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(54) Title: LIQUID DOSAGE MONITORING

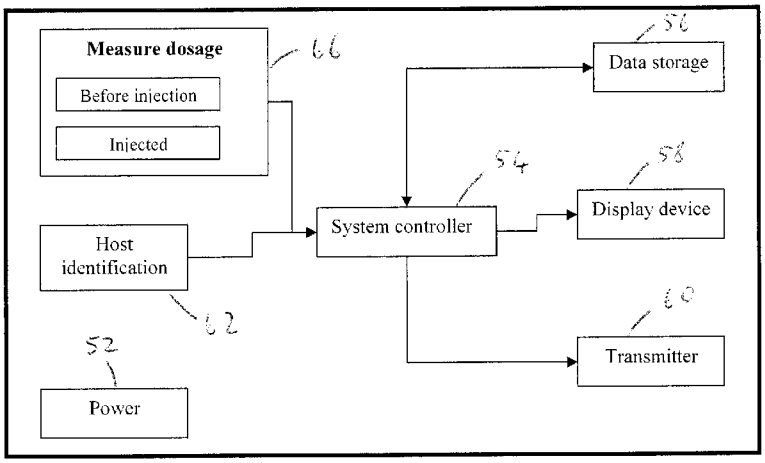

FIGURE 4

(57) Abstract: A dosage monitoring device (46,70) for use in conjunction with a liquid dispenser (10) includes a memory (56), a quantity sensor (66) configured to determine the quantity of an individual dispensed dosage and to record the quantity in the memory, a dispensing sensor (66) configured to sense when said individual dosage is dispensed and to record the event of dispensing in the memory, and feedback means (58,60) that is configured to make the quantity of the individual dosage available for display. The dosage monitoring device (46,70) is releasably attachable to the liquid dispenser (10) and can be re-used.

LIQUID DOSAGE MONITORING

FIELD OF THE INVENTION

This invention relates monitoring the dispensing of liquids. In particular, the invention relates to monitoring doses of liquids injected into mammalian subjects.

BACKGROUND TO THE INVENTION

Various devices are available for dispensing multiple doses of liquids to subjects and these devices typically include means for setting the quantity of the liquid to be dispensed in a single dose and means for dispensing the liquid. A typical example is an injection device for subcutaneous injection of insulin, in which successive doses of insulin are dispensed from a reservoir and are injected into the subject. The user can typically adjust the quantity of each dose.

The background to the present invention is described further herein with reference to the subcutaneous dispensing of insulin, as a convenient example, but the background and the present invention apply equally to the dispensing of other liquids.

Insulin (like many other liquids) needs to be dispensed regularly in order to maintain desired levels of insulin in the subject's body and accordingly, it is essential that subsequent dosages are administered, taking into account the quantities and time of recent dosages. Individual dosages are often administered at predetermined intervals during an otherwise normal life of the subject and circumstances often make accurate record-keeping difficult, so that insulin is administered, based on the subject's recollection of recent dosages. The subject's recollection is obviously prone to inaccuracy with a resulting risk of administering incorrect dosages.

Insulin is typically supplied in multi-dose dispensers, referred to as "pens", which are either disposable or which are re-usable and can be loaded with cartridges of insulin. Attempts have been made to record the quantities and time of dosages with re-

usable insulin pens, as described in US Patent Application No. 12/442,168 (published as US 2009/0318865). The record keeping apparatus in these pens is costly and accordingly, it has not been applied to disposable insulin pens.

The present invention seeks to provide means for keeping record of the quantities and times of liquid dosages dispensed to subjects, in a manner that is cost effective and that can preferably be used in conjunction with different commercially available dispensing apparatus.

SUMMARY OF THE INVENTION

According to the present invention there is provided a dosage monitoring device, for use in conjunction with a liquid dispenser, said dosage monitoring device comprising;

a memory;

a quantity sensor, configured to determine the quantity of an individual dosage, when dispensed from the liquid dispenser and to record said quantity in the memory;

a dispensing sensor, configured to sense when said individual dosage is dispensed from the liquid dispenser and to record the event of dispensing said dosage in the memory; and

feedback means, configured to make the quantity of said individual dosage available for display;

wherein said dosage monitoring device is releasably attachable to said liquid dispenser.

The dosage monitoring device may include a clock and the dispensing sensor may be configured to record the time of the event of dispensing said dosage, according to the clock, in the memory. The feedback means may be configured to make the time of said individual dosage available for display.

The dosage monitoring device may be configured to receive input in the form of a set dosage, to store said set dosage in the memory and the feedback means may

be configured to make said set dosage available for display.

The feedback means may include a display on the dosage monitoring device, on which the quantity and/or time of said individual dosage, and/or said set dose is displayed and/or the feedback means may include means for transmitting a signal containing said data of each individual dosage to a remote device, external to the dosage monitoring device.

The liquid dispenser may include a rotatable dose setting element (e.g. a helically moving scale drum) and the quantity sensor of the dosage monitoring device may include means for determining the rotation of the dose setting element. Instead or in addition, the liquid dispenser may include a linearly displaceable dosing element such as a push button or the like and the dosage monitoring device may include means for determining the linear displacement of the dosing element.

The dosage monitoring device may include a click mechanism, configured to emit a sound upon incremental changes in the quantity of the dosage.

The dosage monitoring device may include a switch such as a button and may be configured to dispense a set quantity of said liquid, when said button is pressed. The liquid dispenser may be actuated to dispense said liquid using stored energy, upon pressing the button of the dosage monitoring device.

The dosage monitoring device may include at least one sensor that is configured to identify a feature of a liquid dispenser to which the device is attached, in order to identify the liquid dispenser.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the present invention, and to show how the same may be carried into effect, the invention will now be described by way of non-limiting example, with reference to the accompanying drawings in which:

Figure 1 is a side elevation of a liquid dispenser in the form of a typical disposable insulin pen in accordance with the prior art;

Figure 2 is a detail end view of a helical dial of the insulin pen of Figure 1;

Figure 3A is a side elevation of a dose setting mechanism of the insulin pen of Figure 1;

Figures 3B to 3D are sectional views of the dose setting mechanism of Figure 3A in different dose setting positions;

Figure 3E is an end view of the dose setting mechanism of Figure 3A;

Figure 4 is a schematic diagram of a dosage monitoring device in accordance with the present invention;

Figure 5 is a three dimensional view of an end of the insulin pen of Figure 1, with its push button removed;

Figure 6 is an end view of the end of the insulin pen of Figure 5;

Figure 7 is a three-dimensional view of a dosage monitoring device in accordance with a first embodiment of the present invention;

Figure 8 is an end view of the dosage monitoring device of Figure 7; and

Figure 9 is three-dimensional view of parts of a dosage monitoring device in accordance with a second embodiment of the present invention, next to parts of the insulin pen of Figure 1.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to Figures 1 to 3, a disposable insulin pen in accordance with the prior art is described and is generally identified by reference numeral 10. As mentioned above, the present invention relates to a dosage monitoring device that is intended to be used in conjunction with a liquid dispensing device and a disposable insulin pen is merely an example of such a liquid dispensing device.

All rotational directions are described as viewed from the “push button” end of the insulin pen 10.

Referring to Figures 1 and 2, the pen 10 includes three detachable parts, being a pen body 12, a cap 14 and a needle (not shown) that screws onto an end of the pen

body and seals against a rubber membrane 16. The body 12 can conveniently be described as housing an insulin cartridge 18 and a dosing mechanism 20. The insulin cartridge serves as a reservoir of insulin to be dispensed through the needle and includes an internal dispensing mechanism that is actuated by rotation. The dosing mechanism includes a rotatable dosage selector 22, a dosing element in the form of a push button 24 and dose indicator 26.

Referring also to Figures 3A to 3E, a dose setting mechanism 28 is shown, which forms part of the dosing mechanism 20. The dose setting mechanism 28 includes a hollow, cylindrical rear part 30 of the pen body 12, with the dosage selector 22 at its one end and a key 32 protruding from its opposite end. The dosage selector 20 is integrally formed with a hollow, cylindrical outer dosage dial 34 that extends inside the body 30, with a helical ridge-and-groove engagement which allows the dial to be displaced helically relative to the body, when the dosage selector is rotated. The clockwise and counter-clockwise rotation thus slides the outer dosage dial 34 in and out of the body 30 and this is done in set increments, which are displayed on the dose indicator 26, which is merely a window in the body's wall, through which a calibration on the outer dosage dial 34 is visible.

The key 32 has a rectangular profile at an end that engages the insulin cartridge 18, so that when the key 32 is rotated, it drives a plunger of the internal dispensing mechanism inside the insulin cartridge 18, which dispenses insulin through the needle. The quantity of insulin dispensed is directly proportional to the rotation of the key 32 (and the plunger) and the key and plunger can only rotate counter-clockwise.

A dosage stop ring 36 is provided inside the outer dosage dial 34 and around a cylindrical extension of the key 32 and the stop ring is configured to interact with an inward ridge of the outer dosage dial, to prevent the dosage dial from being displaced out of the body 30 beyond a certain position, which corresponds to a maximum insulin dosage – as will be described below.

The body 30, key 32 and stop ring 36 are not displaceable relative to each other in an axial direction. The key 32 is rotatable relative to the body 30 in the clockwise direction only and the dosage selector 22 and outer dosage dial 34 are displaceable axially relative to the body 30 and can be rotated in both directions.

An inner dosage dial 38 extends inside the outer dosage dial 34, with an annular space between the dosage dials 34,38 and the inner dosage dial 38 interacts helically with the stop ring 36 and includes a protuberance that extends into a longitudinal grove in the key 32. The inner dosage dial 38 has an external shoulder inside the dosage selector 22, which is held in position inside the selector 22 by the push button 24 (which is not shown in Figures 3A to 3E). The shoulder 40 allows the inner and outer dosage dials 38,34 to move together in the axial direction and to rotate relative to each other. The engagement of the inner dosage dial 38 with the longitudinal groove in the key 32 ensures that the inner dosage dial 38 and key 32 always rotate together (only in the clockwise direction, as mentioned above), but the inner dosage dial 38 can slide axially relative to the key 32, when the outer dosage dial 34 is rotated and slides in and out of the body 30.

In use, when a dosage of insulin is to be dispensed, a user rotates the dosage selector 22 clockwise to increase the dosage and if necessary, counter-clockwise to reduce the dosage. This rotation does not dispense insulin yet, but causes the outer and inner dosage dials 34,38 to slide axially out of the body 30 (and partly inwards again, if rotated counter-clockwise) and to show a dosage corresponding to the axial displacement, on the dose indicator 26. During this movement (while the selector 22 and outer dial 34 are rotated), the inner dosage dial 38 moves axially, but does not rotate relative to the body 30 and the key 30 remains stationary relative to the body 30.

When the user is satisfied with the insulin dosage selected by rotation of the dosage selector 22, he pushes the button 24 in an axial direction and the initial axial movement of the button causes the inner and outer dosage dials 38,34 to be locked against rotation relative to each other. The user then continues to push the button

24 axially towards the body 30, which urges both the inner and outer dosage dials 38,34 to slide into the body 30 and at the same time, the helical engagement between the outer dial 34 and the body 30, causes both dosage dials 34,38 to rotate counter-clockwise. The counter-clockwise rotation of the inner dosage dial 28 causes the key 32 to rotate counter-clockwise and thus causes insulin to be dispensed from the cartridge 18 and to be injected subcutaneously into a subject, such as a human.

The clockwise rotation of the dosage selector 22, the axial displacement of the dosage dials 34,38, the helical rotation of the dosage dials and of the key 32, are all directly proportional to the quantity of insulin that is dispensed. This proportionality explains why limiting axial displacement of the outer dosage dial 34 with the dosage stop ring 36, prevents a predetermined maximum dosage quantity from being exceeded.

Figures 5 and 6 show an end of an embodiment of an insulin pen 10 with its push button 24 removed, similar to that shown in Figures 3A to 3D, but which includes castellated longitudinal ridges 42 on the inside of the dosage selector 22 and ramped protuberances 44 on an inner circumference of the inner dosage dial 38.

Figures 7 and 8 show an example of a dosage monitoring device in accordance with the present invention, which is generally indicated by reference numeral 46. The device 46 is intended to be re-usable and is releasably attachable to the end of the insulin pen 10, by removing the push button 24 from the pen and partly inserting the device 46 into the hollow end of the dosage selector 22. The device 46 can thus be removed from the pen 10 and can be re-used on another pen and it is thus suitable for use on disposable insulin pens.

The device 46 includes outwardly facing hook formations 48 and 50 that are configured to interact in ratchet-fashion with the castellated ridges 42 and ramped protuberances 44, respectively.

Inside, the device 46 houses electronic circuitry, represented by the diagram of Figure 4. This circuitry includes a power source 52 providing electrical power to the system, a system controller 54, memory 56 for data storage, a display device 58 such as a display screen, a signal transmitter 60, host identification means 62 and dosage monitoring means 66.

In use, the device 46 monitors the quantity of each dosage by measuring the actual dosage that is dispensed and/or by receiving a set quantity through user input or pre-programmed input. If the actual dosage quantity needs to be monitored, this can be done by implementing a wide variety of technology options or combinations and these include: optical measurement using LEDs, relying on either reflection or interruption; magnetic speed measurement; strain gauge measurement; mechanical switching; capacitance measurement; inductive rotation measurement; or the like. A wide variety of measurements are possible and as described above, these can measure any one of a number of mechanical parameters in the dose setting mechanism 28, each of which is directly proportional to the selected dosage. As an example, the device 46 can be set up to sense relative rotation between the outer dosage dial 34 and the inner dosage dial 38, by monitoring deflection of the hook formations 42,44. This monitoring can also be used to emit a sound with each deflection of the hook formations, which would serve as an audible aid to the user, indicating of each incremental rotation.

The dosage monitoring means 66 measures the quantity of each dosage and preferably also records the time (and date) of the dosage, using a clock (not shown). The dosage quantity and time is stored in the memory 56, which could implement any suitable technology, e.g. flash memory, EEPROM, RAM, or the like.

The stored dosage-related data and/or other data (such as the type of host pen 10, a set dosage, insulin type, user name, etc.) stored in the memory 56 can be displayed on the display device 58, which could implement any suitable technology, e.g. OLED, LCD, TFT, ELD, bi-stable e-link, character display, or the like.

Preferably, the device 46 is configured to transmit data stored on the memory 56 to a remote device via the transmitter 60, e.g. for diagnostic analysis. Suitable technologies for the transmission include: infrared; wireless options such as RF, Zigbee, Bluetooth, wifi, etc.; cable connection such as USB, firewire, Ethernet, etc.

Preferably, the device 46 can identify the insulin pen 10 or "host" on which it is fitted, by sensing physical attributes of the pen through its host identification means 62, by receiving input from a user, or the like. This information could be used to identify the type of insulin being dispensed.

The power source 52 can be a battery, photovoltaic cell, or the like.

The system controller 54 needs to implement logic to integrate the functional features described above with one another and a microcontroller will be suitable for this purpose.

Referring to Figure 9, parts of another embodiment of a dosage monitoring device are shown and are identified collectively by reference numeral 70 The monitoring device 70 shares many features with the device 46 described above with reference to Figures 4, 7 and 8.

The device 70 is intended to be used in conjunction with the insulin pen 10 of Figures 1 to 3, but it does not require removal of the push button 24 or modification of the dosage selector 22 and inner dosage dial 38 as shown in Figures 5 and 6. Instead, the device 70 is releaseably attached to the insulin pen 10, without any modification. Figure 9 also shows part of the pen body 30, the outer dosage dial 34, and the dosage selector 22. These parts of the insulin pen are identified collectively by reference numeral 10 and are shown alongside the device 70.

The device 70 is slid onto the pen 10 from the dosage selector's 22 end and a monitor body 72 of the device is removably received on the outside of the pen body 30. The engagement between the pen body 30 and monitor body 72 includes a

compressible filler, inwardly protuberances, or the like, so that the monitor body fits on the pen body with some interference and does not move relative to the pen body, once installed, unless a relatively strong force is applied to remove the device 70 from the pen 10. Similarly, a dial monitor 74 of the device 70 is received on the outside of the dosage selector 22 with some interference and does not move relative to the dosage selector until the device 70 is eventually removed from the pen 10, for re-use.

A monitor slider 76 extends between the monitor body 72 and the dial monitor 74. All three these components are cylindrically shaped and the dial monitor is attached to the monitor slider with a radial groove and ridge, so that the dial monitor can rotate relative to the monitor slider, but these two parts cannot move relative to each other in an axial direction. The monitor slider 76 is fitted inside the monitor body 72 with a longitudinal key and groove arrangement (or the like), so that the monitor slider and monitor body can slide longitudinally relative to each other, but cannot rotate relative to each other. As a result, the monitor body 72 can follow all movements of the pen body 30 and the dial monitor can follow all movements of the outer dosage dial 34 and the dosage selector 22, during normal use of the pen 10.

The device 70 includes circuitry similar to that shown in the diagram of Figure 4, but instead of dosage monitoring means 66 that measures angular displacement of rotation, as in the case of the device 46, the monitoring means 66 of the device 70 measures relative linear displacement between the monitor body 72 and the monitor slider 76 in the longitudinal direction. One of many sensors that can be used to measure this relative linear displacement, is a capacitive sensor using patterned electrodes with different patterns on the monitor body 72 and monitor slider 76 and detecting capacitive coupling between the two electrodes to determine direction and distance of the linear displacement.

In addition, the device 70 can also measure relative angular displacement between the dial monitor 74 and the monitor slider 76, using any one of a wide variety of sensing techniques, as mentioned above.

The monitor body 72 defines windows 78, one of which is in register with the dosage indicator, to ensure that the calibration on the outer dosage dial 34, which shows the dosage increments, are visible.

CLAIMS

1. A dosage monitoring device (46,70) for use in conjunction with a liquid dispenser (10), said dosage monitoring device comprising;
   a memory (56);
   a quantity sensor (66), configured to determine the quantity of an individual dosage, when dispensed from the liquid dispenser and to record said quantity in the memory;
   a dispensing sensor (66), configured to sense when said individual dosage is dispensed from the liquid dispenser and to record the event of dispensing said dosage in the memory; and
   feedback means (58,60), configured to make the quantity of said individual dosage available for display;
   characterised in that said dosage monitoring device (46,70) is releasably attachable to said liquid dispenser (10).

2. A dosage monitoring device (46,70) according to claim 1, **characterised in that** said dosage monitoring device includes a clock and the dispensing sensor (66) is configured to record the time of the event of dispensing said dosage, according to the clock, in the memory (56).

3. A dosage monitoring device (46,70) according to claim 2, **characterised in that** said feedback means (58,60) is configured to make the time of said individual dosage available for display.

4. A dosage monitoring device (46,70) according to any one of the preceding claims, **characterised in that** said dosage monitoring device is configured to receive input in the form of a set dosage and to store said set dosage in the memory (56).

5. A dosage monitoring device (46,70) according to claim 4, **characterised in that** said feedback means (58,60) is configured to make said set dosage

available for display.

6. A dosage monitoring device (46,70) according to any one of the preceding claims, **characterised in that** said feedback means includes a display (58) on the dosage monitoring device.

7. A dosage monitoring device (46,70) according to any one of the preceding claims, **characterised in that** said feedback means includes means (60) for transmitting a signal containing said data of each individual dosage, to a remote device, external to the dosage monitoring device.

8. A dosage monitoring device (46) according to any one of the preceding claims, for use in combination with a liquid dispenser (10) that includes a rotatable dose setting element, **characterised in that** said quantity sensor (66) of the dosage monitoring device includes means for determining the rotation of the dose setting element.

9. A dosage monitoring device (70) according to any one of the preceding claims, for use in combination with a liquid dispenser (10) that includes a linearly displaceable dosing element (24), **characterised in that** said dosage monitoring device includes means for determining the linear displacement of said dosing element.

10. A dosage monitoring device (46,70) according to any one of the preceding claims, **characterised in that** the dosage monitoring device includes a click mechanism that is configured to emit a sound upon incremental changes in the quantity of the dosage.

11. A dosage monitoring device (46,70) according to any one of the preceding claims, **characterised in that** said dosage monitoring device includes a switch and said monitoring dispenser is configured to dispense a set quantity of said liquid, when said switch is operated.

12. A dosage monitoring device (46,70) according to claim 11, **characterised in that** said liquid dispenser is actuated to dispense said liquid using stored energy, upon operating said switch.

13. A dosage monitoring device (46,70) according to any one of the preceding claims, **characterised in that** said dosage monitoring device includes at least one sensor that is configured to identify a feature of a liquid dispenser (10) to which the device is attached, in order to identify the liquid dispenser.

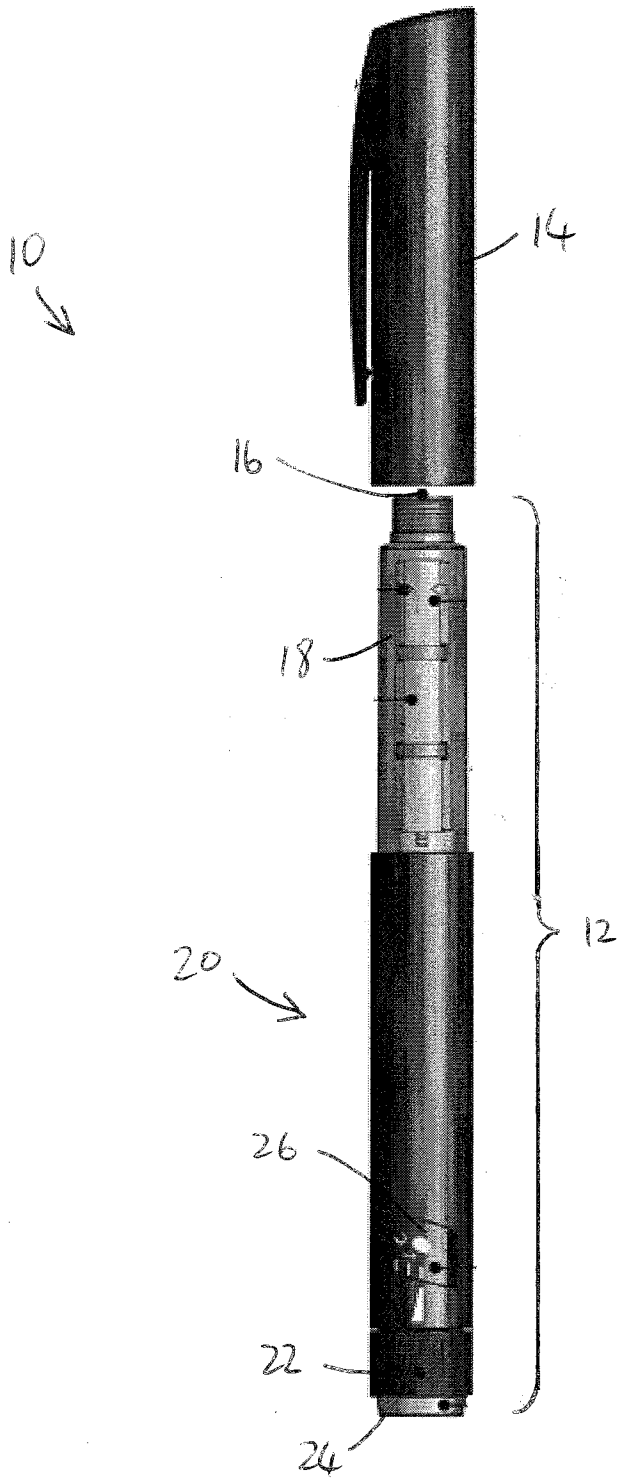

FIGURE 1

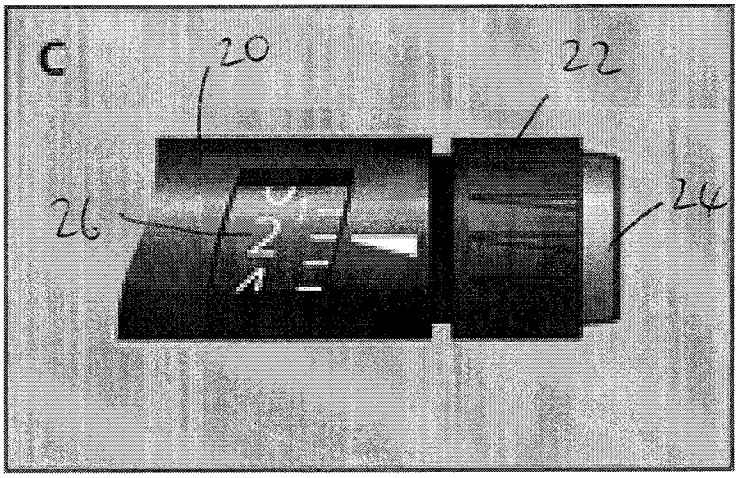

FIGURE 2

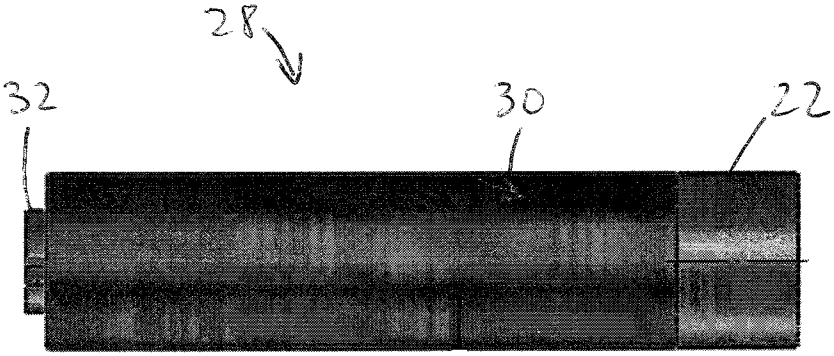

FIGURE 3A

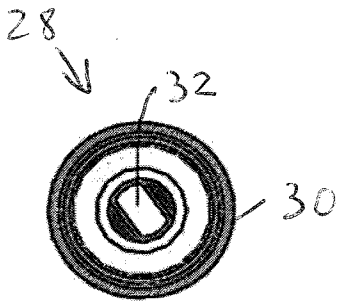

FIGURE 3E

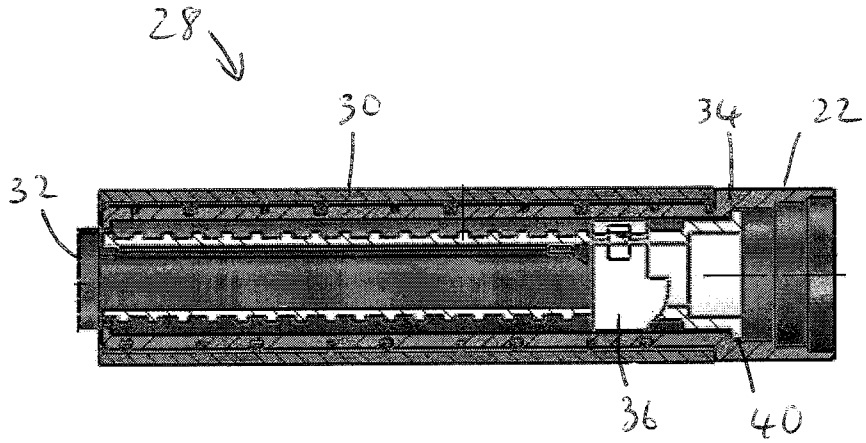

FIGURE 3B

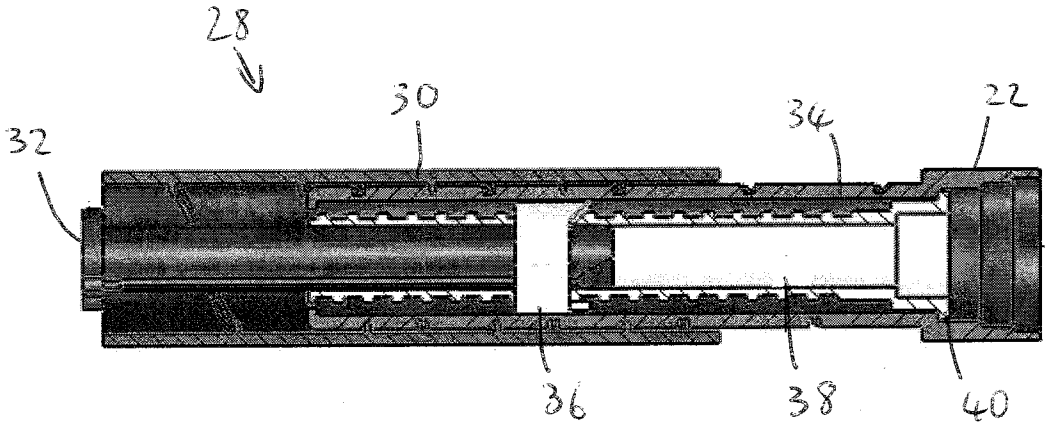

FIGURE 3C

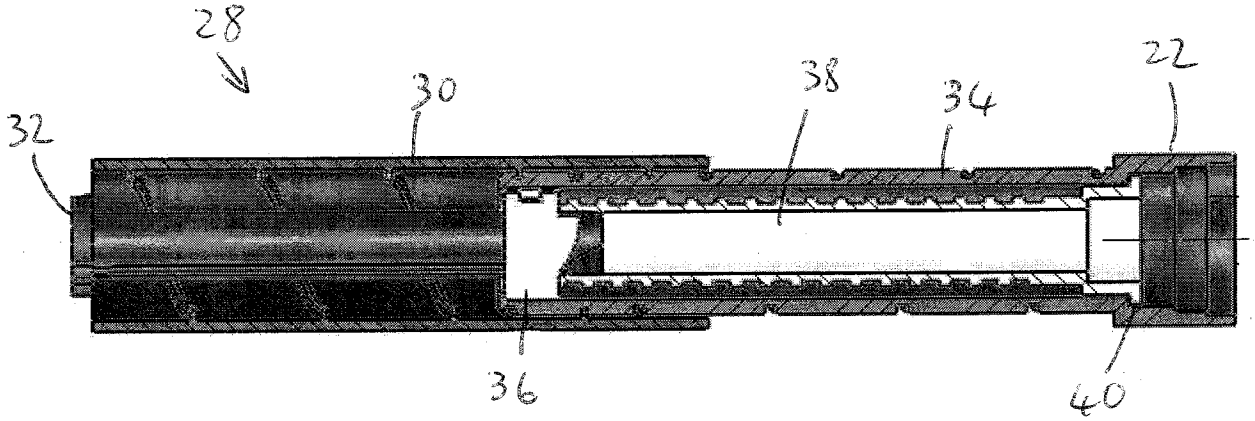

FIGURE 3D

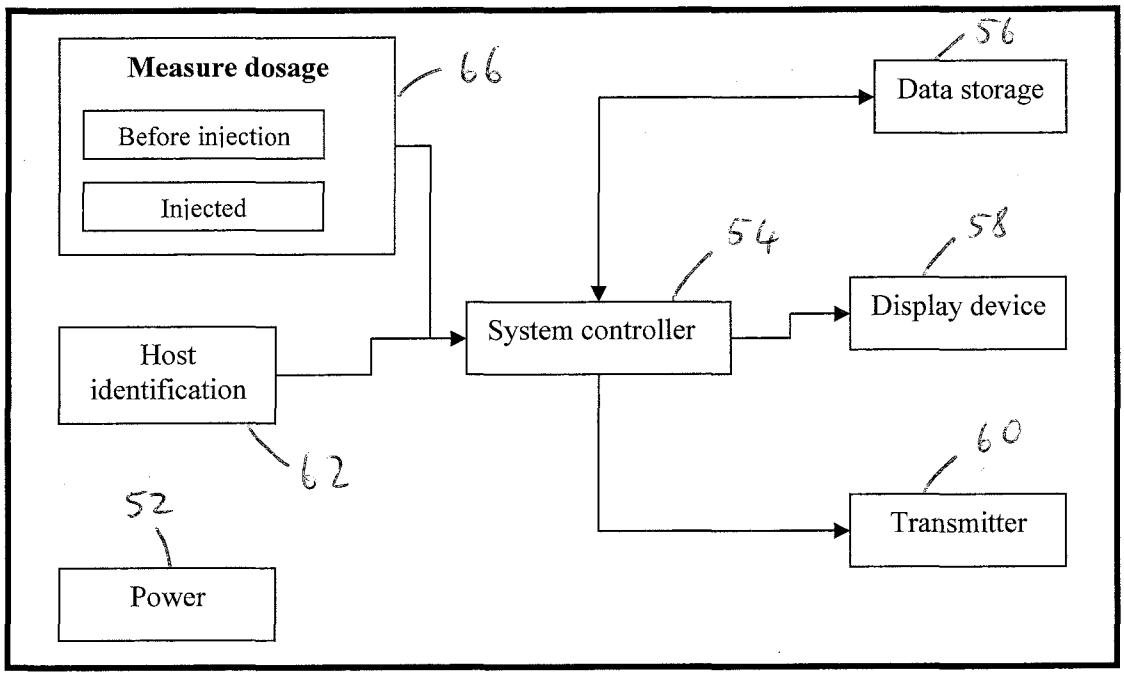

FIGURE 4

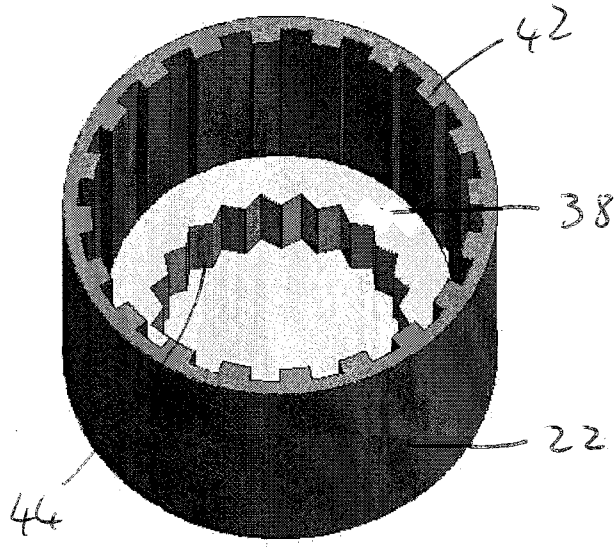

FIGURE 5

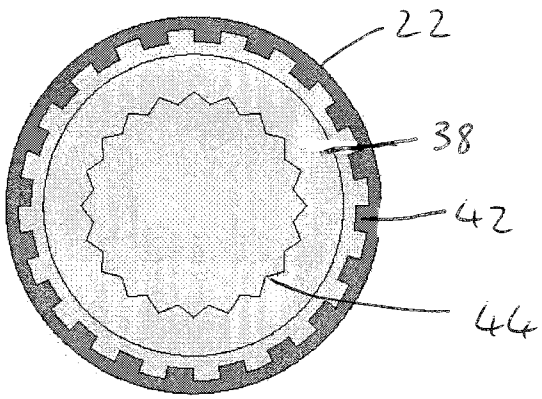

FIGURE 6

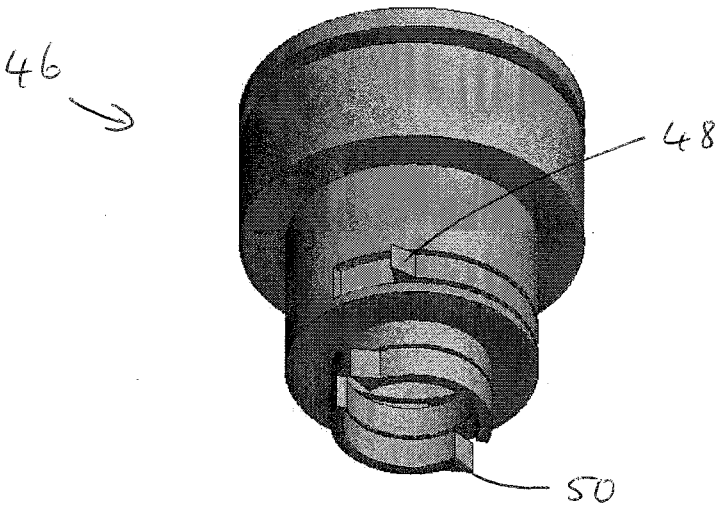

FIGURE 7

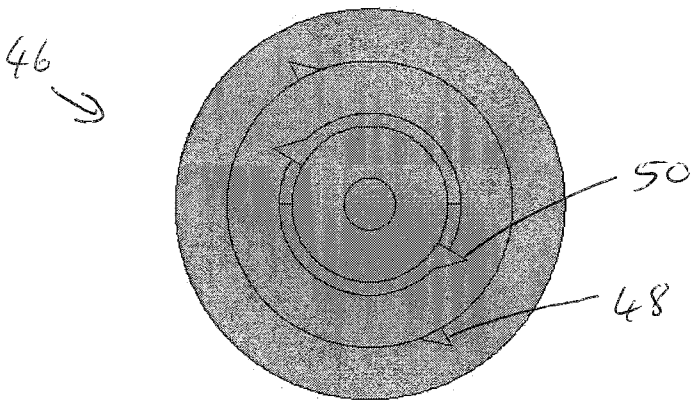

FIGURE 8

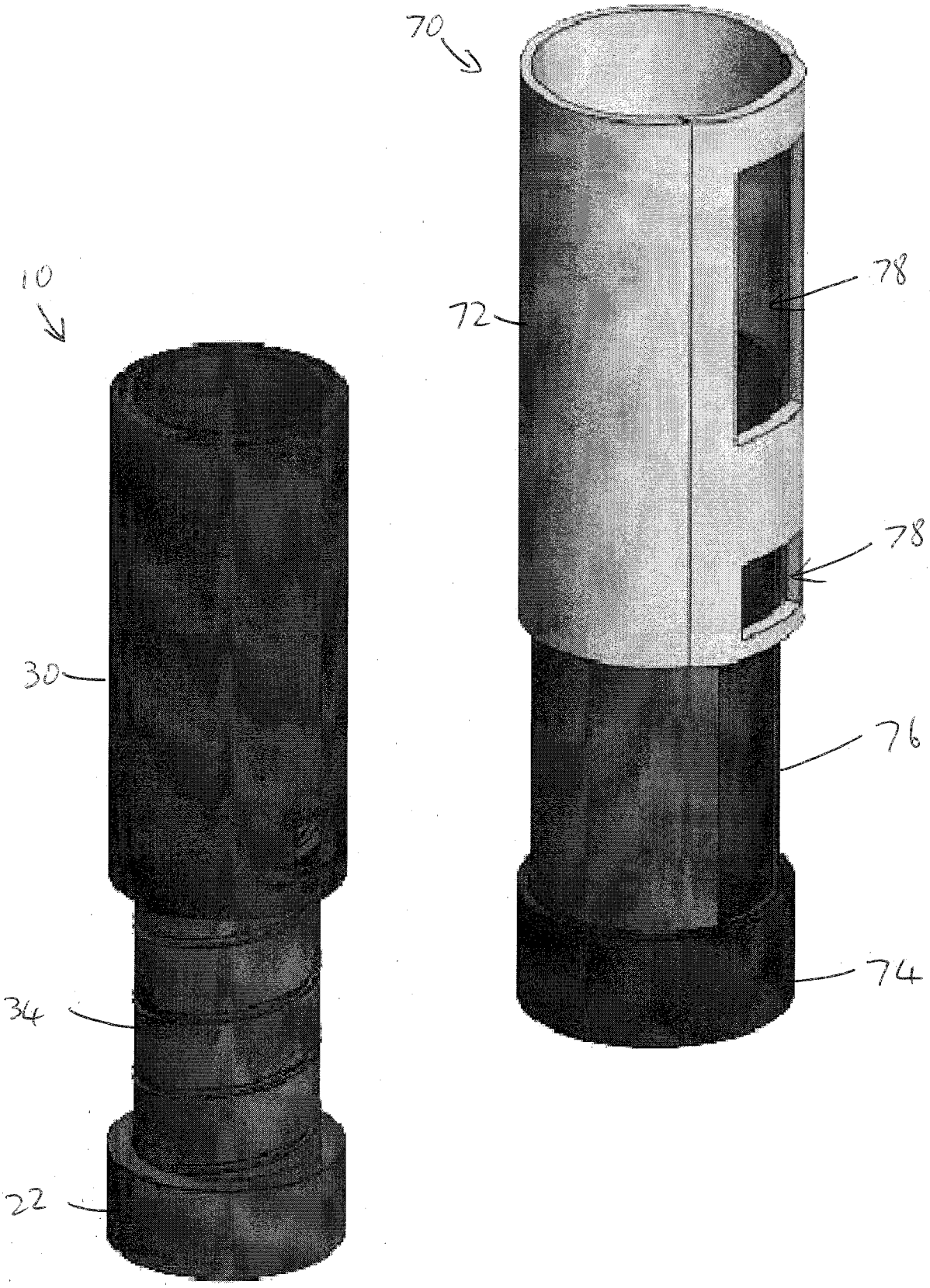

FIGURE 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2011/054392

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 5/20 (2006.01) ***A61M 5/315*** (2006.01)

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)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Espacenet & Google Scholar: Keywords (dosage, quantity, amount, volume) and (measur+, detect+, sense, sensi+, monitor+, sensor) and (record+, memory) and (liquid or fluid) and (dispens+ or contain+ or dispos+) and (feedback) and (display+, interfac+, indicat+, output+) and (pen) and like terms

WPI & EPODOC: IPC & EC A61M 5/168, A61M 5/172; A61M 31/-; A61M 37/-; G06F 19/-; A61M 5/- & Keywords (dosage, quantity, amount, volume, measur+, detect+, sense, RFID, sensi+, monitor+, sensor, record+, memory, liquid, fluid, dispens+, contain+, dispos+, feedback, display+, interfac+, indicat+, output+, signal+, screen, LED, pen, dose, medicament+, medicin+, drug+, insulin) and like terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 1998/019647 A1 (TRI-CONTINENT SCIENTIFIC, INC.) 14 May 1998 Abstract; Page 2, line 9 to Page 4, line 14; Page 5, line 19 to Page 13, line 22; Page 14, Line 13 to Page 19, line 6; Claims; Figures 1-10	1-8 and 11 9, 10 and 12

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

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Date of the actual completion of the international search	Date of mailing of the international search report
16 January 2012	24 JANUARY 2012
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. +61 2 6283 7999	Authorized officer **KAREN VIOLANTE** AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No : +61 2 6283 7933

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	WO 2008/037801 A1 (NOVO NORDISK A/S) 3 April 2008 Abstract; Page 2, line 6 to Page 12, line 9; Page 13, line 9 to Page 22, line 12; Figures 1-21	9, 10 and 12
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A	US 2004/0171983 A1 (SPARKS et al.) 2 September 2004 Abstract; Paragraphs [0012], [0020], [0023]-[0024], [0026]-[0027], [0033], [0035]; Figures 1-4	1-13
X Y	EP 1095668 B1 (BECTON DICKINSON AND COMPANY) 25 April 2007 Abstract; Paragraphs [0006]-[0012] and [0014]-[0033]; Figures 1-6	1-9, 11 and 13 10 and 12
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A	US 2008/0262469 A1 (BRISTER et al.) 23 October 2008 Abstract; Paragraphs [0080], [0202]-[0203], [0221], [0225]-[0230]; Figures 5-7	1-13
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/IB2011/054392

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX