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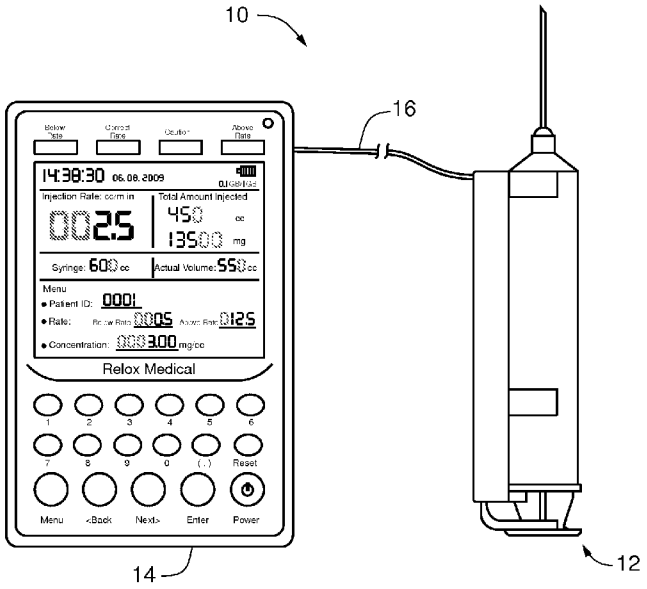
(54) Title: METHOD AND APPARATUS FOR SYRINGE INJECTION OF FLUIDS

(57) Abstract: A system for delivering or withdrawing a fluid to or from the body of a patient in a manner that permits delivery to be controlled based upon feedback from the patient, the system including a syringe assembly providing a syringe operably coupled to one or more sensors adapted to determine one or more corresponding parameters associated with fluid delivery and/or withdrawal, and a monitor adapted to be communicably associated with the one or more sensors of the syringe assembly, and optionally with other sensors or inputs providing additional parameters as well, the monitor comprising one or more read out mechanisms either directly or indirectly corresponding to the one or more fluid delivery/withdrawal parameters, and optionally with one or more of the additional parameters as well.

Fig. 1



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METHOD AND APPARATUS FOR SYRINGE INJECTION OF FLUIDS

TECHNICAL FIELD

The present invention relates to methods and corresponding syringe mechanisms for use in delivering and/or withdrawing fluids to and/or from the body.

BACKGROUND OF THE INVENTION

Syringes have long been used to deliver fluids to the body. Standard approaches in the use of syringes include those that are prefilled with the material (generally solution) to be delivered. Syringes have been described that are capable of manual operation, as well as those that employ automated operation, e.g., on a timed or continual infusion approach.

On a related subject, Applicant has itself developed a method for the treatment of diseases such as stroke. See, for instance, US Publication No. 2006/0280807 (Rind).

SUMMARY OF THE INVENTION

The present invention provides a system for delivering or withdrawing a fluid to or from the body of a patient in a manner that permits delivery to be controlled based upon feedback from the patient, the system including:

a) a syringe assembly comprising a syringe adapted to contain, and to deliver and/or withdraw, a fluid to and/or from the body, the syringe being operably coupled to one or more sensors adapted to determine one or more corresponding parameters associated with fluid delivery and/or withdrawal, and

b) a monitor adapted to be communicably associated with the one or more sensors of the syringe assembly, and optionally with other sensors or inputs providing additional parameters as well, the monitor comprising one or more read out mechanisms (e.g., visual or auditory displays or signals) either directly or indirectly corresponding to the one or more fluid delivery/withdrawal parameters, and optionally with one or more of the additional parameters as well.

The system can be used, for instance, to deliver fluid (e.g., drug or other solution) to the patient in a manner that can be controlled based, in whole or in part, manually by the

infusionist, and upon feedback from the patient. Such feedback can be of any suitable type, e.g., an indication made directly or indirectly by the patient him or herself, and/or it can be based upon one or more parameters determined by the use of corresponding sensors.

Such patient indications can be based upon any suitable criteria, e.g., pain, temperature sensation, dizziness, movement, or other physical manifestation. The indication itself can be provided in any suitable manner, e.g., as a physical or oral indication, or by actuation of a suitable indicator means (e.g., hand-controlled button or switch). In turn, the indication can be binary (e.g., yes or no) or it can be qualified or quantified in some manner (e.g., as an indication of a position along a scale or continuum).

In turn, the parameters determined by the one or more sensors can also be related to either the patient response (e.g., blood pressure, temperature), or to delivery parameters relating to the fluid delivered or withdrawn (e.g., rate, amount), or both.

In a particularly preferred embodiment, the delivery can be manually or semi-manually controlled based upon one or more patient indicators selected from the group consisting of thermal sensation, pain, or other physical sensation (e.g., dizziness). The system preferably also includes associated processors, soft- or firmware and displays related to measurements being taken from the patient related to the infusion or withdrawal, and providing safety and/or efficacy, and/or biological data such as temperature, oxygen saturation, respiratory rate, blood pressure, pressure at the site of the infusion (e.g., to assess extravasation), and heart rate.

The method and system of the present invention can be used for the delivery of any material (e.g., solution) to a patient where such delivery (e.g., by infusion) is given and where control of the rate is desirable or required, and enhanced safety may result. In turn, the system of this invention is particularly well suited for use with the delivery of solutions for the treatment or prevention of various diseases, conditions, syndromes, or disorders, such as stroke and ischemia, where delivery is preferably controlled based upon an indication of temperature sensation by the patient. See, US Publication No. 2006/0280807 (Rind), the disclosure of which is incorporated herein by reference.

In one preferred embodiment, the parameters are selected from the group consisting of the total amount delivered over time, the rate of injection, and one or more corresponding safety ranges or indicators (e.g., yes/no indications), optionally and preferably in combination with other measurements related to the functions and requirements associated with safety considerations, and patient monitoring related to the infusion.

Optionally, and preferably, the system also provides one or more features selected from the group consisting of memory functions, data storage capability, printout capability, download to a computer, calibration, fail safe mechanisms, power indicator, reset function, and alarm notification.

In a preferred embodiment, a syringe assembly of this invention comprises: a) a syringe comprising a barrel, plunger and needle adapted to contain and deliver a fluid, and b) one or more sensors directly or indirectly associated with the syringe assembly and corresponding to one or more respective delivery/withdrawal parameters. Such delivery/withdrawal parameters can include any parameter of relevance or potential relevance to the patient or provider, or both, including those selected from the group consisting of:

Rate of fluid delivery or withdrawal

Amount of fluid delivered or withdrawn at any point in time and/or in total

Amount of drug or material delivered or withdrawn at any point in time and/or in total

Concentration of drug or material being delivered (e.g., mg/ml)

Pressure of fluid delivery or withdrawal

Velocity of the fluid delivered or withdrawn

Time associated with fluid delivery or withdrawal

Size of the syringe being used

Amount of fluid in the syringe being used

Memory capacity of the information being stored and the amount used

Temperature of the fluid and/or patient

Tissue (e.g., blood) levels of one or more analytes (e.g., oxygen, ATP)

The parameters can be selected and in turn determined and used in any suitable manner, e.g., on their own or in combination with other parameters, and in one or more relationships (e.g., the delivery rate as compared to patient temperature).

The sensors can be of any suitable type, e.g., mechanical, electromagnetic, optical, pneumatic, hydraulic, photosensitive sensors, flow meter types, pressure types, Doppler sensing types, imbedded magnets in the head of the plunger, and variations thereof. In turn, the sensors can be used to determine parameters in any suitable manner, e.g., by automated analysis and/or mechanical or other suitable actuation.

A primary sensor can be associated with the syringe assembly in any suitable manner, e.g., with the barrel, plunger and/or needle components of the syringe. In turn, a sensor can be coupled to or with the syringe in any suitable relationship, e.g., with the sensor upon, within, around, adjacent, or integral with one or more syringe components. In one

embodiment, one or more sensors and syringe control features are associated with an aftermarket device that can be coupled together with a conventional syringe or connected to the monitor. In yet another embodiment, one or more sensors and/or syringe control features can be incorporated or built into one or more components of the syringe itself.

In turn, the syringe assembly can be used in any suitable manner, e.g., manual (human powered infusion), automated, and combinations thereof. The syringe itself can be made of any suitable material, e.g., glass, plastic or other materials, and can be either reusable or disposable in whole or in part, and can be provided with conventional connections (e.g., Luer-Lok™ tip, slip-tip, or eccentric tips). In turn, the syringe can be provided in any suitable size, e.g., from 1cc to 200cc. The syringe needle can itself be detachable, retractable or permanently attached, and the needle the syringe can itself be remote from the needle of the syringe, as in a butterfly configuration. The syringe assembly, including portions of the syringe and corresponding sensors, can be provided in sterile form where necessary, and in either single use (e.g., disposable) or reusable form.

For instance, the system can be operated using manual and/or automatic control of any or all aspects, including for instance, feedback from the sensor to the infusionist. Automatic control can include, for instance, automatic feedback of information by a flashing light or sound, as an alarm from the monitor, e.g., if a certain rate of infusion is exceeded, and/or automatic control of the injection *per se*. Such options include manual and/or automated (including semi-automated, e.g., in which certain aspects remain subject to manual control) of the feedback from the sensor to the infusionist.

The operable connection between any aspect of the invention, e.g., between the syringe or its sensors (and the monitor), can be in any suitable form, e.g., manual, mechanical, electrical or other such connection, or wireless.

In a particularly preferred embodiment, the apparatus of this invention is used for intravenous administration, but can be used for all types of injections, including other forms of parenteral injections, such as sub-cutaneous, intra-muscular, intra-arterial, intradermal, and the like.

An apparatus of this invention further provides a monitor adapted to be communicably connected to the one or more sensors associated with the syringe assembly, the monitor comprising one or more displays either directly or indirectly corresponding to the one or more parameters.

Optional features of the monitor include, but are not limited to one or more corresponding memory functions, data storage and printout capabilities, connection to a

computer, calibration and reproducibility features, fail safe mechanisms, thermal (e.g., warmth or coolness) indicators, name of patient, memory capacity and amount used, time of day, time of injection, size of syringe being used, amount of fluid in the syringe, sensation indicators, temperature indicators, as well as reset control, power indicator, and additional information, indicators, ranges, scales (e.g., dizziness).

In a preferred embodiment, the system further provides a solution to be delivered using the syringe mechanism and module of this invention. Suitable fluids are those that benefit from a predictable or controllable delivery, examples of which include, but are not limited to those solutions designed to elicit an immediate response on the part of the patient, e.g., in terms of pain alleviation, anesthesia, or thermal sensation.

In a particularly preferred example, the system of this invention is used to practice a method for treating, preventing, and/or diagnosing (e.g., contrast media) disorders such as stroke, cerebral palsy and brain/head trauma and other injuries. In addition, the method is useful for treating patients after surgery to speed healing and recovery by administering a solution containing certain ions and nutrients to a patient, preferably while the patient is breathing pure or nearly pure oxygen or a mixture of gases having greater than about 20% oxygen. The methods of the invention can also be used to promote healing of damaged tissue, for example, damaged muscle tissue. The method is useful for tissue damage or disease caused by any of a wide variety of factors, including, genetic problems, environmental problems, bruising, ischemia-reperfusion injury, infection, and inflammation.

In such a preferred embodiment, the apparatus can be used in a method for treating a patient comprising: (a) injecting into the bloodstream of a patient is breathing a gas mixture having greater than about 20% oxygen, and more preferably greater than about 25% oxygen, an aqueous solution comprising about 0.1 to about 1 M Mg++ and having an osmolarlity less than about 1500 mOSm/l; and (b) increasing the rate of injection at least until the patient feels a sensation of warmth. In some embodiments, the method entails treating a region of the body of a patient and increasing the rate of injection at least until the patient feels a sensation of warmth in the region of the body to be treated. In some embodiments the patient provides feedback regarding the sensation of warmth so that a sensation of warmth in the target area can be achieved and/or maintained for a desired period of time. In some embodiments are temperature measuring device (e.g., a infrared temperature measuring device) is used to monitor increase in warmth of a target area of the patient's body. In some embodiments the rate of administration of the solution is varied based on feedback from the patient and/or measurements made by the temperature measurement device.

In various embodiments: the patient is administered a breathing mixture comprising at least 40% oxygen; the patient is administered a breathing mixture comprising at least 60% oxygen; the patient is administered a breathing mixture comprising at least 90% oxygen; the breathing mixture includes at least about 0.5% CO2; the breathing mixture includes about 0.5% to about 10% (and more preferably, about 1% to about 6%) CO2; breathing mixture is administered to the patient at greater than normal atmospheric pressure; the rate of injection is increased until the patient feels a sensation of warmth in a part of the body in need of treatment; the rate of injection is not substantially increased after the patient feels a sensation of warmth; the rate of injection varied to maintain the sensation of warmth for a desired period of time; the total amount of solution administered in one treatment session is between 0.5 ml/kg and 2 ml/kg of patient body weight; the average rate of injection is greater than 0.1 ml/sec; the osmolarity of the solution is less than 1200 mOsm/L; osmolarity of the solution is less than 1100 mOsm/L; the osmolarity of the solution is less than 1000 mOsm/L; the osmolarity of the solution is less than 900 mOsm/L; the osmolarity of the solution is between 200 and 1100 mOsm/L; the solution contains up to 6 mg/ml ascorbic acid; the solution contains 0.1 to 0.7 M (0.1 to 0.6 M, 01 to 0.5 M; 0.15 M to 0.6 M; 0.15 to 0.35 M) magnesium chloride; the solution contains 0.1 to 0.7 M (0.1 to 0.6 M, 01 to 0.5 M; 0.15 M to 0.6 M; 0.15 to 0.35 M)magnesium sulfate; the solution contains 0.1 to 0.7 M (0.1 to 0.6 M, 01 to 0.5 M; 0.15 M to 0.6 M; 0.15 to 0.35 M) Mg2+ ions; the patient has suffered a stroke, brain injury, cerebral palsy, viral or chemical injury to the brain; the solution contains one or more of vitamin B12, vitamin B6 and vitamin B5; the solution contains vitamin B12,vitamin B6 and vitamin B5; the solution contains less than 1% by weight calcium gluconate; the solution does not contain calcium gluconate; the solution contain less than 0.001 M Ca2+; the breathing mixture is administered through a masking covering the patient's nose and mouth, which masked is sealed to substantially prevent leakage of the breathing mixture; the patient is reclining during treatment; the patient has consumed at least 200 calories within 3 hours prior to treatment; and the patient consumed or has been administered at least 2 ml/kg body weight of water within 3 hours prior to treatment.

The methods of the invention, which entail administration of a healing solution containing magnesium ions and additional optional components, can promote more rapid healing of brain injury or other physical trauma than can be achieved without treatment or with only physical therapy. The healing solution administered in the method of the invention has a relatively high level of magnesium ions, at least compared to many commonly used intravenous solutions, and is formulated so as permit the healing solution to be safely and

comfortably administered to the patient intravenously at a relatively rapid rate. Thus, the osmolarity and the pH of the solution are set relatively close to physiological levels found in blood.

The healing solution can contain a variety of components in addition to magnesium ions. For example it can contain vitamin C. In some cases, bicarbonate or some other base or a buffer is require to reduce the acidity of solutions containing vitamin C. The healing solution can contain calcium gluconate, but in many cases it is desirable to reduce or eliminate calcium gluconate, particularly where it is desirable to increase the vasodilatory effect of the solution. The healing solution can contain various vitamins, particularly B vitamins, and micronutrients. The healing solution can also include a buffer even where vitamin C is not present.

The healing solution should be injected directly into a vein and should be administered while the patient is breathing a gas mixture that is enriched in oxygen compared to normal air, for example a gas mixture that is greater than 25% (30%, 40%, 50%, 60%, 70%, 80%, 90%) oxygen. In many cases it is desirable to have the patient breath 99-100% oxygen, preferably through a close fitting mask covering the mouth and nose (and preferably sealed to prevent leakage using tape or some other sealant) or through an endotracheal tube. The gas mixture or oxygen is preferably administered at or greater than atmospheric pressure, e.g., at a high flow rate or via a pressure bag. Alternatively, the healing solution can be administered to the patient while the patient is in a hyperbaric chamber and breathing a mixture of gasses having at least 25% (30%, 40%, 50%, 60%, 70%, 80%, 90%, 100%) oxygen.

In yet another embodiment, the present invention provides a kit, comprising a syringe assembly and/or monitor as described herein, in combination with a solution to be delivered, and optionally, in combination with one or more components selected from the group selected from: a) a face mask to permit the delivery of respirable gas in the course of use, b) a computer adapted to interface with the syringe assembly. In a related manner, the invention provides a syringe assembly (including sensor or syringe thereof), or monitor adapted to be used in the preparation and/or use of a system of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings are illustrative of particular embodiments of the present invention and therefore do not limit the scope of the invention. The drawings are not to scale

(unless so stated) and are intended for use in conjunction with the explanations in the following detailed description. Embodiments of the present invention will hereinafter be described in conjunction with the appended drawings, wherein like numerals denote like elements.

Figure 1 illustrates a system for use in delivering and/or withdrawing fluids to and/or from the body according to an embodiment of the invention.

Figure 2A is a perspective view of a syringe assembly according to an embodiment of the invention.

Figure 2B illustrates a syringe assembly showing the separation of a sensor and a syringe according to an embodiment of the invention.

Figure 2C illustrates the syringe assembly of Figure 2B, wherein the sensor and syringe are fastened together according to an embodiment of the invention.

Figure 3A is a cross-section of Figure 2B, taken along line 3A.

Figure 3B is a cross-section of Figure 2C, taken along line 3B.

Figure 3C is a perspective view of the end of a syringe assembly according to an embodiment of the invention.

Figure 4A is a longitudinal cross-section of a sensor according to an embodiment of the invention.

Figure 4B is an exploded view of portion 4B of Figure 4A, including a partial cross-section of a syringe according to an embodiment of the invention.

Figure 4C is a partial cross-section of a syringe assembly illustrating a flip lock in a first position according to an embodiment of the invention.

Figure 4D is a partial cross-section of the syringe assembly of Figure 4C illustrating the flip lock in a second position according to an embodiment of the invention.

Figure 5 is a longitudinal cross-section of a sensor according to an embodiment of the invention.

Figure 6A is a front view of a monitor according to an embodiment of the invention.

Figure 6B is a side view of the monitor of Figure 6A.

Figure 6C is a side view of the monitor of Figure 6A.

Figure 7 is a side view of a monitor including a stand according to an embodiment of the invention.

Figure 8 is a perspective view of a modular system for use in delivering and/or withdrawing fluids to and/or from the body according to an embodiment of the invention.

Figure 9 is a perspective view of an integrated system for use in delivering and/or withdrawing fluids to and/or from the body according to an embodiment of the invention.

Figure 10 is a perspective view of an integrated system for use in delivering and/or withdrawing fluids to and/or from the body according to an embodiment of the invention.

Figure 11 is a perspective view of a modular system for use in delivering and/or withdrawing fluids to and/or from the body according to an embodiment of the invention.

Figure 12 is a perspective view of a syringe driver assembly according to an embodiment of the invention.

Figure 13 is a perspective view of a syringe driver assembly according to an embodiment of the invention.

Figure 14 is a back perspective view of the syringe driver assembly of Figure 13.

Figure 15 shows a syringe pump including a ball valve flow meter according to an embodiment of the invention.

Figure 16 is a perspective view of a syringe driver assembly according to an embodiment of the invention.

Figure 17 is a perspective view of a syringe driver assembly according to an embodiment of the invention.

DETAILED DESCRIPTION

In one preferred embodiment, the system includes a syringe assembly and monitor as shown in Figures 1-7. Figure 1 illustrates a system 10 for use in delivering and/or withdrawing fluids to and/or from the body according to an embodiment of the invention. In certain embodiments, the system 10 includes a syringe assembly 12 and a monitor 14 coupled by a communication link 16. Briefly, in certain embodiments the syringe assembly 12 is adapted to contain and deliver and/or recover a fluid to and/or from the body. The syringe assembly 12 includes one or more delivery and/or recovery sensors that determine one or more corresponding parameters associated with fluid delivery and/or recovery. The monitor communicates with the one or more sensors of the syringe assembly 12 via the communication link 16. For example, the monitor 14 and the syringe assembly 12 can be coupled with a link 16 comprising a wired or a wireless link. The monitor 14 includes one or more read out mechanisms (e.g., visual or auditory displays or signals) that correspond (directly or indirectly) to the one or more parameters.

In certain embodiments the system can be used, for instance, to deliver fluid to the patient in a manner that can be controlled based, in whole or in part, upon feedback from the

patient. Such feedback can be of any suitable type, e.g., an indication made directly or indirectly by the patient him or herself, and/or it can be based upon one or more parameters determined by the use of corresponding sensors, including for example, a visual and/or audible reference to one or more measured parameters.

Figure 2A is a perspective view of a syringe assembly 12 according to certain embodiments of the invention. The syringe assembly 12 preferably comprises a syringe 20 and a sensor 30 (sometimes referred to herein as a "sensor assembly"), which can be coupled together in various fashions depending upon the desired design. For example, as shown in the figures throughout, the syringe assembly 12 can comprise a typical type of syringe and a separate sensor (e.g., a custom or an aftermarket sensor device) that couples to the syringe. In certain embodiments, though, the sensor 30 may be integral with the syringe 20 instead of being formed as a separate, coupled device.

In a preferred embodiment, the syringe 20 includes a barrel 22 defining a flange 28, a plunger 24, and a needle 26 (shown in Figure 2B) and the sensor 30 can be coupled with the syringe 20 in any suitable manner, e.g., with the barrel, plunger and/or needle components of the syringe. The syringe 20 can be made of any suitable material, e.g., glass, plastic or other materials, and can be either reusable or disposable in whole or in part, and can be provided with conventional connections (e.g., Luer-Lok™ tip, slip-tip, or eccentric tips). In turn, the syringe 20 can be provided in any suitable size, e.g., from 1cc to 200cc. The syringe needle 26 can itself be detachable, retractable or permanently attached, and the needle 26 of the syringe can itself be remote from the syringe, as in a butterfly configuration. The syringe assembly 12, including portions of the syringe 20 and corresponding sensors 30, can be provided in sterile form where necessary, and in either single use or reusable form.

In certain embodiments, the sensor 30 includes a sensor plunger 34 adapted to couple with the plunger 24 of the syringe 20. The sensor 30 further includes a sensing device associated with the sensor plunger 34, for sensing parameters related to the functioning of the syringe assembly 12 in any infusion or exfusion application and communicating the parameters to the monitor, more of which will be discussed further herein.

In cases in which the sensor 30 is a separate component from the syringe 20, the sensor 30 and/or syringe 20 can include one or more features that couple and/or lock the syringe 20 and the sensor 30 together. In some embodiments the coupling and/or lock can include a removable and/or semi-permanent style of coupling allowing the syringe 20 and sensor 30 to be separated. In certain embodiments the coupling results in a more permanent fastening of the syringe and sensor. For example, returning to Figure 2A, in some

embodiments the sensor 30 can include one, two, or more fasteners 32 that couple the sensor 30 to the barrel 22 of the syringe 20. The fasteners 32 can take a wide variety of forms. In the illustrated embodiment, for example, the fasteners 32 comprise plastic, resilient partial rings that slip onto the syringe barrel 22. Figure 2A shows an additional feature for coupling and/or locking the sensor 30 with the syringe 20. For instance, the sensor plunger 34 can have a lock 36 formed at an end of the sensor plunger 34, thus allowing the sensor plunger 34 to couple with the plunger 24 of the syringe. Figures 2B and 2C show views of the syringe assembly 12 respectively before and after assembly, according to embodiments of the invention.

Figure 3A is a cross-section of Figure 2B, taken along line 3A, illustrating the lock 36 in greater detail before the sensor plunger 34 and the syringe 20 are coupled together. Figure 3B is a cross-section of Figure 2C, taken along line 3B, illustrating the lock 36 after the syringe 20 and the sensor plunger 34 are coupled together. As shown in Figures 2A-2C, the lock 36 can be formed at the end of the sensor plunger 34 and adapted to couple with the syringe plunger 24. The design of the lock 36 is not fixed, but is preferably formed to engage with the plunger 24 according to the design and shape of the plunger 24. For example, in the illustrated embodiment, the lock 36 includes a generally cross-shaped relief that is adapted to engage with the cross-shaped shaft of the syringe plunger 24. In certain embodiments, the lock 36 includes one or more clips 40 that engage with the syringe plunger to lock the sensor plunger 34 and the syringe plunger 24 together (e.g., semi-permanently or permanently). Figure 3C is a perspective view of the end of a syringe assembly 12 showing a partial engagement of the lock 36 with the syringe plunger 24. The lock 36 and/or clips 40 can be formed of a somewhat resilient material, allowing the clips 40 to flex as the sensor plunger 34 is mounted to the syringe plunger 24 and the clips engage the syringe plunger 24.

Figures 4A-4D illustrate another type of lock or fastener that can couple the syringe 20 and the sensor 30 of the syringe assembly. Figure 4A is a longitudinal cross-section of the sensor 30 according to certain embodiments, and Figure 4B is an exploded view of portion 4B of Figure 4A, with the addition of a partial view of a syringe. As shown in Figure 4B, the sensor 30 is positioned proximate the barrel 22 and flange 28 of the syringe. According to certain embodiments, the sensor 30 includes a flip-lock 50 adapted to engage the syringe barrel 22 and flange 28. The sensor 30 can also include a lock hook 54 adapted to receive the flange 28 of the syringe. In certain embodiments, the sensor 30 may include a resilient member 52 (e.g., a material with a spring constant) that urges the flip-lock 50 into engagement with the syringe once the syringe is properly positioned adjacent the sensor.

Turning to Figure 4C for example, the flip-lock 50 can move inwards (e.g., optionally against the spring constant of the optional resilient member 52) as the syringe 20 and sensor 30 are brought together, thus providing a clear path for engagement. Turning to Figure 4D, as the flange 28 of the syringe is received within the lock hook 54, the flip-lock 50 is urged into frictional engagement with the syringe barrel 22 and flange 28. Accordingly, the flip-lock 50 can provide a manner of coupling and/or locking together the syringe and sensor of the syringe assembly in a preferred embodiment.

Turning to Figure 5, a longitudinal cross-section of a sensor 30 is illustrated according to an embodiment of the invention. Briefly, the sensor 30 includes a housing 60 and the sensor plunger 34 that is movably received and coupled in the housing 60. The housing also includes a sensor device, substrate, or chip 62 (individually or collectively sometimes referred to as a sensor "chip" or "chips") that is operably coupled with the sensor plunger 34. For example, in some embodiments as the sensor plunger 34 passes through the sensor chip 62, the sensor chip 62 detects a change in the voltage of a printed or otherwise deposited circuit board or other substrate 66 positioned within the housing 60. The sensor chip 62 notes the voltage change and outputs a corresponding signal to the monitor in a preferred embodiment. The sensor 30 can further include a plug 64, coupled with the sensor chip 62, adapted to receive a cable or wired communication link to connect the sensor 30 with the monitor.

The sensor chips can be of any suitable type, e.g., mechanical, electromagnetic, optical, pneumatic, hydraulic, photosensitive sensors, flow meter types, pressure types, piezoelectric, Doppler sensing types, imbedded magnets in the head of the plunger, and variations thereof. In turn, the sensor 30 can be used to determine parameters in any suitable manner, e.g., by automated analysis and/or mechanical, hydraulic or other suitable actuation.

Turning to Figure 6A, a front view of a monitor 14 is shown according to one preferred embodiment of the invention. In a preferred embodiment, the monitor 14 includes a number of keys and a variety of displays adapted to display one or more values corresponding (directly or indirectly) to one or more parameters. According to certain embodiments, the displayed values and/or parameters can be selected from the group consisting of, but not limited in either number or function, the total amount of infusate delivered over a defined period of time, the rate of injection over a defined period of time, and one or more corresponding safety ranges or indicators (e.g., yes/no indications). Optional features of the monitor 14 include, but are not limited to, one or more corresponding memory functions, data storage and printout capabilities, computer outputs, calibration and

reproducibility features, fail safe mechanisms, thermal (e.g., warmth or coolness) indicators, sensation indicators, temperature indicators, as well as reset control, power indicator, and additional information, indicators, ranges, scales (e.g., for dizziness).

For example, as shown in Figure 6A, the monitor 14 can include features including, but not limited to:

- A rate alarm 70, including, for example, four color-flash rate indications/zones customizable by a user. One example of rate zones and alarms include: Below Rate – White, Correct Rate – Green, Caution Rate – Yellow, Above Rate – Red.
- A time display 71 that displays the current date and time, precise to the second for example. The time can be set by continually pressing the menu key for 3 seconds.
- An injection rate 72 that is able to, for example, accurately display the injection speed.
- A patient ID input 73 which allows a user to input and display an ID for every patient.
- A rate reset display 74 that allows the rate to be set and displayed.
- A concentration display 75 displaying the corresponding concentration.
- A memory capacity display 76 that displays the used capacity versus total capacity of onboard memory.
- An injected liquid display 77 that displays an automatically calculated volume of liquid that has been infused.
- A total amount injected display 78 which displays a total amount injected (mg) calculated automatically based on a given "Concentration".
- An alarm indicator 80, including a red LED flashing until the “Reset” key is pressed for “Actual Volume.”
- A keypad 81 for the input of various alphanumeric characters.
- A menu key 82.
- Direction keys 83 that allow a user to choose or change one or more of the parameters.
- An enter key 84.
- A power key 85.
- A reset key 86 that when pressed after setting all desired parameters initiates an automatic detection of the actual volume and begins a recording.
- Means (not shown) for recording and/or marking data or other information relating to the procedure.

Figures 6B-6D illustrate various views of the monitor 14 of Figure 6A. For example, Figure 6B illustrates a side view of the monitor 14 showing the inclusion of a computer connection 90 that allows the monitor 14 to be coupled with a computer. Figure 6C illustrates an additional side view of the monitor 14 including a plug 92 that allows the monitor to be coupled to the syringe assembly via the communication link as shown in Figure 1. Figure 6D is a top view of the monitor 14, showing a backlight key 94. Turning to Figure 7, in some embodiments the monitor 14 further includes a stand 96 that allows the monitor 14 to be set upon a work surface, etc. For example, the stand 96 may allow the monitor 14 to recline at an angle A that may be in one embodiment about 30 degrees. Optionally, a hook (not shown) can be included at the top of the monitor in order to permit it to be hung on an IV or other pole or support.

Figures 8-17 illustrate various configurations and aspects of systems and corresponding components according to additionally preferred embodiments of the invention.

According to certain embodiments, preferred systems include a monitor that is or can be operably (e.g., directly or indirectly) connected to a sensor assembly that is itself operably coupled to a syringe assembly containing an infusate, in a manner that permits the sensor(s) to determine (e.g., measure or assess) one or more delivery or other parameters. A "syringe assembly" as used herein can refer to a combination of one or more parts of a syringe, including the barrel, plunger, needle, and in some cases optionally the sensor assembly as well. The syringe assembly can be operated in any suitable manner, e.g., it can be manually and/or automatically driven, and if automatically driven, will preferably include a manual override. In a preferred embodiment, a system includes a monitor with a coupled syringe assembly as shown in Figure 8.

A preferred embodiment provides a sensor assembly that independently monitors one or more physical parameters of injection, and optionally also one or more parameters associated with patient response, and is adaptable in order to permit and/or provide to a plurality of injection modes and/or mechanisms. For example, a sensor according to some embodiments can be configured as an aftermarket sensor assembly that can be coupled to one of any number of types of pre-existing syringes. When coupled to the syringe, the sensor assembly can be considered part of the syringe assembly. In some cases the sensor assembly can sense and monitor delivery of an infusate by a syringe assembly being manually and/or automatically actuated. In some cases the sensor assembly is configured to couple with the syringe assembly such that both can be easily loaded into (and unloaded from) a syringe driver assembly for automatic and/or manual manipulation.

In some embodiments, the system can be used as an interactive device in a manner that guides its very own use, for instance, for coaching or training infusionists, as well as for instructing or guiding therapies. For example, as discussed above, a monitor connected to one or more sensors can be used to display various types of information about the patient and/or infusion procedure, thus allowing an infusionist to determine how best to proceed with the infusion procedure, and in turn, determine whether or not to continue or change course based on the received feedback. In effect, a preferred system of this invention will allow the infusionist to effectively titrate delivery of the solution, in order to obtain, and to the extent desired, to also maintain or alter a particular response or feedback from the paitent. It should be appreciated that a wide variety of tutorial features can be provided depending upon the particular disease and remedy being administered. For example, a software program running on the monitor can receive and process multiple inputs from various sensors and then provide an infusionist with instructions regarding the appropriate procedure. Such capability can be especially useful where the rate of injection can be counter-intuitive to the response from the patient.

In a preferred embodiment, the syringe assembly comprises a syringe and a sensor assembly (sometimes simply referred to herein as a "sensor") that can be coupled together (e.g., as described above with reference to FIGS. 1-5). In certain embodiments, the sensor assembly includes a sensor plunger adapted to couple with the plunger of the syringe. The sensor assembly further includes a sensing device associated with the sensor plunger, for sensing parameters related to the functioning of the syringe assembly in any infusion or aspiration application and communicating the parameters to the monitor.

In certain embodiments, a sensing device capable of sensing the syringe assembly can include, but is not limited to, one or more of a position sensor, linear potentiometer, 2-axis accelerometer, pressure sensor, flow sensor, and/or optical sensor. In certain embodiments, the sensing device is a separate added component and not part of (e.g., integrated within) the syringe, a syringe plunger actuator, and/or the monitor.

In some embodiments in which the sensor assembly is a separate component from the syringe, one or more system components can include security feature(s) that are adapted to prevent reuse of a particular sensor assembly. In a preferred embodiment, a sensor assembly, monitor, syringe driver, and/or syringe can include one or more mechanical and/or electrical security features. For example, in some cases the sensor assembly and syringe include mechanical security features that couple and/or lock the syringe and the sensor assembly together to achieve, alternatively, a permanent, semi-permanent, or removable fastening.

In certain embodiments, the use of an electronic device in the sensor assembly can provide a security mechanism to prevent re-use of the sensor. For example, the sensor assembly can include a small programmable memory device that is programmed upon initially coupling the sensor to a monitor and/or initially sending communications between the sensor and the monitor. In the event of attempted subsequent uses, querying the memory (e.g, by the monitor, syringe driver, external PC, etc.) would reveal the previous programming, thus indicating that communications should not be accepted, acknowledged, and/or acted upon from this particular sensor assembly. In another example, the sensor assembly can be assigned a unique identifier (e.g., via an RFID tag, programmed serial number, etc.) that is transmitted to the monitor upon an initial use. Before validating use of the sensor, the monitor can compare the identifier to a list of previously used identifiers and refuse operation with the sensor assembly if the identifier is already present, or add the identifier to the list to prevent subsequent use.

In a preferred embodiment, a monitor includes a number of keys and displays adapted to display one or more values corresponding directly or indirectly to one or more parameters. According to certain embodiments, the displayed values and/or parameters can be selected from the group consisting of, but not limited in either number or function, the total amount of infusate delivered over a defined period of time, the rate of injection over a defined period of time, and one or more corresponding safety ranges or indicators (e.g., yes/no indications). In certain embodiments, the system monitor can display one or more of an override mode indicator, acceleration calculation, patient tolerance to infusion (e.g., relative magnitude), real time playback, training screens, measurement(s) and/or contribution to controls. Optional features of the monitor include, but are not limited to, one or more corresponding memory functions, data storage and printout capabilities, computer outputs, calibration and reproducibility features, fail safe mechanisms, thermal (e.g., warmth or coolness) indicators, sensation indicators, temperature indicators, a reset control, a power indicator, and additional information, indicators, ranges, and scales (e.g., for dizziness).

In certain embodiments, the system includes the ability for aphasic patients to indicate when they perceive heat from the infusion and when the heat was felt in their head. For example, patients can indicate such perceptions by pressing a button in some cases. In certain embodiments, the system includes the ability to measure blood pressure, oxygen saturation (SpO2) and heart rate. In a preferred embodiment, the system includes the ability to log a permanent record of events measured on the monitor during the infusion. The event

record can be stored within the monitor and also analyzed within the monitor or uploaded to another device, such as a computer for analysis and/or a printer for printing a hard copy.

In some embodiments, the system includes the ability to transfer information from the monitor to a hospital or clinic electronic patient file. For example, in certain embodiments data can be transferred via a removable media, such as a flash drive, a direct wired connection, and/or a wireless connection. Other transfer mechanisms can also be used.

In certain embodiments, the system can also include one or more monitoring sensors apart from a sensor assembly coupled to and/or integrated with the syringe assembly. For example, the system can include any number of other sensors to monitor other parameters, such as flow rate, patient temperature, heart rate, EEG, and/or skin impedance. Turning to FIG. 15, as just one example, a sensing device in the form of a ball valve meter 1502 can be fluidly coupled between the syringe body 1504 and needle 1506 (or at any other point between the syringe body 1504 and the patient) to provide an indication of the velocity of the fluid flow from the syringe to the patient.

As discussed above, embodiments of the invention include both manually driven and/or automated syringe actuation mechanisms. Figure 8 illustrates a manually driven system 800 for use in delivering and/or withdrawing fluids to and/or from the body according to an embodiment of the invention. In certain embodiments, the system includes a syringe assembly 802 and a monitor 804 coupled by a communication link 806. Briefly, in certain embodiments the syringe assembly 802 is adapted to contain and deliver and/or recover a fluid to and/or from the body when actuated by a human operator. The syringe assembly 802 includes a sensor assembly 803 (shown clipped to the back of the syringe assembly) including one or more delivery and/or recovery sensors 810 that determine one or more corresponding parameters associated with fluid delivery and/or recovery. The monitor 804 communicates with the one or more sensors via the communication link 806.

Optionally, in some preferred embodiments, the communication link 806 between the sensor(s) 810 and the monitor 804 includes a sensor interface module 820. The module 820 connects optionally with other sensors or inputs not associated with the syringe assembly 802, providing additional parameters as well. The sensor interface module 820 forwards the sensor signals to the monitor 804. In some cases the module 820 can process one or more sensor signals (e.g., digitize analog signals, combine/multiplex/package various signals) to generate a data stream to communicate to the monitor 804. In a preferred embodiment, additional sensors monitoring additional parameters can provide biological data such as temperature, oxygen saturation, respiratory rate, blood pressure, pressure at the site of the

infusion (e.g., to assess extravasation), and heart rate. For example, the system 800 shown in FIG. 8 includes a blood pressure sensor 822 and a pulse oximeter 824 coupled in communication with the sensor interface module 820.

In certain embodiments the system can be used to deliver fluid to the patient in a manner that can be controlled based, in whole or in part, upon feedback from the patient. Such feedback can be of any suitable type, e.g., an indication made directly or indirectly by the patient him or herself, and/or it can be based upon one or more parameters determined by the use of corresponding sensors, including for example, a visual and/or audible reference to one or more measured parameters.

In some cases, embodiments of the invention can also optionally include an automatically-controlled syringe driver mechanism. In some cases a syringe driver system is provided with a manual control instead of or in addition automatic control. For example, in certain embodiments a syringe power driver mechanism can directly operate on the syringe plunger in response to a manual control dial, lever or plunger that is manually actuated by a human operator. Such manual control can be provided instead of or in addition to a more automatic, computer-driven procedural control. In some cases actuation of the manual control can immediately override an automatic procedure in operation. In some cases the manual control is independent from programmed automatic procedures. For example, the manual control can allow operation outside predefined bounds of the automatic procedure such as exceeding a programmed maximum flow rate and/or decreasing below a programmed minimum flow rate.

Turning to FIGS. 9-11, some preferred embodiments provide systems that include an automated syringe driver assembly for automating actuation of the syringe assembly and fluid delivery and/or recovery according to a preprogrammed procedure. The embodiments shown in FIGS. 9-11 illustrate systems including a syringe driver assembly for the purpose of automating the delivery of the syringe contents to the patient. In a preferred embodiment, a person can override the syringe driver assembly if desired. For example, in some cases the syringe assembly mounts into the syringe driver in a manner that allows the user to easily decouple the syringe assembly and quickly revert to manual operation if so desired. In some embodiments the syringe driver assembly includes a manually-actuated rate control, which allows a person to manually control and vary the actuation rate of an otherwise automatic syringe driver (e.g., as described above in one embodiment).

Manual override capabilities can provide one or more advantages when integrated with a power-assisted driver assembly. For example, an automatic system can use a fixed

protocol for infusion, meaning that it cannot adjust the infusion protocol to respond to various situations, such as an adverse event or patient feedback about the degree of heat. According a preferred embodiment of the invention, a patient's expression of heat and/or adverse events during the infusion can be cues to the infusionist to increase, decrease, and/or stabilize the rate of infusion to achieve the optimum amount of infusion time at the highest rates of infusion (with overall infusion rate and time being elastic to efficacy in some cases). If patient cues indicate to the infusionist that efficacy and patient comfort, for example, require infusion rates (e.g., displayed on the monitor) inconsistent with the rates and times in the pre-programmed automated protocol, the infusionist can override the automated protocol.

According to some embodiments, a manual override can include changing and/or setting a rate of infusion by manually actuating a rate control. For example, in some cases rotating a rheostat type control clockwise can increase the infusion rate, while rotating the control counterclockwise decreases the infusion rate. Accordingly, an infusionist can easily manually override a pre-programmed protocol under appropriate condition by simply actuating the control. According to some embodiments, the manual control is independent from and allows operation outside of the pre-programmed automatic procedures, as described above. Thus operation can be adjusted as desired based upon patient feedback unconstrained by pre-programmed limitations such as maximum/minimum flow rates and/or infusion times.

In certain embodiments, a manual override can include detaching the syringe and sensor assemblies from the automated syringe driver by hand. In some cases detaching the syringe/sensor assembly causes the pre-programmed, automated infusion mode to switch to the manual mode by default (e.g., the driver will stop after the syringe is removed, while the monitor will continue receiving data from any sensors with the syringe). The infusion can then be powered manually by the infusionist pushing on the syringe plunger. This provides the infusionist with a greater degree of control over the infusion as well as the sensations and experience that comes with manually powering and controlling the infusion according to cues coming from the monitor and feedback from the patient. In some cases such a manual override can be especially useful for patients with traumatic brain injury, as a patient may experience a variety of sensations that provide cues for controlling the infusion rate that can lead to increased efficacy.

FIGS. 9 and 10 illustrate examples of an integrated system including a syringe assembly, while FIG. 11 illustrates an exemplary system having a modular configuration.

Referring to FIG. 9, certain embodiments of the invention provide an integrated system 900 including a monitor 904, a syringe assembly 902, a syringe driver assembly 930,

and a sensor interface module 920 coupling additional sensors such as a blood pressure sensor 922 and a pulse oximeter 924 to the system 900. Although not shown in this view, the syringe assembly 902 includes a sensor assembly coupled to the syringe for sensing one or more parameters related to the infusion flow and transmitting the sensor readings to the monitor 904 (e.g., through the sensor interface module 920). In some cases the driver assembly 930 can also include an independent display 932 and a manual control knob 934.

FIG. 10 illustrates a similar, but more compact system 1000, in which the monitor 1004 includes data ports for coupling with various sensors 1022, 1024 to communicate and receive feedback corresponding to monitored parameters. While in some cases actuation of syringe assembly 1002 by the driver assembly 1030 can follow a preprogrammed, automatic procedure, actuation of the syringe driver assembly 1030 can also be manually controlled via a control knob 1032. Such manual control can be based on, for example, parameters displayed on the monitor 1004 and audio/visual feedback from the patient.

FIG. 11 illustrates a system 1100 having similarities to previously illustrated embodiments, but employing a modular configuration. In this embodiment the syringe driver mechanism 1140 and syringe assembly 1102 (including a sensor assembly, not shown) are optionally coupled to the monitor 1104, along with sensors 1122, 1124, via communication links such as wired and/or wireless links 1130. According to some embodiments, the driver assembly 1140 can include an electronic or digital control interface 1142 for programming and/or manually controlling the power-assisted drive mechanism.

Figures 12-14, 16, and 17 illustrate views of various syringe drive assemblies according to multiple embodiments of the invention. According to some embodiments, a typical syringe driver assembly preferably includes at least an energy source, an energy control mechanism, and an energy delivery mechanism. In certain embodiments, an energy source for a driver assembly can include one or more of the following: electrical power from an AC Mains, a rechargeable battery, a disposable battery, operator supplied power, a loaded spring, a pneumatic reservoir (e.g., CO2 cartridge), a hydraulic reservoir, a mixed pneumatic/hydraulic reservoir, a capacitive storage, and/or chemical reaction. In certain embodiments, an energy control mechanism can be provided in the form of, e.g., a manual valve, solenoid, friction brake, and/or remote control (e.g., power steering). In certain embodiments, an energy delivery mechanism can be provided as, e.g., a piston/cylinder, electric motor, gear/pinion, ratchet, and/or linear slide. Of course other forms of, and combinations of, energy sources, controls, and delivery mechanisms are also possible and the scope of the invention is not restricted in this sense.

As discussed above, exemplary syringe driver assemblies can be controlled manually and/or automatically. For example, a computer can automatically control operation of the driver in order to provide infusion characteristics according to a preprogrammed procedure. In some cases a power-assisted driver assembly can be exclusively controlled by hand, or otherwise at the direction of the infusionist during the procedure according to feedback received from the patient. In some embodiments, both automatic and manual control can be provided, such as in the case of a computer-driven automatic procedure that can be interrupted and overridden by a manual control.

In certain embodiments, an automated system can be controlled in a variety of manners as will be appreciated by those skilled in the art, and the following examples are meant to be non-limiting. For example, movement of a syringe driver can be controlled through one or more physical actuators, such as a linear potentiometer, a lever, a control by wire, a mechanical override, valving, and/or a variable rate foot pedal. In some cases an automated system can be computer controlled, such as through software (and optional interactions through a graphic user interface), firmware, and/or a programmed computer programmable logic device (independent of software). In some cases control can also be provided alternatively or additionally based on patient feedback in the form of history records (used to derive parameters for process control), blood pressure, SpO2 and heart rate.

According to certain embodiments, control mechanisms can be positioned and located in any suitable location providing access to the syringe driver assembly. For example, in certain embodiments, control features can optionally be positioned on either the monitor assembly or on the syringe driver assembly. In some cases executable software instructions and/or a programmable processor can be located within the driver assembly, within the monitor, and/or within a remotely connected computer (directly or indirectly connected).

In an automated mode, a syringe driver can be programmed to conduct a wide variety of infusion procedures. In certain embodiments, the automated syringe drive provides a programmed acceleration mode providing the ability to gradually increase the rate of infusion from a rate of A to a rate of B over X seconds (or minutes). In some cases this feature can be stopped and restarted at any point during the infusion process. In some embodiments the rates of infusion can mimic a progression of multiple infusion rates that can be used for a manual syringe. For example, a sequence of multiple rate changes can be programmed to occur over any desirable period, e.g., second, minute, hour, etc.

As discussed above, certain embodiments include an override feature, which allows an operator to manually override a default automated mode. In some cases a system can also

be easily returned to an automated mode after the need for manual operation has passed. In a preferred embodiment, an override feature provides an actuator (e.g. such as a button, lever, and/or knob) to increase or decrease the rate of the syringe assembly actuation, e.g., optionally almost instantaneously. For example, the actuator manually overriding the automation mode could include a foot control, voice control, a hand held control pod, a mouth held control pod, and/or a blink control. In some cases the actuator can take control of the syringe driver assembly. In some embodiments the actuator can instead or alternatively physically decouple the syringe assembly from the automated drive assembly to allow operation by hand.

FIG. 12 is a perspective view of a syringe driver assembly 1200 according to one preferred embodiment of the invention. The driver assembly 1200 includes an energy source, such as an electrical connection or a pneumatic/hydraulic mechanism (not shown), a control mechanism (e.g., including a processor-driven motor and/or a manual control knob 1202), and a deliver mechanism including a linear slide 1204. The driver assembly also includes a data communication port 1206 (e.g., USB, serial, parallel, IEEE 1394, etc.) and/or a wireless data transmitter for connecting the driver assembly 1200 to a monitor or other remote computing device. In a preferred embodiment, the driver 1200 in configured to receive a syringe assembly 1220 including a syringe 1230 and a sensor assembly 1240 coupled to the syringe 1230. In some cases, the driver assembly 1200 can also include a sensor port 1208, which optionally allows the sensor assembly 1240 to be coupled to the driver assembly (e.g., an on to a monitor, etc.) for transmitting sensor information. As shown in FIG. 12, the portion of the driver assembly that receives the syringe assembly 1220 can be configured to allow easy and quick installation and/or removal of the syringe assembly (including the sensor assembly) from the driver assembly.

FIG. 13 is a perspective view of another driver assembly 1300 according to a preferred embodiment of the invention. FIG. 14 is a back perspective view of the driver assembly 1300 with panels removed to illustrate one example of a pneumatic energy system 1350. The driver 1300 includes a number of features in common with the example shown in FIG. 12, including a linear slide 1304, a manual control 1302, a sensor port 1308, and a data communication port 1306. In some cases, the driver assembly 1300 also includes a vent or relief valve control 1360 coupled with the pneumatic system to release the pressure within the system before manually overriding the automatic control. As shown in FIG. 14, the pneumatic system 1350 includes two reservoirs or accumulators 1370 of compressed gas, which are coupled to a cylinder and piston (not shown) via a solenoid valve 1372. Upon

actuating the valve 1372, gas is released in the cylinder to drive the piston and the attached slide 1304.

Turning to FIG. 16, in one preferred embodiment, an pneumatic syringe driver assembly 1600 includes a hand-driven pneumatic pump 1602 as the energy source and a pneumatic accumulator 1604 as the pneumatic energy storage mechanism. A gate valve is employed to control start and stop functions and a needle valve controls for metering pneumatic flow. Energy transmission is accomplished via a pneumatically driven piston coupled to a linear slide 1606 that engages a syringe plunger.

Referring to FIG. 17, in some embodiments a hydraulic syringe driver assembly 1700 includes a hydraulic fluid reservoir 1702. A gate valve is employed to control start and stop functions and a needle valve controls for metering hydraulic flow. Energy transmission is accomplished via a hydraulically driven piston (not shown) coupled with a linear slide 1704 that engages a syringe plunger.

In related embodiments, the invention includes a sensor assembly comprising a housing and a sensing device, the housing adapted to be coupled to a syringe assembly at the time of use for determining one or more parameters associated with fluid delivery and/or withdrawal from the syringe assembly. Optionally, the sensor assembly can further comprise a port for coupling with a data link allowing the sensor assembly to be coupled to a monitor adapted to receive and display data from the sensor assembly. Also optionally, and preferably, the housing is provided with one or more features that couple and/or lock the sensor to the syringe in a removable, semi-permanent, or permanent manner.

In a related manner, the invention provides a kit for use in treating a medical condition, comprising one or more sensor assemblies adapted to determine one ormore parameters associated with fluid delivery and/or withdrawal from one ormore respective syringe assemblies. Such a kit can comprise one or more syringe assemblies, and optionally and preferably, also comprises one or more solutions for delivery with the syringe assembly, such solutions being selected, for instance, from the group consisting of solutions containing magnesium, a buffer, a diluent, and/or B vitamins. In one such embodiment, separate magnesium, buffer and diluent solutions are provided in amounts and concentrations that permit them to be mixed at the time of use in order to provide an injectable solution.

In yet another manner, the syringe assembly of this invention can be manually and/or automatically driven, and if automatically driven and can also include a manual override permitting the syringe assembly to be manually driven, or the syringe assembly with sensor

assemby can be physically detached from the system in order to permit the solution to be infused manually.

Similarly, the where the syringe assembly is automatically driven, the system can further comprise an energy source, an energy control mechanism, and an energy delivery mechanism, for instance, where the energy source is selected from the group consisting of alternating current, a rechargeable battery, a disposable battery, operator supplied power, a loaded spring, a pneumatic reservoir, a hydraulic reservoir, a mixed pneumatic/hydraulic reservoir, a capacitive storage, and/or chemical reaction; where the energy control mechanism is selected from the group consisting of a manual valve, solenoid, friction brake, and/or remote control, and/or where the energy delivery mechanism is selected from the group consisting of a piston and cylinder, electric motor, gear and pinion, ratchet, and/or linear slide. Finally, a monitor as described herein can include a menu driven architecture comprising a touch screen, pointer, or keyboard, the monitor permitting multiple views of data or information.

Thus, embodiments of the invention are disclosed. Although the present invention has been described in considerable detail with reference to certain disclosed embodiments, the disclosed embodiments are presented for purposes of illustration and not limitation and other embodiments of the invention are possible. One skilled in the art will appreciate that various changes, adaptations, and modifications can be made without departing from the spirit of the invention and the scope of the appended claims.

CLAIMS

1. A system for delivering or withdrawing a fluid to or from the body of a patient in a manner that permits delivery to be controlled based upon feedback from the patient, the system comprising:

a) a syringe assembly comprising a syringe adapted to contain, and to deliver and/or withdraw, a fluid to and/or from the body, the syringe being operably coupled to one or more sensors adapted to determine one or more corresponding parameters associated with fluid delivery and/or withdrawal, and

b) a monitor adapted to be communicably associated with the one or more sensors of the syringe assembly, the monitor comprising one or more read out mechanisms either directly or indirectly corresponding to the one or more fluid delivery/withdrawal parameters.

2. A system according to claim 1, wherein at least one sensor and corresponding parameter associated with the syringe is selected from the group consisting of: rate of fluid delivery or withdrawal, amount of fluid delivered or withdrawn at any point in time and/or in total, amount of drug or material delivered or withdrawn at any point in time and/or in total, concentration of drug or material being delivered, pressure of fluid delivery or withdrawal, velocity of the fluid delivered or withdrawn, time associated with fluid delivery or withdrawal, size of the syringe being used, and amount of fluid in the syringe being used.

3. A system according to claim 1, wherein the system comprises one or more additional sensors or inputs, not operably coupled to the syringe assembly but providing corresponding additional parameters that are communicably associated with the monitor.

4. A system according to claim 3, wherein the additional parameters comprise biological data selected from the group consisting of temperature, oxygen saturation, respiratory rate, blood pressure, pressure at the site of infusion, and heart rate.

5. A system according to claim 1, wherein the monitor provides one or more features selected from the group consisting of memory/recall function, printout capability, calibration means, fail safe mechanisms, patient thermal indicator, reset button, and a power indicator.

6. A system according to claim 1 wherein the syringe and sensor are adapted to be coupled at the time of use.

7. A system according to claim 1, wherein the sensor is provided with one or more features that couple and/or lock the sensor to syringe in a removable, semi-permanent, or permanent manner.

8. A system according to claim 7 wherein the coupled sensor is communicably associated with the monitor by communication link selected from the group consisting of wired and wireless links.

9. A system according to claim 1, wherein the syringe contains a fluid to be delivered.

10. A system according to claim 9 wherein the solution comprises magnesium ions, and the syringe assembly is adapted to be manually controlled based upon feedback from the patient regarding thermal sensation.

11. A method of using a system according to claim 9, the method comprising the steps of providing the system of claim 9 and delivering the fluid to a patient in a controlled manner based upon feedback from the patient.

12. A method according to claim 11, wherein the delivery is manually controlled based upon one or more patient indicators selected from the group consisting of thermal sensation, pain, or other physical sensation.

13. A method according to claim 11, wherein at least one sensor and corresponding parameter associated with the syringe is selected from the group consisting of: rate of fluid delivery or withdrawal, amount of fluid delivered or withdrawn at any point in time and/or in total, amount of drug or material delivered or withdrawn at any point in time and/or in total, concentration of drug or material being delivered, pressure of fluid delivery or withdrawal, velocity of the fluid delivered or withdrawn, time associated with fluid delivery or withdrawal, size of the syringe being used, and amount of fluid in the syringe being used.

14. A method according to claim 11, wherein the system comprises one or more additional sensors or inputs, not operably coupled to the syringe but providing corresponding additional parameters that are communicably associated with the monitor.

15. A method according to claim 14, wherein the additional parameters comprise biological data selected from the group consisting of temperature, oxygen saturation, respiratory rate, blood pressure, pressure at the site of infusion, and heart rate.

16. A syringe assembly adapted for use in a system according to claim 1.

17. A monitor adapted for use in a system according to claim 1.

18. A system according to claim 1, comprising a syringe and sensor operably coupled in a permanent manner, and prefilled with a solution to be delivered.

19. A system according to claim 18, wherein the solution comprises a magnesium solution, and the sensor is adapted to determine one or more parameters selected from the group consisting of: rate of fluid delivery or withdrawal, amount of fluid delivered or withdrawn at any point in time and/or in total, amount of drug or material delivered or withdrawn at any point in time and/or in total, concentration of drug or material being delivered, pressure of fluid delivery or withdrawal, velocity of the fluid delivered or withdrawn, time associated with fluid delivery or withdrawal, size of the syringe being used, and amount of fluid in the syringe being used.

20. A system according to claim 19, wherein the system comprises one or more additional sensors or inputs, not operably coupled to the syringe but providing corresponding additional parameters that are communicably associated with the monitor, the additional parameters comprise biological data selected from the group consisting of temperature, oxygen saturation, respiratory rate, blood pressure, pressure at the site of infusion, and heart rate.

21. A sensor assembly comprising a housing and a sensing device, the housing adapted to be coupled to a syringe assembly at the time of use for determining one or more parameters associated with fluid delivery and/or withdrawal from the syringe assembly.

22. The sensor assembly of claim 21, further comprising a port for coupling with a data link allowing the sensor assembly to be coupled to a monitor adapted to receive and display data from the sensor assembly.

23. A system according to claim 21, wherein the housing is provided with one or more features that couple and/or lock the sensor to the syringe in a removable, semi-permanent, or permanent manner.

24. A kit for use in treating a medical condition, comprising one or more sensor assemblies adapted to determine one ormore parameters associated with fluid delivery and/or withdrawal from one ormore respective syringe assemblies.

25. The kit of claim 24, further comprisingone or more syringe assemblies.

26. The kit of claim 25, further comprising asolution for delivery with the syringe assembly.

27. The kit of claim 26, wherein the solutionis selected from the group consisting of solutions containing magnesium, a buffer, a diluent, and/or B vitamins.

28. The kit of claim 27 wherein separate magnesium, buffer and diluent solutions are provided in amounts and concentrations that permit them to be mixed at the time of use in order to provide an injectable solution.

29. A system according to claim 1 wherein the syringe assembly can be manually and/or automatically driven.

30. A system according to claim 29 wherein the syringe assembly can be automatically driven and includes a manual override permitting the syringe assembly to be manually driven, or the syringe assembly with sensor assemby can be physically detached from the system in order to permit the solution to be infused manually.

31. A system according to claim 29, wherein the syringe assembly can be automatically driven, and the system further comprises an energy source, an energy control mechanism, and an energy delivery mechanism.

32. A system according to claim 31 wherein the energy source is selected from the group consisting of alternating current, a rechargeable battery, a disposable battery, operator supplied power, a loaded spring, a pneumatic reservoir, a hydraulic reservoir, a mixed pneumatic/hydraulic reservoir, a capacitive storage, and/or chemical reaction.

33. A system according to claim 31 wherein the energy control mechanism is selected from the group consisting of a manual valve, solenoid, friction brake, and/or remote control.

34. A system according to claim 31 wherein the energy delivery mechanism is selected from the group consisting of a piston and cylinder, electric motor, gear and pinion, ratchet, and/or linear slide.

35. A system according to claim 1 wherein the system further comprises a monitor that provides a menu driven architecture comprising a touch screen, pointer, or keyboard, the monitor permitting multiple views of data or information.

Fig. 1

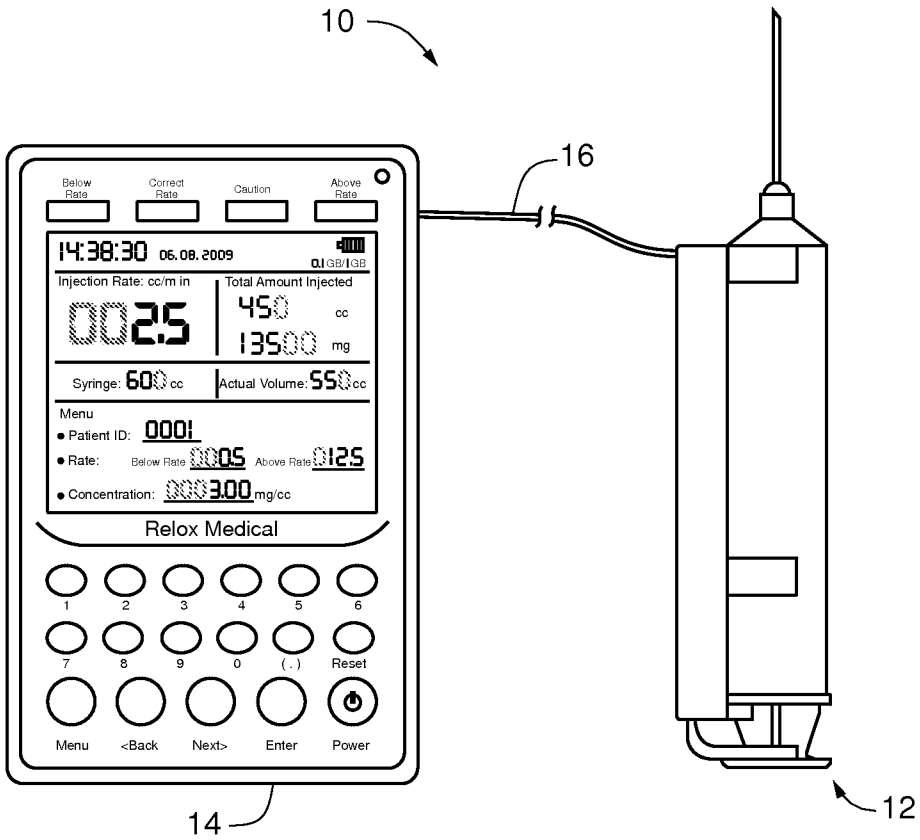

10
16
Below Rate
Correct Rate
Caution
Above Rate
14:38:30 06.08.2009
0.1 GB/1GB
Injection Rate: cc/m in
0025
Total Amount Injected
450 cc
13500 mg
Syringe: 600 cc
Actual Volume: 550 cc
Menu
Patient ID: 0001
Rate: Below Rate 0005 Above Rate 0125
Concentration: 0003.00 mg/cc
Relox Medical
1 2 3 4 5 6
7 8 9 0 (.) Reset
Menu <Back Next> Enter Power
14
12

Fig. 2A

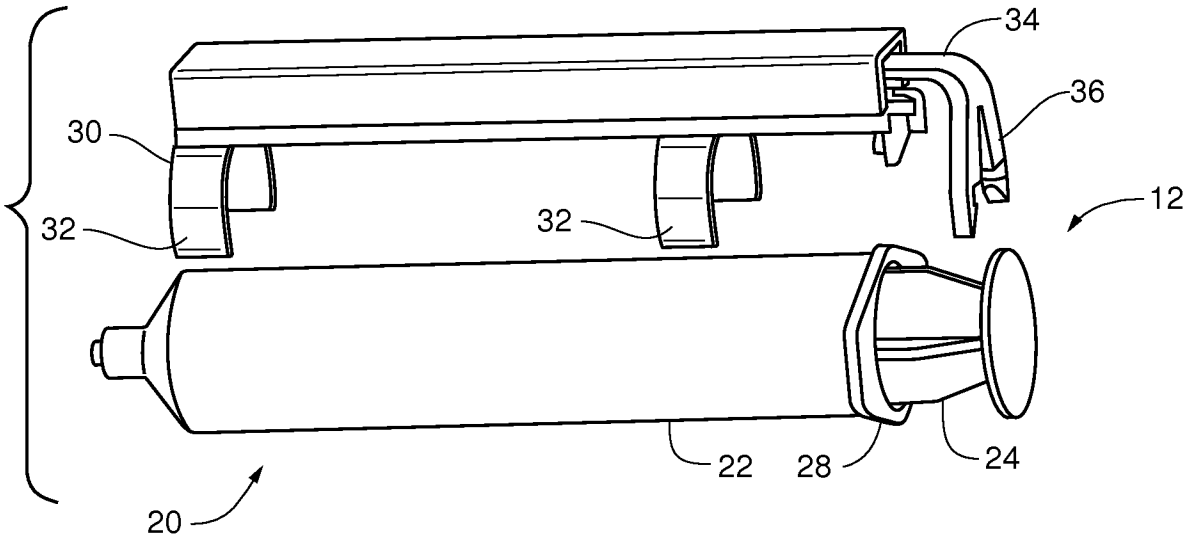


Fig. 2B

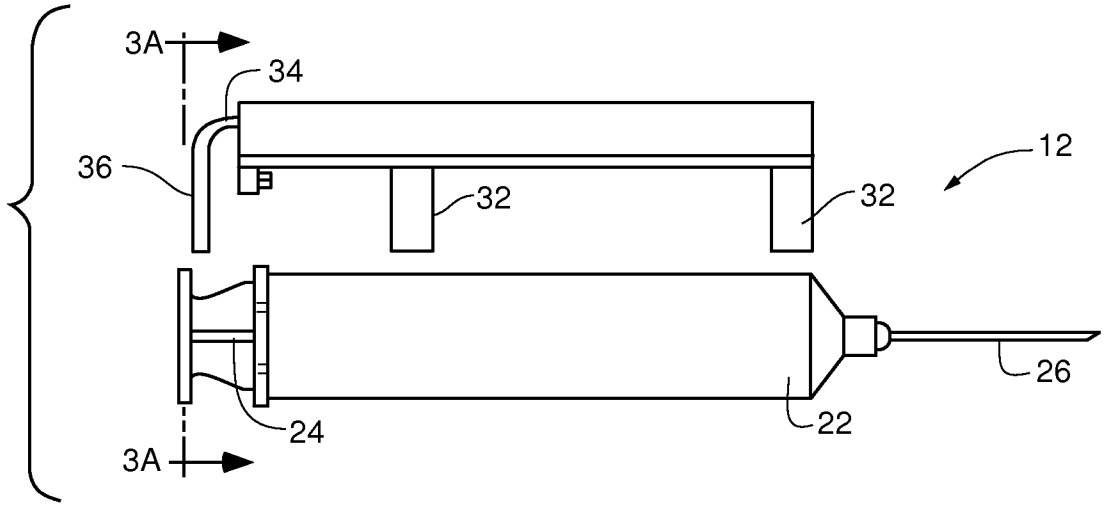


Fig. 2C

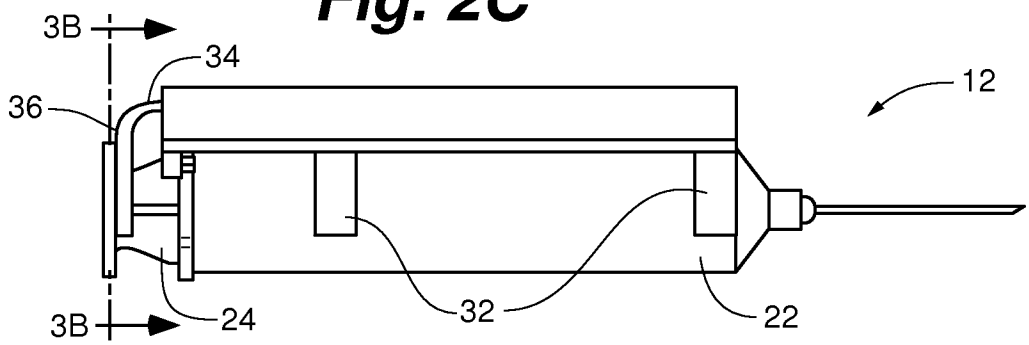


Fig. 3A

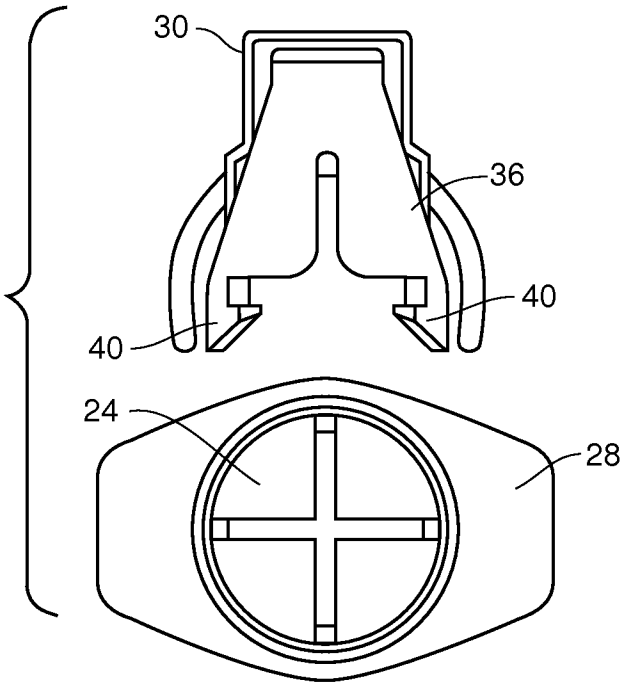


Fig. 3B

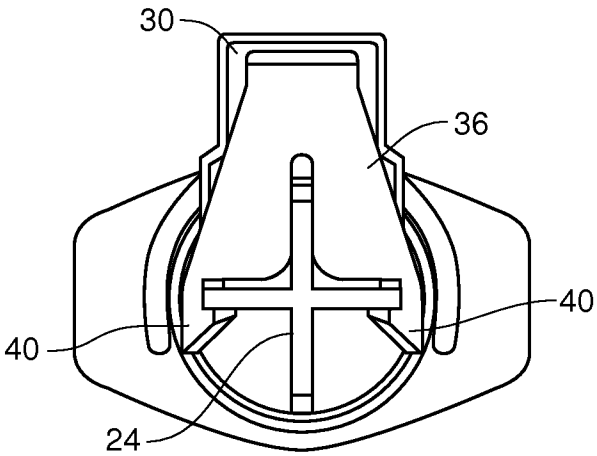


Fig. 3C

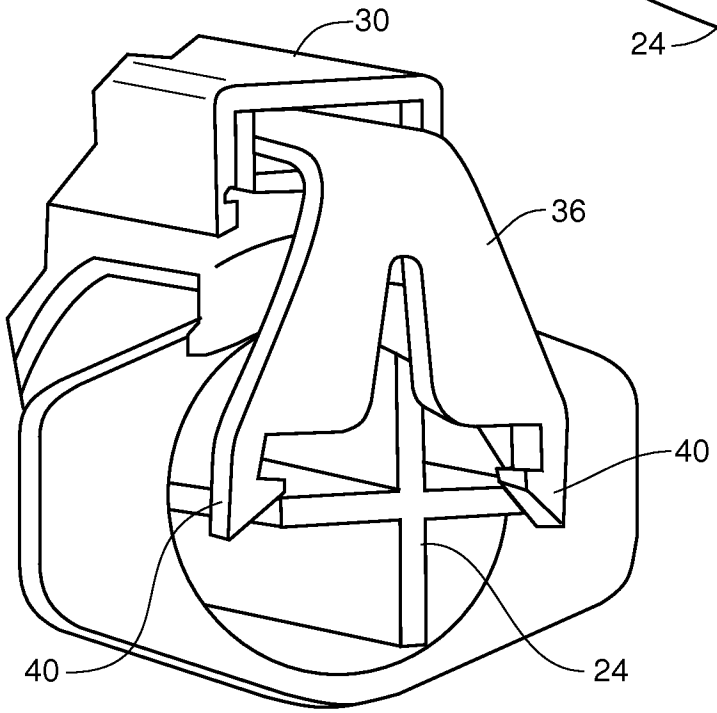


Fig. 4A

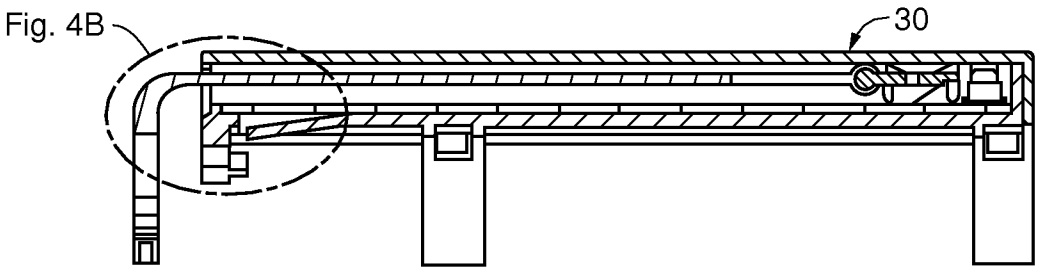


Fig. 4B

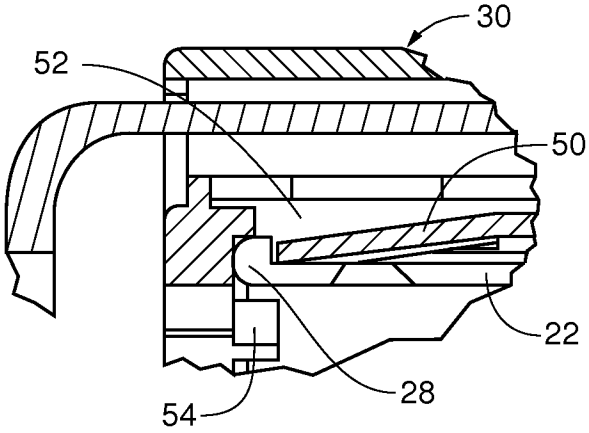


Fig. 4C

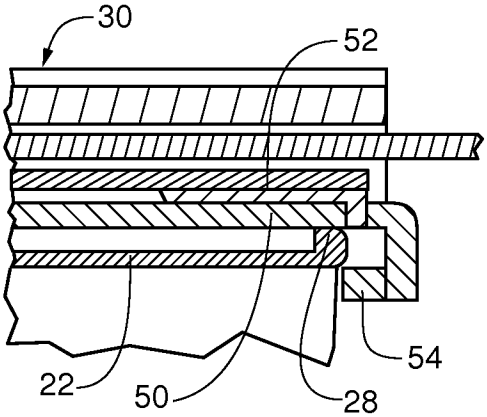
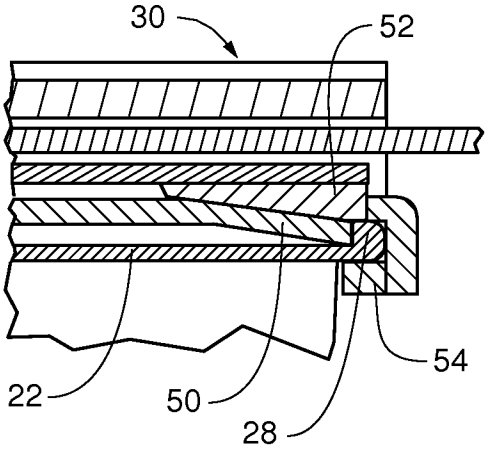


Fig. 4D



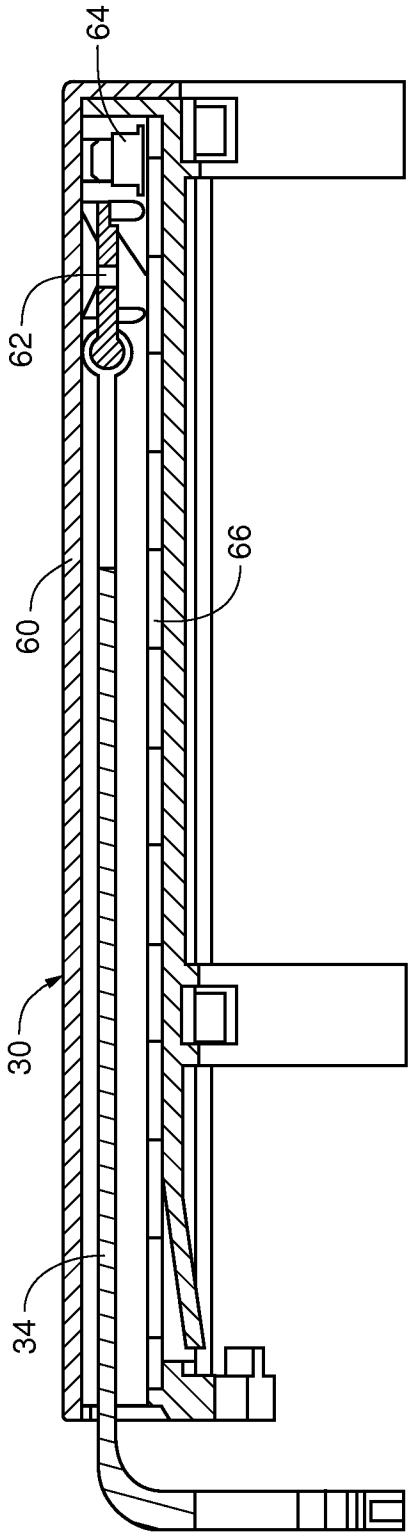


Fig. 5

Fig. 6A

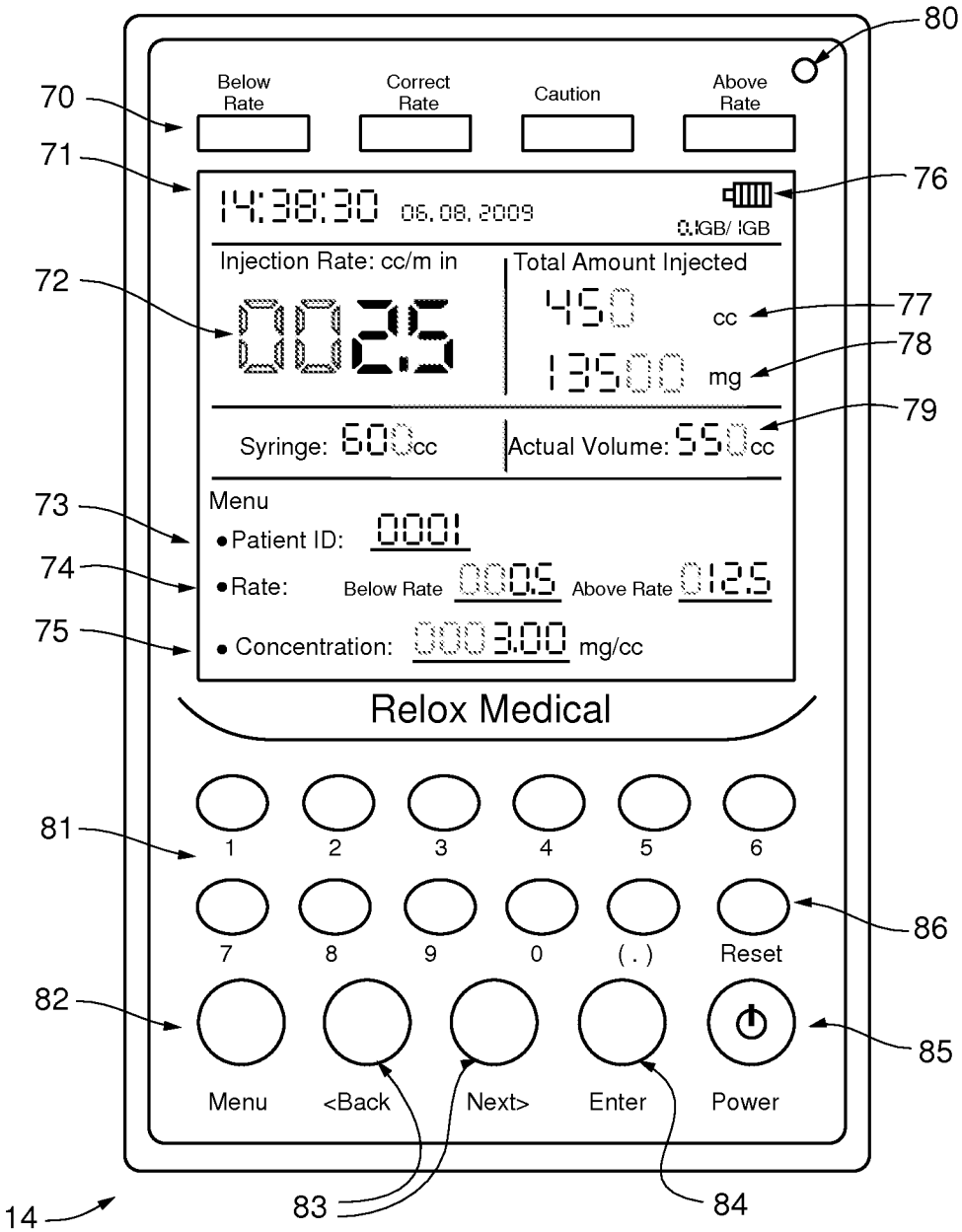

80
70
71
72
73
74
75
76
77
78
79
81
82
83
84
85
86
14
Below Rate
Correct Rate
Caution
Above Rate
14:38:30
06.08.2009
Injection Rate: cc/m in
0025
Total Amount Injected
450
cc
13500
mg
Syringe: 600cc
Actual Volume: 550cc
Menu
• Patient ID: 0001
• Rate: Below Rate 0005 Above Rate 0125
• Concentration: 0003.00 mg/cc
Relox Medical
1
2
3
4
5
6
7
8
9
0
(.)
Reset
Menu
<Back
Next>
Enter
Power

Fig. 6B

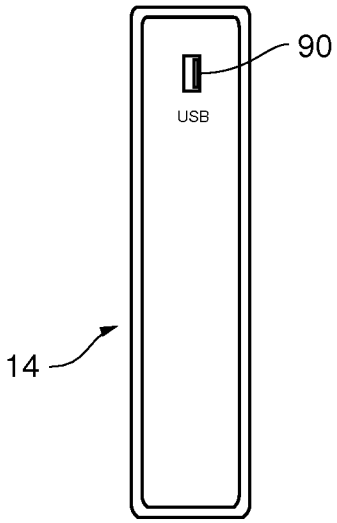


Fig. 6C

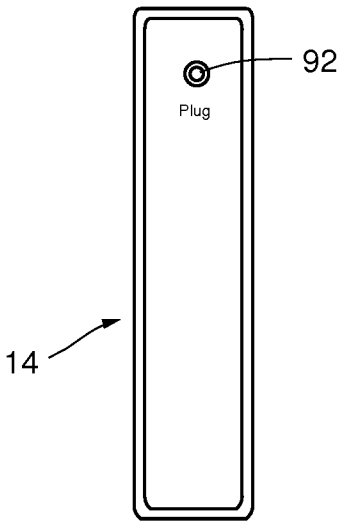


Fig. 6D

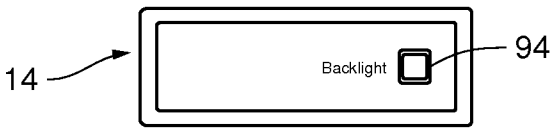
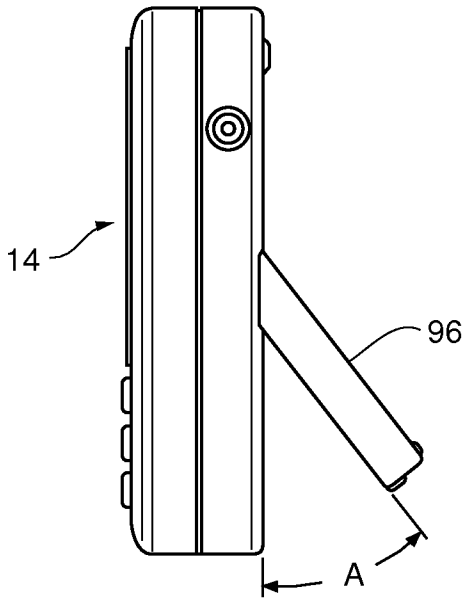


Fig. 7



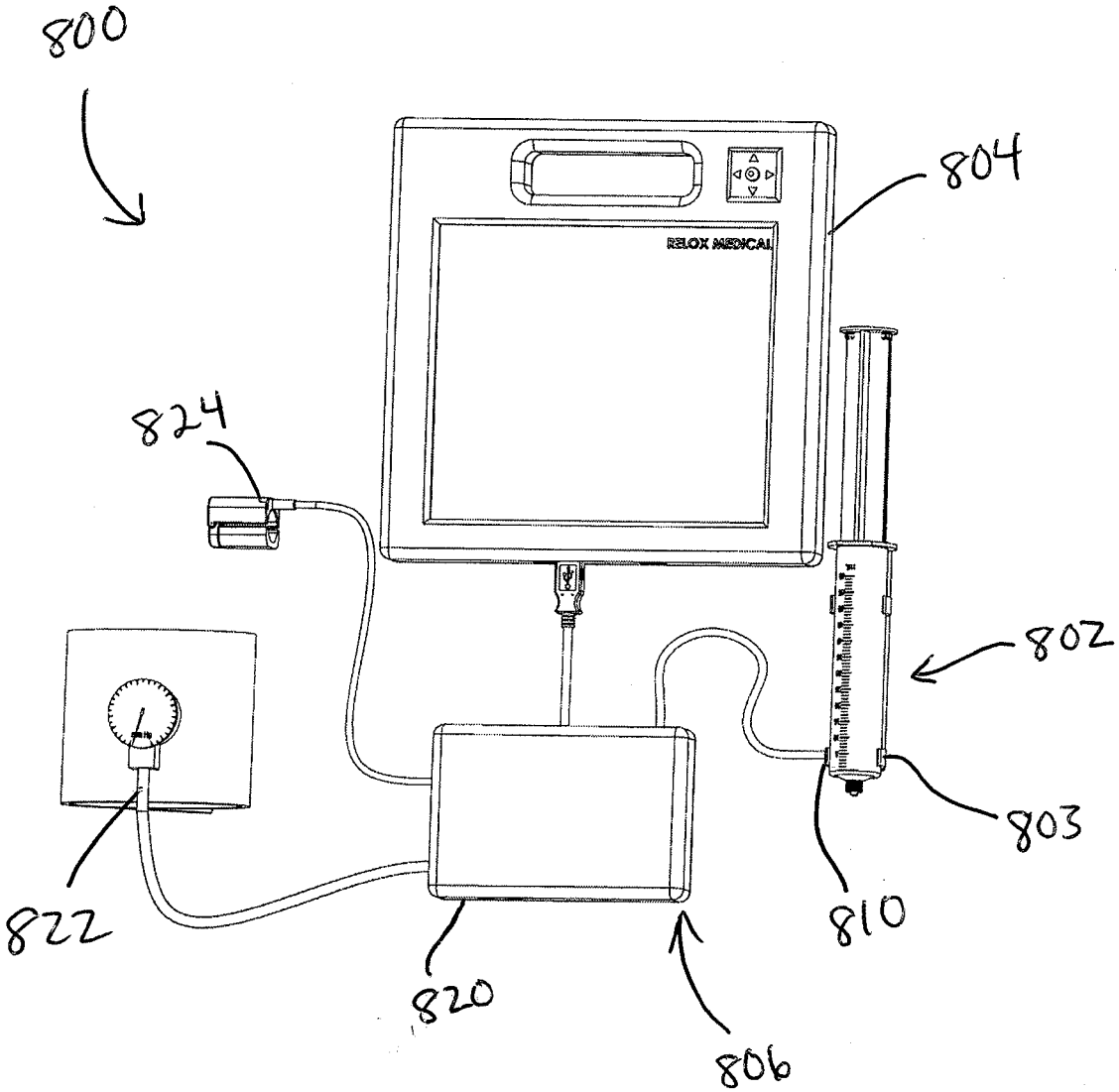


FIG. 8

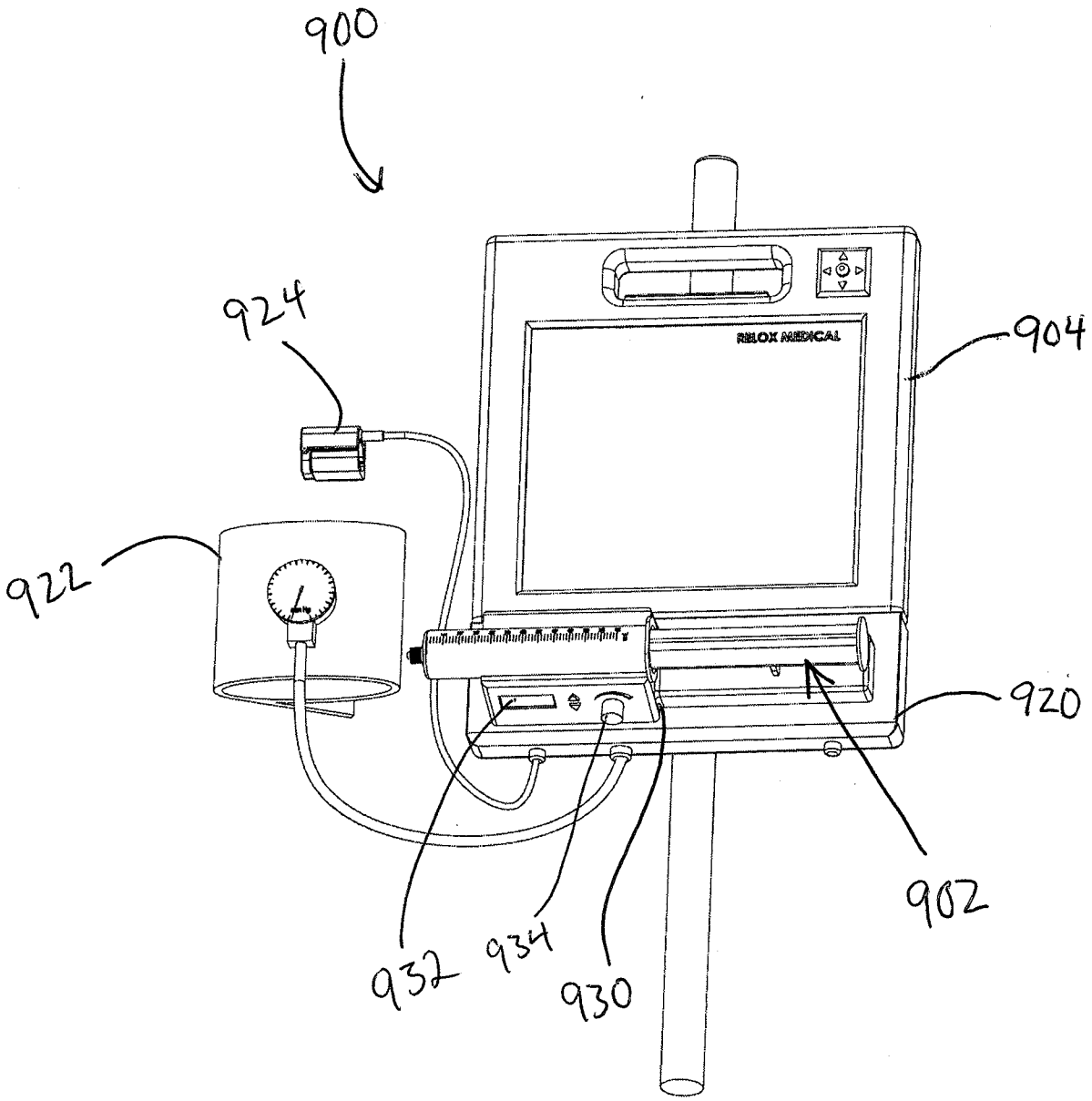


FIG. 9

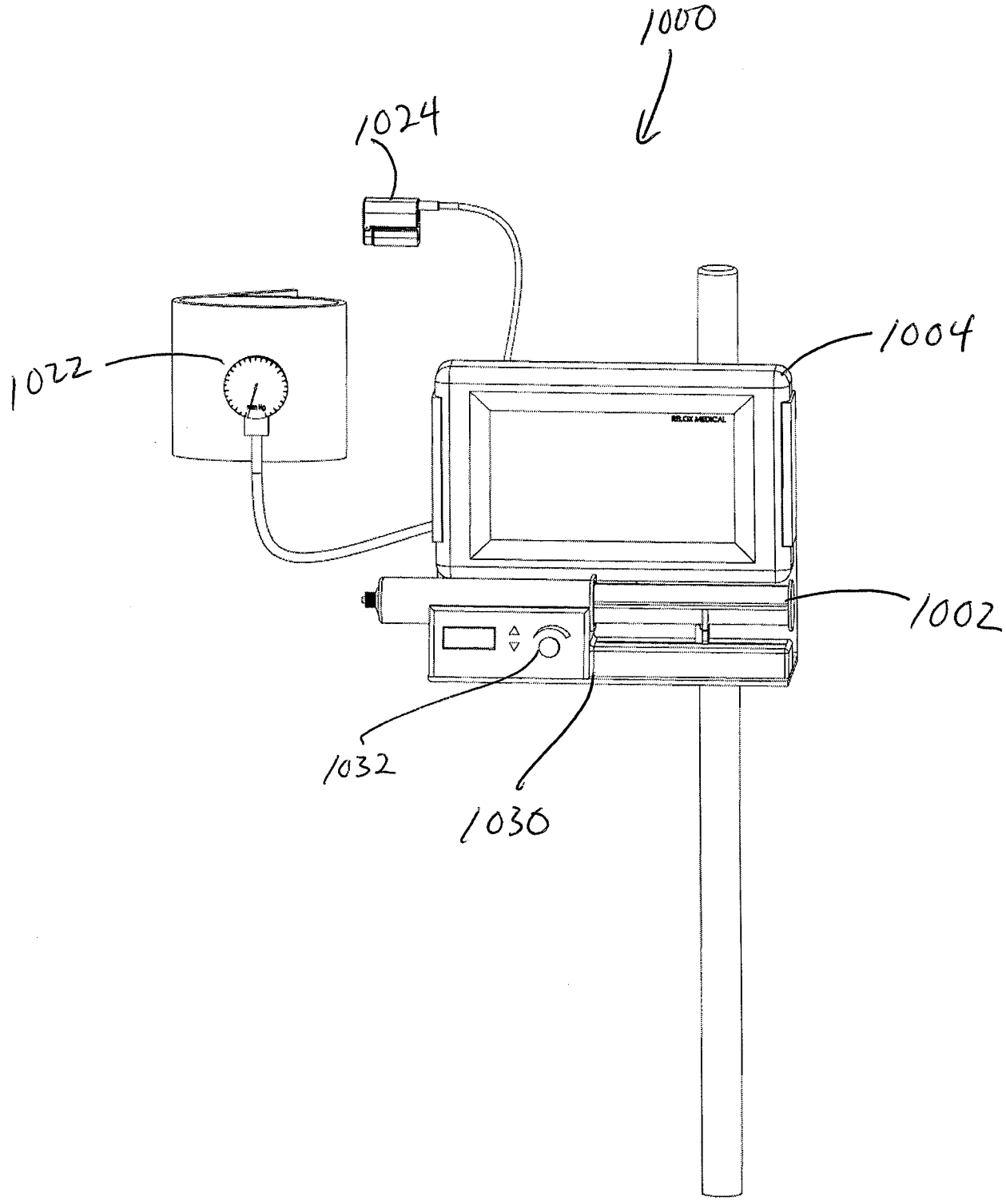


FIG. 10

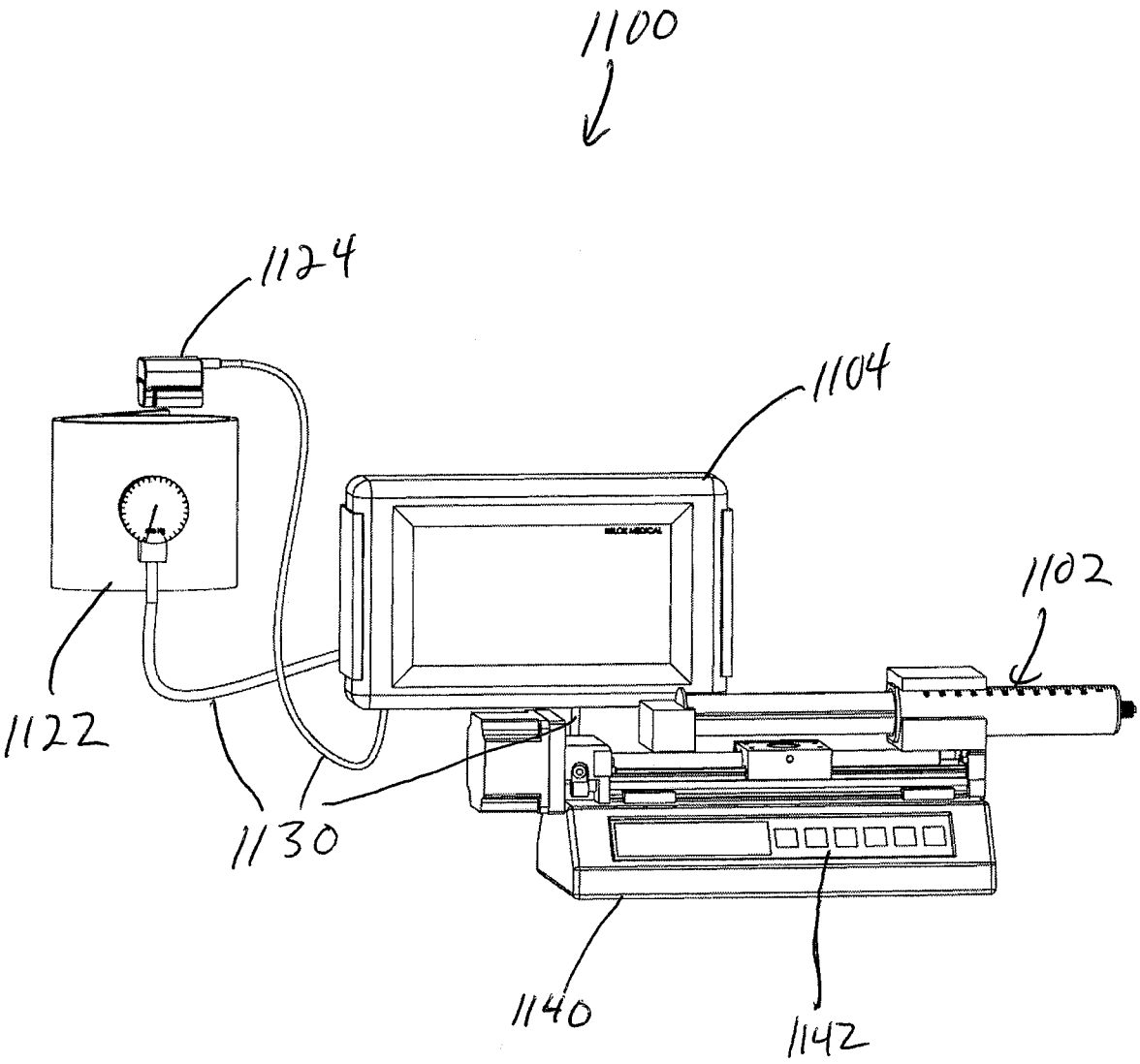


FIG. 11

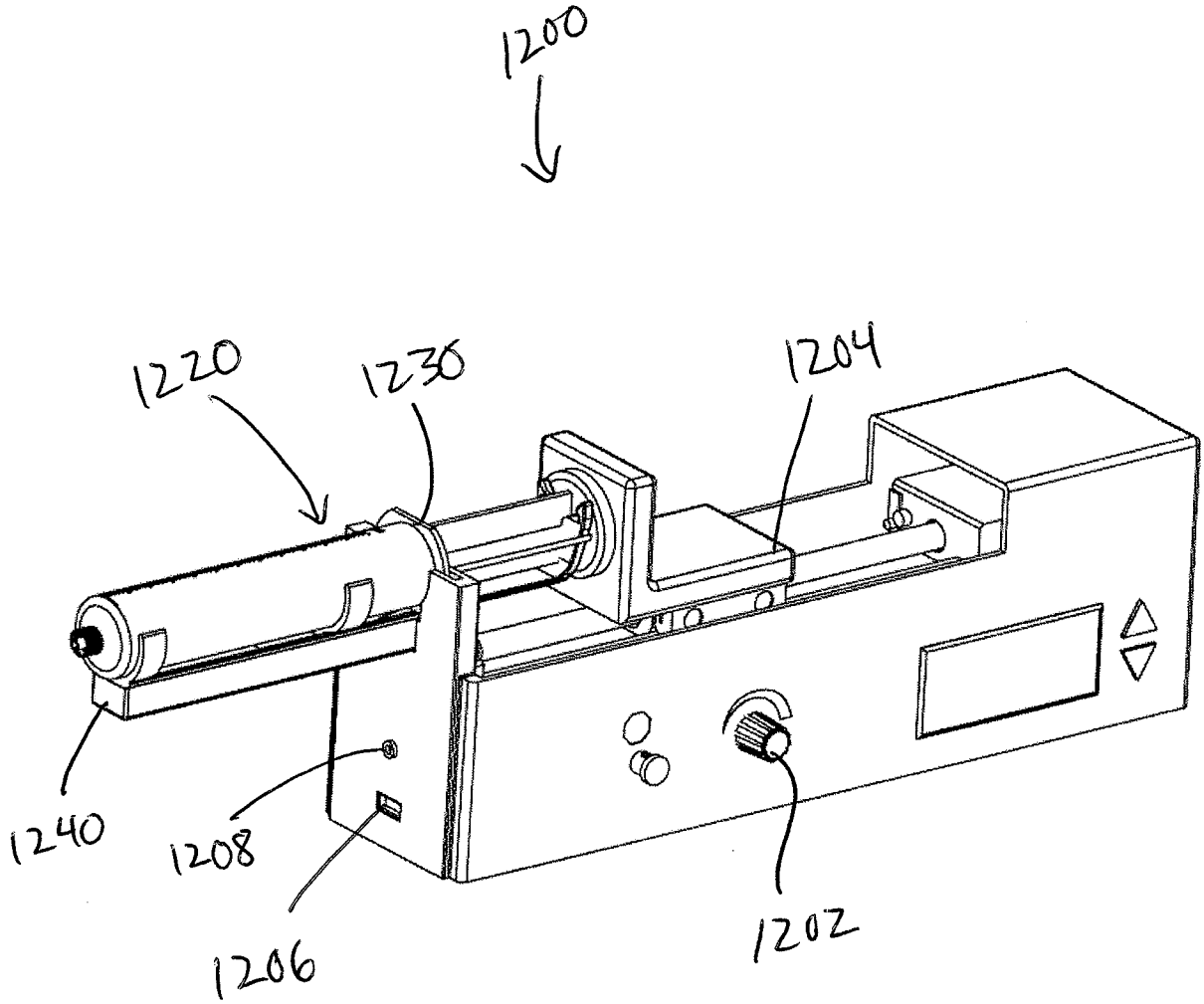


FIG. 12

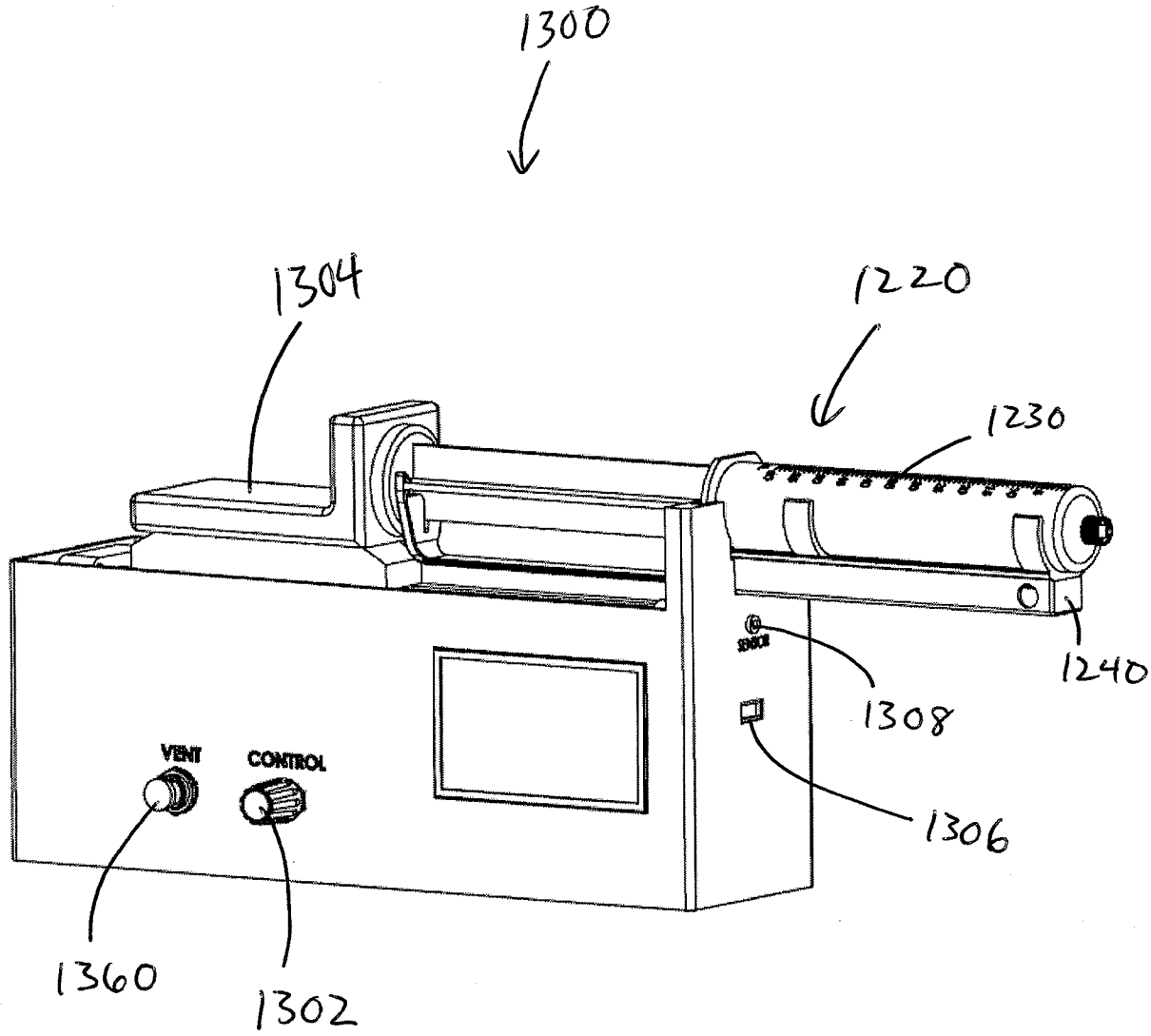


FIG. 13

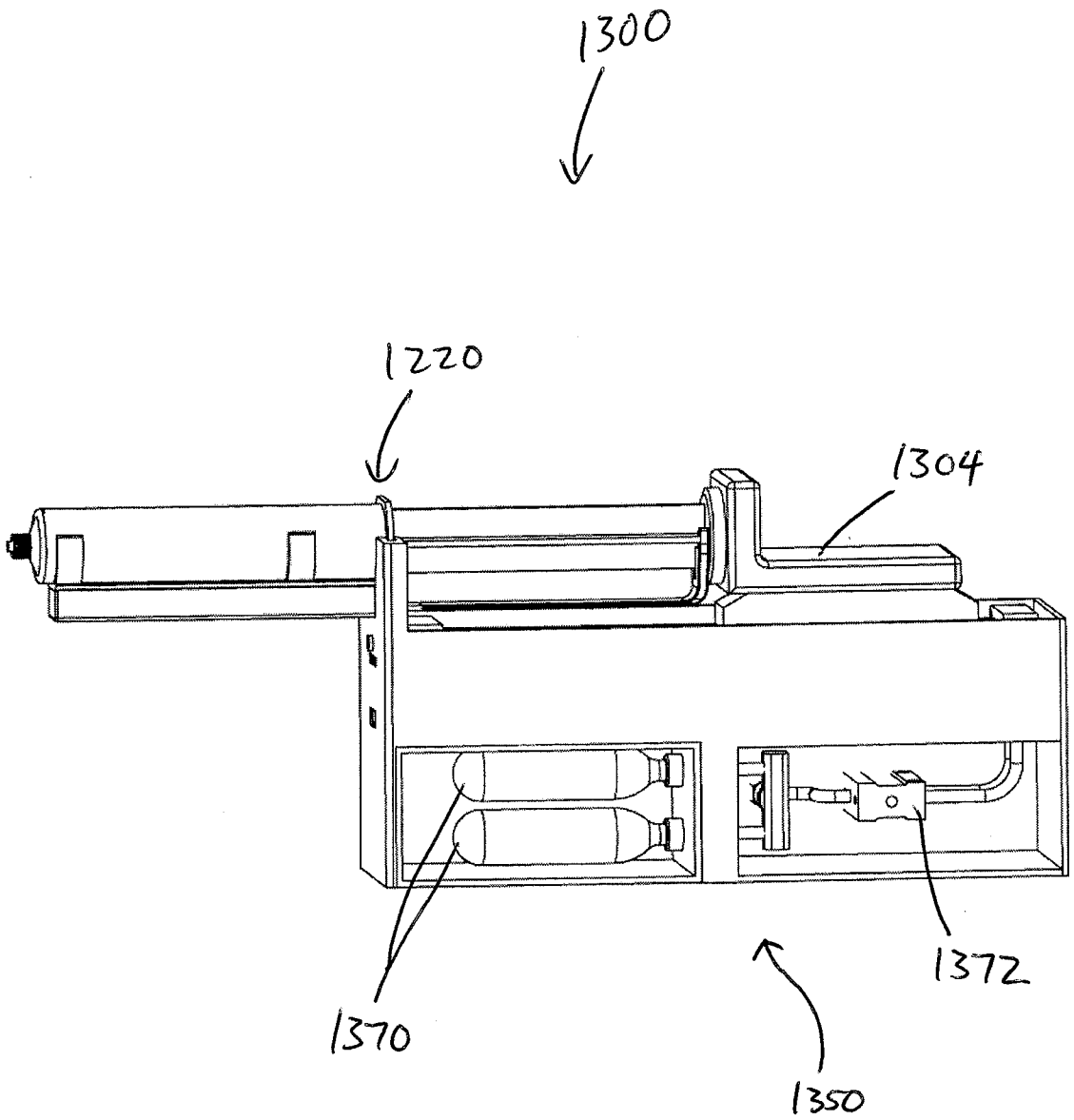


FIG. 14

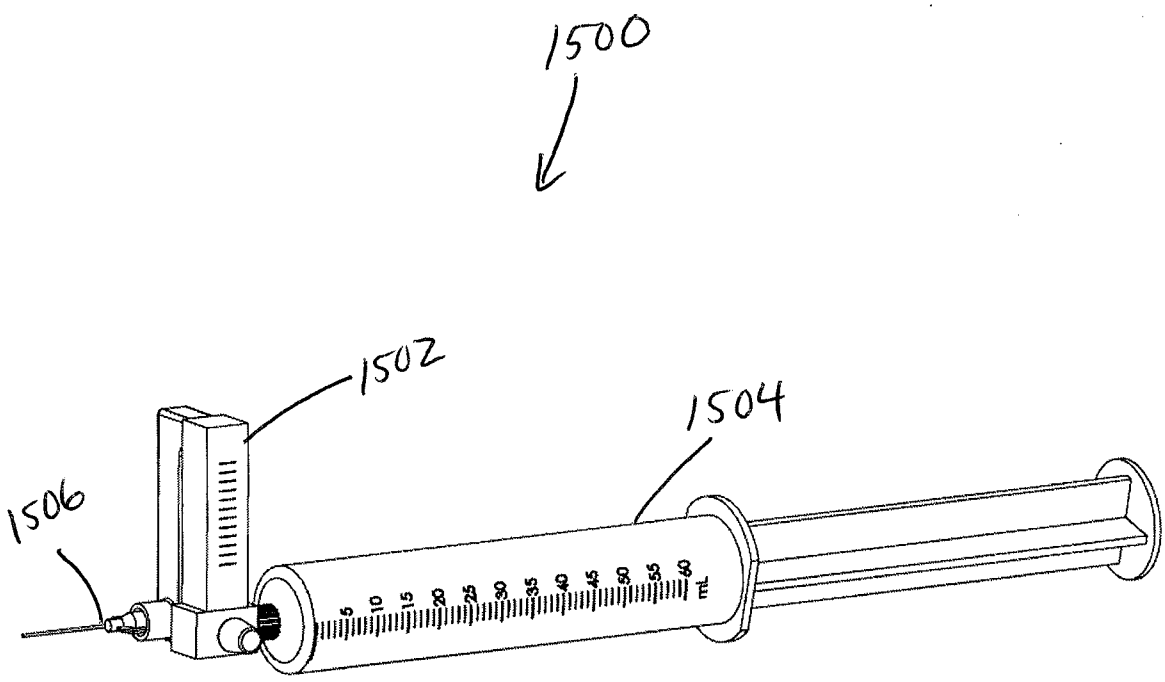


FIG. 15

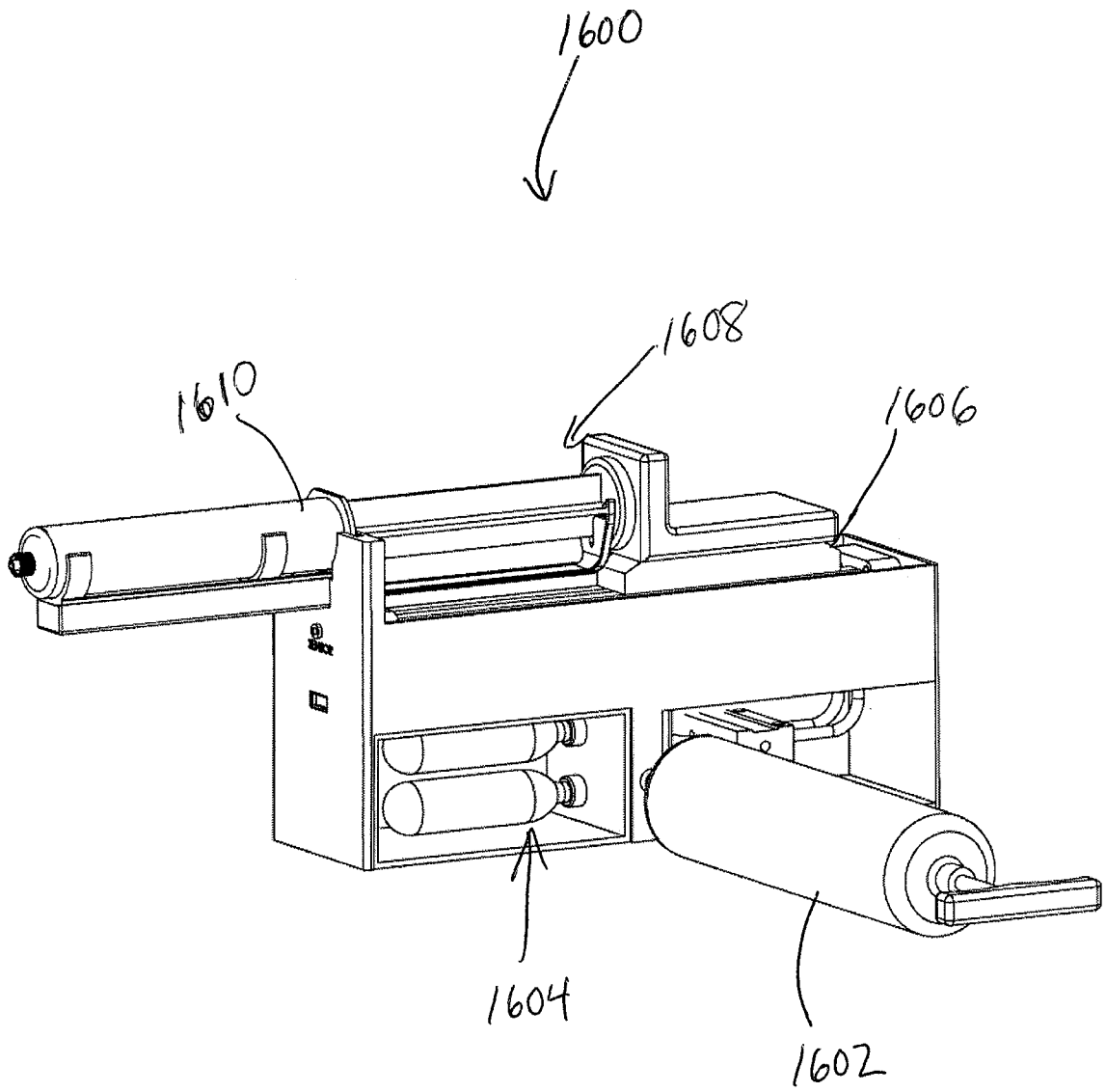


FIG. 16

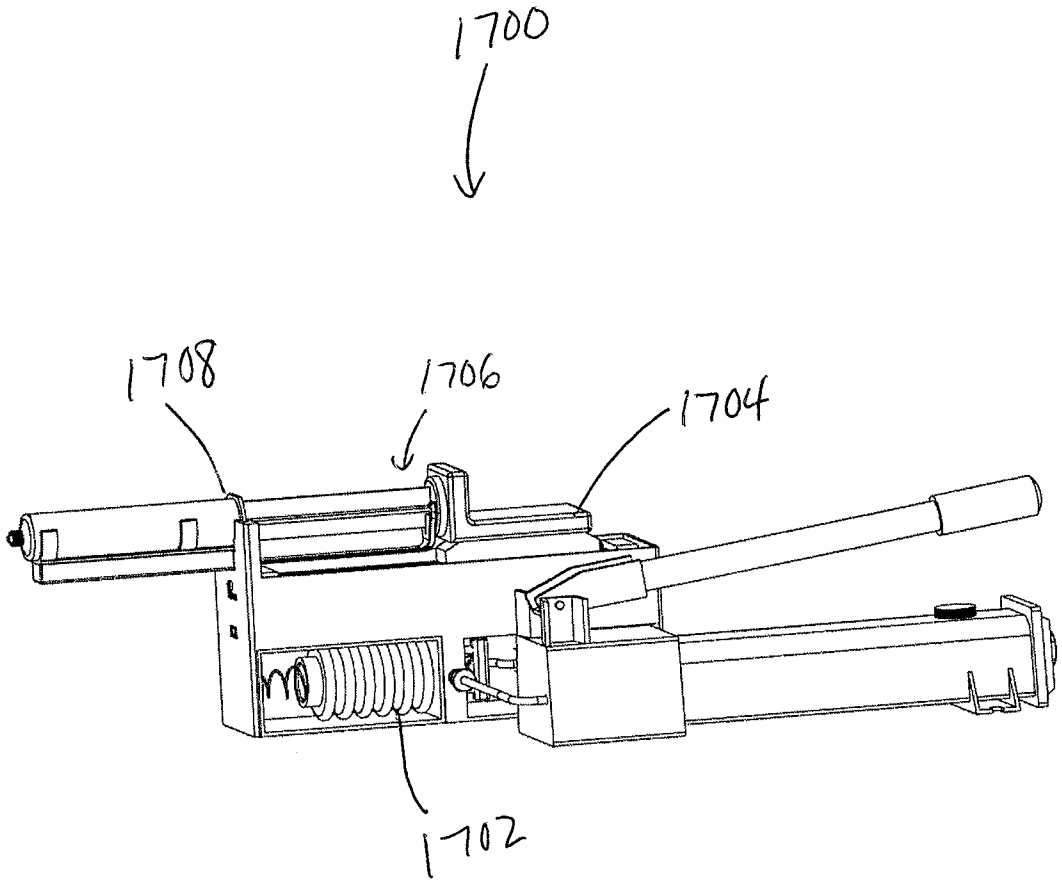


FIG. 17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 10/40893

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 5/48 (2010.01)
USPC - 604/118
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)
USPC: 604/118

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 604/19, 48, 500, 93.01, 118, 121, 181, 186, 187, 207, 218, 224, 246, 253 IPC: A61M1/00, 5/00, 5/14, 5/178, 5/31, 5/315, 5/142
(keyword limited; terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PUBWEST(PGPB, USPT, EPAB, JPAB): GOOGLE
Search Terms Used: syringe, display$3, monitor, interface, screen, lcd, sensor, rate, amount, concentration, pressure, velocity, speed, input, parameter, temperature, respiratory rate, blood pressure, heart rate, oxygen saturation, memory, print$3, reset$3, power, calibrat$

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/0132844 A1 (PETERSON et al) 05 June 2008 (05.06.2008) para [0042]-[0045], [0053]-[0055], [0060], [0062], [0065], [0067], [0069], [0379], [0385], [0407], [0418], [0473], [0475], [0477], [0504]	1-9, 11-17, 21-26, 35
Y		10, 18-20, 27-34
Y	US 2006/0280807 A1 (RIND) 14 December 2006 (14.12.2006) para [0006]-[0011]	10, 19-20, 27-28
Y	US 2008/0306444 A1 (BRISTER et al) 11 December 2008 (11.12.2008) para [0200], [0218], [0227], [0269],	18-20, 29-34

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 August 2010 (11.08.2010)	31 AUG 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)