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(71) Applicant *(for all designated States except US)*: **MEDTRONIC, INC.** [US/US]; 710 Medtronic Parkway Ne, Minneapolis, Minnesota 55432 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **KALPIN, Scott, L.** [US/US]; 4225 430th Street, Harris, Minnesota 55032 (US). **HAASE, James, M.** [US/US]; 3016 Frank Street, Maplewood, Minnesota 55109 (US).

(74) Agents: **MARKS, Scott A.** et al.; Medtronic, Inc., 710 Medtronic Parkway NE, Minneapolis, Minnesota 55432 (US).

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— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

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[Continued on next page]

(54) **Title**: DETECTING A FULL RESERVOIR OF AN IMPLANTABLE INFUSION DEVICE

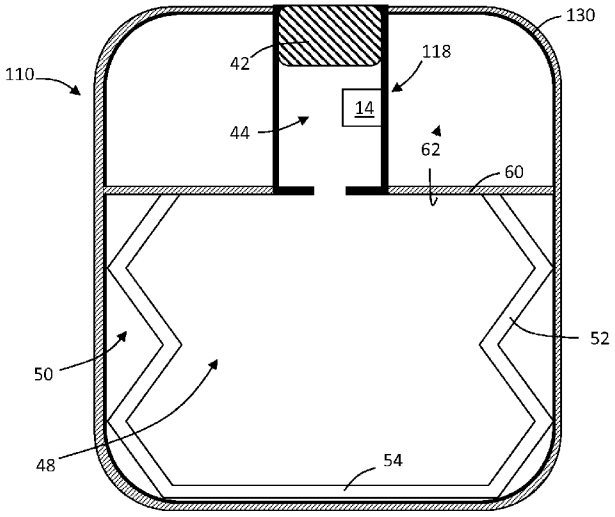

FIG. 3

(57) **Abstract**: An implantable infusion device (110) includes a housing (130) and a collapsible member (50) and an interference member (64) disposed within the housing. The collapsible member defines a reservoir for containing fluid and has an outer surface (56) that moves between an empty position and a full position in response to a change in volume of fluid contained in the reservoir. The interference member is configured to engage the outer surface of the collapsible member as the reservoir approaches the full position and to cause pressure in the reservoir to increase following engagement with the surface of the collapsible member and concomitant fluid introduction into the reservoir. The infusion device further includes a pressure sensor (14) in communication with the reservoir, which can be used to determine whether the reservoir is full by measuring characteristic pressures associated with the interference member engaging the outer surface of the collapsible member and concomitant fluid introduction into the reservoir.

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DETECTING A FULL RESERVOIR OF AN IMPLANTABLE INFUSION DEVICE

FIELD

The present disclosure relates generally to implantable medical devices, and more particularly to systems and methods for detecting whether a reservoir of a refillable implantable infusion device is full.

BACKGROUND

Implantable infusions systems have been used to treat a variety of diseases, such as spasticity, pain and cancer by targeting drug delivery to a selected area of a patient. Therapies employing such systems have proven to be very helpful for patients for which systemic therapy is not effective, possible, or practicable. The implantable systems include an implantable infusion device containing a reservoir for housing the drug and a catheter coupled to the reservoir to direct the drug to the target area. The devices typically include a pump or mechanism for driving fluid from the reservoir, or withdrawing fluid from the reservoir, and through the catheter.

Many implantable infusion devices are configured to allow the reservoir to be transcutaneously refilled. Clinicians who refill the reservoirs of implantable infusion devices would benefit from an indication of reservoir "fullness" during the refill procedure. Such an indication may also increase conformance by ensuring that the reservoir repeatedly reaches a completely full status each time the reservoir is refilled.

Some implantable infusion devices have an over-pressurization mechanism (OPM) that prevents overfilling of the reservoir. The OPM may serve as a valve that closes an entry port into the reservoir when the reservoir is full. Closing the OPM valve results in increased pressure upstream of the valve, which can be felt by a clinician injecting fluid into the reservoir as increased resistance to syringe plunger advancement. This tactile feedback can be used by experienced clinicians as feedback that the reservoir has been filled.

However, due to manufacturing tolerances, the OPM valve is typically set to close when the reservoir is slightly beyond the desired fill level. As such, the OPM valve may

not close every time that a reservoir is refilled. One way to ensure that the OPM valve closes is to reduce the reservoir volume at which the OPM valve closes or to increase the volume of drug in the syringe used to refill the reservoir. Either of these two scenarios would frequently result in undesirable waste of drug.

SUMMARY

This disclosure, among other things, describes devices, systems and methods for detecting when a reservoir of an implantable infusion device reaches fullness during a filling procedure. Infusion devices described herein are configured to create a detectable pressure increase in the reservoir when the reservoir becomes full during a refill procedure. A pressure sensor in communication with the reservoir, and electronics operably coupled to the pressure sensor, may be used to measure pressure in the reservoir and to determine whether a pressure increase characteristic of the reservoir being full is detected. If such as characteristic pressure increase is observed, a clinician refilling the reservoir may be alerted to stop filling the reservoir.

In various embodiments described herein, an implantable infusion device includes a housing and a collapsible member and an interference member disposed in the housing. The collapsible defines a reservoir for containing a variable volume of fluid therein and has an outer surface that moves between an empty position and a full position in response to a change in volume of fluid contained in the reservoir. The interference member is configured to engage the outer surface of the collapsible member as the reservoir approaches the full position and to cause pressure in the reservoir to increase following engagement with the surface of the collapsible member and concomitant fluid introduction into the reservoir. The infusion device also includes a pressure sensor in communication with the reservoir and includes electronics operably coupled to the pressure sensor for detecting the increase in pressure associated with engagement of the interference member with the surface of the collapsible member and concomitant fluid introduction into the reservoir. The electronics may be configured to determine whether a sensed pressure increase is indicative of engagement of the interference member with the outer surface of the collapsible member and concomitant fluid introduction into the

reservoir, which is indicative of the reservoir being full. Data regarding the sensed pressure or whether the reservoir is full may be sent to an external device via telemetry for display to provide feedback regarding the full status of the reservoir during a refill procedure. Accordingly, a user may cease infusion of fluid into the reservoir once the display indicates that the reservoir is full.

Systems and method employing such infusion devices are also discussed herein.

One or more embodiments of the systems, devices and methods described herein may provide one or more advantages over prior systems, devices and methods for detecting when a reservoir of an implantable infusion device reaches fullness during a filling procedure. For example, the devices, methods and systems employed herein may allow for a display that the reservoir is full, as opposed to tactile feedback associated with OPMs, so that clinicians may more reproducibly stop filling a reservoir when the reservoir is full. This will increase reproducibility of therapy and perhaps result in more effective therapy across populations by reducing variability in full status. Of course, the devices methods and systems described herein may also employ OPMs, which can provide an additional safety feature in case of an error in the reservoir full detection system. These and other advantages of one or more embodiments of the methods and systems described herein will be apparent to those of skilled in the art upon reading the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated into and form a part of the specification, illustrate several embodiments of the present disclosure and, together with the description, serve to explain the principles of the disclosure. The drawings are only for the purpose of illustrating embodiments of the disclosure and are not to be construed as limiting the disclosure.

FIG. 1 is schematic view showing an infusion system implanted in a patient, along with an external device.

FIGS. 2-13 are schematic cross-sectional views showing selected components of implantable infusion devices in accordance with various embodiments described herein.

FIGS. 14-17 are simulated plots of pressure versus time or derivative of pressure versus time.

FIG. 18 is a flow diagram of an embodiment of a method.

FIGS. 19-20 are schematic block diagrams showing selected components of systems in accordance with embodiments described herein.

The schematic drawings presented herein are not necessarily to scale. Like numbers used in the figures refer to like components, steps and the like. However, it will be understood that the use of a number to refer to a component in a given figure is not intended to limit the component in another figure labeled with the same number. In addition, the use of different numbers to refer to components is not intended to indicate that the different numbered components cannot be the same or similar.

DETAILED DESCRIPTION

In the following detailed description, reference is made to the accompanying drawings that form a part hereof, and in which are shown by way of illustration several embodiments of devices, systems and methods. It is to be understood that other embodiments are contemplated and may be made without departing from the scope or spirit of the present disclosure. The following detailed description, therefore, is not to be taken in a limiting sense.

All scientific and technical terms used herein have meanings commonly used in the art unless otherwise specified. The definitions provided herein are to facilitate understanding of certain terms used frequently herein and are not meant to limit the scope of the present disclosure.

As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” encompass embodiments having plural referents, unless the content clearly dictates otherwise.

As used in this specification and the appended claims, the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise.

As used herein, "have", "having", "include", "including", "comprise", "comprising" or the like are used in their open ended sense, and generally mean "including, but not limited to."

As used herein, "full" or the like, as it relates to a reservoir volume means a volume to which the reservoir is intended to be filled, and does not necessarily, and often does not, refer to the maximum volume of fluid that the reservoir is capable of containing. For example, a 20 ml reservoir in an implantable infusion device may be capable of containing 22 ml or more of fluid. However, for the purposes of device and therapy reliability, it is often desired or intended for the reservoir to be refilled to a volume of 20 ml. Thus, the intended volume of 20 ml of such a device would be the full volume for the purposes of this disclosure. Regardless of the intended volume of the reservoir, it will be understood that "full" may include +/- 5% of the intended full volume, as manufacturing variability and other design and use constraints often make it difficult or impracticable to precisely make each device perform identically with regard to reservoir full status. Full may refer to the point at which a surface of a collapsible member defining the reservoir contacts an interference member, as described herein

Any direction referred to herein, such as "top", "bottom", "left", "right", "upper", "lower", and other directions or orientations are described herein for clarity in reference to the figures and are not intended to be limiting of an actual device or system. Devices and systems described herein may be used in a number of directions and orientations.

As used herein, "concomitant," as it relates to introduction of fluid into a reservoir in relation to engagement of a surface of a collapsible member defining the reservoir with an interference member, means the fluid is introduced at the time the surface of the collapsible member initially engages the interference member and continues following the initial engagement.

This disclosure relates to, among other things, devices, systems and methods for detecting when a reservoir of an implantable infusion device reaches fullness during a filling procedure. Infusion devices described herein are configured to create a detectable pressure increase in the reservoir when the reservoir becomes full during a refill procedure. A pressure sensor in communication with the reservoir, and electronics operably coupled to the pressure sensor, may be used to measure pressure in the reservoir and to determine whether a pressure increase characteristic of the reservoir being full is detected. If such as characteristic pressure increase is observed, a clinician refilling the reservoir may be alerted or notified and may stop filling the reservoir.

The devices, systems and methods described herein may be employed with any suitable implantable infusion system. **FIG. 1** shows an example of an infusion system **100** that may be employed in accordance with the teachings presented herein. The infusion system depicted in **FIG. 1** includes an infusion device **110** and a catheter **120**. The catheter **120** is operably coupled to the infusion device **110** such that the catheter **120** is in fluid communication with a reservoir (not shown in **FIG. 1**) of the device **110**. The depicted infusion device **110** includes a refill port **118** in communication with the reservoir, which is disposed within the housing of the device **110**. The supply of therapeutic agent in the reservoir may be replenished via the refill port **118**. The infusion device **110** may include any suitable mechanism or structure capable of delivering one or more fluids to a patient. The structures used to drive fluids in the infusion devices may be powered (e.g., piston pumps, diaphragm pumps, peristaltic pumps, etc.), may be activated based on pressure to drive fluid out of a reservoir (e.g., using collapsing diaphragms, expanding bladders, osmotic, etc.), or the like. The infusion device **110** may contain a catheter access port **112** in communication with the catheter **120** at a location upstream of the reservoir.

The infusion system **100** depicted in **FIG. 1** is shown implanted in a patient. The proximal end **122** of the catheter **120** is coupled to the infusion device **110**. The infusion device **110** may be surgically implanted in any suitable location, such as subcutaneously in the pectoral, abdominal or other region of the subject's body. The distal end **124** of the

catheter **120** is implanted in a patient such that the distal end **124** is located at the selected internal delivery site in the patient (in the intrathecal space of the patient as depicted in **FIG. 1,** the cerebroventricles, or elsewhere as desired).

An external device **200** capable of wireless communication with the implanted infusion device **110** is also shown in **FIG. 1**. The depicted external device **200** includes a display **210** for presenting information to a user, such as a healthcare provider. In various embodiments, the external device **210** is capable of presenting information to the user that the reservoir has reached fullness.

Any suitable external device, such as a programmer (e.g., a Medtronic, Inc. N'Vision® clinician programmer or a Medtronic, Inc. myPTM® patient programmer), a tablet computer, a smart phone, a personal data assistance, a laptop computer, or the like, may be employed, provided that it is capable of communicating with the implanted infusion device. In some embodiments, the external device **200** is a desktop computer with an associated monitor serving as the display **210**.

Referring now to **FIGS. 2-13**, schematic cross-sectional drawings of various embodiments of implantable infusion devices configured to allow detection of when a reservoir is full are shown. Only selected components of the infusion device are shown for purposes of clarity. The depicted infusion devices include a refill port **118** in communication with reservoir **48** for containing a variable volume of fluid. A septum **42** seals a port chamber **44** relative to an exterior of the device housing **130**.

The reservoir **48** is defined by a collapsible member **50**, which in the depicted embodiments is a bellows-type reservoir having an accordion-like collapsible, generally cylindrical wall **52**. However, it will be understood that any type of collapsible reservoir, such as an expandable and collapsible bag, an elastomeric balloon-type reservoir, or the like, may be employed.

In the depicted embodiment, the collapsible member **50** is disposed in a chamber **65** defined in part by a bulkhead **60** that partitions the housing **130**. The bulkhead **60** serves to isolate the reservoir **48** from other selected components of the device **110**, such

as certain control electronics. Of course, the chamber **65** may be defined by a structure contained within and fully separate from the housing **130**. At least a portion of the collapsible member **50** (collapsible wall **52** in the depicted embodiment), is connected and sealed to a surface of the bulkhead **60**. Of course, it will be understood that with reservoirs other than bellows-type reservoirs, it may not be desirable to attach a portion of the collapsible member **50** to the surface **62** of the bulkhead **60**, and in some cases a bulkhead **60** may not be desired.

Regardless of the type of collapsible member **50** employed and whether a bulkhead **60** is employed, the collapsible member **50** has a surface **56** that moves between an empty position (see, e.g., **FIGS. 2**, **5**, and **10**) and a full position (see, e.g., **FIGS. 3**, **4**, **6**, **7**, **8** and **11**) in response to a changes in volume of fluid contained in the reservoir **48**. As the reservoir **48** approaches the full position, surface **56** engages with an interference member, which may be an interior surface **64** of the housing **130** that defines a portion of the chamber **65** (see, e.g., **FIGS. 2-9**), a spring member **400** (see, e.g., **FIGS. 10-12**), which may be attached to the interior surface **64** of the housing **130**, or the like. The interference member is positioned such that it contacts the surface **56** at the reservoir full position (e.g., within +/- 5% of the intended full volume). Further infusion of fluid through refill port **118** causes an increase in pressure within the reservoir **48** due to interaction between surface **56** and interference member, which is detected by pressure sensor **14**. However, in any case, the collapsible member **50** and the interference member are configured so that at least some further expansion of the reservoir **48** may occur after the surface **56** engages the interference member.

The pressure sensor **14** may be located anywhere such that it can detect the increase in pressure associated with engagement of the interference member with the surface **56** with concomitant fluid introduction into the reservoir **48**. In the depicted embodiment, the pressure sensor is located in chamber **44** defined by the refill port **118**.

Referring now specifically to **FIGS. 2-3**, the interference member that engages the surface **56** of the collapsible member **50** is the bottom interior surface **64** of the housing **130**. A propellant is disposed in chamber **65**, which surrounds the reservoir **48**

and biases the surface **56** of the collapsible member **50** to the empty position (see **FIG. 2**). As fluid is introduced into the reservoir **48** via refill port **118**, the surface **56** moves towards the full position (see **FIG. 3**). Pressure in the reservoir **48** increases due to a decrease in volume occupied by the propellant in the chamber **65**. The inventors have found that the collapsible member **50**, bulkhead **60**, propellant chamber **65**, and propellant can be configured such that at a constant rate of infusion of fluid into the reservoir, the rate of change of pressure ($\delta P/\delta T$) over the majority of the volume of the reservoir **48** remains nearly constant. However, when the surface **56** of the collapsible member **50** engages the bottom interior surface **64** of the housing **130** while additional fluid is being added, a rapid rise in pressure is observed and the rate of change of pressure ($\delta P/\delta T$) increases. This increase in pressure or increase in rate of pressure increase can be detected by the pressure sensor **14**.

In the embodiment depicted in **FIGS. 2-3**, the bottom interior surface **64** of the housing **130** is configured to contact and engage nearly the entire surface **56** of the collapsible member **50** at the same time, or within a very short period of time, as the reservoir **48** is being filled.

As shown in **FIG. 4**, the bottom interior surface **64** of the housing **130** may be shaped such that only a portion of the surface initially contacts the surface **56** of the collapsible member **50** as the reservoir **48** is filled. This initial contact reflects the full volume of the reservoir **48**. Further infusion of fluid into the reservoir will cause more of the surface **56** of the collapsible member **50** to engage the bottom interior surface **64** of the housing **130**, which in the depicted embodiment is convex. As additional fluid is introduced into the reservoir **48** and more surface contact between surface **56** and surface **64** is made, greater pressure increases and rates of pressure increases are observed in reservoir **48** and detectable by pressure sensor **14**.

While the shape of the bottom interior surface **64** of the housing **130** is depicted in **FIG. 4** as being convex, it will be understood that the surface **64** may be shaped in any suitable manner such that a portion (e.g., less than 50%, less than 40%, less that 30%, less than 20%, less than 10%, or less than 5%) of the surface **64** is configured to engage the

surface **56** of the collapsible member **50** when the reservoir **48** is full, with additional surface contact occurring upon additional fluid being added to the reservoir.

Referring now to **FIGS. 5-6**, embodiments of infusion devices **110** having an over-pressurization mechanism (OPM) **300** are shown. The OPM **300** is positioned within a transfer chamber **340** that forms a portion of the refill passageway and is, therefore, fluidly coupled to both the refill port **118** and the reservoir **48**. Any suitable OPM **300** may be employed, such as those described in, for example, WO 2007/127828 and US Patent No. 6,152,898.

In the embodiment depicted in **FIGS. 5-6**, the OPM **300** includes a valve assembly having a telescoping cylindrical valve body **310** slidable within a valve passageway **330** formed in the bulkhead **60**. A clearance exists between a diameter of the valve body **310** and the valve passageway **330** so that fluid may flow between the transfer chamber **340** and the reservoir **48** during a refill process. A cylindrical or flanged portion or head **320** may be formed at a first, upper end of the valve body **310**. The head **320** has an outer diameter larger than the diameter of the valve body **310** and valve passageway **330**. A sealing member (not shown) such as an O-ring, may be located on the valve body **310** proximate the head **320**. The sealing member may permit selective sealing of the valve passageway **330**.

The OPM **300** may further include a biasing member (not shown), such as a coil spring, positioned to contact the valve body **310** and bias a free distal end **312** of the valve body **310** to abut a reservoir surface **58** that is generally opposed to (i.e., on the opposite side of) the surface **56** of the collapsible member **50** that contacts the interference member, e.g., the bottom interior surface **64** of the housing **130**. The biasing member may bias the free distal end **312** of the valve body **310** to abut the reservoir surface **58** as it moves from the empty position (**FIG. 5**) to the full position (**FIG. 6**). The OPM may include a guide member **350** that serves to ensure proper axial movement of the valve body **310** and to constrain biasing member, e.g. spring (not shown), against lateral movement over all, or substantially all, of the valve plunger's travel.

As depicted in **FIG.6**, when the reservoir is full, the valve body **310** extends to an extent that head (or sealing member – not shown) sealing engages the valve passageway **330** and prevents further infusion of fluid into the reservoir **48**. However, it is often preferred that the OPM **300** is configured such that the valve passageway **330** closes or is sealed at a volume slightly beyond full (e.g., 1% - 10% of reservoir full volume). For example, if the reservoir full volume is 20 ml, it may be desirable for the OPM valve to close at a reservoir volume of between about 20.2 ml to 22 ml, to minimize wasted drug. That is, if a refill syringe is loaded with 20.0 ml of a fluid drug composition and if the OPM were configured to close the OPM valve at a reservoir volume of less than 20 ml, drug would remain in the syringe and would be wasted.

Thus, it may be desirable to allow an additional small amount of fluid (e.g., 1% to 10% of reservoir full volume) to be introduced into a "full" reservoir to avoid wasting of drug. Such small additional amounts of fluid can be well tolerated by most infusion devices.

However, manufacturing tolerances for infusion devices as depicted in **FIGS. 5-6** would be very tight. That is, there is very little room of additional fluid in the reservoir beyond full, and the OPM **300** would need to be set to close at, or very close to, reservoir full volume. For example and with reference to **FIG. 6**, the bottom interior surface **64** of the housing **130** is configured to contact and engage nearly the entire surface **56** of the collapsible member **50** at the same time, or within a very short period of time, of the reservoir **48** becoming full, and thus limits further expansion of the reservoir **48**. Thus, the OPM **300** valve should be configured to close or seal at or before the reservoir full volume in the depicted embodiment. However, as additional fluid infusion into the reservoir **48** is somewhat constrained by the volume of the chamber **65**, an OPM may not be needed in such an embodiment.

One way to overcome the issue associated with tight manufacturing tolerances described above with regard to the embodiment depicted in **FIGS. 5-6** is addressed in the embodiment depicted in **FIG. 7**, where the bottom interior surface **64** of the housing **130** is shaped such that a portion (e.g., less than 50%, less than 40%, less that 30%, less than

20%, less than 10%, or less than 5%) of the surface **64** is configured to engage the surface **56** of the collapsible member **50** when the reservoir **48** is full, with additional surface contact occurring with additional fluid being added to the reservoir **48**. In **FIG. 7**, the reservoir **48** is depicted as full, and introduction of additional fluid into the reservoir **48** will cause an increase in pressure detectable by pressure sensor **14**, which can be determined by electronics of the device **110** to be indicative of a full reservoir. An alert, alarm or notification may be presented to a user to indicate full status.

Additionally, further introduction of fluid into the reservoir **48** will cause further movement of portions of the surface **56** of the collapsible member **50** towards the surface **64** of the housing **60**, allowing further extension of the OPM valve body **310** and sealing of the valve passageway **330**. Upon closing or sealing of the OPM valve passageway **330**, an increase in pressure is observed upstream of the valve with continued attempted infusion of fluid into the refill port **118**. This increase in pressure can be detected by experienced clinicians as feedback that the reservoir is full. Thus, a device **110** configured as depicted in **FIG. 7** may allow for both an indication of reservoir full status via pressure sensor **14** and operably coupled electronics and tactile feedback associated with OPM **300** valve closure, which can provide an additional safety feature in cases of error in the reservoir full status detection components.

In many cases, however, to work effectively, the wall **54** forming the surface **56** of the collapsible member **50** would desirably be sufficiently flexible and resilient to allow for further advancement of the surface **56** beyond the reservoir full position to conform to the shape of the surface **64** of the housing **60**. Preferably the surface **56** would also return substantially to its initial conformation as the reservoir **48** empties so that upon reservoir filling, the surface **56** can again contact only a portion of the surface **64** of the housing **130** (in this case the apex of the convex portion) when the reservoir is full, allowing detection of a pressure response indicative of reservoir full status.

Referring now to **FIGS. 8-9**, an example of an infusion device **110** configuration that may be more suitable for devices **110** having bellows-type reservoirs **48** with a rigid wall that forms the surface **56** of the collapsible member **50** is shown. In this

embodiment, the bottom interior surface **64** of the housing **130** is ramped such that the surface **64** engages the surface **56** of the collapsible member **50** at, or in proximity to, an edge of the surface **56** when the reservoir **48** is full. As additional fluid is introduced into the reservoir **48**, the side of the bellows wall **52** opposite the edge engaging bottom interior surface **64** of the housing **130** may further expand without distorting the shape of the rigid wall that forms the surface **56** of the collapsible member **50**. The OPM valve body member **310** is located and configured to contact the rigid wall that forms the surface **56** of the collapsible member **50** at a position away from the edge that contacts the elevated portion of the ramp of the bottom interior surface **64** of the housing **130** so that fluid infusion into the reservoir **48** beyond full state of the reservoir allows for additional movement of the free distal end **312** of the valve body member **310** towards a less inclined portion of the ramped surface **64**. Thus, the OPM **300** valve may close (e.g., sealing of valve passageway) without distortion of the rigid bottom wall **54** of the collapsible member **50**.

Referring now to **FIGS. 10-12**, an embodiment of an infusion device **110** having a deflectable or compressible member **400** as the interference member configured to engage the surface **56** of the collapsible member **50** when the reservoir is full is shown. As shown in **FIG. 11**, the surface **56** of the collapsible member **50** engages the deflectable member **400** when the reservoir **48** is full. At this point, the OPM **300** valve passageway **330** remains open as the valve body **310** has not fully extended. Further introduction of fluid into the reservoir **48** causes the surface **56** of the collapsible member **50** to press at least a portion of the deflectable member **400** towards the surface **64** of the housing **130**, causing the OPM **300** valve passageway **330** to close (see, **FIG. 12**). As fluid is removed from the reservoir **48** during delivery of therapeutic agent to the patient, the deflectable member **400** returns to its original shape (see, **FIGS. 10-11**) and is again able to result in a detectable increase in pressure at the reservoir full position during a refill procedure as discussed above.

The implementation of a deflectable member **400**, as opposed to a shaped bottom of the housing **130** as described above with regard to **FIGS. 4** and **6-7**, may be desirable.

For example, when a deflectable member **400** is used, the deflectable member deforms and returns to its free state. Thus, the bottom surface of the collapsible member is not subjected to the same levels of deformation stresses as discussed above, providing less wear and tear on the collapsible member **50**, depending on the configuration of the collapsible member. Further, pressure increases in the reservoir **48** may not be as great as would be observed when the collapsible member engages with a rigid, non-resiliently deformable interference member, such as the bottom of the housing **130**. By avoiding exposure of the reservoir **48** to greatly increased pressures, the longevity of the collapsible member may be enhanced.

Any suitable resilient deflectable member **400** may be used in accordance with the teachings presented herein. Preferably, the deflectable member **400** is configured to have a spring rate suitable for causing a sufficient rise in pressure in the reservoir upon engagement of the collapsible member **50** with the deflectable member **400** and continued concomitant infusion of fluid into the reservoir **48**. The deflectable member **400** may be attached to (e.g. fastened to, welded or soldered to, adhered to, or the like), or formed from, the housing **130**.

In some embodiments, the deflectable member **400** is a Belleville spring attached to the housing **130**. A Belleville spring can be designed to have a non-linear spring rate, with maximum stiffnesses at small deflection followed by a drop in spring rate at larger deflections – sometimes to negative spring rates. See, e.g., Design of Mechanical Elements, Chapter 8-8 Belleville Springs, pages 310-31. Such designs would result in a noticeable pressure inflection point, without an excessive increase in reservoir pressure. Use of Belleville springs or other springs, such as finger springs, that have non-linear spring rates and that would allow for a sharp step change in reservoir pressure without causing unacceptably high reservoir pressure may be used. Belleville springs can also be advantageously designed to take up very little space. For example a Belleville spring having a spring height of approximately 0.02 inches can have a height of about 0.004 inches in its fully compressed state. Thus, the addition of such a Belleville spring would add only 0.004 inches to the thickness of the infusion device.

Referring now to **FIG. 13**, in some embodiments, two springs having non-linear spring rates, e.g. as described above, are placed in series (e.g., face-face) to amplify the desired effect of such springs. As shown in **FIG. 13**, one spring **450** is coupled to the bottom of the collapsible member **50** and serves as the surface **56** of the collapsible member that engages the interference member, spring **400** in this case, when the reservoir **48** is full. By placing the springs or deflectable elements **400**, **450** in series, a more distinct and sharp step in reservoir pressure may be observed when the springs **400**, **450** engage as the reservoir **48** is filled. If the springs **400**, **450** have non-linear spring rates, where the spring rates decrease upon increased deflection, there will be an initial spike in pressure in the reservoir that will be transient, with reduced absolute pressure upon further filling (and spring deflection). This can result in a distinctive, characteristic pressure increase in the reservoir **48** that can be readily detected, but which will prevent excessive and unacceptably high reservoir pressures resulting from continued filling of the reservoir (which is in contrast to what would be observed in the embodiments depicted in **FIGS. 2-9** above, particularly **FIGS. 2-3**).

While the springs of deflectable members are shown spanning the distance of the housing or surface of the collapsible member in **FIGS. 10-13**, it will be understood that the springs may expand only a portion of the distance housing or collapsible member. It will also be understood that more than one spring or deflectable member may be placed across the length, or a portion thereof, of the housing or collapsible member.

Regardless of the type of deflectable element used (or whether a deflectable element is used at all), the pressure increase, the rate of pressure increase, or a characteristic pressure profile is detectable and is preferably sufficient to distinguish from background noise or fluctuations in pressure due to changes in rate of fluid infusions, such as when infusion is stopped and suddenly started. For example, and with reference to **FIGS. 14-15**, simulated plots of pressure versus time (**FIG. 14**) and rate of change of pressure versus time ($\delta P/\delta T$, **FIG. 15**) at a constant rate are shown. The simulation assumes that the reservoir is being filled with fluid that is the same temperature as the infusion device. The infusion device includes a propellant and bellows reservoir having a

spring constant that results in a constant rate of increase of pressure if the reservoir is filled at a constant rate with a fluid of the same temperature of as the reservoir and propellant. The arrows indicate the point at which the interference member (in this model, the interference member is rigid – e.g., surface of backshield or device housing) engages the closed end the collapsible member forming the reservoir. After initial contact, the pressure and the rate of pressure change noticeably increases with continued infusion of fluid into the reservoir. As shown in **FIG. 15**, the rate of change of pressure ($\delta P/\delta T$) may provide a more readily detectable and distinguishable signal than the change in pressure. However, in many cases, the change in pressure may be sufficient.

By way of further example and with reference to **FIGS. 16-17**, simulated plots of pressure versus time (**FIG. 16**) and rate of change of pressure versus time ($\delta P/\delta T$, **FIG. 17**) with some fluctuations in infusion rate are shown. In the depicted simulated plots, the infusion rate of fluid into the reservoir is slowed at about 16 seconds and increased at 24 seconds. In addition, the infusion rate of fluid into the reservoir is slowed just after 60 seconds, followed by an increase in infusion rate at about 70 seconds, with initial interaction with the interference member shown just prior to 80 seconds. Further, the fluid introduced into the reservoir is colder than the infusion device, as may occur with a room temperature fluid being infused into a body temperature reservoir. As with the simulated plots of **FIGS. 14-15**, the simulated plots of **FIGS. 16-17** assume a propellant and bellows reservoir, which would have a spring constant that results will result in a constant rate of increase of pressure if the reservoir is filled at a constant rate with a fluid of the same temperature of as the reservoir and propellant. However, due to the colder temperature of the fluid filling the reservoir, the pressure response to fluid filling is different than when the fluid is the same temperature as the infusion device. The propellant is particularly sensitive to temperature fluctuations. The relatively cool temperature of the added fluid reduces the temperature of the propellant and therefore the propellant pressure, thereby causing the overall pressure of the system to stay steady, or even drop, as the colder fluid is added to the reservoir. The simulated plots shown in **FIGS. 16-17** are therefore more indicative of a scenario that may be experienced in the

real world than of a simulated scenario with matching fluid and device temperatures and constant infusion rate. However, as depicted in the simulated plots, the pressure changes due to interaction with an interference member can be readily distinguished from infusion rate variances that may occur during a refill procedure even with fluid of a temperature different from that of the infusion device.

As shown in **FIG. 16**, which is a simulated plot of pressure versus time, pressure does not increase in a linear manner as in **FIG. 14** where the fluid was the same temperature as the reservoir. As the change in pressure is subject to many variables, including relative temperature, the rate of change of pressure (**FIG. 17**) may allow for more reliable determinations of a pressure changes due to engagement of the reservoir with an interference member in some cases.

Of course, any suitable change in reservoir pressure may be employed in determining whether a reservoir is full (or near full) and has engaged an interference member. For example, one or more of the following may be employed: derivative of pressure ($\delta P/\delta T$) increases above a threshold value are observed; measured pressure exceeds a threshold value; pressure derivative exceeds a set threshold value for a set amount of time; measured pressure exceeds exceed a set threshold value for a set amount of time; a combination thereof; and the like.

Regardless of the algorithm employed to detect a pressure change indicative of a full reservoir in accordance with the teachings presented herein, it is desired that a user infusing fluid into the reservoir be notified that the reservoir is full. As depicted in **FIG. 18**, a method in accordance with the teachings presented herein includes infusing fluid into a reservoir (**500**), e.g. with a syringe through a refill port. The method further includes measuring pressure in the reservoir (**510**) and determining whether pressure is indicative of contact between a surface of the reservoir and an interference member with continued infusion (**520**). If the pressure is indicative of engagement with the interference member, the user may be notified that the reservoir is full (**530**) and may stop infusing fluid into the reservoir.

Referring now to **FIGS. 19-20**, schematic block diagrams showing selected components of devices and systems configured to detect a full reservoir during a filling procedure and to notify a user that the reservoir is full are depicted. **FIG. 19** refers to a representative system that includes an implantable infusion device **110** and a syringe assembly **600**. The syringe assembly **600** includes a needle for transcutaneously accessing an implanted infusion device **110** via a fill port **118**. A self-sealing septum **42** is disposed across a chamber **44** of the fill port **118** to seal the chamber **44** from the exterior of the device **110**.

The syringe assembly **600** may be preloaded with a predetermined volume of fluid, which may match the full volume of the reservoir **48**. The plunger of the syringe assembly **600** may be depressed once the needle is inserted through the septum **42** and into the chamber **44** of the fill port **118**. As with the embodiments described above with regard to **FIGS. 2-13**, the chamber **44** is in fluid communication with the reservoir **48**, which may have a configuration as described above relative to an interference member for contacting a surface of the reservoir **48** when the reservoir is full. A pressure sensor **14** is in fluid communication with the reservoir **48** and may be placed any suitable place with respect to the reservoir **48**, such as in chamber **44**.

The pressure sensor **14** is operably coupled to electronics **16**, which may include an analog to digital convertor, a band pass filter, a processor, memory, and the like. The electronics **16** (e.g. processor and memory) may be programmed with instructions for determining whether the reservoir **48** has reached full status during a fill procedure as described above. In some embodiments, the electronics **16** are configured to calculate the change in pressure over time ($\delta P/\delta T$) and may compare values of pressure and derivatives of pressure to values in lookup tables to determine whether a measure pressure or pressure profile is indicative of a surface of the reservoir engaging an interference member with concomitant additional fluid infusion into the reservoir.

In some embodiments, the electronics for determining whether the pressure in the reservoir is indicative of a full reservoir are located in an external device **200** (e.g., an external device as discussed above with regard to **FIG. 1**) as shown in **FIG. 20**. In such

embodiments, the infusion device **110** includes a telemetry circuit **160** (e.g., a telemetry antenna, an analog to digital convertor, and the like) capable of communicating with a telemetry circuit **260** of the external device **200**. Of course, in embodiments where implantable infusion device **110** includes the requisite electronics for making the determinations, the device **110** may also include a telemetry circuit for communicating with an external device.

In embodiments where the determinations as to whether reservoir pressure is indicative or a full reservoir **48**, data transmitted from infusion device **110** to external device **200** via telemetry circuits **160/260** is processes by electronics **216** of external device, which may present the results to a user via display **210**. Of course, if determinations are made by electronics of the implantable device, it may still be desirable to transmit the results to the external device for processing or display.

It will be understood that components such as a power supply, pump, and the like were omitted from the block diagrams in **FIGS. 19-20** for purposes of convenience, brevity and clarity.

It will also be understood that any one or more components or steps presented with regard to embodiments described herein may be applied with regard to other embodiments. For example, the shaped interior surface **64** of the housing shown in **FIG. 4** may be used in conjunction with the deflectable element **450** as shown in **FIG. 13**.

Thus, systems, devices and methods for DETECTING A FULL RESERVOIR OF AN IMPLANTABLE INFUSION DEVICE are described. Those skilled in the art will recognize that the preferred embodiments described herein may be altered or amended without departing from the true spirit and scope of the disclosure, as defined in the accompanying claims.

What is claimed is:

1. An implantable infusion device comprising:

a housing;

a collapsible member disposed within the housing and defining a reservoir for containing a variable volume of fluid and having an outer surface that moves between an empty position and a full position in response to a change in volume of fluid contained in the reservoir;

an interference member disposed within the housing and configured to engage the outer surface of the collapsible member as the reservoir approaches the full position and to cause pressure in the reservoir to increase following engagement with the surface of the collapsible member and concomitant fluid introduction into the reservoir, wherein the collapsible member and the interference member are configured such that the reservoir is capable of further expansion after the surface of the collapsible member engages the interference member and additional fluid is added to the reservoir;

a port in fluid communication with the reservoir for providing access to the reservoir through the housing;

a pressure sensor in communication with the reservoir; and

electronics operably coupled to the pressure sensor for detecting the increase in pressure associated with engagement of the interference member with the surface of the collapsible member and concomitant fluid introduction into the reservoir.

2. The device of claim 1, wherein the electronics are further configured to determine whether a sensed pressure increase is indicative of engagement of the interference member with the outer surface of the collapsible member and concomitant fluid introduction into the reservoir.

3. The device of claim 2, wherein the electronics are configured to send data to an external device via telemetry if a sensed pressure increase is indicative of engagement of the interference member with the outer surface of the collapsible member and

concomitant fluid introduction into the reservoir, wherein the data is configured to relay to the external device that the reservoir is full.

4. The device of claim 1, wherein the electronics are configured to send data regarding sensed pressure to an external device via telemetry.

5. The device of claim 1, further comprising:

a bulkhead partitioning the housing to form a chamber having an interior surface, wherein the collapsible member is disposed within the chamber, wherein movement of the outer surface of the collapsible member from the reservoir empty position to the reservoir full position causes the surface of the collapsible member to approach the interior surface of the chamber.

6. The device of claim 5, wherein the collapsible member forms a bellows reservoir having a cylindrical wall sealingly attached to the bulkhead.

7. The device of claim 5, wherein the interference member is the interior surface of the chamber.

8. The device of claim 7, wherein the interior surface of the chamber is shaped to contact a first portion of the surface of the collapsible member when the reservoir is full and to contact a second portion of the surface of the collapsible member when additional fluid is added to the reservoir, wherein the surface area of the second portion is greater than the surface area of the first portion.

9. The device of claim 5, wherein the interference member is disposed between the surface of the collapsible member and the interior surface of the chamber.

10. The device of claim 7, wherein the interference member is coupled to the interior surface of the chamber.

11. The device of claim 7, wherein the interference member comprises a resiliently deflectable element.

12. The device of claim 7, wherein the interference member comprises a Belleville spring.

13. The device of claim 1, further comprising an over-pressurization mechanism (OPM) configured to prevent flow of fluid into the reservoir via the port when the volume of the reservoir exceeds the reservoir volume at which the surface of the collapsible member initially engages the interference member.

14. The device of claim 13, wherein the OPM comprises:

an OPM chamber disposed between the port and the reservoir,

a valve passageway fluidly coupling the OPM chamber to the reservoir,

a valve assembly comprising a telescoping valve body slidably moveable through the valve passageway, the valve body portion having a distal end configured to abut an interior surface of the collapsible member that generally opposes the outer surface of the collapsible member that is configured to engage the interference member,

wherein the valve assembly is configured to sealingly engage the valve passageway when the distal end of the valve body extends a predetermined distance beyond the valve passageway,

wherein the predetermined distance is greater than the distance from the valve passageway to the interior surface of the collapsible member that the distal end of the valve body abuts when the outer surface of the collapsible member initially contacts the interference member when the reservoir is being filled.

15. The device of claim 14, wherein the interference member comprises a resiliently deflectable element.

16. The device of claim 14, wherein the interference member comprises a Belleville spring.

17. The device of claim 1, wherein the interference member comprises a resiliently deflectable element.

18. The device of claim 1, wherein the interference member comprises a Belleville spring.

19. The device of claim 1, wherein the interference member is shaped to contact a first portion of the surface of the collapsible member when the reservoir is full and to contact a second portion of the surface of the collapsible member when additional fluid is added to the reservoir, wherein the surface area of the second portion is greater than the surface area of the first portion.

20. A system comprising:

an implantable infusion device according to claim 1, wherein the electronics are configured to

determine whether a sensed pressure increase is indicative of engagement of the interference member with the outer surface of the collapsible member and concomitant fluid introduction into the reservoir, and

send data to an external device if a sensed pressure increase is indicative of engagement of the interference member with the outer surface of the collapsible member and concomitant fluid introduction into the reservoir, wherein the data is configured to relay to the external device that the reservoir is full; and

an external device configured to receive the data from the implantable infusion device and to display that the reservoir is full.

21. A system comprising:

an external device configured to receive data regarding sensed pressure from a device according to claim 1, to determine whether the sensed data is indicative of engagement of the interference member with the outer surface of the collapsible member and concomitant fluid introduction into the reservoir, and to display that the reservoir is full if the sensed data is indicative of engagement of the interference member with the outer surface of the collapsible member and concomitant fluid introduction into the reservoir; and

a device according to claim 1, wherein the electronics are configured to send data regarding the sensed pressure to the external device.

22. A method comprising:

measuring interior pressure of a reservoir of an implantable infusion device;

processing data regarding the measured interior pressure to determine whether the measured pressure is indicative of engagement of an interference member of the device with the outer surface of a collapsible member defining the reservoir and concomitant fluid introduction into the reservoir; and

determining that the reservoir is full if the measured pressure is indicative of engagement of the interference member with the outer surface of the collapsible member and concomitant fluid introduction into the reservoir.

23. The method of claim 22, further comprising displaying that the reservoir is full if it is determined that the reservoir is full.

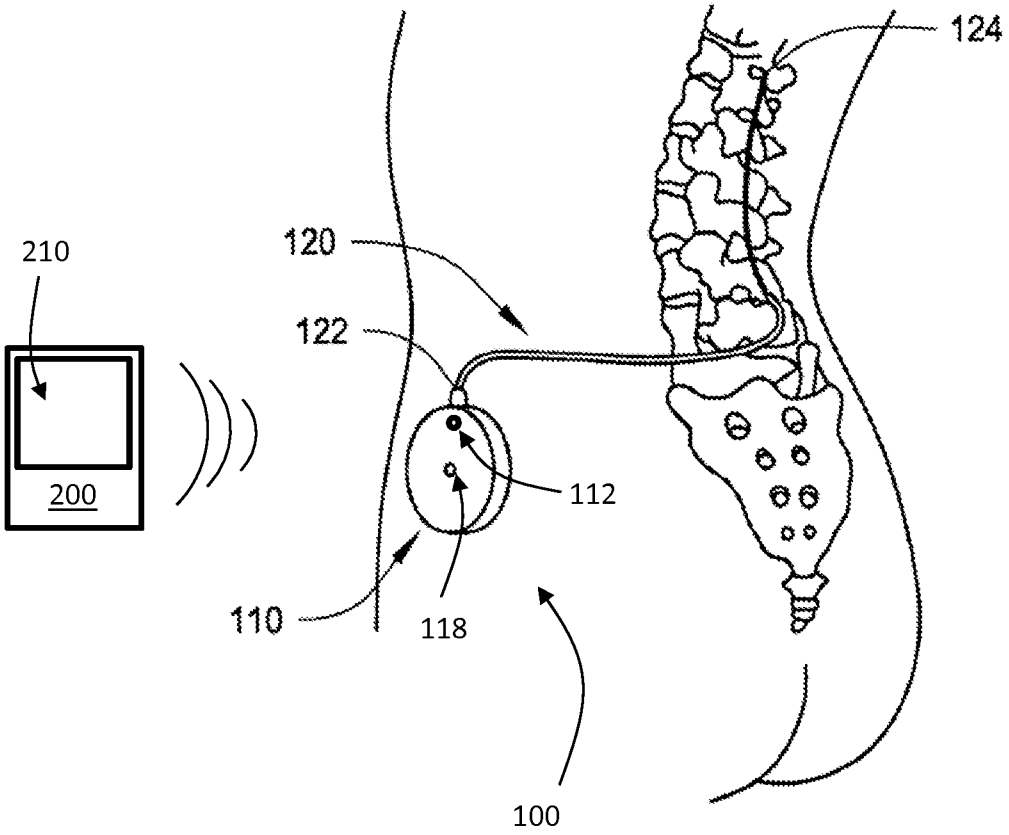
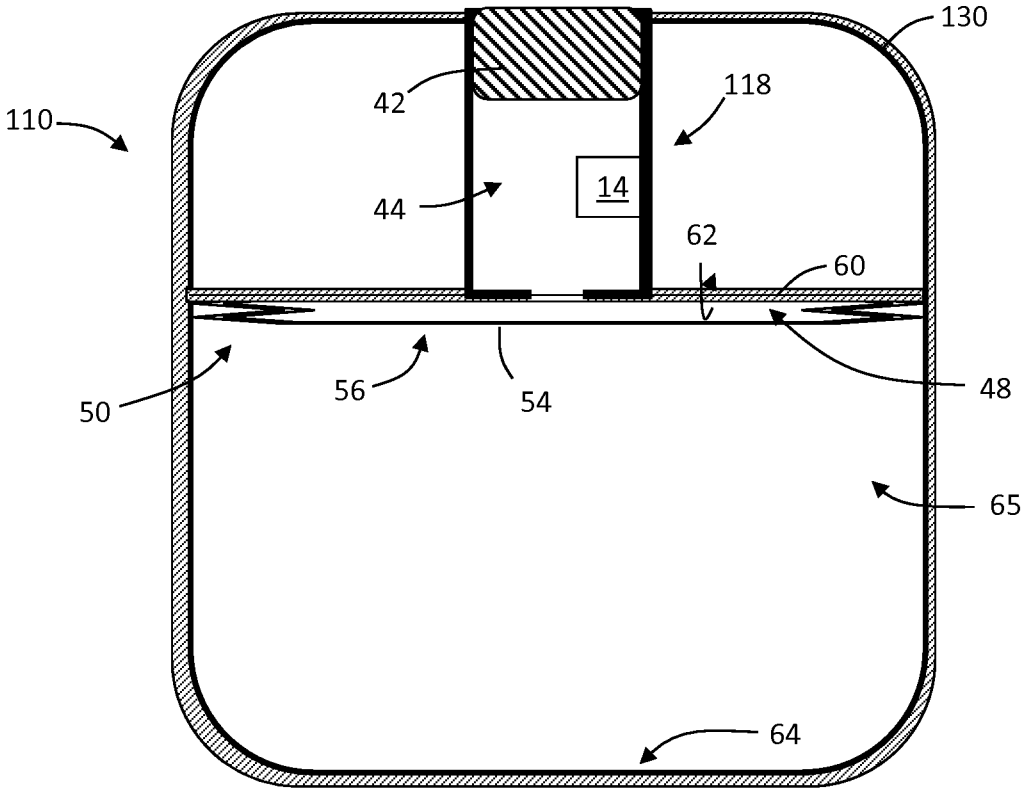


FIG. 1


130
110
42
118
14
44
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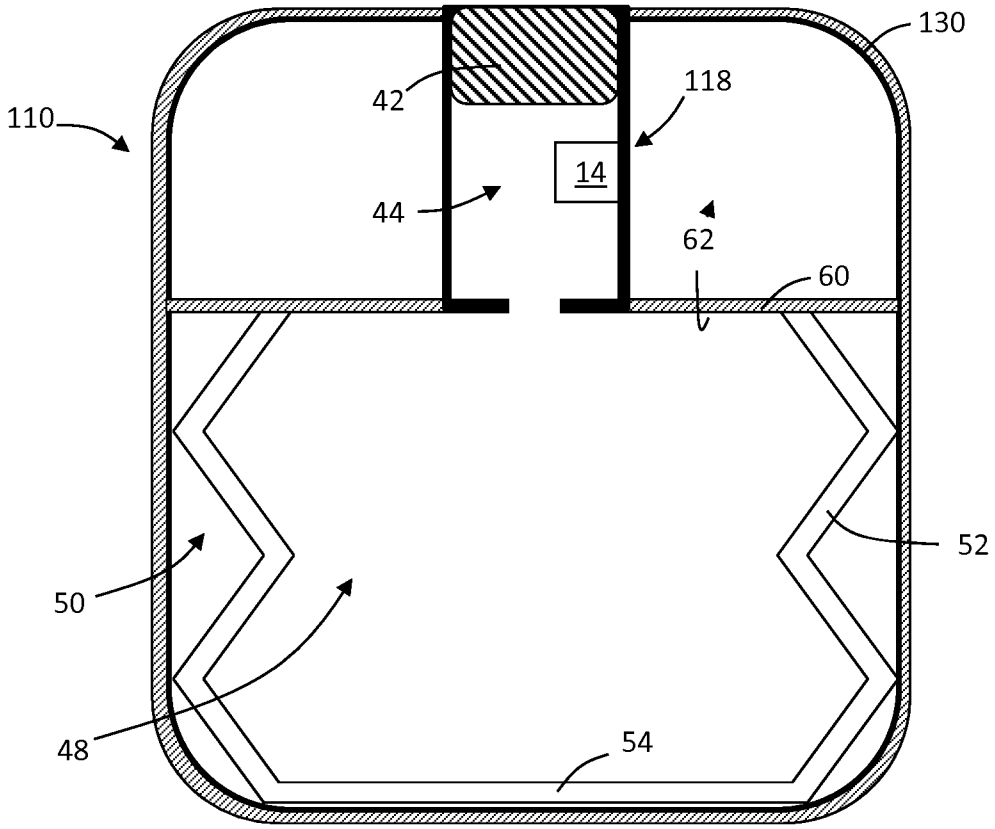
50
56
54
65
64

FIG. 2


130
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44
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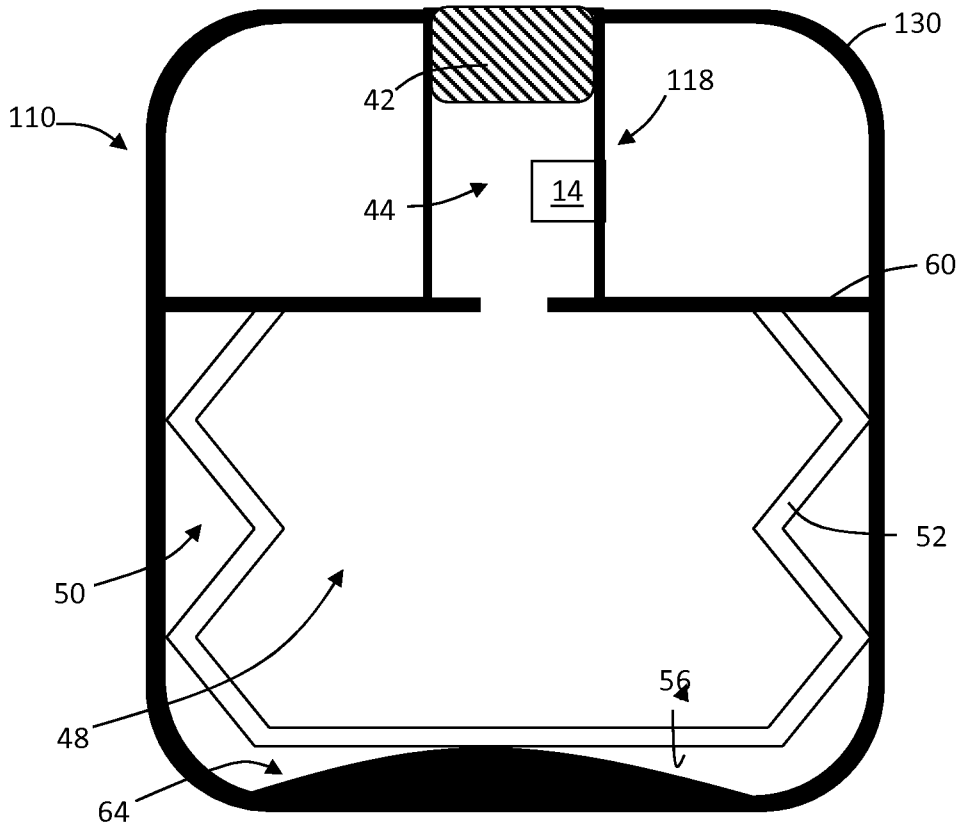
50
48
54

FIG. 3


130
110
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118
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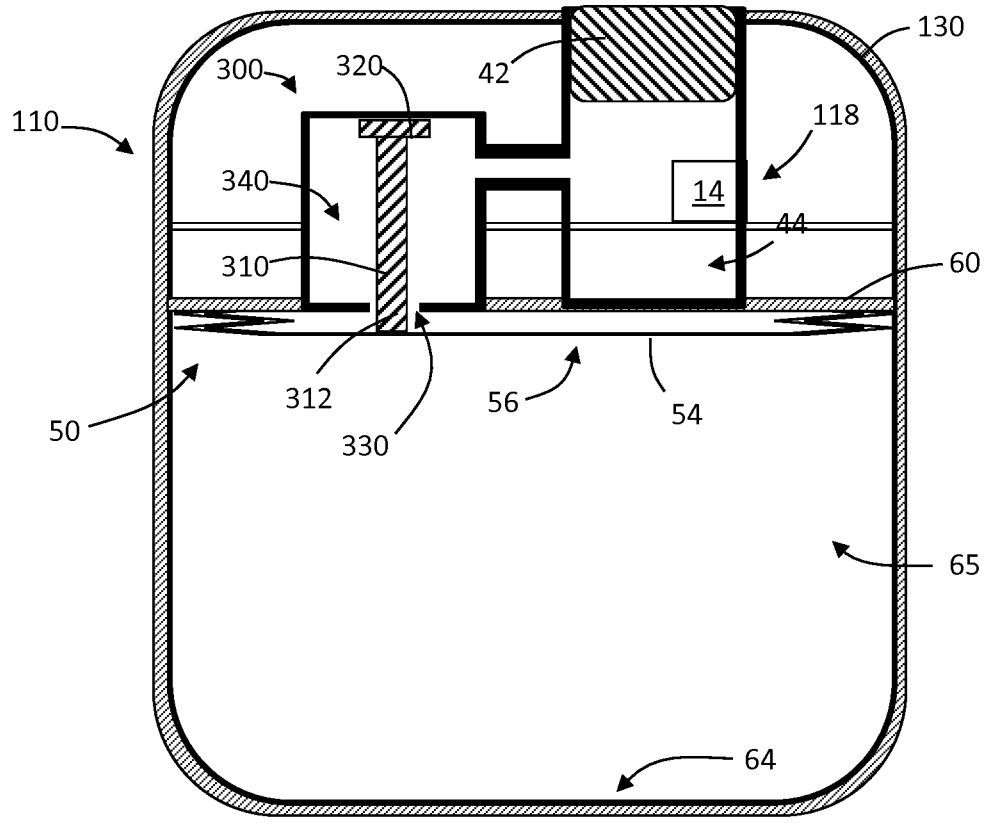
64

FIG. 4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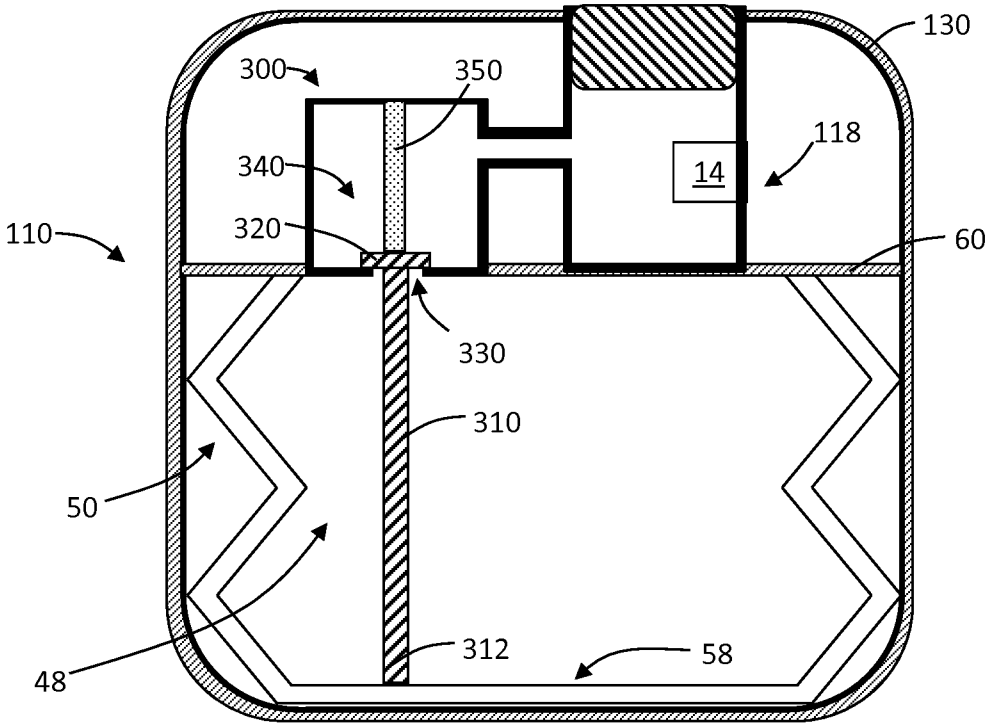
64

FIG. 5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14
110
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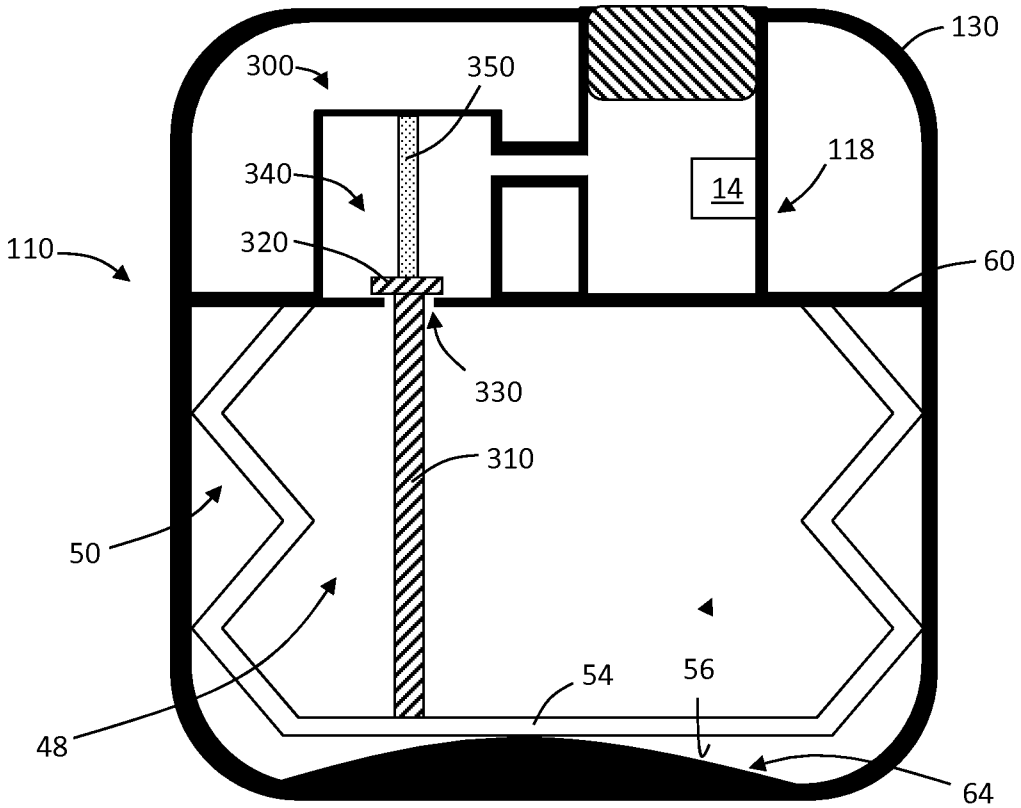
330
310
50
312
58
48

FIG. 6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14
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310
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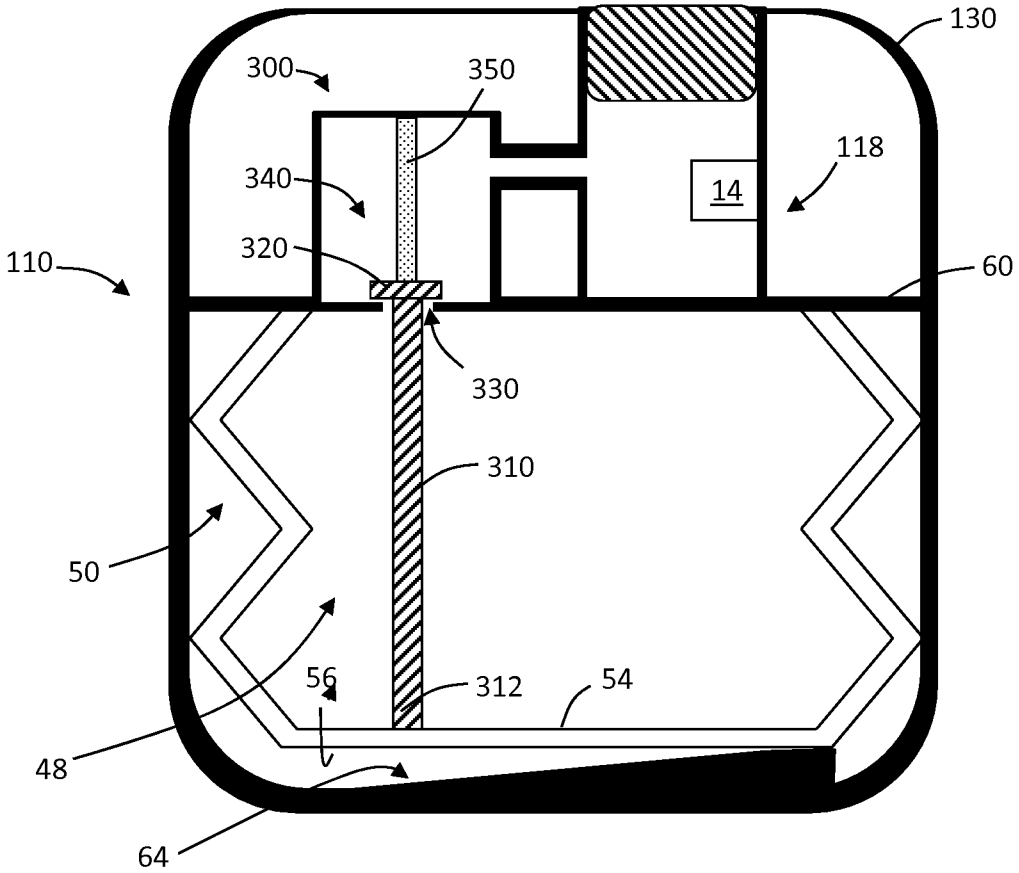
56
48
64

FIG. 7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14
320
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310
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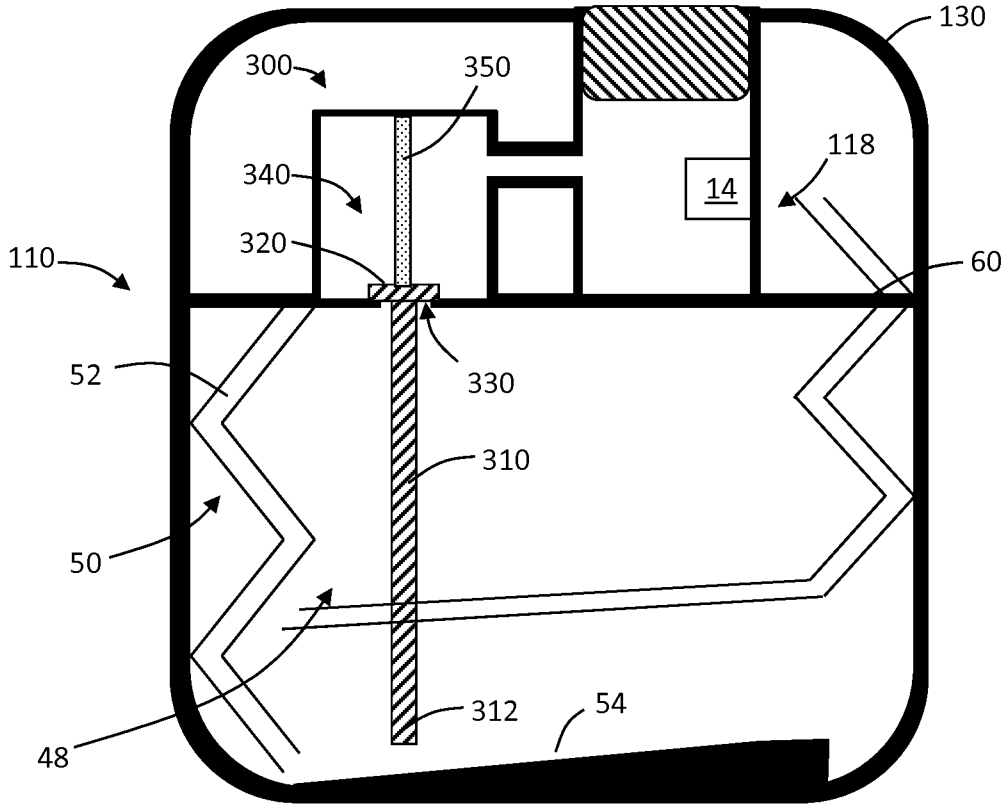
56
312
54
48
64

FIG. 8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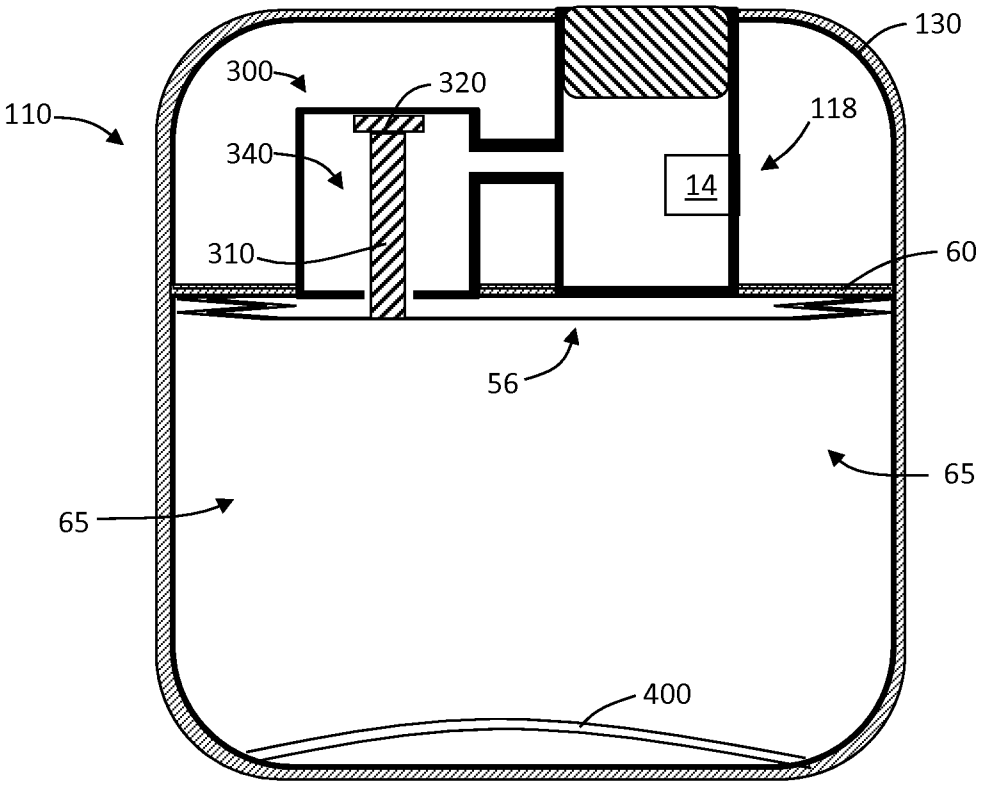
14
320
110
60
52
330
310
50
312
54
48

FIG. 9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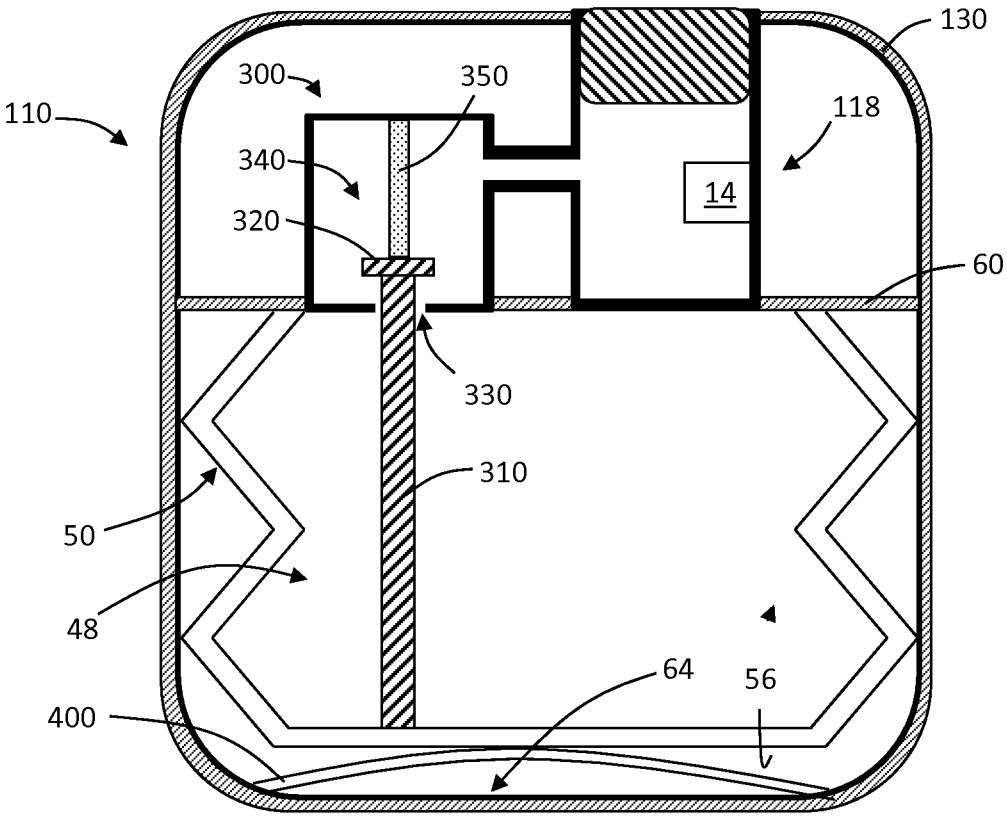
300
320
110
118
340
14
310
60
56
65
65
400

FIG. 10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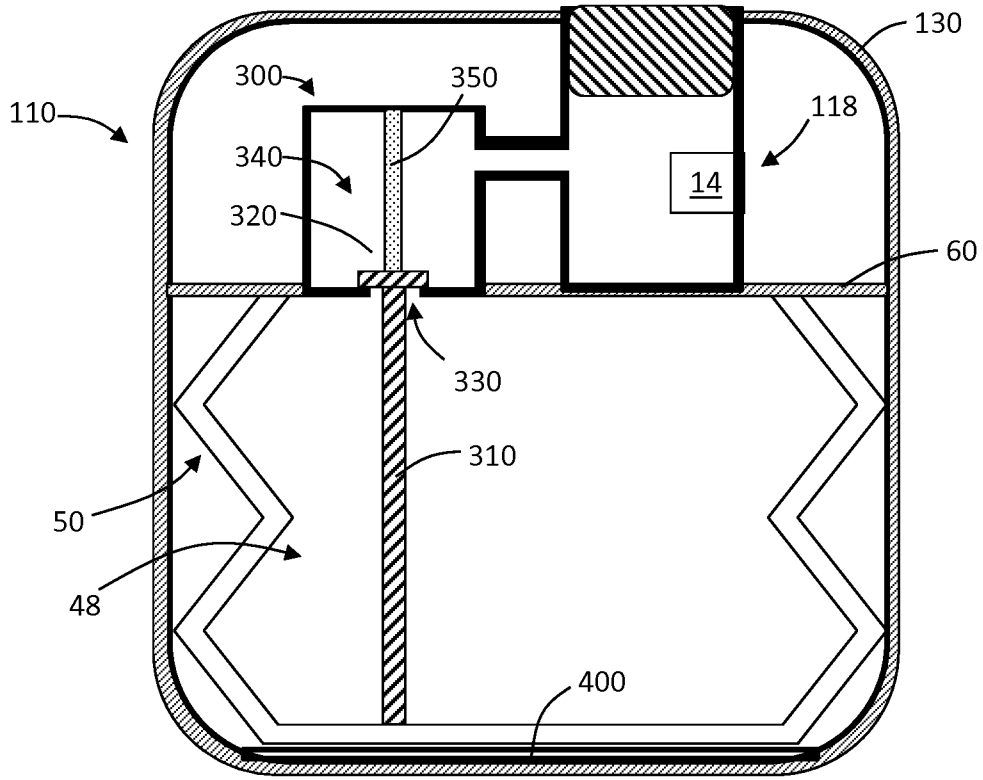
300
350
110
118
340
14
320
60
330
310
50
48
64
56
400

FIG. 11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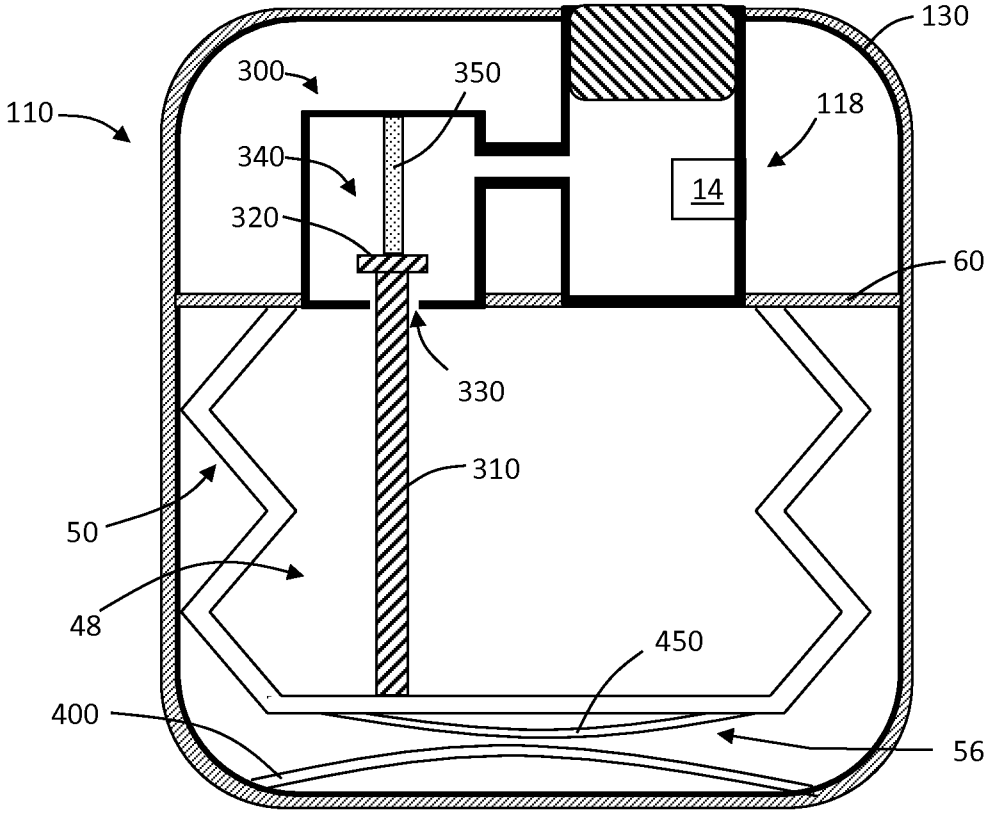
300
350
110
118
340
14
320
60
330
310
50
48
400

FIG. 12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300
350
110
118
340
14
320
60
330
310
50
48
450
400
56

FIG. 13

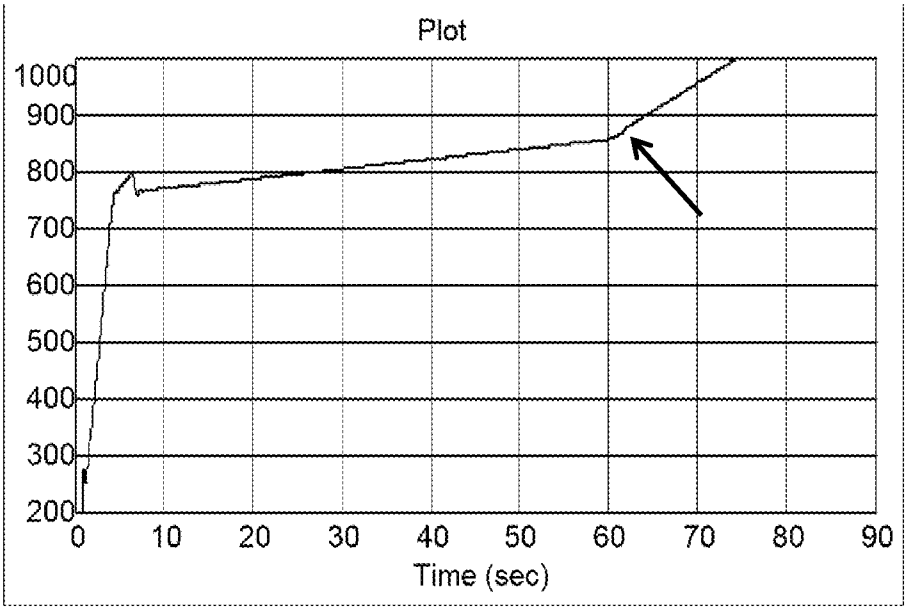
Plot
1000
900
800
700
600
500
400
300
200
0
10
20
30
40
50
60
70
80
90
Time (sec)

FIG. 14

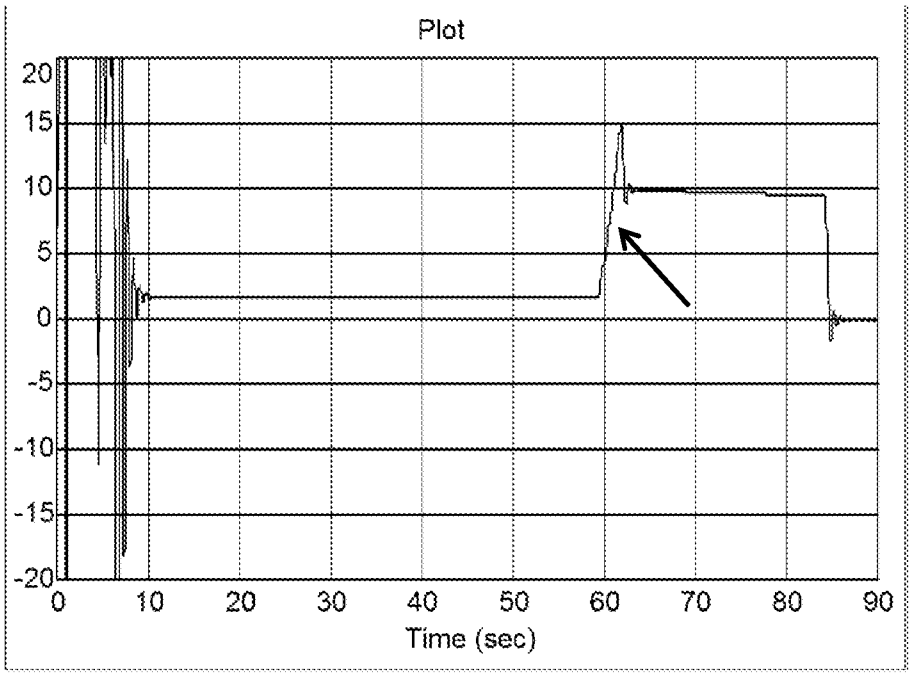
Plot
20
15
10
5
0
-5
-10
-15
-20
0
10
20
30
40
50
60
70
80
90
Time (sec)

FIG. 15

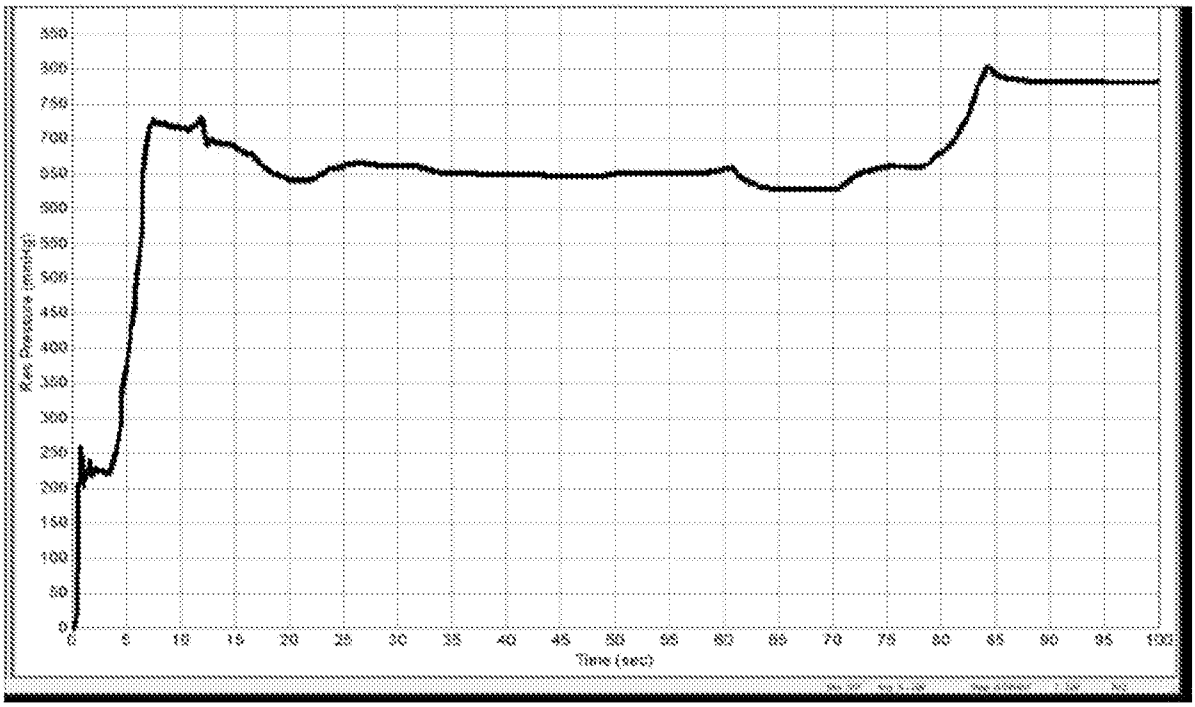

FIG. 16

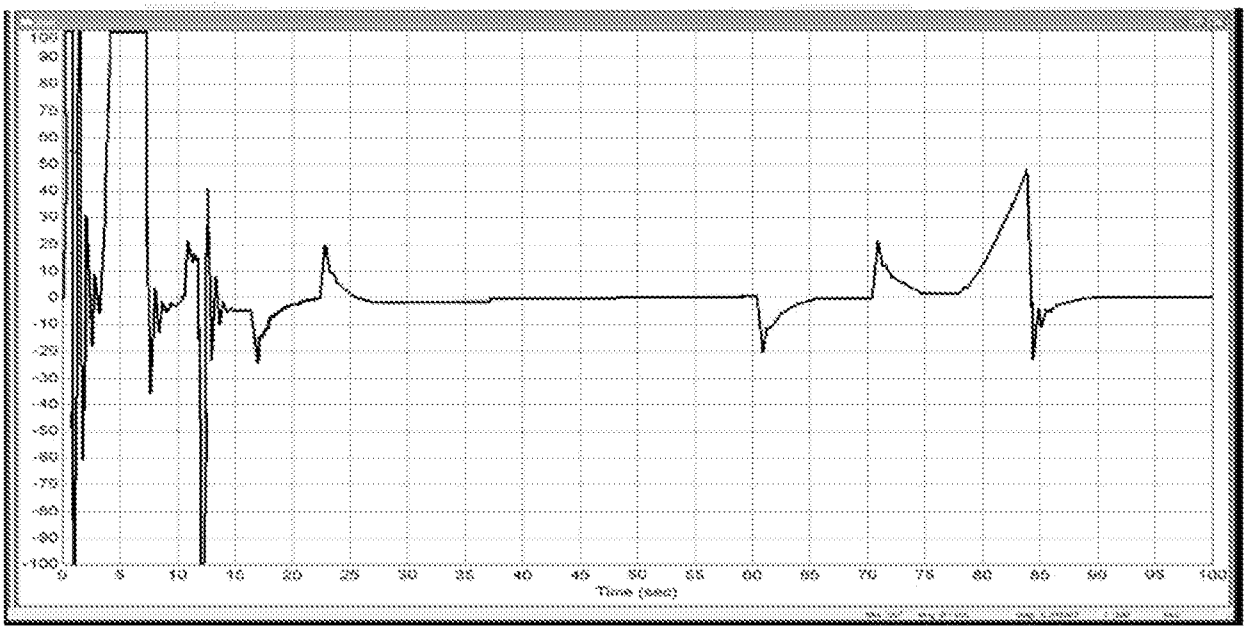

FIG. 17

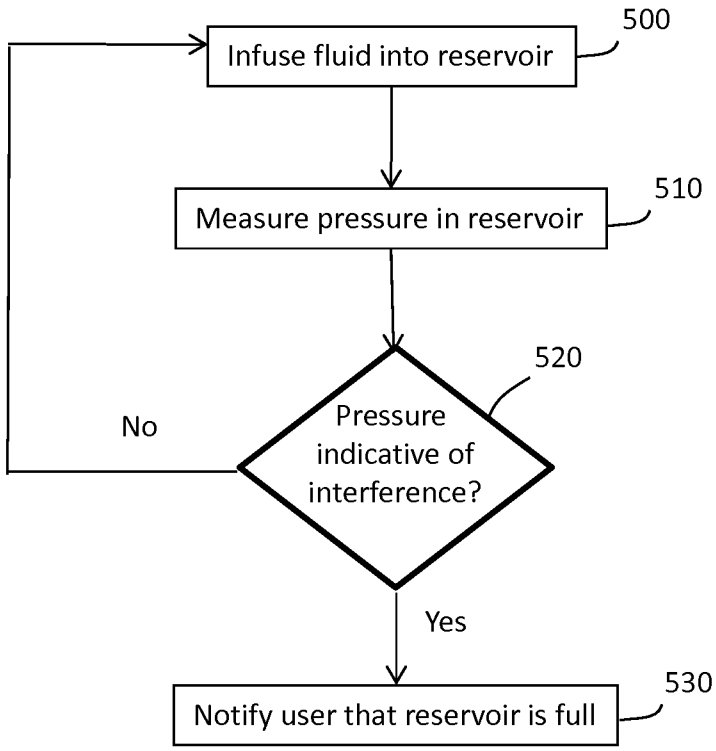
Infuse fluid into reservoir
500
Measure pressure in reservoir
510
Pressure indicative of interference?
520
No
Yes
Notify user that reservoir is full
530

FIG. 18

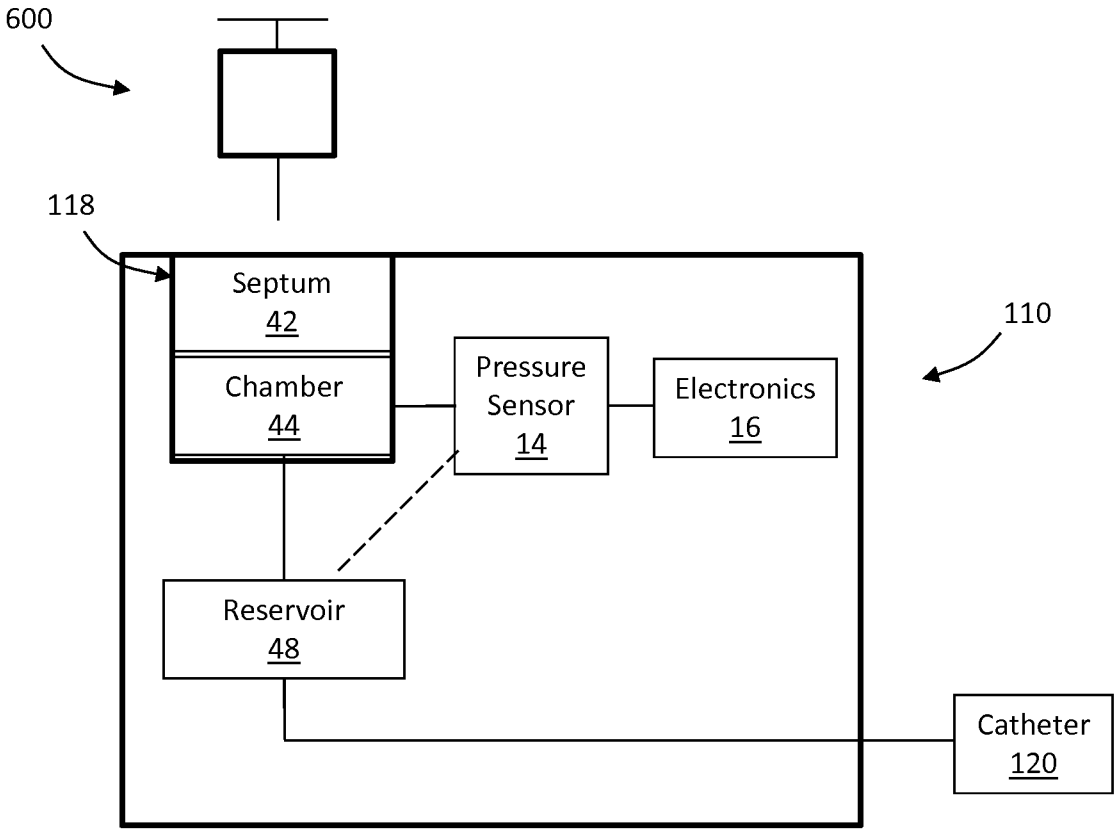
600
118
Septum
42
Chamber
44
Pressure Sensor
14
Electronics
16
110
Reservoir
48
Catheter
120

FIG. 19

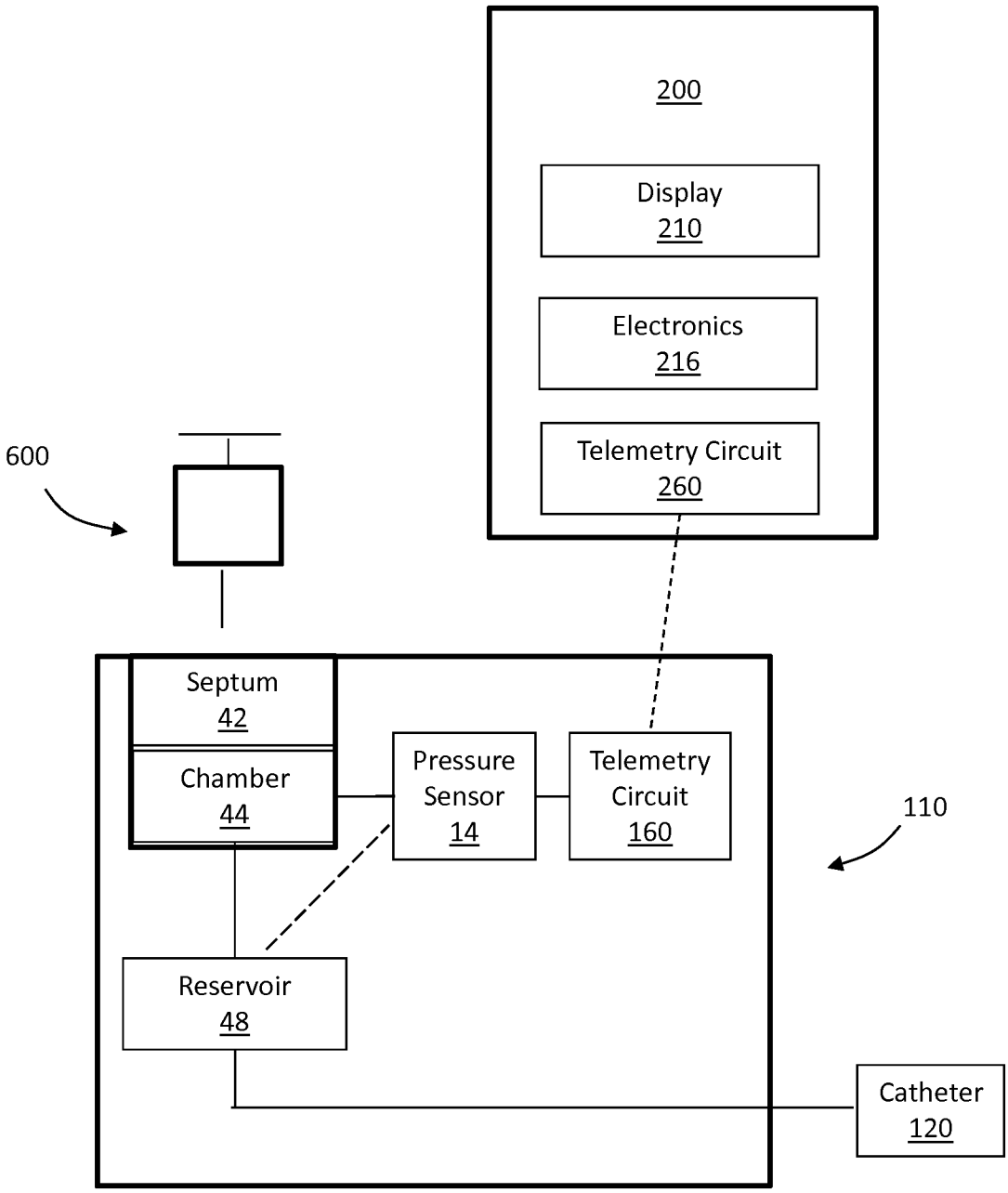
200
Display
210
Electronics
216
Telemetry Circuit
260
600
Septum
42
Chamber
44
Pressure
Sensor
14
Telemetry
Circuit
160
110
Reservoir
48
Catheter
120

FIG. 20

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/023218

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

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 Y A	US 2010/125246 A1 (KALPIN SCOTT L [US]) 20 May 2010 (2010-05-20) paragraph [0030] paragraph [0035] - paragraph [0036] figures 5,9,10,12	1-10,13, 19-23 14 11,12, 15-18

X Y A	US 4 573 994 A (FISCHELL ROBERT E [US] ET AL) 4 March 1986 (1986-03-04) column 4, line 42 - column 6, line 10; figure 2	1-6, 9-12, 17-23 13-16 7,8

X Y A	US 5 507 737 A (PALMSKOG GOERAN [SE]) 16 April 1996 (1996-04-16) the whole document	1-10, 19-23 13,14 11,12, 15-18

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[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

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"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
10 July 2012	18/07/2012

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/023218

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2007/255260 A1 (HAASE JAMES M [US] HAASE JAMES MARTIN [US]) 1 November 2007 (2007-11-01) the whole document -----	13-16

INTERNATIONAL SEARCH REPORT

Information on patent family members

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