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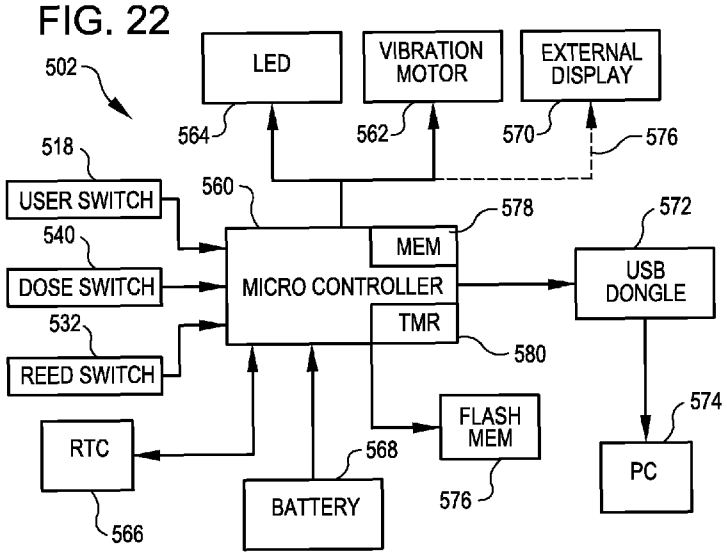
(54) **Title**: DOSAGE SENSING UNIT WITH TACTILE FEEDBACK

FIG. 22



(57) **Abstract**: A drug infusion assembly comprises a drug delivery device arranged to adhere to a patient's skin and includes a reservoir that holds the drug, a cannula that delivers the drug to the patient, and a pump that causes the drug to flow to the cannula. The assembly further includes a monitor device for providing information about the operation of a drug delivery device. The monitor device includes a housing arranged to be attached to and detached from the drug delivery device, a sensor that senses the operation of the drug delivery device and generates an activation signal, a clock mechanism that generates a time signal, a memory that receives and stores the activation signal and the time signal and creates an information packet coordinating the time signal and the activation signal, an interrogator that interrogates the memory such that the memory generates a memory signal in response thereto, and a responder that receives the memory signal and generates a response.

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DOSAGE SENSING UNIT WITH TACTILE FEEDBACK

BACKGROUND OF THE INVENTION

[1] The present invention relates to a device for sensing medicament dosing in a drug infusion set. In some embodiments it also includes the ability to retain and recall dosing history and to provide tactile feedback to a user reflecting recent dosing activity. In some embodiments it also includes the ability to retain and dosing history and to provide a download of that history to an electronic device such as a computer or a similar device specifically for that purpose.

[2] The invention relates to a sensing device that is applicable to infusion devices for liquid medicaments in general, but for purposes of example, the use of the device in connection with disposable infusion devices for the administration of insulin in diabetes is described below.

[3] Glucose is the central source of energy in the human body, and is generated by the digestion of the food, particularly carbohydrates and released into the bloodstream for distribution throughout the body. Insulin is a hormone that allows the glucose in the bloodstream to be absorbed by the cells of the body. A healthy person makes enough insulin for the body's cells to absorb essentially all the glucose generated by the food that the body digests. Insulin is produced in the pancreas and released into the bloodstream and is present at a low basal level at all times, but is sometimes released in larger bolus amounts in response to or anticipation of a person's intake of carbohydrates, for example at a meal.

[4] Diabetes is a disorder of the manufacture and utilization of insulin. It is a huge and growing health problem among virtually all segments of the population. It is an incurable and progressive disease that typically manifests itself in one of two different ways, type 1 diabetes (T1) and type 2 diabetes (T2). In T1 diabetes the patient loses the ability to make insulin at all, generally as a result of destruction of cells of the pancreas. This often happens early in life and was previously sometimes called early onset diabetes. With this type of diabetes, insulin replacement therapy is necessary, and without the administration of insulin the patient dies.

[5] In T2 diabetes, the patient develops an inability to use insulin efficiently. Often diet and exercise will delay progression, but the disease typically progresses to the stage where it is necessary to administer drugs to increase the body's production of insulin or the efficiency of use of the insulin present. At some point thereafter, the disease usually progresses to the point that insulin injections are required.

[6] In both T1 and T2 where insulin injections are required, careful monitoring of the amount and timing of injections is important. Certain insulin analogs have been developed that allow a single or perhaps two daily injections to provide the rough equivalent of the daily basal insulin of a patient without diabetes. However, mimicking the body's bolus insulin amounts is far more delicate. Bolus administrations of insulin are typically given about half an hour before a meal. The amount of insulin that is appropriate varies from one administration to the next depending on the amount and type of the food to be eaten, the amount of exercise that the patient has

recently engaged in, the how tired the patient is, and any number of other factors.

[7] Recent treatment protocols are trending toward a move to earlier treatment of T2 diabetes with insulin, and in more precise and constant monitoring of the blood glucose level of the patient. This protocol is sometimes referred to as Intense Insulin Therapy, or IIT and involves the administration of insulin three or more times per day, or constant administration by a pump. As a result, in addition to the growing problem of diabetes in the population, it is likely that in the future a larger portion of people with diabetes will be treated by the administration of insulin, and IIT will become far more common.

[8] Administration of insulin has traditionally been accomplished using a syringe. Recently, needle carrying pen-like devices have also been employed for this purpose. Both forms of insulin administration require the patients to stick themselves each time they inject insulin, often many times a day. Additionally, the act of injecting themselves or having a helper inject them is socially awkward for the person with diabetes. Thus, these traditional forms of insulin administration have been a rather pervasive intrusion in the lives and routines of the patient's who have had to adopt and employ them. If the social awkwardness results in a patient skipping administrations, that may be detrimental to control of the disease.

[9] More recently, insulin pumps attached by tubing to an infusion set mounted on the patient's skin have been developed as an alternative form of insulin administration. Such pumps may be controlled by a programmable remote electronic system employing short range radio communication between a control device and electronics that control the pump. While such devices may involve fewer needle sticks,

they are expensive to manufacture, complex to operate and cumbersome and awkward to wear. Further, the cost of such devices can be many times the daily expense of using a traditional injection means such as a syringe or an insulin pen.

[10] Devices of the type mentioned above also require a significant amount of training to control and use. Great care in programming the devices is required because the pumps generally carry sufficient insulin to last a few days and improper programming or operation of the pumps can result in delivery of an excessive amount of insulin which can be very dangerous and even fatal.

[11] Many patients are also reluctant to wear a pump device because they too are generally socially awkward. The devices are generally quite noticeable and can be as large as a pager. Adding to their awkwardness is their attachment to the outside of the patients clothes and the need for a catheter like tubing set running from the device to an infusion set located on the patient's body. Besides being obvious and perhaps embarrassing, wearing such a device can also be a serious impediment to many activities such as swimming, bathing, athletic activities, and activities such as sun bathing where portions of the patient's body are necessarily uncovered.

[12] In view of the above, a more cost effective and simple device has been proposed whereby an injection system is discreetly attached directly to the skin of the patient. The device may be attached to the patient under the patient's clothing to deliver insulin into the patient by the manual pumping of small doses of insulin out the distal end of a temporarily indwelling cannula that is made a part of the pump device. The cannula may be made a part of the drug delivery device before, during or after the attachment

of the drug delivery device to the skin of the patient. The device may be made quite small and, when worn under the clothes, entirely unnoticeable in most social situations. It may still carry sufficient insulin to last a patient several days. It can be colored to blend naturally with the patient's skin color so as not to be noticeable when the patient's skin is exposed. As a result, insulin for several days may be carried by the patient discreetly, and conveniently applied in small dosages after only a single needle stick. For a more complete description of devices of this type, reference may be had to co-pending application Serial Number 11/906,130, filed on September 28, 2007 for DISPOSABLE INFUSION DEVICE WITH DUAL VALVE SYSTEM, which application is owned by the assignee of this application and hereby incorporated herein by reference in its entirety.

[13] As noted above, current medical protocol is trending toward IIT where frequent and precise insulin administration is used. Also as noted above, each bolus insulin dosage is unique and will vary from one to the next. It is therefore very important to keep track of the timing and amount of each dosage. Patients are often advised to keep journals whereby they record each insulin administration and their blood glucose in frequent intervals to help carefully monitor their treatment.

[14] Where the administration of the dose of insulin involves loading a syringe or dialing an amount on an insulin pen, and injecting oneself with the dose, the patient is unlikely to forget that they had administered the dose or the amount of the dose. Likewise if a complex electronic unit is controlling an insulin pump, one of its electronic functions can be to recall each dose and display the results on the individual remote unit. However, the very simple and discreet nature of the disposable unit

described above makes it more likely that the patient may not remember the details of the last insulin administration. The fact that the device is worn on the patient's body in an unobtrusive manner also makes a visual display less useful. It is very likely that the patient will be wearing the device where they cannot easily see it. Finally, in furtherance of the goal of making the treatment less of an unpleasant intrusion into the daily life of the patient, it would be helpful to have a means of keeping a record of insulin treatment without the need to carry and maintain a journal.

[15] Thus there is a need for a sensing device for use with an attached drug delivery device that can sense dosing by that device, and respond to a query from a user with information regarding recent dosing activity. There is a need for such a device that can provide that response in a tactile form that may be sensed by the user without the need to see the sensing device. There is a need for such a device to be discreet to be consistent with the ability of such a drug delivery device to be discreet and unobtrusive. Finally it would be useful if such a device could store the history of the insulin administration over a significant period of time and provide that information later to a physician or patient.

[16] As mentioned previously, the administration of insulin is used here for exemplary purposes. However the administration of any liquid medicament, particularly where relatively frequent or constant administration is indicated, would be greatly aided by this invention. For example, where administration of pain medication for a chronic situation is required, an unobtrusive infusion device would be helpful, and a method of sensing and later providing information concerning recent dosing or long term dosing

history would be very helpful. In some chemotherapeutic regimes, a similar system would be very useful. The invention is not limited by the exemplary method described herein except as explicitly stated in the claims.

SUMMARY OF THE INVENTION

[17] In one embodiment, the invention provides a monitoring device for providing information about the operation of a drug delivery device. The monitoring device comprises a housing arranged to attach to the drug delivery device, a sensor that senses the operation of the drug delivery device and provides operational data indicative of the operation of the drug delivery device, a memory that stores the operational data, and an indication generator that generates a perceptible indication of the operational data.

[18] The indication generator may be arranged to provide a tactile response to provide the perceptible indication. The tactile response may be a vibratory response. The indication generator may be a motor. The motor may be an electric motor.

[19] The sensor may comprise an optical sensor and/or a magnetic sensor. The drug delivery device may include a pump that delivers the drug to a patient. For example, the pump may be a mechanical stroke pump and the sensor may sense the strokes of the pump. The monitoring device may further comprise a timer that times a dosing session of the device.

[20] The drug delivery device may include at least one valve. The operation of the drug delivery device initiates with operation of the at least one valve and the magnetic sensor senses the operation of the at least one valve. The optical sensor senses strokes of the pump.

[21] The memory may store each pump stroke occurring during a dosing session. The indication generator may generate a perceptible indication of the number of pump strokes occurring during a last dosing session. The memory may store operational data for a number of dosing sessions in a history file. The monitoring device may further include an interface arranged to provide the history file to an external reader. The interface may comprise a USB interface.

[22] In another embodiment, a monitor device provides information about the operation of a drug delivery device. The monitor device comprises a sensor that senses the operation of the drug delivery device and generates an activation signal, a clock mechanism that generates a time signal, a memory that receives and stores the activation signal and the time signal and creates an information packet coordinating the time signal and the activation signal; an interrogator that interrogates the memory such that the memory generates a memory signal in response thereto, and a responder that receives the memory signal and generates a tactile response.

[23] In another embodiment, a monitor device provides information about the operation of a drug delivery device. The drug delivery device includes a mechanical stroke pump that delivers the drug to a patient and at least one valve, the operation of which initiates operation of the drug delivery device. The monitor device comprises a housing arranged to attach to the drug delivery device, a timer that times a dosing session, a magnetic sensor that senses the operation of the at least one valve, an optical sensor that senses operation of the pump to provide operational data, a memory that stores the operational data provided by the optical sensor during a last dosing session, an interrogator that interrogates the memory such that the memory generates

a memory signal in response thereto representing operation of the drug delivery device during a last dosing session, and a responder that receives the memory signal and generates a tactile response.

[24] In a further embodiment, a drug infusion assembly comprises a drug delivery and a monitor device. The drug delivery device is arranged to adhere to a patient's skin and includes a reservoir that holds the drug, a cannula that delivers the drug to the patient, and a pump that causes the drug to flow to the cannula. The monitor device provides information about the operation of the drug delivery device. The monitor device comprises a housing arranged to be attached to and detached from the drug delivery device, a sensor that senses the operation of the drug delivery device and provides operational data indicative of the operation of the drug delivery device, a memory that stores the operational data, and an indication generator that generates a perceptible indication of the operational data.

[25] In a still further embodiment, a drug infusion assembly comprises a drug delivery device arranged to adhere to a patient's skin and includes a reservoir that holds the drug, a cannula that delivers the drug to the patient, and a pump that causes the drug to flow to the cannula. The assembly further includes a monitor device for providing information about the operation of a drug delivery device. The monitor device includes a housing arranged to be attached to and detached from the drug delivery device, a sensor that senses the operation of the drug delivery device and generates an activation signal, a clock mechanism that generates a time signal, a memory that receives and stores the activation signal and the time signal and creates an information packet coordinating the time signal and the activation signal, an interrogator that interrogates the

memory such that the memory generates a memory signal in response thereto, and a responder that receives the memory signal and generates a response.

BRIEF DESCRIPTION OF THE DRAWINGS

[26] The features of the present invention which are believed to be novel are set forth with particularity in the appended claims. The invention, together with further features and advantages thereof, may best be understood by making reference to the following description taken in conjunction with the accompanying drawings, in the several figures of which like reference numerals identify identical elements, and wherein:

[27] **FIG. 1** is a perspective view of an infusion device which may be employed in an assembly embodying the present invention;

[28] **FIG. 2** is another perspective view of the infusion device of **FIG. 1** shown with a deployed cannula;

[29] **FIG. 3** is an exploded perspective view of the device of **FIG. 1**;

[30] **FIG. 4** is a sectional view, in perspective, to an enlarged scale, taken along lines 4-4 of **FIG. 1**, showing the actuation linkages of the device of **FIG. 1** prior to medicament dosage delivery;

[31] **FIG. 5** is another sectional view, in perspective, to an enlarged scale, taken along lines 5-5 of **FIG. 2**, showing the actuation linkage operation of the device of **FIG. 1** during medicament dosage delivery;

[32] **FIG. 6** is another sectional view similar to that of **FIG. 5**, in perspective, to an enlarged scale, showing the

actuation linkage operation of the device of **FIG. 1** immediately after dosage delivery;

[33] **FIG. 7** is a schematic representation of the valves and pump of the device of **FIG. 1** between medicament dosage deliveries and during the filling of the pump with the medicament;

[34] **FIG. 8** is another schematic representation of the valves and pump of the device of **FIG. 1** during medicament dosage delivery;

[35] **FIG. 9** is a sectional view, in perspective, to an enlarged scale, showing the configuration of the valves of the device of **FIG. 1** during pump filling and prior to medicament dosage delivery;

[36] **FIG. 10** is another sectional view, in perspective, to an enlarged scale, showing the configuration of the valves of the device of **FIG. 1** during dosage delivery;

[37] **FIG. 11** is a perspective view of an infusion assembly embodying the present invention showing the infusion device of **FIG. 1** and a dosage monitor releasably attached thereto in accordance with aspects of the present invention;

[38] FIG. **12** is a perspective view of the dosage monitor of **FIG. 11**;

[39] **FIG. 13** is a bottom plan view of the dosage monitor of **FIG. 11**;

[40] **FIG. 14** is a perspective view taken along lines 14-14 of **FIG. 11**;

[41] **FIG. 15** shows a portion of the perspective view of **FIG. 14** illustrating a magnet carried by a valve actuation button of the infusion device and a magnetic sensor of the

dosage monitor in accordance with aspects of the present invention;

[42] **FIG. 16** is a perspective view taken along lines 16-16 of **FIG. 11**;

[43] **FIG. 17** shows a portion of the perspective view of **FIG. 11** illustrating a reflective surface of a pump actuation button of the infusion device and a light source and an optical sensor of the dosage monitor in accordance with additional aspects of the present invention;

[44] **FIGS. 18-21** are bottom views, with portions cut away, illustrating the sequential operation of the actuator buttons of the infusion device for corresponding magnetic and optical sensing according to aspects of the invention;

[45] **FIG. 22** is a schematic block diagram of an infusion device dosage monitor embodying the present invention; and

[46] **FIG. 23** is flow diagram illustrating the operation of the dosage monitor for incrementing a dosage counter and performing dosage amount read-back.

DETAILED DESCRIPTION OF THE INVENTION

[47] Referring now to **FIGS. 1** and **2**, they are perspective views of an infusion device ***110*** which may be used in an assembly embodying various aspects of the present invention. More particularly, the device ***110*** may receive a monitoring device thereon embodying the present invention and described subsequently to form an infusion assembly capable of providing a drug, such as insulin, to a patient and to report to the patient information pertaining to the drug delivery.

[48] **FIG. 1** shows the device prior to receiving and thus without a cannula while **FIG. 2** illustrates the device after having received a cannula ***130*** that has a distal end ***131***. As may be seen in both **FIGS. 1 and 2**, the device ***110*** generally includes an enclosure ***112***, a base ***114***, a first actuator control button ***116***, and a second actuator control button ***118***.

[49] The enclosure ***112***, as will be seen subsequently, is formed by virtue of multiple device layers being brought together. Each layer defines various components of the device such as, for example, a reservoir, fluid conduits, pump chambers, and valve chambers, for example. This form of device construction results in a compact design and enables manufacturing economy to an extent that the device is disposable after use.

[50] The base ***114*** preferably includes a pad ***115*** attached to the base ***114***. The pad ***115*** has an adhesive coating ***117*** on the side thereof opposite the base ***114*** to permit the device to be adhered to a patient's skin.

[51] The device ***110***, as will be seen herein after is first adhered to the patient's skin followed by the deployment of the cannula ***130*** thereafter. However, it is contemplated herein that various aspects of the present invention may be realized within a device that may alternatively be mated with a previously deployed cannula assembly.

[52] The actuator buttons ***116*** and ***118*** are placed on opposites sides of the device ***110*** and directly across from each other. This renders more convenient the concurrent depression of the buttons when the patient wishes to receive a dose of the liquid medicament contained within the device ***110***. This arrangement also imposes substantially equal and opposite forces on the device during dosage delivery to

prevent the device from being displaced and possibly stripped from the patient. As will be further seen hereinafter, the concurrent depression of the buttons is used to particular advantage. More specifically, the actuator button ***116*** may serve as a valve control which, when in a first position as shown, establishes a first fluid path between the device reservoir and the device pump to support pump filling, and then, when in a second or depressed position, establishes a second fluid path between the device pump and the device outlet or distal end of the cannula to permit dosage delivery to the patient. As will be further seen, a linkage between the control actuator buttons ***116*** and ***118*** permits actuation of the device pump with the actuator control button ***118*** only when the second fluid path has been established by the first actuator control button ***116***. Hence, the first actuator control button ***116*** may be considered a safety control.

[53] The actuator buttons ***116*** and ***118*** are preferably arranged to require a complete through of their travel to achieve activation of the device pump and thus dosage delivery. This, together with the sudden release of resistance to actuator advancement creates a snap action that provides an advantage in positively knowing that dosage delivery has occurred and that no less than a full dose has been delivered. For more description regarding this feature, reference may be had to co-pending application Serial Number 11/906,102, titled DISPOSABLE INFUSION DEVICE WITH SNAP ACTION ACTUATION, which application is owned by the assignee of this application and is incorporated herein by reference in its entirety.

[54] As may be noted in **FIG. 1**, the device ***110*** includes a cavity ***120*** that is arranged to receive a cannula assembly ***122*** (**FIG. 2**) from which the cannula ***130*** extends. When the

cannula is deployed, the outlet ***124*** of the device ***110*** is placed in fluid communication with the cannula ***130*** by a cannula carrier ***128*** of the cannula assembly ***122*** that carries the cannula. When thus deployed, the cannula ***130*** extends from the base ***114*** of the device ***110*** to beneath the skin of the user.

[55] As may further be noted in **FIGS. 1** and **2**, the enclosure ***112*** of the device ***110*** includes a pair of pockets ***140*** and ***142*** on opposite sides of the second actuator button ***118***. A similar pair of pockets, not seen in the figure, are also provided on opposite sides of the first actuator button ***116***. These pockets are used to receive corresponding projections of a cannula placement assembly for releasably joining the cannula placement assembly to the device ***110*** to support cannula deployment as will be described subsequently. Such a cannula placement assembly is fully described in co-pending application Serial No. 12/147,295, filed on June 26, 2008 for DISPOSABLE INFUSION DEVICE WITH AUTOMATICALLY RELEASBLE CANNULA DRIVER, which application is owned by the assignee of the present invention and hereby incorporated herein by reference. As described therein, upon cannula deployment, the cannula placement assembly is automatically released from the device by the driver projections being forced from the pockets.

[56] Referring now to **FIG. 3**, it is an exploded perspective view of the device ***110*** of **FIG. 1**. It shows the various component parts of the device. The main component parts include the aforementioned device layers including the base layer ***160***, a reservoir membrane ***162***, an intermediate layer ***164*** and a top body layer ***166***. As may also be seen in **FIG. 3**, the base layer ***160*** is a substantially rigid unitary structure that defines a first reservoir portion ***168***, a pump chamber ***170***, and a valve chamber ***190*** that receives a shuttle

bar ***200*** of a shuttle valve ***210***. A reservoir membrane layer ***162*** is received over the reservoir portion ***168*** to form an expandable/deflatable reservoir of the device ***110***. The base layer ***160*** may be formed of plastic, for example. The base and the top body layer may be joined together, trapping the intermediate layer there between by any means such as with screws, ultrasonic welding or laser welding.

[57] The valve chamber ***190*** is arranged to receive a valve shuttle bar ***200*** carried by and extending from the first actuator button ***116***. A series of O-rings, to be described subsequently, are seated on the shuttle bar ***200*** to form first, second, and third valves. The actuator button ***116*** also carries a first linkage portion ***240*** of the linkage that permits actuation of the device pump with the actuator control button ***118*** only when the second fluid path has been established by the first actuator control button ***116***. The first linkage portion ***240*** is received within a suitably configured bore ***270*** formed in the base layer ***160*** and will be described subsequently.

[58] The pump actuator button ***118*** is arranged to be linked to a pump piston ***300*** and a second linkage portion ***340*** to interact with the first linkage portion ***240***. The pump piston ***300*** is arranged to be received within the pump chamber ***170*** and the second linkage portion ***340*** is arranged to be received within the bore ***270*** for interacting with the first linkage portion ***240***. O-rings are seated on the piston ***300*** to provide a seal against leakage and to prevent external contaminants from entering the piston chamber.

[59] The intermediate layer ***164*** may be a generally resilient member and received on the base layer ***160*** to cover channels scribed in the base layer as a type of gasket to form fluid channels ***380*** that serve to conduct the medicament from the reservoir to the device outlet and to the distal

end ***131*** (**FIG. 2**) of the cannula ***130***. Springs ***410*** are arranged to spring load the actuator buttons ***116*** and ***118*** away from each other.

[60] The reservoir membrane ***162*** is formed of flexible membrane material and is received over the reservoir portion ***168*** to form the reservoir of the device ***110***. A rigid plate ***420*** is arranged to be adhered to the reservoir membrane ***162*** of the reservoir. Because the membrane ***162*** is flexible, it will move as the reservoir is filled and emptied. The rigid plate ***420*** will then move with it. The plate ***420*** includes an eyelet ***422*** dimensioned to receive an elongated web ***424*** that forms a part of a medicament level indicator. The web ***424*** carries an indicator line or feature ***426*** that may be read through a window ***428*** of the device top most panel ***440***.

[61] Another component of the device ***110*** is a translucent window ***450*** that is received on the underside of the base ***160***. As will be seen hereinafter, the window forms a part of a prime indicator. It is formed of a transparent material such as glass or transparent plastic and has a roughened surface rendering it translucent. However, when it is covered with or at least wetted by liquid medicament, it is rendered essentially transparent creating a visually obvious condition and, for example, permitting indicia to be seen beneath it indicating that the conduit to the device outlet is primed and ready to deliver fixed doses of medicament when desired.

[62] **FIGS. 4-6** show details of the operation of the linkage that permits actuation of the device pump with the actuator control button ***118*** only when the second fluid path from the reservoir to the outlet has been established by the first actuator control button ***116***. The linkage has been given the general reference character ***150***.

[63] As may be seen **FIG. 4**, the first actuator button ***116*** has an extension ***152*** that terminates in a block ***154***. The block ***154*** has a first ramp surface ***156*** and a second ramp surface ***158***. When the device ***110*** is actuated, the button ***116*** is concurrently depressed with pump button ***118***. It and its extension ***152*** and block ***154*** are free to move to the right. As seen in **FIGS. 4** and **5**, the pump actuator button ***118*** has parallel extensions ***250*** and ***252*** which are joined and separated be a rod member ***254***. The extensions ***250*** and ***252*** are pivotally mounted to pivot about a pivot point ***256***. Another extension ***260*** of the pump actuator button ***118*** spring biases the extensions ***250*** and ***252*** as shown in **FIG. 4**. As seen in **FIG. 4**, the extensions ***250*** and ***252*** abut an abutment ***262*** which they must clear to enable the actuator ***118*** to be moved to the left. As shown in **FIG. 5**, as the button ***116*** is depressed, its extension ***152*** moves to the right causing the first ramp surface ***156*** to engage the rod member ***254***. Continued movement of the button causes the rod member ***254*** to ride up the first ramp surface ***156*** which in turn causes the extensions ***250*** and ***252*** to begin to move slightly to the left and bend upward against the loading of extension ***260***. Eventually, the rod member ***254*** rides up the length of the first ramp ***156*** and down the second ramp ***158*** causing the extensions ***250*** and ***252*** to clear the abutment ***262*** and continue their travel to the left until the extensions are received on the opposite side of the abutment as shown in **FIG. 6**. The pump button ***116*** has now been fully depressed to deliver a dose of measured medicament. When the ends of extensions ***250*** and ***252*** totally clear the abutment ***262***, they will snap behind the abutment ***262*** as shown in **FIG. 6** and become temporarily locked. Meanwhile, the rod member ***254*** has traversed all the way down the second ramp surface ***158***. The buttons ***116*** and ***118*** are now fully depressed.

[64] Hence, from the above, it may be seen that the pump button ***118*** could not at first move freely while the first actuator button ***116*** which operates the valves could. As a result, the pump actuation lags behind the valve actuation. This enables the device outlet to be sealed from the reservoir and the pump connected to the outlet before the pump is permitted to pump any medicament to the outlet. Hence, the device establishes a medicament delivery flow path to the cannula before the pump is able to begin pumping the medicament to the patient. Thus, it is assured that there is never an open unobstructed pathway between the reservoir and the fluid outlet. Also, by assuring that the pump only draws fluid from the reservoir when the pathway to the outlet is sealed off, it is also assured that a precise amount of fluid is moved with each pump cycle. This operation is completely timed by the linkage just described and occurs quickly, appearing to the patient that both actuator buttons are moving at the same rate.

[65] When the extensions ***250*** and ***252*** of the pump button clear the abutment ***262***, they become locked in a snap action. This provides positive feedback to the patient that a dosage of medicament was delivered as desired. It also causes a full dose to be delivered. By virtue of the snap action of the pump actuator, only full doses may be administered.

[66] When the medicament has been delivered, the spring loading of the actuator buttons returns the buttons to their first or initial position. During this time, the same timing provided by the block ***154*** is used for recharging the pump. More specifically, ramp ***158*** unlatches the ends of extensions ***250*** and ***252*** by lifting rod member ***254***. While the extensions ***250*** and ***252*** are being lifted by the ramp ***158***, the valve control button ***116*** is returning to the left to cause the outlet to be disconnected from the pump before the reservoir

is reconnected to the pump for charging, thus sealing the outlet from both the pump and the reservoir before the reservoir is connected to the pump for recharging. This assures that the pump does not pull medicament from the patient but only from the reservoir. As the pump returns, a full dose of the medicament is drawn up into the piston chamber ***170*** to ready the device for the next dosage delivery.

[67] Referring now to **FIGS. 7** and **8**, they are schematic representations of the valves and pump of the device of **FIG. 1** between medicament dosage filling (**FIG. 7**) and medicament dosage delivery (**FIG. 8**) As may be seen in **FIGS. 7** and **8**, the device ***110*** further includes a reservoir ***222***, a pump ***224***, and the cannula ***130***. The reservoir ***222*** may be formed as shown in **FIG. 3** by the combination of the device base ***160*** and the flexible membrane ***162***. The device further includes the shuttle valve ***210*** including shuttle bar ***200***. The shuttle bar ***200*** is shown within the valve chamber ***190***. The shuttle bar ***200*** and O-rings ***214*** and ***216*** form a first valve ***212***, shuttle bar ***200*** and O-rings ***220*** and ***222*** form a second valve ***234*** and shuttle bar ***200***, O-ring ***226*** and a bypass channel ***186*** form a third valve ***224***. Although O-rings are used herein to form seals, other types of valve construction may employ forms of seals other than O-rings without departing from the invention.

[68] The pump piston ***300*** is within the piston camber ***170*** to form a piston pump ***172***. The actuator control button ***218*** is directly coupled to and is an extension of the pump piston ***226***. It may also be noted that the actuator buttons ***116*** and ***118*** are spring loaded by springs ***117*** and ***119***, respectively. The springs are provided for returning the actuator buttons to a first or start position after a dosage is administered.

[69] A fluid conduit ***182*** extends between the reservoir ***180*** and the valve ***212***. An annular conduit ***192*** extends between the O-rings ***216*** and ***226***, and an annular conduit ***194*** extends between the O-rings ***226*** and ***220***. A fluid conduit ***184*** provides a fluid connection between the reservoir ***180*** and the annular conduits ***192*** and ***194*** depending upon the position of the shuttle valve ***210***. Also illustrated in **FIG. 7** is the linkage ***150*** that assures that the shuttle valve ***210*** is actuated before the piston pump ***172*** is actuated to provide a dose of medicament.

[70] In **FIG. 7**, the valves are shown in a first configuration immediately after having returned to their first position following a dosage delivery. After the return of the valves, the linkage ***150*** permits the pump actuator ***118*** and piston ***300*** to return for refilling the pump chamber ***300*** in ready for the next medicament dosage delivery. During their return, the medicament flows as indicated by arrows ***202*** from the reservoir ***180***, through the conduit ***182***, through the annular channel ***192***, through conduit ***184***, and into the pump chamber ***170***.

[71] As may be noted, when in the first position, the valves ***218*** and ***224*** isolate the outlet ***124*** from both the reservoir ***180*** and the piston pump ***118***. Having two such valves isolate the outlet ***124*** when the valves are in the first configuration provides an added degree of safety from medicament being inadvertently delivered to the patient between dosage deliveries. For example, this provides additional safety that the liquid medicament is not accidentally administered to the patient notwithstanding the inadvertent application of pressure to the reservoir. In applications such as this, it is not uncommon for the reservoir to be formed of flexible material. While this has its advantages, it does present the risk that the reservoir

may be accidentally squeezed as it is worn. Because the valves ***118*** and ***124*** isolate the outlet ***124*** when the valves are in their first configuration, this redundant protection assures that pressure, accidentally applied to the reservoir, will not cause the fluid medicament to flow to the cannula.

[72] In addition to the linkage ***150*** preventing return of the piston ***300*** until after the valves return to their first and start positions, the O-rings on the shuttle bar ***200*** are also spaced apart to insure that the valves ***218*** and ***224*** isolate the outlet ***124*** from the pump ***172*** and reservoir ***180*** before the pump is again connected to the reservoir. The O-ring spacing thus effectively forms a second linkage to assure that the cannula ***130*** is connected to the pump ***172*** only when a dosage is to be delivered and that it is never connected to the reservoir ***180***.

[73] In operation, the pump chamber ***170*** is first filled as the actuator button ***118*** returns to the first position after having just delivered a medicament dosage. In this state, the shuttle valve ***210*** is set so that the first valve ***212*** will be open and the second and third valves ***218*** and ***224*** will be closed. This establishes a first fluid path indicated by arrows ***202*** from the reservoir ***180*** to the pump chamber ***170*** to fill the piston pump ***172***. When the patient wishes to receive another dose of medicament, the actuator buttons are concurrently pressed. The aforementioned linkages, including linkage ***150***, cause the first valve ***212*** to close and the second and third valves ***218*** and ***224*** to thereafter open. Meanwhile, actuation of the pump ***172*** is precluded until the first valve ***212*** is closed and the second and third valves ***118*** and ***224*** are opened. At this point a second fluid path indicated by arrows ***204*** is established from the pump chamber ***170*** to the cannula ***130***. The medicament

is then administered to the patient through the distal end ***131*** of cannula ***130***.

[74] Once the medication dosage is administered, the piston ***330***, and thus the actuator button ***118***, is returned under the spring pressure of spring ***119*** to its initial position. During the travel of the piston back to its first position, a given volume of the liquid medicament for the next dosage delivery is drawn from the reservoir into the pump chamber ***170*** as described above to ready the device for its next dosage delivery.

[75] Referring now to **FIG. 9**, it is a sectional view in perspective showing the valve configuration of the device ***110*** of **FIG. 1** during medicament filling of the pump chamber ***170*** immediately after a dosage delivery. Here, it may be clearly seen that the first actuator button ***116*** is directly coupled to the shuttle bar ***200*** of the valves ***212***, ***218***, and ***224***. Above the valves are the conduits from the reservoir, from the pump, and to the cannula. More particularly, the conduit ***182*** is in fluid communication with the reservoir, the conduit ***184*** is in fluid communication with the pump, and the conduit ***124*** is in fluid communication with the cannula. The valves are shown with the first valve ***212*** opened, communicating reservoir conduit ***182*** with the pump conduit ***184*** through channel ***192***, the second valve ***218*** closed and blocking the conduit ***124*** to the cannula, and the third valve ***224*** closed and blocking both the reservoir conduit ***182*** and the pump conduit ***184*** from the cannula conduit ***124***. This permits medicament to flow from the reservoir through conduit ***182***, through channel ***192***, and to the pump chamber ***170*** through conduit ***184*** as the actuator button ***116*** returns to its first position. Hence, the pump chamber is filled and ready for the next dosage delivery.

[76] Referring now to **FIG. 10**, it is a sectional view in perspective similar to that of **FIG. 9** but showing the valve configuration of the device ***110*** of **FIG. 1** during medicament delivery. Here, the valves are shown with the first valve ***212*** closed and blocking the reservoir conduit ***182***, the second valve ***218*** opened permitting the outlet conduit ***124*** to communicate with the annular conduit ***194***, and the third valve ***224*** opened permitting medicament to flow from the annular conduit ***192***, through bypass ***186***, and to annular conduit ***194***. Thus, medicament is permitted to flow from the pump conduit ***184***, through annular conduit ***192***, through the bypass ***186***, through annular conduit ***194***, and into the outlet conduit ***124*** to administer the fixed volume dosage. As previously mentioned, the O-rings defining the first valve ***212***, the third valve ***224***, and the second valve ***218*** are spaced apart so that conduit ***182*** is blocked before conduits ***184*** and ***124*** are connected together through the valves ***224*** and ***218***.

[77] **FIG. 11** is a perspective view of an infusion assembly ***500*** embodying the present invention showing the infusion device ***110*** of **FIG. 1** and a dosage monitor ***502*** releasably attached thereto in accordance with aspects of the present invention. The dosage monitor ***502*** includes an enclosure ***504***. With additional reference to **FIG. 12**, the enclosure ***502*** has legs ***506***, ***508***, and ***510***. The legs ***506***, ***508***, and ***510*** are resilient and include feet ***512***, ***514***, and ***516***, respectively, that grip the device ***110*** when snap fitted thereon. The dosage monitor ***502*** further has a user switch button ***518*** that, as will be seen subsequently, when pressed, causes the monitor ***502*** to provide the user with information concerning drug delivery to the user by the device ***110***. As will also be seen, the information is delivered to the user in the form of a perceptible response. In accordance with this embodiment, the perceptible response is tactile, and

more specifically, in the form of a vibration provided by an electric motor. The information delivered may be an indication of the amount of drug delivered to the used during a last dosing session.

[78] **FIG. 13** is a bottom view of the monitor device ***502***. Here it may be seen that the monitor housing ***504*** has a bottom surface ***520***. Within the bottom ***520*** there is a window ***523***. As will be seen subsequently, the monitor ***502*** includes an optical sensor that senses operation of the piston pump. To that end, as will be seen subsequently, the monitor includes a light source, such as an infrared light source, that shines a beam of infrared light through the window ***523*** onto an extension of the piston pump actuator button ***118***. The extension is provided with a reflective coating that passes through the light beam during each stroke of the piston pump. During each such stroke, the infrared light is reflected back from the reflective coating to an infrared light sensor in the monitor ***502*** and counted. The number of such strokes during a dosing session is stored in memory for later response to a user inquiry.

[79] In addition to storing the number of drug deliveries during a last dosing session, the monitor may also store a history of dosage deliveries. The dosing history is preferably stored in a non-volatile memory. The history data associated with the operation of the drug delivery device ***110*** may be transferred to an external device using a plurality of contacts ***524*** that form an external interface ***526***. The external interface ***526*** may be a USB interface. To that end, the interface ***526*** of the monitor ***502*** may be plugged into a USB adapter, such as a USB dongle, that converts the signals on contacts ***524*** to USB format to connect the monitor to an external device such as, for example, a personal computer. Alternatively, the USB

formatting may be accomplished within the monitor ***502*** so that the signals at contacts ***524*** are already USB formatted. Once the monitor ***502*** is interfaced with the computer, the monitor may be powered through the USB port. This eliminates the need for an internal power source for this purpose. The entire contents of the monitor memory may then be downloaded to the computer to render the entire dosing history available. As may further be appreciated by those skilled in the art, the interface 526 may alternatively be coupled to a serial interface for connection to a computer.

[80] In addition to the optical sensor mentioned above, the sensor of the monitor ***502*** includes a magnetic sensor ***530*** which may be seen in the sectional view of **FIG. 14** and the partial view of **FIG. 15**. The magnetic sensor ***530*** includes a reed switch ***532*** carried on a circuit board ***534*** of the monitor ***502***. The reed switch ***532*** is arranged to be above an extension of the first actuator button ***116*** (**FIG. 11**). As previously described, the first actuator button ***116*** configures a valve system for drug delivery prior to actuation of the piston pump with the second actuator button ***118***. The first actuator button ***116*** carries a magnet ***536***. When a drug dose is to be delivered, actuation of the first actuator button ***116*** causes the magnet ***536*** to translate beneath the reed switch ***532***. The reed switch ***532*** then closes to transition the monitor from a sleep mode to an active mode for sensing the stroke of the piston pump and counting the dosage delivery.

[81] The sectional view of **FIG. 16** and the partial view of **FIG. 17** illustrate the optical sensor ***540***. In these views it may be seen that the optical sensor ***540*** includes a light source and sensor unit ***542*** carried on the circuit board ***534*** of the monitor ***502***. As previously mentioned, the light provided and sensed by the light source and sensor unit ***542***

is in the infrared portion of the spectrum. The infrared light is conducted by a light pipe ***522*** within a shaft ***544*** of the drug delivery device ***110*** and is directed from the window ***523*** into the valve chamber ***190***. As previously mentioned, an extension of the pump actuator button ***118*** carries a reflective coating that passes through the beam of light with each stroke of the piston pump. The reflected light is then returned through the light pipe ***522*** to the light source and sensor unit ***542*** to enable the counting of the piston pump stroke and thus the delivered incremental dose.

[82] Referring now to **FIGS. 18-21**, they are bottom views, with portions cut away, illustrating the sequential operation of the actuator buttons of the infusion device for corresponding magnetic and optical sensing according to aspects of the invention. In **FIG. 18**, neither actuator button ***116*** nor actuator button ***118*** has been depressed. In **FIG. 18** it may be seen that the first actuator button ***116*** carries magnet ***536***. As may be seen in **FIG. 19**, and as previously described, when a dose of drug is to be delivered to the user, the device ***110*** forces the first actuator button ***116*** to be depressed before the second actuator button ***118*** to complete required valve operation. As the actuator button ***116*** is depressed, the magnet ***536*** that it carries translates with the actuator button ***116***. The magnet ***536*** moves from its initial position shown in **FIG. 18** to the position shown in **FIG. 19** where it is below and in detectable proximity to the reed switch ***532*** (**FIGS. 14** and **15**). The reed switch ***532*** detects the magnet when the magnet field of the magnet ***536*** causes the reed switch ***532*** to close. This causes the monitor to wake from a sleep mode to prepare it for sensing the stroke of the piston pump.

[83] When the valve operation is completed, the second actuator button ***118*** is permitted to be depressed. As

previously described, the forgoing actuator depressions are completed so quickly that to the user, it appears that the actuator depression of the buttons ***116*** and ***118*** is performed essentially simultaneous. **FIG. 20** shows the device ***110*** as the actuator button ***118*** is being depressed. As seen in **FIG. 20**, the reflective coating ***546*** carried on the extension ***119*** of the actuator button ***118*** is viewable through the light pipe ***522***. In **FIG. 21**, all of the light pipe ***522*** is adjacent the reflective coating ***546*** to permit the light from the light source and sensor unit ***542*** (**FIG. 17**) to be conducted down the light pipe ***522***, reflected from the reflective coating ***546***, and returned to the light source and senor unit ***542*** to cause the delivered incremental dose to be sensed and counted. Now, the actuator buttons ***116*** and ***118*** may be returned to their start positions as shown in **FIG. 18**.

[84] **FIG. 22** is a schematic block diagram of an infusion device dosage monitor embodying the present invention. In addition to the user switch ***518***, the magnetic sensor ***532***, and the optical sensor ***540***, the monitor ***502*** includes a microcontroller or processor ***560***, a vibration motor ***562***, a light emitting diode (LED) ***564***, a real time clock (RTC) ***566***, and a power source, such as battery ***568***. Also illustrated in **FIG. 22** is an external display ***570***, a USB dongle ***572***, an external personnel computer (PC) ***574***, and a flash memory ***576***. The RTC ***566*** may, instead of being external to the processor ***560***, may be embedded within the processor ***560***.

[85] The functions of the magnetic sensor ***532***, the optical sensor ***540***, and the user switch ***518*** have already been described. The processor ***560*** may provide all of the functionality for data acquisition, memory storage, and communication. The RTC ***566*** is coupled to the processor ***560*** to enable the processor ***560*** to keep time. Normally the

processor ***560*** is maintained in a sleep mode to conserve battery power. However, the processor is responsive to interrupts to cause it to wake up and perform its functions. One such interrupt is an overflow interrupt generated by the RTC ***566***. This overflow interrupt occurs every 10 seconds. It causes the processor ***560*** to turn on and increment a seconds register by ten seconds. It then initiates an overflow check to determine if this register is at 60 seconds. If it is, a minute register is incremented and the seconds register is set to zero. In a similar process, the processor ***560*** checks for minute overflow for incrementing an hours register. After the hours, minutes, and seconds registers have been appropriately updated, the processor returns to sleep. The RTC overflow interrupt is preferably a high priority interrupt to supersede any other triggering event. Since only 5-10 processor clock cycles are required for this time keeping function, the processor has ample time to return to sleep and wait for other triggering events without a perceived lapse in function.

[86] The vibration motor ***563*** provides a tactile response when the user requests information concerning drug delivery. The motor ***562*** may be provided with an offset (eccentric) weight on its output shaft to provide a perceived vibration. The information concerning the drug delivery may, in accordance with this embodiment, be the number of dosage deliveries provided during a last dosing interval timed by a timer ***580*** of the processor ***560***. To that end, the motor ***563*** may provide pulses of vibrations, each pulse corresponding to one dosage delivery.

[87] The external display ***570*** is coupled to the processor ***560*** via a wireless connection ***576*** which may be, for example, a wifi connection. The external display ***570*** may be used to display a history file maintained in a processor

memory ***578*** of the processor ***560***. The display may thus be a computer or other device having a wifi receiver and a display. The history file may contain the number of dosage deliveries delivered by the infusion device during each of the dosing sessions occurring over predefined period of time.

[88] The PC ***574*** may be coupled to the processor ***560*** through the USB dongle ***572***. The dongle may in turn be coupled to the processor by using the USB contacts ***524*** (**FIG. 13**) arrayed on the back surface ***520*** of the monitor ***502***. The PC may also be used for displaying the history file.

[89] The flash memory ***576*** may also be used to store the history file. It may be readily removable from the dosage monitor 502 and interfaced with a computer or PDA (not shown) or other similar device for displaying the history file.

[90] **FIG. 23** is a flow diagram illustrating the operation of the dosage monitor for incrementing the dosage counter and performing dosage amount read-back. More specifically, the flow diagram of **FIG. 23** shows how the processor handles interrupts other than time keeping interrupts.

[91] The process ***600*** may be initiated with either the user depressing the user switch ***518*** (**FIG. 1**) as represented by activity block ***602*** or the user depressing the first actuator 116 as represented by activity block ***604***. Either event wakes the processor ***560*** from a power conserving sleep mode.

[92] If the user switch has been depressed, the process advances to activity block 606 to perform the read-back. To that end, the processor will access the memory ***578*** to obtain the number of drug doses that have occurred in the current

dosing session. The processor will then cause the motor ***562*** to provide a number of vibration bursts that corresponds to the number of drug doses that have been counted during the current dosing session.

[93] If the interrupt is caused by the depression of the first actuator button ***116***, the process advances to decision block ***608*** to determine if the subsequent depression of the second actuator button ***118*** (**FIG. 1**) calling for another dosage delivery occurred during the current dosing session. If it has, the process advances to activity block 610 to increment the dose count. The process then returns and the processor falls back to sleep.

[94] If in decision block ***608*** it is determined that a new dosing session has begun since the last dosage delivery request, the process advances to activity block ***612*** wherein the number of dosage deliveries occurring during the last completed dosing session is stored in memory for the history file. The process then advances to activity block ***614*** wherein the current day and time are stored in memory to time stamp the dosage delivery just administered.

[95] The process now advances to activity block ***616*** wherein the timer ***580*** is reset for beginning the timing of a new dosing session. Once the timer ***580*** is reset, the process advances to activity block ***610*** for incrementing the dose counter. The process then returns.

[96] The sensing of a dosage delivery as may be seen from the foregoing is a two event process. This is in response to the requirement for conserving battery power. The first event is the closing of the reed switch ***532***. The reed switch draws no power from the battery ***568***. Once the reed switch ***532*** is closed, the dosage delivery is validated by the optical sensor ***540***. The infrared optical switch has high reliability and is immune from environmental noise.

Since it is an active sensing device, it is only turned on when a dosage delivery is to be validated. Hence reliable dosage delivery sensing is provided while also minimizing the power requirements for such sensing.

[97] While particular embodiments of the present invention have been shown and described, modifications may be made, and it is therefore intended in the appended claims to cover all such changes and modifications which fall within the true spirit and scope of the invention as defined by those claims.

What is claimed is:

1. A device for providing information about the operation of a drug delivery device, the device comprising:

a housing arranged to attach to the drug delivery device;

a sensor that senses the operation of the drug delivery device and provides operational data indicative of the operation of the drug delivery device;

a memory that stores the operational data; and

an indication generator that generates a perceptible indication of the operational data.

2. The device of claim 1, wherein the indication generator is arranged to provide a tactile response to provide the perceptible indication.

3. The device of claim 2, wherein the tactile response is a vibratory response.

4. The device of claim 3, wherein the indication generator is a motor.

5. The device of claim 4, wherein the motor is an electric motor.

6. The device of claim 1, wherein the sensor comprises an optical sensor.

7. The device of claim 1, wherein the sensor comprises a magnetic sensor.

8. The device of claim 1, wherein the drug delivery device includes a pump that delivers the drug to a patient.

9. The device of claim 8, wherein the pump is a mechanical stroke pump and wherein the sensor senses the strokes of the pump.

10. The device of claim 9, further comprising a timer that times a dosing session of the device.

11. The device of claim 10, wherein the sensor includes a magnetic sensor that senses operation of the device.

12. The device of claim 11, wherein the drug delivery device includes at least one valve, wherein operation of the drug delivery device initiates with operation of the at least one valve, and wherein the magnetic sensor senses the operation of the at least one valve.

13. The device of claim 12, wherein the sensor further comprises an optical sensor that senses strokes of the pump.

14. The device of claim 13, wherein the memory stores each pump stroke occurring during a dosing session.

15. The device of claim 14, wherein the indication generator generates a perceptible indication of the number of pump strokes occurring during a last dosing session.

16. The device of claim 15, wherein the memory stores operational data for a number of dosing sessions in a history file.

17. The device of claim 16, further including an interface arranged to provide the history file to an external reader.

18. The device of claim 17, wherein the interface comprises a USB interface.

19. The device of claim 1, wherein the memory stores operational data for a dosing session and wherein the indication generator generates a perceptible indication of the operational data generated during a last dosing session.

20. The device of claim 19, wherein the memory stores operational data for a number of dosing sessions in a history file.

21. The device of claim 20, further including an interface arranged to provide the history file to an external reader.

22. The device of claim 21, wherein the interface comprises a USB interface.

23. The device of claim 6, wherein the drug delivery device includes a pump that delivers the drug to the patient and wherein the optical sensor senses operation of the pump.

24. The device of claim 7, wherein the drug delivery device includes at least one valve, wherein operation of the drug delivery device initiates with operation of the at least one valve, and wherein the magnetic sensor senses the operation of the at least one valve.

25. A device for providing information about the operation of a drug delivery device, the device comprising:

a sensor that senses the operation of the drug delivery device and generates an activation signal;

a clock mechanism that generates a time signal;

a memory that receives and stores the activation signal and the time signal and creates an information packet coordinating the time signal and the activation signal;

an interrogator that interrogates the memory such that the memory generates a memory signal in response thereto; and

a responder that receives the memory signal and generates a tactile response.

26. The device of claim 25, wherein the tactile response is a vibratory response.

27. The device of claim 26, wherein the responder is a motor.

28. The device of claim 26, wherein the motor is an electric motor.

29. The device of claim 25, wherein the sensor comprises an optical sensor.

30. The device of claim 25, wherein the sensor comprises a magnetic sensor.

31. The device of claim 25, wherein the drug delivery device includes a pump that delivers the drug to a patient.

32. The device of claim 31, wherein the pump is a mechanical stroke pump and wherein the sensor senses the strokes of the pump.

33. The device of claim 32, further comprising a timer that times a dosing session of the device.

34. The device of claim 33, wherein the sensor includes a magnetic sensor that senses operation of the device.

35. The device of claim 34, wherein the drug delivery device includes at least one valve, wherein operation of the device initiates with operation of the at least one valve, and wherein the magnetic sensor senses the operation of the at least one valve.

36. The device of claim 35, wherein the sensor further comprises an optical sensor that senses strokes of the pump.

37. The device of claim 36, wherein the memory stores each pump stroke occurring during a dosing session.

38. The device of claim 37, wherein the indication generator generates a perceptible indication of the number of pump strokes occurring during a last dosing session.

39. The device of claim 38, wherein the memory stores operational data for a number of dosing sessions in a history file.

40. The device of claim 39, further including an interface arranged to provide the history file to an external reader.

41. The device of claim 40, wherein the interface comprises a USB interface.

42. The device of claim 25, wherein the memory stores operational data for a dosing session and wherein the indication generator generates a perceptible indication of the operational data generated during a last dosing session.

43. The device of claim 42, wherein the memory stores operational data for a number of dosing sessions in a history file.

44. The device of claim 43, further including an interface arranged to provide the history file to an external reader.

45. The device of claim 44, wherein the interface comprises a USB interface.

46. The device of claim 29, wherein the drug delivery device includes a pump that delivers the drug to the patient and wherein the optical sensor senses operation of the pump.

47. The device of claim 30, wherein the drug delivery device includes at least one valve, wherein operation of the device initiates with operation of the at least one valve, and wherein the magnetic sensor senses the operation of the at least one valve.

48. A device for providing information about the operation of a drug delivery device, the drug delivery device including a mechanical stroke pump that delivers the drug to a patient and at least one valve, the operation of which initiates operation of the drug delivery device, the device comprising:

a housing arranged to attach to the drug delivery device;

a timer that times a dosing session;

a magnetic sensor that senses the operation of the at least one valve;

an optical sensor that senses operation of the pump to provide operational data;

a memory that stores the operational data provided by the optical sensor during a last dosing session;

an interrogator that interrogates the memory such that the memory generates a memory signal in response thereto representing operation of the drug delivery device during a last dosing session; and

a responder that receives the memory signal and generates a tactile response.

49. A drug infusion assembly comprising:

a drug delivery device arranged to adhere to a patient's skin and including a reservoir that holds the drug, a cannula that delivers the drug to the patient, and a pump that causes the drug to flow to the cannula; and

a monitor device that that provides information about the operation of the drug delivery device, the monitor device comprising a housing arranged to be attached to and detached from the drug delivery device, a sensor that senses the operation of the drug delivery device and provides operational data indicative of the operation of the drug delivery device, a memory that stores the operational data, and an indication generator that generates a perceptible indication of the operational data.

50. The assembly of claim 49, wherein the indication generator is arranged to provide a tactile response to provide the perceptible indication.

51. The assembly of claim 50, wherein the tactile response is a vibratory response.

52. The assembly of claim 49, wherein the sensor comprises an optical sensor.

53. The assembly of claim 49, wherein the sensor comprises a magnetic sensor.

54. The assembly of claim 49, wherein the pump is a mechanical stroke pump and wherein the sensor senses the strokes of the pump.

55. The assembly of claim 49, wherein the monitor device further comprises a timer that times a dosing session of the device.

56. The assembly of claim 49, wherein the drug delivery device includes at least one valve, wherein operation of the drug delivery device initiates with operation of the at least one valve, and wherein the sensor senses the operation of the at least one valve.

57. The assembly of claim 56, wherein the sensor includes a magnetic sensor that senses operation of the at least one valve.

58. The assembly of claim 49, wherein the pump is a mechanical stroke pump and wherein the sensor further comprises an optical sensor that senses strokes of the pump.

59. The assembly of claim 58, wherein the memory stores each pump stroke occurring during a dosing session.

60. The assembly of claim 59, wherein the monitor device further includes a timer that times the dosing session.

61. The assembly of claim 60, wherein the indication generator generates a perceptible indication of the number of pump strokes occurring during a last dosing session.

62. The assembly of claim 61, wherein the memory stores operational data for a number of dosing sessions in a history file.

63. The assembly of claim 62, wherein the monitor device further includes an interface arranged to provide the history file to an external reader.

64. The assembly of claim 63, wherein the interface comprises a USB interface.

65. The assembly of claim 49, wherein the memory stores operational data for a dosing session and wherein the indication generator generates a perceptible indication of the operational data generated during a last dosing session.

66. The assembly of claim 65, wherein the memory stores operational data for a number of dosing sessions in a history file.

67. The assembly of claim 66, further including an interface arranged to provide the history file to an external reader.

68. The assembly of claim 67, wherein the interface comprises a USB interface.

69. A drug infusion assembly comprising:

a drug delivery device arranged to adhere to a patient's skin and including a reservoir that holds the drug, a cannula that delivers the drug to the patient, and a pump that causes the drug to flow to the cannula; and

a monitor device for providing information about the operation of a drug delivery device, the monitor device including a housing arranged to be attached to and detached

from the drug delivery device, a sensor that senses the operation of the drug delivery device and generates an activation signal, a clock mechanism that generates a time signal, a memory that receives and stores the activation signal and the time signal and creates an information packet coordinating the time signal and the activation signal, an interrogator that interrogates the memory such that the memory generates a memory signal in response thereto, and a responder that receives the memory signal and generates a response.

70. The assembly of claim 49, wherein the responder is arranged to provide a tactile response to provide the perceptible indication.

71. The assembly of claim 70, wherein the tactile response is a vibratory response.

72. The assembly of claim 69, wherein the sensor comprises an optical sensor.

73. The assembly of claim 69, wherein the sensor comprises a magnetic sensor.

74. The assembly of claim 69, wherein the pump is a mechanical stroke pump and wherein the sensor senses the strokes of the pump.

75. The assembly of claim 69, wherein the clock times a dosing session of the device.

76. The assembly of claim 69, wherein the drug delivery device includes at least one valve, wherein operation of the drug delivery device initiates with operation of the at least one valve, and wherein the sensor senses the operation of the at least one valve.

77. The assembly of claim 76, wherein the sensor includes a magnetic sensor that senses operation of the at least one valve.

78. The assembly of claim 69, wherein the pump is a mechanical stroke pump and wherein the sensor further comprises an optical sensor that senses strokes of the pump.

79. The assembly of claim 78, wherein the memory stores each pump stroke occurring during a dosing session.

80. The assembly of claim 79, wherein the monitor device further includes a timer that times the dosing session.

81. The assembly of claim 80, wherein the responder generates a perceptible indication of the number of pump strokes occurring during a last dosing session.

82. The assembly of claim 81, wherein the memory stores operational data for a number of dosing sessions in a history file.

83. The assembly of claim 82, wherein the monitor device further includes an interface arranged to provide the history file to an external reader.

84. The assembly of claim 83, wherein the interface comprises a USB interface.

85. The assembly of claim 69, wherein the memory stores operational data for a dosing session and wherein the indication generator generates a perceptible indication of the operational data generated during a last dosing session.

86. The assembly of claim 85, wherein the memory stores operational data for a number of dosing sessions in a history file.

87. The assembly of claim 86, further including an interface arranged to provide the history file to an external reader.

88. The assembly of claim 87, wherein the interface comprises a USB interface.

FIG. 1

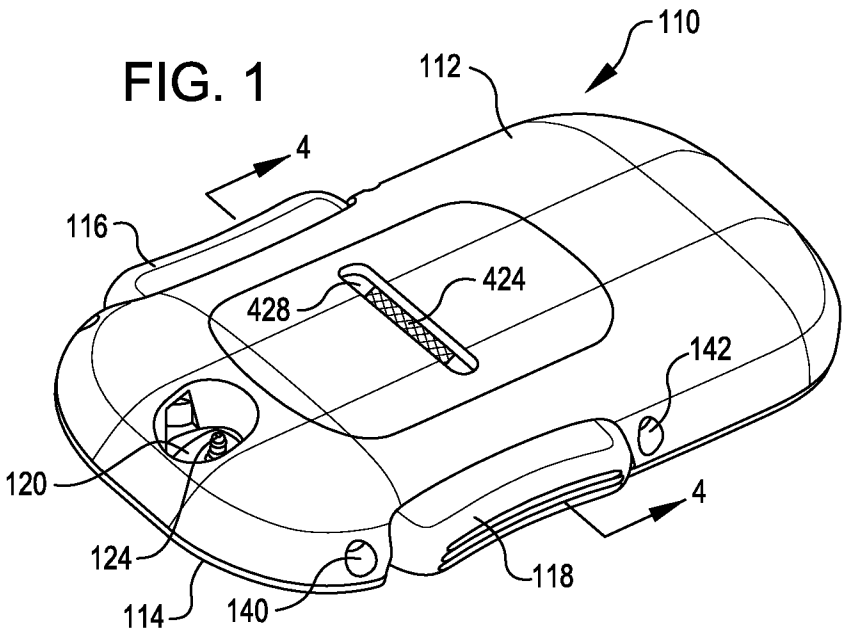
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FIG. 2

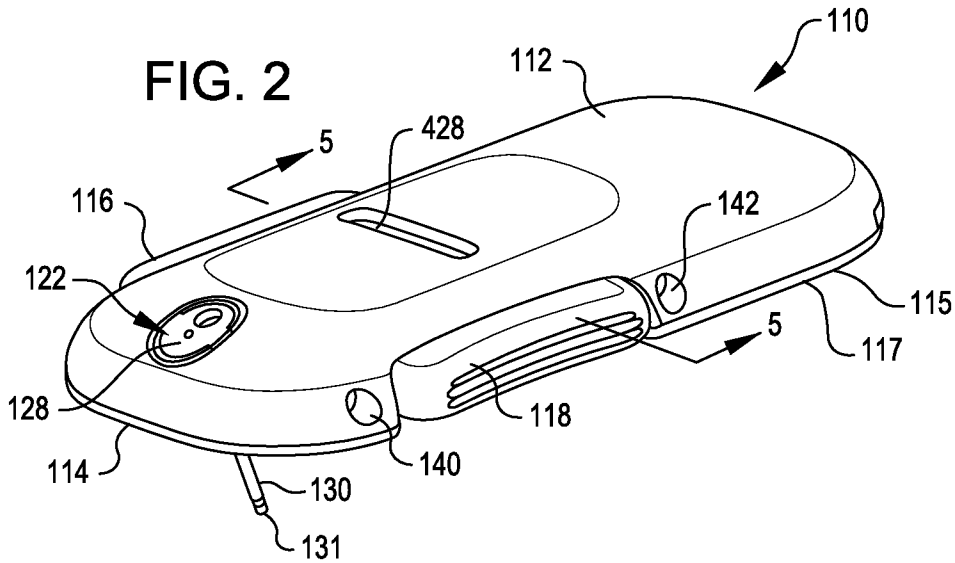
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FIG. 3

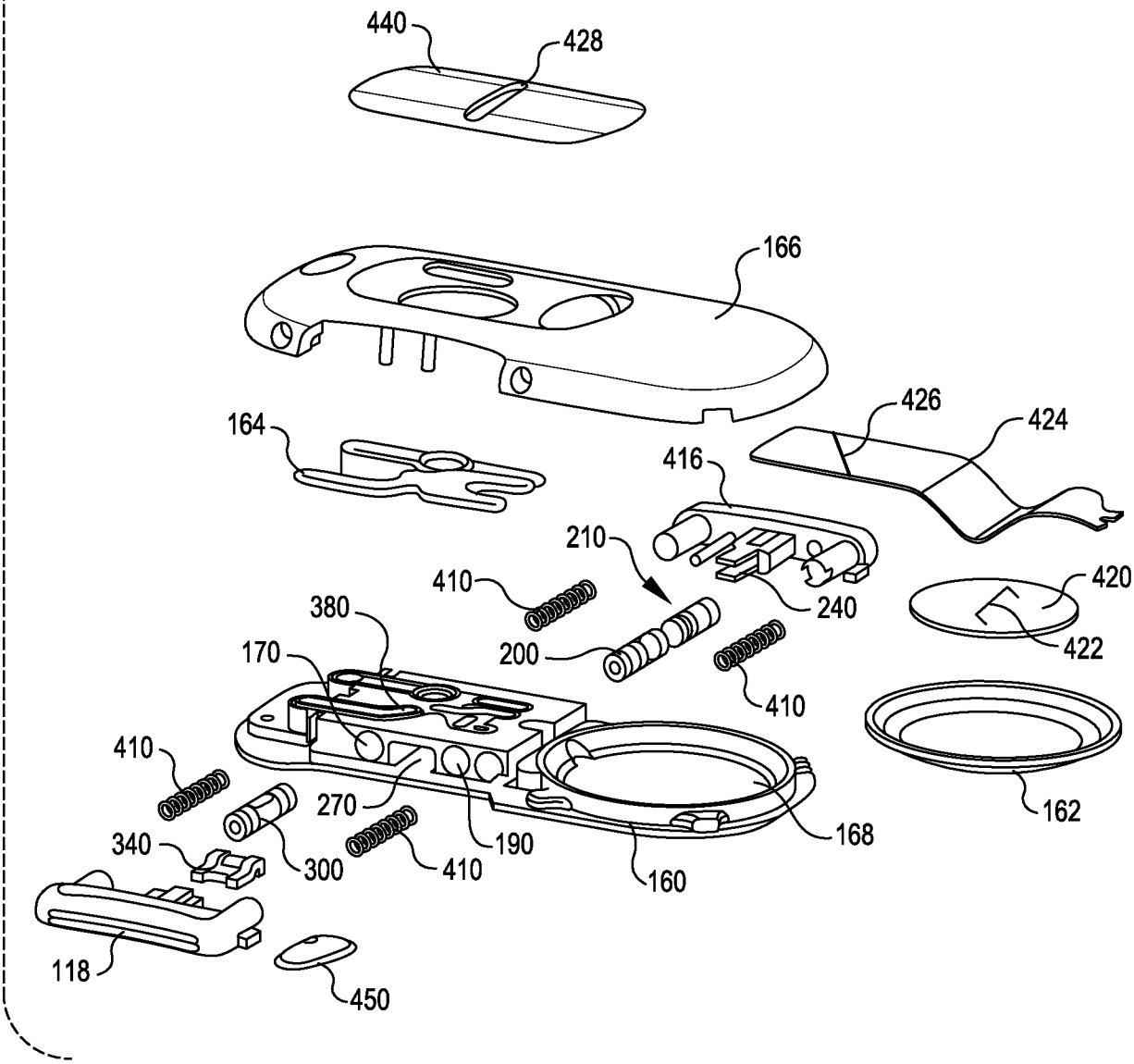
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FIG. 4

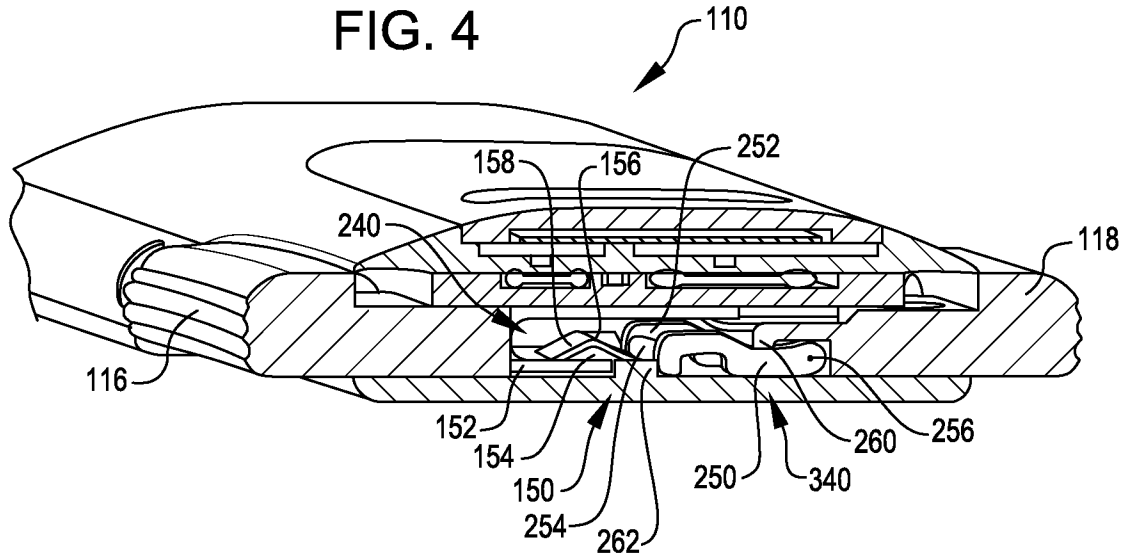

FIG. 5

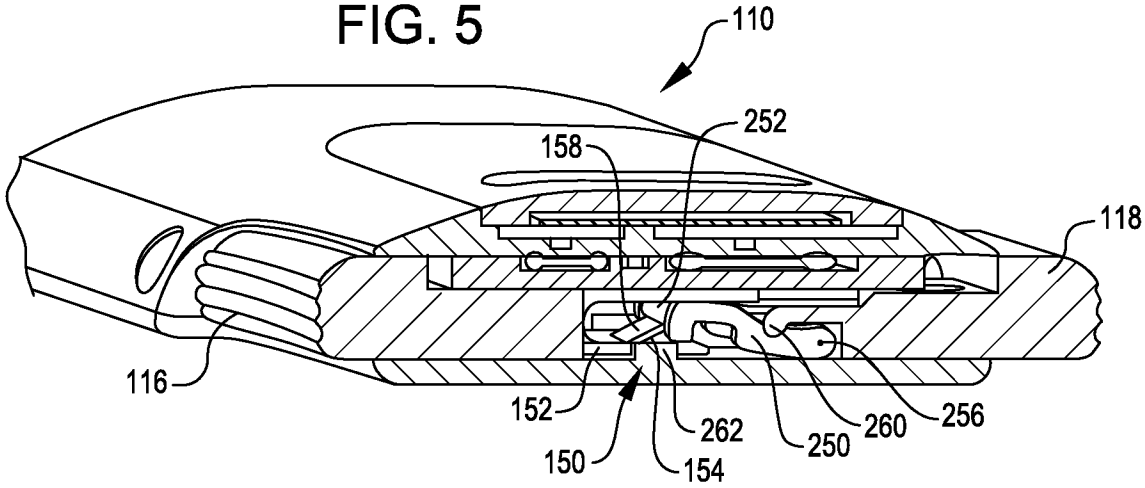

FIG. 6

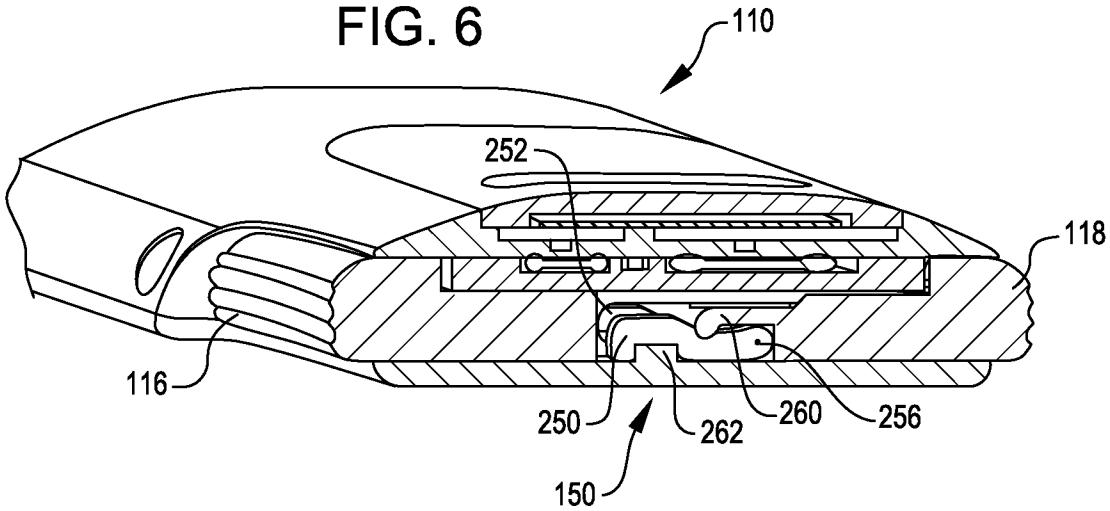

FIG. 7

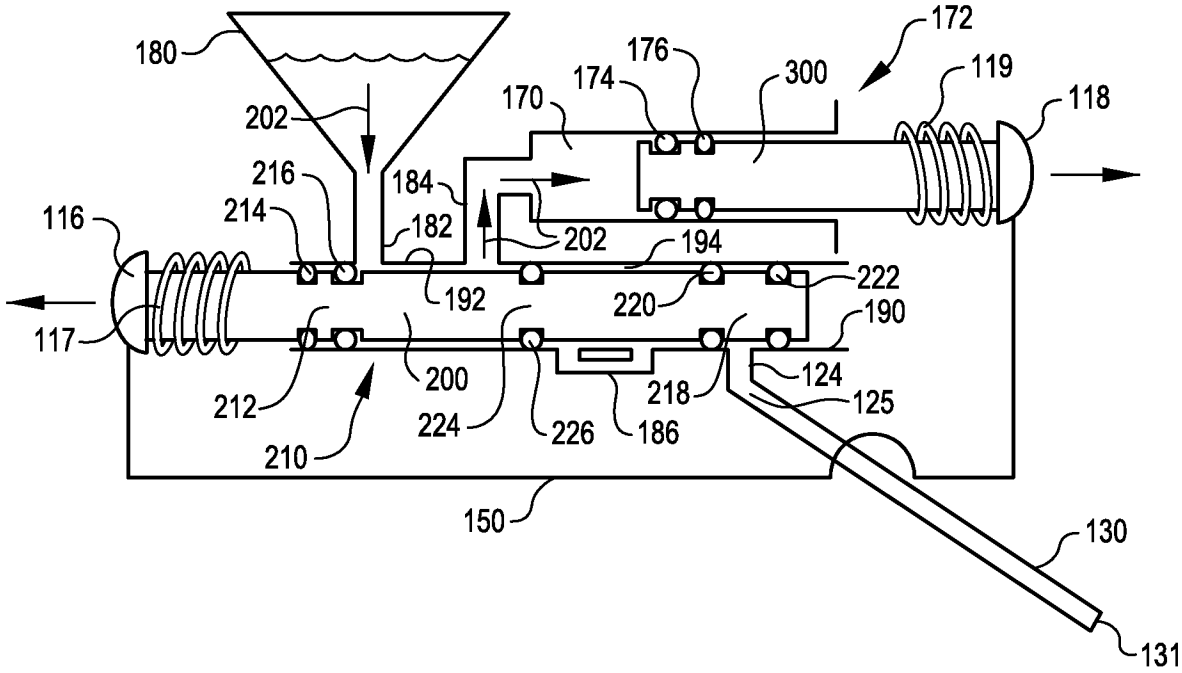
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FIG. 8

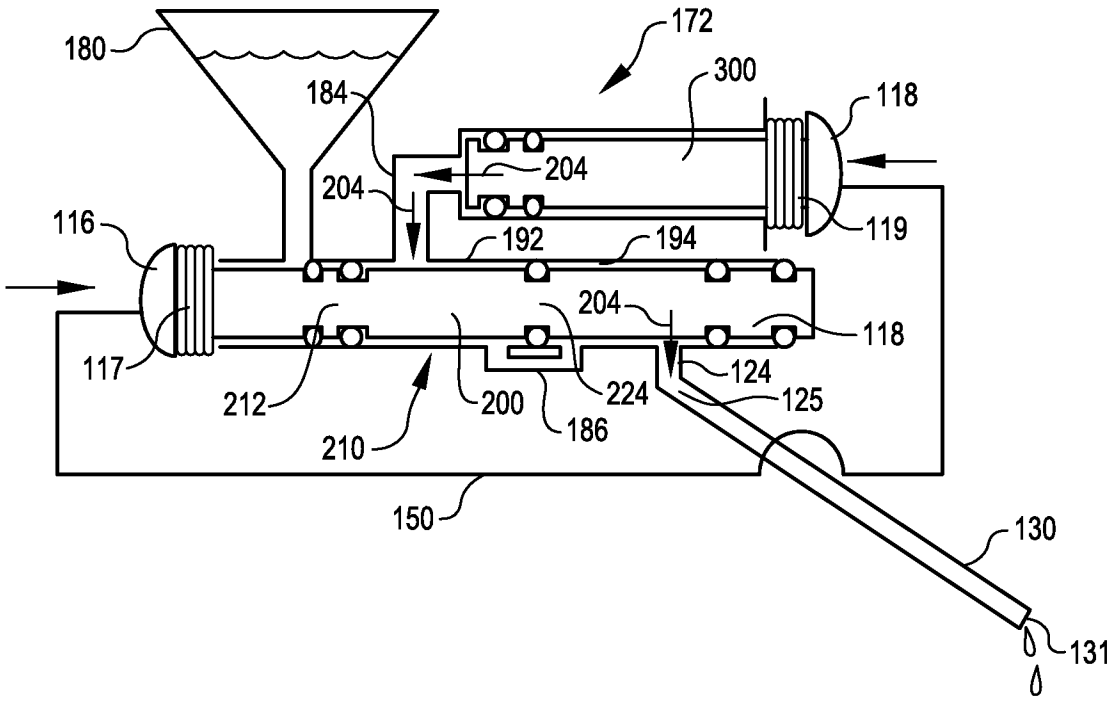
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FIG. 9

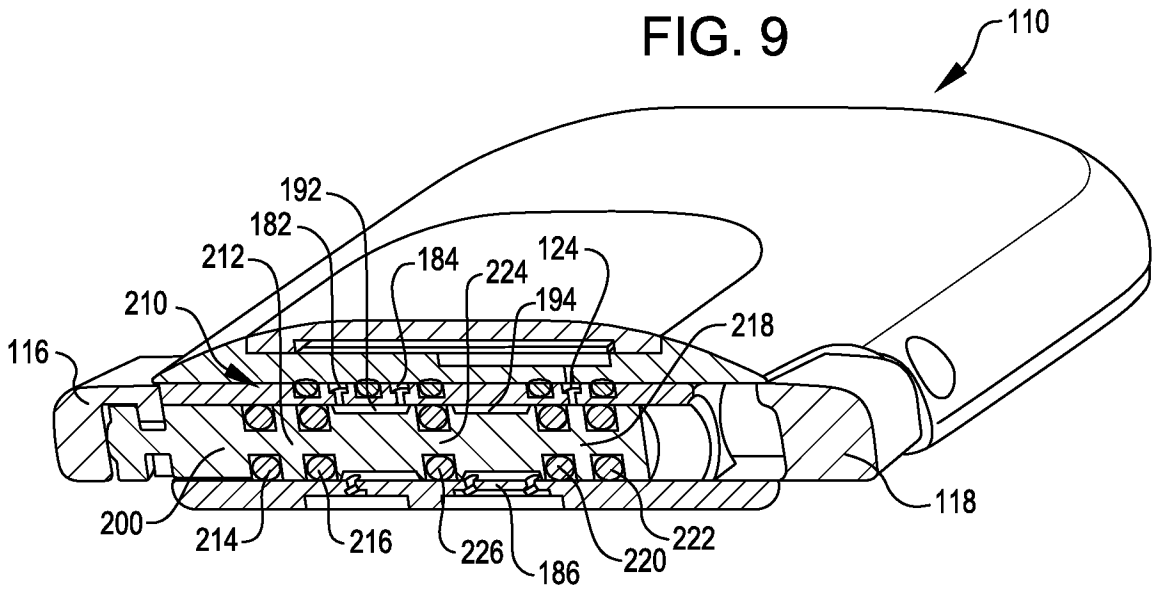
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FIG. 10

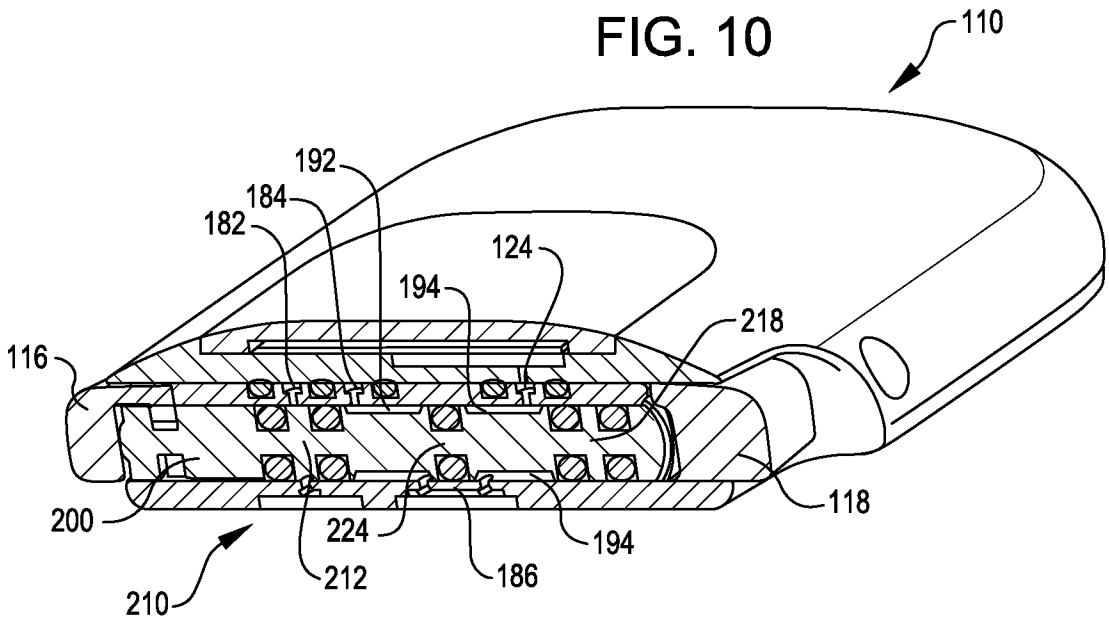
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FIG. 11

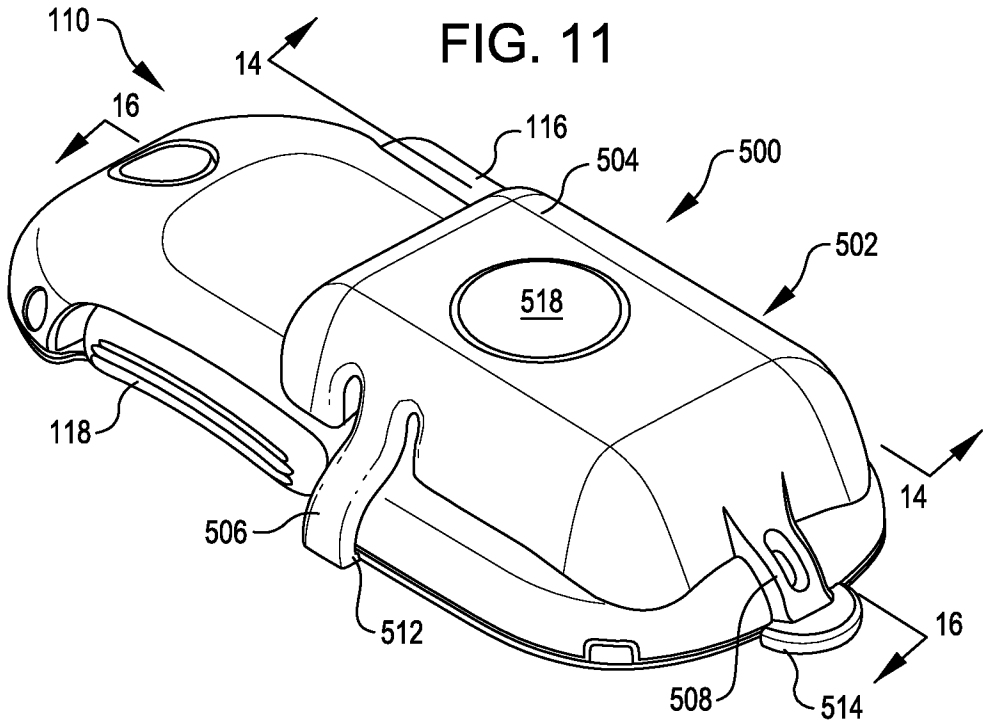

FIG. 12

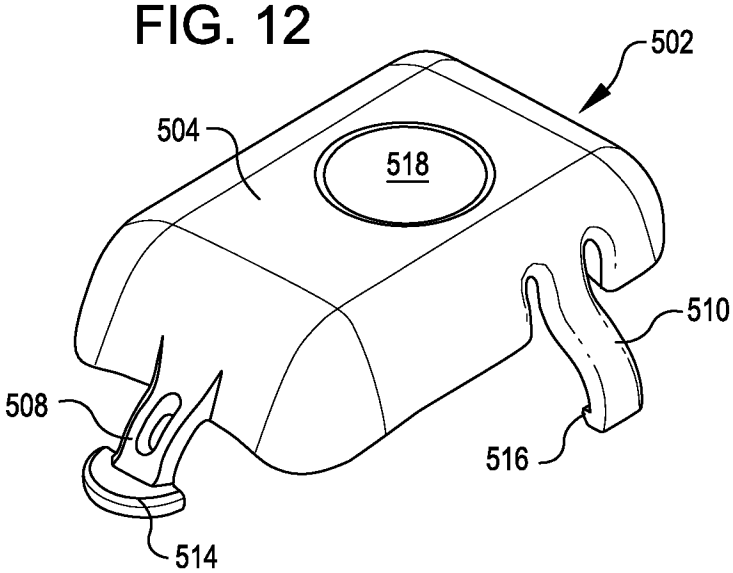

FIG. 13

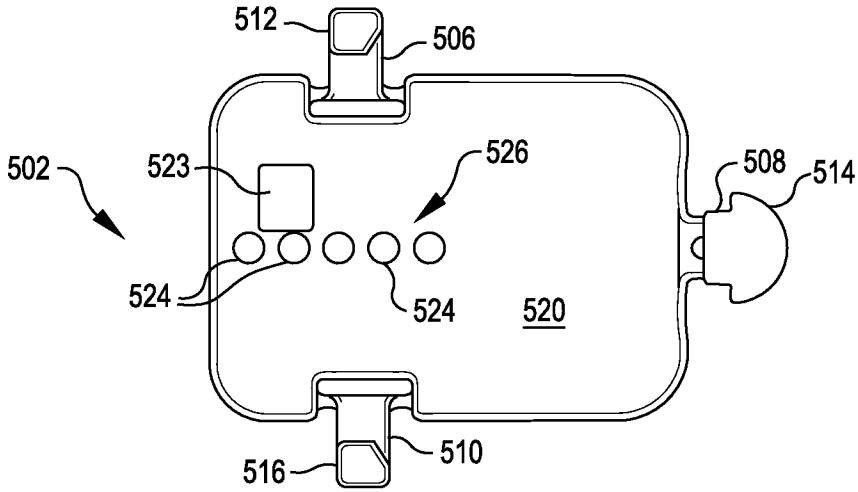

FIG. 14

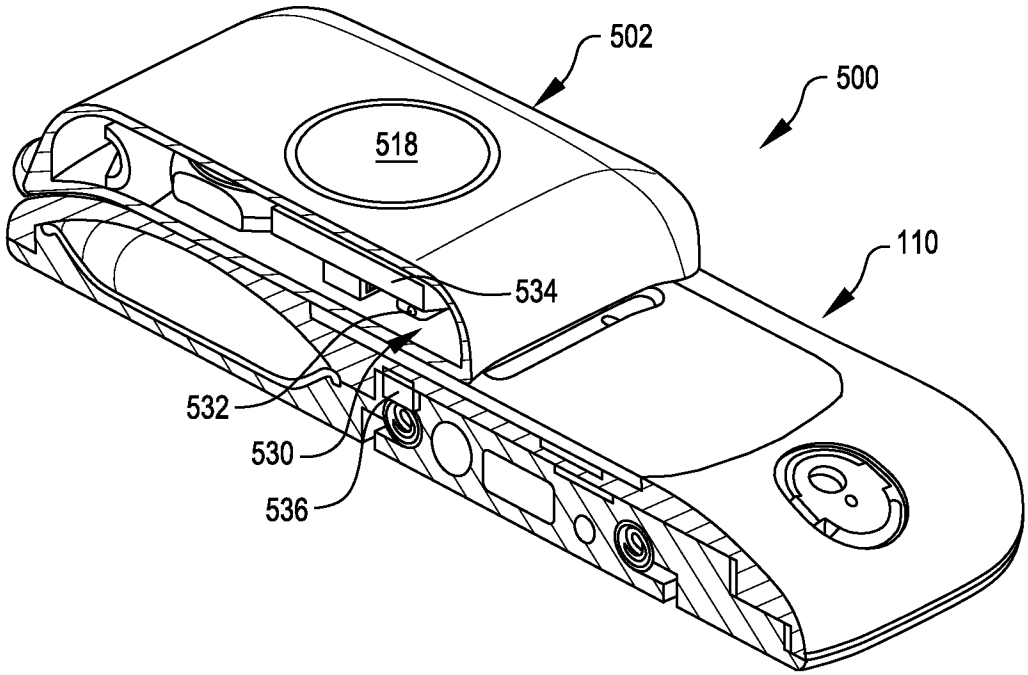

FIG. 15

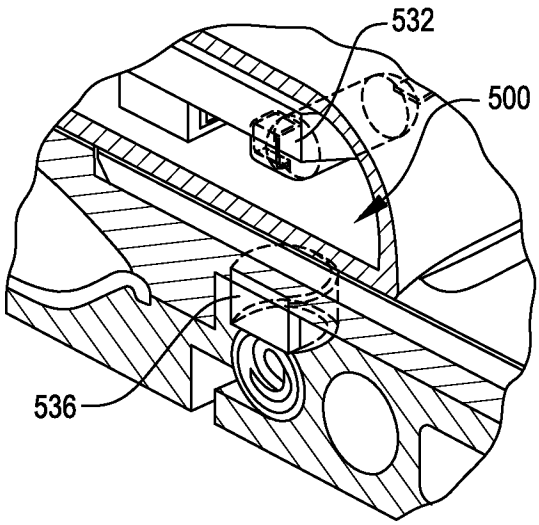

FIG. 16

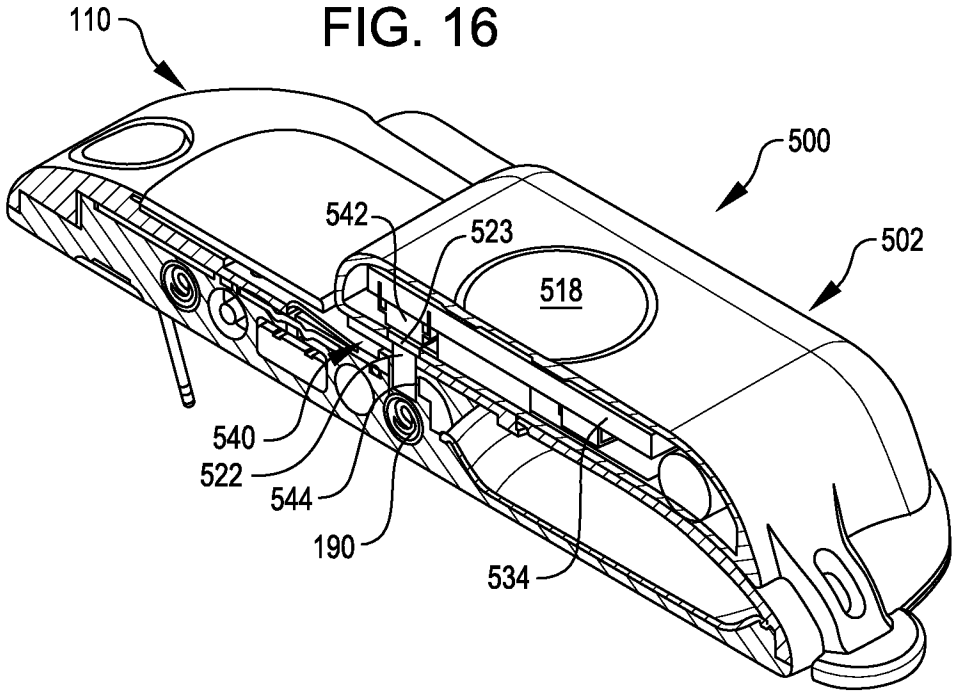
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FIG. 17

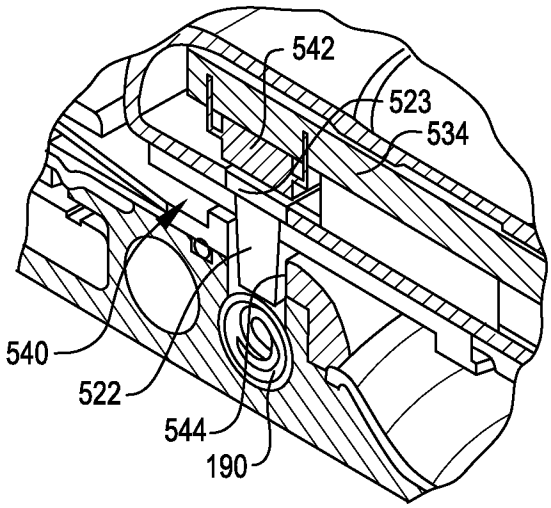
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FIG. 18

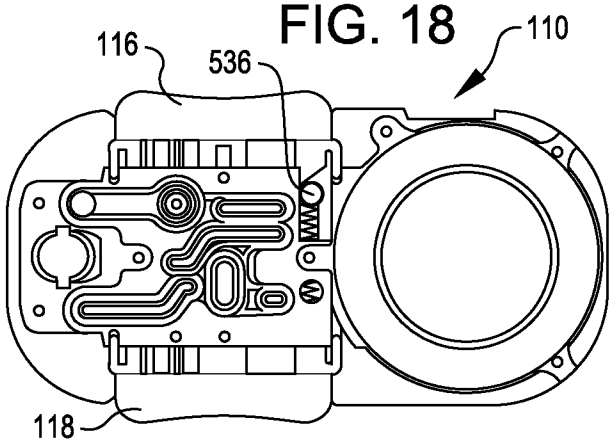


FIG. 19

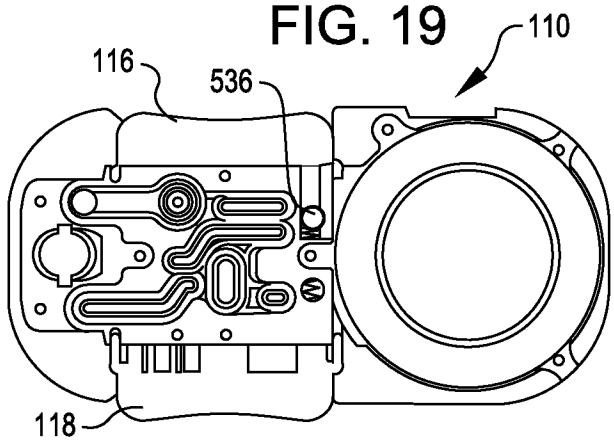


FIG. 20

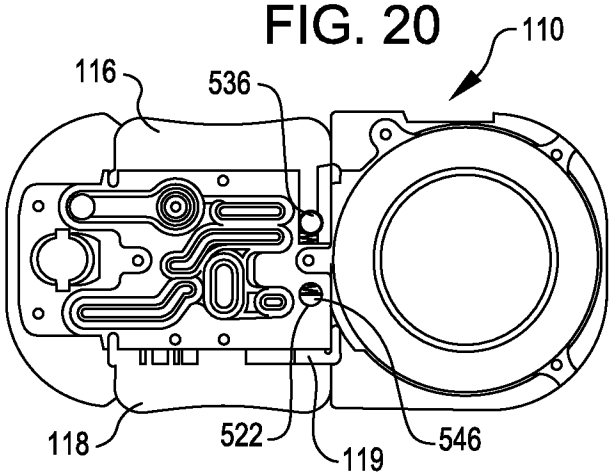


FIG. 21

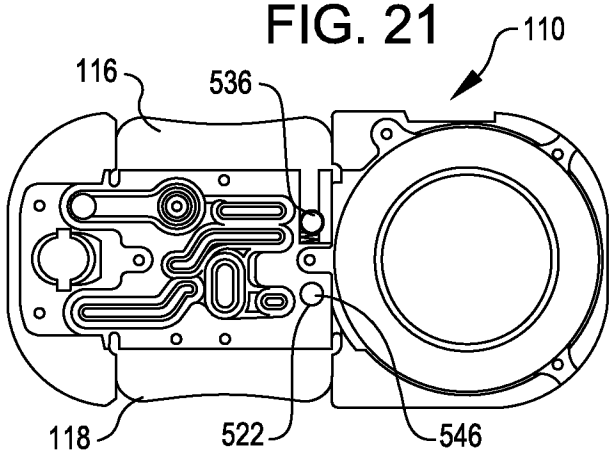
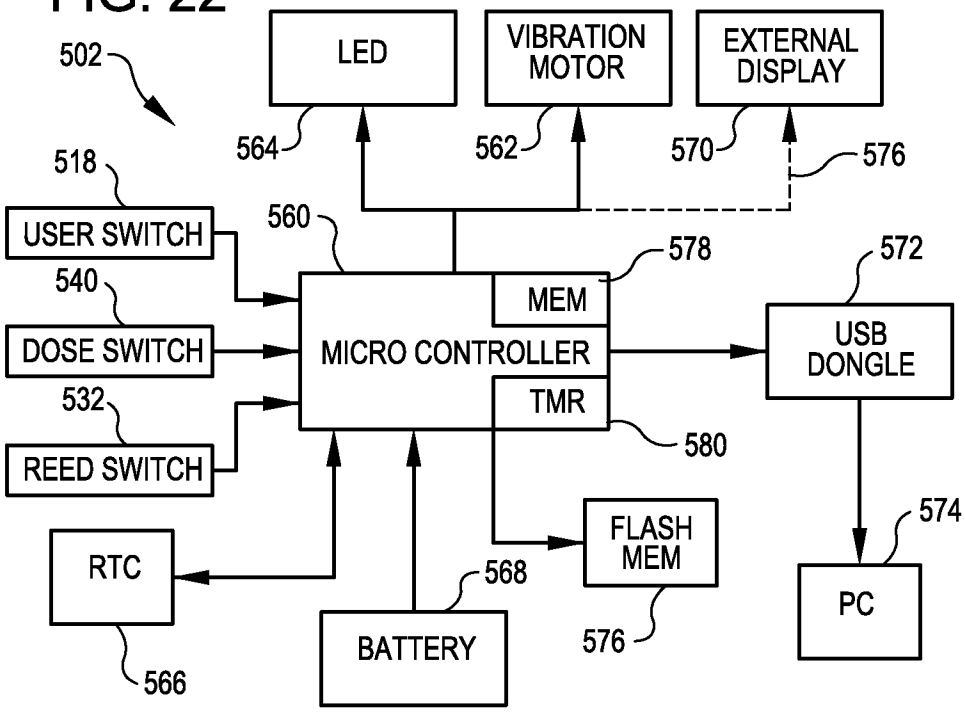


FIG. 22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EXTERNAL DISPLAY
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570
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USER SWITCH
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MEM
DOSE SWITCH
MICRO CONTROLLER
USB DONGLE
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TMR
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REED SWITCH
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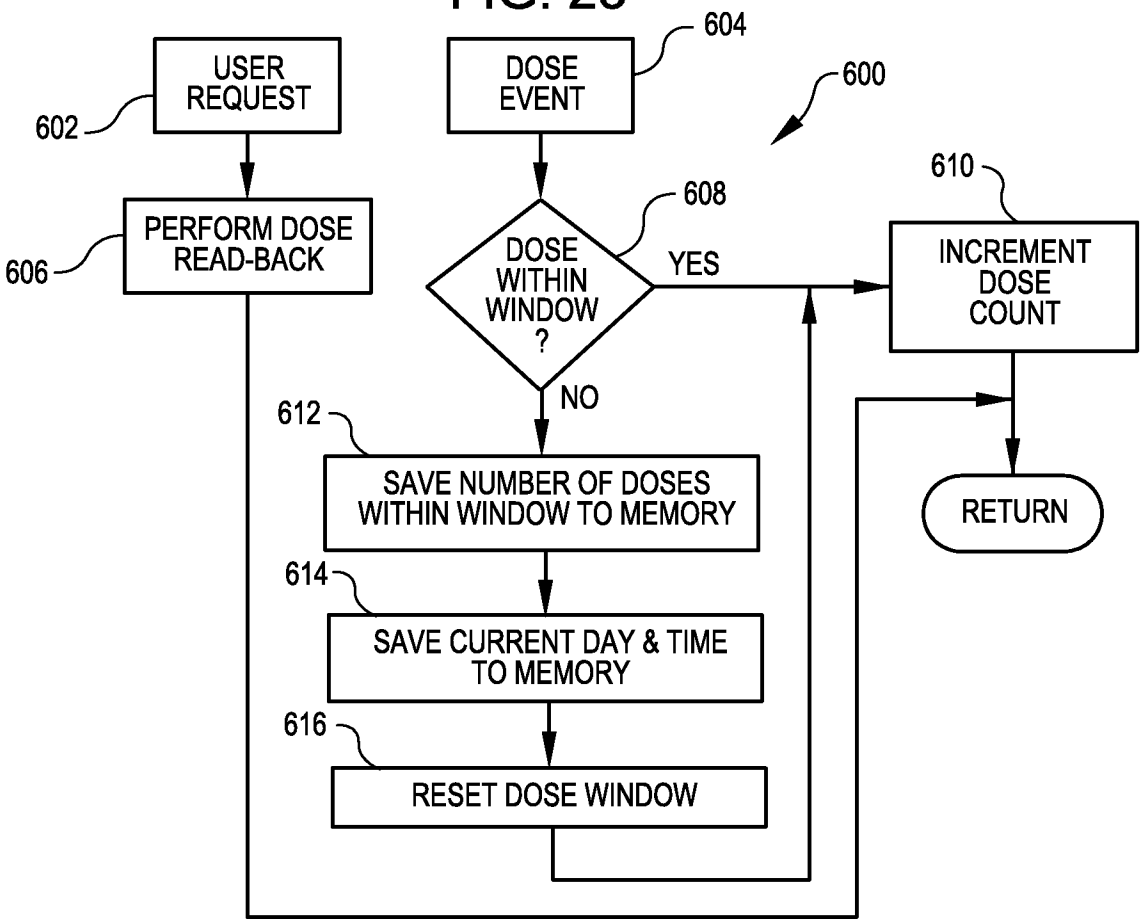
FLASH MEM
RTC
568
PC
BATTERY
576
566

FIG. 23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USER REQUEST
DOSE EVENT
600
602
610
608
PERFORM DOSE READ-BACK
DOSE WITHIN WINDOW ?
YES
INCREMENT DOSE COUNT
606
NO
612
SAVE NUMBER OF DOSES WITHIN WINDOW TO MEMORY
RETURN
614
SAVE CURRENT DAY & TIME TO MEMORY
616
RESET DOSE WINDOW