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(54) Title: DRUG DELIVERY DEVICE FOR DETECTION OF AN END-OF-DOSE

Fig. 4A

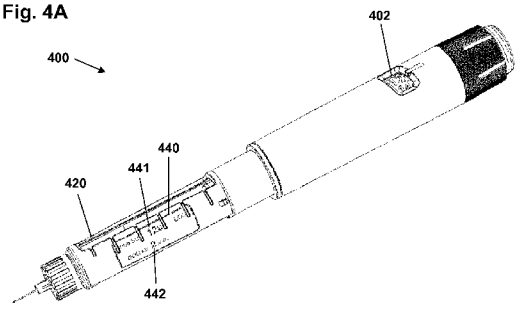
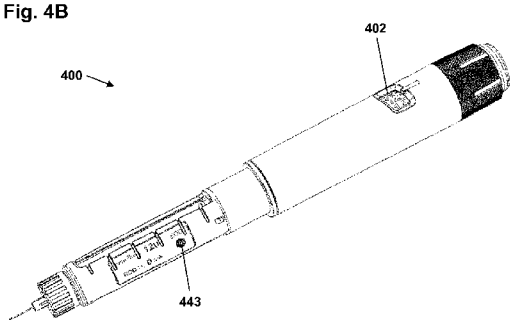


Fig. 4B



(57) Abstract: The invention relates to a method of providing an end-of-dose notification to a user, comprising the steps of (i) providing a drug delivery device comprising a cartridge containing a drug to be expelled, and a user-settable dose expelling mechanism, (ii) setting a dose to be expelled, (iii) expelling the set dose from the cartridge, (iv) monitoring volume change in the cartridge during expelling, and (v) notify the user when volume change has stopped, this indicating an end-of-dose state. In a further aspect the invention relates to a corresponding drug delivery device.

DRUG DELIVERY DEVICE FOR DETECTION OF AN END-OF-DOSE

The present invention generally relates to a drug delivery device adapted to expel a drug of dose from a drug cartridge. More specifically, the invention relates to the issue of informing a user of an end-of-dose condition.

BACKGROUND OF THE INVENTION

In the disclosure of the present invention reference is mostly made to the treatment of diabetes, however, this is only an exemplary use of the present invention.

Drug delivery devices in the form of injection devices for subcutaneous administration of fluid drugs have greatly improved the lives of patients who must self-administer drugs and biological agents. Drug injection devices may take many forms, from simple disposable devices to highly sophisticated electronically controlled motorized instruments with numerous functions. Regardless of their form, they have proven to be great aids in assisting patients to self-administer injectable drugs and biological agents. They also greatly assist care givers in administering injectable medicines to those incapable of performing self-injections.

In particular pen-style injection devices have proven to provide an accurate, convenient, and often discrete, way to administer drugs and biological agents, such as insulin. Typically, injection devices use a pre-filled cartridge containing the medication of interest, e.g. 1.5 or 3.0 ml of insulin or growth hormone. The cartridge is typically in the form of a generally cylindrical transparent ampoule with a needle pierceable septum at one end and an opposed piston designed to be moved by the dosing mechanism of the injection device. The injection devices are generally of two types: “Durable” devices and “disposable” devices. A durable device is designed to allow a user to replace one cartridge with another cartridge, typically a new cartridge in place of an empty cartridge. In contrast, a disposable device is provided with an integrated cartridge which cannot be replaced by the user; when the cartridge is empty the entire device is discarded.

A further distinction can be made for the drive means delivering the force to move the cartridge piston forwards during expelling of a dose of drug. Traditionally injection devices have been manually actuated by the user pushing an extendable button during expelling, however, alternatively the driving force may be provided by a spring being pre-strained or strained during dose setting and subsequently released, this allowing for “automatic” dispensing of drug.

Irrespective of the type of delivery device, when injecting medical drugs by use of injection devices, the internal parts of the device apply pressure to a fluid drug in a container to overcome flow resistance in the device, i.e. mostly the attached injection needle, and the tissue/skin of the recipient. This causes some of the parts to deform elastically during out-dosing, which means that after the mechanism reaches the end-of-dose state and the out-dosing mechanism itself stops moving, the stored energy in the deformed parts is released and cause further out-dosing.

More specifically, injection systems using a cartridge comprising an elastic rubber piston is characterised in that the piston will be more or less deformed when the piston driver, e.g. typically a piston rod, is advanced, this typically providing the largest contribution to elastic deformation build-up during out-dosing.

When the piston driver stops moving when having reached its end-of-dose position, the piston will relax to its original form. The selected dose is thus not fully delivered until the piston has reached its form just before starting the injection. How much the piston is deformed depends mainly on the friction between the piston and the (glass) cartridge plus the counter pressure that builds up when the liquid has to pass through the very thin needle. This is the main reason why the user is recommended to keep the needle inserted for some period - typically six seconds. Removing the needle before six seconds have elapsed might lead to an under-dose of up to 1 IU for a traditional 100 IU/ml insulin formulation which could be substantial for small doses. Indeed, for higher drug concentrations the issue will be aggravated.

Waiting six seconds may be cumbersome and some users might ignore it with the risk of an under-dose as a consequence. In most cases more than 95% of the dosage is delivered within 1-2 seconds after stopping the piston drive.

Having regard to the above, it is an object of the present invention to provide a method and a drug delivery device adapted to receive or comprising a drug-filled cartridge, and which are adapted to detect one or more properties during or after out-dosing which then can be used to determine or detect that a given dose has been (almost) fully delivered, which in most cases will be before six seconds has elapsed, and notify the user correspondingly. The properties should be detected in a simple and effective way, the arrangement being sensitive, cost-effective and reliable.

DISCLOSURE OF THE INVENTION

In the disclosure of the present invention, embodiments and aspects will be described which will address one or more of the above objects or which will address objects apparent from the below disclosure as well as from the description of exemplary embodiments.

Thus, in accordance with a first aspect of the invention a method of providing an end-of-dose notification to a user is provided, comprising the steps of providing a drug delivery device comprising a cartridge containing a drug to be expelled and a user-settable dose expelling mechanism, setting a dose to be expelled, expelling the set dose from the cartridge, monitoring volume change in the cartridge during expelling, and notify the user when volume change has reached a pre-determined value, e.g. stopped, this indicating an end-of-dose state.

In the present context the definition “monitoring volume change in the cartridge during expelling” includes the period after the dose expelling mechanism has stopped moving (or is close to having stopped) and covers the situations in which volume change is monitored (i) both before and after the dose expelling mechanism has stopped moving (or is close to having stopped), and (ii) only after the dose expelling mechanism has stopped moving (or is close to having stopped).

In this way a simple and reliable method is provided allowing a user to be informed when a “true” end-of-dose state has been reached.

The volume change may be calculated using a capacitive sensor arrangement, wherein the capacitive sensor arrangement may comprise at least one transmitter member arranged on the outer surface of the cartridge.

In an exemplary embodiment the dose expelling mechanism comprises an indicator member rotating during expelling of a dose, the method comprising the further step of detecting rotational movement of the indicator member, wherein the monitoring of volume change in the cartridge starts when rotational movement of the indicator member has been detected, i.e. detection starts during rotation. Alternatively, the method comprises the further step of determining when rotational movement of the indicator member has stopped or reached a pre-determined value, wherein the monitoring of volume change in the cartridge starts when it has been determined that rotational movement of the indicator member has stopped or reached a pre-determined value. Rotational movement of the indicator member may be detected using a capacitive sensor arrangement.

An expected end-of-delivery time may be calculated based on at least the expelled dose size, the expelled dose size being calculated based on a determined amount of rotation of the indicator member, wherein the expected end-of-delivery time is displayed to the user. The displayed end-of-delivery time is displayed as a count-down value.

In accordance with a second aspect of the invention a drug delivery device is provided comprising a drug-filled cartridge or means for receiving a drug-filled cartridge, the cartridge comprising an axially displaceable piston and a distal outlet portion. The drug delivery device comprises a drug expelling mechanism comprising dose setting means allowing a user to set the size of a dose of drug to be expelled, and a piston rod adapted to move the piston of a cartridge in a distal direction to thereby expel drug from the cartridge. The drug delivery device further comprises electronic circuitry comprises sensor means adapted to monitoring volume change in a cartridge during expelling, and means for notifying the user when volume change has stopped, this indicating an end-of-dose state.

By this arrangement a simple and reliable device is provided allowing a user to be informed when a true end-of-dose state has been reached.

The sensor means may comprise a capacitive sensor arrangement adapted to detect a variable volume parameter, and a comprised cartridge may comprise at least one capacitive transmitter member arranged on the outer surface of the cartridge.

In an exemplary embodiment the drug expelling mechanism comprises an indicator member rotating during expelling of a dose, and the electronic circuitry comprises sensor means adapted to detect rotational movement of the indicator member. The electronic circuitry is adapted to calculate an expected end-of-delivery time based on at least the expelled dose size, wherein the expelled dose size being calculated based on a determined amount of rotation of the indicator member. The electronic circuitry may comprise a display, wherein the expected end-of-delivery time is displayed to the user on the display. The means for notifying the user when volume change has stopped or reached a pre-determined value may also be provided by the display.

In a further exemplary embodiment the drug expelling mechanism comprises an indicator member rotating during expelling of a dose, and the electronic circuitry comprises sensor means adapted to detect rotational movement of the indicator member. In such an arrange-

ment the monitoring of volume change in the cartridge starts when rotational movement of the indicator member has been detected. Alternatively the monitoring of volume change in the cartridge starts when it has been determined that rotational movement of the indicator member has stopped or reached a pre-determined value.

The drug delivery device may comprise a cartridge holder portion adapted to accommodate a cartridge, the cartridge holder portion comprising the electronic circuitry. In an exemplary embodiment the drug delivery device comprises a flexible sheet on which is formed or mounted the electronic circuitry, comprising the sensor means, a display, a processor, and an energy source. One or more or all of the sensor means, display, processor, and energy source may be in the form of printed electronics.

As used herein, the term "drug" is meant to encompass any flowable medicine formulation capable of being passed through a delivery means such as a cannula or hollow needle in a controlled manner, such as a liquid, solution, gel or fine suspension, and containing one or more drug agents. Representative drugs include pharmaceuticals such as peptides (e.g. insulins, insulin containing drugs, GLP-1 containing drugs as well as derivates thereof), proteins, and hormones, biologically derived or active agents, hormonal and gene based agents, nutritional formulas and other substances in both solid (dispensed) or liquid form. In the description of exemplary embodiments reference will be made to the use of insulin containing drugs, this including analogues thereof as well as combinations with one or more other drugs.

BRIEF DESCRIPTION OF THE DRAWINGS

In the following exemplary embodiments of the invention will be further described with reference to the drawings, wherein

figs. 1A and 1B show a generic drug delivery device with and without a cap mounted,
fig. 2 shows a drug cartridge comprising capacitive transmitters,
fig. 3 shows in a sectional view a piston rod distal portion, and
figs. 4A and 4B show a drug delivery device with an electronic label.

In the figures like structures are mainly identified by like reference numerals.

DESCRIPTION OF EXEMPLARY EMBODIMENTS

When in the following terms such as “upper” and “lower”, “right” and “left”, “horizontal” and “vertical” or similar relative expressions are used, these only refer to the appended figures and not necessarily to an actual situation of use. The shown figures are schematic representations for which reason the configuration of the different structures as well as their relative dimensions are intended to serve illustrative purposes only. In that context it may be convenient to define that the term "distal end" in the appended figures is meant to refer to the end of the injection device which usually is adapted to carry an injection needle as depicted e.g. in fig. 1B whereas the term "proximal end" is meant to refer to the opposite end pointing away from the injection needle end. When the term member or element is used for a given component it generally indicates that in the described embodiment the component is a unitary component, however, the same member or element may alternatively comprise a number of subcomponents just as two or more of the described components could be provided as unitary components, e.g. manufactured as a single injection moulded part.

Before turning to embodiments of the present invention *per se*, an example of a prefilled drug delivery will be described, such a device providing the basis for the exemplary embodiments of the present invention. Although the pen-formed drug delivery assembly 100 shown in figs. 1A and 1B may represent a “generic” drug delivery device, the actually shown device is a FlexTouch® prefilled drug delivery pen as manufactured and sold by Novo Nordisk A/S, Bagsværd, Denmark. A more detailed description of such a device can be found in e.g. WO 2014/161952 which is hereby incorporated by reference.

The pen assembly 100 comprises a cap part 110 and a main drug delivery device (or part) 105 having a proximal body or drive assembly portion with a housing 101 in which a drug expelling mechanism is arranged or integrated, and a distal cartridge holder 120 in which a drug-filled transparent cartridge 130 with a distal drug outlet in the form of a needle-penetrable septum 131 is arranged and retained in place by a non-removable cartridge holder attached to the proximal portion, the cartridge holder having openings allowing a portion of the cartridge to be inspected as well as distal coupling means 125 allowing a needle assembly to be releasably mounted. The cartridge holder 120 comprises proximal coupling means 121 adapted to engage corresponding coupling means arranged on the cap interior surface. Alternatively, the cap may be designed to engage coupling means arranged on the main device distal portion. The cartridge is provided with a piston driven by a piston rod forming part of the expelling mechanism and may for example contain an insulin, GLP-1 or growth hormone formulation. A proximal-most rotatable dose setting member 180 serves to manually

set a desired dose of drug shown in display window 102 and which can then be expelled when the button 190 is actuated. Depending on the type of expelling mechanism embodied in the drug delivery device, the expelling mechanism may comprise a spring as in the shown embodiment which is strained during dose setting and then released to drive the piston rod when the release button is actuated. Alternatively the expelling mechanism may be fully manual in which case the dose member and the actuation button moves proximally during dose setting corresponding to the set dose size, and then is moved distally by the user to expel the set dose, e.g. as in a FlexPen® manufactured and sold by Novo Nordisk A/S.

Although figs. 1A and 1B show a drug delivery device of the pre-filled type, i.e. it is supplied with a pre-mounted cartridge and is to be discarded when the cartridge has been emptied, in alternative embodiments the drug delivery device may be designed to allow a loaded cartridge to be replaced, e.g. in the form of a “rear-loaded” drug delivery device in which the cartridge holder is adapted to be removed from the device main portion, or alternatively in the form of a “front-loaded” device in which a cartridge is inserted through a distal opening in the cartridge holder which is non-removable attached to the main part of the device.

Turning to an exemplary embodiment of the present invention, fig. 2 discloses a modified traditional drug cartridge 200 comprising a cylindrical main portion 201 and a neck portion 202. The main portion is provided with a pair of transmitters 210, 211 formed from conductive material on the outer surface, the transmitters taking up approximately 25% of the cylindrical surface in the shown embodiment. The circumferential width of each of the transmitters vary along the length of the cartridge, the first transmitter 210 having a circumferential width which diminishes towards the distal end of the cartridge, and the second transmitter 211 having a circumferential width which increases towards the distal end of the cartridge. In the shown embodiment the combined circumferential width for the two transmitters is constant along the length of the transmitters.

The portion of the drug delivery device surrounding the cartridge, typically termed a cartridge holder, comprises electronic sensor circuitry adapted to interact with the cartridge transmitters. Two alternating electrical fields shifted in phase are applied on each of the two transmitters on the outer surface of the cartridge. This induces an alternating electrical field in the drug with a phase depending on the size of each of the areas of the two transmitters covered by the drug. A capacitive receiver 220 arranged on the opposite side of the cartridge pick up the electrical field and by measuring the phase-shift, the remaining drug volume in the cartridge can be determined.

By monitoring the volume level and the changes thereof, the continued expelling of drug after the piston rod stops rotating can be detected and an end-of-dose notification can be communicated to the user, e.g. by means of a display. As the end-of-dose detection is based on determination of volume change as a function of time, and not on determination of absolute volume values, the method is not sensitive to normal variations in e.g. cartridge dimensions and thus robust.

Especially for a disposable device it is essential that the sensor system and the display are manufactured cost-effectively. Correspondingly, in an exemplary embodiment the drug delivery device cartridge holder portion comprises a flexible sheet on which is formed or mounted electronic circuitry comprising sensor means adapted to provide the above-described functionality, e.g. electric field generators, capacitive receiver plates, a processor, a display and an energy source, the flexible sheet being mounted at least in part to the exterior and/or interior surface of the cartridge holder housing. Based on input from the capacitive receiver the processor is adapted to control the display to indicate that end-of-dose event has been detected. To cost-effectively provide a flexible “label-like” electronic assembly one or more or all of the sensor means, display, processor, and energy source may be in the form of printed electronics, see e.g. WO 2015/071354 which is hereby incorporated by reference.

By the above arrangements a very simple and inexpensive electronic system is provided on a drug delivery device, the low cost allowing it to be formed integrally with a pre-filled disposable drug delivery device. Indeed, the electronic system could also be incorporated in a durable device.

In an alternative embodiment the energy source may be incorporated in the device cap, this allowing e.g. a conventional button type “battery” cell to be utilized. In such an arrangement the “label electronics” may comprise a capacitor adapted to store energy provided by the battery, the label and the cap comprising corresponding galvanic contacts allowing charging of the capacitor during the time when the cap is mounted on the cartridge holder. In such an arrangement the contacts may be utilized to detect removal of the cap, this providing that the electronics are powered on. The cap may be provided with a replaceable or rechargeable battery allowing the cap to be used as a durable component in combination with disposable pen devices.

With reference to fig. 3 a further embodiment of a drug delivery device 300 with additional detection means will be described. In addition to the above-described volume-sensing circuitry the drug delivery device expelling mechanism is provided with output means allowing rotational movement of an expelling mechanism component to be detected during drug expelling. Many known drug expelling mechanisms, including the above-mentioned FlexTouch® pre-filled drug delivery pen, comprise components which rotate during drug expelling corresponding to the expelled dose, e.g. a piston driver and the piston rod as in the FlexTouch® pen, see the above-mentioned WO 2014/161952. As the piston rod also moves axially just as it has a relatively small diameter and is arranged at a distance from the outer pen housing, the piston rod may not be considered the best component to provide a detectable rotational output. The piston driver in the FlexTouch® has a larger diameter and does not move axially during drug expelling, however, the driver is positioned in the device main part at a distance from the cartridge holder portion.

Correspondingly, to provide an output during drug expelling that can be detected by circuitry arranged on or in the cartridge holder portion, the pen device 300 shown in fig. 3 is provided with an indicator disc 310 which engages the piston rod 330 and rotates therewith yet allows the piston rod to move axially relative to the indicator disc, this allowing the indicator disc to be arranged axially stationary relative to the housing and cartridge holder. The indicator disc comprises a circumferential edge portion 311 on which a number of conductive sensor areas 312 are provided, e.g. by printing.

The electronic circuitry arranged in the cartridge holder portion 320 comprises additional capacitive sensor means 321 allowing rotation of the indicator disc to be detected as the disc conductive areas pass the sensor means. In a simple configuration the system may be adapted to merely sense motion which may be used to initiate volume sensing, e.g. starting when rotation is initially detected or when rotation stops.

In a more advanced configuration the electronic circuitry may be adapted to detect and count the number of passing disc sensor areas to thus determine the amount of expelled drug, i.e. the dose size. A determined dose size may be used to provide different information to the user. For example, for a pre-filled device the initial drug volume is known and it would thus be possible after each expelled dose to calculate and display the amount of remaining drug. Correspondingly, the detected dose amounts could be stored in a dose log and subsequently transmitted to an external device, e.g. via an antenna incorporated in the flexible label. If the electronic circuitry is provided with a timer, e.g. a simple relative timer, a time-dose log could

be created, the relative time being “translated” to real time when the log is transmitted to an external device with a build-in real time clock.

When for a given expelling event the remaining volume in the cartridge is known as well as the actually expelled dose size, it would be possible to predict fairly accurately from a mathematical model based on knowledge of the different components in the particular device the expected end-of-dose time which may then be displayed on the electronically controlled display, e.g. 3 seconds. When the volume-sensing circuitry then detects and end-of-dose state this may be indicated in the display. Alternatively a countdown value could be displayed on the electronically controlled display. Such a countdown value would enhance user confidence in the device and encourage the user to follow the instructions as displayed rather than trusting own judgement. Indeed, such a countdown functionality would require the calculated end-of-dose time to be fairly accurate compared with the volume-sensing based detection of a “real” end-of-dose state, e.g. within 1 second of difference.

Fig. 4A shows a drug delivery device 400 in which a flexible electronic label 440 is mounted on the cartridge holder portion 420, the label comprising electronic circuitry provided with capacitive sensing means for sensing both the current cartridge drug volume and rotation of the above-described indicator disc, as well as a display adapted to display both a detected expelled dose size 441, a calculated count-down value 442 and an indicator 443 (see fig. 4B) for a detected end-of-dose state. In the shown embodiment the electronic label is manufactured using, at least in part, printed electronics. In figs. 4A and 4B the display window 402 should correctly show “0” instead of “12” as the expelling mechanism in the shown states has returned the scale drum the zero position.

In the above description of the preferred embodiments, the different structures and means providing the described functionality for the different components have been described to a degree to which the concept of the present invention will be apparent to the skilled reader. The detailed construction and specification for the different components are considered the object of a normal design procedure performed by the skilled person along the lines set out in the present specification.

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CLAIMS

1. A method of providing an end-of-dose notification to a user, comprising the steps of:

(i) providing a drug delivery device (300, 400) comprising:
- a cartridge (200) containing a drug to be expelled, and
- a user-settable dose expelling mechanism,

(ii) setting a dose to be expelled,

(iii) expelling the set dose from the cartridge,

(iv) monitoring volume change in the cartridge during expelling, and

(v) notify the user when volume change has stopped or reached a pre-determined value, this indicating an end-of-dose state.

2. A method as in claim 1, wherein the dose expelling mechanism comprises an indicator member (310) rotating during expelling of a dose, the method comprising the further step of:

- detecting rotational movement of the indicator member,

wherein the monitoring of volume change in the cartridge starts when rotational movement of the indicator member has been detected.

3. A method as in claim 1, wherein the dose expelling mechanism comprises an indicator member (310) rotating during expelling of a dose, the method comprising the further step of:

- determining when rotational movement of the indicator member has reached a pre-determined value stopped,

wherein the monitoring of volume change in the cartridge starts when it has been determined that rotational movement of the indicator member has stopped or reached a pre-determined value.

4. A method as in claim 2, wherein:

- an expected end-of-delivery time is calculated based on at least the expelled dose size, the expelled dose size being calculated based on a determined amount of rotation of the indicator member, and
- the expected end-of-delivery time is displayed to the user.

5. A method as in claim 4, wherein:

- the displayed end-of-delivery time is displayed as a countdown value (442).

6. A method as in any of claims 2-5, wherein rotational movement of the indicator member (310) is detected using a capacitive sensor arrangement (312, 321, 440).

7. A method as in any of claims 1-6, wherein volume change is calculated using a capacitive sensor arrangement (210, 211, 220, 440), and wherein the capacitive sensor arrangement may comprise at least one transmitter member (210, 211) arranged on the outer surface of the cartridge.

8. A drug delivery device (300, 400) comprising:

- a drug-filled cartridge (200) or means (320, 420) for receiving a drug-filled cartridge, the cartridge comprising an axially displaceable piston and a distal outlet portion,
- a drug expelling mechanism comprising:
  - dose setting means allowing a user to set the size of a dose of drug to be expelled, and
  - a piston rod (330) adapted to move the piston of a cartridge in a distal direction to thereby expel drug from the cartridge, and
- electronic circuitry comprising:
  - sensor means (210, 211, 220, 440) adapted to monitor volume change in a cartridge during expelling, and
  - means (442, 443) for notifying the user when volume change has reached a pre-determined value or stopped, this indicating an end-of-dose state.

9. A drug delivery device as in claim 8, wherein the sensor means comprises a capacitive sensor arrangement (210, 211, 220, 440) adapted to detect a variable volume parameter.

10. A drug delivery device as in claim 9, wherein a comprised cartridge comprises at least one capacitive transmitter member (210, 211) arranged on the outer surface of the cartridge.

11. A drug delivery device as in claim 10, wherein:

- the drug expelling mechanism comprises an indicator member (310, 312) rotating during expelling of a dose,
- the electronic circuitry comprises sensor means (321, 440) adapted to detect rotational movement of the indicator member,
- the electronic circuitry is adapted to calculate an expected end-of-delivery time based on at least the expelled dose size, the expelled dose size being calculated based on a determined amount of rotation of the indicator member,
- the electronic circuitry (440) comprises a display (442),
- the expected end-of-delivery time is displayed to the user on the display, and
- the means for notifying the user when volume change has reached a predetermined value or stopped is provided by the display.

12. A drug delivery device as in claim 10, wherein:
- the drug expelling mechanism comprises an indicator member (310, 312) rotating during expelling of a dose, and
- the electronic circuitry comprises sensor means (321, 440) adapted to detect rotational movement of the indicator member,

wherein the monitoring of volume change in the cartridge starts when rotational movement of the indicator member has been detected, or

wherein the monitoring of volume change in the cartridge starts when it has been determined that rotational movement of the indicator member has stopped.

13. A drug delivery device as in any of claims 8-12, comprising a cartridge holder portion (320, 420) adapted to accommodate a cartridge, the cartridge holder portion comprising the electronic circuitry.

14. A drug delivery device as in claim 13, comprising a flexible sheet (440) on which is formed or mounted the electronic circuitry, the electronic circuitry comprising the sensor means, a display, a processor, and an energy source.

15. A drug delivery device as in claim 14, wherein one or more or all of the sensor means, display, processor, and energy source is/are in the form of printed electronics.

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Fig. 1A

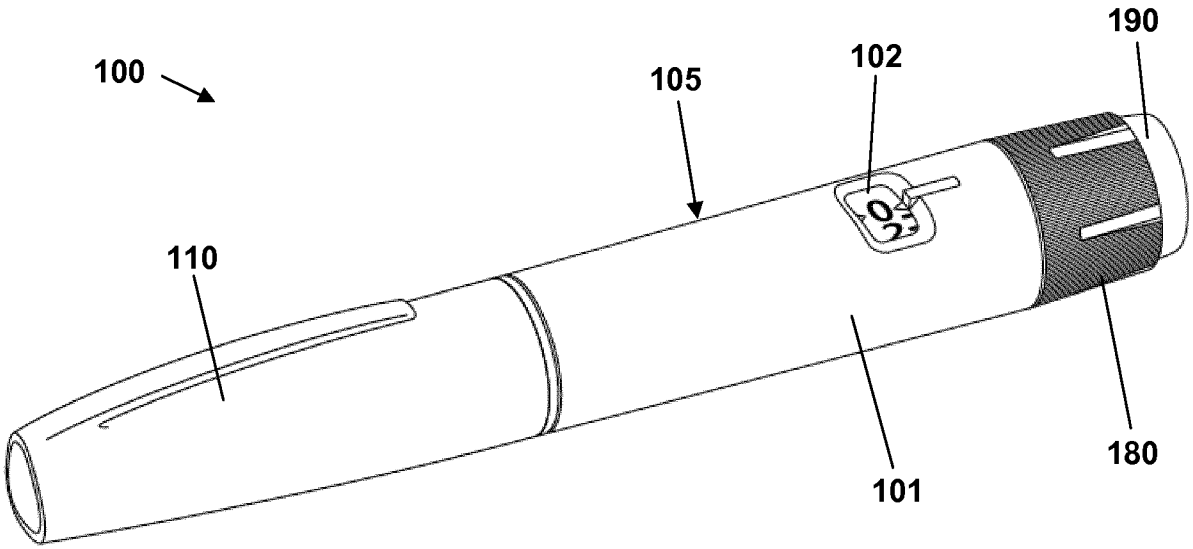


Fig. 1B

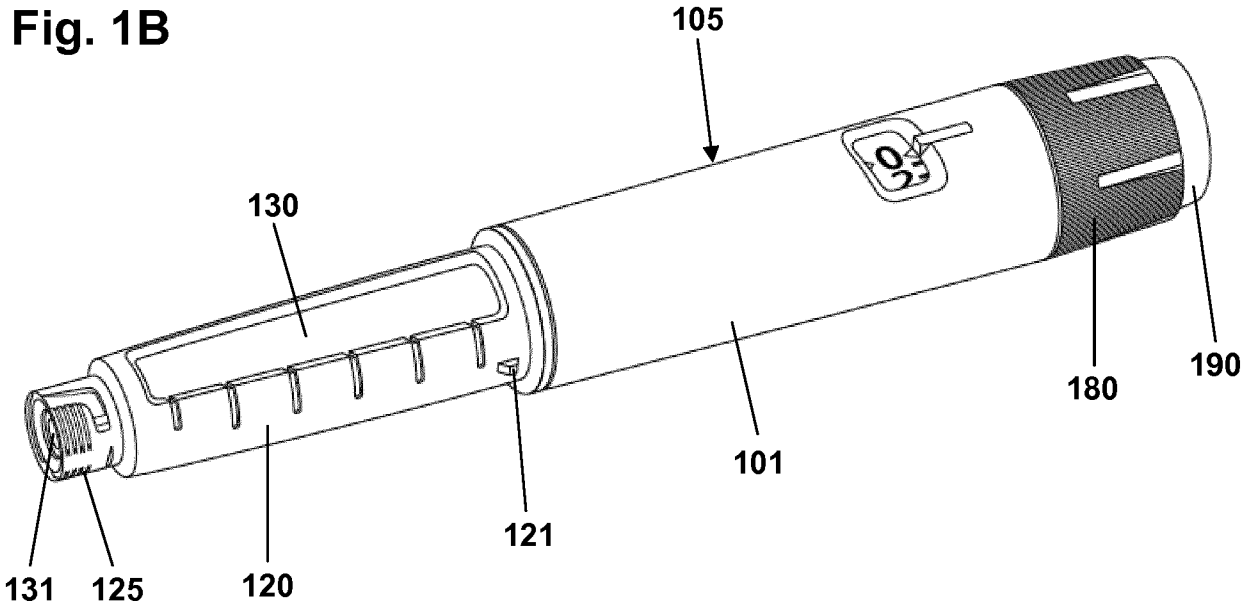


Fig. 2

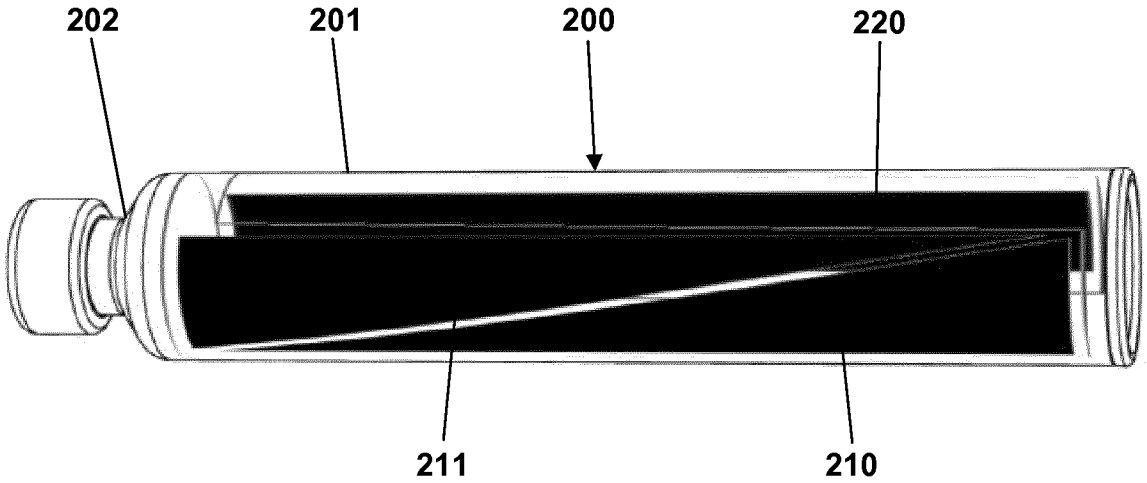


Fig. 3

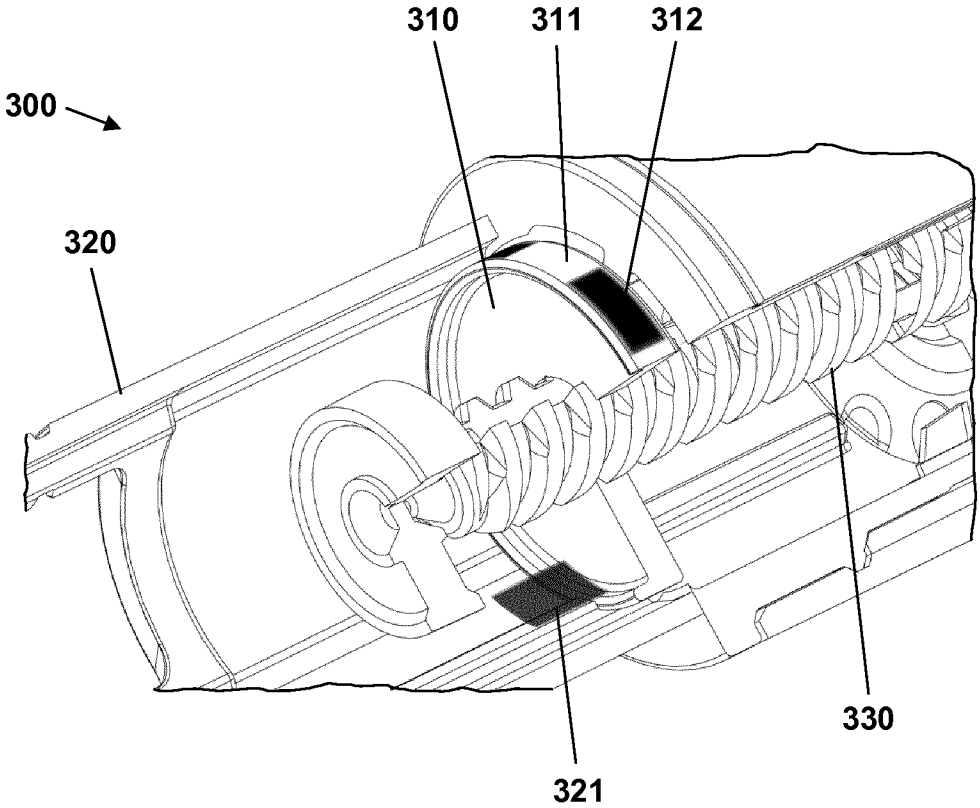


Fig. 4A

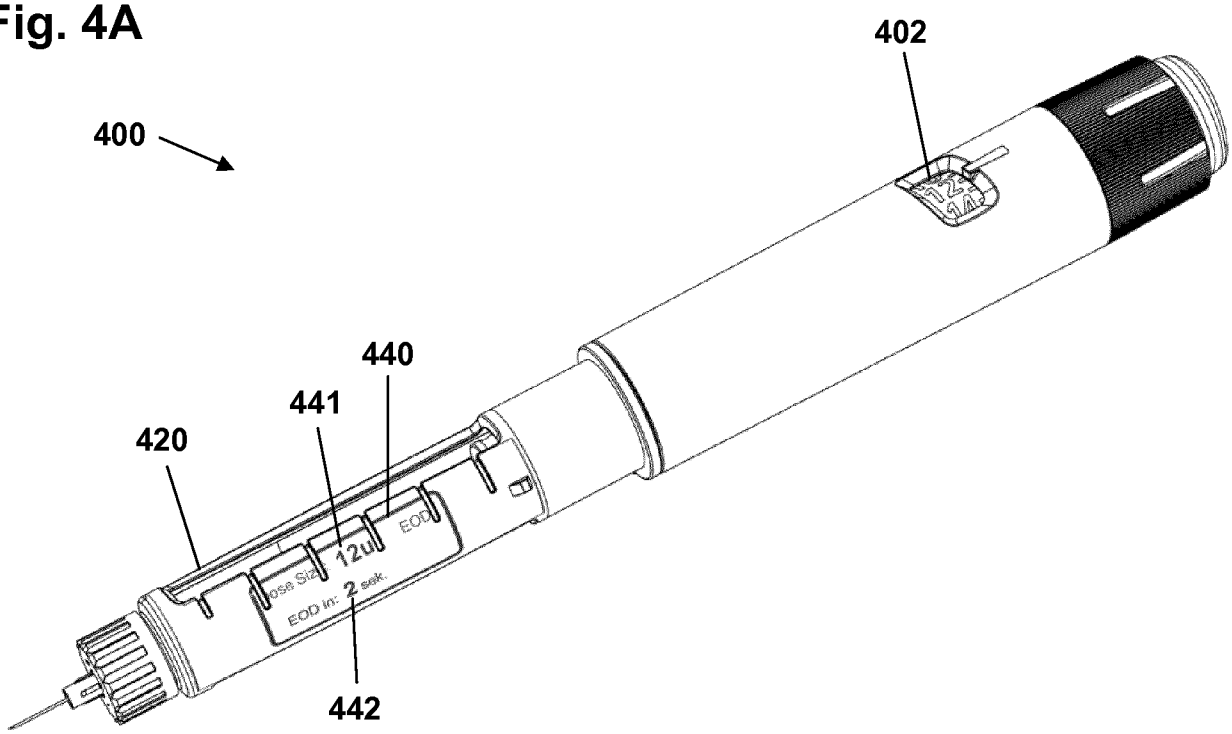
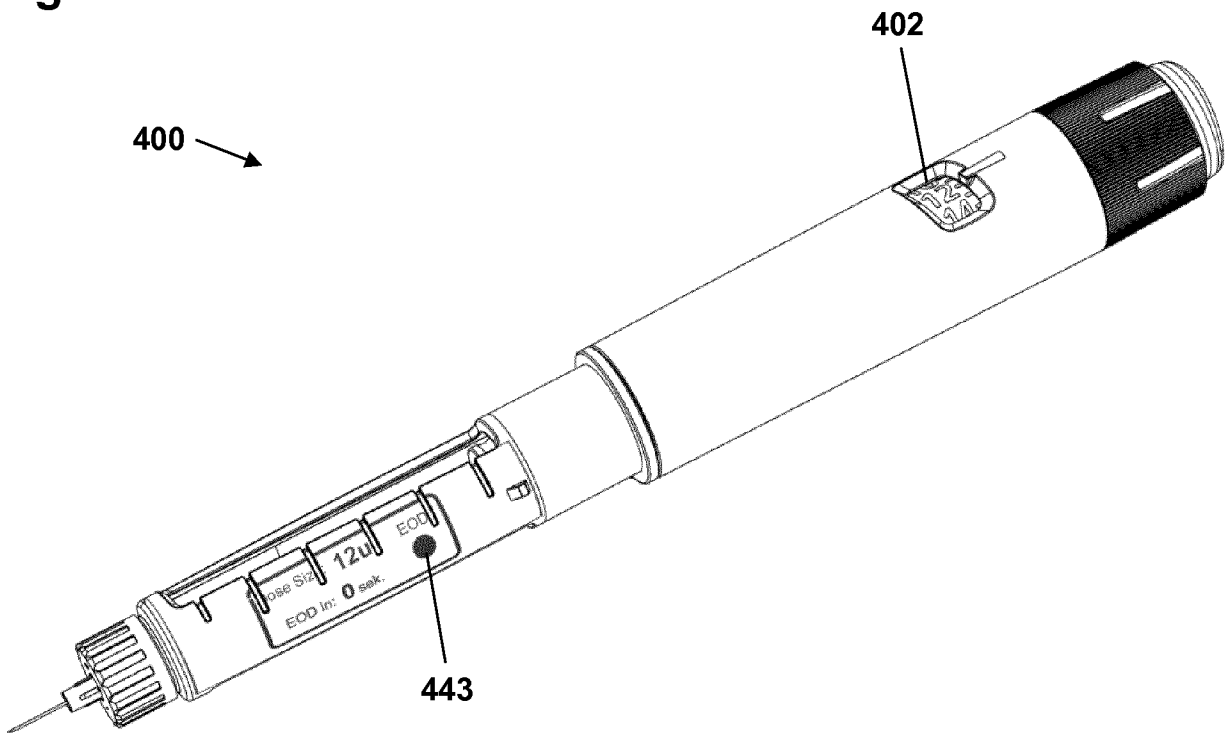

402
400
440
441
420
12u
EOD
Dose Size
EOD in: 2 sek.
442

Fig. 4B


402
400
12u
EOD
Dose Size
EOD in: 0 sek.
443

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/067523

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/315 G01F23/26 A61M5/31
ADD. A61M5/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M G01F

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2007/107558 A2 (NOVO NORDISK AS [DK]; LARSEN ANDRE [DK]) 27 September 2007 (2007-09-27)	8-10, 13-15
A	page 4, lines 24-31 page 6, lines 18-26 page 8, line 20 - page 9, line 2 page 14, lines 7-13 figures 1-8	11,12

X	WO 2012/140097 A2 (NOVO NORDISK AS [DK]; PEDERSEN BENNIE PEDER SMISZEK [DK]; HANSEN MICHA) 18 October 2012 (2012-10-18)	8,9, 13-15
A	page 6, lines 14-17 page 9, lines 3-6 page 18, lines 27-32 page 26, line 10 - page 27, line 13 page 28, lines 6-14 figures 8-10	10-12

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

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 October 2017	30/10/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Diamantouros, S

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2017/067523

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-7
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 1-7

Claims 1-7 are not covered in this opinion, because they refer to a method for treatment of the human or animal body by therapy (Rule 39.1(iv) PCT). More specifically, claim 1 includes the step of "expelling the set dose from the cartridge", which includes the case of administering a medicament to a patient, as explained in the background and the disclosure of the invention in the description. Claims 2-7 are dependent on claim 1.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2017/067523

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2007107558 A2	27-09-2007	CN 101405582 A	08-04-2009
		EP 1999441 A2	10-12-2008
		JP 5225974 B2	03-07-2013
		JP 2009529999 A	27-08-2009
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		WO 2007107558 A2	27-09-2007
WO 2012140097 A2	18-10-2012	CN 103458945 A	18-12-2013
		EP 2696918 A2	19-02-2014
		JP 5989760 B2	07-09-2016
		JP 2014517734 A	24-07-2014
		US 2014074041 A1	13-03-2014
		WO 2012140097 A2	18-10-2012