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(54) Title: METHODS AND APPARATUS FOR TRANSFERRING PRESSURE DURING EXPRESSION OF HUMAN BREAST MILK

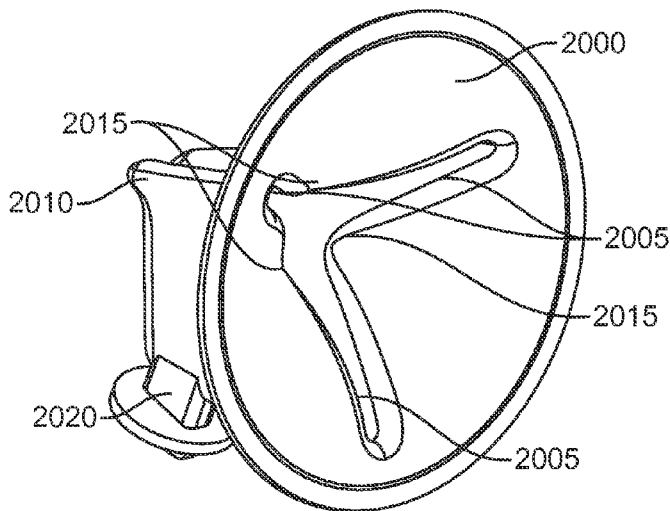


FIG. 20A

(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 actuation 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 actuatable 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 actuatable 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 that 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 actuation 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.

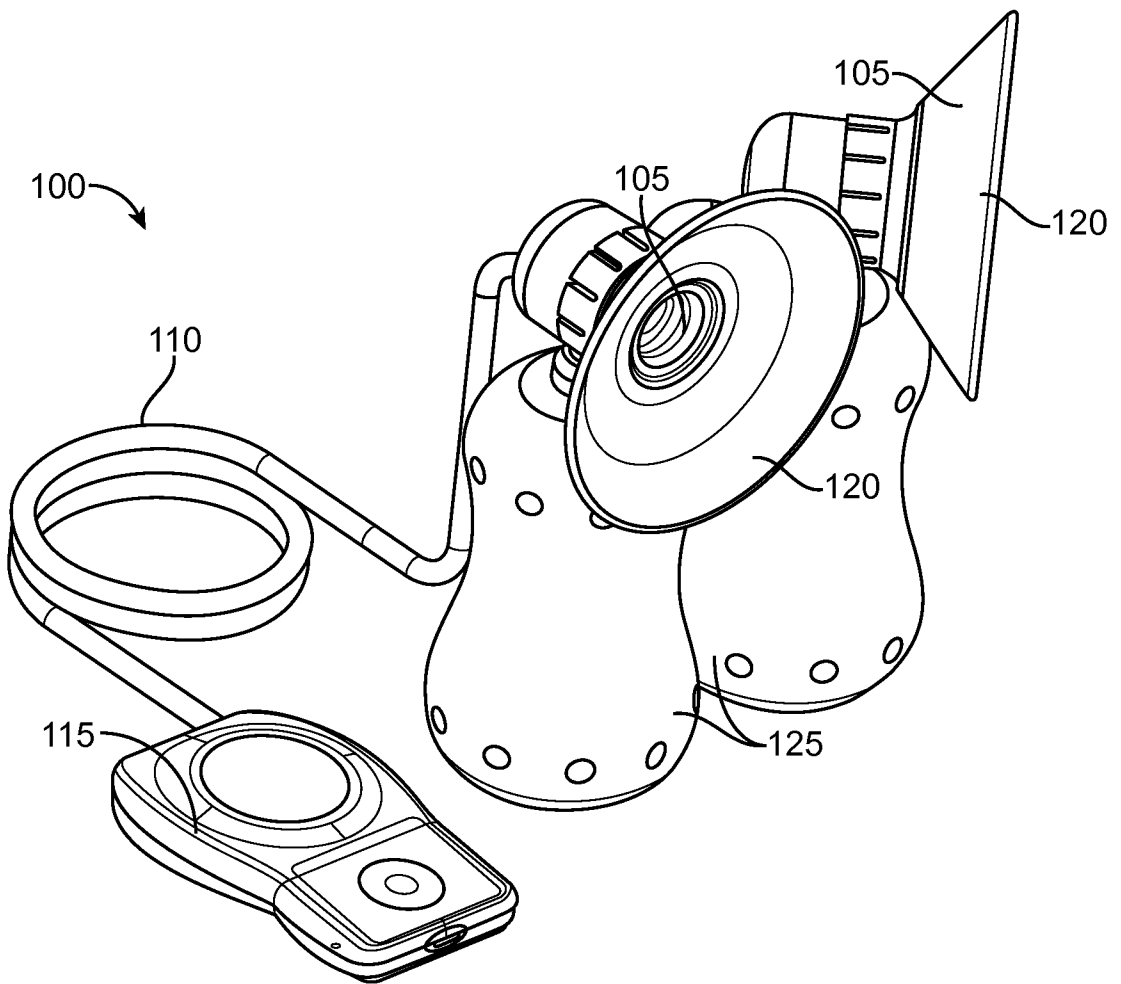


FIG. 1

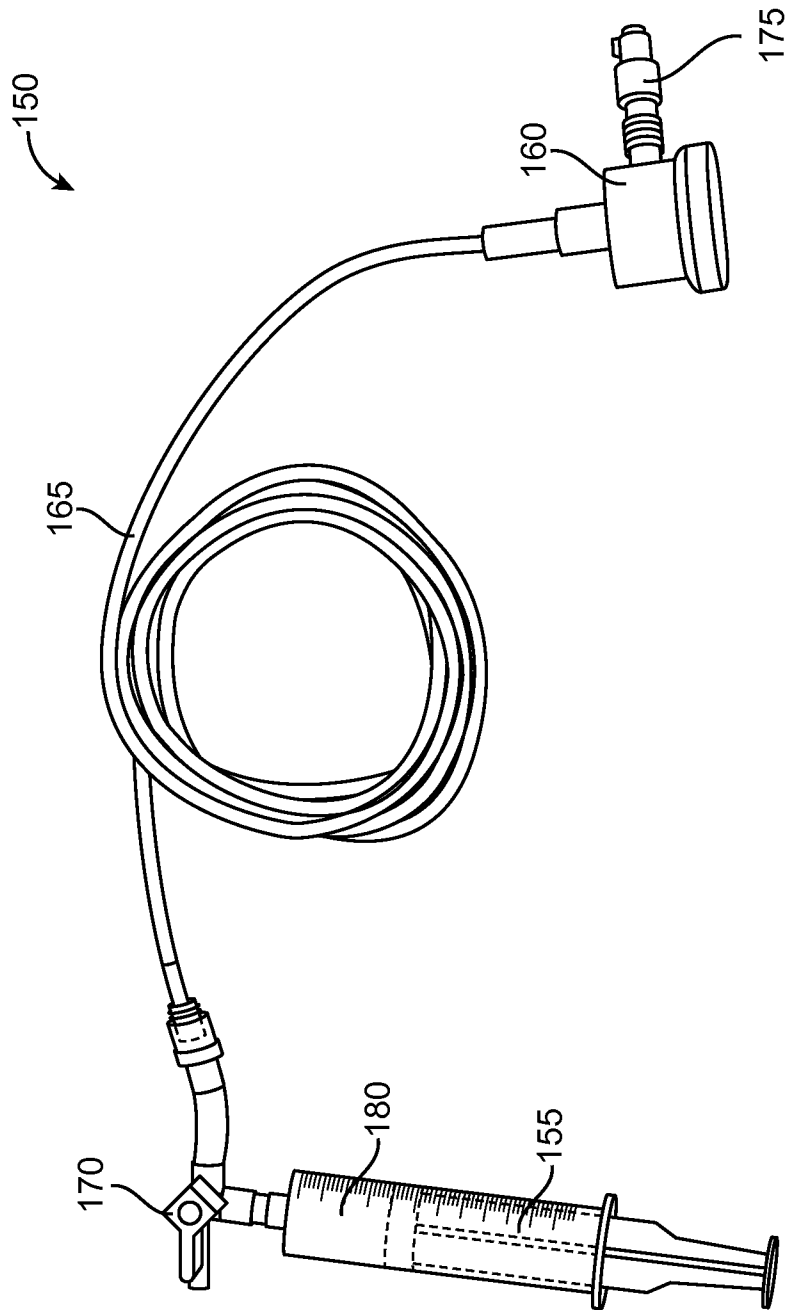


FIG. 2

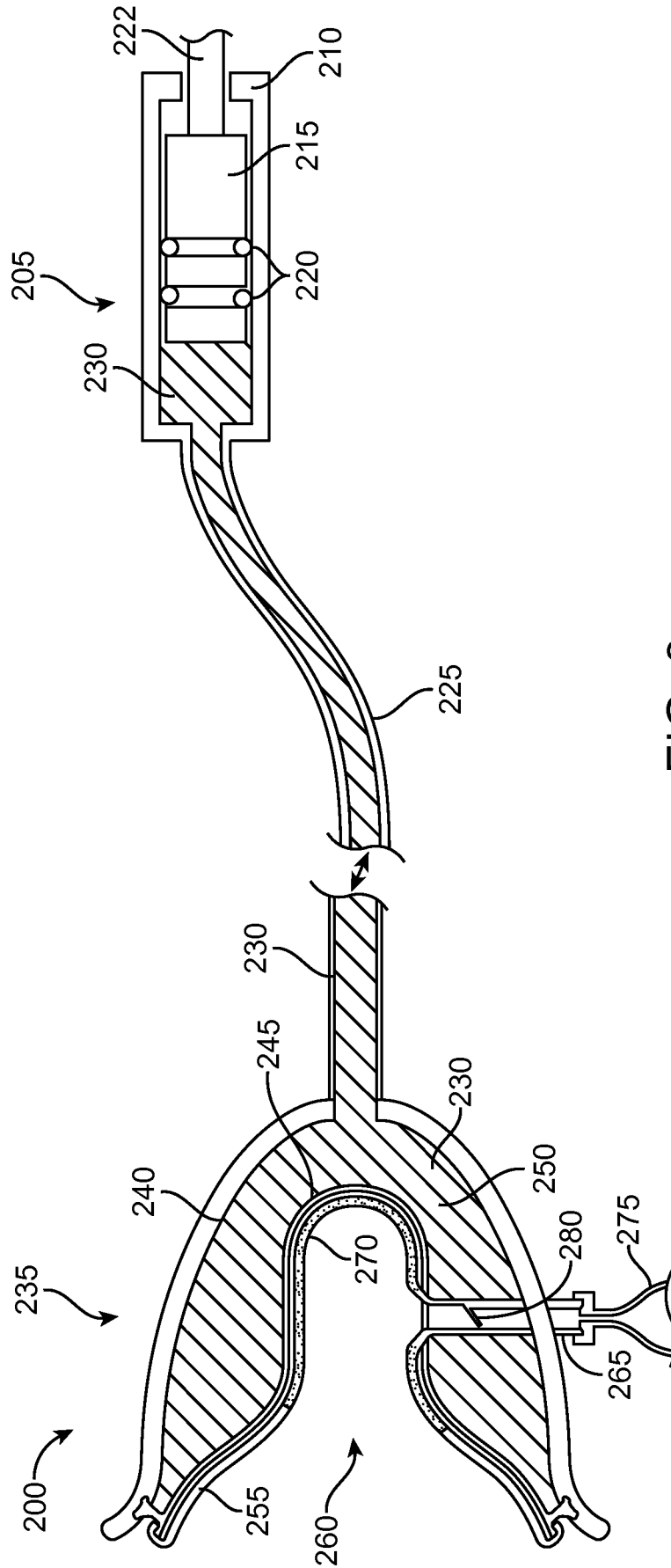


FIG. 3

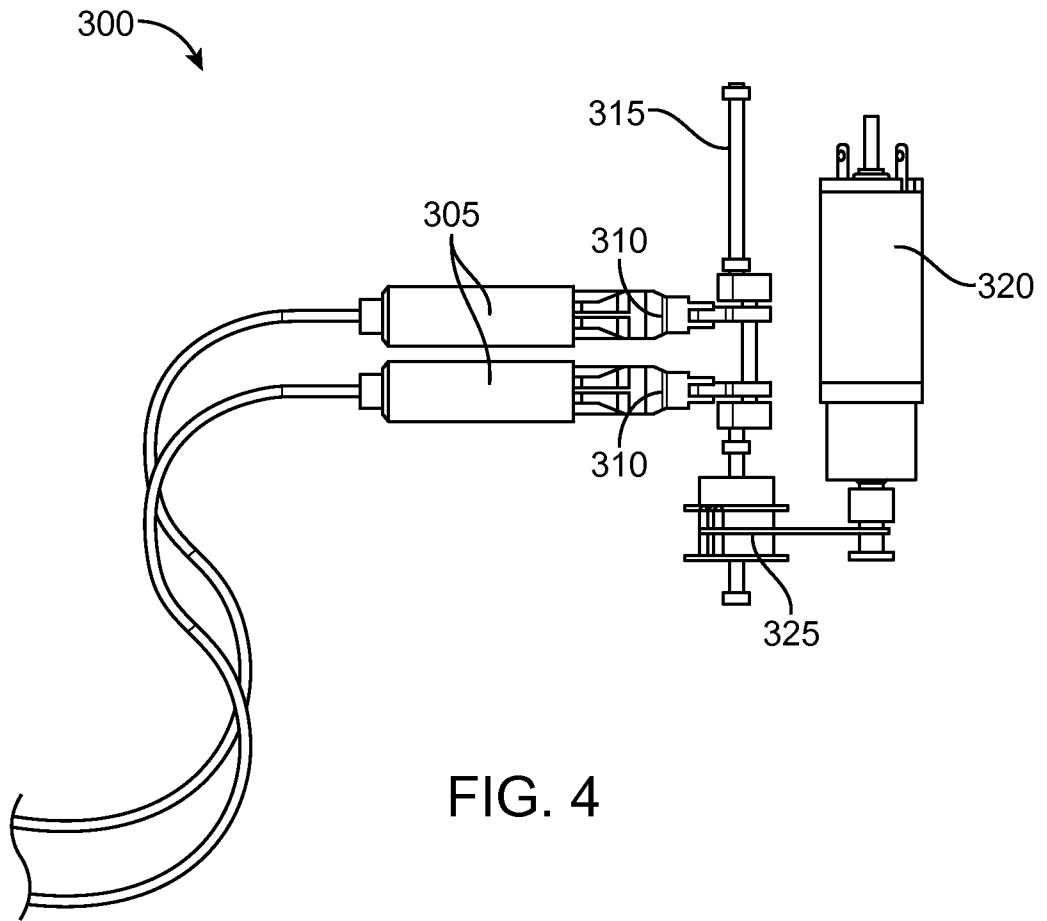


FIG. 4

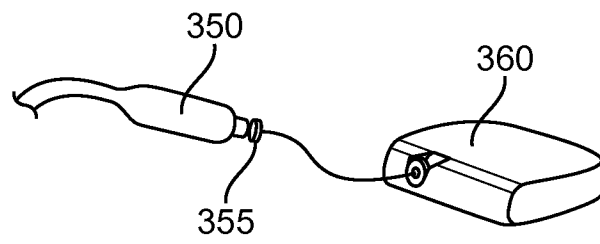


FIG. 5A

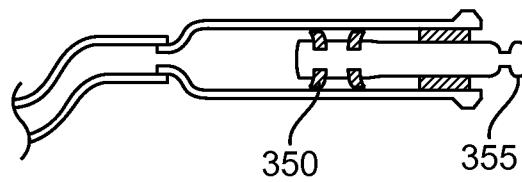


FIG. 5B

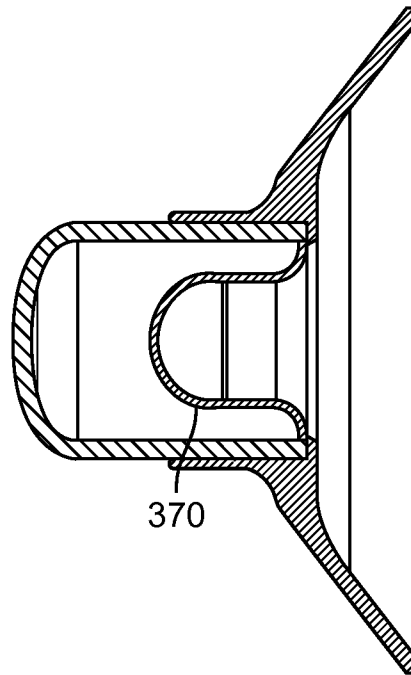


FIG. 6

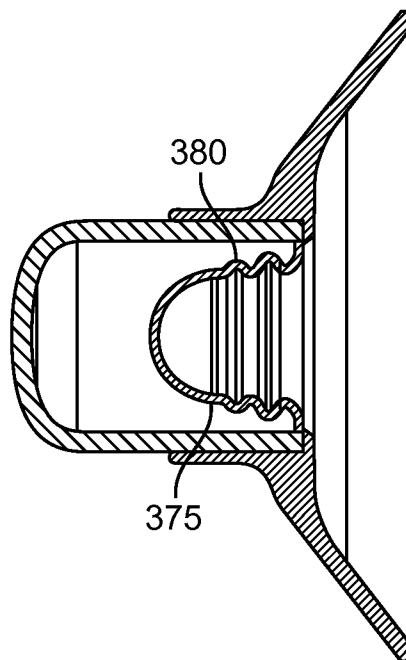


FIG. 7

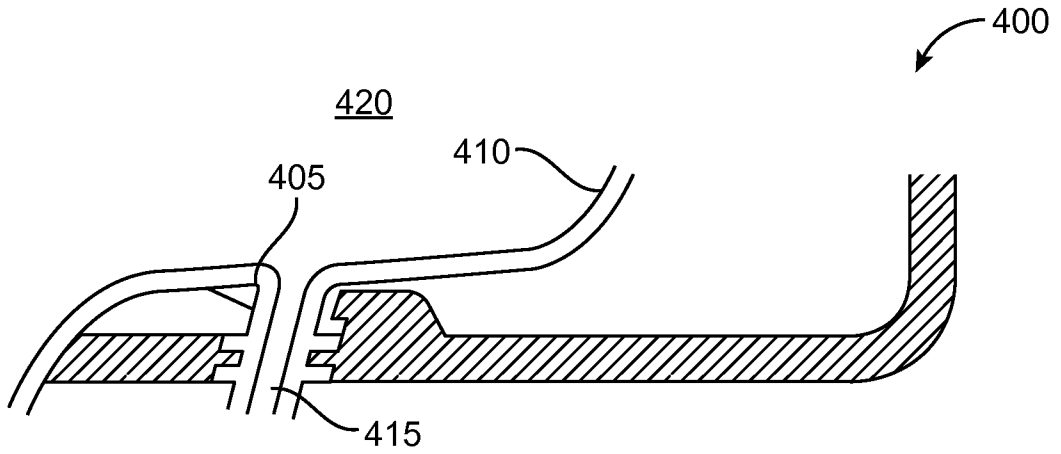


FIG. 8A

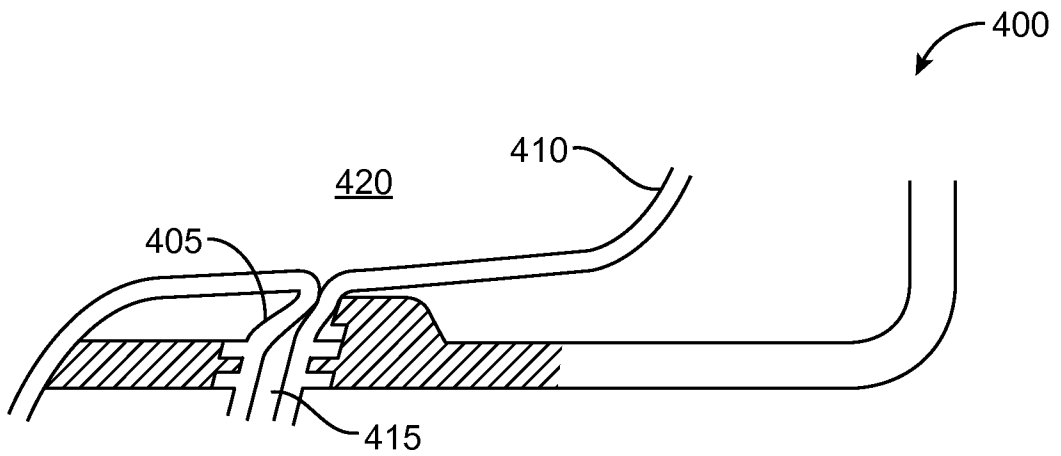


FIG. 8B

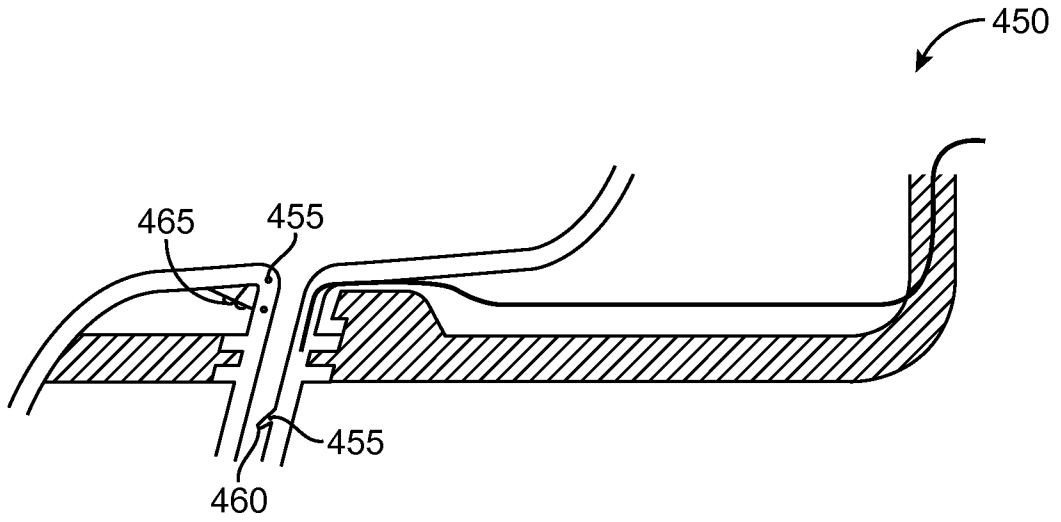


FIG. 9A

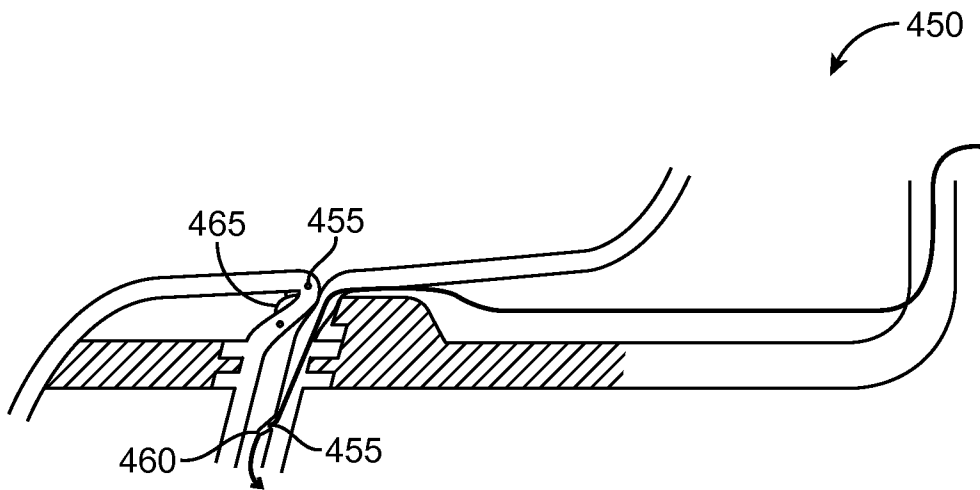


FIG. 9B

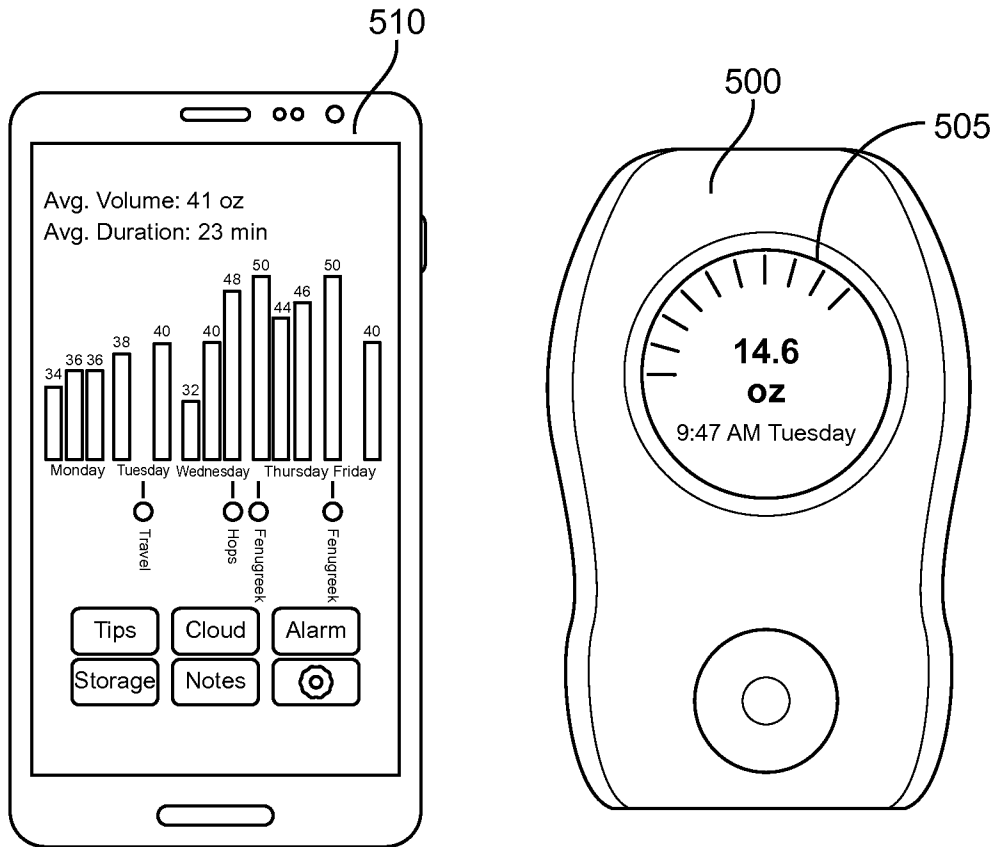


FIG. 10

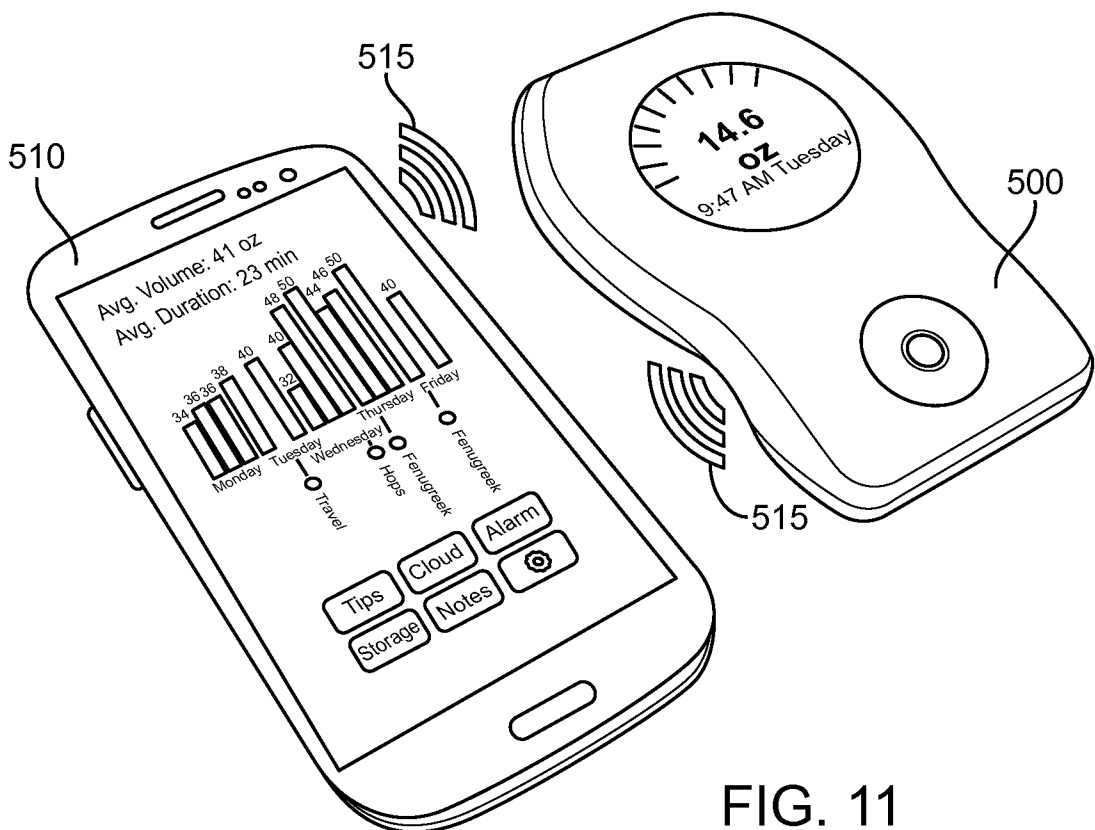


FIG. 11

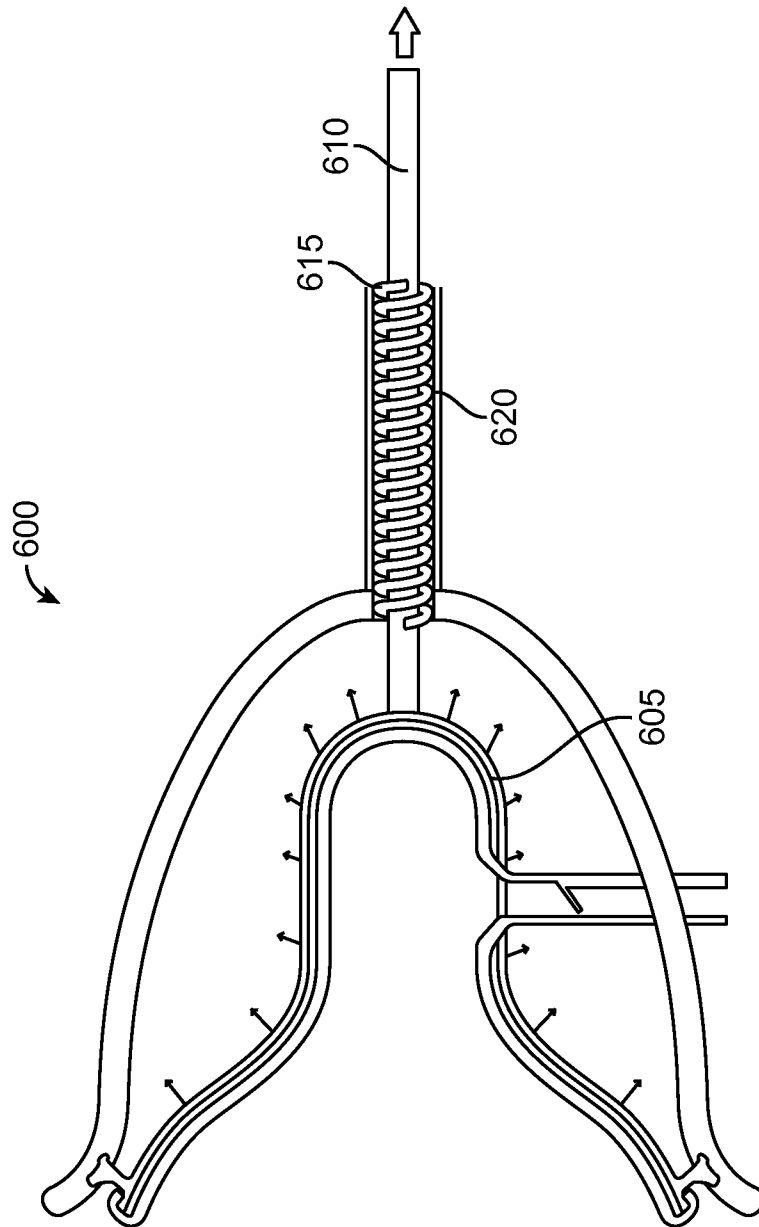


FIG. 12

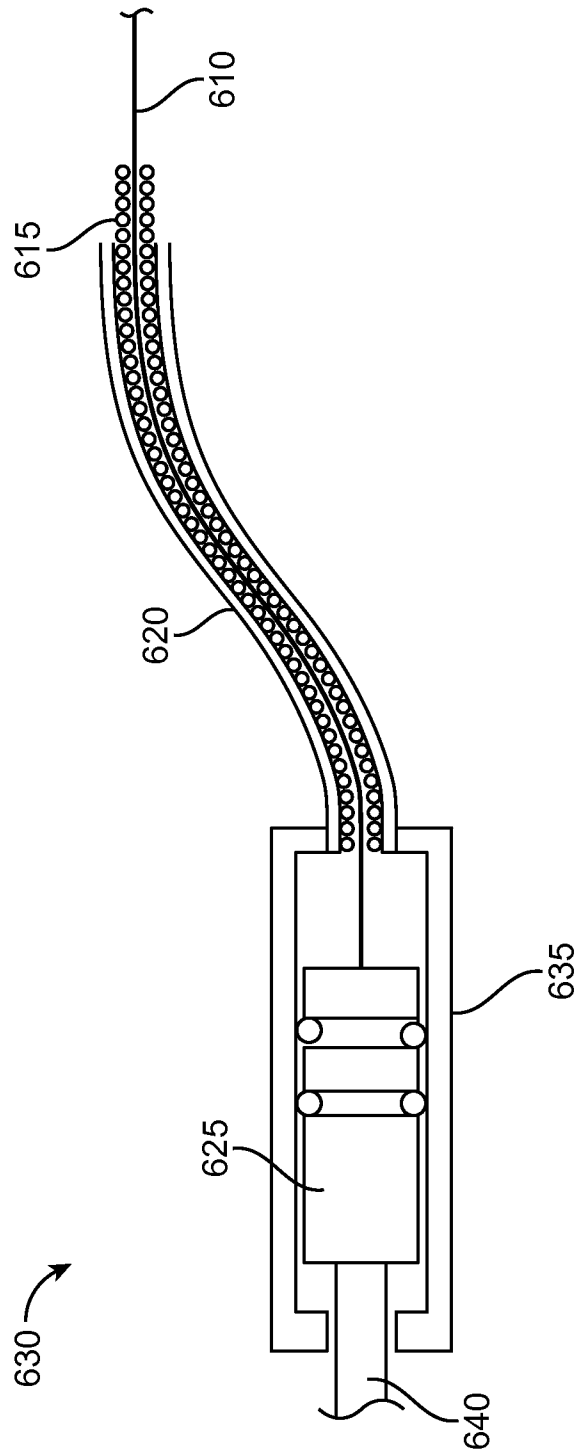


FIG. 13

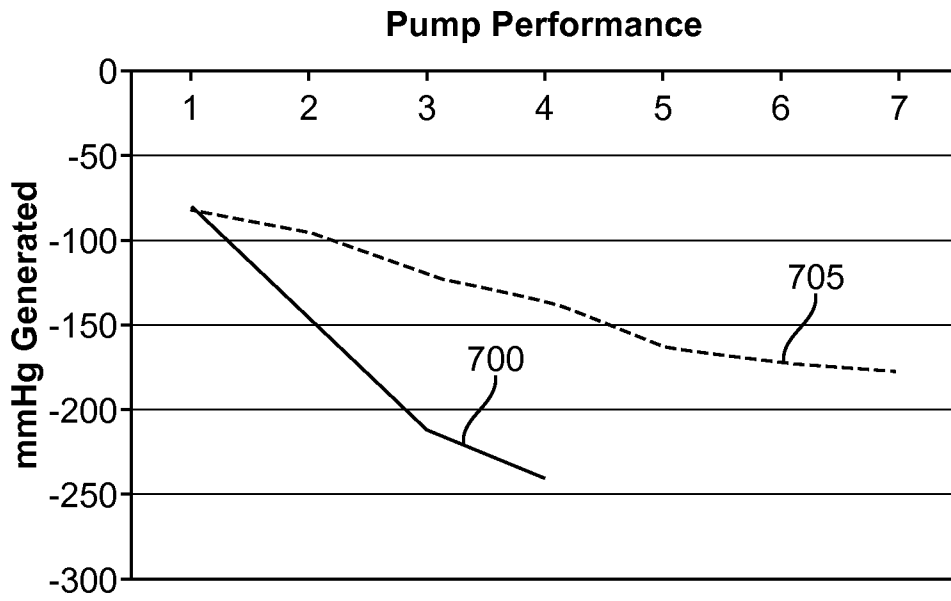


FIG. 14

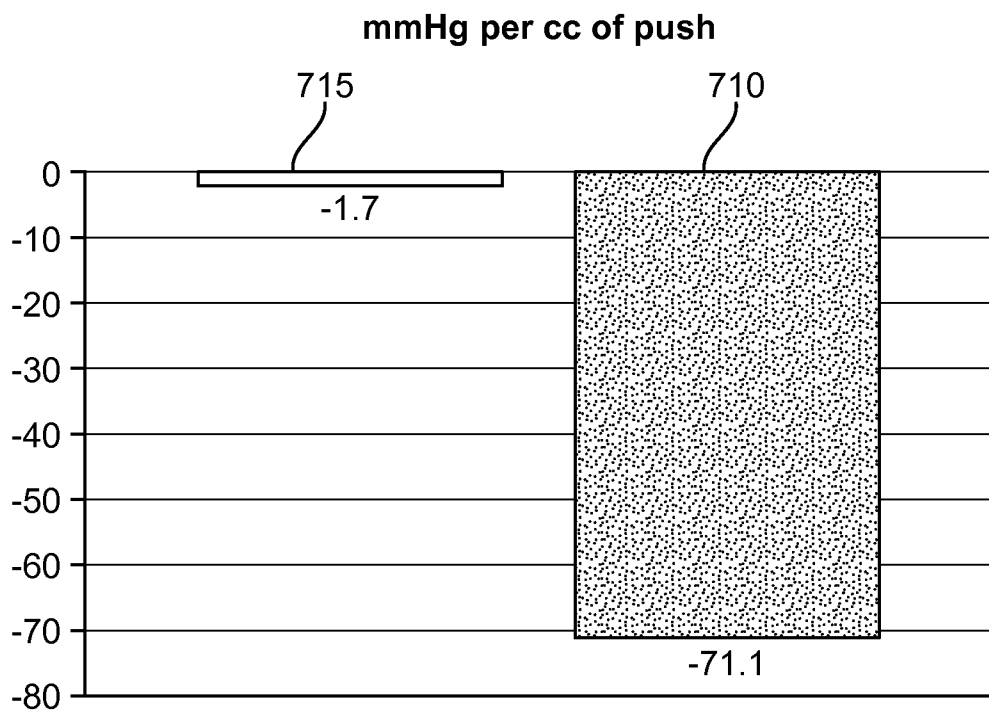


FIG. 15

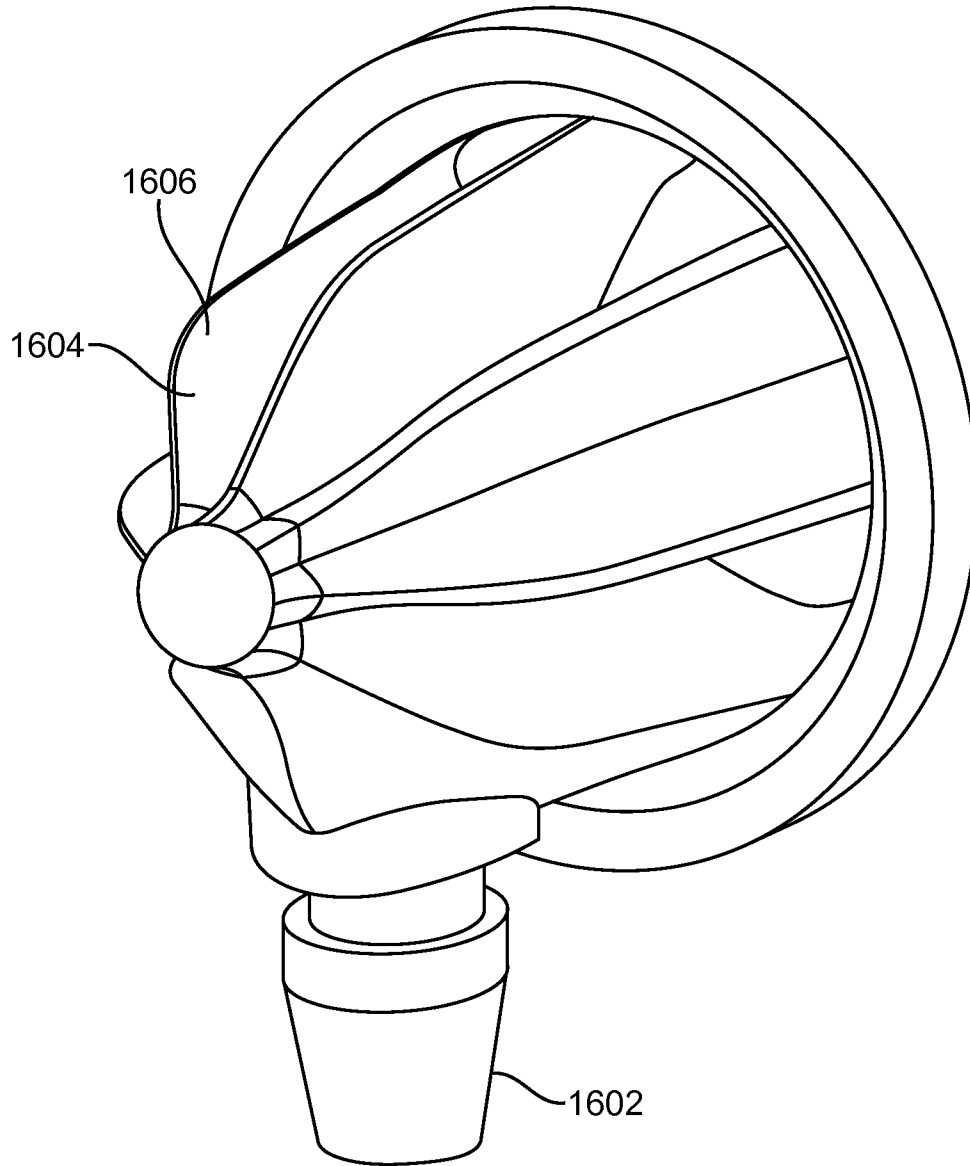


FIG. 16

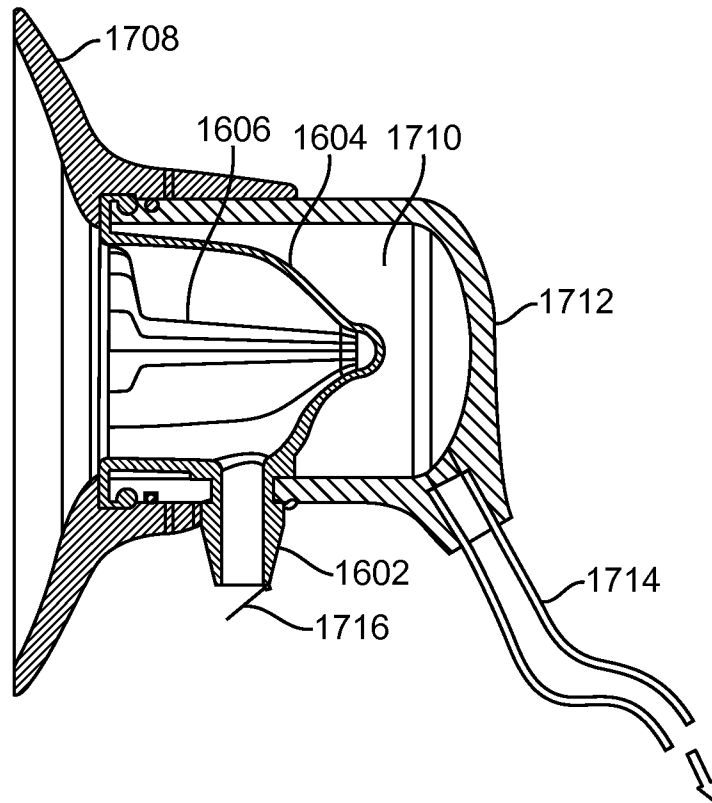


FIG. 17

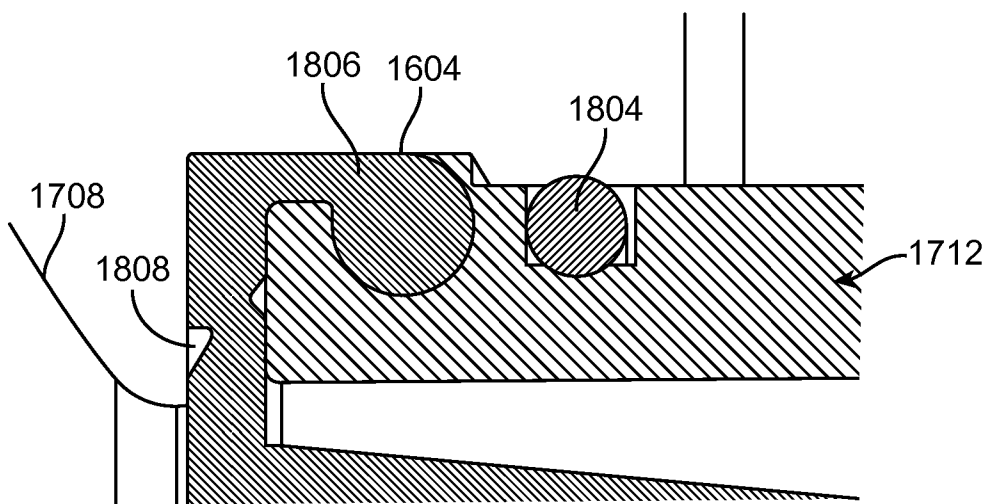


FIG. 18

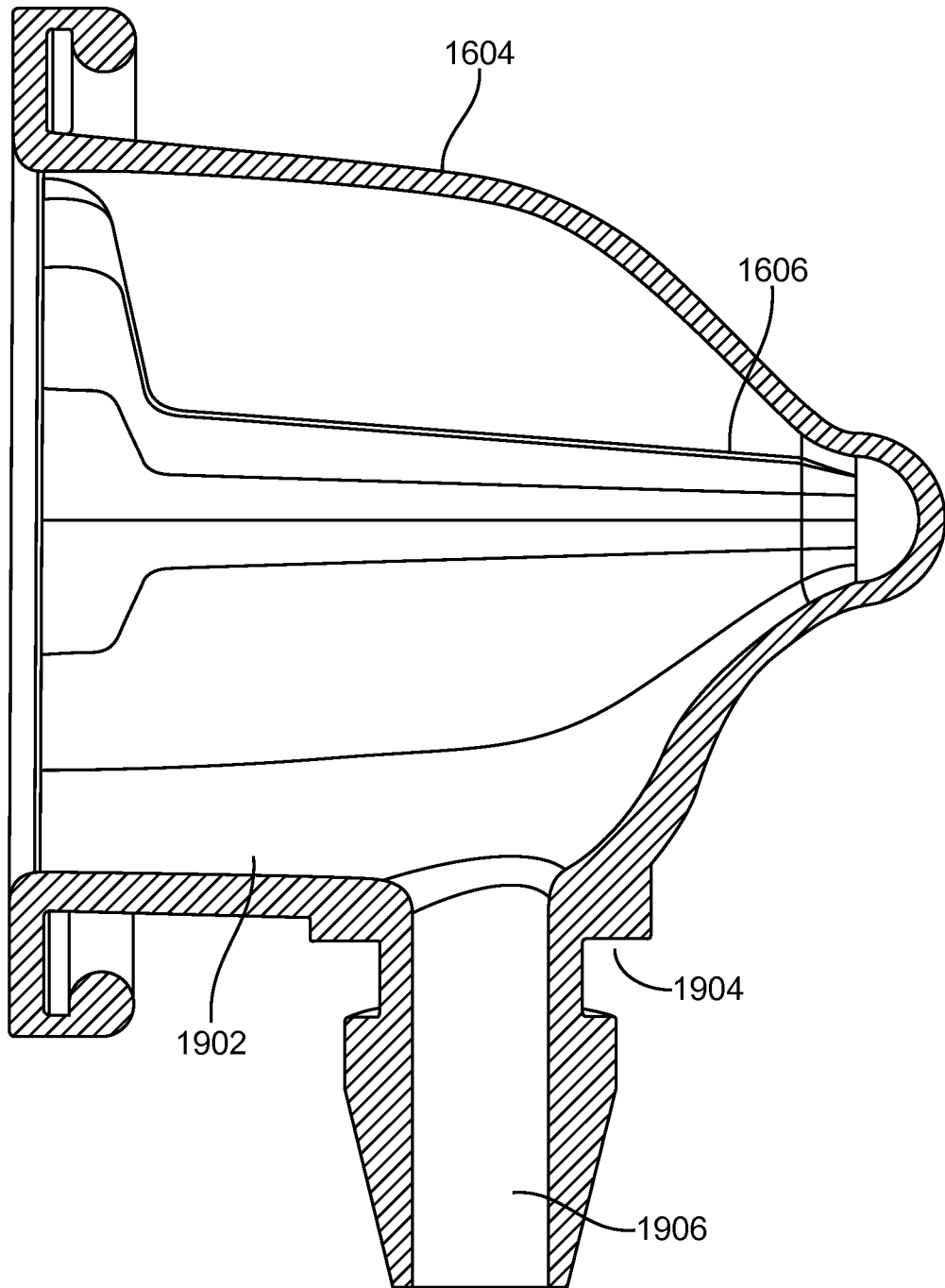


FIG. 19

16/19

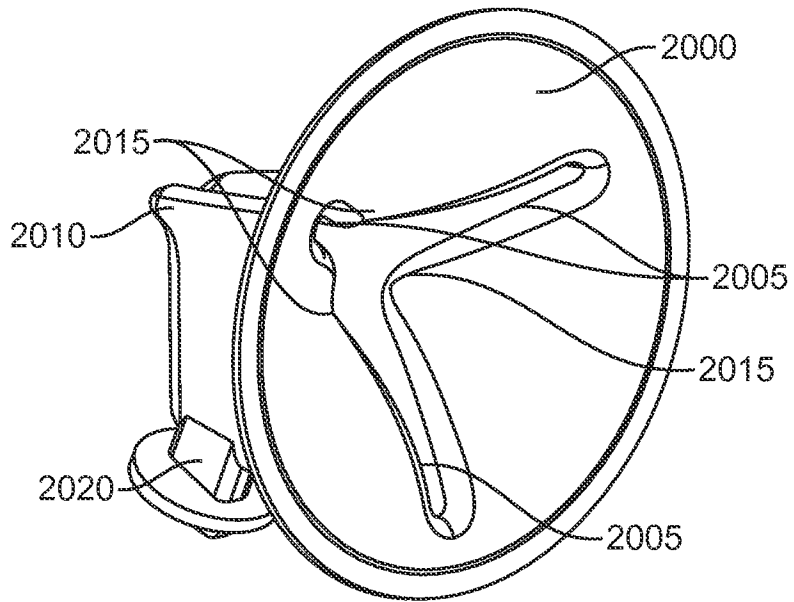


FIG. 20A

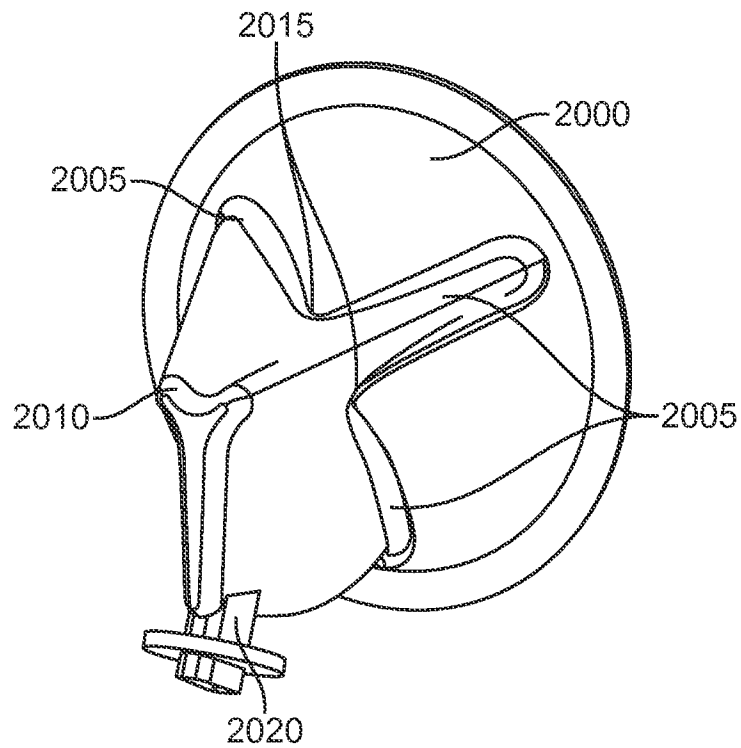


FIG. 20B

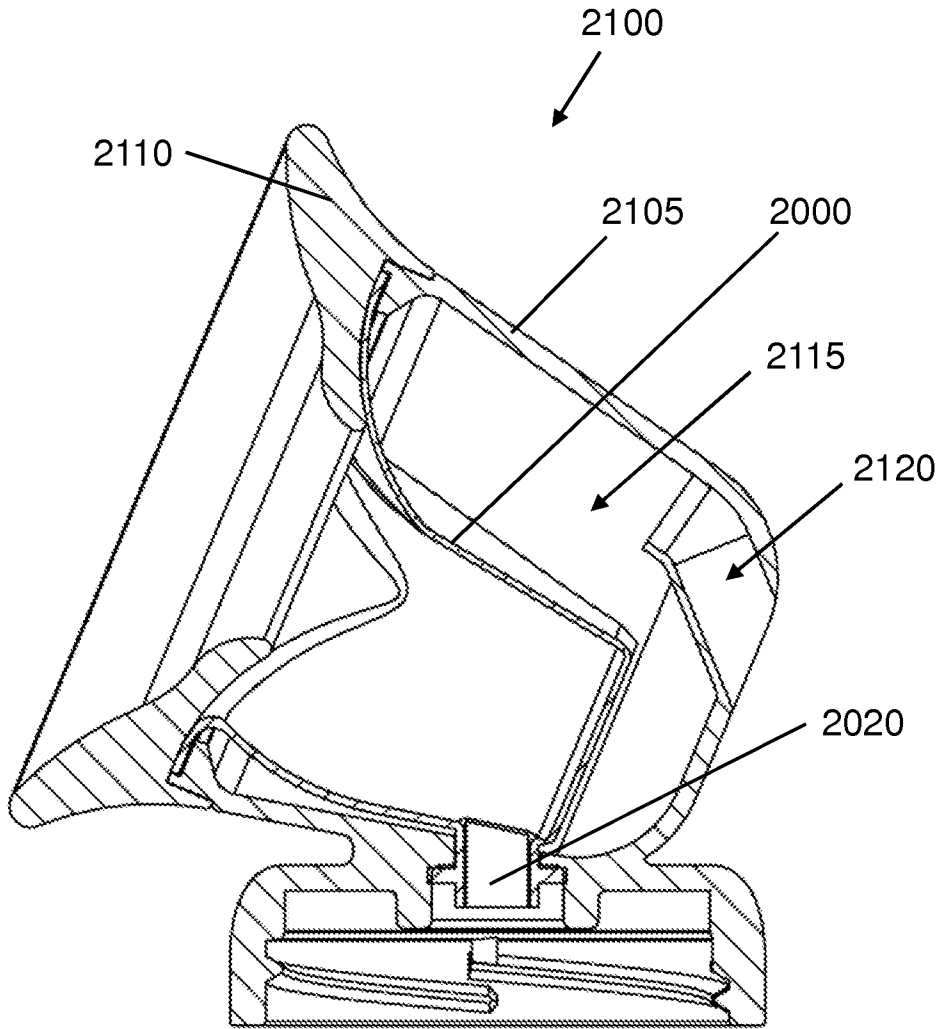


FIG. 21

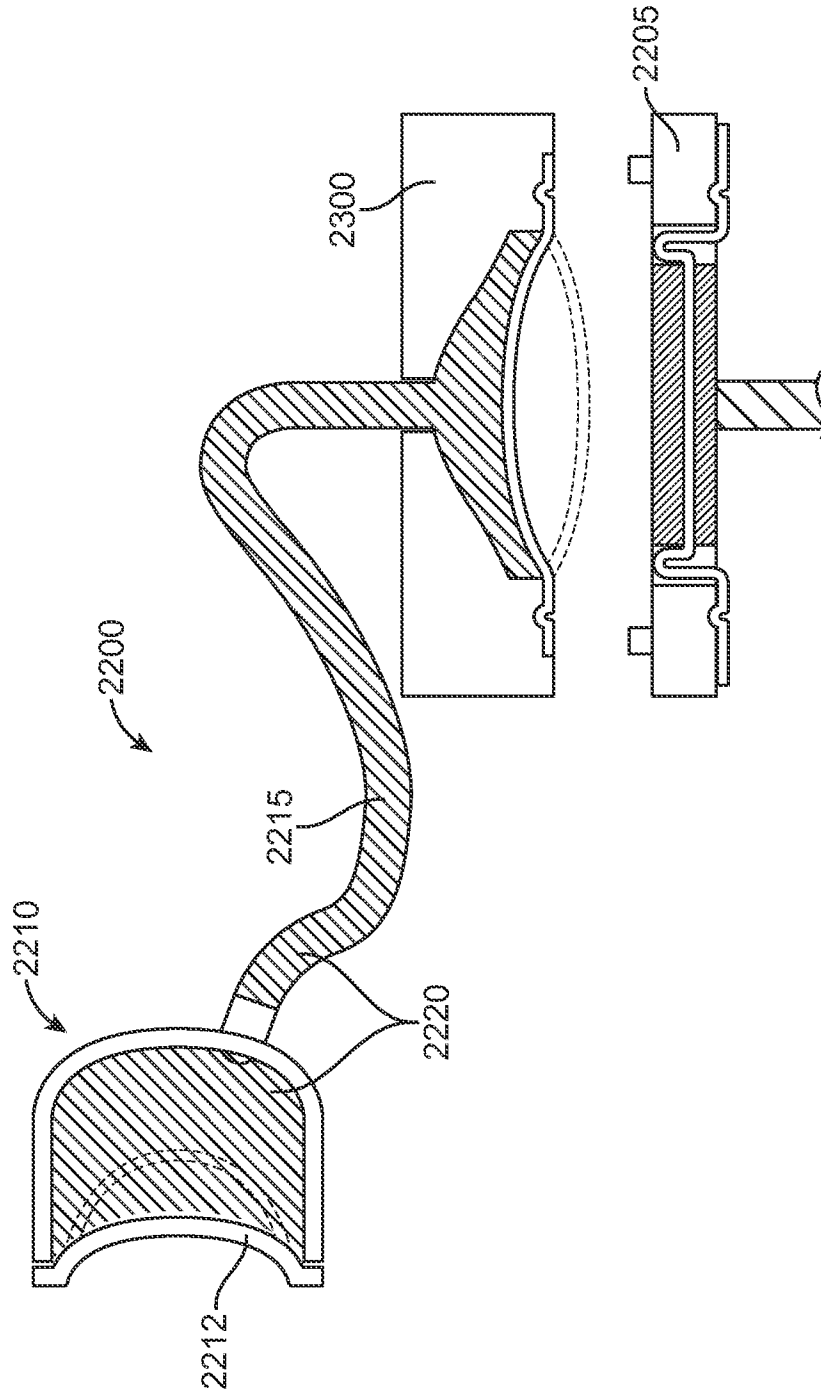


FIG. 22

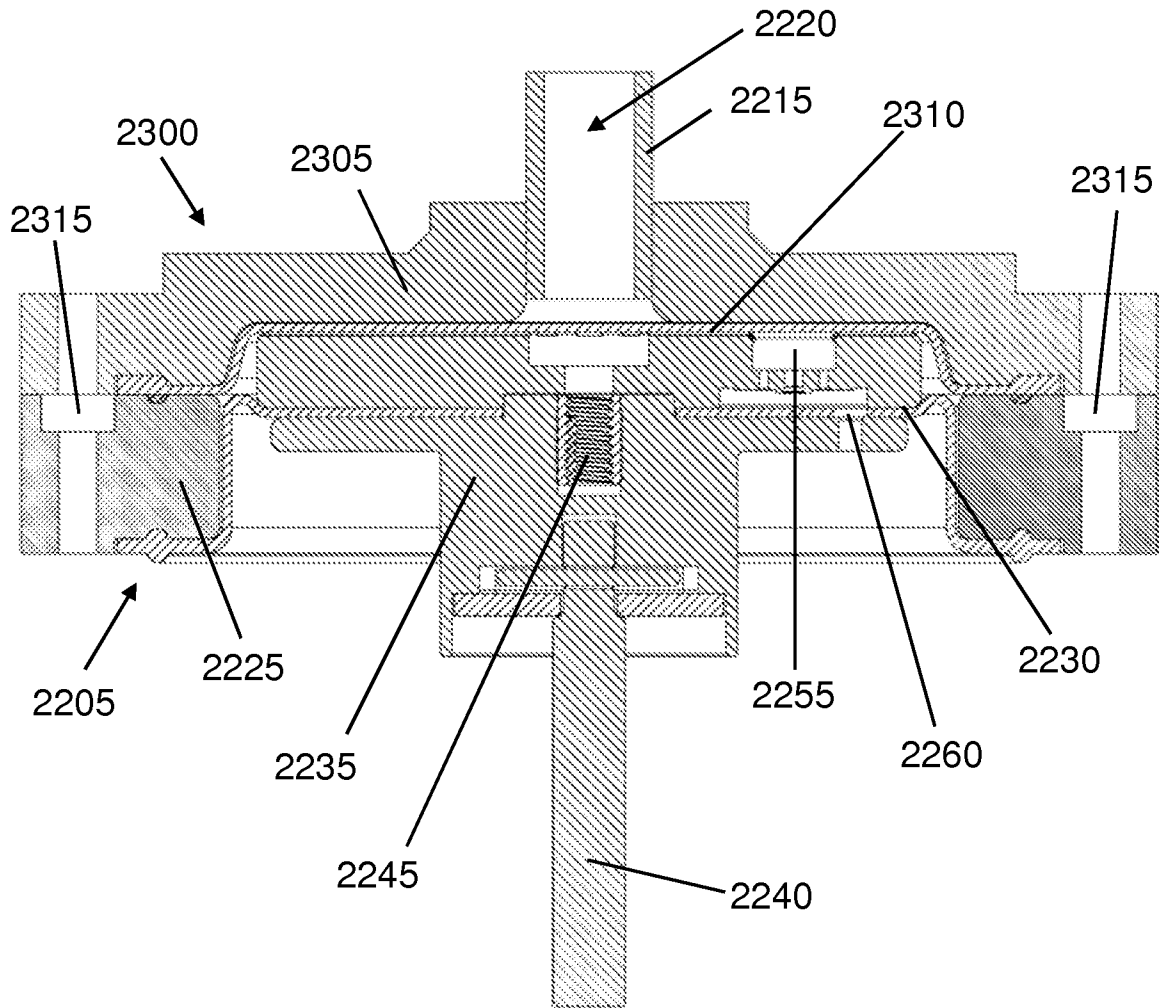


FIG. 23

**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	"I" 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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"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
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 11 September 2015	Date of mailing of the international search report <b>05 OCT 2015</b>
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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
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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.