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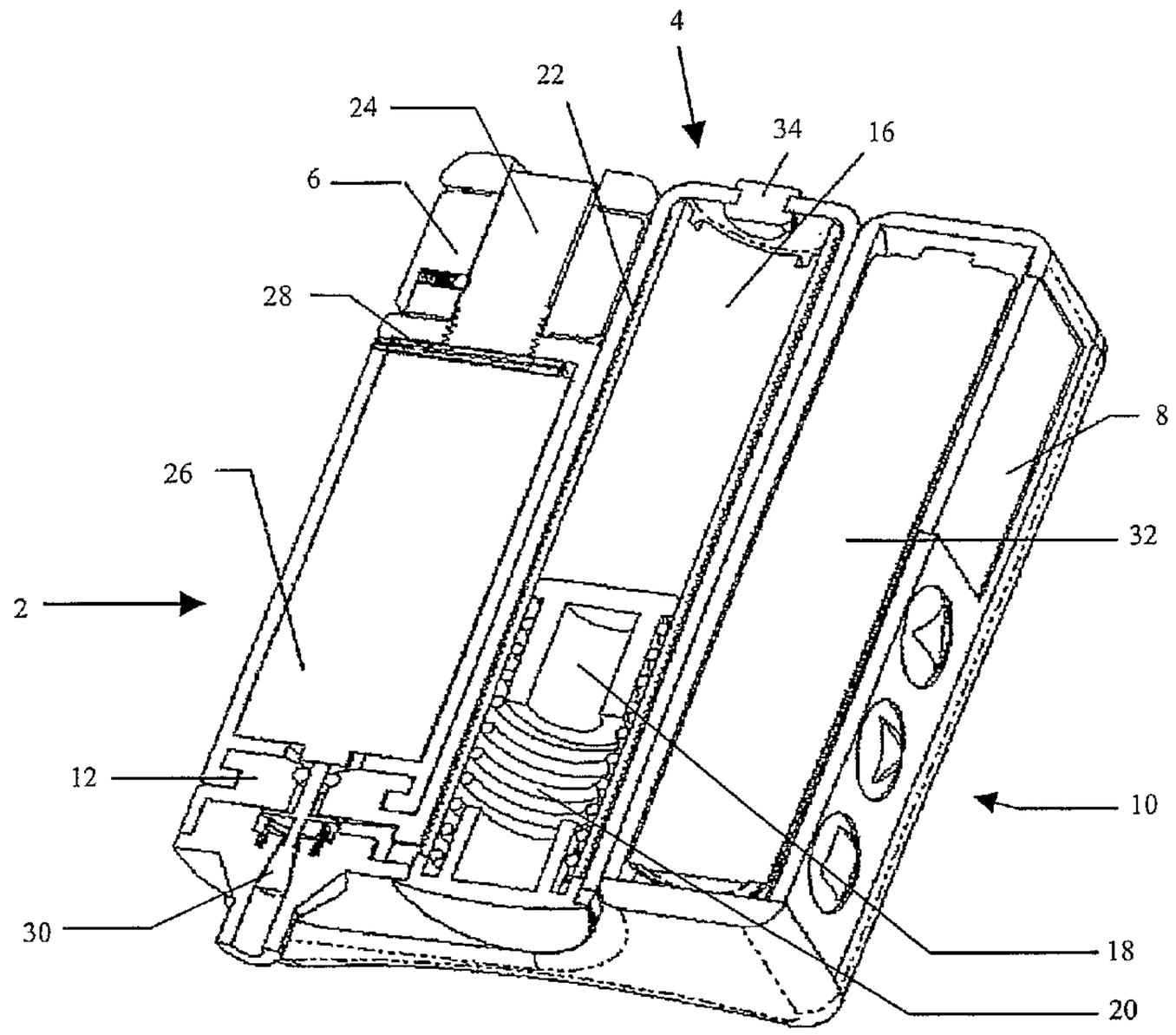

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A portable insulin delivery device that supplies insulin in a pre-pressurized chamber (16), passes the insulin through a pressure-dropping labyrinth (22) to a flow control valve (50, 30). The valve (50, 30) is activated by a piezoelectric actuator (26). This allows for precise insulin delivery. An electronic package provides for programming of basal rates and bolus. A pressure sensor (60, 62, 72, 74) relays data concerning normal operation and pressur changes that indicate problems. The processor (100), keyboard (106), display (102), power source (32), fluid pressure sensor (60, 62, 72, 74) and fluid flow control actuator (26) are housed in a base unit. A removable cartridge unit (4) houses the pre-pressurized fluid reservoir (16), flow path labyrinth (22), and flow control valve (50, 30).

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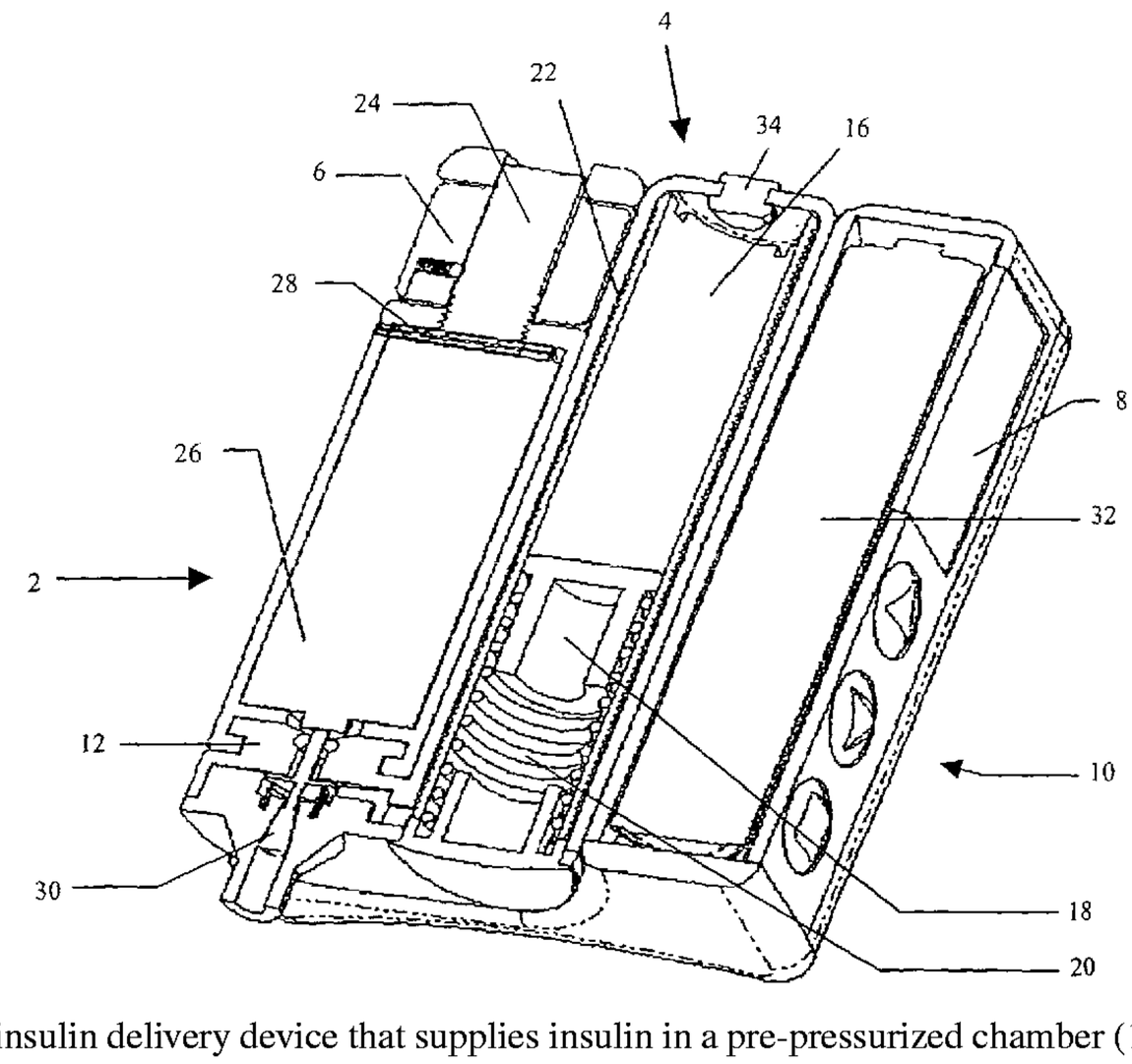

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FLUID DRUG DELIVERY DEVICE

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to fluid drug delivery devices and, in particular, it concerns a portable insulin delivery device.

There are known portable insulin delivery devices, commonly referred to as insulin pumps, that generally consist of a pump mechanism, an insulin container, a processor, and a power source for the processor and pump mechanism. The pump mechanisms of prior art generally use motor driven push rods to push a piston into the insulin containment region of the insulin container, thus forcing the insulin into a delivery tube and therefore into the patient. The inventions of prior art have gone to great lengths to devise variations of the motor driven push rod and piston assembly that is accurate, reliable, and space efficient. Disclosures representative of this case of devices will be found in U.S. Patents No. 6,248,093, No. 5,637,095, No. 5,097,122, and No. 5,505,709. Devices based on this configuration suffer from two inherent problems, the motor and the push rod and piston assembly, as discussed in the following paragraphs.

The amount of insulin delivered to the patient is therefore controlled by the speed at which the motor turns (RPM's) and the amount of time the motor is turning. The accuracy of insulin delivery is, then, dependent on the reliability and accuracy of the motor. Variations on RPM's will cause variations in the amount of insulin delivered to the patient. Due to a limited power supply the motor is turned on and off at preset intervals. Even when the system is operating properly, the medication is delivered in "spurts" and the delivery rate is determined as an average over time.

As the motor turns, it moves a push rod, which in turn moves a piston that forces the insulin out of the container. The seal between the piston and the side of the container must be very tight in order to prevent leakage of insulin. A side effect of this tightness is the tendency of the piston to move forward at an uneven rate. That is to say, that the piston may stick and then jump forward. This uneven movement of the piston causes uneven delivery of the insulin to the patient.

The prior art has developed elaborate devices to detect and respond to occlusion and other flow rate or system malfunctions as is demonstrated in U.S. Patents No. 5,097,122, No. 5,462,525, No. 4,619,653, and No. 5,647,853. In cases of occlusion, most commonly these devices allow the motor to continue to push against the blockage. Due the limitation of the motor, and since this happens only in cases of full occlusion, this is not a very satisfactory solution. Further, if the blockage is opened, the pressure built up in the container and delivery tube is released through the tube, thereby forcing a possibly dangerously larger than prescribed dose of insulin into the patient. One proactive approach to occlusion includes the use of "inert" cleaning fluid being pumped through the device and into the patient.

There is therefore a need for a portable insulin delivery device that is able to deliver the insulin at a substantially consistent dosage rate, quickly detect flow rate malfunction, overcome blockage with substantially no affect on the prescribed dosage or the use of non-medicative cleaning fluids, and has very low energy requirements. It would be preferable if the device had low power requirements, and was more compact and economical than devices currently in use.

SUMMARY OF THE INVENTION

The present invention is a fluid drug delivery device.

According to the teachings of the present invention there is provided, a fluid drug delivery device comprising: a) a fluid supply assembly having a chamber, a piston, and a spring element, the piston deployed within the chamber so as to define a fluid containment volume within the chamber, the spring element deployed so as to bias the piston toward the fluid containment volume so as to pressurize an amount of the fluid drug supplied within the fluid containment volume, the containment volume having a supply outlet; b) a pressure regulator having a fluid inlet in fluid communication with the fluid supply assembly, the pressure regulator also having a fluid outlet; and c) a flow control assembly in fluid communication with the pressure regulator fluid outlet.

According to a further teaching of the present invention, the flow control assembly includes: a) a flow control valve interconnected with the fluid outlet; b) a flow actuator deployed so as to regulate the flow control valve thereby varying amounts of fluid flowing through the flow control valve; c) a positioning component deployed so as to properly position the flow control valve actuator in relationship to the flow control valve; and d) a processing unit electronically interconnected with a pressure sensor and the flow actuator, the processing unit configured so as to use data from the pressure sensor to determine activation of the flow actuator.

According to a further teaching of the present invention, the pressure regulator includes an elongated pressure reduction passageway configured so as to reduce the pressure in the fluid thereby creating a pressure differential between the fluid inlet and the fluid outlet.

According to a further teaching of the present invention, at least one pressure sensor is interconnected with at least a first and a second pressure sensing points, the pressure sensing points being located at intervals along the flow reduction passage.

According to a further teaching of the present invention, the flow actuator includes a piezoelectric actuator.

According to a further teaching of the present invention, the positioning component includes a rotatable adjustment shaft manually rotated by a thumb-wheel, the shaft and the thumb-wheel being connected by way of an over-running clutch mechanism configured to allow the thumb-wheel to continue turning while discontinuing rotation of the shaft when the flow actuator is properly positioned in relationship to the flow control valve.

According to a further teaching of the present invention, the processing unit is further interconnected to an alarm unit, the processing unit using data from the pressure sensor to determine activation of the alarm unit.

According to a further teaching of the present invention, the flow actuator, the manual positioning component, the pressure sensor, and the processing unit are housed in a base unit further including a processing unit display, a processing unit input keypad, and a power supply.

According to a further teaching of the present invention, the fluid supply assembly, the flow reduction passage, and the flow control valve, are housed in a removable cartridge unit.

There is also provided according to the teachings of the present invention, a fluid drug delivery device comprising: a) a fluid supply assembly; b) an elongated pressure reduction passageway having a fluid inlet in fluid communication with the fluid supply assembly, and a fluid outlet, the elongated passageway configured so as to reduce pressure in the fluid thereby creating a pressure differential between the fluid inlet and the fluid outlet; c) at least one pressure sensor interconnected with a first and a second pressure sensing points, the pressure sensing points located at intervals along the elongated passageway so as to discern a pressure differential between the first and second pressure sensing points; and d) a flow control assembly responsive to the pressure sensor and controlled in response to the pressure differential.

According to a further teaching of the present invention, the flow control assembly includes: a) a flow control valve interconnected with the fluid outlet; b) a flow actuator deployed so as to regulate the flow control valve thereby varying amounts of fluid flowing through the flow control valve; c) a positioning component deployed so as to properly position the flow control valve actuator in relationship to the flow control valve; and d) a processing unit electronically interconnected with a pressure sensor and the flow control valve actuator, the processing unit configured so as to use data from the pressure sensor to determine activation of the flow control valve actuator.

According to a further teaching of the present invention, the flow actuator includes a piezoelectric actuator.

According to a further teaching of the present invention, the positioning component includes a rotatable adjustment shaft manually rotated by a thumb-wheel, the shaft and the thumb-wheel being connected by way of an over-running clutch mechanism configured to allow the thumb-wheel to continue turning while

discontinuing rotation of the shaft when the flow control valve actuator is properly positioned in relationship to the flow control valve.

According to a further teaching of the present invention, the processing unit is further interconnected to an alarm unit, the processing unit using data from the pressure sensor to determine activation of the alarm unit.

According to a further teaching of the present invention, the flow actuator, the manual positioning component, the pressure sensor, and the processing unit are housed in a base unit further including a processing unit display, processing unit input keypad, and a power supply.

According to a further teaching of the present invention, the fluid supply assembly, the flow reduction passage, and the flow control valve, are housed in a removable cartridge unit.

There is also provided according to the teachings of the present invention, a fluid drug delivery device comprising: a) a fluid supply assembly; b) a pressure reduction passage having a fluid inlet in fluid communication with the fluid supply assembly, the flow passage also having a fluid outlet; c) a flow control valve interconnected to the fluid outlet; and d) a piezoelectric actuator deployed so as to regulated the flow control valve thereby varying the amount of fluid flowing through the flow control valve.

According to a further teaching of the present invention, there is further included: a) a positioning component deployed so as to position the flow control valve actuator in a predefined spatial relationship to the flow control valve; and b) a processing unit electronically interconnected with a pressure sensor and the flow control valve actuator, the processing unit configured so as to use data from the pressure sensor to determine activation of the flow control valve actuator.

According to a further teaching of the present invention, the positioning component includes a rotatable adjustment shaft manually rotated by a thumb-wheel, the shaft and the thumb-wheel being connected by way of an over-running clutch mechanism configured to allow the thumb-wheel to continue turning while

discontinuing rotation of the shaft when the flow control valve actuator is properly positioned in relationship to the flow control valve.

According to a further teaching of the present invention, the processing unit is further interconnected to an alarm unit, the processing unit using data from the pressure sensor to determine activation of the alarm unit.

According to a further teaching of the present invention, the, flow actuator, the manual positioning component, the pressure sensor, and the processing unit are housed in a base unit further including a processing unit display, processing unit input keypad, and a power supply.

According to a further teaching of the present invention, the fluid supply assembly, the flow reduction passage, and the flow control valve, are housed in a removable cartridge unit.

There is also provided according to the teachings of the present invention, a fluid drug delivery device comprising: a) a portable base unit including, a flow actuator, a manual positioning component, at least one pressure sensor, a processing unit, a display, keypad and a power source for the processing unit are housed in a base unit; and b) a cartridge unit that is removably interconnected to the base unit, the cartridge including a fluid supply assembly, a pressure reduction passage, and a flow control valve, the fluid supply assembly providing a pre-pressurized chamber containing a quantity of fluid drug.

According to a further teaching of the present invention, the flow actuator is a piezoelectric actuator deployed so as to regulate the flow control valve thereby varying the amount of fluid flowing through the flow control valve.

According to a further teaching of the present invention, the manual positioning component includes a rotatable adjustment shaft manually rotated by a thumb-wheel, the shaft and the thumb-wheel being connected by way of an over-running clutch mechanism configured to allow the thumb-wheel to continue turning while discontinuing rotation of the shaft when the flow control valve actuator is properly positioned in relationship to the flow control valve.

According to a further teaching of the present invention, the processing unit is electronically interconnected with the pressure sensor and the piezoelectric actuator, the processing unit configured so as to use data from the pressure sensor to determine activation of the piezoelectric actuator.

According to a further teaching of the present invention, the pre-pressurized chamber is accomplished by use of a piston deployed within the chamber so as to define a fluid containment volume within the chamber, a spring element deployed so as press the piston into the fluid containment volume so as to pressurize the quantity of fluid drug supplied within the fluid containment volume.

According to a further teaching of the present invention, the pressure reduction passage is an elongated passageway interconnected to the fluid supply assembly, the elongated passageway having a fluid inlet and a fluid outlet, the elongated passageway configured so as to reduce the pressure in the fluid thereby creating a pressure differential between the fluid inlet and the fluid outlet.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

FIG. 1 is an isometric view of a device constructed and operative according to the teachings of the present invention, showing the separated base unit and cartridge unit;

FIG. 2 is an isometric cut-away view of a device constructed and operative according to the teachings of the present invention; which uses a coil spring to bias the piston;

FIG. 3 is a cut-away front view of the preferred embodiment of FIG.1;

FIG. 4 is a detailed cut-away front view of section L in FIG. 2, showing a flow control valve constructed and operative according to the teachings of the present invention;

FIG. 5 is a cut-away front view of a base unit constructed and operative according to the teachings of the present invention;

FIG. 6a is a cut-away side view showing a pressure sensing configuration constructed and operative according to the teachings of the present invention;

FIG. 6b is a detail of the pressure sensing configuration of FIG. 5a;

FIG. 7 is a detail of positioning component constructed and operative according to the teachings of the present invention;

FIG. 8 is a cut-away front view of a device constructed and operative according to the teachings of the present invention, which alternatively uses a pneumatic spring to bias the piston;

FIG. 9 is a cut-away front view of a device constructed and operative according to the teachings of the present invention together with a schematic of electronic elements;

FIG. 10 is an isometric view of a cartridge and base unit constructed and operative according to the teachings of the present invention being joined according to the teachings of the present invention; and

FIG. 11 is an isometric view of a fully assembled device constructed and operative according to the teachings of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is portable insulin delivery device.

The principles and operation of a portable insulin delivery device according to the present invention may be better understood from the following non-limiting examples described with reference to the drawings and the accompanying description.

By way of introduction, it should be noted that the present invention includes a number of particularly significant aspects, each of which is believed to be of significance when used alone, and which are most preferably used in synergy through their combination. Specifically, certain main aspects of the invention may be identified as:

- Subdivision of components such that all components coming in contact with the drug are disposable and all electronic and actuating components

are reusable while achieving precise flow regulation at micro-dosing flow rates.

- Use of a pressure reduction labyrinth in series with regulating components (typically at least one valve).
- Use of a pre-pressurized fluid supply.

The significance of these features will be better understood from the following description. The invention will be illustrated by non-limiting examples which combine all of the aforementioned aspects, although the utility of these features individually used in otherwise conventional devices will be clear to one ordinarily skilled in the art from the description given.

Thus, the portable insulin delivery device of the present invention houses sensing, processing and regulatory elements, and power source in a base unit. A fluid containment volume, flow path, valve and fluid pressurization assembly are housed in a removable cartridge unit. In the description below and elsewhere in this document, reference is made to "insulin" as an example of a drug for which the delivery device may be used. It will be appreciated, however, that this example is non-limiting and the delivery device may be used to advantage with substantially any fluid drug or medication for which slow delivery is required.

The insulin is stored in a pressurized fluid containment volume. The pressure forces the insulin out of the containment volume into an elongated flow path, referred to herein as a labyrinth, through a flow control valve and out of the device. There are at least two pressure sensing points located along the labyrinth and a pressure sensing system monitors the differential in pressure between the two points. The resultant data is used by a processing unit to determine activation of the flow control valve. The flow control valve is actuated by an actuator controlled by the processing unit. The actuator is most preferably implemented using a piezoelectric actuator, thereby combining features of low power consumption and high precision. Under normal operating circumstances, the valve is opened just enough to allow the prescribed amount of insulin to flow. This is evidenced by the amount of pressure differential at the two pressure sensing points. If the pressure equalizes, generally indicating a

blockage, the piezoelectric actuator opens the valve to allow the full force of the fluid pressure to be applied to the blockage. If the blockage is opened, the differential in pressure will return and the valve is closed back down to the pre-blockage setting. Generally, the valve is open for a few milliseconds. If the pressure remains equal for a predetermined length of time, indicating the blockage has not been opened, the processing unit sounds an alarm and allows the "normally closed" valve to close and discontinue insulin flow.

It is a particularly preferred feature of most preferred implementations of the present invention that the fluid containment volume is "pre-pressurized" and the supply pressure is reduced by use of a labyrinth prior to reaching the valve. This configuration offers several advantages over devices of prior art that should be noted here. Firstly, use of a pre-pressurized containment volume eliminates the need for the motor and gear reduction assemblies of prior art, which are costly, use considerable amounts of energy, and along with needed extra power sources, i.e. batteries, account for a large percentage of the size of devices that use them.

Secondly, this arrangement facilitates accurate flow rate measurement by monitoring the pressure differential in the fluid at two or more points along the flow path, giving substantially immediate feedback as to the rate of insulin delivery during normal operation. Further, a change in pressure differential would result should a blockage occur, thereby facilitating immediate identification of a blockage condition.

Thirdly, the present invention's use of a valve to release pressurized insulin so as to control the flow rate of the insulin provides a much more precise and substantially constant delivery of the prescribe dosage than the rate at which a piston moves through a cylinder used in the prior art. The provision of a pressure reduction labyrinth in series with the valve reduces the performance requirements on the valve to levels which can readily be achieved with mass-produced disposable components.

And fourthly, the pre-pressurized nature of the insulin, in the present invention, is better suited to quickly open blockages. Of further importance is the ability to close the valve after a blockage has been cleared. The motor driven piston devices of prior art use the motor to apply more pressure to the piston, and thus to the insulin, when a

blockage occurs. In the devices of prior art, once the blockage is cleared, the pressure build up is dissipated through the fluid outlet of the device and into the patient. This may mean a higher than prescribed dosage level delivered to the patient.

In order to optimize the above advantages, the labyrinth is preferably designed to fix an upper limit on the flow rate of no more than about 1 milliliter per hour for a supply pressure of 5 atmospheres. This maximum flow rate is then further modified by opening and closing of the flow control valve by the electronic control system, either in a continuously variable or a pulsed mode, to achieve the required average flow rate. Real time feedback measurement of the actual measured flow is provided from the differential pressure measurements.

Referring now to the drawings, in Figure 1 is seen the base unit **2** and the removable cartridge unit **4** separated from each other. A rotatable adjusting wheel **6**, colloquially herein referred to as a "thumb-wheel", is used to turn a positioning shaft, which will be discussed below. Also shown, are the processing unit display **8** and keypad **10**, and the cartridge unit's portion **12** of the bayonet style quick-connect configuration used to interconnect the two units for operation.

The cut-away isometric view of Figure 2 provides a perspective of the placement relationship of the components of this embodiment of the present invention. The components are numbered here for reference to the following detailed figures at which point each will be discussed, with the exception of the battery **32**, which is the power source for all electrical components and will not be discussed further.

As shown in Figure 3, the insulin is typically introduced into the fluid containment volume **16** portion of the cartridge unit by way of a needle **48** that pierces the plug element **34** prior to use. The needle is generally used in association with a syringe. This filling procedure may optionally be repeated during operation of the device if required for prolonged delivery over an extended period. The insulin is then stored in the fluid containment volume. The piston **18** is biased toward the fluid containment volume by the spring element **20**, thereby pressurizing the insulin. During the course of insulin delivery, the spring element will move the piston within the chamber thereby maintaining the pressure. Under force of pressure, the insulin

leaves the containment volume by way of a plurality of inlet apertures **40** that lead into an elongated flow passageway **22**, herein referred to as a "labyrinth." The labyrinth is formed with a pattern of grooves together with the opposing surface. In the case of a cylindrical passageway, as here, the labyrinth may be produced as an elongated helical flow path around the wall of the fluid containment volume housing **42**. This has advantages for the ease of manufacture and level of precision with which the groove can be produced. Optionally, more than one groove **22** can be deployed in a double- or triple-helix, although a single helix is generally preferred. The grooves may be formed on either of first and second cylindrical surfaces **42** or **44**. The labyrinth functions to restrict the flow of the insulin such that the viscosity of the insulin together with the size of the passageway will reduce the fluid pressure down line, thus creating pressure differential along the length of the labyrinth. This pressure differential will be discussed at greater length below. It should be noted that while the labyrinth described above is a preferred configuration, any suitable configuration that creates a pressure differential between at least two points in a flow passage is within the intentions of the present invention.

In the example shown here, the insulin leaves the labyrinth by way of outlet aperture **46**, and enters the flow control valve detailed in Figure 4. It should be noted that alternative implementations (not shown) may locate the flow control valve in the flow path prior to the labyrinth. The arrows **58** show the flow path of the insulin through the valve assembly. The valve is a conically shaped "normally closed" valve. That is, the spring **56** is pushing against a portion of the valve stem **50** so as to close the valve opening. The valve stem passes through the o-ring **54**, which seals the fluid area. The piezoelectric actuator **26** activates the valve by pushing against the valve stem **50**, thereby moving the valve body **30** away from the valve housing **52** and allowing insulin to flow. Suitable piezoelectric actuators are well known in the art and include, but are not limited to, PZT actuators, examples of which are commercially available from Polytech PI, Inc. (USA). The processing unit controls the piezoelectric actuator so that, under normal operating conditions, opening of the valve is controlled (either continuously-variably or in a pulsed-opening mode) through closed-loop

feedback to maintain the prescribed rate of insulin flow through the valve as measured by the pressure differential in the labyrinth flow path. In the case of an equalization of pressure within the labyrinth, usually indicative of a blockage, the piezoelectric actuator opens the valve. It should be noted that the properties of a labyrinth are such that, under zero flow conditions, there is no pressure loss along the flow path. As a result, the full force of the fluid pressure of the insulin in containment volume **16** acts to push against the blockage, helping to clear it. Typically, the valve will be open for a few milliseconds. Once the blockage is cleared, the pressure differential indicative of normal operation is reestablished and the valve is closed down to allow only the prescribed amount of insulin to flow. That is, when there is a blockage, the valve will allow the full force of the pressure to act upon the obstruction, however, when the force is not longer needed, the valve closes without allowing substantially any excess insulin flow through the valve to the patient.

Figure 5 shows the base unit of this embodiment without the cartridge unit connected. Of interest here are the pressure sensing points **60** and **62** whose relationship to the differential pressure sensor and the labyrinth will be discussed in the context of Figures 6a and 6b.

As seen in the cut-away side view of Figure 6a the location of the pressure sensing configuration, generally referred to as **70**, in the base unit **2** and its relationship to the cartridge unit **4** is readily apparent. Looking now to the detail of Figure 6b. As the insulin flows through the labyrinth **22**, it comes into contact with and applies pressure to a first pressure sensing point **72**. Further along the labyrinth the insulin applies pressure to a second pressure sensing point **74**. The pressure differential created by the labyrinth is detected and monitored by the differential pressure sensor **76**. Even though the two pressure sensing points are relatively close together in the base unit, because of the configuration of the labyrinth, the flow path between the two points is considerably longer so that the pressures that are sensed are at points quite a distance apart. It will be obvious to one skilled in the art that the pressure differential may also be monitored in a variety of ways such as, but not

limited to, determining the pressure at each of the pressure sensing points, that data being used by the processor to determine any differential.

As mentioned above, it is a particular feature of certain preferred implementations of the present invention that all, or substantially all, components coming in contact with the fluid are low-cost disposable components, preferably all housed in a single unitary replaceable cartridge, whereas more expensive components such as the electronic components of the control system and the piezoelectric actuator are re-usable, preferably housed in the base unit. This subdivision requires particularly careful implementation in the present invention because of the precision required for accurate regulation of very low flow rates. It will be noted that the solutions proposed herein are of particular significance for use in systems other than those described herein such as, for example, pump-based micro-dosing systems.

In the case of the flow control valve, this subdivision requires that the valve sealing surfaces are part of the replaceable cartridge while the actuator is part of the base housing. At the same time, in order for the piezoelectric actuator to function properly, it is necessary for it to be in contact with the stem of the flow control valve (see Figure 4) with a predefined initial contact pressure. Figure 7 is a detail of a positioning component for that purpose as configured for this embodiment of the present invention. The rotatable shaft **24** is divided into two sections, a longitudinally grooved section **84** and a threaded section **86**. As the thumb-wheel **6** is turned, a spherical member **80** is pressed into a groove by spring **82** thereby causing the shaft **24** to turn. As the shaft turns, the threads of the threaded section, which are in contact with corresponding threads **88** supplied in the base unit housing **2**, cause the shaft to move longitudinally toward the piezoelectric actuator **26**. When the piezoelectric actuator contacts the stem of the flow control valve, the shaft continues to move until the contacts of the switch **28** touch, at which point the shaft no longer is able to turn. If the thumb-wheel continues to turn, the spherical element simply jumps out of the groove to provide a torque-limiting clutch. The switch **28** therefore, acts as an "on/off" switch not allowing the device to turn "on" until the piezoelectric actuator is properly positioned.

Figure 8 shows a preferred embodiment of the present invention that uses an alternative spring element in the removable cartridge unit. The components of the base unit and some of the cartridge are identical to those discussed above and therefore will not be referred to here. Of interest in this embodiment is the use of a pneumatic spring element to bias the piston **18** toward the fluid containment volume **16**. Compressed air is contained within regions **90** and **92** with passages **94** allowing free flow of air between the regions as need. It should be noted that any suitable gas may be used for this purpose. Further, although the discussion of spring elements has been limited to coil springs and multi-chambered pneumatic springs, any spring that can be adapted for use in this fashion is within the intention of the present invention and may include, but not be limited to, a plurality of concentric coil springs, pneumatic springs using only one side of the chamber to house the compressed gas, and therefore adding no further "elements" to the device, or elastomeric balloons.

Figure 9 shows an embodiment of the present invention identical to that discussed in Figure 3 and where needed, is numbered accordingly, together with a schematic of the electrical components of that preferred embodiment. The processing unit **100** receives input from: the switch **28**, which indicates proper positioning of the piezoelectric actuator; the differential pressure sensor **70** (not shown), which communicates data about the fluid pressure of the insulin; and the keypad **106**, which communicates user entered data including allowing setting of the required fluid flow rate. The processor sends operational instructions to: the display **102**, the piezoelectric actuator **26**, which activates the flow control valve; and an alarm **104**.

Figure 10 shows the removable cartridge unit separated from base unit of a preferred embodiment of the present invention. Shown are the cartridge unit's portion **12** and the base's portion **110** of the bayonet style quick-connect configuration used to interconnect the units for operation. As the arrows indicate, the cartridge **4** is first inserted into the base **2** and then turned to lock it in place for operation.

Finally, Figure 11 shows a completely assembled preferred embodiment of portable insulin delivery device constructed and operative according to the teachings of the present invention.

It will be appreciated that the above descriptions are intended only to serve as examples, and that many other embodiments are possible within the spirit and the scope of the present invention.

WHAT IS CLAIMED IS

1. A fluid drug delivery device comprising:

(a) a portable base unit including, a flow actuator, a manual positioning component, at least one pressure sensor, a processing unit, a display, keypad and a power source for said processing unit are housed in a base unit; and

(b) a cartridge unit that is removably interconnected to said base unit, said cartridge including a fluid supply assembly, a pressure reduction passage, and a flow control valve, said fluid supply assembly providing a pre-pressurized chamber containing a quantity of fluid drug.

2. The fluid drug delivery device of claim 1, wherein said flow actuator includes a piezoelectric actuator deployed so as to regulate said flow control valve thereby varying the amount of fluid flowing through said flow control valve.

3. The fluid drug delivery device of claim 1, wherein said manual positioning component includes a rotatable adjustment shaft manually rotated by a thumb-wheel, said shaft and said thumb-wheel being connected by way of an over-running clutch mechanism configured to allow said thumb-wheel to continue turning while discontinuing rotation of said shaft when said flow control valve actuator is properly positioned in relationship to said flow control valve.

4. The fluid drug delivery device of claim 1, wherein said processing unit is electronically interconnected with said pressure sensor and said piezoelectric actuator, said processing unit configured so as to use data from said pressure sensor to determine activation of said piezoelectric actuator.

5. The fluid drug delivery device of claim 1, wherein said pre-pressurized chamber is accomplished by use of a piston deployed within said chamber so as to define a fluid containment volume within said chamber, a spring element deployed so

as press said piston into said fluid containment volume so as to pressurize said quantity of fluid drug supplied within said fluid containment volume.

6. The fluid drug delivery device of claim 1, wherein said pressure reduction passage is an elongated passageway interconnected to said fluid supply assembly, said elongated passageway having a fluid inlet and a fluid outlet, said elongated passageway configured so as to reduce said pressure in the fluid thereby creating a pressure differential between said fluid inlet and said fluid outlet.

7. A fluid drug delivery device comprising:

(a) a fluid supply assembly;

(b) a pressure reduction passage having a fluid inlet in fluid communication with said fluid supply assembly, said flow passage also having a fluid outlet;

(c) a flow control valve interconnected to said fluid outlet; and

(d) a piezoelectric actuator deployed so as to regulated said flow control valve thereby varying the amount of fluid flowing through said flow control valve.

8. The fluid drug delivery device of claim 7, further comprising:

(a) a positioning component deployed so as to position said flow control valve actuator in a predefined spatial relationship to said flow control valve; and

(b) a processing unit electronically interconnected with a pressure sensor and said flow control valve actuator, said processing unit configured so as to use data from said pressure sensor to determine activation of said flow control valve actuator.

9. The fluid drug delivery device of claim 8, wherein said positioning component includes a rotatable adjustment shaft manually rotated by a thumb-wheel, said shaft and said thumb-wheel being connected by way of an over-running clutch

mechanism configured to allow said thumb-wheel to continue turning while discontinuing rotation of said shaft when said flow control valve actuator is properly positioned in relationship to said flow control valve.

10. The fluid drug delivery device of claim 8, wherein said processing unit is further interconnected to an alarm unit, said processing unit using data from said pressure sensor to determine activation of said alarm unit.

11. The fluid drug delivery device of claim 8, wherein said, flow actuator, said manual positioning component, said pressure sensor, and said processing unit are housed in a base unit further including a processing unit display, processing unit input keypad, and a power supply.

12. The fluid drug delivery device of claim 11, wherein said fluid supply assembly, said flow reduction passage, and said flow control valve, are housed in a removable cartridge unit.

13. A fluid drug delivery device comprising:

(a) a fluid supply assembly;

(b) an elongated pressure reduction passageway having a fluid inlet in fluid communication with said fluid supply assembly, and a fluid outlet, said elongated passageway configured so as to reduce pressure in the fluid thereby creating a pressure differential between said fluid inlet and said fluid outlet;

(c) at least one pressure sensor interconnected with a first and a second pressure sensing points, said pressure sensing points located at intervals along said elongated passageway so as to discern a pressure differential between said first and second pressure sensing points; and

(d) a flow control assembly responsive to said pressure sensor and controlled in response to said pressure differential.

14. The fluid drug delivery device of claim 13, wherein said flow control assembly includes:

(a) a flow control valve interconnected with said fluid outlet;

(b) a flow actuator deployed so as to regulate said flow control valve thereby varying amounts of fluid flowing through said flow control valve;

(c) a positioning component deployed so as to properly position said flow control valve actuator in relationship to said flow control valve; and

(d) a processing unit electronically interconnected with a pressure sensor and said flow control valve actuator, said processing unit configured so as to use data from said pressure sensor to determine activation of said flow control valve actuator.

15. The fluid drug delivery device of claim 14, wherein said flow actuator includes a piezoelectric actuator.

16. The fluid drug delivery device of claim 14, wherein said positioning component includes a rotatable adjustment shaft manually rotated by a thumb-wheel, said shaft and said thumb-wheel being connected by way of an over-running clutch mechanism configured to allow said thumb-wheel to continue turning while discontinuing rotation of said shaft when said flow control valve actuator is properly positioned in relationship to said flow control valve.

17. The fluid drug delivery device of claim 14, wherein said processing unit is further interconnected to an alarm unit, said processing unit using data from said pressure sensor to determine activation of said alarm unit.

18. The fluid drug delivery device of claim 14, wherein said, flow actuator, said manual positioning component, said pressure sensor, and said processing unit are housed in a base unit further including a processing unit display, processing unit input keypad, and a power supply.

19. The fluid drug delivery device of claim 18, wherein said fluid supply assembly, said flow reduction passage, and said flow control valve, are housed in a removable cartridge unit.

20. A fluid drug delivery device comprising:

(a) a fluid supply assembly having a chamber, a piston, and a spring element, said piston deployed within said chamber so as to define a fluid containment volume within said chamber, said spring element deployed so as to bias said piston toward said fluid containment volume so as to pressurize an amount of the fluid drug supplied within said fluid containment volume, said containment volume having a supply outlet;

(b) a pressure regulator having a fluid inlet in fluid communication with said fluid supply assembly, said pressure regulator also having a fluid outlet; and

(c) a flow control assembly in fluid communication with said pressure regulator fluid outlet.

21. The fluid drug delivery device of claim 20, wherein said flow control assembly includes:

(a) a flow control valve interconnected with said fluid outlet;

(b) a flow actuator deployed so as to regulate said flow control valve thereby varying amounts of fluid flowing through said flow control valve;

(c) a positioning component deployed so as to properly position said flow control valve actuator in relationship to said flow control valve; and

(d) a processing unit electronically interconnected with a pressure sensor and said flow actuator, said processing unit configured so as to use data from said pressure sensor to determine activation of said flow actuator.

22. The fluid drug delivery device of claim 21, wherein said pressure regulator includes an elongated pressure reduction passageway configured so as to

reduce said pressure in the fluid thereby creating a pressure differential between said fluid inlet and said fluid outlet.

23. The fluid drug delivery device of claim 22, wherein at least one pressure sensor is interconnected with at least a first and a second pressure sensing points, said pressure sensing points being located at intervals along said flow reduction passage.

24. The fluid drug delivery device of claim 21, wherein said flow actuator includes a piezoelectric actuator.

25. The fluid drug delivery device of claim 21, wherein said positioning component includes a rotatable adjustment shaft manually rotated by a thumb-wheel, said shaft and said thumb-wheel being connected by way of an over-running clutch mechanism configured to allow said thumb-wheel to continue turning while discontinuing rotation of said shaft when said flow actuator is properly positioned in relationship to said flow control valve.

26. The fluid drug delivery device of claim 21, wherein said processing unit is further interconnected to an alarm unit, said processing unit using data from said pressure sensor to determine activation of said alarm unit.

27. The fluid drug delivery device of claim 21, wherein said flow actuator, said manual positioning component, said pressure sensor, and said processing unit are housed in a base unit further including a processing unit display, a processing unit input keypad, and a power supply.

28. The fluid drug delivery device of claim 27, wherein said fluid supply assembly, said flow reduction passage, and said flow control valve, are housed in a removable cartridge unit.

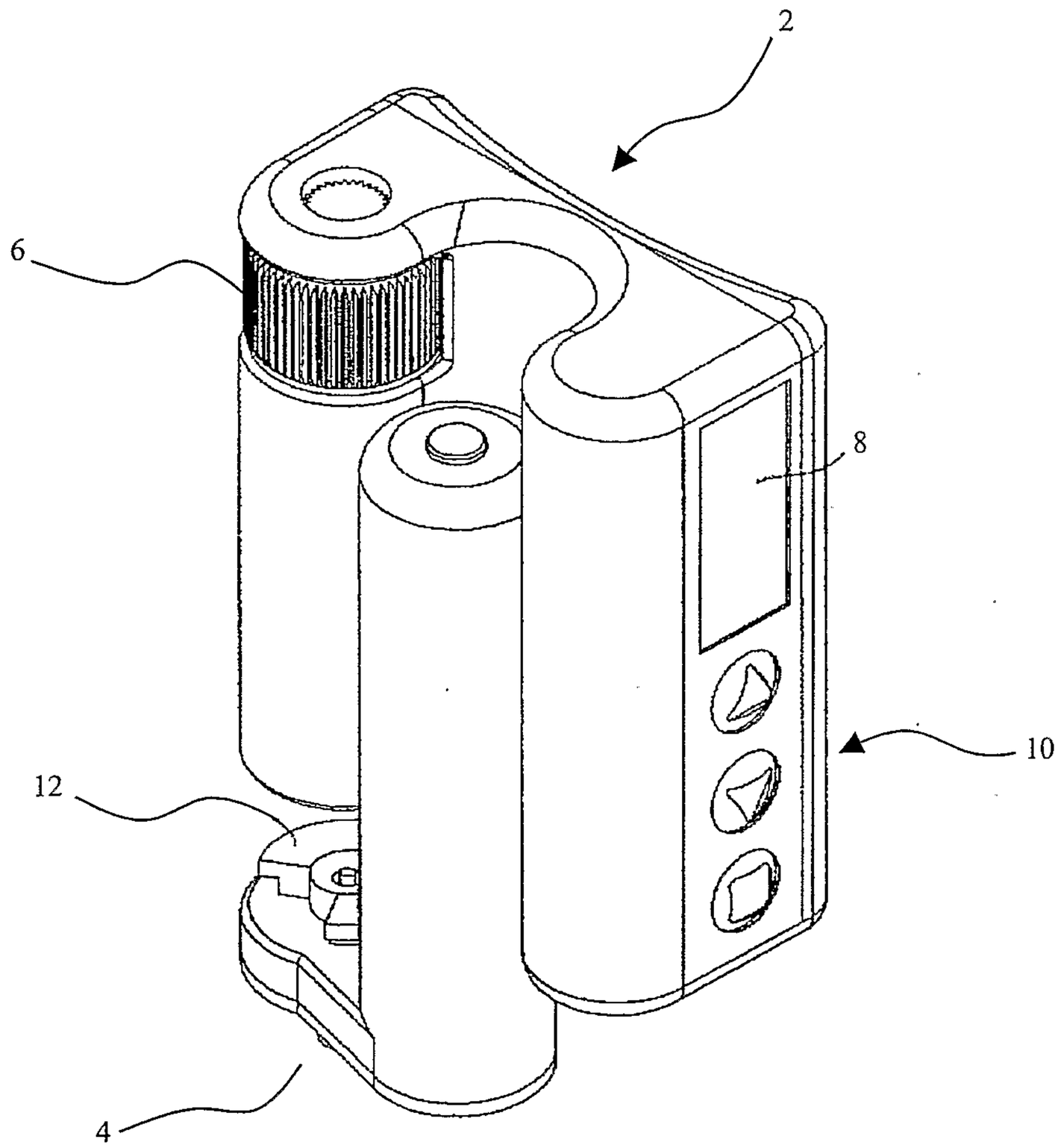


FIG. 1

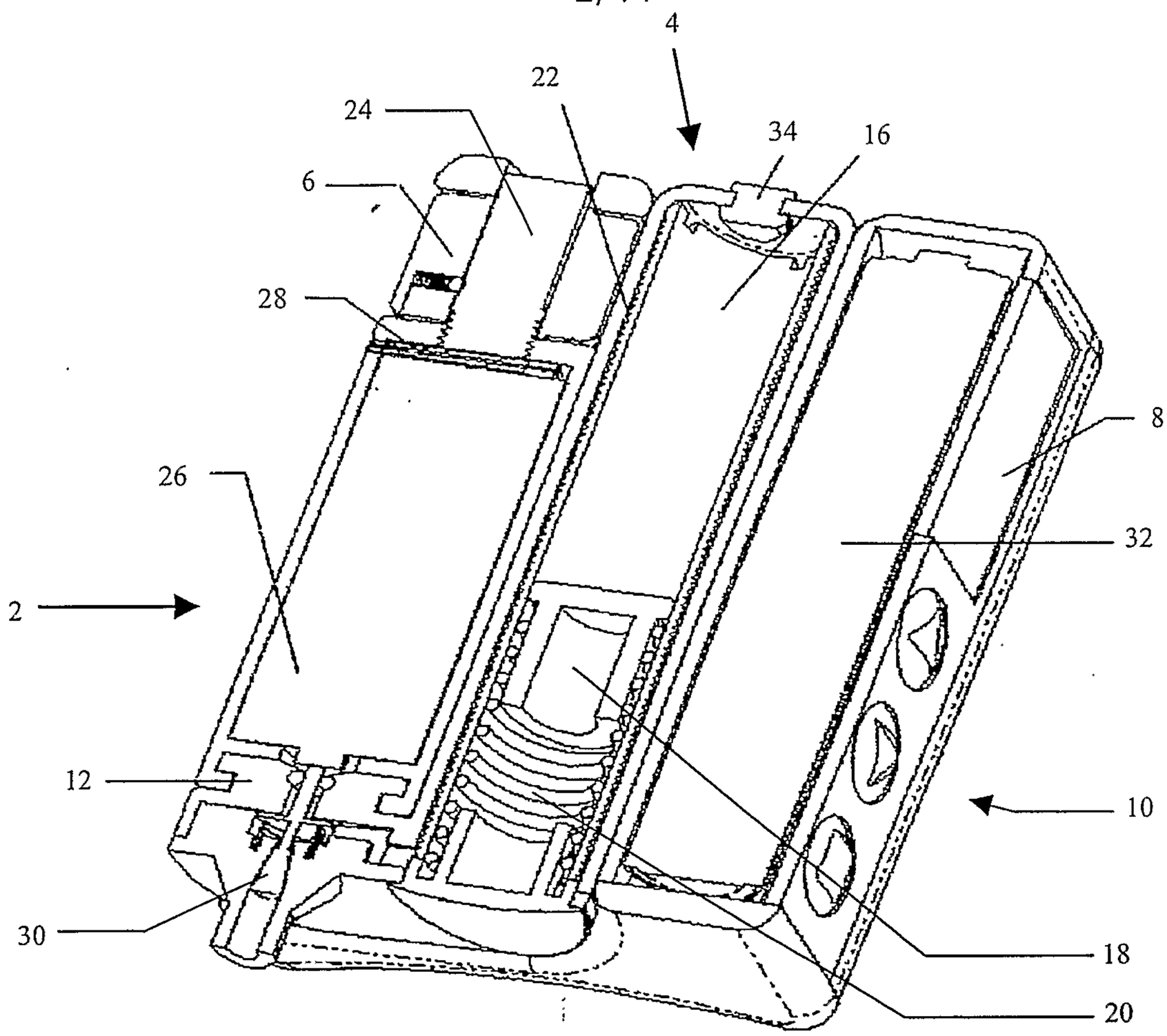


FIG.2

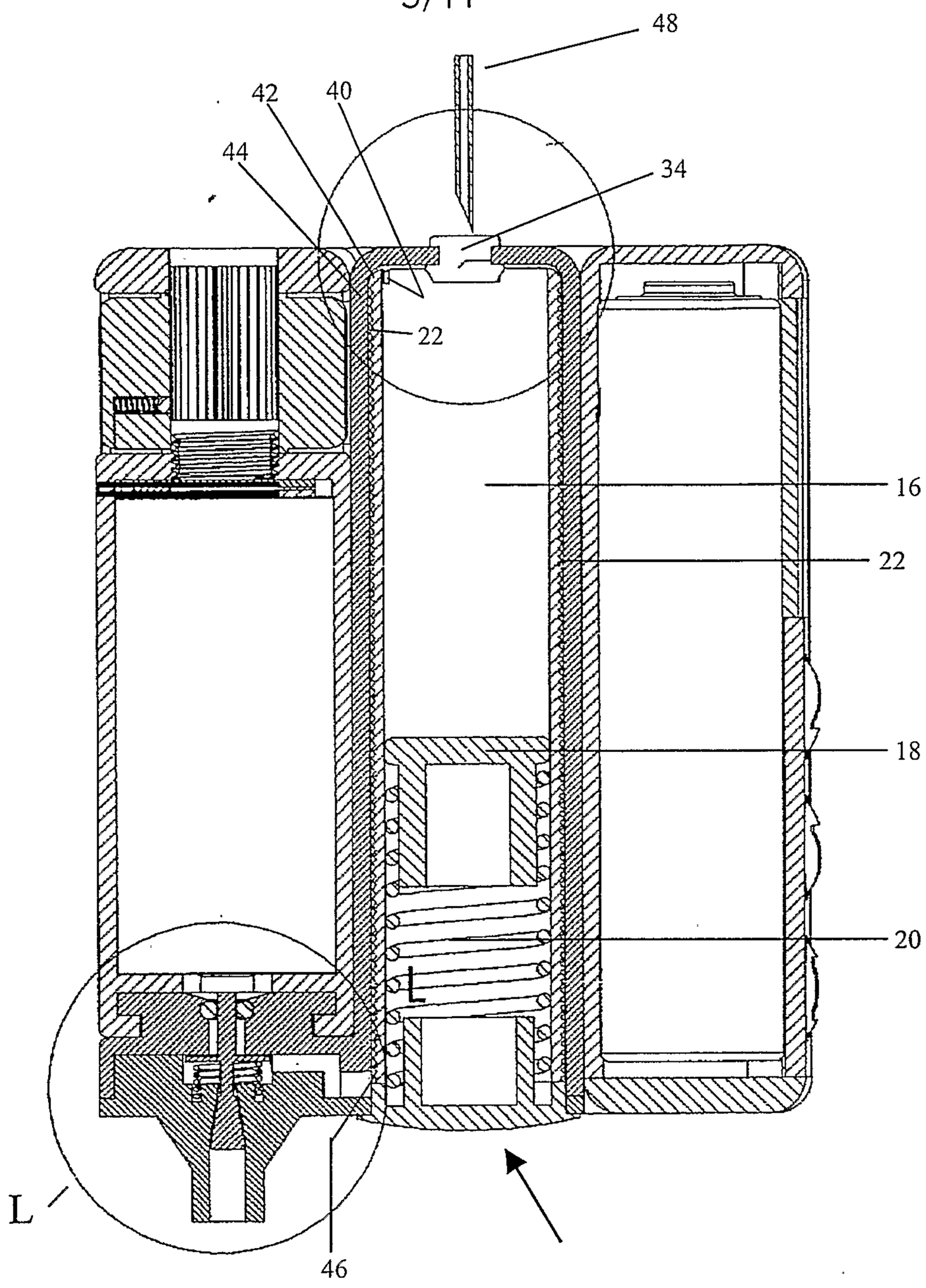


FIG.3

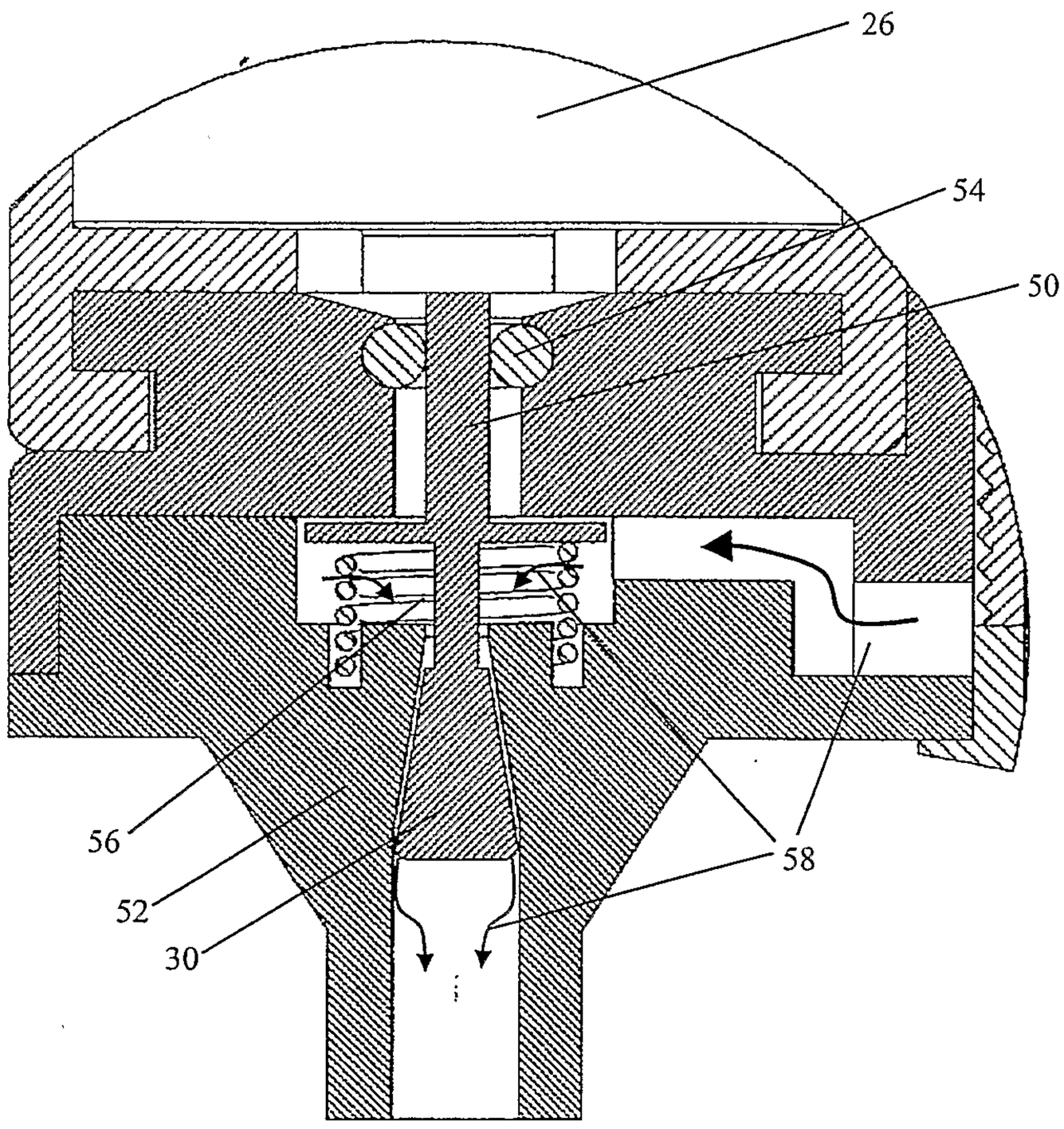


FIG. 4

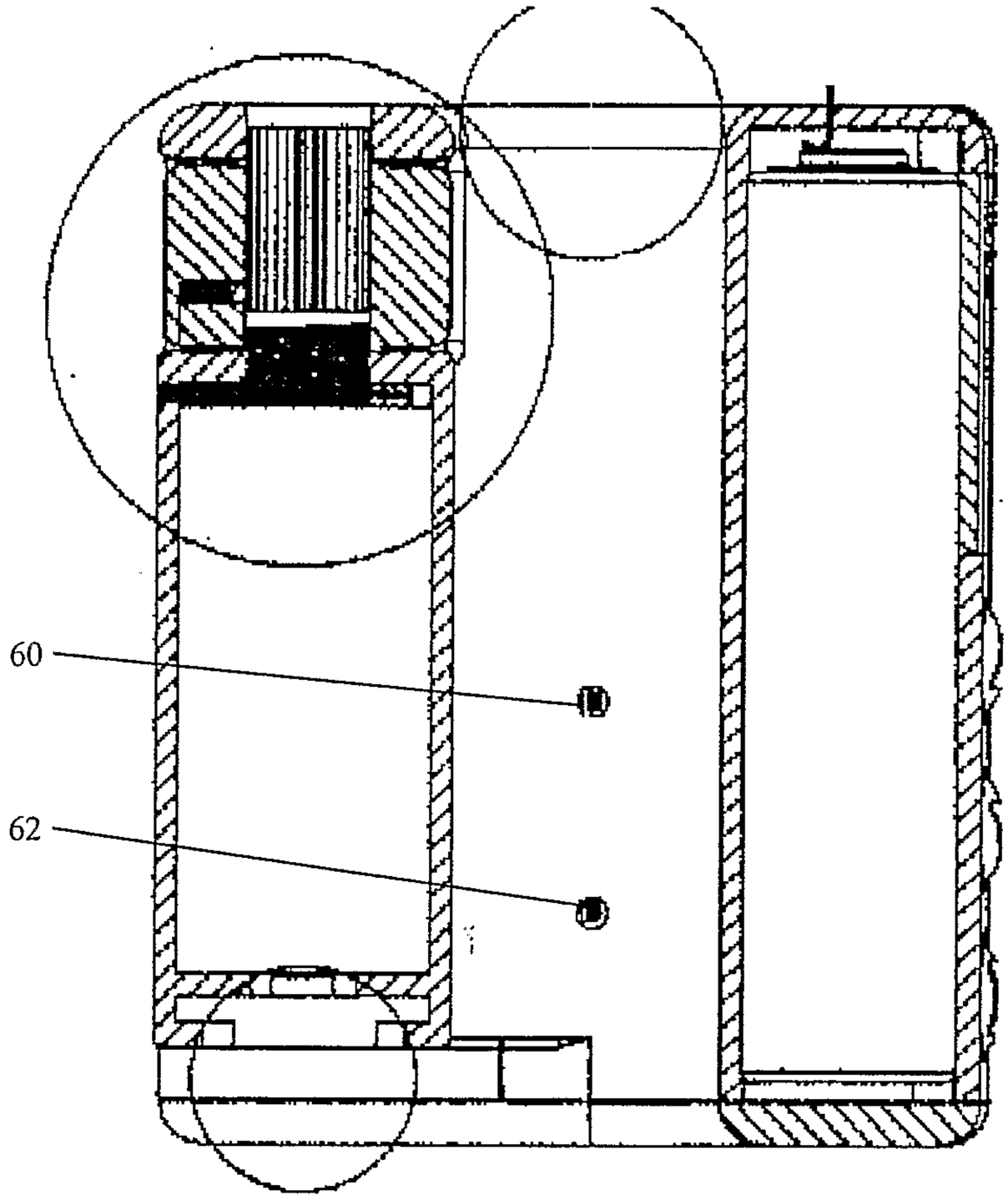


FIG. 5

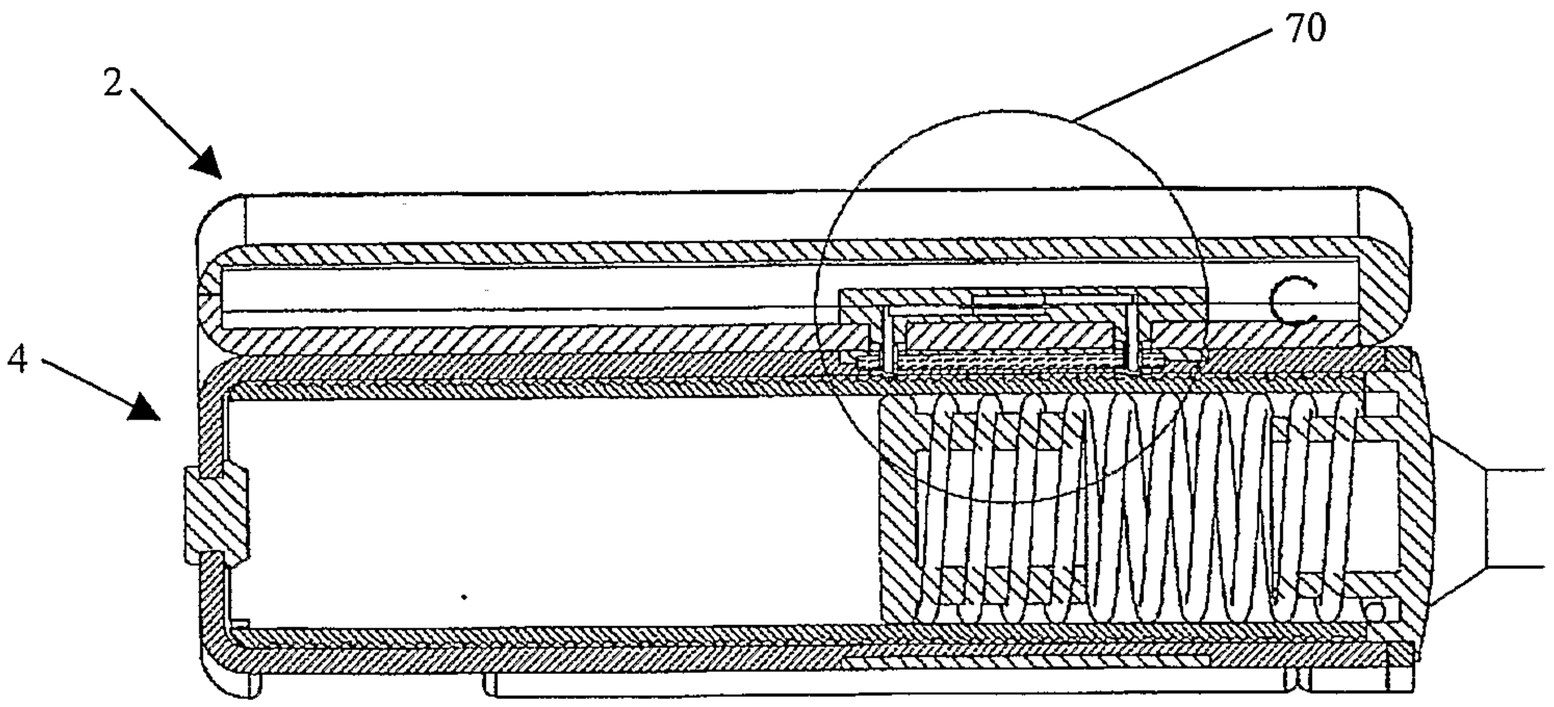


FIG. 6a

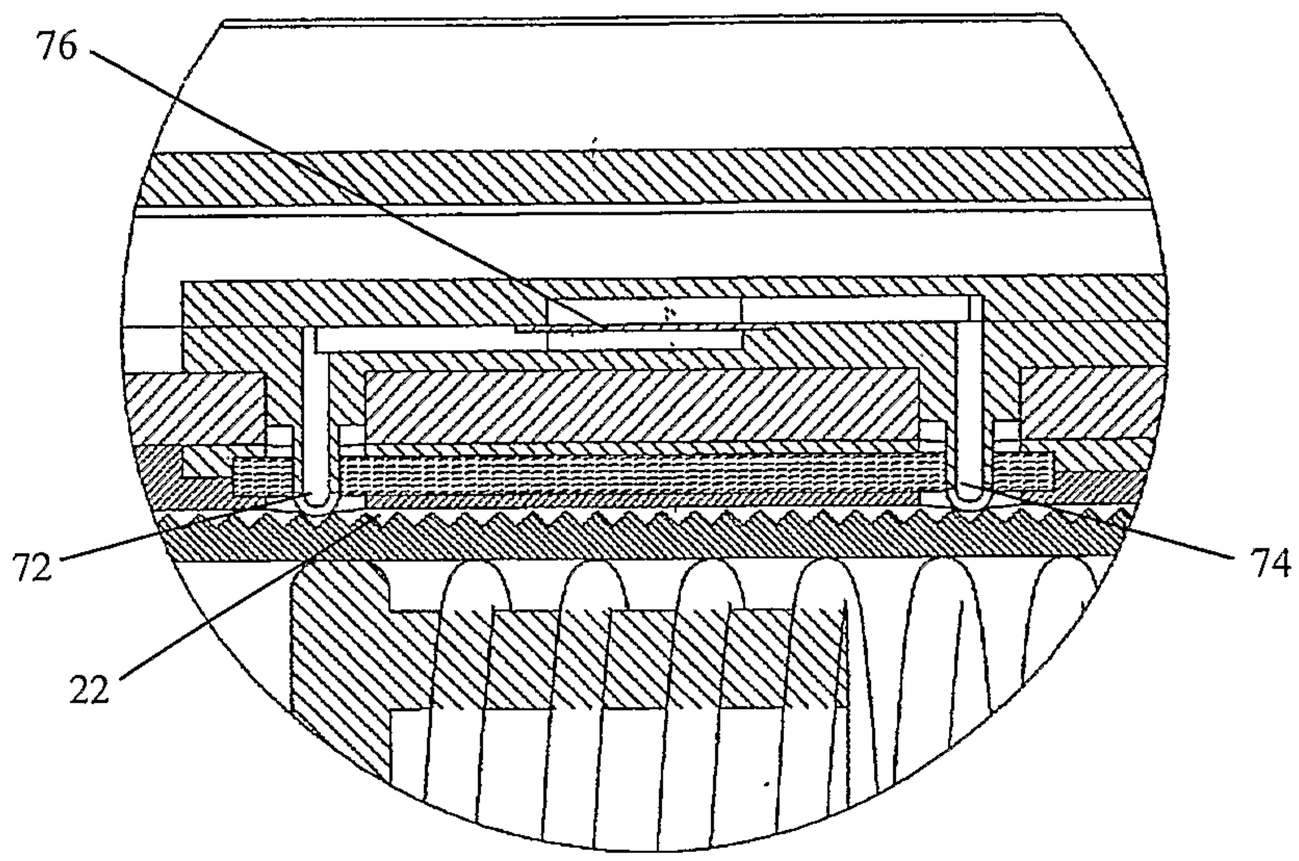


FIG. 6b

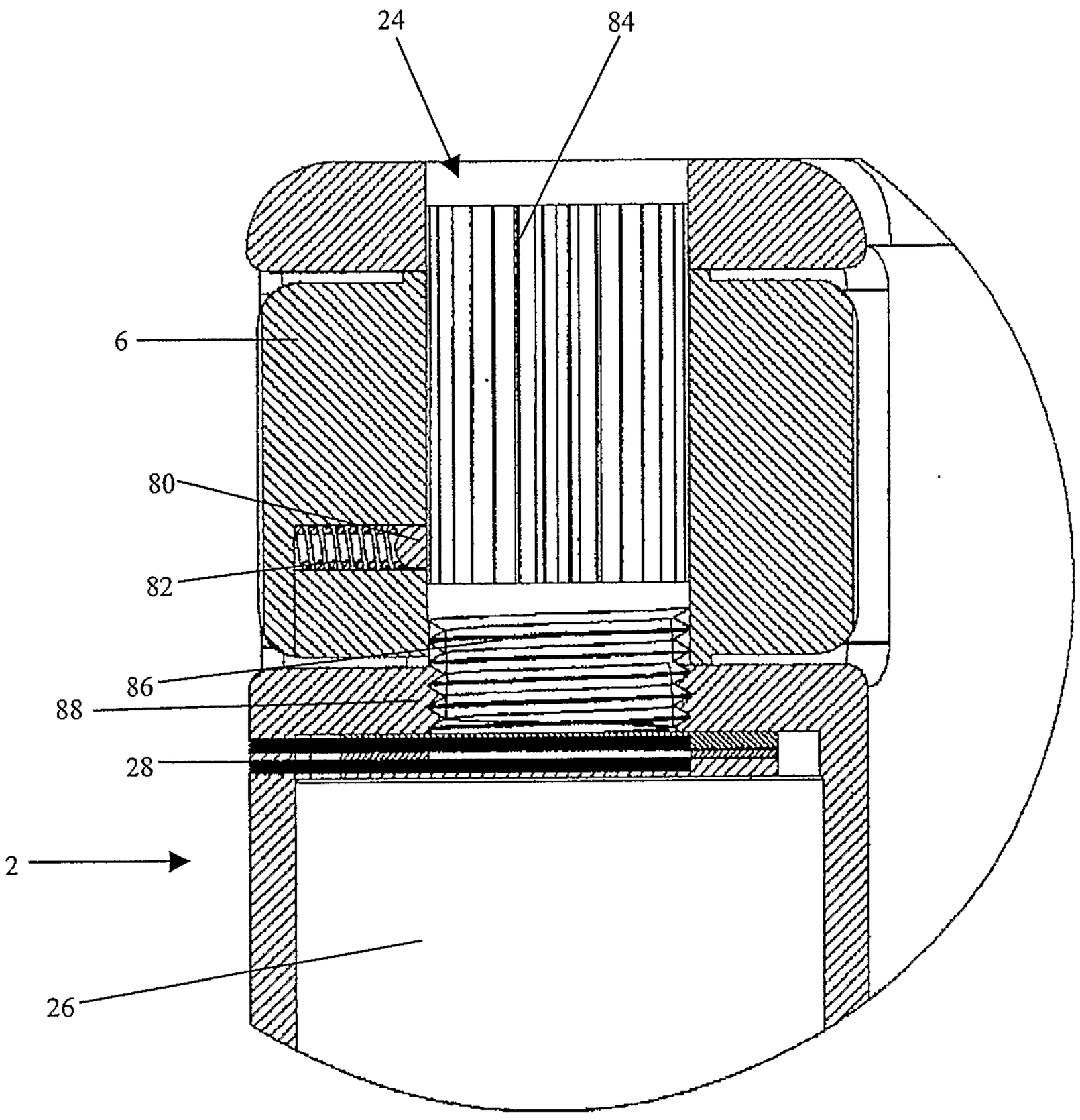


FIG. 7

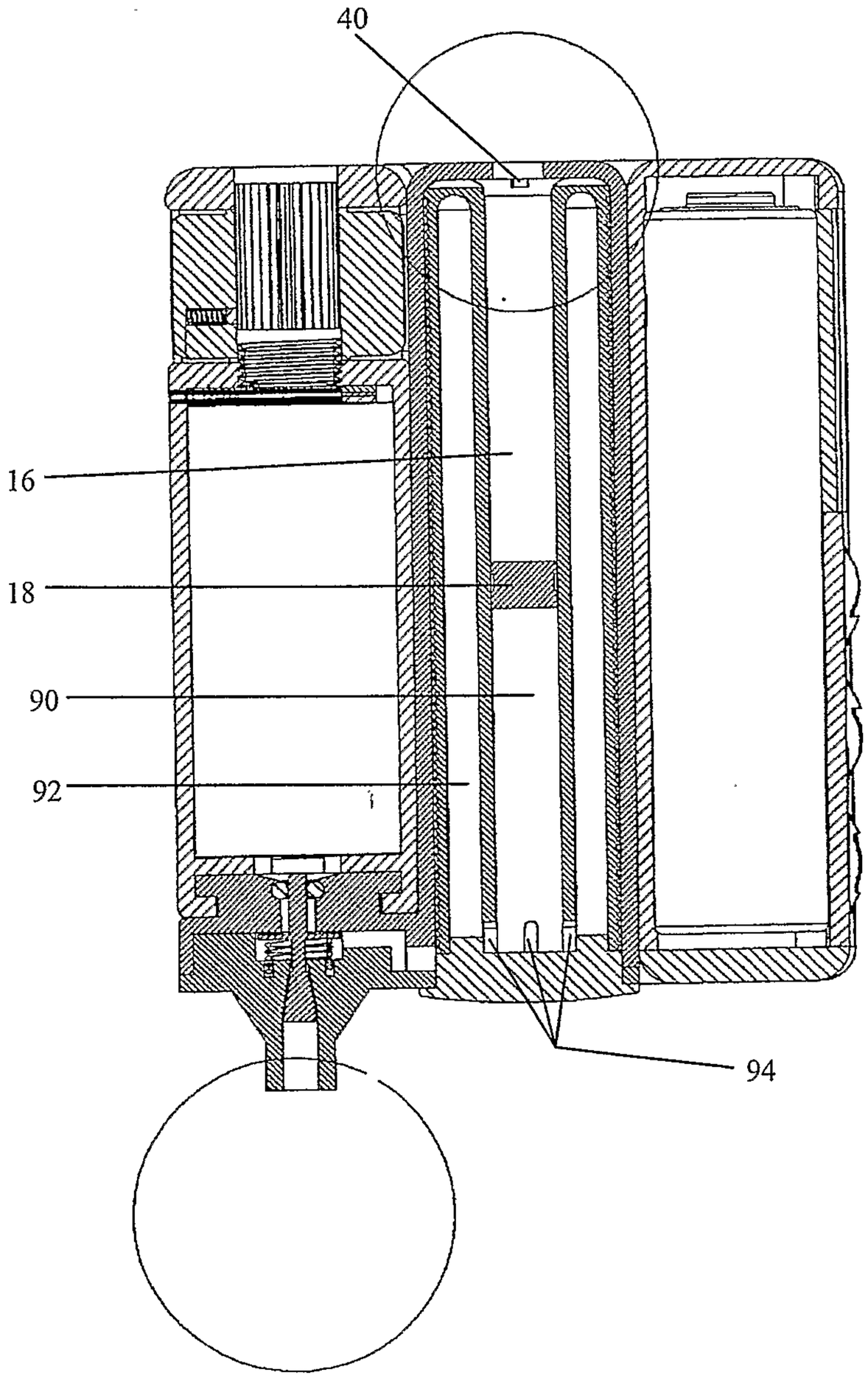


FIG. 8

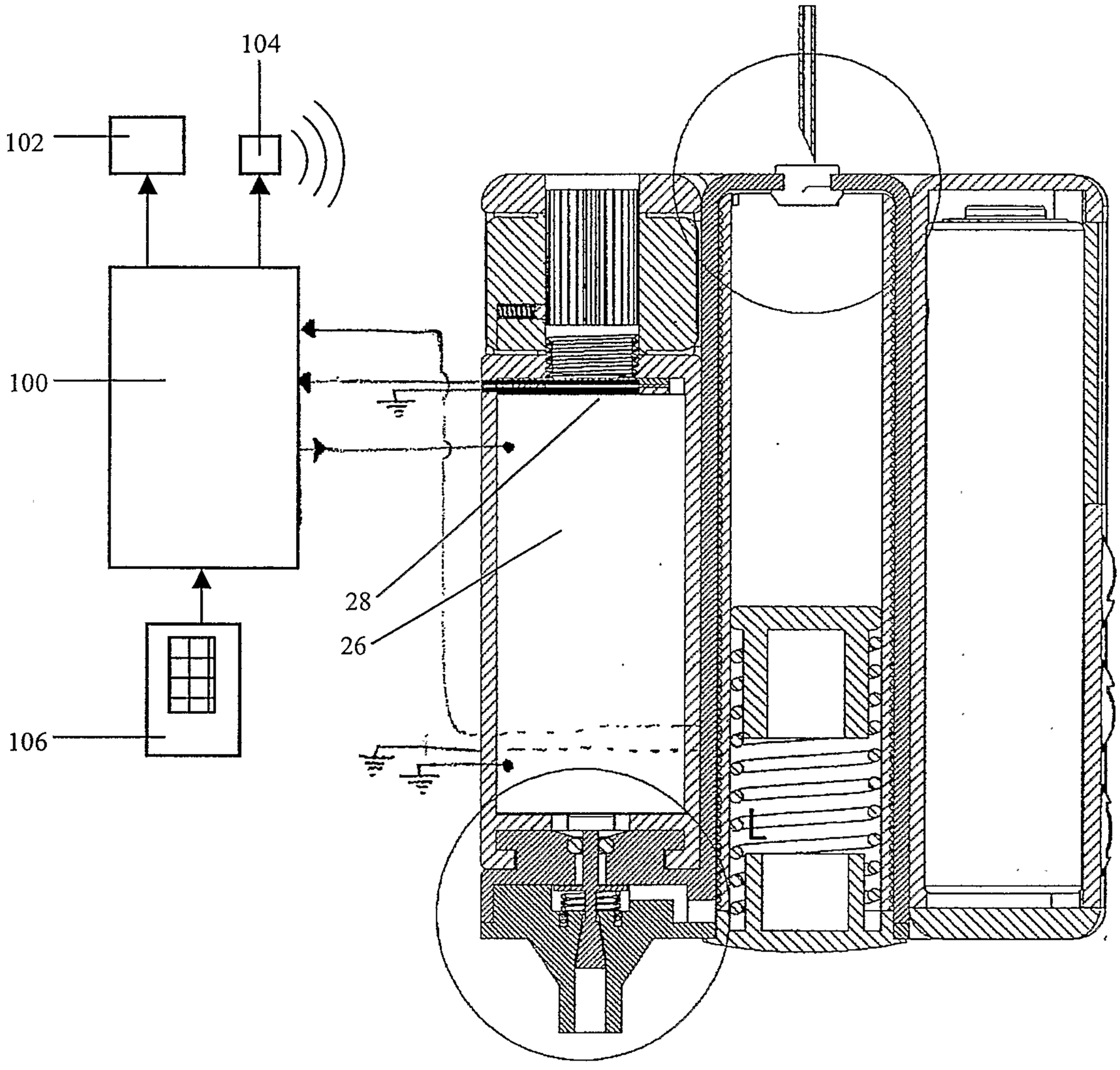


FIG. 9

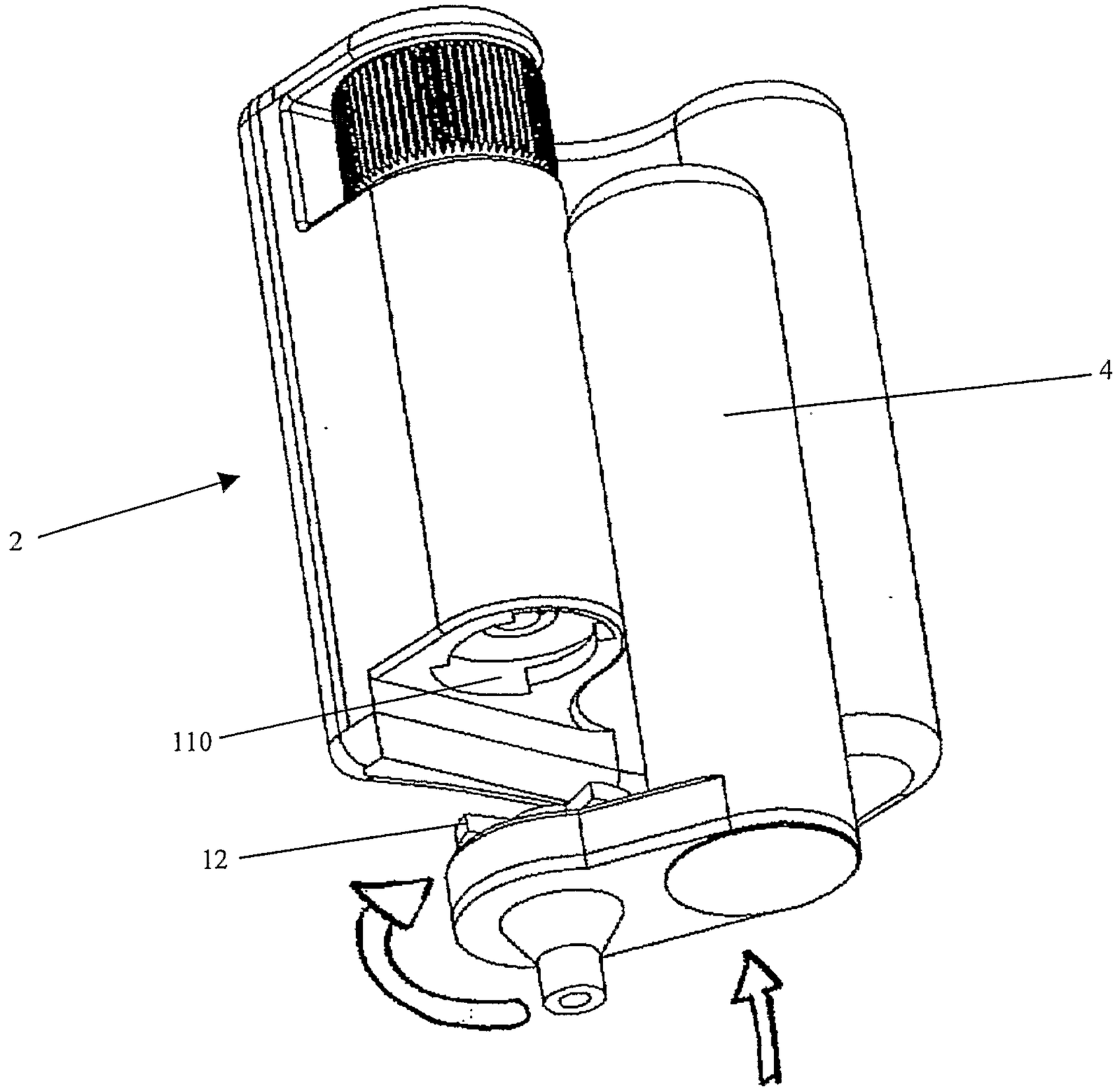


FIG. 10

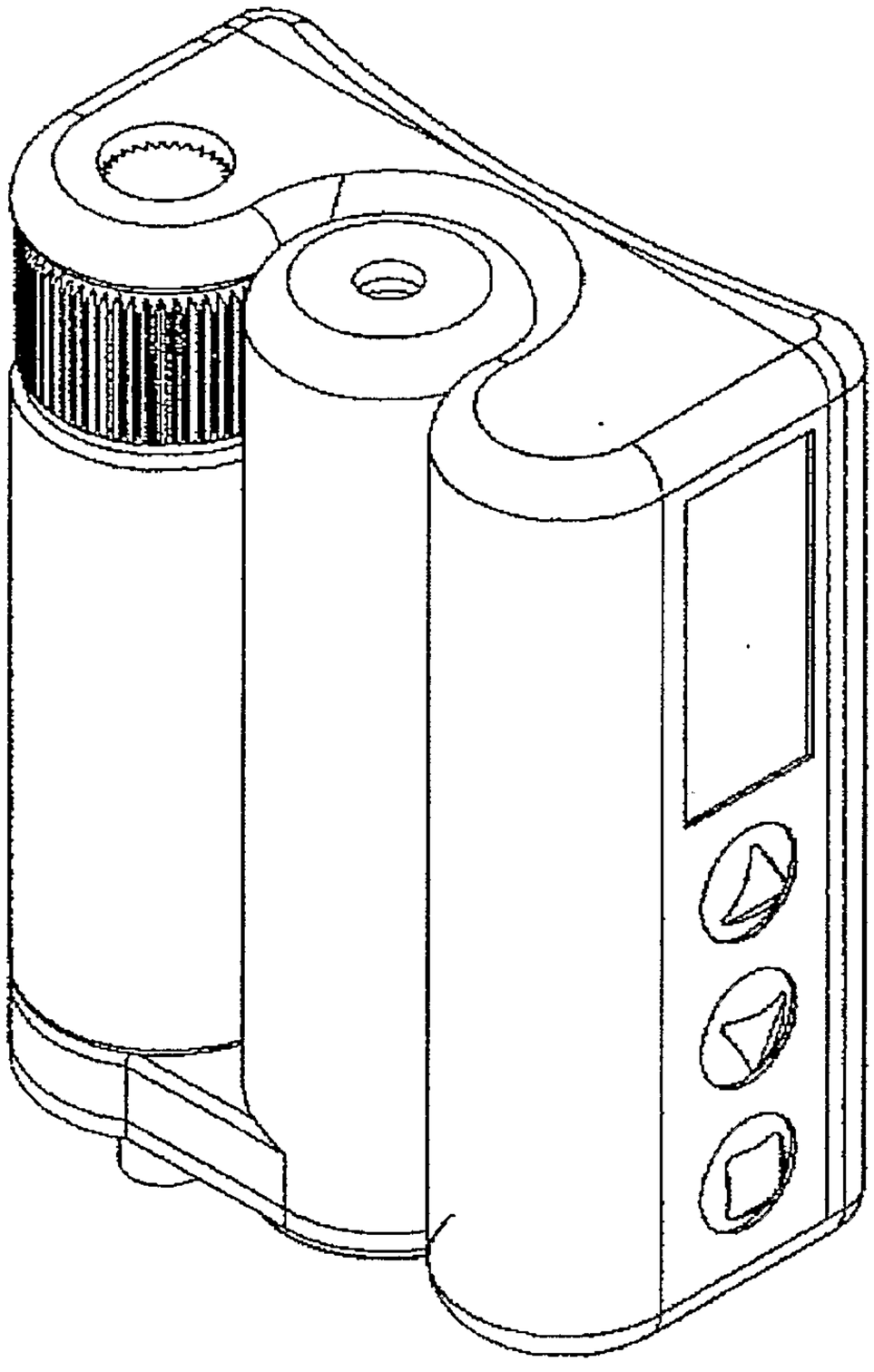
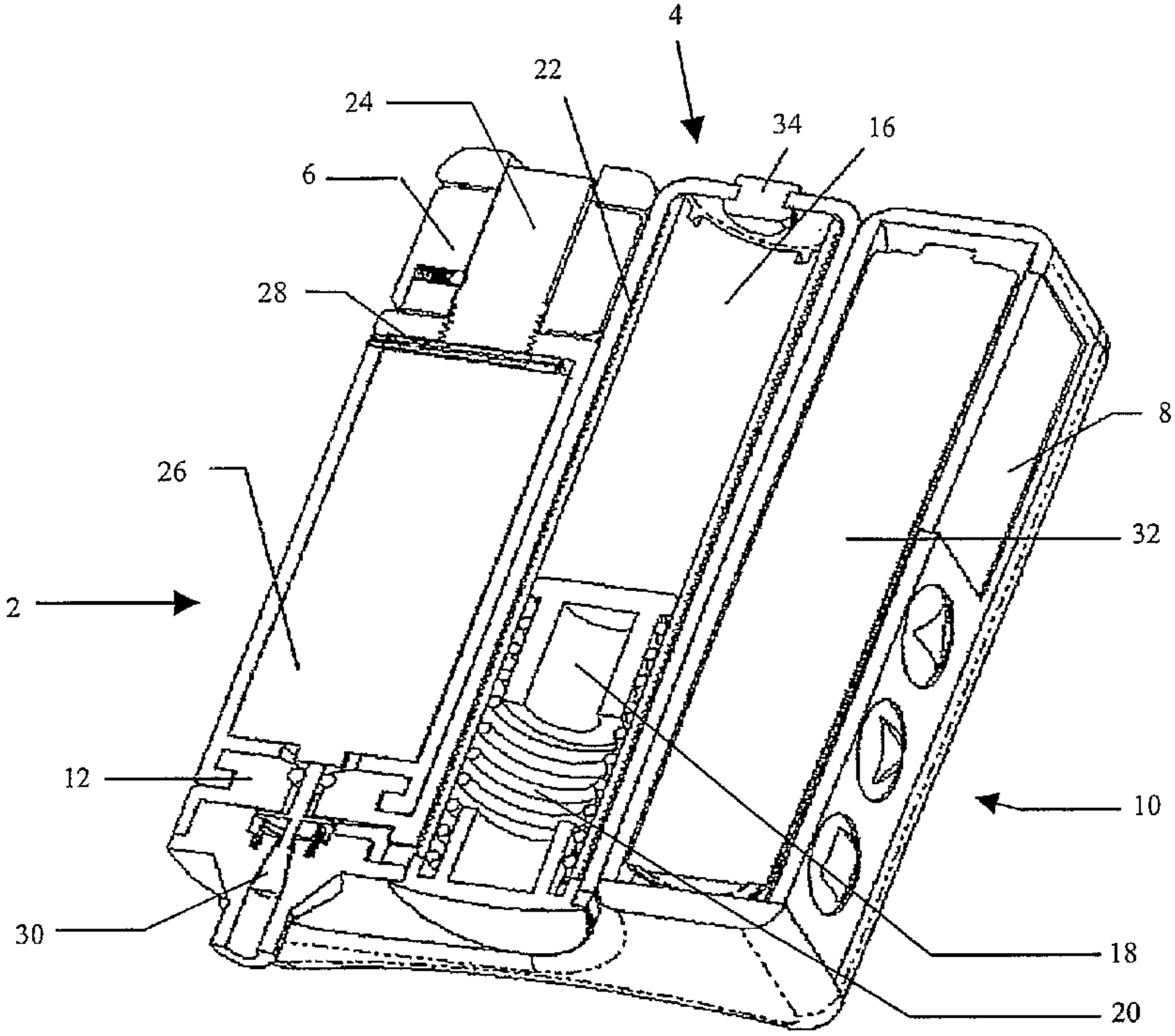


FIG. 11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