(12) STANDARD PATENT (11) Application No. **AU 2010300058 B2**
(19) AUSTRALIAN PATENT OFFICE

(54) Title
Device and method for expressing human breast milk

(51) International Patent Classification(s)
A61M 1/06 (2006.01) ***A61M 1/00*** (2006.01)

(21) Application No: **2010300058** (22) Date of Filing: **2010.09.17**

(87) WIPO No: **WO11/035447**

(30) Priority Data

(31) Number	(32) Date	(33) Country
61/244,636	**2009.09.22**	**US**

(43) Publication Date: **2011.03.31**
(44) Accepted Journal Date: **2013.12.05**

(71) Applicant(s)
Medela Holding AG

(72) Inventor(s)
Weber, Beda;Furrer, Etienne;Schlienger, Andre;Silver, Brian H.;Wackerlin, Daniela;Felber, Armin

(74) Agent / Attorney
Griffith Hack, GPO Box 1285, Melbourne, VIC, 3001

(56) Related Art
US 2004/0087898

(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

(19) Weltorganisation für geistiges Eigentum
Internationales Büro

(43) Internationales Veröffentlichungsdatum
31. März 2011 (31.03.2011)

PCT

(10) Internationale Veröffentlichungsnummer
WO 2011/035447 A1

(51) Internationale Patentklassifikation:
A61M 1/06 (2006.01) *A61M 1/00* (2006.01)

(21) Internationales Aktenzeichen: PCT/CH2010/000225

(22) Internationales Anmeldedatum:
17. September 2010 (17.09.2010)

(25) Einreichungssprache: Deutsch

(26) Veröffentlichungssprache: Deutsch

(30) Angaben zur Priorität:
61/244,636 22. September 2009 (22.09.2009) US

(71) Anmelder *(für alle Bestimmungsstaaten mit Ausnahme von US)*: **MEDELA HOLDING AG** [CH/CH]; Lättichstrasse 4b, CH- 6340 Baar (CH).

(72) Erfinder; und

(75) Erfinder/Anmelder *(nur für US)*: **WEBER, Beda** [CH/CH]; Rigiweg 19b, CH-5643 Sins (CH). **FURRER, Etienne** [CH/CH]; Steinhauserstrasse 31, CH-6300 Zug (CH). **SCHLIENGER, André** [CH/CH]; Dorfstrasse 66, CH-8933 Maschwanden (CH). **SILVER, Brian, H.** [US/US]; 340 Ann Street, Cary, IL 60013 (US). **WÄCKERLIN, Daniela** [CH/CH]; Zugerstrasse 18, CH-6340 Baar (CH). **FELBER, Armin** [CH/CH]; Meyerstrasse 22, CH-6003 Luzern (CH).

(74) Anwalt: **CLERC, Natalia**; Isler & Pedrazzini AG, Gotthardstrasse 53, Postfach 1772, CH-8027 Zürich (CH).

(81) Bestimmungsstaaten *(soweit nicht anders angegeben, für jede verfügbare nationale Schutzrechtsart)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, 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, IS, JP, KE, KG, KM, 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, PE, PG, PH, PL, PT, RO, RS, RU, 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) Bestimmungsstaaten *(soweit nicht anders angegeben, für jede verfügbare regionale Schutzrechtsart)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), eurasisches (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), europäisches (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, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Fortsetzung auf der nächsten Seite]

(54) **Title**: DEVICE AND METHOD FOR EXPRESSING HUMAN BREAST MILK

(54) **Bezeichnung** : VORRICHTUNG UND VERFAHREN ZUM ABPUMPEN VON MENSCHLICHER MUTTERMILCH

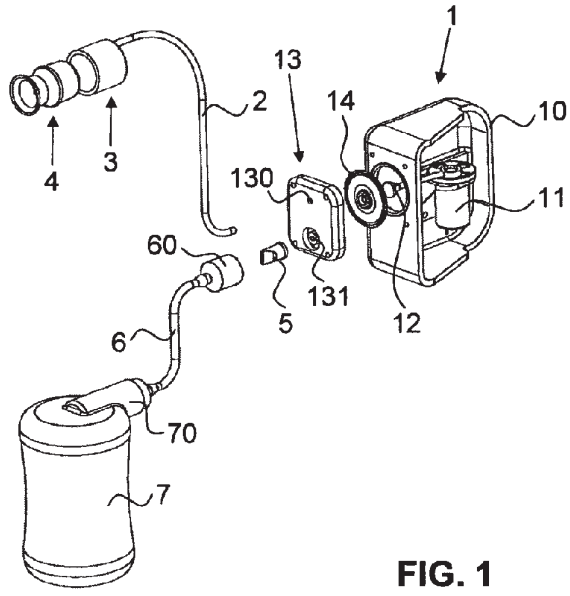


FIG. 1

(57) **Abstract**: A device for expressing human breast milk has a breast cup (4) to be placed on a mother's breast, a vacuum pump (1) for generating a vacuum, a line connecting the vacuum pump (1) to the breast cup (4) for transferring the generated vacuum to the breast cup (4), and a chamber. The line (2) ends at a first connection (130) of said chamber on the pump side. According to the invention, the chamber has a second connection (131) for connecting to a milk-collecting container (7). The two connections (130, 131) are interconnected in the chamber in a fluid-communicating manner. The line (2) forms a milk line during expression for transporting the breast milk expressed in the breast cup (4) to the chamber and from the chamber to the milk-collecting container (7). Said pump can be designed to be small and have a low noise level.

(57) **Zusammenfassung**: Eine Vorrichtung zum Abpumpen von menschlicher Muttermilch weist eine Brusthaube (4) zur Anlage an eine Mutterbrust, eine Vakuumpumpe (1) zur Erzeugung eines Vakuums, eine die Vakuumpumpe (1) mit der Brusthaube (4) verbindenden Leitung zum Übermitteln des erzeugten Vakuums an die Brusthaube (4) und eine Kammer auf. Die Leitung (2) endet pumpenseitig in einem ersten Anschluss (130) dieser Kammer. Erfindungsgemäss weist die Kammer einen zweiten Anschluss (131) zur Verbindung mit einem

[Fortsetzung auf der nächsten Seite]

WO 2011/035447 A1

Veröffentlicht:

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

Milchsammelbehälter (7) auf. Die zwei Anschlüsse (130, 131) stehen in der Kammer in fluidkommunizierender Verbindung miteinander. Die Leitung (2) bildet während des Abpumpens eine Milchleitung zum Transport von in der Brusthaube (4) abgepumpter Muttermilch zur Kammer und von der Kammer zum Milchsammelbehälter (7). Diese Pumpe lässt sich geräuscharm und klein ausbilden.

TITLE

Device and method for expressing human breast milk

TECHNICAL FIELD

The present invention relates to a device for expressing human breast milk to a vacuum pump for expressing human breast milk and to a method for operating a device for expressing human breast milk.

BACKGROUND

In principle, there are two different types of devices for expressing human breast milk: the first device type is operated manually, *i.e.* the negative pressure required for the expressing operation is generated by manual actuation of the vacuum pump. In the devices of the second type, the vacuum pump is operated electrically, it being possible for the vacuum pump to be connected to the power supply network and/or to be operated via a battery or another energy accumulator. Examples for this include WO 96/22116, US 2009/0099511, US 2008/0287037, US 7 094 217 and US 2008/0039781.

Said vacuum pumps are connected to a breast shield either directly or via vacuum lines. The breast shield usually has a funnel-shaped part for receiving part of the mother's breast including the nipple. As a rule, said funnel-shaped part merges into a part, which is in the shape of a hollow cylinder and to which, firstly, either the vacuum pump is connected directly or via a suction line and which, secondly, is likewise connected directly or via a milk line to a milk collecting container. Breast shields are selected in accordance with the size of the breast, thus the size of the funnel-shaped part can be selected according to the mother.

US 6 379 327 discloses a portable, so called "hands-free" expressing device having a relatively small breast shield. In this context, "hands-free" means that, once switched on, the entire expressing device functions without hands, *i.e.* that neither the pump nor the breast shield have to be held by hand. In US'327, a small funnel shaped breast shield is fastened for this purpose to the breast using straps. A first tube leads from the breast shield

2010300058 25 Oct 2013

to a vacuum pump, which is held in a belt. A second tube leads from the breast shield into a milk collecting container, which can be carried in the same belt.

WO 02/102437 and WO 2008/137678 show "hands-free" expressing devices as well. Here, the breast shield is in each case integrated into a pump housing and serves at the same time as a diaphragm for generating a negative pressure.

US 949 414 describes a funnel-shaped breast shield, which can be arranged under a bra. Rather than a vacuum being applied, a tube leads from the breast shield to a baby who is intended to obtain the milk desired by sucking on the tube.

US 6 440 100 shows a device for expressing breast milk with a small breast shield, which can be worn under the bra. A milk tube leads from the breast shield to a milk collecting container. The latter is connected via a vacuum tube to a vacuum source. The milk collecting container is evacuated by means of the vacuum source, with the negative pressure being applied to the breast shield via the milk tube. Owing to the negative pressure prevailing in the milk collecting container, expressed milk is now to pass into the milk collecting container via the milk tube. As an alternative, the milk collecting container itself can serve as a vacuum pump. Said device has the disadvantage that the relatively large volume of the milk collecting container likewise has to be evacuated. Said "dead volume" considerably restricts the performance of the device.

SUMMARY OF THE INVENTION

Embodiments of the invention are directed to an improved device and an improved method for expressing human breast milk.

The device according to the invention for expressing human breast milk has a breast shield for bearing against a mother's breast, a vacuum pump for generating a vacuum, a line that connects the breast shield to the pump chamber and is intended for transmitting the vacuum generated to the breast shield, and a chamber. The line ends on the pump side in a first port of said chamber. According to the invention, the chamber has a second port for connection to a milk collecting container. The two ports in the chamber are connected to each other in terms of fluid communication. During the expressing operation, the line forms a milk line

2010300058 25 Oct 2013

for transporting breast milk expressed in the breast shield to the chamber. The milk is subsequently conducted from the chamber to the milk collecting container.

In another embodiment, the invention provides a method for operating a device for expressing human breast milk, a vacuum is generated in a breast shield by means of a vacuum pump, the vacuum generated being conducted from a chamber via a line to the breast shield, and expressed milk being collected via the breast shield in a milk collecting container. According to the invention, during the expressing operation, the same line, which is used for transmitting the vacuum, conducts the milk expressed in the breast shield to the chamber, and, during the expressing operation, the milk being conducted further from the chamber into a milk collecting container.

Said device therefore changes from an initial pneumatic pumping system to a hydraulic pumping system, wherein the same line is used. In this case, the expressed milk acts as working fluid in order to express further milk from the breast. Furthermore, said milk that has already been expressed heats the breast shield, this being pleasant for the mother.

The device according to some embodiments of the invention and the method according to the invention require only a single tube connection, even if the milk collecting container is not arranged directly on the breast shield. Said device can therefore also be configured and used as a "handsfree" device. The breast shield can be designed to be small and can be fixed in a bra. The single line can be discretely concealed in the clothing.

Since the entire system is flooded by milk and there is therefore no longer a vacuum line in the classic sense, a lower pumping power is required in order to express breast milk. Typical values for air output are up to 500 ml/min and for milk output up to 100 ml/min. The vacuum pump can therefore be configured to be smaller and lighter, which means that it is in turn less conspicuous to onlookers. The mother can use said vacuum pump more discreetly. In addition, owing to the lower pumping power requirement, the vacuum pump is quieter during use, which in turn increases the comfort and discretion.

Since the entire system, *i.e.* the entire system, apart from the pumping-unit-side or driveside region of the vacuum pump, is flooded with milk and there are only very small airfilled dead spaces, if any at all, the applied vacuum can more easily be controlled. The negative

2010300058 25 Oct 2013

pressure present at the breast shield also corresponds more to the vacuum generated in the vacuum pump.

Said milk line can be realized in various ways. In some embodiments, there may be a partition wall, which separates a vacuum pump drive and the line from each other. As a result, the chamber is divided by the partition wall into a breast-shield-side region and a drive-side region. The two regions are completely separated from each other and are connected to each other only via the diaphragm. It is therefore ensured that milk does not pass into the drive-side region of the vacuum pump and further that neither dirt nor air from the drive-side region pass into the milk-conducting line, and therefore into the breast shield and the milk collecting container. Said partition wall may be a diaphragm.

In some embodiments, said diaphragm may be driven and serves to convey the expressed milk. As a result, the milk can be expressed independently of the relative position of the breast shield, the milk collecting container, and the vacuum pump with respect to one another. The mother may, for example, even express milk while lying down. This is optimum in particular in a "hands-free" embodiment since the mother may even bend down and in general move very freely.

A very wide variety of vacuum pumps can be used with the vacuum-transmitting and milk conducting line according to the invention. In some embodiments, a single diaphragm may be used in each case both for transporting the milk and for separation of the media.

The vacuum pump may be a diaphragm pump, wherein the chamber is the vacuum generating pump chamber of the vacuum pump, and the diaphragm is the diaphragm of the pump chamber used for generating the vacuum.

A vacuum pump according to some embodiments of the invention for expressing human breast milk by means of a breast shield may have a drive and a diaphragm that can be driven cyclically by the drive, the diaphragm being arranged in a chamber, the diaphragm separating the chamber into a drive-side part and a breast-shield-side part, and the breast-shield-side part having a vacuum port for producing a connection to the breast shield.

According to some embodiments of the invention, the breast-shield-side part of the chamber furthermore may have a milk port for producing a connection to a milk collecting

container, and the vacuum port and the milk port are connected to each other in terms of fluid communication via the breast-shield-side part of the chamber. Said vacuum pump may be a diaphragm pump and the chamber may be the vacuum-generating pump chamber.

Said vacuum pump may have, but does not have to have, the abovementioned vacuum transmitting and milk-conducting line. It is also possible in said vacuum pump for the breast shield to be connected directly to the first port of the chamber.

In some embodiments, the vacuum pump may be an electric diaphragm pump. In this case, the diaphragm of the diaphragm pump preferably forms the abovementioned diaphragm serving as a drive for the milk and as a partition wall. The drive of the diaphragm preferably serves simultaneously to generate the vacuum in the pump chamber and to convey the flow of milk. Owing to the triple function of the diaphragm, the vacuum can be better controlled.

The diaphragm may have a substantially circular outline. The diaphragm may also be driven in the central region thereof, and may be driven in the center thereof.

Other types of diaphragm pumps having, for example, a flat coil or a moving coil as the drive system can also be used. Alternative pumps without a diaphragm may also be used. Furthermore, manually driven pumps may be used.

In some embodiments there may be a nonreturn valve or another one-way valve, which creates a connection between the chamber and the milk collecting container. As a result, the connection to the milk collecting container is opened only when the remaining system has already been filled as completely as possible with milk or when there is a sufficiently large pressure in the chamber. Heavy loading of the vacuum pump by possible air-filled dead volumes is again also avoided here. The second port and therefore also the valve are arranged at the bottom in the correct position of operation of the vacuum pump. The valve is located in the breast shield-side region of the chamber, which region is also referred to as the line-side region. By contrast, the first port may be arranged in the upper region of the chamber. As a result, air from the chamber may be conducted into the milk collecting container and air-filled dead volumes and air bubbles in the system are avoided.

2010300058 25 Oct 2013

The device according to the invention and the method according to the invention can be used with all types of breast shields. However, small breast shields may be used in order to keep the dead volume also here as small as possible.

Efficient use employs a breast shield which merely surrounds the nipple and at maximum the aerola. Not only can said breast shield be used in a simple manner in a "hands-free" system, for example can be kept in a bra, said breast shield also has scarcely any air-filled regions because of its small size. This has a positive effect on the vacuum pump since the latter requires less power and can therefore operate more quietly. Furthermore, for said reason, said vacuum pump can also be made smaller.

In addition, breast shields of this type have the advantage that there can be less movement of the tissue of the breast within the shield. As a result, the breast shields can bear more tightly against the tissue. A lower pumping power is required as a result. The pump again can be designed to be smaller and operates more quietly.

According to some embodiments of the invention, the device may have a breast shield which adapts itself optimally to the shape of the human mother's breast and therefore creates a tight or less tight connection to the breast, depending on requirements.

Such a breast shield according to some embodiments of the invention has a tubular connector and a funnel that is integrally formed thereon and is intended for resting on a mother's breast, wherein the funnel widens toward the free side thereof that faces away from the connector, and wherein there is a passage, which extends continuously from a breast-side end of the funnel as far as a pump-side end, being opposite said breast-side end, of the connector and which serves to apply a vacuum to the mother's breast and for the flowing away of the expressed breast milk. According to the invention, the funnel is of more flexible design than the connector, and the funnel has a main region extending over a substantial part of the length thereof with a first opening angle of the passage, and a breast-side end region with a second opening angle of the passage. When not in use, the first opening angle is smaller than the second opening angle, wherein, in the use state, at least the first opening angle can be enlarged by axial pressure on the breast shield.

2010300058 25 Oct 2013

Said breast shield can also be used in other devices for expressing breast milk and is not restricted to the use of lines which simultaneously transmit a vacuum and conduct milk or to the use of the above-described chambers.

In contrast to the natural sucking of a baby, the nipple in a breast shield of this type is customarily not expanded to 2.5 times the length thereof. This is pleasant for the mother, in particular if she has painful nipples.

When not in use, typical values of the first opening angle of the breast shield are $\leq 5^o$ (smaller or equal to 5^o) and of the second opening angle are 90^o to 160^o. During use and depending on the axial pressure applied, at least the second opening angle can be enlarged up to 120^o, preferably up to 160^o.

The funnel may have a breast-side diameter of 5 mm to 40 mm and a length of 10 mm to 40 mm, and therefore, in the use state, the nipple, and at maximum the areola, is surrounded by the breast shield. Milk ducts in the breast tissue may not be surrounded by the breast shield.

Between the connector and funnel, there may be a transition region with a third opening angle of the passage, wherein the third opening angle is larger than the first opening angle when the device is not in use.

Typical values of the third opening angle are 60^o to 150^o.

The main region may directly adjoin the transition region. The end region may also directly adjoin the main region.

In some embodiments, the connector may have a wall thickness that is much greater than the wall thickness of the funnel. As an addition or alternative, the connector may also be formed from a material having a greater shore hardness.

In the transition region between the connector and funnel there may be an outer stop, which protrudes over the outer circumference of the connector.

2010300058 25 Oct 2013

The connector can be readily inserted into a recess if the outer circumference of the connector is designed such that it widens conically toward the funnel.

Said breast shield according to some embodiments of the invention may be manufactured from silicone and preferably has a Shore A hardness of 30 to 70. The funnel may have a Shore A hardness of about 50. The connector may have a Shore A hardness of about 70.

In another embodiment there is provided a coupling part for use in a device as described above wherein the coupling part may connect a breast shield with a line, wherein the line connects the breast shield with a vacuum pump and wherein a line forms a milk line for transporting expressed breast milk, wherein the coupling part comprises a port for connection of the line.

So that said relatively small and compact breast shield can be readily held in the hand, a coupling part is provided in a breast shield set (i.e. a unit). The coupling part serves to receive the breast shield connector in a sealing manner, wherein said coupling part is of cylindrical design and is closed on one side by a base such that a blind hole for receiving the connector is formed. There is a port opening, which is connected to the passage of the breast shield in terms of fluid communication.

In accordance with another embodiment of the invention there is provided a breast shield unit, comprising: a breast shield; and a coupling part as described above.

In the assembled state, an end side of the connector remote from the breast shield may end at a distance from the base of the coupling part. The port opening may be arranged eccentrically in the coupling part.

If the port opening is arranged in an upper region of the coupling part and the coupling part has a marking, which defines "this side up" in the space, then, during the expressing operation, stationary air bubbles are avoided in the coupling parts and air-filled dead spaces are eliminated.

In order to be able to insert the conical connector more easily, the blind hole of the coupling part also tapers in diameter toward the base.

2010300058 25 Oct 2013

The coupling part may be of stiff design, this facilitating the insertion of the connector and increasing the stability. The part can therefore be more easily held or fastened.

The combination of the three elements: a vacuum-transmitting and milk-conducting line; a pump chamber diaphragm with its triple function; and the breast shield that is of small design and avoids dead volumes, results in a device that can be designed to be extremely small and provide significant noise reduction and furthermore may be optimised to be suitable for many types of use, including "hands-free" use.

Further advantageous embodiments and variants of the method are indicated in the dependent claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention are described below with reference to the drawings that serve merely for explanation and should not be interpreted as being limiting. In the drawings:

Figure 1 shows an exploded view of a first embodiment of a device according to the invention, in which a side wall of the vacuum pump is not illustrated;

Figure 2 shows the device according to Figure 1 assembled for use, in which a side wall of the vacuum pump is not illustrated;

Figure 3 shows an exploded view of the vacuum pump from a first side;

Figure 4 shows the vacuum pump according to Figure 3 from a second side;

Figure 5 shows the vacuum pump according to Figure 3 assembled for use, but without side wall;

Figure 6 shows a second embodiment of a device according to the invention, in which a side wall of the vacuum pump is not illustrated;

Figure 7a shows a longitudinal section through a breast shield according to the invention, applied to a human breast with a relatively large contact pressure;

Figure 7b shows a longitudinal section through the breast shield according to the invention according to Figure 7a, applied to a human breast with a smaller contact pressure;

Figure 8 shows a longitudinal section through the breast shield according to Figure 7b with a coupling part in a first embodiment;

Figure 9 shows a longitudinal section through a coupling part in a second embodiment;

Figure 10 shows a longitudinal section through a coupling part in a third embodiment;

Figure 11 shows a longitudinal section through the coupling part according to Figure 8;

Figure 12 shows an exploded view of part of the device according to the invention with a pump unit in a third embodiment;

Figure 13 shows a longitudinal section through part of the device according to Figure 12;

Figure 14 shows a longitudinal section through the pump unit according to Figure 12 in a first embodiment, and

Figure 15 shows a longitudinal section through a pump unit in a second embodiment.

The same parts are provided with the same designations in the figures.

DESCRIPTION OF PREFERRED EMBODIMENTS

Figures 1 to 5 illustrate a first embodiment of the device according to the invention. Said device has a vacuum pump 1, a first line 2, a coupling part 3, a breast shield 4, a nonreturn valve 5, a second line 6, and a milk collecting container 7.

The breast shield 4 is connected to the vacuum pump 1 via the coupling part 3 and the first flexible line 2. The second flexible line 6 leads from the vacuum pump 1 to the milk collecting container 7, said connection being provided with the nonreturn valve 5. The two flexible lines 2, 6 are preferably tubes, in particular made of silicone.

As illustrated in Figure 6, the milk collecting container 7 may alternatively also be fastened directly to the vacuum pump 1. For this purpose, there is preferably a suitably shaped adapter 70 on the milk collecting container 7, said adapter being detachably connectable to a housing 10 of the vacuum pump.

The vacuum pump 1 has the abovementioned housing 10, a side wall of the housing 10 not being illustrated in the drawings. As a result, the interior of the housing 10 can be revealed. This can be readily seen in Figures 3 to 5. There is an electric motor 11 in the housing 10. Said electric motor can be operated from the mains and/or battery operated.

A force transfer unit 12, here a piston rod connected to the motor, transfers the rotational movement of the motor into a linear movement. The connecting rod 12 is connected at the second end thereof to a diaphragm 14. The diaphragm 14 is arranged in a recess 112 of the housing 10, which forms part of a pump chamber. A cover 13 that is detachably connectable to the housing 10 secures the diaphragm 14 in its position.

Instead of said drive, other types of drive, in particular even manual drives, can also be used.

The cover 13 is preferably screwed to the housing 10. Other types of connection are likewise possible. The cover 13 likewise has a recess 133 such that said cover forms a second part of the pump chamber. The two parts of the pump chamber are separated from each other by the diaphragm 14. The cover 13 can be formed as a single piece or as a number of pieces.

The principle of operation of the diaphragm pump is not described in detail here since it is well known. By means of a drive, here by means of a motor 11 and connecting rod 12, the diaphragm is moved cyclically to and fro such that a negative pressure is generated in the breast-shield-side or cover-side part of the pump chamber. Instead of the drive illustrated here, other types of drive suitable for moving the diaphragm 14 cyclically can also be used. The electronics required for operating the pump and the control elements are not illustrated here. Use may be made of known means. The pump can be operated with a temporally constant cycle, or, as is known in the prior art, the suction curve may be adapted in the shape, frequency, and intensity thereof to the suction behavior of the baby and/or to the requirements of the mother.

In the cover 13, *i.e.* in the valve plate, there is a first outlet opening 130, which connects the environment to the cover-side part of the pump chamber. Said outlet opening 130 serves as a first port for the first line 2. A second outlet opening 131, which likewise connects the cover- and the breast-side part of the pump chamber to the surroundings, respectively, is designed as a second port. Said second port is provided with the nonreturn valve 5. Use is made here of a duckbill valve, which is plugged onto a connector. However, other types of valve are also usable.

If the device is now used, the breast shield 4 is placed onto the mother's breast such that said breast shield at least surrounds the nipple. Preferably, at maximum the areola is additionally surrounded by the breast shield 4. The vacuum pump 1 is switched on and operated in a known manner. The vacuum generated in the pump chamber evacuates the first line 2 such that there is a negative pressure in the breast shield 4. As a result, milk is expressed from the mother's breast and passes through the breast shield 4 and the coupling part 3 into the first line 2. The milk flows through the first port 130 into the cover-side part of the pump chamber. The expressed milk leaves the pump chamber through the second port 131 and the nonreturn valve 5 and passes into the milk collecting container via the second line 6 (see Figure 2) or else, depending on the embodiment, directly (see Figure 6). There is therefore no separate line for transporting the milk. The first line 2 serves at the same time as a suction line and as a milk transport line. After initial pneumatic pumping, the device therefore changes to hydraulic pumping. This is a further approximation to the natural sucking of babies.

The diaphragm 14 in the pump chamber has three functions. Firstly, it forms the diaphragm of the diaphragm vacuum pump and thus generates the vacuum in the pump chamber. Secondly, it serves as a partition wall between the air in the pump-side part of the pump chamber and the milk in the cover-side part of the pump chamber. It therefore serves as a means of separating media. It thereby prevents milk from being able to pass into the pump unit. However, it also prevents dirt from the pump unit from being able to pass into the first and second lines 2, 6. Thirdly, the cyclic movement of said diaphragm within the pump chamber results in said diaphragm conveying and transporting the milk. Owing to said third function of the diaphragm 14, during the expressing operation, the milk collecting container 7, breast shield 4, and vacuum pump 1 can be arranged in positions which are independent of one another. For example, the milk collecting container 7 can be located above the vacuum pump 1 and/or the breast shield 4. The vacuum pump 1 may also be above the milk collecting container 7 and/or the breast shield 4. This enables the mother to express milk even while lying down or, if she is seated, to place the milk collecting container 7 and the vacuum pump 1 onto a shelf or another raised platform out of the reach of small children.

In the examples according to Figures 1 to 6, a negative pressure of 0 to 300 mmHg is preferably generated. The pumping frequency is preferably between 5 and 120 cycles per minute.

The nonreturn valve 5 preferably opens only when there is sufficient pressure, *i.e.* when the pump chamber is sufficiently filled with milk. As a result, the dead volume, which has to be evacuated, can be kept to a minimum.

In addition, the dead volume can be reduced by use being made of a small breast shield 4, which only surrounds the nipple and as small a part of the remaining breast as possible, if any part of the remaining breast at all. A suitable breast shield 4 according to the invention is illustrated in the figures. Said breast shield and the coupling part 3 thereof can readily be seen in Figures 7 to 11.

Figure 7a shows a breast shield 4 according to the invention applied to a female breast B. The breast shield 4 has a connector 40, a funnel 42, and a transition region 44 connecting these two. There is preferably a radially outwardly protruding flange 41 between the connector 40 and funnel 42. A continuous passage 43 extends through the entire breast shield 4 such that the latter is designed to be open at two opposite ends. The breast shield 4 is preferably of rotationally symmetrical design.

The breast shield 4 is preferably designed as a single piece. It is customarily composed of plastic, preferably of silicone.

The connector 40 is of solid design, *i.e.* relatively stiff design, and serves for the coupling to the coupling part 3. It has a wall thickness which is much greater than the wall thickness of the funnel 42. In this example, the connector 40 is of conical design at the outer circumference thereof while said connector is preferably of rotationally symmetrical design. The conicity facilitates the insertion into the coupling part 3 and, in addition, increases the tightness of the connection to the coupling part 3. The tightness is furthermore obtained by the connector 40, due to the material, being slightly compressed in the coupling part. For this purpose, the outside diameter of the connector 40 is slightly larger than the inside diameter of the coupling part 3. Typical external diameters of the

connector 40 are 8 mm to 40 mm. Typical lengths are 5 mm to 40 mm.

The funnel 42 serves to receive the mother's breast. Said funnel is preferably configured to be highly flexible. It is of substantially more flexible and soft design than the connector 40. Owing to the flexibility thereof, said funnel adapts in its shape to the shape of the breast. It has a much smaller wall thickness here than the wall thickness of the connector 40. Alternatively, the connector 40 and funnel 42 may also have the same wall thickness, wherein, in this case, the connector 40 is preferably manufactured from a material having a greater Shore hardness or has reinforcement. The funnel 42 preferably has a Shore A hardness of about 50 and the connector 40 has a Shore A hardness of about 70.

Figure 8 illustrates the breast shield 4 when not in use. The funnel 42 has at least two regions: a main region 420 and a front, breast-shield-side end region 421. When not in use, the main region 420 has a first opening angle α_1 and the end region has a second opening angle α_2. The first opening angle α_1 is smaller than the second opening angle α_2. In addition, the wall is preferably bent over outward in the end region 421. As can be seen in Figures 7a and 7b, the first opening angle α_1 can be enlarged upon axial contact pressure on the breast such that the end region 421 can be optimally adapted to the shape of the breast.

As can be seen in the figures, the main region 420 directly adjoins the end region 421. At the other end, the main region 420 directly adjoins the transition region 44.

In the transition region 44 there is a further, third opening angle α_3, which is likewise larger than the first opening angle α_1 of the main region 420. Said third opening angle serves as a predetermined value for the main region for enlarging the angle.

The angles when not in use are preferably, for the first opening angle $\alpha_1 \leq 5°$, for the second opening angle α_2, 90° to 160°, and for the third opening angle α_3, 60° to 150°. When in use, at least the first opening angle α_1 can be enlarged to an angle of up to 10°.

The funnel 42 has a length L of 10 mm up to 40 mm. The diameter D in the front end

region is preferably 5 mm to 40 mm, preferably 20 mm to 40 mm. As a result, it is of such a small size that it surrounds the nipple and at most a further part or the entire areola. This corresponds approximately to the portion of the breast, which is taken into the mouth by a baby. The funnel 42 is of frustoconical design in the region of the connector 40, said funnel opening toward the breast. The front, breast-side border thereof is inclined outward to a greater degree than the connector-side part.

Since the breast shield 4 or at least the funnel 42 is configured to be flexible, the mother, by choosing the contact pressure, can herself select how much of the breast is actually surrounded by the breast shield 4. The contact pressure is produced from the axial pressure on the funnel 42 and the counterpressure from the mother's breast. In Figure 7a, the contact pressure is relatively large and the funnel is expanded, and, in Figure 7b, the pressure is smaller and the funnel 42 merely encloses the nipple. By choosing the contact pressure, the tightness of bearing against the breast can also be adjusted and therefore the expressing operation can be adjusted to be as comfortable as possible for the mother.

As can be seen in Figure 8, the breast shield 4 is plugged into the coupling part 3. The coupling part 3 is preferably likewise configured to be small, but to be as stiff as possible. In the outer circumference thereof, said coupling part is preferably of cylindrical design and, in the inner circumference thereof, is frustoconical or conical, respectively. It has a U-shaped cross section, *i.e.* is designed to be open at one end and closed at the opposite end. There is therefore a blind hole, into which the connector 40 of the breast shield 4 can be pushed as far as the stop 41. In Figure 8, the breast shield 4 is not yet fully pushed in. As can be seen, however, in the fully-pushed in state, there is a gap between the end side of the connector 40 and the rear wall of the coupling part 3, the gap forming a fluid passageway from the passage 43 to a port opening 31 in the coupling part 3.

Said port opening 31 serves for the connection of the first line 2. The first line 2 may simply be plugged in here, it may be connected fixedly to the coupling part 3, or there may be plug-in or plug-on means, for example connectors, for connection to the first line 2.

The port opening 31 may be provided at different locations. In Figure 8, it is arranged in the upper region in the rear wall of the coupling part 3. In Figure 9, it is arranged centrally

in the rear wall. In Figure 10, it is arranged in the casing, but in the rear region close to the rear wall. Preferably it is arranged likewise in the upper region. Figure 11 once again shows the situation according to Figure 8, but without the breast shield 4 plugged in.

If the port opening 31 is arranged at the top, the residual air in the coupling part 3 is sucked off together with the milk and the dead volume is reduced once again. In the use state, the breast shield 4 and coupling part 3 no longer have any air chambers. The clearances thereof, if still present, are filled with milk. So that the port opening 31 is actually directed upward during use, a corresponding marking, for example, can be indicated on the coupling part 3.

Figures 12 to 14 illustrate an alternative embodiment. The suction line 2 also forms the milk line here. The expressed milk is transported on the breast side from the breast shield 4 via the first line to a chamber 8 and from there is transported further into the milk collecting container 7. Furthermore, a diaphragm 14' is also arranged here in the chamber 8, the diaphragm dividing the chamber 8 into a breast-shield-side region and a drive-side or unit-side region.

However, said diaphragm 14' is now not the diaphragm of the vacuum pump, as in the previous examples, but an additional diaphragm. However, as before, it has the function of separating media and serves as a partition wall between the breast-shield-side part 81, which is filled with milk during use, and the unit- or pump-side part 80, which has a negative pressure and is filled with air. Furthermore, as before, the diaphragm 14' is moved cyclically, as is described below. As a result, it transports the milk from the breast shield 4 through the breast-shield-side part 81 into the milk collecting container 7, irrespective of the relative position of the breast shield 4, the vacuum pump 9, and the milk collecting container 7 with respect to one another. The system also changes here from a pneumatic pump into a hydraulic pump.

The diaphragm 14' illustrated here has a circular outline, the diaphragm having laterally protruding wings 140'. There are three wings 140' here. The base plate 10', which in turn may be part of a vacuum pump housing has lateral stops 110' between which said wings 140' are held. As a result, the diaphragm 14' can be held in an unambiguous position in the

chamber 8. This facilitates assembling. Said wings can also be used in the embodiments described with reference to Figures 1 to 11.

The embodiment described here is a separate diaphragm pump, referred to here as a pump unit 9. The diaphragm 14' is connected to the pump unit 9 via a vacuum line 12' and is driven by the pump unit 9 on the basis of the cyclically changing pressure in the vacuum line 12'.

The cover 13' has two ports 130' and 131' for the first and second lines 2, 6 and for the milk collecting container 7, respectively. However, the second port 131' is preferably also provided with a nonreturn valve 5 here. The connection to the counterplate, which in turn may be part of a pump housing 10, preferably takes place via snap-in or screw connections, wherein the corresponding holes are provided with the designations 132' and 111 in Figure 12.

The pump unit 9 according to the invention can now be readily seen in Figure 14. It has a housing 90, which is preferably manufactured from metal or plastic. The housing 90 preferably has a cuboidal design. A flat iron core 911 and a permanent magnet 91 attached to the latter are arranged on one side of the housing 90. The iron core 911 rests upon the housing 90 such that the permanent magnet 91 is in a recess of the housing. The permanent magnet 91 consists of two parts, which are spaced from one another such that there is a recess 910 between both parts.

There is an identical construction on an opposite side of the housing available again. An iron core 911 and a permanent magnet 91 attached to the latter are also arranged here.

A flat coil former 92 with a coil 921 wound around the coil former 92 runs between said two mutually opposite pairs of permanent magnets 91. The coil former 92 is of substantially rod-shaped or plate-shaped design. At one end, it is held in a fixed position in a guide bearing 93. The guide bearing 93 is displaceable together with the coil former 92 including the coil 921 relative to the housing 90 and therefore relative to the permanent magnet 91 along the longitudinal axis of the housing 90. For this purpose, the housing 90 has a plain bearing 900. The movement of the coil former 92 is illustrated by a double

arrow in Figure 14.

The other end of the coil former 92 is connected fixedly to a diaphragm, referred to here as the vacuum diaphragm 94. The vacuum diaphragm 94 bears against the housing 90 on the end side thereof and is clamped securely between the housing 90 and a valve plate 95. The diaphragm 94 separates a pump chamber 96 from the coil former 92. The vacuum diaphragm 94 preferably has a circular outline, it preferably having a shape customary for diaphragms of diaphragm vacuum pumps. The valve plate 95 is held between the housing 90 and a cover 99. Said three parts are preferably connected, for example screwed, tightly to one another in a detachable or nondetachable manner. The corresponding holes are provided with the reference number 991 in the cover 99. The cover 99 has a port opening 990 for the vacuum line 12', which is connected to the pump chamber 96. An air inlet opening 992 in the cover 99 likewise connects the environment to the pump chamber 96 via the valve plate 95. The valve plate 95 has the valves, inlets, and outlets customary for diaphragm vacuum pumps. These are not described in detail here.

If an alternating electric current flows through the coil, the electromagnetic field changes and the coil former 92 moves relative to the permanent magnet 91. The coil former 92 acts like a piston or ram and moves the vacuum diaphragm 94 cyclically to and fro. In this case, the force acting on the vacuum diaphragm 94 is proportional to a current applied to the coil. By means of the movement of the vacuum diaphragm 94, a cyclically changing vacuum is built up in the pump chamber 96. Said changes in pressure are passed on via the vacuum line 12' to the chamber 8 where the diaphragm 14' is moved analogously.

The vacuum diaphragm 94 of the pump unit 9 is therefore driven via a linear movement that is generated electromagnetically. It is advantageous that, in comparison to the rotating drives that are otherwise customary, the movement is quieter and fewer vibrations and structure-borne sound are generated. In contrast to the prior art, the stroke length can be changed. It can be electronically controlled. This permits precise control even under low vacuum levels.

In order for the stroke length to be able to be controlled in a specific manner, the displacement and the position of the coil former 92 is monitored, respectively. Position

and/or movement sensors are used for this purpose. In this example, this takes place by means of an optical sensor, which detects a position scale. The position scale 920 is preferably provided on the coil former 92. A light source 97 sends its light perpendicularly to the longitudinal direction of the coil former 92 to an opposite detector 98, said light passing through the position scale 920. The coil former is transparent is said region. The light source 97 and the detector 98 are preferably arranged in the recesses 910 of the permanent magnet 91. Other types of position measurement are possible. The measured signal is sent to an electronic controller of the vacuum pump and the current is applied to the coil according to said signal. As a result, the position, the deflection amplitude, and the frequency can be controlled independently of one another. Vacuum values of 0 to 300 mmHg are customarily obtained. The frequencies are customarily 0 to 150 cycles per minute.

As an alternative, instead of the guide bearing 93, there may also be a second diaphragm, which is of similar or identical design to the vacuum diaphragm 94. This results in a symmetrical construction, which likewise ensures guidance and therefore a linear movement of the coil former 92 within the housing 90. In addition, the second diaphragm can likewise be used to build up the vacuum such that the flow rate can be increased.

Figure 15 shows a further embodiment of a vacuum pump with an electromagnetically generated linear driving movement of the diaphragm. In contrast to the above-described flat coil, a moving coil is used here. The magnet and coil are of annular or cylindrical design, respectively. A housing 90' is also present here. The permanent magnet 91' is held at the rear end of the moving coil remote from the breast shield. Said permanent magnet is passed by an iron core 911', which is in contact to the permanent magnet 91' on a first end side thereof. Against the opposite end side of the permanent magnet 91' bears an iron ring 912'. The coil former 92' engages around the iron core 911' and is axially guided by said iron core. The coil former 92' extends between the iron core 911' and the permanent magnet 91' or the iron ring 912'. Said coil former is guided without contact in the permanent magnet 91' and in the iron ring 912', respectively. The wound coil 921' surrounds the coil former 92' in this region.

The coil former 92' is also fixedly connected here to the vacuum diaphragm 94' and acts as

2010300058 12 Apr 2012

a piston for the linear drive of the vacuum diaphragm 94'. The pump chamber is provided with the reference number 96', the valve plate with the reference number 95' and the cover with the reference number 99'. The port opening has the reference number 990' and the air inlet opening has the reference number 992'. Also here, there is again a position sensor, which indicates the position of the coil former 92' relative to the magnet 91', and therefore the movement and position of the vacuum diaphragm 94', respectively, to a controller in order to control the vacuum. The light source is denoted here by the reference number 97', the detector by 98', and the position scale by 920'. The position scale is preferably of a transparent design. In contrast to the previous example, said sensor here is arranged outside the region of the permanent magnet 91'.

The two vacuum pumps described with reference to Figures 12 to 15 can also be used in known breast pumps. That is to say, for example, in systems in which the suction line between the vacuum pump and breast shield is separate from the flow of milk.

The elements of the above-described embodiments can be combined with one another individually or in groups in order to form further embodiments.

In the claims which follow and in the preceding description of the invention, except where the context requires otherwise due to express language or necessary implication, the word "comprise" or variations such as "comprises" or "comprising" is used in an inclusive sense, i.e. to specify the presence of the stated features but not to preclude the presence or addition of further features in various embodiments of the invention.

It is to be understood that, if any prior art publication is referred to herein, such reference does not constitute an admission that the publication forms a part of the common general knowledge in the art, in Australia or any other country.

2010300058 25 Oct 2013

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A device for expressing human breast milk, wherein the device has a breast shield for bearing against a mother's breast, a vacuum pump for generating a vacuum, a line which connects the vacuum pump to the breast shield and is intended for transmitting the vacuum generated to the breast shield, and a chamber, the line ending on the pump side in a first port of said chamber, wherein the chamber has a second port for connection to a milk collecting container, in that the two ports in the chamber are connected to each other in terms of fluid communication, and in that, during the expressing operation, the line forms a milk line for transporting breast milk expressed in the breast shield to the chamber.

2. The device as claimed in claim 1, wherein there is a partition wall, which separates the chamber into a drive-side region and a breast-shield-side region, and wherein the first and the second port are arranged in the breast-shield-side region.

3. The device as claimed in claim 2, wherein the partition wall is a diaphragm, wherein the diaphragm is driven and is designed for conveying the expressed milk.

4. The device as claimed in claim 3, wherein the vacuum pump is a diaphragm pump, the chamber is a pump chamber of the vacuum pump, and the diaphragm divides the chamber into the two regions mentioned.

5. The device as claimed in either of claims 3 and 4, wherein the drive of the diaphragm serves simultaneously to generate the vacuum in the pump chamber and to convey the flow of milk.

6. The device as claimed in any one of claims 3 to 5, wherein the diaphragm has a substantially circular outline.

7. The device as claimed in any one of claims 3 to 6, wherein the diaphragm is driven in the central region thereof, preferably in the center thereof.

8. The device as claimed in any one of claims 1 to 7, wherein the second port is provided with a one-way valve, which prevents sucked off milk from flowing back

from the milk collecting container to the chamber.

9. The device as claimed in any one of claims 1 to 8, wherein the breast shield has a tubular connector and a funnel, which is integrally formed thereon and is intended for resting on a mother's breast, wherein the funnel widens toward the free side thereof that faces away from the connector, and wherein there is a passage, which extends continuously from a breast-side end of the funnel as far as a pump-side end, being opposite said breast-side end, of the connector and which serves to apply a vacuum to the mother's breast and for the flowing away of the expressed breast milk, wherein the funnel is of more flexible design than the connector, wherein the funnel has a main region extending over a substantial part of the length thereof with a first opening angle of the passage, and a breast-side end region with a second opening angle of the passage, and wherein, when not in use, the first opening angle is smaller than the second opening angle, and wherein, in the use state, at least the first opening angle can be enlarged by axial pressure on the breast shield.

10. The device as claimed in any one of claims 1 to 9, wherein the breast shield has a tubular connecter and a funnel that is integrally formed thereon and is intended for resting against a mother's breast, wherein the funnel has a breast-side diameter of 5 mm to 40 mm and a length of 10 mm to 40 mm, such that, in the use state, the nipple, and at maximum the areola, is surrounded by the breast shield.

11. The device as claimed in any one of claims 1 to 10, wherein the breast shield is arranged in a coupling part, the upper region of which, in the use position, has a port for the connection of the line.

12. A vacuum pump for expressing human breast milk by means of a breast shield, the vacuum pump having a drive and a diaphragm that can be driven cyclically by the drive, the diaphragm being arranged in a chamber, the diaphragm separating the chamber into a drive-side part and a breast-shield-side part, and the breast-shield-side part having a vacuum port serving as a port for a line for producing a connection to the breast shield, wherein the breast-shield-side part of the chamber furthermore has a milk port for producing a connection to a milk collecting container, and wherein the vacuum port and the milk port are connected to each other in terms of fluid communication via the breast-shield-side part of the chamber.

13. The vacuum pump as claimed in claim 12, wherein it is a diaphragm pump, and the chamber is the pump chamber of the diaphragm pump used for generating the vacuum, and the diaphragm is the diaphragm used for generating the vacuum.

14. A method for operating a device according to any one of claims 1 to 11 for expressing human breast milk, the method comprising the following steps: a vacuum being generated in a breast shield by means of a vacuum pump, the vacuum generated being conducted from a chamber via a line to the breast shield, and expressed milk being collected via the breast shield in a milk collecting container, wherein, during the expressing operation, the same line, which is used for transmitting the vacuum, conducts the milk expressed in the breast shield to the chamber, and wherein, during the expressing operation, the milk is conducted further from the chamber into the milk collecting container.

15. The method as claimed in claim 14, wherein use is made of a non-return valve, which, when there is sufficient pressure in the chamber, creates a connection between the chamber and the milk collecting container.

16. A coupling part for use in a device according to any one of claims 1 to 11, wherein the coupling part connects a breast shield with a line, wherein the line connects the breast shield with a vacuum pump and wherein the line forms a milk line for transporting expressed breast milk, wherein the coupling part comprises a port for connection of the line.

17. A breast shield unit, comprising:
a breast shield; and
a coupling part according to claim 16.

18. A device according to any one of claims 1 to 11, wherein the line is flexible.

19. A device for expressing human breast milk, a vacuum pump for expressing human breast milk, or a method for operating a device for expressing human breast milk, substantially as herein described with reference to the accompanying drawings.

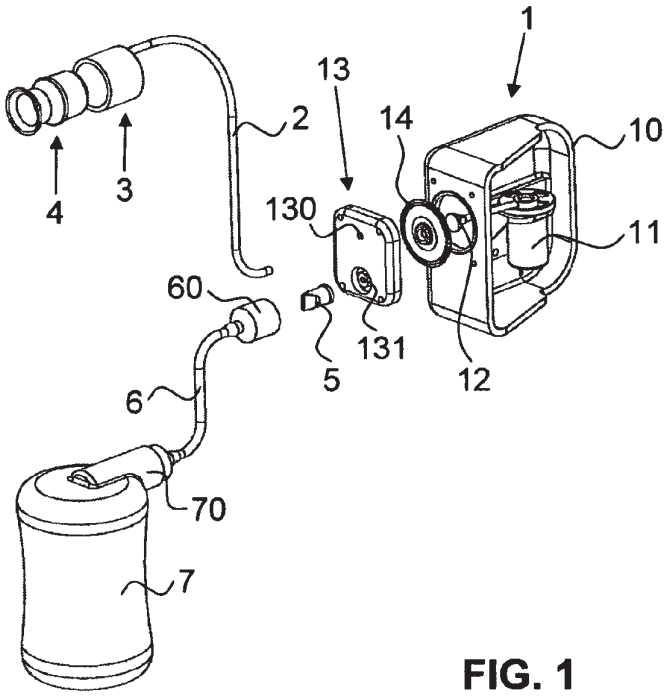


FIG. 1

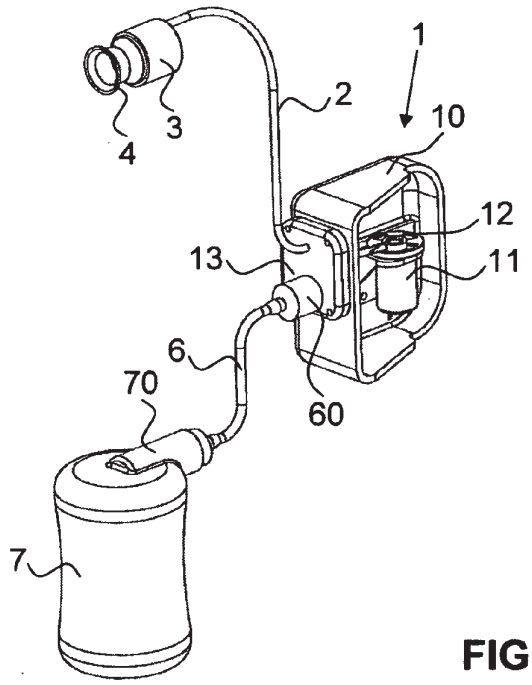


FIG. 2

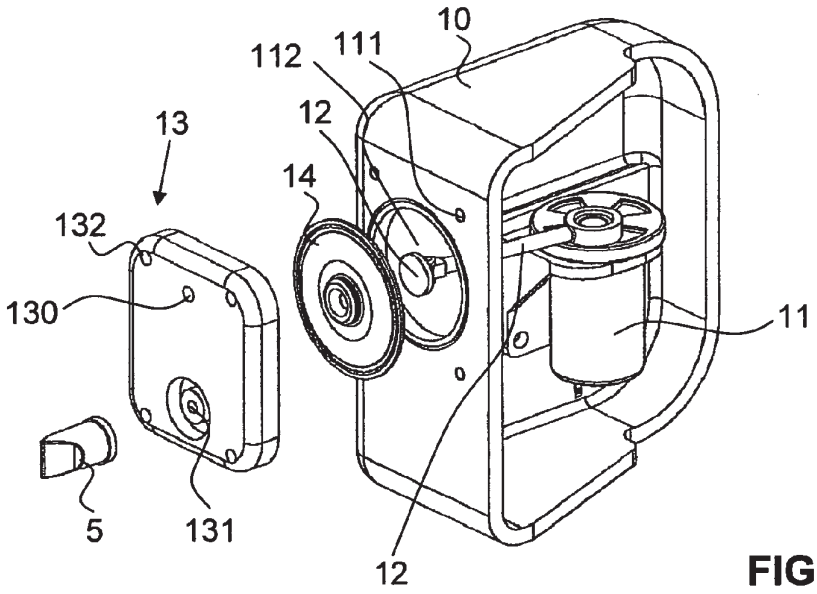


FIG. 3

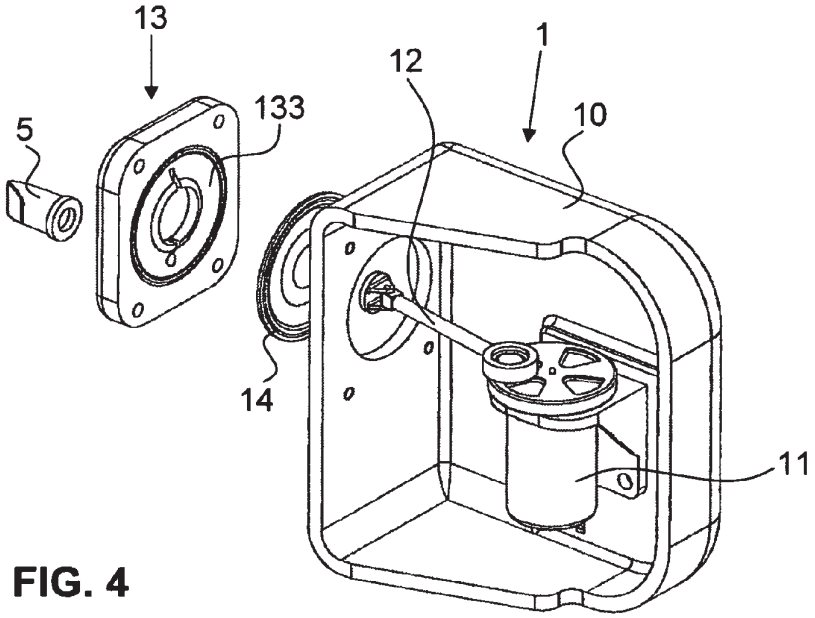


FIG. 4

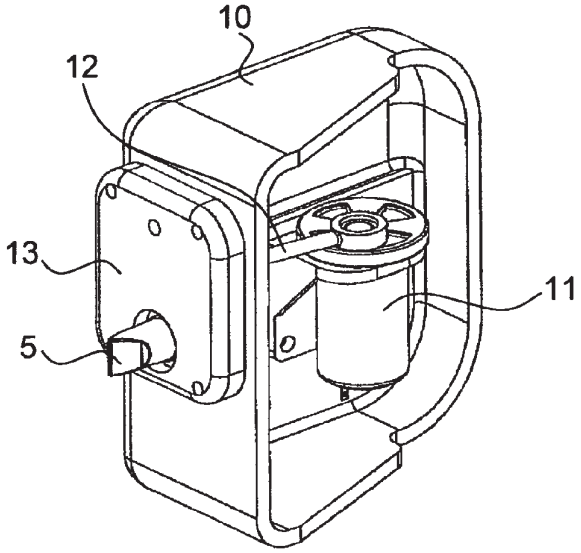


FIG. 5

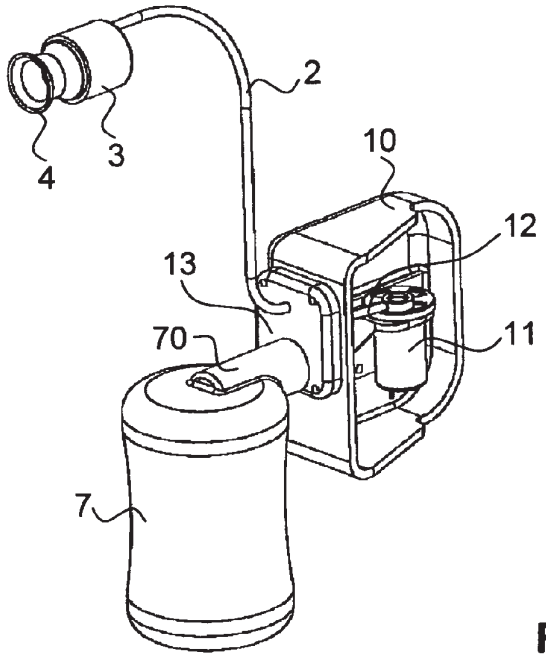


FIG. 6

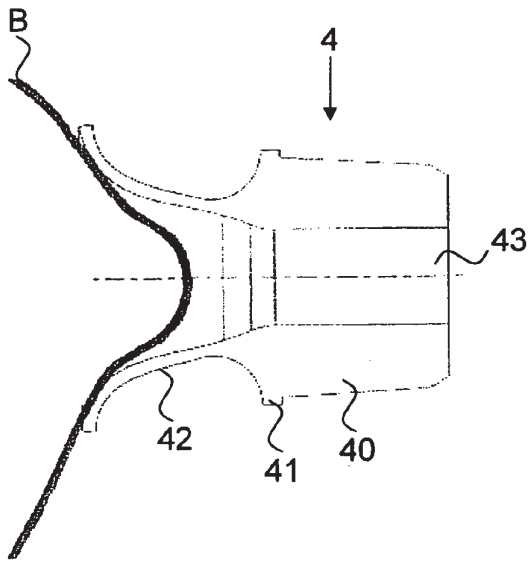


FIG. 7a

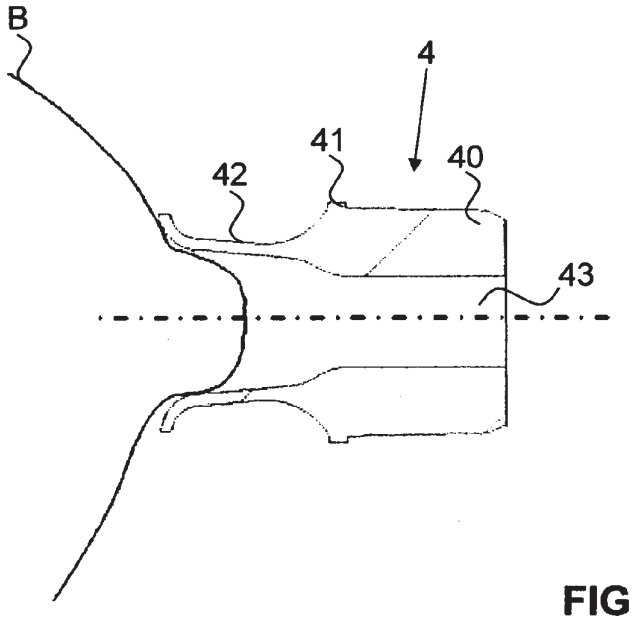


FIG. 7b

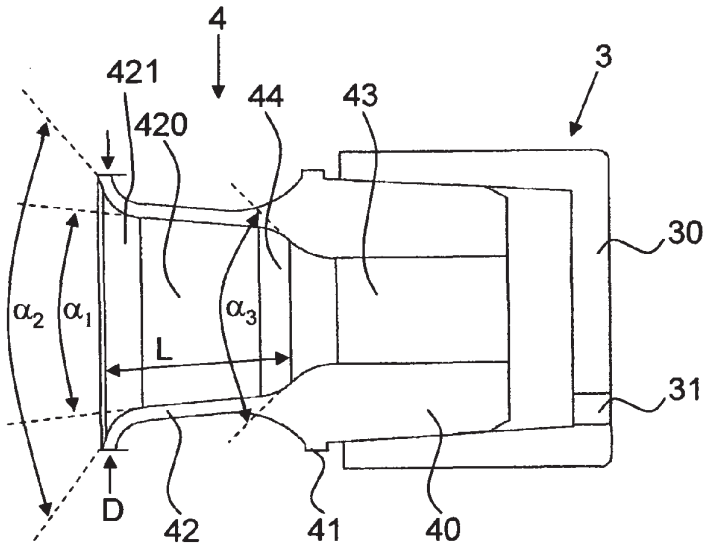


FIG. 8

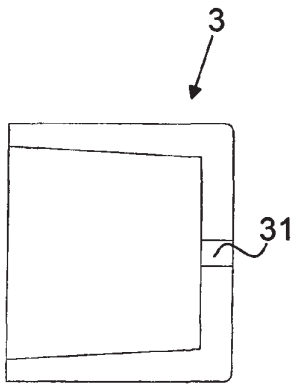


FIG. 9

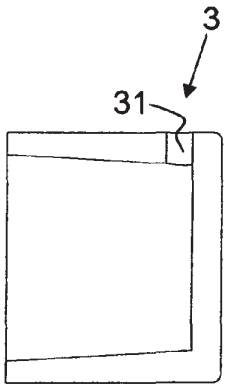


FIG. 10

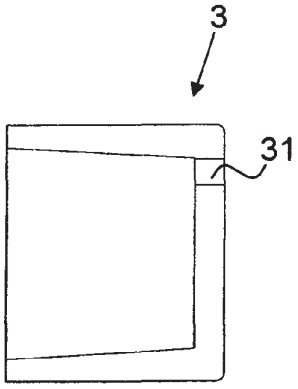


FIG. 11

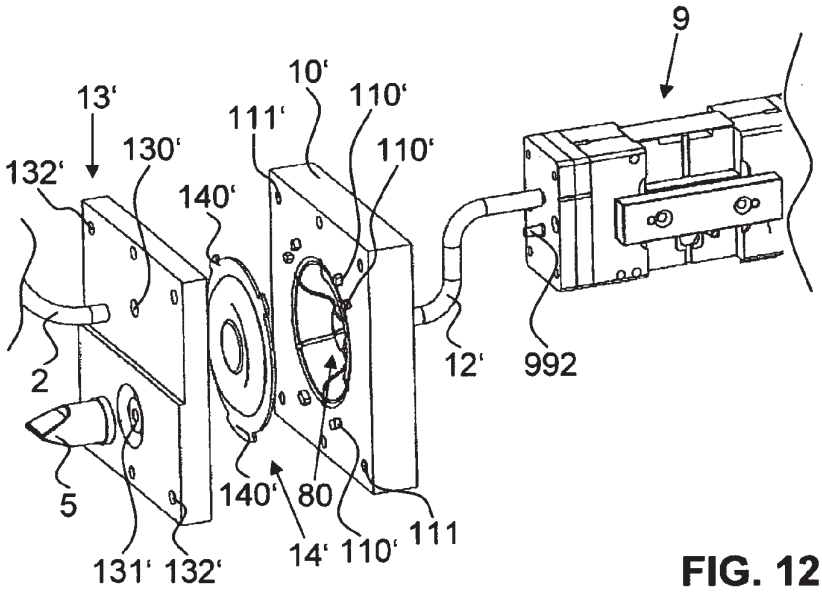

9
10'
13'
110'
111'
110'
130'
132'
140'
2
12'
992
5
140'
80
111
14'
110'
131'
132'

FIG. 12

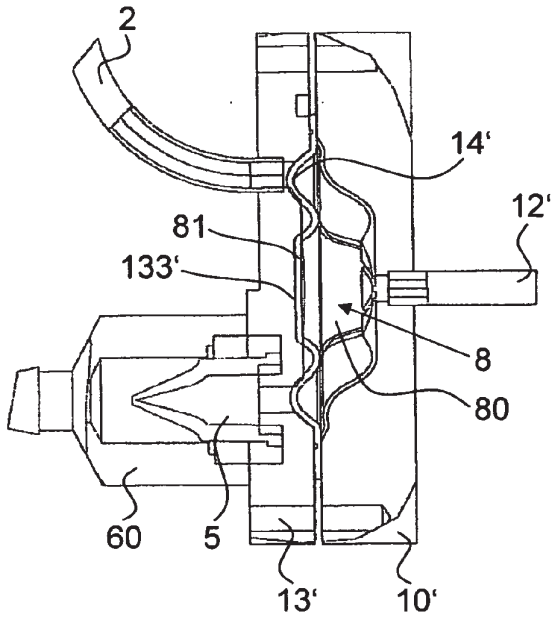

2
14'
12'
81
133'
8
80
60
5
13'
10'

FIG. 13

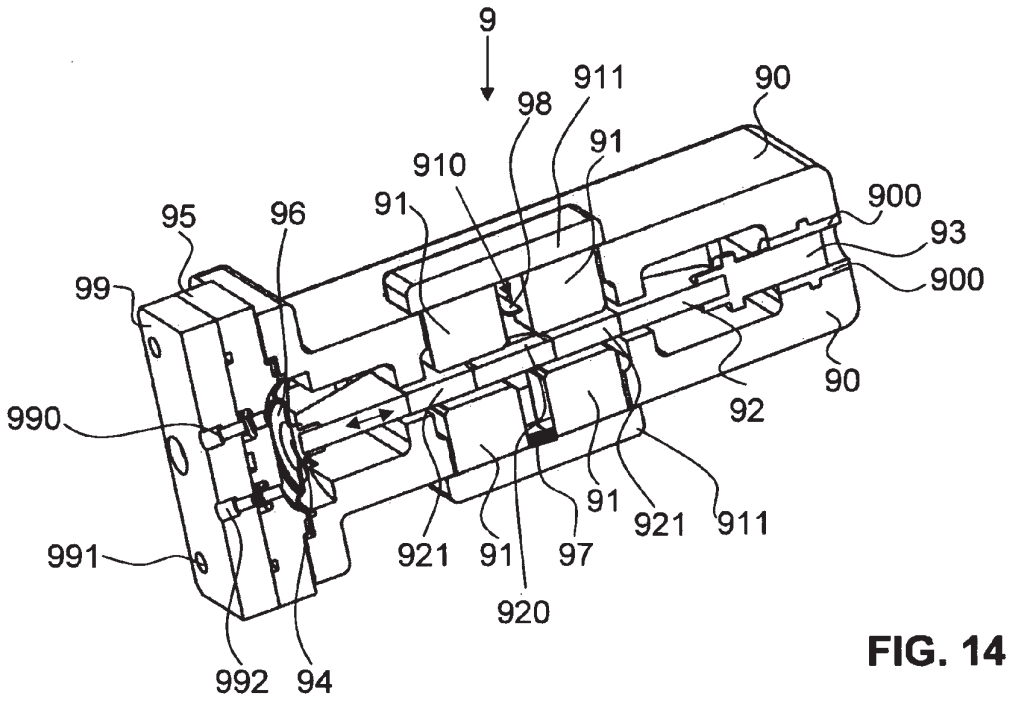

9
911
90
98
91
910
900
95
96
91
93
99
900
990
90
92
91
921
911
991
921
91
97
920
992
94

FIG. 14

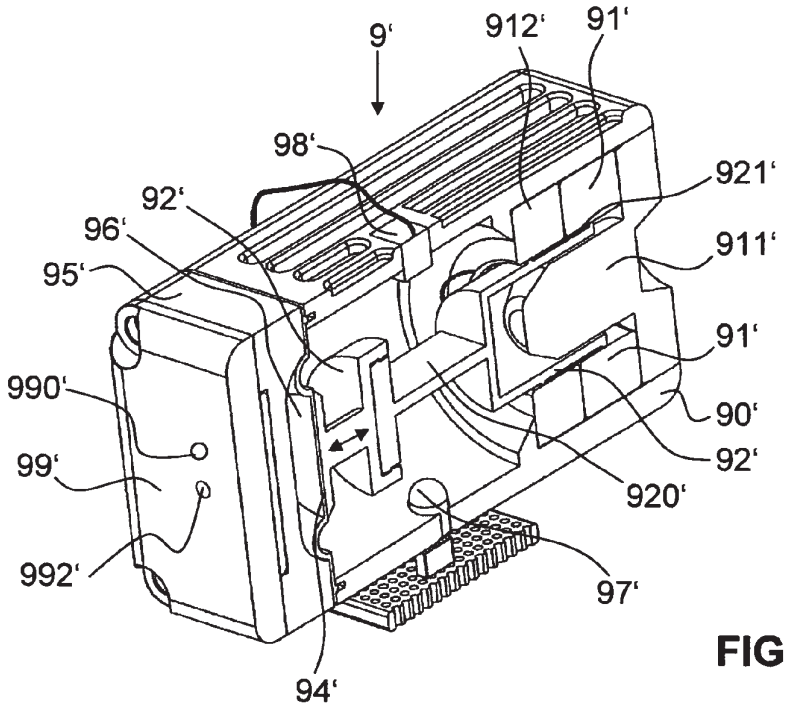

9'
912'
91'
98'
921'
92'
96'
911'
95'
91'
990'
90'
99'
92'
920'
992'
97'
94'

FIG. 15