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(54) Title: PIEZOELECTRIC MEMBRANE PUMP FOR THE INFUSION OF LIQUIDS

(57) Abstract: An infusion pump (10) includes a fluid chamber (28) having an outlet valve (34) and a piezo-stack actuator (36) comprising a stack of piezo-electric layers (38). An electronic processor (18) is programmed to operate the outlet valve and the piezo-stack actuator to pump fluid through the fluid chamber at a programmed flow rate.

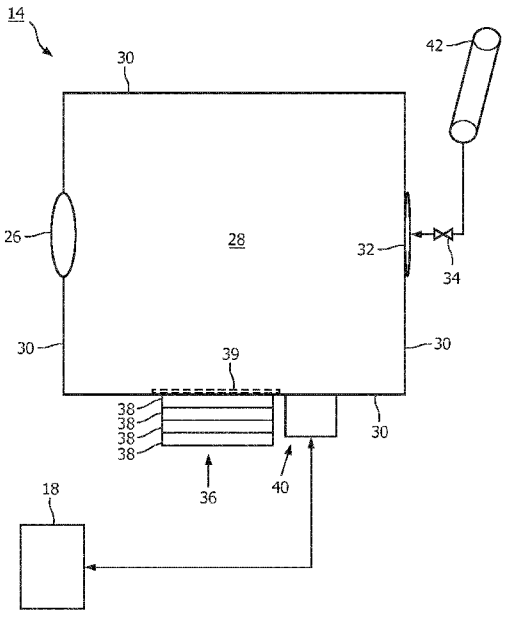


FIG. 2

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# PIEZOELECTRIC MEMBRANE PUMP FOR THE INFUSION OF LIQUIDS

## FIELD

The following relates generally to the medical infusion arts, infusion pump arts, and related arts.

## BACKGROUND

Volumetric infusion pumps deliver fluid to a patient intravascularly at a controlled flow rate. Depending upon the type of therapeutic fluid being delivered, interruption of the flow can present a serious patient safety issue. Such flow interruption can result from an occlusion in the fluid tubing, or from a disconnect of the fluid tubing at any point between the infusion pump and the patient. Similarly, the presence of bubbles in the infused fluid presents a safety concern.

Currently, infusion pumps for general use both in hospital and home incorporate free flow prevention, occlusion detection, and bubble detection as separate systems. Typically there is no indication of disconnection from the patient or downstream leakage.

In addition, current infusion pumps for use in MR environments use ultrasonic Piezo elements, and are complex, expensive, inaccurate, unreliable and have high power consumption.

Improvements disclosed herein address the foregoing and other disadvantages of existing infusion pump systems, methods, and the like.

## BRIEF SUMMARY

In accordance with one illustrative example, an infusion pump includes a fluid chamber having an outlet valve, and a piezo-stack actuator comprising a stack of piezo-electric layers. An electronic processor is programmed to operate the outlet valve and the piezo-stack actuator to pump fluid through the fluid chamber at a programmed flow rate.

In accordance with another illustrative example, a method of using an infusion pump with a fluid chamber that is pumped by a pump motor comprising a piezo-stack actuator is provided. The method includes: with a linear encoder, measuring a displacement of the piezo-stack actuator during operation of the piezo-stack actuator; with at least one processor, comparing the measured

displacement to a reference value to detect the presence of at least one of bubbles in a fluid chamber of the motor, the presence of occlusions in a tube connected to an outlet valve of the fluid chamber, or the presence of line disconnections of the tube connected to the outlet valve of the fluid chamber; and with the at least one processor, outputting a warning indicating the presence of at least one of the bubbles, occlusions and tube disconnections.

In accordance with another illustrative example, an infusion pump includes a fluid chamber having an outlet valve, and a piezo-stack actuator comprising a stack of piezo-electric layers. A linear encoder is connected to the fluid chamber. The linear encoder is configured to measure a displacement of the piezo-stack actuator during operation of the piezo-stack actuator. An electronic processor is programmed to: operate the outlet valve and the piezo-stack actuator to pump fluid through the fluid chamber at a programmed flow rate; and read the linear encoder and, based on the displacement of the piezo-stack actuator measured by the linear encoder, detect the presence of each of: bubbles in the fluid chamber, a tube occlusion, or a tube disconnection.

One advantage resides in providing an infusion pump with a piezo-stack actuator.

Another advantage resides in providing an infusion pump with a piezo-stack actuator and an integrated sensor that detects the presence of bubbles, occlusions, and tube disconnections.

Further advantages of the present disclosure will be appreciated to those of ordinary skill in the art upon reading and understand the following detailed description. It will be appreciated that a given embodiment may provide none, one, two, or more of these advantages.

## BRIEF DESCRIPTION OF THE DRAWINGS

The present disclosure may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating the preferred embodiments and are not to be construed as limiting the invention.

FIGURE 1 diagrammatically illustrates a top view of medical device in accordance with one aspect.

FIGURE 2 diagrammatically illustrates a first operative state of the medical device of FIGURE 1.

FIGURE 3 diagrammatically illustrates a medical device illumination method suitably performed using the medical device of FIGURE 1.

## DETAILED DESCRIPTION

The following relates to volumetric infusion pumps, which have application by way of illustration as MR-compatible infusion pumps. The disclosed volumetric infusion pumps employ fluid chamber pumped by a linear motor in the form of a piezo-stack actuator, consisting of a stack of piezoelectric elements that expands under electrical bias. The choice has a number of advantages over conventional rotary piezoelectric motors, such as less susceptibility to wear and potentially lower cost.

Another advantage of the chosen piezo-stack actuator is that it can be used to detect bubbles, tube occlusions, or tube disconnects. This entails adding a linear encoder to measure the linear displacement of the piezo-stack actuator.

To detect bubbles, the outlet valve of the pump chamber is closed while the piezo-stack actuator is running. As water-based medicines are essentially incompressible while air is highly compressible, the compressibility of the trapped fluid in the pump chamber is a measure of the absence or presence of air bubbles. Specifically, air bubbles will increase compressibility. The compressibility is measured using the linear encoder to measure the linear displacement of the piezo-stack actuator under a reference electrical bias (which may optionally be the same as the operational electrical bias).

To detect tube occlusions or tube disconnects (more generally, tube resistance), a similar process is employed but with the outlet valve open. A tube occlusion will be picked up as decreased actuator movement under a reference electrical bias, while a tube disconnect will be detected as increased actuator movement under the reference electrical bias.

Since bubble detection employs a well-defined closed system, it may be reasonable to empirically calibrate the quantitative increase in linear displacement corresponding to an air bubble. On the other hand, tube resistance depends on numerous factors (e.g. tube length, tube path). To account for this, the calibration may be performed for various tube resistances, tube lengths, and/or tube paths of the tube connected to the outlet valve of the fluid chamber to develop a calibration parameterized by tube resistance, length, and/or path.

The following makes drug delivery in the MR safer and potentially more accurate by implementing a novel actuator that will allow greater delivery accuracy and the combination of several functions into a single component. The disclosed infusion pump motor comprising a piezo-stack actuator is simpler, has no pull and creates no audible noise as it operates at low frequency (i.e. below the audible range). The piezo-stack actuator consumes low power and allows for elimination of complex drive mechanisms. The control pulse shape may be managed to achieve proportional control.

A piezo-stack actuator, with or without mechanical advantage is used to drive a pump membrane. The work function of this stack actuator is known in one of 3 possible ways: (1) from the batch in which it was built if this is sufficiently controlled; (2) from characterization during build; and (3) from a self test function.

In some embodiments, the piezo-stack actuator serves as the motor of the infusion pump has a linear encoder attached directly linked to the point at which it drives the pump membrane. The relationship of the applied current / applied waveform and the resultant displacement of the pump head is known, e.g. by empirical calibration.

Bubble detection, occlusion detection and/or tube disconnection detection may be achieved through monitoring of the linear encoder response once the work function and input signal is known.

With reference now to FIGURE 1, a schematic illustration of an infusion pump **10** is shown. The infusion pump **10** includes a housing **12** that encloses a fluid pump **14**, a power source (or power converter, e.g. to convert 110V or 220V a.c. power to operating power) **16**, and at least one electronic processor **18**. FIGURE 1 shows a top view of the infusion pump **10** with a "top" portion of the housing **12** is removed, so that the internal components disposed therein are visible. The fluid pump **14** is configured to operate the medical device **10** to deliver medication to a patient. The fluid pump **14** is powered by the power source **16** (e.g., a battery). The at least one processor **18** is programmed to control operations of the infusion pump **10**, as described in more detail below.

The infusion pump **10** also includes a display **20** configured to display details of operations of the medical device **10**, as described in more detail below. A keypad **22** (or dials, buttons, or other user controls) is disposed adjacent the display **20**. The illustrative keypad **22** includes a plurality of keys **24**.

The infusion pump **10** is of the volumetric infusion pump type, in which an intravascular (IV) fluid bag (not shown) is connected to an inlet of the infusion pump **10** and the fluid pump **14** draws fluid from the IV fluid bag and pumps it to an IV fluid line connecting with the patient at a controlled flow rate.

With reference now to FIGURE 2, and with continuing reference to FIGURE 1, the fluid pump **14** of the volumetric infusion pump **10** is shown in more detail. The fluid pump **14** includes an inlet **26** (optionally valved by an inlet valve, not shown) to a fluid chamber **28** defined by a plurality of walls **30**. The fluid chamber **28** also has an outlet **32** valved by an outlet valve **34**. As shown in FIGURE 2, the inlet **26** and the outlet **32** are disposed on opposing walls **30** of the fluid chamber **28**; however, in some examples, the inlet and the outlet are disposed on adjacent walls **30**, or the same wall, of the fluid chamber **28**. It is also noted that the outlet valve **34** may be variously placed, e.g. embedded into the wall of the fluid chamber **28** or connected to a tube extending out from the wall, or so forth.

The illustrative fluid pump **14** includes a piezo-stack actuator **36** comprising a stack of piezo-electric layers **38** which is connected to pump the fluid chamber **28**. In the illustrative embodiment, the piezo-stack actuator **36** pushes against a pump membrane **39** formed into a proximate wall of the fluid chamber **28**. The piezo-stack actuator **36** lengthens linearly in response to an applied electrical bias (e.g. voltage) in accordance with a piezo-electric property of the piezo-electric layers **38**. This action deforms the pump membrane **39** inward so as to reduce the volume contained in the fluid chamber **28**, thereby increasing pressure of the infusion fluid in the fluid chamber **28**. Conversely, when the bias is removed (or reduced) the piezo-stack actuator **36** reduces in length, thereby increasing the volume and reducing the chamber pressure. In a typical operating sequence, the outlet valve **34** is closed, the electrical bias is applied to the fluid chamber **28** to pressurize it, the outlet valve **34** is opened to release fluid flow, then closed to complete the cycle. Some illustrative embodiments of the piezo-stack actuator **36** include can include a commercially-available actuator (e.g., from Viking AT, LLC, Sarasota, FL).

In embodiments employing integral sensing of bubbles, occlusions, and/or tube disconnects, a linear encoder **40** is connected to the piezo-stack actuator **36**. The linear encoder **40** is configured to measure a displacement of the piezo-stack actuator **36** during operation of the piezo-stack actuator **36**. As shown in FIGURE 2, the linear encoder **40** is disposed adjacent the

piezo-stack actuator **36**; however, in some examples, the linear encoder **40** can be disposed on a different wall **30** than the wall that the piezo-stack actuator **36** is disposed on, or the linear encoder **40** can integrally formed with the piezo-stack actuator **36**. The linear encoder **40** can be configured as any suitable sensor configured to measure a displacement of the piezo-stack actuator **36** during operation of the motor **14**. For example, the linear encoder **40** may be an optical linear encoder, capacitive or inductive linear encoder, or so forth. A magnetic linear encoder is also contemplated, but is not preferred in the case of an MR-compatible infusion pump.

To provide bubble, occlusion, and/or disconnect detection, the at least one electronic processor **18** is programmed to read the linear encoder **40** and, based on the displacement of the piezo-stack actuator **36** measured by the linear encoder, detect the presence of at least one of bubbles in the fluid chamber **28**, a tube occlusion, or a tube disconnection. In this context, a tube occlusion refers to a blockage of flow through a fluid tube **42** through which IV fluid is flowed into the patient's vascular system. The fluid tube **42** is connected at one end to the outlet **32** of the fluid pump **14** with the outlet valve **34** connected to control (e.g. valve on or off) flow of IV fluid from the fluid chamber **28** into the fluid tube **42**. The opposite end of the fluid tube **42** is operatively connected to flow fluid into the patient's vascular system, e.g. connected with an IV cannula that is inserted into a vein (for intravenous infusion) or artery (for arterial infusion). A "tube occlusion" in this context refers to any blockage that prevents the fluid pump **14** from "seeing" the expected flow resistance at the outlet **32**. Thus, it will be appreciated that an occlusion will be detected if the blockage is in the fluid tube **42**, but will also be detected if the blockage is at the outlet **32** or in the cannula or other tube/patient coupling. Likewise, a "tube disconnect" as used herein refers to any disconnect that produces a low flow resistance as "seen" from the outlet **32**. Thus, it will be appreciated that a tube disconnect will be detected if it occurs at the connection of the tube **42** with the outlet **32** of the fluid chamber **28**, or if it occurs at the tube/cannula connection or of the cannula dislodges from the patient. In other embodiments, the electronic processor **18** is programmed to measure the displacement of the piezo-stack actuator **36** during operation of the piezo-stack actuator **36** to detect each of: the presence of bubbles in the fluid chamber **28**, the presence of occlusions in the tube **42** connected to the outlet valve **34** of the fluid chamber, and the presence of line disconnections of the tube **42** connected to the outlet **32** of the fluid chamber **28**.

In one example, as shown in FIGURE 2, the at least one processor **18** is programmed to detect the presence of bubbles in the fluid chamber **28** based on the displacement of the piezo-stack actuator **36** during operation of the motor **14**. To do so, the at least one processor **18** is programmed to read the linear encoder **40** during operation of the piezo-stack actuator **36** (i.e., while the fluid pump **14** is running) at a reference electrical bias and with the outlet valve **34** closed. A displacement value of the piezo-stack actuator **36** is measured by the linear encoder **40** at the reference electrical bias and with the outlet valve closed. From the measured displacement value, the at least one processor **18** is programmed to compare the measured displacement value with a bubbles detection threshold value that is programmed into the at least one processor. If the measured displacement is greater than the bubbles detection threshold value, then at least one bubble is present in the fluid chamber **28**. Conversely, if the measured displacement is less than the bubbles detection threshold value, then there are no bubbles present in the fluid chamber **28**. The at least one processor **18** is then programmed to output a warning (i.e., on a display, a warning sensor, an audible tone, and the like) to alert a user of the presence of bubbles.

In another example, the electronic processor **18** is programmed to detect the presence of occlusions in the tube **42** connected to the outlet valve **34** of the fluid chamber **28**. To do so, the at least one processor **18** is programmed to read the linear encoder **40** during operation of the piezo-stack actuator **36** (i.e., while the motor **14** is running) at a reference electrical bias and with the outlet valve **32** open (as opposed to the bubble detection operation in which the outlet valve **34** is closed). A displacement value of the piezo-stack actuator **36** is measured by the linear encoder **40** at the reference electrical bias and with the outlet valve open. From the measured displacement value, the at least one processor **18** is programmed to compare the measured displacement value with an occlusion threshold value that is programmed into the at least one processor. The occlusion threshold value is a function of at least one of tube resistance, tube length, and tube path of the tube **42**. If the measured displacement is less than the occlusion threshold value, then at least one occlusion is present in the tube **42**. The at least one processor **18** is then programmed to output a warning (i.e., on a display, a warning sensor, an audible tone, and the like) to alert a user of the presence of occlusions.

In a further example, the electronic processor **18** is programmed to detect the presence of a tube disconnection (i.e., a disconnection between the tube **42** and the inlet value **32**/ outlet valve

**34**). To do so, the at least one processor **18** is programmed to read the linear encoder **40** during operation of the piezo-stack actuator **36** (i.e., while the motor **14** is running) at a reference electrical bias and with the outlet valve **32** open (similar to the occlusion detection operation). A displacement value of the piezo-stack actuator **36** is measured by the linear encoder **40** at the reference electrical bias and with the outlet valve open. From the measured displacement value, the at least one processor **18** is programmed to compare the measured displacement value with a disconnect threshold value that is programmed into the at least one processor. The disconnect threshold value is a function of at least one of tube resistance, tube length, and tube path of the tube **42**. If the measured displacement is greater than the disconnect threshold value, then a tube disconnection is detected (i.e., between the tube **42** and the inlet value **32/** outlet valve **34**). The at least one processor **18** is then programmed to output a warning (i.e., on a display, a warning sensor, an audible tone, and the like) to alert a user of the presence of tube disconnections.

It will be appreciated that the medical device **10** (i.e., the infusion pump **10**) is configured for use in an MR environment to avoid generating MR interference. To prevent generating MR interference, the components of the infusion pump **10**, in particular the motor **14**, are made from non-magnetic materials.

With reference now to FIGURE 4, a method **100** of using a infusion pump **10** in an MR environment is shown. At step **102**, a displacement of a piezo-stack actuator **36** attached to a motor **14** during operation of the motor is measured using a linear enconder **40**. At optional step **104**, with at least one processor **18**, the measured displacement of the piezo-stack actuator **36** is compared to a reference value to detect the presence of bubbles in a fluid chamber **28** of the motor **14**. At optional step **106**, with the at least one processor **18**, the measured displacement of the piezo-stack actuator **36** is compared to a reference value to detect the presence of occlusions in a tube **42** connected to the outlet **34** of the fluid chamber **28**. At optional step **108**, with at least one processor **18**, the measured displacement of the piezo-stack actuator **36** is compared to a reference value to detect the presence of line disconnections of the tube **42** connected to the outlet valve **34** of the fluid chamber **28**. At step **110**, with at least one processor **18**, a warning is outputted to a user to indicate the presence of at least one of the bubbles, occlusions and tube disconnections.

It will be appreciated that the illustrative data processing or data interfacing components of the medical device **10** may be embodied as a non-transitory storage medium storing instructions

executable by an electronic processor (e.g. the at least one electronic processor **18**) to perform the disclosed operations. The non-transitory storage medium may, for example, comprise a hard disk drive, RAID, or other magnetic storage medium; a solid state drive, flash drive, electronically erasable read-only memory (EEROM) or other electronic memory; an optical disk or other optical storage; various combinations thereof; or so forth.

The disclosure has been described with reference to the preferred embodiments. Modifications and alterations may occur to others upon reading and understanding the preceding detailed description. It is intended that the invention be constructed as including all such modifications and alterations insofar as they come within the scope of the appended claims or the equivalents thereof.

CLAIMS:

1. An infusion pump (**10**), comprising:

a fluid chamber (**28**) having an outlet valve (**34**);

a piezo-stack actuator (**36**) comprising a stack of piezo-electric layers (**38**); and

an electronic processor (**18**) programmed to operate the outlet valve and the piezo-stack actuator to pump fluid through the fluid chamber at a programmed flow rate.

2. The infusion pump (**10**) according to claim 1, further comprising:

a linear encoder (**40**) connected to the fluid chamber (**28**), the linear encoder being configured to measure a displacement of the piezo-stack actuator during operation of the piezo-stack actuator (**36**);

wherein the at least one electronic processor (**18**) is further programmed to read the linear encoder and, based on the displacement of the piezo-stack actuator measured by the linear encoder, detect the presence of at least one of bubbles in the fluid chamber, a tube occlusion, or a tube disconnection.

3. The infusion pump (**10**) according to claim 2, wherein the electronic processor (**18**) is programmed to measure the displacement of the piezo-stack actuator (**36**) during operation of the piezo-stack actuator to detect each of: the presence of bubbles in the fluid chamber (**28**), the presence of occlusions in a tube (**42**) connected to the outlet valve (**34**) of the fluid chamber, and the presence of line disconnections of the tube connected to the outlet valve of the fluid chamber.

4. The infusion pump (**10**) according to either one of claims 2 and 3 wherein the electronic processor (**18**) is programmed to detect the presence of bubbles in the fluid chamber (**28**) by performing operations including:

reading the linear encoder (**40**) during operation of the piezo-stack actuator (**36**) at a reference electrical bias and with the outlet valve (**34**) closed; and

detecting bubbles in the fluid chamber based on the measured displacement at the reference electrical bias and with the outlet valve closed being greater than a bubbles detection threshold value.

5. The infusion pump (**10**) according to either one of claims 2 and 3, wherein the electronic processor (**18**) is programmed to detect the presence of a tube occlusion by performing operations including:

reading the linear encoder (**40**) during operation of the piezo-stack actuator (**36**) at a reference electrical bias and with the outlet valve (**32**) open; and

detecting a tube occlusion based on the measured displacement at the reference electrical bias and with the outlet valve open being less than an occlusion threshold value.

6. The infusion pump (**10**) according to claim 5, wherein the occlusion threshold value is a function of at least one of tube resistance, tube length, and tube path of the tube (**42**) connected to the outlet valve of the fluid chamber (**28**).

7. The infusion pump (**10**) according to either one of claims 1 and 2, wherein the electronic processor (**18**) is programmed to detect the presence of a tube disconnection by performing operations including:

reading the linear encoder (**40**) during operation of the piezo-stack actuator (**36**) at a reference electrical bias and with the outlet valve (**34**) open; and

detecting a tube disconnection based on the measured displacement at the reference electrical bias and with the outlet valve open being greater than a disconnect threshold value.

8. The infusion pump (**10**) according to claim 6, wherein the disconnect threshold value is a function of at least one of tube resistance, tube length, and tube path of the tube (**42**).

9. The infusion pump (**10**) according to any one of claims 1-7, wherein the infusion pump includes no magnetic material.

10. A method of using an infusion pump (**10**) with a fluid chamber (**28**) that is pumped by a pump motor comprising a piezo-stack actuator (**36**), the method comprising:

with a linear encoder (**40**), measuring a displacement of the piezo-stack actuator (**36**) during operation of the piezo-stack actuator;

with at least one processor (**18**), comparing the measured displacement to a reference value to detect the presence of at least one of bubbles in a fluid chamber (**28**) of the motor, the presence of occlusions in a tube (**42**) connected to an outlet valve (**34**) of the fluid chamber, or the presence of line disconnections of the tube connected to the outlet valve of the fluid chamber; and

with the at least one processor (**18**), outputting a warning indicating the presence of at least one of the bubbles, occlusions and tube disconnections.

11. The method according to claim 10, further including, with the at least one processor (**18**):

reading the linear encoder (**40**) during operation of the piezo-stack actuator (**36**) at a reference electrical bias and with the outlet valve (**34**) closed; and

detecting bubbles in the fluid chamber based on the measured displacement at the reference electrical bias and with the outlet valve closed being greater than a bubbles detection threshold value.

12. The method according to claim 10, further including, with the at least one processor (**18**):

reading the linear encoder (**40**) during operation of the piezo-stack actuator (**36**) at a reference electrical bias and with the outlet valve (**32**) open; and

detecting a tube occlusion based on the measured displacement at the reference electrical bias and with the outlet valve open being less than an occlusion threshold value.

13. The method according to claim 12, wherein the occlusion threshold value is a function of at least one of tube resistance, tube length, and tube path of the tube (**42**) connected to the outlet valve of the fluid chamber (**28**).

14. The method according to claim 10, further including, with the at least one processor (**18**):

reading the linear encoder (**40**) during operation of the piezo-stack actuator (**36**) at a reference electrical bias and with the outlet valve (**34**) open; and

detecting a tube disconnection based on the measured displacement at the reference electrical bias and with the outlet valve open being greater than a disconnect threshold value.

15. The method according to claim 14, wherein the disconnect threshold value is a function of at least one of tube resistance, tube length, and tube path of the tube (**42**).

16. An infusion pump (**10**), comprising:

a fluid chamber (**28**) having an outlet valve (**34**);

a piezo-stack actuator (**36**) comprising a stack of piezo-electric layers (**38**);

a linear encoder (**40**) connected to the fluid chamber (**28**), the linear encoder being configured to measure a displacement of the piezo-stack actuator during operation of the piezo-stack actuator (**36**); and

an electronic processor (**18**) programmed to:

operate the outlet valve and the piezo-stack actuator to pump fluid through the fluid chamber at a programmed flow rate; and

read the linear encoder and, based on the displacement of the piezo-stack actuator measured by the linear encoder, detect the presence of each of: bubbles in the fluid chamber, a tube occlusion, or a tube disconnection.

17. The infusion pump (**10**) according to claim 16, wherein the electronic processor (**18**) is programmed to detect the presence of bubbles in the fluid chamber (**28**) by performing operations including:

reading the linear encoder (**40**) during operation of the piezo-stack actuator (**36**) at a reference electrical bias and with the outlet valve (**34**) closed; and

detecting bubbles in the fluid chamber based on the measured displacement at the reference electrical bias and with the outlet valve closed being greater than a bubbles detection threshold value.

18. The infusion pump (**10**) according to claim 16, wherein the electronic processor (**18**) is programmed to detect the presence of a tube occlusion by performing operations including:

reading the linear encoder (**40**) during operation of the piezo-stack actuator (**36**) at a reference electrical bias and with the outlet valve (**32**) open; and

detecting a tube occlusion based on the measured displacement at the reference electrical bias and with the outlet valve open being less than an occlusion threshold value,

wherein the occlusion threshold value is a function of at least one of tube resistance, tube length, and tube path of the tube (**42**) connected to the outlet valve of the fluid chamber (**28**).

19. The infusion pump (**10**) according to either one of claims 1 and 2, wherein the electronic processor (**18**) is programmed to detect the presence of a tube disconnection by performing operations including:

reading the linear encoder (**40**) during operation of the piezo-stack actuator (**36**) at a reference electrical bias and with the outlet valve (**34**) open; and

detecting a tube disconnection based on the measured displacement at the reference electrical bias and with the outlet valve open being greater than a disconnect threshold value,

wherein the disconnect threshold value is a function of at least one of tube resistance, tube length, and tube path of the tube (**42**).

20. The infusion pump (**10**) according to any one of claims 16-19, wherein the infusion pump includes no magnetic material.

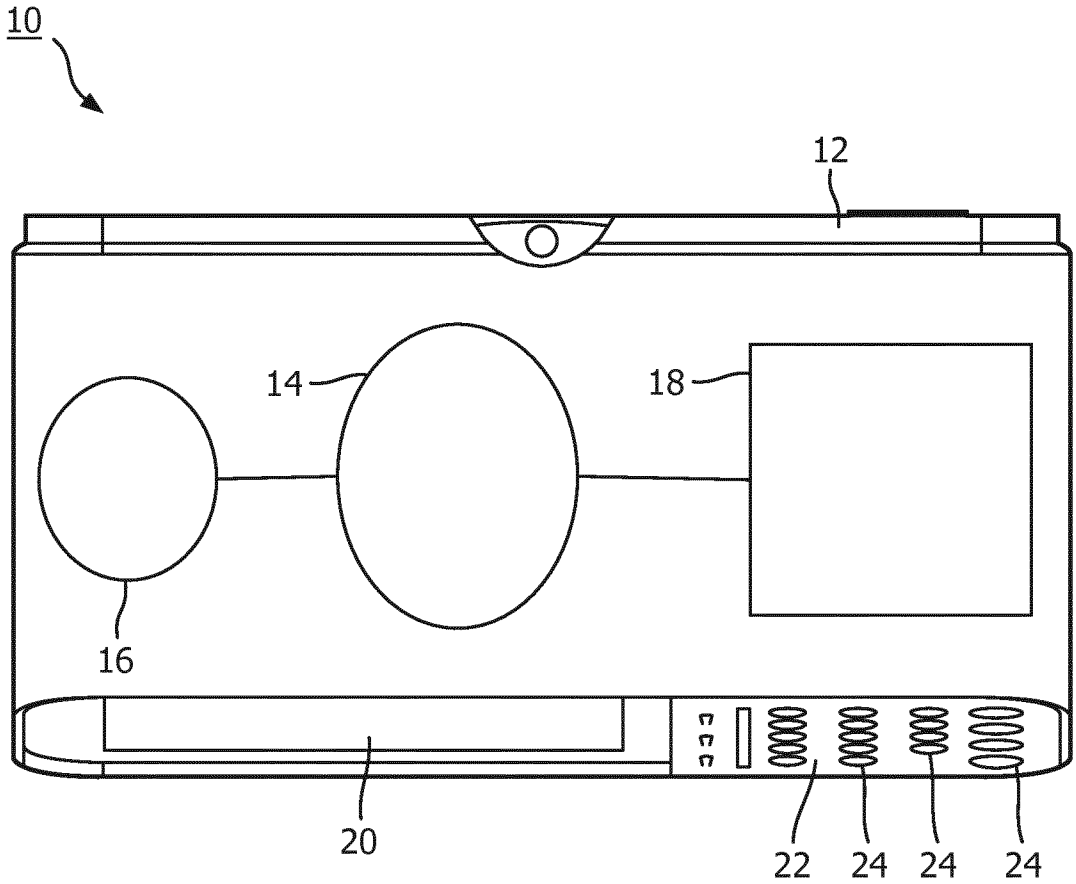


FIG. 1

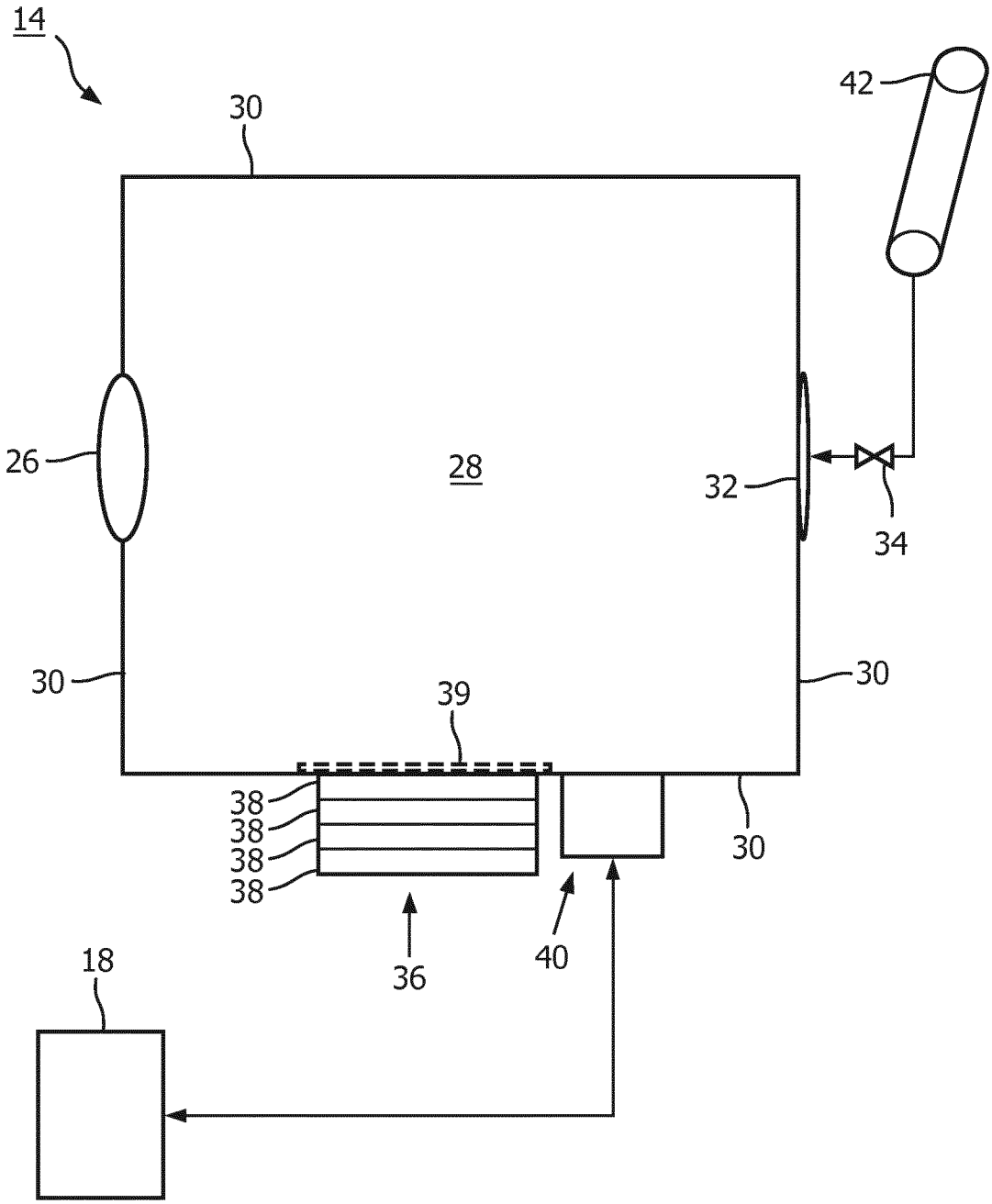


FIG. 2

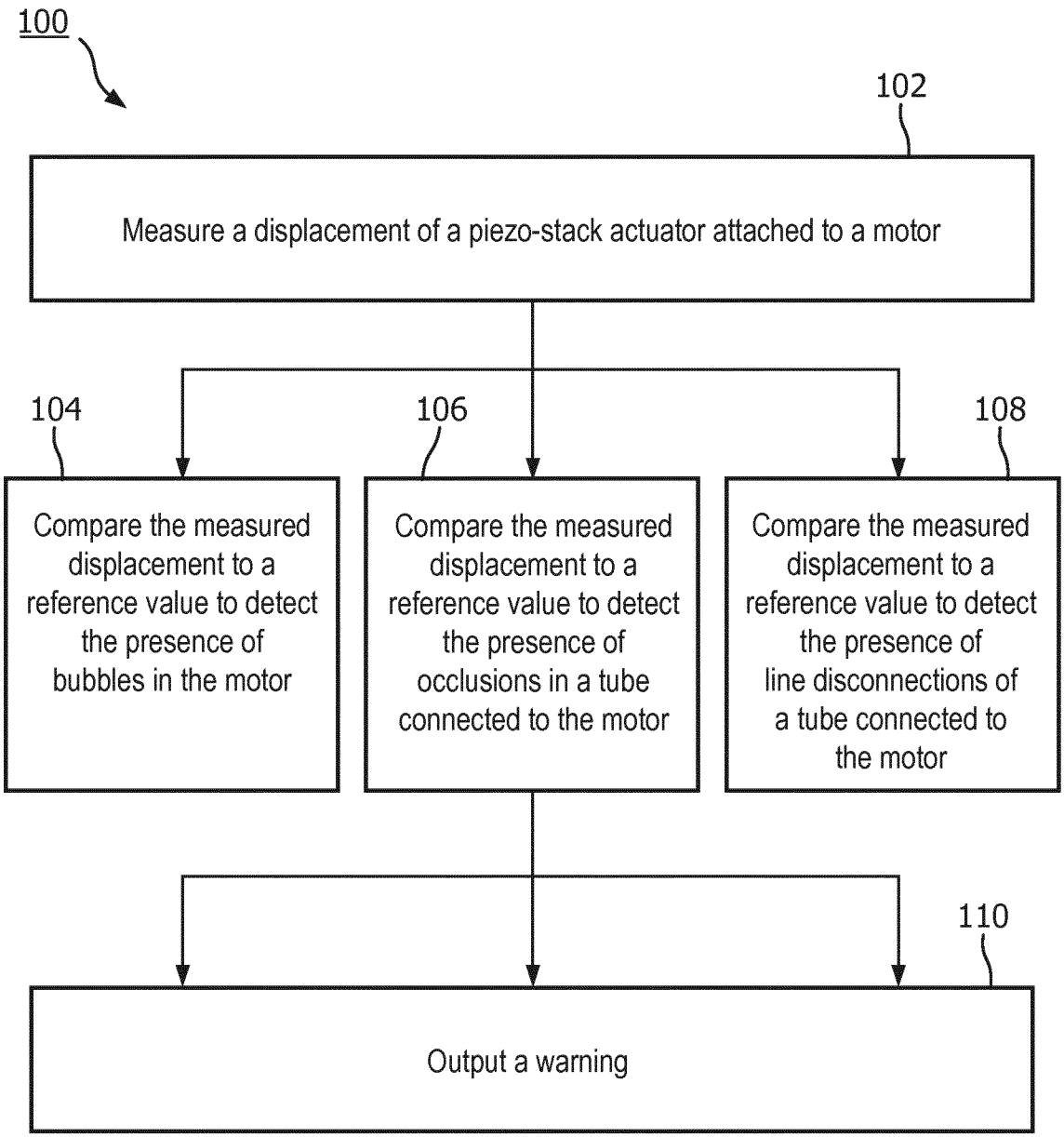
100
102
Measure a displacement of a piezo-stack actuator attached to a motor
104
106
108
Compare the measured displacement to a reference value to detect the presence of bubbles in the motor
Compare the measured displacement to a reference value to detect the presence of occlusions in a tube connected to the motor
Compare the measured displacement to a reference value to detect the presence of line disconnections of a tube connected to the motor
110
Output a warning

FIG. 3

# INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/074915

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/142
ADD. A61M5/168 A61M5/00 A61M5/365

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | EP 0 398 583 A2 (BESPAK PLC [GB])<br>22 November 1990 (1990-11-22)<br>the whole document<br>----- | 1-9,<br>16-20 |
| X | WO 2010/046728 A1 (DEBIOTECH SA [CH];<br>CHAPPEL ERIC [FR]; SCHNEEBERGER NIKLAUS<br>[CH]; NEFTE) 29 April 2010 (2010-04-29)<br>figures 1-14<br>----- | 1-9,<br>16-20 |
| A | US 5 759 014 A (VAN LINTEL HARALD [CH])<br>2 June 1998 (1998-06-02)<br>figure 1<br>----- | 1-9,<br>16-20 |
| X | EP 1 403 519 A1 (NOVO NORDISK AS [DK])<br>31 March 2004 (2004-03-31)<br>paragraphs [0061] - [0063], [0065],<br>[0036]; figures 3A, 3B<br>----- | 1-9,<br>16-20 |
| | -/-- | |

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"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 |
|---|---|
| 20 December 2017 | 15/01/2018 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Krassow, Heiko |

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Form PCT/ISA/210 (second sheet) (April 2005)

# INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/074915

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | WO 2015/102078 A1 (DAIKEN MEDICAL CO LTD [JP]) 9 July 2015 (2015-07-09) figures 5-7 | 1-9, 16-20 |
| A | US 2009/214358 A1 (O'NEILL CONAL [US]) 27 August 2009 (2009-08-27) paragraph [0007]; figures 1-3B | 1-9, 16-20 |

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# INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2017/074915

**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. [X] Claims Nos.: 10-15
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

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:

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 an additional fees, this Authority did not invite payment of additional fees.

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

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

**Remark on Protest**

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

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

[ ] No protest accompanied the payment of additional search fees.

Continuation of Box II.1

Claims Nos.: 10-15

Claims 10-15 define subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT, and no search report has been drawn up on said claims. The subject-matter defined comprises methods of using an infusion pump inevitably resulting in the infusion of medicament into the human being, i.e. the methods being suitable for treatment of the human body by therapy.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2017/074915

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
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