SYSTEM FOR INDICATING LIFETIME STATUS FOR MEDICAL COMPONENT

Abstract: A drug delivery system (105, 500) is provided comprising means for receiving a reservoir assembly (230, 521) containing an amount of drug having a recommended maximum service lifetime, a delivery assembly (220, 510) adapted for cooperation with the reservoir to deliver drug therefrom, display means (515) for displaying information to a user, and electronic control means (210). The control means is adapted to store information representing the recommended maximum service lifetime of the reservoir assembly, detect an initial time when an operation associated with the initial use of the reservoir assembly takes place, calculate the time left until the recommended maximum service lifetime has been reached, and control the display to indicate the time left. In this way the user is automatically kept informed as to when the reservoir assembly should be replaced.

Fig. 8
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SYSTEM FOR INDICATING LIFETIME STATUS FOR MEDICAL COMPONENT

The invention generally relates to systems and components intended for use in a drug delivery system for delivery of a drug from a reservoir, the drug or another component of the system having a recommended in-use time.

BACKGROUND OF THE INVENTION

When delivering a drug to a patient different devices or systems may be used. For example, drugs to be administered subcutaneously may be injected using a handheld manually operated drug delivery device, e.g. in the form of a traditional "pen" formed device used for e.g. diabetes drugs or growth hormone. Alternatively a drug may be infused using a continuous drug delivering device (e.g. an insulin pump) where the user can receive a given drug both on a (near-) continuous base as well as bolus infusions.

Whether using a pen or a pump some of the components will have a limited in-use lifetime. For a pen device the needle and the drug are such examples. For the needle it is normally recommended to use it only once whereas for example an insulin-containing cartridge may have a recommended in-use time (i.e. the time starting from when a cartridge has been removed from its recommended cool storage condition) of 2 or 3 weeks. For an infusion pump the infusion set (or cannula) and the drug are such examples. For the infusion set it is normally recommended to use it for 2 or 3 days whereas for example an insulin-containing reservoir (either user- or pre-filled) may have a recommended in-use time of 1 or 2 weeks from when the insulin or the pre-filled reservoir was removed from its cooled storage condition.

Traditionally the user would have to keep track of when the in-use lifetime has been reached. Correspondingly, it is an object of the present invention to provide devices and systems which would assist the user in keeping track of when a given component for a drug delivery device or system has reached its recommended in-use lifetime.

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 a first aspect of the invention a drug delivery system is provided comprising means for receiving a reservoir assembly containing an amount of drug having a recommended maximum service lifetime, a delivery assembly adapted for cooperation with the reservoir to
deliver drug there from, communication means for communicating information to a user, and electronic control means. The control means is adapted to store information representing the recommended maximum service lifetime of the reservoir assembly, detect an initial time when an operation associated with the initial use of the reservoir assembly takes place, calculate the time left until the recommended maximum service lifetime has been reached, and control the communication means to indicate the time left. The communication means may be in the form of an acoustic alarm or a display, e.g. an LCD or a simple flashing LED.

In an exemplary embodiment the reservoir assembly is in the form of a cylindrical cartridge comprising an axially displaceable piston and containing a pre-filled amount of drug having a recommended maximum service lifetime. Correspondingly, the delivery assembly comprises a piston rod adapted to engage a piston in the reservoir. Alternatively, a cartridge may be adapted to be filled with a drug by a user prior to use, e.g. as used in combination with many drug infusion pumps. Indeed, the component of the reservoir assembly having a recommended maximum service lifetime is the contained drug.

The "true" start time for calculating the time left until the recommended maximum service lifetime for the contained drug has been reached is the time when a reservoir assembly has been removed from its recommended cool storage condition, or when a cartridge has been filled by a user with a drug just removed from its recommended cool storage condition. However, as a user under normal use conditions will place a new reservoir unit (or a newly user-filled reservoir unit) in a drug delivery system almost immediately after a new pre-filled reservoir assembly or the drug has been removed from its recommended cool storage condition (or filled with a drug removed from its recommended cool storage condition), the time when the drug delivery system detects that it has been loaded with a new reservoir can be considered to be an acceptable start time for calculating the time left until the recommended maximum service lifetime for the contained drug has been reached.

Different operations could be associated with the initial use of a reservoir assembly. For example, when the delivery assembly comprises a piston rod adapted to engage a piston in the reservoir assembly, the operation associated with the initial use of a reservoir assembly could be the detection that the piston rod has been positioned corresponding to a substantially filled reservoir assembly, i.e. pushed back or retracted automatically in order to receive a cartridge with a piston in its most proximal position. In case a used reservoir is installed in the system (and the piston rod is forward to the actual position of the piston) this would then incorrectly be detected as initial use of the reservoir assembly. To prevent a corre-
sponding miscalculation of remaining service life the system could be provided with means to
detect that the piston rod is moved forward a considerably length just after a reservoir as-
semble has been loaded, this indicating that a used reservoir assembly has been inserted.
When such a condition is detected the system may be adapted to e.g. ask the user how old
the reservoir actually is or warn the user that the calculated time may be incorrect for the
newly loaded reservoir assembly.

In an alternative embodiment the reservoir assembly receiving means is adapted to receive a
reservoir assembly comprising a unique identifier, e.g. a code pattern detectable by contact
or optical means, a mechanically detectable pattern or an electronic component such a RFID
device, where the operation associated with the initial use of a reservoir assembly is the de-
tection of an identifier that has not been detected before by the detection means. Indeed,
such a setup would not automatically detect when a reservoir unit having been partly used in
another device is loaded. However, the information may be combined with registration of pis-
ton rod movement just after loading of the reservoir assembly.

For example, the electronic controller circuitry may be adapted to detect piston rod move-
ment just after the piston rod has been positioned to a retracted position (e.g. within the first
30 or 60 seconds), the registration of a fast forwarding of the piston rod (e.g. 50% faster than
when a fluid drug is expelled through an outlet device for which the system is designed to be
used with, e.g. a transcutaneous needle assembly having a given bore size) to a position
corresponding to a not fully filled reservoir (e.g. comprising less than 95% of the full amount)
indicating that a not fully filled reservoir has been inserted.

In a further alternative embodiment the reservoir assembly receiving means comprises a clo-
sure member, e.g. a cartridge holder for a pen or a door for an infusion pump, the closure
member having an open state allowing a reservoir assembly to be exchanged and a closed
state for holding the reservoir assembly in place, where the operation associated with the
initial use of a reservoir assembly is the detection that the closure member has been posi-
tioned in its closed state. Again, such a setup would not automatically detect when a reser-
voir unit having been partly used is loaded. The delivery assembly as such may be manually
operated as in a traditional pen-formed drug delivery device, or it may be electronically con-
trolled as in an infusion pump or a drug delivery doser.

The system may comprise a delivery unit, e.g. a pump unit, comprising the reservoir assem-
bly receiving means and the delivery assembly, and a remote unit adapted for wireless
communication with the delivery unit and comprising the display means for displaying information to a user.

The above-described systems may further be adapted to be connected to a transcutaneous device unit comprising a transcutaneous device adapted to be arranged in fluid communication with the reservoir assembly. Such a system may then comprise second detection means for detecting when a transcutaneous device unit has been connected to the delivery unit, and electronic control means adapted to store information representing the recommended maximum service lifetime of the transcutaneous device unit, detect an initial time when an operation associated with the initial use of the transcutaneous device unit takes place, calculate the time left until the recommended maximum service lifetime has been reached, and control the display to indicate the time left. As appears, such a system would be adapted to provide service lifetime information for two components of the system. For example, the transcutaneous device unit may be in the form of an infusion set comprising a flexible tube adapted to be connected to the delivery unit, e.g. as normally used in combination with an infusion pump, or the transcutaneous device unit may be in the form of a needle assembly comprising a needle hub adapted to be connected to the delivery unit, e.g. as normally used in combination with a traditional pen-formed injection device. As a needle assembly for such a pen normally is recommended for single use only, the display means may simply inform the user of how long time the needle assembly has been connected to the system, or, if actuation of the delivery assembly is detected as in an electronically controlled device, inform the user that a new needle assembly should be used.

In a further aspect of the invention a drug delivery system is provided comprising a pump unit having a reservoir prefilled with a drug having a recommended maximum service lifetime and a delivery assembly adapted for cooperation with the reservoir to deliver drug there from, i.e. the pump unit is a component having a recommended maximum service lifetime. The operation associated with the initial use of a reservoir may be the initial use of the delivery assembly.

In a further aspect of the invention a drug delivery system comprises a delivery unit comprising a reservoir and a delivery assembly, and a transcutaneous device unit comprising a transcutaneous device adapted to be arranged in fluid communication with the reservoir, wherein the consumable component is the transcutaneous device unit, the system being provided with detection means for detecting when a transcutaneous device unit has been connected to the pump unit. The transcutaneous device unit may be in the form of an infusion
set comprising a flexible tube adapted to be connected to the delivery unit, or the transcutaneous device unit and the delivery unit may be adapted to be secured to each other in a situation of use, the transcutaneous device unit comprising a mounting surface comprising adhesive means allowing the combined units to be attached to a skin surface of a subject as a unitary unit.

For the above described systems the display may be controlled to display the relevant information in different ways, e.g. the display may be controlled to display time left as an amount of time or a time of the day or a combination thereof, e.g. amount of time when only a short period of time is left, e.g. less than 24 hours, a number of days when a longer period of time is left, or a time of a given day. Further, an alarm (e.g. audible, visual and/or tactile) may be provided when a given time is left until the recommended maximum service lifetime has been reached.

As used herein, the term "drug" is meant to encompass any drug-containing flowable medicine or formulation capable of being passed through a delivery means such as a hollow needle or a nozzle in a controlled manner, such as a liquid, solution, gel, fine suspension or powder. Representative drugs include pharmaceuticals such as peptides, 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 the exemplary embodiments reference will be made to the use of insulin (the term "insulin" covering any drug formulation comprising a component having a blood glucose influencing activity). Correspondingly, the term "subcutaneous" infusion is meant to encompass any method of transcutaneous delivery to a subject. Further, the term needle (when not otherwise specified) defines a piercing member adapted to penetrate the skin of a subject.

**BRIEF DESCRIPTION OF THE DRAWINGS**

In the following the invention will be further described with references to the drawings, wherein

fig. 1 shows a remote control for a drug delivery system,
fig. 2 shows a patch unit for a drug delivery system,
fig. 3 shows the patch unit of fig. 2 in an actuated state,
fig. 4 shows a patch unit with a pump unit partly attached,
fig. 5 shows the pump unit of fig. 4 fully attached to the patch unit,
fig. 6 shows in an exploded view a pump unit,
fig. 7 shows a schematic representation of a pump unit and a control unit, and fig. 8 shows a further embodiment of a drug delivery system.

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 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.

A first exemplary embodiment comprises a skin-mountable drug delivery device and a remote control adapted to be in wireless communication with the device, the drug delivery device comprising a patch unit and a pump unit.

Fig. 1 shows a remote control (RC) which may form part of a drug delivery system embodying aspects of the present invention. The RC 1 comprises an LCD display 30 arranged at the upper portion of the unit and buttons arranged beneath the display. The remote comprises a rocker switch 10 and a left ACCEPT key 21 as well as a right ESCAPE key 22. The rocker switch is the fundamental navigation button and is a four-way switch having four areas 11, 12, 13, 14 supporting respectively the directions: UP-DOWN and LEFT-RIGHT. The accept button is the fundamental "Yes" button and the escape button is the fundamental "No" button. The display is a dot matrix display and may be a monochrome, greyscale or colour display. The display shows the main screen which normally is displayed when the RC is turned on. The MS serves to indicate to the user the status of the system controlled by the RC. Information in respect of time left until the recommended maximum service lifetime has been reached for a given component of the system may either be shown permanently on the MS or it may be activated via the menu system. A more detailed description of the shown remote control and its user interface can be found in WO 2007/000426, which is hereby incorporated by reference.

Fig. 2 shows a skin-mountable device in the form of a patch (or cannula) unit 400. The patch unit comprises a relatively rigid body portion 414 arranged on a flexible sheet member 430 with a lower mounting surface 431 provided with an adhesive allowing the sheet to be adhered to a skin surface of a subject. The sheet member comprises a central opening 432
through which a cannula can be inserted. The body portion comprises a housing portion 412 in which a cannula inserting mechanism is arranged, see below. The body portion further comprises two slider leg members 413 extending from the housing, the legs adding stiffness to the patch and further serves as guiding means when a pump/reservoir unit is attached the patch unit, see below. The housing is provided with a set of opposed grooves 420 serving as attachment means for a packaging and subsequently for a pump unit. The housing further comprises a fluid inlet 415 adapted to be mounted in fluid communication with a corresponding fluid outlet from an attached pump unit 450, an actuator 416 for actuating an electrical contact on the attached pump unit, and a release member 417 adapted to engage a corresponding release member of a pump unit and thereby release a cannula inserting mechanism (see e.g. US 2009/054866) when the pump unit is attached for the first time, the cannula being inserted through the opening 432. The housing portion 412 also comprises a catch 419 adapted to engage a corresponding coupling structure on the pump unit. As appears, when the cannula 951 is inserted (see fig. 3), it is protected by the pump unit, however, the pump unit can be removed for subsequent inspection of the insertion site as shown in fig. 4.

Fig. 4 shows an alternative embodiment of a patch unit 1010 with a pump unit 1050 by its side, and fig. 27 shows the pump unit fully but releasably attached. More specifically, fig. 4 shows an embodiment of a medical device 1000, comprising a cannula unit 1010 of the type shown in fig. 2 and a thereto mountable pump (or reservoir) unit 1050. In the shown embodiment the cannula unit comprises a housing 1015 with a shaft into which a portion 1051 of the pump unit is inserted. The shaft has a lid portion 1011 with an opening 1012, the free end of the lid forming a flexible latch member 1013 with a lower protrusion (not shown) adapted to engage a corresponding depression 1052 in the pump unit, whereby a snap-action coupling is provided when the pump unit is inserted into the shaft of the cannula unit. Also a vent opening 1054 can be seen. The housing 1015 is provided with a pair of opposed legs 1018 and is mounted on top of a flexible sheet member 1019 with a lower adhesive surface 1020 serving as a mounting surface, the sheet member comprising an opening 1016 for the cannula 1017.

Fig. 6 shows in an exploded view a pump unit 300 of the same type as in fig. 4. The pump unit comprises an upper housing portion 310 and a lower housing portion 320 which in an assembled state provides a water-protected enclosure for the additional components of the reservoir unit: A pump assembly 330, an actuator 340, a prefilled reservoir 350, and elec-
tronic control means 360. In an initial state as supplied to the user, a protective cap assembly 370 is attached to the unit.

The lower housing portion is made from a transparent material allowing a reservoir (see below) to be inspected by a user from the outside, and comprises an opening 321 in which a water repelling vent 322 is arranged. A sheet member 325 with a window opening 326 is attached to the lower surface of the lower housing portion, this masking the transparent portion except for a window over the reservoir. The sheet member may be used to display user information, e.g. type and amount of drug.

The pump assembly 330 is in the form of a membrane pump comprising a piston-actuated pump membrane with flow-controlled inlet- and outlet-valves. The pump has a general layered construction comprising a number of body members between which are interposed flexible membrane layers, whereby a pump chamber, inlet and outlet valves, and one or more safety valves can be formed, the layers being held together with clamps 338. The pump further comprises a fluid connector 335 in the form of hollow connection needle slidably positioned within the pump (for illustrative purposes shown outside of the pump), this allowing the pump to be connected with reservoir when the protective cap assembly 370 is activated. For a more detailed description of such a membrane pump reference is made to applicants co-pending application WO 2009/021950, which is hereby incorporated by reference.

The pump actuator is in the form of a coil actuator to which the pump assembly is attached by a clamp. For a more detailed description of such a coil actuator reference is made to applicants co-pending application WO 2005/094919, which is hereby incorporated by reference.

The drug reservoir is in the form of a flexible, prefilled collapsible pouch 350 comprising a needle-penetratable septum 354 allowing the fluid connector to be pushed into the reservoir without leakage, thereby providing a fluid communication with the pump. A clip holder 352 is attached to the reservoir, this allowing the reservoir to be attached to the housing without influencing the reservoir per se. Under the reservoir (as seen from the lower surface of the unit) is arranged a sheet (not shown) comprising a contrast-enhancing pattern, e.g. a black line on a white background, allowing for easier visual identification of impurities in the drug, e.g. fibrillation in insulin.
The electronic control means 360 comprises a PCB or flex-print 362 with a processor 361 for controlling the pump assembly, a battery 366, an acoustic transducer 365 providing an alarm and communication interface with the user, as well as a contact mounted on the actuator allowing the control means to be activated by the user when taken into use for the first time (via the actuator 216). The control means may comprise a receiver and/or a transmitter allowing the reservoir to communicate wirelessly with a remote controller.

The protective cap assembly 370 comprises an attachment member 371 initially locked to the reservoir unit and an activation "push button" member 372 slidingly attached to the attachment member. When the reservoir unit is removed from its primary packaging (not shown) the user depresses the activation member towards the reservoir unit. This actuation results in three actions taking place: A first protrusion on the activation member will actuate a contact on the reservoir unit, this activating the electronics, and a second protrusion will engage the pump assembly and push the fluid connector 335 out from the pump assembly and into the reservoir, thereby establishing a fluid communication between the reservoir and the pump. Thirdly, depression of the activation member will "unlock" the attachment member and allow it, and thereby the activation member, to be removed from the reservoir unit. Thereafter the reservoir unit can be connected to the patch unit. An alternative activation assembly is described in WO 2010/029121, which is hereby incorporated by reference.

Fig. 7 shows a schematic representation of a pump unit 200 (here corresponding to the pump unit 1050) and a controller unit 100 (here in the form of a wireless "remote controller" or "external communication device" for the pump unit). It is considered that the general design of such units is well known to the skilled person, however, for a more detailed description of the circuitry necessary to provide the desired functionality of the present invention reference is made to US 2003/0065308, which is hereby incorporated by reference.

More specifically, fig. 7 depicts a simplified block diagram of various functional components or modules (i.e. single components or groups of components) included in the pump unit 200 and remote controller 100. The remote controller unit includes a housing 101, a remote processor 110 including a CPU, memory elements for storing control programs and operation data and a clock, an LCD display 120 for providing operation for information to the user, a keypad 130 for taking input from the user, an audio alarm 140 for providing information to the user, a vibrator 150 for providing information to the user, a main battery 160 for supplying power to the controller, a backup battery 161 to provide memory maintenance for the controller, a remote radio frequency (RF) telemetry transmitter 170 for sending signals to the pump
unit, and a remote RF telemetry receiver 180 for receiving signals from the pump unit. The controller further comprises a port 185, e.g. an infrared (IR) or RF input/output system, or a USB port for communicating with a further device, e.g. a blood glucose meter (BGM), a continuous blood glucose meter (CGM), a PC or a PDA.

As also depicted in fig. 7, the pump unit 200 includes a housing 201, local processor electronics 210 including a CPU and memory elements for storing control programs and operation data, battery 260 for providing power to the system, a pump unit RF telemetry transmitter 270 for sending communication signals to the remote unit, a pump unit RF telemetry receiver 280 for receiving signals from the remote unit, detection means 240 adapted to cooperate with the patch unit cannula 417, a reservoir 230 for storing a drug, and a pump assembly 220 for expelling drug from the reservoir through a transcutaneous device to the body of a patient. In alternative embodiments the pump unit may also comprise an LCD display for providing information to the user, a keypad for taking input from the user, and a vibrator or other tactile actuator for providing information to the user. RF transmission may be in accordance with a standard protocol such as Bluetooth ®.

As disclosed above, the present invention provides a drug delivery system comprising a consumable component having a recommended maximum service lifetime, a delivery assembly adapted for cooperation with a reservoir to deliver drug there from, display means for displaying information to a user, and electronic control means. The control means is adapted to store information representing the recommended maximum service lifetime of the consumable component, detect an initial time when an operation associated with the initial use of the consumable component takes place, calculate the time left until the recommended maximum service lifetime has been reached, and control the display to indicate the time left. When the system comprises both a pump unit with electronically controlled expelling means and an electronically controlled remote controller, the control means responsible for the lifetime information of the consumable component may be divided between the two units in any desirable way. For example, both the pump unit and the remote controller may be adapted to calculate and display the time left, or, in case the pump unit is not provided with a display, the pump unit may sound an alarm which may be helpful in case the remote controller is not at hand.

With reference to figs. 1-7 an example of a drug delivery system comprising a prefilled pump unit, a patch unit and a remote control unit has been described. In the following two exam-
pies of how aspects of the present invention could be implemented in a medical delivery system will be described.

Thus, as a first example the consumable component is a prefilled reservoir assembly containing an amount of drug having a recommended maximum service lifetime, e.g. 2 weeks for an insulin-containing drug formulation for pump use, and the delivery assembly is electrically driven and electronically controlled. For such a prefilled pump unit the recommended storage temperature would normally be 2-8°C which means that the user will store the pump unit in a refrigerator until immediately before use, i.e. until the pump unit is connected to a patch unit and activated to start pumping. Consequently, an operation associated with the initial use of the reservoir would be the initial activation and use of the delivery assembly. Thus, according to an aspect of the invention, the remote controller 1 will start to show (either permanently or when requested to do so) e.g. "Insulin reservoir status: Time in use: 4 days, insulin expires in: 10 days". A first alarm may be sounded at e.g. beginning of the last day and a second (repeating) alarm may be sounded when the insulin has expired. Alternatively, a prefilled reservoir assembly may used in combination with a conventional durable infusion pump.

As a second example the consumable component is the transcutaneous device unit having a recommended maximum service lifetime of e.g. 3 days, the lifetime being dependent both on the number of days the cannula can be inserted and the number of days the adhesive will keep the patch properly in place. In a simple implementation of the invention the pump unit would merely detect when it is connected to a patch unit and then count the time from that point. However, as the user may disconnect the pump unit a number of times during the lifetime of a patch unit (e.g. when taking a bath or when checking insertion of the cannula) this would not be very helpful. Correspondingly, in an alternative embodiment the pump unit is provided with detection means adapted to detect when the pump unit is connected to a given patch unit for the first time, the first time being associated with activation of the cannula inserting mechanism when the pump unit is attached to the patch unit for the first time. For example, the detection means may sense that the release member 417 has changed configuration after the cannula inserting mechanism has been activated and released. Thus, according to an aspect of the invention, the remote controller 1 will start to show (either permanently or when requested to do so) e.g. "Patch status: Time in use: 2 days, Patch expires in: 18 hours". A first alarm may be sounded at e.g. beginning of the last day and a second (repeating) alarm may be sounded when the patch has expired.
Above embodiments of the invention have been described with reference to the drug delivery system of figs. 1-7, however, aspects of the present invention may also be embodied in a conventional infusion pump system, e.g. of the types provided by Medtronic ® and Roche ®. For example, WO 2009/043564 discloses an infusion pump adapted to receive a reservoir cartridge (which may be either pre-filled or filled by the user), the pump comprising a drive system and a plunger for moving a piston in the cartridge, as well as a locking cap for locking the cartridge in place in the pump. For such an embodiment the unit 200 in fig. 7 would represent an infusion pump, the reservoir 230 would represent a replaceable cartridge, either user-filled or pre-filled, and the pump assembly 220 would represent a piston rod assembly.

When a new cartridge is to be loaded the plunger will have to be moved to an initial position just as the locking cap will have to be re-attached. Both of these actions could be detected and used to indicate to the system that a new cartridge with an (assumed) fresh supply of drug (e.g. insulin) with a recommended maximum service lifetime has been taking into use. The expiration information may be displayed on the pump display and/or on a remote controller. The known type of pump is adapted for connection to an infusion set. Correspondingly, the infusion pump could be adapted to detect when a (new) infusion set with a recommended maximum service lifetime has been taking into use.

Above specific embodiments have been described with reference to drug delivery systems in the form of electronically controlled and actuated infusion pump systems, however, aspects of the present invention may also be embodied in a conventional user-actuated mechanical pen-type injection device when provided with additional electronic means. Referring to fig. 8 a pen-formed drug delivery device 500 will be described.

The pen device comprises a cap portion 501 and a main portion 502 having a proximal part 510 in which a drug expelling mechanism is arranged, and a distal reservoir part 520 in which a replaceable drug-filled transparent cartridge 521 with a distal needle-penetratable septum is arranged and hold in place by a cartridge holder 522 releasably mounted to the proximal part, the cartridge holder having openings allowing a portion of the cartridge to be inspected. The cartridge is provided with a piston 523 driven by a piston rod 511 forming part of the expelling mechanism, the piston rod being adapted to be pushed back when a new cartridge is mounted. A proximal-most button 512 serves to manually set and expel a desired dose of drug. This type of a mechanical pen-formed drug delivery device is well known, see e.g. WO 99/38554 to which reference is made for further details in respect of the internal construction of the shown type of pen. The cartridge (or alternatively the cartridge holder) is provided with distal coupling means in the form of a hub mount 525 having, in the shown ex-
ample, an external thread adapted to engage an inner thread of a needle assembly 530, see below. The proximal part further comprises communication means in the form of a display 515, user actutable keys 516 as well as electronic means (not shown) for detecting and storing information representing operations performed by the expelling mechanism. For example, the electronic means may be adapted to store data representing injections performed by the user, typically in the form of a time and dose log. The display may show the actual dose being set by a user using the button 512, the last dose (e.g. amounts of units expelled) and the time since last dose (or the actual time for the last dose), or the user may use the keys 516 to scroll through the log to display previous expelling data. The pen may also be adapted to transmit data to another system or device, e.g. a PC or a mobile phone. The detection means for detecting a set and/or expelled dose may be adapted to detect directly or indirectly the position of the piston rod, see e.g. US 6,585,698 which is hereby incorporated by reference.

More specifically, US 6,585,698 comprises a first sensor system adapted to measure the number of rotations (including partial rotations) of a setting button and which is coupled to microprocessor keeping track of the accumulated rotations of the setting button. The microprocessor then converts the accumulated number of rotations into a dosage value that is to be administered. A second displacement sensor system provides information about the status of the injection mechanism to the microprocessor, e.g. the displacement sensor can be used to determine the linear displacement of the drive mechanism, which is related to the position of the piston rod and thus the amount of insulin that has been delivered. However, in accordance with aspects of the present invention such a displacement sensor can also be used to detect an operation associated with the initial use of a consumable component in the form of a new cartridge being mounted on the pen device. More specifically, when the piston 511 is pushed back during the mounting procedures for a new cartridge, this condition can be detected by the displacement sensor and used to calculate and display the time left until the recommended maximum service lifetime for a newly loaded new drug cartridge has been reached.

Fig. 8 further shows a needle assembly comprising a hollow infusion needle mounted a cup-formed hub 531 with an inner coupling means in the form of a thread adapted to connect to the external thread of the pen device hub mount 525. The needle comprises a distal pointed portion protruding from the hub as well as a proximal pointed portion adapted to penetrate the cartridge septum when the hub is mounted on the thread. In an alternative embodiment a bayonet coupling may be used instead of the threaded connection, e.g. the cup may be pro-
vided with a plurality of inwardly projecting protrusions adapted to engage corresponding grooves formed distally on the pen device, this as disclosed in e.g. US 2008/0015519. The needle assembly further comprises a needle cap 532 adapted to releasably engage the hub to thereby protect the distal end of the needle.

In the above description of exemplary 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 drug delivery system (105, 500) adapted to receive a reservoir assembly (230, 521) containing an amount of drug having a recommended maximum service lifetime, comprising:
   - a delivery assembly (220, 510) adapted for cooperation with the reservoir assembly to deliver drug there from,
   - communication means (515) for communicating information to a user, and
   - electronic controller circuitry (210) adapted to:
     - store information representing the recommended maximum service lifetime of the reservoir assembly,
     - detect an initial time when an operation associated with the initial use of the reservoir assembly takes place,
     - calculate the time left until the recommended maximum service lifetime has been reached, and
   - control the communication means to indicate the time left.

2. A drug delivery system as in claim 1,
   - wherein the delivery assembly comprises a piston rod (511) adapted to engage a piston in the reservoir assembly, and
   - wherein the operation associated with the initial use of a reservoir assembly is the detection that the piston rod has been positioned to a retracted position corresponding to a substantially filled reservoir assembly.

3. A drug delivery system as in claim 1, the system being adapted to receive a reservoir assembly comprising a unique identifier, wherein:
   - the electronic controller circuitry is adapted to detect the unique identifier, and
   - the operation associated with the initial use of a reservoir assembly is the detection of an identifier that has not been detected before by the detection means.

4. A drug delivery system as in claim 1, further comprising:
   - a closure member (522) having an open state allowing a reservoir assembly to be exchanged and a closed state for holding the reservoir assembly in place, and
   - wherein the operation associated with the initial use of a reservoir assembly is the detection that the closure member has been positioned in its closed state.
5. A drug delivery system as in claim 3 or 4, wherein the delivery assembly comprises a piston rod (511) adapted to engage a piston in the reservoir.

6. A drug delivery system as in claim 2 or 5, wherein the electronic controller circuitry is adapted to detect piston rod movement just after the piston rod has been positioned to a retracted position, the registration of a fast forwarding of the piston rod to a position corresponding to a not fully filled reservoir indicating that a not fully filled reservoir has been inserted.

7. A drug delivery system as in any of claims 1-6, wherein the delivery assembly is electronically controlled.

8. A drug delivery system as in any of claims 1-7, wherein the system comprises:
   - a delivery unit (200) adapted to receive the reservoir assembly and comprising the delivery assembly, and
   - a remote unit (100) adapted for wireless communication with the delivery unit and comprising the display means for displaying information to a user.

9. A drug delivery system as in any of claims 1-7, wherein the system comprises:
   - a delivery unit (200) adapted to receive the reservoir assembly and comprising the delivery assembly, and
   - wherein the delivery unit is adapted to be connected to a transcutaneous device unit comprising a transcutaneous device adapted to be arranged in fluid communication with the reservoir assembly.

10. A drug delivery system as in claim 9, comprising:
    - detection circuitry for detecting when a transcutaneous device unit has been connected to the delivery unit, and
    - electronic control means adapted to:
      - store information representing the recommended maximum service lifetime of the transcutaneous device unit,
      - detect an initial time when an operation associated with the initial use of the transcutaneous device unit takes place,
      - calculate the time left until the recommended maximum service lifetime has been reached, and
      - control the display to indicate the time left.
11. A drug delivery system as in claim 9 or 10, wherein the transcutaneous device unit is in the form of an infusion set comprising a flexible tube adapted to be connected to the delivery unit.

12. A drug delivery system as in claim 9 or 10, wherein the transcutaneous device unit is in the form of a needle assembly (530) comprising a needle hub (531) adapted to be connected to the delivery unit.

13. A drug delivery system as in any of the previous claims, in combination with a reservoir assembly (521) containing an amount of drug having a recommended maximum service lifetime.

14. A drug delivery system as in any of the previous claims, wherein the display (30, 515) can be controlled to display time left as an amount of time or a time of the day.

15. A drug delivery system as in any of the previous claims, wherein an alarm (140) is provided when a given time is left until the recommended maximum service lifetime has been reached.
Fig. 7
### INTERNATIONAL SEARCH REPORT

**International application No**
PCT/EP2011/061392

**A. CLASSIFICATION OF SUBJECT MATTER**

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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)

- G04F  A61M

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 practical, search terms used)

- EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

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

**See patent family annex.**

* Special categories of cited documents:

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**"A"** document member of the same patent family

**Date of the actual completion of the international search**

7 December 2011

**Date of mailing of the international search report**

14/12/2011

**Name and mailing address of the ISA/**

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016

**Authorized officer**

Ceccarello, Davide
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