(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
11 September 2015 (11.09.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/134526 A1

(51) International Patent Classification:
A61M 1/00 (2006.01)

(21) International Application Number:
PCT/US2015/018525

(22) International Filing Date:
3 March 2015 (03.03.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/947,032 3 March 2014 (03.03.2014) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: FLUID DELIVERY PUMP

(57) Abstract: A pump controllably moves a small quantity of fluid from a fluid chamber to an outlet port with a small inexpensive actuator powered for a very short amount of time, thereby optimizing cost, size, and battery efficiency. Multiple pumps can be housed in a single enclosure, allowing multiple drugs to each be injected through a single cannula or needle.

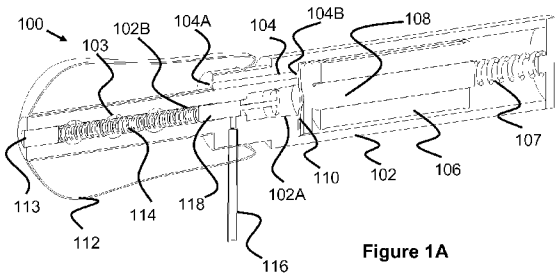


Figure 1A

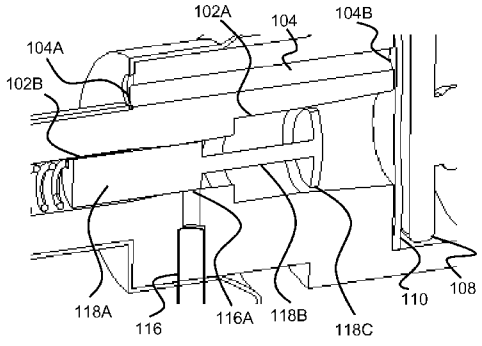


Figure 1B

WO 2015/134526 A1

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

FLUID DELIVERY PUMP

RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application Serial No. 61/947,032 filed March 3, 2014 entitled *Fluid Delivery Damping and Delivery Pump*, which is hereby incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

[0002] Insulin pumps are medical devices used for the administration of insulin in the treatment of diabetes, which is known as continuous subcutaneous insulin infusion therapy. Typically, insulin pumps include a pump mechanism, a disposable reservoir for insulin, and a disposable infusion set (e.g., a cannula for insertion under the user's skin).

[0003] In an attempt to increase battery efficiency and safety, a variety of different pump mechanisms have been contemplated in battery powered insulin pumps. For example, such pump mechanism include servomotors with gear trains; nitinol wires that deform when electrically stimulated; heated wax that changes volume or actuates a check valve, and MEMS valves whose diaphragm motion open and close check valves. These methods however typically require complex, large, and expensive mechanical arrangements, as well as having substantial power consumption, requiring a large battery and/or frequent recharging.

SUMMARY OF THE INVENTION

[0004] In one aspect of the present invention, a pump controllably moves a small quantity of fluid from a fluid chamber to an outlet port with a small inexpensive actuator powered for a very short amount of time, thereby optimizing cost, size, and battery efficiency.

[0005] In another aspect of the present invention, the pump includes a fail-safe position such that component failure will not result in free flow between the fluid chamber and the patient.

[0006] Another aspect of the present invention includes a method of pumping a fluid in which a pulse of a device such as an electrical solenoid pushes on a piston to controllably move a small quantity of fluid by hydraulically filling a pressurized delivery chamber. The delivery chamber slowly dispenses the fluid by adding a restriction to the flow out of the outlet port to dampen the fluid flow rate between actuations to prevent sudden spikes of liquid.

[0007] Another aspect of the present invention includes a pump enclosure having multiple pump mechanisms, which can each be configured to pump a different drug to a patient.

[0008] Yet another aspect of the present invention includes a method of delivering different drugs to a patient from a single pump enclosure.

[0009] Yet another aspect of the present invention includes measuring sensor data from within an air chamber open to the atmosphere within a pump enclosure and determining a volume of fluid remaining in a fluid chamber.

[0010] Another aspect of the present invention includes calibrating a pump enclosure for measuring an accurate volume of fluid in a fluid chamber.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] These and other aspects, features and advantages of which embodiments of the invention are capable of will be apparent and elucidated from the following description of embodiments of the present invention, reference being made to the accompanying drawings, in which

[0012] Figures 1A-5 illustrate one embodiment of a fluid pump according to the present invention.

[0013] Figures 6A-11B illustrate another embodiment of a fluid pump according to the present invention.

[0014] Figures 12A-16B illustrate another embodiment of a fluid pump according to the present invention.

[0015] Figures 17-26 illustrate an embodiment of a pump enclosure having multiple fluid chambers and pumps.

[0016] Figures 26-30 illustrate various options of materials within fluid chambers of the pump enclosure according to Figures 17-26.

[0017] Figure 31 illustrates a feedback system for a pump enclosure.

[0018] Figure 32 illustrates an example pressure measurement from the feedback system in Figure 31.

[0019] Figure 33 illustrates a flow chart of a method for determining a liquid volume via the feedback system of Figure 31.

DESCRIPTION OF EMBODIMENTS

[0020] Specific embodiments of the invention will now be described with reference to the accompanying drawings. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. The terminology used in the detailed description of the embodiments illustrated in the accompanying drawings is not intended to be limiting of the invention. In the drawings, like numbers refer to like elements.

[0021] Pump Mechanism and Operation

[0022] One aspect of the present invention is directed to a pump mechanism and method of use. Specifically, a displacement mechanism is used deliver small quantities of fluid (e.g., insulin) to a patient or to another pumping application. While the present specification primarily describes a solenoid as the displacement mechanism, it should be understood that a number of other devices can also be used, such as a motor, electromagnet, cam actuators, ultrasonic motors, magnets with shielding, Nitinol wire phase change materials, expanding/contracting materials, or similar devices.

[0023] Figures 1A-5 discloses one embodiment of a pump mechanism 100 that is actuated by a solenoid 106. When the solenoid 106 is operated, fluid (e.g., insulin) from a fluid chamber 112 is pumped into the input port 104A, through input lumen 104, and ultimately out the output port 116.

[0024] The solenoid 106 is preferably located within a chamber of a pump housing 102 and, when activated, moves a plunger 108 against a compressible elastomer film or flexible sheet 110. The film 110 is preferably connected around or near its outer edges and is fitted to have slack (i.e., is not pulled tight), allowing the film 110 to deform or bend. In this respect, when the plunger 108 is extended (i.e., moved to the left), the film 110 is pressed against an end port 104B of the input passage 104, closing off the port 104B and preventing any further liquid to enter the pump 100.

[0025] The pump 100 also includes a delivery piston 118 that moves laterally between a larger diameter pump chamber 102A and a smaller diameter pump chamber 102B (seen best in Figure 1B). The delivery piston 118 includes a cylindrical portion 118A which has diameter that is slightly smaller than the chamber 102B, allowing the cylindrical portion 118A to slide within the chamber 102B. A disk portion 118C is connected to the cylindrical portion by an elongated connection portion 118B, and has a diameter that is slightly smaller than the chamber 102A.

[0026] The piston 118 is biased towards the solenoid 106 by a spring 114. The spring 114 is preferably connected to the cylindrical portion 118A and to a location left of the piston, such as the septum 113 or to the wall of the chamber 102B. Since the fast action of the on/off cycle of a solenoid 106 (or similar actuator mechanism) can delivery fluid faster than the patient's tissue can absorb, creates sheer forces on the fluid molecules (e.g., insulin) potentially disrupting their efficacy, and can potentially injure the patient at the injection site, the spring helps dampen the solenoid force. Specifically, as the solenoid causes the delivery piston 118 to move to the left, the spring 114 helps reduce the speed of the piston 118 to create a more gentle movement, as well as stores some of the energy create by the solenoid 106. While a spring 114 is described, it should be understood that a variety of different dampening mechanisms are possible, such as magnetic dampening mechanisms and elastomeric members.

[0027] To allow movement of the delivery piston 118 and injection of fluid via the septum 113, the smaller diameter pump chamber 102B includes one or more fluid return ports 103 (e.g., 3 or 6 ports), which connect the pump chamber 102B with the fluid chamber 112.

[0028] With regard to the operation of the pump 100, Figures 1A and 1B illustrates the pump in a neutral position in which the delivery position 118 covers the entrance 116A to the output port 116.

[0029] Turning to Figure 2, power is applied to the solenoid 106, causing the plunger 108 move to the right, against the plunger return spring 107. The delivery plunger 118 also moves to the right, maintaining the output port 116 in a blocked or closed configuration and pressing against the film 110 so as to open the input lumen 104. In this respect, fluid from the fluid chamber 112 passes into input port 104A, along input passage 104, out the end port 104B, and into the larger diameter chamber 102A.

[0030] Once the larger diameter chamber 102A has filled with fluid, the solenoid 106 is powered off, allowing the plunger release spring 107 to begin moving fluid towards the left of the pump 100, thereby causing the fluid to move the piston 118 to the left, as seen in Figure 3. As such, the end port 104B becomes covered or blocked by the film 110, preventing further passage of fluid through the input passage into the chamber 102A.

[0031] As seen in Figure 4A, the continued movement of the plunger 108 to the left against the film 110, causing the fluid in the chamber 102A to press against the displacement piston 118, moving the piston 118 further to the left. At this position, the cylindrical portion 118A no longer blocks the output port 116 and a portion of the fluid in the smaller diameter chamber 102B (e.g., portion 102C in Figure 4B). In other words, the entire contents of both chambers 102A and 102B do not empty out of the output port 116; instead only a fraction of that fluid is displaced. Additionally, the piston 118 has compressed against the spring 114, storing some of the energy imparted via the solenoid 106 and displacing some of the fluid on the left side of the piston 118 out the fluid return ports 103.

[0032] It should be understood that the amount and rate of fluid leaving the chamber 102B in this position can be controlled by a number of factors. For example, the diameter

and length of the output port 116 can both be increased or decreased to adjust an amount and/or rate of displaced fluid per cycle. Other factors may also influence this, such as the compressibility of the springs 114 and 107, the size of the chambers 102A and 102B, the diameter holding the fluid in the film, and the strength and actuation time/speed of the solenoid 106.

[0033] Referring to Figure 5, with a portion of the fluid displaced, the spring 114 begins to push back the piston 118, closing the output port 116 and returning to a neutral (i.e., nonmoving position). In this position, both the output port 116 and the end port 104 of the input passage 104 are closed. In this respect, if the solenoid 106 or other components controlling the solenoid 106 break, or if the piston sticks, the pump will not allow constant flow of insulin through the pump 100 and into the patient.

[0034] Figures 6A-11B illustrate another embodiment of a pump 130 that is constructed and operates in a generally similar manner to the previously described pump 100. However, instead of single piston and a film, the present pump 130 includes a solid, cylindrical delivery piston 132, a tubular fill piston 134, and a cylindrical refill piston 136.

[0035] The cylindrical delivery piston 132 is preferably sized slightly smaller in diameter than smaller diameter chamber 102B and moves laterally to selectively block the output port 116. The tubular fill piston 134 is sized slightly smaller in diameter than the larger chamber 102A and moves laterally to selectively open and close the input passage 104. The tubular fill piston 134 also includes a passage therethrough in which the cylindrical refill piston 136 slides during operation, creating a small refill chamber.

[0036] Figures 6A and 6B illustrate the pump 130 in a neutral position in which neither the solenoid 106, nor the spring 114 are actively creating motion of the components within the pump 130. The delivery piston 132 can be seen closing off the delivery port 116, preventing fluid from passing to the patient. The fill piston 134 can be seen moved to the right, allowing fluid to enter from the input passage into the area around the delivery piston 132 within the larger chamber 102A.

[0037] In Figures 7A and 7B, the solenoid 106 is actuated (i.e., power is applied), causing the plunger 108 to move to the left. As the plunger moves 108, pressure builds within the chamber 102A, causing the refill piston 136 to push back, to the right. As the

fill piston 134 continues to move to the left, it closes of the input port 104, creating a small, somewhat pressurized chamber of fluid within the fill piston 134.

[0038] As seen in Figures 8A and 8B, the plunger 108 continues to move left, moving with it the fill piston 134, the refill piston 136 and the delivery piston 132. In this position, the delivery piston 132 has moved far enough to the right so as to open output port 116, thereby allowing some of the fluid to be discharged from the pump 130.

[0039] In Figures 9A and 9B, the power to the solenoid 106 is turned off so that the plunger 108 no longer applies leftward pressure. With reduced fluid in the pump chambers and a lack of force from the plunger 108, the compressed spring 114 pushes the delivery piston 132 rightward, thereby blocking off the delivery port 116.

[0040] In Figures 10A and 10B, the delivery piston 132 continues to move to the right, contacting and pushing the fill piston 134. As seen best in Figure 10B, the delivery piston 132 and fill piston 134 stop their movement as a hydraulic lock point is created by the chamber formed at location 135. This hydraulic lock point is eliminated as fluid from within the chamber within the fill piston 134 migrates into area 135 (e.g., via a small gap formed between the right side of the delivery piston 132 and the left side of the fill piston 132). As the fluid moves to area 135, the refill piston 136 moves further to the left while the delivery piston 132 and fill piston 134 move to the right, as seen in Figures 11A and 11B. Eventually, the fill piston 134 moves far enough to the right to open the input passage 104 and the pump cycle can begin again.

[0041] Figures 12-16 illustrate another embodiment of a pump 140 according to the present invention. The pump 140 is generally similar to the previously described pumps 100 and 130. However, the pump 140 includes an elastomeric fill sleeve 144 disposed around the fill piston 142, selectively opening and closing the input passage 104 during operation.

[0042] In Figure 12A, the solenoid 106 remains unactuated (i.e., no power is applied) and the plunger 108 is fully retracted to the right. The delivery piston 132 is positioned to block the output port 116 and the fill piston is positioned against the plunger 108 and the delivery piston 132. As described below, during a normal cycle, hydraulic lock pressure is created in the chamber formed between the delivery piston 132 and the elastomeric fill

sleeve 144. This force pulls the elastomeric sleeve 144 away from a bypass channel 141 (seen in Figure 12B) that connects between the input passage 104 and the larger diameter chamber 102A, thereby opening the input passage 104 and allowing fluid to be sucked into the pump 140.

[0043] In Figure 13A, fluid has entered the chamber 102A. As the solenoid 106 is actuated, the plunger begins to exert pressure on the fill piston 142 and thereby create pressure within the chamber 102A. As seen in Figure 13B, this pressure pushes the elastomeric sleeve upwards into the bypass channel 141, filling the channel 141 and closing of the input passage 104.

[0044] In Figure 14, the plunger 108 moves further to the left, increasing pressure within the chambers 102A and 102B. This increased pressure causes the delivery piston 132 to slide to the left, past the output port 116, causing a portion of the fluid in the pump 140 to be expelled.

[0045] As the fluid leaves the chamber 102B, the pressure in the chamber 102B reduces. Additionally, the power to the solenoid 106 is deactivated, allowing the compressed spring 114 to push the delivery piston 132 back to the right, closing the output port 116 as seen in Figure 15.

[0046] As seen in Figures 16A and 16B, as the delivery piston 132 continues to move to the right, an area 143 is created between the delivery piston 132 and the elastomeric sleeve 144, creating a hydraulic lock. The force of the hydraulic lock pulls downward on the elastomeric sleeve 144, away from the channel 141, pulling additional fluid into the chamber 102A. This ultimately results in the configuration seen in 13A and allows the pump cycle to be repeated.

[0047] Pump Enclosure with Multiple Chambers

[0048] In another embodiment according to the present invention, Figures 17-26 illustrate various aspects of a pump enclosure 150 having multiple chambers to accommodate multiple pumps. While this embodiment of the pump enclosure 150 accommodates up to 4 fluid pumps, it should be understood that the enclosure could also be configured for different numbers of pumps, such as 2, 3, 5, and 6. Any of the pumps

previously described in this specification (or variations thereof) lend themselves particularly well to use in the present pump enclosure 150, due to the relatively small size of the pumps and the relatively low power consumption afforded by the solenoid 106 (or similar actuator mechanism).

[0049] Figure 17 illustrates the pump enclosure 150, having a lower housing member 154, an upper housing cover 152, a cannula 156 (or rigid needle), and a plurality of septums 113 from each of the pumps within the enclosure 150. Figure 18 illustrates the enclosure 150 with the upper housing cover 152 removed, exposing a top sealing cover or film 164, a plurality of solenoids 106 that drive each of the pumps, a battery 158, and a circuit assembly 160 comprising a plurality of electrical components that control and operate the enclosure 150.

[0050] Figure 19 illustrates a similar view of the enclosure 150 as the prior figure, except that the film 164 has been removed to expose four pump chambers 166. Each chamber 166 includes pump housings 165 (also seen in Figure 21) that are similarly shaped to those of the pump housing 102, as described in previously described pump embodiments. In this regard, the pump components shown in Figure 20 (e.g., the septum 113, spring 114, and chambers 102A, 102B) are located within passage created within each housing 165.

[0051] In one embodiment, the walls of the chambers 166 and the film 164 create the fluid chamber (e.g., fluid chamber 112). Alternately, a flexible bag or container can be located within the each chamber 166 to act as the fluid chamber.

[0052] The output ports 116 of each of the pumps are connected to apertures 172 in the lower housing member 154, as seen best in Figures 23-25. These apertures 172 each connect to a channel 176 on the lower side of the housing member 154 that connects to a single aperture 174. These channels 176 can be formed into a sealed passage system with a lower plate or film 162 fixed over both the channels 176 and the aperture 174, as seen in Figure 22. As best seen in Figures 25 and 26, the aperture 177 connects with a curved septum passage 168, which allows the cannula 156 (or rigid needle) to connect with the pump enclosure and receive the fluid from any/all of the pumps.

[0053] In an alternate embodiment, the output port of one or more of the pumps can be directly connected to a fluid chamber of an adjacent pump, allowing the contents of one fluid chamber to be delivered to the fluid chamber of another pump.

[0054] It should be understood that the circuit assembly 160 includes a variety of circuitry to operate the pumps of the controller, as well as any other electrical components that may be present. For example, the circuit assembly 160 may include a microprocessor or microcontroller, a memory, software stored in the memory and executed by the microprocessor/microcontroller, sensors (e.g., pressure sensor, temperature sensor), and a communications port.

[0055] It should be understood that a variety of different drugs and combinations of drugs are possible for each of the fluid chambers of the pump enclosure 150. Several enclosure examples and methods of use are discussed below, however, each of these drugs can be mixed and matched in many different configurations, all of which are contemplated in the present invention.

[0056] In one embodiment, multiple fluid chambers may have two or more types of insulin with different pharma kinetic actions. In one example seen in Figure 26, at least one fluid chamber of the enclosure may contain a fast acting insulin 180, such as lispro, aspart, and glulisine, and another chamber may contain a slow acting insulin 182, such as insulin glargine or insulin detemir. In another example seen in Figure 27, an intermediate acting insulin may also be included in another chamber of the enclosure 150, such as NPH.

[0057] Emergency rescue pens are used by diabetics when their glucose goes low and they begin to show signs of hypoglycemia. These pens combine liquid and lyophilized powder to form a glucagon fluid that is stable for about 24 hours. Typically, all of the fluid is immediately used.

[0058] Another configuration of the enclosure 150 can combine the functionality of such an emergency rescue pens with typical insulin pump functionality. For example, Figure 28 illustrates a first chamber containing insulin 186 for normal insulin pump operation, a lyophilized powder 188 in a second chamber, a diluent 190 in a third chamber, and saline 192 in a fourth chamber. The output port of the third pump can be configured

to lead only to the second chamber, allowing the third chamber's pump to move into the second chamber with the lyophilized powder to create glucagon. The second chamber's pump can then be activated to output glucagon to the patient. Finally, the saline 192 of the fourth chamber can be used to rinse the cannula/needle of any glucagon residue.

[0059] Figure 29 illustrates a similar example to that of Figure 28, except that instead of mixing both a powder and diluent, a liquid stable glucagon is used in a second chamber.

[0060] Figure 30 illustrates another configuration of the enclosure 150 in which amylin 196 is included in one of the chambers to slow post prandial emptying to better regulate the speed of insulin activation and thereby better match glucose uptake.

[0061] As mentioned above, a pump enclosure may include one or more, or even all of the following in different fluid chambers of the enclosure: Fast acting insulin, slow acting insulin, intermediate acting insulin, lyophilized powder, diluent, saline, liquid stable glucagon, and/or amylin. Again, the saline can be used to flush the channels of the enclosure and the cannula/needle to remove any residual drugs and prevent an inadvertent mixing during delivery.

[0062] In another embodiment of the present invention, one of the pumps of the pump enclosure 150 can be configured for measuring glucose. Specifically, one pump is configured to move fluid from the cannula 156 to a testing chamber in the pump. Unlike traditional CGMS needles that require a separate stick, by waiting between interstitial drug dosages, the interstitial fluid washes through the drug. During this time, a small amount of fluid inside the cannula and outside the cannula could be drawn in to test the level of glucose at the site and correlate it back to a blood plasma glucose level. Furthermore, the cannula could have the glucose oxidase inside of it with electrodes to measure within the cannula.

[0063] In another aspect of the present invention, the enclosure 150 includes a plurality of indicators 151, such as LED lights, that correspond to and are located near a specific pump and septum 113 within the enclosure 150. In this respect, activation of the indicator 151 may be used to indicate a status of a pump. For example, the indicator 151 may indicate that a fluid reservoir is empty or that a pump has become broken. The indicator 151 may be capable of illuminating a single color or multiple colors, each of which indicate

a different status (e.g., green means operational, yellow means empty fluid reservoir, and red means a broken pump).

[0064] In another aspect of the present invention, the enclosure may include a single indicator 151 that illuminates in several different colors that each correspond to a color of a septum 113. For example, the first septum 113 may be green and the second may be blue. When the indicator 151 illuminates in either of these colors, the user is made aware that the fluid reservoir for that pump is empty and therefore requires filling. Alternately, each septum 113 could have a different shape (e.g., circle, square, triangle), number, or other indicator, and a display on the enclosure may also display these indicators as necessary to indicate empty fluid reservoirs.

[0065] Pump Feedback

[0066] One further benefit of the pump embodiments and pump enclosure embodiments of the present invention is that they can allow various aspects of pump cycles to be measured, so as to allow onboard circuitry to determine if the pump mechanism is operating properly. For example, with certain measurements, pump enclosure circuitry may determine if the pump mechanism is delivering the proper or expected quantity of fluid.

[0067] Figure 31 illustrates an embodiment of a pump enclosure 200 having a pressure sensor 202, a temperature sensor 204, and a gas restrictor 206, all of which are either located in or are in communication with a gas or air chamber 208. As the pump 140 operates, it increases and decreases the amount of fluid in its flexible fluid chamber 112. For example, the pump 140 may initially increase the amount of fluid in the fluid chamber 112 during its filling portion of its cycle and then decrease the amount of fluid during delivery of the fluid to the patient. These increases and decreases in volume of the fluid within the air chamber 208 of the enclosure 200 increase or decrease the air pressure within the air chamber 208 (e.g., as seen in Figure 32).

[0068] By measuring the pressure and temperature of the air/gas within the air chamber 208, the enclosure's onboard circuitry can determine the volume of the air chamber 208 that is not occupied by the fluid chamber 112 with Boyle's Law. This volume

can be subtracted from the known volume of the air chamber 208 with an empty fluid chamber 112 to determine the fluid volume.

[0069] If the air chamber 208 was completely sealed, a vacuum could be created within the chamber 208 as fluid is pumped out of the fluid chamber 112. Since such a vacuum could ultimately hinder operation of the pump 140, an air restrictor 206 can be used to slowly vent and thereby slowly equalize the air chamber 208 with the atmosphere. The previously described fluid volume calculations can still be performed by also compensating for the resistance to airflow through the restrictor 206 using Poiseuille's Law. Poiseuille's Law of fluid flow determines the amount of fluid that passes through a restriction as a function of the viscosity, pressure differences, size of the restriction and length. By adding a restriction of known physical characteristics and measuring the pressure on one side (and knowing the pressure on the other side by measuring it during static conditions), the changes in the gas and liquid volume can be measured and determined dynamically.

[0070] These measurements and calculations by the onboard circuitry/software could identify how quickly the actuator (e.g., solenoid 106) is moving the pump elements, how far the delivery piston has moved due to the displacement of fluid, how much fluid has returned to the fluid chamber when the motion begins at the neutral position and the rate of flow from the delivery chamber to the output. This occurs because there are two functions at work, the displacement of fluid out of the delivery chamber and the flow of gas through the restriction due to the pressure differentials.

[0071] In this respect, the present invention contemplates a method of a pump enclosure measuring pressure and temperature within an air chamber 208 (step 210), compensating for airflow through a restrictor 206 connected to the air chamber 208 (step 212), and determining a volume of fluid in a fluid chamber 112 (step 214), as seen in Figure 33.

[0072] The restrictor 206 can be made of rigid materials, such as, rubies, diamonds, glass, plastic, and other materials commonly used in the practice. The flow characteristics of the restrictor 206 can be characterized or calibrated during the initial pumps (by the onboard circuitry/software) when the volume in the fluid chamber 112 is known and the

air chamber 208 is known. The enclosure may also be calibrated by performing volume calculations via the circuitry/software, injecting a known volume of liquid into the fluid chamber 206, inputting the volume into an interface associated with the enclosure, performing a second volume measurement, and then comparing the difference between the injected amount and the calculated amount. In the case of either method, the changes in pressure can be used to determine the resistance caused by the restrictor 206, accounting for variations in manufacturing and dirt or other changes that may change the behavior of the restrictor 206 over time.

[0073] Preferably, the restrictor 206 is sized small enough such that the small pressure created in the movements internally are insufficient to pull liquid into the air chamber 208, due to the surface tension characteristics of the restrictor 206. This may prevent water and other fluids from being sucked into the air chamber 208 during cleaning, showers, and swimming, for example.

[0074] It should be understood that by monitoring fluid volume in the fluid chamber 112, a variety of different diagnostics and alerts are possible. For example, Figure 34 illustrates a method of determining if a fluid pump is pumping an expected amount of fluid. First, a pump cycle is actuated as explained with regard to several of the different pump embodiments of the present specification (step 216). Next, the electronics and software of the pump enclosure 200 compare a calculated fluid volume of the fluid chamber 112 from before the previous pump cycle to a calculated fluid volume after the pump cycle (step 218). Finally, the electronics and software of the pump enclosure 200 determine if the expected fluid decrease matches the measured fluid decrease (step 220). If the two fluid volume decreased do not "match" (e.g., are not within 5% of each other), the electronics and software of the pump enclosure 200 may generate a warning (e.g., on an interface on the pump enclosure or a separate interface connected to the pump enclosure via a wired or wireless communications protocol).

[0075] While pressure measurement can be used to monitor pumping cycles, the pumping cycles could also be monitored by including a cycle counting sensor. For example, a Reid or Hall effect sensor could be used to monitor movement of various pistons in the pump. In this respect, the pump enclosure's electronics and software could

alert the user when an expected pump fails to occur or when a greater number of pump cycles occur than expected.

[0076] In one aspect of the present invention, the pump enclosure 200 may include a multicolor light (e.g. a tricolor LED) that indicates the cycle of a pump within the pump enclosure. For example, a yellow light may indicate a pressure increases to an acceptable level, a green light may indicate that the pressure has dissipated due to deliver of the fluid, and a red light may indicate that an unexpected sensor/pressure/volume value.

[0077] Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the claimed invention. Accordingly, it is to be understood that the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

What is claimed is:

1. A pump for delivering small quantities of fluid to a user, comprising:

a pump housing having an internal lumen, an inlet port connecting to said internal lumen, and an outlet port connected to said internal lumen;

a piston assembly located within said internal lumen and having a first position causing said inlet to be close and a second position causing said outlet to be closed;

an actuator configured to move said piston assembly between said first position and said second position; and

a fluid reservoir connected to said inlet port.

2. The pump of claim 1, wherein said actuator is a solenoid, motor, electromagnet, cam actuator, ultrasonic motor, magnets with shielding, Nitinol wire phase change material, or expanding/contracting materials.

3. The pump of claim 1, further comprising a flexible film that selectively blocks said inlet port.

4. The pump of claim 1, further comprising a dampening member configured to dampen movement of said piston by said actuator.

5. The pump of claim 1, wherein said piston assembly further comprises a first piston member, a second piston member located adjacent said first piston member, and a third piston member slideably disposed within a passage within said second piston member.

6. The pump of claim 1, wherein said piston assembly comprises a first piston member, a second piston member located adjacent said first piston member, and a flexible sleeve disposed around at lease said second piston member.

7. An insulin pump enclosure, comprising:

a housing having an outlet;

a first pump located within said housing and being connected to output fluid to said outlet;

a second pump located within said housing and being connected to output fluid to said outlet.

8. The insulin pump enclosure of claim 7, further comprising a third pump located within said housing and being connected to output fluid to said outlet, and a fourth pump located within said housing and being connected to output fluid to said outlet.

9. The insulin pump enclosure of claim 7, wherein said first pump is connected to a first fluid reservoir containing fast acting insulin and said second pump is connected to a second fluid reservoir containing slow acting insulin.

10. The insulin pump enclosure of claim 8, further comprising:

a third pump located within said housing and being connected to output fluid to a second fluid reservoir, and a fourth pump located within said housing and being connected to output fluid to said outlet;

wherein said first pump is connected to a first fluid reservoir containing insulin, said second pump is connected to said second fluid reservoir containing lyophilized power, said third pump is connected to a third fluid reservoir containing diluent, and said fourth pump is connected to a fourth fluid reservoir containing saline; wherein said third pump is configured to deliver said diluent to said second fluid reservoir so as to create glucagon.

11. The insulin pump enclosure of claim 7, further comprising a third pump located within said housing and being connected to output fluid to said outlet, wherein said first pump is connected to a first fluid reservoir containing insulin, said second pump is connected to a second fluid reservoir containing amylin, and said third pump is connected to a third fluid reservoir containing saline.

12. The insulin pump enclosure of claim 7, further comprising a third pump located within said housing and being connected to output fluid to said outlet, wherein said first pump is connected to a first fluid reservoir containing insulin, said second pump is connected to a second fluid reservoir containing liquid stable glucagon, and said third pump is connected to a third fluid reservoir containing saline.

13. An insulin pump enclosure, comprising;

a pump housing;

a pump disposed in said pump housing;

an air chamber located in said pump housing and having a restrictor venting to the atmosphere outside said pump enclosure;

a fluid reservoir located in said air chamber;

a pressure sensor in communication with said air chamber;

a temperature sensor in communication with said air chamber; and,

a circuit assembly connected to said temperature sensor and said circuit assembly; wherein said circuit assembly is configured to measure pressure and temperature within said air chamber, compensate for airflow through said restrictor, and calculate a volume of liquid in said fluid reservoir.

14. The insulin pump enclosure of claim 13, wherein said circuit assembly is further configured to actuate a pump cycle, determine a measured fluid volume decrease, and determine if an expected fluid decrease matches said measured fluid volume decrease.

15. The insulin pump enclosure of claim 13, wherein said circuit assembly is further configured to determine phases of a pump cycle of said pump.

16. The insulin pump enclosure of claim 15, further comprising an indicator configured to communicate a phase of a pump cycle to a user.

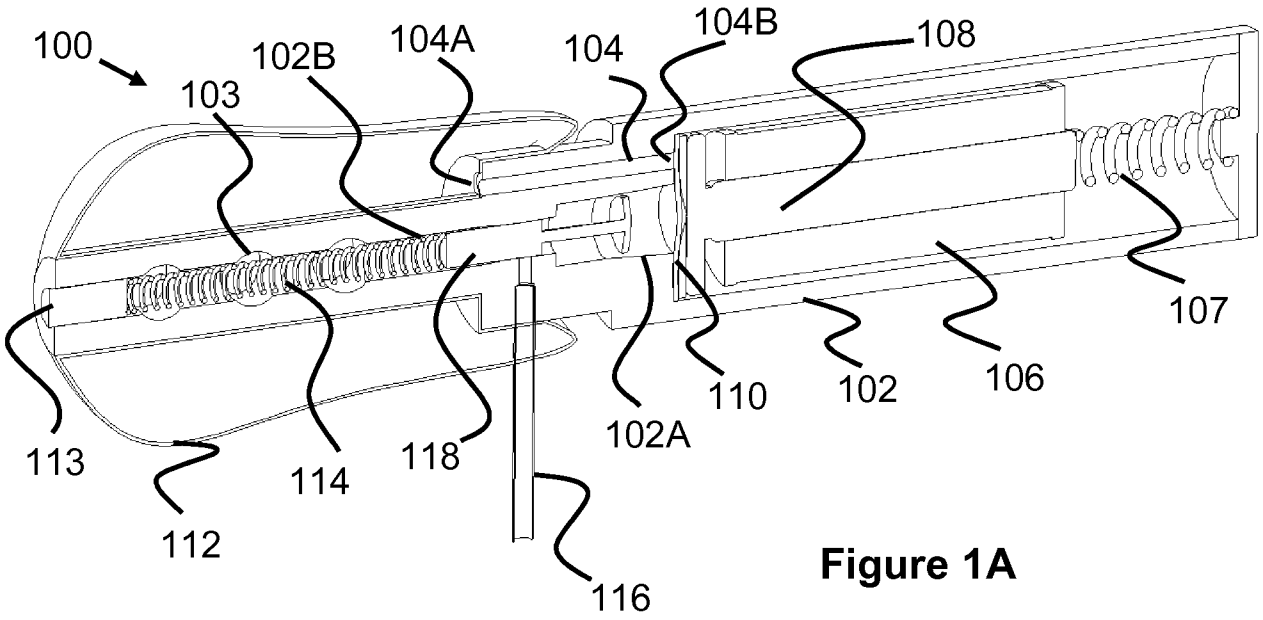


Figure 1A

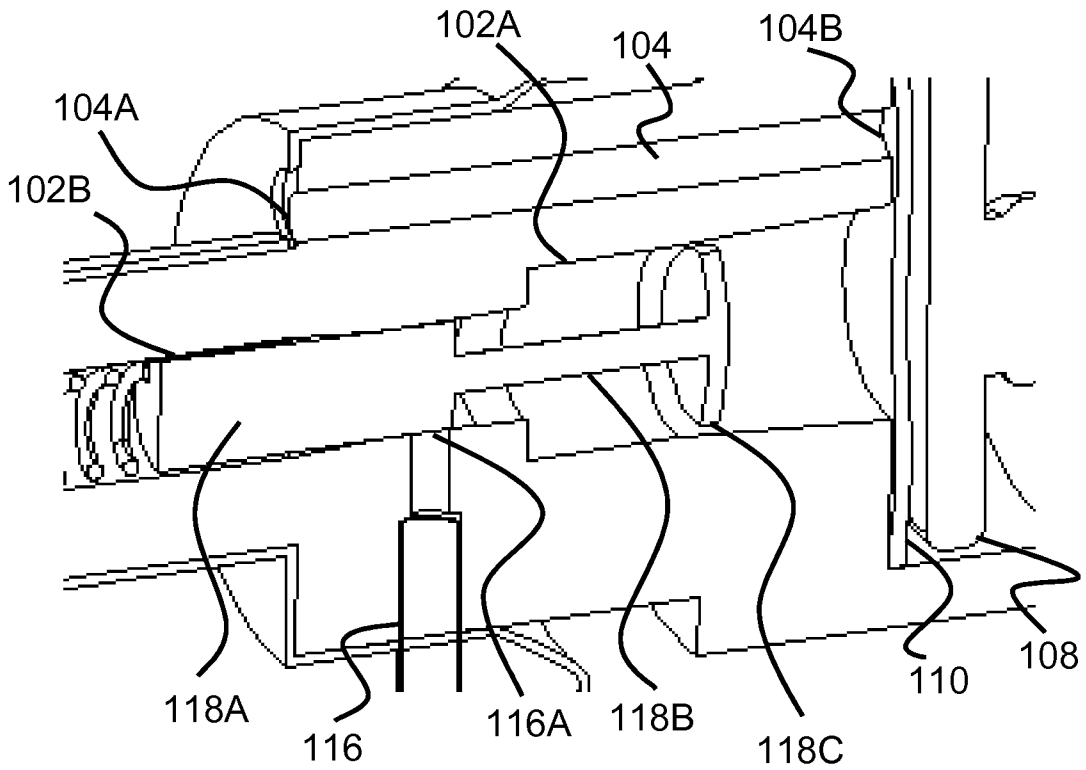


Figure 1B

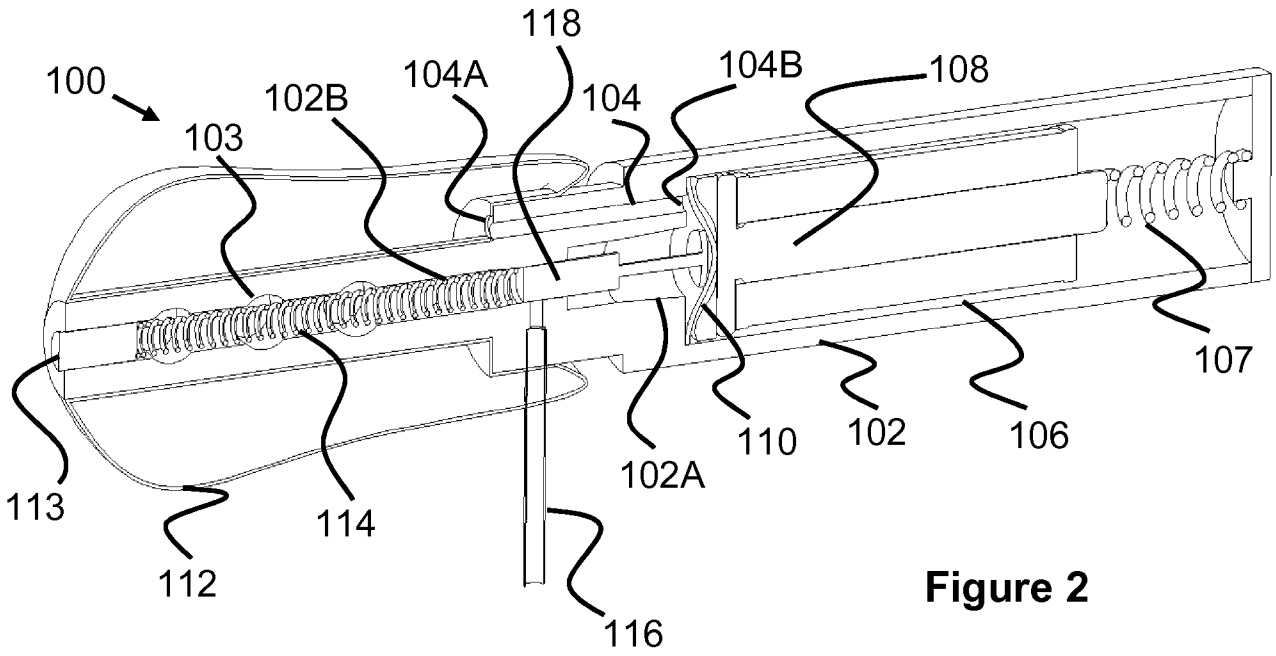


Figure 2

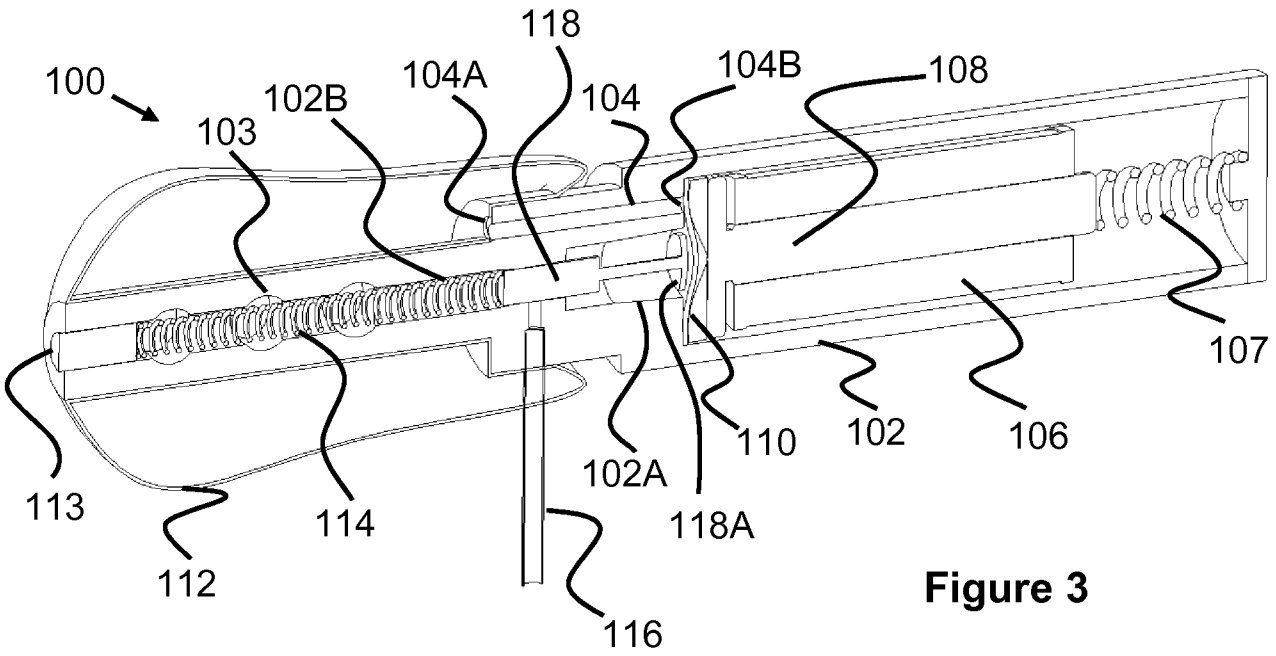


Figure 3

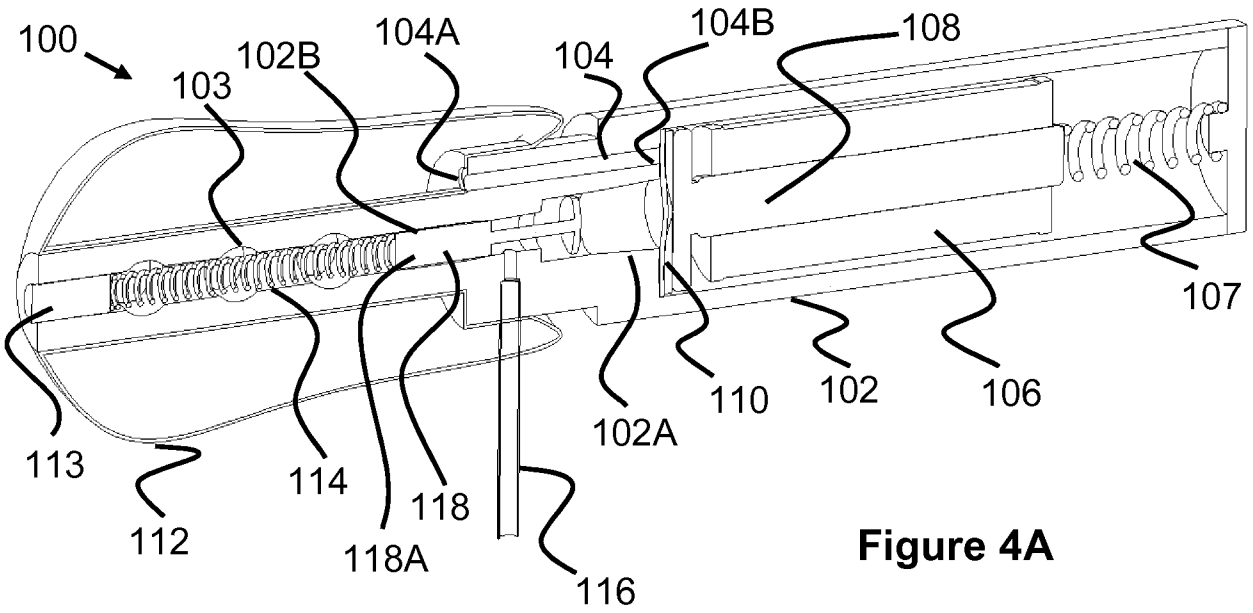


Figure 4A

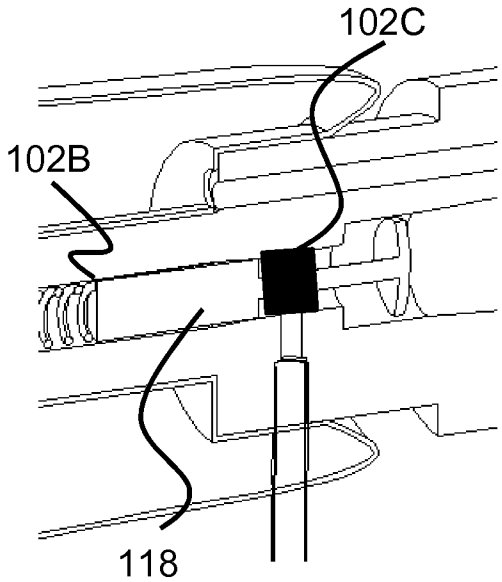
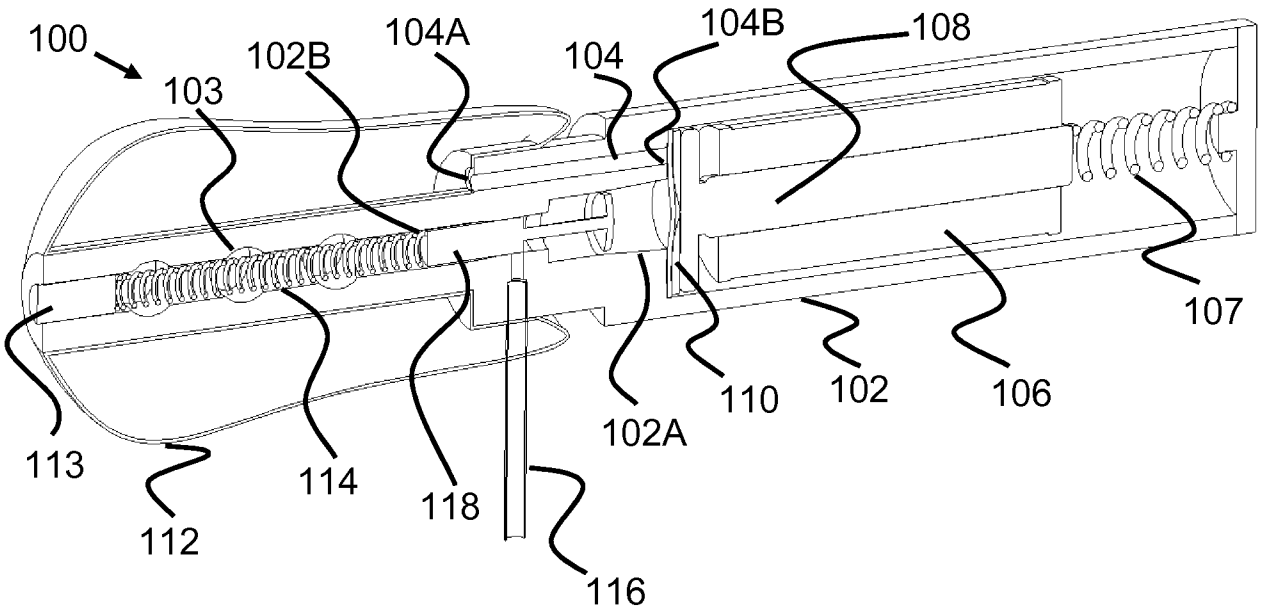


Figure 4B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102A
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Figure 5

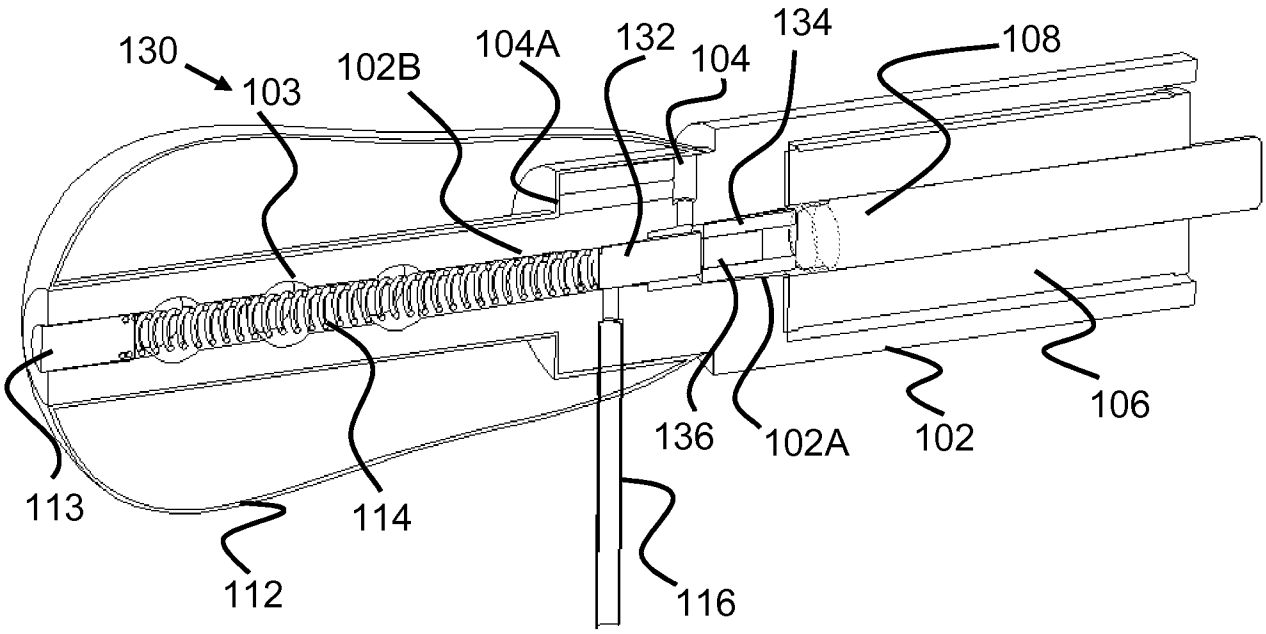


Figure 6A

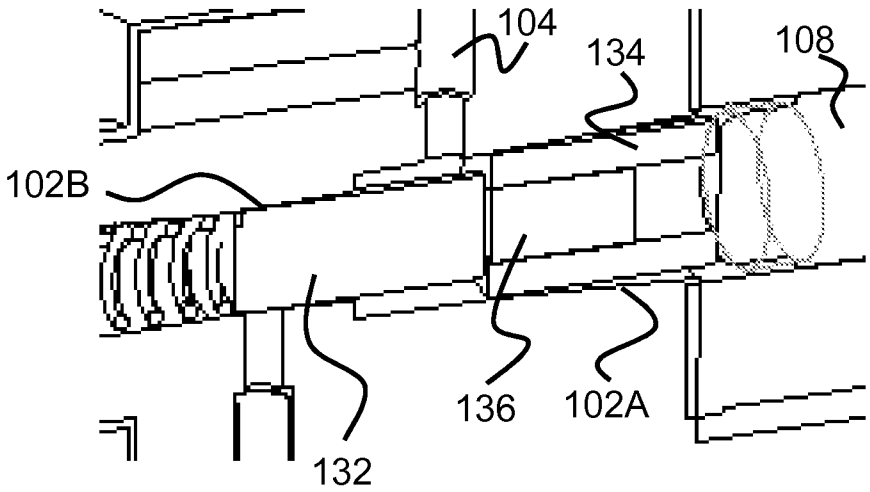


Figure 6B

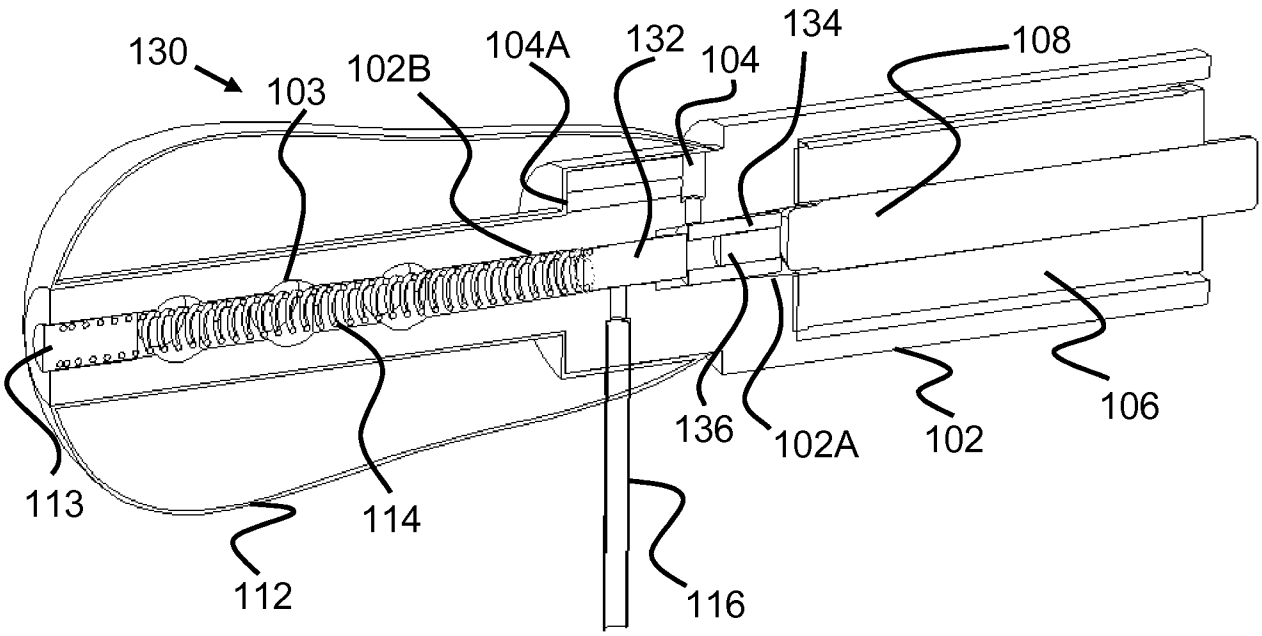


Figure 7A

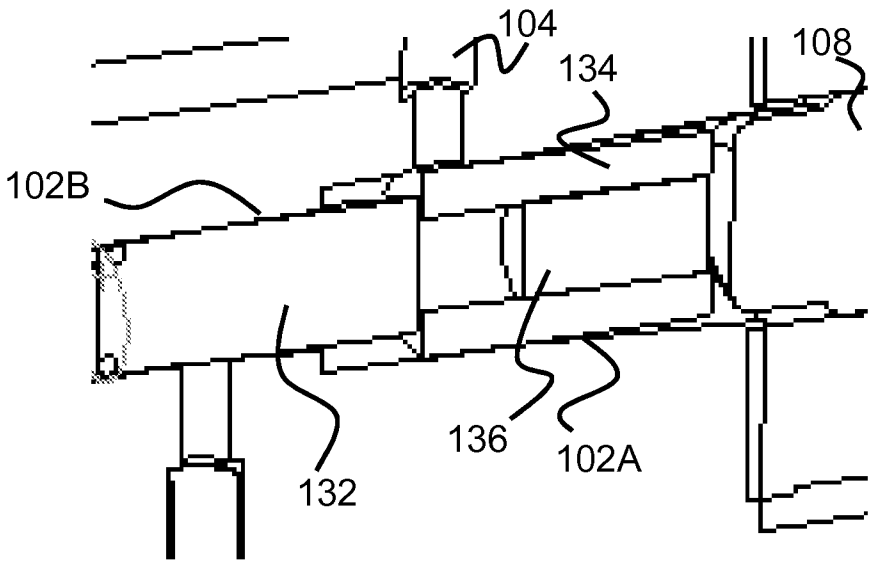


Figure 7B

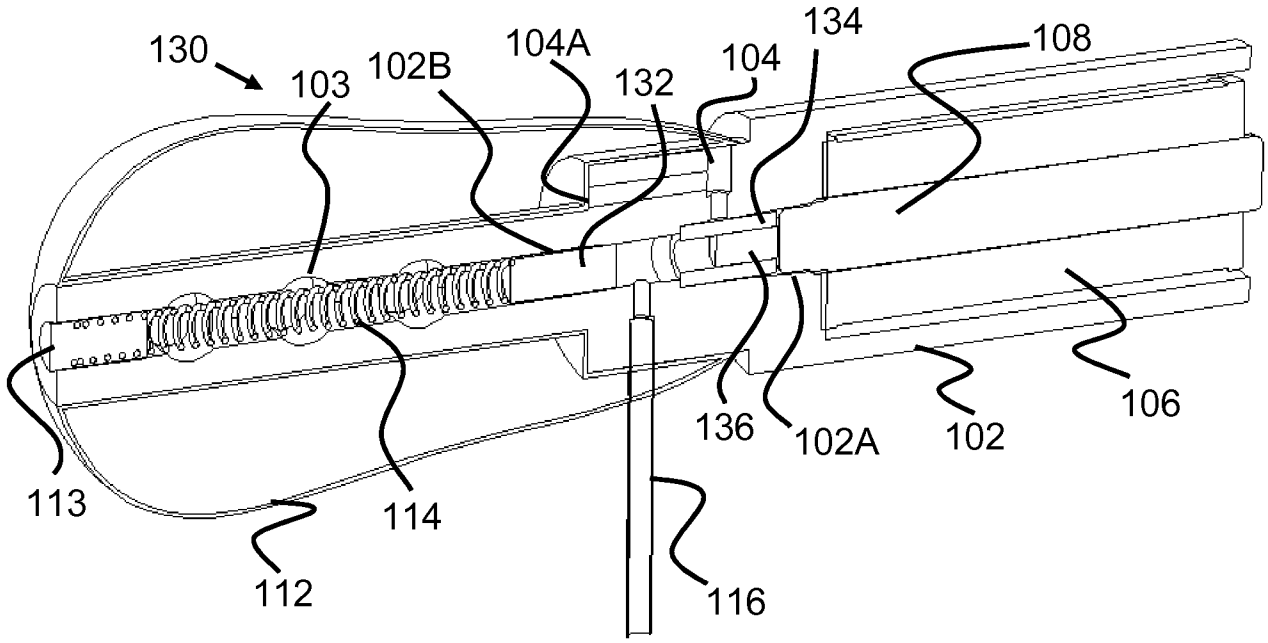


Figure 8A

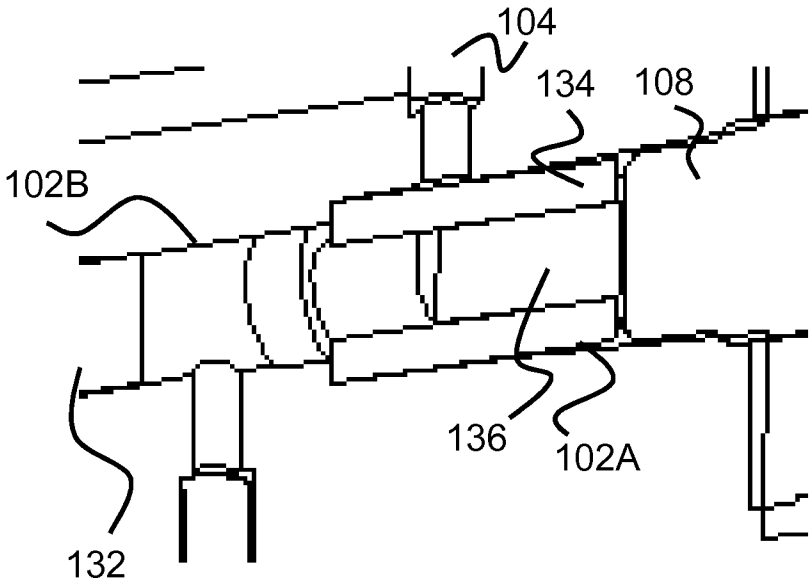


Figure 8B

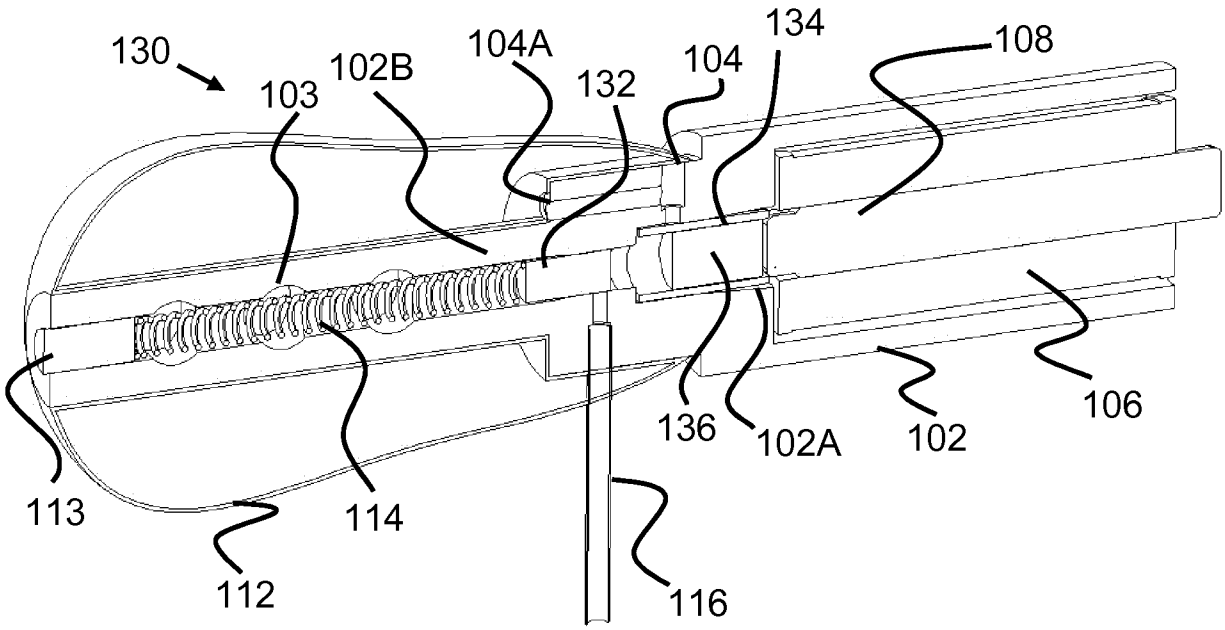


Figure 9A

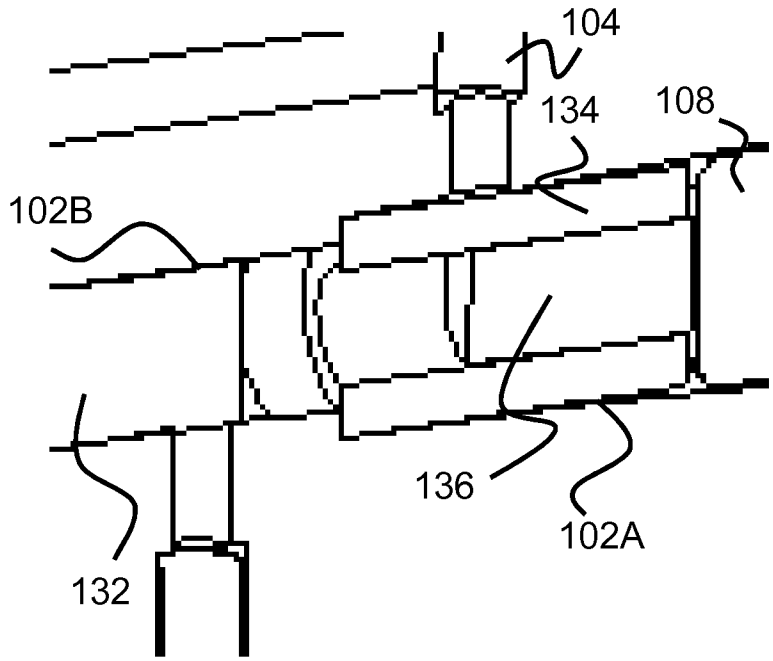


Figure 9B

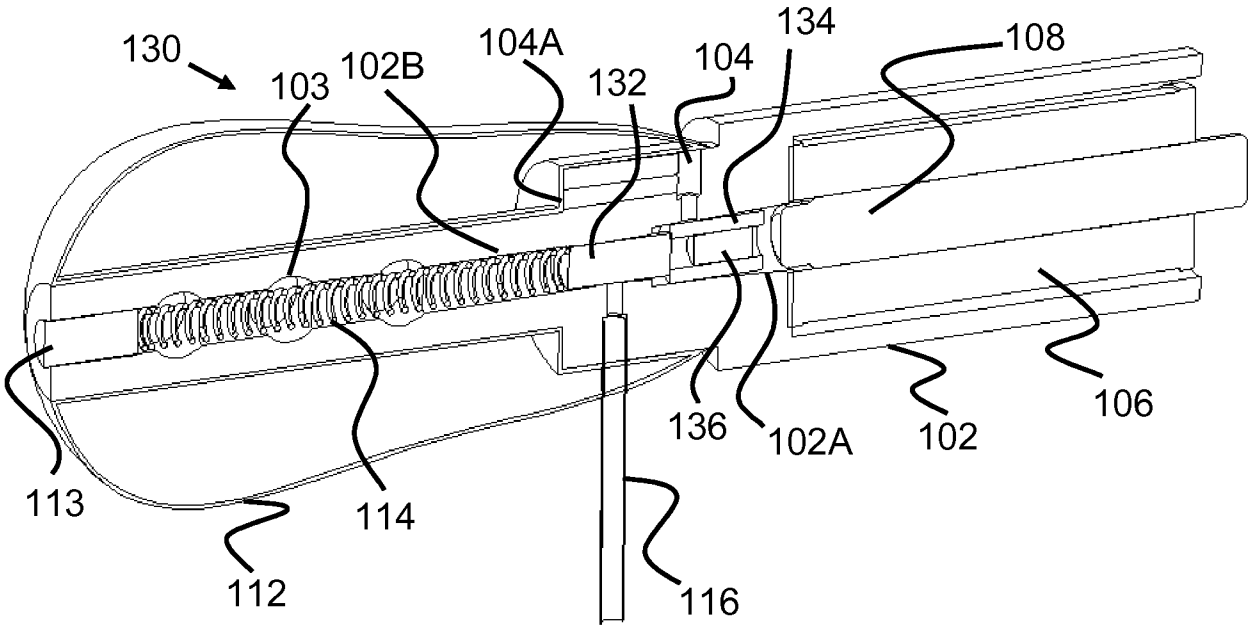


Figure 10A

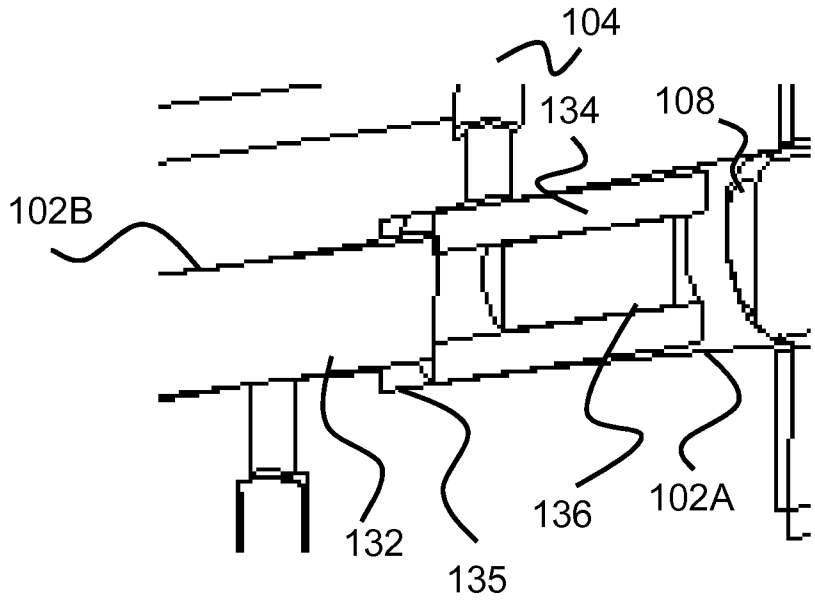


Figure 10B

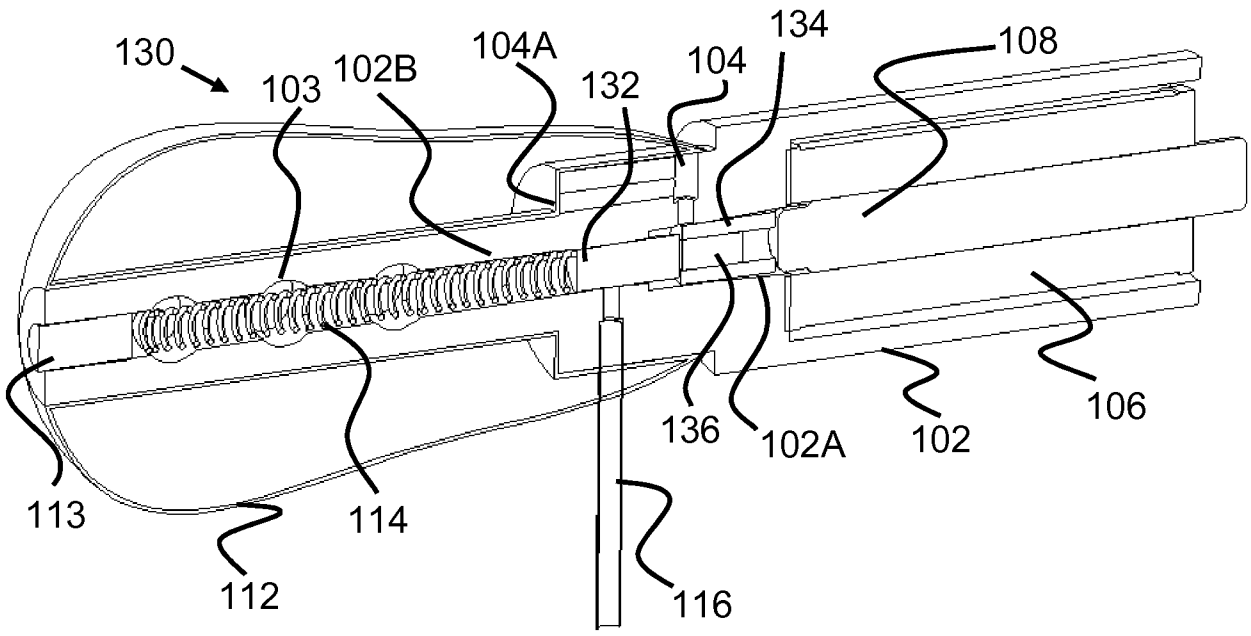


Figure 11A

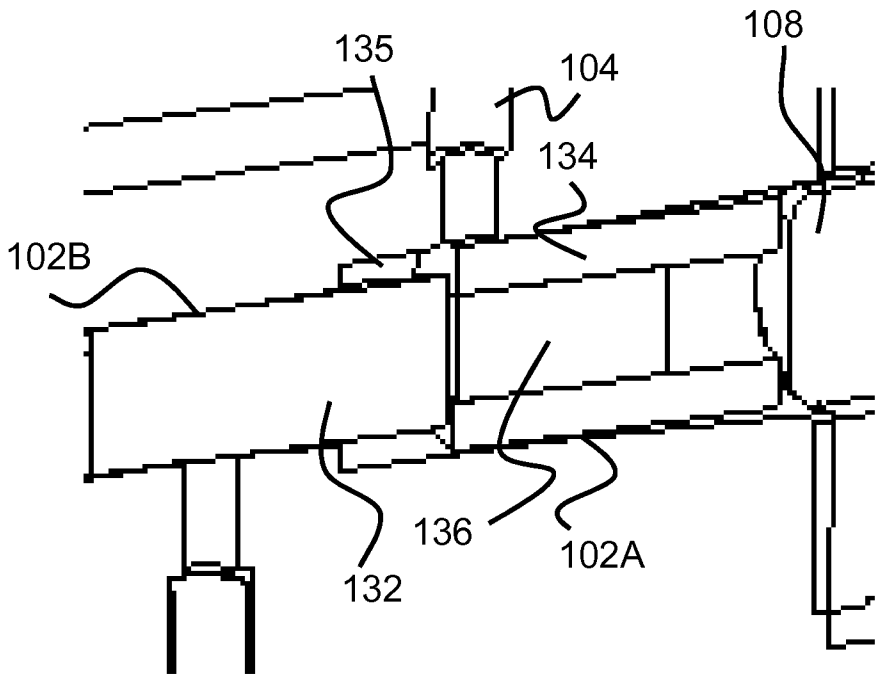


Figure 11B

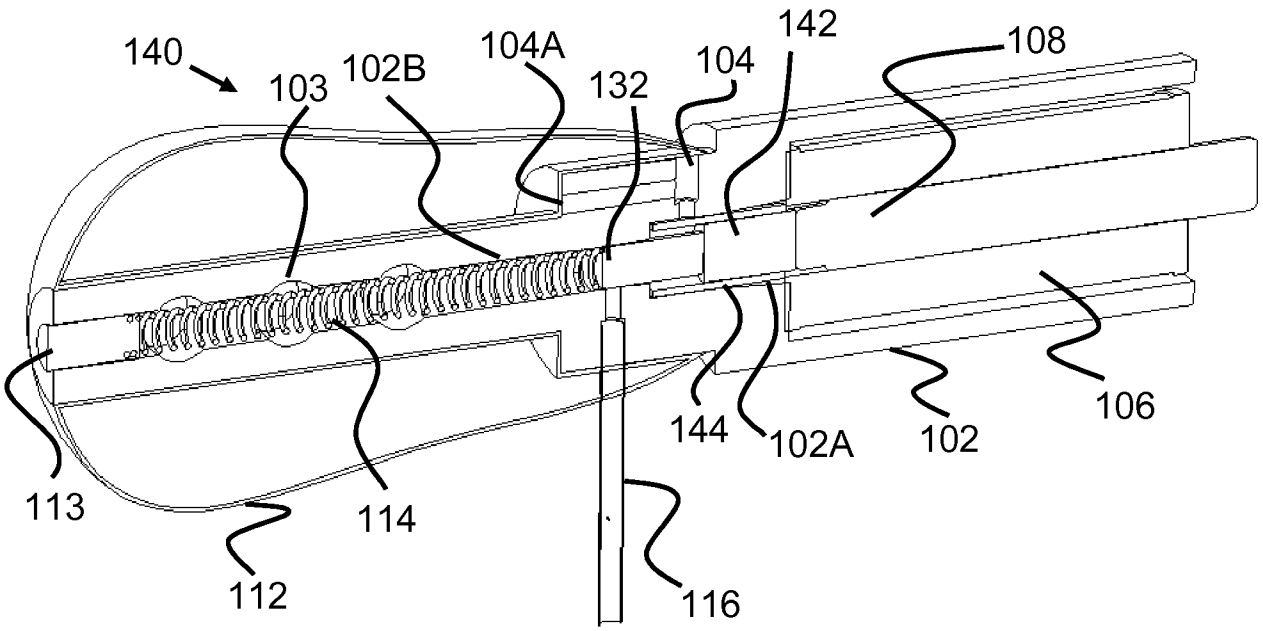


Figure 12A

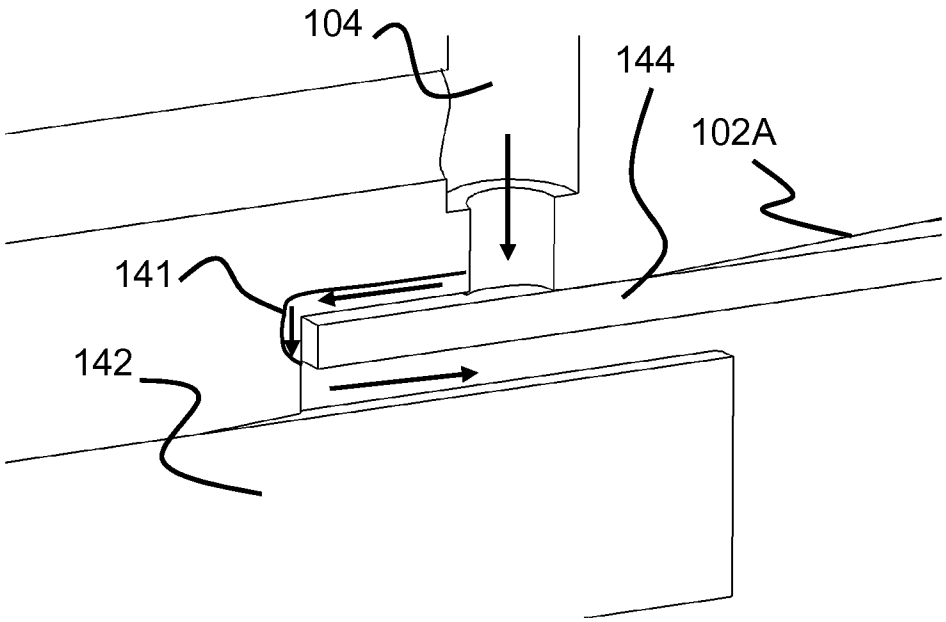


Figure 12B

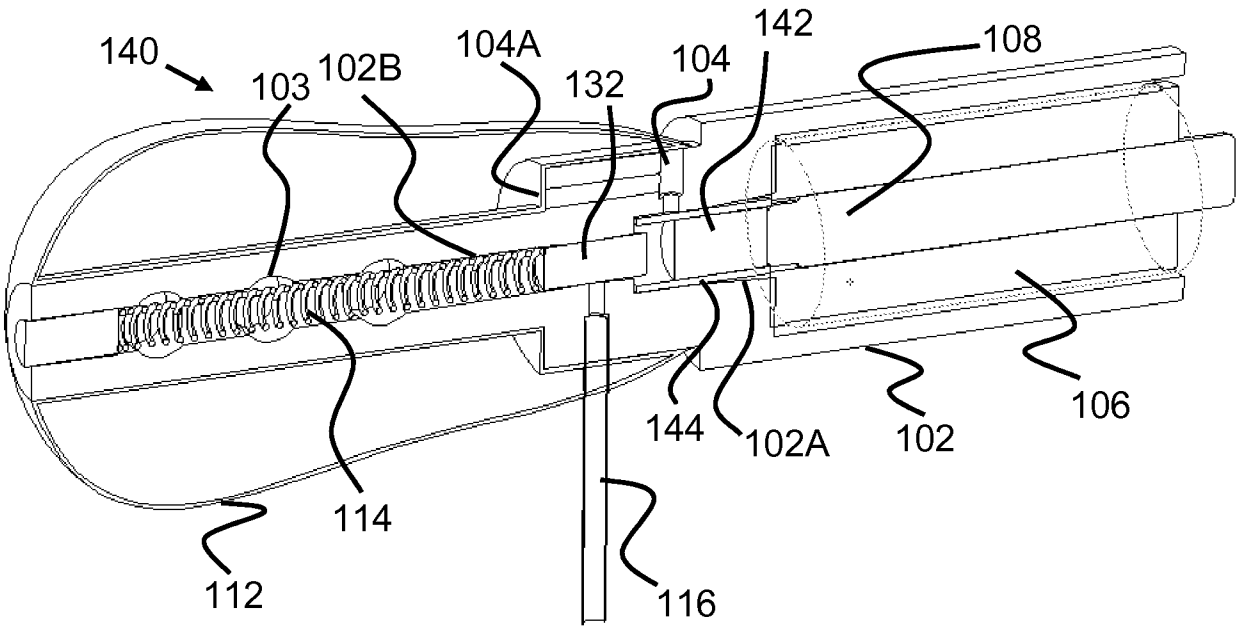


Figure 13A

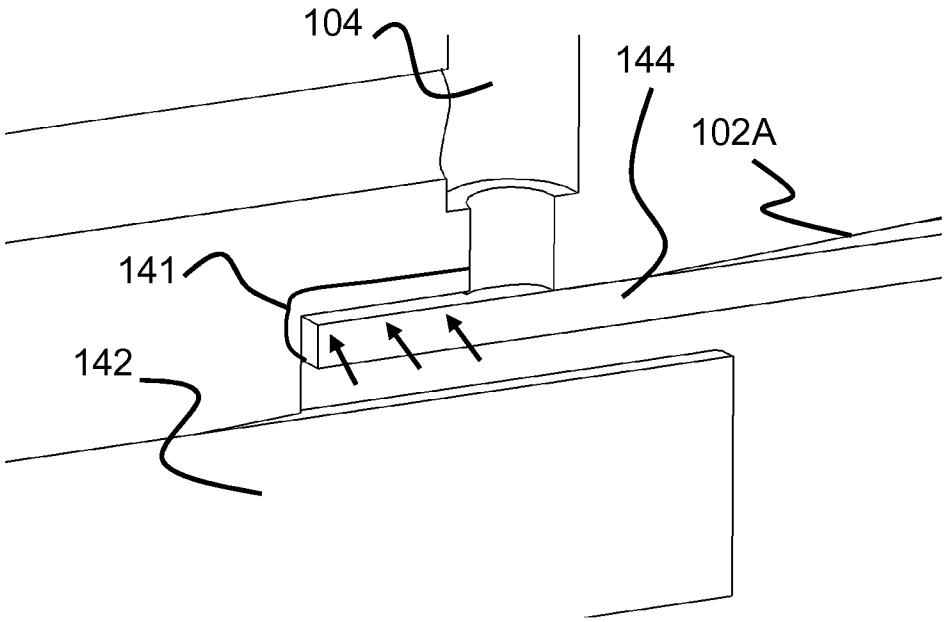


Figure 13B

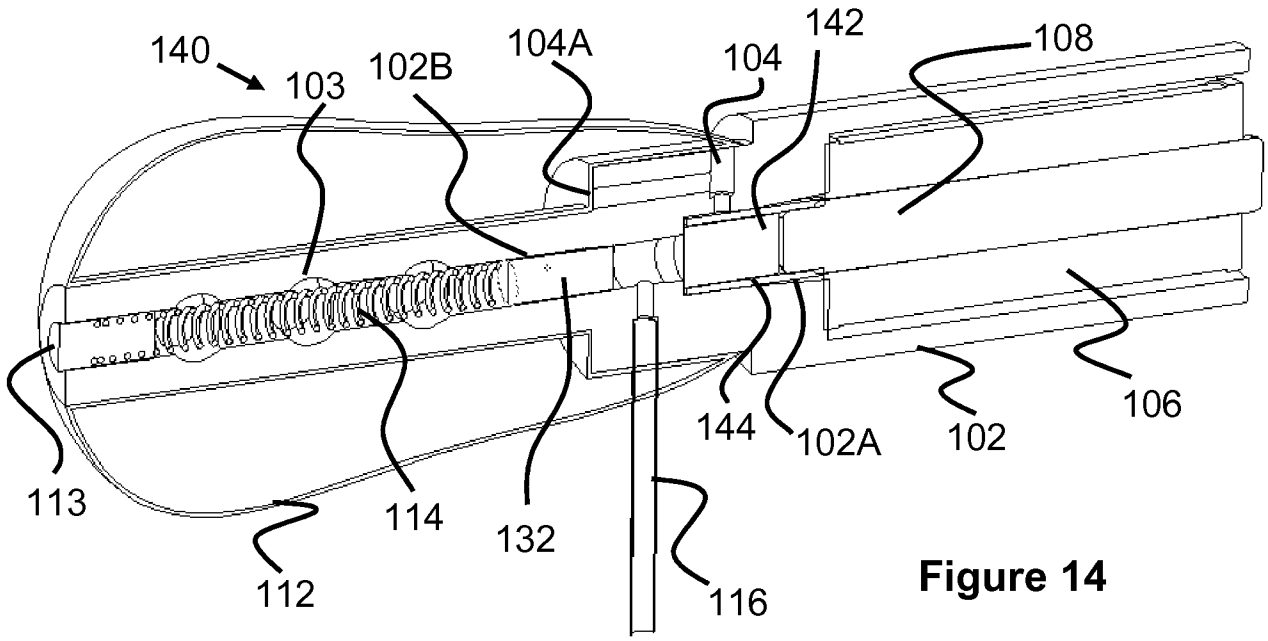


Figure 14

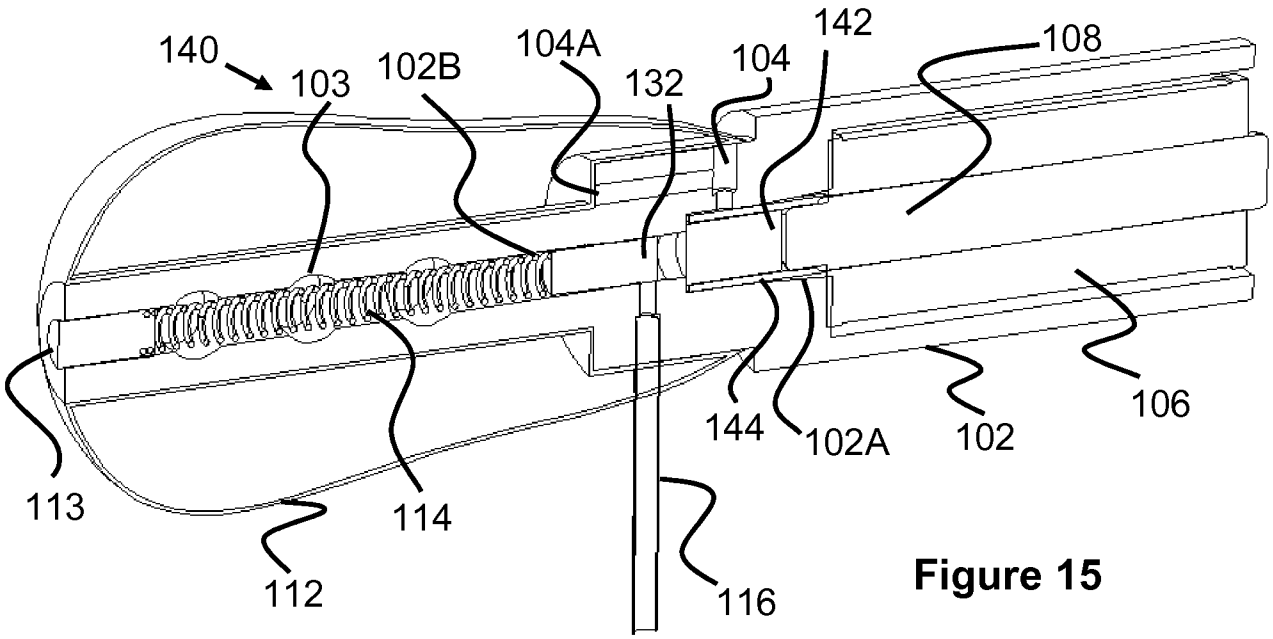


Figure 15

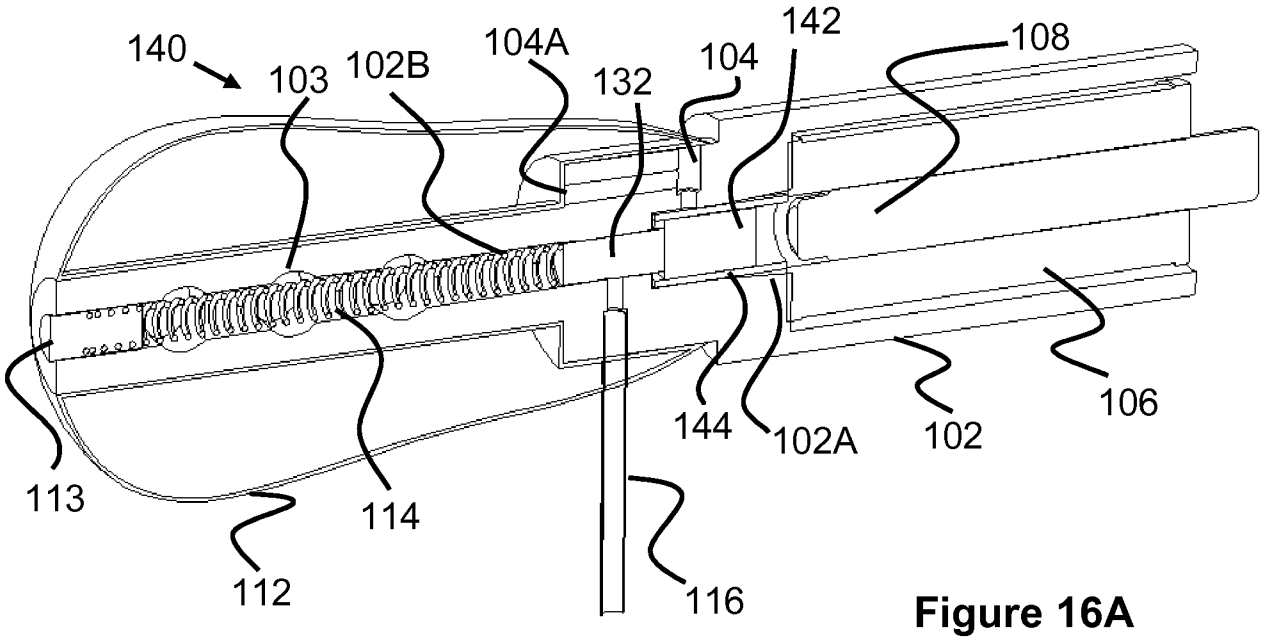


Figure 16A

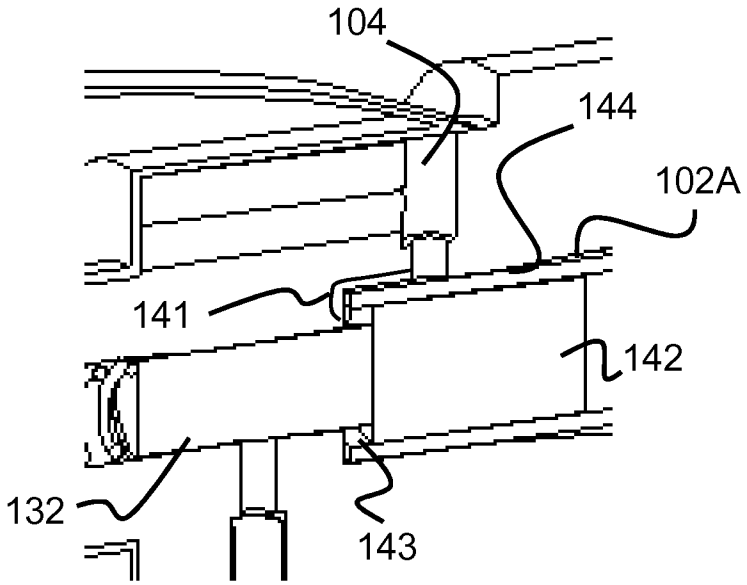


Figure 16B

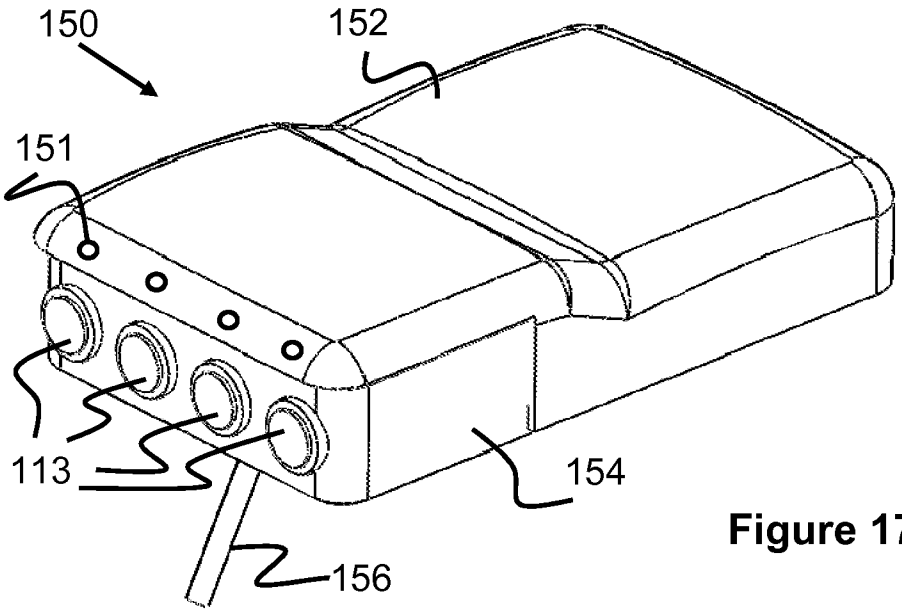
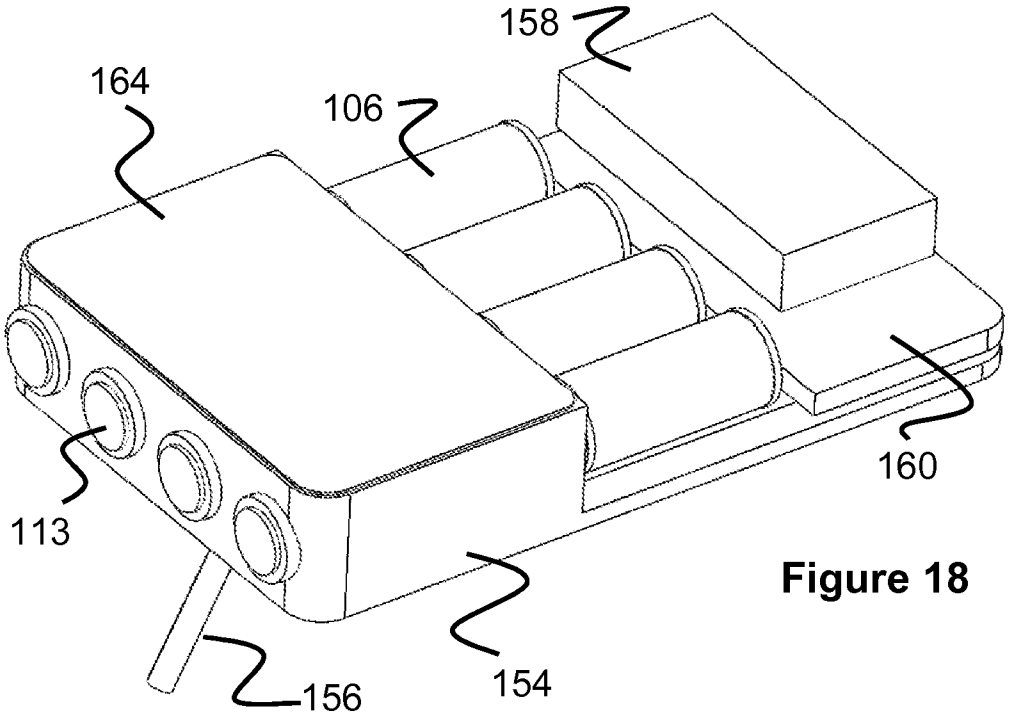


Figure 17



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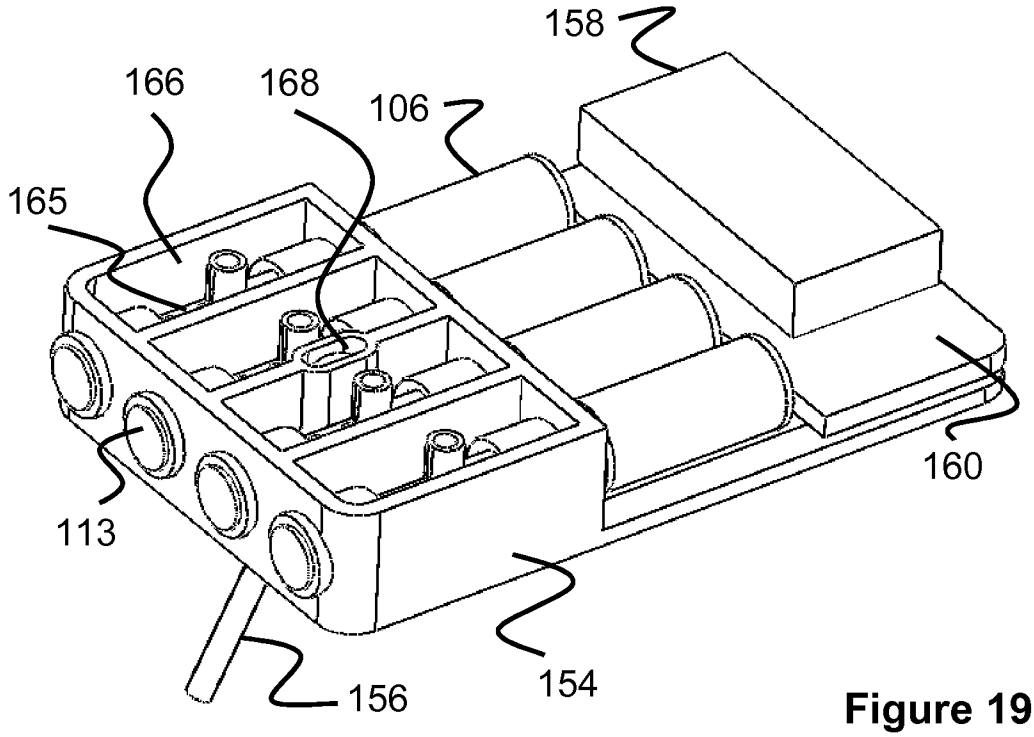


Figure 19

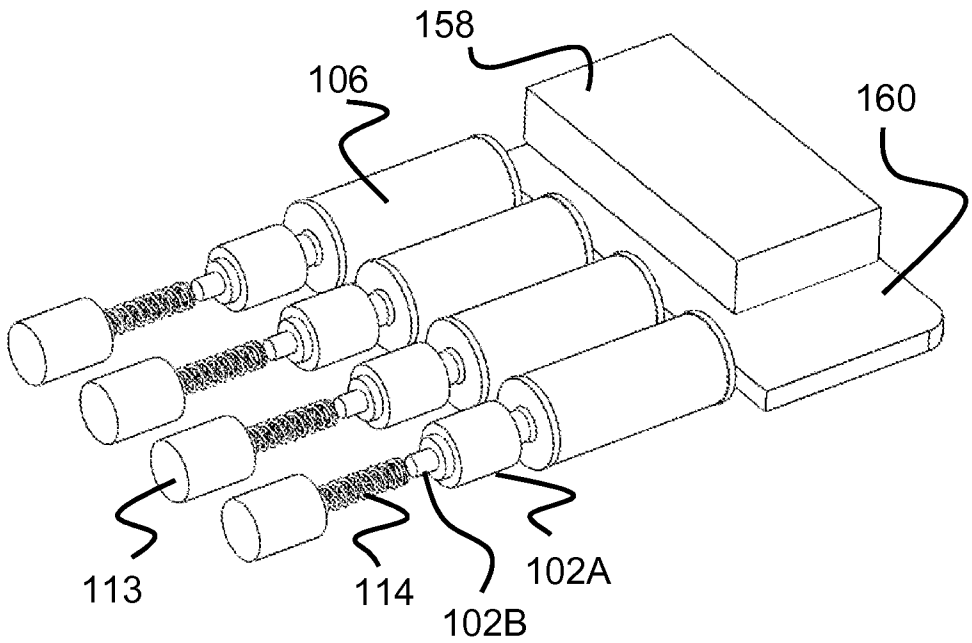


Figure 20

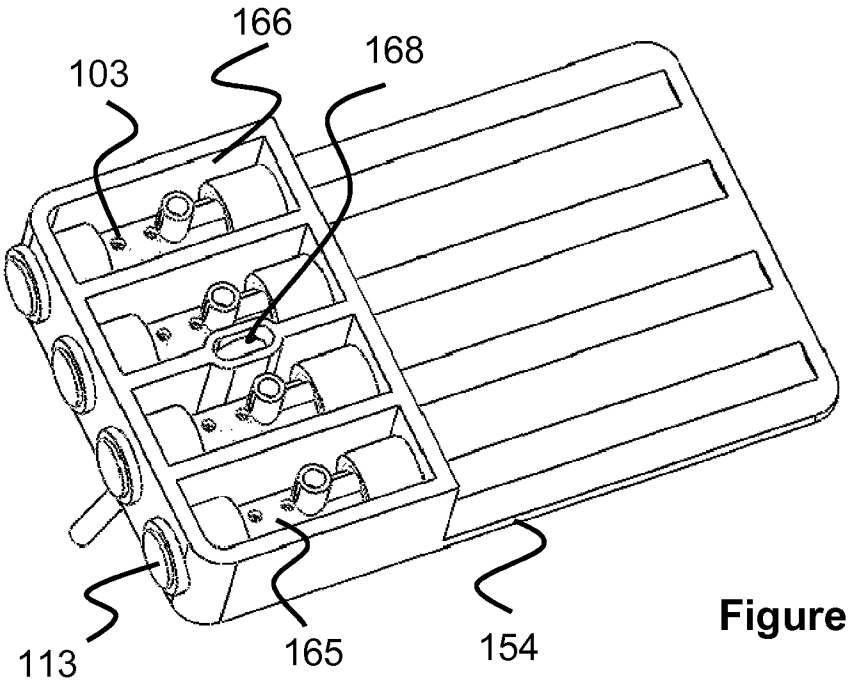


Figure 21

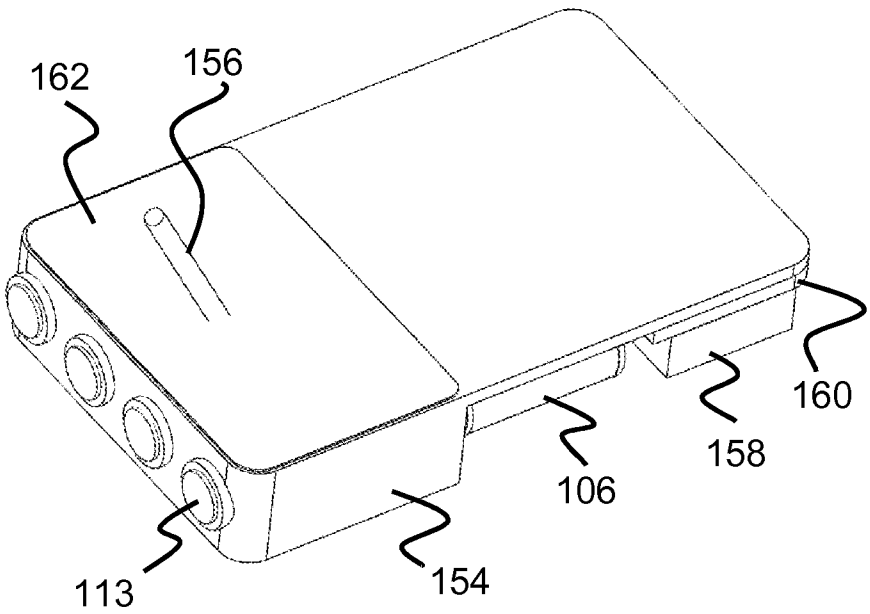


Figure 22

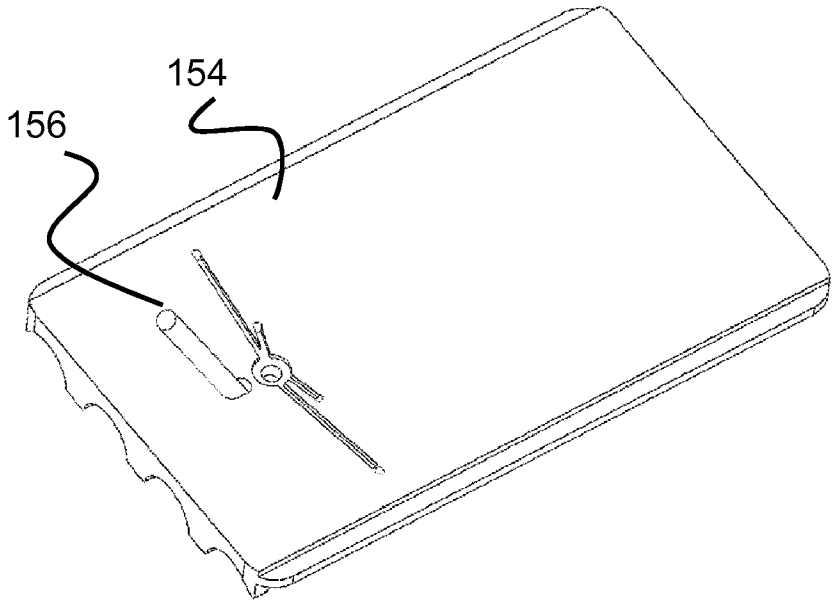


Figure 23

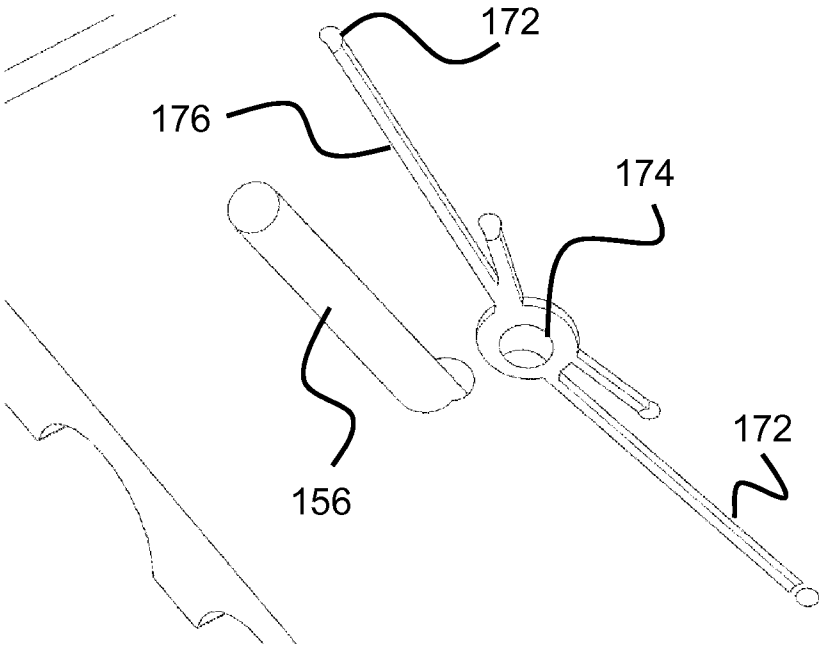
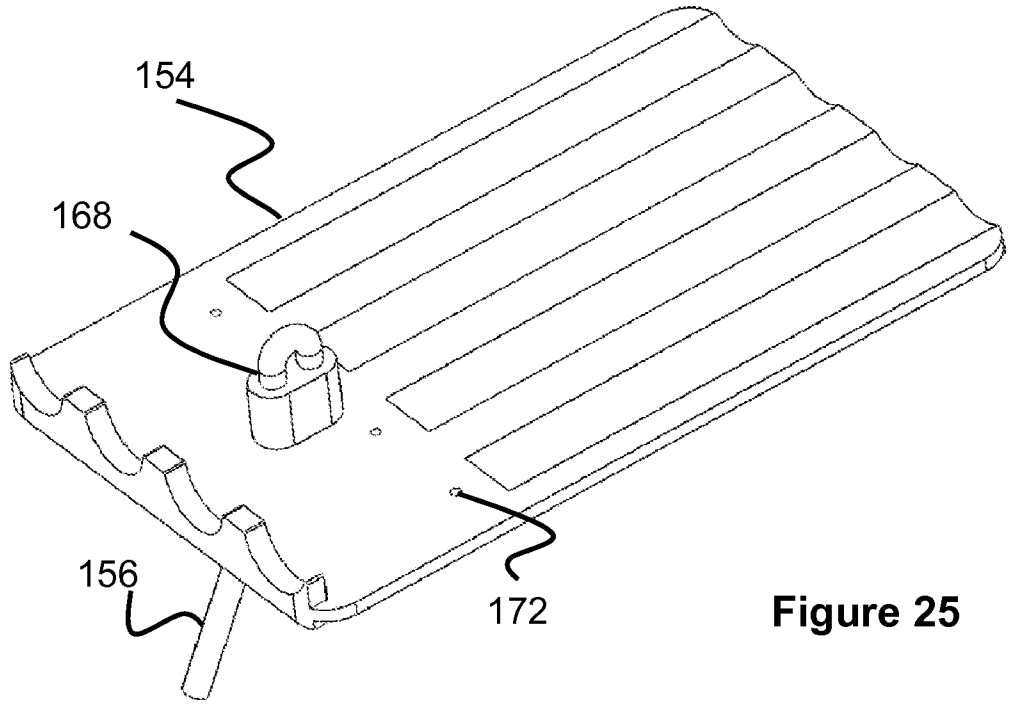


Figure 24



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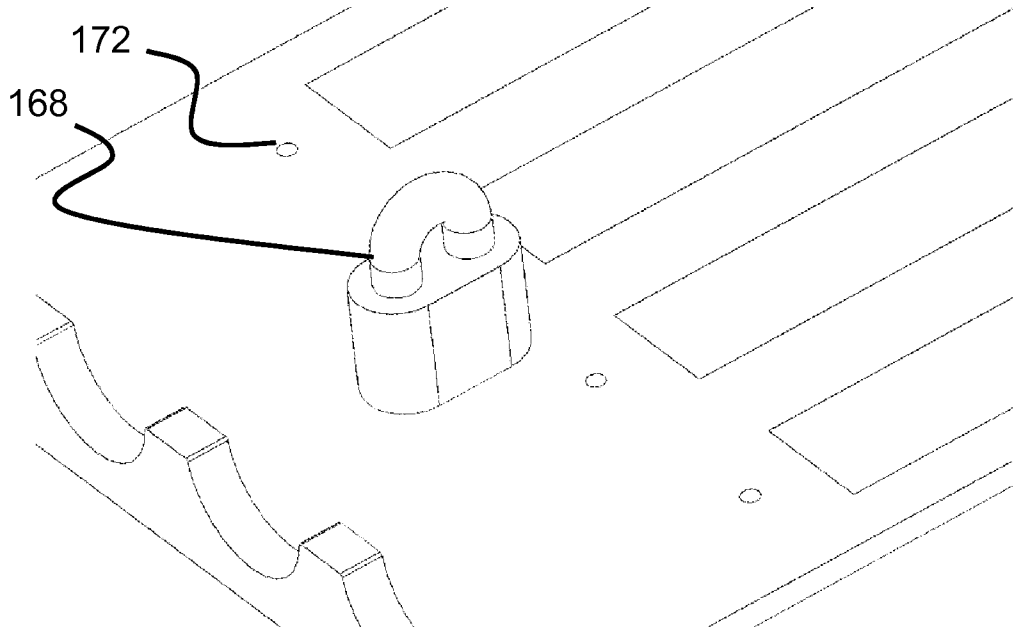

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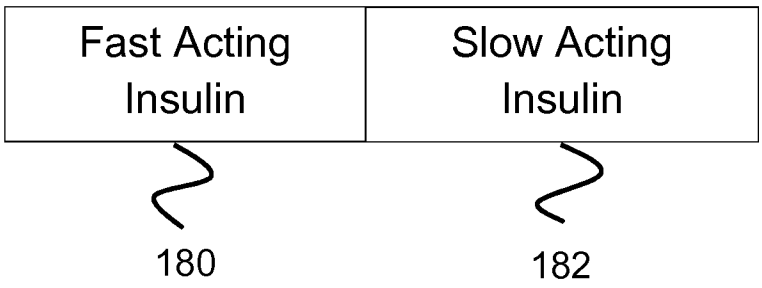

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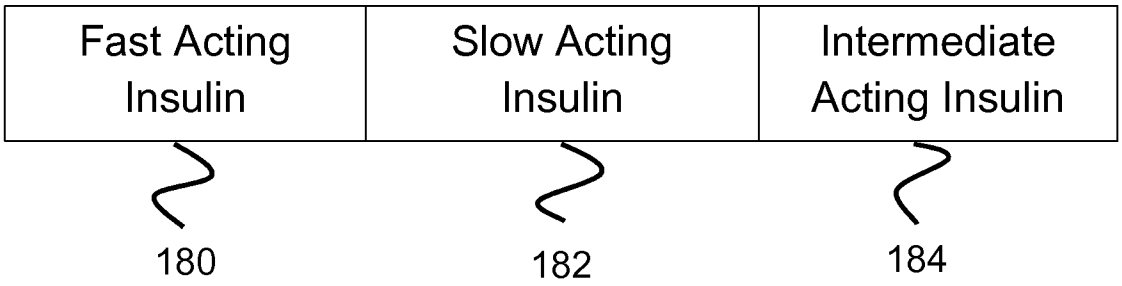

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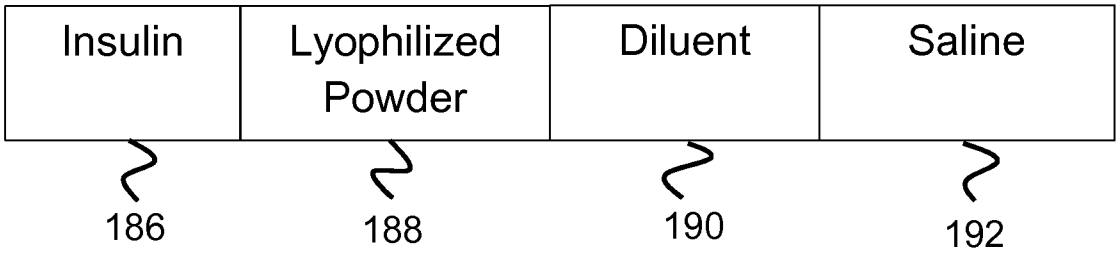

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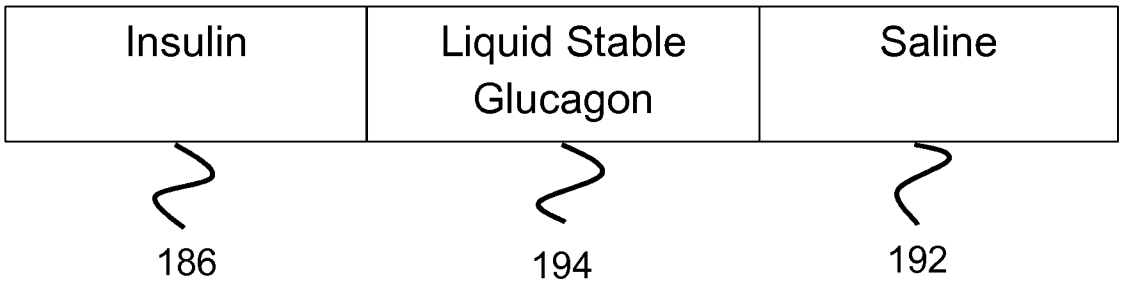

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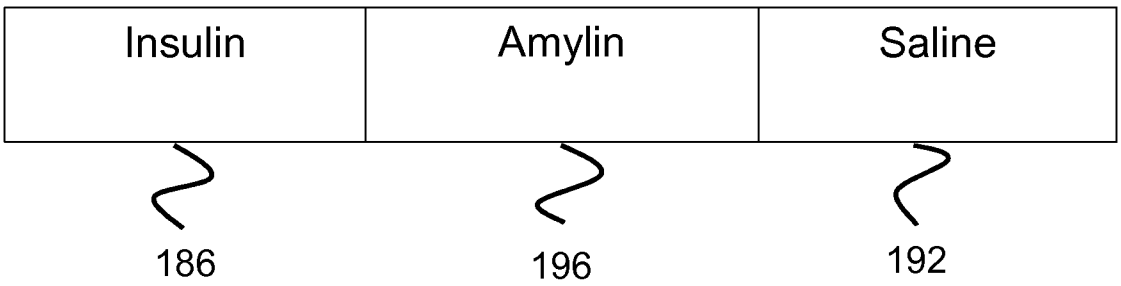

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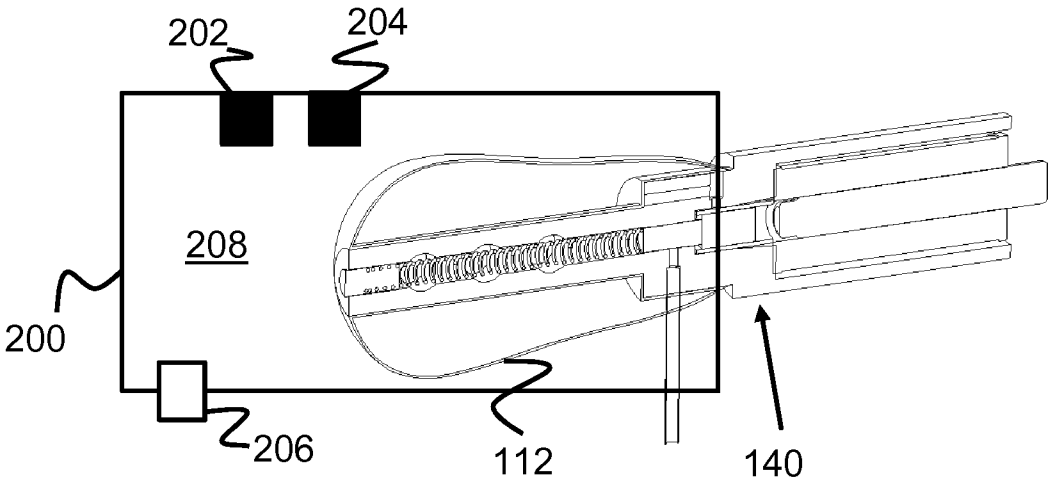

Figure 31

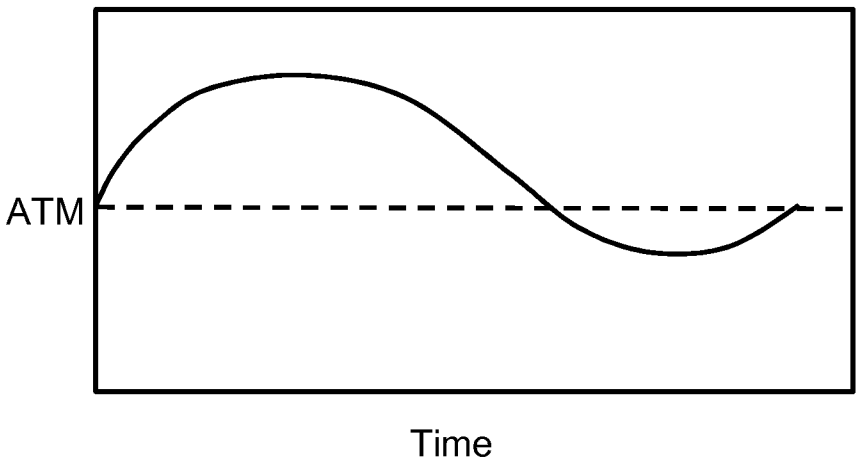

Figure 32

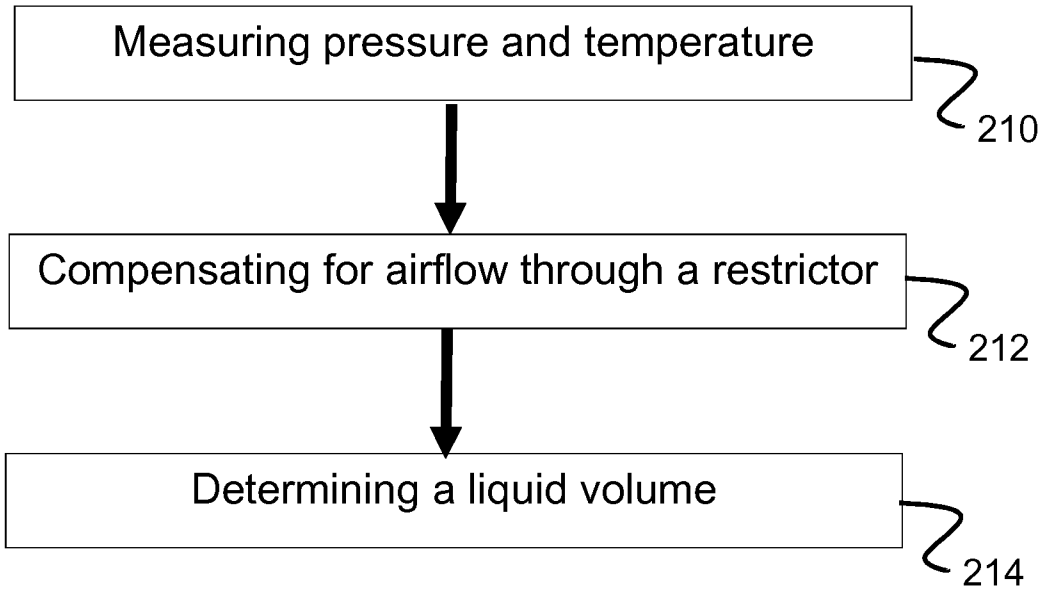

Figure 33

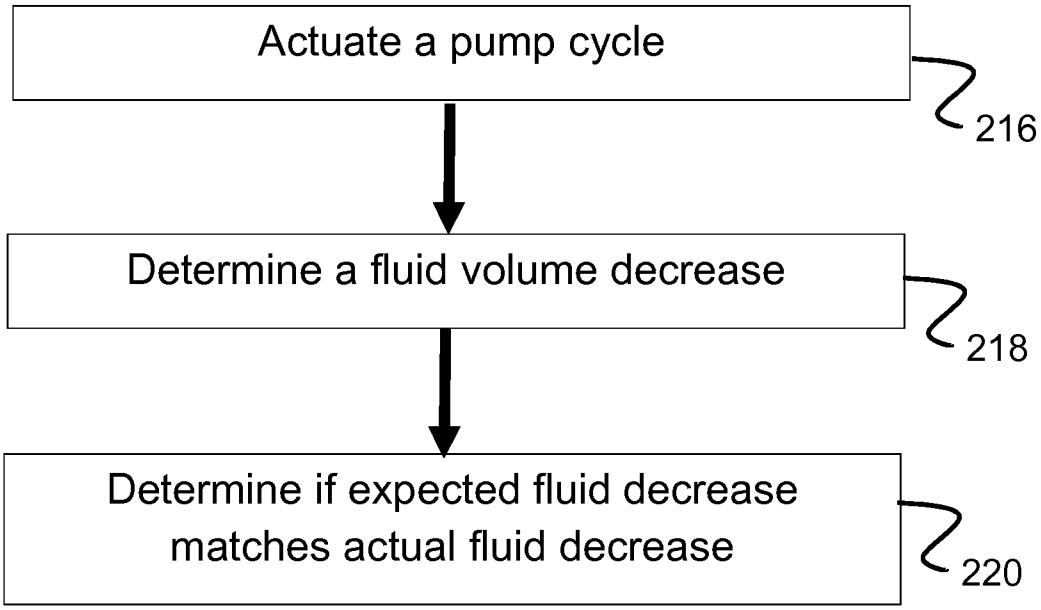

Figure 34

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 15/18525

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 1/00 (2015.01)
CPC - A61M 5/1452
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)
CPC: A61M 5/1452 IPC(8): A61M 1/00 (2015.01).

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 604/151, 152, 153 (keyword limited; terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase; Google Patents; Google
Search Terms Used: infusion, insulin, pump, diaphragm, film, barrier, inlet, outlet, closed, sealed, telescop*, piston%, second piston, housing, reservoir, three, third, tri, third piston, three piston

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/0232992 A1 (GRAY) 16 September 2010 (16.09.2010) fig 3, 7, 8, para [0034]-[0036], [0041]-[0043], [0045], [0047], [0062], [0064]	1-2, 4
A		5
X	US 2011/0021993 A1 (BAR-HAIM et al) 27 January 2011 (27.01.2011) fig 2A, 2B, para [0075]-[0076], [0079]-[0080], [0084]	1, 3
X	US 2008/0051716 A1 (STUTZ) 28 February 2008 (28.02.2008) fig 10-15b, para [0137], [0139]-[0140], [0146], [0153]	1

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
13 July 2015 (13.07.2015)	31 JUL 2015
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 15/18525

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

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

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

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

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

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

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-5, directed to a pump for delivering small quantities of fluid to a user with a three pistons (depicted in figs 1-11b and described in para [0023]-[0040] of the spec).
Group II: Claims 1-2, 4, 6 directed to a pump for delivering small quantities of fluid to a user with two pistons and a flexible sleeve (depicted in figs 12-16 and described in para [0041]-[0046] of the spec).
Group III: Claims 7-12 directed to an insulin pump enclosure having a second pump.
Group IV: Claims 13-16, directed to an insulin pump enclosure having pressure and temperature sensors.

Claim 1-2, 4 are generic to groups I-II.

----Continued on Supplemental Page----

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

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

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

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-5

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 15/18525

Continuation of Box III: Observations where unity of invention is lacking

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The special technical feature of each species (Groups I-II) is provided in the group descriptions above. None of these special technical features are common to the other species, nor do they correspond to a special technical feature in the other species.

The invention of Group III includes the special technical feature of a second pump located within said housing and being connected to output fluid to said outlet, not required by Groups I-II or IV.

The invention of Group IV includes the special technical feature of an air chamber located in said pump housing and having a restrictor venting to the atmosphere outside said pump enclosure; a pressure sensor in communication with said air chamber; a temperature sensor in communication with said air chamber; and, a circuit assembly connected to said temperature sensor and said circuit assembly; wherein said circuit assembly is configured to measure pressure and temperature within said air chamber, compensate for airflow through said restrictor, and calculate a volume of liquid in said fluid reservoir, not required by the claims of Groups I-III.

COMMON TECHNICAL FEATURES

Groups I-II share the common technical features of generic claim 1. Groups I-II are species of generic independent claim 1. The apparatus is known in prior art as shown in US 2008/0051716 A1 (STUTZ).

Regarding claim 1, Stutz discloses a pump (134) for delivering small quantities of fluid to a user, comprising:
a pump housing (136) having an internal lumen (140, fig 10-15b), an inlet port (142) connecting to said internal lumen, and an outlet port (144) connected to said internal lumen (fig 10-15b, para [0139]);
a piston assembly (138, fig 10-15b, para [0139]-[1040]) located within said internal lumen and having a first position causing said inlet to be closed (fig 14 shows piston portion 146 blocking inlet 142) and a second position causing said outlet to be closed (fig 13a shows piston portion 148 blocking outlet 144);
an actuator (84) configured to move said piston assembly between said first position and said second position (fig 10-15b, para [0146]); and a fluid reservoir (126, fig 10) connected to said inlet port (para [0137], [0153]).

Groups I-IV share the common technical feature of a housing having an outlet. However, this special technical feature is known in the art as shown in US 2010/0010443 A1 to Morgan, et al. (hereinafter 'Morgan'), which teaches a housing (10) having an outlet (opening where 16, 22 extends from, fig 1, 4)

Groups I-II and IV share the common technical feature of a fluid reservoir. However, this special technical feature is known in the art as shown in Morgan, which teaches a fluid reservoir (14, fig 1, para [0017]).

Groups III and IV also share the common technical features of a pump disposed in a housing. However, this special technical feature is known in the art as shown in Morgan, which teaches a pump disposed in a housing (10, fig 1, para [0017]).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-IV lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.