

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
30 June 2011 (30.06.2011)

PCT

(10) International Publication Number
WO 2011/079039 A2

(51) International Patent Classification:
A61M 5/145 (2006.01) A61M 5/36 (2006.01)

(21) International Application Number:
PCT/US2010/060949

(22) International Filing Date:
17 December 2010 (17.12.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
12/646,501 23 December 2009 (23.12.2009) US

(71) Applicant (for DE only): **ROCHE DIAGNOSTICS GMBH** [DE/DE]; Sandhofer Strasse 116, 68305 Mannheim (DE).

(71) Applicant (for all designated States except DE, US): **F. HOFFMANN-LA ROCHE AG** [CH/CH]; Grenzacherstrasse 124, CH-4070 Basel (CH).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **BECK, Timothy, L.** [US/US]; 7522 South 25 East, Pendleton, IN 46064 (US). **ALLEN, Janette** [US/US]; 6601 El Paso Drive, Indianapolis, IN 46214 (US). **BURKE, David** [US/US]; 8951 Riverbend Court, Indianapolis, IN 46250 (US).

(74) Agents: **JIVIDEN, William, A.** et al.; Dinsmore & Shohl LLP, Fifth Third Center, Suite 1300, One South Main Street, Dayton, OH 45402-2023 (US).

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

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, 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, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished upon receipt of that report (Rule 48.2(g))

(54) Title: MEDICINAL FLUID DELIVERY SYSTEMS AND METHODS FOR PRIMING THE SAME

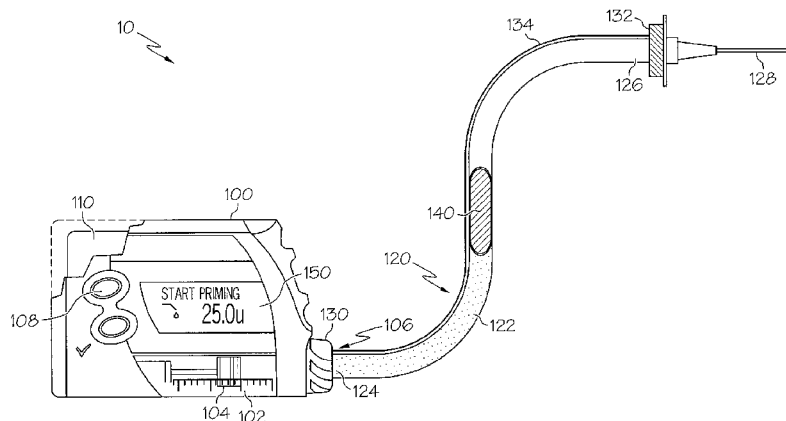


FIG. 1

(57) Abstract: Medicinal fluid delivery systems and methods for priming the same are disclosed. The systems may be configured to measure an electro-transmissive quality of a medicinal fluid when: medicinal fluid is dispensed into a fluid delivery path, a proximal end of the fluid delivery path is in contact with a first electrode, and the distal end of the fluid delivery path is in contact with a second electrode. Methods for priming medicinal fluid delivery systems may include dispensing a medicinal fluid through a fluid delivery path, sensing an electro-transmissive quality of the medicinal fluid, and determining that the fluid delivery path is full based on the electro-transmissive quality.

WO 2011/079039 A2

MEDICINAL FLUID DELIVERY SYSTEMS AND METHODS FOR PRIMING THE SAME

5 Embodiments of the present disclosure generally relate to medicinal fluid delivery systems and, specifically, to priming the fluid delivery path of medicinal fluid delivery systems.

 Persons suffering from diabetes may utilize an insulin pump to administer insulin medication. During the course of insulin pump therapy, the infusion set or the infusion
10 site may be changed. Such changes often require that the infusion set be primed before further administration of insulin. Thus, the infusion set may need to be filled with insulin and be substantially free of air bubbles.

 Accordingly, a need exists for alternative medicinal fluid delivery systems and alternative methods for priming the fluid delivery path of medicinal fluid delivery systems.

15 It is against the above background that embodiments according to the present disclosure are provided which may be configured to measure an electro-transmissive quality of a medicinal fluid when: medicinal fluid is dispensed into a fluid delivery path, a proximal end of the fluid delivery path is in contact with a first electrode, and a distal end of the fluid delivery path is in contact with a second electrode. Methods for priming
20 medicinal fluid delivery systems may include dispensing a medicinal fluid through a fluid delivery path, sensing an electro-transmissive quality of the medicinal fluid, and determining that the fluid delivery path is full based on the electro-transmissive quality.

 In one embodiment, a medicinal fluid delivery system includes a medicinal fluid pump operably connected to a controller and fluidically connected to a tube including at
25 least a portion of a fluid delivery path. The fluid delivery path includes a proximal end and a distal end. A first electrode may be in electrical communication with the controller, and a second electrode may be in electrical communication with the controller. The controller may be configured to measure an electro-transmissive quality of a medicinal fluid when: the pump dispenses the medicinal fluid into the fluid delivery path, the

-2-

proximal end is in contact with the first electrode, and the distal end is in contact with the second electrode.

In another embodiment, a medicinal fluid delivery system includes a medicinal fluid pump operably connected to a controller, and a fluid delivery path at least partially within a tube. The tube may be in fluidic communication with the pump and the fluid
5 delivery path includes a proximal end and a distal end. A first electrode may be disposed on the pump and in electrical communication with the controller, wherein the first electrode may be in contact with the proximal end. A second electrode may be disposed on the pump and in electrical communication with the controller, wherein when the second
10 electrode may be in contact with the distal end. The pump may dispense a medicinal fluid into the fluid delivery path. The pump may be configured to reclaim any of the medicinal fluid that is dispensed beyond the distal end. The controller may be configured to:
measure an electro-transmissive quality of the medicinal fluid, detect that the sterile fluid delivery path is filled with the medicinal fluid based on the electro-transmissive quality,
15 detect a fluidic effervescence of the medicinal fluid based on the electro-transmissive quality, and reduce the fluidic effervescence of the medicinal fluid via a fluidic agitation or a fragmenting signal.

In still another embodiment, a method for priming a medicinal fluid delivery system may include: dispensing a medicinal fluid through a fluid delivery path at least
20 partially within a tube, wherein the fluid delivery path includes a proximal end and a distal end; sensing an electro-transmissive quality of the medicinal fluid between a first electrode in contact with the proximal end and a second electrode in contact with the distal end; and determining that the fluid delivery path is full based on the electro-transmissive quality.

25 These and other embodiments of the present disclosure will become readily apparent to those skilled in the art from the following detailed description with reference to the attached figures, with no limitation to any particular embodiment(s) disclosed herein.

30

The embodiments set forth in the drawings are illustrative and exemplary in nature and not intended to limit the embodiments defined by the claims. The following detailed description of the illustrative embodiments can be understood when read in conjunction with the following drawings, where, when possible, like structure is indicated with like
5 reference numerals and in which:

FIG. 1 depicts a medicinal fluid delivery system with multiple cut-away portions according to one or more embodiments shown and described herein;

FIG. 2 depicts a medicinal fluid delivery system with a cut-away portion according to one or more embodiments shown and described herein;

10 FIG. 3 depicts a medicinal fluid delivery system with a cut-away portion according to one or more embodiments shown and described herein;

FIG. 4A depicts a partial cut-away view the distal end of a medicinal fluid delivery system according to one or more embodiments shown and described herein;

15 FIG. 4B depicts a partial cut-away view the distal end of a medicinal fluid delivery system according to one or more embodiments shown and described herein;

FIG. 5 depicts a block diagram of the internal components of a medicinal fluid pump according to one or more embodiments shown and described herein; and

FIG. 6 depicts a method for priming a medicinal fluid delivery system according to one or more embodiments shown and described herein.

20 The present specification will describe below various illustrative embodiments. Those skilled in the art will appreciate that the present specification may be implemented in a number of different applications and embodiments and is not specifically limited in its application to the particular embodiments depicted herein. In particular, the present specification will be discussed below in connection with systems and methods for priming
25 a medicinal fluid delivery system comprising a pump, although those of ordinary skill will recognize that the present disclosure could be modified to be used with other types of medicinal delivery systems besides those comprising pumps such as for example, an intravenous drip.

As used herein with the various illustrated embodiments described below, the following terms include, but are not limited to, the following meanings.

The term “prime” means to fill a volume with a fluid in a manner such that the volume is substantially free of air, and the like.

5 The term “actuator” means a mechanism which displaces a fluid by physical or mechanical action such as for example, an impeller, a piston, a rotor, a compression member, and the like.

 The term “contact” means to couple multiple electrical components for electrical communication via a conductive mechanism such as for example, terminal blocks, posts,
10 solder joints, integrated circuit traces, wires, and the like.

 The term “user interface” means a mechanism by which a user interacts with a system such as for example, a button, a switch, a touch screen, a roller ball, a voice command system, and the like.

 The term “memory” means a storage device for retaining electronic data for later
15 access such as for example, RAM, ROM, flash memory, hard drive, and the like.

 The term “sterile” means substantially free of biological contaminants such that a medical device or fluid may be suitable for use.

 The term “electro-transmissive quality” means a quantity inherent to a fluid that can be measured by optical or electrical mechanisms such as for example, interruption of a
20 light path, circuit analysis, and the like.

 The term “fluidic effervescence” means a quantity inherent to a contained volume of fluid that can be measured to provide information regarding undesired voids such as for example, air, gas, volumetric impurities, and the like.

 The term “fragmenting signal” means a signal that can be induced to travel through
25 an enclosed volume to remove undesired voids such as for example, an electrical signal, an ultrasonic signal, a wave, and the like.

The term “fluidic agitation” means a mechanical disturbance of a fluid that can remove undesired voids such as for example, an oscillation, a pressure change, a vibration, a translation, and the like.

The embodiments described herein generally relate to medicinal fluid delivery systems and methods for priming the same. As will be described in more detail herein, a medicinal fluid delivery system generally comprises a medicinal fluid pump, a fluid delivery path, a first electrode, a second electrode and a controller. The system may be arranged such that the pump is in fluidic communication with the fluid delivery path and the controller operates to dictate the operations of the pump. The first electrode and the second electrode may be in contact with portions of the fluid delivery path and in electrical communication with the controller. The operation and structure of embodiments of the present disclosure will be described in more detail below, with each of the above stated components described in turn.

As shown in FIG. 1, embodiments of the medicinal fluid delivery system 10 may comprise a medicinal fluid pump 100, or pump 100. The pump 100 may be a portable device, which may comprise a reservoir 102 for holding medicinal fluid 140, and an actuator 104, depicted as a plunger. The pump 100 may also comprise internal components (FIG. 5) such as, a memory 112, a controller 110, a user interface 108, and an alert indicator 150, an inlet 107 and an outlet 106, all of which will be described in more detail herein. The pump 100 may be operable to dispense the medicinal fluid 140 either manually according to user input from the user interface 108 or automatically according to programmed instructions 114 stored in the memory 112. Whether by manual input or automatic instructions, the controller 110, as will be described in more detail below, may cause the actuator 104 to force the medicinal fluid 140 from the reservoir 102 through the outlet 106. For example, an insulin pump may automatically dispense insulin according to an automated schedule by causing a plunger to dispense insulin out of a syringe.

Referring now to FIG. 1-3, embodiments may comprise a fluid delivery path 122. The fluid delivery path 122 may be a volumetric enclosure adapted for the transport of medicinal fluid 140 that spans from the outlet 106 of the medicinal fluid 140 to the delivery point 128. Further, the fluid delivery path 122 may comprise a proximal end 124

-6-

and a distal end 126. Such that, the proximal end 124 may be the portion of the fluid delivery path 122 nearest the outlet 106 and the distal end 126 may be the portion of the fluid delivery path 122 nearest the delivery point 128. For example, as shown in FIG.1, the pump 100 may comprise the outlet 106 and the delivery point 128 may be configured
5 for subcutaneous insertion, such as a cannula. It should be noted that, while the fluid delivery path 122 is depicted as being completely enclosed by a tube 120, it is contemplated that portions of the fluid delivery path 122 may be enclosed by other portions of the medicinal fluid delivery system 10, such as, but not limited to, the pump 100 (FIG. 1) or pump 101 (FIG. 2-3), or delivery point 128. Thus, less than the entire
10 fluid delivery path 122 may be enclosed by the tube 120. It should be noted that the tube 120 may comprise an infusion set, for example, or any other enclosure suitable for the sterile transportation of medicinal fluid 140.

As described above, portions of the fluid delivery path 122 may be in contact with a first electrode 130 and a second electrode 132. Thus embodiments of the medicinal fluid
15 delivery system 10 may comprise a first electrode 130 and a second electrode 132, as best seen in FIG. 1-3. The first electrode 130 and the second electrode 132, or electrodes 130/132, may comprise any material suitable for conducting electricity, such as copper, gold or any known or yet to be discovered conductive material. The electrodes may also comprise any shape such that they are configured to make electrical contact with the
20 medicinal fluid 140 within the fluid delivery path 122. While the first electrode 130 and the second electrode 132 are depicted (FIG. 1) as cylindrical, the electrodes may comprise other shapes. For example, the electrodes may be alternatively configured to be surrounded by the medicinal fluid 140 within the fluid delivery path 122, as opposed to surrounding the medicinal fluid 140 (FIG. 1-3), and thus, be pin-shaped or needle-shaped.
25 It should be noted that, the above embodiments of the electrodes are merely illustrative in nature, and those of ordinary skill will recognize various alternative materials and shapes.

Since the electrodes may be in electrical communication with the controller, embodiments of the present disclosure may comprise a controller 110 (FIG. 1). While the controller 110 is depicted as a microprocessor, the controller 110 may be any type of
30 computing device capable of executing programmed instructions 114, such as, but not

limited to, a computer, a server, an integrated circuit, or silicon chip. Thus, with reference to FIG. 5, the controller 110 may be configured to communicate electronically (depicted as block arrows) to components such as: the memory 112, the actuator 104, the alert indicator 150, and the user interface 108. Such electronic communication may allow the controller 5 110 to receive instructions and dictate operations. And while the controller 110 is depicted in FIG. 1 and FIG. 5 as an integral component of the pump 100, it should be noted that the controller 110 may be a stand alone unit, such as a computer, with an operable connection with the pump 100 or pump 101 (FIG. 2-3) in embodiments of the present disclosure.

10 According to an embodiment of the present disclosure, FIG. 1 depicts a medicinal fluid delivery system 10. The medicinal fluid delivery system 10 may comprise a medicinal fluid pump 100 with an operable connection to a controller 110. The pump may comprise a reservoir 102, an actuator 104, an outlet 106 and an alert indicator 150. The pump 100 may be fluidically connected to a tube 120 such that at least a portion of a fluid 15 delivery path 122 is within the tube 120. The fluid delivery path 122 may span from the outlet 106 through the delivery point 128, which may include any enclosure within the delivery point 128, and may comprise a proximal end 124 and a distal end 126. A first electrode 130 may be in contact with the proximal end 124, and a second electrode 132 may be in contact with the distal end 126, such that the first electrode 130 and the second 20 electrode 132 are in electrical communication with the controller 110. The electrical communication between the electrodes 130 and 132 and the controller 110 may be via a conductive trace 134. The conductive trace 134 may comprise any material suitable for conducting electricity, as described hereinabove. While a conductive trace 134 is depicted as a wire running along the outside of the tube 120, it is contemplated that the conductive 25 trace may be enclosed by the tube 120 or may be integral with the tube 120.

Referring now to FIG. 2-3, another embodiment of the medicinal fluid delivery system 10 is depicted. The medicinal fluid delivery system 10 may comprise a medicinal fluid pump 101 with an operable connection to a controller 110 (not shown in FIG. 2-3). The pump may comprise a reservoir 102, an actuator 104, an outlet 106, a first electrode 30 130, a second electrode 132 and an alert indicator 150. The pump 100 may be fluidically

connected to a tube 120 such that at least a portion of a fluid delivery path 122 is within the tube 120. The fluid delivery path 122 may span from the outlet 106 to the delivery point 128, and may comprise a proximal end 124 and a distal end 126. The first electrode 130 may be in contact with the proximal end 124, and the second electrode may be
5 configured to accept the delivery point 128. Further, the first electrode 130 and the second electrode 132 may be in electrical communication with the controller 110 (not shown in FIG. 2-3).

The controller 110, as shown in FIG. 5, may cause the pump 100 to dispense the medicinal fluid 140 from the reservoir 102 through the outlet 106 by, for example, causing
10 the actuator 104 to translate, thus, forcing the medicinal fluid 140 from the reservoir 102. Such a dispensation may be initiated by a manual command, such as by pressing a user interface 108, depicted as a button in FIG. 1, or according to programmed instructions 114 (FIG. 5) stored on the memory 112 and electronically communicable to the controller 110, such as a basal dosing schedule. Referring now to FIG. 1, upon exiting the outlet 106, the
15 medicinal fluid 140 may enter the fluid delivery path 122 at the proximal end 124. Thus a portion of the proximal end 124 can be filled with the medicinal fluid 140, and the first electrode 130 may be in contact with the proximal end 124 and the medicinal fluid 140. When such contact is made, some of the medicinal fluid 140 may be within the fluid delivery path 122 and between the first electrode 130 and the second electrode 132. As
20 such, the controller 110 can measure an electro-transmissive quality of a medicinal fluid 140, as will be described in more detail below.

The electro-transmissive quality may be determined by, for example, but not limited to, creating an electrical potential difference between the first electrode 130 and the second electrode 132. Since, the first electrode 130 may be in contact with the
25 proximal end 124, and the second electrode 132 may be in contact with the distal end 126, a current can be induced to travel through the medicinal fluid 140 between the two electrodes 130/132. For example, when the medicinal fluid 140 transitions from being in contact with only the proximal end 124 (FIG. 1-2) to being in contact with both electrodes 130/132 (FIG. 3), a change in magnitude of the current traveling between the electrodes
30 130/132 may occur. Such a transition may be analogous to the current flowing through an

open compared to a closed electrical circuit, i.e. when medicinal fluid 140 appears at the second electrode 132 the circuit is closed. Thus when the controller 110 is in electrical communication with the electrodes, the controller 110 may be configured to detect that the fluid delivery path 122 is filled with the medicinal fluid 140 based on the electro-

5 transmissive quality, for example by executing programmed instructions 114 stored on the memory 112 (FIG. 5). Similarly, with reference to FIG. 3, the controller 110 may be configured to detect that the fluid delivery path 122 is filled when the electro-transmissive quality corresponds to a change in impedance or admittance between the electrodes 130/132. Such a change, may be for example, a drop in impedance attributed to the

10 medicinal fluid 140 after correcting for effects caused by the tube 120 that may contribute to the impedance, e.g. latent charges remaining within the tube 120. Furthermore, as described below, the controller may provide feedback regarding detections.

In embodiments of the present disclosure, the controller 110 (FIG. 1) can be configured to provide an indication that the fluid delivery path 122 is filled with medicinal

15 fluid 140. For example, the controller 110 can provide an indication with the alert indicator 150, depicted as a display screen (FIG. 1-3), such that information is communicated with visible light, or the alert indicator 150 may be configured to provide the indication as an audible sound. In other embodiments, the alert indicator 150 may be configured to provide a tactile indication, such as, for example, a vibration. Additionally,

20 the pump 100 (FIG. 1) or 101 (FIG. 2-3) may be configured to automatically stop dispensing the medicinal fluid 140 into the fluid delivery path 122 when the controller 110 (FIG. 1) detects that the fluid delivery path 122 is filled with the medicinal fluid 140, as described hereinabove.

As disclosed in the preceding paragraphs, the electro-transmissive quality may be

25 useful for the detection of a full fluid delivery path 122. Additionally, the electro-transmissive quality may also be useful for detecting the fluidic effervescence of the medicinal fluid 140. Therefore, embodiments of the medicinal fluid delivery system 10 may comprise a controller 110 configured to detect the fluidic effervescence of the medicinal fluid 140 based on the electro-transmissive quality. The controller may detect

30 an electro-transmissive quality, such as, but not limited to an impedance. For example, as

-10-

depicted in FIG. 4A, the medicinal fluid 140 may contain a number of air bubbles 142, and a high number of air bubbles 142 may equate to a high fluidic effervescence.

Correspondingly, when the controller 110 (FIG. 1) is configured to measure impedance, a relatively high impedance value may equate to a high number of air bubbles 142, and,

5 thus, a high fluidic effervescence. As such, the controller 110 may be configured to detect the fluidic effervescence of the medicinal fluid 140. Furthermore, as will be described in more detail below, the controller 110 may also be operative to execute actions according to the fluidic effervescence based on programmed instructions 114, for example causing the pump 100 to agitate the fluid or providing an indication with the alert indicator 150.

10 According to embodiments of the present disclosure, the controller 110 may be configured to reduce the fluidic effervescence of the medicinal fluid 140. As described herein, the fluidic effervescence is related to the number of air bubbles 142 (FIG. 4A) within the medicinal fluid 140, and may be reduced by reducing the number of air bubbles 142. The controller 110 (FIG. 1) may reduce the fluidic effervescence by transmitting a
15 fragmenting signal, such as for example, a current, from the first electrode to the second electrode. Also, the controller 110 may cause the pump 100, or pump 101 (FIG. 2-3), to generate a fluidic agitation such that the number of air bubbles 142 (FIG. 4A) is reduced by, for example, oscillating the actuator 104 or dispensing more medicinal fluid 140. Alternatively, the pump 100 (FIG. 1), or pump 101 (FIG. 2-3), may be configured to
20 reduce the fluidic effervescence via a fluidic agitation independent of the controller 110 (FIG. 1). In further embodiments, the pump 100 (FIG. 1), or pump 101 (FIG. 2-3), may be configured to reduce the fluidic effervescence via a manual agitation, such as, but not limited to, a physical manipulation of the medicinal fluid 140 by an external force. The above mechanisms for reducing the fluidic effervescence may occur manually or
25 automatically, as will be described in more detail below.

The controller 110 may be configured to automatically reduce the fluidic effervescence to an acceptable amount, such as, no air bubbles 142 as depicted in FIG. 4B. However, while FIG. 4B depicts no air bubbles, it should be noted that an acceptable level of fluidic effervescence may correlate to any amount of air bubbles 142 near zero, such as,
30 no air bubbles 142 visible to the human eye, or a number of air bubbles 142 such that the

-11-

administration of the medicinal fluid 140 is not compromised. Thus, the acceptable amount of fluidic effervescence may correspond to a threshold value stored in the memory 112 for a electro-transmissive quality and the controller 110 (FIG. 5) may be configured to automatically initiate one of the above described mechanisms for reducing the fluidic effervescence upon a failure to meet the threshold, or according to programmed instructions 114 stored on the memory 112. Similarly, the controller 110 may be configured to automatically provide an indication of a failure to meet the threshold with the alert indicator 150 (FIG. 1-3), detailed hereinabove.

Embodiments of the medicinal fluid delivery system 10 may be configured to reclaim medicinal fluid 140 that may be dispensed beyond the distal end 126 during the priming of the fluid delivery path 122. Therefore, as shown in FIG. 3, the medicinal fluid delivery system 10 may comprise a sterile fluid path 123 for the reclamation of medicinal fluid 140 by the pump 101. For example, when the tube 120 transitions from the unengaged position (FIG. 2) to an engaged position (FIG. 3) and creates a loop such that the delivery point 128 is within the pump 101, the proximal end 124 may be in contact with the first electrode 130 and the distal end 126 may be in contact with the second electrode 132. As such, a sterile fluid path 123 may be provided and the medicinal fluid 140 may be dispensed through the sterile fluid path 123 back into the reservoir 102 via the inlet 107 (FIG. 5), or any other storage location. Thus, referring back to FIG. 3, the pump 101 may be configured to reclaim any of the medicinal fluid 140 that may be dispensed beyond the distal end 126. It should be noted that, while the pump 101 is depicted as comprising both electrodes 130/132, embodiments of the present disclosure may provide for a sterile fluid path 123 without the pump 101 comprising any electrodes 130/132.

As described herein, embodiments of the medicinal fluid delivery system 10 may be operable such that the fluid delivery path 122 is primed according to programmed instructions 114 stored in the memory 112 and executed by the controller 110. FIG. 6 depicts a method 60 for priming embodiments of the medicinal fluid delivery system 10. At act 600, a user may attach a tube 120 to a pump 101. The tube 120 may be attached such that the proximal end 124 is in contact with the first electrode 130 and the distal end 126 is in contact with the second electrode 132. Additionally, in accordance with act 605,

a user may initiate the priming. The priming may be initiated through interaction with the user interface 108 such as, but not limited to, pushing a "prime" button. As such, the initiation may cause the controller 110 to follow a priming procedure according to programmed instructions 114 stored on in the memory 112.

5 At act 610, the pump 101 may dispense medicinal fluid 140 through a fluid delivery path 122. After dispensing, the fluid delivery path 122, which may be at least partially within the tube 120, may contain medicinal fluid 140 between the proximal end 124 and the distal end 126. At act 615, the controller 110 may sense an electro-transmissive quality, as described in detail above. Based on the electro-transmissive
10 quality, the controller 110 may determine that the fluid delivery path 122 is full, as in act 620. Thus, the fluid delivery path 122 may be filled with medicinal fluid 140 and the controller 110 may store the electro-transmissive quality in memory 112 or provide an indication relating to the fullness of the fluid delivery path 122, as detailed hereinabove.

 In addition to making such a determination, the controller 110 may detect a fluidic
15 effervescence in accordance with act 625. For example, the controller 110 may sense the impedance of the medicinal fluid 140 and make a comparison with information stored on the memory 112 to calculate the fluidic effervescence. Upon calculating the fluidic effervescence, the controller 110 may complete an operation according to programmed instructions 114 stored in memory 112, such as for example, storing the fluidic
20 effervescence in memory 112, or providing an indication, as described above.

 Additionally, in accordance with act 630, the controller 110 may reduce the fluidic effervescence of the medicinal fluid 140. The reduction may be accomplished by transmitting a fragmenting signal from the first electrode 130 to the second electrode 132, or agitating the medicinal fluid 140, as described herein. Upon such a reduction the fluidic
25 effervescence of the medicinal fluid 140 may be reduced such that that the tube 120 is suitable for subcutaneous insertion. Further, the pump 101 may reclaim any medicinal fluid 140, act 635, such that medicinal fluid 140 that may be dispensed out of the fluid delivery path 122 during priming can be reused. For example, the distal end 126 may be inserted into the inlet 107 during priming, and the medicinal fluid 140 dispensed past the
30 distal end 126 may flow through the inlet 107 for storage in the reservoir 102.

-13-

It should now be understood that various embodiments of the medicinal fluid delivery system 10 may be configured to assist in the priming of a fluid delivery path 122, which may comprise a cannula, with insulin. For example, an infusion set may be attached to an insulin pump. The insulin pump may begin priming the infusion set when a
5 "prime" button is pushed. The insulin pump, as described hereinabove, may be configured to detect that the infusion set is filled with insulin and free of air bubbles, such that insulin extends out of the end of the cannula. The insulin pump may be further configured to provide a sterile path to reclaim insulin that is dispensed beyond the cannula during priming for reuse.

10 Thus, embodiments of medicinal fluid delivery systems and methods for priming the same are disclosed. One skilled in the art will appreciate that the teachings can be practiced with embodiments other than those disclosed. The disclosed embodiments are presented for purposes of illustration and not limitation, and the invention is only limited by the claims that follow.

15

CLAIMS

1. A medicinal fluid delivery system comprising:
 - a medicinal fluid pump operably connected to a controller and fluidically
 - 5 connected to a tube comprising at least a portion of a fluid delivery path, wherein the fluid delivery path comprises a proximal end and a distal end;
 - a first electrode in electrical communication with the controller; and
 - a second electrode in electrical communication with the controller wherein, the controller is configured to measure an electro-transmissive quality of a medicinal fluid
 - 10 when:
 - the pump dispenses the medicinal fluid into the fluid delivery path;
 - the proximal end is in contact with the first electrode; and
 - the distal end is in contact with the second electrode.
- 15 2. The system of claim 1 wherein the controller is configured to detect that the fluid delivery path is filled with the medicinal fluid based on the electro-transmissive quality.
3. The system of claim 2 wherein the electro-transmissive quality is a current, an impedance or an admittance.
- 20 4. The system of claim 2 wherein the controller is configured to provide an indication that the fluid delivery path is full when the controller detects that the fluid delivery path is filled with medicinal fluid.
- 25 5. The system of claim 4 wherein the indication is tactile, an audible sound or a visible light.
6. The system of claim 2 wherein the pump is configured to automatically stop dispensing the medicinal fluid into the fluid delivery path when the controller detects that
- 30 the fluid delivery path is filled with the medicinal fluid.

7. The system of claim 1 wherein the controller is configured to detect a fluidic effervescence of the medicinal fluid based on the electro-transmissive quality.
8. The system of claim 7 wherein the controller is configured to reduce the fluidic effervescence of the medicinal fluid via a fluidic agitation or by transmitting a fragmenting signal from the first electrode to the second electrode.
9. The system of claim 7 wherein the controller is configured to provide an alert based on the fluidic effervescence of the medicinal fluid.
10. The system of claim 7 wherein the controller is configured to detect that the fluid delivery path is filled with the medicinal fluid based on the electro-transmissive quality.
11. The system of claim 1 wherein the pump is configured to provide a sterile fluid path when the proximal end is in contact with the first electrode and the distal end is in contact with the second electrode.
12. The system of claim 11 wherein the pump is configured to reclaim any of the medicinal fluid that is dispensed beyond the distal end.
13. The system of claim 12 wherein the pump comprises the first electrode and the second electrode.
14. A medicinal fluid delivery system comprising:
a medicinal fluid pump operably connected to a controller;
a fluid delivery path at least partially within a tube wherein, the tube is in fluidic communication with the pump and the fluid delivery path comprises a proximal end and a distal end;
a first electrode disposed on the pump and in electrical communication with the controller, wherein the first electrode is in contact with the proximal end; and

-16-

a second electrode disposed on the pump and in electrical communication with the controller, wherein when the second electrode is in contact with the distal end and the pump dispenses a medicinal fluid into the fluid delivery path, the controller is configured to:

- 5 measure an electro-transmissive quality of the medicinal fluid;
 detect that the fluid delivery path is filled with the medicinal fluid based on the electro-transmissive quality;
 detect a fluidic effervescence of the medicinal fluid based on the electro-transmissive quality; and
10 reduce the fluidic effervescence of the medicinal fluid via a manual agitation, a fluidic agitation or a fragmenting signal.

15. The system of claim 14 wherein the pump is configured to reclaim any of the medicinal fluid that is dispensed beyond the distal end.

15

16. A method for priming a medicinal fluid delivery system comprising:
 dispensing a medicinal fluid through a fluid delivery path at least partially within a tube, wherein the fluid delivery path comprises a proximal end and a distal end;
 sensing an electro-transmissive quality of the medicinal fluid between a first
20 electrode in contact with the proximal end and a second electrode in contact with the distal end; and
 determining that the fluid delivery path is full based on the electro-transmissive quality.

25 17. The method of claim 16 further comprising:
 detecting a fluidic effervescence of the medicinal fluid based on the electro-transmissive quality.

18. The method of claim 17 further comprising:
30 transmitting a fragmenting signal from the first electrode to the second electrode;
 and reducing the fluidic effervescence of the medicinal fluid.

19. The method of claim 17 further comprising:
agitating the medicinal fluid; and
reducing the fluidic effervescence of the medicinal fluid.
- 5
20. The method of claim 16 further comprising reclaiming any of the medicinal fluid
that is dispensed beyond the distal end.

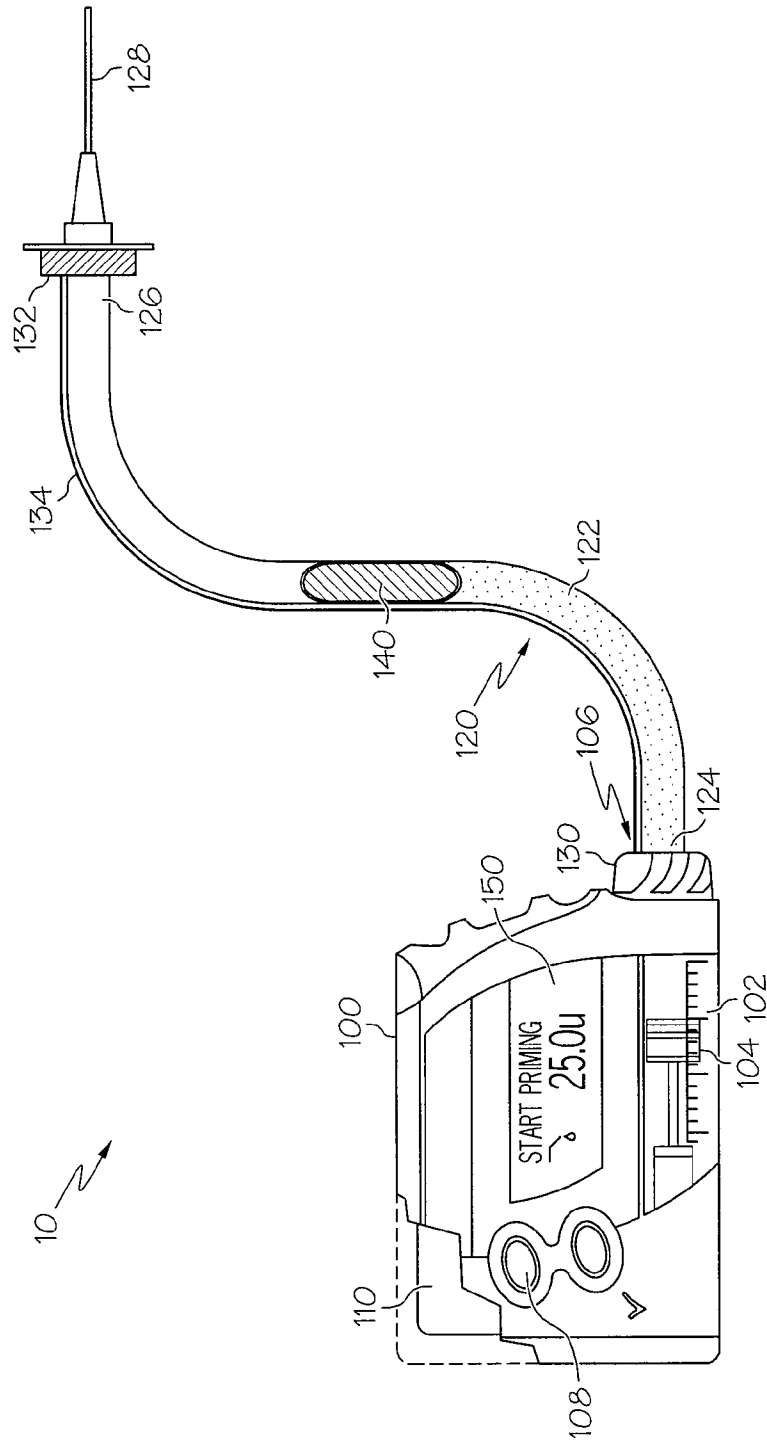


FIG. 1

216

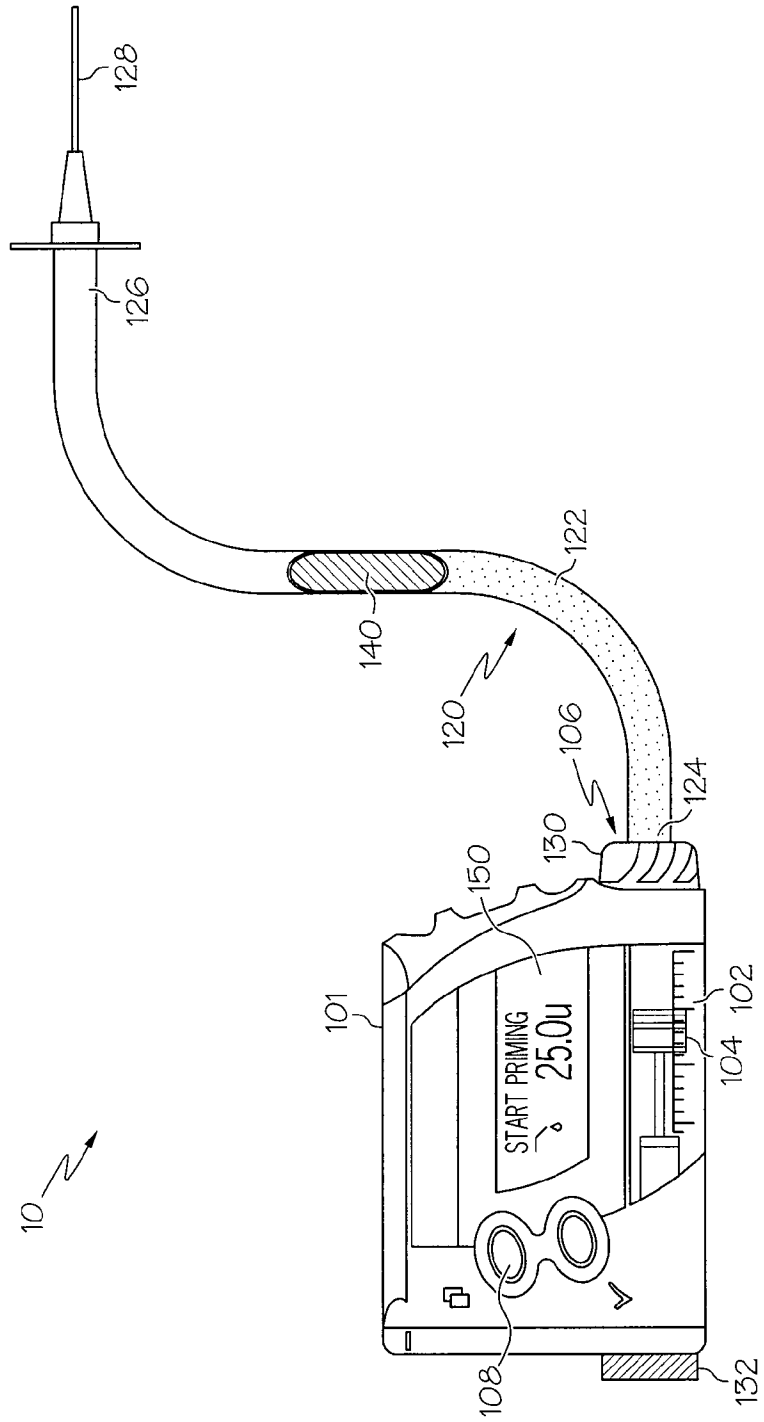


FIG. 2

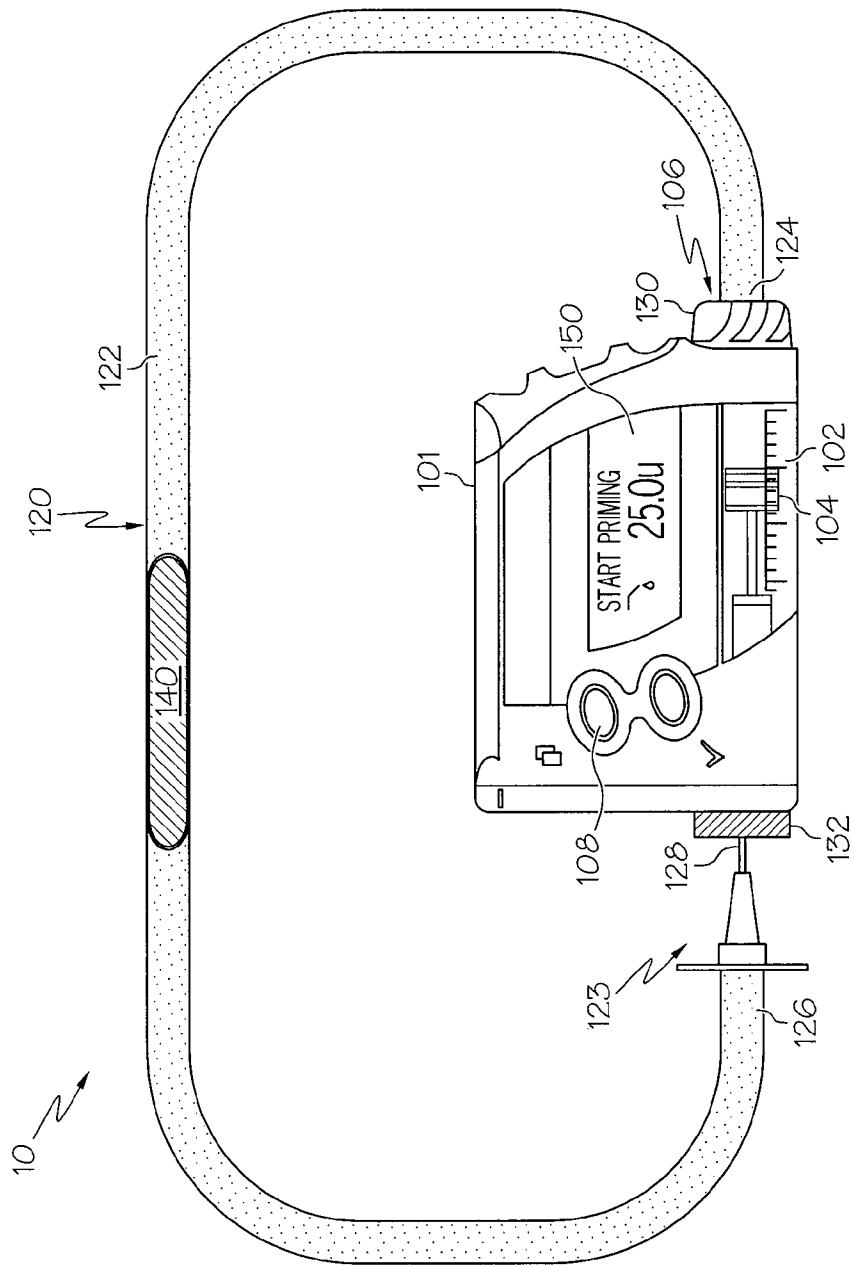


FIG. 3

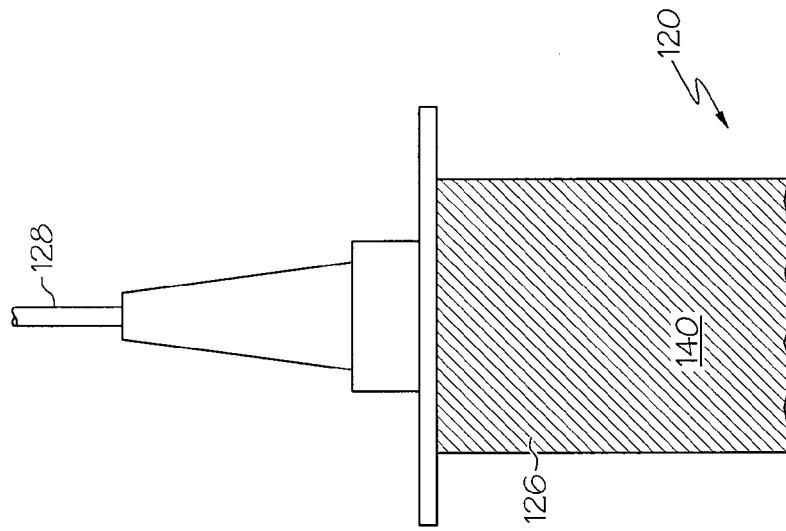


FIG. 4B

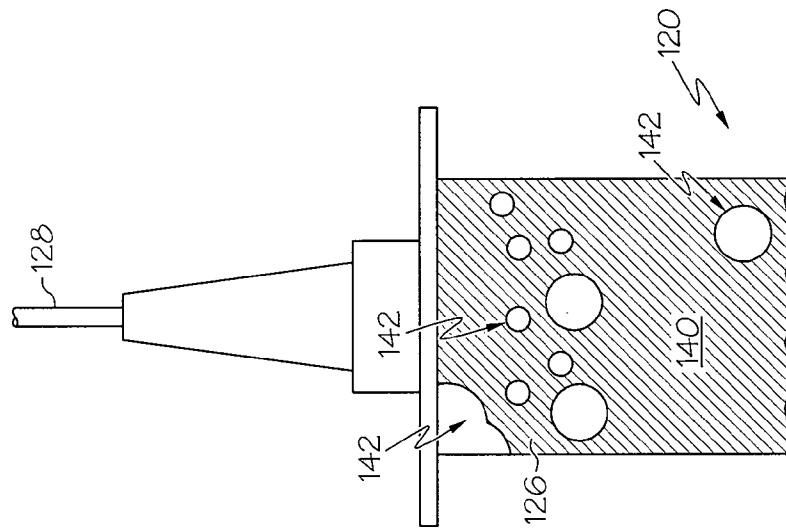


FIG. 4A

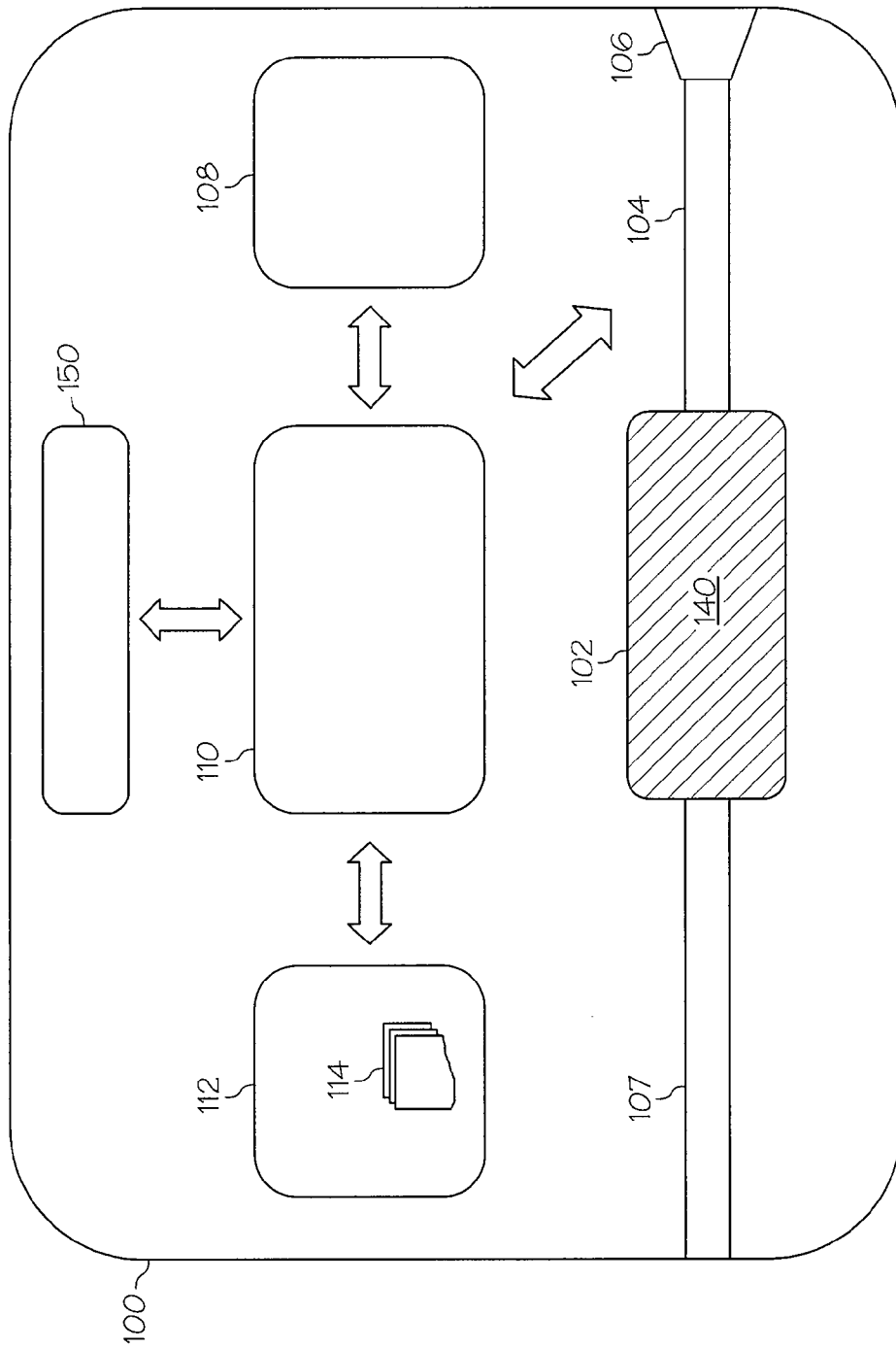


FIG. 5

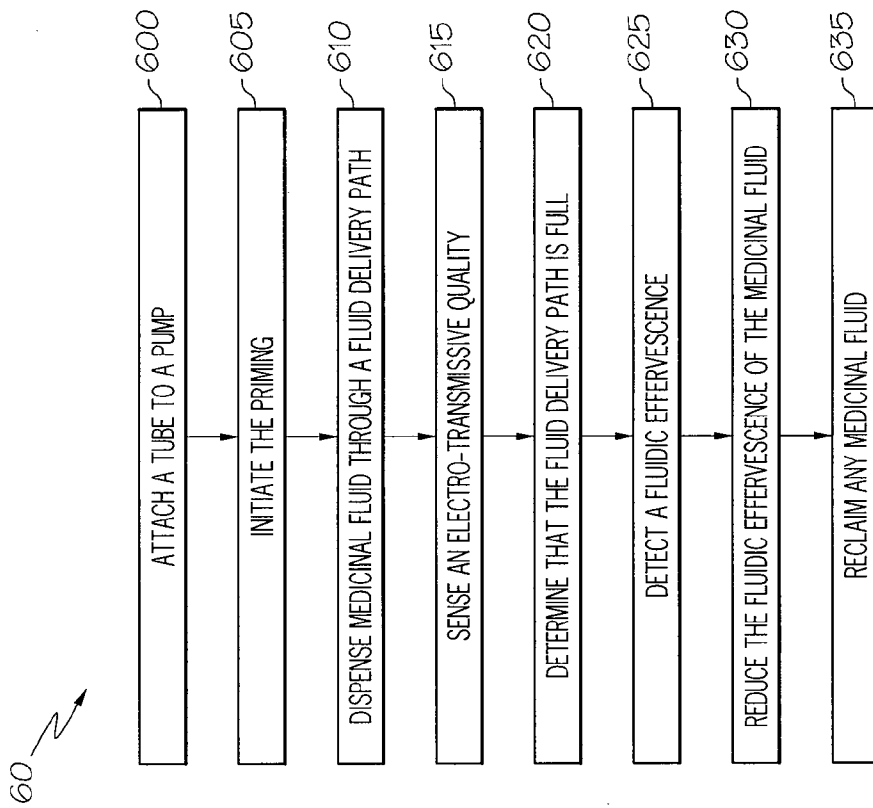


FIG. 6