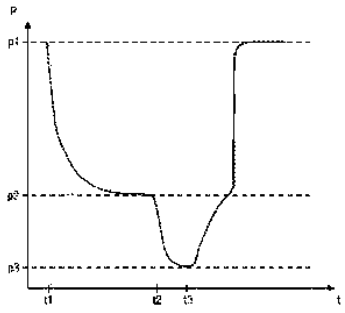


FIG.2

【図３】

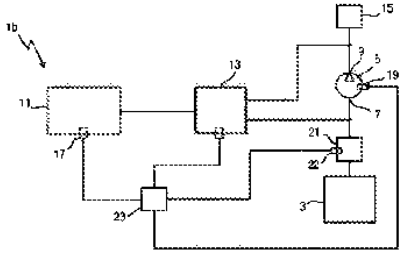


FIG.3

【図４】

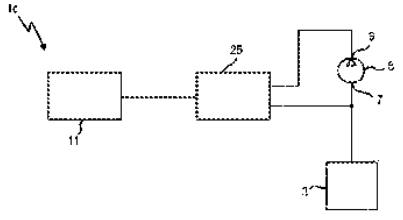


FIG.4

【図５】

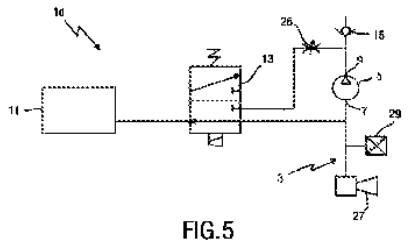


FIG.5

【図６】

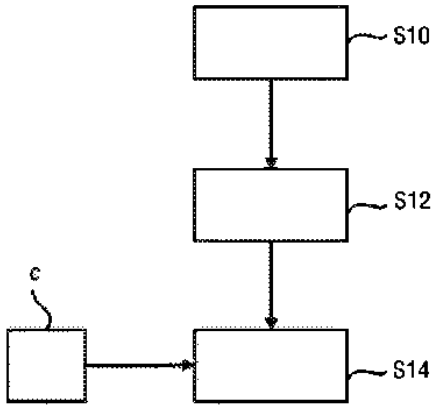


FIG.6

【図７】

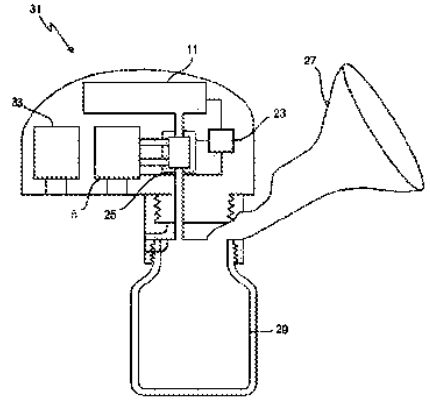


FIG.7

【手続補正書】
【提出日】平成28年1月15日(2016.1.15)
【手続補正１】
【補正対象書類名】特許請求の範囲
【補正対象項目名】全文
【補正方法】変更
【補正の内容】
【特許請求の範囲】
【請求項１】
システムから排出するための機器であって、
ポンプ入口とポンプ出口との間の圧力の低下を生成するための、前記入口によって前記システムと接続されるのに適したポンプと、
かけられた圧力値を保持するための圧力タンクと、
前記ポンプ入口か又は前記ポンプ出口のいずれかに前記圧力タンクを切り換えるための方向制御弁と、
を有し、前記ポンプは、前記圧力タンクが前記ポンプ入口に接続されたときに、前記システム及び前記圧力タンクから外部環境へと媒体を輸送し、
前記方向制御弁は、所定の基準が満たされた場合に、前記ポンプ入口から前記ポンプ出口へと前記圧力タンクを切り換えるよう構成された機器。
【請求項２】
外部環境から前記ポンプ及び／又は前記圧力タンクへの流体の逆流を防ぐための、前記ポンプ出口と前記圧力タンクとの間に結合された一方弁を更に有する、請求項１に記載の機器。
【請求項３】
前記圧力タンクにおける圧力を決定するためのセンサを更に有する、請求項１に記載の機器。
【請求項４】
前記方向制御弁が、前記圧力タンクにおける圧力が所定の圧力閾値を下回ったときに、前記ポンプ入口から前記ポンプ出口へと前記圧力タンクを切り換えるよう構成された、請求項３に記載の機器。
【請求項５】
前記ポンプのスループットを決定するためのセンサを更に有する、請求項１に記載の機器。
【請求項６】
前記方向制御弁は、前記ポンプの前記スループットが所定のスループット閾値を超えたときに、前記ポンプ入口から前記ポンプ出口へと前記圧力タンクを切り換えるよう構成された、請求項５に記載の機器。
【請求項７】
前記システムから及び／又は前記圧力タンクから外部環境へと圧力を放出するための放出弁、及び／又は、前記圧力タンクから前記ポンプ出口への輸送される媒体の流量を制御するための流量制限器、を更に有する、請求項１に記載の機器。
【請求項８】
前記ポンプは、前記ポンプ入口から前記ポンプ出口へと、流体を移動させるための、容積移送式ポンプである、請求項１に記載の機器。
【請求項９】
前記ポンプは、電動ポンプ、又は人間の手及び／又は足の動きによって駆動される機械式ポンプである、請求項１に記載の機器。
【請求項１０】
前記方向制御弁と前記一方弁とが、スマート弁に組み合わせられた、請求項２に記載の機器。

【請求項１１】
前記方向制御弁は、３つのポート及び２つの切り換え位置を持つ３／２弁である、請求項１に記載の機器。
【請求項１２】
前記方向制御弁は、電気的又は機械式に動作させられる弁である、請求項１に記載の機器。
【請求項１３】
前記ポンプ及び／又は前記方向制御弁を制御するためのコントローラを更に有する、請求項１に記載の機器。
【請求項１４】
請求項１に記載の機器と、女性の胸部を受容するための受容漏斗及び母乳を集めるための母乳槽を含むシステムと、を有する搾乳装置。
【請求項１５】
搾乳装置を制御するための方法であって、
システムにおける及び圧力タンクにおける圧力の低下を生成するためのポンプであって、前記圧力タンクがポンプ入口に接続されたときに、前記システム及び前記圧力タンクから外部環境へと媒体を輸送するポンプを構成するステップと、
所定の基準が満たされているか否かを決定するステップと、
前記所定の基準が満たされている場合、前記ポンプ入口からポンプ出口へと前記圧力タンクを切り換えるよう方向制御弁を構成するステップと、
を有する方法。

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2014/065574

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/06 F04B23/02 F04B37/14 F04B41/02
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M F04B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2005/283112 A1 (BRITTO JAMES J [US] BRITTO JAMES JOSEPH [US]) 22 December 2005 (2005-12-22) paragraphs [0018] - [0025], [0035] figures 1-3, 4c	1-15
A	US 2013/165852 A1 (JAEGER-WALDAU REINHOLD [DE]) 27 June 2013 (2013-06-27) paragraphs [0051] - [0072] figures 1a, b	1-15
A	US 2010/075285 A1 (STALLING DAVID L [US] ET AL) 25 March 2010 (2010-03-25) figure 2	1,15

-/--

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 September 2014	01/10/2014

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

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2014/065574

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB 2 392 626 A (UNIV SCHOOL NIHON JURIDIC PER [JP]) 10 March 2004 (2004-03-10) page 16, line 23 - page 19, line 23 figures 1, 3	1,15
A	US 2003/236491 A1 (MCKENDRY BRUCE [US] ET AL) 25 December 2003 (2003-12-25) figure 5	1,15

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2014/065574

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2005283112 A1	22-12-2005	CA 2510385 A1	22-12-2005
		US 2005283112 A1	22-12-2005
US 2013165852 A1	27-06-2013	CN 103170019 A	26-06-2013
		EP 2606918 A1	26-06-2013
		ES 2493073 T3	11-09-2014
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		ES 2438777 T3	20-01-2014
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		WO 02094345 A1	28-11-2002
US 2003236491 A1	25-12-2003	NONE	

Form PCT/ISA/210 (patent family annex) (April 2005)

フロントページの続き

(81)指定国 AP(BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), EA(AM, AZ, BY, KG, KZ, RU, TJ, TM), EP(AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OA(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG), AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US

(72)発明者 アールダース アーノルド
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Ｆターム(参考) 4C077 AA22 DD07 DD10 DD25 DD28 JJ05 JJ13 JJ24 KK25

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DESCRIPTION JP2016526396A

10 Apparatus and Method for Evacuation from System

[0001]

14 The present invention relates to an apparatus for discharging from a system, a breast pump and a method for controlling a breast pump.

[0002]

19 In many applications, vacuum pumps are needed to provide (incomplete) vacuum for various industrial, scientific and medical processes. These various steps require various vacuum levels leading to a wide variety of pump types and pumping principles. The 2 main parameters of the vacuum pump are the achievable flow rate and the achievable vacuum level (i.e., pressure level). Both pumping principles have unique advantages and disadvantages, and both applications have unique requirements for pumps. Pumps capable of providing high levels of vacuum or high flow rates are typically large and difficult to manufacture. Therefore, when selecting or manufacturing a vacuum pump for a particular application, a compromise needs to be found between the required flow rate, maximum vacuum level, manufacturing cost, manufacturing size and other parameters.

[0003]

32 One application area for vacuum pumps is the field of breast pumping devices, i.e. devices for extracting breast milk from the breast of breastfeeding women.

34 Such devices typically include a vacuum pump to provide a (incomplete) vacuum applied to the female chest to draw breast milk from the chest. WO 2012/127405 A1 discloses a breast pump operable to generate negative pressure. The maximum negative pressure that can be achieved by the breast pump is a function of the maximum pressure value that the

(incomplete) vacuum pump used can provide. If a high level of vacuum is required, different types of pumps are required, which typically make the breast pump larger and/or more expensive to manufacture.

[0004]

44 In US 2005/02831112 A1 a breast pump is disclosed.

45 The apparatus includes a chest shield adapted to fit over a papilla of the chest and a streamline coupled to the chest shield. The streamline is configured to allow air to flow through the streamline through a pump coupled to the chest shield via the streamline. The pump includes a pump inlet and a pump outlet, and is operable to create a pressure drop between the nipple and the pump, the pressure drop creating a suction force at the chest shield by reducing the pressure of air at the streamline. A blowback valve is provided between the flow line and the pump, the blowback valve having a valve piston disposed in a valve housing. The valve housing includes a flow line opening in communication with the chest shield via the flow line, a valve inlet configured to communicate an exterior with the flow line, and a valve outlet configured to communicate the exterior with the flow line. The valve piston is configured to alternatively seal the valve inlet and the valve outlet.

[0005]

59 In US 2013/0165852 A1 an electric breast pump is disclosed.

60 The pump has an electric motor, a pump driven by the motor, a suction cup, an electrically operated 1st three-way valve in the suction line, an electrically operated 2nd three-way valve in the pressure line, and an electronic control system, which sets the electric motor in an operating mode or an idling mode depending on the actuation of the switch. In the operating mode, the electric motor and the electrically operated 1st and 2nd three-way valves are operated in a cycle with a suction phase in which the electric motor is switched on, the inlet of the pump is connected to the suction cup via the 1st three-way valve and the float valve, and the pump outlet is connected via the 2nd three-way valve.

[0006]

71 It is an object of the present invention to provide an apparatus for discharging from a system and achieving an appropriate vacuum level, while enabling cost-effective manufacturing and implementation in a compact housing.

74 A further object of the present invention is to provide a breast pump and a method for controlling a breast pump.

[0007]

79 In a first aspect of the invention there is provided an apparatus for discharging from a system,

comprising a pump suitable for being connected to the system by a pump inlet and a pump outlet for generating a drop in pressure between the pump inlet and the pump outlet, a pressure tank for holding an applied pressure value, and a directional control valve for switching the pressure tank to either the pump inlet or the pump outlet, wherein the pump transports media from the system and the pressure tank to an external environment when the pressure tank is connected to the pump inlet, and wherein the directional control valve is configured to switch the pressure tank from the pump inlet to the pump outlet when a predetermined criterion is met.

[0008]

91 In a further aspect of the invention there is provided a breast pump comprising the apparatus described above and a system comprising a receiving funnel for receiving a female chest and a breast milk reservoir for collecting breast milk.

[0009]

97 In yet another aspect of the invention, there is provided a method for controlling a breast pump, the method comprising: configuring a pump for generating a pressure drop in a system and in a pressure tank, the pump transporting a medium from the system and the pressure tank to an external environment when the pressure tank is connected to a pump inlet; determining whether a predetermined criterion is met; and configuring a directional control valve to switch the pressure tank from the pump inlet to a pump outlet if the predetermined criterion is met.

[0010]

107 Preferred embodiments of the invention are defined in the dependent claims. It should be understood that the claimed method and breast pump device have similar and/or identical preferred embodiments as defined in the claimed device and the dependent claims.

[0011]

113 The device according to the invention realizes an increase in the vacuum level achieved by the use of a directional control valve and an additional pressure tank.

115 The pump transports the medium from inside to outside, thereby creating a pressure drop therebetween. The transported medium may comprise any type of fluid, i.e. gas or liquid, which causes a pressure drop in the system when transported out of the system by the pump. If the outlet of the pump is connected to the external environment and the medium to be transported is released to the external environment, the pressure in the system drops compared to the pressure of the external environment.

[0012]

124 According to the invention, the pump not only transports the medium from the system, but also the medium contained in the pressure tank, whereby both the pressure in the system and the pressure in the pressure tank are reduced.

127 Thus, it will be pumped by the pump from both the system and the pressure tank.

[0013]

131 The pressure tank (also referred to as a vacuum tank) allows to retain the applied (low) pressure value by providing a constant value that does not change regardless of the pressure value that changes inside and outside the tank.

134 A possible embodiment of such a pressure tank may be a rigid, gas-tight, non-flexible metal body, for example with a single opening to be connected to the pump. Further, in the present context, holding the applied pressure value refers to applying or causing the pressure value, for example, by sucking out the medium from the pressure tank, then closing or sealing the opening of the pressure tank, and keeping the pressure in the pressure tank constant until pressure compensation is performed (e.g., by opening the tank to release the medium in the tank to the external environment or to pass the medium from the external environment to the tank).

[0014]

145 Instead of varying the pressure in the pressure tank by pumping the medium from or into the pressure tank, it is also possible to adapt the pressure tank (passively) to a pressure level or pressure value and then transport the tank to areas where the ambient pressure is different, so that the pressure state of the internal environment is maintained.

149 The pressure tank can be used in both directions, i.e. it can hold a low pressure or a high pressure with respect to the external environment.

[0015]

154 According to the invention, the pressure tank is connected to the pump inlet or the pump outlet by means of a directional control valve.

156 Such a directional control valve allows switching to different paths, and depending on the setting of the directional control valve, the medium can be guided to different ports. According to the invention, the directional control valve provides in particular the function of switching the pressure tank to the pump inlet in the 1st setting and to the pump outlet in the 2nd setting. Thus, it is possible to connect the opening of the pressure tank to either side of the pump.

[0016]

165 Furthermore, according to the invention, the directional control valve performs such a switching procedure, i.e. a procedure for switching the pressure tank from one side of the pump to the other, when a predetermined criterion is met.

168 For example, the pressure tank is initially connected to the pump inlet and does not draw media from the system and from the pressure tank. As soon as a predetermined criterion is met, the pressure tank is then connected to the pump outlet. In this configuration, when the directional control valve is in the 1st setting, the pump transports the medium from the system and the pressure tank to the external environment. After switching the directional control valve to the 2nd setting, the medium is then transported from the system at the pump inlet and to the pressure tank at the pump outlet.

[0017]

178 One advantage of the device according to the invention is that a reduction or overall reduction in the pressure generated is promoted.

180 Initially, the pump creates a constant pressure drop between the external environment and the system and pressure tank. As soon as a predetermined criterion is met, i.e. the pressure level is no longer lowered, the pressure tank is switched to the pump outlet by means of the directional control valve. Immediately after the switching, this results in a pressure equilibrium at the pump inlet and the pump outlet. Then, it is utilized that if the pressure level at the pump outlet is already lower than the pressure level in the external environment, the pump can generate a lower pressure in the system compared to the external environment. Independently of the pressure level in the external environment, the pump creates a pressure drop between the pump inlet and the pump outlet. Thus, if the pressure level at the pump outlet is already lower than the pressure level in the external environment, it is possible to further reduce the pressure level at the pump inlet. This is utilized according to the invention by means of a directional control valve which can switch the pressure tank from the pump inlet to the pump outlet when a predetermined criterion is met. In particular, the achievable pressure or vacuum level of the pump is improved by switching the pressure tank as outlined above. The achievable vacuum level, i.e. the lowest pressure that can be generated with the pump, is increased compared to the original achievable vacuum level.

[0018]

199 In a first embodiment of the invention, the device further comprises a one-way valve coupled between the pump outlet and the pressure tank to prevent backflow of fluid from the external environment to the pump and/or the pressure tank.

202 The valve, on the one hand, essentially allows the medium to pass in one direction, but prevents the medium from passing in the other direction. According to a first embodiment of the invention, the one-way valve is arranged at the pump outlet. Thus, even if the pressure tank is connected to the pump outlet by the directional control valve, backflow of the

transported medium from the external environment to the pressure tank or pump is prevented. Initially, as long as the pressure tank is connected to the pump inlet, the one-way valve simply seals the pump outlet from the external environment, allowing the medium transported by the pump to escape to the external environment. However, contrary to the direction of the one-way valve, no medium can flow back from the external environment to the pump or to the system. As soon as the pressure tank is then switched from the pump inlet to the pump outlet, as described above, the one-way valve also prevents medium from flowing back from the external environment to the pressure tank. In this configuration, the pump outlet and the pressure tank are separated unidirectionally from the external environment. One advantage of the one-way valve is that the pressure can be maintained compared to the pressure in the external environment.

[0019]

220 According to a further embodiment of the invention, the device comprises a sensor for determining a pressure in the pressure tank.

222 The pressure sensor may be based on, for example, capacitive, electromagnetic, piezoelectric or piezoresistive measurement principles and may provide information about the pressure of the medium or fluid in the pressure tank. The sensor may be a smart sensor that provides a digital corrected output signal with information about the absolute pressure in the pressure tank, or an analog sensor that provides an analog value of the pressure dependent signal in the pressure tank. The signal generated by the sensor makes it possible to control the device according to the invention, for example by enabling the use of a closed-loop control, in which specific parameters of the device are configured directly on the basis of the obtained sensor signal.

[0020]

234 An example of the use of the sensor is further detailed in another embodiment of the invention, wherein the directional control valve is configured to switch the pressure tank from the pump inlet to the pump outlet when a pressure in the pressure tank falls below a predetermined pressure threshold.

238 Thus, the pressure in the pressure tank determined by the sensor described above is used as a criterion for determining when a switching of the pressure tank from the pump inlet to the pump outlet is to be performed. By defining a particular pressure threshold level or predetermined threshold, the configuration of the directional control valve can be directly associated with the current pressure in the pressure tank that is equivalent to the pressure in the system while the pressure tank is connected to the pump inlet. The predetermined threshold value may be selected depending on the characteristics of the pump, for example the maximum pressure difference or the maximum vacuum level achievable. Depending on the selected setting, one of the advantages of the present embodiment is that the control of the switching process is simple and easy to implement.

[0021]

251 Further, according to another embodiment of the present invention, the apparatus further comprises a sensor for determining a throughput of the pump.

253 Such a throughput sensor may be a flow sensor implemented as, for example, one or more pressure sensors, a thermal flowmeter, a mechanical positive displacement meter, or any other flow sensor or flowmeter. The flow sensor can basically be used as an alternative to the sensor for determining the pressure in the pressure tank described above. Equivalent functions may be realized. Advantageously, the use of such sensors for determining the throughput of the pump allows the switching procedure to be activated automatically without the need for further user input.

[0022]

263 In a preferred embodiment of the invention, the directional control valve is configured to switch the pressure tank from the pump inlet to the pump outlet when the throughput exceeds a predetermined throughput threshold.

266 As explained above, the measured values of the sensor for determining the throughput of the pump are evaluated and the obtained sensor values are used as criteria for determining whether the pressure tank should be switched from the pump inlet to the pump outlet. In particular, the principle may be used if a threshold value, i.e. a throughput value, at which the switching is to be performed, is determined on the basis of the characteristics of the pump. One possible setting of the threshold may be a specific percentage of the maximum throughput that can be achieved by the pump. Thus, as soon as the pump operates at a relatively low efficiency, the pressure tank is switched from the inlet to the outlet, increasing the throughput of the pump. As soon as the maximum total pressure drop is reached, the sensor will again record only a small flow rate.

[0023]

279 In another embodiment of the invention, the device further comprises a discharge valve for discharging pressure from the system and/or from the pressure tank to the external environment.

282 In some applications, it is necessary to be able to release pressure or in particular vacuum from the system to the external environment in order to continue its intended use. Such a discharge valve may be electrically operated or manually operated and may be implemented in the form of a simple butterfly valve or any other type of valve. For example, if the pressure tank is currently connected to the pump outlet, it is possible to release pressure from the system and the pressure tank or only from the system, depending on the installation position of the release valve. This allows the release valve to be operated automatically, preferably without requiring any external input in addition to the pressure difference between the

system or pressure tank and the external environment. The discharge valve can then act as a safety valve which prevents the system or tank from becoming too low/high pressure in the event of a pump failure or uncontrolled behavior. For example, if the discharge system is a breast pump of a breast pump, such a safety valve can prevent harm to the user.

[0024]

297 The device for discharging from the system according to the invention further comprises a flow restrictor (optionally adjustable) for controlling the flow rate of the medium transported from the pressure tank to the pump outlet.

300 Such a flow restrictor realizes a smoother and/or gentler pump curve, in particular by allowing maximum throughput restriction.

[0025]

305 In a preferred embodiment of the invention, the pump is a positive displacement vacuum pump for transferring a fluid, in particular a gas, from the pump inlet to the pump outlet.

307 The pump may be either an electric pump or a mechanical pump that is moved by movement of the human hand and/or foot in another embodiment of the invention. Depending on the application, different types of pumps have their respective advantages and disadvantages. A positive displacement vacuum pump is advantageous, in particular, if the gas, i.e. the gas molecules, is to be pumped from the pump inlet to the pump outlet. Such a positive displacement vacuum pump relies on expansion of a given volume, which reduces the pressure in the expanded volume. A portion of the volume is then separated and reexpanded. This procedure may be repeated several times to increase the level of vacuum and can be easily implemented in pumping gas. The main concern here is the vacuum level that the pump can produce, i.e. the minimum number of molecules remaining per volume. One of the advantages of such a positive displacement vacuum pump is its simple construction and its availability on the market.

[0026]

322 Regardless of which pumping principle is utilized, the pump included in the device may be a battery or a powered electric pump powered by a power source, which may be controlled by, for example, a processor device or provide a direct user interface.

325 Alternatively, it is also possible that the device has a mechanical pump that does not require any electrical energy but can be powered by manual power conversion, for example by movement of the human hand and/or foot. One possibility of such a mechanical pump is the use of a handle portion which is moved periodically and converts a pumping mechanism, such as the volume transfer principle described above, into movement. The advantages of mechanical pumps include that they do not require charging of the battery or the use of a cable connection. The risk of failure and the risk of injury to the user, for example in the case

of a breast pump, is also reduced. On the other hand, the electric pump may be more convenient to use.

[0027]

337 In another preferred embodiment of the invention, the directional control valve and one-way valve are combined into a smart valve.

339 Such a smart valve may be an integrated part combining the function of the control valve and the function of the one-way valve into 1 component. The advantage of combining 2 valves into 1 component is that structural space can be reduced. Furthermore, when the number of components of the device is minimized, it may also be possible to reduce costs. Such smart valves may further include a discharge valve, which may further reduce the number of components. Furthermore, the function of the safety valve, i.e. the protection of the user of the device or of the device itself, may be integrated into the smart valve. Such smart valves may be fully mechanically controlled and may function based on pressure differentials and mechanical utilization, i.e., a particular pressure differential may function to deform the material and release the pressure to the external environment. The smart valve may also include an adjustable flow restrictor to control flow between the pressure tank and the pump.

[0028]

354 In another embodiment, the directional control valve is a 3/2 valve with 3 ports and 2 switching positions.

356 Such a 3/2 valve is basically a standard component that provides the functionality required for switching the pressure tank from the pump inlet to the pump outlet. The advantage of the 3/2 valve is that the function of switching the pressure tank from the pump inlet to the pump outlet can be realized in a single piece. Again, the 3/2 valve may function mechanically by pressure changes or electrically by a switching procedure, e.g., activated by a controller device or by user input.

[0029]

365 According to an embodiment of the present invention, the directional control valve may be an electrically operated valve or a mechanically operated valve.

367 If the valve is a motorized valve, a processor can be used to control the pump and automate the switching process. Alternatively, the directional control valve may be operated mechanically. In this case, for example, a mechanical arrangement may be used to activate a switch of the directional control valve from one position to another as soon as the pressure reaches or exceeds a certain threshold. It may also be expected that mechanical operation allows the operator to manually switch the pressure tank from the pump inlet to the pump outlet.

[0030]

377 In another embodiment of the invention, the device further comprises a controller for controlling the pump and/or the directional control valve.

379 Such a controller may be, for example, a microcontroller device programmed to perform the desired function. The controller can be used to control various valves and/or all other components and their interactions in the device according to the invention or in the device comprising such a device. One advantage of such a controller is that it can also be used to perform other control operations in the breast pump.

[0031]

387 In a further aspect of the invention there is provided a breast pump comprising a device for discharging from the system described above and a system comprising a receiving funnel for receiving a female chest and a breast milk reservoir for collecting breast milk.

390 Such a breast pump can be used to collect breast milk of a lactating woman in a container or breast tank. According to this aspect of the invention, the device for discharging from the system discharges from a container hermetically connected to the female chest. The container serves as a breast milk reservoir for collecting breast milk from a lactating woman that is drawn from the chest by the vacuum generated by the device according to the invention. The hermetic connection of the container to the chest is usually realized by a funnel or funnel-shaped part, for example made of plastic material, for receiving the female chest. Depending on the requirements of the individual user, it is also possible to use a replaceable funnel so that chests of different shapes can be accommodated.

[0032]

402 According to yet another aspect of the invention, a method for controlling a breast pump as described above is provided.

404 Depending on the design of the breast pump, the pumps, the various valves and/or the various sensors may be controlled by at least one controller performing the method for controlling the breast pump. Such a controller may be a microprocessor or digital signal processor suitable for performing the necessary computing and control operations. The controller may be connected to a respective valve, said device and/or sensor of the device according to the invention. The method for controlling a breast pump according to the invention may correspond to a closed-loop control in which the determined setting is directly associated with the sensor value or may correspond to an open-loop control comprising user feedback. One advantage of such a method is that all the functions of the device according to the invention or of the milking device can be controlled and/or automatically performed accordingly. There is no or little need for user input to perform the various control steps.

[0033]

These and other aspects of the invention will be described and apparent with reference to the examples described below.

[0034]

FIG. 1 shows a schematic diagram of a first embodiment of the present invention.

An example of pressure reduction in the system produced by the present invention is shown.

A schematic diagram of another embodiment of the present invention is shown.

A schematic illustration of a further embodiment of the invention is shown.

A diagram of an alternative example of the device according to the invention is shown.

A method for controlling a breast pump is shown.

A breast pump according to one embodiment of the present invention is shown.

[0035]

FIG. 1 schematically shows a device 1 afor discharging from a system according to a first embodiment of the invention.

The device 1 ahas a pump 5 which results in a reduction in pressure between the pump inlet 7 and the pump outlet 9, and which is connected to the system 3 by the pump inlet 7.

Pump 5 thus transports the medium from pump inlet 7 to pump outlet 9, thereby resulting in a reduction in pressure.

The device 1a further comprises a pressure tank 11 which allows to retain the pressure applied for a period of time.

Furthermore, a directional control valve 13 is provided for switching the pressure tank 11 to the inlet 7 or outlet 9 of the pump 5.

In order to provide the function according to the invention, i.e. to be able to generate a higher level of vacuum than with only the pump 5, the directional control valve 13 is configured to switch the pressure tank 11 from the inlet 7 to the outlet 9 of the pump 5 when a predetermined criterion is met.

The directional control valve 13 therefore provides different connection ports or openings that allow for the intake of the medium and that can be switched to different configurations.

[0036]

In the illustrated embodiment of the invention, the directional control valve 13 has in particular 3 ports.

These 3 ports can be switched such that the pump inlet 7 or the pump outlet 9 is coupled to the pressure tank 11.

In this context, coupled indicates that the directional control valve 13 is connected such that medium can flow from one port to another port of the directional control valve 13,

depending on the current setting of the directional control valve 13.

459 To provide the switching function, the directional control valve has, for example, a spool in the cylinder that is mechanically or electrically moved from one position to another, thereby allowing the medium to flow through one path or another.

[0037]

465 As outlined above, the device according to the invention makes it possible to achieve a higher level of vacuum than with the pump 5 alone.

467 Usually, the pump 5 is characterized by the maximum achievable pressure drop that the pump can produce between the pump inlet 7 and the pump outlet 9.

469 Thus, when already low pressure is applied at the outlet 9 of the pump 5, the achievable pressure level at the inlet of the pump 5 is higher than when the outlet 9 of the pump 5 is directly connected to the external environment.

472 This behavior is utilized according to the invention.

473 First, both the system 3 and the pressure tank 11 are sucked by the pump 5, and the same level of pressure (pressure level) is generated in both the system 3 and the pressure tank 11.

475 The pressure tank 11 is then switched from the inlet 7 of the pump 5 to the outlet 9 of the pump 5 by means of the directional control valve 13.

477 This allows for higher vacuum levels (lower pressures) to be generated in the system 3 compared to using only the pump 5.

[0038]

482 FIG. 2 shows a typical pressure drop produced by an apparatus according to the invention.

483 The pressure p is shown as a function of time t.

484 Initially, the pressure in the system 3 and the pressure tank 11 is in equilibrium with the pressure p1 in the external environment.

486 Pump 5 is then switched on at t1 resulting in a decrease in pressure in both system 3 and pressure tank 11.

488 At a particular point in time t2, the highest vacuum level p2 achievable in this configuration is reached.

490 Due to the configuration parameters of the pump 5, the pump 5 cannot generate a higher level of vacuum (lower pressure).

492 As soon as the predetermined criterion is met, the directional control valve 13 switches the pressure tank 11 from the inlet 7 to the outlet 9 of the pump 5.

494 The predetermined criterion may be, for example, a pressure threshold.

495 The switching temporarily causes the pressure levels at the inlet 7 and outlet 9 of the pump to be again in equilibrium.

497 Pump 5 can then provide a higher level of vacuum (i.e. lower pressure) in system 3.

498 However, also in this configuration, when a specific pressure value p 3 is reached in the system 3, the pump 5 is saturated.

500 In FIG. 2, when the pump 5 is switched off and/or the discharge valve is opened at t 3, pressure equilibrium with the external environment is induced.

[0039]

505 FIG. 3 shows another embodiment 1 bof the device according to the invention.

506 Compared with the device 1 ashown in FIG. 1, a one-way valve 15 is further provided, which is coupled to the outlet 9 of the pump 5 and to the pressure tank 11.

508 The one-way valve 15 can prevent backflow of the transported medium or any type of fluid from the external environment to the pump 5 and/or the pressure tank 11.

510 Furthermore, a first sensor 17 for determining the pressure in the pressure tank 11 is shown in FIG. 1.

512 The first sensor 17 makes it possible to perform a switching of the pressure tank 11 from the inlet 7 to the outlet 9 of the pump 5 as soon as the pressure in the pressure tank 11 falls below a predetermined threshold value, i.e. a pressure threshold value.

515 Still further, the illustrated embodiment shows a second sensor 19 for determining the throughput of the pump 5.

517 The 2nd sensor 19 may be used as an alternative to the sensor 17 or in combination with the sensor 17 in order to activate the switching of the directional control valve 13.

519 One of the clear possibilities is to determine the throughput by means of the throughput sensor 19 and to determine whether the throughput is continuously below a predetermined threshold, i.e. whether the pump 5 is transporting only a small amount of fluid and there is virtually no pump 5 in a saturation state as described above.

[0040]

526 FIG. 3 further shows a discharge valve 21 for discharging pressure from the system 3 and/or the pressure tank 11 to the external environment.

528 The release valve 21 may have a control connection 22 which allows remote control.

[0041]

532 Still further, FIG. 3 shows a controller 23 for controlling the pump 5, the directional control valve 13, the sensors 17 and 19 and for controlling the discharge valve 21 via the control connection 22.

535 In a further embodiment of the device according to the invention, the controller 23 may also control other sensors or other electronically controllable components.

537 In particular, the pump 5 may be an electric or mechanical pump that requires a specific control pulse or other signal generated by the controller 23.

[0042]

542 The controller may be a combined controller that also controls other functions of the breast pump according to other aspects of the invention, which may enable automatic interruption of the function in response to a suction cycle or a variation in pressure applied, a signal or user interface, or other functions in response to user feedback.

[0043]

549 A further embodiment 1c of the device according to the invention is schematically illustrated in FIG. 4.

551 In the present embodiment, the device 1c has a smart valve 25 that combines the functions of the directional control valve 13, the one-way valve 15 and the release valve 21.

553 The smart valve 25 is connected to the inlet 7 and the outlet 9 of the pump 5 and to the pressure tank 11.

555 One of the major advantages of using smart valve 25 to provide various desired functions is that only 1 part is required instead of multiple parts.

557 This may allow for a cheaper implementation of the device according to the invention.

558 Furthermore, such integrated parts may reduce the failure rate.

559 The smart valve 25 may further include a flow restrictor for speed control.

[0044]

563 In FIG. 5, a further schematic illustration of an embodiment 1 dof the device according to the invention is shown.

565 The directional control valve 13 is shown in more detail to highlight various parts and possible switching functions.

567 Such a 3/2 valve, i.e. a three-way two-position control valve, provides the desired function for switching the pressure tank 11 from the inlet 7 to the outlet 9 of the pump 5.

569 Furthermore, in the present embodiment, an adjustable flow restrictor 26 is arranged between the directional control valve and the outlet 9 of the pump 5.

571 The adjustable flow restrictor allows controlling the flow rate of the transported medium, in particular by adjustably limiting the maximum throughput.

[0045]

576 In the present embodiment, the system 3 to be discharged has a funnel 27 and a breast drum 29.

578 The funnel 27 houses the female chest.

579 The incomplete vacuum generated by the pump 5 is then applied to the chest and milk can be squeezed out.

581 The milk thus squeezed out is collected in a tank 29.

582 Furthermore, a one-way valve 15 is shown for preventing backflow of fluid from the external environment to the directional control valve 13 or pump 5.

584 In particular, in the present invention, the pump 5 transports air from the reservoir 29 and releases the air through the one-way valve 15 to the external environment.

[0046]

589 In FIG. 6, a method for controlling a breast pump according to an embodiment of the present invention is shown.

591 Such a method may be performed, for example, by a controller included in the milking apparatus described above.

593 The controller may control various components (e.g., valves, sensors, pumps, or the like) to achieve a higher vacuum level (i.e., lower pressure).

[0047]

598 According to the embodiment shown in FIG. 6, the pump is initially configured to generate a pressure reduction in the system and the pressure tank (S 10).

600 Depending on the type of pump and the type of connection to the controller, the arrangement comprises in particular the activation of the pump.

602 For example, if the pump can be operated at different levels, the configuration may also include selecting an appropriate level.

604 Next, it is determined whether or not a predetermined criterion is satisfied (S 12).

605 Preferably, the determination is based on sensor values obtained from at least one sensor, in particular a pressure sensor or a throughput sensor.

607 Thus, determining whether a predetermined criterion is met comprises obtaining a sensor value from the sensor (i.e., a throughput sensor or a pressure sensor).

609 At this time, it may be determined whether the predetermined criterion is satisfied based on the sensor value, possibly in combination with the user input.

611 The method for controlling a breast pump according to the invention further comprises switching (S 14) a directional control valve to connect a pressure tank to the outlet of the pump if the predetermined criterion is met (the pressure tank was initially connected to the inlet of the pump).

615 For example, the switching is performed when a certain threshold value is exceeded by the sensor value.

617 The switching of the directional control valve indicates that the necessary control signal is sent to the connection cable to activate the switching procedure.

619 The method for controlling a breast pump device may further comprise determining control settings for further valves (e.g. directional control valves and/or one-way valves) and devices (e.g. pumps) and configuring the valves and devices (not shown) based on the determined control settings.

623 Again, the configuration indicates that the necessary control signals are sent to the connection cable (or the signals are sent via a wireless connection).

625 The method may represent closed loop control or open loop control as outlined above.

[0048]

629 Furthermore, a method (not shown) for discharging from a system according to the invention may comprise generating a pressure drop in the system and the pressure tank, holding a pressure value being applied in the pressure tank, switching the pressure tank from the pump inlet to the outlet when a predetermined criterion is met.

[0049]

636 FIG. 7 shows a breast pump 31 according to another aspect of the invention.

637 The receiving funnel 27 is shaped to accommodate the female chest.

638 As soon as a pressure drop, i.e. an incomplete vacuum, is applied to the chest, the milk is squeezed out.

640 As shown in FIG. 7, the milk thus squeezed out is collected in a tank 29.

641 The reservoir is discharged by a pump 5 connected to the reservoir through a smart valve 25.

642 Further, a pressure tank 11 and a controller 23 are included.

643 Further, a battery 33 is shown which supplies the electrical energy required for the various components.

645 The smart valve 25 shown in the present embodiment includes the functions of a directional control valve, a one-way valve, and a discharge valve.

647 The valve also functions as a safety valve that prevents damage to the user in the event of a failure of the pump 5.

649 The controller 23 controls the smart valve 25, measures the pressure in the pressure tank 11, and controls the pump 5.

[0050]

654 Although not shown, a mechanical pump may be used instead of the electric pump.

655 This means that the controller 23 does not have to be connected to the pump 5.

656 Mechanical pumps typically have a handle portion for manually applying force to create a pressure drop.

658 In addition, peripheral equipment (not shown) is typically provided, such as, for example, a user interface (e.g., acoustic, visual or mechanical feedback means combined with buttons, touch pads, trackballs or other input means), a power source (e.g., a battery, solar cell or other energy generator, or trunk power connector), or design elements to improve visual perception of the breast pump.

[0051]

666 Instead of switching the pressure tank from the inlet to the outlet of the pump, it is also possible to connect a plurality of pumps in series such that the outlet of one pump is directly

connected to the inlet of another pump.

669 This also allows for an increase in vacuum level.

[0052]

673 While the invention has been described and described in the drawings and foregoing description, such description and description are to be regarded as illustrative or exemplary and not restrictive.

676 The invention is not limited to the disclosed embodiments.

677 Other variations to the disclosed embodiments may be understood and effected by those skilled in the art in practicing the claimed invention, from a reading of the drawings, the description, and the appended claims.

[0053]

683 In the claims, the word "comprising" does not exclude other elements or steps, and the indefinite article "1 (a or an)" does not exclude a plurality.

685 A single processor or other unit may perform the functions of several items listed in the claims.

687 The mere fact that certain measures are recited in mutually different dependent claims does not indicate that a combination of these measures cannot be used to advantage.

[0054]

692 Any reference signs in the claims should not be construed as limiting the claims.

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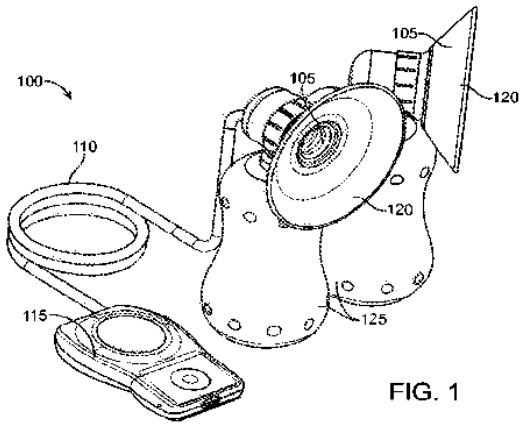


FIG. 1

(57) Abstract: A device for expression and collection of breast milk includes an actuatable assembly, a breast interface, and a tube. The breast interface is sized to receive a breast and form a fluid tight seal against the breast. The breast interface includes a deformable member disposed within at least a portion of the breast interface. The deformable member deforms in response to actuation of the actuatable assembly and applies vacuum pressure against the breast to express milk. The tube operatively couples the actuatable assembly to the breast interface.

METHOD, APPARATUS, AND SYSTEM FOR EXPRESSION AND QUANTIFICATION OF HUMAN BREAST MILK

CROSS-REFERENCE

[0001] The present application claims the benefit of U.S. Provisional Patent Application No. 61/804,722 (Attorney Docket No. 44396-702.101) filed March 24, 2013; U.S. Provisional Patent Application No. 61/879,055 (Attorney Docket No. 44396-703.102) filed September 17, 2013; and U.S. Patent Application No. 14/221,113 (Attorney Docket No. 44936-703.201) filed March 20, 2014; the entire contents of which are incorporate herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention. The present invention generally relates to medical devices and methods, and more particularly relates to devices and methods for expression and collection of human breast milk.

[0003] The exemplary embodiments disclosed herein are preferably directed at expression of breast milk, but one of skill in the art will appreciate that this is not intended to be limiting and that the devices, systems and methods disclosed herein may be used for other treatments requiring application of a differential pressure.

[0004] Breast pumps are commonly used to collect breast milk in order to allow mothers to continue breastfeeding while apart from their children. Currently, there are two primary types of breast pumps: manually-actuated devices, which are small, but inefficient and tiring to use; and electrically-powered devices, which are efficient, but large and bulky. Therefore, it would be desirable to provide improved breast pumps that are small and highly efficient for expression and collection of breast milk. Additional features such as milk production quantification and communication with mobile devices are further desirable for enhanced user convenience. At least some of these objectives will be satisfied by the devices and methods disclosed below.

[0005] 2. Description of the Background Art. The following US patents are related to expression and collection of human breast milk: US Pat. Nos.: 6,673,036; 6,749,582; 6,840,918; 6,887,210; 7,875,000; 8,118,772; and 8,216,179.

SUMMARY OF THE INVENTION

[0006] The present invention generally relates to medical devices, systems and methods, and more particularly relates to devices, systems and methods for expression and collection of human breast milk.

[0007] In a first aspect of the present invention, a device for expression and collection of breast milk comprises an actuatable assembly, a breast interface, and a tube. The breast interface is sized to engage a breast and fluidly seal thereagainst. The breast interface also includes a movable member disposed within at least a portion thereof. The movable member moves in response to actuation of the actuatable assembly and thereby forms a vacuum in the breast interface and applies the vacuum to the breast to express milk therefrom. The tube is operatively coupled to the actuatable assembly and to the breast interface.

[0008] The actuatable assembly may comprise a piston or a pump, or a pair of pistons or a pair of pumps. Actuation of the actuatable assembly may displace a fluid that is disposed in the tube.

[0009] The movable member may comprise a flexible membrane. The flexible membrane may have a corrugated region that is configured to expand and collapse. The flexible membrane may deform in response to actuation of the actuatable assembly, and actuation of the actuatable assembly may displace a fluid contained within the tube. The movable member may comprise a deformable member.

[0010] The breast interface may comprise a resilient and conformable flange for engaging and creating a fluid seal against the breast.

[0011] A fluid may be disposed in the tube. The fluid may be an incompressible fluid such as water or oil. In other embodiments, a tensile element may be disposed in the tube. The tensile element may comprise a rope, a wire, or a cable. The tensile element may be operatively coupled with the movable member and the actuatable assembly, and may also be concentrically disposed with an axial compressive element that absorbs reactive loads of the tensile element.

[0012] The device may further comprise a driving mechanism that is operatively coupled with the actuatable assembly, and that is configured to actuate the actuatable assembly. The driving mechanism may include electromechanical device such as a motor. The driving mechanism may be releasably coupled to the actuatable assembly.

[0013] The breast interface may comprise an exit valve that is configured to control flow of the expressed breast milk into a collection vessel. The exit valve may control the flow by preventing the expressed milk from flowing through the valve when the deformable member

is deformed, and allowing the expressed breast milk to flow through the valve when the deformable member is in an undeformed configuration. The exit valve may be integrally formed into the deformable member.

[0014] The device may further comprise a second actuatable assembly, a second breast interface and a second tube. The second breast interface may be sized to engage a second breast and fluidly seal thereagainst. The second breast interface may have a movable member disposed within at least a portion thereof, and the movable member may deform in response to actuation by either the actuatable assembly or the optional second actuatable assembly and thereby form a vacuum in the second breast interface which is applied to the second breast to express milk therefrom. The second tube may be operatively coupled to the second actuatable assembly and the second breast interface.

[0015] The device may further comprisea housing having a controller for controlling actuation of the actuatable assembly. The controller may control calculation and display of breast milk production information, and the controller may also control communication with other devices. A power source may be disposed in the housing and the power source provides power to the device for expression and collection of milk. The housing may have a drive mechanism disposed therein for actuating the actuatable assembly.

[0016] The device may further comprise a collection vessel fluidly coupled with the breast interface. The device may also comprise a sensor adjacent the breast interface, and that is configured to measure an aspect of mil passage therepast. The device may also comprise a display unit for displaying data related to the expression of the milk. A system for expression and collection of breast milk may include the device previously described above. Any of these components may be separate from the other components or they may be disposed in a housing or pendant.

[0017] In another aspect of the present invention, a device for applying pressure or vacuum to a patient comprises an actuatable assembly, a target tissue interface, and a tube. The target tissue interface is preferably sized to engage a target tissue and fluidly seal thereagainst. The target tissue interface has a deformable member disposed within at least a portion thereof, and the deformable member deforms in response to actuation of the actuatable assembly. This forms a vacuum or pressure in the target tissue interface and applies the vacuum or the pressure to the target tissue. The tube is operatively coupled to the actuatable assembly and the target tissue interface.

[0018] In yet another aspect of the present invention, a method for expressing and collecting breast milk comprises providing a breast expression and collection device having a breast

interface and an actuatable assembly operatively coupled to the breast interface. The breast interface comprises a deformable member. The method also comprises engaging and fluidly sealing a breast with the breast interface and actuating the actuatable assembly. The method also comprises deforming the deformable member in response to actuation of the actuatable assembly thereby creating and applying a vacuum to the breast, and expressing and collecting milk from the breast.

[0019] The engaging step may comprise engaging a resilient and conformable flange on the breast interface with the breast thereby creating a fluid seal between the breast interface and the breast.

[0020] Actuating the actuatable assembly may displace a fluid. The fluid may be disposed in a tube that is fluidly coupled with the actuatable assembly and the deformable member. Actuating the actuatable assembly may comprise moving a piston or applying a tension to a tensile element disposed in the tube. The method may further comprise releasing the actuatable assembly from a driving mechanism that is operatively coupled therewith.

[0021] The method may further comprise repeating the actuating, the deforming and the expressing steps. The method may further comprise quantifying production of the expressed milk and transmitting data related to the expression of breast milk between the breast expression and collection device and a mobile device. The mobile device may be a smart phone, tablet, or computing device. The data may be displayed on a display. The method may also comprise controlling flow of the expressed milk into a collection vessel with a valve fluidly coupled to the breast expression and collection device. Controlling the flow may comprise opening the valve when the deformable member is undeformed, and closing the valve when the deformable member is deformed. Aspects of breast milk may also be sensed with a sensor that may be fluidly or otherwise coupled with the breast interface.

[0022] The breast expression and collection device may further comprise a second breast interface and a second actuatable assembly operatively coupled to the second breast interface. The second breast interface may comprise a deformable member. The method may further comprise engaging and fluidly sealing a second breast with the second breast interface, and actuating the first or the second actuatable assembly. The method may also comprise deforming the deformable member in the second breast interface in response to actuation of the second actuatable assembly thereby creating and applying a vacuum to the second breast, and expressing and collecting milk from the second breast. Expressing and collecting milk from both breasts may occur simultaneously or it may alternate between both breasts.

[0023] In still another aspect of the present invention, a method of applying a differential pressure to a patient comprises providing a differential pressure device having an interface and an actuatable assembly operatively coupled to the differential pressure device. The interface comprises a deformable member and the method further comprises engaging and fluidly sealing the interface with a target region on the patient, and actuating the actuatable assembly. The method also comprises deforming the deformable member in response to actuation of the actuatable assembly thereby creating a positive pressure or a vacuum and applying the positive pressure or the vacuum to the target region. Any of the components may be separate from the other components, or they may be diposed in a housing or pendant.

[0024] Deforming the deformable member may create a positive pressure that is applied to the target region. The target region may comprise the mouth or nose, and applying the positive pressure reduces or eliminates apnea or similar disorders while the patient is sleeping. Deforming the flexible membrane may create a vacuum that is applied to the target region. The target region may comprise a body fluid reservoir, and thus the vacuum causes expression of a body fluid from the reservoir.

[0025] These and other embodiments are described in further detail in the following description related to the appended drawing figures.

INCORPORATION BY REFERENCE

[0026] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0028] Fig. 1 is a perspective view of an exemplary embodiment of a pumping device.

[0029] Fig. 2 is a perspective view of an exemplary embodiment of a pumping device.

[0030] Fig. 3 is a cross-section of an exemplary embodiment of a pumping device.

[0031] Fig. 4 illustrates an exemplary embodiment of an actuatable assembly coupled to a driving mechanism.

[0032] Figs. 5A-5B illustrate an exemplary embodiment of an actuatable assembly coupled to a pendant unit.

[0033] Fig. 6 is a cross-sectional view of an exemplary embodiment of a breast interface.

[0034] Fig. 7 is a cross-sectional view of another exemplary embodiment of a breast interface.

[0035] Fig. 8A is a cross-sectional view of an exemplary embodiment of an integrated valve in an open position.

[0036] Fig. 8B is a cross-sectional view of an exemplary embodiment of an integrated valve in a closed position.

[0037] Fig. 9A is a cross-sectional view of an exemplary embodiment of integrated sensors within a breast interface.

[0038] Fig. 9B is a cross-sectional view of another exemplary embodiment of integrated sensors within a breast interface.

[0039] Fig. 10 illustrates an exemplary embodiment of a pendant unit and a mobile device.

[0040] Fig. 11 illustrates an exemplary embodiment of a pendant unit in communication with a mobile device.

[0041] Fig. 12 is a cross-sectional view of an exemplary embodiment of a breast interface with a mechanical deformable member.

[0042] Fig. 13 is a cross-sectional view of an exemplary embodiment of a mechanical driver for a mechanical deformable member.

[0043] Fig. 14 is a graph illustrating the pump performance of an exemplary embodiment compared to a commercial device.

[0044] Fig. 15 is a graph illustrating the pumping efficiency of an exemplary embodiment compared to a commercial device.

DETAILED DESCRIPTION OF THE INVENTION

[0045] Specific embodiments of the disclosed devices and methods will now be described with reference to the drawings. Nothing in this detailed description is intended to imply that any particular component, feature, or step is essential to the invention. One of skill in the art will appreciate that various features or steps may be substituted or combined with one another.

[0046] The present invention will be described in relation to the expression and collection of breast milk. However, one of skill in the art will appreciate that this is not intended to be limiting, and the devices and methods disclosed herein may be used in other applications involving the creation and transmission of a pressure differential, such as in the treatment of sleep apnea and/or other remote pressure needs.

[0047] Fig. 1 illustrates an exemplary embodiment of the present invention. Pumping device 100 includes breast interfaces 105, a tube 110, and a controller or pendant unit 115 operatively coupled to breast interfaces 105 through tube 110. Breast interfaces 105 include resilient and conformable flanges 120, for engaging and creating a fluid seal against the breasts, and collection vessels 125. The device may optionally only have a single breast interface. Pendant unit 115 houses the power source and drive mechanism for pumping device 100, and also contains hardware for various functions, such as controlling pumping device 100, milk production quantification, and communication with other devices. Tube 110 transmits suitable energy inputs, such as mechanical energy inputs, from pendant unit 115 over a long distance to breast interfaces 105. Breast interfaces 105 convert the energy inputs into vacuum pressure against the breasts in a highly efficient manner, resulting in the expression of milk into collection vessels 125.

[0048] One of skill in the art will appreciate that components and features of this exemplary embodiment can be combined or substituted with components and features of any of the embodiments of the present invention as described below. Similarly, components and features of other embodiments disclosed herein may be substituted or combined with one another.

Hydraulic pumping device

[0049] Hydraulic systems can reduce pumping force requirements, and therefore also reduce the size of the pumping device, while maintaining high pumping efficiency. In a preferred embodiment, the pumping device can utilize a hydraulic pumping device to generate a pressure differential against the breast for the expression and collection of milk.

[0050] Exemplary hydraulic pumping devices are depicted in Figs. 2 and 3. Fig. 2 illustrates a pumping device 150 with a syringe 155 fluidly coupled to breast interface 160 by tube 165. Syringe 155 is coupled to tube 165 through a three-way valve 170. Breast interface 160 contains an exit port 175. The syringe 155 drives a fluid 180 contained within tube 165 against or away from a flexible member contained within breast interface 160 to create the pressure differential necessary for milk expression from the breast.

[0051] Fig. 3 illustrates another embodiment of a pumping device 200. The actuatable assembly 205 includes an assembly housing 210, a driving element 215, radial seals 220, and a shaft 222. Driving element 215 is operatively coupled to a pendant unit, such as pendant unit 115, through shaft 222. The tube 225 contains a fluid 230 and is fluidly coupled to the actuatable assembly 205 and the breast interface 235. The breast interface 235 consists of an interface housing 240, a flexible membrane 245, a reservoir 250, a sealing element 255, an expression area 260, and a drain port 265. The sealing element 255 includes deformable portion 270. The drain port 265 is coupled to a collection vessel 275 and includes a flap valve 280.

[0052] Actuatable assembly 205 displaces fluid 230 contained within tube 225, which can be a flexible line. Fluid 230 occupies reservoir 250 within breast interface 235 and is coupled with flexible membrane 245. Flexible membrane 245 transmits vacuum pressure from fluid 230 to the deformable portion 270 of sealing element 255. When a breast is engaged into and fluidly sealed with breast interface 235 by sealing element 255, displacement of the actuatable element 215 produces substantial vacuum pressure against the breast through flexible membrane 245 and deformable portion 270, resulting in the expression of breast milk into expression area 260. The expressed milk drains through drain port 265 into collection vessel 275. Drain port 265 is configured with a flap valve 280 to provide passage of milk while maintaining vacuum pressure in expression area 260.

[0053] The fluid for the hydraulic pumping device can be any suitable fluid, such as an incompressible fluid. In many embodiments, the incompressible fluid can be water or oil. Alternatively, the fluid can be any suitable gas, such as air. Suitable incompressible fluids and gases for hydraulic systems are known to those of skill in the art.

[0054] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the hydraulic pumping device can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Actuation mechanism

[0055] Many actuation mechanisms known to those of skill in the art can be utilized for the actuatable assembly 205. Actuatable assembly 205 can be a piston assembly, a pump such as a diaphragm pump, or any other suitable actuation mechanism. The optimal configuration for actuatable assembly 205 can depend on a number of factors, such as: vacuum requirements; size, power, and other needs of the pumping device 200; and the properties of the fluid 230, such as viscosity, biocompatibility, and fluid life requirements.

[0056] Fig. 3 illustrates an exemplary embodiment in which actuatable assembly 205 is a piston assembly and driving element 215 is a piston. Actuatable assembly 205 includes radial seals 220, such as O-rings, sealing against assembly housing 210 to prevent undesired egress of fluid 230 and to enable driving of fluid 230.

[0057] Fig. 4 illustrates another exemplary embodiment of an actuatable assembly 300 including a pair of pistons 305.

[0058] In preferred embodiments, the actuatable assembly includes a driving element powered by a suitable driving mechanism, such as a driving mechanism residing in pendant unit 115. Many driving mechanisms are known to those of skill in the art. For instance, the driving element, such as driving element 215, may be actuated electromechanically by a motor, or manually by a suitable user-operated interface, such as a lever. Various drive modalities known to those of skill in the art can be used. In particular, implementation of the exemplary hydraulic pumping devices as described herein enables the use of suitable drive modalities such as direct drive and solenoids, owing to the reduced force requirements of hydraulic systems.

[0059] Referring now to the exemplary embodiment of Fig. 4, the pistons 305 include couplings 310 to a crankshaft 315. The crankshaft 315 is operatively coupled to a motor 320 through a belt drive 325. The crankshaft 315 drives the pair of pistons 305 with the same stroke timing in order to apply vacuum pressure against both breasts simultaneously, a feature desirable for increased milk production. Alternatively, the crankshaft 315 can drive the pair of pistons 305 with any suitable stroke timing, such as alternating or offset stroke cycles.

[0060] The driving mechanism can be powered by any suitable power source, such as a local battery or an AC adaptor. The driving mechanism can be controlled by hardware, such as onboard electronics located within pendant unit 115.

[0061] Fig. 5 illustrates an exemplary embodiment of an actuatable assembly 350 that includes releasable coupling 355. Preferably, actuatable assembly 350 is releasably coupled to a pendant unit 360 and the driving mechanism housed therein. The coupling can be a mechanical coupling or any suitable quick release mechanism known to those of skill in the art. The releasably coupled design allows for flexibility in the configuration and use of the pumping device. For instance, user comfort can be improved through the use of differently sized breast interfaces for compatibility with various breast sizes. Additionally, this feature enables a common pumping device to be used with interchangeable breast interfaces, thus reducing the risk of spreading pathogens. Furthermore, the releasable coupling enables easy replacement of individual parts of the pumping device.

[0062] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the actuation mechanism can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Flexible membrane

[0063] In many embodiments such as the embodiment depicted in Fig. 3, the flexible membrane 245 is located within breast interface 235 and disposed over at least portion thereof, forming reservoir 250 between the interface housing 240 and the flexible membrane 245. Preferably, the flexible membrane 245 deforms substantially when subject to the negative pressures created when the fluid 230 is displaced from reservoir 250 by actuatable assembly 205. The amount of deformation of the flexible membrane 245 can be controlled by many factors, (*e.g.*, wall thickness, durometer, surface area) and can be optimized based on the pumping device (*e.g.*, pump power, vacuum requirements).

[0064] Fig. 6 illustrates an exemplary flexible membrane 370 with a specified thickness and durometer.

[0065] Fig. 7 illustrates another embodiment of flexible membrane 375 with corrugated features 380 for increased surface area.

[0066] Suitable materials for the flexible membrane are known to those of skill in the art. In many embodiments, the flexible membrane can be made of a material designed to expand and contract when subject to pressures from the coupling fluid such as silicone, polyether block amides such as PEBAX, and polychloroprenes such as neoprene. Alternatively, the flexible membrane can be fabricated from a substantially rigid material, such as stainless steel, nitinol, high durometer polymer, or high durometer elastomer. In these embodiments, the rigid material would be designed with stress and/or strain distribution elements to enable the substantial deformation of the flexible membrane without surpassing the yield point of the material.

[0067] Figs. 8A and 8B illustrate preferred embodiments of a breast interface 400 in which an exit valve 405 is integrated into the flexible membrane 410 to control the flow of expressed milk through exit port 415. The exit valve 405 is opened to allow fluid flow when the flexible membrane 410 is relaxed, as shown in Fig. 8A, and is closed to prevent fluid flow when the flexible membrane 410 is deformed, as shown in Fig. 8B. The exit valve 405 enables substantial vacuum pressure to be present in expression area 420 during extraction, while allowing milk to drain during the rest phase of the pump stroke. While many conventional breast pump valves function on pressure differentials alone, the exit valve 405

can preferably be configured to also function on the mechanical movement of flexible membrane 410. Incorporation of an integrated exit valve 405 with mechanical functionality as described herein can improve the sealing of the breast interface 400 during vacuum creation. Furthermore, the implementation of an exit valve integrally formed within the flexible membrane 410 such as exit valve 405 reduces the number of parts to be cleaned.

[0068] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the flexible membrane can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Milk collection and quantification system

[0069] With reference to Fig. 3, expressed milk drains through exit port 265 in flexible membrane 245 into a collection vessel 275. Collection vessel 275 can be any suitable container, such as a bottle or a bag. In many embodiments, collection vessel 275 is removably coupled to flexible membrane 245. Collection vessel 275 can be coupled directly or remotely via any suitable device such as extension tubing.

[0070] In many instances, it can be desirable to track various data related to milk expression and collection, such as the amount of milk production. Currently, the tracking of milk production is commonly accomplished by manual measurements and record-keeping. Exemplary embodiments of the device described herein may provide digital-based means to automatically measure and track milk production for improved convenience, efficiency, and accuracy.

[0071] Figs. 9A and 9B illustrates exemplary embodiments of a breast interface 450 with one or more integrated sensors 455. Sensors 455 are preferably located in flap valve 460, but may also be located in exit valve 465, or any other suitable location for monitoring fluid flow. In a preferred embodiment, at least one sensor 455 is integrated into a valve that is opened by fluid flow and detects the length of time that the valve is opened. The sensor signal can be interrogated to quantify the fluid flow. Suitable sensors are known to those of skill in the art, such as accelerometers, Hall effect sensors, and photodiode/LED sensors. The breast interface can include a single sensor or multiple sensors to quantify milk production.

[0072] Fig. 10 illustrates an exemplary embodiment of pendant unit 500 in which milk expression data is shown on a display screen 505. In many embodiments, the pendant unit 500 collects, processes, stores, and displays data related to milk expression. Preferably, the pendant unit 500 can transmit the data to a second device, such as a mobile phone 510.

[0073] Fig. 11 illustrates data transmission 515 between pendant unit 500 and a mobile phone 510. Suitable methods for communication and data transmission between devices are known to those of skill in the art, such as Bluetooth or near field communication.

[0074] In exemplary embodiments, the pendant unit 500 communicates with a mobile phone 510 to transmit milk expression data, such as expression volume, duration, and date. The mobile phone 510 includes a mobile application to collect and aggregate the expression data and display it in an interactive format. Preferably, the mobile application includes additional features that allow the user to overlay information such as lifestyle choices, diet, and strategies for increasing milk production, in order to facilitate the comparison of such information with milk production statistics. Additionally, the pendant unit 500 can send information about the times of pump usage to the mobile phone 510 so that the mobile application can identify when pumping has occurred and set reminders at desired pumping times. Such reminders can help avoid missed pumping sessions, and thus reduce the incidence of associated complications such as mastitis.

[0075] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the milk collection and quantification system can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Mechanical pumping device

[0076] Fig. 12 illustrates an alternative embodiment of a breast interface 600 in which a mechanical deformable member 605 can be used in place of a flexible membrane. The mechanical deformable member 605 can be constructed from similar techniques as those used for the flexible membrane as described herein. The mechanical deformable member 605 is coupled to a tensile element 610. In some instances, tensile element 610 is disposed within an axial load absorbing member 615. The axial load absorbing member 615 is disposed within tube 620. Preferably, tensile element 610 is concentrically disposed within axial load absorbing member 615 and axial load absorbing member 615 is concentrically disposed within tube 620. Alternative arrangements of tensile element 610, axial load absorbing member 615, and tube 620 can also be used.

[0077] Fig. 13 illustrates the tensile element 610 coupled to driving element 625 of an actuatable assembly 630 within an assembly housing 635. Driving element 625 is operatively coupled to a driving mechanism, such as a driving mechanism housed within a pendant unit, through shaft 640. Axial load absorbing member 615 within tube 620 is fixedly coupled to the assembly housing 635. Displacement of the driving element 625 transmits tensile force

through tensile element 610 to the mechanical deforming member 605 to create vacuum pressure against the breast.

[0078] The tensile element 610 can be any suitable device, such as a wire, coil, or rope, and can be made from any suitable material, such as metals, polymers, or elastomers. Axial load absorbing member 615 can be made from any suitable axially stiff materials, such as metals or polymers, and can be configured into any suitable axially stiff geometry, such as a tube or coil.

[0079] One of skill in the art will appreciate that components and features of any of the exemplary embodiments of the mechanical pumping device can be combined or substituted with components and features of any of the embodiments of the present invention as described herein.

Experimental data

[0080] Figs. 14 and 15 illustrate experimental pumping data obtained from a commercial breast pump device and an exemplary embodiment of the present invention. The exemplary embodiment utilized an incompressible fluid for pumping and had a maximum hydraulic fluid volume of 4 cc, while the commercial device utilized air for pumping and had a maximum volume of 114 cc.

[0081] Fig. 14 illustrates a graph of the pump performance as quantified by vacuum pressure generated per run. For the exemplary embodiment, pressure measurements were taken for 1 cc, 2 cc, 3 cc, and 4 cc of fluid volume displaced by the pump, with the run number corresponding to the volume in cc. For the commercial device, measurements were taken with the pump set to one of seven equally incremented positions along the vacuum adjustment gauge representing 46 cc, 57 cc, 68 cc, 80 cc, 91 cc, 103 cc, and 114 cc of fluid volume displaced by the pump, respectively, with the run number corresponding to the position number. Curve 700 corresponds to the exemplary embodiment and curve 705 corresponds to the commercial device. The exemplary embodiment generated higher levels of vacuum pressure per displacement volume compared to the commercial device, with maximum vacuum pressures of -240.5 mmHg and -177.9 mmHg, respectively.

[0082] Fig. 15 illustrates a graph of the pump efficiency as measured by the maximum vacuum pressure per maximum volume of fluid displaced, with bar 710 corresponding to the exemplary embodiment and bar 715 corresponding to the commercial device. The exemplary embodiment demonstrated a 42-fold increase in pumping efficiency compared to the commercial device, with efficiencies of -71.1 mmHg/cc and -1.7 mmHg/cc, respectively.

[0083] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

CLAIMS

WHAT IS CLAIMED IS:

1. A device for expression and collection of breast milk, said device comprising:

an actuatable assembly;

a breast interface sized to engage a breast and fluidly seal thereagainst, the breast interface having a movable member disposed within at least a portion thereof, wherein the movable member moves in response to actuation of the actuatable assembly and thereby forms a vacuum in the breast interface and applies the vacuum to the breast to express milk therefrom; and

a tube operatively coupling the actuatable assembly to the breast interface.

2. The device of claim 1, wherein the actuatable assembly comprises a piston or a pump.

3. The device of claim 1, wherein the actuatable assembly comprises a pair of pistons or a pair of pumps.

4. The device of claim 1, wherein actuation of the actuatable assembly displaces a fluid disposed in the tube.

5. The device of claim 1, wherein the movable member comprises a flexible membrane.

6. The device of claim 5, wherein the flexible membrane has a corrugated region configured to expand and collapse.

7. The device of claim 5, wherein the flexible membrane deforms in response to actuation of the actuatable assembly, and wherein actuation of the actuatable assembly displaces a fluid contained within the tube.

8. The device of claim 1, wherein the movable member comprises a deformable member.

9. The device of claim 1, wherein the breast interface comprises a resilient and conformable flange for engaging and creating a fluid seal against the breast.

10. The device of claim 1, wherein a fluid is disposed in the tube.

11. The device of claim 10, wherein the fluid is an incompressible fluid.

12. The device of claim 1, wherein a tensile element is disposed in the tube.

13. The device of claim 12, wherein the tensile element comprises a rope, a wire, or a cable.

14. The device of claim 12, wherein the tensile element is operatively coupled with the movable member and the actuatable assembly.

15. The device of claim 1, further comprising a driving mechanism operatively coupled with the actuatable assembly, and configured to actuate the actuatable assembly.

16. The device of claim 15, wherein the driving mechanism is an electromechanical device.

17. The device of claim 15, wherein the driving mechanism comprises a motor.

18. The device of claim 15, wherein the driving mechanism is releasably coupled to the actuatable assembly.

19. The device of claim 1, wherein the breast interface comprises an exit valve, the exit valve configured to control flow of the expressed breast milk into a collection vessel.

20. The device of claim 19, wherein the exit valve controls the flow by preventing the expressed breast milk from flowing through the exit valve when the deformable member is deformed and allowing the expressed breast milk to flow through the exit valve when the deformable member is in an undeformed configuration.

21. The device of claim 19, wherein the exit valve is integrally formed into the deformable member.

22. The device of claim 1, further comprising:

a second breast interface sized to engage a second breast and fluidly seal thereagainst, the second breast interface having a movable member disposed within at least a portion thereof, wherein the movable member deforms in response to actuation of the actuatable assembly and thereby forms a vacuum in the second breast interface and applies the vacuum to the second breast to express milk therefrom; and

a second tube operatively coupling the actuatable assembly to the second breast interface.

23. The device of claim 1, further comprising:

a second actuatable assembly;

a second breast interface sized to engage a second breast and fluidly seal thereagainst, the second breast interface having a movable member disposed within at least a portion thereof, wherein the movable member deforms in response to actuation of the actuatable assembly or the second actuatable assembly and thereby forms a vacuum in the second breast interface and applies the vacuum to the second breast to express milk therefrom; and

a second tube operatively coupling the second actuatable assembly to the second breast interface.

24. The device of claim 1, further comprising a housing having a controller for controlling actuation of the actuatable assembly.

25. The device of claim 1, further comprising a housing having a controller for controlling calculation and display of breast milk production information, and for controlling communication with other devices.

26. The device of claim 1, further comprising a housing having a power source for providing power to the device for expression and collection of breast milk.

27. The device of claim 1, further comprising a housing having a drive mechanism for actuating the actuatable assembly.

28. The device of claim 1, further comprising a collection vessel fluidly coupled with the breast interface.

29. The device of claim 1, further comprising a sensor adjacent the breast interface, the sensor configured to sense at least one aspect of milk flowing therepast.

30. The device of claim 1, further comprising a display unit for displaying data related to the expression of the milk.

31. A system for expression and collection of breast milk, said system comprising: the device of claim 1.

32. A device for applying pressure or vacuum to a patient, said device comprising:

an actuatable assembly;

a target tissue interface sized to engage a target tissue and fluidly seal thereagainst, the target tissue interface having a deformable member disposed within at least a portion thereof, wherein the deformable member deforms in response to actuation of the actuatable assembly and thereby forms a vacuum or pressure in the target tissue interface and applies the vacuum or the pressure to the target tissue; and

a tube operatively coupling the actuatable assembly to the target tissue interface.

33. A method of expressing and collecting breast milk, said method comprising:

providing a breast expression and collection device having at least one breast interface and at least one actuatable assembly operatively coupled to the at least one breast interface, wherein the breast interface comprises a deformable member;

engaging and fluidly sealing a breast with the breast interface;

actuating the actuatable assembly;

deforming the deformable member in response to actuation of the actuatable assembly thereby creating and applying a vacuum to the breast; and

expressing and collecting milk from the breast.

34. The method of claim 33, wherein the engaging comprises engaging a resilient and conformable flange on the breast interface with the breast thereby creating a fluid seal between the breast interface and the breast.

35. The method of claim 33, wherein actuating the actuatable assembly displaces a fluid.

36. The method of claim 35, wherein the fluid is disposed in a tube fluidly coupled with the actuatable assembly and the deformable member.

37. The method of claim 33, wherein actuating the actuatable assembly comprises moving a piston.

38. The method of claim 33, wherein actuating the actuatable assembly comprises applying a tension to a tensile element disposed in the tube.

39. The method of claim 38, wherein an axial load absorbing member is concentrically disposed around the tensile element, the method further comprising absorbing reactive forces of teh tensile element.

40. The method of claim 33, further comprising releasing the actuatable assembly from a driving mechanism that is operatively coupled therewith.

41. The method of claim 33, further comprising repeating the actuating, the deforming and the expressing.

42. The method of claim 33, further comprising quantifying production of the expressed milk.

43. The method of claim 33, further comprising quantifying one or more aspects of the expressed milk.

44. The method of claim 33, further comprising transmitting data related to the expression of breast milk between the breast expression and collection device and a computing device.

45. The method of claim 44, wherein the mobile device comprises a smart phone.

46. The method of claim 44, further comprising displaying the data on a display.

47. The method of claim 33, further comprising controlling flow of the expressed milk into a collection vessel with a valve fluidly coupled to the breast expression and collection device.

48. The method of claim 47, wherein controlling flow comprises opening the valve when the deformable member is undeformed, and closing the valve when the deformable member is deformed.

49. The method of claim 33, further comprising sensing flow of the expressed breast milk with a sensor fluidly coupled with the breast interface.

50. The method of claim 33, wherein the breast expression and collection device further comprises a second breast interface and a second actuatable assembly operatively coupled to the second breast interface, and wherein the second breast interface comprises a deformable member, the method further comprising:

engaging and fluidly sealing a second breast with the second breast interface;

actuating the second actuatable assembly;

deforming the deformable member in the second breast interface in response to actuation of the second actuatable assembly thereby creating and applying a vacuum to the second breast; and

expressing and collecting milk from the second breast.

51. The method of claim 50, wherein expressing and collecting milk from both breasts occurs simultaneously.

52. The method of claim 50, wherein expressing and collecting milk alternates between both breasts.

53. A method of applying a differential pressure to a patient, said method comprising:

providing a differential pressure device having an interface and an actuatable assembly operatively coupled to the differential pressure device, wherein the interface comprises a deformable member;

engaging and fluidly sealing the interface with a target region on the patient;

actuating the actuatable assembly; and

deforming the deformable member in response to actuation of the actuatable assembly thereby creating a positive pressure or a vacuum and applying the positive pressure or the vacuum to the target region.

54. The method of claim 53, wherein deforming the deformable member creates a positive pressure applied to the target region, the target region comprising the mouth or nose, thereby reducing or eliminating apnea while the patient is sleeping.

55. The method of claim 53, wherein deforming the flexible membrane creates a vacuum applied to the target region, the target region comprising a body fluid reservoir, thereby expressing the body fluid therefrom.

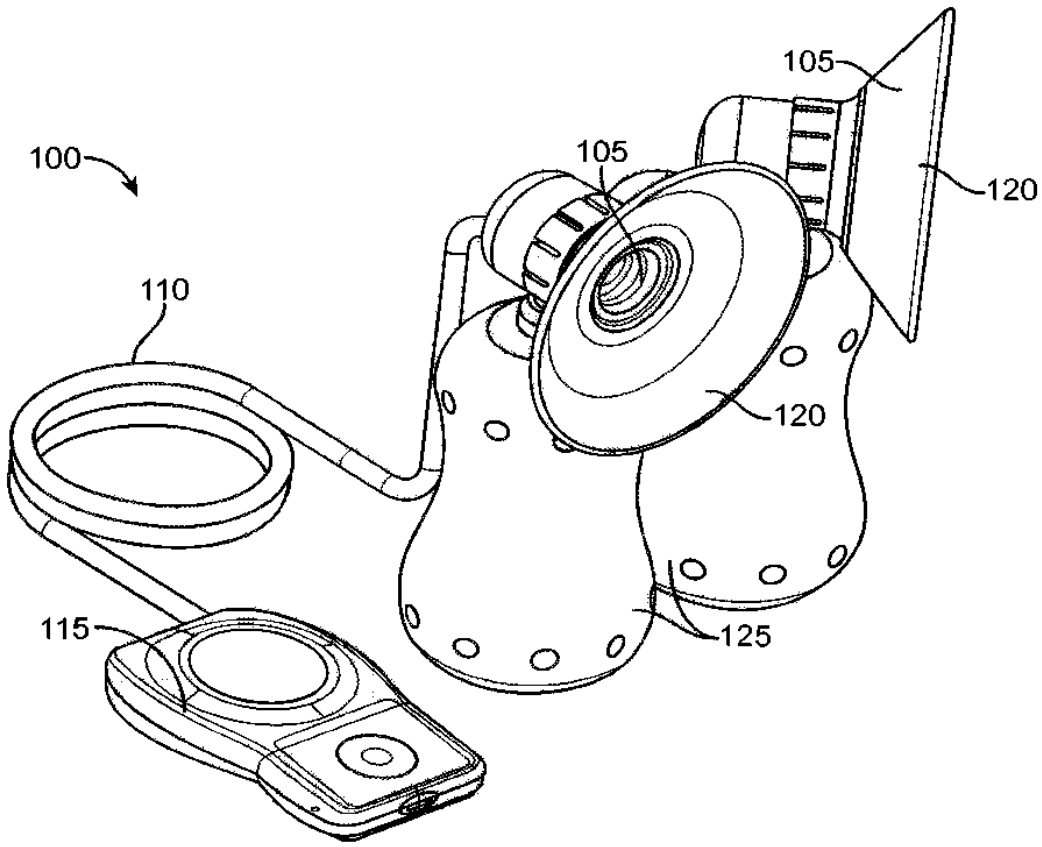


FIG. 1

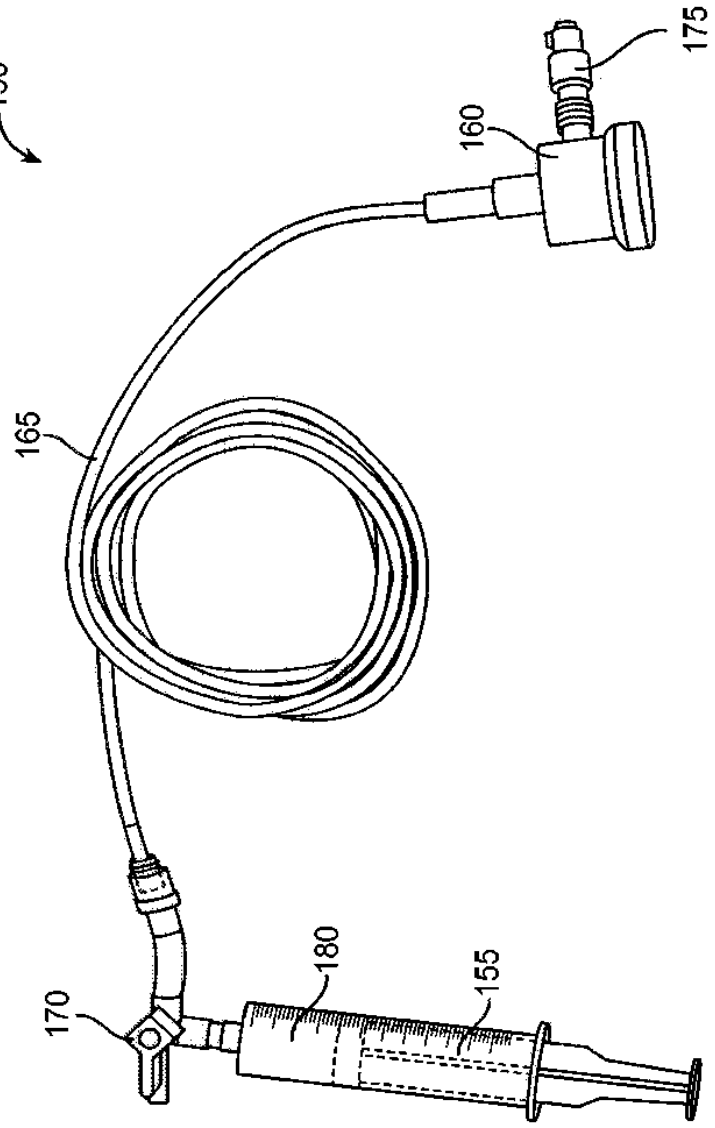


FIG. 2

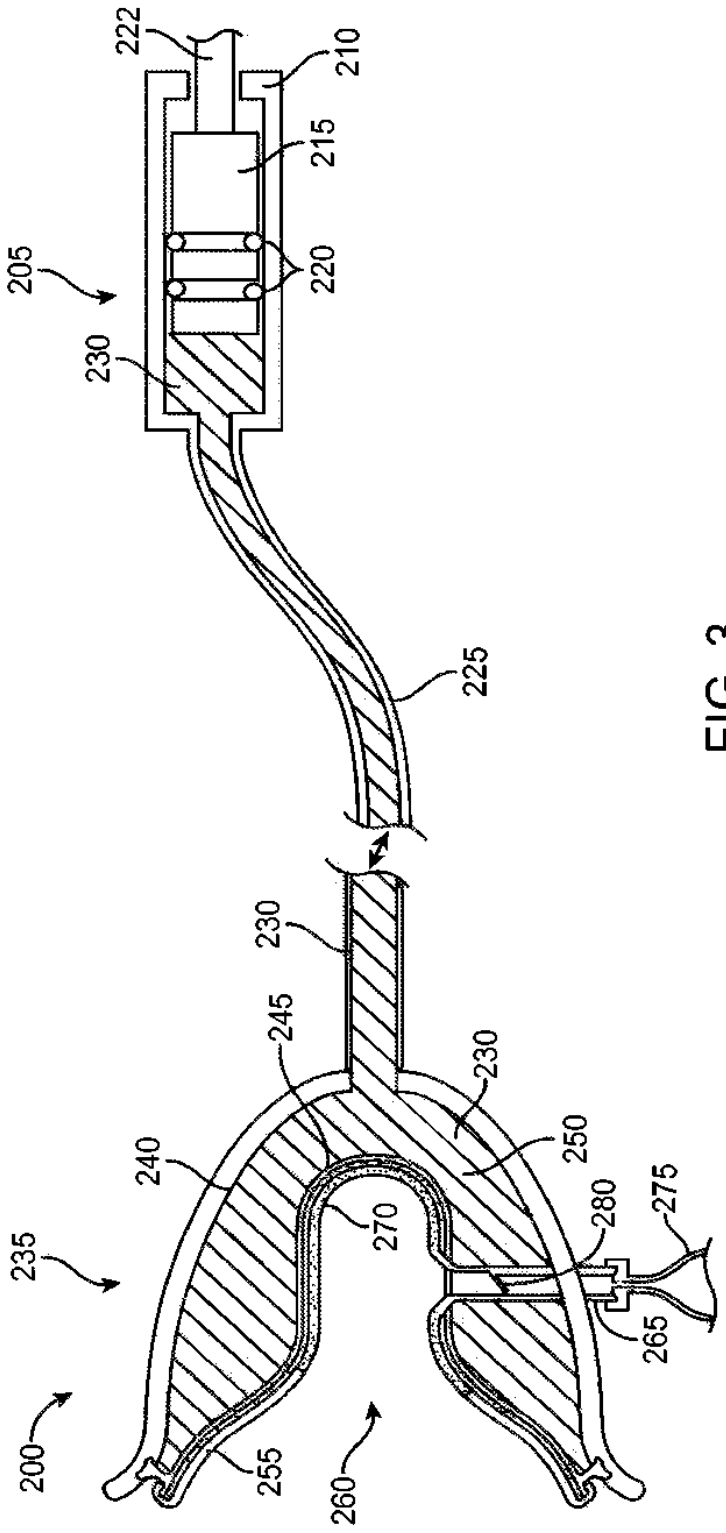

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FIG. 3

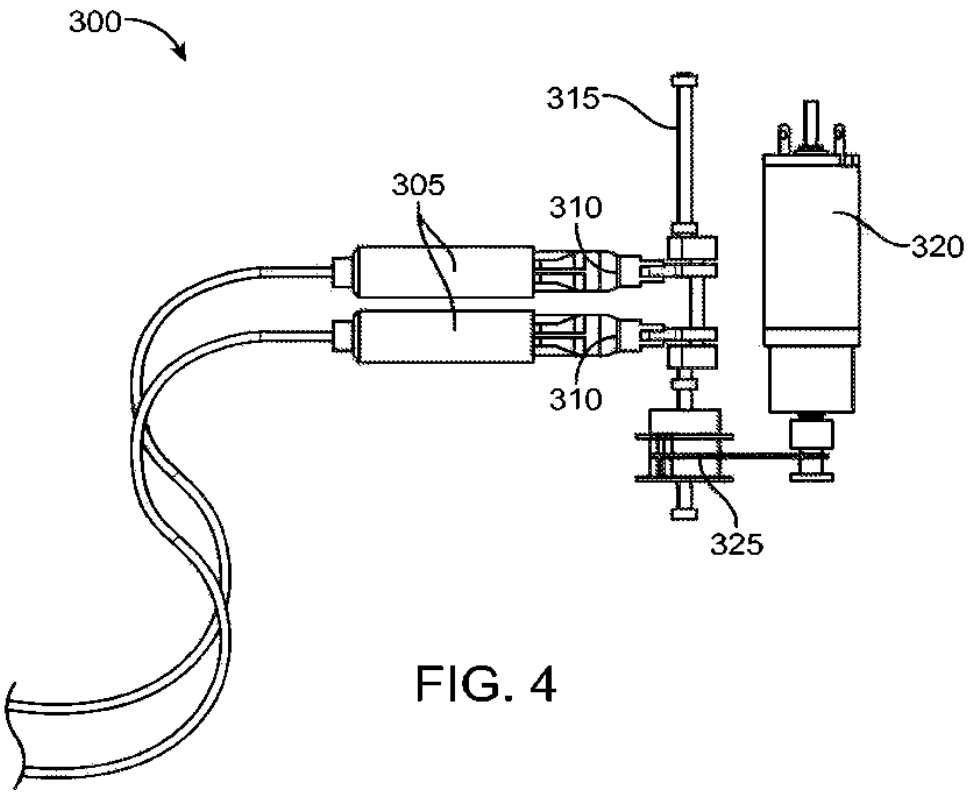


FIG. 4

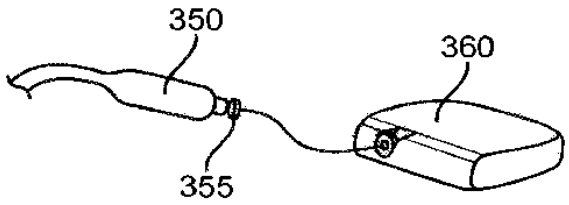


FIG. 5A

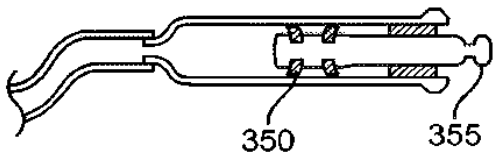


FIG. 5B

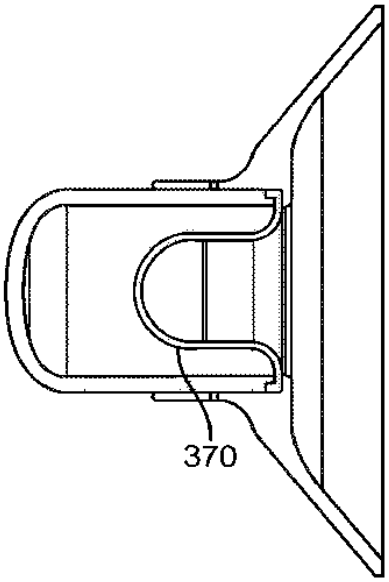


FIG. 6

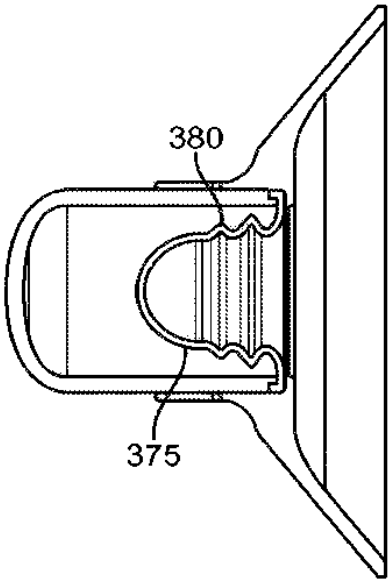


FIG. 7

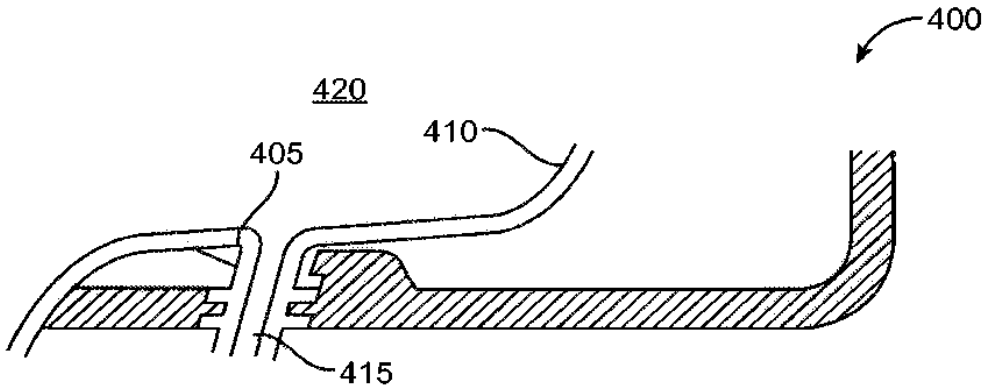


FIG. 8A

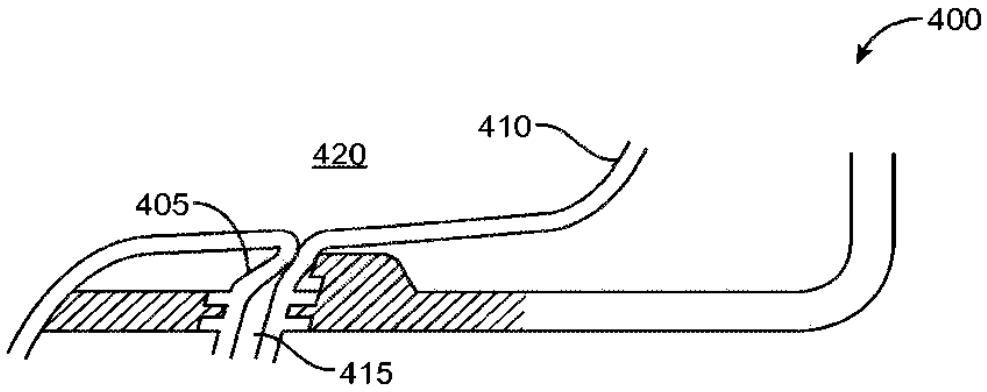


FIG. 8B

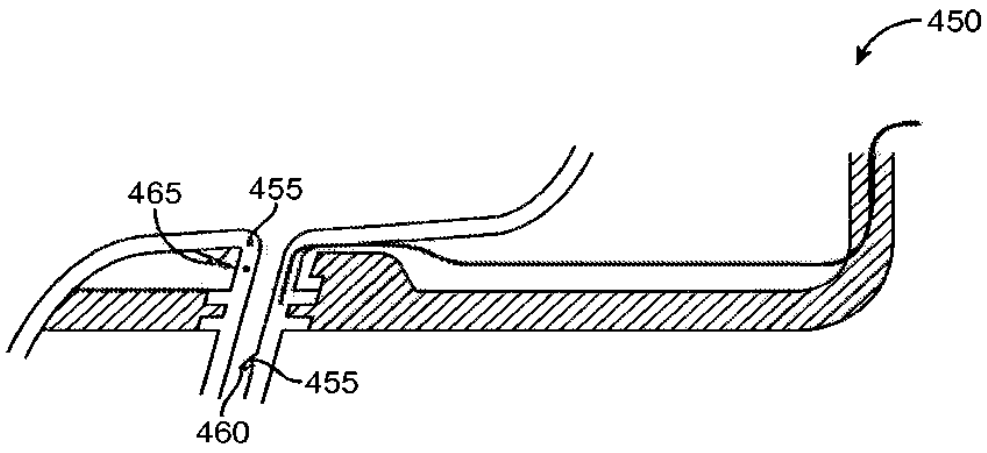


FIG. 9A

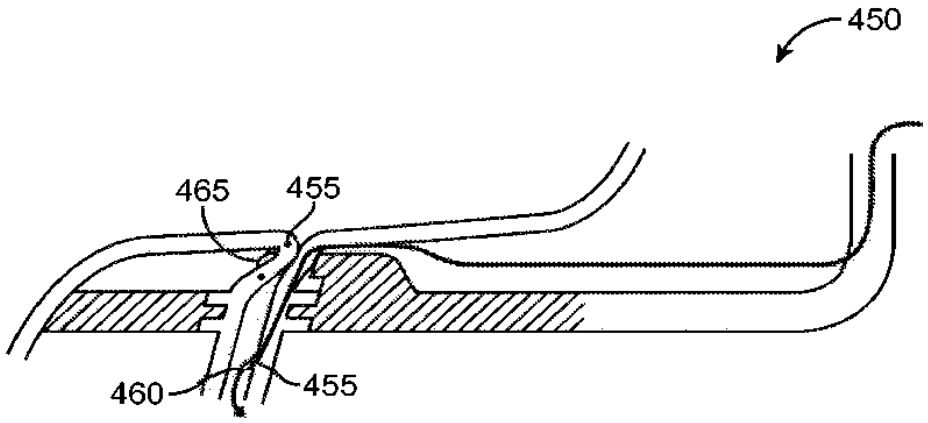


FIG. 9B

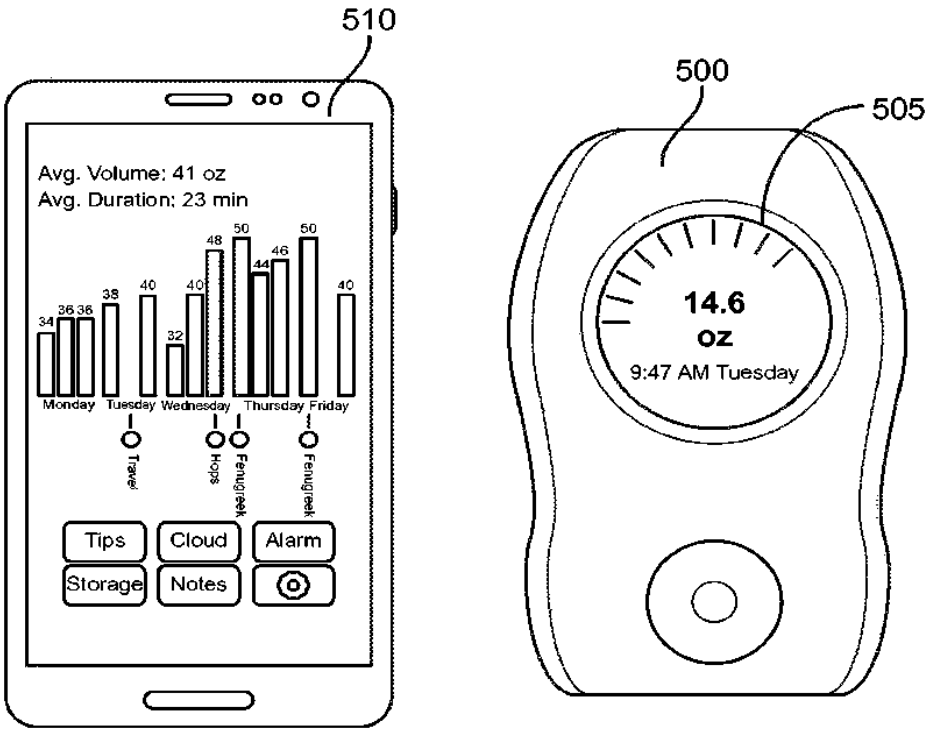

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505
Avg. Volume: 41 oz
Avg. Duration: 23 min
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Wednesday
Thursday
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Travel
Hops
Fenugreek
Fenugreek
Tips
Cloud
Alarm
Storage
Notes
14.6
oz
9:47 AM Tuesday

FIG. 10

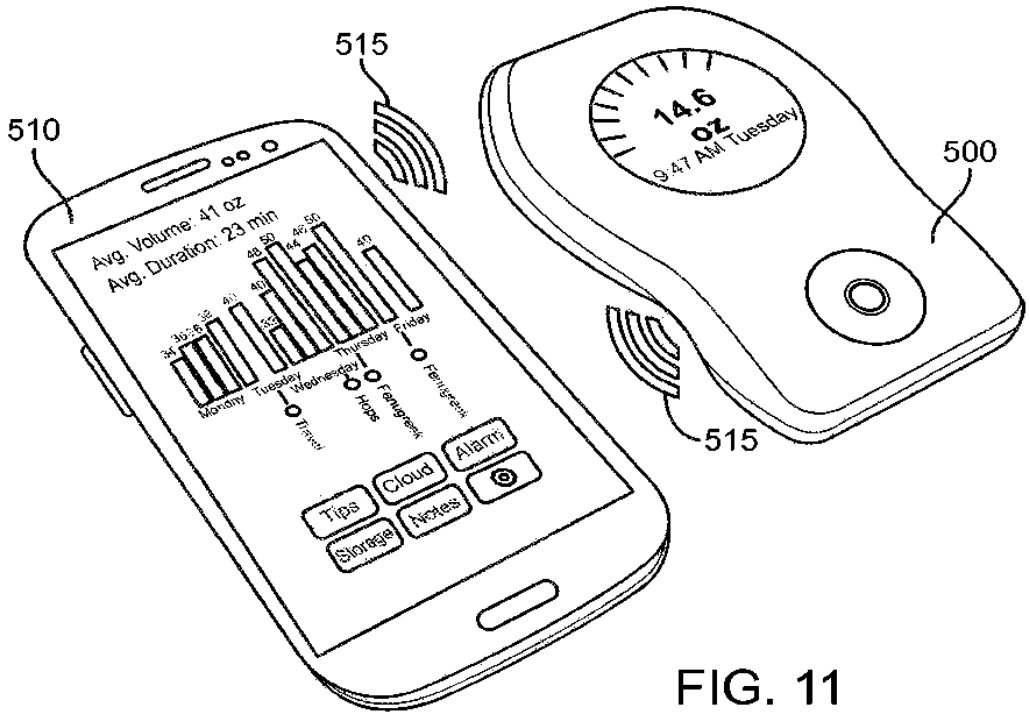

515
510
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Avg. Volume: 41 oz
Avg. Duration: 23 min
Monday
Tuesday
Wednesday
Thursday
Friday
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Hops
Fenugreek
Fenugreek
Tips
Cloud
Alarm
Storage
Notes
14.6
oz
9:47 AM Tuesday

FIG. 11

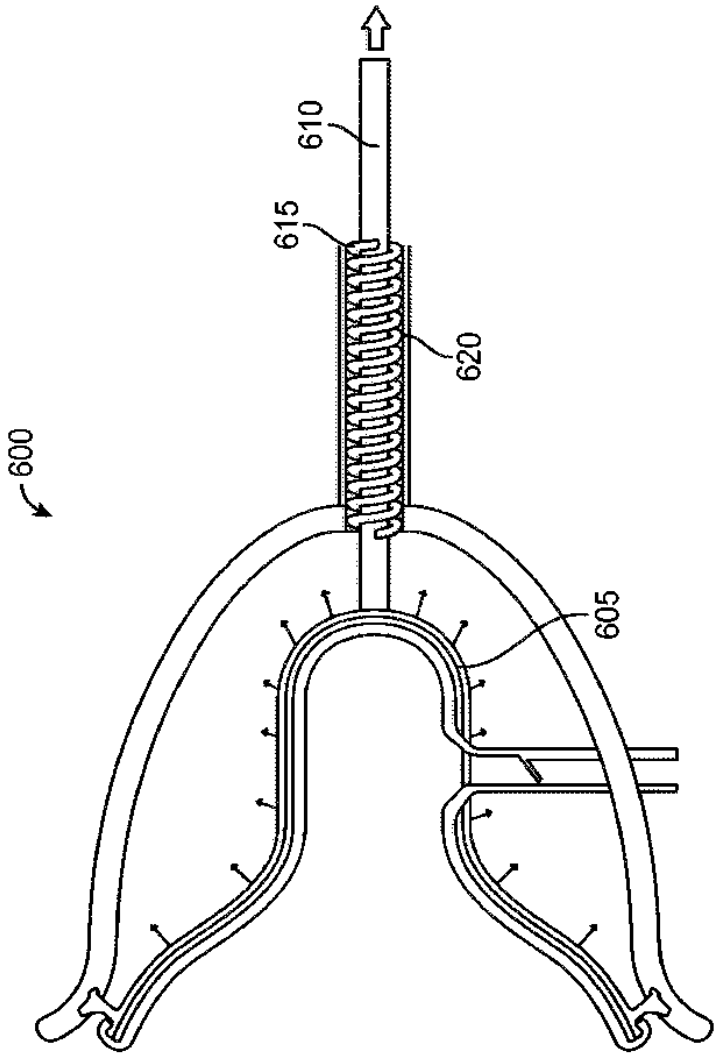


FIG. 12

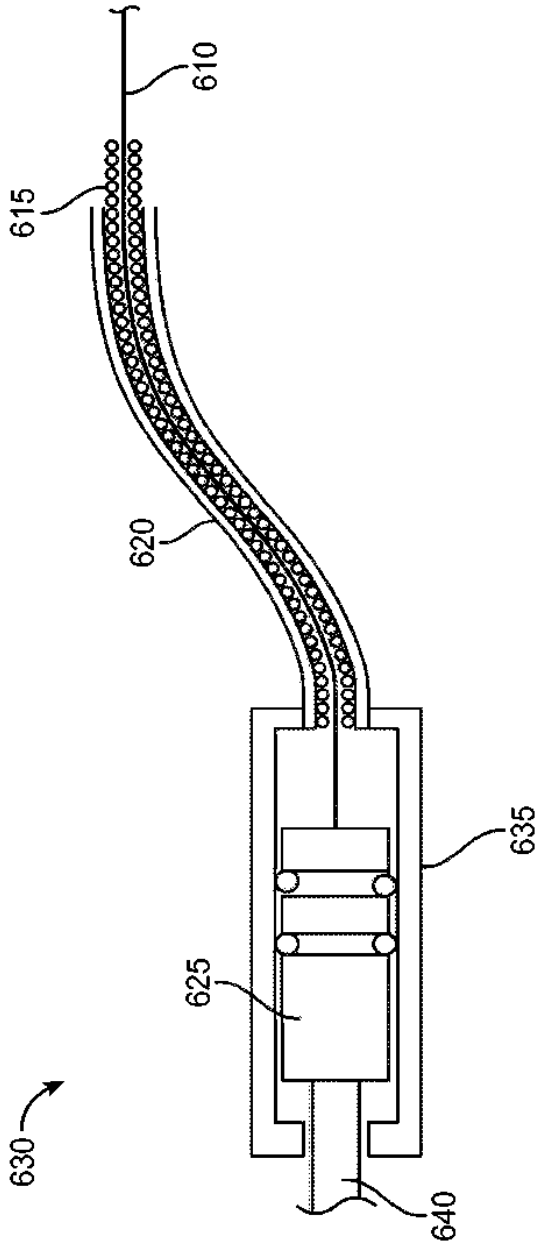


FIG. 13

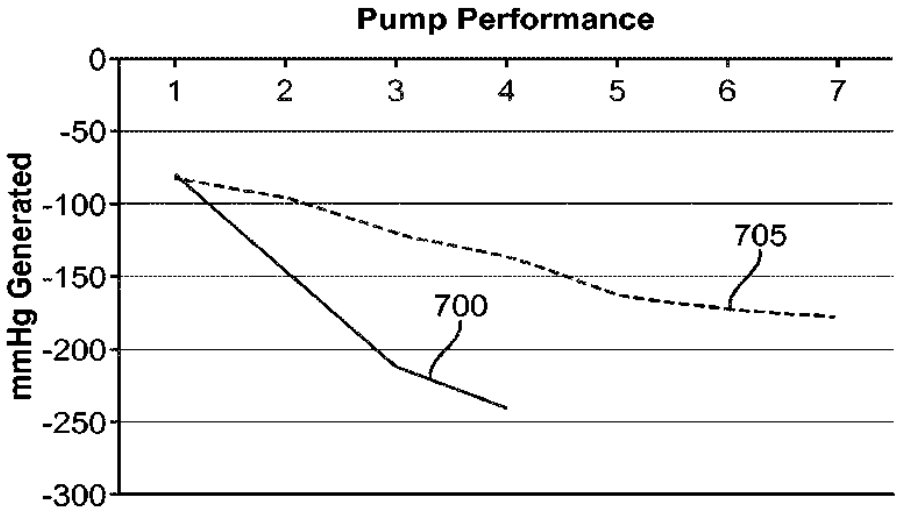

Pump Performance
0
-50
-100
-150
-200
-250
-300
mmHg Generated
1
2
3
4
5
6
7
705
700

FIG. 14

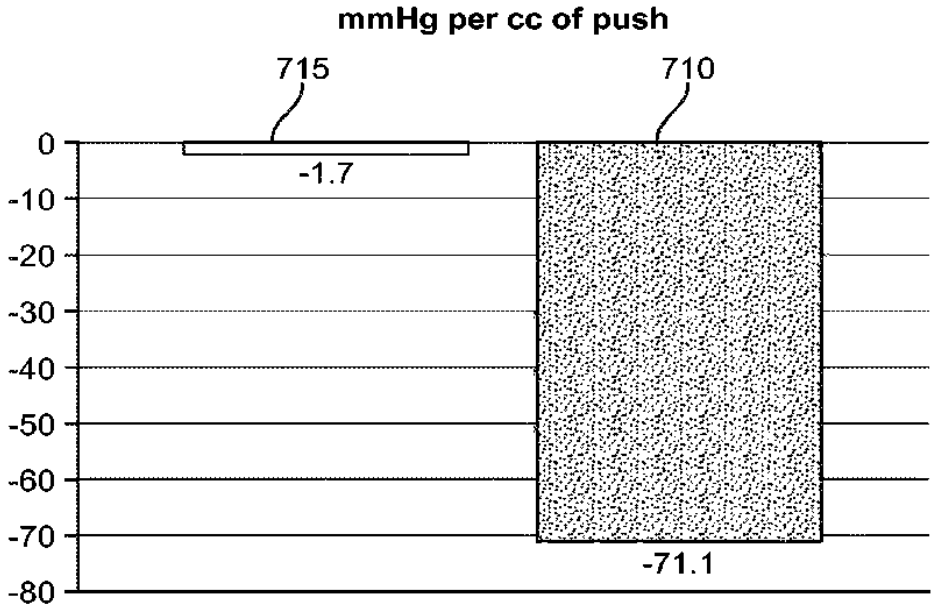


FIG. 15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/031510

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 1/06 (2014.01)
USPC - 604/74
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A41C 3/04; A61J 9/00, 11/00; A61M 1/06 (2014.01)
USPC - 215/11.1; 450/36, 37; 606/73, 74

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61M 1/06, 1/062, 1/064, 1/066 (2014.07)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Orbit, Google Patents, Google Scholar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/0316493 A1 (SCHLIENGER et al) 13 December 2012 (13.12.2012) entire document	1, 2, 4, 5, 7-11, 15-17, 19, 20, 26-28, 31-36, 41, 47, 48, 53, 55
...		
Y		3, 6, 12-14, 18, 21-25, 29, 30, 37-40, 42-46, 49-52, 54
Y	WO 2012/014135 A1 (BOSMAN et al) 02 February 2012 (02.02.2012) entire document	3, 37
Y	US 2003/0153869 A1 (YTTEBORG) 14 August 2003 (14.08.2003) entire document	6
Y	US 2006/0106334 A1 (JORDAN et al) 18 May 2006 (18.05.2006) enire document	12-14, 38, 39
Y	US 5,007,899 A (LARSSON) 16 April 1991 (16.041991) entire document	18, 40
Y	US 2003/0191433 A1 (PRENTISS) 09 October 2003 (09.10.2003) entire document	21
Y	US 6,997,897 B1 (SILVER et al) 14 February 2006 (15.02.2006) entire document	22-24, 50-52
Y	US 2008/0039741 A1 (SHEMESH et al) 14 February 2008 (14.02.2008) entire document	25, 29, 30, 42-46,49
Y	US 2012/004603 A1 (HARARI et al) 05 January 2012 (05.01.2012) entire document	45
Y	US 2012/0325219 A1 (SMITH) 27 December 2012 (27.12.2012) entire document	54

☐ Further documents are listed in the continuation of Box C. ☐

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"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 August 2014	02 SEP 2014
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

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ABSTRACT JP2017503552A

[]

13 The beverage preparation machine (1) is formed from illuminable parts (11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X) and inner parts (110, 120) and a control device (100, 105) for enabling and disabling illumination of the illuminable portion. and a user interface (10, 10', 20, 30, 40, 50). The controller may select a setting that activates only portions of the illuminable portion, e.g., sequentially activates successive portions in a rotational sequence around an inner portion, and optionally activates all portions after all portions. It has at least one setting for disabling simultaneously or for sequentially disabling previously enabled portions at the same speed as the speed of enabling or slower. [Selection drawing] Fig. 1a

(19)日本国特許庁(JP)　(12)公表特許公報(A)　(11)特許出願公表番号
特表2017-503552
(P2017-503552A)
(43)公表日　平成29年2月2日(2017.2.2)

(51)Int.Cl.		F I			テーマコード（参考）
A47J 31/44	*(2006.01)*	A47J	31/44	100	4B104
A47J 31/36	*(2006.01)*	A47J	31/36	120	
A47J 31/52	*(2006.01)*	A47J	31/52		

審査請求 未請求　予備審査請求 未請求　（全 25 頁）

(21)出願番号　特願2016-539285 (P2016-539285)
(86)(22)出願日　平成26年12月12日 (2014.12.12)
(85)翻訳文提出日　平成28年6月14日 (2016.6.14)
(86)国際出願番号　PCT/EP2014/077494
(87)国際公開番号　WO2015/096998
(87)国際公開日　平成27年7月2日 (2015.7.2)
(31)優先権主張番号　13199284.4
(32)優先日　平成25年12月23日 (2013.12.23)
(33)優先権主張国　欧州特許庁 (EP)

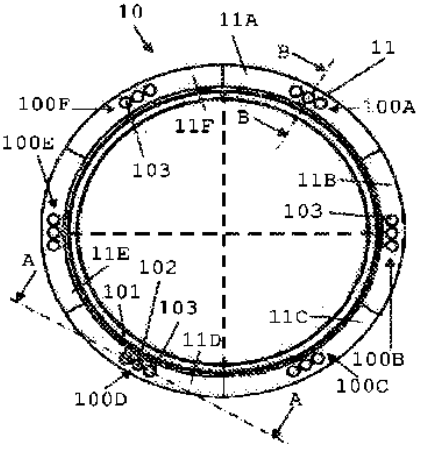
(71)出願人　599132904
ネステク　ソシエテ　アノニム
スイス国，ブベイ，アブニュー　ネスレ　５５
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(74)代理人　100107456
弁理士　池田　成人
(74)代理人　100162352
弁理士　酒巻　順一郎
(74)代理人　100140453
弁理士　戸津　洋介
(74)代理人　100168734
弁理士　石塚　淳一

最終頁に続く

(54)【発明の名称】飲料マシンのための、単純な人間工学的ユーザインタフェース

(57)【要約】
飲料調製マシン（１）は、照明可能な部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）から形成され、内側部分（１１０、１２０）の周囲で延びる、概ね外周の照明可能装置（１１、１１’、２１、３１、４１、５１）と、照明可能部分の照明を有効化及び無効化するための制御装置（１００、１０５）とを有する、ユーザインタフェース（１０、１０’、２０、３０、４０、５０）を含む。制御装置は、照明可能部分の部分のみを有効化する設定、例えば、連続する部分を、内側部分を中心として回転シーケンスで順次有効化し、任意により、全ての部分を有効化した後に全ての部分を同時に無効化するか、又は先に有効化した部分を、有効化速度と同じ速度、若しくはより遅い速度で順次無効化するための、少なくとも１つの設定を有する。
【選択図】　図１ａ

Fig. 1a



【特許請求の範囲】
【請求項１】
給水源（２）、飲料調製ユニット（３）、及び飲料を飲料注出領域（４）に供給するための出口（３ａ）を有するマシンなどの、飲料調製マシン（１）であって、
照明可能部分（１１Ａ、１１Ｂ、１１Ｃ、１１Ｄ、１１Ｅ、１１Ｆ、１１Ａ’、１１Ｂ’、１１Ｃ’、１１Ｄ’、１１Ｅ’、１１Ｆ’、１１Ｇ’、１１Ｈ’、２１Ａ、２１Ｂ、２１Ｃ、２１Ｄ、２１Ｅ、２１Ｆ、２１Ｇ、３１Ａ、３１Ｂ、３１Ｃ、３１Ｄ、３１Ｅ、３１Ｆ、４１Ａ、４１Ｂ、５１Ａ、５１Ｂ、５１Ｃ、５１Ｄ、５１Ｅ、５１Ｆ、５１Ｇ、５１Ｈ、５１Ｘ）により形成され、内側部分（１１０、１２０）の周囲で延びる、概ね外周の照明可能装置（１１、１１’、２１、３１、４１、５１）と、
プログラミング可能な制御装置（１００、１０５）などの、前記照明可能部分の照明を有効化及び無効化するための制御装置（１００、１０５）であって、例えば、プリント回路基板ＰＣＢ（１００）、及び該ＰＣＢにコネクタ（１００’’’）により接続されたコントローラ（１０５）を備え、任意により、飲料調製ユニット（３）のＩＴモジュール、ポンプ、熱調節器、及び／又は動力部など、前記マシン（１）の他の機能部を制御する、制御装置と、を有するユーザインタフェース（１０、１０’、２０、３０、４０、５０）を備え、
前記ユーザインタフェース（１０、１０’、２０、３０、４０、５０）は、任意により、前記マシン（１）の上部（１ａ）、前部（１ｂ）、又は側部（１ｃ）にある、飲料調製マシンにおいて、
前記制御装置（１００、１０５）は、前記照明可能部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）の一部のみを有効化するための、プログラミングされた設定などの少なくとも１つの設定を有することを特徴とする、飲料調製マシン（１）。
【請求項２】
前記照明可能部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）は、前記概ね外周の照明可能装置（１１’）に沿って配置された、丸いスポット、又は、例えば、三角形、四角形、五角形、又は八角形のスポットなどの、多角形のスポットなどの１つ以上のスポット（１１Ａ’～１１Ｈ’）、及び／又は前記概ね外周の照明可能装置（１１、２１、３１、４１、５１）に沿って延びる１つ以上の細長いセグメントを有し、前記細長いセグメントは、
円形セクターに概ね沿って延びるセグメント（１１Ａ～１１Ｆ）、及び／又は楕円形セクターに概ね沿って延びるセグメント（５１Ａ～５１Ｘ）などの、湾曲セグメント（１１Ａ～１１Ｆ、５１Ａ～５１Ｘ）、
真っ直ぐなセグメント（２１Ａ、２１Ｃ、２１Ｅ、２１Ｆ、２１Ｇ、３１Ｂ、２１Ｃ、２１Ｄ、２１Ｅ）、
角度を成すセグメント（２１Ｂ、２１Ｄ、３１Ａ、３１Ｇ、４１Ａ、４１Ｂ）、
前記外周の照明可能装置（２１、３１、４１）の真っ直ぐな辺（２１Ａ、２１Ｂ、３１Ａ、４１Ａ、４１Ｂ）全体に沿って延びるセグメント、
前記外周の照明可能装置（２１、３１、４１）の、真っ直ぐな辺全体にわたって（２１Ｂ、３１Ａ、４１Ａ、４１Ｂ）、及び／若しくは真っ直ぐな辺の一部にわたって（２１Ｄ、３１Ａ、３１Ｆ、４１Ａ、４１Ｂ）延びる、角度を成すセグメント、並びに／又は前記外周の照明可能装置（２１、３１、４１）の、２つの真っ直ぐな辺のみに沿って（２１Ｂ、２１Ｄ、３１Ｆ、４１Ａ、４１Ｂ）、及び／若しくは３つ以上の辺に沿って（３１Ａ）延びるセグメントなど、前記外周の照明可能装置（２１、３１、４１）の複数の真っ直ぐな辺（２１Ｂ、３１Ａ、４１Ａ、４１Ｂ）に沿って延びる、角度を成すセグメント、並びに、
前記外周の照明可能装置（１１、２１、３１、４１、５１）の全長の部分にわたって延びるセグメントであって、この部分は全長（３１Ｃ、３１Ｄ、３１Ｅ）の約半分（３１Ａ、４１Ａ、４１Ｂ）、又は１／３（２１Ｂ）、又は１／４（３１Ｆ）、又は１／５、又

は１／６（１１Ａ～１１Ｆ、２１Ａ、２１Ｄ）、又は１／７、又は１／８（３１Ｂ）、又は１／９（５１Ａ～５１Ｘ）、又は１／１０、又は１／１２（２１Ｃ、２１Ｅ、２１Ｆ、２１Ｇ）、又は１／２４と対応する、セグメント、から選択され得るセグメントを含む、請求項１に記載のマシン。

【請求項３】

前記概ね外周の照明可能装置（１１、１１’、２１、３１、４１、５１）は、単一の内側部分（１１０）の周囲で延び、又は、一対の内側部分（１１０、１２０）などのいくつかの内側部分（１１０、１２０）の周囲で、例えば、前記概ね外周の照明可能装置（５１）が、離間した前記内側部分（１１０、１２０）の周囲及び間でほぼ８の形状になるように延び、任意により、単一の内側部分（１１０）は、複数の部分、例えば、複数の有効インタフェース部分（１１０Ａ、１１０Ｂ、１１０Ｃ、１１０Ｄ）、複数の無効インタフェース部分、又は少なくとも１つの有効インタフェース部分（１１０Ｅ）と少なくとも１つの無効インタフェース部分（１１０Ｆ）との組み合わせから作製され、例えば、前記有効インタフェース部分はユーザセレクタの形態であり、及び／又は無効ユーザインタフェース部分はハウジングの一部の形態である、請求項１又は２に記載のマシン。

【請求項４】

前記内側部分は、セレクタ（１１０Ｅ）若しくは複数のセレクタ（１１０Ａ、１１０Ｂ、１１０Ｃ、１１０Ｄ）などの、例えば、１つ以上のプッシュボタンの形態の、能動部分（１１０）、及び／又は、ハウジングの一部などの受動部分（１１０Ｆ、１２０）である、請求項１～３のいずれか一項に記載のマシン。

【請求項５】

前記概ね外周の照明可能装置（１１、１１’、２１、３１、４１、５１）は、以下の特徴：

発光素子（１０１、１０２、１０３）によって放出される光を拡散するための、半透明ウィンドなどの光拡散ウィンド（１１１）、

前記発光素子（１０１’）の形状をユーザに対して示すための、透明ウィンドなどの光透過ウィンド（１１１’）、

単一の色の発光素子（１０１’）、又は、白色、黄色、橙色、赤色、緑色、青色、及びピンク色、並びにこれらの混合から選択される色など、異なる色の発光素子（１０１、１０２、１０３）のグループ（１００Ａ、１００Ｂ、１００Ｃ、１００Ｄ、１００Ｅ、１００Ｆ）などの異なる色の発光素子（１０１、１０２、１０３）を含む、複数の発光素子（１０１、１０１’、１０２、１０３）、

単一の色の発光素子（１０１’）によって、又は異なる色の発光素子（１０１、１０２、１０３）のグループ（１００Ａ、１００Ｂ、１００Ｃ、１００Ｄ、１００Ｅ、１００Ｆ）によって照明可能である、前記外周の照明可能装置（１１、１１’、２１、３１、４１、５１）の各照明可能部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）であって、前記グループの前記発光素子は別個に又はグループで有効化可能である、各照明可能部分、並びに、

任意により、コネクタの対（１００’、１００’’）などのコネクタ（１００’、１００’’）により前記ＰＣＢ又はあるＰＣＢ１００に接続された、ＬＥＤなどの発光素子（１０１’、１０１、１０２、１０３）、の１つ以上を含む、請求項１～４のいずれか一項に記載のマシン。

【請求項６】

前記概ね外周の照明可能装置（１１、１１’、２１、３１、４１、５１）の前記照明可能部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）は、湾曲した及び／又は角度を成す線状構成など、前記内側部分（１１０、１２０）の周囲で横並びの線状構成にあり、任意により、前記概ね外周の照明可能装置の前記照明可能部分は、

単一の横並び線状構成（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）、又は２つ、３つ、若しくは

４つのほぼ平行な若しくは同心状の横並び線状構成にある、並びに／あるいは、
２つの隣接する照明可能部分が、互いに直接隣接している（１１Ａ～１１Ｆ、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）、又はハウジングの一部（１１ａ）などのスペーサによって離間している（１１Ａ’～１１Ｈ’）、横並び線状構成（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）にある、請求項１～５のいずれか一項に記載のマシン。

【請求項７】

照明可能部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）の前記照明が、実質的に、前記部分全体にわたって広がり、任意により、前記部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）の前記照明は、これらの部分全体にわたって、ほぼ均一な光強度、及び／又は、白色、黄色、橙色、赤色、緑色、青色、及びピンク、又はいくつかのこのような色の混合から生じる色から選択される色などの、ほぼ均一な色をもたらす、請求項１～６のいずれか一項に記載のマシン。

【請求項８】

前記制御装置（１００、１０５）は、連続する部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）、例えば、線状横並び構成の連続する部分を、前記内側部分（１１０、１２０）を中心として、ある回転シーケンスで順次有効化するための少なくとも１つの設定を有し、任意により、

ａ）時計方向及びその後の反時計方向の回転シーケンスで、又は、反時計方向及びその後の時計方向の回転シーケンスで順次有効化するための少なくとも１つの設定、

ｂ）前記回転シーケンスが完了すると、これを一度以上繰り返して順次有効化するための少なくとも１つの設定、

ｃ）回転シーケンスにわたって、及び／若しくは複数の連続する回転シーケンスの間で、例えば、

飲料調製手順、例えば、予備湿潤、及び抽出の連続する工程、及び／若しくは、

サービス手順、例えば、スケール除去手順の連続する工程、という異なる工程を示すように速度を変更し、順次有効化するための少なくとも１つの設定、

あるいは、

ｄ）特徴ａ）～ｃ）の少なくとも２つの組み合わせを有する、請求項１～７のいずれか一項に記載のマシン。

【請求項９】

前記制御装置（１００、１０５）は、前記連続する部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）を、前記内側部分（１１０、１２０）を中心として回転シーケンスで順次有効化し、全ての前記部分を有効化した後に、全ての前記部分を同時に無効化するための、少なくとも１つの設定を有する、請求項８に記載のマシン。

【請求項１０】

前記制御装置（１００、１０５）は、前記連続する部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）を、前記内側部分（１１０、１２０）を中心として回転シーケンスで順次有効化しながら、前に有効化した部分を前記回転シーケンスで順次無効化し、任意により、

ａ）前記部分は、等しい有効化速度及び無効化速度、又は、前記無効化速度よりも速い有効化速度などの、異なる有効化速度及び無効化速度を有する、及び／若しくは、

ｂ）少なくとも２つ又は３つの部分が同時に有効化状態になる、少なくとも１つの設定を有する、請求項８又は９に記載のマシン。

【請求項１１】

前記制御装置（１００、１０５）は、１つの部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）が間欠的に有効化及び無効化される、少なくとも１つの設定を有し、任意により、

ａ）前記内側部分（１１０、１２０）を中心に恒久的に有効化又は無効化された部分によって離間した、例えば、ほぼ均等に離間した、複数の部分又は部分のグループなどの複数の前記部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）が、同時に有効化及び無効化される、

ｂ）複数の２つの部分が交互に有効化及び無効化されるなど、前記部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）の２つが、交互に有効化及び無効化される、

ｃ）前記部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）は、一定の頻度で間欠的に有効化及び無効化され、例えば、いくつかの部分が一定の頻度で間欠的に有効化及び無化される、又は

ｄ）特徴ａ）、ｂ）、及びｃ）の２つ又は３つの組み合わせである、請求項１～１０のいずれか一項に記載のマシン。

【請求項１２】

前記設定に加えて、前記制御装置（１００、１０５）は、前記設定よりも速い速度で、部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）を有効化及び無効化して、例えば、

起動若しくはサービス（例えば、スケール除去）手順の実行など、異なる種類の手順の実行を区別するための少なくとも１つの更なる設定、及び／又は、

例えば、ルンゴ若しくはエスプレッソコーヒーの異なる飲料の調製手順などの同じ種類の異なる手順、又は、例えば、軽度の若しくは集中的スケール除去手順などの異なるサービス手順の実行を区別するための少なくとも１つの更なる設定を有する、請求項８～１１のいずれか一項に記載のマシン。

【請求項１３】

有効化可能及び無効化可能な前記部分に加えて、少なくとも１つの部分が、前記設定又は前記更なる設定において、恒久的に有効化又は無効化されたままである、請求項８～１２のいずれか一項に記載のマシン。

【請求項１４】

前記制御装置（１００、１０５）は、例えば、単一部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）、又は隣接する部分のグループなどの、少なくとも１つの部分が順次有効化される、少なくとも１つの設定を有する、請求項１～１３のいずれか一項に記載のマシン。

【請求項１５】

前記外周の照明可能装置（１１、１１’、２１、３１、４１、５１）は、細長い形状に概ね沿っており、

ａ）例えば、１つ以上の円（１１、１１’）及び／若しくは楕円（５１）、又はその一部などの曲線（１１、１１’）を形成する、

ｂ）三角形（４１）、例えば、正方形（３１）、矩形、台形、若しくは平行四辺形である、四角形（３１）、五角形、六角形（２１）、七角形、八角形（１１’）、九角形、十角形、十一角形、若しくは十二角形などの、規則的若しくは不規則的な多角形（２１、３１、４１）、又はその一部を形成する、

ｃ）ストライプ（１１、２１、３１、４１、５１）の形状、及び／又は、前記細長い形状に概ね沿って配置された、別個の発光素子などの別個の要素（１１’）、例えば、ＬＥＤ（１０１’）又は発光可能光ファイバーの一部の形状に延びる、あるいは、

ｄ）特徴ａ）、ｂ）、及びｃ）の少なくとも２つの組み合わせである、請求項１～１４のいずれか一項に記載のマシン。

【請求項１６】

前記制御装置（１００、１０５）は、ユーザに対して、

例えば、請求項８又は９に定義される設定による、加熱器の起動などの起動手順の実行を示すように、

例えば、請求項１４に定義される設定による、飲料調製の準備完了までに必要な時間に関する指標をインタフェースが提示するスタンバイ手順を示すように、

例えば、請求項８、９、又は１０に定義される設定による、飲料調製手順、例えば、請求項８の選択肢ｂ）と組み合わされた請求項１０など、請求項１０に定義される設定による、例えば、遠心処理の軸線（３ａ）を取り囲む前記概ね外周の照明可能装置（１１、１１’、２１、３１、４１、５１）による、遠心処理による飲料調製手順の実行を示すように、

例えば、請求項１４に定義される設定による、任意により、全ての前記部分が有効化されている（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）、ユーザ命令を受信する準備が完了した状態を示すように、

例えば、請求項１１に記載される設定による、原材料カプセルなどのカプセルから、又は、例えば、ネットワーク又はポータブルメモリ装置に接続される、マシンインタフェースからの情報を読み取る手順の実行を示すように、

例えば、請求項１１に定義される設定による、例えば、水の不足などの原材料の不足を示す、エラーの状態を示すように、

例えば、請求項１４に定義される設定による、飲料調製プロセスのパラメータを設定するため、又はスタンバイ若しくは自動停止プロセスに入るためのタイマーを設定するためなどの、ユーザプログラミングモードの有効化を示すように、

例えば、請求項８～１４のいずれか一項に定義される設定による、すすぎ、洗浄、スケール除去、又は水材料排出手順など、サービス手順の実行を示すように、かつ、

例えば、請求項１１に定義される設定による、例えば、少なくとも１つの部分（１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ）の有効化及び無効化シーケンスのいくつかにより、例えば、ユーザセレクタ（１１０、１１０Ａ、１１０Ｂ、１１０Ｃ、１１０Ｄ）による、ユーザ命令の獲得の完了を示すように、

前記概ね外周の照明可能装置（１１、１１’、２１、３１、４１、５１）を制御するための１つ以上の設定を含む、請求項１～１５のいずれか一項に記載のマシン。

【発明の詳細な説明】

【技術分野】

【０００１】

本発明の分野は、ユーザに情報を示すための、ユーザフレンドリーかつ人間工学的ユーザインタフェースを有する、飲料調製マシンに関する。例えば、典型的には、原材料容器内の飲料を淹出し、かつ飲料をそこから抽出するため、液体の原材料容器への循環、及び原材料容器の遠心作用によって飲料を調製するためのマシンなど、飲料調製マシンは、調製される飲料の原材料の、カプセルなどの容器を使用することがある。

【０００２】

本記載の目的のため、「飲料」は、茶、コーヒー、熱い又は冷たいチョコレート、牛乳、スープ、ベビーフードなど、人間が消費できる任意の液体物質を含むことが意図される。「カプセル」とは、気密又は空気透過性パッケージなどのいずれかの材料の（例えば、プラスチック、アルミニウム、再利用可能、及び／又は生分解性パッケージなど）、任意の形状及び構造の（原材料を含む軟質ポッド又は硬質カートリッジを含む）の封入パッケージ内に、香味料成分などの、任意の予め小分けにされた飲料原材料を含むことを意図されている。

【背景技術】

【０００３】

ある種の飲料調製マシンではカプセルを使用する。カプセルは、抽出若しくは溶解される原材料及び／又はマシン内にて保管され、自動的に供与されるか、そうでなければ、飲

料調製時に添加される原材料を収容する。いくつかの飲料マシンは充填手段を有する。充填手段は、液体（通常は水である）用のポンプを備える。ポンプは給水源から、低温であるか、実際、例えばサーモブロック等の加熱手段により加熱された液体を圧送する。

【０００４】

特にコーヒー調製の分野において、飲料原材料を収容するカプセルが淹出装置内に挿入されるマシンが広範に開発されてきた。淹出装置は、カプセルの周囲で確実に閉鎖され、カプセルの第１面に水が注入され、カプセルの閉じた容積内で飲料が生成され、淹出された飲料が、カプセルの第２面から放出されて、カップ又はグラスなどの容器に回収され得る。

【０００５】

淹出装置は、「新しい」カプセルの挿入、及び使用時のカプセルの取出しを容易にするように開発されてきた。典型的には、このような淹出装置は、カプセル内で原材料を淹出するための構造に対しカプセルを挿入／取り出すために、構造から相対的に可動な２つの部分を含む。淹出装置の可動部分の作動は電動化されてもよい。このようなシステムは例えば、欧州特許第１　７６７　１２９号に開示されている。淹出装置の他の実施例は、国際公開第２００９／０４３６３０号、同第２００５／００４６８３号、及び同第２００７／１３５１３６号に開示されている。

【０００６】

遠心力を使用した飲料の調製もまた既知である。このような飲料の調製は、例えば、カプセルなどの容器内に、例えば、粉末及び／又は葉などの、飲料原材料（香味料成分）を供給する工程と、液体を容器内に循環させ、容器内において液体の圧力の勾配を生じるのに十分な速度で容器を回転させながら、液体と原材料を確実に相互作用させる工程とを含む。このような圧力は、中央から、容器の周縁部に向かって徐々に増加する。液体がコーヒー層などの原材料を通過するにつれて、コーヒー生成物などの原材料の抽出が起こり、容器の周縁部にて流出する液体抽出が得られる。国際公開第２００８／１４８６０１号は、このような遠心原理を使用した装置の可能な実施例を記載している。この場合、原材料容器は、使用前に開けられる密封カプセルである。回転軸と位置合わせされた水注入器を含む、水連絡部分により、カプセルの中央に熱湯が供給される。容器はカプセルホルダに保持され、カプセルホルダは回転モータによって回転させられる。液体連絡部分、及びカプセル保持部分の両方は、ローラーベアリングに沿って取り付けられる。飲料は、容器の蓋に開口部を形成する、複数の周辺針によって、カプセルから抽出される。回転軸を中心としてカプセルに遠心力がかけられると、熱湯が飲料の原材料を通過して、材料と相互作用して液体抽出物を生成し、生じた液体抽出物は、遠心力の効果により周辺開口部を通り、コレクタの衝突壁部に対して射出される。飲料を構成する液体抽出物はその後、装置の飲料ダクトを通じて放出され、カップなどの容器内に回収される。国際公開第２００８／１４８６５０号は、例えば容器から出る遠心力を受けた液体により形成される圧力下で開くか、又は拡大する弁システムにより、容器、特にカプセルの下流に流れの制限が形成される装置について更に記載している。弁システムは、カプセルのリム部分に対して弾性的に付勢される、装置の可動制限部分によって形成され得る。米国特許第５，５６６，６０５号は、熱い飲料用の調製マシンのための、変形可能封止継手を有する、遠心タイプの抽出セルに関する。セルはドラム及びドラムと共に内部容積を画定するカバーを含む。カバーは、傾斜部と係合する取り付け耳部によってドラムと接続される。これらの先行技術の装置において、容器に水を供給する水連絡部分、及び容器を保持する保持部分は、バヨネットシステムなどのクロージャ機構によって、一緒に固定される装置のフレーム部分に沿って回転可能である。保持部分は一般的に、少なくとも１つのローラーベアリングにより、フレーム部分に取り付けられる。液体連絡部分もまた一般的に、これもまた少なくとも１つのローラーベアリングに沿って取り付けられたフレーム部分の一部である。遠心処理の間、高速で装置が回転されると、液体抽出物は、重要な軸方向及び径方向の力を生じ、この力はこれらの回転部分を分離する傾向にある。

【０００７】

マシンに対して動作命令を与えるか、又はマシンからフィードバックを得るべく、ユーザがこのようなマシンと相互作用することを可能にするため、例えば、以下の文献に開示されているような、様々なシステムが当該技術分野において開示されている：オーストリア特許第４１０　３７７号、スイス特許第６８２　７９８号、独国特許第４４　２９　３５３号、同第２０２　００　４１９号、同第２０　２００６　０１９　０３９号、同第２００７　００８　５９０号、欧州特許第１４４８０８４号、同第１６７６５０９号、同第０８１５５８５１．２号、仏国特許第２　６２４　８４４号、英国特許第２　３９７　５１０号、米国特許第４，３７７，０４９号、同第４，４５８，７３５号、同第４，５５４，４１９号、同第４，７６７，６３２号、同第４，９５４，６９７号、同第５，３１２，０２０号、同第５，３３５，７０５号、同第５，３７２，０６１第、同第５，３７５，５０８号、同第５，６４５，２３０号、同第５，６８５，４３５号、同第５，７３１，９８１号、同第５，８３６，２３６号、同第５，９５９，８６９号、同第６，１８２，５５５号、同第６，３５４，３４１号、同第６，７５９，０７２号、米国特許出願公開第２００７／０１５７８２０号、国際公開第９７／２５６３４号、同第９９／５０１７２号、同第２００４／０３０４３５号、同第２００４／０３０４３８号、同第２００６／０６３６４５、同第２００６／０９０１８３、同第２００７／００３０６２、同第２００７／００３９９０、同第２００８／１０４７５１、同第２００８／１３８７１０、同第２００８／１３８８２０号及び同第２０１０／００３９３２号。

【発明の概要】

【発明が解決しようとする課題】

【０００８】

したがって、例えば、コーヒー、チョコレート、カカオ、ミルク、スープ、又は茶調製マシンのインタフェースの人間工学性、相互作用性、直感性、ユーザフレンドリーであること、及び単純さから選択される飲料マシンインタフェースの少なくとも１つの特徴を改善することが、本発明の好ましい目的である。

【課題を解決するための手段】

【０００９】

本発明はしたがって、飲料調製マシンに関する。マシンは、給水源、飲料調製ユニット、及び飲料を飲料注出領域に供給するための出口を有し得る。

【００１０】

例えば、マシンは、コーヒー、茶、チョコレート、カカオ、牛乳、及び／又はスープマシン、例えば、挽いたコーヒーなど、調製する飲料の原材料を含むカプセルに、熱湯若しくは冷水、又は別の液体を通すことによって飲料を調製するためのマシンである。このようなマシンの例は、国際公開第２００７／０４２４１５号、同第２００７／０４２４１４号、同第２００７／１３４９６０号、同第２００９／０７４５５０号、同第２００９／１３００９９号、同第２０１３／１２７４７６号、及びこれらに引用される文献に開示されている。

【００１１】

例えば、飲料マシンは、少なくとも１つの原材料から飲料を調製し、このような調製された飲料を注出するための容器保持ユニットを有する。例えば、マシンは、コーヒー、茶、チョコレート、カカオ、牛乳、及び／又はスープを調製するように構成されている。例えば、マシンは、容器保持ユニットを含む飲料処理モジュール内において、挽いたコーヒー、茶、チョコレート、カカオ、又はミルク粉末など、調製する飲料の香味料成分などの原材料を含む、保持されるカプセルなどのユニット内に保持される容器に、熱湯若しくは冷水、又は別の液体を通すことによって飲料を調製するように構成されている。

【００１２】

このような飲料調製は典型的には、例えば、水とミルク粉末など、複数の飲料原材料を混合する工程、及び／又は、挽いたコーヒー、若しくは水と茶の注入など、飲料原材料を注入する工程を含む。例えば、１回分に対応する所定量の飲料が、ユーザのリクエストによって形成及び注出される。このような１回分の量は、飲料の種類によって２５～２５０

ｍＬの範囲（例えば、カップ又はマグを充填する量）であり得る。形成及び注出される飲料は、リステロット、エスプレッソ、ルンゴ、カプチーノ、カフェラテ、アメリカンコーヒー、茶などから選択され得る。例えば、コーヒーマシンは、エスプレッソを注出する（１回あたり２０～６０ｍＬの調節可能な量）、及び／又はルンゴを注出する（例えば、一回当たり７０～２００ｍＬの範囲の量）ように構成されてもよい。

【００１３】

有利な実施形態において、飲料マシンは、例えば、国際公開第２００８／１４８６０１号、同第２００８／１４８６０４号、同第２００８／１４８６４６号、同第２００８／１４８６５０号、同第２００８／１４８６５６号、同第２００９／１０６１７５号、同第２００９／１０６５９８号、同第２０１０／０６３６４４号、同第２０１０／０６６７３６号、同第２０１０／０８９３２９号、同第２０１１／０２３７１１号、ＰＣＴ／ＥＰ１３／０７７２７６号、及びＰＣＴ／ＥＰ１３／０７７２７５号に開示される、遠心処理により原材料を組み合わせるタイプのものである。したがって、マシンは、例えば、内部に液体が注入され、原材料と液体とを混合するために、遠心軸を中心とした遠心処理を受ける、原材料カプセルを収容するための原材料混合チャンバを含む場合がある。原材料混合チャンバは、回転して原材料を混合するために、開閉することができる。

【００１４】

本発明のマシンは、照明可能部分により形成され、内側部分の周囲で延びる、概ね外周の照明可能装置と、プログラミング可能な制御装置などの、照明可能部分の照明を有効化及び無効化するための制御装置とを有する、ユーザインタフェースを含む。例えば、制御装置は、プリント回路基板ＰＣＢ、及びあるＰＣＢにコネクタにより接続されたコントローラなどのコントローラを含む。ＰＣＢは、単一のプリント基板、又は電気的に、若しくは光学的に、ないしは別の方法により接続された、いくつかの並置された、若しくは離間したプリント基板から形成され得る。任意により、制御装置は、例えば、調製ユニットのＩＴモジュール、ポンプ、熱調節器、及び／又は動力部など、このようなマシンの他の機能部を制御する。

【００１５】

典型的な実施形態において、ユーザインタフェースは、このようなマシンの上部、又は前部、又は側部にある。

【００１６】

本発明により、制御装置は、照明可能部分の一部のみを有効化するために、少なくとも１つの設定を有する。

【００１７】

照明可能部分は、概ね外周の照明可能装置に沿って配置された、例えば、丸いスポット、又は多角形のスポットなどの１つ以上のスポット、及び／又は概ね外周の照明可能装置に沿って延びる１つ以上の細長いセグメントを含み得る。このような細長いセグメントは、

円形セクターに概ね沿って延びるセグメント、及び／又は楕円形セクターに概ね沿って延びるセグメントなどの、湾曲セグメント、

真っ直ぐなセグメント、

角度を成すセグメント、

外周の照明可能装置の真っ直ぐな辺全体に沿って延びるセグメント、

外周の照明可能装置の、真っ直ぐな辺の全体にわたって、及び／若しくは真っ直ぐな辺の一部にわたって延びる、角度を成すセグメント、並びに／又は外周の照明可能装置の、２つの真っ直ぐな辺のみに沿って、及び／若しくは３つ以上の辺に沿って延びるセグメントなど、外周の照明可能装置の複数の真っ直ぐな辺に沿って延びる、角度を成すセグメント、並びに、

外周の照明可能装置の全長の部分にわたって延びるセグメントであって、この部分は全長の、約半分、又は１／３、又は１／４、又は１／５、又は１／６、又は１／７、又は１／８、又は１／９、又は１／１０、又は１／１２、又は１／２４と対応する、セグメン

トと、から選択され得るセグメントを含む。

【００１８】

概ね外周の照明可能装置は、単一の内側部分の周囲で延び、又は一対の内側部分のようないくつかの内側部分の周囲で、例えば、概ね外周の照明可能装置が離間した内側部分の周囲及び間でほぼ８の形状になるように延びてよい。単一の内側部分は、複数の部分、例えば、複数の有効インタフェース部分、若しくは複数の無効インタフェース部分、又は少なくとも１つの有効インタフェース部分と少なくとも１つの無効インタフェース部分との組み合わせから作製され得る。例えば、このような有効インタフェース部分はユーザセレクタの形態である。無効ユーザインタフェース部分はハウジングの一部の形態であり得る。ハウジングの一部は、インタフェースのハウジングに属する、及び／又は外部マシンハウジングに属する。

【００１９】

内側部分は、セレクタ若しくは複数のセレクタなどの、例えば、１つ以上のプッシュボタンの形態の能動部分、及び／又は、例えば、ハウジングの一部などの受動部分であり得る。

【００２０】

概ね外周の照明可能装置は、以下の特徴：

発光素子によって放出される光を拡散するための、半透明ウィンドなどの光拡散ウィンド、

発光素子の形状をユーザに対して示すための、透明ウィンドなどの光透過ウィンド、

単一の色の発光素子、又は、白色、黄色、橙色、赤色、緑色、青色、及びピンク色、並びにこれらの混合から選択される色など、異なる色の発光素子のグループなどの異なる色の発光素子を含む、複数の発光素子、

単一の色の発光素子によって、又は異なる色の発光素子のグループによって照明可能である、外周の照明可能装置の各照明可能部分であって、このようなグループの発光素子は別個に又はグループで有効化可能である、各照明可能部分、並びに、

任意により、コネクタの対などのコネクタにより上記ＰＣＢ又はあるＰＣＢに接続された、ＬＥＤなどの発光素子、の１つ以上を含み得る。

【００２１】

異なる色の光を放出する発光素子は、異なる種類の信号を伝達するために使用されてもよい。例えば、赤色は、警告の指標、又は熱生成の指標を伝達するために使用されてもよい。青色は、冷たい状態に関連する指標を伝達するために使用されてもよい。緑色は、状態、又は準備完了したことを示すために使用されてもよい。赤色又は青色は、飲料を温める、又は冷やす処理の指標を伝達するために使用され得る。橙色又は黄色は、ユーザプログラミングモード、又はサービスモード、例えば、マシンのすすぎ、洗浄、又はスケール除去などを示すために使用されてもよい。したがって、ユーザに異なる指標を伝達するために、直感的なカラーコードを使用してもよい。

【００２２】

概ね外周の照明可能装置の照明可能な部分は、湾曲した及び／又は角度を成す線状構成など、内側部分の周囲で横並びの線状構成にあってもよい。例えば、概ね外周の照明可能装置の照明可能部分は、

単一の横並び線状構成、又は２つ、３つ、若しくは４つのほぼ平行な若しくは同心状の横並び線状構成にある、並びに／あるいは、

２つの隣接する照明可能部分が、互いに直接隣接している、又はハウジングの一部などのスペーサによって離間している、横並び線状構成にある。

【００２３】

各照明可能部分の照明は、実質的に、この部分全体にわたって広がっていてもよい。任意により、各部分の照明は、これらの部分全体にわたって、ほぼ均一な光強度、及び／又はほぼ均一な色をもたらす。色は、白色、黄色、橙色、赤色、緑色、青色、及びピンク、又はいくつかのこのような色の混合から選択され得る。

【００２４】
制御装置は、連続する部分、例えば、線状横並び構成の連続する部分を、内側部分を中心として、ある回転シーケンスで順次有効化するための少なくとも１つの設定を有することができ、例えば：
ａ）時計方向及びその後の反時計方向のシーケンスで、又は、反時計方向及びその後の時計方向のシーケンスで順次有効化するための少なくとも１つの設定、
ｂ）回転シーケンスが完了すると、これを一度以上繰り返して順次有効化するための少なくとも１つの設定、及び／又は、
ｃ）回転シーケンスにわたって、及び／若しくは複数の連続する回転シーケンスの間で、例えば、
飲料調製手順、例えば、予備湿潤、及び抽出の連続する工程、及び／若しくは、
サービス手順、例えば、スケール除去手順の連続する工程、という異なる工程を示すように速度を変更し、順次有効化するための少なくとも１つの設定で行われる。
【００２５】
このような設定は、例えば、起動サイクル、又は飲料調製サイクル、又は清掃サイクルなど、任意の時点におけるサイクルの動作を示すために使用され得る。有利な実施形態において、このような設定は、遠心処理による飲料調製サイクルを示すために使用されてもよく、外周の照明可能装置は、任意により遠心処理軸の周囲で延び、遠心処理は、遠心処理軸を中心とした遠心処理を示す、回転シーケンスの複数の繰り返しなどの回転シーケンスによって示される。
【００２６】
制御装置は、連続する部分を、内側部分を中心として回転シーケンスで順次有効化し、全ての部分を有効化した後に、全ての部分を同時に無効化するための、少なくとも１つの設定を有し得る。
【００２７】
制御装置は、連続する部分を、内側部分を中心として回転シーケンスで順次有効化しながら、前に有効化した部分を回転シーケンスで順次無効化するための、少なくとも１つの設定を有し得る。任意により、これらの部分は、等しい有効化速度及び無効化速度、又は、無効化速度よりも速い有効化速度などの、異なる有効化速度及び無効化速度を有する。少なくとも２つ又は３つの部分が同時に有効化状態になり得る。
【００２８】
制御装置は、１つの部分が、間欠的に有効化及び無効化されるような、少なくとも１つの設定を有し得る。
【００２９】
例えば、このような設定は、エラーの表示、又は、ユーザセレクタによりユーザ命令が適切に獲得されたことを確認するなどの、マシン１が情報を獲得したことを確認する表示と関連付けられ得る。
【００３０】
内側部分を中心に恒久的に有効化又は無効化された部分によって離間した、例えば、ほぼ均等に離間した、複数の部分又は部分のグループなどの複数の部分が、同時に有効化及び無効化されてもよい。
【００３１】
複数の２つの部品が、交互に有効化及び無効化されるなど、これらの部分の２つが、交互に有効化及び無効化されてもよい。
【００３２】
例えば、このような設定は、例えば、ユーザセレクタによるユーザ入力、又はユーザによる別のアクションのマシン１による期待値と関連付けられ得る。
【００３３】
部分は、一定の頻度で間欠的に有効化及び無効化されてもよく、例えば、いくつかの部分が一定の頻度で間欠的に有効化及び無効化されてもよい。

【００３４】
上記の設定のいずれかに加えて、制御装置は、上記の設定よりも速い速度で部分を有効化及び無効化するための、少なくとも１つの更なる設定を有してもよい。
【００３５】
例えば、異なる種類の手順の実行を区別するために、異なる速度が使用されてもよい。例えば、起動又はサービス（スケール除去）手順の実行が、比較的遅い速度における１つ以上の回転シーケンスによって示されてもよく、飲料調製手順は、比較的速い速度における１つ以上の回転シーケンスによって示されてもよい。
【００３６】
例えば、ルンゴ若しくはエスプレッソコーヒーの異なる飲料の調製手順などの同じ種類の異なる手順、又は、例えば、軽度の若しくは集中的スケール除去手順などの異なるサービス手順の実行を区別するために異なる速度が実施され得る。
【００３７】
有効化可能及び無効化可能な部分に加えて、少なくとも１つの部分が、上記の設定又は更なる設定において、恒久的に有効化又は無効化されたままであり得る。
【００３８】
制御装置は、例えば、単一の部分、又は隣接する部分のグループなどの、少なくとも１つの部分が順次有効化される、少なくとも１つの設定を有し得る。
【００３９】
外周の照明可能装置は、細長い形状に概ね沿っており、
ａ）例えば、１つ以上の円、及び／若しくは楕円、又はその一部などの曲線を形成する、
ｂ）三角形、例えば、正方形、矩形、台形、若しくは平行四辺形である、四角形、五角形、六角形、七角形、八角形、十角形、九角形、十角形、十一角形、若しくは十二角形などの、規則的若しくは不規則的な多角形、又はその一部を形成する、並びに／あるいは、
ｃ）ストライプの形状、及び／又は、細長い形状に概ね沿って配置された、別個の発光素子などの別個の要素、例えば、ＬＥＤ又は発光可能光ファイバーの一部の形状に延びる。
【００４０】
制御装置は、ユーザに対して、
例えば、連続する部分、例えば、線状横並び構成の連続する部分を、内側部分を中心として、ある回転シーケンスで順次有効化するための設定、及び任意により、全ての部分を有効化した後に、全ての部分を同時に無効化する種類の設定など、上記の設定による、加熱器の起動などの起動手順の実行を示すように、
例えば、単一部分、又は隣接する部分のグループなどの、少なくとも１つの部分が順次有効化される設定など、上記の設定による、飲料調製の準備完了までに必要な時間に関する指標をインタフェースが提示するスタンバイ手順を示すように、
例えば、連続する部分を内側部分を中心に回転シーケンスで順次有効化し、かつ全ての部分が有効化された後に全ての部分を同時に無効化するか、又は部分を有効化しながら、先に有効化された部分を、回転シーケンスで順次無効化する設定など、上記の設定による、飲料調製手順、例えば、回転シーケンスが完了すると、これを一度以上繰り返すこのような上記の設定のような、例えば、遠心処理の軸線を取り囲む概ね外周の照明可能装置による、遠心処理による飲料調製手順の実行を示すように、
例えば、上記の設定、例えば、少なくとも１つの部分が順次有効化され、任意により全ての部分が順次有効化される設定による、ユーザ命令を受信する準備が完了した状態を示すように、
例えば、上記の設定、例えば、１つの部分が間欠的に有効化及び無効化される設定による、原材料カプセルなどのカプセルから、又は、例えば、ネットワーク又はポータブルメモリ装置に接続される、マシンインタフェースからの情報を読み取る手順の実行を示すように、

例えば、上記の設定、例えば、１つの部分が間欠的に有効化及び無効化される設定による、例えば、例えば水の不足などの原材料の不足を示す、エラーの状態を示すように、

例えば、上記の設定、例えば、少なくとも１つの部分が順次有効化される設定による、飲料調製プロセスのパラメータを設定するため、又はスタンバイ若しくは自動停止プロセスに入るためのタイマーを設定するためなどの、ユーザプログラミングモードの有効化を示すように、

例えば、上記の設定、例えば、全ての部分が有効化された後に全ての部分が同時に無効化されるか、若しくは先に有効化された部分が、回転シーケンスで順次無効化されるようにして、連続する部分が、内側部分を中心にして、回転シーケンスで順次有効化される設定、１つの部分が間欠的に有効化及び無効化される設定、又は少なくとも１つの部分が順次有効化される設定などによる、すすぎ、洗浄、スケール除去、又は水材料排出手順など、サービス手順の実行を示すように、並びに、

例えば、上記の設定、例えば、１つの部分が、間欠的に、例えば２回又は３回、有効化及び無効化される設定による、例えば、ユーザセレクタによる、ユーザ命令の獲得の完了を示すように、概ね外周の照明可能装置を制御するための１つ以上の設定を含み得る。

【００４１】

本発明はここで、概略図を参照して説明される。

【図面の簡単な説明】

【００４２】

【図１】本発明による飲料調製マシンの丸いインタフェースを概略的に例示している。

【図１ａ】図１のインタフェースの水平方向断面図を示している。

【図１Ａ】直線Ａ－Ａに沿った、図１及び図１ａのインタフェースの拡大断面図を例示している。

【図１Ｂ】直線Ｂ－Ｂに沿った、図１及び図１ａのインタフェースの拡大断面図を例示している。

【図１ｘ】本発明によるマシンのインタフェースのバリエーションを例示している。

【図２】本発明によるマシンに設置され得る、多角形の異なるインタフェースを例示している。

【図３】本発明によるマシンに設置され得る、多角形の異なるインタフェースを例示している。

【図４】本発明によるマシンに設置され得る、多角形の異なるインタフェースを例示している。

【図５】本発明によるマシンに設置され得る、湾曲した形状のインタフェースを例示している。

【図６】本発明による飲料調製マシンを例示している。

【発明を実施するための形態】

【００４３】

図１～５は、本発明による飲料調製マシン１のための、異なるユーザインタフェース１０、２０、３０、４０、５０を例示している。インタフェース１０を備える飲料マシン１の実施例が図６に示される。

【００４４】

代表的な飲料調製マシン１は、給水源２、及び飲料調製ユニット３を有し得る。給水源２は、水タンクであり得る。あるいは、マシンの給水源は、飲料マシンのいずれかの水タンクを手動で補充する必要がないように、都市の配水システムに直接接続することが可能なコネクタを含んでもよい。

【００４５】

マシン１は、熱い又は冷たい飲料を調製するように構成されてもよい。マシン１は、例えば、水及び／又はミルクなどの液体キャリア、及び１つ以上の香味料成分並びに／又は質感成分（texturing ingredient）、例えば、チョコレート、カカオ、コーヒー、茶、牛乳、シロップ、砂糖、クリーム、乳化剤、乾燥又はゲルスープなどの、異なる原材料を組

み合わせるように構成され得る。原材料は、これを混合することにより、又は注入することにより、組み合わされ得る。好適なマシンは、例えば、国際公開第２００９／０７４５５０号及び同第２００９／１３００９９号により詳細に開示されている。有利な実施形態において、飲料マシン１は、例えば、国際公開第２００８／１４８６０１号、同第２００８／１４８６０４号、同第２００８／１４８６４６号、同第２００８／１４８６５０号、同第２００８／１４８６５６号、同第２００９／１０６１７５号、同第２００９／１０６５９８号、同第２０１０／０６３６４４号、同第２０１０／０６６７３６号、同第２０１０／０８９３２９号、同第２０１１／０２３７１１号、ＰＣＴ／ＥＰ１３／０７７２７６号、及びＰＣＴ／ＥＰ１３／０７７２７５号に開示される、遠心処理により原材料を組み合わせるタイプのものである。したがって、マシン１は、内部に液体が注入され、原材料と液体とを混合するために、遠心軸３ａを中心とした遠心処理を受ける、原材料カプセルを収容するための原材料混合チャンバ３ｂ（典型的にはマシン１内に配置され、図６に点線で示される）を含む場合がある。原材料混合チャンバ３ｂは、（例えば、ハンドル１ａを作動させることにより上部１ａを旋回させるか、又は昇降させて）開閉することができ、回転させて原材料を混合することができる。

【００４６】

飲料マシン１は、典型的には、単一の出口、又は二重出口であり得る、出口３ａを有する。出口３ａは、注出領域４に飲料を供給するように構成され得る。注出領域４は、グラス、カップ、又はマグなどの容器を受容するように構成され得る。注出領域は、例えば欧州特許第１８６７２６０号、又は国際公開第２００９／０７４５５７号に開示されるような、任意の種類のものであり得る。

【００４７】

飲料マシン１は、ユーザインタフェース１０を含み、これは、図１、図１Ａ、及び図１Ｂにより詳細に例示されている。あるいは、インタフェース１０は、図１ｘ～５に例示されるインタフェース１０’、２０、３０、４０、５０のいずれか、又は本発明の領域に包含される、そのバリエーションにより代替することができる。

【００４８】

ユーザインタフェース１０、１０’、２０、３０、４０、５０は全て、

照明可能部分１１Ａ、１１Ｂ、１１Ｃ、１１Ｄ、１１Ｅ、１１Ｆ、１１Ａ’、１１Ｂ’、１１Ｃ’、１１Ｄ’、１１Ｅ’、１１Ｆ’、１１Ｇ’、１１Ｈ’、２１Ａ、２１Ｂ、２１Ｃ、２１Ｄ、２１Ｅ、２１Ｆ、２１Ｇ、３１Ａ、３１Ｂ、３１Ｃ、３１Ｄ、３１Ｅ、３１Ｆ、４１Ａ、４１Ｂ、５１Ａ、５１Ｂ、５１Ｃ、５１Ｄ、５１Ｅ、５１Ｆ、５１Ｇ、５１Ｈ、５１Ｘにより形成され、内側部分１１０、１２０の周囲で延びる、概ね外周の照明可能装置１１、１１’、２１、３１、４１、５１と、

プログラミング可能な制御装置などの、照明可能部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘの照明を有効化及び無効化するための制御装置１００、１０５であって、例えば、プリント回路基板ＰＣＢ１００、及びＰＣＢにコネクタ１００’’’により接続されたコントローラなどのコントローラ１０５を備えたプログラミング可能な制御装置１００、１０５とを有する。

【００４９】

制御装置１００、１０５は、飲料調製ユニット３のＩＴモジュール、ポンプ、熱調節器、及び／又は動力部など、このようなマシン１の他の機能部を制御し得る。

【００５０】

典型的な実施形態において、ユーザインタフェース１０、１０’、２０、３０、４０、５０は、このようなマシン１の上部１ａ、前部１ｂ、又は側部１ｃにある。図６において、例えば、ユーザインタフェース１０は、マシン１の上部１ａに設けられている。

【００５１】

制御装置１００、１０５は、照明可能部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘの一部のみを有

効化するための、プログラミングされた設定などの少なくとも１つの設定を組み込んでもよい。

【００５２】

例えば、図１ｘに例示されるように、照明可能部分は、概ね外周の照明可能装置１１’に沿って配置された、丸い又は多角形のスポットなど、１つ以上の照明可能スポット１１Ａ’～１１Ｈ’を含む場合がある。例えば、図１、２、３、４、及び５に例示されるように、照明可能部分は、概ね外周の照明可能装置１１、２１、３１、４１、５１に沿って延びる１つ以上の細長いセグメント１１Ａ～１１Ｆ、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘを有する場合がある。

【００５３】

このような細長いセグメントは、

円形セクター１１Ａ～１１Ｆに概ね沿って延びるセグメント（図１）、及び／又は楕円形セクター５１Ａ～５１Ｘに概ね沿って延びるセグメント（図６）などの、湾曲セグメント１１Ａ～１１Ｆ、５１Ａ～５１Ｘ、

真っ直ぐなセグメント２１Ａ、２１Ｃ、２１Ｅ、２１Ｆ、２１Ｇ、３１Ｂ、２１Ｃ、２１Ｄ、２１Ｅ（図２～４）、

角度を成すセグメント２１Ｂ、２１Ｄ、３１Ａ、３１Ｇ、４１Ａ、４１Ｂ（図２～４）、

外周の照明可能装置２１、３１、４１の真っ直ぐな辺２１Ａ、２１Ｂ、３１Ａ、４１Ａ、４１Ｂ全体に沿って延びるセグメント（図２～４）、

外周の照明可能装置２１、３１、４１の、真っ直ぐな辺全体にわたって２１Ｂ、３１Ａ、４１Ａ、４１Ｂ、及び／若しくは真っ直ぐな辺の一部にわたって２１Ｄ、３１Ａ、３１Ｆ、４１Ａ、４１Ｂ延びる、角度を成すセグメント、並びに／又は外周の照明可能装置２１、３１、４１（図２～４）の、２つの真っ直ぐな辺のみに沿って２１Ｂ、２１Ｄ、３１Ｆ、４１Ａ、４１Ｂ、及び／若しくは３つ以上の辺に沿って３１Ａ延びるセグメントなど、外周の照明可能装置２１、３１、４１の複数の真っ直ぐな辺２１Ｂ、３１Ａ、４１Ａ、４１Ｂに沿って延びる、角度を成すセグメント、

外周の照明可能装置１１、２１、３１、４１、５１の全長の部分にわたって延びるセグメントであって、各部分は、外周の照明可能装置の全長の、約半分である３１Ａ、４１Ａ、４１Ｂ（図３及び図４）、又は１／３である２１Ｂ（図２）、又は１／４である３１Ｆ（図３）、又は１／５、又は１／６である１１Ａ～１１Ｆ、２１Ａ、２１Ｄ（図１及び図２）、又は１／７、又は１／８である３１Ｂ（図３）、又は１／９である５１Ａ～５１Ｘ（図５）、又は１／９、又は１／１２である２１Ｃ、２１Ｅ、２１Ｆ、２１Ｇ（図２）、又は１／２４である３１Ｃ、３１Ｄ、３１Ｅ（図３）と対応する、セグメントと、並びに

これらの組み合わせ、例えば、異なる長さのセグメント（図２～５）から、若しくは同じ長さのセグメント（図１）から作製される、及び／又は湾曲セグメント及び真っ直ぐなセグメントの組み合わせ（図示されない）から作製される、外周の照明可能装置であるセグメント、から選択され得る。

【００５４】

外周の照明可能装置１１、１１’、２１、３１、４１、５１は、単一の内側部分１１０（図１～４）、又はいくつかの内側部分１１０、１２０の周辺に延びることがある。例えば、このような配置は、例えば、外周の照明可能装置５１がほぼ８の形状になるように（図５）、一対の内側部分１１０、１２０の周囲で延びる。

【００５５】

単一の内側部分１１０は、いくつかの部分、例えば、複数の有効インタフェース部分１１０Ａ、１１０Ｂ、１１０Ｃ、１１０Ｄ（図１及び図２）、複数の無効インタフェース部分、又は少なくとも１つの有効インタフェース部分１１０Ｅと少なくとも１つの無効インタフェース部分１１０Ｆとの組み合わせ（図４）から作製されることができ、例えば、有効インタフェース部分はユーザセレクタの形態であり、及び／又は無効ユーザインタフェ

ース部分はハウジングの一部の形態である。

【００５６】

内側部分は、例えば、セレクタ１１０Ｅ若しくは複数のセレクタ１１０Ａ、１１０Ｂ、１１０Ｃ、１１０Ｄなどの、例えば、１つ以上のプッシュボタンの形態の、能動部分１１０、及び／又はハウジングの一部などの受動部分１１０Ｆ、１２０、から選択され得る。

【００５７】

ユーザセレクタ１１０、１１０Ａ、１１０Ｂ、１１０Ｃ、１１０Ｄ、１１０Ｅは典型的にはコントローラ１０５、又はＰＣＢ１００に接続され、例えば、生成すべき、所望の量及び／又は濃度、及び／又は味などのいくつかの特徴を有する飲料の調製を開始するか、又は、例えば、すすぎ若しくは洗浄、若しくはスケール除去などサービス手順を実行するため、又はマシン１をオン若しくはオフにするため、又はユーザプログラミングモードに入るための命令などの、ユーザ命令を受信するように設定されてもよい。ユーザセレクタ１１０、１１０Ａ、１１０Ｂ、１１０Ｃ、１１０Ｄ、１１０Ｅは、ユーザ命令のみを受けるように設定されてもよく、又はユーザに対して情報を示すように更に設定されてもよく、例えば、またユーザセレクタ自体がコントローラ１０５によって制御される発光装置を備えてもよい。例えば、ユーザセレクタは、セレクタと関連する機能部が、マシン１の使用時の所定の時点で利用可能であるかどうかによって、照明可能である。例えば、スケール除去プロセス中に飲料調製プロセスを開始することは不可能である。これは、対応するユーザセレクタの適切な照明によって示すことができる。これは、サービス手順中にはユーザが飲料を注文できないということを意味するものではなく、サービス手順が中断される必要があるか、又は最後まで実行されてから、飲料調製の命令を実行することを意味している。例えば、コントローラは、マシン１が、ユーザリクエストを実行可能な状態にある後の時点で実行するために、特定のユーザリクエストを記憶してもよい。例えば、記憶されたユーザリクエストを後で実行する実施例に関しては、例えば、国際公開第２０１１／０２０７７９号を参照せよ。当然、特定のプロセスを実行する入力を、このようなプロセスの実行が不可能であるかぎり、アクセプトしないように、マシンを設定することもまた可能である。

【００５８】

外周の照明可能装置１１、１１’、２１、３１、４１、５１は、以下の特徴：

発光素子１０１、１０２、１０３によって放出される光を拡散するための、半透明ウィンドなどの光拡散ウィンド１１１（図１、図１Ａ、及び図２Ｂ）、

発光素子１０１’の形状をユーザに対して示すための、透明ウィンドなどの光透過ウィンド１１１’（図２ｘ）、

単一の色の発光素子１０１’、又は、白色、黄色、橙色、赤色、緑色、青色、及びピンク色、並びにこれらの混合から選択される色など、異なる色の発光素子１０１、１０２、１０３（図１ａ、及び図１Ａ）のグループ１００Ａ、１００Ｂ、１００Ｃ、１００Ｄ、１００Ｅ、１００Ｆなどの異なる色の発光素子１０１、１０２、１０３を含む、複数の発光素子１０１、１０１’、１０２、１０３、

単一の色の発光素子１０１’によって、又は異なる色の発光素子１０１、１０２、１０４のグループ１００Ａ、１００Ｂ、１００Ｃ、１００Ｄ、１００Ｅ、１００Ｆによって照明可能である、外周の照明可能装置１１、１１’、２１、３１、４１、５１の各照明可能部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘであって、このようなグループの発光素子は別個に又はグループで有効化可能である、各照明可能部分、並びに、

任意により、コネクタの対１００’、１００’’などのコネクタ１００’、１００’’（図１ａ、図１Ａ及び図１Ｂ）により上記ＰＣＢ又はあるＰＣＢ１００に接続された、ＬＥＤなどの発光素子１０１’、１０１、１０２、１０３、の１つ以上を含んでもよい。

【００５９】

外周の照明可能装置１１、１１’、２１、３１、４１、５１の、照明可能部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１

Ａ～５１Ｈ、５１Ｘは、湾曲した構成（図１～１ｘ、及び図５）、及び／又は角度を成す線状構成（図２～４）など、内側部分１１０、１２０の周囲で横並びの線状構成にあってもよい。このような照明可能部分は、

単一の横並び線状構成１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ（図１～５）、又は２つ、若３つ、若しくは４つのほぼ平行な横並び線状構成にある、及び／あるいは、

２つの隣接する照明可能部分が、互いに直接隣接している１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ（図１、図２、図３、図４、及び図５）、又はハウジングの一部１１ａなどのスペーサによって離間している１１Ａ’～１１Ｈ’（図１ｘ）、横並び線状構成１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘにあり得る。

【００６０】

照明部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘの照明は、実質的に、これらの部分全体にわたって広がり得る。任意により、このような部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘの照明は、これらの部分全体にわたって、ほぼ均一な光強度、及び／又は、白色、黄色、橙色、赤色、緑色、青色、及びピンク、又はいくつかのこのような色の混合から生じる色から選択される色などの、ほぼ均一な色をもたらす。

【００６１】

制御装置１００、１０５は、連続する部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ、例えば、線状横並び構成の連続する部分を、内側部分１１０、１２０を中心として、ある回転シーケンスで順次有効化するための少なくとも１つの設定を有し得る。任意により、

ａ）時計方向及びその後の反時計方向のシーケンスで、又は、反時計方向及びその後の時計方向のシーケンスで順次有効化され、

ｂ）回転シーケンスが完了すると、これを一度以上繰り返して順次有効化され、及び／又は、

ｃ）回転シーケンスにわたって、及び／若しくは複数の連続する回転シーケンスの間で、

飲料調製手順、例えば、予備湿潤、及び抽出の連続する工程、及び／若しくは、

サービス手順、例えば、スケール除去手順の連続する工程、という異なる工程を示すように速度を変更し、順次有効化される。

【００６２】

このような設定は、例えば、起動サイクル、又は飲料調製サイクル、又は清掃サイクルなど、任意の時点におけるサイクルの動作を示すために使用され得る。有利な実施形態において、このような設定は、遠心処理による飲料調製サイクルを示すために使用されてもよく、外周の照明可能装置は、任意により遠心処理軸３ａの周囲で延び、遠心処理は、遠心処理軸３ａを中心とした遠心処理を示す、回転シーケンスの複数の繰り返しなどの回転シーケンスによって示される。

【００６３】

制御装置１００、１０５は、連続する部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘを、内側部分１１０、１２０を中心として回転シーケンスで順次有効化し、全ての部分を有効化した後に、全ての部分を同時に無効化するための、少なくとも１つの設定を有し得る。

【００６４】

制御装置１００、１０５は、連続する部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘを、内側部分１１０、１２０を中心として回転シーケンスで順次有効化しながら、前に有効化させた部分

を回転シーケンスで順次無効化するための、少なくとも１つの設定を有し得る。部分は、等しい有効化速度及び無効化速度、又は、無効化速度よりも速い有効化速度などの、異なる有効化速度及び無効化速度を有し得る。少なくとも２つ又は３つの部分が同時に有効化状態になり得る。

【００６５】

制御装置１００、１０５は、１つの部分、１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘが、間欠的に有効化及び無効化される、少なくとも１つの設定を有し得る。

【００６６】

例えば、このような設定は、エラーの表示、又は、ユーザセレクタによりユーザ命令が適切に獲得されたことを確認するなどの、マシン１が情報を獲得したことを確認する表示と関連付けられ得る。

【００６７】

複数のこのような部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘは、同時に有効化及び無効化されてもよい。例えば、複数の部分、又は部分のグループが、内側部分１１０、１２０を中心に他の恒久的に有効化又は無効化された部分により離間している。このような部品、又は部品のグループは、例えば、内側部分１１０、１２０を中心に均等に離間している。

【００６８】

このような部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘの２つが、交互に有効化及び無効化され得る。

【００６９】

例えば、２つの部分が、交互に有効化及び無効化される。

【００７０】

例えば、このような設定は、例えば、ユーザセレクタによるユーザ入力、又はユーザによる別のアクションのマシン１による期待値と関連付けられ得る。

【００７１】

このような部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘが、一定の頻度で間欠的に有効化及び無効化され得る。例えば、いくつかの部分が、一定の頻度で間欠的に有効化及び無効化される。

【００７２】

このような設定に加えて、制御装置１００、１０５は、上記の設定よりも速い速度で、部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘを有効化及び無効化するための少なくとも１つの他の設定を有し得る。

【００７３】

例えば、異なる種類の手順の実行を区別するために、異なる速度が使用されてもよい。例えば、起動又はサービス（例えば、スケール除去）手順の実行が、比較的遅い速度における１つ以上の回転シーケンスによって示されてもよく、飲料調製手順は、比較的速い速度における１つ以上の回転シーケンスによって示されてもよい。

【００７４】

例えば、異なる速度は、例えば、ルンゴ若しくはエスプレッソコーヒーの異なる飲料の調製手順などの同じ種類の異なる手順、又は軽度の若しくは集中的スケール除去手順などの異なるサービス手順実行を区別するために、実施され得る。

【００７５】

有効化可能及び無効化可能な部分に加えて、少なくとも１つの部分が、上記の設定又は上記の更なる設定において、恒久的に有効化又は無効化されたままであってもよい。

【００７６】

例えば、原材料（例えば、水）利用可能性が最低レベルに近づいているなど、非停止警告が、恒久的有効部分によって示されてもよい。非停止警告の別の例は、短い時間内にサービス（例えば、スケール除去）プロセスを行うことの必要性に関連し得る。

【００７７】

制御装置１００、１０５は、例えば、単一部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘ、又は隣接する部分のグループなどの、少なくとも１つの部分が順次有効化される、少なくとも１つの設定を有し得る。

【００７８】

外周の照明可能装置１１、１１’、２１、３１、４１、５１は、細長い形状に概ね沿っており、

ａ）例えば、１つ以上の円１１、１１’（図１、図１ａ、及び図１ｘ）及び／若しくは楕円５１（図５）、又はその一部などの曲線１１，１１’を形成する、

ｂ）三角形４１（図４）、例えば、正方形３１（図３）、矩形、台形、若しくは平行四辺形である、四角形３１、五角形、六角形２１（図２）、七角形、八角形１１’（図１ｘ）、十角形、九角形、十角形、十一角形、若しくは十二角形などの、規則的若しくは不規則的な多角形２１、３１、４１、又はその一部を形成する、

ｃ）ストライプ１１、２１、３１、４１、５１（図１、図２～５）の形状、及び／又は細長い形状に概ね沿って配置された、別個の発光素子などの別個の要素１１’（図１ｘ）、例えば、ＬＥＤ１０１’又は発光可能光ファイバーの一部の形状に延びる、あるいは、

ｄ）湾曲部分、及び真っ直ぐ若しくは角度を成す部分から形成された外周の照明可能装置などの、特徴ａ）、ｂ）、及びｃ）の少なくとも２つの組み合わせである。

【００７９】

制御装置１００、１０５は、ユーザに対して、

例えば、連続する部分、例えば、線状横並び構成の連続する部分を、内側部分を中心として、ある回転シーケンスで順次有効化するための設定、及び任意により、全ての部分を有効化した後に、全ての部分を同時に無効化する種類の設定など、上記の設定による、加熱器の起動などの起動手順の実行を示すように、

例えば、単一部分、又は隣接する部分のグループなどの、少なくとも１つの部分が順次有効化される設定など、上記の設定による、飲料調製の準備完了までに必要な時間に関する指標をインタフェースが提示するスタンバイ手順を示すように、

例えば、連続する部分を内側部分を中心に回転シーケンスで順次有効化し、かつ全ての部分が有効化された後に全ての部分を同時に無効化するか、又は先に有効化された部分を、回転シーケンスで順次無効化する設定など、上記の設定による、飲料調製手順、例えば、回転シーケンスが完了すると、これを一度以上繰り返すこのような上記の設定のような、例えば、遠心処理の軸線を取り囲む概ね外周の照明可能装置による、遠心処理による飲料調製手順の実行を示すように、

例えば、上記の設定、例えば、少なくとも１つの部分が順次有効化され、任意により全ての部分が順次有効化される設定による、ユーザ命令を受信する準備が完了した状態を示すように、

例えば、上記の設定、例えば、１つの部分が間欠的に有効化及び無効化される設定による、原材料カプセルなどのカプセルから、又は、例えば、ネットワーク又はポータブルメモリ装置に接続される、マシンインタフェースからの情報を読み取る手順の実行を示すように、

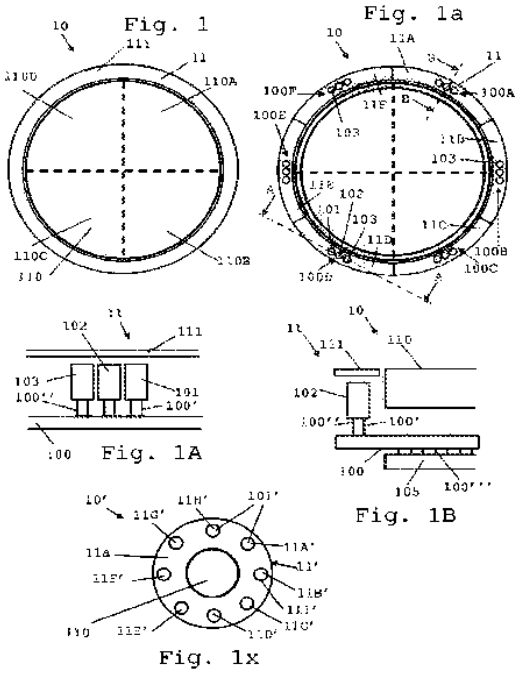
例えば、上記の設定、例えば、１つの部分が間欠的に有効化及び無効化される設定による、例えば、例えば水の不足などの原材料の不足を示す、エラーの状態を示すように、

例えば、上記の設定、例えば、少なくとも１つの部分が順次有効化される設定による、飲料調製プロセスのパラメータを設定するため、又はスタンバイ若しくは自動停止プロセスに入るためのタイマーを設定するためなどの、ユーザプログラミングモードの有効化を示すように、

例えば、上記の設定成、例えば、全ての部分が有効化された後に全ての部分が同時に無効化されるか、若しくは先に有効化された部分が、回転シーケンスで順次無効化されるようにして、連続する部分が、内側部分を中心にして、回転シーケンスで順次有効化される設定、１つの部分が間欠的に有効化及び無効化される設定、又は少なくとも１つの部分が順次有効化される設定などによる、すすぎ、洗浄、スケール除去、又は水材料排出手順など、サービス手順の実行を示すように、並びに、

例えば、上記の設定、例えば、１つの部分１１Ａ～１１Ｆ、１１Ａ’～１１Ｈ’、２１Ａ～２１Ｇ、３１Ａ～３１Ｆ、４１Ａ～４１Ｂ、５１Ａ～５１Ｈ、５１Ｘが、間欠的に、例えば２回又は３回、有効化及び無効化される設定による、例えば、ユーザセレクタ１１０、１１０Ａ、１１０Ｂ、１１０Ｃ、１１０Ｄによる、ユーザ命令の獲得の完了を示すように、概ね外周の照明可能装置１１、１１’、２１、３１、４１、５１を制御するための１つ以上の設定を含み得る。

【図１－１ｘ】



【図２】

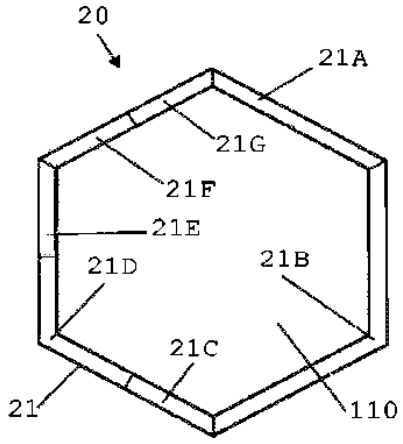


Fig. 2

【図３】

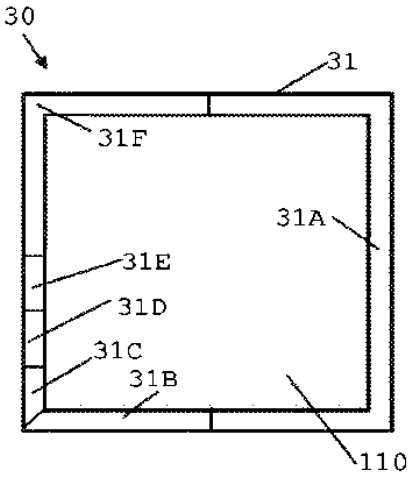


Fig. 3

【図４】

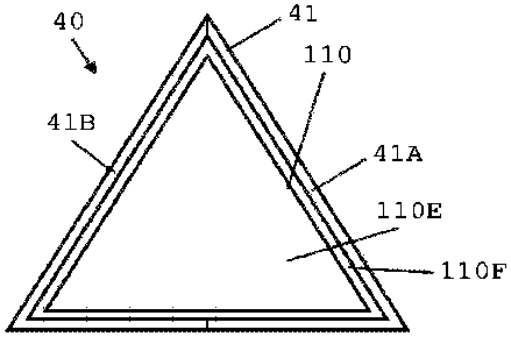


Fig. 4

【図５】

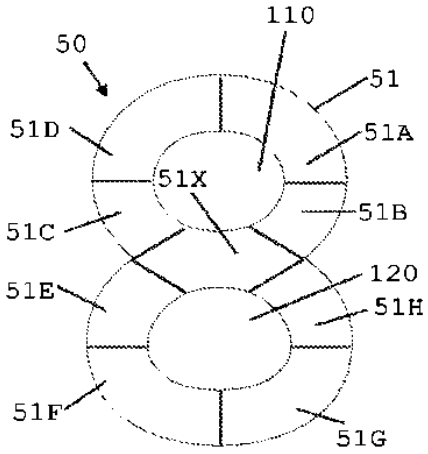


Fig. 5

【図６】

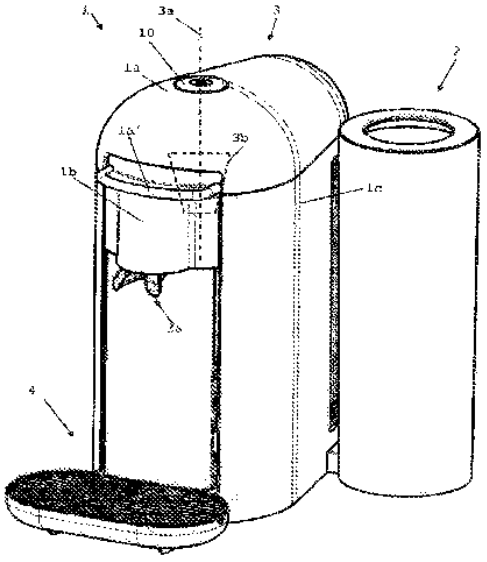


Fig. 6

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2014/077494

A. CLASSIFICATION OF SUBJECT MATTER
INV. A47J31/52 G07F9/02
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A47J G07F

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 2 528 044 A1 (NESTEC SA [CH]) 28 November 2012 (2012-11-28) paragraph [0031] - paragraph [0053]; figures 1,2	1-16
X	WO 2010/037806 A1 (NESTEC SA [CH]; CAHEN ANTOINE [CH]; MOERI PETER [CH]) 8 April 2010 (2010-04-08) page 13, line 26 - page 23, line 28; figures 1-9	1-16
A	US 4 554 419 A (KING EDDIE W [US] ET AL) 19 November 1985 (1985-11-19) cited in the application the whole document	1-16

-/--

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 April 2015	14/04/2015

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

1

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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2014/077494

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 377 049 A (SIMON DONALD R ET AL) 22 March 1983 (1983-03-22) cited in the application the whole document -----	1-16
A	US 6 182 555 B1 (SCHEER RICK [US] ET AL) 6 February 2001 (2001-02-06) cited in the application the whole document -----	1-16

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2014/077494

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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Form PCT/ISA/210 (patent family annex) (April 2005)

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(81)指定国 AP(BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), EA(AM, AZ, BY, KG, KZ, RU, TJ, TM), EP(AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OA(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG), AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US

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Ｆターム(参考) 4B104 AA19 AA20 BA53 BA81 BA82 DA09 DA11 DA51 DA54 DA55
EA20 EA40

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DESCRIPTION JP2017503552A

10 Simple ergonomic user interface for beverage machines.

[0001]

14 The field of the invention relates to a beverage preparation machine having a user-friendly and ergonomic user interface for showing information to a user. For example, beverage preparation machines may use containers, such as capsules, of the raw materials of the beverage to be prepared, such as machines for preparing beverages by circulation of liquid into the raw material container and centrifugal action of the raw material container, typically to brew and extract beverages from the raw material container.

[0002]

23 For the purposes of this description, a "beverage" is intended to include any liquid substance that can be consumed by humans, such as tea, coffee, hot or cold chocolate, milk, soup, baby food, and the like.

26 "Capsules" are intended to include any pre-divided beverage ingredient, such as a flavoring ingredient, within an enclosed package of any material (e.g., plastic, aluminum, reusable, and/or biodegradable packages, etc.), any shape and structure (including soft pods or hard cartridges containing the ingredient), such as an air-tight or air-permeable package.

[0003]

33 Some beverage preparation machines use capsules.

34 The capsule contains the raw materials to be extracted or dissolved and/or stored in a machine and either automatically dispensed or otherwise added during beverage preparation.

36 Some beverage machines have a filling means.

37 The filling means comprises a pump for a liquid (usually water).

38 The pump pumps liquid from a water supply source, which is cold or in fact heated by heating means, for example thermoblocks.

[0004]

43 In particular in the field of coffee preparation, machines have been extensively developed in which capsules containing beverage ingredients are inserted into brewing devices.

45 The brewing device is reliably closed around the capsule, water is injected into the 1stside of the capsule, a beverage is produced in the closed volume of the capsule, and the brewed beverage can be released from the 2ndside of the capsule and collected in a container such as a cup or glass.

[0005]

52 The brewing device has been developed to facilitate the insertion of a "new" capsule and the removal of the capsule in use.

54 Typically, such brewing device comprises 2 parts that are relatively movable from the structure to insert/remove the capsule relative to the structure for brewing the raw material in the capsule.

57 The actuation of the movable part of the brewing device may be motorized.

58 Such a system is disclosed, for example, in EP 1 767 129.

59 Other examples of brewing devices are disclosed in WO 2009/04330, WO 2005/004683, and WO 2007/135136.

[0006]

64 Preparation of beverages using centrifugal force is also known.

65 Preparation of such beverages comprises the steps of providing beverage ingredients (flavour ingredients), such as, for example, powders and/or leaves, into a container, such as, for example, a capsule, and ensuring that the liquid and the ingredients interact while circulating the liquid into the container and rotating the container at a speed sufficient to create a gradient in the pressure of the liquid in the container.

70 Such pressure gradually increases from the center towards the periphery of the container.

71 As the liquid passes through the raw material, such as the coffee layer, extraction of the raw material, such as the coffee product, occurs, resulting in liquid extraction that flows out at the periphery of the container.

74 WO 2008/148601 describes a possible embodiment of a device using such a centrifugal principle.

76 In this case, the ingredient container is a sealed capsule that is opened before use.

77 The hot water is supplied to the center of the capsule by a water connection portion comprising a water injector aligned with the axis of rotation.

79 The container is held in a capsule holder, which is rotated by a rotary motor.

80 Both the liquid communication portion and the capsule holding portion are mounted along the roller bearing.

82 The beverage is extracted from the capsule by a plurality of peripheral needles forming an opening in the lid of the container.

84 When centrifugal force is applied to the capsule about the axis of rotation, hot water passes through the raw material of the beverage and interacts with the material to produce a liquid extract, which is injected against the impingement wall of the collector through the peripheral opening due to the effect of centrifugal force.

88 The liquid extract comprising the beverage is then released through the beverage duct of the device and collected in a container such as a cup.

90 WO 2008/148650 further describes a device in which a flow restriction is formed downstream of a container, in particular a capsule, for example by a valve system that opens or expands under pressure formed by a centrifugally-forced liquid exiting the container.

93 The valve system may be formed by a movement limiting portion of the device, which is resiliently biased against a rim portion of the capsule.

95 U.S. Pat. No. 5,566,605 relates to a centrifugal type extraction cell with a deformable sealing joint for a preparation machine for hot beverages.

97 The cell includes a drum and a cover defining an interior volume with the drum.

98 The cover is connected to the drum by means of a mounting lug that engages the ramp.

99 In these prior art devices, the water communication portion for supplying water to the container and the holding portion for holding the container are rotatable along the frame portion of the device secured together by a closure mechanism such as a bayonet system.

102 The retaining portion is generally attached to the frame portion by at least 1 roller bearing.

103 The liquid communication portion is also generally part of a frame portion which is also mounted along at least one roller bearing.

105 During the centrifugation process, when the device is rotated at high speed, the liquid extract creates significant axial and radial forces, which tend to separate these rotating parts.

[0007]

110 Various systems are disclosed in the art, for example as disclosed in the following documents, to allow a user to interact with such machines to provide operational instructions to or obtain feedback from the machines: Australian Patent 410 377; Swiss Patent 682 798; DE 44 29 353; 202 00 419; 20 2006 019 039; 2007 008 590; EP 1448084; 1676509; 08155851. 2, Korean Patent No. 2 624 844, GB Patent No. 2 397 510, U.S. Pat. Nos. 4,377,049, 4,458,735, 4,554,419, 4,767,632, 4,954,697, 5,312,020, 5,335,705, 5,372,061, 5,375,508, 5,645,230, 5,685,435, 5,731,981, 5,836,236, 5,959,869, 6,182,555, 6,354,341, 6,759,072, U.S. Patent Application Publication Nos. 2007/0157820, WO 97/25634, WO 99/50172, WO 2004/030435, WO 2004/030438, WO 2006/063645, WO 2006/090183, WO 2007/008138, WO 2008/00838, WO 2007/00838, WO 2007/00838, WO 2007/00838, WO 2007/00838, WO 2007/00838, WO 2008/00838, WO 2007/00838, WO 2007/00838, WO 2008/00838, WO 2008/00838, WO 2008/00838, WO

2008/00838, WO.

[0008]

126 It is therefore a preferred object of the invention to improve at least one feature of a beverage machine interface selected from, for example, ergonomics, interactions, insensitivity, user friendly and simplicity of an interface of a coffee, chocolate, cocoa, milk, soup or tea preparation machine.

[0009]

133 The present invention therefore relates to a beverage preparation machine.

134 The machine may have a water supply source, a beverage preparation unit and an outlet for supplying the beverage to the beverage dispensing area.

[0010]

139 For example, the machine is a machine for preparing beverages by passing hot or cold water, or another liquid, through a capsule comprising raw materials of the beverage to be prepared, such as coffee, tea, chocolate, cocoa, milk, and/or soup machines, for example ground coffee.

143 Examples of such machines are disclosed in WO 2007/042415, WO 2007/042414, WO 2007/134960, WO 2009/074550, WO 2009/130099, WO 2013/127476 and the literature cited therein.

[0011]

149 For example, a beverage machine has a container holding unit for preparing beverages from at least 1 raw material and dispensing such prepared beverages.

151 For example, the machine is configured to prepare coffee, tea, chocolate, cocoa, milk, and/or soup.

153 For example, the machine is configured to prepare a beverage by passing hot or cold water, or another liquid, through a container held in a beverage processing module comprising a container holding unit, such as a capsule to be held, comprising raw materials such as flavoring ingredients of the beverage to be prepared, such as ground coffee, tea, chocolate, cocoa, or milk powder.

[0012]

161 Such beverage preparation typically comprises mixing a plurality of beverage ingredients, such as, for example, water and milk powder, and/or injecting beverage ingredients, such as infusion of ground coffee or water and tea.

164 For example, a predetermined amount of beverage corresponding to 1 minute is formed and dispensed according to a user's request.

166 Such a 1 dose amount may range from 25 to 250 mL (e.g., the amount to fill a cup or mug) depending on the type of beverage.

168 The beverage formed and dispensed may be selected from Listeria, espresso, lungo, cappuccino, caffelate, American coffee, tea, and the like.

170 For example, the coffee machine may be configured to dispense espresso (20-60 mL adjustable amount per 1 time) and/or dispense lungo (e.g., an amount in the range of 70-200 mL per time).

[0013]

176 In advantageous embodiments, the beverage machine is of the type that combines raw materials by centrifugal treatment as disclosed, for example, in WO 2008/148601, WO 2008/148604, WO 2008/148646, WO 2008/148650, WO 2008/148656, WO 2009/106175, WO 2009/106598, WO 2010/063644, WO 2010/066736, WO 2010/089329, WO 2011/023711, PCT/EP13/077276, and PCT/EP13/077275.

181 Thus, the machine may comprise a raw material mixing chamber for accommodating raw material capsules, for example, into which a liquid is injected and which undergoes a centrifugal process about a centrifugal axis to mix the raw material and the liquid.

184 The raw material mixing chamber can be opened and closed to rotate and mix the raw materials.

[0014]

189 The machine of the present invention includes a user interface having a generally peripheral illuminable device formed by the illuminable portion and extending around the inner portion and a control device for enabling and disabling illumination of the illuminable portion, such as a programmable control device.

193 For example, the control device includes a controller, such as a printed circuit board PCB and a controller connected to a PCB by a connector.

195 The PCB may be formed from a single printed circuit board or several juxtaposed or spaced printed circuit boards connected electrically, optically or otherwise.

197 Optionally, the control device controls other functions of such a machine, such as, for example, the IT module, pump, heat regulator, and/or power unit of the preparation unit.

[0015]

202 In typical embodiments, the user interface is on the top, or front, or side of such a machine.

[0016]

206 According to the invention, the control device has at least 1 setting in order to enable only a part of the illuminable part.

[0017]

211 The illuminable portion may include 1 or more spots, such as, for example, round spots or polygonal spots, arranged along a generally peripheral illuminable device and/or 1 or more elongated segments extending along a generally peripheral illuminable device.

214 Such elongate segments include segments that may be selected from curved segments, such as segments extending generally along a circular sector and/or segments extending generally along an elliptical sector; straight segments; angled segments; segments extending along the entire straight side of the perimeter illuminable device; angled segments extending along a plurality of straight sides of the perimeter illuminable device, such as segments extending along only 2 straight sides and/or along more than 3 sides of the perimeter illuminable device; and segments extending over a portion of the entire length of the perimeter illuminable device, which portion may be selected from segments that correspond to about half, or 1/3, or 1/4, or 1/5, or 1/6, or 1/7, or 1/8, or 1/9, or 1/10, or 1/12, or 1/4 of the entire length.

[0018]

227 The generally peripheral illuminable device may extend around a single inner portion or around some inner portion, such as a pair of inner portions, for example, such that the generally peripheral illuminable device is generally 8 shaped around and between spaced inner portions.

231 A single inner portion may be made from a plurality of portions, e.g., a plurality of valid interface portions, or a plurality of invalid interface portions, or a combination of at least 1 valid interface portion and at least 1 invalid interface portion.

234 For example, such a valid interface portion is in the form of a user selector.

235 The invalid user interface portion may be in the form of a portion of the housing.

236 A portion of the housing belongs to the housing of the interface and/or belongs to the external machine housing.

[0019]

241 The inner portion may be an active portion, such as a selector or a plurality of selectors, for example in the form of one or more push buttons, and/or a passive portion, such as a portion of a housing, for example.

[0020]

247 The generally peripheral illuminable device may comprise one or more of the following

features: a light diffusing window, such as a translucent window, for diffusing light emitted by the light emitting elements; a light transmitting window, such as a transparent window, for indicating the shape of the light emitting elements to a user; a plurality of light emitting elements, including a single color light emitting element or a different color light emitting element, such as a color selected from white, yellow, orange, red, green, blue, and pink, and mixtures thereof; each illuminable portion of the peripheral illuminable device, illuminable by a single color light emitting element or by a group of different color light emitting elements, wherein the light emitting elements of such a group are separately or group-enabled; and a light emitting element, such as an LED, optionally connected to the PCB or a PCB by a connector, such as a pair of connectors.

[0021]

261 Light emitting elements that emit light of different colors may be used to transmit signals of different types.

263 For example, red color may be used to communicate an indication of warning or an indication of heat generation.

265 The blue color may be used to communicate an indication associated with cold conditions.

266 Green may be used to indicate a state or a ready state.

267 Red or blue may be used to communicate an indication of the process of warming or cooling the beverage.

269 Orange or yellow may be used to indicate a user programming mode or a service mode, such as machine rinsing, cleaning, or descaling.

271 Thus, intuitive color codes may be used to communicate different indicators to the user.

[0022]

275 The illuminable portions of the generally circumferential illuminable device may be in a line configuration that is side-by-side around the inner portion, such as a curved and/or angled line configuration.

278 For example, the illuminable portions of the generally peripheral illuminable device are in a single side-by-side linear configuration, or in 2, 3, or 4 generally parallel or concentric side-by-side linear configurations, and/or in a side-by-side linear configuration, wherein 2 adjacent illuminable portions are directly adjacent to one another or spaced apart by spacers, such as a portion of a housing.

[0023]

286 The illumination of each illuminable portion may spread substantially over the entire portion.

287 Optionally, illumination of each portion results in a substantially uniform light intensity and/or a substantially uniform color throughout these portions.

289 The color may be selected from white, yellow, orange, red, green, blue, and pink, or a mixture

of several such colors.

[0024]

294 The control device may have at least 1 setting for sequentially enabling successive portions, e.g. successive portions of a linear side-by-side configuration, in a rotational sequence about the inner portion, e.g.: a) at least 1 setting for sequentially enabling in a clockwise and subsequent counterclockwise sequence, or in a counterclockwise and subsequent clockwise sequence, b) at least 1 setting for sequentially enabling this repeatedly once or more once the rotational sequence is completed, and/or c) over the rotational sequence and/or between a plurality of successive rotational sequences, e.g., at least 1 setting for changing speed and sequentially enabling to indicate different steps: a beverage preparation procedure, e.g., a continuous pre-wetting and extraction step, and/or a service procedure, e.g., a continuous descaling procedure.

[0025]

307 Such settings may be used to indicate the operation of the cycle at any time point, such as, for example, an activation cycle, or a beverage preparation cycle, or a cleaning cycle.

309 In an advantageous embodiment, such a setting may be used to indicate a beverage preparation cycle by centrifugal processing, wherein the outer circumferential illuminable device optionally extends around a centrifugal processing axis, wherein the centrifugal processing is indicated by a rotational sequence, such as a plurality of iterations of a rotational sequence, indicating the centrifugal processing about the centrifugal processing axis.

[0026]

318 The control device may have at least 1 setting for sequentially enabling successive portions in a rotational sequence about the inner portion and disabling all portions simultaneously after enabling all portions.

[0027]

324 The control device may have at least 1 setting for sequentially disabling the previously enabled portion in the rotation sequence while sequentially enabling the successive portion in the rotation sequence about the inner portion.

327 Optionally, these portions have different activation and deactivation rates, such as equal activation and deactivation rates, or activation rates that are faster than the deactivation rates.

330 At least 2 or 3 portions may be simultaneously in the enabled state.

[0028]

334 The control device may have at least 1 setting such that 1 part is intermittently enabled and disabled.

[0029]

339 For example, such settings may be associated with an indication of an error or an indication confirming that the machine 1 has acquired information, such as confirming that the user instruction has been properly acquired by the user selector.

[0030]

345 Portions, such as portions or groups of portions, spaced apart, e.g., approximately evenly spaced apart, by permanently enabled or disabled portions about the inner portion may be enabled and disabled simultaneously.

[0031]

351 2 of these parts may be alternately enabled and disabled, such as 2 parts are alternately enabled and disabled.

[0032]

356 For example, such a setting may be associated with a user input by a user selector or an expectation by the machine 1 of another action by the user, for example.

[0033]

361 The portions may be intermittently enabled and disabled at a constant frequency, for example, some portions may be intermittently enabled and disabled at a constant frequency.

[0034]

366 In addition to any of the above settings, the controller may have at least 1 further setting to enable and disable the portion at a faster rate than the above settings.

[0035]

371 For example, different speeds may be used to distinguish between the execution of different types of procedures.

373 For example, execution of an activation or service (descaling) procedure may be indicated by

1 or more rotational sequences at a relatively slow speed, and a beverage preparation procedure may be indicated by 1 or more rotational sequences at a relatively fast speed.

[0036]

379 Different speeds may be implemented to distinguish between the execution of different procedures of the same type, such as for example different beverage preparation procedures of lungo or espresso coffee, or different service procedures, such as for example mild or intensive descaling procedures.

[0037]

386 In addition to the activatable and disableable portions, at least 1 portion may remain permanently activated or disabled in the above settings or further settings.

[0038]

391 The control device may have at least 1 setting, for example at least 1 part is sequentially enabled, such as a single part or a group of adjacent parts.

[0039]

396 The perimeter illuminable device extends generally along an elongated shape; a) forms a curve, such as, for example, 1 or more circles and/or ellipses, or portions thereof; b) forms a regular or irregular polygon, such as a triangle, e.g., a square, rectangle, trapezoid, or parallelogram, or portions thereof, such as a quadrangle, pentagon, hexagon, heptagon, octagon, dodecagon, nonagonal, dodecagon, or dodecagon; and/or c) forms a stripe shape and/or a separate element, such as a separate light emitting element, arranged generally along the elongated shape, such as an LED or a portion of a light-emitting optical fiber.

[0040]

406 For example, the control device may include a setting for sequentially enabling successive portions, for example, successive portions of a linear side-by-side configuration, in a rotation sequence about an inner portion, and optionally a setting of a type for simultaneously disabling all portions after enabling all portions, to indicate execution of an activation procedure, for example, activation of a heater, by the setting, such as a setting for sequentially enabling at least 1 portion, such as a single portion or a group of adjacent portions, to indicate execution of a beverage preparation procedure, for example, by a centrifugal process, such as a setting for sequentially enabling successive portions in a rotation sequence about an inner portion and simultaneously disabling all portions after all portions are enabled, or setting for sequentially disabling at least 1 or a setting for

sequentially disabling a previously enabled portion, such as a setting for sequentially disabling a user, such as a setting for sequentially disabling a setting for a setting for sequentially turning a user, such as a setting for sequentially disabling a setting for sequentially disabling a predetermined portion, such as a setting for sequentially turning a predetermined portion, such as a setting for sequentially turning a predetermined portion, such as a setting for sequentially turning a predetermined portion, such as a predetermined portion, such as

[0041]

426 The invention will now be described with reference to the schematic drawings.

[0042]

430 A round interface of a beverage preparation machine according to the invention is schematically illustrated.

432 FIG. 1 shows a horizontal cross-sectional view of the interface.

433 An enlarged cross-sectional view of the interface of FIGS. 1 and 1 a, taken along line A-A, is illustrated.

435 An enlarged cross-sectional view of the interface of FIGS. 1 and 1 a, taken along line B-B, is illustrated.

437 A variation of the interface of the machine according to the invention is illustrated.

438 The different interfaces of polygons are illustrated which may be installed in the machine according to the invention.

440 The different interfaces of polygons are illustrated which may be installed in the machine according to the invention.

442 The different interfaces of polygons are illustrated which may be installed in the machine according to the invention.

444 An example of a curved-shaped interface that can be installed in a machine according to the invention is shown.

446 A beverage preparation machine according to the invention is illustrated.

[0043]

450 FIGS. 1 to 5 illustrate different user interfaces 10, 20, 30, 40, 50 for a beverage preparation machine 1 according to the invention.

452 An embodiment of a beverage machine 1 comprising an interface 10 is shown in FIG. 6.

[0044]

456 The exemplary beverage preparation machine 1 may have a water supply source 2 and a beverage preparation unit 3.

458 The water supply source 2 may be a water tank.

459 Alternatively, the machine water supply may include a connector that can be directly connected to the urban water distribution system such that there is no need to manually refill any water tank of the beverage machine.

[0045]

465 The machine 1 may be configured to prepare hot or cold beverages.

466 The machine 1 may be configured to combine different raw materials, for example a liquid carrier such as water and/or milk, and one or more flavoring and/or texture ingredients (texturing agents), for example chocolate, cocoa, coffee, tea, milk, syrup, sugar, cream, emulsifier, dried or gel soup.

470 The raw materials may be combined by mixing or injecting them.

471 Suitable machines are disclosed in more detail, for example, in WO 2009/074550 and WO 2009/130099.

473 In an advantageous embodiment, the beverage machine 1 is of the type which combines raw materials by centrifugal treatment as disclosed, for example, in WO 2008/148601, WO 2008/148604, WO 2008/148646, WO 2008/148650, WO 2008/148656, WO 2009/106175, WO 2009/106598, WO 2010/063644, WO 2010/066736, WO 2010/089329, WO 2011/023711, PCT/EP13/077276 and PCT/EP13/077275.

478 Thus, the machine 1 may include a raw material mixing chamber 3 b(typically arranged in the machine 1 and shown in dotted lines in FIG. 6) for accommodating raw material capsules into which liquid is injected and which undergoes a centrifugal process about a centrifugal axis 3 ato mix the raw material and the liquid.

482 The raw material mixing chamber 3 bcan be opened and closed (e.g., by turning or raising and lowering the upper portion 1 aby actuating the handle 1 a) and can be rotated to mix the raw materials.

[0046]

488 The beverage machine 1 typically has an outlet 3 a, which may be a single outlet or a double outlet.

490 The outlet 3 amay be configured to supply beverage to the dispensing region 4.

491 The dispensing region 4 may be configured to receive a container such as a glass, cup or mug.

492 The dispensing region may be of any type, for example as disclosed in EP 1867260 or WO 2009/074557.

[0047]

497 The beverage machine 1 comprises a user interface 10, which is illustrated in more detail in FIGS. 1, 1A and 1B.

499 Alternatively, the interface 10 can be replaced by any of the interfaces 10', 20, 30, 40, 50

illustrated in FIGS. 1 x-5 or variations thereof encompassed within the scope of the present invention.

[0048]

505 The user interfaces 10, 10', 20, 30, 40, 50 all comprise: a generally peripheral illuminable device 11, 11', 21, 31, 41, 51 formed by illuminable portions 11A, 11B, 11C, 11D, 11E, 11F, 11A', 11B', 11C', 11D', 11E', 11F', 11H', 21A, 21B, 21C, 21D, 21E, 21F, 21G, 31A, 31B, 31C, 31D, 31E, 31F, 41A, 41B, 51A, 51B, 51C, 51D, 51E, 51F, 51G, 51H, 51X, extending around the inner portions 110, 120, and a controller 105, such as a PCB, 100', and a controller 105 for enabling and disabling illumination of the illuminable portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X, for example a PCB.

[0049]

515 The control device 100, 105 may control other functional parts of such a machine 1, such as IT modules, pumps, heat regulators and/or power parts of the beverage preparation unit 3.

[0050]

520 In an exemplary embodiment, the user interface 10, 10', 20, 30, 40, 50 is on the top 1a, front 1b or side 1c of such a machine 1.

522 In FIG. 6, for example, the user interface 10 is provided on the upper portion 1 aof the machine 1.

[0051]

527 The control device 100, 105 may incorporate at least one setting, such as a programmed setting, to enable only a portion of the illuminable portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X.

[0052]

533 For example, as illustrated in FIG. 1 x, the illuminable portion may include 1 or more illuminable spots 11A'-11H', such as round or polygonal spots, arranged along a generally circumferential illuminable device 11'.

536 For example, as illustrated in FIGS. 1, 2, 3, 4, and 5, the illuminable portion may have one or more elongated segments 11A-11F, 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X extending along a generally circumferential illuminable device 11, 21, 31, 41, 51.

[0053]

542 Such elongated segments may be selected from curved segments 11A-11F, 51A-51X, straight segments 21A, 21C, 21E, 21F, 21G, 31B, 21C, 21D, 21E (FIGS. 2-4), angled segments 21B, 21D, 31A, 31G, 41A, 41B (FIGS. 2-4), straight segments 21A, 21B, 31A, 31A, 41A, 41B (FIGS. 2-4), straight segments 21A, 21B, 31A, 41A, 41B (FIGS. 2-4), straight segments extending along the entire circumference of the outer circumference of the illuminable device 21, 31, 41 (FIGS. 2 to 4), straight segments extending along the entire circumference of the outer circumference of the illuminable device 21, 31A, 31A, 41B, and/or straight segments that are 1/ or more, or straight segments that are 1/ or 1/ or 1/ or 1/ or 1/ or 1 (FIGS. 2), or straight segments that are 1/ or 1/ or 1/ or 1/ or 1 or 1 or 1/ or 1/ or 1 or 1 or 1 or 1 or 1

[0054]

555 The perimeter illuminable devices 11, 11', 21, 31, 41, 51 may extend around a single inner portion 110 (FIGS. 1-4), or a number of inner portions 110, 120.

557 For example, such an arrangement extends around the pair of inner portions 110, 120, for example, such that the outer perimeter illuminable device 51 is approximately 8 shaped (FIG. 5).

[0055]

563 The single inner portion 110 can be made from several portions, for example, a plurality of valid interface portions 110A, 110B, 110C, 110D (FIGS. 1 and 2), a plurality of invalid interface portions, or a combination of at least 1 valid interface portion 110E and at least 1 invalid interface portion 110F (FIG. 4), for example, the valid interface portion is in the form of a user selector and/or the invalid user interface portion is in the form of a portion of the housing.

[0056]

572 The inner portion may be selected from the active portion 110 and/or the passive portion 110F, 120, such as a portion of the housing, for example in the form of one or more push buttons, such as the selector 110E or the plurality of selectors 110A, 110B, 110C, 110D.

[0057]

578 The user selectors 110, 110A, 110B, 110C, 110D, 110E are typically connected to the controller 105 or PCB 100 and may be configured to start preparing beverages having some characteristics such as, for example, desired amounts and/or concentrations and/or tastes to be generated, or to receive user instructions such as instructions to perform service procedures such as, for example, rinsing or cleaning or descaling, or to turn the machine 1 on or off, or to enter a user programming mode.

584 The user selectors 110, 110A, 110B, 110C, 110D, 110E may be configured to receive only user instructions, or may be further configured to indicate information to the user, for example, and the user selector itself may comprise a light emitting device controlled by the controller 105.

588 For example, the user selector can be illuminated by whether a function associated with the selector is available at a predetermined point in time when the machine 1 is in use.

590 For example, it is not possible to initiate the beverage preparation process during the descaling process.

592 This can be indicated by appropriate illumination of the corresponding user selector.

593 This does not mean that the user cannot order the beverage during the service procedure, but rather means that the service procedure needs to be interrupted or executed until the end, and then executes the instructions for beverage preparation.

596 For example, the controller may store a particular user request for execution at a later point in time when the machine 1 is in a state capable of executing the user request.

598 For example, for an embodiment in which a stored user request is executed later, see, for example, WO 2011/020779.

600 Of course, it is also possible to configure the machine such that the input to perform a particular process is not accepted as long as such a process cannot be performed.

[0058]

605 The peripheral illuminable devices 11, 11', 21, 31, 41, 51 may include: a light diffusion window 111 (FIGS. 1, 1A, and 2B), such as a translucent window, for diffusing light emitted by the light emitting elements 101, 102, 103, a light transmission window 111' (FIG. 2x), such as a transparent window, for indicating the shape of the light emitting element 101' to a user, a plurality of light emitting elements 101, 101', 102, 103, including different color light emitting elements 101, 102A, 100B, 100C, 100D, 100E, 100F, or a different color light emitting element 101, 102B, 100C, 100D, 100E, 100F, such as a color selected from white, yellow, orange, red, green, blue, pink, and mixtures thereof, and a connector 100A, 100B, 100C, 100D, 100E, 100F, such as a group of light emitting elements 101, 100A, 100A, 100A, 100A, or a connector 100A, 51A, or a connector 100A, 51B, or a connector 100A, 51B, or a connector 100A, 51B, or a connector

[0059]

619 The illuminatable portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X of the outer circumferential illuminatable devices 11, 11', 21, 31, 41, 51 may be in a line-like configuration that is side-by-side around the inner portion 110, 120, such as a curved configuration (FIGS. 1-1x and 5) and/or an angled line-like configuration (FIGS. 2-4).

623 Such illuminable portions may be in a single side-by-side linear configuration 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X (FIGS. 1-5), or 2, young 3, or 4 generally parallel side-by-side linear configurations, and/or in 11A-11F, 11A'-11H', 21A-21G, 31A-31F,

41A-41B, 51A-51H, 51X (FIGS. 1, 2, 3, 4, and 5), or 11A'-11H' (FIG. 1 x), side-by-side linear configurations 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X, which are directly adjacent to one another.

[0060]

632 The illumination of the illumination portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X may spread substantially across these portions.

634 Optionally, the illumination of such portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X results in a substantially uniform light intensity and/or a substantially uniform color, such as a color selected from white, yellow, orange, red, green, blue, and pink, or a color resulting from a mixture of several such colors, throughout these portions.

[0061]

641 The control device 100, 105 may have at least 1 setting for sequentially enabling successive portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X, e.g. successive portions of a linear side-by-side configuration, in a rotational sequence about the inner portion 110, 120.

645 Optionally, the speed is changed and sequentially validated to indicate different steps: a) in a clockwise and subsequent counterclockwise sequence, or in a counterclockwise and subsequent clockwise sequence; b) when the rotation sequence is completed, this is repeatedly and sequentially validated one or more times; and/or c) over the rotation sequence and/or between a plurality of consecutive rotation sequences: a continuous beverage preparation procedure, e.g., pre-wetting and extraction; and/or a continuous service procedure, e.g., descaling procedure.

[0062]

655 Such settings may be used to indicate the operation of the cycle at any time point, such as, for example, an activation cycle, or a beverage preparation cycle, or a cleaning cycle.

657 In an advantageous embodiment, such a setting may be used to indicate a beverage preparation cycle by centrifugal processing, wherein the outer circumferential illuminable device optionally extends around the centrifugal processing axis 3 a, wherein the centrifugal processing is indicated by a rotational sequence, such as a plurality of iterations of a rotational sequence, indicating the centrifugal processing about the centrifugal processing axis 3 a.

[0063]

666 The control device 100, 105 may have at least 1 setting for sequentially enabling the successive portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X in a

rotational sequence about the inner portions 110, 120 and simultaneously disabling all portions after enabling all portions.

[0064]

673 The control device 100, 105 may have at least one setting for sequentially enabling the successive portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X in a rotational sequence about the inner portions 110, 120 while sequentially disabling the previously enabled portions in a rotational sequence.

677 The portion may have different activation and deactivation rates, such as equal activation and deactivation rates, or activation rates that are faster than the deactivation rates.

679 At least 2 or 3 portions may be simultaneously in the enabled state.

[0065]

683 The control device 100, 105 may have at least 1 setting in which 1 part, 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X, is intermittently enabled and disabled.

[0066]

688 For example, such settings may be associated with an indication of an error or an indication confirming that the machine 1 has acquired information, such as confirming that the user instruction has been properly acquired by the user selector.

[0067]

694 The plurality of such portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X may be enabled and disabled simultaneously.

696 For example, portions, or groups of portions, are spaced apart by other permanently enabled or disabled portions about the inner portions 110, 120.

698 Such parts, or groups of parts, are equally spaced about the inner portions 110, 120, for example.

[0068]

703 2 of such portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X may be alternately enabled and disabled.

[0069]

708 For example, 2 parts are alternately enabled and disabled.

[0070]

712 For example, such a setting may be associated with a user input by a user selector or an expectation by the machine 1 of another action by the user, for example.

[0071]

717 Such portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X may be intermittently enabled and disabled at a constant frequency.

719 For example, some portions are intermittently enabled and disabled at a constant frequency.

[0072]

723 In addition to such settings, the controller 100, 105 may have at least 1 other setting for enabling and disabling the portions 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X at a faster rate than the above settings.

[0073]

729 For example, different speeds may be used to distinguish between the execution of different types of procedures.

731 For example, execution of an activation or service (e.g., descaling) procedure may be indicated by 1 or more rotational sequences at a relatively slow speed, and a beverage preparation procedure may be indicated by 1 or more rotational sequences at a relatively fast speed.

[0074]

737 For example, different speeds may be implemented to distinguish different service procedure runs, such as different beverage preparation procedures of, for example, lungo or espresso coffee, or mild or intensive descaling procedures.

[0075]

743 In addition to the activatable and disableable portions, at least 1 portion may remain permanently activated or disabled in the above configuration or in the above further configuration.

[0076]

749 For example, a non-stop warning may be indicated by the permanently active portion, such as raw material (e.g., water) availability approaching a minimum level.

751 Another example of a non-stop alert may relate to the need to perform a service (e.g.,

descaling) process within a short time.

[0077]

756 The control device 100, 105 may have at least 1 setting, for example, at least 1 part being sequentially enabled, such as a single part 11A-11F, 11A'-11H', 21A-21G, 31A-31F, 41A-41B, 51A-51H, 51X, or a group of adjacent parts.

[0078]

762 The perimeter illuminable devices 11, 11', 21, 31, 41, 51 are generally along an elongated shape, a combination of at least one feature a, such as: a) forming a curve 11, 11', such as, for example, 1 or more circles 11, 11' (FIGS. 1, 1a, and 1x) and/or ellipses 51 (FIG. 5), or a portion thereof; b) forming a triangle 41 (FIG. 4), such as, for example, a square 31 (FIG. 3), a rectangle, a trapezoid, or a parallelogram, such as a square 31, a pentagon, a hexagon 21 (FIG. 2), a heptagon, an octagon 11' (FIG. 1x), a pentagon, a nonagon, a dodecagon, a dodecagon, or a dodecagon; c) forming a regular or irregular polygon 21, 31, 41, or a portion thereof, such as a stripe 11, 21, 31, 41, 51 (FIGS. 1, 2-5) and/or a separate element 11' (FIG. 1x), such as a separate light emitting element, disposed generally along an elongated shape, such as, for example, an LED 101' or a portion of

[0079]

775 For example, the control device 100, 105 may include a standby procedure for presenting an indication of the time required until preparation of beverage preparation by the above setting, such as a setting for sequentially enabling successive portions, for example, successive portions of a linear side-by-side configuration, in a rotation sequence about the inner portion, and optionally a setting of a type for simultaneously disabling all portions after enabling all portions, such as a setting for sequentially enabling at least 1 portion, such as a single portion or a group of adjacent portions, to indicate a standby procedure for presenting an indication of the time required until preparation of beverage preparation by the above setting, such as a setting for sequentially enabling successive portions in a rotation sequence about the inner portion and simultaneously disabling all portions after all portions are enabled, or a setting for sequentially disabling at least 1A to 11 or a setting for intermittently disabling at least 1A to 11 or a setting for sequentially disabling at least 1A to 11 or a setting for sequentially disabling at least 1A to 11 or a setting for intermittently disabling at least 1A to 11 or a setting for intermittently disabling at least 1A to 11 or a setting for selectively disabling at least 1A to 11 or a setting for intermittently disabling at least 1

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
LIMA-PCT		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/GB2021/050764	26 March 2021 (26-03-2021)	26 March 2020 (26-03-2020)
Applicant		
CHIARO TECHNOLOGY LIMITED		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language,** the international search was carried out on the basis of:
      [X] the international application in the language in which it was filed
      [ ] a translation of the international application into ..... , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [X] **Certain claims were found unsearchable** (See Box No. II)

3. [ ] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**
   a. the figure of the **drawings** to be published with the abstract is Figure No. 1
      [X] as suggested by the applicant
      [ ] as selected by this Authority, because the applicant failed to suggest a figure
      [ ] as selected by this Authority, because this figure better characterizes the invention
   b. [ ] none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2021/050764

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

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

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

2. ☒ Claims Nos.: 11-85
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

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

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

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

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

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

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

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

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2021/050764

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2016/007561 A1 (NAYA HEALTH INC [US]) 14 January 2016 (2016-01-14) paragraphs [0047] - [0070]; figures 3-7, 16-18	1-10
X	US 2018/104396 A1 (PARK CHO HEE [KR]) 19 April 2018 (2018-04-19) paragraphs [0037] - [0061]; figures 1-8	1

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 June 2021	06/07/2021

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

2

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2021/050764

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2016007561 A1	14-01-2016	AU 2015287927 A1	02-02-2017
		AU 2020202382 A1	30-04-2020
		CN 106687155 A	17-05-2017
		EP 3166657 A1	17-05-2017
		US 2020246517 A1	06-08-2020
		WO 2016007561 A1	14-01-2016
US 2018104396 A1	19-04-2018	CN 107206135 A	26-09-2017
		KR 101622768 B1	19-05-2016
		US 2018104396 A1	19-04-2018
		WO 2016186452 A1	24-11-2016

Form PCT/ISA/210 (patent family annex) (April 2005)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 11-85

The present application contains 85 claims, 14 of which are independent. There is no clear distinction between the independent claims because of their overlapping scope. In view of the (excessive) number of claims and of their formulation, the claims as a whole do not satisfy the requirements of conciseness and clarity of Art. 6 PCT. Furthermore, the application does not meet the requirements of unity of invention laid down in Rule 13.1 PCT and, prima facie, it appears to relate to 9 separate inventions.

In the present case it is particularly burdensome for a skilled person to establish the subject-matter for which protection is sought. Although all claims relate in one way or another to breast pump systems or components thereof, they define so many different aspects and details of the system and its parts that it results unduly burdensome to determine the matter for which protection is sought.

The non-compliance with the substantive provisions is to such an extent, that a meaningful search of the whole claimed subject-matter cannot be carried out (Art. 17(2) PCT and PCT Guidelines 9.30).

Furthermore, the description contains so many different embodiments that no reasonable basis can be found in the application that clearly indicates the subject-matter which might be expected to form the subject of the claims later in the procedure.

The applicant was invited by this International Searching Authority to provide informal clarification on the issue indicated above, but has not responded to this invitation within the given time limit. Therefore the search has been limited to claims 1-10 as indicated in the formal invitation for clarification.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) PCT declaration be overcome.

Electronic Patent Application Fee Transmittal

Application Number:	17181057
Filing Date:	22-Feb-2021
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Filer:	Yangbeini Wang/Jon Baitlon
Attorney Docket Number:	4944.0120006

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
RCE- 1ST REQUEST	2801	1	544	544
		Total in USD ($)		**544**

Electronic Acknowledgement Receipt	
EFS ID:	47435211
Application Number:	17181057
International Application Number:	
Confirmation Number:	4690
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	26111
Filer:	Yangbeini Wang/Kim Perry
Filer Authorized By:	Yangbeini Wang
Attorney Docket Number:	4944.0120006
Receipt Date:	26-JAN-2023
Filing Date:	22-FEB-2021
Time Stamp:	17:56:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$544
RAM confirmation Number	E20231PH56561609
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	2023-01-26-Transmittal-Form-4944-0120006.pdf	167793 8eab88c1da94fa5b396c752a49d65496883 6b2c5	no	1
Warnings:					
Information:					
2		2023-01-26-Amendment-Reply-114-4944-0120006.pdf	165348 ec793e86b9f242361253d7811783a105d42 76ea8	yes	12

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment Submitted/Entered with Filing of Continued Prosecution Application (CPA)/Request for Continued Examination(RCE)	1	1
Claims	2	6
Applicant Arguments/Remarks Made in an Amendment	7	12

Warnings:					
Information:					
3	Transmittal Letter	2023-01-26-sIDS-Pleading-4944-0120006.pdf	118197 5634749b38b0c29022d1ba8d08a19a2e95f ac853	no	2
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	2022-01-26-sIDS-Form-SB08-4944-0120006.pdf	203675 ec1b53148b4ba29e7d00efa80c774326fcb 225ff	no	4
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					

5	Request for Continued Examination (RCE)	2023-01-26-RCE-4944-0120006.PDF	1349977 433b81065eabca7431344a3cbb28c8fb230e31c4	no	3
Warnings:					
Information:					
6	Foreign Reference	FP1_JP2013545519A-4944-0120006.PDF	985411 733b34af523197e67bb578e5ba232924adce39c7	no	59
Warnings:					
Information:					
7	Foreign Reference	FP2_JP2016524490A-4944-0120006.PDF	846613 c48f7966593882f6fb35c4e14f5a827b70364e9a	no	43
Warnings:					
Information:					
8	Foreign Reference	FP3_WO2013064852A1-4944-0120006.PDF	1417100 3de7ad793b01dd9549292d9acb468550544c146b	no	148
Warnings:					
Information:					
9	Foreign Reference	FP4_JP2014532498A-4944-0120006.PDF	2524601 422967c9c33e52254ab3f30a009523003e5ad773	no	125
Warnings:					
Information:					
10	Foreign Reference	FP5_WO2016006458A1-4944-0120006.PDF	432120 a5a702fef4da6c9ac0ac4807025d4325f67aa5b9	no	36
Warnings:					
Information:					
11	Foreign Reference	FP6_JPH11178917A-4944-0120006.PDF	403589 d58a68b87c92a3048b9e734c89425c13403155a5	no	15
Warnings:					
Information:					

12	Foreign Reference	FP7_JP2000350527A-4944-0120006.PDF	511735 6a14725ef694fd7c556d6f69e87253027563bb5e	no	19
Warnings:					
Information:					
13	Foreign Reference	FP8_WO2016007561A1-4944-0120006.PDF	752974 c19726eb92c8598893266af5a3de342850226d7d	no	44
Warnings:					
Information:					
14	Foreign Reference	FP9_WO2016025405A1-4944-0120006.PDF	808719 4462946e981bddb5cab26008cc9e451236e02323	no	41
Warnings:					
Information:					
15	Foreign Reference	FP10_WO2004108184A2-4944-0120006.PDF	1650019 7821a8c9b8e0ce59bc167dc20b17b9a7ee315fea	no	58
Warnings:					
Information:					
16	Foreign Reference	FP11_JP2016526396A-4944-0120006.PDF	437026 b2c5d4292a1e7596dc75f4855ac6c0f938e6a03d	no	38
Warnings:					
Information:					
17	Foreign Reference	FP12_WO2014160614A1-4944-0120006.PDF	499411 0dea128c97e27bf073109128ad2ebe10898a21c8	no	34
Warnings:					
Information:					
18	Foreign Reference	FP13_JP2017503552A-4944-0120006.PDF	562118 f693f414124512e7a5aef6e2b3074332f7942c8c	no	45
Warnings:					
Information:					

19	Non Patent Literature	NPL1_ISR-4944-0120006.PDF	63565 cc12cc9b97dcb3ae51dade8d1b875bed8631dc19	no	5
Warnings:					
Information:					
20	Non Patent Literature	NPL2_JPSR-4944-0120006.PDF	311182 62560011fd8730f154e63e8fc5f2cd0d3909ed9a	no	20
Warnings:					
Information:					
21	Non Patent Literature	NPL3_EESR-4944-0120006.PDF	381670 e5873042c412e45b83ff6fbdbdaa359396b51381	no	26
Warnings:					
Information:					
22	Fee Worksheet (SB06)	fee-info.pdf	37660 2b259eeefb80a04992925106b5b8cb13c536d12	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	14630503		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
Approved for use through 12/31/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDRICKSON, Courtney B.
Attorney Docket Number	4944.0120006

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
- ☑ Fee Attached
- ☑ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☑ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

Request for Continued Examination Transmittal (PTO/SB/30EFS); FP1-FP13 and NPL1-3.

Remarks

Online Credit Card Authorization for $544.00 to cover the RCE Fee (1st request).

The Office may charge any fee deficiency for any submission made with this transmittal to Deposit Account 19-0036.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Richard D. Coller III/		
Printed name	Richard D. Coller III		
Date	January 26, 2023	Reg. No.	60,390

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: O'TOOLE et al.	Confirmation No.: 4690
Applicant: Chiaro Technology Limited	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, Courtney B.
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Amendment and Reply Under 37 C.F.R. § 1.114

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313–1450

Mail Stop RCE

Commissioner:

In reply to the Office Action dated October 26, 2022, Applicant submits the following amendment and remarks.

If extensions of time are necessary to prevent abandonment of this application, then they are petitioned for under 37 C.F.R. § 1.136(a). Any additional fees required to continue prosecution or appeal of this application (including issue fee, fees for net addition of claims or forwarding to appeal) are hereby authorized to be charged to our Deposit Account No. 19–0036.

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently amended) A breast pump device comprising:

~~a self-contained, in-bra wearable device comprising:~~

a housing comprising:

a battery, and

a pump configured to generate negative air pressure;

a breast shield of a plurality of interchangeable breast shields, each of the plurality of interchangeable breast shields having a different size and being configured to slide in and out of the housing, the breast shield comprising a breast flange and a nipple tunnel comprising a side wall and a front end, and a guide line, wherein the breast shield is transparent or optically clear; and

a milk container configured to be attached to and removed from the housing,

wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast, and

wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel.

2. (Canceled)

3. (Previously presented) The breast pump device of claim 1, wherein the breast shield is rigid.

4. (Previously presented) The breast pump device of claim 1, wherein the breast shield is a dishwasher safe, plastic breast shield.

5. (Previously presented) The breast pump device of claim 1, wherein the breast shield is configured to be attached using magnets to the housing.

6. (Previously presented) The breast pump device of claim 1, wherein the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast.

7. (Previously presented) The breast pump device of claim 1, wherein the breast shield is configured to present, in use, a single continuous surface to a nipple and a breast.

8. (Previously presented) The breast pump device of claim 1, wherein the breast flange and the nipple tunnel are integrally formed.

9. (Previously presented) The breast pump device of claim 1, wherein the breast shield is configured to be generally symmetrical about a center-line running from a top to a bottom of the breast shield when positioned upright for normal use.

10. (Previously presented) The breast pump device of claim 1, wherein the breast shield is configured to slide into the housing with a single push action.

11. (Previously presented) The breast pump device of claim 1, wherein the breast shield is configured to slide out from the housing, together with a membrane that is configured to prevent milk from flowing into the pump.

12. (Previously presented) The breast pump device of claim 1, wherein the milk container is rigid.

13. (Previously presented) The breast pump device of claim 1, wherein the milk container is an optically clear, dishwasher safe, plastic milk container.

14. (Previously presented) The breast pump device of claim 1, wherein the milk container is configured to attach to a lower part of the housing and forms a base of the breast pump device.

15. (Previously presented) The breast pump device of claim 1, wherein the milk container is configured to magnetically attach to the housing.

16. (Currently amended) The breast pump device of claim 1, wherein the ~~nipple tunnel comprises~~ guide line[[s]] is configured to run[[ning]] parallel along one or more sides of the nipple tunnel.

17. (Previously presented) The breast pump device of claim 1, wherein the nipple tunnel comprises an air hole or passage, and wherein the pump is configured to transfer negative air pressure into the nipple tunnel via the air hole or passage.

18. (Previously presented) The breast pump device of claim 1, wherein the nipple tunnel comprises on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container.

19. (Previously presented) The breast pump device of claim 1, wherein the pump comprises one or more piezo air pumps.

20. (Previously presented) The breast pump device of claim 1, wherein the housing further comprises a Universal Serial Bus (USB) charging socket.

21. (Previously presented) The breast pump device of claim 1, wherein the housing comprises a left or right breast selector or toggle switch that, when selected for a particular pumping session, is configured to send data to a connected application configured to track pumping sessions, to indicate whether that particular session is associated with a left or a right breast.

22. (Previously presented) The breast pump device of claim 1, wherein the housing is configured to be shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra.

23. (Canceled)

24. (Previously presented) The breast pump device of claim 1, wherein the breast pump device is configured to deliver a maximum suction of approximately 240 mmHg.

25. (Previously presented) The breast pump device of claim 1, wherein the breast pump device comprises a sensor that is configured to directly measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container.

26. (Canceled)

27. (Canceled)

28. (Previously presented) The breast pump device of claim 1, wherein the pump is configured to deliver in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

29. (Previously presented) The breast pump device of claim 1, wherein the pump is a lightweight air pump that enables a total mass of the breast pump device, unfilled with milk, to be less than 250 gm.

30. (Previously presented) The breast pump device of claim 1, wherein the breast pump device is configured to make less than 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

31. (Previously presented) A kit, comprising:

the breast pump device of claim 1; and

the plurality of interchangeable breast shields.

32. (Previously presented) The kit of claim 31, wherein each of the plurality of interchangeable breast shields comprises fit lines in a nipple tunnel of that breast shield that are configured to

enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel.

33. (Previously presented) The breast pump device of claim 1, wherein the battery is a rechargeable battery, and wherein the housing further comprises:

a power charging circuit configured to control the charging of the rechargeable battery, and

control electronics configured to be powered by the rechargeable battery.

34. (Currently amended) The breast pump device of claim 1, wherein a length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same.

Remarks

Upon entry of the foregoing amendment claims 1, 3–22, 24–25, and 28–34 are pending in the application. Claim 1 is an independent claim. Claims 1, 16, and 34 are amended. Claim 2 is canceled without prejudice or disclaimer. These changes do not introduce any new matter, and Applicant respectfully requests their entry.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Office reconsider and withdraw all outstanding objections and rejections.

Allowable Subject Matter

The Office indicates claim 28 is allowable over the prior art of record excepting the double patenting rejection of the same. (Office Action dated October 26, 2022, p. 42.) Applicant appreciates the Office's indication that claim 28 would be allowable if the double patenting rejection of the same is overcome. (*Id.*) For at least the reasons discussed below, all pending claims are allowable over the cited art.

Claim Objection

The Office objects to claim 34 for an alleged informality. (*Id.*, 2.) Without acquiescing to the propriety of the objection and solely to expedite prosecution, claim 34 is amended.

Applicant asks the Office to withdraw the objection to claim 34.

Rejections under 35 U.S.C. § 103

Independent Claim 1 (Myers, Cook)

The Office rejects claims 1, 3, 6–8, 10–11, 14, 16–18, 22, 24, 31, and 34 under 35 U.S.C. § 103 as allegedly obvious over U.S. Publication No. 2008/0275386 to Myers in view of EP Publication No. 2502640 to Cook *et al.* (*Id.*, 3.)

Without acquiescing to the propriety of the objection and solely to expedite prosecution, claim 1 is amended to recite, in part, "a breast shield of a plurality of interchangeable breast shields … the breast shield comprising … a guide line … wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast,

wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel."

The Office acknowledges that Myers does not teach or disclose "the breast shield being of a plurality of interchangeable breast shields," "the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast." (*Id.*, 4–5.) Instead, the Office relies on Cook. (*Id.*, 5 (citing Cook, ¶ [0042], FIGS. 1A, 1B, refs. 9, 10, 11, 12).) However, both Myers and Cook fail to disclose or suggest at least the claimed guide line of the breast shield "configured to define the spacing of the nipple from the side wall of the nipple tunnel." (*See* Cook, ¶¶ [0042], [0044], FIGS. 2A, 2B.) Cook fails to disclose or suggest how, if at all, the dimensions of its varied diameters of apertures 10, 12 are communicated to a user. (*See id.*)

Accordingly, Myers and Cook, alone or in combination, fail to disclose or suggest these claimed features.

Applicant asks the Office to withdraw the § 103 rejections of claims 1, 3, 6–8, 10–11, 14, 16–18, 22, 24, 31, and 34.

Independent Claim 1 (Khalil, Myers, Cook)

The Office rejects claims 1, 6–10, 14, 17–18, 22, 31, and 34 under 35 U.S.C. § 103 as allegedly obvious over U.S. Publication No. 2013/0023821 to Khalil *et al.* in view of Myers and Cook.[1] (Office Action dated October 26, 2022, p. 8.)

As discussed above, claim 1 recites, in part, "a breast shield of a plurality of interchangeable breast shields … the breast shield comprising … a guide line … wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast, wherein the guide line is configured to define the spacing of the nipple from the side wall of the nipple tunnel."

The Office acknowledges that Khalil does not teach or disclose the breast shield "being of a plurality of interchangeable breast shields each having a different size, the plurality of

[1] The Office refers to claims 20-21 in this rejection. (*Id.*) However, the rejections of these claims over Khalil, Myers, and Cook are not explained. Applicant believes these claims were referred to in this rejection by mistake and responds accordingly.

interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast." (*Id.*, 9–10.) The Office relies on Cook to remedy this deficiency in Khalil. (*Id.*, 10 (citing Cook, ¶ [0042], FIGS. 1A, 1B, refs. 9, 10, 11, 12).) But Cook fails to disclose or suggest at least the claimed guide line of the breast shield "configured to define the spacing of the nipple from the side wall of the nipple tunnel," as discussed above. (*See* Cook, ¶¶ [0042], [0044], FIGS. 2A, 2B.) Khalil and Myers are also deficient.

Accordingly, Khalil, Myers, and Cook, alone or in combination, fail to disclose or suggest these claimed features.

Applicant asks the Office to withdraw the § 103 rejections of claims 1, 6–10, 14, 17–18, 22, 31, and 34.

Remaining Claims

The Office rejects claim 4 under 35 U.S.C. § 103 as allegedly obvious over Myers in view of Cook, in view of U.S. Publication No. 2016/0296682 to Phillips *et al.*, and U.S. Publication No. 2005/0228342 to Yuen. (*Id.*, 8.) Claim 4 depends from and adds features to independent claim 1. Phillips and Yuen do not overcome the deficiencies discussed above. Accordingly, claim 4 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 4.

The Office rejects claim 5 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and U.S. Publication No. 2018/0333523 to Chang *et al.* (*Id.*, 13.) Claim 5 depends from and adds features to independent claim 1. Chang does not overcome the deficiencies discussed above. Accordingly, claim 5 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 5.

The Office rejects claims 12–13 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and Phillips. (*Id.*, 14.) Claims 12–13 depend from and add features to independent claim 1. Phillips does not overcome the deficiencies discussed above. Accordingly, claims 12–13 are allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claims 12–13.

The Office rejects claim 15 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and U.S. Publication No. 2007/0228059 to Karsan. (*Id.*, 15.) Claim 15 depends

from and adds features to independent claim 1. Karsan does not overcome the deficiencies discussed above. Accordingly, claim 15 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 15.

The Office rejects claim 19 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and U.S. Publication No. 2012/0277636 to Blondheim *et al.* (*Id.*, 16.) Claim 19 depends from and adds features to independent claim 1. Blondheim does not overcome the deficiencies discussed above. Accordingly, claim 19 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 19.

The Office rejects claims 20–21 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and U.S. Publication No. 2014/0378895 to Barack.[2] (*Id.*, 17.) Claims 20–21 depend from and add features to independent claim 1. Barack does not overcome the deficiencies discussed above. Accordingly, claims 20–21 are allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claims 20–21.

The Office rejects claim 25 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and U.S. Publication No. 2016/0220743 to Guthrie *et al.* (*Id.*, 18.) Claim 25 depends from and adds features to independent claim 1. Guthrie does not overcome the deficiencies discussed above. Accordingly, claim 25 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 25.

The Office rejects claim 29 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and U.S. Patent No. 6,227,936 to Mendoza. (*Id.*, 19.) Claim 29 depends from and adds features to independent claim 1. Mendoza does not overcome the deficiencies discussed above. Accordingly, claim 29 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 29.

The Office rejects claim 30 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and U.S. Publication No. 2009/0281485 to Baker *et al.* (*Id.*, 20.) Claim 30 depends from and adds features to independent claim 1. Baker does not overcome the deficiencies discussed

[2] The Office Action appears to refer to the Barack publication as "Barak." (*Id.*) Applicant refers to this publication as "Barack" herein.

above. Accordingly, claim 30 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 30.

The Office rejects claim 32 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and U.S. Publication No. 2012/0165729 to Cudworth. (*Id.*) Claim 32 depends from and adds features to independent claim 1. Cudworth does not overcome the deficiencies discussed above. Accordingly, claim 32 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 32.

The Office rejects claim 33 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers, Cook, and U.S. Patent No. 5,542,921 to Meyers *et al.* (*Id.*, 21.) Claim 33 depends from and adds features to independent claim 1. Meyers does not overcome the deficiencies discussed above. Accordingly, claim 33 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 33.

Double Patenting Rejection

The Office rejects claims 1, 3–22, 24–25, and 29–34 on the grounds of non-statutory obviousness type double patenting as allegedly obvious over claim 1 of U.S. Patent No. 10,881,766 in view of Myers, Cook, Philips, Chang, Khalil, Karsan, Blondheim, Barack, Guthrie, Mendoza, Baker, Cudworth, and Meyers. (*Id.*, 23–27.) The Office rejects claims 1, 3–22, 24–25, and 28–34 on the grounds of non-statutory obviousness type double patenting as allegedly obvious over claim 1 of U.S. Patent No. 10,926,011 in view of Khalil, Myers, Cook, Philips, Chang, Khalil, Karsan, Blondheim, Barack, Guthrie, Mendoza, Baker, Cudworth, and Meyers. (*Id.*, 27–31.) The Office rejects claims 1, 3–22, 24–25, and 29–34 on the grounds of non-statutory obviousness type double patenting as obvious over claim 1 of U.S. Patent Nos. 11,357,893, 11,376,352. 11,357,894, 11,324,866, and 11,413,380, in view of Khalil, Myers, Cook, Philips, Chang, Khalil, Karsan, Blondheim, Barack, Guthrie, Mendoza, Baker, Cudworth, and Meyers. (*Id.*, 31–35.) The Office rejects claims 1, 3–22, 24–25, and 28–34 on the grounds of non-statutory obviousness type double patenting as allegedly obvious over claim 1 of U.S. Patent Nos. 11,260,151 and 11,311,654 in view of Khalil, Myers, Cook, Philips, Chang, Khalil, Karsan, Blondheim, Barack, Guthrie, Mendoza, Baker, Cudworth, and Meyers. (*Id.*, 35–38.) The Office rejects claims 1, 3–22, 24–25, and 29–34 are rejected on the grounds of non-statutory obviousness type double patenting as obvious over claims of U.S. Application Nos. 17/203,150, 17/203,179, 17/203,292, 17/203,355, 17/203,384,

17/203,397, and 17/203,418 in view of Khalil, Myers, Cook, Philips, Chang, Khalil, Karsan, Blondheim, Barack, Guthrie, Mendoza, Baker, Cudworth, and Meyers. (*Id.*, 38–42.)

Applicant respectfully requests that the remaining currently asserted double patenting rejections be held in abeyance until the claimed subject matter is otherwise deemed allowable. After analyzing the final allowed claim scope, Applicant will consider filing a terminal disclaimer if necessary to overcome any obviousness-type double patenting rejections.

Conclusion

All grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Office reconsider and withdraw them. A complete reply has been made to the outstanding Office Action. As such, the present application is in condition for allowance. If the Office believes, for any reason, that personal communication will expedite prosecution of this application, the Office is invited to telephone the undersigned at the number provided. Applicant respectfully requests prompt and favorable consideration of this amendment and reply.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Richard D. Coller III
Attorney for Applicant
Registration No. 60,390

Date: January 26, 2023

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: Chiaro Technology Limited	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, Courtney B.
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Supplemental Information Disclosure Statement

Mail Stop RCE

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

Listed on accompanying IDS Forms PTO/SB/08a or its equivalent and PTO/SB/08b or its equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Applicant has listed dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) and is being filed within three months of the date of filing of a national application other than a continued prosecution application (CPA), OR within three months of the date of entry of the national stage as

set forth in 37 C.F.R. § 1.491 in an international application, OR before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

Copies of documents **FP1-FP13** and **NPL1-NPL3** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2)(ii), no copies of the U.S. patents and patent application publications cited on the attached IDS Forms are submitted.

It is expected that the examiner will review the prosecution and cited art in the parent Application No. 16/009,547, filed June 15, 2018 (now U.S. Patent No. 10,926,022), in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/181,057	Filing Date 02/22/2021	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $240 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	01/26/2023	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 30	Minus	** 30	= 0		x $40 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $192 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/NICOLE L NICHOLSON/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006	4690

26111 7590 10/26/2022
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
FREDRICKSON, COURTNEY B	

ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
10/26/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

e-office@sternekessler.com

Office Action Summary	Application No. 17/181,057	Applicant(s) O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	Art Unit 3783	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 27July2022.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1,3-22,24-25 and 28-34 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1,3-22,24-25 and 28-34 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 22February2021 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☑ All b)☐ Some** c)☐ None of the:

1.☑ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

The information disclosure statement (IDS) submitted is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Amendment

This office action is responsive to the amendment filed on July 12, 2022. As directed by the amendment: claims 1, 3-22, 24, 25, and 28-33 have been amended, claim 2 has been cancelled, and claim 34 has been added. Thus, claims 1, 3-22, 24, 25, and 28-34 are presently pending in this application.

Response to Arguments

Applicant's arguments, see pg. 8, filed July 12, 2022, with respect to the rejection(s) of claim(s) 1 under 35 U.S.C 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Applicant's amendments.

Claim Objections

Claim 34 is objected to because of the following informalities: it is recommended to amend the claim in line 1 to recite "a length" to correct for grammar. Appropriate correction is required.

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

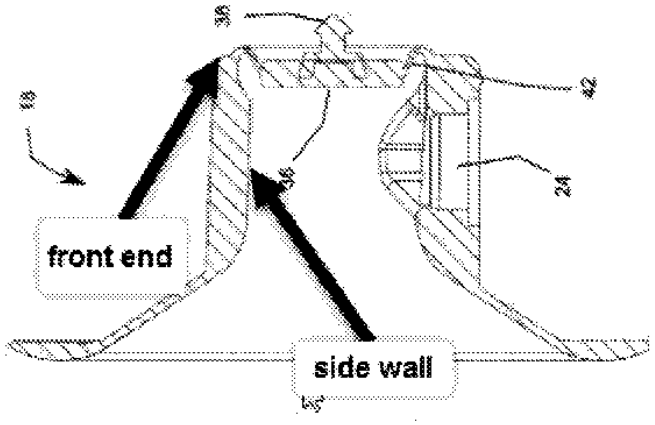
Claims 1, 3, 6-8, 10, 11, 14, 16-18, 22, 24, 31, and 34 is/are rejected under 35 U.S.C. 103 as being unpatentable over Myers (US 20080275386) and in further view of Cook (EP 2502640).

Regarding claim 1, Myers discloses a breast pump device comprising:

a self-contained, in-bra wearable device (breast pump 10 in fig. 1), comprising:

(i) a housing (outer housing 16 in fig. 1) comprising (a) a battery (AA battery 51 in fig. 10), and (b) a pump configured to generate negative air pressure (motor 54 in fig. 10);

(ii) a breast shield (breast cup 16 in fig. 1) being configured to slide in and out of the housing (paragraph 58 discloses that the cup "clicks" into place within the housing; paragraph 42 discloses the breast cup being removable), the breast shield comprising a breast flange (outer flange area 50 in fig. 5) and a nipple tunnel (nipple tunnel 46 in fig. 5) comprising a side wall and a front end (see below), in which the breast shield is transparent or optically clear (paragraph 65); and

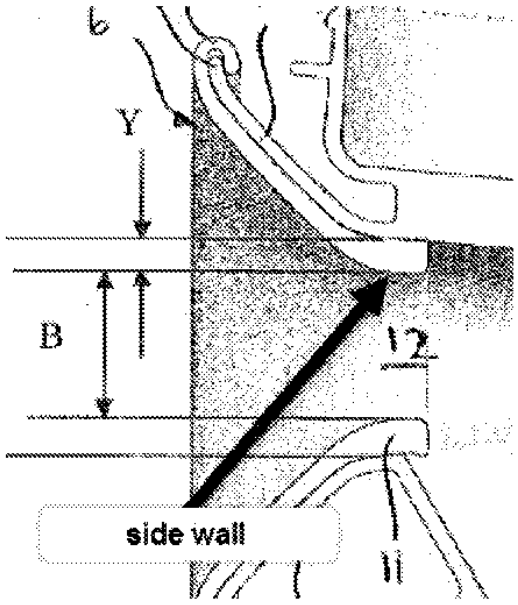


(iii) a milk container that is configured to be attached to and removed from the housing (collection bag 28 is shown to be operatively attached to the housing and is physically engaged to the bottom portion of the housing).

However, Myers does not teach or disclose the breast shield being of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a

nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see below) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple).



Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a

nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Regarding claim 3, in the modified device of Myers, Myers discloses the breast shield is rigid (paragraph 47 discloses the nipple tunnel, which is part of the breast shield, is rigid).

Regarding claim 6, in the modified device of Myers, Myers discloses the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast (the shield of Myers is functionally capable of being rotated smoothly around a nipple since the claim does not require that the shield be fully latched onto the nipple for this rotation to occur).

Regarding claim 7, in the modified device of Myers, Myers discloses the breast shield presents, in use, a single continuous surface to a nipple and a breast (fig. 9A/B shows a singular inner surface which would extend from the nipple to the breast).

Regarding claim 8, in the modified device of Myers, Myers discloses the breast shield integrates the breast flange and the nipple tunnel as a single item (fig. 5 shows a singular item).

Regarding claim 10, in the modified device of Myers, Myers discloses the breast shield is configured to slide into the housing with a single push action (paragraph 58 discloses the shield can click into place).

Regarding claim 11, in the modified device of Myers, Myers discloses the breast shield is configured to slide out from the housing, together with a membrane that prevents milk from flowing into the pump (flange top 36 in fig. 9A).

Regarding claim 14, in the modified device of Myers, Myers discloses milk container attaches to a lower part of the housing (fig. 1 shows a part of the collection bag attached to the bottom part of the housing 16) and forms a base of the breast pump device (fig. 1).

Regarding claim 16, in the modified device of Myers, Myers discloses the nipple tunnel includes guide lines running parallel along one or more sides of the nipple tunnel (detent tabs 52a/b in fig. 15 are shown to be extending in a parallel to the width direction of the nipple tunnel sides).

Regarding claim 17, in the modified device of Myers, Myers discloses the nipple tunnel includes an air hole or passage (24 in fig. 9A), and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage (paragraph 52).

Regarding claim 18, in the modified device of Myers, Myers discloses the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container (outlet 24 in fig. 9A).

Regarding claim 22, in the modified device of Myers, Myers discloses the housing is shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra (fig. 1; paragraph 40).

Regarding claim 24, in the modified device of Myers, Myers discloses the breast pump device is configured to deliver a maximum suction of approximately 240 mmHg (paragraph 72).

Regarding claim 31, modified Myers teaches a kit comprising the breast pump device of claim 1 (see discussion above); and the plurality of interchangeable breast shields (fig. 2a/b of Cook).

Regarding claim 34, in the modified device of Myers, Cook discloses length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same (paragraph 43).

Claim 4 is/are rejected under 35 U.S.C. 103 as being unpatentable over Myers in view of Cook, as applied to claim 1 above, and further in view of Phillips (US 20160296682), as evidenced by Yuen (US 20050228342).

Regarding claim 4, modified Myers teaches all of the claimed limitations set forth in claim 1, as discussed above. Myers further teaches the breast shield is made from plastic (paragraph 40 discloses the breast cup being made from silicone, which is a type of plastic, as evidenced by Yuen in paragraph 24). However, modified Myers does not teach or disclose breast shield is dishwasher safe.

Phillips teaches a breast pump device (fig. 1) comprising a breast shield (110 in fig. 1). Phillips further teaches that the shield can be washed in a dishwasher (paragraph 60). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield of modified Myers to be dishwasher safe for the purpose of enabling the shield to be cleaned in the dishwasher for reuse, as taught by Phillips (paragraph 60).

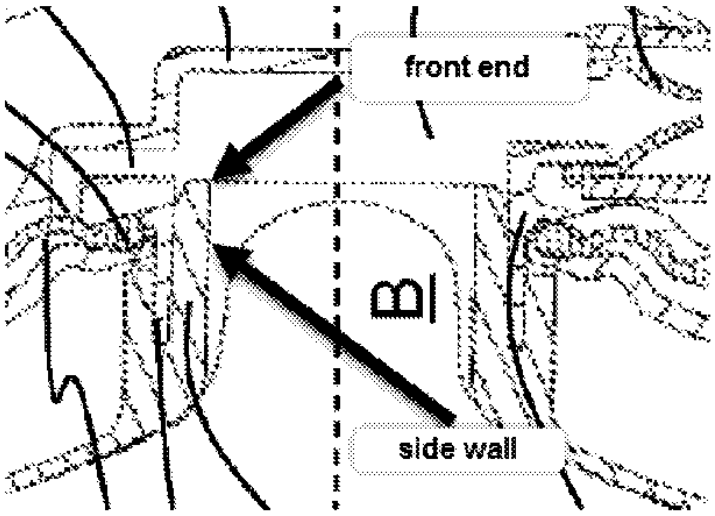
Claims 1, 6-10, 14, 17, 18, 20-22, 31, and 34 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil (US 20130023821) in view of Myers (US 20080275386) and in further view of Cook.

Regarding claim 1, Khalil discloses a breast pump device comprising:

a self-contained, in-bra wearable device (figs. 9-11), comprising:

(i) a housing (6' and 6" form a housing as shown in fig. 9) that includes (a) a power source (paragraph 32 discloses the power source integrated into the housing), and (b) a pump generating negative air pressure (vacuum pump 81 in fig. 10);

(ii) a breast shield (breast interface 1 in fig. 11) being configured to slide in and out of the housing (breast interface 1 is configured to slide in/out from the housing by attaching/detaching the lip 11 to the flange 62 of the housing as shown in fig. 4), the breast shield made up of a breast flange (base part 12 in fig. 4) and a nipple tunnel (stub 10 in fig. 4) comprising a side wall and a front end (see below); and



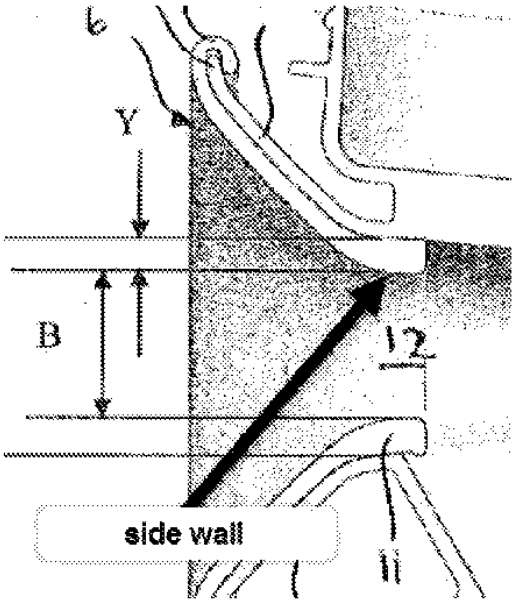
(iii) a milk container that is configured to be attached to and removed from the housing (milk collection container 7' in fig. 11; paragraph 69 discloses the container being releasably connected to the housing part 6').

However, Khalil does not teach or disclose the power source being a battery and the breast shield being transparent or optically clear and being of a plurality of

interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast.

Myers teaches a similar breast pump system (fig. 1) having a housing (outer housing 16 in fig. 1) which comprises a battery (battery 52 in fig. 10) and a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing to include a battery, as taught by Myers, for the purpose of providing power to the device and to have made the breast shield transparent to enable a user to view the condition of a nipple (paragraph 65).

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see below) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple).



Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

Regarding claim 6, in the modified device of Khalil, Khalil discloses the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast (the shield of Khalil is functionally capable of being rotated smoothly around a nipple since the claim does not require that the shield be fully latched onto the nipple for this rotation to occur).

Regarding claim 7, in the modified device of Khalil, Khalil discloses the breast shield presents, in use, a single continuous surface to a nipple and a breast (fig. 11).

Regarding claim 8, in the modified device of Khalil, Khalil discloses the breast shield integrates the breast flange and the nipple tunnel as a single item (fig. 11).

Regarding claim 9, in the modified device of Khalil, Khalil discloses the breast shield is generally symmetrical about a centre-line running from a top to a bottom of the breast shield when positioned upright for normal use (fig. 11).

Regarding claim 10, in the modified device of Khalil, Khalil discloses the breast shield is configured to slide into the housing with a single push action (the shield of Khalil is functionally capable of being pushed into the housing so that the nipple tunnel is located in the housing).

Regarding claim 14, in the modified device of Khalil, Khalil discloses milk container attaches to a lower part of the housing and forms a base of the breast pump device (fig. 9).

Regarding claim 17, in the modified device of Khalil, Khalil discloses the nipple tunnel includes an air hole or passage (opening 13 in fig. 3), and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage (figs. 4 and 5).

Regarding claim 18, in the modified device of Khalil, Khalil discloses the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container (opening 13 in fig. 3 is considered to be on a "lower" surface of the nipple tunnel since "lower" is not further defined; see fig. 5).

Regarding claim 22, in the modified device of Khalil, Khalil discloses the housing is shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra (fig. 9).

Regarding claim 31, modified Khalil teaches a kit comprising the breast pump device of claim 1 (see discussion above); and the plurality of interchangeable breast shields (fig. 2a/b of Cook).

Regarding claim 34, in the modified device of Khalil, Cook discloses length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same (paragraph 43).

Claim 5 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 1 above, and further in view of Chang (US 20180333523).

Regarding claim 5, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast shield is configured to attach using magnets to the housing.

Chang teaches a substantially similar self-contained breast pump system (breast pump system 10 in fig. 1A) having a breast shield (flange 14 in fig. 1A) attached to a housing (housing 12 in fig. 1A) and configured to attach to the housing using one or more magnets (paragraph 108 discloses the shield uses magnets 118 attached to the shield to determine if the shield is properly attached to the housing). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield of modified Khalil to be configured to attach using magnets to the housing since Chang teaches this configuration provides a safeguard

such that the system will not operate unless all components are fully connected (paragraph 108).

Claims 12 and 13 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 1 above, and further in view of Phillips (US 20160296682).

Regarding claim 12, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Although it appears based on fig. 11 of Khalil that the container would be rigid, modified Khalil does not explicitly teach or disclose this limitation.

Phillips teaches a breast pump system (fig. 1) comprising a milk collection container ("collection container" 120 in fig. 1) which is substantially rigid (paragraph 57 discloses the container being made from Tritan; pg. 21 of Applicant's specification discloses that Tritan is a polycarbonate material, which is a known rigid material). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the container of modified Khalil to be made of Tritan for the purpose of enabling the container to maintain its strength when a vacuum is applied, as taught by Phillips (paragraph 57).

Regarding claim 13, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses the milk container is an optically clear, plastic container (paragraph 69 discloses the container is made of plastic like cover 6" and is transparent in its entirety). However, Khalil does not explicitly teach or disclose the milk container is dishwasher safe.

Phillips teaches a breast pump system (fig. 1) comprising a milk collection container ("collection container" 120 in fig. 1) which is dishwasher safe (paragraph 57 discloses the container being made from Tritan; pg. 21, lines 13-18 of Applicant's specification discloses that Tritan a dishwasher safe material). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the container of modified Khalil to be made of Tritan for the purpose of enabling the container to maintain its strength when a vacuum is applied, as taught by Phillips (paragraph 57).

Claim 15 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 1 above, and further in view of Karsan (US 20070228059).

Regarding claim 15, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the milk container is configured to magnetically attach to the housing.

Khalil teaches that the milk container latches to the housing by a locking lug (paragraph 69 discloses a locking lug formed on the container latches engages into a corresponding recess). Karsan teaches a container (1 in fig. 1) having a case (2 in fig. 3) and a base (fig. 3) which are releasably held together (paragraph 51 discloses the connection being releasable) via a latch mechanism (5 and 6 in fig. 3). Karsan further teaches that the latching mechanism is embodied as a lug and recess (5 and 6, respectively in fig. 3; paragraph 65) but may alternatively be embodied as a magnetic means so that the two components may be magnetically latched (paragraph 65).

In Applicant's invention, Applicant uses the magnets to removably secure the milk container to the housing. Thus, Karsan is reasonably pertinent to the problem faced by the inventor since Karsan teaches using magnets as a removable latching connection between two components. As Karsan teaches that the magnetic means (paragraph 65) are functional equivalents to a locking lug and recess (paragraph 65), it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have substituted the locking lug/recess configuration of Khalil with the magnetic means, as taught by Karsan. The substitution would have resulted in providing an equivalent secure attachment of the milk container to the housing.

Claim 19 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 1 above, and further in view of Blondheim (US 20120277636).

Regarding claim 19, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the pump comprises one or more piezo air pumps.

Blondheim is directed towards a breast pump device (fig. 1) which comprises an air pump (66 in fig. 6). Blondheim further teaches that the air pump can be a piezoelectric pump (paragraph 36). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the pump of modified Khalil to be a piezoelectric pump, as taught by Blondheim for the purpose of rendering the pump small in size (paragraph 36).

Claims 20 and 21 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 1 above, and further in view of Barak (US 20140378895).

Regarding claim 20, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the housing further includes a Universal Serial Bus (USB) charging socket.

Barack is directed towards a breast pump device (fig. 1) which comprises a housing which houses a pump (fig. 1 shows a pump 20 which would necessarily have some sort of housing since it is disclosed to have a USB port and a user interface). Barack further teaches a USB charging socket (USB port 34 in fig. 1; paragraph 45). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing of modified Khalil to include the USB charging socket, as taught by Khalil, for the purpose of enabling the device to interface with an external memory (paragraph 45).

Regarding claim 21, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the housing includes a left or right breast selector or toggle switch, that, when selected for a particular pumping session, sends data to a connected application configured to track pumping sessions, to indicate whether that particular session is associated with a left or a right breast.

Barack teaches a breast pump device (fig. 1) which has a control electronics (controller 22 in fig. 1) and a control interface (user interface 30 in fig. 1) that is user selectable to indicate or record if milk is being expressed from the left or right breast

(paragraph 43) and that, when selected for a particular pumping session, sends data to a connected application, running on a device, such as a smartphone, that tracks pumping sessions, to indicate whether that session is associated with the left or the right breast (paragraph 46 discloses transmitting via transceiver the parameters that have been entered at the user interface 30 to a remove device; paragraph 43 discloses that one parameter entered at the user interface is which breast is selected).

Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing of modified Khalil to include a left or right breast selector or toggle switch, that, when selected for a particular pumping session, sends data to a connected application configured to track pumping sessions, to indicate whether that particular session is associated with a left or a right breast, as taught by Barack. This modification would enable a user to track which parameters are best suited for each breast to optimize pumping, as taught by Barack (paragraphs 8 and 43).

Claim 25 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 1 above, and further in view of Guthrie (US 20160220743).

Regarding claim 25, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast pump device includes a sensor that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container.

Guthrie is directed towards a breast pump device comprising a sensor (detector 607 in fig. 6B) that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container (paragraph 63 discloses that the emitter 606 and the detector 607 operate to detect light reflecting off the opaque surface of the milk). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the device to include a sensor that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container, as taught by Guthrie, for the purpose of measuring volume of milk pumped (paragraph 54).

Claim 29 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 1 above, and further in view of Mendoza (US 6227936).

Regarding claim 29, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the pump is a lightweight air pump that enables the total mass of the breast pump system, unfilled with milk, to be less than 250gm.

Mendoza teaches a bra which is designed to support a breast pump to allow the mother's hands to remain free (1:8-12). Mendoza further discloses that the bra must be able to support up to 8 ounces when the pump is full (1:58-62). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed

invention to have modified the system of modified Khalil to be a lightweight air pump that enables the total weight of the system, unfilled with milk, to be less than 250gm, as taught by Mendoza since Mendoza teaches that a lightweight system is crucial for enabling the system to be supported by a bra.

Claim 30 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 1 above, in further view of Baker (US 20090281485).

Regarding claim 30, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast pump device makes less than 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

Baker is directed towards a device for removing fluid from a body (fig. 6) using a vacuum pump embodied as a motor (motor 9 in fig. 6; paragraph 243). Baker further teaches that the device makes less than 20 decibel of noise at full power (paragraph 121) by sound proofing the walls of the housing and by adding a counter balance to the motor (paragraph 144). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the device of modified Khalil to have the device make less than 20 dB of noise during maximum power for the purpose of making the device for discrete and comfortable for the user and others around the user.

Claim 32 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 31 above, in further view of Cudworth (US 20120165729).

Regarding claim 32, modified Khalil teaches all of the claimed limitations set forth in claim 31, as discussed above, but does not teach or disclose each of the plurality of interchangeable breast shields includes fit lines in a nipple tunnel of that breast shield that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel.

Cudworth teaches a breast pump system (fig. 1) having a shield (attachment 1) having a flange (cup 2 in fig. 2) and a nipple tunnel (cylindrical portion 3 in fig. 1). Cudworth further teaches the nipple tunnel includes fit lines in a nipple tunnel of that breast shield that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel (grooves 12 in fig. 1 are functionally capable of serving as "fit lines" to assist a user in determining if the breast shield is correctly sized and since the claimed fit lines are not further structurally defined). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of Khalil to include the claimed fit lines, as taught by Cudworth, for the purpose of providing a massaging pressure on the breast to help stimulate milk production (paragraph 30).

Claim 33 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Cook, as applied to claim 1 above, in further view of Meyers (US 5542921).

Regarding claim 33, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further teaches control electronics ("control

elements and a display" in paragraph 51) which would be powered by the battery (the power source of Khalil is understood to power the device).

However, Khalil does not teach or disclose the battery to be rechargeable and the housing further including a power charging circuit for controlling the charging of the rechargeable battery.

Meyers is directed to a breast pump device (fig. 1) comprising a battery configured to be recharged (9:50-52 discloses recharging the batteries) and a power charging circuit for controlling the charging of the rechargeable battery ("circuit" in 9:50-52). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the battery of modified Khalil to be rechargeable and to have incorporated a power charging circuit for controlling the charging of the rechargeable battery, as taught by Meyers to enable the batteries to be reused.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1, 3-22, 24, 25, 29-34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10881766 in view of Myers, Cook, and the teachings below (see table).

Regarding claim 1, claim 1 of the issued patent claims all of the limitations in instant claim 1 except claim 1 does not claim a self-contained device, the housing having a battery, the breast shield having a breast flange and nipple tunnel and being optically clear or transparent and being a part of a plurality of breast shields, wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast.

Khalil teaches a breast pump device (fig. 10) configured as a self-contained, in-bra wearable device (fig. 10; paragraph 70) having a breast shield (1 in fig. 11) having a flange (12in fig. 6) and a nipple tunnel (13 in fig. 6) and a milk container (7' in fig. 11)configured to be attached and removed from the housing (paragraph 69). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the reference claim to be a self-contained, in-bra wearable device having a breast shield with a flange and nipple tunnel and a milk container configured to be attached and removed from the housing, as taught by Khalil, for the purpose of enabling the device to be a small and hands-free (paragraph 70). The modification of the breast shield would enable the shield to interface with the breast and receive the nipple and the modification of the milk container would enable the milk to be collected after expression.

Myers teaches a self-contained, in bra breast pump (fig. 1) which comprises a breast shield (18 in fig. 2) having a flange (48 in fig. 5) and nipple tunnel (46 in fig. 5) and a housing (16 in fig. 2) for housing a pump (56 in fig. 10) and a battery for powering the pump (52 in fig. 10). Myers further teaches that the breast shield is optically clear

(paragraph 65). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield to be optically clear for the purpose of allowing a user to visualize the placement of the breast and nipple and to have modified the housing to include a battery, as taught by Myers, for the purpose of providing power to the device.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

App Claim	Ref Claim	Teaching
1	1	see discussion above

3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.

19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Cudworth teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Claims 1, 3-22, 24, 25, and 28-34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10926011 in view of Khalil, Myers, and Cook, and the teachings below (see table).

Regarding claim 1, claim 1 of the issued patent claims all of the limitations in instant claim 1 except claim 1 does not claim a self-contained device, the housing

having a battery, the breast shield having a breast flange and nipple tunnel and being optically clear or transparent and being a part of a plurality of breast shields, wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast.

Khalil teaches a breast pump device (fig. 10) configured as a self-contained, in-bra wearable device (fig. 10; paragraph 70) having a breast shield (1 in fig. 11) having a flange (12in fig. 6) and a nipple tunnel (13 in fig. 6) and a milk container (7' in fig. 11)configured to be attached and removed from the housing (paragraph 69). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the reference claim to be a self-contained, in-bra wearable device having a breast shield with a flange and nipple tunnel and a milk container configured to be attached and removed from the housing, as taught by Khalil, for the purpose of enabling the device to be a small and hands-free (paragraph 70). The modification of the breast shield would enable the shield to interface with the breast and receive the nipple and the modification of the milk container would enable the milk to be collected after expression.

Myers teaches a self-contained, in bra breast pump (fig. 1) which comprises a breast shield (18 in fig. 2) having a flange (48 in fig. 5) and nipple tunnel (46 in fig. 5) and a housing (16 in fig. 2) for housing a pump (56 in fig. 10) and a battery for powering the pump (52 in fig. 10). Myers further teaches that the breast shield is optically clear (paragraph 65). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield to be

optically clear for the purpose of allowing a user to visualize the placement of the breast and nipple and to have modified the housing to include a battery, as taught by Myers, for the purpose of providing power to the device.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.

4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.

20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
28	9	
29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Cudworth teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Claims 1, 3-22, 24, 25, 29-34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of the issued patents below in view of Myers, Cook and the teachings below (see table).

- **17203050 (US Patent 11357893)**

- **17203079 (US Patent 11376352)**
- **17203216 (US Patent 11357894)**
- **17203259 (US Patent 11324866)**
- **17203327 (US Patent 11413380)**

Claim 1 of the issued patent claims all of the features claimed in reference claim 1 except in that claim 1 of the patent does not claim a breast shield of a plurality of interchangeable breast shields each being transparent or optically clear and having a different size and being configured to slide in and out of the housing, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple

tunnel (see above with respect to rejection of claim 1) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.

10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Cudworth teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.

33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Claims 1, 3-22, 24, 25, 28-34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of the following US Patents in view of Myers, Cook and the teachings below (see table).

- **17203109 (US Patent 11260151)**
- **17203313 (US Patent 11311654)**

Claim 1 of the issued patent claims all of the features claimed in reference claim 1 except in that claim 1 of the patent does not claim a breast shield of a plurality of interchangeable breast shields each being transparent or optically clear and having a different size and being configured to slide in and out of the housing, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.

6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.

22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
28	18 ('151 patent), 13 ('654 patent)	
29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Cudworth teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Claims 1, 3-22, 24, 25, 29-34 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of the following copending applications in view Myers, Cook and the teachings below.

- **17203150**
- **17203179**
- **17203292**
- **17203355**

- **17203384**
- **17203397**
- **17203418**

Claim 1 of the reference claim claims all of the features claimed in reference claim 1 except in that claim 1 of the reference claim does not claim a breast shield of a plurality of interchangeable breast shields each being transparent or optically clear and having a different size and being configured to slide in and out of the housing, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Cook teaches a plurality of interchangeable breast shields (inserts 1 and 4 in fig. 1a/b) which each comprise a flange (frustoconical shaped wall 5 in fig. 1a/b) and nipple tunnel (cylindrical section 9 and 11 in fig. 1a/b). Cook further teaches that the shields are configured to provide a different spacing of a nipple from a side wall of the nipple tunnel (see above with respect to rejection of claim 1) when each of the plurality of

interchangeable breast shields are placed onto a breast (paragraph 42 discloses that the nipple tunnels each have different wall thicknesses which would alter the inner diameter 10/12 of the shields which would provide different spacings between the side wall of the nipple tunnel and the nipple). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be of a plurality of interchangeable breast shields each having a different size, the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast. Cook teaches that this modification would render the device useful to a greater population since Cook teaches that nipple size can vary across the population (paragraph 5).

App Claim	Ref Claim	Teaching
1	1	see discussion above
3		Myers teaches this limitation above. It would have been obvious to have modified the reference claim so that the walls of the nipple tunnel do not collapse onto the nipple.
4		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
5		Chang teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
6		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
7		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
8		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
9		Khalil teaches this limitation above. It would have been obvious to have modified the reference claim to enable easier positioning of the shield.
10		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.

11		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers teaches this a known configuration.
12		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
13		Philips teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
14		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
15		Karsan teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
16		It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
17		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
18		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
19		Blondheim teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
20		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
21		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
22		Myers and Khalil teach this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
24		Myers teaches this limitation above. It would have been obvious to have modified the reference claim as Myers and Khalil teaches this a known configuration.
25		Guthrie teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
29		Mendoza teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
30		Baker teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
31		Barack teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
32		Cudworth teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.
33		Meyers teaches this limitation above. It would have been obvious to have modified the reference claim for the same reason as provided above.

34		Cook teaches this limitation above. It would have been obvious to have modified the reference claim to ensure all shields fit with the breast pump.

Allowable Subject Matter

Except for the double patenting rejections above, **claim 28** would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not teach or suggest the pump delivers the claimed stall pressure and free air flow.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COURTNEY FREDRICKSON whose telephone number is (571)270-7481. The examiner can normally be reached Monday-Friday (9 AM - 5 PM EST).

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NATHAN PRICE can be reached on 571-270-5421. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COURTNEY B FREDRICKSON/
Examiner, Art Unit 3783

/NATHAN R PRICE/
Supervisory Patent Examiner, Art Unit 3783

Notice of References Cited	Application/Control No. 17/181,057	Applicant(s)/Patent Under Reexamination O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	Art Unit 3783	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
	A					
	B					
	C					
	D					
	E					
	F					
	G					
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	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N	EP-2502640-A1	09-2012	EP	COOK G	A61M1/06
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	**Art Unit**
	COURTNEY FREDRICKSON	3783

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/12/2022	10/17/2022							
	1	✓	✓							
	2	✓	-							
	3	✓	✓							
	4	✓	✓							
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	32	✓	✓							
	33	✓	✓							
	34		✓							

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

CPC - Searched*		
Symbol	Date	Examiner
a61m1/06-069	01/12/2022	cbf

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
see SEARCH history	01/12/2022	cbf
searched inventors in PALM and SEARCH	01/12/2022	cbf
consulted child search history	01/12/2022	cbf
Updated search history	10/17/2022	cbf

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/COURTNEY B FREDRICKSON/ Examiner, Art Unit 3783	

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(54) **Breast pump**

(57) A breast pump comprising a funnel (2) and at least two cone-shaped breast pump inserts (1) interchangeably mountable in said funnel (2) is disclosed. The breast pump inserts (1) each have a central aperture (10,12) therein through which a nipple protrudes when a breast is received in the funnel (2). The diameter of the aperture (10,12) in each breast pump insert (1) is different. A breast pump funnel (2) or insert (1) having a textured finish on a breast interface surface is also disclosed.

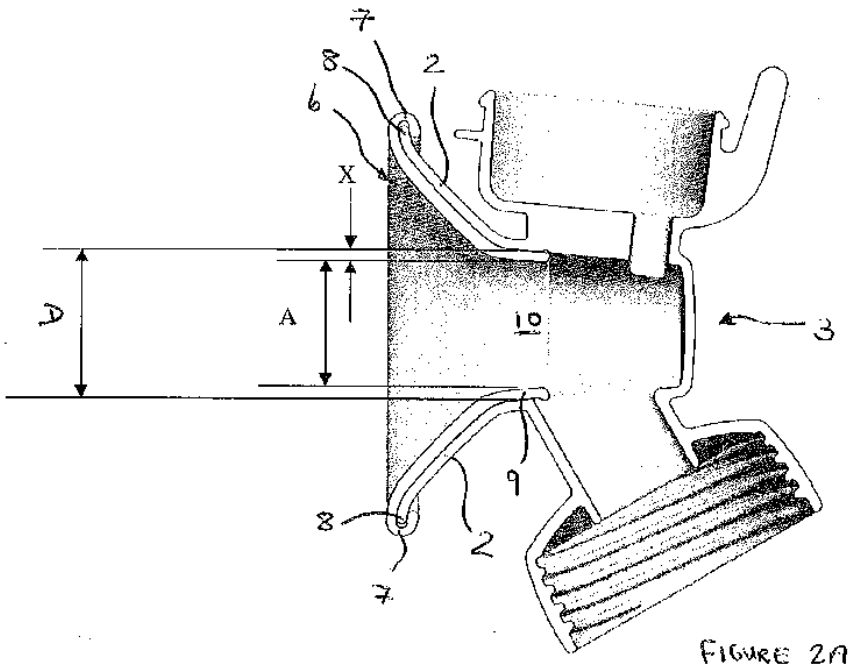


FIGURE 2A

EP 2 502 640 A1

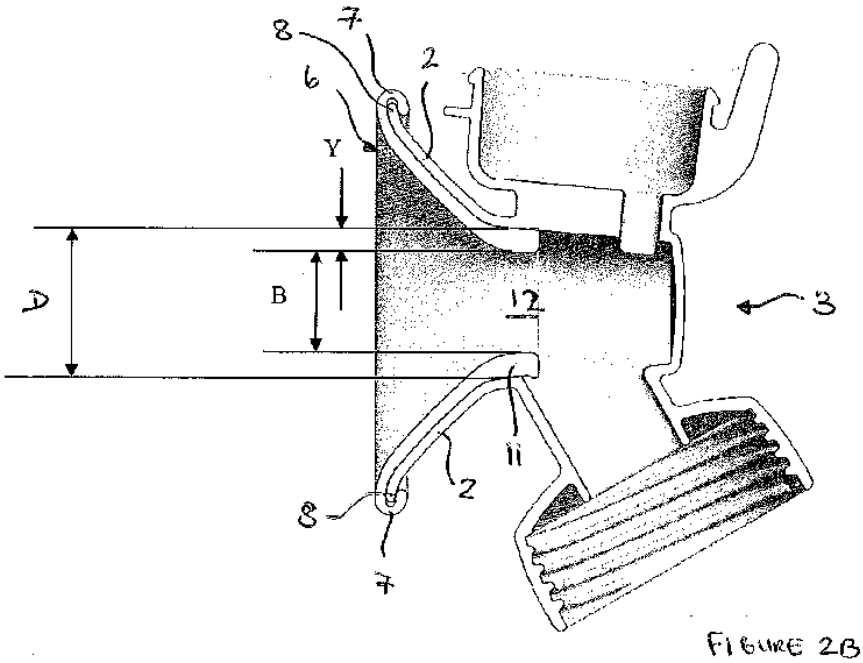


FIGURE 2B

Description

FIELD OF THE INVENTION

[0001] The present invention relates to a breast pump. It also relates to a modified breast pump insert to replace a standard breast pump insert supplied with a breast pump such that the breast pump can be used interchangeably with the standard or modified breast pump insert and, to a breast pump insert kit.

[0002] The invention also relates to a breast pump or breast pump insert that provides an enhanced level of comfort for a user.

BACKGROUND OF THE INVENTION

[0003] Breast pumps are well known devices for extracting milk from a breast of a user. A breast pump may be used if the baby or infant is not itself able to extract milk from the breast, or if the mother is separated from the baby or infant and is to be fed with breast milk by someone else. Breast pumps typically comprise a rigid funnel connected to a vacuum pump having a container for collecting the milk.

[0004] The funnel of a breast pump is the interface between the user's breast and nipple with the pump and so the sizing of the funnel is critical to maintaining the user's comfort whilst using the device. It is also important to ensure that the vacuum seal between the breast and the insert is maintained for optimal pumping. A problem with a conventional breast pump is that it has a funnel of fixed size, so it can only cater for a limited range of breast and nipple sizes. However, if the funnel is too small relative to the nipple, the nipple tends to fill the available space inside the funnel and is likely to touch on the sides of the funnel, resulting in chafing, friction and discomfort as negative pressure generated during use of the pump draws the nipple into the funnel. On the contrary, if the funnel is too large relative to the nipple, then there will be more dead space inside the funnel which will reduce the efficiency of the pump system and limit the negative pressure achievable. It also introduces the possibility that the nipple will be pulled deeper into the pump and that the skin on areola or breast area surrounding the nipple will be subjected to chafing.

[0005] Research has shown that nipple diameter and length varies throughout the population and across different geographic regions and also that the sizing of the nipple can be different before, during and after expressing. Therefore, as fit is an important consideration when attempting to achieve maximum comfort for a user, a breast pump that is capable of accommodating a wide range of breast and nipple sizes is desirable.

[0006] It is known to provide a breast pump body with a removable funnel that may be replaced with another funnel of a different size. However, removable funnels are generally made from a hard plastic material and do not generally offer the user with an enhanced level of comfort whilst using such a device.

[0007] It is also known to provide a soft elastomer insert that may be disposed within a rigid funnel of a breast pump and which is designed to adapt to the contour of the breast so as to provide comfort and a vacuum seal necessary for operating the pump. The resilience and compliance of such an insert helps to provide a vacuum and milk seal around the user's breast and also reduces friction on the breast and/or nipple when the negative pressure draws the breast and nipple in a direction into the pump. A separate cushion or insert also allows for the inclusion of a pressure ducting system on the cushion's rear surface which faces the funnel. A pressure ducting system may include a system of 'petals' that can move in and out to palpate the breast. These petals can be formed from a plurality of regions spaced around the circumference of the insert to define a void or reservoir. The wall thickness in the region of the petals may be less than the remainder of the insert so that they deform more easily in response to the generation of a negative pressure when the pump is in use.

[0008] A cushion or insert may be formed from silicon or thermoplastic elastomer (TPE) which, in addition to providing an enhanced level of comfort, can also provide a warmer feeling to the breast.

[0009] Although an insert may improve the comfort for a user, breast pumps equipped with an insert still suffer from the problem that the insert will only accommodate a relatively small range of breast and/or nipple sizes resulting in a poor fit between the breast and/or the nipple with the insert for a relatively large number of breastfeeding women, causing discomfort and poor vacuum pressure generation.

SUMMARY OF THE INVENTION

[0010] The present invention seeks to overcome or substantially alleviate the aforementioned problems.

[0011] Accordingly, the present invention provides a breast pump comprising a funnel and at least two funnel-shaped breast pump inserts interchangeably mountable in said funnel, each of said breast pump inserts having a central aperture therein through which a nipple extends when a breast is received therein, wherein the diameter of the aperture in each breast pump insert is different.

[0012] Preferably, each breast pump insert comprises a wall having a thickness. The thickness of said wall in a region of the aperture is different for each insert.

[0013] Each breast pump insert may have an outer diameter in the region of the aperture that is defined by the sum of twice the wall thickness and the diameter of the aperture.

[0014] Preferably, the outer diameter in the region of the aperture is substantially constant for all breast pump inserts.

[0015] In a preferred embodiment, each breast pump insert comprises a frustoconical section that tapers to a substantially cylindrical section. In this embodiment, the

aperture is formed at an end of the substantially cylindrical section.

[0016] Preferably, said region of the aperture is defined by the substantially cylindrical section such that the thickness of said wall forming said substantially cylindrical section is different for each insert.

[0017] According to the invention, there is also provided a modified breast pump insert to replace a standard breast pump insert supplied with a breast pump such that said breast pump can be used interchangeably with the standard or modified breast pump insert, each of said breast pump inserts having a central aperture therein through which a nipple extends when a breast is received therein and an overall outer diameter in a region of the aperture, wherein the diameter of the aperture in the modified breast pump insert is different to the diameter of the aperture in the standard breast pump insert, said overall outer diameter of the breast pump insert in the region of said aperture remaining the same in both the modified and standard breast pump inserts irrespective of the difference in the diameter of the aperture between said inserts.

[0018] According to the invention, there is also provided a breast pump insert kit comprising at least two funnel-shaped breast pump inserts interchangeably mountable in a funnel of a breast pump, each breast pump insert having a central aperture therein through which a nipple extends when a breast is received therein, wherein the diameter of the aperture in each breast pump insert is different.

[0019] Preferably, each breast pump insert comprises a wall having a thickness, and wherein the thickness of said wall in a region of the aperture is different for each insert.

[0020] Each breast pump insert may have an outer diameter in the region of the aperture defined by the sum of twice the wall thickness and the diameter of the aperture. Preferably, the outer diameter of all the breast pump inserts is the same.

[0021] In one embodiment, each breast pump insert comprises a frustoconical section that tapers to a substantially cylindrical section. The aperture is then formed at an end of the substantially cylindrical section. Preferably, the length of the cylindrical section remains constant across all the breast pump inserts, despite the change in diameter of the aperture.

[0022] The region of the aperture may be defined by the substantially cylindrical section such that the thickness of said wall forming said substantially cylindrical section is different for each insert.

[0023] According to the invention, the breast pump insert kit may also include a breast pump according to the invention.

[0024] It has been determined that a preferred setting for the let-down of breast milk is one where the woman's breast is warm and she feels relaxed. Many women hold a warm flannel to the breast before expressing and also create a comfortable environment in order to relax and to aid the process of milk let-down.

[0025] Using a breast pump requires the funnel, or a breast pump insert, to make contact with the breast. However, the plain engineering materials and finishes for the surface of the funnel or insert that touches the breast have been perceived as being cold and hard by the user which can potentially inhibit the ease of milk let-down or initially just feel cold and uncomfortable as the user starts their pumping session.

[0026] Furthermore, it has been found that silicon parts with polished surfaces can feel sticky to the touch, feely clammy, and pick up dirt and lint, giving the perception of being dirty or unhygienic.

[0027] The present invention also seeks to overcome or alleviate the aforementioned problems. This aspect of the invention may be independent to the previous aspect of the invention referred to above or, both aspects may be combined.

[0028] According to the present aspect of the invention, there is provided a breast pump having a funnel to receive a breast of a user, wherein a surface of said funnel that comes into contact with a breast received in said funnel has a textured surface finish.

[0029] According to the invention, there is also provided a breast pump insert positionable within the funnel of a breast pump to receive a breast of a user, wherein a surface finish of said breast pump insert that comes into contact with a breast received in said insert has a textured surface finish.

[0030] The surface finish may be created on the funnel or on a breast pump insert during the manufacturing process through virtue of the mould-tool surface. This creates an irregular non-smooth surface that may have an arithmetical mean roughness (Ra) in the order of single digits to tens of digits that reduces the overall surface contact between the user's skin and the breast pump. The arithmetical mean roughness can be between 1 and 50Ra or even 1 to 3 Ra.

[0031] The surface texture reduces the overall surface contact between the user's skin and the breast pump. This results in reduced energy transfer between the skin and insert or funnel, making it seem less cold than it is. Furthermore, the small air pockets trapped in the undulations create a heat isolation layer that results in a warmer and more pleasant overall sensation compared to the colder sensation when using a pump with a smooth surface at the breast interface.

[0032] A textured surface also makes it less sticky, which improves the user's perception of the feel, reducing the tendency for it to feel clammy. It also picks up much less dirt and lint compared to a smooth silicon surface.

[0033] It will be appreciated that a textured surface finish can be applied to the whole or only part of the surface of a funnel or a breast pump insert that may come into contact with a user's breast. Preferably, the textured surface finish is applied to the entire inner surface of a breast pump insert or, if no insert is to be used, the entire conical shaped portion of a breast pump funnel may have a tex-

tured surface. However, it will be appreciated that the textured surface may be applied in a series of repeated patterns or to sections of the surface of the insert or to the funnel.

[0034] In one embodiment, the insert or funnel may have a smooth annular region at its mouth or periphery so that the textured surface covers an inner portion of the funnel or insert. This improves the seal between the funnel or insert and the user's breast whilst still maintaining the benefits of a textured surface.

BRIEF DESCRIPTION OF THE DRAWINGS

[0035] Preferred embodiments will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figures 1A and 1B show perspective views of a two inserts according to one embodiment of the present invention;

Figure 2A shows a cross-sectional side elevation of a breast pump body fitted with the breast pump insert of Figure 1A; and

Figure 2B shows a cross-sectional side elevation of a breast pump body fitted with the breast pump insert of Figure 1B.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0036] Referring now to the drawings, Figures 1A shows a first breast pump insert 1. The insert 1 may be disposed in a funnel 2 of a breast pump body 3 for extracting milk, as shown in Figure 2A.

[0037] Figure 1B shows a second breast pump insert 4. The insert 4 may also be disposed in a funnel 2 of a breast pump body 3 for extracting milk, as shown in Figure 2B, in place of the insert 1 shown in Figure 1A.

[0038] The breast pump body 3, or at least the funnel 2 of the breast pump body 3, shown in Figures 2A and 2B may have identical dimensions.

[0039] Each of the breast pump inserts 1,4 have a generally frustoconical shaped wall 5 having a mouth area 6 through which a breast is inserted into the insert 1,4 when the insert 1,4 is located within a funnel 2 of the breast pump body 3. The wall 5 has a peripheral lip 7 around the mouth 6 that locates around the outer extremity 8 of the funnel 2 to releasably attach the insert 1,4 to the funnel 2.

[0040] The wall 5 of breast pump insert 1 tapers to a short cylindrical section 9 that terminates in an aperture 10. Similarly, the wall 5 of breast pump insert 4 tapers to a short cylindrical section 11 that terminates in an aperture 12. The user's nipple protrudes through the aperture 10,12 of the breast pump insert 1,4 when one of said inserts 1,4 is received within the funnel 2 of the breast pump body 3 and a breast is placed within the insert 1,4 through the mouth 6.

[0041] The short cylindrical section 9, 11 of each breast pump insert 1,4 has an outer, overall diameter (as indicated by dimension "D" in Figures 2A and 2B), that is substantially identical. However, the wall thickness (indicated by dimension "X" in Figure 2A and dimension "Y" in Figure 2B) is different. More specifically, the wall thickness "X" is smaller than the wall thickness "Y". Preferably, the overall outer geometry of the breast pump inserts 1,4 are identical, in addition to the outer diameter of the short cylindrical section 9,11.

[0042] As a result of the difference in wall thickness and as there is no alteration in the overall diameter of the short cylindrical section 9,11 between inserts 1,4, the diameter of the apertures 10,12 are different to each other. In particular, the diameter of the aperture 10 in Figure 2A (indicated by dimension A) is greater than the diameter of the aperture 12 in Figure 2B (indicated by dimension B).

[0043] In a preferred embodiment, the length of the cylindrical sections 9,11 of the inserts remains the same despite the change in diameter of the aperture 10,12. Most preferably, the overall length of the breast pump inserts is the same.

[0044] As at least the outer diameter of the short cylindrical section 9,11 of each breast pump insert 1,4 is the same, either breast pump insert 1,4 may be used interchangeably with the same breast pump 3 or funnel 2 and no modification to the pump body 3 or funnel 2 is required when the breast pump insert 1 is changed for the breast pump insert 4, and vice-versa. A user may select a preferred insert 1,4 depending on their breast and/or nipple size and/or depending on which insert provides them with the most comfort during pumping, and fit that insert 1,4 to the funnel 2 of their pump body 3, without any replacement of, or modification to, their pump body or funnel 2.

[0045] Each of the breast pump inserts 1,4 are formed from a compressible and resilient material such that they easily deform and adapt to the contour of the breast. Preferably, each breast pump insert 1,4 is formed from a silicone gel, silicone rubber material or thermoplastic elastomer (TPE), although it will be appreciated that any material having resilient, deformable properties, that will provide comfort to the user and achieve a vacuum by adapting to the shape of the breast can be used.

[0046] The invention caters for different nipple sizes by providing a number or range of breast pump inserts, each of which have a different diameter aperture in the breast pump insert through which the nipple protrudes or extends.

[0047] Despite the change in aperture diameter across the range of inserts, the outer dimension of the insert, at least in the region of the aperture, remains constant, thereby enabling any of the inserts to be fitted to the same breast pump body or funnel, without modification.

[0048] It will be appreciated that each insert may be provided with integral petals or other features to massage the breast during pumping.

[0049] Although the invention has been described with

reference to two breast pump inserts 1,4, it will be appreciated that any number or range of inserts may be provided, each of which have different aperture diameters, but the same overall or outer diameter, so that they will all fit the same pump body 3 or funnel 2.

[0050] It is envisaged that a breast pump may be provided with two or more inserts each having a different aperture diameter so that a user may select the most appropriate insert for maximum comfort. However, it is also envisaged that one or more modified breast pump inserts(s) may be made available to replace a standard breast pump insert that has previously been supplied with a breast pump. The same breast pump can then be used interchangeably with the standard or modified breast pump insert as the overall outer diameter of the breast pump insert in the region of said aperture remains the same in both the modified and standard breast pump inserts irrespective of the difference in the diameter of the aperture between said inserts. It is also envisaged that a breast pump insert kit may be provided, i.e. a set of two or more breast pump inserts, each of which have a different aperture diameter but the same overall outer diameter, at least in the region of the aperture. Each of the inserts of the kit may then be used interchangeably with the same breast pump.

[0051] In connection with the second aspect of the invention referred to above, it will be appreciated that one or both of the inserts of the first aspect of the invention may be provided with a textured surface. The present invention also includes within its scope a single breast pump insert having a textured breast interface contact surface, as well as a funnel for a breast pump having such a surface.

[0052] The textured surface may cover all or part of the funnel or insert. For example, there can be a series of repeated patterns extending around the circumference of the insert or cushion each of which have a surface texture. In one preferred embodiment, there is a ring of smooth or untextured surface extending around the circumference of the insert or funnel to ensure that a proper seal is formed with a breast inserted therein. The smooth region can be at the mouth of the insert or funnel, i.e. at the end or outer border where the breast is inserted or, it can be spaced inwardly so as to divide the textured surface into two regions separated by said ring.

[0053] If an insert is provided with a series of petals, as previously mentioned above, the surface texture could be associated with those petals, i.e. the surface texture may only be on the surface of the insert forming the petals. Alternatively, it could surround the petals.

[0054] The textured surface may be formed from a surface having an arithmetical mean roughness (Ra) in the order of single digits to tens of digits that reduces the overall surface contact between the user's skin and the breast pump. However, more preferably the arithmetical mean roughness is between 1 and 50Ra or even 1 to 3 Ra.

[0055] The invention has been described with reference to preferred embodiments only. Modifications and alterations to the embodiments falling within the scope of the appended claims are included within the scope of protection.

Claims

1. A breast pump comprising a funnel and at least two funnel-shaped breast pump inserts interchangeably mountable in said funnel, each of said breast pump inserts having a central aperture therein through which a nipple extends when a breast is received therein, wherein the diameter of the aperture in each breast pump insert is different.

2. A breast pump according to claim 1, wherein each breast pump insert has an outer diameter in a region of the aperture and comprises a wall having a thickness, and wherein the thickness of said wall in a region of the aperture is different for each insert.

3. A breast pump according to claim 2, wherein the outer diameter in the region of the aperture is defined by the sum of twice the wall thickness and the diameter of the aperture.

4. A breast pump according to claim 2 or claim 3, wherein the outer diameter of the breast pump inserts is substantially the same.

5. A breast pump according to any of claims 2 to 4, wherein each breast pump insert comprises a frustoconical section that tapers to a substantially cylindrical section, said aperture being formed at an end of the substantially cylindrical section.

6. A breast pump according to claim 5, wherein said region of the aperture is defined by the substantially cylindrical section such that the thickness of said wall forming said substantially cylindrical section is different for each insert.

7. A modified breast pump insert to replace a standard breast pump insert supplied with a breast pump such that said breast pump can be used interchangeably with the standard or modified breast pump insert, each of said breast pump inserts having a central aperture therein through which a nipple extends when a breast is received therein and an overall outer diameter in a region of the aperture, wherein the diameter of the aperture in the modified breast pump insert is different to the diameter of the aperture in the standard breast pump insert, said overall outer diameter of the breast pump insert in the region of said aperture remaining the same in both the modified and standard breast pump inserts irrespective of the difference in the diameter of the aperture be-

tween said inserts.

8. A breast pump insert kit comprising at least two funnel-shaped breast pump inserts interchangeably mountable in a funnel of a breast pump, each breast pump insert having a central aperture therein through which a nipple extends when a breast is received therein and a wall having a thickness, wherein the diameter of the aperture, and the thickness of the wall in a region of the aperture in each breast pump insert is different.

9. A kit according to claim 8, wherein each breast pump insert has an outer diameter in the region of the aperture defined by the sum of twice the wall thickness and the diameter of the aperture, the outer diameter of each breast pump insert being substantially the same.

10. A kit according to claims 8 or 9, wherein each breast pump insert comprises a frustoconical section that tapers to a substantially cylindrical section, said aperture being formed at an end of the substantially cylindrical section.

11. A breast pump according to claim 10, wherein said region of the aperture is defined by the substantially cylindrical section such that the thickness of said wall forming said substantially cylindrical section is different for each insert.

12. A kit according to any of claims 8 to 11, including a breast pump according to any of claims 1 to 6.

13. A breast pump having a funnel to receive a breast of a user, wherein a surface of said funnel that comes into contact with a breast received in said funnel has a textured surface finish.

14. A breast pump insert positionable within the funnel of a breast pump to receive a breast of a user, wherein a surface finish of said breast pump insert that comes into contact with a breast received in said insert has a textured surface finish.

15. A breast pump according to claim 13 or a breast pump insert according to claim 14, wherein the textured surface finish has an arithmetical mean roughness (Ra) in the order of single digits to tens of digits that reduces the overall surface contact between the user's skin and the breast pump.

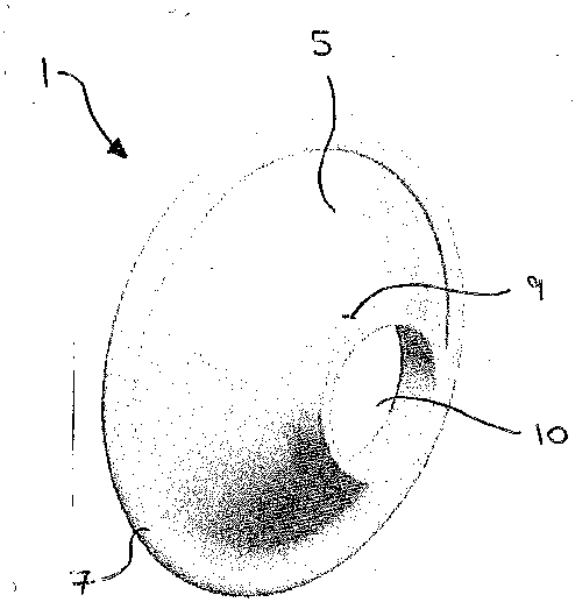


FIGURE 1A

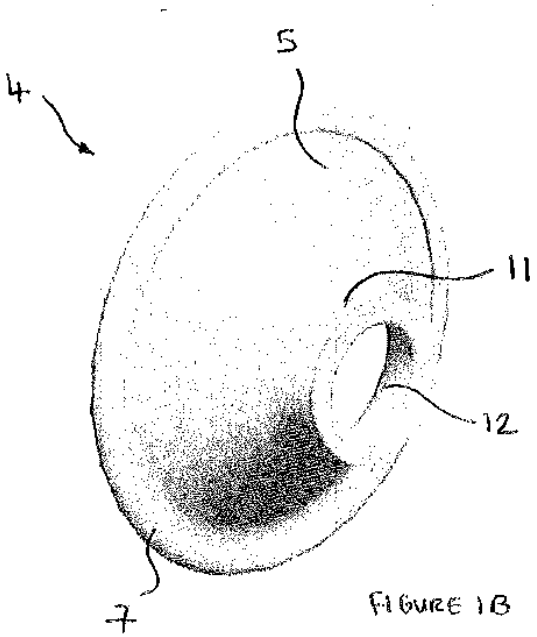


FIGURE 1B

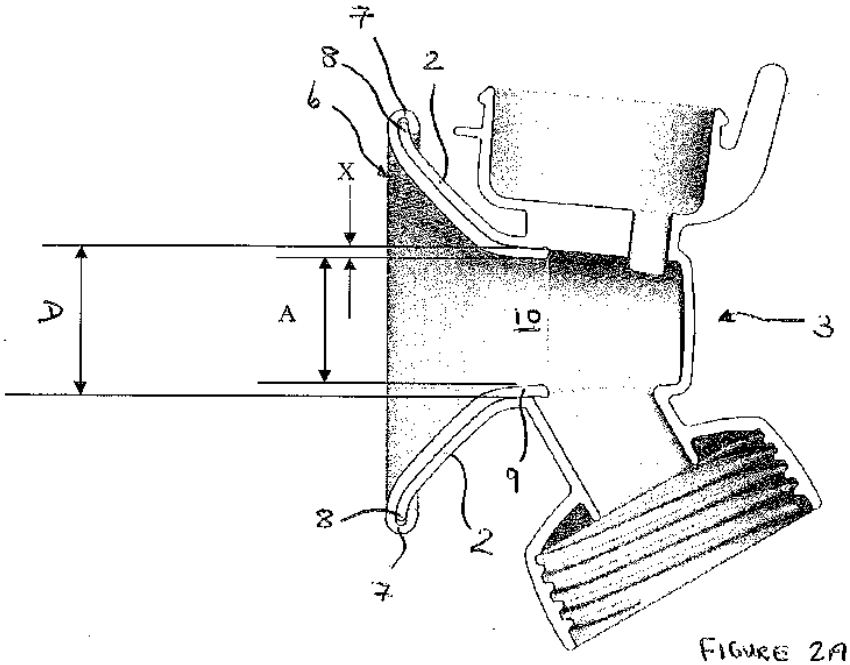


FIGURE 2A

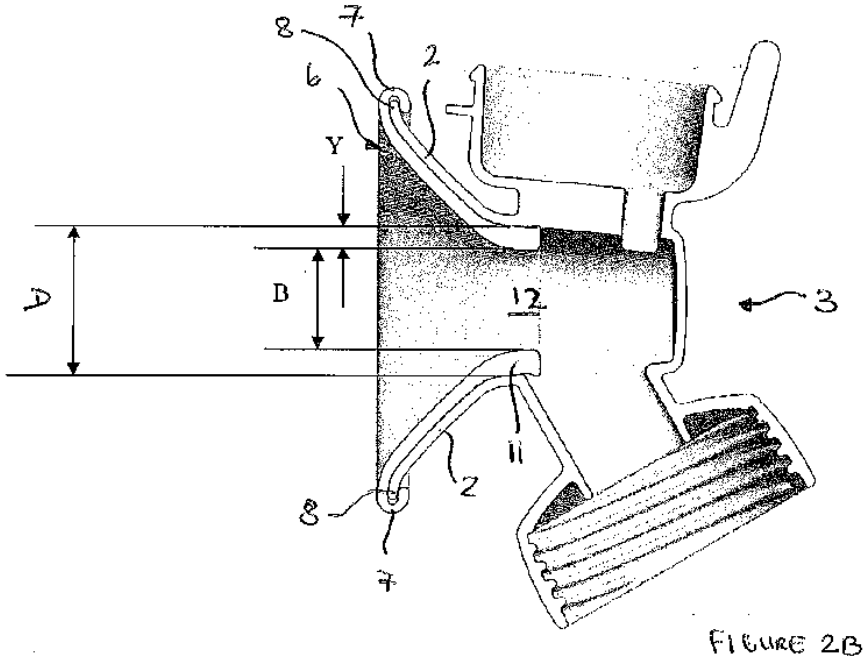


FIGURE 2B

Europäisches Patentamt
European Patent Office
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EUROPEAN SEARCH REPORT

Application Number
EP 11 15 8960

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 4 857 051 A (LARSSON KARL O A H [CH]) 15 August 1989 (1989-08-15) * column 3, lines 48-65 * * column 7, lines 16-62 * * figure 2 *	1-12	INV. A61M1/06
X	US 4 323 067 A (ADAMS FRANK H) 6 April 1982 (1982-04-06) * column 4, line 15 - column 5, line 2 * * figures 1, 2 *	1-12	
X	GB 2 392 626 A (UNIV SCHOOL NIHON JURIDIC PER [JP]) 10 March 2004 (2004-03-10) * page 6, line 16 - page 9, line 3 * * figures 1, 2 *	1-12	
X	US 4 573 969 A (SCHLENSOG KLAUS [CH] ET AL) 4 March 1986 (1986-03-04) * column 5, lines 20-28 * * column 8, lines 10-64 * * figures 1, 2 *	1-12	
			TECHNICAL FIELDS SEARCHED (IPC)
A	US 5 049 126 A (LARSSON KARL O A H [CH]) 17 September 1991 (1991-09-17) * column 2, lines 31-42; figure 1 *	1,7,8	A61M

~~The present search report has been drawn up for all claims~~

Place of search	Date of completion of the search	Examiner
The Hague	24 August 2011	Schlaug, Martin

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

Europäisches Patentamt
European Patent Office
Office européen des brevets

Application Number
EP 11 15 8960

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing claims for which payment was due.

☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due and for those claims for which claims fees have been paid, namely claim(s):

☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

☐ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.

☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:

☒ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

1-12

☐ The present supplementary European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims (Rule 164 (1) EPC).

Europäisches Patentamt
European Patent Office
Office européen des brevets

LACK OF UNITY OF INVENTION
SHEET B

Application Number
EP 11 15 8960

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1-12

A breast pump comprising an insert (claim 1-6), an insert (claim 7) and an insert kit (claim 8-12)
and further features relating to
the insert being interchangable
---

2. claims: 13-15

A breast pump comprising a funnel (claim 13, 15) or an insert (claim 14, 15)
and further features relating to
a textured surface finish

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 11 15 8960

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

24-08-2011

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4857051 A	15-08-1989	NONE	
US 4323067 A	06-04-1982	NONE	
GB 2392626 A	10-03-2004	CN 1509191 A	30-06-2004
		GB 2392626 A	10-03-2004
		JP 2002336347 A	26-11-2002
		US 2004133151 A1	08-07-2004
		WO 02094345 A1	28-11-2002
US 4573969 A	04-03-1986	CA 1218276 A1	24-02-1987
		DE 3364783 D1	28-08-1986
		EP 0116186 A1	22-08-1984
		US 4573969 A	04-03-1986
US 5049126 A	17-09-1991	NONE	

EPO FORM P0458

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	COURTNEY B. FREDRICKSON
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-D788293-S	05-30-2017	ECKSTEIN et al.	
	002	US-D809646-S	02-06-2018	MASON et al.	
	003	US-D832995-S	11-06-2018	MASON et al.	
	004	US-D888225-S	06-23-2020	ASKEM et al.	
	005	US-7641629-B2	01-05-2010	YUEN; Yat Keung William	
	006	US-10398816-B2	09-03-2019	CHANG et al.	
	007	US-10625005-B2	04-21-2020	CHANG et al.	
	008	US-20040127845-A1	07-01-2004	RENZ; Charles J. et al.	
	009	US-20070219486-A1	09-20-2007	MYERS; Kenneth E. et al.	
	010	US-20120021068-A1	01-26-2012	BARNESS; Itzhak et al.	
	011	US-20120035951-A1	02-09-2012	GOETZ; Steven M. et al.	
	012	US-20120043065-A1	02-23-2012	RANNE; Pasi et al.	
	013	US-20120072117-A1	03-22-2012	LODDOCH; Alexander et al.	
	014	US-20120072118-A1	03-22-2012	MANN; Tobias	
	015	US-20120095599-A1	04-19-2012	PAK; H. Ali et al.	
	016	US-20120143879-A1	06-07-2012	STOITSEV; Todor	
	017	US-20120220753-A1	08-30-2012	GERA; Lajos et al.	
	018	US-20150212036-A1	07-30-2015	JIN; Jian et al.	
	019	US-20150212037-A1	07-30-2015	OKAZAKI; Satoshi et al.	
	020	US-20170216505-A1	08-03-2017	KIM; Sang Ha	
	021	US-20180361040-A1	12-20-2018	O'TOOLE; Jonathan et al.	
	022	US-20210030934-A1	02-04-2021	ZHANG; Shu Ting	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.B.F./

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 4

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	COURTNEY B. FREDRICKSON
Attorney Docket Number	4944.0120006

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	WO-2016010524-A1	01-21-2016	HEWLETT PACKARD DEVELOPMENT CO [US]		☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 4

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First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	COURTNEY B. FREDRICKSON
Attorney Docket Number	4944.0120006

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author(in CAPITAL LETTERS),title of the article(when appropriate), title of the item (book,magazine,journal,serial,symposium,catalog,etc.),date,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
	001	4MD Medical, "Assembling Spctra Breast Pump Parts," YouTube [online], dated November13, 2016, URL: http://www.youtube.com/watch?v=ChV8xQfcBxU.	☐
	002	The Best Hands-Free Breast Pumps, posted at healthline.com, earliest date posted on 08/24/2020, [online], acquired on 10/30/2021, Available on internet. url:https://www.healthline.com/health/parenting/breast-feeding/best-hands-free-breast-pumps#Best-hands-free-breast-pumps (Year: 2020).	☐

Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	10/17/2022

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.B.F./

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	4	of	4

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	COURTNEY B. FREDRICKSON
Attorney Docket Number	4944.0120006

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Anupma Sahay #78,704/	Date (YYYY-MM-DD)	2022-07-12
Name/Print	Anupma Sahay	Registration Number	78,704

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.B.F./

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	1	17/181057.app.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:05 PM
L2	128	((("O'TOOLE") near3 ("Jonathan")) OR (("ROLLO") near3 ("Adam")) OR (("CARR") near3 ("Andrew"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/12/31 01:05 PM
L3	8470	a61m1/06-069.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L5	2	("20170216505").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L6	8	("20130023821" "20070219486" "20160296682").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:14 PM
L7	2	("20140378895").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:16 PM
L8	2	("7824363").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU,	OR	ON	ON	2022/01/01 01:04 PM

			SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L9	126	("10881766" OR "10926011" OR "20040087898" OR "20090281482" OR "20100292636" OR "20120165729" OR "20140263611" OR "20160228625" OR "20180110900" OR "20210196873" OR "20210196874" OR "20210196875" OR "20210196876" OR "20210205511" OR "20210205512" OR "20210205513" OR "20210205514" OR "20210205515" OR "20210205516" OR "20210205517" OR "20210205518" OR "20210228789" OR "20210268158" OR "7666162" OR "8608685" OR "20070135761" OR "20070179439" OR "20090281485" OR "20110009824" OR "20160271305" OR "20160296682" OR "20160325031" OR "20170095599" OR "20170112983" OR "20180028733" OR "20180333523" OR "5542921" OR "7833190" OR "10039871" OR "20020193731" OR "20040056641" OR "20040074281" OR "20040267215" OR "20050219302" OR "20060122575" OR "20070051172" OR "20070051727" OR "20080177224" OR "20080262420" OR "20080275386" OR "20110004154" OR "20110196291" OR "20110274566" OR "20120277636" OR "20130023821" OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/01/12 05:14 PM

		"20140031744" OR "20140052056" OR "20140275857" OR "20140323962" OR "20140378895" OR "20150217036" OR "20150217037" OR "20150283311" OR "20160000980" OR "20160058928" OR "20160058929" OR "20160082165" OR "20160082166" OR "20160151551" OR "20160158424" OR "20160166745" OR "20160206794" OR "20160220743" OR "20160220745" OR "20160256617" OR "20160287767" OR "20160296681" OR "20160310650" OR "20170021068" OR "20170035951" OR "20170043065" OR "20170072117" OR "20170072118" OR "20170143879" OR "20170220753" OR "20180021490" OR "20180110906" OR "2849881" OR "4390024" OR "4535627" OR "5474683" OR "5941847" OR "5973770" OR "6045529" OR "6090065" OR "6227936" OR "6328709" OR "6358226" OR "6383163" OR "6440100" OR "6461324" OR "6547756" OR "6579258" OR "6663587" OR "6749582" OR "7048519" OR "7201735" OR "7312554" OR "7314400" OR "7662018" OR "7776008" OR "8057425" OR "8118772" OR					

		"8187227" OR "8262606" OR "8282596" OR "8376986" OR "8702646" OR "8801495" OR "8876760" OR "8926556" OR "9033913" OR "9173587" OR "9345274" OR "9539377" OR "D548831").pn.					
L10	45	9 AND (transparent)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/12 06:05 PM
L11	105	3 AND (batter$4) AND ((interface flange shield cup) WITH (clear transparent))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/13 02:07 PM
L12	382	3 AND (silicone WITH plastic)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 10:40 AM
L13	2	("20180333523").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 11:50 AM
L14	43	3 AND ((USB "universal service bus") WITH (charg$4 recharg$4))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:19 PM
L15	2	("20160220743").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD,	OR	ON	ON	2022/01/14 12:42 PM

			DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L16	5	("5542921").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 12:52 PM
L20	256	3 AND ((shield cup interface flange) WITH (siz$4) WITH different)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 01:23 PM
L21	2	("20120165729").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 01:31 PM
L22	2	("10881766").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:23 PM
L23	2	("10926011").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/01/14 02:38 PM
L24	12	("20080275386" "20140378895" "20130023821" "20180333523" "20160296682" "20070228059" "20120277636" "20160220743" "6227936" "20090281485" "20120165729"	(US-PGPUB; USPAT)	OR	ON	ON	2022/01/14 03:55 PM

		"5542921").pn.					
L25	267	3 AND (nipple WITH (chang$4 differ$4 adjust$4 dissimilar$4) WITH (size width))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/17 03:06 PM
L26	2	"44148977".fmid.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; JPO)	OR	ON	ON	2022/10/17 03:31 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

Equivalent of Form PTO/SB/08

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 2

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	2014/0288466 A1	09-25-2014	Alvarez et al.	
	US2	2017/0173233 A1	06-22-2017	Tanaka	
	US3	2017/0292509 A1	10-12-2017	Kurihara et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	FP1	JP 2007501673 A	02-01-2007	PLAYTEX PRODUCTS INC		X
	FP2	JP 2014529312 A	11-06-2014	MEDELA HOLDING AG		X
	FP3	JP 2016514516 A	05-23-2016	NAIA HEALTH INC		X
	FP4	JP 2017509379 A	04-06-2017	NAIA HEALTH INC		X

Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	10/17/2022

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				Filing Date	February 22, 2021
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				Art Unit	3783
				Examiner Name	COURTNEY B FREDRICKSON
Sheet	2	of	2	Attorney Docket Number	4944.0120006

CERTIFICATION STATEMENT

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OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Anupma Sahay #78,704/	Date (YYYY-MM-DD)	2022-09-16
Name/Print	Anupma Sahay	Registration Number	78,704

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.B.F./

Equivalent of Form PTO/SB/08

Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 2

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	2014/0288466 A1	09-25-2014	Alvarez et al.	
	US2	2017/0173233 A1	06-22-2017	Tanaka	
	US3	2017/0292509 A1	10-12-2017	Kurihara et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	FP1	JP 2007501673 A	02-01-2007	PLAYTEX PRODUCTS INC		X
	FP2	JP 2014529312 A	11-06-2014	MEDELA HOLDING AG		X
	FP3	JP 2016514516 A	05-23-2016	NAIA HEALTH INC		X
	FP4	JP 2017509379 A	04-06-2017	NAIA HEALTH INC		X

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO				Complete if Known	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	17/181,057
				Filing Date	February 22, 2021
				First Named Inventor	Jonathan O'TOOLE
				Art Unit	3783
				Examiner Name	COURTNEY B FREDRICKSON
Sheet	2	of	2	Attorney Docket Number	4944.0120006

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Anupma Sahay #78,704/	Date (YYYY-MM-DD)	2022-09-16
Name/Print	Anupma Sahay	Registration Number	78,704

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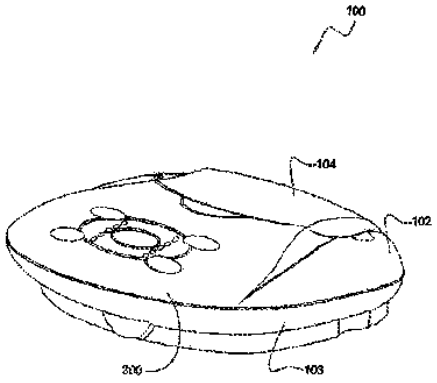
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最終頁に続く

(54)【発明の名称】搾乳ポンプシステム

(57)【要約】
【課題】搾乳ポンプシステム
【解決手段】母乳を得る搾乳ポンプシステムが提供されている。そのシステムは、母乳からの空気の流れを密閉するように分離して、女性の乳房に印加される陽圧と負圧との両方に単一の空気チューブを使用する。搾乳ポンプは、圧力を生成するピストン／シリンダ装置を有することが可能であり、これにより、使用者が吸引力とサイクル時間とを制御することを可能にする。
【選択図】　図１



【特許請求の範囲】
【請求項１】
圧力源と流体連絡し、乳首を有する乳房から母乳を絞り出すように構成された乳房カップであって、この乳房カップは、
乳房を受容して、前記圧力源と流体連絡するフードを備え、このフードは、負圧工程の間乳首への負の力を生成し、この負の力は、横方向成分と軸方向成分とを有し、前記横方向成分は、前記軸方向成分よりも大きい、乳房カップ。
【請求項２】
前記フードに動作的に接続されたバリア部材をさらに備え、このバリア部材は、前記負圧工程の間、前記負の力の前記軸方向成分を減少させる、請求項１に記載の乳房カップ。
【請求項３】
前記フードは、ハウジングと、このハウジングにシール状態で取着された柔軟なインサートと、前記ハウジングと前記柔軟なインサートとの間に形成された排気容積部とを備え、この排気容積部は、前記圧力源と流体連絡する、請求項１に記載の乳房カップ。
【請求項４】
前記排気容積部は、前記乳房が前記フードに受容されるとき前記乳首をほぼ包囲する、請求項３に記載の乳房カップ。
【請求項５】
前記柔軟なインサートは、前記圧力源と流体連絡する空気袋を備え、前記排気容積部は、少なくとも部分的に前記空気袋によって規定され、前記空気袋および前記排気容積部は、前記負圧工程の間、前記乳首への前記負の力を形成するように収縮する、請求項３に記載の乳房カップ。
【請求項６】
前記空気袋にほぼ隣接して配置されたバリア部材をさらに備え、このバリア部材により、前記乳房が前記空気袋に接触することが防止される、請求項５に記載の乳房カップ。
【請求項７】
前記柔軟なインサートは、前記乳房を受容する内側容積部を規定し、前記バリア部材は、円筒形状を有し、前記内側容積部中に配置されている、請求項６に記載の乳房カップ。
【請求項８】
前記柔軟なインサートは、これの上に形成されたマッサージ突起を持つじょうご形状を有する、請求項３に記載の乳房カップ。
【請求項９】
前記マッサージ突起は、星形状を有する、請求項８に記載の乳房カップ。
【請求項１０】
真空源に接続され、乳首を有する乳房から母乳を絞り出すように構成された乳房カップであって、この乳房カップは、
前記真空源と流体連絡する乳房受容部材を備え、この乳房受容部材は、負圧工程の間、前記乳首に負圧を印加し、前記乳首を横方向に沿って広げさせる、乳房カップ。
【請求項１１】
前記負圧により、前記乳首が軸方向に沿って伸びる以上に横方向に沿って乳首を広げさせる、請求項１０に記載の乳房カップ。
【請求項１２】
前記負圧は、平均横方向成分と平均軸方向成分とを有し、前記負圧工程の間、前記平均横方向成分は、前記平均軸方向成分よりも大きい、請求項１０に記載の乳房カップ。
【請求項１３】
前記乳房受容部材に動作的に接続されたバリア部材をさらに備え、このバリア部材は、前記負圧工程の間、前記軸方向に沿う前記乳首の伸張を減少させる、請求項１０に記載の乳房カップ。
【請求項１４】
前記乳房受容部材は、ハウジングと、このハウジングにシール状態で取着された柔軟な

インサートと、前記ハウジングと前記柔軟なインサートとの間に形成された排気容積部とを備え、この排気容積部は、前記真空源と流体連絡する、請求項１０に記載の乳房カップ。

【請求項１５】

前記排気容積部は、前記乳房が前記乳房受容部材に受容されるとき、前記乳首をほぼ包囲する、請求項１４に記載の乳房カップ。

【請求項１６】

前記柔軟なインサートは、前記真空源と流体連絡する空気袋を備え、前記排気容積部は、少なくとも部分的にこの空気袋によって規定され、前記空気袋および前記排気容積部は、前記負圧工程の間、前記乳首への負の力を形成するように収縮する、請求項１４に記載の乳房カップ。

【請求項１７】

前記空気袋にほぼ隣接して配置されたバリア部材をさらに備え、このバリア部材により、前記乳房が前記空気袋に接触することが防止されている、請求項１６に記載の乳房カップ。

【請求項１８】

前記柔軟なインサートは、前記乳房を受容する内側容積部を規定し、前記バリア部材は、円筒形状を有し、前記内側容積部に配置されている、請求項１７に記載の乳房カップ。

【請求項１９】

前記柔軟なインサートは、これの中に形成されているマッサージ突起を持つじょうご形状を有する、請求項１４に記載の乳房カップ。

【請求項２０】

乳首を有する乳房から母乳を絞り出す搾乳ポンプシステムであって、このシステムは、

圧力源と、

前記乳房を受容して、この圧力源と流体連絡し、負圧工程の間、前記乳首への負の力を生成し、前記負の力は、前記横方向成分と軸方向成分とを有し、前記横方向成分は、前記軸方向成分よりも大きい、乳房カップと、

を備える、搾乳ポンプシステム。

【請求項２１】

前記乳房カップに動作的に接続されたバリア部材をさらに備え、このバリア部材は、前記負圧工程の間、前記負の力の前記軸方向成分を減少させる、請求項２０に記載の搾乳ポンプシステム。

【請求項２２】

前記乳房カップは、ハウジングと、前記ハウジングにシール状態で取着された柔軟なインサートと、前記ハウジングと前記柔軟なインサートとの間に形成された排気容積部とを備え、この排気容積部は、前記圧力源と流体連絡する、請求項２０に記載の搾乳ポンプシステム。

【請求項２３】

前記排気容積部は、前記乳房が前記乳房カップに受容されたとき前記乳首をほぼ包囲する、請求項２２に記載の搾乳ポンプシステム。

【請求項２４】

前記柔軟なインサートは、前記圧力源と流体連絡する空気袋を備え、前記排気容積部は、少なくとも部分的に前記空気袋によって規定され、前記空気袋および前記排気容積部は、前記負圧工程の間、前記乳首への前記負の力を形成するように収縮する、請求項２２に記載の搾乳ポンプシステム。

【請求項２５】

前記空気袋にほぼ隣接して配置されたバリア部材をさらに備え、このバリア部材により、前記乳房が前記空気袋に接触することが防止されている、請求項２４に記載の搾乳ポンプシステム。

【請求項２６】

前記柔軟なインサートは、これの中に形成されたマッサージ突起を持つじょうご形状を有する、請求項２２に記載の搾乳ポンプシステム。

【請求項２７】

乳首を有する乳房から母乳を絞り出す搾乳ポンプシステムであって、このシステムは、

真空源と、

前記真空源と流体連絡し、負圧工程の間、乳首に負圧を印加し、前記乳首を横方向に沿って広げさせる乳房受容部材と、

を備える、搾乳ポンプシステム。

【請求項２８】

前記負圧により、前記乳首が軸方向に沿って伸びる以上に横方向に沿って乳首を広げさせる、請求項２７に記載の搾乳ポンプシステム。

【請求項２９】

前記負圧は、平均横方向成分と平均軸方向成分とを有し、前記平均横方向成分は、前記負圧工程の間、前記平均軸方向成分よりも大きい、請求項２７に記載の搾乳ポンプシステム。

【請求項３０】

前記乳房受容部材に動作的に接続されたバリア部材をさらに備え、このバリア部材は、前記負圧工程の間、前記軸方向に沿う前記乳首の伸張を減少させる、請求項２７に記載の搾乳ポンプシステム。

【請求項３１】

前記乳房受容部材は、ハウジングと、このハウジングにシール状態で取着された柔軟なインサートと、前記ハウジングと前記柔軟なインサートとの間に形成された排気容積部と、この排気容積部および前記真空源と流体連絡する空気用オリフィスとを備える、請求項２７に記載の搾乳ポンプシステム。

【請求項３２】

前記排気容積部は、前記乳房が前記乳房受容部材に受容されたとき前記乳首をほぼ包囲する、請求項３１に記載の搾乳ポンプシステム。

【請求項３３】

前記柔軟なインサートは、前記真空源と流体連絡する空気袋を備え、前記排気容積部は、少なくとも部分的にこの空気袋によって規定され、前記空気袋および前記排気容積部は、前記負圧工程の間、前記乳首への負の力を形成するように収縮する、請求項３１に記載の搾乳ポンプシステム。

【請求項３４】

前記空気袋にほぼ隣接して配置されたバリア部材をさらに備え、このバリア部材により、前記乳房が前記空気袋に接触することが防止されている、請求項３３に記載の搾乳ポンプシステム。

【請求項３５】

前記柔軟なインサートは、前記乳房を受容する内側容積部を規定し、前記バリア部材は、円筒形状を有し、前記内側容積部内に配置されている、請求項３４に記載の搾乳ポンプシステム。

【請求項３６】

前記柔軟なインサートは、これの上に形成されたマッサージ突起を持つじょうご形状を有する、請求項３１に記載の搾乳ポンプシステム。

【請求項３７】

前記真空源は、シリンダ内に移動可能に配置されたピストンである、請求項２７に記載の搾乳ポンプシステム。

【請求項３８】

前記ピストンに動作的に接続された可逆モータをさらに備える、請求項３７に記載の搾乳ポンプシステム。

【請求項３９】

第１の歯を有するラックと、第２の歯を有するギヤとをさらに備え、前記ラックは、前記ピストンに接続され、前記ギヤは、前記可逆モータに動作的に接続され、前記第１の歯は、前記第２の歯と係合して、前記シリンダ内でピストンを往復移動させる、請求項３８に記載の搾乳ポンプシステム。

【請求項４０】

前記シリンダは、第１の直径と空気穴とを有し、この空気穴は、第２の直径を有して、大気と流体連絡し、前記第１の直径は、前記第２の直径よりもかなり大きい、請求項３７に記載の搾乳ポンプシステム。

【請求項４１】

前記可逆モータに動作的に接続されたコントローラをさらに備え、このコントローラは、前記ピストンが前記シリンダに対して進んだ移動量を測定し、前記コントローラは、前記移動量に基づき前記モータを逆転させる、請求項３８に記載の搾乳ポンプシステム。

【請求項４２】

前記可逆モータに動作的に接続されたコントローラをさらに備え、前記モータは、可変速であり、前記コントローラは、前記乳房に前記負圧を印加する所望のサイクル時間に基づき前記速度を調節する、請求項３８に記載の搾乳ポンプシステム。

【請求項４３】

乳房から母乳を絞り出す圧力源と共に使用する搾乳ポンプキットであって、このキットは、

ホルダと、

乳房を受容する複数のフードとを備え、これら複数のフードの各々は、前記乳房から前記母乳を絞り出すために前記圧力源と前記ホルダとに選択的に係合可能であり、前記複数のフードの少なくとも１つは、前記複数のフードの他のものに比べて異なるサイズまたは異なる形状を有する、

搾乳ポンプキット。

【請求項４４】

前記複数のフードの各々は、ハウジングと、このハウジングにシール状態で取着された柔軟なインサートと、前記ハウジングと前記柔軟なインサートとの間に形成されて、前記圧力源と流体連絡する排気容積部とを備える、請求項４３に記載の搾乳ポンプキット。

【請求項４５】

前記複数のフードの前記少なくとも１つの前記ハウジングと前記柔軟なインサートとは、前記複数のフードの前記他のものの前記ハウジングと前記柔軟なインサートとに比べて、異なるサイズまたは異なる形状を有する、請求項４４に記載の搾乳ポンプキット。

【請求項４６】

前記複数のフードの前記少なくとも１つの前記ハウジングは、前記複数のフードの前記他のものの前記ハウジングに比べて異なるサイズまたは異なる形状を有する、請求項４４に記載の搾乳ポンプキット。

【請求項４７】

前記複数のフードの前記少なくとも１つの前記柔軟なインサートは、前記複数のフードの前記他のものの前記柔軟なインサートに比べて異なるサイズまたは異なる形状を有する、請求項４４に記載の搾乳ポンプキット。

【請求項４８】

容器をさらに備え、前記ホルダは、この容器と選択的に係合可能である、請求項４３に記載の搾乳ポンプキット。

【請求項４９】

前記ホルダは、複数の異なるサイズの容器に選択的に係合するために複数の係合構造を有する、請求項４８に記載の搾乳ポンプキット。

【請求項５０】

前記複数のフードの前記少なくとも１つの前記柔軟なインサートは、第１のマッサージ突起を有し、前記複数のフードの前記他のものの前記柔軟なインサートは、第２のマッサ

ージ突起を有し、前記第１のマッサージ突起および第２のマッサージ突起は、異なるサイズまたは異なる形状を有する、請求項４７に記載の搾乳ポンプキット。

【請求項５１】

乳房から母乳を絞り出す搾乳ポンプシステムであって、このシステムは、

圧力を生成するポンプと、

前記乳房を受容する複数のフードとを備え、これらフードの各々は、前記乳房から前記母乳を絞り出す前記ポンプに選択的に、流動的に接続可能であり、前記複数のフードの少なくとも１つは、前記複数のフードの他のものに比べて異なるサイズまたは異なる形状を有する、

搾乳ポンプシステム。

【請求項５２】

前記複数のフードの各々と選択的に係合可能なホルダをさらに備える、請求項５１に記載のシステム。

【請求項５３】

前記複数のフードの各々は、ハウジングと、このハウジングにシール状態で取着された柔軟なインサートと、前記ハウジングと前記柔軟なインサートとの間に形成されて、前記ポンプと流体連絡する排気容積部とを備える、請求項５１に記載のシステム。

【請求項５４】

前記複数のフードの前記少なくとも１つの前記ハウジングおよび前記柔軟なインサートは、前記複数のフードの前記他のものの前記ハウジングおよび前記柔軟なインサートに比べて、異なるサイズまたは異なる形状を有する、請求項５３に記載のシステム。

【請求項５５】

前記複数のフードの前記少なくとも１つの前記ハウジングは、前記複数のフードの前記他のものの前記ハウジングに比べて異なるサイズまたは異なる形状を有する、請求項５３に記載のシステム。

【請求項５６】

前記複数のフードの前記少なくとも１つの前記柔軟なインサートは、前記複数のフードの前記他のものの前記柔軟なインサートに比べて異なるサイズまたは異なる形状を有する、請求項５３に記載のシステム。

【請求項５７】

容器をさらに備え、前記ホルダは、この容器と選択的に係合可能である、請求項５２に記載のシステム。

【請求項５８】

前記ホルダは、複数の異なるサイズの容器に選択的に係合するために複数の係合構造を有する、請求項５７に記載のシステム。

【請求項５９】

前記複数のフードの前記少なくとも１つの前記柔軟なインサートは、第１のマッサージ突起を有し、前記複数のフードの前記他のものの前記柔軟なインサートは、第２のマッサージ突起を有し、前記第１のマッサージ突起と第２のマッサージ突起とは、異なるサイズまたは異なる形状を有する、請求項５６に記載のシステム。

【請求項６０】

乳房から母乳を絞り出す搾乳ポンプであって、このポンプは、

圧力工程の間、圧力を生成する移動可能な構造体を有し、この移動可能な構造体は、可変圧力または可変サイクル時間を有する、圧力源と、

この圧力源に動作的に接続されたコントローラとを備え、このコントローラは、前記移動可能な構造体によって進められた移動量に基づき前記圧力を調整する、または、前記移動可能な構造体の速度に基づき前記可変サイクル時間を調整し、また、このコントローラは、進められた前記移動量または前記速度のほぼリアルタイムなモニタリングを行う、

搾乳ポンプ。

【請求項６１】

前記コントローラは、前記圧力対可変サイクル時間の非正弦波信号に基づき前記圧力サイクルを調整できる、請求項６０に記載のポンプ。

【請求項６２】

乳房から母乳を絞り出す搾乳ポンプシステムであって、

圧力を生成する排気容積部と空気穴とを有する圧力源と、

前記乳房を受容し、前記圧力を前記乳房に印加するように前記圧力源と流体連絡する乳房カップとを備え、前記空気穴は、所定の直径を有し、また、この空気穴は、大気と前記排気容積部と流体連絡し、前記直径は、約０．１５ｍｍから０．７５ｍｍの間である、

搾乳ポンプシステム。

【請求項６３】

前記直径は、約０．２５ｍｍから０．５ｍｍの間である、請求項６２に記載のシステム。

【請求項６４】

前記直径は、約０．３ｍｍである、請求項６２に記載のシステム。

【請求項６５】

乳房から母乳を絞り出す方法であって、

真空工程の間、圧力源から前記乳房に負圧を印加することと、

マッサージ工程の間、前記圧力源から前記乳房に陽圧を印加することと、

前記真空工程の間、前記圧力源に大気から空気を供給することと、

を備える、方法。

【請求項６６】

前記真空工程の間、前記圧力源に大気から空気を供給する前記ステップは、前記圧力源および前記大気と流体連絡する空気穴を設けることを備え、前記空気穴は、約０．１５ｍｍから０．７５ｍｍの間の直径を有する、請求項６５に記載の方法。

【請求項６７】

乳首を有する乳房から母乳を絞り出す方法であって、

少なくとも前記乳首の一部に負圧を印加し、前記乳首を横方向に沿って広げさせることを備える、方法。

【請求項６８】

前記負圧により、前記乳首が軸方向に沿って伸びる以上に前記横方向に沿って前記乳首を広げさせる、請求項６７に記載の方法。

【請求項６９】

前記負圧は、負圧工程の間、平均横方向成分と平均軸方向成分とを有し、前記平均横方向成分は、前記平均軸方向成分よりも大きい、請求項６７に記載の方法。

【請求項７０】

乳房から母乳を絞り出す方法であって、

前記乳房に圧力を印加することと、

コントローラで前記圧力のほぼリアルタイムなモニタリングおよび制御を行うことと、

を備える、方法。

【請求項７１】

前記圧力は、移動可能な構造体の可変圧力または前記移動可能な構造体の可変サイクル時間に基づき幾分制御され、前記コントローラは、前記移動可能な構造体によって進められる移動量に基づき前記圧力を調整する、または、前記移動可能な構造体の速度に基づき前記可変サイクル時間を調整し、前記コントローラは、進められた前記移動量または前記速度のほぼリアルタイムなモニタリングを行う、請求項７０に記載の方法。

【請求項７２】

前記コントローラは、前記圧力対可変サイクル時間の非正弦波信号に基づき前記圧力を調整する、請求項７０に記載の方法。

【請求項７３】

圧力を供給するポンプであって、

容積部を規定し、圧力排出装置を有するハウジングと、
前記容積部内に前記圧力を生成するように前記ハウジングに動作的に接続されたアクチュエータと、
前記ハウジングに接続されたインサートとを備え、このインサートは、インサートを通るように配置されている穴を有し、この穴は、前記容積部と大気との間の流体連絡をもたらす、
ポンプ。
【請求項７４】
前記ハウジングは、第１の材料でできており、前記インサートは第２の材料でできている、請求項７３に記載のポンプ。
【請求項７５】
前記ハウジングは、プラスチックでできており、前記インサートは金属でできている、請求項７４に記載のポンプ。
【請求項７６】
前記ハウジングは、シリンダであり、前記アクチュエータは、ピストンである、請求項７３に記載のポンプ。
【請求項７７】
前記シリンダは、オリフィスを有し、前記インサートは、このオリフィス内に配置されている、請求項７６に記載のポンプ。
【請求項７８】
前記インサートは、前記オリフィス内にプレス嵌合されている、請求項７７に記載のポンプ。
【請求項７９】
前記インサートは、複数のインサートであり、前記複数のインサートの各々は、前記シリンダと選択的に係合可能である、請求項７６に記載のポンプ。
【請求項８０】
前記インサートは、複数のインサートであり、前記複数のインサートの各々は、前記オリフィスと選択的に係合可能である、請求項７７に記載のポンプ。
【請求項８１】
第１の容器と第２の容器と流体連絡して乳房に当てる乳房カップであって、前記第１の容器および第２の容器は、異なる直径を持つ開口を有し、乳房カップは、
前記乳房を受容するじょうご形体と、
前記じょうご形体に接続され、ベースを有するハウジングとを備え、前記ベースは、周方向壁と、開口を規定するために前記周方向壁から内方に延出するフランジと、第１のねじ山と、第２のねじ山とを有し、
前記第１のねじ山は、第１の直径と第１のピッチとを有し、これら第１の直径および前記第１のピッチは、前記第１の容器との選択的係合を可能にし、前記第２のねじ山は、第２の直径と第２のピッチとを有し、これら第２の直径および前記第２のピッチは、前記第２の容器との選択的係合を可能にし、前記第１のねじ山と第２のねじ山とは、前記ベースに沿って同軸を有するように配置されている、乳房カップ。
【請求項８２】
前記第１のピッチは、前記第２のピッチに等しい、請求項８１に記載の乳房カップ。
【請求項８３】
前記第１のねじ山は、前記フランジから延出し、前記第２のねじ山は、前記周方向壁に配置されている、請求項８１に記載の乳房カップ。
【請求項８４】
前記じょうご形体は、前記ハウジングから選択的に除去可能である、請求項８１に記載の乳房カップ。
【請求項８５】
第１の容器および第２の容器を哺乳瓶の乳首に係合する、哺乳瓶の乳首リングであって

、これら第１の容器および第２の容器は、異なる直径を持つ開口を有し、この哺乳瓶の乳首リングは、
周方向壁と、開口を規定するために前記周方向壁から内方に延出するフランジと、第１のねじ山と、第２のねじ山とを有する、本体を備え、
前記第１のねじ山は、第１の直径と第１のピッチとを有し、これら第１の直径および前記第１のピッチは、前記第１の容器との選択的係合を可能にし、前記第２のねじ山は、第２の直径と前記第２のピッチとを有し、これら第２の直径および前記第２のピッチは、前記第２の容器との選択的係合を可能にし、前記第１のねじ山と前記第２のねじ山とは、前記本体に沿って同軸を有するように配置されている、哺乳瓶の乳首リング。
【請求項８６】
前記第１のピッチは、前記第２のピッチに等しい、請求項８５に記載の哺乳瓶の乳首リング。
【請求項８７】
前記第１のねじ山は、前記フランジから延出し、前記第２のねじ山は、前記周方向壁に配置されている、請求項８５に記載の哺乳瓶の乳首リング。
【請求項８８】
第１の容器と第２の容器とに係合するキャップであって、これら第１の容器および第２の容器は、異なる直径を持つ開口を有し、このキャップは、
周方向壁と、前記周方向壁に接続された頂部壁と、第１のねじ山と、第２のねじ山とを有する、本体を備え、
前記第１のねじ山は、第１の直径と第１のピッチとを有し、これら第１の直径および前記第１のピッチは、前記第１の容器との選択的係合を可能にし、前記第２のねじ山は、第２の直径と第２のピッチとを有し、これら第２の直径および前記第２のピッチは、前記第２の容器との選択的係合を可能にし、前記第１のねじ山と前記第２のねじ山とは、前記本体に沿って同軸を有するように配置されている、キャップ。
【請求項８９】
前記第１のピッチは、前記第２のピッチに等しい、請求項８８に記載のキャップ。
【請求項９０】
前記第１のねじ山は、前記フランジから延出し、前記第２のねじ山は、前記周方向壁に配置されている、請求項８８に記載のキャップ。
【発明の詳細な説明】
【技術分野】
【０００１】
本発明は、母乳を得る装置および方法に関する。より詳細には、本発明は、母乳を絞り出すために乳房に陽圧または負圧を印加可能な搾乳ポンプシステムに関する。
【背景技術】
【０００２】
手動および自動の両方で、母乳を得る搾乳ポンプシステムは、技術上周知である。従来のシステムは、乳房に当てられる乳房フードまたはカップに管を介して送られる、負圧または真空を生成するために真空源を使用する。この従来の装置および方法は、母乳を絞り出すために乳房に負圧を使用する。
【０００３】
上述のシステムは、母乳の絞り出しを誘発するために、負圧として真空源だけを乳房に印加するという欠点をもつ。その上、上述の従来のシステムは、乳首に軸方向に負圧または負の力を印加するという欠点をもち、母乳の絞り出しに不快で、かつ、不十分な軸方向での乳首の伸張および膨張という結果になる。
【発明の開示】
【発明が解決しようとする課題】
【０００４】
本発明の目的は、母乳を絞り出すために陽圧または負圧を乳房に印加可能な、母乳を絞

り出す搾乳ポンプシステムを提供することである。
【０００５】
本発明の別の目的は、単一の源から陽圧と負圧とを供給する上述のシステムを提供することである。
【０００６】
本発明のさらに別の目的は、乳房に印加される陽圧と負圧との制御を容易にする上述のシステムを提供することである。
【０００７】
本発明のさらなる別の目的は、乳汁を絞り出すために、乳首を広げる上述のシステムを提供することである。
【０００８】
本発明の別の目的は、乳首の軸方向の伸張または膨張を減少する上述のシステムを提供することである。
【０００９】
本発明の別のさらなる目的は、軸方向成分に比べてより大きい横方向成分を有する、負の力または負圧勾配を乳首に印加することである。
【００１０】
本発明のさらに別の目的は、異なるサイズおよび／または形状の互換性のある乳房フードを持つキットを提供することによって、異なるサイズおよび／または形状の乳房を収容することである。
【００１１】
本発明のさらに別の目的は、リアルタイムで圧力源を実質的にモニタして、制御することである。
【００１２】
本発明の以上および他の目的および利点は、乳房を受容するフードを有し、圧力源と流体連絡する乳房カップによってもたらされる。フードは、負圧工程の間、乳首への負の力を生成する。負の力は、横方向成分と軸方向成分とを有する。横方向成分は、軸方向成分よりも大きい。
【課題を解決するための手段】
【００１３】
本発明は、真空源と流体連絡する乳房受容部材を有する、乳房カップを含む。乳房受容部材は、負圧工程の間乳首に負圧を印加し、乳首を横方向に沿って広げさせる。
【００１４】
本発明は、圧力源と、乳房を受容する乳房カップとを有する、搾乳ポンプシステムを含む。乳房カップは、圧力源と流体連絡する。乳房カップは、負圧工程の間乳首への負の力を生成する。負の力は、横方向成分と軸方向成分とを有する。横方向成分は軸方向成分よりも大きい。
【００１５】
本発明は、真空源と、その真空源と流体連絡する乳房受容部材とを有する、搾乳ポンプシステムを含む。乳房受容部材は、負圧工程の間乳首に負圧を印加し、乳首を横方向に沿って広げさせる。
【００１６】
本発明は、ホルダと乳房を受容する複数のフードとを有する、搾乳ポンプキットを含む。複数のフードの各々は、ホルダと乳房から母乳を絞り出すための圧力源とに、選択的に係合可能である。複数のフードの少なくとも１つは、複数のフードの他のものに比べて異なるサイズまたは異なる形状を有する。
【００１７】
本発明は、圧力を生成するポンプと、乳房を受容する複数のフードとを有する、搾乳ポンプシステムを含む。複数のフードの各々は、乳房から母乳を絞り出すポンプに選択的に、流動的に接続可能である。複数のフードの少なくとも１つは、複数のフードの他のもの

に比べて異なるサイズまたは異なる形状を有する。

【００１８】

本発明は、圧力工程の間圧力を生成する移動可能な構造体を持つ圧力源を有する搾乳ポンプを含む。移動可能な構造体は、可変圧力または可変サイクル時間とを有する。ポンプは、さらに、圧力源に動作的に接続されるコントローラを有する。コントローラは、移動可能な構造体によって進められる移動量に基づき圧力を調整する、または、移動可能な構造体の速度に基づき可変サイクル時間を調整する。コントローラは、進められる移動量または速度のほぼリアルタイムなモニタリングを行う。

【００１９】

本発明は、圧力を生成する排気容積部を持つ圧力源と、空気穴とを有する搾乳ポンプシステムを含む。システムは、乳房を受容し、圧力を乳房に印加する圧力源と流体連絡する乳房カップをさらに有する。空気穴は、直径を有し、大気と排気容積部と流体連絡する。空気穴の直径は、約０．１５ｍｍから０．７５ｍｍとの間である。

【００２０】

本発明は、真空工程の間圧力源から乳房に負圧を印加することと、マッサージ工程の間圧力源から乳房に陽圧を印加することと、真空工程の間圧力源に大気から空気を供給することと、の各ステップを有する、乳房から母乳を絞り出す方法を含む。

【００２１】

本発明は、少なくとも乳首の部分に負圧を印加し、乳首を横方向に沿って広げさせるステップを有する、乳房から母乳を絞り出す方法を含む。

【００２２】

本発明は、乳房に圧力を印加することと、コントローラで前記圧力のほぼリアルタイムなモニタリングおよび制御を行うことと、の各ステップとを有する、乳房から母乳を絞り出す方法を含む。

【００２３】

本発明は、ハウジングと、アクチュエータと、インサートとを有する、圧力を供給するポンプを含む。ハウジングは、容積部を規定し、圧力排出装置を有する。アクチュエータは、容積部内に圧力を生成するハウジングに動作的に接続されている。インサートは、ハウジングに接続されている。インサートは、それを通って配置されている穴を有する。穴は、容積部と大気との間の流体連絡をもたらす。

【００２４】

本発明は、異なる直径を持つ開口を有する第１の容器と第２の容器と流体連絡して乳房に当てる乳房カップを含む。乳房カップは、乳房を受容するじょうご形体と、そのじょうご形体に接続されているハウジングとを有する。じょうご形体は、ベースを有する。ベースは、周方向壁と、開口を規定するために周方向壁から内方に延出するフランジと、第１のねじ山と、第２のねじ山とを有する。第１のねじ山は、第１の直径と第１のピッチとを有する。第１の直径および第１のピッチは、第１の容器との選択的係合を可能にする。第２のねじ山は、第２の直径と第２のピッチとを有する。第２の直径および第２のピッチは、第２の容器との選択的係合を可能にする。第１のねじ山および第２のねじ山は、ベースに沿って同軸を有するように配置されている。

【００２５】

本発明は、異なる直径を持つ開口を有する第１の容器および第２の容器を哺乳瓶の乳首に係合する、哺乳瓶の乳首リングを含む。哺乳瓶の乳首リングは、周方向壁と、開口を規定するためにその周方向壁から内方に延出するフランジと、第１のねじ山と、第２のねじ山とを有する、本体を有する。第１のねじ山は、第１の直径と第１のピッチとを有する。第１の直径および第１のピッチは、第１の容器との選択的係合を可能にする。第２のねじ山は、第２の直径と第２のピッチとを有する。第２の直径および第２のピッチは、第２の容器との選択的係合を可能にする。第１のねじ山および第２のねじ山は、本体に沿って同軸を有するように配置されている。

【００２６】

本発明は、異なる直径を持つ開口を有する第１の容器および第２の容器と係合するキャップを含む。キャップは、周方向壁と、その周方向壁に接続されている頂部壁と、第１のねじ山と、第２のねじ山とを持つ、本体を有する。第１のねじ山は、第１の直径と第１のピッチとを有する。第１の直径および第１のピッチは、第１の容器との選択的係合を可能にする。第２のねじ山は、第２の直径と第２のピッチとを有する。第２の直径および第２のピッチは、第２の容器との選択的係合を可能にする。第１のねじ山および第２のねじ山は、本体に沿って同軸を有するように配置されている。

【００２７】

第１のピッチは、第２のピッチに等しくてよい。第１のねじ山は、フランジから延出可能である。第２のねじ山は、周方向壁に配置可能である。じょうご形体は、ハウジングから選択的に除去可能である。

【００２８】

ハウジングは第１の材料であってよく、インサートは第２の材料であってよい。ハウジングはプラスチックであってよく、インサートは金属であってよい。ハウジングはシリンダであってよく、アクチュエータはピストンであってよい。シリンダはオリフィスであってよく、インサートはそのオリフィス内に配置可能である。インサートは、オリフィス内にプレス嵌合可能である。インサートは、複数のインサートであり、複数のインサートの各々は、シリンダと選択的に係合可能である。

【００２９】

乳房カップは、さらに、フードに動作的に接続されているバリア部材を有し、そのバリア部材は、負圧工程の間負の力の軸方向成分を減少する。フードは、ハウジングと、そのハウジングに密閉固定されている柔軟なインサートと、ハウジングと柔軟なインサートとの間に形成されている排気容積部とを有することが可能であり、その排気容積部は、圧力源と流体連絡する。排気容積部は、乳房がフードに受容されるとき乳首をほぼ包囲可能である。柔軟なインサートは、圧力源と流体連絡する空気袋を有することが可能であり、排気容積部は、少なくとも部分的にその空気袋によって規定されている。空気袋および排気容積部は、負圧工程の間乳首への負の力を形成するように収縮させることが可能である。

【００３０】

乳房カップは、さらに、空気袋にほぼ隣接して配置されているバリア部材を有し、それによって、乳房が空気袋に接触することを防止する。柔軟なインサートは、乳房を受容する内側容積部を規定することが可能であり、バリア部材は、円筒形状を有し、内側容積部に配置可能である。柔軟なインサートは、これの上に形成されたマッサージ突起を持つじょうご形状を有することが可能である。マッサージ突起は、星形状を有する。

【００３１】

乳房カップに生成される負圧により、乳首が軸方向に沿って伸びる以上に横方向に沿って沿って乳首を広げさせることが可能である。負圧は、平均横方向成分と平均軸方向成分とを有することが可能であり、負圧工程の間、平均横方向成分は、平均軸方向成分よりも大きい。バリア部材は、乳房受容部材に動作的に接続可能であり、負圧工程の間軸方向に沿う乳首の伸張を減少することが可能である。乳房受容部材は、ハウジングと、そのハウジングに密閉固定されている柔軟なインサートと、ハウジングと柔軟なインサートとの間に形成されている排気容積部とを有することが可能であり、その排気容積部は、真空源と流体連絡する。

【００３２】

真空源または圧力源は、シリンダ内に移動可能に配置されているピストンであってよい。システムは、そのピストンに動作的に接続されている可逆モータを有することが可能である。システムは、さらに、第１の歯を有するラックと、第２の歯を有するギヤを有することが可能である。ラックは、ピストンに接続可能であり、ギヤは、可逆モータに動作的に接続可能である。第１の歯は、第２の歯と係合可能であり、シリンダ内でピストンを往復移動させる。シリンダは、第１の直径と空気穴とを有することが可能である。空気穴は、第２の直径を有して、大気と流体連絡することが可能である。シリンダの第１の直径は

、空気穴の第２の直径よりもかなり大きくてよい。

【００３３】

システムは、可逆モータに動作的に接続されているコントローラを有することが可能である。コントローラは、ピストンがシリンダに対して進んだ移動量を測定することが可能である。コントローラは、少なくとも部分的にその移動量に基づきモータを逆転させることが可能である。システムは、さらに、可変速度を持つモータを有することが可能である。コントローラは、乳房に負圧を印加する所望のサイクル時間に基づき速度を調節することが可能である。コントローラは、圧力対可変サイクル時間の非正弦波信号に基づき圧力サイクルを調整することが可能である。

【００３４】

キットの複数のフードの各々は、ハウジングと、そのハウジングに密閉固定されている柔軟なインサートと、ハウジングと柔軟なインサートとの間に形成されて、圧力源と流体連絡する排気容積部とを有することが可能である。複数のフードのうち少なくとも１つのハウジングおよび／または柔軟なインサートは、ハウジングおよび／または複数のフードのうち他のものの柔軟なインサートに比べて、異なるサイズまたは異なる形状を有することが可能である。キットは、さらに、容器を有することが可能であり、ホルダは、その容器と選択的に係合可能である。ホルダは、複数の異なるサイズの容器に選択的に係合するために複数の係合構造を有することが可能である。複数のフードのうち少なくとも１つの柔軟なインサートは、第１のマッサージ突起を有することが可能であり、複数のフードのうち他のものの柔軟なインサートは、第２のマッサージ突起を有することが可能である。第１のマッサージ突起および第２のマッサージ突起は、異なるサイズまたは異なる形状を有することが可能である。

【００３５】

本発明のこれ以外の、さらなる目的、利点および特徴は、以下を参照することにより理解されるであろう。

【発明を実施するための最良の形態】

【００３６】

図面、特に、図１と図２とを参照すると、全体として参照符号１００で表わされている本発明の搾乳ポンプが示されている。この搾乳ポンプ１００は、図１１に示されている乳房カップ４００と共に、本発明の搾乳ポンプシステムの重要構成要素を形成している。搾乳ポンプ１００は、組立ユニットを形成するように構成されている頂部ハウジング１０２と底部ハウジング１０３とを有する。

【００３７】

図１から図３を参照すると、頂部ハウジング１０２は、平坦な前部面２００と区画ドア１０４を有する貯蔵区画２１０とを持つ、ほぼ楕円の形状を有する。ドア１０４は、搾乳ポンプ１００をシステムの他の構成要素に接続する空気管または導管３５０を貯蔵するために、選択的に密閉可能な貯蔵区画２１０を形成するように、頂部ハウジング１０２にヒンジ式に接続されることが好ましく、このことについては、以下により詳細に論じる。

【００３８】

面２００は、ＬＥＤカバー１０６を有するボタンパッド１０５を受容することができる。パッド１０５は、搾乳ポンプ１００を制御するために消費者によって使用される。底部ハウジング１０３は、搾乳ポンプの様々な構成要素を確実に収容することが可能であり、ラックギヤ１０９と、ラックギヤに係合可能なピニオンギヤ１１０と、ピストン１１２と、ピストンを受容可能なシリンダ１１３と、ピニオンギヤが取り付けられるシャフト１２６を有するモータ１２５とを含む。ある程度この設計により、搾乳ポンプ１００は、低騒音のポンプ吸い出しをもたらす。搾乳ポンプ１００は、例えば、プラスチックなどのあらゆる剛性材料で作られることが可能である。

【００３９】

図３から図７を参照すると、搾乳ポンプ１００は、母乳を得るために陽圧と負圧との両方を生成するためにピストン１１２とシリンダ１１３とを利用している。このピストン１

１２は、これに固定されているラックギヤ１０９によって駆動される。ピストン１１２は、第１のヘッド３０００と第２のヘッド３１００とを持つほぼ円筒の形状を有する。第１のヘッド３０００および第２のヘッド３１００は、各々、中に形成されている環状チャネル３０２０、３１２０を有することが好ましい。チャネル３０２０、３１２０は、各々、第１のヘッド３０００と第２のヘッド３１００との外側周辺に沿って配置されている。チャネル３０２０、３１２０は、第１のヘッド３０００と第２のヘッド３１００との外側周辺に沿って中心に位置されていることが好ましい。チャネル３０２０、３１２０内に着座されているのは、各々に、密閉部材３０５０、３１５０である。密閉部材３０５０、３１５０は、Ｏ－リングガスケットであることが好ましい。密閉部材３０５０、３１５０は、チャネル３０２０とチャネル３１２０との深さまたは高さよりも大きい直径または幅を有する。密閉部材３０５０、３１５０は、第１のヘッド３０００と第２のヘッド３１００の外側周辺を越えて延在し、ピストン１１２がシリンダ内を往復して駆動されるときシリンダ１１３の内部表面１３０との密閉係合を形成している。

【００４０】

複数の密閉部材、すなわち、ピストン１１２へのＯ－リングガスケット３０５０とＯ－リングガスケット３１５０との使用により、ダブル密閉をもたらし、陽圧と負圧とを生成する効果を増大する。この実施形態が、２つの独立した密閉表面を生成するために２つの密閉部材を使用するのに対して、かなり多数の密閉部材が、ピストン１１２をシリンダ１１３と密閉するかなり多数の密閉表面を生成するのに使用可能である。加えて、この実施形態が、Ｏ－リング密閉ガスケット３０５０、３１５０を有するピストン１１２を使用するのに対して、別の密閉構造が、ピストンとシリンダ１１３との間に使用可能である。

【００４１】

ラックギヤ１０９は、歯１１００を有するピニオンギヤ１１０と係合する歯１０９０を有する。ピニオンギヤ１１０は、好ましくは、シャフト１２６によってモータ１２５に機能的に接続されている。モータ１２５が始動されるとき、シャフト１２６およびピニオンギヤ１１０は、回転する。ラック１０９の歯１０９０およびピニオン１１０の歯１１００は、噛み合い、モータ１２５とシャフト１２６との相互の回転運動を、両方向に単一軸に沿う相互の長手方向運動に変換する。

【００４２】

ラックギヤ１０９は、ピストン１１２内に形成されている凹部３２００と係合する第１の端部１０９５を有することが好ましい。凹部３２００は、ピストン１１２において中心に位置されることが好ましい。ラックギヤ１０９の第１の端部１０９５は、ピストン１１２の凹部３２００とのスナップ嵌合係合または摩擦嵌合係合を有することが好ましい。各々に、第１の端部１０９５および凹部３２００に形成されているデテント構造１０９６、３２９６があることが好ましい。これにより、これら構成要素の製造を容易にし、さらに、ラックギヤ１０９に対してピストン１１２に必要とされる場合がある、わずかなピボットのような動きをもたらす。

【００４３】

ピストンの別の方法の実施形態が図８に示され、全体として参照符号８１１２で表わされている。ピストン８１１２は、前縁８１２０と後縁８１２１とを持つほぼＶ字の形状を有する。前縁８１２０および後縁８１２１は、ピストン８１１２がシリンダ内を往復して駆動されるとき、シリンダ１１３の内部表面１１３０に密閉係合している。複数の縁、すなわち、シリンダ１１３の内部表面１１３０に密閉係合するピストン８１１２の前縁８１２０と追従縁８１２１の使用により、ダブル密閉をもたらし、陽圧と負圧とを生成する効果を増大する。

【００４４】

図３から図７を参照すると、モータ１２５は、可変速度であることが好ましい。これにより、使用者が乳房のポンプ吸い出しのサイクル時間を制御して変えることを可能にする。搾乳ポンプ１００は、さらに、振動を減少して、底部ハウジング１０３にモータ１２５を固定するために、モータカバー１０７とベアリング１０８とを有する。

【００４５】
陽圧および負圧は、シリンダ１１３の排気量を変更することによって変えられることが可能である。この実施形態では、これは、光電子または光センサシステムの使用によって行われる。光センサシステムは、２つ以上の光センサ１２１と位置スイッチ１２４とを有する。光センサ１２１は、ラックギヤが往復して移動するとき、ラックギヤ１０９の開口５０の数をカウントする。したがって、使用者は、ラックギヤ１０９が進む移動量を制御することが可能であり、相応じて、シリンダ１１３内の排気量を制御することが可能である。例えば、ホイール上のスロットをカウントするコード化したホイール、ベルトの歯のカウント、これ自体の回転をカウントするロータリーエンコーダ、または、ホール効果センサなどの、別の排気量または移動量モニタがさらに使用可能である。

【００４６】
ピストン１１２がシリンダ１１３の前に適切に移動することを確実にするために、光センサシステムは、さらに、シリンダの前に位置されることが好ましい、カウンタ用スタータとして機能する位置スイッチ１２４を含む。別の方法として、この位置スイッチは、光センサ１２１によって探知可能な異なるサイズまたは形状を有する開口５０であってよい。

【００４７】
ラックギヤ１０９は、さらに、それに取り付けられる安全メカニズムを有することが可能である。光センサ１２１は、ラックギヤ１０９が後方に移動するとき開口５０を読み取り続ける。なんらかの理由のために、ラックギヤ１０９がターゲットを見失い、はるか遠くに移動する場合、安全装置が、位置スイッチを起動する。ラックギヤ１０９が後方に移動する間に位置スイッチが起動されるとき、ソフトウェアが、再度前方に移動して、位置決め位置に戻るように、そのシステムを起動することが可能である。

【００４８】
搾乳ポンプ１００は、ラックギヤ１０９全体にわたり位置決めされているガイドカバー１１１を有する。ガイドカバー１１１は、ラックギヤ１０９の相互の動きをガイドして、消振することによって、搾乳ポンプに安全性を追加する。ガイドカバー１１１は、さらに、光センサ１２１と開口５０との整列不良のリスクを減少することによって、光センサシステムに精度をもたらす。

【００４９】
光センサシステムおよびモータ１２５は、ＰＣまたは回路基板１２０に接続されることが好ましい。したがって、陽圧および負圧の量に応じて変換するピストン１１２の移動量、およびサイクル時間に応じて変換するピストン速度は、電子的に制御される。

【００５０】
図１５から図１９を参照すると、本発明の駆動システムの好ましい実施形態が示され、全体として参照符号１５００で表わされている。駆動システム１５００は、図１から図７の搾乳ポンプ１００と共に使用可能であり、シリンダ１１３とのピストン１１２の線形の相互の動きをもたらす。

【００５１】
駆動システム１５００は、中に組み込まれるギヤ減速を有するラックおよびピニオン駆動のためのベルト駆動システムである。駆動システム１５００は、第１の駆動ホイールまたはプーリ１５１０と、第１の駆動ホイール１５１０に固定されている第２のギヤ、駆動ホイールまたはプーリ１５２０と、第３のギヤ、駆動ホイールまたはプーリ４５３０と、第３のギヤに固定されているピニオンギヤ１５４０とを有する。

【００５２】
第１の駆動ホイール１５１０は、第１のベルト１５５０によってモータ駆動シャフト１２６に動作的に接続されている。好ましい実施形態では、第１のベルト１５５０は、歯形のないベルトである。第１のベルト１５５０は、弾力性または柔軟性を有することがより好ましい。柔軟性または弾力性のあるベルト１５５０の使用により、駆動シャフト１２６と第１の駆動ホイール１５１０との間の確実な接続をもたらし、さらに、騒音と振動とを

減少する。駆動シャフト１２６および第１の駆動ホイール１５１０は、円滑な外側表面を有し、これの上に第１のベルト１５５０は固定されている。

【００５３】

第１の駆動ホイール１５１０は、第１の同軸シャフト１５１５によって第２のギヤ１５２０に動作的に接続されている。好ましい実施形態では、第１のシャフト１５１５は、対向する第１のベアリング１５１７間に回転可能に取り付けられる。しかしながら、別の方法の回転可能な取付構成または固定構造も使用可能である。騒音と振動とを減少するために、モータシャフト１２６および第１の駆動ホイール１５１０は、金属で作られる。第１の駆動ホイール１５１０および第２のギヤ１５２０は、モータシャフト１２６とピニオンギヤ１５４０との間のギヤ減速を部分的にもたらす異なる直径を有する。

【００５４】

第２のギヤ１５２０は、第２のベルト１５７０によって第３のギヤ１５３０に動作的に接続されている。第２のベルト１５７０は、第２のギヤ１５２０と第３のギヤ１５３０との周辺に沿って形成されている歯１５８０と噛み合う、歯１５７５を有することが好ましい。第２のギヤ１５２０および第３のギヤ１５３０は、モータシャフト１２６とピニオンギヤ１５４０との間にギヤ減速を部分的にもたらす異なる直径を有する。駆動システム１５００は、さらに、第２のベルト１５７０に引張りをもたらす引張りプーリ１５８０を有することが可能である。

【００５５】

第３のギヤ１５３０は、第２の同軸シャフト１５３５によってピニオンギヤ１５４０に動作的に接続されている。好ましい実施形態では、第２のシャフト１５３５は、対向する第２のベアリング１５３７間に回転可能に取り付けられる。しかしながら、別の方法の回転可能な取り付け構成または固定構造も使用可能である。第３のギヤ１５３０は、第２のシャフト１５３５に沿うピニオンギヤ１５４０と一体化して成形されることが好ましい。

【００５６】

ピニオンギヤ１５４０は、ラックギヤ１０９の歯１０９０と係合する歯１５４５を有する。モータ１２５が始動されるとき、シャフト１２６の回転運動は、両方向にラックギヤ１０９の単一軸に沿う相互の長手方向運動に変換される。駆動システム１５００は、第１のベルト１５５０と、第２のベルト１５７０と、第１の駆動ホイールまたはギヤ１５１０と、第２の駆動ホイールまたはギヤ１５２０と、第３の駆動ホイールまたはギヤ１５３０との使用を介して、モータシャフト１２６とピニオンギヤ１５４０との間の動きの所望の割合、すなわち、ギヤ減速をもたらすことができる。

【００５７】

歯形のないベルト１５５０と歯形ベルト１５７０との組合せの使用により、騒音と振動とを減少すると同時に、搾乳ポンプ１００のための所望の速度と圧力とで、必要な往復の線形運動をもたらすことができる確実で、丈夫な駆動システム１５００を維持する。

【００５８】

図２０から図２６を参照すると、本発明の駆動システムの別の方法の実施形態が示され、全体として参照符号４５００で表わされている。駆動システム４５００は、図１から図７の搾乳ポンプ１００と共に使用可能であり、シリンダ１１３とのピストン１１２の線形の相互の動きをもたらす。

【００５９】

駆動システム４５００は、中に組み込まれるギヤ減速を有するベルト駆動システムである。駆動システム４５００は、第１のギヤ、駆動ホイール、またはプーリ４５１０と、第１のギヤに固定されている第２のギヤ、駆動ホイールまたはプーリ４５２０と、第３のギヤ、駆動ホイールまたはプーリ４５３０と、第３のギヤに固定されているピニオンギヤ４５４０とを有する。

【００６０】

第１のギヤ４５１０は、第１のベルト４５５０によってモータ駆動シャフト１２６に動作的に接続されている。好ましい実施形態では、第１のベルト４５５０は複数のベルトで

あり、３つのベルトであることがより好ましい。第１のベルト４５５０は、歯形のないベルトであることが好ましい。第１のベルト４５５０は、弾力性または柔軟性を有するＯ－リングであることがより好ましい。例えば、Ｏ－リングなどの柔軟な、または弾力性のあるベルト４５５０の使用により、駆動シャフト１２６と第１のギヤ４５１０との間の確実な接続をもたらし、さらに、騒音と振動とを減少する。駆動シャフト１２６および第１のギヤ４５１０は、各々に、中に形成されている環状のチャネル４５５５、４５６０を有する。環状のチャネル４５５５、４５６０は、第１のベルト４５５０を適所に保持するのを助け、駆動システム４５００のアセンブリを容易にするガイドである。

【００６１】

第１のギヤ４５１０は、第１の同軸シャフト４５１５によって第２のギヤ４５２０に動作的に接続されている。この別の方法の実施形態では、第１のシャフト４５１５は、対向する第１のベアリング４５１７間に回転可能に取り付けられる。しかしながら、別の方法の回転可能な取付構成または固定構造も使用可能である。騒音と振動とを減少するために、モータシャフト１２６および第１のギヤ４５１０は、金属で作られる。第１のギヤ４５１０および第２のギヤ４５２０は、モータシャフト１２６とピニオンギヤ４５４０との間にギヤ減速を部分的にもたらす異なる直径を有する。

【００６２】

第２のギヤ４５２０は、第２のベルト４５７０によって第３のギヤ４５３０に動作的に接続されている。この第２のベルト４５７０は、第２のギヤ４５２０と第３のギヤ４５３０との周辺に沿って形成されている歯４５８０と噛み合っている、歯４５７５を有することが好ましい。第２のギヤ４５２０および第３のギヤ４５３０は、モータシャフト１２６とピニオンギヤ４５４０との間にギヤ減速を部分的にもたらす異なる直径を有する。駆動システム４５００は、さらに、第２のベルト４５７０に引張りをもたらす引張りプーリ４５８０を有することが可能である。

【００６３】

第３のギヤ４５３０は、第２の同軸シャフト４５３５によってピニオンギヤ４５４０に動作的に接続されている。この別の方法の実施形態では、第２のシャフト４５３５は、対向する第２のベアリング４５３７間に回転可能に取り付けられる。しかしながら、別の方法の回転可能な取り付け構成または固定構造も使用可能である。第３のギヤ４５３０は、第２のシャフト４５３５に沿うピニオンギヤ４５４０と一体化して成形されることが好ましい。

【００６４】

ピニオンギヤ４５４０は、ラックギヤ１０９の歯１０９０と係合する歯４５４５を有する。モータ１２５が始動されるとき、シャフト１２６の回転運動は、両方向にラックギヤ１０９の単一軸に沿う相互の長手方向運動に変換される。駆動システム４５００は、第１のベルト４５５０と、第２のベルト４５７０と、第１のギヤ４５１０と、第２のギヤ４５２０と、第３のギヤ４５３０との使用を介して、モータシャフト１２６とピニオンギヤ４５４０との間の動きの所望の割合、すなわち、ギヤ減速をもたらすことができる。

【００６５】

歯形のないＯ－リングベルト４５５０と歯形ベルト４５７０との組合せの使用により、騒音と振動とを減少すると同時に、搾乳ポンプ１００のための所望の速度と圧力とで、必要な往復の線形運動をもたらすことができる、確実で丈夫な駆動システム４５００を維持する。

【００６６】

上記に説明されている駆動システム１５００、４５００の実施形態は、ギヤ減速のためにベルトを利用する。しかしながら、別の方法の実施形態は、搾乳ポンプ１００を駆動するラックおよびピニオンギヤ装置に伝達される所望の割合にギヤ装置を減速する、ギヤボックスを使用することが可能である。

【００６７】

図３から図９を参照すると、シリンダ１１３は、乳房カップ４００に陽圧と負圧とを供

給する供給コネクタ１１５に固定されている供給チューブ１１６を有する。供給コネクタは、貯蔵区画２１０に配置されている出口２１５を有することが好ましい。空気管３５０は、出口２１５に固定され、さらに、乳房カップ４００に固定可能である。貯蔵区画２１０は、ポンプ吸い出し操作の間、開口または閉鎖可能である。シリンダ１１３は、約１．５ｉｎ．Ｈｇに設定されることが好ましい圧力リリーフバルブ２０００（図９に図示）と流体連絡する。

【００６８】

圧力リリーフバルブ２０００は、取り入れ口２０１０と排気装置２０５０とを有する。取り入れ口２０１０は、シリンダ１１３と流体連絡し、排気装置２０５０は、管３５０によって、乳房カップ４００と流体連絡する。圧力リリーフバルブ２０００は、取り入れ口２０１０と排気装置２０５０と流体連絡するリリーフ排気装置２１００を有する。リリーフ排気装置２１００は、ほぼ管状であり、リリーフアセンブリ２２００に固定されている。

【００６９】

リリーフアセンブリ２２００は、柔軟なインサート２２１０と、付勢部材２２２０と、保持部材２２３０とを有する。柔軟なインサート２２１０は、リリーフ排気装置２１００の内部表面と密閉係合し、空気がリリーフ排気装置を通って抜け出ることを防止する。インサート２２１０は、付勢部材２２２０と噛み合う固定部材２２１５を有する。この実施形態では、固定部材２２１５は、付勢部材２２２０の内側容積部に受容される十字形構造である。付勢部材２２２０は、スプリングであることが好ましい。付勢部材２２２０は、コイルスプリングであることがより好ましい。保持部材２２３０は、リリーフ排気装置２１００の外側表面に位置決めされている対応する１対の係合突出部２１０５と係合する、対向する保持アーム２２３５を有するキャップ状構造である。インサート２２１０およびスプリング２２２０は、キャップ２２３０によってリリーフ排気装置２１００の内側容積部に保持されている。

【００７０】

スプリング２２２０は、圧力リリーフバルブ２０００のリリーフ圧力に等しい付勢強度または抵抗を有する。陽圧が、この実施形態では約１．５ｉｎ．Ｈｇに設定されることが好ましい、リリーフ圧力を超えるとき、インサート２２１０の内部表面に生成される力が、スプリング２２２０の付勢力を圧倒し、インサートはキャップ２２３０の方へ向い、リリーフ排気装置２１００の内側容積部の外側に移動する。空気は、圧力リリーフバルブの陽圧がスプリング２２２０の付勢強度未満に減少するまで、リリーフ排気装置２１００を通って圧力リリーフバルブ２０００を抜け出て、その時にインサート２２１０は、リリーフ排気装置の内側容積部内に戻って移動し、リリーフ排気装置の内部表面に密閉係合する。

【００７１】

さらに、図３２を参照すると、圧力リリーフバルブ２０００は、インサート２２１１と付勢部材２２２１とを含む好ましいリリーフアセンブリ２２０１と共に示されている。リリーフアセンブリ２２０１は、上記に説明されているように、リリーフアセンブリ２２００のインサート２２１０とスプリング２２２０と同様に機能する。インサート２２１１は、ボールであり、付勢部材２２２１は、シリンダ形状を有する発泡体である。リリーフアセンブリ２２０１は、ボール２２１１がリリーフ排気装置２１００内でいっそう容易に組立られるのが利点である。加えて、発泡体シリンダ２２２１は、これがボール２２１１と容易に噛み合い、不変のスプリング稼働力をもたらすのでいっそう不変である。加えて、別の方法の圧力リリーフバルブが使用されることが可能であり、それは、「マッサージ強度」、すなわち、使用者の乳房への陽圧の量が制御可能であるように調節可能である。

【００７２】

図３に示されている回路基板１２０により、使用者がいくつかのレベルの速度といくつかのレベルの吸引力をプログラムすることを可能にする。この実施形態では、速度（サイクル時間）は、約４５サイクル／分（ｃｐｍ）から約７５ｃｐｍの範囲にわたる。本発明

は、速度範囲内でかなり多数の速度レベルの事前設定プログラミングを行う。レベルの数は、約２つから約８つのレベルであることが好ましい。使用者は、速度範囲内で５つのレベルの速度をプログラムすることが可能であることがより好ましい。本発明は、さらに、使用者による速度レベルのプログラミングも想定している。

【００７３】

単一の乳房カップ４００および図１５から図２１に示されている好ましい駆動システム１５００と共に使用する吸引力範囲は、約３ｉｎ．Ｈｇから約１０ｉｎ．Ｈｇであり、２つの乳房カップのためには、約３ｉｎ．Ｈｇから約８ｉｎ．Ｈｇである。単一の乳房カップ４００および図３および図４に示されているギヤボックスシステムと共に使用する吸引力範囲は、約３ｉｎ．Ｈｇから約９ｉｎ．Ｈｇであり、２つの乳房カップのためには、約３ｉｎ．Ｈｇから約８ｉｎ．Ｈｇである。本発明は、吸引力範囲内でかなり多数の吸引レベルの事前設定プログラミングを行う。レベルの数は、約２つから約８つのレベルであることが好ましい。使用者は、吸引力範囲内で５つのレベルの吸引をプログラムすることが可能であることがより好ましい。本発明は、さらに、使用者による吸引レベルのプログラミングも想定している。

【００７４】

コンピュータソフトウェアは、さらに、陽圧および負圧の量を制御するのに使用可能である。これにより、陽圧および負圧の量が、使用者用に個人化され、さらに、効率を最大にするために、ポンプ吸い出しプロセスの期間全体にわたり変えられることを可能にする。

【００７５】

搾乳ポンプ１００は、ギヤモータ１２５、ラックおよびピニオンセット１０９、１１０およびピストンシステム１１２、１１３と共に、ソフトウェア駆動型回路基板１２０によって制御されることが好ましい。ソフトウェアおよびシステムは、最大の柔軟性をもたらすように、そして、圧力曲線または「波」の変更を容易にするように設計される。ソフトウェアが、モータ１２５の速度と、ピストン１１２がシリンダ１１３内で進む移動量とを制御するので、このことは実現可能である。ピストン１１２の移動量は、圧力レベルに関連する。ソフトウェアで、速度と圧力レベルとを制御することによって、圧力曲線または「波」は、制御可能である。

【００７６】

乳児の吸引力に類似するまたは母にもっとも心地よい特定の「波」または圧力曲線であるという決定が行われると、その場合、所望の波は、タイミング（モータ速度とピストンの移動量）を変更することによって得ることが可能である。ソフトウェアの使用を介して、使用者が、使用者のための心地よさを最大にするように、長期にわたり特定の圧力曲線とその圧力曲線の変化にメモリを適用する能力を有する。

【００７７】

この実施形態では、正弦波が、搾乳ポンプ１００の制御に使用されている。これは、もっとも心地よい圧力曲線が、使用者に挟んで締め付ける感触を与える鋭い圧力の高低がなく、正弦波に類似する圧力を徐々に増加したり減少したりするものであるという推定に基づく。ピストン１１２の往復運動は、所望の正弦波に似ている。しかしながら、鋭い圧力の頂点を回避するために、ピストン１１２のタイミングは、これらの高い点でスローダウンされ、圧力は、その波の最大および最小吸引力ポイントで時間の期間の間一定に保持される。これにより、使用者にいっそう心地よい安定した正弦波を有する圧力曲線という結果になる。

【００７８】

別の方法の波も、上述の波が母によって望ましいと決定される場合、圧力曲線に使用可能である。例えば、母が鋭い頂点を持つ「鋸歯」圧力曲線を好む場合、ピストン１１２のタイミングは、単純に往復サイクルに変更されることが可能であり、ピストン１１２が方向を変更するときの一時停止を最小にする。さらに、例えば、母が、「矩形曲線」を好む場合、ピストン１１２のタイミングは、ピストンが方向を変更しようとするときピストン

の位置を保持し、次に、迅速に下方に傾斜をつけて、これが上方に戻る傾斜をつける前に再度これの位置を保持するように変更可能である。これにより、「矩形曲線」波を生成することになる。

【００７９】

ソフトウェア制御の使用により、波または圧力曲線の多数の選択をもたらす。これにより、さらに、その柔軟性が１つの搾乳ポンプ１００でのより大きい選択を変更または提供することを可能にする。対照的に、最新のポンプは、圧力曲線波を変更する柔軟性を可能にしないという欠点を有する。搾乳ポンプ１００により、圧力と速度とのサイクル間制御が可能になる。好ましい実施形態では、これは、ピストン１１２とシリンダ１１３とを組み込む線形システムに動作的に接続されている可逆可変速度モータ１２５の使用を介して行われる。したがって、最新の装置は、繰り返して特定の正弦波圧力曲線を表面上使用することが可能であるのに対して、搾乳ポンプ１００は、あらゆるタイプの波を使用して、サイクルの間その波を変更する能力を有する。

【００８０】

本発明の制御システムおよびソフトウェアは、閉ループ制御システムまたはサイクル間リアルタイム調節をもたらす。したがって、進められるピストンの移動量および速度などの制御変数のリアルタイムなモニタリングが生じる。モータおよび他の構成要素が老化して、摩耗するとき、閉ループ制御システムは、使用者によって求められる精密なサイクル時間と圧力とを与えるために、上述の有害な変化の原因となる。リアルタイムなモニタリングおよび制御により、トルクの変化にもかかわらず、単一のおよび２つのカップのポンプ吸い出しの両方のために効果的に等しい速度レベルを供給する。

【００８１】

シリンダ１１３は、圧力差穴７５を有する。圧力差穴７５は、シリンダ１１３の底部面８０に沿って位置されていることが好ましい。圧力差穴７５は、排気装置穴１０１３および供給チューブ１１６よりも実質的に小さく、それを通して、空気は、陽圧と負圧とを生成するために流動する。圧力差穴７５は、負圧の量と比べると、陽圧の量の変化をもたらす。圧力差穴７５は、真空工程の終りに、「損失した」空気を供給するために、高い範囲の真空に効力がある。陽圧工程時、少量の空気が圧力差穴７５を通してリリースされるが、空気は、圧力のレベルが高くなるとき、負圧工程の間に再導入される。

【００８２】

図３３を参照すると、圧力差インサート７６の好ましい実施形態を持つシリンダ１１３が示されている。圧力差穴７５は、圧力差インサート７６を通して配置されている。インサート７６は、次に、シリンダの壁を通して配置されているシリンダ穴７７を通ってシリンダ１１３に接続されている。インサート７６は、シリンダ穴７７にプレス嵌合されることが好ましい。しかしながら、例えば、ねじまたは接着剤などの別の方法の接続方法も使用可能である。圧力差インサート７６は、きわめて小さい許容差内の精密な直径を持つ圧力差穴７５の機械加工を可能にする、機械加工金属部品である。

【００８３】

インサート７６の使用により、プラスチック部分に穴を成形する、または穴をあけることのいずれかにおいて、精度がかなり欠如するため、シリンダ１１３の壁を通して直接圧力差穴７５を配置することが、より有利である。加えて、圧力差インサート７６は、シリンダの穴７７を通して選択的に挿入されることが可能であり、そのために、複数のサイズの異なる圧力差穴７５を有する複数のインサートが使用可能である。圧力差穴７５のために異なる直径を設けることによって、ポンプによって生成される吸引レベルが変えられることが可能である。

【００８４】

圧力差穴７５により、搾乳ポンプ１００の使用の間長期にわたり損失される空気を、負圧工程の間に再生することを可能にし、そのために、陽圧は、長期にわたり正確に維持可能である。搾乳ポンプ１００のテストの間、予期しない重大な結果が、圧力差穴７５の異なるサイズの直径の使用から生じた。約０．１５ｍｍから約０．７５ｍｍとの間の直径を

有する圧力差穴７５が、所望の負圧をもたらす間の長期にわたり精密な陽圧を維持したということが発見された。シリンダ１１３の容量は、１２６ｃｍ^{3}であった。圧力差穴７５は、約０．２５ｍｍから約０．５ｍｍの間の直径を有することが好ましく、直径が約０．３ｍｍであることが最も好ましい。

【００８５】

図１０を参照すると、シリンダ１１３は、ゼロドラフトシリンダとして形成されている。ピストン１１２の外径は、シリンダの内部で空気を移動させるために、シリンダ１１３の内径ｄとの密閉を生成し、乳房への真空と圧力を生成する。搾乳ポンプ１００は、ピストン１１２に対する妨害または抵抗を最小にしながら、適切な密閉を生成するために、シリンダの全長を通して不変の内径ｄを有するシリンダ１１３を必要とする。典型的な射出成形部品は、シリンダ１１３の一様でない内径ｄを生成するドラフト角度を必要とする。

【００８６】

シリンダ１１３は、一様な内径ｄを設けるゼロドラフトシリンダとして成形されることが好ましく、単一の部品に成形されることがより好ましい。図１０に示されているように、シリンダ１１３は、一体形のプラスチック射出成形部品である。２つの部分からなるシリンダまたは機械加工シリンダは、単一の部品のゼロドラフトシリンダ１１３が克服する欠点を有する。２つの部品からなるシリンダは、端部キャップに取り付けられる押出し加工チューブを必要とし、２つの部品は、溶接を使用して、または、接着剤を使用して接合されている。機械加工部品は、一般に金属チューブである。ゼロドラフトの一体形シリンダ１１３に対する利点の１つは、これが射出成形可能であることである。

【００８７】

図３から図１０を参照すると、ボタンパッド１０５が、搾乳ポンプ１００用ユーザインターフェースまたは制御メカニズムである。ボタンパッド１０５は、吸引と速度とのレベルを増大または減少する、１対の正のキーおよび負のキーを有する。パッド１０５は、さらに、オン／オフスイッチを含む。

【００８８】

シリンダ１１３内のピストン１１２の相互の往復運動により、搾乳ポンプ１００は、単一のホースまたは管３５０を通して、女性の乳房に陽圧と負圧との両方を供給する。この実施形態が、陽圧と負圧とを生成するのにピストン／シリンダメカニズムを使用するのに対して、別の方法の膨張可能な容積部または圧力源もまた、使用できる。上述の別の方法の実施形態は、よりわずかな部品を必要とするベローメカニズムまたはダイヤフラムを含む。

【００８９】

図１１と図１２とを参照すると、本発明の乳房カップ、フードまたは乳房受容部材４００が示されている。乳房カップ４００は、空気用オリフィス５６０と、柔軟なインサート６００と、ホルダ７００とを有する、ハウジング５００を有する。ハウジング５００は、剛性構造であり、柔軟なインサート６００は、柔軟な構造である。ハウジング５００は、ハウジングとインサートとの間に排気容積部５１０を形成するために、インサート６００と密閉係合するように構成されている。じょうご状形状のインサート６００は、乳房を受容するために内側容積部６５５を設ける。空気用オリフィス５６０は、排気容積部５１０と流体連絡している。

【００９０】

搾乳ポンプ１００は、空気用オリフィス５６０に接続されて、シリンダ１１３と流体連絡する空気管３５０によって、乳房カップ４００と流体連絡して配置されている。搾乳ポンプは、乳房カップ４００に陽圧と負圧との両方を供給する。搾乳ポンプ１００によって生成される陽圧および負圧は、空気用オリフィス５６０を介して排気容積部５１０の内外に空気を流動させる。乳房カップ４００に供給される陽圧および負圧は、柔軟なインサート６００、特に、排気容積部５１０を膨張および収縮させて、往復する正の力と負の力とを使用者の乳房に印加する。

【００９１】

排気容積部５１０の排気と、ハウジング５００へのインサート６００のかなりのへこみとによって生成される負圧により、乳房カップ４００は、本質的に中に組み込まれる最大吸引レベルを有する。真空源から直接乳首に真空をもたらす、したがって、過剰吸引に対して損傷を受けやすい最新の装置とは違って、乳房カップ４００は、排気容積部５１０に基づき最大負圧をもたらすことだけが可能である。すべての空気が排気容積部５１０から排気されると、乳房カップ４００は、乳房に印加される負圧または負の力をもはや増大しないことが好ましい。搾乳ポンプ１００および乳房カップ４００は、空気用オリフィス５６０に接続されている単一の空気管３５０を介して、使用者の乳房に陽圧と負圧とを印加することができる。

【００９２】

排気容積部５１０内に設定される容量は、２２立方センチメートルから５２立方センチメートルの間であることが好ましく、３２立方センチメートルから４２立方センチメートルの間であることがより好ましい。膨張可能で、収縮可能な排気容積部５１０は、使用者の乳房に印加可能である負圧の量に上限を設け、それは、さらに、搾乳ポンプ１００の使用における安全な機構としての役割を果たす。加えて、インサート６００とハウジング５００との密閉係合は、使用者の乳房と搾乳ポンプ１００との間にバリアを設け、少しの母乳も空気管３５０または搾乳ポンプに入らないようにする。インサート６００は、さらに、マッサージ部材６３４を含むことが可能である。マッサージ部材６３４は、星形状を有し、これは、乳房への付加的なマッサージ作用をもたらす。別の形状が、さらに、マッサージ部材６３４に使用可能である。

【００９３】

図２７から図２９を参照すると、乳房カップ４００は、乳房１について部分断面で示されている。乳房１は、乳輪３を持つ乳首２と、乳腺５によって供給される乳湖またはダクト４とを有する。乳房カップ４００は、インサート６００の空気袋６８５とホルダ７００の管状部材７３５とを有する。空気袋６８５は、排気容積部５１０を部分的に規定する。空気が空気袋６８５と排気容積部５１０とから排出され、そのために、インサート６００がハウジング５００の方へ向って、および、ハウジング５００に対抗して引張られるとき、負圧、真空または負の力は、乳房１に印加される。

【００９４】

管状部材７３５は、空気袋６８５にほぼ隣接して配置されて、インサート６００を部分的に延通する。管状部材７３５は、乳房１と空気袋６８５との間の剛性バリアであり、乳房が空気袋と接触して突き当ることを防止し、それにより、それらの膨張と収縮との量を減少する、したがって、乳房に印加される往復圧力を減少する。

【００９５】

乳房１への乳房カップ４００の位置決めは、排気容積部５１０によってほぼ包囲される乳首２と、乳輪３と、乳ダクト４という結果になる。排気容積部によってほぼ包囲される乳首２、および乳輪３の前部で空気袋６８５に隣接する剛性のバリアを生成するための管状部材７３５の使用は、図２９に表わされているように、負圧工程またはサイクルの間の排気容積部５１０内の空気排出時、乳首２に印加される負圧勾配、真空または負の力１０という結果になる。負圧勾配またはカ１０は、軸方向成分または軸方向Ａよりも大きい横方向成分または横方向Ｌを有する。負圧勾配またはカ１０およびより大きい横方向成分Ｌにより、乳首２を軸方向以上に横方向に引張らさせるまたは吸引させ、それは、乳ダクト４から母乳を搾り出させるのにかなり大きい効果があることを示した。負圧勾配または力１０は、さらに、軸方向Ａに沿って乳首を軸方向に伸張または膨張するのに相反して乳首２を幾分広げることにより、使用者にとっていっそう心地よく、授乳の間の乳児の吸引に近いことを示した。

【００９６】

排気容積部５１０は、ハウジングがインサート６００に固定されているハウジング５００の前縁にほとんど延入し、それにより、横方向成分Ｌに沿って乳首２の横方向吸引と横方向の動きとを生じる負圧工程またはサイクルの間、負圧勾配またはカ１０を生成するの

に役に立つ。図２９に示されているように、負圧勾配、真空または力１０は、乳輪３の外側周辺を越えて延在し、負圧工程またはサイクルの間それにほぼ横方向に印加され、それにより、さらに、軸方向成分Ａと比べてより大きい横方向成分Ｌで乳首２への力を生成するのに役立ち、したがって、乳首を広げる。

【００９７】

管状部材７３５の位置決めは、負圧工程またはサイクルの間、乳首２からまたは乳首２の前部で軸方向に負圧勾配または力１０を減少する手助けをし、それにより、乳首の軸方向膨張に関連する不快感を減少する。管状部材７３５は、管状部材壁に沿って形成されている開口（図示せず）を有する。負圧工程の間に管状部材７３５の方へ引張られる柔らかい乳房１に対して、開口により、乳首２の末端部への負圧の印加または真空が可能になる。

【００９８】

図３０と図３１とを参照すると、真空ライン２１を介して真空源に接続される最新の乳房カップ２０が示されている。最新の乳房カップ２０は、乳房１に係合することが可能なフ―ド２２と、そのフ―ドに取り付けられる円筒形延長部２３とを有する。円筒形延長部２３は、真空ライン２１と収集部材２４とに流体連絡する。真空または負圧は、真空ラインから、円筒形延長部２３を介して、乳輪２に供給される。分離壁２７により、外観上、母乳が真空ライン２１に入ることを防止する。円筒形延長部２３内の空気の排出により、図３１に表わされているように、負圧工程の間、負圧勾配または力３０を生成する。

【００９９】

負圧勾配または力３０は、負圧工程の間、横方向成分Ｌと比べてより大きい軸方向成分Ａを有し、乳首２を横方向以上に軸方向に引張らさせるまたは吸引させ、それは、乳ダクトから母乳を搾り出させるのにかなり効果のないことを示した。負圧工程の間、横方向成分Ｌと比べてより大きい軸方向成分Ａを有する負圧勾配または力３０は、さらに、使用者にとって不快であることを示した。真空または負圧は、負圧工程またはサイクルの間、乳首２からまたは乳首２の前部で軸方向に供給され、それにより、乳首の軸方向伸張と膨張に関連する不快感を生じる。

【０１００】

乳房カップ４００は、負圧工程またはサイクルの間、乳首２に負圧勾配、真空または力１０を印加する排気容積部５１０を部分的に規定する、柔軟なインサート６００を使用すると同時に、本発明は、負圧勾配、真空または力１０を生成する他の設計と構成との使用を意図している。負圧工程またはサイクルの間、軸方向成分Ａに沿う乳首の伸張または膨張に相反して、横方向成分Ｌに沿って乳首をより大きく広げさせる乳房カップ４００のための別の方法の設計が、本発明によって意図されている。さらに、負圧工程の間、平均軸方向成分Ａよりも大きい平均横方向成分Ｌを有する負の力を乳首２に印加する乳房カップ４００のための別の方法の設計が、本発明によって意図されている。さらに、負圧工程の間、平均軸方向成分Ａよりも大きい平均横方向成分Ｌを有する負圧勾配または真空を乳首２に印加する乳房カップ４００のための別の方法の設計が本発明によって意図されている。

【０１０１】

好ましい実施形態は、乳房カップ４００に圧力を供給するモータ付きポンプ１００の使用を説明すると同時に、本発明は、乳房カップ４００に固定されるポンプ吸い出しメカニズムを含む、乳房カップ４００と共に使用する手動ポンプの使用を意図する。加えて、本発明は、乳首２の末端端部または前部に印加される負圧、真空または負の力を減少する、および／または、横方向成分Ｌに比べて、乳首２に印加される負圧、真空または負の力の軸方向成分Ａを減少する、他のバリア構造、設計または方法を意図する。

【０１０２】

本発明は、使用者が搾乳ポンプ１００にだけではなく乳房カップ４００に、陽圧または負圧の量を別の方法で選択的に制御できるように、排気容積部５１０と流体連絡するバルブまたは他の周知のリリ―スメカニズム（図示せず）の使用を意図する。乳房カップ４０

０のバルブまたはリリースメカニズムは、さらに、使用者にとって不快である場合、安全な機構としての迅速なリリースメカニズムでよい。バルブまたはリリースメカニズムは、さらに、陽圧または負圧だけが乳房カップ４００で生成されることを選択的に可能にするために使用できる。

【０１０３】

容易に組立可能である３つの独立した部品、すなわち、ハウジング５００と、インサート６００と、ホルダ７００の使用による乳房カップ４００のモジュール性により、本発明が可変サイズと形状との乳房を収容するためにキットを含むことを可能にする。キットは、複数の異なるサイズのハウジング５００およびインサート６００と、異なる形状のハウジング５００およびインサート６００とを含み、異なるサイズの乳房と異なる形状の乳房とを収容する。複数の異なるハウジング５００およびインサート６００は、すべて、ホルダ７００に組立可能であり、搾乳ポンプ１００に接続可能である。ハウジング５００とインサート６００とのサイズの変化の一例は、ハウジングとインサートとの端から端までの内径と外径と、ハウジングとインサートとの全長とを含む。ハウジング５００とインサート６００との形状の変化の一例は、テーパ角度を変えることと、ハウジングとインサートとの前縁の円形形状を変更することとを含む。加えて、本発明のモジュール性および互換性により、異なるインサート６００への異なる形状またはサイズのマッサージ部材、あるいは突起６３４の使用を可能にする。

【０１０４】

本発明は、さらに、搾乳ポンプ１００と共に使用する複数の異なる乳房カップ４００を形成するために、ハウジング５００とホルダ７００とにすべて組立可能である、複数の異なるサイズまたは形状のインサート６００を含むキットを意図する。複数の異なるサイズのインサート６００は、異なるサイズの乳房を収容するために、さらに、排気容積部５１０を変更するために使用可能である。複数の異なる形状のインサート６００は、異なる形状の乳房を収容するために、また、例えば、インサートに形成される異なるマッサージ部材６３４などの異なるマッサージ効果を乳房に供給するために使用可能である。いくつかの別の方法のインサート６００の例示は、２００２年１２月２７日に出願された米国特許同時係属出願第１０／３３１，１８３号にいっそう完全に説明され、これの開示は、全体が参照してここに組み込まれる。

【０１０５】

搾乳ポンプシステムの好ましい実施形態は、使用者の乳房から流体分離する排気容積部５１０を有する乳房カップ４００を使用するのに対して、別の方法の乳房カップは、さらに、搾乳ポンプ１００と共に使用可能である。本発明の搾乳ポンプシステムの唯一の特徴は、例えば、本発明の制御システムまたはラックおよびピニオン駆動メカニズムなどの他のタイプの乳房カップと共に使用可能である。

【０１０６】

図３４を参照すると、本発明の乳房カップの別の方法の実施形態が示され、全体として参照符号５４００で表わされている。乳房カップ５４００は、インサート６００と共に使用可能である。乳房カップ５４００は、円筒形状ホルダ５７００に接続されているじょうご形状ハウジング５５００を有する。ホルダ５７００は、ハンドル５７２５と、圧力オリフィス５７５０と、圧力調節器５７７５とを有する。ハンドル５７２５は、人間工学に基づき輪郭付けされ、異なる保持角度をもたらす波状形状５７３０を有する。ハンドル５７２５は、じょうご形体５５００から対向する側のホルダ５７００に沿って配置されている。ハンドル５７２５は、握ることを容易にする材料で作られる、またはカバーされることが好ましい。ハンドル５７２５は、ポンプ吸い出しプロセスの間、使用者の手を和らげるように、様々なテクスチャ、突起および／または浮き出し加工を含む。

【０１０７】

圧力オリフィス５７５０は、搾乳ポンプ１００と流体連絡して乳房カップ５４００を配置するために、管３５０に取り付け可能である。圧力調節器５７７５は、圧力オリフィス５７５０と流体連絡し、使用者が搾乳ポンプ１００で調節を行う必要なく、乳房カップ５

４００で圧力を調節することを可能にする。この実施形態では、圧力調節器５７７５はダイアルであるが、別の方法のアクチュエータも使用可能である。

【０１０８】

図３５を参照すると、本発明の乳房カップの別の方法の実施形態が示され、全体として参照符号６４００で表わされている。乳房カップ６４００は、インサート６００と共に使用可能である。乳房カップ６４００は、ホルダ６７００に接続されているじょうご形体６５００を有する。ホルダ６７００は、ハンドル部分６７２５、６７２６と、圧力オリフィス６７５０と、圧力調節器６７７５とを有する。ハンドル部分６７２５、６７２６は、ホルダ６７００の両側に配置され、ホルダの握りを容易にする。ハンドル部分６７２５、６７２６は、握ることを容易にする材料で作られる、またはカバーされることが好ましい。ハンドル部分６７２５、６７２６は、ポンプ吸い出しプロセスの間、使用者の手を和らげるように、様々なテクスチャ、突起および／または浮き出し加工を含む。

【０１０９】

図１２に戻って参照すると、乳房カップ４００のホルダ７００は、第１のセットのねじ山７０１と、第２セットのねじ山７０２とを設ける。第１のねじ山７０１および第２のねじ山７０２は、異なる直径を有し、授乳と乳房ポンプ吸い出しに使用される２つの標準サイズのボトルまたはホルダ、すなわち、再利用可能な容器と使い捨て容器にフィットするようなサイズに作られる。第１のねじ山７０１および第２のねじ山７０２は、同じピッチを有し、同軸に整列されている。成形加工プロセスの間、これにより、スチール型枠コアがホルダ７００からねじを抜いて外されることが可能になる。

【０１１０】

図示されている実施形態は、乳房カップ４００に２つのねじ山、すなわち、第１のねじ山７０１と第２のねじ山７０２を示すのに対して、本発明は、例えば、哺乳瓶の乳首リングまたはキャップなどのホルダまたはボトルの使用を必要とする、他の乳児ケア製品への２つのねじ山の使用を意図する。図３６および図３７を参照すると、哺乳瓶の乳首リングが示され、全体として参照符号７０００で表わされている。哺乳瓶の乳首リング７０００は、開口７２５０を規定する内方に延長するフランジ７２００を持つ、周方向壁７１００を有する。哺乳瓶の乳首リング７０００は、上述の２つのねじ山、すなわち、第１のセットのねじ山７０１と第２のセットのねじ山７０２とを有する。哺乳瓶の乳首リング７０００は、第１のねじ山７０１によって再利用可能な容器か、または、第２のねじ山７０２によって使い捨て可能な容器かのいずれかと、哺乳瓶の乳首７５００との係合をもたらす。第１のねじ山７０１は、フランジ７２００から下方に延出し、第２のねじ山７０２は、周方向壁７１００に沿って形成されることが好ましい。

【０１１１】

図３８と図３９とを参照すると、キャップが示され、全体として参照符号８０００で表わされている。キャップ８０００は、頂部壁８２００に接続されている周方向壁８１００を有する。キャップ８０００は、さらに、上述の２つのねじ山、すなわち、第１のセットのねじ山７０１と第２のセットのねじ山７０２とを有する。キャップ８０００は、第１のねじ山７０１によって再利用可能な容器か、または、第２のねじ山７０２によって使い捨て可能な容器の、いずれかとの密閉をもたらす。第１のねじ山７０１は、頂部壁８２００から下方に延出し、第２のねじ山７０２は、周方向壁８１００に沿って形成されることが好ましい。

【０１１２】

図１３を参照すると、Ｔ－コネクタ３００は、三角形状バルブであり、それにより、使用者が、第１のオリフィス３１０と第２のオリフィス３２０との使用により、単一の乳房カップ４００か、または、２つの乳房カップかのいずれかを使用することを可能にする。搾乳ポンプ１００は、入口３３０で空気管３５０を介してｔ－コネクタ３００に接続されている。ｔ－コネクタ３００の単一の割りバルブ構成は、ダブルポンプ吸い出しに必要な管３５０の量を最小にする。Ｔ－コネクタ３００は、単一のポンプ吸い出しが望まれる場合、第１のオリフィス３１０か、または第２のオリフィス３２０かのいずれかを閉鎖する

、プラグ３４０を有する。プラグ３４０は、第１のオリフィス３１０または第２のオリフィス３２０との係合を容易にするために、ｔーコネクタ３００の外側表面に係留されることが好ましい。

【０１１３】

図１４を参照すると、本発明の搾乳ポンプシステムにより母乳を絞り出す方法が示されている。使用者は、ステップ８００のように、搾乳ポンプ１００を「オン」にして搾乳ポンプ吸い出し操作を開始する。これにより、動力が搾乳ポンプ１００に供給される（ステップ８１０）。使用者は、次に、ステップ８２０のように、所望のサイクル時間と吸引レベルとを入力する。好ましい実施形態では、使用者は、選択するための５つのサイクル時間と吸引レベルとを有する。サイクル時間および吸引レベルは、ボタンパッド１０５を使用して入力される。

【０１１４】

ステップ８３０で、ＰＣボード１２０は、サイクル時間と吸引とに対する使用者の入力レベルに応じて、モータ速度とターゲットピストンの移動量とを設定する。サイクル時間および吸引レベルは、次に、ステップ８４０のように、使用者に表示される。この実施形態では、サイクル時間および吸引レベルは、レベルに対応する照明された光の数を持つ光２２５によって示される。ステップ８５０で、モータ１２５は始動され、ピストン１１２をシリンダ１１３の底部１７５の方へ向って移動させる。これにより、空気管３５０によって乳房カップ４００に供給される陽圧を生成する。

【０１１５】

ステップ８５５で、ＰＣボードは、それがピストン１１２との接触によって起動されたかどうかを決定するために、ホームスイッチをモニタする。ステップ８６０で、ホームスイッチが起動されたかどうかが決定される。ホームスイッチが起動された場合、ステップ８７０のようにそれはリセットされる。ステップ８８０で、モータ１２５は、次に逆転にされ、ピストン１１２をシリンダ１１３の頂部１８０の方へ向って移動させる。これにより、空気管３５０によって乳房カップ４００に供給される負圧を生成する。本発明の搾乳ポンプシステムの利点の１つは、同じ空気管３５０を介して陽圧と負圧との両方を供給することである。これにより洗浄を減少し、使用者の操作を簡素化する。

【０１１６】

使用者によって入力されるような吸引の適当な量を与えるために、光センサ１２１が、ステップ８９０のように、ラックの開口５０の数をカウントする。ステップ９００で、ＰＣボード１２０は、カウントされたラックの開口５０の数が、使用者によって入力されるようにターゲットのピストンの移動量と同等であるかどうかを決定する。ステップ９１０で、搾乳ポンプ１００が「オン」のままであるかどうかが決定される。搾乳ポンプ１００が止められた場合、ポンプ吸い出し操作は、ステップ９１５のように終了する。

【０１１７】

ステップ９２０で、使用者は新しいサイクル時間または吸引レベルを入力したかどうかが決定される。新しいサイクル時間または吸引レベルが入力された場合、ＰＣボード１２０は、サイクル時間と吸引力に対する使用者の入力レベルに応じてモータ速度とターゲットのピストン移動量とを設定し、ステップ８３０に逆戻りして、上述のステップを繰り返す。使用者が新しいサイクル時間または吸引レベルを入力しなかった場合、モータは再度逆転にされ、ピストン１１２をシリンダ１１３の底部１７５の方へ向って移動させる。これにより、空気管３５０によって乳房カップ４００に供給される陽圧を生成する。このプロセスにより、搾乳ポンプ１００は、搾乳ポンプが止められるまで、乳房カップ４００に陽圧と、次に負圧とを供給し続ける（ステップ９１０）。

【０１１８】

本発明の搾乳ポンプシステムは、かなり多数の構成要素を含み、使用者が旅行するときなどの遠い位置で使用可能である。様々な構成要素は、使いやすいようにバッグシステム内に配置可能である。上述のバッグシステムと上述のシステムの構成要素との一例は、２００２年１２月２７日に出願された、同一所有の米国特許同時係属出願第１０／３３１，

１３０号に開示され、これの開示は、参照してここに組み込まれる。

【０１１９】

本発明は、それの好ましい形態を特に参照して説明されてきたが、様々な変更および修正が、添付の特許請求の範囲に定義されているような本発明の精神と範囲とから逸脱することなく行われることは明らかである。

【図面の簡単な説明】

【０１２０】

【図１】本発明の搾乳ポンプシステムの搾乳ポンプの正面斜視図である。

【図２】開いた状態における、図１の搾乳ポンプの正面斜視図である。

【図３】図１の搾乳ポンプの分解斜視図である。

【図４】カバーのない図１の搾乳ポンプの平面図である。

【図５】本発明のピストンおよびシリンダの分解斜視図である。

【図６】図５のピストンおよびシリンダの一部分の分解側面図である。

【図７】図５のピストンの正面斜視図である。

【図８】本発明のピストンの別の方法の実施形態の分解斜視図である。

【図９】図１のシステムの圧力リリーフバルブの分解斜視図である。

【図１０】図５のシリンダの断面平面図である。

【図１１】本発明の乳房カップの正面斜視図である。

【図１２】図１１の乳房カップの側面断面図である。

【図１３】本発明のＴ－コネクタの背面斜視図である。

【図１４】図１と図１１とのシステムによる、乳房をポンプで吸い出す方法を示すフローチャートである。

【図１５】本発明の搾乳ポンプシステムのための搾乳ポンプの好ましい実施形態の平面斜視図である。

【図１６】図１５の搾乳ポンプの平面図である。

【図１７】図１５の搾乳ポンプの駆動システムの平面斜視図である。

【図１８】図１７の駆動システムの側面斜視図である。

【図１９】部分的に組立された、図１５の駆動システムのギヤ減速システムの部分の平面斜視図である。

【図２０】本発明の搾乳ポンプシステムのための搾乳ポンプの、別の方法の実施形態の平面斜視図である。

【図２１】図２０の搾乳ポンプの平面図である。

【図２２】図２０の搾乳ポンプの駆動システムの平面斜視図である。

【図２３】図２０の駆動システムの側面斜視図である。

【図２４】図２０の駆動システムのモータの平面斜視図である。

【図２５】部分的に組立された、図２０の駆動システムのギヤ減速システムの部分の平面斜視図である。

【図２６】部分的に組立された、図２０の駆動システムのギヤ減速システムの平面斜視図である。

【図２７】乳房と共に示した、図１１の乳房カップの部分断面側面図である。

【図２８】負圧工程前に乳房に当てられる、図２７の乳房カップの部分断面側面図である。

【図２９】乳房への負圧勾配または力の表示を示す、負圧工程の間の図２７の乳房カップと乳房の分解断面図である。

【図３０】負圧工程前に乳房に当てられる、従来技術の乳房カップの断面側面図である。

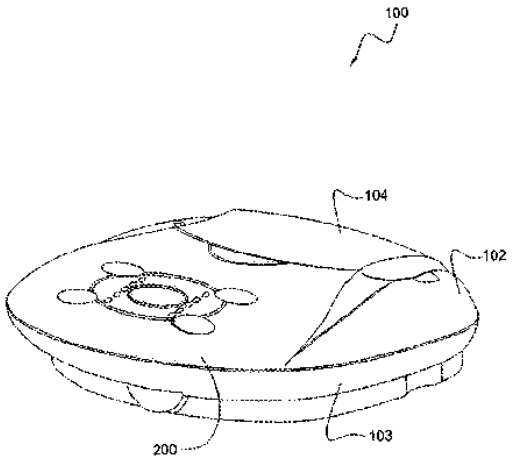
【図３１】乳房への負圧勾配または力の表示を示す、負圧工程の間の図３０の従来技術の乳房カップと乳房の分解断面図である。

【図３２】リリーフアセンブリの別の実施形態を持つ、図９の圧力リリーフバルブの分解斜視図である。

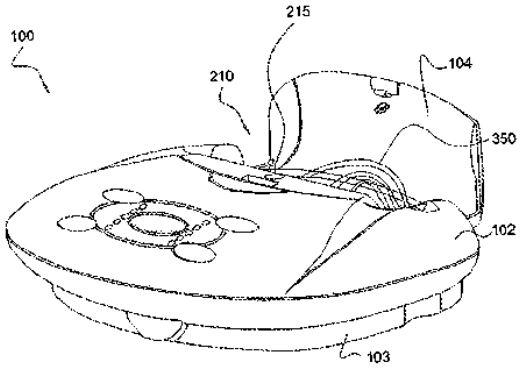
【図３３】圧力差穴の別の実施形態を持つ図５のシリンダの斜視図である。

【図３４】本発明の乳房カップの別の方法の実施形態である。
【図３５】本発明の乳房カップのもう１つの別の方法の実施形態である。
【図３６】本発明の哺乳瓶の乳首を持つ哺乳瓶の乳首リングの底面斜視図である。
【図３７】図３６の哺乳瓶の乳首リングと哺乳瓶の乳首との側面断面図である。
【図３８】本発明のキャップの底面斜視図である。
【図３９】図３８のキャップの側面断面図である。

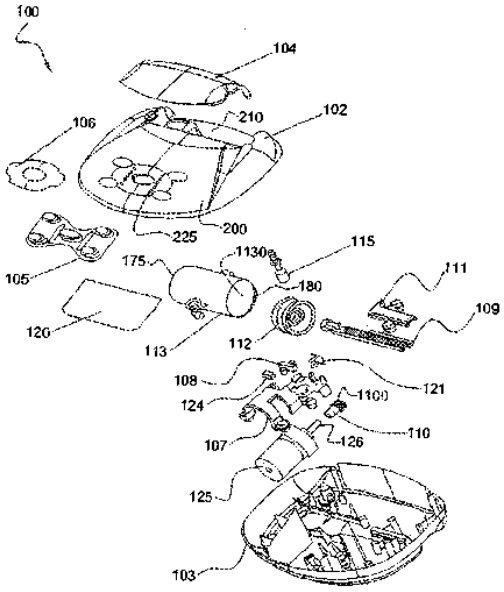
【図１】



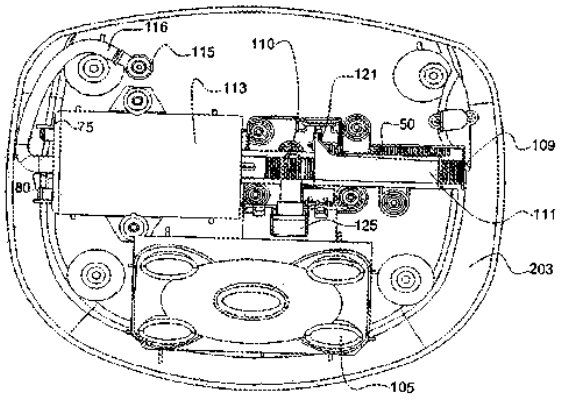
【図２】



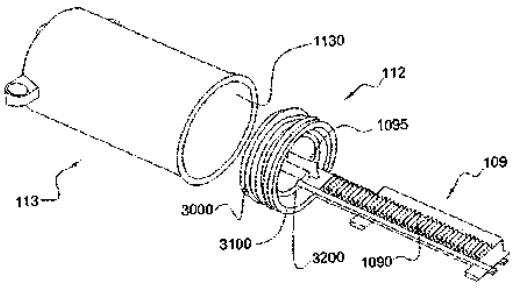
【図３】


100
104
106
210
102
225
200
105
175
1130
115
180
111
109
120
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1100
107
126
110
125
103

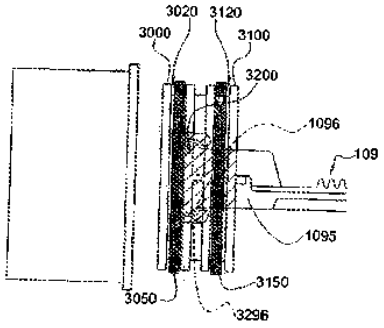
【図４】


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115
110
121
113
75
50
109
80
111
125
203
105

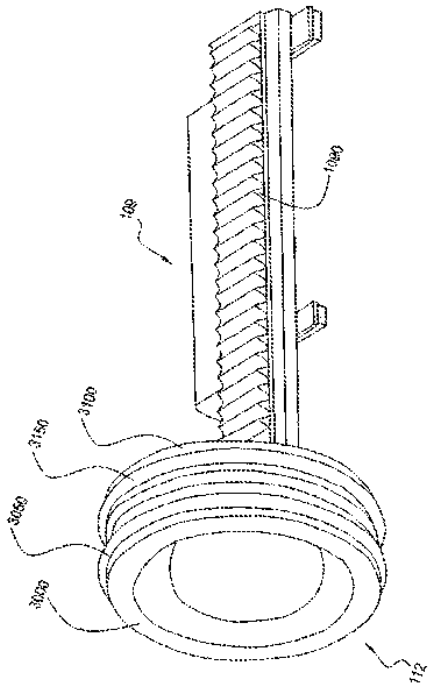
【図５】


1130
112
1095
109
113
3000
3100
3200
1090

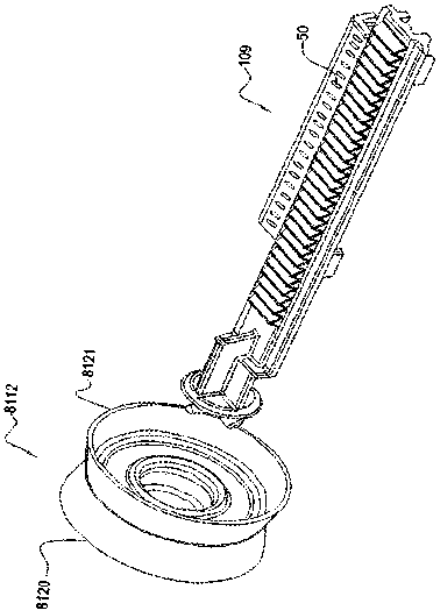
【図６】


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3050
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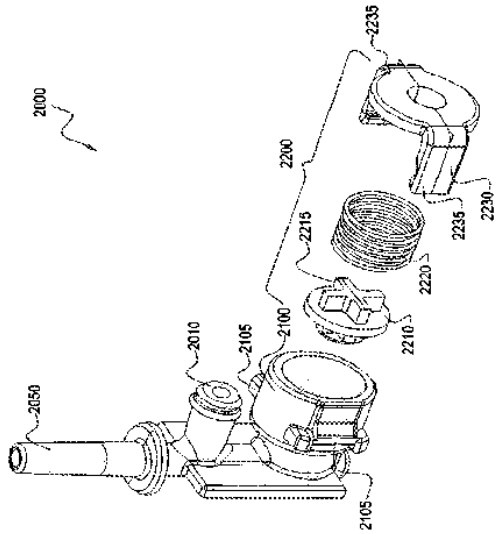
【図７】


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3150
3050
3020
112

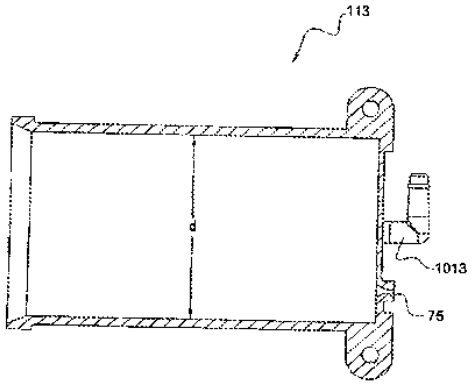
【図８】


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50
8121
8112
8120

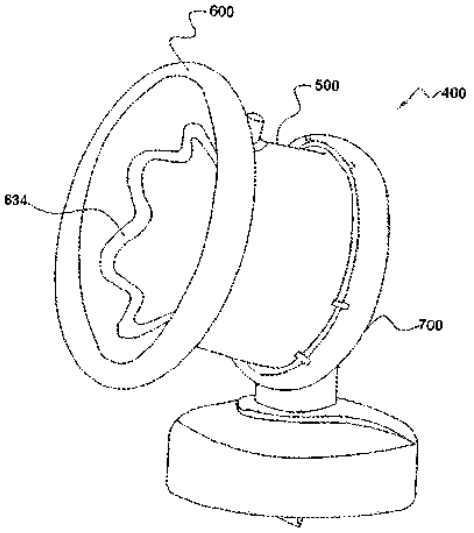
【図９】


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2230
2215
2235
2220
2210
2100
2010
2105
2050
2105

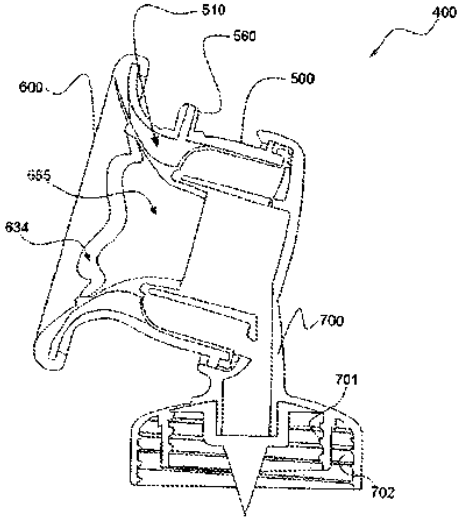
【図１０】


113
d
1013
75

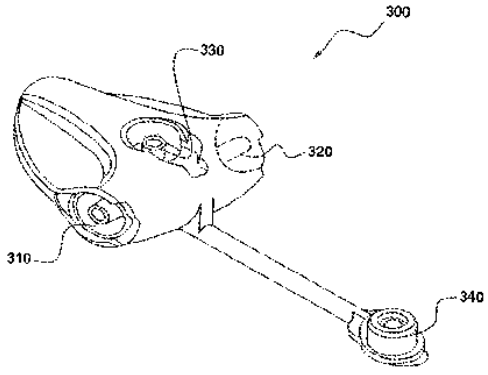
【図１１】



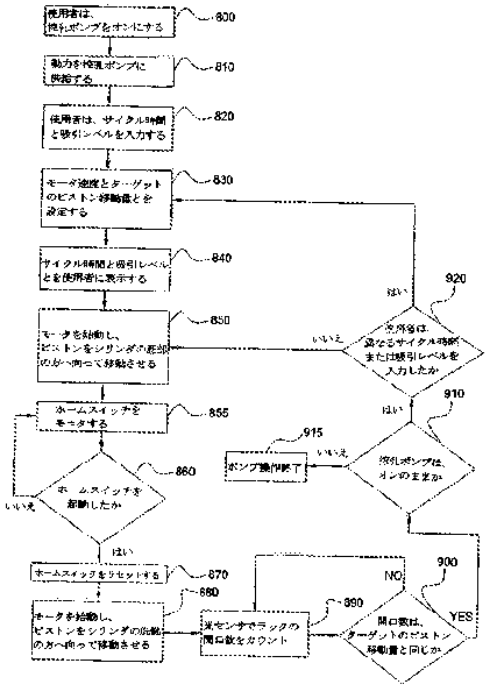
【図１２】



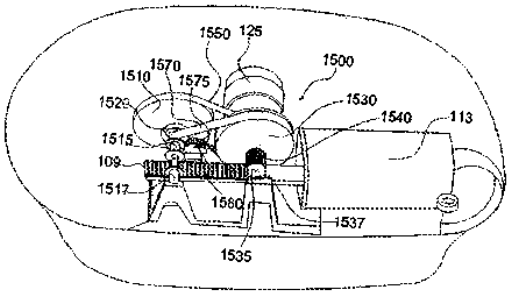
【図１３】



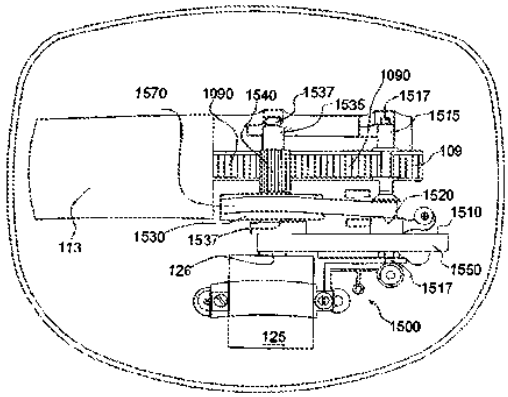
【図１４】



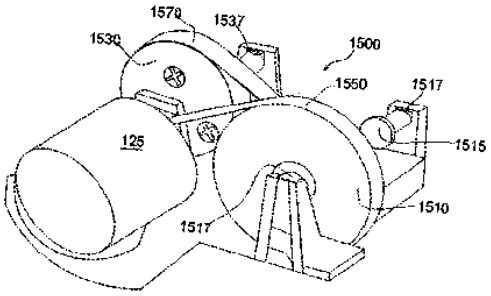
【図１５】



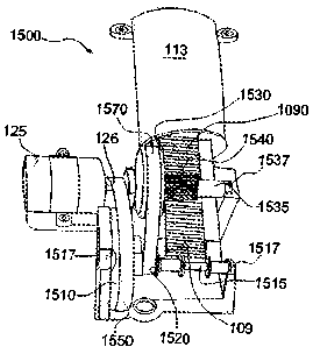
【図１６】



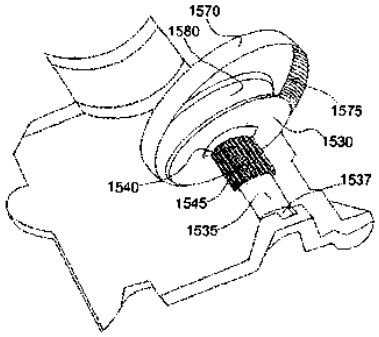
【図１７】



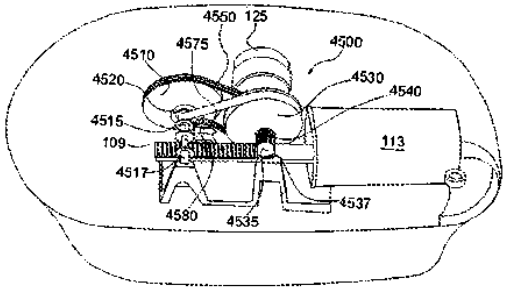
【図１８】



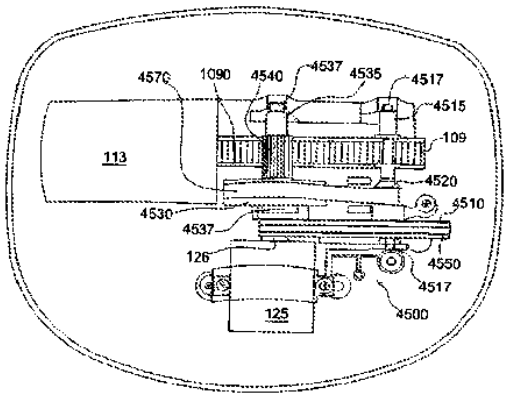
【図１９】



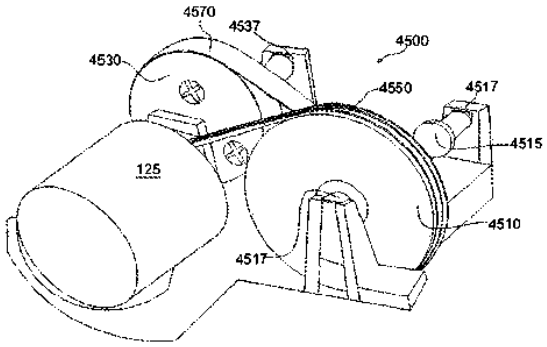
【図２０】



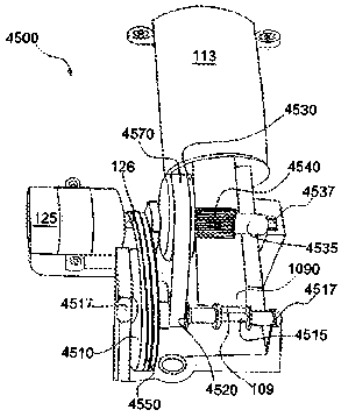
【図２１】



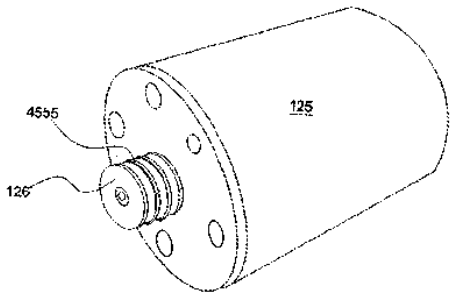
【図２２】



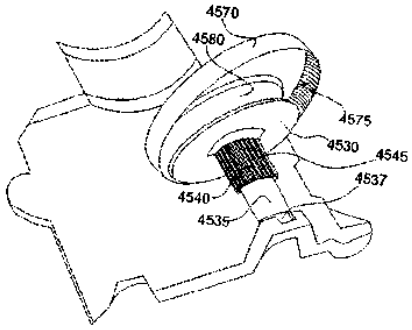
【図２３】



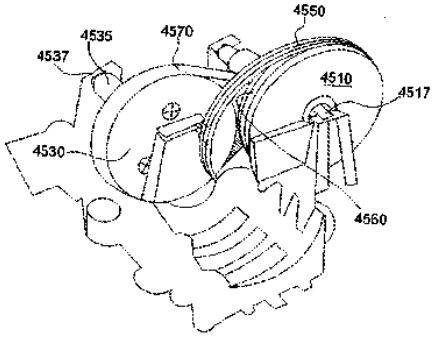
【図２４】



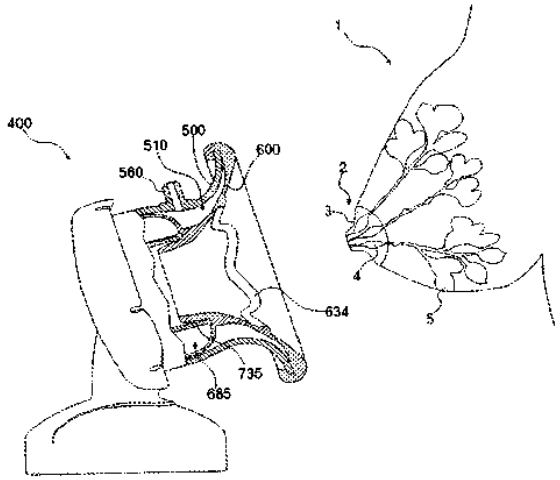
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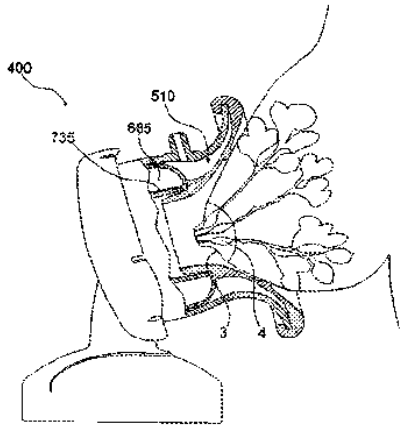
【図２６】



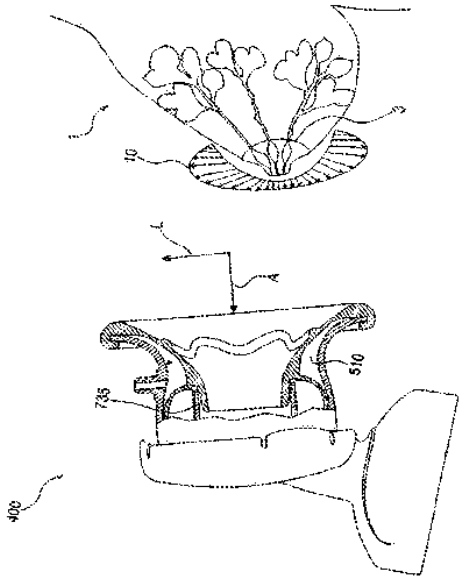
【図２７】



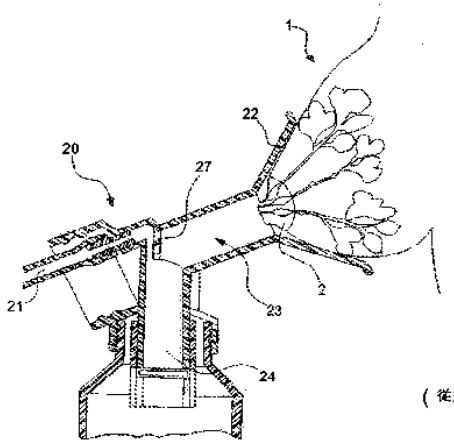
【図２８】



【図２９】

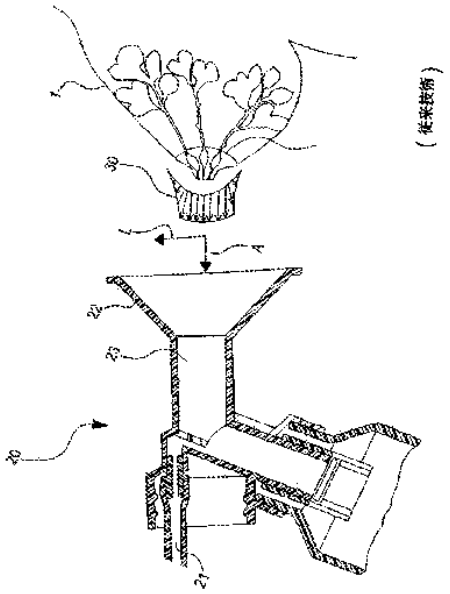


【図３０】

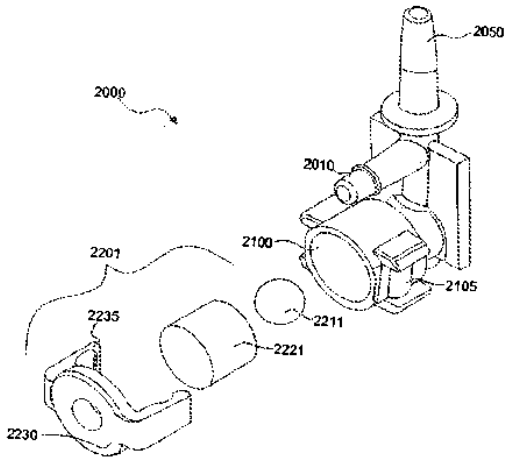


（従来技術）

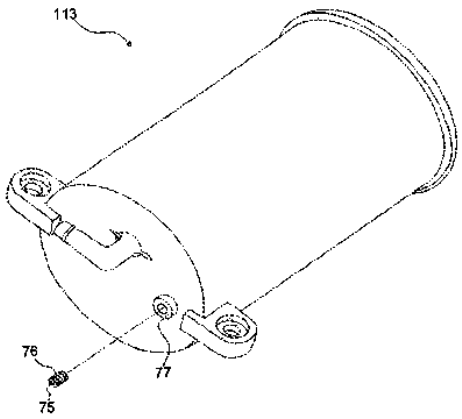
【図３１】



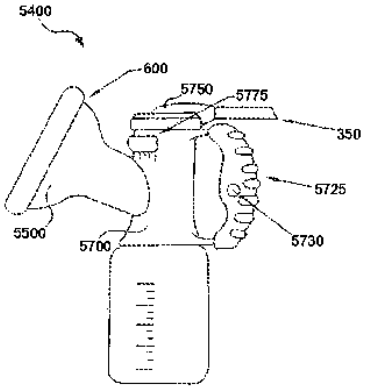
【図３２】



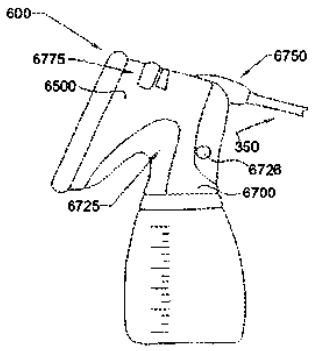
【図３３】



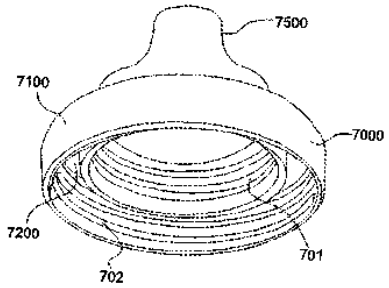
【図３４】



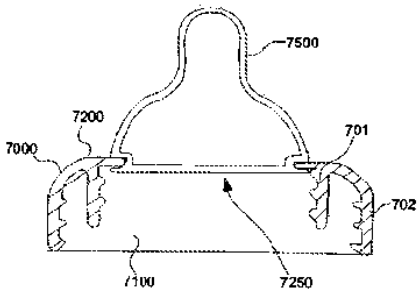
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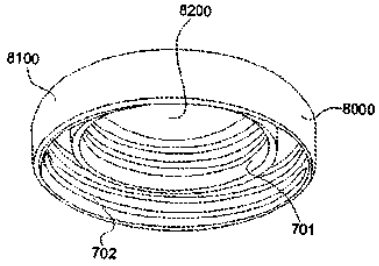
【図３６】



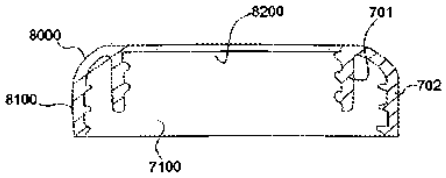
【図３７】



【図３８】



【図３９】



【国際調査報告】



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/25285

A. CLASSIFICATION OF SUBJECT MATTER
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US CL : 604/74
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 604/74

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
None

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
None

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2002/0198489 A1 (SILVER) 26 December 2002 (26.12.2002), see Para. 0007.	65, 66
A		1-64, 70-90
A	US 5,049,126 A (LARSSON) 17 September 1991 (17.09.1991), see entire document.	1-90
Y	US 2003/0149398 A1 (RENZ et al.) 07 August 2003 (07.08.2003), see Para. 0008.	65, 66
A		1-64, 67-90

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
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Patents JP2007501673

Milking pump system

Abstract

translated from Japanese

A milking pump system is provided that obtains breast milk. The system uses a single air tube for both positive and negative pressure applied to a woman's breast, separating the air flow from breast milk to seal it. The milking pump can have a piston / cylinder device that generates pressure, thereby allowing the user to control the suction force and cycle time.
[Selection] Figure 1

Images (39)



Classifications

- A61M1/066 Inserts therefor

View 11 more classifications

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2004-08-05 Application filed by ウレイディックス コーポレイション

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2007-02-01 Publication of JP2007501673A

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Info: Patent citations (101), Cited by (49), Similar documents, Priority and Related Applications

External links: Espacenet, Global Dossier, Discuss

Claims (90)

Hide Dependent

translated from Japanese

A breast cup in fluid communication with a pressure source and configured to squeeze breast milk from a breast having a nipple,
A hood that receives the breast and is in fluid communication with the pressure source, the hood generates a negative force on the nipple during the negative pressure process, the negative force comprising a lateral component and an axial component. A breast cup, wherein the lateral component is greater than the axial component. The breast cup according to claim 1, further comprising a barrier member operatively connected to the hood, wherein the barrier member reduces the axial component of the negative force during the negative pressure step. The hood includes a housing, a flexible insert attached to the housing in a sealed state, and an exhaust volume formed between the housing and the flexible insert. The breast cup of claim 1, in fluid communication with a pressure source. The breast cup according to claim 3, wherein the exhaust volume substantially surrounds the nipple when the breast is received in the hood. The flexible insert includes an air bag in fluid communication with the pressure source, the exhaust volume is at least partially defined by the air bag, and the air bag and the exhaust volume are in the negative pressure process. 4. A breast cup according to claim 3, wherein the breast cup contracts to form the negative force on the nipple during a period of time. The breast cup according to claim 5, further comprising a barrier member disposed substantially adjacent to the bladder, wherein the barrier member prevents the breast from contacting the bladder. The breast cup according to claim 6, wherein the flexible insert defines an inner volume that receives the breast, and the barrier member has a cylindrical shape and is disposed in the inner volume. 4. A breast cup according to claim 3, wherein the flexible insert has a funnel shape with massage protrusions formed thereon. The breast cup according to claim 8, wherein the massage protrusion has a star shape. A breast cup connected to a vacuum source and configured to squeeze breast milk from a breast having a nipple,
A breast cup comprising a breast receiving member in fluid communication with the vacuum source, wherein the breast receiving member applies a negative pressure to the nipple during a negative pressure process, causing the nipple to spread laterally. The breast cup according to claim 10, wherein the negative pressure causes the nipple to expand along the lateral direction more than the nipple extends along the axial direction. The breast cup according to claim 10, wherein the negative pressure has an average lateral component and an average axial component, and the average lateral component is greater than the average axial component during the negative pressure step. . The breast cup of claim 10, further comprising a barrier member operatively connected to the breast receiving member, the barrier member reducing extension of the nipple along the axial direction during the negative pressure process. . The breast receiving member comprises a housing, a flexible insert sealed to the housing, and an exhaust volume formed between the housing and the flexible insert, the exhaust volume being The breast cup of claim 10, in fluid communication with the vacuum source. The breast cup according to claim 14, wherein the exhaust volume substantially surrounds the nipple when the breast is received in the breast receiving member. The flexible insert includes an air bag in fluid communication with the vacuum source, the exhaust volume being at least partially defined by the air bag, the air bag and the exhaust volume being in the negative pressure step. 15. A breast cup according to claim 14, wherein the breast cup contracts to create a negative force on the nipple during the period. The breast cup according to claim 16, further comprising a barrier member disposed substantially adjacent to the bladder, wherein the barrier member prevents the breast from contacting the bladder. The breast cup of claim 17, wherein the flexible insert defines an inner volume that receives the breast, and the barrier member has a cylindrical shape and is disposed in the inner volume. 16. A breast cup according to claim 14, wherein the flexible insert has a funnel shape with a massage projection formed therein. A milking pump system that squeezes breast milk from a breast with a nipple,
A pressure source;
Receives the breast and is in fluid communication with the pressure source and generates a negative force on the nipple during a negative pressure process, the negative force having the lateral component and the axial component. The lateral component is larger than the axial component and the breast cup;
A milking pump system. 21. The milking pump system of claim 20, further comprising a barrier member operatively connected to the breast cup, wherein the barrier member

reduces the axial component of the negative force during the negative pressure step. . The breast cup includes a housing, a flexible insert sealed to the housing, and an exhaust volume formed between the housing and the flexible insert. 21. A milking pump system according to claim 20, in fluid communication with the pressure source. 24. The milking pump system of claim 22, wherein the exhaust volume substantially surrounds the nipple when the breast is received in the breast cup. The flexible insert includes an air bag in fluid communication with the pressure source, the exhaust volume is at least partially defined by the air bag, and the air bag and the exhaust volume are in the negative pressure process. 23. A milking pump system according to claim 22, wherein the milking pump system contracts to create the negative force on the nipple during a period of time. 25. The milking pump system according to claim 24, further comprising a barrier member disposed substantially adjacent to the bladder, wherein the barrier member prevents the breast from contacting the bladder. 24. The milking pump system according to claim 22, wherein the flexible insert has a funnel shape with massage protrusions formed therein. A milking pump system that squeezes breast milk from a breast with a nipple,

A vacuum source,

A breast receiving member that is in fluid communication with the vacuum source, applies a negative pressure to the nipple during a negative pressure process, and causes the nipple to spread laterally,

A milking pump system. 26. The milking pump system according to claim 27, wherein the negative pressure causes the nipple to expand along the lateral direction more than the nipple extends along the axial direction. 28. The milking pump according to claim 27, wherein the negative pressure has an average lateral component and an average axial component, the average lateral component being greater than the average axial component during the negative pressure process. system. 38 The milking pump of claim 27, further comprising a barrier member operatively connected to the breast receiving member, the barrier member reducing extension of the nipple along the axial direction during the negative pressure process. system The breast receiving member includes a housing, a flexible inset sealed to the housing, an exhaust volume formed between the housing and the flexible insert, the exhaust volume and the vacuum. 28. The milking pump system of claim 27, comprising an air orifice in fluid communication with the source. 32. The milking pump system of claim 31, wherein the exhaust volume substantially surrounds the nipple when the breast is received by the breast receiving member. The flexible insert includes an air bag in fluid communication with the vacuum source, the exhaust volume being at least partially defined by the air bag, the air bag and the exhaust volume being in the negative pressure step. 32. The milking pump system of claim 31, wherein the milking pump system contracts to create a negative force on the nipple during a period of time. 34. The milking pump system of claim 33, further comprising a barrier member disposed substantially adjacent to the bladder, wherein the barrier member prevents the breast from contacting the bladder. 35. The milking pump system of claim 34, wherein the flexible insert defines an inner volume that receives the breast, and the barrier member has a cylindrical shape and is disposed within the inner volume. 32. The milking pump system according to claim 31, wherein the flexible insert has a funnel shape with massage protrusions formed thereon. 28. The milking pump system according to claim 27, wherein the vacuum source is a piston movably disposed in a cylinder. 36. The milking pump system of claim 37, further comprising a reversible motor operatively connected to the piston. A rack having first teeth; and a gear having second teeth, the rack is connected to the piston; the gear is operatively connected to the reversible motor, and the first teeth 40. The milking pump system of claim 38, wherein the pump engages the second tooth to reciprocate a piston within the cylinder. The cylinder has a first diameter and an air hole, the air hole having a second diameter and in fluid communication with the atmosphere, wherein the first diameter is greater than the second diameter. 38 The milking pump system of claim 37, wherein the milking pump system is substantially large. A controller operably connected to the reversible motor, wherein the controller measures the amount of movement of the piston relative to the cylinder, the controller reverses the motor based on the amount of movement; 40. A milking pump system according to claim 38. A controller operably connected to the reversible motor, wherein the motor is variable speed and the controller adjusts the speed based on a desired cycle time to apply the negative pressure to the breast. Item 39. A milking pump system according to Item 38. A milking pump kit for use with a pressure source that squeezes breast milk from the breast,

A holder,

A plurality of hoods for receiving breasts, each of the plurality of hoods being selectively engageable with the pressure source and the holder to squeeze the breast milk from the breasts; At least one has a different size or a different shape compared to the others of the plurality of hoods,

Milking pump kit. Each of the plurality of hoods includes a housing, a flexible insert sealed to the housing, and an exhaust volume formed between the housing and the flexible insert and in fluid communication with the pressure source. The milking pump kit according to claim 43, comprising a portion. The at least one housing and the flexible insert of the plurality of hoods have a different size or shape compared to the housing and the flexible insert of the other of the plurality of hoods. 44. A milking pump kit according to 44. 45. The milking pump kit of claim 44, wherein the at least one housing of the plurality of hoods has a different size or a different shape than the housings of the other of the plurality of hoods. 45 The milking pump kit of claim 44, wherein the at least one flexible insert of the plurality of hoods has a different size or a different shape than the flexible inserts of the other of the plurality of hoods. 44. The milking pump kit of claim 43, further comprising a container, wherein the holder is selectively engageable with the container. 49. The milking pump kit of claim 48, wherein the holder has a plurality of engagement structures for selectively engaging a plurality of different sized containers. The at least one flexible insert of the plurality of hoods has a first massage protrusion, the flexible insert of the other of the plurality of hoods has a second massage protrusion, and the first 48. The milking pump kit of claim 47, wherein the one massage protrusion and the second massage protrusion have different sizes or different shapes. A milking pump system that squeezes breast milk from the breast,

A pump for generating pressure;

A plurality of hoods for receiving the breasts, each of the hoods being selectively fluidly connectable to the pump for squeezing the breast milk from the breast, wherein at least one of the plurality of hoods is Having a different size or different shape compared to the others of the plurality of hoods,

Milking pump system. 52. The system of claim 51, further comprising a holder that is selectively engageable with each of the plurality of hoods. Each of the plurality of hoods includes a housing, a flexible insert sealed to the housing, and an exhaust volume formed between the housing and the flexible insert and in fluid communication with the pump. 52. The system of claim 51, comprising. 54. The at least one housing and the flexible insert of the plurality of hoods have a different size or shape compared to the housing and the flexible insert of the other of the plurality of hoods The described system 54 The system of claim 53, wherein the at least one housing of the plurality of hoods has a different size or shape compared to the housing of the other of the plurality of hoods. 54. The system of claim 53, wherein the at least one flexible insert of the plurality of hoods has a different size or shape compared to the flexible insert of the other of the plurality of hoods. 53. The system of claim 52, further comprising a container, wherein the holder is selectively engageable with the container. 58. The system of claim 57, wherein the holder has a plurality of engagement structures for selectively engaging a plurality of different sized containers. The at least one flexible insert of the plurality of hoods has a first massage protrusion, the flexible insert of the other of the plurality of hoods has a second massage protrusion, and the first 57. The system of claim 56, wherein the first massage protrusion and the second massage protrusion have different sizes or different shapes. A milking pump that squeezes breast milk from the breast,

A pressure source having a movable structure for generating pressure during the pressure process, the movable structure having a variable pressure or a variable cycle time, and

A controller operatively connected to the pressure source, wherein the controller adjusts the pressure based on the amount of movement advanced by the movable structure, or adjusts the speed of the movable structure. Adjusts the variable cycle time based on, and the controller also provides near real-time monitoring of the amount of travel or the speed advanced;

Milking pump. 61. The pump of claim 60, wherein the controller is capable of adjusting the pressure cycle based on a non-sinusoidal signal of the pressure versus variable cycle time. A milking pump system that squeezes breast milk from the breast,

A pressure source having an exhaust volume and an air hole for generating pressure;

A breast cup in fluid communication with the pressure source to receive the breast and apply the pressure to the breast, the air hole having a predetermined diameter, and in fluid communication with the exhaust volume, the diameter being between about 0.15 mm and 0.75 mm;

Milking pump system. 64. The system of claim 62, wherein the diameter is between about 0.25 mm and 0.5 mm. 64. The system of claim 62, wherein the diameter is about 0.3 mm. A method of squeezing breast milk from the breast,

Applying a negative pressure to the breast from a pressure source during the vacuum process;

Applying a positive pressure from the pressure source to the breast during a massage process,

Supplying air from the atmosphere to the pressure source during the vacuum process;

A method comprising: During the vacuum process, the step of supplying air from the atmosphere to the pressure source comprises providing an air hole in fluid communication

with the pressure source and the atmosphere, wherein the air hole is between about 0.15 mm and. 66. The method of claim 65, having a diameter between 75 mm. A method of extracting breast milk from a breast having a nipple,

Applying a negative pressure to at least a portion of the nipple and causing the nipple to spread laterally. 68. The method of claim 67, wherein the negative pressure causes the nipple to expand along the transverse direction more than the nipple extends along the axial direction. 69. The method of claim 67, wherein the negative pressure has an average lateral component and an average axial component during a negative pressure step, the average lateral component being greater than the average axial component. A method of squeezing breast milk from the breast,

Applying pressure to the breast,

Performing near real-time monitoring and control of the pressure with a controller;

A method comprising: The pressure is controlled somewhat based on the variable pressure of the movable structure or the variable cycle time of the movable structure, and the controller adjusts the pressure based on the amount of movement advanced by the movable structure. 71. The method of claim 70, wherein the controller adjusts or adjusts the variable cycle time based on the speed of the movable structure, and the controller provides near real-time monitoring of the amount of travel or the speed advanced. Method 71. The method of claim 70, wherein the controller adjusts the pressure based on the pressure versus variable cycle time non-sinusoidal signal. A pump for supplying pressure,

A housing defining a volume and having a pressure exhaust device;

An actuator operatively connected to the housing to generate the pressure in the volume;

An insert connected to the housing, the insert having a hole disposed through the insert, the hole providing fluid communication between the volume and the atmosphere, pump. 74. The pump of claim 73, wherein the housing is made of a first material and the insert is made of a second material. 75. A pump according to claim 74, wherein the housing is made of plastic and the insert is made of metal. 74. The pump according to claim 73, wherein the housing is a cylinder and the actuator is a piston. 77. The pump of claim 76, wherein the cylinder has an orifice and the insert is disposed within the orifice. 78. The pump of claim 77, wherein the insert is press fit within the orifice. 77. The pump of claim 76, wherein the insert is a plurality of inserts, each of the plurality of inserts being selectively engageable with the cylinder. 78. The pump of claim 77, wherein the insert is a plurality of inserts, and each of the plurality of inserts is selectively engageable with the orifice. A breast cup that is in fluid communication with a first container and a second container and applied to a breast, wherein the first container and the second container have openings with different diameters.

A funnel shape for receiving the breast.

A housing connected to the funnel shape and having a base, the base including a circumferential wall, a flange extending inwardly from the circumferential wall to define an opening, and a first thread & second thread,

The first thread has a first diameter and a first pitch, the first diameter and the first pitch enabling selective engagement with the first container; The second thread has a second diameter and a second pitch, the second diameter and the second pitch allowing selective engagement with the second container; The breast cup, wherein the first thread and the second thread are arranged to be coaxial along the base. 82. The breast cup according to claim 81, wherein the first pitch is equal to the second pitch. 82. The breast cup of claim 81, wherein the first thread extends from the flange and the second thread is disposed on the circumferential wall. 82. The breast cup of claim 81, wherein the funnel feature is selectively removable from the housing. A baby bottle nipple ring that engages a first container and a second container with a baby bottle nipple, the first container and the second container having openings with different diameters, The nipple ring of the baby bottle

A body having a circumferential wall, a flange extending inwardly from the circumferential wall to define an opening, a first thread, and a second thread;

The first thread has a first diameter and a first pitch, the first diameter and the first pitch enabling selective engagement with the first container; The second thread has a second diameter and the second pitch, and the second diameter and the second pitch enable selective engagement with the second container. The baby bottle nipple ring, wherein the first thread and the second thread are arranged to be coaxial along the body. 86. The baby bottle nipple ring according to claim 85, wherein the first pitch is equal to the second pitch. 86. The baby bottle nipple ring according to claim 85, wherein the first thread extends from the flange and the second thread is disposed on the circumferential wall. A cap that engages a first container and a second container, the first container and the second container having openings with different diameters;

A body having a circumferential wall, a top wall connected to the circumferential wall, a first thread, and a second thread,

The first thread has a first diameter and a first pitch, the first diameter and the first pitch enabling selective engagement with the first container; The second thread has a second diameter and a second pitch, the second diameter and the second pitch allowing selective engagement with the second container, The first screw thread and the second screw thread are arranged so as to have a coaxial line along the main body. 90. A cap according to claim 88, wherein the first pitch is equal to the second pitch. The cap of claim 88, wherein the first thread extends from the flange and the second thread is disposed on the circumferential wall.

Description

translated from Japanese

The present invention relates to an apparatus and method for obtaining breast milk. More particularly, the present invention relates to a milking pump system that can apply positive or negative pressure to the breast to squeeze breast milk

Milking pump systems that obtain breast milk, both manually and automatically, are well known in the art. Conventional systems use a vacuum source to create a negative pressure or vacuum that is sent through a tube to a breast hood or cup that is applied to the breast. This conventional apparatus and method uses negative pressure on the breast to squeeze breast milk.

The system described above has the disadvantage that only a vacuum source is applied to the breast as a negative pressure in order to induce milk extraction. In addition, the conventional systems described above have the disadvantage of applying a negative pressure or force in the axial direction to the nipple, uncomfortable with milk squeezing, and insufficient nipple stretching and expansion in the axial direction. Result

It is an object of the present invention to provide a milking pump system for squeezing breast milk that can apply positive or negative pressure to the breast to squeeze the breast milk.

Another object of the present invention is to provide a system as described above that supplies positive and negative pressure from a single source.

Yet another object of the present invention is to provide a system as described above that facilitates control of positive and negative pressure applied to the breast

Yet another object of the present invention is to provide a system as described above for spreading the nipple to squeeze milk.

Another object of the present invention is to provide a system as described above that reduces the axial extension or expansion of the nipple

Another further object of the present invention is to apply a negative force or negative pressure gradient to the nipple that has a greater lateral component compared to the axial component.

Yet another object of the present invention is to accommodate breasts of different sizes and / or shapes by providing a kit with compatible breast hoods of different sizes and / or shapes.

Yet another object of the present invention is to substantially monitor and control the pressure source in real time.

These and other objects and advantages of the present invention are provided by a breast cup having a hood for receiving a breast and in fluid communication with a pressure source. The hood generates a negative force on the nipple during the negative pressure process. The negative force has a lateral component and an axial component. The lateral component is larger than the axial component.

The present invention includes a breast cup having a breast receiving member in fluid communication with a vacuum source. The breast receiving member applies a negative pressure to the nipple during the negative pressure process, causing the nipple to spread laterally.

The present invention includes a milking pump system having a pressure source and a breast cup that receives a breast. The breast cup is in fluid communication with a pressure source. The breast cup generates a negative force on the nipple during the negative pressure process. The negative force has a lateral component and an axial component. The lateral component is larger than the axial component.

The present invention includes a milking pump system having a vacuum source and a breast receiving member in fluid communication with the vacuum source. The breast receiving member applies a negative pressure to the nipple during the negative pressure process, causing the nipple to spread laterally.

The present invention includes a milking pump kit having a holder and a plurality of hoods for receiving breasts. Each of the plurality of hoods is selectively engageable with a holder and a pressure source for squeezing breast milk from the breast. At least one of the plurality of hoods has a different size or shape compared to the others of the plurality of hoods.

The present invention includes a milking pump system having a pump for generating pressure and a plurality of hoods for receiving breasts. Each of the plurality of hoods can be selectively fluidly connected to a pump that squeezes breast milk from the breast. At least one of the plurality of hoods has a different size or shape compared to the others of the plurality of hoods.

The present invention includes a milking pump having a pressure source with a movable structure that generates pressure during the pressure process. The movable structure has a variable pressure or variable cycle time. The pump further has a controller operatively connected to the pressure source. The controller adjusts the pressure based on the amount of movement advanced by the movable structure, or adjusts the variable cycle time based on the speed of the movable structure. The controller provides near real-time monitoring of the amount of travel or speed being advanced

The present invention includes a milking pump system having a pressure source having an exhaust volume for generating pressure and an air hole. The system further includes a breast cup that receives the breast and is in fluid communication with a pressure source that applies pressure to the breast. The air holes have a diameter and are in fluid communication with the atmosphere and the exhaust volume. The diameter of the air hole is between about 0.15 mm and 0.75 mm.

The present invention applies negative pressure from the pressure source to the breast during the vacuum process, applies positive pressure from the pressure source to the breast during the massage process, and supplies air from the atmosphere to the pressure source during the vacuum process. And squeezing breast milk from the breast.

The present invention includes a method of squeezing breast milk from a breast, comprising applying a negative pressure to at least a portion of the nipple to cause the nipple to spread laterally.

The present invention includes a method of squeezing breast milk from a breast, comprising the steps of applying pressure to the breast and performing near real-time monitoring and control of the pressure with a controller.

The present invention includes a pump for supplying pressure having a housing, an actuator, and an insert. The housing defines a volume and has a pressure exhaust device. The actuator is operatively connected to a housing that generates pressure within the volume. The insert is connected to the housing. The insert has a hole disposed therethrough. The hole provides fluid communication between the volume and the atmosphere.

The present invention includes a breast cup that is in fluid communication with a first container and a second container that have openings with different diameters and applied to the breast. The breast cup has a funnel shape that receives the breast and a housing connected to the funnel shape. The funnel shape has a base. The base has a circumferential wall, a flange extending inwardly from the circumferential wall to define an opening, a first thread, and a second thread. The first thread has a first diameter and a first pitch. The first diameter and the first pitch allow selective engagement with the first container. The second thread has a second diameter and a second pitch. The second diameter and the second pitch allow selective engagement with the second container. The first thread and the second thread are arranged so as to be coaxial along the base.

The present invention includes a baby bottle nipple ring that engages a first container and a second container having openings with different diameters to the baby bottle nipple. A nipple ring of a baby bottle has a body having a circumferential wall, a flange extending inwardly from the circumferential wall to define an opening, a first thread, and a second thread. Have. The first thread has a first diameter and a first pitch. The first diameter and the first pitch allow selective engagement with the first container. The second thread has a second diameter and a second pitch. The second diameter and the second pitch allow selective engagement with the second container. The first thread and the second thread are arranged to have a coaxial axis along the body.

The present invention includes a cap that engages a first container and a second container having openings with different diameters. The cap has a body having a circumferential wall, a top wall connected to the circumferential wall, a first thread, and a second thread. The first thread has a first diameter and a first pitch. The first diameter and the first pitch allow selective engagement with the first container. The second thread has a second diameter and a second pitch. The second diameter and the second pitch allow selective engagement with the second container. The first thread and the second thread are arranged to have a coaxial axis along the body.

The first pitch may be equal to the second pitch. The first thread can extend from the flange. The second thread can be disposed on the circumferential wall. The funnel shape can be selectively removed from the housing.

The housing may be a first material and the insert may be a second material. The housing may be plastic and the insert may be metal. The housing may be a cylinder and the actuator may be a piston. The cylinder can be an orifice and the insert can be disposed within the orifice. The insert can be press fit into the orifice. The insert is a plurality of inserts, and each of the plurality of inserts is selectively engageable with the cylinder.

The breast cup further has a barrier member that is operatively connected to the hood, which reduces the axial component of negative forces during the negative pressure process. The hood can have a housing, a flexible insert hermetically secured to the housing, and an exhaust volume formed between the housing and the flexible insert, the exhaust volume being in fluid communication with the pressure source. The exhaust volume can substantially surround the nipple when the breast is received in the hood. The flexible insert may have a bladder in fluid communication with the pressure source, with the exhaust volume being at least partially defined by the bladder. The bladder and the exhaust volume can be contracted to create a negative force on the nipple during the negative pressure process.

The breast cup further has a barrier member disposed substantially adjacent to the bladder, thereby preventing the breast from contacting the bladder. The flexible insert can define an inner volume that receives the breast, and the barrier member has a cylindrical shape and can be disposed in the inner volume. The flexible insert can have a funnel shape with massage protrusions formed thereon. The massage protrusion has a star shape.

The negative pressure generated in the breast cup can cause the nipple to spread along the lateral direction more than the nipple extends along the axial direction. The negative pressure can have an average lateral component and an average axial component, and during the negative pressure process, the average lateral component is greater than the average axial component. The barrier member can be operatively connected to the breast receiving member and can reduce nipple extension along the

axial direction during the negative pressure process. The breast receiving member may have a housing, a flexible insert hermetically secured to the housing, and an exhaust volume formed between the housing and the flexible insert, is in fluid communication with a vacuum source.

The vacuum source or pressure source may be a piston movably disposed in the cylinder. The system can have a reversible motor operatively connected to its piston. The system can further include a rack having first teeth and a gear having second teeth. The rack can be connected to the piston, and the gear can be operably connected to the reversible motor. The first tooth is engageable with the second tooth and causes the piston to reciprocate within the cylinder. The cylinder can have a first diameter and an air hole. The air holes have a second diameter and can be in fluid communication with the atmosphere. The first diameter of the cylinder may be significantly larger than the second diameter of the air holes.

The system can have a controller operatively connected to the reversible motor. The controller can measure the amount of movement that the piston has advanced relative to the cylinder. The controller can reverse the motor based at least in part on the amount of movement. The system can further have a motor with variable speed. The controller can adjust the speed based on the desired cycle time for applying negative pressure to the breast. The controller can adjust the pressure cycle based on a non-sinusoidal signal of pressure versus variable cycle time.

Each of the plurality of hoods of the kit includes a housing, a flexible insert hermetically secured to the housing, and an exhaust volume formed between the housing and the flexible insert and in fluid communication with the pressure source. It is possible. The at least one housing and / or the flexible insert of the plurality of hoods can have a different size or a different shape compared to the flexible insert of the other of the housing and / or the plurality of hoods. The kit can further include a container, and the holder is selectively engageable with the container. The holder can have a plurality of engagement structures for selectively engaging a plurality of different sized containers. At least one flexible insert of the plurality of hoods can have a first massage protrusion, and a flexible insert of the other of the plurality of hoods can have a second massage protrusion. is there. The first massage protrusion and the second massage protrusion can have different sizes or different shapes.

Other and further objects, advantages and features of the present invention will be understood by reference to the following.

With reference to the figures, and in particular with reference to FIGS. 1 and 2, there is shown a milking pump of the present invention, generally designated by the reference numeral 100. This milking pump 100, together with the breast cup 400 shown in FIG. 11, forms an important component of the milking pump system of the present invention. The milking pump 100 has a top housing 102 and a bottom housing 103 that are configured to form an assembly unit.

With reference to FIGS. 1-3, the top housing 102 has a generally oval shape with a flat front surface 200 and a storage compartment 210 having a compartment door 104. The door 104 is hinged to the top housing 102 to form a selectively sealable storage compartment 210 for storing an air tube or conduit 350 that connects the milking pump 100 to other components of the system. This is preferably connected and will be discussed in more detail below.

The surface 200 can receive a button pad 105 having an LED cover 106. Pad 105 is used by the consumer to control milking pump 100. The bottom housing 103 can reliably accommodate various components of the milking pump, and includes a rack gear 109, a pinion gear 110 that can be engaged with the rack gear, a piston 112, and a cylinder 113 that can receive the piston. And a motor 125 having a shaft 126 to which a pinion gear is attached. To some extent this design allows milking pump 100 to provide low noise pumping. The milking pump 100 can be made of any rigid material such as, for example, plastic.

Referring to FIGS. 3-7, the milking pump 100 utilizes a piston 112 and a cylinder 113 to generate both positive and negative pressure to obtain breast milk. The piston 112 is driven by a rack gear 109 fixed thereto. The piston 112 has a substantially cylindrical shape having a first head 3000 and a second head 3100. The first head 3000 and the second head 3100 preferably each have an annular channel 3020, 3120 formed therein. The channels 3020 and 3120 are arranged along the outer periphery of the first head 3000 and the second head 3100, respectively. The channels 3020 and 3120 are preferably located at the center along the outer periphery of the first head 3000 and the second head 3100. Seated within channels 3020, 3120 are sealing members 3050, 3150, respectively. The sealing members 3050 and 3150 are preferably O-ring gaskets. Sealing members 3050, 3150 have a diameter or width that is greater than the depth or height of channel 3020 and channel 3120. The sealing members 3050 and 3150 extend beyond the outer periphery of the first head 3000 and the second head 3100 and seal with the inner surface 130 of the cylinder 113 when the piston 112 is driven back and forth within the cylinder. Engagement is formed.

The use of multiple sealing members, i.e., O-ring gasket 3050 and O-ring gasket 3150 on piston 112, provides a double seal and increases the effectiveness of generating positive and negative pressure. Whereas this embodiment uses two sealing members to generate two independent sealing surfaces, a significant number of sealing members generate a significant number of sealing surfaces that seal the piston 112 with the cylinder 113. Can be used to In addition, while this embodiment uses a piston 112 having O-ring sealing gaskets 3050, 3150, other sealing structures can be used between the piston and cylinder 113.

Rack gear 109 has teeth 1090 that engage with pinion gear 110 having teeth 1100. Pinion gear 110 is preferably operatively connected to motor 125 by shaft 126. When the motor 125 is started, the shaft 126 and the pinion gear 110 rotate. The teeth 1090 of the rack 109 and the teeth 1100 of the pinion 110 mesh and convert the mutual rotational movement of the motor 125 and the shaft 126 into a mutual longitudinal movement along a single axis in both directions

The rack gear 109 preferably has a first end 1095 that engages a recess 3200 formed in the piston 112. The recess 3200 is preferably located at the center of the piston 112. The first end 1095 of the rack gear 109 preferably has a snap fit engagement or a friction fit engagement with the recess 3200 of the piston 112. Each preferably has a detent structure 1096, 3296 formed in the first end 1095 and recess 3200. This facilitates the manufacture of these components and provides a slight pivot-like movement that may be required for the piston 112 relative to the rack gear 109.

Another method embodiment of the piston is shown in FIG. 8 and is generally designated 8112. The piston 8112 has a substantially V shape with a leading edge 8120 and a trailing edge 8121. The leading edge 8120 and the trailing edge 8121 are in sealing engagement with the inner surface 1130 of the cylinder 113 when the piston 8112 is driven back and forth within the cylinder. The use of multiple edges, ie, the leading edge 8120 and trailing edge 8121 of the piston 8112 that sealingly engage the inner surface 1130 of the cylinder 113 provides a double seal and increases the effect of generating positive and negative pressure.

Referring to FIGS. 3-7, the motor 125 is preferably variable speed. This allows the user to control and change the cycle time for breast pumping. The milking pump 100 further includes a motor cover 107 and a bearing 108 to reduce vibration and secure the motor 125 to the bottom housing 103.

The positive pressure and the negative pressure can be changed by changing the displacement of the cylinder 113. In this embodiment, this is done by use of an optoelectronic or photosensor system. The optical sensor system includes two or more optical sensors 121 and a position switch 124. The optical sensor 121 counts the number of openings 50 of the rack gear 109 when the rack gear moves back and forth. Therefore, the user can control the amount of movement of the rack gear 109, and can control the exhaust amount in the cylinder 113 correspondingly. Additional displacement or displacement monitors can be used, for example, a coded wheel that counts slots on the wheel, a belt tooth count, a rotary encoder that counts its own rotation, or a Hall effect sensor if is.

To ensure that the piston 112 moves properly in front of the cylinder 113, the photosensor system further includes a position switch 124 that functions as a counter starter, preferably located in front of the cylinder. Alternatively, the position switch may be an aperture 50 having a different size or shape that can be detected by the optical sensor 121.

The rack gear 109 can further have a safety mechanism attached to it. The optical sensor 121 continues to read the opening 50 when the rack gear 109 moves backward. If for some reason the rack gear 109 loses sight of the target and moves far away, the safety device activates the position switch. When the position switch is

activated while the rack gear 109 moves backward, the system can be activated so that the software moves forward again and returns to the positioning position.

The milking pump 100 has a guide cover 111 positioned over the entire rack gear 109. The guide cover 111 adds safety to the milking pump by guiding the mutual movement of the rack gear 109 and vibrating it. The guide cover 111 further provides accuracy to the optical sensor system by reducing the risk of misalignment between the optical sensor 121 and the opening 50.

The optical sensor system and motor 125 are preferably connected to a PC or circuit board 120. Therefore, the moving amount of the piston 112 to be converted according to the positive pressure and the negative pressure and the piston speed to be converted according to the cycle time are electronically controlled.

Referring to FIGS. 15-19, a preferred embodiment of the drive system of the present invention is shown and designated generally by the reference numeral 1500. The drive system 1500 can be used with the milking pump 100 of FIGS. 1-7 and provides linear reciprocal movement of the piston 112 with the cylinder 113.

Drive system 1500 is a belt drive system for rack and pinion drive with gear reduction incorporated therein. The drive system 1500 includes a first drive wheel or pulley 1510, a second gear, drive wheel or pulley 1520 fixed to the first drive wheel 1510, a third gear, drive wheel or pulley 4530, And a pinion gear 1540 fixed to the third gear.

First drive wheel 1510 is operatively connected to motor drive shaft 126 by a first belt 1550. In a preferred embodiment, the first belt 1550 is a toothless belt. More preferably, the first belt 1550 has elasticity or flexibility. The use of a flexible or elastic belt 1550 provides a secure connection between the drive shaft 126 and the first drive wheel 1510, and further reduces noise and vibration. The drive shaft 126 and the first drive wheel 1510 have a smooth outer surface on which the first belt 1550 is fixed.

First drive wheel 1510 is operatively connected to second gear 1520 by first coaxial shaft 1515. In a preferred embodiment, the first shaft 1515 is rotatably mounted between opposing first bearings 1517. However, other methods of rotatable mounting arrangements or fixing structures can also be used. To reduce noise and vibration, the motor shaft 126 and the first drive wheel 1510 are made of metal. First drive wheel 1510 and second gear 1520 have different diameters that provide in part a gear reduction between motor shaft 126 and pinion gear 1540.

Second gear 1520 is operatively connected to third gear 1530 by second belt 1570. Second belt 1570 preferably has teeth 1575 that mesh with teeth 1580 formed along the periphery of second gear 1520 and third gear 1530. Second gear 1520 and third gear 1530 have different diameters that partially provide gear reduction between motor shaft 126 and pinion gear 1540. The drive system 1500 can further include a tension pulley 1580 that provides tension to the second belt 1570.

Third gear 1530 is operatively connected to pinion gear 1540 by a second coaxial shaft 1535. In a preferred embodiment, the second shaft 1535 is rotatably mounted between opposing second bearings 1537. However, other methods of rotatable mounting arrangements or securing structures can also be used. The third gear 1530 is preferably molded integrally with the pinion gear 1540 along the second shaft 1535.

Pinion gear 1540 has teeth 1545 that engage with teeth 1090 of rack gear 109. When the motor 125 is started, the rotational movement of the shaft 126 is converted into mutual longitudinal movement along a single axis of the rack gear 109 in both directions. The drive system 1500 uses a first belt 1550, a second belt 1570, a first drive wheel or gear 1510, a second drive wheel or gear 1520, and a third drive wheel or gear 1530. , The desired rate of movement between the motor shaft 126 and the pinion gear 1540 can be provided, ie, gear reduction

The use of the combination of the toothless belt 1550 and the tooth profile belt 1570 can reduce noise and vibration while providing the required reciprocating linear motion at the desired speed and pressure for the milking pump 100. Maintain a secure and rugged drive system 1500.

Referring to FIGS. 20-26, another method embodiment of the drive system of the present invention is shown and generally designated by reference numeral 4500. The drive system 4500 can be used with the milking pump 100 of FIGS. 1-7 and provides linear reciprocal movement of the piston 112 with the cylinder 113.

The drive system 4500 is a belt drive system having a gear reduction incorporated therein. The drive system 4500 includes a first gear, drive wheel or pulley 4510, a second gear, drive wheel or pulley 4520 fixed to the first gear, and a third gear, drive wheel or pulley 4530. And a pinion gear 4540 fixed to the third gear.

First gear 4510 is operatively connected to motor drive shaft 126 by a first belt 4550. In a preferred embodiment, the first belt 4550 is a plurality of belts, more preferably three belts. The first belt 4550 is preferably a belt without a tooth profile. More preferably, the first belt 4550 is an O-ring having elasticity or flexibility. For example, the use of a flexible or elastic belt 4550 such as an O-ring provides a secure connection between the drive shaft 126 and the first gear 4510, and further reduces noise and vibration. Drive shaft 126 and first gear 4510 each have an annular channel 4555, 4560 formed therein. The annular channels 4555, 4560 are guides that help hold the first belt 4550 in place and facilitate assembly of the drive system 4500.

First gear 4510 is operatively connected to second gear 4520 by a first coaxial shaft 4515. In this alternative method embodiment, the first shaft 4515 is rotatably mounted between opposing first bearings 4517. However, other methods of rotatable mounting arrangements or fixing structures can also be used. To reduce noise and vibration, the motor shaft 126 and the first gear 4510 are made of metal. First gear 4510 and second gear 4520 have different diameters that partially provide gear reduction between motor shaft 126 and pinion gear 4540

Second gear 4520 is operatively connected to third gear 4530 by second belt 4570. The second belt 4570 preferably has teeth 4575 that mesh with teeth 4580 formed along the periphery of the second gear 4520 and the third gear 4530. Second gear 4520 and third gear 4530 have different diameters that partially provide gear reduction between motor shaft 126 and pinion gear 4540. The drive system 4500 can further include a tension pulley 4580 that provides tension to the second belt 4570.

Third gear 4530 is operatively connected to pinion gear 4540 by second coaxial shaft 4535. In this alternative method embodiment, the second shaft 4535 is rotatably mounted between opposing second bearings 4537. However, other methods of rotatable mounting arrangements or securing structures can also be used. Third gear 4539 is preferably molded integrally with pinion gear 4540 along second shaft 4535.

Pinion gear 4540 has teeth 4545 that engage with teeth 1090 of rack gear 109. When the motor 125 is started, the rotational movement of the shaft 126 is converted into mutual longitudinal movement along a single axis of the rack gear 109 in both directions. Drive system 4500 includes motor shaft 126 and pinion gears through the use of first belt 4550, second belt 4570, first gear 4510, second gear 4520, and third gear 4530. A desired rate of movement between 4540, ie gear reduction, can be provided.

Use of a combination of O-ring belt 4550 without tooth profile and tooth profile belt 4570 reduces noise and vibration while providing the required reciprocating linear motion at the desired speed and pressure for milking pump 100. Maintain a secure and robust drive system 4500 that can.

The embodiments of the drive systems 1500, 4500 described above utilize a belt for gear reduction. However, another method embodiment may use a gearbox that decelerates the gearing to a desired rate that is transmitted to the rack and pinion gearing that drives the milking pump 100.

Referring to FIGS. 3 to 9, the cylinder 113 has a supply tube 116 fixed to a supply connector 115 that supplies positive and negative pressure to the breast cup 400. The supply connector preferably has an outlet 215 located in the storage compartment 210. The air tube 350 is fixed to the outlet 215 and can be fixed to the breast cup 400.

The storage compartment 210 can be opened or closed during the pumping operation. The cylinder 113 is about 1.5 in. in fluid communication with a pressure relief valve 2000 (shown in FIG. 9), which is preferably set to Hg.

The pressure relief valve 2000 has an intake port 2010 and an exhaust device 2050. The intake 2010 is in fluid communication with the cylinder 113, and the exhaust device 2050 is in fluid communication with the breast cup 400 via a tube 350. Pressure relief valve 2000 has a relief exhaust device 2100 in fluid communication with intake 2010 and exhaust device 2050. The relief exhaust device 2100 is substantially tubular and is fixed to the relief assembly 2200.

The relief assembly 2200 includes a flexible insert 2210, a biasing member 2220, and a holding member 2230. The flexible insert 2210 is in sealing engagement with the internal surface of the relief exhaust device 2100 and prevents air from escaping through the relief exhaust device. The insert 2210 has a fixing member 2215 that meshes with the biasing member 2220. In this embodiment, the securing member 2215 is a cruciform structure that is received in the inner volume of the biasing member 2220. The biasing member 2220 is preferably a spring. The urging member 2220 is more preferably a coil spring. The retention member 2230 is a cap-like structure having opposing retention arms 2235 that engage a corresponding pair of engagement protrusions 2105 positioned on the outer surface of the relief exhaust device 2100. The insert 2210 and the spring 2220 are held in the inner volume portion of the relief exhaust device 2100 by a cap 2230.

The spring 2220 has a biasing strength or resistance equal to the relief pressure of the pressure relief valve 2000. Positive pressure is about 1.5 in. In this embodiment. When the relief pressure is exceeded, which is preferably set to Hg, the force generated on the inner surface of the insert 2210 overwhelms the biasing force of the spring 2220, the insert faces toward the cap 2230, and the relief exhaust system 2100 Move outside the inner volume. Air exits the pressure relief valve 2000 through the relief exhaust device 2100 until the positive pressure of the pressure relief valve decreases below the biasing strength of the spring 2220, at which time the insert 2210 is within the inner volume of the relief exhaust device. Move back into a sealing engagement with the internal surface of the relief exhaust.

Further, referring to FIG. 32, the pressure relief valve 2000 is shown with a preferred relief assembly 2201 that includes an insert 2211 and a biasing member 2221. Relief assembly 2201 functions similarly to insert 2210 and spring 2220 of relief assembly 2200, as described above. The insert 2211 is a ball, and the biasing member 2221 is a foam having a cylinder shape. The relief assembly 2201 has the advantage that the ball 2211 is more easily assembled within the relief exhaust device 2100. In addition, the foam cylinder 2221 is more invariant because it easily engages the ball 2211 and provides a constant spring actuation force. In addition, another method of pressure relief valve can be used, which can be adjusted so that the "massage intensity", ie the amount of positive pressure on the user's breast, is controllable .

The circuit board 120 shown in FIG. 3 allows the user to program several levels of speed and several levels of suction. In this embodiment, the rate (cycle time) ranges from about 45 cycles / minute (cpm) to about 75 cpm. The present invention provides for a number of speed level preset programming within a speed range. The number of levels is preferably from about 2 to about 8 levels. More preferably, the user can program five levels of speed within the speed range. The present invention further contemplates speed level programming by the user.

The suction force range for use with a single breast cup 400 and the preferred drive system 1500 shown in FIGS. 15-21 is about 3 in. About 10 in. From Hg. Hg and for the two breast cups about 3 in. About 8 in. From Hg. Hg. The suction range for use with the single breast cup 400 and the gearbox system shown in FIGS. 3 and 4 is about 3 in. About 9 in. From Hg. Hg and for the two breast cups about 3 in. About 8 in. From Hg. Hg. The present invention provides for a number of preset programming of suction levels within the suction force range. The number of levels is preferably from about 2 to about 8 levels. More preferably, the user can program five levels of suction within the suction force range. The present invention further contemplates suction level programming by the user.

Computer software can also be used to control the amount of positive and negative pressure. This allows the amount of positive and negative pressure to be personalized for the user and further changed throughout the duration of the pumping process to maximize efficiency.

Milking pump 100 is preferably controlled by software driven circuit board 120 along with gear motor 125, rack and pinion sets 109, 110 and piston systems 112, 113. The software and system are designed to provide maximum flexibility and to facilitate pressure curve or "wave" changes. This is feasible because the software controls the speed of the motor 125 and the amount that the piston 112 travels in the cylinder 113. The amount of movement of the piston 112 is related to the pressure level. By controlling the speed and pressure level with software, the pressure curve or "wave" can be controlled.

When a determination is made that the specific "wave" or pressure curve is similar to the infant's suction force or most comfortable to the mother, then the desired wave changes timing (motor speed and piston travel). Can be obtained. Through the use of software, the user has the ability to apply memory to a specific pressure curve and changes in that pressure curve over time to maximize comfort for the user.

In this embodiment, a sine wave is used to control the milking pump 100. This is based on the assumption that the most comfortable pressure curve does not have a sharp pressure level that gives the user a feeling of tightening and gradually increases or decreases the pressure similar to a sine wave. The reciprocating motion of the piston 112 is similar to the desired sine wave. However, to avoid sharp pressure peaks, the piston 112 timing is slowed down at these high points, and the pressure is held constant for a period of time at the maximum and minimum suction points of the wave. . This results in a pressure curve with a stable sine wave that is more comfortable for the user.

Another method of waves can also be used for the pressure curve if the above waves are determined by the mother to be desirable. For example, if the mother prefers a "sawtooth" pressure curve with a sharp apex, the timing of the piston 112 can simply be changed to a reciprocating cycle, minimizing the pause when the piston 112 changes direction. To. Further, for example, if the mother prefers a "rectangular curve", the timing of the piston 112 will hold the position of the piston as the piston attempts to change direction, and then quickly ramp down, it can be changed to hold this position again before applying an upward tilt. This will generate a "rectangular curve" wave

Use of software control results in a large selection of wave or pressure curves. This further allows that flexibility to change or provide a greater choice with one milking pump 100. In contrast, modern pumps have the disadvantage of not allowing the flexibility to change the pressure curve wave. The milking pump 100 allows control between cycles of pressure and speed. In the preferred embodiment, this is done through the use of a reversible variable speed motor 125 operatively connected to a linear system that incorporates a piston 112 and a cylinder 113. Thus, modern devices can repeatedly use a specific sinusoidal pressure curve on the surface, whereas the milking pump 100 uses any type of wave and uses that wave during the cycle. Has the ability to change

The control system and software of the present invention provides a closed loop control system or real-time adjustment between cycles. Therefore, real-time monitoring of control variables such as the amount and speed of movement of the piston to be advanced occurs. As motors and other components age and wear, the closed loop control system is responsible for the detrimental changes described above to provide the precise cycle time and pressure required by the user. Real-time monitoring and control provides effectively equal speed levels for both single and two cup pump pumps despite torque changes.

The cylinder 113 has a pressure differential hole 75. The pressure differential hole 75 is preferably located along the bottom surface 80 of the cylinder 113. The pressure differential hole 75 is substantially smaller than the exhaust device hole 1013 and the supply tube 116, through which air flows to generate positive and negative pressure. The pressure differential hole 75 changes the amount of positive pressure compared to the amount of negative pressure. The pressure differential hole 75 is effective over a high range of vacuum to provide "lost" air at the end of the vacuum process. During the positive pressure process, a small amount of air is released through the pressure differential hole 75, but air is reintroduced during the negative pressure process when the pressure level increases.

Referring to FIG. 33, a cylinder 113 with a preferred embodiment of the pressure differential insert 76 is shown. The pressure differential hole 75 is disposed through the pressure differential insert 76. The insert 76 is then connected to the cylinder 113 through a cylinder hole 77 located through the cylinder wall. The insert 76 is preferably press-fitted into the cylinder hole 77. However, other methods of connection such as, for example, screws or adhesives can also be used. The pressure differential insert 76 is a machined metal part that allows machining of the pressure differential hole 75 with a precise diameter within very small tolerances.

It is more advantageous to place the pressure differential hole 75 directly through the wall of the cylinder 113 because of the considerable lack of accuracy in either molding or drilling the hole in the plastic part by using the insert 76, is there. In addition, the pressure differential insert 76 can be selectively inserted through a hole 77 in the cylinder, and therefore a plurality of inserts having a plurality of different pressure differential holes 75 can be used. By providing different diameters for the pressure differential hole 75, the suction level generated by the pump can be varied.

The pressure differential hole 75 allows air lost over time during use of the milking pump 100 to be regenerated during the negative pressure process, so that the positive pressure can be accurately maintained over time. During testing of the milking pump 100, unexpected and significant results resulted from the use of different sized diameters of the pressure differential hole 75. It was discovered that the pressure differential hole 75 having a diameter between about 0.15 mm and about 0.75 mm maintained a precise positive pressure over time while providing the desired negative pressure. The capacity of the cylinder 113 was 126 cm^3. The pressure differential hole 75 preferably has a diameter between about 0.25 mm and about 0.5 mm, and most preferably has a diameter of about 0.3 mm.

Referring to FIG. 10, the cylinder 113 is formed as a zero draft cylinder. The outer diameter of the piston 112 creates a seal with the inner diameter d of the cylinder 113 to move air inside the cylinder, creating a vacuum and pressure on the breast. The milking pump 100 requires a cylinder 113 with a constant inner diameter d through the entire length of the cylinder in order to create a proper seal while minimizing obstruction or resistance to the piston 112. A typical injection molded part requires a draft angle that produces a non-uniform inner diameter d of the cylinder 113.

The cylinder 113 is preferably formed as a zero draft cylinder having a uniform inner diameter d, and more preferably formed into a single part. As shown in FIG. 10, the cylinder 113 is an integral plastic injection molded part. Two-part cylinders or machining cylinders have the disadvantages that a single part zero draft cylinder 113 overcomes. A two-part cylinder requires an extruded tube that is attached to the end cap, and the two parts are joined using welding or using an adhesive. The machined part is typically a metal tube. One advantage over the zero draft integral cylinder 113 is that it can be injection molded.

Referring to FIGS. 3-10, the button pad 105 is the user interface or control mechanism for the milking pump 100. The button pad 105 has a pair of positive and negative keys that increase or decrease the level of suction and speed. Pad 105 further includes an on / off switch.

Due to the reciprocal movement of the piston 112 within the cylinder 113, the milking pump 100 supplies both positive and negative pressure to the female breast through a single hose or tube 350. While this embodiment uses a piston / cylinder mechanism to generate positive and negative pressure, another method of inflatable volume or pressure source can also be used. Another method embodiment described above includes a bellows mechanism or diaphragm that requires fewer parts.

Referring to FIGS. 11 and 12, a breast cup, hood or breast receiving member 400 of the present invention is shown. The breast cup 400 has a housing 500 having an air orifice 560, a flexible insert 600 and a holder 700. The housing 500 is a rigid structure, and the flexible insert 600 is a flexible structure. The housing 500 is configured to sealingly engage the insert 600 to form an exhaust volume 510 between the housing and the insert. Funnel-shaped insert 600 provides an inner volume 655 for receiving the breast. Air orifice 560 is in fluid communication with exhaust volume 510.

Milking pump 100 is placed in fluid communication with breast cup 400 by an air tube 350 connected to air orifice 560 and in fluid communication with cylinder 113. The milking pump supplies both positive and negative pressure to the breast cup 400. The positive pressure and negative pressure generated by the milking pump 100 cause air to flow into and out of the exhaust volume 510 through the air orifice 560. The positive and negative pressure supplied to the breast cup 400 expands and contracts the flexible insert 600, particularly the exhaust volume 510, to apply reciprocating positive and negative forces to the user's breast. .

Due to the negative pressure created by the exhaust of the exhaust volume 510 and the significant indentation of the insert 600 into the housing 500, the breast cup 400 has a maximum suction level that is inherently incorporated therein. Unlike modern devices that provide vacuum directly from the vacuum source to the nipple, and therefore are susceptible to damage from over-suction, the breast cup 400 can only provide maximum negative pressure based on the exhaust volume 510, is there. When all air is exhausted from the exhaust volume 510, the breast cup 400 preferably no longer increases the negative pressure or negative force applied to the breast. Milking pump 100 and breast cup 400 can apply positive and negative pressure to the user's breast via a single air tube 350 connected to air orifice 560.

The capacity set in the exhaust volume 510 is preferably between 22 cubic centimeters and 52 cubic centimeters, and more preferably between 32 cubic centimeters and 42 cubic centimeters. The inflatable and retractable exhaust volume 510 places an upper limit on the amount of negative pressure that can be applied to the user's breast, which further serves as a safe mechanism in the use of the milking pump 100. In addition, the hermetic engagement of the insert 600 and the housing 500 provides a barrier between the user's breast and the milking pump 100 to prevent any breast milk from entering the air tube 350 or the milking pump. The insert 600 can further include a massage member 634. The massage member 634 has a star shape, which provides an additional massage action to the breast. Other shapes can also be used for the massage member 634.

With reference to FIGS. 27 to 29, the breast cup 400 is shown in partial cross-section with respect to the breast 1. The breast 1 has a nipple 2 with a areola 3 and a milk lake or duct 4 supplied by a mammary gland 5. The breast cup 400 has an air bag 685 of the insert 600 and a tubular member 735 of the holder 700. The air bag 685 partially defines the exhaust volume 510. When air is exhausted from the bladder 685 and the exhaust volume 510 so that the insert 600 is pulled toward the housing 500 and against the housing 500, negative pressure, vacuum or negative force is , Applied to the breast 1.

Tubular member 735 is disposed substantially adjacent to bladder 685 and partially extends through insert 600. Tubular member 735 is a rigid barrier between breast 1 and bladder 685 that prevents the breast from bumping into contact with the bladder, thereby reducing the amount of their expansion and contraction. Thus, the reciprocating pressure applied to the breast is reduced.

The positioning of the breast cup 400 on the breast 1 results in the nipple 2, the areola 3, and the milk duct 4 that are substantially surrounded by the exhaust volume 510. The use of a tubular member 735 to create a rigid barrier adjacent the bladder 685 at the front of the nipple 2 and the areola 3 that is substantially surrounded by the exhaust volume, as illustrated in FIG. When exhausting air in the exhaust volume 510 during the negative pressure process or cycle, this results in a negative pressure gradient, vacuum or negative force 10 applied to the nipple 2. The negative pressure gradient or force 10 has a lateral component or lateral direction L that is greater than the axial component or axial direction A. The negative pressure gradient or force 10 and the larger lateral component L cause the nipple 2 to be pulled or sucked laterally beyond the axial direction, which has a considerable effect on milking the milk duct 4. Showed that. The negative pressure gradient or force 10 is also more comfortable for the user by extending the nipple 2 somewhat in contradistinction to the axial extension or expansion of the nipple along the axial direction A. It was shown to be close to aspiration.

The exhaust volume 510 extends almost at the front edge of the housing 500 where the housing is fixed to the insert 600, thereby causing lateral suction and lateral movement of the nipple 2 along the lateral component L. Helps generate a negative pressure gradient or force 10 during the negative pressure process or cycle. As shown in FIG. 29, a negative pressure gradient, vacuum or force 10 extends beyond the outer periphery of the areola 3 and is applied substantially laterally thereto during

the negative pressure process or cycle, thereby Furthermore, it helps to generate a force on the nipple 2 with a greater lateral component L compared to the axial component A, thus spreading the nipple.

The positioning of the tubular member 735 helps to reduce the negative pressure gradient or force 10 axially from the nipple 2 or at the front of the nipple 2 during the negative pressure process or cycle, thereby reducing the axial expansion of the nipple. Reduce associated discomfort. Tubular member 735 has an opening (not shown) formed along the tubular member wall. 8 or a soft breast 1 that is pulled towards the tubular member 735 during the negative pressure process, the opening allows for the application of a negative pressure or vacuum to the distal end of the nipple 2.

Referring to FIGS. 30 and 31, a modern breast cup 20 connected to a vacuum source via a vacuum line 21 is shown. A modern breast cup 20 has a hood 22 capable of engaging the breast 1 and a cylindrical extension 23 attached to the hood. Cylindrical extension 23 is in fluid communication with vacuum line 21 and collection member 24. Vacuum or negative pressure is supplied from the vacuum line to the areola 2 via the cylindrical extension 23. The separation wall 27 prevents the breast milk from entering the vacuum line 21 in appearance. The discharge of air in the cylindrical extension 23 generates a negative pressure gradient or force 30 during the negative pressure process, as shown in FIG.

The negative pressure gradient or force 30 has a larger axial component A compared to the lateral component L during the negative pressure process, causing the nipple 2 to be pulled or sucked axially more than laterally. It has been shown to be ineffective at pumping breast milk from the milk duct. During the negative pressure process, a negative pressure gradient or force 30 having a larger axial component A compared to the lateral component L has also been shown to be uncomfortable for the user. Vacuum or negative pressure is supplied axially from the nipple 2 or at the front of the nipple 2 during the negative pressure process or cycle, thereby creating discomfort associated with the axial extension and expansion of the nipple

While the breast cup 400 uses a flexible insert 600 that partially defines an exhaust volume 510 that applies a negative pressure gradient, vacuum or force 10 to the nipple 2 during a negative pressure process or cycle, the present invention simultaneously intended for use with negative pressure gradients, vacuum or other designs and configurations that generate force 10. Another method design for the breast cup 400 that causes the nipple to expand more widely along the transverse component L, as opposed to stretching or expanding the nipple along the axial component A during the negative pressure process or cycle, intended by the present invention. Furthermore, another method design for the breast cup 400 is contemplated by the present invention that applies a negative force to the nipple 2 having a mean lateral component L greater than the mean axial component A during the negative pressure process. ing. Furthermore, the design of another method for the breast cup 400 for applying a negative pressure gradient or vacuum to the nipple 2 with a mean lateral component L greater than the mean axial component A during the negative pressure process is contemplated by the present invention. Has been.

While the preferred embodiment describes the use of a motorized pump 100 that supplies pressure to the breast cup 400, the present invention provides for a manual pump for use with the breast cup 400 that includes a pump suction mechanism that is secured to the breast cup 400, intended for use. In addition, the present invention reduces the negative pressure, vacuum or negative force applied to the distal end or front of the nipple 2 and / or is applied to the nipple 2 relative to the transverse component L. Other barrier structures, designs, or methods that reduce the axial component A of negative pressure, vacuum, or negative force are contemplated.

The present invention provides a valve or other that is in fluid communication with the exhaust volume 510 so that the user can selectively control the amount of positive or negative pressure in the breast cup 400 as well as in the milking pump 100. Is intended to use a known release mechanism (not shown). The valve or release mechanism of the breast cup 400 may also be a quick release mechanism as a safe mechanism if it is uncomfortable for the user. The valve or release mechanism can also be used to selectively allow only positive or negative pressure to be generated in the breast cup 400.

Due to the modularity of the breast cup 400 through the use of three independent parts that can be easily assembled: the housing 500, the insert 600, and the holder 700, the present invention accommodates a breast of variable size and shape. Allows to include kits. The kit includes a plurality of different sized housings 500 and inserts 600 and different shaped housings 500 and inserts 600 to accommodate different sized and differently shaped breasts. A plurality of different housings 500 and inserts 600 can all be assembled to the holder 700 and connected to the milking pump 100. An example of a change in size between the housing 500 and the insert 600 includes the inner and outer diameters of the housing and the insert from end to end, and the total length of the housing and the insert. An example of a change in shape between the housing 500 and the insert 600 includes changing the taper angle and changing the circular shape of the leading edge of the housing and insert. In addition, the modularity and interchangeability of the present invention allows the use of differently shaped or sized massage members or protrusions 634 on different inserts 600.

The present invention further includes a kit that includes a plurality of different sized or shaped inserts 600 that can all be assembled into the housing 500 and holder 700 to form a plurality of different breast cups 400 for use with the milking pump 100. Intended. A plurality of different sized inserts 600 can be used to accommodate different sized breasts and also to modify the exhaust volume 510. A plurality of differently shaped inserts 600 can be used to accommodate differently shaped breasts and to provide different massage effects to the breast, such as, for example, different massage members 634 formed on the inserts. An illustration of several alternative method inserts 600 is more fully described in US Patent Application No. 10 / 331,183, filed December 27, 2002, the disclosure of which is hereby incorporated by reference in its entirety And incorporated here.

The preferred embodiment of the milking pump system uses a breast cup 400 having an exhaust volume 510 that fluidly separates from the user's breast, whereas another method breast cup can also be used with the milking pump 100. It is. The only features of the milking pump system of the present invention can be used with other types of breast cups such as, for example, the control system of the present invention or rack and pinion drive mechanisms.

Referring to FIG. 34, another method embodiment of the breast cup of the present invention is shown and generally designated by the reference numeral 5400. The breast cup 5400 can be used with the insert 600. The breast cup 5400 has a funnel-shaped housing 5500 that is connected to a cylindrical holder 5700. Holder 5700 has a handle 5725, a pressure orifice 5750, and a pressure regulator 5775. The handle 5725 is ergonomically contoured and has a wavy shape 5730 that provides different holding angles. The handle 5725 is disposed along the holder 5700 on the side facing away from the funnel shape 5500. The handle 5725 is preferably made of or covered with a material that facilitates gripping. The handle 5725 includes various textures, protrusions and / or relief processes to ease the user's hands during the pumping process

A pressure orifice 5750 can be attached to the tube 350 to place the breast cup 5400 in fluid communication with the milking pump 100. The pressure regulator 5775 is in fluid communication with the pressure orifice 5750 and allows the user to adjust the pressure at the breast cup 5400 without having to make adjustments at the milking pump 100. In this embodiment, the pressure regulator 5775 is a dial, but other methods of actuators can be used.

Referring to FIG. 35, another method embodiment of the breast cup of the present invention is shown and generally designated by reference numeral 6400. The breast cup 6400 can be used with the insert 600. The breast cup 6400 has a funnel shape 6500 connected to a holder 6700. Holder 6700 has handle portions 6725, 6726, a pressure orifice 6750, and a pressure regulator 6775. Handle portions 6725, 6726 are disposed on either side of the holder 6700 to facilitate gripping of the holder. The handle portions 6725, 6726 are preferably made of or covered with a material that facilitates gripping. The handle portions 6725, 6726 include various textures, protrusions and / or relief processes to ease the user's hands during the pumping process.

Referring back to FIG. 12, the holder 700 of the breast cup 400 provides a first set of threads 701 and a second set of threads 702. The first thread 701 and the second thread 702 have different diameters and are in two standard sized bottles or holders used for breastfeeding and breast pumping; reusable containers and disposable

containers. Made to fit size. The first thread 701 and the second thread 702 have the same pitch and are coaxially aligned. During the molding process, this allows the steel formwork core to be unscrewed from the holder 700.

While the illustrated embodiment shows two threads on the breast cup 400, a first thread 701 and a second thread 702, the present invention is, for example, a nipple ring in a baby bottle Or the use of two threads on other infant care products that require the use of a holder or bottle such as a cap. 36 and 37, a baby bottle nipple ring is shown and generally designated by the reference numeral 7000. The baby bottle nipple ring 7000 has a circumferential wall 7100 with an inwardly extending flange 7200 defining an opening 7250. The baby bottle nipple ring 7000 has the two threads described above: a first set of threads 701 and a second set of threads 702. The baby bottle nipple ring 7000 engages the baby bottle nipple 7500 with either a container reusable by the first thread 701 or a container disposable by the second thread 702. Bring. The first thread 701 preferably extends downward from the flange 7200 and the second thread 702 is formed along the circumferential wall 7100.

Referring to FIGS. 38 and 39, the cap is shown and is generally designated by the reference numeral 8000. The cap 8000 has a circumferential wall 8100 that is connected to the top wall 8200. The cap 8000 further has two threads as described above: a first set of threads 701 and a second set of threads 702. Cap 8000 provides a seal with either a reusable container with first thread 701 or a disposable container with second thread 702. The first thread 701 preferably extends downward from the top wall 8200 and the second thread 702 is formed along the circumferential wall 8100.

Referring to FIG. 13, the T-connector 300 is a triangular valve that allows the user to use either the single breast cup 400 or the first orifice 310 and the second orifice 320, or it makes it possible to use either of the two breast cups. The milking pump 100 is connected to the t-connector 300 via an air pipe 350 at an inlet 330. The single split valve configuration of the t-connector 300 minimizes the amount of tubing 350 required for double pump suction. The T-connector 300 has a plug 340 that closes either the first orifice 310 or the second orifice 320 if a single pump suction is desired. Plug 340 is preferably anchored to the outer surface of t-connector 300 to facilitate engagement with first orifice 310 or second orifice 320.

Referring to FIG. 14, a method of squeezing breast milk with the milking pump system of the present invention is shown. As shown in step 800, the user turns on the milking pump 100 and starts the milking pump sucking operation. Thereby, power is supplied to the milking pump 100 (step 810). The user then enters the desired cycle time and suction level as in step 820. In a preferred embodiment, the user has five cycle times to select and a suction level. The cycle time and suction level are entered using the button pad 105.

In step 830, the PC board 120 sets the motor speed and the amount of movement of the target piston according to the user input level for the cycle time and suction. The cycle time and suction level are then displayed to the user, as in step 840. In this embodiment, the cycle time and suction level are indicated by light 225 with the number of illuminated lights corresponding to the level. At step 850, the motor 125 is started and moves the piston 112 toward the bottom 175 of the cylinder 113. Thereby, a positive pressure supplied to the breast cup 400 by the air tube 350 is generated.

In step 855, the PC board monitors the home switch to determine if it was activated by contact with the piston 112. At step 860, it is determined whether the home switch has been activated. If the home switch is activated, it is reset as in step 870. At step 880, the motor 125 is then reversed to move the piston 112 toward the top 180 of the cylinder 113. Thereby, a negative pressure supplied to the breast cup 400 by the air tube 350 is generated. One advantage of the milking pump system of the present invention is that it supplies both positive and negative pressure through the same air tube 350. This reduces cleaning and simplifies user operation.

In order to provide an appropriate amount of suction as input by the user, the optical sensor 121 counts the number of rack openings 50 as in step 890. In step 900, the PC board 120 determines whether the counted number of rack openings 50 is equal to the amount of movement of the target piston as entered by the user. At step 910, it is determined whether milking pump 100 remains "on". If the milking pump 100 is stopped, the pump suction operation ends as in step 915.

At step 920, it is determined whether the user has entered a new cycle time or suction level. When a new cycle time or suction level is input, the PC board 120 sets the motor speed and the target piston movement amount according to the user input level with respect to the cycle time and the suction force, and returns to step 830. Repeat the above steps. If the user does not enter a new cycle time or suction level, the motor is reversed again, causing the piston 112 to move toward the bottom 175 of the cylinder 113. Thereby, a positive pressure supplied to the breast cup 400 by the air tube 350 is generated. This process causes milking pump 100 to continue supplying positive and then negative pressure to breast cup 400 until the milking pump is turned off (step 910).

The milking pump system of the present invention includes a significant number of components and can be used at a remote location, such as when a user travels. Various components can be placed in the bag system for ease of use. An example of the bag system described above and the components of the system described above is disclosed in co-owned US patent application Ser. No. 10 / 331,130 filed on Dec. 27, 2002, the disclosure of which is , incorporated herein by reference.

Although the invention has been described with particular reference to preferred forms thereof, various changes and modifications can be departed from the spirit and scope of the invention as defined in the appended claims. Obviously it will be done.

It is a front perspective view of the milking pump of the milking pump system of this invention. FIG. 2 is a front perspective view of the milking pump of FIG. 1 in an open state. It is a disassembled perspective view of the milking pump of FIG. It is a top view of the milking pump of FIG. 1 without a cover. It is a disassembled perspective view of the piston and cylinder of this invention. FIG. 6 is an exploded side view of a portion of the piston and cylinder of FIG. 5. It is a front perspective view of the piston of FIG. FIG. 6 is an exploded perspective view of another piston method embodiment of the present invention. FIG. 2 is an exploded perspective view of a pressure relief valve of the system of FIG. FIG. 6 is a cross-sectional plan view of the cylinder of FIG. 5. It is a front perspective view of the breast cup of the present invention. FIG. 12 is a side cross-sectional view of the breast cup of FIG. 11. It is a back perspective view of the T-connector of the present invention. 12 is a flow chart illustrating a method of pumping a breast according to the system of FIGS. 1 and 11. It is a top perspective view of a preferred embodiment of a milking pump for the milking pump system of the present invention. it is a top view of the milking pump of FIG. It is a top perspective view of the drive system of the milking pump of FIG. FIG. 18 is a side perspective view of the drive system of FIG. 17. FIG. 16 is a top perspective view of a portion of the gear reduction system portion of the drive system of FIG. 15 partially assembled. FIG. 6 is a top perspective view of another method embodiment of a milking pump for the milking pump system of the present invention. it is a top view of the milking pump of FIG. It is a top perspective view of the drive system of the milking pump of FIG. FIG. 21 is a side perspective view of the drive system of FIG. 20. It is a top perspective view of the motor of the drive system of FIG. FIG. 21 is a top perspective view of a portion of the gear reduction system portion of the drive system of FIG. 20 partially assembled. FIG. 21 is a top perspective view of the gear reduction system of the drive system of FIG. 20 partially assembled. FIG. 12 is a partial cross-sectional side view of the breast cup of FIG. 11 shown with a breast. FIG. 28 is a partial cross-sectional side view of the breast cup of FIG. 27 applied to the breast prior to the negative pressure process. FIG. 28 is an exploded cross-sectional view of the breast cup and breast of FIG. 27 during a negative pressure process showing a display of negative pressure gradient or force on the breast. 1 is a cross-sectional side view of a prior art breast cup applied to a breast prior to a negative pressure process. FIG. FIG. 31 is an exploded cross-sectional view of the prior art breast cup and breast of FIG. 30 during a negative pressure process showing a negative pressure gradient or force display on the breast. FIG. 10 is an exploded perspective view of the pressure relief valve of FIG. 9 with another embodiment of a relief assembly. FIG. 6 is a perspective view of the cylinder of FIG. 5 with another embodiment of a pressure differential hole. 3 is another method embodiment of the breast cup of the present invention. Figure 5 is another alternative method embodiment of the breast cup of the present invention. It is a bottom perspective view of the nipple ring of the baby bottle having the nipple of the baby bottle of the present invention. It is side surface sectional drawing of the teat ring of the baby bottle of FIG. 36, and the teat of a baby bottle. It is a bottom perspective view of the cap of the present invention. It is side surface sectional drawing of the cap of FIG.

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US20030073951A1 *	2001-05-30	2003-04-17	Morton Kevin B.	Disposable patient interface for intraductal fluid aspiration system
US6663587B2 *	2001-06-22	2003-12-16	Medela Holding Ag	Breastshield with multi-pressure and expansible chamber construction, related breastpump and method
RU2272600C2 *	2001-12-27	2006-11-20	Playtex Products Inc	Breast cup
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JP2010525899A *	2007-05-04	2010-07-29	ウィスパーウエア，インク．	Hands-free milking machine with balanced reciprocating drive
JP2012511324A *	2008-12-12	2012-05-24	ユーニンクレックカフィリップスエレクトロニクスエヌヴィ	Automatic head for milking machine
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WO2017082409A1 *	2015-11-13	2017-05-18	ピジョン株式会社	Breast pump
JP2020523179A *	2017-06-15	2020-08-06	チアロテクノロジーリミテッドChiaro Technology Limited	Milking system

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US6749582B2 *	2002-04-30	2004-06-15	The First Years Inc.	Pumping breast milk
GB0224986D0	2002-10-26	2002-12-04	Smith & Nephew	Apparatus
US7776008B2 *	2003-08-08	2010-08-17	Playtex Products, Inc.	Manual breast pump
US11298455B2	2003-10-28	2022-04-12	Smith & Nephew Plc	Apparatus and method for wound cleansing with actives
US20050154348A1 *	2004-01-08	2005-07-14	Daniel Lantz	Breast pump
US8529548B2	2004-04-27	2013-09-10	Smith & Nephew Plc	Wound treatment apparatus and method
US7753894B2 *	2004-04-27	2010-07-13	Smith & Nephew Plc	Wound cleansing apparatus with stress
US10413644B2	2004-04-27	2019-09-17	Smith & Nephew Plc	Wound treatment apparatus and method
GB0409446D0	2004-04-28	2004-06-02	Smith & Nephew	Apparatus
US7396338B2	2004-04-30	2008-07-08	The First Years Inc.	Pumping breast milk
US7806855B2	2006-04-11	2010-10-05	Playtex Products, Inc.	Manual breast pump
US9162016B2	2006-09-22	2015-10-20	Medela Holding Ag	Breastpump with irregular milk expression sequences
DE102006056321B4 *	2006-11-24	2010-01-07	Maps Gmbh	Manual breast pump
US8377016B2	2007-01-10	2013-02-19	Wake Forest University Health Sciences	Apparatus and method for wound treatment employing periodic sub-atmospheric pressure
US8070718B2	2007-04-11	2011-12-06	Medela Holding Ag	Method and apparatus for minimum negative pressure control, particularly for breastpump with breastshield pressure control system
US8070718B2	2007-04-11	2011-12-06	Medela Holding Ag	Method and apparatus for minimum negative pressure control, particularly for a breastpump with breastshield pressure control system
RU2489993C2	2007-10-10	2013-08-20	Уэйк Форест Юниверсити Хелс Сайенсиз	Device and method of treating spinal cord tissue
US8366692B2	2008-01-08	2013-02-05	Richard Scott Weston	Sustained variable negative pressure wound treatment and method of controlling same
AU2009222057A1	2008-03-12	2009-09-17	Smith & Nephew Plc	Negative pressure dressing and method of using same
EP2136698B1	2008-03-18	2017-04-12	Wake Forest University Health Sciences	Apparatus for cardiac tissue modulation by topical application of vacuum to minimize cell death and damage
WO2010054174A1 *	2008-11-07	2010-05-14	Simplisse, Inc.	Breast pump
US8398584B2	2009-01-16	2013-03-19	Learning Curve Brands, Inc.	Breast pump and method of use
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EP2324868A1 *	2009-07-28	2011-05-25	Koninklijke Philips Electronics N.V.	Flexible drive for breast pump
EP2506816A1	2011-12-22	2012-06-26	Koninklijke Philips Electronics N.V.	A method and system for providing an indication as to the amount of milk remaining in a breast during lactation
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US10207052B2	2013-03-14	2019-02-19	Medela Holding Ag	Small-volume collection for a breastpump system
RU2015152032A3	2013-05-10	2018-03-21		
CA2955605A1 *	2014-07-22	2016-01-28	John Y. Chang	Breast pump system and methods
CN105919194934A	2014-07-22	2020-02-27	Exploramed Nc7 inc	Breast pump system and methods
WO2016014488A1 *	2014-07-22	2016-01-28	Exploramed Nc7, Llc	Breast pump system and methods
WO2016014483A1	2014-07-22	2016-01-28	Exploramed Nc7, Llc	Breast pump system and methods
US10668171B2 *	2015-04-14	2018-08-07	Asha M. Pollen	Milk repellent breast pump
AU2016258207B2	2015-05-07	2020-10-15	Jared Miller	Breast pump system
USD809646S1 *	2016-02-10	2018-02-06	Exploramed Nc7, Inc.	Breast pump
EP3461513A1 *	2017-09-27	2019-04-03	Koninklijke Philips N.V.	Pump device, comprising a pump and a housing accommodating the pump
USD882061S1 *	2018-02-09	2020-04-21	Ningbo YouHe Electric Technology Co., Ltd	Breast pump
USD954303S1 *	2018-06-01	2022-06-14	Chiaro Technology Limited	Breast pump accessory
JP1662265S *	2019-08-01	2020-06-22		
EP3780058A1	2019-09-03	2021-03-10	Koninklijke Philips N.V	Electric breast pump

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JP5799135B2	2015-09-18	Milking pump equipment
JP4481904B2	2010-06-16	Chest pump system
JP3744570B2	2006-02-15	Milking machine
US6257847B1	2001-07-10	Diaphragm pump and pump for double-breast pumping
RU2449811C2	2012-05-10	Breast pump with synchronised diaphragm and pressure control system in pumping cycle
JP2005514116A5	2006-02-16	
JP6403575B2	2018-10-10	Milking machine
GB2435617A	2007-09-05	Breast pump
GB2435618A	2007-09-05	Breast cup
JPH07136245A	1995-05-30	Milker
JP3598218B2	2005-09-21	Milking machine
JPH06292729A	1994-10-21	Electric milking machine
AU744212B2	2002-02-21	Diaphragm pump useful in breast pumping
KR20020086931Y1	2002-12-02	Pressure controller for a milking machine

Priority And Related Applications

Priority Applications (2)

Application	Priority date	Filing date	Title
US10/637,979	2002-12-27	2003-08-08	Breast pump system
PCT/US2004/025285	2003-08-08	2004-08-05	Breast pump system

Concepts

machine-extracted

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Name	Image	Sections	Count	Query match
Breast		claims,abstract,description	223	0.000
Milk, Human		claims,abstract,description	31	0.000
human milk		claims,abstract,description	31	0.000
Nipples		claims,description	92	0.000
method		claims,description	54	0.000
communication		claims,description	45	0.000
fluid		claims,description	45	0.000
Urinary Bladder		claims,description	18	0.000
reversible		claims,description	8	0.000
material		claims,description	7	0.000
metal		claims,description	6	0.000
pressing		claims,description	2	0.000

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(33)優先権主張国　スイス(CH)

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最終頁に続く

(54)【発明の名称】乳房シールドユニット

(57)【要約】
ヒトの母乳を搾り出すための乳房シールドユニットが、ヒトの乳頭を受容するための受容部（１０）と、前記乳頭に負圧を印加するための負圧室（４０）と、前記負圧室（４０）に負圧を発生させるための膜（３）とを有し、前記受容部（１０）はこの負圧室（４０）に開いている。前記膜（３）は１枚又は複数枚に設計され、少なくとも部分的に前記受容部（１０）を取り囲む。この乳房シールドユニットは、乳房に近接する領域での媒体の分離を可能にする。これは小型で洗浄が容易であり、特にハンズフリーの乳房シールドユニットとしての使用に適している。
【選択図】図３

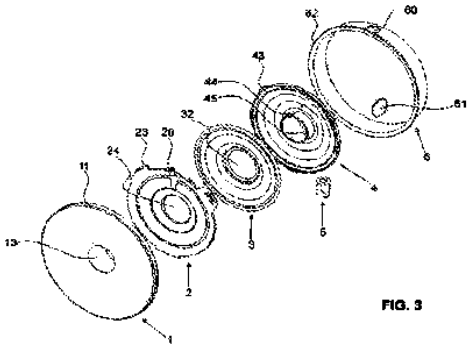


FIG. 3

【特許請求の範囲】
【請求項１】
ヒトの母乳を搾り出すための乳房シールドユニットであって、
ヒトの乳頭を受容するための受容部（１０）と、
前記乳頭に負圧を印加するための　　負圧室（４０）と、
前記負圧室（４０）に負圧を発生させるための膜（３）と、
を有し、前記受容部（１０）は前記負圧室（４０）に開口する乳房シールドユニットにおいて、
前記膜（３）が１枚又は複数枚に設計され、少なくとも部分的に前記受容部（１０）を取り囲むことを特徴とする、乳房シールドユニット。
【請求項２】
ヒトの母乳を搾り出すための乳房シールドユニットであって、
乳頭を受容するための受容部（１０）と、
前記乳頭に負圧を印加するための　　負圧室（４０）と、
前記負圧室（４０）に負圧を発生させるための膜（３）と、
を有し、前記受容部（１０）は中心軸（Ａ）を画定し、前記負圧室（４０）に開口する乳房シールドユニットにおいて、
前記中心軸（Ａ）の延長方向に見て、前記膜（３）が前記負圧室（４０）の前記乳頭に面する側に配置されることを特徴とする、乳房シールドユニット。
【請求項３】
ヒトの母乳を搾り出すための乳房シールドユニットであって、
母親の乳房の乳頭を受容するための受容部（１０）と、
前記乳頭に負圧を印加するための　　負圧室（４０）と、
前記負圧室（４０）をミルク収集容器（７、７’）に接続するためのミルクポート（４５）と、
前記負圧室（４０）に負圧を発生させるための膜（３）と、
を有し、前記受容部（１０）は中心軸（Ａ）を画定し、前記負圧室（４０）に開口する乳房シールドユニットにおいて、
前記中心軸（Ａ）の延長方向に見て、前記膜（３）が前記ミルクポート（４５）の前記母親の乳房に面する側に配置されることを特徴とする、乳房シールドユニット。
【請求項４】
前記膜（３）が円又は部分的円の形状の開口部を取り囲む、請求項１～３のいずれか１項に記載の乳房シールドユニット。
【請求項５】
前記膜（３）が１枚に形成され、円環形状であることを特徴とする、請求項４に記載の乳房シールドユニット。
【請求項６】
前記膜（３）が少なくとも２つの個別のパーツ（３’、３’’、３’’’）を有し、組み立てられた状態の前記個別のパーツ（３’、３’’、３’’’）が円又は部分的円を包囲する、請求項４に記載の乳房シールドユニット。
【請求項７】
乳房側膜ハウジング部（２）と乳房から遠い膜ハウジング部（４）を有し、これらの膜ハウジング部（２、４）が共通の膜ハウジングを形成し、前記膜（３）がこれらの２つの膜ハウジング部（２、４）の間に移動可能に保持される、請求項１～６のいずれか１項に記載の乳房シールドユニット。
【請求項８】
前記膜（３）が静止位置で円錐台形状である、請求項１～７のいずれか１項に記載の乳房シールドユニット。
【請求項９】
母親の乳房に置くための乳房接触面（１）を有し、この乳房接触面（１）を前記膜（３

）を包囲するハウジングシェル（６）に固定させることができる、請求項１～８のいずれか１項に記載の乳房シールドユニット。
【請求項１０】
前記乳房接触面（１）が前記乳頭を受容するための円錐台形状又は円筒形状の第一のスタブ（１０）を有し、この第一のスタブ（１０）を前記負圧室（４０）の第二のスタブ（４４）に接続させることができ、この第一のスタブ（１０）と前記第二のスタブ（４４）が前記受容部を形成する、請求項９に記載の乳房シールドユニット。
【請求項１１】
前記乳房シールドユニットに一体化されたミルク収集容器（７’）を有し、前記ミルク収集容器（７’）が前記乳房シールドユニットの残りの部分に取り外し可能に配置される、請求項１～１０のいずれか１項に記載の乳房シールドユニット。
【請求項１２】
真空ポンプ（８、８１）に接続させることができる真空ポート（２０）を有し、前記膜（３）が前記真空ポート（２０）を前記負圧室（４０）から分離する、請求項１～１１のいずれか１項に記載の乳房シールドユニット。
【請求項１３】
前記膜（３）が、前記真空ポート（２０）に通じる第一の出口（２２）と、前記負圧室（４０）に通じる第二の出口（４２）を有するポンプ室（４６）に配置される、請求項１２に記載の乳房シールドユニット。
【請求項１４】
請求項１２又は１３に記載の乳房シールドユニットと、真空ライン（８０）と、真空ポンプ（８、８１）とを備える乳房ポンプであって、前記真空ライン（８０）が前記真空ポート（２０）を前記真空ポンプ（８、８１）に接続する、乳房ポンプ。
【請求項１５】
前記乳房ポンプユニットがハウジングシェル（６）を有し、このハウジングシェル（６）が前記膜（３）を包囲し、このハウジングシェル（６）の中に前記真空ポンプ（８１）が配置される、請求項１４に記載の乳房ポンプ。
【発明の詳細な説明】
【技術分野】
【０００１】
本発明は、請求項１、２、３のいずれかのプリアンブルに記載の乳房シールドユニット及び請求項１４のプリアンブルに記載の乳房ポンプに関する。
【背景技術】
【０００２】
ヒトの母乳を搾り出すための装置は良く知られている。手動又は電動の真空ポンプが直接又は真空ラインを介して乳房シールドに接続され、この乳房シールドが乳頭を含む母親の乳房の一部を受容するために使用される。
【０００３】
特許文献１は、真空ポンプと、真空ラインと、ベースと、このベース上に固定させることができる漏斗状の硬い乳房シールドを備える乳房ポンプを開示する。真空ラインは真空ポンプをベースに接続する。真空ラインと真空ポンプを汚染から保護するために、大表面の膜形状のバリアがベースに配置される。この膜はポンプ室に配置され、その中で、ポンプユニットによって発生させられた負圧が膜の反対側に伝達される。
【０００４】
特許文献２は同様にベース部を備えた乳房ポンプを記載し、ベース部に漏斗状の硬い乳房シールドと、真空ポンプに接続するための真空ラインと、ミルク収集容器とを接続することができる。ベース部は同様に真空ラインを保護するために膜を有する。
【０００５】
特許文献３と特許文献４は、いわゆるハンズフリーの乳房ポンプを開示し、ブラジャーの下に装着することができる。乳房接触面が母親の乳房の上に密着して置かれ、同時に真

空ポンプの膜としての役割を果たす。即ち、真空ポンプのポンプ室が柔らかい乳房接触面と母親の乳房との間に形成される。

【０００６】

特許文献５は別のハンズフリーの乳房ポンプを開示する。ここでは、小型の乳房シールドがブラジャーの中に配置される。この乳房シールドから、真空ラインが真空ポンプユニットに通じ、ミルクラインがミルク収集容器に通じる。真空ポンプユニットとミルク収集容器はストラップに配置され、母親はこのストラップをウエストに巻き付ける。

【０００７】

特許文献６では、ミルクを収集するための柔軟な袋を硬い乳房シールドに固定して、これら両方をブラジャーに装着する。乳房シールドの上部領域の中に開いている真空ラインが、ストラップにつけられた真空ポンプにつながっている。

【０００８】

特許文献７もまた、ハンズフリーの乳房ポンプを開示する。ここでも、真空ラインは乳房シールドから真空ポンプへつなげられる。このラインは同時にミルクラインとして使用される。

【０００９】

特許文献８は硬い乳房シールドのための支持装置に関し、この支持装置はブラジャーに固定させることができる。

【００１０】

特許文献９は母乳の自然流出を捕えるように設計された乳房シールドを開示する。乳房シールドは柔らかい乳房接触面と、これに接続されたキャップとを有し、ミルクはこのキャップ内に流れ込むことができる。

【００１１】

特許文献１０はヒトの母乳を搾り出すための乳房ポンプを開示し、真空ラインは同時にミルクラインとして使用され、隔膜真空ポンプの膜は媒体分離器としての役目を果たす。

【先行技術文献】

【特許文献】

【００１２】

【特許文献１】国際公開第２００８／０５７２１８号
【特許文献２】国際公開第２０１１／０３７８４１号
【特許文献３】米国特許第７２２３２５５号明細書
【特許文献４】国際公開第２００８／１３７６７８号
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【特許文献６】米国特許出願公開第２００８／０２６２４２０号明細書
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【発明の概要】

【発明が解決しようとする課題】

【００１３】

本発明の目的は、ヒトの母乳を搾り出すための改良された装置を創造することである。

【課題を解決するための手段】

【００１４】

この目的は、請求項１、２、３の特徴を備える乳房シールドユニットによって、及び、請求項１４の特徴を備える乳房ポンプによって達成される。

【００１５】

ヒトの母乳を搾り出すための本発明による乳房シールドユニットは、ヒトの乳頭を受容するための受容部と、乳頭に負圧を印加するための負圧室と、負圧室に負圧を発生させるための膜とを有し、受容部は負圧室に開口している。

【００１６】
本発明によれば、膜は１枚又は複数枚に設計され、少なくとも部分的に受容部を取り囲む。
【００１７】
或いは又は加えて、膜は、受容部の中心軸の延長方向に見て、負圧室の乳頭に面する側に配置される。この位置の指示は、膜が負圧室を乳頭から分離することを意味するのではなく、先行技術で公知のように、膜が中心軸の方向において、負圧室よりも乳頭から遠くに配置されないことを意味する。この負圧室と膜の配置により、コンパクトな乳房シールドユニットの形成が可能となる。
【００１８】
また、或いは又は加えて、本発明による乳房シールドユニットは、負圧室をミルク収集容器に接続するためのミルクポートを有する。負圧室内に負圧を発生させるための膜は、受容部の中心軸の延長方向に見て、このミルクポートの母親の乳房に面する側に配置される。ここでもまた、この位置の指示は、上記の段落で述べたことを再び意味する。前の例と同様の利点がここでもまた達成される。
【００１９】
本発明による乳房シールドユニットは、膜のこの特別な配置のおかげで、非常に小型でコンパクトにすることができる。それでもなお、大表面の膜を使用することができるので、ミルクの搾り出しに必要な負圧を乳房シールドの領域で発生させることを確実にするのに、膜の小さなストロークで十分である。死容積が最小に抑えられる、即ち、乳頭の領域にある負圧室の容積が小さいため、ストロークの必要量もまた低減される。
【００２０】
膜の直径が大きいこともまた、装置の組み立てと、さらに洗浄も容易にする。媒体の分離、即ち、空気又は真空とミルクとの分離もまた膜の大表面により最適に確保される。
【００２１】
膜は１枚又は複数枚に設計することができる。円又は部分的円の形状の開口部を含むことが好ましい。この開口部は中央に配置されることが好ましい。好ましい実施形態では、受容部は開口部を貫通する。
【００２２】
好ましい実施形態では、膜は１枚に形成され、円環形状である。この膜は製造が容易であり、組み立てが容易であり、洗浄が容易であるという利点を有する。また、大きな表面を有する。
【００２３】
別の好ましい実施形態では、膜は少なくとも２つの個別のパーツ、好ましくは３つの個別のパーツから構成される。これらの個別のパーツは、組み立てられた状態では、円又は部分的円を囲む。この実施形態は、乳房シールドユニットの残りの部分の設計を膜の円環形状に合わせる必要がなく、代わりに膜のパーツをユニットの形状に合わせることができるという利点を有する。ポンプ室を膜の分割に応じて分割してもよく、又は連続したポンプ室として設計してもよい。個々の膜パーツは同一の設計にしてもよいし、又は異なる形状と大きさにしてもよい。
【００２４】
別の好ましい実施形態では、単一の膜パーツのみが存在し、その片側に、部分的円形状の凹部を有する。組み立てられた状態では、この凹部は受容部に割り当てられ、受容部がこの凹部を貫通することが好ましい。この凹部と反対側の膜の縁も同様に湾曲していることが好ましい。例えば、膜は腎臓形であってもよい。
【００２５】
その静止位置、即ち、負圧が印加されない状況では、１枚からなる円環状の膜は、母親の乳房の形状に最適に適合させられるように円錐台形状にすることが好ましい。複数枚からなる膜のパーツ及び部分的円として形成された１枚からなる膜は、このような円錐台のパーツとして設計されることが好ましい。膜は柔軟な可撓性材料、特にシリコーンで製造

される。６０ショアＡの硬度が好ましい。
【００２６】
膜は膜ハウジング内で移動可能の保持されることが好ましい。この目的のために、例えば、膜はその縁に膜ハウジングの対応する台座部に保持される周囲ビードを有する。
【００２７】
膜ハウジングは複数の部分、特に、乳房側の部分と乳房から遠い部分の２つの部分からなることが好ましい。
【００２８】
好ましい実施形態では、本発明による乳房シールドユニットは、母親の乳房に置くための乳房接触面を有し、この乳房接触面は膜を包囲するハウジングシェルに固定させることができる。ハウジングシェルは、乳房から遠い膜ハウジング部によって、又はこの膜ハウジング部を同様に包囲する部分によって形成することができる。乳房接触面が通常使用される乳房シールドの代わりとなることが好ましい。
【００２９】
好ましい実施形態では、乳房接触面は柔軟な材料、特にシリコーンで製造される。硬度が５０ショアＡであることが好ましい。
【００３０】
好ましい実施形態では、乳房接触面は、乳頭を受容するための円錐台形又は円筒形の第一のスタブ（ｓｔｕｂ）を有し、この第一のスタブは負圧室の第二のスタブに接続させることができ、この第一のスタブと第二のスタブが受容部を形成する。乳房シールドが通常乳輪のみに、場合により隣接組織にも接触するように、円錐台形部は非常に短く、大きな開口角と大きな表面をもつように設計されることが好ましい。
【００３１】
乳房接触面は膜とは別のパーツにすることができ、又はこの膜と一体に接続させることができる。
【００３２】
膜ハウジングは好ましくはハウジングシェルに対して移動可能に保持される。好ましくは、そこに配置させた膜で膜懸架を形成し、これらをこのハウジングシェル内に移動可能に配置する。これは、乳房接触面が使用中に変形した場合、膜ハウジングは変形せず、従ってポンプ室と負圧室、即ち、死容積はその容積に関して変化しないという利点を有する。これにより使用中に均一なポンプ出力が確保される。
【００３３】
本発明による乳房シールドユニットはハンズフリーユニットとして設計でき、ブラジャーの下に装着することができる。好ましい実施形態では、ミルク収集容器をユニットのハウジングに一体化させる、又は、そこに直接連結させることができる。或いは又は加えて、手動制御又はモーター駆動の真空ポンプをハウジングに一体化させる、又はそこに直接接続させることができる。モーター駆動の真空ポンプを使用する場合、電源をハウジングに一体化させる、又はそこに直接接続させることもまた好ましい。
【００３４】
別の好ましい実施形態では、乳房シールドユニットは外部ラインを介してミルク収集容器及び／又は外部真空源に接続される。
【００３５】
その他の実施形態は、従属請求項に記載される。
【図面の簡単な説明】
【００３６】
【図１】図１は、本発明による乳房シールドユニットを備える乳房ポンプの概略図である。
【図２】図２は、図１の乳房ポンプの第二の斜視図である。
【図３】図３は、図１の乳房シールドユニットの分解図である。
【図４】図４は、母親の乳房の上に置かれてミルクポートが開いている場合の図１の乳房

シールドユニットの長手方向断面を示す。
【図５】図５は、ミルクポートが閉じている図４の乳房シールドユニットを示す。
【図６】図６は、本発明による乳房シールドユニットの第二の実施形態の分解図である。
【図７】図７は、本発明による乳房シールドユニットの第三の実施形態の分解図である。
【図８】図８は、組み立てた状態の図７の乳房シールドユニットを示す。
【図９】図９は、乳房シールドユニット、一体化されたミルク収集容器、一体化された真空ポンプを備える本発明による乳房ポンプの斜視図である。
【図１０】図１０は、カバーを外した図９の乳房ポンプを示す。
【図１１】図１１は、図９の乳房ポンプの分解図である。
【発明を実施するための形態】
【００３７】
本発明の好ましい実施形態を、図を参照して以下に説明するが、これらの図は、説明のためだけのものであって、本発明を限定するものと解釈されるべきではない。同一のパーツには同一の参照符号を付している。
【００３８】
図１～５は、本発明による乳房シールドユニット９の第一の実施形態を示す。
【００３９】
乳房シールドユニット９は、ヒトの母親の乳房に置くための乳房接触面１とシェル６を有し、シェル６に乳房接触面１が取り外し可能に固定される。乳房接触面１は好ましくは円形であり、周囲固定用リップ１１がシェル６の周囲固定用フランジ６２を取り囲む。
【００４０】
乳房接触面１は柔軟な弾性材料、特にシリコーンで製造され、母親の乳房の形状に一致する。乳房接触面１は開口部１３を有し、これは円錐台形又は円筒形のスタブ１０で取り囲まれる。この開口部１３は、乳房接触面１の中央に配置されることが好ましい。
【００４１】
シェル６はドーム形又は半球形であることが好ましい。一体であり、剛性であることが好ましい。通常、プラスチック製である。
【００４２】
図１～５の例示的実施形態では、シェル６は第一の貫通開口６０を有し、これを通って真空ライン８０、ここではシリコーンホースが、乳房シールドユニットの対応するポートに接続される。接続は解除可能であることが好ましい。この真空ライン８０は外部吸引ポンプユニット８につながり、このユニットには真空ポンプが配置される。これはモーター駆動の真空ポンプであることが好ましい。真空ポンプは電源に接続して作動させる（ｍａｉｎｓ－ｏｐｅｒａｔｅｄ）ことができる。加えて又は或いは、電源を吸引ポンプユニットに一体化させてもよい。吸引ポンプユニット８は通常、制御要素と表示部８４を有する。
【００４３】
シェル６には第二の貫通開口６１が設けられる。ミルクライン７０の第一の端部は、ここでも同様にシリコーンホースであり、この貫通開口６１を通って乳房ポンプユニット９のミルクポートに解除可能に接続させることができる。ミルクライン７０の他方の端部は外部のミルク収集容器７に解除可能に接続される。
【００４４】
本発明による乳房シールドユニット９の個々のパーツは、図３に明確に見られる。既に説明した乳房接触面１は、第一の外壁を形成し、シェル６は、ユニット９の反対側の第二の外壁を形成する。これらの間に、乳房側膜ハウジング部２と、膜３と、乳房から遠い膜ハウジング部４と、逆止め弁５、ここではダックビル弁（ｄｕｃｋｂｉｌｌ　ｖａｌｖｅ）とが配置される。
【００４５】
２つの膜ハウジング部２、４は、好ましくは硬い材料、特にプラスチックで製造される。これらはそれぞれ、好ましくは一体に形成される。膜３は好ましくは可撓性材料、特に

シリコーンで製造される。好ましい硬度は６０ショアＡである。

【００４６】

個々のパーツは、逆止め弁５を除いて、円形であることが好ましい。乳房接触面１、乳房側膜ハウジング部２及び膜３は好ましくは、互いに位置合わせされて本ケースでは中央に配置された開口部１３、２４、３２を有する。乳房から遠い膜ハウジング部４はスタブ４４を有し、このスタブ４４はこれらの開口部１３、２４、３２と位置合わせされる。

【００４７】

乳房に近い膜ハウジング部２はその外周に複数の、本ケースでは３つの、角度を付けた固定用小穴２３を有する。これらの固定用小穴２３は、乳房から遠い膜ハウジング部４の対応する固定用突起４３の上にかぶせることができる。このようにして、挿入された膜３と組み合わせて、密封された環状のポンプ室４６を備えた閉じた膜ハウジング部２、４が形成される。膜３はこのポンプ室４６に移動可能に保持される。

【００４８】

組み立てられたこの状態は図４及び５で明確に見られる。好ましくは隆起部３３が設けられた１枚からなる環状膜３は、外側及び内側固定用ビード３０、３１を有し、これらのビードは対応する台座部に保持され、適所に固定されて密封作用を有する。これらの台座部は、結合された２つのハウジング部２、４によって形成される。膜３の領域では、２つのハウジング部２、４がポンプ側開口部２２と乳房側開口部４２を有する環状のポンプ室４６を形成する。

【００４９】

ポンプ側開口部２２は、ポート２０に終わる真空チャネル２１を経由して、真空ライン８０に通じる。乳房側開口部４２は接続チャネル４１を経由して負圧室４０に通じる。この負圧室４０は乳房から遠い膜ハウジング部４によって境界が決められ、乳房接触面１の方向に開いている。負圧室４０はミルクポート４５を有し、これは負圧室４０の、接続チャネル４１から遠い端部に配置されることが好ましい。逆止め弁５はこのミルクポート４５に配置される。大気圧に対して真空室４０が過圧になると、逆止め弁５が開き、ミルクライン７０への接続が確立される。真空室４０が負圧になると、逆止め弁５が閉じて、ミルクライン７０への接続が遮断される。逆止め弁５はミルクポート４５又はミルクライン７０に固定的に接続させることができる。

【００５０】

真空室４０は、その開いた領域でスタブ４４に合流する。乳房接触面１のスタブ１０はこのスタブ４４の上にかぶせられる。このスタブ１０はこの目的のために環状の受け溝１００を有する。

【００５１】

ここに見られるように、乳房接触面１は、わずかに漏斗状になった構造のベース部１２と、そこに一体に形成されたスタブ１０を有することが好ましい。このスタブは中心軸Ａを画定する。図４及び５では、乳房接触面１は、乳頭Ｂがスタブ１０とスタブ４４によって形成される受容部内に突出するように、ヒトの母親の乳房上に置かれている。このようにして、負圧室４０のこの開口部は密閉される。

【００５２】

ここで、脈動真空圧又は周波数と強度が変化する真空圧が吸引ポンプユニット８によって発生させられ、真空ライン８０を通ってポンプ室４６に移送されると、膜３はポンプ側開口部２２に引き寄せられてポンプ側開口部２２を閉じる。この状況は図５に示される。膜３の移動によって、負圧がポンプ室４６に、従って、負圧室４０に発生させられる。図５の矢印で表されるように、ミルクが母親の乳房から搾り出される。負圧室４０は少なくとも部分的に母乳で満たされる。

【００５３】

今度は、真空チャネル２１に印加された負圧が乳房ポンプによって発生させられた吸引周期に応じて低減される、又は大気圧までさらに下げられると、膜３は乳房側開口部４２に引き寄せられて乳房側開口部４２を閉じ、従って、ポンプ側開口部２２を解放する。こ

のようにして、負圧室４０内の圧力が上昇し、逆止め弁５が開く。搾り出されたミルクはミルクライン７０を通って流出することができる。この状況は図４に見られる。

【００５４】

膜３もまた、吸引ポンプユニット８によって発生させられた負圧のリズムで動き、従って、負圧室４０へとそのリズムと真空レベルを伝達する。膜３の比較的大きな表面と負圧室４０の小容量のおかげで、ミルクを搾り出すのに必要な負圧を乳頭Ｂの領域内で発生させることを確実にするのに、比較的小さなストロークで十分である。

【００５５】

図６は第二の例示的実施形態を示す。これは、第一の例示的実施形態と基本的に同じパーツを有する。しかし、膜３は複数枚である。ここでは、３つの膜パーツ３’、３’’、３’’’が存在し、これらは膜ハウジング部２、４の対応する台座部に保持され、ここでもまた、ポンプ室内でポンプ側開口部と乳房側開口部の間を行ったり来たり移動することができる。膜パーツ３’、３’’、３’’’は円形の開口部を包囲し、そこを乳房接触面１のスタブ１０と乳房から遠い膜ハウジング部４のスタブ４４がまたしても貫通する。

【００５６】

図７と８は、第三の例示的実施形態を示す。ここでは、膜３は再び１枚に設計されているが、リングの一部の領域のみを形成する。これもまた腎臓形であってもよい。これは２つの前述のスタブ１０、４４を一部だけ包囲する。これに応じて、膜ハウジング部２、４も同様に部分的円の形状の横断面のみを有する。乳房から遠い膜ハウジング部４では、当然ながら断面が丸く、全体に閉じたジャケットを有するスタブ４４が、この部分的円に一体に形成される。シェル６は、乳房から遠い膜ハウジング部４がよく見えるように、図８では透明の形状で示されている。

【００５７】

図９～１１は別の例示的実施形態を示し、乳房シールドユニットは一体化された吸引ポンプユニット８’を備えた完全な乳房ポンプとして設計されている。乳房接触面１、膜ハウジング部２、４及び膜３は図１～５の実施形態に対応する。しかし、図６～８の実施形態をこのようなポンプに使用することも可能である。

【００５８】

しかし、ドーム形のシェル６の代わりに、ここではシェルリング６’が存在する。シェルリング６’はここでもまた剛性で、特にプラスチック製である。シェルリング６’は、乳房接触面１を固定するための周囲固定用フランジ６２を備える開口部を有する。その後面、即ち、乳房とは反対の方向を向く面は、カバー６’’によって部分的に閉じられる。真空ポンプ８１を中に保持するポンプ台座部８２が、このカバー６’’に一体に形成される。電源はこの真空ポンプ８１に一体化されることが好ましい。真空ポンプ８１は、電気モーターによって作動される、公知のタイプのダイヤフラム真空ポンプであることが好ましい。

【００５９】

真空ポンプ８１を起動させるための制御要素８４はカバー６’’の外側に存在する。さらに、乳房ポンプユニットは対応する制御系を備え、この制御系によって、使用者が制御要素８４を介して入力したコマンドが真空ポンプに伝達される。この制御系はハウジング内に別に配置させてもよく、又は、真空ポンプ８１に一体化させてもよい。

【００６０】

ミルク収集容器７’はカバー６’’に隣接する下部領域に配置される。これはカバー６’’と同様にプラスチック製であることが好ましい。係止突起７１はこのミルク収集容器７’に一体に形成され、シェルリング６’の対応する窪み（図示せず）に係合することができる。このようにして、ミルク収集容器７’はシェルリング６’に解除可能に接続される。さらに、ミルク収集容器７’は一体化された弁（図示せず）を備える連結部７２を有し、この弁は乳房から遠い膜ハウジング部４のミルクポート４５に差し込むことができ、搾り出されたミルクは負圧室４０からミルク収集容器７’の内部に流出することができる。この弁は上述の実施形態の逆止め弁５に相当する。目盛り形状の充填レベル指示器７３

がミルク収集容器７’上に存在することが好ましい。ミルク収集容器７’は、その全体が透明又は部分的に透明であるか、或いは、目盛り７３の領域に透明又は部分的に透明の窓を有する。

【００６１】

本発明による乳房シールドユニットは、乳房に近接する領域での媒体の分離を可能とする。これは小型で洗浄が容易であり、特に、ブラジャーに装着することができるハンズフリーの乳房ポンプユニットとしての使用に適している。

【符号の説明】

【００６２】

１　乳房接触面
１０　スタブ
１００　受け溝
１１　固定用リップ
１２　ベース部
１３　中央開口部
２　乳房側膜ハウジング部
２０　ポート
２１　真空チャネル
２２　ポンプ側開口部
２３　固定用小穴
２４　中央開口部
３　膜
３’、３’’、３’’’　膜パーツ
３０　外側固定用ビード
３１　内側固定用ビード
３２　中央開口部
３３　隆起部
４　乳房から遠い膜ハウジング部
４０　負圧室
４１　接続チャネル
４２　乳房側開口部
４３　固定用突起
４４　スタブ
４５　ミルクポート
４６　ポンプ室
５　逆止め弁
６　シェル
６’　シェルリング
６’’　カバー
６０　第一の貫通開口
６１　第二の貫通開口
６２　固定用フランジ
７、７’　ミルク収集容器
７０　ミルクライン
７１　係止突起
７２　連結部
７３　充填レベル指示器
８、８’　吸引ポンプユニット
８０　真空ライン
８１　真空ポンプ

８２　ポンプ台座部
８３　ねじ穴
８４　制御要素／表示部
９　乳房シールドユニット
Ａ　中心軸
Ｂ　乳頭

【図１】

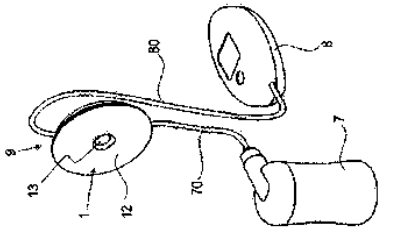


FIG. 1

【図２】

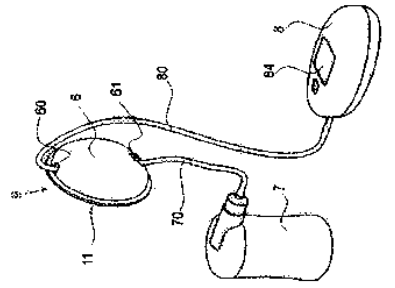


FIG. 2

【図３】

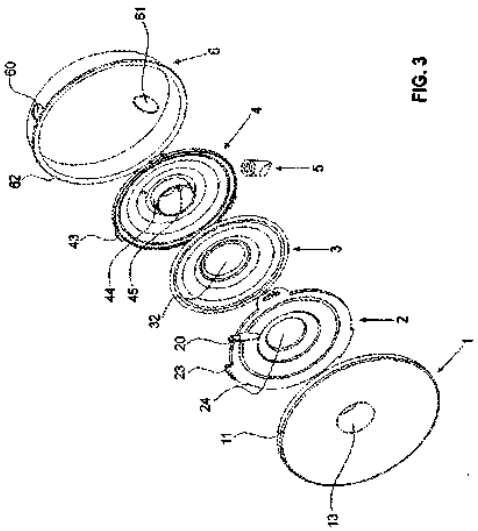


FIG. 3

【図４】

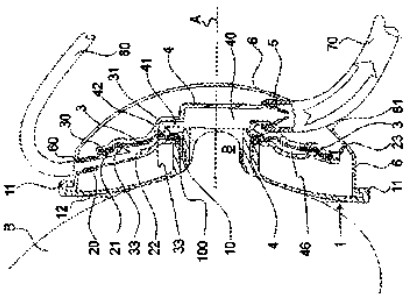


FIG. 4

【図５】

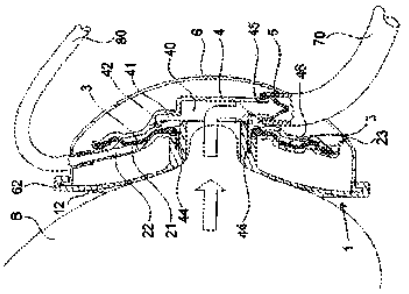


FIG. 5

【図６】

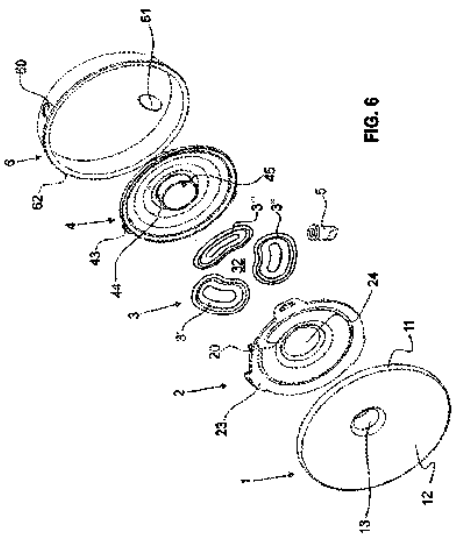


FIG. 6

【図７】

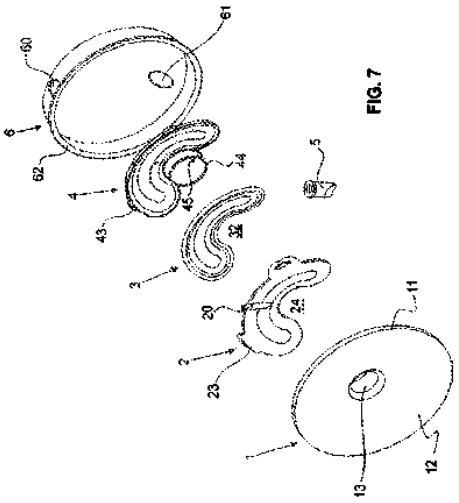


FIG. 7

【図８】

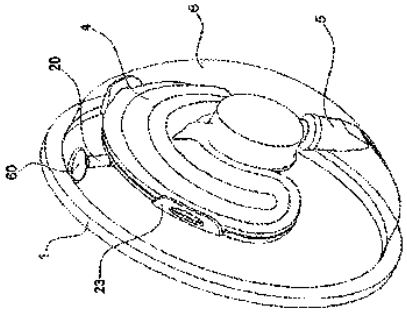


FIG. 8

【図９】

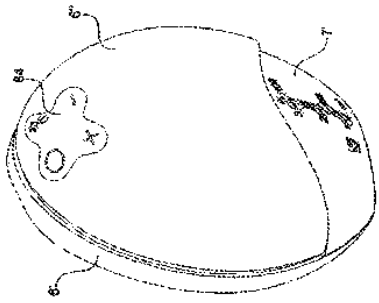


FIG. 9

【図１０】

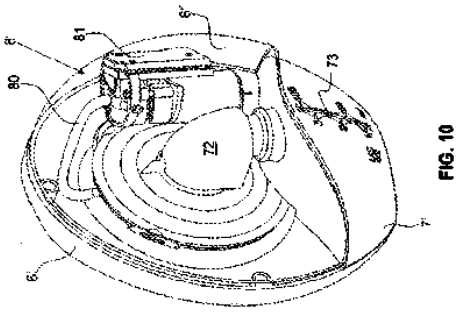


FIG. 10

【図１１】

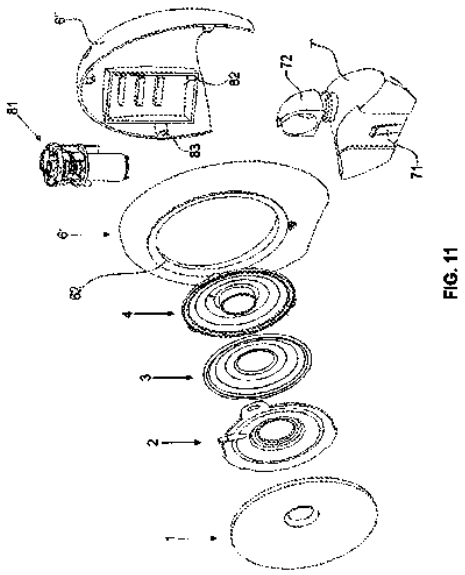


FIG. 11

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No
PCT/CH2012/000164

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

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

B. FIELDS SEARCHED

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

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/071466 A1 (SILVER BRIAN H [US] ET AL) 24 March 2011 (2011-03-24) cited in the application abstract; figures 14,15 paragraphs [0092] - [0098]	1-5,7-11
X	US 6 461 324 B1 (SCHLENSOG KLAUS [CH]) 8 October 2002 (2002-10-08) abstract; figure 1 column 4, line 40 - column 5, line 19	2-6, 8-10, 12-15
X	EP 2 138 197 A1 (TRIMED AG [LI]) 30 December 2009 (2009-12-30) abstract; figure 3 paragraphs [0015] - [0017]	1,4-6,8, 9

-/--

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
24 September 2012	01/10/2012

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

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INTERNATIONAL SEARCH REPORT

International application No
PCT/CH2012/000164

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2008/262420 A1 (DAO STELLA [US] ET AL) 23 October 2008 (2008-10-23) abstract; figures paragraphs [0023] - [0028] -----	11

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/CH2012/000164

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011071466 A1	24-03-2011	AU 2010300011 A1	08-03-2012
		AU 2010300058 A1	03-05-2012
		CN 102596280 A	18-07-2012
		CN 102665783 A	12-09-2012
		EP 2480264 A1	01-08-2012
		EP 2480265 A1	01-08-2012
		KR 20120074279 A	05-07-2012
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		TW 201121593 A	01-07-2011
		TW 201127426 A	16-08-2011
		US 2011071466 A1	24-03-2011
		WO 2011035447 A1	31-03-2011
		WO 2011035448 A1	31-03-2011
		WO 2011037841 A2	31-03-2011
US 6461324 B1	08-10-2002	AU 3328799 A	20-09-1999
		US 6461324 B1	08-10-2002
		WO 9944650 A1	10-09-1999
EP 2138197 A1	30-12-2009	AT 492308 T	15-01-2011
		EP 2138197 A1	30-12-2009
US 2008262420 A1	23-10-2008	NONE	

Form PCT/ISA/210 (patent family annex) (April 2005)

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/CH2012/000164

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

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

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
A61M

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

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

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	US 2011/071466 A1 (SILVER BRIAN H [US] ET AL) 24. März 2011 (2011-03-24) in der Anmeldung erwähnt Zusammenfassung; Abbildungen 14,15 Absätze [0092] - [0098]	1-5,7-11
X	US 6 461 324 B1 (SCHLENSOG KLAUS [CH]) 8. Oktober 2002 (2002-10-08) Zusammenfassung; Abbildung 1 Spalte 4, Zeile 40 - Spalte 5, Zeile 19	2-6, 8-10, 12-15
X	EP 2 138 197 A1 (TRIMED AG [LI]) 30. Dezember 2009 (2009-12-30) Zusammenfassung; Abbildung 3 Absätze [0015] - [0017]	1,4-6,8, 9

-/--

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

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24. September 2012	01/10/2012

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

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INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/CH2012/000164

C. (Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	US 2008/262420 A1 (DAO STELLA [US] ET AL) 23. Oktober 2008 (2008-10-23) Zusammenfassung; Abbildungen Absätze [0023] - [0028] -----	11

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INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationales Aktenzeichen
PCT/CH2012/000164

Im Recherchenbericht angeführtes Patentdokument		Datum der Veröffentlichung	Mitglied(er) der Patentfamilie		Datum der Veröffentlichung
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			AU	2010300058 A1	03-05-2012
			CN	102596280 A	18-07-2012
			CN	102665783 A	12-09-2012
			EP	2480264 A1	01-08-2012
			EP	2480265 A1	01-08-2012
			KR	20120074279 A	05-07-2012
			KR	20120074296 A	05-07-2012
			SG	179094 A1	27-04-2012
			SG	179162 A1	27-04-2012
			TW	201121592 A	01-07-2011
			TW	201121593 A	01-07-2011
			TW	201127426 A	16-08-2011
			US	2011071466 A1	24-03-2011
			WO	2011035447 A1	31-03-2011
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US 2008262420	A1	23-10-2008	KEINE		

Formblatt PCT/ISA/210 (Anhang Patentfamilie) (April 2005)

フロントページの続き

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Breast shield unit

Abstract

translated from Japanese

A breast shield unit for expressing human breast milk includes a receiving part (10) for receiving a human nipple, a negative pressure chamber (40) for applying a negative pressure to the nipple, and the negative pressure chamber (40) has a membrane (3) for generating a negative pressure, and the receiving part (10) is open to the negative pressure chamber (40). The membrane (3) is designed as one or more and at least partly surrounds the receiving part (10). This breast shield unit allows the separation of media in the area close to the breast. This is small and easy to clean, and is particularly suitable for use as a hands-free breast shield unit. [Selection] Figure 3

Images (11)



Classifications

- A61M1/06 Milking pumps

View 3 more classifications

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Other languages: Japanese

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External links: Espacenet, Global Dossier, Discuss

Claims (15)

Hide Dependent

translated from Japanese

A breast shield unit for milking human breast milk,
A receiving portion (10) for receiving a human teat;
A negative pressure chamber (40) for applying negative pressure to the nipple;
A membrane (3) for generating a negative pressure in the negative pressure chamber (40),
A breast shield unit that opens into the negative pressure chamber (40),
Breast shield unit, characterized in that the membrane (3) is designed in one or more and at least partly surrounds the receiving part (10). A breast shield unit for milking human breast milk,
A receiving portion (10) for receiving the nipple,
A negative pressure chamber (40) for applying negative pressure to the nipple,
A membrane (3) for generating a negative pressure in the negative pressure chamber (40),
A breast shield unit, wherein the receptacle (10) defines a central axis (A) and opens into the negative pressure chamber (40),
A breast shield unit characterized in that the membrane (3) is arranged on the side of the negative pressure chamber (40) facing the nipple as viewed in the direction of extension of the central axis (A). A breast shield unit for milking human breast milk,
A receiving part (10) for receiving the mother's breast nipple;
A negative pressure chamber (40) for applying negative pressure to the nipple;
A milk port (45) for connecting the negative pressure chamber (40) to a milk collection container (7, 7 ');
A membrane (3) for generating a negative pressure in the negative pressure chamber (40),
A breast shield unit, wherein the receptacle (10) defines a central axis (A) and opens into the negative pressure chamber (40);
Breast shield unit, characterized in that the membrane (3) is arranged on the side of the milk port (45) facing the mother's breast when viewed in the direction of extension of the central axis (A). Breast shield unit according to any of the preceding claims, wherein the membrane (3) surrounds an opening in the shape of a circle or a partial circle. Breast shield unit according to claim 4, characterized in that the membrane (3) is formed in one piece and has an annular shape The membrane (3) has at least two individual parts (3 ', 3 ", 3 '"), and the assembled individual parts (3 ', 3 ", 3 '") 5. The breast shield unit according to claim 4, wherein) surrounds a circle or a partial circle. It has a breast membrane housing part (2) and a membrane housing part (4) far from the breast. These membrane housing parts (2, 4) form a common membrane housing, and the membrane (3) is the 2 Breast shield unit according to any one of the preceding claims, which is movably held between two membrane housing parts (2, 4). Breast shield unit according to any one of the

preceding claims, wherein the membrane (3) is frustoconical in a rest position. 9. A breast contact surface (1) for placing on a mother's breast, the breast contact surface (1) being fixable to a housing shell (6) surrounding the membrane (3). The breast shield unit according to any one of the above. The breast contact surface (1) has a frustoconical or cylindrical first stub (10) for receiving the teat, and this first stub (10) is connected to the negative pressure chamber (40). Breast shield unit according to claim 9, which can be connected to a second stub (44), the first stub (10) and the second stub (44) forming the receptacle. 11. A milk collection container (7') integrated into the breast shield unit, wherein the milk collection container (7') is removably disposed on the rest of the breast shield unit. The breast shield unit according to any one of the above. A vacuum port (20) that can be connected to a vacuum pump (8, 81), wherein the membrane (3) separates the vacuum port (20) from the negative pressure chamber (40). The breast shield unit according to any one of 11. The membrane (3) is disposed in a pump chamber (46) having a first outlet (22) leading to the vacuum port (20) and a second outlet (42) leading to the negative pressure chamber (40). The breast shield unit according to claim 12. A breast pump comprising a breast shield unit according to claim 12 or 13, a vacuum line (80), and a vacuum pump (8, 81), wherein the vacuum line (80) connects the vacuum port (20). Breast pump connected to the vacuum pump (8, 81). The breast pump unit has a housing shell (6), which surrounds the membrane (3), in which the vacuum pump (81) is arranged. The breast pump according to claim 14.

Description

translated from Japanese

The present invention relates to a breast shield unit according to any one of the preambles of claims 1, 2, and 3 and a breast pump according to the preamble of claim 14.

Devices for expressing human breast milk are well known. A manual or motorized vacuum pump is connected to the breast shield, either directly or through a vacuum line, and this breast shield is used to receive a portion of the mother's breast, including the nipple.

Patent document 1 discloses a breast pump including a vacuum pump, a vacuum line, a base, and a funnel-shaped hard breast shield that can be fixed on the base. The vacuum line connects the vacuum pump to the base. In order to protect the vacuum line and the vacuum pump from contamination, a large surface membrane shaped barrier is placed on the base. This membrane is placed in the pump chamber, in which the negative pressure generated by the pump unit is transmitted to the opposite side of the membrane.

Patent document 2 similarly describes the breast pump provided with the base part, and can connect the funnel-like hard breast shield, the vacuum line for connecting to the vacuum pump, and the milk collection container to the base part. The base part also has a membrane to protect the vacuum line.

Patent Documents 3 and 4 disclose so-called hands-free breast pumps that can be mounted under a brassiere. The breast contact surface is placed in close contact with the mother's breast and at the same time serves as a membrane for the vacuum pump. That is, the pump chamber of the vacuum pump is formed between the soft breast contact surface and the mother's breast.

U.S. Pat. No. 6,057,077 discloses another hands-free breast pump. Here, a small breast shield is placed in the brassiere. From this breast shield, a vacuum line leads to the vacuum pump unit and a milk line leads to the milk collection container. The vacuum pump unit and milk collection container are placed on a strap, and the mother wraps the strap around the waist.

In Patent Document 6, a flexible bag for collecting milk is fixed to a hard breast shield, and both are attached to a brassiere. An open vacuum line in the upper area of the breast shield leads to a vacuum pump attached to the strap.

U.S. Patent No. 6,099,077 also discloses a hands-free breast pump. Again, the vacuum line is connected from the breast shield to the vacuum pump. This line is simultaneously used as a milk line.

Patent document 8 relates to a support device for a hard breast shield, which can be fixed to a brassiere.

U.S. Patent No. 6,099,077 discloses a breast shield designed to catch natural spillage of breast milk. The breast shield has a soft breast contact surface and a cap connected thereto, so that milk can flow into the cap.

U.S. Pat. No. 6,057,077 discloses a breast pump for expressing human breast milk, the vacuum line being used simultaneously as a milk line, and the membrane of the diaphragm vacuum pump serves as a media separator.

International Publication No. 2008/057218 International Publication No. 2011/037841 US Pat. No. 7,223,255 International Publication No. 2008/137678 US Pat. No. 6,379,327 US Patent Application Publication No. 2006/0252420 US Pat. No. 6,440,109 US Patent Application Publication No. 2008/0039781 US Pat. No. 4,270,538 International Publication No. 2011/035448

The object of the present invention is to create an improved device for expressing human breast milk.

This object is achieved by a breast shield unit comprising the features of claims 1, 2, 3 and by a breast pump comprising the features of claim 14.

Breast shield unit according to the present invention for milking human breast milk generates a receiving part for receiving a human nipple, a negative pressure chamber for applying negative pressure to the nipple, and a negative pressure in the negative pressure chamber And the receiving part is open to the negative pressure chamber.

According to the invention, the membrane is designed as one or more and at least partly surrounds the receiving part.

Alternatively or additionally, the membrane is arranged on the side of the negative pressure chamber facing the nipple as viewed in the direction of extension of the central axis of the receiving part. This position indication does not mean that the membrane separates the negative pressure chamber from the nipple, but as is known in the prior art, the membrane is located farther from the nipple than the negative pressure chamber in the direction of the central axis. Means not. The arrangement of the negative pressure chamber and the membrane makes it possible to form a compact breast shield unit.

Alternatively or additionally, the breast shield unit according to the invention has a milk port for connecting the negative pressure chamber to the milk collection container. A membrane for generating a negative pressure in the negative pressure chamber is arranged on the side of the milk port facing the mother's breast as viewed in the direction of extension of the central axis of the receiving part. Again, this position indication means again what was said in the paragraph above. Similar advantages as in the previous example are also achieved here.

The breast shield unit according to the invention can be very small and compact thanks to this special arrangement of membranes. Nevertheless, because a large surface membrane can be used, a small stroke of the membrane is sufficient to ensure that the negative pressure required for milking is generated in the area of the breast shield. Since the dead volume is minimized, i.e. the volume of the negative pressure chamber in the area of the teat is small, the required stroke is also reduced.

The large membrane diameter also facilitates assembly and further cleaning of the device. The separation of the medium, i.e. the separation of air or vacuum and milk, is also optimally ensured by the large surface of the membrane.

The film can be designed as one sheet or a plurality of sheets. It preferably includes an opening in the shape of a circle or a partial circle. This opening is preferably arranged in the center. In a preferred embodiment, the receptacle passes through the opening.

In a preferred embodiment, the membrane is formed in one piece and has an annular shape. This membrane has the advantage of being easy to manufacture, easy to assemble and easy to clean. It also has a large surface.

In another preferred embodiment, the membrane is composed of at least two individual parts, preferably three individual parts. These individual parts, when assembled, enclose a circle or a partial circle. This embodiment has the advantage that the design of the rest of the breast shield unit need not be matched to the toroidal shape of the membrane, but instead the membrane parts can be matched to the shape of the unit. The pump chamber may be divided according to the membrane division, or may be designed as a continuous pump chamber. Individual membrane parts may have the same design, or different shapes and sizes.

In another preferred embodiment, there is only a single membrane part with a partially circular recess on one side. In the assembled state, it is preferred that this recess is assigned to a receiving part, and that the receiving part passes through this recess. It is preferable that the edge of the film on the side opposite to the concave portion is similarly curved. For example, the membrane may be kidney-shaped.

In its rest position, i.e., when no negative pressure is applied, the single toroidal membrane is preferably frustoconical so as to be optimally adapted to the shape of the mother's breast. A plurality of membrane parts and a single membrane formed as a partial circle are preferably designed as such a truncated cone part. The membrane is made of a soft flexible material, in particular silicone. A hardness of 60 Shore A is preferred.

The membrane is preferably held movable within the membrane housing. For this purpose, for example, the membrane has a peripheral bead at its edge which is held in a corresponding pedestal of the membrane housing.

The membrane housing preferably comprises a plurality of parts, in particular two parts, a part on the breast side and a part far from the breast.

In a preferred embodiment, a breast shield unit according to the present invention has a breast contact surface for placement on the mother's breast, which can be secured to a housing shell surrounding the membrane. The housing shell can be formed by a membrane housing part remote from the breast or by a part that also surrounds the membrane housing part. The breast contact surface is preferably an alternative to the commonly used breast shield

In a preferred embodiment, the breast contact surface is made of a flexible material, particularly silicone. The hardness is preferably 50 Shore A

In a preferred embodiment, the breast contacting surface has a frustoconical or cylindrical first stub for receiving the teat, which first stub is connected to the second stub of the negative pressure chamber. The first stub and the second stub form a receptacle. The frustoconical part is preferably designed to be very short, with a large opening angle and a large surface, so that the breast shield is usually in contact with the areola only and possibly also with adjacent tissue.

The breast contact surface can be a separate part from the membrane, or it can be integrally connected to the membrane.

The membrane housing is preferably held movably with respect to the housing shell. Preferably, a membrane suspension is formed from the membrane disposed therein and is movably disposed within the housing shell. This has the advantage that if the breast contact surface deforms in use, the membrane housing will not deform, and therefore the pump chamber and negative pressure chamber, ie the dead volume, will not change with respect to its volume. This ensures a uniform pump output during use.

The breast shield unit according to the invention can be designed as a hands-free unit and can be mounted under a brassiere. In a preferred embodiment, the milk collection container can be integrated into the unit housing or directly connected thereto. Alternatively or additionally, a manually controlled or motor driven vacuum pump can be integrated into the housing or directly connected thereto. If a motor driven vacuum pump is used, it is also preferred that the power source be integrated into the housing or directly connected thereto.

In another preferred embodiment, the breast shield unit is connected to a milk collection container and / or an external vacuum source via an external line.

Other embodiments are set forth in the dependent claims.

FIG. 1 is a schematic view of a breast pump comprising a breast shield unit according to the present invention. FIG. 2 is a second perspective view of the breast pump of FIG. FIG. 3 is an exploded view of the breast shield unit of FIG. 4 shows a longitudinal section of the breast shield unit of FIG. 1 when placed on the mother's breast and the milk port is open. FIG. 5 shows the breast shield unit of FIG. 4 with the milk port closed. FIG. 6 is an exploded view of a second embodiment of the breast shield unit according to the present invention. FIG. 7 is an exploded view of a third embodiment of a breast shield unit according to the present invention. FIG. 8 shows the breast shield unit of FIG. 7 in an assembled state. FIG. 9 is a perspective view of a breast pump according to the present invention comprising a breast shield unit, an integrated milk collection container, and an integrated vacuum pump. FIG. 10 shows the breast pump of FIG. 9 with the cover removed. FIG. 11 is an exploded view of the breast pump of FIG.

Preferred embodiments of the invention are described below with reference to the figures, which are for illustration purposes only and are not to be construed as limiting the invention. The same parts have the same reference numerals

1 to 5 show a first embodiment of a breast shield unit 9 according to the invention.

The breast shield unit 9 has a breast contact surface 1 and a shell 6 to be placed on the breast of a human mother, and the breast contact surface 1 is detachably fixed to the shell 6. The breast contact surface 1 is preferably circular and the perimeter fixing lip 11 surrounds the perimeter fixing flange 62 of the shell 6.

The breast contact surface 1 is made of a flexible elastic material, in particular silicone, and matches the shape of the mother's breast. The breast contact surface 1 has an opening 13 that is surrounded by a frustoconical or cylindrical stub 10. The opening 13 is preferably arranged at the center of the breast contact surface 1.

The shell 6 is preferably dome-shaped or hemispherical. It is preferably integral and rigid. Usually made of plastic.

In the exemplary embodiment of FIGS. 1-5, the shell 6 has a first through opening 60, through which a vacuum line 80, here a silicone hose, is connected to a corresponding port of the breast shield unit. The connection is preferably releasable. This vacuum line 80 is connected to an external suction pump unit 8, in which a vacuum pump is arranged. This is preferably a motor driven vacuum pump. The vacuum pump can be mains-operated by connecting to a power source. In addition or alternatively, the power source may be integrated into the suction pump unit. The suction pump unit 8 usually has a control element and a display part 84.

The shell 6 is provided with a second through opening 61. The first end of the milk line 70 is again a silicone hose and can be releasably connected to the milk port of the breast pump unit 9 through this through opening 61. The other end of the milk line 70 is releasably connected to an external milk collection container 7.

The individual parts of the breast shield unit 9 according to the invention can be clearly seen in FIG. The breast contact surface 1 already described forms a first outer wall and the shell 6 forms a second outer wall on the opposite side of the unit 9. Between these are the breast-side membrane housing part 2, the membrane 3, the

membrane housing part 4 remote from the breast, and a check valve 5, here a duckbill valve.

The two membrane housing parts 2, 4 are preferably made of a rigid material, in particular plastic. Each of these is preferably integrally formed. The membrane 3 is preferably made of a flexible material, in particular silicone. A preferred hardness is 60 Shore A.

The individual parts are preferably circular except for the check valve 5. The breast contact surface 1, the breast side membrane housing part 2 and the membrane 3 preferably have openings 13, 24, 32 aligned with each other and centrally arranged in this case. The membrane housing part 4 remote from the breast has stubs 44 which are aligned with these openings 13, 24, 32.

The membrane housing part 2 close to the breast has a plurality of angled fixing holes 23 on the outer periphery thereof, in this case, three. These fixing holes 23 can be placed on the corresponding fixing protrusions 43 of the membrane housing part 4 far from the breast. In this way, in combination with the inserted membrane 3, closed membrane housing parts 2, 4 with a sealed annular pump chamber 46 are formed. The membrane 3 is movably held in the pump chamber 46.

This assembled state is clearly seen in FIGS. Preferably, the single annular membrane 3 provided with a raised portion 33 has outer and inner fixing beads 30, 31 which are held by corresponding pedestals and fixed in place for sealing action. Have These pedestals are formed by two housing parts 2, 4 joined together. In the region of the membrane 3, the two housing parts 2, 4 form an annular pump chamber 46 having a pump side opening 22 and a breast side opening 42.

The pump side opening 22 leads to the vacuum line 80 via the vacuum channel 21 ending at the port 20. The breast opening 42 communicates with the negative pressure chamber 40 via the connection channel 41. The negative pressure chamber 40 is delimited by the membrane housing part 4 far from the breast and opens in the direction of the breast contact surface 1. The negative pressure chamber 40 has a milk port 45 which is preferably arranged at the end of the negative pressure chamber 40 remote from the connection channel 41. The check valve 5 is arranged in this milk port 45. When the vacuum chamber 40 is overpressured relative to atmospheric pressure, the check valve 5 opens and a connection to the milk line 70 is established. When the vacuum chamber 40 becomes negative pressure, the check valve 5 is closed and the connection to the milk line 70 is cut off. The check valve 5 can be fixedly connected to the milk port 45 or the milk line 70.

The vacuum chamber 40 joins the stub 44 in the open area. The stub 10 of the breast contact surface 1 is placed on the stub 44. The stub 10 has an annular receiving groove 100 for this purpose.

As can be seen, the breast contact surface 1 preferably has a base portion 12 with a slightly funnel-like structure and a stub 10 formed integrally therewith. This stub defines a central axis A. 4 and 5, the breast contact surface 1 is placed on the breast of a human mother so that the teat B protrudes into the receptacle formed by the stub 10 and stub 44. In this way, this opening of the negative pressure chamber 40 is sealed.

Here, when a pulsating vacuum pressure or a vacuum pressure changing in frequency and intensity is generated by the suction pump unit 8 and transferred to the pump chamber 46 through the vacuum line 80, the membrane 3 is attracted to the pump side opening 22. Then, the pump side opening 22 is closed. This situation is shown in FIG. Due to the movement of the membrane 3, a negative pressure is generated in the pump chamber 46 and thus in the negative pressure chamber 40. As represented by the arrow in FIG. 5, milk is squeezed out of the mother's breast. The negative pressure chamber 40 is at least partially filled with breast milk.

This time, when the negative pressure applied to the vacuum channel 21 is reduced according to the suction cycle generated by the breast pump, or further reduced to atmospheric pressure, the membrane 3 is attracted to the breast side opening 42. The breast side opening 42 is closed, thus releasing the pump side opening 22. In this way, the pressure in the negative pressure chamber 40 increases and the check valve 5 opens. The milk that has been expressed can flow through the milk line 70. This situation can be seen in FIG.

The membrane 3 also moves with a negative pressure rhythm generated by the suction pump unit 8 and thus transmits that rhythm and vacuum level to the negative pressure chamber 40. Thanks to the relatively large surface of the membrane 3 and the small volume of the negative pressure chamber 40, a relatively small stroke is ensured in order to ensure that the negative pressure required to express the milk is generated in the area of the teat B. Is enough.

FIG. 6 shows a second exemplary embodiment. This has essentially the same parts as the first exemplary embodiment. However, there are a plurality of films 3. Here, there are three membrane parts 3 ', 3 ", 3 '", which are held on corresponding pedestals of the membrane housing parts 2, 4 and again here the pump side opening in the pump chamber And back and forth between the breast opening. The membrane parts 3 ', 3 ", 3" surround a circular opening through which the stub 10 of the breast contact surface 1 and the stub 44 of the membrane housing part 4 remote from the breast penetrate again.

7 and 8 show a third exemplary embodiment. Here, the film 3 is again designed as a single sheet, but only a partial region of the ring is formed. This may also be in kidney form. This only partially encloses the two aforementioned stubs 10,44. Correspondingly, the membrane housing parts 2, 4 likewise have only a partial circular cross section. In the membrane housing part 4 remote from the breast, of course, a stub 44 having a rounded cross section and a closed jacket is integrally formed in this partial circle. The shell 6 is shown in a transparent shape in FIG. 8 so that the membrane housing part 4 far from the breast can be seen well.

9-11 illustrate another exemplary embodiment, where the breast shield unit is designed as a complete breast pump with an integrated suction pump unit 8 '. The breast contact surface 1, membrane housing parts 2, 4 and membrane 3 correspond to the embodiment of FIGS. However, the embodiments of FIGS. 6-8 can also be used with such a pump.

However, instead of the dome-shaped shell 6, a shell ring 6 'is present here. The shell ring 6' is again rigid, in particular made of plastic. The shell ring 6 ' has an opening provided with a peripheral fixing flange 62 for fixing the breast contact surface 1. The rear face, ie the face facing away from the breast, is partially closed by the cover 6 '. A pump base 82 for holding the vacuum pump 81 therein is formed integrally with the cover 6 '. The power source is preferably integrated with the vacuum pump 81. The vacuum pump 81 is preferably a known type of diaphragm vacuum pump operated by an electric motor.

A control element 84 for activating the vacuum pump 81 is present outside the cover 6 '. In addition, the breast pump unit has a corresponding control system by which commands entered by the user via the control element 84 are transmitted to the vacuum pump. This control system may be separately arranged in the housing, or may be integrated with the vacuum pump 81.

The milk collection container 7 'is arranged in the lower region adjacent to the cover 6 '. This is preferably made of plastic like the cover 6 '. The locking protrusion 71 is formed integrally with the milk collection container 7 'and can engage with a corresponding recess (not shown) in the shell ring 6'. In this way, the milk collection container 7 'is releasably connected to the shell ring 6'. Furthermore, the milk collection container 7 'has a connection 72 with an integrated valve (not shown), which can be inserted into the milk port 45 of the membrane housing part 4 remote from the breast and squeezed out. The milk can flow out of the negative pressure chamber 40 into the milk collection container 7 '. This valve corresponds to the check valve 5 of the above-described embodiment. A scale-shaped filling level indicator 73 is preferably present on the milk collection container 7 '. The milk collection container 7 ' is entirely or partially transparent, or has a transparent or partially transparent window in the area of the scale 73.

The breast shield unit according to the present invention allows the separation of media in the area close to the breast. It is small and easy to clean, and is particularly suitable for use as a hands-free breast pump unit that can be mounted on a brassiere.

1 breast contact surface 10 stub 100 receiving groove 11 fixing lip 12 base portion 13 central opening 2 breast side membrane housing portion 20 port 21 vacuum channel 22 pump side opening 23 fixing small hole 24 central opening 3 membrane 3 ', 3 " 3 "Membrane part 30 Outside fixing bead 31 Inner fixing bead 32 Central opening 33 Raised part 4 Membrane housing part 40 far from the breast Negative pressure chamber 41 Connection channel 42 Breast side opening 43 Fixing protrusion 44 Stud 45 Milk port 46 Pump chamber 5 Check valve 6 Shell 6 'Shell ring 6 "Cover 60 First through opening 61 Second through opening 62 Fixing flange 7, 7' Milk collection container 70 Milk line 71 Locked Projection 72 Connecting portion 73 Filling level indicator 8, 8 'Suction pump unit 80 Vacuum line 81 Vacuum pump 82 Pump base 83 Screw hole 8 Control element / display unit 9 breastshield unit A central axis B papilla

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JP2019509090A *	2016-02-10	2019-04-04	エクスプロラメッド・エヌシー7・インコーポレイテッド Exploramed NC7, Inc.	Milking container assembly and method
JP2020523179A *	2017-06-15	2020-08-06	キアロテクノロジーリミテッド Chiaro Technology Limited	Milking system
Family To Family Citations				

US9872782 *	2006-11-01	2018-05-29	Medela Holding Ag	Self returning contamination barrier
US9615682	2013-03-24	2017-04-11	Naya Health, Inc.	Method, apparatus, and system for expression and quantification of human breast milk
CH708400A1 *	2013-07-16	2015-01-30	Medela Holding Ag	Breastpump unit.
CN203716438U *	2013-12-06	2014-07-16	陈俊淑	Cup and breast pump comprising cup
WO2016007500A1 *	2014-07-07	2016-01-14	Naya Health, Inc.	Pump apparatus and methods for expression of human breast milk
SG10201911994QA *	2014-07-22	2020-02-27	Exploramed Nc7 Inc	Breast pump system and methods
WO2016014488A1 *	2014-07-22	2016-01-28	Exploramed Nc7, Llc	Breast pump system and methods
CA2955605A1 *	2014-07-22	2016-01-28	John Y. Chang	Breast pump system and methods
WO2016014488A1 *	2014-07-22	2016-01-28	Exploramed Nc7, Llc	Breast pump system and methods
CN110639972B	2014-08-11	2022-05-17	威洛创新股份有限公司	Synchronization of breast pumping with infant feeding
WO2016033107A1	2014-08-26	2016-03-03	Mimec Labs, Inc	Breast fluid expression device
SG10201906186RA	2014-09-16	2019-08-27	Exploramed Nc7 Inc	Systems, devices and methods for assessing milk volume expressed from a breast
US9782503B1	2015-02-20	2017-04-25	Medela Holding Ag	Membrane for a breastshield of a breast pump
US10220126B2 *	2015-04-06	2019-03-05	P.H.D. Devices, LLC	Breast shield and breast pump device
EP3341040B1 *	2015-08-27	2021-07-21	Medela Holding AG	Lacteal extractor safety system
WO2017139389A1	2016-02-09	2017-08-17	Delphinus Medical Technologies, Inc.	System for shaping and positioning a tissue body
SG11201806521YA	2016-02-10	2018-08-30	Exploramed Nc7 Inc	Breast pump assembly and methods
EP3318225B1 *	2016-11-03	2021-01-06	This AG	Clean venturi aspiration
US10626004B2 *	2017-04-18	2020-04-21	Regents Of The University Of Minnesota	Lactation system and method
SG10201705663TA *	2017-07-10	2019-02-27	Pumpables Pte Ltd	Breast pump system
US11298165B2 *	2017-09-07	2022-04-12	Delphinus Medical Technologies, Inc.	System having anchored interface for shaping and positioning a tissue body
USD851859S1	2017-12-01	2019-06-25	Davielle Jackson	Bra with breast milk collection
KR102085749B1 *	2018-04-05	2020-03-06	홍성수	Breast pump
USD907194S1 *	2019-01-10	2021-01-05	Think Green Limited	Breast pump
CN109621042B *	2019-01-23	2022-05-14	鼎正医疗(苏州)有限公司	Wearable electric breast pump host
US11285093B1 *	2020-10-13	2022-02-01	Lansinoh Laboratories, Inc.	Breastmilk collection system
WO2022128899A1	2020-12-15	2022-06-23	Medela Holding Ag	Breast shield and breast shield unit
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* Cited by examiner, † Cited by third party, ‡ Family to family citation

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JP6062937B2	2017-01-18	Breast shield unit
EP1017296B1	2017-04-24	Breast shield for expressing human breast milk
US11471161B1	2018-11-06	Soft breastshield
US5941847A	1999-08-24	Breast shield with vacuum isolation element
US20140121593A1	2014-05-01	Breastshield with media separation
JP2012254307A	2012-12-27	Breastshield with multi-pressure and expansible chamber construction, related breastpump and method

MXPA05002068A	2005-06-06	Manual breastpump with stimulation feature.
US20140052056A1	2014-02-20	Submersible Valve for a Breast Milk Collection Device with Self Contained Reservoir
TW201634067A	2016-10-01	Breast shield
TW201922302A	2019-06-16	Breastpump
US6964651B1	2005-11-15	Apparatus for expressing milk
EP4000681A1	2022-05-25	Breast shield for a breast pump
MXPA06011403A	2007-04-20	Soft breastshield

Priority And Related Applications

Priority Applications (3)

Application	Priority date	Filing date	Title
CH1201/11		2011-07-18	
CH01201/11A	2011-07-18	2011-07-18	Breastshield unit.
PCT/CH2012/000164	2011-07-18	2012-07-12	Breastshield unit

Legal Events

Date	Code	Title	Description
2015-05-11	A621	Written request for application examination	**Free format text**: JAPANESE INTERMEDIATE CODE: A621 **Effective date**: 20150511
2016-03-14	A977	Report on retrieval	**Free format text**: JAPANESE INTERMEDIATE CODE: A971007 **Effective date**: 20160311
2016-03-15	A131	Notification of reasons for refusal	**Free format text**: JAPANESE INTERMEDIATE CODE: A131 **Effective date**: 20160315
2016-06-15	A521	Request for written amendment filed	**Free format text**: JAPANESE INTERMEDIATE CODE: A523 **Effective date**: 20160615
2016-11-09	TRDD	Decision of grant or rejection written	
2016-11-22	A01	Written decision to grant a patent or to grant a registration (utility model)	**Free format text**: JAPANESE INTERMEDIATE CODE: A01 **Effective date**: 20161122
2016-12-22	A61	First payment of annual fees (during grant procedure)	**Free format text**: JAPANESE INTERMEDIATE CODE: A61 **Effective date**: 20161215
2016-12-22	R150	Certificate of patent or registration of utility model	**Ref document number**: 6062937 **Country of ref document**: JP **Free format text**: JAPANESE INTERMEDIATE CODE: R150
2019-12-17	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250
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2021-12-16	R250	Receipt of annual fees	**Free format text**: JAPANESE INTERMEDIATE CODE: R250

Concepts

machine-extracted

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Breast		title,claims,abstract,description	154	0.000
membrane		claims,abstract,description	101	0.000
Nipples		claims,abstract,description	20	0.000
human milk		claims,abstract,description	10	0.000
Milk		claims,description	48	0.000
milk		claims,description	48	0.000
milk		claims,description	48	0.000
separation method		abstract,description	4	0.000
easy-to-clean		abstract,description	3	0.000

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最終頁に続く

(54)【発明の名称】ヒトの母乳の圧出および定量化のための方法、装置、およびシステム

(57)【要約】
母乳の圧出および採取のための装置は、作動可能なアセンブリと、胸部インターフェースと、チューブとを含む。胸部インターフェースは、胸部を受ける大きさであり、胸部に対し流体密封シールを形成する。胸部インターフェースは、胸部インターフェースの少なくとも一部に設けられた変形可能部材を含む。変形可能部材は、作動可能なアセンブリの作動に応じて変形し、胸部に真空圧をかけて乳を圧出させる。チューブは、作動可能なアセンブリを胸部インターフェースに操作可能に結合する。

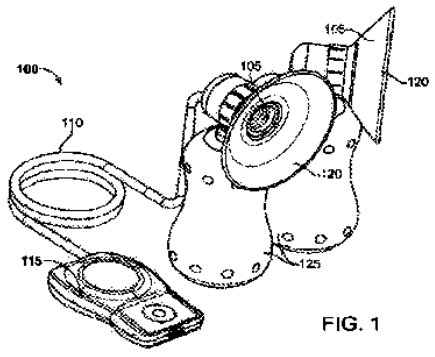


FIG. 1

【特許請求の範囲】
【請求項１】
母乳の圧出および採取のための装置であって、前記装置は、
作動可能なアセンブリと、
胸部インター－フェ－スであって、前記胸部インター－フェ－スは、胸部に係合し、これに対し流体密封を行う大きさであり、前記胸部インターフェースは、その少なくとも一部内に配置された可動部材を有する、胸部インター－フェ－スと、
前記作動可能なアセンブリを前記胸部インターフェースに操作可能に結合するチューブと、
を備え、
前記可動部材は、前記作動可能なアセンブリの作動に応じて動作し、それによって前記胸部インター－フェ－ス内に真空を形成し、前記胸部に前記真空を適用してそこから乳を圧出させる、装置。
【請求項２】
前記作動可能なアセンブリは、ピストンまたはポンプを備える、請求項１に記載の装置。
【請求項３】
前記作動可能なアセンブリは、一対のピストンまたは一対のポンプを備える、請求項１に記載の装置。
【請求項４】
前記作動可能なアセンブリの作動は、前記チューブ内にある流体を移動させる、請求項１に記載の装置。
【請求項５】
前記可動部材は、柔軟膜を備える、請求項１に記載の装置。
【請求項６】
前記柔軟膜は、膨張・収縮するように構成された波形領域を有する、請求項５に記載の装置。
【請求項７】
前記柔軟膜は、前記作動可能なアセンブリの作動に応じて変形し、前記作動可能なアセンブリの作動が前記チュ－ブ内に収められた流体を移動させる、請求項５に記載の装置。
【請求項８】
前記可動部材は、変形可能部材を備える、請求項１に記載の装置。
【請求項９】
前記胸部インターフェースは、前記胸部に係合し、前記胸部に対して流体密封を形成する弾力性があり馴染みやすいフランジを備える、請求項１に記載の装置。
【請求項１０】
流体は、前記チュ－ブ内に配置される、請求項１に記載の装置。
【請求項１１】
前記流体は、非圧縮性流体である、請求項１０に記載の装置。
【請求項１２】
引張要素は、前記チューブ内に配置される、請求項１に記載の装置。
【請求項１３】
前記引張要素は、ロープ、ワイヤ、またはケーブルを備える、請求項１２に記載の装置。
【請求項１４】
前記引張要素は、前記可動部材および前記作動可能なアセンブリと操作可能に結合される、請求項１２に記載の装置。
【請求項１５】
前記作動可能なアセンブリと操作可能に結合され、前記作動可能なアセンブリを作動させるように構成された駆動機構をさらに備える、請求項１に記載の装置。

【請求項１６】
前記駆動機構は、電気機械装置である、請求項１５に記載の装置。
【請求項１７】
前記駆動機構は、モータを備える、請求項１５に記載の装置。
【請求項１８】
前記駆動機構は、前記作動可能なアセンブリに解放自在に結合される、請求項１５に記載の装置。
【請求項１９】
前記胸部インターフェースは、出口弁を備え、前記出口弁は、前記圧出した母乳の流れを採取容器内に向けて制御するように構成された、請求項１に記載の装置。
【請求項２０】
前記出口弁は、前記変形可能部材が変形されたときには前記出口弁を通して前記圧出した母乳が流れないようにし、前記変形可能部材が非変形形状のときには前記出口弁を通して前記圧出した母乳が流れるようにすることによって前記流れを制御する、請求項１９に記載の装置。
【請求項２１】
前記出口弁は、前記変形可能部材内に一体的に形成される、請求項１９に記載の装置。
【請求項２２】
第２の胸部インターフェースであって、前記第２の胸部インターフェースは、第２の胸部に係合し、これに対し流体密封を行う大きさであり、前記第２の胸部インターフェースは、その少なくとも一部内に配置された可動部材を有する、第２の胸部インターフェースと、
前記作動可能なアセンブリを前記第２の胸部インターフェースに操作可能に結合する第２のチューブと、
をさらに備え、
前記可動部材は、前記作動可能なアセンブリの作動に応じて変形し、それによって前記第２の胸部インターフェース内に真空を形成し、前記第２の胸部に真空を適用してそこから乳を圧出させる、請求項１に記載の装置。
【請求項２３】
第２の作動可能なアセンブリと、
第２の胸部インターフェースであって、前記第２の胸部インターフェースは、第２の胸部に係合し、これに対し流体密封を行う大きさであり、前記第２の胸部インターフェースは、その少なくとも一部内に配置された可動部材を有する、第２の胸部インターフェースと、
前記第２の作動可能なアセンブリを前記第２の胸部インターフェースに操作可能に結合する第２のチューブと、
をさらに備え、
前記可動部材は、前記作動可能なアセンブリまたは前記第２の作動可能なアセンブリの作動に応じて変形し、それによって前記第２の胸部インターフェース内に真空を形成し、前記第２の胸部に前記真空を適用してそこから乳を圧出させる、請求項１に記載の装置。
【請求項２４】
前記作動可能なアセンブリの作動を制御するためのコントローラを有する筐体をさらに備える、請求項１に記載の装置。
【請求項２５】
母乳産出情報の計算および表示を制御し、他の装置との通信を制御するためのコントローラを有する筐体をさらに備える、請求項１に記載の装置。
【請求項２６】
母乳の圧出および採取のための前記装置に電力を提供する電源を有する筐体をさらに備える、請求項１に記載の装置。
【請求項２７】

前記作動可能なアセンブリを作動させるための駆動用機構を有する筐体をさらに備える、請求項１に記載の装置。
【請求項２８】
前記胸部インターフェースと流体的に結合された採取容器をさらに備える、請求項１に記載の装置。
【請求項２９】
前記胸部インターフェースに隣接するセンサをさらに備え、前記センサは、そこを流れる乳の少なくとも１つの側面を感知するように構成される、請求項１に記載の装置。
【請求項３０】
前記乳の圧出に関するデータを表示するための表示ユニットをさらに備える、請求項１に記載の装置。
【請求項３１】
母乳の圧出および採取のためのシステムであって、請求項１に記載の装置を備えるシステム。
【請求項３２】
患者に圧力または真空を適用するための装置であって、前記装置は、
作動可能なアセンブリと、
標的組織インターフェースであって、前記標的組織インターフェースは、標的組織に係合し、これに対し流体密封を行う大きさであり、前記標的組織インターフェースは、その少なくとも一部内に配置された変形可能部材を有する、標的組織インターフェースと、
前記作動可能なアセンブリを前記標的組織インターフェースに操作可能に結合するチューブと、
を備え、
前記変形可能部材は、前記作動可能なアセンブリの作動に応じて変形し、それによって標的組織インターフェース内に真空または圧力を形成し、前記標的組織に前記真空または圧力を適用する、装置。
【請求項３３】
母乳を圧出させ採取する方法であって、前記方法は、
少なくとも１つの胸部インターフェースと、前記少なくとも１つの胸部インターフェースに操作可能に結合された少なくとも１つの作動可能なアセンブリとを有する胸部圧出および採取装置を提供するステップであって、前記胸部インターフェースは、変形可能部材を含む、ステップと、
胸部を前記胸部インターフェースに係合させて流体密封するステップと、
前記作動可能なアセンブリを作動させるステップと、
前記作動可能なアセンブリの作動に応じて変形可能部材を変形させ、それによって真空を形成し前記胸部に適用するステップと、
前記胸部から乳を圧出させて採取するステップと、
を含む、方法。
【請求項３４】
前記係合ステップが、前記胸部インターフェース上の弾力性があり馴染みやすいフランジを前記胸部に係合させ、それによって前記胸部インターフェースと前記胸部との間に流体密封を形成するステップを含む、請求項３３に記載の方法。
【請求項３５】
前記作動可能なアセンブリは、流体を移動させる、請求項３３に記載の方法。
【請求項３６】
前記流体は、前記作動可能なアセンブリおよび前記変形可能部材に流体的に結合されたチューブ内に配置される、請求項３５に記載の方法。
【請求項３７】
前記作動可能なアセンブリを作動させるステップは、ピストンを動作させるステップを含む、請求項３３に記載の方法。

【請求項３８】
前記作動可能なアセンブリを作動させるステップは、前記チューブ内に配置された引張要素に張力を適用するステップを含む、請求項３３に記載の方法。
【請求項３９】
軸荷重吸収部材は、前記引張要素の周囲に同心円状に配置され、前記方法が、前記引張要素の反力を吸収するステップをさらに含む、請求項３８に記載の方法。
【請求項４０】
前記作動可能なアセンブリを、それと操作可能に結合された駆動機構から解放するステップをさらに含む、請求項３３に記載の方法。
【請求項４１】
前記作動ステップと、前記変形ステップと、前記圧出ステップとを繰り返すステップをさらに含む、請求項３３に記載の方法。
【請求項４２】
前記圧出された乳の産出を定量するステップをさらに含む、請求項３３に記載の方法。
【請求項４３】
前記圧出された乳の１つまたはそれより多い側面を定量するステップをさらに含む、請求項３３に記載の方法。
【請求項４４】
前記母乳の圧出に関するデータを前記胸部圧出および採取装置と計算機との間で伝送するステップをさらに含む、請求項３３に記載の方法。
【請求項４５】
前記モバイル装置は、スマートフォンを含む、請求項４４に記載の方法。
【請求項４６】
前記データをディスプレイに表示するステップをさらに含む、請求項４４に記載の方法。
【請求項４７】
前記圧出された乳の採取容器への流れを、前記胸部圧出および採取装置に流体的に結合された弁で制御するステップをさらに含む、請求項３３に記載の方法。
【請求項４８】
流れを制御するステップは、前記変形可能部材が未変形の時には前記弁を開け、前記変形可能部材が変形されたときには前記弁を閉めるステップを含む、請求項４７に記載の方法。
【請求項４９】
前記圧出した母乳の流れを、前記胸部インターフェースに流体的に結合されたセンサで感知するステップをさらに含む、請求項３３に記載の方法。
【請求項５０】
前記胸部圧出および採取装置は、第２の胸部インターフェースと、前記第２の胸部インターフェースに操作可能に結合された第２の作動可能なアセンブリとをさらに備え、前記第２の胸部インターフェースは、変形可能部材を含み、前記方法は、
第２の胸部を前記第２の胸部インターフェースに係合させて流体密封させるステップと、
前記第２の作動可能なアセンブリを作動させるステップと、
前記第２の胸部インターフェース内の前記変形可能部材を前記第２の作動可能なアセンブリの作動に応じて変形させ、それによって前記第２の胸部に真空を形成し適用するステップと、
前記第２の胸部から乳を圧出させて採取するステップと、
をさらに含む、請求項３３に記載の方法。
【請求項５１】
両方の胸部から乳を圧出させ採取するステップは、同時に起こる、請求項５０に記載の方法。

【請求項５２】
乳を圧出させ採取するステップは、両方の胸部の間を交互に繰り返す、請求項５０に記載の方法。
【請求項５３】
差圧を患者に適用する方法であって、前記方法は、
インターフェースと、差圧装置に操作可能に結合された作動可能なアセンブリと、を有する差圧装置を提供するステップであって、前記インターフェースは、変形可能部材を備える、ステップと、
前記インターフェースを前記患者上の標的領域に係合させ、流体的に密封するステップと、
前記作動可能なアセンブリを作動させるステップと、
前記変形可能部材を前記作動可能なアセンブリの作動に応じて変形させ、それによって正圧または真空を形成し、前記正圧または前記真空を前記標的領域に適用するステップと、
を含む、方法。
【請求項５４】
前記変形可能部材を変形させるステップは、前記標的領域に適用される正圧を形成し、前記標的領域が、口または鼻を含み、それによって前記患者が睡眠している間の無呼吸状態を低減または解消する、請求項５３に記載の方法。
【請求項５５】
前記柔軟膜を変形させるステップは、前記標的領域に適用される真空を形成し、前記標的領域は、体液貯蔵器官を含み、それによって、そこから前記体液を圧出させるステップを含む、請求項５３に記載の方法。

【発明の詳細な説明】
【技術分野】
【０００１】
（関連出願）
本願は、２０１３年３月２４日に出願された、米国仮特許出願第６１／８０４，７２２号（代理人管理番号第４４３９６－７０２．１０１号）、２０１３年９月１７日に出願された、米国仮特許出願第６１／８７９，０５５号（代理人管理番号第４４３９６－７０３．１０２号）、２０１４年３月２０日に出願された、米国特許出願第１４／２２１，１１３号（代理人管理番号第４４９３６－７０３．２０１号）の利益を主張するものであり、これらの全内容は、参照により本明細書中に援用される。
【０００２】
本発明は、概して、医療装置および方法に関し、より具体的には、ヒトの母乳の圧出および採取のための装置および方法に関する。
【０００３】
本明細書で開示される例示的実施形態は、好ましくは、母乳の圧出を対象とするが、当業者は、これが限定を意図するものではなく、本明細書で開示される装置、システム、および方法が差圧の適用を必要とする他の治療法にも用いられ得ることを認識するであろう。
【０００４】
胸部ポンプは、母親が自らの子供と離れていても授乳を続けられるように母乳を採取するため一般に用いられている。今のところ、胸部ポンプには、２種類の基本型、すなわち、小型ではあるが非効率的で使用の疲れを生じる手動措置と、効率的ではあるが大きくかさばる電動装置とがある。このため、母乳の圧出および採取のために小型で非常に効率的な改良された胸部ポンプを提供することが望ましいであろう。乳産出の定量化やモバイル装置との通信等の追加的な特徴は、ユーザの利便性を高める上でさらに望ましい。これら

の目的の少なくともいくつかは、以下に開示される装置および方法によって満足されるであろう。

【背景技術】

【０００５】

以下の米国特許は、ヒトの母乳の圧出および採取に関する。米国特許第６，６７３，０３６号（特許文献１）、第６，７４９，５８２号（特許文献２）、第６，８４０，９１８号（特許文献３）、第６，８８７，２１０号（特許文献４）、第７，８７５，０００号（特許文献５）、第８，１１８，７７２号（特許文献６）、および第８，２１６，１７９号（特許文献７）。

【先行技術文献】

【特許文献】

【０００６】

【特許文献１】米国特許第６，６７３，０３６号明細書
【特許文献２】米国特許第６，７４９，５８２号明細書
【特許文献３】米国特許第６，８４０，９１８号明細書
【特許文献４】米国特許第６，８８７，２１０号明細書
【特許文献５】米国特許第７，８７５，０００号明細書
【特許文献６】米国特許第８，１１８，７７２号明細書
【特許文献７】米国特許第８，２１６，１７９号明細書

【発明の概要】

【発明が解決しようとする課題】

【０００７】

本発明は、概して、医療装置、システム、および方法に関し、より具体的には、ヒトの母乳の圧出および採取のための装置、システム、および方法に関する。

【課題を解決するための手段】

【０００８】

本発明の第１の側面では、母乳の圧出および採取のための装置が、作動可能なアセンブリと、胸部インターフェースと、チューブとを備える。胸部インターフェースは、胸部と係合し、それを流体密封する大きさになっている。胸部インターフェースはまた、その少なくとも一部内に配置された可動部材を含む。可動部材は、作動可能なアセンブリの作動に応じて動作し、それによって胸部インターフェースに真空を形成し、真空を胸部に適用し、そこから乳を圧出させる。チューブは、作動可能なアセンブリと、胸部インターフェースとに、操作可能に結合されている。

【０００９】

作動可能なアセンブリは、ピストンもしくはポンプ、または一対のピストンもしくは一対のポンプを備えてもよい。作動可能なアセンブリの作動は、チューブ内に配置された流体を移動させ得る。

【００１０】

可動部材は、柔軟膜を備え得る。柔軟膜は、膨張し収縮するように構成された波形領域を有してもよい。柔軟膜は、作動可能なアセンブリの作動に応じて変形し、作動可能なアセンブリの作動が、チューブに含まれる流体を移動させ得る。可動部材は、変形可能部材を備えてもよい。

【００１１】

胸部インターフェースは、胸部に係合して流体密封を形成する弾力性があり馴染みやすいフランジを備えてもよい。

【００１２】

流体が、チューブ内に配置されてもよい。流体は、水や油等の非圧縮性流体であり得る。他の実施形態では、チューブ内に、引張要素が配置されてもよい。引張要素は、ロープ、ワイヤ、またはケーブルを含み得る。引張要素は、可動部材および作動可能なアセンブリに操作可能に結合され、引張要素の反荷重を吸収する軸方向圧縮要素と同心円状に配置

されてもよい。

【００１３】

本装置は、作動可能なアセンブリに操作可能に結合され、作動可能なアセンブリを作動させるように構成された駆動機構を備えてもよい。駆動機構は、モータ等の電気機械装置を含み得る。駆動機構は、作動可能なアセンブリに解放自在に結合され得る。

【００１４】

胸部インターフェースは、圧出した母乳の採取容器内への流れを制御するように構成された出口弁を備えてもよい。出口弁は、変形可能部材が変形されたときには、圧出された乳が弁を通して流れることを防ぎ、変形可能部材が非変形形状にあるときは、圧出した母乳が弁を通して流れることを可能にすることによって、流れを制御し得る。出口弁は、変形可能部材内に一体的に形成され得る。

【００１５】

本装置は、第２の作動可能なアセンブリと、第２の胸部インターフェースと、第２のチューブとをさらに備えてもよい。第２の胸部インターフェースは、第２の胸部と係合し、それに対し流体密封する大きさになり得る。第２の胸部インターフェースは、少なくともその一部内に配置された可動部材を有し得、可動部材は、作動可能なアセンブリまたは随意の第２の作動可能なアセンブリのいずれかによる作動に応じて変形し、それによって第２の胸部インターフェース内に真空を形成し、これを第２の胸部に適用し、そこから乳を圧出させてもよい。第２のチューブは、第２の作動可能なアセンブリおよび第２の胸部インターフェースに操作可能に結合され得る。

【００１６】

本装置は、作動可能なアセンブリの作動を制御するためのコントローラを有する筐体をさらに備えてよい。コントローラは、母乳産出情報の計算および表示を制御し得、またコントローラは、他の装置との通信も制御し得る。筐体内に電源を配置し、電源が、乳の圧出および採取のための装置に電力を提供し得る。筐体は、その内部に配置され、作動可能なアセンブリを作動させるための駆動用機構を有し得る。

【００１７】

本装置は、胸部インターフェースと流体的に結合された採取容器をさらに備えてよい。本装置はまた、胸部インターフェースに隣接し、そこを過ぎる乳通過のある側面を測定するように構成されたセンサを備えてもよい。本装置はまた、乳の圧出に関するデータを表示する表示ユニットを備えてもよい。母乳の圧出および採取のためのシステムは、これまで上に記された装置を含み得る。これらの構成要素はいずれも、他の構成要素とは別個であってもよく、もしくはこれらは、筐体またはペンダント内に配置され得る。

【００１８】

本発明の別の側面では、患者に圧力または真空を適用するための装置が、作動可能なアセンブリと、標的組織インターフェースと、チューブとを備える。標的組織インターフェースは、好ましくは、標的組織と係合しそれに対し流体密封する大きさになっている。標的組織インターフェースは、その少なくとも一部内に配置された変形可能部材を有し、変形可能部材は、作動可能なアセンブリの作動に応じて変形する。これが、標的組織インターフェース内に真空または圧力を形成し、真空または圧力を標的組織に適用する。チューブは、作動可能なアセンブリおよび標的組織インターフェースに操作可能に結合される。

【００１９】

本発明のさらに別の側面では、母乳を圧出させ、採取するための方法が、胸部インターフェースと、胸部インターフェースに操作可能に結合された作動可能なアセンブリとを有する胸部圧出および採取装置を提供するステップを含む。胸部インターフェースは、変形可能部材を備える。本方法はまた、胸部を胸部インターフェースと係合させ流体密封するステップと、作動可能なアセンブリを作動させるステップとを含む。本方法はまた、作動可能なアセンブリの作動に応じて変形可能部材を変形させるステップを含み、それによって真空を胸部に形成し適用して、胸部から乳を圧出させて採取するステップを含む。

【００２０】

係合ステップは、胸部インターフェース上の弾力性があり馴染みやすいフランジを胸部と係合させ、それによって胸部インターフェースと胸部との間に流体密封を形成するステップを含んでもよい。

【００２１】

作動可能なアセンブリを作動させると、流体が移動し得る。作動可能なアセンブリおよび変形可能部材と流体的に結合されたチューブ内に流体を配置してもよい。作動可能なアセンブリを作動させるステップは、ピストンを動作させること、またはチューブ内に配置された引張要素に張力を適用することを含んでもよい。本方法は、作動可能なアセンブリを、それと操作可能に結合された駆動機構から解放することをさらに含み得る。

【００２２】

本方法は、作動、変形、および圧出のステップを繰り返すことをさらに含んでよい。本方法は、圧出された乳の産出を定量するステップと、胸部圧出および採取装置とモバイル装置との間で、母乳の圧出に関するデータを伝送するステップをさらに含み得る。モバイル装置は、スマートフォン、タブレット、または計算機であり得る。データは、ディスプレイに表示され得る。本方法はまた、圧出された乳の採取容器への流れを、胸部圧出および採取装置に流体的に結合された弁によって制御するステップを含み得る。流れを制御するステップは、変形可能部材が未変形のときに弁を開き、変形可能部材が変形したときに弁を閉じることを含み得る。また母乳の側面は、胸部インターフェースに流体的に、または別様に結合されたセンサで感知してもよい。

【００２３】

胸部圧出および採取装置は、第２の胸部インターフェースと、第２の胸部インターフェースに操作可能に結合された第２の作動可能なアセンブリとをさらに備えてもよい。第２の胸部インターフェースは、変形可能部材を備え得る。本方法は、第２の胸部を第２の胸部インターフェースと係合させ流体密封するステップと、第１または第２の作動可能なアセンブリを作動させるステップとをさらに含み得る。本方法はまた、第２の胸部インターフェース内の変形可能部材を第２の作動可能なアセンブリの作動に応じて変形させ、それによって第２の胸部に真空を形成して適用し、第２の胸部から乳を圧出させ採取するステップを含み得る。両方の胸部からの乳の圧出と採取は、両方の胸部で同時に行なってもよく、または交互に行ってもよい。

【００２４】

本発明のさらに別の側面では、患者に差圧を適用する方法が、インターフェースを有する差圧装置と、差圧装置に操作可能に結合された作動可能なアセンブリとを提供することを含む。インターフェースは変形可能部材を備え、本方法は、インターフェースを患者上の標的領域と係合させ流体密封し、作動可能なアセンブリを作動させるステップをさらに含む。本方法はまた、作動可能なアセンブリの作動に応じて変形可能部材を変形させ、それによって正圧または真空を形成し、標的領域に正圧または真空を適用するステップを含む。いずれの構成要素も他の構成要素から切り離してよく、またはこれらを筐体もしくはペンダント内に配置してもよい。

【００２５】

変形可能部材を変形させるステップは、標的領域に適用される正圧を形成し得る。標的領域は、口または鼻を含み、正圧の適用が、患者の睡眠時の無呼吸または同様な障害を低減または解消し得る。柔軟膜を変形させるステップは、標的領域に適用される真空を形成し得る。標的領域は、体液貯蔵器官を含み、そのようにして、真空が、貯蔵器官からの体液の圧出を引き起こす。

【００２６】

これらおよび他の実施形態は、添付図面に関連する以下の記述により詳細に記される。

（参照による組み込み）

【００２７】

本明細書で述べられる全ての出版物、特許、および特許出願は、個々の出版物、特許、および特許出願が具体的かつ個々に参照によって組み込まれるのと同程度に参照によって本

明細書に組み込まれる。

【図面の簡単な説明】

【００２８】

本発明の新規の特徴は、具体性をもって添付の請求項に示される。本発明の特徴および利点のより深い理解は、本発明の原理が活用された例証的実施形態を示す以下の詳細な記述および付随の図面の参照によって得られるであろう。

【図１】図１は、ポンプ装置の例示的実施形態の斜視図である。

【図２】図２は、ポンプ装置の例示的実施形態の斜視図である。

【図３】図３は、ポンプ装置の例示的実施形態の断面である。

【図４】図４は、駆動機構に結合された作動可能なアセンブリの例示的実施形態を図示する。

【図５Ａ】図５Ａ－５Ｂは、ペンダントユニットに結合された作動可能なアセンブリの例示的実施形態を図示する。

【図５Ｂ】図５Ａ－５Ｂは、ペンダントユニットに結合された作動可能なアセンブリの例示的実施形態を図示する。

【図６】図６は、胸部インターフェースの例示的実施形態の断面図である。

【図７】図７は、胸部インターフェースの別の例示的実施形態の断面図である。

【図８Ａ】図８Ａは、開位置にある一体化された弁の例示的実施形態の断面図である。

【図８Ｂ】図８Ｂは、閉位置にある一体化された弁の例示的実施形態の断面図である。

【図９Ａ】図９Ａは、胸部インターフェース内に一体化されたセンサの例示的実施形態の断面図である。

【図９Ｂ】図９Ｂは、胸部インターフェース内に一体化されたセンサの別の例示的実施形態の断面図である。

【図１０】図１０は、ペンダントユニットおよびモバイル装置の例示的実施形態を図示する。

【図１１】図１１は、モバイル装置と通信中のペンダントユニットの例示的実施形態を図示する。

【図１２】図１２は、機械的変形可能部材のついた胸部インターフェースの例示的実施形態の断面図である。

【図１３】図１３は、機械的変形可能部材用の機械的駆動機の例示的実施形態の断面図である。

【図１４】図１４は、商用装置と比較した例示的実施形態のポンプ性能を図示するグラフである。

【図１５】図１５は、商用装置と比較した例示的実施形態のポンプ効率を図示するグラフである。

【発明を実施するための形態】

【００２９】

開示された装置および方法の具体的な実施形態を、図面を参照しつつ以下に記述する。いかなる詳細な記述も、特定の構成要素、特徴、またはステップが本発明にとって絶対必要であることを示唆することを意図しない。当業者は、様々な特徴またはステップが、互いに置き換え、または組み合わせされ得ることを理解するであろう。

【００３０】

本発明は、母乳の圧出および採取に関連して記述される。しかしながら、当業者は、それが限定を意図するものではなく、本明細書で開示される装置および方法が、睡眠時無呼吸の治療および／または他の遠隔圧力ニーズ等、圧力差の形成と伝達を必要とする他の用途にも使用し得ることを理解するであろう。

【００３１】

図１は、本発明の例示的実施形態を図示する。ポンプ装置１００は、胸部インターフェース１０５と、チューブ１１０と、チューブ１１０を通して胸部インターフェース１０５に操作可能に結合されたコントローラまたはペンダントユニット１１５とを含む。胸部イ

ンターフェース１０５は、胸部と係合し、それに対し流体密封を形成する弾力性があり馴染みやすいフランジ１２０と、採取容器１２５とを含む。本装置は、随意に、単一の胸部インターフェースのみを有してもよい。ペンダントユニット１１５は、ポンプ装置１００の電源および駆動用機構を収容し、また、ポンプ装置１００の制御、乳産出の定量化、他の装置との通信等、様々な機能のためのハードウェアを含む。チューブ１１０は、機械的なエネルギー入力等の好適なエネルギー入力を、ペンダントユニット１１５から胸部インターフェース１０５までの長い距離にわたって伝達する。胸部インターフェース１０５は、エネルギー入力を胸部に対する真空圧力に効率よく変換し、採取容器１２５内への乳の圧出を引き起こす。

【００３２】

当業者は、本例示的実施形態の構成要素および特徴が、以下に示すいずれの本発明の実施形態の構成要素および特徴とも組み合わせ、または代替ができることを理解するであろう。同様に、本明細書で開示される他の実施形態の構成要素および特徴は、互いに代替または組み合わされ得る。

（液圧ポンプ装置）

【００３３】

液圧システムは、必要とされるポンプ力を減らすことができ、そのため、ポンプ効率を維持しながらポンプ装置のサイズを減らすことができる。好適な実施形態では、ポンプ装置が、液圧ポンプ装置を利用して、乳の圧出および採取のため、胸部に対する圧力差を発生させることができる。

【００３４】

例示的液圧ポンプ装置が、図２および３に示される。図２は、チューブ１６５によって胸部インターフェース１６０に流体的に結合された注射器１５５を有するポンプ装置１５０を図示する。注射器１５５は、三方弁１７０を通してチューブ１６５に結合される。胸部インターフェース１６０は、出口ポート１７５を含む。注射器１５５は、チューブ１６５内に含まれる流体１８０を、胸部インターフェース１６０内に収容された柔軟な部材に向けて、またはこれから離れるように駆動し、胸部からの乳の圧出に必要な圧力差を作り出す。

【００３５】

図３は、ポンプ装置２００の別の実施形態を図示する。作動可能なアセンブリ２０５は、アセンブリ筐体２１０と、駆動要素２１５と、ラジアルシール２２０と、シャフト２２２と、を含む。駆動要素２１５は、シャフト２２２を通してペンダントユニット１１５等のペンダントユニットに操作可能に結合される。チューブ２２５は、流体２３０を含み、作動可能なアセンブリ２０５および胸部インターフェース２３５に流体的に結合される。胸部インターフェース２３５は、インターフェース筐体２４０と、柔軟膜２４５と、貯蔵器２５０と、密封要素２５５と、圧出領域２６０と、排出ポート２６５とから成る。密封要素２５５は、変形可能部分２７０を含む。排出ポート２６５は、採取容器２７５に結合され、フラップ弁２８０を含む。

【００３６】

作動可能なアセンブリ２０５は、たわみ管路であり得るチューブ内２２５に含まれる流体２３０を移動させる。流体２３０は、胸部インターフェース２３５内の貯蔵器２５０内を占め、柔軟膜２４５と結合される。柔軟膜２４５は、流体２３０から密封要素２５５の変形可能部分２７０に真空圧力を伝達する。胸部が密封要素２５５によって胸部インターフェース２３５と係合し流体的に密封されたとき、作動可能な要素２１５の移動が、柔軟膜２４５および変形可能部分２７０を通して、胸部に対する実質的な真空圧力を作り出し、その結果、圧出領域２６０中への母乳の圧出が引き起こされる。圧出された乳は、排出ポート２６５を通して採取容器２７５中に排出される。排出ポート２６５は、フラップ弁２８０を持つ構成になっており、圧出領域２６０内の真空圧力を維持しながら乳の通路を確保する。

【００３７】

液圧ポンプ装置の流体は、非圧縮性流体等、任意の好適な流体とすることができる。多くの実施形態では、非圧縮性流体は、水または油であり得る。代わりに、流体は、空気等、任意の好適な気体とすることができる。液圧システム用の好適な非圧縮性流体およびガスは、当業者に知られている。

【００３８】

当業者は、液圧ポンプ装置のいずれの例示的実施形態の構成要素および特徴が、本明細書に記載される本発明のいずれの例示的実施形態の構成要素および特徴とも組み合わせ、または置き換えができることを理解するであろう。

（作動機構）

【００３９】

当業者に知られる多くの作動機構が、作動可能なアセンブリ２０５に利用されることができる。作動可能なアセンブリ２０５は、ピストンアセンブリ、ダイアフラムポンプ等のポンプ、または任意の他の好適な作動機構とすることができる。作動可能なアセンブリ２０５の最適な構成は、真空要件、サイズ、電力、およびポンプ装置２００のその他の必要性、ならびに粘度、生体適合性、および流体寿命要件等の流体２３０の特性等、多くの要因によって異なり得る。

【００４０】

図３は、作動可能なアセンブリ２０５がピストンアセンブリで、駆動要素２１５がピストンである例示的実施形態を図示する。作動可能なアセンブリ２０５は、流体２３０の不要な滲出を防ぎ、流体２３０の駆動を可能にするようにアセンブリ筐体２１０に対して密封を行うＯリング等のラジアルシール２２０を含む。

【００４１】

図４は、一対のピストン３０５を含む作動可能なアセンブリ３００の別の例示的実施形態を図示する。

【００４２】

好適な実施形態では、作動可能なアセンブリが、ペンダントユニット１１５内の駆動機構等、好適な駆動機構によって動く駆動要素を含む。多くの駆動機構が当業者に知られている。例えば、駆動要素２１５等の駆動要素は、モータによって電気機械的に作動されてもよく、レバー等の好適なユーザー・オペレータインターフェースによって手動で作動されてもよい。当業者に知られる様々な駆動モードが用いられることができる。特に、本明細書に記載されるような例示的液圧ポンプ装置の実施は、液圧システムにより低減された力の要件により、直接駆動やソレノイド等の好適な駆動モードの使用を可能にする。

【００４３】

図４の例示的実施形態を参照すると、ピストン３０５は、クランクシャフト３１５へのカップリング３１０を含む。クランクシャフト３１５は、ベルト駆動３２５を通してモータ３２０に操作可能に結合されている。クランクシャフト３１５は、両方の胸部に同時に真空圧力を適用するように一対のピストン３０５を同じストロークタイミングで駆動するが、この特徴は、乳の産出増大に望ましい。代わりに、クランクシャフト３１５は、交互またはオフセットストロークサイクル等の任意の好適なストロークタイミングで一対のピストン３０５を駆動できる。

【００４４】

駆動機構は、局部電池またはＡＣアダプタ等の任意の好適な電源で動かすことができる。駆動機構は、ペンダントユニット１１５内に配置された内臓電子装置等のハードウェアにより制御することができる。

【００４５】

図５は、解放自在なカップリング３５５を含む作動可能なアセンブリ３５０の例示的実施形態を図示する。好ましくは、作動可能なアセンブリ３５０が、ペンダントユニット３６０と、そこに収納される駆動機構とに解放自在に結合される。カップリングは、機械的カップリング、または当業者に公知の任意の好適な簡易脱着機構であり得る。解放自在に結合された設計は、構成の柔軟性とポンプ装置の使用とを可能にする。例えば、使い心地

は、様々な胸部サイズと適合する異なる大きさの胸部インターフェースによって改良され得る。加えて、この特徴は、取り換え可能な胸部インターフェースとともに一般のポンプ装置の使用を可能にし、病原体の拡散リスクを低減する。さらに、解放自在カップリングは、ポンプ装置の個々の部品の容易な交換を可能にする。

【００４６】

当業者は、作動機構のいずれの例示的実施形態の構成要素および特徴も、本明細書に記述されるような本発明のいずれの実施形態の構成要素および特徴と組み合わせまたは代替できることを理解するであろう。

（柔軟膜）

【００４７】

図３に示される実施形態等、多くの実施形態において、柔軟膜２４５は、胸部インターフェース２３５内に位置し、少なくともその一部を覆うように配置されており、インターフェース筐体２４０と柔軟膜２４５との間に貯蔵器２５０を形成する。好ましくは、柔軟膜２４５は、流体２３０が作動可能なアセンブリ２０５によって貯蔵器２５０から移動されたときに形成される負圧にさらされたとき、実質的に変形する。柔軟膜２４５の変形量は、多くの要因（例えば、壁厚、ゴム硬さ、表面積）によって制御することができ、ポンプ装置（例えば、ポンプ電力、真空要件）に基づいて最適化できる。

【００４８】

図６は、特定の厚さとゴム硬さとを有する例示的柔軟膜３７０を図示する。

【００４９】

図７は、表面積を増大させる波形の特徴３８０が付いた柔軟膜３７５の別の実施形態を図示する。

【００５０】

柔軟膜に好適な材料は、当業者に知られている。多くの実施形態では、柔軟膜は、シリコーン、ＰＥＢＡＸ等のポリエーテルブロックアミド、およびネオプレン等のポリクロロプレン等の結合流体からの圧力にさらされたとき、膨張および収縮するように設計された材料で作ることができる。代わりに、柔軟膜は、ステンレス鋼、ニチノール、硬質ポリマー、または硬質エラストマー等の実質的剛体材料から作られ得る。これらの実施形態では、剛体材料が、材料の降伏点を超えない柔軟膜の実質的な変形を可能にする応力および／またはひずみ分散要素とともに設計されるであろう。

【００５１】

図８Ａおよび８Ｂは、出口弁４０５が柔軟膜４１０に一体化され、圧出された乳の流れを、出口ポート４１５を通して制御する胸部インターフェース４００の好適な実施形態を図示する。出口弁４０５は、図８Ａに示されるように、柔軟膜４１０が緩和されたときに開かれて流体の流れを可能にし、また、図８Ｂに示されるように、柔軟膜４１０が変形されたときに閉じられて流体の流れを阻止する。出口弁４０５は、抽出の間には圧出領域４２０に実質的な真空圧力が存在できるようにする一方、ポンプストロークの休止状態の間は、乳が排出できるようにする。多くの従来型胸部ポンプバルブは、圧力差のみで機能する一方、出口弁４０５は、好ましくは、柔軟膜４１０の機械的動きにも機能するように構成されることができる。一体化された出口弁４０５に、本明細書に記載されるような機械的機能を組み込むことで、真空形成の間、胸部インターフェース４００の密封が改良され得る。さらに、出口弁４０５のように、柔軟膜４１０内に一体的に形成された出口弁を使用すると、洗浄すべき部品の数が減る。

【００５２】

当業者は、柔軟膜のいずれの例示的実施形態の構成要素および特徴が、本明細書に記述されるような本発明のいずれの実施形態の構成要素および特徴とも組み合わせまたは代替できることを理解するであろう。

（乳採取および定量化システム）

【００５３】

図３を参照すると、圧出された乳は、柔軟膜２４５内の出口ポート２６５を通して採取

容器２７５中に排出される。採取容器２７５は、ビンや袋等の任意の好適な容器であり得る。多くの実施形態で、採取容器２７５は、柔軟膜２４５に、取り外し可能に結合されている。採取容器２７５は、延長配管等の任意の好適な装置を介して、直接または離れて結合されることができる。

【００５４】

多くの場合、乳産出の量等、乳圧出および採取に関する様々なデータを追跡することが望まれ得る。現在のところ、乳産出の追跡は、手動測定と記録管理によって一般に行われている。本明細書に記載される本装置の例示的実施形態は、改良された利便性、効率、および精度のため、乳産出を自動測定し追跡するデジタルに基づく手段を提供し得る。

【００５５】

図９Ａおよび９Ｂは、１つまたはそれより多い一体化されたセンサ４５５の付いた胸部インター－フェ－ス４５０の例示的実施形態を図示する。センサ４５５は、好ましくは、フラップ弁４６０内に位置されるが、出口弁４６５または流体の流れを監視するのに好適な任意の他の場所に位置されてもよい。好適な実施形態では、少なくとも１つのセンサ４５５が、流体の流れによって開かれる弁に一体化され、弁が開いている延べ時間を検知する。センサ信号は、流体の流れを定量するように問い合わられ得る。好適なセンサは、加速度計、ホール効果センサ、およびフォトダイオード／ＬＥＤセンサ等が当業者に知られている。胸部インターフェースは、乳産出を定量する単一センサまたは多重センサを含むことができる。

【００５６】

図１０は、乳圧出データがディスプレイスクリーン５０５に表示されたペンダントユニット５００の例示的実施形態を図示する。多くの実施形態では、ペンダントユニット５００は、乳圧出に関するデータを採取し、処理し、貯蔵し、表示する。好ましくは、ペンダントユニット５００は、モバイルフォン５１０等の第２の装置にデータを伝送することができる。

【００５７】

図１１は、ペンダントユニット５００とモバイルフォン５１０との間のデータ伝送５１５を図示する。装置間の通信およびデータ伝送の好適な方法は、Ｂｌｕｅｔｏｏｔｈ（登録商標）や近距離無線通信等が当業者に知られている。

【００５８】

例示的実施形態では、ペンダントユニット５００が、モバイルフォン５１０と通信し、圧出体積、持続時間、および日付等の乳圧出データを伝送する。モバイルフォン５１０は、圧出データを採取して集計し、それを対話式フォーマットで表示するモバイルアプリケーションを含む。好ましくは、モバイルアプリケーションは、ライフスタイルの選択、食生活、乳産出増大のための方略等の情報をユーザがオーバーレイできるようにする追加的な特徴を含み、このような情報と乳産出統計との比較を容易にする。加えて、ペンダントユニット５００が、ポンプの使用回数に関する情報をモバイルフォン５１０に送り、モバイルアプリケーションが、ポンプ動作がいつ起こるかを識別し、所望のポンプ動作回数にリマインダを設定できるようにすることができる。このようなリマインダは、ポンプセッションの忘れ防止に役立ち、その結果、乳腺炎等の合併症の発生率を低減することができる。

【００５９】

当業者は、乳採取および定量化システムのいずれの例示的実施形態の構成要素および特徴が、本明細書に記述されるような本発明のいずれの実施形態の構成要素および特徴とも組み合わせまたは代替できることを理解するであろう。

（機械的ポンプ装置）

【００６０】

図１２は、柔軟膜の代わりに機械的変形可能部材６０５が用いられ得る、胸部インターフェース６００の代替的実施形態を図示する。機械的変形可能部材６０５は、本明細書に記載の柔軟膜に用いられるのと同様な手法で構成されることができる。機械的変形可能部

材６０５は、引張要素６１０に結合される。ある場合には、引張要素６１０は、軸荷重吸収部材６１５内に配置される。軸荷重吸収部材６１５は、チューブ６２０内に配置される。好ましくは、引張要素６１０が、軸荷重吸収部材６１５内に同心円状に配置され、軸荷重吸収部材６１５が、チューブ６２０内に同心円状に配置される。引張要素６１０の代替的構成では、軸荷重吸収部材６１５およびチュ―ブ６２０を使用することもできる。

【００６１】

図１３は、作動可能なアセンブリ６３０のアセンブリ筐体６３５内の駆動要素６２５に結合された引張要素６１０を図示する。駆動要素６２５は、シャフト６４０を介して、ペンダントユニット内に収納された駆動機構等の駆動機構に操作可能に結合される。チューブ６２０内の軸荷重吸収部材６１５は、アセンブリ筐体６３５に固定的に結合される。駆動要素６２５の移動が、引張要素６１０を通して機械的変形部材６０５に張力を伝達し、胸部に対し真空圧力を形成する。

【００６２】

引張要素６１０は、ワイヤ、コイル、またはロープ等の任意の好適な装置であることができ、また金属、ポリマー、またはエラストマー等の任意の好適な材料で作られることができる。軸荷重吸収部材６１５は、金属やポリマー等、軸方向に剛い任意の好適な材料で作られることができ、チューブやコイル等、軸方向に剛い任意の好適な形状で構成されることができる。

【００６３】

当業者は、機械的ポンプ装置のいずれの例示的実施形態の構成要素および特徴も、本明細書に記述されるような本発明のいずれの実施形態の構成要素および特徴と組み合わせまたは代替できることを理解するであろう。

（実験データ）

【００６４】

図１４および１５は、商用の胸部ポンプ装置および本発明の例示的実施形態から得られた実験的ポンプ動作のデータを図示する。例示的実施形態は、ポンプ動作に非圧縮性流体を用い、４ｃｃの最大液圧流体体積を有し、一方、商用装置は、空気ポンプ動作を用い、１１４ｃｃの最大体積を有した。

【００６５】

図１４は、１行程あたりに発生される真空圧力で定量されたポンプ性能のグラフを図示する。例示的実施形態については、ポンプによって移動された流体体積の１ｃｃ、２ｃｃ、３ｃｃ、および４ｃｃについて圧力測定を行い、行程番号は体積ｃｃに対応する。商用装置については、ポンプによって移動された流体体積の４６ｃｃ、５７ｃｃ、６８ｃｃ、８０ｃｃ、９１ｃｃ、１０３ｃｃ、および１１４ｃｃをそれぞれ代表する真空調整ゲージに沿った７つの等間隔位置の１つにポンプを設定して測定が行われ、行程番号が位置番号に対応する。曲線７００は、例示的実施形態に対応し、曲線７０５は、商用装置に対応する。例示的実施形態は、商用装置に比べ移動体積あたりにより高レベルな真空圧力を発生させ、最高真空圧力は、それぞれ、－２４０．５ｍｍＨｇおよび－１７７．９ｍｍＨｇであった。

【００６６】

図１５は、流体移動の最大体積当たりの最大真空圧力で測定されたポンプ効率のグラフを図示し、棒７１０は、例示的実施形態に対応し、棒７１５は、商用装置に対応する。例示的実施形態は、商用装置に比べて４２倍のポンプ効率増加を実証し、効率は、それぞれ、－７１．１ｍｍＨｇ／ｃｃおよび－１．７ｍｍＨｇ／ｃｃであった。

【００６７】

本発明の好適な実施形態が、本明細書に示され記述されたが、このような実施形態が、例としてのみ提示されることは当業者にとって当然である。多くの変形、変更、および代替が、本発明から逸脱することなく当業者に想起されることであろう。本明細書に記載された本発明の実施形態への様々な代替が、本発明の実施に使われ得るものと理解されるべきである。以下の請求項は、本発明の範囲を画定することを意図したもので、これら請求

項の範囲内にある方法、構成、およびそれらの均等物は、それによって包含されることを意図する。

【図１】

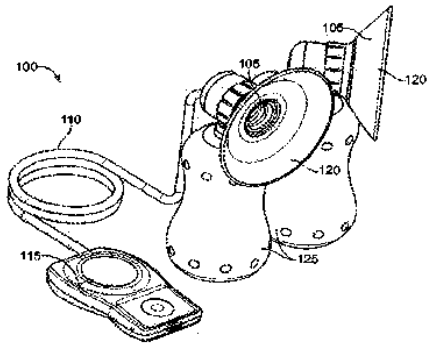


FIG. 1

【図２】

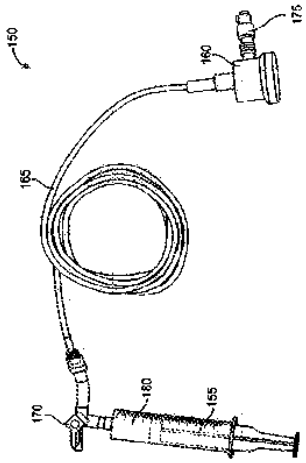


FIG. 2

【図３】

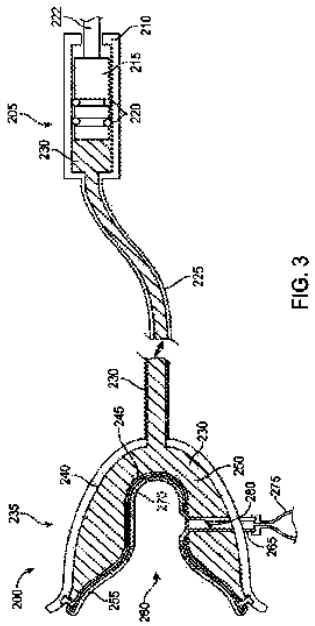


FIG. 3

【図４】

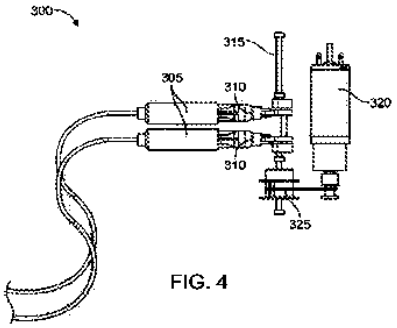


FIG. 4

【図５Ａ】

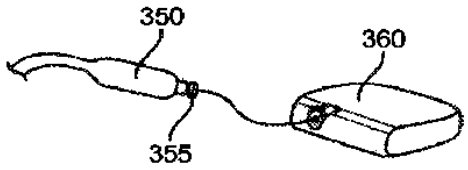


FIG. 5A

【図５Ｂ】

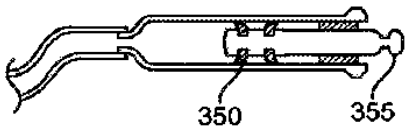


FIG. 5B

【図６】

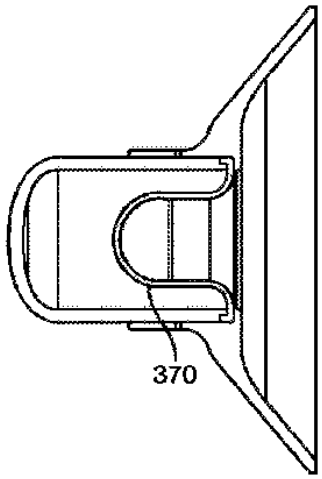


FIG. 6

【図７】

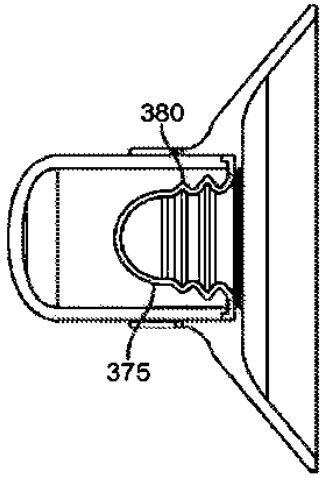


FIG. 7

【図８Ａ】

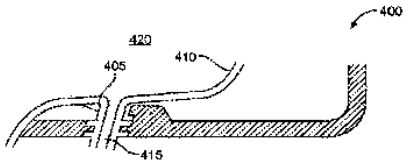


FIG. 8A

【図８Ｂ】

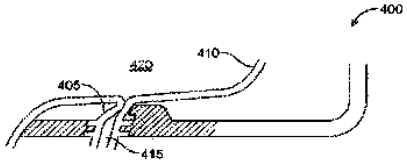


FIG. 8B

【図９Ａ】

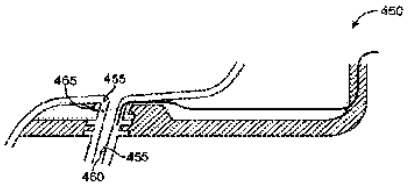


FIG. 9A

【図９Ｂ】

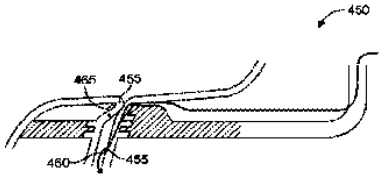


FIG. 9B

【図１０】

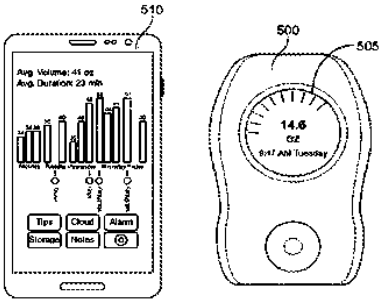


FIG. 10

【図１１】

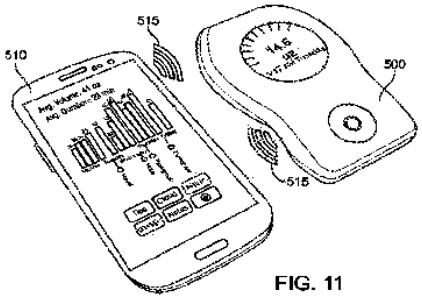


FIG. 11

【図１２】

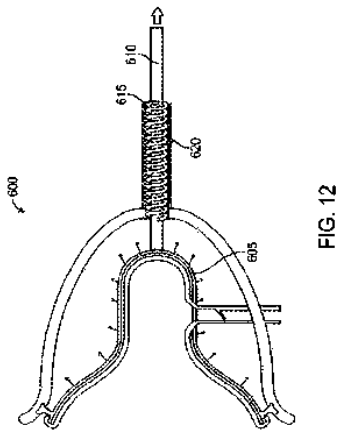


FIG. 12

【図１３】

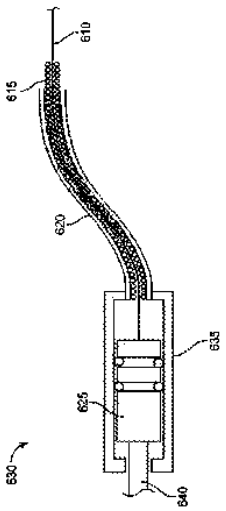


FIG. 13

【図１４】

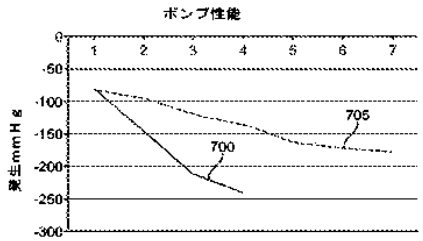


FIG. 14

【図１５】

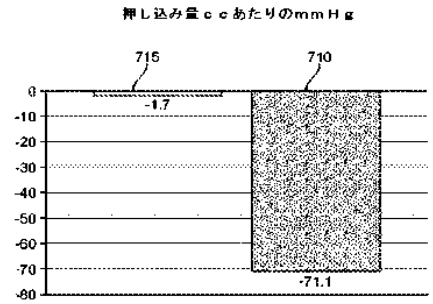


FIG. 15

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/031510

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 1/06 (2014.01)
USPC - 604/74
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A41C 3/04; A61J 9/00, 11/00; A61M 1/06 (2014.01)
USPC - 215/11.1; 450/36, 37; 606/73, 74

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61M 1/06, 1/062, 1/064, 1/066 (2014.07)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Orbit, Google Patents, Google Scholar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/0316493 A1 (SCHLIENGER et al) 13 December 2012 (13.12.2012) entire document	1, 2, 4, 5, 7-11, 15-17, 19, 20, 26-28, 31-36, 41, 47, 48, 53, 55
Y		3, 6, 12-14, 18, 21-25, 29, 30, 37-40, 42-46, 49-52, 54
Y	WO 2012/014135 A1 (BOSMAN et al) 02 February 2012 (02.02.2012) entire document	3, 37
Y	US 2003/0153869 A1 (YTTEBORG) 14 August 2003 (14.08.2003) entire document	6
Y	US 2006/0106334 A1 (JORDAN et al) 18 May 2006 (18.05.2006) entire document	12-14, 38, 39
Y	US 5,007,899 A (LARSSON) 16 April 1991 (16.04.1991) entire document	18, 40
Y	US 2003/0191433 A1 (PRENTISS) 09 October 2003 (09.10.2003) entire document	21
Y	US 6,997,897 B1 (SILVER et al) 14 February 2006 (14.02.2006) entire document	22-24, 50-52
Y	US 2008/0039741 A1 (SHEMESH et al) 14 February 2008 (14.02.2008) entire document	25, 29, 30, 42-46,49
Y	US 2012/004603 A1 (HARARI et al) 05 January 2012 (05.01.2012) entire document	45
Y	US 2012/0325219 A1 (SMITH) 27 December 2012 (27.12.2012) entire document	54

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Date of the actual completion of the international search	Date of mailing of the international search report
13 August 2014	02 SEP 2014
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

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(81)指定国 AP(BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), EA(AM, AZ, BY, KG, KZ, RU, TJ, TM), EP(AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OA(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG), AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US

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Ｆターム(参考) 4C077 AA22 DD01

Patents JP2016514516

Methods, apparatus, and systems for expression and quantification of human breast milk

Abstract

translated from Japanese

The apparatus for breast milk expression and collection includes an operable assembly, a breast interface, and a tube. The chest interface is sized to receive the chest and forms a fluid tight seal with the chest. The chest interface includes a deformable member provided on at least a portion of the chest interface. The deformable member deforms in response to actuation of the actuatable assembly and applies vacuum pressure to the breast to squeeze out the milk. The tube operably couples the actuatable assembly to the chest interface.

Images (18)



FIG. 5A

Classifications

- A61M1/064 Suction cups

View 6 more classifications

JP2016514516A

Japan

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Other languages: Japanese

Inventor: ジョアリービー、アルバレス、ジュアリービー アルバレス、ジョセフビー、アルバレス、ジョセフビー アルバレス、ジョセフ リッドフォース、ジョン リッドフォース、

Worldwide applications

2014 US WO CN AU BR JP EP 2017 KR

Application JP2016504391A events

2013-03-24 Priority to US201361804722P

2014-03-21 Application filed by アダルバス、インコーポレイテッド, アダルバス、インコーポレイテッド

2016-05-23 Publication of JP2016514516A

2017-04-27 Publication of JP2016514516A5

Status Pending

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External links: Espacenet, Global Dossier, Discuss

Claims (55)

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translated from Japanese

A device for the expression and collection of breast milk, said device comprising,
An operable assembly;
A chest interface, wherein the chest interface is sized to engage and fluid seal against the chest, the chest interface having a movable member disposed within at least a portion thereof, and ,
A tube operably coupling the actuatable assembly to the chest interface;
With
The movable member operates in response to actuation of the actuatable assembly, thereby creating a vacuum in the breast interface and applying the vacuum to the breast to pump milk therefrom. The apparatus of claim 1, wherein the actuatable assembly comprises a piston or a pump. The apparatus of claim 1, wherein the actuatable assembly comprises a pair of pistons or a pair of pumps. The apparatus of claim 1, wherein actuation of the actuatable assembly moves fluid within the tube. The apparatus of claim 1, wherein the movable member comprises a flexible membrane. The apparatus of claim 5, wherein the flexible membrane has a corrugated region configured to expand and contract. The apparatus of claim 5, wherein the flexible membrane deforms in response to actuation of the actuatable assembly, and actuation of the actuatable assembly moves fluid contained within the tube. The apparatus of claim 1, wherein the movable member comprises a deformable member. The apparatus of claim 1, wherein the chest interface comprises a resilient and familiar flange that engages the chest and forms a fluid tight seal with the chest. The apparatus of claim 1, wherein fluid is disposed within the tube. The apparatus of claim 10, wherein the fluid is an incompressible fluid. The apparatus of claim 1, wherein a tension element is disposed within the tube. The apparatus of claim 12, wherein the tensioning element comprises a rope, wire, or cable. The apparatus of claim 12, wherein the tensioning element is operably coupled to the movable member and the actuatable assembly. The apparatus of claim 1, further comprising a drive mechanism operably coupled to the actuatable assembly and configured to actuate the actuatable assembly. The apparatus of claim 15, wherein the drive mechanism is an electromechanical device. The apparatus of claim 15, wherein the drive mechanism comprises a motor. The apparatus of claim 15, wherein the drive mechanism is releasably coupled to the actuatable assembly. The apparatus of claim 1, wherein the breast interface comprises an outlet valve, the outlet valve configured to control the flow of the pumped breast milk into a collection container. The outlet valve prevents the pumped milk from flowing through the outlet valve when the deformable member is deformed, and the pumped breast milk flows through the outlet valve when the deformable member is in a non-deformed shape 20. The apparatus of claim 19, wherein the flow is controlled by. The apparatus of claim 19, wherein the outlet valve is integrally formed within the deformable member. A second chest interface, wherein the second chest interface is sized to engage and fluid seal against the second chest, the second chest interface being within at least a portion of the second chest interface; A second chest interface having a movable member disposed on the
A second tube operably coupling the actuatable assembly to the second chest interface;
Further comprising
The movable member deforms in response to actuation of the actuatable assembly, thereby creating a vacuum in the second chest interface and applying vacuum to the second chest to pump milk therefrom. The apparatus of claim 1. A second operable assembly;
A second chest interface, wherein the second chest interface is sized to engage and fluid seal against the second chest, the second chest interface being within at least a portion

of the second chest interface; A second chest interface having a movable member disposed on the
A second tube operably coupling the second actuatable assembly to the second chest interface;
Further comprising
The movable member deforms in response to actuation of the actuatable assembly or the second actuatable assembly, thereby creating a vacuum in the second chest interface, and the vacuum on the second chest. The apparatus of claim 1 wherein said device is applied to express milk therefrom. The apparatus of claim 1, further comprising a housing having a controller for controlling operation of the actuatable assembly. The apparatus according to claim 1, further comprising a housing having a controller for controlling calculation and display of breast milk production information and controlling communication with other apparatuses. The apparatus of claim 1, further comprising a housing having a power supply that provides power to the apparatus for milking and collecting milk. The apparatus of claim 1, further comprising a housing having a drive mechanism for actuating the actuatable assembly The apparatus of claim 1, further comprising a collection container fluidly coupled to the chest interface. The apparatus of claim 1, further comprising a sensor adjacent to the breast interface, wherein the sensor is configured to sense at least one side of milk flowing therethrough. The apparatus of claim 1, further comprising a display unit for displaying data relating to the milk expression A system for milking and collecting milk comprising the apparatus according to claim 1 A device for applying pressure or vacuum to a patient, the device comprising:
An operable assembly;
A target tissue interface, wherein the target tissue interface is sized to engage and fluid seal against the target tissue, the target tissue interface including a deformable member disposed within at least a portion thereof. Having a target tissue interface,
A tube operably coupling the actuatable assembly to the target tissue interface;
With
The apparatus wherein the deformable member deforms in response to actuation of the actuatable assembly, thereby creating a vacuum or pressure in a target tissue interface and applying the vacuum or pressure to the target tissue. A method for extracting and collecting breast milk, the method comprising:
Providing a chest expression and collection device having at least one chest interface and at least one actuable assembly operably coupled to the at least one chest interface, the chest interface comprising: including a possible member, and
Engaging the chest with the chest interface to fluid-tight;
Actuating the actuatable assembly,
Deforming the deformable member in response to actuation of the actuatable assembly, thereby creating a vacuum and applying it to the chest;
Extracting milk from the chest and collecting it,
Including a method. 34. The engaging step includes engaging a resilient and familiar flange on the chest interface to the chest, thereby forming a fluid seal between the chest interface and the chest. The method described in 1. 34. The method of claim 33, wherein the actuatable assembly moves fluid. 36. The method of claim 35, wherein the fluid is disposed in a tube fluidly coupled to the actuatable assembly and the deformable member. 34. The method of claim 33, wherein actuating the actuatable assembly includes actuating a piston. 34. The method of claim 33, wherein actuating the actuatable assembly comprises applying tension to a tensioning element disposed within the tube. 39. The method of claim 38, wherein an axial load absorbing member is disposed concentrically around the tension element, and the method further comprises absorbing a reaction force of the tension element. 34. The method of claim 33, further comprising releasing the actuatable assembly from a drive mechanism operably coupled thereto. 34. The method of claim 33, further comprising the step of repeating the actuating step, the deforming step, and the extruding step. 34. The method of claim 33, further comprising quantifying the production of the expressed milk. 34. The method of claim 33, further comprising quantifying one or more aspects of the pumped milk. 34 The method of claim 33, further comprising the step of transmitting data relating to the breast milk expression between the breast expression and collection device and a computer. 45. The method of claim 44, wherein the mobile device comprises a smartphone. 45. The method of claim 44, further comprising displaying the data on a display. 34. The method of claim 33, further comprising controlling the flow of the pumped milk to a collection container with a valve fluidly coupled to the chest pumping and collection device. 48. The method of claim 47, wherein controlling the flow comprises opening the valve when the deformable member is undeformed and closing the valve when the deformable member is deformed. 34. The method of claim 33, further comprising sensing the pumped breast milk flow with a sensor fluidly coupled to the breast interface. The chest expression and collection device further comprises a second chest interface and a second actuable assembly operably coupled to the second chest interface, the second chest interface being deformed
Comprising a possible member, the method comprising:
Engaging a second chest with the second chest interface to fluid-tight;
Activating the second actuatable assembly;
Deforming the deformable member in the second chest interface in response to actuation of the second actuatable assembly, thereby creating and applying a vacuum to the second chest;
Extracting and extracting milk from the second breast,
34. The method of claim 33, further comprising: 51. The method of claim 50, wherein the steps of pumping and collecting milk from both breasts occur simultaneously. 51. The method of claim 50, wherein the step of pumping and collecting the milk alternates between both breasts. A method of applying a differential pressure to a patient, the method comprising:
Providing a differential pressure device having an interface and an actuatable assembly operably coupled to the differential pressure device, the interface comprising a deformable member,
Engaging the interface with a target area on the patient and fluidly sealing,
Actuating the actuatable assembly,
Deforming the deformable member in response to actuation of the actuatable assembly, thereby creating a positive pressure or vacuum, and applying the positive pressure or the vacuum to the target area;
Including a method. The step of deforming the deformable member creates a positive pressure applied to the target area, the target area including the mouth or nose, thereby reducing apnea conditions while the patient is sleeping. 54. The method of claim 53, wherein the method resolves. 54. The step of deforming the flexible membrane forms a vacuum applied to the target area, the target area including a body fluid storage organ, thereby squeezing out the body fluid therefrom. The method described in 1.

Description

translated from Japanese

(Related application)
The present application was filed on March 24, 2013, US Provisional Patent Application No. 61 / 804,722 (attorney management number 44396-702101), filed on September 17, 2013, US Provisional Patent Application No. 61 / 879,055 (Agent Management No. 44396-703.102), US Patent Application No. 14 / 221,313 (Agent Management) filed on March 20, 2014 No. 44936-703.201), the entire contents of which are hereby incorporated by reference.

The present invention relates generally to medical devices and methods, and more specifically to devices and methods for the expression and collection of human breast milk.

The exemplary embodiments disclosed herein are preferably directed to breast milk expression, although those of ordinary skill in the art are not intended to be limiting, and the devices, systems, it will be appreciated that and the method can be used for other therapies that require the application of differential pressure.

Chest pumps are commonly used to collect breast milk so that mothers can continue breastfeeding even when they are separated from their children. At present, there are two basic types of chest pumps: manual measures that are small but inefficient and tired of use, and efficient but bulky electric devices. Thus, it would be desirable to provide an improved chest pump that is small and very efficient for milking and collecting milk. Additional features such as quantification of milk production and communication with mobile devices are more desirable to enhance user convenience. At least some of these objectives will be met by the apparatus and methods disclosed below.

The following US patents relate to the expression and collection of human breast milk. US Pat. No. 6,673,036 (Patent Document 1), 6,749,582 (Patent Document 2), 6,840,918 (Patent Document 3), 6,887,210 (Patent) Document 4), 7,875,000 (Patent Document 5), 8,118,772 (Patent Document 6), and 8,216,179 (Patent Document 7).

US Pat. No. 6,673,036 US Pat. No. 6,749,582 US Pat. No. 6,840,918 US Pat. No. 6,887,210 US Pat. No. 7,875,000 US Pat. No. 8,118,772 US Pat. No. 8,216,179

The present invention relates generally to medical devices, systems, and methods, and more specifically to devices, systems, and methods for the expression and collection of human breast milk.

In a first aspect of the present invention, an apparatus for breast milk expression and collection comprises an actuable assembly, a breast interface, and a tube. The chest interface is sized to engage and fluid-tighten the chest. The chest interface also includes a movable member disposed within at least a portion thereof. The movable member operates in response to actuation of the actuatable assembly, thereby creating a vacuum at the chest interface, applying the vacuum to the chest and pumping milk therefrom. The tube is operably coupled to the actuatable assembly and the chest interface.

The actuatable assembly may comprise a piston or pump, or a pair of pistons or a pair of pumps. Actuation of the actuatable assembly may move fluid disposed within the tube.

The movable member may comprise a flexible membrane. The flexible membrane may have a corrugated region configured to expand and contract. The flexible membrane deforms in response to actuation of the actuatable assembly, and actuation of the actuatable assembly can move the fluid contained in the tube. The movable member may comprise a deformable member.

The chest interface may include a resilient and familiar flange that engages the chest to form a fluid seal.

A fluid may be placed in the tube. The fluid may be an incompressible fluid such as water or oil. In other embodiments, tension elements may be disposed within the tube. The tensioning element can include a rope, wire, or cable. The tensioning element may be operably coupled to the movable member and the actuatable assembly and arranged concentrically with an axial compression element that absorbs the counterload of the tensioning element.

The apparatus may comprise a drive mechanism operably coupled to the actuatable assembly and configured to actuate the actuatable assembly. The drive mechanism may include an electromechanical device such as a motor. The drive mechanism can be releasably coupled to the actuatable assembly.

The breast interface may comprise an outlet valve configured to control the flow of pumped breast milk into the collection container. The outlet valve prevents pumped milk from flowing through the valve when the deformable member is deformed, and allows pumped milk to flow through the valve when the deformable member is in an undeformed shape. By doing so, the flow can be controlled. The outlet valve can be integrally formed in the deformable member.

The apparatus may further comprise a second actuatable assembly, a second chest interface, and a second tube. The second chest interface may be sized to engage and fluid-tightly engage the second chest. The second chest interface may have a movable member disposed within at least a portion thereof, the movable member deforming in response to actuation by either the actuatable assembly or the optional second actuatable assembly. , Thereby creating a vacuum in the second breast interface, which may be applied to the second breast and pumping milk therefrom. The second tube can be operably coupled to the second actuatable assembly and the second chest interface.

The apparatus may further comprise a housing having a controller for controlling the operation of the operable assembly. The controller may control the calculation and display of breast milk production information, and the controller may also control communication with other devices. A power source may be placed within the housing, and the power source may provide power to a device for milking and collecting milk. The housing may have a drive mechanism disposed therein for operating the actuatable assembly.

The apparatus may further comprise a collection container fluidly coupled to the chest interface. The device may also include a sensor configured to measure the side of the breast interface adjacent and past the breast interface. The apparatus may also include a display unit that displays data relating to milk expression. A system for

milk expression and collection can include the devices previously described above. Any of these components may be separate from the other components or they may be placed in a housing or pendant.

In another aspect of the invention, an apparatus for applying pressure or vacuum to a patient comprises an actuatable assembly, a target tissue interface, and a tube. The target tissue interface is preferably sized to engage and fluid seal against the target tissue. The target tissue interface has a deformable member disposed within at least a portion thereof, the deformable member deforming in response to actuation of the actuatable assembly. This creates a vacuum or pressure within the target tissue interface and applies the vacuum or pressure to the target tissue. The tube is operably coupled to the actuatable assembly and the target tissue interface

In yet another aspect of the invention, a method for expressing and collecting breast milk provides a chest expression and collection device having a chest interface and an operable assembly operably coupled to the chest interface, including the steps of: The chest interface includes a deformable member. The method also includes engaging and fluid-sealing the chest with the chest interface and actuating the actuatable assembly. The method also includes the step of deforming the deformable member in response to actuation of the actuatable assembly, thereby forming and applying a vacuum to the chest to squeeze and collect milk from the chest.

The engaging step may include engaging a resilient and familiar flange on the chest interface with the chest, thereby creating a fluid seal between the chest interface and the chest.

Actuating the actuatable assembly can move fluid. The fluid may be disposed in a tube fluidly coupled to the actuatable assembly and the deformable member. Actuating the actuatable assembly may include actuating the piston or applying tension to a tensioning element disposed within the tube. The method may further include releasing the actuatable assembly from a drive mechanism operably coupled thereto.

The method may further comprise repeating the steps of actuation, deformation and extrusion. The method may further comprise the steps of quantifying the production of the expressed milk and transmitting data relating to the expression of the breast milk between the chest expression and collection device and the mobile device. The mobile device can be a smartphone, a tablet, or a calculator. The data can be displayed on a display. The method may also include controlling the flow of pumped milk to the collection container by a valve fluidly coupled to the chest pumping and collection device. Controlling the flow may include opening the valve when the deformable member is undeformed and closing the valve when the deformable member is deformed. The side of the breast milk may also be sensed with a sensor fluidly or otherwise coupled to the breast interface.

The chest expression and collection device may further comprise a second chest interface and a second actuatable assembly operably coupled to the second chest interface. The second chest interface may comprise a deformable member. The method may further include engaging and fluid-sealing the second chest with the second chest interface and activating the first or second actuatable assembly. The method also deforms the deformable member in the second chest interface in response to actuation of the second actuatable assembly, thereby creating a vacuum in the second chest and applying the second chest from which milk may be expressed and collected. The expression and collection of milk from both breasts may be performed simultaneously on both breasts or alternately.

In yet another aspect of the invention, a method of applying differential pressure to a patient includes providing a differential pressure device having an interface and an actuable assembly operably coupled to the differential pressure device. The interface includes a deformable member, and the method further includes engaging the interface with a target region on the patient to fluid seal and actuate the actuatable assembly. The method also includes deforming the deformable member in response to actuation of the actuatable assembly, thereby creating a positive pressure or vacuum, and applying the positive pressure or vacuum to the target area. Either component may be separated from the other components, or they may be placed in a housing or pendant.

The step of deforming the deformable member may create a positive pressure applied to the target area. The target area includes the mouth or nose, and application of positive pressure may reduce or eliminate apnea or similar disturbances during patient sleep. The step of deforming the flexible membrane can create a vacuum applied to the target area. The target area includes a fluid storage organ, so that a vacuum causes the fluid to be pumped out of the storage organ.

These and other embodiments are described in more detail in the following description with reference to the accompanying drawings.
(Incorporation by reference)

All publications, patents, and patent applications mentioned herein are hereby incorporated by reference to the same extent as if each individual publication, patent, and patent application were specifically and individually incorporated by reference. It is.

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. 1 is a perspective view of an exemplary embodiment of a pump device. FIG. 2 is a perspective view of an exemplary embodiment of a pump device. FIG. 3 is a cross section of an exemplary embodiment of a pump device. FIG. 4 illustrates an exemplary embodiment of an actuatable assembly coupled to a drive mechanism. 5A-5B illustrate an exemplary embodiment of an actuatable assembly coupled to a pendant unit. 5A-5B illustrate an exemplary embodiment of an actuatable assembly coupled to a pendant unit. FIG. 6 is a cross-sectional view of an exemplary embodiment of a chest interface. FIG. 7 is a cross-sectional view of another exemplary embodiment of a chest interface. FIG. 8A is a cross-sectional view of an exemplary embodiment of an integrated valve in an open position. FIG. 8B is a cross-sectional view of an exemplary embodiment of an integrated valve in a closed position. FIG. 9A is a cross-sectional view of an exemplary embodiment of a sensor integrated within a chest interface. FIG. 9B is a cross-sectional view of another exemplary embodiment of a sensor integrated within a chest interface. FIG. 10 illustrates an exemplary embodiment of a pendant unit and mobile device. FIG. 11 illustrates an exemplary embodiment of a pendant unit in communication with a mobile device. FIG. 12 is a cross-sectional view of an exemplary embodiment of a chest interface with a mechanically deformable member. FIG. 13 is a cross-sectional view of an exemplary embodiment of a mechanical drive for a mechanically deformable member. FIG. 14 is a graph illustrating the pump performance of an exemplary embodiment compared to a commercial device. FIG. 15 is a graph illustrating the pump efficiency of an exemplary embodiment compared to a commercial device.

Specific embodiments of the disclosed apparatus and method are described below with reference to the drawings. Any detailed description is not intended to imply that a particular component, feature, or step is absolutely necessary for the present invention. Those skilled in the art will appreciate that various features or steps may be substituted for or combined with each other.

The present invention will be described in the context of milk expression and collection. However, those skilled in the art are not intended to limit it, and the devices and methods disclosed herein may create and communicate pressure differentials, such as sleep apnea treatment and / or other remote pressure needs. It will be understood that it can be used for other applications that require.

FIG. 1 illustrates an exemplary embodiment of the present invention. The pump device 100 includes a chest interface 105, a tube 110, and a controller or pendant unit 115 operably coupled to the chest interface 105 through the tube 110. The chest interface 105 includes a resilient and familiar flange 120 that engages the chest and forms a fluid seal thereto, and a collection container 125. The device may optionally have only a single chest interface. The pendant unit 115 houses a power source and a driving mechanism for the pump device 100, and includes hardware for various functions such as control of the pump device 100, quantification of milk production, communication with other devices, and the like. The tube 110 transmits a suitable energy input, such as a mechanical energy input, over a long distance from the pendant unit 115 to the chest interface 105. The breast interface 105 efficiently converts the energy input into vacuum pressure on the breast, causing milk to be pumped into the collection container 125.

Those skilled in the art will appreciate that the components and features of the present exemplary embodiment can be combined or substituted with the components and features of any of the embodiments of the present invention described below. Similarly, the components and features of other embodiments disclosed herein may be substituted or combined with each other.
(Hydraulic pump device)

The hydraulic system can reduce the pump power required, and thus reduce the size of the pump device while maintaining pump efficiency. In a preferred embodiment, the pump device can utilize a hydraulic pump device to generate a pressure differential across the breast for milk extraction and collection.

An exemplary hydraulic pump device is shown in FIGS. FIG. 2 illustrates a pump device 150 having a syringe 155 fluidly coupled to the chest interface 160 by a tube 165. Syringe 155 is coupled to tube 165 through three-way valve 170. Chest interface 160 includes an outlet port 175. The syringe 155 drives the fluid 180 contained in the tube 165 toward or away from the flexible member housed in the chest interface 160 to create the pressure differential required for pumping milk from the chest. produce.

FIG. 3 illustrates another embodiment of the pump device 200. The actuatable assembly 205 includes an assembly housing 210, a drive element 215, a radial seal 220, and a shaft 222. The drive element 215 is operably coupled to a pendant unit such as the pendant unit 115 through the shaft 222. Tube 225 contains fluid 230 and is fluidly coupled to actuatable assembly 205 and chest interface 235. The chest interface 235 comprises an interface housing 240, a flexible membrane 245, a reservoir 250, a sealing element 255, a pressure area 260, and a discharge port 265. The sealing element 255 includes a deformable portion 270. The discharge port 265 is coupled to the collection container 275 and includes a flap valve 280.

Actuable assembly 205 moves fluid 230 contained within tube 225, which can be a flexible conduit. The fluid 230 occupies the reservoir 250 in the chest interface 235 and is coupled to the flexible membrane 245. The flexible membrane 245 transmits vacuum pressure from the fluid 230 to the deformable portion 270 of the sealing element 255. When the chest is engaged and fluidly sealed with the chest interface 235 by the sealing element 255, movement of the actuatable element 215 creates a substantial vacuum pressure on the chest through the flexible membrane 245 and the deformable portion 270. As a result, the milk is pumped into the pumping area 260.

The pumped milk is discharged into the collection container 275 through the discharge port 265. The discharge port 265 is configured to have a flap valve 280 and secures a milk passage while maintaining the vacuum pressure in the pumping region 260.

The fluid of the hydraulic pump device can be any suitable fluid, such as an incompressible fluid. In many embodiments, the incompressible fluid can be water or oil. Alternatively, the fluid can be any suitable gas, such as air. Suitable incompressible fluids and gases for hydraulic systems are known to those skilled in the art.

Those skilled in the art will be able to combine or replace the components and features of any exemplary embodiment of the hydraulic pump apparatus with the components and features of any exemplary embodiment of the invention described herein. Will understand.
(Operating mechanism)

Many actuation mechanisms known to those skilled in the art can be utilized for actuatable assembly 205. The actuatable assembly 205 can be a piston assembly, a pump such as a diaphragm pump, or any other suitable actuation mechanism. The optimal configuration of the actuatable assembly 205 depends on a number of factors, such as vacuum requirements, size, power, and other needs of the pump device 200, and the characteristics of the fluid 230 such as viscosity, biocompatibility, and fluid life requirements. May vary.

FIG. 3 illustrates an exemplary embodiment where the actuatable assembly 205 is a piston assembly and the drive element 215 is a piston. The actuatable assembly 205 includes a radial seal 220, such as an O-ring, that seals against the assembly housing 210 to prevent unwanted exudation of the fluid 230 and allow the fluid 230 to be driven.

FIG. 4 illustrates another exemplary embodiment of an actuatable assembly 300 that includes a pair of pistons 305.

In a preferred embodiment, the actuatable assembly includes a drive element that is moved by a suitable drive mechanism, such as a drive mechanism in pendant unit 115. Many drive mechanisms are known to those skilled in the art. For example, a drive element such as drive element 215 may be electromechanically actuated by a motor or manually actuated by a suitable user-operator interface such as a lever. Various drive modes known to those skilled in the art can be used, in particular, the implementation of an exemplary hydraulic pump device as described herein allows for the use of a suitable drive mode such as direct drive or solenoids due to the reduced force requirements of the hydraulic system.

With reference to the exemplary embodiment of FIG. 4, piston 305 includes a coupling 310 to crankshaft 315. Crankshaft 315 is operably coupled to motor 320 through belt drive 325. Crankshaft 315 drives a pair of pistons 305 with the same stroke timing to apply vacuum pressure to both breasts simultaneously, a feature that is desirable for increased milk production. Instead, the crankshaft 315 can drive the pair of pistons 305 at any suitable stroke timing, such as alternating or offset stroke cycles.

The drive mechanism can be powered by any suitable power source such as a local battery or an AC adapter. The drive mechanism can be controlled by hardware such as a built-in electronic device arranged in the pendant unit 115.

FIG. 5 illustrates an exemplary embodiment of an actuatable assembly 350 that includes a releasable coupling 355. Preferably, the actuatable assembly 350 is releasably coupled to the pendant unit 360 and the drive mechanism housed therein. The coupling can be a mechanical coupling or any suitable simple description mechanism known to those skilled in the art. The releasably coupled design allows for configuration flexibility and use of the pump device. For example, comfort can be improved by different sized breast interfaces that are compatible with various breast sizes. In addition, this feature allows the use of a common pump device with a replaceable chest interface, reducing the risk of pathogen spread. Furthermore, the releasable coupling allows easy replacement of the individual parts of the pump device.

Those skilled in the art will appreciate that the components and features of any exemplary embodiment of the actuation mechanism can be combined or replaced with the components and features of any embodiment of the invention as described herein. I will.
(Flexible membrane)

In many embodiments, such as the embodiment shown in FIG. 3, the flexible membrane 245 is located within the chest interface 235 and is disposed to cover at least a portion thereof, and the interface housing 240, the flexible membrane 245, Between which the reservoir 250 is formed. Preferably, the flexible membrane 245 substantially deforms when exposed to the negative pressure created when the fluid 230 is moved from the reservoir 250 by the actuable assembly 205. The amount of deformation of the flexible membrane 245 can be controlled by a number of factors (eg, wall thickness, rubber hardness, surface area) and can be optimized based on the pump device (eg, pump power, vacuum requirements).

FIG. 6 illustrates an exemplary flexible membrane 370 having a specific thickness and rubber hardness.

FIG. 7 illustrates another embodiment of a flexible membrane 375 with corrugated features 380 that increase surface area.

Suitable materials for the flexible membrane are known to those skilled in the art. In many embodiments, the flexible membrane is a material designed to expand and contract when exposed to pressure from a binding fluid such as silicone, polyether block amides such as PEBAX, and polychloroprene such as neoprene. Can be made. Alternatively, the flexible membrane can be made from a substantially rigid material such as stainless steel, nitinol, a rigid polymer, or a rigid elastomer. In these embodiments, the rigid material will be designed with stress and / or strain distribution elements that allow substantial deformation of the flexible membrane that does not exceed the yield point of the material.

FIGS. 8A and 8B illustrate a preferred embodiment of a chest interface 400 in which an outlet valve 405 is integrated into the flexible membrane 410 and controls the flow of pumped milk through the outlet port 415. The outlet valve 405 is opened when the flexible membrane 410 is relaxed, as shown in FIG. 8A, and when the flexible membrane 410 is deformed, as shown in FIG. 8B. Closed to prevent fluid flow. Outlet valve 405 allows substantial vacuum pressure to be present in pumping area 420 during extraction while allowing milk to be drained during the rest of the pump stroke. While many conventional chest pump valves function only with pressure differentials, the outlet valve 405 can preferably be configured to function also with mechanical movement of the flexible membrane 410. Incorporating a mechanical function as described herein into the integrated outlet valve 405 can improve the sealing of the chest interface 400 during vacuum formation. Furthermore, the use of an outlet valve integrally formed in the flexible membrane 410, such as the outlet valve 405, reduces the number of parts to be cleaned.

Those skilled in the art will appreciate that the components and features of any exemplary embodiment of the flexible membrane can be combined or replaced with the components and features of any embodiment of the invention as described herein. I will.
(Milk collection and quantification system)

Referring to FIG. 3, the pumped milk is discharged into the collection container 275 through the outlet port 265 in the flexible membrane 245. The collection container 275 can be any suitable container such as a bottle or bag. In many embodiments, collection container 275 is removably coupled to flexible membrane 245. The collection vessel 275 can be coupled directly or remotely via any suitable device such as an extension line.

In many cases, it may be desirable to track various data related to milk expression and collection, such as the amount of milk production. Currently, tracking milk production is commonly done by manual measurement and record keeping. The exemplary embodiments of the apparatus described herein may provide a digital-based

means for automatically measuring and tracking milk production for improved convenience, efficiency, and accuracy

9A and 9B illustrate an exemplary embodiment of a chest interface 450 with one or more integrated sensors 455. The sensor 455 is preferably located within the flap valve 460, but may be located at the outlet valve 465 or any other location suitable for monitoring fluid flow. In a preferred embodiment, at least one sensor 455 is integrated into a valve that is opened by fluid flow to detect the total time that the valve is open. The sensor signal can be queried to quantify the fluid flow. Suitable sensors are known to those skilled in the art, such as accelerometers, Hall effect sensors, and photodiode / LED sensors. The chest interface can include a single sensor or multiple sensors that quantify milk production.

FIG. 10 illustrates an exemplary embodiment of a pendant unit 500 with milk expression data displayed on the display screen 505. In many embodiments, the pendant unit 500 collects, processes, stores, and displays data regarding milk expression. Preferably, the pendant unit 500 can transmit data to a second device such as the mobile phone 510.

FIG. 11 illustrates data transmission 515 between the pendant unit 500 and the mobile phone 510. Bluetooth (registered trademark), near field communication, and the like are known to those skilled in the art as suitable methods for communication and data transmission between devices.

In the exemplary embodiment, pendant unit 500 communicates with mobile phone 510 and transmits milk expression data such as expression volume, duration, and date. The mobile phone 510 includes a mobile application that collects and aggregates the compressed data and displays it in an interactive format. Preferably, the mobile application includes additional features that allow the user to overlay information such as lifestyle choices, dietary habits, strategies for increasing milk production, and the like. Make comparisons easier. In addition, the pendant unit 500 may send information about the number of times the pump is used to the mobile phone 510 so that the mobile application can identify when pumping occurs and set a reminder for the desired number of pumping operations. it can. Such a reminder helps prevent forgetting of the pump session, and as a result, can reduce the incidence of complications such as mastitis.

One of ordinary skill in the art can combine or substitute the components and features of any exemplary embodiment of the milking and quantification system with the components and features of any embodiment of the invention as described herein. Will understand.

(Mechanical pump device)

FIG. 12 illustrates an alternative embodiment of a chest interface 600 where a mechanically deformable member 605 can be used instead of a flexible membrane. The mechanically deformable member 605 can be configured in a manner similar to that used for the flexible membrane described herein. Mechanically deformable member 605 is coupled to tensioning element 610. In some cases, the tension element 610 is disposed within the axial load absorbing member 615. The axial load absorbing member 615 is disposed in the tube 620. Preferably, the tension element 610 is concentrically disposed within the axial load absorbing member 615 and the axial load absorbing member 615 is concentrically disposed within the tube 620. In an alternative configuration of the tension element 610, an axial load absorbing member 615 and a tube 620 can be used.

FIG. 13 illustrates tensioning element 610 coupled to drive element 625 in assembly housing 635 of actuatable assembly 630. Drive element 625 is operably coupled to a drive mechanism, such as a drive mechanism housed within the pendant unit, via shaft 640. An axial load absorbing member 615 within the tube 620 is fixedly coupled to the assembly housing 635. Movement of the drive element 625 transmits tension through the tension element 610 to the mechanical deformation member 605 and creates a vacuum pressure on the chest.

The tensile element 610 can be any suitable device such as a wire, coil, or rope, and can be made of any suitable material such as a metal, polymer, or elastomer. The axial load absorbing member 615 can be made of any suitable material that is rigid in the axial direction, such as metal or polymer, and can be configured in any suitable shape that is rigid in the axial direction, such as a tube or coil. it can.

Those skilled in the art will appreciate that the components and features of any exemplary embodiment of the mechanical pumping device can be combined or replaced with the components and features of any embodiment of the present invention as described herein. Will do

(Experimental data)

14 and 15 illustrate experimental pumping data obtained from a commercial chest pumping device and an exemplary embodiment of the present invention. The exemplary embodiment used an incompressible fluid for pump operation and had a maximum hydraulic fluid volume of 4 oz, while the commercial device used an air pump operation and had a maximum volume of 114 cc.

FIG. 14 illustrates a graph of pump performance quantified by the vacuum pressure generated per stroke. For the exemplary embodiment, pressure measurements are made for 1 cc, 2 cc, 3 cc, and 4 cc of the fluid volume moved by the pump, with the stroke number corresponding to the volume cc. For commercial equipment, set the pump to one of seven equally spaced positions along the vacuum adjustment gauges representing 46cc, 57cc, 68cc, 80cc, 91cc, 103cc, and 114cc, respectively, of the fluid volume moved by the pump. The measurement is performed and the stroke number corresponds to the position number. Curve 700 corresponds to an exemplary embodiment and curve 705 corresponds to a commercial device. The exemplary embodiment generated a higher level of vacuum pressure per moving volume compared to commercial equipment, with the highest vacuum pressures being -240.5 mmHg and -177.9 mmHg, respectively.

FIG. 15 illustrates a graph of pump efficiency measured at maximum vacuum pressure per maximum volume of fluid transfer, with bar 710 corresponding to an exemplary embodiment and bar 715 corresponding to a commercial device. The exemplary embodiment demonstrated a 42-fold increase in pump efficiency compared to commercial equipment, with efficiencies of -71.1 mmHg / cc and -1.7 mmHg / cc, respectively.

While preferred embodiments of the present invention have been shown and described herein, it will be appreciated by those skilled in the art that such embodiments are presented by way of example only. Many variations, modifications, and alternatives will occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein can be used to practice the invention. The following claims are intended to define the scope of the invention, and the methods, configurations, and equivalents within the scope of these claims are intended to be encompassed thereby.

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JP2015073777A *	2007-12-21	2015-04-20	ホーロックレッカ フィリップス エレクトロニクス エヌヴィ	Milking machine to express milk from the chest

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US6673038B1	1999-10-13	2004-01-06	The First Years Inc.	Pumping breast milk
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Priority And Related Applications

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Application	Priority date	Filing date	Title
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Legal Events

Date	Code	Title	Description
2017-03-21	A521	Written amendment	**Free format text**: JAPANESE INTERMEDIATE CODE: A523 **Effective date**: 20170321
2017-03-21	A621	Written request for application examination	**Free format text**: JAPANESE INTERMEDIATE CODE: A621 **Effective date**: 20170321
2018-02-14	A977	Report on retrieval	**Free format text**: JAPANESE INTERMEDIATE CODE: A971007 **Effective date**: 20180214
2018-02-26	A131	Notification of reasons for refusal	**Free format text**: JAPANESE INTERMEDIATE CODE: A131 **Effective date**: 20180226
2018-05-25	A601	Written request for extension of time	**Free format text**: JAPANESE INTERMEDIATE CODE: A601 **Effective date**: 20180525
2018-10-18	A02	Decision of refusal	**Free format text**: JAPANESE INTERMEDIATE CODE: A02 **Effective date**: 20181018

Concepts

machine-extracted

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Name	Image	Sections	Count	Query match
human milk		title,claims,abstract,description	20	0.000
quantification		title,description	5	0.000
chest		claims,abstract,description	125	0.000
fluid		claims,abstract,description	54	0.000
Milk		claims,abstract,description	52	0.000
milk		claims,abstract,description	52	0.000
milk		claims,abstract,description	52	0.000
Breast		claims,abstract,description	26	0.000
Milk, Human		claims,abstract,description	16	0.000
response		claims,abstract,description	16	0.000
membrane		claims,description	38	0.000
pumping		claims,description	15	0.000
tissues		claims,description	15	0.000
manufacturing process		claims,description	12	0.000
coupling		claims,description	9	0.000
coupling process		claims,description	9	0.000
coupling reaction		claims,description	9	0.000
controlling effect		claims,description	8	0.000
sealing		claims,description	8	0.000

communication	claims,description	7	0.000
organs	claims,description	3	0.000
rope	claims,description	3	0.000
storage	claims,description	3	0.000
Apnea	claims,description	2	0.000
Apnoea	claims,description	2	0.000
Nose	claims,description	2	0.000
activating	claims,description	2	0.000
pressing	claims,description	2	0.000
Body Fluids	claims	2	0.000
body fluid	claims	2	0.000
chemical reaction	claims	1	0.000

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H04Q	***9/00***	***(2006.01)***	H04Q	9/00	301Z	5K127
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最終頁に続く

(54)【発明の名称】ヒト母乳の搾乳のための方法、装置およびシステム

(57)【要約】
母乳の搾乳のためのシステム、方法、およびデバイスが、提供される。一側面では、システムは、乳房に係合するように構成されるインターフェースと、インターフェースに動作可能に結合される作動アセンブリとを有する、搾乳装置を含む。作動アセンブリの作動は、インターフェースに、減圧圧力を乳房に対して印加させ、乳房から母乳を搾乳させる。システムはまた、データ接続を介して搾乳装置と通信するように構成される、コンピューティングデバイスを含む。

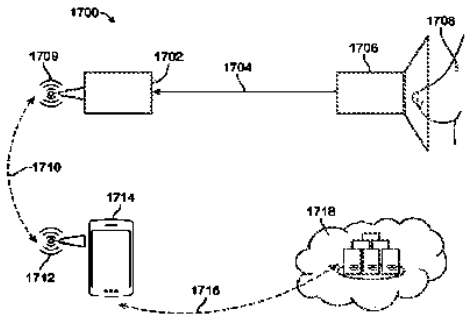


FIG. 17

【特許請求の範囲】
【請求項１】
乳房からの母乳の搾乳のためのシステムであって、
乳房に係合するように構成されるインターフェースと、前記インターフェースに動作可能に結合される作動アセンブリとを備える、搾乳装置であって、前記作動アセンブリの作動は、前記インターフェースに、減圧圧力を前記乳房に対して印加させ、そこから母乳を搾乳させる、搾乳装置と、
データ接続を介して前記搾乳装置と通信するように構成される、コンピューティングデバイスと、
を備える、システム。
【請求項２】
前記インターフェースは、前記乳房に対して流体的にシールするように構成される、請求項１に記載のシステム。
【請求項３】
前記データ接続は、無線通信、近距離通信、およびＵＳＢケーブルのうちの１つまたはそれを上回るものを利用し、前記搾乳装置の少なくとも一部と前記コンピューティングデバイスとの間でデータを伝送する、請求項１に記載のシステム。
【請求項４】
前記コンピューティングデバイスは、スマートフォン、タブレット、およびパーソナルコンピュータから選択される、請求項１に記載のシステム。
【請求項５】
前記搾乳装置はさらに、母乳の搾乳の１つまたはそれを上回る特性を示す測定データを生成するように構成される、感知ユニットを備える、請求項１に記載のシステム。
【請求項６】
前記測定データは、前記データ接続を介して前記コンピューティングデバイスに伝送される、請求項５に記載のシステム。
【請求項７】
前記コンピューティングデバイスは、前記測定データを分析するように構成される、アプリケーションを備える、請求項６に記載のシステム。
【請求項８】
前記コンピューティングデバイスは、前記測定データをサーバに伝送する、請求項６に記載のシステム。
【請求項９】
前記搾乳装置はさらに、前記測定データを分析し、それによって、分析結果を生成するように構成される、処理ユニットを備える、請求項５に記載のシステム。
【請求項１０】
前記搾乳装置はさらに、前記分析結果をユーザに表示するように構成される、ディスプレイユニットを備える、請求項９に記載のシステム。
【請求項１１】
前記分析結果は、グラフ、チャート、または表に表示される、請求項１０に記載のシステム。
【請求項１２】
前記分析結果は、前記データ接続を介して前記コンピューティングデバイスに伝送される、請求項９に記載のシステム。
【請求項１３】
前記コンピューティングデバイスは、前記分析結果をユーザに表示する、請求項１２に記載のシステム。
【請求項１４】
前記コンピューティングデバイスは、前記データ接続を介して、前記搾乳装置の少なくとも１つの機能性を制御する、請求項１に記載のシステム。

【請求項１５】
前記機能性は、前記搾乳装置の電力、前記搾乳装置によって印加される減圧圧力、および前記搾乳装置の１分あたりのサイクルのうちの１つまたはそれを上回るものを含む、請求項１４に記載のシステム。
【請求項１６】
母乳を搾乳するようにユーザにリマインドする通知は、前記データ接続を介して前記コンピュ―ティングデバイスに伝送される、請求項１に記載のシステム。
【請求項１７】
母乳を搾乳するようにユーザにリマインドする通知は、前記データ接続を介して、前記搾乳装置の少なくとも一部に伝送される、請求項１に記載のシステム。
【請求項１８】
ファ―ムウェア更新が、前記デ―タ接続を介して、前記搾乳装置の少なくとも一部に伝送される、請求項１に記載のシステム。
【請求項１９】
前記コンピューティングデバイスは、ネットワークを介してサーバと通信する通信モジュールを備える、請求項１に記載のシステム。
【請求項２０】
母乳を搾乳するようにユーザにリマインドする通知は、前記サーバから前記コンピューティングデバイスに伝送される、請求項１９に記載のシステム。
【請求項２１】
前記コンピューティングデバイスは、携帯電話番号と関連付けられた携帯電話を備え、前記通知は、ショートメッセージサービス（ＳＭＳ）によって、前記ネットワークを介して前記携帯電話番号に伝送される、請求項２０に記載のシステム。
【請求項２２】
乳房からの母乳の搾乳を測定するための方法であって、
インターフェースと、前記インターフェースに動作可能に結合される作動アセンブリと、感知ユニットとを備える、母乳搾乳装置を提供するステップと、
前記インターフェースと乳房を係合するステップと、
前記作動アセンブリを作動させ、それによって、前記インターフェースに、減圧圧力を前記乳房に対して印加させるステップと、
前記乳房から母乳を搾乳するステップと、
前記感知ユニットを使用して、母乳の搾乳の特性を測定し、それによって、測定デ―タを生成するステップと、
データ接続を介して、前記測定データを前記感知ユニットからコンピューティングデバイスに伝送するステップと、
を含む、方法。
【請求項２３】
前記測定データを前記コンピューティングデバイスの１つまたはそれを上回るデータ記憶内に記憶するステップをさらに含む、請求項２２に記載の方法。
【請求項２４】
前記コンピューティングデバイスのアプリケーションを介して前記測定データを分析し、分析結果を生成するステップをさらに含む、請求項２２に記載の方法。
【請求項２５】
前記コンピューティングデバイスを介して前記分析結果をユーザに表示するステップをさらに含む、請求項２４に記載の方法。
【請求項２６】
前記分析結果は、グラフ、チャート、または表に表示される、請求項２５に記載の方法。
【請求項２７】
乳房からの母乳の搾乳を制御するための方法であって、

インターフェースと、前記インターフェースに動作可能に結合される作動アセンブリとを備える、母乳搾乳装置を提供するステップと、
前記インターフェースと乳房を係合するステップと、
データ接続を介して、制御信号をコンピューティングデバイスから受信するステップと、
前記制御信号に基づいて、前記作動アセンブリを作動させ、それによって、前記インターフェースに、減圧圧力を前記乳房に対して印加させるステップと、
前記乳房から母乳を搾乳するステップと、
を含む、方法。
【請求項２８】
乳房からの母乳の搾乳のための装置であって、
乳房に係合するように構成されるインターフェースと、
前記インターフェースに動作可能に結合される作動アセンブリであって、前記作動アセンブリの作動は、前記インターフェースに、減圧圧力を前記乳房に対して印加させ、そこから母乳を搾乳させる、作動アセンブリと、
ネットワークを介してサーバと通信する通信モジュールと、
を備える、装置。
【請求項２９】
前記インターフェースは、前記乳房に対して流体的にシールするように構成される、請求項２８に記載の装置。
【請求項３０】
前記ネットワークは、インターネットネットワークを備える、請求項２８に記載の装置。
【請求項３１】
母乳の搾乳の１つまたはそれを上回る特性を示す測定データを生成するように構成される、感知ユニットをさらに備える、請求項２８に記載の装置。
【請求項３２】
前記測定データは、前記ネットワークを介して前記サーバに伝送される、請求項３１に記載の装置。
【請求項３３】
前記サーバは、前記測定データを分析するように構成される、アプリケーションを備える、請求項３２に記載の装置。
【請求項３４】
前記測定データを分析し、それによって、分析結果を生成するように構成される、処理ユニットをさらに備える、請求項３１に記載の装置。
【請求項３５】
前記分析結果をユーザに表示するように構成される、ディスプレイユニットをさらに備える、請求項３４に記載の装置。
【請求項３６】
前記分析結果は、前記ネットワークを介して前記サーバに伝送される、請求項３４に記載の装置。
【請求項３７】
前記分析結果は、前記サーバと通信するコンピューティングデバイス上に表示される、請求項３６に記載の装置。
【請求項３８】
前記作動アセンブリの少なくとも１つの機能性は、前記ネットワークを介して、前記サーバ上のアプリケーションによって制御される、請求項２８に記載の装置。
【請求項３９】
前記機能性は、前記作動アセンブリの電力、前記作動アセンブリによって印加される減圧圧力、および前記作動アセンブリの１分あたりのサイクルのうちの１つまたはそれを上

回るものを含む、請求項３８に記載の装置。
【請求項４０】
母乳を搾乳するようにユーザにリマインドする通知は、前記ネットワークを介して電子メールアドレスに伝送される、請求項２８に記載の装置。
【請求項４１】
母乳を搾乳するようにユーザにリマインドする通知は、ショートメッセージサービス（ＳＭＳ）によって、前記ネットワークを介して携帯電話番号に伝送される、請求項２８に記載の装置。
【請求項４２】
前記通知は、ＳＭＳによって、前記サーバから前記携帯電話番号と関連付けられたスマートフォンに伝送される、請求項４１に記載の装置。
【請求項４３】
母乳を搾乳するようにユーザにリマインドする通知は、前記ネットワークを介して前記通信モジュールに伝送される、請求項２８に記載の装置。
【請求項４４】
ファームウェア更新が、前記ネットワークを介して前記通信モジュールに伝送される、請求項２８に記載の装置。
【請求項４５】
乳房からの母乳の搾乳を測定するための方法であって、
インターフェースと、前記インターフェースに動作可能に結合される作動アセンブリと、感知ユニットとを備える、母乳搾乳装置を提供するステップと、
前記インターフェースと乳房を係合するステップと、
前記作動アセンブリを作動させ、それによって、前記インターフェースに、減圧圧力を前記乳房に対して印加させるステップと、
前記乳房から母乳を搾乳するステップと、
前記感知ユニットを使用して、母乳の搾乳の特性を測定し、それによって、測定データを生成するステップと、
ネットワークを介して前記測定データをサーバに伝送するステップと、
を含む、方法。
【請求項４６】
前記サーバは、分散型コンピューティングサーバである、請求項４５に記載の方法。
【請求項４７】
前記母乳の搾乳の特性は、前記母乳が前記インターフェースから前記インターフェースと流体連通する収集リザーバに移動するにつれて、前記感知ユニットによって測定される、請求項４５に記載の方法。
【請求項４８】
前記測定データを前記サーバと関連付けられた１つまたはそれを上回るデータ記憶内に記憶するステップをさらに含む、請求項４５に記載の方法。
【請求項４９】
前記サーバ上のアプリケーションを介して前記測定データを分析し、分析結果を生成するステップをさらに含む、請求項４５に記載の方法。
【請求項５０】
前記分析結果を前記サーバからコンピューティングデバイスに伝送するステップと、
前記コンピューティングデバイスを介して前記分析結果をユーザに表示するステップと、
をさらに含む、請求項４９に記載の方法。
【請求項５１】
乳房からの母乳の搾乳を遠隔制御するための方法であって、
インターフェースと、前記インターフェースに動作可能に結合される作動アセンブリとを備える、母乳搾乳装置を提供するステップと、
前記インターフェースと乳房を係合するステップと、

ネットワークを介して、制御信号をサーバから受信するステップと、
前記制御信号に基づいて、前記作動アセンブリを作動させ、それによって、前記インターフェースに、減圧圧力を前記乳房に対して印加させるステップと、
前記乳房から母乳を搾乳するステップと、
を含む、方法。
【請求項５２】
乳房からの流体の搾乳を測定するための装置であって、
乳房に係合するように構成されるインターフェースと、
前記インターフェースに動作可能に結合されるであって、前記作動アセンブリの作動は、前記インターフェースに、減圧圧力を前記乳房に対して印加させ、そこから流体を搾乳させる、作動アセンブリと、
前記乳房から搾乳された流体の体積を示す測定データを生成するように構成される、感知ユニットと、
を備える、装置。
【請求項５３】
前記インターフェースは、前記乳房に対して流体的にシールするように構成される、請求項５２に記載の装置。
【請求項５４】
前記流体は、母乳および初母乳のうちの１つまたはそれを上回るものである、請求項５２に記載の装置。
【請求項５５】
前記測定データは、前記搾乳された流体の時間の単位あたりの体積を示す、請求項５２に記載の装置。
【請求項５６】
前記作動アセンブリは、ポンプを備え、前記測定データは、前記搾乳された流体の前記ポンプのストロークあたりの体積を示す、請求項５２に記載の装置。
【請求項５７】
前記作動アセンブリは、ポンプを備え、前記測定データは、前記搾乳された流体のポンプ電力サイクルあたりの体積を示す、請求項５２に記載の装置。
【請求項５８】
前記インターフェースは、前記搾乳された流体の通過を可能にする弁を備え、前記感知ユニットは、前記弁の運動を測定する加速度計を備える、請求項５２に記載の装置。
【請求項５９】
前記測定データは、前記弁の運動に基づいて生成される、請求項５８に記載の装置。
【請求項６０】
第２の乳房に係合するように構成される、第２のインターフェースをさらに備え、前記作動アセンブリの作動は、減圧圧力を前記乳房および前記第２の乳房に対して交互に印加させ、そこから交互に流体を搾乳させ、前記第２のインターフェースは、前記第２の乳房から搾乳された流体の通過を可能にする第２の弁を備え、前記感知ユニットは、前記第２の弁の運動を測定する第２の加速度計を備える、請求項５８に記載の装置。
【請求項６１】
前記感知ユニットは、前記加速度計および前記第２の加速度計の両方によって検出された運動に基づいて、ユーザ運動を判定する、請求項６０に記載の装置。
【請求項６２】
前記ユーザ運動は、前記第１の弁または第２の弁のうちの少なくとも１つの運動を判定するとき、前記加速度計または前記第２の加速度計のうちの少なくとも１つによって検出される運動から減算される、請求項６１に記載の装置。
【請求項６３】
前記インターフェースは、前記搾乳された流体の通過を可能にする弁を備え、前記感知ユニットは、前記インターフェースに結合される第１の加速度計と、前記弁に結合される

第２の加速度計とを備える、請求項５２に記載の装置。
【請求項６４】
前記第１の加速度計は、前記インターフェースの運動を測定するように構成される、請求項６３に記載の装置。
【請求項６５】
前記第２の加速度計は、前記弁の運動を測定するように構成される、請求項６３に記載の装置。
【請求項６６】
前記測定データは、前記インターフェースの運動および前記弁の運動に基づいて生成される、請求項６３に記載の装置。
【請求項６７】
前記感知ユニットは、前記第１の加速度計によって検出される運動に基づいて、背景運動を判定する、請求項６３に記載の装置。
【請求項６８】
前記背景運動は、前記弁の運動を判定するとき、前記第２の加速度計によって検出される運動から減算される、請求項６７に記載の装置。
【請求項６９】
前記インターフェースは、前記搾乳された流体を収集するように構成されるリザーバに結合され、前記感知ユニットは、前記リザーバに結合され、前記リザーバは、前記感知ユニットと通信する処理ユニットを備え、前記処理ユニットは、前記感知ユニットによって生成される測定データを受信するように構成される、請求項５２に記載の装置。
【請求項７０】
前記処理ユニットは、データ接続を介して前記測定データをコンピューティングデバイスに伝送するように構成される、通信モジュールを備える、請求項６９に記載の装置。
【請求項７１】
前記処理ユニットは、ネットワークを介して前記測定データをサーバに伝送するように構成される、通信モジュールを備える、請求項６９に記載の装置。
【請求項７２】
前記感知ユニットは、ビーム遮断センサの１つまたはそれを上回るセンサ構成要素の近傍の前記搾乳された流体の通過を検出するように構成される、ビーム遮断センサを備える、請求項５２に記載の装置。
【請求項７３】
前記測定データは、前記搾乳された流体が前記センサ構成要素間を通過する時間の長さに基づいて生成される、請求項７２に記載の装置。
【請求項７４】
前記インターフェースは、前記搾乳された流体の通過を可能にする弁を備え、前記感知ユニットは、前記弁を通して通過する前記搾乳された流体の液滴を計数するように構成される、電荷結合素子（ＣＣＤ）を備える、請求項５２に記載の装置。
【請求項７５】
前記測定データは、前記液滴の１つまたはそれを上回るＣＣＤ画像に基づいて生成される、請求項７４に記載の装置。
【請求項７６】
前記インターフェースは、前記搾乳された流体の通過を可能にする管を備え、前記感知ユニットは、前記管内に含まれる前記搾乳された流体を感知するように構成される、容量センサを備える、請求項５２に記載の装置。
【請求項７７】
前記インターフェースは、前記搾乳された流体を収集するように構成されるリザーバに結合され、前記感知ユニットは、前記リザーバ内に含まれる前記搾乳された流体の体積を測定するように構成される、容量センサを備える、請求項５２に記載の装置。
【請求項７８】

前記感知ユニットは、前記搾乳された流体の体積を測定するように構成される、歪みゲージを備える、請求項５２に記載の装置。
【請求項７９】
前記インターフェースは、前記搾乳された流体の通過を可能にする弁を備え、前記歪みゲージは、前記弁に結合され、前記弁の経時的変位を判定するように構成される、請求項７８に記載の装置。
【請求項８０】
前記インターフェースは、前記搾乳された流体を収集するように構成されるリザーバに結合され、前記歪みゲージは、前記リザーバに結合され、前記リザーバ内に含まれる前記搾乳された流体の体積を測定するように構成される、請求項７８に記載の装置。
【請求項８１】
前記リザーバは、蛇腹要素を有する底部内部表面を備え、前記蛇腹要素は、前記搾乳された流体によって前記底部内部表面上にかかる負荷の前記底部内部表面による吸収を最小限にするように構成される、請求項８０に記載の装置。
【請求項８２】
前記感知ユニットは、前記インターフェースに結合され、前記搾乳された流体の１つまたはそれを上回る画像を捕捉するように構成される、カメラを備える、請求項５２に記載の装置。
【請求項８３】
前記１つまたはそれを上回る画像を分析し、前記搾乳された流体の体積を判定するように構成される、処理ユニットをさらに備える、請求項８２に記載の装置。
【請求項８４】
前記１つまたはそれを上回る画像は、前記１つまたはそれを上回る画像を分析し、前記搾乳された流体の体積を判定するように構成されるコンピューティングデバイスに伝送される、請求項８２に記載の装置。
【請求項８５】
前記コンピューティングデバイスは、スマートフォンである、請求項８４に記載の装置。
【請求項８６】
前記カメラは、モバイル装置上に据え付けられる、請求項８２に記載の装置。
【請求項８７】
処理ユニットと、
前記作動アセンブリに動作可能に結合され、その少なくとも１つの機能性を制御する、制御ユニットと、
をさらに備え、前記測定データの少なくともサブセットは、フィードバックとして、前記処理ユニットおよび前記制御ユニットのうちの少なくとも１つに伝送される、請求項５２に記載の装置。
【請求項８８】
前記作動アセンブリは、ポンプを備え、前記フィードバックは、前記ポンプの減圧ストロークを調節し、最適流体搾乳を維持するために使用される、請求項８７に記載の装置。
【請求項８９】
前記作動アセンブリは、ポンプを備え、前記フィードバックは、前記ポンプの１分あたりのサイクルを調節し、最適流体搾乳を維持するために使用される、請求項８７に記載の装置。
【請求項９０】
乳房から搾乳された流体の体積を測定するための方法であって、
インターフェースと、前記インターフェースに動作可能に結合される作動アセンブリと、感知ユニットとを備える、乳房流体搾乳装置を提供するステップと、
前記インターフェースと乳房を係合するステップと、
前記作動アセンブリを作動させ、それによって、前記インターフェースに、減圧圧力を

前記乳房に対して印加させるステップと、
前記乳房から流体を搾乳するステップと、
前記感知ユニットを介して、前記搾乳された流体の体積を示す測定データを生成するステップと、
を含む、方法。
【請求項９１】
前記測定データの少なくともサブセットに基づいて、前記作動アセンブリの作動パラメータを変更するステップと、
前記変更された作動パラメータに基づいて、前記作動アセンブリを作動させるステップと、
をさらに含む、請求項９０に記載の方法。
【発明の詳細な説明】
【技術分野】
【０００１】
（相互参照）
本出願は、２０１４年２月７日に出願された米国仮特許出願番号第６１／９３７，０２７号［代理人書類番号４４９３６－７０４．１０１］の非仮出願であって、この仮出願の利益を主張しており、この仮出願の全体の内容は本明細書中に参考として援用される。
【０００２】
本願の主題は、２０１４年３月２０日に出願された米国特許出願第１４／２２１，１１３号［代理人書類番号４４９３６－７０３．２０１］、２０１４年７月７日に出願された米国仮特許出願番号第６２／０２１，６０１号［代理人書類番号４４９３６－７０５．１０１］、２０１４年７月７日に出願された米国仮特許出願番号第６２／０２１，５９７号［代理人書類番号４４９３６－７０６．１０１］、２０１４年７月２３日に出願された米国仮特許出願番号第６２／０２８，２１９号［代理人書類番号４４９３６－７０８．１０１］、および２０１４年９月１９日に出願された米国仮特許出願番号第６２／０５２，９４１号［代理人書類番号４４９３６－７０９．１０１］に関連し、これら出願の全体の内容は、参考として本明細書中に援用される。
【０００３】
（発明の背景）
（１．発明の分野）
本発明は、概して、医療デバイスおよび方法に関し、より具体的には、ヒトの母乳の搾乳および採取のためのデバイスおよび方法に関する。
【背景技術】
【０００４】
乳房ポンプは、母親が自らの子供と離れていても授乳を続けられるように母乳を採取するため一般に用いられている。今のところ、乳房ポンプには、２種類の基本型、すなわち、小型ではあるが非効率的で使用するために疲れを生じる手動デバイスと、効率的ではあるが大きくかさばる電動デバイスとがある。このため、母乳の搾乳および採取のために小型で非常に効率的な改良された乳房ポンプを提供することが望ましいであろう。母乳産出量の定量化、母乳特性評価、およびモバイルデバイスとの通信等の追加的な特徴は、ユーザの利便性を高める上でさらに望ましい。これらの目的の少なくともいくつかは、以下に開示されるデバイスおよび方法によって満足される。
【０００５】
（２．背景技術の記載）
以下の米国特許は、ヒトの母乳の搾乳および採取に関する。米国特許第６，６７３，０３６号、第６，７４９，５８２号、第６，８４０，９１８号、第６，８８７，２１０号、第７，８７５，０００号、第８，１１８，７７２号、および第８，２１６，１７９号。
【先行技術文献】
【特許文献】

【０００６】
【特許文献１】米国特許第６，６７３，０３６号明細書
【特許文献２】米国特許第６，７４９，５８２号明細書
【特許文献３】米国特許第６，８４０，９１８号明細書
【特許文献４】米国特許第６，８８７，２１０号明細書
【特許文献５】米国特許第７，８７５，０００号明細書
【特許文献６】米国特許第８，１１８，７７２号明細書
【特許文献７】米国特許第８，２１６，１７９号明細書
【発明の概要】
【０００７】
（発明の要旨）
本発明は、概して、医療デバイスおよび方法に関し、より具体的には、ヒトの母乳の搾乳ならびに採取のためのデバイスおよび方法に関する。
【０００８】
本発明の第１の側面では、乳房からの母乳の搾乳のためのシステムが、提供される。本システムは、乳房に係合するように構成されるインターフェースと、インターフェースに動作可能に結合される作動アセンブリとを有する、搾乳装置を備えてもよい。作動アセンブリの作動は、インターフェースに、減圧圧力を乳房に対して印加させ、乳房から母乳を搾乳させることができる。本システムはさらに、データ接続を介して搾乳装置と通信するように構成される、コンピューティングデバイスを備える。
【０００９】
多くの実施形態では、乳房は、ヒト乳房である。インターフェースは、乳房に対して流体的にシールするように構成されることができる。
【００１０】
多くの実施形態では、データ接続は、無線通信、近距離通信、またはＵＳＢケーブルを利用し、搾乳装置の少なくとも一部とコンピューティングデバイスとの間でデータを伝送する。コンピューティングデバイスは、スマートフォン、タブレット、またはパーソナルコンピュータであってもよい。
【００１１】
多くの実施形態では、搾乳装置はさらに、母乳の搾乳の１つまたはそれを上回る特性を示す測定データを生成するように構成される、感知ユニットを含む。測定データは、データ接続を介してコンピューティングデバイスに伝送されることができる。コンピューティングデバイスは、測定データを分析するように構成される、アプリケーションを含むことができる。コンピューティングデバイスは、測定データをサーバに伝送することができる。搾乳装置はさらに、測定データを分析し、分析結果を生成するように構成される、処理ユニットと、分析結果をユーザに表示するように構成される、ディスプレイユニットとを含むことができる。分析結果は、グラフ、チャート、または表に表示されることができる。分析結果は、データ接続を介してコンピューティングデバイスに伝送されることができ、コンピューティングデバイスは、分析結果をユーザに表示することができる。
【００１２】
多くの実施形態では、コンピューティングデバイスは、データ接続を介して搾乳装置の少なくとも１つの機能性を制御することができる。機能性は、搾乳装置の電力、搾乳装置によって印加される減圧圧力、または搾乳装置の１分あたりのサイクルのうちの１つまたはそれを上回るものを備えることができる。
【００１３】
多くの実施形態では、母乳を搾乳するようにユーザにリマインドする通知は、データ接続を介してコンピューティングデバイスに伝送されてもよい。通知は、データ接続を介して、搾乳装置の少なくとも一部に伝送されることができる。ファームウェア更新が、データ接続を介して、搾乳装置の少なくとも一部に伝送されることができる。
【００１４】

多くの実施形態では、コンピューティングデバイスは、ネットワークを介してサーバと通信する通信モジュールを備えることができる。母乳を搾乳するようにユーザにリマインドする通知は、サーバからコンピューティングデバイスに伝送されてもよい。コンピューティングデバイスは、携帯電話番号と関連付けられた携帯電話を備えてもよく、通知は、ショートメッセージサービス（ＳＭＳ）によって、ネットワークを介して携帯電話番号に伝送されてもよい。

【００１５】

本発明の別の側面では、乳房からの母乳の搾乳を測定するための方法が、提供される。本方法は、インターフェースと、インターフェースに動作可能に結合される作動アセンブリと、感知ユニットとを有する、母乳搾乳装置を提供するステップを含む。本方法はさらに、インターフェースと乳房を係合するステップと、作動アセンブリを作動させ、それによって、インターフェースに、減圧圧力を乳房に対して印加させるステップとを含む。本方法はさらに、乳房から母乳を搾乳するステップを含む。本方法はさらに、測定データを生成するために、感知ユニットを使用して、母乳の搾乳の特性を測定するステップを含んでもよい。測定データは、データ接続を介して、感知ユニットからコンピューティングデバイスに伝送されてもよい。

【００１６】

多くの実施形態では、測定データは、コンピューティングデバイスの１つまたはそれを上回るデータ記憶内に記憶されてもよい。測定データは、コンピューティングデバイスのアプリケーションを介して分析され、分析結果を生成することができ、分析結果は、コンピューティングデバイスを介してユーザに表示されることができる。分析結果は、グラフ、チャート、表、または任意の他の視覚的、聴覚的、もしくは触知的インジケータに表示されることができる。

【００１７】

本発明の別の側面では、乳房からの母乳の搾乳を制御するための方法が、提供される。本方法は、インターフェースと、インターフェースに動作可能に結合される作動アセンブリとを有する、母乳搾乳装置を提供するステップを含む。本方法はさらに、インターフェースと乳房を係合するステップを含む。制御信号は、データ接続を介して、コンピューティングデバイスから受信されてもよい。本方法はさらに、制御信号に基づいて、作動アセンブリを作動させ、インターフェースに、減圧圧力を乳房に対して印加させるステップを含んでもよい。本方法はさらに、乳房から母乳を搾乳するステップを含む。

【００１８】

本発明の別の側面では、乳房からの母乳の搾乳のための装置が、提供される。本装置は、乳房に係合するように構成されるインターフェースと、インターフェースに動作可能に結合される作動アセンブリとを備える。作動アセンブリの作動は、インターフェースに、減圧圧力を乳房に対して印加させ、乳房から母乳を搾乳させることができる。本装置はまた、ネットワークを介してサーバと通信する通信モジュールを含むことができる。

【００１９】

多くの実施形態では、ネットワークは、インターネットネットワークを含む。本装置はさらに、母乳の搾乳の１つまたはそれを上回る特性を示す測定データを生成するように構成される、感知ユニットを含むことができ、測定データは、ネットワークを介してサーバに伝送されることができる。サーバは、測定データを分析するように構成される、アプリケーションを含むことができる。

【００２０】

多くの実施形態では、本装置はさらに、測定データを分析し、分析結果を生成するように構成される、処理ユニットと、分析結果をユーザに表示するように構成される、ディスプレイユニットとを含む。分析結果は、ネットワークを介してサーバに伝送されることができる。分析結果は、サーバと通信するコンピューティングデバイス上に表示されることができる。

【００２１】

多くの実施形態では、作動アセンブリの少なくとも１つの機能性は、ネットワークを介して、サーバ上のアプリケーションによって制御される。機能性は、作動アセンブリの電力、作動アセンブリによって印加される減圧圧力、または作動アセンブリの１分あたりのサイクルを含むことができる。

【００２２】

多くの実施形態では、母乳を搾乳するようにユーザにリマインドする通知は、ネットワークを介して電子メールアドレスに伝送されてもよい。母乳を搾乳するようにユーザにリマインドする通知は、サーバから携帯電話番号と関連付けられたスマートフォンへのＳＭＳ等、ショートメッセージサービス（ＳＭＳ）によって、ネットワークを介して携帯電話番号に伝送されることができる。母乳を搾乳するようにユーザにリマインドする通知は、ネットワークを介して通信モジュールに伝送されることができる。ファームウェア更新は、ネットワークを介して通信モジュールに伝送されることができる。

【００２３】

別の側面では、本発明は、乳房からの母乳の搾乳を測定するための方法を提供する。本方法は、インターフェースと、インターフェースに動作可能に結合される作動アセンブリと、感知ユニットとを含む、母乳搾乳装置を提供するステップを含む。インターフェースは、乳房と係合されてもよい。作動アセンブリは、作動され、インターフェースに、減圧圧力を乳房に対して印加させることができる。母乳は、乳房から搾乳される。感知ユニットは、母乳の搾乳の特性を測定し、測定データを生成するために使用されてもよい。測定データは、ネットワークを介してサーバに伝送されてもよい。

【００２４】

多くの実施形態では、サーバは、分散型コンピューティングサーバである。母乳の搾乳の特性は、母乳がインターフェースからインターフェースと流体連通する収集リザーバに移動するにつれて、感知ユニットによって測定されることができる。測定データは、サーバと関連付けられた１つまたはそれを上回るデータ記憶内に記憶されることができる。測定データは、サーバ上のアプリケーションを介して分析され、分析結果を生成することができる。分析結果は、サーバからコンピューティングデバイスに伝送され、コンピューティングデバイスを介してユーザに表示されることができる。

【００２５】

本発明の別の側面では、乳房からの母乳の搾乳を遠隔制御するための方法が、提供される。本方法は、インターフェースと、インターフェースに動作可能に結合される作動アセンブリとを備える、母乳搾乳装置を提供するステップを含む。インターフェースは、乳房と係合されてもよい。制御信号が、ネットワークを介してサーバから受信されることができる。作動アセンブリは、制御信号に基づいて作動され、インターフェースに、減圧圧力を乳房に対して印加させてもよい。母乳は、乳房から搾乳されてもよい。

【００２６】

本発明の別の側面では、乳房からの流体の搾乳を測定するための装置が、提供される。本装置は、乳房に係合するように構成されるインターフェースと、インターフェースに動作可能に結合される作動アセンブリとを含む。作動アセンブリの作動は、インターフェースに、減圧圧力を乳房に対して印加させ、乳房から母乳を搾乳させる。本装置は、乳房から搾乳された流体の体積を示す測定データを生成するように構成される、感知ユニットを含む。

【００２７】

多くの実施形態では、乳房は、ヒト乳房である。インターフェースは、乳房に対して流体的にシールするように構成されることができる。流体は、母乳または初母乳であることができる。測定データは、搾乳された流体の単位時間あたりの体積、ポンプのストロークあたりの体積、またはポンプ電力サイクルあたりの体積を示すことができる。

【００２８】

多くの実施形態では、インターフェースは、搾乳された流体の通過を可能にする弁を含み、感知ユニットは、弁の運動を測定する加速度計を備える。測定データは、弁の運動に

基づいて生成されることができる。

【００２９】

多くの実施形態では、本装置はさらに、第２の乳房に係合するように構成される、第２のインターフェースを含むことができる。作動アセンブリの作動は、減圧圧力を乳房および第２の乳房に対して交互に印加させ、交互に乳房から流体を搾乳させてもよい。第２のインターフェースは、第２の乳房から搾乳された流体の通過を可能にする第２の弁を含むことができ、感知ユニットは、第２の弁の位置を測定する第２の加速度計を含むことができる。感知ユニットは、加速度計および第２の加速度計の両方によって検出された運動に基づいて、ユーザ運動を判定することができる。ユーザ運動は、第１の弁または第２の弁のうちの少なくとも１つの位置を判定するとき、加速度計または第２の加速度計のうちの少なくとも１つによって検出される運動から減算されることができる。

【００３０】

多くの実施形態では、インターフェースは、インターフェース筐体と、搾乳された流体の通過を可能にする弁とを備えてもよい。感知ユニットは、インターフェース筐体に結合される第１の加速度計と、弁に結合される第２の加速度計とを備えてもよい。第１の加速度計は、インターフェース筐体の位置を測定するように構成されてもよい。第２の加速度計は、弁の位置を測定するように構成されてもよい。測定データは、インターフェース筐体の位置および弁の位置に基づいて、生成されてもよい。感知ユニットは、第１の加速度計によって検出される運動に基づいて、背景運動を判定することができる。背景運動は、弁の位置を判定するとき、第２の加速度計によって検出される運動から減算されてもよい。

【００３１】

多くの実施形態では、インターフェースは、搾乳された流体を収集するように構成されるリザーバに結合されてもよい。感知ユニットは、リザーバに結合されてもよい。リザーバは、感知ユニットと通信する処理ユニットを備えてもよく、処理ユニットは、感知ユニットによって生成される測定データを受信するように構成されてもよい。処理ユニットはさらに、データ接続を介して測定データをコンピューティングデバイスに伝送するように構成される、通信モジュールを備えてもよい。処理ユニットの通信モジュールは、ネットワークを介して測定データをサーバに伝送するように構成されてもよい。

【００３２】

多くの実施形態では、感知ユニットは、ビーム遮断センサの１つまたはそれを上回るセンサ構成要素の近傍の搾乳された流体の通過を検出するように構成される、ビーム遮断センサを含む。測定データは、搾乳された流体がセンサ構成要素間を通過する時間の長さに基づいて生成されることができる。

【００３３】

多くの実施形態では、インターフェースは、搾乳された流体の通過を可能にする弁を含み、感知ユニットは、弁を通して通過する搾乳された流体の液滴を計数するように構成される、電荷結合素子（ＣＣＤ）を含む。測定データは、液滴の１つまたはそれを上回るＣＣＤ画像に基づいて生成されることができる。

【００３４】

多くの実施形態では、インターフェースは、搾乳された流体の通過を可能にする管を含み、感知ユニットは、管内に含まれる搾乳された流体を感知するように構成される、容量センサを含む。インターフェースは、搾乳された流体を収集するように構成されるリザーバに結合されることができ、感知ユニットは、リザーバ内に含まれる搾乳された流体の体積を測定するように構成される、容量センサを含むことができる。

【００３５】

多くの実施形態では、感知ユニットは、搾乳された流体の体積を測定するように構成される、歪みゲージを含む。インターフェースは、搾乳された流体の通過を可能にする弁を含むことができ、歪みゲージは、弁に結合され、弁の経時的変位を判定するように構成されることができる。インターフェースは、搾乳された流体を収集するように構成されるリ

ザーバに結合されることができ、歪みゲージは、リザーバに結合され、リザーバ内に含まれる搾乳された流体の体積を測定するように構成されることができる。リザーバは、蛇腹要素を有する底部内部表面を備えてもよい。蛇腹要素は、搾乳された流体によって底部内部表面にかかる負荷の底部内部表面による吸収を最小限にするように構成されることができる。

【００３６】

多くの実施形態では、感知ユニットは、インターフェースに結合され、搾乳された流体の１つまたはそれを上回る画像を捕捉するように構成される、カメラを含む。本装置はさらに、１つまたはそれを上回る画像を分析し、搾乳された流体の体積または搾乳された流体の他の特性を判定するように構成される、処理ユニットを含むことができる。１つまたはそれを上回る画像は、１つまたはそれを上回る画像を分析し、搾乳された流体の体積を判定するように構成されるコンピューティングデバイスに伝送されることができる。コンピューティングデバイスは、スマートフォンであることができる。カメラは、モバイルデバイス上に据え付けられることができる。

【００３７】

多くの実施形態では、本装置はさらに、処理ユニットと、作動アセンブリに動作可能に結合され、作動アセンブリの少なくとも１つの機能性を制御する、制御ユニットとを備える。測定データの少なくともサブセットは、フィードバックとして、処理ユニットおよび制御ユニットのうちの少なくとも１つに伝送されてもよい。作動アセンブリは、ポンプを含むことができ、フィードバックは、ポンプの減圧ストロークまたはポンプの１分あたりのサイクルを調節し、最適流体搾乳を維持するために使用されることができる。

【００３８】

本発明の別の側面では、乳房から搾乳された流体の体積を測定するための方法が、提供される。本方法は、インターフェースと、インターフェースに動作可能に結合される作動アセンブリと、感知ユニットとを含む、乳房流体搾乳装置を提供するステップを含む。インターフェースは、乳房と係合される。作動アセンブリは、作動され、インターフェースに、減圧圧力を乳房に対して印加させる。流体は、乳房から搾乳される。搾乳された流体の体積を示す測定データは、感知ユニットを介して生成される。

【００３９】

多くの実施形態では、本方法はさらに、測定データの少なくともサブセットに基づいて、作動アセンブリの作動パラメータを変更するステップを含む。作動アセンブリは、変更された作動パラメータに基づいて作動される。

【００４０】

本発明の他の目的および特徴は、明細書、請求項、および添付の図の精査によって明白となる。

【００４１】

（参照による引用）

本明細書に記載される全ての刊行物、特許、および特許出願は、各個々の刊行物、特許、または特許出願が、具体的かつ個々に、参照することによって組み込まれることが示される場合と同程度まで、参照することによって本明細書に組み込まれる。

【００４２】

本発明の新規の特徴は、具体性をもって添付の請求項に示される。本発明の特徴および利点のより深い理解は、本発明の原理が活用された例証的実施形態を示す以下の詳細な記述および付随の図面の参照によって得られ得る。

【図面の簡単な説明】

【００４３】

【図１】図１は、実施形態による、ポンプデバイスの斜視図である。

【図２】図２は、実施形態による、水圧ポンプデバイスの斜視図である。

【図３】図３は、実施形態による、水圧ポンプデバイスの断面図である。

【図４】図４は、実施形態による、駆動機構に結合される作動アセンブリを図示する。

【図５】図５Ａ－５Ｂは、実施形態による、コントローラに結合される作動アセンブリを図示する。
【図６】図６は、実施形態による、乳房インターフェースの断面図である。
【図７】図７は、実施形態による、別の乳房インターフェースの断面図である。
【図８】図８Ａは、実施形態による、開位置にある、可撓性膜内に統合される弁の断面図である。図８Ｂは、実施形態による、閉位置にある、可撓性膜内に統合される弁の断面図である。
【図９】図９は、実施形態による、機械的変形可能部材を伴う乳房インターフェースの断面図である。
【図１０】図１０は、実施形態による、機械的変形可能部材のための機械的駆動装置の断面図である。
【図１１Ａ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｂ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｃ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｄ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｅ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｆ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｇ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｈ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｉ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｊ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｋ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｌ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｍ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｎ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｏ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｐ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１１Ｑ】図１１Ａ－１１Ｑは、流体を検出するためのセンサの例示的実施形態を図示する。
【図１２】図１２は、実施形態による、コントローラおよびモバイルデバイスを図示する。
【図１３】図１３は、実施形態による、コントローラとモバイルデバイスとの間の短距離通信を図示する。
【図１４】図１４は、実施形態による、コンピュ―ティングデバイスおよびサ―バと通信

するポンプデバイスの概略図である。
【図１５】図１５は、実施形態による、市販のデバイスと比較した例示的ポンプデバイスのポンプの性能を図示するグラフである。
【図１６】図１６は、実施形態による、市販のデバイスと比較した例示的ポンプデバイスのポンプ効率を図示するグラフである。
【図１７】図１７は、母乳の搾乳のためのシステムの概略図を図示する。
【図１８】図１８は、母乳の搾乳のためのシステムの別の例示的実施形態を図示する。
【図１９】図１９Ａ－１９Ｃは、コンピューティングデバイス上の例示的ディスプレイを図示する。
【図２０】図２０Ａ－２０Ｂは、母乳搾乳システム内の例示的ディスプレイを図示する。
【図２１】図２１は、母乳搾乳デバイスを制御するためのフィードバック制御ループの使用を図示する。
【図２２】図２２は、二重搾乳システムを図示する。
【発明を実施するための形態】
【００４４】
（発明の詳細な説明）
開示されたシステム、デバイス、および方法の具体的な実施形態を、ここで、図面を参照しつつ以下に記述する。いかなる詳細な記述も、任意の特定の構成要素、特徴、またはステップが本発明にとって必須であることを示唆することを意図しない。本発明は、主に、母乳に関するが、母乳の搾乳および採取の本明細書における任意の説明はまた、初母乳等の乳房から搾乳される他のタイプの流体にも適用されることができる。さらに、開示される実施形態は、他の用途、特に、睡眠時無呼吸の治療および／または他の遠隔圧力ニーズ等、圧力差の形成と伝達を含む用途において使用されてもよい。
【００４５】
本発明のシステム、デバイス、および方法は、ヒトの母乳等の母乳の搾乳ならびに採取のための改良されたポンプデバイスを提供する。既存のデバイスと対照的に、本明細書に説明される機構は、より小型かつより効率的な電気ポンプデバイスの開発を可能にし、それによって、利便性および使用の容易性を向上させる。加えて、本明細書に開示される例示的実施形態の少なくともいくつかは、母乳の搾乳の特性を測定するためのセンサを組み込む。得られたデータは、例えば、ポンプ効率を改善し、かつ母乳の搾乳に関連する情報および／または分析をユーザに提供するためのフィードバックとして、使用されることができる。さらに、好適な実施形態では、データは、ポンプデバイスと通信する別のデバイスに伝送され、それによって、母乳の搾乳の制御、表示、および／または分析が、遠隔で行われることを可能にすることができる。
【００４６】
図１は、本発明の例示的実施形態を図示する。ポンプデバイス１００は、（「搾乳装置」としても知られる）は、乳房インターフェース１０５と、管１１０と、管１１０を通して乳房インターフェース１０５に動作可能に結合される、コントローラ１１５（「ペンダントユニット」とも称される場合がある）とを含む。乳房インターフェース１０５は、乳房に係合し、それに対して流体シールを形成するための弾性かつ整合的なフランジ１２０と、採取容器１２５とを含む。コントローラ１１５は、本明細書にさらに詳細に説明されるように、電源およびポンプデバイス１００の駆動機構を格納し、また、ポンプデバイス１００の制御、母乳産出量の定量化、他のデバイスとの通信等、種々の機能のためのハードウェアを含む。管１１０は、機械的なエネルギー入力等の好適なエネルギー入力を、コントローラ１１５から乳房インターフェース１０５までの長い距離にわたって伝達する。乳房インターフェース１０５は、エネルギー入力を乳房に対する減圧圧力に高度に効率的な様式で変換し、採取容器１２５の中への母乳の搾乳をもたらす。デバイス１００はさらに、本明細書にさらに詳細に説明されるように、収集された流体の種々の特性を追跡するように構成される、１つまたはそれを上回るセンサを備えてもよい。電力が、コントローラ１１５もしくは別の電力源への接続を介して、１つまたはそれを上回るセンサに提供さ

れてもよい。１つまたはそれを上回るセンサが、乳房インターフェース１０５もしくは採取容器１２５の１つまたはそれを上回る部分に結合される実施形態では、センサはさらに、センサとコントローラとの間で信号を伝送するように構成される１つまたはそれを上回る通信ラインを介して、コントローラ１１５に結合されてもよい。

【００４７】

水圧（油圧）ポンプデバイス

水圧システムは、必要とされるポンプ力を低減させることができ、したがって、高ポンプ効率を維持しながらポンプデバイスのサイズを低減させることができる。好適な実施形態では、ポンプデバイスは、水圧ポンプシステムを利用して、母乳の搾乳および採取のため、乳房に対する圧力差を発生させることができる。

【００４８】

例示的水圧ポンプデバイスが、図２および３に示される。図２は、管１６５によって乳房インターフェース１６０に流体的に結合された注射器１５５を有する、ポンプデバイス１５０を図示する。注射器１５５は、三方弁１７０を通して管１６５に結合される。乳房インターフェース１６０は、出口ポート１７５を含む。注射器１５５は、管１６５内に含まれる流体１８０を、乳房インターフェース１６０内に格納された可撓性部材に向けて駆動し、乳房からの母乳の搾乳に必要な圧力差を生成する。

【００４９】

図３は、ポンプデバイス２００の別の実施形態を図示する。作動アセンブリ２０５は、アセンブリ筐体２１０と、駆動要素２１５と、シール２２０と、シャフト２２２とを含む。駆動要素２１５は、シャフト２２２を通してコントローラ１１５等のコントローラに動作可能に結合される。管２２５は、流体２３０を含み、作動アセンブリ２０５および乳房インターフェース２３５に流体的に結合される。乳房インターフェース２３５は、インターフェース筐体２４０と、可撓性膜２４５と、リザーバ２５０と、シール要素２５５と、搾乳面積２６０と、排出ポート２６５とから成る。シール要素２５５は、変形可能部分２７０を含む。代替として、可撓性膜２４５は、変形可能部分２７０を有するシール要素２５５を備えてもよく、可撓性膜２４５は、乳房インターフェース２３５の中に係合される乳房に対して流体的にシールすることによって、シール要素として機能するように構成される。排出ポート２６５は、採取容器２７５に結合され、フラップ弁２８０を含む。

【００５０】

作動アセンブリ２０５は、可撓性ラインであり得る、管内２２５に含有まれる流体２３０を変位させる。流体２３０は、乳房インターフェース２３５内のリザーバ２５０を占有し、可撓性膜２４５と結合される。好ましくは、可撓性膜２４５、シール要素２５５、およびインターフェース筐体２４０間の結合は、流体２３０が、リザーバ２５０内に含まれ、搾乳面積２６０の中に浸潤することができないような液密結合である。可撓性膜２４５は、流体２３０からシール要素２５５の変形可能部分２７０に減圧圧力を伝達する。乳房がシール要素２５５によって乳房インターフェース２３５の中に係合され、それと流体的にシールされると、作動要素２１５の変位が、可撓性膜２４５および変形可能部分２７０を通して、乳房に対する実質的な減圧圧力を生成し、その結果、搾乳面積２６０中への母乳の搾乳をもたらす。代替として、可撓性膜２４５は、可撓性膜２４５が、乳房インターフェース２３５の中に係合される乳房に対して流体シールを形成し、減圧圧力を流体２３０から可撓性膜２４５の変形可能部分に伝達するように、変形可能部分２７０を有するシール要素２５５を備えてもよい。搾乳された母乳は、排出ポート２６５を通して採取容器２７５中に排出される。排出ポート２６５は、フラップ弁２８０とともに構成され、搾乳面積２６０内の減圧圧力を維持しながら、母乳の通過をもたらす。採取容器２７５は、瓶またはバッグ等の任意の好適な容器であることができる。多くの実施形態では、採取容器２７５は、可撓性膜２４５に取り外し可能に結合される。採取容器２７５は、直接または延在管類等の任意の好適なデバイスを介して遠隔で、結合されることができる。好ましくは、採取容器は、ポンプデバイス２００の他の構成要素から迅速に分断されることができる（例えば、母乳貯蔵、清浄等のため）。

【００５１】
水圧ポンプデバイスの流体は、非圧縮性流体等、任意の好適な流体であることができる。多くの実施形態では、非圧縮性流体は、水または油等の液体であることができる。多くの実施形態では、流体は、ポンプデバイスによって流体に付与される減圧圧力が、流体の脱ガスをもたらさないような特性を有する流体であることができる。代替として、流体は、空気等の任意の好適なガスであることができる。水圧システムと併用するために好適な任意の液体またはガスが、本明細書に説明される水圧ポンプデバイスのために使用されることができる。

【００５２】
作動機構
当業者に公知の多くの作動機構が、作動アセンブリ２０５のために利用されることができる。作動アセンブリ２０５は、ピストンアセンブリ、ダイアフラムポンプ等のポンプ、または任意の他の好適な作動機構とすることができる。作動アセンブリ２０５の最適な構成は、減圧要件、サイズ、電力、およびポンプデバイス２００のその他の必要性、ならびに粘度、生体適合性、および流体寿命要件等の流体２３０の特性等、多くの要因に依存し得る。

【００５３】
図３は、作動アセンブリ２０５がピストンアセンブリであって、駆動要素２１５がピストンである、例示的実施形態を図示する。作動アセンブリ２０５は、Ｏリング、回転ダイヤフラムシール、またはワイパシール等のシール２２０を含み、流体２３０の望ましくない滲出を防止し、流体２３０の駆動を可能にするようにアセンブリ筐体２１０に対してシールする。

【００５４】
図４は、一対のピストン３０５を含む、作動アセンブリ３００の別の例示的実施形態を図示する。

【００５５】
好適な実施形態では、作動アセンブリは、コントローラ１１５内の駆動機構等、好適な駆動機構によって動力供給される駆動要素を含む。多くの駆動機構が、当業者に公知である。例えば、駆動要素２１５等の駆動要素は、モータによって電気機械的に作動されてもよく、レバー等の好適なユーザ作動式インターフェースによって手動で作動されてもよい。当業者に公知の種々の駆動モードが、使用されることができる。特に、本明細書に記載されるような例示的水圧ポンプデバイスの実装は、水圧システムの低減された力要件により、直接駆動およびソレノイド等の好適な駆動様式の使用を可能にする。

【００５６】
ここで図４の例示的実施形態を参照すると、ピストン３０５は、クランクシャフト３１５へのカップリング３１０を含む。クランクシャフト３１５は、ベルト駆動３２５を通してモータ３２０に動作可能に結合される。クランクシャフト３１５は、両方の乳房に同時に減圧圧力を印加するように一対のピストン３０５を同じストロークタイミングで駆動するが、この特徴は、母乳の産出増大に望ましい。代替として、クランクシャフト３１５は、交互またはオフセットストロークサイクル等の任意の好適なストロークタイミングで一対のピストン３０５を駆動することができる。交互またはオフセットストロークサイクルは、モータ３２０の電力要件を低減させる利点を有し得る。

【００５７】
駆動機構は、局部電池またはＡＣアダプタ等の任意の好適な電源によって給電されることができる。駆動機構は、コントローラ１１５内に配置された内蔵電子装置等のハードウェアによって制御されることができる。

【００５８】
図２２は、交互ポンプシステム２２００の別の実施形態を図示する。システム２２００は、標的組織、ここでは、乳房２２２０に一致するようなサイズおよび形状にされるインターフェース２２１２を伴う、二重搾乳デバイスを含む。リザーバ２２１４は、搾乳デバ

イスに螺合または別様に結合される。水圧ライン２２１０は、各搾乳デバイスを、ピストンチャンバ内の油等の非圧縮性流体と、作動可能ピストン２２０６とを有する、水圧ピストンアセンブリ２２０４に流体的に結合する。一方の水圧ライン２２１０は、水圧ピストンの高圧側２２０８に結合され、他方の水圧ラインは、ピストンの低圧側２２０８に結合される。モータ２２０２が、ピストン２２０６を作動させる。したがって、動作時、ピストンが作動されるにつれて、高圧側は、搾乳デバイスの一方内には、より高い圧力を、他方の搾乳デバイス内には、低い圧力を生成する。より低い圧力の搾乳デバイスは、減圧をもたらし、母乳の搾乳を生じさせる一方、高圧側は、母乳を搾乳しない。次いで、ピストンが、そのストロークの端部に到達し、反対方向に往復運動するにつれて、高圧側および低圧側は、反転され、それによって、反対側に母乳の搾乳を生じさせ、元の側には搾乳を生じさせない。本プロセスは、母乳が、交互方式において収集されることを可能にする。本システムにおける搾乳デバイス、リザーバは、本開示のいずれかに開示される構成要素のいずれかであってもよい。

【００５９】

図５Ａ－５Ｂは、取り外し可能カップリング３５５を含む、作動アセンブリ３５０の例示的実施形態を図示する。図５Ａは、取り外し可能カップリング３５５を介して結合される、作動アセンブリ３５０およびコントローラ３６０の等角図である。図５Ｂは、取り外し可能カップリング３５５を備える、作動アセンブリ３５０の断面図である。好ましくは、作動アセンブリ３５０は、コントローラ３６０およびその中に格納される駆動機構に取り外し可能に結合される。カップリングは、機械的カップリングまたは当業者に公知の任意の好適な迅速脱着機構であり得る。取り外し可能に結合された設計は、ポンプデバイスの構成および使用の柔軟性を可能にする。例えば、ユーザの使い心地は、種々の乳房サイズとの適合性のために、異なるサイズの乳房インターフェースを通して改良され得る。加えて、本特徴は、一般のポンプデバイスが、取り換え可能な乳房インターフェースと併用されることを可能にし、したがって、病原体の拡散リスクを低減させる。さらに、取り外し可能カップリングは、ポンプデバイスの個々のパーツの容易な交換を可能にする。

【００６０】

可撓性膜

図３に示される実施形態等、多くの実施形態において、可撓性膜２４５は、乳房インターフェース２３５内に位置し、少なくともその一部を覆うように配置され、インターフェース筐体２４０と可撓性膜２４５との間にリザーバ２５０を形成する。好ましくは、可撓性膜２４５は、流体２３０が作動アセンブリ２０５によってリザーバ２５０から変位されたときに形成される負圧に曝されると、実質的に変形する。可撓性膜２４５の変形量は、多くの要因（例えば、壁厚、デュロメータ、表面積）によって制御することができ、ポンプデバイス（例えば、ポンプ電力、減圧要件）に基づいて最適化することができる。

【００６１】

図６は、特定の厚さとデュロメータとを有する、例示的可撓性膜３７０を図示する。

【００６２】

図７は、表面積増加のためのひだのついた特徴３８０を伴う、可撓性膜３７５の別の実施形態を図示する。

【００６３】

可撓性膜に好適な材料は、当業者に公知である。多くの実施形態では、可撓性膜は、シリコーン、ＰＥＢＡＸ等のポリエーテルブロックアミド、およびネオプレン等のポリクロロプレン等の結合流体からの圧力に曝されると、膨張および収縮するように設計された材料から作製されることができる。代替として、可撓性膜は、ステンレス鋼、ニチノール、高デュロメータのポリマー、または高デュロメータのエラストマー等の実質的に剛性の材料から作製されることができる。これらの実施形態では、剛性の材料は、材料の降伏点を超えない可撓性膜の実質的な変形を可能にする応力および／または歪み分散要素とともに設計されるであろう。

【００６４】

図８Ａおよび８Ｂは、出口弁４０５が可撓性膜４１０の中に統合され、搾乳された母乳の流れを出口ポート４１５を通して制御する、乳房インターフェース４００の好適な実施形態を図示する。出口弁４０５は、図８Ａに示されるように、可撓性膜４１０が弛緩されたときに開放され、流体の流れを可能にし、また、図８Ｂに示されるように、可撓性膜４１０が変形されたときに閉鎖され、流体の流れを防止する。出口弁４０５は、抽出の間は、搾乳面積４２０に実質的な減圧圧力が存在するようにする一方、ポンプストロークの休止相の間は、母乳が排出することを可能にする。多くの従来型乳房ポンプ弁は、圧力差のみで機能する一方、出口弁４０５は、好ましくは、可撓性膜４１０の機械的移動にも機能するように構成されることができる。統合された出口弁４０５に、本明細書に記載されるような機械的機能性を組み込むことで、減圧形成の間、乳房インターフェース４００のシールを改良することができる。さらに、出口弁４０５等の可撓性膜４１０内における一体的に形成された出口弁の実装は、洗浄されるべきパーツの数を低減させる。

【００６５】

機械的ポンプデバイス

図９は、可撓性膜の代わりに機械的変形可能部材６０５が使用され得る、乳房インターフェース６００の代替的実施形態を図示する。機械的変形可能部材６０５は、本明細書に記載の可撓性膜のために使用されるものと類似技法から構成されることができる。機械的変形可能部材６０５は、引張要素６１０に結合される。ある場合には、引張要素６１０は、軸荷重吸収部材６１５内に配置される。軸荷重吸収部材６１５は、管６２０内に配置される。好ましくは、引張要素６１０が、軸荷重吸収部材６１５内に同心円状に配置され、軸荷重吸収部材６１５が、管６２０内に同心円状に配置される。引張要素６１０の代替的構成では、軸荷重吸収部材６１５および管６２０もまた、使用されることができる。

【００６６】

図１０は、アセンブリ筐体６３５内の作動アセンブリ６３０の駆動要素６２５に結合される引張要素６１０を図示する。駆動要素６２５は、シャフト６４０を通して、コントローラ内に格納された駆動機構等の駆動機構に動作可能に結合される。管６２０内の軸荷重吸収部材６１５は、アセンブリ筐体６３５に固定して結合される。駆動要素６２５の変位は、引張要素６１０を通して機械的変形部材６０５に張力を伝達し、減圧圧力を乳房に対して生成する。駆動要素６２５は、本明細書に前述される実施形態等の好適な駆動機構によって作動されることができる。

【００６７】

引張要素６１０は、ワイヤ、コイル、管、編組、ロープ、または任意のそれらの組み合わせ等の任意の好適なデバイスであることができる。例えば、引張要素６１０は、その周囲に配置されるステンレス鋼編組を伴う、小型ニチノールワイヤであることができる。引張要素６１０は、金属、ポリマー、またはエラストマー等、高い引張強度を有する多くの好適な材料から作製されることができる。軸荷重吸収部材６１５は、金属またはポリマー等、軸方向に合成の任意の好適な材料から作製されることができ、管またはコイル等、軸方向に合成の任意の好適な幾何学形状に構成されることができる。

【００６８】

流体収集および定量化システム

多くの事例では、母乳産出量の量（例えば、体積、重量）、搾乳頻度（例えば、時間、日付）、および／または搾乳持続時間等、母乳の搾乳ならびに収集等の収集された流体の種々の特性を測定および追跡することが望ましくあり得る。既存のアプローチでは、母乳産出の追跡は、一般に、手動測定および記録付けによって遂行される。本明細書に説明されるデバイスの例示的実施形態は、改良された利便性、効率、および正確度のために、デジタルベースの手段を提供し、母乳産出を自動的に測定および追跡してもよい。例えば、センサが、搾乳された母乳の体積を測定するために使用されることができる。好適な実施形態では、体積は、単位時間あたりの体積、ポンプストローク（例えば、作動アセンブリのストローク）あたりの体積、またはポンプ電力サイクル（例えば、作動アセンブリの電力サイクル）あたりの体積として測定されることができる。

【００６９】
例示的実施形態では、本明細書に説明されるポンプデバイスは、搾乳された母乳の体積等、母乳の搾乳の１つまたはそれを上回る特性を示す測定データを生成するために、１つまたはそれを上回るセンサを含む。体積の測定に関する本明細書における任意の説明はまた、他の特性の測定にも適用されることができ、その逆も同様である。加速度計、ホール効果センサ、およびフォトダイオード／ＬＥＤセンサ、ＣＣＤセンサ、カメラ、および他の撮像デバイス、容量センサ、歪みゲージ等の任意の好適なタイプのセンサが、使用されることができ、そのようなセンサは、任意の数および組み合わせにおいて使用されることができる。センサは、乳房インターフェース上またはその近傍等、乳房からの流体流れを監視するために好適な任意の場所（例えば、搾乳面積２６０、排出ポート２６５、採取容器２７５）に位置付けられることができる。母乳が、一対の乳房インターフェースを介して、一対の乳房から同時に搾乳される実施形態では、センサは、乳房インターフェースの両方の上もしくはその近傍、または乳房インターフェースの一方のみの上もしくはその近傍に位置することができる。センサは、ポンプデバイスと一体的に形成されるか、またはそれに恒久的に添着されてもよい。代替として、センサは、別個に提供され、使用に先立って、ポンプデバイスに結合されてもよい。

【００７０】
図１１Ａおよび１１Ｂは、弁統合式センサ４５５を伴う、乳房インターフェース４５０の例示的実施形態を図示する。センサ４５５は、好ましくは、フラップ弁４６０等の弁内に位置するが、また、流体流れによって開放される出口弁４６５または任意の他の弁（例えば、採取容器上またはその近傍）内に位置してもよい。例示的実施形態では、センサ４５５は、弁が開放される時間の長さ等、弁の位置および／または運動を測定する加速度計を含み、得られた測定データは、流体流れを定量化するために照会されることができる。好ましくは、乳房インターフェース４５０は、一対の乳房から母乳を並行して搾乳するために（例えば、同時に、交互に、または連続して）、第２の同じ乳房インターフェースと併用される。一対の加速度計が、各インターフェース内の対応する弁の位置および／または運動を検出するために使用されることができる。いくつかの事例では、ユーザの移動は、加速度計に、弁運動として誤って解釈される運動信号を生成させ得る。故に、好適な実施形態では、好適なアプローチが、ユーザの運動から生じる信号と、弁の運動によって生成される信号とを区別するために使用される。例えば、ポンプデバイスは、対応する弁もまた、交互に開放されるように、各乳房から交互に母乳を搾乳するように構成されることができる。その結果、両方の加速度計から同時に検出される運動は、弁運動からではなく、ユーザ運動から生じたものと見なされることができる。ユーザ運動は、弁運動を得るために、加速度計によって得られる総運動信号から減算され、それによって、各弁の位置を判定することができる。代替として、または組み合わせて、センサ４５５は、一式の弁加速度計に加え、一式の背景運動加速度計を備えてもよく、背景運動加速度計は、本明細書にさらに詳細に説明されるように、ユーザの運動を含む背景運動を測定するように構成される。背景運動加速度計によって測定される背景運動は、単離された弁運動を得るために、弁加速度計によって測定される運動から減算されてもよい。

【００７１】
図１１Ｃは、加速度計４７０を伴う実施形態をより明確に図示する。加速度計４７０は、乳房インターフェース４７４（本明細書では、遠位アセンブリとも称される場合がある）を有する、搾乳デバイス４７２の出力上の弁４７６に結合される。弁４７６は、フラップ弁、ダックビル弁、または同等物であってもよい。搾乳デバイスおよび乳房インターフェースは、本明細書に開示される実施形態のいずれかであってもよい。母乳４６８が搾乳されるにつれて、それは、デバイスの出力に収集される。十分な流体が収集されると、フラップ弁４７０は、開放し、母乳４６８は、リザーバ４６２の中に排出され、層４６４をその中に収集する。リザーバ４６２は、好ましくは、それが容易に取り付けられ、かつ取り外され得るように、搾乳デバイス４７２に螺合接続される。弁４７６の移動は、加速度計４７０を使用して追跡される。加速度計からのデータは、次いで、本明細書に開示され

る方法または手段のいずれかを使用して、処理、伝送、または表示される。

【００７２】

図１１Ｌ－１１Ｎは、背景運動加速度計４７３および弁運動加速度計４７８を有する、例示的実施形態を図示する。図１１Ｌは、例示的実施形態の等角図である。図１１Ｍは、例示的実施形態の側面断面図である。背景運動加速度計４７３は、乳房インター－フェース２３５の一部、例えば、乳房インターフェースの筐体２４０に結合されてもよい。弁運動加速度計４７８は、弁４７１に結合されてもよく、弁４７１は、フラップ弁、ダックビル弁、または搾乳された母乳４６８によって付与される圧力もしくは重量に応答して開放するように構成される、任意の他の弁であってもよい。背景運動加速度計４７３および弁運動加速度計４７８は、電力ライン４８２を通して、電源、例えば、コントローラ１１５に結合されてもよい。背景運動加速度計４７３および弁運動加速度計４７８はさらに、通信ライン４８０を通して、コントロ－ラ１１５等のポンプ制御ユニットの処理デバイスまたは通信モジュールに結合されてもよい。代替として、または組み合わせて、加速度計は、乳房インターフェースまたはリザーバの一部上に配置される通信モジュールに結合されてもよく、通信モジュールは、コントローラまたはコンピューティングデバイスと無線通信するように構成される。電力ライン４８２および通信ライン４８０は、１つまたはそれを上回るワイヤを備えてもよく、可撓性管類１１０の異なるチャネルまたは同一チャネル４８４内に配置され、乳房インターフェース２３５をポンプデバイスの作動アセンブリに結合してもよい。背景運動加速度計４７３は、電力ライン４８２および通信ライン４８０に近接して位置付けられるように、筐体２４０の表面上に配置されてもよい。同様に、弁運動加速度計４７８は、電力ラインおよび通信ラインに近接して位置付けられるように、弁４７１の表面上に配置されてもよい。弁４７１は、その上に配置される弁加速度計４７８が電力および通信ラインに近接して位置付けられることができるような構成に配列されてもよい。好ましくは、背景運動加速度計４７３は、加速度計によって生成される位置データの一貫性を最適化するように、その感知軸を弁加速度計４７１の軸に整合される場所および配向に配置されてもよい。

【００７３】

図１１Ｍに示されるように、搾乳された母乳４６８は、乳房インターフェース２３５の搾乳面積２６０に進入し、続いて、採取容器に結合される排出ポート２６５に進入することができる。母乳４６８の流体流れは、弁４７１に対して圧力を生成し、弁４７１を開放させることができる。例えば、弁４７１は、構成４８６まで矢印４８５によって示される方向に変位されてもよい。弁４７１の移動は、弁運動加速度計４７８によって追跡されてもよい。弁運動加速度計４７８は、多くの場合、弁の運動４７１に加え、ユーザ運動等の弁の運動４７１と関連しない背景運動を測定し得る。背景運動に対して弁運動加速度計４７８の測定を正規化するために、背景運動加速度計４７３は、弁の運動４７１と関連しないデバイスの背景運動を測定するように、空間内のポンプデバイスの全体的移動を追跡するように構成されることができる。加速度計４７３および４７８によって生成されるデータは、通信ライン４８０を介してポンプ制御ユニットの通信モジュールに伝送されてもよく、通信モジュールは、データ分析および／または表示のために、データをポンプ制御ユニットまたは別のコンピューティングデバイスのいずれかの処理デバイスに伝送するように構成されてもよい。代替として、または組み合わせて、加速度計によって生成されるデータは、乳房インターフェースまたはリザーバの一部と統合される通信モジュールを介して、無線で伝送されてもよい。

【００７４】

図１１Ｎは、背景運動加速度計４７３および弁運動加速度計４７８によって生成される運動信号の例示的グラフを示す。グラフに示されるように、弁運動加速度計４７８によって生成される弁信号４８７は、背景運動加速度計４７３によって生成される背景信号４８８と異なる。測定された弁運動への背景運動の寄与を除外または最小限にするために、背景信号４８８は、弁信号４８７から減算され、正規化された弁信号４８９を生成してもよい。

【００７５】
他の例示的実施形態では、本明細書に説明されるポンプデバイスは、ポンプデバイス内の好適な場所（例えば、弁、出口ポート、または流体通過を可能にする他の構成要素内もしくはその近傍）に据え付けられる、１つまたはそれを上回るビーム遮断センサ（例えば、赤外線ペース、レーザベース等）を利用することができる。ビーム遮断センサは、複数のセンサ構成要素を含むことができ、構成要素のうちの１つまたはそれを上回るものの間またはその近傍の流体の通過を検出するように構成されることができる。好ましくは、センサは、ビームエミッタとビーム検出器との間を通過することによって、搾乳された流体がビームを遮断すると、信号を生成するように構成されることができる。得られた信号は、搾乳された流体の体積を示す測定データを生成するために使用されることができる。例えば、測定データは、流体がセンサ構成要素間またはその近傍を通過する時間の長さに基づくことができる。
【００７６】
図１１Ｄは、ビーム遮断センサ４７７を採用する、母乳搾乳デバイスの例示的実施形態を図示する。搾乳デバイス４７２は、乳房インターフェース４７４と、リザーバ４６２とを含む。リザーバは、搾乳デバイス４６６に螺合または別様に結合される。本明細書に開示される搾乳デバイス、インターフェース、リザーバ等の例示的実施形態のいずれも、本例示的システムにおいて使用されてもよい。ビーム遮断センサ４７７は、搾乳デバイスの出力に隣接して配置され、したがって、母乳の液滴４６８が、搾乳デバイス出口からリザーバ４６２の中に排出されるにつれて、光ビーム４７７ａを遮断し、搾乳された流体の測定を可能にする。流体は、リザーバ４６２内の層４６４に収集される。センサからのデータは、次いで、本明細書に開示される方法のいずれかを使用して、処理、伝送、または別様に表示されることができる。
【００７７】
別の例示的実施形態では、本明細書に説明されるポンプデバイスは、電荷結合素子（ＣＣＤ）、相補型金属－酸化物－半導体（ＣＭＯＳ）内のアクティブピクセルセンサ、またはカメラ等の、搾乳体積を定量化するために、流体の画像を捕捉するための１つまたはそれを上回る画像センサを含むことができる。画像センサは、ポンプデバイスの好適な部分と統合されるか、またはそこに結合されてもよい。逆に言えば、画像センサは、スマートフォンまたは他のモバイルデバイス等、ポンプデバイスと別個の別のデバイス上に位置することができる。例示的実施形態では、乳房インターフェースは、本明細書に前述されるように、搾乳された流体の通過を可能にする弁を含み、好適な画像センサが、弁を通して通過する流体の画像を捕捉するために、弁上またはその近傍に位置付けられる。好ましくは、画像センサは、流体体積を判定するために、画像データを分析する（例えば、好適な画像分析アルゴリズムを使用して）ように構成される、処理ユニットに動作可能に結合される。例えば、画像センサは、流体の液滴の画像を捕捉するために使用されることができ、画像は、液滴の数を計数するために分析されることができる。いくつかの事例では、画像データは、以下にさらに詳細に説明されるように、分析のために、コンピューティングデバイス（例えば、スマートフォン）に伝送されることができる。
【００７８】
図１１Ｅは、搾乳デバイスの出口に隣接するＣＣＤまたはＣＭＯＳデバイス４７９を有する、例示的実施形態を図示する。搾乳デバイス４７２は、インターフェース４７４と、リザーバ４６２とを含み、いずれも、本明細書に開示される実施形態のいずれかであってもよい。母乳４６８が搾乳されるにつれて、それは、前述のように、流体を検出し、その定量化を可能にする、ＣＣＤまたはＣＭＯＳ４７９を越えて搾乳デバイスの出口を通過する。母乳４６８は、次いで、リザーバ４６２内の層４６４に蓄積される。デバイス４７９からのデータは、次いで、本明細書に開示される方法のいずれかを使用して、処理、伝送、または別様に表示されてもよい。
【００７９】
図１１Ｆは、リザーバの画像を使用して、搾乳された母乳を特性評価する、例示的実施

形態を図示する。いったん母乳４６８が、リザーバ４６２内に収集されると、リザーバは、随意に、搾乳デバイスから取り外されてもよい。写真を分析し、搾乳された母乳の量を判定し、随意に、搾乳された母乳についての他の詳細を提供するための好適なアプリケーションを有する、携帯電話が、次いで、リザーバの写真４６３ａを撮影するために使用されてもよい。データは、本明細書に開示される方法のいずれかを使用して、処理、伝送、または別様に表示される。

【００８０】

図１１Ｇは、光センサシステムの代替実施形態を図示する。母乳４６８が、搾乳され、リザーバ４６２内に収集された後、ポンプ制御ユニット４６５内のカメラが、リザーバ内の母乳の画像を得て、量または他の特性のために、それを分析するために使用されてもよい。ポンプ制御４６５は、本願のいずれかに説明されるポンプ制御のいずれかであってもよく、データは、本明細書に開示される方法のいずれかを使用して、処理、伝送、または表示されてもよい。

【００８１】

いくつかの例示的実施形態では、本明細書に説明されるポンプデバイスは、流体体積を測定するために、１つまたはそれを上回る容量センサを採用することができる。容量センサは、収集リザーバおよび／または乳房インターフェース内に含まれる流体等、ポンプデバイスの任意の好適な部分（例えば、搾乳面積２６０、弁、出口ポート、または管等のインターフェースからの流体の通過を可能にする構成要素）内に含まれる流体の体積を検出するように構成されることができる。

【００８２】

図１１Ｈ－１１Ｉは、容量センサを使用する、搾乳デバイスの例示的実施形態を図示する。搾乳デバイス４７２は、本明細書に開示される搾乳デバイスのいずれかであってもよく、同様に、本明細書に開示されるインターフェースのいずれかであり得る、インターフェース４７４を有する。リザーバ４６２は、搾乳デバイスに螺合４６６または別様に結合され、リザーバは、本明細書に説明されるリザーバのいずれかであってもよい。母乳４６８が、搾乳され、搾乳デバイスの出口に収集されるにつれて、それは、容量センサ４７５を通して通過し、これは、次いで、流体体積を測定することが可能となる。図１１Ｉは、図１１Ｈにおける実施形態に類似するが、主な差異は、容量センサ４７５ａが、搾乳デバイスの出口内ではなく、底部近傍のリザーバ４６２内に配置されることである。いずれの実施形態におけるセンサからのデータも、次いで、本明細書に説明される技法のいずれかを使用して、処理、伝送、または表示されてもよい。

【００８３】

他の例示的実施形態では、１つまたはそれを上回る歪みゲージが、搾乳された流体の体積を測定するために使用されることができる。歪みゲージは、ポンプデバイス内の任意の好適な位置に据え付けられることができる。例えば、歪みゲージは、フラップ弁（または搾乳された流体の通過を可能にする任意の他の弁）に結合され、弁の経時的変位に基づいて、体積を判定するように構成されることができる。代替として、または加えて、歪みゲージは、収集リザーバに結合され、リザーバ内に含まれる搾乳された流体の体積を測定するように構成されることができる。

【００８４】

図１１Ｊは、歪みゲージの例示的実施形態を図示する。搾乳デバイス４７２は、インターフェース４７４と、そこに螺合または別様に結合される４６６、リザーバ４６２とを含む。本システムの任意の部分は、本明細書のいずれかに説明される構成要素のいずれかであってもよい。母乳が搾乳される４６８につれて、それは、搾乳デバイスの出口内に蓄積する。最終的に、蓄積された母乳の重量は、弁４７６を作動および開放させるために十分である。歪みゲージ４８１は、フラップ弁に結合され、本センサは、次いで、弁の移動に関するデータを収集するために使用され、したがって、これは、収集された流体に相関する。流体は、リザーバ４６２内の層４６４に蓄積する。センサからのデータは、次いで、本明細書に開示される方法のいずれかを使用して、処理、伝送、または表示される。

【００８５】
図１１Ｋは、歪みゲージの代替実施形態を図示する。本実施形態は、概して、前述の実施形態と同一形態をとるが、主な差異は、収集された流体層４６４が、収集された流体の重量に耐える、プレート４８３上に配置されることである。したがって、重量が増加または減少するにつれて、プレート４８３下に配置される歪みゲージ４８１ａが、重量変化を検出し、これは、収集された流体体積に相関されることができる。センサからのデータは、次いで、本明細書に開示される方法のいずれかに従って、処理、伝送、または表示される。

【００８６】
図１１０－１１Ｑは、統合処理ユニットを備える、歪みゲージまたは力感応抵抗器（ＦＳＲ）の例示的実施形態を図示する。図１１０は、実施形態の断面図である。歪みゲージ４９０は、搾乳された母乳４６８の負荷４６９を歪みゲージまたはＦＳＲ４９０のセンサ面積上に配置するような構成において、リザーバ４６２または本明細書に説明される任意のリザーバ等のリザーバの底部の中に統合されてもよい。歪みゲージ４９０は、それにかかる圧縮力に基づいてその抵抗を調節する、小型の力感応抵抗器を備えてもよい。負荷４６９に対する歪みゲージ４９０の感度を最大限にするために、リザーバ４６２の底部内部表面４９１は、負荷が歪みゲージに伝達されるにつれて、負荷４６９の吸収を最小限にするように設計されてもよい。例えば、底部内部表面４９１は、蛇腹要素４９２を備え、表面４９１を伸展させることによって、表面４９１が上下に移動することを可能にし、それによって、負荷４６９の吸収を最小限にしてもよい。好ましくは、リザーバ４６２は、内蔵タイプの電子機器を備え、歪みゲージ４９０を使用して生成されるデータを収集、処理、および通信する。図１１０における実施形態の分解図である、図１１Ｐに示されるように、歪みゲージ４９０は、支持体４９３上に搭載され、処理ユニット４９４に結合されてもよい。電力が、バッテリまたはケーブルもしくはパッドコネクタ等の直接接触接続を介して、または好ましくは、誘導充電システムを介して、処理ユニット４９４に供給されてもよい。誘導充電システムは、処理ユニットに結合されるバッテリ４９５と、バッテリに結合され、当技術分野において公知の誘導充電方法を使用して充電され得る、無線充電器４９６とを備えてもよい。図１１Ｑは、処理ユニット４９４の詳細図である。処理ユニット４９４は、マイクロコントローラ４９４ａ、通信モジュール４９４ｂ、歪みゲージ接続４９４ｃ、電力接続４９４ｄ、およびタイマ４９４ｅのうちの１つまたはそれを上回るものを格納する、印刷回路基板（ＰＣＢ）を備えてもよい。処理ユニット４９４は、信号を歪みゲージ４９０から歪みゲージ接続４９４ｃを通して受信してもよく、信号は、マイクロコントローラ４９４ａに伝送されてもよい。マイクロコントローラ４９４ａは、歪みゲージ４９０から受信された信号を収集および処理するための命令を備える、非一過性コンピュータ可読媒体を備えてもよい。マイクロコントローラ４９４ａはさらに、収集および／または処理された信号を通信モジュール４９４ｂに伝送するための命令を備えてもよい。通信モジュール４９４ｂは、例えば、Ｂｌｕｅ　Ｔｏｏｔｈモジュール等の無線送信機／受信機を備えてもよい。通信モジュール４９４ｂは、データ分析および／または表示のために、歪みゲージデータを搾乳デバイスのポンプ制御ユニットまたは携帯電話等の別のコンピューティングデバイスに伝送するように構成されてもよい。

【００８７】
図１１０－１１Ｑの実施形態の統合処理ユニットはまた、本明細書に説明される任意の他のセンサと好適に組み合わせられてもよい。説明されるような統合センサおよび処理ユニットを有するリザーバを伴う、搾乳デバイスは、母乳産出の管理および監視の自動化に役立ち、したがって、母乳産出に関連する記録を手動で維持する必要性を低減させることができる。例えば、説明されるような歪みゲージシステムは、産生された母乳の量を監視し、自動的に、データを処理し、ユーザが情報に容易にアクセスし得る、コンピューティングデバイスに送信することができる。そのようなシステムは、ユーザにとって利便性を大幅に改善し、また、手動記録維持に関連する人的エラーを低減させるのに役立つことができる。

【００８８】
例示的実施形態では、センサによって収集された測定データの一部または全部は、流体搾乳を最適化するために、ポンプデバイスにフィードバックされることができる。好ましくは、フィードバックは、作動アセンブリの１つまたはそれを上回る機能性を制御するように構成される、ポンプデバイスの処理ユニットおよび／または制御ユニット（例えば、コントローラ１１５内に位置する好適なハードウェア）に伝送されることができる。フィードバックに基づいて、処理ユニットは、最適流体搾乳を達成および／または維持するために、作動アセンブリの作動パラメータへの変更を判定することができる。例えば、フィードバックは、ポンプ、ピストンアセンブリ、または任意の他の好適な作動アセンブリの減圧ストロークまたは１分あたりのサイクルへの調節を判定するために使用されることができる。

【００８９】
図２１は、フィードバック制御を伴う、例示的搾乳システムを図示する。システムは、好ましくは、コントローラおよびプロセッサ２１０４ならびにデバイスを作動させるためのモータ２１０２を含む、ポンプユニット２１００と、標的生体構造、ここでは、乳房２１１２と嵌合するようなサイズおよび形状にされる、遠位アセンブリ２１１０とを含む。本例示的システムにおける要素のいずれも、他の例示的実施形態における本明細書にいずれかに開示される構成要素のいずれかであってもよい。本実施形態では、搾乳デバイス２１１０内の搾乳された母乳を監視する、センサからのフィードバック２１０６は、遠位アセンブリ（インターフェースを伴う搾乳デバイス）からコントローラおよびプロセッサ２１０４に伝送される。データは、処理され、本情報は、搾乳デバイスの作動を増加または減少させる命令をモータ２１０２に提供するために使用され、次いで、これは、通信２１０８によって、搾乳デバイスまたは遠位アセンブリ２１１０に返信される。フィードバック情報はまた、搾乳デバイスの１分あたりのストロークまたはサイクル数を変更するための命令をモータ２０１２に提供するために使用されてもよい。本明細書における実施形態のいずれも、そのようなフィードバックループを含んでもよい。

【００９０】
図１２は、ディスプレイ画面５０５を含むポンプデバイスのためのコントローラ５００の例示的実施形態を図示する。コントローラ５００は、本明細書に説明される母乳の搾乳データならびに搾乳データの処理から得られた分析結果を収集、処理、および記憶するために好適なハードウェアを含むことができる。好適な実施形態では、本情報は、ディスプレイ画面５０５を介してポンプデバイスのユーザに表示される。さらに、図１３に示されるように、情報はまた、以下にさらに詳細に説明されるように、コントローラ５００から伝送され、モバイルデバイス５１０等の別個のコンピューティングデバイス上に表示されることができる。情報は、グラフ、チャート、表、画像、または異なる色の１つもしくはそれを上回る光等の他の視覚的要素を含む、任意の好適な形式で提示されることができる。代替として、または組み合わせて、情報は、聴覚的インジケータを介して提供されてもよい。情報は、静的または動的である（例えば、リアルタイムで更新される等）形式で提示されてもよい。加えて、コントローラ５００は、ボタン５１５、ならびにキーボード、ジョイスティック、タッチスクリーン、スイッチ、またはノブ、もしくはそれらの好適な組み合わせ等、ユーザが表示される情報と相互作用することを可能にする入力デバイスを含むことができる。

【００９１】
コンピューティングデバイスとの通信
本明細書に開示される実施形態のいずれかでは、本明細書に説明されるポンプデバイスは、１つまたはそれを上回るコンピューティングデバイスおよび／またはサーバ等、別のエンティティと通信するように構成されることができる。例示的コンピューティングデバイスとして、パーソナルコンピュータ、ラップトップ、タブレット、およびモバイルデバイス（例えば、スマートフォン、携帯電話）が挙げられる。本明細書に説明されるサーバは、物理的ハードウェア、仮想化コンピューティングリソース（例えば、仮想機械）、ま

たは任意の好適なそれらの組み合わせを横断して実装されることができる。好適な実施形態では、サーバは、公共および／または私的分散型コンピューティングリソースの任意の好適な組み合わせを利用する、分散型コンピューティングサーバ（クラウドサーバとしても知られる）である。コンピューティングデバイスおよび／またはサーバは、ポンプデバイスに近接近してもよく（短距離通信）、またはポンプデバイスから遠隔に据え付けられてもよい（長距離通信）。コンピューティングデバイスとポンプデバイスとの間の通信に関する本明細書における任意の説明はまた、サーバとポンプデバイスおよびその逆との間の通信にも適用されることができる。

【００９２】

図１３は、ポンプデバイスのコントローラ５００とモバイルデバイス５１０との間の短距離通信５１５を図示する。通信５１５は、以下に説明されるように、無線通信方法を利用することができる。多くの実施形態では、コントローラ５００およびモバイルデバイス５１０はまた、長距離通信可能である。

【００９３】

図１４は、コンピューティングデバイス８０５およびサーバ８１０と通信する、ポンプデバイス８００の概略図である。ポンプデバイス８００は、１つまたはそれを上回る乳房インターフェース８１５と、作動アセンブリ８２０と、感知ユニット８２５と、通信モジュール８３５とを含む。好ましくは、通信モジュール８３０は、ポンプデバイスのコントローラ（例えば、コントローラ５００）内の好適なハードウェアを横断して実装される。ポンプデバイス８００は、通信モジュール８３０を介して、コンピューティングデバイス８０５およびサーバ８１０と通信することができる。多くの実施形態では、通信モジュール８３０は、第１および第２のデータ接続８３５、８４０を介して、コンピューティングデバイス８０５およびサーバ８１０に通信可能に結合される。さらに、サーバ８１０は、第３のデータ接続８４５を介して、コンピューティングデバイス８０５に通信可能に結合され得る。ポンプデバイス８００は、本明細書ではコンピューティングデバイス８０５およびサーバ８１０と直接通信するように描写されるが、他の構成もまた、可能性として考えられる。例えば、ポンプデバイス８００は、コンピューティングデバイス８０５を介して、サーバ８１０と間接的に通信するか、または逆も同様であってもよい。逆に、サーバ８１０は、コンピューティングデバイス８０５を介して、ポンプデバイス８００と間接的に通信してもよく、コンピューティングデバイス８０５は、サーバ８１０を介して、ポンプデバイス８００と通信してもよい。ポンプデバイス８００、コンピューティングデバイス８０５、またはサーバ８１０間の通信に関する本明細書における任意の説明は、これらのエンティティ間の直接通信ならびに間接通信に適用されることができる。

【００９４】

データ接続８３５、８４０、および８４５は、ポンプデバイス８００、コンピューティングデバイス８０５、およびサーバ８１０間でデータを伝送するための好適な任意の通信方法を利用することができる。そのような通信方法は、有線通信（例えば、ワイヤ、ＵＳＢケーブル等のケーブル、光ファイバ）および／または無線通信（Ｂｌｕｅｔｏｏｔｈ（登録商標）、ＷｉＦｉ、近距離通信）を含むことができる。多くの実施形態では、データは、ローカルエリアネットワーク（ＬＡＮ）、広域ネットワーク（ＷＡＮ）、電気通信ネットワーク、インターネット、またはそれらの好適な組み合わせ等、１つまたはそれを上回るネットワークを経由して伝送されることができる。

【００９５】

例示的実施形態では、ポンプデバイス８００は、母乳の搾乳データをコンピューティングデバイス８０５またはサーバ８１０（直接もしくは間接的に）に伝送する。母乳の搾乳データは、本明細書に前述されるように、ポンプデバイス８００の感知ユニット８２５によって生成される測定データを含むことができる。多くの実施形態では、ポンプデバイス８００は、測定データを分析し（例えば、好適な内蔵ハードウェアおよび／またはソフトウェアを使用して）、分析結果をコンピューティングデバイス８０５またはサーバ８１０に伝送する。代替として、測定データは、１つまたはそれを上回るアプリケーションを使

用して等、コンピューティングデバイス８０５またはサーバ８１０によって分析されることができる。コンピューティングデバイス８０５またはサーバ８１０は、測定データおよび／または分析結果の記憶のために、データ記憶と関連付けられてもよい。

【００９６】

（コンピューティングデバイス８０５またはサーバ８１０の）アプリケーションはまた、本明細書に前述されるように、測定データおよび／または分析結果を収集ならびに集積し、好適な形式（例えば、チャート、表、グラフ、画像等）において、それらをユーザに表示することができる。好ましくは、アプリケーションは、そのような情報と母乳産出統計の比較を促進するために、ユーザが、母乳産出を増加させるため生活様式選択肢、食事、および方略等の情報をオーバーレイすることを可能にする、付加的特徴を含む。本明細書に説明される分析および表示機能性は、単一エンティティまたはエンティティの任意の好適な組み合わせによって行われてもよい。例えば、多くの実施形態では、データ分析は、サーバ８１０によって実施され、分析結果が、ユーザへの表示のために、ポンプデバイス８００またはコンピューティングデバイス８０５に伝送されることができる。

【００９７】

加えて、コンピューティングデバイス８０５またはサーバ８１０は、電力、印加される減圧圧力（インターフェース８１５を介して）、または１分あたりのサイクル等、ポンプデバイス８００またはその一部（例えば、作動アセンブリ８２０）の少なくとも１つの機能性を制御するように構成される、アプリケーションを含むことができる。例えば、通信モジュール８３０は、コンピューティングデバイス８０５および／またはサーバ８１０からの制御信号を受信し、制御信号を作動アセンブリ８２０に伝送し、所望の作動をもたらすことができる。好適な実施形態では、制御信号は、本明細書に前述されるように、感知ユニット８２５によって提供される測定データに基づいて、そのようなフィードバックとしてポンプデバイス８００によって提供されるフィードバックを使用して生成されることができる。加えて、コンピューティングデバイス８０５またはサーバ８１０は、ポンプ性能を経時的に改善および最適化するために、ポンプデバイス８００の制御に関する機械学習技法を実装してもよい。

【００９８】

さらに、ポンプデバイス８００、コンピューティングデバイス８０５、および／またはサーバ８１０は、母乳を搾乳するようにユーザにリマインドする通知を提供するように構成されることができる。そのような通知は、ポンプセッションの逸失を回避するのに役立ち、したがって、乳腺炎等の関連付けられた合併症の発生を低減させることができる。通知は、以前のポンプセッションの搾乳頻度および／またはタイミングに関するデータ等、以前に収集された母乳の搾乳データに基づいて、かつユーザ選好に基づいて、生成されることができる。好ましくは、通知機能性は、コンピューティングデバイス８０５またはサーバ８１０上で起動する好適なアプリケーション内に含まれる。例えば、ポンプデバイス８００は、アプリケーションが、ポンプ圧送が生じたときを識別し、所望のポンプ時間にリマインダを識別し得るように、ポンプの使用時間についての情報をコンピューティングデバイス８０５またはサーバ８１０に送信することができる。

【００９９】

通知は、任意の好適な方法を使用して、そして任意の好適な形式において提供されることができる。例えば、通知は、コンピューティングデバイス８０５またはサーバ８１０によって生成され、ポンプデバイス８００（例えば、通信モジュール８３０）に伝送され、ユーザに表示される（例えば、ディスプレイ画面５０５等のポンプデバイス８００のディスプレイ上に）ことができる。逆に、通知は、ポンプデバイス８００によって生成され、コンピューティングデバイス８０５および／またはサーバ８１０に伝送されることができる。多くの実施形態では、通知は、コンピューティングデバイス８０５によって、ユーザに表示される。代替として、ポンプデバイス８００、コンピューティングデバイス８０５、および／またはサーバ８１０は、他の方法を使用して、通知をユーザに提供することができる。例えば、通知は、電子メールアドレスに、ショートメッセージサービス（ＳＭＳ

）を介して携帯電話番号と関連付けられたスマートフォンもしくは他のモバイル装置に、またはユーザによってアクセス可能なウェブページに送信されることができる。

【０１００】

他のタイプのデータもまた、ポンプデバイス８００、コンピューティングデバイス８０５、および／またはサーバ８１０間で伝送されることができる。例えば、多くの実施形態では、ポンプデバイス８００の１つまたはそれを上回る構成要素のためのファームウェア更新が、コンピューティングデバイス８０５および／またはサーバ８１０からポンプデバイス８００に伝送されることができる。

【０１０１】

図１７は、母乳の搾乳または他の流体を監視するためのシステムの別の例示的実施形態を図示する。システム１７００は、ポンプユニット１７０２と、遠位アセンブリ１７０６（本明細書では、インターフェースとも称される場合がある）と、無線通信送信機および受信機１７０９、１７１２と、コンピューティングデバイス１７１４と、遠隔サーバ１７１８とを含む。ポンプユニット１７０２は、本明細書に説明されるか、または当技術分野において公知のポンプユニットのいずれかであってもよく、遠位アセンブリ１７０８はまた、それらの本明細書に説明されるか、または当技術分野において公知のもののいずれかであってもよい。遠位アセンブリ１７０６は、好ましくは、本例示的実施形態では、乳房１７０８である、標的生体構造に一致するようなサイズおよび形状にされる。ポンプユニット１７０２は、遠位アセンブリ１７０６を作動させ１７０４、本明細書に開示される作動機構のいずれかを使用して、乳房１７０８からの母乳の搾乳を生じさせる。送信機１７０９は、好ましくは、ポンプユニット上に、またはそこに隣接して配置され、データ１７１０をポンプユニットからコンピューティングデバイス１７１４上の受信機１７１２に伝送するように構成される。データは、本明細書に開示されるもの等の当技術分野において公知の方法を使用して、無線で伝送されてもよい。代替実施形態では、ＵＳＢケーブルを用いて等、有線接続が、ポンプ１７０２およびコンピューティングデバイス１７１４をともに動作可能に結合するために使用されてもよい。コンピューティングデバイスは、スマートフォン、タブレット、パーソナルコンピュータ、またはポンプユニット１７０２から伝送されたデータを表示することができる、任意の他の電子コンピューティングデバイスであってもよい。コンピューティングデバイスはまた、情報をポンプユニットに返信し、遠位アセンブリの動作の制御に役立ててもよい。コンピューティングデバイス１７１４はまた、データを記憶または表示し得る、遠隔サーバ１７１８と通信１７１６してもよい。遠隔サービス１７１８へのアクセスは、インターネットまたは当技術分野において公知の他の手段によって行われてもよく、したがって、クラウドベースのデータが、インターネットアクセスを用いて、任意の他のデバイスから容易にアクセスされ得る。

【０１０２】

図１８は、母乳の搾乳のためのシステム１８００の別の例示的実施形態を図示する。本実施形態では、システム１８００は、ポンプユニット１８０２と、遠位アセンブリ１８０６と、クラウドベースまたは遠隔サーバ１８１２とを含む。ポンプユニット１８０２は、本明細書に開示されるポンプのいずれかであってもよく、乳房１８０８等の標的に一致するようなサイズおよび形状にされる、遠位アセンブリ１８０６と動作可能に結合される。遠位アセンブリは、本明細書に説明される遠位アセンブリのいずれかであってもよい。ポンプユニット１８０２は、本明細書に開示される機構のいずれかを使用して、遠位アセンブリを作動１８０４させ、乳房１８０８からの母乳の搾乳を生じさせる。ポンプユニット１８０２はまた、ポンプデータ１８１０を、本実施形態では、クラウドベースのサーバである、遠隔サーバ１８１２に伝送するための送信機および受信機１８０９を含む。したがって、データは、インターネットを介して、遠隔サービスに伝送され、インターネットを介して、ポンプ１８０２または任意の他のコンピューティングデバイスによって、クラウドベースのサーバからアクセスされてもよい。好ましくは、クラウドベースのサーバとの通信は、無線通信によって行われる。

【０１０３】

図１９Ａ－１９Ｃは、例示的コンピューティングデバイスディスプレイ１９０４を図示する。例えば、図１９Ａは、携帯電話１９０２上の例示的ディスプレイを図示し、母乳産出、最後のポンプセッションの時間、目標達成のグラフィック、およびユーザの流体消費を図示するグラフィックを図式的に図示する。加えて、ディスプレイ１９０４はまた、母乳産出の量に基づいて、ユーザ奨励またはユーザフィードバックを提供してもよい。図１９Ｂは、図１９Ａにおけるディスプレイ１９０４の拡大図である。図１９Ｃは、ディスプレイ１９０４が、タッチスクリーンが作動される（例えば、画面をスワイプまたはタッチすることによって）ときに示し得る、付加的情報を図示する。例えば、搾乳された母乳の体積が、ディスプレイの「最終ポンプセッション」区分が選択された後に示される。一部または全部のアイテムは、同様に図１９Ｃに示されるように、拡張されてもよい。付加的情報、またはいくつかの状況では、より少ない情報が、所望に応じて表示されてもよい。

【０１０４】

図２０Ａ－２０Ｂは、母乳搾乳システムにおいて使用され得る、他の例示的ディスプレイを図示する。例えば、図２０Ａは、本明細書に開示されるコンピューティングデバイスのいずれか上にあって、本明細書に説明されるポンプユニットのいずれかと動作可能に結合される、例示的ディスプレイ２００２である。ディスプレイは、その同一期間の間の搾乳セッションの平均持続時間とともに、任意の期間にわたって搾乳された母乳の平均体積を示してもよい。グラフィック（例えば、棒グラフ、円グラフ、ｘ－ｙプロット等）が、ここでは、月曜日から金曜日までの数日の経過にわたる個々のセッションの間に搾乳された体積を示すために使用されてもよい。ディスプレイは、ユーザが、例えば、セッションが旅行に起因して省略される場合、逸失したセッションが考慮され得るように、ディスプレイに注釈を付けることを可能にしてもよく、ディスプレイは、その期間の間の旅行を示してもよい。ここでは、ホップまたはフェヌグリークである、ある食品または栄養補助剤が摂取されたとき等、他の注釈もまた、付けられてもよい。これは、ユーザが、搾乳された母乳サンプルが、食品または栄養補助剤の消費に対して得られたときを思い出させることを可能にする。ディスプレイは、アドバイスを求める、クラウドにアクセスする、アラームを設定する、メモをとる、データを記憶する、またはシステム選好を確立するため等の他の機能ボタンを有してもよい。図２０Ａ－２０Ｂにおけるコンピューティングデバイスとポンプユニットとの間の通信は、図１３に関連して前述でより完全に論じられている。

【０１０５】

図２０Ｂは、システム内のコンピューティングデバイス上にあり得るか、またはより好ましくは、本明細書に開示されるポンプのいずれか上にある、例示的ディスプレイ２００４を図示する。ディスプレイ２００４は、ダッシュボード式ゲージに類似し、搾乳および収集された流体の体積およびその時間を示す。他の情報もまた、表示されてもよい。

【０１０６】

実験データ

図１５および１６は、市販の乳房ポンプデバイスおよび本発明の例示的実施形態から得られた実験的ポンプ動作のデータを図示する。例示的実施形態は、ポンプ圧送のために非圧縮性流体を利用し、４ｃｃの最大水圧流体体積を有する一方、市販のデバイスは、ポンプ圧送のために空気を利用し、１１４ｃｃの最大体積を有した。

【０１０７】

図１５は、１行程あたり生成される減圧圧力によって定量化された際のポンプ性能のグラフを図示する。例示的実施形態に関しては、ポンプによって変位された流体体積の１ｃｃ、２ｃｃ、３ｃｃ、および４ｃｃに対して圧力測定が行われ、行程番号は、体積ｃｃに対応する。市販のデバイスに関しては、それぞれ、ポンプによって変位された流体体積の４６ｃｃ、５７ｃｃ、６８ｃｃ、８０ｃｃ、９１ｃｃ、１０３ｃｃ、および１１４ｃｃを表す減圧調整ゲージに沿った７つの等間隔で増分された位置の１つに設定されたポンプを用いて測定が行われ、行程番号は、位置番号に対応する。曲線７００は、例示的実施形態に対応し、曲線７０５は、市販のデバイスに対応する。例示的実施形態は、市販のデバイ

スと比較して、変位体積あたりより高レベルの減圧圧力を生成し、最高減圧圧力は、それぞれ、－２４０．５ｍｍＨｇおよび－１７７．９ｍｍＨｇであった。

【０１０８】

図１６は、変位された流体の最大体積あたりの最大減圧圧力によって測定されたポンプ効率のグラフを図示し、バ―７１０は、例示的実施形態に対応し、バ―７１５は、市販のデバイスに対応する。例示的実施形態は、市販のデバイスと比較して、４２倍のポンプ効率増加を実証し、効率は、それぞれ、－７１．１ｍｍＨｇ／ｃｃおよび－１．７ｍｍＨｇ／ｃｃであった。

【０１０９】

本明細書に説明される種々の技法は、記憶媒体およびコンピュータ可読媒体上に記憶可能であって、コンピュータシステムの１つまたはそれを上回るプロセッサによって実行可能なコ―ドを使用して、部分的または完全に実装されてもよい。コ―ドまたはコ―ドの一部を含む記憶媒体およびコンピュータ可読媒体は、ＲＡＭ、ＲＯＭ、ＥＥＰＲＯＭ、フラッシュメモリまたは他のメモリ技術、ＣＤ－ＲＯＭ、デジタル多用途ディスク（ＤＶＤ）または他の光学記憶、磁気カセット、磁気テープ、磁気ディスク記憶または他の磁気記憶デバイス、ソリッドステートドライブ（ＳＳＤ）または他の固体ソリッドステート記憶デバイス、もしくは所望の情報を記憶するために使用されることができ、かつシステムデバイスによってアクセスされることができる、任意の他の媒体を含む、コンピュータ可読命令、データ構造、プログラムモジュール、または他のデータ等の情報の記憶および／または伝送のための任意の方法または技術において実装される、限定ではないが、揮発性および不揮発性、取り外し可能および取り外し不可能な媒体等の記憶媒体および通信媒体を含む、当技術分野において公知のまたは使用される任意の適切な媒体を含むことができる。本明細書に提供される開示および教示に基づいて、当業者は、種々の実施形態を実装する他のやり方および／または方法を理解し得る。

【０１１０】

本発明の異なる側面は、個々に、集合的に、または相互に組み合わせて、認識され得ることを理解されたい。本明細書に説明される実施形態のいずれかの好適な要素または特徴は、任意の他の実施形態の要素または特徴と組み合わせられる、もしくはそれと置換されることができる。

【０１１１】

本発明の好適な実施形態が、本明細書に示され記述されたが、このような実施形態が、例としてのみ提示されることは当業者にとって当然である。多くの変形、変更、および代替が、今や、本発明から逸脱することなく当業者に想起され得る。本明細書に記載された本発明の実施形態への種々の代替が、本発明の実施に使われ得るものと理解されるべきである。以下の請求項は、本発明の範囲を画定することを意図したもので、これら請求項の範囲内にある方法、構成、およびそれらの均等物は、それによって包含されることが意図される。

【図１】

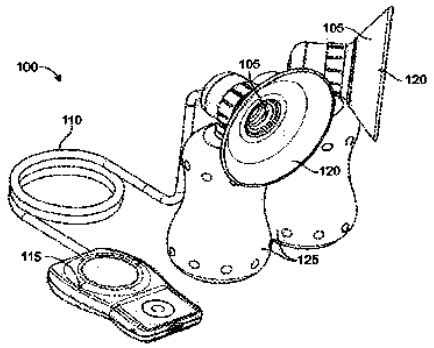


FIG. 1

【図２】

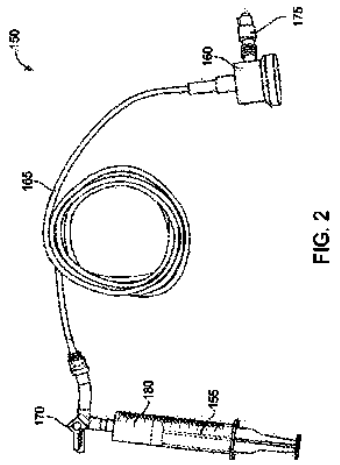


FIG. 2

【図３】

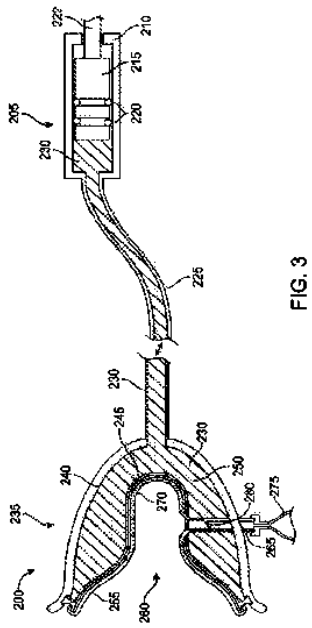


FIG. 3

【図４】

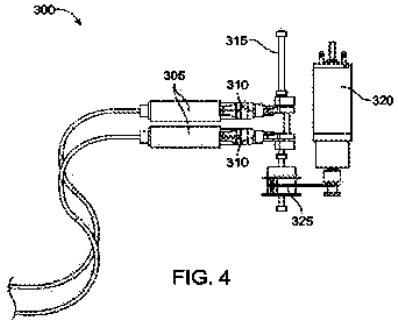


FIG. 4

【図５Ａ】

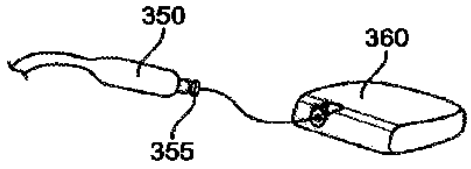


FIG. 5A

【図５Ｂ】

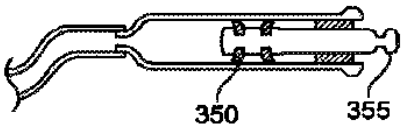


FIG. 5B

【図６】

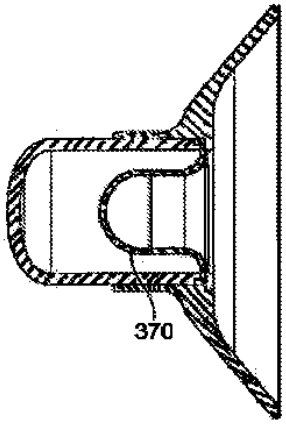


FIG. 6

【図７】

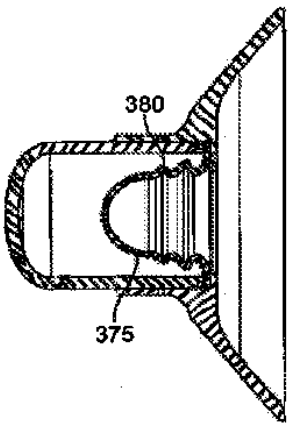


FIG. 7

【図８Ａ】

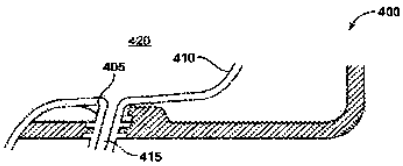


FIG. 8A

【図８Ｂ】

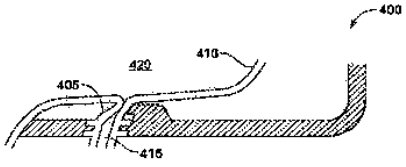


FIG. 8B

【図９】

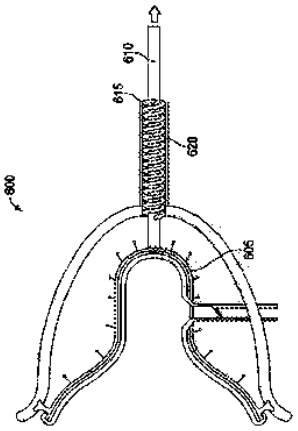


FIG. 9

【図１０】

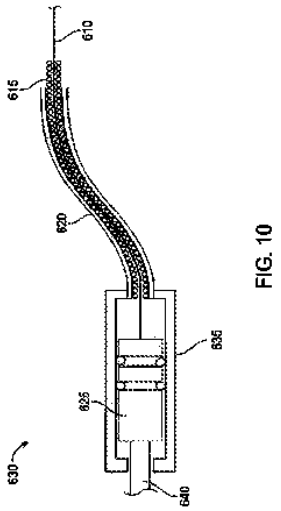


FIG. 10

【図１１Ａ】

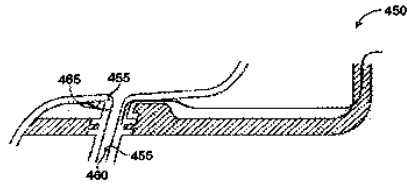


FIG. 11A

【図１１Ｂ】

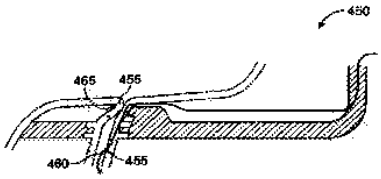


FIG. 11B

【図１１Ｃ】

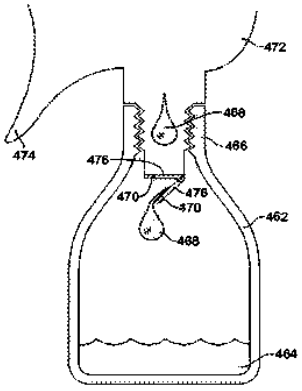


FIG. 11C

【図１１Ｄ】

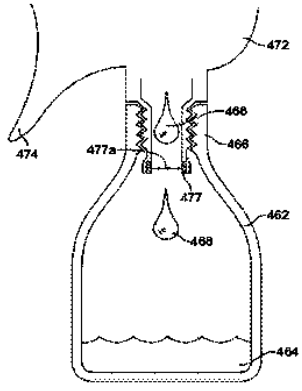


FIG. 11D

【図１１Ｅ】

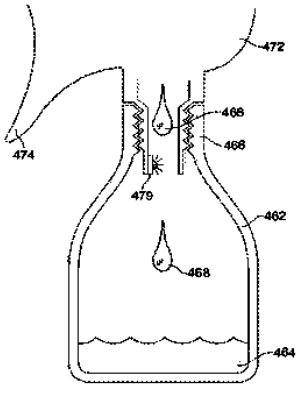


FIG. 11E

【図１１Ｆ】

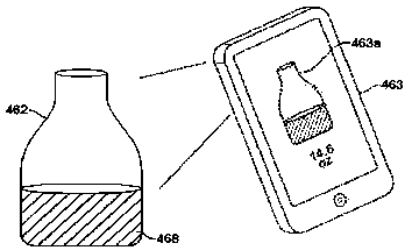


FIG. 11F

【図１１Ｇ】

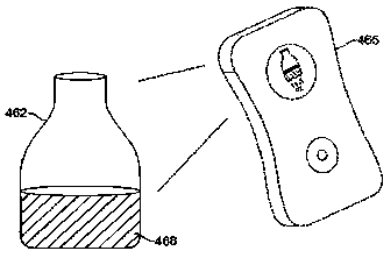


FIG. 11G

【図１１Ｈ】

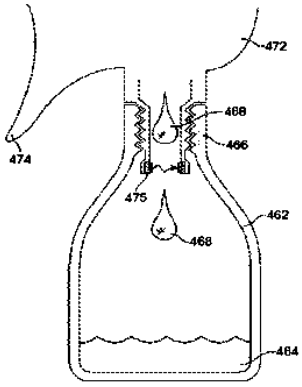


FIG. 11H

【図１１Ｉ】

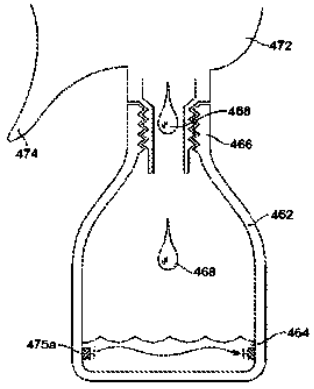


FIG. 11I

【図１１Ｊ】

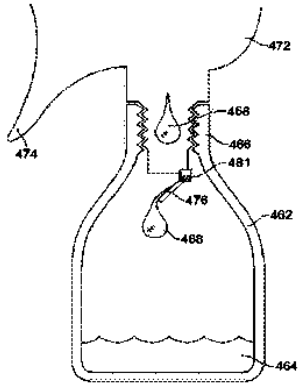


FIG. 11J

【図１１Ｋ】

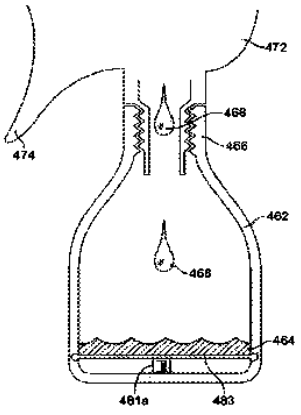


FIG. 11K

【図１１Ｌ】

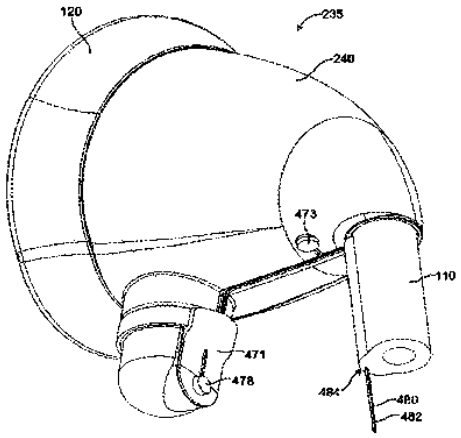


FIG. 11L

【図１１Ｍ】

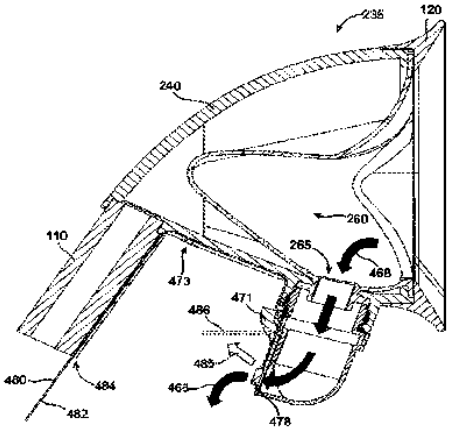


FIG. 11M

【図１１Ｎ】

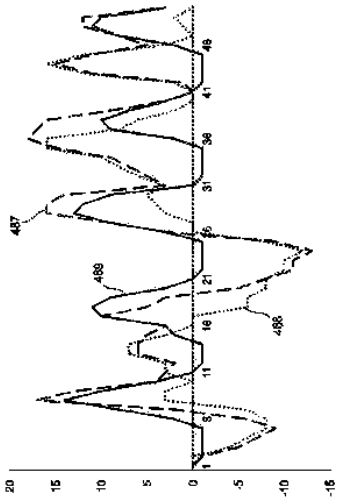


FIG. 11N

【図１１Ｏ】

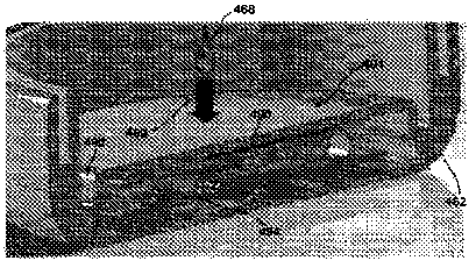


FIG. 11O

【図１１Ｐ】

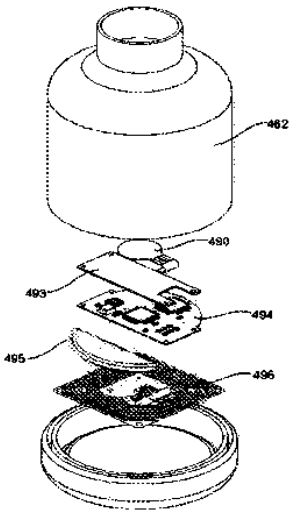


FIG. 11P

【図１１Ｑ】

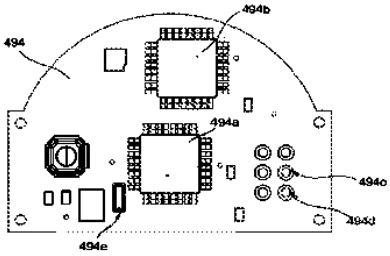


FIG. 11Q

【図１２】

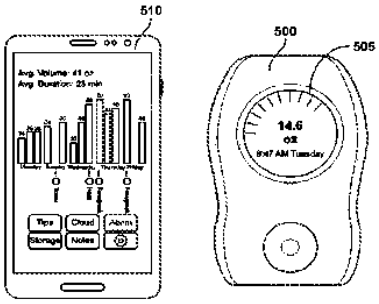


FIG. 12

【図１３】

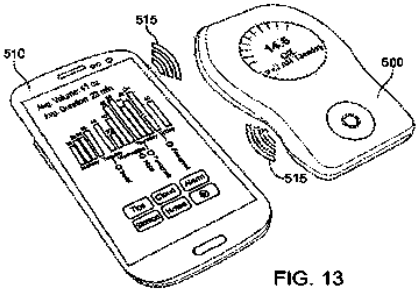


FIG. 13

【図１４】

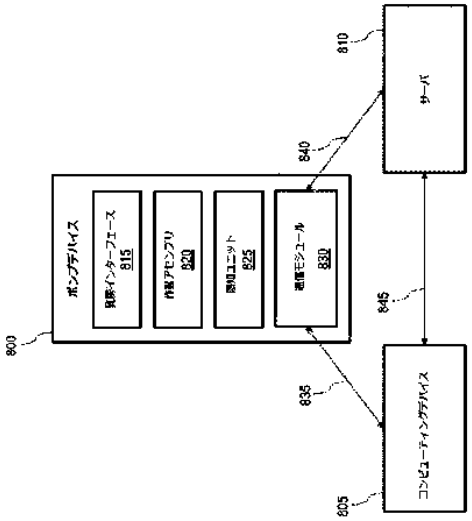


FIG. 14

【図１５】

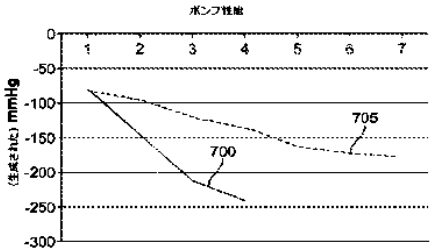


FIG. 15

【図１６】

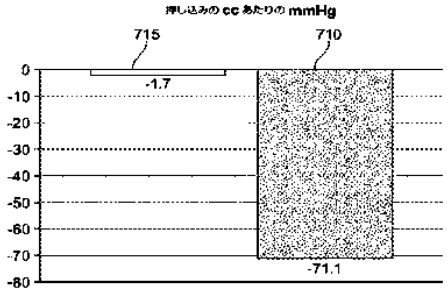


FIG. 16

【図１７】

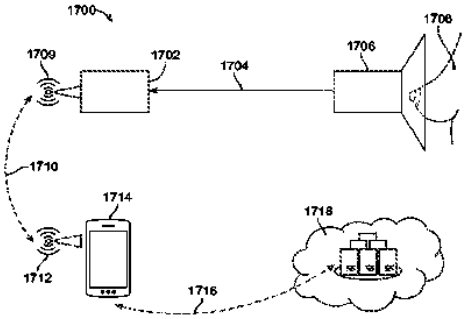


FIG. 17

【図１８】

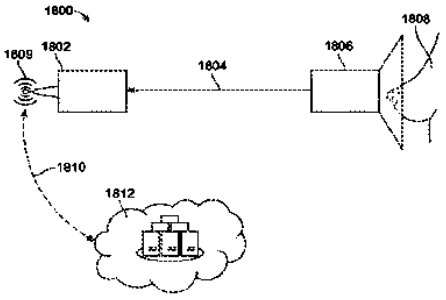


FIG. 18

【図１９Ａ】

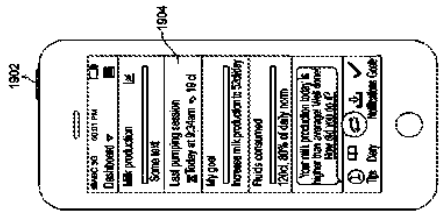


FIG. 19A

【図１９Ｂ】

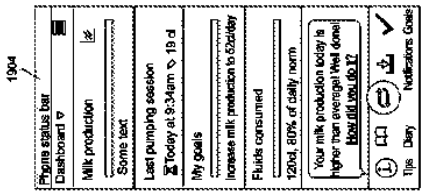


FIG. 19B

【図１９Ｃ】

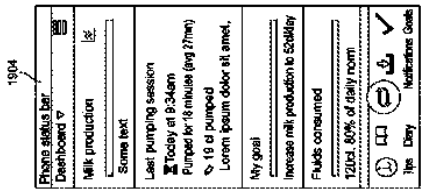


FIG. 19C

【図２０Ａ】

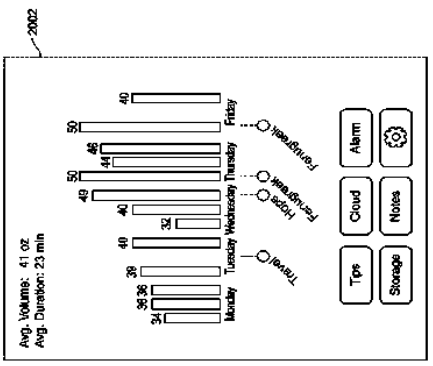


FIG. 20A

【図２０Ｂ】

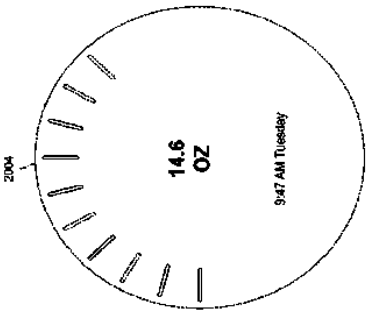


FIG. 20B

【図２１】

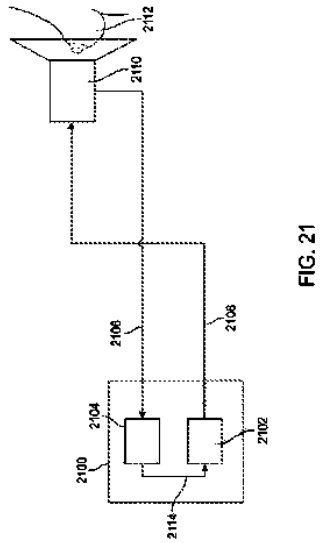


FIG. 21

【図２２】

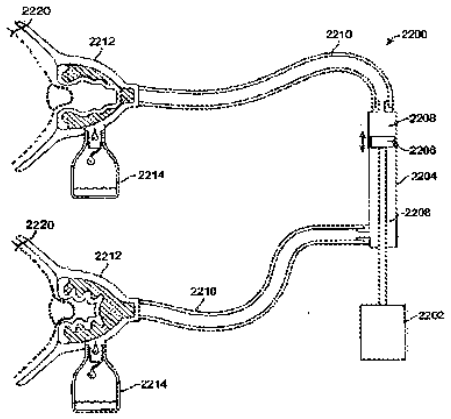


FIG. 22

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US15/14901

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A01J 5/00, 5/007; A61M 1/05 (2015.01)
CPC - A01J 5/047; A61M 1/05
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8): A01J 5/00, 5/007; A61M 1/05 (2015.01)
CPC: A01J 5/047; A61M 1/05; USPC: 119/14.02; 604/74, 346

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatSeer (US, EP, WO, JP, DE, GB, CN, FR, KR, ES, AU, IN, CA, INPADOC Data); Google; Google Scholar; Google Patent; ProQuest; Medline/PubMed. Search terms: Breast*, Milk*, Mammar* W5 Pump*, Express*, Vacuum*, Draw*, Computer*, Processor*, CPU, Microprocess*, Data*, Internet*, Server*, Informat*, Network*, Wireless*, Near, Field, USB, Connect*, Communicat*, Transfer*, SMS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X – Y	US 6547756 B1 (GRETER, A. et al.) April 15, 2003; abstract; figure 1; column 2, lines 24-37; column 5, lines 46-57; column 7, lines 53-56; column 8, lines 8-11; column 9, lines 39-55; claims 8,20, 25, 29-31	1, 3-8, 14, 15, 19, 22-24, 26, 30-33, 38, 39, 45, 48, 49 2, 9-13, 16-18, 20, 21, 25, 28, 29, 34-37, 40-44, 46, 47, 50
Y	US 2010/0121266 A1 (BRYAN, RG et al.) May 13, 2010; figure 2; paragraph [0070]	2, 29
Y	US 2007/0209595 A1 (UMEGARD, A. et al.) September. 13, 2007; paragraphs [0016], [0023]-[0024]; claim 10	9-13, 25, 28, 34-37, 46, 47, 50
Y	WO 00/41744 A1 (TAGGART MEDO) July 20, 2000; page 2, lines 10-21; page 11, lines 28-31; page 12, lines 1-2; claims 1, 7	16, 17, 20, 43
Y	WO 2013/070063 A1 (LELY PATENT N.V.) May 16, 2013; page 6, fourth paragraph	18, 44
Y	US 2013/0125821 A1 (GIBBS, RN et al.) May 23, 2013; paragraphs [0053], [0054]	20, 21, 40-42
A	US 2010/0284251 A1 (CHANG, S) November 11, 2010; abstract; paragraph [0004]	1-26, 28-50

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 April 2015 (30.04.2015)	08 JUL 2015
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US15/14901

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

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

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

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

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

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

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

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: Claims 1-26 and 28-50 are directed toward a method, system and apparatus for measuring milk expression from a breast.

Group II: Claims 27 and 51 are directed toward a method for controlling and remotely controlling expression of milk from a breast comprising receiving a control signal from a server via a network.

Group III: Claims 52-91 are directed toward an apparatus and method for measuring the volume of fluid expressed from a breast, comprising: a sensing unit configured to generate measurement data indicative of volume of expressed fluid from the breast.

-***-Continued Within the Extra Sheet-***-

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

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

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

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-26, 28-50

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (January 2015)

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/US15/14901

"""Continuation of Box No. III - Observations where unity of invention is lacking:"""

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Group I include transmitting the measurement data from the sensing unit to a computing device via a data connection, which are not present in Groups II-III; the special technical features of Group II include receiving a control signal from a computing device via a data connection, which are not present in Groups I and III; the special technical features of Group III include generating, via the sensing unit, measurement data indicative of volume of the expressed fluid, which are not present in Groups I-II.

The common technical features of Groups I, II and III are an apparatus, system and method relating to expression of fluid/milk from a breast, comprising: providing a breast fluid expression apparatus comprising an interface, an actuation assembly operably coupled to the interface, and a sensing unit; engaging the interface with a breast; actuating the actuation assembly, thereby causing the interface to apply vacuum pressure against the breast; expressing fluid from the breast.

These common technical features are disclosed by US 6,547,756 B1 to Greter et al. (hereinafter "Greter"). Greter discloses an apparatus, system and method relating to expression of fluid/milk from a breast (breastpump which can be programmed to generate a plurality of differing milk expression sequences; abstract), comprising: providing a breast fluid expression apparatus comprising an interface (breastpump with breastshield; claim 1), an actuation assembly operably coupled to the interface (programmable controller having an interface for the inputting of programs; figures 9-10; claim 1), and a sensing unit (sensing mechanism 78 uses a toothed wheel 78a mounted to the shaft 29 of motor 28, which is registered by counter 78b; signals generated by the counter 78b are processed by the cpu of the breastpump; column 7, lines 1-4); engaging the interface with a breast (a breastshield having a portion within which a woman's breast is received for the expression of milk; claim 1); actuating the actuation assembly, thereby causing the interface to apply vacuum pressure against the breast (a source of vacuum in communication with said breastshield; claim 11); expressing fluid from the breast (claim 1).

Since the common technical features are previously disclosed by the Greter reference, the common features are not special and so Groups I, II and III lack unity.

Form PCT/ISA/210 (patent family annex) (January 2015)

フロントページの続き

(81)指定国 AP(BW,GH,GM,KE,LR,LS,MW,MZ,NA,RW,SD,SL,ST,SZ,TZ,UG,ZM,ZW),EA(AM,AZ,BY,KG,KZ,RU,TJ,TM),EP(AL,AT,BE,BG,CH,CY,CZ,DE,DK,EE,ES,FI,FR,GB,GR,HR,HU,IE,IS,IT,LT,LU,LV,MC,MK,MT,NL,NO,PL,PT,RO,RS,SE,SI,SK,SM,TR),OA(BF,BJ,CF,CG,CI,CM,GA,GN,GQ,GW,KM,ML,MR,NE,SN,TD,TG),AE,AG,AL,AM,AO,AT,AU,AZ,BA,BB,BG,BH,BN,BR,BW,BY,BZ,CA,CH,CL,CN,CO,CR,CU,CZ,DE,DK,DM,DO,DZ,EC,EE,EG,ES,FI,GB,GD,GE,GH,GM,GT,HN,HR,HU,ID,IL,IN,IR,IS,JP,KE,KG,KN,KP,KR,KZ,LA,LC,LK,LR,LS,LU,LY,MA,MD,ME,MG,MK,MN,MW,MX,MY,MZ,NA,NG,NI,NO,NZ,OM,PA,PE,PG,PH,PL,PT,QA,RO,RS,RU,RW,SA,SC,SD,SE,SG,SK,SL,SM,ST,SV,SY,TH,TJ,TM,TN,TR,TT,TZ,UA,UG,US

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Method, apparatus and system for milking human breast milk

Abstract

translated from Japanese

Systems, methods, and devices for milking milk are provided. In one aspect, the system includes a milking device having an interface configured to engage the breast and an actuation assembly operably coupled to the interface. Actuation of the actuating assembly causes the interface to apply reduced pressure to the breast and milk the breast from the breast. The system also includes a computing device configured to communicate with the milking device via a data connection.

Images (43)



Classifications

- A61M1/06 Milking pumps

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Claims (91)

Hide Dependent
translated from Japanese

A system for milking breast milk from the breast,
A milking device comprising an interface configured to engage a breast and an actuation assembly operably coupled to the interface, the actuation of the actuation assembly applying a reduced pressure to the interface A milking device for applying to and milking the milk from there,
A computing device configured to communicate with the milking device via a data connection;
A system comprising: The system of claim 1, wherein the interface is configured to fluidly seal against the breast. The data connection utilizes one or more of wireless communication, near field communication, and USB cable to transmit data between at least a portion of the milking device and the computing device; The system of claim 1. The system of claim 1, wherein the computing device is selected from a smartphone, a tablet, and a personal computer. The system of claim 1, wherein the milking device further comprises a sensing unit configured to generate measurement data indicative of one or more characteristics of breast milking. The system of claim 5, wherein the measurement data is transmitted to the computing device via the data connection. The system of claim 6, wherein the computing device comprises an application configured to analyze the measurement data. The system of claim 6, wherein the computing device transmits the measurement data to a server. The system of claim 5, wherein the milking device further comprises a processing unit configured to analyze the measurement data and thereby generate an analysis result. The system of claim 9, wherein the milking device further comprises a display unit configured to display the analysis results to a user. The system according to claim 10, wherein the analysis result is displayed in a graph, a chart, or a table. The system of claim 9, wherein the analysis result is transmitted to the computing device via the data connection. The system of claim 12, wherein the computing device displays the analysis results to a user. The system of claim 1, wherein the computing device controls at least one functionality of the milking device via the data connection. 15. The functionality of claim 14, wherein the functionality includes one or more of: a power of the milking device, a reduced pressure applied by the milking device, and a cycle per minute of the milking device. system. The system of claim 1, wherein a notification to remind a user to milk breast milk is transmitted to the computing device via the data connection. The system of claim 1, wherein a notification to remind a user to milk breast milk is transmitted to at least a portion of the milking device via the data connection. The system of claim 1, wherein firmware updates are transmitted to at least a portion of the milking device via the data connection. The system of claim 1, wherein the computing device comprises a communication module that communicates with a server over a network. The system of claim 19, wherein a notification to remind a user to milk breast milk is transmitted from the server to the computing device. 21. The computing device of claim 20, wherein the computing device comprises a mobile phone associated with a mobile phone number, and the notification is transmitted to the mobile phone number over the network by a short message service (SMS). system. A method for measuring milking of breast milk from a breast,
Providing a breast milking device comprising an interface, an actuation assembly operably coupled to the interface, and a sensing unit;
Engaging the breast with the interface;
Activating the actuation assembly, thereby causing the interface to apply a reduced pressure to the breast;
Milking breast milk from the breast;

Using said sensing unit to measure milking characteristics of breast milk, thereby generating measurement data;
Transmitting the measurement data from the sensing unit to a computing device via a data connection;
Including the method. 23. The method of claim 22, further comprising storing the measurement data in one or more data stores of the computing device. 23. The method of claim 22, further comprising analyzing the measurement data via the computing device application and generating an analysis result. 25. The method of claim 24, further comprising displaying the analysis results to a user via the computing device. 26. The method of claim 25, wherein the analysis results are displayed in a graph, chart or table. A method for controlling milking of breast milk from a breast,
Providing a breast milking device comprising an interface and an actuation assembly operably coupled to the interface;
Engaging the breast with the interface;
Receiving a control signal from a computing device via a data connection;
Activating the actuation assembly based on the control signal, thereby causing the interface to apply a reduced pressure to the breast;
Milking breast milk from the breast;
Including the method. A device for milking breast milk from the breast,
An interface configured to engage the breast;
An actuating assembly operably coupled to the interface, wherein actuating the actuating assembly causes the interface to apply a reduced pressure to the breast and milk milk therefrom;
A communication module for communicating with a server via a network;
An apparatus comprising: 30. The apparatus of claim 28, wherein the interface is configured to fluidly seal against the breast. 30. The apparatus of claim 28, wherein the network comprises an internet network. 30. The apparatus of claim 28, further comprising a sensing unit configured to generate measurement data indicative of one or more characteristics of breast milking. 32. The apparatus of claim 31, wherein the measurement data is transmitted to the server via the network. 35. The apparatus of claim 32, wherein the server comprises an application configured to analyze the measurement data. 32. The apparatus of claim 31, further comprising a processing unit configured to analyze the measurement data and thereby generate an analysis result. 35. The apparatus of claim 34, further comprising a display unit configured to display the analysis results to a user. The apparatus according to claim 34, wherein the analysis result is transmitted to the server via the network. 37. The apparatus of claim 36, wherein the analysis result is displayed on a computing device that communicates with the server. 30. The apparatus of claim 28, wherein at least one functionality of the actuation assembly is controlled by an application on the server via the network. 39. The functionality of claim 38, wherein the functionality includes one or more of: power of the actuation assembly, reduced pressure applied by the actuation assembly, and cycles per minute of the actuation assembly. apparatus. 30. The apparatus of claim 28, wherein a notification to remind a user to milk breast milk is transmitted to an email address via the network. 30. The apparatus of claim 28, wherein a notification to remind a user to milk breast milk is transmitted to the mobile phone number via the network by a short message service (SMS). 42. The apparatus of claim 41, wherein the notification is transmitted by SMS from the server to a smartphone associated with the mobile phone number. 29. The apparatus of claim 28, wherein a notification to remind a user to milk breast milk is transmitted to the communication module via the network. 30. The apparatus of claim 28, wherein firmware updates are transmitted to the communication module over the network. A method for measuring milking of breast milk from a breast,
Providing a breast milking device comprising an interface, an actuation assembly operably coupled to the interface, and a sensing unit;
Engaging the breast with the interface;
Activating the actuation assembly, thereby causing the interface to apply a reduced pressure to the breast;
Milking breast milk from the breast;
Using said sensing unit to measure milking characteristics of breast milk, thereby generating measurement data;
Transmitting the measurement data to a server via a network;

Including the method. 46. The method of claim 45, wherein the server is a distributed computing server. 46. The method of claim 45, wherein the milking characteristics of the breast milk are measured by the sensing unit as the breast milk moves from the interface to a collection reservoir in fluid communication with the interface. 46. The method of claim 45, further comprising storing the measurement data in one or more data stores associated with the server. 46. The method of claim 45, further comprising analyzing the measurement data via an application on the server and generating an analysis result. Transmitting the analysis result from the server to a computing device;

Displaying the analysis results to a user via the computing device;

50. The method of claim 49, further comprising: A method for remotely controlling milking of breast milk from a breast,

Providing a breast milking device comprising an interface and an actuation assembly operably coupled to the interface;

Engaging the breast with the interface;

Receiving a control signal from a server via a network;

Activating the actuation assembly based on the control signal, thereby causing the interface to apply a reduced pressure to the breast;

Milking breast milk from the breast;

Including the method. A device for measuring the milking of fluid from the breast,

An interface configured to engage the breast;

An actuating assembly operatively coupled to the interface, wherein actuating the actuating assembly causes the interface to apply a reduced pressure to the breast and milk fluid therefrom;

A sensing unit configured to generate measurement data indicative of the volume of fluid pumped from the breast;

An apparatus comprising: 53. The apparatus of claim 52, wherein the interface is configured to fluidly seal against the breast. 53. The apparatus of claim 52, wherein the fluid is one or more of breast milk and colostrum. 53. The apparatus of claim 52, wherein the measurement data indicates a volume per unit of time of the milked fluid. 53. The apparatus of claim 52, wherein the actuation assembly comprises a pump and the measurement data indicates a volume per stroke of the pumped fluid. 53. The apparatus of claim 52, wherein the actuation assembly comprises a pump and the measurement data indicates the volume per pump power cycle of the milked fluid. 53. The apparatus of claim 52, wherein the interface comprises a valve that allows passage of the milked fluid and the sensing unit comprises an accelerometer that measures movement of the valve. 59. The apparatus of claim 58, wherein the measurement data is generated based on movement of the valve. A second interface configured to engage a second breast, wherein actuation of the actuation assembly causes reduced pressure to be applied alternately to the breast and the second breast; Alternately milking the fluid, the second interface comprises a second valve that allows the passage of fluid pumped from the second breast, and the sensing unit controls the movement of the second valve. 59. The apparatus of claim 58, comprising a second accelerometer to measure. 61. The apparatus of claim 60, wherein the sensing unit determines user movement based on movement detected by both the accelerometer and the second accelerometer. The user movement is subtracted from movement detected by at least one of the accelerometer or the second accelerometer when determining movement of at least one of the first valve or second valve. 62. The apparatus of claim 61, wherein: The interface includes a valve that allows passage of the milked fluid, and the sensing unit includes a first accelerometer coupled to the interface and a second accelerometer coupled to the valve. 54. The apparatus of claim 52, comprising. 64. The apparatus of claim 63, wherein the first accelerometer is configured to measure movement of the interface. 64. The apparatus of claim 63, wherein the second accelerometer is configured to measure movement of the valve. 64. The apparatus of claim 63, wherein the measurement data is generated based on movement of the interface and movement of the valve. 64. The apparatus of claim 63, wherein the sensing unit determines background motion based on motion detected by the first accelerometer. 68. The apparatus of claim 67, wherein the background motion is subtracted from motion detected by the second accelerometer when determining motion of the valve.

The interface is coupled to a reservoir configured to collect the milked fluid, the sensing unit is coupled to the reservoir, the reservoir comprising a processing unit in communication with the sensing unit; 53. The apparatus of claim 52, wherein the unit is configured to receive measurement data generated by the sensing unit. 70. The apparatus of claim 69, wherein the processing unit comprises a communication module configured to transmit the measurement data to a computing device via a data connection. 70. The apparatus of claim 69, wherein the processing unit comprises a communication module configured to transmit the measurement data to a server over a network. 53. The apparatus of claim 52, wherein the sensing unit comprises a beam block sensor configured to detect the passage of the milked fluid in the vicinity of one or more sensor components of the beam block sensor. . 73. The apparatus of claim 72, wherein the measurement data is generated based on a length of time that the milked fluid passes between the sensor components. The interface includes a valve that allows passage of the milked fluid, and the sensing unit is configured to count droplets of the milked fluid that pass through the valve. 53. The apparatus of claim 52, comprising a CCD). 75. The apparatus of claim 74, wherein the measurement data is generated based on one or more CCD images of the droplet. The interface comprises a tube that allows passage of the milked fluid, and the sensing unit comprises a capacitive sensor configured to sense the milked fluid contained within the tube. 52. The apparatus according to 52. The interface is coupled to a reservoir configured to collect the milked fluid, and the sensing unit is configured to measure a volume of the milked fluid contained within the reservoir 54. The apparatus of claim 52, comprising a sensor. 53. The apparatus of claim 52, wherein the sensing unit comprises a strain gauge configured to measure a volume of the milked fluid. 80. The interface of claim 78, wherein the interface comprises a valve that allows passage of the milked fluid, and the strain gauge is coupled to the valve and configured to determine displacement of the valve over time. Equipment. The interface is coupled to a reservoir configured to collect the milked fluid, and the strain gauge is coupled to the reservoir to measure the volume of the milked fluid contained within the reservoir. 80. The apparatus of claim 78, wherein the apparatus is configured as follows. The reservoir includes a bottom inner surface having a bellows element, the bellows element configured to minimize absorption by the bottom inner surface of a load applied on the bottom inner surface by the milked fluid. The apparatus of claim 80. 53. The apparatus of claim 52, wherein the sensing unit comprises a camera coupled to the interface and configured to capture one or more images of the milked fluid. 84. The apparatus of claim 82, further comprising a processing unit configured to analyze the one or more images and determine a volume of the milked fluid. 83. The one or more images are transmitted to a computing device configured to analyze the one or more images and determine a volume of the milked fluid. Equipment. The apparatus of claim 84, wherein the computing device is a smartphone. The apparatus of claim 82, wherein the camera is mounted on a mobile device. A processing unit;

A control unit operably coupled to the actuation assembly and controlling at least one functionality thereof;

53. The apparatus of claim 52, wherein at least a subset of the measurement data is transmitted as feedback to at least one of the processing unit and the control unit. 88. The apparatus of claim 87, wherein the actuation assembly comprises a pump and the feedback is used to adjust the pump's vacuum stroke and maintain optimal fluid milking. 88. The apparatus of claim 87, wherein the actuating assembly comprises a pump and the feedback is used to regulate a cycle per minute of the pump and maintain optimal fluid milking. A method for measuring the volume of fluid pumped from a breast, comprising:

Providing a breast fluid milking device comprising an interface, an actuation assembly operably coupled to the interface, and a sensing unit;

Engaging the breast with the interface;

Activating the actuation assembly, thereby causing the interface to apply a reduced pressure to the breast;

Milking fluid from the breast;

Generating measurement data indicative of the volume of the milked fluid via the sensing unit;

Including the method. Changing operating parameters of the operating assembly based on at least a subset of the measurement data;

Activating the actuation assembly based on the altered actuation parameter;

92. The method of claim 90, further comprising:

Description

translated from Japanese

(Cross-reference)
This application is a non-provisional application of US Provisional Patent Application No. 61 / 937,027 [Attorney Document No. 44936-704.101] filed on Feb. 7, 2014, and the benefit of this provisional application. The entire contents of this provisional application are incorporated herein by reference.

The subject matter of this application is US Patent Application No. 14 / 221,113 filed on March 20, 2014 [Attorney Document No. 44936-703.201], and US Provisional Patent filed on July 7, 2014. Application No. 62 / 021,601 [Attorney Document No. 44936-705.101], US Provisional Patent Application No. 62 / 021,597 filed July 7, 2014 [Attorney Document No. 44936- 706.101], US Provisional Patent Application No. 62 / 028,219 filed July 23, 2014 [Attorney Document Number 44936-708.101], and filed September 19, 2014 No. 62 / 052,941 [Attorney Document No. 44936-709.101], the entire contents of these applications are hereby incorporated by reference. It is use.

(Background of the Invention)
(1. Field of the Invention)
The present invention relates generally to medical devices and methods, and more particularly to devices and methods for milking and collecting human breast milk.

Breast pumps are commonly used to collect breast milk so that mothers can continue breastfeeding even when they are separated from their children. Currently, there are two basic types of breast pumps: small but inefficient and manual devices that cause fatigue due to use, and efficient but bulky electric devices. For this reason, it would be desirable to provide an improved breast pump that is small and very efficient for milking and collecting milk. Additional features such as quantifying breast milk output, evaluating breast milk characteristics, and communicating with mobile devices are further desirable to enhance user convenience. At least some of these objectives will be met by the devices and methods disclosed below.

(2. Description of background art)
The following US patents relate to milking and collection of human breast milk. U.S. Patent Nos. 6,673,036, 6,749,582, 6,840,918, 6,887,210, 7,875,000, 8,118,772, And No. 8,216,179.

US Pat. No. 6,673,036 US Pat. No. 6,749,582 US Pat. No. 6,840,918 US Pat. No. 6,887,210 US Pat. No. 7,875,000 US Pat. No. 8,118,772 US Pat. No. 8,216,179

(Summary of the Invention)
The present invention relates generally to medical devices and methods, and more specifically to devices and methods for milking and collecting human breast milk.

In a first aspect of the invention, a system for milking breast milk from a breast is provided. The system may comprise a milking device having an interface configured to engage the breast and an actuation assembly operably coupled to the interface. Actuation of the actuating assembly can cause the interface to apply reduced pressure to the breast and milk milk from the breast. The system further comprises a computing device configured to communicate with the milking device via a data connection.

In many embodiments, the breast is a human breast. The interface can be configured to fluidly seal against the breast.

In many embodiments, the data connection utilizes wireless communication, near field communication, or a USB cable to transmit data between at least a portion of the milking device and the computing device. The computing device may be a smartphone, tablet, or personal computer.

In many embodiments, the milking device further includes a sensing unit configured to generate measurement data indicative of one or more characteristics of breast milking. Measurement data can be transmitted to a computing device via a data connection. The computing device can include an application configured to analyze the measurement data. The computing device can transmit the measurement data to the server. The milking device can further include a processing unit configured to analyze the measurement data and generate an analysis result, and a display unit configured to display the analysis result to a user. The analysis results can be displayed in a graph, chart or table. The analysis results can be transmitted to the computing device via the data connection, and the computing device can display the analysis results to the user.

In many embodiments, the computing device can control at least one functionality of the milking device via a data connection. The functionality may comprise one or more of milking machine power, reduced pressure applied by the milking machine, or a cycle per minute of the milking machine.

In many embodiments, a notification to remind the user to milk the milk may be transmitted to the computing device via the data connection. The notification can be transmitted to at least a portion of the milking device via a data connection. Firmware updates can be transmitted to at least a portion of the milking device via a data connection.

In many embodiments, the computing device can comprise a communication module that communicates with a server over a network. A notification to remind the user to milk the milk may be transmitted from the server to the computing device. The computing device may comprise a mobile phone associated with the mobile phone number and the notification may be transmitted over the network to the mobile phone number by a short message service (SMS).

In another aspect of the present invention, a method for measuring milking of breast milk from the breast is provided. The method includes providing a breast milking apparatus having an interface, an actuation assembly operably coupled to the interface, and a sensing unit. The method further includes engaging the interface and the breast and activating the actuation assembly, thereby causing the interface to apply reduced pressure to the breast. The method further includes milking breast milk from the breast. The method may further include measuring the milking characteristics of the breast milk using the sensing unit to generate measurement data. Measurement data may be transmitted from the sensing unit to the computing device via a data connection.

In many embodiments, the measurement data may be stored in one or more data stores of the computing device. The measurement data can be analyzed via an application on the computing device and an analysis result can be generated, and the analysis result can be displayed to the user via the computing device. The analysis results can be displayed in a graph, chart, table, or any other visual, audible, or tactile indicator.

In another aspect of the invention, a method for controlling milking of breast milk from a breast is provided. The method includes providing a breast milking device having an interface and an actuation assembly operably coupled to the interface. The method further includes engaging the interface and the breast. The control signal may be received from the computing device via a data connection. The method may further include activating the actuation assembly based on the control signal and causing the interface to apply a reduced pressure to the breast. The method further includes milking breast milk from the breast.

In another aspect of the invention, an apparatus for milking breast milk from a breast is provided. The apparatus includes an interface configured to engage the breast and an actuation assembly operably coupled to the interface. Actuation of the actuating assembly can cause the interface to apply reduced pressure to the breast and milk milk from the breast. The apparatus can also include a communication module that communicates with the server over a network.

In many embodiments, the network includes an Internet network. The apparatus can further include a sensing unit configured to generate measurement data indicative of one or more characteristics of breast milking, wherein the measurement data is transmitted to a server via a network. be able to. The server can include an application configured to analyze the measurement data.

In many embodiments, the apparatus further includes a processing unit configured to analyze the measurement data and generate an analysis result, and a display unit configured to display the analysis result to a user. . The analysis result can be transmitted to the server via the network. The analysis results can be displayed on a computing device that communicates with the server.

In many embodiments, at least one functionality of the actuation assembly is controlled by an application on the server via a network. Functionality can include the power of the actuation assembly, the reduced pressure applied by the actuation assembly, or the cycles per minute of the actuation assembly.

In many embodiments, a notification to remind the user to milk the milk may be transmitted over the network to an email address. A reminder to the user to milk the milk can be transmitted to the mobile phone number over the network by a short message service (SMS), such as SMS from the server to the smartphone associated with the mobile phone number. . A notification to remind the user to milk the milk can be transmitted to the communication module via the network. The firmware update can be transmitted to the communication module via the network.

In another aspect, the present invention provides a method for measuring milking of breast milk from a breast. The method includes providing a breast milking device that includes an interface, an actuation assembly operably coupled to the interface, and a sensing unit. The interface may be engaged with the breast. The actuation assembly can be actuated to cause the interface to apply a reduced pressure to the breast. Breast milk is milked from the breast. The sensing unit may be used to measure milking characteristics of milk and generate measurement data. The measurement data may be transmitted to the server via the network.

In many embodiments, the server is a distributed computing server. The characteristics of breast milking can be measured by the sensing unit as the milk moves from the interface to a collection reservoir in fluid communication with the interface. The measurement data can be stored in one or more data stores associated with the server. The measurement data can be analyzed through an application on the server and an analysis result can be generated. The analysis results can be transmitted from the server to the computing device and displayed to the user via the computing device.

In another aspect of the invention, a method for remotely controlling milking of breast milk from a breast is provided. The method includes providing a breast milking device comprising an interface and an actuation assembly operably coupled to the interface. The interface may be engaged with the breast. A control signal can be received from the server via the network. The actuation assembly may be actuated based on the control signal and cause the interface to apply a reduced pressure to the breast. Breast milk may be milked from the breast.

In another aspect of the invention, an apparatus for measuring fluid milking from a breast is provided. The apparatus includes an interface configured to engage the breast and an actuation assembly operably coupled to the interface. Actuation of the actuating assembly causes the interface to apply reduced pressure to the breast and milk the breast from the breast. The apparatus includes a sensing unit configured to generate measurement data indicative of a volume of fluid pumped from the breast.

In many embodiments, the breast is a human breast. The interface can be configured to fluidly seal against the breast. The fluid can be breast milk or colostrum. The measurement data can indicate the volume per unit time of the milked fluid, the volume per pump stroke, or the volume per pump power cycle.

In many embodiments, the interface includes a valve that allows passage of milked fluid, and the sensing unit comprises an accelerometer that measures the movement of the valve. Measurement data can be generated based on valve motion.

In many embodiments, the apparatus can further include a second interface configured to engage the second breast. Actuation of the actuating assembly may alternately apply reduced pressure to the breast and the second breast to alternately pump fluid from the breast. The second interface can include a second valve that allows passage of fluid pumped from the second breast, and the sensing unit includes a second accelerometer that measures the position of the second valve. Can be included. The sensing unit can determine user movement based on movement detected by both the accelerometer and the second accelerometer. The user motion may be subtracted from the motion detected by at least one of the accelerometer or the second accelerometer when determining the position of at least one of the first valve or the second valve. it can.

In many embodiments, the interface may comprise an interface housing and a valve that allows passage of milked fluid. The sensing unit may comprise a first accelerometer coupled to the interface housing and a second accelerometer coupled to the valve. The first accelerometer may be configured to measure the position of the interface housing. The second accelerometer may be configured to measure the position of the valve. Measurement data may be generated based on the position of the interface housing and the position of the valve. The sensing unit can determine the background motion based on the motion detected by the first accelerometer. The background motion may be subtracted from the motion detected by the second accelerometer when determining the position of the valve.

In many embodiments, the interface may be coupled to a reservoir configured to collect milked fluid. The sensing unit may be coupled to the reservoir. The reservoir may comprise a processing unit in communication with the sensing unit, and the processing unit may be configured to receive measurement data generated by the sensing unit. The processing unit may further comprise a communication module configured to transmit the measurement data to the computing device via the data connection. The communication module of the processing unit may be configured to transmit measurement data to the server via a network.

In many embodiments, the sensing unit includes a beam block sensor configured to detect the passage of milked fluid in the vicinity of one or more sensor components of the beam block sensor. The measurement data can be generated based on the length of time that the milked fluid passes between the sensor components.

In many embodiments, the interface includes a valve that allows passage of milked fluid, and the sensing unit is configured to count milked fluid droplets passing through the valve. (CCD).

Measurement data can be generated based on one or more CCD images of the droplet.

In many embodiments, the interface includes a tube that allows passage of milked fluid and the sensing unit includes a capacitive sensor configured to sense the milked fluid contained within the tube. The interface can be coupled to a reservoir configured to collect milked fluid, and the sensing unit is configured to measure the volume of milked fluid contained in the reservoir Can be included.

In many embodiments, the sensing unit includes a strain gauge configured to measure the volume of milked fluid. The interface can include a valve that allows passage of milked fluid, and a strain gauge can be coupled to the valve and configured to determine displacement of the valve over time. The interface can be coupled to a reservoir configured to collect milked fluid, and a strain gauge is coupled to the reservoir and configured to measure the volume of milked fluid contained within the reservoir Can be done. The reservoir may comprise a bottom inner surface having a bellows element. The bellows element can be configured to minimize absorption by the bottom inner surface of the load applied to the bottom inner surface by the milked fluid.

In many embodiments, the sensing unit includes a camera coupled to the interface and configured to capture one or more images of the milked fluid. The apparatus can further include a processing unit configured to analyze one or more images and determine a volume of milked fluid or other characteristics of the milked fluid. The one or more images can be transmitted to a computing device configured to analyze the one or more images and determine the volume of the milked fluid. The computing device can be a smartphone. The camera can be installed on a mobile device.

In many embodiments, the apparatus further comprises a processing unit and a control unit operably coupled to the actuation assembly and controlling at least one functionality of the actuation assembly. At least a subset of the measurement data may be transmitted as feedback to at least one of the processing unit and the control unit. The actuation assembly can include a pump and feedback can be used to adjust the pump's vacuum stroke or pump's cycle per minute to maintain optimal fluid milking.

In another aspect of the invention, a method for measuring the volume of fluid pumped from a breast is provided. The method includes providing a breast fluid milking device that includes an interface, an actuation assembly operably coupled to the interface, and a sensing unit. The interface is engaged with the breast. The actuation assembly is actuated, causing the interface to apply a reduced pressure to the breast. The fluid is milked from the breast. Measurement data indicative of the volume of the milked fluid is generated via the sensing unit.

In many embodiments, the method further includes altering the operating parameters of the operating assembly based on at least a subset of the measurement data. The actuation assembly is actuated based on the altered actuation parameter.

Other objects and features of the invention will become apparent upon review of the specification, claims and appended drawings.

(Quoted by reference)
All publications, patents, and patent applications mentioned in this specification are intended to indicate that each individual publication, patent, or patent application is specifically and individually indicated to be incorporated by reference. To the same extent, it is incorporated herein by reference.

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention may be obtained by reference

to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. 1 is a perspective view of a pump device according to an embodiment. FIG. 2 is a perspective view of a hydraulic pump device, according to an embodiment. FIG. 3 is a cross-sectional view of a hydraulic pump device according to an embodiment. FIG. 4 illustrates an actuation assembly coupled to a drive mechanism, according to an embodiment. 5A-5B illustrate an actuation assembly coupled to a controller, according to an embodiment. FIG. 6 is a cross-sectional view of a breast interface, according to an embodiment. FIG. 7 is a cross-sectional view of another breast interface, according to an embodiment. FIG. 8A is a cross-sectional view of a valve integrated into a flexible membrane in an open position, according to an embodiment. FIG. 8B is a cross-sectional view of a valve integrated into a flexible membrane in a closed position, according to an embodiment. FIG. 9 is a cross-sectional view of a breast interface with a mechanically deformable member, according to an embodiment. FIG. 10 is a cross-sectional view of a mechanical drive for a mechanically deformable member, according to an embodiment. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. 11A-11Q illustrate an exemplary embodiment of a sensor for detecting fluid. FIG. 12 illustrates a controller and mobile device according to an embodiment. FIG. 13 illustrates short range communication between a controller and a mobile device, according to an embodiment. FIG. 14 is a schematic diagram of a pump device in communication with a computing device and a server, according to an embodiment. FIG. 15 is a graph illustrating the pump performance of an exemplary pump device compared to a commercially available device, according to an embodiment. FIG. 16 is a graph illustrating the pump efficiency of an exemplary pump device compared to a commercially available device, according to an embodiment. FIG. 17 illustrates a schematic diagram of a system for milking milk. FIG. 18 illustrates another exemplary embodiment of a system for milking breast milk. 19A-19C illustrate exemplary displays on a computing device. 20A-20B illustrate exemplary displays within a breast milking system. FIG. 21 illustrates the use of a feedback control loop to control a breast milking device. FIG. 22 illustrates a double milking system.

(Detailed description of the invention)
Specific embodiments of the disclosed systems, devices, and methods will now be described below with reference to the drawings. Any detailed description is not intended to suggest that any particular component, feature, or step is essential to the invention. Although the present invention is primarily concerned with breast milk, any description herein of milking and collection of milk can also be applied to other types of fluids that are milked from the breast, such as colostrum. Furthermore, the disclosed embodiments may be used in other applications, particularly in applications involving pressure differential formation and transmission, such as sleep apnea treatment and / or other remote pressure needs.

The systems, devices, and methods of the present invention provide an improved pump device for milking and collecting breast milk, such as human breast milk. In contrast to existing devices, the mechanisms described herein allow for the development of smaller and more efficient electric pump devices, thereby improving convenience and ease of use. In addition, at least some of the exemplary embodiments disclosed herein incorporate sensors for measuring milking characteristics of breast milk. The obtained data can be used, for example, as feedback to improve pump efficiency and provide users with information and / or analysis related to milking milk. Further, in a preferred embodiment, the data is transmitted to another device that communicates with the pump device, thereby allowing control, display and / or analysis of milking of the milk to be performed remotely. Can do.

FIG. 1 illustrates an exemplary embodiment of the present invention. The pump device 100 (also known as a "milking device") is also referred to as a controller 115 (also referred to as a "pendant unit") that is operatively coupled to the breast interface 105 through the breast interface 105, the tube 110, and the tube 110. May be included). The breast interface 105 includes a resilient and conforming flange 120 for engaging the breast and forming a fluid seal thereto, and a collection container 125. The controller 115 stores the power supply and the drive mechanism of the pump device 100, as described in further detail herein, and also controls the pump device 100, quantifies breast milk output, and communicates with other devices. Etc., including hardware for various functions. Tube 110 transmits a suitable energy input, such as a mechanical energy input, over a long distance from controller 115 to breast interface 105. The breast interface 105 converts the energy input to reduced pressure on the breast in a highly efficient manner, resulting in milking the milk into the collection container 125. The device 100 may further comprise one or more sensors configured to track various properties of the collected fluid, as described in further detail herein. Power may be provided to one or more sensors via a connection to the controller 115 or another power source. In embodiments in which one or more sensors are coupled to one or more portions of breast interface 105 or collection container 125, the sensors are further configured to transmit signals between the sensors and the controller. May be coupled to the controller 115 via one or more communication lines.

Hydraulic (Hydraulic) Pump Device The hydraulic system can reduce the required pumping force and thus reduce the size of the pump device while maintaining high pump efficiency. In a preferred embodiment, the pump device can utilize a hydraulic pump system to generate a pressure differential with respect to the breast for milking and collection of breast milk.

An exemplary hydraulic pump device is shown in FIGS. FIG. 2 illustrates a pump device 150 having a syringe 155 fluidly coupled to the breast interface 160 by a tube 165. Syringe 155 is coupled to tube 165 through three-way valve 170. The breast interface 160 includes an outlet port 175. The syringe 155 drives the fluid 180 contained in the tube 165 toward a flexible member stored in the breast interface 160 to generate the pressure differential required for milking the breast milk from the breast.

FIG. 3 illustrates another embodiment of the pump device 200. Actuation assembly 205 includes an assembly housing 210, a drive element 215, a seal 220, and a shaft 222. Drive element 215 is operatively coupled to a controller, such as controller 115, through shaft 222. Tube 225 contains fluid 230 and is fluidly coupled to actuation assembly 205 and breast interface 235. The breast interface 235 comprises an interface housing 240, a flexible membrane 245, a reservoir 250, a sealing element 255, a milking area 260, and a discharge port 265. Seal element 255 includes a deformable portion 270. Alternatively, the flexible membrane 245 may comprise a sealing element 255 having a deformable portion 270 that is fluidly sealed against the breast engaged in the breast interface 235. By doing so, it is configured to function as a sealing element. The discharge port 265 is coupled to the collection container 275 and includes a flap valve 280.

Actuating assembly 205 displaces fluid 230 contained within tube 225, which can be a flexible line. Fluid 230 occupies reservoir 250 in breast interface 235 and is coupled with flexible membrane 245. Preferably, the coupling between the flexible membrane 245, the sealing element 255, and the interface housing 240 is a liquid tight coupling such that the fluid 230 is contained within the reservoir 250 and cannot infiltrate into the milking area 260. it is. The flexible membrane 245 transmits reduced pressure from the fluid 230 to the deformable portion 270 of the sealing element 255. When the breast is engaged into the breast interface 235 by the sealing element 255 and fluidly sealed therewith, the displacement of the actuating element 215 causes a substantial vacuum to the breast through the flexible membrane 245 and the deformable portion 270. Pressure is generated, resulting in milking of the milk into the milking area 260. Alternatively, the flexible membrane 245 forms a fluid seal against the breast with which the flexible membrane 245 is engaged in the breast interface 235 and deforms the flexible membrane 245 from the fluid 230 with reduced pressure. A sealing element 255 having a deformable portion 270 may be provided to communicate to the possible portion. Milked milk is discharged into the collection container 275 through the discharge port 265. The discharge port 265 is configured with a flap valve 280 and provides passage of breast milk while maintaining a reduced pressure within the milking area 260. The collection container 275 can be any suitable container such as a bottle or bag. In many embodiments, the collection container 275 is removably coupled to the flexible membrane 245. Collection vessel 275 can be coupled directly or remotely via any suitable device, such as extended tubing. Preferably, the collection container can be quickly disconnected from other components of the pump device 200 (eg, for breast milk storage, cleaning, etc.).

The fluid of the hydraulic pump device can be any suitable fluid, such as an incompressible fluid. In many embodiments, the incompressible fluid can be a liquid such as water or oil. In many embodiments, the fluid can be a fluid having properties such that the reduced pressure applied to the fluid by the pump device does not result in degassing of the fluid. Alternatively, the fluid can be any suitable gas, such as air. Any liquid or gas suitable for use with the hydraulic system can be used for the hydraulic pump device described herein.

Actuation Mechanisms Many actuation mechanisms known to those skilled in the art can be utilized for actuation assembly 205. The actuation assembly 205 can be a piston assembly, a pump such as a diaphragm pump, or any other suitable actuation mechanism. The optimal configuration of the actuating assembly 205 depends on many factors, such as decompression requirements, size, power, and other needs of the pump device 200, and the characteristics of the fluid 230 such as viscosity, biocompatibility, and fluid life requirements Can do.

FIG. 3 illustrates an exemplary embodiment where the actuation assembly 205 is a piston assembly and the drive element 215 is a piston. Actuating assembly 205 includes a seal 220, such as an O-ring, rotating diaphragm seal, or wiper seal, to seal against assembly housing 210 to prevent undesired exudation of fluid 230 and allow fluid 230 to be driven. .

FIG. 4 illustrates another exemplary embodiment of an actuation assembly 300 that includes a pair of pistons 305.

In a preferred embodiment, the actuation assembly includes a drive element that is powered by a suitable drive mechanism, such as a drive mechanism in controller 115. Many drive mechanisms are known to those skilled in the art. For example, a drive element, such as drive element 215, may be electromechanically actuated by a motor or manually actuated by a suitable user-actuated interface such as a lever. Various drive modes known to those skilled in the art can be used. In particular, the implementation of an exemplary hydraulic pump device as described herein allows the use of suitable

drive modes such as direct drive and solenoids due to the reduced force requirements of the hydraulic system.

Referring now to the exemplary embodiment of FIG. 4, the piston 305 includes a coupling 310 to the crankshaft 315. Crankshaft 315 is operably coupled to motor 320 through belt drive 325. Crankshaft 315 drives a pair of pistons 305 at the same stroke timing so as to apply reduced pressure to both breasts simultaneously, a feature that is desirable for increased milk production. Alternatively, the crankshaft 315 can drive the pair of pistons 305 at any suitable stroke timing, such as alternating or offset stroke cycles. Alternate or offset stroke cycles can have the advantage of reducing the power requirements of the motor 320.

The drive mechanism can be powered by any suitable power source such as a local battery or an AC adapter. The drive mechanism can be controlled by hardware such as a built-in electronic device arranged in the controller 115.

FIG. 22 illustrates another embodiment of an alternating pump system 2200. System 2200 includes a dual milking device with an interface 2212 that is sized and shaped to match a target tissue, here a breast 2220. Reservoir 2214 is threaded or otherwise coupled to the milking device. A hydraulic line 2210 fluidly couples each milking device to a hydraulic piston assembly 2204 having an incompressible fluid, such as oil in the piston chamber, and an actuatable piston 2206. One hydraulic line 2210 is coupled to the high pressure side 2208 of the hydraulic piston, and the other hydraulic line is coupled to the low pressure side 2208 of the piston. A motor 2202 activates the piston 2206. Thus, in operation, as the piston is actuated, the high pressure side generates a higher pressure in one of the milking devices and a lower pressure in the other milking device. Lower pressure milking devices result in reduced pressure and cause milking of the milk, while the high pressure side does not milk the milk. Then, as the piston reaches the end of its stroke and reciprocates in the opposite direction, the high and low pressure sides are reversed, thereby producing milking on the opposite side and the original side Does not cause milking. This process allows breast milk to be collected in an alternating fashion. The milking device, reservoir in the system may be any of the components disclosed in any of the present disclosure.

5A-5B illustrate an exemplary embodiment of an actuation assembly 350 that includes a removable coupling 355. FIG. 5A is an isometric view of the actuation assembly 350 and controller 360 coupled via a removable coupling 355. FIG. 5B is a cross-sectional view of actuation assembly 350 with removable coupling 355. Preferably, the actuation assembly 350 is removably coupled to the controller 360 and the drive mechanism stored therein. The coupling can be a mechanical coupling or any suitable rapid desorption mechanism known to those skilled in the art. The releasably coupled design allows flexibility in configuration and use of the pump device. For example, the user experience can be improved through different sized breast interfaces for compatibility with different breast sizes. In addition, this feature allows a common pump device to be used in conjunction with a replaceable breast interface, thus reducing the risk of pathogen spread. Furthermore, the removable coupling allows for easy replacement of individual parts of the pump device.

Flexible Membrane In many embodiments, such as the embodiment shown in FIG. 3, the flexible membrane 245 is located within the breast interface 235 and disposed to cover at least a portion thereof, and the interface housing 240 and A reservoir 250 is formed between the flexible membrane 245. Preferably, the flexible membrane 245 substantially deforms when exposed to negative pressure formed when the fluid 230 is displaced from the reservoir 250 by the actuation assembly 205. The amount of deformation of the flexible membrane 245 can be controlled by a number of factors (eg,

wall thickness, durometer, surface area) and can be optimized based on the pump device (eg, pump power, decompression requirements). .

FIG. 6 illustrates an exemplary flexible membrane 370 having a specific thickness and durometer.

FIG. 7 illustrates another embodiment of a flexible membrane 375 with pleated features 380 for increased surface area.

Suitable materials for the flexible membrane are known to those skilled in the art. In many embodiments, the flexible membrane is designed to expand and contract when exposed to pressure from binding fluids such as silicone, polyether block amides such as PEBAX, and polychloroprene such as neoprene. It can be made from a material. Alternatively, the flexible membrane can be made from a substantially rigid material, such as stainless steel, nitinol, a high durometer polymer, or a high durometer elastomer. In these embodiments, the rigid material will be designed with stress and / or strain distribution elements that allow substantial deformation of the flexible membrane that does not exceed the yield point of the material.

FIGS. 8A and 8B illustrate a preferred embodiment of a breast interface 400 in which an outlet valve 405 is integrated into the flexible membrane 410 to control the flow of milked breast milk through the outlet port 415. The outlet valve 405 is opened when the flexible membrane 410 is relaxed, as shown in FIG. 8A, allowing fluid flow, and as shown in FIG. 8B, the flexible membrane 410 is Closed when deformed to prevent fluid flow. The outlet valve 405 allows substantial vacuum pressure to be present in the milking area 420 during extraction while allowing breast milk to drain during the rest phase of the pump stroke. While many conventional breast pump valves function only with pressure differentials, the outlet valve 405 can preferably be configured to function also for mechanical movement of the flexible membrane 410. Incorporating mechanical functionality as described herein into the integrated outlet valve 405 can improve the seal of the breast interface 400 during decompression formation. Furthermore, the integrally formed outlet valve implementation within the flexible membrane 410, such as the outlet valve 405, reduces the number of parts to be cleaned.

Mechanical Pump Device FIG. 9 illustrates an alternative embodiment of a breast interface 600 where a mechanically deformable member 605 can be used instead of a flexible membrane. The mechanically deformable member 605 can be constructed from techniques similar to those used for the flexible membranes described herein. Mechanically deformable member 605 is coupled to tensioning element 610. In some cases, the tension element 610 is disposed within the axial load absorbing member 615. The axial load absorbing member 615 is disposed in the tube 620. Preferably, the tension element 610 is concentrically disposed within the axial load absorbing member 615 and the axial load absorbing member 615 is concentrically disposed within the tube 620. In an alternative configuration of the tensioning element 610, an axial load absorbing member 615 and a tube 620 can also be used.

FIG. 10 illustrates a tensioning element 610 that is coupled to the drive element 625 of the actuation assembly 630 in the assembly housing 635. Drive element 625 is operably coupled through shaft 640 to a drive mechanism, such as a drive mechanism stored in the controller. The axial load absorbing member 615 in the tube 620 is fixedly coupled to the assembly housing 635. The displacement of the drive element 625 transmits tension through the tension element 610 to the mechanical deformation member 605 and generates a reduced pressure against the breast. The drive element 625 can be actuated by a suitable drive mechanism such as the embodiments previously described herein.

The tensioning element 610 can be any suitable device such as a wire, coil, tube, braid, rope, or any combination thereof. For example, the tension element 610 can be a miniature nitinol wire with a

stainless steel braid placed around it. The tensile element 610 can be made from a number of suitable materials having a high tensile strength, such as a metal, polymer, or elastomer. The axial load absorbing member 615 can be made from any suitable material that is axially synthetic, such as metal or polymer, and is configured in any suitable geometric shape that is axially synthetic, such as a tube or coil. Can.

Fluid collection and quantification systems In many cases, collection such as milk production and collection, such as the amount of milk production (eg, volume, weight), frequency of milking (eg, time, date), and / or milking duration It may be desirable to measure and track various properties of the treated fluid. In existing approaches, tracking milk production is typically accomplished by manual measurement and recording. The exemplary embodiments of the devices described herein provide digital-based means for improved convenience, efficiency, and accuracy, and can automatically measure and track breast milk production. Good. For example, a sensor can be used to measure the volume of milked milk. In preferred embodiments, the volume is measured as volume per unit time, volume per pump stroke (eg, stroke of the actuation assembly), or volume per pump power cycle (eg, power cycle of the actuation assembly). Can do.

In an exemplary embodiment, the pump device described herein may use one or more measurement data to generate one or more characteristics of breast milking, such as the volume of milk pumped. Including more sensors. Any description herein relating to measuring volume can also be applied to measuring other properties, and vice versa. Any suitable type of sensor can be used, such as accelerometers, Hall effect sensors, and photodiode / LED sensors, CCD sensors, cameras, and other imaging devices, capacitive sensors, strain gauges, etc. The sensors can be used in any number and combination. The sensor can be located at any location suitable for monitoring fluid flow from the breast, such as on or near the breast interface (eg, milking area 260, drain port 265, collection container 275). In embodiments where breast milk is milked simultaneously from a pair of breasts via a pair of breast interfaces, the sensor is located on or near both breast interfaces or only one of the breast interfaces. be able to. The sensor may be integrally formed with the pump device or permanently attached thereto. Alternatively, the sensor may be provided separately and coupled to the pump device prior to use.

FIGS. 11A and 11B illustrate an exemplary embodiment of a breast interface 450 with a valve integrated sensor 455. Sensor 455 is preferably located in a valve, such as flap valve 460, but is also located in outlet valve 465 or any other valve (eg, on or near the collection vessel) that is opened by fluid flow. May be. In the exemplary embodiment, sensor 455 includes an accelerometer that measures valve position and / or movement, such as the length of time that the valve is opened, and the resulting measurement data is for quantifying fluid flow. Can be queried. Preferably, breast interface 450 is used in conjunction with a second identical breast interface to milk milk from a pair of breasts in parallel (eg, simultaneously, alternately or sequentially). A pair of accelerometers can be used to detect the position and / or movement of the corresponding valve in each interface. In some cases, the user's movement may cause the accelerometer to generate a motion signal that is misinterpreted as a valve motion. Thus, in a preferred embodiment, a preferred approach is used to distinguish between signals resulting from user movement and signals generated by valve movement. For example, the pump device can be configured to milk milk alternately from each breast so that the corresponding valves are also opened alternately. As a result, motion detected simultaneously from both accelerometers can be considered to have resulted from user motion, not from valve motion. User motion can be subtracted from the total motion signal obtained by the accelerometer to obtain valve motion, thereby determining the position of each valve. Alternatively or in combination, the sensor 455 may comprise a set of background motion accelerometers in addition to the set of valve accelerometers, the background motion accelerometer, as described in further detail herein. It is

configured to measure background motion including user motion. The background motion measured by the background motion accelerometer may be subtracted from the motion measured by the valve accelerometer to obtain an isolated valve motion.

FIG. 11C more clearly illustrates an embodiment with an accelerometer 470. The accelerometer 470 is coupled to a valve 476 on the output of the milking device 472 having a breast interface 474 (which may also be referred to herein as a distal assembly). Valve 476 may be a flap valve, a duckbill valve, or the like. The milking device and the breast interface may be any of the embodiments disclosed herein. As breast milk 468 is milked, it is collected at the output of the device. When sufficient fluid is collected, the flap valve 470 opens and the breast milk 468 is drained into the reservoir 462 and collects the layer 464 therein. The reservoir 462 is preferably threadably connected to the milking device 472 so that it can be easily installed and removed. The movement of valve 476 is tracked using accelerometer 470. Data from the accelerometer is then processed, transmitted, or displayed using any of the methods or means disclosed herein.

FIGS. 11L-11N illustrate an exemplary embodiment having a background motion accelerometer 473 and a valve motion accelerometer 478. FIG. 11L is an isometric view of an exemplary embodiment. FIG. 11M is a side cross-sectional view of an exemplary embodiment. The background motion accelerometer 473 may be coupled to a portion of the breast interface 235, for example, the housing 240 of the breast interface. The valve accelerometer 478 may be coupled to a valve 471 that is configured to open in response to pressure or weight applied by a flap valve, duckbill valve, or milked breast milk 468. Any other valve may be used. Background motion accelerometer 473 and valve motion accelerometer 478 may be coupled to a power source, eg, controller 115, through power line 482. The background motion accelerometer 473 and the valve motion accelerometer 478 may further be coupled via a communication line 480 to a processing device or communication module of a pump control unit, such as the controller 115. Alternatively or in combination, the accelerometer may be coupled to a communication module disposed on a portion of the breast interface or reservoir, the communication module configured to communicate wirelessly with a controller or computing device. . The power line 482 and the communication line 480 may comprise one or more wires and are located in different channels or the same channel 484 of the flexible tubing 110 to connect the breast interface 235 to the actuation assembly of the pump device. May be combined. The background motion accelerometer 473 may be disposed on the surface of the housing 240 so as to be positioned in proximity to the power line 482 and the communication line 480. Similarly, the valve motion accelerometer 478 may be placed on the surface of the valve 471 so as to be positioned proximate to the power line and communication line. The valve 471 may be arranged in a configuration such that a valve accelerometer 478 disposed thereon can be positioned in proximity to the power and communication lines. Preferably, the background motion accelerometer 473 may be placed in a location and orientation whose sensing axis is aligned with the axis of the valve accelerometer 471 so as to optimize the consistency of the position data generated by the accelerometer. Good.

As shown in FIG. 11M, the milked milk 468 can enter the milking area 260 of the breast interface 235 and subsequently enter the drain port 265 coupled to the collection container. The fluid flow of breast milk 468 can generate pressure on the valve 471 and cause the valve 471 to open. For example, valve 471 may be displaced in the direction indicated by arrow 485 up to configuration 486. The movement of the valve 471 may be tracked by the valve motion accelerometer 478. Valve motion accelerometer 478 can often measure background motion that is not associated with valve motion 471, such as user motion, in addition to valve motion 471. In order to normalize the measurement of the valve motion accelerometer 478 relative to the background motion, the background motion accelerometer 473 measures the overall pump device in space to measure the background motion of the device unrelated to the valve motion 471. Can be configured to track global movement. Data generated by

accelerometers 473 and 478 may be transmitted via communication line 480 to the communication module of the pump control unit, which communicates the data to the pump control unit for data analysis and / or display. Or it may be configured to transmit to any processing device of another computing device. Alternatively, or in combination, the data generated by the accelerometer may be transmitted wirelessly via a communication module that is integrated with a portion of the breast interface or reservoir.

FIG. 11N shows an exemplary graph of the motion signal generated by the background motion accelerometer 473 and the valve motion accelerometer 478. As shown in the graph, the valve signal 487 generated by the valve motion accelerometer 478 is different from the background signal 488 generated by the background motion accelerometer 473. To exclude or minimize the background motion contribution to the measured valve motion, the background signal 488 may be subtracted from the valve signal 487 to produce a normalized valve signal 489.

In other exemplary embodiments, the pump device described herein is in a suitable location within the pump device (eg, within or near a valve, outlet port, or other component that allows fluid passage). One or more beam block sensors (eg, infrared-based, laser-based, etc.) installed in The beam block sensor can include a plurality of sensor components and can be configured to detect the passage of fluid between or near one or more of the components. Preferably, the sensor can be configured to generate a signal when the milked fluid blocks the beam by passing between the beam emitter and the beam detector. The resulting signal can be used to generate measurement data indicative of the volume of the milked fluid. For example, the measurement data can be based on the length of time that the fluid passes between or near sensor components.

FIG. 11D illustrates an exemplary embodiment of a breast milking device that employs a beam block sensor 477. Milking device 472 includes a breast interface 474 and a reservoir 462. The reservoir is threaded or otherwise coupled to the milking device 466. Any of the exemplary embodiments disclosed herein, such as milking devices, interfaces, reservoirs, etc., may be used in the exemplary system. The beam block sensor 477 is positioned adjacent to the output of the milking device, thus blocking and milking the light beam 477a as the milk droplet 468 is discharged from the milking device outlet into the reservoir 462. Allows fluid measurement. Fluid is collected in layer 464 within reservoir 462. Data from the sensor can then be processed, transmitted, or otherwise displayed using any of the methods disclosed herein.

In another exemplary embodiment, the pump device described herein is a milking volume, such as a charge coupled device (CCD), an active pixel sensor in a complementary metal-oxide-semiconductor (CMOS), or a camera. Can be included to include one or more image sensors for capturing an image of the fluid. The image sensor may be integrated with or coupled to a suitable part of the pump device. Conversely, the image sensor can be located on another device separate from the pump device, such as a smartphone or other mobile device. In an exemplary embodiment, the breast interface includes a valve that allows passage of milked fluid, as previously described herein, and a suitable image sensor captures an image of the fluid passing through the valve. Therefore, it is positioned on or near the valve. Preferably, the image sensor is operably coupled to a processing unit configured to analyze the image data (eg, using a suitable image analysis algorithm) to determine fluid volume. For example, an image sensor can be used to capture an image of a fluid droplet, and the image can be analyzed to count the number of droplets. In some instances, the image data can be transmitted to a computing device (eg, a smartphone) for analysis, as described in further detail below.

FIG. 11E illustrates an exemplary embodiment having a CCD or CMOS device 479 adjacent to the exit of the milking device. Milking device 472 includes an interface 474 and a reservoir 462, any of which may be any of the embodiments disclosed herein. As breast milk 468 is milked, it passes through the outlet of the milking device beyond the CCD or CMOS 479, which detects fluid and allows its quantification as described above. Breast milk 468 then accumulates in layer 464 within reservoir 462. Data from device 479 may then be processed, transmitted, or otherwise displayed using any of the methods disclosed herein.

FIG. 11F illustrates an exemplary embodiment of characterizing milked breast milk using an image of the reservoir. Once breast milk 468 is collected in reservoir 462, the reservoir may optionally be removed from the milking device. A cell phone with a suitable application to analyze the photos, determine the amount of milked milk, and optionally provide other details about the milked milk, then take a photo 463a of the reservoir May be used to The data is processed, transmitted, or otherwise displayed using any of the methods disclosed herein.

FIG. 11G illustrates an alternative embodiment of the optical sensor system. After breast milk 468 is milked and collected in reservoir 462, a camera in pump control unit 465 obtains an image of breast milk in the reservoir and analyzes it for volume or other characteristics May be used. The pump control 465 may be any of the pump controls described herein, and the data is processed, transmitted, or displayed using any of the methods disclosed herein. May be.

In some exemplary embodiments, the pump devices described herein can employ one or more capacitive sensors to measure fluid volume. The capacitive sensor allows passage of fluid from any suitable part of the pump device, such as fluid contained within the collection reservoir and / or breast interface (eg, milking area 260, valve, outlet port, or tubing interface) The volume of fluid contained within the component.

11H-11I illustrate an exemplary embodiment of a milking device using a capacitive sensor. The milking device 472 may be any of the milking devices disclosed herein and similarly has an interface 474, which may be any of the interfaces disclosed herein. Reservoir 462 is threaded 466 or otherwise coupled to the milking device, and the reservoir may be any of the reservoirs described herein. As breast milk 468 is milked and collected at the outlet of the milking device, it passes through the volume sensor 475, which then allows the fluid volume to be measured. FIG. 11I is similar to the embodiment in FIG. 11H, but the main difference is that the capacitive sensor 475a is located in the reservoir 462 near the bottom rather than in the outlet of the milking device. Data from the sensor in any embodiment may then be processed, transmitted, or displayed using any of the techniques described herein.

In other exemplary embodiments, one or more strain gauges can be used to measure the volume of the milked fluid. The strain gauge can be installed at any suitable location within the pump device. For example, the strain gauge may be coupled to a flap valve (or any other valve that allows passage of milked fluid) and configured to determine volume based on the displacement of the valve over time. it can. Alternatively or additionally, a strain gauge can be coupled to the collection reservoir and configured to measure the volume of milked fluid contained within the reservoir.

FIG. 11J illustrates an exemplary embodiment of a strain gauge. The milking device 472 includes an interface 474, a thread 466 or otherwise coupled thereto 466, a reservoir 462. Any part of the system may be any of the components described elsewhere herein. As the milk is milked 468, it accumulates in the outlet of the milking device. Ultimately, the accumulated breast milk weight is sufficient to activate and open valve 476. A strain gauge 481 is coupled to the flap valve and the sensor is then used to collect data regarding the movement of the valve, thus it correlates with the collected fluid.

Fluid accumulates in layer 464 within reservoir 462. Data from the sensor is then processed, transmitted, or displayed using any of the methods disclosed herein.

FIG. 11K illustrates an alternative embodiment of a strain gauge. This embodiment generally takes the same form as the previous embodiment, the main difference being that the collected fluid layer 464 is placed on a plate 483 that bears the weight of the collected fluid. . Thus, as the weight increases or decreases, the strain gauge 481a disposed under the plate 483 detects the weight change, which can be correlated to the collected fluid volume. Data from the sensor is then processed, transmitted, or displayed according to any of the methods disclosed herein.

FIGS. 11O-11Q illustrate an exemplary embodiment of a strain gauge or force sensitive resistor (FSR) comprising an integrated processing unit. FIG. 11O is a cross-sectional view of the embodiment. The strain gauge 490 is located in the bottom of the reservoir, such as the reservoir 462 or any reservoir described herein, in a configuration that places the load 469 of the milked milk 468 on the sensor area of the strain gauge or FSR 490. May be integrated. The strain gauge 490 may include a small force sensitive resistor that adjusts its resistance based on the compressive force applied thereto. To maximize the sensitivity of the strain gauge 490 to the load 469, the bottom inner surface 491 of the reservoir 462 may be designed to minimize the absorption of the load 469 as the load is transmitted to the strain gauge. Good. For example, the bottom inner surface 491 may comprise a bellows element 492, allowing the surface 491 to move up and down by extending the surface 491, thereby minimizing the absorption of the load 469. Preferably, reservoir 462 comprises a self-contained electronic device that collects, processes, and communicates data generated using strain gauge 490. A strain gauge 490 may be mounted on the support 493 and coupled to the processing unit 494, as shown in FIG. 11P, which is an exploded view of the embodiment in FIG. Power may be supplied to the processing unit 494 via a direct contact connection such as a battery or cable or pad connector, or preferably via an inductive charging system. The inductive charging system may include a battery 495 coupled to the processing unit and a wireless charger 496 coupled to the battery and may be charged using inductive charging methods known in the art. FIG. 11Q is a detailed view of the processing unit 494. The processing unit 494 may comprise a printed circuit board (PCB) that stores one or more of the microcontroller 494a, the communication module 494b, the strain gauge connection 494c, the power connection 494d, and the timer 494e. . The processing unit 494 may receive a signal from the strain gauge 490 through the strain gauge connection 494c and the signal may be transmitted to the microcontroller 494a. The microcontroller 494a may comprise a non-transitory computer readable medium comprising instructions for collecting and processing signals received from the strain gauge 490. The microcontroller 494a may further comprise instructions for transmitting the collected and / or processed signals to the communication module 494b. The communication module 494b may include a wireless transmitter / receiver such as a Blue Tooth module, for example. Communication module 494b may be configured to transmit strain gauge data to another computing device, such as a pump control unit of a milking device or a mobile phone, for data analysis and / or display.

The integrated processing unit of the embodiment of FIGS. 11O-11Q may also be suitably combined with any other sensor described herein. A milking device with a reservoir with an integrated sensor and processing unit as described helps to automate the management and monitoring of breast milk production, thus reducing the need to manually maintain records related to breast milk production Can do. For example, a strain gauge system as described can monitor the amount of milk produced and automatically process the data and send it to a computing device where the user can easily access the information. . Such a system can greatly improve the convenience for the user and can help reduce human errors associated with manual record keeping.

In an exemplary embodiment, some or all of the measurement data collected by the sensor can be fed back to the pump device to optimize fluid milking. Preferably, the feedback is a processing unit and / or control unit (eg, suitable hardware located within controller 115) of the pump device configured to control one or more functionalities of the actuation assembly. Can be transmitted. Based on the feedback, the processing unit can determine changes to the operating parameters of the operating assembly to achieve and / or maintain optimal fluid milking. For example, the feedback can be used to determine the adjustment of the pump, piston assembly, or any other suitable actuation assembly to a reduced pressure stroke or cycle per minute.

FIG. 21 illustrates an exemplary milking system with feedback control. The system is preferably sized and shaped to mate with a pump unit 2100 and a target anatomy, here a breast 2112, including a controller and processor 2104 and a motor 2102 for operating the device. Assembly 2110. Any of the elements in the present exemplary system may be any of the components disclosed elsewhere herein in other exemplary embodiments. In this embodiment, feedback 2106 from a sensor that monitors milked milk in the milking device 2110 is transmitted from the distal assembly (milking device with interface) to the controller and processor 2104. The data is processed and this information is used to provide instructions to the motor 2102 to increase or decrease the operation of the milking device, which is then sent back to the milking device or distal assembly 2110 via communication 2108. The The feedback information may also be used to provide instructions to the motor 2012 to change the number of strokes or cycles per minute of the milking device. Any of the embodiments herein may include such a feedback loop.

FIG. 12 illustrates an exemplary embodiment of a controller 500 for a pump device that includes a display screen 505. The controller 500 may include suitable hardware for collecting, processing, and storing milking data as described herein, and analysis results obtained from processing the milking data. In the preferred embodiment, this information is displayed to the user of the pump device via display screen 505. Further, as shown in FIG. 13, information can also be transmitted from the controller 500 and displayed on a separate computing device, such as the mobile device 510, as described in more detail below. Information can be presented in any suitable form, including graphs, charts, tables, images, or other visual elements such as one or more lights of different colors. Alternatively or in combination, the information may be provided via an audible indicator. Information may be presented in a form that is static or dynamic (eg, updated in real time, etc.). In addition, the controller 500 includes buttons 515 and input devices that allow a user to interact with displayed information, such as a keyboard, joystick, touch screen, switch, or knob, or a suitable combination thereof. be able to.

Communicating with a computing device In any of the embodiments disclosed herein, the pump device described herein can communicate with another entity, such as one or more computing devices and / or servers. Can be configured to communicate. Exemplary computing devices include personal computers, laptops, tablets, and mobile devices (eg, smartphones, cell phones). The servers described herein can be implemented across physical hardware, virtualized computing resources (eg, virtual machines), or any suitable combination thereof. In a preferred embodiment, the server is a distributed computing server (also known as a cloud server) that utilizes any suitable combination of public and / or private distributed computing resources. The computing device and / or server may be in close proximity to the pump device (short range communication) or may be remotely located from the pump device (long range communication). Any description herein relating to communication between a computing device and a pump device can also be applied to communication between a server and a pump device and vice versa.

FIG. 13 illustrates short range communication 515 between the controller 500 of the pump device and the mobile device 510. The communication 515 can use a wireless communication method as will be described below. In many embodiments, the controller 500 and mobile device 510 are also capable of long-range communication.

FIG. 14 is a schematic diagram of a pump device 800 in communication with a computing device 805 and a server 810. The pump device 800 includes one or more breast interfaces 815, an actuation assembly 820, a sensing unit 825, and a communication module 835. Preferably, the communication module 830 is implemented across suitable hardware in the controller (eg, controller 500) of the pump device. The pump device 800 can communicate with the computing device 805 and the server 810 via the communication module 830. In many embodiments, the communication module 830 is communicatively coupled to the computing device 805 and the server 810 via first and second data connections 835, 840. Further, server 810 may be communicatively coupled to computing device 805 via third data connection 845. Although the pump device 800 is depicted herein as communicating directly with the computing device 805 and the server 810, other configurations are also possible. For example, pump device 800 may communicate indirectly with server 810 via computing device 805, or vice versa. Conversely, server 810 may communicate indirectly with pump device 800 via computing device 805, and computing device 805 may communicate with pump device 800 via server 810. Any description herein regarding communication between pump device 800, computing device 805, or server 810 can be applied to direct communication as well as indirect communication between these entities.

Data connections 835, 840, and 845 can utilize any suitable communication method for transmitting data between pump device 800, computing device 805, and server 810. Such communication methods may include wired communication (eg, wire, cable such as USB cable, optical fiber) and / or wireless communication (Bluetooth®, WiFi, near field communication). In many embodiments, data is transmitted over one or more networks, such as a local area network (LAN), a wide area network (WAN), a telecommunications network, the Internet, or a suitable combination thereof. be able to.

In the exemplary embodiment, pump device 800 transmits milking data for breast milk to computing device 805 or server 810 (directly or indirectly). Breast milking data may include measurement data generated by the sensing unit 825 of the pump device 800, as previously described herein. In many embodiments, the pump device 800 analyzes the measurement data (eg, using suitable built-in hardware and / or software) and transmits the analysis results to the computing device 805 or server 810. Alternatively, the measurement data can be analyzed by computing device 805 or server 810, such as using one or more applications. A computing device 805 or server 810 may be associated with data storage for storage of measurement data and / or analysis results.

The application (of computing device 805 or server 810) also collects and aggregates measurement data and / or analysis results, as described earlier in this specification, in a suitable format (eg, chart, table, graph, image). Etc.) can be displayed to the user. Preferably, the application allows the user to overlay information such as lifestyle choices, meals, and strategies to increase breast milk output to facilitate comparison of such information with milk output statistics. , Including additional features. The analysis and display functionality described herein may be performed by a single entity or any suitable combination of entities. For example, in many embodiments, data analysis can be performed by server 810 and the analysis results can be transmitted to pump device 800 or computing device 805 for display to the user.

In addition, the computing device 805 or server 810 may be configured to power the pump device 800 or a portion thereof (eg, the actuation assembly 820), such as power, applied reduced pressure

(via the interface 815), or cycles per minute. An application configured to control at least one functionality can be included. For example, the communication module 830 can receive control signals from the computing device 805 and / or the server 810 and transmit the control signals to the actuation assembly 820 to effect the desired actuation. In a preferred embodiment, the control signal is based on the measurement data provided by the sensing unit 825, using feedback provided by the pump device 800 as such feedback, as previously described herein. Can be generated. In addition, the computing device 805 or server 810 may implement machine learning techniques for controlling the pump device 800 to improve and optimize pump performance over time.

Further, the pump device 800, the computing device 805, and / or the server 810 can be configured to provide a reminder to the user to milk the breast milk. Such notifications can help avoid loss of pump sessions and thus reduce the occurrence of associated complications such as mastitis. The notification may be generated based on previously collected milking data for breast milk, such as data regarding milking frequency and / or timing of previous pump sessions, and based on user preferences. Preferably, the notification functionality is included in a suitable application that runs on computing device 805 or server 810. For example, the pump device 800 sends information about the pump usage time to the computing device 805 or server 810 so that the application can identify when the pumping has occurred and identify the reminder at the desired pump time. can do.

Notifications can be provided using any suitable method and in any suitable form. For example, the notification is generated by computing device 805 or server 810 and transmitted to pump device 800 (eg, communication module 830) and displayed to the user (eg, on the display of pump device 800 such as display screen 505).)be able to. Conversely, the notification can be generated by pump device 800 and transmitted to computing device 805 and / or server 810. In many embodiments, the notification is displayed to the user by the computing device 805. Alternatively, pump device 800, computing device 805, and / or server 810 can use other methods to provide notifications to the user. For example, the notification can be sent to an email address, via a short message service (SMS) to a smartphone or other mobile device associated with a mobile phone number, or to a web page accessible by the user.

Other types of data can also be transmitted between pump device 800, computing device 805, and / or server 810. For example, in many embodiments, firmware updates for one or more components of pump device 800 can be transmitted from computing device 805 and / or server 810 to pump device 800.

FIG. 17 illustrates another exemplary embodiment of a system for monitoring milking or other fluids of breast milk. The system 1700 includes a pump unit 1702, a distal assembly 1706 (sometimes referred to herein as an interface), a wireless communication transmitter and receiver 1709, 1712, a computing device 1714, a remote server. 1718. The pump unit 1702 may be any of the pump units described herein or known in the art, and the distal assembly 1708 may also be described herein. Or any of those known in the art. Distal assembly 1706 is preferably sized and shaped to match the target anatomy, which in this exemplary embodiment is breast 1708. Pump unit 1702 operates distal assembly 1706 1704 to produce milk from breast 1708 using any of the activation mechanisms disclosed herein. The transmitter 1709 is preferably disposed on or adjacent to the pump unit and is configured to transmit data 1710 from the pump unit to a receiver 1712 on the computing device 1714. Data may be transmitted wirelessly using methods known in the art, such as those disclosed herein. In an alternative embodiment, a wired connection, such as with a USB cable, may be used to operably couple pump 1702 and computing device 1714 together. The computing device may be a smartphone, tablet, personal computer, or any other electronic computing device that can display data transmitted from the pump unit 1702. The computing device may also send information back to the

pump unit to help control the operation of the distal assembly. Computing device 1714 may also communicate 1716 with remote server 1718, which may store or display data. Access to remote service 1718 may be by the Internet or other means known in the art, so that cloud-based data can be easily accessed from any other device using internet access. obtain.

FIG. 18 illustrates another exemplary embodiment of a system 1800 for milking milk. In this embodiment, system 1800 includes a pump unit 1802, a distal assembly 1806, and a cloud-based or remote server 1812. The pump unit 1802 can be any of the pumps disclosed herein and is operably coupled to a distal assembly 1806 that is sized and shaped to match a target, such as a breast 1808. . The distal assembly may be any of the distal assemblies described herein. Pump unit 1802 activates the distal assembly 1804 using any of the mechanisms disclosed herein to produce milk from breast 1808. Pump unit 1802 also includes a transmitter and receiver 1809 for transmitting pump data 1810 to remote server 1812, which in this embodiment is a cloud-based server. Thus, data may be transmitted to a remote service via the internet and accessed from a cloud-based server via the internet by pump 1802 or any other computing device. Preferably, communication with the cloud-based server is performed by wireless communication.

19A-19C illustrate an exemplary computing device display 1904. FIG. For example, FIG. 19A illustrates an exemplary display on the mobile phone 1902 and schematically illustrates breast milk production, time of the last pump session, goal achievement graphics, and graphics illustrating user fluid consumption. In addition, display 1904 may also provide user incentives or user feedback based on the amount of milk production. FIG. 19B is an enlarged view of the display 1904 in FIG. 19A. FIG. 19C illustrates additional information that the display 1904 may show when the touch screen is activated (eg, by swiping or touching the screen). For example, the milked milk volume is shown after the "Final Pump Session" section of the display is selected. Some or all items may be expanded as shown in FIG. 19C as well. Additional information, or in some situations, less information may be displayed as desired.

20A-20B illustrate another exemplary display that may be used in a breast milking system. For example, FIG. 20A is an exemplary display 2002 on any of the computing devices disclosed herein and operably coupled with any of the pump units described herein. The display may show the average volume of breast milk milked over any period, along with the average duration of the milking session during that same period. Graphics (eg, bar charts, pie charts, xy plots, etc.) may be used here to show the milked volume during individual sessions over the course of several days from Monday to Friday. The display may allow the user to annotate the display so that a lost session may be considered if, for example, the session is omitted due to travel, the display may be May indicate a trip. Other annotations may also be added here, such as when a food or nutritional supplement is taken, which is hops or fenugreek. This allows the user to remind when a milked milk sample is obtained for consumption of food or nutritional supplements. The display may have other function buttons such as seeking advice, accessing the cloud, setting an alarm, taking notes, storing data, or establishing system preferences. Communication between the computing device and the pump unit in FIGS. 20A-20B is discussed more fully above with respect to FIG.

FIG. 20B illustrates an exemplary display 2004 that may be on a computing device in the system or, more preferably, on any of the pumps disclosed herein. The display 2004 is similar to a dashboard gauge and shows the volume and time of the milked and collected fluid. Other information may also be displayed.

Experimental Data FIGS. 15 and 16 illustrate experimental pump operation data obtained from a commercial breast pump device and an exemplary embodiment of the present invention. The

exemplary embodiment utilizes an incompressible fluid for pumping and has a maximum hydraulic fluid volume of 4 cc, while commercially available devices utilize air for pumping and have a maximum volume of 114 cc. did.

FIG. 15 illustrates a graph of pump performance as quantified by the reduced pressure generated per stroke. For the exemplary embodiment, pressure measurements are made on fluid volumes 1 cc, 2 cc, 3 cc, and 4 cc displaced by the pump, and the stroke number corresponds to volume cc. For commercially available devices, one of seven equally spaced positions along the vacuum adjustment gauge representing 46 cc, 57 cc, 68 cc, 80 cc, 91 cc, 103 cc, and 114 cc of the fluid volume displaced by the pump, respectively. Measurement is performed using a pump set to, and the stroke number corresponds to the position number. Curve 700 corresponds to an exemplary embodiment and curve 705 corresponds to a commercially available device. The exemplary embodiment produced higher levels of reduced pressure per displacement volume compared to commercially available devices, with the highest reduced pressure being -240.5 mmHg and -177.9 mmHg, respectively.

FIG. 16 illustrates a graph of pump efficiency as measured by maximum reduced pressure per maximum volume of displaced fluid, with bar 710 corresponding to an exemplary embodiment and bar 715 corresponding to a commercially available device. . The exemplary embodiment demonstrated a 42-fold increase in pump efficiency compared to commercially available devices, with efficiencies of −71.1 mmHg / cc and −1.7 mmHg / cc, respectively.

The various techniques described herein may be partially or fully performed using code that can be stored on storage media and computer-readable media and that can be executed by one or more processors of a computer system. May be implemented. Storage media and computer readable media containing code or part of code include: RAM, ROM, EEPROM, flash memory or other memory technology, CD-ROM, digital versatile disc (DVD) or other optical storage, magnetic cassette, Magnetic tape, magnetic disk storage or other magnetic storage device, solid state drive (SSD) or other solid state storage device, or can be used to store desired information and accessed by system devices Implemented in any method or technique for storing and / or transmitting information such as computer readable instructions, data structures, program modules, or other data, including any other medium Not volatile and non-volatile Nonvolatile, including storage media and communication media, such as removable and non-removable media, may include any suitable medium that is known or used in the art. Based on the disclosure and teachings provided herein, one of ordinary skill in the art may appreciate other ways and / or methods to implement various embodiments.

It should be understood that different aspects of the present invention may be recognized individually, collectively, or in combination with each other. Any suitable element or feature of the embodiments described herein can be combined with or substituted for the element or feature of any other embodiment.

While preferred embodiments of the present invention have been shown and described herein, it will be appreciated by those skilled in the art that such embodiments are presented by way of example only. Many variations, modifications, and alternatives can now be devised by those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein can be used to practice the invention. The following claims are intended to define the scope of the invention, and the methods, configurations, and equivalents within the scope of these claims are intended to be encompassed thereby.

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Family To Family Citations				
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Priority And Related Applications

Priority Applications (3)

Application	Priority date	Filing date	Title
US201461937027P	2014-02-07	2014-02-07	*US Provisional Application*
US61/937,027		2014-02-07	
PCT/US2015/014901	2014-02-07	2015-02-06	Methods, apparatus, and system for expression of human breast milk

Concepts

machine-extracted

Download Filter table

Name	Image	Sections	Count	Query match
human milk		title,claims,description	76	0.000
Breast		claims,abstract,description	176	0.000
Milk		claims,abstract,description	61	0.000
milk		claims,abstract,description	56	0.000
milk		claims,abstract,description	56	0.000
fluid		claims,description	156	0.000
measurement		claims,description	75	0.000
Milk, Human		claims,description	71	0.000
communication		claims,description	67	0.000
analytical method		claims,description	38	0.000
activating		claims,description	8	0.000
controlling effect		claims,description	7	0.000
displacement reaction		claims,description	6	0.000
absorption reaction		claims,description	4	0.000
Colostrum		claims,description	3	0.000
colostrum		claims,description	3	0.000

Show all concepts from the description section

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Electronic Patent Application Fee Transmittal

Application Number:	17181057
Filing Date:	22-Feb-2021
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Filer:	Anupma Sahay/Renee Bennett
Attorney Docket Number:	4944.0120006

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	130	130
		Total in USD ($)		**130**

Electronic Acknowledgement Receipt	
EFS ID:	46632776
Application Number:	17181057
International Application Number:	
Confirmation Number:	4690
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	26111
Filer:	Anupma Sahay/Renee Bennett
Filer Authorized By:	Anupma Sahay
Attorney Docket Number:	4944.0120006
Receipt Date:	16-SEP-2022
Filing Date:	22-FEB-2021
Time Stamp:	16:47:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$130
RAM confirmation Number	E20229FG48081468
Deposit Account	
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The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	2022-09-16-IDS_Transmittal_4944-0120006.PDF	222882 ca8762094b02f19f8b1610652a757453f74573dd	no	1
Warnings:					
Information:					
2	Transmittal Letter	2022-09-16-IDS-Pleading-4944-0120006.pdf	103253 eef2733232d207cc198e6e2607a9f40da811aeed	no	2
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	2022-09-16-IDS-SB08a-4944-0120006.pdf	171431 e11f4562794d91d0166c7a52dc98a57164dbb021	no	2
Warnings:					
Information:					
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4	Foreign Reference	FP1_JP2007501673A.PDF	1047933 ded1cff23953f063a92ff6b940b429861238b620	no	56
Warnings:					
Information:					
5	Foreign Reference	FP2_JP2014529312A.PDF	502800 85aca051c5292465ee8a0d28fda804d31c2603d6	no	28
Warnings:					
Information:					
6	Foreign Reference	FP3_JP2016514516A.PDF	568791 5010bc4d9e8d89fbde11360d405db7b6a01ab5ff	no	32
Warnings:					

Information:					
7	Foreign Reference	FP4_JP2017509379A.PDF	1442845 4361e48dfc0bfc140b4793248b976d2904431915	no	73
Warnings:					
Information:					
8	Fee Worksheet (SB06)	fee-info.pdf	37817 19fe2b8f34f4292f0b320c70487211c3a02e3d65	no	2
Warnings:					
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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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Document Description: Transmittal Letter

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	COURTNEY B FREDRICKSON
Attorney Docket Number	4944.0120006

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
- ☑ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☑ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

Copies of cited documents FP1-FP4.

Remarks

The Office may charge any fee deficiency for any submission made with this transmittal to Deposit Account No. 19-0036.

Online Payment Authorization for $130.00 to cover the IDS fee

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Anupma Sahay #78,704/		
Printed name	Anupma Sahay		
Date	September 16, 2022	Reg. No.	78,704

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I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: CHIARO TECHNOLOGY LIMITED	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, COURTNEY B
Filing Date: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Supplemental Information Disclosure Statement

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

Listed on accompanying IDS Form PTO/SB/08a or its equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Applicant has listed publication dates on the attached IDS Form based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

Filing under 37 C.F.R. § 1.97(c). This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on

the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application.

The required fee is provided through online credit card payment authorization in the amount of **$130.00** in payment of the fee under 37 C.F.R. § 1.17(p).

Copies of documents **FP1-FP4** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2)(ii), no copies of the U.S. patent application publications cited as documents **US1-US3** on the attached IDS Form are submitted.

It is expected that the examiner will review the prosecution and cited art in the parent Application No. 16/009,547, filed June 15, 2018 (now U.S. Patent No. 10,926,011) in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Anupma Sahay #78,704/

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Date: September 16, 2022

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: Chiaro Technology Limited	Art Unit: 3783
Application No.: 17/181,057	Examiner: FREDRICKSON, Courtney B.
Filed: February 22, 2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Amendment and Reply Under 37 C.F.R. § 1.111

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

In reply to the Office Action dated January 26, 2022, Applicant submits the following amendment and remarks.

If extensions of time are necessary to prevent abandonment of this application, then they are petitioned for under 37 C.F.R. § 1.136(a). Any additional fees required to continue prosecution or appeal of this application (including issue fee, fees for net addition of claims or forwarding to appeal) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently amended) A breast pump device ~~that is configured as a self-contained, in-bra wearable device,~~ comprising:

a self-contained, in-bra wearable device comprising:

~~(i)~~ a housing comprising: ~~that includes~~

~~(a)~~ a battery, and

~~(b)~~ a pump configured to generate ~~generating~~ negative air pressure;

~~(ii)~~ a breast shield of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing, the breast shield comprising ~~made up of~~ a breast flange and a nipple tunnel comprising a side wall and a front end, wherein ~~in which~~ the breast shield is transparent or optically clear; and

~~(iii)~~ a milk container ~~that is~~ configured to be attached to and removed from the housing,

wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast.

2. (Canceled)

3. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast shield is rigid.

4. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast shield is a dishwasher safe, plastic breast shield.

5. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast shield is configured to be attached using magnets to the housing.

6. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast.

7. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast shield is configured to present[[s]], in use, a single continuous surface to a nipple and a breast.

8. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which the breast shield integrates~~ the breast flange and the nipple tunnel are integrally formed ~~as a single item~~.

9. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast shield is configured to be generally symmetrical about a center-line ~~centre-line~~ running from a top to a bottom of the breast shield when positioned upright for normal use.

10. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast shield is configured to slide into the housing with a single push action.

11. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast shield is configured to slide out from the housing, together with a membrane that is configured to prevent[[s]] milk from flowing into the pump.

12. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the milk container is rigid.

13. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the milk container is an optically clear, dishwasher safe, plastic milk container.

14. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein the ~~in which~~ milk container is configured to attach[[es]] to a lower part of the housing and forms a base of the breast pump device.

15. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the milk container is configured to magnetically attach to the housing.

16. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the nipple tunnel comprises ~~includes~~ guide lines running parallel along one or more sides of the nipple tunnel.

17. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the nipple tunnel comprises ~~includes~~ an air hole or passage, and wherein the pump is configured to transfer[[s]] negative air pressure into the nipple tunnel via the air hole or passage.

18. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the nipple tunnel comprises ~~includes~~ on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container.

19. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the pump comprises ~~includes~~ one or more piezo air pumps.

20. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the housing further comprises ~~includes~~ a Universal Serial Bus (USB) charging socket.

21. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the housing comprises ~~includes~~ a left or right breast selector or toggle switch that, when selected

for a particular pumping session, is configured to send[[s]] data to a connected application configured to track pumping sessions, to indicate whether that particular session is associated with a left or a right breast.

22. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the housing is configured to be shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra.

23. (Canceled).

24. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast pump device is configured to deliver a maximum suction of approximately 240_mmHg.

25. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast pump device comprises ~~includes~~ a sensor that is configured to directly measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container.

26. (Canceled)

27. (Canceled)

28. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the pump is configured to deliver[[s]] in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

29. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the pump is a lightweight air pump that enables a total mass of the breast pump device, unfilled with milk, to be less than 250 gm.

30. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein ~~in which~~ the breast pump device is configured to make ~~makes~~ less than 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

31. (Currently amended) A kit, comprising:

the breast pump device of claim ~~Claim~~ 1; and

the plurality of interchangeable breast shields.

32. (Currently amended) The kit of claim ~~Claim~~ 31, wherein each of the plurality of interchangeable breast shields comprises ~~includes~~ fit lines in a nipple tunnel of that breast shield that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel.

33. (Currently amended) The breast pump device of claim ~~Claim~~ 1, wherein the battery is a rechargeable battery, and wherein the housing further comprises: ~~includes (c)~~

a power charging circuit configured to control ~~for controlling~~ the charging of the rechargeable battery, and

~~(d)~~ control electronics configured to be powered by the rechargeable battery.

34. (New) The breast pump device of claim 1, wherein length from the breast flange to the front end of each of the nipple tunnels of the plurality of interchangeable breast shields is the same.

Remarks

Upon entry of the foregoing amendment, claims 1, 3–22, 24–25, and 28–34 are pending in the application. Claim 1 is an independent claim. Claims 1, 3–22, 24–25, and 28–34 are amended. Claim 2 is canceled without prejudice or disclaimer. New claim 34 is added. These changes do not introduce any new matter, and Applicant respectfully requests their entry.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Office reconsider and withdraw all outstanding objections and rejections.

Allowable Subject Matter

The Office indicates claim 28 is allowable over the prior art of record excepting the double patenting rejection of the same. (Office Action dated January 26, 2022, p. 53.) Applicant appreciates the Office's indication that claim 28 would be allowable if the double patenting rejection is overcome. (*Id.*) For at least the reasons discussed below, all pending claims are allowable over the cited art.

Claim Objections

The Office objects to claims 14, 28, and 29 because of alleged informalities. (*Id.*, 2.) Without acquiescing to the propriety of the objections and in an effort to expedite prosecution, Applicant amends claims 14, 28, and 29 to recite "the milk container," recite "the pump is configured to deliver," and to end in a period, respectively. Accordingly, Applicant asks the Office to withdraw the objections to claims 14, 28, and 29.

Rejections under 35 U.S.C. § 103

The Office rejects claim 1 under 35 U.S.C. § 103 as allegedly obvious over U.S. Publication No. 2008/0275386 to Myers in view of U.S. Publication No. 2014/0378895 to Barack. (*Id.*, 4.) The Office also rejects claim 1 under 35 U.S.C. § 103 as allegedly obvious over U.S. Publication No. 2013/0023821 to Khalil *et al.* in view of Myers and Barack. (*Id.*, 8.)

Without acquiescing to the propriety of the rejection and in an effort to expedite prosecution, Applicant amends claim 1. For at least the reasons discussed below, Khalil, Myers, and Barack,

alone or in combination, do not disclose or suggest the features of claim 1, and do not render obvious claim 1 or its dependents.

Independent Claim 1

Claim 1 recites, in part, "wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast." The Office acknowledges that Myers and Khalil do not teach or disclose "the breast shield being of a plurality of interchangeable breast shields each having a different size." (*Id.*, 5, 9.) Instead, the Office relies on Barack as allegedly teaching "interchangeable breast shields each having a different size." (*Id.* (citing Barack, ¶[0054]).) However, Barack's limited disclosure simply states that says that one breast shield with one tunnel size may be switched with another breast shield with another tunnel size. (Barack, ¶[0054].) Barack fails to disclose or suggest how the tunnel sizes are different, let alone that the tunnel sizes provide "a different spacing of a nipple from the side wall of the nipple tunnel," as claimed.

Accordingly, Khalil, Myers, and Barack, alone or in combination, fail to disclose or suggest "wherein the plurality of interchangeable breast shields are each configured to provide a different spacing of a nipple from the side wall of the nipple tunnel when each of the plurality of interchangeable breast shields is placed onto a breast" and do not render claim 1 obvious. Applicant asks the Office to withdraw the § 103 rejections of claim 1.

Dependent Claims

The Office rejects claims 2–3, 6–8, 10, 11, 14, 16–18, 22, 24, and 31 under 35 U.S.C. § 103 as allegedly obvious over Myers in view of Barack. (Office Action dated January 26, 2022, p. 4.) Claim 2 is canceled rendering its rejection moot. Claims 3, 6–8, 10–11, 14, 16–18, 22, 24, and 31 depend from and add features to claim 1. Accordingly, claims 3, 6–8, 10–11, 14, 16–18, 22, 24, and 31 are allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claims 3, 6–8, 10–11, 14, 16–18, 22, 24, and 31.

The Office rejects claim 4 under 35 U.S.C. § 103 as allegedly obvious over Myers in view of Barack, as applied to claim 1 above, and further in view of U.S. Publication No. 2016/0296682 to

Phillips *et al.*, as evidenced by U.S. Publication No. 2005/0228342 to Yuen. (*Id.*, 7.) Claim 4 depends from and adds features to independent claim 1. Phillips and Yuen do not overcome the deficiencies discussed above. Accordingly, claim 4 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 4.

The Office rejects claims 2, 6–10, 14, 17, 18, 20–22, and 31 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and Barack. (*Id.*, 8.) Claim 2 is canceled rendering its rejection moot. Claims 6–10, 14, 17, 18, 20–22, and 31 depend from and add features to claim 1. Accordingly, claims 6–10, 14, 17, 18, 20–22, and 31 are allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claims 6–10, 14, 17, 18, 20–22, and 31.

The Office rejects claim 5 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of U.S. Publication No. 2018/0333523 to Chang. (*Id.*, 13.) Claim 5 depends from and adds features to independent claim 1. Chang does not overcome the deficiencies discussed above. Accordingly, claim 5 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 5.

The Office rejects claims 12 and 13 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Phillips. (*Id.*, 13.) Claims 12–13 depend from and add features to independent claim 1. Phillips does not overcome the deficiencies discussed above. Accordingly, claims 12–13 are allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claims 12–13.

The Office rejects claim 15 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of U.S. Publication No. 2007/0228059 to Karsan. (*Id.*, 15.) Claim 15 depends from and adds features to independent claim 1. Karsan does not overcome the deficiencies discussed above. Accordingly, claim 15 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 15.

The Office rejects claim 19 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of U.S. Publication No. 2012/0277636 to Blondheim *et al.* (*Id.*, 16.) Claim 19 depends from and adds features to independent claim 1. Blondheim does not overcome the deficiencies discussed above. Accordingly, claim 19 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 19.

The Office rejects claim 25 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of U.S. Publication No. 2016/0220743 to Guthrie *et al.* (*Id.*) Claim 25 depends from and adds features to independent claim 1. Guthrie does not overcome the deficiencies discussed above. Accordingly, claim 25 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 25.

The Office rejects claim 29 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of U.S. Patent No. 6,227,936 to Mendoza. (*Id.*, 17.) Claim 29 depends from and adds features to independent claim 1. Mendoza does not overcome the deficiencies discussed above. Accordingly, claim 29 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 29.

The Office rejects claim 30 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, in further view of U.S. Publication No. 2009/0281485 to Baker *et al.* (*Id.*, 18.) Claim 30 depends from and adds features to independent claim 1. Baker does not overcome the deficiencies discussed above. Accordingly, claim 30 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 30.

The Office rejects claim 32 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and in further view of Barack, as applied to claim 31 above, in further view of U.S. Publication No. 2012/0165729 to Cudworth. (*Id.*, 18.) Claim 32 depends from and adds features to independent claim 1. Cudworth does not overcome the deficiencies discussed above. Accordingly, claim 32 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 32.

The Office rejects claim 33 under 35 U.S.C. § 103 as allegedly obvious over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, in further view of U.S. Patent No. 5,542,921 to Meyers *et al.* (*Id.*, 19.) Claim 33 depends from and adds features to independent claim 1. Meyers does not overcome the deficiencies discussed above. Accordingly, claim 33 is allowable for at least the reasons that independent claim 1 is allowable. Applicant asks the Office to withdraw the § 103 rejection of claim 33.

Double Patenting Rejections

The Office rejects claims 1–22, 24, 25, and 29–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of U.S. Patent No. 10,881,766 in view of Khalil, Myers, and Barack. (*Id.*, 21.) The Office rejects claims 1–22, 24, 25, and 28–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of U.S. Patent No. 10,926,011 in view of Khalil, Myers, and Barack. (*Id.*, 23.) The Office provisionally rejects claims 1–22, 24, 25, and 28–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,050. (*Id.*, 26.) The Office provisionally rejects claims 1–22, 24, 25, and 29–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,079. (*Id.*, 29.) The Office provisionally rejects claims 1–22, 24, 25, and 28–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,109. (*Id.*, 30.) The Office provisionally rejects claims 1–22, 24, 25, and 28–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,150. (*Id.*, 32.) The Office provisionally rejects claims 1–22, 24, 25, and 28–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,179. (*Id.*, 34.) The Office provisionally rejects claims 1–22, 24, 25, and 29–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,216. (*Id.*, 36.) The Office provisionally rejects claims 1–22, 24, 25, and 29–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,259. (*Id.*, 38.) The Office provisionally rejects claims 1–22, 24, 25, and 28–33 on the ground of nonstatutory double patenting as allegedly obvious over claims 1 and 31 of copending U.S. Application No. 17/203,292. (*Id.*, 39.) The Office provisionally rejects claims 1–22, 24, 25, and 28–33 on the ground

of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,313. (*Id.*, 41.) The Office provisionally rejects claims 1–22, 24, 25, and 29–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,327. (*Id.*, 43.) The Office provisionally rejects claims 1–22, 24, 25, and 29–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,355. (*Id.*, 45.) The Office provisionally rejects claims 1–22, 24, 25, and 29–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,384. (*Id.*, 47.) The Office provisionally rejects claims 1–22, 24, 25, and 29–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,397. (*Id.*, 49.) The Office provisionally rejects claims 1–22, 24, 25, and 29–33 on the ground of nonstatutory double patenting as allegedly obvious over claim 1 of copending U.S. Application No. 17/203,418. (*Id.*, 51.)

Application Nos. 17/203,109, 17/203,259, and 17/203,313 issued rendering the rejections with respect to these applications moot. Additionally, Applicant respectfully requests that the remaining currently asserted double patenting rejections be held in abeyance until the claimed subject matter is otherwise deemed allowable. After analyzing the final allowed claim scope, Applicant will consider filing a terminal disclaimer if necessary to overcome any obviousness-type double patenting rejections.

New Claim

New claim 34 is added. Claim 34 depends from and adds features to independent claim 1. Accordingly, claim 34 is allowable for at least the same reasons as claim 1.

Conclusion

All grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Office reconsider and withdraw them. A complete reply has been made to the outstanding Office Action. As such, the present application is in condition for allowance. If the Office believes, for any reason, that personal communication will expedite prosecution of this application, the Office is asked to telephone the undersigned at the number provided. Applicant respectfully requests prompt and favorable consideration of this amendment and reply.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Anupma Sahay #78,704/

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Date: July 12, 2022

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18100718.1

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	4944.0120006
	Application Number	17/181,057
Title of Invention	BREAST PUMP SYSTEM	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Inventor Information:

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	4944.0120006
	Application Number	17/181,057
Title of Invention	BREAST PUMP SYSTEM	

City	London	**State/Province**	
Postal Code	ECIN 8LE	**Country**	GB

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Anupma Sahay #78,704/			**Date (YYYY-MM-DD)**	2022-07-12
First Name	Anupma	**Last Name**	Sahay	**Registration Number**	78,704

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet | 1 | of | 4

Complete if Known	
Application Number	17/181,057
Filing Date	02-22-2021
First Named Inventor	O'TOOLE; Jonathan
Art Unit	3783
Examiner Name	COURTNEY B. FREDRICKSON
Attorney Docket Number	4944.0120006

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-D788293-S	05-30-2017	ECKSTEIN et al.	
	002	US-D809646-S	02-06-2018	MASON et al.	
	003	US-D832995-S	11-06-2018	MASON et al.	
	004	US-D888225-S	06-23-2020	ASKEM et al.	
	005	US-7641629-B2	01-05-2010	YUEN; Yat Keung William	
	006	US-10398816-B2	09-03-2019	CHANG et al.	
	007	US-10625005-B2	04-21-2020	CHANG et al.	
	008	US-20040127845-A1	07-01-2004	RENZ; Charles J. et al.	
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	010	US-20120021068-A1	01-26-2012	BARNESS; Itzhak et al.	
	011	US-20120035951-A1	02-09-2012	GOETZ; Steven M. et al.	
	012	US-20120043065-A1	02-23-2012	RANNE; Pasi et al.	
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	020	US-20170216505-A1	08-03-2017	KIM; Sang Ha	
	021	US-20180361040-A1	12-20-2018	O'TOOLE; Jonathan et al.	
	022	US-20210030934-A1	02-04-2021	ZHANG; Shu Ting	

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Attorney Docket Number	4944.0120006

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	WO-2016010524-A1	01-21-2016	HEWLETT PACKARD DEVELOPMENT CO [US]		☐

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Sheet 3 of 4

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NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author(in CAPITAL LETTERS),title of the article(when appropriate), title of the item (book,magazine,journal,serial,symposium,catalog,etc.),date,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
	001	4MD Medical, "Assembling Spctra Breast Pump Parts," YouTube [online], dated November13, 2016, URL: http://www.youtube.com/watch?v=ChV8xQfcBxU.	☐
	002	The Best Hands-Free Breast Pumps, posted at healthline.com, earliest date posted on 08/24/2020, [online], acquired on 10/30/2021, Available on internet. url:https://www.healthline.com/health/parenting/breast-feeding/best-hands-free-breast-pumps#Best-hands-free-breast-pumps (Year: 2020).	☐

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Sheet	4	of	4

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Examiner Name	COURTNEY B. FREDRICKSON
Attorney Docket Number	4944.0120006

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Anupma Sahay #78,704/	Date (YYYY-MM-DD)	2022-07-12
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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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Declarations under Rule 4.17:

— *as to the identity of the inventor (Rule 4.17(i))*

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

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(54) Title: VIRTUAL KEYBOARD

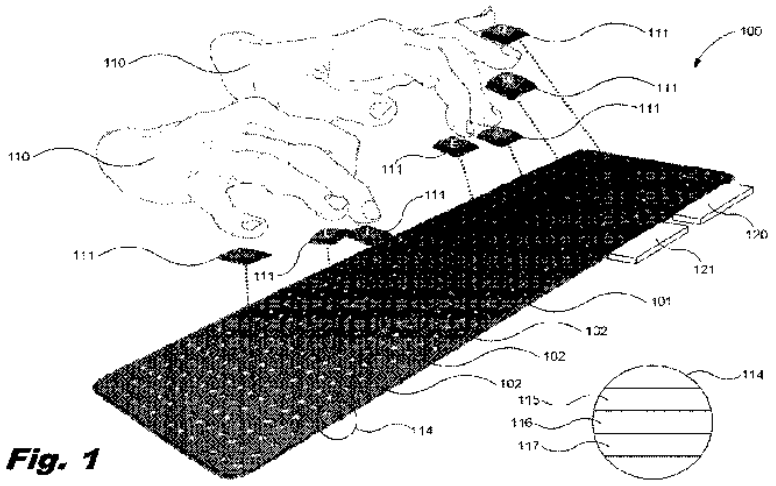


Fig. 1

(57) Abstract: A virtual keyboard includes a pad, a number of motion sensors coupled to the pad to detect the presence of a user's hands over the pad, a processor, and a memory. The memory includes executable code that, when executed by the processor calibrates the virtual keyboard based on a number of criteria of the user's hand upon detection of the user's hands by the motion sensors, in which the criteria comprises the user's unique keyboard profile.

WO 2016/010524 A1

VIRTUAL KEYBOARD

BACKGROUND

[0001] Computer keyboards are typewriter-style devices that use an arrangement of buttons or keys with a number of alphanumeric characters, graphemes, symbols, and other types of characters printed or engraved on the buttons or keys. The buttons and keys act as mechanical levers or electronic switches that cause input of a character to a computing device or otherwise control a computing device to which the keyboard is communicatively coupled. Keyboards, however, are bulky and are not easily mobile. Keyboards also contain mechanical parts that are easily broken. In addition, a user of a keyboard must strike the buttons or keys as they are laid out on the keyboard with no ability to fit the layout of the keyboard to a user. Even if customized keyboards were produced, such customized keyboards would be disadvantageous in shared computing environments such as workshops and call centers were several individuals may use the same keyboard. Further, keyboards provide no form of user authentication to secure and protect data on an associated computing device from unauthorized access. Still further, keyboards increase the potential to suffer from injuries or illnesses such as carpal tunnel syndrome or other repetitive strain injury and illness due to the extensive spread of bacteria.

BRIEF DESCRIPTION OF THE DRAWINGS

[0002] The accompanying drawings illustrate various examples of the principles described herein and are a part of the specification. The illustrated

examples are given merely for illustration, and do not limit the scope of the claims.

[0003] Fig. 1 is a perspective view of the virtual keyboard, according to one example of the principles described herein.

[0004] Fig. 2 is a block diagram of a virtual input computing system for processing data obtained from the virtual keyboard of Fig. 1, according to one example of the principles described herein.

[0005] Fig. 3 is a flowchart showing a method of calibrating the virtual keyboard, according to one example of the principles described herein.

[0006] Fig. 4 is a flowchart showing a method of processing signals from the virtual keyboard, according to one example of the principles described herein.

[0007] Fig. 5 is a flowchart showing a method of processing authentication signals from the virtual keyboard, according to one example of the principles described herein.

[0008] Throughout the drawings, identical reference numbers designate similar, but not necessarily identical, elements.

DETAILED DESCRIPTION

[0009] The present systems and methods provide a virtual keyboard that detects user's hands over the virtual keyboard and maps a number of virtual input keys to the user's hands and builds a unique keyboard profile for authentication purposes and character entry. The virtual keyboard is communicatively coupled to a computing device to provide for data input to the computing device control the computing device to which the virtual keyboard is communicatively coupled. The virtual keyboard comprises a pad, a number of motion sensors coupled to the pad to detect the presence of a user's hands over the pad, and a tracking system to track hand and finger movements of the user's hand. In this manner, the user does not touch any hardware device when utilizing the virtual keyboard. Detection of the user's hands by the motion sensors activates the tracking system. The tracking system comprises a

number of wave detectors to detect wavelengths reflected off the user's hands. The wave detectors may, for example, detect electromagnetic wavelengths or acoustical frequencies. The virtual keyboard may be calibrated to a user's hand positioning, hand size, or any other criteria to define a keyboard profile unique to that user. This keyboard profile may be used to identify the user as well as provide a number of security and access controls.

[0010] As used in the present specification and in the appended claims, the term "a number of" or similar language is meant to be understood broadly as any positive number comprising 1 to infinity; zero not being a number, but the absence of a number.

[0011] In the following description, for purposes of explanation, numerous specific details are set forth in order to provide a thorough understanding of the present systems and methods. It will be apparent, however, to one skilled in the art that the present apparatus, systems, and methods may be practiced without these specific details. Reference in the specification to "an example" or similar language means that a particular feature, structure, or characteristic described in connection with that example is included as described, but may not be included in other examples.

[0012] Fig. 1 is a perspective view of the virtual keyboard (100), according to one example of the principles described herein. The user's hands and fingers (110) are depicted in Fig. 1 above the pad (101). A number of keys (111) are depicted in Fig. 1 to depict how movements of the user's hands and fingers (110) over an area of the pad (101) virtually activate the input of a character or otherwise control a computing device to which the pad (101) is communicatively coupled much like activation of keys (111) of a non-virtual keyboard function.

[0013] The pad (101) may be shaped or sized approximately similar to a non-virtual keyboard. In another example, the pad (101) may be larger or smaller than a non-virtual keyboard. A number of sensing devices (102) are included in the pad (101) to detect the presence of the user's hands and fingers (110) over the pad (101), to track the hand and finger movements of the user's hands and fingers (110), and to detect tissue density of the user's hands and

fingers (110), to detect palm and fingerprints of the user's hands and fingers (110), and to create and store a keyboard profile of a user, among other functions as will be described in more detail below.

[0014] The sensing devices (102) may be located along the surface of the pad (101) as depicted in Fig. 1 in a pattern to provide homogeneous and uniform coverage along the surface of the pad (101). The sensing devices (102) are depicted as bumps along the surface of the pad (101). In one example, the sensing devices (102) may be any type of sensor device that can detect the presence of the user's hands and fingers (110) over the pad (101), track the hand and finger movements of the user's hands and fingers (110), and/or detect a keyboard profile of a user, among other functions. The sensing devices (102) may be, for example, video-based devices that capture video data for processing in the manner described herein, image-based devices that capture image data for processing in the manner described herein, electromagnetic-based devices that use electromagnetic waves and light detectors such as, for example, photodiodes to detect movement, acoustic-based devices such as an ultrasonic-based device that produce acoustical waves and detect the acoustical frequencies reflected from an object, backscatter x-ray devices to detect radiation reflected from the hands and fingers (110), or other types of motion and tracking devices.

[0015] As to the ultrasonic-based device, this type of device may detect the position and motion of the user's hands and fingers (110), as well as the tissue density of the user's hands and fingers (110) for authentication and security purposes. As to the electromagnetic-based devices, this type of device may use light-emitting diodes (LEDs), lasers, infrared light emitters, or other types of electromagnetic wave propagation devices.

[0016] In one example, the sensing devices (102) may be protected by a layer of flexible material such as, for example, silicone that allows the pad (101) to be rolled up or folded for storage and mobility. In one example as depicted in the call-out circle (114), the pad (101) may comprise a top layer (115) of silicone, a middle layer (116) in which the sensor devices (102) and associated wiring are disposed, and a bottom layer (117) of silicone. Although the top layer

(115) and bottom layer (117) are described as being made of silicone, any other insulating, flexible material may be used to house the array of sensor devices (102) and associated wiring.

[0017] The pad (101) may further include a communication module (120) to provide communication with a computing device with which the pad (101) interacts with to manipulate the operation of the computing device. In one example, the communication module (120) may be a wired or wireless communication device. The types of communication utilized by the communication module (120) may include, for example, any communication type that supports any Open Systems Interconnection (OSI) model standardized communication type, any communication type that supports any Institute of Electrical and Electronics Engineers (IEEE) standardized communication type, BLUETOOTH communication types developed by the Bluetooth Special Interest Group, Ethernet communication types, WI-FI communication types as defined by the Wi-Fi Alliance, near field communication types, infrared communication types, among many other types of communications and their respective types of networks, or combinations thereof. The communication module (120) may be embedded within the pad (101) or communicatively coupled to the pad (101) as depicted in Fig. 1.

[0018] A power source (121) may also be coupled to the pad (101) to provide electrical power to the pad (101). The power module may provide AC or DC power to the pad. In the example of an AC power source, the power source (121) may be coupled to a wall outlet, the computing device with which the virtual keyboard (100) communicates, or other AC power supply. In the example of a DC power source, the power source may comprise a battery, a rechargeable battery, or other type of DC power supply. The power source (121) may also be a solar panel that directly powers the virtual keyboard (100) or indirectly powers the virtual keyboard (100) through charging a battery, for example.

[0019] In one example, the pad (101) of the virtual keyboard (100) may be built into or installed in a user's desk, a wall, the dashboard of a car, or other fixture.

[0020] Fig. 2 is a block diagram of a virtual input computing system (200) for processing data obtained from the virtual keyboard (100) of Fig. 1, according to one example of the principles described herein. The virtual input computing system (200) may be incorporated into the pad (101) of the virtual keyboard (100), may be a coupled to the virtual keyboard (100), may be a standalone computing device, or may be incorporated into a computing device to which the virtual keyboard (100) is communicatively coupled. In the example where the virtual input computing system (200) is incorporated into a computing device to which the virtual keyboard (100) is communicatively coupled, the various computing elements and resources provided by the virtual input computing system (200) may be part of the computing device, and the modules comprising executable program code used in the implementation of the virtual keyboard (100) and its associated functions may be stored within a data storage device of the computing device.

[0021] The virtual input computing system (200) may be utilized in any data processing scenario including, stand-alone hardware, mobile applications, through a computing network, or combinations thereof. Further, the virtual input computing system (200) may be used in a computing network, a public cloud network, a private cloud network, a hybrid cloud network, other forms of networks, or combinations thereof. In one example, the methods provided by the virtual input computing system (200) are provided as a service over a network by, for example, a third party. In this example, the service may comprise, for example, the following: a Software as a Service (SaaS) hosting a number of applications; a Platform as a Service (PaaS) hosting a computing platform comprising, for example, operating systems, hardware, and storage, among others; an Infrastructure as a Service (IaaS) hosting equipment such as, for example, servers, storage components, network, and components, among others; application program interface (API) as a service (APIaaS), other forms of network services, or combinations thereof. The present systems may be implemented on one or multiple hardware platforms, in which the modules in the system can be executed on one or across multiple platforms. Such modules can run on various forms of cloud technologies and hybrid cloud technologies or

offered as a SaaS (Software as a service) that can be implemented on or off the cloud. In another example, the methods provided by the virtual input computing system (200) are executed by a local administrator.

[0022] To achieve its desired functionality, the virtual input computing system (200) comprises various hardware components. Among these hardware components may be a number of processors (201), a number of data storage devices (202), a number of peripheral device adapters (203), and a number of network adapters (204). These hardware components may be interconnected through the use of a number of busses and/or network connections. In one example, the processor (201), data storage device (202), peripheral device adapters (203), and a network adapter (204) may be communicatively coupled via a bus (205).

[0023] The processor (201) may include the hardware architecture to retrieve executable code from the data storage device (202) and execute the executable code. The executable code may, when executed by the processor (201), cause the processor (101) to implement at least the functionality of detect the presence of the user's hands and fingers (110) over the pad (101), track the hand and finger movements of the user's hands and fingers (110), detect a keyboard profile of a user, and provide security and access controls to a computing device to which the virtual keyboard (100) is coupled among other functions according to the methods of the present specification described herein. In the course of executing code, the processor (201) may receive input from and provide output to a number of the remaining hardware units.

[0024] The data storage device (202) may store data such as executable program code that is executed by the processor (201) or other processing device. As will be discussed, the data storage device (202) may specifically store computer code representing a number of applications that the processor (201) executes to implement at least the functionality described herein.

[0025] The data storage device (202) may include various types of memory modules, including volatile and nonvolatile memory. For example, the data storage device (202) of the present example includes Random Access Memory (RAM) (206), Read Only Memory (ROM) (207), and Hard Disk Drive

(HDD) memory (208). Many other types of memory may also be utilized, and the present specification contemplates the use of many varying type(s) of memory in the data storage device (202) as may suit a particular application of the principles described herein. In certain examples, different types of memory in the data storage device (202) may be used for different data storage needs. For example, in certain examples the processor (201) may boot from Read Only Memory (ROM) (207), maintain nonvolatile storage in the Hard Disk Drive (HDD) memory (208), and execute program code stored in Random Access Memory (RAM) (206).

[0026] The data storage device (202) may comprise a computer readable medium, a computer readable storage medium, or a non-transitory computer readable medium, among others. For example, the data storage device (202) may be, but not limited to, an electronic, magnetic, optical, electromagnetic, infrared, or semiconductor system, apparatus, or device, or any suitable combination of the foregoing. More specific examples of the computer readable storage medium may include, for example, the following: an electrical connection having a number of wires, a portable computer diskette, a hard disk, a random access memory (RAM), a read-only memory (ROM), an erasable programmable read-only memory (EPROM or Flash memory), a portable compact disc read-only memory (CD-ROM), an optical storage device, a magnetic storage device, or any suitable combination of the foregoing. In the context of this document, a computer readable storage medium may be any tangible medium that can contain, or store computer usable program code for use by or in connection with an instruction execution system, apparatus, or device. In another example, a computer readable storage medium may be any non-transitory medium that can contain, or store a program for use by or in connection with an instruction execution system, apparatus, or device.

[0027] The hardware adapters (203, 204) in the virtual input computing system (200) enable the processor (201) to interface with various other hardware elements, external and internal to the virtual input computing system (200). For example, the peripheral device adapters (203) may provide an interface to input/output devices, such as, for example, display device (209), a

mouse, or a non-virtual keyboard in addition to the virtual keyboard (100). The peripheral device adapters (203) may also provide access to other external devices such as an external storage device, a number of network devices such as, for example, servers, switches, and routers, client devices, other types of computing devices, and combinations thereof.

[0028] The display device (209) may be provided to allow a user of the virtual input computing system (200) to interact with and implement the functionality of the virtual input computing system (200). In one example, an image of a keyboard (250) may be presented to a user of the virtual keyboard (100) on the display device (209). In this example, the user may input data through the user of the virtual keyboard (100), and the processor (201) may execute code to display to the user keystrokes associated with the hand movements of the user on the keyboard (250) displayed on the display device (209). The peripheral device adapters (203) may also create an interface between the processor (101) and the display device (109), a printer, or other media output devices.

[0029] In another example, the display device (209) may display the image of the keyboard (250) on the pad (101). In one example, the image of the keyboard (250) may be displayed on the pad (102) using a projection system to project the image of the keyboard (250) on the pad (101). In another example, a keyboard (250) may not be displayed on the pad (101).

[0030] In another example, the image of the keyboard (250) may be displayed on the pad (102) using a number of LEDs embedded within the pad (101). In this example, the LEDs light up to create a pattern in the pad. In one example, the pattern may be the pattern of a keyboard as arranged within a non-virtual keyboard. In another example, the pattern, although arranged similarly to a non-virtual keyboard, may be sized to fit the user's hand sizes, typing patterns, hand positioning during typing various keystrokes or keystroke combinations, or any hand positioning detected by the virtual keyboard (100) from an initial hand position through any subsequent hand position, keystroke or keystroke combination. Thus, in this example, the image of the keyboard as outlined on the pad (101) through lighting of the LEDs may look significantly

different from the tight and inline layout of a non-virtual keyboard and will fit to a user's distinct hand posturing, hand positioning, and keystroke style.

[0031] In still another example, the image of the keyboard (250) may be displayed on the pad (102) using a number of laser devices embedded within the pad (101) or that project light onto the pad (101). In this example, the laser devices function in a manner similar to the above-described LEDs. In one example, the display of the keyboard (250) on the display device (209) or the pad (101) as described above may be performed only during a keyboard profile calibration and learning phase as will be described in more detail below in order to assist a user in visualizing placement of keystrokes and help with typing while the user's keystrokes are being learned.

[0032] The network adapter (204) may provide an interface to other computing devices within, for example, a network, thereby enabling the transmission of data between the virtual input computing system (200) and other devices located within the network. In an example where the virtual input computing system (200) is incorporated into a computing device to which the virtual keyboard (100) is communicatively coupled, the network adapter (204) provides network connectivity with the virtual keyboard (100).

[0033] The virtual input computing system (200) may, when executed by the processor (101), display the number of graphical user interfaces (GUIs) on the display device (109) associated with the executable program code representing the number of applications stored on the data storage device (102). The GUIs may include aspects of the executable code including the displayed keyboard (250) described above. The GUIs may display, for example, a real time indication of which keys are being selected by a user of the virtual keyboard by presenting those keys in an activated state to the user on the GUI displayed on the display device (209). Examples of display devices (209) include a computer screen, a laptop screen, a mobile device screen, a personal digital assistant (PDA) screen, a tablet screen, and a touch screen, among other display devices (106).

[0034] The virtual input computing system (200) further comprises a number of modules used in the implementation of the virtual keyboard (100).

The various modules within the virtual input computing system (200) comprise executable program code that may be executed separately. In this example, the various modules may be stored as separate computer program products. In another example, the various modules within the virtual input computing system (200) may be combined within a number of computer program products; each computer program product comprising a number of the modules.

[0035] The virtual input computing system (200) may include a gesture calibration and learning module (210) to, when executed by the processor (201), calibrate user interactions with the virtual keyboard (100) and learn gestures used by the user in attempting to input data using the virtual keyboard (100). The a gesture calibration and learning module (210) may prompt a user to perform an initial calibration procedure in which the user is requested to demonstrate a number of keystrokes for detection by the pad (101). For example, the user may be prompted to demonstrate a home row hand gesture where the user places his or her hands above the pad (101) and positions his or her fingers as if the user were placing his or her hands and fingers on a home row of a keyboard. This provides the virtual input computing system (200) with data representing a home row position of the user and orients the home row keys and the remainder of the keys on the virtual keyboard (100) with respect to the home row gesture.

[0036] The gesture calibration and learning module (210) may also request a user to demonstrate a number of individual keystrokes. For example, the gesture calibration and learning module (210) may request a user to demonstrate keystrokes associated with each of the characters displayed on a keyboard or the keyboard (250) displayed on the display device (209). The gesture calibration and learning module (210) may also request a user to demonstrate a number of combination keystrokes where the user is requested to demonstrate instances where the user would simultaneously press two or more keys on a keyboard. For example, the "shift" key along with the "a" key to produce a capital "A." In this manner, the gesture calibration and learning module (210) may calibrate the virtual keyboard (100) for the user. The calibration is unique to that particular user. The gesture calibration and learning

module (210) may also learn a user's distinct hand posturing, hand positioning, and keystroke styles from the outset of that user utilizing the virtual keyboard (100) and throughout the user's use of the virtual keyboard (100). In this manner, the virtual keyboard adapts to the user's potentially changing hand posturing, hand positioning, and keystroke styles.

[0037] The gesture calibration and learning module (210) may perform calibration and learning techniques for a number of users of a particular virtual keyboard (100). This is advantageous in situations where a number of individuals have access to a particular computing device via the virtual keyboard (100) such as, for example, in a classroom setting where may groups of students utilize a set of computing devices. In one example, the gesture calibration and learning module (210) may begin calibration and learning for a particular user once the user logs onto a computing device coupled to the virtual keyboard (100). Thus, each user that logs into the computing device may be prompted to initiate a calibration and learning sequence to prepare and continue to fine-tune each user's individual and unique keyboard profile. Calibration and learning processes will be described in more detail below.

[0038] In one example, the gesture calibration and learning module (210) identifies an initial interaction by the user with the virtual keyboard (100) when the user interacts with any number of sensing devices (102) within the pad (101). The sensing devices (102) of the pad (101) may detect the initial interaction by the user and the gesture calibration and learning module (210) may identify that initial interaction as the position from which the user's keyboard profile is mapped. Thus, if a user presents his or her hands and fingers (110) on a left portion of the pad (101), then the virtual keyboard (100) and gesture calibration and learning module (210) maps the virtual keyboard (100) around the user's hands and fingers (110) from the left portion of the pad (101). In one example, the pad (101) may be larger than a non-virtual keyboard to accommodate for the possibility of this type of off-center initiation.

[0039] The virtual input computing system (200) may include a data input processing module (220) to, when executed by the processor (201), process a number of keystrokes a user performs on the virtual keyboard (100). The data

input processing module (220) receives input data from the virtual keyboard (100), and identifies a number of the inputs or a series of the inputs as being associated with keystrokes based on the calibrated and learned gestures obtained by the calibration and learning module (210). The data input processing module (220) may submit the identified inputs to a computing device to which the virtual keyboard (100) is coupled for controlling the computing device according to the identified inputs and commands.

[0040] The data input processing module (220) of the virtual input computing system (200) may also provide feedback to the user of the virtual keyboard (100). In one example, feedback may be provided to the user as the user types on the virtual keyboard (100). The feedback may be provided in the form of haptic feedback, audio feedback, visual feedback, or other types of feedback that indicate to the user that keystrokes are being made. In the example of haptic feedback, the pad (101) may include a rumble device to provide a tactile response when the user touches a certain portion of the pad (101) if the user were to touch the pad (101) during typing.

[0041] In the example of audio feedback, a speaker or other audio device may provide an audible noise when the user makes a keystroke in the space above the pad (101). In this example, the audible noise may mimic the sound of a key on a non-virtual keyboard being pressed, or make any other noise to indicate to the user that their keystrokes are being received by the virtual keyboard (100) and interpreted by the computing device to which the virtual keyboard (100) is coupled.

[0042] In the example of visual feedback, the computing device to which the virtual keyboard (100) is coupled may display the a keyboard (250) as described above, and provide feedback to the user that the display device (209) may indicate that keystrokes are being received by the virtual keyboard (100) and interpreted by the computing device to which the virtual keyboard (100) is coupled by changing an aspect of the displayed keyboard (250) such as lighting or filling in a key corresponding to the user's keystrokes.

[0043] A keyboard profile module (230) may also be included within the virtual input computing system (200) to, when executed by the processor (201),

identify, refine, amend or build on an individual user's unique keyboard profile. As described above, the user's unique keyboard profile may include information regarding the user's distinct hand posturing, hand positioning, and keystroke style. The keyboard profile module (230) may store each user's keyboard profile in memory such as the data storage device (202) or another data storage associated with the virtual keyboard (100).

[0044] The virtual input computing system (200) may include a security module (240) to, when executed by the processor (201), provide security to a computing device to which the virtual keyboard (100) is communicatively coupled. The security module (240) may detect an initial presence of a user's hands and fingers (110) over the pad (101) and within the detection range of the sensor devices (102). Once the user's hands and fingers (110) are detected, the security module (240) analyzes the user's hand posturing, hand positioning, keystroke style, the tissue density of the user's hands and fingers, the user's palm and fingerprints, other aspects of the movement and characteristics of the user's hands and fingers (110), and combinations thereof. Based on this analysis, the security module (240) compares these collected aspects of the user's hands and fingers (110) with keyboard profiles stored in memory. If the collected aspects of the user's hands and fingers (110) match a keyboard profile stored in memory, then the user is allowed access to the computing resources of the computing device to which the virtual keyboard (100) is communicatively coupled.

[0045] The security module (240) may also lock out a subsequent individual who attempts to gain access to the computing device while a first user is utilizing the virtual keyboard (110) and the computing device. For example, if a first user is logged onto the computing device and walks away from the computing device, the subsequent user's hand posturing, hand positioning, keystroke style, the tissue density of the subsequent user's hands and fingers, the subsequent user's palm and fingerprints, other aspects of the movement and characteristics of the subsequent user's hands and fingers (110) will not be recognized as the first user's keyboard profile and/or will not be recognized as a keyboard profile stored in memory. In this scenario, the virtual keyboard (100)

and the computing device will lock up or otherwise deny access. Once the first user who is authorized to access the computing device via the virtual keyboard (100) once again place his or her hands and fingers (110) over the pad (101) and within the detection range of the sensor devices (102) to compares the first user's collected aspects of the user's hands and fingers (110) with keyboard profiles stored in memory and provides access to the first user. Thus, the security module (240) detects an unauthorized keyboard profile, locks the computing device, and prompts a user to authenticate his or herself.

[0046] The modules described above (210, 220, 230, 240) may utilize a number of technologies to detect and track movement of the user's hands and fingers (110) above or within the vicinity of the pad (101). In one example, the modules (210, 220, 230, 240) may use motion tracking hardware and software developed and distributed by Leap Motion, Inc.

[0047] Software and drivers associated with the modules (210, 220, 230, 240) may be obtained from a network using the network adaptor (204), from a disk, or any other source. More details in connection with the calibration and learning module (210), the data input processing module (220), the keyboard profile module (230), and the a security module (240) will now be described in more detail in connection with Figs. 3 through 5.

[0048] Fig. 3 is a flowchart showing a method (300) of calibrating the virtual keyboard (100), according to one example of the principles described herein. The method of Fig. 3 may include determining (block 301), with the processor (201) executing the gesture calibration and learning module (210), whether the user's hands are detected. This determination (block 301) may be a condition by which waking the virtual keyboard and/or the computing device is achieved. If the user the user's hands are not detected (block 301, determination NO), then the method (300) loops back to determining (block 301) whether the user's hands are detected. If the user's hands are detected (block 301, determination YES), then the processor (201) executing the gesture calibration and learning module (210), determines (block 302) whether the user is a new user of the virtual keyboard (100). If the user is a new user of the virtual keyboard (100) (block 302, determination YES), then the processor (201)

executing the gesture calibration and learning module (210), performs (block 303) an initial calibration of the user's hand posturing, hand positioning, and keystroke style.

[0049] For example, at block 303, the gesture calibration and learning module (210) may prompt a user to demonstrate a home row hand gesture where the user places his or her hands above the pad (101) and positions his or her fingers as if the user were placing his or her hands and fingers on a home row of a keyboard as described above. This provides the virtual input computing system (200) with data representing a home row position of the user and orients the home row keys and the remainder of the keys on the virtual keyboard (100) with respect to the home row gesture. The gesture calibration and learning module (210) may also prompt a user to demonstrate a number of individual keystrokes and a number of combination keystrokes as described above.

[0050] The gesture calibration and learning module (210) may also learn a user's distinct hand posturing, hand positioning, and keystroke styles from the outset of that user utilizing the virtual keyboard (100) and throughout the user's use of the virtual keyboard (100). In this manner, the virtual keyboard adapts to the user's potentially changing hand posturing, hand positioning, and keystroke styles.

[0051] The gesture calibration and learning module (210) may perform calibration and learning techniques for a number of users of a particular virtual keyboard (100). This is advantageous in situations where a number of individuals have access to a particular computing device via the virtual keyboard (100) such as, for example, in a classroom setting where may groups of students utilize a set of computing devices. In one example, the gesture calibration and learning module (210) may begin calibration and learning for a particular user once the user logs onto a computing device coupled to the virtual keyboard (100). Thus, each user that logs into the computing device may be prompted to initiate a calibration and learning sequence to prepare and continue to fine-tune each user's individual and unique keyboard profile. Calibration and learning processes will be described in more detail below.

[0052] The gesture calibration and learning module (210) and keyboard profile module (230), when executed by the processor, may store (block 304) the calibration from block 303 as the user's keyboard profile. The user's keyboard profile may be data representing the detected hand posturing, hand positioning, and keystroke styles, among other aspects of the user's hand movements as detected by the sensing devices (102) of the pad (101). The user's keyboard profile may be stored in the memory located at the virtual keyboard (100), in the data storage device (202) of the virtual input computing system (200), or another storage device accessible by the processor (201), the virtual keyboard (100) or other processing device for use in execution of the various functions of the present systems and methods.

[0053] If the user is a not new user of the virtual keyboard (100) (block 302, determination NO), or after performing an initial calibration (block 303), then the gesture calibration and learning module (210) may determine (block 305) if the user's keyboard profile should be updated. A number of aspects of the user's hand posturing, hand positioning, and keystroke style may change through time as the user becomes more comfortable using the virtual keyboard (100). A number of criteria may indicate that a user's keyboard profile should be updated including, for example, changes in initial home row positioning, changes in keystrokes or keystroke combinations, or other nuanced changes in the user's hand posturing, hand positioning, and keystroke style. Further, the user's keyboard profile may be updated upon identification by the sensing devices (102) that an injury such as a loss of a portion of the user's hand or the loss of a finger has cause the user accommodate in order to make keystrokes or present a particular hand position. Thus, the gesture calibration and learning module (210) continues to learn the user's hand posturing, hand positioning, and keystroke style by performing (block 303) subsequent learning of the user's keyboard profile if it is determined that the user's keyboard profile should be updated (block 305, determination YES).

[0054] The method (300) loops back to blocks 305 and 306 as long as it is determined that the user's keyboard profile should be updated (block 305, determination YES). The method may terminate if it is determined that the

user's keyboard profile should not be updated (block 305, determination NO). In this manner, the user's keyboard profile may be initially created and continually updated to accommodate the user's changing hand posturing, hand positioning, and keystroke style.

[0055] Fig. 4 is a flowchart showing a method (400) of processing signals from the virtual keyboard (100), according to one example of the principles described herein. The method of Fig. 4 may include determining (block 401), with the processor (201) executing the data input processing module (220), whether the user's hands are detected. If the user the user's hands are not detected (block 401, determination NO), then the method (400) loops back to determining (block 401) whether the user's hands are detected. Again, this determination (block 401) may be a condition by which waking the virtual keyboard and/or the computing device is achieved. If the user's hands are detected (block 401, determination YES), then the processor (201), executing the data input processing module (220), determines keystroke identity based on the user's keyboard profile identified in Fig. 3. The keystroke identity identifies the how the user's hand posturing, hand positioning, and keystroke style correlate with input to the computing device to which the virtual keyboard is communicatively coupled.

[0056] Using the keystroke identity, the data input processing module (220), when executed by the processor (201), instructs (block 403) the computing device to process data in accordance with the keystroke identity. In this manner, the user's input at the virtual keyboard (100) is translated into computer readable instructions that are consumed by the computing device in order to perform the tasks the user wishes the computing device to perform such as, for example, typing in a word processing application, or any other application of user input from a keyboard.

[0057] The method may continue by determining (block 404) whether the user is inputting data though the virtual keyboard (100). If the user is still utilizing the virtual keyboard (100), then those keystrokes should be identified and translated into computer readable instructions for consumption by the computing device in order to perform the tasks the user wishes the computing

device to perform. Thus, if the user is inputting data though the virtual keyboard (100), then the method (400) of Fig. 4 may loop back to block 402 for processing as described above. If the user is not inputting data though the virtual keyboard (100), then the method (400) may terminate.

[0058] Fig. 5 is a flowchart showing a method (500) of processing authentication signals from the virtual keyboard (100), according to one example of the principles described herein. As described above, the virtual keyboard (100) may be used to permit access to individuals who are permitted to use a computing device to which the virtual keyboard (100) is communicatively coupled, while denying access to others who are not permitted. The method of Fig. 5 may include determining (block 501), with the processor (201) executing the security module (240), whether the user's hands are detected. Again, this determination (block 501) may be a condition by which waking the virtual keyboard and/or the computing device is achieved. If the user the user's hands are not detected (block 501, determination NO), then the method (500) loops back to determining (block 501) whether the user's hands are detected. If the user's hands are detected (block 501, determination YES), then the processor (201) executing the security module (240), identifies (block 402) an initial hand characteristics of the user attempting to access the computing device via the virtual keyboard (100).

[0059] The method (500) of Fig. 5 may continue by the processor (201) executing the security module (240) to determine (block 503) if the initial hand characteristics match a number of hand characteristics defined by a keystroke identity such as the keystroke identity defined and stored at blocks 303 and 304 of Fig. 3. In one example, the initial hand characteristics may be compared to the keystroke identity of an individual currently logged into the computing device. In this example, a user who is authorized to access the computer, but is not the current user of the computer may still be denied access. In another example, the processor (201) may compare the initial hand characteristics to the keystroke identity of a number of users. If the initial hand characteristics match hand characteristics defined by a keystroke identity (block 503, determination YES), then access to the computing device may be allowed. The method (500)

may loop back to block 501 to ensure that every time a user's hands are detected, that this security measure may be performed. The hand characteristics compared at block 503 may include, hand movements, hand sizes, hand posturing, hand positioning, and keystroke style, tissue density of the user's hands and fingers (110), palm prints, fingerprints, among many other characteristics of the user's hands and fingers as detected by the sensing devices (102), or combinations thereof.

[0060] If, however, the initial hand posture does not match a hand posture defined by a keystroke identity (block 503, determination NO), then the processor (201), executing the security module (240) may deny access (block 505) to the computing device. Denying access to the computing device may include, for example, not registering input from the virtual keyboard (100), locking the computing device, shutting down the computing device, alerting a valid user or an administrator of an unauthorized access to the computing device, requesting the accessing user for additional credentials such as a password or fingerprint identification, other security measures, or combinations thereof. The method (500) of Fig. 5 may terminate, and may be initiated once again when a user's hands are detected at block 501.

[0061] In this manner, the virtual keyboard (100) may be used to provide access control and security to any computing device. These computing devices may include, for example, desktop computers, laptop computers, tablet computers, mobile phone devices, as well as objects or devices that user computing devices such as vehicles, automated teller machines (ATMs), buildings, musical instruments such as keyboards, checkout stands at retail stores, among many other devices and objects.

[0062] Aspects of the present system and method are described herein with reference to flowchart illustrations and/or block diagrams of methods, apparatus (systems) and computer program products according to examples of the principles described herein. Each block of the flowchart illustrations and block diagrams, and combinations of blocks in the flowchart illustrations and block diagrams, may be implemented by computer usable program code. The computer usable program code may be provided to a processor of a general

purpose computer, special purpose computer, or other programmable data processing apparatus to produce a machine, such that the computer usable program code, when executed via, for example, the processor (201) of the virtual input computing system (200) or other programmable data processing apparatus, implement the functions or acts specified in the flowchart and/or block diagram block or blocks. In one example, the computer usable program code may be embodied within a computer readable storage medium; the computer readable storage medium being part of the computer program product. In one example, the computer readable storage medium is a non-transitory computer readable medium.

[0063] The specification and figures describe a virtual keyboard. The virtual keyboard includes a pad, a number of motion sensors coupled to the pad to detect the presence of a user's hands over the pad, and a tracking system to track hand and finger movements of the user's hand. A computing device for processing input from a virtual keyboard is also described. The computing device includes a processor and a memory. The memory includes executable code that, when executed by the processor initiates a tracking system to track hand and finger movements of the user's hand, in response to receiving data from a number of motion sensors coupled to a pad of the virtual keyboard to detect the presence of a user's hands over the pad. The executable code also calibrates the virtual keyboard based on a number of criteria of the user's hand.

[0064] This virtual keyboard may have a number of advantages, including: (1) the virtual keyboard is easy to store by rolling it up, folding it, or laying it on top of a computing device for storage; (2) due to its virtual aspects, a user need not come in physical contact with his or her fingers or hands to operate the virtual keyboard; (3) the virtual keyboard conforms to a user's hand positions and learns from the user's usage patterns to increase comfort and utility; and (4) the virtual keyboard provides increased security to a computing device to which the virtual keyboard is communicatively coupled, among many other advantages.

[0065] The preceding description has been presented to illustrate and describe examples of the principles described. This description is not intended

to be exhaustive or to limit these principles to any precise form disclosed. Many modifications and variations are possible in light of the above teaching.

CLAIMS

WHAT IS CLAIMED IS:

1. A virtual keyboard comprising:

a pad;

a number of motion sensors coupled to the pad to detect the presence of a user's hands over the pad;

a processor; and

a memory, the memory comprising executable code that, when executed by the processor:

calibrates the virtual keyboard based on a number of criteria of the user's hand upon detection of the user's hands by the motion sensors,

in which the criteria comprises the user's unique keyboard profile.

2. The virtual keyboard of claim 1, in which detection of the user's hands by the motion sensors activates the tracking system.

3. The virtual keyboard of claim 1, in which the tracking system comprises a number of wave detectors to detect wavelengths reflected off the user's hands.

4. The virtual keyboard of claim 1, in which the pad is dimensioned to approximate the size of a keyboard.

5. The virtual keyboard of claim 1, further comprising a tracking system to track hand and finger movements of the user's hand.

6. The virtual keyboard of claim 1, in which the user's unique keyboard profile comprises hand position, hand size, hand posturing, keystroke style, or combinations thereof.

7. The virtual keyboard of claim 1, further comprising

a processor, and

a memory, the memory comprising executable code that, when executed by the processor:

builds a hand position profile; and

authenticates the user based on the hand position profile.

8. The virtual keyboard of claim 7, in which access to a computing device to which the pad is communicatively coupled is denied if the hand position profile is not recognized.

9. A computing device for processing input from a virtual keyboard, comprising:

a processor; and

a memory, the memory comprising executable code that, when executed by the processor:

initiates a tracking system to track hand and finger movements of the user's hand in response to receiving data from a number of motion sensors coupled to a pad of the virtual keyboard to detect the presence of a user's hands over the pad; and

calibrates the virtual keyboard based on a number of criteria of the user's hand, the criteria comprising the user's unique keyboard profile,

in which the user's unique keyboard profile comprises hand position, hand size, hand posturing, keystroke style, or combinations thereof.

10. The computing device of claim 9, in which the memory further comprises executable code that, when executed by the processor:

builds a hand position profile; and

authenticates the user based on the hand position profile.

11. The computing device of claim 9, in which the virtual keyboard comprises:

a pad;

a number of motion sensors coupled to the pad to detect the presence of a user's hands over the pad; and

a tracking system to track hand and finger movements of the user's hand.

12. The computing device of claim 9, further comprising:

a display system, in which a number of keys of a keyboard are displayed on the pad using the display system.

13. A computer program product for dynamically learning a user's unique keyboard profile in association with a virtual keyboard, the computer program product comprising:

a computer readable storage medium comprising computer usable program code embodied therewith, the computer usable program code comprising:

computer usable program code to, when executed by a processor, with a number of motion sensors coupled to a pad, detect a user's hands above the pad;

computer usable program code to, when executed by a processor, with a number of lasers, track movements of the hands; and

computer usable program code to, when executed by a processor, based on information transmitted from the motion sensors and the lasers, build a hand position profile for the user.

14. The computer program product of claim 13, further comprising computer usable program code to, when executed by a processor, identify the user as a user authorized to access a computing device to which the pad is communicatively coupled using the hand position profile.

15. The computer program product of claim 14, further comprising computer usable program code to, when executed by a processor, restrict access to computing resources of the computing device if the hand position profile of the individual does not match an authorized hand position profile.

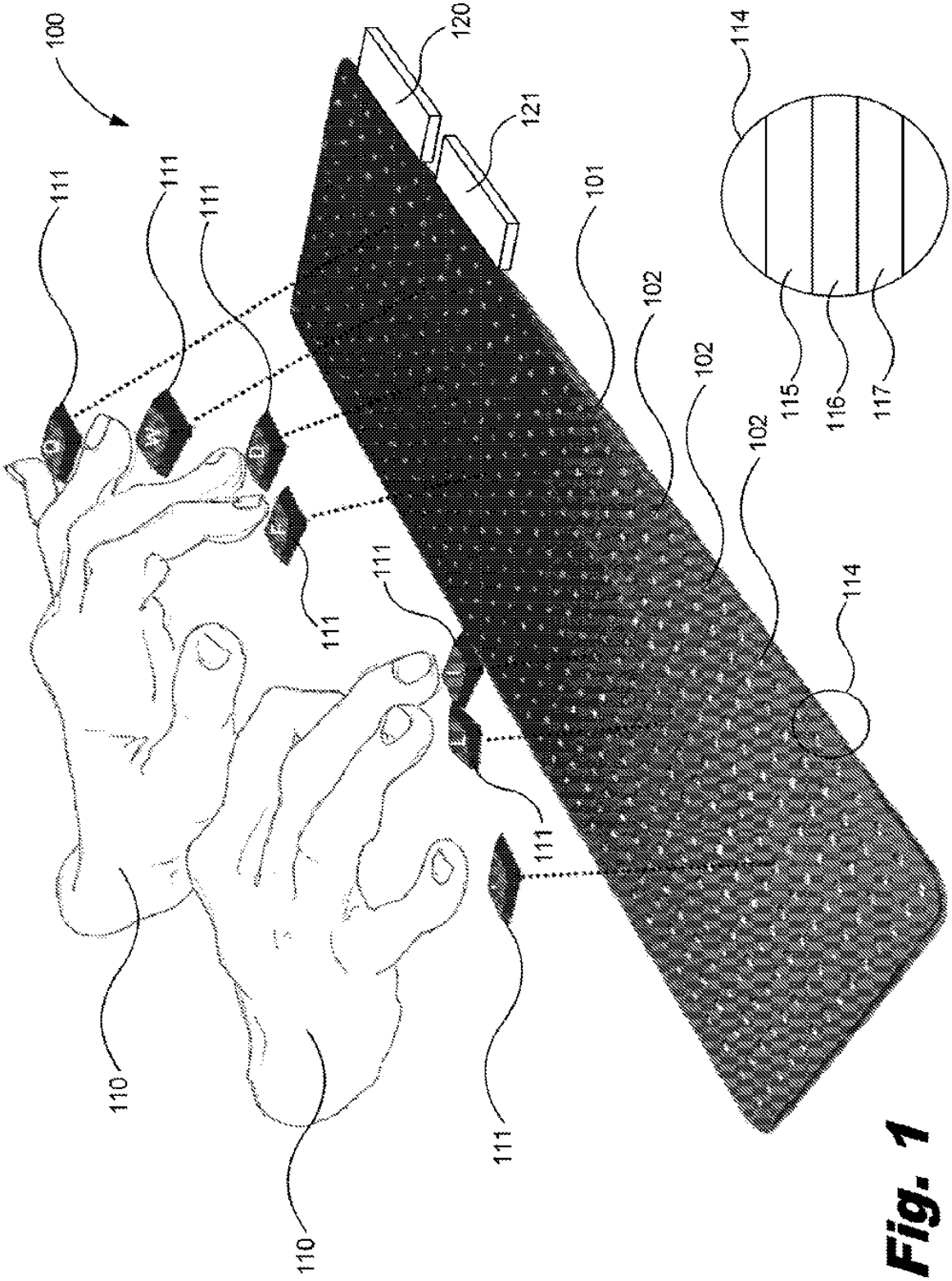

100
120
121
114
111
111
111
101
102
102
102
115
116
117
111
111
114
111
110
110
111

Fig. 1

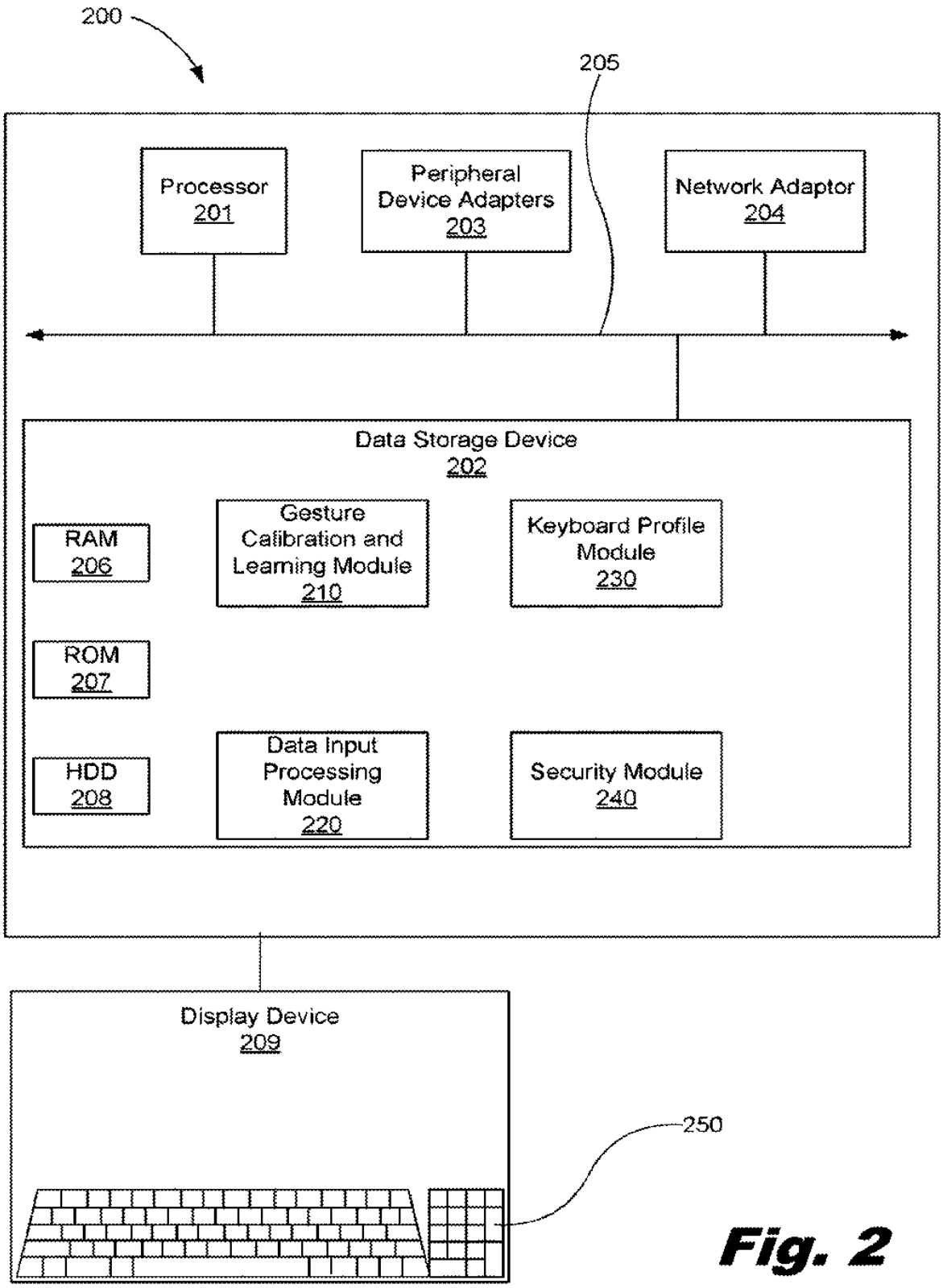

200
205
Processor
201
Peripheral
Device Adapters
203
Network Adaptor
204
Data Storage Device
202
RAM
206
Gesture
Calibration and
Learning Module
210
Keyboard Profile
Module
230
ROM
207
HDD
208
Data Input
Processing
Module
220
Security Module
240
Display Device
209
250

Fig. 2

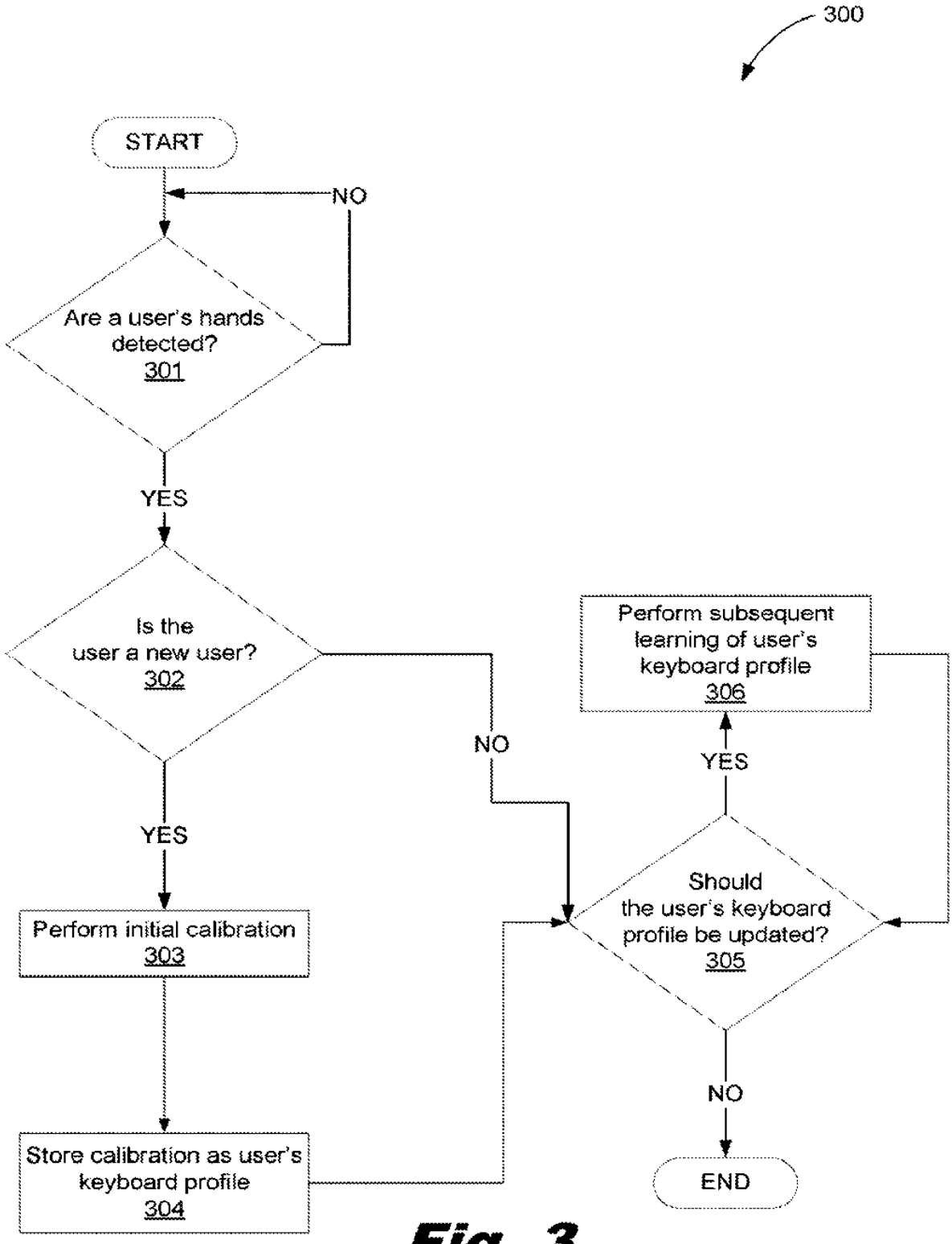

300
START
NO
Are a user's hands detected?
301
YES
Is the user a new user?
302
YES
Perform initial calibration
303
Store calibration as user's keyboard profile
304
NO
Should the user's keyboard profile be updated?
305
YES
Perform subsequent learning of user's keyboard profile
306
NO
END

Fig. 3

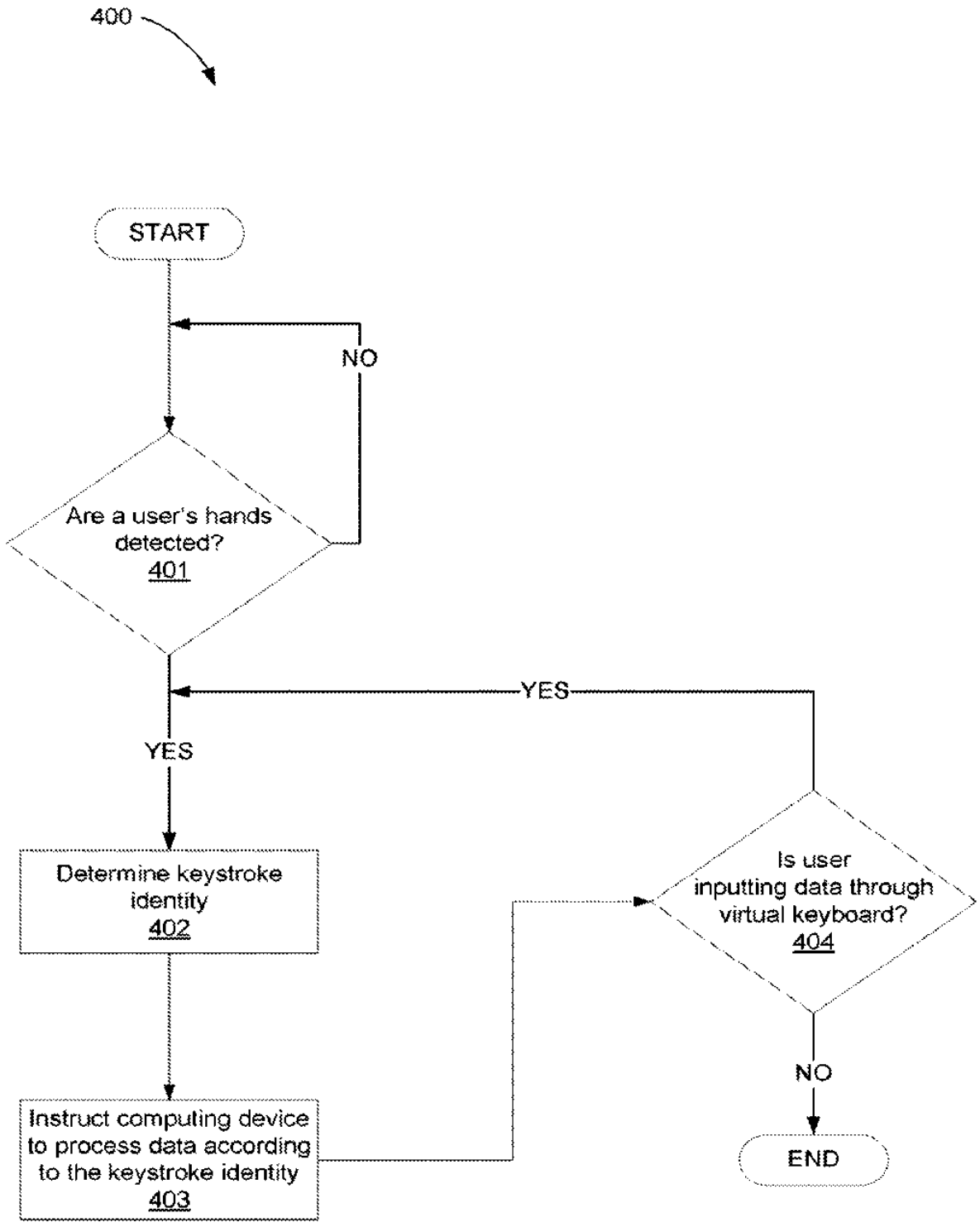

400
START
NO
Are a user's hands detected?
401
YES
YES
Determine keystroke identity
402
Instruct computing device to process data according to the keystroke identity
403
Is user inputting data through virtual keyboard?
404
NO
END

Fig. 4

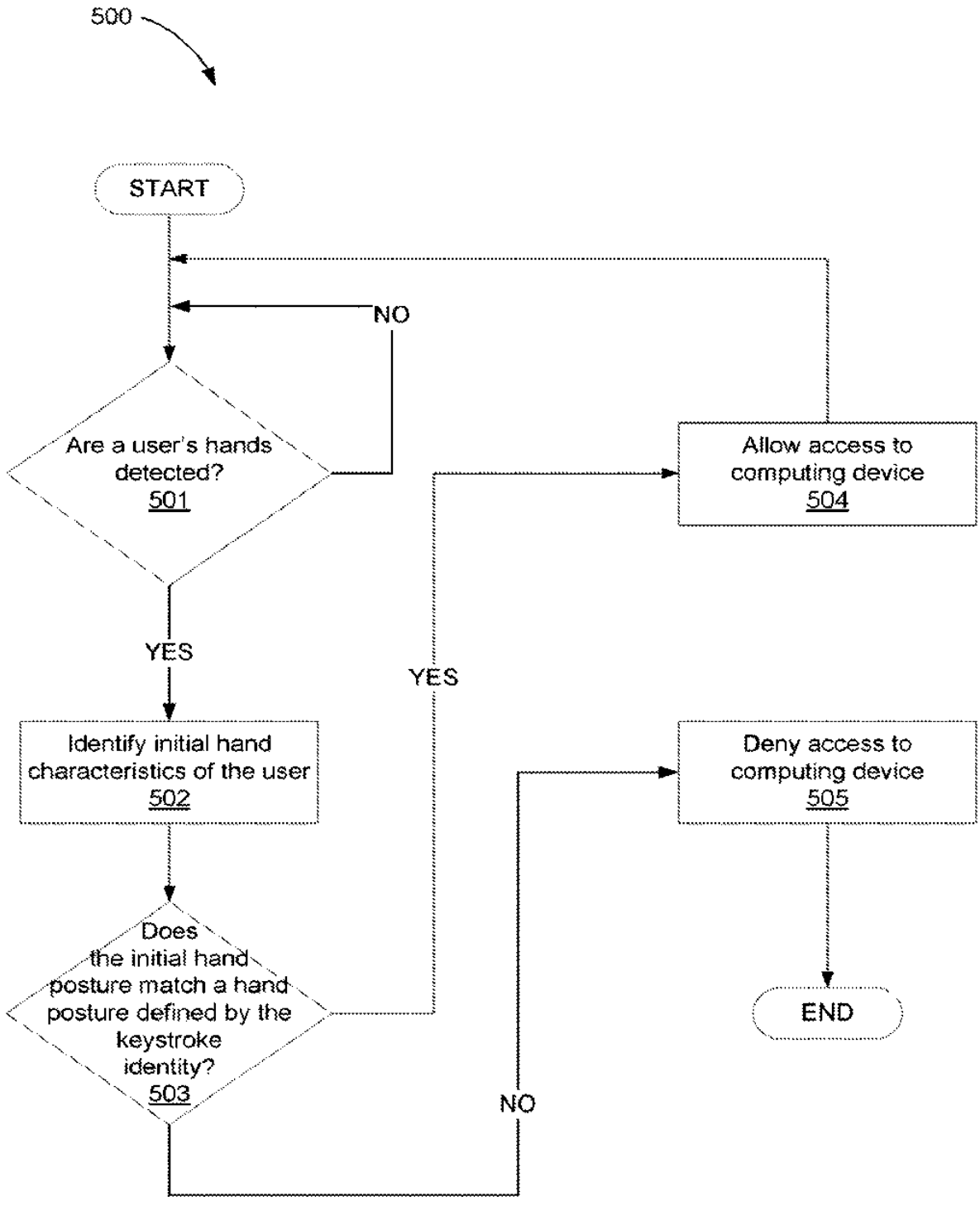

500
START
NO
Are a user's hands detected? 501
YES
Identify initial hand characteristics of the user 502
Does the initial hand posture match a hand posture defined by the keystroke identity? 503
YES
NO
Allow access to computing device 504
Deny access to computing device 505
END

Fig. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/046715

A. CLASSIFICATION OF SUBJECT MATTER

G06F 3/02(2006.01)i, G06F 3/048(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
G06F 3/02; G06F 3/048; H04M 1/24; G06F 3/041; G09G 5/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & keywords: virtual keyboard, sensor, detect, hand, user, profile, and similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012-0260207 A1 (ANTON TRESKUNOV et al.) 11 October 2012 See paragraphs 7, 27-52; claims 4, 16, 29; and figures 1-6B.	1-6,9-13
Y		7-8,14-15
Y	US 2013-0109369 A1 (BABAK FORUTANPOUR et al.) 02 May 2013 See paragraphs 73-74; and figure 7.	7-8,14-15
A	US 2013-0127729 A1 (TIMOTHY J. MOSBY et al.) 23 May 2013 See paragraphs 27-43; and figures 1-4.	1-15
A	US 2009-0303200 A1 (JOEL GRAD) 10 December 2009 See paragraphs 47-63; and figures 2-7.	1-15
A	US 2005-0225538 A1 (WILHELMUS VERHAEGH) 13 October 2005 See paragraphs 18-32; and figures 1-4.	1-15

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 February 2015 (25.02.2015)	**25 February 2015 (25.02.2015)**

Name and mailing address of the ISA/KR	Authorized officer
International Application Division Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea Facsimile No. ++82 42 472 3473	BYUN, Sung Cheal Telephone No. +82-42-481-8262

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2014/046715

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2012-0260207 A1	11/10/2012	KR 10-2012-0114139 A	16/10/2012
US 2013-0109369 A1	02/05/2013	CN 103931163 A	16/07/2014
		EP 2772044 A1	03/09/2014
		JP 2014-532915 A	08/12/2014
		US 2014-235225 A1	21/08/2014
		US 8750852 B2	10/06/2014
		WO 2013-062771 A1	02/05/2013
US 2013-0127729 A1	23/05/2013	US 2009-237361 A1	24/09/2009
		US 8358277 B2	22/01/2013
		US 8619036 B2	31/12/2013
US 2009-0303200 A1	10/12/2009	CN 101634932 A	27/01/2010
		EP 2133778 A2	16/12/2009
		EP 2133778 A3	27/01/2010
		GB 0810613 D0	16/07/2008
		GB 2462579 A	17/02/2010
		US 8619034 B2	31/12/2013
US 2005-0225538 A1	13/10/2005	AT 538130 T	15/01/2012
		AU 2004-244973 A1	23/01/2004
		AU 2004-244973 A8	23/01/2004
		CN 00280700 C	18/10/2006
		CN 100666170 A	07/09/2005
		EP 1522007 A2	13/04/2005
		EP 1522007 B1	21/12/2011
		JP 04828826 B2	30/11/2011
		JP 2005-531861 A	20/10/2005
		US 8576173 B2	05/11/2013
		WO 2004-006080 A2	15/01/2004
		WO 2004-006080 A3	02/09/2004

Electronic Patent Application Fee Transmittal	
Application Number:	17181057
Filing Date:	22-Feb-2021
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Filer:	Anupma Sahay/Tierra Brown
Attorney Docket Number:	4944.0120006
Filed as Small Entity	

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 3 months with $0 paid	2253	1	740	740
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	130	130
		Total in USD ($)		**870**

Electronic Acknowledgement Receipt	
EFS ID:	46171157
Application Number:	17181057
International Application Number:	
Confirmation Number:	4690
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	26111
Filer:	Anupma Sahay/Tierra Brown
Filer Authorized By:	Anupma Sahay
Attorney Docket Number:	4944.0120006
Receipt Date:	12-JUL-2022
Filing Date:	22-FEB-2021
Time Stamp:	16:33:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$870
RAM confirmation Number	E20227BG33514836
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	2022-07-12-Transmittal-Form-4944-0120006.PDF	220103 d3d040249e346affb1793345a77a30bbcc757178	no	1
Warnings:					
Information:					
2	Extension of Time	2022-07-12-EOT-4944-0120006.PDF	167612 bf684690e0a81d6bdb7e27c6a30d0c71b470cdb1	no	1
Warnings:					
Information:					
3		2022-07-12-Amendment-Reply-111-4944-0120006.PDF	150019 10890028d3f5c8bb27aefdf6e44e814bfd2d215b	yes	13

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment/Request for Reconsideration-After Non-Final Rejection	1	1
Claims	2	6
Applicant Arguments/Remarks Made in an Amendment	7	13

Warnings:					
Information:					
4	Application Data Sheet	2022-07-12-Marked-Up-ADS-4944-0120006.PDF	110254 cea4233788a433b504fbb0d08aefa20091e71e79	no	2
Warnings:					
Information:					

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5	Information Disclosure Statement (IDS) Form (SB08)	2022-07-12-IDS-Form-SB08a-4944-0120006.PDF	121895 f932f16bcfad204fa3c9892721473715d3df5027	no	4
Warnings:					
Information:					
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6	Non Patent Literature	NPL1_4MD-Medical-4944-0120006.PDF	435766 40a5e5c20aba669620948e4f8130a31cbc0611dd	no	3
Warnings:					
Information:					
7	Non Patent Literature	NPL2_Best-Hands-Free-Breast-Pumps-4944-0120006.PDF	858447 1f513f3e5a82aeacd71f1eee85427355bb3d864c	no	11
Warnings:					
Information:					
8	Foreign Reference	FP1_WO2016010524A1-4944-0120006.PDF	2679431 2cc0f68f12b62c66f40c29d3a44a697615b59710	no	34
Warnings:					
Information:					
9	Fee Worksheet (SB06)	fee-info.pdf	40606 02fc0ff0b27370e65a3d7a9aedb2a90547d59de8	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	4784133		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

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Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	FREDRICKSON, Courtney B.
Attorney Docket Number	4944.0120006

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
- ☑ Fee Attached
- ☑ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☑ Extension of Time Request
- ☐ Express Abandonment Request
- ☑ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

  Marked-Up Application Data Sheet; FP1; NPL1-NPL2

Remarks

Online Credit Card Authorization for $870.00 to cover:

$130.00 - Information Disclosure Statement Fee;
$740.00 - 3 Month Extension of Time Fee

The Office may charge any fee deficiency for any submission made with this transmittal to Deposit Account 19-0036.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Anupma Sahay #78,704/		
Printed name	Anupma Sahay		
Date	July 12, 2022	Reg. No.	78,704

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)	Docket Number (Optional) 4944.0120006
Application Number 17/181,057	Filed February 22, 2021
For BREAST PUMP SYSTEM	
Art Unit 3783	Examiner FREDRICKSON, Courtney B.

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

		Fee	Small Entity Fee	Micro Entity Fee	
☐	One month (37 CFR 1.17(a)(1))	$220	$110	$55	$
☐	Two months (37 CFR 1.17(a)(2))	$640	$320	$160	$
☑	Three months (37 CFR 1.17(a)(3))	$1,480	$740	$370	$ 740.00
☐	Four months (37 CFR 1.17(a)(4))	$2,320	$1,160	$580	$
☐	Five months (37 CFR 1.17(a)(5))	$3,160	$1,580	$790	$

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 19-0036.

☑ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant.

☑ attorney or agent of record. Registration number 78,704.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/Anupma Sahay #78,704/	July 12, 2022
Signature	Date
Anupma Sahay	(202) 371-2600
Typed or printed name	Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☑ * Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/181,057	02/22/2021	Jonathan O'TOOLE	ELVI-002/06US

CONFIRMATION NO. 4690

58249
COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004

POWER OF ATTORNEY NOTICE

OC000000131861528

Date Mailed: 02/17/2022

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/11/2022.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/tnguyen/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/181,057	02/22/2021	Jonathan O'TOOLE	4944.0120006

CONFIRMATION NO. 4690

26111
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

POA ACCEPTANCE LETTER

OC000000131861557

Date Mailed: 02/17/2022

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/11/2022.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/tnguyen/

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
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TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Title	BREAST PUMP SYSTEM
Art Unit	3783
Examiner Name	Courtney B. FREDRICKSON
Attorney Docket Number	4944.0120006

SIGNATURE of Applicant or Patent Practitioner

Signature	/Anupma Sahay #78,704/	Date (Optional)	
Name	Anupma Sahay	Registration Number	78,704
Title (if Applicant is a juristic entity)	Attorney for Applicant		
Applicant Name (if Applicant is a juristic entity)	Chiaro Technology Limited		

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ *Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
Approved for use through 05/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 26111

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

CHIARO TECHNOLOGY LIMITED

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	/Hannah Brunskill/	Date (Optional)	8 December 2021
Name	Hannah Brunskill		
Title	Head of Legal		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Electronic Acknowledgement Receipt

EFS ID:	44977990
Application Number:	17181057
International Application Number:	
Confirmation Number:	4690
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	58249
Filer:	Anupma Sahay/Rolonda Lee
Filer Authorized By:	Anupma Sahay
Attorney Docket Number:	ELVI-002/06US
Receipt Date:	11-FEB-2022
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	2022-02-11-Transmittal-Form-4944-0120006.pdf	1287494 d725f03d80fa6bab0960448fdd84cce8ad30d36e	no	2

Warnings:

Information:					
2	Authorization for Extension of Time all replies	2022-02-11-EOT-Authorization-4944-0120006.pdf	97945 5a79c260d0beb35644b7d6278f18c0531f4390aa	no	1
Warnings:					
Information:					
3	Power of Attorney	2022-02-11-POA-82A-4944-0120006.pdf	514012 43965031c9a62c01effef034e091baca721ab214	no	1
Warnings:					
Information:					
4	Power of Attorney	2022-02-11-POA-82B-4944-0120006.pdf	511087 f8a9fa77ddb50636ad50d2b6e5e926a62169a6dd	no	1
Warnings:					
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		Total Files Size (in bytes):	2410538		

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New International Application Filed with the USPTO as a Receiving Office

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Doc Code: TRAN.LET

Document Description: Transmittal Letter

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	17/181,057
Filing Date	02/22/2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	Courtney B. FREDRICKSON
Attorney Docket Number	4944.0120006

Total Number of Pages in This Submission

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☑ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please identify below):

Authorization under 37 CFR 1.136(a)(3)

Remarks

The Office may charge any fee deficiency for any submission made with this transmittal to Deposit Account 19-0036.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.		
Signature	/Anupma Sahay #78,704/		
Printed name	Anupma Sahay		
Date	February 11, 2022	Reg. No.	78,704

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Signature			
Typed or printed name		Date	

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jonathan O'TOOLE	Confirmation No.: 4690
Applicant: Chiaro Technology Limited	Art Unit: 3783
Application No.: 17/181,057	Examiner: Courtney B. FREDRICKSON
Filing Date: 02/22/2021	Atty. Docket: 4944.0120006

Title: **BREAST PUMP SYSTEM**

Authorization to Treat a Reply as Incorporating an Extension of Time Under 37 C.F.R. § 1.136(a)(3)

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

The U.S. Patent and Trademark Office is hereby authorized to treat any concurrent or future reply that requires a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. The U.S. Patent and Trademark Office is hereby authorized to charge all required extension of time fees to our Deposit Account No. 19-0036, if such fees are not otherwise provided for in such reply.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Anupma Sahay #78,704/

Anupma Sahay
Attorney for Applicant
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Date: February 11, 2022

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/181,057	02/22/2021	Jonathan O'TOOLE	ELVI-002/06US	4690

58249 7590 01/26/2022

COOLEY LLP
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1299 Pennsylvania Avenue, NW
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EXAMINER	
FREDRICKSON, COURTNEY B	

ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
01/26/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

zIPPatentDocketingMailboxUS@cooley.com

Office Action Summary	Application No. 17/181,057	Applicant(s) O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	Art Unit 3783	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 17December2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-22,24-25 and 28-33 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-22,24-25 and 28-33 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 22February2021 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☑ All b)☐ Some** c)☐ None of the:

1.☑ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

The information disclosure statement (IDS) submitted is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Amendment

This office action is responsive to the Preliminary amendment filed on December 17, 2021. As directed by the amendment: claims 1, 2, 4-9, 13-16, 18-22, 24, 25, 28-30 have been amended, claims 23, 26, and 27 have been cancelled, and claims 31-33 have been added. Thus, claims 1-22, 24, 25, and 28-33 are presently pending in this application.

Claim Objections

Claims 14, 28, and 29 are objected to because of the following informalities:

Regarding claim 14, the claim should be amended to recite "in which the milk container" in line 1 to correct for grammar.

Regarding claim 28, it is recommended to amend the claim to recite that "the pump is configured to deliver in excess..." to clarify that the feature is a functional aspect of the pump.

Claim 29 should end in a period.

Appropriate correction is required.

Claim Interpretation

The preamble in claim 1 recites "A breast pump device that is configured as a self-contained, in-bra wearable device". The examiner notes that this limitation gives life and meaning to the claim since it sets forth structural limitations to the overall breast pump device. For examination purposes, the term "self-contained, in-bra wearable device' is interpreted to mean "complete, or having all that is needed, in itself' and is capable of being worn in a bra. Applicant's disclosure appears to support this interpretation in fig. 1 of the Drawings which shows a fully complete breast pump device which is capable of being worn in a bra due to the device being self-contained.

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 6-8, 10, 11, 14, 16-18, 22, 24, and 31 is/are rejected under 35 U.S.C. 103 as being unpatentable over Myers (US 20080275386) and in further view of Barack (US 20140378895).

Regarding claim 1, Myers discloses a breast pump device that is configured as a self-contained, in-bra wearable device (breast pump 10 in fig. 1), comprising:

(i) a housing (outer housing 16 in fig. 1) that includes (a) a battery (AA battery 51 in fig. 10), and (b) a pump generating negative air pressure (motor 54 in fig. 10);

(ii) a breast shield (breast cup 16 in fig. 1) being configured to slide in and out of the housing (paragraph 58 discloses that the cup "clicks" into place within the housing; paragraph 42 discloses the breast cup being removable), the breast shield made up of a breast flange (outer flange area 50 in fig. 5) and a nipple tunnel (nipple tunnel 46 in fig. 5), in which the breast shield is transparent or optically clear (paragraph 65); and

(iii) a milk container that is configured to be attached to and removed from the housing (collection bag 28 is shown to be operatively attached to the housing and is physically engaged to the bottom portion of the housing).

However, Myers does not teach or disclose the breast shield being of a plurality of interchangeable breast shields each having a different size.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield of modified Khalil to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

Regarding claim 2, in the modified device of Myers, Barack discloses the plurality of interchangeable breast shields each provide a different spacing of a nipple from side walls of the nipple tunnel when that breast shield has been placed onto a breast (paragraph 54).

Regarding claim 3, in the modified device of Myers, Myers discloses the breast shield is rigid (paragraph 47 discloses the nipple tunnel, which is part of the breast shield, is rigid).

Regarding claim 6, in the modified device of Myers, Myers discloses the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast (the shield of Myers is

functionally capable of being rotated smoothly around a nipple since the claim does not require that the shield be fully latched onto the nipple for this rotation to occur).

Regarding claim 7, in the modified device of Myers, Myers discloses the breast shield presents, in use, a single continuous surface to a nipple and a breast (fig. 9A/B shows a singular inner surface which would extend from the nipple to the breast).

Regarding claim 8, in the modified device of Myers, Myers discloses the breast shield integrates the breast flange and the nipple tunnel as a single item (fig. 5 shows a singular item).

Regarding claim 10, in the modified device of Myers, Myers discloses the breast shield is configured to slide into the housing with a single push action (paragraph 58 discloses the shield can click into place).

Regarding claim 11, in the modified device of Myers, Myers discloses the breast shield is configured to slide out from the housing, together with a membrane that prevents milk from flowing into the pump (flange top 36 in fig. 9A).

Regarding claim 14, in the modified device of Myers, Myers discloses milk container attaches to a lower part of the housing (fig. 1 shows a part of the collection bag attached to the bottom part of the housing 16) and forms a base of the breast pump device (fig. 1).

Regarding claim 16, in the modified device of Myers, Myers discloses the nipple tunnel includes guide lines running parallel along one or more sides of the nipple tunnel (detent tabs 52a/b in fig. 15 are shown to be extending in a parallel to the width direction of the nipple tunnel sides).

Regarding claim 17, in the modified device of Myers, Myers discloses the nipple tunnel includes an air hole or passage (24 in fig. 9A), and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage (paragraph 52).

Regarding claim 18, in the modified device of Myers, Myers discloses the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container (outlet 24 in fig. 9A).

Regarding claim 22, in the modified device of Myers, Myers discloses the housing is shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra (fig. 1; paragraph 40).

Regarding claim 24, in the modified device of Myers, Myers discloses the breast pump device is configured to deliver a maximum suction of approximately 240 mmHg (paragraph 72).

Regarding claim 31, modified Myers teaches a kit comprising the breast pump device of claim 1 (see discussion above); and the plurality of interchangeable breast shields (paragraph 54 of Barack).

Claim 4 is/are rejected under 35 U.S.C. 103 as being unpatentable over Myers in view of Barack, as applied to claim 1 above, and further in view of Phillips (US 20160296682), as evidenced by Yuen (US 20050228342).

Regarding claim 4, modified Myers teaches all of the claimed limitations set forth in claim 1, as discussed above. Myers further teaches the breast shield is made from plastic (paragraph 40 discloses the breast cup being made from silicone, which is a type of plastic, as evidenced by Yuen in paragraph 24). However, modified Myers does not teach or disclose breast shield is dishwasher safe.

Phillips teaches a breast pump device (fig. 1) comprising a breast shield (110 in fig. 1). Phillips further teaches that the shield can be washed in a dishwasher (paragraph 60). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield of modified Myers to be dishwasher safe for the purpose of enabling the shield to be cleaned in the dishwasher for reuse, as taught by Phillips (paragraph 60).

Claims 1, 2, 6-10, 14, 17, 18, 20-22, and 31 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil (US 20130023821) in view of Myers (US 20080275386) and in further view of Barack (US 20140378895).

Regarding claim 1, Khalil discloses a breast pump device that is configured as a self-contained, in-bra wearable device (figs. 9-11), comprising:

(i) a housing (6' and 6" form a housing as shown in fig. 9) that includes (a) a power source (paragraph 32 discloses the power source integrated into the housing), and (b) a pump generating negative air pressure (vacuum pump 81 in fig. 10);

(ii) a breast shield (breast interface 1 in fig. 11) being configured to slide in and out of the housing (breast interface 1 is configured to slide in/out from the housing by attaching/detaching the lip 11 to the flange 62 of the housing as shown in fig. 4), the breast shield made up of a breast flange (base part 12 in fig. 4) and a nipple tunnel (stub 10 in fig. 4); and

(iii) a milk container that is configured to be attached to and removed from the housing (milk collection container 7' in fig. 11; paragraph 69 discloses the container being releasably connected to the housing part 6').

However, Khalil does not teach or disclose the power source being a battery and the breast shield being of a plurality of interchangeable breast shields each having a different size and each breast shield being transparent or optically clear.

Myers teaches a similar breast pump system (fig. 1) having a housing (outer housing 16 in fig. 1) which comprises a battery (battery 52 in fig. 10) and a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing to include a battery, as taught by Myers, for the purpose of providing power to the device and to have made the breast shield transparent to enable a user to view the condition of a nipple (paragraph 65).

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield of modified Khalil to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

Regarding claim 2, in the modified device of Khalil, Barack discloses the plurality of interchangeable breast shields each provide a different spacing of a nipple

from side walls of the nipple tunnel when that breast shield has been placed onto a breast (paragraph 54).

Regarding claim 6, in the modified device of Khalil, Khalil discloses the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast (the shield of Khalil is functionally capable of being rotated smoothly around a nipple since the claim does not require that the shield be fully latched onto the nipple for this rotation to occur).

Regarding claim 7, in the modified device of Khalil, Khalil discloses the breast shield presents, in use, a single continuous surface to a nipple and a breast (fig. 11).

Regarding claim 8, in the modified device of Khalil, Khalil discloses the breast shield integrates the breast flange and the nipple tunnel as a single item (fig. 11).

Regarding claim 9, in the modified device of Khalil, Khalil discloses the breast shield is generally symmetrical about a centre-line running from a top to a bottom of the breast shield when positioned upright for normal use (fig. 11).

Regarding claim 10, in the modified device of Khalil, Khalil discloses the breast shield is configured to slide into the housing with a single push action (the shield of Khalil is functionally capable of being pushed into the housing so that the nipple tunnel is located in the housing).

Regarding claim 14, in the modified device of Khalil, Khalil discloses milk container attaches to a lower part of the housing and forms a base of the breast pump device (fig. 9).

Regarding claim 17, in the modified device of Khalil, Khalil discloses the nipple tunnel includes an air hole or passage (opening 13 in fig. 3), and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage (figs. 4 and 5).

Regarding claim 18, in the modified device of Khalil, Khalil discloses the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container (opening 13 in fig. 3 is considered to be on a "lower" surface of the nipple tunnel since "lower" is not further defined; see fig. 5).

Regarding claim 20, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the housing further includes a Universal Serial Bus (USB) charging socket.

As discussed above, Barack is directed towards a breast pump device (fig. 1) which comprises a housing which houses a pump (fig. 1 shows a pump 20 which would necessarily have some sort of housing since it is disclosed to have a USB port and a user interface). Barack further teaches a USB charging socket (USB port 34 in fig. 1; paragraph 45). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing of modified Khalil to include the USB charging socket, as taught by Khalil, for the purpose of enabling the device to interface with an external memory (paragraph 45).

Regarding claim 21, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the housing includes a left or right breast selector or toggle switch, that, when selected for a particular pumping session, sends data to a connected application configured to track

pumping sessions, to indicate whether that particular session is associated with a left or a right breast.

Barack teaches a breast pump device (fig. 1) which has a control electronics (controller 22 in fig. 1) and a control interface (user interface 30 in fig. 1) that is user selectable to indicate or record if milk is being expressed from the left or right breast (paragraph 43) and that, when selected for a particular pumping session, sends data to a connected application, running on a device, such as a smartphone, that tracks pumping sessions, to indicate whether that session is associated with the left or the right breast (paragraph 46 discloses transmitting via transceiver the parameters that have been entered at the user interface 30 to a remove device; paragraph 43 discloses that one parameter entered at the user interface is which breast is selected).

Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing of modified Khalil to include a left or right breast selector or toggle switch, that, when selected for a particular pumping session, sends data to a connected application configured to track pumping sessions, to indicate whether that particular session is associated with a left or a right breast, as taught by Barack. This modification would enable a user to track which parameters are best suited for each breast to optimize pumping, as taught by Barack (paragraphs 8 and 43).

Regarding claim 22, in the modified device of Khalil, Khalil discloses the housing is shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra (fig. 9).

Regarding claim 31, modified Khalil teaches a kit comprising the breast pump device of claim 1 (see discussion above); and the plurality of interchangeable breast shields (paragraph 54 of Barack).

Claim 5 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Chang (US 20180333523).

Regarding claim 5, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast shield is configured to attach using magnets to the housing.

Chang teaches a substantially similar self-contained breast pump system (breast pump system 10 in fig. 1A) having a breast shield (flange 14 in fig. 1A) attached to a housing (housing 12 in fig. 1A) and configured to attach to the housing using one or more magnets (paragraph 108 discloses the shield uses magnets 118 attached to the shield to determine if the shield is properly attached to the housing). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield of modified Khalil to be configured to attach using magnets to the housing since Chang teaches this configuration provides a safeguard such that the system will not operate unless all components are fully connected (paragraph 108).

Claims 12 and 13 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Phillips (US 20160296682).

Regarding claim 12, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Although it appears based on fig. 11 of Khalil that the container would be rigid, modified Khalil does not explicitly teach or disclose this limitation.

Phillips teaches a breast pump system (fig. 1) comprising a milk collection container ("collection container" 120 in fig. 1) which is substantially rigid (paragraph 57 discloses the container being made from Tritan; pg. 21 of Applicant's specification discloses that Tritan is a polycarbonate material, which is a known rigid material). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the container of modified Khalil to be made of Tritan for the purpose of enabling the container to maintain its strength when a vacuum is applied, as taught by Phillips (paragraph 57).

Regarding claim 13, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses the milk container is an optically clear, plastic container (paragraph 69 discloses the container is made of plastic like cover 6" and is transparent in its entirety). However, Khalil does not explicitly teach or disclose the milk container is dishwasher safe.

Phillips teaches a breast pump system (fig. 1) comprising a milk collection container ("collection container" 120 in fig. 1) which is dishwasher safe (paragraph 57 discloses the container being made from Tritan; pg. 21, lines 13-18 of Applicant's specification discloses that Tritan a dishwasher safe material). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the container of modified Khalil to be made of Tritan for the

purpose of enabling the container to maintain its strength when a vacuum is applied, as taught by Phillips (paragraph 57).

Claim 15 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Karsan (US 20070228059).

Regarding claim 15, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the milk container is configured to magnetically attach to the housing.

Khalil teaches that the milk container latches to the housing by a locking lug (paragraph 69 discloses a locking lug formed on the container latches engages into a corresponding recess). Karsan teaches a container (1 in fig. 1) having a case (2 in fig. 3) and a base (fig. 3) which are releasably held together (paragraph 51 discloses the connection being releasable) via a latch mechanism (5 and 6 in fig. 3). Karsan further teaches that the latching mechanism is embodied as a lug and recess (5 and 6, respectively in fig. 3; paragraph 65) but may alternatively be embodied as a magnetic means so that the two components may be magnetically latched (paragraph 65).

In Applicant's invention, Applicant uses the magnets to removably secure the milk container to the housing. Thus, Karsan is reasonably pertinent to the problem faced by the inventor since Karsan teaches using magnets as a removable latching connection between two components. As Karsan teaches that the magnetic means (paragraph 65) are functional equivalents to a locking lug and recess (paragraph 65), it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have substituted the locking lug/recess configuration of Khalil with

the magnetic means, as taught by Karsan. The substitution would have resulted in providing an equivalent secure attachment of the milk container to the housing.

Claim 19 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Blondheim (US 20120277636).

Regarding claim 19, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the pump comprises one or more piezo air pumps.

Blondheim is directed towards a breast pump device (fig. 1) which comprises an air pump (66 in fig. 6). Blondheim further teaches that the air pump can be a piezoelectric pump (paragraph 36). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the pump of modified Khalil to be a piezoelectric pump, as taught by Blondheim for the purpose of rendering the pump small in size (paragraph 36).

Claim 25 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Guthrie (US 20160220743).

Regarding claim 25, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast pump device includes a sensor that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container.

Guthrie is directed towards a breast pump device comprising a sensor (detector 607 in fig. 6B) that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container (paragraph 63 discloses that the emitter 606 and the detector 607 operate to detect light reflecting off the opaque surface of the milk). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the device to include a sensor that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container, as taught by Guthrie, for the purpose of measuring volume of milk pumped (paragraph 54).

Claim 29 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Mendoza (US 6227936).

Regarding claim 29, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the pump is a lightweight air pump that enables the total mass of the breast pump system, unfilled with milk, to be less than 250gm.

Mendoza teaches a bra which is designed to support a breast pump to allow the mother's hands to remain free (1:8-12). Mendoza further discloses that the bra must be able to support up to 8 ounces when the pump is full (1:58-62). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed

invention to have modified the system of modified Khalil to be a lightweight air pump that enables the total weight of the system, unfilled with milk, to be less than 250gm, as taught by Mendoza since Mendoza teaches that a lightweight system is crucial for enabling the system to be supported by a bra.

Claim 30 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, in further view of Baker (US 20090281485).

Regarding claim 30, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast pump device makes less than 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

Baker is directed towards a device for removing fluid from a body (fig. 6) using a vacuum pump embodied as a motor (motor 9 in fig. 6; paragraph 243). Baker further teaches that the device makes less than 20 decibel of noise at full power (paragraph 121) by sound proofing the walls of the housing and by adding a counter balance to the motor (paragraph 144). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the device of modified Khalil to have the device make less than 20 dB of noise during maximum power for the purpose of making the device for discrete and comfortable for the user and others around the user.

Claim 32 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 31 above, in further view of Cudworth (US 20120165729).

Regarding claim 32, modified Khalil teaches all of the claimed limitations set forth in claim 31, as discussed above, but does not teach or disclose each of the plurality of interchangeable breast shields includes fit lines in a nipple tunnel of that breast shield that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel.

Cudworth teaches a breast pump system (fig. 1) having a shield (attachment 1) having a flange (cup 2 in fig. 2) and a nipple tunnel (cylindrical portion 3 in fig. 1). Cudworth further teaches the nipple tunnel includes fit lines in a nipple tunnel of that breast shield that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel (grooves 12 in fig. 1 are functionally capable of serving as "fit lines" to assist a user in determining if the breast shield is correctly sized and since the claimed fit lines are not further structurally defined). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of Khalil to include the claimed fit lines, as taught by Cudworth, for the purpose of providing a massaging pressure on the breast to help stimulate milk production (paragraph 30).

Claim 33 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, in further view of Meyers (US 5542921).

Regarding claim 33, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further teaches control electronics ("control

elements and a display" in paragraph 51) which would be powered by the battery (the power source of Khalil is understood to power the device).

However, Khalil does not teach or disclose the battery to be rechargeable and the housing further including a power charging circuit for controlling the charging of the rechargeable battery.

Meyers is directed to a breast pump device (fig. 1) comprising a battery configured to be recharged (9:50-52 discloses recharging the batteries) and a power charging circuit for controlling the charging of the rechargeable battery ("circuit" in 9:50-52). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the battery of modified Khalil to be rechargeable and to have incorporated a power charging circuit for controlling the charging of the rechargeable battery, as taught by Meyers to enable the batteries to be reused.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-22, 24, 25, 29-33 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10881766 in view of Khalil, Myers, Barack, and the teachings below (see table).

Regarding claim 1, claim 1 of the issued patent claims all of the claimed limitations of instant claim 1 except the device being a self-contained, in-bra device having a breast shield being substantially rigid and formed from dishwasher safe plastic.

Khalil teaches a breast pump device (fig. 10) configured as a self-contained, in-bra wearable device (fig. 10; paragraph 70). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the reference claim to be a self-contained, in-bra wearable device, as taught by Khalil, for the purpose of enabling the device to be a small and hands-free (paragraph 70).

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65).

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may

change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5	8	
6		Myers and Khalil teach this limitation above.
7	7	
8	27	
9		Khalil teaches this limitation above.
10	8	
11		Myers teaches this limitation above.
12		Philips teaches this limitation above.
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.
15	2	
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19	18	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25	26	
29		Mendoza teaches this limitation above.
30		Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

Claims 1-22, 24, 25, and 28-33 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10926011 in view of Khalil, Myers, and Barack, and the teachings below (see table).

Regarding claim 1, claim 1 of the issued patent claims all of the limitations in instant claim 1 except claim 1 does not claim a self-contained device, the housing having a battery, the breast shield having a breast flange and nipple tunnel and being substantially rigid and formed of an optically clear, dishwasher safe plastic and being configured to slide into the housing and the milk container being configured for attachment and removal from the housing.

Khalil teaches a breast pump device (fig. 10) configured as a self-contained, in-bra wearable device (fig. 10; paragraph 70) having a breast shield (1 in fig. 11) having a flange (12in fig. 6) and a nipple tunnel (13 in fig. 6) and a milk container (7' in fig. 11)configured to be attached and removed from the housing (paragraph 69). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the reference claim to be a self-contained, in-bra wearable device having a breast shield with a flange and nipple tunnel and a milk container configured to be attached and removed from the housing, as taught by Khalil, for the purpose of enabling the device to be a small and hands-free (paragraph 70). The modification of the breast shield would enable the shield to interface with the breast and receive the nipple and the modification of the milk container would enable the milk to be collected after expression.

Myers teaches a self-contained, in bra breast pump (fig. 1) which comprises a breast shield (18 in fig. 2) having a flange (48 in fig. 5) and nipple tunnel (46 in fig. 5) and a housing (16 in fig. 2) for housing a pump (56 in fig. 10) and a battery for powering the pump (52 in fig. 10). Myers further teaches that the breast shield is optically clear (paragraph 65). Therefore, it would have been obvious to one of ordinary skill before

the effective filing date of the claimed invention to have modified the shield to be optically clear for the purpose of allowing a user to visualize the placement of the breast and nipple and to have modified the housing to include a battery, as taught by Myers, for the purpose of providing power to the device.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6		Myers and Khalil teach this limitation above.
7	30	
8		Myers and Khalil teach this limitation above.
9		Khalil teaches this limitation above.
10	14	
11		Myers teaches this limitation above.
12	12	
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.

15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19	1	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25	19	
28	9	
29	28	
30	10	
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

Claims 1-22, 24, 25, 28-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203050 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph

65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	6	
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	7	
7	8	
8	9	
9	11	
10		Myers and Khalil teach this limitation above.
11		Myers teaches this limitation above.
12		Philips teaches this limitation above.
13		Philips teaches this limitation above.
14	20	
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.

19	2	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22	21	
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
28	4	
29	4	
30	5	
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203079 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph

65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6		Myers and Khalil teach this limitation above.
7		Myers and Khalil teach this limitation above.
8		Myers and Khalil teach this limitation above.
9		Khalil teaches this limitation above.
10		Myers and Khalil teach this limitation above.
11		Myers teaches this limitation above.
12		Philips teaches this limitation above.
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.

19		Blondheim teaches this limitation above.
20		Barack teaches this limitation above.
21	1	
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
29		Mendoza teaches this limitation above.
30		Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33	31	

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 28-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203109 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	20	
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	21	
7	22	
8	22	
9		Khalil teaches this limitation above.
10		Myers and Khalil teach this limitation above.
11	23	
12	29	
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19	6	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.

24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
28	18	
29		Mendoza teaches this limitation above.
30	19	
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 28-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203150 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each

having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

This is a provisional nonstatutory double patenting rejection.

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	2	
4		Philips teaches this limitation above.
5	1	
6	3	
7	4	
8	6	
9	7	
10		Myers and Khalil teach this limitation above.
11	8	
12	15	
13		Philips teaches this limitation above.
14	16	
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18	23	
19	28	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22	17	

24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
28	29	
29	29	
30	30	Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

Claims 1-22, 24, 25, 28-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203179 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several

breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	10	
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	11	
7	12	
8	13	
9	15	
10		Myers and Khalil teach this limitation above.
11	16	
12	2	
13		Philips teaches this limitation above.
14	3	
15	1	
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18	23	
19	28	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
28	29	
29	29	
30	30	

31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203216 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of

ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6		Myers and Khalil teach this limitation above.
7		Myers and Khalil teach this limitation above.
8		Myers and Khalil teach this limitation above.
9		Khalil teaches this limitation above.
10		Myers and Khalil teach this limitation above.
11		Myers teaches this limitation above.
12		Philips teaches this limitation above.
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19		Blondheim teaches this limitation above.
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25	1	
29		Mendoza teaches this limitation above.
30		Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33	31	

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203259 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may

change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6		Myers and Khalil teach this limitation above.
7		Myers and Khalil teach this limitation above.
8		Myers and Khalil teach this limitation above.
9		Khalil teaches this limitation above.
10		Myers and Khalil teach this limitation above.
11		Myers teaches this limitation above.
12	22	
13		Philips teaches this limitation above.
14	23	
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19	28	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25	13	
29	29	
30		Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33	31	

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 28-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 and 31 of copending Application No. 17/203292 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching

1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	3	
7	4	
8	5	
9	7	
10		Myers and Khalil teach this limitation above.
11		Myers teaches this limitation above.
12	12	
13		Philips teaches this limitation above.
14	16	
15		Karsan teaches this limitation above.
16	1	
17		Myers and Khalil teach this limitation above.
18	23	
19	28	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24	32	
25		Guthrie teaches this limitation above.
28	29	
29	29	
30	30	
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 28-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203313 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or

optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	16	
4		Philips teaches this limitation above.

5		Chang teaches this limitation above.
6	17	
7	18	
8	18	
9	19	
10		Myers and Khalil teach this limitation above.
11	20	
12	27	
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19	1	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
28	13	
29	14	
30	15	
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203327 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	3	
7	4	

8	4	
9	7	
10		Myers and Khalil teach this limitation above.
11	8	
12	15	
13		Philips teaches this limitation above.
14	16	
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18	23	
19		Blondheim teaches this limitation above.
20	1	
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
29		Mendoza teaches this limitation above.
30		Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203355 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses

the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	2	
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	3	
7	4	
8	5	
9	7	
10		Myers and Khalil teach this limitation above.
11	8	
12	15	
13		Philips teaches this limitation above.

14	16	
15		Karsan teaches this limitation above.
16	1	
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19	28	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22	17	
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
28		
29	30	
30	31	
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33	32	

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203384 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast

shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6		Myers and Khalil teach this limitation above.
7		Myers and Khalil teach this limitation above.
8		Myers and Khalil teach this limitation above.
9		Khalil teaches this limitation above.
10		Myers and Khalil teach this limitation above.
11		Myers teaches this limitation above.
12		Philips teaches this limitation above.
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.

17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19		Blondheim teaches this limitation above.
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
29		Mendoza teaches this limitation above.
30		Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33	29	

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203397in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	1	
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	3	
7	4	
8	5	
9	7	
10		Myers and Khalil teach this limitation above.
11	8	
12	15	
13	32	
14	16	
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18	23	
19	28	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.

24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
29	30	
30	31	
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203418 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several

breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	2	
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	3	
7	4	
8	5	
9	7	
10		Myers and Khalil teach this limitation above.
11	8	
12	1	
13	1	
14	16	
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18	23	
19	28	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
29	30	
30	31	
31		Barack teaches this limitation above.

32		Cudworth teaches this limitation above.
33	32	

This is a provisional nonstatutory double patenting rejection.

Allowable Subject Matter

Except for the double patenting rejection above, **claim 28** would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not teach or suggest the pump delivers the claimed stall pressure and free air flow.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COURTNEY FREDRICKSON whose telephone number is (571)270-7481. The examiner can normally be reached Monday-Friday (9 AM - 5 PM EST).

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NATHAN PRICE can be reached on 571-270-5421. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COURTNEY B FREDRICKSON/
Examiner, Art Unit 3783

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EXAMINER	
FREDRICKSON, COURTNEY B	

ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
01/26/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

zIPPatentDocketingMailboxUS@cooley.com

Office Action Summary	Application No. 17/181,057	Applicant(s) O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	Art Unit 3783	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 17December2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-22,24-25 and 28-33 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-22,24-25 and 28-33 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 22February2021 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☑ All b)☐ Some** c)☐ None of the:

1.☑ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

The information disclosure statement (IDS) submitted is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Amendment

This office action is responsive to the Preliminary amendment filed on December 17, 2021. As directed by the amendment: claims 1, 2, 4-9, 13-16, 18-22, 24, 25, 28-30 have been amended, claims 23, 26, and 27 have been cancelled, and claims 31-33 have been added. Thus, claims 1-22, 24, 25, and 28-33 are presently pending in this application.

Claim Objections

Claims 14, 28, and 29 are objected to because of the following informalities:

Regarding claim 14, the claim should be amended to recite "in which the milk container" in line 1 to correct for grammar.

Regarding claim 28, it is recommended to amend the claim to recite that "the pump is configured to deliver in excess..." to clarify that the feature is a functional aspect of the pump.

Claim 29 should end in a period.

Appropriate correction is required.

Claim Interpretation

The preamble in claim 1 recites "A breast pump device that is configured as a self-contained, in-bra wearable device". The examiner notes that this limitation gives life and meaning to the claim since it sets forth structural limitations to the overall breast pump device. For examination purposes, the term "self-contained, in-bra wearable device' is interpreted to mean "complete, or having all that is needed, in itself' and is capable of being worn in a bra. Applicant's disclosure appears to support this interpretation in fig. 1 of the Drawings which shows a fully complete breast pump device which is capable of being worn in a bra due to the device being self-contained.

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 6-8, 10, 11, 14, 16-18, 22, 24, and 31 is/are rejected under 35 U.S.C. 103 as being unpatentable over Myers (US 20080275386) and in further view of Barack (US 20140378895).

Regarding claim 1, Myers discloses a breast pump device that is configured as a self-contained, in-bra wearable device (breast pump 10 in fig. 1), comprising:

(i) a housing (outer housing 16 in fig. 1) that includes (a) a battery (AA battery 51 in fig. 10), and (b) a pump generating negative air pressure (motor 54 in fig. 10);

(ii) a breast shield (breast cup 16 in fig. 1) being configured to slide in and out of the housing (paragraph 58 discloses that the cup "clicks" into place within the housing; paragraph 42 discloses the breast cup being removable), the breast shield made up of a breast flange (outer flange area 50 in fig. 5) and a nipple tunnel (nipple tunnel 46 in fig. 5), in which the breast shield is transparent or optically clear (paragraph 65); and

(iii) a milk container that is configured to be attached to and removed from the housing (collection bag 28 is shown to be operatively attached to the housing and is physically engaged to the bottom portion of the housing).

However, Myers does not teach or disclose the breast shield being of a plurality of interchangeable breast shields each having a different size.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield of modified Khalil to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

Regarding claim 2, in the modified device of Myers, Barack discloses the plurality of interchangeable breast shields each provide a different spacing of a nipple from side walls of the nipple tunnel when that breast shield has been placed onto a breast (paragraph 54).

Regarding claim 3, in the modified device of Myers, Myers discloses the breast shield is rigid (paragraph 47 discloses the nipple tunnel, which is part of the breast shield, is rigid).

Regarding claim 6, in the modified device of Myers, Myers discloses the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast (the shield of Myers is

functionally capable of being rotated smoothly around a nipple since the claim does not require that the shield be fully latched onto the nipple for this rotation to occur).

Regarding claim 7, in the modified device of Myers, Myers discloses the breast shield presents, in use, a single continuous surface to a nipple and a breast (fig. 9A/B shows a singular inner surface which would extend from the nipple to the breast).

Regarding claim 8, in the modified device of Myers, Myers discloses the breast shield integrates the breast flange and the nipple tunnel as a single item (fig. 5 shows a singular item).

Regarding claim 10, in the modified device of Myers, Myers discloses the breast shield is configured to slide into the housing with a single push action (paragraph 58 discloses the shield can click into place).

Regarding claim 11, in the modified device of Myers, Myers discloses the breast shield is configured to slide out from the housing, together with a membrane that prevents milk from flowing into the pump (flange top 36 in fig. 9A).

Regarding claim 14, in the modified device of Myers, Myers discloses milk container attaches to a lower part of the housing (fig. 1 shows a part of the collection bag attached to the bottom part of the housing 16) and forms a base of the breast pump device (fig. 1).

Regarding claim 16, in the modified device of Myers, Myers discloses the nipple tunnel includes guide lines running parallel along one or more sides of the nipple tunnel (detent tabs 52a/b in fig. 15 are shown to be extending in a parallel to the width direction of the nipple tunnel sides).

Regarding claim 17, in the modified device of Myers, Myers discloses the nipple tunnel includes an air hole or passage (24 in fig. 9A), and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage (paragraph 52).

Regarding claim 18, in the modified device of Myers, Myers discloses the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container (outlet 24 in fig. 9A).

Regarding claim 22, in the modified device of Myers, Myers discloses the housing is shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra (fig. 1; paragraph 40).

Regarding claim 24, in the modified device of Myers, Myers discloses the breast pump device is configured to deliver a maximum suction of approximately 240 mmHg (paragraph 72).

Regarding claim 31, modified Myers teaches a kit comprising the breast pump device of claim 1 (see discussion above); and the plurality of interchangeable breast shields (paragraph 54 of Barack).

Claim 4 is/are rejected under 35 U.S.C. 103 as being unpatentable over Myers in view of Barack, as applied to claim 1 above, and further in view of Phillips (US 20160296682), as evidenced by Yuen (US 20050228342).

Regarding claim 4, modified Myers teaches all of the claimed limitations set forth in claim 1, as discussed above. Myers further teaches the breast shield is made from plastic (paragraph 40 discloses the breast cup being made from silicone, which is a type of plastic, as evidenced by Yuen in paragraph 24). However, modified Myers does not teach or disclose breast shield is dishwasher safe.

Phillips teaches a breast pump device (fig. 1) comprising a breast shield (110 in fig. 1). Phillips further teaches that the shield can be washed in a dishwasher (paragraph 60). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield of modified Myers to be dishwasher safe for the purpose of enabling the shield to be cleaned in the dishwasher for reuse, as taught by Phillips (paragraph 60).

Claims 1, 2, 6-10, 14, 17, 18, 20-22, and 31 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil (US 20130023821) in view of Myers (US 20080275386) and in further view of Barack (US 20140378895).

Regarding claim 1, Khalil discloses a breast pump device that is configured as a self-contained, in-bra wearable device (figs. 9-11), comprising:

(i) a housing (6' and 6" form a housing as shown in fig. 9) that includes (a) a power source (paragraph 32 discloses the power source integrated into the housing), and (b) a pump generating negative air pressure (vacuum pump 81 in fig. 10);

(ii) a breast shield (breast interface 1 in fig. 11) being configured to slide in and out of the housing (breast interface 1 is configured to slide in/out from the housing by attaching/detaching the lip 11 to the flange 62 of the housing as shown in fig. 4), the breast shield made up of a breast flange (base part 12 in fig. 4) and a nipple tunnel (stub 10 in fig. 4); and

(iii) a milk container that is configured to be attached to and removed from the housing (milk collection container 7' in fig. 11; paragraph 69 discloses the container being releasably connected to the housing part 6').

However, Khalil does not teach or disclose the power source being a battery and the breast shield being of a plurality of interchangeable breast shields each having a different size and each breast shield being transparent or optically clear.

Myers teaches a similar breast pump system (fig. 1) having a housing (outer housing 16 in fig. 1) which comprises a battery (battery 52 in fig. 10) and a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing to include a battery, as taught by Myers, for the purpose of providing power to the device and to have made the breast shield transparent to enable a user to view the condition of a nipple (paragraph 65).

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield of modified Khalil to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

Regarding claim 2, in the modified device of Khalil, Barack discloses the plurality of interchangeable breast shields each provide a different spacing of a nipple

from side walls of the nipple tunnel when that breast shield has been placed onto a breast (paragraph 54).

Regarding claim 6, in the modified device of Khalil, Khalil discloses the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast (the shield of Khalil is functionally capable of being rotated smoothly around a nipple since the claim does not require that the shield be fully latched onto the nipple for this rotation to occur).

Regarding claim 7, in the modified device of Khalil, Khalil discloses the breast shield presents, in use, a single continuous surface to a nipple and a breast (fig. 11).

Regarding claim 8, in the modified device of Khalil, Khalil discloses the breast shield integrates the breast flange and the nipple tunnel as a single item (fig. 11).

Regarding claim 9, in the modified device of Khalil, Khalil discloses the breast shield is generally symmetrical about a centre-line running from a top to a bottom of the breast shield when positioned upright for normal use (fig. 11).

Regarding claim 10, in the modified device of Khalil, Khalil discloses the breast shield is configured to slide into the housing with a single push action (the shield of Khalil is functionally capable of being pushed into the housing so that the nipple tunnel is located in the housing).

Regarding claim 14, in the modified device of Khalil, Khalil discloses milk container attaches to a lower part of the housing and forms a base of the breast pump device (fig. 9).

Regarding claim 17, in the modified device of Khalil, Khalil discloses the nipple tunnel includes an air hole or passage (opening 13 in fig. 3), and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage (figs. 4 and 5).

Regarding claim 18, in the modified device of Khalil, Khalil discloses the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container (opening 13 in fig. 3 is considered to be on a "lower" surface of the nipple tunnel since "lower" is not further defined; see fig. 5).

Regarding claim 20, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the housing further includes a Universal Serial Bus (USB) charging socket.

As discussed above, Barack is directed towards a breast pump device (fig. 1) which comprises a housing which houses a pump (fig. 1 shows a pump 20 which would necessarily have some sort of housing since it is disclosed to have a USB port and a user interface). Barack further teaches a USB charging socket (USB port 34 in fig. 1; paragraph 45). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing of modified Khalil to include the USB charging socket, as taught by Khalil, for the purpose of enabling the device to interface with an external memory (paragraph 45).

Regarding claim 21, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the housing includes a left or right breast selector or toggle switch, that, when selected for a particular pumping session, sends data to a connected application configured to track

pumping sessions, to indicate whether that particular session is associated with a left or a right breast.

Barack teaches a breast pump device (fig. 1) which has a control electronics (controller 22 in fig. 1) and a control interface (user interface 30 in fig. 1) that is user selectable to indicate or record if milk is being expressed from the left or right breast (paragraph 43) and that, when selected for a particular pumping session, sends data to a connected application, running on a device, such as a smartphone, that tracks pumping sessions, to indicate whether that session is associated with the left or the right breast (paragraph 46 discloses transmitting via transceiver the parameters that have been entered at the user interface 30 to a remove device; paragraph 43 discloses that one parameter entered at the user interface is which breast is selected).

Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the housing of modified Khalil to include a left or right breast selector or toggle switch, that, when selected for a particular pumping session, sends data to a connected application configured to track pumping sessions, to indicate whether that particular session is associated with a left or a right breast, as taught by Barack. This modification would enable a user to track which parameters are best suited for each breast to optimize pumping, as taught by Barack (paragraphs 8 and 43).

Regarding claim 22, in the modified device of Khalil, Khalil discloses the housing is shaped to fit inside a bra by having an outer surface that is curved to fit contours of a bra (fig. 9).

Regarding claim 31, modified Khalil teaches a kit comprising the breast pump device of claim 1 (see discussion above); and the plurality of interchangeable breast shields (paragraph 54 of Barack).

Claim 5 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Chang (US 20180333523).

Regarding claim 5, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast shield is configured to attach using magnets to the housing.

Chang teaches a substantially similar self-contained breast pump system (breast pump system 10 in fig. 1A) having a breast shield (flange 14 in fig. 1A) attached to a housing (housing 12 in fig. 1A) and configured to attach to the housing using one or more magnets (paragraph 108 discloses the shield uses magnets 118 attached to the shield to determine if the shield is properly attached to the housing). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the shield of modified Khalil to be configured to attach using magnets to the housing since Chang teaches this configuration provides a safeguard such that the system will not operate unless all components are fully connected (paragraph 108).

Claims 12 and 13 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Phillips (US 20160296682).

Regarding claim 12, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Although it appears based on fig. 11 of Khalil that the container would be rigid, modified Khalil does not explicitly teach or disclose this limitation.

Phillips teaches a breast pump system (fig. 1) comprising a milk collection container ("collection container" 120 in fig. 1) which is substantially rigid (paragraph 57 discloses the container being made from Tritan; pg. 21 of Applicant's specification discloses that Tritan is a polycarbonate material, which is a known rigid material). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the container of modified Khalil to be made of Tritan for the purpose of enabling the container to maintain its strength when a vacuum is applied, as taught by Phillips (paragraph 57).

Regarding claim 13, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further discloses the milk container is an optically clear, plastic container (paragraph 69 discloses the container is made of plastic like cover 6" and is transparent in its entirety). However, Khalil does not explicitly teach or disclose the milk container is dishwasher safe.

Phillips teaches a breast pump system (fig. 1) comprising a milk collection container ("collection container" 120 in fig. 1) which is dishwasher safe (paragraph 57 discloses the container being made from Tritan; pg. 21, lines 13-18 of Applicant's specification discloses that Tritan a dishwasher safe material). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the container of modified Khalil to be made of Tritan for the

purpose of enabling the container to maintain its strength when a vacuum is applied, as taught by Phillips (paragraph 57).

Claim 15 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Karsan (US 20070228059).

Regarding claim 15, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the milk container is configured to magnetically attach to the housing.

Khalil teaches that the milk container latches to the housing by a locking lug (paragraph 69 discloses a locking lug formed on the container latches engages into a corresponding recess). Karsan teaches a container (1 in fig. 1) having a case (2 in fig. 3) and a base (fig. 3) which are releasably held together (paragraph 51 discloses the connection being releasable) via a latch mechanism (5 and 6 in fig. 3). Karsan further teaches that the latching mechanism is embodied as a lug and recess (5 and 6, respectively in fig. 3; paragraph 65) but may alternatively be embodied as a magnetic means so that the two components may be magnetically latched (paragraph 65).

In Applicant's invention, Applicant uses the magnets to removably secure the milk container to the housing. Thus, Karsan is reasonably pertinent to the problem faced by the inventor since Karsan teaches using magnets as a removable latching connection between two components. As Karsan teaches that the magnetic means (paragraph 65) are functional equivalents to a locking lug and recess (paragraph 65), it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have substituted the locking lug/recess configuration of Khalil with

the magnetic means, as taught by Karsan. The substitution would have resulted in providing an equivalent secure attachment of the milk container to the housing.

Claim 19 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Blondheim (US 20120277636).

Regarding claim 19, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the pump comprises one or more piezo air pumps.

Blondheim is directed towards a breast pump device (fig. 1) which comprises an air pump (66 in fig. 6). Blondheim further teaches that the air pump can be a piezoelectric pump (paragraph 36). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the pump of modified Khalil to be a piezoelectric pump, as taught by Blondheim for the purpose of rendering the pump small in size (paragraph 36).

Claim 25 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Guthrie (US 20160220743).

Regarding claim 25, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast pump device includes a sensor that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container.

Guthrie is directed towards a breast pump device comprising a sensor (detector 607 in fig. 6B) that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container (paragraph 63 discloses that the emitter 606 and the detector 607 operate to detect light reflecting off the opaque surface of the milk). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the device to include a sensor that is configured to directly measures the measure a level of milk in the milk container by measuring an intensity of light reflected from a surface of the milk stored in the milk container, as taught by Guthrie, for the purpose of measuring volume of milk pumped (paragraph 54).

Claim 29 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, and further in view of Mendoza (US 6227936).

Regarding claim 29, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the pump is a lightweight air pump that enables the total mass of the breast pump system, unfilled with milk, to be less than 250gm.

Mendoza teaches a bra which is designed to support a breast pump to allow the mother's hands to remain free (1:8-12). Mendoza further discloses that the bra must be able to support up to 8 ounces when the pump is full (1:58-62). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed

invention to have modified the system of modified Khalil to be a lightweight air pump that enables the total weight of the system, unfilled with milk, to be less than 250gm, as taught by Mendoza since Mendoza teaches that a lightweight system is crucial for enabling the system to be supported by a bra.

Claim 30 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, in further view of Baker (US 20090281485).

Regarding claim 30, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above, but does not teach or disclose the breast pump device makes less than 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

Baker is directed towards a device for removing fluid from a body (fig. 6) using a vacuum pump embodied as a motor (motor 9 in fig. 6; paragraph 243). Baker further teaches that the device makes less than 20 decibel of noise at full power (paragraph 121) by sound proofing the walls of the housing and by adding a counter balance to the motor (paragraph 144). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the device of modified Khalil to have the device make less than 20 dB of noise during maximum power for the purpose of making the device for discrete and comfortable for the user and others around the user.

Claim 32 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 31 above, in further view of Cudworth (US 20120165729).

Regarding claim 32, modified Khalil teaches all of the claimed limitations set forth in claim 31, as discussed above, but does not teach or disclose each of the plurality of interchangeable breast shields includes fit lines in a nipple tunnel of that breast shield that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel.

Cudworth teaches a breast pump system (fig. 1) having a shield (attachment 1) having a flange (cup 2 in fig. 2) and a nipple tunnel (cylindrical portion 3 in fig. 1). Cudworth further teaches the nipple tunnel includes fit lines in a nipple tunnel of that breast shield that are configured to enable a user to visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel (grooves 12 in fig. 1 are functionally capable of serving as "fit lines" to assist a user in determining if the breast shield is correctly sized and since the claimed fit lines are not further structurally defined). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the nipple tunnel of Khalil to include the claimed fit lines, as taught by Cudworth, for the purpose of providing a massaging pressure on the breast to help stimulate milk production (paragraph 30).

Claim 33 is/are rejected under 35 U.S.C. 103 as being unpatentable over Khalil in view of Myers and in further view of Barack, as applied to claim 1 above, in further view of Meyers (US 5542921).

Regarding claim 33, modified Khalil teaches all of the claimed limitations set forth in claim 1, as discussed above. Khalil further teaches control electronics ("control

elements and a display" in paragraph 51) which would be powered by the battery (the power source of Khalil is understood to power the device).

However, Khalil does not teach or disclose the battery to be rechargeable and the housing further including a power charging circuit for controlling the charging of the rechargeable battery.

Meyers is directed to a breast pump device (fig. 1) comprising a battery configured to be recharged (9:50-52 discloses recharging the batteries) and a power charging circuit for controlling the charging of the rechargeable battery ("circuit" in 9:50-52). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the battery of modified Khalil to be rechargeable and to have incorporated a power charging circuit for controlling the charging of the rechargeable battery, as taught by Meyers to enable the batteries to be reused.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-22, 24, 25, 29-33 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10881766 in view of Khalil, Myers, Barack, and the teachings below (see table).

Regarding claim 1, claim 1 of the issued patent claims all of the claimed limitations of instant claim 1 except the device being a self-contained, in-bra device having a breast shield being substantially rigid and formed from dishwasher safe plastic.

Khalil teaches a breast pump device (fig. 10) configured as a self-contained, in-bra wearable device (fig. 10; paragraph 70). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the reference claim to be a self-contained, in-bra wearable device, as taught by Khalil, for the purpose of enabling the device to be a small and hands-free (paragraph 70).

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65).

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may

change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5	8	
6		Myers and Khalil teach this limitation above.
7	7	
8	27	
9		Khalil teaches this limitation above.
10	8	
11		Myers teaches this limitation above.
12		Philips teaches this limitation above.
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.
15	2	
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19	18	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25	26	
29		Mendoza teaches this limitation above.
30		Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

Claims 1-22, 24, 25, and 28-33 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10926011 in view of Khalil, Myers, and Barack, and the teachings below (see table).

Regarding claim 1, claim 1 of the issued patent claims all of the limitations in instant claim 1 except claim 1 does not claim a self-contained device, the housing having a battery, the breast shield having a breast flange and nipple tunnel and being substantially rigid and formed of an optically clear, dishwasher safe plastic and being configured to slide into the housing and the milk container being configured for attachment and removal from the housing.

Khalil teaches a breast pump device (fig. 10) configured as a self-contained, in-bra wearable device (fig. 10; paragraph 70) having a breast shield (1 in fig. 11) having a flange (12in fig. 6) and a nipple tunnel (13 in fig. 6) and a milk container (7' in fig. 11)configured to be attached and removed from the housing (paragraph 69). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the reference claim to be a self-contained, in-bra wearable device having a breast shield with a flange and nipple tunnel and a milk container configured to be attached and removed from the housing, as taught by Khalil, for the purpose of enabling the device to be a small and hands-free (paragraph 70). The modification of the breast shield would enable the shield to interface with the breast and receive the nipple and the modification of the milk container would enable the milk to be collected after expression.

Myers teaches a self-contained, in bra breast pump (fig. 1) which comprises a breast shield (18 in fig. 2) having a flange (48 in fig. 5) and nipple tunnel (46 in fig. 5) and a housing (16 in fig. 2) for housing a pump (56 in fig. 10) and a battery for powering the pump (52 in fig. 10). Myers further teaches that the breast shield is optically clear (paragraph 65). Therefore, it would have been obvious to one of ordinary skill before

the effective filing date of the claimed invention to have modified the shield to be optically clear for the purpose of allowing a user to visualize the placement of the breast and nipple and to have modified the housing to include a battery, as taught by Myers, for the purpose of providing power to the device.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6		Myers and Khalil teach this limitation above.
7	30	
8		Myers and Khalil teach this limitation above.
9		Khalil teaches this limitation above.
10	14	
11		Myers teaches this limitation above.
12	12	
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.

15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19	1	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25	19	
28	9	
29	28	
30	10	
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

Claims 1-22, 24, 25, 28-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203050 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph

65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	6	
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	7	
7	8	
8	9	
9	11	
10		Myers and Khalil teach this limitation above.
11		Myers teaches this limitation above.
12		Philips teaches this limitation above.
13		Philips teaches this limitation above.
14	20	
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.

19	2	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22	21	
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
28	4	
29	4	
30	5	
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203079 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph

65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6		Myers and Khalil teach this limitation above.
7		Myers and Khalil teach this limitation above.
8		Myers and Khalil teach this limitation above.
9		Khalil teaches this limitation above.
10		Myers and Khalil teach this limitation above.
11		Myers teaches this limitation above.
12		Philips teaches this limitation above.
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.

19		Blondheim teaches this limitation above.
20		Barack teaches this limitation above.
21	1	
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
29		Mendoza teaches this limitation above.
30		Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33	31	

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 28-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203109 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	20	
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	21	
7	22	
8	22	
9		Khalil teaches this limitation above.
10		Myers and Khalil teach this limitation above.
11	23	
12	29	
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19	6	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.

24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
28	18	
29		Mendoza teaches this limitation above.
30	19	
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 28-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203150 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each

having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

This is a provisional nonstatutory double patenting rejection.

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	2	
4		Philips teaches this limitation above.
5	1	
6	3	
7	4	
8	6	
9	7	
10		Myers and Khalil teach this limitation above.
11	8	
12	15	
13		Philips teaches this limitation above.
14	16	
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18	23	
19	28	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22	17	

24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
28	29	
29	29	
30	30	Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

Claims 1-22, 24, 25, 28-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203179 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several

breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	10	
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	11	
7	12	
8	13	
9	15	
10		Myers and Khalil teach this limitation above.
11	16	
12	2	
13		Philips teaches this limitation above.
14	3	
15	1	
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18	23	
19	28	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
28	29	
29	29	
30	30	

31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203216 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of

ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6		Myers and Khalil teach this limitation above.
7		Myers and Khalil teach this limitation above.
8		Myers and Khalil teach this limitation above.
9		Khalil teaches this limitation above.
10		Myers and Khalil teach this limitation above.
11		Myers teaches this limitation above.
12		Philips teaches this limitation above.
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19		Blondheim teaches this limitation above.
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25	1	
29		Mendoza teaches this limitation above.
30		Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33	31	

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203259 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may

change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6		Myers and Khalil teach this limitation above.
7		Myers and Khalil teach this limitation above.
8		Myers and Khalil teach this limitation above.
9		Khalil teaches this limitation above.
10		Myers and Khalil teach this limitation above.
11		Myers teaches this limitation above.
12	22	
13		Philips teaches this limitation above.
14	23	
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19	28	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25	13	
29	29	
30		Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33	31	

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 28-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 and 31 of copending Application No. 17/203292 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching

1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	3	
7	4	
8	5	
9	7	
10		Myers and Khalil teach this limitation above.
11		Myers teaches this limitation above.
12	12	
13		Philips teaches this limitation above.
14	16	
15		Karsan teaches this limitation above.
16	1	
17		Myers and Khalil teach this limitation above.
18	23	
19	28	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24	32	
25		Guthrie teaches this limitation above.
28	29	
29	29	
30	30	
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 28-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203313 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or

optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	16	
4		Philips teaches this limitation above.

5		Chang teaches this limitation above.
6	17	
7	18	
8	18	
9	19	
10		Myers and Khalil teach this limitation above.
11	20	
12	27	
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19	1	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
28	13	
29	14	
30	15	
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203327 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	3	
7	4	

8	4	
9	7	
10		Myers and Khalil teach this limitation above.
11	8	
12	15	
13		Philips teaches this limitation above.
14	16	
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18	23	
19		Blondheim teaches this limitation above.
20	1	
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
29		Mendoza teaches this limitation above.
30		Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203355 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses

the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	2	
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	3	
7	4	
8	5	
9	7	
10		Myers and Khalil teach this limitation above.
11	8	
12	15	
13		Philips teaches this limitation above.

14	16	
15		Karsan teaches this limitation above.
16	1	
17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19	28	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22	17	
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
28		
29	30	
30	31	
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33	32	

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203384 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast

shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3		Myers teaches this limitation above.
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6		Myers and Khalil teach this limitation above.
7		Myers and Khalil teach this limitation above.
8		Myers and Khalil teach this limitation above.
9		Khalil teaches this limitation above.
10		Myers and Khalil teach this limitation above.
11		Myers teaches this limitation above.
12		Philips teaches this limitation above.
13		Philips teaches this limitation above.
14		Myers and Khalil teach this limitation above.
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.

17		Myers and Khalil teach this limitation above.
18		Myers and Khalil teach this limitation above.
19		Blondheim teaches this limitation above.
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
29		Mendoza teaches this limitation above.
30		Baker teaches this limitation above.
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33	29	

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203397in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	1	
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	3	
7	4	
8	5	
9	7	
10		Myers and Khalil teach this limitation above.
11	8	
12	15	
13	32	
14	16	
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18	23	
19	28	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.

24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
29	30	
30	31	
31		Barack teaches this limitation above.
32		Cudworth teaches this limitation above.
33		Meyers teaches this limitation above.

This is a provisional nonstatutory double patenting rejection.

Claims 1-22, 24, 25, 29-33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of copending Application No. 17/203418 in view of the teachings below.

Regarding claim 1, the independent claim(s) claim all of the limitations of instant claim 1 except in that the claim(s) does not claim he breast shield is transparent or optically clear and is of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing.

Myers teaches a breast pump system (fig. 1) having a breast shield (breast cup 18 in fig. 2) which is transparent (paragraph 65 discloses the silicone breast cup being transparent) and configured to slide in and out of the housing (paragraph 42 discloses the cup being removable. Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be transparent to enable a user to view the condition of a nipple (paragraph 65) and to be enabled to slide in and out of the housing for the purpose of removing the breast shield after use.

Barack is directed to a breast pump device (fig. 1) having a breast shield (breast shield 12 in fig. 1) which is a part of a plurality of interchangeable breast shields each having a different size (paragraph 54 discloses the device is provided with several

breast shields which are each configured to be used with a singular breast pump device and have their own tunnel size). Therefore, it would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the breast shield to be a part of a plurality of interchangeable breast shields each having a different size, as taught by Barack, since Barack teaches that a user's nipples may change in size during the course of nursing which would necessitate a different shield (paragraph 54).

App Claim	Ref Claim	Teaching
1		See discussion above
2		Barack teaches this limitation above.
3	2	
4		Philips teaches this limitation above.
5		Chang teaches this limitation above.
6	3	
7	4	
8	5	
9	7	
10		Myers and Khalil teach this limitation above.
11	8	
12	1	
13	1	
14	16	
15		Karsan teaches this limitation above.
16		Myers teaches this limitation above.
17		Myers and Khalil teach this limitation above.
18	23	
19	28	
20		Barack teaches this limitation above.
21		Barack teaches this limitation above.
22		Myers and Khalil teach this limitation above.
24		Myers teaches this limitation above.
25		Guthrie teaches this limitation above.
29	30	
30	31	
31		Barack teaches this limitation above.

32		Cudworth teaches this limitation above.
33	32	

This is a provisional nonstatutory double patenting rejection.

Allowable Subject Matter

Except for the double patenting rejection above, **claim 28** would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not teach or suggest the pump delivers the claimed stall pressure and free air flow.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COURTNEY FREDRICKSON whose telephone number is (571)270-7481. The examiner can normally be reached Monday-Friday (9 AM - 5 PM EST).

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NATHAN PRICE can be reached on 571-270-5421. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COURTNEY B FREDRICKSON/
Examiner, Art Unit 3783

/NATHAN R PRICE/
Supervisory Patent Examiner, Art Unit 3783

Notice of References Cited	Application/Control No. 17/181,057	Applicant(s)/Patent Under Reexamination O'TOOLE et al.	
	Examiner COURTNEY FREDRICKSON	Art Unit 3783	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
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*	B	US-6227936-B1	05-2001	Mendoza; Amelia	A41C3/04	2/104
*	C	US-20070228059-A1	10-2007	Karsan; Chettan	B65D43/16	220/824
*	D	US-20080275386-A1	11-2008	Myers; Kenneth E.	A61M1/81	604/74
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*	F	US-20120165729-A1	06-2012	Cudworth; Nicholas	A61J13/00	604/74
*	G	US-20120277636-A1	11-2012	Blondheim; David Simeon	A61B5/742	600/595
*	H	US-20130023821-A1	01-2013	KHALIL; Gamal	A61M1/82	604/74
*	I	US-20140378895-A1	12-2014	Barack; Doron	A61M1/06	604/74
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*	K	US-20160296682-A1	10-2016	Phillips; Andrew Luke	A61J13/00	1/1
*	L	US-20180333523-A1	11-2018	Chang; John	A61M1/06	1/1
	M					

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

CPC - Searched*		
Symbol	Date	Examiner
a61m1/06-069	01/12/2022	cbf

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
see SEARCH history	01/12/2022	cbf
searched inventors in PALM and SEARCH	01/12/2022	cbf
consulted child search history	01/12/2022	cbf

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/181,057	O'TOOLE et al.
	Examiner	Art Unit
	COURTNEY FREDRICKSON	3783

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS										
☐ Claims renumbered in the same order as presented by applicant						☐ CPA		☐ T.D.		☐ R.1.47
CLAIM		DATE								
Final	Original	01/12/2022								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
	7	✓								
	8	✓								
	9	✓								
	10	✓								
	11	✓								
	12	✓								
	13	✓								
	14	✓								
	15	✓								
	16	✓								
	17	✓								
	18	✓								
	19	✓								
	20	✓								
	21	✓								
	22	✓								
	23	-								
	24	✓								
	25	✓								
	26	-								
	27	-								
	28	✓								
	29	✓								
	30	✓								
	31	✓								
	32	✓								
	33	✓								

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	
First Named Inventor	Jonathan O'Toole
Art Unit	
Examiner Name	
Attorney Docket Number	373499.00049

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	Application Number	
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	First Named Inventor	Jonathan O'Toole
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

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	Art Unit	
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	Attorney Docket Number	373499.00049

	20	7201735	B2	2007-04-10	ATKIN, et al.	
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	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

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	First Named Inventor	Jonathan O'Toole
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020193731	A1	2002-12-19	MYERS, et al.	
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	First Named Inventor	Jonathan O'Toole
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

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	13	20110196291	A1	2011-08-11	VISCHER, et al.	
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	First Named Inventor	Jonathan O'Toole
	Art Unit	
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	Attorney Docket Number	373499.00049

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	First Named Inventor	Jonathan O'Toole
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	5	1586340	EP	A2	2005-10-19	SEA PROFIT (HONG KONG) LIMITED		
	6	2005114116	WO	A1	2005-12-01	LANE, JOHN, DENNIS; ESPARZA, JOSEPH, LUIS; NICHOLS		
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	First Named Inventor	Jonathan O'Toole
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	16	1404393	EP	B1	2014-12-24	MEDELA HOLDING AG		
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	First Named Inventor	Jonathan O'Toole
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	Attorney Docket Number	373499.00049

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	First Named Inventor	Jonathan O'Toole
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	Examiner Name	
	Attorney Docket Number	373499.00049

	38	2017139480	WO	A1	2017-08-17	EXPLORAMED NC7, INC.		

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	1	Whisper Wear Hands-Free Breast Pump, Model: WWPMP01, User Guide, pps. 1-20, Distributed with product at least as early as 2007 (see https://web.archive.org/web/20070621162539/http://www.whisperwear.com/pump_single.html)	

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	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

✓ A certification statement is not submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Mark D. Simpson/	Date (YYYY-MM-DD)	2021-02-22
Name/Print	Mark D Simpson	Registration Number	32942

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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(Not for submission under 37 CFR 1.99)

Application Number	17181057
Filing Date	2021-02-22
First Named Inventor	Jonathan O'Toole
Art Unit	3783
Examiner Name	
Attorney Docket Number	373499.00049

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5542921	A	1996-08-06	MEYERS, et al.	
	2	7833190	B1	2010-11-16	HALL	

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	1	20070135761	A1	2007-06-14	CHENG, et al.	
	2	20070179439	A1	2007-08-02	VOGELIN, et al.	
	3	20090281485	A1	2009-11-12	BAKER, et al.	
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	Application Number	17181057
	Filing Date	2021-02-22
	First Named Inventor	Jonathan O'Toole
	Art Unit	3783
	Examiner Name	
	Attorney Docket Number	373499.00049

	5	20160271305	A1	2016-09-22	KURIHARA, et al.	
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	Filing Date	2021-02-22
	First Named Inventor	Jonathan O'Toole
	Art Unit	3783
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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17181057
	Filing Date	2021-02-22
	First Named Inventor	Jonathan O'Toole
	Art Unit	3783
	Examiner Name	
	Attorney Docket Number	373499.00049

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

✓ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Mark D. Simpson/	Date (YYYY-MM-DD)	2021-09-05
Name/Print	Mark D. Simpson	Registration Number	32942

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	1	17/181057.app.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:05 PM
L2	128	((("O'TOOLE") near3 ("Jonathan")) OR (("ROLLO") near3 ("Adam")) OR (("CARR") near3 ("Andrew"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/12/31 01:05 PM
L3	8470	a61m1/06-069.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L5	2	("20170216505").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:06 PM
L6	8	("20130023821" "20070219486" "20160296682").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:14 PM
L7	2	("20140378895").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/31 01:16 PM
L8	2	("7824363").pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, CA, CH, CN, DD, DE, EA, EP, ES, FR, GB, JP, KR, OA, RU,	OR	ON	ON	2022/01/01 01:04 PM

			SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

Bibliographic Data

Application No: 17/181,057

Foreign Priority claimed: (•) Yes ( ) No

35 USC 119 (a-d) conditions met: [✓] Yes [ ] No [ ] Met After Allowance

Verified and Acknowledged: /COURTNEY B FREDRICKSON/ Examiner's Signature | Initials

Title: BREAST PUMP SYSTEM

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
02/22/2021	604	3783	ELVI-002/06US
RULE			

APPLICANTS

CHIARO TECHNOLOGY LIMITED, London, UNITED KINGDOM

INVENTORS

Jonathan O'TOOLE, London, UNITED KINGDOM

Adam ROLLO, London, UNITED KINGDOM

Andrew CARR, London, UNITED KINGDOM

CONTINUING DATA

This application is a CON of 16009547 06/15/2018 PAT 10926011

FOREIGN APPLICATIONS

UNITED KINGDOM GB1709566.2 06/15/2017

UNITED KINGDOM GB1709561.3 06/15/2017

UNITED KINGDOM GB1709564.7 06/15/2017

UNITED KINGDOM GB1809036.5 06/01/2018

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COOLEY LLP
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Suite 700
Washington, DC 20004

UNITED STATES

FILING FEE RECEIVED

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 2

Complete if Known	
Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Art Unit	3783
Examiner Name	Courtney B. FREDRICKSON
Attorney Docket Number	ELVI-002/06US 339454-2025

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	7,666,162 B2	02-23-2010	Renz et al.	
	2.	8,608,685 B2	12-17-2013	Tashiro	
	3.	10,881,766 B2	01-05-2021	O'Toole et al.	
	4.	10,926,011 B2	02-23-2021	O'Toole et al.	
	5.	2004/0087898 A1	05-06-2004	Weniger	
	6.	2009/0281482 A1	11-12-2009	Baker et al.	
	7.	2010/0292636 A1	11-18-2010	Renz et al.	
	8.	2012/0165729 A1	06-28-2012	Cudworth	
	9.	2014/0263611 A1	09-18-2014	Bauer	
	10.	2016/0228625 A1	08-11-2016	Holtz et al.	
	11.	2018/0110900 A1	04-26-2018	Barack	
	12.	2021/0196873 A1	07-01-2021	O'Toole et al.	
	13.	2021/0196876 A1	07-01-2021	O'Toole et al.	
	14.	2021/0196874 A1	07-01-2021	O'Toole et al.	
	15.	2021/0196875 A1	07-01-2021	O'Toole et al.	
	16.	2021/0205511 A1	07-08-2021	O'Toole et al.	
	17.	2021/0205512 A1	07-08-2021	O'Toole et al.	
	18.	2021/0205513 A1	07-08-2021	O'Toole et al.	
	19.	2021/0205514 A1	07-08-2021	O'Toole et al.	
	20.	2021/0205515 A1	07-08-2021	O'Toole et al.	
	21.	2021/0205516 A1	07-08-2021	O'Toole et al.	
	22.	2021/0205517 A1	07-08-2021	O'Toole et al.	
	23.	2021/0205518 A1	07-08-2021	O'Toole et al.	
	24.	2021/0228789 A1	07-29-2021	O'Toole et al.	
	25.	2021/0268158 A1	09-02-2021	O'Toole et al.	

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Sheet 2 of 2

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	26.	CN 101549180 A	10-07-2009	Pigeon Corp.	Corresponds to US8608685	
	27.	EP 0503280 A2	02-08-1992	Pierburg GmbH		
	28.	GB 2435617 B	03-05-2008	Playtex Products Inc.		
	29.	WO 2005/079441 A2	09-01-2005	Childrens Hospital Medical Center		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	30.	GB Search Report, dated Nov. 15, 2017, issued in priority GB Application No. GB1709561.3.	
	31.	GB Search Report, dated Nov. 28, 2017, issued in priority GB Application No. GB1709566.2.	
	32.	GB Search Report, dated Nov. 29, 2017, issued in priority GB Application No. GB1709564.7.	
	33.	International Search Report issued in PCT/GB2018/051659 dated December 4, 2018, 9 pages.	

Examiner Signature	/COURTNEY B FREDRICKSON/	Date Considered	01/12/2022

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Sheet 1 of 2

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Application Number	17/181,057
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	3.	10,881,766 B2	01-05-2021	O'Toole et al.	
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	20.	2021/0205515 A1	07-08-2021	O'Toole et al.	
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Sheet 2 of 2

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Filing Date	February 22, 2021
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Art Unit	3783
Examiner Name	Courtney B. FREDRICKSON
Attorney Docket Number	ELVI-002/06US 339454-2025

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	26.	CN 101549180 A	10-07-2009	Pigeon Corp.	Corresponds to US8608685	
	27.	EP 0503280 A2	02-08-1992	Pierburg GmbH		
	28.	GB 2435617 B	03-05-2008	Playtex Products Inc.		
	29.	WO 2005/079441 A2	09-01-2005	Childrens Hospital Medical Center		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	30.	GB Search Report, dated Nov. 15, 2017, issued in priority GB Application No. GB1709561.3.	
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261314587 v1

Bibliographic data

Title:	Breast pump
Pub/Pat no:	CN101549180A
Pub/Issue Date:	2009-10-07
Inventor(s):	MITSUO TASHIRO[JP]| SHINICHI KATAOKA[JP]|TASHIRO MITSUO |KATAOKA SHINICHI
Applicant(s):	PIGEON CORP[JP]
Classification:	A61M1/06AI
Application number:	CN200910134014 2009-04-03
Priority number:	JP20080098492 2008-04-04;

Abstract of CN101549180A

A breast pump can be configured to be capable of easily attaching/detaching a primary side serving as a sealed space which is in communication with a milking space and allows the passage of breast milk, with a secondary side in which a case is connected with a pressure changing apparatus 51. The breast pump can include a breast pump main body 21 connected to the pressure changing apparatus by a conduit, wherein a milking part is disposed so as to liquid-tightly separate a sealed space (or a space that is in fluid communication with the sealed space), and the pressure changing apparatus from each other. A pressure transmission part 30 for transmitting pressure changed by the pressure changing apparatus can be provided. The pressure transmission part can include a deformable part 32 where a volume in the sealed space can be deformed by a pressure fluctuation generated by the pressure changing apparatus. A case 31 can accommodate the deformable part and be connected with the pressure changing apparatus at one end, and the other end of the case can include attachment structure 33 for communicably attaching/detaching the case with the portion of the milking part that forms the sealed space.

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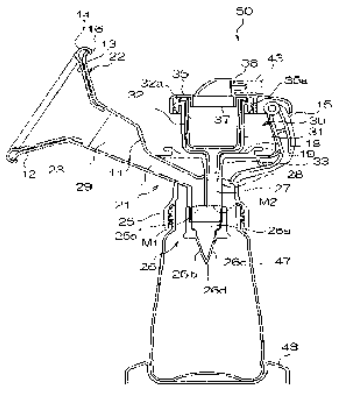
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[54] 发明名称

吸奶器

[57] 摘要

本发明提供一种吸奶器，能够容易地对与吸奶空间连通的母乳所通过的密闭空间即一次侧和与压力改变机构连接的壳体所存在的一侧即二次侧进行装拆。吸奶器具有吸奶器主体(21)和压力改变机构(51)，吸奶部具有用于传递通过所述压力改变机构被改变的压力的压力传递部(30)，该压力传递部将密闭空间或与其连通的空间和所述压力改变机构液密地分离。所述压力传递部具有：变形部(32)，该变形部使所述密闭空间或与该密闭空间连通的空间内所占的体积或容积因所述压力改变机构所产生的压力变化而变形；壳体(31)，用于收容该变形部，并且一端与所述压力改变机构侧连接，在该壳体的另一端，具有用于以能够连通的方式对该壳体内和所述密闭空间进行装拆的装拆机构(33)。



1. 一种吸奶器，具有：与使用者的乳房抵接的大致圆锥状的吸奶部；包含所述吸奶部、以连通的方式与瓶进行装拆的吸奶器主体；与所述吸奶部连接，交替地产生负压状态以及比该负压状态压力高的至少大气压状态的压力改变机构，其特征在于，

具有用于传递通过所述压力改变机构被改变的压力的压力传递部，该压力传递部被配置成，当所述吸奶部进行吸奶时，将因抵接使用者的乳房而形成的密闭空间或与该密闭空间连通的空间和所述压力改变机构液密地分离，

所述压力传递部具有：变形部，该变形部使所述密闭空间或与该密闭空间连通的空间内所占的体积或容积因所述压力改变机构所产生的压力变化而变形；壳体，用于收容该变形部，并且一端与所述压力改变机构侧连接，

在该壳体的另一端，具有用于以能够连通的方式对该壳体内和所述密闭空间进行装拆的装拆机构。

2. 如权利要求 1 所述的吸奶器，其特征在于，所述壳体是在内部收容了所述变形部的筒状体，在该筒状体上具有作为所述装拆机构的、从与所述另一端对应的端部突出的管状突出部，而在所述密闭空间中，具有在该空间内延伸的筒状连接部，使所述筒状连接部的内径比所述壳体侧的所述管状突出部的外径稍大，由此，将所述管状突出部插入所述筒状连接部，成为所述壳体和所述密闭空间被气密接合的结构。

3. 如权利要求 2 所述的吸奶器，其特征在于，所述壳体的所述管状突出部的周边为平坦的底部，在所述吸奶器主体的所述筒状连接部的开口周边形成有平坦的接触面部，将所述管状突出部插入所述筒状连接部，将所述壳体的所述平坦的底部推入至与所述平坦的接触面部抵接的位置，由此，成为所述壳体和所述密闭空间气密接合的结构。

4. 如权利要求 3 所述的吸奶器，其特征在于，所述筒状连接部以在将所述吸奶器主体载置在所述瓶上的状态下、向瓶下方大致垂直延伸的方式形成，并且，所述管状突出部向前端逐渐变细。

5. 如权利要求 1～4 的任一项所述的吸奶器，其特征在于，具有盖部件，该盖部件将收纳所述变形部的所述壳体的一端侧覆盖，并且，与作为所述压力改变机构的负压形成机构连接的管相对于该盖部件装拆，所述盖部件具有卡定机构，在所述壳体和所述密闭空间被接合的状态下，所述卡定机构用于在将所述盖部件安装在所述壳体的一端侧的位置上，将该盖部件相对于所述吸奶器主体的所述密闭空间侧进行卡定。

6. 如权利要求 5 所述的吸奶器，其特征在于，所述卡定机构设置在所述盖部件的周缘部，该卡定机构相对于从所述吸奶器主体侧向上方突出的支承机构被卡定。

7. 如权利要求 5 所述的吸奶器，其特征在于，使从所述盖部件的周缘部延伸的卡定机构相对于在所述吸奶器主体的所述筒状连接部的开口周边所设置的接触面部的周缘部进行卡定。

吸奶器

技术领域

本发明涉及用于吸取母乳的吸奶器的改进。

背景技术

供母亲等吸取母乳使用的吸奶器，例如具有用于与乳房抵接的喇叭部、和用于在因乳房抵接该喇叭部而形成的空间中产生负压的泵等的负压形成机构。被吸引到负压空间的母乳流入瓶等中而被贮存，负压形成空间和所述泵通过连接机构连接（参照专利文献1）。

在这样的吸奶器中，被收容在设置于所述连接机构的外壳中的阀体根据母乳液面的上升而可动，从而阻塞向负压形成机构即所述泵侧的开口。由此，能够防止母乳回流到负压形成机构即泵侧，并能够防止机械结构生锈及被污染。另外，即使在负压形成机构不是由泵等的机械构造构成、而是由杆等的手动机构构成的情况下，也能够避免因母乳回流到该杆等而沾污使用者的手等不良情况。

但是，在这样的吸奶器中，设置在所述连接机构上的、将所述负压空间和所述泵侧连通的开口，是会因阀体的动作而被阻塞的构造。

因此，负压空间和泵侧无法成为始终完全地液密分离的构造，即使阀体将所述开口阻塞，也存在着母乳本身以及随负压成为雾状的母乳等从微小的间隙回流到泵侧的危险。

因此，可能会造成泵的机械部分污损、杂菌繁殖，在手动的负压形成机构中也同样存在着污损和不卫生的问题。

因此，本申请中提出了专利文献2所示的吸奶器。

该吸奶器中具有压力传递部，该压力传递部被配置成，当吸奶部进行吸奶时，能够将因与使用者的乳房抵接而形成的密闭空间、

或与该密闭空间连通的空间和所述压力改变机构液密地分离，该压力传递部用于传递被所述压力改变机构改变了的压力，所述压力传递部具有变形部，该变形部在所述密闭空间或与该密闭空间连通的空间内所占的体积或容积因所述压力改变机构的动作而变化。

因此，由于压力传递部将形成于所述吸奶部的所述密闭空间和泵等的压力改变机构完全液密分离，因而能够有效地防止吸取出的母乳从所述密闭空间侧回流到所述压力改变机构。其结果是，能够有效地防止压力改变机构侧接触母乳而产生腐蚀和破损，或是被污染成为不卫生的状态。

专利文献 1：日本特开平 11-226117

专利文献 2：日本特开 2006-102220

但是，在专利文献 2 的吸奶器中，虽然能够实现将与吸奶空间连通的母乳所通过的密闭空间即一次侧和与压力改变机构连接的壳体所存在的一侧即二次侧液密分离的结构，但它们在构造上是相互结合的构造。

因此，在搬运时、收纳时等，一次侧的构造和二次侧的构造是结合的，因而产生了操作、清洁时等不方便的另外的问题。

发明内容

因此，本发明的目的在于提供一种吸奶器，能够容易地对与吸奶空间连通的母乳所通过的密闭空间即一次侧和与压力改变机构连接的壳体所存在的一侧即二次侧进行装拆，并能够使清洁等的操作变得极其容易。

上述目的在第一发明中是通过如下所述的吸奶器实现的，吸奶器具有：与使用者的乳房抵接的大致圆锥状的吸奶部；包含所述吸奶部、以连通的方式与瓶进行装拆的吸奶器主体；与所述吸奶部连接，交替地产生负压状态以及比该负压状态压力高的至少大气压状态的压力改变机构，其中，具有用于传递通过所述压力改变机构被改变的压力的压力传递部，该压力传递部被配置成，当所述吸奶部

进行吸奶时，将因抵接使用者的乳房而形成的密闭空间或与该密闭空间连通的空间和所述压力改变机构液密地分离，所述压力传递部具有：变形部，该变形部使所述密闭空间或与该密闭空间连通的空间内所占的体积或容积因所述压力改变机构所产生的压力变化而变形；壳体，用于收容该变形部，并且一端与所述压力改变机构侧连接，在该壳体的另一端，具有用于以能够连通的方式对该壳体内和所述密闭空间进行装拆的装拆机构。

根据第一发明的结构，所述压力传递机构通过壳体内收容的所述变形部的体积变化使所述密闭空间的内压变化，由此，改变对抵接于所述吸奶部的乳房的吸引压。

而且，因此，由于所述压力传递部将形成于所述吸奶部的所述密闭空间和泵等的压力改变机构完全地分离，因而能够有效地防止吸取出的母乳从所述密闭空间侧回流到所述压力改变机构。因此，能够有效地防止压力改变机构侧与母乳接触发生腐蚀、破损而被污染成为不卫生的状态。

而且，所述压力传递部具有一端与所述压力改变机构侧连接的壳体，在该壳体的另一端具有用于将该壳体内和所述密闭空间以能够连通的方式进行装拆的装拆机构。因此，例如，能够容易地将收容有变形部的壳体装拆，与密闭空间侧分离，不仅便于携带、移动，尤其在清洗时等，能够容易地仅对需要频繁清洗的一次侧即密闭空间侧进行分离、清洗。

第二发明在第一发明的结构的基础上，所述壳体是在内部收容了所述变形部的筒状体，在该筒状体上具有作为所述装拆机构的、从与所述另一端对应的端部突出的管状突出部，而在所述密闭空间中，具有在该空间内延伸的筒状连接部，使所述筒状连接部的内径比所述壳体侧的所述管状突出部的外径稍大，由此，将所述管状突出部插入所述筒状连接部，成为所述壳体和所述密闭空间被气密接合的结构。

根据第二发明的结构，在所述密闭空间中设置有筒状连接部，

由于该筒状连接部具有比壳体侧的管状突出部的外径稍大的内径，所以通过仅将该管状突出部插入筒状连接部这一简单的操作，就能够将压力改变机构侧和密闭空间侧连接。

第三发明在第二发明的结构的基础上，所述壳体的所述管状突出部的周边为平坦的底部，在所述吸奶器主体的所述筒状连接部的开口周边形成有平坦的接触面部，将所述管状突出部插入所述筒状连接部，将所述壳体的所述平坦的底部推入至与所述平坦的接触面部抵接的位置，由此，成为所述壳体和所述密闭空间气密接合的结构。

根据第三发明的结构，所述壳体的所述管状突出部的周边为平坦的底部，在所述吸奶器主体的所述筒状连接部的开口周边形成有平坦的接触面部，只要将所述管状突出部插入所述筒状连接部、将所述壳体的所述平坦的底部压入到与所述平坦的接触面部抵接的位置，便能够极其容易地将所述壳体和所述密闭空间接合。

第四发明在第三发明的结构的基础上，所述筒状连接部以在将所述吸奶器主体载置在所述瓶上的状态下、向瓶下方大致垂直延伸的方式形成，并且，所述管状突出部向前端逐渐变细。

根据第四发明的结构，只要将管状突出部向下插入筒状连接部，由于前端细而插入容易，并且当插入得较深时，随着该管状突出部的外径扩大，该管状突出部能够与筒状连接部的内表面紧密地接触、实现嵌合，能够极其容易地接合。

第五发明在第一～第四任意一个发明的结构的基础上，具有盖部件，该盖部件将收纳所述变形部的所述壳体的一端侧覆盖，并且，与作为所述压力改变机构的负压形成机构连接的管相对于该盖部件装拆，所述盖部件具有卡定机构，在所述壳体和所述密闭空间被接合的状态下，所述卡定机构用于在将所述盖部件安装在所述壳体的一端侧的位置上，将该盖部件相对于所述吸奶器主体的所述密闭空间侧进行卡定。

根据第五发明的结构，所述盖部件具有所述卡定机构，由此，

能够使壳体相对于密闭空间侧的接合状态不会轻易脱落。

第六发明在第五发明的结构的基础上，所述卡定机构设置在所述盖部件的周缘部，该卡定机构相对于从所述吸奶器主体侧向上方突出的支承机构被卡定。

根据第六发明的结构，卡定机构设置在所述盖部件的周缘部，由于该卡定机构是相对于从所述吸奶器主体侧向上方突出的支承机构被卡定的结构，因此，在与所述管状突出部和筒状连接部的接合位置不同的位置进行所述卡定机构的卡定，能够更稳定地维持接合状态。

第七发明在第五发明的结构的基础上，使从所述盖部件的周缘部延伸的卡定机构相对于在所述吸奶器主体的所述筒状连接部的开口周边所设置的接触面部的周缘部进行卡定。

根据第七发明的结构，由于能够利用在吸奶器主体的所述筒状连接部的开口周边所设置的接触面部来卡定盖部件，因而不需要在吸奶器主体侧形成用于卡定的特别的机构，另外，还能够相应地谋求小型化。

（发明的效果）

如上所述，根据本发明，能够提供一种吸奶器，能够容易地对与吸奶空间连通的母乳所通过的密闭空间即一次侧和与压力改变机构连接的壳体所存在的一侧即二次侧进行装拆，并能够使清洁等的操作变得极其容易。

附图说明

图 1 是本发明的第一实施方式的吸奶器的概略立体图。

图 2 是图 1 的吸奶器的吸奶单元的概略剖视图。

图 3 是图 1 的吸奶器的盖部件的概略立体图。

图 4 是图 1 的吸奶器的电机部的分解立体图。

图 5 是图 1 的吸奶器的活塞部的分解立体图。

图 6 是图 1 的吸奶器的压力调整部的分解立体图。

图 7 是图 1 的吸奶器的变形例一的说明图。

图 8 是图 1 的吸奶器的变形例二的说明图。

图 9 是本发明的第二实施方式的吸奶器的主要部位的图。

（附图标记的说明）

15...支承机构，20...吸奶器，21...（吸奶器）主体，22...吸奶部，23...通气路，28...筒状连接部，29...密闭空间，30...压力传递部，31...壳体，32...变形部（件），33...（装拆机构）管状突出部，35...盖部件，50...吸奶单元，51...泵单元

具体实施方式

以下，参照附图详细说明本发明的优选实施方式。

另外，由于以下所述的实施方式是本发明的优选具体例，因而在技术方面附加了优选的各种限定，但只要在以下的说明中没有特别限定本发明的主旨的记载，本发明的范围就不限于这些实施方式。

图 1 是表示本发明的实施方式的吸奶器的结构的概略立体图。

图 1 表示吸奶器 20 的整体，在图中，吸奶器 20 具有吸奶单元 50 和通过管 43 与该吸奶单元 50 连接的作为压力改变机构的泵单元 51。

首先，对吸奶单元 50 进行说明。

图 2 是吸奶单元 50 的概略剖视图，在图 1 以及图 2 中，吸奶单元 50 具有吸奶器主体 21（以下称为“主体”），该吸奶器主体 21 能够相对于用于贮存吸取出的母乳的容器即瓶 47 装拆。

主体 21 例如其整体由较轻的、牢固的合成树脂材料成形，例如，由聚碳酸酯、聚环烯烃、聚醚砜、聚酰胺、聚丙烯等形成。

如图 2 所示，主体 21 具有与用于贮存吸取出的母乳的瓶 47 进行装拆的装拆部 25。装拆部 25 是例如扁平的筒状部分，在内侧具有内螺纹部 25a，该内螺纹部 25a 与形成在瓶 47 的瓶口周围的外螺纹部螺合。此外，瓶 47 可以是吸奶器 20 的专用品，也可以使用能与装拆部 25 配合的哺乳瓶等瓶体。此外，瓶 47 被载置在支承台 48 上。

在图 2 中，在主体 21 的装拆部 25 的上部，设置有以斜向倾斜的状态向外敞开的圆锥状或喇叭状的吸奶部 22。

该吸奶部 22 具有：构成通气路 23 的稍微扩开的开放通路 11；一体设置在开放通路 11 的前端侧的、大幅扩开成喇叭状的开放前端部 12。它们由与主体 21 相同的材料成形，具有较高的刚性，不易变形。

另外，在开放前端部 12 的内侧，设置有形状与开放前端部 12 大致相同的筒状的吸奶口变形部件 13。吸奶口变形部件 13 能够相对于开放前端部 12 装拆。该吸奶口变形部件 13 由硅橡胶、人造橡胶、天然橡胶等弹性体形成。

另外，在吸奶口变形部件 13 的开放前端部 12，以覆盖其全周的方式设有凸状刺激部 14。

在密闭空间的负压升高时，凸状刺激部 14 与乳房抵接、提高乳房与密闭空间的密闭性，并且，推压乳房、随着吸奶的进行给予良性刺激，发挥按摩的效果。

吸奶部 22 的通气路 23 作为通气以及吸取出的母乳的通路，是向斜上方逐渐扩大的筒状，其下端侧向下方弯折并朝向瓶 47 侧。

另外，吸奶部 22 的通气路 23 的开口 M1 位于主体 21 与瓶 47 之间的装拆部 25 的内侧，并安装有小室阀 26。与通气路 23 邻接地设置有另一个通气路 27。

通气路 27 的下端开口 M2 如图所示地在小室阀 26 中与通气路 23 连通，通气路 27 的上端向上方延伸并与压力传递部 30 的壳体 31 下端连通。

因此，由吸奶部 22 的内侧和通气路 23、通气路 27 形成在吸奶时形成吸引母乳的负压的密闭空间 29。

如图 2 所示，上述小室阀 26 是整体由硅橡胶、人造橡胶、天然橡胶等弹性体形成的帽状的形态，图 2 的两侧壁 26b、26c 是向下端幅宽逐渐相互接近地形成的弹性体的倾斜壁。在两侧壁 26b、26c 的接近的下端，设置有狭缝 26d，吸取的母乳在小室 26a 中贮存到规定

量时，伴随其重量和如下所述的负压解除时的压力的变化，两侧壁26b、26c的前端侧打开，狭缝26d开放，母乳流入瓶47内。另外，通过在倾斜壁的下端形成狭缝26d，能够发挥防止负压时瓶47内的空气进入小室26a的空气阀的功能。

主体21的通气路27的上部与后述的筒状连接部28一体形成，在其上部，沿着该筒状连接部28的开口的周边部形成有接触面部18。该接触面部18是当装拆后述的壳体31时进行抵接、配置的部分，是呈适于容纳该壳体31的底面的形态的平坦或略呈凹状的皿状的部分，在其外缘形成有凸缘部19。

而且，在与主体21的吸奶部22外伸的部位相反的一侧，形成有向上方突出的支承机构15。在本实施方式中，支承机构15是例如从上述接触面部18的侧方的位置向上方延伸的部分，是以支柱状或臂状起立的突出体。支承机构15的上端到达图2的壳体31的上端附近。相对于该支承机构15，通过如下述那样支承壳体31的盖部件35，从而经由该盖部件35稳定地支承壳体31。

图3是表示壳体31的从下方观察的概略立体图，图3（a）是将盖部件35安装在壳体31上的状态，图3（b）是分解立体图。

压力传递部30的壳体31在该情况下例如是纵向长的圆筒体，其内部空间也是纵向长的空间，并收容有变形部。变形部在本实施方式中是与壳体31分体的独立部件，作为能够相对于壳体31装拆的变形部件32而构成。

变形部件32由不透气的薄材料形成，具有柔软的性质，能够容易地变形。

尤其，在本实施方式中，如图2以及图3所示，变形部件32是以与由硬质的合成树脂的成形品等形成的圆筒壳体即壳体31的内侧空间内接的形状形成的、一端开口而另一端被封闭的有底圆筒形的变形部件，例如是由硅橡胶、人造橡胶、天然橡胶等的弹性体、以极其柔软、不会因反复伸缩的变形而产生断裂等情况的材料形成的。

如图2以及图3所示，变形部件32在其上端的开口周缘部一体

地具有凸缘部 32a，该凸缘部 32a 载置、抵接在壳体 31 的上端开口的周缘部上。

在壳体 31 的上端开口的外缘部，形成有外螺纹部等的装拆机构 34，通过螺纹旋入盖部件 35 的下侧内周 35a 等方法，盖部件 35 能够相对于壳体 31 装拆（参照图 2）。

在盖部件 35 的内侧，在其下端设置有较低地向下方突出的肋 37。

由此，在盖部件 35 通过螺纹旋入而相对于壳体 31 完成安装的图 2 的状态下，由于该变形部件 32 的凸缘部 32a 以紧密接触的方式被夹在壳体 31 的开口周缘部的上表面与盖部件 35 的下表面之间，因而变形部件 32 的内侧成为气密的状态。

而且，在盖部件 35 的上端，在本实施方式的情况下，具有向横向略微突出的安装部 38，通过将其插入图 1 所示的可挠性的管 43 的端部，能够与该管 43 实现装拆，在图 2 的状态下，管 43 经由盖部件 35 与变形部件 32 的内侧空间连通。因此，该空间经由管 43 成为与后述的压力改变机构连通的二次侧的空间。

该二次侧的空间通过变形部件 32 与一次侧的空间即密闭空间 29 液密地分离，该一次侧的空间包括经由从图 2 的吸奶部 22 的通气路 23 连续的小室 26a 而连通的通气路 27、以及经由后述的装拆机构 33 连接的壳体 31 的内部。也就是说，以气体或液体都完全不会漏出的方式气密且液密地实现密封。

而且，如图 2 以及图 3 所示，在壳体 31 的下端，平坦的底部 39 的中央部较细地向下方垂直突出，形成有内部为空洞的筒状的作为上述装拆机构的管状突出部 33。该管状突出部 33 优选随着趋向前端其外径逐渐变细。

与此相应地，在图 2 所说明的主体 21 的接触面部 18 的中心附近，形成有筒状连接部 28。如图所示，该筒状连接部 28 向瓶 47 垂直地延伸并与小室 26a 连通。而且，通过使筒状连接部 28 的内径比壳体 31 的管状突出部 33 的外径略大，当该管状突出部 33 被插入时，

筒状连接部 28 的内径与其以紧密接触的方式外接，在该状态下能够保持气密状态。

图 2 表示了如上述这样、将管状突出部 33 嵌入筒状连接部 28 中的状态，另外，在盖部件 35 被安装到壳体 31 上的状态下，盖部件 35 的卡定机构 36 卡定于支承机构 15，从而稳定地维持壳体 31 的安装状态。

即，盖部件 35 的外周缘部横向延长，形成由收容支承机构 15 的上端的凹部等构成的卡定机构 36。

由此，在通过螺纹旋入等方法将盖部件 35 安装在收容了变形部件 32 的壳体 31 的上端的状态下，与将该壳体 31 的管状突出部 33 嵌入筒状连接部 28 同时地，通过使支承机构 15 的前端收容到盖部件 35 的卡定机构 36 中，由此，不但能够简单地进行安装，还能够通过安装部和卡定部这两点进行支承，从而稳定地保持安装状态。

以下说明作为压力改变机构的泵单元 51。

图 1 中表示了泵单元 51 的概略立体图。

如图 1 所说明的那样，泵单元 51 通过可挠性的管 43 与吸奶单元 50 连接。泵单元 51 作为真空泵，当后述的开关被打开时，能够将吸奶单元 50 的二次侧的空间即压力传递部 30 的壳体 31 内以及与其连通的空间吸成负压。在此情况下，根据后述的构造，能够以脉动状态实现负压形成。即，能够进行如下的脉动压力变动：使压力变动而连续地进行从负压状态至少到大气压状态的变动。

在图 1 中，在泵单元 51 的箱体 52 上露出有：将泵单元 51 的驱动打开、关闭的开关（按钮）54；用于调整负压形成过程中的脉动的周期的循环按钮 55；用于调整负压压力的旋钮 53。另外，在泵单元 52 上还安装有可挠性的管 43。

参照图 4 至图 6。

在泵单元 51 的箱体 52 的内侧，收容有电机部 70、气缸部 60、压力调整部 90 等。

电机部 70 具有电机 72 和该电机 72 的电机轴结合于其上的齿轮

单元 73。电机 72 在本实施方式中使用直流电机。

齿轮单元 73 中，延伸有使电机轴的旋转适当减速而进行传递的驱动轴 74，该驱动轴 74 与偏心凸轮 63 连接。偏心凸轮 63 的凸轮轴与气缸部 60 的活塞杆连接，驱动轴 74 的旋转运动被转换成活塞杆的往复运动。

即，气缸部 60 具有气缸 62，在该气缸 62 内，以能够进退的方式插入活塞杆 67。在活塞杆 67 的活塞头上安装有其间夹有垫片 66 的两个活塞环 64a、64b，利用固定板 65 将其用螺丝固定。

在气缸 62 内部，连通有吸引管 85、排气管 86、压力调整管 87。由此，通过活塞杆 67 进行往复运动，借助规定的阀驱动，在气缸 62 内形成负压，该负压经由吸引管 85 进行传递。

在此，通过适当地选择活塞环 64a、64b 的材质，能够降低活塞杆 67 在气缸 62 内的滑动阻力，减少电力损耗，能够谋求节能化，并能够提高密封性。

因此，这些活塞环 64a、64b 优选由特氟隆（注册商标）、尼龙、聚甲醛等耐热性较好且滑动阻力低的材料形成，具有比气缸内径稍大的外径，并形成有活塞鳍片，随着活塞杆 67 的往复运动，该活塞鳍片与气缸 62 的内壁接触的凸缘状的外缘部能够变形。

为了谋求活塞杆 67 在气缸 62 内的滑动阻力的降低、并使密封性良好，作为活塞环 64a、64b 的材质，可以选择特氟隆（注册商标）。

但是，由于特氟隆（注册商标）无法在模具内成形，因而存在着制造成本升高的缺点。

因此，在本实施方式中，以聚甲醛的成形品来形成这些活塞环 64a、64b。由此，能够降低活塞杆 67 在气缸 62 内的滑动阻力，减少电力损耗，能够谋求节能化，并且能够提高密封性，还能够实现制造成本的降低。

排气管 86 与排气阀连接。吸引管 85 经由管安装口如图 1 所示从箱体 52 露出，与可挠性的管 43 连接，从而与吸奶单元 50 的盖部件 35 连接。压力调整管 87 与压力调整部 90 连接。

在箱体 52 内收纳有控制电路基板，该控制电路基板例如被固定支承在收纳单元中，该控制电路基板控制泵单元 51 的驱动，并连接有泵单元 51 的打开关闭开关（按钮）54 和用于调整负压形成中的脉动周期的循环按钮 55 等。

压力调整部 90 与气缸部 60 的气缸 62 连通，具有零件的收纳壳体 91。在该收纳壳体 91 内具有板 92，为了调整气缸 62 内的负压，该板 92 具有直径大的负压调整用孔和直径小的负压调整用孔。通过使该板 92 旋转来进行板 92 的这些孔的切换。板 92 通过衬垫 93 和垫块 94 被固定在按钮 53 上。

本实施方式的吸奶器 20 如上所述地构成，在图 1 中，操作泵单元 51 打开关闭开关按钮 54，起动该泵单元 51 时，电机 72 旋转，驱动轴 74 经由齿轮单元 73 旋转，该旋转运动经由偏心凸轮 63 被转换成气缸 62 内的活塞杆 67 的往复运动。通过活塞杆的往复运动，气缸 62 内形成的负压脉动变化，经由吸引管 85 以及可挠性的管 43 被传递到图示的吸奶单元 50 的压力传递部 30。

由此，在图 2 中，壳体 31 内的变形部件 32 内部的气压降低。因此，在壳体 31 内，由于与变形部件 32 的外侧的空间之间的气压差，变形部件 32 的内部空间以被压溃的方式变形，其底部上升、接近盖部件 35 侧。即，由于变形部 32 在壳体 31 内大幅度地减小体积，所以与变形部件 32 的外侧的壳体 31 的空间连通的密闭空间 29 内，气压大幅度地减小。

即，由于在密闭空间 29 内负压增大，因而母乳被从乳房吸引，被吸取出的母乳通过通气路 23 内，流入小室 26a。而且，此时，伴随着压力差，吸奶口变形部件 13 的凸状刺激部 14 向乳房侧变形，推压乳房进行刺激，因而能够进一步促进母乳的分泌。

接着，当基于泵单元 51 的气缸杆 67 的往复动作，负压状态被解除时，再次如图 2 所示地，变形部件 32 以恢复其形态的方式变位。由此，在壳体 31 内，当由于变形部件 32 使体积增大而使密闭空间内的气压升高时，母乳的吸引压降低。

通过重复进行以上动作，作为压力改变机构的泵单元 51 的动作通过压力传递部 30 的变形部件 32 的动作被传递至密闭空间 29，从而密闭空间 29 的负压被增减，由此，实现与婴儿的哺乳动作接近的状态，能够使吸取出的母乳贮存在瓶 47 中。

另外，在此，在上述动作中，当经由管 43 作用负压时，变形部件 32 以向盖部件 35 侧贴靠的方式收缩变形。此时，虽然收缩变形了的变形部件 32 欲贴靠盖部件 35 侧，但由于肋 37 的存在，能够阻止其完全地贴靠。

而且，压力传递部 30 具有上端经由盖部件 35 与泵单元 51 连接的壳体 31，在该壳体 31 的下端具有装拆机构 33，该装拆机构 33 用于将该壳体 31 内和密闭空间 29 以能够连通的方式装拆。由此，例如，能够容易地对收容有变形部件 32 的壳体 31 进行装拆，并能够使其与密闭空间 29 侧分离，不仅便于携带、移动，尤其在清洗时等，能够容易地仅对需要频繁清洗的一次侧即密闭空间 29 侧进行分离、清洗。

这样，能够容易地对与吸奶空间连通的母乳所通过的密闭空间 29 即一次侧和与压力改变机构即泵单元 51 侧连接的壳体 31 的侧即二次侧进行装拆，能够使清扫等的操作变得极其容易。

另外，由于压力传递部 30 将形成于吸奶部 22 的密闭空间和泵等的压力改变机构完全液密且气密地分离，所以能够有效地防止滞留在密闭空间侧即小室 26a 等的母乳或成为雾状的母乳回流到泵单元 51。因此，能够有效地防止泵单元 51 等的压力改变机构侧接触到母乳而发生腐蚀、破损以及被污染成为不卫生的状态。

另外，在本实施方式中，壳体 31 是内部收容有变形部件 32 的筒状体，在该筒状体上具有作为装拆机构的管状突出部 33。

而且，在密闭空间 29 中，具有在该密闭空间 29 内延伸的筒状连接部 28，通过使筒状连接部 28 的内径比管状突出部 33 的外径稍大，从而成为将管状突出部 33 插入筒状连接部 28、壳体 31 和密闭空间 29 气密地接合的结构。

由此，通过仅将管状突出部 33 插入筒状连接部 28 这一简单的操作，就能够将泵单元 51 侧和密闭空间 29 侧连接。

而且，如上所述，壳体 31 的管状突出部 33 的周边为平坦的底部，在主体 21 的筒状连接部 28 的开口周边形成有平坦的接触面部 18。因此，只要将管状突出部 33 插入筒状连接部 28、将壳体 31 的平坦的底部压入到与平坦的接触面部 18 抵接的位置，便能够极其容易地以气密状态将壳体 31 和密闭空间 29 接合。

而且，上述筒状连接部 28 是如图 2 所示、在载置瓶 47 的状态下向瓶 47 下方大致垂直延伸而形成的，管状突出部 33 以向前端逐渐变细的方式形成。

因此，只通过将管状突出部 33 向下插入筒状连接部 28，由于前端细而插入容易，并且当插入得较深时，随着该管状突出部 33 的外径扩大，该管状突出部 33 能够与筒状连接部 28 的内表面紧密地接触、实现嵌合，能够极其容易地接合。

而且，在本实施方式中，具有盖部件 35，该盖部件 35 覆盖收纳变形部 32 的壳体 31 的上端侧，并且，与作为压力改变机构的负压形成机构即管单元 51 连接的管 43 能够相对于该盖部件 35 装拆。

而且，在壳体 31 和密闭空间 29 被接合的状态下，在将盖部件 35 安装到壳体 31 的上端侧的位置上，具有用于将盖部件 35 相对于主体 21 的密闭空间 29 侧进行卡定的卡定机构 36，因此，壳体 31 的相对于密闭空间 29 侧的接合状态被稳定地支承，不会轻易脱落。

而且，在本实施方式中，图 3 的卡定机构 36 设置在盖部件 35 的周缘部上。该卡定机构 36 是如图 2 所说明的那样、相对于从主体 21 侧向上方突出的支承机构 15 被卡定的结构。

由此，在与管状突出部 33 和筒状连接部 28 的接合位置不同的位置进行该卡定，能够更稳定地维持接合状态。

图 7 及图 8 表示设置在盖部件上的卡定机构的变形例。

图 7 表示第一变形例，盖部件的结构与图 3 的情况稍有不同。

在该例中，盖部件 35-1 的外缘具有向下方延长的一对脚片 36-1、

36-1，该脚片 36-1、36-1 能够根据规定的弹性向相互接近、远离的方向变形。在各脚片 36-1、36-1 的下端附近形成有钩状的卡定部 45、45。

因此，如图 7 的下部所示，当使盖部件 35-1 相对于壳体 31 从上方下降进行覆盖时，各脚片 36-1、36-1 与接触面部 18 的凸缘部 19 接触，通过略微打开各脚片 36-1、36-1 便能够越过凸缘部 19 的外缘，该凸缘部 19 进入各脚片 36-1、36-1 的卡定部 45、45 而被卡定。

图 8 表示第二变形例，盖部件的结构与图 3 的情况稍有不同。

在该例中，在盖部件 35-2 上不仅形成有与图 3 的盖部件 35 相同的卡定机构 36，而且其相反侧的端部外缘向下方延长，形成有脚片 36-2。在该脚片 36-2 的下端部形成有钩状的卡定部 46。

由此，盖部件 35-2 通过卡定部 46 在卡定在凸缘部 19 上的同时，相对于支承机构 15 也被卡定。

这样，根据各变形例，在与管状突出部和筒状连接部的接合位置不同的位置，通过卡定机构实现卡定，能够更稳定地维持接合状态。不仅如此，由于能够利用主体 21 的筒状连接部的开口周边所设置的接触面部 18 卡定盖部件，因而不需要在主体 21 侧形成用于卡定的特别的机构，另外，还能够相应地谋求小型化。

图 9 表示第二实施方式的主要部位，图示的结构以外的结构与第一实施方式相同，因此以下以不同点为中心进行说明。

在图 9（a）中，壳体 31 能够相对于吸奶单元 50-1 的主体 21 装拆。该壳体 31 的下端部如图 9（b）所示，成为在径向上鼓出的凸缘状的卡定机构 41。

即，该卡定机构 41 具有鼓出成凸缘状的周缘向下方弯折且其前端趋向内侧的阶梯部 41b，接触面部 18 的凸缘部 19 的前端能够卡定在该阶梯部上。

如图 9（a）所示，在卡定机构 41 上，沿其圆周方向形成有多个狭缝 41a，由此，该卡定机构 41 能够弹性变形，通过如图 9（b）所示那样嵌入接触面部 18 的凸缘部 19，能够容易地变形、装拆。

本实施方式如上所述地构成，不仅能够发挥与第一实施方式相同的作用效果，即使不使用图 2 那样的支承机构 15，也能够形成用于维持壳体 31 的接合状态的卡定机构。

因此，即使省略图 2 那样的支承机构 15，也能够得到与第一实施方式同等的接合稳定性。

此外，本发明不限于上述实施方式。

例如，壳体 31 中收容的变形部件可以与壳体一体地构成，成为作为其一部分的“变形部”。

变形部不仅可以是有底圆筒体，也可以使用折皱构造等各种形态。

装拆机构即管状突出部 33 可以适当地改变成与实施方式不同的形状、构造。

此外，上述各实施方式、变形例的个别结构可以根据需要省略，或与未说明的其他结构进行组合。

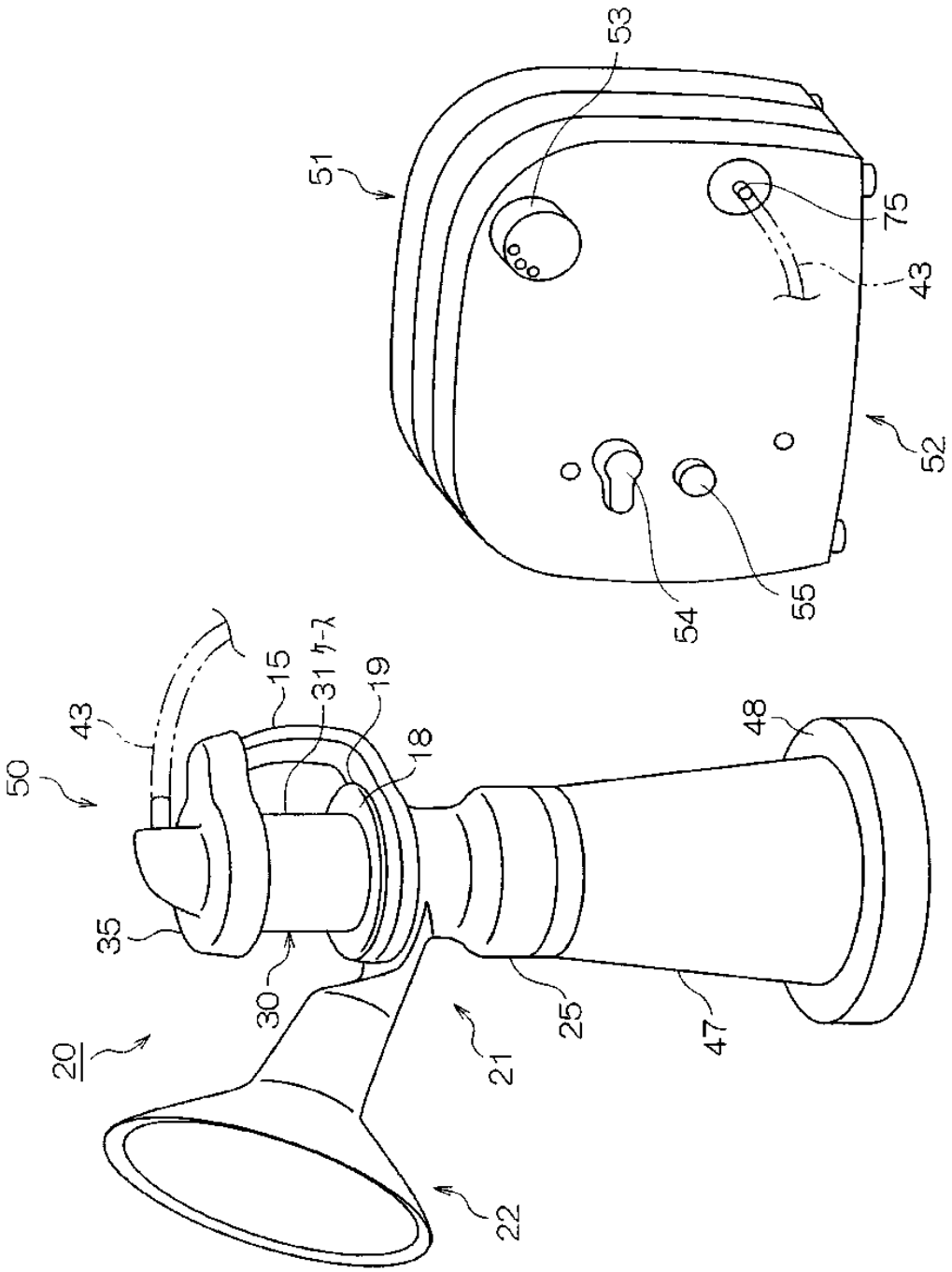


图 1

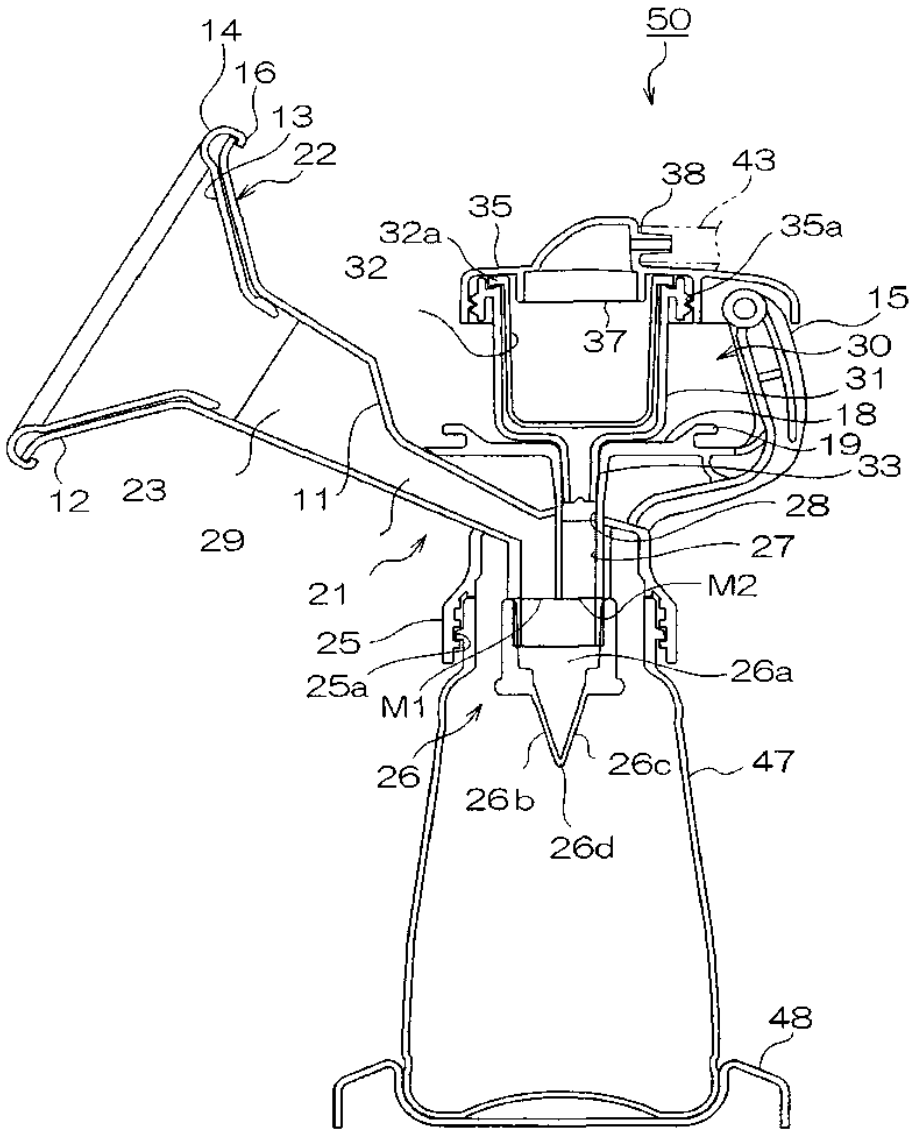

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M2
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25a
M1
26a
26
26c
47
26b
26d
48

图 2

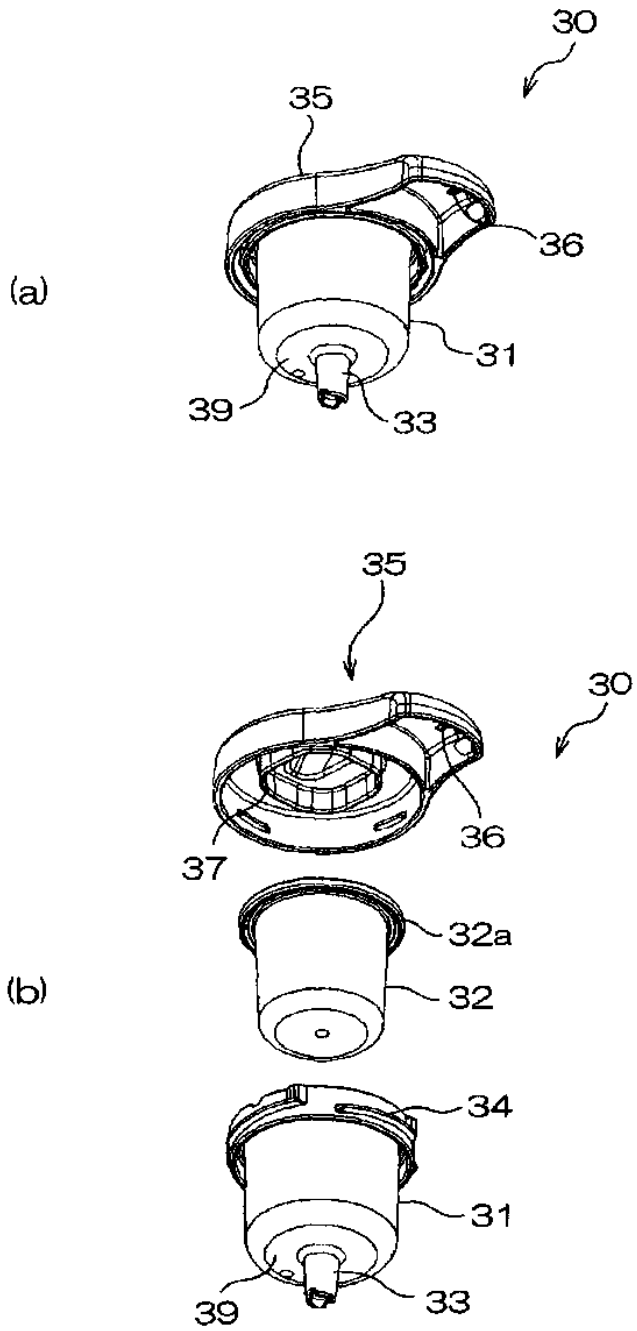


图 3

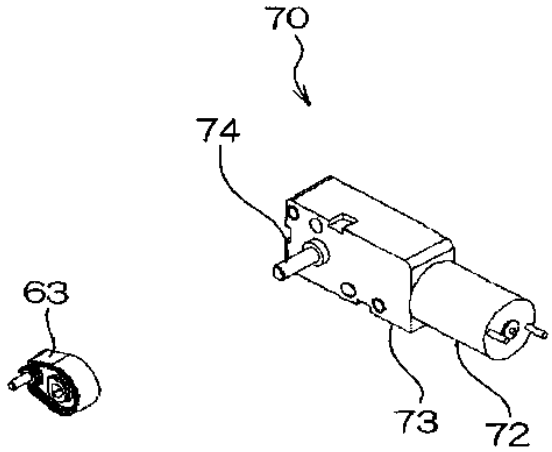


图 4

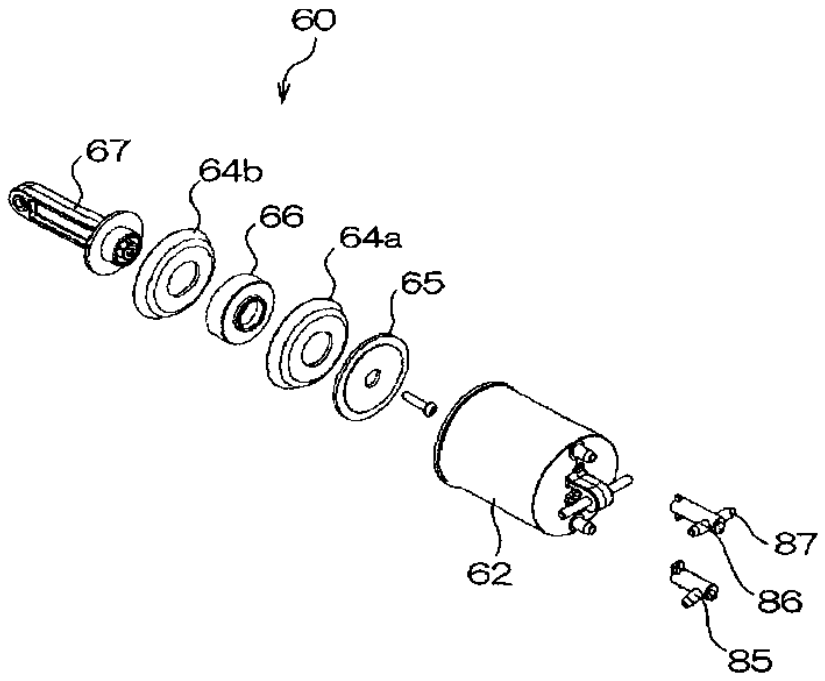


图 5

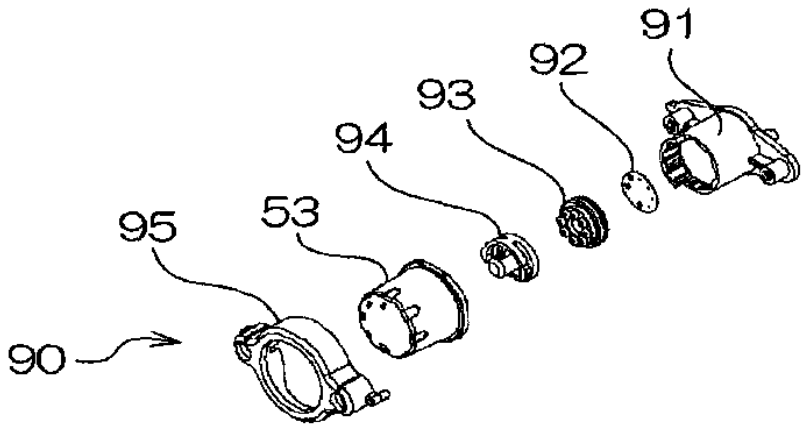


图 6

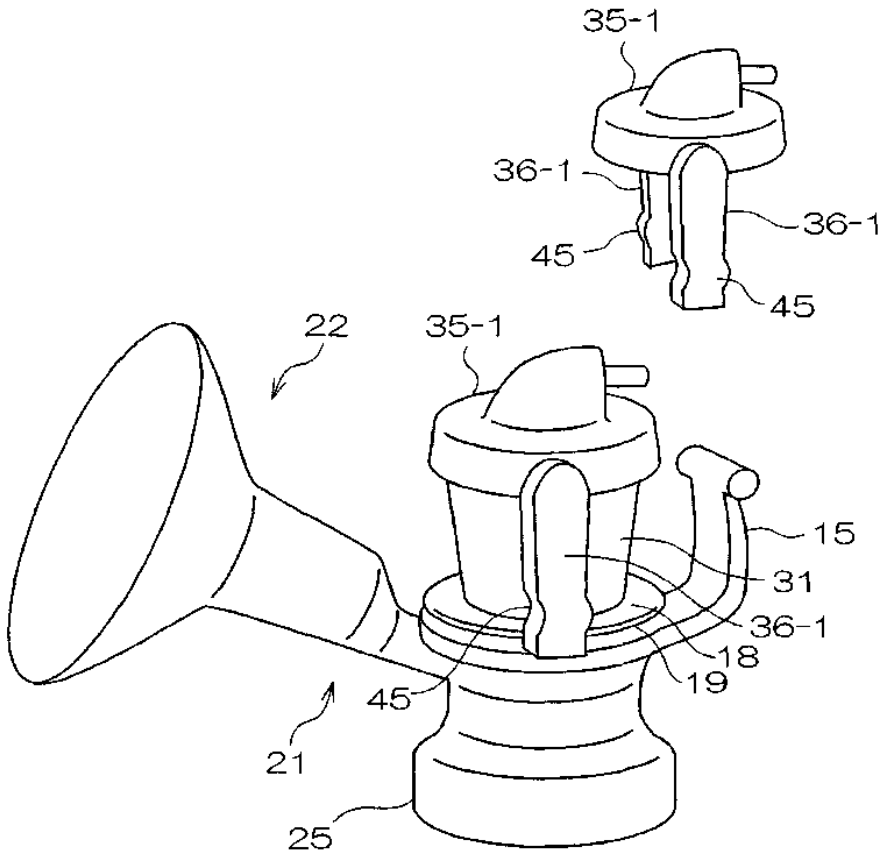


图 7

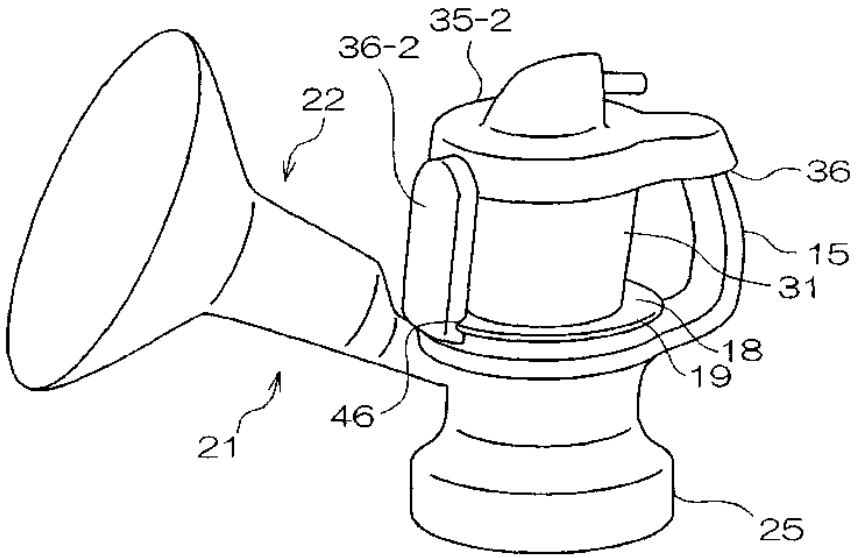
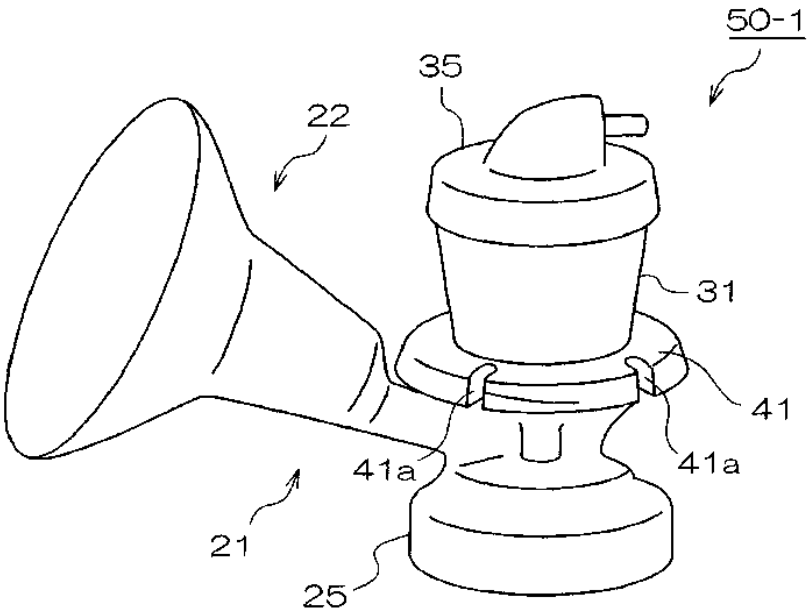


图 8

(a)



(b)

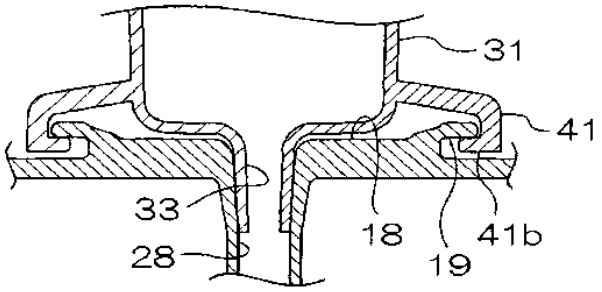


图 9

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US 20050043677 A1

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INT CL **A61M**
Other
ONLINE: WPI, EPODOC
updated as appropriate

Additional Fields
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INT CL **A61M**
Other
ONLINE: WPI, EPODOC

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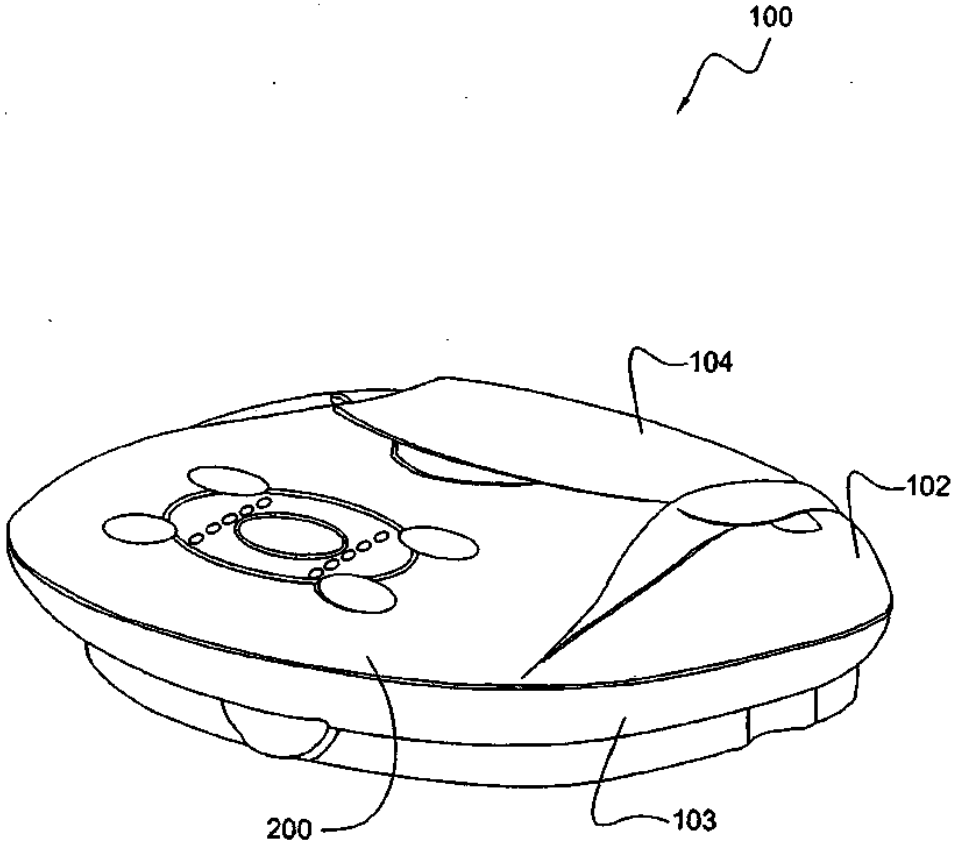


Fig. 1

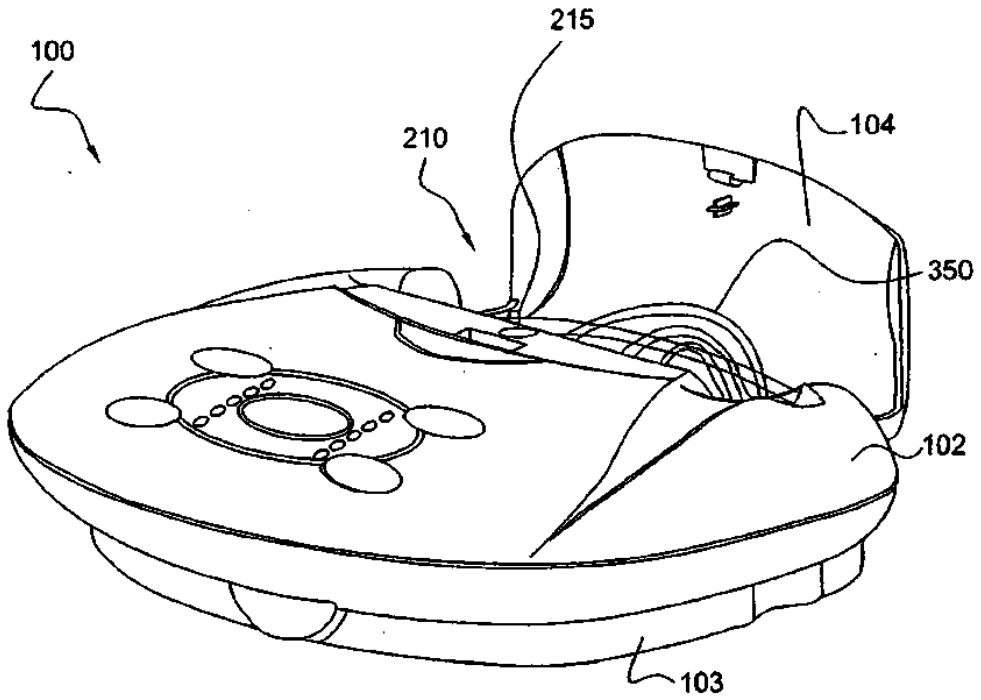


Fig. 2

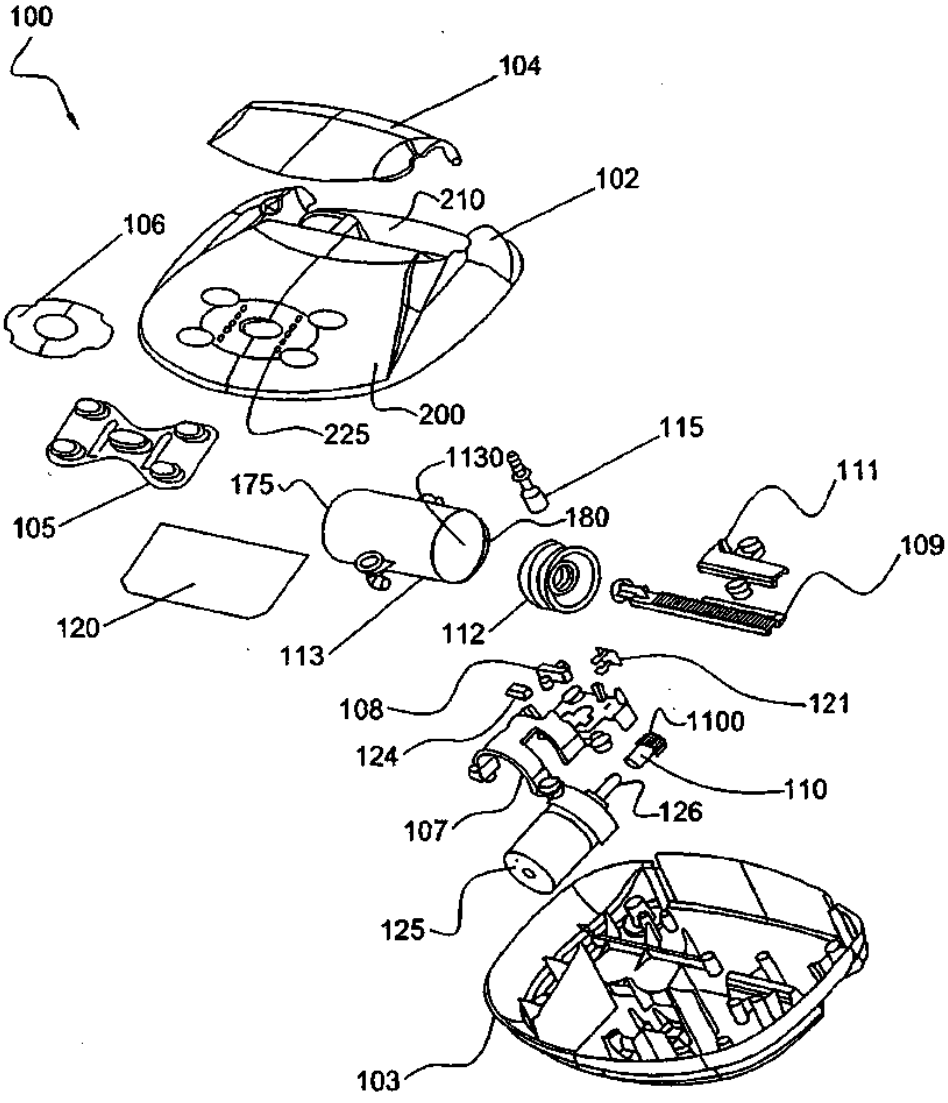

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Fig. 3

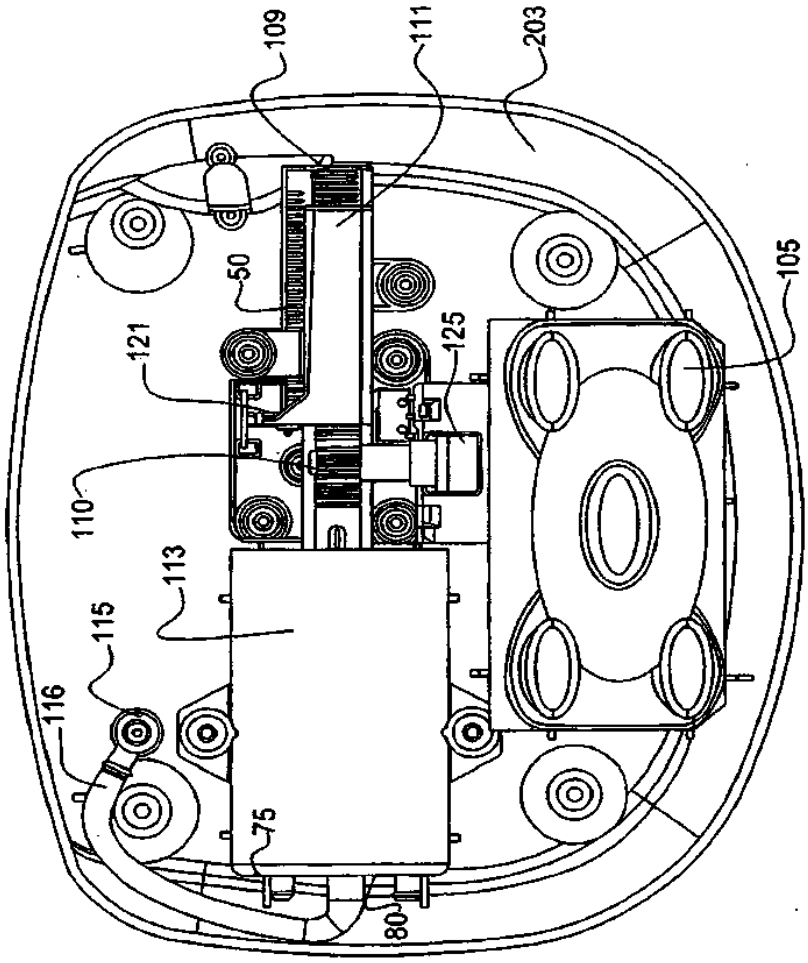


Fig. 4

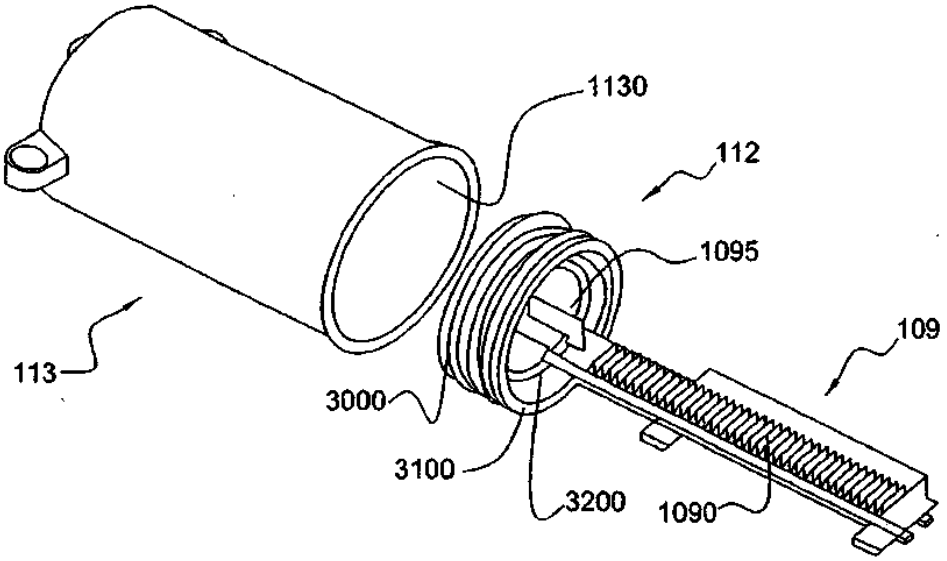

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Fig. 5

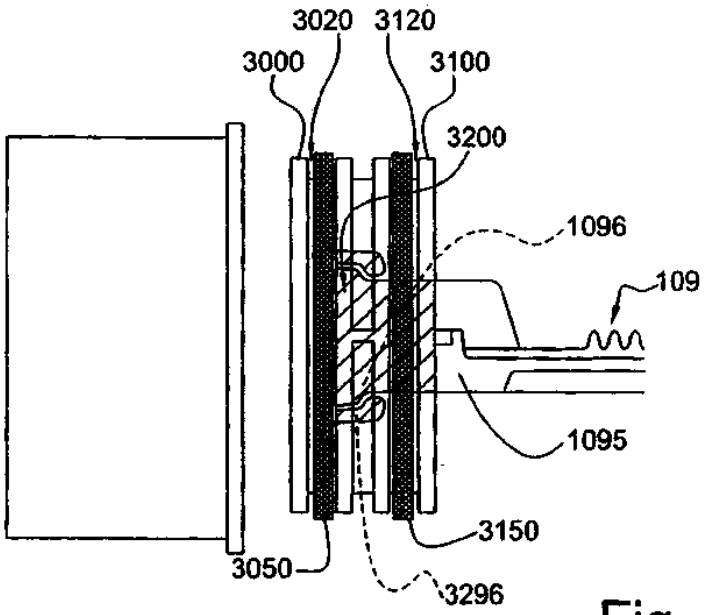

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Fig. 6

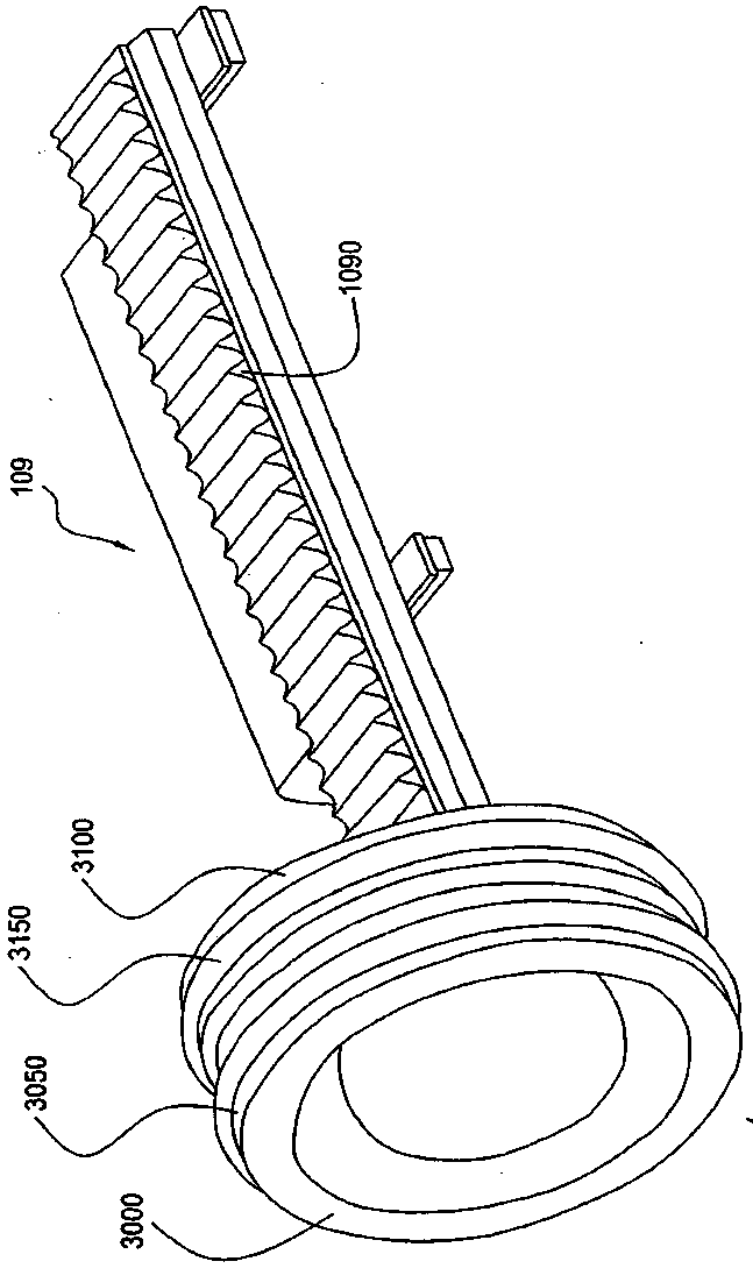


Fig. 7

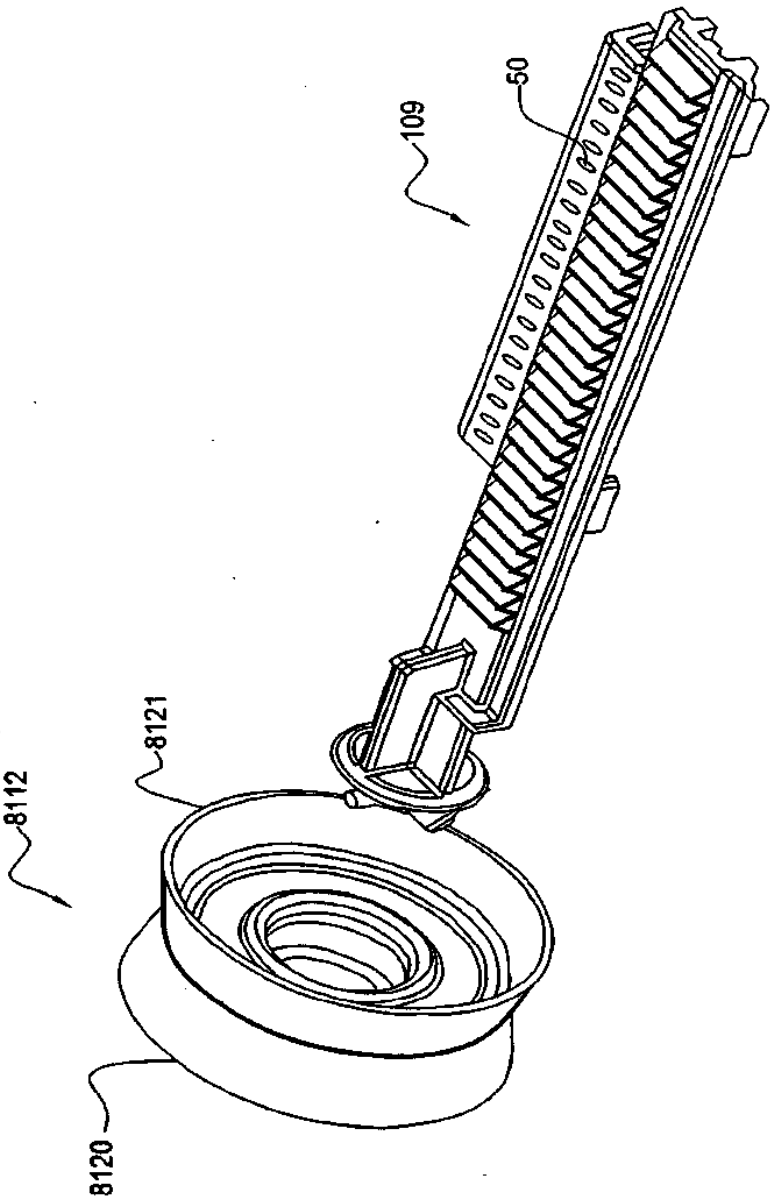


Fig. 8

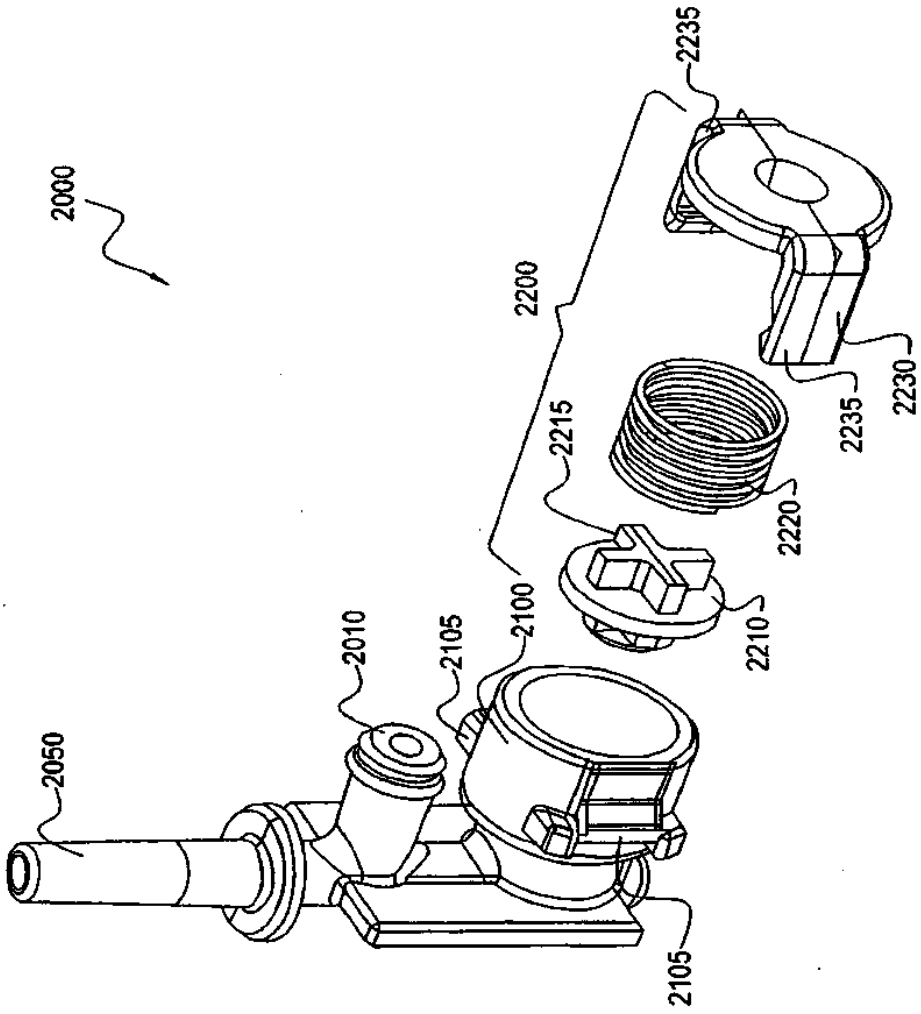

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Fig. 9

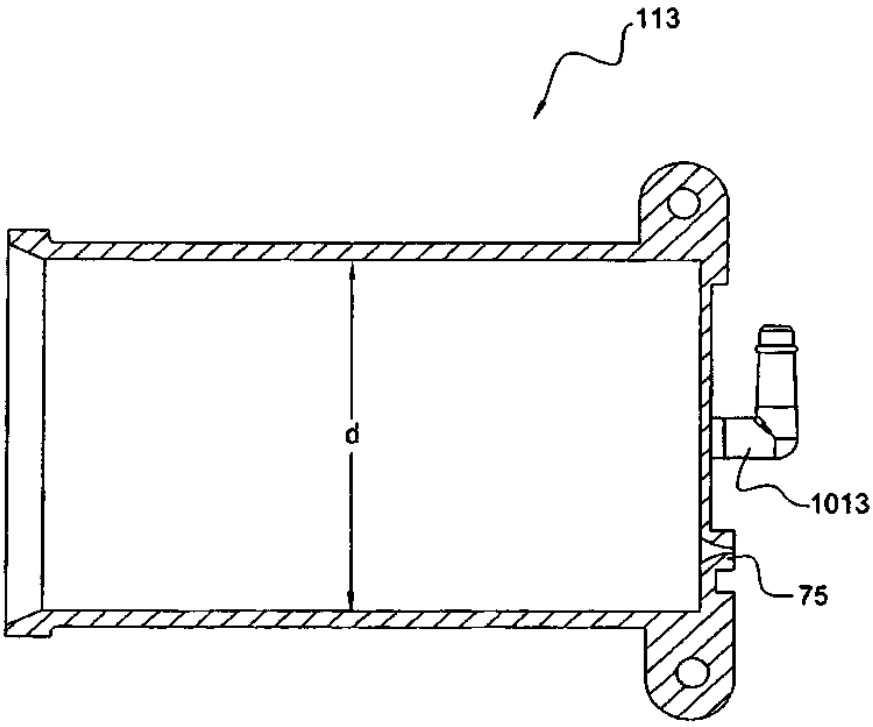


Fig. 10

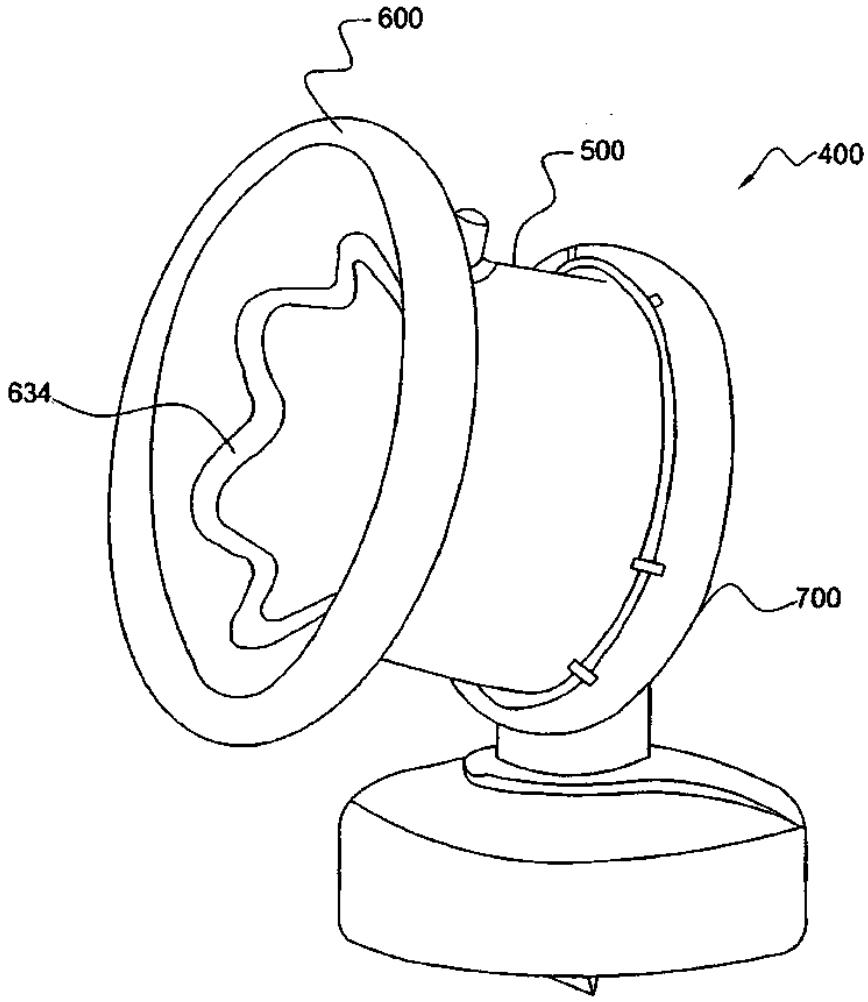


Fig. 11

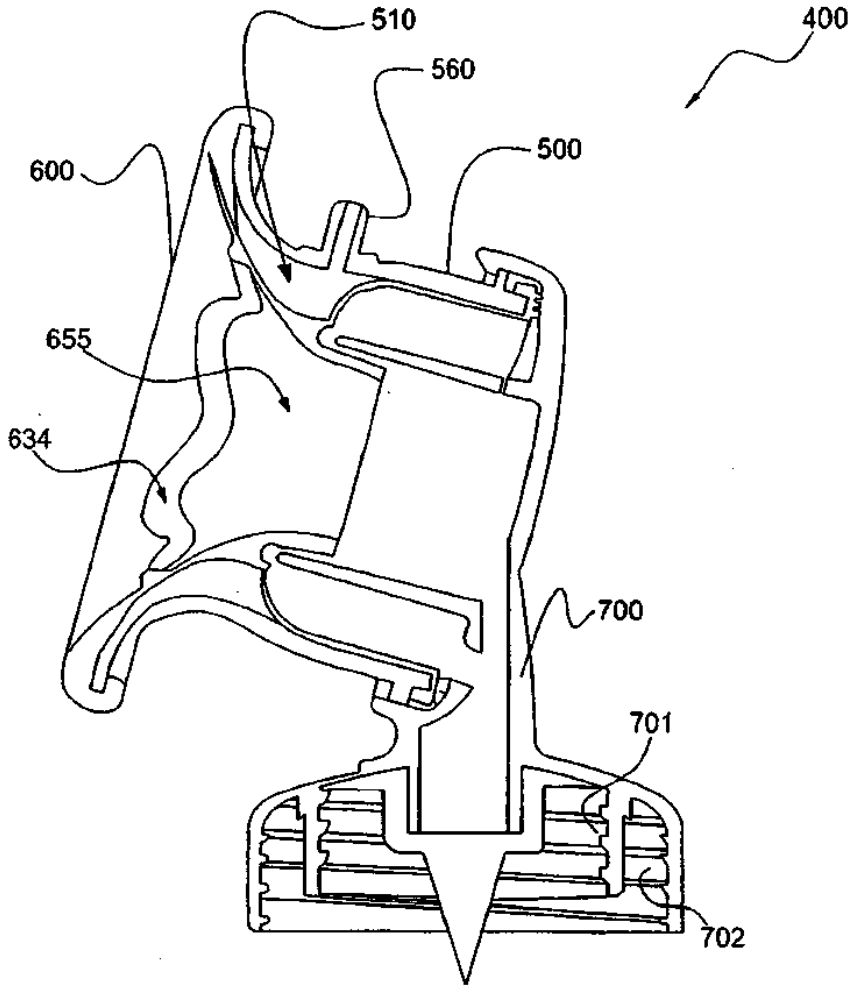


Fig. 12

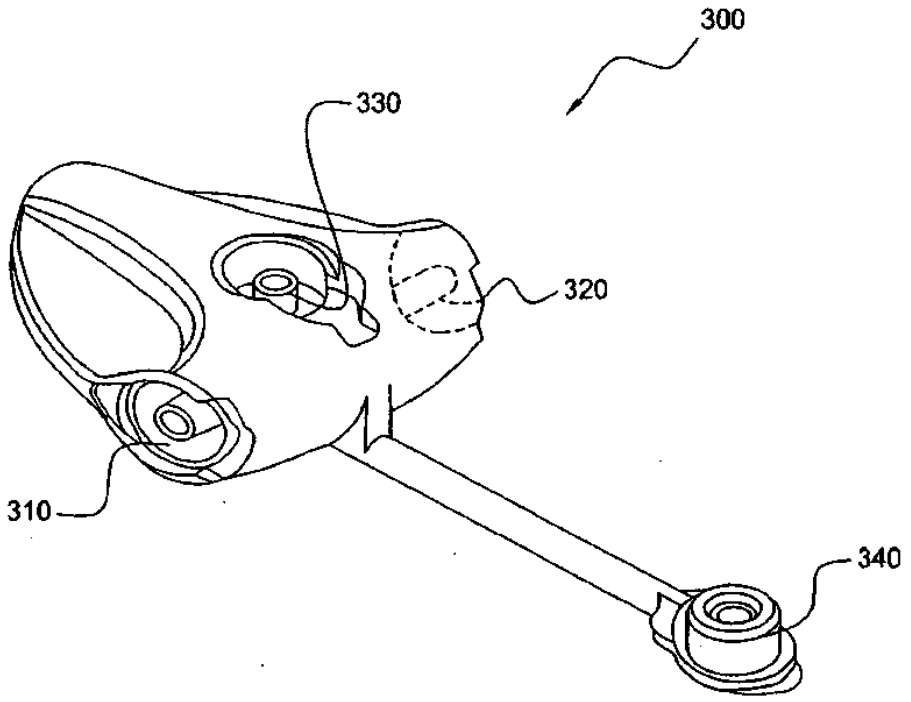


Fig. 13

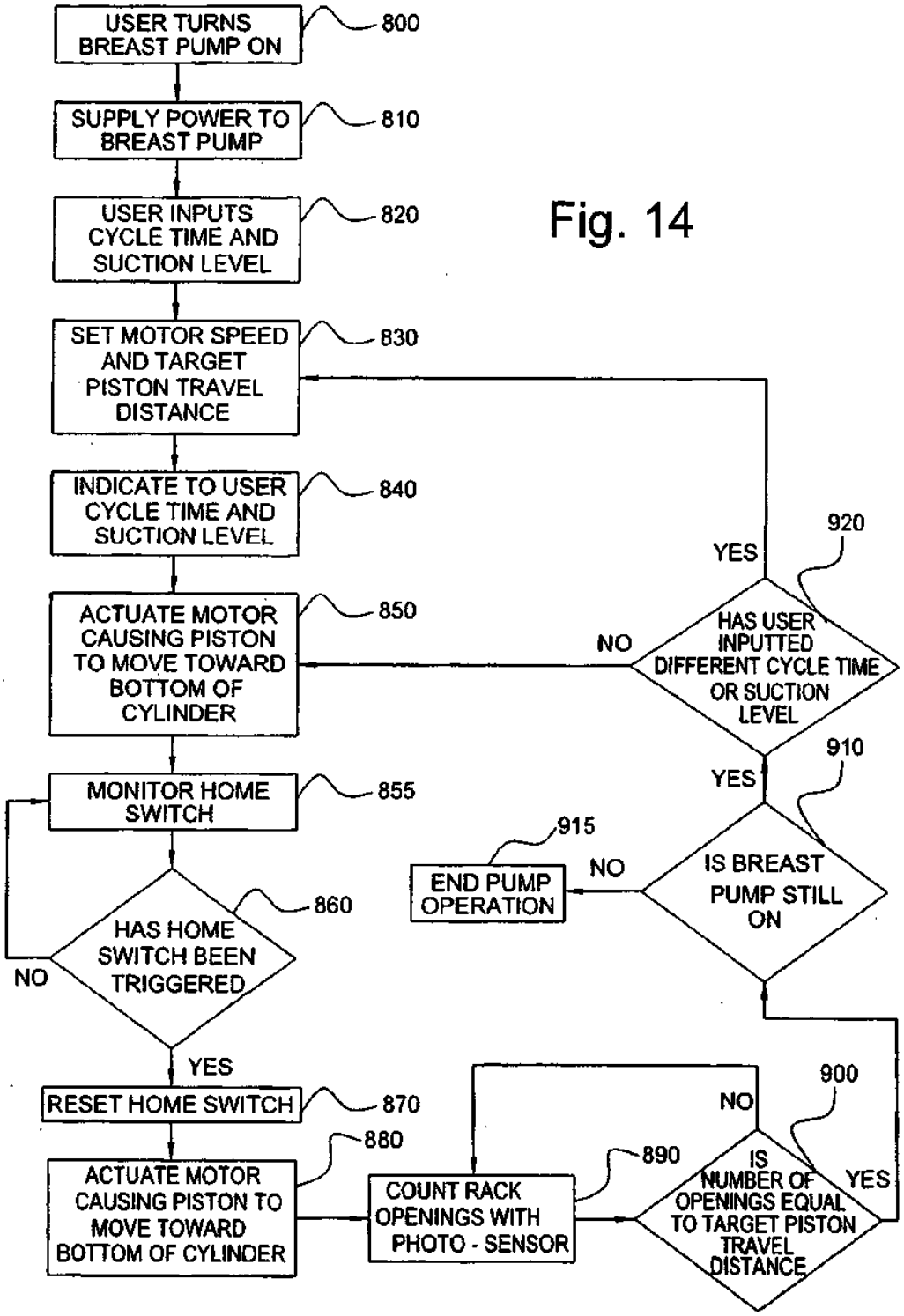

USER TURNS BREAST PUMP ON
800
SUPPLY POWER TO BREAST PUMP
810
USER INPUTS CYCLE TIME AND SUCTION LEVEL
820
SET MOTOR SPEED AND TARGET PISTON TRAVEL DISTANCE
830
INDICATE TO USER CYCLE TIME AND SUCTION LEVEL
840
ACTUATE MOTOR CAUSING PISTON TO MOVE TOWARD BOTTOM OF CYLINDER
850
MONITOR HOME SWITCH
855
HAS HOME SWITCH BEEN TRIGGERED
860
NO
YES
RESET HOME SWITCH
870
ACTUATE MOTOR CAUSING PISTON TO MOVE TOWARD BOTTOM OF CYLINDER
880
COUNT RACK OPENINGS WITH PHOTO - SENSOR
890
IS NUMBER OF OPENINGS EQUAL TO TARGET PISTON TRAVEL DISTANCE
900
NO
YES
IS BREAST PUMP STILL ON
910
NO
YES
END PUMP OPERATION
915
HAS USER INPUTTED DIFFERENT CYCLE TIME OR SUCTION LEVEL
920
NO
YES

Fig. 14

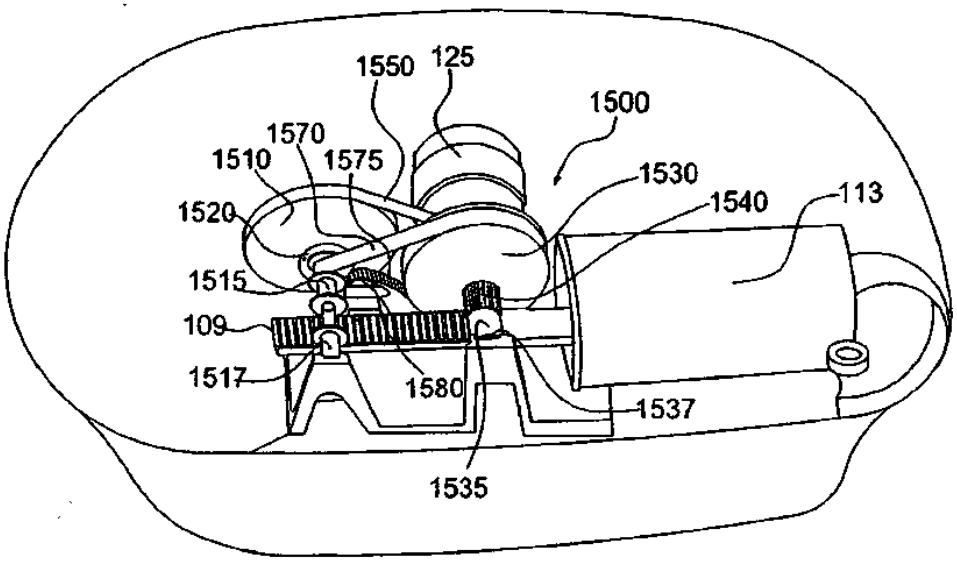

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Fig. 15

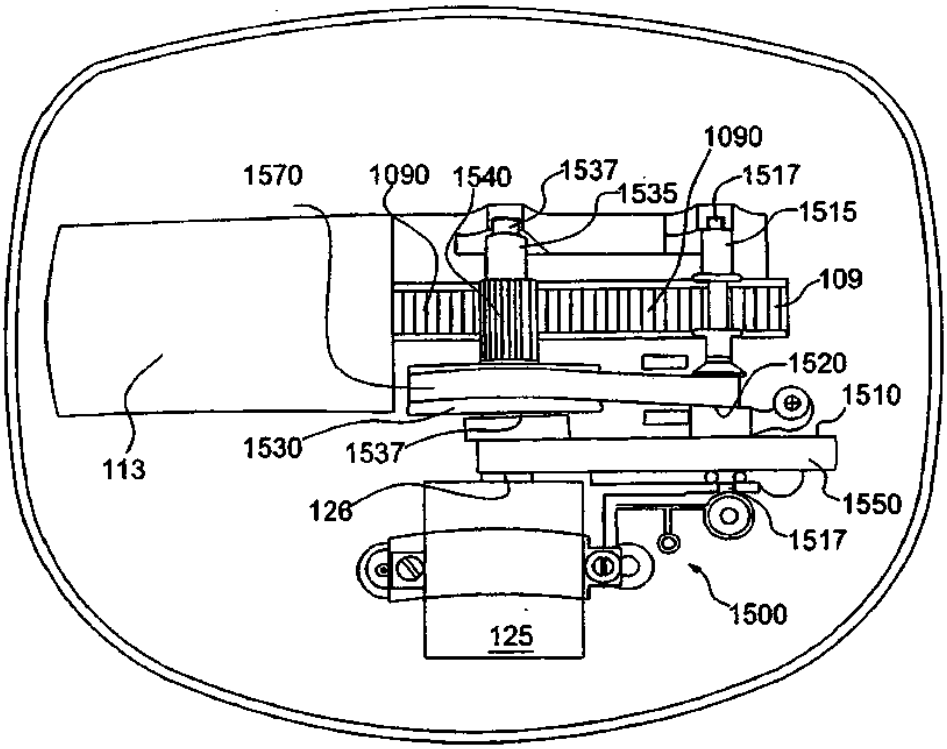

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Fig. 16

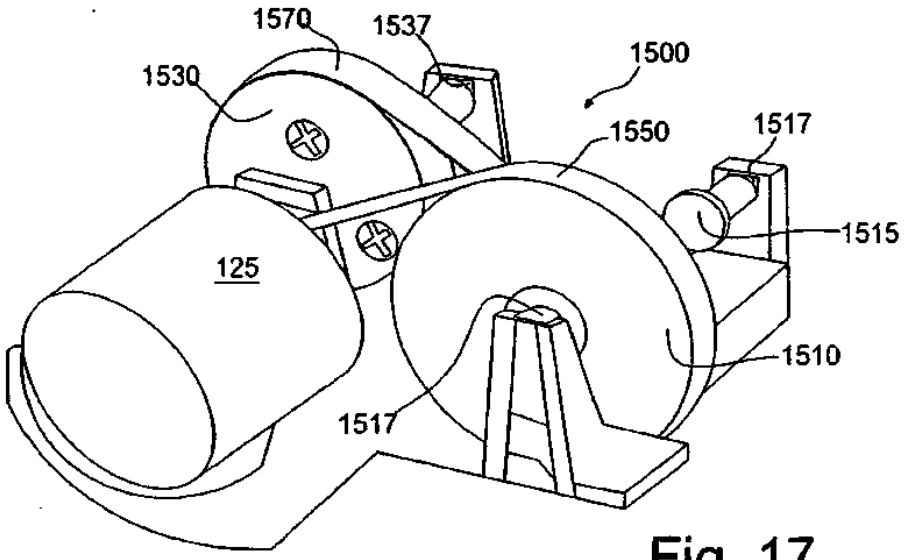

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Fig. 17

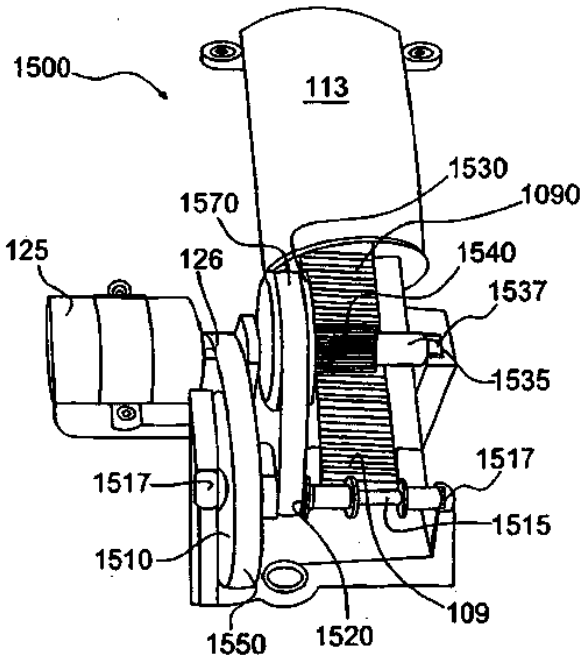

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Fig. 18

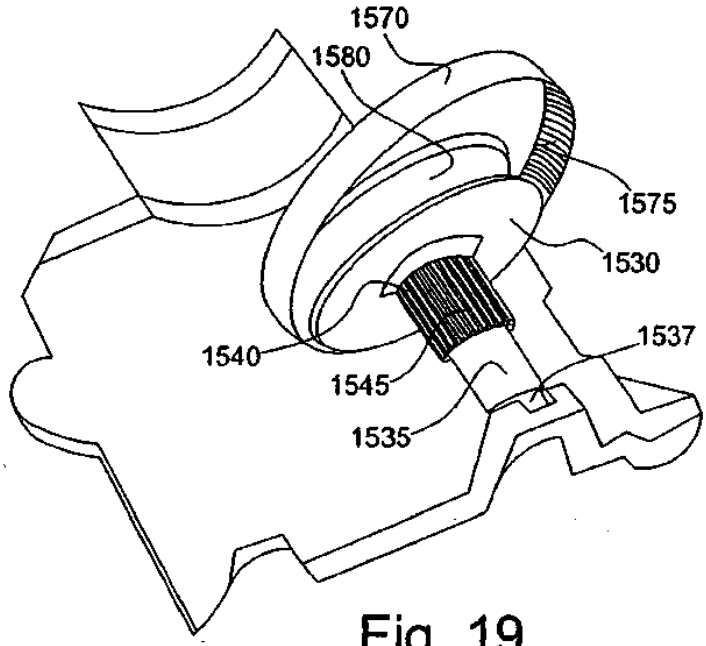

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Fig. 19

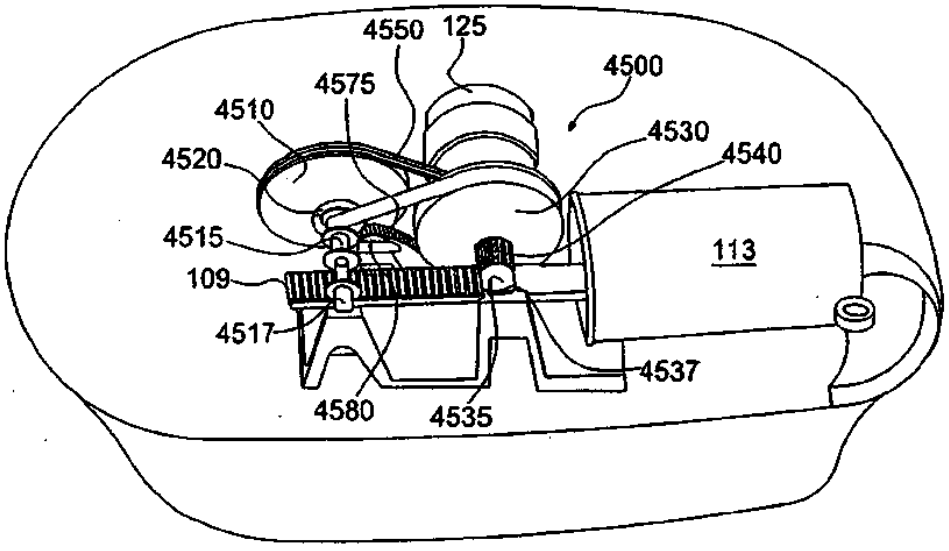

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Fig. 20

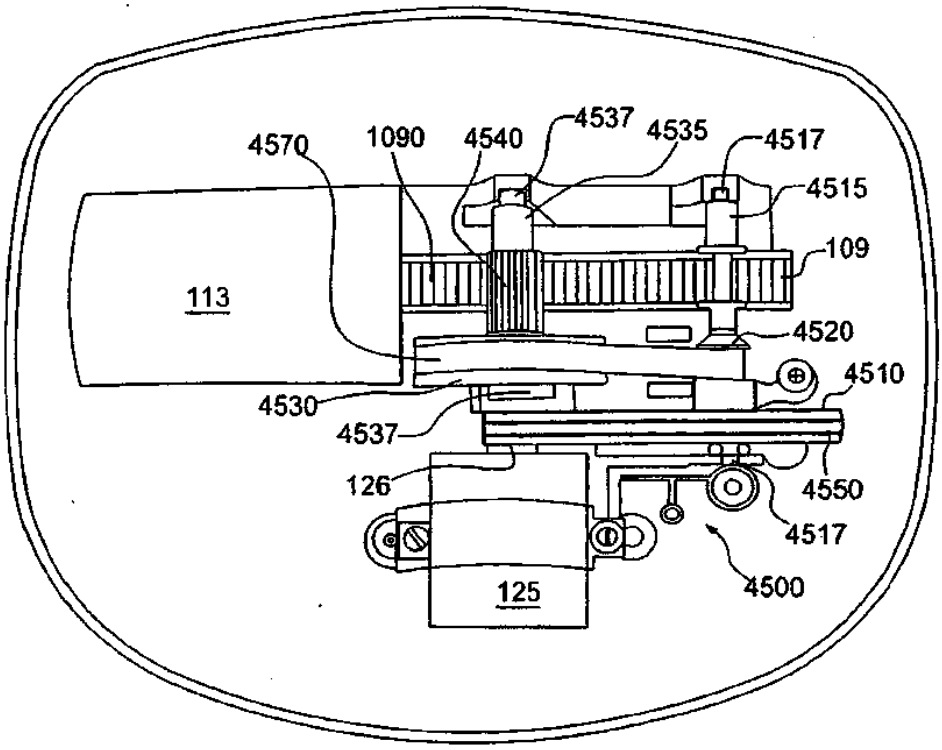

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125

Fig. 21

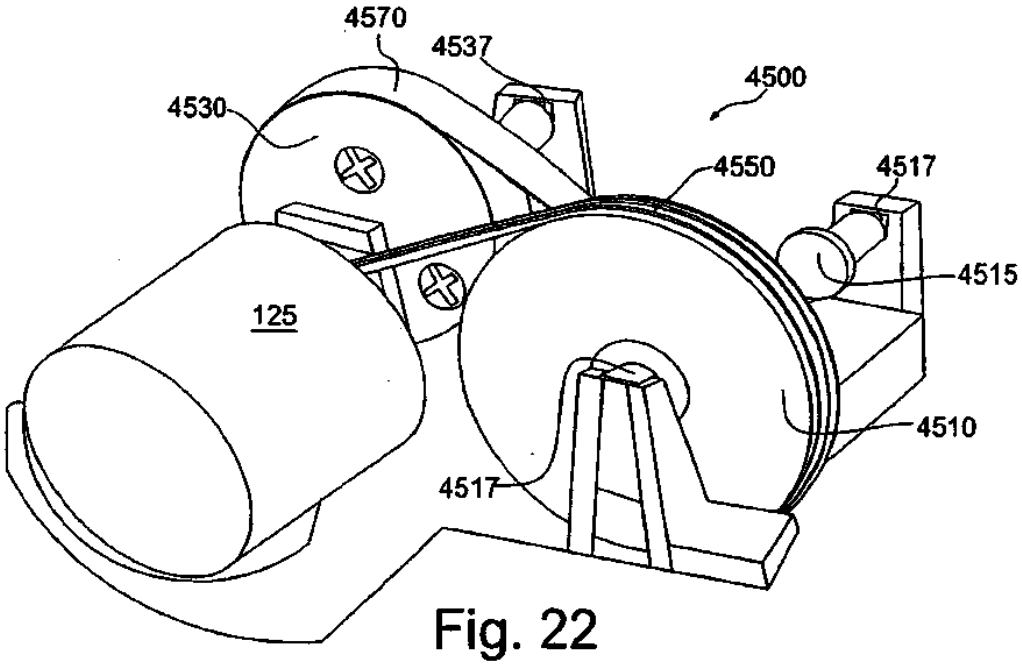

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4530
4550
4517
4515
125
4510
4517

Fig. 22

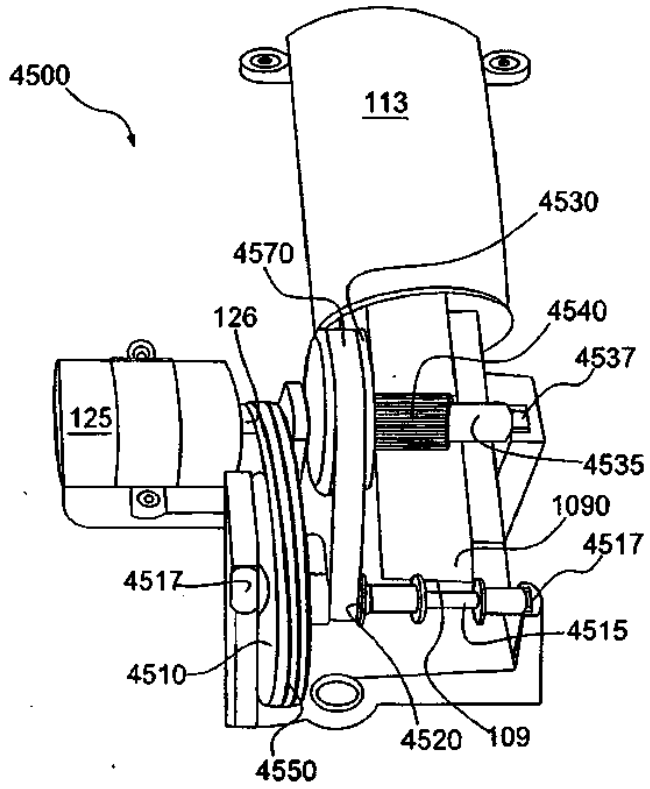

4500
113
4530
4570
126
4540
4537
125
4535
1090
4517
4517
4515
4510
4520
109
4550

Fig. 23

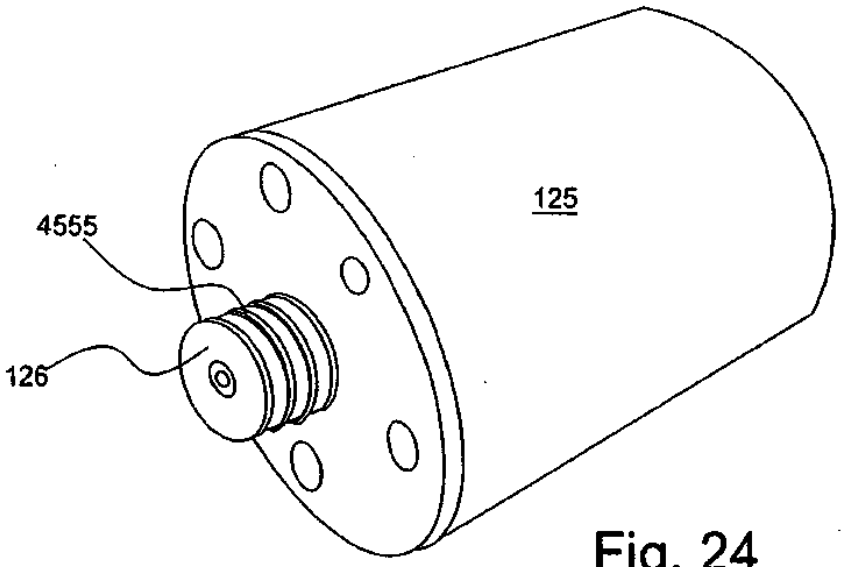

125
4555
126

Fig. 24

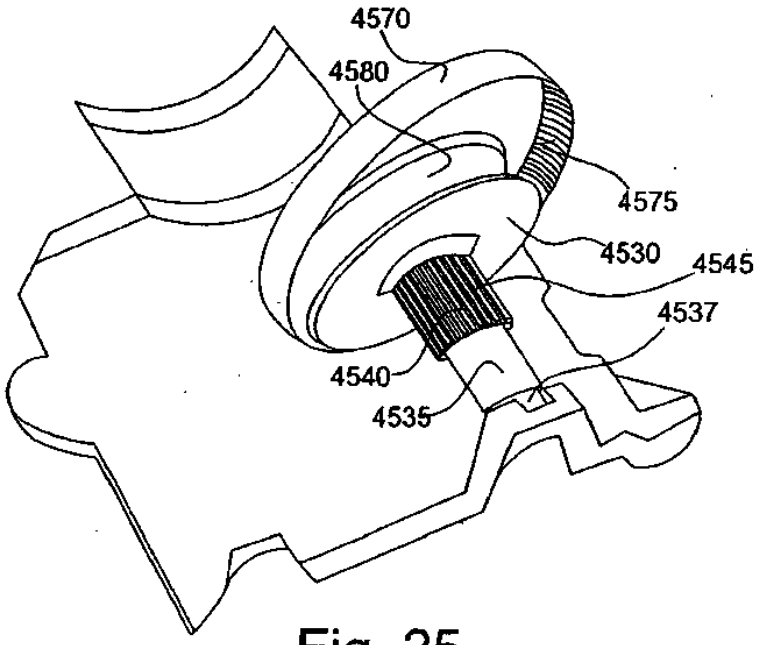

4570
4580
4575
4530
4545
4537
4540
4535

Fig. 25

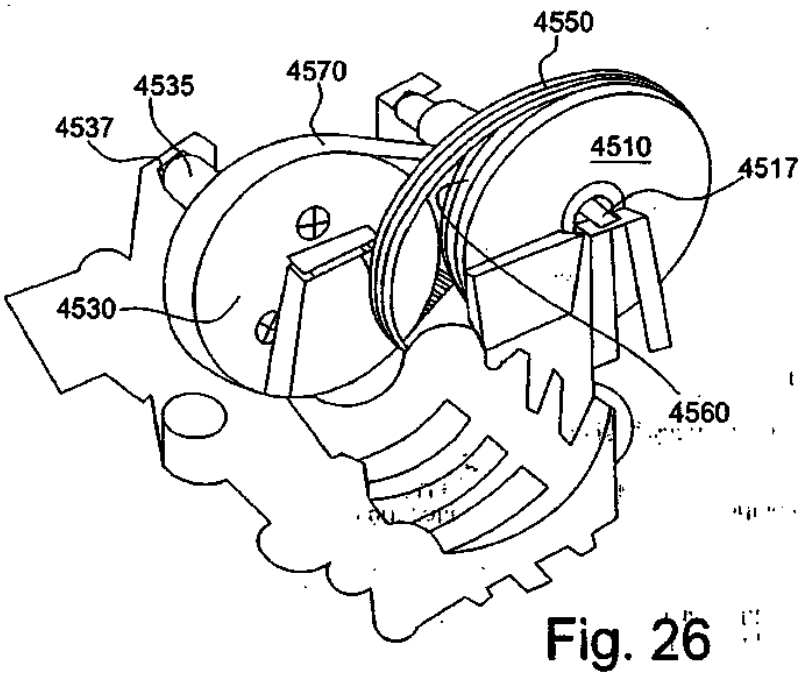

4550
4535
4570
4537
4510
4517
4530
4560

Fig. 26

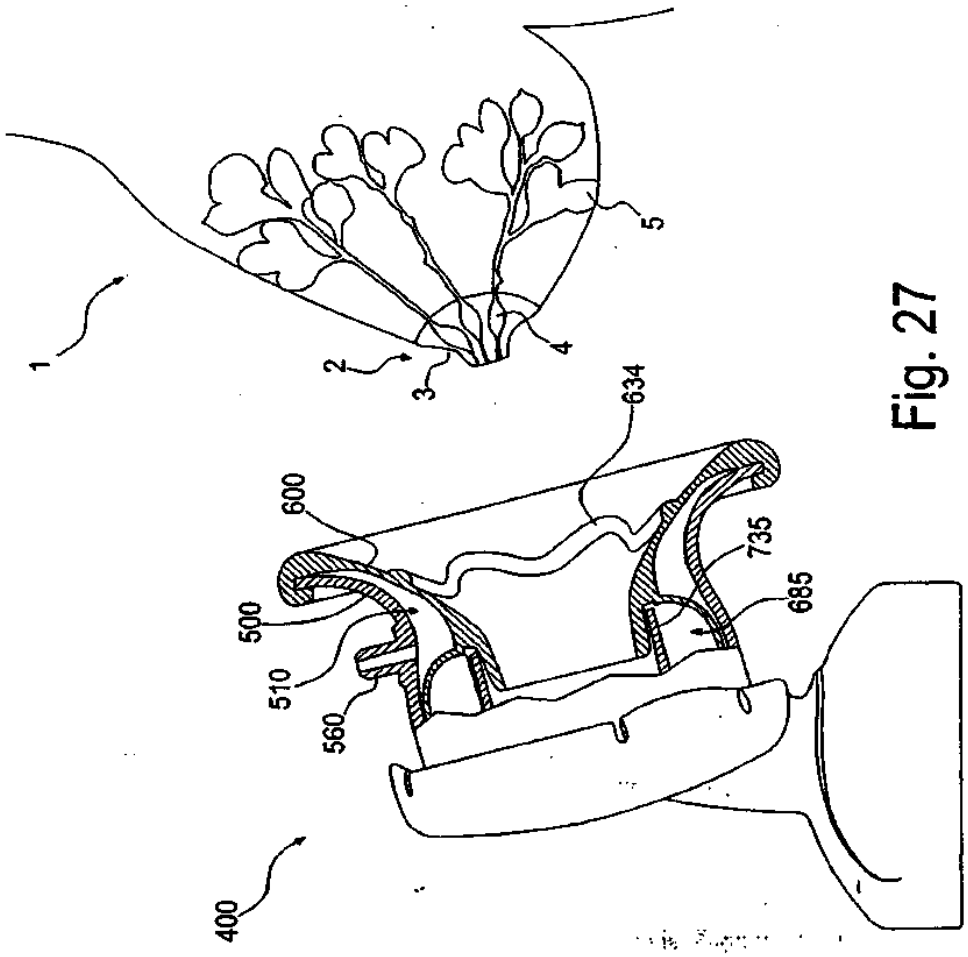


Fig. 27

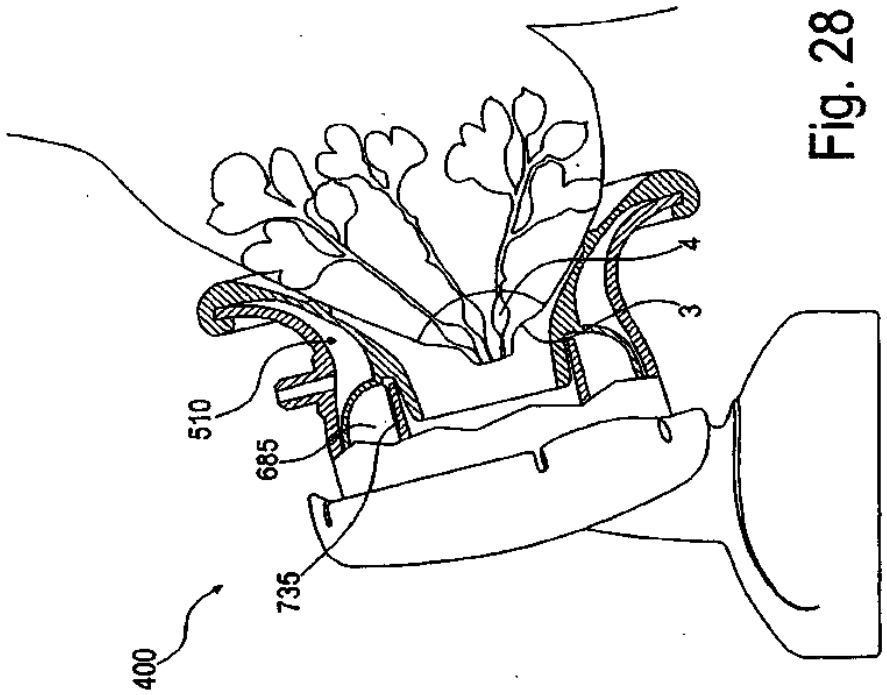


Fig. 28

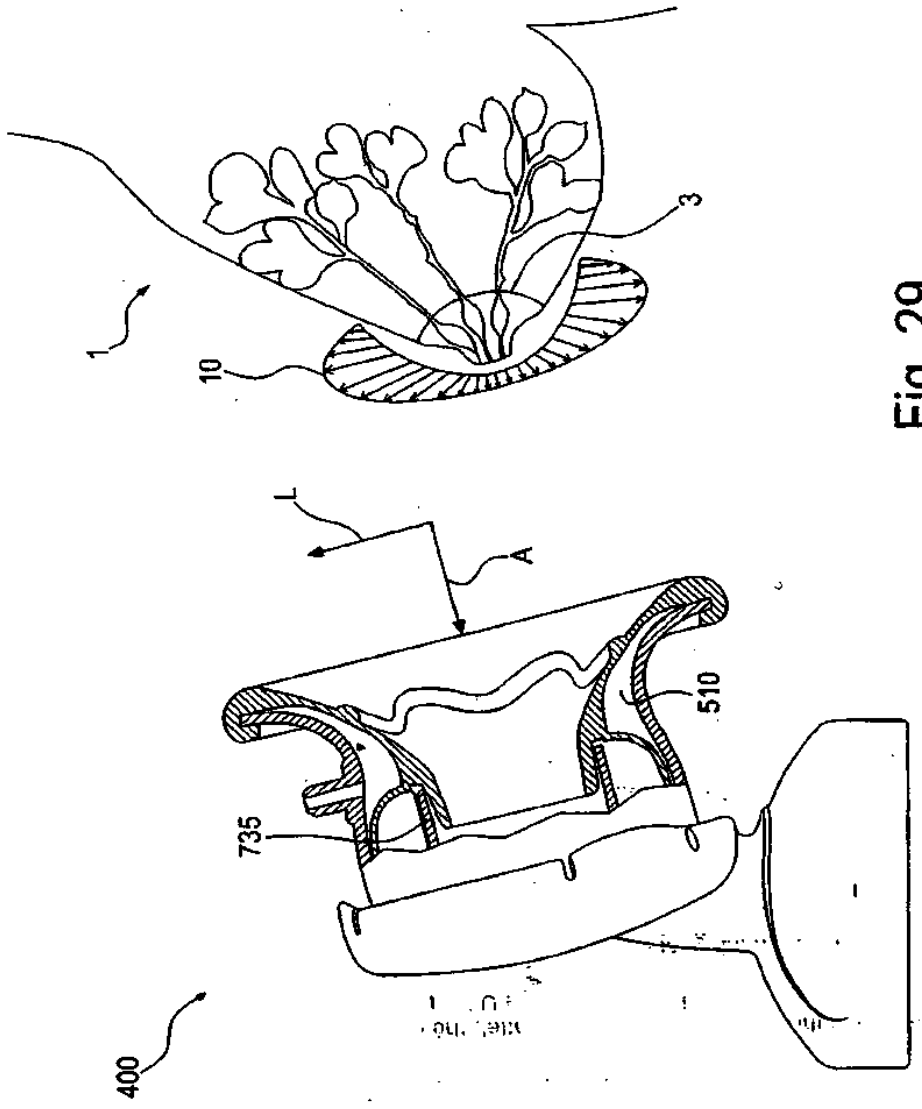


Fig. 29

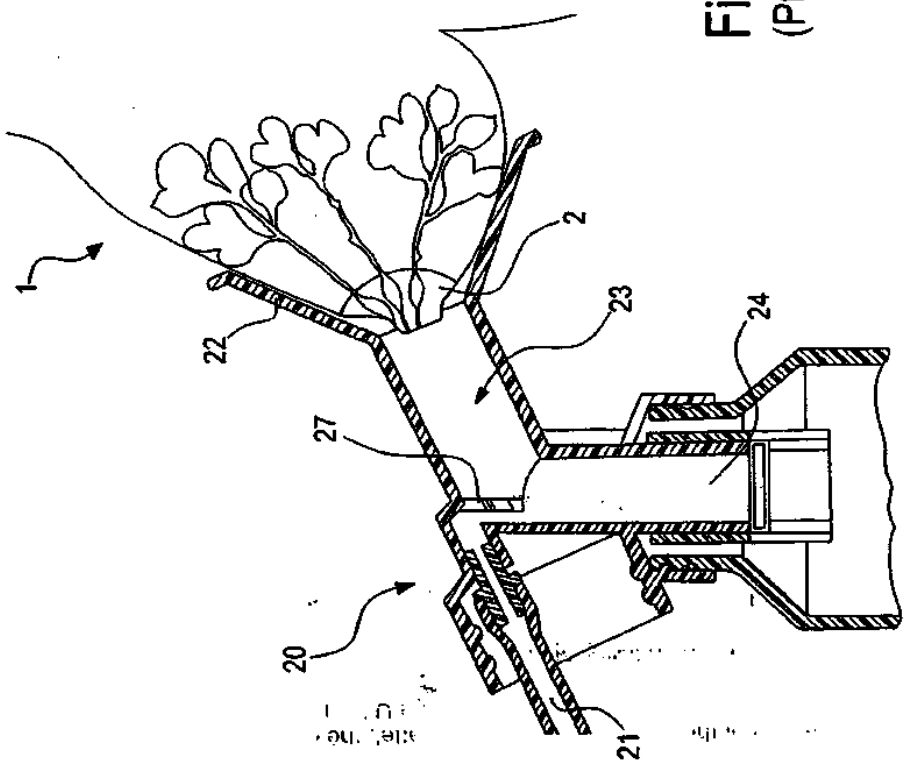


Fig. 30
(Prior Art)

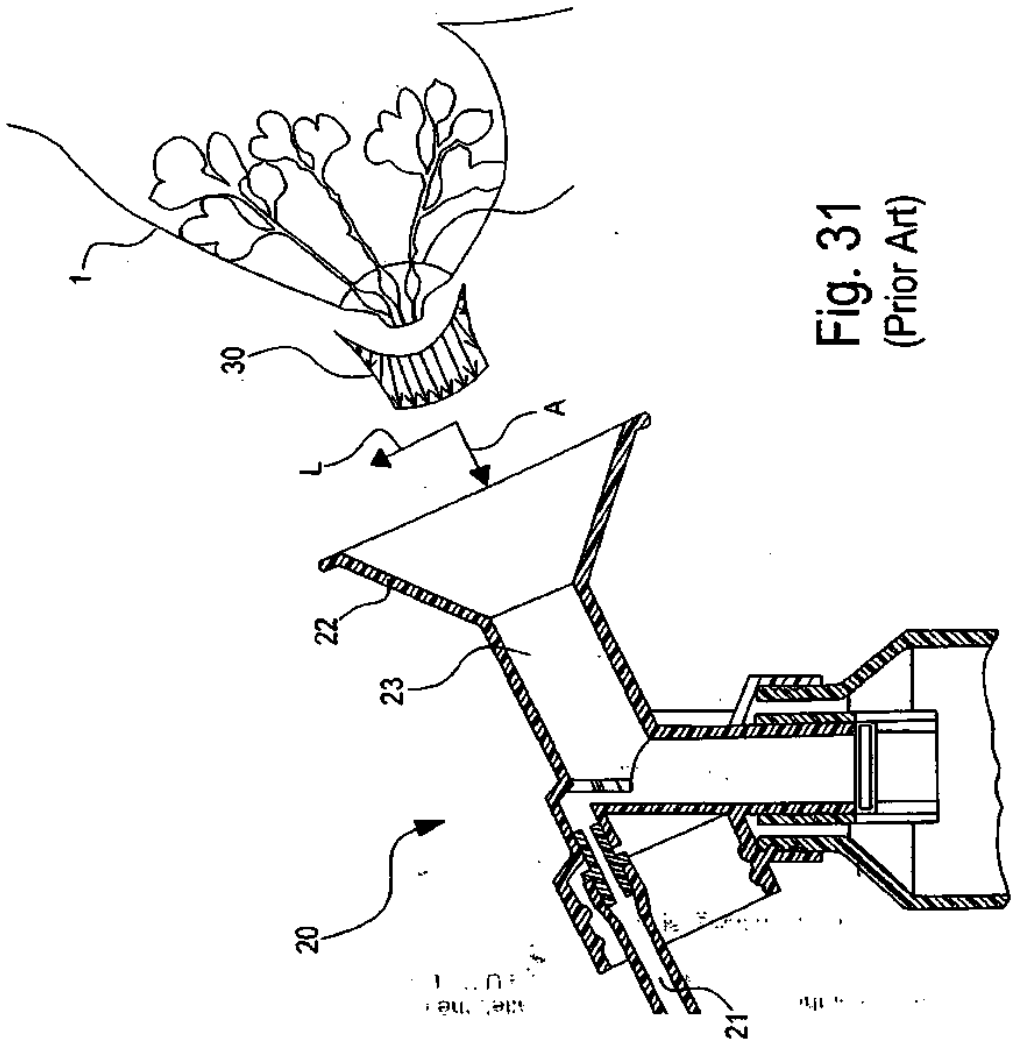


Fig. 31
(Prior Art)

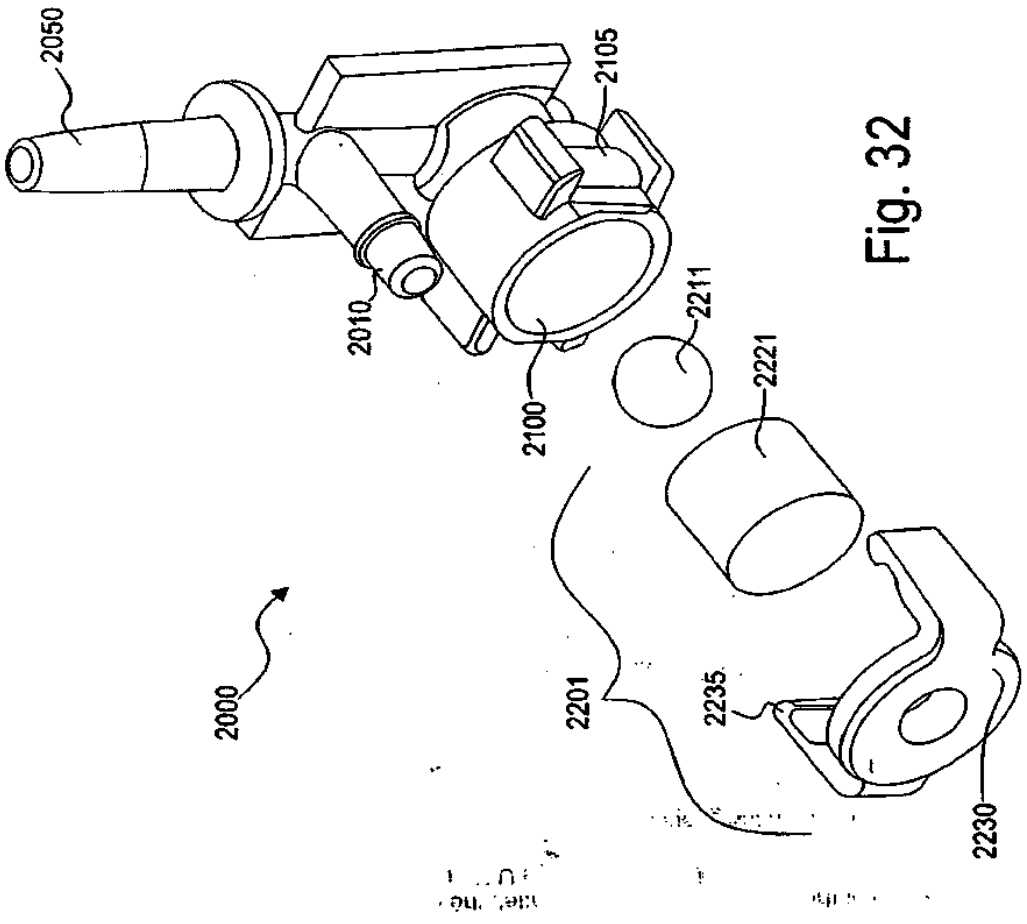


Fig. 32

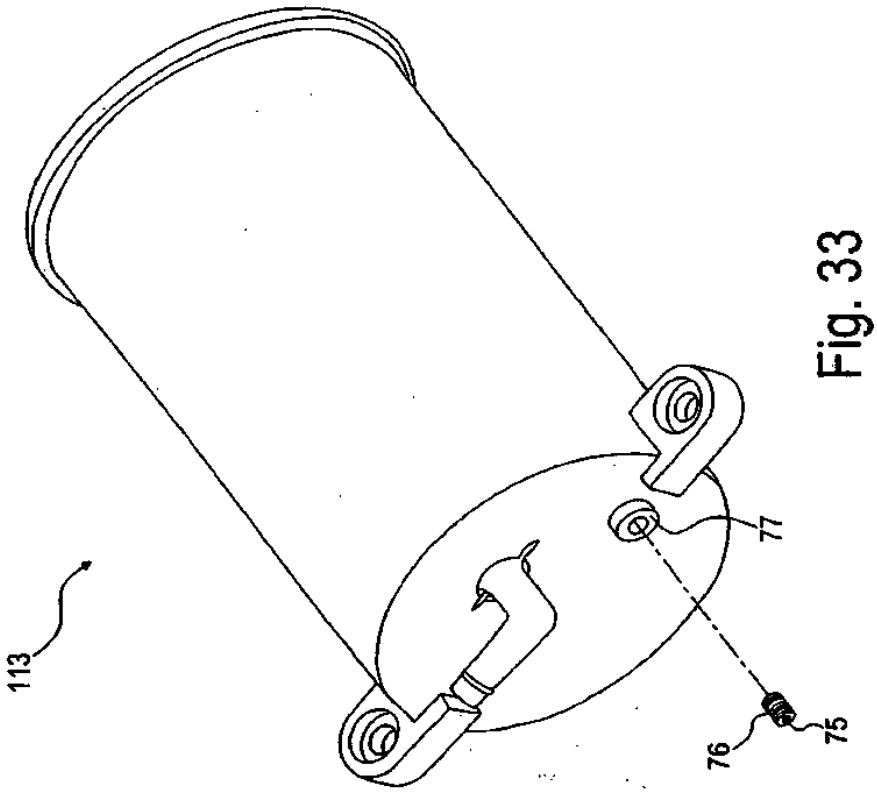


Fig. 33

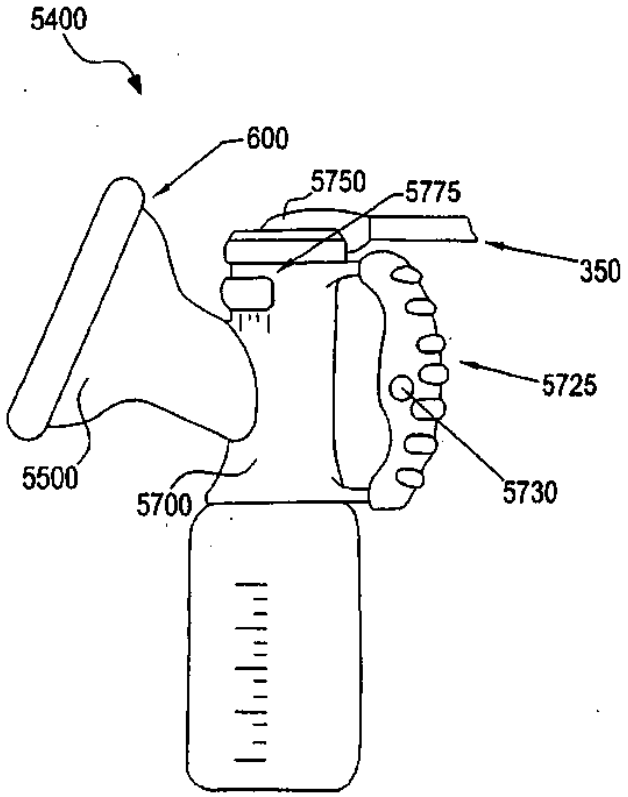

5400
600
5750
5775
350
5725
5500
5700
5730

Fig. 34

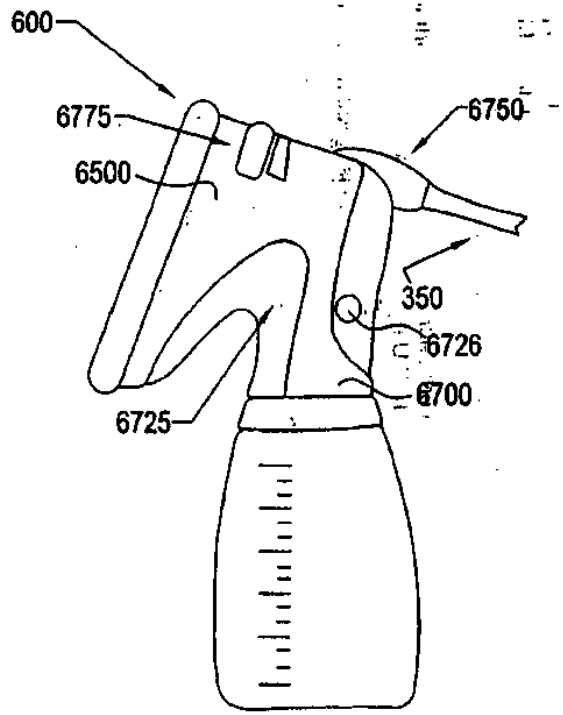

600
6775
6750
6500
350
6726
6700
6725

Fig. 35

Fig. 36

Fig. 37

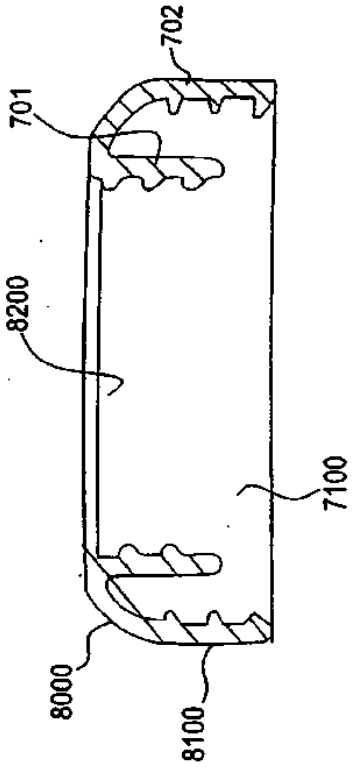


Fig. 39

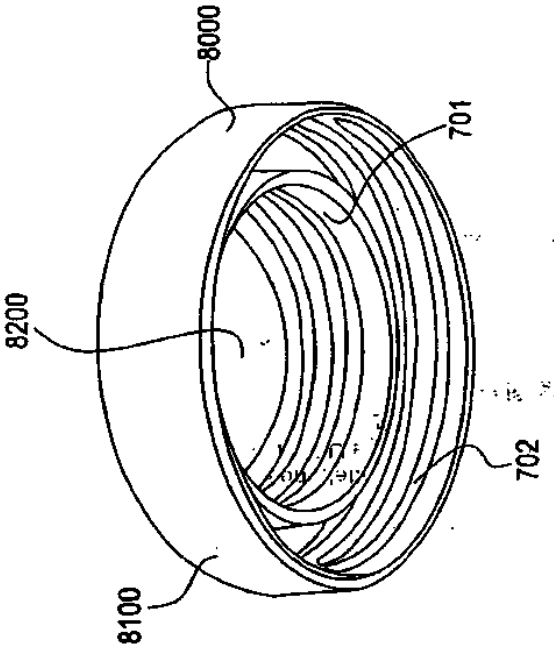


Fig. 38

BREAST PUMP

BACKGROUND OF THE INVENTION

The present invention relates to apparatus and methods for obtaining breast milk. More particularly, the present invention relates to a breast pump that can apply a variable pressure to a breast to express breast milk and to a method effecting the same.

Breast pump systems for obtaining breast milk, both manually and automatically, are known in the art. Conventional systems use a vacuum source to generate a negative pressure or vacuum that is transmitted through tubing to a breast hood or cup that is placed on the breast. This conventional device and method uses a negative pressure on the breast to express the breast milk.

Such systems suffer from the drawback of applying only a vacuum source as negative pressure to the breast to induce the expression of breast milk. Moreover, such conventional systems suffer from the drawback of applying the negative pressure or force axially to the nipple, resulting in elongation and distention of the nipple in an axial direction that is both uncomfortable and inefficient for the expression of breast milk.

SUMMARY OF THE INVENTION

It is an object of the present invention to substantially monitor and control the pressure source of a breast pump in real-time.

It is an object of the present invention to provide a breast pump system for expressing milk that can apply a positive pressure or a negative pressure to a breast to express the milk.

It is another object of the present invention to provide such a system that supplies the positive and negative pressure from a single source.

It is still another object of the present invention to provide such a system that facilitates control of the positive and negative pressure applied to the breast.

It is yet another object of the present invention to provide such a system that widens the nipple to express milk.

It is a further object of the present invention to provide such a system that reduces axial elongation or distention of the nipple.

It is another further object of the present invention to apply a negative force or negative pressure gradient to the nipple that has a greater lateral component than axial component.

It is yet a further object of the present invention to accommodate breasts of differing size and/or shape by providing a kit with interchangeable breast hoods of differing size and/or shape.

These and other objects and advantages are provided by a breast cup having a hood for receiving the breast and in fluid communication with a pressure source. The hood creates a negative force on the nipple during a negative pressure stroke. The negative force has a lateral component and an axial component. The lateral component is greater than the axial component.

The present invention includes a breast pump for expressing breast milk from a breast, the pump comprising a pressure source with a movable structure for generating

pressure during a pressure stroke. The movable structure has a variable pressure volume or variable cycle time. The pump also has a controller operably connected to the pressure source. The controller regulates the pressure volume based upon a distance traveled by the movable structure and regulates the variable cycle time based upon a speed of the movable structure. The controller provides substantially real-time monitoring of the distance traveled and the speed.

Preferably, the controller regulates the pressure cycle based on a non-sinusoidal wave signal of the pressure versus variable cycle time.

A method of expressing breast milk from a breast is described having the steps of applying a pressure to the breast; and performing substantially real-time monitoring and controlling of the pressure with a controller. Said pressure may be controlled in part based on a variable pressure volume of a movable structure or a variable cycle time of said movable structure. As before, the controller regulates the pressure volume based upon a distance traveled by the movable structure or regulates the variable cycle time based upon a speed of the movable structure and the controller provides substantially real-time monitoring of the distance traveled or the speed.

Preferably, the controller regulates the pressure cycle based on a non-sinusoidal wave signal of the pressure versus a cycle time.

There is disclosed a breast cup having a breast receiving member in fluid communication with a vacuum source. The breast receiving member applies a negative pressure to the nipple during a negative pressure stroke causing the nipple to widen along a lateral direction.

Described is a breast pump system having a pressure source and a breast cup for receiving the breast. The breast cup is in fluid communication with the pressure source.

The breast cup creates a negative force on the nipple during a negative pressure stroke. The negative force has a lateral component and an axial component. The lateral component is greater than the axial component.

A breast pump system is also disclosed having a vacuum source and a breast receiving member that is in fluid communication with the vacuum source. The breast receiving member applies a negative pressure to the nipple during a negative pressure stroke causing the nipple to widen along a lateral direction.

Additionally disclosed is a breast pump kit having a holder and a plurality of hoods for receiving the breast. Each of the plurality of hoods are selectively engageable to the holder and a pressure source for expressing the breast milk from the breast. At least one of the plurality of hoods has a different size or a different shape than another of the plurality of hoods.

There is described a breast pump system having a pump generating pressure and a plurality of hoods for receiving the breast. Each of the plurality of hoods are selectively fluidly connectable to the pump for expressing the breast milk from the breast. At least one of the plurality of hoods has a different size or a different shape than another of the plurality of hoods.

A breast pump system is disclosed having a pressure source with an evacuation volume for generating a pressure and an air hole. The system also has a breast cup for receiving the breast and in fluid communication with the pressure source for applying the pressure to the breast. The air hole has a diameter and is in fluid communication with the atmosphere and the evacuation volume. The diameter of the air hole is between about 0.15 mm to 0.75 mm.

A method describes expressing breast milk from a breast having the steps of applying a negative pressure to the breast from a pressure source during a vacuum stroke; applying a positive pressure to the breast from the pressure source during a massage stroke; and providing air from the atmosphere to the pressure source during the vacuum stroke.

There is also a method disclosing the expression of breast milk from a breast having the step of applying a negative pressure on at least a portion of the nipple causing the nipple to widen along a lateral direction.

A pump for providing pressure is described which has a housing, an actuator and an insert. The housing defines a volume and has a pressure exhaust. The actuator is operably connected to the housing for producing the pressure in the volume. The insert is connected to the housing. The insert has a hole disposed therethrough. The hole provides fluid communication between the volume and atmosphere.

A breast cup is disclosed for placing a breast in fluid communication with a first container and a second container that have openings with different diameters. The breast cup has a funnel for receiving the breast and a housing connected to the funnel. The funnel has a base. The base has a circumferential wall, a flange extending inwardly from the circumferential wall to define an opening, first threads, and second threads. The first threads have a first diameter and a first pitch. The first diameter and the first pitch allow for selective engagement with the first container. The second threads have a second diameter and a second pitch. The second diameter and the second pitch allow for selective engagement with the second container. The first threads and the second threads are concentrically disposed along the base.

There is also described a nipple ring for engaging a nipple with a first container and a second container that have openings with different diameters. The nipple ring has a

body having a circumferential wall, a flange extending inwardly from the circumferential wall to define an opening, first threads, and second threads. The first threads have a first diameter and a first pitch. The first diameter and the first pitch allow for selective engagement with the first container. The second threads have a second diameter and a second pitch. The second diameter and the second pitch allow for selective engagement with the second container. The first threads and the second threads are concentrically disposed along the body.

Also disclosed is a cap for engaging with a first container and a second container that have openings with different diameters. The cap has a body with a circumferential wall, a top wall connected to the circumferential wall, first threads, and second threads. The first threads have a first diameter and a first pitch. The first diameter and the first pitch allow for selective engagement with the first container. The second threads have a second diameter and a second pitch. The second diameter and the second pitch allow for selective engagement with the second container. The first threads and the second threads are concentrically disposed along the body.

The first pitch can be equal to the second pitch. The first threads can extend from the flange. The second threads can be disposed on the circumferential wall. The funnel can be selectively removable from the housing.

The housing can be a first material and the insert can be a second material. The housing can be plastic and the insert can be metal. The housing can be a cylinder and the actuator can be a piston. The cylinder can be an orifice and the insert can be disposed in the orifice. The insert can be press fit into the orifice. The insert can be a plurality of inserts, and each of the plurality of inserts can be selectively engageable with the cylinder.

The breast cup can also have a barrier member operably connected to the hood, wherein the barrier member reduces the axial component of the negative force during the

negative pressure stroke. The hood can have a housing, a flexible insert sealingly secured to the housing, and a displacement volume formed between the housing and the flexible insert, wherein the displacement volume is in fluid communication with the pressure source. The displacement volume can substantially surround the nipple when the breast is received in the hood. The flexible insert can have a bladder in fluid communication with the pressure source with the displacement volume being defined at least partially by the bladder. The bladder and the displacement volume can contract to form the negative force on the nipple during the negative pressure stroke.

The breast cup can also have a barrier member disposed substantially adjacent to the bladder, thereby preventing the breast from contacting the bladder. The flexible insert can define an inner volume for receiving the breast, and the barrier member can have a cylindrical shape and be disposed in the inner volume. The flexible insert can have a funnel shape with a massaging projection formed thereon. The massaging projection can have a star-like shape.

The negative pressure created at the breast cup can cause the nipple to widen along a lateral direction more than the nipple elongates along an axial direction. The negative pressure can have an average lateral component and an average axial component, wherein during the negative pressure stroke the average lateral component is greater than the average axial component. The barrier member can be operably connected to the breast receiving member, and can reduce elongation of the nipple along the axial direction during the negative pressure stroke. The breast receiving member can have a housing, a flexible insert sealingly secured to the housing, and a displacement volume formed between the housing and the flexible insert, wherein the displacement volume is in fluid communication with the vacuum source.

The vacuum or pressure source can be a piston movably disposed in a cylinder. The system can have a reversible motor operably connected to the piston. The system can

also have a rack having first teeth and a gear having second teeth. The rack can be connected to the piston and the gear can be operably connected to the reversible motor. The first teeth can engage with the second teeth to reciprocally move the piston in the cylinder. The cylinder can have a first diameter and an air hole. The air hole can have a second diameter and be in fluid communication with the atmosphere. The first diameter of the cylinder can be significantly larger than the second diameter of the air hole.

The system can have a controller operably connected to the reversible motor. The controller can determine a distance that the piston has traveled relative to the cylinder. The controller can reverse the motor based at least in part upon that distance. The system can also have a motor with variable speed. The controller can adjust the speed based upon a desired cycle time for applying the negative pressure to the breast. The controller can regulate the pressure cycle based on a non-sinusoidal wave signal of pressure versus variable cycle time.

Each of the plurality of hoods of the kit can have a housing, a flexible insert sealingly secured to the housing, and a displacement volume formed between the housing and the flexible insert and in fluid communication with the pressure source. The housing and/or the flexible insert of the at least one of the plurality of hoods can have a different size or a different shape than the housing and/or the flexible insert of the another of the plurality of hoods. The kit can also have a container, wherein the holder is selectively engageable with the container. The holder can have a plurality of engagement structures for selectively engaging a plurality of different sized containers. The flexible insert of the at least one of the plurality of hoods can have a first massaging projection, and the flexible insert of the another of the plurality of hoods can have a second massaging projection. The first and second massaging projections can have a different size or a different shape.

BRIEF DESCRIPTION OF THE DRAWINGS

Other and further objects, advantages and features of the present invention will be understood by reference to the following:

Fig. 1 is a front perspective view of a breast pump of the breast pump system of the present invention;

Fig. 2 is a front perspective view of the breast pump of Fig. 1 in an opened position;

Fig. 3 is an exploded perspective view of the breast pump of Fig. 1;

Fig. 4 is a top view of the breast pump of Fig. 1 without the cover;

Fig. 5 is an exploded perspective view of a piston and cylinder of the present invention;

Fig. 6 is an exploded side view of a portion of the piston and cylinder of Fig. 5;

Fig. 7 is a front perspective view of the piston of Fig. 5;

Fig. 8 is an exploded perspective view of an alternative embodiment of the piston;

Fig. 9 is an exploded perspective view of a pressure relief valve of the system of Fig. 1;

Fig. 10 is a cross-sectional plan view of the cylinder of Fig. 5;

Fig. 11 is a front perspective view of a breast cup;

Fig. 12 is a side cross-sectional view of the breast cup of Fig. 11;

Fig. 13 is a rear perspective view of a T-connector;

Fig. 14 is a flow chart depicting a method for pumping a breast according to the system of Figs. 1 and 11;

Fig. 15 is a top perspective view of a preferred embodiment of breast pump for the breast pump system of the present invention;

Fig. 16 is a top view of the breast pump of Fig. 15;

Fig. 17 is a top perspective view of the drive system of the breast pump of Fig. 15;

Fig. 18 is a side perspective view of the drive system of Fig. 17;

Fig. 19 is a top perspective view of a portion of the gear reduction system of the drive system of Fig. 15, partially assembled;

Fig. 20 is a top perspective view of an alternative embodiment of breast pump for the breast pump system of the present invention;

Fig. 21 is a top view of the breast pump of Fig. 20;

Fig. 22 is a top perspective view of the drive system of the breast pump of Fig. 20;

Fig. 23 is a side perspective view of the drive system of Fig. 20;

Fig. 24 is a top perspective view of the motor of the drive system of Fig. 20;

Fig. 25 is a top perspective view of a portion of the gear reduction system of the drive system of Fig. 20, partially assembled;

Fig. 26 is a top perspective view of the gear reduction system of the drive system of Fig. 20, partially assembled;

Fig. 27 is a partial cross-sectional side view of the breast cup of Fig. 11 with a breast;

Fig. 28 is a partial cross-sectional side view of the breast cup of Fig. 27 applied to the breast prior to the negative pressure stroke;

Fig. 29 is an exploded cross-sectional view of the breast cup and breast of Fig. 27 during the negative pressure stroke showing a representation of the negative pressure gradient or force on the breast;

Fig. 30 is a cross-sectional side view of a prior art breast cup applied to a breast prior to the negative pressure stroke;

Fig. 31 is an exploded cross-sectional view of the prior art breast cup and breast of Fig. 30 during the negative pressure stroke showing a representation of the negative pressure gradient or force on the breast;

Fig. 32 is an exploded perspective view of the pressure relief valve of Fig. 9 with another embodiment of a relief assembly;

Fig. 33 is a perspective view of the cylinder of Fig. 5 with another embodiment of the pressure differential hole;

Fig. 34 is an alternative embodiment of a breast cup;

Fig. 35 is another alternative embodiment of a breast cup;

Fig. 36 is a bottom perspective view of a nipple ring with a nipple;

Fig. 37 is a side cross-sectional view of the nipple ring and nipple of Fig. 36;

Fig. 38 is a bottom perspective view of a cap; and

Fig. 39 is a side cross-sectional view of the cap of Fig. 38.

DESCRIPTION OF THE INVENTION

Referring to the drawings and, in particular, Figs. 1 and 2, there is shown a breast pump of the present invention generally represented by reference numeral 100. Breast pump 100, along with breast cup 400 shown in Fig. 11, form the major components of the breast pump system of the present invention. Breast pump 100 has a top housing 102 and a bottom housing 103 that are adapted to form an assembled unit.

Referring to Figs. 1 through 3, top housing 102 has a substantially ellipsoidal shape with a flat front face 200 and a storage compartment 210 having a compartment door 104. Preferably, door 104 is hingedly connected to top housing 102 to form a selectively sealable storage compartment 210 for storing air tubing or conduit 350 that connects breast pump 100 to the other components of the system, which will be discussed later in greater detail.

Face 200 can receive a button pad 105 having an LED cover 106. Pad 105 is used by the consumer to control breast pump 100. Bottom housing 103 can securely house the various components of the breast pump, which include a rack gear 109, a pinion gear 110 that can engage the rack gear, a piston 112, a cylinder 113 that can receive the piston, and a motor 125 having a shaft 126 upon which the pinion gear is mounted. Due in part to this design, breast pump 100 provides pumping with low noise. Breast pump 100 can be made of any rigid material, such as, for example, plastic.

Referring to Figs. 3 through 7, breast pump 100 utilizes piston 112 and cylinder 113 to create both a positive pressure and a negative pressure for obtaining breast milk. Piston 112 is driven by rack gear 109, which is affixed thereto. Piston 112 has a substantially cylindrical-shape with a first head 3000 and a second head 3100. First and second heads 3000, 3100 preferably have annular channels 3020, 3120 formed therein, respectively. Channels 3020, 3120 are disposed along the outer circumference of first and second heads 3000, 3100, respectively. Preferably, channels 3020, 3120 are centrally located along the outer circumference of first head 3000 and second head 3100. Seated in channels 3020, 3120 are sealing members 3050, 3150, respectively. Preferably, sealing members 3050, 3150 are o-ring gaskets. Sealing members 3050, 3150 have a diameter or width that is larger than the depth or height of channel 3020 and channel 3120. Sealing members 3050, 3150 extend beyond the outer circumference of first head 3000 and second head 3100 forming a sealing engagement with an inner surface 1130 of cylinder 113 as piston 112 is driven back and forth in the cylinder.

The use of multiple sealing members, i.e., o-ring gasket 3050 and o-ring gasket 3150 on piston 112, provide a double sealing to increase the efficiency of creating the positive pressure and negative pressure. While this embodiment uses two sealing members to create two separate sealing surfaces, any number of sealing members can be used to create any number of sealing surfaces for sealing piston 112 with cylinder 113.

Additionally, while this embodiment uses piston 112 having o-ring sealing gaskets 3050, 3150, alternative sealing structures can be used between the piston and cylinder 113.

Rack gear 109 has teeth 1090 that engage with pinion gear 110 having teeth 1100. Pinion gear 110 is operatively connected to motor 125, preferably via shaft 126. When motor 125 is activated, shaft 126 and pinion gear 110 rotate. Teeth 1090 on rack 109 and teeth 1100 on pinion 110 mesh and translate the reciprocal rotational motion of motor 125 and shaft 126 into a reciprocal longitudinal motion along a single axis in both directions.

Preferably, rack gear 109 has a first end 1095 that engages with a recess 3200 formed in piston 112. Recess 3200 is preferably centrally located in piston 112. First end 1095 of rack gear 109 preferably has a snap fit or friction fit engagement with recess 3200 of piston 112. Preferably, there are detent structures 1096, 3296 formed on first end 1095 and recess 3200, respectively. This facilitates production of these components and also provides for any slight pivotal movement that may be required of piston 112 with respect to rack gear 109.

An alternative embodiment of a piston is shown in Fig. 8 and generally represented by reference numeral 8112. Piston 8112 has a substantially V-shape with a leading edge 8120 and a trailing edge 8121. Leading edge 8120 and trailing edge 8121 sealingly engage an inner surface 1130 of cylinder 113 as piston 8112 is driven back and forth in the cylinder. The use of multiple edges, i.e., leading edge 8120 and following edge 8121, on piston 8112 that sealingly engage inner surface 1130 of cylinder 113, provide a double sealing to increase the efficiency of creating the positive pressure and negative pressure.

Referring to Figs. 3 through 7, motor 125 is preferably variable speed. This allows a user to control and vary the cycle time of the pumping of the breast. Breast

pump 100 further has a motor cover 107 and a bearing 108 to reduce vibration and to secure motor 125 to bottom housing 103.

The positive and negative pressures can be varied by changing the displacement of air volume in cylinder 113. In this embodiment, this is done by use of a photoelectric or photo-sensor system. The photo-sensor system has two or more photo-sensors 121 and a position switch 124. The photo-sensors 121 count the number of openings 50 on rack gear 109, as the rack gear moves back and forth. Thus, a user can control the distance that rack gear 109 travels and correspondingly control the air volume displacement in cylinder 113. Alternative displacement or distance monitors can also be used, such as, for example a coded wheel for counting the slots on the wheel; counting of the belt teeth; rotary encoder which counts its own revolutions; or a hall effect sensor.

To ensure that piston 112 is properly moving to the front of cylinder 113, the photo-sensor system further includes position switch 124, preferably located at the front of the cylinder, which acts as a starter for the counter. Alternatively, the position switch can be an opening 50 having a different size or shape that is detectable by photo-sensor 121.

Rack gear 109 can also have a safety mechanism attached thereto. Photo-sensor 121 will be reading openings 50 as rack gear 109 moves backwards. If for some reason rack gear 109 misses its target and moves too far, the safety will trigger the position switch. When the position switch is triggered while rack gear 109 is moving backwards, the software can trigger the system to move forward again and return to the position position.

Breast pump 100 has a guide cover 111 positioned over rack gear 109. Guide cover 111 provides added stability to the breast pump by guiding and vibration dampening the reciprocal movement of rack gear 109. Guide cover 111 also provides

accuracy to the photo-sensor system by reducing the risk of misalignment of photo-sensors 121 and openings 50.

The photo-sensor system and motor 125 are preferably connected to a PC or circuit board 120. Thus, the distance piston 112 travels, which translates to the amount of positive and negative pressure, and the piston speed, which translates to the cycle time, are electronically controlled.

Referring to Figs. 15 through 19, a preferred embodiment of a drive system is shown and generally represented by reference numeral 1500. Drive system 1500 is usable with breast pump 100 of Figs. 1 through 7 to provide the linear reciprocal movement of piston 112 with cylinder 113.

Drive system 1500 is a belt drive system for a rack and pinion drive having gear reduction incorporated therein. Drive system 1500 has a first drive wheel or pulley 1510; a second gear, drive wheel or pulley 1520 secured to the first drive wheel 1510; a third gear, drive wheel or pulley 4530; and a pinion gear 1540 secured to the third gear.

First drive wheel 1510 is operably connected to motor drive shaft 126 by a first belt 1550. In the preferred embodiment, first belt 1550 is a non-toothed belt. More preferably, first belt 1550 has resiliency or flexibility. The use of flexible or resilient belt 1550 provides a secure connection between drive shaft 126 and first drive wheel 1510 and also reduces noise and vibration. Drive shaft 126 and first drive wheel 1510 have smooth outer surfaces upon which the first belt 1550 is secured.

First drive wheel 1510 is operably connected to second gear 1520 by a first co-axial shaft 1515. In the preferred embodiment, first shaft 1515 is rotatably mounted between opposing first bearings 1517. However, alternative rotatable mounting arrangements or securing structures could also be used. To reduce noise and vibration,

motor shaft 126 and first drive wheel 1510 are made of metal. First drive wheel 1510 and second gear 1520 have different diameters that partially provide for gear reduction between motor shaft 126 and pinion gear 1540.

Second gear 1520 is operably connected to third gear 1530 by a second belt 1570. Preferably, second belt 1570 has teeth 1575 that mesh with teeth 1580 formed along the circumference of second gear 1520 and third gear 1530. Second and third gears 1520, 1530 have different diameters that partially provide for gear reduction between motor shaft 126 and pinion gear 1540. Drive system 1500 can also have a tension pulley 1580 that provides tension to second belt 1570.

Third gear 1530 is operably connected to pinion gear 1540 by a second co-axial shaft 1535. In the preferred embodiment, second shaft 1535 is rotatably mounted between opposing second bearings 1537. However, alternative rotatable mounting arrangements or securing structures could also be used. Preferably, third gear 1530 is integrally molded with pinion gear 1540 along second shaft 1535.

Pinion gear 1540 has teeth 1545 that engage with teeth 1090 of rack gear 109. When motor 125 is activated, the rotational motion of shaft 126 is translated into a reciprocal longitudinal motion along a single axis of rack gear 109 in both directions. Drive system 1500, through use of first and second belts 1550, 1570 and first, second and third drive wheels or gears 1510, 1520, 1530, is able to provide a desired ratio of movement between motor shaft 126 and pinion gear 1540, i.e., gear reduction.

The use of a combination of the non-toothed belt 1550 and the toothed belt 1570 reduces noise and vibration, while maintaining a secure, sturdy drive system 1500 that is able to provide the necessary back and forth linear motion at the desired speeds and pressure for breast pump 100.

Referring to Figs. 20 through 26, an alternative embodiment of a drive system is shown and generally represented by reference numeral 4500. Drive system 4500 is also usable with breast pump 100 of Figs. 1 through 7 to provide the linear reciprocal movement of piston 112 with cylinder 113.

Drive system 4500 is a belt drive system having gear reduction incorporated therein. Drive system 4500 has a first gear, drive wheel or pulley 4510; a second gear, drive wheel or pulley 4520 secured to the first gear; a third gear, drive wheel or pulley 4530; and a pinion gear 4540 secured to the third gear.

First gear 4510 is operably connected to motor drive shaft 126 by a first belt 4550. In the preferred embodiment, first belt 4550 is a plurality of belts, and more preferably, three belts. First belts 4550 are preferably non-toothed belts. More preferably, first belts 4550 are o-rings having resiliency or flexibility. The use of flexible or resilient belts 4550, such as, for example, o-rings, provides a secure connection between drive shaft 126 and first gear 4510, and also reduces noise and vibration. Drive shaft 126 and first gear 4510 have annular channels 4555, 4560, formed therein, respectively. Annular channels 4555, 4560 are guides that assist in holding first belts 4550 in place and facilitate assembly of drive system 4500.

First gear 4510 is operably connected to second gear 4520 by a first co-axial shaft 4515. In this alternative embodiment, first shaft 4515 is rotatably mounted between opposing first bearings 4517. However, alternative rotatable mounting arrangements or securing structures could also be used. To reduce noise and vibration, motor shaft 126 and first gear 4510 are made of metal. First and second gears 4510, 4520 have different diameters that partially provide for gear reduction between motor shaft 126 and pinion gear 4540.

Second gear 4520 is operably connected to third gear 4530 by a second belt 4570. Preferably, second belt 4570 has teeth 4575 that mesh with teeth 4580 formed along the circumference of second gear 4520 and third gear 4530. Second and third gears 4520, 4530 have different diameters that partially provide for gear reduction between motor shaft 126 and pinion gear 4540. Drive system 4500 can also have a tension pulley 4580 that provides tension to second belt 4570.

Third gear 4530 is operably connected to pinion gear 4540 by a second co-axial shaft 4535. In this alternative embodiment, second shaft 4535 is rotatably mounted between opposing second bearings 4537. However, alternative rotatable mounting arrangements or securing structures could also be used. Preferably, third gear 4530 is integrally molded with pinion gear 4540 along second shaft 4535.

Pinion gear 4540 has teeth 4545 that engage with teeth 1090 of rack gear 109. When motor 125 is activated, the rotational motion of shaft 126 is translated into a reciprocal longitudinal motion along a single axis of rack gear 109 in both directions. Drive system 4500, through use of first and second belts 4550, 4570 and first, second and third gears 4510, 4520, 4530, is able to provide a desired ratio of movement between motor shaft 126 and pinion gear 4540, i.e., gear reduction.

The use of a combination of the non-toothed o-ring belts 4550 and the toothed belt 4570 reduces noise and vibration, while maintaining a secure, sturdy drive system 4500 that is able to provide the necessary back and forth linear motion at the desired speeds and pressure for breast pump 100.

The embodiments of the drive systems 1500 and 4500 described above utilize belts for gear reduction. However, alternative embodiments can use a gear-box that reduces the gearing to the desired ratio that is transferred to the rack and pinion gearing that drives breast pump 100.

Referring back to Figs. 3 through 9, cylinder 113 has a supply tube 116 that is secured to a supply connector 115 for supplying the positive and negative pressure to breast cup 400. Preferably, supply connector has an outlet 215 disposed in storage compartment 210. Air tubing 350 can be secured to outlet 215 and also secured to breast cup 400. Storage compartment 210 can be opened or closed during the pumping operation. Cylinder 113 is in fluid communication with a pressure relief valve 2000 (shown in Fig. 9) that is preferably set at about 1.5 in. Hg.

Pressure relief valve 2000 has an intake 2010 and an exhaust 2050. Intake 2010 is in fluid communication with cylinder 113 and exhaust 2050 is in fluid communication with breast cup 400, by tubing 350. Pressure relief valve 2000 has a relief exhaust 2100 that is in fluid communication with intake 2010 and exhaust 2050. Relief exhaust 2100 is substantially tubular and is secured to a relief assembly 2200.

Relief assembly 2200 has a flexible insert 2210, a biasing member 2220 and a retaining member 2230. Flexible insert 2210 sealing engages with the inner surface of relief exhaust 2100 to prevent air from exiting through the relief exhaust. Insert 2210 has a securing member 2215 that mates with biasing member 2200. In this embodiment, securing member 2215 is a cross-shaped structure that is received in the inner volume of biasing member 2200. Preferably, biasing member 2220 is a spring. More preferably, biasing member 2220 is a coil spring. Retaining member 2230 is a cap-like structure having opposing retaining arms 2235 that engage with a corresponding pair of engaging protrusions 2105 positioned on the outer surface of relief exhaust 2100. Insert 2210 and spring 2220 are held in the inner volume of relief exhaust 2100 by cap 2230.

Spring 2220 has a biasing strength or resistance that is equal to the relief pressure of relief pressure valve 2000. When a positive pressure exceeds the relief pressure, which in this embodiment is preferably set at about 1.5 in. Hg, the force created on the inner

surface of insert 2210 overcomes the biasing force of spring 2220 and the insert moves toward cap 2230 and outside of the inner volume of relief exhaust 2100. Air exits pressure relief valve 2000 through relief exhaust 2100 until the positive pressure in the pressure relief valve decreases below the biasing strength of spring 2220, at which time insert 2210 moves back in the inner volume of the relief exhaust, sealingly engaging the inner surfaces of the relief exhaust.

Referring also to Fig. 32, pressure relief valve 2000 is shown with a preferred relief assembly 2201 that includes an insert 2211 and a biasing member 2221. Relief assembly 2201 functions similarly to the insert 2210 and the spring 2220 of relief assembly 2200, as described above. Insert 2211 is a ball and biasing member 2221 is foam having a cylindrical shape. Relief assembly 2201 is advantageous because the ball 2211 is more easily assembled in relief exhaust 2100. Additionally, the foam cylinder 2221 is more consistent because it easily mates with the ball 2211 and provides a consistent spring actuation force. Additionally, alternative pressure relief valves can be used which are adjustable so that the "massage strength", i.e., the amount of positive pressure on the user's breast, can be controlled.

Circuit board 120, shown in Fig. 3, allows a user to program several levels of speed and several levels of suction. In this embodiment, the speed (cycle time) ranges from about 45 cycles/minute (cpm) to about 75 cpm. The embodiment provides for pre-set programming of a number of speed levels within the speed range. Preferably, the number of levels can be from about two to about eight levels. More preferably, the user can program five levels of speeds within the speed range. The embodiment also envisions programming of the speed levels by the user.

The suction range for use with a single breast cup 400 and the preferred drive system 1500 shown in Figs. 15 through 21, is from about 3 in. Hg to about 10 in. Hg, and from about 3 in. Hg to about 8 in. Hg for two breast cups. The suction range for use with

a single breast cup 400 and the gear box system shown in Figs. 3 and 4 is from about 3 in. Hg to about 9 in. Hg, and from about 3 in. Hg to about 8 in. Hg for two breast cups. The embodiment provides for pre-set programming of a number of suction levels within the suction range. Preferably, the number of levels can be from about two to about eight levels. More preferably, the user can program five levels of suction within the suction range. The present invention also envisions programming of the suction levels by the user.

Computer software can also be used to control the amount of positive and negative pressure. This allows the amounts of positive and negative pressure to be personalized for the user and also varied over the duration of the pumping process to maximize efficiency.

Breast pump 100 is preferably controlled by a software-driven circuit board 120, along with a gear motor 125, a rack and pinion set 109, 110, and a piston system 112, 113. The software and system are designed to provide maximum flexibility and to facilitate changing of the pressure curve or "wave." This is feasible because the software controls the speed of motor 120 and the distance that piston 112 will travel in cylinder 113. The distance piston 112 travels relates to the pressure levels. By controlling speed and pressure levels with software, the pressure curve or "wave" can be controlled.

Once a determination is made that there is a specific "wave" or pressure curve that is similar to the sucking of an infant or most comfortable to the mother, then the desired wave can be obtained by changing the timing (motor speed and piston distance). Through use of software, a user has the ability to apply memory to a particular pressure curve and the variation of that pressure curve over time so as to maximize the comfort for the user.

In this embodiment, a sine wave is used for the control of breast pump 100. This is based on the assumption that the most comfortable pressure curve would be one that

increases and decreases in pressure gradually, similar to a sine wave, without sharp pressure peaks and valleys providing a pinching feeling on the user. The back and forth motion of piston 112 approximates the desired sine wave. However, to avoid sharp pressure peaks, the timing of piston 112 is slowed down at these peaks, and the pressure is held constant for a duration of time at the maximum and minimum suction points on the wave. This results in a pressure curve having a steady sine wave that is more comfortable to the user.

Alternative waves can also be used for the pressure curve, if such a wave is determined to be desirable by the mother. For example, if a mother prefers a "saw tooth" pressure curve with sharp peaks, the timing of piston 112 can be changed to simply cycle back and forth, minimizing the pause when piston 112 changes direction. Also, for example, if a mother prefers a "square curve", the timing of piston 112 can be changed to hold the piston position when the piston is ready to change direction, and then quickly ramp down and hold its position again before it ramps back up. This will create a "square curve" wave.

Use of software control provides for numerous choices of waves or pressure curves. This further allows the flexibility to change or offer greater choice with one breast pump 100. In contrast, contemporary pumps have the drawback of not allowing the flexibility of changing pressure curve waves. Breast Pump 100 allows for inter-cycle control of the pressure and speed. In the preferred embodiment, this is done through use of a reversible, variable speed motor 125 operably connected to a linear system incorporating piston 112 and cylinder 113. Thus, contemporary devices could seemingly use a particular sinusoidal pressure curve repeatedly, while the breast pump 100 has the ability to use any type of wave and to change the wave during the cycle.

The control system and software provide for a closed-loop control system or inter-cycle real-time adjustment. Thus, real-time monitoring of the control variables occurs,

such as piston distance traveled and speed. As the motor and other components age and wear, the closed-loop control system accounts for such detrimental changes to provide accurate cycle time and pressure sought by the user. The real-time monitoring and control provides effectively equal speed levels for both single and double cup pumping even with the changes in torque.

Cylinder 113 has a pressure differential hole 75. Preferably, pressure differential hole 75 is located along bottom face 80 of cylinder 113. Pressure differential hole 75 is substantially smaller than exhaust hole 1013 and supply tube 116 through which the air flows for generating the positive and negative pressure. Pressure differential hole 75 provides a variance in the amount of positive pressure as compared to the amount of negative pressure. Pressure differential hole 75 is effective for the higher ranges of vacuum to provide the "lost" air at the end of the vacuum stroke. On the positive pressure stroke, a small amount of air will be released through pressure differential hole 75 but the air will be reintroduced during the negative pressure stroke when the level of pressure is higher.

Referring to Fig. 33, cylinder 113 is shown with a preferred embodiment of a pressure differential insert 76. Pressure differential hole 75 is disposed through pressure differential insert 76. Insert 76 is then connected to cylinder 113 through a cylinder hole 77 disposed through the wall of the cylinder. Insert 76 is preferably press fit into cylinder hole 77. However, alternative connection methods can also be used, such as, for example, threads or adhesive. Pressure differential insert 76 is a machined metal piece that allows for the machining of pressure differential hole 75 with a precise diameter within very small tolerances.

The use of insert 76 is advantageous over disposing pressure differential hole 75 directly through the wall of cylinder 113 because of the significant lack of precision in either molding the hole or drilling the hole through a plastic part. Additionally, pressure

differential insert 76 can be selectively inserted through cylinder hole 77 so that a plurality of inserts having a plurality of differently sized pressure differential holes 75 can be used. By providing for different diameters for pressure differential hole 75, the suction levels produced by the pump can be altered.

Pressure differential hole 75 allows for reclaiming of the air during the negative pressure stroke that is lost over time during use of breast pump 100 so that the positive pressure can be accurately maintained over time. During testing of breast pump 100, unexpected and significant results occurred from the use of differently sized diameters of pressure differential hole 75. It was discovered that a pressure differential hole 75 having a diameter of between about 0.15 mm to about 0.75 mm maintained an accurate positive pressure over time while providing the desired negative pressure. The volume of cylinder 113 was 126 cm^3. Preferably, pressure differential hole 75 has a diameter of between about 0.25 mm to about 0.5 mm, and most preferably the diameter is about 0.3 mm.

Referring to Fig. 10, cylinder 113 is formed as a zero- draft cylinder. The outer diameter of piston 112 creates a seal with the inner diameter d of cylinder 113 to move the volume of air inside the cylinder, creating vacuum and pressure on the breast. Breast pump 100 requires a cylinder 113 that has a consistent inner diameter d through the entire length of the cylinder to create an appropriate seal while minimizing interference or resistance to piston 112. Typical injection molded parts require a draft angle that would create a non-uniform inner diameter d of cylinder 113.

Cylinder 113 is preferably molded as a zero-draft cylinder that provides a uniform inner diameter d and more preferably, molded in a single piece. As shown in Fig. 10, cylinder 113 is a one piece, plastic injection molded part. A two-part cylinder or a machined-cylinder have drawbacks which the single piece, zero draft cylinder 113 overcomes. The two-part cylinder requires an extruded tube attached to an end cap, with the two parts joined using a weld or using an adhesive. The machined part is typically a

metal tube. One of the advantages to the zero-draft, one-piece cylinder 113 is that it is injection moldable.

Referring to Figs. 3 through 10, button pad 105 is the user interface or control mechanism for breast pump 100. Button pad 105 has a pair of positive and negative keys for increasing or decreasing the level of suction and speed. Pad 105 further includes an on/off switch.

Due to the reciprocal back and forth motion of piston 112 in cylinder 113, breast pump 100 supplies both a positive pressure and a negative pressure to a woman's breast through a single hose or tubing 350. While this embodiment uses a piston/cylinder mechanism to create positive and negative pressure, alternative expandable volumes or pressure sources can also be used. Such alternative embodiments include a bellows mechanism or a diaphragm that would require fewer parts.

Referring to Figs. 11 and 12, breast Cup, hood, or breast receiving member 400 is shown. Breast cup 400 has a housing 500 having an air orifice 560, a flexible insert 600, and a holder 700. Housing 500 is a rigid structure and flexible insert 600 is a flexible structure. Housing 500 is adapted for sealing engagement with insert 600 to form a displacement volume 510 between the housing and the insert. The funnel-like shape of insert 600 provides for an inner volume 655 for receiving of the breast. Air orifice 560 is in fluid communication with displacement volume 510.

Breast pump 100 is placed in fluid communication with breast cup 400 via air tubing 350 that is connected to air orifice 560 and in fluid communication with cylinder 113. Breast pump supplies both a positive and negative pressure to breast cup 400. The positive and negative pressure created by breast pump 100 causes air to flow through air orifice 560 into and out of displacement volume 510. The positive and negative pressure supplied to breast cup 400 causes flexible insert 600 and, in particular, displacement

volume 510 to expand and contract to apply reciprocating positive and negative forces on the user's breast.

Due to the negative pressure being created by evacuation of displacement volume 510 and the substantial collapsing of insert 600 upon housing 500, breast cup 400 has a maximum suction level inherently incorporated therein. Unlike contemporary devices that provide vacuum directly to the nipple from the vacuum source and are thus vulnerable to over-sucking, breast cup 400 can only provide a maximum negative pressure based upon the displacement volume 510. Once all of the air is evacuated from displacement volume 510, breast cup 400 preferably no longer increases the negative pressure or force applied to the breast. Breast pump 100 and breast cup 400 are able to apply both a positive and a negative pressure to a user's breast through a single air tubing 350, which is connected to air orifice 560.

The volume disposed in displacement volume 510 is preferably between 22 to 52 cubic centimeters, and more preferably between 32 to 42 cubic centimeters. The expandable and contractible displacement volume 510 provides an upper limit to the amount of negative pressure that can be applied to a user's breast, which can further serve as a safety feature in use of breast pump 100. Additionally, the sealing engagement of insert 600 and housing 500 provides a barrier between the user's breast and breast pump 100 to prevent any breast milk from entering air tubing 350 or the breast pump. Insert 600 can also include a massaging member 634. Massaging member 634 has a star-like shape, which provides additional massaging action to the breast. Alternative shapes can also be used for massaging member 634.

Referring to Figs. 27 through 29, breast cup 400 is shown in partial cross-section with a breast 1. The breast 1 has a nipple 2 with an areola 3, and milk lakes or ducts 4, which are supplied by milk glands 5. Breast cup 400 has bladders 685 on insert 600 and tubular member 735 on holder 700. Bladders 685 partially define displacement volume

510. When air is evacuated from the bladders 685 and the displacement volume 510 such that insert 600 is pulled toward and against housing 500, then the negative pressure, vacuum or negative force is applied to breast 1.

Tubular member 735 is disposed substantially adjacent to bladders 685 and extends partially through insert 600. Tubular member 735 is a rigid barrier between the breast 1 and bladders 685 to prevent the breast from making contact with and impinging the bladders, which would reduce the amount of their inflation and deflation, and thus reduce the reciprocating pressure applied to the breast.

Positioning of the breast cup 400 on the breast 1, results in the nipple 2, areola 3 and milk ducts 4 being substantially surrounded by displacement volume 510. Nipple 2 being substantially surrounded by the displacement volume and the use of tubular member 735 to create a rigid barrier in front of areola 3 and adjacent to bladders 685, results in a negative pressure gradient, vacuum or negative force 10 being applied to nipple 2 upon evacuation of the air in displacement volume 510 during the negative pressure stroke or cycle, as represented in Fig. 29. The negative pressure gradient or force 10 has a lateral component or direction L that is greater than an axial component or direction A. The negative pressure gradient or force 10 and the larger lateral component L causes the nipple 2 to be pulled or sucked laterally more than axially, which has been shown to be significantly more efficient at causing expression of breast milk from the milk ducts 4. The negative pressure gradient or force 10 has also been shown to be more comfortable for the user and more like the sucking of a baby during breast-feeding, due in part to the widening of the nipple 2 as opposed to axially elongating or distending the nipple along axial direction A.

Displacement volume 510 extends almost to the leading edge of housing 500 where the housing is secured to insert 600, which assists in creating the negative pressure gradient or force 10 during the negative pressure stroke or cycle that causes lateral

sucking and lateral movement of the nipple 2 along the lateral component L. As shown in Fig. 29, the negative pressure gradient, vacuum or force 10 extends beyond the outer circumference of the areola 3 and is substantially laterally applied thereto during the negative pressure stroke or cycle, which further assists in creating a force on the nipple 2 with a greater lateral component L than axial component A and thus a widening of the nipple.

The positioning of tubular member 735 helps reduce the negative pressure gradient or force 10 axially from or in front of, the nipple 2 during the negative pressure stroke or cycle, which reduces discomfort associated with axial distention of the nipple. Tubular member 735 has an opening (not shown) formed along the tubular member wall. For softer breasts 1, which are pulled into the tubular member 735 during the negative pressure stroke, the opening allows application of the negative pressure or vacuum to the distal end of the nipple 2.

Referring to Figs. 30 through 31, a contemporary breast cup 20 is shown which is connected to a vacuum source through a vacuum line 21. The contemporary breast cup 20 has a hood 22 that can engage the breast 1 and a cylindrical extension 23 attached to the hood. The cylindrical extension 23 is in fluid communication with the vacuum line 21 and a collection member 24. The vacuum or negative pressure is supplied from the vacuum line through the cylindrical extension 23 and to the areola 2. A separation wall 27 seemingly prevents the breast milk from entering the vacuum line 21. The evacuation of the air in cylindrical extension 23 creates a negative pressure gradient or force 30 during the negative pressure stroke, as represented in Fig. 31.

The negative pressure gradient or force 30 has a greater axial component A than lateral component L during the negative pressure stroke, causing the nipple 2 to be pulled or sucked axially more than laterally, which has been shown to be significantly less efficient at causing expression of breast milk from the milk ducts. The negative pressure

gradient or force 30 having a greater axial component A than lateral component L during the negative pressure stroke, has also been shown to be uncomfortable for the user. The vacuum or negative pressure is supplied axially from or in front of, nipple 2 during the negative pressure stroke or cycle, which causes discomfort associated with axial elongation and distention of the nipple.

While breast cup 400 uses a flexible insert 600 partially defining a displacement volume 510 that applies the negative pressure gradient, vacuum or force 10 to the nipple 2 during the negative pressure stroke or cycle, the embodiment contemplates the use of other designs and arrangements that create the negative pressure gradient, vacuum or force 10. Alternative designs for breast cup 400 that cause greater widening of the nipple along the lateral component L as opposed to elongation or distention of the nipple along the axial component A during the negative pressure stroke or cycle are contemplated. Also, alternative designs for breast cup 400 that apply a negative force to nipple 2 during the negative pressure stroke having an average lateral component L that is greater than the average axial component A are contemplated. Further, alternative designs for breast cup 400 that apply a negative pressure gradient or vacuum to nipple 2 during the negative pressure stroke having an average lateral component L that is greater than the average axial component A are contemplated.

While the preferred embodiment describes the use of a motorized pump 100 that supplies the pressure to breast cup 400, the use of manual pumps for use with breast cup 400 is contemplated, including pumping mechanisms that are affixed to breast cup 400. Additionally, other barrier structures, designs or methods are contemplated which reduce the negative pressure, vacuum or negative force applied to the distal end or front of nipple 2, and/or reduce the axial component A of the negative pressure, vacuum or negative force applied to the nipple 2, as compared to the lateral component L.

It is contemplated that a valve or other known release mechanism (not shown) in fluid communication with displacement volume 510 could be used so that a user could alternatively selectively control the amount of positive or negative pressure at the breast cup 400 rather than only at the breast pump 100. The valve or release mechanism on the breast cup 400 could also be a quick release mechanism as a safety feature in the event of discomfort to the user. The valve or release mechanism could also be used to selectively allow only positive or negative pressure to be generated at the breast cup 400.

The modularity of breast cup 400 through use of three separate pieces that can be easily assembled, i.e., housing 500, insert 600 and holder 700, allows a kit to accommodate breasts of varying sizes and shapes. The kit can include a plurality of differently sized housings 500 and inserts 600, as well as differently shaped housings 500 and inserts 600, to accommodate different sized breasts and different shaped breasts. The plurality of different housings 500 and inserts 600 can all be assembled to holder 700 and can be connected to breast pump 100. An example of the variation in sizes of housings 500 and inserts 600 includes the inner and outer diameters throughout the housings and inserts, as well as the length of the housings and inserts. An example of the variation in shapes of housings 500 and inserts 600 includes varying the taper angle, as well as changing the circular shape of the leading edge of the housing and insert. Additionally, the modularity and interchangeability allows for the use of different shaped or sized massaging members or projections 634 on different inserts 600.

A kit containing a plurality of differently sized or shaped inserts 600 that can all be assembled to housing 500 and holder 700, to form a plurality of different breast cups 400 for use with breast pump 100 is also contemplated. The plurality of differently sized inserts 600 can be used to accommodate different sized breasts and also to change the displacement volume 510. The plurality of differently shaped inserts 600 can be used to accommodate differently shaped breasts, as well as to provide different massaging effects to the breasts, such as, for example, different massaging members 634 formed on the

insert. Examples of some alternative inserts 600 are described more fully in copending U.S. Published Patent No. 20030149398, filed December 27, 2002, the disclosure of which has been incorporated by reference herein in its entirety.

While the preferred embodiment of the breast pump system uses breast cup 400 having a displacement volume 510 in fluid isolation from the user's breast, alternative breast cups can also be used with breast pump 100. The unique features of the breast pump system can be used with other types of breast cups, such as, for example, the control system or the rack and pinion driving mechanism.

Referring to Fig. 34, an alternative embodiment of the breast cup is shown and generally represented by reference numeral 5400. Breast cup 5400 is usable with insert 600. Breast cup 5400 has a funnel shaped housing 5500 that is connected to a cylindrically-shaped holder 5700. Holder 5700 has a handle 5725, a pressure orifice 5750, and a pressure adjuster 5775. Handle 5725 is ergonomically contoured and has a wave-like shape 5730 that provides for different holding angles. Handle 5725 is disposed along holder 5700 on the opposing side from funnel 5500. Handle 5725 is preferably made of, or covered by, a material that facilitates gripping. Handle 5725 can include various textures, projections and/or embossments to sooth the users hand during the pumping process.

Pressure orifice 5750 can be attached to tubing 350 to place breast cup 5400 in fluid communication with breast pump 100. Pressure adjuster 5775 is in fluid communication with pressure orifice 5750 and allows a user to adjust the pressure at the breast cup 5400 without having to make an adjustment at the breast pump 100. In this embodiment, pressure adjuster 5775 is a dial but alternative actuators can also be used.

Referring to Fig. 35, another alternative embodiment of the breast cup is shown and generally represented by reference numeral 6400. Breast cup 6400 is usable with

insert 600. Breast cup 6400 has a funnel 6500 that is connected to a holder 6700. Holder 6700 has handle portions 6725, 6726, a pressure orifice 6750, and a pressure adjuster 6775. Handle portions 6725, 6726 are disposed on opposing sides of holder 6700 and facilitate grasping of the holder. Handle portions 6725, 6726 are preferably made of, or covered by, a material that facilitates gripping. Handle portions 6725, 6726 can include various textures, projections and/or embossments to sooth the users hand during the pumping process.

Referring back to Fig. 12, holder 700 of breast cup 400 provides a first set of threads 701 and a second set of threads 702. First and second threads 701, 702 have different diameters and are sized to fit the two standard sized bottles or holders that are used with infant feeding and breast pumping, i.e., reusable containers and disposable containers. The first and second threads 701, 702 have the same pitch and are concentrically aligned. During the molding process, this allows the steel mold core to be unscrewed from holder 700.

While the embodiment illustrated shows the dual threads, i.e., first and second threads 701, 702 on breast cup 400, the use of the dual threads on other infant care products that require the use of a holder or bottle, such as, for example, a nipple ring or a cap is contemplated. Referring to Figs. 36 and 37, a nipple ring is shown and generally represented by reference numeral 7000. Nipple ring 7000 has a circumferential wall 7100 with an inwardly extending flange 7200 defining an opening 7250. Nipple ring 7000 has the dual threads described above, i.e., a first set of threads 701 and a second set of threads 702. The nipple ring 7000 provides for engagement of nipple 7500 with either reusable containers by way of first threads 701 or disposable containers by way of second threads 702. Preferably, first threads 701 downwardly extend from flange 7200 and second threads 702 are formed along circumferential wall 7100.

Referring to Figs. 38 and 39, a cap is shown and generally represented by reference numeral 8000. Cap 8000 has a circumferential wall 8100 connected to a top wall 8200. Cap 8000 also has the dual threads described above, i.e., a first set of threads 701 and a second set of threads 702. The cap 8000 provides sealing of either reusable containers by way of first threads 701 or disposable containers by way of second threads 702. Preferably, first threads 701 downwardly extend from top wall 8200 and second threads 702 are formed along circumferential wall 8100.

Referring to Fig. 13, T-connector 300 is a triangular shaped valve that allows a user to utilize either a single breast cup 400 or two breast cups through use of a first orifice 310 and a second orifice 320. Breast pump 100 is connected to t-connector 300 through air tubing 350 at inlet 330. The single split valve configuration of t-connector 300 minimizes the amount of tubing 350 necessary for double pumping. T-connector 300 has a plug 340 for closing off either of first or second orifices 310, 320 if single pumping is desired. Preferably, plug 340 is tethered to an outer surface of t-connector 300 to facilitate engagement with first or second orifices 310, 320.

Referring to Fig. 14, a method of expressing breast milk according to the breast pump system, is shown. The user commences the breast pumping operation by turning breast pump 100 "on," as in step 800. This causes power to be supplied to breast pump 100 (step 810). The user then inputs the cycle time and suction level that is desired, as in step 820. In the preferred embodiment, the user has five cycle times and suction levels from which to choose. The cycle time and suction level is inputted by use of button pad 105.

In step 830, PC board 120 sets the motor speed and target piston travel distance according to the user's inputted levels for cycle time and suction. The cycle time and suction level are then displayed to the user, as in step 840. In this embodiment, the cycle time and suction level are indicated by lights 225 with the number of illuminated lights

corresponding to the level. In step 850, motor 125 is actuated causing piston 112 to move toward bottom 175 of cylinder 113. This creates a positive pressure that is supplied to breast cup 400 by air tubing 350.

In step 855, the PC Board monitors the home switch to determine whether it has been triggered by contact with piston 112. In step 860, it is determined whether the home switch has been triggered. If the home switch has been triggered then it is reset as in step 870. In step 880, motor 125 is then reversed causing piston 112 to move toward top 180 of cylinder 113. This creates a negative pressure that is supplied to breast cup 400 by air tubing 350. One of the advantages of the breast pump system is that is supplies both a positive pressure and a negative pressure through the same air tubing 350. This reduces cleaning and simplifies the operation for a user.

To provide the proper amount of suction as inputted by the user, photo-sensors 121 count the number of rack openings 50, as in step 890. In step 900, PC board 120 determines if the number of rack openings 50 that have been counted is the equivalent of the target piston travel distance as inputted by the user. In step 910, it is determined whether breast pump 100 is still "on." If breast pump 100 has been shut off then the pumping operation ends, as in step 915.

In step 920, it is determined whether the user has inputted a new cycle time or suction level. If a new cycle time or suction level has been inputted, then PC Board 120 sets the motor speed and target piston travel distance according to the user's inputted levels for cycle time and suction, reverting back to step 830 and repeating the above described steps. If the user has not inputted a new cycle time or suction level then the motor is again reversed causing piston 112 to move toward bottom 175 of cylinder 113. This creates a positive pressure that is supplied to breast cup 400 by air tubing 350. The process continues with breast pump 100 supplying positive pressure and then negative pressure to breast cup 400 until the breast pump is shut off (step 910).

The breast pump system includes a number of components and can be used in remote locations, such as when a user is traveling. The various components can be disposed within a bag system for ease of use. An example of such a bag system, as well as the components of such a system, is disclosed in the co-pending and commonly owned U.S. Published Patent No. 20030149398, filed December 27, 2002, the disclosure of which is incorporated herein by reference.

The present invention having been thus described with particular reference to the preferred forms thereof, it will be obvious that changes may be made therein without departing from the scope of the present invention as defined in the appended claims.

WHAT IS CLAIMED IS:

1. A breast pump for expressing breast milk from a breast, the pump comprising:

a pressure source having a movable structure for generating pressure during a pressure stroke, said movable structure having a variable pressure volume or variable cycle time; and

a controller operably connected to said pressure source,

wherein said controller regulates said pressure volume based upon a distance traveled by said movable structure and regulates said variable cycle time based upon a speed of said movable structure, and wherein said controller provides substantially real-time monitoring of said distance traveled and said speed.

2. The pump of Claim 1, wherein said controller can regulate said pressure cycle based upon a non-sinusoidal wave signal of said pressure versus said variable cycle time.

3. The pump of Claim 2, wherein said non-sinusoidal wave signal comprises a square curve wave signal.

4. The pump of Claim 1, wherein said controller can regulate said pressure cycle based upon a sine wave signal of said pressure versus said variable cycle time.

5. The pump of Claim 1, wherein said pressure comprises both a positive pressure and a negative pressure.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
ElviePumpPCT		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/GB2018/051659	15 June 2018 (15-06-2018)	15 June 2017 (15-06-2017)
Applicant		
CHIARO TECHNOLOGY LIMITED		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 9 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language,** the international search was carried out on the basis of:
      ☒ the international application in the language in which it was filed
      ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (See Box No. II)

3. ☒ **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**
   ☒ the text is approved as submitted by the applicant
   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
   ☒ the text is approved as submitted by the applicant
   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**
   a. the figure of the **drawings** to be published with the abstract is Figure No. 1
      ☒ as suggested by the applicant
      ☐ as selected by this Authority, because the applicant failed to suggest a figure
      ☐ as selected by this Authority, because this figure better characterizes the invention
   b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2018/051659

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

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

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

2. ☒ Claims Nos.: 31-72(completely); 73-158(partially)
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

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

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

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

see additional sheet

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

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

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

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-6, 11-14, 108-119(completely); 158(partially)

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2018/051659

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

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M F04B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JP 2016 010524 A (MURATA MANUFACTURING CO) 21 January 2016 (2016-01-21) abstract figures 1-5,8	1-6, 11-14, 108-119, 158
X	US 2013/023821 A1 (KHALIL GAMAL [CH] ET AL) 24 January 2013 (2013-01-24) cited in the application page 3, paragraph 51-53 page 4, paragraph 66 - paragraph 69 figures 3-5,9-11	1-6, 11-14, 108-119, 158

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

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 September 2018	04/12/2018

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

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2018/051659

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2017/095599 A1 (KONDO DAISUKE [JP] ET AL) 6 April 2017 (2017-04-06) page 3, paragraph 55 - paragraph 57 page 7, paragraph 146 - page 8, paragraph 175 figures 1,15,16	1,2,4-6, 108, 112-114, 158
A	US 2016/271305 A1 (KURIHARA KIYOSHI [JP] ET AL) 22 September 2016 (2016-09-22) page 3, paragraph 51 - paragraph 56 page 4, paragraph 61 page 6, paragraph 91 - paragraph 93 figures 1,2,6	1,2,14, 118,158

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2018/051659

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
JP 2016010524 A	21-01-2016	NONE	
US 2013023821 A1	24-01-2013	AU 2012286462 A1	13-02-2014
		BR 112014001185 A2	21-02-2017
		CH 705295 A1	31-01-2013
		CN 103687634 A	26-03-2014
		EP 2734250 A1	28-05-2014
		IL 230280 A	28-06-2018
		JP 6062937 B2	18-01-2017
		JP 2014529312 A	06-11-2014
		KR 20140040232 A	02-04-2014
		MY 166874 A	24-07-2018
		PL 2734250 T3	31-03-2017
		RU 2014104019 A	27-08-2015
		TW 201304827 A	01-02-2013
		US 2013023821 A1	24-01-2013
		WO 2013010286 A1	24-01-2013
US 2017095599 A1	06-04-2017	JP 6213677 B2	18-10-2017
		JP WO2016002606 A1	27-04-2017
		US 2017095599 A1	06-04-2017
		WO 2016002606 A1	07-01-2016
US 2016271305 A1	22-09-2016	EP 3037116 A1	29-06-2016
		JP 6245280 B2	13-12-2017
		JP 2017205654 A	24-11-2017
		JP WO2015115516 A1	23-03-2017
		US 2016271305 A1	22-09-2016
		WO 2015115516 A1	06-08-2015

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-6, 11-14, 108-119(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the piezo air-pump; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump.

1.1. claims: 2(completely); 158(partially)

A wearable breast pump system as in claim 1, configured as a self-contained wearable device with an internal rechargeable battery; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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2. claims: 7-10, 120-127(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the diaphragm.

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3. claims: 15, 27, 28, 30, 87-95(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the milk container; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

---

4. claims: 16, 29, 73-86(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the breast shield; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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5. claims: 17-19, 21, 23, 128-157(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features related to flow measurement and indication; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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6. claims: 22(completely); 158(partially)

A wearable breast pump system as in claim 1, in which the centre of gravity with an empty milk container attached to te housing is at or below (i) the half-way height line of the housing or (ii) the horizontal line passing through a nipple tunnel or filling point on a breast shield (so that

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

the device that is not top-heavy for a woman using the pump); A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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7. claims: 24(completely); 158(partially)

A wearable breast pump system as in claim 1, including a data sub-system that collects and provides data to a connected device or remote application or remote sensor; A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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8. claims: 20, 25, 26, 96-107(completely); 158(partially)

A wearable breast pump system as in claim 1, including special technical features of the pump (control); A method of expressing and collecting milk, comprising the step of using such a wearable breast pump

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 31-72(completely); 73-158(partially)

The present application contains 158 claims, of which 44 are independent.

There is no clear distinction between several of the 44 independent claims because of overlapping scope. Various independent claims directed to subject-matter that does not (completely) overlap do not meet the requirements of unity of invention (Rule 13 PCT).

According to what can be understood from the description, it seems that a protection is sought after for several a spects of a breast pump system:

- wearability (including a housing shaped at least in part to fit inside a bra)
- technical features of the breast shield
- technical features of the milk container
- technical features of the pump and its control to improve user comfort
- the pump is specifically a piezo air-pump (possibly two piezo air-pumps in series or in parallel), and details thereof
- a separate deformable diaphragm to generate negative air pressure inside the breast shield, the diaphragm as such separating the (piezo) air-pump from the breast shield such that the (piezo) air-pump forms part of a closed loop system
- a flow measurement and milk volume indication means

The 44 independent claims are either directed to one of the above aspects, or to what appears to be an aleatory mix and match of two or several of these aspects.

Moreover, from the 114 dependent claims, 85 claims are dependent on any of the 41 independent claims directed to a "system" (as well as on any of the other dependent claims). They too are directed to one of the above aspects, or to what appears to be an aleatory mix and match of two or several of these aspects.

There are thus so many claims, and they are drafted in such a way that the claims as a whole are not in compliance with the provisions of clarity and conciseness of Article 6 PCT, as it is particularly burdensome for a skilled person to establish the subject-matter for which protection is sought.

The non-compliance with the s ubstantive provisions is to such an extent, that the search was performed taking into consideration the non-compliance in determining the extent of the search (PCT Guidelines 9.19 and 9.25).

The search was based on the subject-matter that is expected to be claimed later in the procedure, and the corresponding independent claim 1. Moreover, independent claim 158, directed to a method of expressing and collecting milk, comprising the step of using a system as defined in claim 1, has also been searched. Independent claims 31-72 and independent claim 158 when referring to any of the independent

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

claims 31-72 were not searched. Claims 73-157 when being dependent on any of claims 31-72 were also not searched.
Since the claims dependent on
claim 1 are not complying with unity of invention (Rule 13 PCT) (see non unity reasoning), the extent of the search was further limited to the technical features as claimed in claim 1 in combination with the first and second invention for which protection is sought, namely dependent claim 2 and the dependent claims further specifying details concerning the piezo air-pump (claims 3-6, 11-14, 108-119).

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
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PCT

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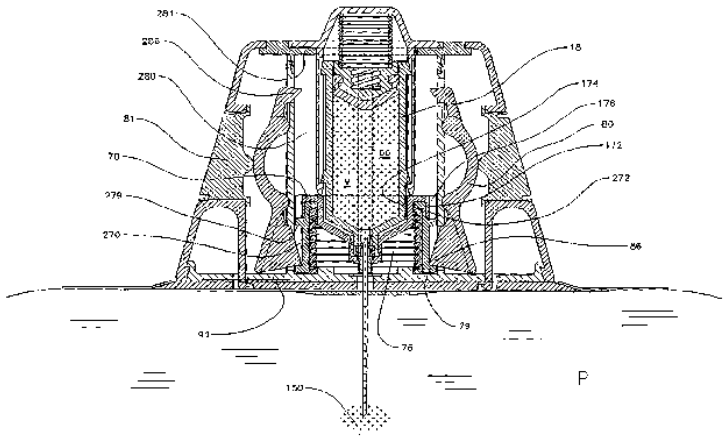
(74) Agent: **NESBITT, Daniel, F.**; Hasse & Nesbitt LLC, 7550 Central Parke Blvd., Mason, OH 45040 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

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[Continued on next page]

(54) Title: INJECTION DEVICE FOR ADMINISTERING A VACCINE



(57) Abstract: A manually-powered injection device that self-administers a painless injection. The injection device provides a method for substantially painless injections of vaccine and other medication into a patient that does not require the use of an anesthetic, that does not require the medical personnel to spend a substantial amount of time performing the injection procedure, that is relatively simple and inexpensive to perform and operate, and that provides a relatively high degree of safety for both the medical personnel and for the patient. The injection needle can have an outside diameter greater than 0.10 mm and less than about 0.38 mm. The vaccine or other medicament can be injected painlessly through the needle and into the patient at a substantially constant volumetric flow rate of about 0.05 μL/s to about 50 μL/s, typically over a 3- to 5-minute period of time. The injection device is configured for easy handling, and is manuallypowered by the use of the hand or fingers of the medical technician, patient or other person.

WO 2005/079441 A2

Declaration under Rule 4.17:

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

Published:

— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INJECTION DEVICE FOR ADMINISTERING A VACCINE

BACKGROUND OF THE INVENTION

[0001] The present invention relates to the injection of vaccines and other medication and, more particularly, to an injection device that can be used in a method for administering vaccine injections painlessly for a patient.

[0002] Conventional medical injection devices for injecting medication into the muscle or tissue of a patient typically comprise some form of a manual hypodermic syringe. Generally speaking, a hypodermic syringe consists of a cylindrical barrel having a chamber that provides a reservoir for a liquid medication, a distal end adapted to be connected to a hollow hypodermic needle and for placing one end of the needle into flow communication with the medication contained within the chamber, and a proximal end adapted for receiving a stopper and plunger assembly. The stopper and plunger assembly includes a stopper effective for moving along the barrel chamber and an elongated plunger effective for causing movement of the stopper. The needle of the hypodermic syringe is manually inserted into the patient through the skin. The stopper is moved along the barrel chamber by applying axial force to the plunger, thereby forcing the liquid medication out of the barrel chamber, through the hypodermic needle and into the muscle or tissue of the patient.

[0003] Receiving an injection by such a conventional device can be a very traumatic experience, particularly for a child. The child's fears, and that of the child's parent, can become a significant medical problem if it leads to the child not receiving a required vaccination. These fears are predominately caused by pain that is associated with injections given by conventional injection devices and methods.

[0004] We have found that the pain associated with an injection is related to the size of the needle and the flow rate at which the medication is injected. It has been found that the amount of pain or discomfort experienced by a patient increases as the outside diameter of the needle increases. It is believed that high flow rates of medication injection (e.g., about 0.5-2 ml per second) into the patient can tear internal tissue and cause pain. The tearing of tissue is caused by the build-up of excessive pressure within the tissue when the surrounding tissue is unable to quickly absorb the injected medication.

[0005] While the injection of a medication at a relatively slow flow rate is more comfortable for the patient, the increased amount of time the syringe remains in the hand of the medical personnel can make the technique tiring for such personnel as well as the patient. In addition, small vibrations or disturbances of the needle caused by movement of the medical personnel or the patient can result in pain to the patient. It is known that the fluctuation of flow rate of the injection of medication being delivered by a hand-held syringe can vary greatly. It is extremely difficult, if not impossible, to deliver a steady, very slow flow of medication from a hand-operated syringe (the human thumb depressing the syringe plunger) over an extended amount of time.

[0006] It has also been found that the sight of the hypodermic needle by itself is often enough to cause many patients to become anxious and tense. This reaction in turn may cause the patient's muscles to become tight and hard, making needle penetration even more difficult and painful.

[0007] A number of methods and devices have been developed for reducing or eliminating the pain and discomfort associated with medical injections. One such method includes the application of a topical anesthetic to the injection site on the patient's skin prior to the injection, which itself can be painful. While this method has reduced some of the discomfort associated with injections, the topical anesthetic does not substantially penetrate the skin into the deeper skin and muscle tissue, and can take significant time (up to 45 minutes) to show effects. Substantial pain and discomfort with intramuscular injections can remain.

[0008] Another technique for reducing the pain and discomfort associated with medical injections includes the step of injecting an anesthetic at the site of the injection using a fine gauge needle, then inserting the larger medication hypodermic needle through the anesthetized skin to inject the medication at a constant and slow flow rate intramuscularly at the desired depth. Unfortunately, injecting an anesthetic into a patient can be painful, and is not always desirable, and the technique is relatively expensive and impractical for many routine injection procedures.

[0009] In addition to reducing pain or discomfort to the patient, safety has also become a principal concern to medical personnel. Special precautions must be taken to avoid accidental needle sticks that could place a user at serious risk because of the danger from fluid borne pathogens. Despite the taking of special precautions, there still remains the possibility of an accidental needle contact and attendant injury.

Accordingly, medical injection devices should operate to minimize the possibility of injury caused by accidental needle sticks.

[0010] In recent years, increased emphasis has been placed on establishing treatment protocols aimed at providing a patient as well as medical personnel with greater freedom of movement. To this end, there is a great deal of interest in the development of light weight and easy-to-use portable injection devices.

[0011] Accordingly, a need exists for substantially painless method and an apparatus for performing the method of injecting medication into a patient that does not require the use of an anesthetic, that does not require the medical personnel to spend a substantial amount of time performing a particular procedure, that is relatively simple, portable and inexpensive to perform and operate, that permits the patient a relatively high degree of movement during the injection, and that provides a relatively high degree of safety for both the medical personnel and for the patient.

SUMMARY OF THE INVENTION

[0012] The present invention relates to an injection device that is manually-powered and configured for self-administering painlessly an injectable liquid composition, such as a vaccine or medicament. The device can be used in a method for providing a substantially painless injection of the injectable liquid composition to a patient that does not require the use of an anesthetic, that does not require the medical personnel to spend a substantial amount of time performing the injection procedure, that is relatively simple and inexpensive to prepare and operate, and that provides a relatively high degree of safety for both the medical personnel and for the patient.

[0013] The present invention further relates to a manually-powered injection device for self-administering painlessly an inter-muscular injection of an injectable liquid composition contained within a reservoir, comprising a) a housing having a base for semi-permanent attachment to the skin of a patient, b) an injection needle disposed substantially perpendicular to the base and within the housing, the needle having an injection end, and configured for axial movement manually between a first position wherein the injection end is within the housing and a second position wherein the injection end extends outwardly from the base to a distance sufficient for intramuscular insertion thereof, the injection needle having an outside diameter greater than 0.10 mm and less than about 0.38 mm, c) a means for retaining a reservoir for containing an

injectable liquid composition, d) a means for providing liquid communication between the retained reservoir and the injection needle, e) a means for injecting the injectable liquid composition from the retained reservoir through the needle.

[0014] The present invention also relates to a manually-powered injection device for self-administering painlessly an inter-muscular injection of an injectable liquid composition, comprising a) a housing having a base for semi-permanent attachment to the skin of a patient, b) an injection needle disposed substantially perpendicular to the base and within the housing, the needle having an injection end, and configured for axial movement manually between a first position wherein the injection end is within the housing and a second position wherein the injection end extends outwardly from the base to a distance sufficient for intramuscular insertion thereof, the injection needle having an outside diameter greater than 0.10 mm and less than about 0.38 mm, c) a reservoir for containing the injectable liquid composition, d) a means for liquid communication between the reservoir and the injection needle, and e) a means for injecting the injectable liquid composition from the reservoir to the needle.

[0015] The present invention also provides an improved cartridge for use in a self-administering injection device, that comprises separate and spaced-apart filling and dispensing ports, and which allows a dispensing plunger to ascend within the cartridge during the injection in a direction toward the filling port. This can provide a visual signal when the distal end of the plunger approaches the filling end of the cartridge, at the completion of the liquid composition injection.

[0016] In typical embodiments of the present invention, the needle is affixed to a needle carriage that is configured for axial movement between a first position associated with the first position of the injection needle, and a second position associated with the second position of the injection needle, in response to the manual force applied by the person. Upon manual insertion of the needle, a needle insertion securement secures the carriage in the second position the liquid composition is injected. The device is typically employs a manually-powered spring that is compressed during the manual needle insertion, which exerts pressure upon the injectable liquid composition within the retained reservoir. The needle carriage and the reservoir comprise cooperating threads that can engage and retain the reservoir within the carriage, and which can cause penetration of a penetrable membrane in the reservoir by the inlet end of the injection needle to establish liquid communication there between. At the end of the injection

cycle, a needle retracting means can be activated, typically manually, to retract the injection needle, whereby the injection end of the needle is retracted from its second position in the body to a third position wherein the injection end of the needle is within the housing. The needle retracting means can employ a disengagement means configured to disengage the needle insertion securement from the needle carriage, and a power means configured to bias the needle carriage to the third position. An implement, such as a plunger or stem, can be used in place of the finger or hand to apply the manual insertion force to the needle carriage. The device can also comprises a separable base, a base securement means configured for separable securement of the separable base to the housing, and a base separation means configured for separation of the separable base from the housing, wherein the separable base comprising an adhesive for attachment thereof to the skin of the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Figure 1 shows a cross-sectioned elevation view of a housing of a manually-powered painless injection device of the present invention in an extracted position, taken through line 1-1 of the housing shown in Figure 4.

[0018] Figure 2 shows the cross-sectioned elevation view of Figure 1 of the housing in an inserted position.

[0019] Figure 3 shows a cross-sectioned elevation view of the housing shown in Figure 4, taken through line 3-3 of Figure 4.

[0020] Figure 3A shows a detailed cross-sectional view of the housing of Figure 3.

[0021] Figure 4 shows a top plan view of the housing of the manually-powered painless injection device.

[0022] Figure 5 shows a cross-sectioned elevation view of the housing of Figure 4, taken through line 5-5.

[0023] Figure 6 shows a cross-sectioned elevation view of the housing of Figure 4 taken through line 6-6.

[0024] Figure 7 shows a cross-sectioned plan view of the housing of Figure 1, taken through line 7-7.

[0025] Figure 8 shows a cross-sectioned plan view of the housing of Figure 1, taken through line 8-8.

[0026] Figure 9 shows an exploded cross-sectioned elevation view of the elements of the housing of Figure 1.

[0027] Figure 10 shows a cross-sectioned elevation view of a syringe cartridge of a manually-powered painless injection device of the present invention in an extended position, taken through line 10-10 of the syringe cartridge shown in Figure 12.

[0028] Figure 11 shows a cross-sectioned elevation view of the syringe cartridge in an extended position, taken through line 11-11 of Figure 12.

[0029] Figure 12 shows a plan view of the syringe cartridge of Figure 10.

[0030] Figure 13 shows a detailed cross-sectional elevation view of the syringe cartridge of Figure 10.

[0031] Figure 14 shows another detailed cross-sectional elevation view of the syringe cartridge of Figure 10.

[0032] Figure 15 shows a plan view of the syringe cartridge shown in Figure 14.

[0033] Figure 16 shows a cross-sectioned plan view of the syringe cartridge of Figure 11.

[0034] Figure 17 shows a bottom plan view of the syringe cartridge of Figure 11.

[0035] Figure 18 shows an exploded cross-sectioned elevation view of the elements of the syringe cartridge of Figure 10.

[0036] Figure 19 shows a cross-sectioned elevation view of the syringe cartridge of Figure 10 containing an injectable liquid composition in a pressurized position.

[0037] Figure 20 shows a cross-sectioned elevation view of the housing and a separable base assembly prior to its attachment to the housing, and of a syringe cartridge prior to its installation into the housing.

[0038] Figure 21 shows the housing and syringe cartridge of Figure 20, with the housing being affixed to a patient's skin.

[0039] Figure 22 shows the syringe cartridge being installed into the housing of Figure 21.

[0040] Figure 23 shows the syringe cartridge being force into an inserted position within the housing.

[0041] Figure 24 shows the syringe cartridge in the inserted position within the housing, injecting the liquid composition.

[0042] Figure 25 shows the syringe cartridge in the inserted position within the housing, at the completion of the liquid composition injection.

[0043] Figure 26 shows the syringe cartridge in the inserted position within the housing of Figure 25, being manipulated to retract the needle.

[0044] Figure 27 shows the syringe cartridge and housing of Figure 26, with the needle retracted.

[0045] Figure 28 shows the housing and the syringe cartridge of Figure 27 being removed from the separable base that remains attached to the patient.

[0046] Figure 29 shows a top plan view of another embodiment of the invention, of a device having a housing that can accommodate two syringe cartridges.

[0047] Figure 30 shows an elevation view of the device of Figure 29.

[0048] Figure 31 shows a cross-sectioned elevation view of the dual-syringe device of Figure 29 taken through line 31-31.

[0049] Figure 32 shows a separable base assembly having an adhesive flap for use in attaching the device of the present invention to the skin of a patient.

[0050] Figure 33 shows a cross-sectioned elevation view of the separable base assembly of Figure 32 through lines 33-33.

[0051] Figure 34 shows a detailed cross-sectioned elevation view of the separable base assembly of Figure 33.

[0052] Figure 35 shows another detailed cross-sectioned elevation view of the separable base assembly of Figure 33.

[0053] Figure 36 shows a cross-sectional plan view of a base shown in Figure 22 through lines 36-36, which has been modified to provide blocking plate that is in a deployment position to allow needle deployment.

[0054] Figure 37 shows a cross-sectional elevation view of the base of Figure 36.

[0055] Figure 38 shows a cross-sectional plan view of the base of Figure 36, which is in a blocking position to prevent needle deployment.

[0056] Figure 39 shows a cross-sectioned elevation view of an alternative embodiment of the device having an improved means for establishing liquid communication between the injection needle and the reservoir.

[0057] Figure 39A shows a detailed cross-sectional view of the device of Figure 39.

[0058] Figure 40 shows cross-sectioned elevation view of an alternative embodiment of a syringe cartridge in a first configuration.

[0059] Figure 41 shows the syringe cartridge of Figure 40 is a second configuration.

[0060] Figure 42 shows cross-sectioned elevation view of an alternative embodiment of the injection device having a means for selectively restraining the axial movement of the needle carriage.

[0061] Figure 42A shows a detailed cross-sectional view of the device of Figure 42.

[0062] Figure 43 shows cross-sectioned elevation view of another alternative embodiment of a syringe cartridge.

[0063] Figure 44 shows cross-sectioned elevation view of an alternative embodiment of the device having a needle retracting means.

DETAILED DESCRIPTION OF INVENTION

Definitions:

[0064] As used herein, "patient" means a mammal, including a person, including a child or infant, or an animal, typically a mammal, on which the device is attached, and into whom the device injects an injectable liquid composition.

[0065] As used herein, unless specified otherwise, the phrase "manually powered" means that the power provided to the device of the present invention to at least insert the injection needle into the patient's body is provided manually by a person, including a medical technician (a nurse, doctor, or other person who can administer the injection) or a patient, by manipulating the injection device with the hands or fingers, or by manipulating an appropriate implement that interacts with the device.

[0066] As used herein, unless specified otherwise, the term "self-administering" describes the ability of the device of the present invention to be held or to hold itself in a position attached to the skin of a patient by a securement means, without requiring a medical technician, the patient, or other person, to hold the device, during the time that an injectable liquid composition contained within the device is injected into the patient through the injection needle.

[0067] As used herein, unless specified otherwise, the term "upward" means in a direction or oriented away from the patient's skin or the base of the device; the term "downward" means in a direction or oriented toward the patient's skin or the base of the device; the term "inward" means in a direction or oriented toward the centerline of the device, typically the needle; and the term "outward" means in a direction or oriented away from the centerline of the device.

[0068] The manually-powered, self-administering injection device of the present invention typically comprises a housing, an injection needle, a reservoir for containing an injectable liquid composition, such as a vaccine or a medicament, and a plurality of elements associated with and at least semi-permanently attached to the housing. The other associated elements can also include the various means of providing power or energy for the functional operations of the device, such as the insertion and retraction of the injection needle, and the pumping or injecting of vaccine to the injection needle. Typically, these associated elements are contained within the confines of the housing, although these elements can also partially confront or penetrate through the outer surface of the housing.

[0069] In the course of administering most injections of vaccines and other medicaments, the injection can be advantageously administered intramuscularly (that is, into the muscle). The injection is made with an injection needle that is configured for insertion through the outer layer of the patient's skin, and more typically into the muscle tissue of the patient. Typically, the depth of insertion is at least about 5 mm, and typically up to about 35 mm or more, more typically from about 10 mm to about 25 mm, and even more typically from about 15 mm to about 20 mm. For a young child or infant, the depth of insertion is typically from about 10 mm to about 25 mm, more typically from about 12 mm to about 15 mm. Alternatively, some injections can be administered intradermally, or into other internal organs or the general body cavity of the patient.

[0070] Painless injections can be achieved when the size or diameter of the injection needle is minimized, typically by using a needle of gauge size 28 or small (typically up to gauge size 33), and when the injectable liquid composition, such as a vaccine or other medicament, is injected at a volumetric flow rate significantly lower than that of a conventional injection made by hand, typically less than about 50 microliter per second (μL/s) and more typically about 1-4 μL/s. To achieve such low flow rates when administering a typical injection dose of between 0.5 ml to about 1.0 ml, an injection time of about 3 to 5 minutes may be needed. Typically, the human hand, using a conventional syringe, can not accurately or reproducibly control the flow rate within a range that ensures a painless injection. Furthermore, the desired slower injection rate of the medicament would require that the medical technician (or the patient) hold the conventional syringe carefully in place against the skin of the patient, and that the

patient not move the limb or body part that is the site of the injection while the injection is being administered. The present invention overcomes these problems by providing a self-administering device that remains in position on the skin of the patient at the injection site, and administers the injection of the injectable liquid composition, without requiring a medical technician or patient to hold the injecting device in its place by hand, and without requiring that the patient remain still and not move while the injection is being administered. These problems are particularly troublesome when the patient is an infant or young child.

The manually-powered device of the invention is intended to be attached semi-permanently to the skin of the patient before, during or after the injection. The device is typically configured to be attached to the upper arm or to the thigh area, providing access to the larger skeletal muscles (the deltoids and the quadriceps) for intramuscular injection. The attachment is preferably semi-permanent, whereby the device can be removed reasonably easily from the skin. The device is configured to attach to the body of the patient so that it does not move or migrate along the surface of the skin after attachment. In many situations, an adhesive attachment is sufficient. Alternative attachment means can include strapping, such as with a buckle strap or with a "hook and loop" attachment means commonly referred to as "Velcro", or cuffing, as with a sphygmomanometer cuff. In an other alternative embodiment, a portion of the device, such as a bandage associated with the device or a portion of the base of the housing, can be configured to remain affixed to the patient's skin after the housing of the device has been removed.

[0071] A typical adhesive for securing the device directly to the skin is a pressure sensitive adhesive (PSA). The direct-attaching PSA and the base where the PSA is affixed are typically configured whereby the PSA adheres to the device more strongly than the PSA adheres to the skin. The PSA is typically permanently affixed to the device, such that no PSA will remain adhered to the skin of the patient when the device, or at least the housing portion of the device, is removed from the skin. The PSA is also selected for a secure though releasable affixment to the skin. These criteria ensure that the device, or at least the bandage or base portion of the device, can be securely affixed to the skin for the vaccination procedure, and can be safely and efficiently removed from the skin thereafter.

[0072] Typically, the manually-powered device having a skin-attaching PSA will also include a release member, such as a release paper or film, which overlies the adhesive on its skin-contacting side. After the release member is peeled from the PSA, the exposed adhesive layer can be placed against the patient's skin to attach the device thereto.

[0073] A main objective for initiating the development of the present injection was effecting a painless injection of injectable liquid compositions. While pain can be a relative experience, typically the painless device of the present invention will, after having been secured to the skin of the patient, effect the insertion of the injection needle and injection of the injectable liquid composition into the body without a sensation or feeling of pain, and more typically without any sensation or feeling whatsoever. In other words, the patient in most circumstances will have no sensation that the device has inserted a needle into the body, or that the injectable liquid compositions is or has been injected into the body, except perhaps visually observing the device or touching the device with a hand, or feeling the attachment of the device to the outside of the skin.

[0074] Typically the manually-powered device is configured to complete the vaccination or injection of medicament into the patient utilizing a source of power or energy that is external to the device itself. The source of power can be provided by a person, such as a medical technician (a nurse, doctor, or other person who can administer the injection) or the patient, typically by manually (or bodily) manipulating the injection device with the hands or fingers, or by using an appropriate implement, as hereinafter described. The self-administering feature of the device and method of the invention enables injection of injectable liquid compositions without requiring medical personnel to hold the device against the skin of the patient during the time that the injectable liquid composition is in liquid communication with the needle, and is being pumped from the device into the patient. The use of the device that self-administers an injection allows medical personnel to perform other tasks while the injection proceeds. The device also allows the patient to have freedom of movement for the minutes of time that the injection proceeds. Typically, the source of power for arming the manually-powered device from its unarmed configuration comprises a manual power. This can be the use of the hands or fingers of a technician or an adult patient to manipulate the device or elements thereof with force. The manipulating force can also be applied using an implement, such as a key, push rod, or other inanimate object. The manually-applied

kinetic force is stored by a power means within the device as potential energy, which can, upon subsequent activation, power one or more of the functions of the device. Typically, the external force used for the needle insertion function can also be used to store potential energy within the device, such as in a compressed spring or other biased resilient member. The external force can also be stored as electrical power or pneumatic power.

[0075] Typically, the device is manufactured and shipped to a use center, such as a clinic or hospital, with the needle insertion function in a first unarmed configuration. The unarmed configuration provides that the injection needle, which in its first position has it's the distal end or tip of the injection needle wholly within the housing, can not be intentionally or accidentally extended to a second position wherein the injection tip extends through the base of the device and outside of the device. In the unarmed configuration, there is typically no potential energy source, such as a compressed wire spring, available to the needle insertion means for spontaneous insertion of the needle. The unarmed condition can also be termed a fail-safe position, since, in this configuration, even a malfunction of the device will no allow the needle to extend from the housing. By contrast, if the needle insertion means is armed, then the device has potential energy stored on board, such as in a compressed, extended or torsioned spring, or other power means for insertion of the needle. If this armed device is activated, such as when an actuation button is depressed, the potential energy of the power means is released as kinetic energy that can move the needle insertion means from its first position to its second, extended position. If the device is shipped, stored, or handled in an armed configuration, there is a risk of an inadvertent, or even an intentional, activation of the needle insertion means. Consequently, the shipment and handling of the manually-powered device of the present invention in an unarmed configuration can avoid both an intentional and accidental needle sticks prior to its use in administering an injectable liquid composition. This improves the safety and security of the device during, storage, and pre-injection handling. In this configuration, at least the needle extension function (also called the insertion function when the needle tip extends into the skin of the patient) is unarmed.

[0076] Other functions, such as the pumping or injection means (for passing the injectable liquid composition through the injection needle) and the needle retracting means (to withdraw the needle from its second position in the body, back toward its first

position in the housing) can be configured for shipment and storage as either armed or unarmed. Preferably, the power means for the pumping means has an unarmed configuration, to avoid an accidental activation of the pumping of injectable liquid composition from the reservoir, which could prematurely empty the reservoir and render the device useless. Likewise, any needle retracting means is preferably shipped and stored in an unarmed configuration, to avoid the possibility of an unintentional or accidental activation, which in some embodiments may make the opposing needle insertion function inoperable, where the needle retraction is irreversible.

[0077] The power means can be used to provide energy to one or more of the elements of the device, such as insertion and retraction of the injection needle, or pumping of the medicament. Two or more power means can be used to provide energy for different elements, such as where the injection needle is moved from one position to another by a first power means, and an injectable liquid composition is pumped from a reservoir to the injection needle by a different, second power means.

[0078] The device can be at least partially self-controlled, wherein at least one of the elements of the device can initiate operation automatically in response to the operation of another element.

[0079] The typical device of the present invention has a housing comprising a base for placement against the skin of a patient, for attachment of the device. The base can have a contoured surface that generally conforms to the shape of the body (typically, the arm or leg), to maintain the base surface in optimum confronting relationship with the skin. For example, the base of the device can have a slightly concave surface, which arches inwardly toward the interior of the housing.

[0080] The housing is typically made of a thermoplastic material that is light and inexpensive to manufacture, such as by molding, and yet is durable and resilient to gross deformation or breakage. A typical plastic material can include polyethylene, polypropylene and polycarbonate. The housing can be designed with a shape that is both aesthetically pleasing and functional, for example, to allow insertion of the reservoir, to allow activation of one or more of the elements, such as the injection needle and liquid communication means, and other elements of the device. The housing can be made as a single part or as a plurality of parts configured to associate and secure together in both either static or moving relation to one another.

[0081] The housing also provides a visual enclosure for the injection needle that keeps the needle out of sight of the patient at all times during the injection procedure. This can reduce or eliminate the patient's apprehension or fear caused by the sight of a needle, thereby reducing the tendency of the patient's muscles to tighten and harden, which can make needle penetration more difficult and painful for the patient.

[0082] The housing also provides a physical enclosure for the injection needle that helps to avoid accidental needle stick, particularly after an injection, which could place a user at serious risk from fluid-borne pathogens. The device can be configured for use only once (unless completely disassembled and retrofitted), thereby minimizing the likelihood of reuse of a contaminated hypodermic needle. The device can also advantageously be configured wherein some parts or assemblies, such as the housing and it associated elements, can be reused.

[0083] The housing can also be configured to receive and secure the needle and optionally the reservoir of injectable liquid composition as a modular insert into the housing body. The housing can include two or more parts, at least one of which is movable relative to another, which can be configured into an open position wherein either the needle or the reservoir, or both, can be inserted into the body of the housing, or a closed position wherein the needle and/or reservoir are not accessible or retrievable from within the housing. The movable part can be a door or a panel that is movable to provide an access port into the housing. The door or panel can be hinged or removably affixed to the housing, or can be slidable away from the access port.

[0084] The injection needle of the device provides for liquid communication of the injectable liquid composition passing from the reservoir and through other liquid communication means of the device, into the body tissue of the patient, from where the injectable liquid composition can dissipate into the surrounding tissue and throughout the body. The injection needle should be shaped and configured to provide painless insertion and painless injection of the injectable liquid composition. Generally an injection needle having a smooth circular outer surface and an outer diameter D of about 0.36 mm (28 gauge needle) and less can be inserted painlessly through the skin of a patient. For small children, infants and patients having more sensitive skin, an outer diameter D of about 0.30 mm (30 gauge needle) and less (31 gauge to 33 gauge), will typically ensure painless needle insertion.

[0085] Typically the injection needle is configured to be substantially linear or straight, from its distal end or tip, toward the opposed inlet opening. The needle can be configured to be linear completely to its inlet end, or can be configured with a bent or curved portion near the inlet opening.

[0086] The needle size should be sufficiently large to allow passage of the required volume of liquid medicament into the body within a period of time that is suitable to avoid causing pain. For a typical medicament volume of about 0.5 ml to about 1.0 ml, a substantially painless to completely painless injection can be achieved over an injection period of from about 1 minute to about 10 minutes, more typically from about 3 minutes to about 5 minutes. The volumetric flow rate is at least about 0.05 microliter per second (μL/s), and up to about 50 μL/s. Typically, the volumetric flow rate is about 0.5 μL/s to about 20 μL/s, and more typically about 1 μL/s to about 4 μL/s. The injection needle should be sufficiently durable and axially rigid to avoid bending or breaking when inserted into the skin and muscle. Typically, a needle having an outer diameter of from about 0.10 mm (about 36 gauge), more typically of from about 0.23 mm (32 gauge), up to about 0.36 mm (28 gauge), is sufficiently painless, durable, and liquid conductive.

[0087] It is also within the practice of the device and method of the present invention to inject medicament volumes of greater than about 1.0 ml, and to deliver the injection over time periods greater than 10 minutes.

[0088] Typically, the injection needle is pre-installed into the injection device during its manufacture, prior to its distribution to the facility or site where the injection shall occur. Although the device can be configured for installation of the injection needle at the use facility, the small, fine size of the injection needle may make it difficult for a medical technician or patient to manipulate it into position within the device. Likewise, after a vaccination, the injection needle and the housing or assembly thereof into which the needle is secured, can be disposed of in accordance with health and safety regulations and guidelines.

[0089] The injectable liquid composition is typically contained within the cavity of the reservoir, and flows from the reservoir to the injection needle during injection. The reservoir is typically positioned within the housing although the structure of the reservoir can also form a portion of the outer surface of the housing. The reservoir can have a rigid structure having a fixed volume with a moveable member, such as a plunger that defines a variable volume cavity. The reservoir can also have a flexible

structure where its volume can decrease as its content of injectable liquid composition is removed there from. Typical materials for use in making the reservoir include natural and synthetic rubber, polyolefin, and other elastomeric plastics. The selection of the structure and material of construction of the reservoir will depend in part on the specific means of pumping the medicament from the reservoir to the injection needle. Selection of the material of the reservoir should also be chemically stable with the injectable liquid composition. In another typical embodiment, the reservoir can be affixed to the injection needle as part of a injectable liquid composition product, for assembly into the device. A reservoir will generally have a volume sufficient to contain about 0.1 ml to about 10 ml, typically about 0.1 ml to about 3 ml, of medicament. In a more typical embodiment, the reservoir would hold about 0.5 ml to about 1.0 ml of medicament.

[0090] The reservoir comprises an outlet port that is in liquid communication with, or can be brought into liquid communication with, the injection needle. The reservoir outlet can be temporarily sealed, such as with a penetrable membrane that can provide an air-tight and leak-proof seal over the outlet opening of the reservoir during manufacture, shipment and storage of the filled reservoir, and that can provide a self-sealing, leak-proof joint when pierced by the inlet end of the needle or a separate piercing conduit at the time of the injection. A typical reservoir membrane comprises natural or synthetic rubber or a thermoplastic material. Alternatively, a wall of the reservoir can be adapted to allow penetration thereof by the piercing conduit, such as the inlet end of a needle.

[0091] A typical embodiment of a reservoir comprises a reservoir body having a cavity that has been pre-filled with the injectable liquid composition and sealed. The pre-filled reservoir can be assembled into the device during manufacture. In this case, the device is labeled to identify the particular injectable liquid composition that is contained therein.

[0092] More typically, pre-filled reservoir will be configured for installation or insertion into the housing of the injection device at the facility or site where the injection will occur. The technician would typically remove the reservoir from a storage area, such as a refrigerator, and insert it into position within the housing of the device. An identity label associated with the reservoir can be provided that is conveniently transferred to the patient's records.

[0093] Alternatively, a device can have secured within an empty reservoir can be filled by medical personnel with the appropriate quantity and type of medicament, prior to injection. Typically, this embodiment of the reservoir comprises a liquid flow valve that has a self-closing, self-sealing opening to the cavity of the reservoir. The flow valve can be a one-way flow valve, also referred to as a check valve. The liquid composition flow valve is typically an elastomeric or rubber material.

[0094] One type of one-way flow valve is a flapper or so-called duckbill valve (available from MiniValve International Yellow Springs, OH) that allows flow of liquid in one direction, but which self-seals in response to liquid flow or pressure in the opposite direction. Another type of one-way flow valve is a cylindrical member having a slit opening formed axially there through, through which a hypodermic needle of a syringe is inserted to inject a desired dose of the liquid composition into the cavity of the reservoir. When withdrawn, the slit opening closes and seals. When the device is used by medical personnel as supplied from a manufacturer with the reservoir securely inserted within the housing, the device can have a companion flow valve in communication with the reservoir flow valve that is disposed in the outer surface of the housing, or otherwise accessible to the medial personnel. The liquid composition flow value can be inserted into a bore formed in the sidewall of the reservoir that is slightly smaller in diameter than the flow valve.

[0095] If the reservoir is configured so that a portion of the reservoir is integral with the housing, then a single flow valve can be used, with an inlet accessible to the medical technician and an outlet into the cavity of the reservoir. Alternatively, the device can be configured with a second liquid composition flow valve positioned in the housing, disposed adjacent to and aligned with the first flow valve disposed in the reservoir.

[0096] An important requirement of the liquid communication means is to ensure that the liquid composition can flow from the reservoir to the injection needle regardless of the specific orientation of the device. Typically, the attachment of the device to the skin of the patient can position the reservoir and the injection needle into a variety of relative spatial orientations that can sometimes require the liquid composition to flow upward against gravity, or that can position the outlet of the reservoir in an upward position, opposite the pool of liquid composition disposed in the reservoir.

[0097] Consequently, a preferred configuration of the reservoir and liquid communication means provides that the outlet of the reservoir is maintained in

communication with the remaining liquid composition in the reservoir. A typical configuration comprises a collapsible reservoir comprising an outlet that maintains liquid communication with any residual liquid composition present in the reservoir. This reservoir has an upper flexible wall that can be conformed to the volume of the liquid remaining therein. The reservoir typically contains little or no air or gas when filled with the supply of liquid composition and during its displacement and injection operation. Thus, the reservoir collapses to become essentially empty, terminating delivery. In like manner, when a non-flexible material is used for a reservoir, such as a conventional tube-with-plunger syringe, the displacement of the plunger empties the reservoir, which terminates delivery.

[0098] The housing can also comprise an outer support structure that confines and protects the reservoir from outside elements that might puncture it, and which can define the initial shape of the reservoir.

[0099] The reservoir can also be constructed of an elastomeric material that can be expanded in volume when filled with the liquid composition, and holds the liquid composition under pressure. After puncture by a piercing conduit, such as the inlet end of the injection needle or an intermediate member that is in liquid communication, such as via tube, with the injection needle, the expanded reservoir can contract to reduce the effective volume of the reservoir as liquid composition is pumped there from. One or more of the walls of the reservoir can be made of an elastomeric material, while other walls or surfaces are made of other elastic or inelastic rubber or plastic material.

[0100] The reservoir can also comprise an adaptable structure having a means of varying its effective volume, such as a piston-plunger construction or an accordion construction, as in a bellows. In the embodiments described herein, a self-contained reservoir can be replaced with a more conventional syringe and plunger for storing and injecting the liquid composition to the injection needle.

[0101] Non-limiting examples of a reservoir of the present invention are those described in US Patent 5,527,288 (element 10), US Patent 5,704,520 (element 12), and US Patent 5,858,001 (elements 16 and 17), all such publications incorporated herein by reference.

[0102] A first embodiment of the invention is shown in Figures 1-3, 3A, and 4-28. The device includes a housing, shown in Figs. 1-3, 3A, and 4-9, and a cylindrical syringe cartridge shown in Figs. 10-19. The use and operation of the device for

manually self-administering a painless injection is illustrated in Figs. 20-28. A device having a housing for retaining a plurality of cylindrical syringe cartridges is shown in Figures 29-31. Figures 32-25 show a separable base and means for attaching the device to a patient's skin.

[0103] Figures 1-8 show an assembled housing 10 in various views and aspects. Figure 1 shows the housing 10 having an outer body 11, a needle carriage 70, a means for retaining a reservoir for an injectable liquid composition, and a base 12 for placement of the device against the skin of a patient. The carriage 70 is configured for movement along an axial centerline 100 in a direction perpendicular to the base 12. The cylindrical carriage has a cylindrical recess 71 having a tapered bottom 78, that opens to a connector portion 73 having internal female threads, which provide the at least a portion of the retaining means for the reservoir, described below. A needle 40 lies along the centerline 100 and is disposed through the axial center of a needle hub 72 that is secured to the connector 73. The inlet 42 end of the needle 40 extends within the connector portion 73 sufficiently below the opening in the tapered bottom 78 to prevent the sticking of a finger that may probe the recess. A retracting spring 76 is positioned about the centerline 100, having one end disposed within an annular groove 74 in the underside of carriage 70, and the other end disposed around an annular flange 94 projecting up from the base 12. The needle 40 extends downward from the lower end of the needle hub 72 toward the base 12. The needle is completely within the housing when the carriage 70 when in the first retracted position shown in Figure 1.

[0104] As will become more evident, the retracting spring 76 disposed as shown in Figs. 1, 3, and 20 should have an amount of pre-tensioning or compression that is sufficient to completely retract the carriage 70 back to the top of the housing 10 when the needle 40 is retracted from the body.

[0105] In a second inserted position, shown in Fig. 2, the carriage 70 has moved axially toward a position proximate to the base 12 of the device, and the needle 40 extends downwardly and out through the opening 13 in the base. The guide wall 14 comprises an inwardly-projecting, axially-oriented guide, shown as elongated rib 19, that registers along its length with an axially-oriented peripheral groove 77 in the outer wall 75 of the carriage 70, shown in Figure 3, to prevent the carriage 70 from rotating within the guide wall 14. A retainer heel 86 is biased inward from an opening in the cylindrical guide wall 14. As the carriage 70 passes down the guide wall 14, the heel

86 is temporarily biased outward, allowing the carriage to pass. The retracting spring 76 is compressed between the underside of the carriage 70 and the base 12. When the carriage arrives at the fully inserted position shown in Fig. 2, the lower end flange 79 of the carriage has cleared past the heel 86, which returns to its inwardly-biased position, where it can secure the carriage 70 and the needle 40 in the inserted position, and secures the retracting spring 76 in a compressed state. The heel 86 is part of a release arm 80, described herein after.

[0106] Figure 4 shows a plan view of the housing 10 in its first retracted position, with selected cross-sectional views taken as Figures 1, 3, 5, and 6 to illustrate certain elements of the housing. Figures 7 and 8 are sectional views of the housing in Figure 1. An exploded view of the elements of the housing 10 is shown in Fig. 9.

[0107] Figs. 10 and 11 are sectional views of the syringe cartridge 18 taken through perpendicular section lines 10-10 and 11-11 of Fig. 12. Figs. 13-17 provide additional detailed views of the syringe cartridge 18 shown in Figures 10 and 11. Figure 18 shows an exploded view of the elements of the syringe cartridge 18.

[0108] The syringe cartridge 18 shown in Figures 10 and 11 comprises a syringe assembly 20 and a telescoping pressurizing assembly 30, configured as a reservoir having liquid cavity 66 for the injectable liquid composition. The syringe cartridge 18 is configured to be associated with and retained within the housing 10 of the device. In the illustrated embodiment, the cylindrical recess 71 of the needle carriage 70 provides the means for retaining the reservoir of injectable liquid composition, embodied by the syringe cartridge 18. The syringe assembly 20 comprises a syringe body comprising a cylindrical wall 21 that has an open upper end 25 and a tapering base 22 that has, at the lower end, an externally-threaded syringe port 64 having an aperture 23. A cylindrical plunger 24 can be inserted through the opening in the upper end 25 for engagement with the inner surface of the wall 21. The space between the plunger 24 and the syringe body in Fig. 10 defines the reservoir cavity 66. The respective threads of the syringe port 64 of the syringe cartridge and of connector portion 73 of the needle carriage cooperate and engage when the syringe cartridge is placed into the needle carriage and rotated, which secures or locks the syringe cartridge into its retained position within the needle carriage. The cooperating threads also provide liquid communication between the injection needle and the reservoir of the syringe cartridge, as the inlet 42 end of the

needle advances and penetrates a membrane 65 of the membrane plug 67 disposed in the opening of the syringe port 64 (see Figure 14).

[0109] The plunger 24 is typically a flexible, resilient rubber material that can form an effective liquid seal about its periphery with the sidewall 21 of the syringe. The plunger 24 is secured around a rigid plunger plug 26 to maintain its cylindrical shape. As can be seen in greater detail in called-out Fig. 13, the inner surface of the syringe wall 21 has, at its upper end, a slight inwardly-extending rim 38 that can engage the upper end of the outer wall 43 of the plunger 24, which can prevent the plunger 24 from incidentally withdrawing from and falling out of the upper opening of the syringe wall 21. Nevertheless, the plunger wall 43 is sufficiently flexible to be inserted into or extracted out of the syringe opening by force. The threaded bore in the plunger plug 26 is provided for attachment of a stem (not shown) having a mating thread so that the plug 26 and the plunger 24 secured thereto can be manipulated into and out of the syringe opening, and along the length of the syringe.

[0110] The telescoping pressurizing assembly 30 comprises a cylindrical body 31 that is closed at an upper end 34 and has an opening 32 at the opposed lower end. The lower edge of the cylindrical body 31 has a pair of opposed mechanical engaging means shown as inwardly-extending ribs 36 that can engage an outwardly-extending rim 28 disposed on the upper end 25 of the syringe wall 21, to secure the pressurizing assembly 30 to the upper end 25 of the syringe assembly 20 in a first extended position, as shown in Figs. 10 and 13. A pressurizing spring 33 is restrained within the body 31 between an annular groove 35 at the closed end 34, and an annular groove 27 in the plunger plug 26. When the pressurizing assembly 30 is in the extended position shown in Figure 10, the pressurizing spring 33 is typically under minimal compression. Nevertheless, this amount of pre-tensioning or compression of the spring 33 should be sufficient to maintain an adequate rate of flow of liquid composition from the cavity 66 at the end of the injection term, as shown in Fig. 25. Figure 11 shows the same syringe cartridge as in Fig. 10, but with the plunger 24 and the pressurizing spring 33 extended to the bottom of the syringe body 21. In this configuration, a medical technician can fill the syringe assembly. The upper pressurizing assembly 30 and the membrane plug 67 are first removed. Then, using a threaded stem (not shown), the plunger can be pulled upward to draw in injectable liquid composition through the aperture 23. The membrane plug 67 and the upper assembly 30 can then be reinstalled.

[0111] The wall 31 of the pressurizing assembly 30 is configure to telescope axially over the outside of the syringe wall 21 to a second pressurizing position (shown in Figure 19) where the ribs 36 can engage a second set of outwardly-extending rims 29 disposed near the lower end of the syringe wall 21, also shown in Figure 10. This causes the closed upper end 34 of the pressurizing body 31 to compress fully the pressurizing spring 33 against the plunger plug 26, which causes the plunger 24 to move to the bottom 22 of the syringe 21 when no liquid is contained in the cavity 66 of the syringe. The engagement of the ribs 36 with the lower rims 29 retains cylindrical body 31 in the fully pressurized configuration. When the cavity 66 of syringe 21 contains a volume of injectable liquid composition, such as vaccine V as shown in Figure 19, the manual depressing of the syringe cartridge causes the compression of the pressurizing spring 33. The engagement of ribs 36 with rims 29 restrains the compressed pressurizing spring 33, and retains the potential energy within the compressed spring 33 as a means for injecting the liquid composition from the retainer. The manually-powered, compressed spring 33 exerts a downward force upon the plunger 24, which exerts pressure upon the liquid composition in the cavity 66. When the cavity 66 is put into liquid communication with the needle, the pressurized liquid composition can flow out of the cavity 66 under pressure. The pressurizing spring 33 is configured and designed to maintain a relatively constant force, resulting in a relatively constant pressure and liquid composition flow rate through the needle throughout the injection process.

[0112] Optionally, the device 1 of the present invention can comprise a separable base 92, from which the housing 10 can be removed at any time, particularly and advantageously after completion of the injection. The separable base 92 is typically configured for separable securement to the base 12 of the housing by a base securement means, and typically provides the skin-contacting surface of the device 1. A base separation means provides selective separation of the separable base 92 from the device. Figs. 2, 27 and 28 illustrate an embodiment of a separable base 92, as embodied in a separable attachment assembly 93 that removably associates with the base 12 of the housing 10.

[0113] The base securement means can comprise a mechanical engagement, such as a catch 89 formed on a distal end of a release finger 88 that depends downward from a portion of the housing body 11. The distal end of the finger 88 extends through an

opening 95 in an inner base member 91 shown in Fig. 2. The finger 88 further extends through an opening 98 in the removable base 92 when the removable base 92 is positioned against the base 12 of the housing. The finger 88 is configured to bias the catch 89 toward and into engagement with a latch 96 formed in the separable base 92, shown in Figure 27. The separable base 92 remains affixed to the housing of the device provided that the catch 89 remains engaged with the latch 96.

[0114] The base separation means for separating the separable base 92 from the permanent housing base 12 can comprise a mechanically-biased member associated with the housing 10 that is configured for manipulation that forces to disengage the base securement means, specifically in the illustrated embodiment by moving the catch 89 out of engagement with the latch 96. In Figure 27, after the needle 40 and carriage 70 have been retracted, the person can depress the release button 81 even further, thereby causing a toe 87 on a release arm 80 to pivot into engagement with the release finger 88, and to bias the catch 89 out of engagement with latch 96. With the catch 89 disengaged from latch 96, and with the needle 40 fully retracted, the housing can be safely and easily separated from the separable base 92 for post-injection inspection, and for disposal.

[0115] The separable base further comprises a means for attachment to the skin of the patient. Typically, the means for attachment comprises an adhesive means adhered to the skin-contacting surface of the separable base.

[0116] While the figures and associated description describe the separation of the separable base from the housing while the device is attached to the skin of a patient, it can be understood that the separable base can also be removed from the housing while the device is free from attachment to the body.

[0117] In a method of using the device of the invention, a device 1 is provided as shown in Figure 20 comprising a housing 10 having an optional separable attachment assembly 93 comprising a separable case 92, and a syringe cartridge 18. The three members are shown separated to illustrate, that prior to use as an assembled product, the components can be separated and visually inspected.

[0118] The separable attachment assembly 93 can be attached manually to the base 12 of the housing 10 as previously described. Prior to attachment of the device to a person, a release paper 111 that covers the separable base 92 and adhesive flaps 112, is peeled away and disposed of.

[0119] As shown in Fig. 21, the separable attachment assembly 93 of the housing 10 can be attached to an area of the patient's skin on the upper arm or leg of the patient P, designated as the injection site, secured by the adhesive on the underside of the adhesive flap 112 that extends outward from the periphery of the separable base 92.

[0120] After attachment of the device to the skin, a seal 105 is removed that covers the opening to the carriage recess 71 to protect the inlet end 42 of the needle 40 from contamination, as shown in Figures 21 and 22. The syringe cartridge 18 is then inserted into the recess 71 of the carriage 70. The threaded syringe port 64 engages the threaded connector 73, so that manual axial rotation of the syringe cartridge 18 mates the respective threads and secures the syringe cartridge 18 to the carriage 70. As that occurs, a membrane 65 disposed in the opening of the syringe port 64 (see Figure 14) is penetrated by the inlet 42 end of the needle, which establishes liquid communication with the syringe cavity 66. A pair of tabs 45 extending out from the top of the pressurizing body 31 provides a grip for manually rotating the syringe cartridge 18 into the carriage 70. Relative axial rotation between the syringe assembly 20 and the pressurizing assembly 30 is prevented by disposing the outwardly-extending rims 28 of the syringe wall 21 into longitudinal grooves 37 formed in the inner surface of the pressurizing body 31.

[0121] In an alternative method, the syringe cartridge 18 can be provided in its pressurized configuration, as shown in Figure 19, just after the technician has compressed the telescoping pressurizing assembly 30 down onto the syringe assembly 20, and just prior to insertion of the cartridge 18 into the carriage 70, shown in Fig. 22. When the technician inserts the pressurized cartridge 18 into the recess 17 of the carriage 70, and rotates or twists the cartridge 18 to establish liquid communication between the reservoir cavity 66 and the needle 40, liquid composition may begin to flow from the syringe cavity and into and through the needle 40.

[0122] The device can also be configured to prevent rotation and removal of the modular syringe from its position in fluid communication with the needle, once the carriage 70 has been moved to and secured in the injection position. The tabs 45 extending from the closed end 34 of the pressurizing assembly 30 nest within the oblong recess 17 in the top of the housing 10 to inhibit finger access to the assembly, and to prevent manual rotation and removal of the syringe cartridge 18 in the injection

position. This prevents an unwanted exposure of a needle that is penetrating the skin from being open at its inlet 42 end to the atmosphere.

[0123] As shown in Figure 23, the needle 40 is then inserted into the patient by manual force downward on the syringe cartridge 18 to move it into the housing 10 and toward the base 12, thereby inserting the injection needle 40 into the body and initiating the injection. The pressing downward of the syringe cartridge 18 has also compressed the retracting spring 76. Fully manually pressing the syringe cartridge 18 downward causes the carriage 70 to be retained in a second position associated with the second injection position of the injection needle. A needle insertion securement, such as the retainer heel 86 shown in Figure 24, is configured to retain the needle carriage, and the injection needle, in the second, inserted position while the liquid composition is injected. Under the relatively constant force of the pressurizing spring 33, the vaccine V is slowly though constantly expressed out of the syringe cavity 66 and into the targeted body tissue 150. The size of the needle 40 and the force factor of the pressurizing spring 33 can be configured and designed to cause the liquid composition to flow under pressure through the needle within a target volumetric flow rate, to complete the injection within a prescribed period of time.

[0124] At the end of the injection term, shown in Figure 25, the plunger 24 has moved under the force of spring 33 to the bottom 22 of the syringe, and has collapsed the reservoir cavity 66 and driven substantially all of the vaccine out of the syringe cartridge 18.

[0125] An alternative method of inserting the needle 40 can employ the syringe cartridge 18 itself as an implement or plunger for depressing the needle cartridge to its inserted position, without having the needle inlet 42 penetrate the membrane 65 to the syringe cavity and placing the needle into liquid communication with the cavity. The syringe port 64 of syringe cartridge 18 can be rested against the bottom of the carriage 70, as shown by the left-side syringe in Figure 31, and pressed downward without having engaged the threads, or having only partially engaged the threads, of needle hub 72 and connector 73. Alternatively, the syringe port 64 and the connector 73 can be configured to provide a first position wherein the threads partial engage without establishing liquid communication between the needle and the cavity (that is, without rupturing the membrane 65), and a second position wherein the threads further engage

and establish liquid communication by penetration of the membrane by the inlet end of the needle.

[0126] Once the injection has been completed, or at any time during the vaccination, the needle can be retracted from its second or inserted position by activating a needle retracting means. The needle retracting means can comprise a disengagement means that is configured to disengage the needle insertion securement, and a power means configured to bias the needle, and the needle carriage, to respective third positions where the injection end of the needle is disposed within the housing. In the illustrated embodiment of Figure 26, the disengagement means comprises one or more release arms 80 and one or more release buttons 81. The release arm 80 comprises an upper end 82 shown as a ball having an inward flat surface that is secured within a socket 15 formed in the main body 11. The release arm 80 also comprises a pivot 83 that resides in a detent in the outside of the guide wall 14, and a resilient, flexible elbow portion 84 intermediate the ball end 82 and the pivot 83. A lateral bar 85 on the inside of the release button 81 is disposed proximate the elbow 84. In response to an inwardly-directed force on the button 81 that moves the button inward, as shown in Fig. 26, bar 85 causes the release arm 80 to flex inwardly at the elbow 84, causing heel 86 to pivot outwardly and out of engagement with the carriage lower flange 79. As shown in Figure 27, the power means comprises a compressed retracting spring 76 that had been manually disposed into a compressed configuration when the needle was manually inserted, and biases the needle toward a third position. With the needle carriage 70 unsecured by the needle insertion securement, retainer heel 86, the compressed retracting spring 76 can drive the carriage 70 upward from the base 12, and retract the distal end of the needle, needle tip 41, completely out of the body of the patient P and into the third position where the needle tip is within the housing 10. As described earlier, the retracting spring 76 should be disposed within the housing 10 with an amount of pre-tensioning or compression that is sufficient to completely retract the carriage 70 back to the top of the housing 10, so that the needle 40 will be retracted completely back into the housing.

[0127] The needle insertion securement and the disengagement means can function through or comprise the same element of the device (like the release arm 80 which functions to both secure the carriage and to disengage the securement), or can employ distinct elements.

[0128] After retraction of the needle 40, the syringe cartridge 18 can be grasped and removed by oppositely rotating the cartridge to disengage the threaded connection of the cartridge with the carriage. The cartridge assembly 18 can be inspected to confirm that all the liquid composition from the syringe cavity 66 had been injected, and then is disposed. If for any reason a significant amount of the liquid composition remained in the syringe, the syringe cartridge 18 can be reinserted into the carriage 70 and again rotated into liquid communication with the inlet of the needle 40, and the carriage and needle reinserted into the patient to complete the injection.

[0129] The illustrated embodiment shown in Figures 5, 25 and 27 shows that the release button 81 can have a generally cylindrical shape. The button can have a main inner wall 104 and an annular outer wall 101 having an annular periphery that is slightly larger than the annular opening 102 in the housing body 11 in which the button is disposed. The flared outer wall 101 resist movement of the button 81 into the opening 102 until a manual force is applied that is sufficient to bias inward the outer wall 101. As the button 81 is depressed, it biases elbow 84 of the release arm 80. When the force on the button 81 is released, the resilient elbow 84 will spring back against, and move, button 80 outward to its original position. The button 81 can also provided with a small aperture in its face, through which a small hooked implement can be inserted to pull out the button if it should become lodged inwardly.

[0130] In an alternative embodiment of the device, the means for establishing liquid communication can comprise a separate piercing conduit for establishing liquid communication with the reservoir, and which is in liquid communication with the injection needle. Fig. 39 shows a carriage 70 having a connector portion 73 that comprises a piercing needle 120 configured to penetrate a seal or membrane in the syringe cartridge 18 (not shown), and which is in liquid communication with the inlet end 42 of the injection needle 40. Fig. 39A shows in more detail a needle hub 72 positioned within a recessed bore in the end of the connector portion 73. The inlet end 42 of the needle 40 is flared so that the injection needle is retained within the needle hub 72. A conduit hub 121 is securely positioned over the needle hub and retains the piercing needle 120 in position. The distal end 122 of the piercing needle 120 is typically sharpened or pointed to facilitate penetration of the liquid seal or membrane. The piercing needle 120 is typically of a smaller gauge (larger diameter) than the injection needle to ensure penetration of the liquid membrane without crimping or

bending. Alternatively, the injection needle 40 can be made with an integral piercing conduit at the inlet end 42 that has a larger diameter and thickness than the skin-inserted portion of the needle.

[0131] Another alternative embodiment of the device can comprise the syringe cartridge shown in Fig. 40. The syringe cartridge 218 illustrated comprises a body having a cylindrical wall 221, a tapered base portion 222 having an aperture 223, and an upper closed end 234. The syringe cartridge 218 also comprises a plunger 224 that is configured for axial movement along the length of the cylinder wall 221. Figure 40 illustrates the plunger 224 both at a first position prior to filling of the cartridge reservoir with liquid composition, and at the end of the injection when the last amount of liquid composition has been evaluated from the cavity 66. A pressurizing spring 233 is disposed within the cartridge between the plunger 224 and the closed end 234, and is typically pre-tensioned to maintain a minimal force upon the plunger 224 when the plunger is in the first position. The cartridge 218 also comprises an outlet connector 264, comprising a one-way flow valve 267, illustrated as a duckbill valve having confronting flaps 268a and 268b.

[0132] The syringe cartridge 218 shown in Fig. 40 is in its configuration prior to filling. The medical technician or patient can draw the injectable liquid composition from a source, such as a glass vial, into a standard syringe (not shown) fitted with an outlet connector, such as a threaded female luer connector, that can be secured to the outlet 264 of the cartridge 218. After sealably connecting the supply syringe to the outlet port 264 of the cartridge 218, the person depresses the stem of the supply syringe plunger, causing the liquid composition to flow under pressure through the one-way valve 267 and into the cartridge. The pressurized composition moves the plunger 224 toward the closed end 234 and forms the reservoir of liquid composition V within the cavity 66. The pressurized composition also compresses the pressurizing spring 233 back toward the closed end 234. When the force applied to the plunger stem of the supply syringe is released, the pressurized liquid composition within the cavity 66 collapses and closes the one-way valve 267, as shown in Fig. 41. The one-way valve 267 can be positioned so that the inlet end 42 of the needle or the piercing needle 120 can penetrate the flappers 268 sufficiently to establish liquid communication. The filled cartridge 218 can then be inserted into the housing as described herein before.

[0133] In another alternative embodiment of the invention of a dual-port syringe cartridge 318. The dual-port cartridge has a first port 323 at a first end of the cartridge, configured for filling the cartridge with liquid composition V, and a second opposed port 364 at a second end of the cartridge, configured for dispensing the liquid composition from the reservoir to the injection needle 40. The cartridge 318 comprises a plunger 324 disposed in the cartridge for movement toward the first end for dispensing the liquid composition from the cavity 66. The plunger 324 is associated with a liquid dispensing means shown as pressurizing spring 333 for maintaining pressure upon the composition V within the cavity 66 to cause the liquid composition to flow from the cavity. The pressurizing spring it typically pre-tensioned to ensure sufficient force is exerted through the entire length of the plunger travel to maintain adequate liquid flow through the injection needle.

[0134] The cartridge 318 comprises a means to establish liquid communication between the first or filling end of the cartridge, and the second or dispensing end of the cartridge. This liquid communication means can comprise a flow channel 341 in liquid communication between the distal end of the cavity 66 and the dispensing end 364 of the cartridge. In the illustrated embodiment, an tube 342 having the flow channel 341 is secured to the second end 322 of the cartridge, and extends to a distal end 343 that terminates proximate the inlet port 323. The dip tube 342 is preferably aligned along the axial centerline of the cartridge. In the illustrated embodiment, the plunger 324 is configured with an orifice through its longitudinal centerline, and forms an annular liquid seal 326 with the outside surface of the dip tube 342 and a peripheral seal 325 with the inside of the cylindrical wall.

[0135] The filling port 323 can be fitted with a one-way valve 357 and filled as described above. As the reservoir is filled under pressure, the pressurizing spring 333 compresses toward the dispensing end 322. The one-way valve 357 seals inlet port 323 to prevent leakage of the pressurized liquid V within the cavity 66. The membrane seal 367 seals the outlet port 364 and maintains the cavity of the filled cartridge 318 under pressure. The filled cartridge can then be inserted into the housing of a device as described herein. An optional cap 334 can be secured to the filling port 323 after filling to prevent curious fingers form pulling on the cartridge during injection.

[0136] The illustrated cartridge 318 in Fig. 43 provides distinct features that can be advantageous. The cartridge has separate and spaced-apart filling and dispensing ports,

which can allow the cartridge to be filled after it has been positioned and secured to the device. This avoids the need to handle the cartridge after it has been filled. The filling port 323 is typically oriented toward the top of the device. The configuration of the cartridge also provides for the dispensing plunger to ascend within the syringe during the injection in a direction other than downward and toward the base of the device. When the plunger has completed the dispensing of the composition V and has voided the cavity 66, the patient or medical technician will be able to see the distal end of the plunger proximate to the filling end 352 of the cartridge, which serves as a convenient visual signal that the injection is nearing completion or has been completed.

[0137] To assist in installing the separable attachment assembly 93 to the housing of the device, the lower surface of the housing base 12 can optionally be provided with a wide indent 97 surrounding the opening 95 in the inner base 91, and the separable base 92 can be provided with a raised flange 94 that registers with the indent 97, as shown in Fig. 20. Pressing upward on this area assists engaging the catch 89 onto the latch 96 of the separable base 92.

[0138] A top plan view of a typical separable base assembly 93 is shown in Fig. 32, with a sectional view Fig. 33 taken through line 33-33, and detailed sectional views shown in Figures 34-35. The adhesive flap 112 extends outwardly from the periphery of the separable base 92, and is covered on its slower surface with the release paper 111. The adhesive flap 112 comprises a first film layer 114 that is affixed on its upper surface to cover the skin-facing surface of the separable base 92, and extends outward from the peripheral circumference of the base 92. The flap 112 has a PSA on its lower surface (not shown) for attachment to the skin. Flap 112 also comprises a second film layer 115 that is shaped as a ring with an inner circular edge 116 and an outer edge 117. The inner edge 116 extends inwardly and is affixed, typically with PSA, to the upper surface of the separable base 92 inboard of its circumferential edge. The second film layer 115 extends outwardly from the separable base 92, to overlap the first film layer 114 to its periphery, and there beyond to its outer edge 117. Typically, the adhesive flap layers 114 and 115 can be made of a flexible plastic film, and can be optionally vapor permeable or breathable.

[0139] Alternatively, the second film layer 114 can be eliminated, and the underside of the separable base 92 can have a coating of PSA for direct-contact adhesion to the skin.

Optionally a gauze bandage 113 can be secured to the underside of the separable base 92 over the opening 13, as shown in Fig. 35.

[0140] In an alternative embodiment, the base separating means can comprise other mechanical securements, an adhesive securement, and a magnetic securement of the separable bas to the housing of the device. The other mechanical securements could include a mechanical "hook-and-loop" device that can include Velcro®, a hasp, a frangible joint, and a threaded joint). The magnetic securement can comprise a first magnetic member proximate the upwardly-facing surface of the separable base; and a second magnetic member proximate to the base portion and inside of the housing; wherein first magnet member and the second magnetic member have a magnetic attraction that secures the removable base to the housing, and wherein the removable base can be manually separated from the base portion of the housing by a manually-applied force that overcomes the force of the magnetic attraction.

[0141] The separable base provides a means for obtaining a secure attachment of the housing of the device to the patient's skin, by providing for outwardly-extending adhesive flaps that are securely affixed to the relatively rigid structure of the separable base. In most circumstances, the separable base that remains behind on the skin of the patient is well tolerated by the patient, and can be removed at any time, since most vaccinations, particularly with very small needle diameters, leave little wounding of the skin

[0142] The separable base 92 can also be removed for pre-injection inspection of the device, by fully depressing the release button 81, prior to installing the reservoir or the initiating needle insertion. The inner base 91, or a portion thereof, can be made of a transparent thermoplastic material to allow a visual inspection of the needle and the internal assembly prior to use. The separable base 92 can then be easily reaffixed.

As shown in Figure 28, after completing the injection, the syringe cartridge 18 can be removed from the attached housing 10, before the housing is removed from the separable base 92; or, the housing 10 with the syringe cartridge 18 attached can be removed from the separable base 92 as a unit, and then the syringe cartridge can be removed.

[0143] The device can also comprise a means for preventing deployment of the needle through the opening in the base of the housing, particularly after the needle has been inside the skin and body of a person. A typical deployment prevention means for

preventing needle deployment comprises a sliding or rotating plate disposed in the base that can moved between a first position where the needle opening in the base is not covered by the plate, and a second position wherein the plate covers the opening. In the embodiment illustrated in Figs. 36-38, a rotating plate 131 is disposed in an annular recess 130 on the annular flange 94 of the inner base 91. The recess 130 and plate 131 have a center that is positioned off the centerline 100 passing through needle 40, though they overlap the needle opening 13 in the base 12. The plate 131 has an opening 136 disposed between the center of the plate 131 and its periphery. The plate 131 can rotate between a first deployment position shown in Figs. 36 and 37 wherein the plate opening 136 registers with and leaves exposed the opening 13, and a second blocking position shown in Fig. 38 wherein the plate 131 covers the opening 13, and prevents deployment of the needle 40. The plate is movable between the first and second positions by a knob 132 that is attached to the plate by a stem 133. The stem is disposed within arc-shaped stem slot 134. The knob 132 moves along a knob recess 135 formed in the inner surface of the removable base 92, and that lies below the knob slot 134. The knob retains the plate in position, and can be manipulated by finger to move the plate between its first and second positions. Prior to injection, the technician can remove the removable base plate and manipulate the knob 132 to move the plate 131 to its deployment position. After the device is removed from the skin following the injection, and the device has been removed from the separable base 92, the exposed knob 132 can be manipulated to move the plate 131 to its blocking position. This physically closes the opening 13 to ensure that the needle 40 can not be redeployed accidentally and cause an undesired stick.

[0144] In a further embodiment of the present invention, a device can have a plurality of injection needles and reservoirs disposed within the housing. The device can provide for injecting at least two injectable liquid compositions to a patient. Figs. 29 and 30 show a top plan view and an elevation view of a device 1 for injecting at least two liquid compositions from separate reservoirs contained in the housing. As shown in Figure 31, the device 1 can comprise a housing 10 and base 12 for two needle carriages 70a and 70b and two injection needles 40a and 40b, which can be configured to be separately and independently manipulated for insertion, injection and retraction, as described herein above.

[0145] Alternatively, the two needle carriages and needles can be configured for simultaneous insertion, injection, and retraction using shared elements, including a shared, unitary dual-recess needle carriage, and a dual unitary pressurizing assembly.

[0146] If only one injectable liquid composition will be administered, there is a potential for the patient, during the injection procedure, to pick at and possibly poke a finger though the seal 105 that is initially positioned over the cavity recess 71. To prevent this, the seal 105 can be affixed to a cylindrical member 106 that partly supports the underside of the seal 105 layer, as shown in Figure 3A. Alternatively, the seal can be removed and replaced with a "dummy" plunger that has the upper appearance of the active syringe cartridge, but which fits securely in the opening in the housing above the carriage to block any attempt to depress the carriage.

[0147] Another alternative embodiment of the device can comprise a means for selectively positioning and optionally securing the needle carriage 70 to respective positions that either prevent or enable its movement in the axial direction within the housing. This embodiment also is an alternative deployment prevention means. Fig. 42 illustrates this embodiment in the context of the dual-needle device. Each of the carriages 70a and 70b in Fig. 42 are shown in their first axial position, disposed within the carriage passageway 280 proximate the upper end 281. This is also the position in which the syringe cartridge 18 is inserted into or removed from the needle carriage 70. In the first axial position, the carriage can be rotated between a first rotational position wherein the carriage is restrained from movement in the axial direction, and a second rotational position wherein the carriage can move in the axial direction.

[0148] Looking first at the carriage 70a on the left side of the device, which is in the axially restrained configuration, the vertically-oriented guide rib 19 projects outward from the cylindrical wall 14. The toe 79 of the carriage is positioned within a notch 119 formed in the guide rib 19, allowing the carriage to rotate, but preventing the carriage from moving downward axially so long as the toe 19 is disposed within notch 119. The cooperation of the toe 79 of the carriage disposed within the notch 119 of the guide rib 19 provides a means for restraining the movement of the carriage in the axial direction.

[0149] The carriage 70b on the right side of the device is shown in the axially un-restrained configuration. In this configuration, the carriage 70b has been rotated (typically in the clockwise direction) to a position where the gap 179 in the toe 79 registers with the notch 119 in the guide rib 19, which allows the carriage 70b to move

axially toward its second axial position proximate the base of the housing. As the carriage 70b first begins to descend, the gap 179 in the toe 79 slides along the guide rib 19, preventing the carriage from rotating after it has moved axially out of the first axial position.

[0150] The carriage can also comprise a means for registering the rotation of the carriage in a direction that corresponds with either the axially restrained configuration (typically, counter-clockwise direction in the plan view shown in Fig. 29) or with the axially un-restricted configuration (typically clockwise). In the illustrated embodiment, a stop lug 180 is provided to assist registering the gap 179 with the notch 119, by limiting the rotation of the carriage. At the appropriate configuration, a stop lug 80 will engage the upper end 219 of the guide rib 19. The stop lug 180 is shown as a downwardly-extending projection from the outer wall 75 of the carriage 70, over a portion of the wall-contacting periphery of the carriage. As viewed in Fig. 42A, in the top-right of carriage 70b, a first end of the stop lug 180 is engaging the upper end 219 of the guide rib 19 from behind the guide rib, when the carriage is rotated in the clockwise direction. Conversely, as shown in Fig. 42, the stop lug 180 (which is not shown since it is out of the page in front of the section line), a second end of the stop lug 180 is engaging the upper end 219 of the guide rib 19 from in front the guide rib, when the carriage is rotated in the counter-clockwise direction.

[0151] Fig. 44 shows an alternative embodiment of a device having a needle retracting means that comprises a pre-tensioned retracting spring that is associated with a separate member for retracting the needle. As illustrated in Fig. 44, the retracting means comprises an auxiliary retracting carriage 270. The retracting carriage 270 is configured for movement within the housing between a first secured position, shown in Fig. 44 where the retracting carriage is disposed proximate the base 91, and a second position where the retracting carriage is disposed proximate the upper end 281 of the carriage passageway 280. In the first position, the retracting spring 76 is in a fully compressed position, restrained by the retracting carriage 270, the toe 79 of which is restrained by the lower heels 86 of the release arms 80. As described above, when buttons 81 are depressed, heels 86 bias outwardly and out of engagement with toe 79, allowing the retracting spring 76 to move the unrestrained retracting carriage 270 toward and to its second position. It can be understood that depressing of the buttons 81 also bias the upper heels 286 to pivot or move outwardly. The force factor of the

retracting spring 270 can be sufficient to cause the upper toe 279 of the retracting carriage 270 to pass over the upper heels 286 of the release arms 80 and into its second position proximate upper end 281 in the carriage passageway (not shown). Upon releasing of the pressing force upon buttons 81, the upper heels 286 return and are placed into an interference position that can prevent the retracting carriage 270 from being moved axially in a direction back toward its first position shown in Fig. 44. It can also be understood that the retracting carriage 270 can be moved from its second position proximate the upper end 281, to its first position, by sufficiently depressing buttons 81 to release the upper toe 279 from engagement with the upper heels 286, and manually pushing the retracting carriage 270 (and compressing the retracting spring 76) toward the base 91.

[0152] It can also be understood that the needle carriage 70 can move within the carriage passageway 280 separately from the retracting carriage 270. The needle carriage 70 is typically positioned in its first position adjacent the upper end 281 of the carriage passageway 280 (such as shown in Fig. 22) for attachment of the syringe cartridge 18. In this position, the needle carriage can be restrained temporarily from axial movement (the needle carriage's axially restrained configuration, as described in the aforementioned embodiment and illustrated by the left-hand carriage 70a of Fig. 42). Alternatively, the needle carriage can be biased toward its first position by a second mechanical spring (not shown). At the same time, the retracting carriage 270 is typically in its pre-tensioned position shown in Fig. 44, adjacent the base 91. After the syringe cartridge 18 containing the liquid composition V has been secured in place to the needle carriage 70, also as shown in Fig. 22, the needle carriage bearing the injection needle 40 can be rotated from its axially restrained configuration into the axially un-restrained configuration (also described above and illustrated by the right-hand carriage 70b of Fig. 42).

[0153] From its axially un-restrained configuration, the needle carriage 70 can be moved to its second position shown in Fig. 44 by manually pressing downward on the inserted syringe cartridge 18. The annular outer wall of the needle carriage 70 can have cut-out grooves 176 that align axially with the upper heels 286 when the carriage is in the axially un-restrained configuration, to allow free passage of the carriage past the upper heels 286. The needle carriage 70 can have an annular recess formed between the inner wall 174 and the outer annular wall 172. The respective carriages can become

engaged and frictionally coupled together when the upper rim 272 of the retracting carriage 270 is nested within the annular recess of the needle carriage 70, but can be separated by hand. The frictional coupling of the needle carriage 70 to the restrained retracting carriage 270 assists in holding the inserted injection needle 40 within the injection site, as shown in Fig. 44.

[0154] A further embodiment of the invention can comprise a means of indicating the extent of liquid composition dispensed from the reservoir. The indication means can comprise a visual means that allows personnel to actually view the remaining contents of the reservoir. An embodiment of a visual indication means can comprise a transparent section positioned in a portion of the housing adjacent the reservoir, to view the reservoir. Alternatively, the housing can comprise a door or panel that can be opened to permit inspection. Further, the reservoir can be provided with a corresponding transparent portion to permit the medical personnel to see the medication contained within the reservoir. The transparent portion can include a portion of the base or a portion of the housing, or both. The transparent portion can be a small area relative to the total surface area of the housing body, or can be a significant portion of the housing body surface. In a typical embodiment, the transparent portion is positioned on one side of the housing body that, when applied to the patient's arm, can face away for the patient's line of sight. This allows the medical technician to see through the transparent portion, but provides no indication to the patient, typically a small child, that the inside of the device contains something interesting that might arouse the patient's curiosity.

[0155] The indication means can also comprise a signal means that signals the end or the approaching end of medicament dispensing. A signal means can comprise a mechanical or electrical switch that is activated by the plunger member as the last remaining contents of the reservoir is dispensed. The signal can be a flag, a pop-out tab, an illuminated light, or any other well known signal.

[0156] Another embodiment of the invention can comprise a covering or disguise configured for attachment or placement over the injection device either to provide the device with a pleasurable impression, or to direct the patient's attention away from the device. The covering can be formed as a cartoon character, a zoo animal, or the like. In this way, much of the patient's fear that might be caused by the sight of the device can be alleviated.

[0157] In another embodiment of the invention, the housing of the device can be colored coded or have a colored indicator or marking that identifies the particular type or quantity of medication contained within the reservoir. For example, for one certain medication the outer casing may be blue in color. The device can also display various warnings, such as a precaution to avoid needle stick and possible side effects to the medication. The device can also comprise a removable label comprising information about the liquid composition to be administered (such as the type of vaccine or medicament, the manufacturer and lot number, and volume), which can be placed into a medical record or patient chart.

[0158] Another embodiment of the invention, shown in the figures, is an improved injection device for self-administering an injection that does not provide the patient with any convenient fingerhold to grasp the device for jostling or removing the device from the skin during the injection procedure. A preferred design of the device will include an outer surface that has not sharp edges or deep groove with which the patient can get a fingerhold. Preferably, the housing and the base are constructed of a thermoplastic material that has a non-grip or non-sticky surface, and is preferably a resilient material that can flex but not deform in shape. A matte finish on the outside surface can make the housing difficult to grasp, except when properly grasped by a medical technician by its release buttons. Typically, the indentures and grooves in the housing, and including the base, have a breadth not greater than 3 mm, more typically not greater than 1 mm. Typically, external edges can be rounded, maintaining an edge radius of about at least 1 mm, more typically of about at least 3 mm.

[0159] While specific embodiments of the apparatus and method of the present invention have been described, it will be apparent to those skilled in the art that various modifications thereto can be made without departing from the spirit and scope of the present invention as defined in the appended claims.

We claim:

1. A manually-powered injection device for painless inter-muscular injection of an injectable liquid composition from with a reservoir, comprising:

a) a housing having a base for semi-permanent attachment to the skin of a patient,

b) an injection needle disposed substantially perpendicular to the base and within the housing, the needle having an injection end, and configured for axial movement manually between a first position wherein the injection end is within the housing and a second position wherein the injection end extends outwardly from the base to a distance sufficient for intramuscular insertion thereof, the injection needle having an outside diameter greater than 0.10 mm and less than about 0.38 mm,

c) a means for retaining a reservoir containing an injectable liquid composition,

d) a means for providing liquid communication between the retained reservoir and the injection needle, and

e) a means for injecting the injectable liquid composition from the retained reservoir through the needle.

2. The injection device of Claim 1 wherein the means for injecting is a manually-powered spring that is configured to exert pressure upon the injectable liquid composition within the retained reservoir.

3. The injection device of Claim 1, further comprising a needle insertion securement configured to retain the inserted needle in its second position while injecting the liquid composition.

4. The injection device of Claim 3 further comprising a means for retracting the injection needle, whereby the injection end of the needle can be retracted from its second position to a third position wherein the injection end of the needle is within the housing.

5. The injection device of Claim 3 further comprising a needle carriage to which the injection needle is affixed, the needle carriage being configured for axial movement

between a first position associated with the first position of the injection needle, and a second position associated with the second position of the injection needle, in response to a manual force applied by a person.

6. The injection device according to Claim 5 further comprising an implement for use in applying the manual force to the needle carriage.

7. The injection device according to Claim 5 wherein the needle insertion securement is configured to retain the needle carriage in its second position.

8. The injection device according to Claim 7, further comprising a retracting means comprising a disengagement means configured to disengage the needle insertion securement from the needle carriage, and a power means configured to bias the needle carriage to a third position that is associated with a third position of the injection needle wherein the injection end of the needle is within the housing.

9. The injection device according to Claim 1 wherein the device further comprises a separable base, a base securement means configured for separable securement of the separable base to the housing, and a base separation means configured for separation of the separable base from the housing, wherein the separable base comprising an adhesive for attachment thereof to the skin of the patient.

10. A manually-powered injection device for painless inter-muscular injection of an injectable liquid composition, comprising:

a) a housing having a base for semi-permanent attachment to the skin of a patient,

b) an injection needle disposed substantially perpendicular to the base and within the housing, the needle having an injection end, and configured for axial movement manually between a first position wherein the injection end is within the housing and a second position wherein the injection end extends outwardly from the base to a distance sufficient for intramuscular insertion thereof, the injection needle having an outside diameter greater than 0.10 mm and less than about 0.38 mm,

c) a reservoir containing an injectable liquid composition,

d) a means for liquid communication between the reservoir and the injection needle, and

e) a means for injecting the liquid composition from the reservoir to the injection end of the needle.

11. The injection device of Claim 10 wherein the means for injecting is a manually-powered spring that is configured to exert pressure upon the injectable liquid composition within the retained reservoir.

12. The injection device of Claim 10, further comprising a needle insertion securement configured to retain the inserted needle in its second position while injecting the liquid composition.

13. The injection device of Claim 12 further comprising a means for retracting the injection needle, whereby the injection end of the needle can be retracted from its second position to a third position wherein the injection end of the needle is within the housing.

14. The injection device of Claim 12 further comprising a needle carriage to which the injection needle is affixed, the needle carriage being configured for axial movement between a first position associated with the first position of the injection needle, and a second position associated with the second position of the injection needle, in response to a manual force applied by a person.

15. The injection device according to Claim 14 further comprising an implement for use in applying the manual force to the needle carriage.

16. The injection device according to Claim 14 wherein the needle insertion securement is configured to retain the needle carriage in its second position.

17. The injection device according to Claim 16, further comprising a retracting means comprising a disengagement means configured to disengage the needle insertion securement from the needle carriage, and a power means configured to bias the needle

carriage to a third position that is associated with a third position of the injection needle wherein the injection end of the needle is within the housing.

18. The injection device according to Claim 14 wherein the needle carriage comprises threads, and the reservoir comprises cooperating threads that can engage and retain the threads of the reservoir.

19. The injection device according to Claim 18 wherein the reservoir comprises a penetrable membrane, wherein when the cooperating threads of the reservoir and the needle carriage are engaged, a piercing conduit in liquid communication with the injection needlecan penetrate the penetrable membrane to establish liquid communication between the reservoir and the injection needle.

20. The injection device according to Claim 10 wherein the device further comprises a separable base, a base securement means configured for separable securement of the separable base to the housing, and a base separation means configured for separation of the separable base from the housing, wherein the separable base comprising an adhesive for attachment thereof to the skin of the patient.

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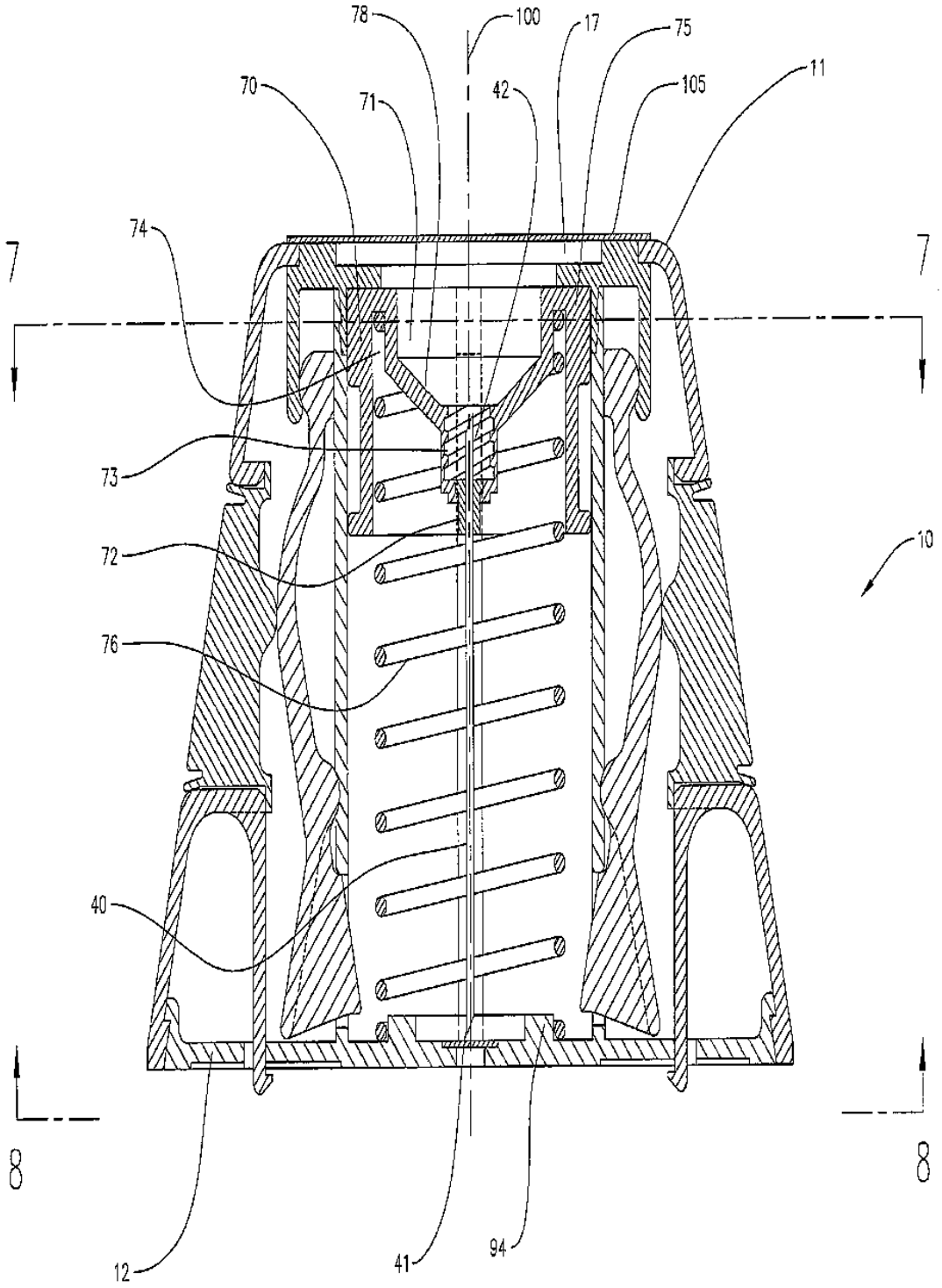


Fig. 1

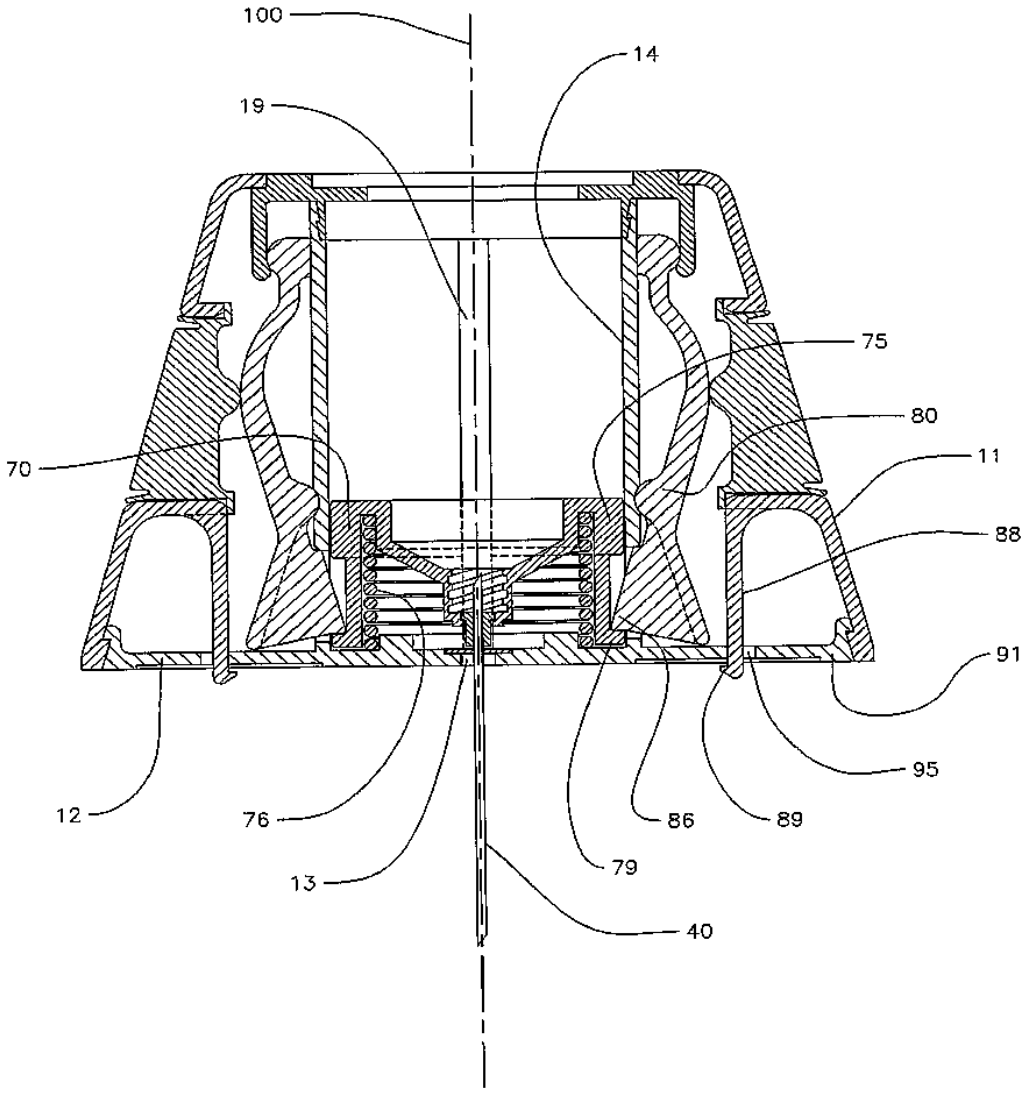


Fig. 2

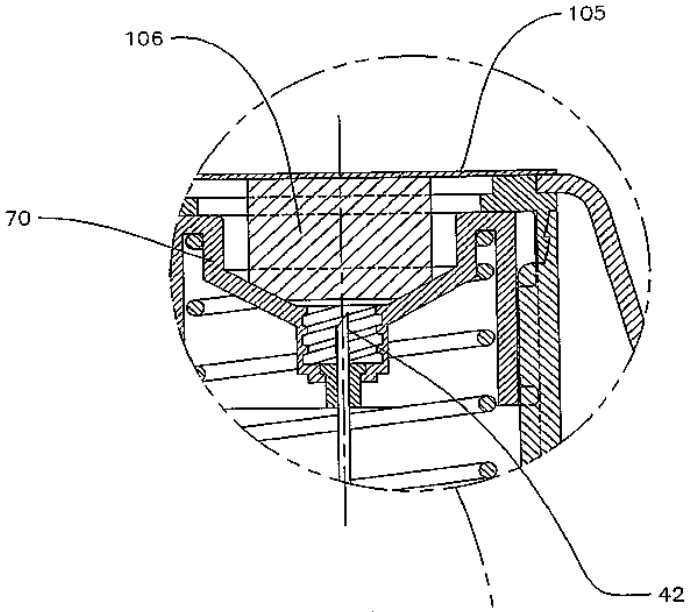


Fig. 3A

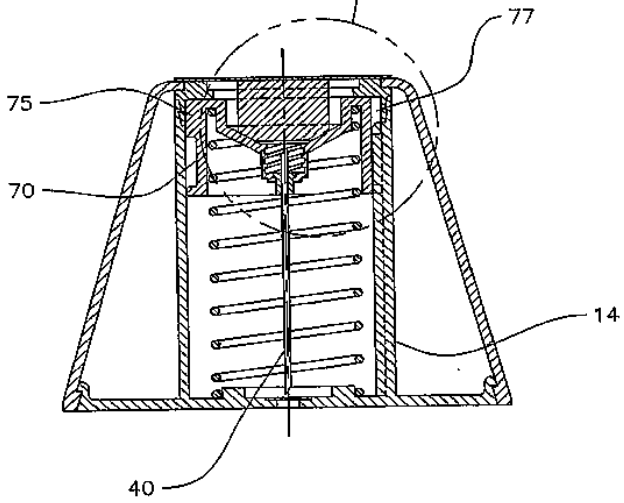


Fig. 3

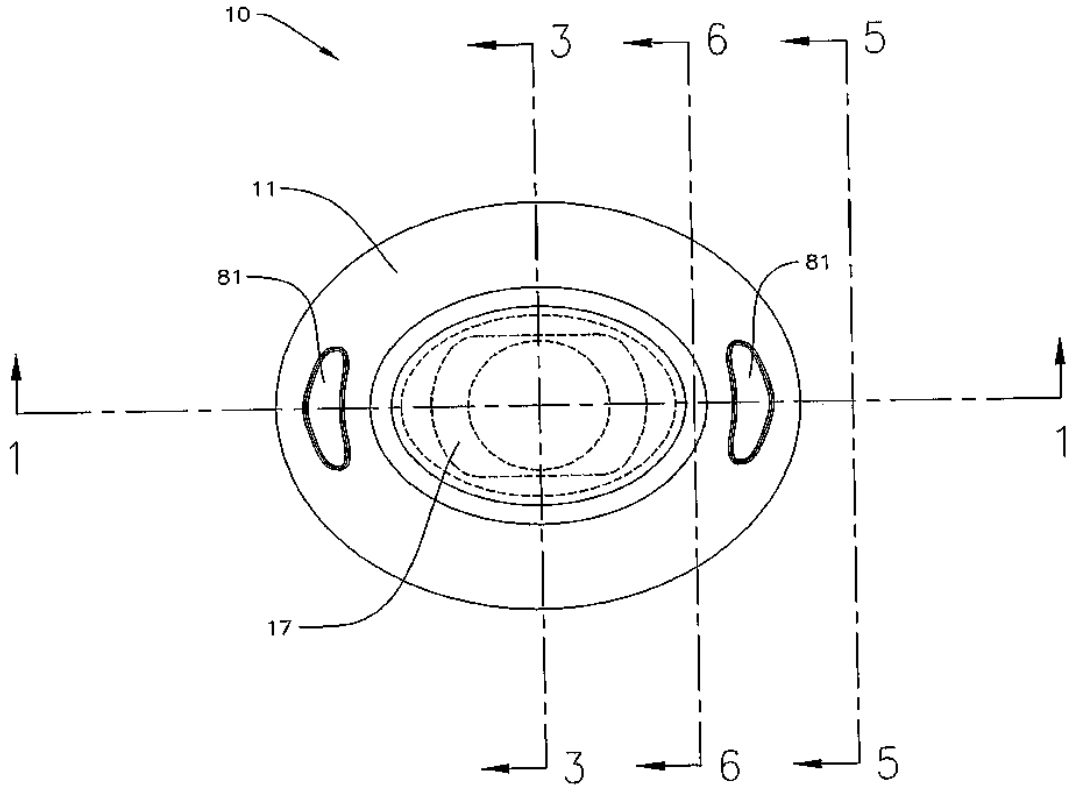


Fig. 4

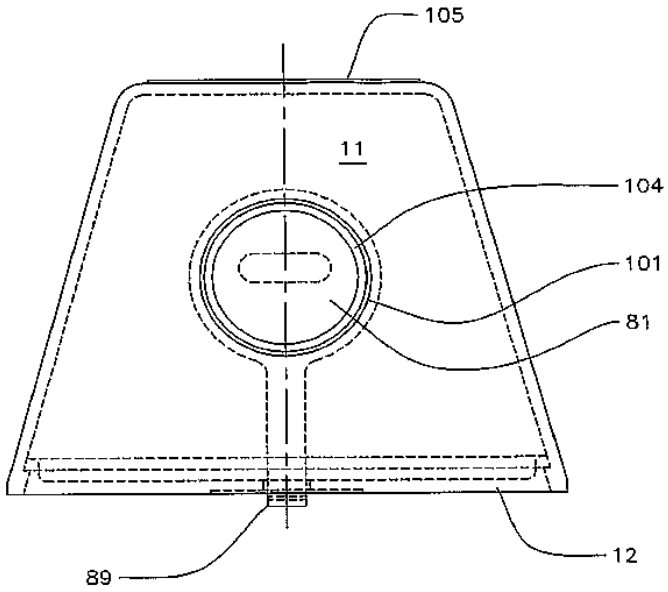


Fig. 5

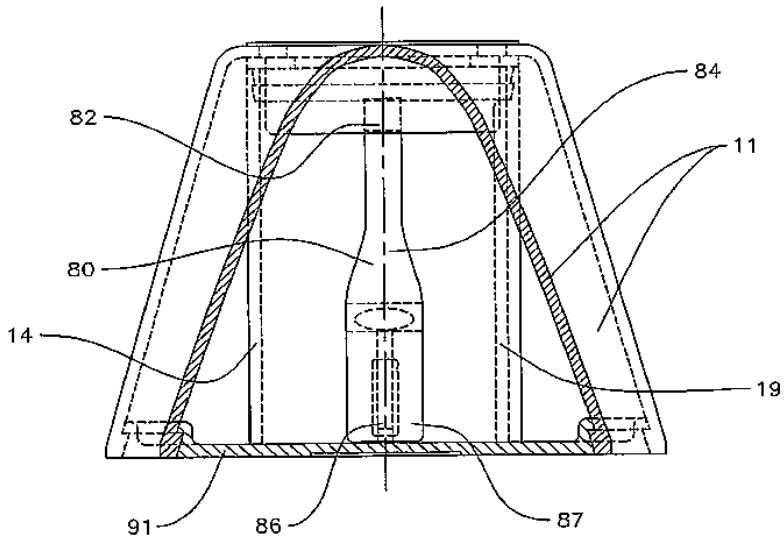


Fig. 6

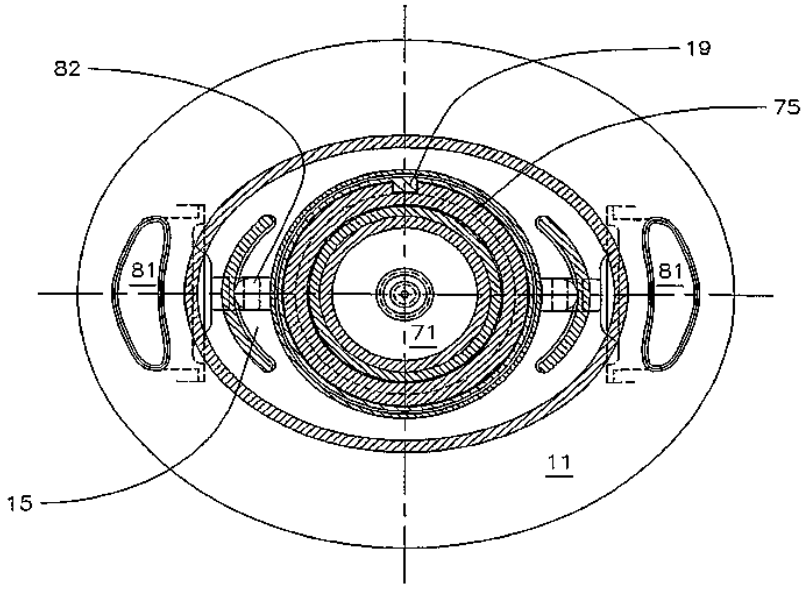


Fig. 7

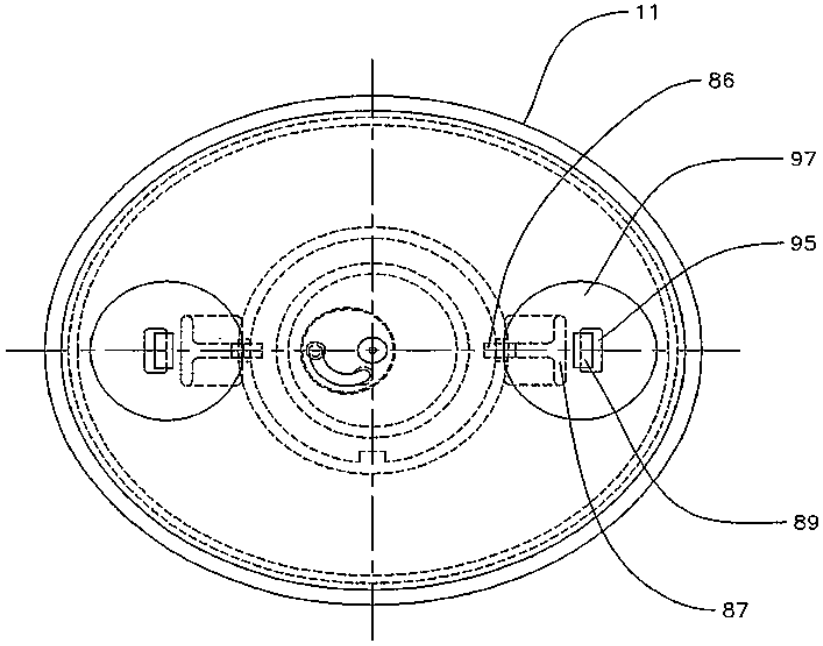


Fig. 8

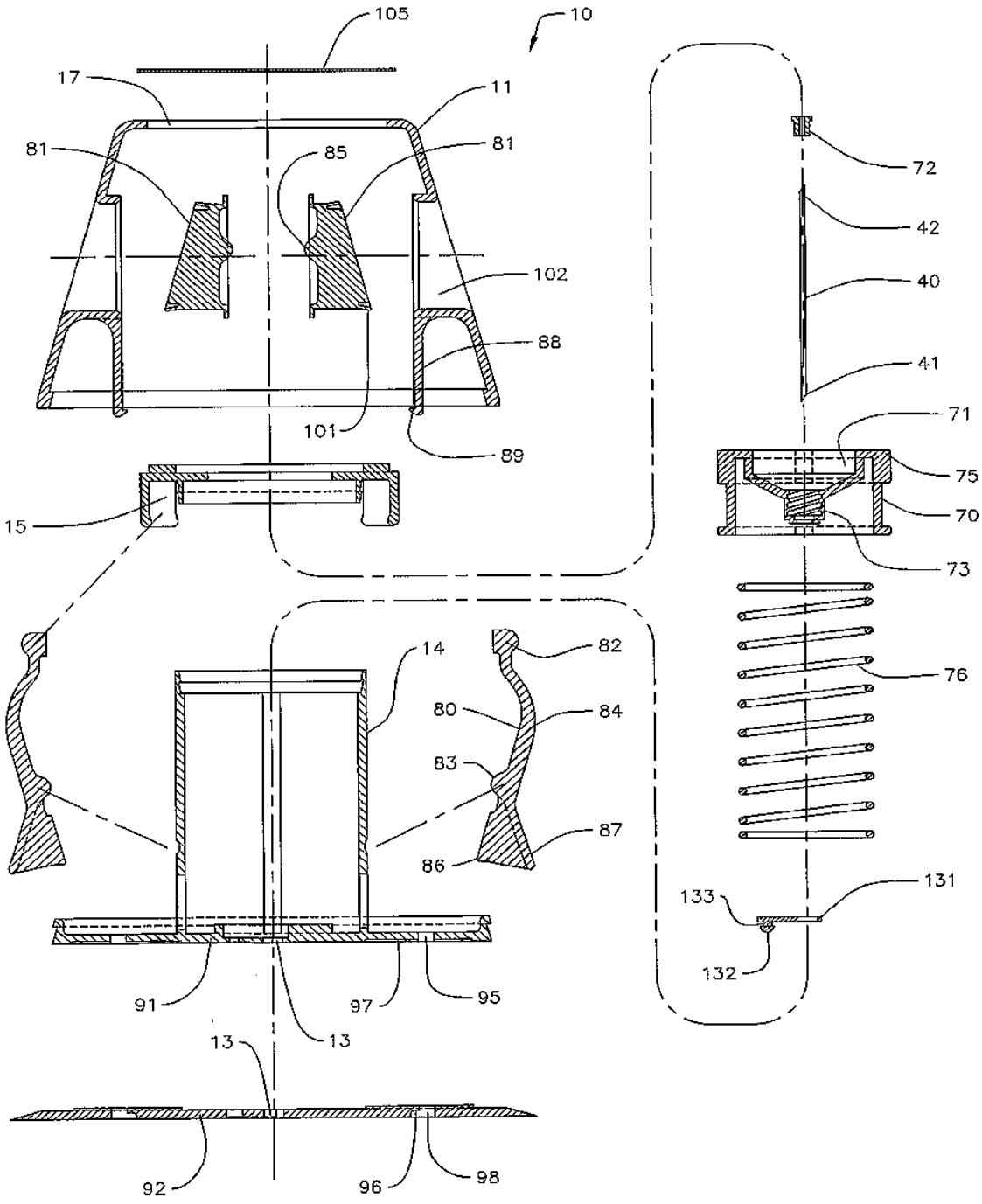

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Fig. 9

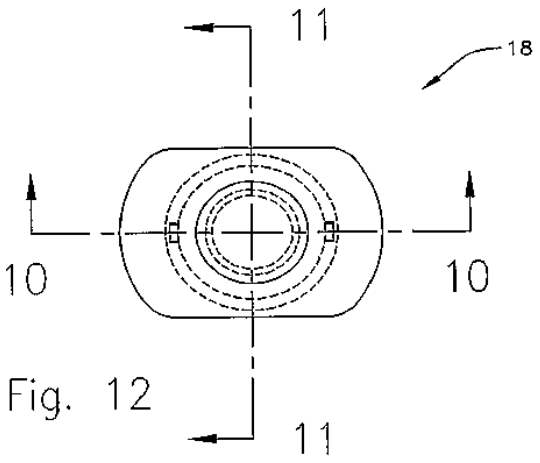


Fig. 12

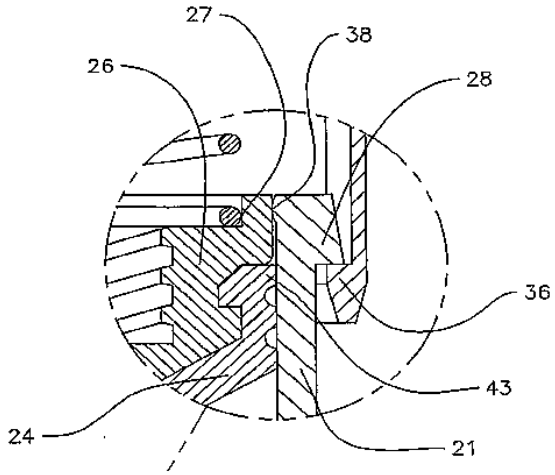


Fig. 13

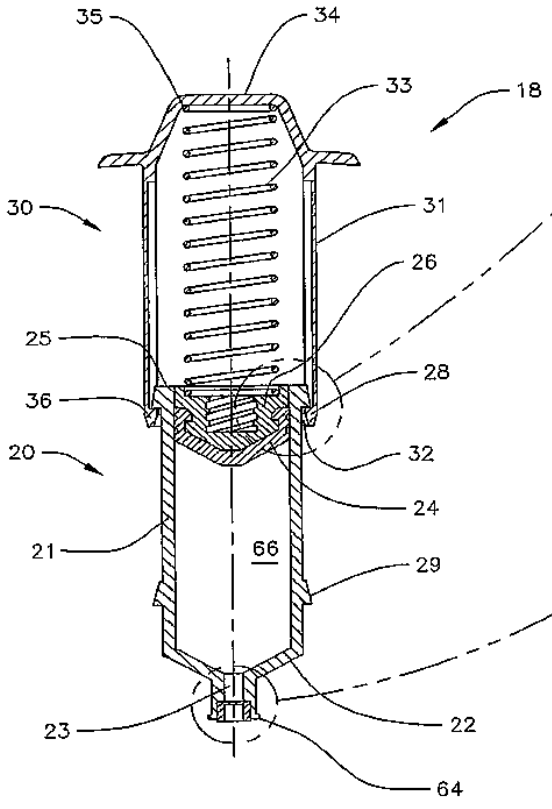


Fig. 10

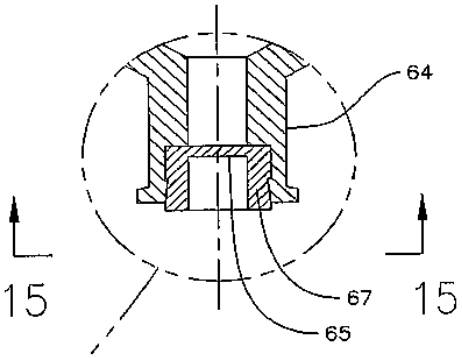


Fig. 14

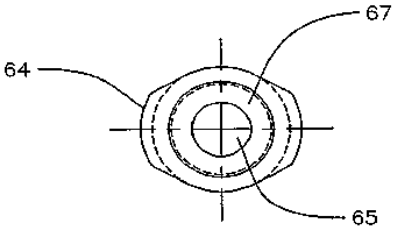


Fig. 15

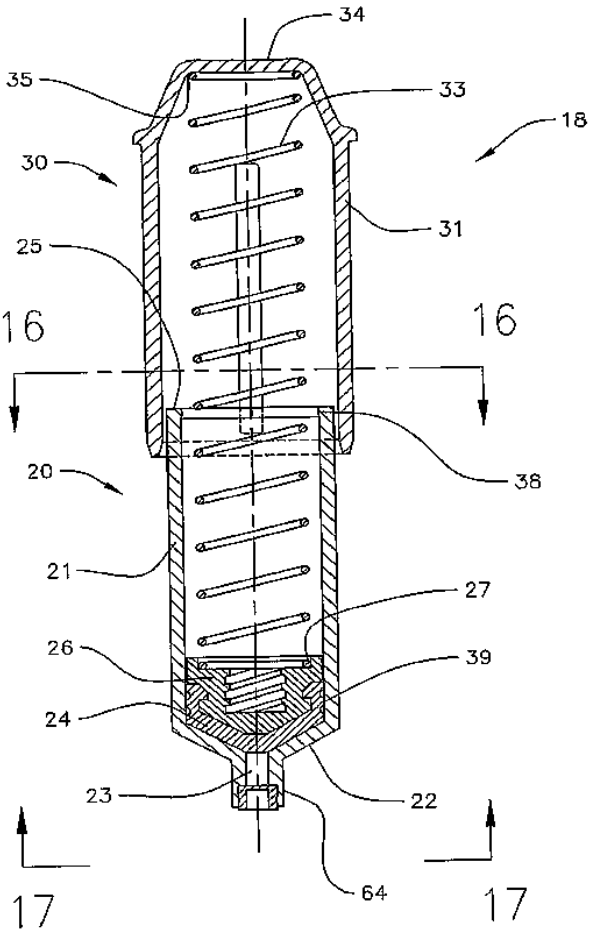


Fig. 11

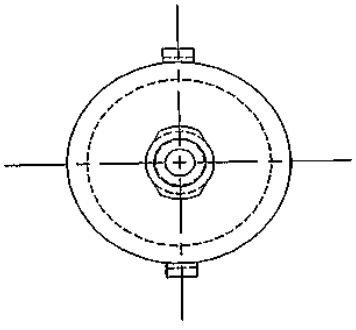


Fig. 17

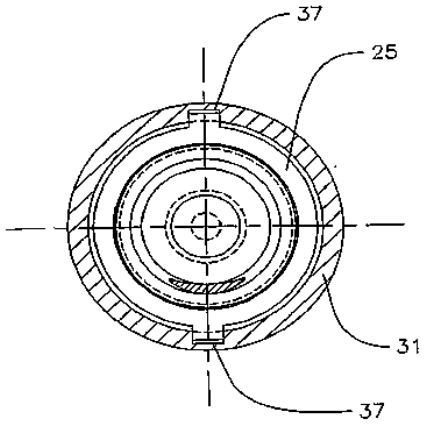


Fig. 16

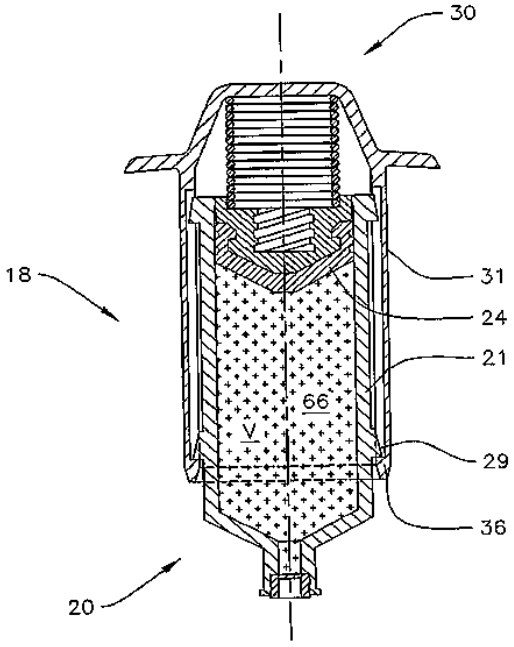


Fig. 19

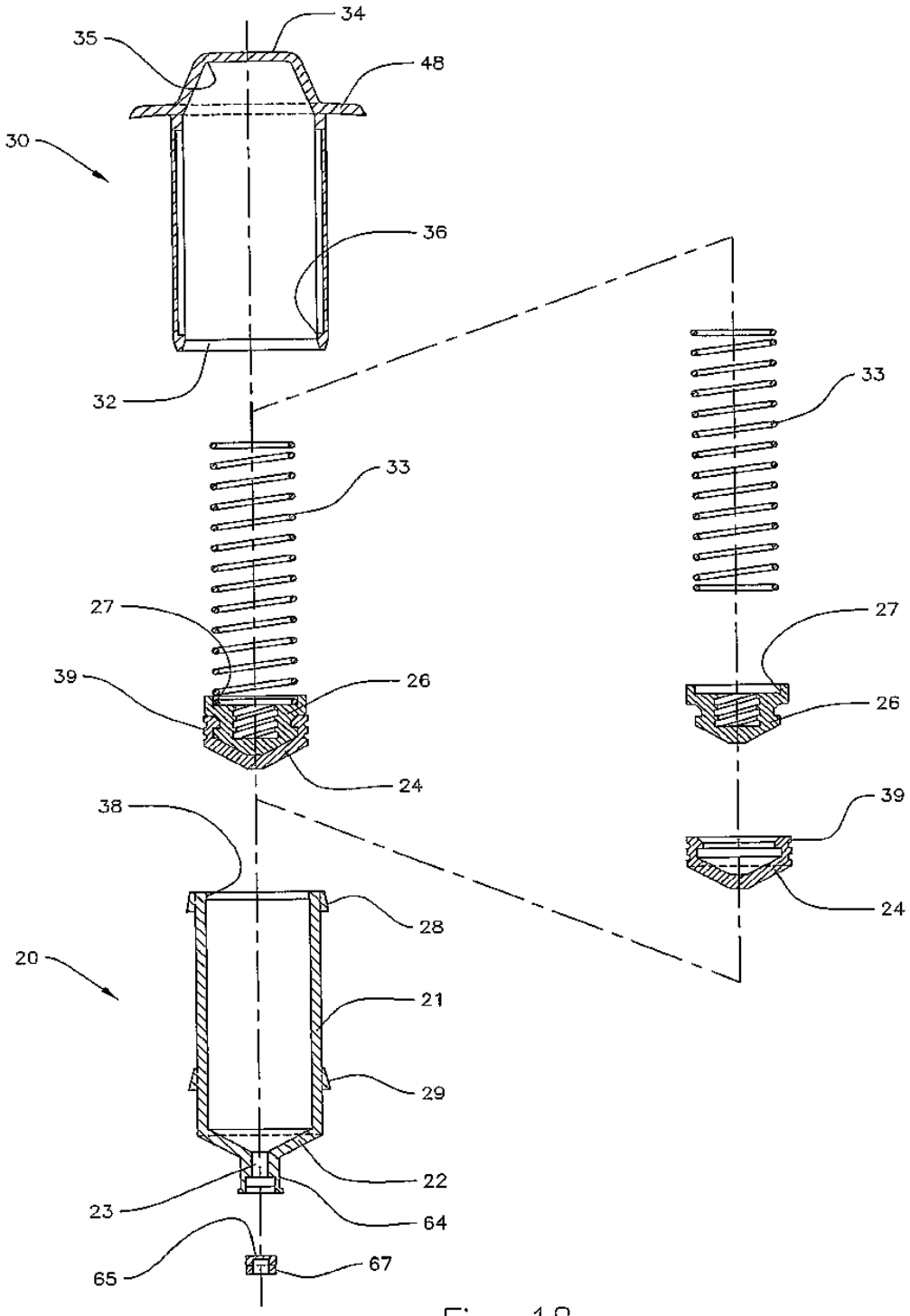

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Fig. 18

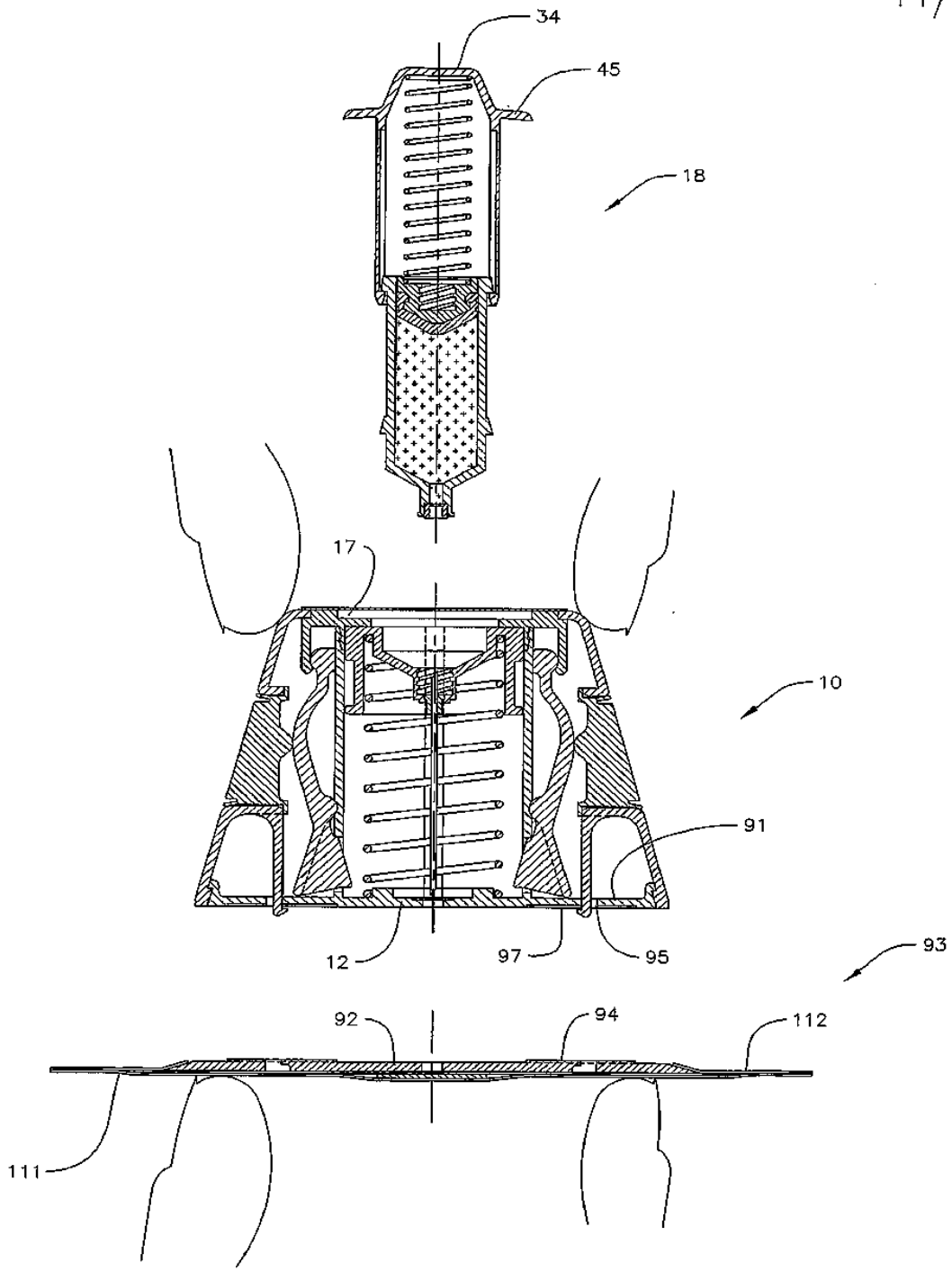


Fig. 20

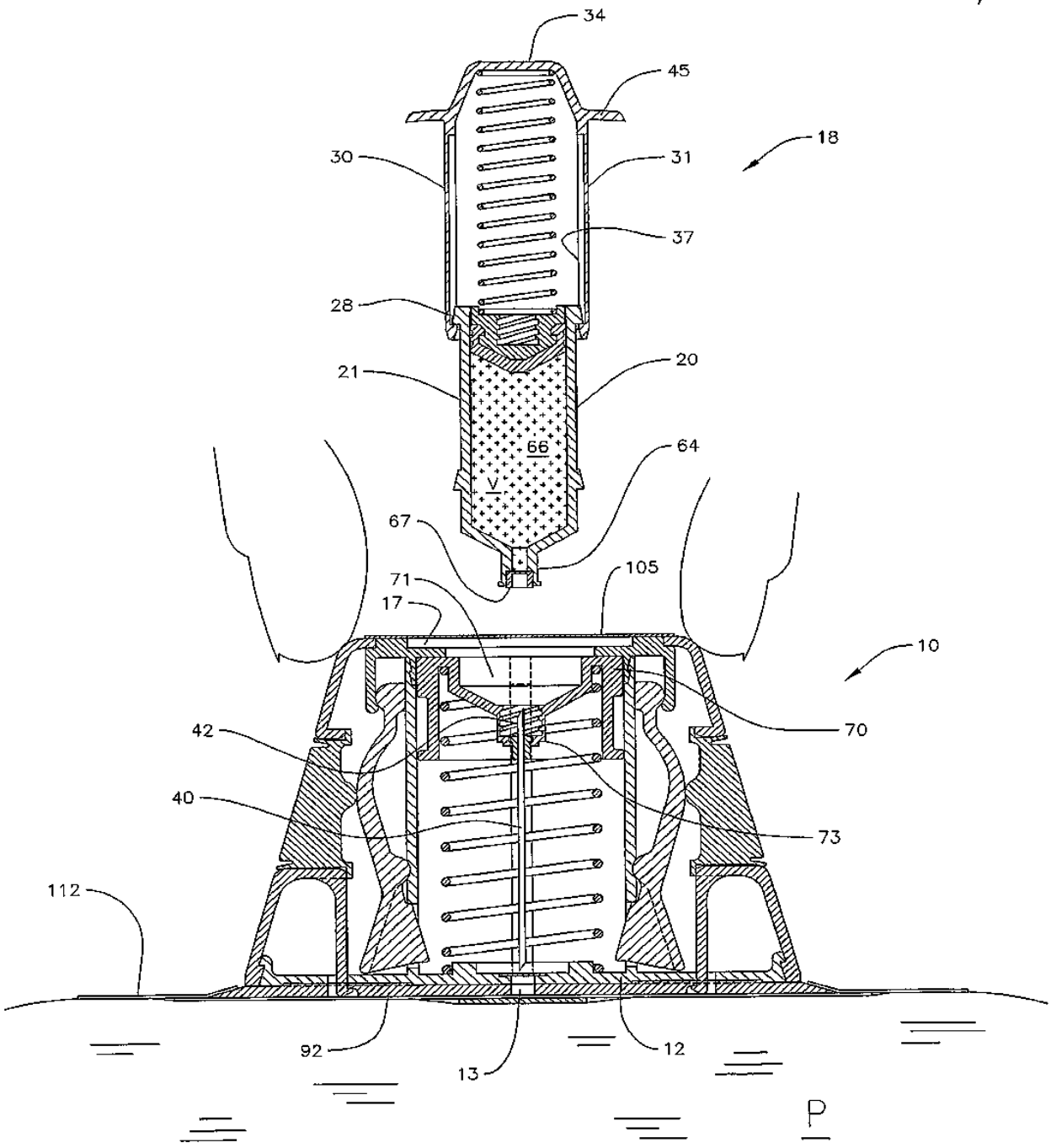

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Fig. 21

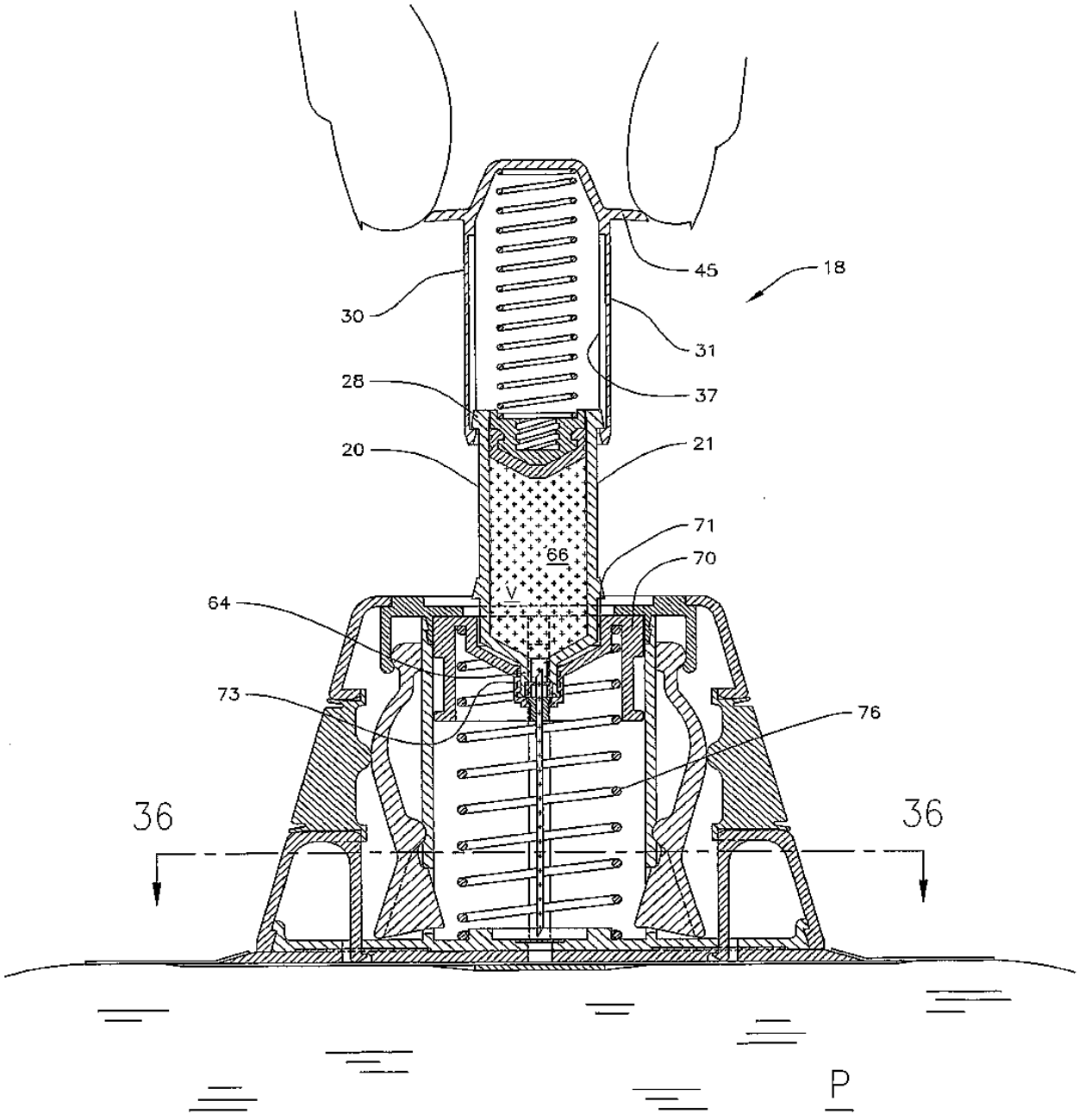


Fig. 22

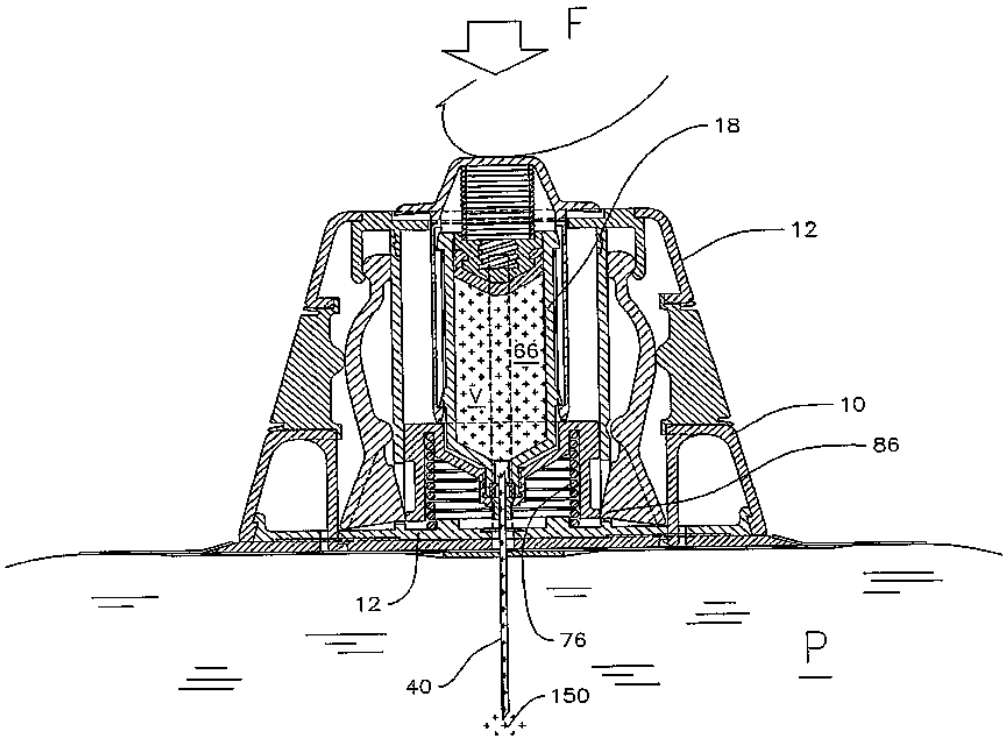


Fig. 23

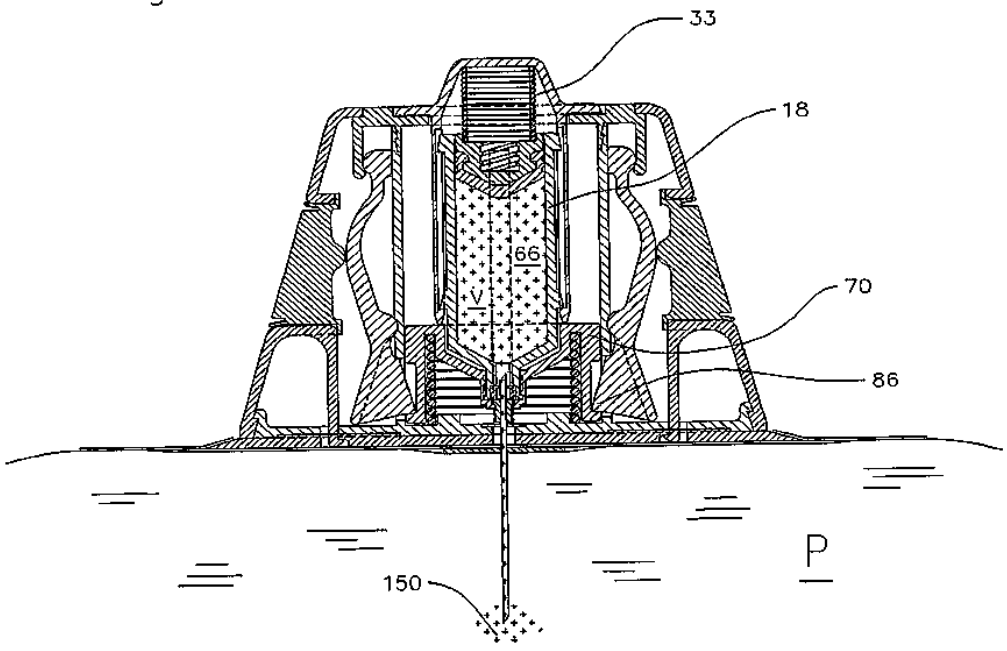


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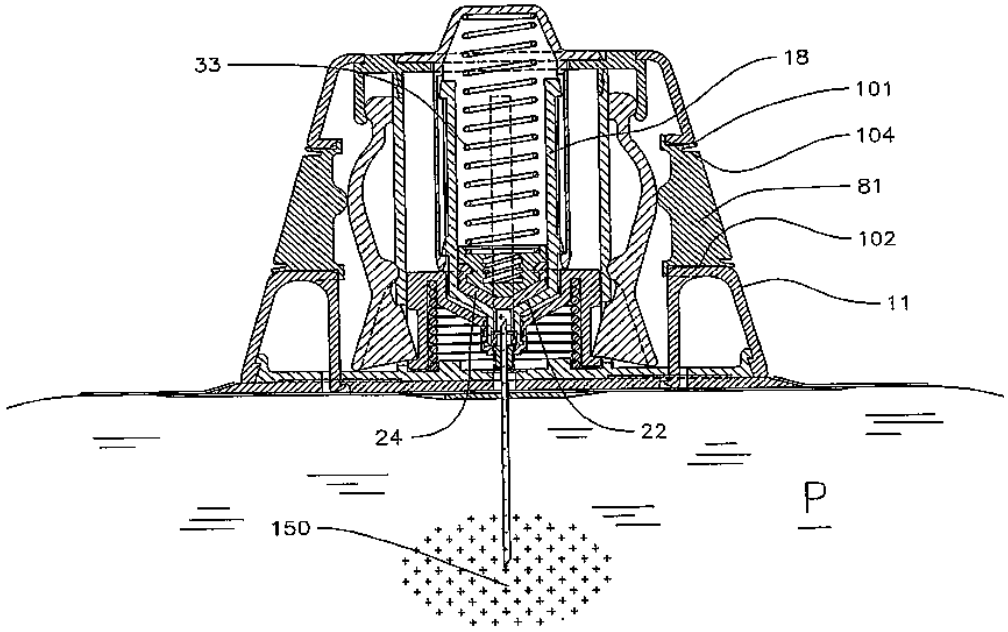

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Fig. 25

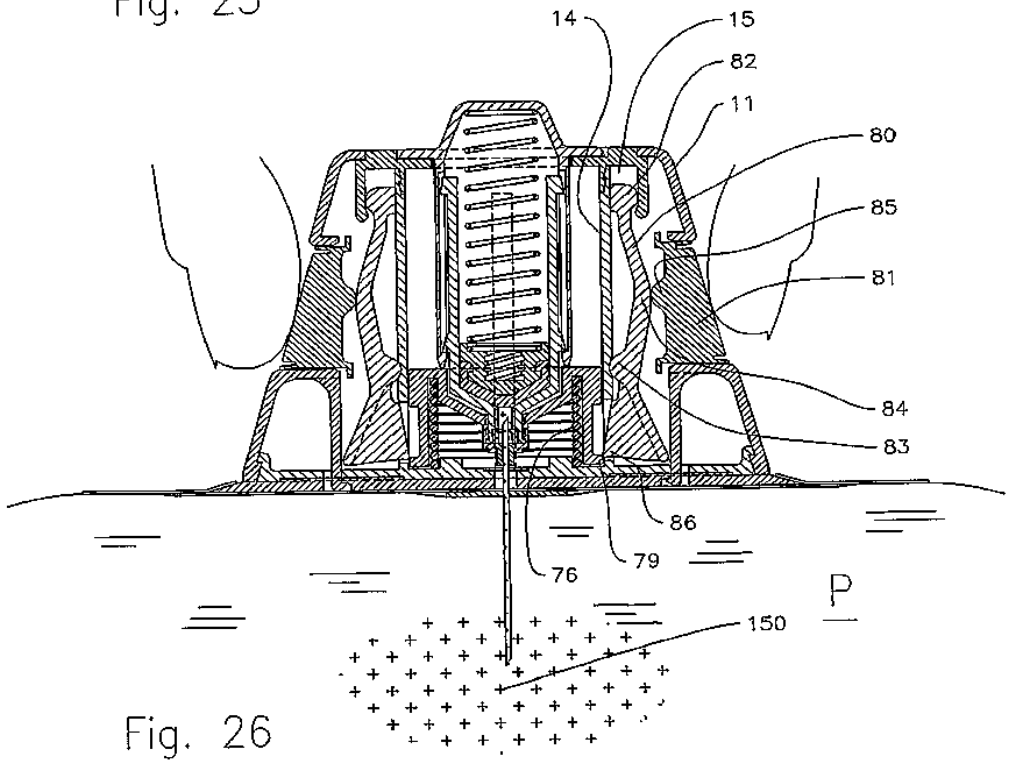

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Fig. 26

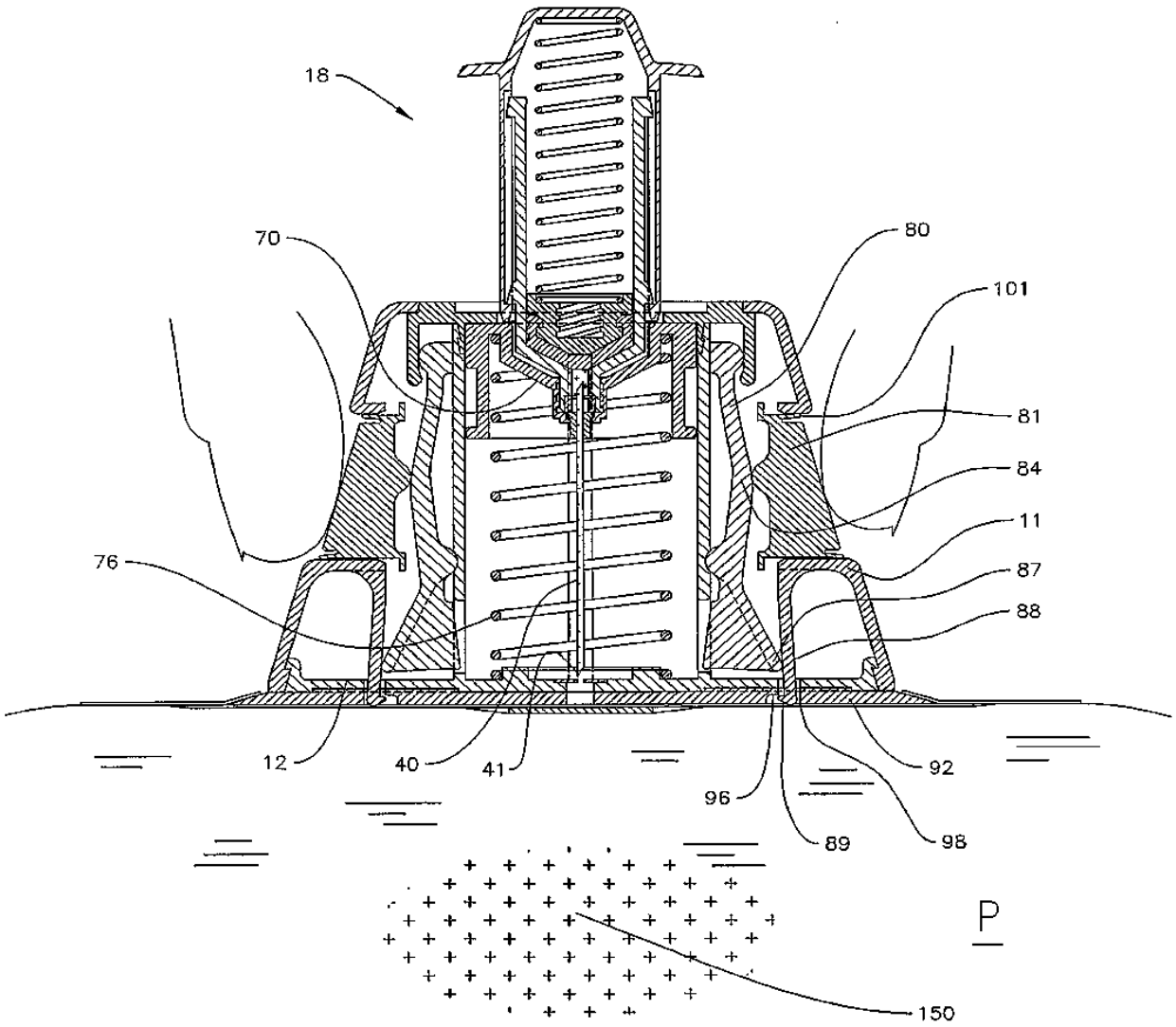


Fig. 27

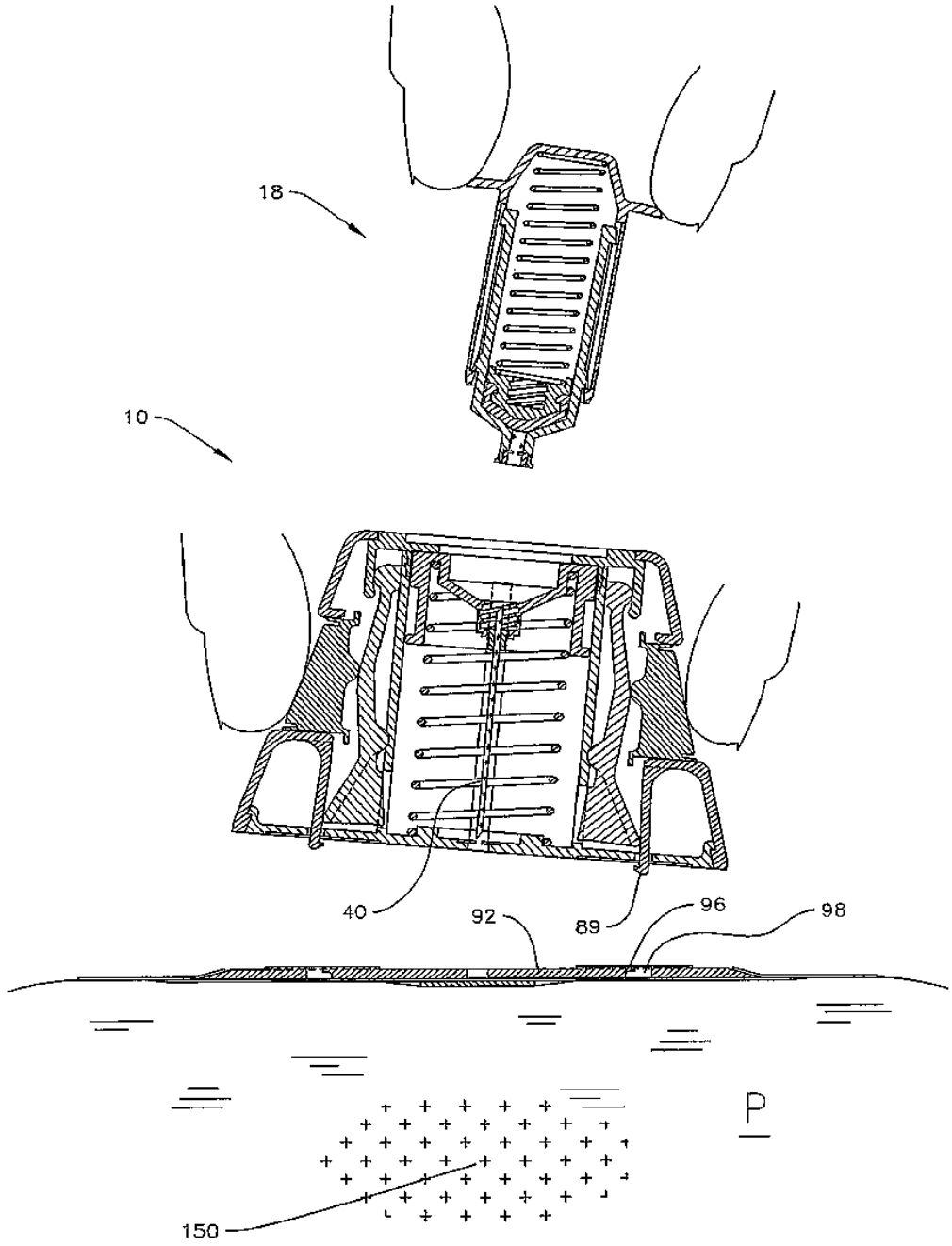


Fig. 28

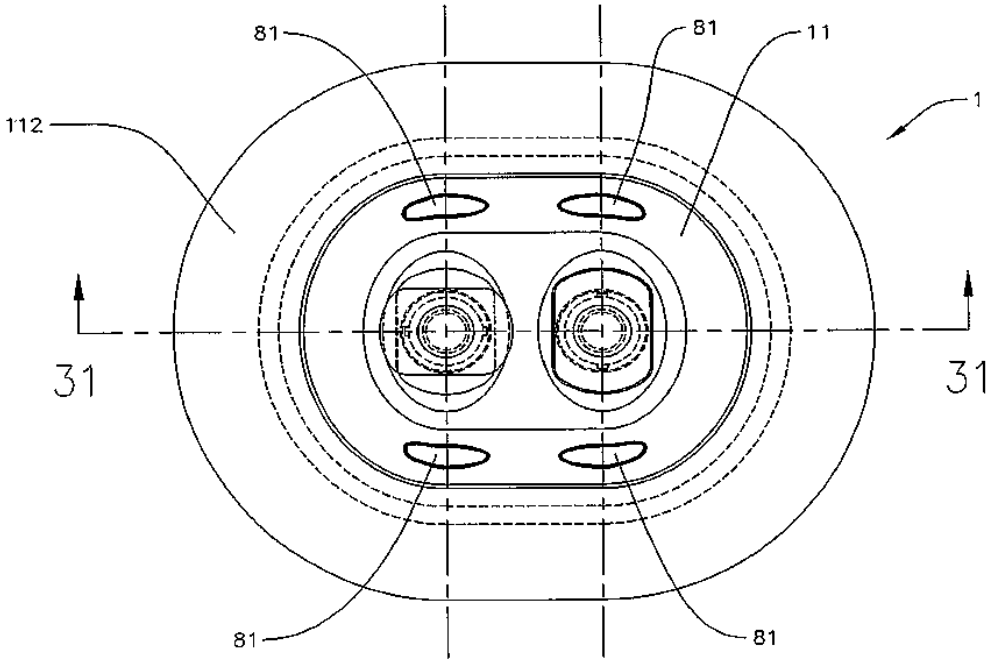


Fig. 29

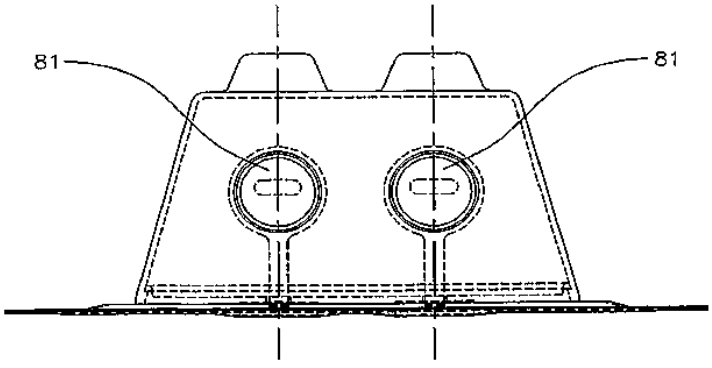


Fig. 30

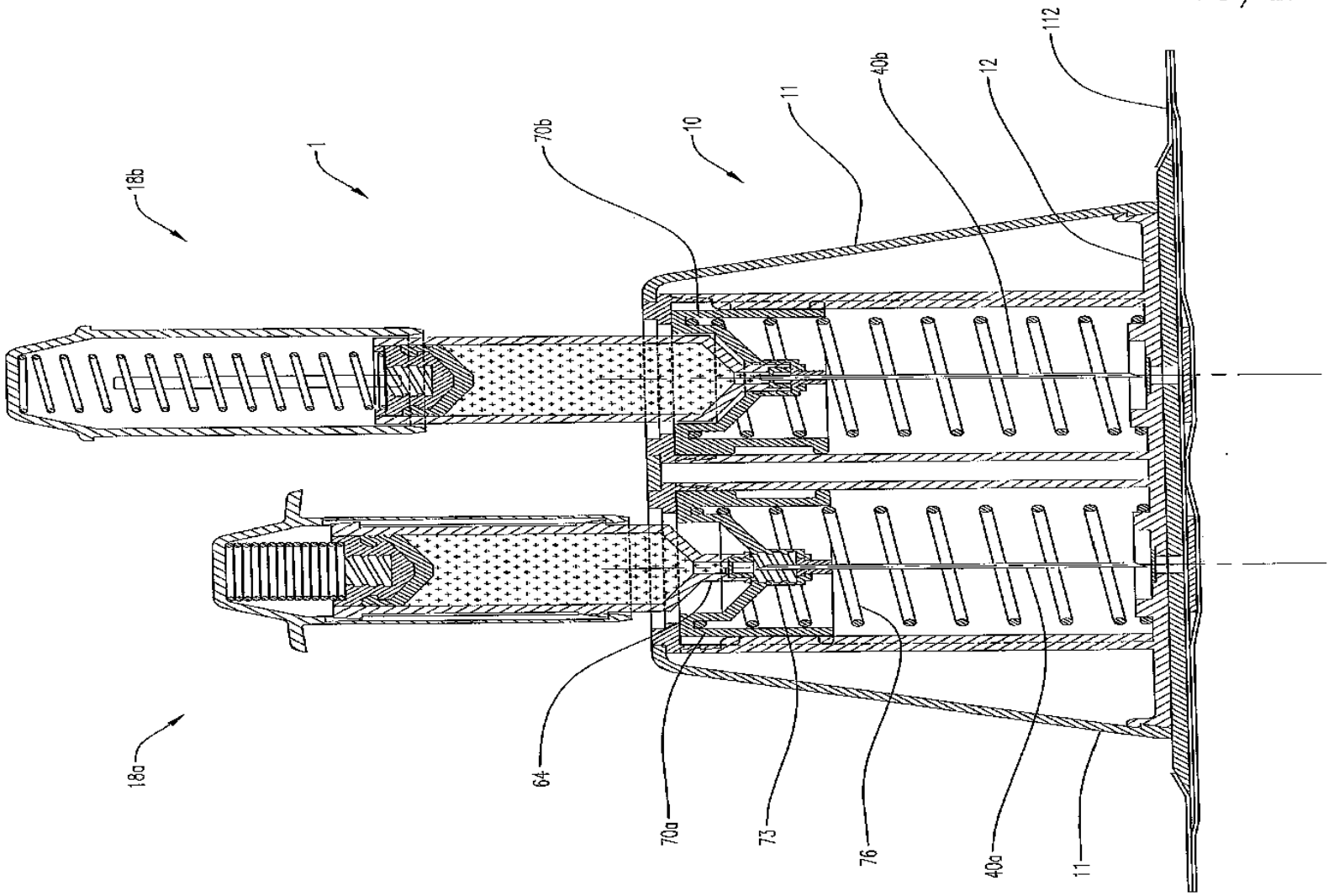


Fig. 31

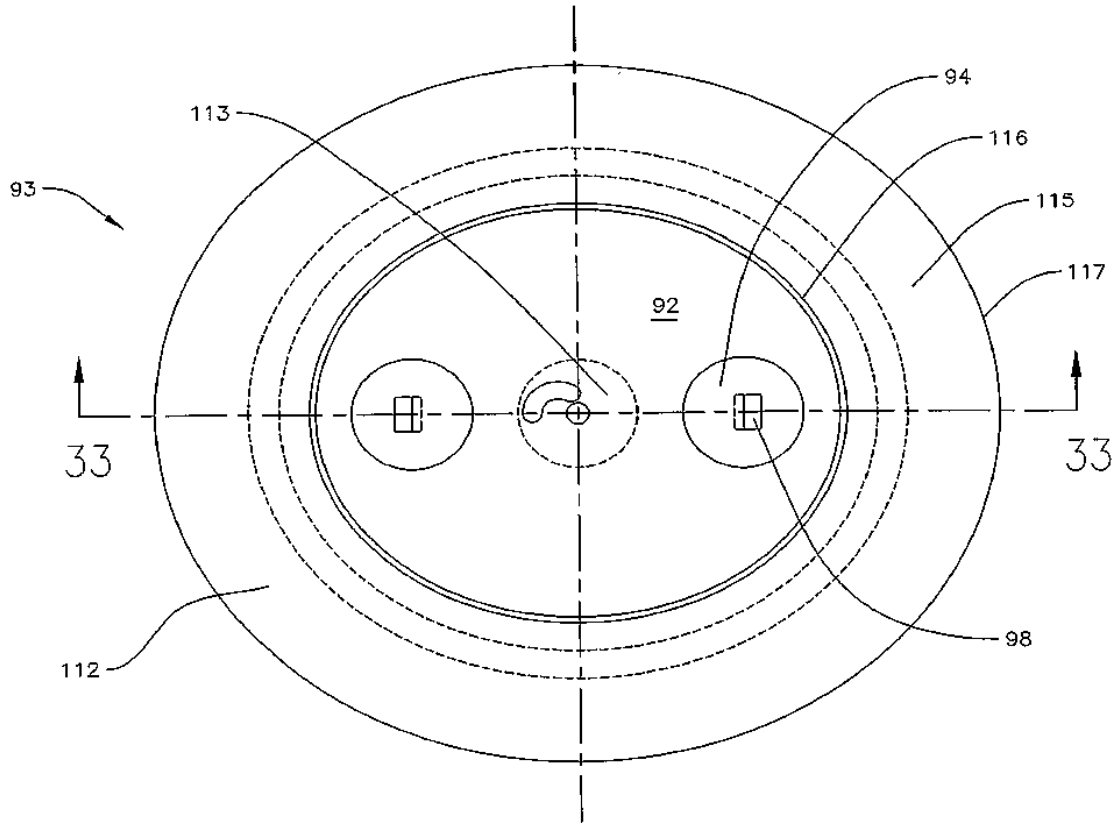


Fig. 32

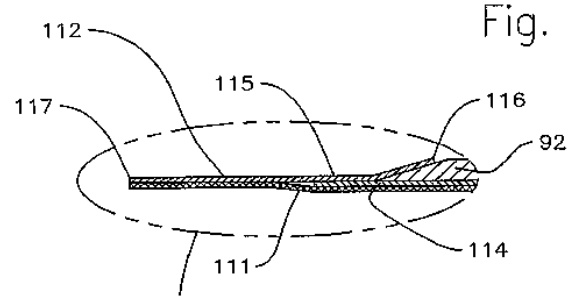


Fig. 34

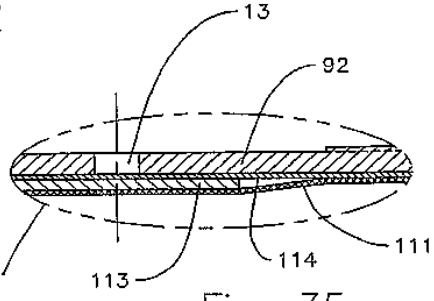


Fig. 35

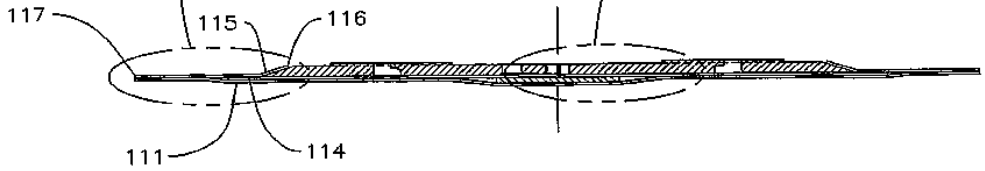


Fig. 33

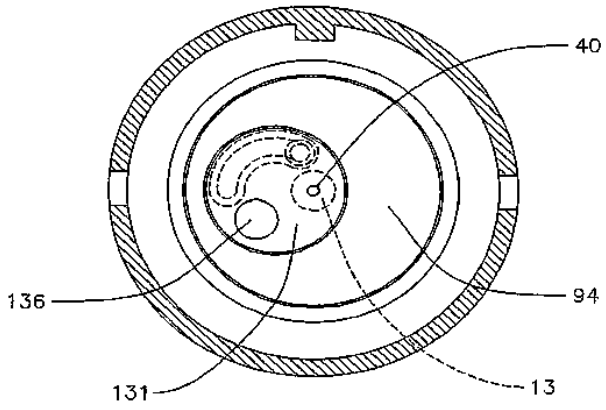


Fig. 38

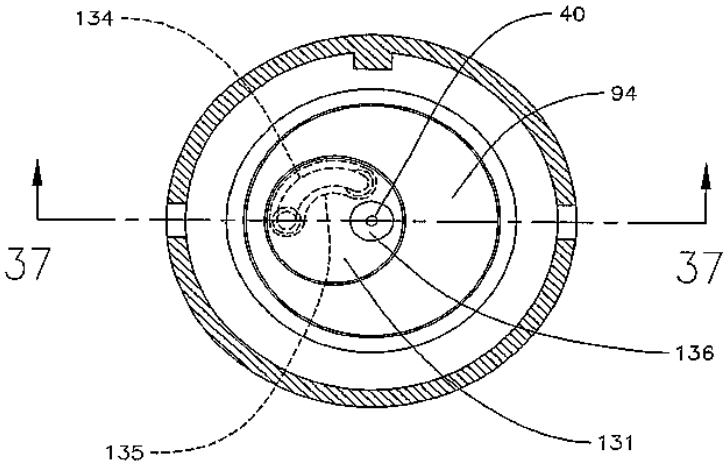


Fig. 36

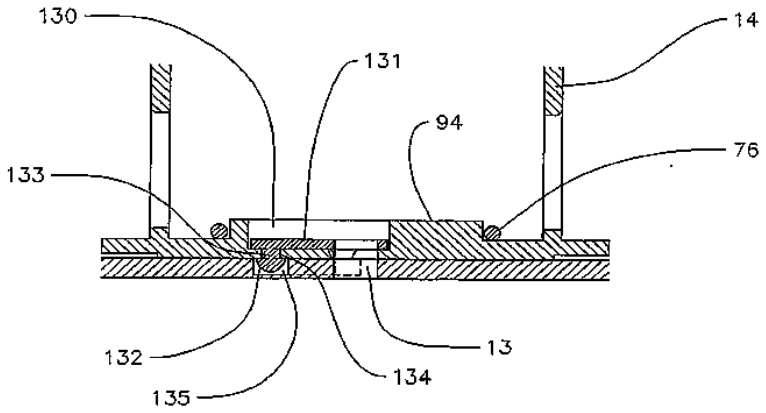


Fig. 37

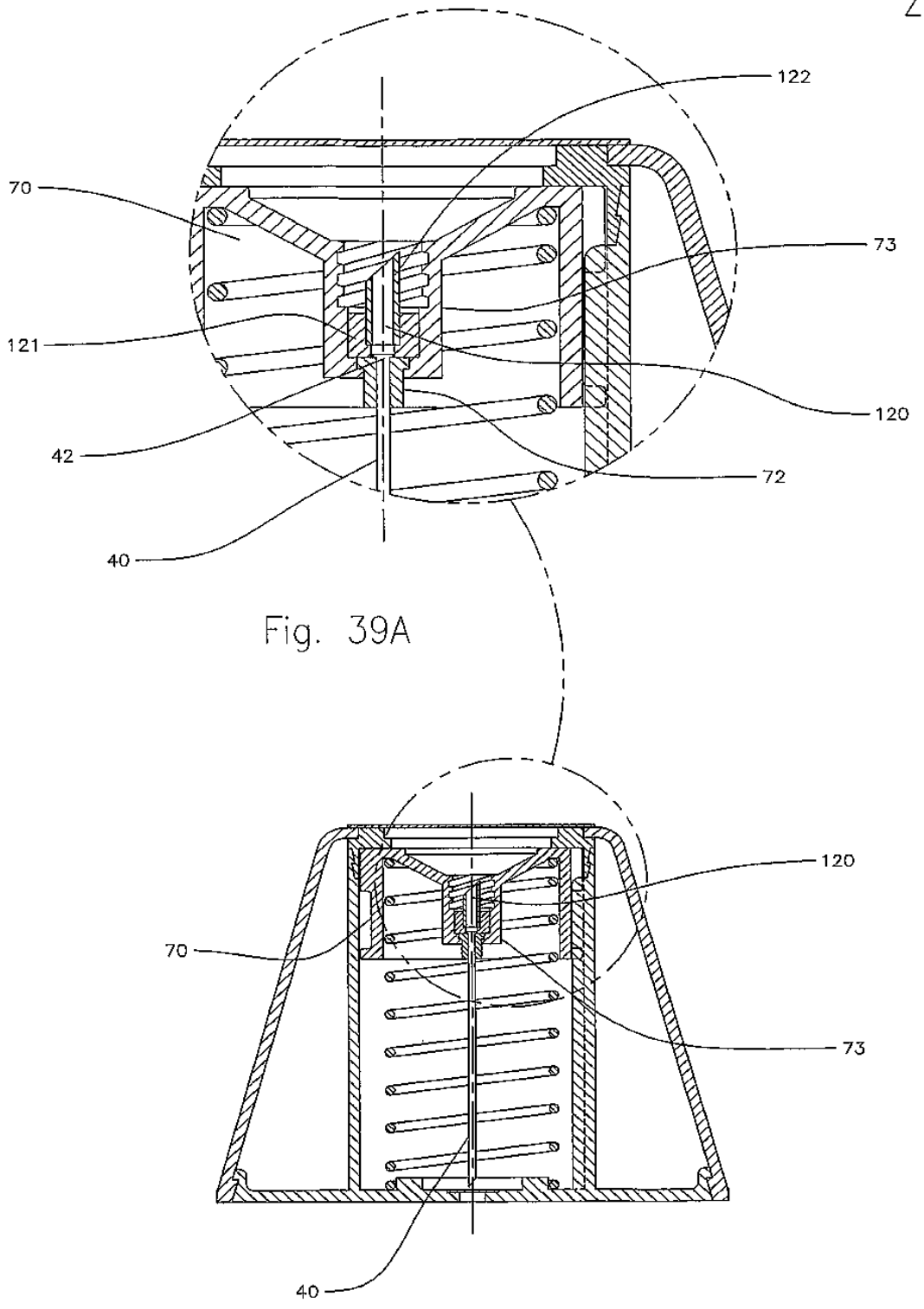


Fig. 39A

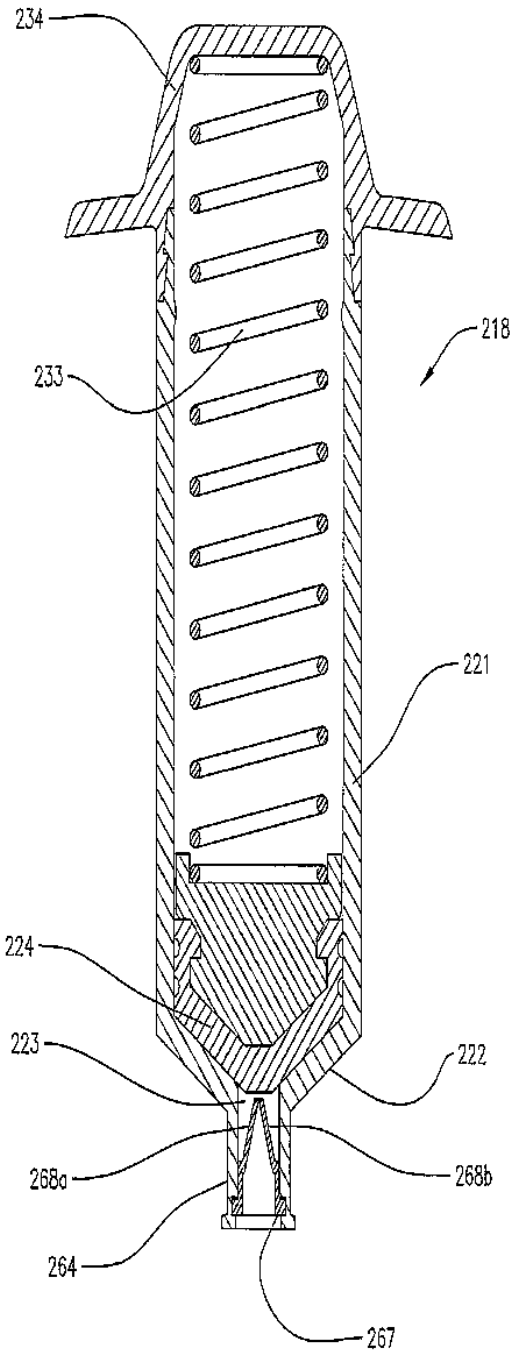

234
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Fig. 40

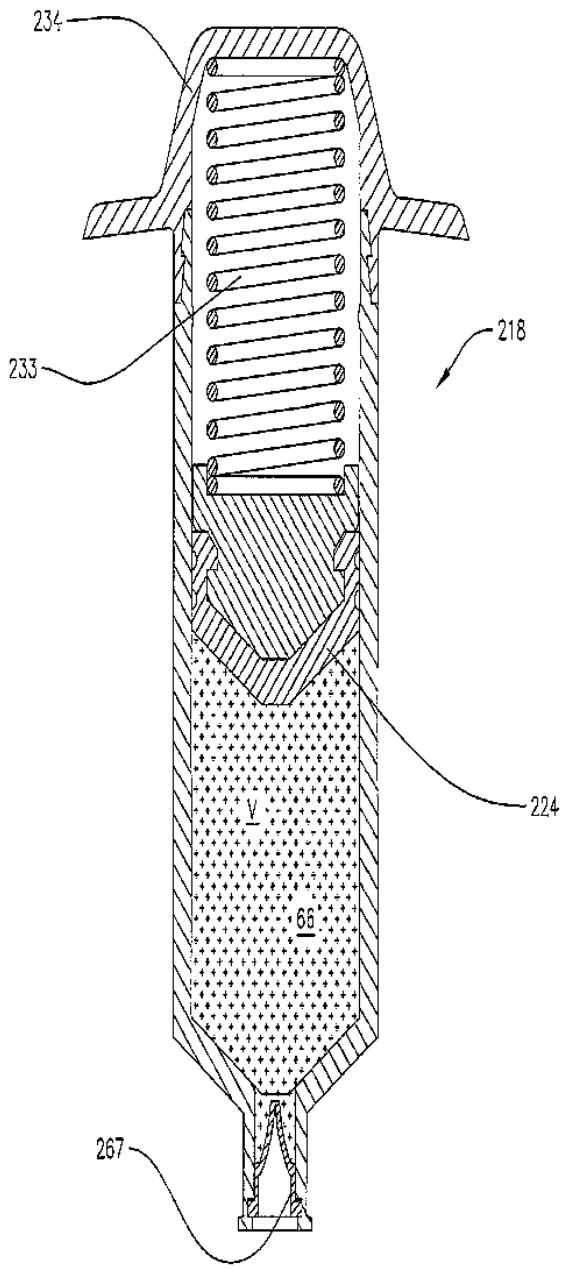

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Fig. 41

Fig. 42A

Fig. 42

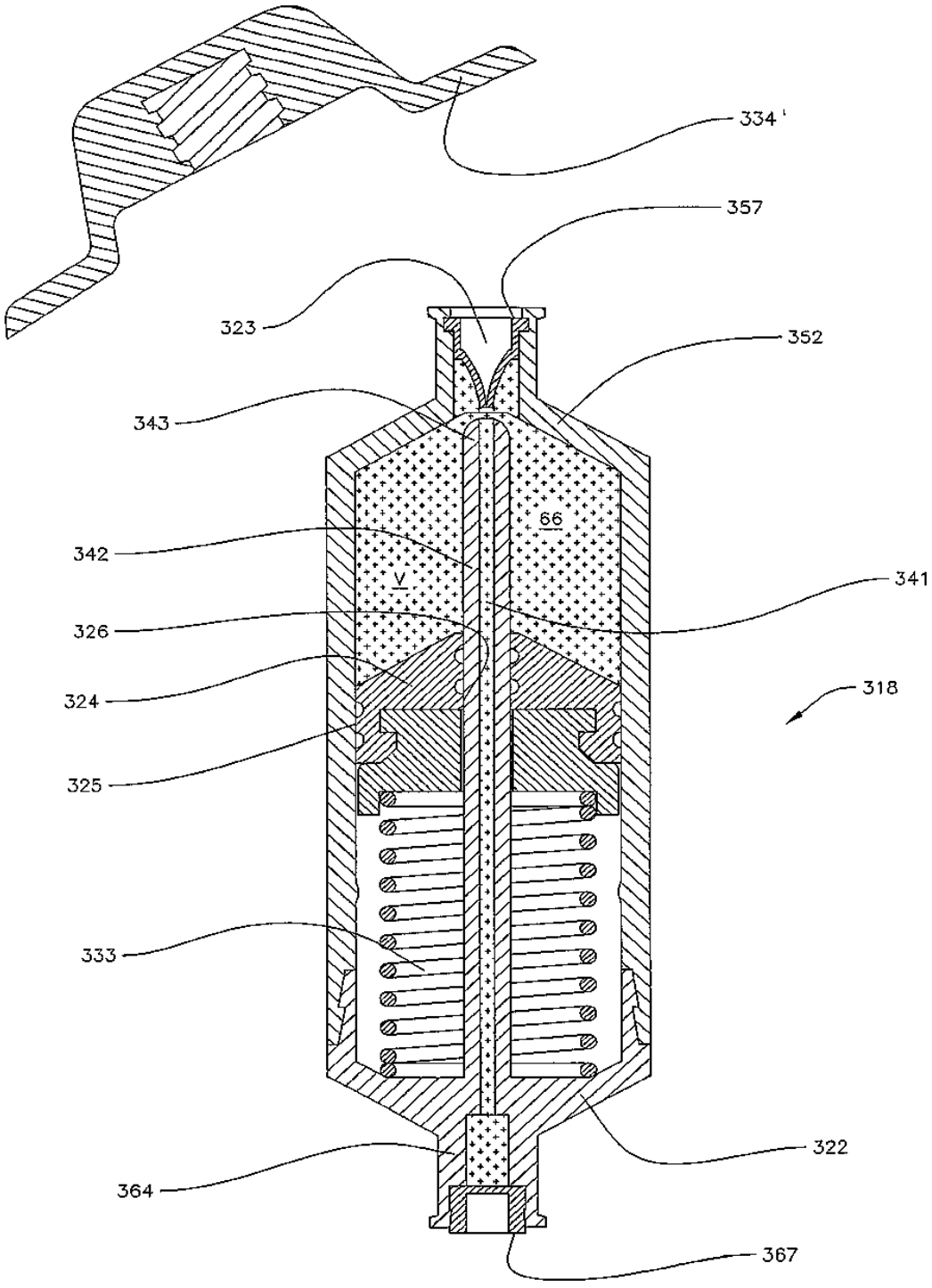


Fig. 43

281
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Fig. 44

Electronic Acknowledgement Receipt

EFS ID:	44551001
Application Number:	17181057
International Application Number:	
Confirmation Number:	4690
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	58249
Filer:	Kassity L. Mai/Donna Doyle
Filer Authorized By:	Kassity L. Mai
Attorney Docket Number:	ELVI-002/06US
Receipt Date:	17-DEC-2021
Filing Date:	22-FEB-2021
Time Stamp:	18:41:20
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		ELVI_002_06US_Preliminary_Amendment.pdf	140479 949ea1289cd835f3ad42a4577092106ea29b755b	yes	7

	Multipart Description/PDF files in .zip description			
	Document Description	**Start**	**End**	
	Preliminary Amendment	1	1	
	Claims	2	6	
	Applicant Arguments/Remarks Made in an Amendment	7	7	
Warnings:				
Information:				
2	Transmittal Letter	ELVI-002-06US_IDS_Transmittal.pdf	121422 8cdd4991c96e1104e84665ec4c9e788ff70bf52	no	5
Warnings:				
Information:				
3	Information Disclosure Statement (IDS) Form (SB08)	ELVI-002_06US_SB08.pdf	198710 93ee84ef4b3b6e1dd6a95df4f599b3d720561dba	no	2
Warnings:				
Information:				
This is not an USPTO supplied IDS fillable form				
4	Foreign Reference	CN101549180A_EFS.pdf	1275076 f54627a3a1fd62e612dbea1ab0f2629f45e1ee73	no	29
Warnings:				
Information:				
5	Foreign Reference	GB2435617B_EFS.pdf	1960765 a0a3627bb157bf6bb2c164b58166364714e910b0	no	67
Warnings:				
Information:				
6	Other Reference-Patent/App/Search documents	002-04WO_ISR.pdf	309414 d00a7d0b55be23742a16f08f55945a2aa00c3979	no	9
Warnings:				
Information:				

7	Foreign Reference	WO2005079441A2.pdf	3510260 39d881c285fcb2a70a4f5ef12d44bf42845c7d56	no	69
Warnings:					
Information:					
			Total Files Size (in bytes):	7516126	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Docket No.: ELVI-002/06US 339454-2025
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Jonathan O'TOOLE	Confirmation No.:	4690
Application No.:	17/181,057	Group Art Unit:	3783
Filed:	February 22, 2021	Examiner:	C. B. Fredrickson

For: BREAST PUMP SYSTEM

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Prior to examination of the above-identified application, please amend the above-captioned application as follows:

Amendments to the Claims are reflected on the listing of the claims which begins on page 2 of this paper.

Remarks begin on page 7 of this paper.

IN THE CLAIMS:

Set forth below in ascending order, with status identifiers, is a complete listing of all claims currently under examination. Changes to any amended claims are indicated by [[double brackets]], ~~strikethrough~~ and/or underlining. This listing also reflects any cancellation and/or addition of claims.

1. (Currently Amended) A breast pump device that is configured as a self-contained, in-bra wearable device, comprising ~~and includes~~:

(i) a housing that includes (a) a ~~rechargeable~~ battery, and (b) ~~control electronics, (c)~~ a pump generating negative air pressure;

(ii) a breast shield of a plurality of interchangeable breast shields each having a different size and being configured to slide in and out of the housing, the breast shield made up of a breast flange and a nipple tunnel ~~and that is configured to be slid in and out of the housing~~, in which the breast shield is transparent or optically clear ~~and comes in several different sizes, each of which are configured to slide in and out of the same housing~~; and

(iii) a milk container that is configured to be attached to and removed from the housing ~~device~~.

2. (Currently Amended) The kit of Claim 31~~breast pump device of Claim 1~~, in which the plurality of interchangeable breast shields ~~different sizes of the breast shield~~ each provide a different spacing of [[the]]a nipple from side walls of the nipple tunnel[[,]] when [[the]]that breast shield has been placed onto a breast.

3. (Original) The breast pump device of Claim 1, in which the breast shield is rigid.

4. (Currently Amended) The breast pump device of Claim 1, in which the breast shield is a ~~an optically clear,~~ dishwasher safe, plastic ~~polycarbonate~~ breast shield.

5. (Currently Amended) The breast pump device of Claim 1, in which the breast shield is configured to attach ~~attaches~~ using magnets to the housing.

6. (Currently Amended) The breast pump device of Claim 1, in which the breast shield is configured to rotate smoothly around [[the]]a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto [[the]]a breast.

7. (Currently Amended) The breast pump device of Claim 1, in which the breast shield presents, in use, a single continuous surface to [[the]]a nipple and a breast.

8. (Currently Amended) The breast pump device of Claim 1, in which the breast shield integrates the breast flange and the nipple tunnel as a single item.

9. (Currently Amended) The breast pump device of Claim 1, in which the breast shield is generally symmetrical about a centre-line running from [[the]]a top to [[the]]a bottom of the breast shield when positioned upright for normal use.

10. (Original) The breast pump device of Claim 1, in which the breast shield is configured to slide into the housing with a single push action.

11. (Original) The breast pump device of Claim 1, in which the breast shield is configured to slide out from the housing, together with a membrane that prevents milk from flowing into the pump.

12. (Original) The breast pump device of Claim 1, in which the milk container is rigid.

13. (Currently Amended) The breast pump device of Claim 1, in which the milk container is an optically clear, dishwasher safe, plastic ~~polycarbonate~~ milk container.

14. (Currently Amended) The breast pump device of Claim 1, in which milk container attaches to a lower part of the housing and forms [[the]]a base of the breast pump device.

15. (Currently Amended) The breast pump device of Claim 1, in which the milk container is configured to magnetically attach ~~attaches~~ to the housing.

16. (Currently Amended) The breast pump device of Claim 1, in which the nipple tunnel includes guide lines running parallel ~~to the~~ along one or more sides of the nipple tunnel.

17. (Original) The breast pump device of Claim 1, in which the nipple tunnel includes an air hole or passage, and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage.

18. (Currently Amended) The breast pump device of Claim 1, in which the nipple tunnel includes on [[its]]a lower surface of the nipple tunnel an opening through which expressed milk flows into the milk container.

19. (Currently Amended) The breast pump device of Claim 1, in which the pump ~~the housing~~ includes one or more piezo air pumps.

20. (Currently Amended) The breast pump device of Claim 1, in which the housing further includes a Universal Serial Bus (USB) charging socket.

21. (Currently Amended) The breast pump device of Claim 1, in which the housing includes a left or right breast selector or toggle switch ~~on the housing,~~ that, when selected for a particular pumping session ~~sessions~~, sends data to a connected [[app]]application configured to track ~~that tracks~~ pumping sessions, to indicate whether that particular session is associated with [[the]]a left or [[the]]a right breast.

22. (Currently Amended) The breast pump device of Claim 1, in which the housing is shaped to fit inside a bra by having an outer surface that is curved to fit [[the]] contours of a bra.

23. (Canceled) .

24. (Currently Amended) The breast pump device of Claim 1, in which the breast pump device is configured to deliver a maximum suction of approximately 240 mmHg.

25. (Currently Amended) The breast pump device of Claim 1, in which the breast pump device includes a sensor that is configured to directly ~~measures the~~ measure a level of [[the]] milk in the milk container by measuring [[the]]an intensity of light reflected from [[the]]a surface of the milk stored in the milk container.

26. (Canceled)

27. (Canceled)

28. (Currently Amended) The breast pump device of Claim 1, in which the pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

29. (Currently Amended) The breast pump device of Claim 1, in which the pump is a lightweight air pump that enables [[the]]a total mass of the breast pump device, unfilled with milk, to be less than 250 gm

30. (Currently Amended) The breast pump device of Claim 1, in which the breast pump device makes less than 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

31. (New) A kit, comprising:

the breast pump device of Claim 1; and

the plurality of interchangeable breast shields.

32. (New) The kit of Claim 31, wherein each of the plurality of interchangeable breast shields includes fit lines in a nipple tunnel of that breast shield that are configured to enable a user to

visually inspect whether that breast shield is sized for a nipple of the user when the nipple is placed in the nipple tunnel.

33. (New) The breast pump device of Claim 1, wherein the battery is a rechargeable battery, and the housing further includes (c) a power charging circuit for controlling the charging of the rechargeable battery, and (d) control electronics powered by the rechargeable battery.

REMARKS

Entry and consideration of the foregoing amendments is respectfully requested. The above-noted amendments are supported by the application as originally filed and do not introduce any new matter.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

Dated: December 17, 2021

Respectfully submitted,
COOLEY LLP

By: /Kassity L. Mai/
Kassity L. Mai
Reg. No. 68,774
C. Scott Talbot
Reg. No. 34,262

USPTO CUSTOMER NO. 58249

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Tel: (202) 842-7853
Fax: (202) 842-7899

Docket No.: ELVI-002/06US 339454-2025
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Jonathan O'TOOLE	Confirmation No.:	4690
Application No.:	17/181,057	Group Art Unit:	3783
Filed:	February 22, 2021	Examiner:	Courtney B. FREDRICKSON

For: BREAST PUMP SYSTEM

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.56, 1.97, AND 1.98

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98. It is respectfully requested that the information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

[x] Pursuant to 37 C.F.R. §1.98, a copy of each non-US patent document except for cite nos. 26, 28, 29 and 33 cited on the attached Form used in lieu of PTO/SB/08 is enclosed.

[x] No copies of the foreign patent, foreign patent application, or non-patent literature publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98(d) except for cite nos. 26, 28, 29 and 33 because the publications were previously cited by or submitted to the Office in prior Application Serial No(s). 16/009,547 to which the above-identified application claims priority under 35 U.S.C. §120.

[x] No copies of any U.S. patents or U.S. patent application publications listed on the attached Form used in lieu of PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98.

[] Publication(s) listed on the attached Form used in lieu of PTO/SB/08 were cited in a foreign search or examination report corresponding to application serial no. and mailed on .

[] Enclosed is a copy of a non-English publication(s) _____ Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).

[] Enclosed is a copy of a non-English publication(s) _____ English language publication _____ (copy enclosed) claims priority from this non-English publication.

[] Enclosed is an explanation of non-English publication(s) _____ for which an English translation is not available.

[] Enclosed is an English translation of non-English publication(s) _____ cited on the attached Form used in lieu of PTO/SB/08.

[] Enclosed is an English language Abstract of non-English publication(s) _____ cited on the attached Form used in lieu of PTO/SB/08.

[] Enclosed is a copy of pending patent Application No. _____.

[x] In accordance with **37 C.F.R. §1.97(b)**, no additional fee for submission of this Information Disclosure Statement is required, as it is filed within any one of the following time periods:

[] within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);

[] within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;

[x] before the mailing date of a first Office action on the merits; or

[] before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

[] In accordance with **37 C.F.R. §1.97(c)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of any of the following: a final action under 37 C.F.R. §1.113; a notice of allowance under 37 C.F.R. §1.311; or an action that otherwise closes prosecution in this application.

In accordance with 37 C.F.R. §1.97(c) also enclosed is:

[] Fee under 37 C.F.R. §1.17(p) in the amount of $260.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $130.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $65.00; or

[] Statement as specified in 37 C.F.R. §1.97(e):

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] This Information Disclosure Statement is filed after payment of the issue fee, but before issuance of the patent under the Quick Path Information Disclosure Statement pilot program.

In accordance with the Quick Path Information Disclosure Statement pilot program also enclosed is:

[] Fee under 37 C.F.R. §1.17(p) in the amount of $260.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $130.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $65.00;

and

[] Statement as specified in 37 C.F.R. §1.97(e):

[] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or

[] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. §1.97(d)**, this Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(c), but with or before the payment of the issue fee.

In accordance with 37 C.F.R. §1.97(d) also enclosed is:

[] Fee under 37 C.F.R. §1.17(p) in the amount of $260.00;

[] Fee under 37 C.F.R. §1.17(p) in the amount of $130.00; or

[] Fee under 37 C.F.R. §1.17(p) in the amount of $65.00;

and

[] Statement as specified in 37 C.F.R. §1.97(e):

- [] Each item of information contained in the Information Disclosure Statement cited herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or
- [] No item of information contained in the Information Disclosure Statement submitted herewith was cited in any communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

[] In accordance with **37 C.F.R. § 1.704(d)**, Applicant notes that to our knowledge each item of information contained in the information disclosure statement:

- [] was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.
- [] is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § **1.56(c)** more than thirty days prior to the filing of the information disclosure statement.

In accordance with 37 C.F.R. § 1.97(g), this Information Disclosure Statement shall not be construed as to mean that a search has been made.

In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be material to patentability as defined by 37 C.F.R § 1.56(b).

Remarks

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form used in lieu of PTO/SB/08 to the undersigned.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Applicant believes no fee is due with this response.

Dated: December 17, 2021

Respectfully submitted,
COOLEY LLP

Electronic signature: /Kassity L. Mai/
Kassity L. Mai
Reg. No. 68,774
C. Scott Talbot
Reg. No. 34,262

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PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/181,057	Filing Date 02/22/2021	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $240 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	12/17/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 29	Minus	** 30	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $240 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/LISA R EPPS/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/181,057	02/22/2021	Jonathan O'TOOLE	373499.00049

CONFIRMATION NO. 4690

78905
Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

POWER OF ATTORNEY NOTICE

OC000000128525873

Date Mailed: 09/21/2021

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 09/16/2021.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/ttran/

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/181,057	02/22/2021	Jonathan O'TOOLE	ELVI-002/06US

CONFIRMATION NO. 4690

58249
COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004

POA ACCEPTANCE LETTER

OC000000128525909

Date Mailed: 09/21/2021

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 09/16/2021.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/ttran/

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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If the TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	17/181,057
Filing Date	February 22, 2021
First Named Inventor	Jonathan O'TOOLE
Title	BREAST PUMP SYSTEM
Art Unit	3783
Examiner Name	Courtney B. Fredrickson
Attorney Docket Number	ELVI-002/06US

SIGNATURE of Applicant or Patent Practitioner

Signature	/Kassity L. Mai/	Date (Optional)	September 16, 2021
Name	Kassity L. Mai	Registration Number	68,774
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ *Total of 1 forms are submitted.

256907869 v1

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

[X] I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 58249

OR

[ ] I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

[X] The address associated with the above-mentioned Customer Number

OR

[ ] The address associated with Customer Number:

OR

[ ] Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Chiaro Technology Limited

[ ] Inventor or Joint Inventor (title not required below)

[ ] Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

[X] Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

[ ] Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	Hannah Brunskill	Date (Optional)	September 13, 2021
Name	Hannah Brunskill		
Title	Head of Legal		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

[X] Total of 1 forms are submitted.

Electronic Acknowledgement Receipt

EFS ID:	43786749
Application Number:	17181057
International Application Number:	
Confirmation Number:	4690
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	78905
Filer:	Kassity L. Mai/Julie Chandler
Filer Authorized By:	Kassity L. Mai
Attorney Docket Number:	373499.00049
Receipt Date:	16-SEP-2021
Filing Date:	22-FEB-2021
Time Stamp:	16:52:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	ELVI_002_06US_Power_Of_attorney.pdf	119126 c86d0c5919fa8711974Ba8b379a058ebcaaa8ab2	no	2

Warnings:

Information:	
Total Files Size (in bytes):	119126

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17181057
Filing Date	2021-02-22
First Named Inventor	Jonathan O'Toole
Art Unit	3783
Examiner Name	
Attorney Docket Number	373499.00049

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5542921	A	1996-08-06	MEYERS, et al.	
	2	7833190	B1	2010-11-16	HALL	

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20070135761	A1	2007-06-14	CHENG, et al.	
	2	20070179439	A1	2007-08-02	VOGELIN, et al.	
	3	20090281485	A1	2009-11-12	BAKER, et al.	
	4	20110009824	A1	2011-01-13	YODFAT, et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17181057
	Filing Date	2021-02-22
	First Named Inventor	Jonathan O'Toole
	Art Unit	3783
	Examiner Name	
	Attorney Docket Number	373499.00049

	5	20160271305	A1	2016-09-22	KURIHARA, et al.	
	6	20160296682	A1	2016-10-13	PHILLIPS, et al.	
	7	20160325031	A1	2016-11-10	MILLER, et al.	
	8	20170095599	A1	2017-04-06	KONDO, et al.	
	9	20170112983	A1	2017-04-27	THORNE, et al.	
	10	20180028733	A1	2018-02-01	RIGERT, et al.	
	11	20180333523	A1	2018-11-22	CHANG, et al.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							

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NON-PATENT LITERATURE DOCUMENTS Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	17181057
	Filing Date	2021-02-22
	First Named Inventor	Jonathan O'Toole
	Art Unit	3783
	Examiner Name	
	Attorney Docket Number	373499.00049

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17181057
	Filing Date	2021-02-22
	First Named Inventor	Jonathan O'Toole
	Art Unit	3783
	Examiner Name	
	Attorney Docket Number	373499.00049

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

✓ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Mark D. Simpson/	Date (YYYY-MM-DD)	2021-09-05
Name/Print	Mark D. Simpson	Registration Number	32942

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	43688914
Application Number:	17181057
International Application Number:	
Confirmation Number:	4690
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	78905
Filer:	Mark D. Simpson/Lynn White
Filer Authorized By:	Mark D. Simpson
Attorney Docket Number:	373499.00049
Receipt Date:	05-SEP-2021
Filing Date:	22-FEB-2021
Time Stamp:	19:42:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	38945165_1.PDF	1035283 f7c2571aacda3d7b74c7754f87b8c232447b a959	no	5

Warnings:

Information:	
Total Files Size (in bytes):	1035283

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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UNITED STATES DEPARTMENT OF COMMERCE
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Alexandria, Virginia 22313-1450
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/181,057	02/22/2021	Jonathan O'TOOLE	373499.00049

CONFIRMATION NO. 4690

78905
Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

PUBLICATION NOTICE

OC000000126216052

Title:BREAST PUMP SYSTEM

Publication No.US-2021-0170080-A1
Publication Date:06/10/2021

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently https://portal.uspto.gov/pair/PublicPair. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
17/181,057	02/22/2021	3783	1540	373499.00049	30	1

CONFIRMATION NO. 4690

78905
Saul Ewing Arnstein & Lehr LLP (Philadelphia)
Attn: Patent Docket Clerk
Centre Square West
1500 Market Street, 38th Floor
Philadelphia, PA 19102-2186

FILING RECEIPT

OC000000123774298

Date Mailed: 03/03/2021

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Jonathan O'TOOLE, London, UNITED KINGDOM;
Adam ROLLO, London, UNITED KINGDOM;
Andrew CARR, London, UNITED KINGDOM;

Applicant(s)

CHIARO TECHNOLOGY LIMITED, London, UNITED KINGDOM;

Power of Attorney: The patent practitioners associated with Customer Number 78905

Domestic Priority data as claimed by applicant

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UNITED KINGDOM 1709561.3 06/15/2017 Access Code Provided
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The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/181,057**

Projected Publication Date: 06/10/2021

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

BREAST PUMP SYSTEM

Preliminary Class

604

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 17/181,057

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	80		N/A	
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	350		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	400		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	30 minus 20 =	* 10	x 50 =	500	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	x 240 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			210			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	1540		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)	OR	RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

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Dated 19 June 2017

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Patents Act 1977 *(Rule 12)*

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Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

Application number GB 1709566.2

1.	Your reference	**MJD/P153992GB00**
2.	Full name, address and postcode of the applicant or of each applicant	**CHIARO TECHNOLOGY LIMITED** **Second Floor 63-66 Hatton Garden** **London EC1N 8LE** **Greater London** **United Kingdom**
	Patents ADP number *(if you know it)*	**11287869002**
3.	Title of the invention	**BREAST PUMP**
4.	Name of your agent *(if you have one)*	**Boult Wade Tennant**
	"Address for service" to which all correspondence should be sent. This may be in the European Economic area or Channel Islands (see warning note below) *(including the postcode)*	**Boult Wade Tennant** **Verulam Gardens** **70, Gray's Inn Road** **London WC1X 8BT** **United Kingdom**
	Patents ADP number *(if you know it)*	**42001**
5.	Priority declaration: Are you claiming priority from one or more earlier-filed patent applications? If so, please give details of the application(s)	

Country	Application number	Date of filing	PDAS Access Code
6. Divisionals etc: Is this application a divisional application, or being made following resolution of an entitlement dispute about an earlier application. If so, please give the application number and filing date of the earlier application		Number of earlier UK application	Date of filing *(day / month / year)*

7.	Inventorship: (Inventors must be individuals not companies) Are all the applicants named above also inventors?	**No**
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Patents Form 1

9. Accompanying documents: please enter the number of pages of each item accompanying this form.

Continuation sheets of this form

Description:	**20**
Claim(s):	**6**
Abstract:	**n/a**
Drawing(s):	**13**

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Priority documents:	**0**
Statement of inventorship and right to grant of a patent (Patents Form 7):	**1**
Request for search (Patents Form 9A):	**1**
Request for a substantive examination (Patents Form 10):	**0**
Any other documents (please specify):	**PDAS Registration Form**

11. I/We request the grant of a patent on the basis of this application.

Signature: **/DRAPER, Martyn John/** Date: **15 Jun 2017**

12. Name, e-mail address, telephone, fax and/or mobile number, if any, of a contact point for the applicant

DRAPER, Mr Martyn
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Fax: 020 7430 7600

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BREAST PUMP

BACKGROUND

A breast pump is a mechanical device that extracts milk from the breasts of a lactating woman.

The typical breast pump design is as shown in WO 96/25187 A1. A large suction generating device is provided, which is freestanding. This is attached by air lines to one or two breast shields which engage with the user's breasts. A pressure cycle is applied from the suction generating device, via the air lines, to the breast shields. This generates a pressure cycle on the user's breasts to simulate the suction generated by a feeding child. The suction generating device is a large component that connects to mains power to operate the pumps therein.

Milk collection bottles are provided to store the expressed breast milk. In the system of WO 96/36298 A1 separate bottles are provided attached to each breast shield. However, in alternative embodiments there may be a single bottle with tubing connecting the breast shields thereto. For a mother to use this somewhat discretely, such as in an office environment, specialised bras must be used. In particular, breast-pumping bras which have a central slit, for the spout of the breast shield to extend through are typically used. The breast shield is held within the bra, with the suction generating device and milk bottle outside the bra.

The fundamental breast pump system has not been significantly altered from this, with minor technical improvements being the main developments.

However, these systems present a number of significant disadvantages. As the suction generating device is a large freestanding unit connected to the mains power, the user may feel tethered to the wall. The devices also require a specific user posture and undressing to function normally. This is obviously difficult for a user to do discretely, such as in an office setting.

Fully integrated wearable breast pumps have begun to enter the market, such as US 2016 206794 A1. In such pumps, the suction source, power supply and milk container are locally provided, without the need for bulky external components or connections. Such devices can be provided with a substantially breast shaped profile so as to fit within a

user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations.

In US 2016 206794 A1, the breast pump has an offset shape favouring the lower half of the pump, and requires complex collapsible bag systems as milk collection devices. This is to force the pump to fit within the user's existing bras.

As the collection bag systems are collapsible, it will be very difficult for a user to extract all of their milk from the bag due to the small cut opening and capillary action between the bonded plastic sheets. This waste can be disheartening for the user as this is food for their child. The bags are also not re-usable, so the user is required to purchase and maintain a stock of these. As well as presenting a recurring cost, if the user runs out of stock they are unable to use the product until more bags are purchased.

Furthermore, as a result of the collapsible bags, a complex pumping arrangement is necessary. In particular, the breast shield connects to a tube which is provided with a plurality of compression units which "step" the expressed milk through the tube to the collection bag. This uses the breast milk as a hydraulic fluid to generate suction on the breast. In order to carry this out, a complex sequenced pulsing arrangement must be implemented.

In addition to these systems being particularly complex and wasteful, a relatively small bag must be used. In US 2016 206794, approximately 110 ml (4 fluid ounces) of milk can be collected before the bag must be changed. While this may be sufficient for some users, others may produce much more milk in a session.

A further integrated wearable breast pump is shown in US 2013 0023821 A1. In the third embodiment in this document, an integral breast pump is provided including a motor driven vacuum pump and power source. An annular (or punctured disc) membrane is provided, with the flow path of the milk going through the centre of the annulus. The membrane is housed in separate housing components and is sealed at its inner and outer edges. The breast shield has a small protrusion to engage with these housing components. However, the design of this breast pump results in a number of problems. The use of an annular membrane, with the fluid flow path running through the opening of the annulus is undesirable as it results in a large and bulky device.

There is therefore a need for improved integrated breast pump systems.

SUMMARY OF THE INVENTION

A breast pump according to a first embodiment of the present invention is provided according to claim 1. This breast pump is for wearing inside a bra, and comprises: a breast shield for engagement with the user's breast; a housing for receiving at least a portion of the breast shield; a pump inside the housing for generating a negative pressure in the breast shield; a battery inside the housing for powering the pump; a detachable rigid milk collection container attachable, in use, to a lower face of the housing and being in connected to the breast shield for collecting milk expressed by the user, with a milk-flow pathway defined from an opening in the breast shield to the milk collection container; and a barrier, the pump acting on one side of the barrier to generate a pressure on the opposite, milk-flow side of the barrier, the barrier having an outer periphery, wherein: the shield, housing, pump, battery and container are provided as a unit with a convex outer surface contoured to fit in a bra; and the milk-flow pathway extends past the outer periphery of the barrier.

This breast pump allows discrete wearing and use, which can fit within a user's bra. The milk-flow path extending past the outer periphery of the barrier allows for a simpler and more robust design, without the milk-flow pathway extending through the barrier. This provides increased interior space and functionality of the device.

A breast pump according to a second embodiment of the present invention is provided according to claim 2. The breast pump is for wearing inside a bra, the breast pump comprising: a breast shield for engagement with the user's breast; a housing for receiving at least a portion of the breast shield; a pump inside the housing for generating a negative pressure in the breast shield; a battery inside the housing for powering the pump; a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user with a milk-flow pathway defined from an opening in the breast shield to the milk collection container, wherein: the shield, housing, pump, battery and container are provided as a unit with a convex outer surface contoured to fit in a bra; and the breast shield comprises a shield flange for engaging the user's breast, and an elongate spout aligned with the opening and extending away from the user's breast, the spout being substantially aligned, in use, with the user's nipple and areolae; the spout comprising a first opening for depositing milk into

the collection container and a second opening for transferring pressure generated by the pump to the user's nipple, the shield flange and spout being detachable from the housing together.

This breast pump allows discrete wearing and use, which can fit within a user's bra. The shield flange and spout being detachable together helps further simplify the design, and reduce the number of components which must be removed for cleaning and sterilisation.

A breast pump according to a third embodiment of the present invention is provided according to claim 3. This breast pump is for wearing inside a bra, and comprises: a breast shield for engagement with the user's breast; a housing for receiving at least a portion of the breast shield; a piezo pump inside the housing for generating a negative pressure in the breast shield; a battery inside the housing for powering the pump; a detachable milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user with a milk-flow pathway defined from an opening in the breast shield to the milk collection container, wherein the shield, housing, pump, battery and container are provided as a unit with a convex outer surface contoured to fit in a bra.

This breast pump allows discrete wearing and use, which can fit within a user's bra. The piezo pump is ideally suited for this environment as it is low noise and high strength with a compact size.

The breast shield of embodiments 1 or 3 may further comprise a shield flange for engaging the user's breast, and an elongate spout aligned with the opening and extending away from the user's breast, the spout being substantially aligned, in use, with the user's nipple and areolae; the spout comprising a first opening for depositing milk into the collection container and a second opening for transferring pressure generated by the pump to the user's nipple.

The shield flange and spout may be detachable from the housing together. Preferably, the spout will be integral with the breast shield. This helps to simplify the design and reduce the number of components which must be removed for cleaning and sterilisation.

The breast shield cup may extend over a majority of the inner surface of the unit, preferably the breast shield extends over 80% of the inner surface of the unit. This reduces the risk of milk contacting a part of the device which cannot be easily sterilised. This also helps to disperse the pressure applied to the user's breast across a larger area. Additionally, by covering the majority of the inner surface, the breast shield is the only component which contact's the wearer's breast. This leaves fewer surfaces which require thorough cleaning.

The spout may connect directly to the container. By reducing the distance covered by the milk, the device is reduced in size and complexity of small intermediate portions.

The spout may comprise an opening directly above the milk collection container. By reducing the distance covered by the milk, the device is reduced in size and complexity of small intermediate portions.

The breast pump of the second or third embodiments may further comprise a barrier mounted in the breast pump, the pump acting on one side of the barrier to generate a pressure on the opposite, milk-flow, side of the barrier.

Preferably, the barrier has an outer periphery and the milk-flow pathway extends past the outer periphery of the barrier. This allows for a simpler and more robust design, without the milk-flow pathway extending through the barrier.

Preferably the milk-flow pathway extends beneath the barrier. This provides an added benefit of having gravity tend the milk away from the barrier.

Preferably the milk-flow pathway does not pass through the barrier. This results in a simpler and smaller barrier design.

Preferably, the barrier is mounted on a housing on the breast shield. More preferably, the housing is integral with the breast shield. This further helps increase the ease of cleaning and sterilisation as all of the components on the "dirty" side can be removed.

Preferably, the barrier is not an annulus.

The barrier may provide a seal to isolate the pump from the milk-flow side of the barrier. This helps to avoid the milk becoming contaminated from the "dirty" airflow side.

Preferably, the only seal is around an outer edge of the barrier. This is a simple design as only a single seal needs to be formed and maintained. Having multiple seals, such as for an annular membrane, introduces additional complexity and potential failure points.

Preferably, the barrier is a diaphragm.

Preferably, the diaphragm is a continuous membrane which is devoid of any openings or holes. This provides a larger effective "working" area of the diaphragm (i.e. the area of the surface in contact with the pneumatic gasses) than an annular membrane and hence the membrane may be smaller to have the same working area.

The breast pump may further comprise a pressure sensor in pneumatic connection with the piezo pump. This allows the output of the pump to be determined.

Preferably, the width of the breast pump is less than 110 mm.

Preferably, the height of the breast pump is less than 180 mm.

Preferably, the plane to plane depth of the breast pump less than 100 mm.

Preferably, in use, the breast pump extends from the user's breasts by between 3 to 4 cup sizes as per the European standard EN 13402.

Preferably, the milk container has a volume of greater than 120 ml. More preferably, the milk container has a volume of greater than 140 ml.

Preferably, the milk container has a volume of less than 150 ml.

The milk container and housing may form a substantially continuous outer surface of the breast pump. This helps ensure that the breast pump in use fits within a conventional bra system discretely.

The milk container may be at least partially transparent on the outer surface of the breast pump. This allows the level of milk within the container to be easily observed even while pumping.

The milk container may be provided with a spout. This makes it easier for the end user to pour the collected milk into other containers for use or storage.

The milk container may be provided with attachment means for attaching a teat to the container. This allows the milk container to be used directly as a drinking vessel for a child.

The breast shield may be removable. This allows the shield to be easily washed and sterilised.

The milk collection container may be formed of at least two rigid sections which are connectable. This allows simple cleaning of the container for re-use.

The breast pump may further comprise a one-way valve between an inner surface of the breast shield, for engaging with the breast in use, and the milk container.

The one-way valve may be located in an opening to the container.

The pump of the first or second embodiments may be a piezo pump.

The breast shield may be detachable from the breast pump.

The breast pump of the may further comprise a single pole, double throw pneumatic valve, wherein: the pole is in pneumatic connection with the pump and pressure sensor; one of the throws is in pneumatic connection with the diaphragm; and the other throw is in pneumatic connection with a dead-end.

The breast pump may further comprise: a first non-return valve between the milk-flow side of the diaphragm and the breast shield, configured to allow only a negative pressure to be applied to the breast shield by the pump; a second non-return valve between the milk-flow side of the diaphragm and the milk collection container configured to allow only a positive pressure to be applied to the milk collection container by the pump; and a pressure sensor in pneumatic connection with the pressure-generation side of the diaphragm.

A method of estimating the pressure applied by a breast pump according to an aspect of the present invention is provided according to claim 42, comprising the steps of: providing a breast pump according to the third embodiment; selecting a pressure cycle from a pre-defined list of pressure cycles; applying pressure with the pump to stimulate milk expression; reading the output of the pressure sensor; and adjusting the applied pressure of the pump to match the pressure profile selected. This allows for repeatable application of force to the breast, even as the pump performance degrades.

Preferably the method further comprises the steps of: approximating the elasticity and extension of the diaphragm at the relevant pressure; and calculating an estimated applied pressure based upon the output of the pressure sensor and the approximated elasticity and extension of the diaphragm.

A method of estimating the milk collected by a breast pump according to an aspect of the present invention is provided according to claim 44, comprising the steps of: providing a breast pump according to claim 33; generating a positive pressure with the pump; transmitting the positive pressure via the diaphragm and second non-return valve to only the milk collection container; measuring the increase in pressure by the pressure sensor in pneumatic connection with the diaphragm; estimating the volume of milk inside the milk collection container based upon the rate of increase of pressure. In this manner, the volume of milk can be estimated remotely.

DESCRIPTION OF THE FIGURES

The invention will now be described with respect to the Figures in which:

Figure 1 is a front view of an assembled breast pump;

Figure 2 is a rear view of the assembled breast pump of Figure 1;

Figure 3 is a front view of a partially disassembled breast pump;

Figure 4 is a rear view of the partially disassembled breast pump of Figure 3;

Figure 5 is a front view of a further partially disassembled breast pump;

Figure 6 is a rear view of the further partially disassembled breast pump of Figure 5;

Figure 7 is a front view of the breast pump of Figure 1, with the outer shell translucent for ease of explanation;

Figure 8 is a further front view of the breast pump of Figure 1, with the front of the outer shell removed for ease of explanation;

Figure 9 is a schematic view of a spout for a breast shield;

Figure 10 is a schematic of a pneumatic system for a breast pump;

Figure 11 is a schematic of an alternative pneumatic system for a breast pump;

Figure 12 is a schematic of a further alternative pneumatic system for a breast pump; and

Figure 13 is a graph depicting measured pressure in the breast pump system of Figure 12 over time.

DETAILED DESCRIPTION

Figure 1 is a front view of a breast pump 100 according to the present invention. The breast pump 100 comprises a housing 1 and a milk collection container (or bottle) 3. The milk collection container 3 is attached to a lower face 1A of the housing 1. While the breast pump 100 may be arranged to be used with one of the right or the left breast specifically, it is preferred the breast pump 100 can be used with either breast without modification. To this end, the outer surfaces of the breast pump 100 are preferably substantially symmetrical

The breast pump 100 is further provided with a user interface 5. This may take the form of a touchscreen and/or physical buttons. In particular, this may include buttons, sliders, any form of display, lights, or any other componentry necessary to control and indicate use of the breast pump 100. Such functions might include turning the breast pump 100 on, specifying which breast is being pumped, or increasing the peak pump pressure. Alternatively, the information provided through the user interface 5 might also be conveyed through haptic feedback, such as device vibration, driven from a miniature vibration motor within the pump housing 1.

In the particular embodiment of the Figures, the user interface 5 comprises power button 5A for turning the pump on and off. The user interface 5 further comprises pump up

button 5B and pump down button 5C. These buttons adjust the pressure generated by the pump and hence applied to the user's breast. In preferable embodiments, the pump up button 5B is physically larger than the pump down button 5C. A play/pause button 5D is provided for the user to interrupt the pumping process without turning the device on and off.

The user interface 5 further comprises a breast toggle button 5E for the user to toggle a display of which breast is being pumped. This may be used for data collection, which is discussed in more detail later, or for the user to keep track of which breast has most recently been pumped. In particular, there may be a pair of LEDs, one to the left of the toggle button 5E and one to the right. When the user is pumping the left breast, the LED to the right of the toggle button 5E will illuminate, so that when the user looks down at the toggle it is the leftmost LED from their point of view that is illuminated. When the user then wishes to switch to the right breast, the toggle button can be pressed and the LED to the left of the toggle button 5E will illuminate.

As depicted in Figure 1, the housing 1 and milk collection container 3 form a substantially continuous outer surface, with a generally convex shape. This shape roughly conforms with the shape of a breast. This allows the breast pump 100 to fit within the cup of a user's bra. The milk collection container 3 is retained in attachment with the housing 3 by means of a latch system, which is released by button 2.

The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting an additional 2 cm difference. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc. In preferred embodiments, the breast pump 100 of the present invention corresponds to an increase of between 3 or 4 cup sizes of the user according to EN 13402.

A plane-to-plane depth of the breast pump can also be defined. This is defined as the distance between two parallel planes, the first of which is aligned with the innermost point of the breast pump 100, and the second of which is aligned with the outermost point of the breast pump 100. This distance is preferably less than 100 mm.

Figure 2 is a rear view of the breast pump 100 of Figure 1. The inner surface of the housing 1 and milk collection container 3 are shown, along with a breast shield 7. The

housing 1, milk collection container 3 and breast shield 7 form the three major sub-components of the breast pump 100. In use, these sub-components clip together to provide the functioning breast pump 100. The breast shield 7 is designed to engage with the user's breast, and comprises a concave inner flange 7A which contacts the breast. To allow the breast pump 100 to be used on either of the user's breasts, the breast shield 7 is preferably substantially symmetrical on its inner flange 7A.

The inner flange 7A is substantially oval-shaped. While the inner flange 7A is concave, it is relatively shallow such that it substantially fits the body form of the user's breast. In particular, when measured side-on the inner-most point of the flange 7A and the outer-most point may be separated by less than 25 mm. By having a relatively shallow concave surface, the forces applied can be spread out over more surface area of the breast. The flatter form also allows easier and more accurate location of the user's nipple. In particular, the flange 7A of the breast shield 7 may extend over the majority of the inner surface of the housing 1 and milk collection container 3. Preferably, it may extend over 80% of this surface.

The breast shield 7 substantially aligns with the outer edge 1B of the housing 1. The milk collection container 3 may be provided with an arcuate groove for receiving a lower part of the breast shield 7. This is best shown in later Figures. In the assembled arrangement of Figures 1 and 2, the inner surface of the breast pump 100 is substantially continuous.

The breast shield 7 further comprises a spout 9 extending from an opening 7B in the breast shield 7. In preferable embodiments the spout 9 is integral with the breast shield 7. However, it is appreciated that separate removable/interchangeable spouts may be used. The opening 7B is aligned with the user's nipple and areola in use. The breast shield 7 forms an at least partial seal with the rest of the user's breast around this portion. This spout 9 defines a milk-flow path from the inner surface of the breast shield 7A, through the spout 9 and into the milk collection container 3. The spout 9 is preferably quite short in order to minimise the length of the milk-flow path in order to minimise losses. In particular, the spout 9 may extend less than 70 mm from its start to end, more preferably less than 50 mm,

Figures 3 and 4 are of a partially disassembled breast pump 100 of the present invention. In these Figures, the breast shield 7 has been disengaged from the housing 1 and milk collection bottle 3. As shown in Figure 4, the housing 1 comprises a slot 11 for receiving the spout 9 of the breast shield 7. The breast shield 7 is held in place by means of a clip 15 engaging with a slot 17 in the housing 1. While this clip 15 is shown at the top of the breast shield 7, it may be placed at any suitable point on the shield 7, with the slot 17 in a corresponding location. The spout 9 of the breast shield 7, is provided with a protrusion 9A on its lower surface. This protrusion 9A is configured to engage with the milk collection bottle 3.

The breast pump 100 further comprises a barrier for transferring the pressure from the pump to the milk-collection side of the system. In the depicted example, this is flexible diaphragm 13. However, it is appreciated that the barrier could be any other suitable component such as a filter or an air transmissive material.

The diaphragm 13 is arranged so that the milk-flow pathway extends past the outer periphery of the diaphragm 13. This means that the milk-flow pathway does not extend through the diaphragm 13. In particular, the milk-flow pathway is beneath the diaphragm 13. However, is appreciated that the diaphragm 13 may be offset in any direction with respect to the milk-flow pathway provided that the milk-flow pathway does not extend through the diaphragm 13.

Preferably, the diaphragm 13 is a continuous membrane, devoid of any openings.

The diaphragm 13 is held in a diaphragm housing 19, which is formed in two parts. The first half 19A of the diaphragm housing 19 is provided on the outer surface of the breast shield 7, above the spout 9 and hence the milk-flow pathway. In preferred embodiments, the first half 19A of the diaphragm housing 19 is integral with the breast shield. The second half 19B of the diaphragm housing is provided in a recessed portion of the housing 1. The diaphragm 13 seals in this diaphragm housing 19 around its outer edge, to form a watertight and airtight seal. Preferably, the seal around the outer edge of the diaphragm 13 is the only seal of the diaphragm 13. This is beneficial over systems with annular diaphragms which must seal at an inner edge as well. Having the diaphragm 13 mounted in the breast pump 100 in this manner ensures that it is easily accessible for

cleaning and replacement. It also ensures that the breast shield 7 and diaphragm 13 are the only components which need to be removed from the pump 100 for cleaning.

Figures 5 and 6 show a breast pump 100 according to the present invention in a further disassembled state. In addition to the breast shield 7 and diaphragm 13 being removed, the milk collection container 3 has been unclipped.

Preferably, the milk collection container 3 is a substantially rigid component. This ensures that expressed milk does not get wasted therein, while also enhancing re-usability. In some embodiments, the milk collection container 3 may be formed of three sections: a front bottle potion, a rear bottle potion, and a cap. These three sections may clip together to form the milk collection container 3. This three part system is easy to empty, easily cleanable, and easily re-usable.

However, in the preferred embodiments the milk bottle 3 is a single integral part with a cap 35. The milk collection container 3 has a capacity of approximately 5 fluid ounces (148 ml).

To achieve this, the milk collection container 3 preferably has a depth in a direction extending away from the breast in use, of between 50 to 80 mm, more preferably between 60 mm to 70 mm, and most preferably between 65 mm to 68 mm.

The milk collection container 3 further preferably has a height, extending in the direction from the bottom of the container 3 in use to the cap 35, of between 40 mm to 60 mm, more preferably between 45 mm to 55 mm, and most preferably between 48 mm to 52 mm.

Further preferably, the milk collection container has a length, extending from the leftmost point to the rightmost point of the container 3 in use, of between 100 mm to 120 mm, more preferably between 105 mm to 115 mm, and most preferably between 107 mm to 110 mm.

This cap 35 is provided with a one-way valve 37, through which milk can flow. This valve 37 prevents milk from spilling from the bottle once it has been collected. In addition, the valve 37 automatically seals completely unless engaged to the breast shield 7. This

ensures that when the pump 100 is dismantled immediately after pumping, no milk is lost from the collection bottle 3. It can be appreciated that this one-way valve 37 might also be placed on the breast shield 7 rather than in this bottle cap 35. The cap 35 may screw into the milk collection bottle 3. In particular, it may be provided with a threaded connection or a bayonet and slot arrangement.

In certain embodiments, a teat may be provided to attach to the annular protrusion 31A to allow the container 3 to be used directly as a bottle. Alternatively, or in addition, a spout may be provided to attach to the protrusion 31A for ease of pouring.

Figures 7 and 8 show front views of a breast pump 100 according to the present invention. The outer-surface of the housing 1 has been drawn translucent to show the components inside. The control circuitry 71 for the breast pump 100 is shown in these figures. The control circuitry in the present embodiment comprises four separate printed circuit boards, but it is appreciated that any other suitable arrangement may be used.

The control circuitry may include sensing apparatus for determining the level of milk in the container 3. The control circuitry may further comprise a wireless transmission device for communicating over a wireless protocol (such as Bluetooth) with an external device. This may be the user's phone, and information about the pumping may be sent to this device. In embodiments where the user interface 5 comprises a breast toggle button 5E, information on which breast has been selected by the user may also be transmitted with the pumping information. This allows the external device to separate pumping data for the left and right breasts.

There should also be charging means within the control circuitry 71 for charging the battery 81. While an external socket, cable or contact point may be required for charging, a form of wireless charging may instead be used such as inductive or resonance charging. In the Figures, charging port 6 is shown for charging the battery 81. This port 6 may be located anywhere appropriate on the housing 1.

Figure 8 shows the location of the battery 81 and the pumps 83A, 83B mounted in series inside the housing 1. While the depicted embodiment shows two pumps 83A, 83B it is appreciated that the present invention may have a single pump.

Preferably, an air filter 86 is provided at the output to the pumps 83A, 83B.In preferable embodiments, the pumps 83A, 83B are piezoelectric pumps (or piezo pump). A suitable piezo pump is manufactured by TTP Ventus, which can deliver in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free flow.

The rear side of the second half of the diaphragm housing 19B in the housing 1 is provided with a pneumatic connection spout. The pumps 83A, 83B are pneumatically connected with this connection spout.

Operation of the breast pump 100 will not be described. Once the breast pump 100 is activated and a pumping cycle is begun, the pumps 83A, 83B generates a negative pressure which is transmitted via the connection spout 85 to a first side of the diaphragm 13 in the diaphragm housing 19. This side of the diaphragm 13 is denoted the pumping side 13B of the diaphragm 13.

The diaphragm 13 transmits this negative pressure to its opposite side (denoted the milk-flow side 13A). This negative pressure is transferred from the first side of the diaphragm housing 19A to the opening 7B of the breast shield 7 via the spout 9. This acts to apply the pressure cycle to the breast of the user, in order to express milk. The milk is then drawn through the spout 9, through the one way valve 37 and into the milk collection container 3. The negative pressure is then released, and periodically reapplied in a manner to imitate the sucking of a child.

While the depicted embodiment of the breast pump 100 is provided with two pumps, the following schematics will be described with a single pump 83. It is understood that the single pump 83 could be replaced by two separate pumps 83A, 83B as above.

Figure 9 depicts a schematic of a further embodiment of a spout 9 for a breast pump 100. The spout 9 is provided with an antechamber 91 and a separation chamber 93. A protrusion 95 extends from the walls of the spout 9 to provide a tortuous air-liquid labyrinth path through the spout 9. In the separation chamber 93 there are two opening 97, 99. An air opening 97 is provided in an upper surface 93A of the separation chamber 93. This upper surface 93 is provided transverse to the direction of the spout 9. This opening 97 connects to the first side of the diaphragm housing 19A and is the source of the negative pressure. This airflow opening 97 also provides a route for air to flow as shown

with arrow 96. It is appreciated that the tortuous pathway is not necessary and that a spout 9 without such a pathway will work.

The other opening 99 is a milk opening 99. The milk opening 99 is provided on a lower surface 93B of the separation chamber 93 and connects in use to the container 3. After flowing through the tortuous spout 9 pathway, the milk is encouraged to flow through this opening 99 into the container 3. This is further aided by the transverse nature of the upper surface 93A.

In this manner, expressed milk is kept away from the diaphragm 13. As such, the breast pump 100 can be separated into a "clean" air-flow side comprising the pump 83, the connection spout 85 and the pumping side 13B of the diaphragm 13 and a "dirty" milk-flow side comprising the breast shield 7, the milk collection container 3 and the milk-flow side 13A of the diaphragm 13. This ensures that all of the "dirty" components are easily detachable for cleaning, maintenance and replacement. Additionally, the milk is kept "clean" by ensuring it does not contact the mechanical components.

While the present embodiment discusses the generation of negative pressure with the pump 83, it will be appreciated that positive pressure may instead be generated.

While the embodiments described herein use a diaphragm 13, any suitable structure to transmit pressure while isolating either side of the system may be used.

Figure 10 shows a schematic of a basic pneumatic system 200 for a breast pump 100. In the system 200 milk expressed into the breast shield 7 is directed through the breast shield spout 9 through the torturous air-liquid labyrinth interface 95. The milk is directed through the non-return valve 37 to the collection container 3. This side of the system forms the "dirty" side 201.

The rest of the pneumatic system 200 forms the "clean" side 202 and is separated from contact with milk. This is achieved by way of a flexible diaphragm 13 which forms a seal between the two sides of the system. The diaphragm 13 has a milk-flow side 13A and an air-flow side 13B.

The "clean" side 202 of the system 200 is a closed system. This side 202 may contain a pressure sensor 101 in pneumatic connection with the diaphragm 13 and the pump 83. Preferably, the pump 83 is a piezoelectric pump (or piezo pump). Due to their low noise, strength and compact size, piezoelectric pumps are ideally suited to the embodiment of a small, wearable breast pump. The pump 83 has an output 83A for generating pressure, and an exhaust to the atmosphere 83B. In a first phase of the expression cycle, the pump 83 gradually applies negative pressure to clean half of the closed system 202 behind the diaphragm 13. This causes the diaphragm 13 to extend away from the breast, and thus the diaphragm 13 conveys a decrease in pressure into the breast shield 7. The reduced pressure encourages milk expression from the breast, which is directed through the tortuous labyrinth system 95 and the one-way valve 37 to the collection bottle 3.

While in the depicted embodiment the exhaust 83B is not used, it may be used for functions including, but not limited to, cooling of electrical components, inflation of the bottle to determine milk volume (discussed further later) or inflation of a massage bladder against the breast. This massage bladder may be used to help mechanically encourage milk expression.

The "clean" side 202 further comprises a two-way solenoid valve 103 connected to a filtered air inlet 105 and the pump 83. Alternatively, the filter could be fitted on the pump line 83A. If the filter is fitted here, all intake air is filtered but the performance of the pump may drop. After the negative pressure has been applied to the user's breast, air is bled into the system 202 through the valve 103 in a second phase of the expression cycle. In this embodiment, the air filter 105 is affixed to this inlet to protect the delicate components from degradation. In particular, in embodiments with piezoelectric components these are particularly sensitive.

The second phase of the expression cycle and associated switching of valve 103 is actioned once a predefined pressure threshold has been reached. The pressure is detected by a pressure sensor 101.

In certain embodiments, if the elasticity and extension of the diaphragm 13 may be approximated mathematically at different pressures, the pressure measured by sensor 101 can be used to infer the pressures exposed to the nipple on the opposite side of the diaphragm 13.

Figure 11 shows an alternative pneumatic system 300. The core architecture of this system is the same as the system shown in Figure 10.

In this system 300, the closed loop 202 is restricted with an additional three way solenoidal valve 111. This valve 111 allows the diaphragm 13 to be selectively isolated from the rest of the closed loop 202. This additional three way valve 111 is located between the diaphragm 13 and the pump 83. The pressure sensor 101 is on the pump 83 side of the three way valve 111. The three way valve 111 is a single pole double throw (SPDT) valve, with the diaphragm 13 connected to one of the throws 111B. The pump 83 is connected to the pole 111A. The final throw 111C is connected to a dead-end 113. This dead-end 113 may either be a simple closed pipe, or any component(s) that does not allow the flow of air into the system 202. This could include, for example, an arrangement of one-way valves.

In this system 300, therefore, the pump 83 has the option of applying negative pressure directly to the pressure sensor 101. This allows repeated testing of the pump in order to calibrate pump systems, or to diagnose issues with the pump in what is called a dead end stop test. This is achieved by throwing the valve to connect the pump 83 to the dead end 113. The pump 83 then pulls directly against the dead end 113 and the reduction of pressure within the system can be detected by the pressure sensor 101.

Using this function, material fatigue of the pump 83 can be assessed directly. Principally, this knowledge can be used to ensure user experience is not altered, despite the changing output of the pump 83 as it degrades over time. For example, the pump cycle may be changed to drive longer or operate under increased voltage to ensure the same pressures are met. This is particularly relevant for piezo pumps where the output may vary significantly.

Figure 12 shows a schematic for a system 400 for a breast pump 100 which can estimate the volume of milk collected in the collection container 3 from data collected on the "clean" airflow part 202 of the system 400.

The pump 83 is connected to the circuit via two bleed valves 126, 128. The first bleed valve 126 is arranged to function when the pump 83 applies a negative pressure. As

such, this valve 126 is connected to a "bleed in" 127, for supplying atmospheric air to the system 202.

The second bleed valve 128 is arranged to function when the pump 83 applies a positive pressure. As such, this valve 128 is connected to a "bleed out" 129 for bleeding air in the system 202 to the atmosphere.

During a milking pump cycle, the pump 83 applies negative pressure on the "clean" side 13B of the diaphragm 13 which causes its extension towards the pump 83. This increases the volume of the space on the "dirty" side 13B of the diaphragm 13. This conveys the decrease in pressure to the breast to encourage expression of milk. A set of three non-return valves 121, 123, 125 ensure that this decrease in pressure is applied only to the breast (via the breast shield 7) and not the milk collection container 3.

To measure the volume of milk collected in the container 3, the pump 83 is used instead to apply positive pressure to the diaphragm 13. The diaphragm 13 is forced to extend away from the pump 83 and conveys the pressure increase to the "dirty side" 201 of the system 400. The three non-return valves 121, 123, 125 ensure that this increase in pressure is exclusively conveyed to the milk collection container 13.

The resulting pressure increase is monitored behind the diaphragm 13 from the "clean" side 202 by a pressure sensor 101. Preferably, the pressure sensor 101 is a piezoelectric pressure sensor (piezo pressure sensor). The rate at which the pump 83 (at constant strength) is able to increase the pressure in the system 400 is a function of the volume of air that remains in the milk collection container 3. As air is many times more compressible than liquid, the rate at which pressure increases in the system 400 can be expressed as an approximate function of the volume of milk held in the collection container 3.

Thus by increasing the pressure in this fashion, the rate of pressure increase can be determined, from which the volume of milk held in the container 3 is calculable.

The inventor has proved this method for estimating milk volume. Figure 13 shows repeated milking and volume measurement cycles as the collection container 3 is filled. To determine the rate of pressure increase the pump 83 was run for a fixed time. As pumping

proceeds and the volume of air reduces in the system 400, the pump 83 is able to achieve a higher pressure. Each milking cycle is represented by a positive pressure spike 41. There is a clear upwards trend 43 in magnitude of positive pressures achieved as the collection container 3 is filled.

In this manner, an estimate can be obtained for the volume of milk in the container 3 based upon the measured pressures.

Figure 13 also shows a dead end stop pump test 45 as described above. The negative spike 45 shows the application of negative pressure directly to the pressure sensor 101.

CLAIMS:

1. A breast pump for wearing inside a bra, the breast pump comprising:

a breast shield for engagement with the user's breast;

a housing for receiving at least a portion of the breast shield;

a pump inside the housing for generating a negative pressure in the breast shield;

a battery inside the housing for powering the pump;

a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user with a milk-flow pathway defined from an opening in the breast shield to the milk collection container; and

a barrier, the pump acting on one side of the barrier to generate a pressure on the opposite, milk-flow, side of the barrier, the barrier having an outer periphery,

wherein:

the shield, housing, pump, battery and container are provided as a unit with a convex outer surface contoured to fit in a bra; and

the milk-flow pathway extends past the outer periphery of the barrier.

2. A breast pump for wearing inside a bra, the breast pump comprising:

a breast shield for engagement with the user's breast;

a housing for receiving at least a portion of the breast shield;

a pump inside the housing for generating a negative pressure in the breast shield;

a battery inside the housing for powering the pump;

a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user with a milk-flow pathway defined from an opening in the breast shield to the milk collection container,

wherein:

the shield, housing, pump, battery and container are provided as a unit with a convex outer surface contoured to fit in a bra; and

the breast shield comprises a shield flange for engaging the user's breast, and an elongate spout aligned with the opening and extending away from the user's breast, the spout being substantially aligned, in use, with the user's nipple and areolae; the spout comprising a first opening for depositing milk into the collection container and a second opening for transferring pressure generated by the pump to the user's nipple, the shield flange and spout being detachable from the housing together.

3. A breast pump for wearing inside a bra, the breast pump comprising:

a breast shield for engagement with the user's breast;

a housing for receiving at least a portion of the breast shield;

a piezo pump inside the housing for generating a negative pressure in the breast shield;

a battery inside the housing for powering the pump;

a detachable milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user with a milk-flow pathway defined from an opening in the breast shield to the milk collection container,

wherein the shield, housing, pump, battery and container are provided as a unit with a convex outer surface contoured to fit in a bra.

4. The breast pump according to claim 1 or 3 wherein the breast shield comprises a shield flange for engaging the user's breast, and an elongate spout aligned with the opneing extending away from the user's breast, the spout being substantially aligned, in use, with the user's nipple and areolae; the spout comprising a first opening for depositing milk into the collection container and a second opening for transferring pressure generated by the pump to the user's nipple.

5. The breast pump of claim 4, wherein the shield flange and spout are detachable from the housing together

6. The breast pump of claim 2, 4 or 5, wherein the spout is integral with the breast shield.

7. The breast pump according to claim 2 or 4 to 6, wherein the breast shield cup extends over a majority of the inner surface of the unit.

8. The breast pump of claim 7, wherein the breast shield extends over 80% of the inner surface of the unit.

9. The breast pump of any of claims 2 or 4 to 8, wherein the spout connects directly to the container.

10. The breast pump of any of claims 2 or 4 to 9, wherein the spout comprises an outflow opening for depositing milk directly above the milk collection container.

11. The breast pump of any of claims 2 or 3, and claims 4 to 10 when dependent upon claims 2 or 3, further comprising a barrier, the pump acting on one side of the barrier to generate a pressure on the opposite, milk-flow, side of the barrier.

12. The breast pump of claim 10, wherein the barrier has an outer periphery and the milk-flow pathway extends past the outer periphery of the barrier.

13. The breast pump of any of claims 2, 11 or 12, wherein the milk-flow pathway is beneath the barrier.

14. The breast pump of any of claims 2 or 11 to 13, wherein the milk-flow pathway does not pass through the barrier.

15. The breast pump of any of claims 2 or 11 to 14, wherein the barrier is mounted in a housing on the breast shield.

16. The breast pump of claim 15, wherein the housing is integral with the breast shield.

17. The breast pump of any of claims 2 or 11 to 16, wherein the barrier is not an annulus.

18. The breast pump of any of claims 2 or 11 to 17, wherein the barrier provides a seal to isolate the pump from the milk-flow side of the barrier.

19. The breast pump of claim 18, wherein the only seal is around an outer edge of the barrier.

20. The breast pump of any of claims 2 or 11 to 19, wherein the barrier is a diaphragm.

21. The breast pump of claim 20, wherein the diaphragm is a continuous membrane which is devoid of any openings or holes.

22. The breast pump according to any preceding claim, further comprising a pressure sensor in pneumatic connection with the pump.

23. The breast pump of any preceding claim, wherein the width of the breast pump is less than 110 mm.

24. The breast pump of any preceding claim, wherein the height of the breast pump is less than 180 mm.

25. The breast pump of any preceding claim, wherein the plane to plane depth of the breast pump is less than 100 mm.

26. The breast pump of any preceding claim, wherein, in use, the breast pump extends from the user's breasts by 3 to 4 cup sizes as per the European standard EN 13402.

27. The breast pump of any preceding claim, wherein the milk container has a volume of greater than 120 ml.

28. The breast pump of claim 27, wherein the milk container has a volume of greater than 140 ml.

29. The breast pump of claim 27 or 28, wherein the milk container has a volume of less than 150 ml.

30. The breast pump of any preceding claim, wherein the milk container and housing form a substantially continuous outer surface of the breast pump.

31. The breast pump of any preceding claim, wherein the milk container is at least partially transparent on the outer surface of the breast pump.

32. The breast pump of any preceding claim, wherein the milk container is provided with a spout.

33. The breast pump of any preceding claim, wherein the milk container is provided with attachment means for attaching a teat to the container.

34. The breast pump of any preceding claim, wherein the breast shield is removable.

35. The breast pump of any preceding claim, wherein the milk collection container is formed of at least two rigid sections which are connectable.

36. The breast pump of any preceding claim, further comprising a one-way valve between an inner surface of the breast shield, for engaging with the breast in use, and the milk container.

37. The breast pump of claim 36, wherein the one-way valve is located in an opening to the container.

38. The breast pump of claim 1 or 2, wherein the pump is a piezo pump.

39. The breast pump of any of any preceding claim, wherein the breast shield is detachable from the breast pump.

40. The breast pump of any of claims 22 or 23 to 39 when dependent upon claim 22, further comprising a single pole, double throw pneumatic valve, wherein:

the pole is in pneumatic connection with the pump and pressure sensor;

one of the throws is in pneumatic connection with the diaphragm; and

the other throw is in pneumatic connection with a dead-end.

41. The breast pump of any of claim22 or 23 to 40 when dependent upon claim 22, further comprising:

a first non-return valve between the milk-flow side of the diaphragm and the breast shield, configured to allow only a negative pressure to be applied to the breast shield by the pump;

a second non-return valve between the milk-flow side of the diaphragm and the milk collection container configured to allow only a positive pressure to be applied to the milk collection container by the pump; and

a pressure sensor in pneumatic connection with the pressure-generation side of the diaphragm.

42. A method of estimating the pressure applied by a breast pump according to claim 40, comprising the steps of:

providing a breast pump according to claim 40;

selecting a pressure cycle from a pre-defined list of pressure cycles;

applying pressure with the pump to stimulate milk expression;

reading the output of the pressure sensor;

adjusting the applied pressure of the pump to match the pressure profile selected by the user.

43. The method of claim 42, further comprising:

approximating the elasticity and extension of the diaphragm at the relevant pressure; and

calculating an estimated applied pressure based upon the output of the pressure sensor and the approximated elasticity and extension of the diaphragm.

44. A method of estimating the milk collected by a breast pump according to claim 41, comprising the steps of:

providing a breast pump according to claim 41;

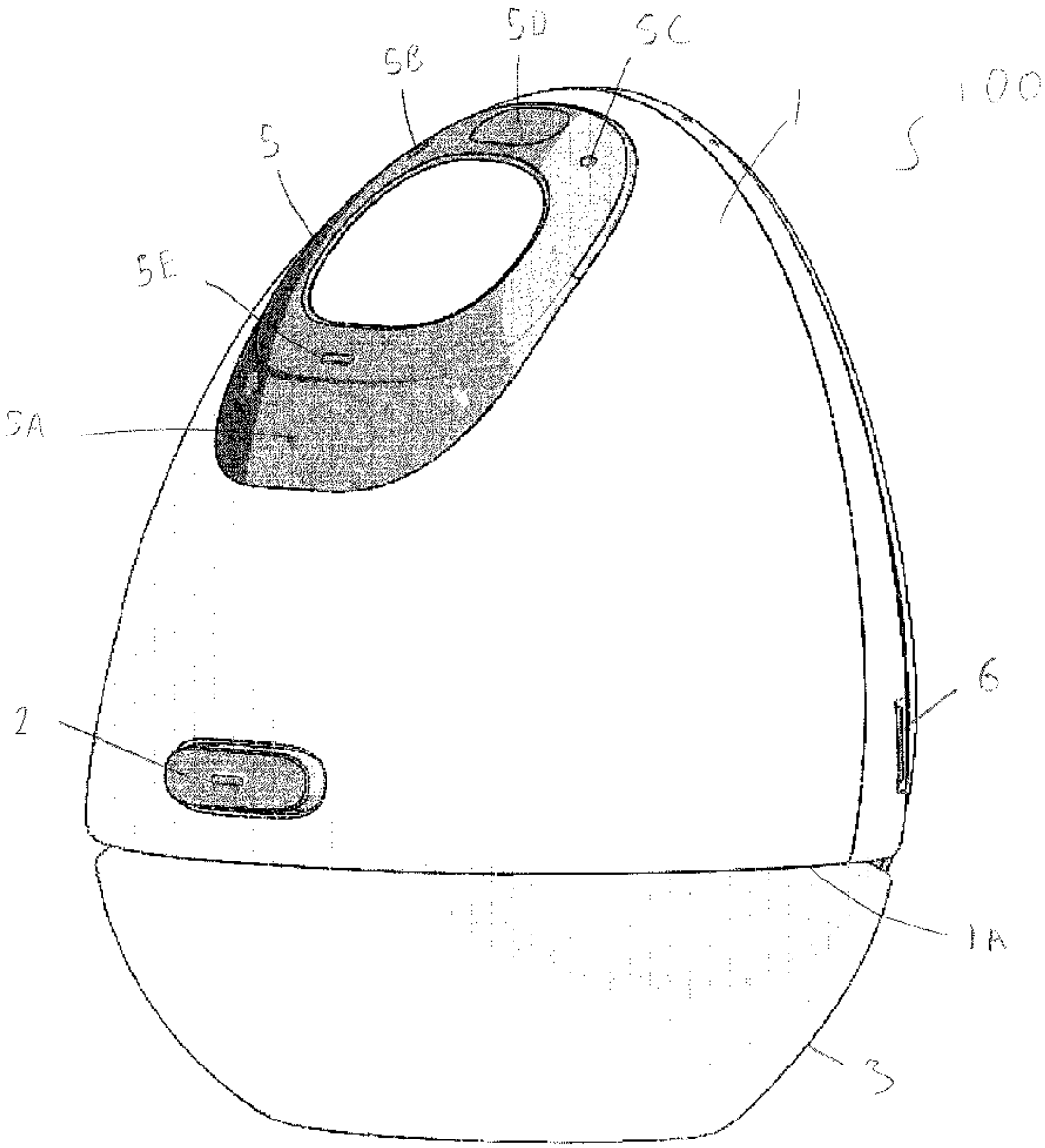
generating a positive pressure with the pump;

transmitting the positive pressure via the diaphragm and second non-return valve to only the milk collection container;

measuring the increase in pressure by the pressure sensor in pneumatic connection with the diaphragm;

estimating the volume of milk inside the milk collection container based upon the rate of increase of pressure.

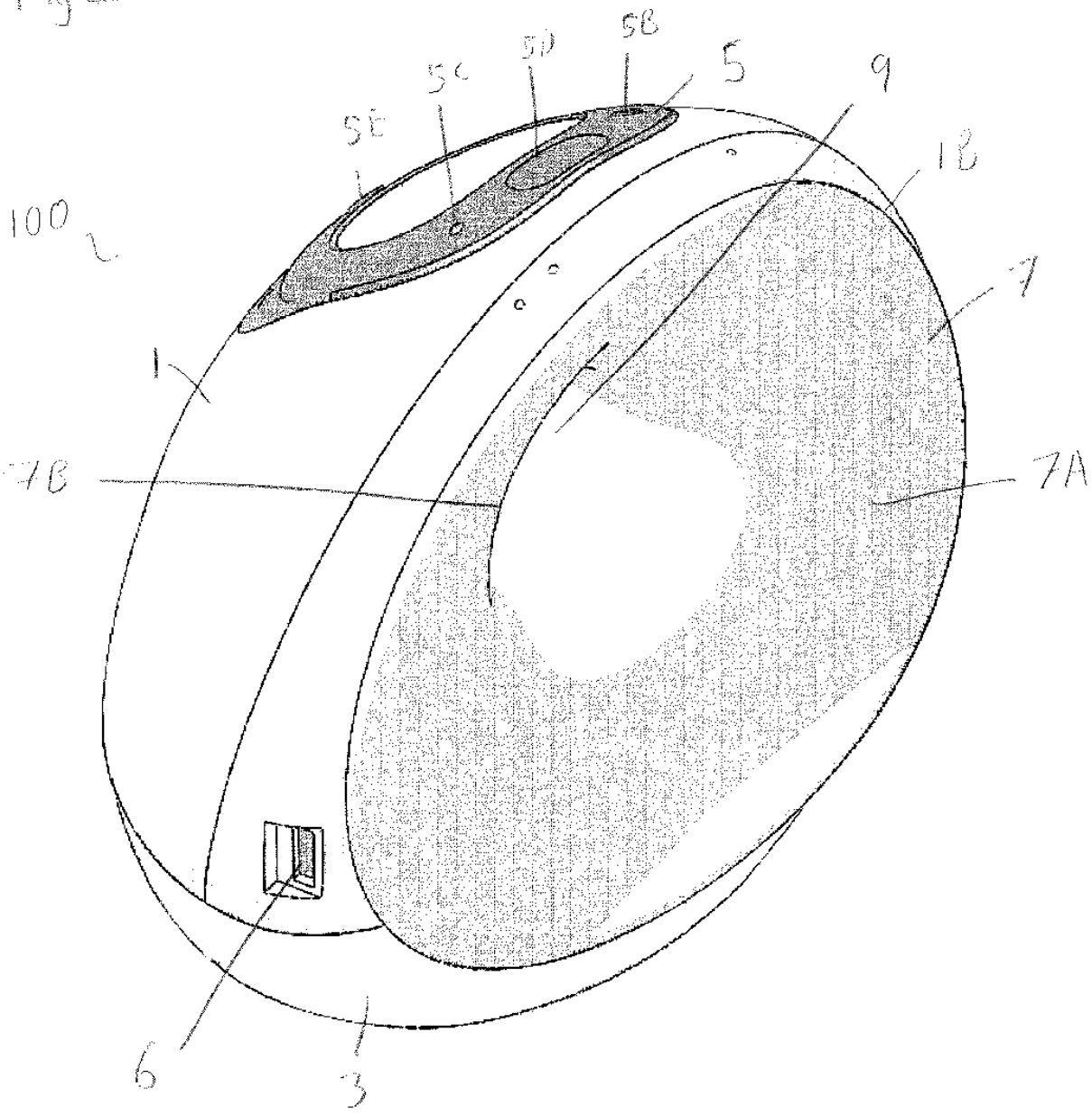
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7397102, JCP2, JCP2

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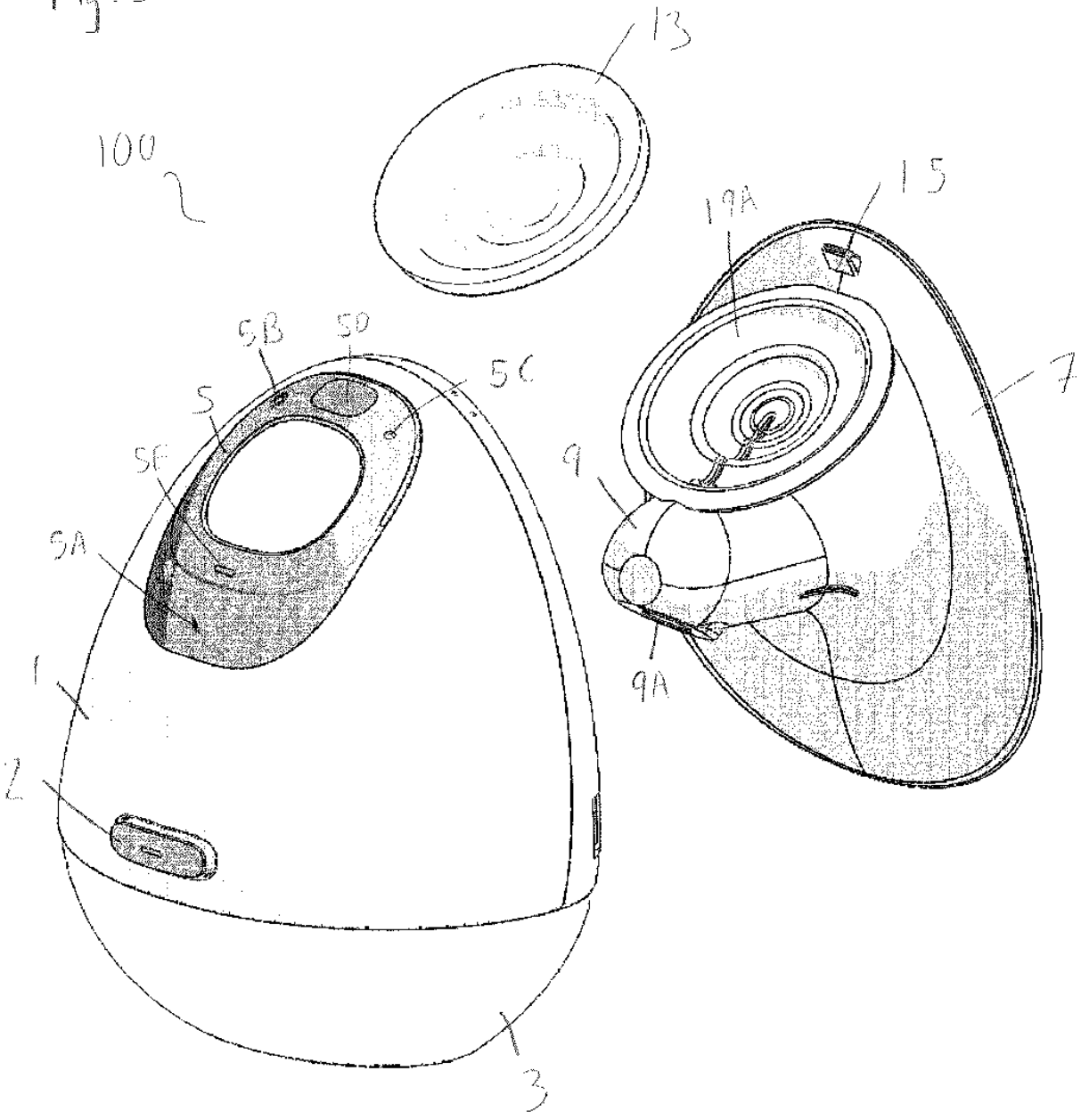
Fig 2



7397102; JCP2; JCP2

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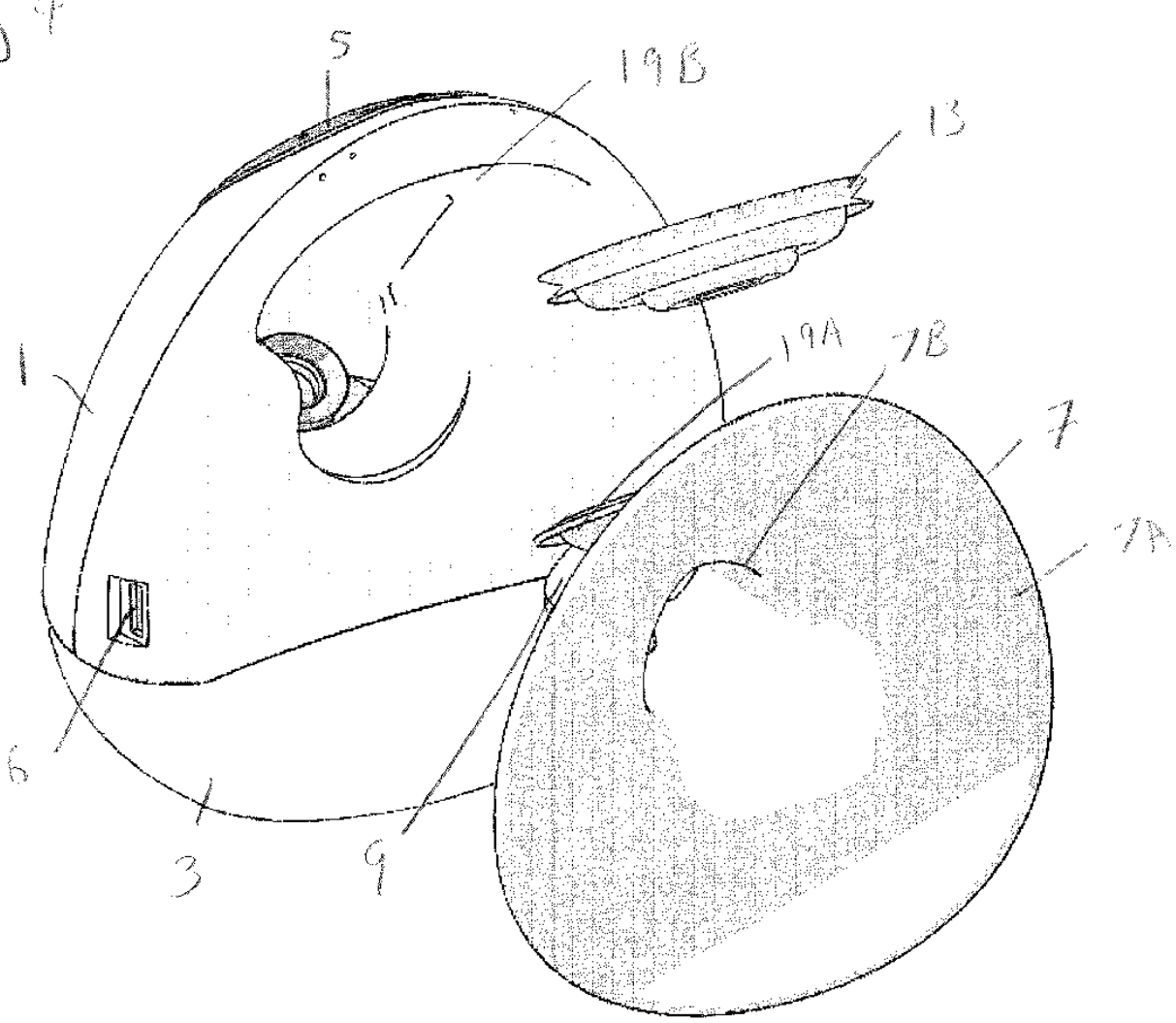
Fig. 3



7397102; JCP2; JCP2

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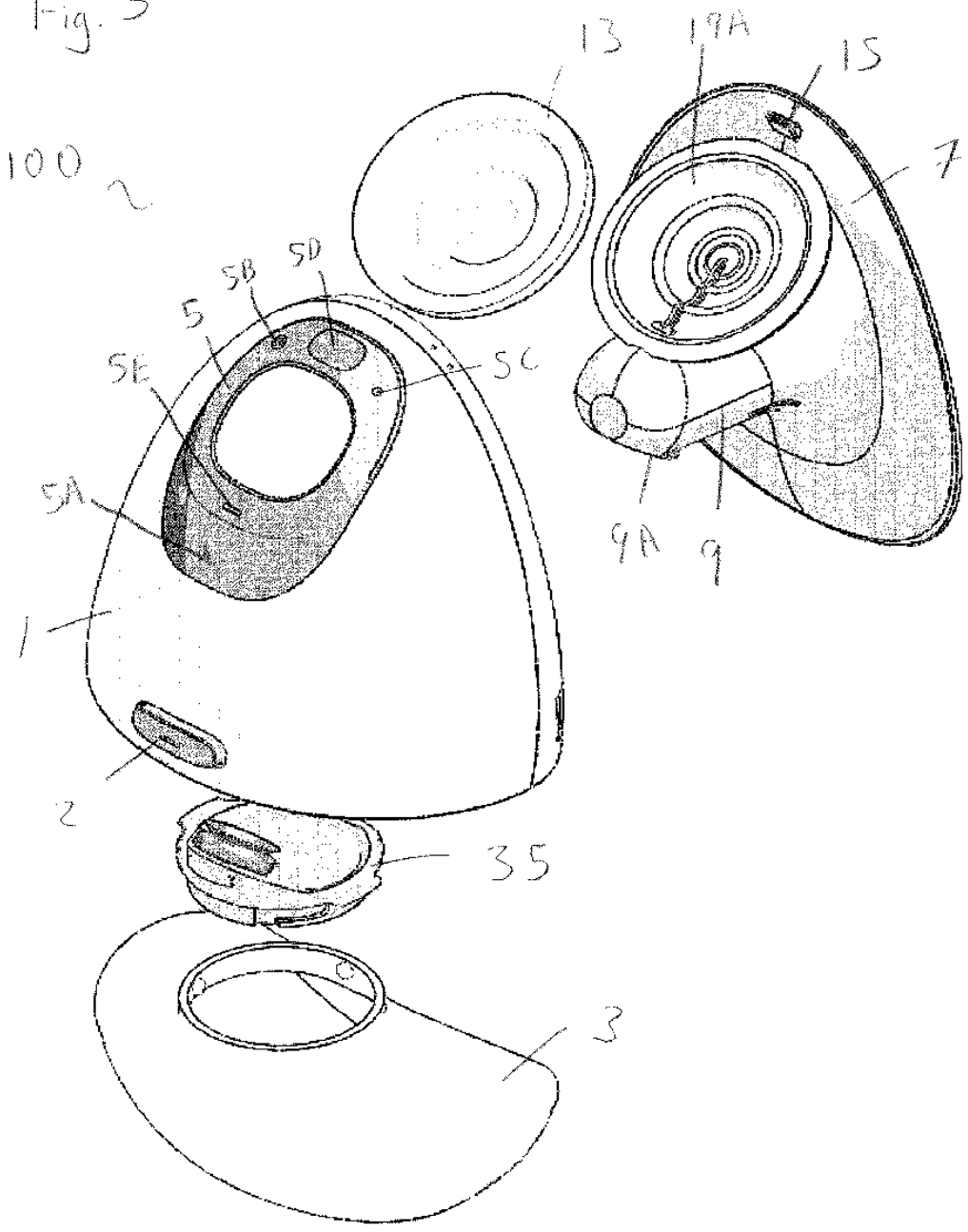
Fig 4



7397102; JCP2; JCP2

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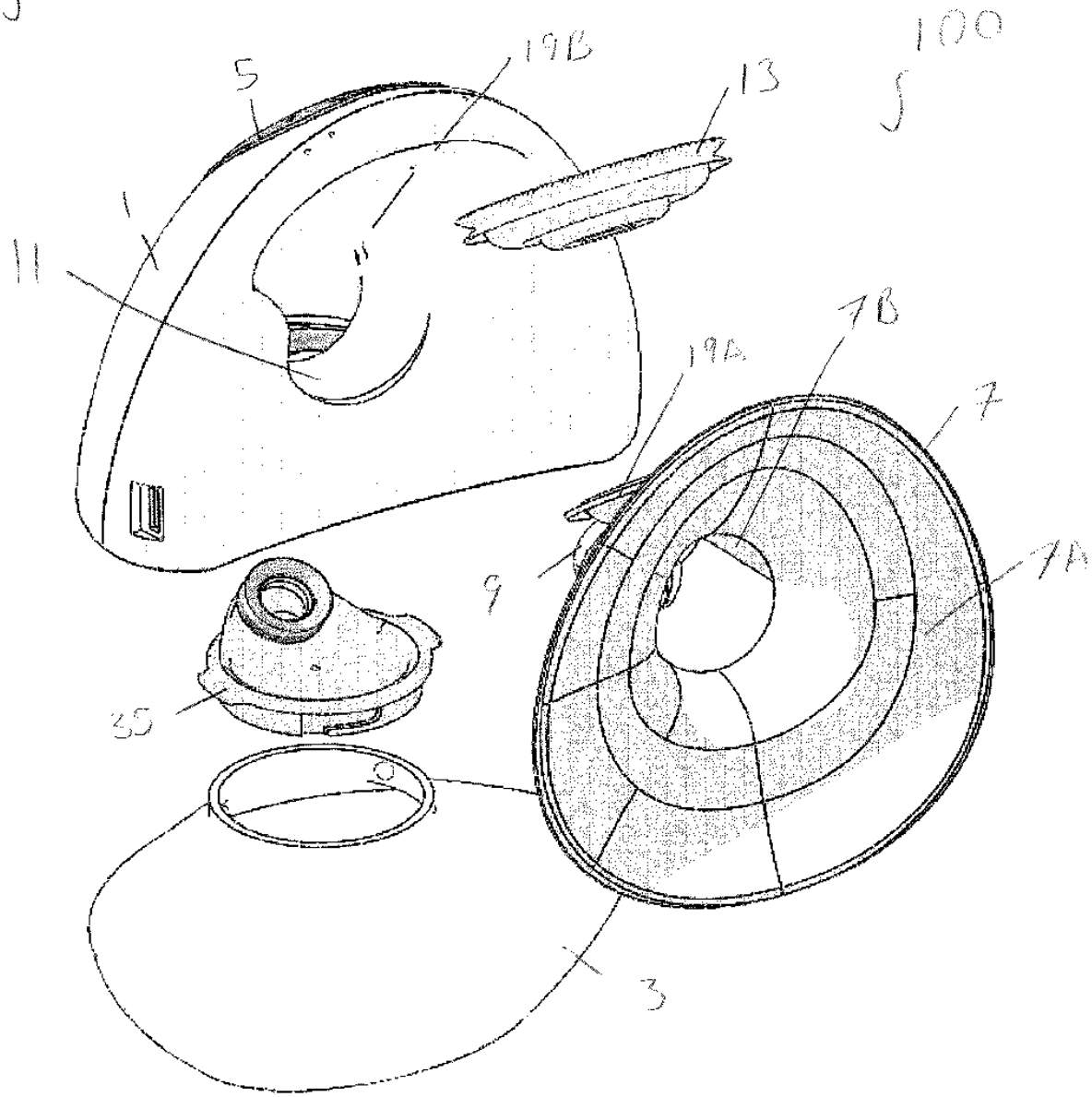
Fig. 5



7397102, JCP2, JCP2

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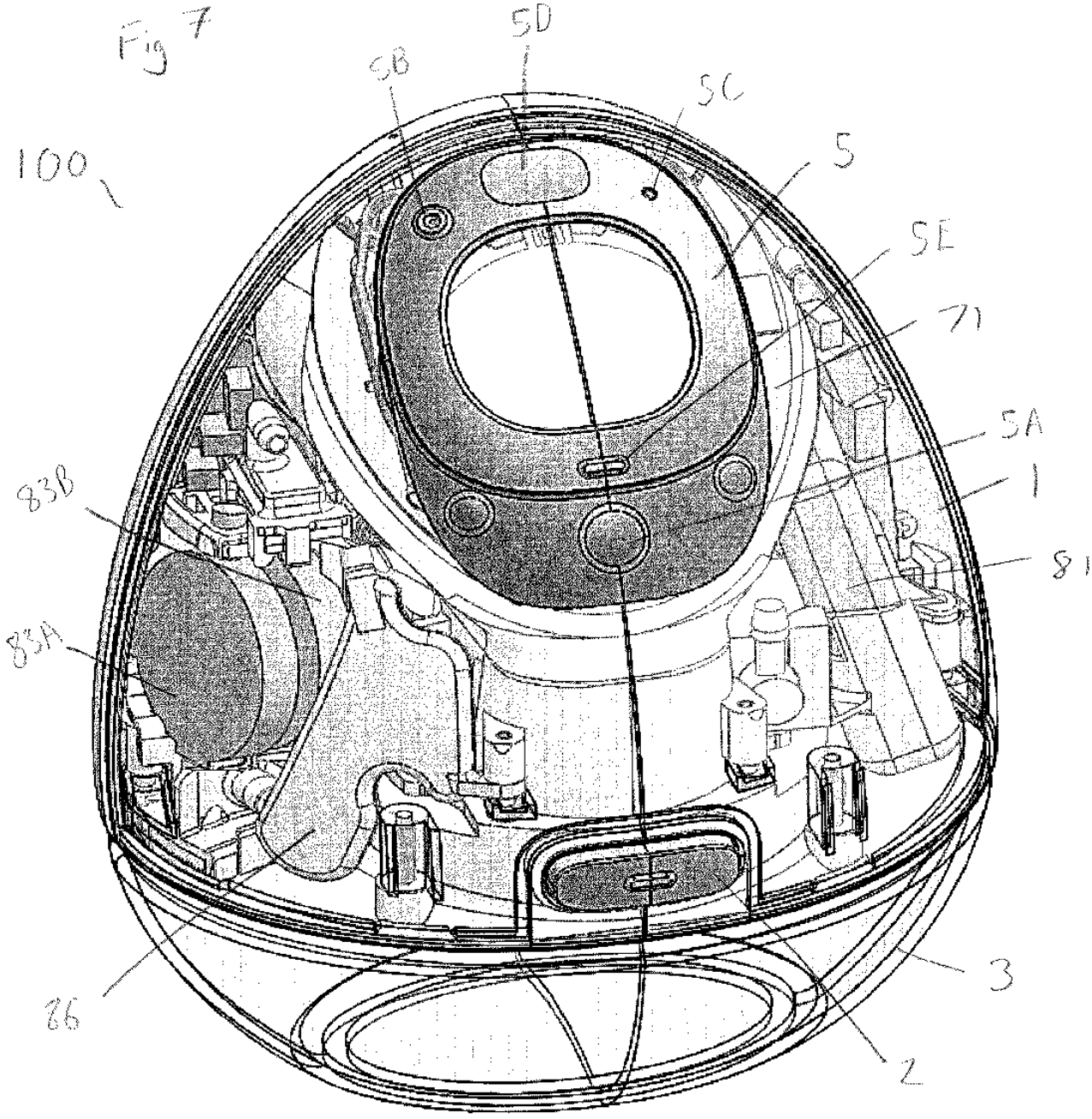
Fig 6



7397102, JCP2; JCP2

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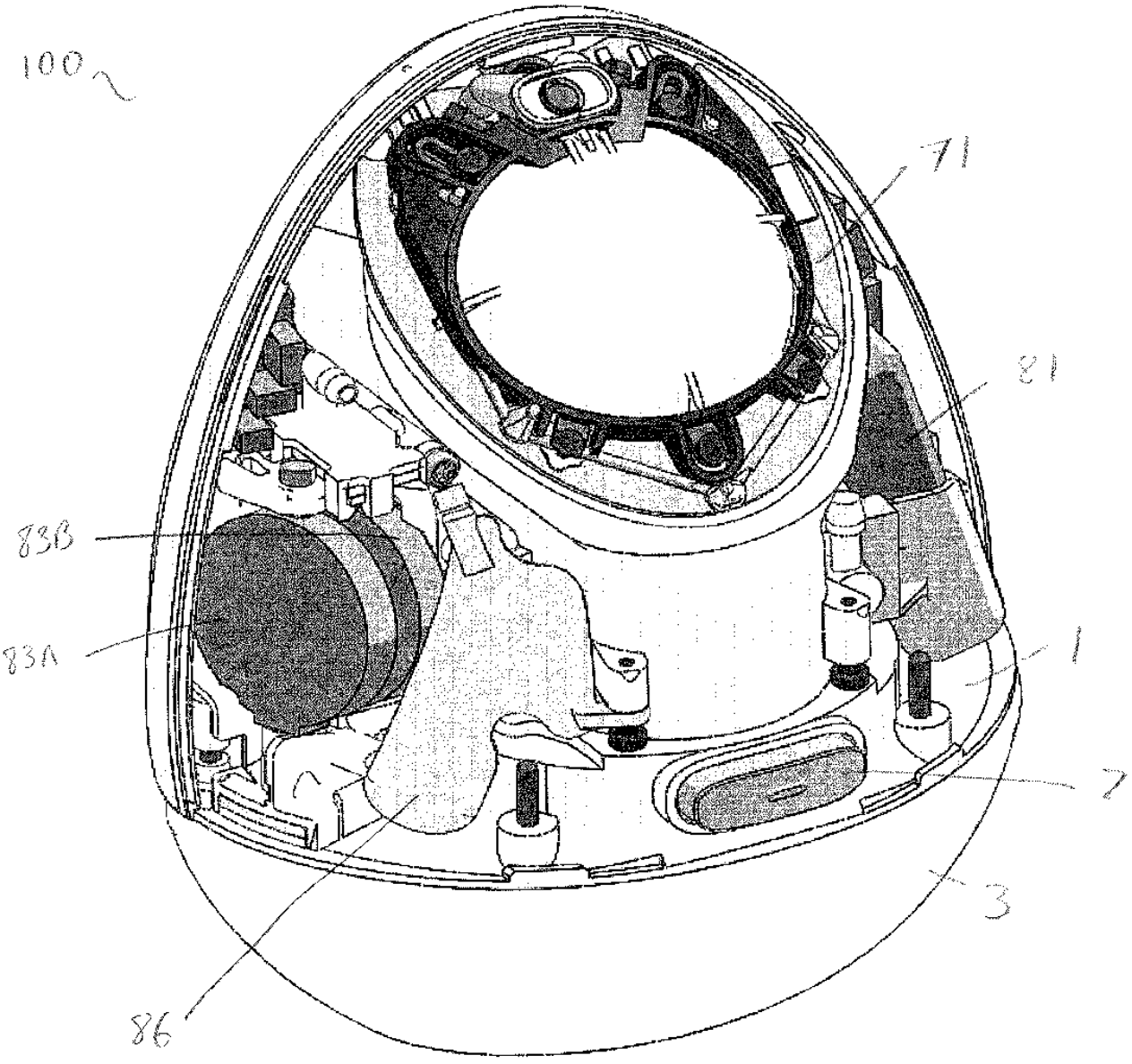
Fig 7



7397102; JCP2; JCP2

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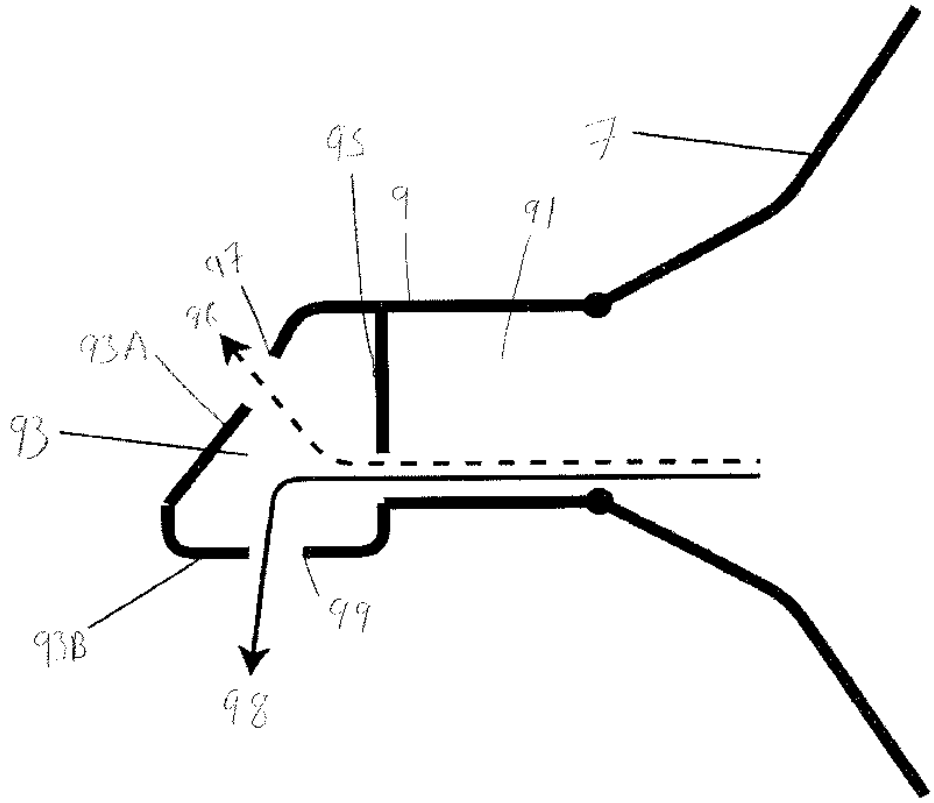
Fig 8



7397102; JCP2. JCP2

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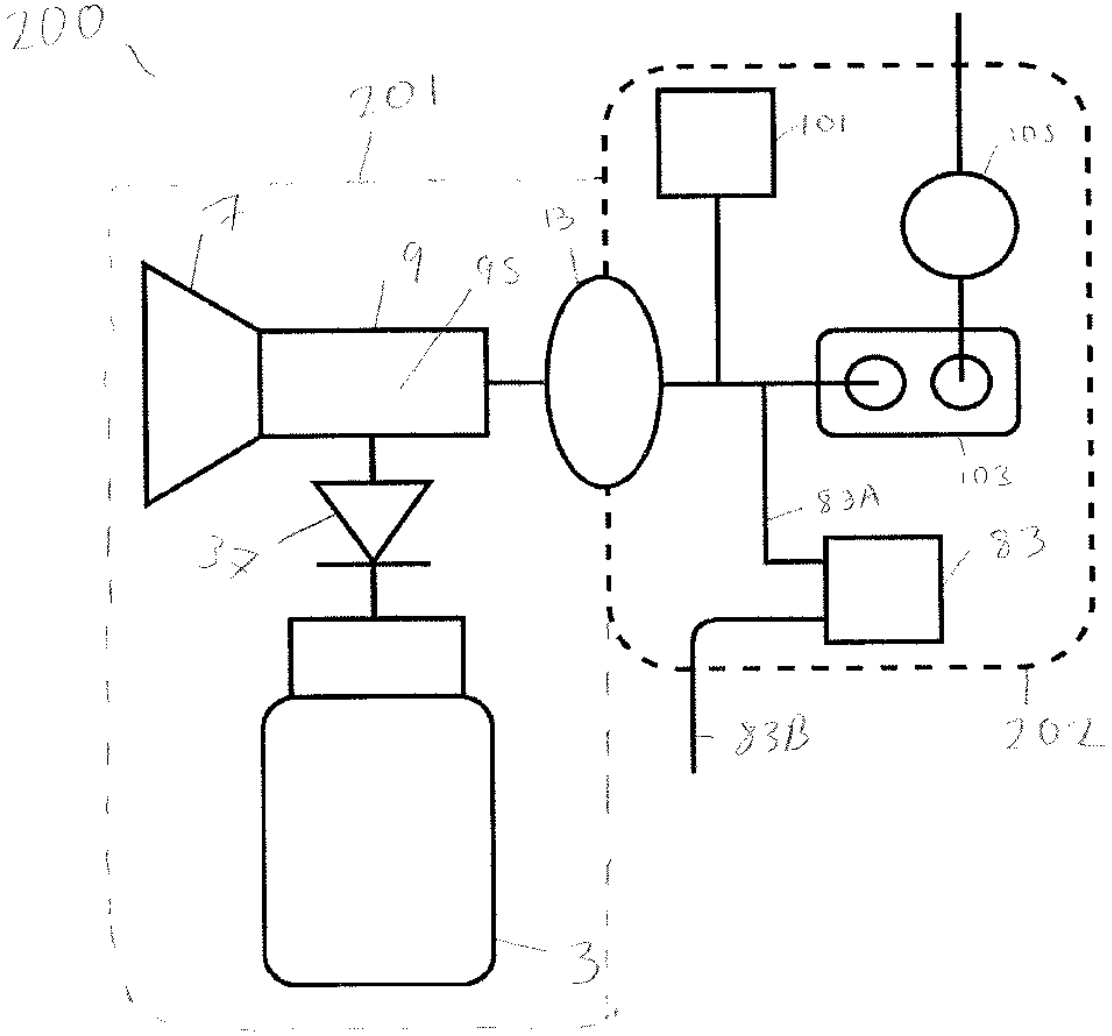
Fig 9



7397102; JCP2; JCP2

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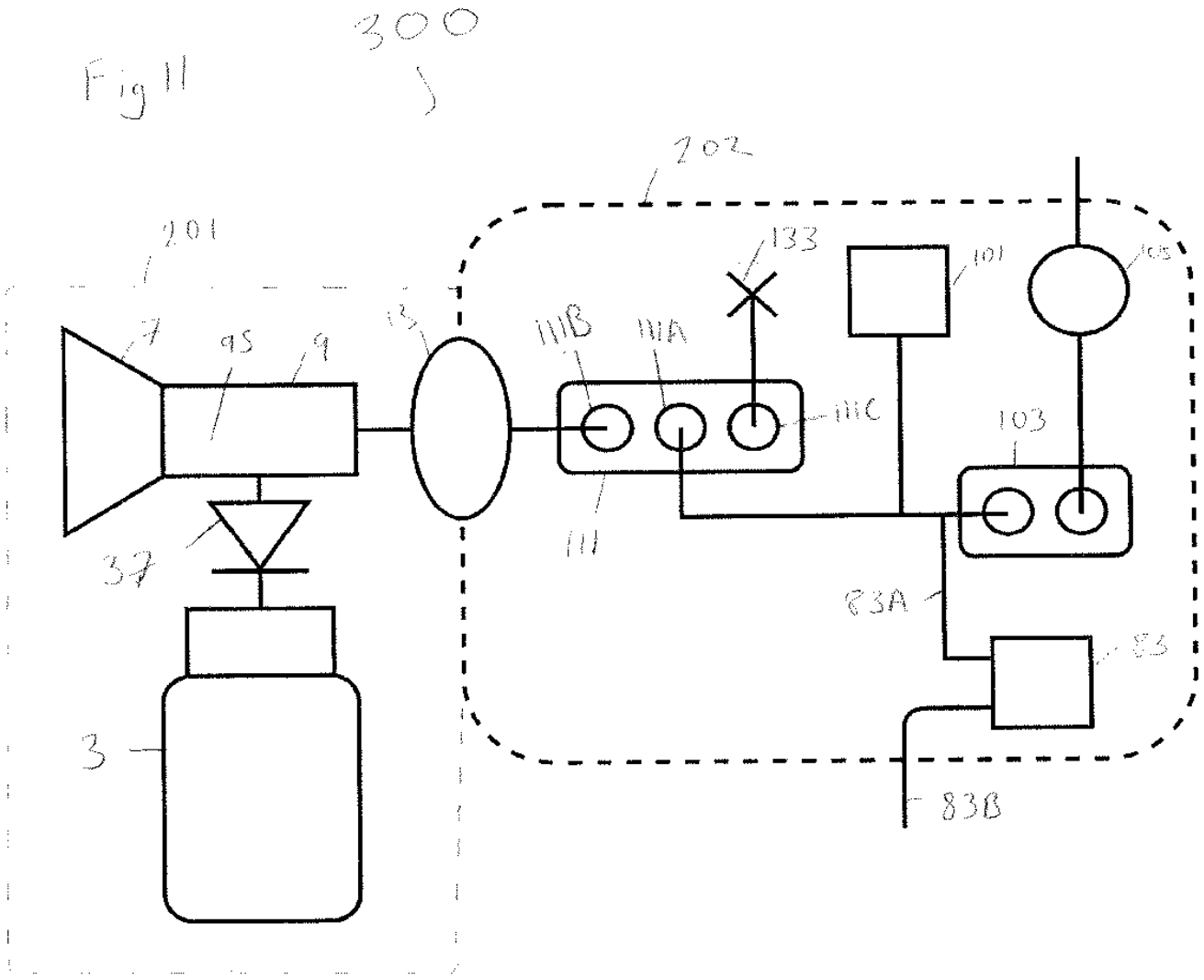
Fig 10



7397102; JCP2; JCP2

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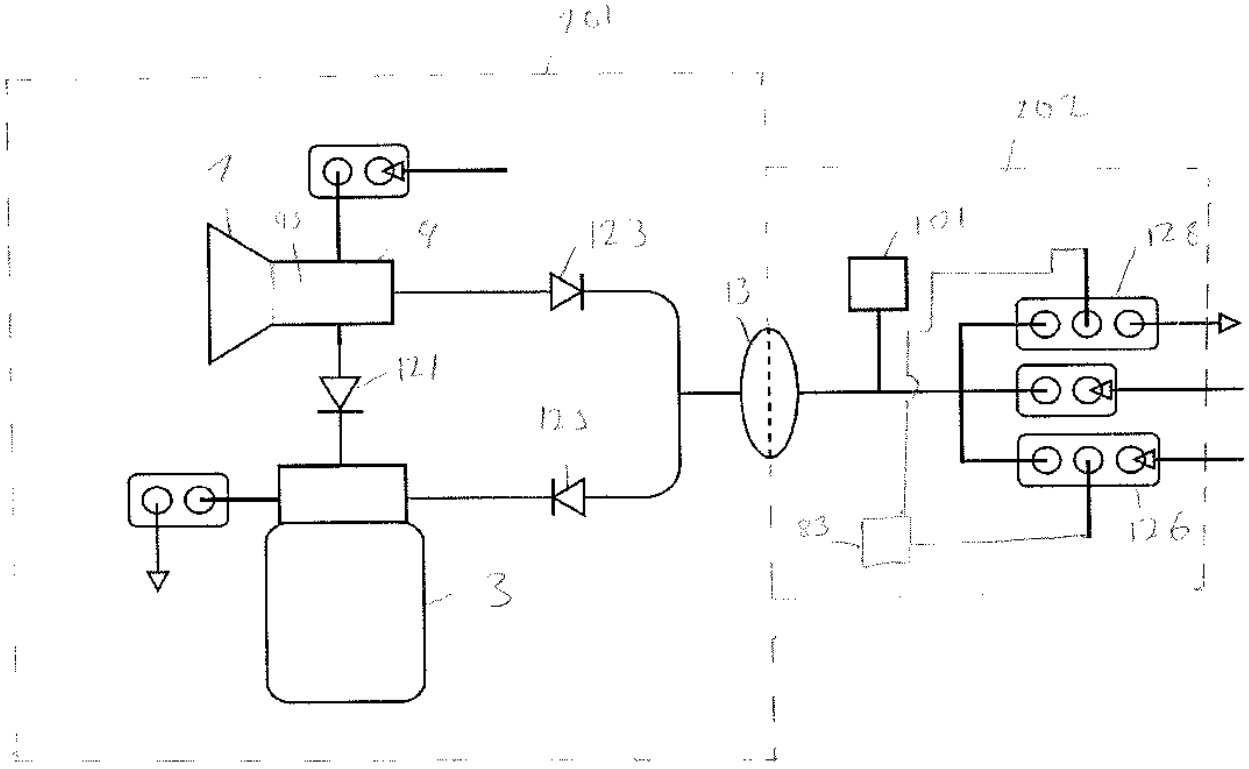
Fig 11



7397102; JCP2; JCP2

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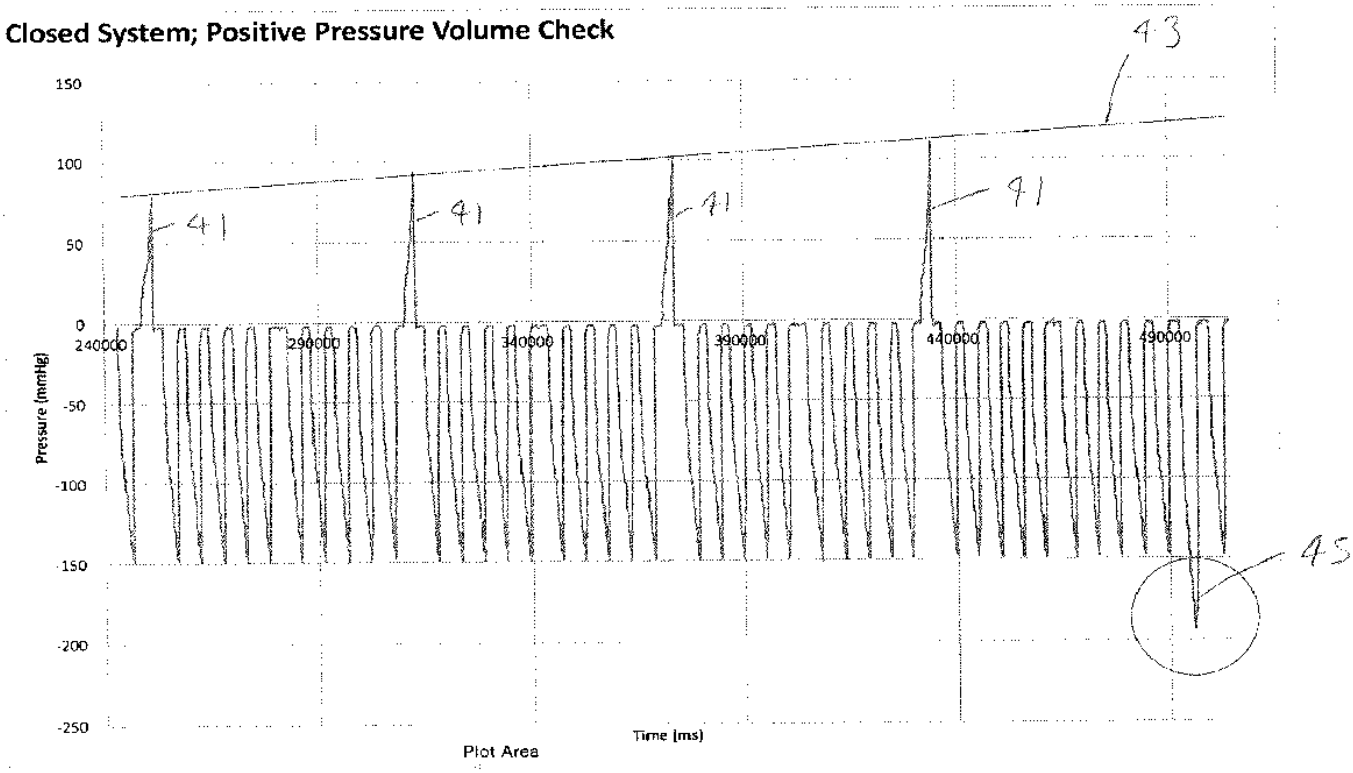
Fig 12



7397102; JCP2; JCP2

P153992GB00

Fig 13



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Dated 07 June 2018

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2018013286

01/06/2018 0.00 NONE

Patents Form 1
Patents Act 1977 *(Rule 12)*

Request for grant of a patent

Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

Application number GB1809036.5

1.	Your reference	**Elvie Pump (UK)**
2.	Full name, address and postcode of the applicant or of each applicant Patents ADP number *(if you know it)*	**CHIARO TECHNOLOGY LIMITED** **63 - 66 Hatton Garden** **London EC1N 8LE** **United Kingdom** 11287869002
3.	Title of the invention	**Breast pump system**
4.	Name of your agent *(if you have one)* "Address for service" to which all correspondence should be sent. This may be in the European Economic area or Channel Islands (see warning note below) *(including the postcode)* Patents ADP number *(if you know it)*	**Langley, Mr Peter** **Origin Limited** **Twisden Works** **Twisden Road** **London NW5 1DN** **United Kingdom** 11436136001 ~~**09541046001**~~
5.	Priority declaration: Are you claiming priority from one or more earlier-filed patent applications? If so, please give details of the application(s)	

Country	Application number	Date of filing	PDAS Access Code

6.	Divisionals etc: Is this application a divisional application, or being made following resolution of an entitlement dispute about an earlier application. If so, please give the application number and filing date of the earlier application	Number of earlier UK application	Date of filing *(day / month / year)*
7.	Inventorship: (Inventors must be individuals not companies) Are all the applicants named above also inventors?	**No**	
8.	Are you paying the application fee with this form?	**No**	

Patents Form 1

9. Accompanying documents: please enter the number of pages of each item accompanying this form.

Continuation sheets of this form

Description: **121**

Claim(s): **n/a**

Abstract: **n/a**

Drawing(s): **44**

If you are not filing a description, please give details of the previous application you are going to rely upon

Country	Application number	Date of filing	PDAS Access Code

10. If you are also filing any of the following, state how many against each item.

Priority documents: **0**

Statement of inventorship and right to grant of a patent (Patents Form 7): **0**

Request for search (Patents Form 9A): **0**

Request for substantive examination (Patents Form 10): **0**

Any other documents (please specify): **PDAS Registration Form**

11. I/We request the grant of a patent on the basis of this application.

Date: **01 Jun 2018**

12. Name, e-mail address, telephone, fax and/or mobile number, if any, of a contact point for the applicant

Langley, Mr Peter
Email: roland@origin.co.uk
Telephone: 02074241952
Fax: 02072090643

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BREAST PUMP SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

The field of the invention relates to a breast pump system; one implementation of the system is a wearable, electrically powered breast pump system for extracting milk from a mother.

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2. Description of the Prior Art

The specification of the present disclosure is broad and deep. We will now describe the prior art in relation to key aspects of the present disclosure.

Prior art related to breast pump systems

A breast pump system is a mechanical or electro-mechanical device that extracts milk from the breasts of a lactating woman.

A typical breast pump design is as shown in WO 96/25187 A1. A large suction generating device is provided, which is freestanding. This is attached by air lines to one or two breast shields which engage with the user's breasts. A pressure cycle is applied from the suction generating device, via the air lines, to the breast shields. This generates a pressure cycle on the user's breasts to simulate the suction generated by a feeding child.

The suction generating device is a large component that connects to mains power to operate the pumps therein. Milk collection bottles are provided to store the expressed

breast milk. In the system of WO 96/36298 A1 separate bottles are provided attached to each breast shield. A single bottle with tubing connecting to each breast shield may also be used. But for a mother to use this discretely, such as in an office environment, specialised bras must be used. In particular, breast-pumping bras which have a central slit, for the nipple tunnel of the breast shield to extend through, are typically used. The breast shield is held within the bra, with the suction generating device and milk bottle outside the bra.

The fundamental breast pump system has not significantly evolved from this approach, only minor technical improvements have been made.

However, these systems present a number of significant disadvantages. As the suction generating device is a large freestanding unit connected to mains power, the user may feel tethered to the wall. The known devices typically also require a specific user posture and undressing to function normally. This is obviously difficult for a user to do discretely, such as in an office setting. The known devices are also typically noisy, uncomfortable, and hard to clean.

Fully integrated wearable breast pump systems have begun to enter the market, such as described in US 2016 0206794 A1. In such pump systems, the suction source, power supply and milk container are contained in a single, wearable device; there is no need for bulky external components or connections. Such devices can be provided with a substantially breast shaped convex profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations. The internal breast shield is naturally convex to fit over a breast.

In US 2016 0206794 A1, when viewed from the front, the breast pump device has a 'tear-drop' rounded shape, fuller at its base than at its top. But it uses collapsible bags as milk collection devices. As the collection bag systems are collapsible, it can be difficult for a user to extract all of their milk from the bag, due to the small cut opening that is needed and the capillary action between the bonded plastic sheets that form the bag. This waste can be disheartening for the user, as this is food for their child. The bags are also not re-usable, so the user is required to purchase and maintain a stock of these. As well as presenting a recurring cost, if the user runs out of stock they are unable to use the

product until more bags are purchased.

Furthermore, as a result of the collapsible bags, a complex and somewhat noisy pumping arrangement is necessary. In particular, the breast shield connects to a tube which is provided with compression units which "step" the expressed milk through the tube to the collection bag. This uses the breast milk as a hydraulic fluid to generate suction on the breast. In order to carry this out, a complex sequenced pulsing arrangement must be implemented.

In addition to these systems being particularly complex and wasteful, only a relatively small bag can be used. In US 2016 206794, approximately 110 ml (4 fluid ounces) of milk can be collected before the bag must be changed. While this may be sufficient for some users, others may produce much more milk in a session.

A further integrated wearable breast pump system is shown in US 2013 0023821 A1. In the third embodiment in this document, the breast pump system includes a motor driven vacuum pump and power source. An annular (or punctured disc) membrane is provided, with the flow path of the milk going through the centre of the annulus. The membrane is housed in separate housing and is sealed at its inner and outer edges. The breast shield has a small protrusion to engage with these housing components. However, the design of this breast pump system results in a number of problems. The use of an annular membrane, with the fluid flow path running through the opening of the annulus is undesirable as it results in a large and bulky device. There is therefore a need for improved integrated breast pump systems.

Prior Art related to liquid measurement systems

In the context of breast pump systems, it is useful to measure the quantity of expressed milk. One way to do this is to have a clear container for the breast pump, through which the level of expressed milk inside the container can be seen. However, viewing the milk bottle is not always possible, for example in a breast pump that collects milk while being worn inside a maternity bra.

An existing apparatus for detecting the level of liquid inside a container of a breast pump is that disclosed in US 2016/296681. In this apparatus, a sensing mechanism is provided

at the top of a container, which detects droplets of liquid, specifically breast milk, entering the container. By detecting these droplets entering the container, the apparatus can determine the quantity of liquid which enters the container. In this apparatus, an accurate indication of the level of liquid in the container is reliant on the sensing mechanism being able to accurately record every droplet entering the container.

Particularly at times when liquid enters the container at a high flow rate, this accuracy cannot be guaranteed, leading to significant cumulative errors. An accurate indication of the level of liquid in the container in this apparatus is also reliant on the sensing mechanism always being on during the pumping process, so that power consumption of the sensing mechanism is correspondingly high.

In view of the above, there is the need for an improved way to determine the level of liquid inside a container connected to a breast pump.

Prior Art related to bra clips

Many specialised bras (or brassieres) exist for maternity use and that facilitate nursing and/or breast pumping for milk collection, without the need to remove the bra itself. In a traditional nursing bra, this is achieved with the use of an at least partially detachable cup, which can be unhooked for feeding and/or pumping.

Further specialised bras are known which are provided with cut-out portions or slits which substantially align with the wearer's areola and nipple. Traditional breast pump systems comprise an elongate breast shield which extends away from the breast towards an external bottle and source of suction. The breast shield is arranged to extend through the cut-out portion or slit, with the collection bottle and pumping apparatus placed outside of the bra. These systems require the user to remove or unbutton any over-garments, and are uncomfortable when not pumping.

Integrated, wearable breast pump systems have begun to enter the market, such as previously noted US 2016 0206794 A1. In such pumps, the suction source, power supply and milk container are all in a single, wearable device, as noted above, without the need for bulky external components or connections. Such devices can be provided with a substantially breast shaped profile so as to fit within a user's bra for discrete pumping, as

well as pumping on-the-go without any tethers to electrical sockets or collection stations.

Maternity (or nursing) bras such as disclosed in US 4,390,024 A have partially detachable cups, with several hooks provided along the bra strap for attaching the cups to the strap. The cups can then be attached to different hooks in order to adjust the bra strap length. However, these attachment points are fixed. Additionally, this bra has been designed to accommodate the change in breast size before and after the feeding/pumping process. It is not designed to accommodate a breast pump. Accordingly, there is a need for a better system to accommodate integrated wearable breast pumps.

SUMMARY OF THE INVENTION

The invention is a wearable breast pump system including: a housing shaped at least in part to fit inside a bra and including a pumping mechanism; a breast shield; a rigid or non-collapsible milk container; and in which the breast pump system includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and the rigid, non-collapsible milk container.

BRIEF DESCRIPTION OF THE FIGURES

Aspects of the invention will now be described, by way of example(s), with reference to the following Figures, which each show features of various implementations of the invention including optional features that may be utilised:

Figure 1 is a front view of an assembled breast pump system.

Figure 2 is a rear view of the assembled breast pump system of Figure 1.

Figure 3 is a front view of a partially disassembled breast pump system.

Figure 4 is a rear view of the partially disassembled breast pump system of Figure 3.

Figure 5 is a front view of a further partially disassembled breast pump system.

Figure 6 is a rear view of the further partially disassembled breast pump system of Figure 5.

Figure 7 is a front view of the breast pump system of Figure 1, with the outer shell translucent for ease of explanation.

Figure 8 is a further front view of the breast pump system of Figure 1, with the front of the outer shell removed for ease of explanation.

Figure 9 is a schematic view of a nipple tunnel for a breast shield.

Figure 10 is a schematic of a pneumatic system for a breast pump system.

Figure 11 is a schematic of an alternative pneumatic system for a breast pump system.

Figure 12 is a schematic of a further alternative pneumatic system for a breast pump system.

Figure 13 is a graph depicting measured pressure in the breast pump system of Figure 12 over time.

Figure 14 shows schematics for breast shield sizing and nipple alignment.

Figure 15 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 16 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 17 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 18 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 19 shows a screenshot of an application running on a device connected to the

breast pump system.

Figure 20 shows a screenshot of an application running on a connected device.

Figure 21 shows a screenshot of an application running on a connected device.

Figure 22 shows a screenshot of an application running on a connected device.

Figure 23 shows a screenshot of an application running on a connected device.

Figure 24 shows a screenshot of an application running on a connected device.

Figure 25 shows a screenshot of an application running on a connected device.

Figure 26 shows a diagram of a breast pump sensor network,

Figure 27 shows a sectional view of a device being used to determine the level of liquid in a container;

Figure 28 shows a sectional view of the device and the container from Figure 27 being used at a different orientation.

Figure 29 shows a sectional view of the device and the container from Figure 27 being used whilst undergoing acceleration.

Figure 30 shows a sectional view of the device from Figure 27 being used as part of a breast pump assembly.

Figure 31 shows a sectional view of a device connected between a container and its lid, and which is operable to determine the level of liquid inside the container.

Figure 32 depicts a prior art design for a maternity bra;

Figure 33 depicts a clip and clasp being fitted to a maternity bra.

Figure 34 depicts an alternative clip for adjustment of a maternity bra.

Figure 35 depicts the alternative clip of Figure 34.

Figure 36 depicts an alternative clip for adjustment of a maternity bra.

Figure 37 depicts an alternative clip for adjustment of a maternity bra.

Figure 38 depicts an alternative clip for adjustment of a maternity bra.

Figure 39 depicts adjustment of the maternity bra of Figure 37.

Figure 40 shows a configuration with two piezo pumps mounted in series.

Figure 41 shows a configuration of two piezo pumps mounted in parallel.

Figure 42 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in series and mounted in parallel respectively.

Figure 43 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration.

Figure 44 shows a figure of a pump including two piezo pumps in which each piezo pump is connected to a heat sink.

DETAILED DESCRIPTION

We will now describe an implementation of the invention, called the Elvie™ pump, in the following sections:

Section A: The Elvie™ Breast Pump System

Section B: An IR System

Section C: A Bra Clip

Section D: Piezo Pumps and Wearable Devices

Section A: The Elvie™ Breast Pump System

1. Elvie™ Breast Pump System Overview

An implementation of the invention, called the Elvie™ pump, is a breast pump system that is, at least in part, wearable inside a bra. The breast pump system comprises a breast shield for engagement with the user's breast, a housing for receiving at least a portion of the breast shield and a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user, with a milk-flow pathway defined from an opening in the breast shield to the milk collection container. The housing inside also includes a pump for generating a negative pressure in the breast shield, as well as battery and control electronics Unlike other wearable breast pumps, the only parts of the system that come into contact with milk in normal use are the breast shield and the milk container; milk only flows through the breast shield and then directly into the milk container. Milk does not flow through any parts of the housing at all, for maximum hygiene and ease of cleaning.

With reference to Figure 1 and Figure 2, the assembled breast pump system 100 includes a housing 1 shaped to substantially fit inside a bra. The housing 1 includes one or more pumps and a rechargeable battery. The breast pump system includes two parts that are directly connected to the housing 1: the breast shield 7 and a milk container 3. The breast shield 7 and the milk container 3 are directly removable or attachable from the housing 1 in normal use or during normal dis-assembly (most clearly shown in Figure 5). All other parts that are user-removable in normal use or during normal dis-assembly are attached to either the breast shield 7 or the milk container 3. The breast shield 7 and milk container 3 may be removed or attached for example using a one click or one press action or a push button or any other release mechanism. Audible and/or haptic feedbacks confirm that the pump is properly assembled.

The modularity of the breast pump allows for easy assembly, disassembly and replacement of different parts such as the breast shield and milk collection container. This also allows for different parts of the pump to be easily washed and/or sterilised. The breast shield and bottle assembly, both of which are in contact with milk during

pumping, may therefore be efficiently and easily cleaned; these are the only two items that need to be cleaned; in particular, the housing does not need to be cleaned.

The housing 1, breast shield 7 that is holding a flexible diaphragm, and milk container 3 attach together to provide a closed-loop pneumatic system powered by piezoelectric pumps located in the housing 1. This system then applies negative pressure directly to the nipple, forms an airtight seal around the areola, and provides a short path for expressed milk to collect in an ergonomically shaped milk container 3.

The different parts of the breast shield system are also configured to automatically self-seal under negative pressure for convenience of assembly and disassembly and to reduce the risk of milk spillage. Self-sealing refers to the ability of sealing itself automatically or without the application of adhesive, glue, or moisture (such as for example a self-sealing automobile tire or self-sealing envelopes). Hence once the breast pump system is assembled it self-seals under its assembled condition without the need to force seals into interference fits to create sealed chambers. A degree of interference fitting is usual however, but is not the predominating attachment mechanism. Self-sealing enables simple components to be assembled together with a light push: for example, the diaphragm just needs to be placed lightly against the diaphragm housing; it will self-seal properly and sufficiently when the air-pump applies sufficient negative air-pressure. The diaphragm itself self-seals against the housing when the breast shield is pushed into the housing. Likewise, the breast shield self-seals against the milk container when the milk container is pushed up to engage the housing. This leads to simple and fast assembly and dis-assembly, making it quick and easy to set the device up for use, and to clean the device after a session.

Self-sealing has a broad meaning and may also relate to any, wholly or partly self-energising seals. It may also cover any interference seals, such as a press seal or a friction seal, which are achieved by friction after two parts are pushed together.

Whilst one particular embodiment of the invention's design and a specific form of each of the parts of the breast pump system is detailed below, it can be appreciated that the overall description is not restrictive, but an illustration of topology and function that the design will embody, whilst not necessary employing this exact form or number of

discrete parts.

The breast pump system 100 comprises a housing 1 and a milk collection container (or bottle) 3. The housing 1 (including the one or more pumps and a battery) and the container 3 are provided as a unit with a convex outer surface contoured to fit inside a bra. The milk collection container 3 is attached to a lower face 1A of the housing 1 and forms an integral part of the housing when connected, such that it can be held comfortably inside a bra. While the breast pump 100 may be arranged to be used with just the right or the left breast specifically, the breast pump 100 is preferably used with both breasts, without modification. To this end, the outer surfaces of the breast pump 100 are preferably substantially symmetrical.

Preferably, the width of the complete breast pump device (housing 1 and milk container 3) is less than 110 mm and the height of the complete breast pump device is less than 180 mm.

Overall, the breast pump system 100 gives discrete and comfortable wear and use. The system weighs about 224 grams when the milk container is empty, making it relatively lighter as compared to current solutions; lightness has been a key design goal from the start, and has been achieved through a lightweight piezo pump system and engineering design focussed on minimising the number of components.

The breast pump system 100 is small enough to be at least in part held within any bra without the need to use a specialized bra, such as a maternity bra or a sports bra. The rear surface of the breast pump is also concave so that it may sit comfortably against the breast. The weight of the system has also been distributed to ensure that the breast pump is not top heavy, ensuring comfort and reliable suction against the breast. The centre of gravity of the pump system is, when the container is empty, substantially at or below the horizontal line that passes through the filling point on the breast shield, so that the device does not feel top-heavy to a person while using the pump.

Preferably, when the container is empty, the centre of gravity is substantially at or below the half-way height line of the housing so that the device does not feel top-heavy to a user using the pump.

The centre of gravity of the breast pump, as depicted by Figure 1, is at around 60mm high on the centreline from the base of the breast pump when the milk container is empty. During normal use, and as the milk container gradually receives milk, the centre of gravity lowers, which increases the stability of the pump inside the bra. It reduces to around 40mm high on the centreline from the base of the breast pump when the milk container is full.

The centre of gravity of the breast pump is at about 5.85mm below the centre of the nipple tunnel when the milk container is empty, and reduced to about 23.60mm below the centre of the nipple tunnel when the milk container is full. Generalising, the centre of gravity should be at least 2mm below the centre of the nipple tunnel when the container is empty.

The breast pump 100 is further provided with a user interface 5. This may take the form of a touchscreen and/or physical buttons. In particular, this may include buttons, sliders, any form of display, lights, or any other componentry necessary to control and indicate use of the breast pump 100. Such functions might include turning the breast pump 100 on or off, specifying which breast is being pumped, increasing or decreasing the peak pump pressure. Alternatively, the information provided through the user interface 5 might also be conveyed through haptic feedback, such as device vibration, driven from a miniature vibration motor within the pump housing 1.

In the particular embodiment of the Figures, the user interface 5 comprises power button 5A for turning the pump on and off. The user interface 5 further comprises pump up button 5B and pump down button 5C. These buttons adjust the pressure generated by the pump and hence the vacuum pressure applied to the user's breast. In preferable embodiments, the pump up button 5B could be physically larger than the pump down button 5C. A play/pause button 5D is provided for the user to interrupt the pumping process without turning the device off.

The user interface 5 further comprises a breast toggle button 5E for the user to toggle a display of which breast is being pumped. This may be used for data collection, e.g. via an application running on a connected smartphone; the app sends data to a remote server, where data analysis is undertaken (as discussed in more detail later), or for the user to keep track of which breast has most recently been pumped. In particular, there may be a

pair of LEDs, one to the left of the toggle button 5E and one to the right. When the user is pumping the left breast, the LED to the right of the toggle button 5E will illuminate, so that when the user looks down at the toggle it is the rightmost LED from their point of view that is illuminated. When the user then wishes to switch to the right breast, the toggle button can be pressed and the LED to the left of the toggle button 5E, when the user looks down will illuminate. The connected application can automatically track and allocate how much milk has been expressed, and when, by each breast.

The breast pump system also comprises an illuminated control panel, in which the level of illumination can be controlled at night or when stipulated by the user. A day time mode, and a less bright night time mode that are suitable to the user, are available. The control of the illumination level is either implemented in hardware within the breast pump system itself or in software within a connected device application used in combination with the breast pump system.

As depicted in Figure 1, the housing 1 and milk collection container 3 form a substantially continuous outer surface, with a generally convex shape. This shape roughly conforms with the shape of a 'tear-drop' shaped breast. This allows the breast pump 100 to substantially fit within the cup of a user's bra. The milk collection container 3 is retained in attachment with the housing 1 by means of a latch system, which is released by a one-click release mechanism such as a push button 2 or any other one-handed release mechanism. An audible and/or haptic feedback may also be used to confirm that the milk collection container 3 has been properly assembled.

The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting an additional 2 cm difference. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc. In preferred embodiments, the breast pump 100 of the present invention corresponds to an increase of between 3 or 4 cup sizes of the user according to EN 13402.

A plane-to-plane depth of the breast pump can also be defined. This is defined as the distance between two parallel planes, the first of which is aligned with the innermost

point of the breast pump 100, and the second of which is aligned with the outermost point of the breast pump 100. This distance is preferably less than 100 mm.

Figure 2 is a rear view of the breast pump 100 of Figure 1. The inner surface of the housing 1 and milk collection container 3 are shown, along with a breast shield 7. The housing 1, milk collection container 3 and breast shield 7 form the three major subcomponents of the breast pump system 100. In use, these sub-components clip together to provide the functioning breast pump system 100. The breast shield 7 is designed to engage with the user's breast, and comprises a concave inner flange 7A which contacts the breast. To allow the breast pump 100 to be used on either of the user's breasts, the breast shield 7 is preferably substantially symmetrical on its inner flange 7A.

The inner flange 7A is substantially oval-shaped. While the inner flange 7A is concave, it is relatively shallow such that it substantially fits the body form of the user's breast. In particular, when measured side-on the inner-most point of the flange 7A and the outer-most point may be separated by less than 25 mm. By having a relatively shallow concave surface, the forces applied can be spread out over more surface area of the breast. The flatter form also allows easier and more accurate location of the user's nipple. In particular, the flange 7A of the breast shield 7 may extend over the majority of the inner surface of the housing 1 and milk collection container 3. Preferably, it may extend over 80% of this surface. By covering the majority of the inner surface, the breast shield is the only component which contact's the wearer's breast. This leaves fewer surfaces which require thorough cleaning as it reduces the risk of milk contacting a part of the device which cannot be easily sterilized. Additionally, this also helps to disperse the pressure applied to the user's breast across a larger area.

The breast shield 7 substantially aligns with the outer edge 1B of the housing 1. The milk collection container 3 may be provided with an arcuate groove for receiving a lower part of the breast shield 7. This is best shown in later Figures. In the assembled arrangement of Figures 1 and 2, the inner surface of the breast pump 100 is substantially continuous.

The breast shield 7 comprises a shield flange for engaging the user's breast, and an elongate nipple tunnel 9) aligned with the opening and extending away from the user's

breast. Breast shield nipple tunnel 9 extends from a curved section 7B in the breast shield 7. In preferable embodiments the nipple tunnel 9 is integral with the breast shield 7. However, it is appreciated that separate removable/interchangeable nipple tunnels may be used. Curved section 7B is positioned over the user's nipple and areola in use. The breast shield 7 forms an at least partial seal with the rest of the user's breast around this portion, under the negative air pressure created by an air-pressure pump.

This breast shield nipple tunnel 9 defines a milk-flow path from the inner surface of the breast shield 7A, through the breast shield nipple tunnel 9 and into the milk collection container 3. The breast shield nipple tunnel 9 is preferably quite short in order to minimise the length of the milk-flow path in order to minimise losses. By reducing the distance covered by the milk, the device is also reduced in size and complexity of small intermediate portions. In particular, the breast shield nipple tunnel 9 may extend less than 70 mm from its start to end, more preferably less than 50 mm. In use, the nipple tunnel 9 is substantially aligned with the user's nipple and areolae. The nipple tunnel comprises a first opening 9A for depositing milk into the collection container and a second opening 19A for transferring negative air pressure generated by the pump to the user's nipple.

The shield flange 7A and nipple tunnel 9 may be detachable from the housing 1 together. The shield flange 7A and nipple tunnel 9 being detachable together helps further simplify the design, and reduce the number of components which must be removed for cleaning and sterilization. However, preferably, the nipple tunnel 9 will be integral with the breast shield 7, in order to simplify the design and reduce the number of components which must be removed for cleaning and sterilisation.

Figures 3 and 4 are of a partially disassembled breast pump 100 of the present invention. In these Figures, the breast shield 7 has been disengaged from the housing 1 and milk collection bottle 3. As shown in Figure 4, the housing 1 comprises a region or slot 11 for receiving the breast shield nipple tunnel 9 of the breast shield 7. The breast shield is held in place thanks to a pair of channels (9B) included in the nipple tunnel 9, each channel including a small indent. When pushing the housing 1 onto the breast shield 7, which has been placed over the breast, ridges in the housing (9C) engage with the channels, guiding the housing into position; a small, spring plunger, such as ball bearing in each

ridge facilitates movement of the housing on to the nipple tunnel 9. The ball bearings locate into the indent to secure the housing on to the nipple tunnel with a light clicking sound. In this way, the user can with one hand place and position the breast shield 7 onto her breast and with her other hand, position and secure the housing 1 on to the breast shield 7. The breast shield 7 can be readily separated from the housing 1 since the ball bearing latch only lightly secures the breast shield 7 to the housing 1.

Alternatively, the breast shield 7 may also be held in place by means of a clip engaging with a slot located on the housing. The clip may be placed at any suitable point on the shield 7, with the slot in a corresponding location.

The breast shield nipple tunnel 9 of the breast shield 7 is provided with an opening 9A on its lower surface through which expressed milk flows. This opening 9A is configured to engage with the milk collection bottle 3.

The breast pump 100 further comprises a barrier or diaphragm for transferring the pressure from the pump to the milk-collection side of the system. In the depicted example, this includes flexible rubber diaphragm 13 seated into diaphragm housing 19A. The barrier could be any other suitable component such as a filter or an air transmissive material. Diaphragm housing 19A includes a small air hole into the nipple tunnel 9 to transfer negative air pressure into nipple tunnel 9 and hence to impose a sucking action on the nipple placed in the nipple tunnel 9.

Hence, the air pump acts on one side of the barrier or diaphragm 13 to generate a negative air pressure on the opposite, milk-flow side of the barrier. The barrier has an outer periphery or surface, i.e. the surface of diaphragm housing 19A that faces towards the breast, and the milk-flow pathway extends underneath the outer periphery or surface of the barrier or diaphragm housing 19A. The milk-flow path extending under the outer periphery or surface of the barrier 19A allows for a simpler and more robust design, without the milk-flow pathway extending through the barrier. This provides increased interior space and functionality for the device.

As noted, the milk-flow pathway extends beneath or under the barrier 13 or surface of diaphragm housing 19A. This provides an added benefit of having gravity move the milk down and away from the barrier.

Preferably the milk-flow pathway does not pass through the barrier 32. This results in a simpler and smaller barrier design.

As noted, the diaphragm 13 is mounted on diaphragm housing 19A that is integral to the breast shield. This further helps increase the ease of cleaning and sterilisation as all of the components on the "milk" flow side can be removed.

The barrier 13 may also provide a seal to isolate the air pump from the milk-flow side of the barrier. This helps to avoid the milk becoming contaminated from the airflow or pumping side (i.e. the non-milk-flow side).

Alternatively, the only seal is around an outer edge of the barrier 13. This is a simple design as only a single seal needs to be formed and maintained. Having multiple seals, such as for an annular membrane, introduces additional complexity and potential failure points.

As illustrated in Figures 3 and 4, the barrier may include a flexible diaphragm 13 formed by a continuous circular disc shaped membrane which is devoid of any openings or holes. This provides a larger effective "working" area of the diaphragm (i.e. the area of the surface in contact with the pneumatic gasses) than an annular membrane and hence the membrane may be smaller in diameter to have the same working area.

The diaphragm 13 is arranged so that the milk-flow pathway extends below and past the outer surface or periphery of the diaphragm 13. This means that the milk-flow pathway does not extend through the diaphragm 13. In particular, the milk-flow pathway is beneath the diaphragm 13. However, the diaphragm 13 may be offset in any direction with respect to the milk-flow pathway, provided that the milk-flow pathway does not extend through the diaphragm 13.

Preferably, the diaphragm 13 is a continuous membrane, devoid of any openings. The diaphragm 13 is held in a diaphragm housing 19, which is formed in two parts. The first half 19A of the diaphragm housing 19 is provided on the outer surface of the breast shield 7, above the breast shield nipple tunnel 9 and hence the milk-flow pathway. In

preferred embodiments, the first half 19A of the diaphragm housing 19 is integral with the breast shield. The second half 19B of the diaphragm housing is provided in a recessed portion of the housing 1. The diaphragm 13 self-seals in this diaphragm housing 19 around its outer edge, to form a watertight and airtight seal. Preferably, the self-seal around the outer edge of the diaphragm 13 is the only seal of the diaphragm 13. This is beneficial over systems with annular diaphragms which must seal at an inner edge as well. Having the diaphragm 13 mounted in the breast pump 100 in this manner ensures that it is easily accessible for cleaning and replacement. It also ensures that the breast shield 7 and diaphragm 13 are the only components which need to be removed from the pump 100 for cleaning. Because the diaphragm 13 self-seals under vacuum pressure, it is easily removed for cleaning when the device is turned off.

Figures 5 and 6 show a breast pump 100 according to the present invention in a further disassembled state. In addition to the breast shield 7 and diaphragm 13 being removed, the milk collection container 3 has been unclipped. Preferably, the milk collection container 3 is a substantially rigid component. This ensures that expressed milk does not get wasted, while also enhancing re-usability. In some embodiments, the milk collection container 3 may be formed of three sections: a front bottle potion, a rear bottle potion, and a cap. These three sections may clip together to form the milk collection container 3. This three-part system is easy to empty, easily cleanable since it can be dis-assembled, and easily re-usable. The milk collection container or milk bottle may be formed of at least two rigid sections which are connectable. This allows simple cleaning of the container for re-use. Alternatively, the container may be a single container made using a blow moulding construction, with a large opening to facilitate cleaning. This large opening is then closed with a cap with an integral spout 35 or 'sealing plate' (which is bayonet-mounted and hence more easily cleaned than a threaded mount spout). A flexible rubber valve 37 (or 'sealing plate seal') is mounted onto the cap or spout 35 and includes a rubber duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump; this ensures that negative air-pressure does not need to be applied to the milk container and hence adds to the efficiency of the system. The flexible valve 37 self-seals against opening 9A in nipple tunnel 9. Because it self-seals under vacuum pressure, it automatically releases when the system is off, making it easy to remove the milk container.

Preferably, the milk collection container resides entirely below the milk flow path defined by the breast shield when the breast pump system 100 is positioned for normal use, hence ensuring fast and reliable milk collection.

The milk collection container 3 has a capacity of approximately 5 fluid ounces (148 ml). Preferably, the milk collection container has a volume of greater than 120 ml. More preferably, the milk collection container has a volume of greater than 140 ml. To achieve this, the milk collection container 3 preferably has a depth in a direction extending away from the breast in use, of between 50 to 80 mm, more preferably between 60 mm to 70 mm, and most preferably between 65 mm to 68 mm.

The milk collection container 3 further preferably has a height, extending in the direction from the bottom of the container 3 in use to the cap or spout or sealing plate 35, of between 40 mm to 60 mm, more preferably between 45 mm to 55 mm, and most preferably between 48 mm to 52 mm. The cap 35 may screw into the milk collection bottle 3. In particular, it may be provided with a threaded connection or a bayonet and slot arrangement.

Further preferably, the milk collection container has a length, extending from the leftmost point to the rightmost point of the container 3 in use, of between 100 mm to 120 30 mm, more preferably between 105 mm to 115 mm, and most preferably between 107 mm to 110 mm.

This cap 35 is provided with a one-way valve 37, through which milk can flow only into the bottle. This valve 37 prevents milk from spilling from the bottle once it has been collected. In addition, the valve 37 automatically seals completely unless engaged to the breast shield 7. This ensures that when the pump 100 is dismantled immediately after pumping, no milk is lost from the collection bottle 3. It can be appreciated that this one-way valve 37 might also be placed on the breast shield 7 rather than in this bottle cap 35.

Alternatively, the milk bottle 3 may form a single integral part with a cap 35. Cap 35 may include an integral milk pouring spout.

In certain embodiments, a teat may be provided to attach to the annular protrusion 31A

or attach to the spout that is integral with cap 35, to allow the container 3 to be used directly as a bottle. This allows the milk container to be used directly as a drinking vessel for a child. The milk collection container may also be shaped with broad shoulders such that it can be adapted as a drinking bottle that a baby can easily hold.

Alternatively, or in addition, a spout may be provided to attach to the protrusion 31A for ease of pouring. A cap may also be provided to attach to the protrusion 31A in order to seal the milk collection bottle 3 for easy storage.

The pouring spout, drinking spout, teat or cap may also be integral to the milk collection container.

Further, the removable milk collection container or bottle includes a clear or transparent wall or section to show the amount of milk collected. Additionally, measurement markings (3A) may also be present on the surface of the container. This allows the level of milk within the container to be easily observed, even while pumping. The milk collection container or bottle may for example be made using an optically clear, dishwasher safe polycarbonate material such as Tritan™.

The milk collection container or bottle may include a memory or a removable tag, such as a tag including an NFC chip, that is programmed to store the date and time it was filled with milk, using data from the breast pump system or a connected device such as a smartphone. The container therefore includes wireless connectivity and connects to a companion app. The companion app then tracks the status of multiple milk collection containers or bottles to select an appropriate container or bottle for feeding. The tag of the bottle may also be programmed to store the expiry date of the milk as well as the quantity of the milk stored.

Figures 7 and 8 show front views of a breast pump system 100. The outer-surface of the housing 1 has been drawn translucent to show the components inside. The control circuitry 71 for the breast pump 100 is shown in these figures. The control circuitry in the present embodiment comprises four separate printed circuit boards, but it is appreciated that any other suitable arrangement may be used.

The control circuitry may include sensing apparatus for determining the level of milk in the container 3. The control circuitry may further comprise a wireless transmission device for communicating over a wireless protocol (such as Bluetooth) with an external device. This may be the user's phone, and information about the pumping may be sent to this device. In embodiments where the user interface comprises a breast toggle button 5E, information on which breast has been selected by the user may also be transmitted with the pumping information. This allows the external device to separately track and record pumping and milk expression data for the left and right breasts.

There should also be a power charging means within the control circuitry 71 for charging the battery 81. While an external socket, cable or contact point may be required for charging, a form of wireless charging may instead be used such as inductive or resonance charging. In the Figures, charging port 6 is shown for charging the battery 81. This port 6 may be located anywhere appropriate on the housing 1.

Figure 8 shows the location of the battery 81 and the pumps 83A, 83B mounted in series inside the housing 1. While the depicted embodiment shows two pumps 83A, 83B it is appreciated that the present invention may have a single pump. Preferably, an air filter 86 is provided at the output to the pumps 83A, 83B. In preferable embodiments, the pumps 83A, 83B are piezoelectric air pumps (or piezo pumps), which operate nearly silently and with minimal vibrations. A suitable piezo pump is manufactured by TTP Ventus, which can deliver in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free flow. The rear side of the second half of the diaphragm housing 19B in the housing 1 is provided with a pneumatic connection spout. The pumps 83A, 83B are pneumatically connected with this connection spout.

Operation of the breast pump 100 will now be described. Once the breast pump 100 is activated and a pumping cycle is begun, the pumps 83A, 83B generates a negative air pressure which is transmitted via an air channel to a first side of the diaphragm 13 mounted on the diaphragm housing 19A. This side of the diaphragm 13 is denoted the pumping side 13B of the diaphragm 13.

The diaphragm 13 transmits this negative air pressure to its opposite side (denoted the milk-flow side 13A). This negative pressure is transferred through a small opening in the

diaphragm housing 19A to the breast shield nipple tunnel 9 and the curved opening 7B of the breast shield 7 that contacts the breast. This acts to apply the pressure cycle to the breast of the user, in order to express milk. The milk is then drawn through the nipple tunnel 9, to the one way valve 37 that remains closed whilst negative pressure is applied. When the negative air pressure is released, the valve 37 opens and milk flows under gravity past the valve 37 and into milk container 3. Negative air pressure is periodically (e.g. cyclically, every few seconds) applied to deliver pre-set pressure profiles such as profiles that imitate the sucking of a child.

While the depicted embodiment of the breast pump 100 is provided with two pumps, the following schematics will be described with a single pump 83. It is understood that the single pump 83 could be replaced by two separate piezo air-pumps 83A, 83B as above.

Figure 9 depicts a schematic of a further embodiment of a breast shield nipple tunnel 9 for a breast pump 100. The breast shield nipple tunnel 9 is provided with an antechamber 91 and a separation chamber 93. A protrusion 95 extends from the walls of the breast shield nipple tunnel 9 to provide a tortuous air-liquid labyrinth path through the breast shield nipple tunnel 9. In the separation chamber 93 there are two opening 97, 99. An air opening 97 is provided in an upper surface 93A of the separation chamber 93. This upper surface 93 is provided transverse to the direction of the breast shield nipple tunnel 9. This opening 97 connects to the first side of the diaphragm housing 19A and is the source of the negative pressure. This airflow opening 97 also provides a route for air to flow as shown with arrow 96. It is appreciated that the tortuous pathway is not necessary and that a breast shield nipple tunnel 9 without such a pathway will work.

The other opening 99 is a milk opening 99. The milk opening 99 is provided on a lower surface 93B of the separation chamber 93 and connects in use to the container 3. After flowing through the tortuous breast shield nipple tunnel 9 pathway, the milk is encouraged to flow through this opening 99 into the container 3. This is further aided by the transverse nature of the upper surface 93A. In this manner, expressed milk is kept away from the diaphragm 13. As such, the breast pump 100 can be separated into a "air" side comprising the pump 83, the connection spout 85 and the pumping side 13B of the diaphragm 13 and a "milk-flow" side comprising the breast shield 7, the milk collection container 3 and the milk-flow side 13A of the diaphragm 13. This ensures that all of the

"milk-flow" components are easily detachable for cleaning, maintenance and replacement. Additionally, the milk is kept clean by ensuring it does not contact the mechanical components. While the present embodiment discusses the generation of negative pressure with the pump 83, it will be appreciated that positive pressure may instead be generated.

While the embodiments described herein use a diaphragm 13, any suitable structure to transmit air pressure while isolating either side of the system may be used.

The breast pump may further comprise a pressure sensor in pneumatic connection with the piezo pump. This allows the output of the pump to be determined.

Figure 10 shows a schematic of a basic pneumatic system 200 for a breast pump 100. In the system 200 milk expressed into the breast shield 7 is directed through the breast shield nipple tunnel 9 through the torturous air-liquid labyrinth interface 95. The milk is directed through the non-return valve 37 to the collection container 3. This side of the system forms the "milk-flow" side 201.

The rest of the pneumatic system 200 forms the air side 202 and is separated from contact with milk. This is achieved by way of a flexible diaphragm 13 which forms a seal between the two sides of the system. The diaphragm 13 has a milk-flow side 13A and an air side or pumping side 13B.

The air side 202 of the system 200 is a closed system. This air side 202 may contain a pressure sensor 101 in pneumatic connection with the diaphragm 13 and the pump 83. Preferably, the pump 83 is a piezoelectric pump (or piezo pump). Due to their low noise, strength and compact size, piezoelectric pumps are ideally suited to the embodiment of a small, wearable breast pump. The pump 83 has an output 83A for generating pressure, and an exhaust to the atmosphere 83B. In a first phase of the expression cycle, the pump 83 gradually applies negative pressure to half of the closed system 202 behind the diaphragm 13. This causes the diaphragm 13 to extend away from the breast, and thus the diaphragm 13 conveys a decrease in pressure into the breast shield 7. The reduced pressure encourages milk expression from the breast, which is directed through the tortuous labyrinth system 95 and the one-way valve 37 to the collection bottle 3.

While in the depicted embodiment the air exhaust 83B is not used, it may be used for functions including, but not limited to, cooling of electrical components, inflation of the bottle to determine milk volume (discussed further later) or inflation of a massage bladder or liner against the breast. This massage bladder may be used to help mechanically encourage milk expression. More than one massage bladder may be inflated regularly or sequentially to massage one or more parts of the breast. Alternatively, the air pump may be used to provide warm air to one or more chambers configured to apply warmth to one or more parts of the breast to encourage let-down.

The air side 202 further comprises a two-way solenoid valve 103 connected to a filtered air inlet 105 and the pump 83. Alternatively, the filter could be fitted on the pump line 83A. If the filter is fitted here, all intake air is filtered but the performance of the pump may drop. After the negative pressure has been applied to the user's breast, air is bled into the system 202 through the valve 103 in a second phase of the expression cycle. In this embodiment, the air filter 105 is affixed to this inlet to protect the delicate components from degradation. In particular, in embodiments with piezoelectric components, these are particularly sensitive.

The second phase of the expression cycle and associated switching of valve 103 is actioned once a predefined pressure threshold has been reached. The pressure is detected by a pressure sensor 101.

In certain embodiments, if the elasticity and extension of the diaphragm 13 may be approximated mathematically at different pressures, the pressure measured by sensor 101 can be used to infer the pressures exposed to the nipple on the opposite side of the diaphragm 13. Figure 11 shows an alternative pneumatic system 300. The core architecture of this system is the same as the system shown in Figure 10.

In this system 300, the closed loop 202 is restricted with an additional three way solenoid valve 111. This valve 111 allows the diaphragm 13 to be selectively isolated from the rest of the closed loop 202. This additional three way valve 111 is located between the diaphragm 13 and the pump 83. The pressure sensor 101 is on the pump 83 side of the three way valve 111. The three way valve 111 is a single pole double throw (SPDT) valve,

wherein: the pole 111A is in pneumatic connection with the pump 83 and pressure sensor; one of the throws 11 is in pneumatic connection with the diaphragm 13; and the other throw 111C is in pneumatic connection with a dead-end 113. This dead-end 113 may either be a simple closed pipe, or any component(s) that does not allow the flow of air into the system 202. This could include, for example, an arrangement of one-way valves.

In this system 300, therefore, the pump 83 has the option of applying negative pressure directly to the pressure sensor 101. This allows repeated testing of the pump in order to calibrate pump systems, or to diagnose issues with the pump in what is called a dead end stop test. This is achieved by throwing the valve to connect the pump 83 to the dead end 113. The pump 83 then pulls directly against the dead end 113 and the reduction of pressure within the system can be detected by the pressure sensor 101.

The pressure sensor detects when pressure is delivered and is then able to measure the output of the pumping mechanism. The results of the pressure sensor are then sent to an external database for analysis such as a cloud database, or are fed back to an on-board microcontroller that is located inside the housing of the breast pump system.

Based on the pressure sensor measurements, the breast pump system is able to dynamically tune the operation of the pumping mechanism (i.e. the duty or pump cycle, duration of a pumping session, the voltage applied to the pumping mechanism, the peak negative air pressure) in order to ensure a consistent pressure performance across different breast pump systems.

In addition, the breast pump system, using the pressure sensor measurements, is able to determine if the pump is working correctly, within tolerance levels. Material fatigue of the pump is therefore directly assessed by the breast pump system. Hence, if the output of the pumping mechanism degrades over time, the breast pump system can tune the pumping mechanism operation accordingly. As an example, the breast pump system may increase the duration of a pumping session or the voltage applied to the pumping mechanism to ensure the expected pressures are met.

This ensures that the user experience is not altered, despite the changing output of the pump as it degrades over time. This is particularly relevant for piezo pumps where the output of the pump may vary significantly.

The microcontroller can also be programmed to deliver pre-set pressure profiles. The pressure profiles may correspond to, but not necessarily, any suction patterns that would mimic the sucking pattern of an infant. The patterns could mimic for example the sucking pattern of a breastfed infant during a post birth period or at a later period in lactation.

The profiles can also be manually adjusted by the user using a control interface on the housing of the breast pump system or on an application running on a connected device.

Additionally, the user is able to manually indicate the level of comfort that they are experiencing when they are using the system. This can be done using a touch or voice-based interface on the housing of the breast pump system itself or on an application running on a connected device.

The system stores the user-indicated comfort levels together with associated parameters of the pumping system. The pressure profiles may then be fine scaled in order to provide the optimum comfort level for a particular user.

The profiles or any of the pumping parameters may be calculated in order to correlate with maximum milk expression rate or quantity.

The pressure profiles or any of the pumping parameters may also be dynamically adjusted depending on the real time milk expression rate or quantity of milk collected. The pressure profiles or any of the pumping parameters may also be dynamically adjusted when the start of milk let-down has been detected.

Additionally, the system is also able to learn which parameters improve the breast pump system efficiency. The system is able to calculate or identify the parameters of the pumping mechanism that correlate with the quickest start of milk let-down or the highest volume of milk collected for a certain time period. The optimum comfort level for a particular user may also be taken into account.

Figure 12 shows a schematic for a system 400 for a breast pump 100 which can estimate the volume of milk collected in the collection container 3 from data collected on the air-side part 202 of the system 400.

The pump 83 is connected to the circuit via two bleed valves 126, 128. The first bleed valve 126 is arranged to function when the pump 83 applies a negative pressure. As such, this valve 126 is connected to a "bleed in" 127, for supplying atmospheric air to the system 202.

The second bleed valve 128 is arranged to function when the pump 83 applies a positive pressure. As such, this valve 128 is connected to a "bleed out" 129 for bleeding air in the system 202 to the atmosphere.

Although Section C describes the preferred embodiment for measuring or inferring the volume of milk collected in the milk collection container using IR sensors, an alternative method for measuring or inferring the volume of milk collected in the milk collection container using pressure sensors is described also below.

During a milking pump cycle, the pump 83 applies negative pressure on the air side 13B of the diaphragm 13 which causes its extension towards the pump 83. This increases the volume of the space on the milk side 13B of the diaphragm 13. This conveys the decrease in pressure to the breast to encourage expression of milk. A set of three non-return valves 121, 123, 125 ensure that this decrease in pressure is applied only to the breast (via the breast shield 7) and not the milk collection container 3. To measure the volume of milk collected in the container 3, the pump 83 is used instead to apply positive pressure to the diaphragm 13. The diaphragm 13 is forced to extend away from the pump 83 and conveys the pressure increase to the milk side 201 of the system 400. The three non-return valves 121, 123, 125 ensure that this increase in pressure is exclusively conveyed to the milk collection container 13.

The breast pump may further comprise: a first non-return valve between the milk flow side of the diaphragm and the breast shield, configured to allow only a negative pressure to be applied to the breast shield by the pump; a second non-return valve between the milk-flow side of the diaphragm and the milk collection container configured to allow only a positive pressure to be applied to the milk collection container by the pump; and a pressure sensor in pneumatic connection with the pressure-generation side of the diaphragm.

The resulting pressure increase is monitored behind the diaphragm 13 from the air-side 202 by a pressure sensor 101. Preferably, the pressure sensor 101 is a piezoelectric pressure sensor (piezo pressure sensor). The rate at which the pump 83 (at constant strength) is able to increase the pressure in the system 400 is a function of the volume of air that remains in the milk collection container 3. As air is many times more compressible than liquid, the rate at which pressure increases in the system 400 can be expressed as an approximate function of the volume of milk held in the collection container 3.

Thus by increasing the pressure in this fashion, the rate of pressure increase can be determined, from which the volume of milk held in the container 3 is calculable. Figure 13 shows repeated milking and volume measurement cycles as the collection container 3 is filled. To determine the rate of pressure increase the pump 83 was run for a fixed time. As pumping proceeds and the volume of air reduces in the system 400, the pump 83 is able to achieve a higher pressure. Each milking cycle is represented by a positive pressure spike 41. There is a clear upwards trend 43 in magnitude of positive pressures achieved as the collection container 3 is filled.

A method of estimating the pressure applied by a breast pump may comprise the steps of: selecting a pressure cycle from a pre-defined list of pressure cycles; applying pressure with the pump to stimulate milk expression; reading the output of the pressure sensor; and adjusting the applied pressure of the pump to match the pressure profile selected. This allows for repeatable application of force to the breast, even as the pump performance degrades.

Preferably the method further comprises the steps of: approximating the elasticity and extension of the diaphragm at the relevant pressure; and calculating an estimated applied pressure based upon the output of the pressure sensor and the approximated elasticity and extension of the diaphragm.

Alternatively, a method of estimating the milk collected by a breast pump may comprise the steps of: generating a positive pressure with the pump; transmitting the positive pressure via the diaphragm and second non-return valve to only the milk collection

container; measuring the increase in pressure by the pressure sensor in pneumatic connection with the diaphragm; estimating the volume of milk inside the milk collection container based upon the rate of increase of pressure. In this manner, the volume of milk can be estimated remotely.

In this manner, an estimate can be obtained for the volume of milk in the container 3 based upon the measured pressures.

Figure 13 also shows a dead end stop pump test 45 as described above. The negative spike shows the application of negative pressure directly to the pressure sensor 101.

2. Breast shield sizing and nipple alignment

The correct sizing of the breast shield and the alignment of the nipple in the breast shield are key for an efficient and comfortable use of the breast pump. However breast shape, size as well as nipple size and position on the breast vary from one person to another and one breast from another. In addition, women's bodies often change during the pumping life cycle and consequently breast shield sizing may also need to be changed. Therefore, a number of breast shield sizes are available. Guide lines for correct nipple alignment are also provided.

With reference to Figure 14, three breast shield sizes are shown (A1, B1, C1). The substantially clear breast shield gives an unobstructed view of the breast and allows a user to easily confirm that she has the appropriate sized shield for her breast.

In order to determine the correct breast shield size and nipple alignment, the breast shield and the diaphragm are detached from the housing and placed on the breast with the sizing symbol facing upwards (with the diaphragm positioned below the nipple) and the nipple aligned in the centre of the fit lines (as shown in A2, B2, C2). The transparent breast shield allows the user to observe the nipple while adjusting the position of the breast shield in order to align the nipple correctly near the centre of the breast shield nipple tunnel. Prior to using the pump, the nipple is aligned correctly, and the breast shield is pushed into place ensuring the seal is correctly positioned on the breast shield. The fit lines should be directly aligned with the outside of the nipple. The correct

alignment is illustrated B2.

When the nipple is correctly aligned, the user then rotates the breast shield in order for the diaphragm to be positioned on top of the nipple. The user may then quickly assemble the rest of the breast pump (i.e. the housing and the milk container) on the breast shield via a one-click attachment mechanism confirming correct engagement, which may be performed one-handed. Nipple alignment may therefore be easily maintained. Audio and/or haptic feedback may also be provided to further confirm correct engagement.

3. Connected Device Application

Figures 15 to 20 show examples of screenshots of a connected device application that may be used in conjunction with the breast pump system as described above. The interface shown here is an example only and the same data may be presented via any conceivable means including animated graphics, device notifications, audio or text descriptions.

Figure 15 shows a homepage of the application with different functions provided to the user which can be accessed either directly while pumping or at a later time in order for example: to review pump settings or the history of previous pumping sessions.

Figure 16 shows a status page with details of remaining battery life, pumping time elapsed and volume of milk inside the milk container.

Figure 17 shows screenshots of a control page, in which a user is able to control different pump parameters for a single breast pump (A) or two breast pumps (B). The user may press on the play button to either start, pause, or resume a pumping activity. The user may also directly increase or decrease the rate of expression using the (+) or (-) buttons. When only one breast is being pumped (A), the user may also indicate if it is either the right or left breast that is being pumped. The user may also control the pump peak pressure or alternatively may switch between different pre-programmed pressure profiles such as one mimicking the sucking pattern of a baby during expression or stimulation cycle.

Figure 18 shows a page providing a summary of the last recorded pumping session.

Figure 19 shows a page providing a history of previous pumping sessions. The user may scroll down through the page and visualize the data related to specific pumping sessions as a function of time.

The application is also capable of providing notifications relating to pumping. Figure 20 shows a screenshot of the application, in which a user is provided a notification when the milk collection bottle is full. Other generated notifications may include warnings about battery life, Bluetooth connection status or any other wireless communication status, status of miss-assembly, excessive movement or lack of expression.

Figure 21 shows a further example with a screenshot of an application running on a connected device. The page shows the pumping status when a user is using a double pump mode of operation with a pump on each breast. The user is able to manually control each pump individually and may start, stop or change a pumping cycle, increase or decrease each pump peak pressure, or switch between different pre-program pressure profiles such as one mimicking the sucking pattern of a baby during an expression or stimulation cycle. The application also notifies the user when a milk collection container is nearly full as shown in Figure 22.

Figure 23 shows a status page with an alert notifying the user that the milk collection container of the pump on the right breast is full. A message is displayed that the pump session has paused and that the milk collection container should be changed or emptied before resuming pumping.

With reference to Figure 24, when the left and right pump are stopped or paused, the application displays the elapsed time since the start of each session (right and left), the total volume of milk collected in each bottle.

With reference to Figure 25, a page summarising the last session (with a double pump mode) is displayed.

In addition to the data provided to the user, and their interactions with the application, the app will also hold data that the user does not interact with. For example, this may include data associated with pump diagnostics. In addition to all functions and sources of

data discussed above, the application may itself generate metadata associated with its use or inputs, notes or files uploaded by the user. All data handled within the mobile application can be periodically transferred to a cloud database for analysis. An alternative embodiment of the breast pump system may include direct contact between the database and the pump, so that pumping data may be conveyed directly, without the use of a smartphone application.

In addition to providing data to the cloud, the application may also provide a platform to receive data including for example firmware updates.

4. Breast pump data analysis

The discreet, wearable and fully integrated breast pump may offer live expression monitoring and intelligent feedback to the user in order to provide recommendations for improving pump efficiency or performance, user comfort or other pumping/sensing variables, and to enable the user to understand what variables correlate to good milk flow.

Examples of variables automatically collected by the device are: time of day, pump speed, pressure level setting, measured pressure, pressure cycle or duty cycle, voltage supplied to pumps, flow rate, volume of milk, tilt,, temperature, events such as when let-down happens, when a session is finished. The user can also input the following variables: what side they have pump with (left or right or both), and the comfort level.

This is in part possible because the live milk volume measurement system functions reliably (as discussed in Section B). The breast pump system includes a measurement sub system including IR sensors that measures or infers milk flow into the milk container, and that enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. The generated data may then be distributed to a connected device and/or to a cloud server for analysis in order to provide several useful functions.

Figure 26 illustrates an outline of a smart breast pump system network which includes the breast pump system (100) in communication with a peripheral mobile device and application (270) and several cloud-based databases (268, 273). The breast pump system

(100) includes several sensors (262). Sensor data refers to a broad definition including data generated from any sensor or any other analogue/digital reading directly from the motherboard or any other component. However, within the embodiment detailed, these measurements include one or more of the following, but not limited to: milk volume measurements, temperature sensor readings, skin temperature sensing, pressure sensor readings, accelerometer data and user inputs through any physical device interface.

The device also contains a number of actuators, including, but not restricted to: piezoelectric pump(s), solenoid valve(s), IREDs and an LED display. Sensors and actuators within the device are coordinated by the CPU (263). In addition, any interactions, and data from these components, may be stored in memory (264).

Further to these components, the device also contains a communication chip, such as a Bluetooth chip (265) which can be used to communicate wirelessly with connected devices such as a peripheral mobile device (270). Through this connection any sensor data (267) generated in the breast pump can be sent to the connected device. This user data, along with any other metadata generated from a connected device app, can be provided to an online database which aggregates all user data (273). In addition, the communication chip will also allow the sending of user control data / firmware updates from the connected device to the breast pump system (266).

Raw data (271) collected from the measurement sub-system including sensors (262) may be analysed on a cloud database and the analysed data may be stored on the cloud (272). Through inferences provided by the analysed data, firmware updates (269) may be developed. These can be provided for download to the pump through, for example, an online firmware repository or bundled with the companion app in the connected device app store (268).

In addition, it should be appreciated that despite the sophistication of the proposed breast pump network, the breast pump still retains complete functionality without wireless integration into this network. Relevant data may be stored in the device's memory (264) which may then be later uploaded to the peripheral portion of the system when a connection is established, the connection could be via USB cable or wireless.

The measurement sub-system may analyse one or more of the following:

- the quantity of the liquid in the container above its base;
- the height of the liquid in the container above its base;
- the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.

Based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase, a haptic and/or visual indicator indicates if the pump is operating correctly to pump milk. For example, the visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.

The visual indicator may provide:

- an estimation of the flow rate;
- an estimation of the fill rate;
- an indication of how much of the container has been filled.

As a further example, an accelerometer may infer the amount of movement or tilt angle during a pumping session. If the tilt angle excesses a threshold, the system warns or alerts the user of an imminent spillage, or provides the user with an alert to change position. Alternatively, the system may also stop pumping to prevent spillage, and once the tilt angle reduces below the threshold, pumping may resume automatically. By sensing the movement or title angle during a pumping session, the system may also derive the user's activity such as walking, standing or lying.

Many variables can affect milk expression and data analysis of these multiple variables can help mothers to achieve efficient pumping regimes and improve the overall user experience.

Therefore, the measurement sub-system measures or infers milk flow into the milk container and enables a user to understand what variables (e.g. time of day, pump setting) correlates to good milk flow. The amount of milk expressed over one or more sessions is recorded as well as additional metrics such as: time of day, pump setting, length of a single pumping session, vacuum level, cycle times, comfort, liquids consumed by the mother. Live data or feedback is then provided to the user to ensure the breast pump is

being used properly and to support the user in understanding the variables that would correspond to the specific individual optimum use of the breast pump.

Furthermore, live data can be used to automatically and intelligently affect specific pumping parameters in order to produce the most efficient pumping session. For example, if the rate of expression increases, the milking cycle might be adjusted accordingly to achieve a more efficient, or more comfortable pumping cycle.

The measurement sub-system also enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. Collected metrics are transferred through wireless connections between the pump, a connected device or app and a cloud database. Additionally, the application can also connect to other apps residing on the connected device, such as fitness app or social media app or any other apps. Further metrics may also include the behaviour or specific usage of the user associated with the connected device while using the pump (detection of vision and/or audio cues, internet usage, application usage, calls, text message).

Different aspects of pumping can be automatically changed based on dynamic sensor feedback within the breast pump device. The data analysis system is able to access real-time data of pumping sessions and may be used to perform one or more of the following functions, but not limited to:

- indicate whether the milk is flowing or not flowing,
- measure or infer the quantity and/or height of the liquid in the container above its base,
- give recommendations to the mother for optimal metrics for optimal milk flow,
- give recommendations to the mother for optimal metrics for weaning,
- give recommendations to the mother for optimal metrics for increasing milk supply (e.g. power pumping),
- give recommendations to the mother for optimal metrics if an optimal session start time or a complete session has been missed,
- automatically set metrics for the pumping mechanism, such as length of a single pumping session, vacuum level, cycle times.
- automatically stop pumping when the milk container is full,
- automatically adjust one or more pumping parameters to achieve an optimum

pumping session,

- automatically adjust one or more pumping parameters to achieve a comfortable pumping session,
- automatically change the pumping cycle from a programmed cycle to another different programmed cycle, such as from a stimulation cycle to an expression cycle.

In addition, sensor feedback might be used to improve the physical function of the breast pump system itself. For example, an array of piezoelectric pumps may be dynamically adjusted in response to their operating temperatures so as to optimise the total life of the component whist maintaining peak pressures.

Many additional embodiments may be described for these simple feedback systems, yet the premise remains: real-time sensor feedback is used to automatically and dynamically adjust actuator function. Each feedback program may feasibly include any number and combination of data sources and affect any arrangement of actuators.

The data generated can also be used to generate large datasets of pumping parameters, user metadata and associated expression rates, therefore allowing the analysis of trends and the construction of associations or correlations that can be used to improve pumping efficiency, efficacy or any function related to effective milk expression. The analysis of large user datasets may yield useful general associations between pumping parameters and expression data, which may be used to construct additional feedback systems to include on firmware updates.

Multiple data sources can be interpreted simultaneously and several different changes to pumping might be actuated to increase pumping efficiency, user experience or optimize pump performance.

Collected metrics may be anonymised and exported for sharing to other apps, community or social media platforms on the connected device, or to an external products and services, such as community or social media platform. By contrasting the performance of different users in the context of associated metadata, users may be grouped into discrete 'Pumper profiles' or communities, which may then be used to

recommend, or action the most appropriate selection of intelligent feedback systems to encourage efficient expression. For example, a higher peak pressure may be recommended for women who tend to move more whilst pumping, so as to achieve more efficient expression.

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SECTION B: IR SYSTEM

This section describes the milk detecting system used in the Elvie™ pump.

With reference to Figures 27 and 28, there is shown a device 270 for use in detecting the level of liquid inside a container 275. The device 270 is formed of a housing 271 in which is located a sensing assembly 272 comprising a series of optical emitters 273 (an array of three optical emitters is used on one implementation) which are relative to, and each located at a distance from, an optical receiver 274. In operation of the device as will be described, each optical emitter 273 is operable to emit radiation which is received by the optical receiver 274. In an embodiment of the invention, the series of optical emitters are each located equidistant from the optical receiver 274.

The optical emitters 273 and the optical receiver 274 from the sensing assembly 272 are located in a portion 276 of the device 270 which faces the container 275 when the device is connected to the container 275. The portion 276 of the device 270 containing the optical emitters 273 and the optical receiver 274 comprises a window 277 of material which is transparent to optical radiation. In this way, each of the optical emitters 273 and the optical receiver 274 have a line of sight through the window 277 into the container 275 when the device 270 is connected thereto.

A controller 278 comprising a CPU 279 and a memory 280 is provided in the device 270 for controlling the operation of the sensing assembly 272. An accelerometer 281 is also provided in the housing 271, which is operatively connected to the controller 278. Operation of the device 270 when connected to the container 275 will now be described.

In a principal mode of operation, to determine the level L of liquid inside the container 275, the controller 278 instructs the optical emitters 273 to each emit radiation towards the surface of the liquid inside the container 275 at a given intensity. The optical receiver 274 receives the reflected radiation from each optical emitter 273 via the surface of the liquid and each of these intensities is recorded by the controller.

For each operation of the sensing assembly 272, the controller 278 records the intensities of radiation emitted by each of the optical emitters 273 as intensities IE1; IE2...IEn

(where n is the total number of optical emitters), and records the intensities of radiation received by the optical receiver 274 from each of the optical emitters 273 as received intensities IR1; IR2...IRn.

By comparing the emitted radiation intensities IE1; IE2...IEn with the received radiation intensities IR1; IR2...IRn, the controller 278 calculates a series of intensity ratios IE1:IR1; IE2:IR2...IEn:IRn, which are then used to determine the level of the liquid inside the container. At the most basic level, if the intensity ratio of IE1:IR1 is the same as IE2:IR2, given the optical emitters 273 are equidistant from the optical receiver 274, this indicates that the level of the liquid inside the container is parallel to the top of the bottle, as shown in Figure 27. In contrast, if these two intensity ratios are different, this indicates that the liquid level is at a different angle, such as that shown in Figure 28.

To accurately determine the level and the quantity of liquid inside the container 275, the controller 278 processes the recorded intensity ratios using a database located in the memory 280. The database contains an individual record for each container which is operable to connect with the device 270. Each record from the database contains a look-up table of information, which contains expected intensity ratios (IE1:IR1 and IE2:IR2) for the container 275 when filled at different orientations, and with different quantities of liquid.

By comparing the information from the look-up table with the recorded intensity ratios, the controller 278 calculates the level and quantity of liquid inside the container 275 and stores this information in the memory 280.

In situations where a container 275 to the device 270 contains no stored record in the database, the sensing assembly 272 can be used in a calibration mode to create a new record. In the calibration mode, the sensing assembly 272 is operated as the container is filled from empty, and as it is positioned at different orientations. At each point during the calibration mode, the controller 278 calculates the recorded intensity ratios (IE1:IR1 and IE2:IR2) and stores them in the record relating to the container 275. For each set of recorded intensity ratios, the user includes information in the record relating to the orientation and fill level of liquid inside of the container 275.

To improve the accuracy of the results obtained by the device 270 during its use, the controller 278 when recording each intensity ratio also records a parameter from the accelerometer 281 relating to the acceleration experienced by the device 270. For each recorded acceleration parameter, the controller 278 determines whether the parameter 278 exceeds a predetermined threshold acceleration parameter stored in the memory 280. The predetermined threshold is indicative of an excessive acceleration, which causes sloshing of liquid inside the container 275 connected to the device 270. In the event of a recorded acceleration parameter exceeding the predetermined threshold acceleration parameter, the controller 278 flags the recorded intensity ratios associated with the recorded acceleration parameter as being unreliable (due to sloshing).

Even without the use of the accelerometer 281, the controller 278 is nonetheless operable to determine whether a set of recorded intensity ratios occur during a period of excess acceleration. In this regard, for each set of intensity ratios recorded at a given time, the controller 278 checks whether any of these intensity ratios is of a predetermined order of magnitude different than the remaining recorded intensity ratios from the set. In the event that the controller 278 determines that this is the case, this indicates that the liquid inside the container has 'sloshed' as a result of the excess acceleration, as shown in Figure 29. In this event, the controller 278 flags the set of recorded intensity ratios as being unreliable.

It will be appreciated that instead of recording the relative intensities of radiation emitted by the optical emitters 273 with the radiation received by the optical emitter 274, the controller 278 could instead record the time taken for radiation emitted by each of the optical emitters 273 to be received by the optical receiver 274. In this arrangement, the look up table would instead contain time periods as opposed to intensity ratios.

In terms of the applications for the device 270, it will be appreciated that the device can be used in a wide variety of applications. One possible application is the use of the device 270 to determine the level of liquid located within a container 275, such as a baby bottle, used as part of a breast pump assembly. In this arrangement, the device 270 is associated with a breast pump 301 which assists with the expression of milk from a breast. The breast pump may be located in the housing 271 of the device 270 as shown in Figure 30, or it may be realisably connected to the housing 271.

Either way, the device 270 would be connectable to the container 275 such that milk expressed by the breast pump can pass from the pump via a channel 302 into the container 275.

The breast pump may be any type of breast pump system including any shapes of milk container or bottle and may comprise a pump module for pumping milk from a breast. The pump module being contained within the housing may comprise: a coupling, a container attachable to the housing via the coupling to receive milk from the pump, a sensing assembly within the housing and comprising at least one optical emitter operable to emit optical radiation towards the surface of the body of milk held in the container when the housing is connected to the container, an optical receiver for receiving the reflected radiation from the surface of the milk, and a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the milk inside the container based on the reflected radiation received by the optical receiver.

By determining the level of milk inside the container based on reflected radiation from the surface of the milk in the container, there is no need to monitor the individual droplets of milk entering the container, such that the sensing assembly can avoid errors associated with measuring these droplets. For example, because we take multiple reflection-based measurements once the container is filled, we can generate an average measurement that that is more accurate than a single measurement. But with systems that rely in counting individual droplets, that is not possible – further, systemic errors (e.g. not counting droplets below a certain size) will accumulate over time and render the overall results unreliable. Furthermore, by not needing to measure these droplets, the sensing assembly from the breast pump need not always be on during the pumping process, which saves power.

When at least two optical emitters are used, the sensing assembly from the breast pump may determine the level of milk inside the container more accurately and irrespective of the orientation of the liquid level inside the container.

Each optical emitter may be equidistant from the optical receiver in order for the

controller to easily calculate the level of the milk inside the container based on the reflected radiation originating from each optical emitter. The signals from the optical receiver preferably comprise information relating to the intensity of the radiation received by the optical receiver.

Each optical emitter may be operable to emit radiation at a different wavelength, or at a different time, than the other optical emitters. In this way, the controller can more easily process the signals from the optical receiver, and more easily distinguish between the radiation emitted by each of the optical emitters.

The optical emitter may emit radiation in the visible range of wavelengths. Alternatively, it may be UV or IR light. The emitted wavelength may be for example between 10nm and 1mm.

The sensing assembly may also comprise at least one accelerometer electrically connected to the controller. The controller may be configured to record an accelerometer parameter from the accelerometer and determine whether the accelerometer parameter exceeds a predetermined threshold. The predetermined threshold may be indicative of an excessive acceleration, which might cause sloshing of milk inside any container connected to the breast pump.

Another application for the device 270 is as a collar for detecting the level/quantity of liquid in a container 275, such as a baby bottle, via its lid 310. An example of the device 270 being used as such a collar is shown in Figure 31. In this arrangement, the device 270 is located between the container 275 and the lid 310, and comprises a first end 311 having a first coupling 312 for attaching the collar to the lid 310. The device comprises a second end 313 having a second coupling 314 for attaching the device 270 to the container 275. The second coupling may be a screw thread, shown in Figure 31, on the inside surface of the container 275. In this way, the distinctive bottom inside surface can be used by the sensing assembly 272 to more easily calibrate itself to the container 275 on which the distinctive bottom inside surface is located. The distinctive bottom may also be used to help identify which container 275 the device is connected to, and thus which record should be used from the database when the device 270 is used.

To further improve the accuracy of the sensing assembly 272, the controller 278 may also be configured to use the recorded information from the accelerometer 281, in situations where the record acceleration is below the predetermined threshold acceleration parameter, to calculate a more accurate liquid level and/or quantity of liquid located inside the container which is compensated for acceleration.

In one particular arrangement, the controller 278 may poll the accelerometer 281 prior to each operation of the sensing assembly 272 to verify that the device 270 is not currently undergoing excessive acceleration. In the event of the controller 278 determining excessive acceleration in the device 270, the controller 278 would continually re-poll the accelerometer, and not operate the sensing assembly 272, until the parameter from the accelerometer is determined as being below the predetermined threshold acceleration parameter stored in the memory 280.

It will also be appreciated that for each container record stored in the database, the container record may comprise a plurality of look up tables, wherein each look up table is associated with a particular liquid used in the container, and wherein each look up table contains its own set of intensity ratios. In this way, the device 270 can more accurately determine the level/quantity of different liquids used in a particular container 275.

As described herein, the sensing assembly 272 has been described as having a plurality of optical emitters 273. It will be appreciated however that the sensing assembly could operate using a single optical emitter 273 and plurality of optical receivers 274. In this arrangement, each record from the database would contain a plurality of ratios relating to the emitted radiation from the optical emitter 273 as received by each of the optical receivers 274. In use of the device 270, the controller 278 would then similarly record the emitted radiation from the optical emitter 273 as received by each of the optical receivers 274. In an alternate arrangement, there may be provided a plurality of optical emitters 273 and a plurality of optical receivers 274, wherein each optical emitter 273 is associated with a respective optical receiver 274. In its simplest arrangement, the sensing assembly 272 may comprise a single optical emitter 273 and a single optical receiver 274.

In certain configurations, the optical emitters 273 may together emit radiation having the same wavelength. In other configurations, the optical emitters 273 may each emit

radiation having a different wavelength. In this latter configuration, the optical receiver 274 would then be able to determine which optical emitter 273 is associated with any given received radiation, based on the wavelength of the received radiation.

The optical emitters 273 may also each emit radiation at different times, such to allow the controller 278 to more easily process the signals from the optical receiver 274, and more easily distinguish between the radiation emitted by each of the optical emitters 273.

In relation to the electrical connection between the controller 278 and the sensing assembly 272, it will be appreciated this electrical connection may be either a wired/wireless connection as required.

Although not shown in the Figures, the device 270 herein described is preferably powered by a battery or some other power source located in the device 270. In other embodiments, the device 270 may be powered using mains electricity.

In one configuration, it is also envisaged that rather than the controller 278 comparing the information from the look-up table with the recorded intensity ratios to calculate the level and quantity of liquid inside the container 275, the controller 278 could instead process the recorded intensity ratios through a liquid-level equation stored in the memory 280. In this configuration, the liquid-level equation could be a generalised equation covering a family of different containers, or could be an equation specific to a container having a given shape and/or type of liquid inside.

It will also be appreciated that in some applications of the device 270, the device could be used to detect the level of a solid, as opposed to a liquid, in a container. As used herein, the terms 'optical emitter' and 'optical receiver' are intended to cover sensors which can emit radiation in or close to the optical wavelength. Any type of radiation at or close to the optical wavelength is suitable provided that it does not have any harmful effects. The exact wavelength is not important in the context of the invention. Such sensors thus include those which can emit visible radiation (such as radiation having wavelengths in the region of 400nm-700nm), and/or those which can emit IR radiation (such as radiation having wavelengths in the region of 700nm-1mm and/or those which can emit UV radiation (such as radiation having wavelengths in the region of 10nm to

400nm).

Existing prior art for such a sensor module is the apparatus disclosed in RU2441367. In this apparatus, the container is an industrially sized milk tank, which only includes a single laser mounted at the top of the tank. Whilst this apparatus is suited for large-sized containers, which do not move in use, the apparatus is less-suited for applications where the container moves in use, or where the liquid level inside the container is non perpendicular to the laser beam shone into the container. In contrast, the sensor module described above can be used in a variety of different applications, is conveniently located within a housing, and which by virtue of it having at least two optical emitters, can determine the level of liquid even inside containers of irregular shapes, and which can determine the level of liquid inside a container irrespective of the orientation of the liquid level inside the container.

Further to the embodiments of the fluid measurement system in different contexts, it can be appreciated that different functions entirely may be possible using the same component structure. For example, it is known that certain molecules within breast milk absorb specific wavelengths of light at characteristic propensities. Whilst the proposed system uses multiplexed IREDs at the same wavelengths to perform proximity measurements, the same array of IREDs may instead be used to emit several different wavelengths of light and determine their absorption upon reflection. If appropriately calibrated, the system may be able to report on the presence or concentration of specific compounds in the expressed milk, such as fat, lactose or protein content.

In addition to this embodiment, it is feasible that the system might be applied to monitor the change in volume of any other container of liquid, given there is sufficient reflection of IR off its surface. These embodiments might include for example: liquid vessel measurement such as for protein shakes, cement or paint, or volume measurements within a sealed beer keg.

SECTION C: BRA CLIP

This section describes a bra clip that forms an accessory to the Elvie™ pump.

It relates to a system allowing a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump. As such, the user does not need a specialised adjustable bra; instead the present system works with all conventional maternity bras. The user also does not have to purchase any larger bras to wear while pumping.

As shown in Figure 32, a typical maternity bra 320 comprises a support structure made up of shoulder straps 321 which support the bra 320 on the wearer's shoulders, and a bra band 322 for extending around a user's ribcage, comprising two wings 323 and a central panel or bridge 324. The straps 321 are typically provided with adjustment mechanisms 325 for varying the length of the straps 321 to fit the bra 320 to the wearer. At the outermost end of each wing, an attachment region 326 is provided. Typically, hooks 327 and loops 328 are provided for securing the bra 320 at the user's back. However, any other suitable attachment mechanism may be used. Alternatively, the attachment region 326 may be provided at the front of the bra 320 in the bridge region 324, with a continuous wing 323 extending continuously around the wearer's back. Typically, a number of sets of loops 328 are provided to allow for variation in the tightness of the bra 320 on the wearer. While shown as having a separation in Figure 32, the wings 323 and bridge 324 may form a single continuous piece in certain designs. Likewise, while shown with a distinct separation in Figure 32, the shoulder straps 321 and the wings 323 may likewise form a single continuous piece.

The maternity bra 320 is further provided with two breast-supporting cups 329 attached to the support structure. The cups 329 define a cup size, which defines the difference in protrusion of the cups 329 from the band 322. The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting a 2 cm difference between the protrusion of the cups 329 from the band 322. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes

of S, M, L, XL, etc.

The cups 329 may be stitched to the bra band 321. At least one of the cups 329, is in detachable attachment with the corresponding strap 321. In particular, this is achieved at attachment point 330 where a hook 331 attached to the bra strap 321 engages with a clasp 331 attached to the cup 329. The hook 331 and the bra strap adjuster 325 are set such that in the closed position, the cup size of the bra 320 fits the wearer's breasts.

In Figure 32, the left cup 329 is shown attached to its attachment point 330, which the right cup 329 is unattached. In this manner, the wearer is able to detach the cup 329 to expose their breast for feeding or for breast pumping. Once this is completed, the cup 329 is reattached and the maternity bra 320 continues to function as a normal bra.

While in the depicted embodiments, a hook 331 is shown on the bra strap 321 and a clasp 332 is shown on the cup 329, it is appreciated that the provision of these may be reversed, or that alternative attachment mechanisms may be used.

A maternity bra therefore may comprise a support structure comprising shoulder straps and a bra band and a first and a second cup each attached to the support structure to provide a first cup size, at least one cup being at least partially detachable from the support structure at an attachment point.

In other embodiments, the detachable attachment point 330 may be provided at a different location, such as at the attachment between the bra band 322 and the cup 329. The mechanism for such an attachment point is the same as described above.

A clip has been designed such that it is configured to be attached to the support structure at a position away from the attachment point. This results in the original attachment point being usable, with the clip providing an alternative attachment point to give, in effect, an adjusted cup size.

Alternatively, the clip may also be attachable to the support structure at a plurality of non-discrete positions. This ensures essentially infinite adjustment of the clip position such that the perfect position for the user can be found.

The clip can also extend between an unextended and an extended state, and can attach to the support structure at the attachment point; the first cup size is providable when the at least partially detachable cup is attached to the clip when the clip is an unextended state; the second cup size is providable when the at least partially detachable cup is attached to the clip when the clip is in an extended state. An extendable clip like this allows quick switching between the two states in use.

Figure 33 depict a clip 335 according to the present invention, along with a clasp 332 shown in isolation from the bra cup 329 it is normally attached to. The clip comprises a first engagement mechanism and at least one second engagement mechanism(s). The clip is attachable in a releasable manner to the support structure at a first position via the first engagement mechanism and attachable in a releasable manner to one of the partially detachable cups via the second engagement mechanism to provide a second cup size different to the first cup size. The clip 335 is provided with a material pathway 336 which receives a portion of the bra strap 321. In the particular embodiment of these Figures, the clip 335 is substantially U-shaped, with a narrowing profile towards its open end. However, it is appreciated that any other suitable shape with a material pathway may be used, such as an S-shape or E-shape. The clip 335 is designed to be attached to the bra strap 321 in a releasable manner, with the slot 336 acting as a support engaging mechanism. The releasable manner means that the clip 335 may be simply removed from the bra 320 without causing any damage to the functioning of the bra 320. To enhance the ease of attachment, the clip 335 may be provided with outwardly extending wings 204 which help direct the bra strap 321 into the clip 335. The clip 335 is further provided with a hook 220 acting as a cup engaging mechanism which can engage with the clasp 332.

Figure 33 (c) shows the clip 335 being attached to a bra strap 321 in order to provide a second attachment point 337 for the clasp 332 to attach to, and hence to provide a second cup size for the bra 320. In this particular embodiment, the clip 335 is attached in a portion of strap 321A below the original attachment point 330 and hence the second attachment point 337 is likewise below the original attachment point. This results in a second cup size larger than the first cup size. In preferred embodiments, as shown in these Figures, the clip 335 engages with the support structure in a direction transverse to

the direction in which it engages with the cup.

Figure 33 (d) and (e) show how a wearer is able to move between the first and second cup sizes. In 33(d), the cup 329 is attached at the first attachment point 330 to provide a first cup size. The wearer then disengages the clasp 332 from the hook 331 at the hook 338 at the second engagement point 239. In this manner, the wearer is easily able to transition between the two cup sizes.

Figures 34 and 35 show an alternative design for a clip 340. This clip 340 is substantially "E-shaped", with a back portion 341 and first, second and 5 third prongs 342A, 342B, 342C extending transverse from this back portion 341. The three prongs 342A, 342B, 342C are spaced apart along the length of the back portion 341. The first and third prongs 342A, 342C are provided with attachment clips 343A, 343B.

These attachment clips 343A, 343B can engage with the clasp 332 of a bra to provide the second cup size. Depending upon the orientation of the clip 300, one or the other of the attachment clips 343A, 343B will be used to attach the clasp 332 of the bra. By providing these clips 343A, 343B on both of the first and the third prongs 342A, 342C the clip is easily reversible so it can be used on either side of the bra. Preferably the clip 340 is also symmetrical, to aid the reversibility of the clip 340.

Figure 35 shows the clip 340 attached to a bra. As can be seen, the first and third prongs 342A, 342C extend on the front side of the bra strap, with the second prong 342B extending on the rear side of the bra strap. In this manner, the clip 340 is attached to the strap. In preferable embodiments, a grip-enhancing member 344 such as a number of projections and/or roughened patches can be provided on the second prong 342B in order to strengthen this grip.

In alternative embodiments, the attachment clip could be provided on the second, centremost prong 342B. In such an arrangement, the centremost prong 342B would be on the outside of the bra, with the first and third prongs 342A, 342C on the inside.

The provision of the attachable clip allows maternity bras already owned by the wearer to be quickly transformed into bras with quick switchable double cup size options.

This allows the use of integrated wearable breast pumps which increase the user's required cup size. This allows more design freedom for the breast pump in terms of size and shape, while still allowing the user to discretely pump with the pump held within their bra. By allowing conversion of the user's existing maternity bras, they are not forced to purchase specially designed bras to wear with the pump. The bra is hence normally at the first engagement point 330 when the breast pump device is not being used. As shown in Figure 33, the clasp 332 is then engaged by the user to discretely switch between the two configurations, and the user then inserts the pump without any complex adjustment or removal of clothing.

Preferably, the clip will be relatively unobtrusive in size and shape and hence can be left in place when the bra is first put on and used when necessary. To this end, the clip is preferably machine washable without significant damage or degradation.

In some embodiments, the clip may be switchable between positions for engaging with each cup so that a single clip may be used on either side of the bra. To achieve this, the clip is preferably reversible. This may provide the user with a visual indication of which breast has produced milk most recently so switching can take place.

In a preferred embodiment, the first engagement mechanism engages with the support structure in a first direction and the second engagement mechanism engages with the cup in a second direction transverse to the first direction. This increases ease of attachment as with this structure the sideways engagement of the clip to the support structure ensures that the second attachment mechanism is correctly orientated for the cup.

The second engagement mechanism may be one or more of a hook or a snap or a clip. This ensures easy interfacing with the traditional hook and clasp systems already provided on maternity bras.

Preferably the clip further comprises two distinct second engagement mechanisms which can be used interchangeably dependent upon the orientation of the clip. This makes the clip easier to use as it can be quickly switched between each bra strap, and the user does not have to worry which way up to put the clip on.

Preferably, the clip comprises a material pathway with an opening for receiving a portion of the support structure as the first engagement mechanism for securing the clip to the bra. This ensures a quick and simple method for attaching the clip to the bra. In particular, the clip may substantially U-shaped, and the material pathway is between the arms of the U.

Preferably, the clip comprises three prongs extending from a central support, the three prongs arranged as a central prong and two outer prongs so as to receive the support structure on one side of the central prong and on the opposite side of each respective outer prong, at least one prong being provided with the second engagement mechanism. This ensures a strong attachment to the bra and a simple design.

Preferably, both outer prongs are each provided with a respective second engagement mechanism. This ensures that the clip is reversible for easier attachment to the bra.

A method of adjusting the cup size of a maternity bra is provided according to the present invention, comprising: providing a maternity bra comprising: a support structure comprising shoulder straps and a bra band; and a first and second cup each attached to the support structure to provide a first cup size, the at least one cup being detachable from the support structure at an attachment point, providing a clip comprising first and section engagement mechanisms, attaching the first engagement mechanism of the clip in a releasable manner to a first position of the support structure of the maternity bra, attaching one of the detachable cup to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

This clip and method allow a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump.

Preferably, the method further comprises the step of inserting a breast pump into the detachable cup. The adjustment of the size of the bra allows the bra to support the breast pump against the user's breast for comfort and ease.

Preferably, the method further comprises the steps of: detaching the first engagement mechanism of the clip from the first position support structure of the maternity bra; attaching the first engagement mechanism of the clip in a releasable manner to a second position of the support structure of the maternity bra; and attaching the other of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size. This allows the user to use a single clip on either of the cups.

An alternative embodiment may be provided, with an extendable clip 360 as shown in Figure 36. In such an embodiment the clip is attached to the hook 331 on the strap 321 in a releasable manner, with the clasp 332 attached to an expandable portion of the clip. The clip is then able to expand between an unexpanded state where the clasp 332 is held in substantially the same position as the first attachment point 330 to provide the first cup size, and an expanded state, where the clasp 332 is held in a second position away from the first attachment point 330 to provide the second cup size.

For example, an elongate clip with first and second opposite ends may be provided. A first attachment point for attaching to the hook 331 is provided at the first end, and a second attachment point for attaching to the clasp 332 is provided at the second end. The elongate clip is hinged between the two ends, such that the clip can be folded between an elongate configuration to a closed configuration where the second end touches the first end. A clasp can be provided on the clip to hold the second end in this closed configuration. Thus, in the closed position the clasp 332 is held in substantially the same location as the first attachment point 330 to provide the first cup size, and in the open position the clasp is held away from the first attachment point 330 to provide the second cup size.

Other extendable clip embodiments are also possible, for example sliding clips or elastic clips.

Additional embodiments of a maternity bra adjuster are provided in Figures 37 and 38. The alternative proposed solution is a small adapter device, which comprises a first portion 370 including a clasp 373 and a second portion 372 including a hook 374, in which the first and second portions are separated by a small distance 371 in order to

provide two different adjustable sizes. The first portion includes a clasp 373 that is designed to attach to the hook on the bra strap 321. It may also include a top hook 375 positioned underneath the clasp, and a clip 376 on the rear side. The second portion includes a bottom hook 372.

The clasp 332 that is present on the cup 329 of the maternity bra, may then either engage with the top hook (321) to provide a first cup size, and engage with the bottom hook (332) to provide a second cup size that is different from the first cup size, as illustrated in Figure 39. The user may then discretely switch between a non pumping position, provided by the first cup size, and a second pumping position without any complex adjustment or removal of clothing needed, while using a wearable breast pump system (100).

The first portion and second portion may be made of plastic and may be separated by a stretchy material such as elastic or elastomeric material. The first portion may also include a clip on the rear side, the purpose of which is to allow the user to leave the clip attached to the bra for an extended time period.

Section D: Use of Piezo Pump in Wearables

As described in Section A, the breast pump system includes a piezo air pump, resulting in a fully wearable system that delivers a quiet, comfortable and discreet operation in normal use. This section gives further information on the piezo air pump.

In comparison with other pumps of comparable strength, piezo pumps are smaller, lighter and quieter. In operation, the Elvie breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise; tests indicate that it makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

Piezo pumps also have lower current draw, allowing for increased battery life. A piezo pump is therefore ideally suited for wearable devices with its low noise, high strength and compact size. Further, as shown in the breast pump system of Figures 7 and 8, more than one piezo pump may be used.

Whilst a breast pump system is largely described in previous sections, the use of piezo mounted either in series or in parallel can also be implemented in any medical wearable devices or any wearable device. The piezo pump may pump air as well as any liquid.

With reference to Figure 40, a diagram illustrating a configuration of two piezo pumps mounted in series is shown.

With reference to Figure 41, a diagram illustrating a configuration of two piezo pumps mounted in parallel is shown.

With reference to Figure 42, the air pressure generated as a function of time by two piezo pumps mounted in series and two piezo pumps mounted in parallel are compared. In this example, the parallel configuration produces higher flow rate and achieves -100mmHg negative air pressure faster than the series configuration. In comparison, the series configuration produces lower flow rate and takes slightly longer to reach 100mmHg. However, the parallel configuration cannot achieve as high as a vacuum as the series configuration and plateaus at -140mmHg. In comparison, the series

configuration is able to generate about -240mmHg.

A dual configuration is also implemented in which more than one piezo pump is configured such that they can easily switch between a parallel mode and a series mode. This dual configuration would suit wearable devices that would need to achieve either lower or higher pressure faster.

Figure 43 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration. In this dual configuration, the piezo pumps first start with a parallel mode in order to benefit from faster flow rate, and then switch to a series mode (as indicated by the switch-over point) when stronger vacuums are required, enabling to save up to 500ms on cycle time with elastic loads.

Additionally, a piezo pump may be used in combination with a heat sink in order to efficiently manage the heat produced by the wearable pump. This configuration may be used to ensure that the wearable device can be worn comfortably. The heat sink or heat sinks are configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin (especially prolonged contact for greater than 1 minute) are no more than 48°C and preferably no more than 43°C.

The heat sink may store the heat produced by a piezo pump in order to help diverting the heat produced to another location. This not only ensures that the wearable system can be worn comfortably, but also increases the lifetime of a piezo pump.

Figure 44 shows a picture of a wearable breast pump housing including multiple piezo pumps (440). The breast pump system is wearable and the housing is shaped at least in part to fit inside a bra. By applying a voltage to the piezo pumps, the pressure provided by the pumps increase. The generation of higher pressure by the piezo pumps also means higher heat produced that needs to be managed. Each piezo pump is therefore connected to a heat sink (441), such as a thin sheet of copper. The heat sink has a long thermal path length that diverts the heat away from the piezo pump.

The use of a heat sink in combination with a piezo pump is particularly relevant when the wearable device is worn directly or near the body, and where the management of heat induced by the piezo pump is crucial.

A wearable device including a piezo pump may therefore include a thermal cut out, and may allow for excess heat to be diverted to a specific location. The heat sink may be connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere. For example, the wearable system is a breast pump system and the heat sink stores heat, which can then be diverted to warm the breast shield of the breast pump system.

Use cases application include but are not limited to:

- Wound therapy;
- High degree burns;
- Sleep apnoea;
- Deep vein thrombosis;
- Sports injury.

APPENDIX: SUMMARY OF KEY FEATURES

In this section, we summarise the various features implemented in the Elvie™ pump system. We organize these features into six broad categories:

A. Elvie Breast Pump: General Usability Feature Cluster

B. Elvie Piezo Air Pump Feature Cluster

C. Elvie Milk Container Feature Cluster

D. Elvie IR System Feature Cluster

E. Elvie Bra Clip Feature Cluster

F. Other Features, outside the breast pump context

Drilling down, we now list the features for each category:

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is wearable and includes only two parts that are removable from the pump main housing in normal use.

Feature 2 Elvie is wearable and includes a clear breast shield giving an unobstructed view of the breast for easy nipple alignment.

Feature 3 Elvie is wearable and includes a clear breast shield with nipple guides for easy breast shield sizing.

Feature 4 Elvie is wearable and includes a breast shield that audibly attaches to the housing.

Feature 5 Elvie is wearable and includes a breast shield that attaches to the housing with a single push.

Feature 6 Elvie is wearable and not top heavy, to ensure comfort and reliable suction against the breast.

Feature 7 Elvie is wearable and has a Night Mode for convenience.

Feature 8 Elvie is wearable and includes a haptic or visual indicator showing when milk is flowing or not flowing well.

Feature 9 Elvie is wearable and collects data to enable the mother to understand what variables (e.g. time of day, pump speed etc.) correlate to good milk-flow.

Feature 10 Elvie is wearable and collects data that can be exported to social media.

Feature 11 Elvie is wearable and has a smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 12 A smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 13 Elvie is wearable and includes a sensor to infer the amount of movement or tilt angle during normal use.

Feature 14 Elvie includes a control to toggle between expressing milk from the left breast and the right breast.

Feature 15 Elvie includes a pressure sensor.

Feature 16 Elvie includes a microcontroller to enable fine tuning between pre-set pressure profiles.

Feature 17 Elvie enables a user to set the comfort level they are experiencing.

Feature 18 Elvie includes a microcontroller to dynamically and automatically alter pump operational parameters.

Feature 19 Elvie automatically learns the optimal conditions for let-down.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is wearable and has a piezo air-pump for quiet operation.

Feature 21 Elvie has a piezo air-pump and self-sealing diaphragm

Feature 22 Elvie uses more than one piezo air pump in series.

Feature 23 Elvie is wearable and has a piezo air-pump, a breast shield and a diaphragm that fits directly onto the breast shield.

Feature 24 Elvie is wearable and has a piezo air-pump for quiet operation and a re-useable, rigid milk container for convenience.

Feature 25 Elvie has a piezo-pump for quiet operation and is a connected device.

Feature 26 Elvie uses a piezo in combination with a heat sink that manages the heat produced by the pump.

Feature 27 Elvie is wearable and gently massages a mother's breast using small bladders inflated by air from its negative pressure air-pump.

Feature 28 Elvie is wearable and gently warms a mother's breast using small chambers inflated by warm air from its negative pressure air-pump.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is wearable and includes a re-useable, rigid milk container that forms the lower part of the pump, to fit inside a bra comfortably.

Feature 30 Elvie is wearable and includes a milk container that latches to the housing with a simple push to latch action.

Feature 31 Elvie is wearable and includes a removable milk container with an integral milk pouring spout for convenience.

Feature 32 Elvie is wearable and includes a removable milk container below the milk flow path defined by a breast shield for fast and reliable milk collection.

Feature 33 Elvie is wearable and includes a breast shield and removable milk container of optically clear, dishwasher safe plastic for ease of use and cleaning.

Feature 34 Elvie is wearable and includes various components that self-seal under negative air pressure, for convenience of assembly and disassembly.

Feature 35 Elvie is wearable and includes a spout at the front edge of the milk container for easy pouring.

Feature 36 Elvie is wearable and includes a milk container that is shaped with broad shoulders and that can be adapted as a drinking bottle that baby can easily hold.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the quantity of milk in the container for fast and reliable feedback.

Feature 38 The separate IR puck for liquid quantity measurement.

Feature 39 The separate IR puck combined with liquid tilt angle measurement.

E. Bra Clip Feature

Feature 40 Bra Adjuster.

F. Other Features that can sit outside the breast pump context

Feature 41 Wearable device using more than one piezo pump connected in series or in parallel.

Feature 42 Wearable medical device using a piezo pump and a heat sink attached together.

We define these features in terms of the device; methods or process steps which correspond to these features or implement the functional requirements of a feature are also covered.

We'll now explore each feature 1 – 41 in depth. Note that each feature can be combined with any other feature; any sub-features described as 'optional' can be combined with any other feature or sub-feature.

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is wearable and includes only two parts that are removable from the pump main housing in normal use

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a rigid or non-collapsible milk container;

and in which the breast pump system includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and the rigid, non-collapsible milk container.

Optional:

- The only parts of the system that come into contact with milk in normal use are the breast shield and the milk container.
- Milk only flows through the breast shield and then directly into the milk container.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings, in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- No other parts are removable from the breast shield, apart from the flexible diaphragm.
- The milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.
- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

- No other parts are removable from the milk container, apart from the cap and the valve.
- All parts that are user-removable in normal use are attached to either the breast shield or the milk container.
- Audible or haptic feedback confirms the pump system is properly assembled for normal use with the milk container locked to the housing and the breast shield locked to the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 2 Elvie is wearable and includes a clear breast shield giving an unobstructed view of the breast for easy nipple alignment

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel, shaped to receive a nipple, providing to the mother placing the breast shield onto her breast a clear and unobstructed view of the nipple when positioned inside the nipple tunnel, to facilitate correct nipple alignment.

Optional:

- The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is completely out, of or separated from, the housing.
- The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is partially out of, or partially separated from, the housing.
- Entire breast shield is substantially transparent.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.

- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

Feature 3 Elvie is wearable and includes a clear breast shield with nipple guides for easy breast shield sizing

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel shaped to receive a nipple, the nipple tunnel including guide lines that define the correct spacing of the nipple from the side walls of the nipple tunnel.

Optional:

- The guide lines run generally parallel to the sides of the nipple placed within the nipple tunnel.
- Breast shield is selected by the user from a set of different sizes of breast shield to give the correct spacing.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers in the housing locate into small indents in the breast shield.

- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 4 Elvie is wearable and includes a breast shield that audibly attaches to the housing.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield that is attachable to the housing with a mechanism that latches with an audible click when the breast shield is slid on to or against the housing with sufficient force.

Optional:

- The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.

- Breast shield is removable from the housing with an audible click when the breast shield is pulled away from the housing with sufficient force.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.

- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 5 Elvie is wearable and includes a breast shield that attaches to the housing with a single push

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield configured to attach to the housing with a single, sliding push action.

Optional:

- The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.
- The single push action overcomes a latching resistance.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into a nipple tunnel in the breast shield to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield when the breast shield has been placed onto a breast using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b)

transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

- The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.
- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

Feature 6 Elvie is wearable and not top heavy, to ensure comfort and reliable suction against the breast

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism

(b) and a breast shield;

(c) a milk container;

and in which the centre of gravity of the pump system is, when the milk container is empty, substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through a nipple tunnel or filling point on a breast shield, so that the device is not top-heavy for a woman using the pump.

Optional:

- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- In which the centre of gravity only moves lower during use as the milk container gradually receives milk, which increases the stability of the pump inside the bra.
- In which milk only passes downwards when moving to the milk container, passing through the nipple tunnel and then through an opening in the lower surface of the nipple tunnel directly into the milk container, or components that are attached to the milk container.
- System is configured so that its centre of gravity is no more than 60mm up from the base of the milk container also below the top of the user's bra cup.
- In which the pumping mechanism and the power supply for that mechanism are positioned within the housing to provide a sufficiently low centre of gravity.
- In which the pumping mechanism is one or more piezo air pumps, and the low weight of the piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.
- In which the pumping mechanism is one or more piezo air pumps, and the small size of the piezo air pumps enables the components in the housing to be arranged so that the centre of gravity is substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.
- In which the pumping mechanism is one or more piezo air pumps, and the low weight of the battery or batteries needed to power that piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of

the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.

- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 7 Elvie is wearable and has a Night Mode for convenience

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) an illuminated control panel;

(c) a control system that reduces or adjusts the level or colour of illumination of the control panel at night or when stipulated by the user.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Control system is implemented in hardware in the pump itself using a 'night mode' button.
- Control system is implemented in software within a connected device app running on the user's smartphone.
- Control system is linked to the illumination level on a connected device app., so that when the connected app is in 'night mode', the illuminated control panel is also in 'night mode', with a lower level of illumination, and when the illuminated control panel on the housing is in 'night mode', then the connected app is also in 'night mode'.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast. The pumping mechanism is one or more piezo air pumps, selected for quiet operation.

Feature 8 Elvie is wearable and includes a haptic or visual indicator showing when milk is flowing or not flowing well

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a milk container that is configured to be concealed within a bra and is hence not visible to the mother in normal use;

(c) a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

Optional:

- A haptic and/or visual indicator indicates if the pump is operating correctly to pump milk, based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase
- The visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.
- The haptic and/or visual indicator provides an indication of an estimation of the flow rate.
- The visual indicator provides a colour-coded indication of an estimation of the flow rate.
- The visual indicator provides an indication of how much of the container has been filled.
- The visual indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.
- The haptic indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.
- A sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect

light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

- Sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- A sub-system measures or infers the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.
- A haptic and/or visual indicator indicates if the amount of milk in the milk container has reached a preset quantity or level.
- A haptic and/or visual indicator indicates if there is too much movement of the breast pump system for viable operation.
- Milk container is attached to the lower part of the housing and forms the base of the breast pump system.
- Milk container is made of transparent material.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 9 **Elvie is wearable and collects data to enable the mother to understand what variables (e.g. time of day, pump speed etc.) correlate to good milk-flow**

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a measurement sub-system that measures or infers milk flow into the milk container;

and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- User-defined requirement is to enhance or increase milk-flow.
- User-defined requirement is to reduce milk-flow.
- The data analysis system analyses data such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system determines metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.
- The data analysis system determines metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.
- Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.
- measurement sub-system measures or infers the quantity and/or the height of the liquid in the container above its base.
- Measurement sub-system measures or infers angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.
- Data analysis system gives recommended metrics for improving milk flow
- Data analysis system gives recommended metrics for weaning.
- Data analysis system gives recommended metrics for increasing milk supply (e.g. power pumping).
- Data analysis system gives recommended metrics if an optimal session start time or a complete session has been missed.

- Data analysis system leads to automatic setting of metrics for the pumping mechanism, such as pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session.
- Data analysis system enables sharing across large numbers of connected devices or apps information that in turn optimizes the milk pumping or milk weaning efficacy of the breast pump.
- Metrics include the specific usage of the connected device by a woman while using the pump (for example by the detection of vision and/or audio cues).
- The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- The measurement sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the measurement sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 10 Elvie is wearable and collects data that can be exported to social media.

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a data sub-system that collects and provides data to a connected device or remote application or remote server;

(d) and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.
- The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.
- Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.
- The social media or community function or platform organizes the collected data into different profiles.
- The social media or community function or platform enables a user to select a matching profile from a set of potential profiles.
- each profile is associated with a specific kind of milk expression profile, and provides information or advice that is specifically relevant to each milk expression profile.
- Information or advice includes advice on how to increase milk expression by varying parameters, such as time of milk expression, frequency of a milk

expression session, pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session and any other parameter that can be varied by a mother to help her achieve her milk expression goals.

- The application is connected to other applications residing on the connected device, such as a fitness app.
- The collected data includes data received from other connected apps.
- The collected data is anonymised before it is shared.
- The sub-system includes a wi-fi connectivity component for direct connectivity to a remote server.
- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 11 Elvie is wearable and has a smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh

A breast pump system including a pumping mechanism and a milk container and including:

(a) a housing including the pumping mechanism;

(b) a milk container;

(c) and in which the milk container or any associated part, such as a lid, includes a memory or tag that is automatically programmed to store the time and/or date it was filled with milk.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Memory or tag is programmed to store the quantity of milk in the milk container.
- Memory or tag stores the milk expiry date.

- Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.
- System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.
- Clock is in the housing.
- Clock is in the milk container.
- Milk container includes a display that shows the time and/or date it was filled with milk.
- Milk container includes a display that shows the quantity of milk that it was last filled with milk.
- Milk container includes a display that shows whether the left or right breast was used to fill the milk container.
- Memory or tag is connected to a data communications sub-system.
- Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone, and have the time and/or date that container was filled with milk, displayed on the reader device.
- Reader device shows the time and/or date a specific milk container was filled with milk.
- Reader device shows the quantity of milk that a specific milk container was last filled with.
- Reader device shows the time and/or date and/or quantity that each of several different milk containers were filled with.
- Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.
- A sub-system measures or infers milk flow into the milk container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/Ir the height of the liquid in the container.
- The sub-system is in the housing.
- Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 12 A smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

A smart bottle or container that includes or is associated with a memory or a tag that is programmed to store the date and time it is filled using data from a pump or a connected device, such as a smartphone.

Optional:

- The container includes wireless connectivity and connects to a companion app.
- The memory or tag includes an NFC chip and is read using a NFC reader.
- The memory or tag stores also an expiry date.
- Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.
- The memory or tag stores also the quantity of milk stored.
- System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.
- Clock is in the housing.
- Clock is in the container.
- Milk container includes a display that shows the time and/or date it was filled with milk.
- Milk container includes a display that shows the quantity of milk that it was last filled with milk.

- Milk container includes a display that shows whether the left or right breast was used to fill the milk contained.
- Milk container includes a display that shows the expiry date.
- memory or tag is connected to a data communications sub-system.
- Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone.
- Reader device shows the time and/or date a specific milk container was filled with milk.
- Reader device shows the quantity of milk that a specific milk container was last filled with.
- Reader device shows the time and/or date and/or quantity that each of several different containers were filled with.
- Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.
- Reader device shows the expiry date.
- Container includes wireless connectivity and connects to a companion application.
- An application tracks status of one or more smart containers and enables a user to select an appropriate smart container for a feeding session.
- The pump is wearable.
- The pump is in a housing shaped to fit inside a bra and the container is a milk container that is connected to the housing and is positioned to form the base of the housing.
- Container is used for liquids other than milk.

Feature 13 Elvie is wearable and includes a sensor to infer the amount of movement or tilt angle during normal use.

A breast pump system including:

(a) a housing;

(b) a milk container;

(c) the housing including a sensor, such as an accelerometer, that measures or determines the movement and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by warning or alerting the mother of a potential imminent spillage (e.g. from milk flowing back out of a breast shield) using an audio, or visual or haptic alert, or a combination of audio, haptic and visual alerts.
- If the tilt angle of the housing exceeds a threshold, then the system automatically adjusts the operation of the system by stopping the pump to prevent spillage.
- When the tilt angle of the housing reduces below the threshold, the system automatically adjusts the operation of the system by causing pumping to resume automatically.
- If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by providing the mother with an alert to change position.
- The container includes an optically clear region.
- There are one or more light emitters and detectors positioned in the base of the housing, the light emitters and receivers operating as part of a sub-system that measures or infers the tilt angle of the milk in the container.
- The sub-system measures the quantity of liquid in the milk container and also takes the measured tilt angle of the housing into account.
- If the tilt angle is above a certain threshold, the system ignores the quantity of liquid measured.
- The sub-system derives or infers the mother's activity, such as walking, standing or lying activities, from the sensor.
- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

- Sub-system stores a time-stamped record of movement and/or tilt angles of the housing in association with milk flow data.
- System includes a breast shield that attaches to the housing.
- System includes a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 14 Elvie includes a control to toggle between recording whether milk is being expressed from the left breast and the right breast.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a control interface that the user can select to indicate or record if milk is being expressed from the left or the right breast.

Optional:

- Control interface is a physical interface on the housing.
- Control interface is a single button on the housing.
- Control interface is from an application running on a device, such as a smartphone or smart ring.
- Visual indicators on the housing indicate whether the breast pump system is being set up the left or the right breast.
- The visual indicator for the left breast is on the right-hand side of the housing, when viewed from the front; and the visual indicator for the right breast is on the left-hand side of the housing, when viewed from the front.
- The housing includes a button labeled to indicate the left breast and a button labeled to indicate the right breast, that are respectively illuminated to indicate from which breast the milk is being expressed.
- Breast pump system is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 15 Elvie includes a pressure sensor.

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) an air pressure sensor configured to measure the negative pressure delivered by the negative air-pressure mechanism and (iii) a measurement sub-system that measures or infers milk flow or milk volume.

Optional:

- The system also includes a control sub-system that combines or relates the air-pressure measurements with the milk flow or milk volume measurements
- The control sub-system automatically adjusts the negative air-pressure to give the optimal milk flow or milk volume.
- The control sub-system automatically adjusts the negative air-pressure during a pumping session to give the optimal milk flow or milk volume within comfort constraints defined by the user.
- The air pressure sensor detects pressure created by the pumping mechanism.
- Sensor is a piezo air pressure sensor
- Air pressure sensor measures the negative air pressure during a normal milk expression session.
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that it deliver consistent performance over time.
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that different pumping mechanisms in different breast pump systems all deliver consistent performance
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to determine if the pumping mechanism is working correctly, within tolerance levels.
- The operation of the pumping mechanism is varied by altering the duty or pump cycle.
- The operation of the pumping mechanism is varied by altering the voltage applied to the pumping mechanism.
- Pumping mechanism is a piezo air pump.

- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 16 Elvie includes a microcontroller to enable fine tuning between pre-set pressure profiles

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to cause the pumping mechanism to deliver various pre-set pressure profiles and to permit the user to manually vary the pressure to a value or values that are in-between the values available from a pre-set pressure profile.

Optional:

- The user manually varies the pressure using a control interface on a housing of the breast pump system
- The user manually varies the pressure using a control interface on an application running on a wireless device such as a smartphone that is wirelessly connected to the breast pump system.
- The user manually varies the pressure by altering a control parameter of the pumping mechanism.
- The user manually varies the pressure by altering the duty cycle or timing of the

pumping mechanism.

- The user manually varies the pressure by altering the voltage applied to the pumping mechanism.
- The system includes an air pressure sensor configured to measure the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Pressure profile defines one or more maximum negative air pressure levels.
- Pressure profile defines one or more maximum negative air pressure levels, each for a pre-set time.
- Pressure profile defines one or more cycle time.
- Pressure profile defines peak flow rate.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 17 Elvie enables a user to set the comfort level they are experiencing

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to control the pumping mechanism and to permit the user to manually indicate the level of comfort that they are experiencing when the system is in use.

Optional:

- The user manually indicates the level of comfort that they are experiencing using a touch or voice-based interface on a housing of the breast pump system
- The user manually indicate the level of comfort that they are experiencing using a touch or voice-based interface on an application running on a wireless device, such as a smartphone, that is wirelessly connected to the breast pump system.
- The system stores user-indicated comfort levels together with associated parameters of the pumping system.
- The system is a connected device and a remote server stores user-indicated comfort levels together with associated parameters of the pumping system.
- The parameters of the pumping system include one or more of: pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System automatically varies parameters of the pumping system and then enables the user to indicate which parameters are acceptable.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the

intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 18 Elvie includes a microcontroller to dynamically and automatically alter pump operational parameters

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to automatically change one or more parameters of the pumping mechanism, and to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

Optional:

- The milk expression data includes one or more of the following: milk expression rate or quantity; comfort; optimal pumping mode; optimal pumping mode given remaining battery power.
- The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters.
- The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters if the comfort experienced by the user when those parameters are used is above a threshold.
- The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user.
- The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user and enables the user to manually select those parameters if they are acceptable.
- Parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.

- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 19 Elvie automatically learns the optimal conditions for let-down

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to dynamically change one or more parameters of the pumping mechanism, and to automatically detect the start of milk let-down.

Optional:

- The microcontroller is programmed to dynamically change one or more parameters of the pumping mechanism, to enable it to learn or optimize the parameters relating to milk let-down.
- The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down.
- The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and uses that set of parameters if the comfort experienced by the user when those

parameters are used is above a threshold or are otherwise acceptable to the user.

- The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down to the user.
- The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and enables the user to manually select those parameters if they are acceptable.
- parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is wearable and has a piezo air-pump for quiet operation

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a separate, deformable diaphragm to generate negative air pressure.

Optional:

- The deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- Deformable diaphragm is removably mounted against a part of a breast shield.
- Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.
- Deformable diaphragm is not physically connected to the piezo air-pump.
- Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield
- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 25gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise. The piezo pump is fed by air that passes through an air filter.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 21 Elvie has a piezo air-pump and self-sealing diaphragm

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a physically separate, deformable, self-sealing diaphragm, to generate negative air pressure.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement .
- The closed system is separated from a 'milk' side by the flexible diaphragm.
- Deformable diaphragm is removably mounted against a part of a breast shield.
- Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.
- Deformable diaphragm is not physically connected to the piezo air-pump.
- Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield.
- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the

diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- The piezo pump is fed by air that passes through an air filter.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 22 Elvie uses more than one piezo air pump in series

A breast pump system including:

(a) a housing;

(b) multiple piezo air-pumps in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure; in which the multiple piezo air-pumps can be operated at different times in series-connected and in parallel-connected modes.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Parallel connected mode is used during a first part of a pumping cycle to reach a defined negative air pressure more quickly than series connected mode would, and then the system switches to a series connected mode to reach a greater negative air pressure than series connected mode can reach.
- An actuator switches the system from parallel-connected piezo pump mode to series-connected piezo pump mode.

- Each piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- Each piezo air pump weighs less than 10 gm, and may weigh less than 6gm..
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- Each piezo pump is fed by air that passes through an air filter.
- Each piezo air pump forms part of a closed or closed loop system.
- Each piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- The piezo-air pumps are a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

Feature 23 Elvie is wearable and has a piezo air-pump, a breast shield and a diaphragm that fits directly onto the breast shield

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a breast shield that attaches to the housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm that fits directly onto the breast shield.

Optional:

- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Deformable diaphragm is removable from the diaphragm housing for cleaning.

- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- Piezo air pump is position at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum. power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.The piezo pump is fed by air that passes through an air filter.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Feature 24 Elvie is wearable and has a piezo air-pump for quiet operation and a re-useable, rigid milk container for convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing;

(c) and a re-useable, rigid or non-collapsible milk container that when connected to the housing forms an integral part of the housing and that is also removable from the housing.

Optional:

- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The closed system is separated from a 'milk' side by a flexible diaphragm.

- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- The deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.

Feature 25 Elvie has a piezo-pump for quiet operation and is a connected device

A breast pump system including

(a) a housing;

(b) a piezo air-pump in the housing;

(c) a milk container;

(d) a data connectivity module that enables data collection relating to the operation of the piezo air-pump and transmission of that data to a data analysis system.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Transmission is to an application running on a connected device such as a smartphone, or a server, or the cloud.
- The data collection and transmission relates to any other operational data of the system.
- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- A sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with the data connectivity module.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level,

peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.

- The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.

Feature 26 Elvie uses a piezo in combination with a heat sink that manages the heat produced by the pump.

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure;

(c) a heat sink to manage the heat produced by the piezo-air pump to ensure it can be worn comfortably.

Optional:

- The heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48°C and preferably no more than 43°C.
- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Heat sink is connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere.
- Heat sink warms a breast shield.
- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.

- There are two or more piezo air pumps, each connected to its own or a shared heat sink.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- The deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 25g.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

Feature 27 Elvie is wearable and gently massages a mother's breast using small bladders inflated by air from its negative pressure air-pump

A breast pump system including:

(a) a housing;

(b) an air-pump in the housing that drives a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides air to regularly or sequentially inflate one or more air bladders or liners that are configured to massage one or more parts of the breast.

Optional:

- Air-pump is a piezo pump.
- Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- Bladders or liners are formed in a breast shield that attaches to the housing.

Feature 28 Elvie is wearable and gently warms a mother's breast using small chambers inflated by warm air from its negative pressure air-pump

A breast pump system including:

(a) a housing;

(b) an air-pump, such as a piezo pump, in the housing that drive a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides warm air to regularly or sequentially inflate one or more air chambers that are configured to apply warmth to one or more parts of the breast.

Optional:

- Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- The air chamber is a deformable diaphragm positioned on a breast shield that attaches to the housing.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is wearable and includes a re-useable, rigid milk container that forms the lower part of the pump, to fit inside a bra comfortably

A wearable breast pump system configured including:

(a) a housing shaped at least in part with a curved surface to fit inside a bra and including a pumping mechanism;

(b) and a re-useable rigid or non-collapsible milk container that when connected to the housing forms an integral, lower part of the housing, with a surface shaped to continue the curved shape of the housing, so that the pump system can be held comfortably inside the bra.

Optional:

- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is attached to the housing with a push action.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture, spout or lid that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a

breast shield, and milk flows under gravity through the opening into the milk container.

- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump mechanism to ensure that negative air-pressure is not applied to the milk container.
- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 30 Elvie is wearable and includes a milk container that latches to the housing with a simple push to latch action

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that is attachable to the housing with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

Optional:

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Milk container, when connected to the housing, forms an integral, lower part of the housing and that is removable from the housing with a release mechanism that can be operated with one hand.

- Mechanism that releasably attaches or latches is a mechanical or magnetic mechanism.
- Mechanical mechanism includes flanges on the top of the milk container, or the sealing plate that seals the opening to the milk contained, that engage with and move past a surface to occupy a latched position over that surface when the milk container is pressed against the housing to lock into the housing.
- The housing includes a button that when pressed releases the milk container from the housing by flexing the surface away from the flanges so that the flanges no longer engage with and latch against the surface.
- Mechanism that attaches or latches the milk container into position does so with an audible click.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing by releasing the latch and moving the housing off the milk container.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.

- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 31 Elvie is wearable and includes a removable milk container with an integral milk pouring spout for convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a re-useable milk container that is connected to the housing with a surface shaped to continue the curved or breast-like shape of the pump, so that the pump can be held comfortably inside a bra and where the milk container includes a pouring spout for pouring milk.

Optional:

- Spout is integral to the milk container.
- Spout is integral to a removable lid to the milk container.
- Spout is positioned at or close to the front edge of the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.

- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 32 Elvie is wearable and includes a removable milk container below the milk flow path defined by a breast shield for fast and reliable milk collection

A wearable breast pump system including:

(a) a housing including a pumping mechanism, the housing being shaped at least in part to fit inside a bra;

(b) and a breast shield including a nipple tunnel shaped to receive a nipple, and including an opening that defines the start of a milk flow path;

(c) a re-useable milk container that when connected to the housing is positioned entirely below the opening or the milk flow path, when the breast pump is positioned or oriented for normal use.

Optional:

- The milk container includes an aperture that sits directly underneath the opening in the nipple tunnel in the breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- Milk flows from the opening directly into the milk container.
- Milk flows from the opening directly into the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against the opening in the breast shield, and milk flows under gravity through the opening into the milk container.
- Milk flows from the opening directly onto a valve that is attached to the milk container, the valve closing whilst there is sufficient negative air pressure in the volume of air between the valve and the breast shield opening, and then opening to release the milk into the container when the air pressure rises sufficiently.
- Milk flows from the opening directly onto a valve that is attached to a spout, that is in turn attached to the milk container.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the milk container cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container, and milk flows towards and is retained by the duck bill valve whilst the valve is closed, and flows past the valve into the milk container when the negative air pressure is released and the valve opens.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 33 Elvie is wearable and includes a breast shield and removable milk container of optically clear, dishwasher safe plastic for ease of use and cleaning

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) and a breast shield defining a region shaped to receive a nipple, the region defining the start of a milk flow path;

(c) a re-useable, rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the breast shield and the milk container are made substantially of an optically clear, dishwasher safe material.

Optional:

- The material is a polycarbonate material, such as Tritan™.

- breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield operates with a flexible diaphragm that flexes when negative air pressure is applied to it by an air pump system in the housing, and transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 34 Elvie is wearable and includes various components that self-seal under negative air pressure, for convenience of assembly and disassembly

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including an air pumping mechanism;

(b) a breast shield;

(c) a diaphragm that flexes in response to changes in air pressure caused by the air pumping mechanism and that seals to the breast shield;

(d) a re-useable milk container that seals to the breast shield;

and in which either or both of the diaphragm and the re-useable milk container substantially self-seal under the negative air pressure provided by the pumping mechanism.

Optional:

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a

breast shield, and milk flows under gravity through the opening into the milk container.

- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.
- The 1 way valve is attached to the milk container, or a lid or spout of the milk container with an interference fit and is readily removed in normal use for separate cleaning.
- The diaphragm partly or wholly self-seals to the breast shield under the negative air pressure provided by the pumping mechanism.
- The diaphragm partly or wholly self-seals to the housing under the negative air pressure provided by the pumping mechanism.
- The diaphragm is attached to the diaphragm housing using elastomeric or rubber latches and is readily removed in normal use for separate cleaning.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.

- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 35 Elvie is wearable and includes a spout at the front edge of the milk container for easy pouring

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that forms an integral part of the housing;

(c) a re-useable pouring spout that is positioned at or close to the front edge of the milk container.

Optional:

- Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigeratable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.
- Spout is integral to a removable lid to the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- By placing the spout at or close to the front edge of the milk container, the milk container fully empties more readily than where the spout is placed in the middle of the lid of a milk container.
- The spout sits generally under an opening in the breast shield spout or nipple tunnel through which expressed milk flows.
- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Feature 36 Elvie is wearable and includes a milk container that is shaped with broad shoulders and that can be adapted as a drinking bottle that baby can easily hold

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a milk container that is removable from the housing and is shaped or configured to also serve as a drinking bottle that is readily held by a baby because it is wider than it is tall.

Optional:

- Teat is attachable directly to the milk container.
- Pouring or drinking spout is integral to the milk container.
- The shoulders are at least 2cm in width, and the neck is no more than 1 cm in height, to enable a baby to readily grip and hold the container when feeding from the milk in the container.
- Spout/teat/straw resides near the edge of the container's rim.
- Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigertable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.
- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals

against the conduit under the negative air pressure provided by the pumping mechanism.

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Spout is integral to the milk container.
- Spout is integral to a removable lid to the milk container.
- Spout is positioned at or close to the front edge of the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the quantity of milk in the container for fast and reliable feedback

A system for milk volume determination, for use as part of a breast pump, or breast milk collecting device, including:

(a) a re-useable rigid or non-collapsible milk container;
(b) at least one light emitter, configured to direct radiation towards the surface of the milk;
(c) at least one light detector, configured to detect reflected radiation from the surface of the milk;

wherein the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container.

Optional:

The wearable breast pump system includes:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield;

(c) a re-useable rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the top of the container includes an optically clear region that is aligned below one or more light emitters positioned in the base of the housing.

- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

- The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.
- Where the quantity or level exceeds a threshold, then the pumping mechanism automatically changes mode, e.g. from a stimulation mode to an expression mode.
- Where the quantity or level exceeds a threshold, then the pumping mechanism automatically stops.
- Milk-flow data is captured and stored.
- If milk-flow falls below a threshold, then a notification is provided to the mother.

Feature 38 The separate IR puck for liquid quantity measurement

A liquid-level measuring system for measuring the quantity of liquid in a container for a breast pump; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to detect light from the light emitters that has been reflected from the liquid;

(c) a sub-system that infers, measures or calculates the quantity in the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

- The quantity of milk is measured as milk enters the container or as milk is removed from the container.
- Measured property includes the reflected light intensity

Feature 39 The separate IR puck combined with liquid tilt angle measurement

A liquid-level measuring system for measuring the tilt angle of liquid in a container; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to measure properties of the light reflected from the liquid;

(c) a sub-system including an accelerometer that infers, measures or calculates the tilt angle of the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

- Measured property includes the reflected light intensity
- The quantity of liquid is measured as liquid enters the container or as liquid is removed from the container.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.

Generally applicable optional features

- Weight of the entire unit, unfilled, is under 250g and preferably 214g.
- Silver based bactericide is used on all parts that are not steam or heat sterilized in normal cleaning.
- Housing includes a rechargeable battery.
- System is self-contained.
- System is a closed loop system.
- Breast pump system is a self-contained, wearable device that includes an integral rechargeable battery, control electronics, and one or more air pumps operating as a closed system, driving a flexible diaphragm that in turn delivers negative air-pressure to the breast, to cause milk to be expressed.
- Housing has a generally rounded or convex front surface and has a generally tear-drop shape when seen from the front.

E. Bra Clip Feature Cluster

Feature 40 Bra Adjuster

A bra adjuster for a nursing or maternity bra, the nursing or maternity bra including a bra cup with a flap that can be undone to expose the nipple, and the flap attaching to the shoulder strap using a clasp, hook or other fastener attached to the flap, and a corresponding fastener attached to the shoulder strap;

and in which the bra adjuster is attachable at one end to the fastener attached to the flap, and at its other end to the fastener attached to the shoulder strap, and hence increases the effective bra cup size sufficiently to accommodate a wearable breast pump, and is also detachable from the flap and shoulder strap.

Optional:

- Bra adjuster is retained in position on the bra during normal wearing of the bra, even when the flap is attached directly to the shoulder strap, and is used to increases the effective bra cup size only when the wearable breast pump is used.
- Bra adjuster is extensible or elastic.
- Bra adjuster is of a fixed length.
- Bra adjuster includes a clip that the user can slide onto the bra strap to secure the bra adjuster in position.
- Bra adjuster is machine-washing washable.

F. Other Features that can sit outside the breast pump context

Feature 41 Wearable device using more than one piezo pump connected in series or in parallel

A wearable device including multiple piezo pumps mounted together either in series or in parallel.

Optional:

- The wearable device is a medical wearable device.
- The piezo pumps air or any liquid etc.
- The system can switch between a parallel mode and a series mode to arrive to lower or higher pressure quicker.

Feature 42 Wearable medical device using a piezo pump and a heat sink attached together.

A wearable medical device including a piezo pump and a heat sink attached together.

Optional

- The wearable device uses more than one piezo pump connected in series.
- The wearable device uses more than one piezo pump connected in parallel.
- Each piezo pump is connected to its own heat sink, or to a common heat sink.
- The or each heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48°C and preferably no more than 43°C
- The wearable device includes a thermal cut out.
- Excess heat is diverted to a specific location on the device that is selected to not be in prolonged contact with the skin of the user, in normal use.
- Use cases application:
    - Wound therapy
    - High degree burns
    - Sleep apnea
    - Deep vein thrombosis
    - Sports injury.
- Wearable medical device is powered/charged via USB.

Note

It is to be understood that the above-referenced arrangements are only illustrative of the application for the principles of the present invention. Numerous modifications and alternative arrangements can be devised without departing from the spirit and scope of

the present invention. While the present invention has been shown in the drawings and fully described above with particularity and detail in connection with what is presently deemed to be the most practical and preferred example(s) of the invention, it will be apparent to those of ordinary skill in the art that numerous modifications can be made without departing from the principles and concepts of the invention as set forth herein.

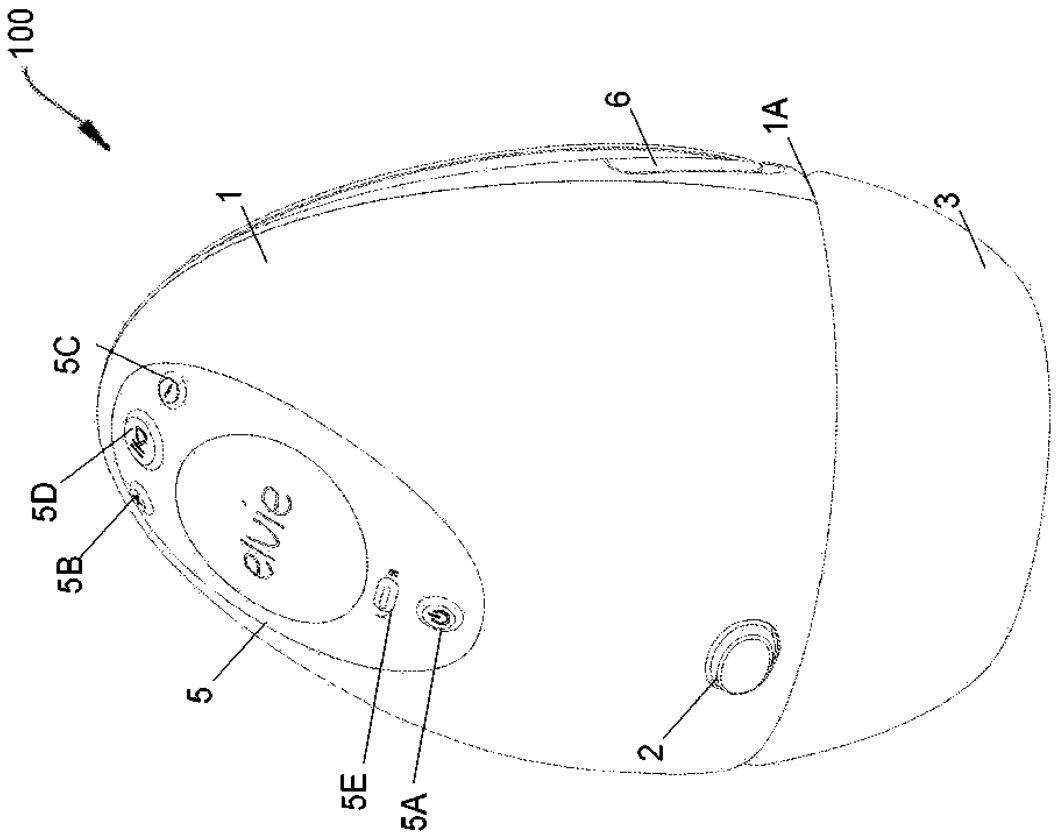


FIGURE 1

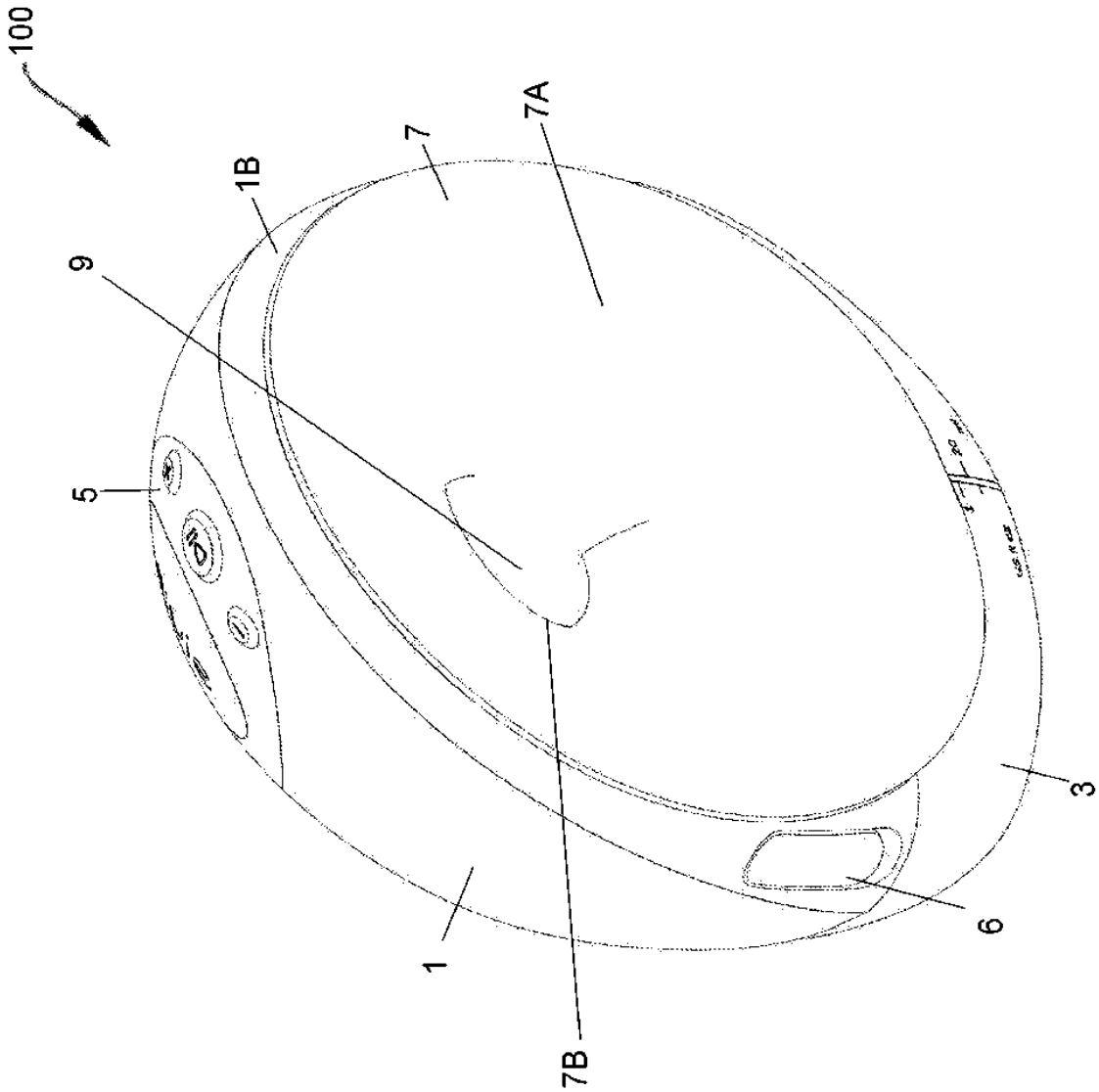


FIGURE 2

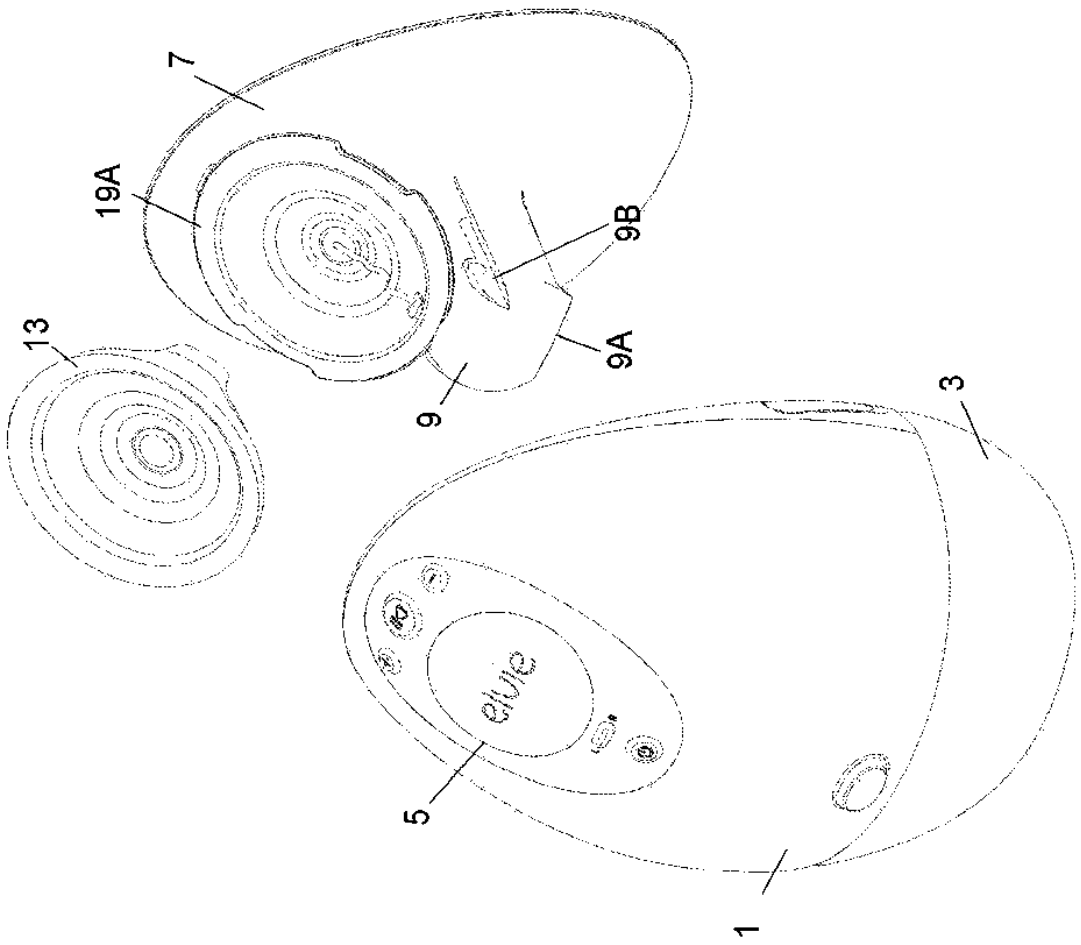


FIGURE 3

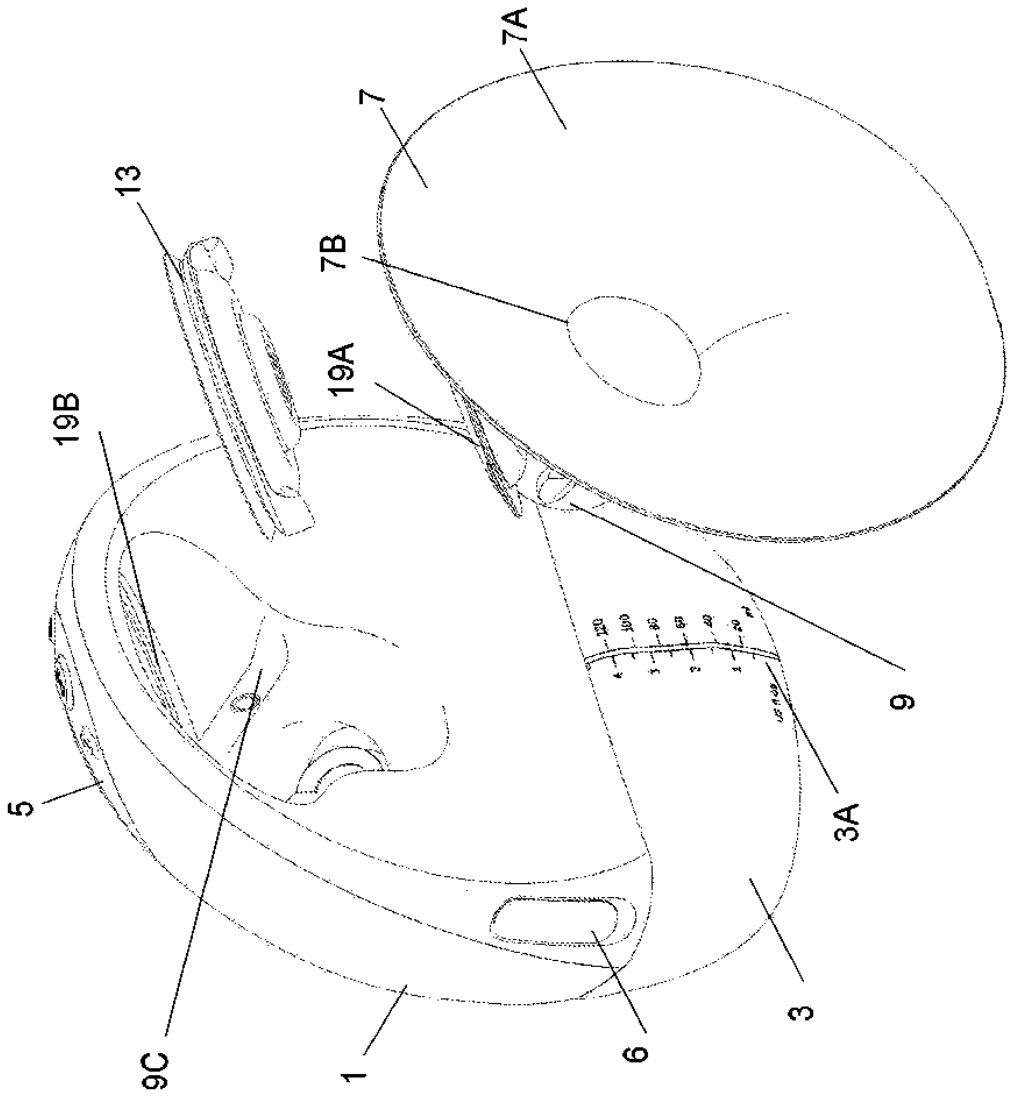


FIGURE 4

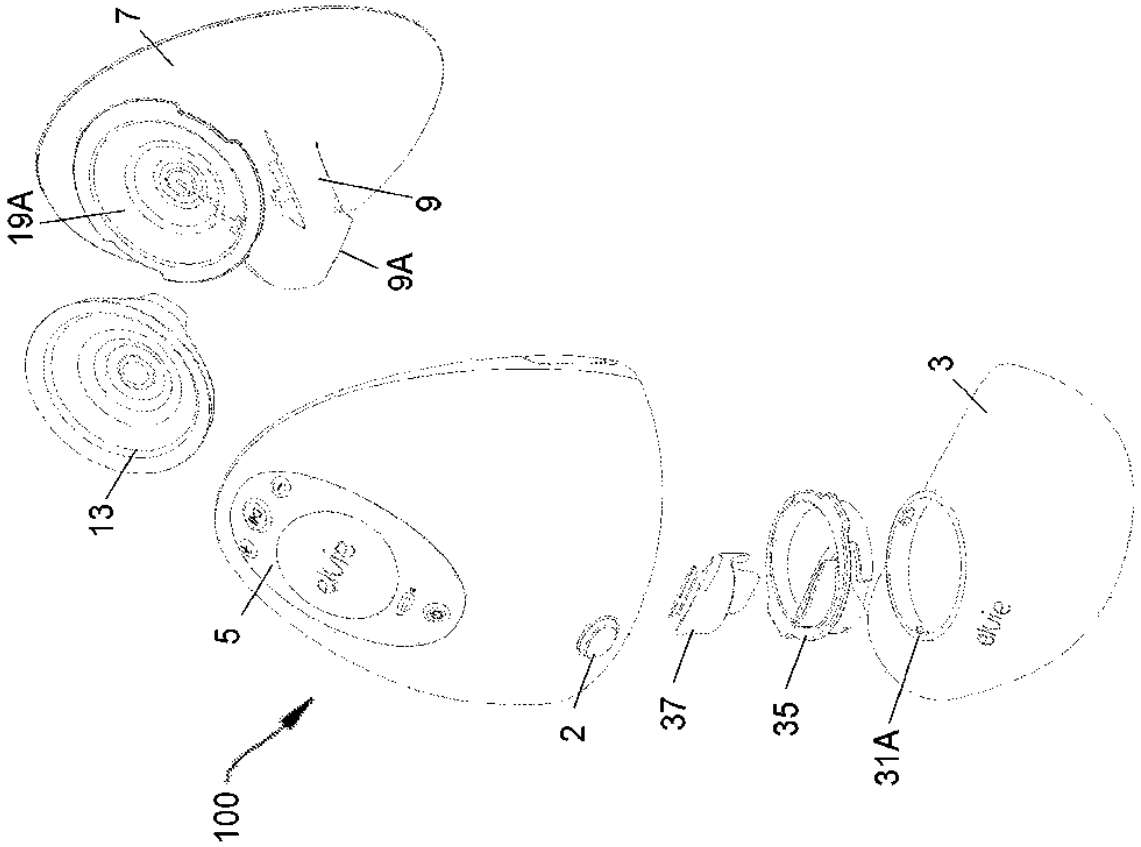


FIGURE 5

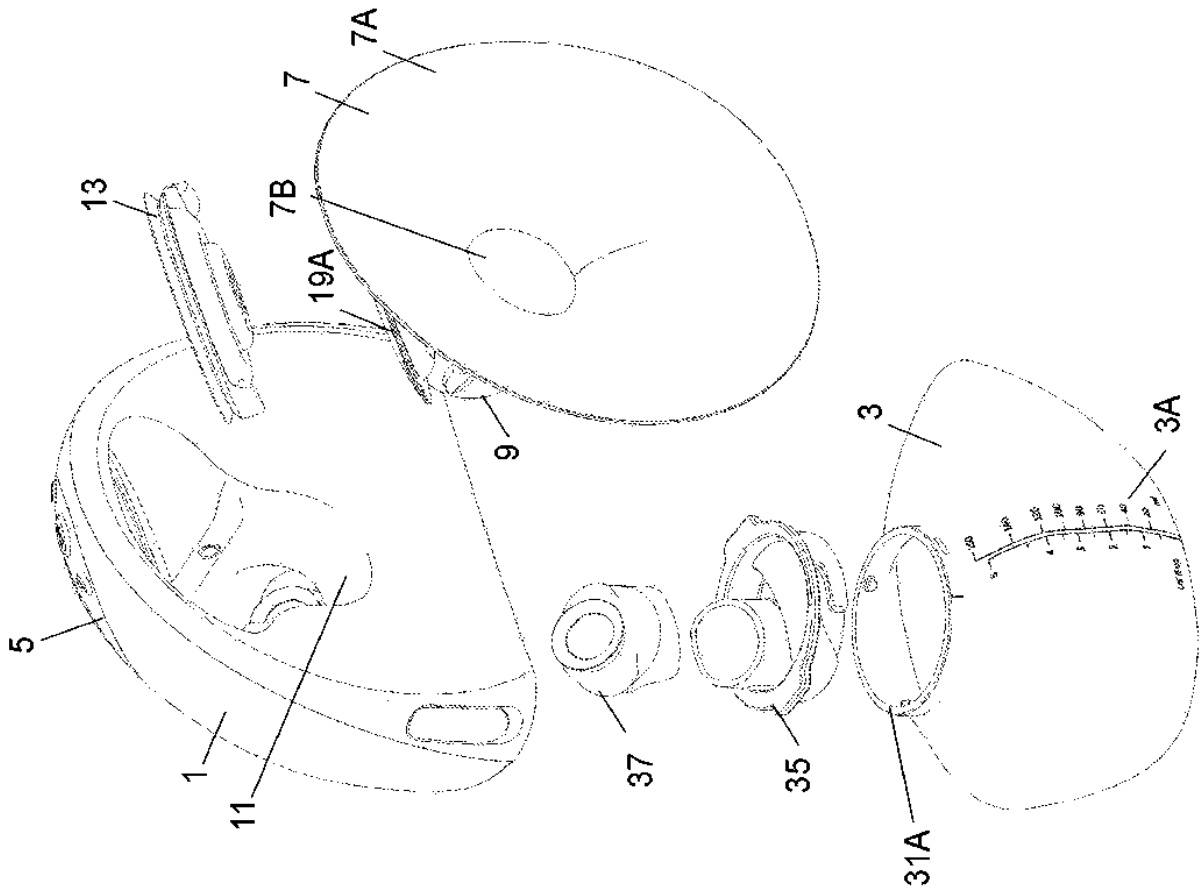


FIGURE 6

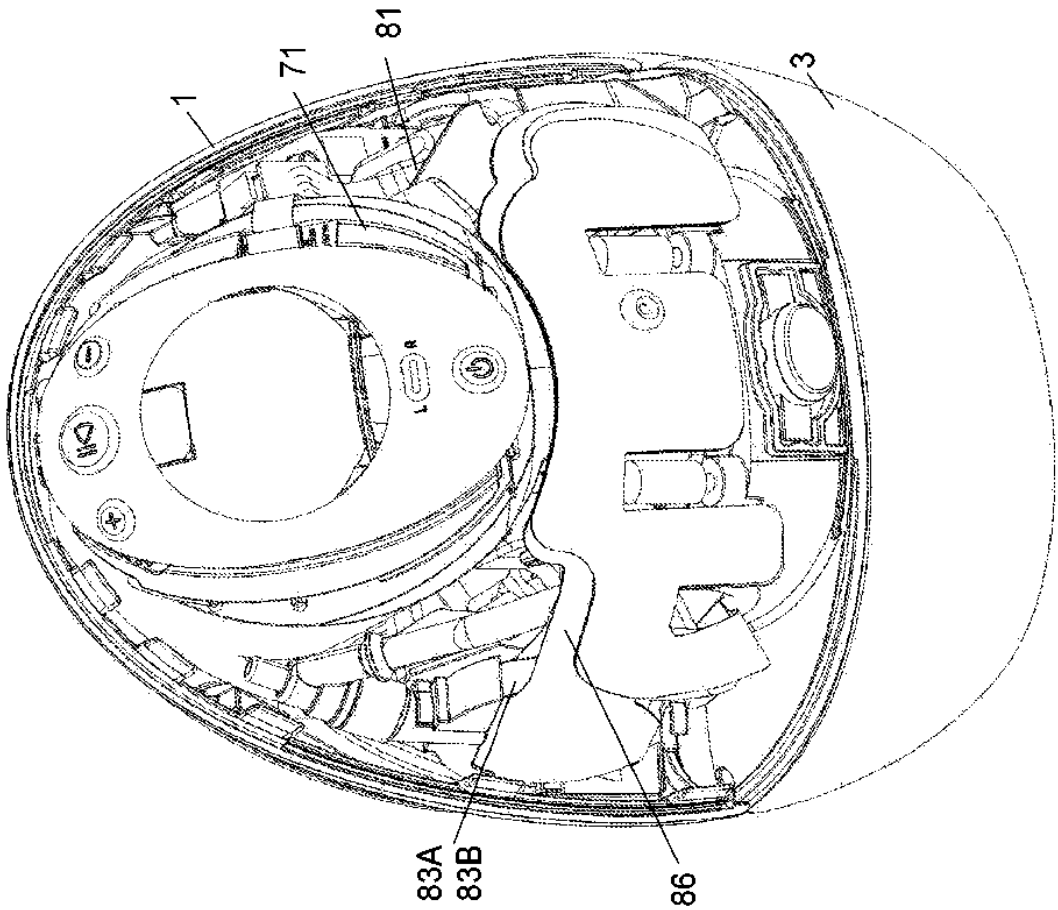


FIGURE 7

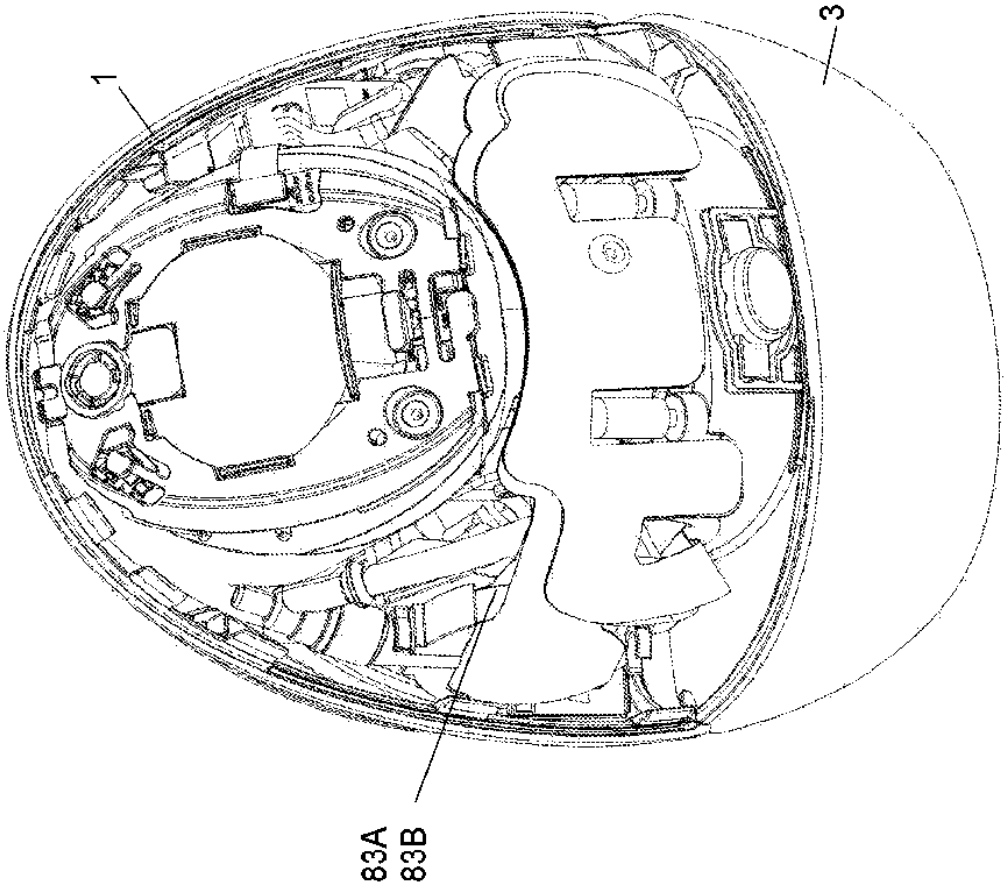


FIGURE 8

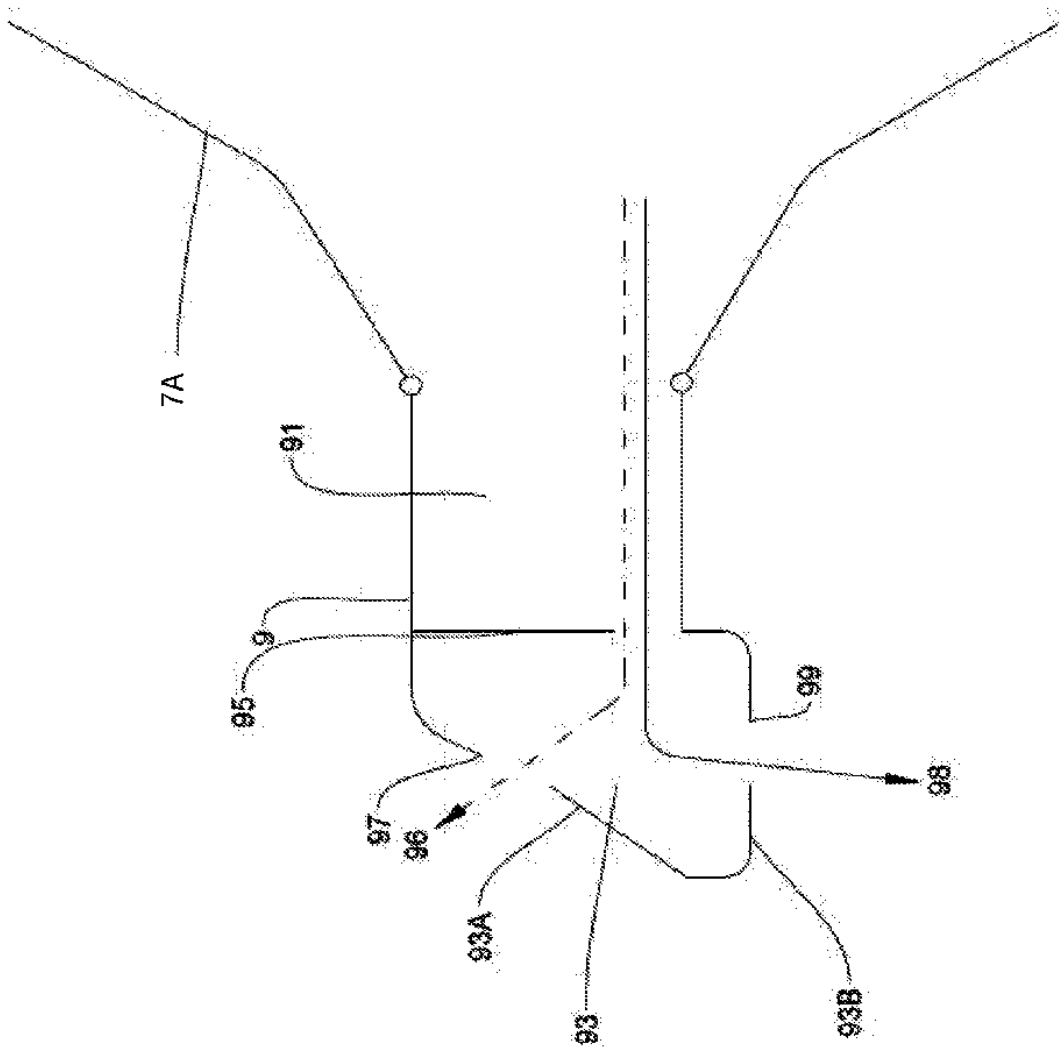


FIGURE 9

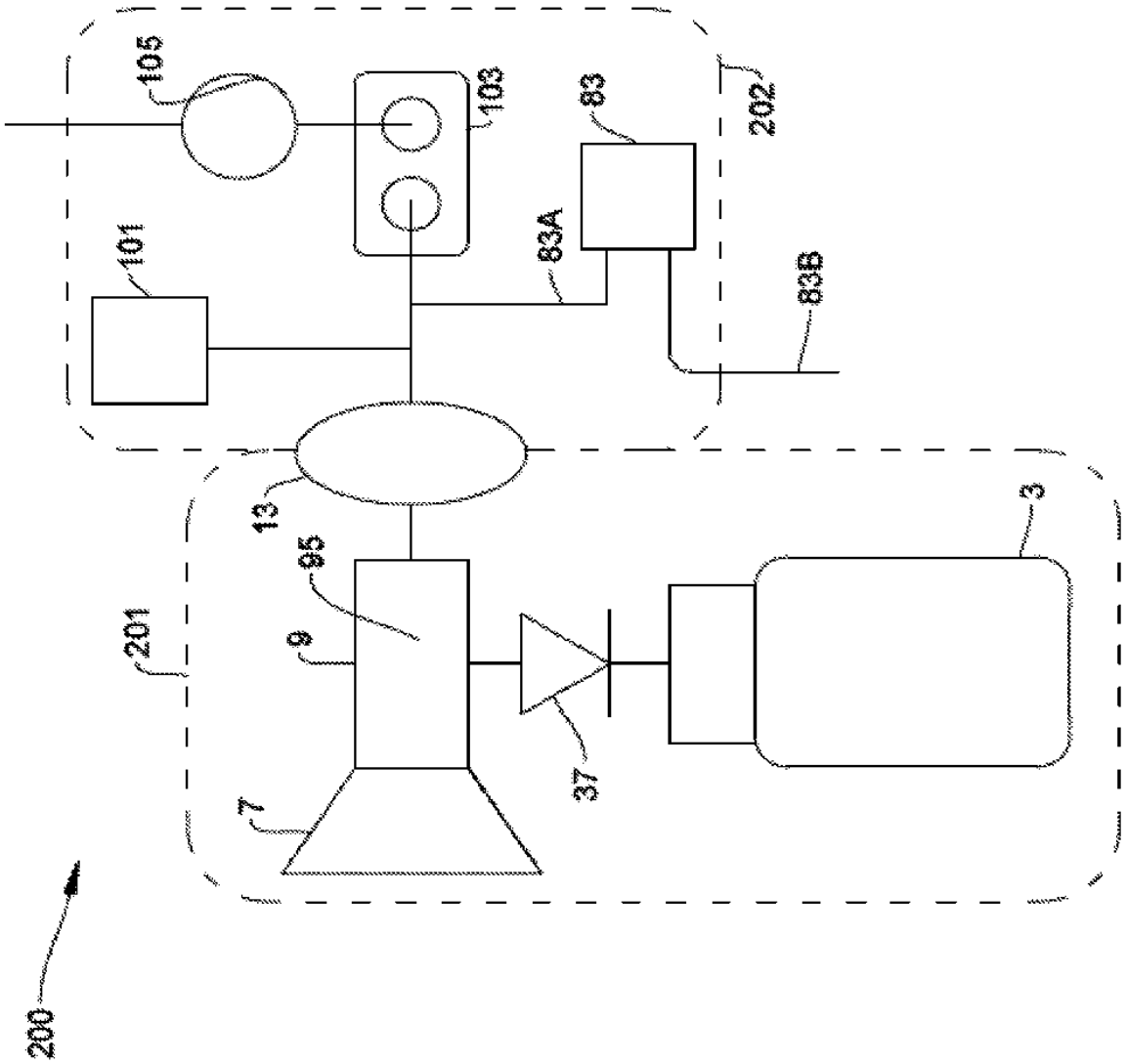


FIGURE 10

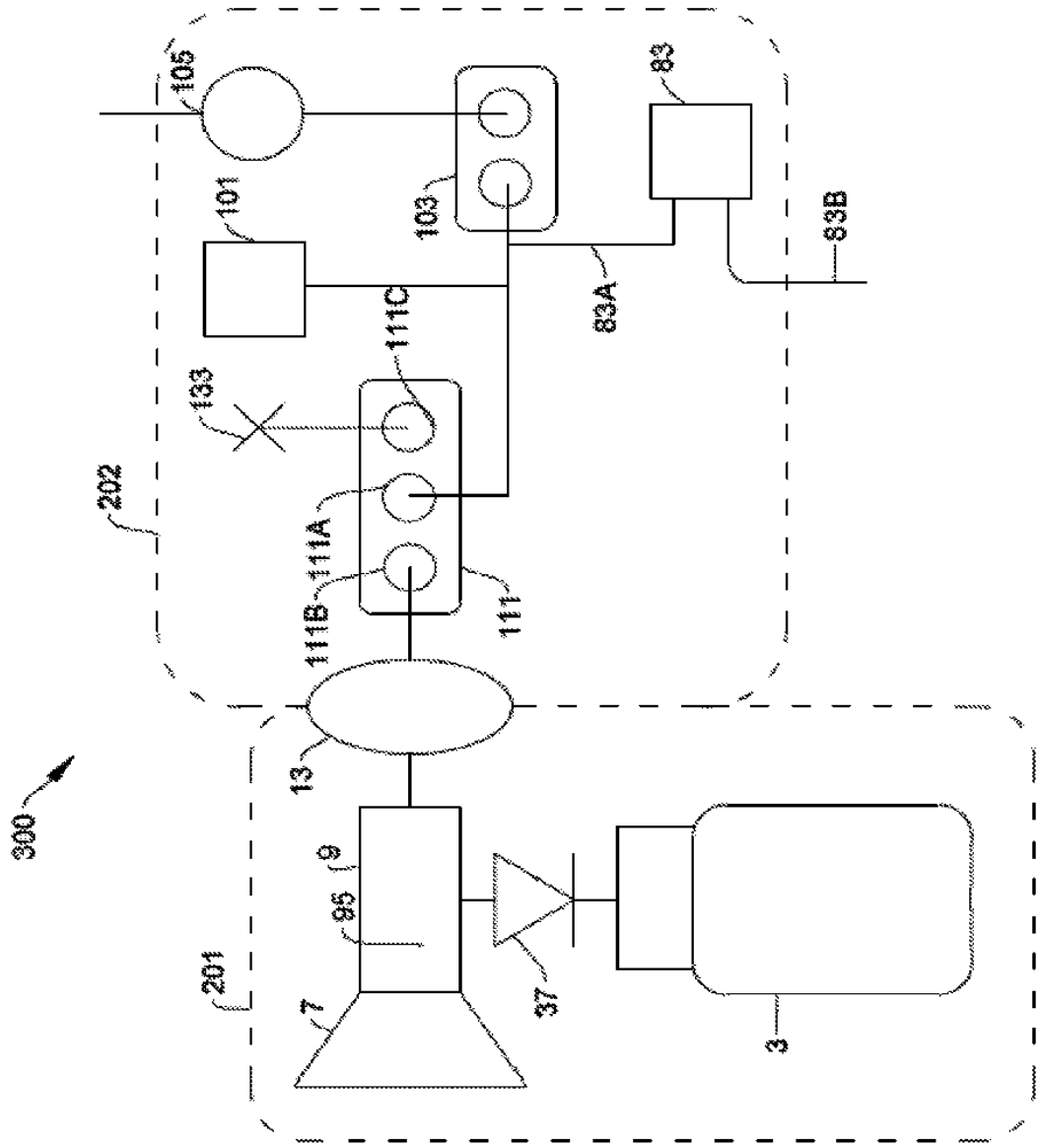

300
105
101
103
83
83B
83A
111C
133
202
111A
111B
111
13
9
95
201
7
37
3

FIGURE 11

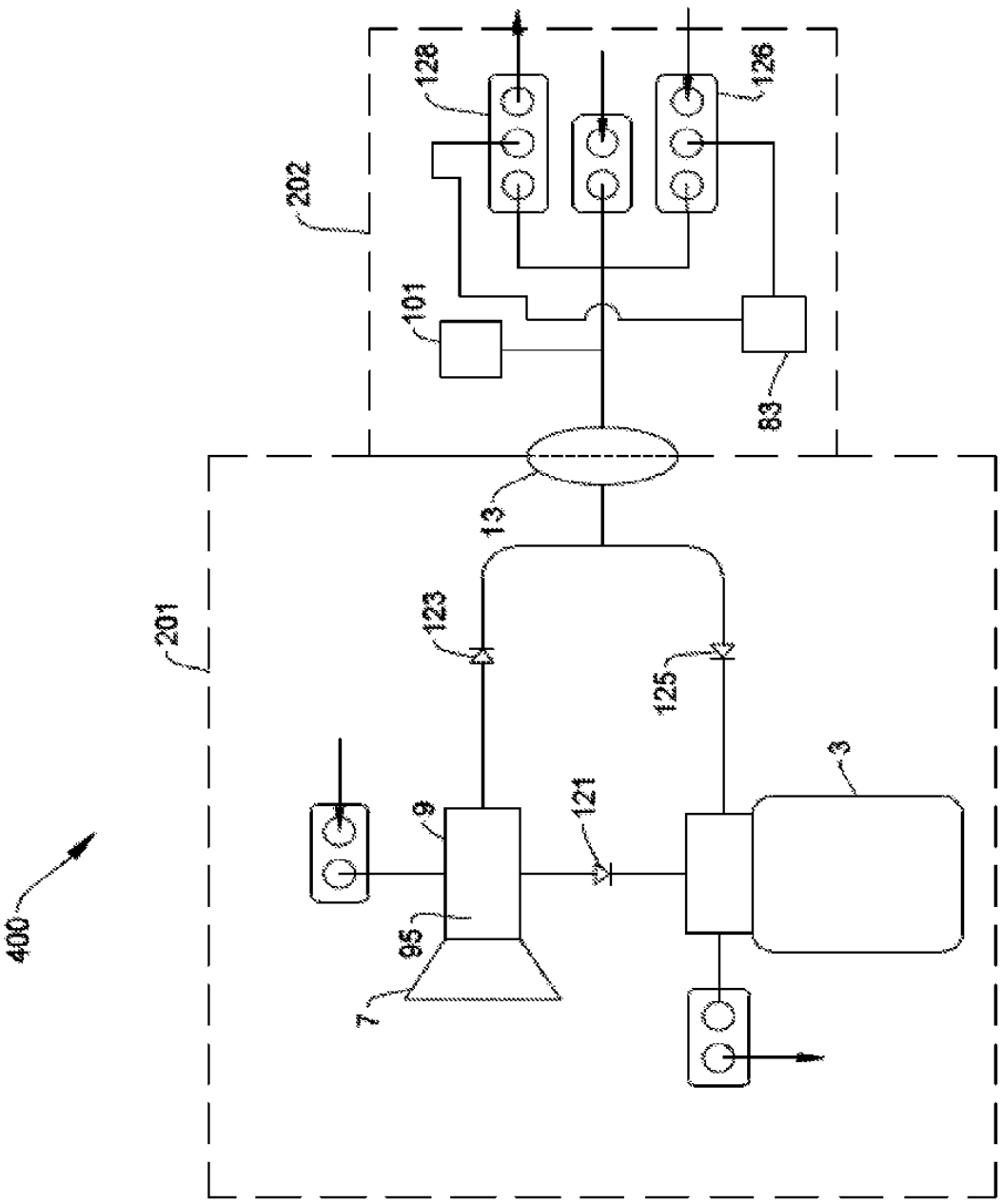


FIGURE 12

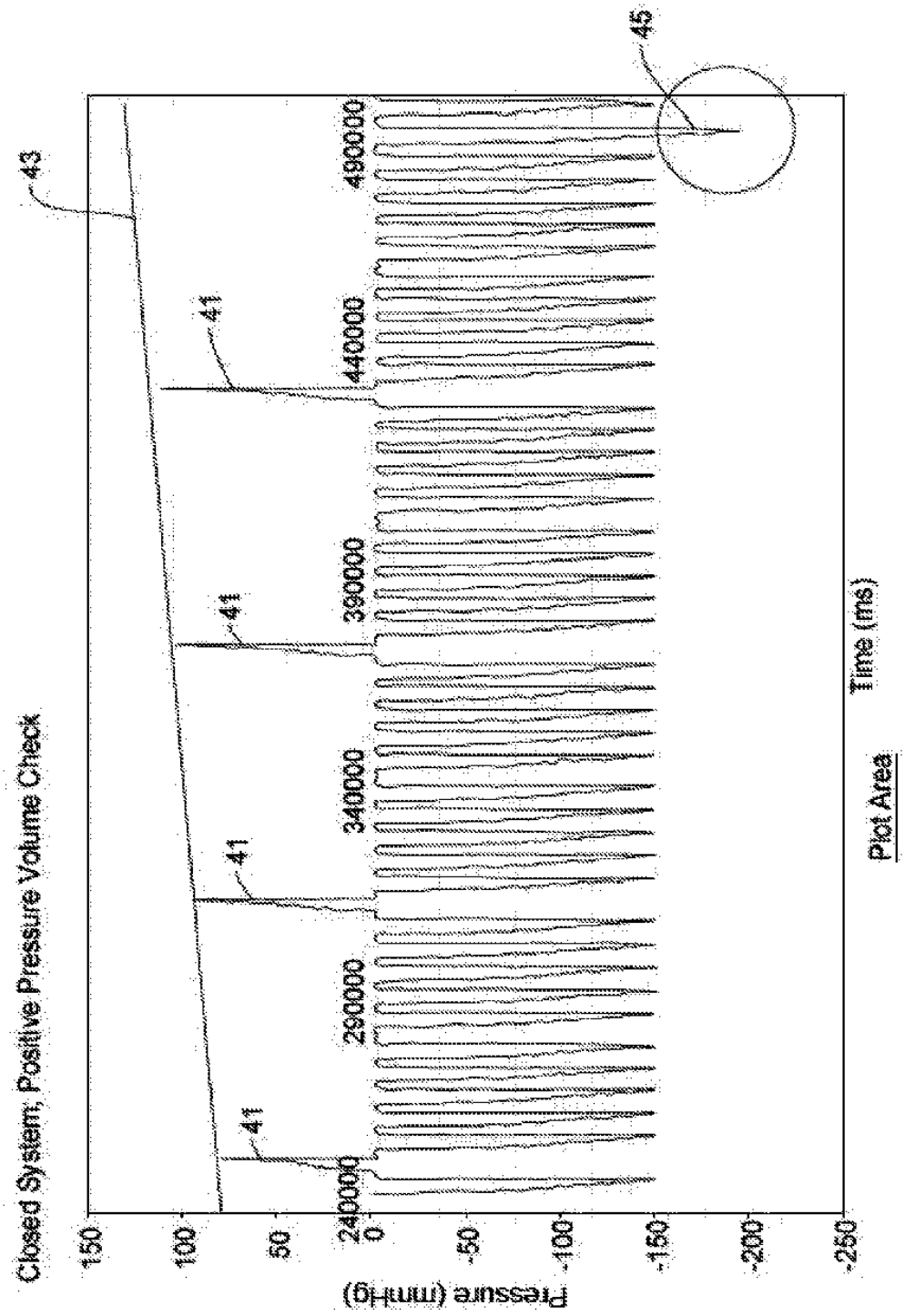

Closed System; Positive Pressure Volume Check
43
41
41
41
41
45
240000
290000
340000
390000
440000
490000
150
100
50
0
-50
-100
-150
-200
-250
Pressure (mmHg)
Time (ms)
Plot Area

FIGURE 13

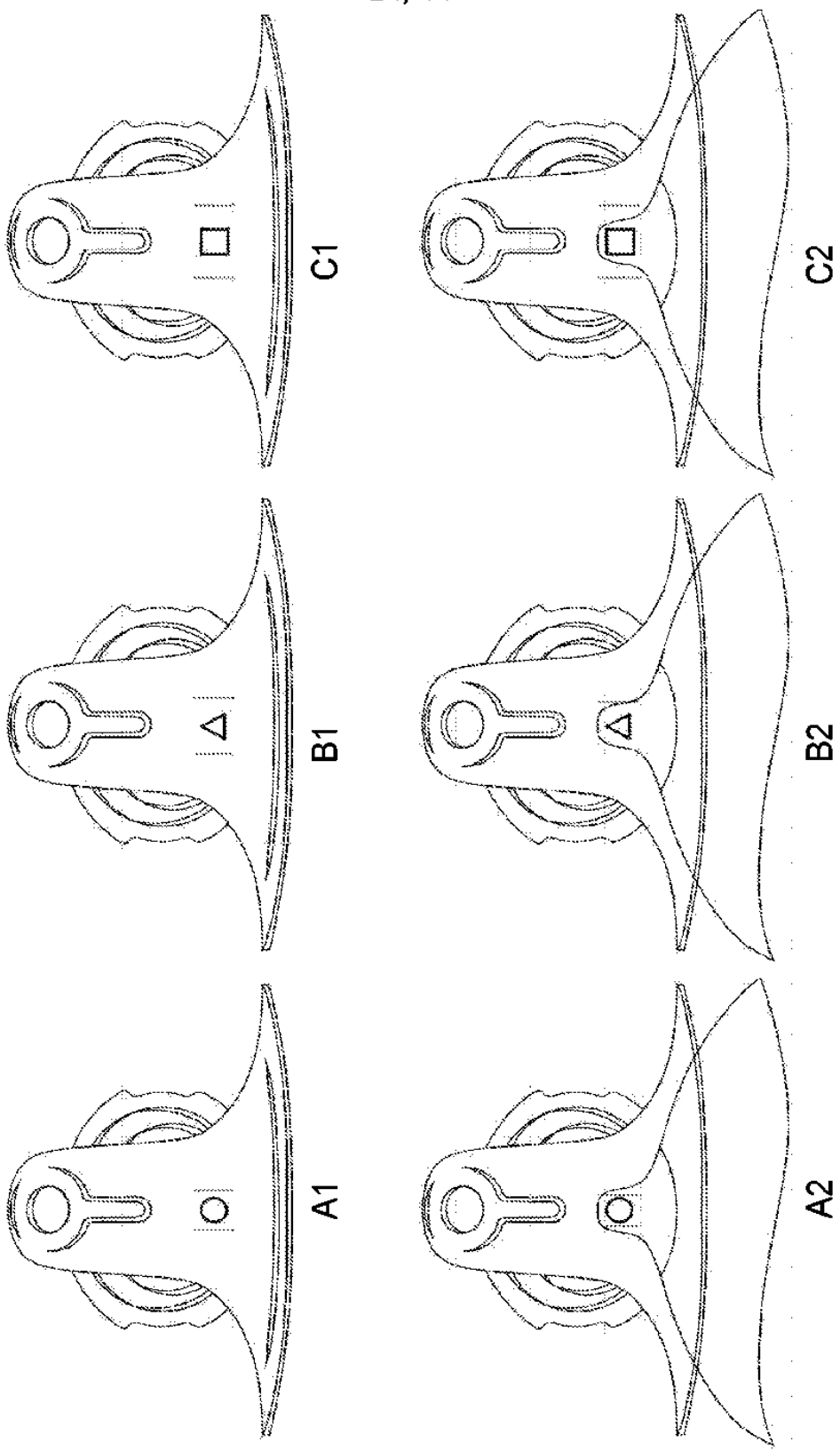


FIGURE 14

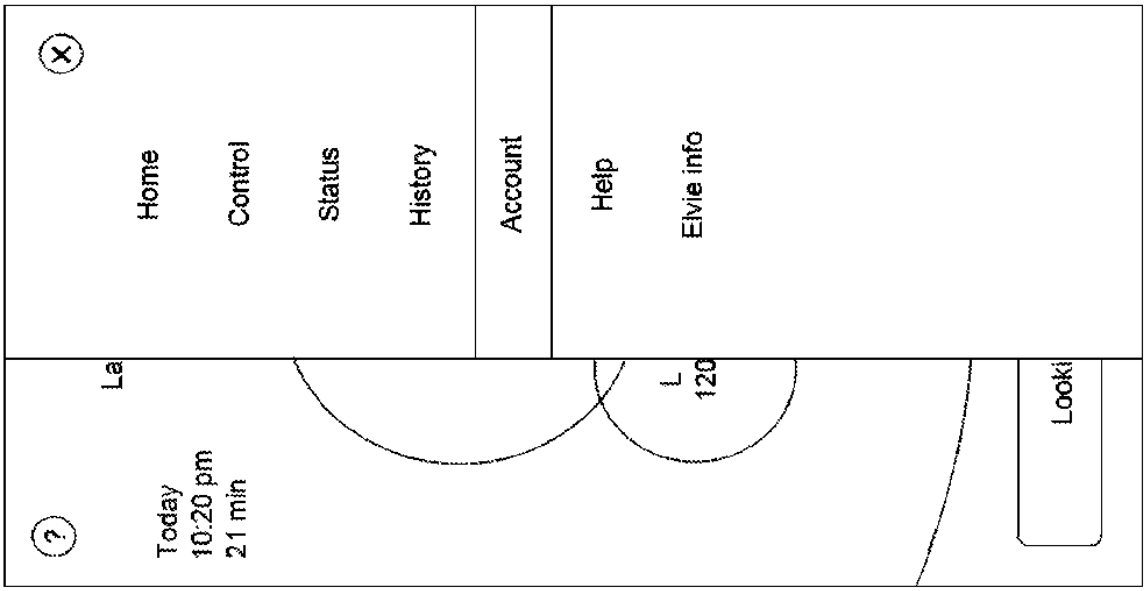

Home
Control
Status
History
Account
Help
Elvie info
Today
10:20 pm
21 min
Looki

FIGURE 15

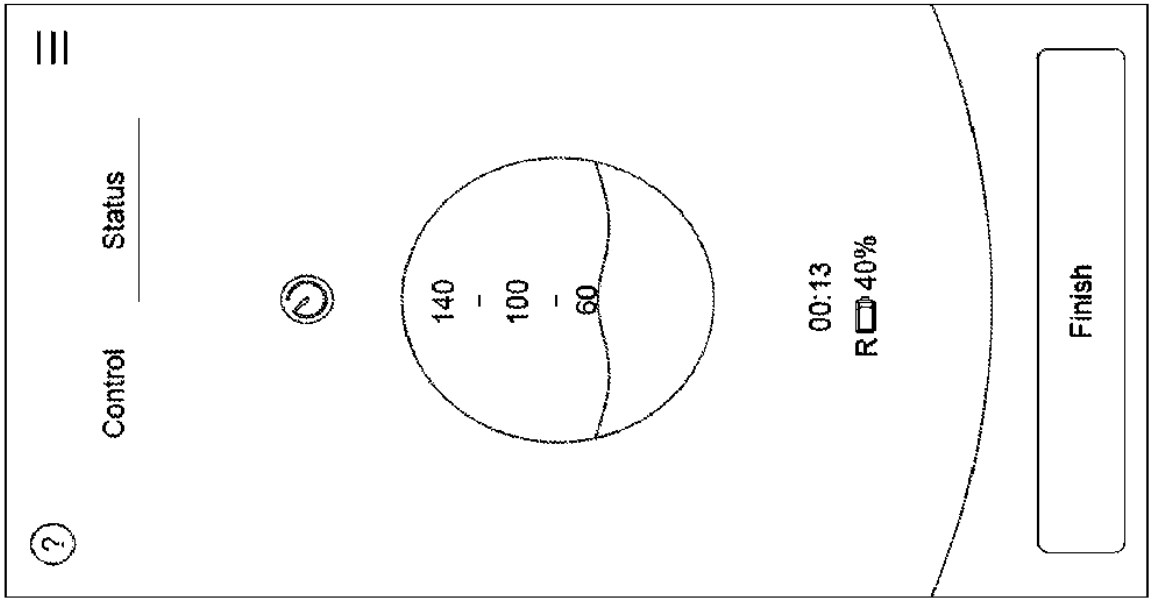


FIGURE 16

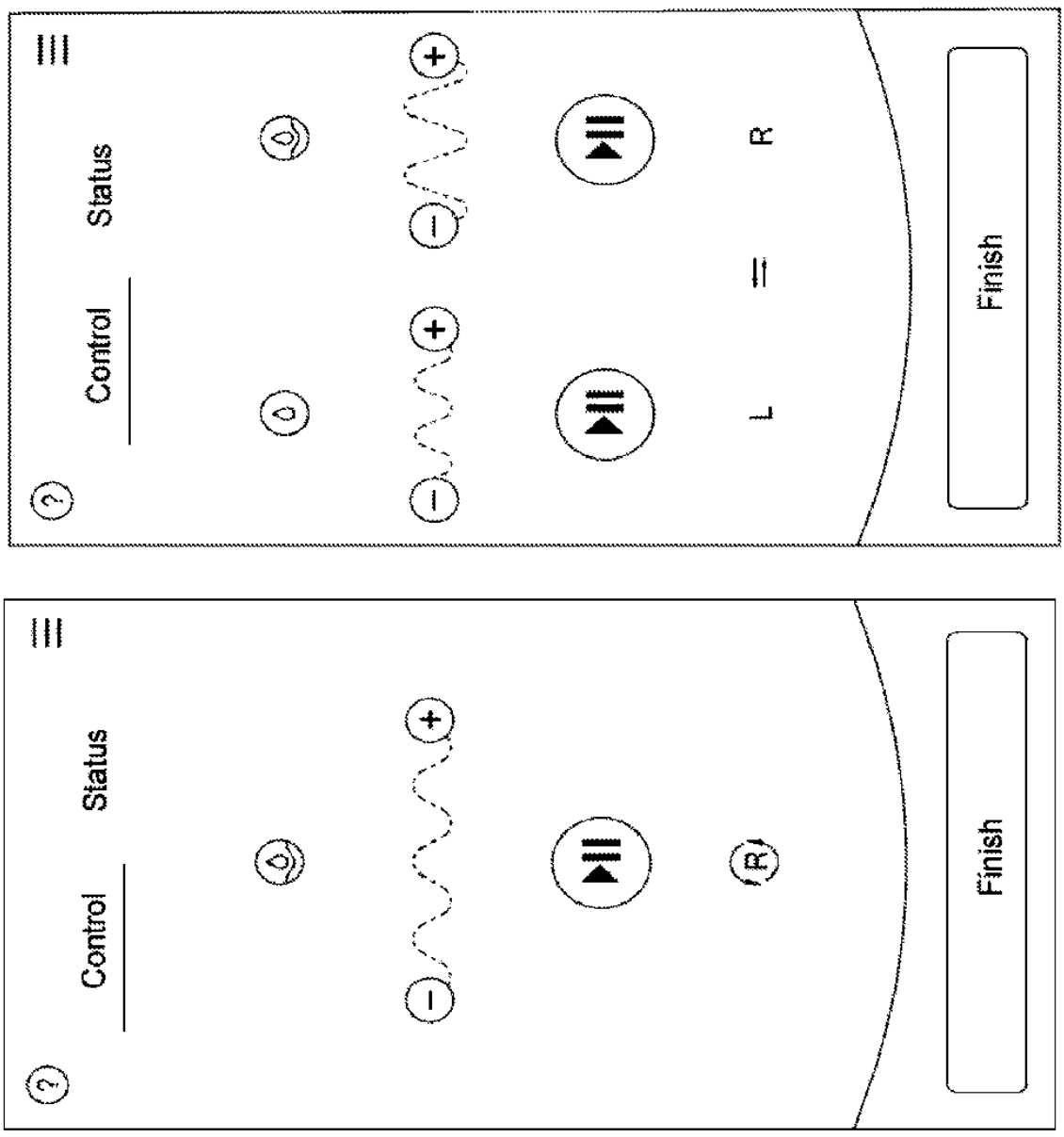


FIGURE 17

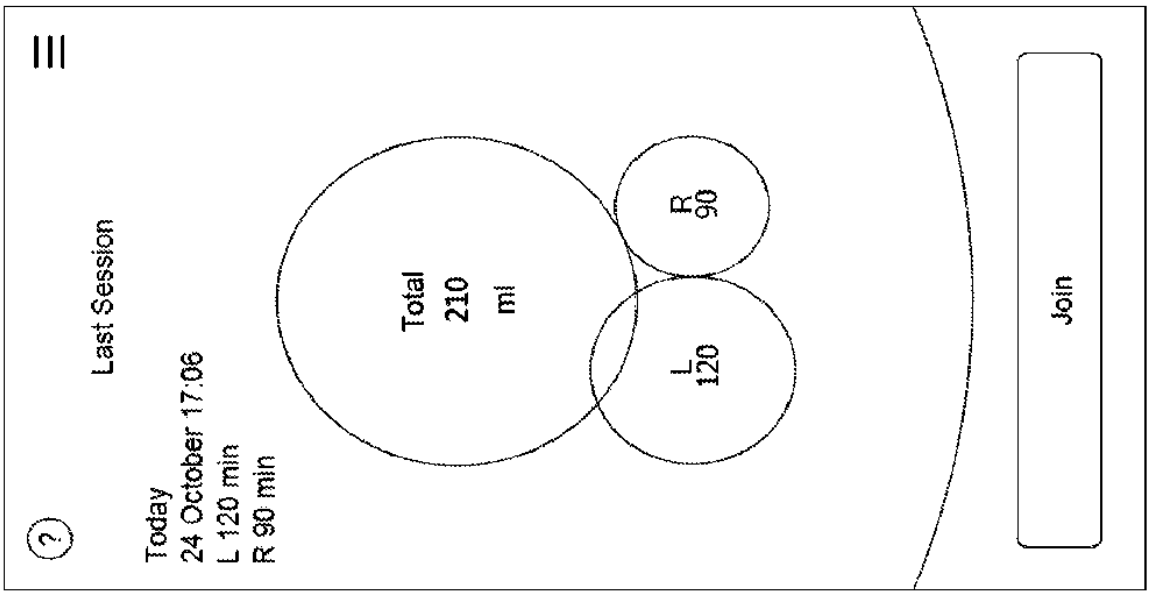

Last Session
Today
24 October 17:06
L 120 min
R 90 min
Total
210
mi
L
120
R
90
Join

FIGURE 18

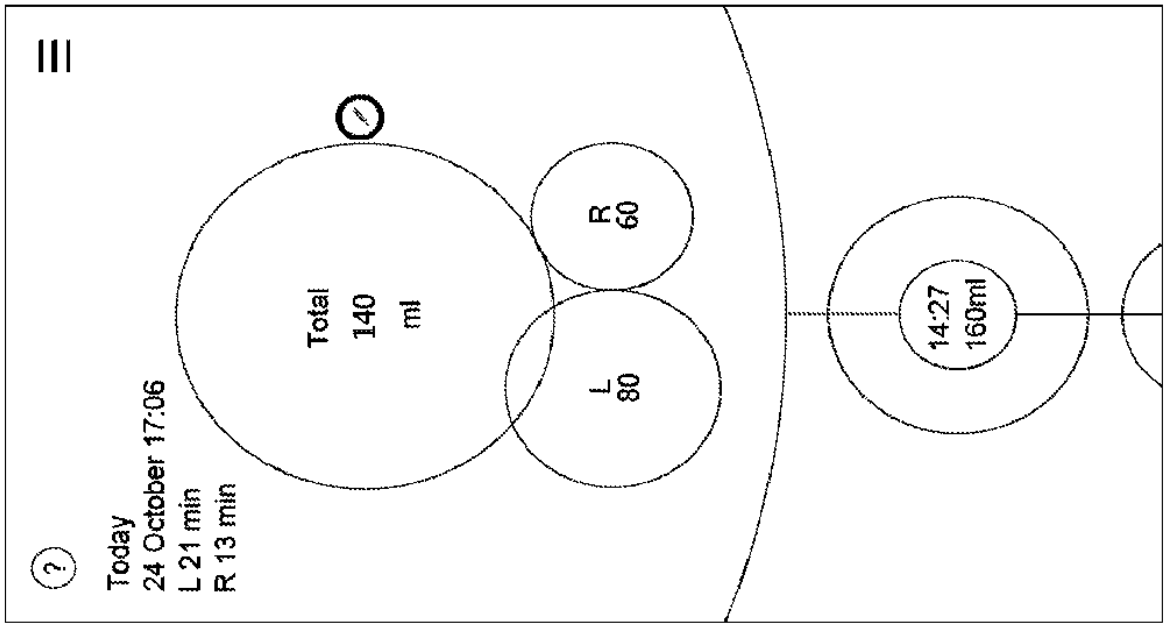

Today
24 October 17:06
L 21 min
R 13 min
Total
140
ml
L
80
R
60
14:27
160ml

FIGURE 19

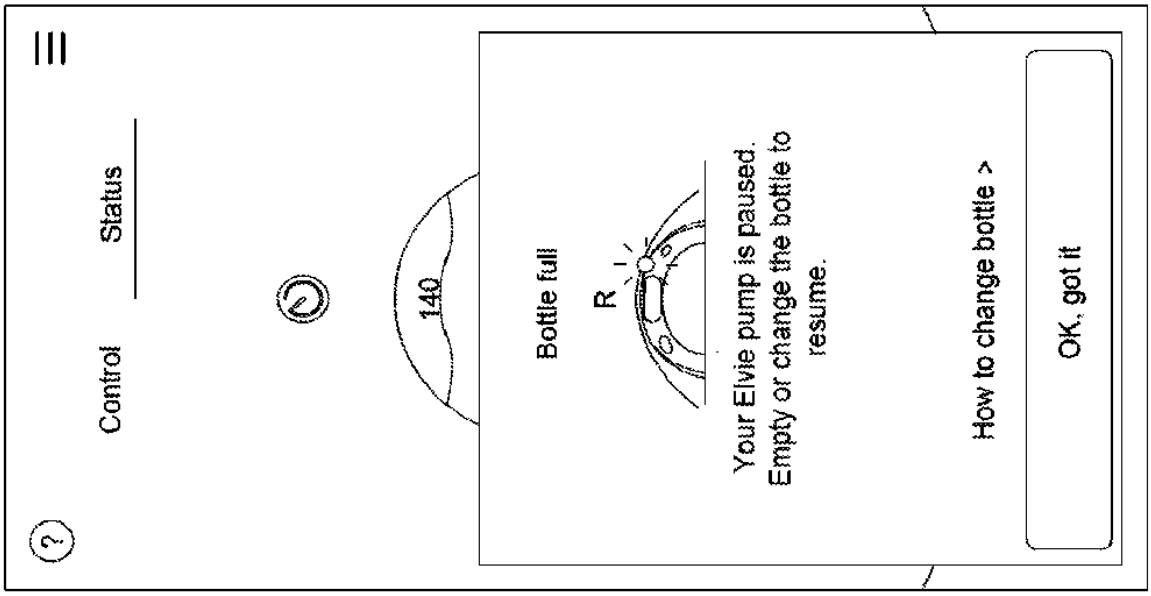

Control
Status
140
Bottle full
Your Elvie pump is paused.
Empty or change the bottle to resume.
How to change bottle >
OK, got it

FIGURE 20

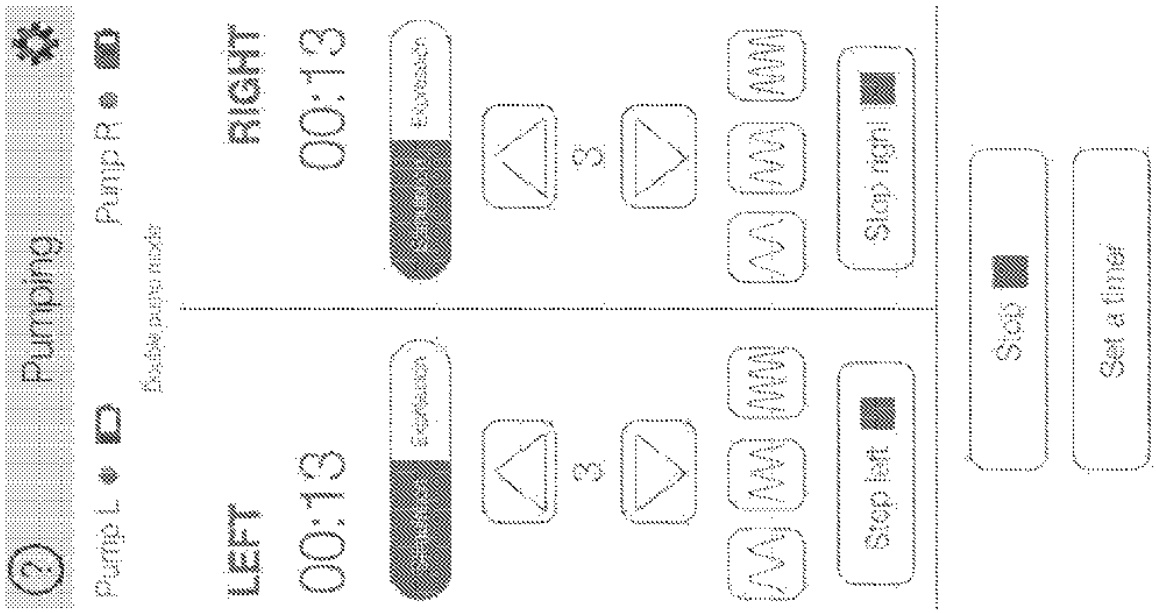

Pumping
Pump L
Pump R
Auto suction mode
LEFT
00:13
Suction
Expulsion
RIGHT
00:13
Suction
Expulsion
Stop left
Stop right
Stop
Set a timer

FIGURE 21

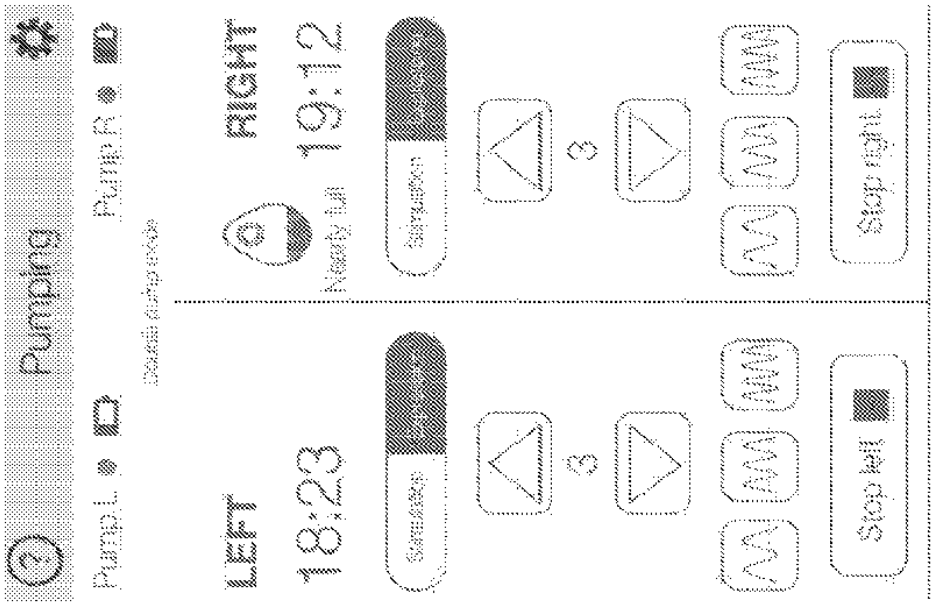

Pumping
Pump L
Pump R
Double-tap to pause
LEFT
18:23
Sensation
Custom
3
3
Stop left
RIGHT
19:12
Sensation
Custom
3
3
Stop right
Stop
Set a timer

FIGURE 22

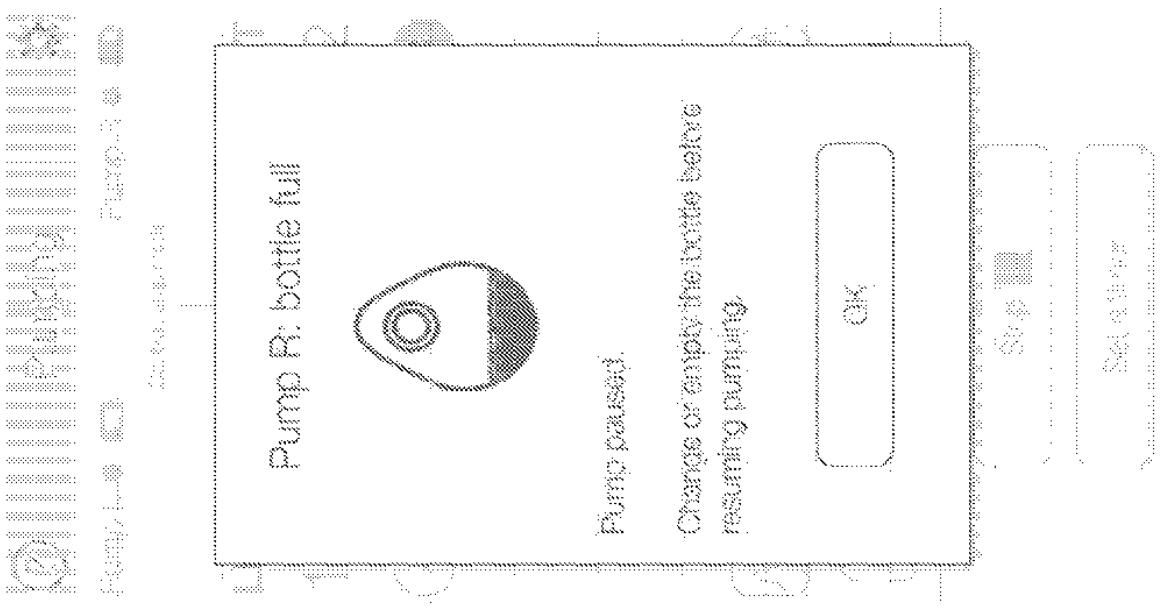

Pump R: bottle full
Pump paused
Change or empty the bottle before resuming pumping
OK

FIGURE 23


Stopped
Pump L
Pump R
Online nursing mode
LEFT
21:02
STOPPED
RIGHT
20:38
STOPPED
Total volume in bottle
Total volume in bottle
60 ml
65 ml
Tick if you emptied the bottle
Tick if you emptied the bottle
Resume left
Resume right
Resume
End session

FIGURE 24

PUMP
Pump L
Pump R
Check pump cord
LAST SESSION
Start time: 3:30pm today
Total volume: 125ml
LEFT
20mins 16s
60ml
RIGHT
18mins 10s
65ml
Full history >
NEW SESSION
Start

FIGURE 25

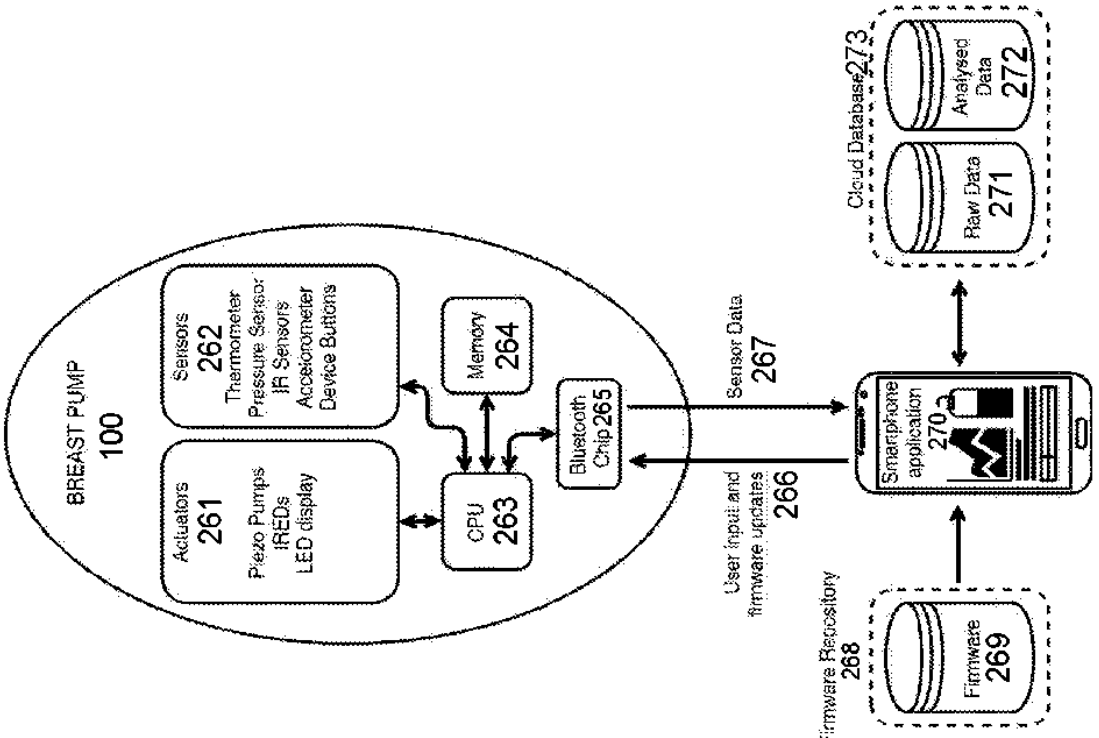

BREAST PUMP
100
Actuators
261
Piezo Pumps
IREDs
LED display
Sensors
262
Thermometer
Pressure Sensor
IR Sensors
Accelerometer
Device Buttons
CPU
263
Memory
264
Bluetooth
Chip 265
Sensor Data
267
User input and
firmware updates
266
Smartphone
application
270
Cloud Database 273
Raw Data
271
Analysed
Data
272
Firmware Repository
268
Firmware
269

FIGURE 26

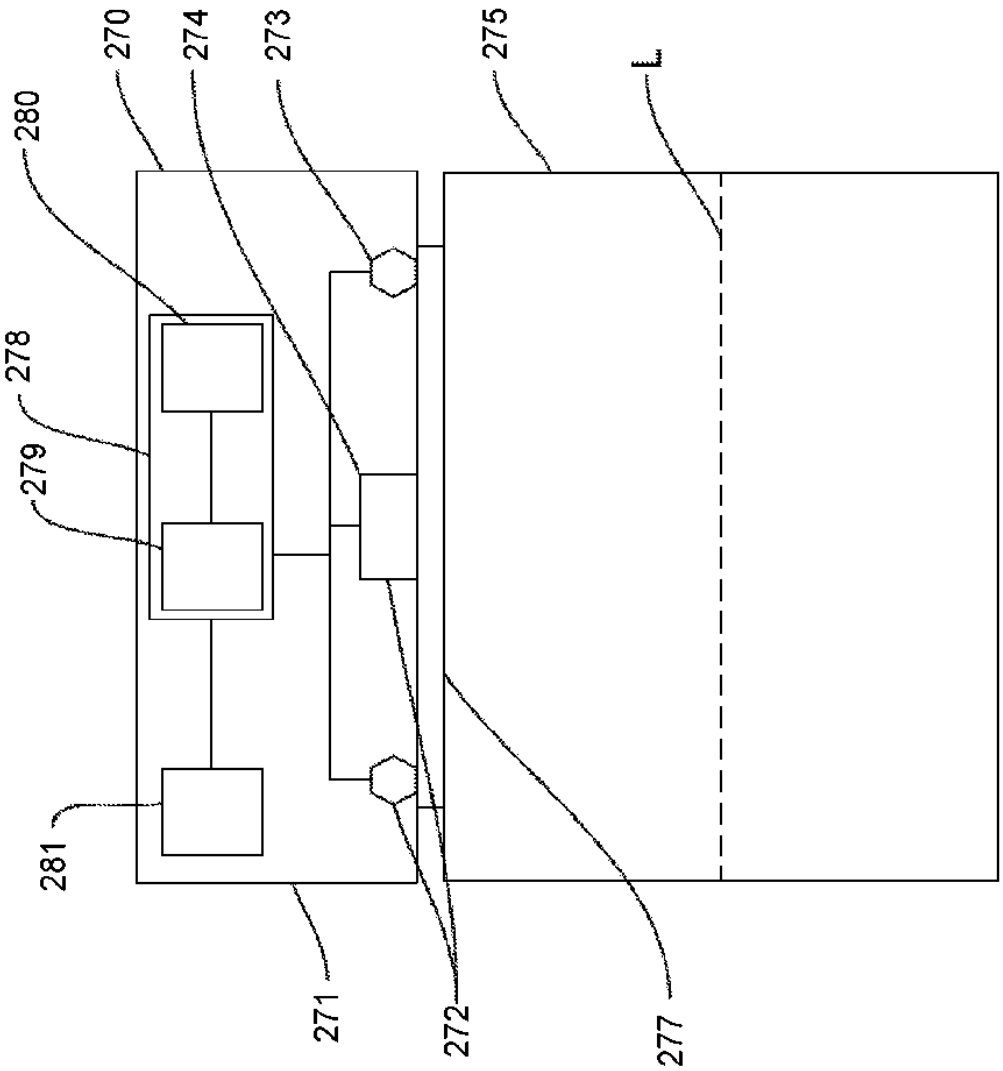


FIGURE 27

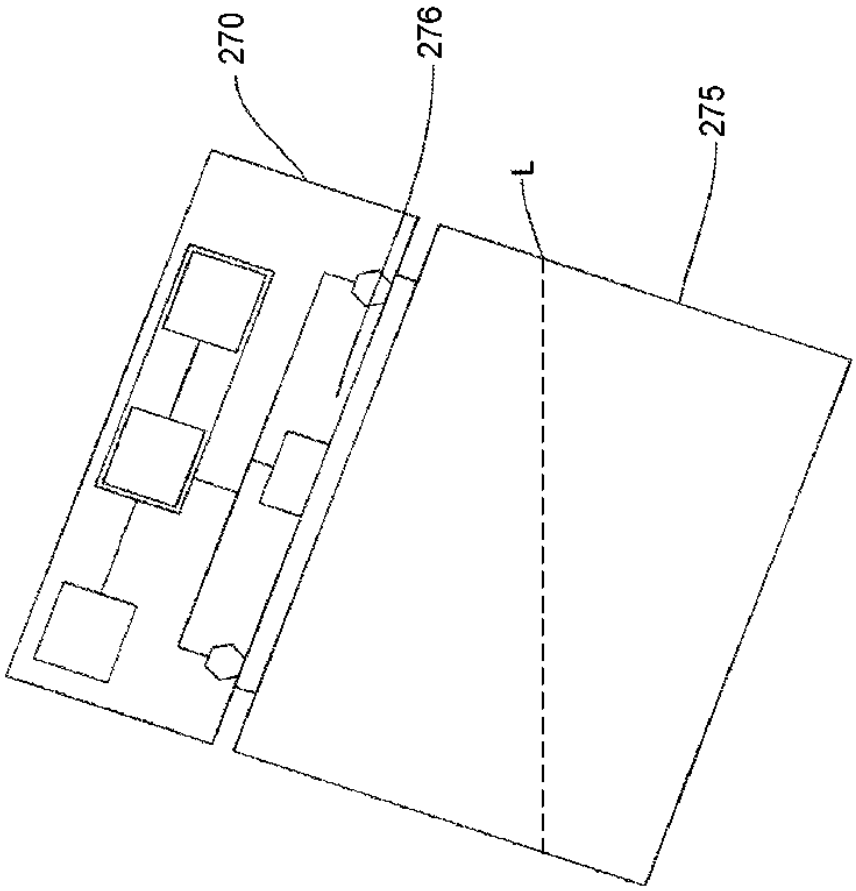


FIGURE 28

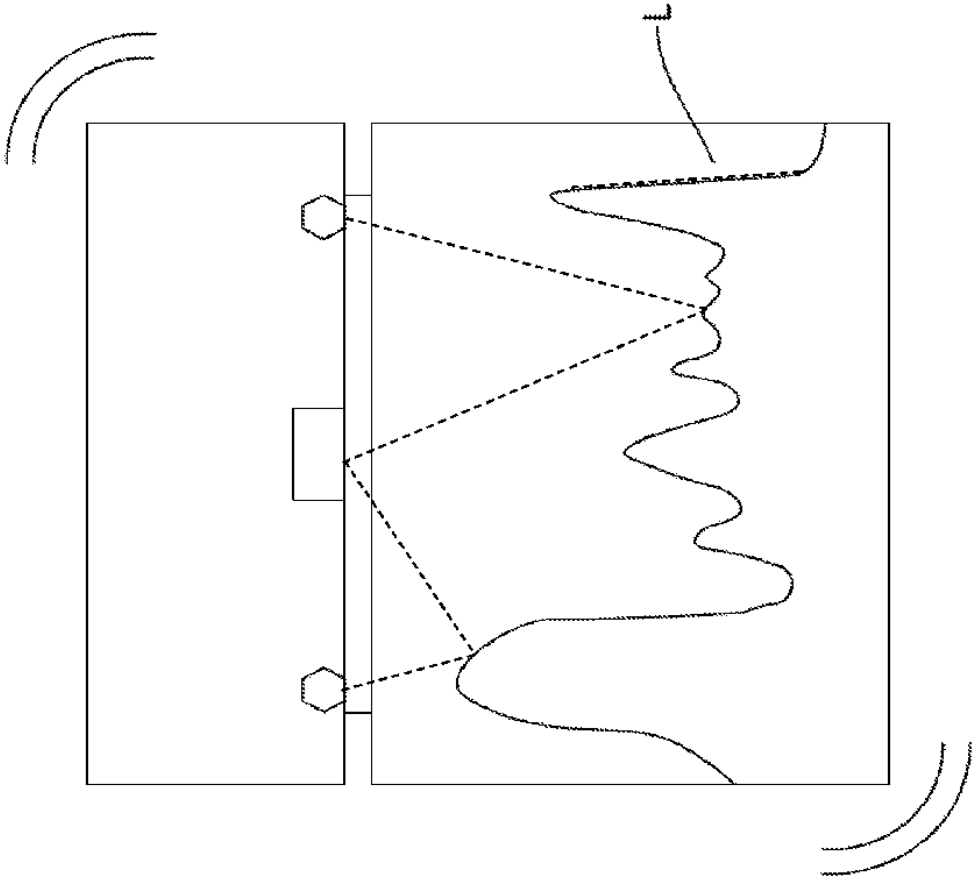


FIGURE 29

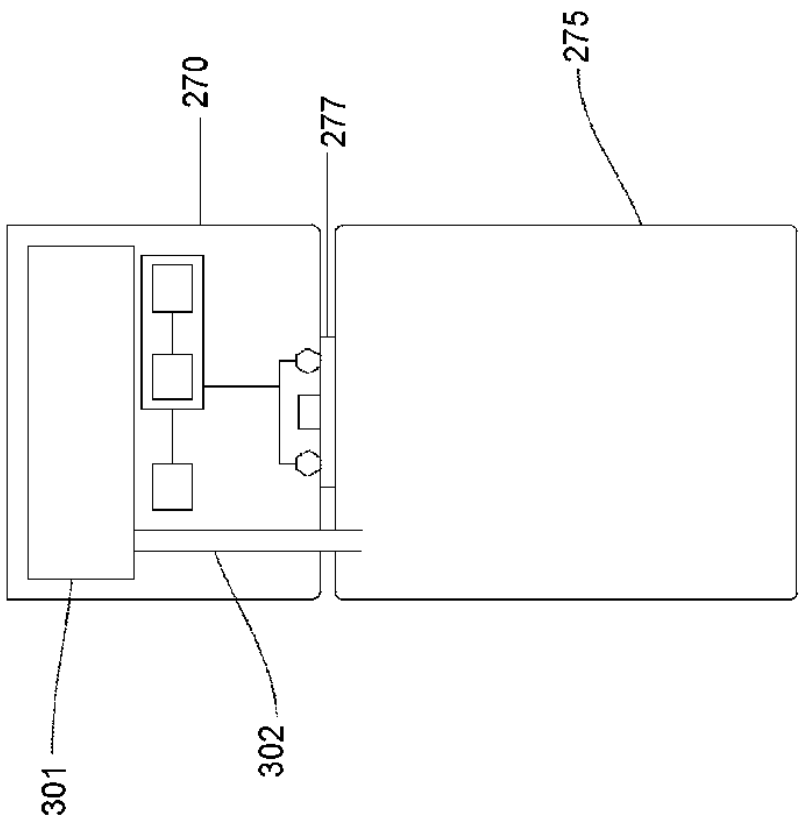


FIGURE 30

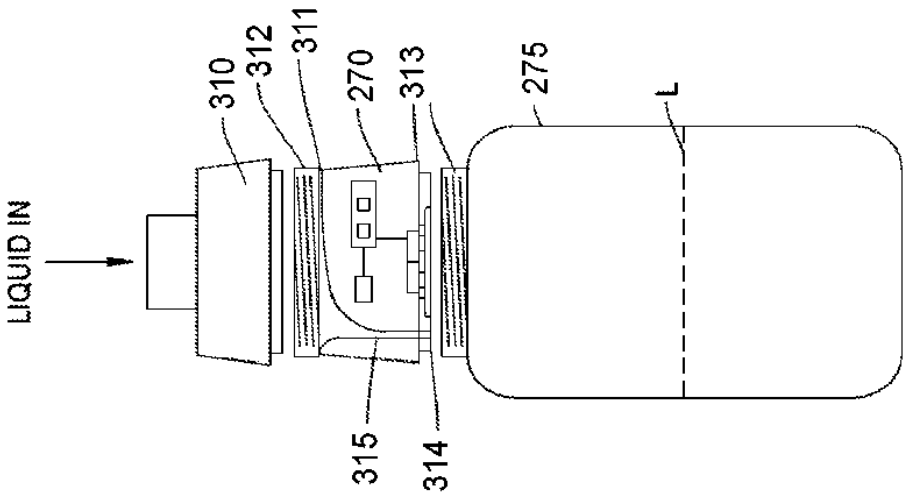


FIGURE 31

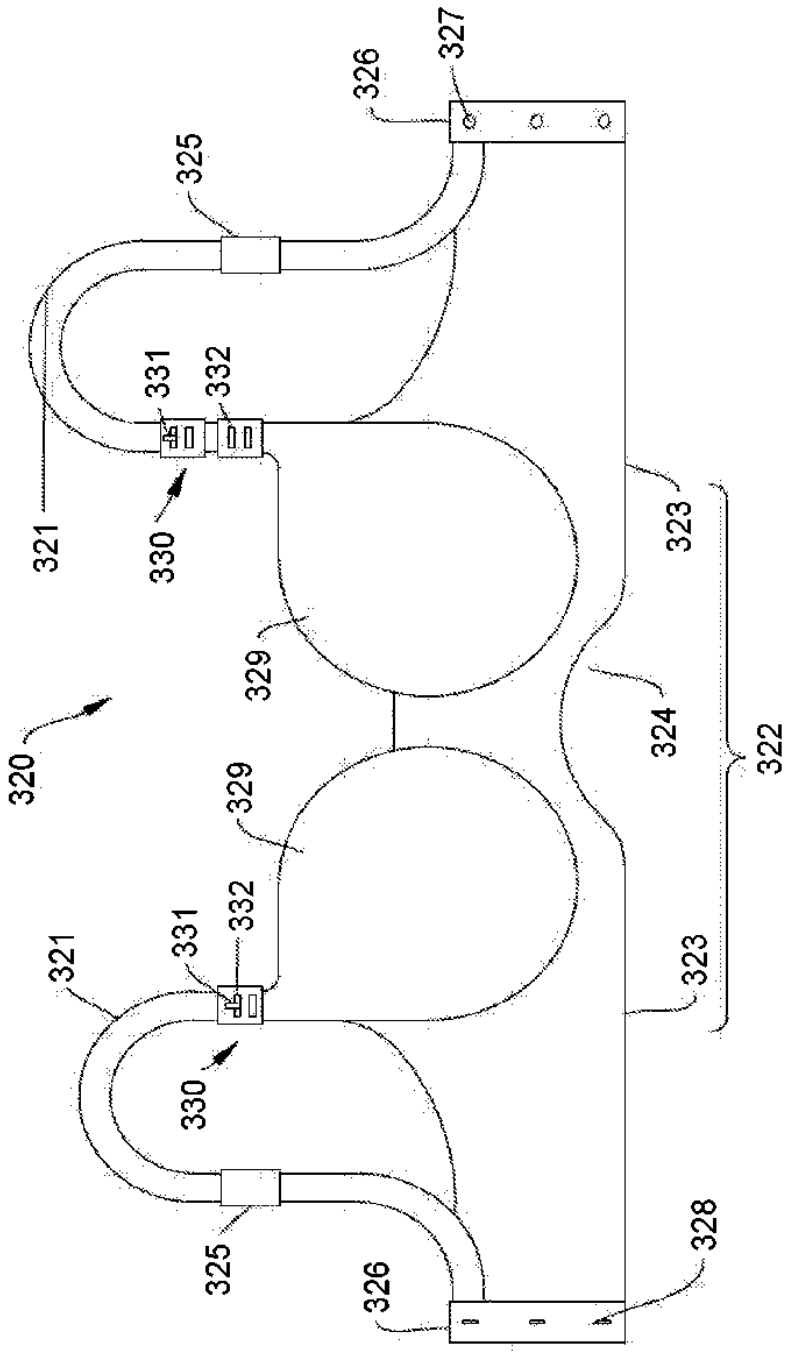


FIGURE 32

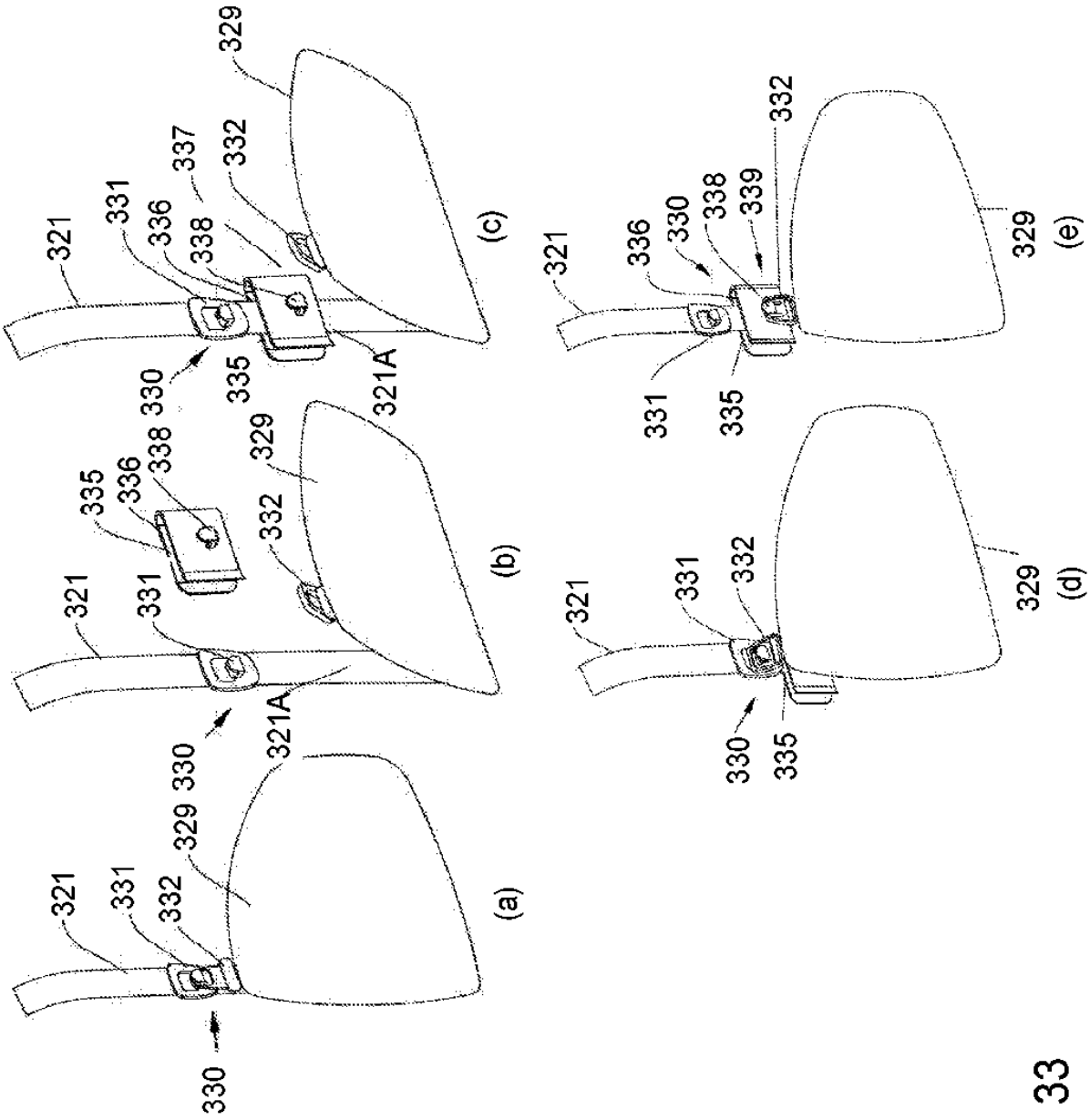

321
331
332
329
330
(a)
321
331
335
336
338
329
332
321A
330
(b)
321
331
336
338
337
332
329
335
321A
330
(c)
321
336
330
338
339
332
329
331
335
(e)
321
331
332
329
330
335
(d)

FIGURE 33

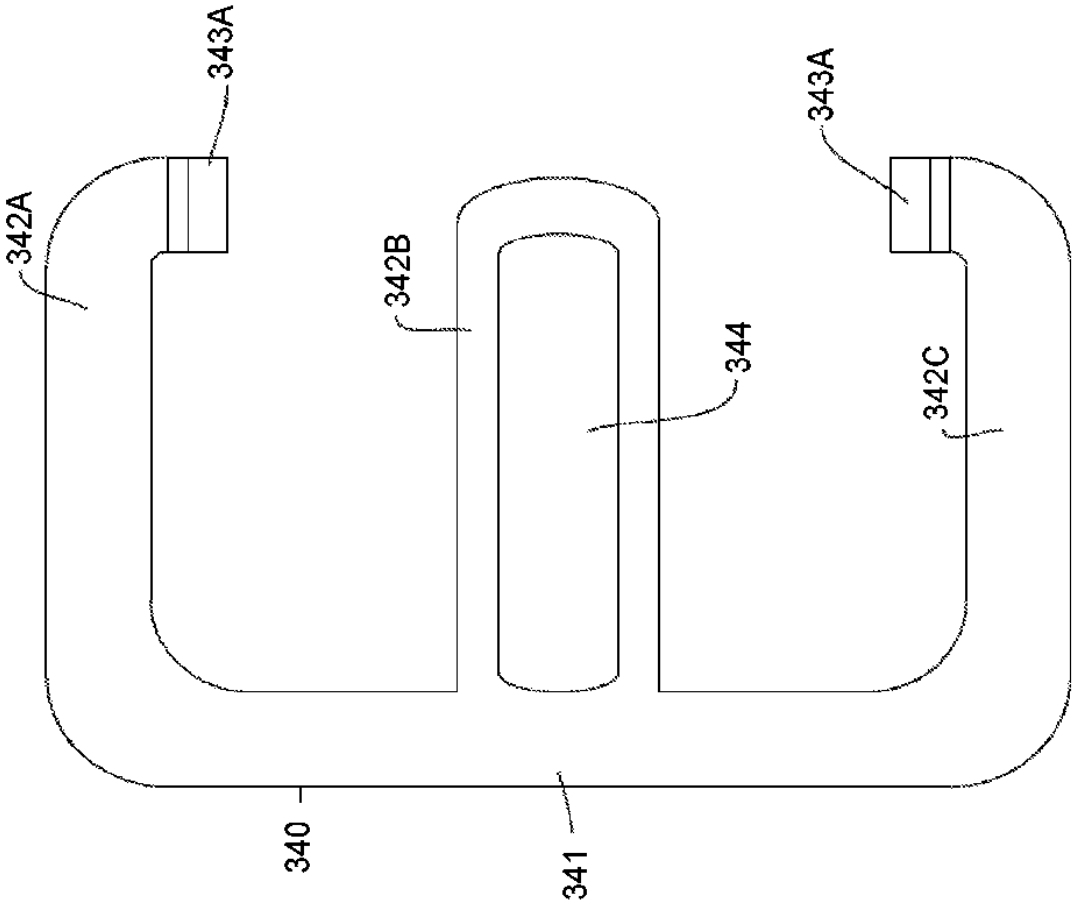


FIGURE 34

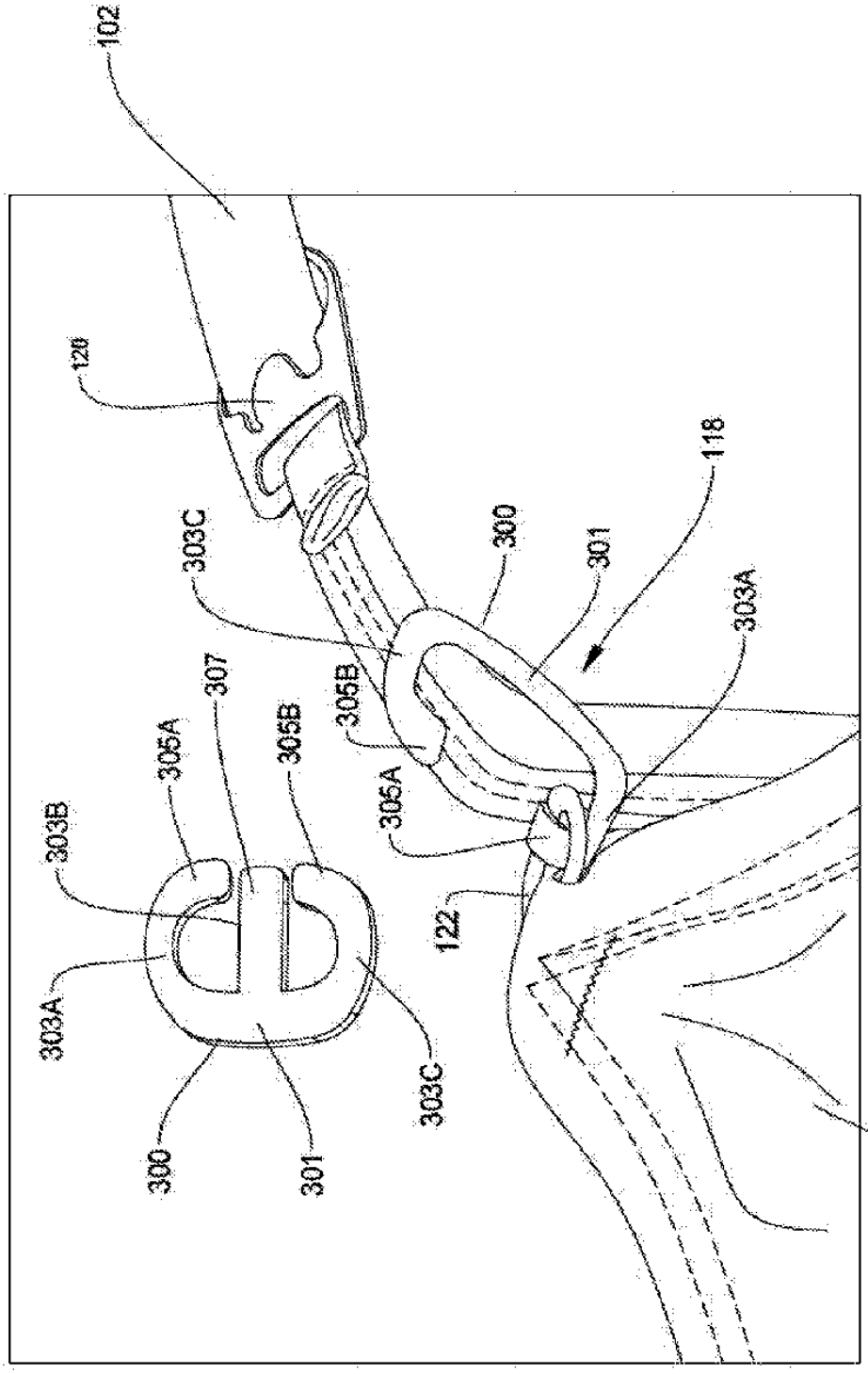

102
120
303C
300
301
118
303A
307
305B
305A
305B
305A
303B
303A
122
303C
300
301
116

FIGURE 35

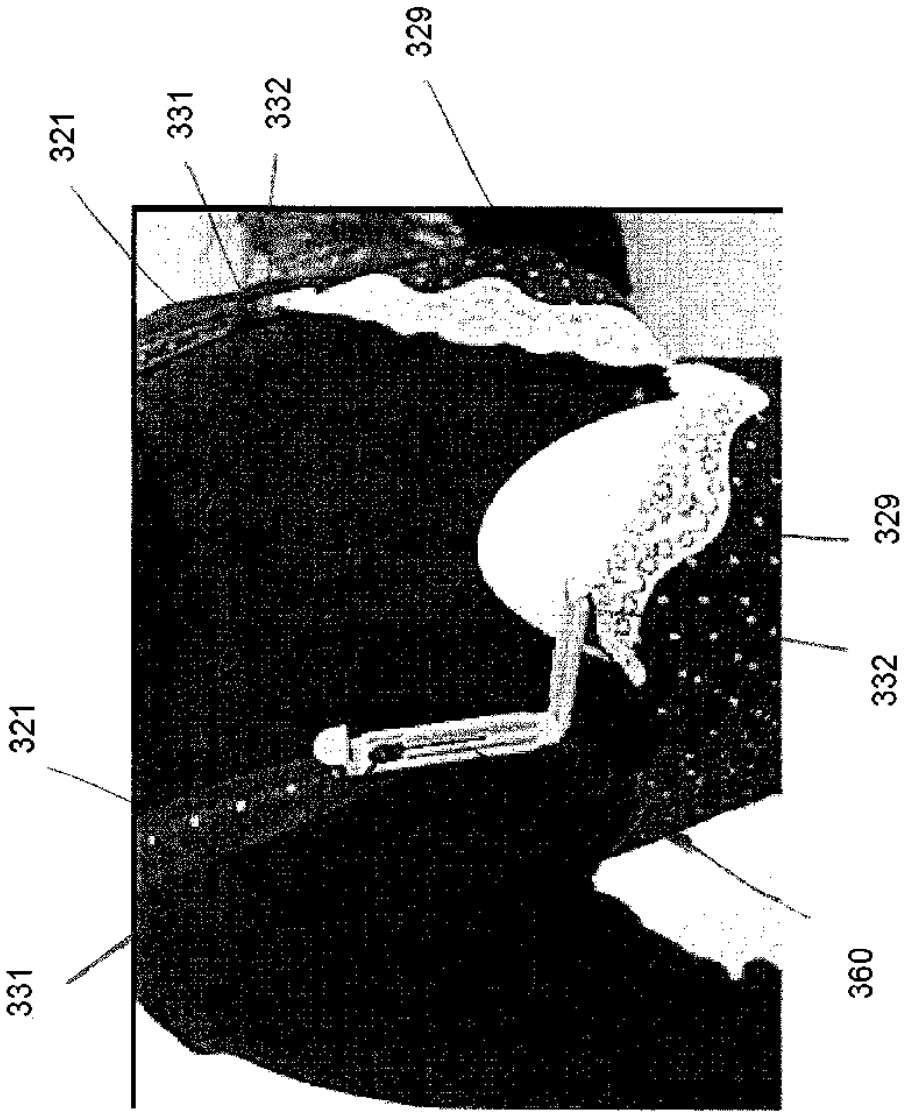


FIGURE 36

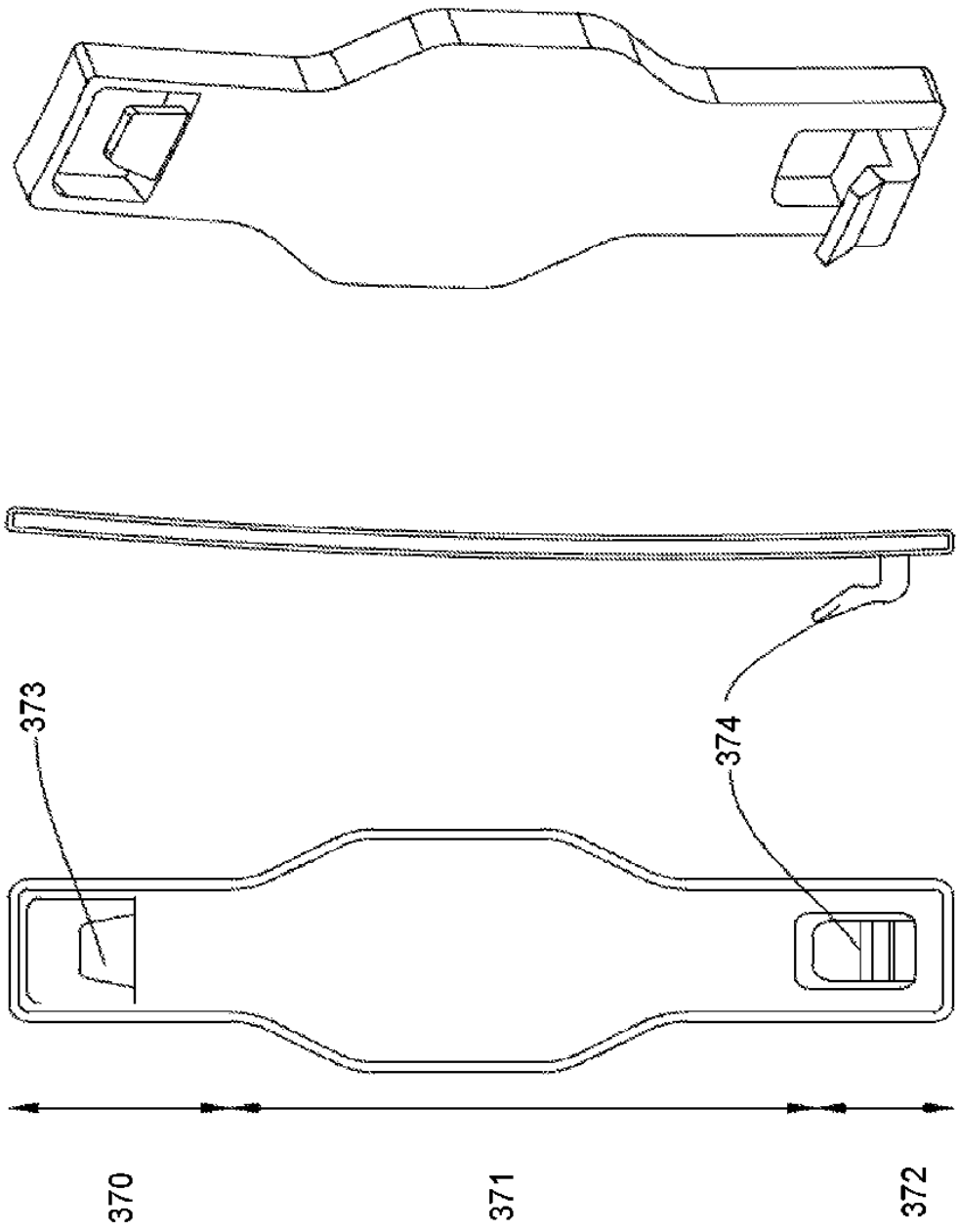


FIGURE 37

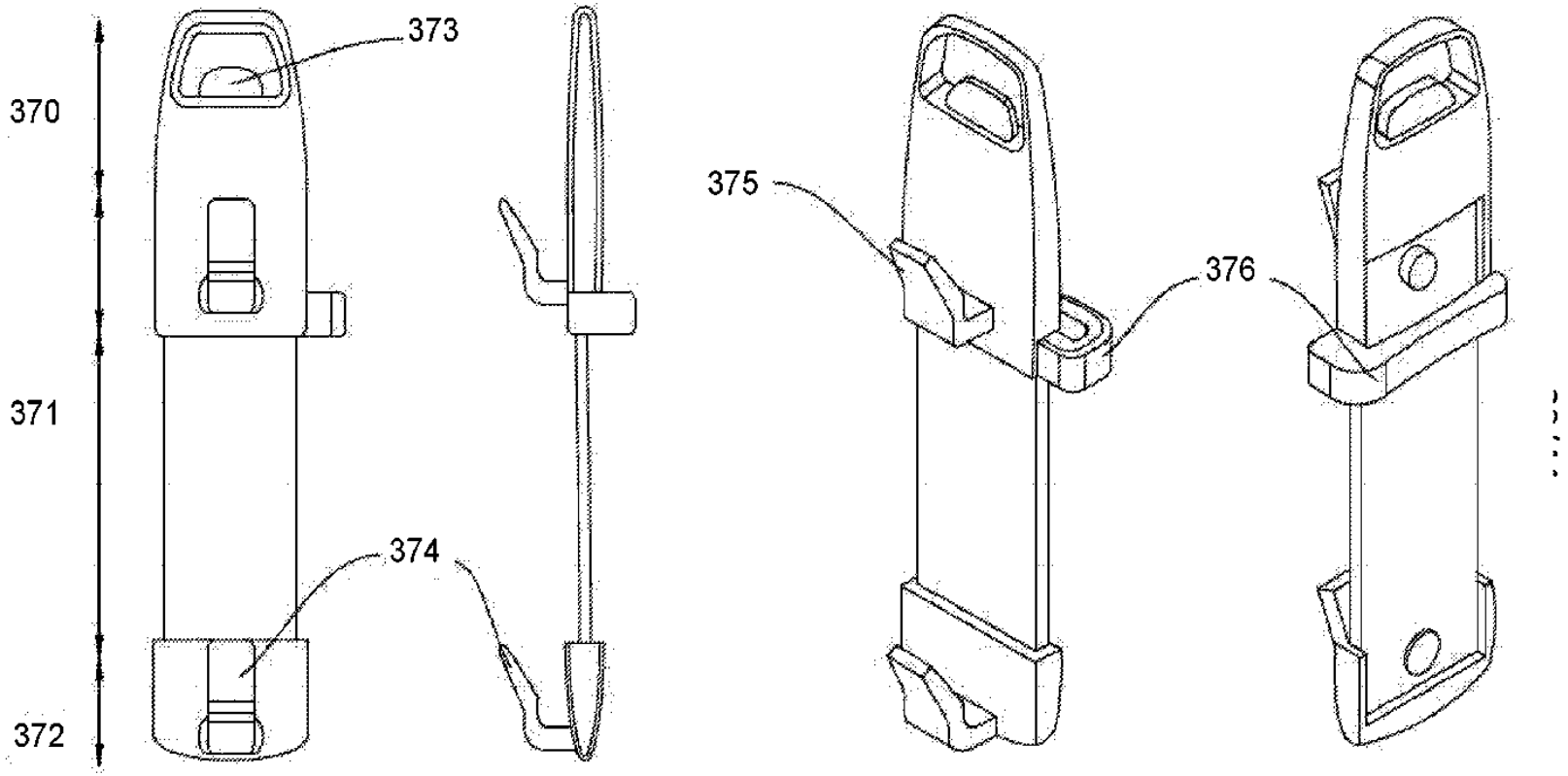


FIGURE 38

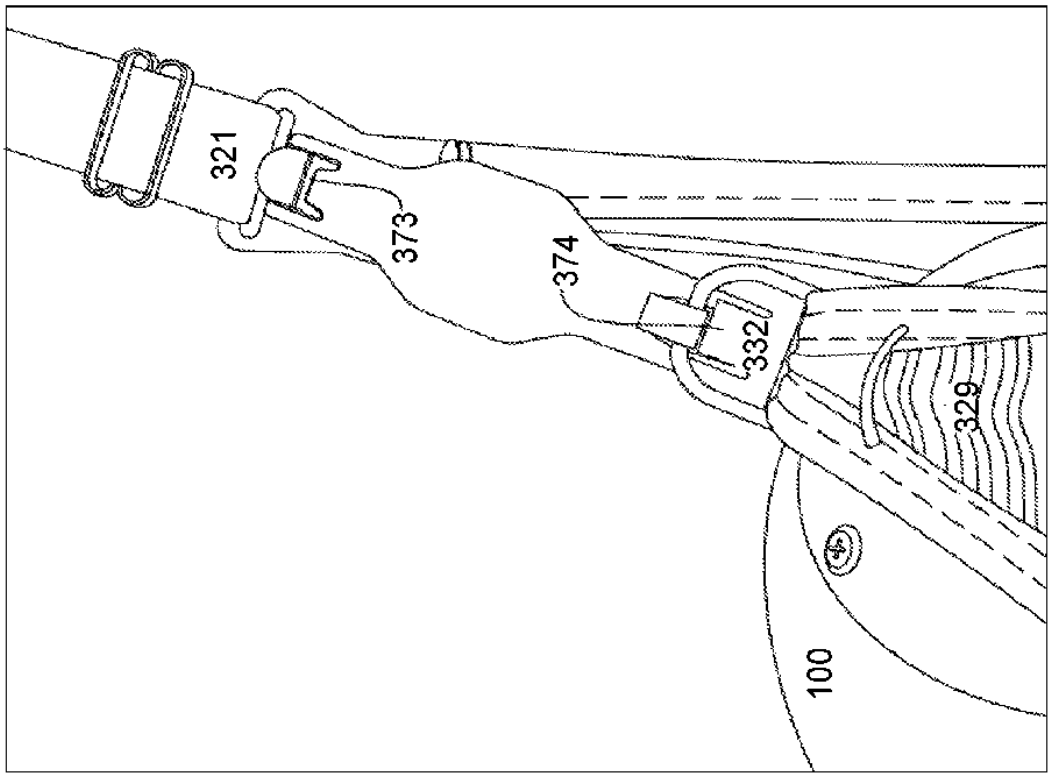


FIGURE 39

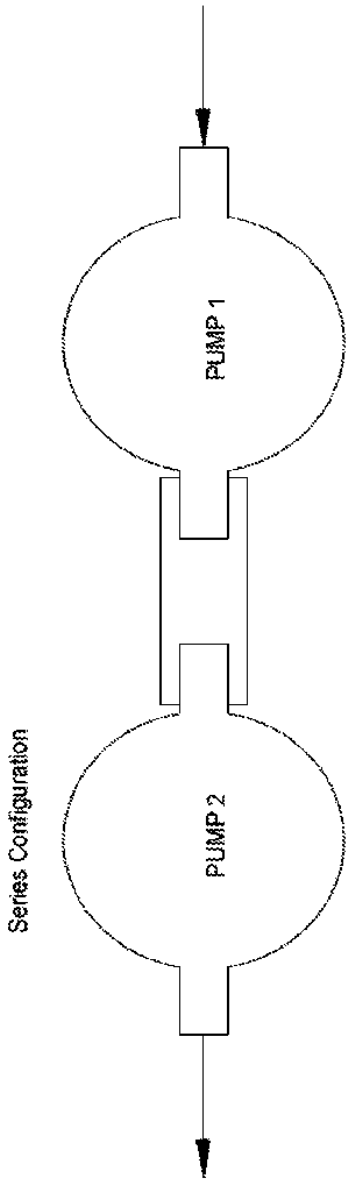


FIGURE 40

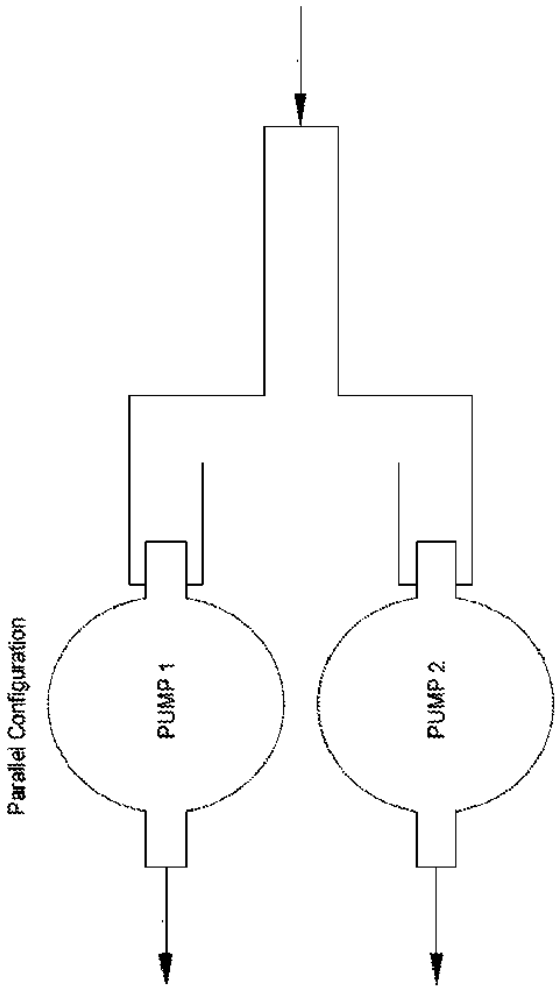


FIGURE 41

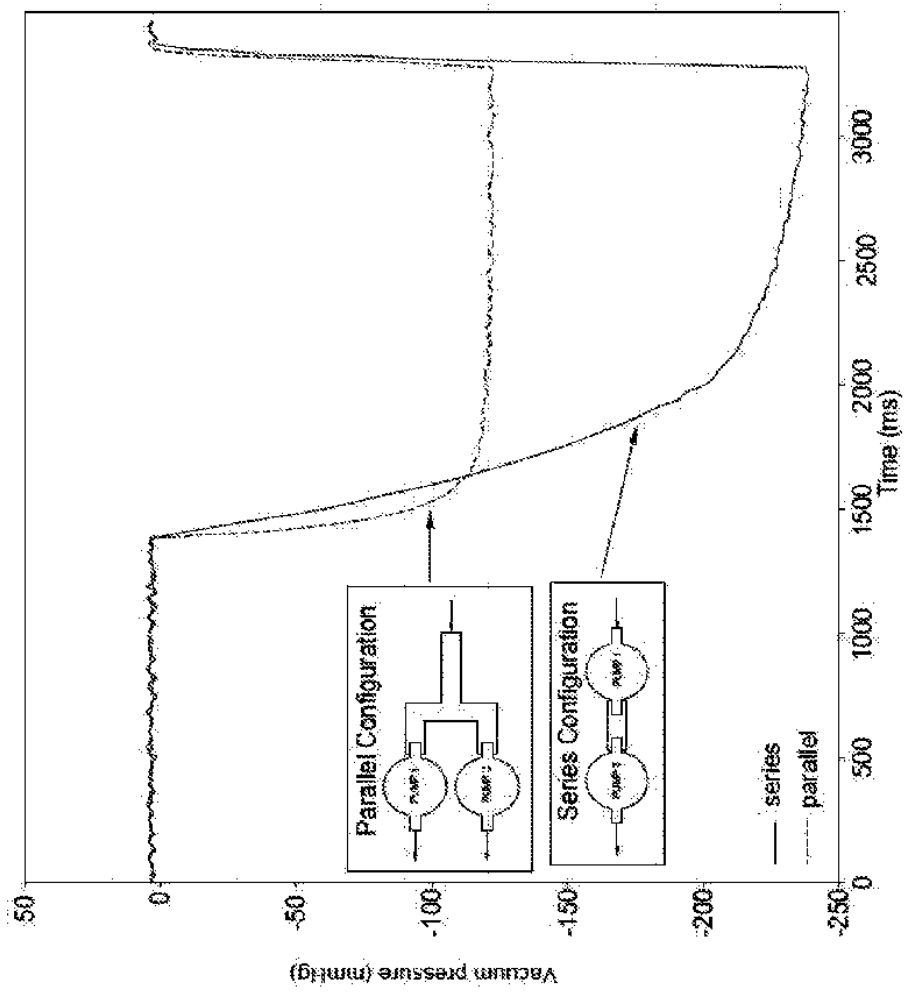

Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
Parallel Configuration
Series Configuration
series
parallel

FIGURE 42

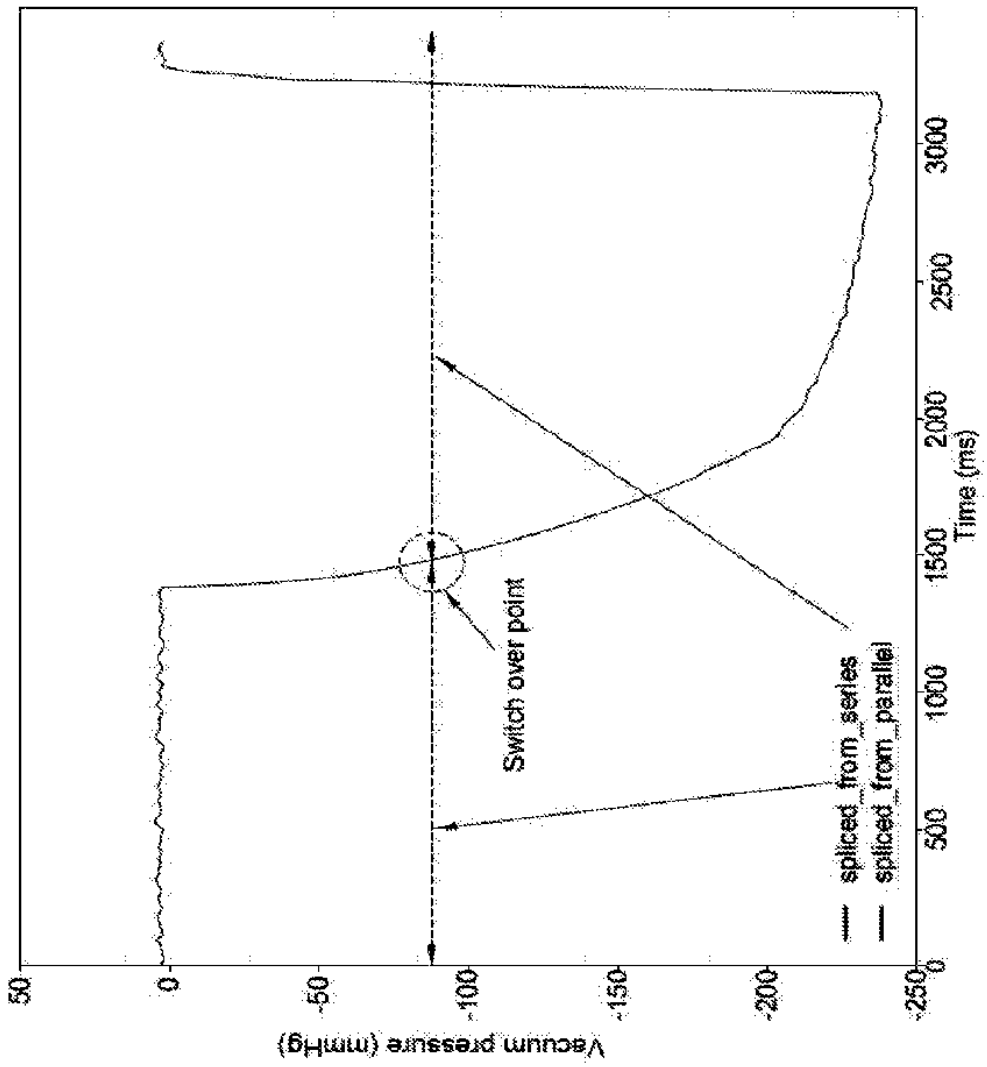

Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
Switch over point
spliced_from_series
spliced_from_parallel

FIGURE 43

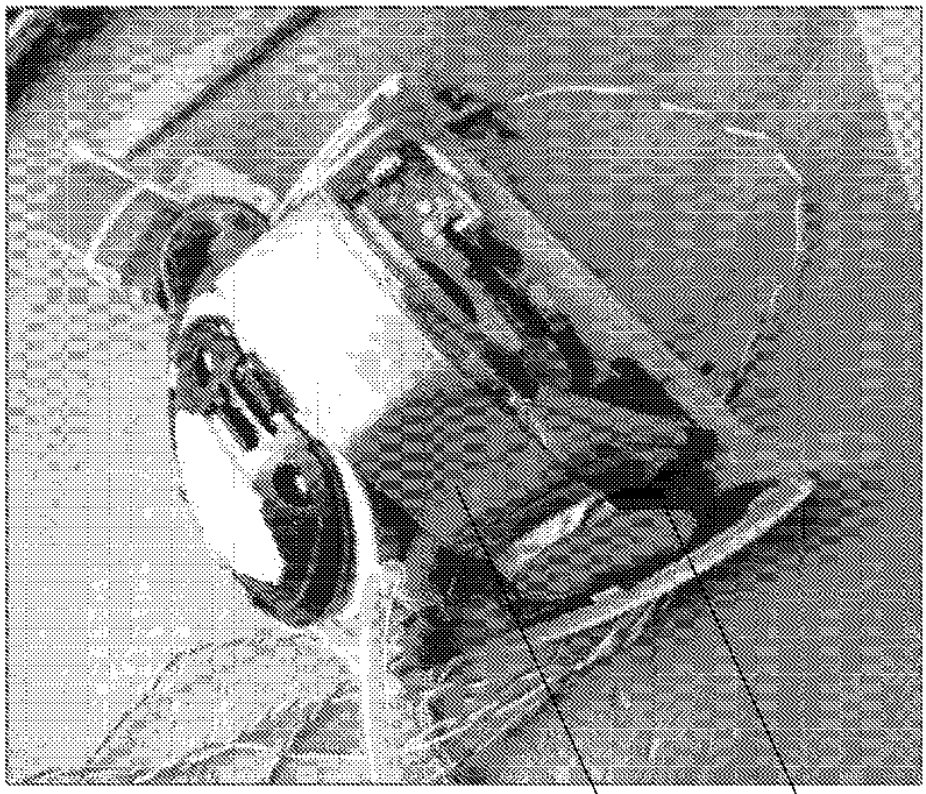


FIGURE 44

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Filing date: 15 Jun 2017 (15.06.2017)
Application number: 1709561.3

Date of availability of document: 27 Jul 2017 (27.07.2017)

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Newport
South Wales
NP10 8QQ

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Signed A HAYES

Dated 19 June 2017

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Intellectual Property Office

Patents Form 1
Patents Act 1977 *(Rule 12)*

Request for grant of a patent

Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

Application number GB 1709561.3

1.	Your reference	**MJD/P153994GB00**
2.	Full name, address and postcode of the applicant or of each applicant	**CHIARO TECHNOLOGY LIMITED** **Second Floor 63-66 Hatton Garden** **London EC1N 8LE** **Greater London** **United Kingdom**
	Patents ADP number *(if you know it)*	**11287869002**
3.	Title of the invention	**BRA CLIP**
4.	Name of your agent *(if you have one)*	**Boult Wade Tennant**
	"Address for service" to which all correspondence should be sent. This may be in the European Economic area or Channel Islands (see warning note below) *(including the postcode)*	**Boult Wade Tennant** **Verulam Gardens** **70, Gray's Inn Road** **London WC1X 8BT** **United Kingdom**
	Patents ADP number *(if you know it)*	**42001**
5.	Priority declaration: Are you claiming priority from one or more earlier-filed patent applications? If so, please give details of the application(s)	

Country	Application number	Date of filing	PDAS Access Code
6. Divisionals etc: Is this application a divisional application, or being made following resolution of an entitlement dispute about an earlier application. If so, please give the application number and filing date of the earlier application		Number of earlier UK application	Date of filing *(day / month / year)*

7.	Inventorship: (Inventors must be individuals not companies) Are all the applicants named above also inventors?	**No**
8.	Are you paying the application fee with this form?	**Yes**

Patents Form 1

9. Accompanying documents: please enter the number of pages of each item accompanying this form.

Continuation sheets of this form

Description: **9**

Claim(s): **3**

Abstract: **n/a**

Drawing(s): **7**

If you are not filing a description, please give details of the previous application you are going to rely upon

Country	Application number	Date of filing	PDAS Access Code

10. If you are also filing any of the following, state how many against each item.

Priority documents: **0**

Statement of inventorship and right to grant of a patent (Patents Form 7): **1**

Request for search (Patents Form 9A): **1**

Request for a substantive examination (Patents Form 10): **0**

Any other documents (please specify): **PDAS Registration Form**

11. I/We request the grant of a patent on the basis of this application.

Signature: **/DRAPER, Martyn John/** Date: **15 Jun 2017**

12. Name, e-mail address, telephone, fax and/or mobile number, if any, of a contact point for the applicant

DRAPER, Mr Martyn
Email: boult@boult.com
Telephone: 020 7430 7500
Fax: 020 7430 7600

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BRA CLIP

BACKGROUND

Many specialised bras (or brassieres) exist for maternity that facilitate nursing and/or breast pumping for milk collection without the need to remove the bra itself. In a traditional nursing bra, this is achieved with the use of an at least partially detachable cup, which can be unhooked for feeding and/or pumping.

Further specialised bras are known which are provided with cut-out portions or slits which substantially align with the wearer's areola and nipple. Traditional breast pumps comprise an elongate breast shield which extends away from the breast towards an external bottle and source of suction. The breast shield is arranged to extend through the cut-out portion or slit, with the collection bottle and pumping apparatus connected thereto outside of the bra. These require the user to remove or unbutton any over-garments, and are uncomfortable for use when not pumping.

Integrated wearable breast pumps have begun to enter the market, such as US 2016 206794 A1. In such pumps, the suction source, power supply and milk container are locally provided, without the need for bulky external components or connections. Such devices can be provided with a substantially breast shaped profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations.

In US 2016 206794 A1, the applicant has appreciated that the added size of the breast pump means that the combination of the user's breast and the breast pump may no longer fit within the user's regular bra. This is particularly relevant as over-compression of the user's breast will result in the closing of the user's milk ducts and hence reduced expression. To address this, the breast pump of US 2016 206794 A1 has an offset shape favouring the lower half of the pump, and requires complex collapsible bag systems as milk collection devices. This is to force the pump to fit within the user's existing bras. This works by breast milk leaving the breast and enters the bag, and the breast shrinking in a corresponding volume to the expansion of the bag. The inventors consider that this is unlikely to be a perfect 1 to 1 transfer of volume, and hence the compression on the breast may increase as the collapsible bags fill.

In addition to these systems being particularly complex and wasteful, a relatively smaller bag must be used. In US 2016 206794, approximately 110 ml (4 fluid ounces) of milk can be collected before the bag must be changed. While this may be sufficient for some users, others may produce much more milk in a session. Additionally, even this small increase in cup size may make bras less comfortable for the user.

It is our understanding that in the product which has been brought to market based on the disclosure of US 2016 206794 does increase the effective cup size of the wearer by around 2 cup sizes based upon European standard EN 13402 which is discussed later.

Maternity (or nursing) bras such as disclosed in US 4,390,024 A have partially detachable cups, with a plurality of attaching means provided along the bra strap for attaching the cups to the strap. The cup can then be attached to different points in order to adjust the support provided. However, these attachment points are fixed. Additionally, this bra has been designed to accommodate the change in breast size before and after the feeding/pumping process. It is not designed to accommodate a breast pump.

Accordingly, there is a need for a better system to accommodate integrated wearable breast pumps.

SUMMARY OF THE INVENTION

A maternity bra system is provided according to the present invention comprising: a maternity bra comprising: a support structure comprising shoulder straps and a bra band; and a first and a second cup each attached to the support structure to provide a first cup size, at least one cup being at least partially detachable from the support structure at an attachment point, the system further comprising: a clip comprising a first engagement mechanism and at least one second engagement mechanism(s), the clip being attachable in a releasable manner to the support structure at a first position via the first engagement mechanism and attachable in a releasable manner to one of the partially detachable cups via the second engagement mechanism to provide a second cup size different to the first cup size.

This system allows a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump. As such, the user does not need a specialised adjustable bra; instead the present

system works with all conventional maternity bras. The user also does not have to purchase any larger bras to wear while pumping.

The clip may be configured to be attached to the support structure at a position away from the attachment point. This results in the original attachment point being usable, with the clip providing an alternative attachment point for the adjusted cup size.

The clip may be attachable to the support structure at a plurality of non-discrete positions. This ensures essentially infinite adjustment of the clip position such that the perfect position for the user can be found.

The clip may be extendable between an unextended and an extended state, and attaches to the support structure at the attachment point; the first cup size is providable when the at least partially detachable cup is attached to the clip when the clip is an unextended state; the second cup size is providable when the at least partially detachable cup is attached to the clip when the clip is in an extended state.

An extendable clip like this allows quick switching between the two states in use.

Preferably, the attachment point is on at least one of the shoulder straps. Again this matches the standard system used in most maternity bras.

A clip is provided for use in the system described above according to the present invention. The clip comprising first and section engagement mechanisms and being releasably attachable to a support structure of a maternity bra with the first engagement mechanism and an at least partially detachable cup of a maternity bra with the second engagement mechanism to provide a second cup size which is different to a first cup size providable when the cup is attached to the support structure of the bra at an attachment point.

In a preferred embodiment, the first engagement mechanism engages with the support structure in a first direction and the second engagement mechanism engages with the cup in a second direction transverse to the first direction. This increases ease of attachment as with this structure the sideways engagement of the clip to the support

structure ensures that the second attachment mechanism is correctly orientated for the cup.

The second engagement mechanism may be one or more of a hook or a snap or a clip. This ensures easy interfacing with the traditional hook and clasp systems already provided on maternity bras.

Preferably the clip further comprises two distinct second engagement mechanisms which can be used interchangeably dependent upon the orientation of the clip. This makes the clip easier to use as it can be quickly switched between each bra strap, and the user does not have to worry which way up to put the clip on.

Preferably, the clip comprises a material pathway with an opening for receiving a portion of the support structure as the first engagement mechanism for securing the clip to the bra. This ensures a quick and simple method for attaching the clip to the bra. In particular, the clip may substantially U-shaped, and the material pathway is between the arms of the U.

Preferably, the clip comprises three prongs extending from a central support, the three prongs arranged as a central prong and two outer prongs so as to receive the support structure on one side of the central prong and on the opposite side of each respective outer prong, at least one prong being provided with the second engagement mechanism. This ensures a strong attachment to the bra and a simple design.

Preferably, both outer prongs are each provided with a respective second engagement mechanism. This ensures that the clip is reversible for easier attachment to the bra.

A method of adjusting the cup size of a maternity bra is provided according to the present invention, comprising: providing a maternity bra comprising: a support structure comprising shoulder straps and a bra band; and a first and second cup each attached to the support structure to provide a first cup size, the at least one cup being detachable from the support structure at an attachment point, providing a clip comprising first and section engagement mechanisms, attaching the first engagement mechanism of the clip in a releasable manner to a first position of the support structure of the maternity bra, attaching one of the detachable cup to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

This clip and method allow a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump.

Preferably, the method further comprises the step of inserting a breast pump into the detachable cup. The adjustment of the size of the bra allows the bra to support the breast pump against the user's breast for comfort and ease.

Preferably, the method further comprises the steps of: detaching the first engagement mechanism of the clip from the first position support structure of the maternity bra; attaching the first engagement mechanism of the clip in a releasable manner to a second position of the support structure of the maternity bra; and attaching the other of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size. This allows the user to use a single clip on either of the cups.

DESCRIPTION OF THE FIGURES

The following invention will be described with reference to the following Figures in which:

Figure 1 depicts a prior art design for a maternity bra;

Figures 2A and 2B depict a clip and clasp according to the present invention;

Figures 3A, 3B and 3C depict the clip of Figures 2A and 2B being fitted to a maternity bra according to the present invention;

Figures 4A and 4B depict adjustment of the maternity bra of Figures 3A, 3B and 3C according to the present invention;

Figure 5 depicts an alternative clip for adjustment of a maternity bra according to the present invention;

Figure 6 depicts the alternative clip of Figure 5; and

Figure 7 depicts an alternative clip for adjustment of a maternity bra according to the present invention.

DETAILED DESCRIPTION

As shown in Figure 1, a typical maternity bra 100 comprises a support structure made up of shoulder straps 102 which support the bra 100 on the wearer's shoulders, and a bra band 104 for extending around a user's ribcage, comprising two wings 106 and a

central panel or bridge 108. The straps 102 are typically provided with adjustment mechanisms 103 for varying the length of the straps 102 to fit the bra 100 to the wearer.

At the outermost end of each wing, an attachment region 110 is provided. Typically, hooks 112 and loops 114 are provided for securing the bra 100 at the user's back. However, any other suitable attachment mechanism may be used. Alternatively, the attachment region 110 may be provided at the front of the bra 100 in the bridge region 108, with a continuous wing 106 extending continuously around the wearer's back. Typically, a number of sets of loops 114 are provided to allow for variation in the tightness of the bra 100 on the wearer.

While shown as having a separation in Figure 1, the wings 106 and bridge 108 may form a single continuous piece in certain designs. Likewise, while shown with a distinct separation in Figure 1, the shoulder straps 102 and the wings 106 may likewise form a single continuous piece.

The maternity bra 100 is further provided with two breast-supporting cups 116 attached to the support structure. The cups 116 define a cup size, which defines the difference in protrusion of the cups 116 from the band 104. The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting a 2 cm difference between the protrusion of the cups 116 from the band 104. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc.

The cups 116 may be stitched to the bra band 102. At least one of the cups 116, is in detachable attachment with the corresponding strap 102. In particular, this is achieved at attachment point 118 where a hook 120 attached to the bra strap 102 engages with a clasp 122 attached to the cup 116. The hook 120 and the bra strap adjuster 103 are set such that in the closed position, the cup size of the bra 100 fits the wearer's breasts. In Figure 1, the left cup 116 is shown attached to its attachment point 118, which the right cup 116 is unattached. In this manner, the wearer is able to detach the cup 116 to expose their breast for feeding or for breast pumping. Once this is completed, the cup 116 is reattached and the maternity bra 100 continues to function as a normal bra.

While in the depicted embodiments, a hook 120 is shown on the bra strap 102 and a clasp 122 is shown on the cup 116, it is appreciated that the provision of these may be reversed, or that alternative attachment mechanisms may be used.

In other embodiments, the detachable attachment point 118 may be provided at a different location, such as at the attachment between the bra band 104 and the cup 116. The mechanism for such an attachment point is the same as described above.

Figure 2A and 2B depict a clip 200 according to the present invention, along with a clasp 122 shown in isolation from the bra cup 116 it is normally attached to. The clip 200 is provided with a material pathway 203 which receives a portion of the bra strap 102. In the particular embodiment of these Figures, the clip 200 is substantially U-shaped, with a narrowing profile towards its open end 202. However, it is appreciated that any other suitable shape with a material pathway may be used, such as an S-shape or E-shape. The clip 200 is designed to be attached to the bra strap 102 in a releasable manner, with the slot 203 acting as a support engaging mechanism. The releasable manner means that the clip 200 may be simply removed from the bra 100 without causing any damage to the functioning of the bra 100. To enhance the ease of attachment, the clip 200 may be provided with outwardly extending wings 204 which help direct the bra strap 102 into the clip 200. The clip 200 is further provided with a hook 220 acting as a cup engaging mechanism which can engage with the clasp 122.

Figures 3A, 3B and 3C show the clip 200 being attached to a bra strap 102 in order to provide a second attachment point 228 for the clasp 122 to attach to, and hence to provide a second cup size for the bra 100. In this particular embodiment, the clip 200 is attached in a portion of strap 102A below the original attachment point 118 and hence the second attachment point 228 is likewise below the original attachment point. This results in a second cup size larger than the first cup size. In preferred embodiments, as shown in these Figures, the clip 200 engages with the support structure in a direction transverse to the direction in which it engages with the cup.

Figures 4A and 4B show how a wearer is able to move between the first and second cup sizes. In Figure 4A, the cup 116 is attached at the first attachment point 118 to provide a first cup size. The wearer then disengages the clasp 122 from the hook 120 at the first engagement point 118. As shown in Figure 4B, the clasp 122 is then engaged with

the hook 220 at the second engagement point 218. In this manner, the wearer is easily able to transition between the two cup sizes.

Figures 5 and 6 show an alternative design for a clip 300. This clip 300 is substantially "E-shaped", with a back portion 301 and first, second and third prongs 303A, 303B, 303C extending transverse from this back portion 301. The three prongs 303A, 303B, 303C are spaced apart along the length of the back portion 301. The first and third prongs 303A, 303C are provided with attachment clips 305A, 305B.

These attachment clips 305A, 305B are engageable with the clasp 122 of a bra to provide the second cup size. Depending upon the orientation of the clip 300, one or the other of the attachment clips 305A, 305B will be used to attach the clasp 122 of the bra. By providing these clips 305A, 305B on both of the first and the third prongs 303A, 303C the clip is easily reversible so it can be used on either side of the bra. Preferably the clip 300 is also symmetrical, to aid the reversibility of the clip 300.

Figure 6 shows the clip 300 attached to a bra. As can be seen, the first and third prongs 303A, 303C extend on the front side of the bra strap, with the second prong 303B extending on the rear side of the bra strap. In this manner, the clip 300 is attached to the strap. In preferably embodiments, a grip-enhancing member 307 such as a number of projections and/or roughened patches can be provided on the second prong 303B in order to strengthen this grip.

In alternative embodiments, the attachment clip could be provided on the second, centremost prong 303B. In such an arrangement, the centremost prong 303B would be on the outside of the bra, with the first and third prongs 303A, 303C on the inside.

The provision of the attachable clip allows maternity bras already owned by the wearer to be quickly transformed into bras with quick switchable double cup size options. This allows the use of integrated wearable breast pumps which increase the user's cup size. This allows more design freedom for the breast pump in terms of size and shape, while still allowing the user to discretely pump with the pump held within their bra. By allowing conversion of the user's existing maternity bras, they are not forced to purchase specially designed bras to wear with the pump. As such, the present invention allows a

user to discretely switch between the two configurations, and insert the pump without any complex adjustment or removal of clothing.

Preferably, the clip will be relatively unobtrusive in size and shape and hence can be left in place when the bra is first put on and used when necessary. To this end, the clip is preferably machine washable without significant damage or degradation.

In some embodiments, the clip may be switchable between positions for engaging with each cup so that a single clip may be used on either side of the bra. To achieve this, the clip is preferably reversible. This may provide the user with a visual indication of which breast has produced milk most recently so switching can take place.

An alternative embodiment may be provided, with an extendable clip as shown in Figure 7. In such an embodiment the clip is attached to the hook 120 on the strap 102 in a releasable manner, with the clasp 122 attached to an expandable portion of the clip. The clip is then able to expand between an unexpanded state where the clasp 122 is held in substantially the same position as the first attachment point 118 to provide the first cup size, and an expanded state, where the clasp 122 is held in a second position away from the first attachment point 118 to provide the second cup size.

For example, an elongate clip with first and second opposite ends may be provided. A first attachment point for attaching to the hook 120 is provided at the first end, and a second attachment point for attaching to the clasp 122 is provided at the second end. The elongate clip is hinged between the two ends, such that the clip can be folded between an elongate configuration to a closed configuration where the second end touches the first end. A clasp can be provided on the clip to hold the second end in this closed configuration. Thus, in the closed position the clasp 122 is held in substantially the same location as the first attachment point 118 to provide the first cup size, and in the open position the clasp is held away from the first attachment point 118 to provide the second cup size.

Other extendable clip embodiments are also possible, for example sliding clips or elastic clips.

CLAIMS:

1. A maternity bra system comprising:

a maternity bra comprising:

a support structure comprising shoulder straps and a bra band; and

a first and a second cup each attached to the support structure to provide a first cup size, at least one cup being detachable from the support structure at an attachment point,

the system further comprising:

a clip comprising a first engagement mechanism and at least one second engagement mechanism(s), the clip being attachable in a releasable manner to the support structure at a first position via the first engagement mechanism and attachable in a releasable manner to one of the detachable cups via the second engagement mechanism to provide a second cup size different to the first cup size.

2. The maternity bra system of claim 1, wherein the clip is configured to be attached to the support structure at a position away from the attachment point.

3. The maternity bra system of claim 2, wherein the clip is attachable to the support structure at a plurality of non-discrete positions.

4. The maternity bra system of claim 1, wherein:

the clip is extendable between an unextended and an extended state, and attaches to the support structure at the attachment point;

the first cup size is providable when the at least partially detachable cup is attached to the clip when the clip is an unextended state;

the second cup size is providable when the at least partially detachable cup is attached to the clip when the clip is in an extended state.

5. The maternity bra system of any preceding claim, wherein the attachment point is on at least one of the shoulder straps.

6. The maternity bra system of any preceding claim, wherein the second cup size is larger than the first cup size.

7. A clip for use in a system according to any preceding claim, the clip comprising first and section engagement mechanisms and being attachable in a releasable manner to a support structure of a maternity bra with the first engagement mechanism and an at least partially detachable cup of a maternity bra with the second engagement mechanism to provide a second cup size which is different to a first cup size providable when the cup is attached to the support structure of the bra at an attachment point.

8. The maternity bra system or clip of any preceding claim, wherein the first engagement mechanism engages with the support structure in a first direction and the second engagement mechanism engages with the cup in a second direction transverse to the first direction.

9. The maternity bra system of clip of any preceding claim, wherein the second engagement mechanism is one or more of a hook or a snap or a clip.

10. The maternity bra system or clip of any preceding claim, wherein the clip further comprises two distinct second engagement mechanisms which can be used interchangeably dependent upon the orientation of the clip.

11. The maternity bra system or clip of any preceding claim, wherein the clip comprises a material pathway with an opening for receiving a portion of the support structure as the first engagement mechanism for securing the clip to the bra.

12. The maternity bra system or clip of claim 11, wherein the clip is substantially U-shaped, and the material pathway is between the arms of the U.

13. The maternity bra system or clip of any of claims 1 to 11, wherein the clip comprises three prongs extending from a central support, the three prongs arranged as a central prong and two outer prongs so as to receive the support structure on one side of the central prong and on the opposite side of each respective outer prong, at least one prong being provided with the second engagement mechanism.

14. The maternity bra system or clip of claim 13, wherein both outer prongs are each provided with a respective second engagement mechanism.

15. A method of adjusting the cup size of a maternity bra, comprising:

providing a maternity bra comprising:

a support structure comprising shoulder straps and a bra band; and

a first and second cup each attached to the support structure to provide a first cup size, at least one cup being detachable from the support structure at an attachment point,

providing a clip comprising first and section engagement mechanisms;

attaching the first engagement mechanism of the clip in a releasable manner to a first position of the support structure of the maternity bra;

attaching one of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

16. The method of claim 15, further comprising the step of inserting a breast pump into the one of the detachable cup.

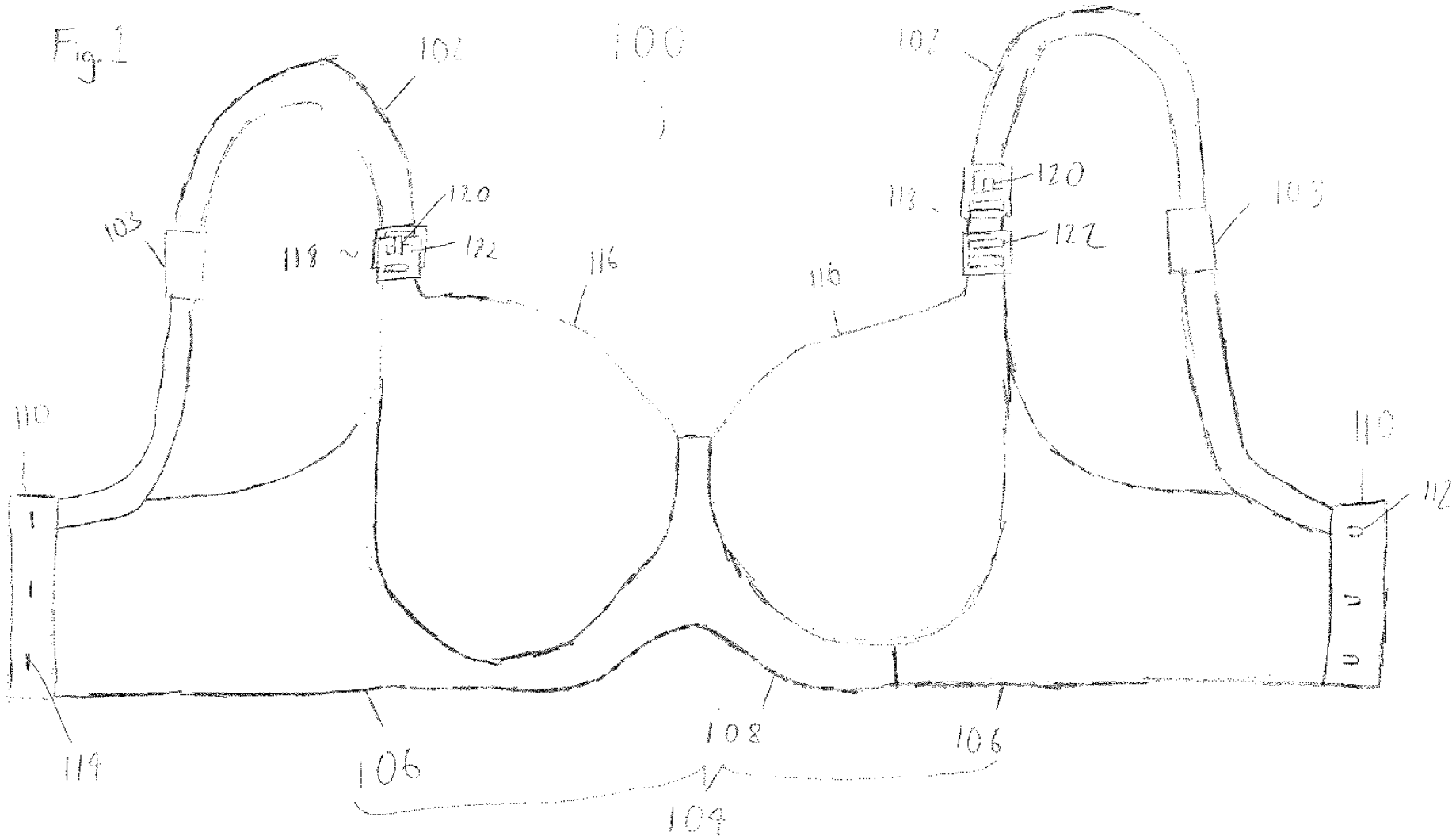
17. The method of claim 15 or 16, further comprising the steps of:

detaching the first engagement mechanism of the clip from the first position support structure of the maternity bra;

attaching the first engagement mechanism of the clip in a releasable manner to a second position of the support structure of the maternity bra; and

attaching the other of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

Fig. 1



PRIOR ART

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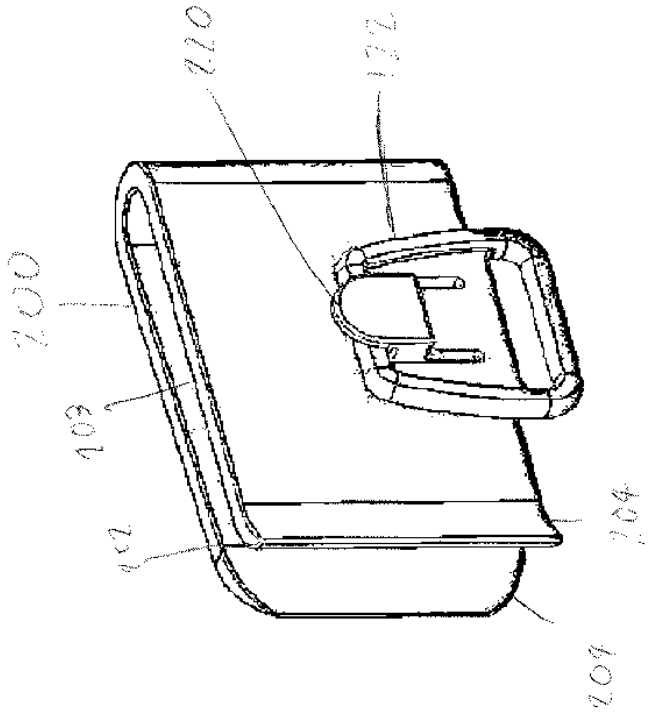


Fig 2B

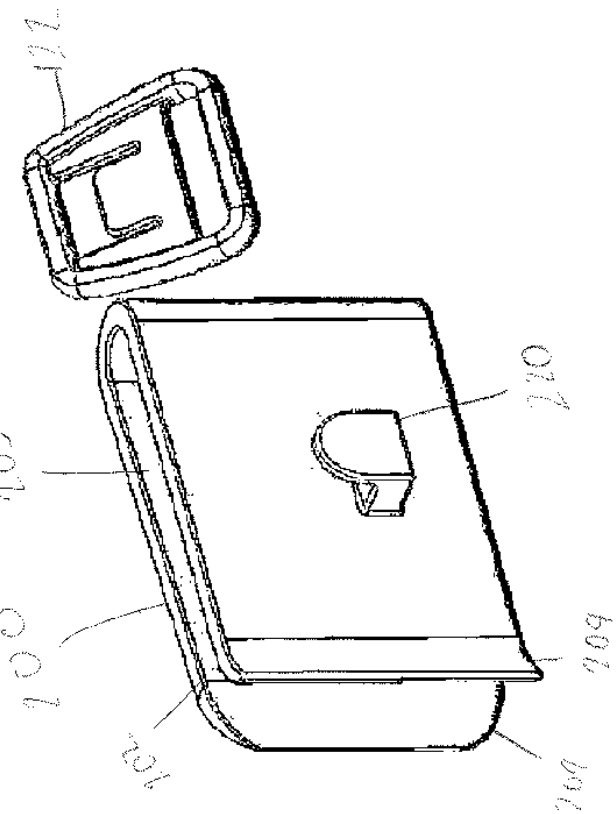


Fig 2A

Fig. 3A

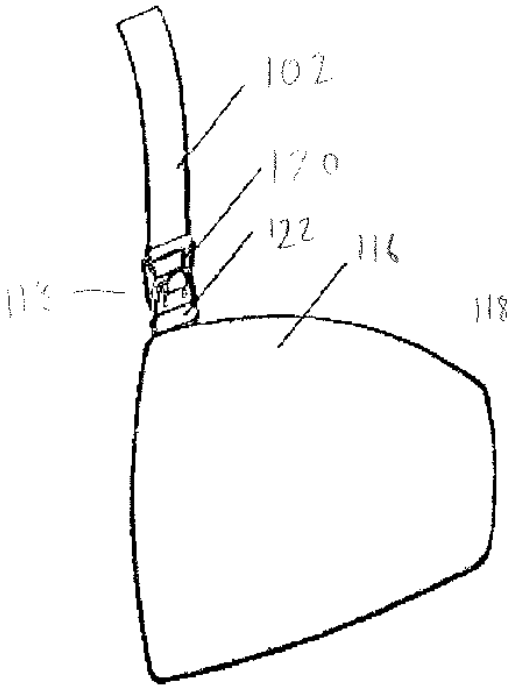


Fig. 3B

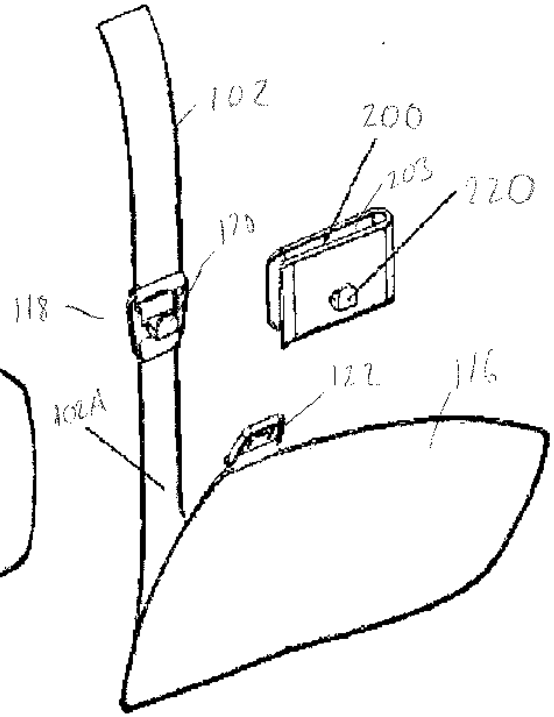
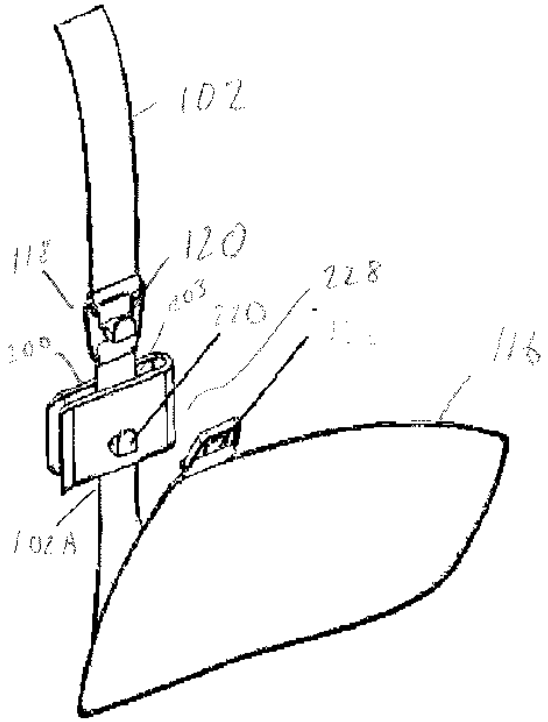


Fig. 3C



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Fig. 4A

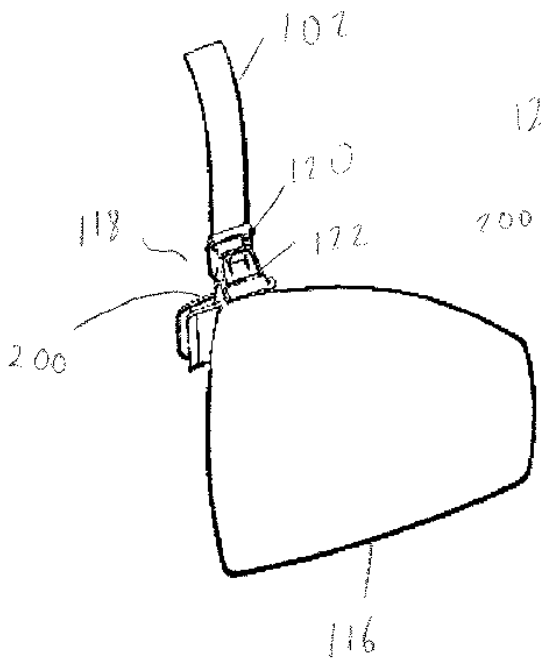
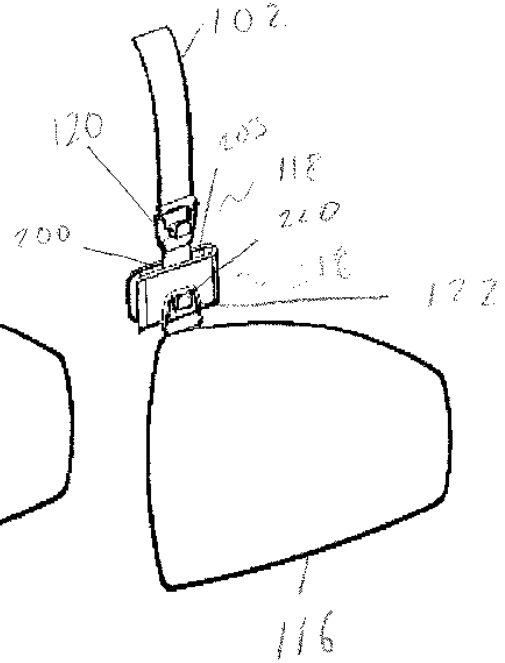
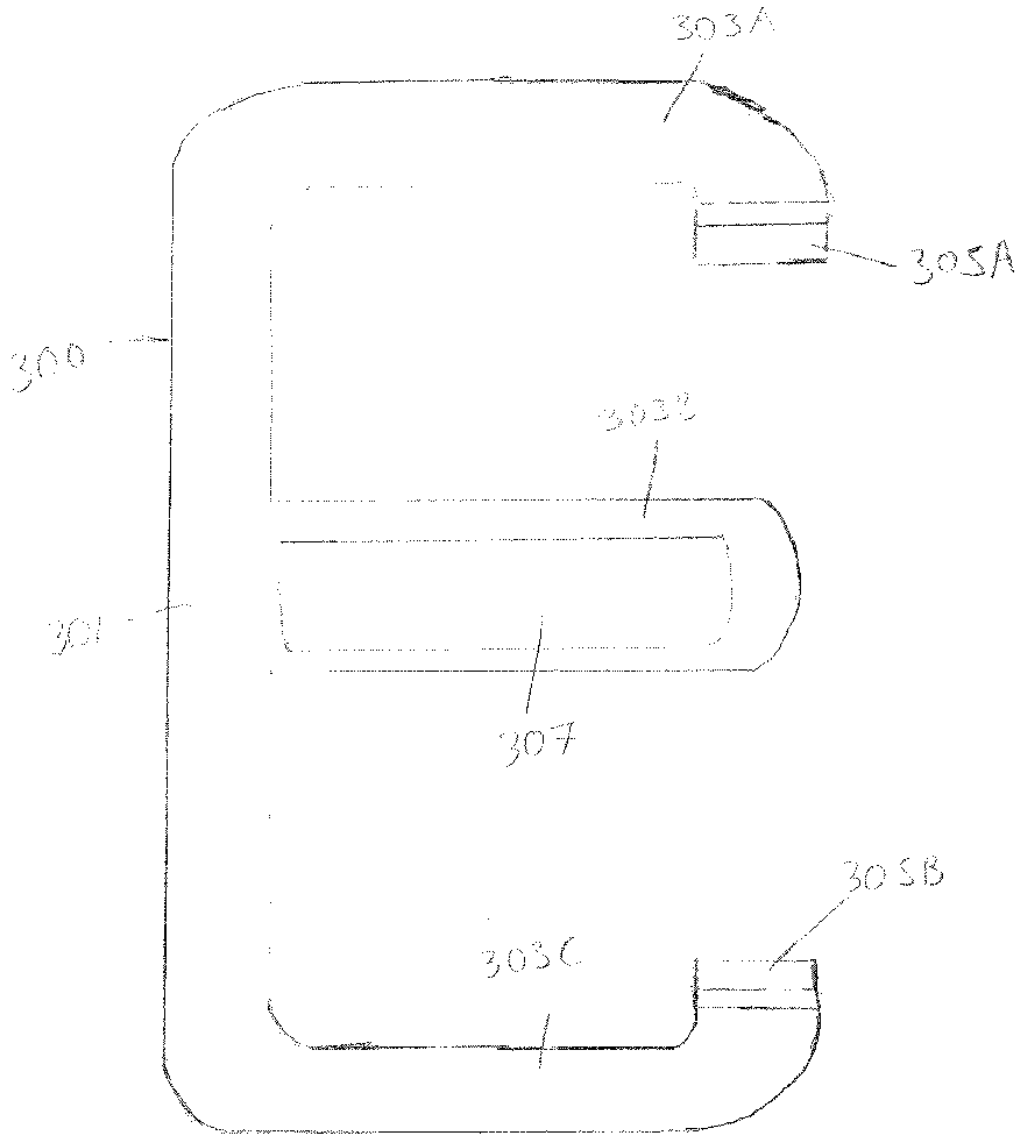


Fig. 4B



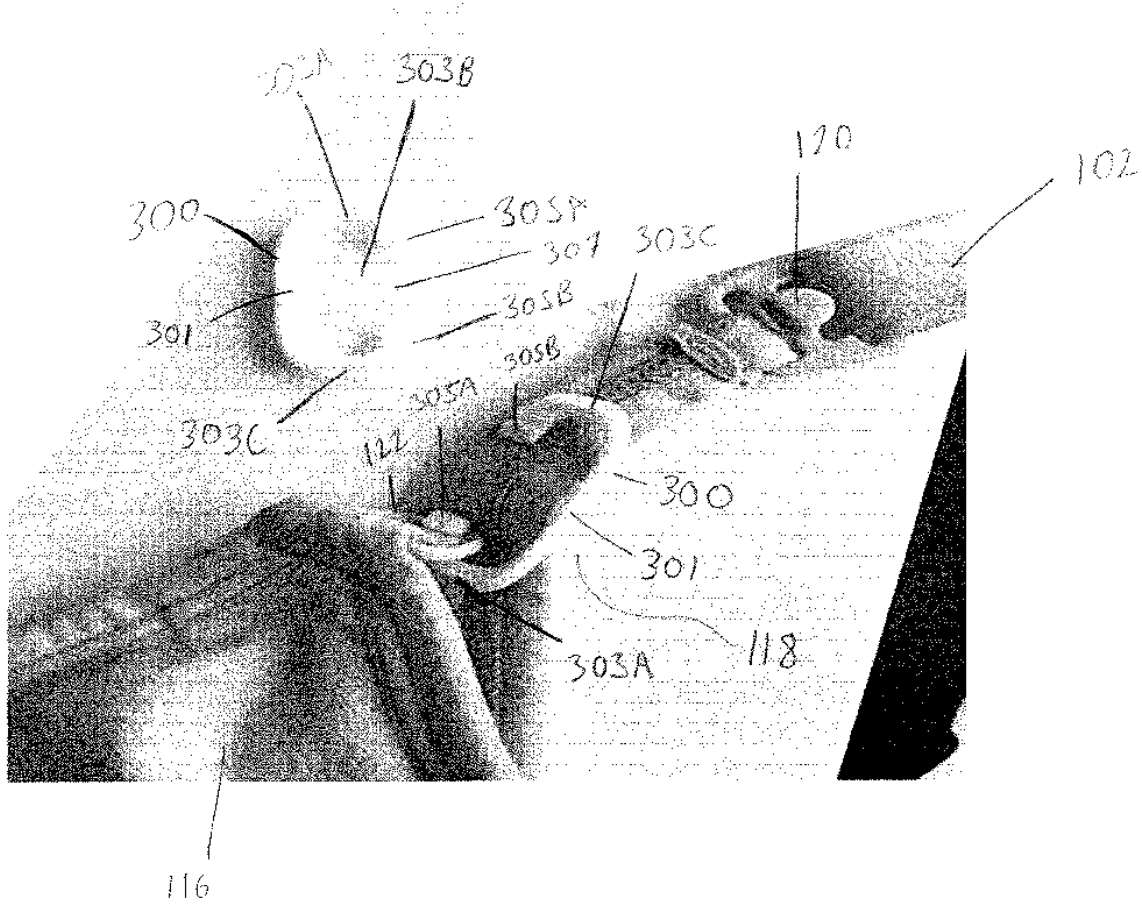
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Fig. 5



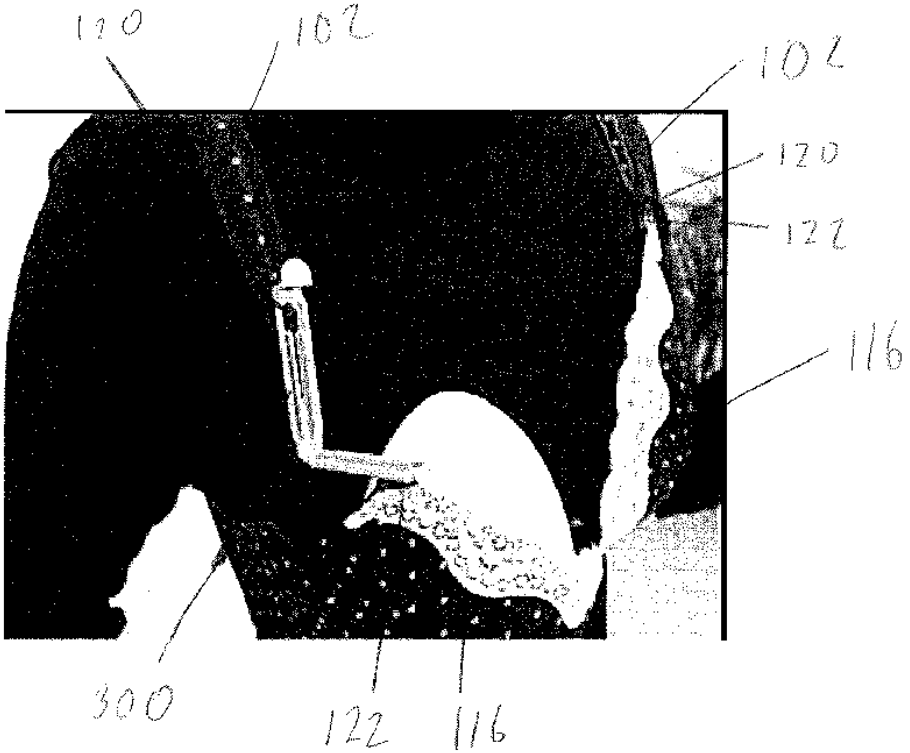
3258

Fig 6


303B
303A
300
305A
301
305B
303C
170
102
303C
305B
305A
122
300
301
118
303A
116

3259

Fig 7



3260

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Concept House
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NP10 8QQ

Application number GB 1709564.7

1.	Your reference	**MJD/P153993GB00**
2.	Full name, address and postcode of the applicant or of each applicant	**CHIARO TECHNOLOGY LIMITED** **Second Floor 63-66 Hatton Garden** **London EC1N 8LE** **Greater London** **United Kingdom**
	Patents ADP number *(if you know it)*	**11287869002**
3.	Title of the invention	**A LIQUID LEVEL MEASUREMENT SYSTEM**
4.	Name of your agent *(if you have one)*	**Boult Wade Tennant**
	"Address for service" to which all correspondence should be sent. This may be in the European Economic area or Channel Islands (see warning note below) *(including the postcode)*	**Boult Wade Tennant** **Verulam Gardens** **70, Gray's Inn Road** **London WC1X 8BT** **United Kingdom**
	Patents ADP number *(if you know it)*	**42001**
5.	Priority declaration: Are you claiming priority from one or more earlier-filed patent applications? If so, please give details of the application(s)	

Country	Application number	Date of filing	PDAS Access Code
6. Divisionals etc: Is this application a divisional application, or being made following resolution of an entitlement dispute about an earlier application. If so, please give the application number and filing date of the earlier application		Number of earlier UK application	Date of filing *(day / month / year)*
7. Inventorship: (Inventors must be individuals not companies) Are all the applicants named above also inventors?		**No**	
8. Are you paying the application fee with this form?		**Yes**	

Patents Form 1

9. Accompanying documents: please enter the number of pages of each item accompanying this form.

Continuation sheets of this form

Description: **12**

Claim(s): **3**

Abstract: **n/a**

Drawing(s): **4**

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Statement of inventorship and right to grant of a patent (Patents Form 7): **1**

Request for search (Patents Form 9A): **1**

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Any other documents (please specify): **PDAS Registration Form**

11. I/We request the grant of a patent on the basis of this application.

Signature: **/DRAPER, Martyn John/** Date: **15 Jun 2017**

12. Name, e-mail address, telephone, fax and/or mobile number, if any, of a contact point for the applicant

DRAPER, Mr Martyn
Email: boult@boult.com
Telephone: 020 7430 7500
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A LIQUID LEVEL MEASUREMENT SYSTEM

BACKGROUND

The present invention relates to a sensing mechanism for detecting the level of liquid in a container. In a particular arrangement, the present invention relates to such a sensing mechanism when used along with a breast pump.

In the context of breast pumps, it is useful to measure the quantity of expressed milk. One way to do this is to have a clear container affixed to the breast pump, through which the level of expressed milk inside the container can be visibly determined. However, such visual determinations are not always possible, for example in a breast pump that collects milk while being worn inside a maternity bra.

An existing apparatus for detecting the level of liquid inside a container of a breast pump is that disclosed in US 2016/296681. In this apparatus, a sensing mechanism is provided at the top of a container, which measures droplets of liquid, specifically breast milk, entering the container. By measuring the properties of these droplets entering the container, the apparatus can determine the quantity of liquid which enters the container. In this apparatus, an accurate indication of the level of liquid in the container is reliant on the sensing mechanism being able to accurately record every droplet entering the container. Particularly at times when large flow rates of liquid enter the container, this accuracy cannot be guaranteed leading to significant cumulative errors. An accurate indication of the level of liquid in the container in this apparatus is also reliant on the sensing mechanism always being on during the pumping process, so that power consumption of the sensing mechanism is correspondingly high.

In view of the above, there is the need for an improved way to determine the level of liquid inside a container connected to a breast pump.

SUMMARY OF THE INVENTION

According to a first aspect of the present invention, there is provided a breast pump comprising:

a pump module for pumping milk from a breast, the pump module being contained within a housing comprising a coupling;

a container attachable to the housing via the coupling to receive milk from the pump;

a sensing assembly within the housing and comprising at least one optical emitter operable to emit optical radiation towards the surface of the body of milk held in the container when the housing is connected to the container, and an optical receiver for receiving the reflected radiation from the surface of the milk; and

a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the milk inside the container based on the reflected radiation received by the optical receiver.

By determining the level of milk inside the container based on reflected radiation from the surface of the milk in the container, there is no need to monitor the individual droplets of milk entering the container, such that the sensing assembly can avoid errors associated with measuring these droplets. Furthermore, by not needing to measure these droplets, the sensing assembly from the breast pump need not always be on during the pumping process.

Preferably, the at least one optical emitter comprises at least two optical emitters. In this way, the sensing assembly from the breast pump can determine the level of milk inside the container more accurately and irrespective of the orientation of the liquid level inside the container.

Preferably, each optical emitter is equidistant from the optical receiver. In this way, the controller can more easily calculate the level of the milk inside the container based on the reflected radiation originating from each optical emitter.

Each optical emitter may be operable to emit radiation at a different wavelength, or at a different time, than the other optical emitters. In this way, the controller can more easily process the signals from the optical receiver, and more easily distinguish between the radiation emitted by each of the optical emitters.

Preferably, the optical emitter may emit radiation in the visible range of wavelengths. Alternatively it may be UV or IR light. The emitted wavelength is preferably between 10nm and 1mm.

The signals from the optical receiver preferably comprise information relating to the intensity of the radiation received by the optical receiver.

Preferably, the sensing assembly comprises at least one accelerometer electrically connected to the controller. In one embodiment, the controller may be configured to record an accelerometer parameter from the accelerometer, and determine whether the accelerometer parameter exceeds a predetermined threshold. The predetermined threshold may be indicative of an excessive acceleration, which might cause sloshing of milk inside any container connected to the breast pump.

In some cases, the coupling may be a screw thread.

Preferably, the breast pump is sized to be similar to that of a female breast. On this basis, the breast pump is preferably no longer than 20cm in any given linear direction; more preferably no longer than 18cm in any given linear direction; and even more preferably no longer than 15cm in any given linear direction.

The breast pump may contain any suitable power source, such as a battery. The power source is preferably located in the housing.

In some cases, the container may comprise a window through which optical radiation can pass, wherein when the container is connected to the housing, radiation is operable to pass between the optical emitters/receiver and the inside of the container via the window. In other cases, the container may be made entirely of a material through which the optical radiation can pass.

When the container is connected to the housing, each optical emitter and the optical receiver are preferably located adjacent to the container, to ensure reliable transmission of radiation between the device and the container.

In this case, the portion of the container adjacent to each optical emitter and the optical receiver preferably comprises a surface inside the container which comprises at least one channel and/or feature for directing milk away from each optical emitter and/or the optical receiver. In this way the formation of milk on this surface, which would cause erroneous signals from the optical receiver, can be inhibited.

To further inhibit the formation of milk in the vicinity of each optical emitter/receiver, the portion of the container adjacent to each optical emitter and the optical receiver may comprise a surface inside the container which comprises an oleophobic and/or hydrophobic coating.

Preferably, the container has a volumetric capacity of no more than 200ml. These volumetric capacities are particularly relevant when the container is a baby bottle.

It will be appreciated that the sensing assembly from the above breast pump has applications in other fields. Thus according to a second aspect of the present invention, there is provided a sensor module operable to be connected with a container for holding liquid, and suitable for use in detecting the level of liquid inside the container, the sensor module comprising:

a housing having a coupling for attachment to the top of the container;

a sensing assembly within the housing and comprising at least two optical emitters operable to emit optical radiation towards the surface of the body of liquid held in the container when the housing is connected to the container, and an optical receiver for receiving the reflected radiation from the surface of the liquid; and

a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the liquid inside the container based on the reflected radiation received by the optical receiver.

Existing prior art for such a sensor module is the apparatus disclosed in RU2441367. In this apparatus, the container is an industrially sized milk tank, which only includes a single laser mounted at the top of the tank. Whilst this apparatus is suited for large-sized containers, which do not move in use, the apparatus is less-suited for applications where the container moves in use, or where the liquid level inside the container is non-perpendicular to the laser beam shone into the container. In contrast, the sensor module described above can be used in a variety of different applications, is conveniently located within a housing, and which by virtue of it having at least two optical emitters, can determine the level of liquid even inside containers of irregular shapes, and which can determine the level of liquid inside a container irrespective of the orientation of the liquid level inside the container.

Although not fully recited herein, it will be appreciated that the sensor module according to the second aspect of the invention may include any or all of the optional features described in relation to the breast pump from the first aspect of the present invention.

According to a third aspect of the present invention, there is provided a collar incorporating the sensor module according to the second aspect of the invention, wherein the collar comprises a first end having the coupling, and a second end having a second coupling for attaching the collar to a lid of the container.

In the above case, the second coupling may be a screw thread.

According to fourth aspect of the present invention, there is provided a lid attachable to a container, wherein the lid comprises the sensor module according to the second aspect of the invention.

DESCRIPTION OF THE FIGURES

Figure 1A shows a sectional view of a device being used to determine the level of liquid in a container; and

Figure 1B shows a sectional view of the device and the container from Figure 1A being used at a different orientation.

Figure 2 shows a sectional view of the device and the container from Figure 1A being used whilst undergoing acceleration.

Figure 3 shows a sectional view of the device from Figure 1A being used as part of a breast pump assembly.

Figure 4 shows a sectional view of a device connected between a container and its lid, and which is operable to determine the level of liquid inside the container.

DETAILED DESCRIPTION

With reference to Figures 1A and 1B, there is shown a device 10 for use in detecting the level of liquid inside a container 100.

The device 10 is formed of a housing 12 in which is located a sensing assembly 14 comprising a series of optical emitters 16 which are angled relative to, and each located equidistant from, an optical receiver 18. In operation of the device as will be described, each optical emitter 16 is operable to emit radiation which is received by the optical receiver 18.

The optical emitters 16 and the optical receiver 18 from the sensing assembly 14 are located in a portion 20 of the device 10 which faces the container 100 when the device 10 is connected to the container 100. The portion 20 of the device 10 containing the optical emitters 16 and the optical receiver 18 comprises a window 22 of material which is transparent to optical radiation. In this way, each of the optical emitters 16 and the optical receiver 18 have a line of sight through the window 22 into the container 100 when the device 10 is connected thereto.

A controller 30 comprising a CPU 32 and a memory 34 is provided in the device 10 for controlling the operation of the sensing assembly 14. An accelerometer 36 is also provided in the housing 10, which is operatively connected to the controller 30.

Operation of the device 10 when connected to the container 100 will now be described.

In a principal mode of operation, to determine the level L of liquid inside the container 100, the controller 30 instructs the optical emitters 16 to each emit radiation towards the surface of the liquid inside the container 100 at a given intensity. The optical receiver 18 receives the reflected radiation from each optical emitter 16 via the surface of the liquid and each of these intensities is recorded by the controller.

For each operation of the sensing assembly 14, the controller 30 records the intensities of radiation emitted by each of the optical emitters 16 as intensities IE_1; $IE_{2...}IE_n$ (where n is the total number of optical emitters), and records the intensities of radiation received by the optical receiver 18 from each of the optical emitters 16 as received intensities IR_1; $IR_{2...}IR_n$.

By comparing the emitted radiation intensities IE_1; $IE_{2...}IE_n$ with the received radiation intensities IR_1; $IR_{2...}IR_n$, the controller 30 calculates a series of intensity ratios IE_1:IR_1; IE_2:IR_2...IE_n:IR_n, which are then used to determine the level of the liquid inside the container. At the most basic level, if the intensity ratio of IE_1:IR_1 is the same as IE_2:IR_2,

given the optical emitters 16 are equidistant from the optical receiver 18, this indicates that the level of the liquid inside the container is parallel to the top of the bottle, as shown in Figure 1A. In contrast, if these two intensity ratios are different, this indicates that the liquid level is at a different angle, such as that shown in Figure 1B.

To accurately determine the level and the quantity of liquid inside the container 100, the controller 30 processes the recorded intensity ratios using a database located in the memory 34. The database contains an individual record for each container which is operable to connect with the device 10. Each record from the database contains a look-up table of information, which contains expected intensity ratios (IE_1:IR_1 and IE_2:IR_2) for the container 100 when filled at different orientations, and with different quantities of liquid.

By comparing the information from the look-up table with the recorded intensity ratios, the controller 30 calculates the level and quantity of liquid inside the container 100 and stores this information in the memory 34.

In situations where a container 100 to the device 10 contains no stored record in the database, the sensing assembly 14 can be used in a calibration mode to create a new record. In the calibration mode, the sensing assembly 14 is operated as the container is filled, and as it is located at different orientations. At each point during the calibration mode, the controller 30 calculates the recorded intensity ratios (IE_1:IR_1 and IE_2:IR_2) and stores them in the record relating to the container 100. For each set of recorded intensity ratios, the user includes information in the record relating to the orientation and fill level of liquid inside of the container 100.

To improve the accuracy of the results obtained by the device 10 during its use, the controller 30 when recording each intensity ratio also records a parameter from the accelerometer 36 relating to the acceleration experienced by the device 10. For each recorded acceleration parameter, the controller 30 determines whether the parameter exceeds a predetermined threshold acceleration parameter stored in the memory 34. The predetermined threshold is indicative of an excessive acceleration, which causes sloshing of liquid inside the container 100 connected to the device 10. In the event of a recorded acceleration parameter exceeding the predetermined threshold acceleration parameter, the controller 30 flags the recorded intensity ratios associated with the recorded acceleration parameter as being unreliable (due to sloshing).

Even without the use of the accelerometer 36, the controller 30 is nonetheless operable to determine whether a set of recorded intensity ratios occur during a period of excess acceleration. In this regard, for each set of intensity ratios recorded at a given time, the controller 30 checks whether any of these intensity ratios is of a predetermined order of magnitude different than the remaining recorded intensity ratios from the set. In the event that the controller 30 determines that this is the case, this indicates that the liquid inside the container has 'sloshed' as a result of the excess acceleration, as shown in Figure 2. In this event, the controller 30 flags the set of recorded intensity ratios as being unreliable.

It will be appreciated that instead of recording the relative intensities of radiation emitted by the optical emitters 16 with the radiation received by the optical emitter 18, the controller 30 could instead record the time taken for radiation emitted by each of the optical emitters 16 to be received by the optical receiver 18. In this arrangement, the look up table would instead contain time periods as opposed to intensity ratios.

In terms of the applications for the device 10, it will be appreciated that the device can be used in a wide variety of applications.

One possible application is the use of the device 10 to determine the level of liquid located within a container 100, such as a baby bottle, used as part of a breast pump assembly. In this arrangement, the device 10 is associated with a breast pump 200 which assists with the expression of milk from a breast. The breast pump may be located in the housing 12 of the device 10 as shown in Figure 3, or it may be realisably connected to the housing 12. Either way, the device 10 would be connectable to the container 100 such that milk expressed by the breast pump can pass from the pump via a channel 202 into the container 100.

Another application for the device 10 is as a collar for detecting the level/quantity of liquid in a container 100, such as a baby bottle, via its lid 102. An example of the device 10 being used as such a collar is shown in Figure 4. In this arrangement, the device 10 is located between the container 100 and the lid 102, and comprises a first end 42 having a first coupling 44 for attaching the collar to the lid 102. The device comprises a second end 46 having a second coupling 48 for attaching the device 10 to the container 100. In Figure 4,

the first and second couplings are shown as screw threads which engage with respective screw heads on the lid 102 and the container 100.

To allow the device 10 to pass liquid from the lid 102 to the container 100, the device comprises a channel 50 passing from the first end 42 to the second end 46.

In a further application, the device 10 may be integrated into the lid 102 of a container 100. In this application, the device 10 has a similar configuration to that shown in Figure 4, except that the first end 42 is covered and has no coupling 44.

It will be appreciated the device may be connected to a wide variety of different containers 100. In some applications, the container 100 may be a baby bottle, or a drinks bottle.

In certain applications, the container 100 connected to the device 10 may have a volumetric capacity of no more than 500ml, less than 400ml, less than 300ml, and/or less than 200ml. These volumetric capacities are particularly relevant when the container is a baby bottle/drink bottle.

It will also be appreciated that the container 100 connected to the device 10 may comprise an inside surface which comprises an oleophobic and/or hydrophobic coating. In this way, the container 100 is easy to clean between uses. When such a coating is applied to the portion of the container 100 which is adjacent to the optical emitters 16 and the optical receiver 18 from the device 10, this coating also helps prevent liquid from forming in front of these emitters/receiver, which might cause erroneous signals to be recorded by the optical receiver 18 from the sensing assembly 14.

To further reduce such erroneous signals, the portion of the container adjacent to the optical emitters and the optical receiver may comprise a surface inside the container having at least one channel and/or feature for directing liquid away from the optical emitters and/or the optical receiver.

To improve the accuracy of the sensing assembly 14, the container 100 may be made opaque to prevent ambient radiation outside the container 100 from reaching the optical receiver 18. Other possibilities to improve the accuracy to the accuracy of the sensing assembly 14 include the provision of a distinctive pattern/colour/texture on the bottom

inside surface of the container 100. In this way, the distinctive bottom inside surface can be used by the sensing assembly 14 to more easily calibrate itself to the container 100 on which the distinctive bottom inside surface is located. The distinctive bottom may also be used to help identify which container 100 the device is connected to, and thus which record should be used from the database when the device 10 is used.

To further improve the accuracy of the sensing assembly 14, the controller 30 may also be configured to use the recorded information from the accelerometer 36, in situations where the record acceleration is below the predetermined threshold acceleration parameter, to calculate a more accurate liquid level and/or quantity of liquid located inside the container which is compensated for acceleration.

In one particular arrangement, the controller 30 may poll the accelerometer 36 prior to each operation of the sensing assembly 14 to verify that the device 10 is not currently undergoing excessive acceleration. In the event of the controller 30 determining excessive acceleration in the device 10, the controller 30 would continually re-poll the accelerometer, and not operate the sensing assembly 14, until the parameter from the accelerometer is determined as being below the predetermined threshold acceleration parameter stored in the memory 34.

It will also be appreciated that for each container record stored in the database, the container record may comprise a plurality of look up tables, wherein each look up table is associated with a particular liquid used in the container, and wherein each look up table contains its own set of intensity ratios. In this way, the device 10 can more accurately determine the level/quantity of different liquids used in a particular container 100.

As described herein, the sensing assembly 14 has been described as having a plurality of optical emitters 16. It will be appreciated however that the sensing assembly could operate using a single optical emitter 16 and plurality of optical receivers 18. In this arrangement, each record from the database would contain a plurality of ratios relating to the emitted radiation from the optical emitter 16 as received by each of the optical receivers 18. In use of the device 10, the controller 30 would then similarly record the emitted radiation from the optical emitter 16 as received by each of the optical receivers 18. In an alternate arrangement, there may be provided a plurality of optical emitters 16 and a plurality of optical receivers 18, wherein each optical emitter 16 is associated with a respective optical

receiver 18. In its simplest arrangement, the sensing assembly 14 may comprise a single optical emitter 16 and a single optical receiver 18.

In certain configurations, the optical emitters 16 may together emit radiation having the same wavelength. In other configurations, the optical emitters 16 may each emit radiation having a different wavelength. In this latter configuration, the optical receiver 18 would then be able to determine which optical emitter 16 is associated with any given received radiation, based on the wavelength of the received radiation.

The optical emitters 16 may also each emit radiation at different times, such to allow the controller 30 to more easily process the signals from the optical receiver 18, and more easily distinguish between the radiation emitted by each of the optical emitters 16.

In relation to the electrical connection between the controller 30 and the sensing assembly 14, it will be appreciated this electrical connection may be either a wired/wireless connection as required.

Although not shown in the Figures, the device 10 herein described is preferably powered by a battery or some other power source located in the device 10. In other embodiments, the device 10 may be powered using mains electricity.

In one configuration, it is also envisaged that rather than the controller 30 comparing the information from the look-up table with the recorded intensity ratios to calculate the level and quantity of liquid inside the container 100, the controller 30 could instead process the recorded intensity ratios through a liquid-level equation stored in the memory 34. In this configuration, the liquid-level equation could be a generalised equation covering a family of different containers, or could be an equation specific to a container having a given shape and/or type of liquid inside.

It will also be appreciated that in some applications of the device 10, the device could be used to detect the level of a solid, as opposed to a liquid, in a container.

As used herein, the terms 'optical emitter' and 'optical receiver' are intended to cover sensors which can emit radiation in or close to the optical wavelength. Any type of radiation at or close to the optical wavelength is suitable provided that it does not have any harmful

effects. The exact wavelength is not important in the context of the invention. Such sensors thus include those which can emit visible radiation (such as radiation having wavelengths in the region of 400nm-700nm), and/or those which can emit IR radiation (such as radiation having wavelengths in the region of 700nm-1mm and/or those which can emit UV radiation (such as radiation having wavelengths in the region of 10nm to 400nm).

CLAIMS:

1. A breast pump comprising:

a pump module for pumping milk from a breast, the pump module being contained within a housing comprising a coupling;

a container attachable to the housing via the coupling to receive milk from the pump;

a sensing assembly within the housing and comprising at least one optical emitter operable to emit optical radiation towards the surface of the body of milk held in the container when the housing is connected to the container, and an optical receiver for receiving the reflected radiation from the surface of the milk; and

a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the milk inside the container based on the reflected radiation received by the optical receiver.

2. A breast pump according to claim 1, wherein the at least one optical emitter comprises at least two optical emitters.

3. A breast pump according to claim 2, wherein each optical emitter is equidistant from the optical receiver.

4. A breast pump according to claim 2 or 3, wherein each optical emitter is operable to emit radiation at a different wavelength, or at a different time, than the other optical emitters.

5. A breast pump according to any preceding claim, wherein each optical emitter is an IR optical emitter, and the optical receiver is an IR optical receiver.

6. A breast pump according to any preceding claim, wherein the signals from the optical receiver comprise information relating to the intensity of the radiation received by the optical receiver.

7. A breast pump according to any preceding claim, wherein the sensing assembly comprises at least one accelerometer electrically connected to the controller.

8. A breast pump according to any preceding claim, wherein the coupling is a screw thread.

9. A breast pump according to any preceding claim, wherein the breast pump is no longer than 20cm in any given linear direction.

10. A breast pump according to any preceding claim, wherein the breast pump contains a power source.

11. A breast pump according to any preceding claim, wherein the container comprises a window through which optical radiation can pass, wherein when the container is connected to the housing, radiation is operable to pass between each optical emitter/receiver and the inside of the container via the window.

12. A breast pump according to any preceding claim, wherein when the container is connected to the housing, each optical emitter and the optical receiver are located adjacent to the container.

13. A breast pump according to claim 12, wherein the portion of the container adjacent to each optical emitter and the optical receiver comprises a surface inside the container which comprises at least one channel and/or feature for directing milk away from each optical emitter and/or the optical receiver.

14. A breast pump according to claim 12 or 13, wherein the portion of the container adjacent to each optical emitter and the optical receiver comprises a surface inside the container which comprises an oleophobic and/or hydrophobic coating.

15. A breast pump according to any preceding claim, wherein the container has a volumetric capacity of no more than 200ml.

16. A sensor module operable to be connected with a container for holding liquid, and suitable for use in detecting the level of liquid inside the container, the sensor module comprising:

a housing having a coupling for attachment to the top of the container;

a sensing assembly within the housing and comprising at least two optical emitters operable to emit optical radiation towards the surface of the body of liquid held in the container when the housing is connected to the container, and an optical receiver for receiving the reflected radiation from the surface of the liquid; and

a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the liquid inside the container based on the reflected radiation received by the optical receiver.

17. A collar incorporating the sensor module according to claim 16, wherein the collar comprises a first end having the coupling, and a second end having a second coupling for attaching the collar to a lid of the container.

18. A collar according to claim 17, wherein the second coupling is a screw thread.

19. A lid attachable to a container, wherein the lid comprises the sensor module according to claim 16.

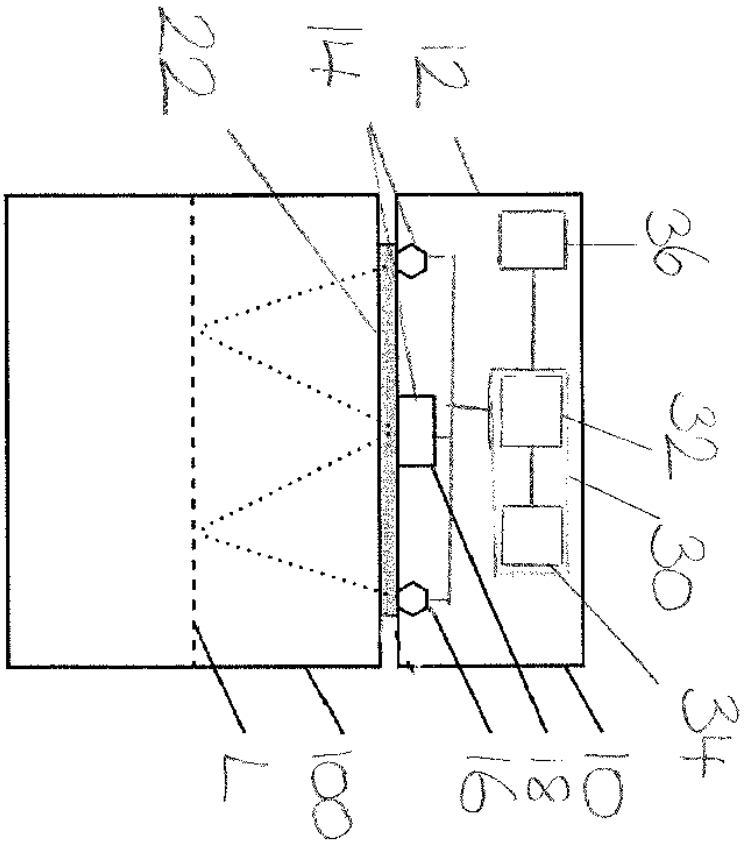


FIG 1A

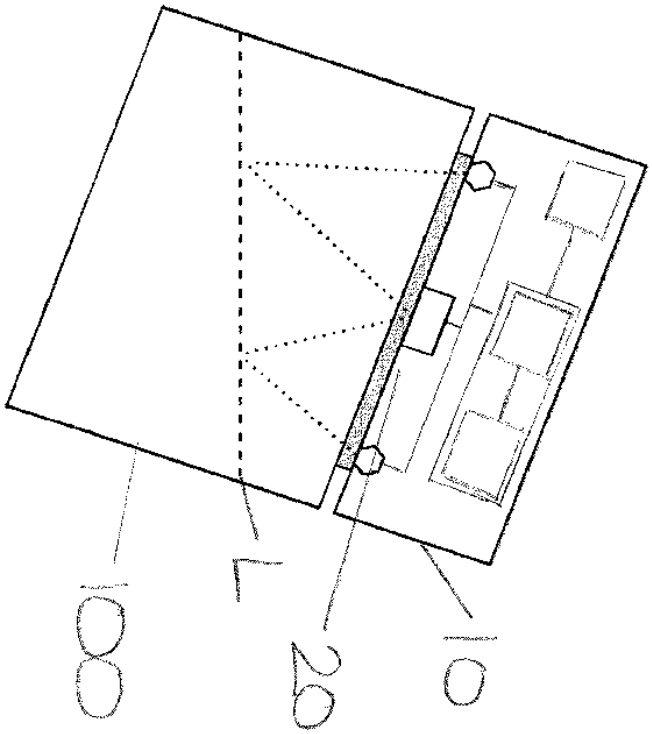


FIG 1B

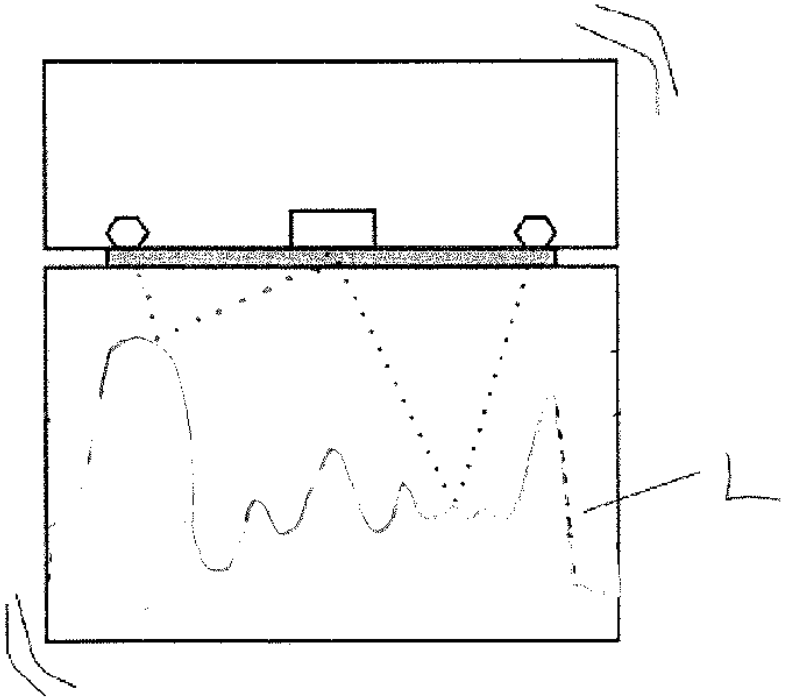


FIG 2

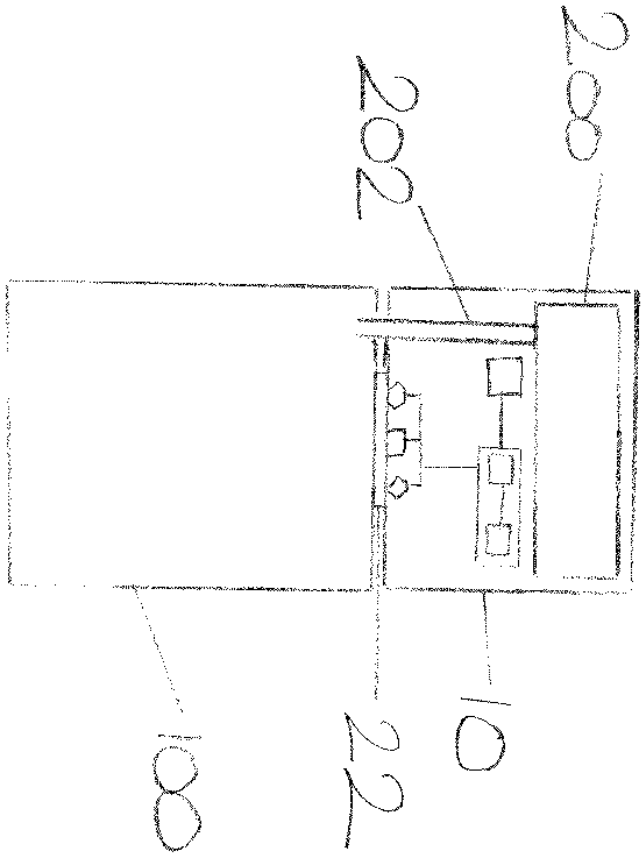


FIG 3

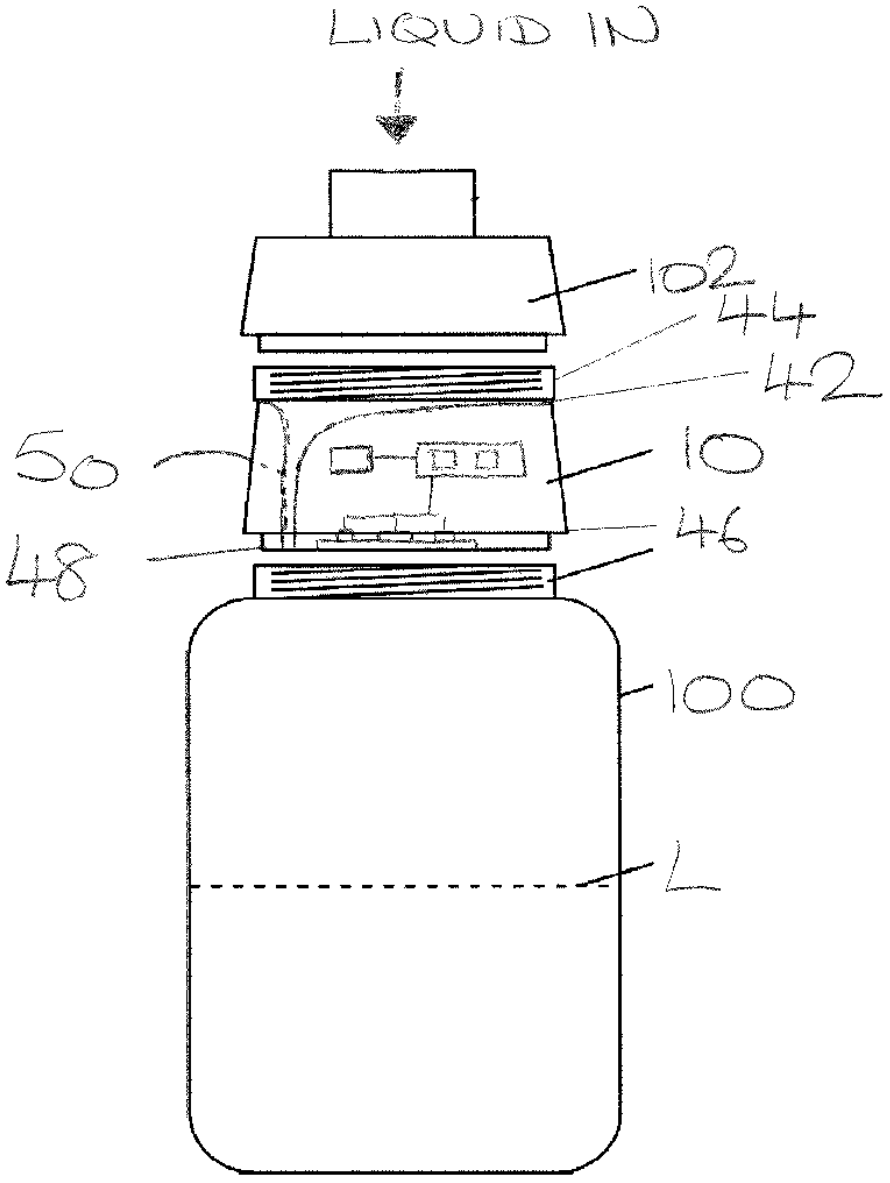


FIG 4.

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I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

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I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

CHIARO TECHNOLOGY LIMITED

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	18 JULY 2018
Name	ANDREA ZITNA		
Title	CHIEF REVENUE OFFICER		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ Total of 1 forms are submitted.

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	BREAST PUMP SYSTEM

As the below named inventor, I hereby declare that:

This declaration is directed to:

- ☐ The attached application, or
- ■ United States application or PCT international application number 16/009,547 filed on 15 June 2018.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

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LEGAL NAME OF INVENTOR

Inventor: Jonathan O'TOOLE

Signature: _____ Date (Optional): _____

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LEGAL NAME OF INVENTOR

Inventor: Adam ROLLO Date (Optional): _____

Signature: _____

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LEGAL NAME OF INVENTOR

Inventor: Andrew CARR Date (Optional): _____

Signature: _____

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This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PATENT **Docket No. 373499.00049**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INVENTORS:	**Jonathan O'TOOLE et al.**	Confirmation No.
APPLICATION NO.	**TBD**	
FILED:	**Herewith**	Examiner:
CASE NO.	**373499.00049**	Group Art Unit:
TITLE:	**BREAST PUMP SYSTEM**	

FILED ELECTRONICALLY ON February 22, 2021

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUBMISSION OF INFORMATION DISCLOSURE
STATEMENT UNDER 37 CFR §§1.97 AND 1.98

Sir:

Submitted herewith for the above-identified application is an Information Disclosure Statement under 37 CFR §§1.97 and 1.98. Pursuant to 37 CFR §1.98(d)(1), Applicant has not provided copies of the foreign patent and non-patent literature cited in the accompanying Information Disclosure Statement ("IDS"), since copies of these publications were submitted in IDS's filed on June 15, 2018; December 7, 2018; or November 3, 2020, in parent Application No. 16/009,547, of which the present application is a continuation.

The Examiner is requested to initial a copy of the enclosed Form PTO-1449 and return a copy to applicant.

Respectfully submitted

February 22, 2021
Date

/Mark D. Simpson/
Mark D. Simpson, Esquire
Registration No. 32,942

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1500 Market Street, 38th Floor
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Email: Mark.Simpson@saul.com

38100234.1

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	
First Named Inventor	Jonathan O'Toole
Art Unit	
Examiner Name	
Attorney Docket Number	373499.00049

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	2849881	A	1958-09-02	ANDERSON	
	2	4390024	A	1983-06-28	WILLIAMS	
	3	4535627	A	1985-08-20	PROST, et al.	
	4	5474683	A	1995-12-12	BRYANT, et al.	
	5	5941847	A	1999-08-24	HUBER, et al.	
	6	5973770	A	1999-10-26	CARTER, et al.	
	7	6045529	A	2000-04-04	NUEESCH	
	8	6090065	A	2000-07-18	GILES	

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	Examiner Name	
	Attorney Docket Number	373499.00049

	9	6227936	B1	2001-05-08	MENDOZA	
	10	6328709	B1	2001-12-11	HUNG, et al.	
	11	6358226	B1	2002-03-19	RYAN	
	12	6383163	B1	2002-05-07	KELLY, et al.	
	13	6440100	B1	2002-08-27	PRENTISS	
	14	6461324	B1	2002-10-08	SCHLENSOG	
	15	6547756	B1	2003-04-15	GRETER, et al.	
	16	6579258	B1	2003-06-17	ATKIN, et al.	
	17	6663587	B2	2003-12-16	SILVER, et al.	
	18	6749582	B2	2004-06-15	BRITTO, et al.	
	19	7048519	B2	2006-05-23	FONG, et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
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	First Named Inventor	Jonathan O'Toole
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	Examiner Name	
	Attorney Docket Number	373499.00049

	20	7201735	B2	2007-04-10	ATKIN, et al.	
	21	D548831	S	2007-08-14	CHARLEZ	
	22	7312554	B2	2007-12-25	VOGELEY	
	23	7314400	B2	2008-01-01	FILDAN, et al.	
	24	7662018	B1	2010-02-16	THOMPSON	
	25	7776008	B2	2010-08-17	RENZ, et al.	
	26	8057425	B1	2011-11-15	MYERS, et al.	
	27	8118772	B2	2012-02-21	DAO, et al.	
	28	8187227	B2	2012-05-29	LUZBETAK, et al.	
	29	8262606	B2	2012-09-11	GRETER, et al.	
	30	8282596	B2	2012-10-09	GRETER, et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	Jonathan O'Toole
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	Examiner Name	
	Attorney Docket Number	373499.00049

	31	8376986	B2	2013-02-19	VAN, et al.	
	32	8702646	B2	2014-04-22	GARBEZ, et al.	
	33	8801495	B1	2014-08-12	GUINDON	
	34	8876760	B2	2014-11-04	BOSMAN, et al.	
	35	8926556	B2	2015-01-06	VAN EIJKELENBORG, et al.	
	36	9033913	B2	2015-05-19	KHALIL, et al.	
	37	9173587	B2	2015-11-03	VAN SCHIJNDEL, et al.	
	38	9345274	B1	2016-05-24	PRILL	
	39	9539377	B2	2017-01-10	MAKOWER, et al.	
	40	10039871	B2	2018-08-07	POLLEN, et al.	

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	Application Number	
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	First Named Inventor	Jonathan O'Toole
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	Examiner Name	
	Attorney Docket Number	373499.00049

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020193731	A1	2002-12-19	MYERS, et al.	
	2	20040056641	A1	2004-03-25	MYERS, et al.	
	3	20040074281	A1	2004-04-22	LOBDELL, et al.	
	4	20040267215	A1	2004-12-30	CHARLEZ, et al.	
	5	20050219302	A1	2005-10-06	VOGELEY, et al.	
	6	20060122575	A1	2006-06-08	WAKABAYASHI	
	7	20070051172	A1	2007-03-08	PERINET, et al.	
	8	20070051727	A1	2007-03-08	HOLLEY	
	9	20080177224	A1	2008-07-24	KELLY, et al.	
	10	20080262420	A1	2008-10-23	DAO, et al.	

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	Application Number	
	Filing Date	
	First Named Inventor	Jonathan O'Toole
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

	11	20080275386	A1	2008-11-06	MYERS	
	12	20110004154	A1	2011-01-06	VAN, et al.	
	13	20110196291	A1	2011-08-11	VISCHER, et al.	
	14	20110274566	A1	2011-11-10	AMIROUCHE, et al.	
	15	20120277636	A1	2012-11-01	BLONDHEIM, et al.	
	16	20130023821	A1	2013-01-24	KHALIL, et al.	
	17	20140031744	A1	2014-01-30	CHEN	
	18	20140052056	A1	2014-02-20	GARBEZ, et al.	
	19	20140275857	A1	2014-09-18	TOTH, et al.	
	20	20140323962	A1	2014-10-30	KOOIJKER, et al.	
	21	20140378895	A1	2014-12-25	BARACK	

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	Attorney Docket Number	373499.00049

	22	20150217036	A1	2015-08-06	POLLEN, et al.	
	23	20150217037	A1	2015-08-06	POLLEN, et al.	
	24	20150283311	A1	2015-10-08	ALVAREZ, et al.	
	25	20160000980	A1	2016-01-07	ALVAREZ, et al.	
	26	20160058928	A1	2016-03-03	NOWROOZI, et al.	
	27	20160058929	A1	2016-03-03	MEDVEDEV, et al.	
	28	20160082165	A1	2016-03-24	ALVAREZ, et al.	
	29	20160082166	A1	2016-03-24	GUTHRIE, et al.	
	30	20160151551	A1	2016-06-02	FELBER	
	31	20160158424	A1	2016-06-09	CHEN, et al.	
	32	20160166745	A1	2016-06-16	AALDERS	

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	Application Number	
	Filing Date	
	First Named Inventor	Jonathan O'Toole
	Art Unit	
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	Attorney Docket Number	373499.00049

	33	20160206794	A1	2016-07-21	MAKOWER, et al.	
	34	20160220743	A1	2016-08-04	GUTHRIE, et al.	
	35	20160220745	A1	2016-08-04	GUTHRIE, et al.	
	36	20160256617	A1	2016-09-08	HANSEN	
	37	20160287767	A1	2016-10-06	SIMMONS, et al.	
	38	20160296681	A1	2016-10-13	GASKIN, et al.	
	39	20160310650	A1	2016-10-27	MAKOWER, et al.	
	40	20170021068	A1	2017-01-26	GASKIN, et al.	
	41	20170035951	A1	2017-02-09	TANAKA	
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	Attorney Docket Number	373499.00049

	44	20170072118	A1	2017-03-16	MAKOWER, et al.	
	45	20170143879	A1	2017-05-25	OKAGUCHI	
	46	20170220753	A1	2017-08-03	GUTHRIE, et al.	
	47	20180021490	A1	2018-01-25	CHANG, et al.	
	48	20180110906	A1	2018-04-26	BARACK	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	3311982	DE	C2	1983-10-13	BATTELLE MEMORIAL INSTITUTE		
	2	9503280	EP	A2	1992-02-08	PIERBURG GMBH		
	3	9420158	WO	A1	1994-09-15	DEKA PRODUCTS LIMITED PARTNERSHIP		
	4	19750620	DE	A1	1999-06-02	SIEMENS AG, 80333 MUENCHEN, DE		

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	Application Number	
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	First Named Inventor	Jonathan O'Toole
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	Examiner Name	
	Attorney Docket Number	373499.00049

	5	1586340	EP	A2	2005-10-19	SEA PROFIT (HONG KONG) LIMITED		
	6	2005114116	WO	A1	2005-12-01	LANE, JOHN, DENNIS; ESPARZA, JOSEPH, LUIS; NICHOLS		
	7	2005114113	WO	A3	2006-03-02	ACCU-GAUGE LIMITED		
	8	1430918	EP	B1	2008-05-14	MEDELA HOLDING AG		
	9	2344380	RU	C1	2009-01-20	GOSUDARSTVENNOE OBRAZOVATEL'NOE UCHREZHDENIE VYSSH		
	10	2009134271	WO	A1	2009-11-05	UTC POWER CORPORATION		
	11	2473022	GB	B	2011-12-14			
	12	2441367	RU	C2	2012-02-10	OBSHCHESTVO S OGRANICHENNOJ OTVETSTVENNOST'JU 'NAU		
	13	2436277	EP	A1	2012-04-04	DREW, LORNA		
	14	2210628	EP	B1	2013-02-13	MEDELA HOLDING AG		
	15	2499248	GB	B	2014-04-02	ELIZABETH MORANA		

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	Attorney Docket Number	373499.00049

	16	1404393	EP	B1	2014-12-24	MEDELA HOLDING AG		
	17	2015081459	WO	A1	2015-06-11	CHEN, JUNBO		
	18	2015116749	WO	A1	2015-08-06	CORNING INCORPORATED		
	19	2015120321	WO	A1	2015-08-13	NAIA HEALTH, INC.		
	20	2015150225	WO	A1	2015-10-08	KONINKLIJKE PHILIPS N.V.		
	21	2015174330	WO	A1	2015-11-19	MURATA MANUFACTURING CO., LTD.		
	22	2016002606	WO	A1	2016-01-07	MURATA MANUFACTURING CO., LTD.		
	23	2016006494	WO	A1	2016-01-14	MURATA MANUFACTURING CO., LTD.		
	24	2016006496	WO	A1	2016-01-14	MURATA MANUFACTURING CO., LTD.		
	25	2016007560	WO	A1	2016-01-14	NAYA HEALTH, INC.		
	26	2016010524	JP	A	2016-01-21	MURATA MFG CO LTD		

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	Examiner Name	
	Attorney Docket Number	373499.00049

	27	2016014469	WO	A1	2016-01-28	EXPLORAMED NC7, LLC		
	28	2016014488	WO	A1	2016-01-28	EXPLORAMED NC7, LLC		
	29	105288759	CN	A	2016-02-03	SHANGHAI NORMAL UNIVERSITY		
	30	2016024558	WO	A1	2016-02-18	MURATA MANUFACTURING CO., LTD.		
	31	2016039083	WO	A1	2016-03-17	MURATA MANUFACTURING CO., LTD.		
	32	2016104673	WO	A1	2016-06-30	MURATA MANUFACTURING CO., LTD.		
	33	2077868	EP	B1	2016-07-27	MEDELA HOLDING AG		
	34	2016164853	WO	A1	2016-10-13	NAYA HEALTH, INC.		
	35	1263487	EP	B2	2016-11-23	MEDELA HOLDING AG		
	36	2017061349	WO	A1	2017-04-13	MURATA MANUFACTURING CO., LTD.		
	37	2017108555	WO	A1	2017-06-29	KONINKLIJKE PHILIPS N.V.		

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	First Named Inventor	Jonathan O'Toole
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	Examiner Name	
	Attorney Docket Number	373499.00049

	38	2017139480	WO	A1	2017-08-17	EXPLORAMED NC7, INC.		

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Whisper Wear Hands-Free Breast Pump, Model: WWPMP01, User Guide, pps. 1-20, Distributed with product at least as early as 2007 (see https://web.archive.org/web/20070621162539/http://www.whisperwear.com/pump_single.html)	

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	Filing Date	
	First Named Inventor	Jonathan O'Toole
	Art Unit	
	Examiner Name	
	Attorney Docket Number	373499.00049

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

✓ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Mark D. Simpson/	Date (YYYY-MM-DD)	2021-02-22
Name/Print	Mark D Simpson	Registration Number	32942

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Filer:	Mark D. Simpson/Lynn White
Attorney Docket Number:	373499.00049

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	80	80
UTILITY SEARCH FEE	2111	1	350	350
UTILITY EXAMINATION FEE	2311	1	400	400
Pages:				
UTILITY APPL SIZE FEE PER 50 SHEETS >100	2081	1	210	210
Claims:				
CLAIMS IN EXCESS OF 20	2202	10	50	500
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1540**

Electronic Acknowledgement Receipt	
EFS ID:	41980268
Application Number:	17181057
International Application Number:	
Confirmation Number:	4690
Title of Invention:	BREAST PUMP SYSTEM
First Named Inventor/Applicant Name:	Jonathan O'TOOLE
Customer Number:	78905
Filer:	Mark D. Simpson/Lynn White
Filer Authorized By:	Mark D. Simpson
Attorney Docket Number:	373499.00049
Receipt Date:	22-FEB-2021
Filing Date:	
Time Stamp:	11:50:41
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$1540
RAM confirmation Number	E20212LB51264897
Deposit Account	504364
Authorized User	Lynn White
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

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37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	38100216_1.PDF	1840898 e18d5b636885ae687cdded5ad7ebb66abebb9982	no	9
Warnings:					
Information:					
2		38102084_1.PDF	439142 2b118aabea10baabd2f13e20ff86170a6c16a544	yes	127

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Abstract	127	127
	Claims	122	126
	Specification	1	121

Warnings:					
Information:					
3	Drawings-other than black and white line drawings	38100202_1.PDF	7248994 dd8a02bde993a3f9fd699c5d98244e20a84d91cd	no	44
Warnings:					
The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing					
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4		38100214_1.PDF	236689 25e4ff64342b479b953e8a937054b7c94bfca5f4	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**

	Power of Attorney		4	4	
	Oath or Declaration filed		1	3	
Warnings:					
Information:					
5	Transmittal Letter	38102041_1.PDF	95914 ebd8d3ceb20517464b70d30c0f34916230cd9a65	no	1
Warnings:					
Information:					
6	Information Disclosure Statement (IDS) Form (SB08)	38100228_1.PDF	1043546 c571836125d6d166fa35653984d73323480d172	no	15
Warnings:					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	38319 fc50b9ebe01f7e6d704f97e531e411f95b06881d	no	2
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Information:					
		Total Files Size (in bytes):	10943502		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00049
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jonathan		O'TOOLE	

Residence Information (Select One) US Residency ● Non US Residency Active US Military Service

City	London	Country of Residence [i]	GB

Mailing Address of Inventor:

Address 1	c/o Chiaro Technology Limited
Address 2	63-66 Hatton Garden
City	London
State/Province	
Postal Code	EC1N 8LE
Country [i]	GB

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Adam		ROLLO	

Residence Information (Select One) US Residency ◉ Non US Residency Active US Military Service

City	London	Country of Residence [i]	GB

Mailing Address of Inventor:

Address 1	c/o Chiaro Technology Limited
Address 2	63-66 Hatton Garden
City	London
State/Province	
Postal Code	EC1N 8LE
Country [i]	GB

Inventor 3 Remove

Legal Name

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00049
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

Prefix	Given Name	Middle Name	Family Name	Suffix
	Andrew		CARR	

Residence Information (Select One) US Residency ◉ Non US Residency Active US Military Service

City	London	Country of Residence [i]	GB

Mailing Address of Inventor:

Address 1	c/o Chiaro Technology Limited		
Address 2	63-66 Hatton Garden		
City	London	State/Province	
Postal Code	EC1N 8LE	Country [i]	GB

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	78905		
Email Address	patents@saul.com	Add Email	Remove Email

Application Information:

Title of the Invention	BREAST PUMP SYSTEM		
Attorney Docket Number	373499.00049	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	44	Suggested Figure for Publication (if any)	1

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00049
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	78905		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	16009547	2018-06-15

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00049
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)
1709561.3	GB	2017-06-15	1DE1
1709564.7	GB	2017-06-15	B3B5
1709566.2	GB	2017-06-15	D6F6
1809036.5	GB	2018-06-01	D82C

Remove

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00049
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00049
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 — Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	CHIARO TECHNOLOGY LIMITED		
Mailing Address Information For Applicant:			
Address 1	63-66 Hatton Garden		
Address 2			
City	London	**State/Province**	
Country	GB	Postal Code	EC1N 8LE
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00049
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Mark D. Simpson/			Date (YYYY-MM-DD)	2021-02-22
First Name	Mark D.	Last Name	Simpson	Registration Number	32942

Additional Signature may be generated within this form by selecting the Add button. Add

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	373499.00049
	Application Number	
Title of Invention	BREAST PUMP SYSTEM	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1 The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ABSTRACT

The invention is a wearable breast pump system including a housing shaped at least in part to fit inside a bra and a piezo air-pump. The piezo air-pump is fitted in the housing and forms part of a closed loop system that drives a separate, deformable diaphragm to generate negative air pressure. The diaphragm is removably mounted on a breast shield.

CLAIMS

1. A breast pump device that is configured as a self-contained, in-bra wearable device, and includes:

(i) a housing that includes (a) a rechargeable battery, (b) control electronics; (c) a pump generating negative air pressure;

(ii) a breast shield made up of a breast flange and a nipple tunnel and that is configured to be slid in and out of the housing, in which the breast shield is transparent or optically clear and comes in several different sizes, each of which are configured to slide in and out of the same housing; and

(iii) a milk container that is configured to be attached to and removed from the device.

2. The breast pump device of Claim 1, in which the different sizes of the breast shield each provide a different spacing of the nipple from side walls of the nipple tunnel, when the breast shield has been placed onto a breast.

3. The breast pump device of Claim 1, in which the breast shield is rigid.

4. The breast pump device of Claim 1, in which the breast shield is an optically clear, dishwasher safe polycarbonate breast shield.

5. The breast pump device of Claim 1, in which the breast shield attaches using magnets to the housing.

6. The breast pump device of Claim 1, in which the breast shield is configured to rotate smoothly around the nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto the breast.

7. The breast pump device of Claim 1, in which the breast shield presents in use a single continuous surface to the nipple and breast.

8. The breast pump device of Claim 1, in which the breast integrates the breast flange and nipple tunnel as a single item.

9. The breast pump device of Claim 1, in which the breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

10. The breast pump device of Claim 1, in which the breast shield is configured to slide into the housing with a single push action.

11. The breast pump device of Claim 1, in which the breast shield is configured to slide out from the housing, together with a membrane that prevents milk from flowing into the pump.

12. The breast pump device of Claim 1, in which the milk container is rigid.

13. The breast pump device of Claim 1, in which the milk container is an optically clear, dishwasher safe polycarbonate milk container.

14. The breast pump device of Claim 1, in which milk container attaches to a lower part of the housing and forms the base of the device.

15. The breast pump device of Claim 1, in which milk container magnetically attaches to the housing.

16. The breast pump device of Claim 1, in which the nipple tunnel includes guide lines running parallel to the sides of the nipple tunnel.

17. The breast pump device of Claim 1, in which the nipple tunnel includes an air hole or passage, and the pump transfers negative air pressure into the nipple tunnel via the air hole or passage.

18. The breast pump device of Claim 1, in which the nipple tunnel includes on its lower surface an opening through which expressed milk flows into the milk container.

19. The breast pump device of Claim 1, in which the housing includes one or more piezo air pumps.

20. The breast pump device of Claim 1, in which the housing includes a USB charging socket.

21. The breast pump device of Claim 1, in which the housing includes a left or right breast selector or toggle switch on the housing, that when selected for a

particular pumping sessions, sends data to a connected app that tracks pumping sessions, to indicate whether that session is associated with the left or the right breast.

22. The breast pump device of Claim 1, in which the housing is shaped to fit inside a bra by having an outer surface that is curved to fit the contours of a bra.

23. The breast pump device of Claim 1, in which the housing is configured to slide in and out of the several different sized breast shields, when the breast shield has been placed onto a breast.

24. The breast pump device of Claim 1, in which the device is configured to deliver a maximum suction of approximately 240mmHg.

25. The breast pump device of Claim 1, in which the device includes a sensor that directly measures the level of the milk in the milk container by measuring the intensity of light reflected from the surface of the milk stored in the container.

26. The breast pump device of Claim 1, in which the includes a tilt sensor system that automatically alerts the mother and/or stops pumping if the tilt angle of the breast pump device exceeds a threshold so that milk spillage is imminent.

27. The breast pump device of Claim 1, in which the includes a left or right breast selector or toggle switch on the housing, that when selected for a particular pumping sessions, sends data to a connected app that tracks pumping sessions, to indicate whether that session is associated with the left or the right breast.

28. The breast pump device of Claim 1, in which the pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

29. The breast pump device of Claim 1, in which the pump is a lightweight air pump that enables the total mass of the breast pump device, unfilled with milk, to be less than 250gm

30. The breast pump device of Claim 1, in which the device makes less than 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.

BREAST PUMP SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This is a continuation of U.S. Application No. 16/009,547, filed on June 15, 2018, which is based on, and claims priority to, GB Application No. 1709561.3, filed June 15, 2017; GB Application No. 1709564.7, filed on June 15, 2017; GB Application No. 1709566.2, filed on June 15, 2017; and GB Application No. 1809036.5, filed on June 1, 2018, the entire contents of each of which being fully incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The field of the invention relates to a breast pump system; one implementation of the system is a wearable, electrically powered breast pump system for extracting milk from a mother.

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2. Description of the Prior Art

The specification of the present disclosure is broad and deep. We will now describe the prior art in relation to key aspects of the present disclosure.

Prior art related to breast pump systems

A breast pump system is a mechanical or electro-mechanical device that extracts milk from the breasts of a lactating woman.

A typical breast pump design is as shown in WO 96/25187 A1. A large suction generating device is provided, which is freestanding. This is attached by air lines to one or two breast shields which engage with the user's breasts. A pressure cycle is applied

from the suction generating device, via the air lines, to the breast shields. This generates a pressure cycle on the user's breasts to simulate the suction generated by a feeding child.

The suction generating device is a large component that connects to mains power to operate the pumps therein. Milk collection bottles are provided to store the expressed breast milk. In the system of WO 96/36298 A1 separate bottles are provided attached to each breast shield. A single bottle with tubing connecting to each breast shield may also be used. But for a mother to use this discretely, such as in an office environment, specialised bras must be used. In particular, breast-pumping bras which have a central slit, for the nipple tunnel of the breast shield to extend through, are typically used. The breast shield is held within the bra, with the suction generating device and milk bottle outside the bra.

The fundamental breast pump system has not significantly evolved from this approach, only minor technical improvements have been made.

However, these systems present a number of significant disadvantages. As the suction generating device is a large freestanding unit connected to mains power, the user may feel tethered to the wall. The known devices typically also require a specific user posture and undressing to function normally. This is obviously difficult for a user to do discretely, such as in an office setting. The known devices are also typically noisy, uncomfortable, and hard to clean.

Fully integrated wearable breast pump systems have begun to enter the market, such as described in US 2016 0206794 A1. In such pump systems, the suction source, power supply and milk container are contained in a single, wearable device; there is no need for bulky external components or connections. Such devices can be provided with a substantially breast shaped convex profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations. The internal breast shield is naturally convex to fit over a breast.

In US 2016 0206794 A1, when viewed from the front, the breast pump device has a 'tear-drop' rounded shape, fuller at its base than at its top. But it uses collapsible bags as milk collection devices. As the collection bag systems are collapsible, it can be difficult

for a user to extract all of their milk from the bag, due to the small cut opening that is needed and the capillary action between the bonded plastic sheets that form the bag. This waste can be disheartening for the user, as this is food for their child. The bags are also not re-usable, so the user is required to purchase and maintain a stock of these. As well as presenting a recurring cost, if the user runs out of stock they are unable to use the product until more bags are purchased.

Furthermore, as a result of the collapsible bags, a complex and somewhat noisy pumping arrangement is necessary. In particular, the breast shield connects to a tube which is provided with compression units which "step" the expressed milk through the tube to the collection bag. This uses the breast milk as a hydraulic fluid to generate suction on the breast. In order to carry this out, a complex sequenced pulsing arrangement must be implemented.

In addition to these systems being particularly complex and wasteful, only a relatively small bag can be used. In US 2016 206794, approximately 110 ml (4 fluid ounces) of milk can be collected before the bag must be changed. While this may be sufficient for some users, others may produce much more milk in a session.

A further integrated wearable breast pump system is shown in US 2013 0023821 A1. In the third embodiment in this document, the breast pump system includes a motor driven vacuum pump and power source. An annular (or punctured disc) membrane is provided, with the flow path of the milk going through the centre of the annulus. The membrane is housed in separate housing and is sealed at its inner and outer edges. The breast shield has a small protrusion to engage with these housing components. However, the design of this breast pump system results in a number of problems. The use of an annular membrane, with the fluid flow path running through the opening of the annulus is undesirable as it results in a large and bulky device. There is therefore a need for improved integrated breast pump systems.

Prior Art related to liquid measurement systems

In the context of breast pump systems, it is useful to measure the quantity of expressed milk. One way to do this is to have a clear container for the breast pump, through which the level of expressed milk inside the container can be seen. However, viewing the milk

bottle is not always possible, for example in a breast pump that collects milk while being worn inside a maternity bra.

An existing apparatus for detecting the level of liquid inside a container of a breast pump is that disclosed in US 2016/296681. In this apparatus, a sensing mechanism is provided at the top of a container, which detects droplets of liquid, specifically breast milk, entering the container. By detecting these droplets entering the container, the apparatus can determine the quantity of liquid which enters the container. In this apparatus, an accurate indication of the level of liquid in the container is reliant on the sensing mechanism being able to accurately record every droplet entering the container.

Particularly at times when liquid enters the container at a high flow rate, this accuracy cannot be guaranteed, leading to significant cumulative errors. An accurate indication of the level of liquid in the container in this apparatus is also reliant on the sensing mechanism always being on during the pumping process, so that power consumption of the sensing mechanism is correspondingly high.

In view of the above, there is the need for an improved way to determine the level of liquid inside a container connected to a breast pump.

Prior Art related to bra clips

Many specialised bras (or brassieres) exist for maternity use and that facilitate nursing and/or breast pumping for milk collection, without the need to remove the bra itself. In a traditional nursing bra, this is achieved with the use of an at least partially detachable cup, which can be unhooked for feeding and/or pumping.

Further specialised bras are known which are provided with cut-out portions or slits which substantially align with the wearer's areola and nipple. Traditional breast pump systems comprise an elongate breast shield which extends away from the breast towards an external bottle and source of suction. The breast shield is arranged to extend through the cut-out portion or slit, with the collection bottle and pumping apparatus placed outside of the bra. These systems require the user to remove or unbutton any over-garments, and are uncomfortable when not pumping.

Integrated, wearable breast pump systems have begun to enter the market, such as previously noted US 2016 0206794 A1. In such pumps, the suction source, power supply and milk container are all in a single, wearable device, as noted above, without the need for bulky external components or connections. Such devices can be provided with a substantially breast shaped profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations.

Maternity (or nursing) bras such as disclosed in US 4,390,024 A have partially detachable cups, with several hooks provided along the bra strap for attaching the cups to the strap. The cups can then be attached to different hooks in order to adjust the bra strap length. However, these attachment points are fixed. Additionally, this bra has been designed to accommodate the change in breast size before and after the feeding/pumping process. It is not designed to accommodate a breast pump. Accordingly, there is a need for a better system to accommodate integrated wearable breast pumps.

SUMMARY OF THE INVENTION

The invention is a wearable breast pump system including: a housing shaped at least in part to fit inside a bra; a piezo air-pump fitted in the housing and forming part of a closed loop system that drives a separate, deformable diaphragm to generate negative air pressure, that diaphragm being removably mounted on a breast shield.

BRIEF DESCRIPTION OF THE FIGURES

Aspects of the invention will now be described, by way of example(s), with reference to the following Figures, which each show features of various implementations of the invention including optional features that may be utilised:

Figure 1 is a front view of an assembled breast pump system.

Figure 2 is a rear view of the assembled breast pump system of Figure 1.

Figure 3 is a front view of a partially disassembled breast pump system.

Figure 4 is a rear view of the partially disassembled breast pump system of Figure 3.

Figure 5 is a front view of a further partially disassembled breast pump system.

Figure 6 is a rear view of the further partially disassembled breast pump system of Figure 5.

Figure 7 is a front view of the breast pump system of Figure 1, with the outer shell translucent for ease of explanation.

Figure 8 is a further front view of the breast pump system of Figure 1, with the front of the outer shell removed for ease of explanation.

Figure 9 is a schematic view of a nipple tunnel for a breast shield.

Figure 10 is a schematic of a pneumatic system for a breast pump system.

Figure 11 is a schematic of an alternative pneumatic system for a breast pump system.

Figure 12 is a schematic of a further alternative pneumatic system for a breast pump system.

Figure 13 is a graph depicting measured pressure in the breast pump system of Figure 12 over time.

Figure 14 shows schematics for breast shield sizing and nipple alignment.

Figure 15 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 16 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 17 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 18 shows a screenshot of an application running on a device connected to the breast pump system.

Figure 19 shows a screenshot of an application running on a device connected to the

breast pump system.

Figure 20 shows a screenshot of an application running on a connected device.

Figure 21 shows a screenshot of an application running on a connected device.

Figure 22 shows a screenshot of an application running on a connected device.

Figure 23 shows a screenshot of an application running on a connected device.

Figure 24 shows a screenshot of an application running on a connected device.

Figure 25 shows a screenshot of an application running on a connected device.

Figure 26 shows a diagram of a breast pump sensor network,

Figure 27 shows a sectional view of a device being used to determine the level of liquid in a container;

Figure 28 shows a sectional view of the device and the container from Figure 27 being used at a different orientation.

Figure 29 shows a sectional view of the device and the container from Figure 27 being used whilst undergoing acceleration.

Figure 30 shows a sectional view of the device from Figure 27 being used as part of a breast pump assembly.

Figure 31 shows a sectional view of a device connected between a container and its lid, and which is operable to determine the level of liquid inside the container.

Figure 32 depicts a prior art design for a maternity bra;

Figure 33 depicts a clip and clasp being fitted to a maternity bra.

Figure 34 depicts an alternative clip for adjustment of a maternity bra.

Figure 35 depicts the alternative clip of Figure 34.

Figure 36 depicts an alternative clip for adjustment of a maternity bra.

Figure 37 depicts an alternative clip for adjustment of a maternity bra.

Figure 38 depicts an alternative clip for adjustment of a maternity bra.

Figure 39 depicts adjustment of the maternity bra of Figure 37.

Figure 40 shows a configuration with two piezo pumps mounted in series.

Figure 41 shows a configuration of two piezo pumps mounted in parallel.

Figure 42 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in series and mounted in parallel respectively.

Figure 43 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration.

Figure 44 shows a figure of a pump including two piezo pumps in which each piezo pump is connected to a heat sink.

DETAILED DESCRIPTION

We will now describe an implementation of the invention, called the Elvie™ pump, in the following sections:

Section A: The Elvie™ Breast Pump System

Section B: An IR System

Section C: A Bra Clip

Section D: Piezo Pumps and Wearable Devices

Section A: The Elvie™ Breast Pump System

1. Elvie™ Breast Pump System Overview

An implementation of the invention, called the Elvie™ pump, is a breast pump system that is, at least in part, wearable inside a bra. The breast pump system comprises a breast shield for engagement with the user's breast, a housing for receiving at least a portion of the breast shield and a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user, with a milk-flow pathway defined from an opening in the breast shield to the milk collection container. The housing inside also includes a pump for generating a negative pressure in the breast shield, as well as battery and control electronics Unlike other wearable breast pumps, the only parts of the system that come into contact with milk in normal use are the breast shield and the milk container; milk only flows through the breast shield and then directly into the milk container. Milk does not flow through any parts of the housing at all, for maximum hygiene and ease of cleaning.

With reference to Figure 1 and Figure 2, the assembled breast pump system 100 includes a housing 1 shaped to substantially fit inside a bra. The housing 1 includes one or more pumps and a rechargeable battery. The breast pump system includes two parts that are directly connected to the housing 1: the breast shield 7 and a milk container 3. The breast shield 7 and the milk container 3 are directly removable or attachable from the housing 1 in normal use or during normal dis-assembly (most clearly shown in Figure 5). All other parts that are user-removable in normal use or during normal dis-assembly are attached to either the breast shield 7 or the milk container 3. The breast shield 7 and milk container 3 may be removed or attached for example using a one click or one press action or a push button or any other release mechanism. Audible and/or haptic feedbacks confirm that the pump is properly assembled.

The modularity of the breast pump allows for easy assembly, disassembly and replacement of different parts such as the breast shield and milk collection container. This also allows for different parts of the pump to be easily washed and/or sterilised. The breast shield and bottle assembly, both of which are in contact with milk during

pumping, may therefore be efficiently and easily cleaned; these are the only two items that need to be cleaned; in particular, the housing does not need to be cleaned.

The housing 1, breast shield 7 that is holding a flexible diaphragm, and milk container 3 attach together to provide a closed-loop pneumatic system powered by piezoelectric pumps located in the housing 1. This system then applies negative pressure directly to the nipple, forms an airtight seal around the areola, and provides a short path for expressed milk to collect in an ergonomically shaped milk container 3.

The different parts of the breast shield system are also configured to automatically self-seal under negative pressure for convenience of assembly and disassembly and to reduce the risk of milk spillage. Self-sealing refers to the ability of sealing itself automatically or without the application of adhesive, glue, or moisture (such as for example a self-sealing automobile tire or self-sealing envelopes). Hence once the breast pump system is assembled it self-seals under its assembled condition without the need to force seals into interference fits to create sealed chambers. A degree of interference fitting is usual however, but is not the predominating attachment mechanism. Self-sealing enables simple components to be assembled together with a light push: for example, the diaphragm just needs to be placed lightly against the diaphragm housing; it will self-seal properly and sufficiently when the air-pump applies sufficient negative air-pressure. The diaphragm itself self-seals against the housing when the breast shield is pushed into the housing. Likewise, the breast shield self-seals against the milk container when the milk container is pushed up to engage the housing. This leads to simple and fast assembly and dis-assembly, making it quick and easy to set the device up for use, and to clean the device after a session.

Self-sealing has a broad meaning and may also relate to any, wholly or partly self-energising seals. It may also cover any interference seals, such as a press seal or a friction seal, which are achieved by friction after two parts are pushed together.

Whilst one particular embodiment of the invention's design and a specific form of each of the parts of the breast pump system is detailed below, it can be appreciated that the overall description is not restrictive, but an illustration of topology and function that the design will embody, whilst not necessary employing this exact form or number of

discrete parts.

The breast pump system 100 comprises a housing 1 and a milk collection container (or bottle) 3. The housing 1 (including the one or more pumps and a battery) and the container 3 are provided as a unit with a convex outer surface contoured to fit inside a bra. The milk collection container 3 is attached to a lower face 1A of the housing 1 and forms an integral part of the housing when connected, such that it can be held comfortably inside a bra. While the breast pump 100 may be arranged to be used with just the right or the left breast specifically, the breast pump 100 is preferably used with both breasts, without modification. To this end, the outer surfaces of the breast pump 100 are preferably substantially symmetrical.

Preferably, the width of the complete breast pump device (housing 1 and milk container 3) is less than 110 mm and the height of the complete breast pump device is less than 180 mm.

Overall, the breast pump system 100 gives discrete and comfortable wear and use. The system weighs about 224 grams when the milk container is empty, making it relatively lighter as compared to current solutions; lightness has been a key design goal from the start, and has been achieved through a lightweight piezo pump system and engineering design focussed on minimising the number of components.

The breast pump system 100 is small enough to be at least in part held within any bra without the need to use a specialized bra, such as a maternity bra or a sports bra. The rear surface of the breast pump is also concave so that it may sit comfortably against the breast. The weight of the system has also been distributed to ensure that the breast pump is not top heavy, ensuring comfort and reliable suction against the breast. The centre of gravity of the pump system is, when the container is empty, substantially at or below the horizontal line that passes through the filling point on the breast shield, so that the device does not feel top-heavy to a person while using the pump.

Preferably, when the container is empty, the centre of gravity is substantially at or below the half-way height line of the housing so that the device does not feel top-heavy to a user using the pump.

The centre of gravity of the breast pump, as depicted by Figure 1, is at around 60mm high on the centreline from the base of the breast pump when the milk container is empty. During normal use, and as the milk container gradually receives milk, the centre of gravity lowers, which increases the stability of the pump inside the bra. It reduces to around 40mm high on the centreline from the base of the breast pump when the milk container is full.

The centre of gravity of the breast pump is at about 5.85mm below the centre of the nipple tunnel when the milk container is empty, and reduced to about 23.60mm below the centre of the nipple tunnel when the milk container is full. Generalising, the centre of gravity should be at least 2mm below the centre of the nipple tunnel when the container is empty.

The breast pump 100 is further provided with a user interface 5. This may take the form of a touchscreen and/or physical buttons. In particular, this may include buttons, sliders, any form of display, lights, or any other componentry necessary to control and indicate use of the breast pump 100. Such functions might include turning the breast pump 100 on or off, specifying which breast is being pumped, increasing or decreasing the peak pump pressure. Alternatively, the information provided through the user interface 5 might also be conveyed through haptic feedback, such as device vibration, driven from a miniature vibration motor within the pump housing 1.

In the particular embodiment of the Figures, the user interface 5 comprises power button 5A for turning the pump on and off. The user interface 5 further comprises pump up button 5B and pump down button 5C. These buttons adjust the pressure generated by the pump and hence the vacuum pressure applied to the user's breast. In preferable embodiments, the pump up button 5B could be physically larger than the pump down button 5C. A play/pause button 5D is provided for the user to interrupt the pumping process without turning the device off.

The user interface 5 further comprises a breast toggle button 5E for the user to toggle a display of which breast is being pumped. This may be used for data collection, e.g. via an application running on a connected smartphone; the app sends data to a remote server, where data analysis is undertaken (as discussed in more detail later), or for the user to keep track of which breast has most recently been pumped. In particular, there may be a

pair of LEDs, one to the left of the toggle button 5E and one to the right. When the user is pumping the left breast, the LED to the right of the toggle button 5E will illuminate, so that when the user looks down at the toggle it is the rightmost LED from their point of view that is illuminated. When the user then wishes to switch to the right breast, the toggle button can be pressed and the LED to the left of the toggle button 5E, when the user looks down will illuminate. The connected application can automatically track and allocate how much milk has been expressed, and when, by each breast.

The breast pump system also comprises an illuminated control panel, in which the level of illumination can be controlled at night or when stipulated by the user. A day time mode, and a less bright night time mode that are suitable to the user, are available. The control of the illumination level is either implemented in hardware within the breast pump system itself or in software within a connected device application used in combination with the breast pump system.

As depicted in Figure 1, the housing 1 and milk collection container 3 form a substantially continuous outer surface, with a generally convex shape. This shape roughly conforms with the shape of a 'tear-drop' shaped breast. This allows the breast pump 100 to substantially fit within the cup of a user's bra. The milk collection container 3 is retained in attachment with the housing 1 by means of a latch system, which is released by a one-click release mechanism such as a push button 2 or any other one-handed release mechanism. An audible and/or haptic feedback may also be used to confirm that the milk collection container 3 has been properly assembled.

The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting an additional 2 cm difference. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc. In preferred embodiments, the breast pump 100 of the present invention corresponds to an increase of between 3 or 4 cup sizes of the user according to EN 13402.

A plane-to-plane depth of the breast pump can also be defined. This is defined as the distance between two parallel planes, the first of which is aligned with the innermost

point of the breast pump 100, and the second of which is aligned with the outermost point of the breast pump 100. This distance is preferably less than 100 mm.

Figure 2 is a rear view of the breast pump 100 of Figure 1. The inner surface of the housing 1 and milk collection container 3 are shown, along with a breast shield 7. The housing 1, milk collection container 3 and breast shield 7 form the three major subcomponents of the breast pump system 100. In use, these sub-components clip together to provide the functioning breast pump system 100. The breast shield 7 is designed to engage with the user's breast, and comprises a concave inner flange 7A which contacts the breast. To allow the breast pump 100 to be used on either of the user's breasts, the breast shield 7 is preferably substantially symmetrical on its inner flange 7A.

The inner flange 7A is substantially oval-shaped. While the inner flange 7A is concave, it is relatively shallow such that it substantially fits the body form of the user's breast. In particular, when measured side-on the inner-most point of the flange 7A and the outer-most point may be separated by less than 25 mm. By having a relatively shallow concave surface, the forces applied can be spread out over more surface area of the breast. The flatter form also allows easier and more accurate location of the user's nipple. In particular, the flange 7A of the breast shield 7 may extend over the majority of the inner surface of the housing 1 and milk collection container 3. Preferably, it may extend over 80% of this surface. By covering the majority of the inner surface, the breast shield is the only component which contact's the wearer's breast. This leaves fewer surfaces which require thorough cleaning as it reduces the risk of milk contacting a part of the device which cannot be easily sterilized. Additionally, this also helps to disperse the pressure applied to the user's breast across a larger area.

The breast shield 7 substantially aligns with the outer edge 1B of the housing 1. The milk collection container 3 may be provided with an arcuate groove for receiving a lower part of the breast shield 7. This is best shown in later Figures. In the assembled arrangement of Figures 1 and 2, the inner surface of the breast pump 100 is substantially continuous.

The breast shield 7 comprises a shield flange for engaging the user's breast, and an elongate nipple tunnel 9) aligned with the opening and extending away from the user's

breast. Breast shield nipple tunnel 9 extends from a curved section 7B in the breast shield 7. In preferable embodiments the nipple tunnel 9 is integral with the breast shield 7. However, it is appreciated that separate removable/interchangeable nipple tunnels may be used. Curved section 7B is positioned over the user's nipple and areola in use. The breast shield 7 forms an at least partial seal with the rest of the user's breast around this portion, under the negative air pressure created by an air-pressure pump.

This breast shield nipple tunnel 9 defines a milk-flow path from the inner surface of the breast shield 7A, through the breast shield nipple tunnel 9 and into the milk collection container 3. The breast shield nipple tunnel 9 is preferably quite short in order to minimise the length of the milk-flow path in order to minimise losses. By reducing the distance covered by the milk, the device is also reduced in size and complexity of small intermediate portions. In particular, the breast shield nipple tunnel 9 may extend less than 70 mm from its start to end, more preferably less than 50 mm. In use, the nipple tunnel 9 is substantially aligned with the user's nipple and areolae. The nipple tunnel comprises a first opening 9A for depositing milk into the collection container and a second opening 19A for transferring negative air pressure generated by the pump to the user's nipple.

The shield flange 7A and nipple tunnel 9 may be detachable from the housing 1 together. The shield flange 7A and nipple tunnel 9 being detachable together helps further simplify the design, and reduce the number of components which must be removed for cleaning and sterilization. However, preferably, the nipple tunnel 9 will be integral with the breast shield 7, in order to simplify the design and reduce the number of components which must be removed for cleaning and sterilisation.

Figures 3 and 4 are of a partially disassembled breast pump 100 of the present invention. In these Figures, the breast shield 7 has been disengaged from the housing 1 and milk collection bottle 3. As shown in Figure 4, the housing 1 comprises a region or slot 11 for receiving the breast shield nipple tunnel 9 of the breast shield 7. The breast shield is held in place thanks to a pair of channels (9B) included in the nipple tunnel 9, each channel including a small indent. When pushing the housing 1 onto the breast shield 7, which has been placed over the breast, ridges in the housing (9C) engage with the channels, guiding the housing into position; a small, spring plunger, such as ball bearing in each

ridge facilitates movement of the housing on to the nipple tunnel 9. The ball bearings locate into the indent to secure the housing on to the nipple tunnel with a light clicking sound. In this way, the user can with one hand place and position the breast shield 7 onto her breast and with her other hand, position and secure the housing 1 on to the breast shield 7. The breast shield 7 can be readily separated from the housing 1 since the ball bearing latch only lightly secures the breast shield 7 to the housing 1.

Alternatively, the breast shield 7 may also be held in place by means of a clip engaging with a slot located on the housing. The clip may be placed at any suitable point on the shield 7, with the slot in a corresponding location.

The breast shield nipple tunnel 9 of the breast shield 7 is provided with an opening 9A on its lower surface through which expressed milk flows. This opening 9A is configured to engage with the milk collection bottle 3.

The breast pump 100 further comprises a barrier or diaphragm for transferring the pressure from the pump to the milk-collection side of the system. In the depicted example, this includes flexible rubber diaphragm 13 seated into diaphragm housing 19A. The barrier could be any other suitable component such as a filter or an air transmissive material. Diaphragm housing 19A includes a small air hole into the nipple tunnel 9 to transfer negative air pressure into nipple tunnel 9 and hence to impose a sucking action on the nipple placed in the nipple tunnel 9.

Hence, the air pump acts on one side of the barrier or diaphragm 13 to generate a negative air pressure on the opposite, milk-flow side of the barrier. The barrier has an outer periphery or surface, i.e. the surface of diaphragm housing 19A that faces towards the breast, and the milk-flow pathway extends underneath the outer periphery or surface of the barrier or diaphragm housing 19A. The milk-flow path extending under the outer periphery or surface of the barrier 19A allows for a simpler and more robust design, without the milk-flow pathway extending through the barrier. This provides increased interior space and functionality for the device.

As noted, the milk-flow pathway extends beneath or under the barrier 13 or surface of diaphragm housing 19A. This provides an added benefit of having gravity move the milk down and away from the barrier.

Preferably the milk-flow pathway does not pass through the barrier 32. This results in a simpler and smaller barrier design.

As noted, the diaphragm 13 is mounted on diaphragm housing 19A that is integral to the breast shield. This further helps increase the ease of cleaning and sterilisation as all of the components on the "milk" flow side can be removed.

The barrier 13 may also provide a seal to isolate the air pump from the milk-flow side of the barrier. This helps to avoid the milk becoming contaminated from the airflow or pumping side (i.e. the non-milk-flow side).

Alternatively, the only seal is around an outer edge of the barrier 13. This is a simple design as only a single seal needs to be formed and maintained. Having multiple seals, such as for an annular membrane, introduces additional complexity and potential failure points.

As illustrated in Figures 3 and 4, the barrier may include a flexible diaphragm 13 formed by a continuous circular disc shaped membrane which is devoid of any openings or holes. This provides a larger effective "working" area of the diaphragm (i.e. the area of the surface in contact with the pneumatic gasses) than an annular membrane and hence the membrane may be smaller in diameter to have the same working area.

The diaphragm 13 is arranged so that the milk-flow pathway extends below and past the outer surface or periphery of the diaphragm 13. This means that the milk-flow pathway does not extend through the diaphragm 13. In particular, the milk-flow pathway is beneath the diaphragm 13. However, the diaphragm 13 may be offset in any direction with respect to the milk-flow pathway, provided that the milk-flow pathway does not extend through the diaphragm 13.

Preferably, the diaphragm 13 is a continuous membrane, devoid of any openings. The diaphragm 13 is held in a diaphragm housing 19, which is formed in two parts. The first half 19A of the diaphragm housing 19 is provided on the outer surface of the breast shield 7, above the breast shield nipple tunnel 9 and hence the milk-flow pathway. In

preferred embodiments, the first half 19A of the diaphragm housing 19 is integral with the breast shield. The second half 19B of the diaphragm housing is provided in a recessed portion of the housing 1. The diaphragm 13 self-seals in this diaphragm housing 19 around its outer edge, to form a watertight and airtight seal. Preferably, the self-seal around the outer edge of the diaphragm 13 is the only seal of the diaphragm 13. This is beneficial over systems with annular diaphragms which must seal at an inner edge as well. Having the diaphragm 13 mounted in the breast pump 100 in this manner ensures that it is easily accessible for cleaning and replacement. It also ensures that the breast shield 7 and diaphragm 13 are the only components which need to be removed from the pump 100 for cleaning. Because the diaphragm 13 self-seals under vacuum pressure, it is easily removed for cleaning when the device is turned off.

Figures 5 and 6 show a breast pump 100 according to the present invention in a further disassembled state. In addition to the breast shield 7 and diaphragm 13 being removed, the milk collection container 3 has been unclipped. Preferably, the milk collection container 3 is a substantially rigid component. This ensures that expressed milk does not get wasted, while also enhancing re-usability. In some embodiments, the milk collection container 3 may be formed of three sections: a front bottle potion, a rear bottle potion, and a cap. These three sections may clip together to form the milk collection container 3. This three-part system is easy to empty, easily cleanable since it can be dis-assembled, and easily re-usable. The milk collection container or milk bottle may be formed of at least two rigid sections which are connectable. This allows simple cleaning of the container for re-use. Alternatively, the container may be a single container made using a blow moulding construction, with a large opening to facilitate cleaning. This large opening is then closed with a cap with an integral spout 35 or 'sealing plate' (which is bayonet-mounted and hence more easily cleaned than a threaded mount spout). A flexible rubber valve 37 (or 'sealing plate seal') is mounted onto the cap or spout 35 and includes a rubber duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump; this ensures that negative air-pressure does not need to be applied to the milk container and hence adds to the efficiency of the system. The flexible valve 37 self-seals against opening 9A in nipple tunnel 9. Because it self-seals under vacuum pressure, it automatically releases when the system is off, making it easy to remove the milk container.

Preferably, the milk collection container resides entirely below the milk flow path defined by the breast shield when the breast pump system 100 is positioned for normal use, hence ensuring fast and reliable milk collection.

The milk collection container 3 has a capacity of approximately 5 fluid ounces (148 ml). Preferably, the milk collection container has a volume of greater than 120 ml. More preferably, the milk collection container has a volume of greater than 140 ml. To achieve this, the milk collection container 3 preferably has a depth in a direction extending away from the breast in use, of between 50 to 80 mm, more preferably between 60 mm to 70 mm, and most preferably between 65 mm to 68 mm.

The milk collection container 3 further preferably has a height, extending in the direction from the bottom of the container 3 in use to the cap or spout or sealing plate 35, of between 40 mm to 60 mm, more preferably between 45 mm to 55 mm, and most preferably between 48 mm to 52 mm. The cap 35 may screw into the milk collection bottle 3. In particular, it may be provided with a threaded connection or a bayonet and slot arrangement.

Further preferably, the milk collection container has a length, extending from the leftmost point to the rightmost point of the container 3 in use, of between 100 mm to 120 30 mm, more preferably between 105 mm to 115 mm, and most preferably between 107 mm to 110 mm.

This cap 35 is provided with a one-way valve 37, through which milk can flow only into the bottle. This valve 37 prevents milk from spilling from the bottle once it has been collected. In addition, the valve 37 automatically seals completely unless engaged to the breast shield 7. This ensures that when the pump 100 is dismantled immediately after pumping, no milk is lost from the collection bottle 3. It can be appreciated that this one-way valve 37 might also be placed on the breast shield 7 rather than in this bottle cap 35.

Alternatively, the milk bottle 3 may form a single integral part with a cap 35. Cap 35 may include an integral milk pouring spout.

In certain embodiments, a teat may be provided to attach to the annular protrusion 31A

or attach to the spout that is integral with cap 35, to allow the container 3 to be used directly as a bottle. This allows the milk container to be used directly as a drinking vessel for a child. The milk collection container may also be shaped with broad shoulders such that it can be adapted as a drinking bottle that a baby can easily hold.

Alternatively, or in addition, a spout may be provided to attach to the protrusion 31A for ease of pouring. A cap may also be provided to attach to the protrusion 31A in order to seal the milk collection bottle 3 for easy storage.

The pouring spout, drinking spout, teat or cap may also be integral to the milk collection container.

Further, the removable milk collection container or bottle includes a clear or transparent wall or section to show the amount of milk collected. Additionally, measurement markings (3A) may also be present on the surface of the container. This allows the level of milk within the container to be easily observed, even while pumping. The milk collection container or bottle may for example be made using an optically clear, dishwasher safe polycarbonate material such as Tritan™.

The milk collection container or bottle may include a memory or a removable tag, such as a tag including an NFC chip, that is programmed to store the date and time it was filled with milk, using data from the breast pump system or a connected device such as a smartphone. The container therefore includes wireless connectivity and connects to a companion app. The companion app then tracks the status of multiple milk collection containers or bottles to select an appropriate container or bottle for feeding. The tag of the bottle may also be programmed to store the expiry date of the milk as well as the quantity of the milk stored.

Figures 7 and 8 show front views of a breast pump system 100. The outer-surface of the housing 1 has been drawn translucent to show the components inside. The control circuitry 71 for the breast pump 100 is shown in these figures. The control circuitry in the present embodiment comprises four separate printed circuit boards, but it is appreciated that any other suitable arrangement may be used.

The control circuitry may include sensing apparatus for determining the level of milk in the container 3. The control circuitry may further comprise a wireless transmission device for communicating over a wireless protocol (such as Bluetooth) with an external device. This may be the user's phone, and information about the pumping may be sent to this device. In embodiments where the user interface comprises a breast toggle button 5E, information on which breast has been selected by the user may also be transmitted with the pumping information. This allows the external device to separately track and record pumping and milk expression data for the left and right breasts.

There should also be a power charging means within the control circuitry 71 for charging the battery 81. While an external socket, cable or contact point may be required for charging, a form of wireless charging may instead be used such as inductive or resonance charging. In the Figures, charging port 6 is shown for charging the battery 81. This port 6 may be located anywhere appropriate on the housing 1.

Figure 8 shows the location of the battery 81 and the pumps 83A, 83B mounted in series inside the housing 1. While the depicted embodiment shows two pumps 83A, 83B it is appreciated that the present invention may have a single pump. Preferably, an air filter 86 is provided at the output to the pumps 83A, 83B. In preferable embodiments, the pumps 83A, 83B are piezoelectric air pumps (or piezo pumps), which operate nearly silently and with minimal vibrations. A suitable piezo pump is manufactured by TTP Ventus, which can deliver in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free flow. The rear side of the second half of the diaphragm housing 19B in the housing 1 is provided with a pneumatic connection spout. The pumps 83A, 83B are pneumatically connected with this connection spout.

Operation of the breast pump 100 will now be described. Once the breast pump 100 is activated and a pumping cycle is begun, the pumps 83A, 83B generates a negative air pressure which is transmitted via an air channel to a first side of the diaphragm 13 mounted on the diaphragm housing 19A. This side of the diaphragm 13 is denoted the pumping side 13B of the diaphragm 13.

The diaphragm 13 transmits this negative air pressure to its opposite side (denoted the milk-flow side 13A). This negative pressure is transferred through a small opening in the

diaphragm housing 19A to the breast shield nipple tunnel 9 and the curved opening 7B of the breast shield 7 that contacts the breast. This acts to apply the pressure cycle to the breast of the user, in order to express milk. The milk is then drawn through the nipple tunnel 9, to the one way valve 37 that remains closed whilst negative pressure is applied. When the negative air pressure is released, the valve 37 opens and milk flows under gravity past the valve 37 and into milk container 3. Negative air pressure is periodically (e.g. cyclically, every few seconds) applied to deliver pre-set pressure profiles such as profiles that imitate the sucking of a child.

While the depicted embodiment of the breast pump 100 is provided with two pumps, the following schematics will be described with a single pump 83. It is understood that the single pump 83 could be replaced by two separate piezo air-pumps 83A, 83B as above.

Figure 9 depicts a schematic of a further embodiment of a breast shield nipple tunnel 9 for a breast pump 100. The breast shield nipple tunnel 9 is provided with an antechamber 91 and a separation chamber 93. A protrusion 95 extends from the walls of the breast shield nipple tunnel 9 to provide a tortuous air-liquid labyrinth path through the breast shield nipple tunnel 9. In the separation chamber 93 there are two opening 97, 99. An air opening 97 is provided in an upper surface 93A of the separation chamber 93. This upper surface 93 is provided transverse to the direction of the breast shield nipple tunnel 9. This opening 97 connects to the first side of the diaphragm housing 19A and is the source of the negative pressure. This airflow opening 97 also provides a route for air to flow as shown with arrow 96. It is appreciated that the tortuous pathway is not necessary and that a breast shield nipple tunnel 9 without such a pathway will work.

The other opening 99 is a milk opening 99. The milk opening 99 is provided on a lower surface 93B of the separation chamber 93 and connects in use to the container 3. After flowing through the tortuous breast shield nipple tunnel 9 pathway, the milk is encouraged to flow through this opening 99 into the container 3. This is further aided by the transverse nature of the upper surface 93A. In this manner, expressed milk is kept away from the diaphragm 13. As such, the breast pump 100 can be separated into a "air" side comprising the pump 83, the connection spout 85 and the pumping side 13B of the diaphragm 13 and a "milk-flow" side comprising the breast shield 7, the milk collection container 3 and the milk-flow side 13A of the diaphragm 13. This ensures that all of the

"milk-flow" components are easily detachable for cleaning, maintenance and replacement. Additionally, the milk is kept clean by ensuring it does not contact the mechanical components. While the present embodiment discusses the generation of negative pressure with the pump 83, it will be appreciated that positive pressure may instead be generated.

While the embodiments described herein use a diaphragm 13, any suitable structure to transmit air pressure while isolating either side of the system may be used.

The breast pump may further comprise a pressure sensor in pneumatic connection with the piezo pump. This allows the output of the pump to be determined.

Figure 10 shows a schematic of a basic pneumatic system 200 for a breast pump 100. In the system 200 milk expressed into the breast shield 7 is directed through the breast shield nipple tunnel 9 through the torturous air-liquid labyrinth interface 95. The milk is directed through the non-return valve 37 to the collection container 3. This side of the system forms the "milk-flow" side 201.

The rest of the pneumatic system 200 forms the air side 202 and is separated from contact with milk. This is achieved by way of a flexible diaphragm 13 which forms a seal between the two sides of the system. The diaphragm 13 has a milk-flow side 13A and an air side or pumping side 13B.

The air side 202 of the system 200 is a closed system. This air side 202 may contain a pressure sensor 101 in pneumatic connection with the diaphragm 13 and the pump 83. Preferably, the pump 83 is a piezoelectric pump (or piezo pump). Due to their low noise, strength and compact size, piezoelectric pumps are ideally suited to the embodiment of a small, wearable breast pump. The pump 83 has an output 83A for generating pressure, and an exhaust to the atmosphere 83B. In a first phase of the expression cycle, the pump 83 gradually applies negative pressure to half of the closed system 202 behind the diaphragm 13. This causes the diaphragm 13 to extend away from the breast, and thus the diaphragm 13 conveys a decrease in pressure into the breast shield 7. The reduced pressure encourages milk expression from the breast, which is directed through the tortuous labyrinth system 95 and the one-way valve 37 to the collection bottle 3.

While in the depicted embodiment the air exhaust 83B is not used, it may be used for functions including, but not limited to, cooling of electrical components, inflation of the bottle to determine milk volume (discussed further later) or inflation of a massage bladder or liner against the breast. This massage bladder may be used to help mechanically encourage milk expression. More than one massage bladder may be inflated regularly or sequentially to massage one or more parts of the breast. Alternatively, the air pump may be used to provide warm air to one or more chambers configured to apply warmth to one or more parts of the breast to encourage let-down.

The air side 202 further comprises a two-way solenoid valve 103 connected to a filtered air inlet 105 and the pump 83. Alternatively, the filter could be fitted on the pump line 83A. If the filter is fitted here, all intake air is filtered but the performance of the pump may drop. After the negative pressure has been applied to the user's breast, air is bled into the system 202 through the valve 103 in a second phase of the expression cycle. In this embodiment, the air filter 105 is affixed to this inlet to protect the delicate components from degradation. In particular, in embodiments with piezoelectric components, these are particularly sensitive.

The second phase of the expression cycle and associated switching of valve 103 is actioned once a predefined pressure threshold has been reached. The pressure is detected by a pressure sensor 101.

In certain embodiments, if the elasticity and extension of the diaphragm 13 may be approximated mathematically at different pressures, the pressure measured by sensor 101 can be used to infer the pressures exposed to the nipple on the opposite side of the diaphragm 13. Figure 11 shows an alternative pneumatic system 300. The core architecture of this system is the same as the system shown in Figure 10.

In this system 300, the closed loop 202 is restricted with an additional three way solenoid valve 111. This valve 111 allows the diaphragm 13 to be selectively isolated from the rest of the closed loop 202. This additional three way valve 111 is located between the diaphragm 13 and the pump 83. The pressure sensor 101 is on the pump 83 side of the three way valve 111. The three way valve 111 is a single pole double throw (SPDT) valve,

wherein: the pole 111A is in pneumatic connection with the pump 83 and pressure sensor; one of the throws 11 is in pneumatic connection with the diaphragm 13; and the other throw 111C is in pneumatic connection with a dead-end 113. This dead-end 113 may either be a simple closed pipe, or any component(s) that does not allow the flow of air into the system 202. This could include, for example, an arrangement of one-way valves.

In this system 300, therefore, the pump 83 has the option of applying negative pressure directly to the pressure sensor 101. This allows repeated testing of the pump in order to calibrate pump systems, or to diagnose issues with the pump in what is called a dead end stop test. This is achieved by throwing the valve to connect the pump 83 to the dead end 113. The pump 83 then pulls directly against the dead end 113 and the reduction of pressure within the system can be detected by the pressure sensor 101.

The pressure sensor detects when pressure is delivered and is then able to measure the output of the pumping mechanism. The results of the pressure sensor are then sent to an external database for analysis such as a cloud database, or are fed back to an on-board microcontroller that is located inside the housing of the breast pump system.

Based on the pressure sensor measurements, the breast pump system is able to dynamically tune the operation of the pumping mechanism (i.e. the duty or pump cycle, duration of a pumping session, the voltage applied to the pumping mechanism, the peak negative air pressure) in order to ensure a consistent pressure performance across different breast pump systems.

In addition, the breast pump system, using the pressure sensor measurements, is able to determine if the pump is working correctly, within tolerance levels. Material fatigue of the pump is therefore directly assessed by the breast pump system. Hence, if the output of the pumping mechanism degrades over time, the breast pump system can tune the pumping mechanism operation accordingly. As an example, the breast pump system may increase the duration of a pumping session or the voltage applied to the pumping mechanism to ensure the expected pressures are met.

This ensures that the user experience is not altered, despite the changing output of the pump as it degrades over time. This is particularly relevant for piezo pumps where the output of the pump may vary significantly.

The microcontroller can also be programmed to deliver pre-set pressure profiles. The pressure profiles may correspond to, but not necessarily, any suction patterns that would mimic the sucking pattern of an infant. The patterns could mimic for example the sucking pattern of a breastfed infant during a post birth period or at a later period in lactation.

The profiles can also be manually adjusted by the user using a control interface on the housing of the breast pump system or on an application running on a connected device.

Additionally, the user is able to manually indicate the level of comfort that they are experiencing when they are using the system. This can be done using a touch or voice-based interface on the housing of the breast pump system itself or on an application running on a connected device.

The system stores the user-indicated comfort levels together with associated parameters of the pumping system. The pressure profiles may then be fine scaled in order to provide the optimum comfort level for a particular user.

The profiles or any of the pumping parameters may be calculated in order to correlate with maximum milk expression rate or quantity.

The pressure profiles or any of the pumping parameters may also be dynamically adjusted depending on the real time milk expression rate or quantity of milk collected. The pressure profiles or any of the pumping parameters may also be dynamically adjusted when the start of milk let-down has been detected.

Additionally, the system is also able to learn which parameters improve the breast pump system efficiency. The system is able to calculate or identify the parameters of the pumping mechanism that correlate with the quickest start of milk let-down or the highest volume of milk collected for a certain time period. The optimum comfort level for a particular user may also be taken into account.

Figure 12 shows a schematic for a system 400 for a breast pump 100 which can estimate the volume of milk collected in the collection container 3 from data collected on the air-side part 202 of the system 400.

The pump 83 is connected to the circuit via two bleed valves 126, 128. The first bleed valve 126 is arranged to function when the pump 83 applies a negative pressure. As such, this valve 126 is connected to a "bleed in" 127, for supplying atmospheric air to the system 202.

The second bleed valve 128 is arranged to function when the pump 83 applies a positive pressure. As such, this valve 128 is connected to a "bleed out" 129 for bleeding air in the system 202 to the atmosphere.

Although Section C describes the preferred embodiment for measuring or inferring the volume of milk collected in the milk collection container using IR sensors, an alternative method for measuring or inferring the volume of milk collected in the milk collection container using pressure sensors is described also below.

During a milking pump cycle, the pump 83 applies negative pressure on the air side 13B of the diaphragm 13 which causes its extension towards the pump 83. This increases the volume of the space on the milk side 13B of the diaphragm 13. This conveys the decrease in pressure to the breast to encourage expression of milk. A set of three non-return valves 121, 123, 125 ensure that this decrease in pressure is applied only to the breast (via the breast shield 7) and not the milk collection container 3. To measure the volume of milk collected in the container 3, the pump 83 is used instead to apply positive pressure to the diaphragm 13. The diaphragm 13 is forced to extend away from the pump 83 and conveys the pressure increase to the milk side 201 of the system 400. The three non-return valves 121, 123, 125 ensure that this increase in pressure is exclusively conveyed to the milk collection container 13.

The breast pump may further comprise: a first non-return valve between the milk flow side of the diaphragm and the breast shield, configured to allow only a negative pressure to be applied to the breast shield by the pump; a second non-return valve between the milk-flow side of the diaphragm and the milk collection container configured to allow only a positive pressure to be applied to the milk collection container by the pump; and a pressure sensor in pneumatic connection with the pressure-generation side of the diaphragm.

The resulting pressure increase is monitored behind the diaphragm 13 from the air-side 202 by a pressure sensor 101. Preferably, the pressure sensor 101 is a piezoelectric pressure sensor (piezo pressure sensor). The rate at which the pump 83 (at constant strength) is able to increase the pressure in the system 400 is a function of the volume of air that remains in the milk collection container 3. As air is many times more compressible than liquid, the rate at which pressure increases in the system 400 can be expressed as an approximate function of the volume of milk held in the collection container 3.

Thus by increasing the pressure in this fashion, the rate of pressure increase can be determined, from which the volume of milk held in the container 3 is calculable. Figure 13 shows repeated milking and volume measurement cycles as the collection container 3 is filled. To determine the rate of pressure increase the pump 83 was run for a fixed time. As pumping proceeds and the volume of air reduces in the system 400, the pump 83 is able to achieve a higher pressure. Each milking cycle is represented by a positive pressure spike 41. There is a clear upwards trend 43 in magnitude of positive pressures achieved as the collection container 3 is filled.

A method of estimating the pressure applied by a breast pump may comprise the steps of: selecting a pressure cycle from a pre-defined list of pressure cycles; applying pressure with the pump to stimulate milk expression; reading the output of the pressure sensor; and adjusting the applied pressure of the pump to match the pressure profile selected. This allows for repeatable application of force to the breast, even as the pump performance degrades.

Preferably the method further comprises the steps of: approximating the elasticity and extension of the diaphragm at the relevant pressure; and calculating an estimated applied pressure based upon the output of the pressure sensor and the approximated elasticity and extension of the diaphragm.

Alternatively, a method of estimating the milk collected by a breast pump may comprise the steps of: generating a positive pressure with the pump; transmitting the positive pressure via the diaphragm and second non-return valve to only the milk collection

container; measuring the increase in pressure by the pressure sensor in pneumatic connection with the diaphragm; estimating the volume of milk inside the milk collection container based upon the rate of increase of pressure. In this manner, the volume of milk can be estimated remotely.

In this manner, an estimate can be obtained for the volume of milk in the container 3 based upon the measured pressures.

Figure 13 also shows a dead end stop pump test 45 as described above. The negative spike shows the application of negative pressure directly to the pressure sensor 101.

2. Breast shield sizing and nipple alignment

The correct sizing of the breast shield and the alignment of the nipple in the breast shield are key for an efficient and comfortable use of the breast pump. However breast shape, size as well as nipple size and position on the breast vary from one person to another and one breast from another. In addition, women's bodies often change during the pumping life cycle and consequently breast shield sizing may also need to be changed. Therefore, a number of breast shield sizes are available. Guide lines for correct nipple alignment are also provided.

With reference to Figure 14, three breast shield sizes are shown (A1, B1, C1). The substantially clear breast shield gives an unobstructed view of the breast and allows a user to easily confirm that she has the appropriate sized shield for her breast.

In order to determine the correct breast shield size and nipple alignment, the breast shield and the diaphragm are detached from the housing and placed on the breast with the sizing symbol facing upwards (with the diaphragm positioned below the nipple) and the nipple aligned in the centre of the fit lines (as shown in A2, B2, C2). The transparent breast shield allows the user to observe the nipple while adjusting the position of the breast shield in order to align the nipple correctly near the centre of the breast shield nipple tunnel. Prior to using the pump, the nipple is aligned correctly, and the breast shield is pushed into place ensuring the seal is correctly positioned on the breast shield. The fit lines should be directly aligned with the outside of the nipple. The correct

alignment is illustrated B2.

When the nipple is correctly aligned, the user then rotates the breast shield in order for the diaphragm to be positioned on top of the nipple. The user may then quickly assemble the rest of the breast pump (i.e. the housing and the milk container) on the breast shield via a one-click attachment mechanism confirming correct engagement, which may be performed one-handed. Nipple alignment may therefore be easily maintained. Audio and/or haptic feedback may also be provided to further confirm correct engagement.

3. Connected Device Application

Figures 15 to 20 show examples of screenshots of a connected device application that may be used in conjunction with the breast pump system as described above. The interface shown here is an example only and the same data may be presented via any conceivable means including animated graphics, device notifications, audio or text descriptions.

Figure 15 shows a homepage of the application with different functions provided to the user which can be accessed either directly while pumping or at a later time in order for example: to review pump settings or the history of previous pumping sessions.

Figure 16 shows a status page with details of remaining battery life, pumping time elapsed and volume of milk inside the milk container.

Figure 17 shows screenshots of a control page, in which a user is able to control different pump parameters for a single breast pump (A) or two breast pumps (B). The user may press on the play button to either start, pause, or resume a pumping activity. The user may also directly increase or decrease the rate of expression using the (+) or (-) buttons. When only one breast is being pumped (A), the user may also indicate if it is either the right or left breast that is being pumped. The user may also control the pump peak pressure or alternatively may switch between different pre-programmed pressure profiles such as one mimicking the sucking pattern of a baby during expression or stimulation cycle.

Figure 18 shows a page providing a summary of the last recorded pumping session.

Figure 19 shows a page providing a history of previous pumping sessions. The user may scroll down through the page and visualize the data related to specific pumping sessions as a function of time.

The application is also capable of providing notifications relating to pumping. Figure 20 shows a screenshot of the application, in which a user is provided a notification when the milk collection bottle is full. Other generated notifications may include warnings about battery life, Bluetooth connection status or any other wireless communication status, status of miss-assembly, excessive movement or lack of expression.

Figure 21 shows a further example with a screenshot of an application running on a connected device. The page shows the pumping status when a user is using a double pump mode of operation with a pump on each breast. The user is able to manually control each pump individually and may start, stop or change a pumping cycle, increase or decrease each pump peak pressure, or switch between different pre-program pressure profiles such as one mimicking the sucking pattern of a baby during an expression or stimulation cycle. The application also notifies the user when a milk collection container is nearly full as shown in Figure 22.

Figure 23 shows a status page with an alert notifying the user that the milk collection container of the pump on the right breast is full. A message is displayed that the pump session has paused and that the milk collection container should be changed or emptied before resuming pumping.

With reference to Figure 24, when the left and right pump are stopped or paused, the application displays the elapsed time since the start of each session (right and left), the total volume of milk collected in each bottle.

With reference to Figure 25, a page summarising the last session (with a double pump mode) is displayed.

In addition to the data provided to the user, and their interactions with the application, the app will also hold data that the user does not interact with. For example, this may include data associated with pump diagnostics. In addition to all functions and sources of

data discussed above, the application may itself generate metadata associated with its use or inputs, notes or files uploaded by the user. All data handled within the mobile application can be periodically transferred to a cloud database for analysis. An alternative embodiment of the breast pump system may include direct contact between the database and the pump, so that pumping data may be conveyed directly, without the use of a smartphone application.

In addition to providing data to the cloud, the application may also provide a platform to receive data including for example firmware updates.

4. Breast pump data analysis

The discreet, wearable and fully integrated breast pump may offer live expression monitoring and intelligent feedback to the user in order to provide recommendations for improving pump efficiency or performance, user comfort or other pumping/sensing variables, and to enable the user to understand what variables correlate to good milk flow.

Examples of variables automatically collected by the device are: time of day, pump speed, pressure level setting, measured pressure, pressure cycle or duty cycle, voltage supplied to pumps, flow rate, volume of milk, tilt,, temperature, events such as when let-down happens, when a session is finished. The user can also input the following variables: what side they have pump with (left or right or both), and the comfort level.

This is in part possible because the live milk volume measurement system functions reliably (as discussed in Section B). The breast pump system includes a measurement sub system including IR sensors that measures or infers milk flow into the milk container, and that enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. The generated data may then be distributed to a connected device and/or to a cloud server for analysis in order to provide several useful functions.

Figure 26 illustrates an outline of a smart breast pump system network which includes the breast pump system (100) in communication with a peripheral mobile device and application (270) and several cloud-based databases (268, 273). The breast pump system

(100) includes several sensors (262). Sensor data refers to a broad definition including data generated from any sensor or any other analogue/digital reading directly from the motherboard or any other component. However, within the embodiment detailed, these measurements include one or more of the following, but not limited to: milk volume measurements, temperature sensor readings, skin temperature sensing, pressure sensor readings, accelerometer data and user inputs through any physical device interface.

The device also contains a number of actuators, including, but not restricted to: piezoelectric pump(s), solenoid valve(s), IREDs and an LED display. Sensors and actuators within the device are coordinated by the CPU (263). In addition, any interactions, and data from these components, may be stored in memory (264).

Further to these components, the device also contains a communication chip, such as a Bluetooth chip (265) which can be used to communicate wirelessly with connected devices such as a peripheral mobile device (270). Through this connection any sensor data (267) generated in the breast pump can be sent to the connected device. This user data, along with any other metadata generated from a connected device app, can be provided to an online database which aggregates all user data (273). In addition, the communication chip will also allow the sending of user control data / firmware updates from the connected device to the breast pump system (266).

Raw data (271) collected from the measurement sub-system including sensors (262) may be analysed on a cloud database and the analysed data may be stored on the cloud (272). Through inferences provided by the analysed data, firmware updates (269) may be developed. These can be provided for download to the pump through, for example, an online firmware repository or bundled with the companion app in the connected device app store (268).

In addition, it should be appreciated that despite the sophistication of the proposed breast pump network, the breast pump still retains complete functionality without wireless integration into this network. Relevant data may be stored in the device's memory (264) which may then be later uploaded to the peripheral portion of the system when a connection is established, the connection could be via USB cable or wireless.

The measurement sub-system may analyse one or more of the following:

- the quantity of the liquid in the container above its base;
- the height of the liquid in the container above its base;
- the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.

Based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase, a haptic and/or visual indicator indicates if the pump is operating correctly to pump milk. For example, the visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.

The visual indicator may provide:

- an estimation of the flow rate;
- an estimation of the fill rate;
- an indication of how much of the container has been filled.

As a further example, an accelerometer may infer the amount of movement or tilt angle during a pumping session. If the tilt angle excesses a threshold, the system warns or alerts the user of an imminent spillage, or provides the user with an alert to change position. Alternatively, the system may also stop pumping to prevent spillage, and once the tilt angle reduces below the threshold, pumping may resume automatically. By sensing the movement or title angle during a pumping session, the system may also derive the user's activity such as walking, standing or lying.

Many variables can affect milk expression and data analysis of these multiple variables can help mothers to achieve efficient pumping regimes and improve the overall user experience.

Therefore, the measurement sub-system measures or infers milk flow into the milk container and enables a user to understand what variables (e.g. time of day, pump setting) correlates to good milk flow. The amount of milk expressed over one or more sessions is recorded as well as additional metrics such as: time of day, pump setting, length of a single pumping session, vacuum level, cycle times, comfort, liquids consumed by the mother. Live data or feedback is then provided to the user to ensure the breast pump is

being used properly and to support the user in understanding the variables that would correspond to the specific individual optimum use of the breast pump.

Furthermore, live data can be used to automatically and intelligently affect specific pumping parameters in order to produce the most efficient pumping session. For example, if the rate of expression increases, the milking cycle might be adjusted accordingly to achieve a more efficient, or more comfortable pumping cycle.

The measurement sub-system also enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. Collected metrics are transferred through wireless connections between the pump, a connected device or app and a cloud database. Additionally, the application can also connect to other apps residing on the connected device, such as fitness app or social media app or any other apps. Further metrics may also include the behaviour or specific usage of the user associated with the connected device while using the pump (detection of vision and/or audio cues, internet usage, application usage, calls, text message).

Different aspects of pumping can be automatically changed based on dynamic sensor feedback within the breast pump device. The data analysis system is able to access real-time data of pumping sessions and may be used to perform one or more of the following functions, but not limited to:

- indicate whether the milk is flowing or not flowing,
- measure or infer the quantity and/or height of the liquid in the container above its base,
- give recommendations to the mother for optimal metrics for optimal milk flow,
- give recommendations to the mother for optimal metrics for weaning,
- give recommendations to the mother for optimal metrics for increasing milk supply (e.g. power pumping),
- give recommendations to the mother for optimal metrics if an optimal session start time or a complete session has been missed,
- automatically set metrics for the pumping mechanism, such as length of a single pumping session, vacuum level, cycle times.
- automatically stop pumping when the milk container is full,
- automatically adjust one or more pumping parameters to achieve an optimum

pumping session,

- automatically adjust one or more pumping parameters to achieve a comfortable pumping session,
- automatically change the pumping cycle from a programmed cycle to another different programmed cycle, such as from a stimulation cycle to an expression cycle.

In addition, sensor feedback might be used to improve the physical function of the breast pump system itself. For example, an array of piezoelectric pumps may be dynamically adjusted in response to their operating temperatures so as to optimise the total life of the component whist maintaining peak pressures.

Many additional embodiments may be described for these simple feedback systems, yet the premise remains: real-time sensor feedback is used to automatically and dynamically adjust actuator function. Each feedback program may feasibly include any number and combination of data sources and affect any arrangement of actuators.

The data generated can also be used to generate large datasets of pumping parameters, user metadata and associated expression rates, therefore allowing the analysis of trends and the construction of associations or correlations that can be used to improve pumping efficiency, efficacy or any function related to effective milk expression. The analysis of large user datasets may yield useful general associations between pumping parameters and expression data, which may be used to construct additional feedback systems to include on firmware updates.

Multiple data sources can be interpreted simultaneously and several different changes to pumping might be actuated to increase pumping efficiency, user experience or optimize pump performance.

Collected metrics may be anonymised and exported for sharing to other apps, community or social media platforms on the connected device, or to an external products and services, such as community or social media platform. By contrasting the performance of different users in the context of associated metadata, users may be grouped into discrete 'Pumper profiles' or communities, which may then be used to

recommend, or action the most appropriate selection of intelligent feedback systems to encourage efficient expression. For example, a higher peak pressure may be recommended for women who tend to move more whilst pumping, so as to achieve more efficient expression.

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SECTION B: IR SYSTEM

This section describes the milk detecting system used in the Elvie™ pump.

With reference to Figures 27 and 28, there is shown a device 270 for use in detecting the level of liquid inside a container 275. The device 270 is formed of a housing 271 in which is located a sensing assembly 272 comprising a series of optical emitters 273 (an array of three optical emitters is used on one implementation) which are relative to, and each located at a distance from, an optical receiver 274. In operation of the device as will be described, each optical emitter 273 is operable to emit radiation which is received by the optical receiver 274. In an embodiment of the invention, the series of optical emitters are each located equidistant from the optical receiver 274.

The optical emitters 273 and the optical receiver 274 from the sensing assembly 272 are located in a portion 276 of the device 270 which faces the container 275 when the device is connected to the container 275. The portion 276 of the device 270 containing the optical emitters 273 and the optical receiver 274 comprises a window 277 of material which is transparent to optical radiation. In this way, each of the optical emitters 273 and the optical receiver 274 have a line of sight through the window 277 into the container 275 when the device 270 is connected thereto.

A controller 278 comprising a CPU 279 and a memory 280 is provided in the device 270 for controlling the operation of the sensing assembly 272. An accelerometer 281 is also provided in the housing 271, which is operatively connected to the controller 278. Operation of the device 270 when connected to the container 275 will now be described.

In a principal mode of operation, to determine the level L of liquid inside the container 275, the controller 278 instructs the optical emitters 273 to each emit radiation towards the surface of the liquid inside the container 275 at a given intensity. The optical receiver 274 receives the reflected radiation from each optical emitter 273 via the surface of the liquid and each of these intensities is recorded by the controller.

For each operation of the sensing assembly 272, the controller 278 records the intensities of radiation emitted by each of the optical emitters 273 as intensities IE1; IE2...IEn

(where n is the total number of optical emitters), and records the intensities of radiation received by the optical receiver 274 from each of the optical emitters 273 as received intensities IR1; IR2…IRn.

By comparing the emitted radiation intensities IE1; IE2…IEn with the received radiation intensities IR1; IR2…IRn, the controller 278 calculates a series of intensity ratios IE1:IR1; IE2:IR2…IEn:IRn, which are then used to determine the level of the liquid inside the container. At the most basic level, if the intensity ratio of IE1:IR1 is the same as IE2:IR2, given the optical emitters 273 are equidistant from the optical receiver 274, this indicates that the level of the liquid inside the container is parallel to the top of the bottle, as shown in Figure 27. In contrast, if these two intensity ratios are different, this indicates that the liquid level is at a different angle, such as that shown in Figure 28.

To accurately determine the level and the quantity of liquid inside the container 275, the controller 278 processes the recorded intensity ratios using a database located in the memory 280. The database contains an individual record for each container which is operable to connect with the device 270. Each record from the database contains a look-up table of information, which contains expected intensity ratios (IE1:IR1 and IE2:IR2) for the container 275 when filled at different orientations, and with different quantities of liquid.

By comparing the information from the look-up table with the recorded intensity ratios, the controller 278 calculates the level and quantity of liquid inside the container 275 and stores this information in the memory 280.

In situations where a container 275 to the device 270 contains no stored record in the database, the sensing assembly 272 can be used in a calibration mode to create a new record. In the calibration mode, the sensing assembly 272 is operated as the container is filled from empty, and as it is positioned at different orientations. At each point during the calibration mode, the controller 278 calculates the recorded intensity ratios (IE1:IR1 and IE2:IR2) and stores them in the record relating to the container 275. For each set of recorded intensity ratios, the user includes information in the record relating to the orientation and fill level of liquid inside of the container 275.

To improve the accuracy of the results obtained by the device 270 during its use, the controller 278 when recording each intensity ratio also records a parameter from the accelerometer 281 relating to the acceleration experienced by the device 270. For each recorded acceleration parameter, the controller 278 determines whether the parameter 278 exceeds a predetermined threshold acceleration parameter stored in the memory 280. The predetermined threshold is indicative of an excessive acceleration, which causes sloshing of liquid inside the container 275 connected to the device 270. In the event of a recorded acceleration parameter exceeding the predetermined threshold acceleration parameter, the controller 278 flags the recorded intensity ratios associated with the recorded acceleration parameter as being unreliable (due to sloshing).

Even without the use of the accelerometer 281, the controller 278 is nonetheless operable to determine whether a set of recorded intensity ratios occur during a period of excess acceleration. In this regard, for each set of intensity ratios recorded at a given time, the controller 278 checks whether any of these intensity ratios is of a predetermined order of magnitude different than the remaining recorded intensity ratios from the set. In the event that the controller 278 determines that this is the case, this indicates that the liquid inside the container has 'sloshed' as a result of the excess acceleration, as shown in Figure 29. In this event, the controller 278 flags the set of recorded intensity ratios as being unreliable.

It will be appreciated that instead of recording the relative intensities of radiation emitted by the optical emitters 273 with the radiation received by the optical emitter 274, the controller 278 could instead record the time taken for radiation emitted by each of the optical emitters 273 to be received by the optical receiver 274. In this arrangement, the look up table would instead contain time periods as opposed to intensity ratios.

In terms of the applications for the device 270, it will be appreciated that the device can be used in a wide variety of applications. One possible application is the use of the device 270 to determine the level of liquid located within a container 275, such as a baby bottle, used as part of a breast pump assembly. In this arrangement, the device 270 is associated with a breast pump 301 which assists with the expression of milk from a breast. The breast pump may be located in the housing 271 of the device 270 as shown in Figure 30, or it may be realisably connected to the housing 271.

Either way, the device 270 would be connectable to the container 275 such that milk expressed by the breast pump can pass from the pump via a channel 302 into the container 275.

The breast pump may be any type of breast pump system including any shapes of milk container or bottle and may comprise a pump module for pumping milk from a breast. The pump module being contained within the housing may comprise: a coupling, a container attachable to the housing via the coupling to receive milk from the pump, a sensing assembly within the housing and comprising at least one optical emitter operable to emit optical radiation towards the surface of the body of milk held in the container when the housing is connected to the container, an optical receiver for receiving the reflected radiation from the surface of the milk, and a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the milk inside the container based on the reflected radiation received by the optical receiver.

By determining the level of milk inside the container based on reflected radiation from the surface of the milk in the container, there is no need to monitor the individual droplets of milk entering the container, such that the sensing assembly can avoid errors associated with measuring these droplets. For example, because we take multiple reflection-based measurements once the container is filled, we can generate an average measurement that that is more accurate than a single measurement. But with systems that rely in counting individual droplets, that is not possible – further, systemic errors (e.g. not counting droplets below a certain size) will accumulate over time and render the overall results unreliable. Furthermore, by not needing to measure these droplets, the sensing assembly from the breast pump need not always be on during the pumping process, which saves power.

When at least two optical emitters are used, the sensing assembly from the breast pump may determine the level of milk inside the container more accurately and irrespective of the orientation of the liquid level inside the container.

Each optical emitter may be equidistant from the optical receiver in order for the

controller to easily calculate the level of the milk inside the container based on the reflected radiation originating from each optical emitter. The signals from the optical receiver preferably comprise information relating to the intensity of the radiation received by the optical receiver.

Each optical emitter may be operable to emit radiation at a different wavelength, or at a different time, than the other optical emitters. In this way, the controller can more easily process the signals from the optical receiver, and more easily distinguish between the radiation emitted by each of the optical emitters.

The optical emitter may emit radiation in the visible range of wavelengths. Alternatively, it may be UV or IR light. The emitted wavelength may be for example between 10nm and 1mm.

The sensing assembly may also comprise at least one accelerometer electrically connected to the controller. The controller may be configured to record an accelerometer parameter from the accelerometer and determine whether the accelerometer parameter exceeds a predetermined threshold. The predetermined threshold may be indicative of an excessive acceleration, which might cause sloshing of milk inside any container connected to the breast pump.

Another application for the device 270 is as a collar for detecting the level/quantity of liquid in a container 275, such as a baby bottle, via its lid 310. An example of the device 270 being used as such a collar is shown in Figure 31. In this arrangement, the device 270 is located between the container 275 and the lid 310, and comprises a first end 311 having a first coupling 312 for attaching the collar to the lid 310. The device comprises a second end 313 having a second coupling 314 for attaching the device 270 to the container 275. The second coupling may be a screw thread, shown in Figure 31, on the inside surface of the container 275. In this way, the distinctive bottom inside surface can be used by the sensing assembly 272 to more easily calibrate itself to the container 275 on which the distinctive bottom inside surface is located. The distinctive bottom may also be used to help identify which container 275 the device is connected to, and thus which record should be used from the database when the device 270 is used.

To further improve the accuracy of the sensing assembly 272, the controller 278 may also be configured to use the recorded information from the accelerometer 281, in situations where the record acceleration is below the predetermined threshold acceleration parameter, to calculate a more accurate liquid level and/or quantity of liquid located inside the container which is compensated for acceleration.

In one particular arrangement, the controller 278 may poll the accelerometer 281 prior to each operation of the sensing assembly 272 to verify that the device 270 is not currently undergoing excessive acceleration. In the event of the controller 278 determining excessive acceleration in the device 270, the controller 278 would continually re-poll the accelerometer, and not operate the sensing assembly 272, until the parameter from the accelerometer is determined as being below the predetermined threshold acceleration parameter stored in the memory 280.

It will also be appreciated that for each container record stored in the database, the container record may comprise a plurality of look up tables, wherein each look up table is associated with a particular liquid used in the container, and wherein each look up table contains its own set of intensity ratios. In this way, the device 270 can more accurately determine the level/quantity of different liquids used in a particular container 275.

As described herein, the sensing assembly 272 has been described as having a plurality of optical emitters 273. It will be appreciated however that the sensing assembly could operate using a single optical emitter 273 and plurality of optical receivers 274. In this arrangement, each record from the database would contain a plurality of ratios relating to the emitted radiation from the optical emitter 273 as received by each of the optical receivers 274. In use of the device 270, the controller 278 would then similarly record the emitted radiation from the optical emitter 273 as received by each of the optical receivers 274. In an alternate arrangement, there may be provided a plurality of optical emitters 273 and a plurality of optical receivers 274, wherein each optical emitter 273 is associated with a respective optical receiver 274. In its simplest arrangement, the sensing assembly 272 may comprise a single optical emitter 273 and a single optical receiver 274.

In certain configurations, the optical emitters 273 may together emit radiation having the same wavelength. In other configurations, the optical emitters 273 may each emit

radiation having a different wavelength. In this latter configuration, the optical receiver 274 would then be able to determine which optical emitter 273 is associated with any given received radiation, based on the wavelength of the received radiation.

The optical emitters 273 may also each emit radiation at different times, such to allow the controller 278 to more easily process the signals from the optical receiver 274, and more easily distinguish between the radiation emitted by each of the optical emitters 273.

In relation to the electrical connection between the controller 278 and the sensing assembly 272, it will be appreciated this electrical connection may be either a wired/wireless connection as required.

Although not shown in the Figures, the device 270 herein described is preferably powered by a battery or some other power source located in the device 270. In other embodiments, the device 270 may be powered using mains electricity.

In one configuration, it is also envisaged that rather than the controller 278 comparing the information from the look-up table with the recorded intensity ratios to calculate the level and quantity of liquid inside the container 275, the controller 278 could instead process the recorded intensity ratios through a liquid-level equation stored in the memory 280. In this configuration, the liquid-level equation could be a generalised equation covering a family of different containers, or could be an equation specific to a container having a given shape and/or type of liquid inside.

It will also be appreciated that in some applications of the device 270, the device could be used to detect the level of a solid, as opposed to a liquid, in a container. As used herein, the terms 'optical emitter' and 'optical receiver' are intended to cover sensors which can emit radiation in or close to the optical wavelength. Any type of radiation at or close to the optical wavelength is suitable provided that it does not have any harmful effects. The exact wavelength is not important in the context of the invention. Such sensors thus include those which can emit visible radiation (such as radiation having wavelengths in the region of 400nm-700nm), and/or those which can emit IR radiation (such as radiation having wavelengths in the region of 700nm-1mm and/or those which can emit UV radiation (such as radiation having wavelengths in the region of 10nm to

400nm).

Existing prior art for such a sensor module is the apparatus disclosed in RU2441367. In this apparatus, the container is an industrially sized milk tank, which only includes a single laser mounted at the top of the tank. Whilst this apparatus is suited for large-sized containers, which do not move in use, the apparatus is less-suited for applications where the container moves in use, or where the liquid level inside the container is non perpendicular to the laser beam shone into the container. In contrast, the sensor module described above can be used in a variety of different applications, is conveniently located within a housing, and which by virtue of it having at least two optical emitters, can determine the level of liquid even inside containers of irregular shapes, and which can determine the level of liquid inside a container irrespective of the orientation of the liquid level inside the container.

Further to the embodiments of the fluid measurement system in different contexts, it can be appreciated that different functions entirely may be possible using the same component structure. For example, it is known that certain molecules within breast milk absorb specific wavelengths of light at characteristic propensities. Whilst the proposed system uses multiplexed IREDs at the same wavelengths to perform proximity measurements, the same array of IREDs may instead be used to emit several different wavelengths of light and determine their absorption upon reflection. If appropriately calibrated, the system may be able to report on the presence or concentration of specific compounds in the expressed milk, such as fat, lactose or protein content.

In addition to this embodiment, it is feasible that the system might be applied to monitor the change in volume of any other container of liquid, given there is sufficient reflection of IR off its surface. These embodiments might include for example: liquid vessel measurement such as for protein shakes, cement or paint, or volume measurements within a sealed beer keg.

SECTION C: BRA CLIP

This section describes a bra clip that forms an accessory to the Elvie™ pump.

It relates to a system allowing a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump. As such, the user does not need a specialised adjustable bra; instead the present system works with all conventional maternity bras. The user also does not have to purchase any larger bras to wear while pumping.

As shown in Figure 32, a typical maternity bra 320 comprises a support structure made up of shoulder straps 321 which support the bra 320 on the wearer's shoulders, and a bra band 322 for extending around a user's ribcage, comprising two wings 323 and a central panel or bridge 324. The straps 321 are typically provided with adjustment mechanisms 325 for varying the length of the straps 321 to fit the bra 320 to the wearer. At the outermost end of each wing, an attachment region 326 is provided. Typically, hooks 327 and loops 328 are provided for securing the bra 320 at the user's back. However, any other suitable attachment mechanism may be used. Alternatively, the attachment region 326 may be provided at the front of the bra 320 in the bridge region 324, with a continuous wing 323 extending continuously around the wearer's back. Typically, a number of sets of loops 328 are provided to allow for variation in the tightness of the bra 320 on the wearer. While shown as having a separation in Figure 32, the wings 323 and bridge 324 may form a single continuous piece in certain designs. Likewise, while shown with a distinct separation in Figure 32, the shoulder straps 321 and the wings 323 may likewise form a single continuous piece.

The maternity bra 320 is further provided with two breast-supporting cups 329 attached to the support structure. The cups 329 define a cup size, which defines the difference in protrusion of the cups 329 from the band 322. The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting a 2 cm difference between the protrusion of the cups 329 from the band 322. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes

of S, M, L, XL, etc.

The cups 329 may be stitched to the bra band 321. At least one of the cups 329, is in detachable attachment with the corresponding strap 321. In particular, this is achieved at attachment point 330 where a hook 331 attached to the bra strap 321 engages with a clasp 331 attached to the cup 329. The hook 331 and the bra strap adjuster 325 are set such that in the closed position, the cup size of the bra 320 fits the wearer's breasts.

In Figure 32, the left cup 329 is shown attached to its attachment point 330, which the right cup 329 is unattached. In this manner, the wearer is able to detach the cup 329 to expose their breast for feeding or for breast pumping. Once this is completed, the cup 329 is reattached and the maternity bra 320 continues to function as a normal bra.

While in the depicted embodiments, a hook 331 is shown on the bra strap 321 and a clasp 332 is shown on the cup 329, it is appreciated that the provision of these may be reversed, or that alternative attachment mechanisms may be used.

A maternity bra therefore may comprise a support structure comprising shoulder straps and a bra band and a first and a second cup each attached to the support structure to provide a first cup size, at least one cup being at least partially detachable from the support structure at an attachment point.

In other embodiments, the detachable attachment point 330 may be provided at a different location, such as at the attachment between the bra band 322 and the cup 329. The mechanism for such an attachment point is the same as described above.

A clip has been designed such that it is configured to be attached to the support structure at a position away from the attachment point. This results in the original attachment point being usable, with the clip providing an alternative attachment point to give, in effect, an adjusted cup size.

Alternatively, the clip may also be attachable to the support structure at a plurality of non-discrete positions. This ensures essentially infinite adjustment of the clip position such that the perfect position for the user can be found.

The clip can also extend between an unextended and an extended state, and can attach to the support structure at the attachment point; the first cup size is providable when the at least partially detachable cup is attached to the clip when the clip is an unextended state; the second cup size is providable when the at least partially detachable cup is attached to the clip when the clip is in an extended state. An extendable clip like this allows quick switching between the two states in use.

Figure 33 depict a clip 335 according to the present invention, along with a clasp 332 shown in isolation from the bra cup 329 it is normally attached to. The clip comprises a first engagement mechanism and at least one second engagement mechanism(s). The clip is attachable in a releasable manner to the support structure at a first position via the first engagement mechanism and attachable in a releasable manner to one of the partially detachable cups via the second engagement mechanism to provide a second cup size different to the first cup size. The clip 335 is provided with a material pathway 336 which receives a portion of the bra strap 321. In the particular embodiment of these Figures, the clip 335 is substantially U-shaped, with a narrowing profile towards its open end. However, it is appreciated that any other suitable shape with a material pathway may be used, such as an S-shape or E-shape. The clip 335 is designed to be attached to the bra strap 321 in a releasable manner, with the slot 336 acting as a support engaging mechanism. The releasable manner means that the clip 335 may be simply removed from the bra 320 without causing any damage to the functioning of the bra 320. To enhance the ease of attachment, the clip 335 may be provided with outwardly extending wings 204 which help direct the bra strap 321 into the clip 335. The clip 335 is further provided with a hook 220 acting as a cup engaging mechanism which can engage with the clasp 332.

Figure 33 (c) shows the clip 335 being attached to a bra strap 321 in order to provide a second attachment point 337 for the clasp 332 to attach to, and hence to provide a second cup size for the bra 320. In this particular embodiment, the clip 335 is attached in a portion of strap 321A below the original attachment point 330 and hence the second attachment point 337 is likewise below the original attachment point. This results in a second cup size larger than the first cup size. In preferred embodiments, as shown in these Figures, the clip 335 engages with the support structure in a direction transverse to

the direction in which it engages with the cup.

Figure 33 (d) and (e) show how a wearer is able to move between the first and second cup sizes. In 33(d), the cup 329 is attached at the first attachment point 330 to provide a first cup size. The wearer then disengages the clasp 332 from the hook 331 at the hook 338 at the second engagement point 239. In this manner, the wearer is easily able to transition between the two cup sizes.

Figures 34 and 35 show an alternative design for a clip 340. This clip 340 is substantially "E-shaped", with a back portion 341 and first, second and 5 third prongs 342A, 342B, 342C extending transverse from this back portion 341. The three prongs 342A, 342B, 342C are spaced apart along the length of the back portion 341. The first and third prongs 342A, 342C are provided with attachment clips 343A, 343B.

These attachment clips 343A, 343B can engage with the clasp 332 of a bra to provide the second cup size. Depending upon the orientation of the clip 300, one or the other of the attachment clips 343A, 343B will be used to attach the clasp 332 of the bra. By providing these clips 343A, 343B on both of the first and the third prongs 342A, 342C the clip is easily reversible so it can be used on either side of the bra. Preferably the clip 340 is also symmetrical, to aid the reversibility of the clip 340.

Figure 35 shows the clip 340 attached to a bra. As can be seen, the first and third prongs 342A, 342C extend on the front side of the bra strap, with the second prong 342B extending on the rear side of the bra strap. In this manner, the clip 340 is attached to the strap. In preferable embodiments, a grip-enhancing member 344 such as a number of projections and/or roughened patches can be provided on the second prong 342B in order to strengthen this grip.

In alternative embodiments, the attachment clip could be provided on the second, centremost prong 342B. In such an arrangement, the centremost prong 342B would be on the outside of the bra, with the first and third prongs 342A, 342C on the inside.

The provision of the attachable clip allows maternity bras already owned by the wearer to be quickly transformed into bras with quick switchable double cup size options.

This allows the use of integrated wearable breast pumps which increase the user's required cup size. This allows more design freedom for the breast pump in terms of size and shape, while still allowing the user to discretely pump with the pump held within their bra. By allowing conversion of the user's existing maternity bras, they are not forced to purchase specially designed bras to wear with the pump. The bra is hence normally at the first engagement point 330 when the breast pump device is not being used. As shown in Figure 33, the clasp 332 is then engaged by the user to discretely switch between the two configurations, and the user then inserts the pump without any complex adjustment or removal of clothing.

Preferably, the clip will be relatively unobtrusive in size and shape and hence can be left in place when the bra is first put on and used when necessary. To this end, the clip is preferably machine washable without significant damage or degradation.

In some embodiments, the clip may be switchable between positions for engaging with each cup so that a single clip may be used on either side of the bra. To achieve this, the clip is preferably reversible. This may provide the user with a visual indication of which breast has produced milk most recently so switching can take place.

In a preferred embodiment, the first engagement mechanism engages with the support structure in a first direction and the second engagement mechanism engages with the cup in a second direction transverse to the first direction. This increases ease of attachment as with this structure the sideways engagement of the clip to the support structure ensures that the second attachment mechanism is correctly orientated for the cup.

The second engagement mechanism may be one or more of a hook or a snap or a clip. This ensures easy interfacing with the traditional hook and clasp systems already provided on maternity bras.

Preferably the clip further comprises two distinct second engagement mechanisms which can be used interchangeably dependent upon the orientation of the clip. This makes the clip easier to use as it can be quickly switched between each bra strap, and the user does not have to worry which way up to put the clip on.

Preferably, the clip comprises a material pathway with an opening for receiving a portion of the support structure as the first engagement mechanism for securing the clip to the bra. This ensures a quick and simple method for attaching the clip to the bra. In particular, the clip may substantially U-shaped, and the material pathway is between the arms of the U.

Preferably, the clip comprises three prongs extending from a central support, the three prongs arranged as a central prong and two outer prongs so as to receive the support structure on one side of the central prong and on the opposite side of each respective outer prong, at least one prong being provided with the second engagement mechanism. This ensures a strong attachment to the bra and a simple design.

Preferably, both outer prongs are each provided with a respective second engagement mechanism. This ensures that the clip is reversible for easier attachment to the bra.

A method of adjusting the cup size of a maternity bra is provided according to the present invention, comprising: providing a maternity bra comprising: a support structure comprising shoulder straps and a bra band; and a first and second cup each attached to the support structure to provide a first cup size, the at least one cup being detachable from the support structure at an attachment point, providing a clip comprising first and section engagement mechanisms, attaching the first engagement mechanism of the clip in a releasable manner to a first position of the support structure of the maternity bra, attaching one of the detachable cup to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

This clip and method allow a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump.

Preferably, the method further comprises the step of inserting a breast pump into the detachable cup. The adjustment of the size of the bra allows the bra to support the breast pump against the user's breast for comfort and ease.

Preferably, the method further comprises the steps of: detaching the first engagement mechanism of the clip from the first position support structure of the maternity bra; attaching the first engagement mechanism of the clip in a releasable manner to a second position of the support structure of the maternity bra; and attaching the other of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size. This allows the user to use a single clip on either of the cups.

An alternative embodiment may be provided, with an extendable clip 360 as shown in Figure 36. In such an embodiment the clip is attached to the hook 331 on the strap 321 in a releasable manner, with the clasp 332 attached to an expandable portion of the clip. The clip is then able to expand between an unexpanded state where the clasp 332 is held in substantially the same position as the first attachment point 330 to provide the first cup size, and an expanded state, where the clasp 332 is held in a second position away from the first attachment point 330 to provide the second cup size.

For example, an elongate clip with first and second opposite ends may be provided. A first attachment point for attaching to the hook 331 is provided at the first end, and a second attachment point for attaching to the clasp 332 is provided at the second end. The elongate clip is hinged between the two ends, such that the clip can be folded between an elongate configuration to a closed configuration where the second end touches the first end. A clasp can be provided on the clip to hold the second end in this closed configuration. Thus, in the closed position the clasp 332 is held in substantially the same location as the first attachment point 330 to provide the first cup size, and in the open position the clasp is held away from the first attachment point 330 to provide the second cup size.

Other extendable clip embodiments are also possible, for example sliding clips or elastic clips.

Additional embodiments of a maternity bra adjuster are provided in Figures 37 and 38. The alternative proposed solution is a small adapter device, which comprises a first portion 370 including a clasp 373 and a second portion 372 including a hook 374, in which the first and second portions are separated by a small distance 371 in order to

provide two different adjustable sizes. The first portion includes a clasp 373 that is designed to attach to the hook on the bra strap 321. It may also include a top hook 375 positioned underneath the clasp, and a clip 376 on the rear side. The second portion includes a bottom hook 372.

The clasp 332 that is present on the cup 329 of the maternity bra, may then either engage with the top hook (321) to provide a first cup size, and engage with the bottom hook (332) to provide a second cup size that is different from the first cup size, as illustrated in Figure 39. The user may then discretely switch between a non pumping position, provided by the first cup size, and a second pumping position without any complex adjustment or removal of clothing needed, while using a wearable breast pump system (100).

The first portion and second portion may be made of plastic and may be separated by a stretchy material such as elastic or elastomeric material. The first portion may also include a clip on the rear side, the purpose of which is to allow the user to leave the clip attached to the bra for an extended time period.

Section D: Use of Piezo Pump in Wearables

As described in Section A, the breast pump system includes a piezo air pump, resulting in a fully wearable system that delivers a quiet, comfortable and discreet operation in normal use. This section gives further information on the piezo air pump.

In comparison with other pumps of comparable strength, piezo pumps are smaller, lighter and quieter.

Each individual Piezo pump weighs approximately 6gm and may, with material and design improvements, weigh less than 6gm.

In operation, the Elvie breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise; tests indicate that it makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

Piezo pumps also have lower current draw, allowing for increased battery life. A piezo pump is therefore ideally suited for wearable devices with its low noise, high strength and compact size. Further, as shown in the breast pump system of Figures 7 and 8, more than one piezo pump may be used.

Whilst a breast pump system is largely described in previous sections, the use of piezo mounted either in series or in parallel can also be implemented in any medical wearable devices or any wearable device. The piezo pump may pump air as well as any liquid.

With reference to Figure 40, a diagram illustrating a configuration of two piezo pumps mounted in series is shown.

With reference to Figure 41, a diagram illustrating a configuration of two piezo pumps mounted in parallel is shown.

With reference to Figure 42, the air pressure generated as a function of time by two piezo pumps mounted in series and two piezo pumps mounted in parallel are compared. In

this example, the parallel configuration produces higher flow rate and achieves -100mmHg negative air pressure faster than the series configuration. In comparison, the series configuration produces lower flow rate and takes slightly longer to reach 100mmHg. However, the parallel configuration cannot achieve as high as a vacuum as the series configuration and plateaus at -140mmHg. In comparison, the series configuration is able to generate about -240mmHg.

A dual configuration is also implemented in which more than one piezo pump is configured such that they can easily switch between a parallel mode and a series mode. This dual configuration would suit wearable devices that would need to achieve either lower or higher pressure faster.

Figure 43 shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration. In this dual configuration, the piezo pumps first start with a parallel mode in order to benefit from faster flow rate, and then switch to a series mode (as indicated by the switch-over point) when stronger vacuums are required, enabling to save up to 500ms on cycle time with elastic loads.

Additionally, a piezo pump may be used in combination with a heat sink in order to efficiently manage the heat produced by the wearable pump. This configuration may be used to ensure that the wearable device can be worn comfortably. The heat sink or heat sinks are configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin (especially prolonged contact for greater than 1 minute) are no more than 48°C and preferably no more than 43°C.

The heat sink may store the heat produced by a piezo pump in order to help diverting the heat produced to another location. This not only ensures that the wearable system can be worn comfortably, but also increases the lifetime of a piezo pump.

Figure 44 shows a picture of a wearable breast pump housing including multiple piezo pumps (440). The breast pump system is wearable and the housing is shaped at least in part to fit inside a bra. By applying a voltage to the piezo pumps, the pressure provided by the pumps increase. The generation of higher pressure by the piezo pumps also means higher heat produced that needs to be managed. Each piezo pump is therefore

connected to a heat sink (441), such as a thin sheet of copper. The heat sink has a long thermal path length that diverts the heat away from the piezo pump.

The use of a heat sink in combination with a piezo pump is particularly relevant when the wearable device is worn directly or near the body, and where the management of heat induced by the piezo pump is crucial.

A wearable device including a piezo pump may therefore include a thermal cut out, and may allow for excess heat to be diverted to a specific location. The heat sink may be connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere. For example, the wearable system is a breast pump system and the heat sink stores heat, which can then be diverted to warm the breast shield of the breast pump system.

Use cases application include but are not limited to:

- Wound therapy;
- High degree burns;
- Sleep apnoea;
- Deep vein thrombosis;
- Sports injury.

APPENDIX: SUMMARY OF KEY FEATURES

In this section, we summarise the various features implemented in the Elvie™ pump system. We organize these features into six broad categories:

A. Elvie Breast Pump: General Usability Feature Cluster

B. Elvie Piezo Air Pump Feature Cluster

C. Elvie Milk Container Feature Cluster

D. Elvie IR System Feature Cluster

E. Elvie Bra Clip Feature Cluster

F. Other Features, outside the breast pump context

Drilling down, we now list the features for each category:

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is wearable and includes only two parts that are removable from the pump main housing in normal use.

Feature 2 Elvie is wearable and includes a clear breast shield giving an unobstructed view of the breast for easy nipple alignment.

Feature 3 Elvie is wearable and includes a clear breast shield with nipple guides for easy breast shield sizing.

Feature 4 Elvie is wearable and includes a breast shield that audibly attaches to the housing.

Feature 5 Elvie is wearable and includes a breast shield that attaches to the housing with a single push.

Feature 6 Elvie is wearable and not top heavy, to ensure comfort and reliable suction against the breast.

Feature 7 Elvie is wearable and has a Night Mode for convenience.

Feature 8 Elvie is wearable and includes a haptic or visual indicator showing when milk is flowing or not flowing well.

Feature 9 Elvie is wearable and collects data to enable the mother to understand what variables (e.g. time of day, pump speed etc.) correlate to good milk-flow.

Feature 10 Elvie is wearable and collects data that can be exported to social media.

Feature 11 Elvie is wearable and has a smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 12 A smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 13 Elvie is wearable and includes a sensor to infer the amount of movement or tilt angle during normal use.

Feature 14 Elvie includes a control to toggle between expressing milk from the left breast and the right breast.

Feature 15 Elvie includes a pressure sensor.

Feature 16 Elvie includes a microcontroller to enable fine tuning between pre-set pressure profiles.

Feature 17 Elvie enables a user to set the comfort level they are experiencing.

Feature 18 Elvie includes a microcontroller to dynamically and automatically alter pump operational parameters.

Feature 19 Elvie automatically learns the optimal conditions for let-down.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is wearable and has a piezo air-pump for quiet operation.

Feature 21 Elvie has a piezo air-pump and self-sealing diaphragm

Feature 22 Elvie uses more than one piezo air pump in series.

Feature 23 Elvie is wearable and has a piezo air-pump, a breast shield and a diaphragm that fits directly onto the breast shield.

Feature 24 Elvie is wearable and has a piezo air-pump for quiet operation and a re-useable, rigid milk container for convenience.

Feature 25 Elvie has a piezo-pump for quiet operation and is a connected device.

Feature 26 Elvie uses a piezo in combination with a heat sink that manages the heat produced by the pump.

Feature 27 Elvie is wearable and gently massages a mother's breast using small bladders inflated by air from its negative pressure air-pump.

Feature 28 Elvie is wearable and gently warms a mother's breast using small chambers inflated by warm air from its negative pressure air-pump.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is wearable and includes a re-useable, rigid milk container that forms the lower part of the pump, to fit inside a bra comfortably.

Feature 30 Elvie is wearable and includes a milk container that latches to the housing with a simple push to latch action.

Feature 31 Elvie is wearable and includes a removable milk container with an integral milk pouring spout for convenience.

Feature 32 Elvie is wearable and includes a removable milk container below the milk flow path defined by a breast shield for fast and reliable milk collection.

Feature 33 Elvie is wearable and includes a breast shield and removable milk container of optically clear, dishwasher safe plastic for ease of use and cleaning.

Feature 34 Elvie is wearable and includes various components that self-seal under negative air pressure, for convenience of assembly and disassembly.

Feature 35 Elvie is wearable and includes a spout at the front edge of the milk container for easy pouring.

Feature 36 Elvie is wearable and includes a milk container that is shaped with broad shoulders and that can be adapted as a drinking bottle that baby can easily hold.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the quantity of milk in the container for fast and reliable feedback.

Feature 38 The separate IR puck for liquid quantity measurement.

Feature 39 The separate IR puck combined with liquid tilt angle measurement.

E. Bra Clip Feature

Feature 40 Bra Adjuster.

F. Other Features that can sit outside the breast pump context

Feature 41 Wearable device using more than one piezo pump connected in series or in parallel.

Feature 42 Wearable medical device using a piezo pump and a heat sink attached together.

We define these features in terms of the device; methods or process steps which correspond to these features or implement the functional requirements of a feature are also covered.

We'll now explore each feature 1 – 42 in depth. Note that each feature can be combined with any other feature; any sub-features described as 'optional' can be combined with any other feature or sub-feature.

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is wearable and includes only two parts that are removable from the pump main housing in normal use

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a rigid or non-collapsible milk container;

and in which the breast pump system includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and the rigid, non-collapsible milk container.

Optional:

- The only parts of the system that come into contact with milk in normal use are the breast shield and the milk container.
- Milk only flows through the breast shield and then directly into the milk container.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings, in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- No other parts are removable from the breast shield, apart from the flexible diaphragm.
- The milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.
- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

- No other parts are removable from the milk container, apart from the cap and the valve.
- All parts that are user-removable in normal use are attached to either the breast shield or the milk container.
- Audible or haptic feedback confirms the pump system is properly assembled for normal use with the milk container locked to the housing and the breast shield locked to the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 2 Elvie is wearable and includes a clear breast shield giving an unobstructed view of the breast for easy nipple alignment

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel, shaped to receive a nipple, providing to the mother placing the breast shield onto her breast a clear and unobstructed view of the nipple when positioned inside the nipple tunnel, to facilitate correct nipple alignment.

Optional:

- The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is completely out, of or separated from, the housing.
- The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is partially out of, or partially separated from, the housing.
- Entire breast shield is substantially transparent.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.

- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

Feature 3 Elvie is wearable and includes a clear breast shield with nipple guides for easy breast shield sizing

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel shaped to receive a nipple, the nipple tunnel including guide lines that define the correct spacing of the nipple from the side walls of the nipple tunnel.

Optional:

- The guide lines run generally parallel to the sides of the nipple placed within the nipple tunnel.
- Breast shield is selected by the user from a set of different sizes of breast shield to give the correct spacing.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers in the housing locate into small indents in the breast shield.

- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 4 Elvie is wearable and includes a breast shield that audibly attaches to the housing.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield that is attachable to the housing with a mechanism that latches with an audible click when the breast shield is slid on to or against the housing with sufficient force.

Optional:

- The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.

- Breast shield is removable from the housing with an audible click when the breast shield is pulled away from the housing with sufficient force.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.

- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 5 Elvie is wearable and includes a breast shield that attaches to the housing with a single push

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield configured to attach to the housing with a single, sliding push action.

Optional:

- The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.
- The single push action overcomes a latching resistance.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into a nipple tunnel in the breast shield to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield when the breast shield has been placed onto a breast using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b)

transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

- The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.
- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

Feature 6 Elvie is wearable and not top heavy, to ensure comfort and reliable suction against the breast

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism

(b) and a breast shield;

(c) a milk container;

and in which the centre of gravity of the pump system is, when the milk container is empty, substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through a nipple tunnel or filling point on a breast shield, so that the device is not top-heavy for a woman using the pump.

Optional:

- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- In which the centre of gravity only moves lower during use as the milk container gradually receives milk, which increases the stability of the pump inside the bra.
- In which milk only passes downwards when moving to the milk container, passing through the nipple tunnel and then through an opening in the lower surface of the nipple tunnel directly into the milk container, or components that are attached to the milk container.
- System is configured so that its centre of gravity is no more than 60mm up from the base of the milk container also below the top of the user's bra cup.
- In which the pumping mechanism and the power supply for that mechanism are positioned within the housing to provide a sufficiently low centre of gravity.
- In which the pumping mechanism is one or more piezo air pumps, and the low weight of the piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.
- In which the pumping mechanism is one or more piezo air pumps, and the small size of the piezo air pumps enables the components in the housing to be arranged so that the centre of gravity is substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.
- In which the pumping mechanism is one or more piezo air pumps, and the low weight of the battery or batteries needed to power that piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of

the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.

- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 7 Elvie is wearable and has a Night Mode for convenience

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) an illuminated control panel;

(c) a control system that reduces or adjusts the level or colour of illumination of the control panel at night or when stipulated by the user.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Control system is implemented in hardware in the pump itself using a 'night mode' button.
- Control system is implemented in software within a connected device app running on the user's smartphone.
- Control system is linked to the illumination level on a connected device app., so that when the connected app is in 'night mode', the illuminated control panel is also in 'night mode', with a lower level of illumination, and when the illuminated control panel on the housing is in 'night mode', then the connected app is also in 'night mode'.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast. The pumping mechanism is one or more piezo air pumps, selected for quiet operation.

Feature 8 Elvie is wearable and includes a haptic or visual indicator showing when milk is flowing or not flowing well

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a milk container that is configured to be concealed within a bra and is hence not visible to the mother in normal use;

(c) a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

Optional:

- A haptic and/or visual indicator indicates if the pump is operating correctly to pump milk, based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase
- The visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.
- The haptic and/or visual indicator provides an indication of an estimation of the flow rate.
- The visual indicator provides a colour-coded indication of an estimation of the flow rate.
- The visual indicator provides an indication of how much of the container has been filled.
- The visual indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.
- The haptic indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.
- A sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect

light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

- Sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- A sub-system measures or infers the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.
- A haptic and/or visual indicator indicates if the amount of milk in the milk container has reached a preset quantity or level.
- A haptic and/or visual indicator indicates if there is too much movement of the breast pump system for viable operation.
- Milk container is attached to the lower part of the housing and forms the base of the breast pump system.
- Milk container is made of transparent material.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 9 Elvie is wearable and collects data to enable the mother to understand what variables (e.g. time of day, pump speed etc.) correlate to good milk-flow

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a measurement sub-system that measures or infers milk flow into the milk container;

and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- User-defined requirement is to enhance or increase milk-flow.
- User-defined requirement is to reduce milk-flow.
- The data analysis system analyses data such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system determines metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.
- The data analysis system determines metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.
- Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.
- measurement sub-system measures or infers the quantity and/or the height of the liquid in the container above its base.
- Measurement sub-system measures or infers angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.
- Data analysis system gives recommended metrics for improving milk flow
- Data analysis system gives recommended metrics for weaning.
- Data analysis system gives recommended metrics for increasing milk supply (e.g. power pumping).
- Data analysis system gives recommended metrics if an optimal session start time or a complete session has been missed.

- Data analysis system leads to automatic setting of metrics for the pumping mechanism, such as pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session.
- Data analysis system enables sharing across large numbers of connected devices or apps information that in turn optimizes the milk pumping or milk weaning efficacy of the breast pump.
- Metrics include the specific usage of the connected device by a woman while using the pump (for example by the detection of vision and/or audio cues).
- The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- The measurement sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the measurement sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 10 Elvie is wearable and collects data that can be exported to social media.

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a data sub-system that collects and provides data to a connected device or remote application or remote server;

(d) and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.
- The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.
- Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.
- The social media or community function or platform organizes the collected data into different profiles.
- The social media or community function or platform enables a user to select a matching profile from a set of potential profiles.
- each profile is associated with a specific kind of milk expression profile, and provides information or advice that is specifically relevant to each milk expression profile.
- Information or advice includes advice on how to increase milk expression by varying parameters, such as time of milk expression, frequency of a milk

expression session, pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session and any other parameter that can be varied by a mother to help her achieve her milk expression goals.

- The application is connected to other applications residing on the connected device, such as a fitness app.
- The collected data includes data received from other connected apps.
- The collected data is anonymised before it is shared.
- The sub-system includes a wi-fi connectivity component for direct connectivity to a remote server.
- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 11 Elvie is wearable and has a smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh

A breast pump system including a pumping mechanism and a milk container and including:

(a) a housing including the pumping mechanism;

(b) a milk container;

(c) and in which the milk container or any associated part, such as a lid, includes a memory or tag that is automatically programmed to store the time and/or date it was filled with milk.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Memory or tag is programmed to store the quantity of milk in the milk container.
- Memory or tag stores the milk expiry date.

- Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.
- System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.
- Clock is in the housing.
- Clock is in the milk container.
- Milk container includes a display that shows the time and/or date it was filled with milk.
- Milk container includes a display that shows the quantity of milk that it was last filled with milk.
- Milk container includes a display that shows whether the left or right breast was used to fill the milk container.
- Memory or tag is connected to a data communications sub-system.
- Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone, and have the time and/or date that container was filled with milk, displayed on the reader device.
- Reader device shows the time and/or date a specific milk container was filled with milk.
- Reader device shows the quantity of milk that a specific milk container was last filled with.
- Reader device shows the time and/or date and/or quantity that each of several different milk containers were filled with.
- Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.
- A sub-system measures or infers milk flow into the milk container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- The sub-system is in the housing.
- Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 12 A smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

A smart bottle or container that includes or is associated with a memory or a tag that is programmed to store the date and time it is filled using data from a pump or a connected device, such as a smartphone.

Optional:

- The container includes wireless connectivity and connects to a companion app.
- The memory or tag includes an NFC chip and is read using a NFC reader.
- The memory or tag stores also an expiry date.
- Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.
- The memory or tag stores also the quantity of milk stored.
- System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.
- Clock is in the housing.
- Clock is in the container.
- Milk container includes a display that shows the time and/or date it was filled with milk.
- Milk container includes a display that shows the quantity of milk that it was last filled with milk.

- Milk container includes a display that shows whether the left or right breast was used to fill the milk contained.
- Milk container includes a display that shows the expiry date.
- memory or tag is connected to a data communications sub-system.
- Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone.
- Reader device shows the time and/or date a specific milk container was filled with milk.
- Reader device shows the quantity of milk that a specific milk container was last filled with.
- Reader device shows the time and/or date and/or quantity that each of several different containers were filled with.
- Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.
- Reader device shows the expiry date.
- Container includes wireless connectivity and connects to a companion application.
- An application tracks status of one or more smart containers and enables a user to select an appropriate smart container for a feeding session.
- The pump is wearable.
- The pump is in a housing shaped to fit inside a bra and the container is a milk container that is connected to the housing and is positioned to form the base of the housing.
- Container is used for liquids other than milk.

Feature 13 Elvie is wearable and includes a sensor to infer the amount of movement or tilt angle during normal use.

A breast pump system including:

(a) a housing;

(b) a milk container;

(c) the housing including a sensor, such as an accelerometer, that measures or determines the movement and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by warning or alerting the mother of a potential imminent spillage (e.g. from milk flowing back out of a breast shield) using an audio, or visual or haptic alert, or a combination of audio, haptic and visual alerts.
- If the tilt angle of the housing exceeds a threshold, then the system automatically adjusts the operation of the system by stopping the pump to prevent spillage.
- When the tilt angle of the housing reduces below the threshold, the system automatically adjusts the operation of the system by causing pumping to resume automatically.
- If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by providing the mother with an alert to change position.
- The container includes an optically clear region.
- There are one or more light emitters and detectors positioned in the base of the housing, the light emitters and receivers operating as part of a sub-system that measures or infers the tilt angle of the milk in the container.
- The sub-system measures the quantity of liquid in the milk container and also takes the measured tilt angle of the housing into account.
- If the tilt angle is above a certain threshold, the system ignores the quantity of liquid measured.
- The sub-system derives or infers the mother's activity, such as walking, standing or lying activities, from the sensor.
- The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

- Sub-system stores a time-stamped record of movement and/or tilt angles of the housing in association with milk flow data.
- System includes a breast shield that attaches to the housing.
- System includes a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 14 Elvie includes a control to toggle between recording whether milk is being expressed from the left breast and the right breast.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a control interface that the user can select to indicate or record if milk is being expressed from the left or the right breast.

Optional:

- Control interface is a physical interface on the housing.
- Control interface is a single button on the housing.
- Control interface is from an application running on a device, such as a smartphone or smart ring.
- Visual indicators on the housing indicate whether the breast pump system is being set up the left or the right breast.
- The visual indicator for the left breast is on the right-hand side of the housing, when viewed from the front; and the visual indicator for the right breast is on the left-hand side of the housing, when viewed from the front.
- The housing includes a button labeled to indicate the left breast and a button labeled to indicate the right breast, that are respectively illuminated to indicate from which breast the milk is being expressed.
- Breast pump system is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 15 Elvie includes a pressure sensor.

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) an air pressure sensor configured to measure the negative pressure delivered by the negative air-pressure mechanism and (iii) a measurement sub-system that measures or infers milk flow or milk volume.

Optional:

- The system also includes a control sub-system that combines or relates the air-pressure measurements with the milk flow or milk volume measurements
- The control sub-system automatically adjusts the negative air-pressure to give the optimal milk flow or milk volume.
- The control sub-system automatically adjusts the negative air-pressure during a pumping session to give the optimal milk flow or milk volume within comfort constraints defined by the user.
- The air pressure sensor detects pressure created by the pumping mechanism.
- Sensor is a piezo air pressure sensor
- Air pressure sensor measures the negative air pressure during a normal milk expression session.
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that it deliver consistent performance over time.
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that different pumping mechanisms in different breast pump systems all deliver consistent performance
- Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to determine if the pumping mechanism is working correctly, within tolerance levels.
- The operation of the pumping mechanism is varied by altering the duty or pump cycle.
- The operation of the pumping mechanism is varied by altering the voltage applied to the pumping mechanism.
- Pumping mechanism is a piezo air pump.

- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 16 Elvie includes a microcontroller to enable fine tuning between pre-set pressure profiles

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to cause the pumping mechanism to deliver various pre-set pressure profiles and to permit the user to manually vary the pressure to a value or values that are in-between the values available from a pre-set pressure profile.

Optional:

- The user manually varies the pressure using a control interface on a housing of the breast pump system
- The user manually varies the pressure using a control interface on an application running on a wireless device such as a smartphone that is wirelessly connected to the breast pump system.
- The user manually varies the pressure by altering a control parameter of the pumping mechanism.
- The user manually varies the pressure by altering the duty cycle or timing of the

pumping mechanism.

- The user manually varies the pressure by altering the voltage applied to the pumping mechanism.
- The system includes an air pressure sensor configured to measure the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Pressure profile defines one or more maximum negative air pressure levels.
- Pressure profile defines one or more maximum negative air pressure levels, each for a pre-set time.
- Pressure profile defines one or more cycle time.
- Pressure profile defines peak flow rate.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 17 Elvie enables a user to set the comfort level they are experiencing

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to control the pumping mechanism and to permit the user to manually indicate the level of comfort that they are experiencing when the system is in use.

Optional:

- The user manually indicates the level of comfort that they are experiencing using a touch or voice-based interface on a housing of the breast pump system
- The user manually indicate the level of comfort that they are experiencing using a touch or voice-based interface on an application running on a wireless device, such as a smartphone, that is wirelessly connected to the breast pump system.
- The system stores user-indicated comfort levels together with associated parameters of the pumping system.
- The system is a connected device and a remote server stores user-indicated comfort levels together with associated parameters of the pumping system.
- The parameters of the pumping system include one or more of: pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System automatically varies parameters of the pumping system and then enables the user to indicate which parameters are acceptable.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the

intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 18 Elvie includes a microcontroller to dynamically and automatically alter pump operational parameters

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to automatically change one or more parameters of the pumping mechanism, and to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

Optional:

- The milk expression data includes one or more of the following: milk expression rate or quantity; comfort; optimal pumping mode; optimal pumping mode given remaining battery power.
- The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters.
- The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters if the comfort experienced by the user when those parameters are used is above a threshold.
- The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user.
- The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user and enables the user to manually select those parameters if they are acceptable.
- Parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.

- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 19 Elvie automatically learns the optimal conditions for let-down

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to dynamically change one or more parameters of the pumping mechanism, and to automatically detect the start of milk let-down.

Optional:

- The microcontroller is programmed to dynamically change one or more parameters of the pumping mechanism, to enable it to learn or optimize the parameters relating to milk let-down.
- The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down.
- The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and uses that set of parameters if the comfort experienced by the user when those

parameters are used is above a threshold or are otherwise acceptable to the user.

- The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down to the user.
- The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and enables the user to manually select those parameters if they are acceptable.
- parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.
- System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.
- The air pressure sensor is a piezo air pressure sensor.
- Pumping mechanism is a piezo air pump.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.
- Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.
- Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.
- The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is wearable and has a piezo air-pump for quiet operation

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a separate, deformable diaphragm to generate negative air pressure.

Optional:

- The deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- Deformable diaphragm is removably mounted against a part of a breast shield.
- Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.
- Deformable diaphragm is not physically connected to the piezo air-pump.
- Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield
- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

- The piezo pump is fed by air that passes through an air filter.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 21 Elvie has a piezo air-pump and self-sealing diaphragm

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a physically separate, deformable, self-sealing diaphragm, to generate negative air pressure.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement .
- The closed system is separated from a 'milk' side by the flexible diaphragm.
- Deformable diaphragm is removably mounted against a part of a breast shield.
- Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.
- Deformable diaphragm is not physically connected to the piezo air-pump.
- Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield.
- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing,

and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- The piezo pump is fed by air that passes through an air filter.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 22 Elvie uses more than one piezo air pump in series

A breast pump system including:

(a) a housing;

(b) multiple piezo air-pumps in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure; in which the multiple piezo air-pumps can be operated at different times in series-connected and in parallel-connected modes.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Parallel connected mode is used during a first part of a pumping cycle to reach a defined negative air pressure more quickly than series connected mode would, and then the system switches to a series connected mode to reach a greater negative air pressure than series connected mode can reach.
- An actuator switches the system from parallel-connected piezo pump mode to series-connected piezo pump mode.

- Each piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- Each piezo air pump weighs less than 10 gm, and may weigh less than 6gm..
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- Each piezo pump is fed by air that passes through an air filter.
- Each piezo air pump forms part of a closed or closed loop system.
- Each piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- The piezo-air pumps are a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

Feature 23 Elvie is wearable and has a piezo air-pump, a breast shield and a diaphragm that fits directly onto the breast shield

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a breast shield that attaches to the housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm that fits directly onto the breast shield.

Optional:

- Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Deformable diaphragm is removable from the diaphragm housing for cleaning.

- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Piezo air pump forms part of a closed or closed loop system.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- Piezo air pump is position at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum. power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.The piezo pump is fed by air that passes through an air filter.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Feature 24 Elvie is wearable and has a piezo air-pump for quiet operation and a re-useable, rigid milk container for convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing;

(c) and a re-useable, rigid or non-collapsible milk container that when connected to the housing forms an integral part of the housing and that is also removable from the housing.

Optional:

- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The closed system is separated from a 'milk' side by a flexible diaphragm.

- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- The deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.

Feature 25 Elvie has a piezo-pump for quiet operation and is a connected device

A breast pump system including

(a) a housing;

(b) a piezo air-pump in the housing;

(c) a milk container;

(d) a data connectivity module that enables data collection relating to the operation of the piezo air-pump and transmission of that data to a data analysis system.

Optional:

- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Transmission is to an application running on a connected device such as a smartphone, or a server, or the cloud.
- The data collection and transmission relates to any other operational data of the system.
- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- Deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.
- A sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with the data connectivity module.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.
- The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level,

peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.

- The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.

Feature 26 Elvie uses a piezo in combination with a heat sink that manages the heat produced by the pump.

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure;

(c) a heat sink to manage the heat produced by the piezo-air pump to ensure it can be worn comfortably.

Optional:

- The heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48°C and preferably no more than 43°C.
- The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.
- Heat sink is connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere.
- Heat sink warms a breast shield.
- Piezo air pump forms part of a closed or closed loop system.
- Piezo air pump is positioned at or close to the base of the housing.
- There are two or more piezo air pumps.

- There are two or more piezo air pumps, each connected to its own or a shared heat sink.
- There are two or more piezo air pumps mounted in a series arrangement.
- There are two or more piezo air pumps mounted in a parallel arrangement.
- The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.
- The closed system is separated from a 'milk' side by a flexible diaphragm.
- A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.
- The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.
- The deformable diaphragm is removable from the diaphragm housing for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.
- The piezo pump delivers in excess of 400mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.
- The piezo air pump weighs less than 10 gm, and may weigh less than 6gm.
- In operation, the breast pump system makes less then 30dB noise at maximum power and less than 25dB at normal power, against a 20dB ambient noise.
- In operation, the breast pump system makes approximately 24dB noise at maximum power and 22dB at normal power, against a 20dB ambient noise.

Feature 27 Elvie is wearable and gently massages a mother's breast using small bladders inflated by air from its negative pressure air-pump

A breast pump system including:

(a) a housing;

(b) an air-pump in the housing that drives a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides air to regularly or sequentially inflate one or more air bladders or liners that are configured to massage one or more parts of the breast.

Optional:

- Air-pump is a piezo pump.
- Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- Bladders or liners are formed in a breast shield that attaches to the housing.

Feature 28 Elvie is wearable and gently warms a mother's breast using small chambers inflated by warm air from its negative pressure air-pump

A breast pump system including:

(a) a housing;

(b) an air-pump, such as a piezo pump, in the housing that drive a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides warm air to regularly or sequentially inflate one or more air chambers that are configured to apply warmth to one or more parts of the breast.

Optional:

- Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- The air chamber is a deformable diaphragm positioned on a breast shield that attaches to the housing.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is wearable and includes a re-useable, rigid milk container that forms the lower part of the pump, to fit inside a bra comfortably

A wearable breast pump system configured including:

(a) a housing shaped at least in part with a curved surface to fit inside a bra and including a pumping mechanism;

(b) and a re-useable rigid or non-collapsible milk container that when connected to the housing forms an integral, lower part of the housing, with a surface shaped to continue the curved shape of the housing, so that the pump system can be held comfortably inside the bra.

Optional:

- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is attached to the housing with a push action.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture, spout or lid that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a

breast shield, and milk flows under gravity through the opening into the milk container.

- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump mechanism to ensure that negative air-pressure is not applied to the milk container.
- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 30 Elvie is wearable and includes a milk container that latches to the housing with a simple push to latch action

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that is attachable to the housing with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

Optional:

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Milk container, when connected to the housing, forms an integral, lower part of the housing and that is removable from the housing with a release mechanism that can be operated with one hand.

- Mechanism that releasably attaches or latches is a mechanical or magnetic mechanism.
- Mechanical mechanism includes flanges on the top of the milk container, or the sealing plate that seals the opening to the milk contained, that engage with and move past a surface to occupy a latched position over that surface when the milk container is pressed against the housing to lock into the housing.
- The housing includes a button that when pressed releases the milk container from the housing by flexing the surface away from the flanges so that the flanges no longer engage with and latch against the surface.
- Mechanism that attaches or latches the milk container into position does so with an audible click.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing by releasing the latch and moving the housing off the milk container.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.

- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 31 Elvie is wearable and includes a removable milk container with an integral milk pouring spout for convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a re-useable milk container that is connected to the housing with a surface shaped to continue the curved or breast-like shape of the pump, so that the pump can be held comfortably inside a bra and where the milk container includes a pouring spout for pouring milk.

Optional:

- Spout is integral to the milk container.
- Spout is integral to a removable lid to the milk container.
- Spout is positioned at or close to the front edge of the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.

- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 32 Elvie is wearable and includes a removable milk container below the milk flow path defined by a breast shield for fast and reliable milk collection

A wearable breast pump system including:

(a) a housing including a pumping mechanism, the housing being shaped at least in part to fit inside a bra;

(b) and a breast shield including a nipple tunnel shaped to receive a nipple, and including an opening that defines the start of a milk flow path;

(c) a re-useable milk container that when connected to the housing is positioned entirely below the opening or the milk flow path, when the breast pump is positioned or oriented for normal use.

Optional:

- The milk container includes an aperture that sits directly underneath the opening in the nipple tunnel in the breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- Milk flows from the opening directly into the milk container.
- Milk flows from the opening directly into the milk container.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against the opening in the breast shield, and milk flows under gravity through the opening into the milk container.
- Milk flows from the opening directly onto a valve that is attached to the milk container, the valve closing whilst there is sufficient negative air pressure in the volume of air between the valve and the breast shield opening, and then opening to release the milk into the container when the air pressure rises sufficiently.
- Milk flows from the opening directly onto a valve that is attached to a spout, that is in turn attached to the milk container.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.
- A flexible rubber or elastomeric valve is mounted onto the milk container cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container, and milk flows towards and is retained by the duck bill valve whilst the valve is closed, and flows past the valve into the milk container when the negative air pressure is released and the valve opens.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 33 Elvie is wearable and includes a breast shield and removable milk container of optically clear, dishwasher safe plastic for ease of use and cleaning

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) and a breast shield defining a region shaped to receive a nipple, the region defining the start of a milk flow path;

(c) a re-useable, rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the breast shield and the milk container are made substantially of an optically clear, dishwasher safe material.

Optional:

- The material is a polycarbonate material, such as Tritan™.

- breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield operates with a flexible diaphragm that flexes when negative air pressure is applied to it by an air pump system in the housing, and transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 34 Elvie is wearable and includes various components that self-seal under negative air pressure, for convenience of assembly and disassembly

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including an air pumping mechanism;

(b) a breast shield;

(c) a diaphragm that flexes in response to changes in air pressure caused by the air pumping mechanism and that seals to the breast shield;

(d) a re-useable milk container that seals to the breast shield;

and in which either or both of the diaphragm and the re-useable milk container substantially self-seal under the negative air pressure provided by the pumping mechanism.

Optional:

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a

breast shield, and milk flows under gravity through the opening into the milk container.

- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.
- The 1 way valve is attached to the milk container, or a lid or spout of the milk container with an interference fit and is readily removed in normal use for separate cleaning.
- The diaphragm partly or wholly self-seals to the breast shield under the negative air pressure provided by the pumping mechanism.
- The diaphragm partly or wholly self-seals to the housing under the negative air pressure provided by the pumping mechanism.
- The diaphragm is attached to the diaphragm housing using elastomeric or rubber latches and is readily removed in normal use for separate cleaning.
- The breast shield and milk container are each pressed or pushed into engagement with the housing.
- The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.
- The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Breast shield slides into the housing using guide members.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.

- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.

Feature 35 Elvie is wearable and includes a spout at the front edge of the milk container for easy pouring

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that forms an integral part of the housing;

(c) a re-useable pouring spout that is positioned at or close to the front edge of the milk container.

Optional:

- Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigeratable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.
- Spout is integral to a removable lid to the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- By placing the spout at or close to the front edge of the milk container, the milk container fully empties more readily than where the spout is placed in the middle of the lid of a milk container.
- The spout sits generally under an opening in the breast shield spout or nipple tunnel through which expressed milk flows.
- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Feature 36 Elvie is wearable and includes a milk container that is shaped with broad shoulders and that can be adapted as a drinking bottle that baby can easily hold

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a milk container that is removable from the housing and is shaped or configured to also serve as a drinking bottle that is readily held by a baby because it is wider than it is tall.

Optional:

- Teat is attachable directly to the milk container.
- Pouring or drinking spout is integral to the milk container.
- The shoulders are at least 2cm in width, and the neck is no more than 1 cm in height, to enable a baby to readily grip and hold the container when feeding from the milk in the container.
- Spout/teat/straw resides near the edge of the container's rim.
- Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigertable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.
- The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals

against the conduit under the negative air pressure provided by the pumping mechanism.

- The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.
- Spout is integral to the milk container.
- Spout is integral to a removable lid to the milk container.
- Spout is positioned at or close to the front edge of the milk container.
- Spout is removable from the container, such as by clipping off the container.
- A teat is attachable to the spout.
- A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.
- The milk container forms the base of the system.
- The milk container has a flat base so that it can rest stably on a surface.
- The milk container is removable from the housing.
- The milk container includes a clear or transparent wall or section to show the amount of milk collected.
- The milk container is sealable for storage.
- The milk container obviates the need for consumable or replaceable milk pouches.
- The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.
- The milk container is made using a blow moulding construction.
- The milk container has a large diameter opening to facilitate cleaning that is at least 3cm in diameter.
- The large opening is closed with a bayonet-mounted cap with an integral spout.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the quantity of milk in the container for fast and reliable feedback

A system for milk volume determination, for use as part of a breast pump, or breast milk collecting device, including:

(a) a re-useable rigid or non-collapsible milk container;
(b) at least one light emitter, configured to direct radiation towards the surface of the milk;
(c) at least one light detector, configured to detect reflected radiation from the surface of the milk;

wherein the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container.

Optional:

The wearable breast pump system includes:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield;

(c) a re-useable rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the top of the container includes an optically clear region that is aligned below one or more light emitters positioned in the base of the housing.

- The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

- The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.
- Where the quantity or level exceeds a threshold, then the pumping mechanism automatically changes mode, e.g. from a stimulation mode to an expression mode.
- Where the quantity or level exceeds a threshold, then the pumping mechanism automatically stops.
- Milk-flow data is captured and stored.
- If milk-flow falls below a threshold, then a notification is provided to the mother.

Feature 38 The separate IR puck for liquid quantity measurement

A liquid-level measuring system for measuring the quantity of liquid in a container for a breast pump; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to detect light from the light emitters that has been reflected from the liquid;

(c) a sub-system that infers, measures or calculates the quantity in the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

- The quantity of milk is measured as milk enters the container or as milk is removed from the container.
- Measured property includes the reflected light intensity

Feature 39 The separate IR puck combined with liquid tilt angle measurement

A liquid-level measuring system for measuring the tilt angle of liquid in a container; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to measure properties of the light reflected from the liquid;

(c) a sub-system including an accelerometer that infers, measures or calculates the tilt angle of the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

- Measured property includes the reflected light intensity
- The quantity of liquid is measured as liquid enters the container or as liquid is removed from the container.
- Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.
- The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.

Generally applicable optional features

- Weight of the entire unit, unfilled, is under 250g and preferably 214g.
- Silver based bactericide is used on all parts that are not steam or heat sterilized in normal cleaning.
- Housing includes a rechargeable battery.
- System is self-contained.
- System is a closed loop system.
- Breast pump system is a self-contained, wearable device that includes an integral rechargeable battery, control electronics, and one or more air pumps operating as a closed system, driving a flexible diaphragm that in turn delivers negative air-pressure to the breast, to cause milk to be expressed.
- Housing has a generally rounded or convex front surface and has a generally tear-drop shape when seen from the front.

E. Bra Clip Feature Cluster

Feature 40 Bra Adjuster

A bra adjuster for a nursing or maternity bra, the nursing or maternity bra including a bra cup with a flap that can be undone to expose the nipple, and the flap attaching to the shoulder strap using a clasp, hook or other fastener attached to the flap, and a corresponding fastener attached to the shoulder strap;

and in which the bra adjuster is attachable at one end to the fastener attached to the flap, and at its other end to the fastener attached to the shoulder strap, and hence increases the effective bra cup size sufficiently to accommodate a wearable breast pump, and is also detachable from the flap and shoulder strap.

Optional:

- Bra adjuster is retained in position on the bra during normal wearing of the bra, even when the flap is attached directly to the shoulder strap, and is used to increases the effective bra cup size only when the wearable breast pump is used.
- Bra adjuster is extensible or elastic.
- Bra adjuster is of a fixed length.
- Bra adjuster includes a clip that the user can slide onto the bra strap to secure the bra adjuster in position.
- Bra adjuster is machine-washing washable.

F. Other Features that can sit outside the breast pump context

Feature 41 Wearable device using more than one piezo pump connected in series or in parallel

A wearable device including multiple piezo pumps mounted together either in series or in parallel.

Optional:

- The wearable device is a medical wearable device.
- The piezo pumps air or any liquid etc.
- The system can switch between a parallel mode and a series mode to arrive to lower or higher pressure quicker.

Feature 42 Wearable medical device using a piezo pump and a heat sink attached together.

A wearable medical device including a piezo pump and a heat sink attached together.

Optional

- The wearable device uses more than one piezo pump connected in series.
- The wearable device uses more than one piezo pump connected in parallel.
- Each piezo pump is connected to its own heat sink, or to a common heat sink.
- The or each heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48°C and preferably no more than 43°C
- The wearable device includes a thermal cut out.
- Excess heat is diverted to a specific location on the device that is selected to not be in prolonged contact with the skin of the user, in normal use.
- Use cases application:
    - Wound therapy
    - High degree burns
    - Sleep apnea
    - Deep vein thrombosis
    - Sports injury.
- Wearable medical device is powered/charged via USB.

Note

It is to be understood that the above-referenced arrangements are only illustrative of the application for the principles of the present invention. Numerous modifications and alternative arrangements can be devised without departing from the spirit and scope of

the present invention. While the present invention has been shown in the drawings and fully described above with particularity and detail in connection with what is presently deemed to be the most practical and preferred example(s) of the invention, it will be apparent to those of ordinary skill in the art that numerous modifications can be made without departing from the principles and concepts of the invention as set forth herein.

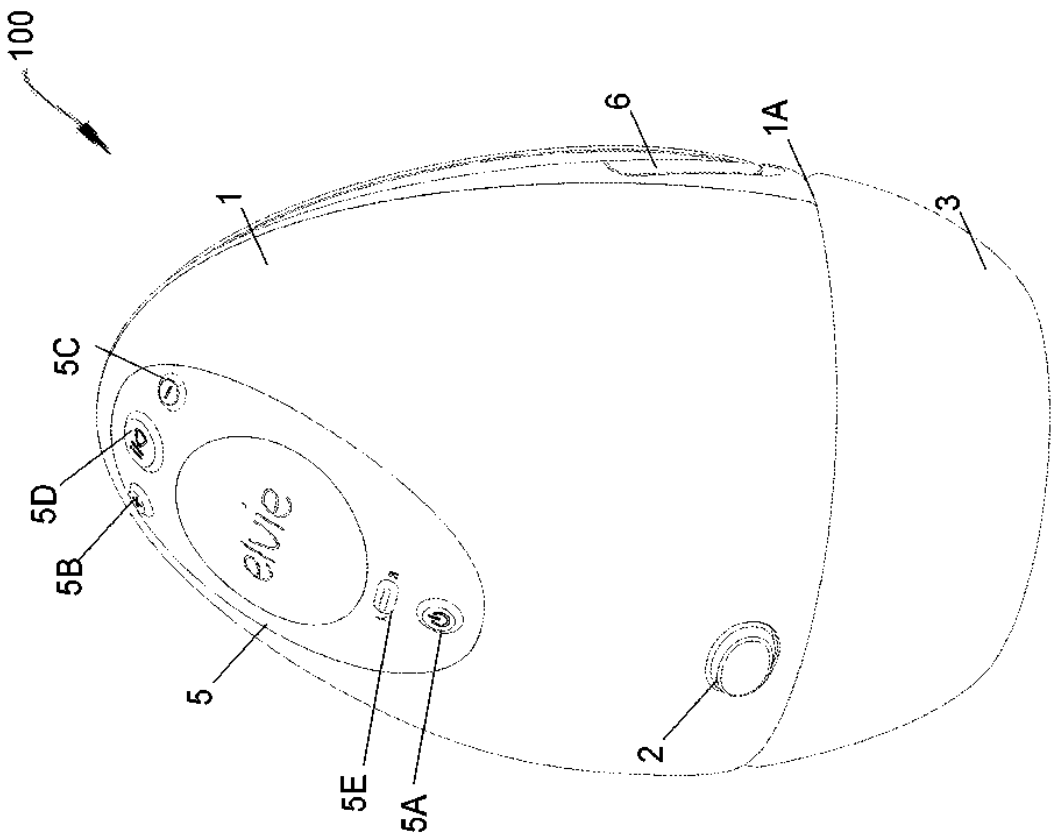


FIGURE 1

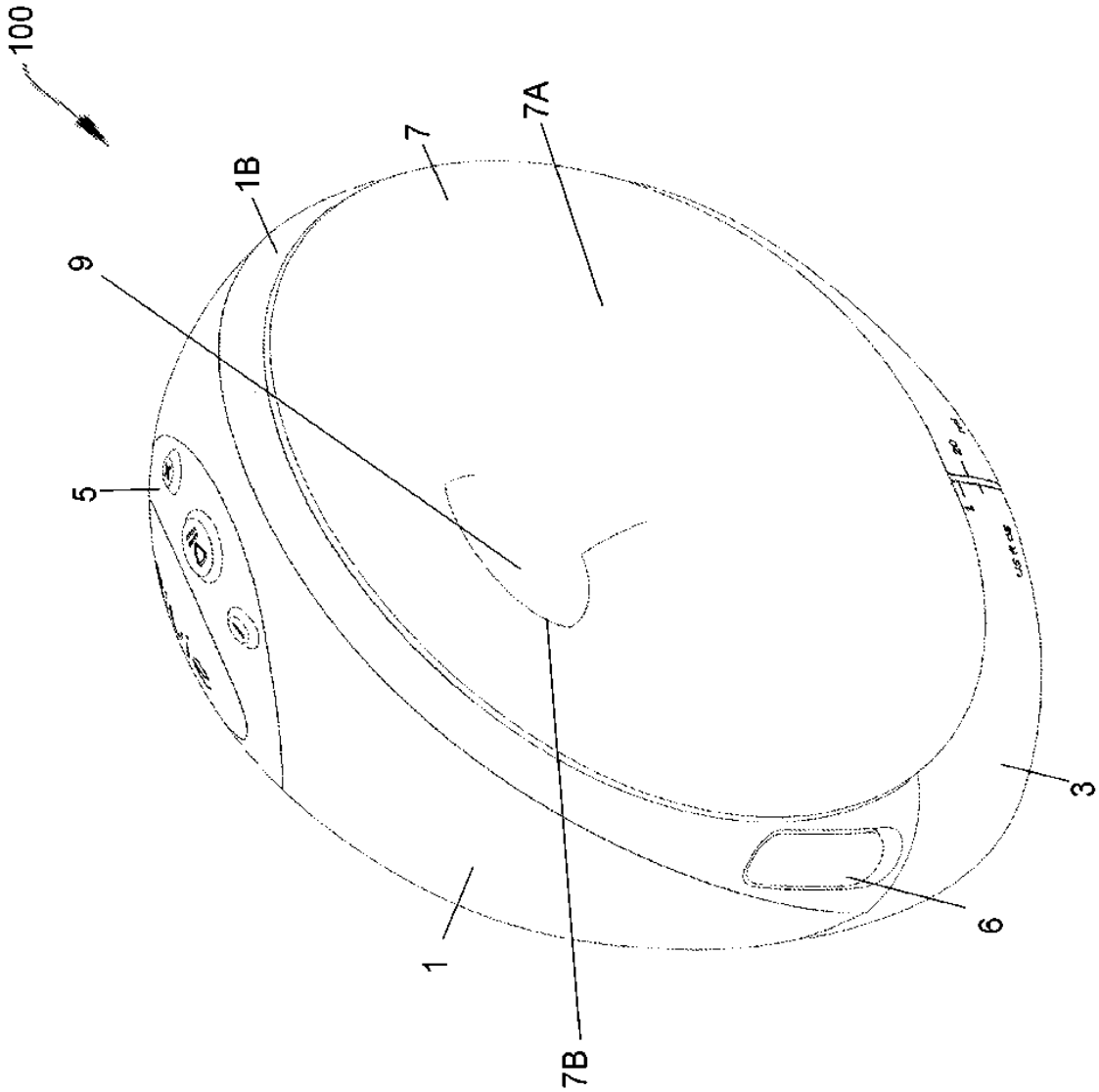


FIGURE 2

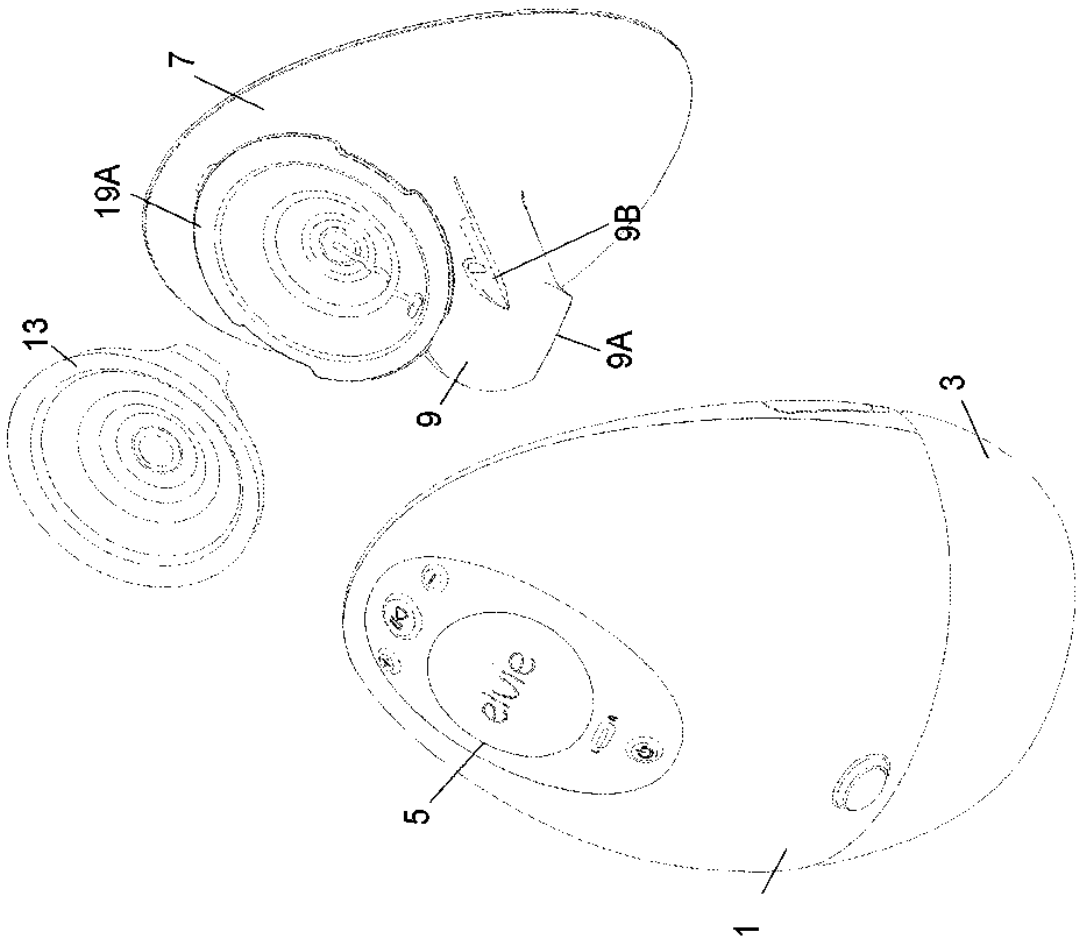


FIGURE 3

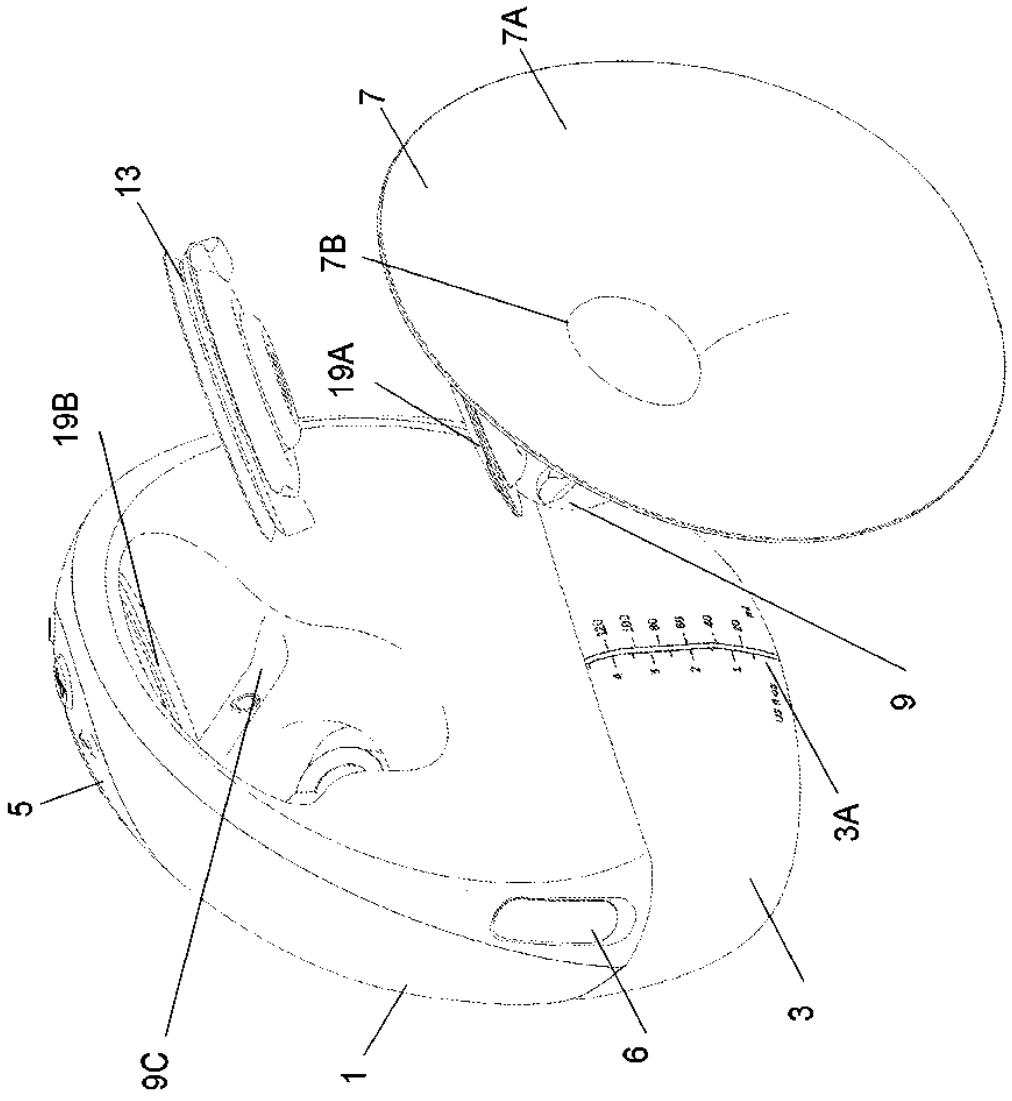


FIGURE 4

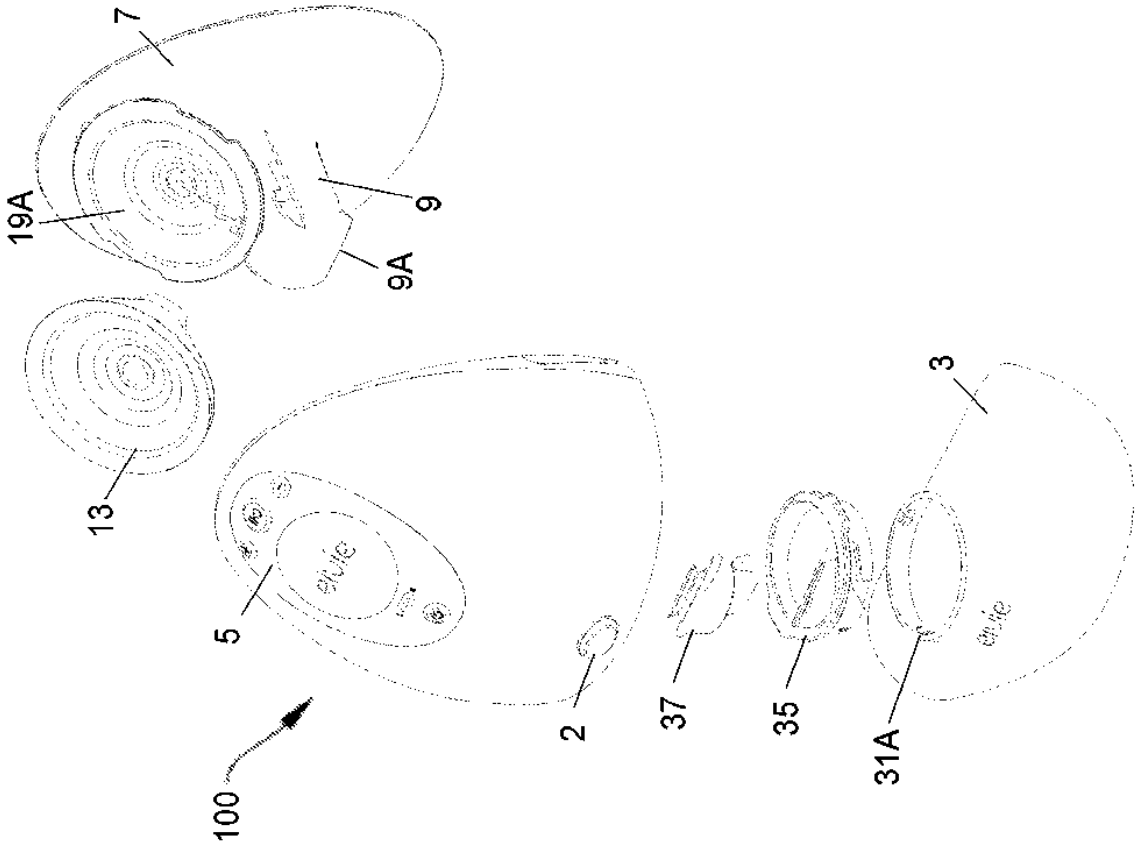


FIGURE 5

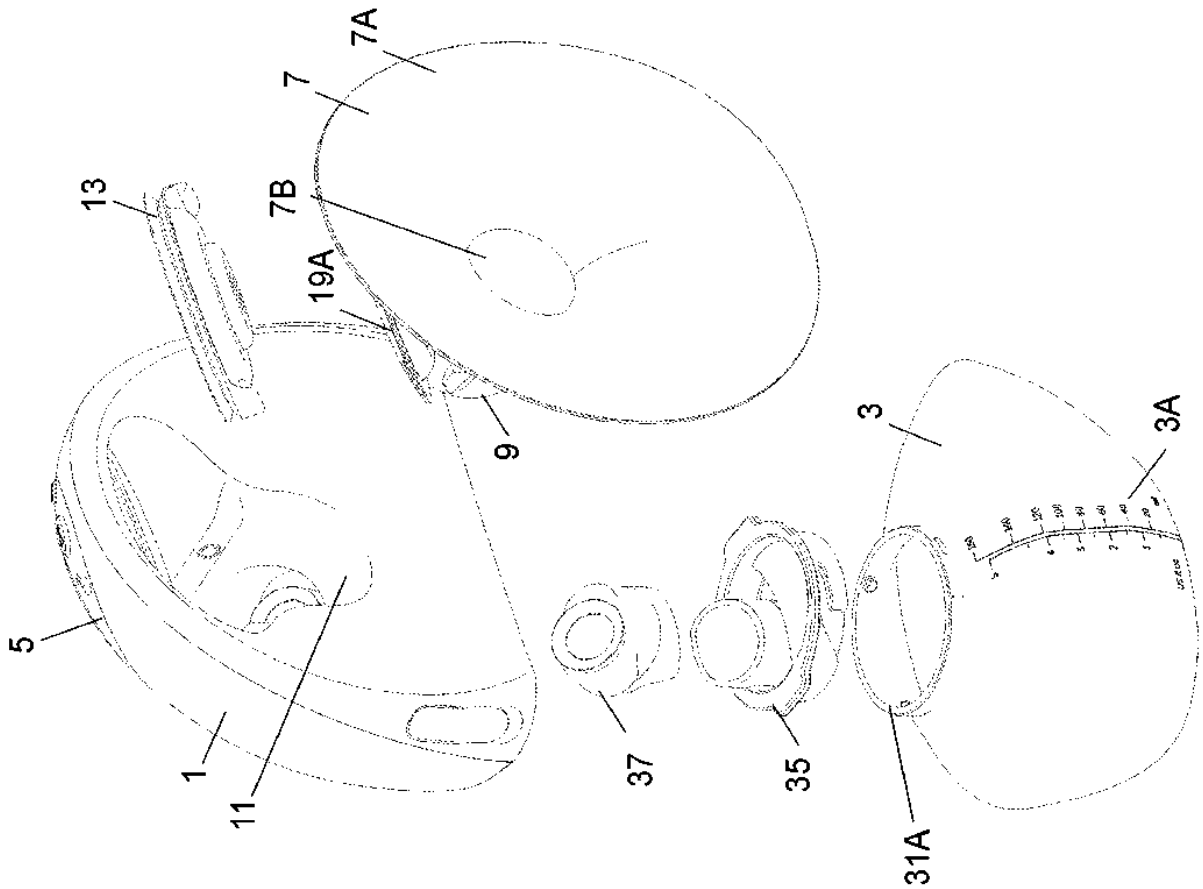


FIGURE 6

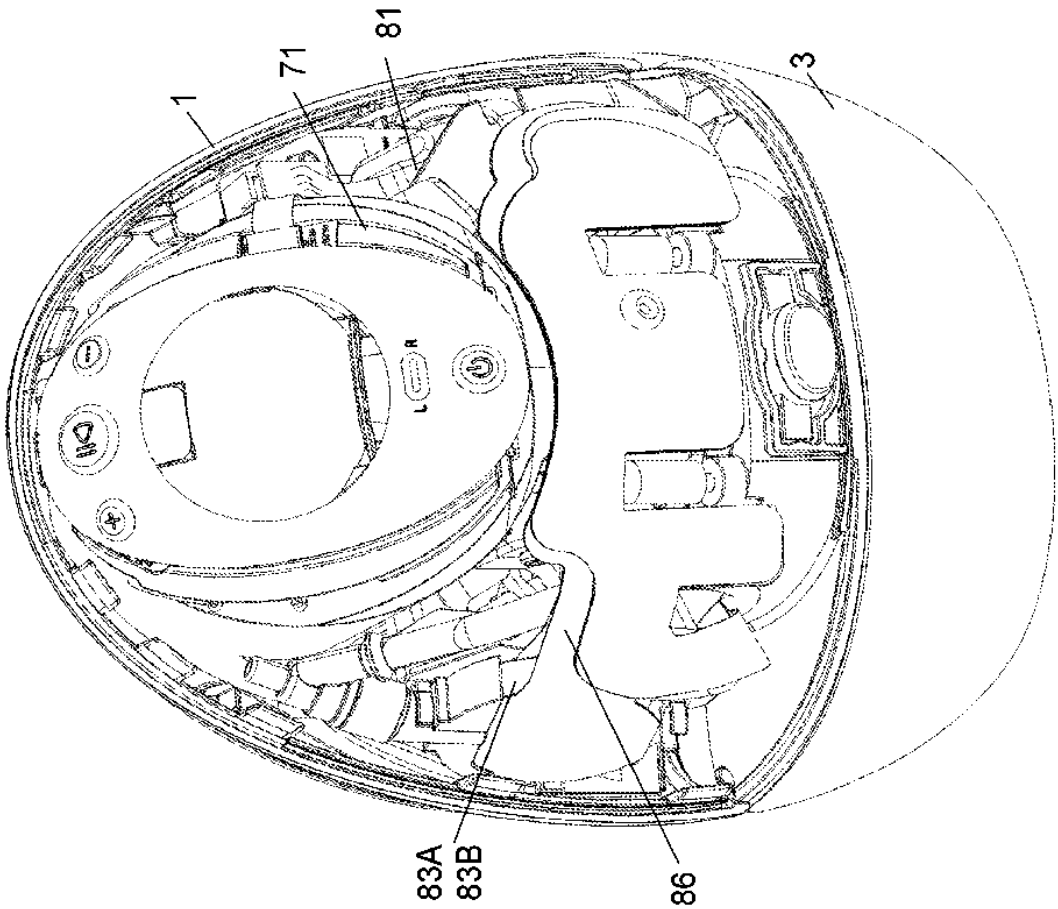


FIGURE 7

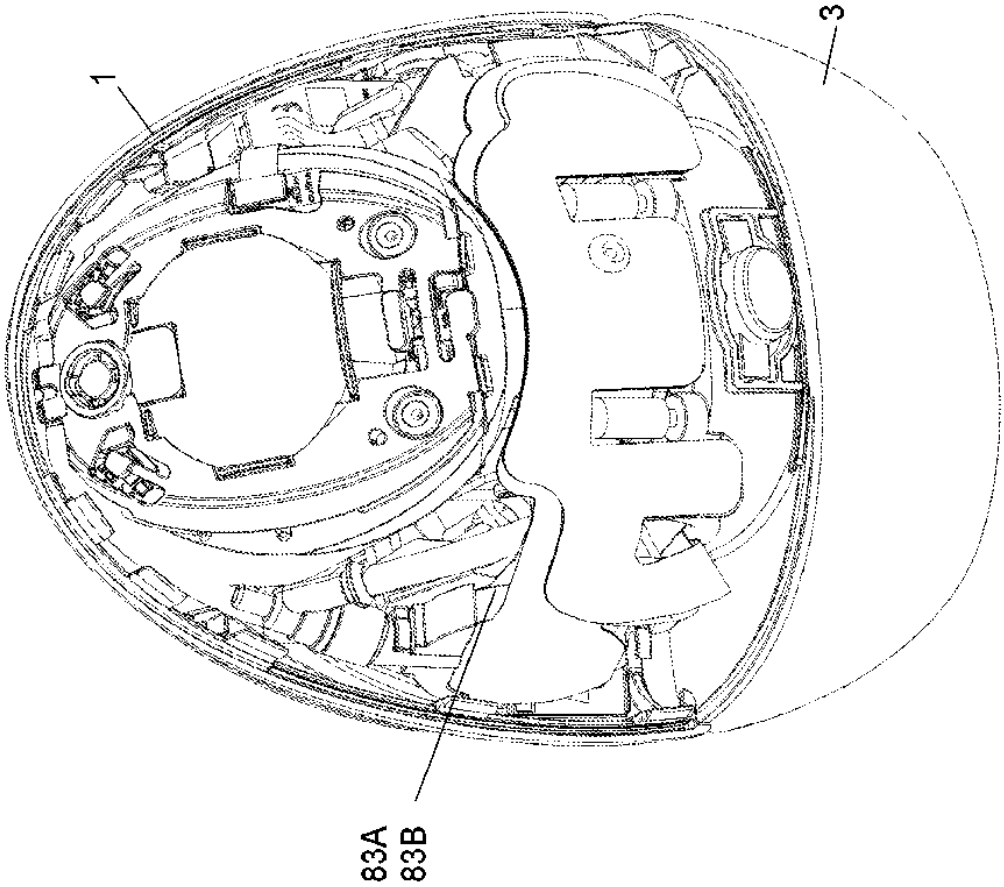


FIGURE 8

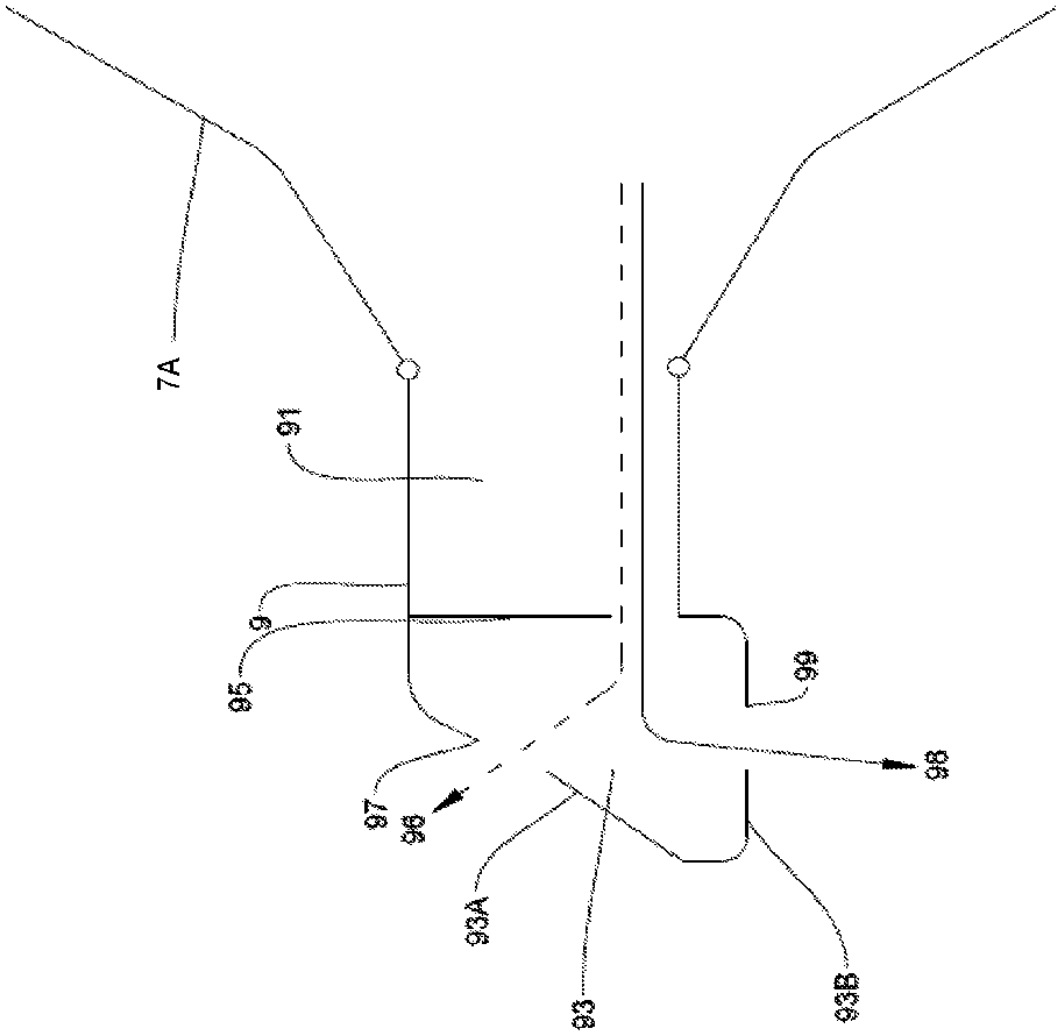


FIGURE 9

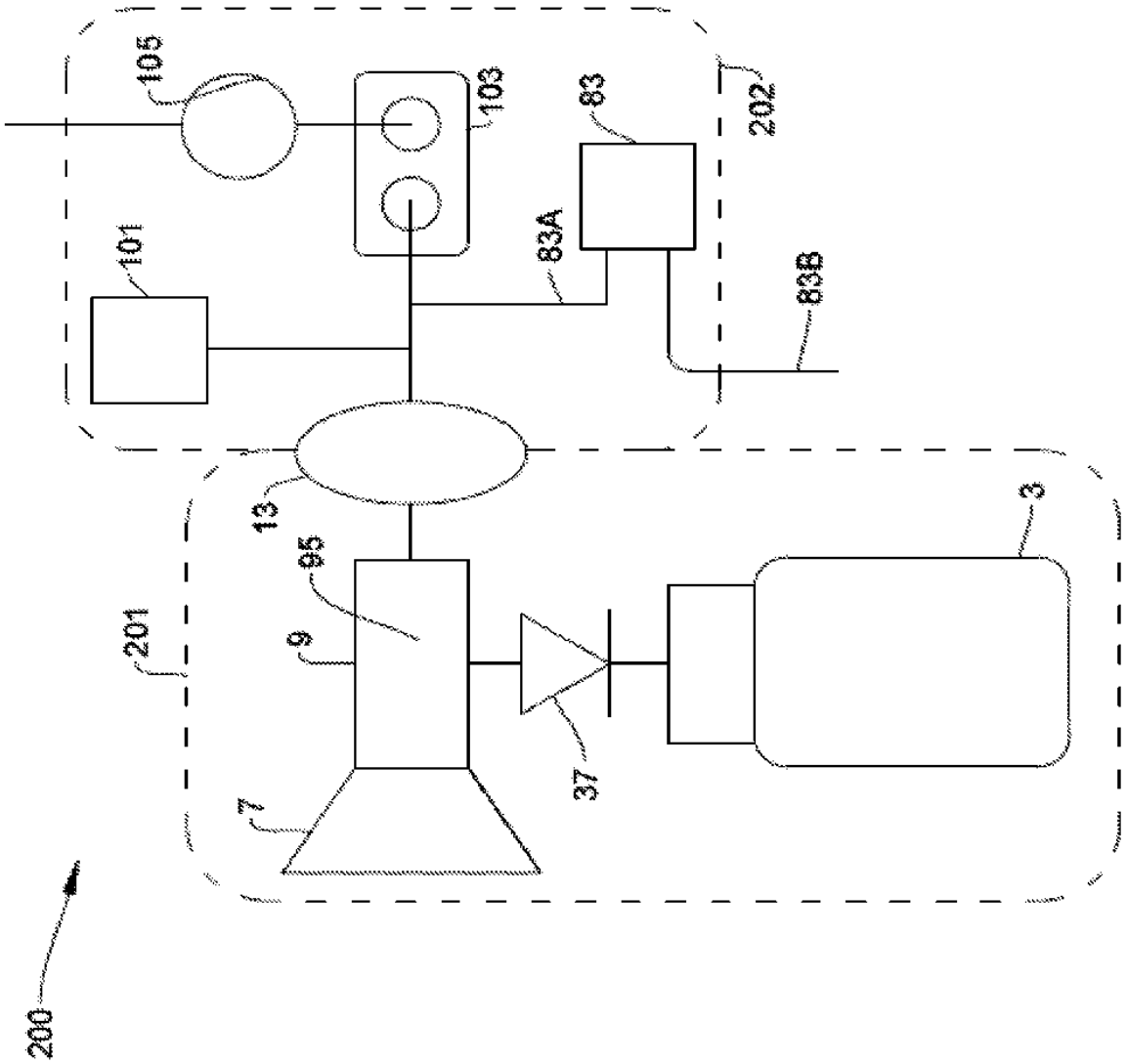


FIGURE 10

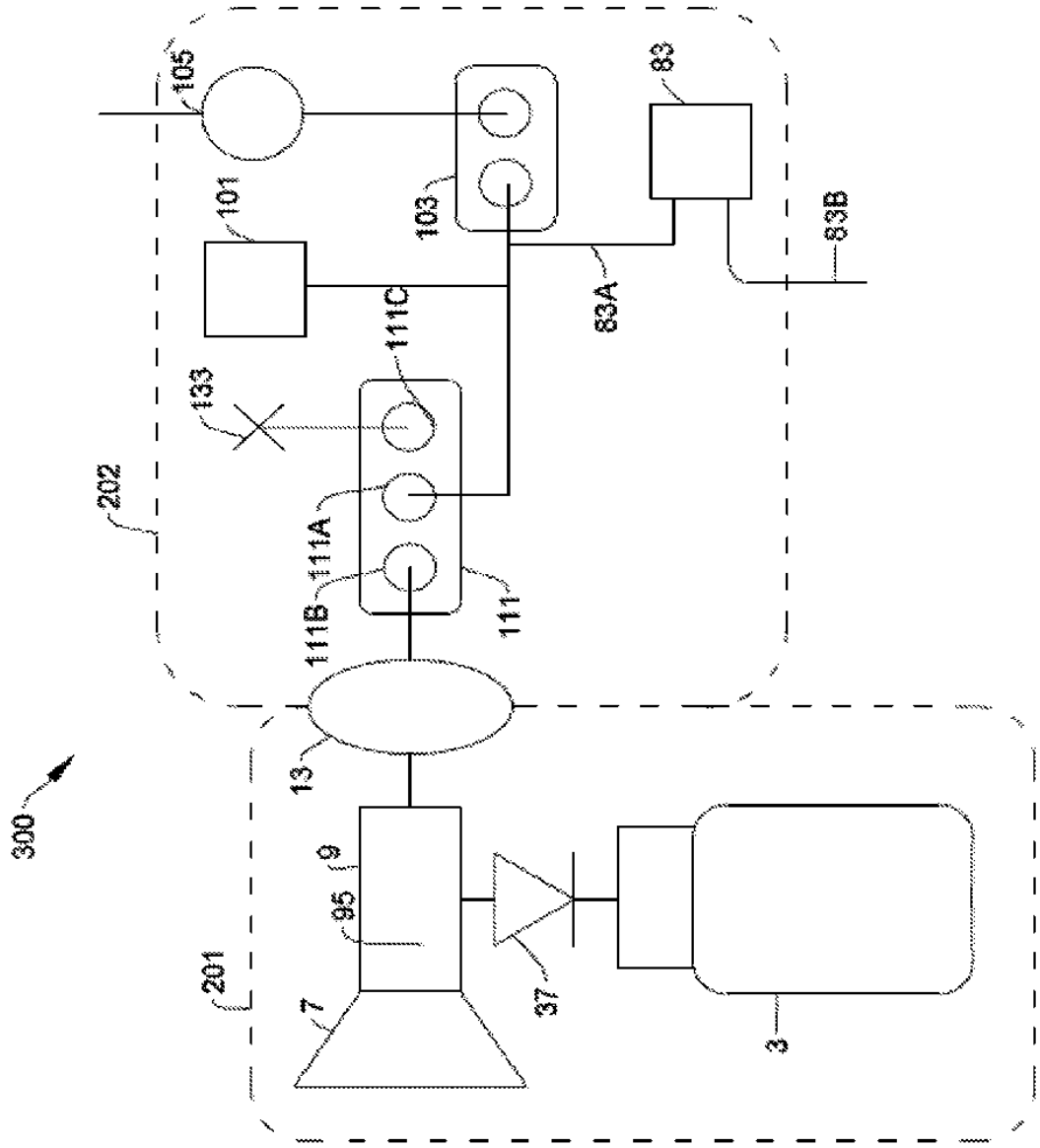

300
202
201
105
101
103
83
83B
83A
111C
133
111A
111B
111
13
9
95
7
37
3

FIGURE 11

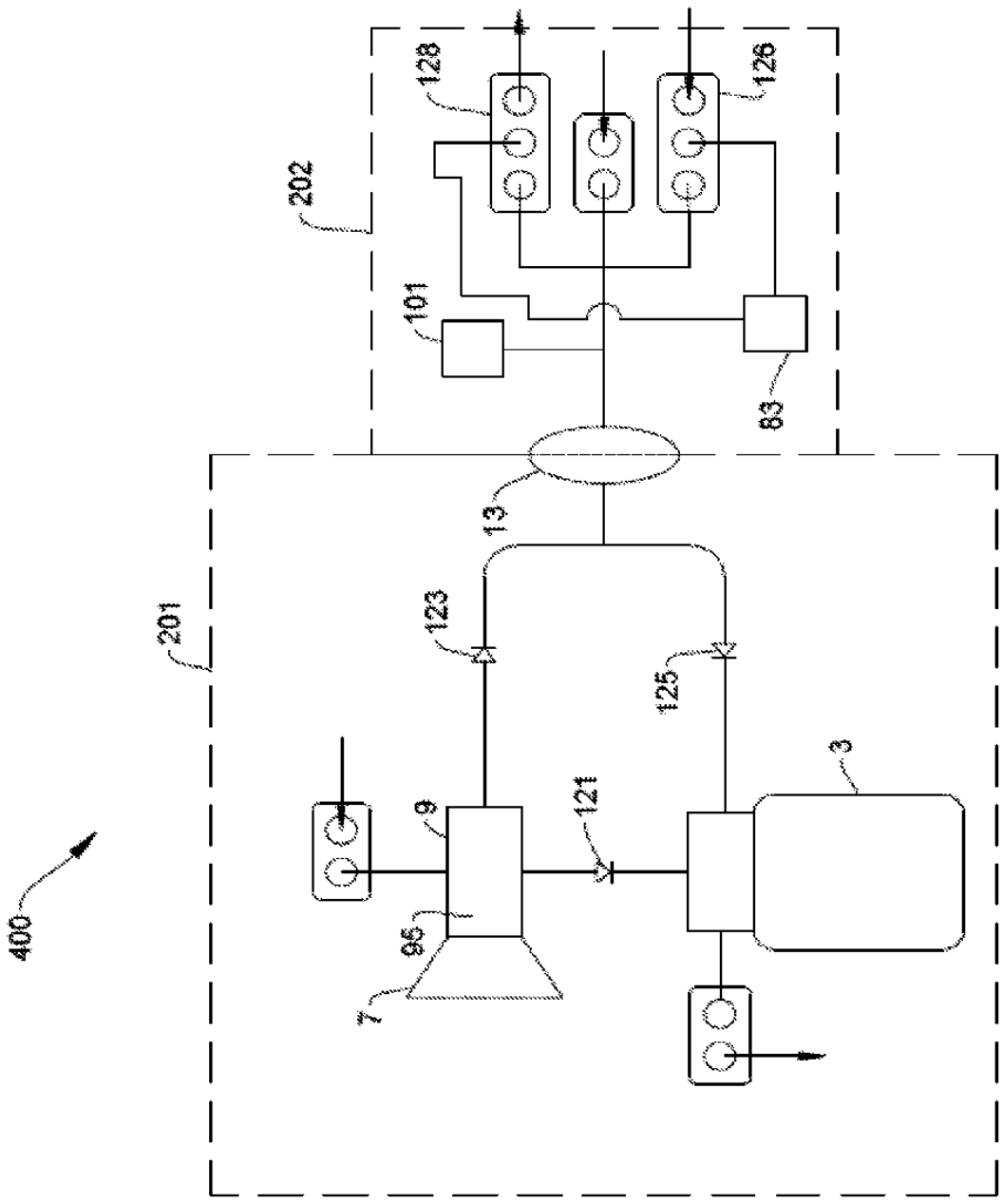


FIGURE 12

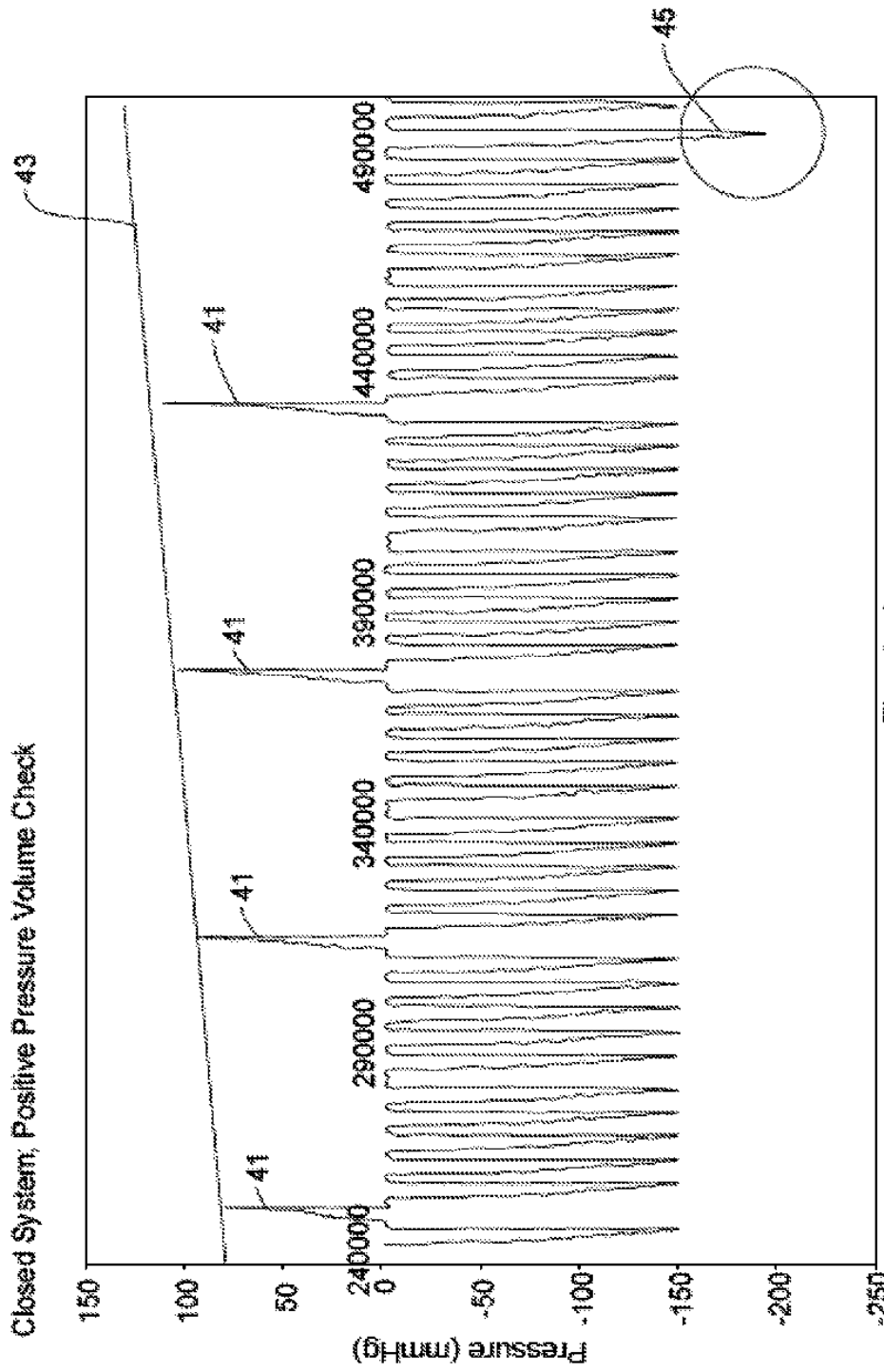

Closed System, Positive Pressure Volume Check
43
41
41
41
41
45
240000
290000
340000
390000
440000
490000
150
100
50
0
-50
-100
-150
-200
-250
Pressure (mmHg)
Time (ms)
Plot Area

FIGURE 13

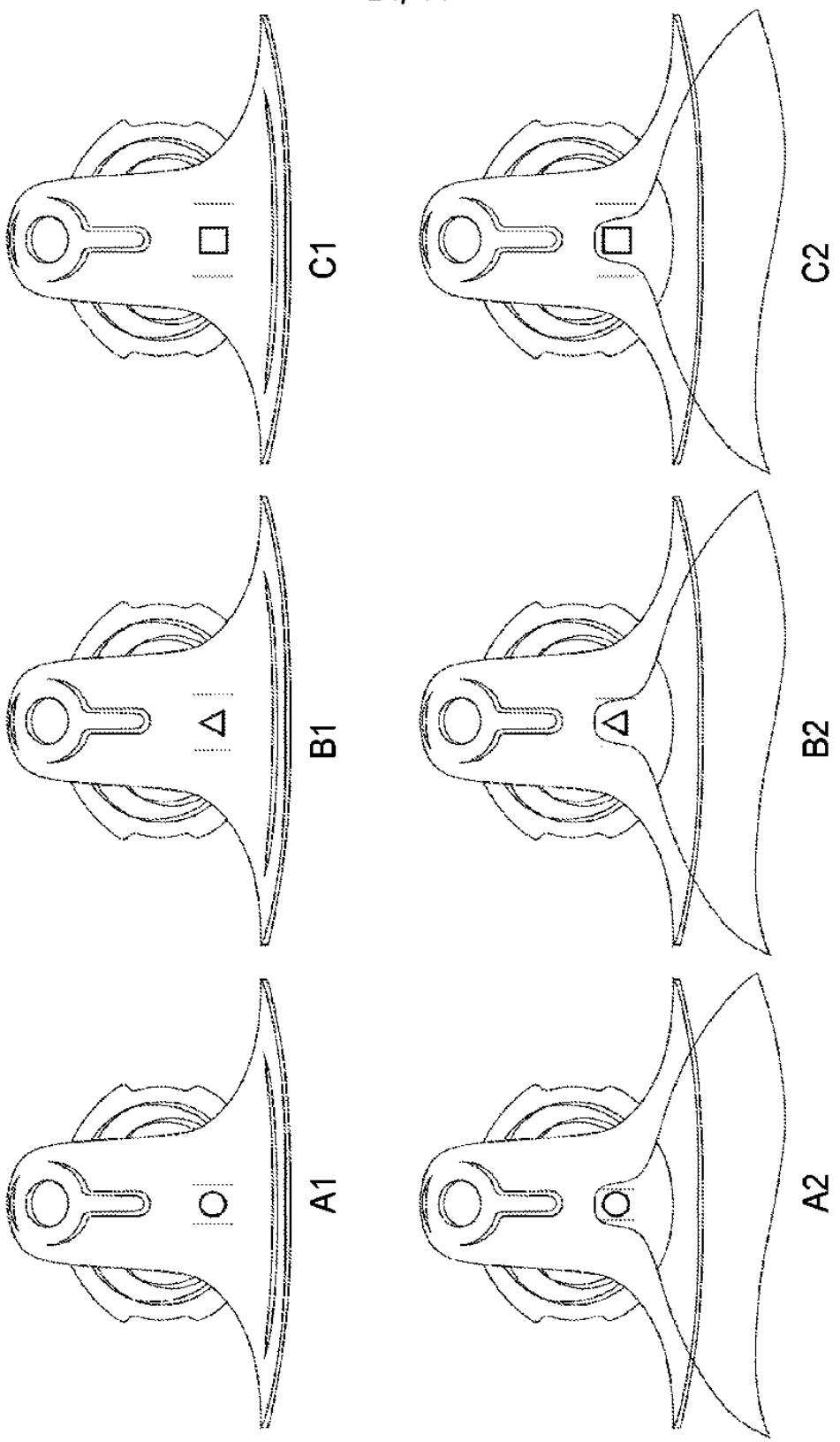


FIGURE 14

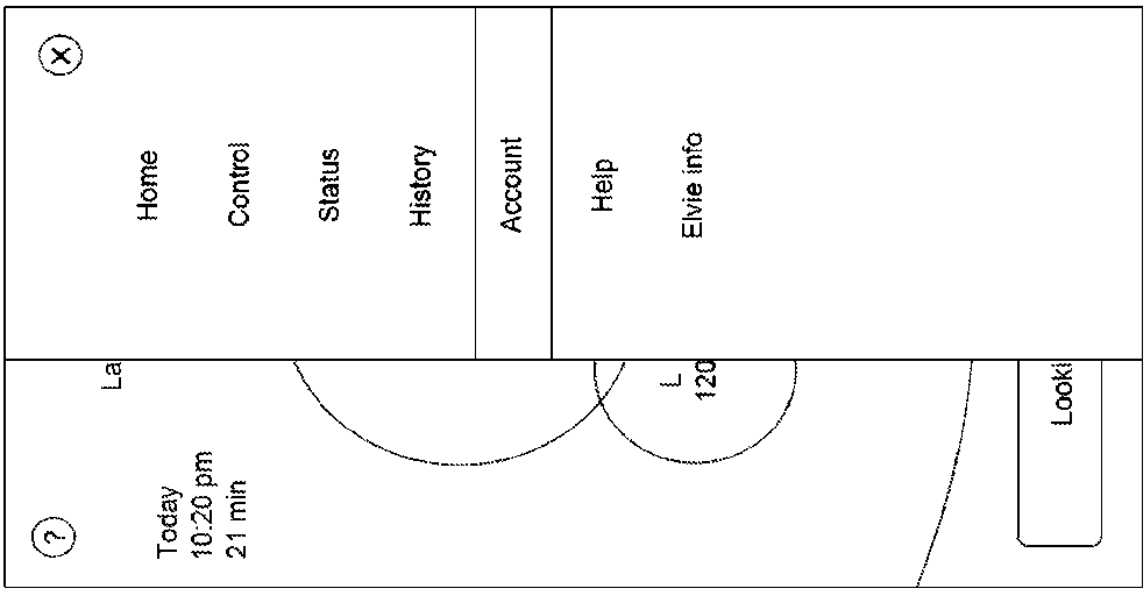

Home
Control
Status
History
Account
Help
Elvie info
Today
10:20 pm
21 min
Looki

FIGURE 15

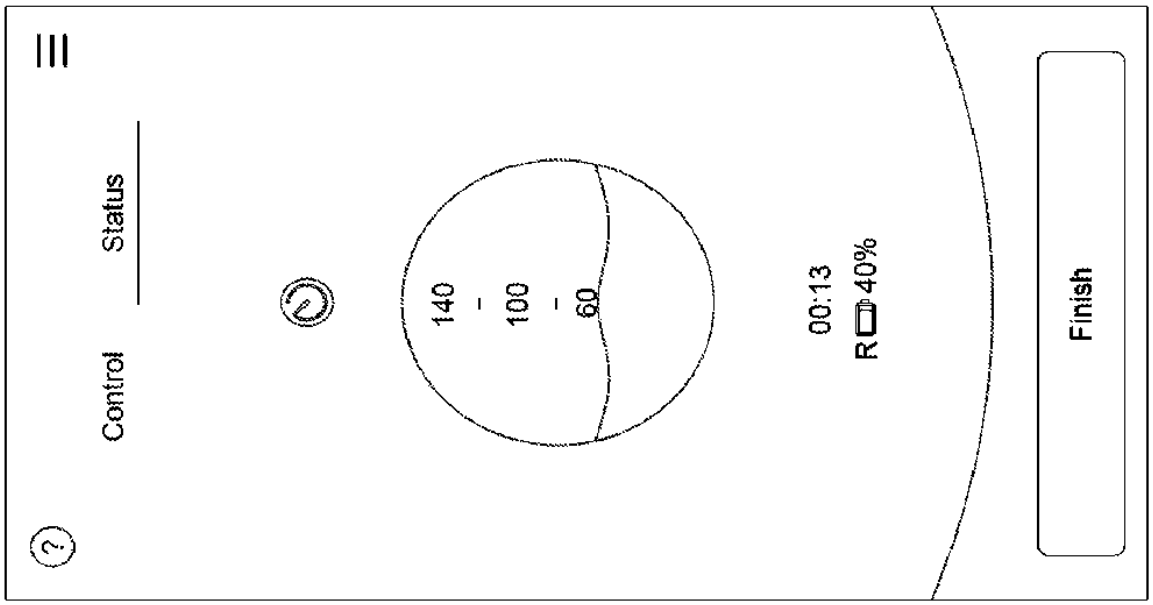


FIGURE 16

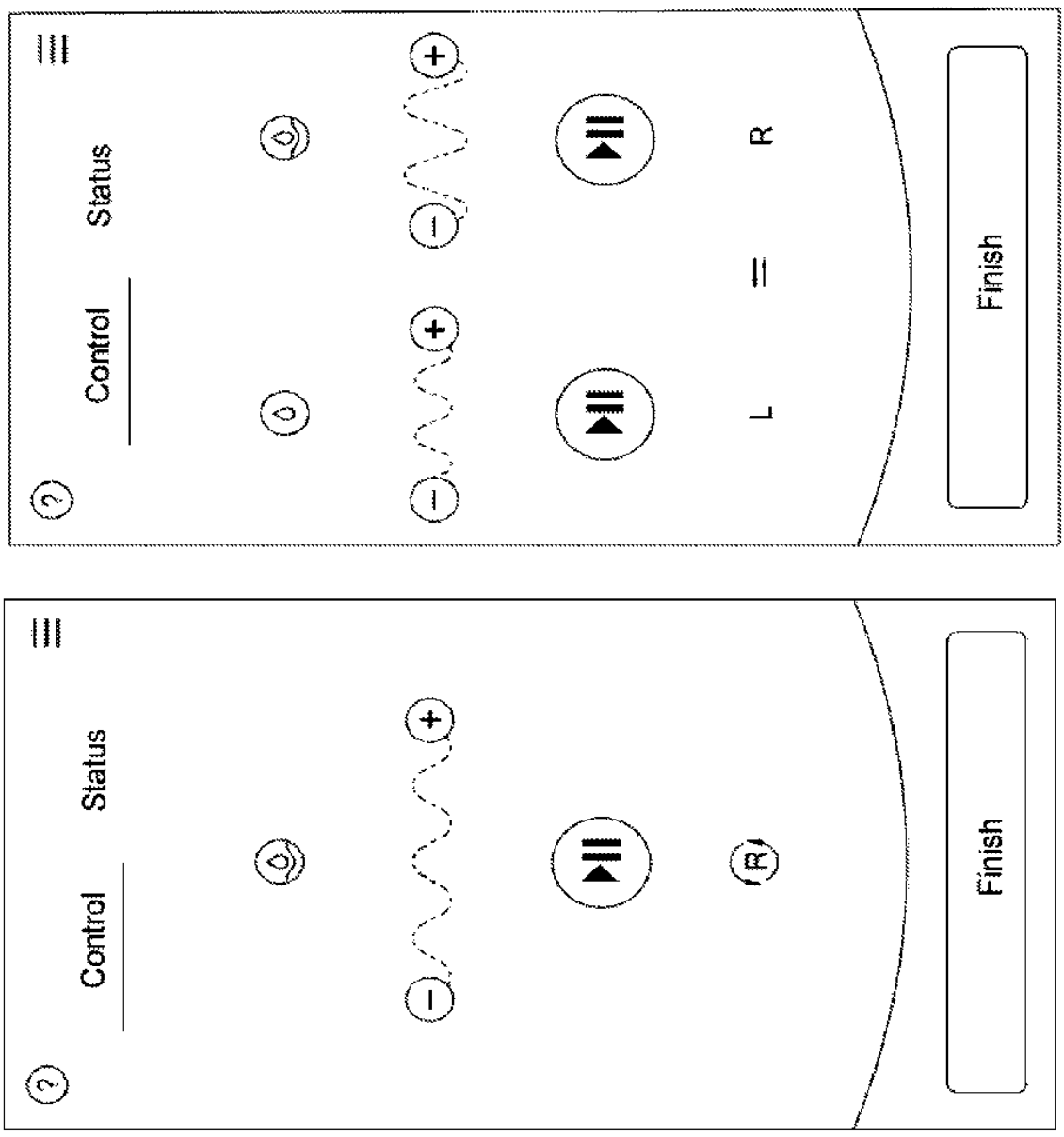


FIGURE 17

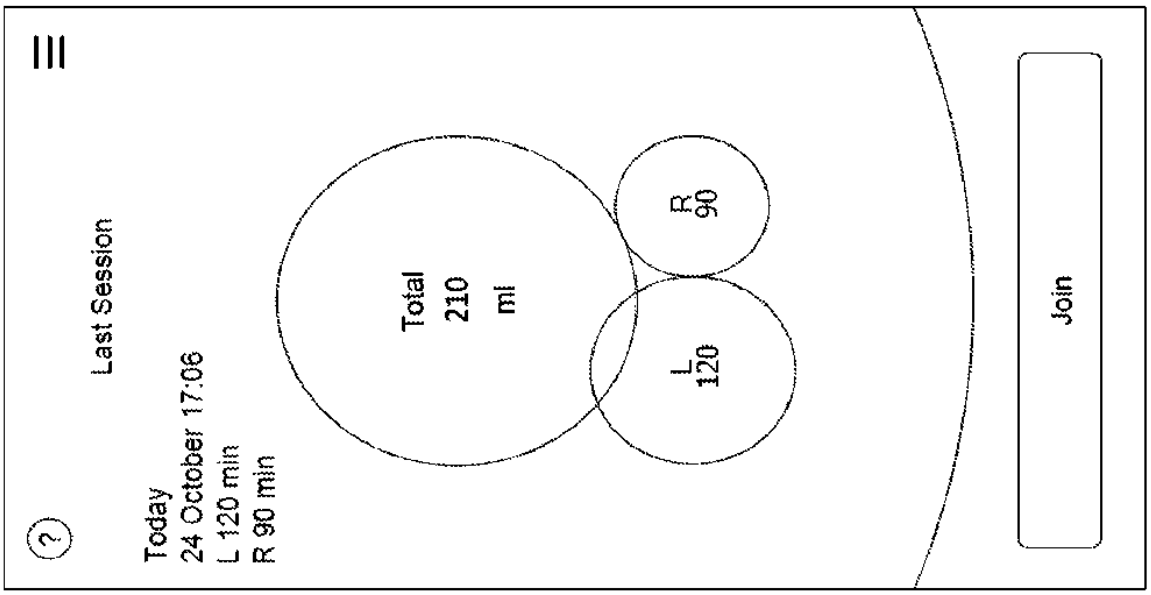

Last Session
Today
24 October 17:06
L 120 min
R 90 min
Total
210
mi
L
120
R
90
Join

FIGURE 18

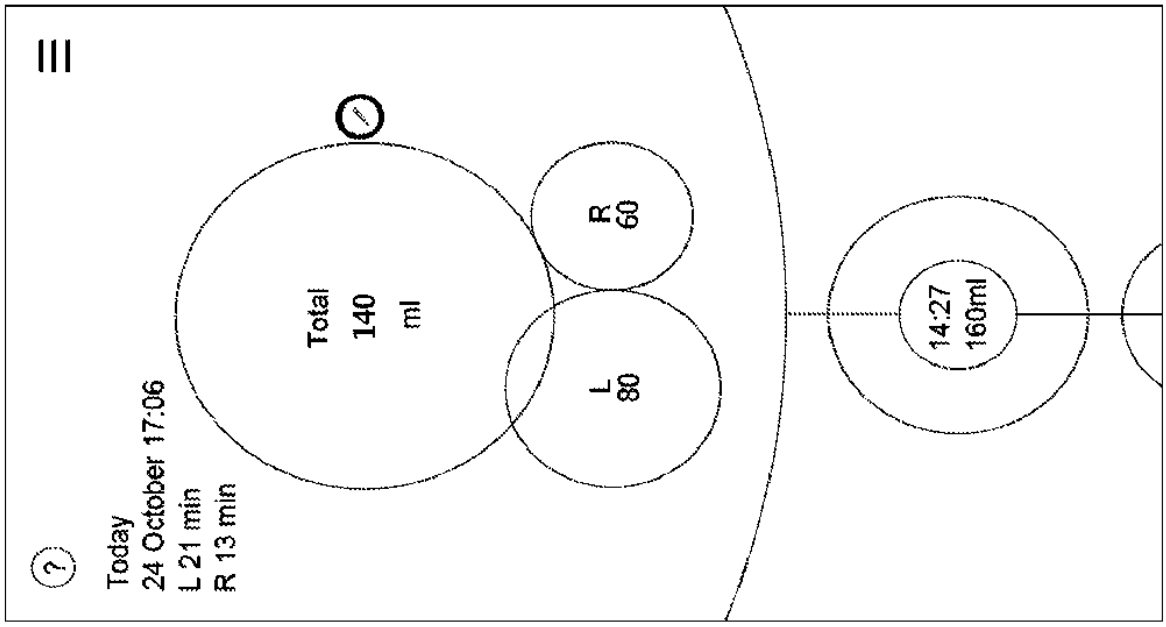

Today
24 October 17:06
L 21 min
R 13 min
Total
140
ml
L
80
R
60
14:27
160ml

FIGURE 19

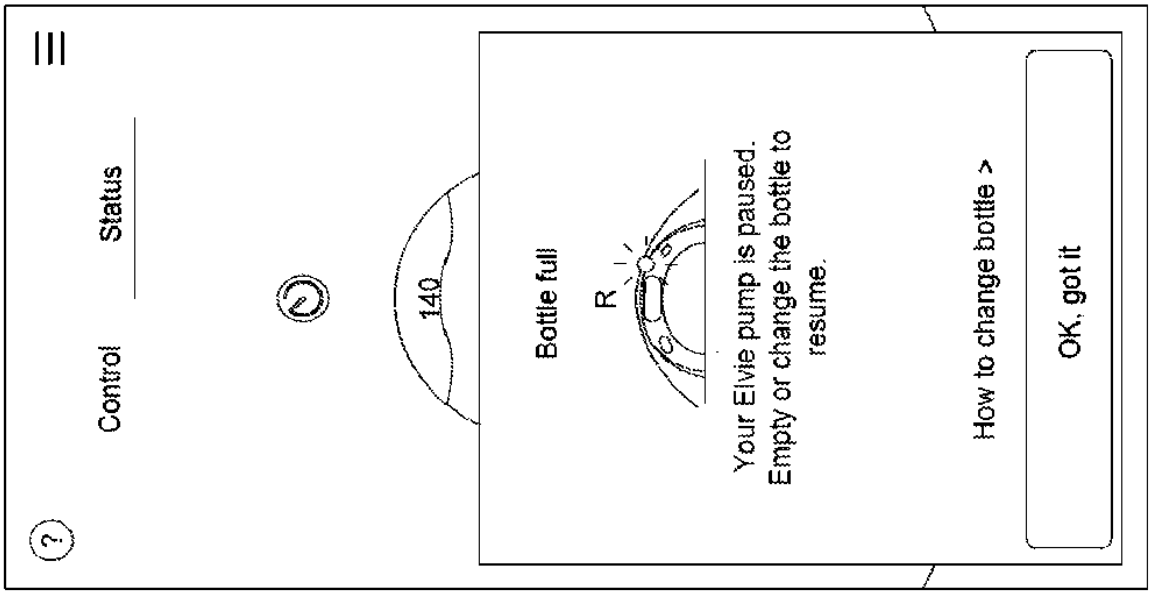

Control
Status
140
Bottle full
R
Your Elvie pump is paused.
Empty or change the bottle to resume.
How to change bottle >
OK, got it

FIGURE 20

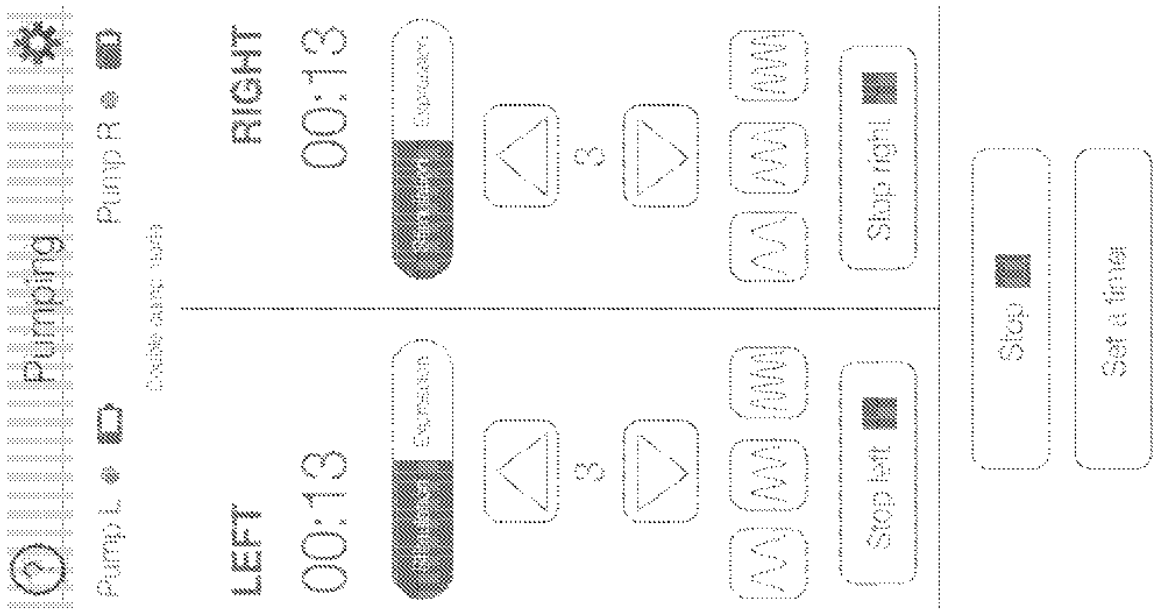

Pumping
Pump 1
Pump 2
Pump 3
Delete all sessions
LEFT
00:13
Pumping
Extend
RIGHT
00:13
Pumping
Extend
Stop left
Stop right
Step
Set a time

FIGURE 21

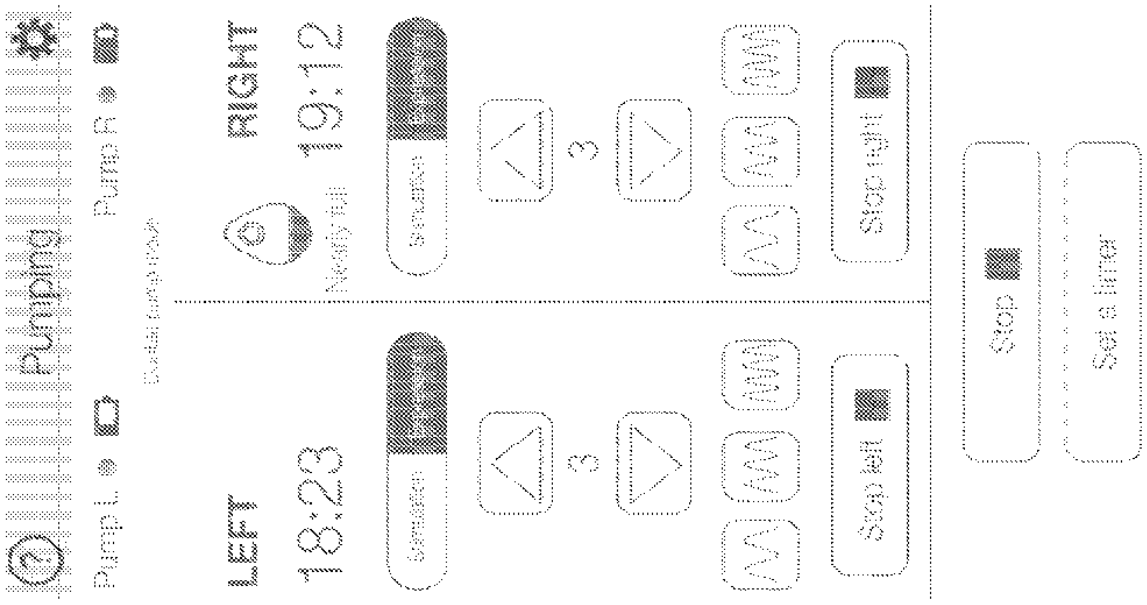

Pumping
Pump L
Pump R
Battery temp: n/a
LEFT
18:23
Ready full
Simulation
Pumping
3
Stop left
RIGHT
19:12
Ready full
Simulation
Pumping
3
Stop right
Stop
Set e timer

FIGURE 22

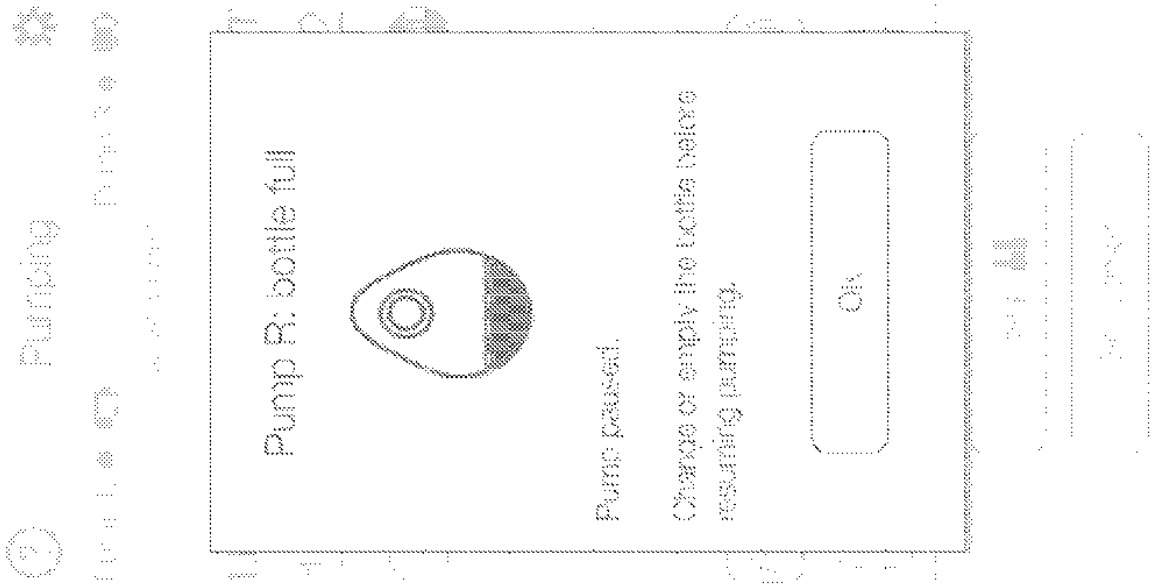

Pumping
Pump R: bottle full
Pump stopped.
Change or empty the bottle before restarting pumping.
OK

FIGURE 23


Stopped
Pump L
Pump R
LEFT
21:02
STOPPED
RIGHT
20:38
STOPPED
Total volume in bottle
60 ml
Total volume in bottle
65 ml
Resume left
Resume right
Resume
End session

FIGURE 24

PUMP
Pump L
25s
Pump R
Double pump mode
LAST SESSION
Start time: 3:50pm today
Total volume: 125ml
LEFT
20mins 13s
90ml
RIGHT
19mins 10s
65ml
Full history >
NEW SESSION
Start

FIGURE 25

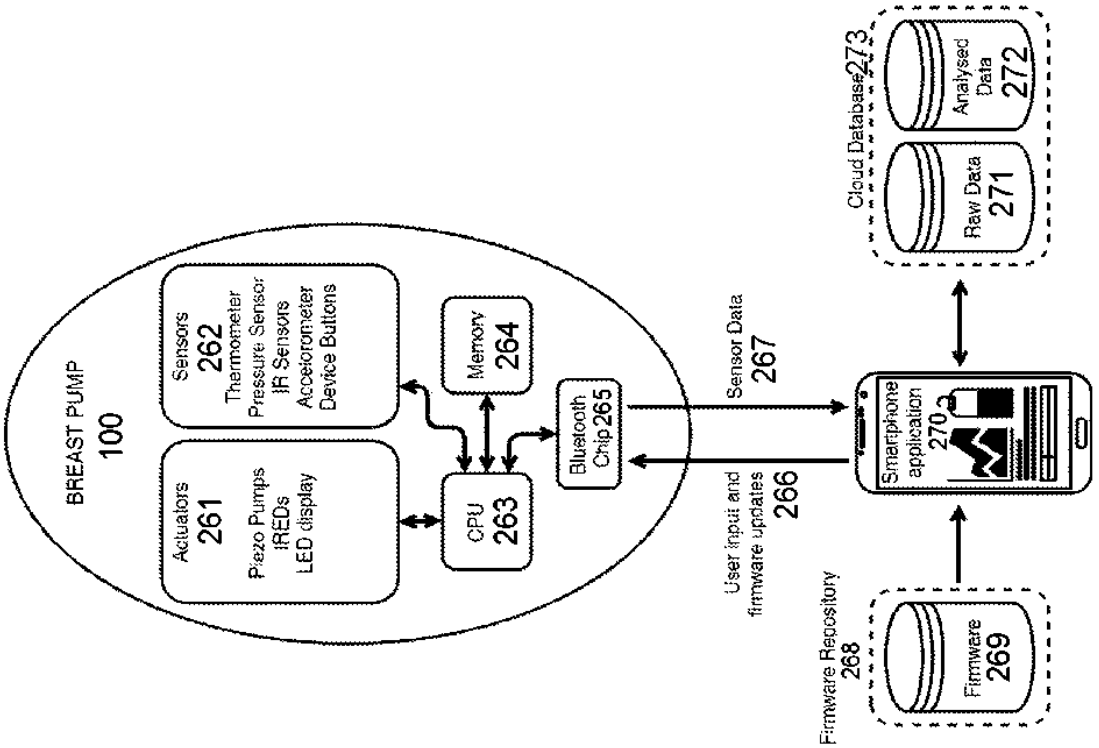

BREAST PUMP
100
Actuators
261
Piezo Pumps
IREDs
LED display
Sensors
262
Thermometer
Pressure Sensor
IR Sensors
Accelerometer
Device Buttons
CPU
263
Memory
264
Bluetooth
Chip 265
Sensor Data
267
User input and
firmware updates
266
Smartphone
application
270
Cloud Database 273
Raw Data
271
Analysed
Data
272
Firmware Repository
268
Firmware
269

FIGURE 26

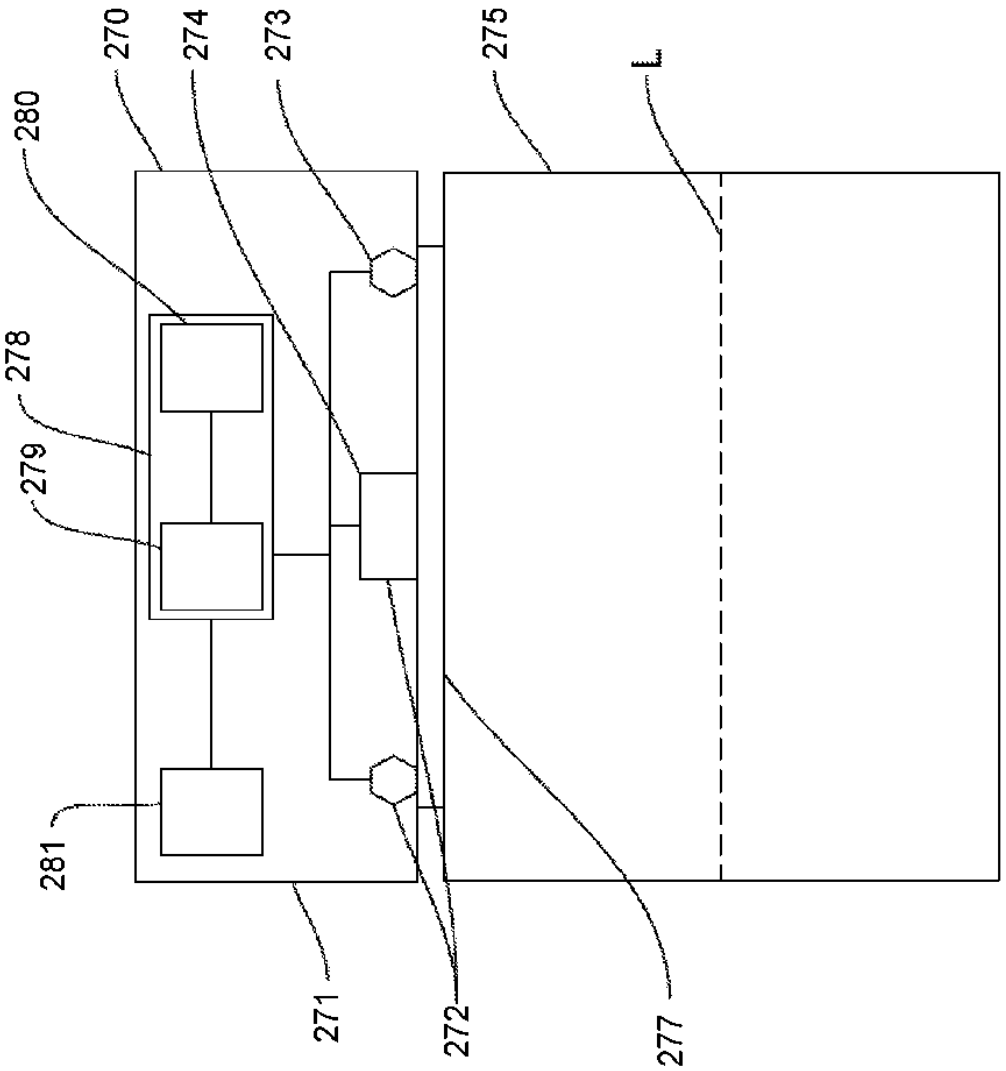


FIGURE 27

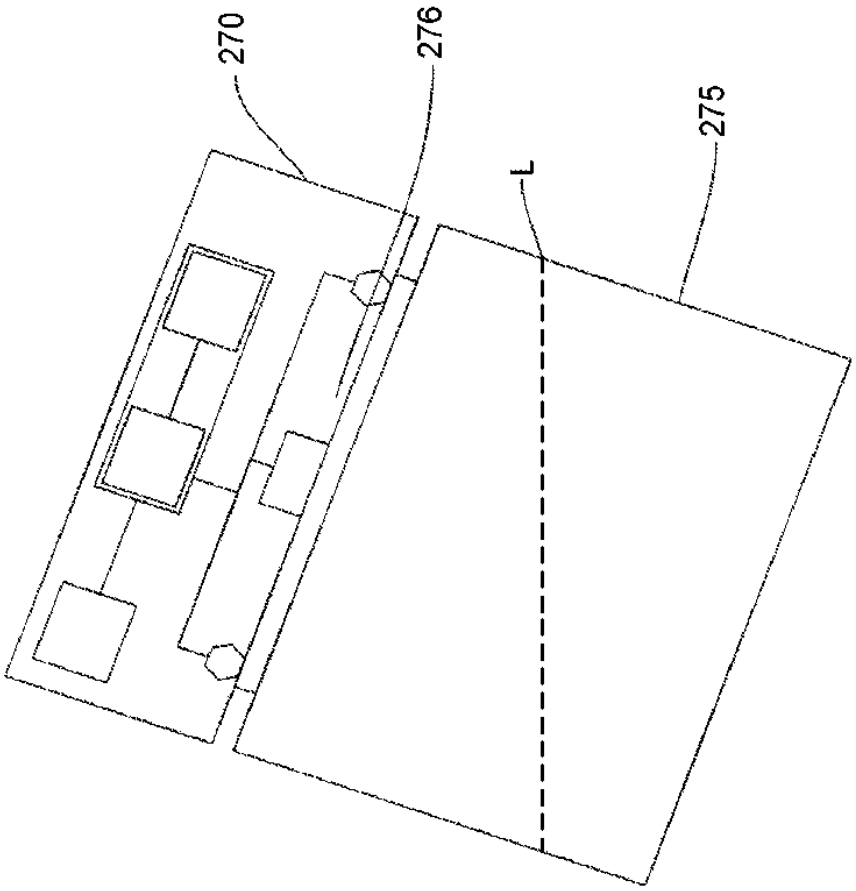


FIGURE 28

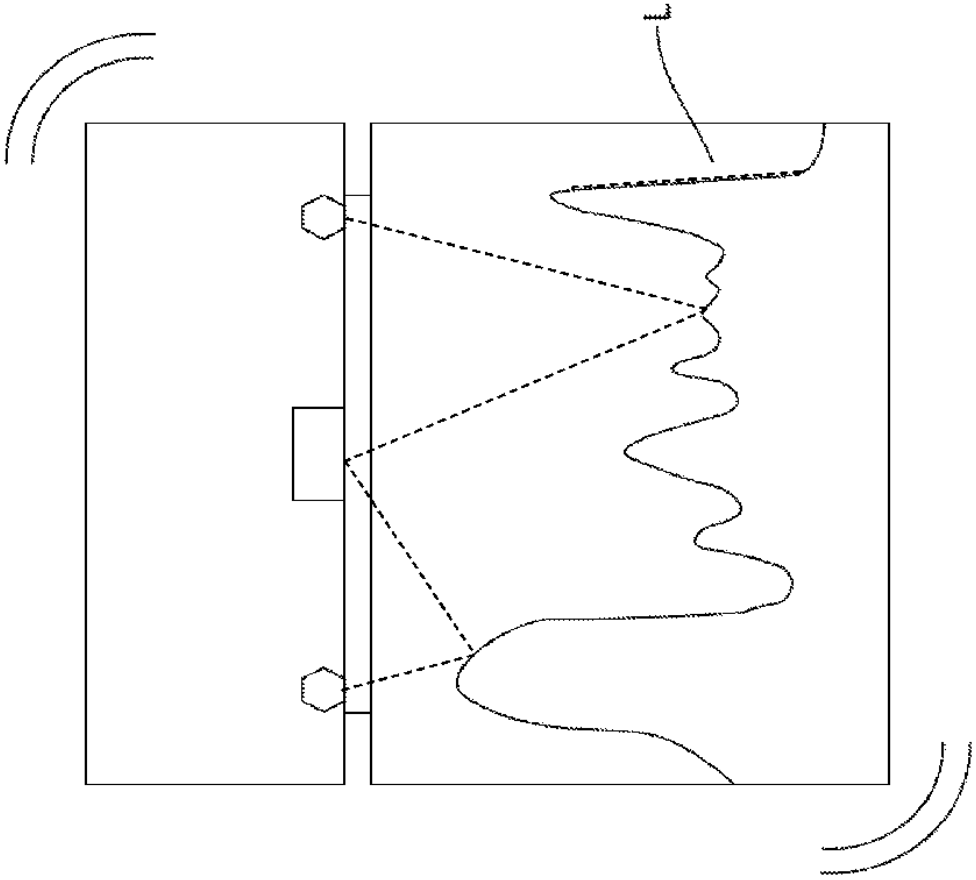


FIGURE 29

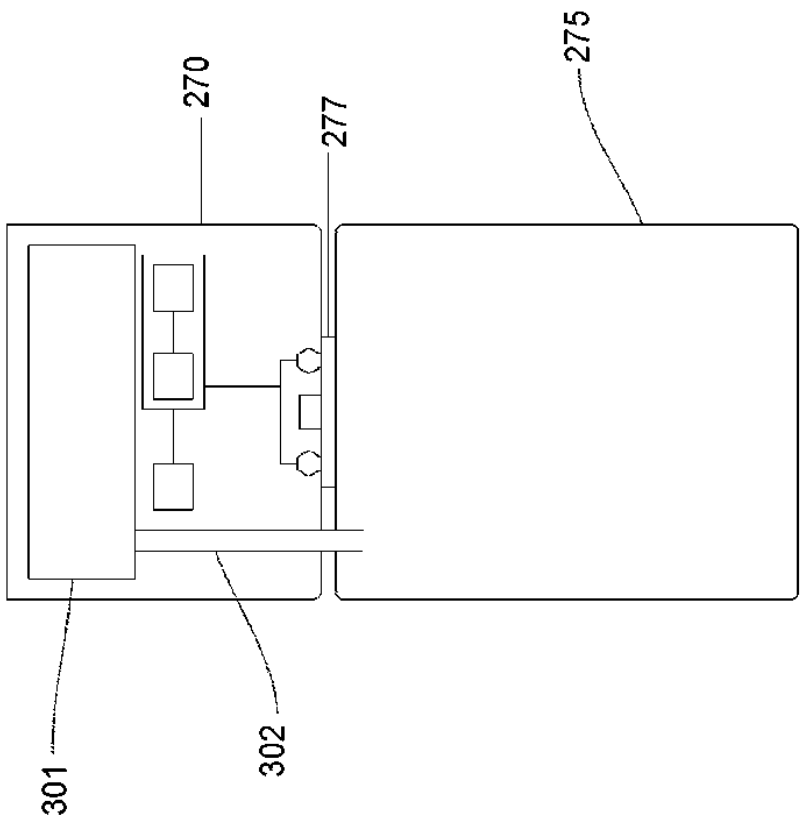


FIGURE 30

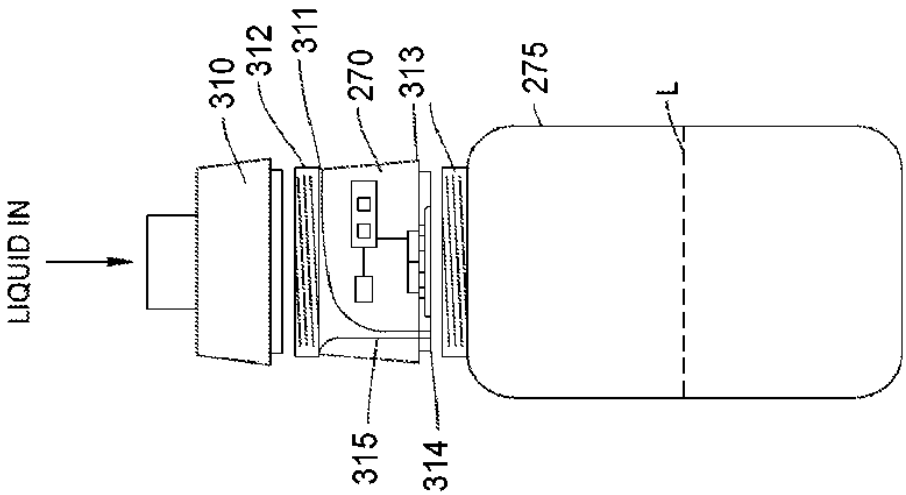


FIGURE 31

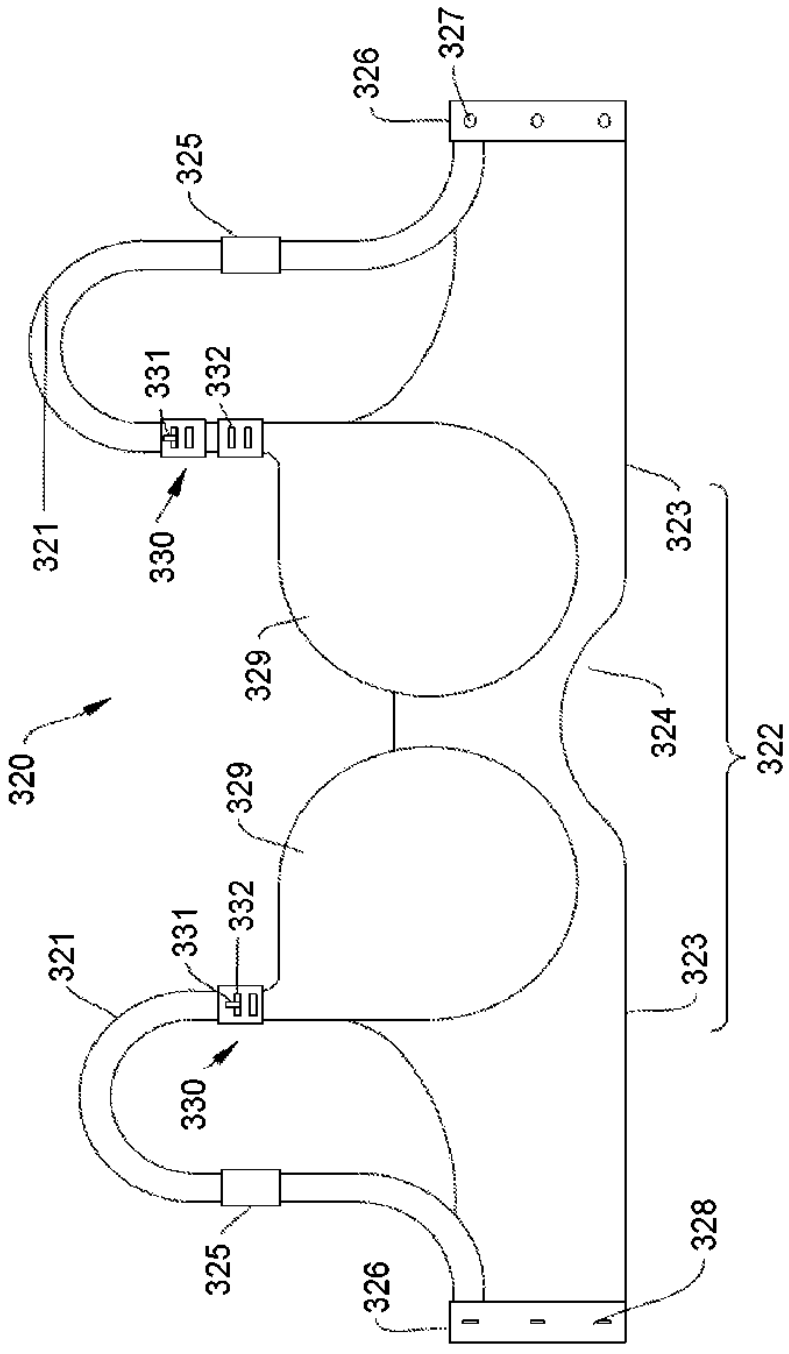


FIGURE 32

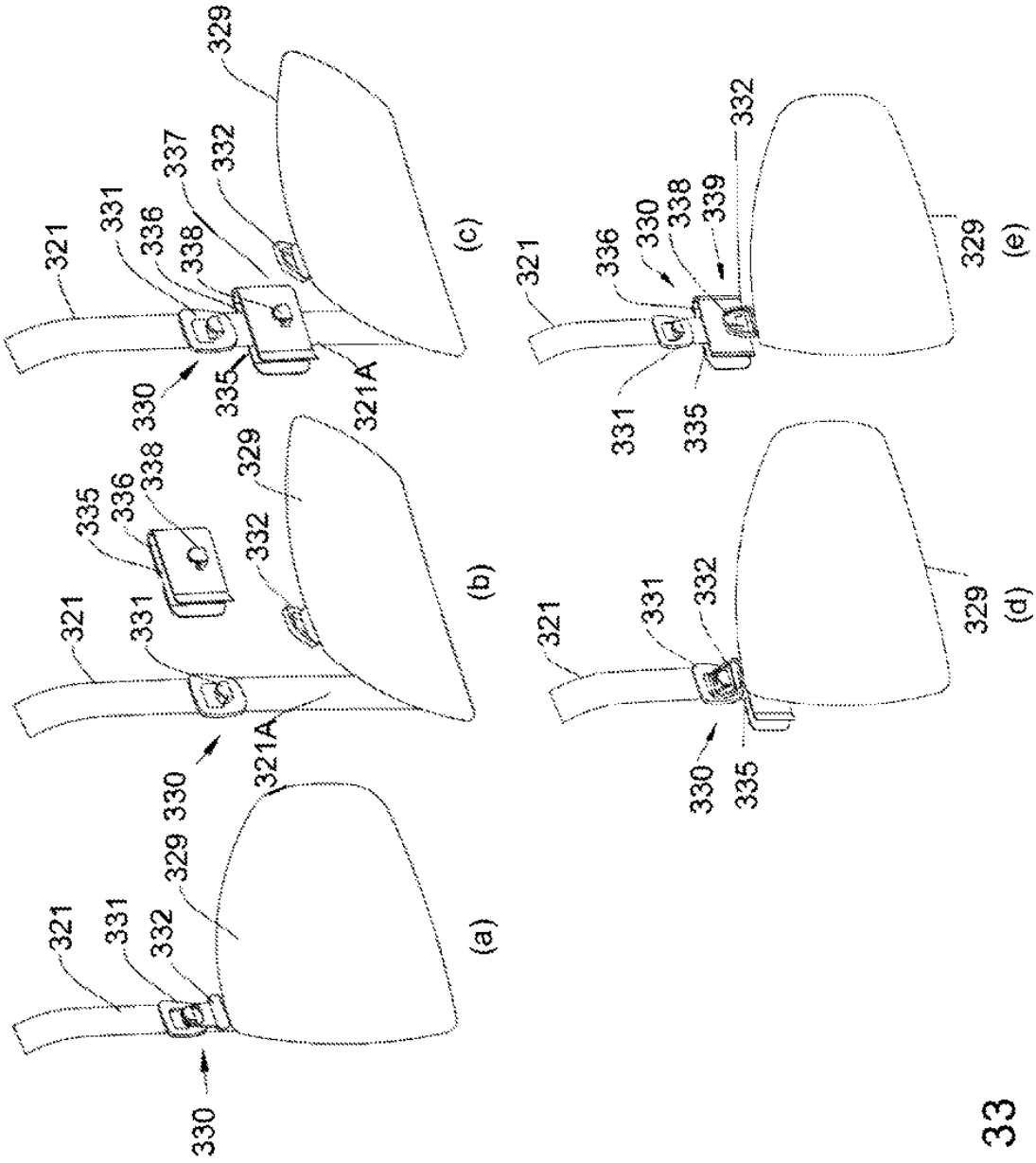

321
331
332
329
330
(a)
321
331
335
336
338
329
332
330
321A
(b)
321
331
335
336
338
337
332
329
330
335
321A
(c)
321
331
336
330
338
339
332
329
(e)
321
331
332
329
330
335
(d)

FIGURE 33

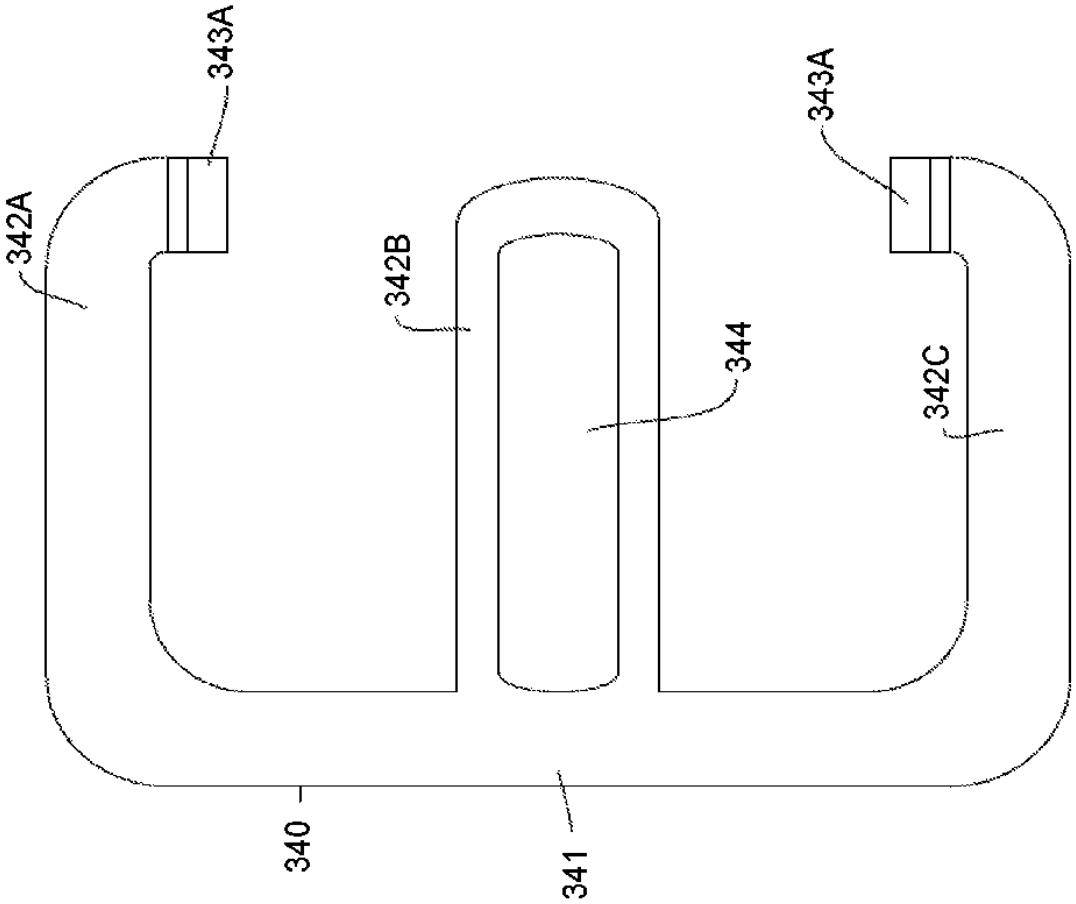


FIGURE 34

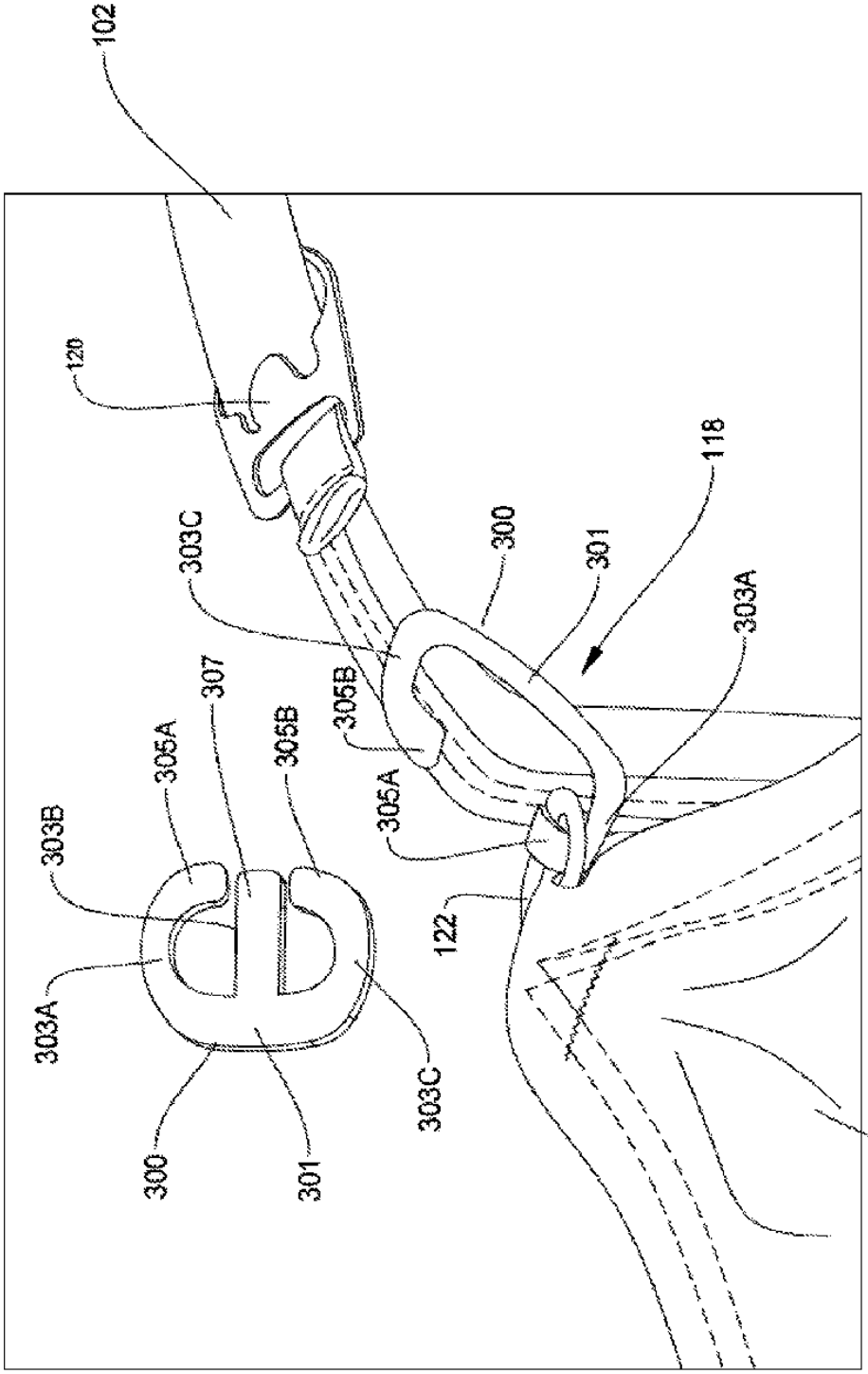

102
120
303C
300
301
118
303A
307
305B
305A
305A
305B
303B
303A
122
303C
300
301
116

FIGURE 35

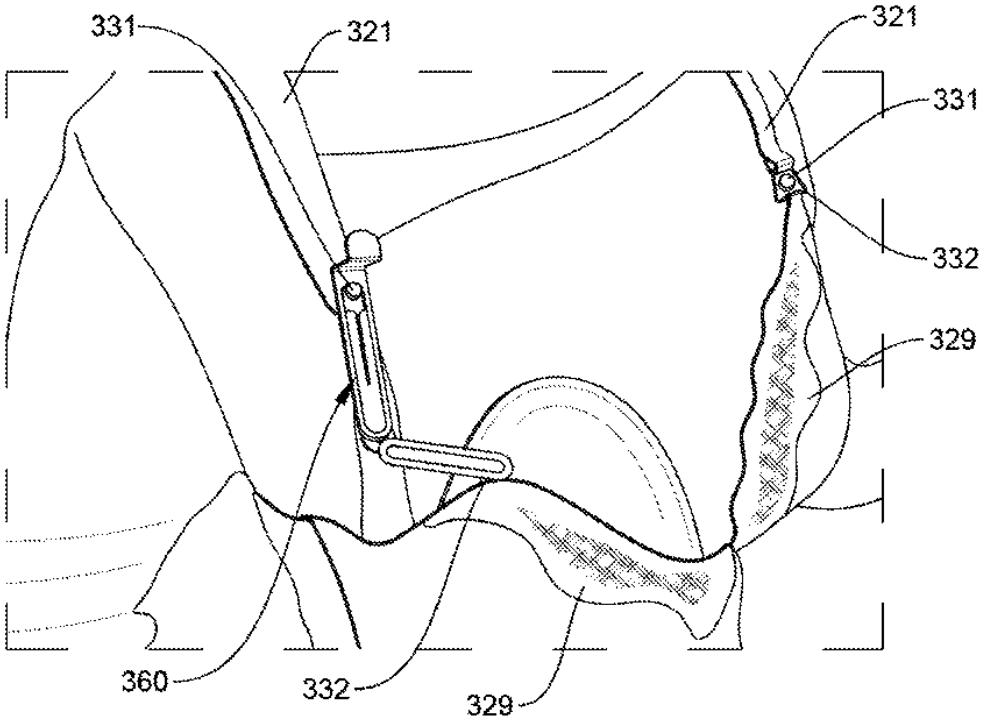


FIGURE 36

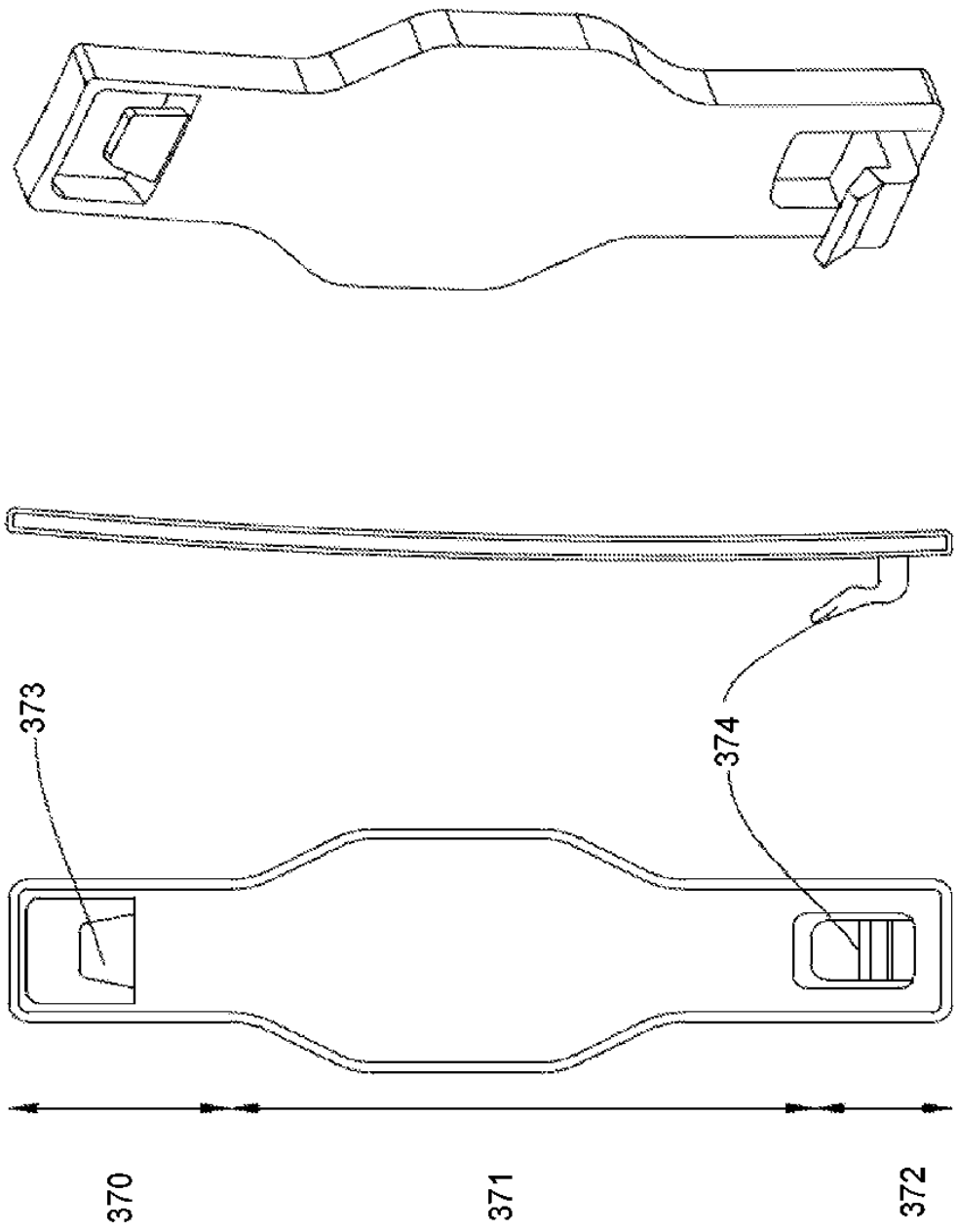


FIGURE 37

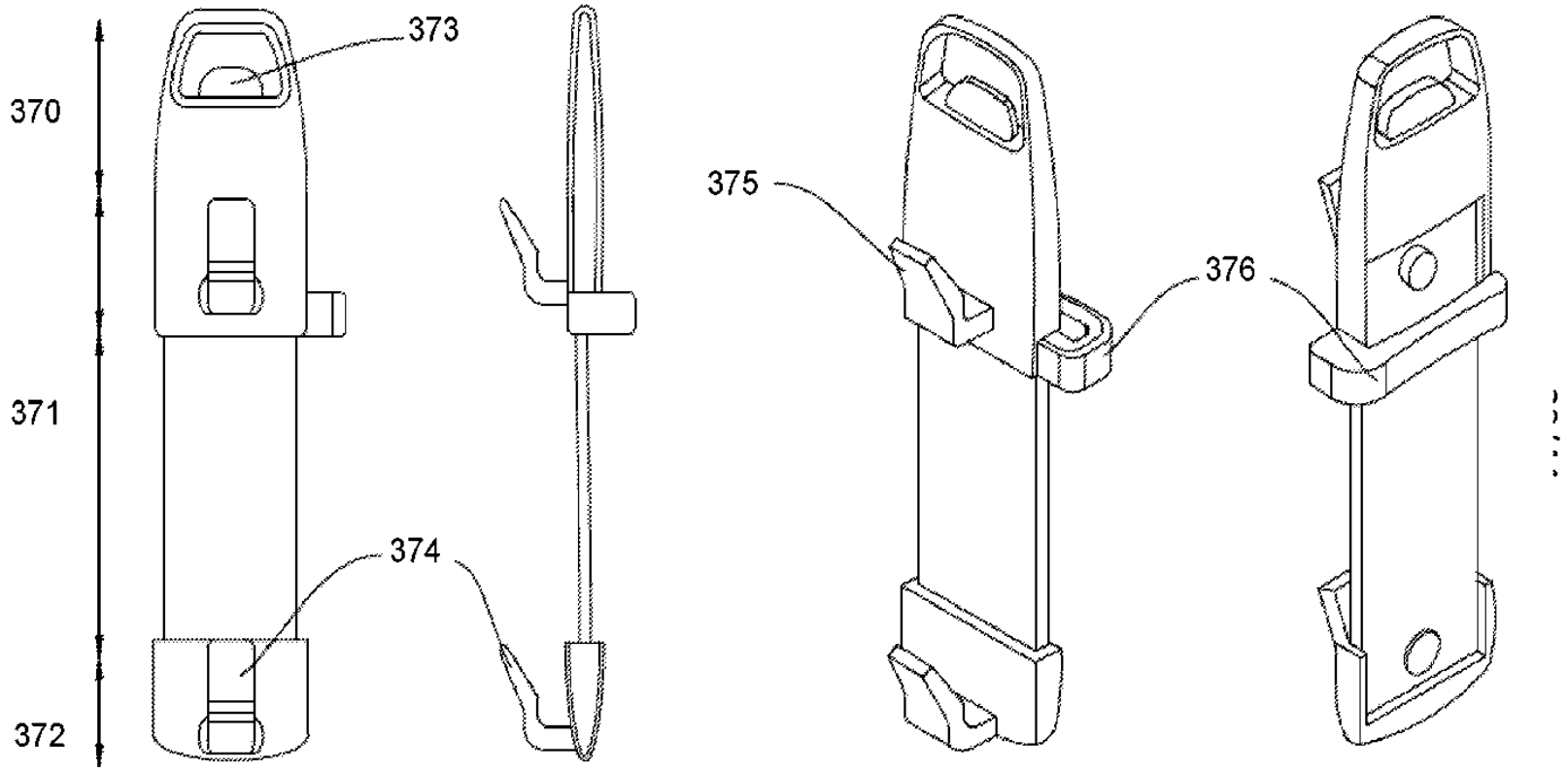


FIGURE 38

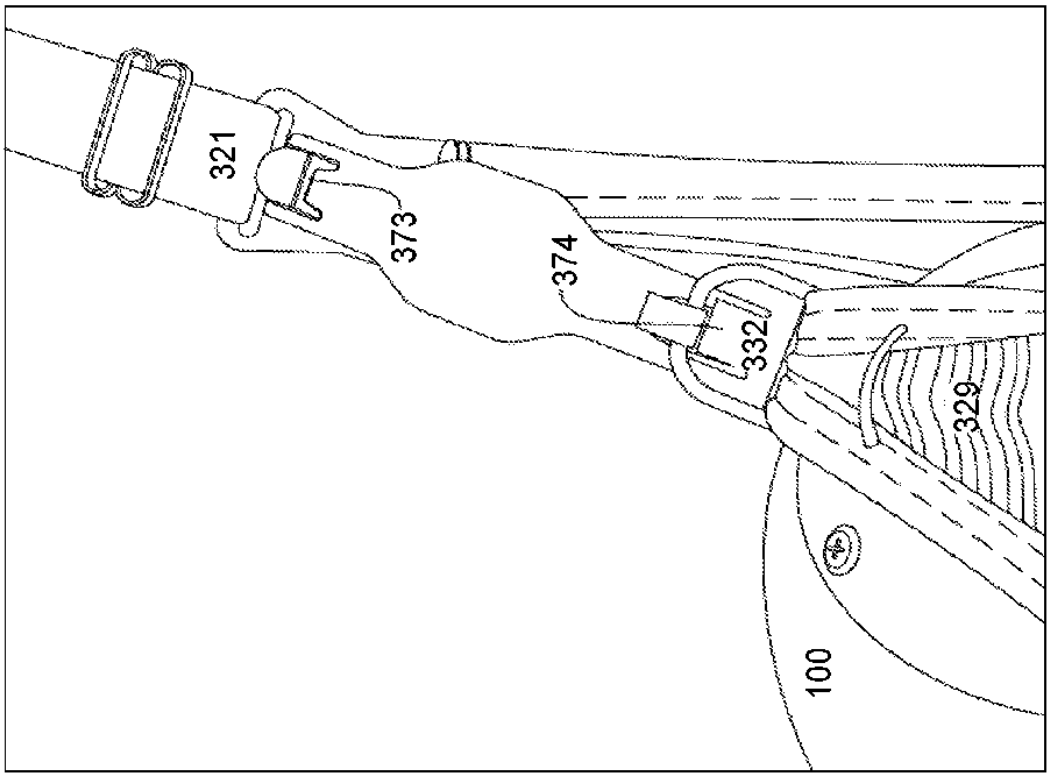


FIGURE 39

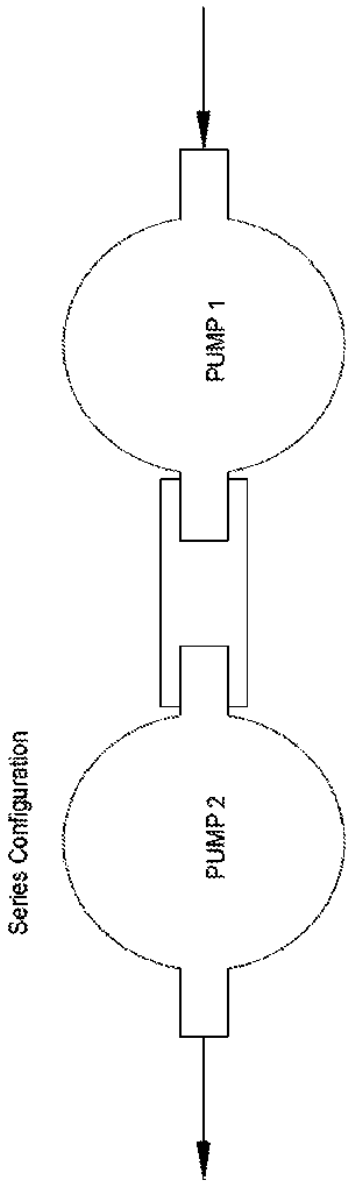


FIGURE 40

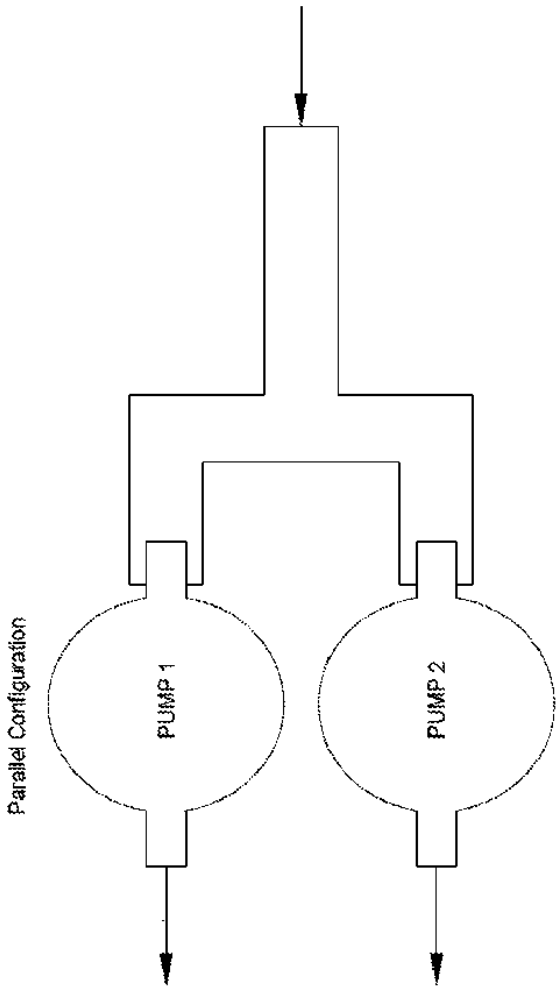


FIGURE 41

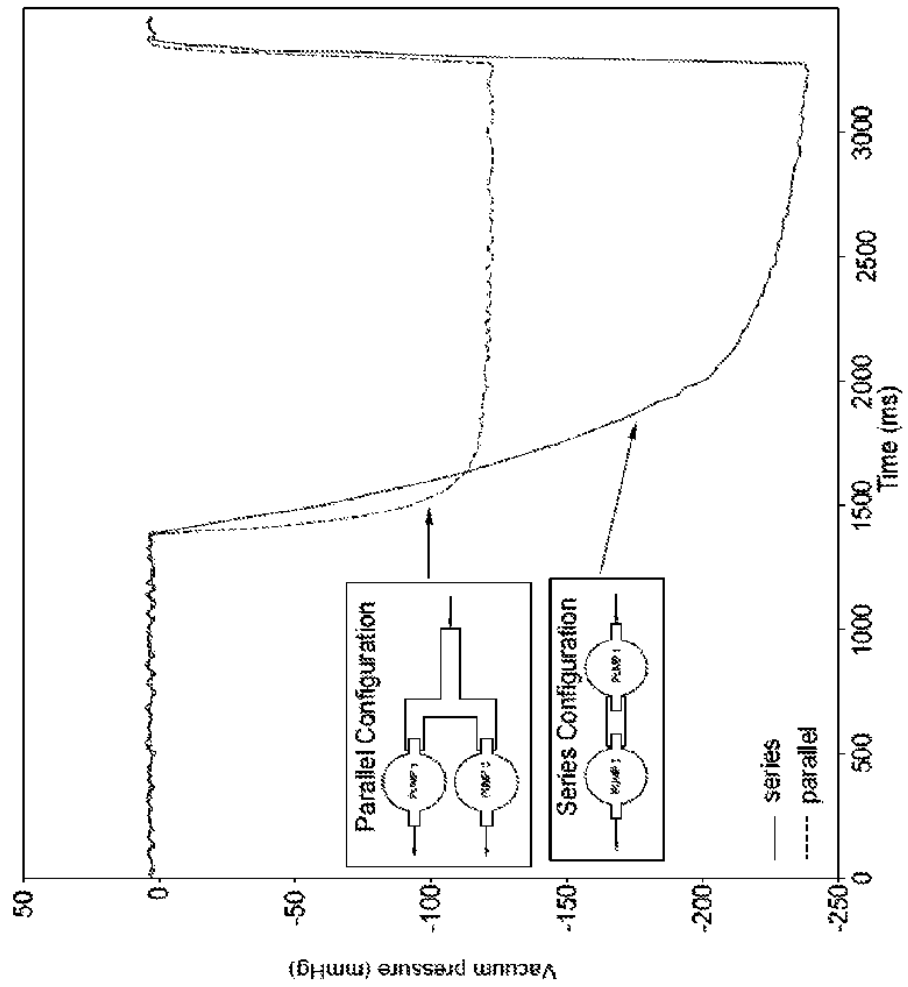

Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
series
parallel
Parallel Configuration
Series Configuration

FIGURE 42

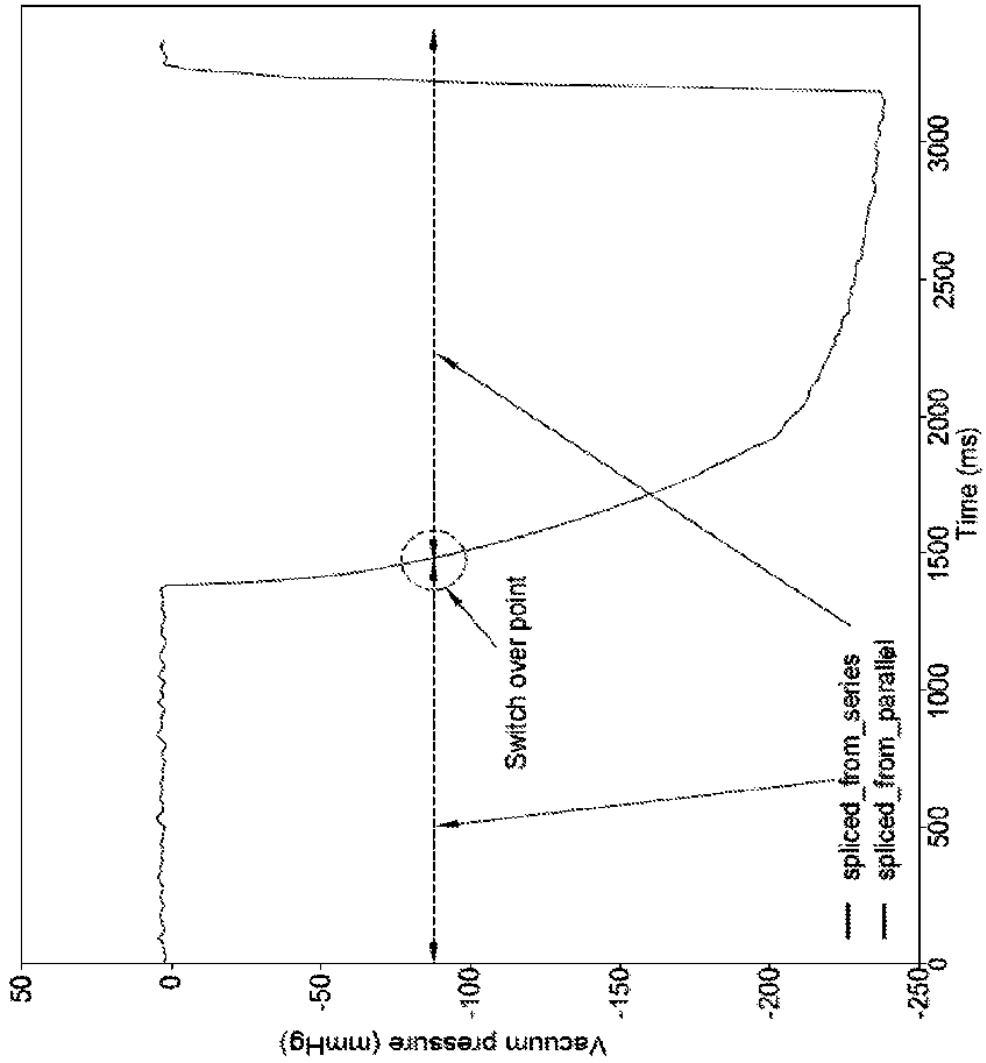

Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
Switch over point
spliced_from_series
spliced_from_parallel

FIGURE 43

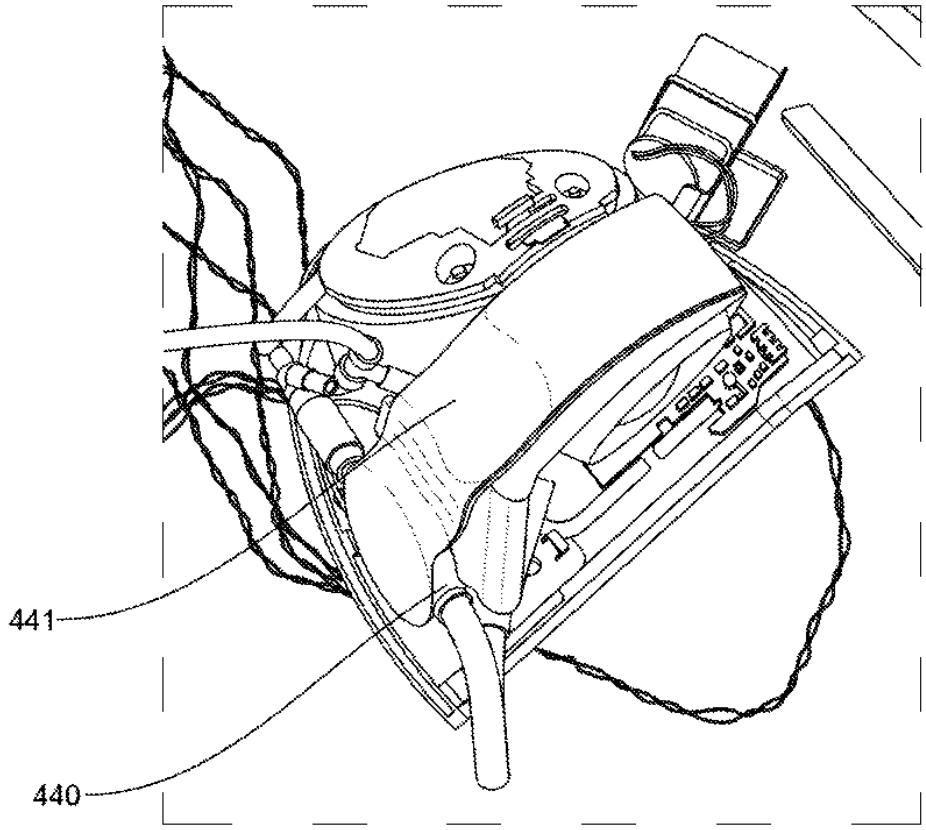


FIGURE 44

DocCode – SCORE

SCORE Placeholder Sheet for IFW Content

Application Number: 17181057 Document Date: 02/22/2021

The presence of this form in the IFW record indicates that the following document type was received in electronic format on the date identified above. This content is stored in the SCORE database.

Since this was an electronic submission, there is no physical artifact folder, no artifact folder is recorded in PALM, and no paper documents or physical media exist. The TIFF images in the IFW record were created from the original documents that are stored in SCORE.

- Drawing

At the time of document entry (noted above):

- USPTO employees may access SCORE content via DAV or via the SCORE web page.
- External customers may access SCORE content via PAIR using the Supplemental Content tab.

Form Revision Date: March 1, 2019