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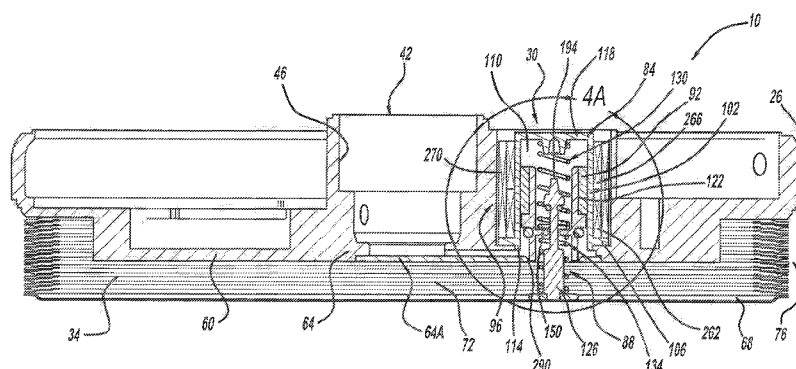


FIG. 4

(57) Abstract: A volume sensing system for use in determining a volume of a variable volume reservoir can include a lower plunger (126) that can have a first end (190) adapted to move with a bottom (68) of the reservoir (34). An upper plunger (122) can be slidable relative to the lower plunger (126). A lower biasing member (134, 230) can be positioned substantially between a base (68) of the reservoir (34) and the upper plunger (122), and the upper biasing member (130, 226) can be positioned between the upper plunger (122) and an interference member (118). The upper biasing member (130, 226) can have a predetermined stiffness relative to the lower biasing member (134, 230) such that upon movement of the lower plunger (126), the upper plunger (122) can move at a predetermined fraction of the amount of movement of the lower plunger (126), where the predetermined fraction can be determined at least in part by the predetermined stiffness of the upper biasing member (130, 226) relative to the lower biasing member (134, 230).

RATIOMETRIC PLUNGER ASSEMBLY FOR VOLUME SENSING APPLICATIONS

FIELD

5 The present disclosure relates generally to a ratiometric plunger assembly for volume sensing applications including, but not limited to, volume sensing in an implantable infusion device.

BACKGROUND

10 This section provides background information related to the present disclosure that is not necessarily prior art.

 Medical devices, such as medical pumps, can be used to treat a variety of physiological, psychological, and emotional conditions. For some medical conditions, medical pumps can assist an individual in overcoming such conditions. For example, 15 medical pumps may be used for chronic delivery of therapeutic agents, such as drugs. As one specific example, a medical pump may be used to deliver insulin to a diabetic patient. Other examples include delivery of pain relief medication, e.g., to the intrathecal or epidural space of a patient, to alleviate chronic pain.

 Some medical pumps are wholly implantable. Implantable medical pumps may 20 be implanted at a location in the body of a patient and deliver a fluid medication through a catheter to a selected delivery site within the body of the patient. Typically, the catheter connects to an outlet of the medical pump and delivers a therapeutic agent at a programmed infusion rate to a predetermined location to treat a medical condition. An implantable medical pump is implanted by a clinician into a patient at a location 25 that interferes as little as practicable with patient activity. For example, implantable medical pumps are often implanted subcutaneously in the lower abdomen of a patient. Implantable medical pumps may include self-sealing fluid reservoirs accessible through ports to facilitate in-service refilling by percutaneous injection.

30 SUMMARY

 This section provides a general summary of the disclosure, and is not a comprehensive disclosure of its full scope or all of its features.

In one form, a volume sensing system for use in determining a volume of a variable volume reservoir is provided in accordance with various aspects of the present teachings. The system can include a plunger assembly having lower and upper plungers and lower and upper biasing members. The lower plunger can have a first end and an opposite second end, where the first end can be adapted to move with a bottom of the reservoir. The upper plunger can have a first end and an opposite second end, where the upper plunger can be slidable relative to the lower plunger. The lower biasing member can be positioned substantially between a base of the reservoir and the upper plunger, and the upper biasing member can be adapted to be positioned between the upper plunger and an interference member. The upper biasing member can be configured to have a predetermined stiffness relative to the lower biasing member such that upon movement of the lower plunger in a first direction, the upper plunger can be configured to move in the first direction at a predetermined fraction of the amount of movement of the lower plunger. The predetermined fraction of the amount of movement can be determined at least in part by the predetermined stiffness of the upper biasing member relative to the lower biasing member, wherein a position of the upper plunger can be adapted to be correlated to a corresponding volume of the reservoir.

In another form, a volume sensing system for use in determining a volume of a variable volume reservoir is provided in accordance with various aspects of the present teachings. The system can include a housing and a volume sensor assembly. The housing can maintain the variable volume reservoir and can include a bulkhead. The bulkhead can define in part a top of the variable volume reservoir and an internal passage open to the reservoir. The variable volume reservoir can include a base wall that is movable relative to the bulkhead, wherein a volume of an internal region of the reservoir can be a function of a distance between the base wall and the bulkhead. The volume sensor assembly can generate information indicative of a current volume of the internal region and can include a plunger assembly, a ferromagnetic target and circuitry. The plunger assembly can include lower and upper plungers and lower and upper biasing members. The lower plunger can have a first end and an opposite second end, where the first end can be coupled to the base wall. The upper plunger can have a first end and an opposite second end facing the base wall, where the upper plunger can be slidably coupled to the lower plunger. The lower biasing member can be positioned substantially between the base wall and the upper plunger, and the upper biasing

member can be positioned substantially between the upper plunger and a closed end of the internal passage. The upper biasing member can be configured to have a predetermined stiffness relative to the lower biasing member such that upon movement of the lower plunger in a first direction, the upper plunger is configured to move in the first direction at a predetermined fraction of the amount of movement of the lower plunger. The ferromagnetic target can be coupled to the upper plunger and moveable therewith relative to the internal passage. The circuitry can be associated with the internal passage and can be configured to detect a longitudinal position of the target relative to the internal passage. The longitudinal position of the target relative to the internal passage can be representative of a volume of the internal region of the reservoir.

In yet another form, a method for use in determining a volume of a variable volume reservoir is provided in accordance with various aspects of the present teachings. The method can include generating position information of a target coupled to an upper plunger through operation of a volume sensor assembly. The upper plunger can be coupled to a lower plunger and positioned between an upper biasing member and a lower biasing member. The lower plunger can be coupled to a base of the reservoir and can be configured for movement therewith. A position of the base relative to a housing associated with the variable volume reservoir can be representative of a volume of an internal region of the reservoir. First and second sealing members associated with the respective lower and upper plungers can be moved into sealing positions to seal off fluid communication between a fill port defined by the housing when the reservoir is in a full condition. The fill port can be in selective fluid communication with the internal region of the reservoir.

Further areas of applicability will become apparent from the description provided herein. The description and specific examples in this summary are intended for purposes of illustration only and are not intended to limit the scope of the present disclosure.

DRAWINGS

The present teachings will become more fully understood from the detailed description, the appended claims and the following drawings. The drawings are for

illustrative purposes only of selected embodiments and not all possible limitations, and are not intended to limit the scope of the present disclosure.

Figure 1 is a diagram illustrating an exemplary fluid delivery system, which includes an implantable infusion device in accordance with the teachings of the present disclosure along with a delivery catheter;

Figure 2 is a diagram of the implantable infusion device and delivery catheter of Figure 1 configured to deliver a therapeutic agent or substance to a patient;

Figure 3 is a simplified functional block diagram of the implantable infusion device in accordance with the teachings of the present disclosure;

Figure 4 is cross-sectional view taken along line 4-4 of the implantable infusion device of Figure 2 illustrating a volume sensing assembly and a reservoir in an exemplary partially full condition in accordance with the teachings of the present disclosure;

Figure 4A is an enlarged view of a portion of the implantable infusion device of Figure 4 in accordance with the teachings of the present disclosure;

Figure 5 is a similar cross-sectional view of the implantable infusion device of Figure 4 illustrating the volume sensing assembly and the reservoir in an exemplary full condition in accordance with the teachings of the present disclosure;

Figure 5A is an enlarged view of a portion of the implantable infusion device of Figure 5 in accordance with the teachings of the present disclosure;

Figure 5B is an enlarged view of a portion of the implantable infusion device of Figure 5 illustrating an exemplary alternative volume sensing assembly in accordance with the teachings of the present disclosure;

Figure 6 is a similar cross-sectional view of the implantable infusion device of Figure 4 illustrating the volume sensing assembly and the reservoir in an exemplary empty condition in accordance with the teachings of the present disclosure; and

Figures 7-9 are diagrammatic views of exemplary operational characteristics of primary and secondary coils of the volume sensing assembly in accordance with the teachings of the present disclosure.

DETAILED DESCRIPTION

The following description is merely exemplary in nature and is not intended to limit the present disclosure, its application, or uses. It should be understood that

throughout the drawings, corresponding reference numerals indicate like or corresponding parts and features with the various elements in each view being drawn to scale. Although the following description is related generally to a volume sensing assembly for implantable infusion devices, such as implantable medical or drug pumps for use in delivering a therapeutic substance or agent to a patient, it should be appreciated that the volume sensing assembly and associated telescoping plunger assembly discussed herein can be applicable to other medical devices including, but not limited to, non-implantable medical pumps or other medical devices configured to contain a fluid therein.

Exemplary embodiments are provided so that this disclosure will be thorough, and will fully convey the scope to those who are skilled in the art. Numerous specific details are set forth such as examples of specific components, devices, systems and/or methods, to provide a thorough understanding of exemplary embodiments of the present disclosure. It will be apparent to those skilled in the art that specific details need not be employed, that exemplary embodiments may be embodied in many different forms and that neither should be construed to limit the scope of the disclosure. In some exemplary embodiments, well-known processes, well-known device structures, and well-known technologies are not described in detail.

Turning now to Figures 1-2, an overview of an exemplary implantable infusion device 10 is shown operatively associated with an intrathecal delivery catheter 14. In general terms, the implantable infusion device 10, also known as an implantable drug pump, medical pump or therapeutic substance delivery device, can assume a variety of forms, and can be provided as part of an intrathecal infusion system that further includes an external programmer (not shown), for example as provided with a SynchroMed® EL Infusion System available from Medtronic, Inc., of Minneapolis, Minnesota. Regardless, the implantable infusion device 10 can operate to infuse a therapeutic fluid or substance 18 (drawn generally in Figure 1) into a patient 22 via the delivery catheter 14. The therapeutic substance 18 can be any infusion agent, product, or fluid substance intended to have a therapeutic effect, such as pharmaceutical compositions, genetic materials, biologics, and others (e.g., insulin, saline solution, fluoroscopy agents, etc.).

With additional reference to Figure 3, the implantable infusion device 10 can include a housing 26 and a volume sensor assembly 30. The housing 26 can define in

part, a reservoir 34 for containing the therapeutic substance 18 and can define a variable volume, as discussed below. In some embodiments, a propellant chamber 38 can be provided, formed against the reservoir 34, and serving to place a constant positive pressure on to the reservoir 34. The therapeutic substance 18 can be filled into the reservoir 34 via an inlet 42 (e.g., a fill/refill port 46 including a septum), and can release the therapeutic substance 18 via an outlet 50. In this regard, the implantable infusion device 10 can include a pump mechanism and/or metering device 54 in some embodiments that dictates the amount or volume of the therapeutic substance 18 to be drawn from the reservoir 34. To this end, the pump mechanism 54 can assume a wide variety of forms as is known in the art. Regardless, the outlet 50 can be fluidly connected to the delivery catheter 14 for subsequent delivery of a desired amount of the therapeutic substance 18 from the outlet 50 to the patient 22. As will be discussed in greater detail below, the volume sensor assembly 30 can be maintained by housing 26 and configured to sense information indicative of a volume of the reservoir 34, and thus indicative of a volume of the therapeutic substance 18 contained within the reservoir 34. As will also be discussed below, the volume sensor assembly 30 can include an upper member that can telescopically travel at a predetermined fraction of an amount of travel of an associated lower member thereby providing for a lower profile or more compact implantable infusion device 10. The volume sensor assembly 30 can also cooperate with housing 26 and fill port 46 to limit an amount of therapeutic substance 18 that can be supplied to reservoir 34 to prevent overfilling of reservoir 34.

The implantable infusion device 10 can incorporate a number of features not otherwise described or illustrated in the figures. For example, a power source (not shown) can be provided as part of the pump mechanism 54 along with an electronics module or controller, such as with a positive or peristaltic configuration. Alternatively, the implantable infusion device 10 can assume a passive infusion configuration whereby the propellant chamber 38 serves as a pump drive, with flow from the reservoir outlet 50 being passively controlled, in some embodiments, through capillary tubing (not shown) or similar structure(s) (akin, for example, to the IsoMed™ Implantable Constant-Flow Infusion Pump available from Medtronic, Inc., of Minneapolis, Minnesota.). Further, other programmable module(s) (not shown) can be included. Thus, the implantable infusion device 10 is not limited to the configuration represented in figures.

With additional reference to Figures 4-9, and in particular Figure 4A, the volume sensor assembly 30 and exemplary associated portions of the implantable infusion device 10 will now be discussed in greater detail. The housing 26 can include a stationary wall 60 with which the volume sensor assembly 30 can be associated. As a point of reference, the housing 26 can include a number of other walls; however, the stationary wall 60 with which the volume sensor assembly 30 is associated with can provide a consistent reference point relative to the reservoir 34. In some embodiments, the stationary wall 60 can form a part of the reservoir 34 (e.g., the stationary wall 60 can be a bulkhead 64 of the reservoir 34); in other embodiments the stationary wall 60 can be provided apart from the reservoir 34. Regardless, the reservoir 34 can be defined in part by a bottom or base wall 68 and can be fluidly coupled to the refill port 46 and outlet 50 (Figure 3), as well as an internal region 72 within which the therapeutic substance 18 can be contained. In some embodiments, the base wall 68 can be formed as part of a bellows assembly 76 that otherwise translates a positive pressure onto the contained therapeutic substance 18. Alternatively, the reservoir 34 can be defined in a variety of other forms. However, the base wall 68 is movable relative to the bulkhead 64 such that the internal region 72 is variable. In other words, the reservoir 34 can have a variable volume dictated by a position of the base wall 68 relative to the bulkhead 64.

In some embodiments, the base wall 68 can be connected to the bulkhead 64 via the bellows assembly 76 such that the internal region 72 can increase in volume as the base wall 68 moves away from the bulkhead 64, such as during filling of reservoir 34 (and can decrease in volume as the base wall 68 moves towards the bulkhead 64). For example, in one embodiment, the propellant (not shown) within the propellant chamber 38 (Figure 3) can assert a continuous, positive pressure onto the base wall 68, and thus onto the reservoir 34. Alternatively, and as previously described, the implantable infusion device 10 can be configured such that a powered mechanism is coupled to the base wall 68 (or a corresponding component) that otherwise dictates a position of the base wall 68 relative to the bulkhead 64.

Regardless of an exact configuration of the implantable infusion device 10, one exemplary embodiment of the volume sensor assembly 30 is shown in greater detail in Figures 4-6 and can include a cap member 84, a plunger assembly 88, a target or core 92, and volume detection circuitry 96 (referenced generally). In general terms, the

plunger assembly 88 and target 92 can be configured to move longitudinally relative to the cap member 84 and circuitry 96 based on a change in volume of the internal region 72 of reservoir 34. The circuitry 96 can generate information indicative of a sensed longitudinal position of the target 92 and thereby a volume of reservoir 34, as will be discussed in greater detail below.

In one embodiment, the cap member 84 includes a tubular member 102 and a flange 106. The tubular member 102 can form a passage 110 extending from a first, open end 114 to a second, closed end 118. Further, the tubular member 102 can define an exterior surface 120 approximating a length of the passage 110. The flange 106 can be configured for sealed mounting to the bulkhead 64, extending in a generally radial fashion from the tubular member 102 at the open end 114. In one embodiment, the cap member 84 can be formed of a hardened, generally non-ferromagnetic material, for example titanium, capable of achieving a hermetic seal upon assembly to the bulkhead 64. In this regard, the cap member 84 can be mounted to the bulkhead 64 in a wide variety of fashions. For example, in one embodiment, the annular flange 106 can be welded to the bulkhead 64. In other embodiments, the flange 106 can be supported in part by an additional structural member, such as washer 64A. Regardless, upon final assembly, the cap member 84 can be assembled to the bulkhead 64 such that the passage 110, and in particular the open end 114, can be fluidly open to and in communication with the internal region 72 of reservoir 34. Thus, with the exemplary embodiment shown in Figures 4-6 in which the bulkhead 64 can form a portion of the reservoir 34, the passage 110 is fluidly open to and in communication with the internal region 72.

In one exemplary embodiment, the plunger assembly 88 can include a first or upper member 122 and a second or lower member 126 along with a first or upper biasing member 130 and a second or lower biasing member 134. In the exemplary embodiment illustrated in Figures 4-6, the upper member 122 can be in the form of a generally tubular member 138 having an inner surface 142 and an outer surface 146. The tubular member 138 can define an internal wall 150 positioned between a lower end 154 and an opposite upper end 158 of tubular member 138. In one exemplary embodiment, the internal annular wall 150 can define an aperture 162 configured to slidably receive a portion of the lower member 126 therethrough, as will be discussed in greater detail below. An annular flange 166 can extend radially outward from the

outer surface 146 and can include a width or diameter complimentary to a corresponding width or diameter of cap member passage 110 such that lower member 126 can be slidably received in and moveable relative to passage 110. The outer surface 146 can carry a first sealing member 170 proximate annular flange 166.

5 In the exemplary embodiment illustrated in Figures 4-6, outer surface 146 can define an annular groove 174 adjacent flange 166 and configured to receive a portion of first sealing member 170 therein such that the first sealing member 170 can be in engagement with annular groove 174 and flange 166.

The outer surface 146 of upper member 122 can carry the target 92. In one exemplary embodiment, the target 92 can be formed of a ferromagnetic material appropriate for magnetically inducing or varying a current into circuitry 96, as will be discussed in greater detail below. The target 92 can assume a variety of sizes and shapes, but generally can have an annular form so as to encircle the tubular member 138. In the exemplary embodiment illustrated in Figures 4-6, target 92 can

10 have an outer diameter equal to or substantially equal to the outer diameter of annular flange 166. In this regard, target 92 can extend longitudinally from annular flange 166 toward upper end 158 of tubular member 138. In one exemplary embodiment, target 92 can extend to the upper end 158.

In the exemplary embodiment illustrated, lower member 126 of plunger assembly 88 can be provided in the form of a shaft 182 having body 186 defining a first or lower end 190 and an opposite second or upper end 194. The body 186 can be formed of a hardened and generally non-ferromagnetic material, such as titanium or a polymeric material, that is otherwise compatible with the therapeutic substance 18 contained within internal region 72. The lower end 190 can be fixed to the base wall 68, such as by laser welding, and the body 186 can extend through aperture 162

20 such that the upper end 194 is positioned on an opposite side of internal wall 150 as the lower end 190.

In one exemplary embodiment, the body 186 of lower member 126 can include an increased thickness portion 198 at the upper end 194 configured to support one side of a second sealing member 202, as will be discussed in greater detail below. In this regard, body 186 can also define an annular groove 206 proximate the increased thickness portion 198 configured to receive a portion of second sealing member 202 therein. In one exemplary embodiment, the increased thickness portion 202 can

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cooperate with annular groove 206 to form a shoulder for supporting sealing member 202. The increased thickness portion 198 can include a longitudinal projection 210 extending longitudinally therefrom and configured to aid in locating and/or guiding the lower member 126 relative to the second closed end 118 of cap member 84. In this regard, in one exemplary embodiment, the second end 118 can include a corresponding locating feature 214 projecting from second end 118 and defining an internal recess 218 configured to nestingly receive projection 210 when reservoir 34 is in an empty or substantially empty or depleted state, as will also be discussed in greater detail below.

In one exemplary embodiment, the upper biasing member 130 can be an upper spring 226 having a first predetermined spring rate or stiffness and the lower biasing member 134 can be a lower spring 230 having a second predetermined spring rate or stiffness. The upper spring 226 can include a first end 234 positioned into upper member 122 via upper end 158 and a second end 238 in engagement with second end 118 of cap member 84. In the exemplary embodiment illustrated in Figures 4-6, the first end 234 can engage an upper side 242 of internal wall 150 of tubular member 138, and the second end 238 can engage and be retained by the locating feature 214 extending from the second end 118 of cap member 84. It is appreciated that second end 238 can be retained by other means than optional locating feature 214.

In a similar manner, the lower spring 230 can include a first end 248 in engagement with the lower end 190 of lower member 126 and/or base wall 68, and a second opposite end 252 in engagement with a second opposite side 256 of internal wall 150 and can be positioned around the lower member 126. In one exemplary embodiment, the lower spring 230 can have a larger inner diameter or width such that the lower member 126 can move relative to the lower spring 230. In the exemplary embodiment illustrated, the upper and lower springs 226, 230 can extend along the same longitudinal axis 260, as shown for example in Figure 5A. In one exemplary embodiment, the upper and lower members 122, 126 and the upper and lower springs 226, 230 can be concentric about longitudinal axis 260. In this regard, the upper member 122 of plunger assembly 88 can be suspended at a center of the stacked upper and lower springs 226, 230, as shown for example in Figure 5A.

This configuration of plunger assembly 88 can facilitate the lower member 126 telescopically moving relative to the upper member 122 in a predictable manner as the

base wall 68 moves with a change in the volume of the internal region 72 of reservoir 34, as will be discussed in greater detail below. Briefly, however, the dual plunger configuration (e.g., upper or outer and lower or inner telescoping members 122, 126) in conjunction with the associated upper and lower springs 226, 230 can provide
5 for reducing the overall travel range of the plunger assembly 88 and thereby facilitate using a more compact or thinner implantable infusion device 10. In other words, for example, a thickness of housing 26 can be reduced to provide for a lower profile implantable infusion device 10. In this regard, the upper member 122 can be configured to move at a predetermined fraction of the travel of lower member 126
10 based on the selected spring rate of the upper spring 226 relative to the lower spring 230, as will also be discussed below in greater detail.

With continuing reference to Figures 4-6 and additional reference to Figures 7-9, the target 92 and circuitry 96 will now be discussed in greater detail. As discussed above, target 92 can be indirectly coupled to the base wall 68 via plunger
15 assembly 88, and thus can move with movement of the base wall 68. Conversely, the cap member 84 can be mounted to the bulkhead 64, and thus can remain stationary with movement of the base wall 68 and/or plunger assembly 88. Thus, a known relationship can be established between a longitudinal position of the target 92 relative to the passage 110 and a position of bulkhead 64 relative to the base wall 68. Because a
20 volume (or "current volume") of the reservoir 34 can be defined as a function of a distance between the base wall 68 and the bulkhead 64, then, the longitudinal position of target 92 relative to passage 110 can be a function of, or can be indicative of, the current volume of the reservoir 34. With this in mind, the circuitry 96 can be configured to sense and/or provide information indicative of the position of the
25 target 92 relative to the passage 110 and thus the current volume of reservoir 34.

In one embodiment, the circuitry 96 can include first and second secondary wire coils 262, 266, and a primary wire coil 270, each of which are schematically illustrated in Figures 4-6. The first and second secondary coils 262, 266 can be wound about the
30 outer or exterior surface 120 of cap member 84. Relative to the orientation shown in Figures 4-6, the first secondary wire coil 262 constitutes a lower secondary coil, whereas the second secondary wire coil 266 constitutes an upper secondary coil. Regardless, each of the secondary coils 262, 266 can be formed of a material characterized as self-inducting in the presence of a magnetic body, for example the

ferromagnetic target or core 92. Further, each of the secondary coils 262, 266 can have a length L_{COIL} (e.g., longitudinal distance between opposing, leading and trailing sides 266A, 266B identified for the upper secondary coil 266 in Figure 5A) that is directly related to a length of travel L_{TRAVEL} associated with the base wall 68 of reservoir 34 relative to bulkhead 64, and in turn relative to a length L_{TARGET} of the target 92, as discussed in greater detail below.

In one embodiment, however, lower and upper secondary coils 262, 266 can be partially overlapped or co-axially wound relative to the lengths L_{COIL} thereof. The overlapped region is indicated at 268 in Figure 5A, and has a length L_O . For reasons made clear below, in one embodiment, a direction of winding of the lower secondary coil 262 can be opposite that of the upper secondary coil 266. In other embodiments, the secondary coils 262, 266 can be wound in the same direction. Regardless, each of the secondary coils 262, 266 can be electrically connected to a sensing circuit or module (not shown, but can be provided as part of a controller or other circuitry otherwise conventionally provided with an implantable infusion device and/or external programmer) for measuring an output of the individual secondary coils 262, 266.

The primary wire coil 270 can be wound about an exterior of the secondary coils 262, 266, as shown for example in Figure 5A. In one embodiment, the primary wire coil 270 can extend a full length of the combined secondary coils 262, 266; in other embodiments, the primary wire coil 270 can have a reduced length, for example sufficient to encompass only the overlapped region 268, etc. In the exemplary embodiment illustrated, the primary wire coil 270 can be wrapped about the length L_{COIL} of each of the secondary coils 262, 266. With this arrangement, a mutual inductance relationship can be created between the primary coil 270 and each of the secondary coils 262, 266 such that an electrical signal (or input signal) 274 placed across the primary coil 270 can be coupled into each of the secondary coils 262, 266. The amount of energy from the primary coil 270 actually inducted is enhanced by the presence of the ferromagnetic target 92. Thus, where the input signal 274 is an alternating current defined by a sine wave, the resultant sine wave induced in the secondary coils 262, 266, and in particular the amplitude thereof, is increased via inductance caused by the ferromagnetic target 92.

In light of the above, the circuitry 96 can be configured to effectively measure a longitudinal position of the target 92 relative to the passage 110 based upon a

comparison of the output signals from the secondary coils 262, 266. For example, the two output signals from the secondary coils 262, 266 can be added to one another and processed to produce a resultant combined output signal 264 being indicative of a longitudinal position of the target 92. In the position of Figures 5-5A, where the reservoir 34 is shown in the full condition, the target 92 can be entirely within the lower secondary coil 262. As a result, the lower secondary coil 262 output signal can be a large, in-phase sine wave. Conversely, the target 92 is fully displaced from the upper secondary coil 266, resulting in a low output signal from the upper secondary coil 266.

Appropriate comparison of the output signal can be performed in a variety of manners. For example, in one embodiment in which the lower secondary coil 262 is wound in the same direction as the primary coil 270 and the upper secondary coil 266 is wound in the opposite direction, the output signal from the upper secondary coil 266 can be 180 degrees out of phase from that of the lower secondary coil 262. Thus, the secondary coil 262, 266 outputs 264 can be directly added to one another. Alternatively, where the secondary coils 262, 266 are wound in the same direction, the output signal from the upper secondary coil 266 can be inverted prior to comparison with the lower secondary coil 262 output (or vice versa). Regardless, in the configuration of Figure 5A, a comparison of the lower and upper secondary coil 262, 266 outputs 264 results in a large, in-phase signal that is otherwise indicative of the target 92 being at the lower-most position, as also shown schematically in Figure 8. This, in turn, is indicative of the base wall 68 being spaced a maximum distance from the bulkhead 64, and thus of the reservoir 34 having a current volume approximating a maximum fill amount (or 100% full). In a similar manner, when the reservoir 34 is in an empty configuration and the target 92 is adjacent the upper secondary coil 266 as shown in Figure 6, the resultant output signal 264 can be an out of phase signal, as shown schematically in Figure 9. Further, with the inverted or counter wound secondary coils 262, 266, the resultant output signal 264 from secondary coils 262, 266 will be flat when the reservoir 34 is in the half-full condition of Figures 4-4A, as schematically shown in Figure 7. In other words, the signals from the combined coils cancel out.

In particular, as the therapeutic substance 18 is dispensed from reservoir 34, the base wall 68 can move relative to the bulkhead 64 (for example due to the positive pressure exerted thereon via the propellant chamber 38). As a result, the current

volume of the reservoir 34 can be reduced. Once again, the target 92 can move relative to the passage 110 via indirect connection to base wall 68. For example, as target 92 moves from the full reservoir 34 condition shown in Figures 5-5A toward the empty condition shown in Figure 6, a greater length of the target 92 can be within the lower secondary coil 262 as compared to the upper secondary coil 266. Thus, the output signal from the lower secondary coil 262 has an increased amplitude as compared to the output signal from the upper secondary coil 266. When the output signals are compared or combined, the combined signal 264 is an out-of-phase sine wave with a decreased amplitude (as compared to that associated with the combined secondary coil 262, 266 outputs when the target 92 is in the lower-most position of Figures 5-5A).

Thus, as the target 92 travels from the lower-most position to a mid-point of travel, the combined output signal 264 can be an in-phase sine wave of decreasing amplitude. At the mid-point of travel shown in Figures 4-4A, then, the lower and upper secondary coil 262, 266 outputs can effectively cancel out, as shown in Figure 7. With further upward travel of the target 92 toward the empty condition of Figure 6, the output signal amplitude of the upper secondary coil 266 can increase while that of the lower secondary coil 262 can decrease. The combined output signal 264 can thus be a 180 degree out-of-phase sine wave (Figure 9), the amplitude of which increases as the target 92 travels from the mid-point to the top-most position shown in Figure 6. A further discussion of the operation of circuitry 96 is included in commonly owned U.S. Pub. No. 2007/0255259 assigned to Medtronic, Inc., the disclosure of which is hereby incorporated by reference herein. It is also appreciated that the telescoping plunger assembly 88 can be associated with alternative sensing means in lieu of the target 92 and circuitry 96 such as, for example, optical sensing means.

The circuitry 96 output can be processed, manipulated and/or provided to a clinician in a wide variety of manners. For example, the combined output signal can simply be presented to and reviewed by the clinician, and a manual evaluation performed thereof to estimate a current volume of the reservoir 34 and thus the current volume of the contained therapeutic substance 18. Alternatively, the circuitry 96 (or in other embodiments, circuitry associated with an external programmer) can be configured to correlate and/or compare the combined output signal with a base line signal to estimate or indicate a fill percentage of the reservoir 34. For example, the combined output signal can be compared with the combined output signal generated

when the target 92 is in the lower-most (and/or upper-most) position that is otherwise representative of the reservoir 34 being completely filled (or completely empty). Based upon this comparison, an estimate can be made as to the current percent fill volume. In other embodiments, the combined output signal can be compared with predetermined data points (e.g., a look-up table) that otherwise correlates signal information with volumetric values. For example, the amplitude and in-phase and out-of-phase components of the combined output signal can be compared with a table establishing a known relationship between the phase/amplitude values and corresponding volumes; or the reference table can equate fill percentage with combined output signal parameters. It is also appreciated that the circuitry 96 discussed herein is but one example of a circuitry means for use with the plunger assembly 88 in accordance with principles of the present disclosure.

With continuing reference to Figures 4-6, operation of the volume sensor assembly 30 and, in particular, the plunger assembly 88, will now be discussed in greater detail. As briefly discussed above, the plunger assembly 88 can use the upper and lower telescoping members 122, 126 in conjunction with the upper and lower springs 226, 230 to ratio down the amount of overall travel of upper and lower members 122, 126 as compared to the amount of travel L_{TRAVEL} of base wall 68 when the volume of reservoir 34 decreases from the full condition to the empty condition.

In particular, in the exemplary embodiment illustrated, the upper and lower springs 226, 230 can have an equal unloaded length and can cooperate with the internal wall 150 of upper member 122 to operatively suspend upper member 122 between the closed end 118 of cap member 84 and the base wall 68 of reservoir 34, as generally shown in Figures 4-5A. In this regard, in one exemplary embodiment, the internal wall 150 can be positioned relative to a longitudinal length of upper member 122 such that the springs 226, 230 can position the target 92 (that is carried by upper member 122) in alignment or substantial alignment with lower secondary coil 262 when the reservoir 34 is in a full condition (Figures 5-5A) and in alignment or substantial alignment with the upper secondary coil 266 when the reservoir 34 is in an empty condition (Figure 6). In this exemplary embodiment, the target 92 length L_{TARGET} can be equal or substantially equal to a non-overlapping portion of the length L_{COIL} of secondary coils 262, 266. Further, a longitudinal length 280 of lower member 126 can be sized such that the longitudinal projection 210 can be received in

the internal recess 218 when the reservoir 34 is in the empty condition shown in Figure 6. In this regard, in one exemplary embodiment, the lower member 126 can be configured with longitudinal length 280 so as to limit the travel of the base wall 68 toward bulkhead 64 when the reservoir 34 is empty or substantially empty.

5 Similarly, a sub-length 284 (Figure 5A) of the lower member 126 from the lower end 190 to the annular groove 206 can be sized to cooperate with the location of the internal wall 150 relative to the annular flange 166 of upper member 122 so as to position the first sealing member 170 in engagement with the internal wall 150 and the second sealing member 202 in engagement with the bulkhead 64 when the reservoir 34
10 is in the full condition. In this regard, in one exemplary embodiment, the upper and lower members 122, 126 of plunger assembly 88 can thus be configured to limit the travel of base wall 68 in a direction away from bulkhead 64 and thereby define a maximum travel length of base wall 68 corresponding to the full condition of reservoir 34.

15 In an exemplary embodiment where the upper and lower springs 226, 230 have the same spring rate or stiffness, the upper member 122 can be configured to move at one-half the travel of the lower member 126. Thus, as the therapeutic substance 18 is delivered from reservoir 34 and the base wall 68 moves from the full condition shown in Figure 5 toward the empty condition shown in Figure 6, both the upper and lower
20 members 122, 126 can move in the same direction toward the closed end 118 of cap member 84. However, for a given distance of travel L_{TRAVEL} of the base wall 68, the lower member 126 can travel the same given distance L_{TRAVEL} while the upper member 122 can travel only one-half of that distance. As a result, the lower member 126 can telescopically move relative to both the upper member 122 and the
25 cap member 84 during movement of the base wall 68. In the exemplary embodiment illustrated in Figures 4-6, the lower member 126 can be configured to telescopically move relative to and within the upper member 122, as shown for example in Figures 4-6.

30 This dual member telescoping plunger configuration can facilitate, among other things, an ability to utilize a more compact implantable infusion device 10. In this regard, for example, by reducing the travel of the upper member 122 to a predetermined fraction of the lower member 126, the length of travel of the upper member 122 can be reduced. This reduction in travel can provide for utilizing a shorter length for the

primary coil 270 as well as a shorter L_{COIL} for both secondary coils 262, 266 and can thus provide for using a reduced thickness or lower profile housing 26. Further, the relative movement of the lower member 126 relative to the upper member 122 can also provide for the length of passage 110 of cap member 84 being shorter than the length of travel L_{TRAVEL} of the base wall 68 from the full condition (Figure 5) to the empty condition (Figure 6). This can be contrasted to a single plunger mechanism that can require the length of a member supporting the primary coil, as well as the primary coil, to be at least as long as the length of travel of a base wall 68 of an associated reservoir.

It should be appreciated that while the dual member plunger assembly 88 has been discussed above in connection with two springs of the same spring stiffness, the plunger assembly 88 can alternatively utilize an upper spring 226 with a different stiffness or rate than the lower spring 230 to provide a different ratio or fraction of travel of the upper member 122 relative to the lower member 126. For example, to further reduce the travel of the upper member 122 relative to the lower member 126 for a given travel distance L_{TRAVEL} of base wall 68, the stiffness of the upper spring 226 can be increased relative to the lower spring 230. In this example, the upper spring 226 could include a stiffness of twice the stiffness of the lower spring 230. This configuration could therefore result in the upper member 122 traveling one-quarter of the distance of travel of the lower member 126 and base wall 68. It is appreciated that other spring stiffness configurations or ratios could be utilized to tailor the rate of travel of the upper member 122 relative to the lower member 126 to a desired ratio for a desired application. It should also be appreciated that in various embodiments the lower member 126 may not be utilized and the lower spring 230 may directly couple the base wall 68 to the internal wall 150 of upper member 122.

Turning now to Figure 5B, the volume sensor assembly 30 is shown with an exemplary alternative upper member 122'. Upper member 122' can form a hermetic enclosure or encapsulation around target 92 so as to seal off target 92 from the therapeutic substance 18, as will be discussed in greater detail below. Upper member 122' can similarly be formed of a titanium material and can include a tubular member 138' having outer and inner annular members 320, 324 spaced apart from each other to form a slot or channel 332 therebetween, as shown in Figure 5B. The core 92 can be positioned in slot 332 and an annular cap or top member 328 can be secured to the outer and inner annular members 320, 324 to seal off target 92 from the therapeutic

substance 18. In one exemplary configuration, cap member 328 can be welded to the outer and inner annular members 320, 324.

It should be appreciated that other configurations of the upper member can be used to seal off the target 92 from therapeutic substance 18. For example, the cap member 328 and the outer annular member 320 can be an integral component configured to be secured, such as by welding, to the annular flange 166 (Figure 5A) and the inner annular member 324. Sealing off the target 92 from the therapeutic substance 18 can provide for an ability to utilize various different materials for the target 92, including materials that may not be compatible with the therapeutic fluid 18 since target 92 would be sealed off from the fluid 18 in this exemplary configuration.

The plunger assembly 88 can also serve as an overfill and/or over pressure prevention arrangement in addition to providing an ability to tailor the ratio of travel of the upper member 122 relative to the lower member 126. In this regard, and as briefly discussed above, the upper and lower members 122, 126 can be sized such that the first sealing member 170 engages the internal wall 150 relative to aperture 162, and the second sealing member 202 engages the bulkhead 64 relative to an opening or aperture 290 therethrough, as shown for example in Figure 5A. This configuration can prevent any therapeutic substance 18 from fill port 46 entering reservoir 34, as will be discussed in greater detail below.

With initial reference to Figure 6, a flow path from fill port 46 to reservoir 34 can be defined by implantable infusion device 10. In one exemplary embodiment, a channel 294 can extend from port 46 to a cavity 298 that is formed in housing 26 and contains cap member 84 therein. As discussed above, cap member 84 can be sealingly secured to housing 26 such that cap member 84 creates a hermetic barrier. Regardless, the therapeutic substance 18 can flow from the fill port 46 through channel 294 and into cavity 298 and/or the internal passage 110 defined by cap member 84. From there, the therapeutic substance 18 can flow into reservoir 34 via two different flow paths. The first flow path can extend from channel 294 along a space defined between an inner surface 302 of cap member 84 and outer surface 146 of tubular member 138 and an outer surface of target 92. The first flow path can then extend in an opposite direction through tubular member 138 and aperture 162 of internal wall 150 toward reservoir 34. Fluid following the first flow path can then flow through aperture 290 into reservoir 34. The second flow path can extend from channel 294 through aperture 290 into

reservoir 34. In this regard, it should be appreciated that as upper member 122 extends through aperture 290 during filling of reservoir 34, a space or gap 306 (Figure 5A) can be defined between outer surface 146 and aperture 290 such that fluid can flow therethrough. In one exemplary embodiment where aperture 290 can be utilized to provide guiding support to tubular member 138, the aperture 290 can include longitudinal grooves or splines (not shown) in a sidewall thereof to increase fluid flow in the space 306 while also providing the guiding support.

As discussed above, the upper and lower members 122, 126 of plunger assembly 88 can be sized such that the first sealing member 170 engages the internal wall 150 and the second sealing member 202 engages bulkhead 64 proximate aperture 290 when reservoir 34 is in a full condition, as shown for example in Figures 5-5A. In particular, the sub-length 284 of lower member 126 can be sized to bring first sealing member 170 into sealing engagement with internal wall 150 and thereby bring second sealing member 202 into sealing engagement with bulkhead 64 (and/or washer 64A) when reservoir 34 is in the full condition shown in Figures 5-5A. In other words, the sub-length 284 of lower member 126 can be correlated to the L_{TRAVEL} so as to cooperate with the upper member 122 to bring the first and second sealing members 170, 202 into sealing engagement in the manner discussed above at the maximum L_{TRAVEL} of base wall 68 of reservoir 34.

In bringing first sealing member 170 into sealing engagement with internal wall 150 when reservoir 34 is in the full condition, the plunger assembly 88 can seal off the first flow path upstream of reservoir 34 by preventing therapeutic substance 18 from flowing through aperture 162 of internal wall 150. In this regard, first sealing member 170 can include an o-ring having a larger diameter or dimension so as to extend around aperture 162 and provide a sealed connection between the increased thickness portion 198 and a surface of the internal wall 150 adjacent aperture 162, as shown for example in Figure 5A.

Similarly, in bringing the second sealing member 202 into sealing engagement with bulkhead 64 when reservoir 34 is in the full condition, the plunger assembly 88 can also seal off the first flow path upstream of reservoir 34 by preventing the therapeutic substance 18 from flowing through aperture 290 from channel 294. In particular, sealing member 202 can include an o-ring and can form a sealed connection between annular flange 166 and/or increased thickness portion 198 and a surface of

bulkhead 64 (and/or washer 64A) adjacent aperture 290 so as to prevent therapeutic substance 18 from flowing into reservoir 34 via aperture 290, as also shown for example in Figure 5A. It is appreciated that while the implantable infusion device 10 has been discussed as having first and second flow paths in connection with channel 294, implantable infusion device 10 could alternatively include only one of the first and second flow paths along with only one of the corresponding first and second sealing members 170, 202.

The plunger assembly 88 of the present teachings can thus serve to both facilitate the use of a more compact implantable infusion device via the telescoping dual member plunger arrangement discussed herein, as well as provide protection against an overfill or over pressure condition by sealing off the flow path or paths from the fill port to the reservoir when the reservoir is in the full condition.

While one or more specific examples have been described and illustrated, it will be understood by those skilled in the art that various changes may be made and equivalence may be substituted for elements thereof without departing from the scope of the present teachings as defined in the claims. Furthermore, the mixing and matching of features, elements and/or functions between various examples may be expressly contemplated herein so that one skilled in the art would appreciate from the present teachings that features, elements and/or functions of one example may be incorporated into another example as appropriate, unless described otherwise above. Moreover, many modifications may be made to adapt a particular situation or material to the present teachings without departing from the essential scope thereof.

CLAIMS

What is claimed is:

- 5 1. A volume sensing system for use in determining a volume of a variable volume reservoir, the system comprising:
- a plunger assembly, including:
- a lower plunger having a first end and an opposite second end, the first end adapted to move with a bottom of the reservoir;
- 10 an upper plunger having a first end and an opposite second end, the upper plunger slidable relative to the lower plunger;
- a lower biasing member positioned substantially between a base of the reservoir and the upper plunger; and
- an upper biasing member adapted to be positioned between the upper
- 15 plunger and an interference member;
- wherein the upper biasing member is configured to have a predetermined stiffness relative to the lower biasing member such that upon movement of the lower plunger in a first direction, the upper plunger is configured to move in the first direction at a predetermined fraction of the amount of movement of the lower
- 20 plunger, and wherein a position of the upper plunger is adapted to be correlated to a corresponding volume of the reservoir.
2. The system of claim 1, wherein movement of the lower plunger in the first direction is configured to compress the lower biasing member thereby causing
- 25 movement of the upper plunger in the first direction, which compresses the upper biasing member between the upper plunger and the interference member.
3. The system of claim 1, wherein the upper plunger comprises a tubular member, and wherein at least a portion of the lower plunger is configured to
- 30 telescopically move relative to and within the upper plunger.

4. The system of claim 3, wherein the upper and lower plungers and the upper and lower biasing members are concentric about a longitudinal axis of the plunger assembly.

5. The system of claim 3, wherein at least a first portion of the lower plunger is positioned within the lower biasing member and a first portion of the upper plunger, and wherein at least a second portion of the lower plunger is positioned within a second portion of the upper plunger and the upper biasing member.

6. The system of claim 3, wherein the upper plunger is configured to be suspended between the upper biasing member and the lower biasing member.

7. The system of claim 3, wherein the upper plunger comprises an internal wall, the internal wall engaging the upper biasing member on an upper side thereof and engaging the lower biasing member on an opposite lower side thereof.

8. The system of claim 7, wherein the internal wall defines an aperture, the lower plunger slidably extending through the aperture so as to be slidably coupled to the upper plunger.

9. The system of claim 7, further comprising a first sealing member carried by the lower plunger and a second sealing member carried by an outer surface of the upper plunger, the first sealing member configured to engage the upper side of the internal wall when the reservoir is in a full condition and adapted to thereby seal off a first flow path to the reservoir, the second sealing member adapted to engage a housing associated with the reservoir when the reservoir is in the full condition to seal off a second flow path to the reservoir.

10. The system of claim 3, wherein the upper and lower biasing members comprise respective upper and lower springs, the predetermined stiffness of the upper spring being equal to the stiffness of the lower spring such that the upper plunger moves at one-half the amount of movement of the lower plunger.

11. The system of claim 3, wherein the upper and lower biasing members comprise respective upper and lower springs, the predetermined stiffness of the upper spring being twice the stiffness of the lower spring such that the upper plunger moves at one-quarter the amount of movement of the lower plunger.

5

12. The system of claim 3, further comprising a cap defining an internal passage extending between an open end and a closed end, the cap positioned in a housing associated with the reservoir, the interference member comprising the closed end of the cap, the open end of the cap receiving a portion of the plunger assembly therein.

10

13. The system of claim 12, further comprising a ferromagnetic target coupled to the upper plunger for movement therewith, and circuitry associated with the cap and configured to detect a longitudinal position of the target relative to the passage and generate information indicative of the longitudinal position of the target relative to a dimension of the cap, the longitudinal position of the target relative to the dimension of the cap being representative of a volume of the reservoir.

15

14. A volume sensing system for use in determining a volume of a variable volume reservoir, the system comprising:

20

a housing maintaining the variable volume reservoir and including a bulkhead defining in part a top of the variable volume reservoir and an internal passage open to the reservoir, the variable volume reservoir including a base wall that is movable relative to the bulkhead, wherein a volume of an internal region of the reservoir is a function of a distance between the base wall and the bulkhead;

25

a volume sensor assembly for generating information indicative of a current volume of the internal region, the volume sensor assembly including:

a plunger assembly, comprising:

a lower plunger having a first end and an opposite second end, the first end coupled to the base wall;

30

an upper plunger having a first end and an opposite second end facing the base wall, the upper plunger slidably coupled to the lower plunger;

a lower biasing member positioned substantially between the base wall and the upper plunger; and

an upper biasing member positioned substantially between the upper plunger and a closed end of the internal passage, the upper biasing member
5 configured to have a predetermined stiffness relative to the lower biasing member such that upon movement of the lower plunger in a first direction, the upper plunger is configured to move in the first direction at a predetermined fraction of the amount of movement of the lower plunger;

a ferromagnetic target coupled to the upper plunger and moveable
10 therewith relative to the internal passage; and

circuitry associated with the internal passage and configured to detect a longitudinal position of the target relative to the internal passage, the longitudinal position of the target relative to the internal passage being representative of a volume of the internal region of the reservoir.

15
15. The system of claim 14, further comprising a cap associated with the housing and defining the internal passage, the internal passage extending from an open end to a closed end, the cap being mounted to the bulkhead such that the open end is facing the movable wall of the reservoir, the upper biasing member being positioned
20 between the upper plunger and the closed end of the cap.

16. The system of claim 15, wherein movement of the base wall in a first direction toward the bulkhead moves the lower plunger in the first direction thereby compressing the lower biasing member, which in turn causes movement of the upper
25 plunger in the first direction thereby compressing the upper biasing member between the upper plunger and the closed end of the cap.

17. The system of claim 15, wherein the upper plunger comprises a tubular member, and wherein the lower plunger is configured to telescopically move relative to
30 and within the upper plunger.

18. The system of claim 15, wherein the upper and lower plungers, the upper and lower biasing members and the cap are concentric about a longitudinal axis of the plunger assembly.

5 19. The system of claim 14, wherein the upper plunger is configured to be suspended between the upper biasing member and the lower biasing member.

10 20. The system of claim 14, wherein the upper and lower biasing members comprise respective upper and lower springs, the predetermined stiffness of the upper spring being equal to the stiffness of the lower spring such that the upper plunger moves at one-half the amount of movement of the lower plunger.

15 21. The system of claim 14, wherein the upper plunger comprises an internal wall, the internal wall engaging the upper biasing member on an upper side thereof and engaging the lower biasing member on an opposite lower side thereof, and wherein the internal wall comprises an aperture, the lower plunger slidably extending through the aperture.

20 22. The system of claim 14, further comprising a first sealing member carried by the lower plunger and a second sealing member carried by the upper plunger, the first sealing member configured to engage the upper side of the internal wall when the reservoir is in a full condition to thereby seal off a first flow path to the reservoir, the second sealing member configured to engage the housing when the reservoir is in the full condition to thereby seal off a second flow path to the reservoir.

25 23. The system of claim 22, wherein the housing defines a channel in fluid communication with a fill port defined by the housing and the internal region, the second sealing member configured to engage the housing to seal off a portion of the flow path from the channel to the internal region.

30 24. The system of claim 22, wherein the second sealing member is an o-ring carried by an outer surface of upper plunger.

25. The system of claim 15, wherein the circuitry includes a primary coil and first and second secondary coils each carried by the cap.

5 26. The system of claim 14, further comprising a delivery catheter coupled to an outlet of the housing that is in fluid communication with the reservoir.

27. The system of claim 14, wherein the target is encapsulated by the upper plunger so as to be hermetically sealed within the upper plunger.

10 28. The system of claim 27, wherein the upper plunger comprises a tubular member and a top member, the tubular member having an inner annular wall and an outer annular wall spaced apart from the inner annular wall so as to define a slot therebetween, the target being positioned in the slot and the top member being fixed to the inner and outer annular members to cover the slot and hermetically seal the target
15 within the upper plunger.

29. A method for use in determining a volume of a variable volume reservoir, the method comprising:

generating position information of a target coupled to an upper plunger
20 through operation of a volume sensor assembly, the upper plunger being coupled to a lower plunger and positioned between an upper biasing member and a lower biasing member, the lower plunger being coupled to a base of the reservoir and configured for movement therewith, wherein a position of the base relative to a housing associated with the variable volume reservoir is representative of a volume of an internal region of
25 the reservoir; and

moving first and second sealing members associated with the respective lower and upper plungers into sealing positions to seal off fluid communication between a fill port defined by the housing when the reservoir is in a full condition, the fill port being in selective fluid communication with the internal region of the reservoir.

30

30. The method of claim 29, wherein moving upper and lower sealing members associated with the respective upper and lower plungers into sealing positions includes:

moving the first sealing member coupled to the lower plunger into sealed engagement with the upper plunger to seal off a first flow path from the fill port through the upper plunger to the reservoir when the reservoir is in the full condition; and

5 moving the second sealing member coupled to the upper plunger into sealed engagement with the housing to seal off a second flow path from the fill port to the reservoir when the reservoir is in the full condition.

31. The method of claim 29, wherein moving the first sealing member into
10 sealed engagement with the upper plunger causes the upper plunger to move and position the second sealing member into the sealed engagement with the housing.

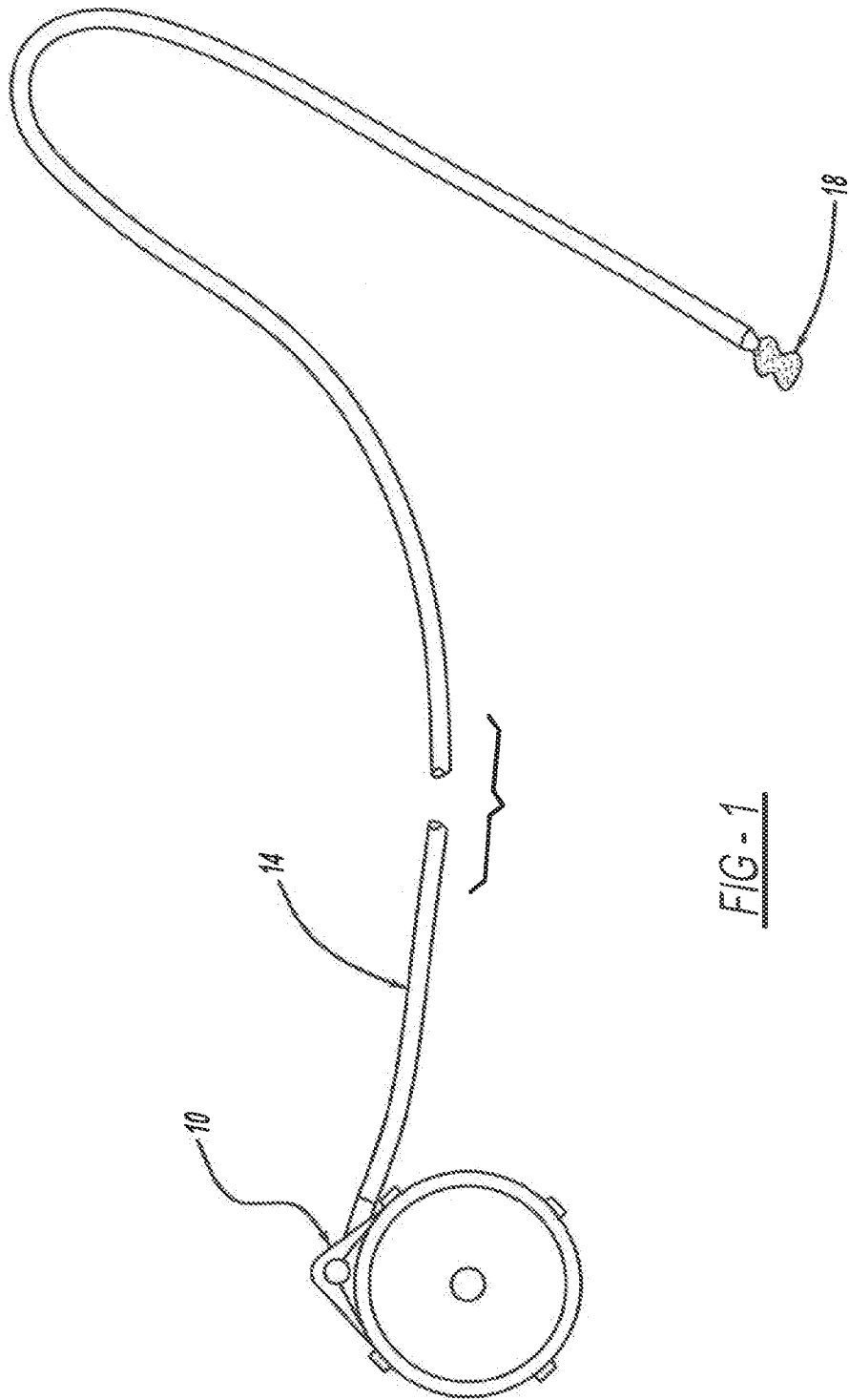
32. The method of claim 29, further comprising moving the first and second
15 sealing members away from the sealing positions when the reservoir is in a condition other than the full condition to open fluid communication between the fill port and the internal region of the reservoir.

33. The method of claim 29, wherein generating position information of a
20 target coupled to an upper plunger through operation of a volume sensor assembly includes moving the lower plunger with movement of the base of the reservoir, which causes movement of the upper plunger via the first biasing member, which in turn causes compression of the second biasing member.

34. The method of claim 33, further comprising the upper biasing member
25 having a predetermined stiffness relative to the lower biasing member such that movement of the lower plunger causes corresponding movement of the upper plunger that is a predetermined fractional amount of the lower plunger.

35. The method of claim 34, wherein movement of the base of the reservoir by a first amount causes corresponding movement of the lower plunger by the first amount, which in turn causes movement of the upper plunger by a fractional amount equal to one-half the first amount.

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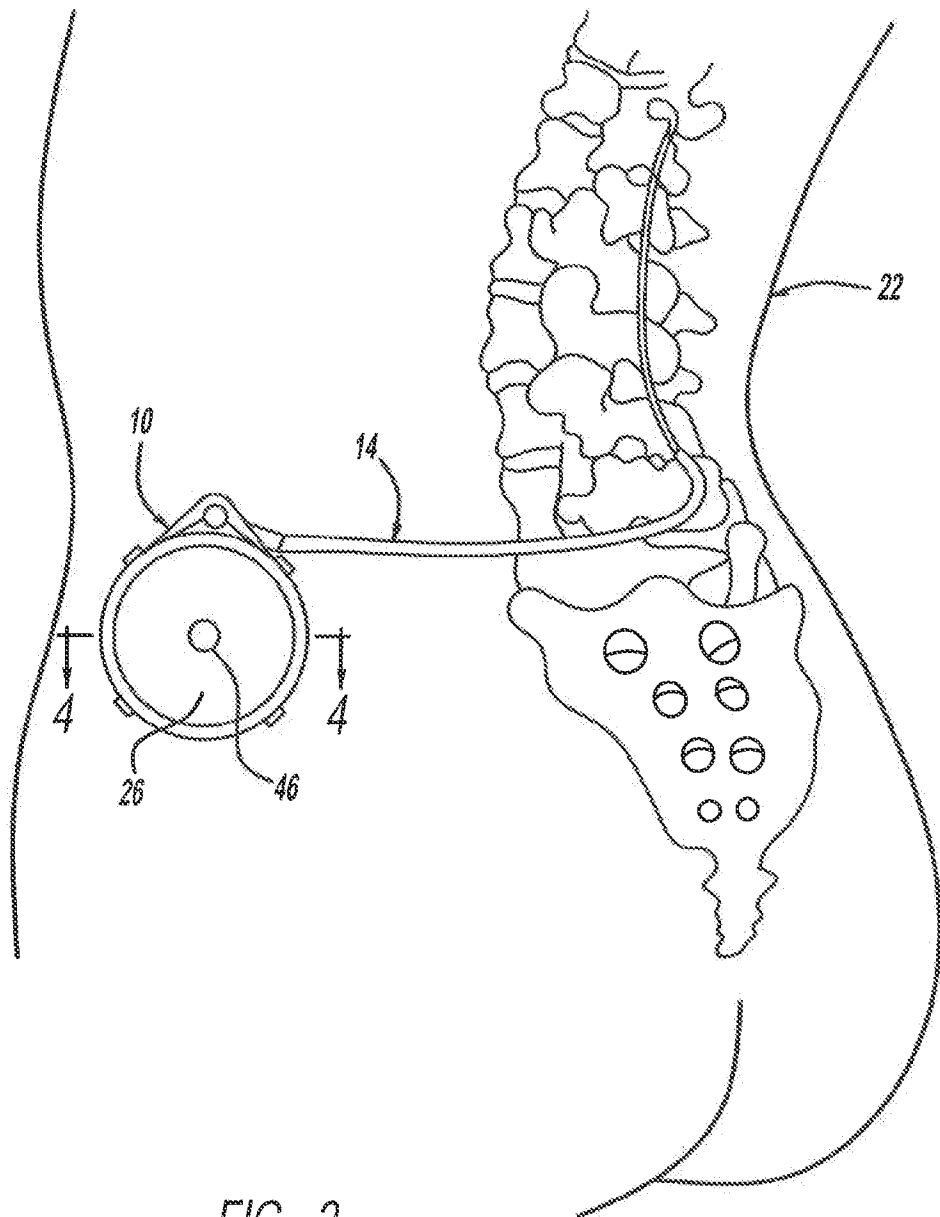


FIG - 2

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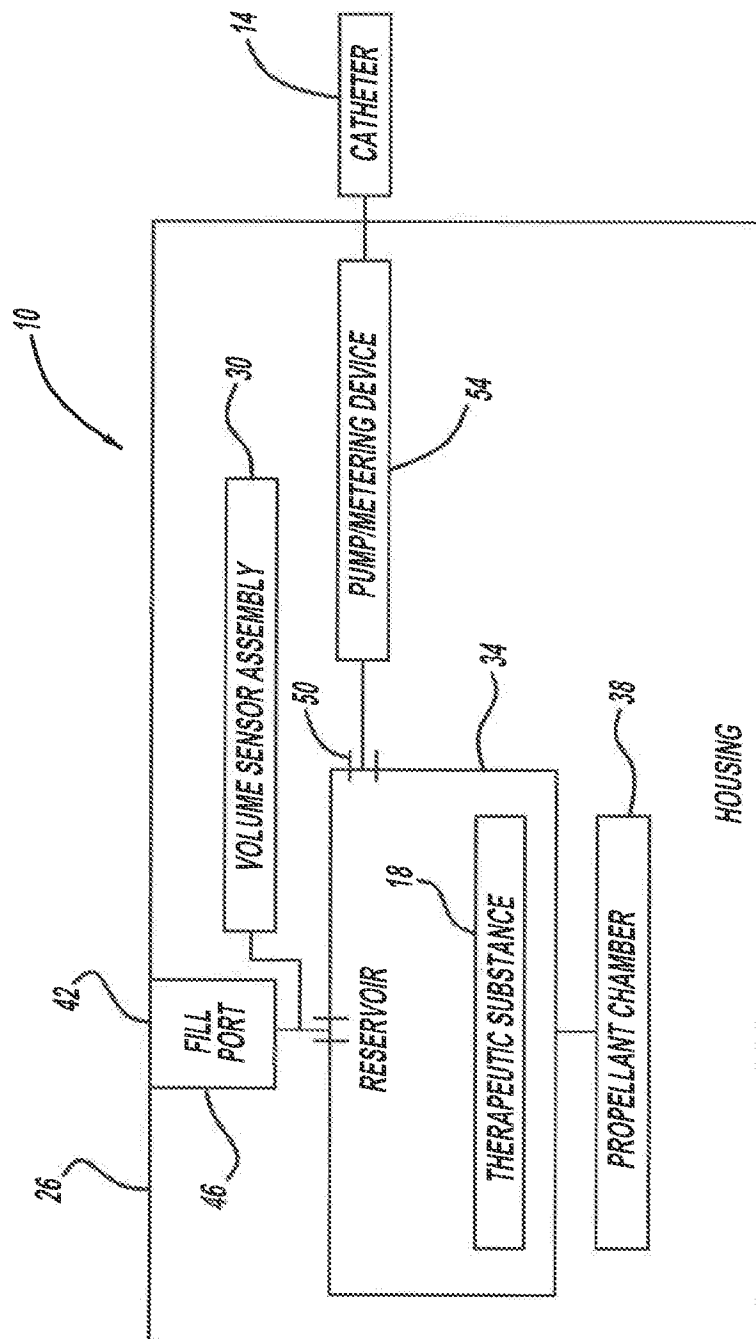
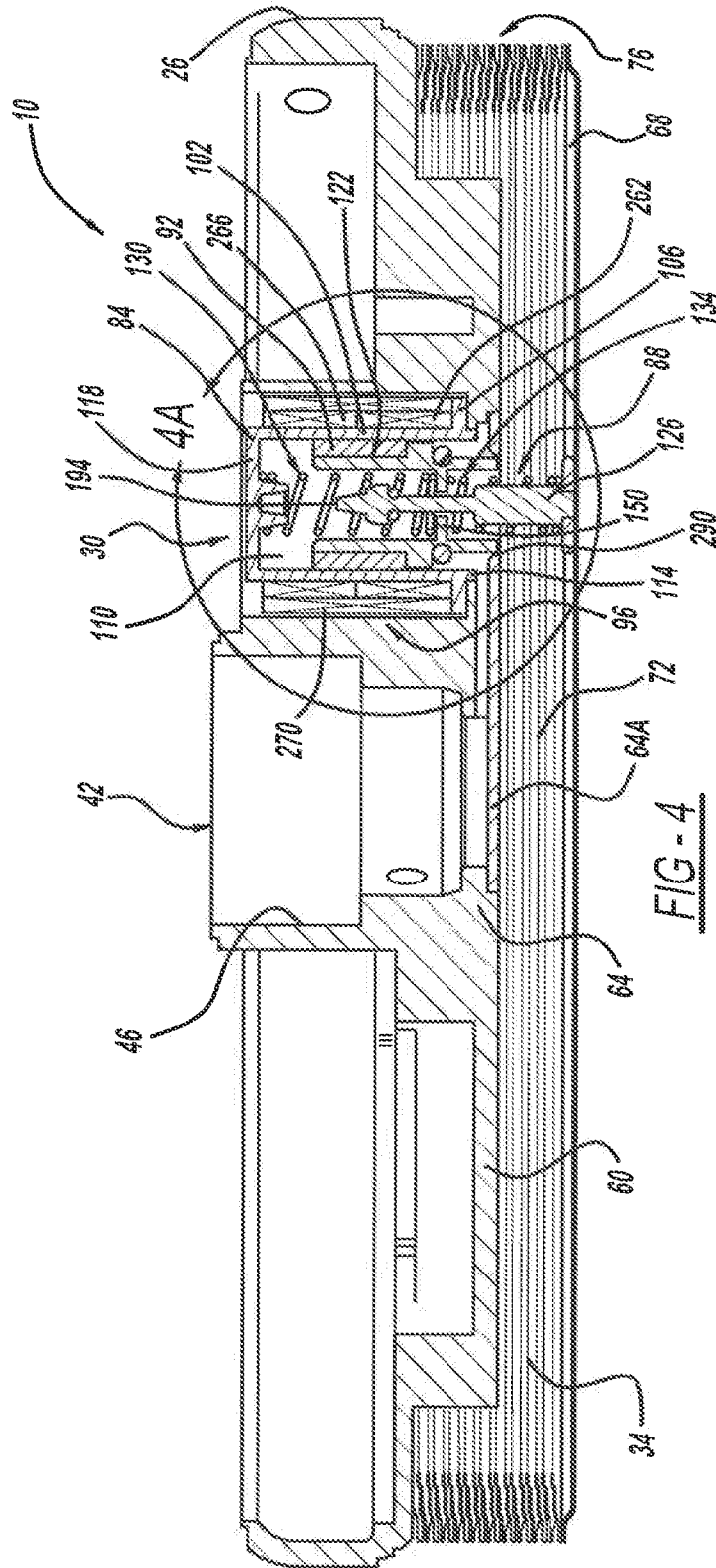


FIG - 3

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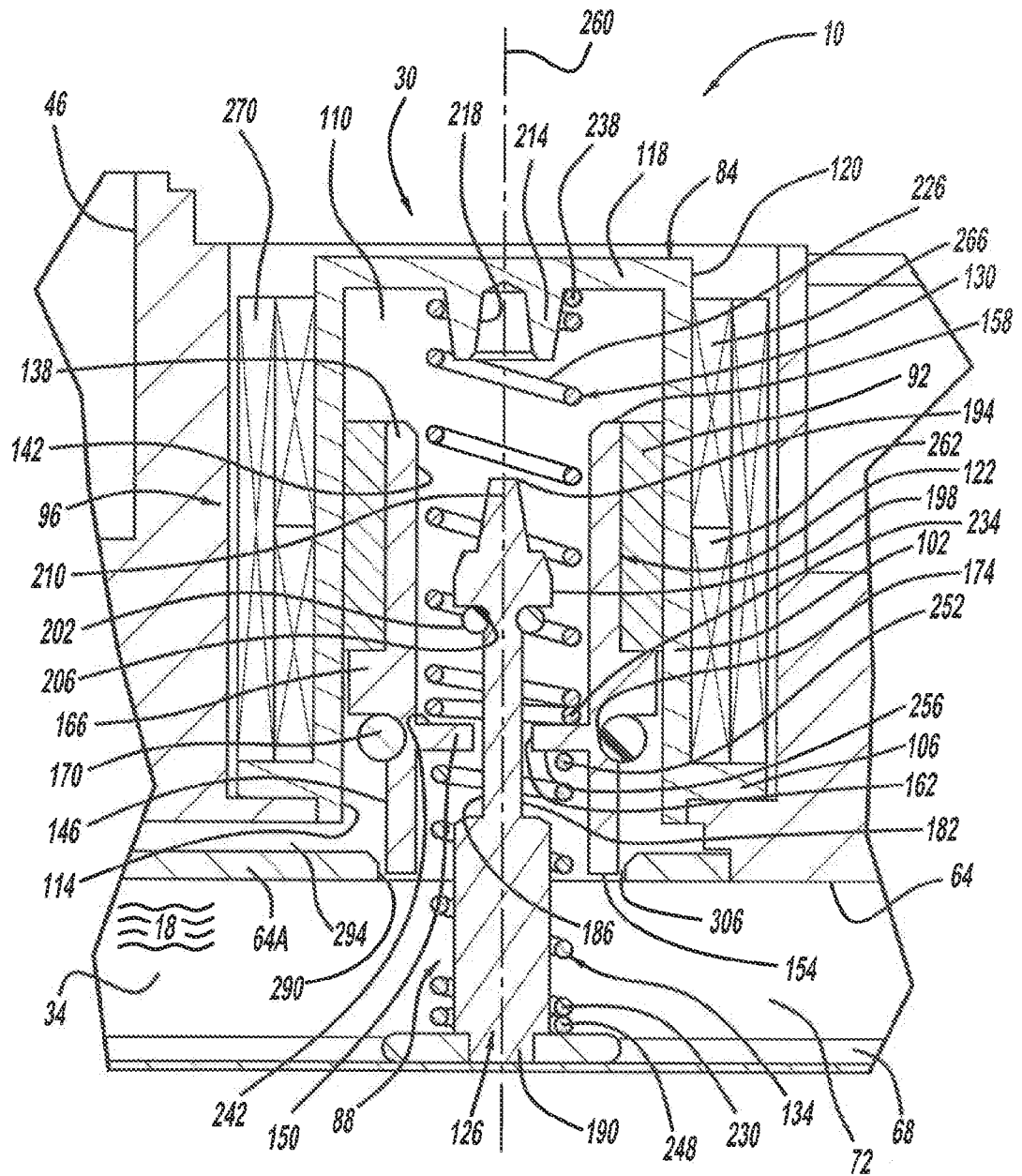
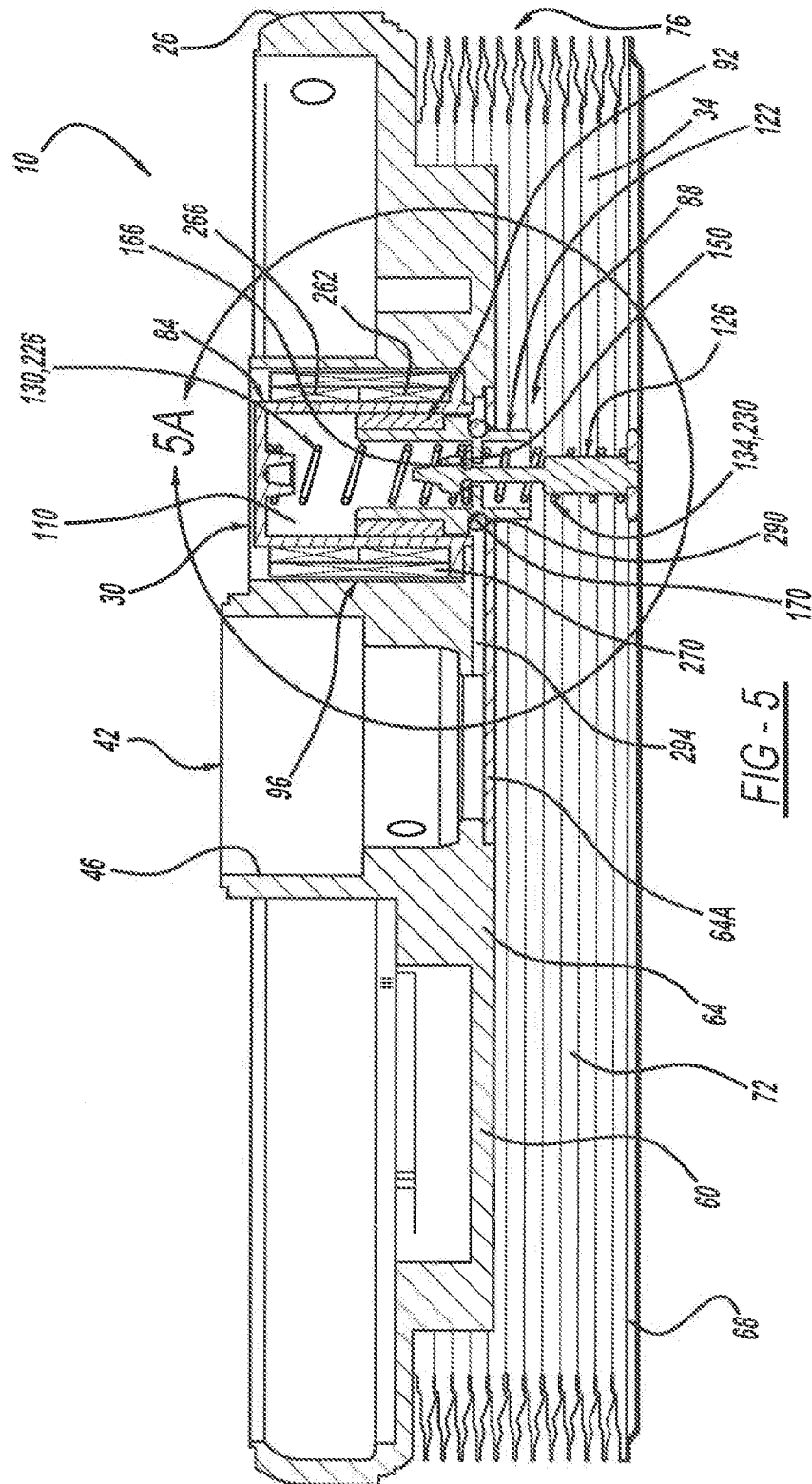


FIG - 4A

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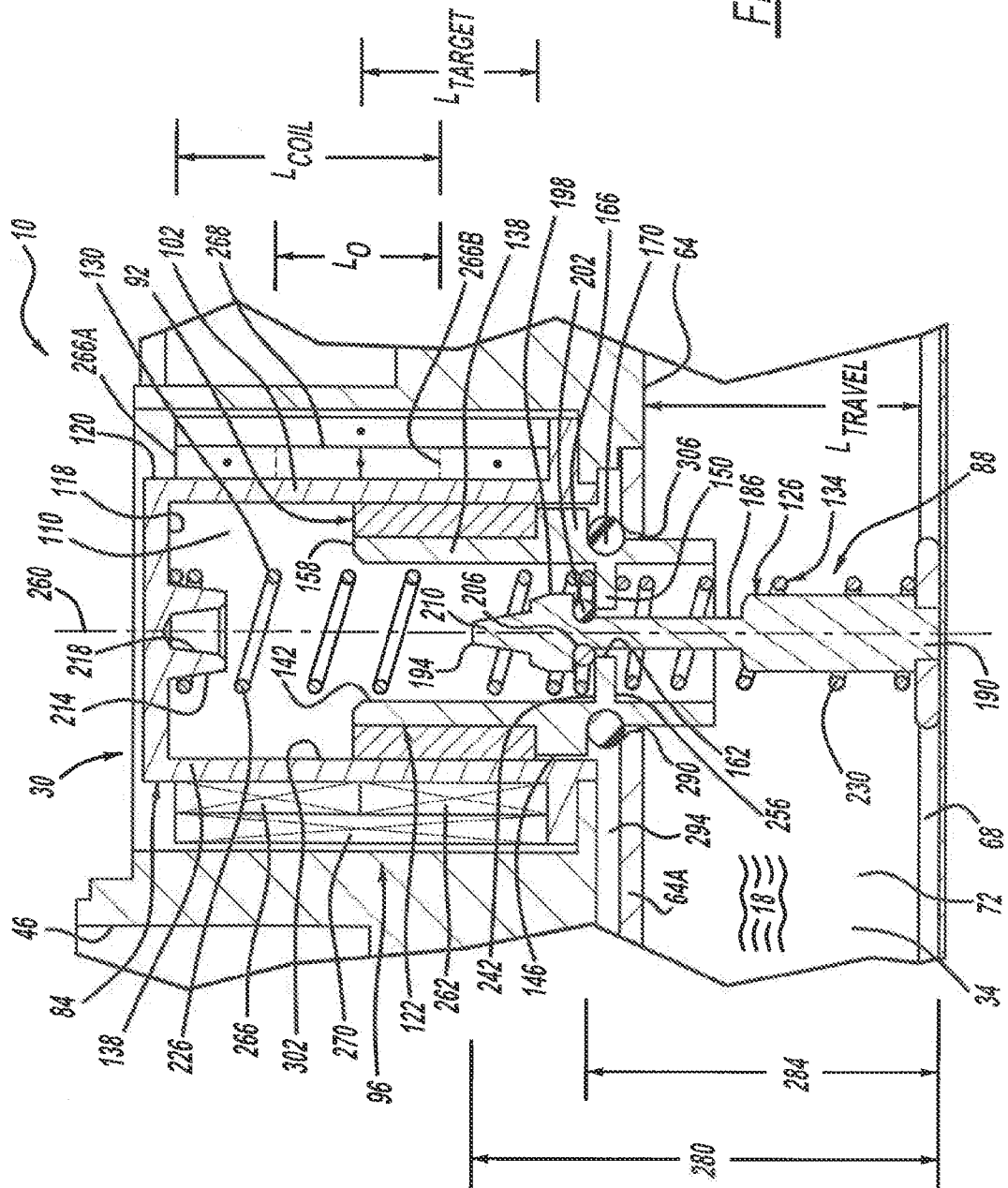


FIG. 5A

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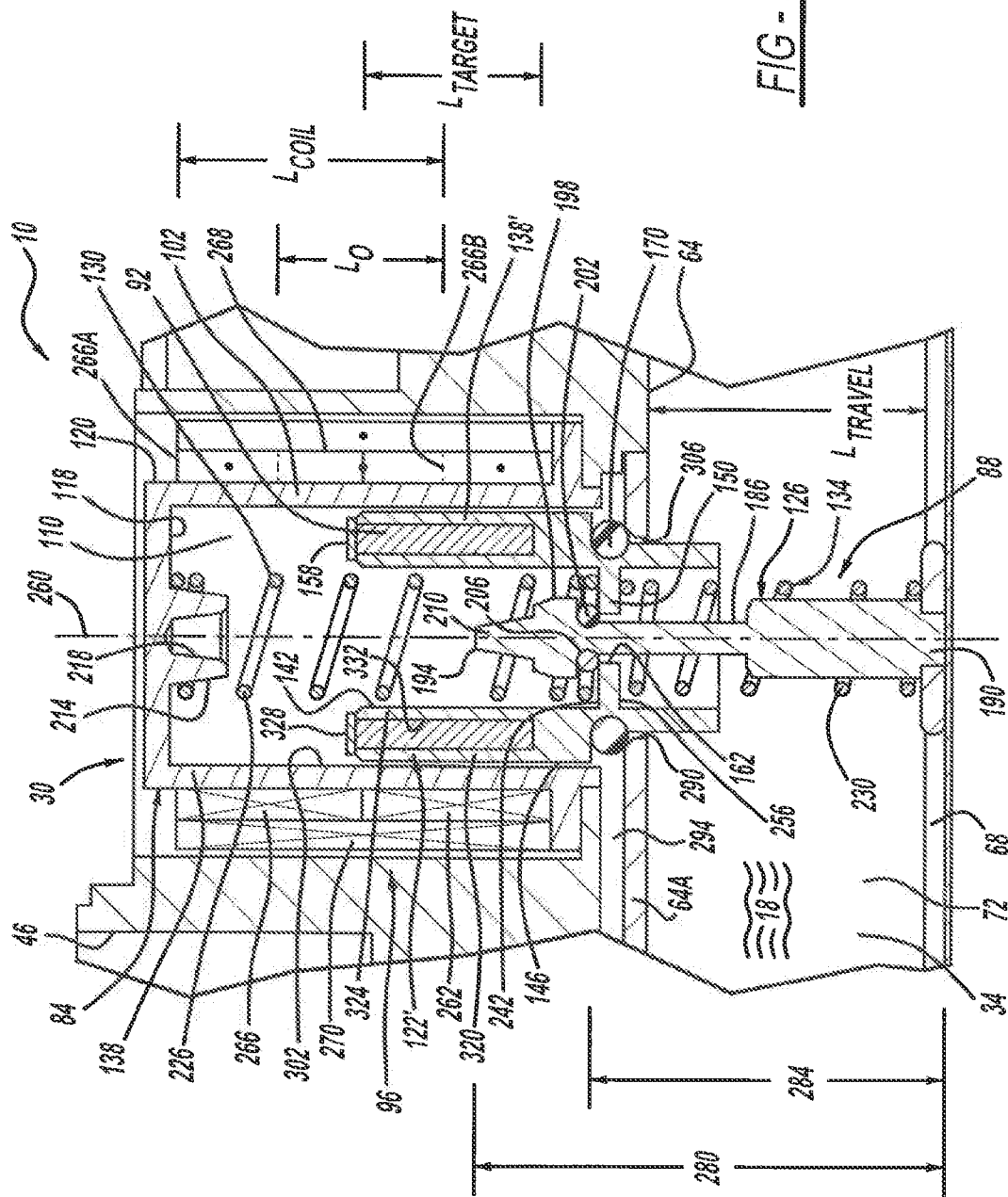
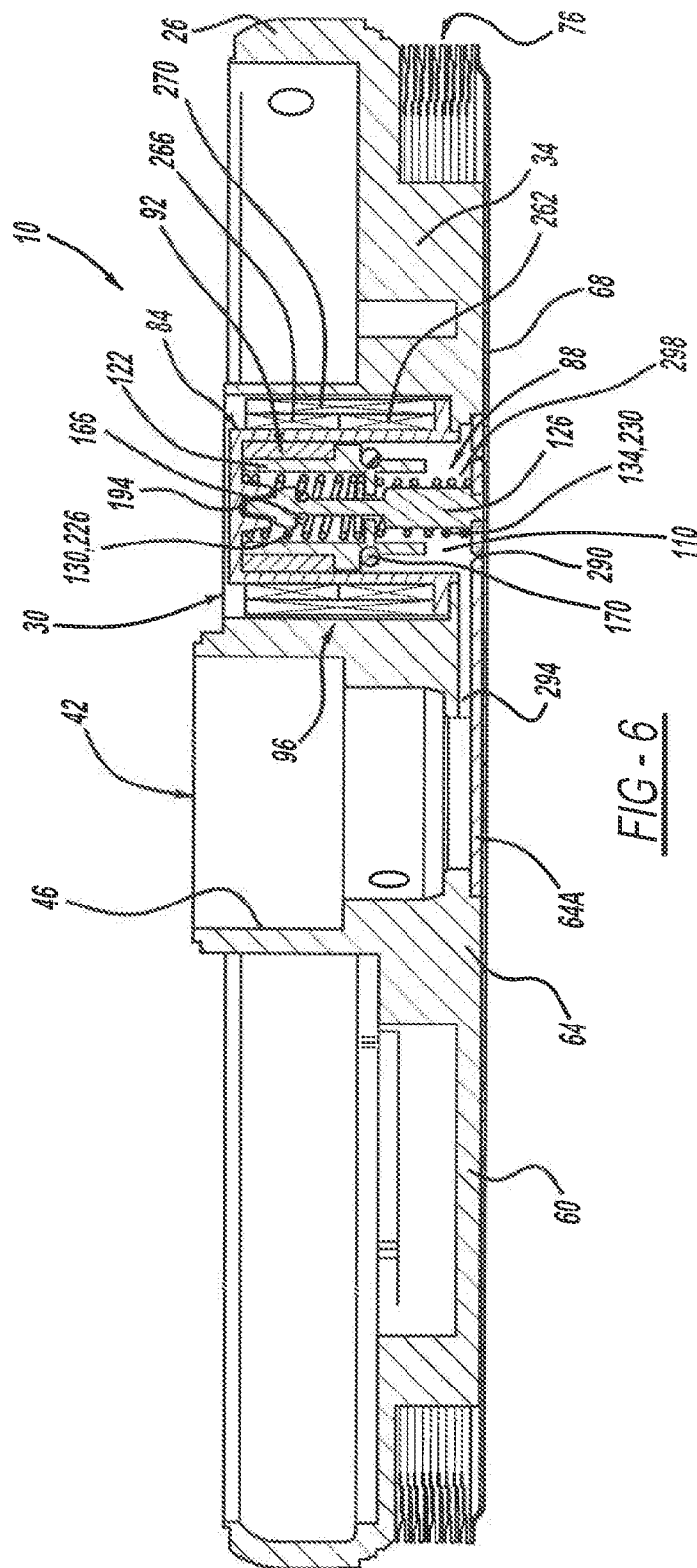


FIG - 5B

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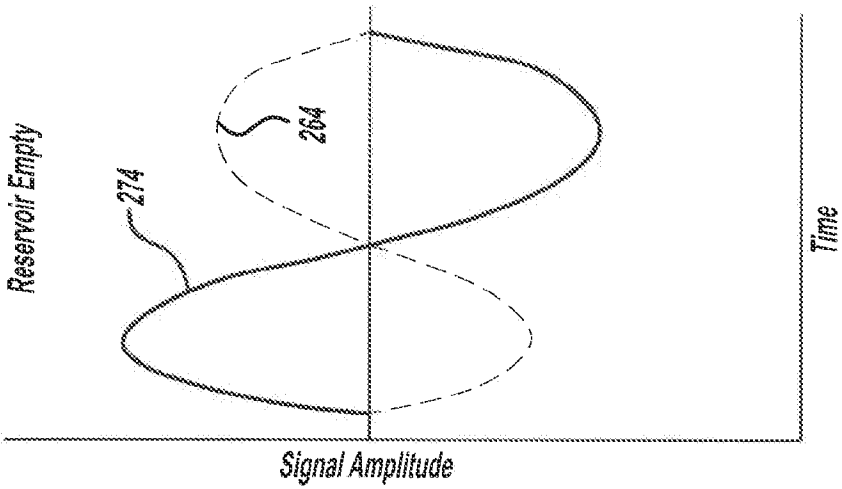


FIG - 9

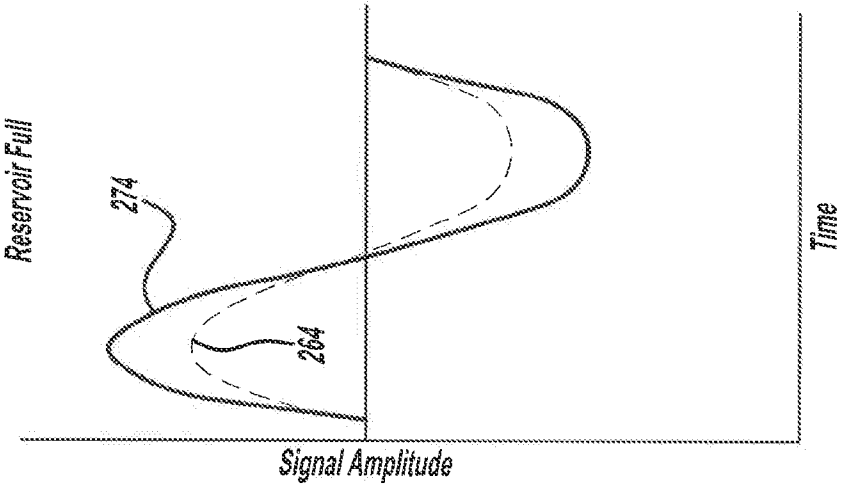


FIG - 8

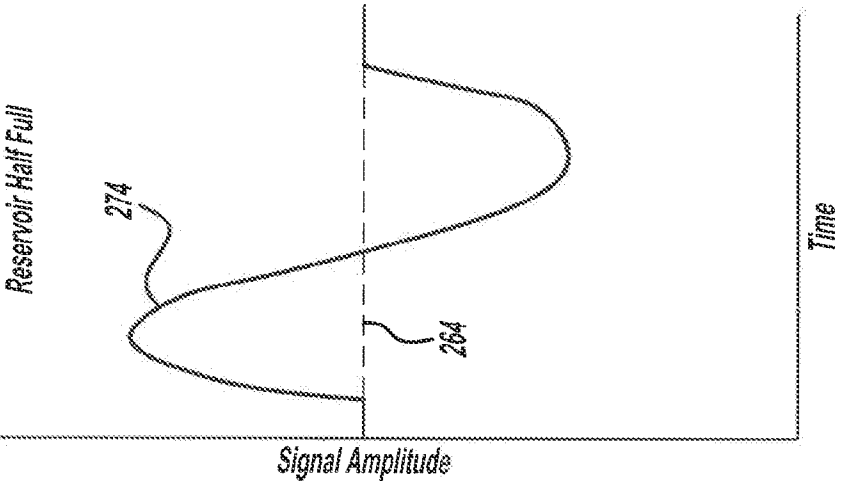


FIG - 7

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2012/058614

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M5/168 G01F23/16 G01F23/54
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 G01F

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)

EP0-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 A	EP 1 048 309 A2 (MEDTRONIC INC [US]) 2 November 2000 (2000-11-02) figures 3,5 paragraphs [0004], [0006], [0020], [0023]	1-12, 29-34 13-28
A	----- US 2007/255260 A1 (HAASE JAMES M [US]) HAASE JAMES MARTIN [US] 1 November 2007 (2007-11-01) figures 4a,4c,5 -----	1-34

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

☒ 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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"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

15 January 2013

Date of mailing of the international search report

24/01/2013

Name and mailing address of the ISA/

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Authorized officer

Herz, Markus

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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