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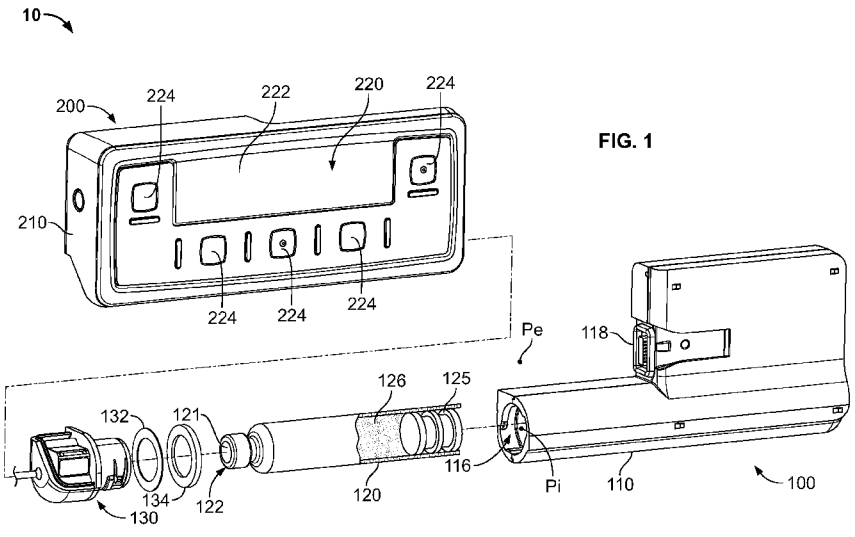


FIG. 1

(57) Abstract: Some embodiments of an infusion pump system may be configured to provide air pressure equilibrium between the ambient air pressure external to the infusion pump system and the internal air pressure inside the infusion pump system. In particular embodiments, the infusion pump system can be equipped with an air-transmissible, liquid-tight seal along an interface between a pump body and a cap device configured to attach to the pump body.

Pump System and Method

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to U.S. Application Serial No. 13/553,921, filed on July 20, 2012, and U.S. Application Serial No. 13/886,589, filed on May 3, 2013, the disclosures of which are incorporated herein by reference.

TECHNICAL FIELD

This document relates to an infusion pump system, such as a portable infusion pump system for dispensing a medicine.

BACKGROUND

Pump devices are commonly used to deliver one or more fluids to a targeted individual. For example, a medical infusion pump device may be used to deliver a medicine to a patient as part of a medical treatment. The medicine that is delivered by the infusion pump device can depend on the condition of the patient and the desired treatment plan. For example, infusion pump devices have been used to deliver insulin to the vasculature of diabetes patients so as to regulate blood-glucose levels.

In some circumstances, the air pressure external to an infusion pump can be different from the air pressure inside the pump housing. This situation may arise, for example, when a user of an infusion pump travels in an airplane or travels to a location with a different ambient air pressure. In such circumstances, the pressure differential between the interior of the infusion pump and the exterior of the infusion pump can cause unintended dispensation of the medicine from the pump body.

SUMMARY

Some embodiments of an infusion pump system may be configured to provide air pressure equilibrium between the ambient air pressure external to the infusion pump system and the internal air pressure inside the infusion pump system. In particular embodiments, the infusion pump system can be equipped with an air-transmissible, water-resistant seal along an interface between a pump body and a cap device configured to attach to the pump body. In such circumstances, the air-transmissible gasket can protect the internal components housed inside the pump body

from water migration or other contamination while also providing an air-transmissible path for air pressure equalization. Also, in some embodiments in which the cap device and pump body are disposable, single-use components that retain a prefilled medicine cartridge therein, the air-transmissible gasket may also be a single-use component, thereby providing the user with a new gasket and seal interface each time a new prefilled medicine cartridge is used.

In particular embodiments, a portable infusion pump system may include a portable housing defining an opening to receive a medicine. The infusion pump system may optionally include a pump drive system arranged in the portable housing and configured to dispense medicine from the portable housing when the medicine is received in the space. Further, the infusion pump system may include a cap device configured to engage with the portable housing to enclose the medicine in the portable housing when the medicine is received in the space. The infusion pump system may also include an air-transmissible gasket positioned at an interface between the portable housing and the cap device. The air-transmissible gasket may include a gasket aperture generally aligned with the opening of the portable housing when the cap device engages with the portable housing. The gasket may be air-transmissible so that air is passable through the interface between the portable housing and the cap device while the gasket resists migration of liquids into the portable housing.

Other embodiments described herein include a portable infusion pump system that may include a pump device. The pump device may include a pump housing that defines a space to receive a medicine. The pump device may optionally include a drive system positioned in the pump housing to dispense the medicine from the pump device when the medicine is received in the space of the pump housing. Further, the pump device may include a cap device configured to directly attach with the pump housing to enclose the medicine in the pump housing when the medicine is received in the space of the pump housing. The pump device may also include a gasket assembly positioned at an interface between the pump housing and the cap device when the cap device engages with the portable housing. The gasket assembly may be configured to permit the passage of air into and out of the pump housing while resisting the passage of liquids into the pump housing. The gasket assembly may include a hydrophobic member and an elastomeric member. A first major surface of

the hydrophobic member may be entirely abutted by the elastomeric member. The infusion pump system may also optionally include a controller device that may be removably attachable to the pump housing so as to electrically connect with the pump device. The controller device may house control circuitry, and may be configured to communicate with the drive system positioned in the pump housing to control dispensation of the medicine from the pump device.

Some embodiments include a method of equalizing an air pressure in a space defined by a pump housing of an infusion pump system with an ambient air pressure. The method may include receiving a cap device into attachment with an infusion pump housing so that an air-transmissible gasket is positioned proximate to a cavity opening defined by the infusion pump housing. The method may also include maintaining the air-transmissible gasket in a position at an interface between the cap device and a rim of cavity opening of the pump housing. The air-transmissible gasket can be configured to permit passage of air into and out of an interior space defined by the pump housing while resisting migration of liquid into the interior space defined by the pump housing.

Some or all of the embodiments described herein may provide one or more of the following advantages. First, some embodiments of the infusion pump system may be configured to equalize the air pressure inside the pump device with the air pressure in the region proximately external to the pump device. Second, certain embodiments of an infusion pump system may reduce the likelihood of inadvertent dispensation of medicine caused by a difference in air pressures between an interior space of the pump device and the ambient air pressure. Third, some embodiments of the infusion pump system may provide an air-transmissible and water-resistant seal along an interface between a pump body and a cap device configured to attach to the pump body. In such circumstances, the air-transmissible and water-resistant seal may have a central aperture aligned with a cavity opening of the pump device, thereby facilitating a secure seating from the air-transmissible and water-resistant seal along the cap device (prior to attachment with the pump device). Fourth, the infusion pump system may be configured to be portable, wearable, and (in some circumstances) concealable. For example, a user can conveniently wear the infusion pump system on the user's skin under clothing or can carry the pump device in the user's pocket (or

other portable location) while receiving the medicine dispensed from the pump device.

The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

FIG. 1 is an exploded perspective view of an infusion pump system in accordance with some embodiments.

FIG. 2 is a perspective view of the infusion pump system of FIG. 1 in a detached state.

FIG. 3 is a perspective view of an infusion pump system, in accordance with some embodiments.

FIGS. 4-5 are perspective views of the pump device of FIGS. 1-2 being discarded and the controller device of FIGS. 1-2 being reused with a new pump device.

FIG. 6 is an exploded perspective view of a controller device for an infusion pump system, in accordance with some embodiments.

FIG. 7 is an exploded perspective view of a pump device for an infusion pump system, in accordance with some embodiments.

FIG. 8 is a perspective view of a pump device assembled with a cap device including an air-transmissible gasket of the infusion pump system of FIG. 1.

FIG. 9 is a cross-sectional view of a pump device assembled with a cap device including an air-transmissible gasket of the infusion pump system of FIGS. 1 and 8.

FIG. 10 is a flow chart of a process for using an infusion pump system equipped with an air-transmissible gasket.

Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

Referring to FIG. 1, an infusion pump system 10 can include a pump device 100 and a controller device 200 that communicates with the pump device 100. The pump device 100 in this embodiment includes a housing structure 110 that defines a

cavity 116 in which a fluid cartridge 120 can be received. The pump device 100 also can include a cap device 130 to retain the fluid cartridge 120 in the cavity 116 of the housing structure 110. The pump device 100 can include a drive system that advances a plunger 125 in the fluid cartridge 120 so as to dispense fluid therefrom. As described in more detail below in connection with FIGS. 7-10, some embodiments of the pump device 100 can be advantageously equipped with a water-resistant, air-venting gasket assembly such as an air-transmissible gasket 132 in combination with a ring seal 134. The air-transmissible gasket 132 can facilitate equalization of air pressure between a proximal region external to the pump P_e and a region internal to the pump P_i. The air-transmissible gasket 132 and ring seal 134 can also comprise materials that provide a water-resistant seal. This type of water-resistant, air-venting gasket assembly can prevent changes in ambient air pressure from adversely affecting the dosage amount delivered by the infusion pump system 10, while maintaining resistance to water migration to the pump device 100. Moreover, the position of the air-transmissible gasket 132 (e.g., on the cap device 130 and proximate to the opening of the cavity 116) can provide improve functionality while reducing the complexity of manufacturing the pump device 100.

In some embodiments, the controller device 200 communicates with the pump device 100 to control the operation of the drive system. When the controller device 200, the pump device 100 (including the cap device 130), and the fluid cartridge 120 are assembled together, the user can (in some embodiments) conveniently wear the infusion pump system 10 on the user's skin under clothing, in a pouch clipped at the waist (e.g., similar to a cell phone pouch), or in the user's pocket while receiving the fluid dispensed from the pump device 100. Optionally, the controller device 200 may be configured as a reusable component that provides electronics and a user interface to control the operation of the pump device 100. In such circumstances, the pump device 100 can be a disposable component that is disposed of after a single use. For example, as described in more detail below in connection with FIGS. 4-5, the pump device 100 can be a "one time use" component that is thrown away after the fluid cartridge 120 therein is exhausted. Thereafter, the user can removably attach a new pump device 100' (having a new medicine cartridge 120') to the reusable controller device 200 for the dispensation of fluid from a new fluid cartridge 120'. Accordingly,

the user is permitted to reuse the controller device 200 (which may include complex or valuable electronics, as well as a rechargeable battery) while disposing of the relatively low-cost pump device 100 after each use. Such a pump system 10 can provide enhanced user safety as a new pump device 100' (and drive system therein) is employed with each new fluid cartridge 120'.

Briefly, in use, the pump device 100 is configured to removably attach to the controller device 200 in a manner that provides a secure fitting, an overall compact size, and a reliable electrical connection that is resistant to water migration. For example, as described in more detail below in connection with FIGS. 1-5, the controller device 200 can include a housing 210 having a number of features that mate with complementary features of the pump housing 110. In such circumstances, the controller device 200 can removably attach with the pump device 100 in a generally side-by-side configuration. The compact size permits the infusion pump system 10 to be discrete and portable (as described below in connection with FIG. 3). Moreover, at least one of the pump device 100 or the controller device 200 can include a release member that facilitates an easy-to-use detachment and replacement process.

Referring again to FIG. 1, the pump system 10 can be a medical infusion pump system that is configured to controllably dispense a medicine from the cartridge 120. As such, the fluid cartridge 120 can contain a medicine 126 to be infused into the tissue or vasculature of a targeted individual, such as a human or animal patient. For example, the pump device 100 can be adapted to receive a medicine cartridge 120 in the form of a carpule that is preloaded with insulin or another medicine for use in the treatment of Diabetes (e.g., Byetta®, Symlin®, or others). Such a cartridge 120 may be supplied, for example, by Eli Lilly and Co. of Indianapolis, IN. Other examples of medicines that can be contained in the fluid cartridge 120 include: pain relief drugs, hormone therapy, blood pressure treatments, anti-emetics, osteoporosis treatments, or other injectable medicines. The fluid cartridge 120 may have other configurations. For example, the fluid cartridge 120 may comprise a reservoir that is integral with the pump housing structure 110 (e.g., the fluid cartridge 120 can be defined by one or more walls of the pump housing structure 110 that surround a plunger to define a reservoir in which the medicine is injected or otherwise received).

In some embodiments, the pump device 100 can include one or more structures that interfere with the removal of the medicine cartridge 120 after the medicine cartridge 120 is inserted into the cavity 116. For example, the pump housing structure 110 can include one or more retainer wings (not shown in FIG. 1) that at least partially extend into the cavity 116 to engage a portion of the medicine cartridge 120 when the medicine cartridge 120 is installed therein. Such a configuration may facilitate the "one-time-use" feature of the pump device 100. In some embodiments, the retainer wings can interfere with attempts to remove the medicine cartridge 120 from the pump device 100, thus ensuring that the pump device 100 will be discarded along with the medicine cartridge 120 after the medicine cartridge 120 is emptied, expired, or otherwise exhausted. In another example, the cap device 130 can be configured to irreversible attach to the pump body 110 so as to cover the opening of the cavity 116. For example, a head structure of the cap device 130 can be configured to turn so as to threadably engage the cap device 130 with a mating structure along an inner wall of the cavity 116, but the head structure may prevent the cap device from turning in the reverse direction so as to disengage the threads. Accordingly, the pump device 100 can operate in a tamper-resistant and safe manner because the pump device 100 can be designed with a predetermined life expectancy (e.g., the "one-time-use" feature in which the pump device is discarded after the medicine cartridge 120 is emptied, expired, or otherwise exhausted).

Still referring to FIG. 1, the controller device 200 can be removably attached to the pump device 100 so that the two components are mechanically mounted to one another in a fixed relationship. Such a mechanical mounting can form an electrical connection between the removable controller device 200 and the pump device 100. For example, the controller device 200 can be in electrical communication with a portion of a drive system (not shown in FIG. 1) of the pump device 100. As described in more detail below, the pump device 100 can include a drive system that causes controlled dispensation of the medicine or other fluid from the cartridge 120. In some embodiments, the drive system incrementally advances a piston rod (not shown in FIG. 1) longitudinally into the cartridge 120 so that the fluid is forced out of an output end 122. A septum 121 (FIG. 1) at the output end 122 of the fluid cartridge 120 can be pierced to permit fluid outflow when the cap device 130 is connected to the pump

housing structure 110. For example, the cap device 130 may include a penetration needle that punctures the septum 121 during attachment of the cap device to the housing structure 110. Thus, when the pump device 100 and the controller device 200 are attached and thereby electrically connected, the controller device 200 communicates electronic control signals via a hardwire-connection (e.g., electrical contacts or the like) to the drive system or other components of the pump device 100. In response to the electrical control signals from the controller device 200, the drive system of the pump device 100 causes medicine to incrementally dispense from the medicine cartridge 120. Power signals, such as signals from the rechargeable battery 245 (refer to FIG. 6) of the controller device 200 and from the power source 310 (refer to FIG. 7) of the pump device 100 may also be passed between the controller device 200 and the pump device 100.

As shown in FIG. 1, the pump device 100 can include an electrical connector 118 (e.g., having conductive pads, pins, and the like) that is exposed to the controller device 200 and that mates with a complementary electrical connector (refer to connector 218 in FIG. 2) on the adjacent face of the controller device 200. The electrical connectors 118 and 218 provide the electrical communication between the control circuitry (refer, for example, to FIG. 6) housed in the controller device 200 and at least a portion of the drive system or other components of the pump device 100. For example, in some embodiments, the electrical connectors 118 and 218 can permit the transmission of electrical control signals to the pump device 100 and the reception of feedback signals (e.g., sensor signals) from particular components within the pump device 100. The electrical connectors 118 and 218 may similarly facilitate transmission of one or more power signals from the rechargeable battery pack 245 to the pump device 100, where the signals may be used to provide power to components of the pump device 100, or to transmit one or more power signals from the power source 310 to the controller device, where the signals may be used to charge the rechargeable battery 245 or to power components of the controller device 200.

Still referring to FIG. 1, the controller device 200 can include a user interface 220 that permits a user to monitor the operation of the pump device 100. In some embodiments, the user interface 220 can include a display device 222 and one or more user-selectable buttons (e.g., several buttons 224 are shown in the embodiment of FIG.

1). The display device 222 can include an active area in which numerals, text, symbols, images, or a combination thereof can be displayed. For example, the display device 222 can be used to communicate a number of settings or menu options for the infusion pump system 10. In this embodiment, the user may press one or more of the buttons to shuffle through a number of menus or program screens that show particular settings and data (e.g., review data that shows the medicine dispensing rate, the total amount of medicine dispensed in a given time period, the amount of medicine scheduled to be dispensed at a particular time or date, the approximate amount of medicine remaining in the cartridge 120, or the like). In some embodiments, the user can adjust the settings or otherwise program the controller device 200 by pressing one or more buttons of the user interface 220. For example, in embodiments of the infusion pump system 10 configured to dispense insulin, the user may press one or more of the buttons to change the dispensation rate of insulin or to request that a bolus of insulin be dispensed immediately or at a scheduled, later time. In some implementations, the display device 222 may also be used to communicate information regarding remaining battery life.

Accordingly, when the controller device 200 is connected to the pump device 100, the user can be provided with the opportunity to readily monitor the infusion pump operation by simply viewing the user interface 220 of the controller device 200 connected to the pump device 100. Such monitoring capabilities may provide comfort to a user who may have urgent questions about the current operation of the pump device 100. Also, in these embodiments, there may be no need for the user to carry and operate a separate module to monitor the operation of the pump device 100, thereby simplifying the monitoring process and reducing the number of devices that must be carried by the user. If a need arises in which the user desires to monitor the operation of the pump device 100 or to adjust the settings of the pump system 10 (e.g., to request a bolus amount of medicine), the user can readily operate the user interface 220 of the controller device 200, which is removably attached to the pump device 100, without the requirement of locating and operating a separate monitoring module.

Referring now to FIG. 2, when the infusion pump system 10 operates, the controller device 200 can be removably attached to the pump device 100 in a side-by-

side arrangement. For example, the pump device 100 may be moved in a longitudinal direction (e.g., refer to direction 219 in FIG. 4) toward the controller device 200 until the complementary features connect and secure the separate components in the side-by-side arrangement. The controller device 200 can include a controller housing structure 210 having a number of features that are configured to mate with complementary features of the pump housing structure 110 so as to form a releasable mechanical connection. For example, the pump housing structure 110 can include a barrel 111 that mates with a complementary barrel channel 211 of the controller housing 210. In various implementations, the pump device 100 and the controller device 200 can be mounted to one another so that the assembled system 10 is resistant to water migration both into the pump housing structure 110 and the controller housing structure 210. Such a configuration can also provide water-resistant protection for the electrical connection between the pump device 100 and the controller device 200. Thus, the sensitive internal components in the controller device 200 and the pump device 100 can be reliably protected from water migration if the user encounters water (e.g., rain, incidental splashing, and the like) while using the pump system 10.

Referring to FIG. 3, the infusion pump system 10 can be configured to be portable and can be wearable and concealable. For example, a user can conveniently wear the infusion pump system 10 on the user's skin (e.g., skin adhesive) underneath the user's clothing or carry the pump device 100 in the user's pocket (or other portable location) while receiving the medicine dispensed from the pump device 100. The pump system 10 is shown in FIG. 3 as being held in a user's hand 5 so as to illustrate an exemplary size of the system 10 in accordance with some embodiments. This embodiment of the infusion pump system 10 is compact so that the user can wear the portable infusion pump system 10 (e.g., in the user's pocket, connected to a belt clip, adhered to the user's skin, or the like) without the need for carrying and operating a separate module. In such embodiments, the cap device 130 of the pump device 100 can be configured to mate with an infusion set 146. In general, the infusion set 146 can be a tubing system that connects the infusion pump system 10 to the tissue or vasculature of the user (e.g., to deliver medicine into the tissue or vasculature under the user's skin). The infusion set 146 can include a flexible tube

147 that extends from the pump device 100 to a subcutaneous cannula 149 that may be retained by a skin adhesive patch (not shown) that secures the subcutaneous cannula 149 to the infusion site. The skin adhesive patch can retain the infusion cannula 149 in fluid communication with the tissue or vasculature of the patient so that the medicine dispensed through the tube 147 passes through the cannula 149 and into the user's body. The cap device 130 can provide fluid communication between the output end 122 (FIG. 1) of the medicine cartridge 120 and the tube 147 of the infusion set 146.

In some embodiments, the infusion pump system 10 can be pocket-sized so that the pump device 100 and controller device 200 can be worn in the user's pocket or in another portion of the user's clothing. In some circumstances, the user may desire to wear the pump system 10 in a more discrete manner. Accordingly, the user can pass the tube 147 from the pocket, under the user's clothing, and to the infusion site where the adhesive patch can be positioned. As such, the pump system 10 can be used to deliver medicine to the tissues or vasculature of the user in a portable, concealable, and discrete manner.

In some embodiments, the infusion pump system 10 can be configured to adhere to the user's skin directly at the location in which the skin is penetrated for medicine infusion. For example, a rear surface 102 (FIG. 2) of the pump device 100 can include a skin adhesive patch so that the pump device 100 can be physically adhered to the skin of the user at a particular location. In these embodiments, the cap device 130 can have a configuration in which medicine passes directly from the cap device 130 into an infusion cannula 149 that is penetrated into the user's skin. In some examples, the user can temporarily detach the controller device 200 (while the pump device 100 remains adhered to the skin) so as to view and interact with the user interface 220.

Referring now to FIGS. 4-5, the infusion pump system 10 can be operated such that the pump device 100 is a disposable, non-reusable component while the controller device 200 is a reusable component. In these circumstances, the pump device 100 may be configured as a "one-time-use" device that is discarded after the medicine cartridge is emptied, expired, or otherwise exhausted. Thus, in some embodiments, the pump device 100 can be designed to have an expected operational

life of about 1 day to about 30 days, about 1 day to about 20 days, about 1 to about 14 days, or about 1 day to about 7 days—depending on the volume of medicine in the cartridge 120, the dispensation patterns that are selected for the individual user, and other factors. For example, a medicine cartridge 120 containing insulin can have an expected usage life of about 7 days after the cartridge is removed from a refrigerated state and the septum 121 is punctured. In some circumstances, the dispensation pattern selected by the user can cause the insulin to be emptied from the medicine cartridge 120 before the 7-day period. If the insulin is not emptied from the medicine cartridge 120 after the 7-day period, the remaining insulin can become expired sometime thereafter. In either case, the pump device 100 and the medicine cartridge 120 therein can be collectively discarded after exhaustion of the medicine cartridge 120 (e.g., after being emptied, expired, or otherwise not available for use).

The controller device 200, however, may be reused with subsequent new pump devices 100' and new medicine cartridges 120'. As such, the control circuitry, the user interface components, the rechargeable battery pack 245, and other components that may have relatively higher manufacturing costs can be reused over a longer period of time. For example, in some embodiments, the controller device 200 can be designed to have an expected operational life of about 1 year to about 7 years, about 2 years to about 6 years, or about 3 years to about 5 years—depending on a number of factors including the usage conditions for the individual user. Accordingly, the user can be permitted to reuse the controller device 200 (which can include complex or valuable electronics, and a rechargeable battery pack) while disposing of the relatively low-cost pump device 100 after each use. Such a pump system 10 can provide enhanced user safety as a new pump device 100' (and drive system therein) is employed with each new medicine cartridge 120'.

Referring to FIGS. 4-5, the same controller device 200 can be reused with a new pump device 100' having a new medicine cartridge 120' retained therein, and the previously used pump device 100, including the exhausted medicine cartridge, can be discarded in a discard bin 20. The new pump device 100' (FIG. 4) can have a similar appearance, form factor, and operation as the previously used pump device 100, and thus the new pump device 100' can be readily attached to the controller device 200 for controlled dispensation of medicine from the new medicine cartridge 120'. In some

embodiments, the user can prepare the new pump device 100' for use with the controller device 200. For example, the user may insert the new medicine cartridge 120' in the cavity 116 of the new pump device 100' and then join the cap device 130 to the pump housing to retain the new medicine cartridge 120' therein (refer, for example, to FIG. 1). Although the tubing 147 of the infusion set 146 is not shown in FIG. 4, it should be understood that the tubing 147 can be attached to the cap device 130 prior to the cap device 130 being joined with the housing 110. For example, a new infusion set 146 can be connected to the cap device 130 so that the tubing 147 can be primed (e.g., a selected function of the pump device 100 controlled by the controller device 200) before attaching the cannula's adhesive patch to the user's skin. As shown in FIG. 4, the new medicine cartridge 120' may be filled with medicine such that the plunger 125 is not viewable through the barrel 111.

The new pump device 100' can be removably attached to the controller device 200 to assemble into the infusion pump system 10 for delivery of medicine to the user. As previously described, the guided motion in the longitudinal direction 219 provides the user with a convenient "one-movement" process to attach the pump device 100' and the controller device 200. For example, the user can readily slide the pump device 100' and the controller device 200 toward one another in a single movement (e.g., in the longitudinal direction 219) that causes both a physical connection and an electrical connection. Thus, the infusion pump system 10 can permit users to readily join the pump device 100' and the controller device 200 without compound or otherwise difficult hand movements—a feature that can be particularly beneficial to child users or to elderly users.

Referring now to FIG. 6, the controller device 200 (shown in an exploded view) houses a number of components that can be reused with a series of successive pump devices 100. In particular, the controller device 200 can include controller circuitry 240 and a rechargeable battery pack 245, each arranged in the controller housing 210. As described above, rechargeable battery pack 245 may provide electrical energy to components of controller circuitry 240, other components of the controller device (e.g., a display device 222 and other user interface components, sensors, or the like), or to components of the pump device 100. Controller circuitry 240 may be configured to communicate control or power signals to the drive system

of the pump device 100, or to receive power or feedback signals from the pump device 100.

Still referring to FIG. 6, the user interface 220 of the controller device 200 can include input components and/or output components that are electrically connected to the controller circuitry 240. For example, the user interface 220 can include the display device 222 having an active area that outputs information to a user and buttons 224 that the user can use to provide input. Here, the display device 222 can be used to communicate a number of settings or menu options for the infusion pump system 10. In some embodiments, the controller circuitry 240 can receive input commands from a user's button selections and thereby cause the display device 222 to output a number of menus or program screens that show particular settings and data (e.g., review data that shows the medicine dispensing rate, the total amount of medicine dispensed in a given time period, the amount of medicine scheduled to be dispensed at a particular time or date, the approximate amount of medicine remaining the cartridge 120, the amount of battery life remaining, or the like). The controller circuitry 240 can be programmable to cause the controller circuitry 240 to change any one of a number of settings for the infusion pump system 10. For example, the user may provide one or more instructions to adjust a number of settings for the operation of the infusion pump system 10. Such settings may be stored in one or more memory devices arranged in the controller circuitry 240.

In some optional embodiments, the controller circuitry 240 can include a cable connector (e.g., a USB connection port or another data cable port) that is accessible on an external portion of the controller housing 210. As such, a cable can be connected to the controller circuitry 240 to upload data or program settings to the controller circuitry or to download data from the controller circuitry. For example, historical data of medicine delivery can be downloaded from the controller circuitry 240 (via the cable connector) to a computer system of a physician or a user for purposes of analysis and program adjustments. Optionally, the data cable can also provide recharging power.

Referring now to FIG. 7, the pump device 100 can include a drive system 300 that is controlled by the controller device 200. As described in more detail below, the drive system 300 can incrementally dispense fluid in a controlled manner from

cartridge 120 inserted into the pump device 100. Also, the pump device 100 may include a connector circuit 318 to facilitate the transfer of signals to and from the electrical connector 118. In some implementations, the connector circuit 318 in the pump device 100 may include a memory device that can store data regarding the pump device 100 and its operational history. As previously described, the electrical connector 118 of the pump device 100 can mate with the connector 218 (FIG. 2) of the controller device 200 so that electrical communication can occur between the pump device 100 and the controller device 200. In some embodiments, the connector circuit 318 can operate as a passageway to transmit electrical control signals from the controller circuitry 240 of the controller device 200 to the drive system 300. The connector circuit 318 can also operate as a passageway for the electrical power from a power source 310 housed in the pump device 300 to pass to the controller device 200 for recharging of the rechargeable battery 245. Furthermore, the connector circuit 318 can operate as a passageway for feedback signals from the drive system 300 to the controller circuitry 240 of the controller device 200.

In this embodiment, the pump device 100 houses the drive system 300 and the power source 310. For example, the power source 310 may comprise an alkaline battery cell, such as a 1.5 Volt "AAA" alkaline battery cell, which is contained in a dedicated space of the pump housing structure 110. The power source 310 may be capable of transmitting electrical energy to the controller device 200 when the pump device 100 is attached to the controller device 200, via connectors 118 and 218 as described above. For example, the power source 310 may be used to charge the rechargeable battery pack 245 when the pump device 100 is attached to the controller device 200. In some embodiments, the power source 310 is used to provide energy to the drive system 300 of the pump device 100, and also to electronic components of the controller device 200. In particular embodiments, the power source 310 may provide the energy to power all aspects of the infusion pump system 10. In some alternative embodiments, the rechargeable battery 245 housed in the controller 200 may provide the energy to power all aspects of the infusion pump system 10. In other embodiments, the rechargeable battery 245 and the power source 310 may each be responsible for powering particular aspects of the infusion pump system 10. In further embodiments, the rechargeable battery 245 may provide the energy to

supplement the energy provided by the power source 310 to power aspects of the infusion pump system.

Still referring to FIG. 7, in some embodiments, the drive system 300 may include a number of components, such as an electrically powered actuator (e.g., reversible motor 320 or the like), a drive wheel 360, a bearing 365, a flexible piston rod 370, a piston rod guide 363, and a plunger engagement device 375. In this embodiment, the reversible motor 320 drives a gear system (not shown in FIG. 7) to cause the rotation of the drive wheel 360 that is coupled with the bearing 365. The drive wheel 360 may include a central aperture with an internal thread pattern, which mates with an external thread pattern on the flexible piston rod 370. The interface of the threaded portions of the drive wheel 360 and flexible piston rod 370 may be used to transmit force from the drive wheel to the piston rod 370. Accordingly, in the embodiment of FIG. 7, the drive wheel 360 is the driver while the flexible piston rod 370 is the driven member. As further described below, the rotation of the drive wheel 360 can drive the flexible piston rod 370 forward in a linear longitudinal direction. The flexible piston rod 370 can, in turn, contact and drive forward a plunger 125 in the fluid cartridge 120 so as to dispense fluid therefrom.

As shown in FIG. 7, some embodiments of the pump device 100 can be equipped with the water-resistant, air-venting gasket assembly including the air-transmissible gasket 132 in combination with the ring seal 134. In the depicted embodiment, the water-resistant, air-venting gasket assembly is secured to the cap device 130 and positioned to provide a water resistant seal along the interface between the cap device 130 and the pump housing 110. As previously described, the pump housing 110 defines the cavity 116 configured to slidably receive the fluid cartridge 120. Accordingly, the air-transmissible gasket 132 and ring seal 134 are arranged so that interior air pressure P_i in the cavity 116 can reach approximate equilibrium with the exterior air pressure P_e even though the seal resists water migration into the cavity 116.

In this embodiment, the air-transmissible gasket 132 and the ring seal 134 can both have a generally circular shape with a central aperture therethrough. For example, as shown in FIG. 7 (and also shown later in FIG. 9), the air-transmissible gasket 132 may comprise a generally flat disc-shaped structure that is configured to

abut with the ring seal. The air-transmissible gasket 132 can comprise a first major surface 133 that is generally planar, a second, opposite major surface 135 that is generally planner, and an inner rim 138 that defines a central aperture therethrough. The first major surface 133 of the air-transmissible gasket 132 can be sized so that it entirely abuts with a first major surface 137 of the ring seal 134. Even though the ring seal 134 is not necessarily air-transmissible and thereby may prevent air transmission in a path exiting from or passing into the first major surface 133 of the air-transmissible gasket 132, the air-transmissible gasket 132 may provide air transmission in a path exiting from or passing into the surface of the inner rim 138 of the air-transmissible gasket 132 (as described below in connection with FIG. 9). In this embodiment, the ring seal 134 may comprise a generally "L-shaped" cross-section so that an inner rim 139 of the ring seal 134 is configured to be retained in an annular seat 136 (FIG. 9) of the cap device 130, as described in more detail below. Also, in this embodiment, the inner rim 138 of the air-transmissible gasket 132 and the inner rim 139 of the ring seal 134 can be substantially similar in size, with both of them being generally axially aligned and being generally aligned with the cavity 116 of the pump housing (when the cap device 130 is attached to the pump housing 110).

Still referring to FIG. 7 such a water-resistant seal between the cap device 130 and the pump housing 110 provides a functional benefit in that it protects sensitive internal components in the pump device 100 from damage by water migration in the event that the user encounters water (e.g. rain, incidental splashing, and the like). To accomplish this, air-transmissible gasket 132 and ring seal 134 can be constructed from materials that are generally resistant to liquid penetration. Further, at least one of the air-transmissible gasket 132 and ring seal 134 can preferably be sufficiently compliant to enable a tight and conformant physical seal between the cap device 130 and the pump housing 110. For example, the ring seal 134 can comprise a pliable elastomeric material such as silicone, nitrile rubber, natural rubber, polyurethane, and neoprene. Those materials can enable ring seal 134 to be compliant, pliable, and to provide a water-resistant seal.

In particular embodiments, the air-transmissible gasket 132 can comprise a material that is different from the elastomeric material of the ring seal 134. For example, the air-transmissible gasket 132 can be configured to allow the passage of

air between the internal and external regions of the pump device 100 while also resisting water migration into the pump cavity 116. As such, the air-transmissible gasket 132 may comprise a hydrophobic material (e.g., a material that permits air to pass therethrough while resisting the passage of water or other liquids from doing so). For example, the air-transmissible gasket 132 may comprise a hydrophobic material such as GORE-TEX® (W.L. Gore & Associates, Inc. of Newark, DE), POREX® (Porex Corporation of Fairburn, GA), PTFE, or HDPE.

This air-venting capability of the air-transmissible gasket 132 can serve to prevent changes in ambient air pressure from potentially adversely affecting the dosage delivered by the infusion pump system 10. For example, a user of the infusion pump system 10 may take an airplane flight during which the air pressure external to the pump system P_e will be reduced as compared to the air pressure on land. If the air pressure within the pump housing P_i is not allowed to vent, it will remain higher than the external pressure P_e. That pressure differential could result in a pressure being exerted on the plunger 125, which in turn could result in an inadvertent dispensation of fluid from the fluid cartridge 120. Conversely, if the air pressure external P_e to the pump device 100 is higher than inside the pump housing P_i, the plunger may be subject to a suction force that may cause an inadvertent retraction of medicine from infusion set tubing. Consequently, the infusion pump system 10 can benefit from a system which permits an equalization of an air pressure differential between the regions external to the pump P_e and internal to the pump P_i. As described in more detail below, the air-transmissible gasket 132 can function to provide such equalization of air pressures.

Referring now to FIGS. 8-9, the water-resistant, air-venting gasket assembly can be provided by air-transmissible gasket 132 and ring seal 134 located between the cap device 130 and the pump housing 110, with the gasket 132 and seal 134 being compressed between the pump housing 116 and the cap device 130. In this embodiment, the air-transmissible gasket 132 and ring seal 134 can be physically seated and retained in a groove 136 (FIG. 9) located on the outer barrel of cap device 130. With the air-transmissible gasket 132 and ring seal 134 seated in groove 136, the water-resistant, air-venting gasket assembly can be retained by the cap device 130 even before it is attached to the pump housing 110. Furthermore, the seating of the

air-transmissible gasket 132 and ring seal 134 in the groove 136 facilitates proper positioning and functionality of the water-resistant, air-venting seal during attachment of the cap device 130 with the pump housing 110, which can thereafter be maintained during the life of the pump device 100 (e.g., until exhaustion of the medicine cartridge 120 or other such events).

As shown, the air-transmissible gasket 132 and ring seal 134 can be maintained in physical contact with each other. In this example configuration, the first major surface 133 of air-transmissible gasket 132 is in contact with first major surface 137 of the ring seal 134 (as previously described in connection with FIG. 7). As such, in some cases, the path for air transmission through air-transmissible gasket 132 can be through the smaller surface at the inner rim 138 (FIG. 7) rather than through the first major surface 137 (which abuts the elastomeric material of the ring seal 134). Such an air path through air-transmissible gasket 132 can enable an air flow for the equalization of an air pressure differential between the pressure in a region external to the pump P_e and internal to the pump P_i. For example, the air path can pass from the interior of the cavity 116, along the annular surface of the seat 136, through the inner rim 138 of the gasket 132, through the outer periphery of the gasket 132, and out through a gap 131 between the pump housing 110 and an opposing face of the cap device 130. (It should be understood that the gap 131 can be smaller than what is depicted in FIG. 9.) The ring seal 134, as shown, can be in contact with the air-transmissible gasket 132 on one side and the rim of the cavity 116 of the housing structure 110 on the other side. Thus, when the cap device 130 is threaded into engagement with the pump housing 110, the ring seal 134 is subject to axial compression between the pump housing 110 and the cap device 130. This example configuration of air-transmissible gasket 132 and ring seal 134 can provide the aforementioned water-resistant, air-venting capabilities during use of the pump device 100.

FIG. 10 illustrates a process 400 by which a medicine infusion pump device can provide pressure equalization between an interior pressure (e.g., inside the pump device) and the ambient pressure. This process 400 can be implemented, for example, by an infusion pump system like the pump system 10 described in connection with FIGS. 1-9. In those embodiments, the pump system 10 can realize a state of air

pressure equilibrium between a space that is external to the pump system 10 and a space that is internal to the pump system 10 even when the pump system 10 is exposed to a gradient in ambient pressure.

Optionally, the infusion pump pressure equilibrium process 400 includes operation 410 of slidably receiving a medicine cartridge through a cavity opening of an infusion pump housing and into an interior space of the infusion pump housing. For example, in some implementations involving the pump system 10 (FIGS. 1-9), the medicine cartridge 120 is slidably received in the cavity 116 of the pump housing 110.

The process 400 may also include the operation 420 of receiving a cap device into attachment with the infusion pump housing so that an air-transmissible gasket of the cap device is positioned proximate to the cavity opening defined by the infusion pump housing. For example, in some implementations involving the pump system 10 (FIGS. 1-9), the cap device 130 is received into attachment with the pump housing 110 so that the air-transmissible gasket 132 is proximate to the opening of the cavity 116, which (as previously described) permits air transmission between the interior and exterior regions of the pump system 10 in the event of an air pressure differential between those two regions.

In operation 430, the air-transmissible gasket is maintained in a position between the cap device and a rim of the cavity opening of the infusion pump housing. Such positioning of the air-transmissible gasket is configured to permit a water-resistant seal with air-venting capabilities. For example, in some implementations involving the pump system 10 (FIGS. 1-9), the air-transmissible gasket 132 is part of the water-resistant, air-venting gasket assembly arranged along an interface of the cap device 130 and the pump housing 110. As described in detail above, the air-transmissible gasket 132 in combination with the ring seal 134 can provide the air-venting capabilities while also protecting against water migration into the interior of the pump device 100.

The process 400 may also include the operation 440 of equalizing pressures between the interior space of the infusion pump housing and an external space proximate to the infusion pump housing in response to a change in ambient pressure. For example, in some implementations involving the pump system 10 (FIGS. 1-9), the infusion pump system 10 may be exposed to an ambient pressure change. In

response, the pump system 10 can be configured to equalize the internal air pressure P_i in the cavity 116 with the ambient air pressure P_e via the air-transmissible gasket 132. For example, if a user takes the pump system 10 onto an airplane the air pressure in the cabin of the airplane while in-flight will be lower than the air pressure on land prior to take-off. Using the infusion pump pressure equilibrium process 400, the higher air pressure in the interior of pump system will be vented through an air-transmissible gasket so that the pump system's interior air pressure will be reduced to equal the air pressure in the cabin of the airplane. In this manner, the potentially adverse effects of a pressure gradient between the interior and exterior of an infusion pump system 10 can be mitigated.

A number of embodiments of the invention have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and scope of the invention. Accordingly, other embodiments are within the scope of the following claims.

WHAT IS CLAIMED IS:

1. A portable infusion pump system, comprising:

a portable housing defining an opening to receive a medicine;

a pump drive system arranged in the portable housing and configured to dispense medicine from the portable housing when the medicine is received in the space;

a cap device configured to engage with the portable housing to enclose the medicine in the portable housing when the medicine is received in the space; and

an air-transmissible gasket positioned at an interface between the portable housing and the cap device and comprising a gasket aperture generally aligned with the opening when the cap device engages with the portable housing, wherein the gasket is air-transmissible so that air is passable through the interface between the portable housing and the cap device while the gasket resists migration of liquids into the portable housing.

2. The portable infusion pump system of claim 1, wherein the air-transmissible gasket is seated in an annular groove defined by the cap device.

3. The portable infusion pump system of claim 1, wherein the air-transmissible gasket comprises a hydrophobic material.

4. The portable infusion pump system of claim 1, further comprising a ring seal abutted with the air-transmissible gasket, wherein the ring seal comprises an elastomeric material.

5. The portable infusion pump system of claim 4, wherein the air-transmissible gasket comprises a first major surface, a second major surface, and an inner rim that defines the gasket aperture, and wherein the entire first major surface is positioned in abutment with the elastomeric material of the ring seal.

6. The portable infusion pump system of claim 5, wherein the ring seal comprises a generally L-shaped cross-section that defines an inner rim of the

elastomeric member, the inner rim of the elastomeric member being seated within an annular grove defined by the cap device.

7. The portable infusion pump system of claim 6, wherein the inner rim of the ring seal defines a seal aperture, wherein both the gasket aperture of the gasket and the seal aperture of the ring seal are generally axially aligned the opening of the portable housing when the cap device engages with the portable housing.

8. The portable infusion pump system of claim 7, wherein the inner rim of the gasket provides an air path for passage of air into and out of the portable housing.

9. The portable infusion pump system of claim 1, further comprising control circuitry that electrically communicates with the pump drive system to control dispensation of the medicine from the portable housing when the medicine is received in the space.

10. The portable medical infusion pump system of claim 9, wherein the control circuitry is housed in a removable controller device that is removably attachable to the portable housing.

11. A portable infusion pump system, comprising:

a pump device including a pump housing that defines a space to receive a medicine, a drive system positioned in the pump housing to dispense the medicine from the pump device when the medicine is received in the space of the pump housing, a cap device configured to directly attach with the pump housing to enclose the medicine in the pump housing when the medicine is received in the space of the pump housing, and a gasket assembly positioned at an interface between the pump housing and the cap device when the cap device engages with the portable housing, wherein the gasket assembly is configured to permit the passage of air into and out of the pump housing while resisting the passage of liquids into the pump housing, the gasket assembly comprising a hydrophobic member and an elastomeric member,

wherein a first major surface of the hydrophobic member is entirely abutted by the elastomeric member; and

a controller device removably attachable to the pump housing so as to electrically connect with the pump device, wherein the controller device houses control circuitry configured to communicate with the drive system positioned in the pump housing to control dispensation of the medicine from the pump device.

12. The portable infusion pump system of claim 11, wherein the gasket assembly is seated in an annular groove defined by the cap device.

13. The portable infusion pump system of claim 12, wherein the elastomeric member comprises a generally L-shaped cross-section that defines an inner rim of the elastomeric member, the inner rim of the elastomeric member being seated within the annular grove defined by the cap device.

14. The portable infusion pump system of claim 11, wherein the hydrophobic member comprises the first major surface, a second major surface, and an inner rim that defines an aperture through the hydrophobic member, the aperture of the hydrophobic member being generally aligned with an opening defined by the pump housing when the cap device engages with the portable housing.

15. The portable infusion pump system of claim 11, wherein the inner rim of the hydrophobic member provides an air path for the passage of air into and out of the pump housing.

16. A method of equalizing an air pressure in a space defined by a pump housing of an infusion pump system with an ambient air pressure, the method comprising:

receiving a cap device into attachment with an infusion pump housing so that an air-transmissible gasket is positioned proximate to a cavity opening defined by the infusion pump housing; and

maintaining the air-transmissible gasket in a position at an interface between the cap device and a rim of cavity opening of the pump housing, wherein the air-

transmissible gasket is configured to permit passage of air into and out of an interior space defined by the pump housing while resisting migration of liquid into the interior space defined by the pump housing.

17. The method of claim 16, further comprising, in response to a change in ambient air pressure, equalizing an air pressure in the interior space defined by the pump housing with an air pressure external to the pump housing.

18. The method of claim 16, further comprising slidably receiving a medicine cartridge through the cavity opening of the pump housing and into the interior space defined by the pump housing.

19. The method of claim 16, wherein the cap device comprises a ring seal abutted with the air-transmissible gasket, wherein the ring seal comprises an elastomeric material.

20. The method of claim 19, wherein the air-transmissible gasket comprises a first major surface, a second major surface, and an inner rim that defines a gasket aperture, wherein the gasket aperture is generally aligned with the cavity opening when the cap device attaches with the portable housing, and wherein the entire first major surface is positioned in abutment with the elastomeric material of the ring seal.

21. A portable infusion pump system, comprising:

a portable housing defining an opening to receive a medicine;

a pump drive system arranged in the portable housing and configured to dispense medicine from the portable housing when the medicine is received in the space;

a cap device configured to engage with the portable housing to enclose the medicine in the portable housing when the medicine is received in the space; and

an air-transmissible gasket positioned at an interface between the portable housing and the cap device and positioned adjacent to the opening when the cap device engages with the portable housing, wherein the gasket is air-transmissible so

that air is passable through the interface between the portable housing and the cap device while the gasket resists migration of liquids into the portable housing.

22. The portable infusion pump system of claim 21, wherein the air-transmissible gasket is seated in a groove defined by the cap device.

23. The portable infusion pump system of claim 21, wherein the air-transmissible gasket comprises a hydrophobic material.

24. The portable infusion pump system of claim 21, further comprising a seal abutted with the air-transmissible gasket, wherein the seal comprises an elastomeric material.

25. The portable infusion pump system of claim 24, wherein the air-transmissible gasket comprises a first major surface and a second major surface, and wherein the entire first major surface is positioned in abutment with the elastomeric material of the seal.

26. The portable infusion pump system of claim 25, wherein the seal comprises a generally L-shaped cross-section that defines an inner rim of the seal, the inner rim of the seal being seated within a grove defined by the cap device.

27. The portable infusion pump system of claim 21, wherein the cap device defines a fluid output path for the medicine in the portable housing when the medicine is received in the space.

28. The portable infusion pump system of claim 27, wherein the cap device includes a structure that is irreversibly attachable to the portable housing so as to cover the opening defined by the portable housing.

29. The portable infusion pump system of claim 21, further comprising control circuitry that electrically communicates with the pump drive system to control

dispensation of the medicine from the portable housing when the medicine is received in the space.

30. The portable medical infusion pump system of claim 29, wherein the control circuitry is housed in a removable controller device that is removably attachable to the portable housing.

31. A portable infusion pump system, comprising:

a pump device including a pump housing that defines a space to receive a medicine, a drive system positioned in the pump housing to dispense the medicine from the pump device when the medicine is received in the space of the pump housing, a cap device configured to directly attach with the pump housing to enclose the medicine in the pump housing when the medicine is received in the space of the pump housing, and a hydrophobic gasket assembly positioned at an interface between the pump housing and the cap device when the cap device engages with the portable housing, wherein the hydrophobic gasket assembly is configured to permit the passage of air into and out of the pump housing while resisting the passage of liquids into the pump housing; and

a controller device removably attachable to the pump housing so as to electrically connect with the pump device, wherein the controller device houses control circuitry configured to communicate with the drive system positioned in the pump housing to control dispensation of the medicine from the pump device.

32. The portable infusion pump system of claim 31, the hydrophobic gasket assembly comprising a hydrophobic member and an elastomeric member, wherein a first major surface of the hydrophobic member is abutted by the elastomeric member.

33. The portable infusion pump system of claim 32, wherein the elastomeric member comprises a generally L-shaped cross-section that defines an inner rim of the elastomeric member, the inner rim of the elastomeric member being seated within an annular grove defined by the cap device.

34. The portable infusion pump system of claim 32, wherein the hydrophobic member comprises the first major surface, a second major surface, and an inner rim that defines an aperture through the hydrophobic member, the aperture of the hydrophobic member being generally aligned with an opening defined by the pump housing when the cap device engages with the portable housing.

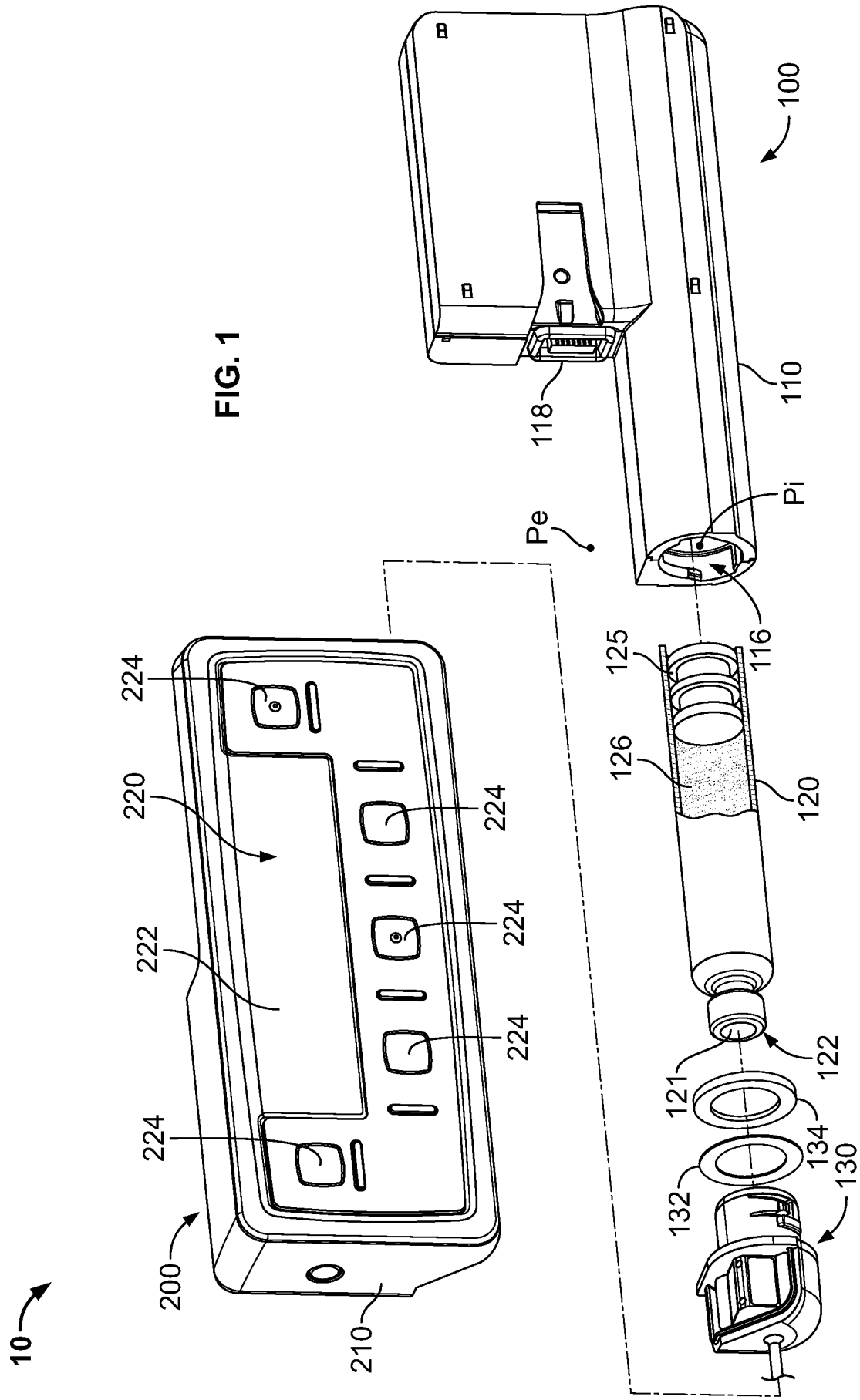
35. The portable infusion pump system of claim 31, wherein an inner rim of the hydrophobic gasket assembly provides an air path for the passage of air into and out of the pump housing.

36. The portable infusion pump system of claim 31, wherein the cap device defines a fluid output path for the medicine in the pump housing when the medicine is received in the space.

37. The portable infusion pump system of claim 36, wherein the cap device includes a structure that is irreversibly attachable to the pump housing so as to cover an opening defined by the pump housing.

38. The portable infusion pump system of claim 31, wherein the controller device comprises a user interface display device.

FIG. 1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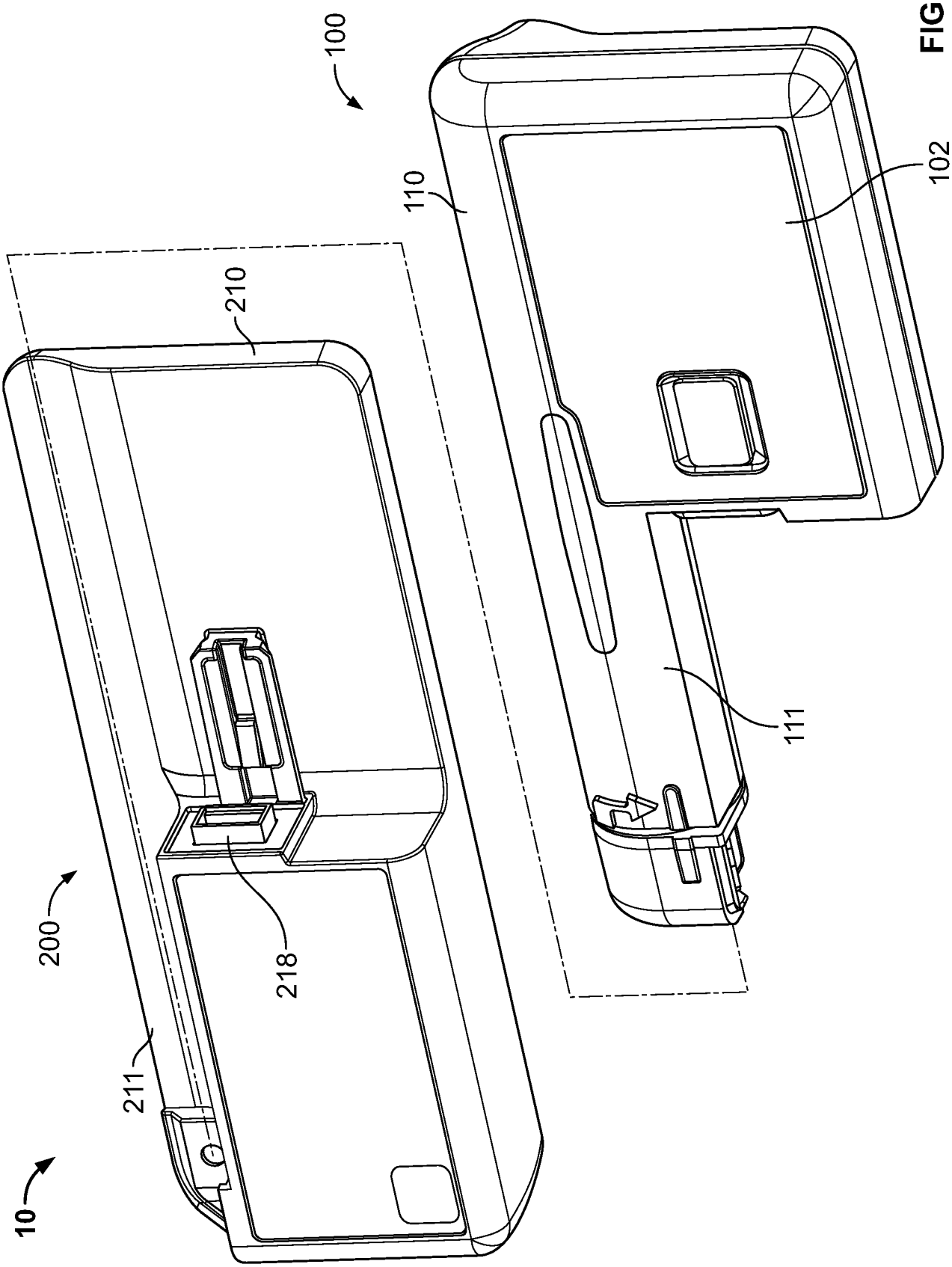

FIG. 2

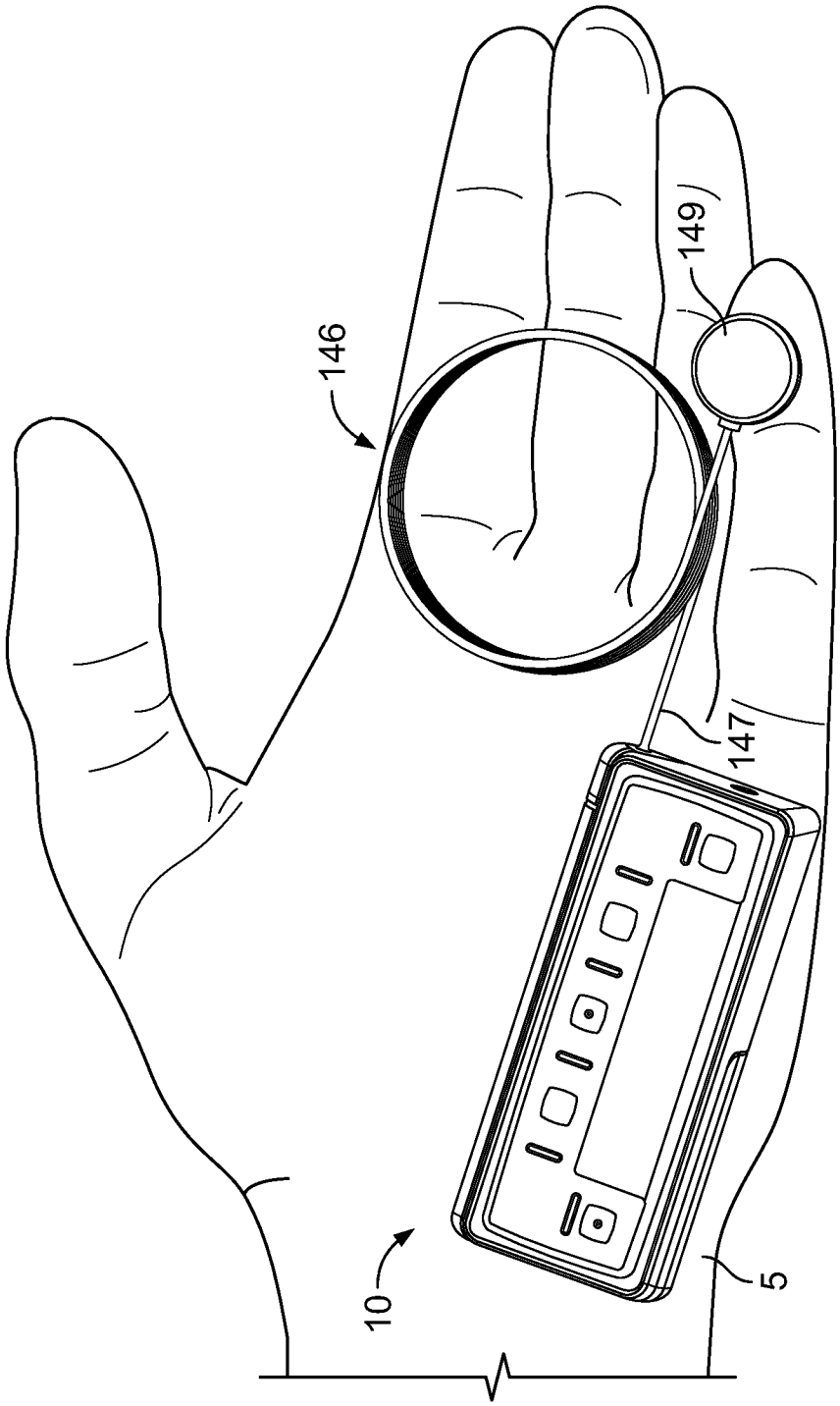

FIG. 3

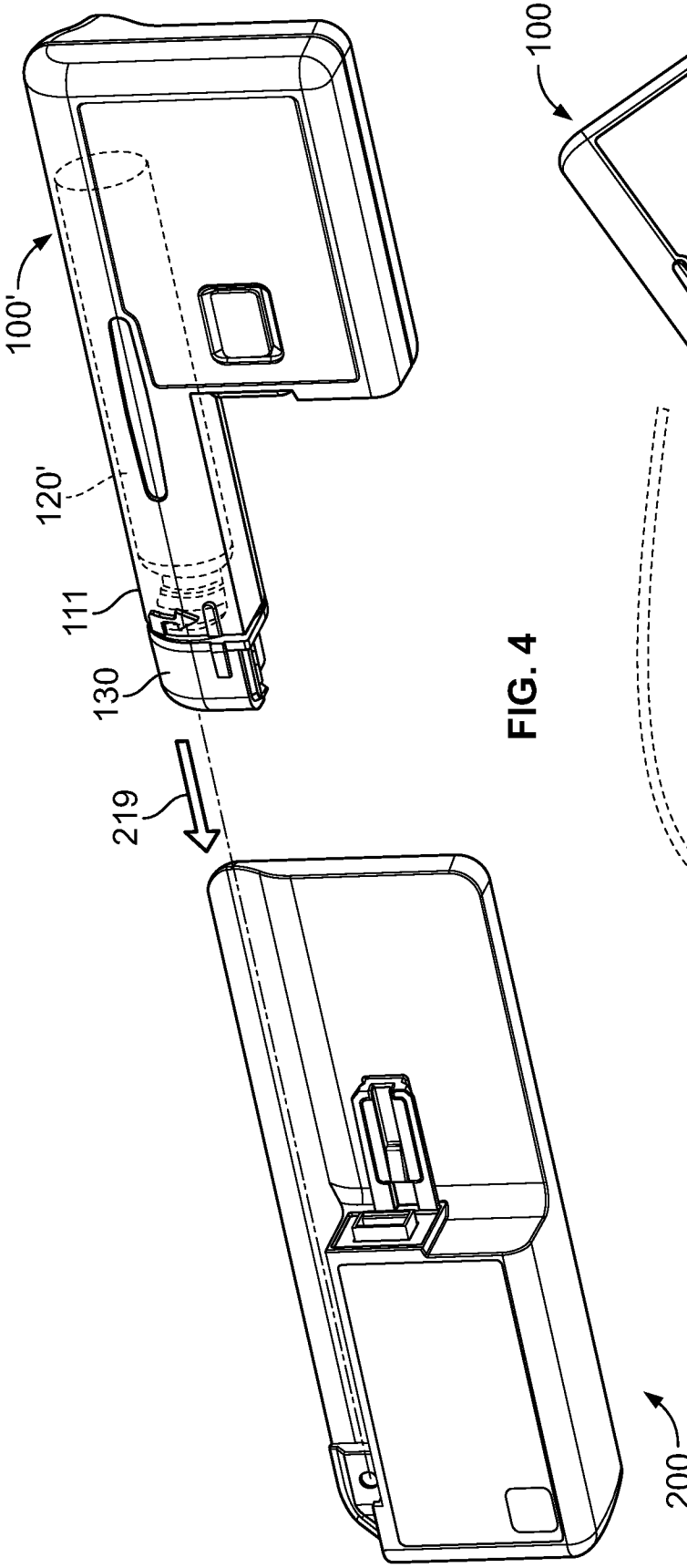

FIG. 4

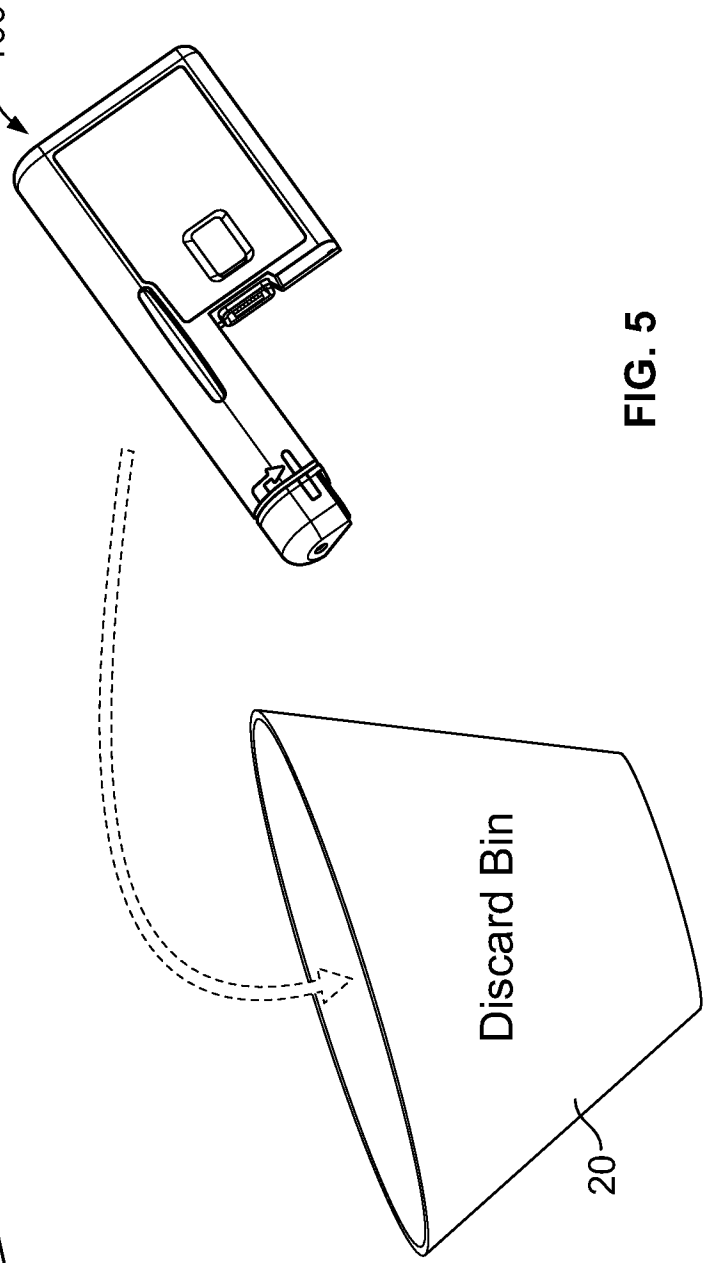

FIG. 5

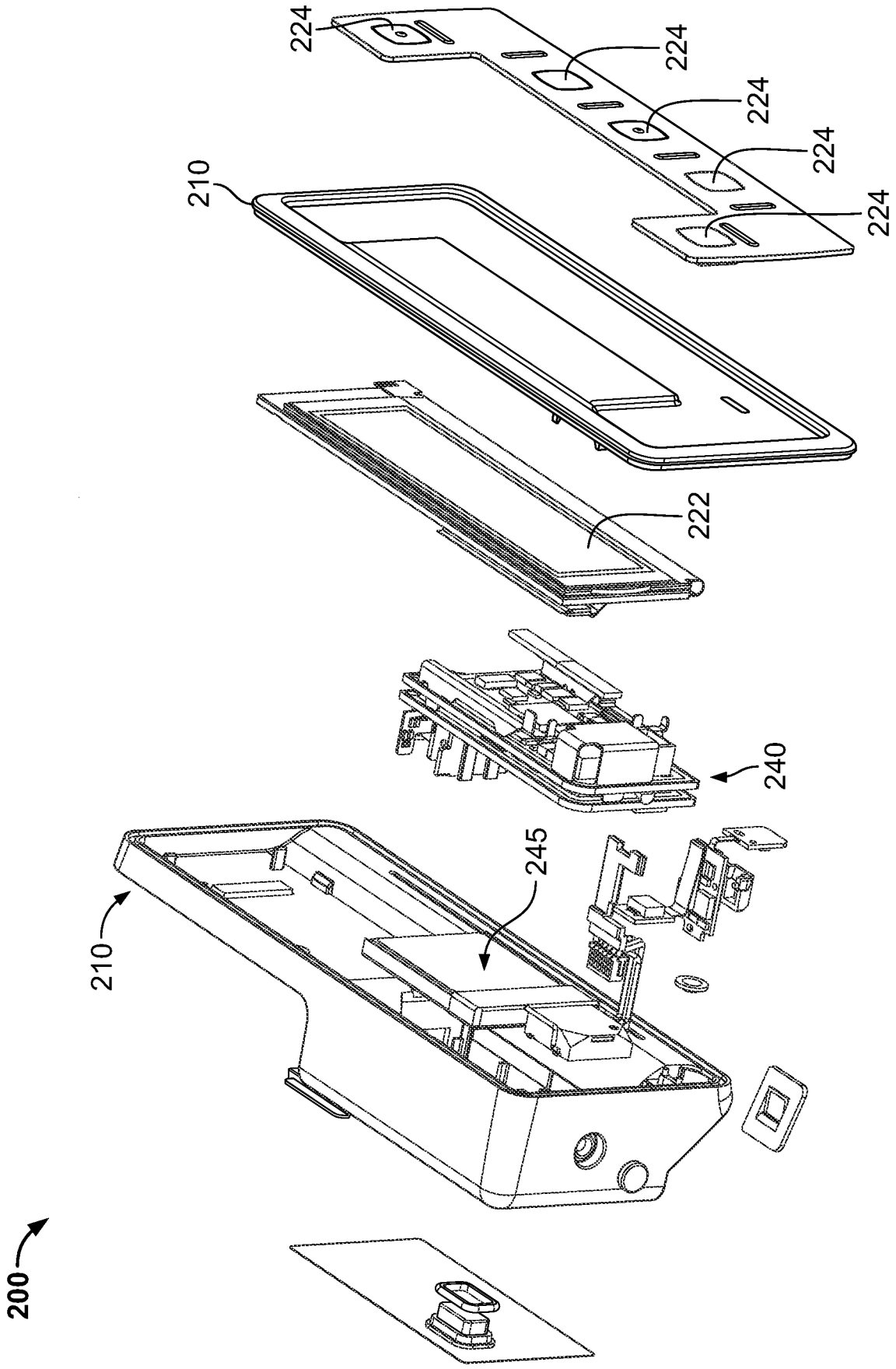

FIG. 6

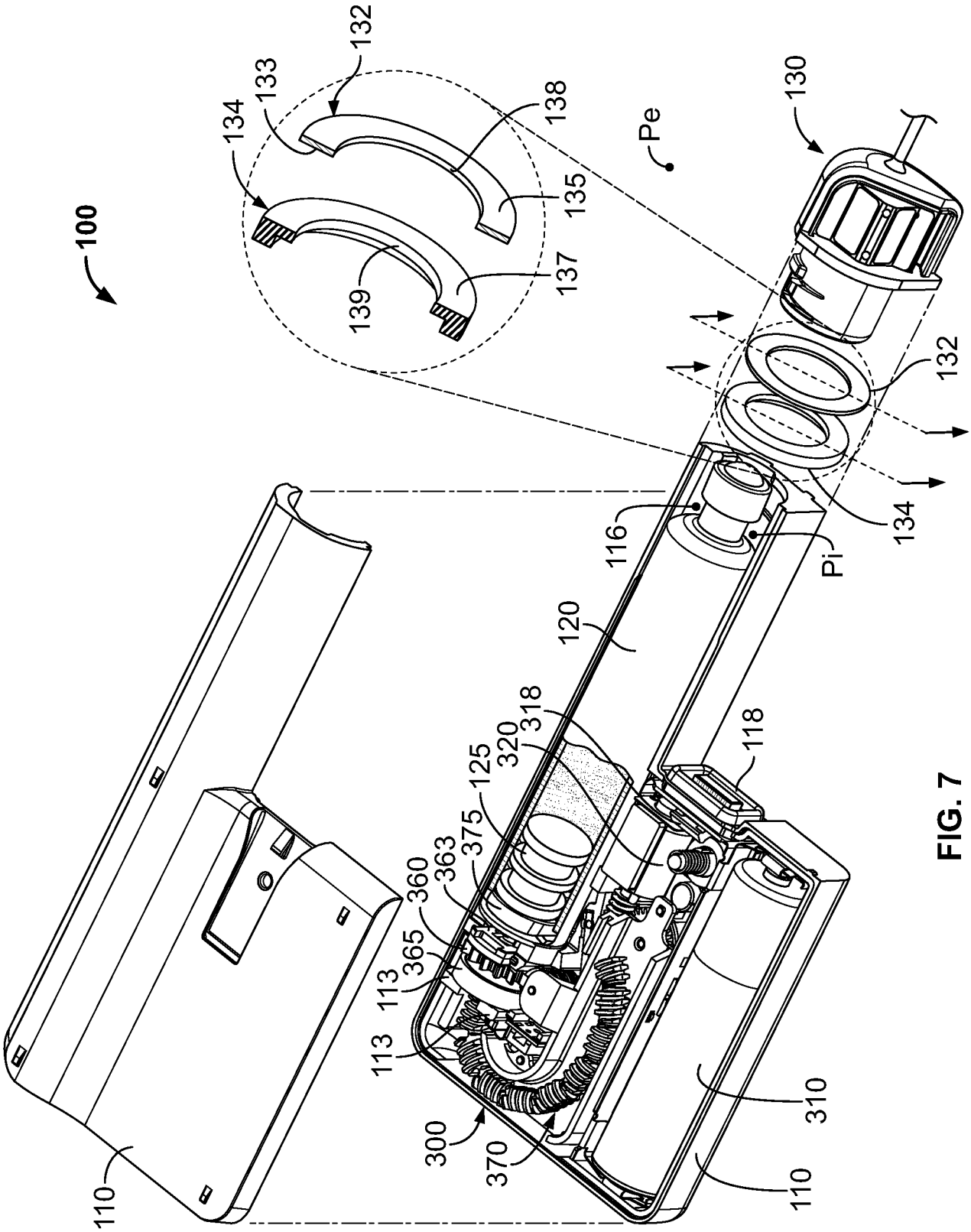
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FIG. 7

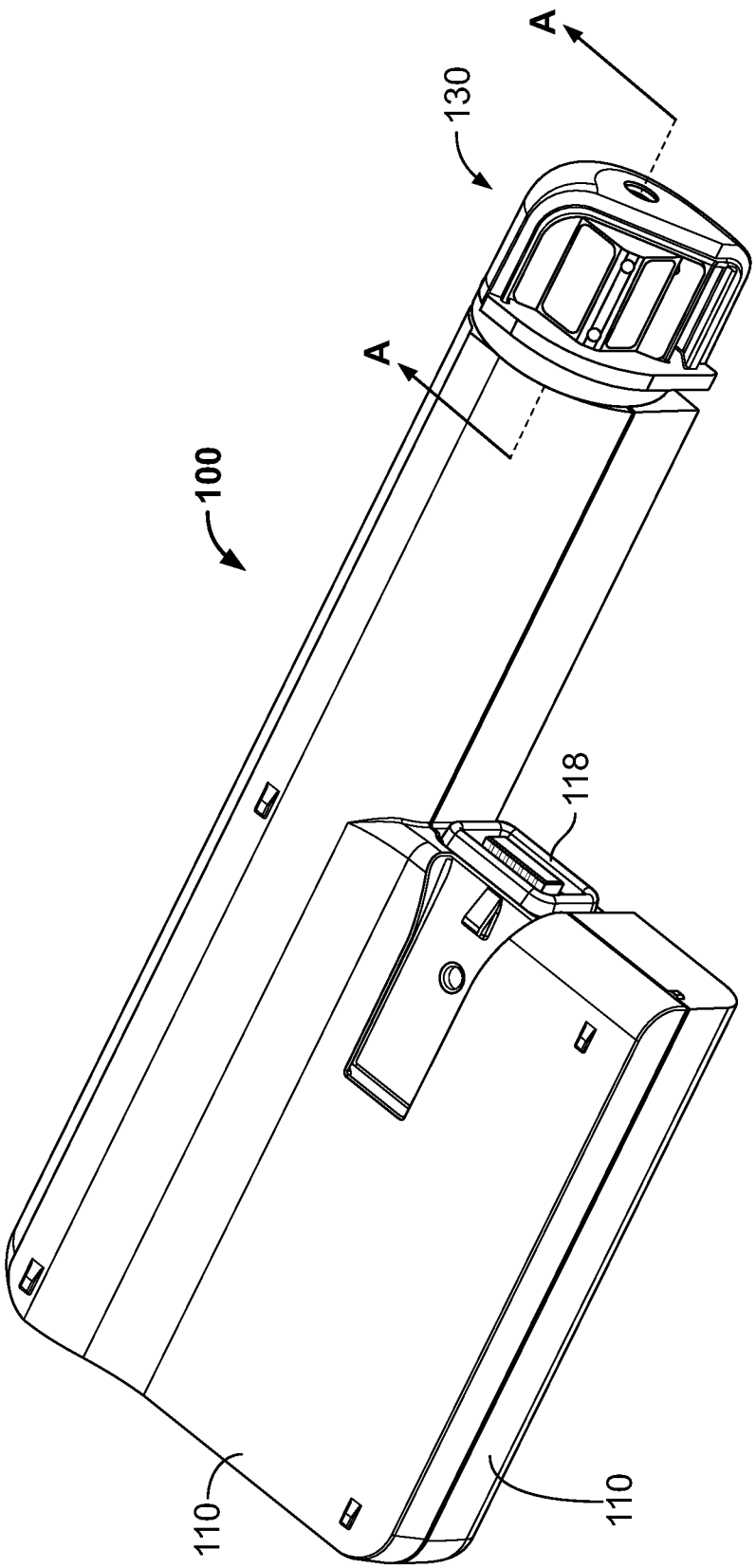

FIG. 8

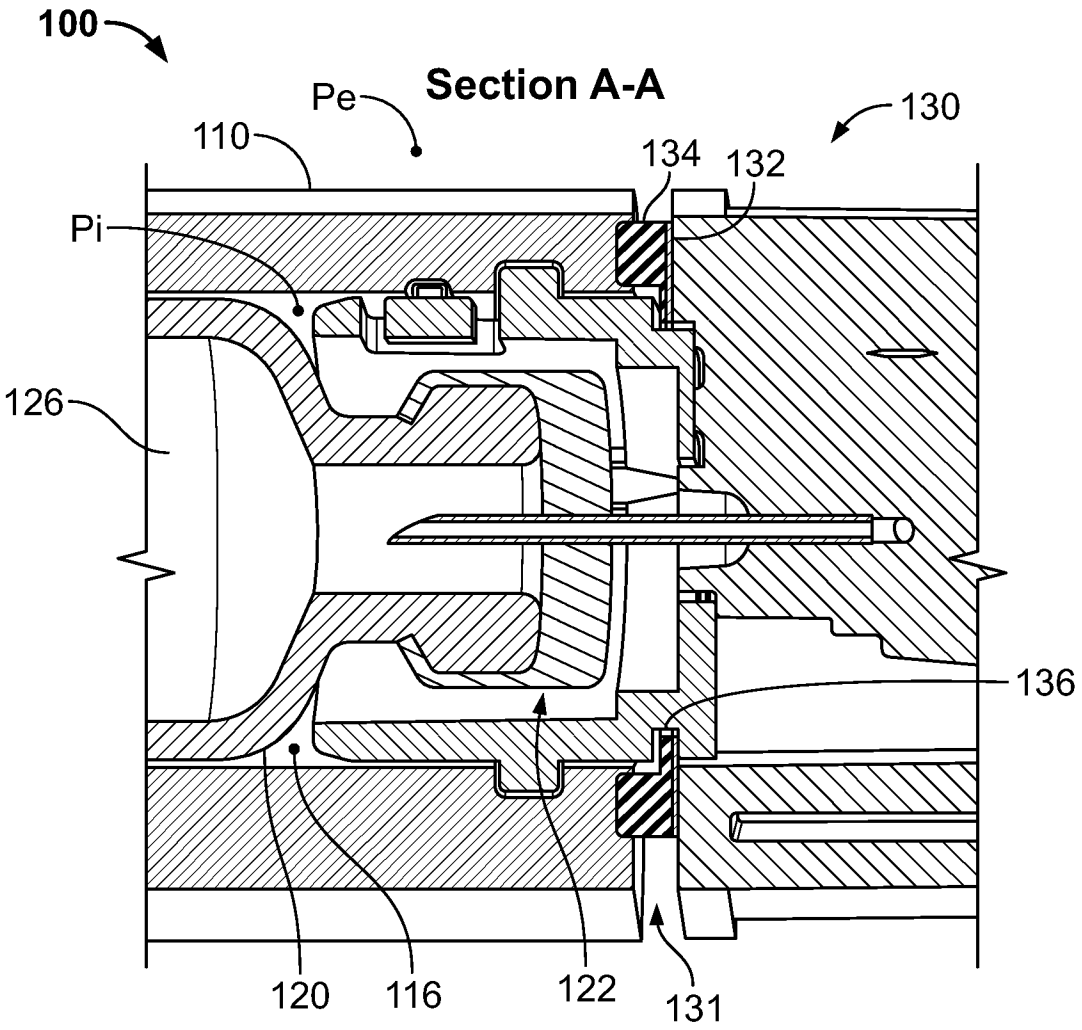

FIG. 9

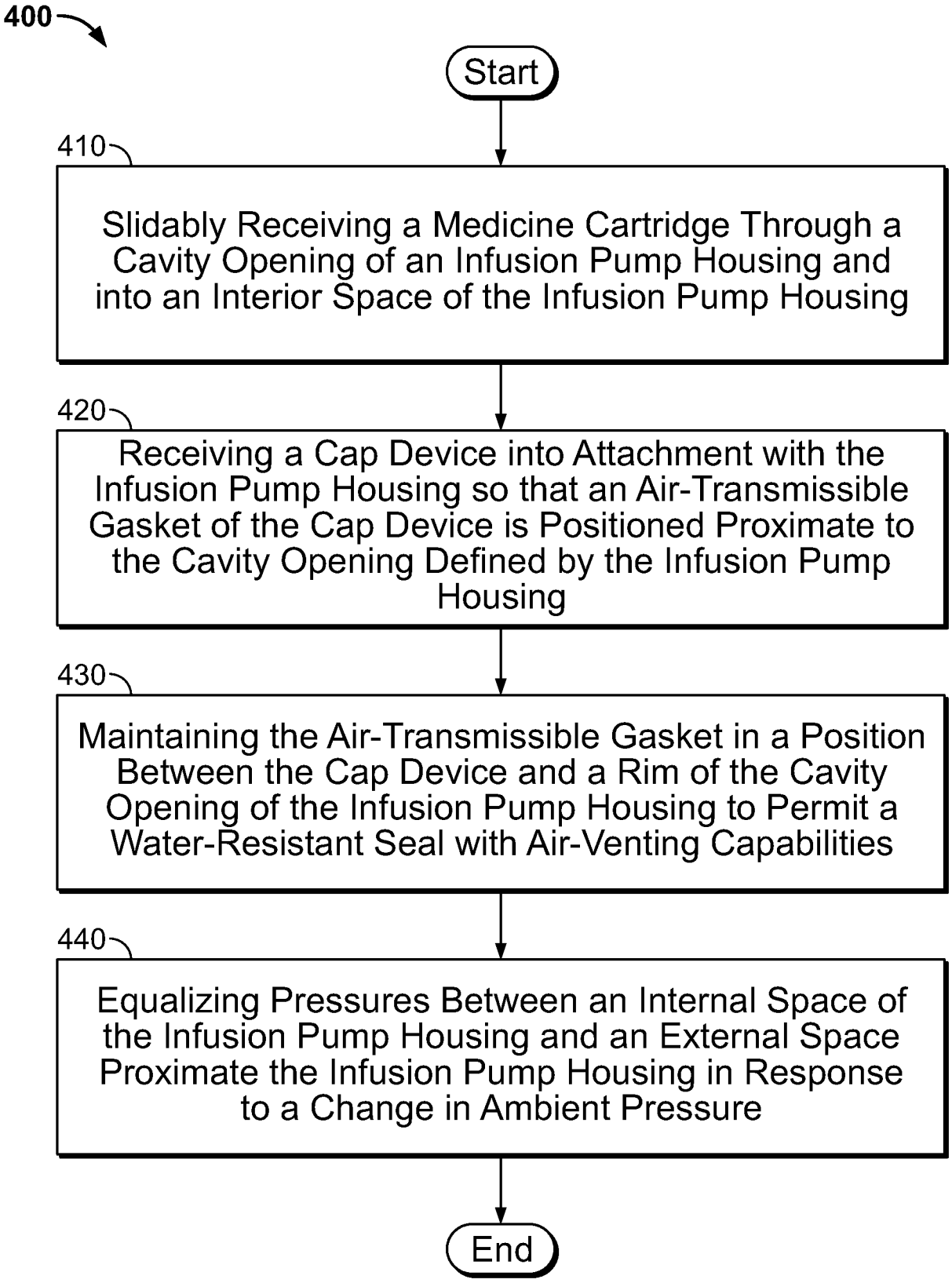
400
Start
410
Slidably Receiving a Medicine Cartridge Through a Cavity Opening of an Infusion Pump Housing and into an Interior Space of the Infusion Pump Housing
420
Receiving a Cap Device into Attachment with the Infusion Pump Housing so that an Air-Transmissible Gasket of the Cap Device is Positioned Proximate to the Cavity Opening Defined by the Infusion Pump Housing
430
Maintaining the Air-Transmissible Gasket in a Position Between the Cap Device and a Rim of the Cavity Opening of the Infusion Pump Housing to Permit a Water-Resistant Seal with Air-Venting Capabilities
440
Equalizing Pressures Between an Internal Space of the Infusion Pump Housing and an External Space Proximate the Infusion Pump Housing in Response to a Change in Ambient Pressure
End

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/051273

A. CLASSIFICATION OF SUBJECT MATTER

A61M 5/142(2006.01)i, A61M 5/172(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M 5/142; A61M 5/00; A61M 37/00; A61B 17/50; A61M 1/00; A61M 5/172

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: , ,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2007-0167912 A1 (CAUSEY, J. et al.) 19 July 2007 See abstract; claim 1; figure 1.	1-38
A	US 7654982 B2 (CARLISLE, J. A. et al.) 2 February 2010 See abstract; page 7, lines 51-65; figure 8.	1-38
A	US 2003-0125672 A1 (ADAIR, R. W. et al.) 3 July 2003 See abstract; claim 1; figure 6.	1-38
A	US 2006-0206054 A1 (SHEKALIM, A.) 14 September 2006 See abstract; claim 1; figures 4, 10.	1-38
A	US 6106498 A (FRIEDLI, K. et al.) 22 August 2000 See abstract; claim 1; figure 4.	1-38

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2013/051273

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2007-0167912 A1	19/07/2007	AU 2007-223700 A1	13/09/2007
		AU 2007-223700 B2	11/11/2010
		CA 2643088 A1	13/09/2007
		CN 101489827 A	22/07/2009
		CN 101489827 B	29/05/2013
		EP 1933901 A2	25/06/2008
		EP 1933902 A2	25/06/2008
		EP 2007472 A2	31/12/2008
		EP 2162168 A2	17/03/2010
		JP 2009-529454 A	20/08/2009
		US 2007-0073228 A1	29/03/2007
		US 2007-0073235 A1	29/03/2007
		US 2007-0073236 A1	29/03/2007
		US 2007-0156092 A1	05/07/2007
		US 2007-0167905 A1	19/07/2007
		US 2007-0173762 A1	26/07/2007
		US 2007-0179444 A1	02/08/2007
		US 2007-0210639 A1	13/09/2007
		US 2008-0045902 A1	21/02/2008
		US 2008-0045904 A1	21/02/2008
		US 2008-0045931 A1	21/02/2008
		US 2009-0198186 A1	06/08/2009
		US 2010-0052402 A1	04/03/2010
		US 2011-0112504 A1	12/05/2011
		US 7534226 B2	19/05/2009
		US 7644986 B2	12/01/2010
		US 7708717 B2	04/05/2010
		US 7776030 B2	17/08/2010
		US 7789859 B2	07/09/2010
		US 7794427 B2	14/09/2010
		US 7794428 B2	14/09/2010
		US 7887512 B2	15/02/2011
		US 7922708 B2	12/04/2011
		US 7938803 B2	10/05/2011
		US 8057436 B2	15/11/2011
		US 8105279 B2	31/01/2012
		US 8409142 B2	02/04/2013
		WO 2007-038059 A2	05/04/2007
		WO 2007-038059 A3	21/06/2007
		WO 2007-038060 A2	05/04/2007
		WO 2007-038060 A3	11/10/2007
		WO 2007-038091 A2	05/04/2007
		WO 2007-038091 A3	18/10/2007
		WO 2007-103641 A2	13/09/2007
		WO 2007-103641 A3	02/04/2009
US 7654982 B2	02/02/2010	CA 2643907 A1	20/09/2007
		CA 2644559 A1	30/08/2007
		CA 2644742 A1	30/08/2007

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2013/051273

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		EP 1991839 A2	19/11/2008
		EP 1991839 A4	13/01/2010
		EP 1999536 A2	10/12/2008
		EP 1999536 A4	13/01/2010
		EP 2013793 A2	14/01/2009
		EP 2013793 A4	06/01/2010
		US 2009-0026146 A1	29/01/2009
		US 2009-0131863 A1	21/05/2009
		US 2010-0063765 A1	11/03/2010
		US 2011-0028937 A1	03/02/2011
		WO 2007-098265 A2	30/08/2007
		WO 2007-098265 A3	03/07/2008
		WO 2007-098287 A2	30/08/2007
		WO 2007-098287 A3	28/02/2008
		WO 2007-106232 A2	20/09/2007
		WO 2007-106232 A3	16/04/2009
US 2003-0125672 A1	03/07/2003	AU 1330500 A	22/05/2000
		AU 1456700 A	22/05/2000
		AU 2000-13305 A1	22/05/2000
		AU 2000-14567 A1	22/05/2000
		AU 2001-13485 A1	08/05/2001
		CA 2345439 A1	11/05/2000
		CA 2346525 A1	11/05/2000
		CA 2390298 A1	03/05/2001
		CA 2533850 A1	11/05/2000
		CA 2669175 A1	11/05/2000
		CA 2672887 A1	29/05/2008
		EP 1124600 A1	22/08/2001
		EP 1124600 B1	23/02/2005
		EP 1124608 A1	22/08/2001
		EP 1124608 B1	07/12/2005
		EP 1227855 A2	07/08/2002
		EP 1227855 B1	09/06/2004
		EP 1642615 A2	05/04/2006
		EP 1642615 A3	30/08/2006
		EP 1642615 B1	16/02/2011
		EP 1716884 A1	02/11/2006
		EP 1971381 A2	24/09/2008
		EP 2101845 A2	23/09/2009
		EP 2204203 A2	07/07/2010
		EP 2223713 A2	01/09/2010
		JP 2002-528234 A	03/09/2002
		JP 2002-528676 A	03/09/2002
		JP 2006-320757 A	30/11/2006
		JP 2009-233388 A	15/10/2009
		JP 2009-521998 A	11/06/2009
		JP 2010-509984 A	02/04/2010
		JP 2012-091068 A	17/05/2012
		JP 2012-205929 A	25/10/2012

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2013/051273

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		US 2002-0077598 A1	20/06/2002
		US 2002-0173748 A1	21/11/2002
		US 2002-043951 A1	18/04/2002
		US 2003-0167039 A1	04/09/2003
		US 2004-0003493 A1	08/01/2004
		US 2004-0085215 A1	06/05/2004
		US 2004-0092873 A1	13/05/2004
		US 2004-0243065 A1	02/12/2004
		US 2005-0021000 A1	27/01/2005
		US 2005-0197626 A1	08/09/2005
		US 2006-0184154 A1	17/08/2006
		US 2007-0149926 A1	28/06/2007
		US 2007-0191770 A1	16/08/2007
		US 2008-0221522 A1	11/09/2008
		US 2008-0221523 A1	11/09/2008
		US 2009-0137979 A1	28/05/2009
		US 2009-0299290 A1	03/12/2009
		US 2010-0037680 A1	18/02/2010
		US 2010-0049135 A1	25/02/2010
		US 2010-0049144 A1	25/02/2010
		US 2010-0082010 A1	01/04/2010
		US 2010-0125247 A1	20/05/2010
		US 2010-0217192 A1	26/08/2010
		US 2010-0217193 A1	26/08/2010
		US 2011-0119033 A1	19/05/2011
		US 2011-238031 A1	29/09/2011
		US 2013-018357 A1	17/01/2013
		US 6248093 B1	19/06/2001
		US 6362591 B1	26/03/2002
		US 6555986 B2	29/04/2003
		US 6585695 B1	01/07/2003
		US 6800071 B1	05/10/2004
		US 6817990 B2	16/11/2004
		US 7063684 B2	20/06/2006
		US 7193521 B2	20/03/2007
		US 7597682 B2	06/10/2009
		US 7621893 B2	24/11/2009
		US 7628772 B2	08/12/2009
		US 7628782 B2	08/12/2009
		US 7658734 B2	09/02/2010
		US 7766873 B2	03/08/2010
		US 7892206 B2	22/02/2011
		US 7981105 B2	19/07/2011
		US 7988683 B2	02/08/2011
		US 7998111 B2	16/08/2011
		US 7998131 B2	16/08/2011
		US 8062257 B2	22/11/2011
		US 8065096 B2	22/11/2011
		US 8182447 B2	22/05/2012
		US 8257345 B2	04/09/2012

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2013/051273

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		US 8273061 B2	25/09/2012
		US 8303572 B2	06/11/2012
		US 8500716 B2	06/08/2013
		WO 00-25844 A1	11/05/2000
		WO 00-25852 A1	11/05/2000
		WO 01-30421 A2	03/05/2001
		WO 01-30421 A3	10/01/2002
		WO 2007-079016 A2	12/07/2007
		WO 2007-079016 A3	06/12/2007
		WO 2008-063429 A2	29/05/2008
		WO 2008-063429 A3	18/09/2008
US 2006-0206054 A1	14/09/2006	AU 2002-353476 A1	10/06/2003
		CA 2468338 A1	05/06/2003
		CA 2527512 A1	09/12/2004
		CA 2640881 A1	01/11/2007
		CN 101511402 A	19/08/2009
		CN 101511402 B	06/06/2012
		EP 1471867 A2	03/11/2004
		EP 1471867 B1	05/11/2008
		EP 1638639 A2	29/03/2006
		EP 2010246 A2	07/01/2009
		EP 2010246 A4	05/06/2013
		JP 2009-538640 A	12/11/2009
		JP 2011-131070 A	07/07/2011
		KR 10-2008-0113250 A	29/12/2008
		US 2003-0100863 A1	29/05/2003
		US 2003-0216683 A1	20/11/2003
		US 2004-0176727 A1	09/09/2004
		US 2007-0088267 A1	19/04/2007
		US 6736796 B2	18/05/2004
		US 7291126 B2	06/11/2007
		US 7311693 B2	25/12/2007
		US 7377907 B2	27/05/2008
		US 8021334 B2	20/09/2011
		WO 03-045302 A2	05/06/2003
		WO 2003-045302 A3	18/03/2004
		WO 2004-105827 A2	09/12/2004
		WO 2004-105827 A3	29/09/2005
		WO 2007-122621 A2	01/11/2007
		WO 2007-122621 A3	09/04/2009
US 6106498 A	22/08/2000	EP 0836493 A1	22/04/1998
		EP 0836493 B1	29/12/1999
		JP 11-508465 A	27/07/1999
		US 5345577 A	06/09/1994
		WO 97-02059 A1	23/01/1997