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(71) Applicant: **BECTON, DICKINSON AND COMPANY** [US/US]; 1 Becton Drive, Franklin Lakes, New Jersey 07417-1880 (US).

(72) Inventor: **GYORY, J. Richard**; 10 Curry Lane, Sudbury, Massachusetts 01776 (US).

(74) Agent: **HOLMES, John** et al.; DICKINSON WRIGHT PLLC, 1825 Eye Street, NW, Suite 900, Washington, District of Columbia 20006 (US).

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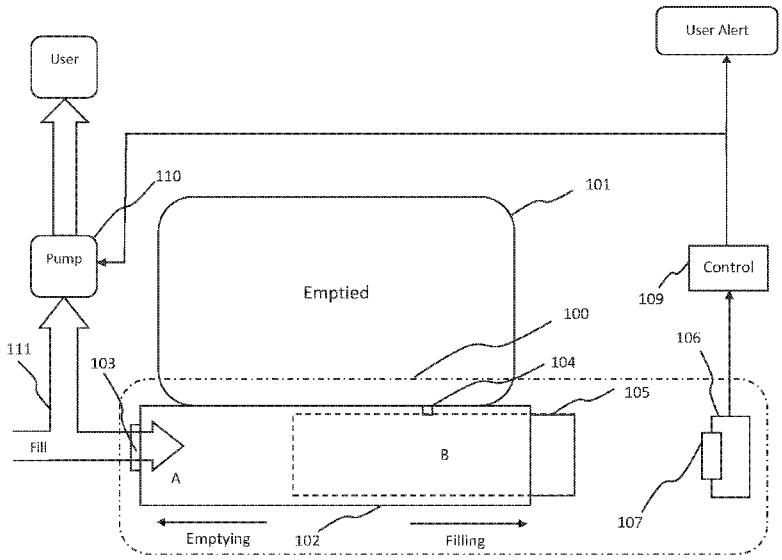


FIG. 2

(57) Abstract: A medical device with a volume sensor is provided for administering liquid drug therapy to a user. The medical device comprises a flexible reservoir (101) for housing a supply of a liquid drug, a rigid structure (120) with a chamber (102) and a side hole (104) in fluid communication with the flexible reservoir, a plunger (105) mounted inside the chamber and configured to seal one side of the chamber, and a switch (106) implemented to indicate the position of the plunger. When the inside end of the plunger (105) passes the side hole (104), the switch (106) is activated to transmit a signal indicating liquid volume in the flexible reservoir (101).

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[Continued on next page]

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Published:

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RESERVOIR WITH LOW VOLUME SENSOR

FIELD OF THE INVENTION

[0001] The present invention relates generally to a reservoir for delivering liquid. A specific embodiment of the invention relates to a flexible reservoir with a low volume sensor for delivering liquid medicinal products, such as insulin. An additional embodiment provides a method for operating a flexible reservoir with a low volume sensor including providing a warning that replacement of the flexible reservoir is needed.

BACKGROUND OF THE INVENTION

[0002] Diabetes is a group of diseases characterized by high levels of blood glucose resulting from the inability of diabetic patients to maintain proper levels of insulin production when required. Persons with diabetes will require some form of daily insulin therapy to maintain control of their glucose levels. Diabetes can be dangerous to the affected patient if it is not treated, and it can lead to serious health complications and premature death. However, such complications can be minimized by utilizing one or more treatment options to help control the diabetes and reduce the risk of complications.

[0003] The treatment options for diabetic patients include specialized diets, oral medications and/or insulin therapy. The main goal of diabetes treatment is to control the diabetic patient's blood glucose or sugar level. However, maintaining proper diabetes management may be complicated because it has to be balanced with the activities of the diabetic patient.

[0004] For the treatment of type 1 diabetes, there are two principal methods of daily insulin therapy. In the first method, diabetic patients use syringes or insulin pens to self-inject insulin when needed. This method requires a needle stick for each injection, and the diabetic patient may require three to four injections daily. The syringes and insulin pens that are used to inject insulin are relatively simple to use and cost effective.

[0005] Another effective method for insulin therapy and managing diabetes is infusion therapy in which an insulin pump is used. The insulin pump can provide continuous infusion of insulin to a diabetic patient at varying rates in order to more closely match the

functions and behavior of a properly operating pancreas of a non-diabetic person that produces the required insulin, and can help the diabetic patient maintain his/her blood glucose level within target ranges based on the diabetic patient's individual needs.

[0006] To facilitate infusion therapy, there are generally two types of insulin pumps, namely, conventional pumps and patch pumps. Conventional pumps require the use of a disposable component, typically referred to as an infusion set, tubing set or pump set, which conveys the insulin from a reservoir within the pump into the skin of a user. By contrast, a patch pump is an integrated device that combines most or all of the fluidic components, including the fluid reservoir, pumping mechanism and a mechanism for automatically inserting the cannula, in a single housing which is adhesively attached to an infusion site on the patient's skin, and does not require the use of a separate infusion or tubing set. Some patch pumps may wirelessly communicate with a separate controller (as in one device sold by Insulet Corporation under the brand name OmniPod®), while others are completely self-contained. Such devices are replaced on a frequent basis, such as every three days, when the insulin reservoir is exhausted.

[0007] As a patch pump is designed to be a self-contained unit that is worn by the diabetic patient, it is preferable to be as small as possible so that it does not interfere with the activities of the user. However, in order to minimize the overall size of the patch pump, its constituent parts should be reduced in size as much as possible. One such part is the reservoir for containing the insulin.

[0008] A conventional rigid reservoir, such as a syringe pump, controls the position of a plunger to dispense liquid. A major constraint of such a mechanism is the size of the system because it needs to accommodate both the length of the reservoir and the length of the plunger. Thus, a conventional rigid reservoir is difficult to deploy in a compact configuration. According, a need exists for an improved reservoir that can be efficiently deployed in a compact configuration to further reduce the overall size of a patch pump.

[0009] Low liquid level detection in the reservoir is important to ensure that the patch pump system functions correctly and/or to signal the need for replacement of the reservoir or patch pump. Various fill level detection systems have been proposed for various different applications. Currently, there are two principal methods for fill level detection. One provides electrical contacts points for metering doses. The other implements contactless fill level detection using capacitance measurement.

[00010] There are many advantages of conventional fill level detection systems when the flow rate and fill level need to be constantly monitored and/or adjusted. Conventional fill level detection systems provide accurate fill level data constantly or at a plurality of time points. Such systems are well suited where constant monitoring and adjustment is necessary. When only a low volume warning is needed to signal the need for replacement of the reservoir, a system with fill level detection function is unnecessarily more costly and more complicated.

[00011] An approach to reduce the overall size of a patch pump is to replace the syringe-type dosing mechanism by a downstream pump system drawing from a fluid reservoir. In such a device, a miniaturized pump is arranged downstream of the fluid reservoir to produce a negative pressure gradient that conveys the fluid from the reservoir to its destination. The miniaturized pump can alternatively be arranged to produce a positive pressure gradient that conveys the fluid from another larger fluid source into the reservoir to fill the reservoir.

[00012] Accordingly, there is a need in the art for providing a compact and more cost-effective reservoir with a low volume detector for warning of the need to replace the reservoir, so that many more diabetes patients can benefit from the advantages that patch pump devices provide.

SUMMARY OF THE INVENTION

[00013] It is an object of exemplary embodiments of the present invention to provide a flexible liquid reservoir with a low volume detector. It is a further object of the exemplary embodiments of the present invention to provide a notification of low liquid level in the flexible reservoir.

[00014] According to one aspect of the present invention, there is provided a medical device for administering liquid drug therapy to a user with a low volume sensor, said medical device comprising a flexible reservoir for containing a supply of a liquid drug, a rigid structure with a chamber and a side hole in fluid communication with the flexible reservoir, a plunger mounted inside the chamber and configured to seal one side of the chamber and a sensor for detecting low liquid volume in the flexible reservoir, wherein, when the inside end of the plunger passes the side hole, the sensor is activated to transmit a signal indicating low liquid volume in the flexible reservoir.

[00015] A third aspect of the present invention provides a method for a method for detecting low liquid volume and notifying a user of time-to-empty in a system comprising a pump mechanism, a flexible reservoir for housing a supply of a liquid drug, a rigid structure with a chamber and a side hole in fluid communication with the flexible reservoir, a plunger mounted inside the chamber and configured to seal one side of the chamber, a sensor for detecting low liquid volume in the flexible reservoir, and a control module in functional connection with the pump mechanism for controlling the operation of the pump mechanism, wherein when the inside end of the plunger passes the side hole, the sensor is activated to transmit a signal indicating low liquid volume in the flexible reservoir, the method comprising the steps of providing the rigid structure with the chamber connected to the flexible reservoir, applying a negative pressure to end A of the rigid structure, removing fluid from the flexible reservoir, detecting moment that the plunger loses contact with the switch, calculating estimated time for empty based on current flow rate and volume of the chamber and the conduit, alerting the user that volume is low and notifying user of approximate time when system will run out of liquid.

[00016] Other objects, advantages and salient features of the invention will become apparent to those skilled in the art from the following detailed description, which, taken in conjunction with the annexed drawings, discloses exemplary embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[00017] The above and other exemplary features and advantages of certain exemplary embodiments of the present invention will become more apparent from the following description of certain exemplary embodiments thereof when taken in conjunction with the accompanying drawings, in which:

[00018] **FIG. 1** is an illustration depicting a medical device in accordance with an embodiment of the present invention;

[00019] **FIG. 2** is an illustration of the empty condition of the medical device of **FIG. 1**;

[00020] **FIG. 3** is an illustration of the filled condition of the medical device of **FIG. 1**;

[00021] **FIG. 4** is a perspective view of a flexible reservoir implemented in a patch pump system;

[00022] **FIG. 5** is a fluidic architecture and metering sub-system diagram of the patch pump system of **Fig. 4**; and

[00023] **FIG. 6** is a flowchart illustrating a method for detecting low liquid volume and for notifying the user of estimated time-to-empty.

[00024] Throughout the drawings, like reference numerals will be understood to refer to like elements, features and structures.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

[00025] The matters exemplified in this description are provided to assist in a comprehensive understanding of exemplary embodiments of the invention, and are made with reference to the accompanying drawings. Those of ordinary skill in the art will recognize that various changes and modifications in the exemplary embodiments described herein can be made without departing from the scope and spirit of the claimed invention. Also, descriptions of well-known functions and constructions are omitted for clarity and conciseness.

[00026] As shown in **FIG. 1**, an exemplary embodiments of the present invention includes a flexible reservoir **101** for housing a supply of a liquid drug, a rigid structure **120** with a chamber **102** and a side hole **104** in fluid communication with the flexible reservoir **101**, and a plunger **105** mounted inside the chamber and configured to seal one side of the chamber **102**. The term "flexible reservoir" includes reservoir structures that are both entirely flexible, such as collapsible fluid pouches or bladders, as well as reservoir structures that are only partially flexible by virtue of having both flexible and rigid wall portions. An exit/entrance **103** of the chamber **102** allows fluid in and out of the chamber **102**. The plunger **105** is capable of moving in the axial direction of the chamber **102** from end A to end B for filling the chamber, or alternatively from end B to end A for emptying the chamber. The plunger **105** is positioned in the chamber **102** such that it prevents liquid from leaking out of the chamber **102**. When the plunger **105** moves from end A to end B for filling, a fluid source is connected to end A. When the plunger **105** passes the side hole **104**, fluid fills the chamber **102** and flows through the side hole **104** into the flexible reservoir **101** until the flexible reservoir **101** is filled. At the same time, a sensor **106** is triggered to transmit a volume signal. When the plunger **105** moves from end B to end A for emptying, the flexible reservoir **101** is emptied first. When the plunger **105** passes the side hole **104**, the flexible

reservoir **101** is emptied. The sensor **106** is triggered again to transmit another volume signal to indicate low fluid volume in the reservoir.

[00027] One of ordinary skill in the art will appreciate that medical device shown in **FIG.1** may be configured to be fully functional when the sensor **106** is an electrical switch. For instance, when the plunger **105** passes the side hole **104**, an electrical signal is transmitted from the sensor **106** to indicate the volume information. The sensor **106** may also alternatively be implemented using an optical sensor. For instance, when the plunger **105** passes the side hole **104**, an optical signal is transmitted from the sensor **106** to indicate the volume information. Alternatively, the sensor **106** may be implemented using a magnetic sensor.

[00028] When emptying the flexible reservoir **101**, a pump or means can be arranged downstream of the flexible reservoir **101** and the chamber **102**, to produce a negative pressure that conveys the fluid from the flexible reservoir **101** to its destination. When filling the flexible reservoir **101**, similar means can be arranged to produce a positive pressure that conveys the fluid from another fluid source into the flexible reservoir **101** through the exit/entrance **103**.

[00029] In one exemplary embodiment of the present invention, the sensor **106** is an electrical switch aligned with the end B of the chamber **102**. The button or actuator **107** of the switch **106** is pointed toward the opening of the chamber **102**. When the plunger **105** moves from end A to end B and passes the side hole **104**, the end of the plunger **105** touches the button **107** of the electrical switch and triggers the switch **106** to transmit a volume signal. One of ordinary skill in the art will appreciate that additional supporting and housing structure may exist to support and house the above components.

[00030] **FIG. 2** is an illustration of the low volume state of the present invention with a pump mechanism. To empty the flexible reservoir **101**, the pump mechanism **110** is located downstream of the flexible reservoir **101**. The initial position of the plunger **105** is in position B. The pump mechanism produces a negative pressure on the fluid inside the chamber **102** and the flexible reservoir **101**. Fluid inside the flexible reservoir **101** flows through the side hole **104** into the chamber **102**, and through the chamber exit/entrance **103** to conduit **111** to the pump mechanism **110**. The negative pressure causes the flexible reservoir **101** to be emptied first. When the flexible reservoir **101** is emptied, continued negative pressure from the pump mechanism **110** causes the plunger **105** to move from position B toward position A, and the button **107** on the switch **106** is activated to transmit a low volume

signal to a control module **109**. Control module **109** then sends a low-volume warning signal to the user.

[00031] **FIG. 3** is an illustration of the high volume state of the device of **FIG. 2**. To fill the flexible reservoir **101**, a fill syringe or other device is used to forcibly inject fluid through a valve or seal into the exit/entrance **103**. The initial position of the plunger **105** is position A. The plunger **105** is pushed back by the positive pressure inside the chamber **102** produced by the filling device. When the plunger **105** passes the side hole **104** in the chamber **102**, fluid starts to flow into the flexible reservoir **101** through the side hole **104**. When the flexible reservoir **101** is filled with fluid, the positive pressure increases and pushes the plunger **105** further back to position B to activate the button **107** on the switch **106** to transmit a high volume signal to the control module **109**. Then the pump means **110** can be started to run at a pre-determined speed, the liquid in the flexible reservoir **101** will be pumped to the user and the flexible reservoir **101** will be emptied as illustrated in **FIG. 2**, when the sensor **106** will be activated to transmit a low liquid volume signal.

[00032] **FIG. 4** is a perspective view of the flexible reservoir **101** implemented in a patch pump **1A** illustrated without a cover. Such arrangement may further reduce the external dimensions of the patch pump **1A**, with the flexible reservoir **101** filling voids within the patch pump **1A**. The patch pump **1A** is illustrated with a cannula insertion device **7A** that inserts the cannula into the surface of a user's skin. The patch pump **1A** further comprises a power source **5A** in the form of batteries; a metering sub-system **41** that monitors the volume of insulin and includes a low volume detecting means; control electronics **8A** for controlling the components of the device; and a reservoir fill port **43** for receiving a fill syringe **45** to fill the reservoir **101**.

[00033] **FIG. 5** is a fluidic architecture and metering sub-system diagram of the patch pump **1A** of **FIG. 4**. The power storage sub-system for the patch pump **1A** includes batteries **5A**. The control electronics **8A** of the patch pump **1A** may include a microcontroller **81**, sensing electronics **82**, pump and valve controller **83**, sensing electronics **85** and deployment electronics **87**, that control the operation of the patch pump **1A**. The patch pump **1A** includes a fluidics sub-system that comprises the reservoir **101**, a volume sensor **48** for the reservoir **101**, and a reservoir fill port **43** for receiving a fill syringe **45** to fill the reservoir **4A**. The fluidics sub-system may include a metering system comprising a pump and valve actuator **411** and an integrated pump and valve mechanism **413**. The fluidics sub-system may further include an occlusion sensor **49**, a deploy actuator or cannula insertion device **7**, as well as a

cannula **47** for insertion into an infusion site on the user's skin. In one embodiment of the present invention, the volume sensor is implemented with the sensor **106** of FIGs 1, 2 and 3.

[00034] **FIG. 6** is a flowchart illustrating the method for alerting the user of low liquid volume and for notifying the user of an estimated time-to-empty. In step **602**, when the flexible reservoir **101** is emptied by the application of a negative pressure to end A of the chamber **102**, fluid flows out of the flexible reservoir **101** and through the chamber **102**. In step **603**, this continues until all of the fluid is removed from the flexible reservoir **101**. At this moment, the negative pressure will build until it is sufficient to cause the plunger **105** to slide forward in the chamber **102**. When the plunger **105** begins to move, the back edge of the plunger **105** will lose contact with the button **107** of the switch, causing a low volume signal to be transmitted to the control module **109**. In step **604**, the moment that the plunger **105** loses contact with the button **107** of the switch **106** is detected. The exact volume remaining in the system at this moment is known since it is equal to the volume of the conduit **111** and the portion of the chamber **102** not occupied by the plunger **105**. Dividing this volume by the current flow rate of the liquid, which is known from the operating speed of the pump mechanism **110**, yields the estimated amount of time left before the system becomes empty of fluid in step **605**. In step **606** the user of the system is alerted that the volume is low. If the flow rate is known, in step **607**, the user can be notified of the approximate time that the system will run out of fluid.

[00035] One of ordinary skill in the art will appreciate that the features of the above exemplary embodiments may be similarly provided in a number of applications and are not limited to the above disclosure.

[00036] While the present invention has been shown and described with reference to particular illustrative embodiments, it is not to be restricted by the exemplary embodiments but only by the appended claims and their equivalents. It is to be appreciated that those skilled in the art can change or modify the exemplary embodiments without departing from the scope and spirit of the present invention, and that the features of different embodiments and claims can be combined with each other as long as they do not contradict each other.

CLAIMS

1. A medical device for administering liquid drug therapy to a user with a low volume sensor, said medical device comprising:
a flexible reservoir for containing a supply of a liquid drug;
a rigid structure with a chamber and a side hole in fluid communication with the flexible reservoir;
a plunger mounted inside the chamber and configured to seal one side of the chamber; and
a sensor for detecting low liquid volume in the flexible reservoir, wherein:
when the inside end of the plunger passes the side hole, the sensor is activated to transmit a signal indicating low liquid volume in the flexible reservoir.

2. The medical device of claim 1, wherein the sensor comprises an electrical switch.

3. The medical device of claim 2, wherein the electrical switch is triggered by a button.

4. The medical device of claim 1, wherein the sensor comprises an optical sensor.

5. The medical device of claim 1, wherein the sensor comprises a magnetic sensor.

6. The medical device of claim 1, further comprising a control module connected to the sensor for receiving the low liquid volume signal.

7. The medical device of claim 1, further comprising an alarm system for warning of a low liquid volume state of the reservoir.

8. The medical device of claim 7, wherein the alarm system transmits a light signal as a warning of low liquid volume in the reservoir.

9. The medical device of claim 7, wherein the alarm system transmits sound signal as a warning of low liquid volume in the reservoir.

10. The medical device of claim 7, wherein the alarm system transmits a vibrational signal as a warning of low liquid volume in the reservoir.

11. The medical device of claim 7, wherein the alarm system transmits a combined light, sound and/or vibration signal as a warning of low liquid volume in the reservoir.

12. The medical device of claim 1, further comprising a pump mechanism for pumping liquid out of the flexible reservoir.

13. A medical system for administering liquid drug therapy to a user with a low volume sensor, said medical device comprising:
a flexible reservoir for containing liquid;
a pump mechanism in fluid connection with the flexible reservoir for pumping liquid out of the flexible reservoir;
a sensor means for detecting fluid volume inside the flexible reservoir; and
a control module in functional connection with the sensor for receiving a volume signal from the sensor.

14. A method for detecting low liquid volume and notifying a user of time-to-empty in a system comprising a pump mechanism, a flexible reservoir for housing a supply of a liquid drug, a rigid structure with a chamber and a side hole in fluid communication with the flexible reservoir, a plunger mounted inside the chamber and configured to seal one side of the chamber, a sensor for detecting low liquid volume in the flexible reservoir, and a control module in functional connection with the pump mechanism for controlling the operation of the pump mechanism, wherein when the inside end of the plunger passes the side hole, the sensor is activated to transmit a signal indicating low liquid volume in the flexible reservoir, the method comprising the steps of:
providing the rigid structure with the chamber connected to the flexible reservoir;
applying a negative pressure to an end of the rigid structure;
removing fluid from the flexible reservoir;
detecting moment that the plunger loses contact with the switch;
calculating estimated time for empty based on current flow rate and volume of the chamber and the conduit;

alerting the user that volume is low; and

notifying user of approximate time when system will run out of liquid.

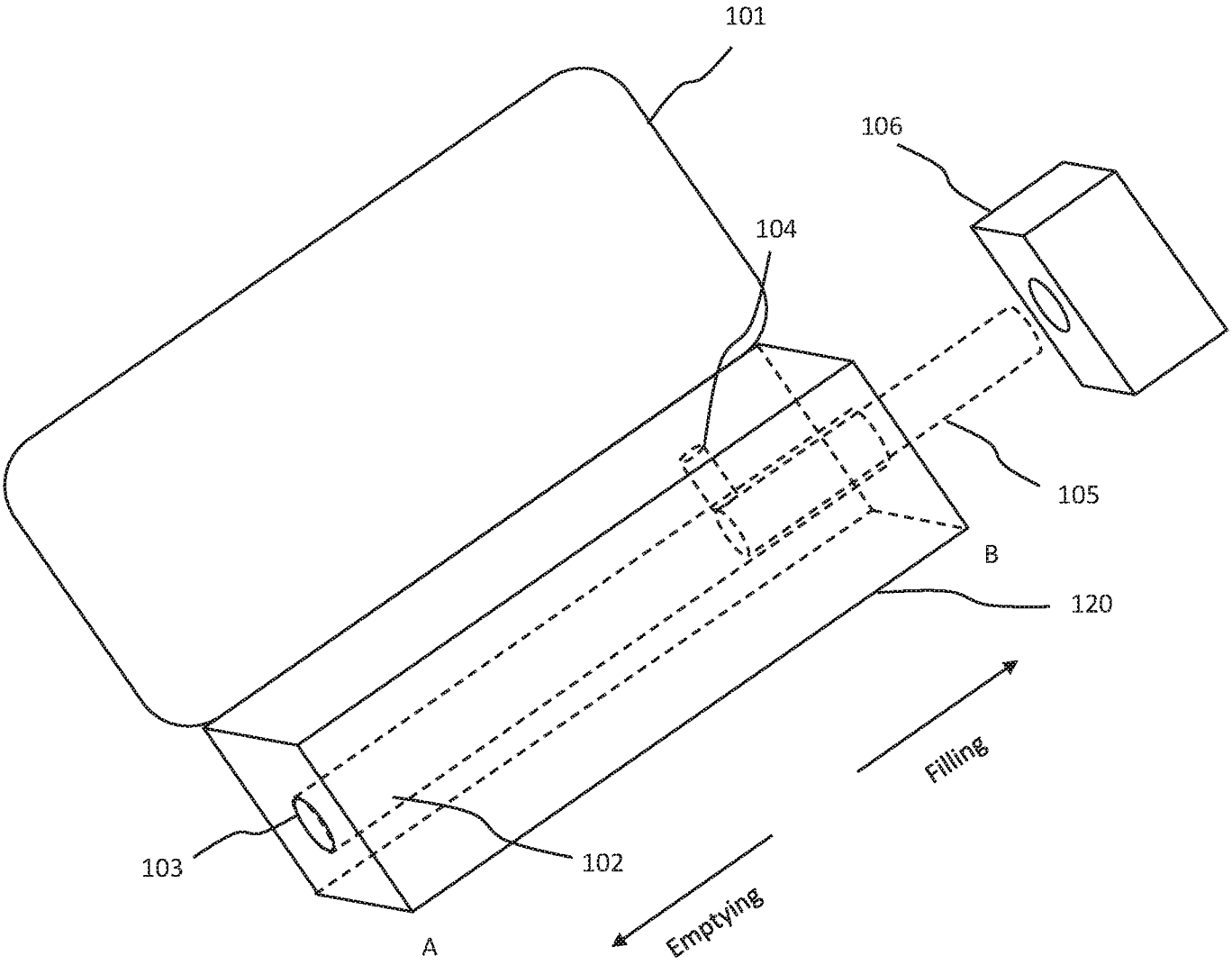


FIG. 1

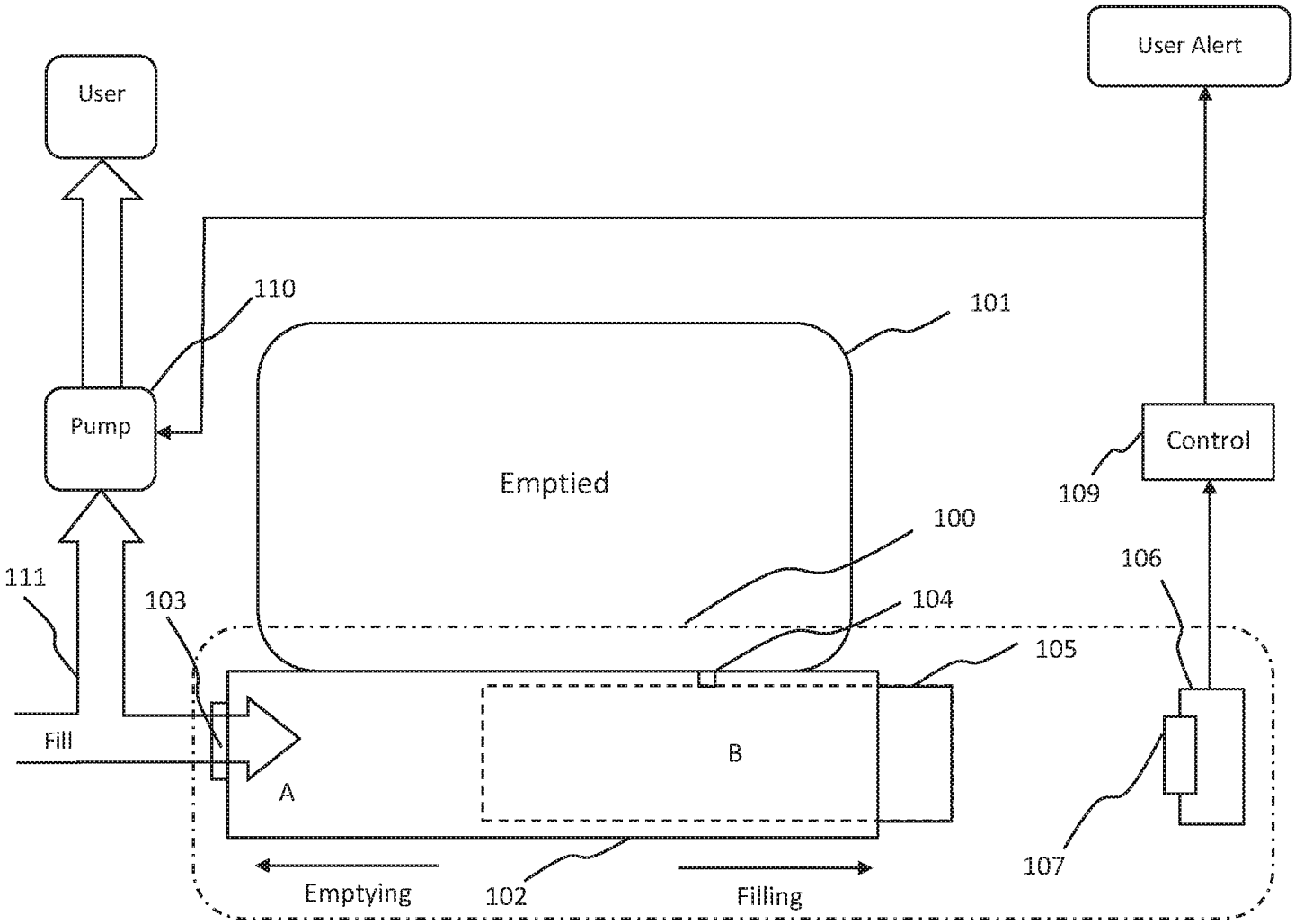

User Alert
User
110
101
Pump
Emptied
Control
109
100
106
111
103
104
105
Fill
B
A
Emptying
102
Filling
107

FIG. 2

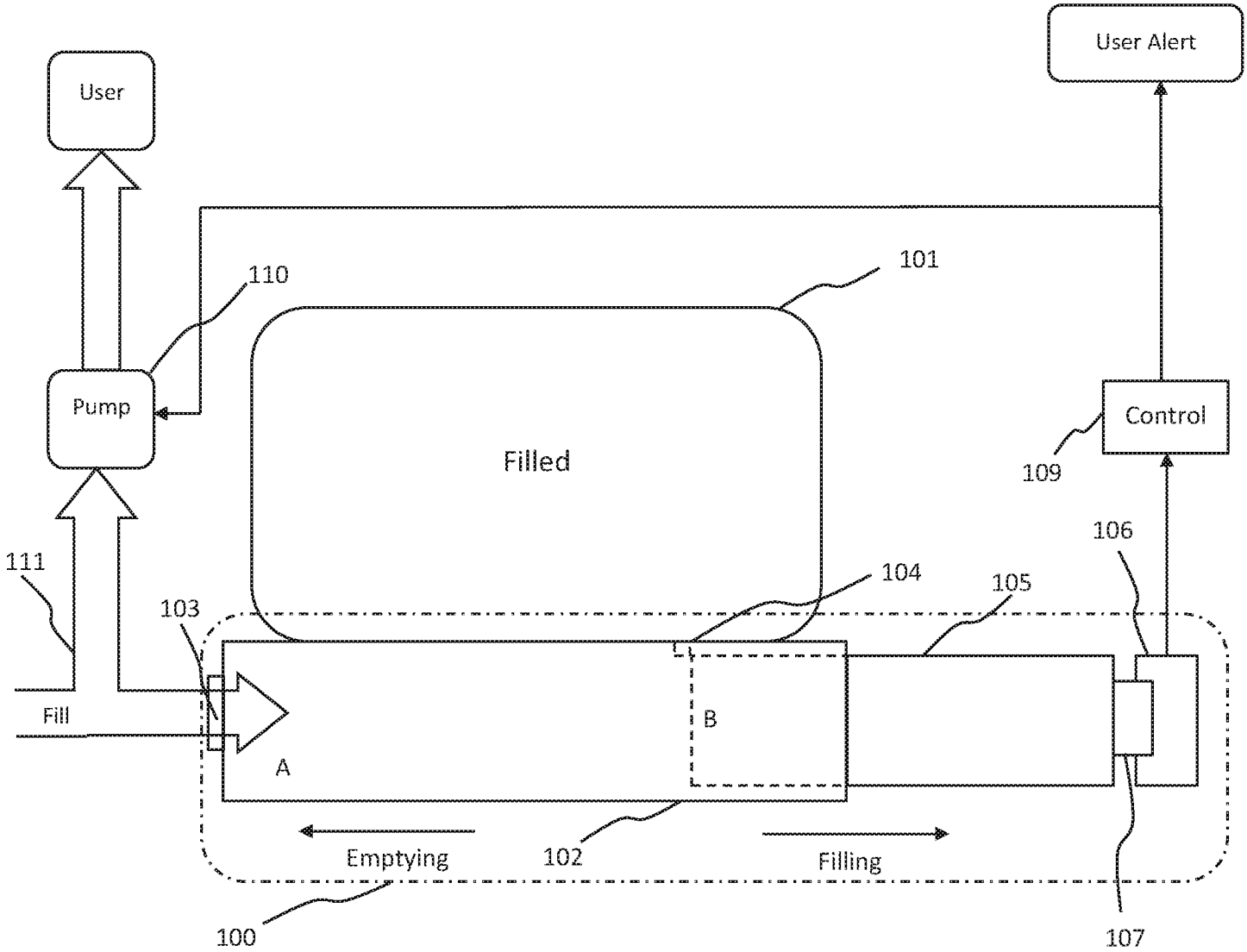

User Alert
User
110
101
Pump
Filled
Control
109
111
106
104
105
103
Fill
A
B
Emptying
102
Filling
100
107

FIG. 3

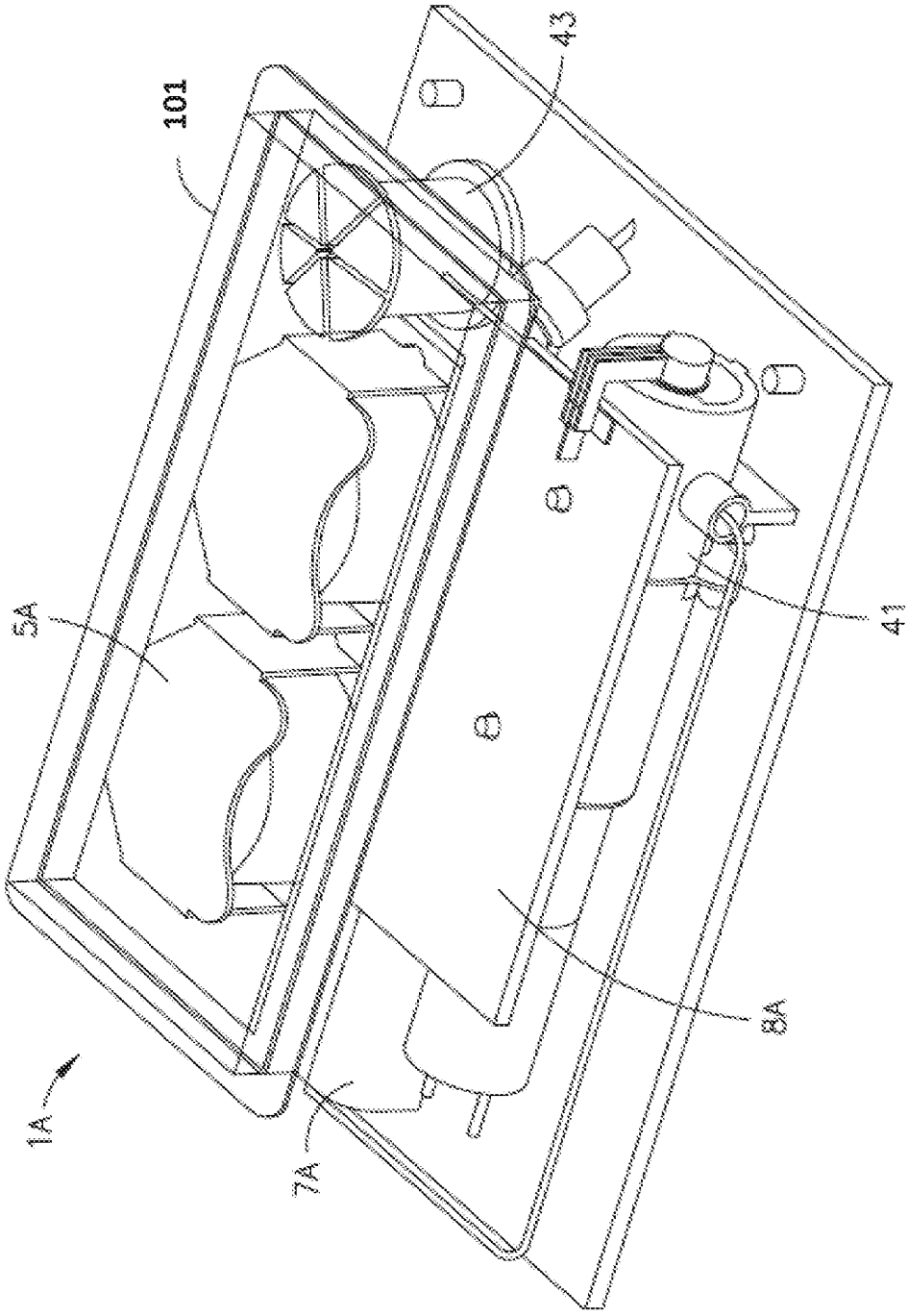


FIG. 4

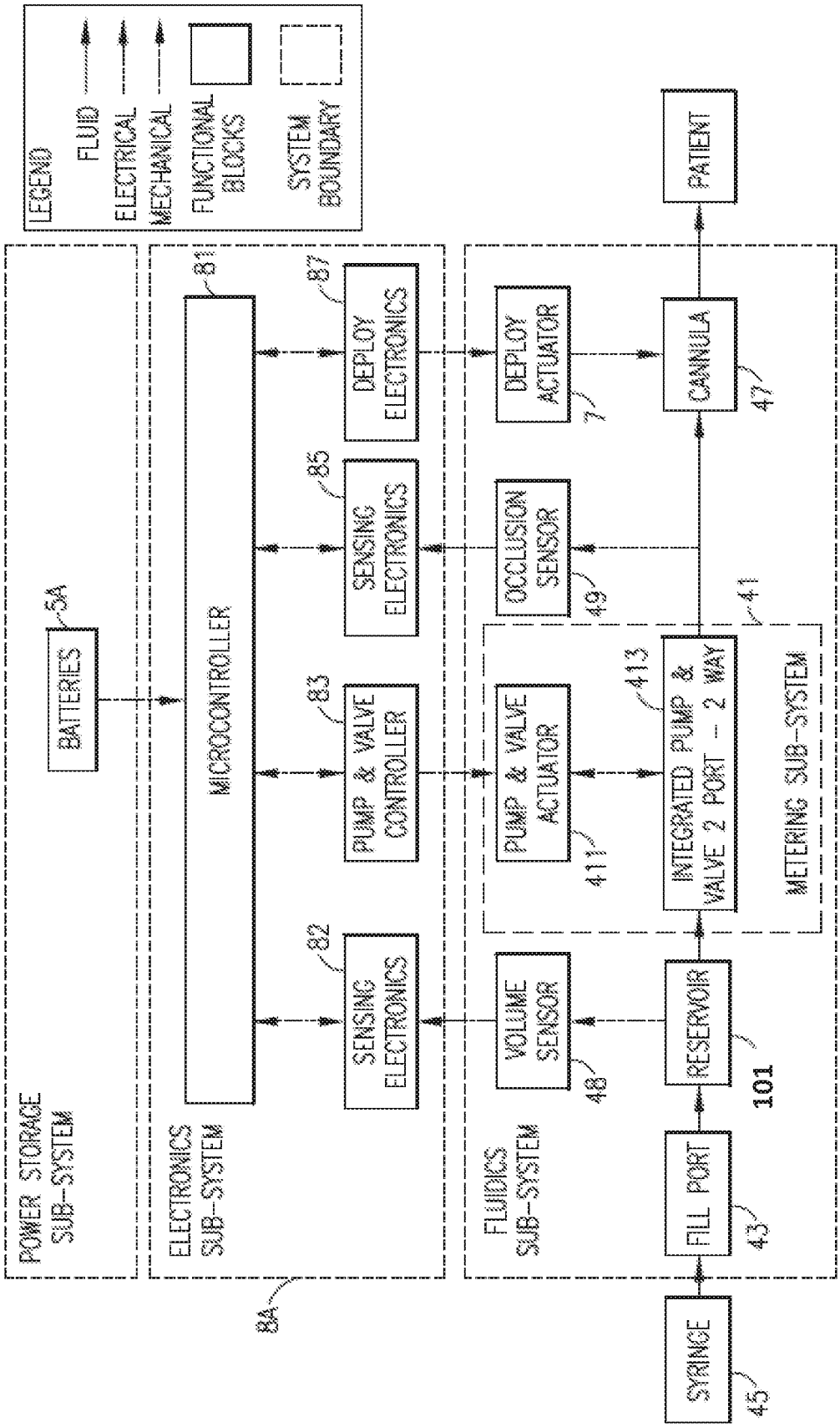

LEGEND
FLUID
ELECTRICAL
MECHANICAL
FUNCTIONAL BLOCKS
SYSTEM BOUNDARY
POWER STORAGE SUB-SYSTEM
BATTERIES
5A
ELECTRONICS SUB-SYSTEM
MICROCONTROLLER
81
SENSING ELECTRONICS
82
PUMP & VALVE CONTROLLER
83
SENSING ELECTRONICS
85
DEPLOY ELECTRONICS
87
8A
FLUIDICS SUB-SYSTEM
VOLUME SENSOR
48
PUMP & VALVE ACTUATOR
411
OCCLUSION SENSOR
49
DEPLOY ACTUATOR
7
INTEGRATED PUMP & VALVE 2 PORT - 2 WAY
413
METERING SUB-SYSTEM
41
RESERVOIR
101
CANNULA
47
PATIENT
FILL PORT
43
SYRINGE
45

FIG. 5

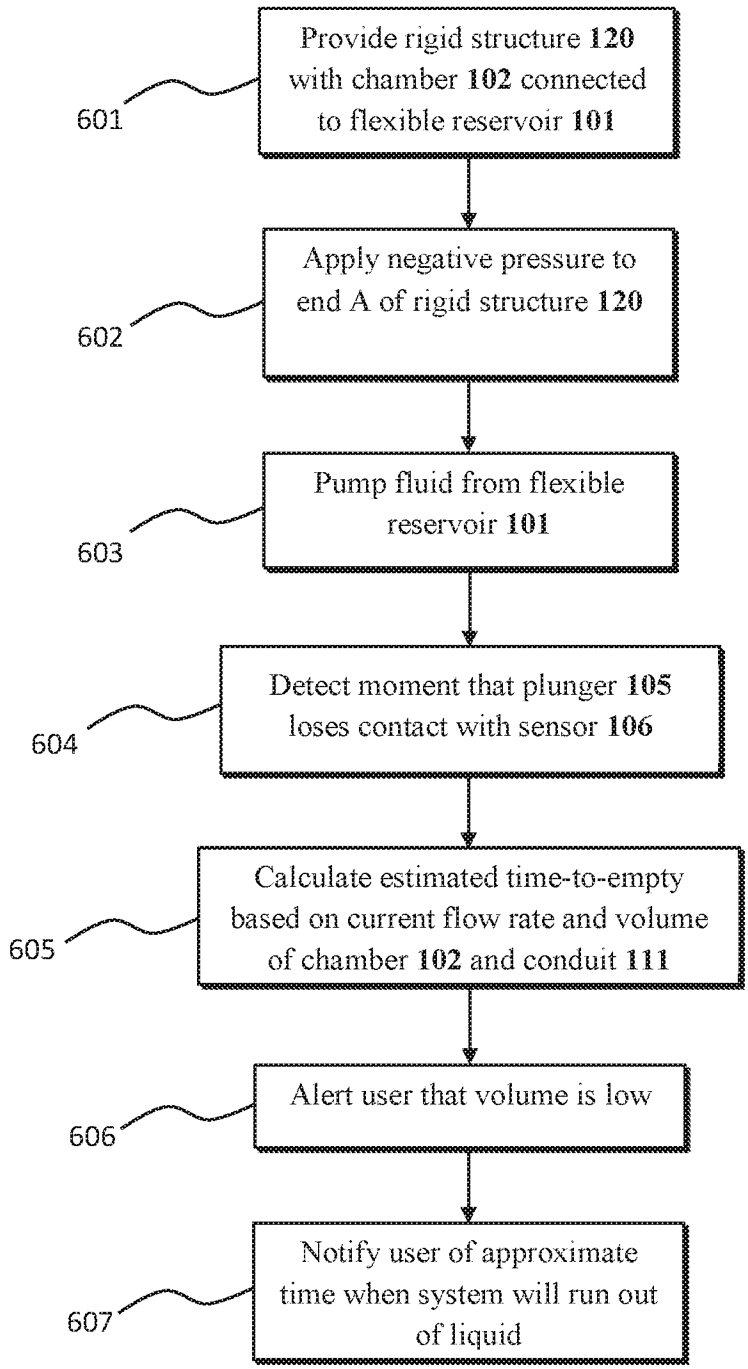

Provide rigid structure 120 with chamber 102 connected to flexible reservoir 101
601
Apply negative pressure to end A of rigid structure 120
602
Pump fluid from flexible reservoir 101
603
Detect moment that plunger 105 loses contact with sensor 106
604
Calculate estimated time-to-empty based on current flow rate and volume of chamber 102 and conduit 111
605
Alert user that volume is low
606
Notify user of approximate time when system will run out of liquid
607

FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 18/48537

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61J 1/05, A61M 5/14, 5/142 (2018.01)

CPC - A61J 7/04, 7/0481, 7/0472, 7/0445, 7/0436, 7/0418, 7/0409, 7/00, 7/0076, 1/05, 1/00, 1/20, 1/03, 2205/70, 2200/30, B67D 7/08, A61M 5/172, 5/14, 5/142, 5/14244, 5/172, 2005/1726, 2205/18, G06F 19/3462

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)

See Search History Document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History Document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2017/0000946 A1 (IBT INCORPORATED) 5 January 2017 (05.01.2017) entire document, especially Figs. 1-4; para [0008], [0032]-[0035], [0055]-[0057]	13
A	US 9,446,193 B2 (ROCHE DIAGNOSTICS INTERNATIONAL AG) 20 September 2016 (20.09.2016) entire document, especially Figs. 1-4; col 1, ln 39-40, col 4, ln 27-28, col 6, ln 20-23, col 10, ln 50-51, col 18, ln 56-59	1-12, 14
A	US 2011/062703 A1 (LOPEZ et al.) 17 March 2011 (17.03.2011) entire document	1-14
A	US 9,039,653 B2 (CHONG et al.) 26 May 2015 (26.05.2015) entire document	1-14
A	US 2016/0184514 A1 (DEKA PRODUCTS LIMITED PARTNERSHIP) 30 June 2016 (30.06.2016) entire document	1-14
A	WO 2013/096713 A2 (DEKA PRODUCTS LIMITED PARTNERSHIP) 27 June 2013 (27.06.2013) entire document	1-14
A	US 2011/0306931 A1 (KAMEN et al.) 15 December 2011 (15.12.2011) entire document	1-14

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Date of the actual completion of the international search	Date of mailing of the international search report
26 December 2018	17 JAN 2019
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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 18/48537

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2009/0026146 A1 (CARLISLE et al.) 29 January 2009 (29.01.2009) entire document	1-14
A	US 2004/0068224 A1 (COUVILLON, JR. et al.) 8 April 2004 (08.04.2004) entire document	1-14
A	US 2014/0088555 A1 (LI et al.) 27 March 2014 (27.03.2014) entire document	1-14