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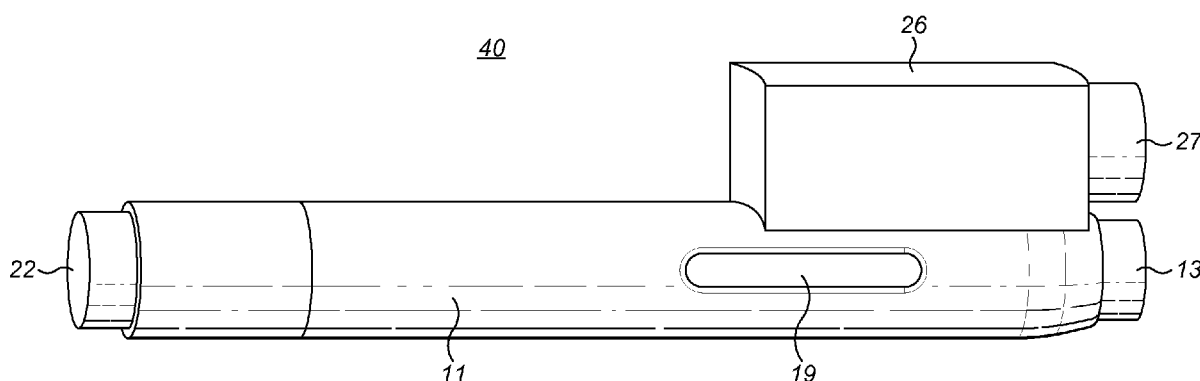


FIG. 3

(57) **Abstract:** An injection device comprising: a housing arranged to contain a medicament cartridge; and an ink dispensing device comprising an ink pad, wherein the ink pad is arranged to print injection-related information on a surface of an injection site when the ink dispensing device is pressed against the surface, wherein the ink dispensing device comprises a casing, an ink pad sleeve that is configured to be urged into the casing of the ink dispensing device, and a printing mechanism, the printing mechanism comprising a wheel on which a plurality of ink pads are arranged, and wherein when the ink pad sleeve is urged into the casing of the ink dispensing device, the wheel is caused to rotate so as to allow a subsequent ink pad on the wheel to be exposed.



AN INJECTION DEVICE

The present invention relates to an injection device.

Background of the Invention

Current therapies delivered by means of self-administered injections include drugs for diabetes (both insulin and new GLP-A class drugs), migraine, hormone therapies, anticoagulants etc. Administering an injection is a process which presents a number of risks and challenges for user and healthcare professionals, both mental and physical.

Conventional injection devices typically fall under two categories – manual devices and auto-injectors. In a conventional manual device, a user must provide a force to drive a liquid medicament out of the device, e.g. by depressing a plunger.

Auto-injectors aim to make self-administration of injected therapies easier for users. Auto-injectors are devices which completely or partially replace activities involved in medicament delivery of manual devices. These activities may include removal of a protective syringe cap, insertion of a needle into a patient's skin, injection of the medicament, removal of the needle, shield of the needle and preventing reuse of the device. This overcomes many of the disadvantages of manual devices. Injection forces/button extension, hand-shaking and the likelihood of delivering an incomplete dose are reduced. Triggering may be performed by numerous means, for example a trigger button or the action of the needle reaching its injection depth.

It is important for some injection devices users, such as diabetic patients, to remember to perform injection at regular intervals. However, conventional injection devices are not equipped with features that allow users of the devices to be reminded of when and where they performed their last injection. Hence, some users of these injection devices, particular those with reduced mental retentiveness, often find it difficult remembering when and where they performed their last injection.

Summary of the Invention

According to an aspect of the present invention, there is provided an injection device comprising a housing arranged to contain a medicament cartridge; and an ink dispensing device comprising an ink pad, wherein the ink pad is arranged to print injection-related information on a surface of an injection site when the ink dispensing device is pressed against the surface, wherein the ink dispensing device comprises a casing, an ink pad sleeve that is configured to be urged into the casing of the ink dispensing device, and a printing mechanism, the printing mechanism comprising a wheel on which a plurality of ink pads are arranged, and wherein when the ink pad sleeve is urged into the casing of the ink dispensing device, the wheel is caused to rotate so as to allow a subsequent ink pad on the wheel to be exposed.

The ink pad may be arranged at a distal end of the housing of the injection device.

The ink dispensing device may be laterally coupled to the injection device such that it is aligned with a needle sleeve of the injection device.

The ink dispensing device may comprise an actuator for urging the ink dispensing device against the surface.

The injection-related information may comprise at least one of: a specific pattern, a time at which injection is performed, date on which injection is performed, weekday on which injection is performed, and area of body on which injection is performed.

Ink dispensed by the ink dispensing device may be water resistant ink.

The ink dispensing device may be arranged at a distal end of a housing of the injection device.

The ink dispensing device may be fixedly attached to the injection device.

The ink dispensing device may be removably coupled to the injection device.

The ink dispensing device may comprise an automatic date and/or time stamp.

The ink dispensing device may comprise a manually operated date and/or time stamp.

The injection device may contain a medicament.

According to another aspect of the present invention, there is provided a method of dispensing ink from an injection device, the injection device comprising an ink dispensing device which comprises an ink pad, an ink pad sleeve that is configured to be urged into the casing of the ink dispensing device, a casing, and a printing mechanism, the printing mechanism comprising a wheel on which a plurality of ink pads are arranged, the method comprising use of the ink pad for printing injection-related information on a surface of an injection site when the ink dispensing device is pressed against the surface, and urging of the ink pad sleeve into the casing of the ink dispensing device when the ink dispensing device is pressed against the surface, causing the rotation of the wheel so as to allow a subsequent ink pad on the wheel to be exposed.

According to an aspect of the present invention, there is provided an injection device comprising: a housing arranged to contain a medicament cartridge; and an ink dispensing device arranged to print injection-related information on a surface of an injection site.

The ink dispensing device may comprise an ink pad, wherein the ink pad is arranged to print injection-related information on the surface when the ink dispensing device is pressed against the surface.

The ink pad may be arranged at a distal end of the housing of the injection device.

The ink dispensing device may comprise a retractable ink pad sleeve, and wherein when the ink dispensing device is laterally coupled to the injection device such that it is aligned with a needle sleeve of the injection device.

The ink dispensing device may comprise a printing mechanism, the printing mechanism comprising a wheel on which a plurality of ink pads are arranged, and wherein the printing mechanism is configured such that when the ink pad sleeve retracts the wheel is configured to rotate so as to allow a subsequent ink pad on the wheel to be exposed.

The ink dispensing device may comprise an actuator for urging the ink dispensing device against the surface.

The injection-related information may comprise at least one of: a specific pattern, a time at which injection is performed, date on which injection is performed, weekday on which injection is performed, and area of body on which injection is performed.

Ink dispensed by the ink dispensing device may be water resistant ink.

The ink dispensing device may be arranged at a distal end of a housing of the injection device.

The ink dispensing device may be fixedly attached to the injection device.

The ink dispensing device may be removably coupled to the injection device.

The ink dispensing device may comprise an automatic date and/or time stamp.

The ink dispensing device may comprise a manually operated date and/or time stamp.

The injection device may contain a medicament.

According to another aspect of the present invention, there is provided a method of dispensing ink from an injection device, the injection device comprising an ink dispensing device, the method comprising printing injection-related information on a surface of an injection site when the ink dispensing device is pressed against the surface.

Also provided is an injection device comprising: a housing arranged to contain a medicament cartridge; and an ink dispensing device arranged to print injection-related information on a surface of an injection site, wherein the ink dispensing device comprises an ink pad attached to a distal portion of the injection device. The injection device may be an auto-injector, and the ink pad may be located on the activation mechanism of the auto-injector. For instance, the activation components of the

activation mechanism may include a needle sleeve or needle shield, and the ink pad may be located on the needle sleeve or needle shield. The ink pad may be positioned such that the ink pad is pressed onto the surface when the activation mechanism is activated, for instance the ink pad may be located on the distal end of a component, such as a needle sleeve or needle shield, which is required to be depressed to activate the auto-injector.

These and other aspects of the invention will be apparent from and elucidated with reference to the embodiments described hereinafter.

The terms "drug" or "medicament" which are used interchangeably herein, mean a pharmaceutical formulation that includes at least one pharmaceutically active compound. The term "drug delivery device" shall be understood to encompass any type of device, system or apparatus designed to immediately dispense a drug to a human or non-human body (veterinary applications are clearly contemplated by the present disclosure). By "immediately dispense" is meant an absence of any necessary intermediate manipulation of the drug by a user between discharge of the drug from the drug delivery device and administration to the human or non-human body. Without limitation, typical examples of drug delivery devices may be found in injection devices, inhalers, and stomach tube feeding systems. Again without limitation, exemplary injection devices may include, e.g., syringes, autoinjectors, injection pen devices and spinal injection systems.

Brief Description of the Drawings

Exemplary embodiments of the present invention are described with reference to the accompanying drawings, in which:

Figures 1A and 1B are side-on views of an injection device according to an embodiment of the present invention;

Figure 2 shows an injection device according to a first embodiment;

Figure 3 shows an injection device according to a second embodiment;

Figure 4A shows an injection device in an initial state according to a third embodiment;

Figure 4B shows the injection device in an intermediate state according to the third embodiment;

Figure 4C shows the injection device in a final state according to the third embodiment;

Figure 5A shows the ink dispensing device of the injection device in a first state according to the third embodiment;
Figure 5B shows the ink dispensing device of the injection device in a second state according to the third embodiment;
Figure 5C shows a schematic view of the ink dispensing device of the injection device according to the third embodiment; and
Figure 5D shows a plan view of the ink dispensing device of the injection device according to the third embodiment.

Reference will now be made in detail to the embodiments, examples of which are illustrated in the accompanying drawings, wherein like reference numerals refer to like elements throughout.

Details Description of the Embodiments

An injection device including an ink dispensing device is provided. The ink dispensing device is arranged to print injection-related information on a surface. By printing this injection-related information on a body part of a patient, e.g. on the arm of the patient, the patient is reminded of a previous injection so as to determine whether and when another injection should be performed.

A drug delivery device, as described herein, may be configured to inject a medicament into a patient. For example, delivery could be sub-cutaneous, intra-muscular, or intravenous. Such a device could be operated by a patient or care-giver, such as a nurse or physician, and can include various types of safety syringe, pen-injector, or auto-injector. The device can include a cartridge-based system that requires piercing a sealed ampule before use. Volumes of medicament delivered with these various devices can range from about 0.5 ml to about 2 ml. Yet another device can include a large volume device ("LVD") or patch pump, configured to adhere to a patient's skin for a period of time (e.g., about 5, 15, 30, 60, or 120 minutes) to deliver a "large" volume of medicament (typically about 2 ml to about 10 ml).

In combination with a specific medicament, the presently described devices may also be customized in order to operate within required specifications. For example, the device may be customized to inject a medicament within a certain time period (e.g., about 3 to about 20 seconds for auto-injectors, and about 10 minutes to about 60

minutes for an LVD). Other specifications can include a low or minimal level of discomfort, or to certain conditions related to human factors, shelf-life, expiry, biocompatibility, environmental considerations, etc. Such variations can arise due to various factors, such as, for example, a drug ranging in viscosity from about 3 cP to about 50 cP. Consequently, a drug delivery device will often include a hollow needle ranging from about 25 to about 31 Gauge in size. Common sizes are 27 and 29 Gauge.

The delivery devices described herein can also include one or more automated functions. For example, one or more of needle insertion, medicament injection, and needle retraction can be automated. Energy for one or more automation steps can be provided by one or more energy sources. Energy sources can include, for example, mechanical, pneumatic, chemical, or electrical energy. For example, mechanical energy sources can include springs, levers, elastomers, or other mechanical mechanisms to store or release energy. One or more energy sources can be combined into a single device. Devices can further include gears, valves, or other mechanisms to convert energy into movement of one or more components of a device.

The one or more automated functions of an auto-injector may each be activated via an activation mechanism. Such an activation mechanism can include one or more of a button, a lever, a needle sleeve, or other activation component. Activation of an automated function may be a one-step or multi-step process. That is, a user may need to activate one or more activation components in order to cause the automated function. For example, in a one-step process, a user may depress a needle sleeve against their body in order to cause injection of a medicament. Other devices may require a multi-step activation of an automated function. For example, a user may be required to depress a button and retract a needle shield in order to cause injection.

In addition, activation of one automated function may activate one or more subsequent automated functions, thereby forming an activation sequence. For example, activation of a first automated function may activate at least two of needle insertion, medicament injection, and needle retraction. Some devices may also require a specific sequence of steps to cause the one or more automated functions to occur. Other devices may operate with a sequence of independent steps.

Some delivery devices can include one or more functions of a safety syringe, pen-injector, or auto-injector. For example, a delivery device could include a mechanical energy source configured to automatically inject a medicament (as typically found in an auto-injector) and a dose setting mechanism (as typically found in a pen-injector).

According to some embodiments of the present disclosure, an exemplary drug delivery device 10 is shown in Figs. 1A & 1B. Device 10, as described above, is configured to inject a medicament into a patient's body. Device 10 includes a housing 11 which typically contains a reservoir containing the medicament to be injected (e.g., a syringe) and the components required to facilitate one or more steps of the delivery process. Device 10 can also include a cap assembly 12 that can be detachably mounted to the housing 11. Typically a user must remove cap 12 from housing 11 before device 10 can be operated.

As shown, housing 11 is substantially cylindrical and has a substantially constant diameter along the longitudinal axis X. The housing 11 has a distal region 20 and a proximal region 21. The term "distal" refers to a location that is relatively closer to a site of injection, and the term "proximal" refers to a location that is relatively further away from the injection site.

Device 10 can also include a needle sleeve 13 coupled to housing 11 to permit movement of sleeve 13 relative to housing 11. For example, sleeve 13 can move in a longitudinal direction parallel to longitudinal axis X. Specifically, movement of sleeve 13 in a proximal direction can permit a needle 17 to extend from distal region 20 of housing 11.

Insertion of needle 17 can occur via several mechanisms. For example, needle 17 may be fixedly located relative to housing 11 and initially be located within an extended needle sleeve 13. Proximal movement of sleeve 13 by placing a distal end of sleeve 13 against a patient's body and moving housing 11 in a distal direction will uncover the distal end of needle 17. Such relative movement allows the distal end of needle 17 to extend into the patient's body. Such insertion is termed "manual" insertion as needle 17 is manually inserted via the patient's manual movement of housing 11 relative to sleeve 13.

Another form of insertion is “automated,” whereby needle 17 moves relative to housing 11. Such insertion can be triggered by movement of sleeve 13 or by another form of activation, such as, for example, a button 22. As shown in Figs. 1A & 1B, button 22 is located at a proximal end of housing 11. However, in other embodiments, button 22 could be located on a side of housing 11.

Other manual or automated features can include drug injection or needle retraction, or both. Injection is the process by which a bung or piston 23 is moved from a proximal location within a syringe (not shown) to a more distal location within the syringe in order to force a medicament from the syringe through needle 17. In some embodiments, a drive spring (not shown) is under compression before device 10 is activated. A proximal end of the drive spring can be fixed within proximal region 21 of housing 11, and a distal end of the drive spring can be configured to apply a compressive force to a proximal surface of piston 23. Following activation, at least part of the energy stored in the drive spring can be applied to the proximal surface of piston 23. This compressive force can act on piston 23 to move it in a distal direction. Such distal movement acts to compress the liquid medicament within the syringe, forcing it out of needle 17.

Following injection, needle 17 can be retracted within sleeve 13 or housing 11. Retraction can occur when sleeve 13 moves distally as a user removes device 10 from a patient's body. This can occur as needle 17 remains fixedly located relative to housing 11. Once a distal end of sleeve 13 has moved past a distal end of needle 17, and needle 17 is covered, sleeve 13 can be locked. Such locking can include locking any proximal movement of sleeve 13 relative to housing 11.

Another form of needle retraction can occur if needle 17 is moved relative to housing 11. Such movement can occur if the syringe within housing 11 is moved in a proximal direction relative to housing 11. This proximal movement can be achieved by using a retraction spring (not shown), located in distal region 20. A compressed retraction spring, when activated, can supply sufficient force to the syringe to move it in a proximal direction. Following sufficient retraction, any relative movement between needle 17 and housing 11 can be locked with a locking mechanism. In addition, button 22 or other components of device 10 can be locked as required.

Figure 2 shows an injection device according to a first embodiment.

As shown in Figure 2, an injection device 30 of the first embodiment comprises a housing 11, a window 19, an ink pad 24, and a removable cap 25. The removable cap 25 is configured to be removably engaged with a distal end of the housing 11, and is shown in the drawing being in a disengaged state from the housing 11.

The cap 25 comprises a collar that can be inserted into the distal end of the housing 11 so as to engage with the housing 11. When the cap 25 is engaged with the housing 11, the ink pad 24 is covered by the cap 25 such that inadvertent stamping or printing on a surface can be avoided. Moreover, by covering the ink pad 24 with the cap 25 when the ink pad 24 is not in use, the problem of ink leakage or ink drying can be prevented. In addition, an injection needle (not shown in Figure 1) contained within the housing 11 is covered by the cap 25.

The window 19 is formed on the housing 11 through which a user can observe the amount of medicament contained within the housing 11, and specifically the amount of medicament contained within a syringe (not shown in Figure 1) that is included in the housing 11. Therefore, before an injection the user is able to determine whether the medicament contained in the housing 11 is accurate, and after an injection the user is able to determine whether all medicament has been injected.

The ink pad 24 is arranged at a distal end of the injector device 30, therefore during injection when the distal end of the housing 11 is pressed against a surface (e.g. an injection site), the ink pad 24 is arranged to transfer ink onto the surface. The ink pad 24 has a specific pattern (not shown in the drawing) such that when it is urged against the surface, it prints ink in the specific pattern on the surface. The ink used in this embodiment is water-resistant ink, so that the specific pattern printed onto the surface can be retained for a longer period of time.

A sequence of operation of the first embodiment is described as follows:

In order to perform an injection, the user removes cap 25 from housing 11, so as to expose the ink pad 24 as well as the needle contained within the housing. The user then holds the housing 11 firmly using one hand and presses the distal end of the housing 11 against an injection site. Since the ink pad 24 is arranged at the distal end

of the housing 11, the ink pad 24 transfers ink in the specific pattern onto an area near the injection site. The printed ink then dries to serve as a visual indication of a body part on which an injection has been performed. An amount of fading of the printed ink would also allow the user to estimate the amount of time since the injection.

Figure 3 shows an injection device according to a second embodiment.

As shown in Figure 3, an injection device 40 of the second embodiment comprises a housing 11, a window 19, a needle sleeve 13, a button 22, and an ink dispensing device 26. The ink dispensing device 26 comprises an ink pad sleeve 27. The ink pad sleeve 27 is arranged to cover an ink pad (not shown in Figure 3) and also arranged to be movable relative to the rest of the ink dispensing device 26 so as to expose the ink pad.

The window 19 is formed on the housing 11 through which a user can observe the amount of medicament contained within the housing 11, and specifically the amount of medicament contained within a syringe (not shown in Figure 3) that is included in the housing 11. Therefore, before an injection the user is able to determine whether the medicament contained in the housing 11 is accurate, and after an injection the user is able to determine whether all medicament has been injected.

The ink dispensing device 26 in the present embodiment is fixedly attached to the housing 11 of the injection device 40, in a manner such that the ink pad sleeve 27 and an opening of the injection device 40 are aligned. Specifically, in this embodiment, the ink pad sleeve 27 is aligned with the needle sleeve 13 of the injection device 40.

The ink pad (not shown in Figure 3) of the ink dispensing device 26 comprises an automatic rotatable time stamp (not shown in the drawing) in the form of four digits. The ink dispensing device 26 comprises a control unit which is arranged to control the rotatable time stamp such that it is consistent with a current time. For example, if the current time is 18:03, the control unit is configured to control the rotatable time stamp of the ink pad such that the numbers '1' '8' '0' '3' are facing downwards, i.e. when the injection device 40 is held vertically with the distal end pointing downwards.

Therefore, as a user performs an injection using the injection device 40, s/he urges a distal end of the injection device 40, specifically a distal end of the needle sleeve 13, against the injection site. Due to the alignment of the ink pad sleeve 27 and the needle sleeve 13, the ink pad is also urged against an area near the injection site. This causes a printing operation whereby ink is transferred from the ink pad onto the area near the injection site. Since the rotatable time stamp of the ink pad is controlled by the control unit such that respective digits indicative of a current time are facing downwards, the printed ink on the area can serve as a visual indication of the injection time. The ink used in this embodiment is water-resistant ink, so that the specific pattern printed onto the surface can be retained for a longer period of time.

Figures 4A, 4B, and 4C show an injection device according to a third embodiment respectively in an initial state, an intermediate state, and a final state.

As shown in Figures 4A to 4C, an injection device 50 of the third embodiment comprises a housing 11, a window 19, a needle sleeve 13, a button 22, and an ink dispensing device 28. The ink dispensing device 28 comprises an ink pad sleeve 29. The ink pad sleeve 29 is arranged to cover an ink pad (not shown in Figure 4) and also arranged to be movable relative to the rest of the ink dispensing device 28 so as to expose the ink pad.

The window 19 is formed on the housing 11 through which a user can observe the amount of medicament contained within the housing 11, and specifically the amount of medicament contained within a syringe (not shown in Figure 4) that is included in the housing 11. Therefore, before an injection the user is able to determine whether the medicament contained in the housing 11 is accurate, and after an injection the user is able to determine whether all medicament has been injected.

The ink dispensing device 28 in the present embodiment is removably attached to the housing 11 of the injection device 50, and is configured in a manner such that when the ink dispensing device 28 is attached to the housing 11, the ink pad sleeve 29 and an opening of the injection device 50 are aligned. Specifically, in this embodiment, when the ink dispensing device 28 is attached to the housing 11, the ink pad sleeve 29 is aligned with the needle sleeve 13 of the injection device 50.

As shown in Figures 4A, 4B, and 4C, the ink dispensing device 28 comprises a ring 31. The ring 31 of the ink dispensing device 28 is arranged such that it can be engaged with the distal end of the housing 11 by being fit around the needle sleeve 13. Specifically, the ring 31 has an aperture through which the needle sleeve 13 of the injection device 50 can be fitted as shown in Figures 4B and 4C. When the ink dispensing device 28 is fully attached to the housing 11 of the injection device 50, the ring 31 surrounds a distal opening of the housing 11 as illustrated in Figure 4C.

The ink dispensing device 28 further comprises a first arm and a second arm, wherein a hole 32 arranged at the first arm. The hole 32 is configured to be coupled with a protrusion 33 arranged on an outer surface of the housing 11, so as to provide an anti-roll functionality. In other words, by coupling the hole 32 of the ink dispensing device 28 with the protrusion 33 at the housing 11 of the injection device 50, when the ink dispensing device 28 is attached to the housing 11 it would be temporarily fixed with the housing 11 such that it does not roll around the housing 11. This eliminates problems such as the unsteady dispensing of ink from the ink dispensing device 28.

In the initial state as shown in Figure 4A, the ink dispensing device 28 is not attached to the housing 11 of the injection device 50. In order to attach the ink dispensing device 28, a user may hold the housing 11 of the injection device 50 and insert the distal end of the housing 11 through the ring 31 of the ink dispensing device 29. This action is indicated by an arrow in Figure 4A.

After the needle sleeve 13 is fit through the ring 31, the ink dispensing device 28 is urged against the housing 11 of the injection device 50, as indicated by the arrow in Figure 4B. As the first arm and the second arm of the ink dispensing device 28 become coupled with the outer surface of the housing 11, the hole 32 at the first arm is coupled with the protrusion 33 at the housing 11 such that the ink dispensing device 28 is locked in place relative to the housing 11.

Once the ink dispensing device 28 is attached to the housing 11 of the injection device 50, the user can perform an injection using the injection device 50 by urging a distal end of the injection device 50, specifically a distal end of the needle sleeve 13, against the injection site. Due to the alignment of the ink pad sleeve 29 and the needle sleeve 13, the ink pad would also be urged against an area near the injection site. This causes

a printing operation whereby ink is transferred from the ink pad onto the area near the injection site. Since the rotatable time stamp of the ink pad is controlled by the control unit such that respective digits indicative of a current time are facing downwards, the printed ink on the area can serve as a visual indication of the injection time. The ink used in this embodiment is water-resistant ink, so that the specific pattern printed onto the surface can be retained for a longer period of time.

Figure 5A shows the ink dispensing device of the injection device in a first state according to the third embodiment, and Figure 5B shows the ink dispensing device of the injection device in a second state.

As described with respect to Figures 4A to 4C, the ink dispensing device 28 of the third embodiment comprises an ink pad sleeve 29. The ink pad sleeve 29 is retractable such that when it is urged against a surface, it retracts into a casing of the ink dispensing device 28 to expose an ink pad. This is illustrated in Figure 5B which shows the ink pad sleeve 29 being retracted into the casing, as compared to Figure 5A. The features of the ink pad of the ink dispensing device 28 will be explained in further detail with respect to Figures 5C and 5D.

Figure 5C shows a schematic view of the ink dispensing device of the injection device according to the third embodiment. Figure 5D shows a plan view of the ink dispensing device of the injection device according to the third embodiment. Specifically, Figure 5D shows the bottom plan view of the ink dispensing device 28.

As shown in Figure 5C, a printing mechanism 34 is arranged within the ink dispensing device. The printing mechanism 34 comprises a wheel 35 on which a plurality of ink pads 36 are arranged. Each of the plurality of ink pads 36 face away from a centre of the wheel 35, and each of the plurality of ink pads 36 has a specific ink pattern. An example of a specific ink pattern is illustrated in Figure 5D, which shows a bottom view of the ink dispensing device 28 with an ink pattern on an ink pad 36 currently facing downwards.

The printing mechanism 34 is configured such that as the user presses the ink dispensing device 28 against a surface, ink is transferred from an ink pad 36 which is currently facing downwards. Moreover, the retracting action of the ink pad sleeve 29

into the casing of the ink dispensing device 28 (as shown in Figures 5A and 5B) causes the wheel 35 to rotate so as to allow a subsequent ink pad on the wheel to be exposed. Specifically, when the ink pad sleeve 29 is urged into the casing of the ink dispensing device 28, the wheel 35 rotates such that an adjacent ink pad 36 faces downwards, ready for a subsequent printing operation. The direction of rotation is indicated by the arrow in Figure 5C.

In alternative embodiments, the ink dispensing device of the second embodiment may be removably coupled to an injection device, instead of being fixedly attached to an injection device.

In alternative embodiments, the ink dispensing device may contain other ink dispensing elements instead of an ink pad. For example, an ink spraying element may be used in the ink dispensing device.

In alternative embodiments, a rotatable date stamp may be used instead of a rotatable time stamp.

In alternative embodiments, manually operated time and/or date stamps may be used in the ink dispensing device instead of automatic time and/or date stamp(s) as described in the second embodiment. In these alternative embodiments, the ink dispensing device may comprise one or more rotatable dials for rotating the manually operated time and/or date stamps to select a current time and/or date to be printed onto a surface.

In alternative embodiments, the ink dispensing device may be configured to print other types of injection-related information. For example, in some other embodiments, the ink dispensing device may be configured to print at least one of: a weekday on which injection is performed, an area of body on which injection is performed, and a name of the medicament onto a surface.

In alternative embodiments, the ink dispensed by the ink dispensing device may not be water-resistant ink. Other types of ink may be used according to the requirements of the user.

Although claims have been formulated in this application to particular combinations of features, it should be understood that the scope of the disclosure also includes any novel features or any novel combinations of features disclosed herein either explicitly or implicitly or any generalisation thereof, whether or not it relates to the same invention as presently claimed in any claim and whether or not it mitigates any or all of the same technical problems as does the present invention. The applicant hereby gives notice that new claims may be formulated to such features and/or combinations of features during the prosecution of the present application or of any further application derived therefrom.

Those skilled in the art will understand that modifications (additions and/or removals) of various components of the substances, formulations, apparatuses, methods, systems and embodiments described herein may be made without departing from the full scope and spirit of the present invention, which encompass such modifications and any and all equivalents thereof.

The terms “drug” or “medicament” are used synonymously herein and describe a pharmaceutical formulation containing one or more active pharmaceutical ingredients or pharmaceutically acceptable salts or solvates thereof, and optionally a pharmaceutically acceptable carrier. An active pharmaceutical ingredient (“API”), in the broadest terms, is a chemical structure that has a biological effect on humans or animals. In pharmacology, a drug or medicament is used in the treatment, cure, prevention, or diagnosis of disease or used to otherwise enhance physical or mental well-being. A drug or medicament may be used for a limited duration, or on a regular basis for chronic disorders.

As described below, a drug or medicament can include at least one API, or combinations thereof, in various types of formulations, for the treatment of one or more diseases. Examples of API may include small molecules having a molecular weight of 500 Da or less; polypeptides, peptides and proteins (e.g., hormones, growth factors, antibodies, antibody fragments, and enzymes); carbohydrates and polysaccharides; and nucleic acids, double or single stranded DNA (including naked and cDNA), RNA, antisense nucleic acids such as antisense DNA and RNA, small interfering RNA (siRNA), ribozymes, genes, and oligonucleotides. Nucleic acids may be incorporated

into molecular delivery systems such as vectors, plasmids, or liposomes. Mixtures of one or more drugs are also contemplated.

The term "drug delivery device" shall encompass any type of device or system configured to dispense a drug or medicament into a human or animal body. Without limitation, a drug delivery device may be an injection device (e.g., syringe, pen injector, auto injector, large-volume device, pump, perfusion system, or other device configured for intraocular, subcutaneous, intramuscular, or intravascular delivery), skin patch (e.g., osmotic, chemical, micro-needle), inhaler (e.g., nasal or pulmonary), an implantable device (e.g., drug- or API-coated stent, capsule), or a feeding system for the gastrointestinal tract. The presently described drugs may be particularly useful with injection devices that include a needle, e.g., a hypodermic needle for example having a Gauge number of 24 or higher.

The drug or medicament may be contained in a primary package or "drug container" adapted for use with a drug delivery device. The drug container may be, e.g., a cartridge, syringe, reservoir, or other solid or flexible vessel configured to provide a suitable chamber for storage (e.g., short- or long-term storage) of one or more drugs. For example, in some instances, the chamber may be designed to store a drug for at least one day (e.g., 1 to at least 30 days). In some instances, the chamber may be designed to store a drug for about 1 month to about 2 years. Storage may occur at room temperature (e.g., about 20°C), or refrigerated temperatures (e.g., from about -4°C to about 4°C). In some instances, the drug container may be or may include a dual-chamber cartridge configured to store two or more components of the pharmaceutical formulation to-be-administered (e.g., an API and a diluent, or two different drugs) separately, one in each chamber. In such instances, the two chambers of the dual-chamber cartridge may be configured to allow mixing between the two or more components prior to and/or during dispensing into the human or animal body. For example, the two chambers may be configured such that they are in fluid communication with each other (e.g., by way of a conduit between the two chambers) and allow mixing of the two components when desired by a user prior to dispensing. Alternatively or in addition, the two chambers may be configured to allow mixing as the components are being dispensed into the human or animal body.

The drugs or medicaments contained in the drug delivery devices as described herein can be used for the treatment and/or prophylaxis of many different types of medical disorders. Examples of disorders include, e.g., diabetes mellitus or complications associated with diabetes mellitus such as diabetic retinopathy, thromboembolism disorders such as deep vein or pulmonary thromboembolism. Further examples of disorders are acute coronary syndrome (ACS), angina, myocardial infarction, cancer, macular degeneration, inflammation, hay fever, atherosclerosis and/or rheumatoid arthritis. Examples of APIs and drugs are those as described in handbooks such as Rote Liste 2014, for example, without limitation, main groups 12 (anti-diabetic drugs) or 86 (oncology drugs), and Merck Index, 15th edition.

Examples of APIs for the treatment and/or prophylaxis of type 1 or type 2 diabetes mellitus or complications associated with type 1 or type 2 diabetes mellitus include an insulin, e.g., human insulin, or a human insulin analogue or derivative, a glucagon-like peptide (GLP-1), GLP-1 analogues or GLP-1 receptor agonists, or an analogue or derivative thereof, a dipeptidyl peptidase-4 (DPP4) inhibitor, or a pharmaceutically acceptable salt or solvate thereof, or any mixture thereof. As used herein, the terms "analogue" and "derivative" refer to any substance which is sufficiently structurally similar to the original substance so as to have substantially similar functionality or activity (e.g., therapeutic effectiveness). In particular, the term "analogue" refers to a polypeptide which has a molecular structure which formally can be derived from the structure of a naturally occurring peptide, for example that of human insulin, by deleting and/or exchanging at least one amino acid residue occurring in the naturally occurring peptide and/or by adding at least one amino acid residue. The added and/or exchanged amino acid residue can either be codable amino acid residues or other naturally occurring residues or purely synthetic amino acid residues. Insulin analogues are also referred to as "insulin receptor ligands". In particular, the term "derivative" refers to a polypeptide which has a molecular structure which formally can be derived from the structure of a naturally occurring peptide, for example that of human insulin, in which one or more organic substituent (e.g. a fatty acid) is bound to one or more of the amino acids. Optionally, one or more amino acids occurring in the naturally occurring peptide may have been deleted and/or replaced by other amino acids, including non-codeable amino acids, or amino acids, including non-codeable, have been added to the naturally occurring peptide.

Examples of insulin analogues are Gly(A21), Arg(B31), Arg(B32) human insulin (insulin glargine); Lys(B3), Glu(B29) human insulin (insulin glulisine); Lys(B28), Pro(B29) human insulin (insulin lispro); Asp(B28) human insulin (insulin aspart); human insulin, wherein proline in position B28 is replaced by Asp, Lys, Leu, Val or Ala and wherein in position B29 Lys may be replaced by Pro; Ala(B26) human insulin; Des(B28-B30) human insulin; Des(B27) human insulin and Des(B30) human insulin.

Examples of insulin derivatives are, for example, B29-N-myristoyl-des(B30) human insulin, Lys(B29) (N-tetradecanoyl)-des(B30) human insulin (insulin detemir, Levemir®); B29-N-palmitoyl-des(B30) human insulin; B29-N-myristoyl human insulin; B29-N-palmitoyl human insulin; B28-N-myristoyl LysB28ProB29 human insulin; B28-N-palmitoyl-LysB28ProB29 human insulin; B30-N-myristoyl-ThrB29LysB30 human insulin; B30-N-palmitoyl-ThrB29LysB30 human insulin; B29-N-(N-palmitoyl-gamma-glutamyl)-des(B30) human insulin, B29-N-omega-carboxypentadecanoyl-gamma-L-glutamyl-des(B30) human insulin (insulin degludec, Tresiba®); B29-N-(N-lithocholyl-gamma-glutamyl)-des(B30) human insulin; B29-N-(omega-carboxyheptadecanoyl)-des(B30) human insulin and B29-N-(omega-carboxyheptadecanoyl) human insulin.

Examples of GLP-1, GLP-1 analogues and GLP-1 receptor agonists are, for example, Lixisenatide (Lyxumia®, Exenatide (Exendin-4, Byetta®, Bydureon®, a 39 amino acid peptide which is produced by the salivary glands of the Gila monster), Liraglutide (Victoza®), Semaglutide, Taspoglutide, Albiglutide (Syncria®), Dulaglutide (Trulicity®), rExendin-4, CJC-1134-PC, PB-1023, TTP-054, Langlenatide / HM-11260C, CM-3, GLP-1 Eligen, ORMD-0901, NN-9924, NN-9926, NN-9927, Nodexen, Viador-GLP-1, CVX-096, ZYOG-1, ZYD-1, GSK-2374697, DA-3091, MAR-701, MAR709, ZP-2929, ZP-3022, TT-401, BHM-034, MOD-6030, CAM-2036, DA-15864, ARI-2651, ARI-2255, Exenatide-XTEN and Glucagon-Xten.

An example of an oligonucleotide is, for example: mipomersen sodium (Kynamro®), a cholesterol-reducing antisense therapeutic for the treatment of familial hypercholesterolemia.

Examples of DPP4 inhibitors are Vildagliptin, Sitagliptin, Denagliptin, Saxagliptin, Berberine.

Examples of hormones include hypophysis hormones or hypothalamus hormones or regulatory active peptides and their antagonists, such as Gonadotropine (Follitropin, Lutropin, Choriongonadotropin, Menotropin), Somatropine (Somatropin), Desmopressin, Terlipressin, Gonadorelin, Triptorelin, Leuprorelin, Buserelin, Nafarelin, and Goserelin.

Examples of polysaccharides include a glucosaminoglycane, a hyaluronic acid, a heparin, a low molecular weight heparin or an ultra-low molecular weight heparin or a derivative thereof, or a sulphated polysaccharide, e.g. a poly-sulphated form of the above-mentioned polysaccharides, and/or a pharmaceutically acceptable salt thereof. An example of a pharmaceutically acceptable salt of a poly-sulphated low molecular weight heparin is enoxaparin sodium. An example of a hyaluronic acid derivative is Hylan G-F 20 (Synvisc®), a sodium hyaluronate.

The term “antibody”, as used herein, refers to an immunoglobulin molecule or an antigen-binding portion thereof. Examples of antigen-binding portions of immunoglobulin molecules include F(ab) and F(ab')₂ fragments, which retain the ability to bind antigens. The antibody can be polyclonal, monoclonal, recombinant, chimeric, de-immunized or humanized, fully human, non-human, (e.g., murine), or single chain antibody. In some embodiments, the antibody has effector function and can fix a complement. In some embodiments, the antibody has reduced or no ability to bind an Fc receptor. For example, the antibody can be an isotype or subtype, an antibody fragment or mutant, which does not support binding to an Fc receptor, e.g., it has a mutagenized or deleted Fc receptor binding region. The term antibody also includes an antigen-binding molecule based on tetravalent bispecific tandem immunoglobulins (TBTI) and/or a dual variable region antibody-like binding protein having cross-over binding region orientation (CODV).

The terms “fragment” or “antibody fragment” refer to a polypeptide derived from an antibody polypeptide molecule (e.g., an antibody heavy and/or light chain polypeptide) that does not comprise a full-length antibody polypeptide, but that still comprises at least a portion of a full-length antibody polypeptide that is capable of binding to an antigen. Antibody fragments can comprise a cleaved portion of a full length antibody polypeptide, although the term is not limited to such cleaved fragments. Antibody fragments that are useful in the present invention include, for example, Fab fragments,

F(ab')₂ fragments, scFv (single-chain Fv) fragments, linear antibodies, monospecific or multispecific antibody fragments such as bispecific, trispecific, tetraspecific and multispecific antibodies (e.g., diabodies, triabodies, tetrabodies), monovalent or multivalent antibody fragments such as bivalent, trivalent, tetravalent and multivalent antibodies, minibodies, chelating recombinant antibodies, tribodies or bibodies, intrabodies, nanobodies, small modular immunopharmaceuticals (SMIP), binding-domain immunoglobulin fusion proteins, camelized antibodies, and VHH containing antibodies. Additional examples of antigen-binding antibody fragments are known in the art.

The terms “Complementarity-determining region” or “CDR” refer to short polypeptide sequences within the variable region of both heavy and light chain polypeptides that are primarily responsible for mediating specific antigen recognition. The term “framework region” refers to amino acid sequences within the variable region of both heavy and light chain polypeptides that are not CDR sequences, and are primarily responsible for maintaining correct positioning of the CDR sequences to permit antigen binding. Although the framework regions themselves typically do not directly participate in antigen binding, as is known in the art, certain residues within the framework regions of certain antibodies can directly participate in antigen binding or can affect the ability of one or more amino acids in CDRs to interact with antigen.

Examples of antibodies are anti PCSK-9 mAb (e.g., Alirocumab), anti IL-6 mAb (e.g., Sarilumab), and anti IL-4 mAb (e.g., Dupilumab).

Pharmaceutically acceptable salts of any API described herein are also contemplated for use in a drug or medicament in a drug delivery device. Pharmaceutically acceptable salts are for example acid addition salts and basic salts.

Those of skill in the art will understand that modifications (additions and/or removals) of various components of the APIs, formulations, apparatuses, methods, systems and embodiments described herein may be made without departing from the full scope and spirit of the present invention, which encompass such modifications and any and all equivalents thereof.

Claims

1. An injection device comprising:
a housing arranged to contain a medicament cartridge; and
an ink dispensing device comprising an ink pad, wherein the ink pad is arranged to print injection-related information on a surface of an injection site when the ink dispensing device is pressed against the surface,
wherein the ink dispensing device comprises a casing, an ink pad sleeve that is configured to be urged into the casing of the ink dispensing device, and a printing mechanism, the printing mechanism comprising a wheel on which a plurality of ink pads are arranged, and wherein when the ink pad sleeve is urged into the casing of the ink dispensing device, the wheel is caused to rotate so as to allow a subsequent ink pad on the wheel to be exposed.
2. The injection device of claim 1, wherein the ink pad is arranged at a distal end of the housing of the injection device.
3. The injection device of any of the preceding claims, wherein the ink dispensing device is laterally coupled to the injection device such that it is aligned with a needle sleeve of the injection device.
4. The injection device of any of the preceding claims, wherein the ink dispensing device comprises an actuator for urging the ink dispensing device against the surface.
5. The injection device of any of the preceding claims, wherein the injection-related information comprises at least one of: a specific pattern, a time at which injection is performed, date on which injection is performed, weekday on which injection is performed, and area of body on which injection is performed.
6. The injection device of any of the preceding claims, wherein ink dispensed by the ink dispensing device is water resistant ink.

7. The injection device of any of the preceding claims, wherein the ink dispensing device is arranged at a distal end of a housing of the injection device.
8. The injection device of any of the preceding claims, wherein the ink dispensing device is fixedly attached to the injection device.
9. The injection device of claims 1 to 7, wherein the ink dispensing device is removably coupled to the injection device.
10. The injection device of any of the preceding claims, wherein the ink dispensing device comprises an automatic date and/or time stamp.
11. The injection device of any of claims 1 to 9, wherein the ink dispensing device comprises a manually operated date and/or time stamp.
12. The injection device of any of the preceding claims, wherein the injection device contains a medicament.
13. A method of dispensing ink from an injection device, the injection device comprising an ink dispensing device which comprises an ink pad, an ink pad sleeve that is configured to be urged into the casing of the ink dispensing device, a casing, and a printing mechanism, the printing mechanism comprising a wheel on which a plurality of ink pads are arranged, the method comprising:
 - use of the ink pad for printing injection-related information on a surface of an injection site when the ink dispensing device is pressed against the surface, and
 - urging of the ink pad sleeve into the casing of the ink dispensing device when the ink dispensing device is pressed against the surface, causing the rotation of the wheel so as to allow a subsequent ink pad on the wheel to be exposed.

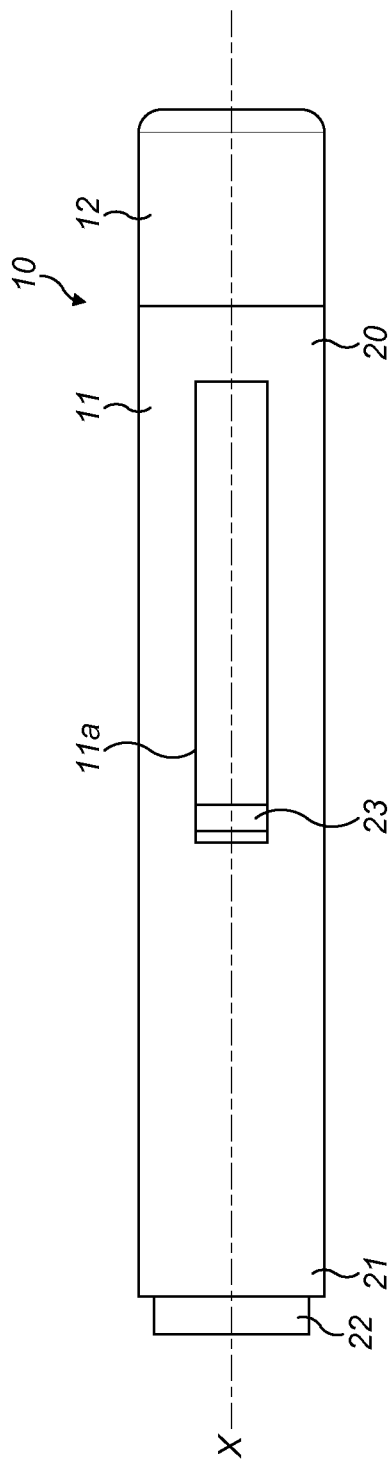


FIG. 1a

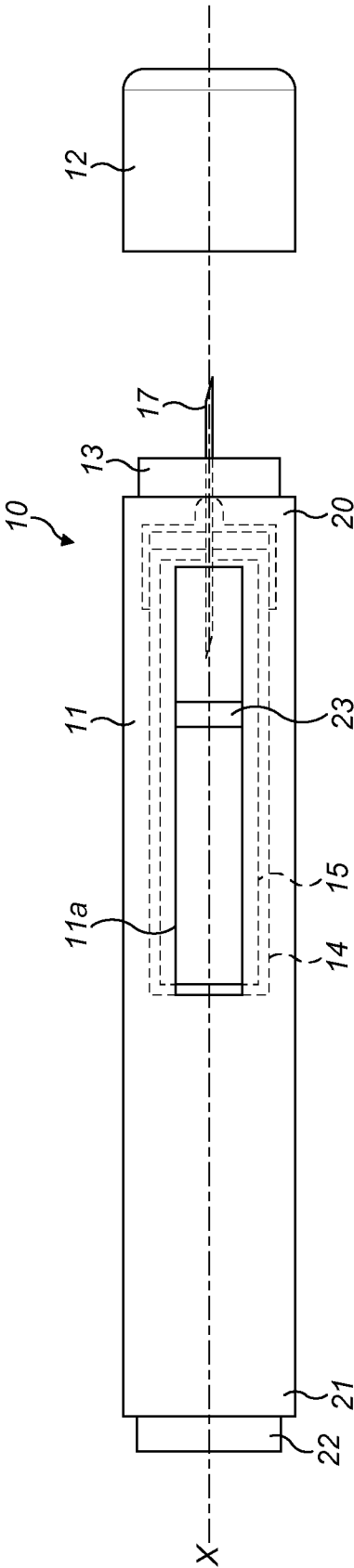


FIG. 1b

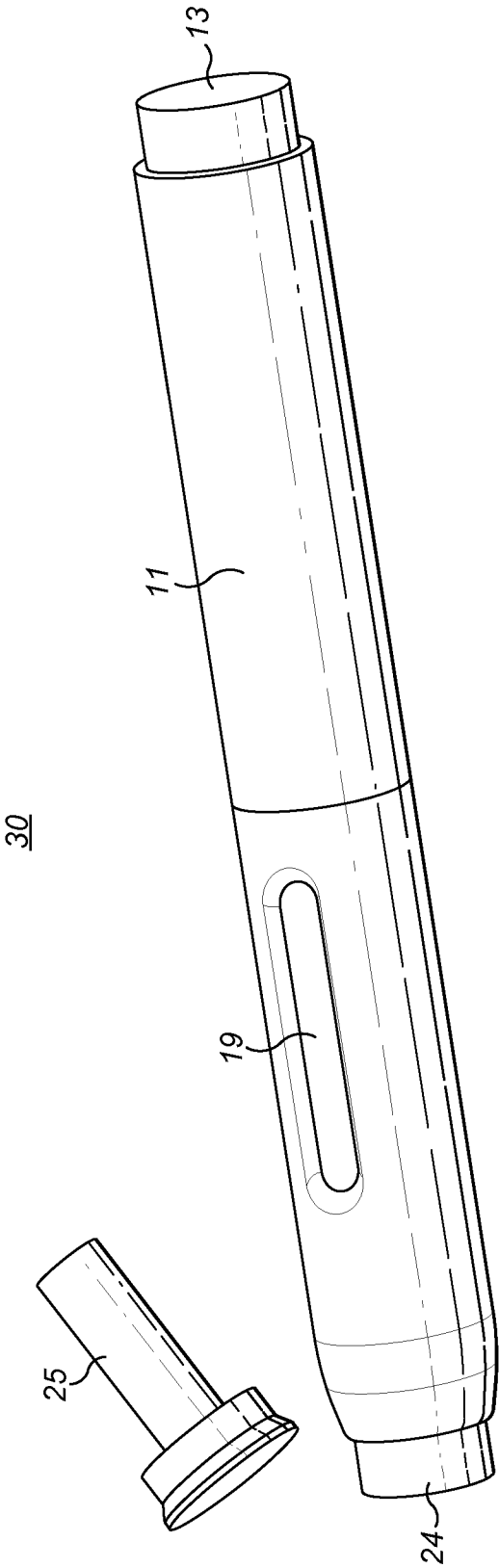


FIG. 2

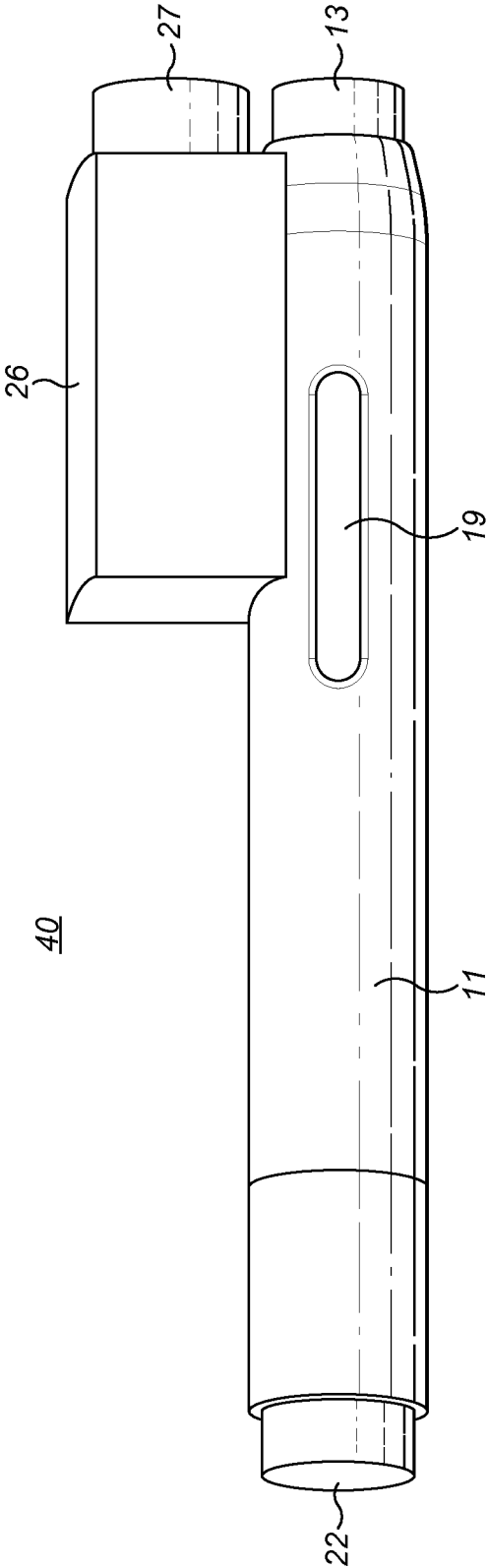
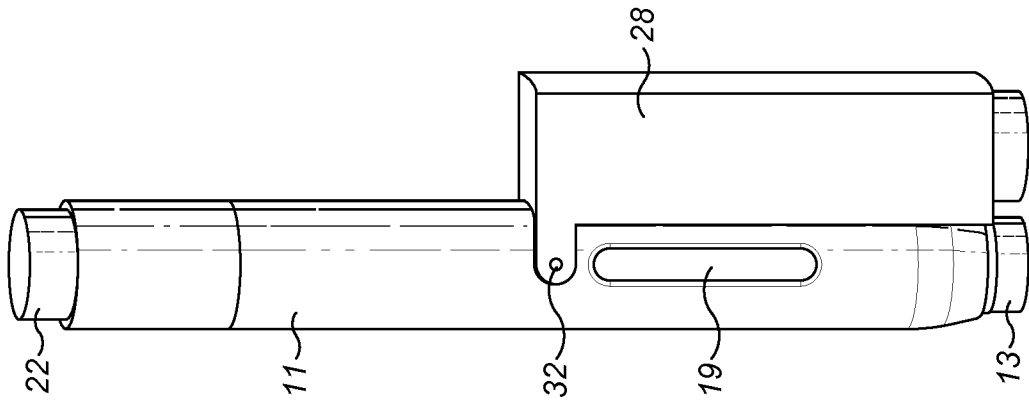
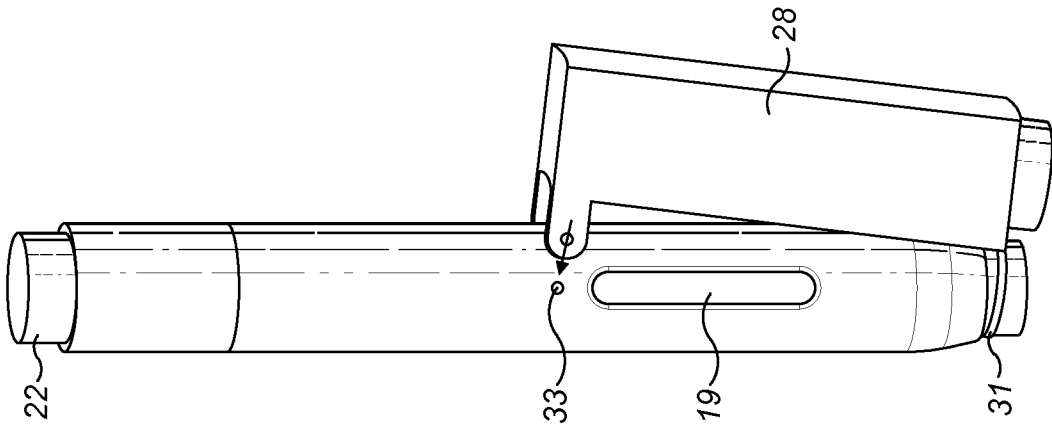
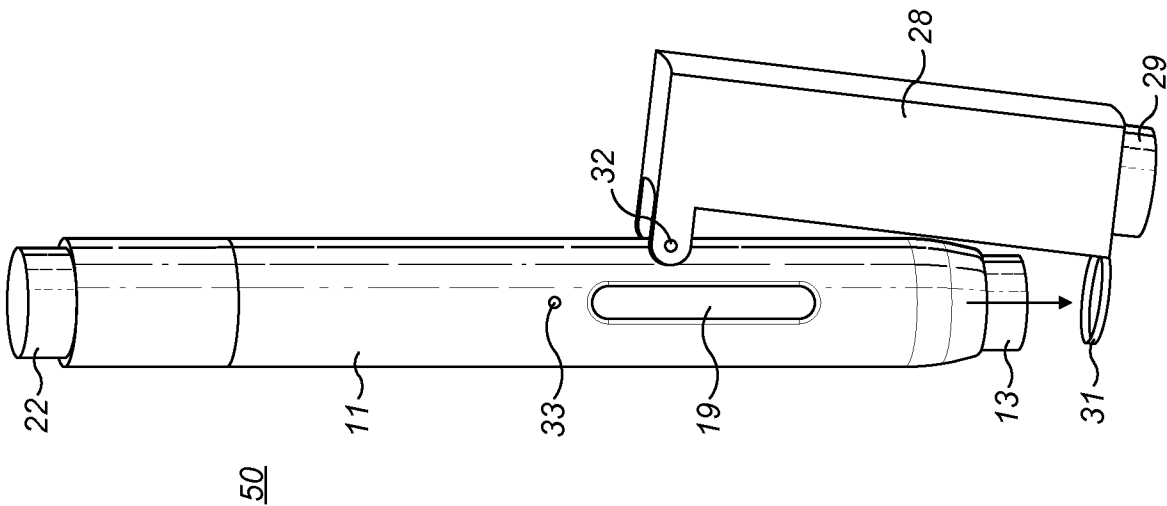


FIG. 3



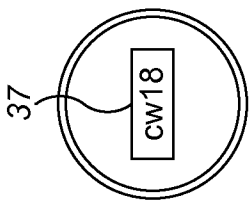
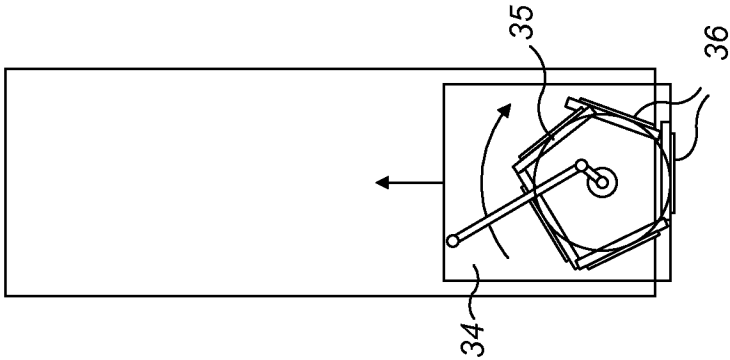
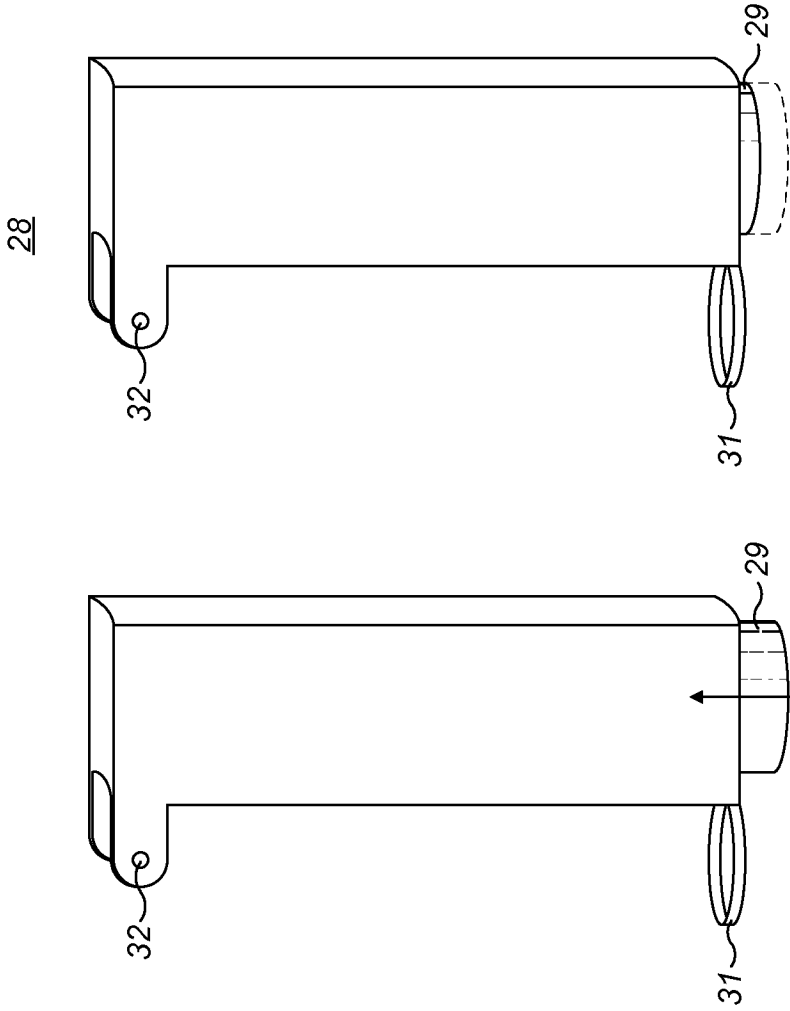


FIG. 5A

FIG. 5B

FIG. 5C

FIG. 5D

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/067506

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/42
ADD.

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 A61B B41K

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.
Y	US 2014/188074 A1 (JACQUES RACHAEL [US] ET AL) 3 July 2014 (2014-07-03) paragraphs [0014], [0045] - [0047], [0065], [0087]; figures 3-23 -----	1-13
Y	US 2012/283637 A1 (COHEN CYNTHIA E [US]) 8 November 2012 (2012-11-08) paragraphs [0021] - [0024]; figures 1-7 -----	1-13
A	US 3 580 779 A (SCHRIEVER FRED G ET AL) 25 May 1971 (1971-05-25) figure 1 -----	1-13
A	US 2006/079910 A1 (TARTAGLIA ARTHUR A [US]) 13 April 2006 (2006-04-13) paragraphs [0008], [0009]; figures 1-6 ----- -/-	1-13



Further documents are listed in the continuation of Box C.



See patent family annex.

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"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

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"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

24 August 2017

Date of mailing of the international search report

06/09/2017

Name and mailing address of the ISA/

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Authorized officer

Knychalla, Verena

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/067506

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	US 4 031 889 A (PIKE WILLIAM FLOYD) 28 June 1977 (1977-06-28) column 4, line 53 - column 5, line 2; figures 1-12 -----	1-13
Y	GB 2 007 597 A (OLAVE SOLOZABAL Y CIA SA) 23 May 1979 (1979-05-23) column 1, line 16 - line 35; figures 1-5 column 2, line 104 - column 3, line 8 -----	1-13

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2017/067506

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