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(54) **Title**: AUTOMATIC INJECTION DEVICE

(57) **Abstract**: An injection device se curable to the body of a user for the automatic administration of a substance, including a housing, a reservoir for the substance, a piston slide able relative to the reservoir to expel substance from the reservoir, a holder to accommodate the reservoir, the holder lovably coupled to the housing, a annular extending from the injection device, a drive mechanism to force substance from the reservoir into the annular to administer the substance, a triggering mechanism including a release element and a control device coupled to the triggering mechanism and the drive mechanism, wherein the control device is movable relative to the housing, wherein by activating the triggering mechanism by moving the release element, the control device is moved from a first position to a second position thereby releasing the drive mechanism, wherein upon completion of administering the substance the control device is moved from the second to a third position and an acoustic signal is produced upon reaching the third position, and wherein the movements of the control device are opposite the direction of the movement of the piston during administration.

AUTOMATIC INJECTION DEVICE

Background

This application relates to device for delivering, injecting, infusing, administering or dispensing a substance, and to methods of making and using such devices. More particularly, it relates to devices for administering a therapeutic substance to a patient at a selected rate for a selected time. It also relates to automatic devices, e.g. a stick-on automatic injection device or automatic injector, which may also be thought of, referred to and/or regarded as an infusion device or infusion pump, as well as to individual separate components of such devices.

Some automatic injectors, e.g. "patch injectors," typically have an adhesive or stick-on region with which they can be attached to a surface, a patients skin, for example, through which a substance can be dispensed by the injection device in as controlled a manner as possible for a period of time. Such devices can be used to administer a liquid or a fluid, a medicament such as insulin or a substance for treating lupus erythematosus, or hormones or foods or food supplements, to a patient's body or circulation system. In principle, substances can be administered in various ways by such injectors, for example subcutaneously, through the arteries, intravenously or by spinal, epidural or peridural methods.

WO 89/12473 A1 discloses an automatic injection device of the patch injector type, whereby the processes of piercing by the injection needle and dispensing of the medicament are operated by the same compression spring. The patient adheres the device to the skin and triggers the injection by depressing the trigger button. As a result, the injection needle pierces the patient's tissue in a first step and the medicament is administered in a second step. The injection needle remains in the patient's tissue for the entire duration of the injection which can be painful as soon as the patient moves, e.g. in the case of longer lasting injections, especially when using to viscous medicaments. Since the device is pre-filled, very high demands are made of the material and processing and there is no mention of using standard containers fitted immediately before the injection.

US 7250037 B2 discloses an automatic injection device of the patch injector type in which dispensing of the medicament is forced by a Belville spring. The device has a collapsible reservoir, which can be filled at the factory or by the patient immediately prior to the injection. On the side which is adhered to the patient's skin, the device has a guard plate with a handle. The plate prevents premature triggering of the injection device. The guard plate contains an element which prevents the Belville spring from applying pressure to the reservoir prematurely, an element which blocks or locks the trigger button and a needle guard cap. The patient removes the guard plate together with the described elements immediately before sticking the device onto the skin. The spring then pushes on the reservoir and the trigger button is released, which means that there is a risk of the device being inadvertently triggered before the patient has finished sticking the device onto the skin. During triggering, the trigger button firstly pushes the septum needle through the septum of the reservoir to establish a fluid connection between the reservoir and injection needle. Continued pushing causes the insertion spring of the injection needle to be released, as a result of which the injection needle pierces the patient's tissue. The injection needle described in US 7250037 B2 is a steel needle which remains in the tissue during the entire injection duration. This can be painful for the patient when moving, e.g. in the case of longer lasting injections or substance deliveries. The design of the device does not make provision for the use of standard medicament containers.

Summary

It is an object of the present invention to provide an automatic injection device which is convenient and reliable to operate, which enables viscous medicaments to be administered to the patient ergonomically, and which also enables the use of standard medicament containers of different sizes. At the same time, it should be easy to sterilize the device.

In one embodiment, the present invention comprises an injection device securable to the body of a user for the automatic administration of a substance, comprising a housing, a reservoir for the substance, a piston slideable relative to the reservoir to expel

substance from the reservoir, a holder to accommodate the reservoir, the holder movably coupled to the housing, a cannula extending from the injection device, a drive mechanism to force substance from the reservoir into the cannula to administer the substance, a triggering mechanism comprising a release element and a control device coupled to the triggering mechanism and the drive mechanism, wherein the control device is movable relative to the housing, wherein by activating the triggering mechanism by moving the release element, the control device is moved from a first position to a second position thereby releasing the drive mechanism, wherein upon completion of administering the substance the control device is moved from the second to a third position and an acoustic signal is produced upon reaching the third position, and wherein the movements of the control device are opposite the direction of the movement of the piston during administration.

In some embodiments, an injection or infusion device in accordance with the present invention is able to administer a fluid or active substance contained in a standard carpoule (which also may be thought of and/or referred to as an ampoule, container, reservoir or vial) uniformly or with a pre-definable dispensing profile over a selected period of time. For example, a quantity of substance, e.g. within the range of 1 ml to 10 ml, can be dispensed within a few minutes as a single dose, and/or a different or similar quantity can be delivered over a longer period, e.g. a period of hours, as several doses.

As a functional unit, an injection device in accordance with the present invention may be packaged in a sterile manner together with an injection needle or cannula, for example. A carpoule fitted before use may also be provided in a separate sterile package. Optionally, the carpoule may also be already fitted in the injection device.

Brief Description of the Drawings

Figure 1is a perspective view of an embodiment of an injection device in accordance with the present invention;

Figure 2is a perspective view of the injection device illustrated in Figure 1, without the housing;

Figure 3is an exploded diagram of the injection device;

Figure 4shows the injection device prior to inserting a carpoule;

Figure 5is a plan view of the injection device in an initial state;

Figure 5A is a view in cross-section along line A-A indicated in Figure 5;

Figure 5Bis a view in cross-section along line B-B indicated in Figure 5;

Figure 6is a plan view of the injection device illustrated in Figure 5 with the carpoule inserted;

Figure 7is a plan view of the injection device illustrated in Figure 6 with an embodiment of a carpoule holder folded in;

Figure 7A is a perspective view of a detail showing an embodiment of a blocking slide in a locked position;

Figure 8 is a perspective view of the injection device with the blocking slide in a released position;

Figure 9A is a plan view of the injection device in a triggered or actuated state;

Figure 9B is a view of the injection device in cross-section along line B-B indicated in Figure 9A;

Figure 10A is a plan view of the injection device after dispensing, with a control sleeve in a distal position;

Figure 10B is a plan view of the injection device after dispensing, with the control sleeve in a proximal abutment position;

Figure 11A is a plan view of an embodiment of an injection device in accordance with the present invention, including an embodiment of a telescope-flange element in an initial state;

Figure 11B is a plan view of an embodiment of an injection device in accordance with the present invention, including an embodiment of a carpoule holder folded in;

Figure 11C is a detailed view of the telescope-flange element;

Figure 11D is a view of the injection device in cross-section along line D-D indicated in Figure 11B;

Figure 12 illustrates an embodiment of a carpoule insertion mechanism;

Figures 13A-13B illustrate an embodiment of a carpoule insertion mechanism;

Figures 14A-14C illustrate an embodiment of a carpoule insertion mechanism;

Figures 15A-15B illustrate an embodiment of a carpoule insertion mechanism;

Figures 16A-16B illustrate an embodiment of a carpoule insertion mechanism;

Figures 17A-17B illustrate an embodiment of a carpoule insertion mechanism;

Figures 18A-18D illustrate an embodiment of a carpoule insertion mechanism;

Figures 19A-19D illustrate an embodiment of a release button lock;

Figures 19E-19K illustrate an embodiment with a trigger lock;

Figures 20A-20B illustrate an embodiment of an injection spring retaining and releasing mechanism;

Figures 21A-21B illustrate an embodiment of an injection spring retaining and releasing mechanism;

Figures 22A-22B illustrate a release slide;

Figures 23A-23B illustrate a release rotating knob;

Figures 24A-24B illustrate an embodiment of an injection device in accordance with the present invention, with tactile user feedback;

Figures 25A-25C illustrate an embodiment of an injection device with a decelerated idle stroke movement; and

Figures 26A-26C illustrate an embodiment of an injection device with a decelerated idle stroke movement.

Detailed Description

With regard to fastening, mounting, attaching or connecting components, unless specifically described as otherwise, conventional mechanical fasteners and methods may be used. Other appropriate fastening or attachment methods include adhesives, welding and soldering, including with regard to an electrical system, if any. In embodiments with electrical features or components, suitable electrical components and circuitry, wires, wireless components, chips, boards, microprocessors, inputs, outputs, displays, control

components, etc. may be used. Generally, unless otherwise indicated, the materials for making embodiments and/or components thereof may be selected from appropriate materials such as metal, metallic alloys, ceramics, plastics, etc. Unless otherwise indicated specifically or by context, positional terms (e.g., up, down, front, rear, distal, proximal, etc.) are descriptive not limiting. Same reference numbers are used to denote same parts or components.

The expressions axial, longitudinal direction and/or length as used herein should be understood as meaning the direction in which an injection device has its longest extension, which is generally the same as or parallel with the axial length of the carpoule 18 in the state when the injection device is folded in as illustrated in Figures 2, 7, 9A, 10 and 11B. By distal is meant the region or end of the injection device in which the dispensing orifice of the carpoule lies. By proximal is meant the region or end of the injection spring in which the injection spring is disposed. Transverse direction is defined as being the direction across and/or generally perpendicular to the axial direction and across and/or perpendicular to the vertical axis (from the base plate to the housing top face).

Figure 1 is a perspective view illustrating an embodiment of an injection device with a carpoule 18 inserted in the carpoule holder 2 and folded into the housing 1. A blocking or locking slide 3 can be pushed in the axial or longitudinal direction of the housing 1 along the slide guide 9, which is fixedly mounted on the housing 1 (distally or to the left in Figure 1) to release a release button 4 positioned underneath, as illustrated in Figure 2, for subsequent operation. In the initial position illustrated in Figure 1, the blocking slide 3 blocks operation of the release button 4.

In some embodiments, the carpoule holder 2 is made from transparent material or is transparent at least in some areas or at least at a point from which it is possible to tell whether a carpoule 18 has been inserted and/or what state the carpoule 18 is in, e.g. full, partially dispensed or fully dispensed. To display the operating status of the injection

device, a display orifice 1a is provided in the housing 1, axially offset from the carpoule holder 2, which will be described in more detail below.

Figure 2 shows the injection device illustrated in Figure 1 with the housing cover 1 removed.

Figure 3 shows an exploded view of the injection device with a base plate 5 which can be fixedly connected to the housing 1 and which bears or carries an adhesive layer on its bottom face, although this is not visible in Figure 3, which may be disposed on the full surface of the base plate 5 or on only a part of the base plate 5, and which is covered buy a tear-off film so that the adhesive layer is exposed when the tear-off film applied to the adhesive layer is pulled off and the injection device can be adhered to a surface, for example to a patient's skin. The carpoule holder 2 may be inserted at a recess or orifice 5a of the base plate 5, for example by and/or guided by a pin 2a disposed on the bottom face of the carpoule holder 2, allowing for a pivoting movement about the pin 2a. To provide a guiding action during rotation, another pin 2b is provided on the top face of the carpoule holder 2 lying opposite the bottom pin 2a, which can be inserted in an orifice 1b of the housing 1 so that when the carpoule holder 2 is in the assembled state it can be pivoted about the axis of rotation formed by the pins 2a and 2b. The carpoule holder 2 also has another pin 2c projecting downwardly from its bottom face which can be guided in a recess or guide 5b of the base plate extending in the shape of a circle arc to enable a guided rotating movement of the carpoule holder 2.

Disposed in the front or distal region of the carpoule holder 2 illustrated on the left in Figure 2 is an orifice in which the carpoule adapter 12 can be fixedly inserted in the carpoule holder 2 and connected to it. For example, the carpoule adapter 12 can be snapped into the carpoule holder 2. The carpoule adapter 12 has a carpoule seat 12a at its end facing the inserted carpoule 18 into which the front end or flanged cap 18b of the carpoule 18 can be inserted and latched. The carpoule seat 12a for inserting the carpoule 18 terminates at a continuous base 12b of the carpoule adapter 12, which carries and centers a vertically protruding connector needle 17 which points toward the carpoule 18.

The connector needle 17 is able to pierce the septum 18a of the carpoule as the carpoule 18 is being inserted, thereby establishing a fluid connection between the interior of the carpoule 18 and a connector hose element or line element 12c which is fitted on the internally hollow connector needle 17 on the end of the carpoule adapter 12 lying opposite the carpoule 18. In some preferred embodiments, the connector needle 17, carpoule adapter 12 and connector hose 12c are fixedly connected to one another, for example adhered to one another.

The contents of the carpoule 18 can be conveyed via the adapter hose 12c to the injection needle inserting device 15, which may also be referred to as an inserter.

The inserter 15 may be of a known type and fulfills the function of positioning a cannula below the surface to which the injection device is applied by piercing the surface. The cannula may be pushed on an inserter-needle, which is disposed inside the injection device together with the cannula in the initial state, which is pushed, by depressing the release button 4 from the bottom face of the injection device for example, through a cannula orifice 5c of the base plate 5. The cannula with the carrier needle may be pushed out by the force of a pre-tensioned spring, for example. Once and/or after the cannula has penetrated a patient's or user's skin, the inserter or cannula needle is pulled back again, for example by a return spring. The cannula orifice is part of a fluid connection to the connector or adapter hose 12c so that the active substance contained in the carpoule 18 is dispensed via the connector needle 17, connector hose 12c and cannula and administered to a user.

With regard to the design of the inserter 15, reference may be made to the disclosure and teaching of WO 2004/006982 A2 (English equivalent US 2004/010207), incorporated entirely herein by reference, although the inserter may also be of other suitable designs.

Fixedly connected to the carpoule holder 2 is a closure lock lever 11 which is able to pivot or turn relative to the carpoule holder 2. As may be seen from Figure 5, the

closure lock lever 11 is mounted on the end of the carpoule holder 2 facing the internal face of the carpoule holder 2 and is rotatable about the vertical axis 11b extending perpendicular to the longitudinal axis of the injection device in the plan view illustrated in Figure 5. When the injection device is in the initial position or state illustrated in Figures 4 and 5, the carpoule holder 2 is open and the carpoule holder 2, which as yet contains no carpoule 18, is prevented from being pushed in by the closure lock lever 11 locating in the support corner 5d of the base plate by its cam 11a.

A clamping element 7 is secured to the proximal or rear end in the orifice 5e of the base plate 5, illustrated on the right in Figure 3, and is retained so that it is not able to move in translation relative to the base plate 5 and housing 1 by a corresponding half-opening of the housing 1. The clamping element 7 has a cylindrically shaped guide 7d lying radially inwardly for an injection spring 13, which is pushed onto the guide element 7d. The tensioned injection spring 13 illustrated in the initial position in Figure 5 is supported at the proximal end against the base 7a of the clamping element 7 and at the distal end against an internal edge 6a of the plunger element 6 pointing in the proximal direction. The plunger element 6 is of a cylindrical shape and is disposed radially outside the injection spring 13 and is seated on the injection spring 13 fitted on the guide 7d. Both the plunger element 6 and the injection spring 13 are surrounded by an outer guide 7e lying radially outwardly and coaxially with the inner guide 7d of the clamping element 7. Disposed at the distal end of the clamping element 7 are four catch or snapper elements 7b offset in the circumferential direction. The snapper elements 7b have projections 7c pointing radially inwardly, which hold the plunger element 6 in the initial position illustrated in Figure 5 and thus prevent the plunger element 6 from being pushed out of the clamping element 7 due to the force of the injection spring 13. Projections 7f of the snapper elements 7b pointing or extending radially outwardly lie on the internal face of the cylindrical control sleeve 8 and thus prevent the snapper elements 7b from being pushed radially outward.

A release button 4 is mounted in a sliding arrangement in a sleeve 5f of the base plate 5 extending in the vertical direction and can be pushed in toward the base plate 5

perpendicular to the axial direction of the injection device. A lock-slide element 10 is of a plate-shaped design and has an orifice 10b for the release button 4.

As may be seen from Figure 5A, the release button 4 is held in an upper position by a corner 10c into the orifice 10b of the lock element 10 locating in a rib 4b and is locked to prevent it from being pushed in the direction toward the housing 1 or base plate 5.

An upwardly projecting cam 10a of the lock element 10, which is horizontally slidable in the transverse direction, locks the blocking slide 3 by locating in a groove 3a of the blocking slide 3 to prevent a movement in translation and thus prevents a relative movement of the blocking slide 3 with respect to the housing 1.

A sleeve spring 14 is supported in the proximal direction against the base 8a of the control sleeve 8 and in the distal direction against an apron 7g of the clamping element 7 so that the control sleeve 8 is pushed by the sleeve spring 14 in the proximal direction (toward the right in Figure 5 and toward the left in the view in section shown in Figure 5B). Accordingly, as illustrated in Figure 5B, the chamfer 8b provided on the edge of the orifice 8c of the horizontally extending apron 8d of the control sleeve 8 is pushed into a chamfered cam 4a of the release button 4 so that the release button 4 is held in the upper position illustrated by the control sleeve 8 and the force of the sleeve spring 14.

In the described embodiments, the control sleeve 8 moves in the axial direction and offset from the operating or push-in direction of the release button 4 by 90°. Accordingly, the force of the sleeve spring 14 acts on the control sleeve 8 so that it would move into a trigger position at any time if this movement were not prevented by the release button 4. When the release button 4 is depressed, therefore, only the movement of the control sleeve 8 is released.

In this respect, the release button 4 may be biased by the sleeve spring 14 because the control sleeve 8 is moved by a short distance in the direction opposite the triggering

direction during the triggering operation, as a result of which the sleeve spring 14 is additionally tensed before it is then released. To this end, oblique surfaces 4a, 8b are provided respectively on the trigger button 4 and control sleeve 8.

The movement of the control sleeve 8 is halted again by the arms of the clamping element 7 after only a relatively short distance, for example approximately 2 mm. The control sleeve 8 is not released to permit another movement until the end of the injection, when it is accelerated backward in the proximal direction so that when the control sleeve 8 hits a stop element, which may be mounted on the housing 1, base plate 5 or some other element or structure, an acoustic noise, e.g. an end-click, can be generated, thereby indicating to the user that the injection has ended.

A plurality of functions can be provided by the same spring 14 and there are relatively few restrictions as to the choice of which spring 14 should be used specifically. For example, the opposing force for the release button 4 can be adjusted by the chamfering of the oblique elements 4a, 8b and hence the distance translation.

The control sleeve 8 serving as a lock or locking element can be moved axially, although the release button 4 is moved or pushed along an axis offset from it. The control sleeve 8 moves during both the steps of "triggering" and "end of dispensing" so that the control sleeve 8 can be used to provide a visual display of these steps, for example in the region of the display orifice 1a of the housing 1.

When a carpoule 18 is inserted into the carpoule holder 2 as illustrated in Figure 6, a lever arm or tab 11c of the closure lever 11 is displaced by the inserted carpoule 18 and pushed relative to the carpoule holder 2 radially outwardly. The closure lever 11 rotates about its axis of rotation 11b so that the cam 11a is moved out of the retaining engagement with the cam or support 5d of the base plate 5, thereby releasing the carpoule holder 2, which can then be pivoted or pushed into the housing 1, as illustrated in Figure 7. In this respect, the carpoule 18 is fully inserted in the carpoule holder 2 so that the septum 18a of the carpoule 18 is pierced by the connector needle 17, which is fixedly

connected to the carpoule adapter 12. The carpoule 18 is held in the carpoule holder 12 by its flanged cap 18b on the front end, which has snapper elements 12a for receiving the carpoule 18 which snap behind the flanged cap 18b when the carpoule 18 has been inserted, thereby connecting the carpoule 18 to the carpoule holder 2 by the carpoule adapter 12. In some preferred embodiments, the carpoule 18 can no longer be removed from the carpoule holder 2 once and/or after it has been completely inserted in it. If the carpoule 18 is not fully inserted in the carpoule holder 2, the carpoule holder 2 cannot be pushed into the housing 1, even though the closure lock lever 11 should have already unlocked, because the carpoule holder 2 and housing 1 are dimensioned so that a carpoule 18 protruding out from the insertion opening of the carpoule holder 2 will prevent the carpoule holder 2 from being pushed in due to an abutment against the external face of the housing 1.

When the carpoule holder 2 with the inserted carpoule 18 is pivoted into the housing 1 about the axis of rotation formed by the pins 2a and 2b, guided by the guide 2c, 5b, a snapper hook 11d of the lock lever 11 travels along an arcuate or circular guide rib 5g of the base plate 5; when the carpoule holder 2 is in the state fully pivoted in, it moves into engagement at the end of the rib or web 5g with the snapper element 11d on a rear edge of the rib 5g and thus latches on the rib 5g of the base plate 5 and prevents the carpoule holder 2 from being folded open, as illustrated in Figure 7.

Pivoting the carpoule holder 2 into the housing 1 causes the lock element 10 to be pushed in the transverse direction of the injection device by the apron 2d of the carpoule holder 2 lying against an abutment edge 10d of the lock element 10, as illustrated in Figure 7. As a result, the locking cam 10a of the lock element 10 is also pushed in the transverse direction of the injection device and thus moved out of engagement with the groove 3a of the blocking slide 3. Once and/or after the carpoule holder 2 has been completely pushed in, therefore, the blocking slide 3 is unblocked and can be operated or moved. When the lock element 10 is moved in translation, the lock corner 10c which was locking the release button 4 to prevent it from being pushed in is also moved in translation so that the release button 4 could already be pushed in, even though it is still

protected from any operation by the blocking slide 3 lying above, which still has to be moved in translation.

In this operating or operational state, for example once and/or after a film has been torn off to expose an adhesive layer on the bottom face of the base plate 5, the injection device can be adhered adhesively to the injection site.

When the injection device is ready for operation, it can be unlocked by moving the blocking slide 3 in translation in the distal direction of the injection device along the slide guide 9, as illustrated in Figure 8, thereby exposing the release button 4 for subsequent operation. Catches are provided in the proximal (Figure 7A) and/or distal (Figure 8) end position of the blocking slide 3, and the catch connection in the proximal position of the blocking slide 3 is releasable.

When the release button 4 is operated by a user and pushed inwardly in the direction of the housing 1, as illustrated in Figure 9B, the needle or cannula inserter 15 is triggered by a lug 4c projecting in the distal direction of the release button 4. This lug 4c pushes on a trigger mechanism of the inserter 15, which releases an insertion needle with a cannula push-fitted onto it so that the insertion needle together with the cannula is pushed by the force of an insertion spring of the inserter 15 out through the needle outlet orifice 5c in the base plate 5 and subcutaneously pierces the skin of a user to which the injection device is adhered. In some preferred embodiments, the inserter 15 is designed so that once and/or after the cannula has been fully pushed in, it is held in the piercing position pushed out of the inserter 15 and latched, for example. The insertion needle is then advantageously pulled back out of the cannula.

When pushed into the housing 1, the release button 4 firstly pushes the oblique surface 8b of the control sleeve 8 locating in the chamfered cam 4a of the release element 4 out of the engagement illustrated in Figure 5B in the distal direction (on the right in Figure 5B and Figure 9B) against the force of the sleeve spring 14. Since the control sleeve 8 is biased in the proximal direction by the sleeve spring 14, the control sleeve 8

moves in the proximal direction as soon as the release button 4 is pushed in to the degree that the control sleeve 8 can be pushed through the groove 4d so that the control sleeve 8 moves in the proximal direction. As a result, the orifices or recesses 8e of the control sleeve 8 provided in the control sleeve 8 move into the region of the outwardly lying cams 7f of the snapper elements 7b of the clamping element 7 so that the snapper elements 7b can be pushed radially outwardly by the force of the injection spring 13, as illustrated in Figure 9A. As a result the plunger 6 is released and is no longer held against the chamfered retaining edge 6b pointing in the distal direction by the plunger holder 7c of the clamping element 7.

The release button 4 is held in the pushed-in position due to the control sleeve 8 engaging in the groove 4d.

The cams 7f of the clamping element 7, which locate in the orifice 8e of the control sleeve 8, restrict the movement of the control sleeve 8 in the proximal direction caused by the sleeve spring 14. The minimal distance traveled by the control sleeve 8 inside the housing 1 is fixed by the width of the orifices 8e or the smallest axial width of an orifice 8e in the axial direction minus the width of the cam 7f of the clamping element 7 in the axial direction.

To display the operating status of the injection device, colored elements 8f may be applied to the external face of the control sleeve 8, offset from one another in the axial direction, as illustrated in Figure 3, which lie opposite the display orifice 1a of the housing 1. When the control sleeve 8 is moved in translation in the axial direction, it is possible to switch from a first colored element 8f visible through the display orifice 1a of the housing 1, which displays an initial state for example, to a second, axially offset colored element 8f at the display orifice 1a of the housing, which indicates the "triggered" state.

During the ensuing fully automated dispensing process, the plunger 6 is pushed out of the clamping element 7 by the injection spring 13 and moves so that its distal end

face lies in abutment with the proximal end of the stopper 21, which is able to move and can be pushed in the carpoule 18. The stopper 21 is pushed into the carpoule 18 by the plunger 6 and thus forces the substance contained in the carpoule 18 out of the carpoule 18, which causes this substance to be dispensed through a fluid path comprising the connector needle 17, connector hose 12c and catheter fitted by the inserter 15, through this catheter.

In some embodiments, the rate at which the substance is dispensed depends on the fluidity or viscosity of the substance and on the dimensioning of the fluid path traveled. For example, dispensing can be delayed if the cross-section of the fluid path is made smaller and/or the fluid path made longer, which will increase the flow resistance as a result. Conversely, dispensing can be accelerated or shortened if the fluid path is made shorter and/or the flow cross-section of the fluid path is made bigger.

After the start of dispensing, the carpoule holder 2 is locked by the plunger 6 pushed into the carpoule 18 so that it is prevented from folding open, in addition to the lock afforded by the closure lock lever 11 described above.

Figures 10A and 10B illustrate the injection device after dispensing has been completed. In this instance, the plunger 6 has moved so far into the carpoule 18 that the stopper 21 of the carpoule 18 lies at the distal end in the region of the tapering of the carpoule 18 so that no more substance can be dispensed from the carpoule 18.

The end 6c of the plunger element 6 moves beyond the snapper element 7b of the clamping element 7 toward or at the end of the injection, as a result of which the snapper element 7b can be deflected inwardly or can snap back again. As a result, the cams 7f of the clamping element 7 move out of engagement with the orifices 8e of the control sleeve 8 so that the control sleeve 8 is released. The sleeve spring 14 pushing the control sleeve 8 in the proximal direction causes the control sleeve 8, which is now no longer retained, to be pushed in the proximal direction. Accordingly, the control sleeve 8 is able to travel by a distance D illustrated in Figure 9A and defined by the axial distance from a rib or

stop element 5h of the base plate 5. The control sleeve 8 is accelerated across the distance D by the sleeve spring 14 and hits the control sleeve stop 5h, thereby enabling an acoustic feed-back to be generated for a user, indicating that the dispensing process has ended.

Since the control sleeve 8 also moves in the axial direction as a result, a third colored mark can be applied to the external face, offset from the colored marks mentioned above, which lies opposite the display orifice 1a in the housing 1 when the control sleeve 8 is in the state illustrated in Figure 10B in which it lies against the control sleeve stop 5h so that a user looking at the display orifice 1a will be able to tell what the operating status of the injection device is at any time (for example grey: initial position; red: triggered; green: dispensed).

Figures 11A and 11D illustrate an alternative embodiment of an injection device by which the impact of the plunger 6 on the stopper 21 of the carpoule 18 can be damped, slowed or prevented. In this respect, the operating sequence is as described above up to the release of the plunger 6 by the axial displacement of the control sleeve 8. The clamping element 7 is not fixedly connected to the housing 1 or base 5 and is axially displaceable. However, in this alternative embodiment, the plunger rod 6 and clamping element 7 are axially further forward in the initial position, in other words in a position offset in the distal direction. Closing the carpoule holder 2 causes the plunger 6 and clamping element 7 to be pushed backward in the proximal direction against the force of the sleeve spring 14. This may be achieved by a chamfer 2e on the carpoule holder 2, for example, which moves into contact with the distal front end of the clamping element 7 when pushed in, thereby pushing the clamping element 7 with the plunger 6 disposed in it in the proximal direction, as illustrated in Figure 11B. Figure 11D shows a view in cross-section of the injection device illustrated in Figure 11B along line D-D.

When the clamping element 7 is pushed in the proximal direction, the cams 71 of the clamping element 7 projecting radially outwardly, shown in the initial position in Figure 11A in which they are not yet lying opposite the cut-outs 8h of the control sleeve 8, are pushed over the cut-outs 8h of the control sleeve 8, as illustrated in Figure 11B.

Consequently, the retaining arms or snapper elements 7b of the clamping element 7, against which a telescopic additional part 19 pushes, biased by the telescope spring 20, are bent radially outward, causing the telescopic additional part 19 to be released and accelerated in the direction toward the stopper 21 by the force of the telescope spring 20 supported against the clamping element 7 until it moves into abutment with the stopper 21, as illustrated in Figure 11C.

The additional part 19 pushed out by the telescope spring 20 has catch elements 19a on its proximal end, which become radially wider at least in a part-region in the proximal direction and which are elastic so that they can also be compressed. In the state illustrated in Figure 11B, the catch elements 19a of the peripheral part 19 are still disposed inside the plunger 6 and can be pushed through an opening in the distal end face of the plunger 6 by the telescope spring 20. As soon as the additional part 19 has been completely pushed out of the plunger 6, the catch elements 19a are able to expand again automatically and relax in the radial direction so that the pushed-out additional part 19 cannot be pushed back into the plunger 6 again. Consequently, the pressure acting on the plunger 6 due to the injection spring 13 can be transmitted to the additional part 19, which transmits this pressure to the stopper 21 to displace the substance contained in the carpoule 18. The total length of the additional part 19 is adapted to the distance between the distal end of the plunger 6 and the proximal end of the stopper 21.

The advantage of the telescopic design of the plunger of this embodiment is that only a relatively lightweight additional element 19 is accelerated (and hits the stopper 21) by the telescope spring 20 which is weak compared with the injection spring 13. This being the case, it is not necessary for the plunger 6, which is heavier than the additional part 19, to be moved or accelerated to make contact with the stopper 21.

As described above, cams 7f may be provided on the clamping element 7, for example offset in the circumferential direction, which, in co-operation with cut-outs or orifices 8e in the control sleeve 8, likewise offset in the circumferential direction, cause the plunger 6 to be released once and/or after the release button 4 has been pushed in so

that the plunger 6 with the additional part 19 on it and the stopper 21 are pushed into the carpoule 18 to run the dispensing operation, as illustrated in Figure 11D.

Figures 12 to 18D illustrate alternative embodiments for inserting the carpoule 18 in the injection device, each of which can be used in combination with the features described above, for example locking the carpoule holder 2 to prevent it from being pushed in before the carpoule 18 has been fully inserted or releasing operation of the injection device after inserting the carpoule holder 2 in the injection device.

Figure 12 illustrates an embodiment in which the carpoule holder 2 is provided in the form of a drawer. In this instance, the carpoule holder 2 is not folded into the injection device but is pushed in, i.e. the direction in which it is pushed into the injection device is cross-wise and perpendicular to the longitudinal axis of the injection device. This being the case, a closure lock lever 11 may be provided which principally operates in the manner described above, i.e. the closure lock lever 11, which may comprise a single part or several parts, may hold the carpoule holder 2 in the form of a drawer in the external position of the injection device illustrated in Figure 12B. Only when or after a carpoule 18 has been inserted is the closure lock lever 11 released, enabling the carpoule holder drawer 2 to be pushed in. The closure lock lever 11 may be designed to hold the drawer 2 in the injection device when the carpoule holder drawer2 has been completely pushed into the injection device.

Figures 13A to 13B illustrate another embodiment of an injection device in which a carpoule 18 can be inserted in the device from the front (distally) or the rear (proximally). To this end, the injection device may have a front-end or rear-end opening, which is used to insert the carpoule 18. In the case of the embodiment illustrated in Figure 13B, the carpoule is pushed from the distal end as far as the carpoule stop 5j. In addition, a fit-on or fold-down cover 1e may be provided for closing the housing 1. The tab 1f of the cover 1e runs in the guide groove 5i. The lateral cam 1g runs in the guide 1d. Guides 1d and 5i are used for opening and closing the closure.

In this instance, too, it is possible for the injection device to be provided with a lock, for example the trigger mechanism and/or operating devices (which may be thought of and/or referred to as comprising elements 3, 4), which are locked before the carpoule 18 has been fully inserted and/or before a cover which may optionally be provided has been fully closed.

Figures 14A-14C illustrate another alternative embodiment in which a carpoule 18 is inserted or clipped in the injection device from the side. Here too, a cover 2f or lid may optionally be provided along with the features described in connection with Figure 13A. When the injection device is closed, the closure 2f pushes the lock element 10 backward so that the lock between the cam 10a and groove 3a is released, as illustrated in Figures 14B to 14C. When the blocking slide 3 is moved in translation, the pin 3b slides in the guide slot 2g on the closure 2f and thus prevents the injection device from being opened.

Figures 15A and 15B illustrate another embodiment of an injection device in which a carpoule holder 2 can be rotated or screwed into the injection device. The carpoule holder 2 is inserted by screwing or turning it about the longitudinal axis 2i of the carpoule holder 2, which may also be parallel with the longitudinal axis of the injection device.

Figures 16A and 16B illustrate another embodiment of an injection device in which the injection device comprises more than one part and in the case of the embodiment illustrated two parts. Accordingly, the injection device may be opened at a specifically provided dividing surface 16 or dividing plane, which then enables a carpoule 18 to be inserted. The (two) parts of the injection device 1h and 1i can then be joined to one another again, for example rotated or screwed or latched or nested or pushed onto one another, as illustrated in Figures 17A and 17B. The dividing surface 16 at which the injection device can be taken apart or folded open may extend in the axial direction or alternatively transversely or in the transverse direction of the injection device, as illustrated in Figures 16A to 17B. When the injection device is in the

assembled state, a latching or locking action may be provided, which makes it more difficult or impossible to open the injection device again once and/or after a carpoule 18 has been inserted.

Figures 18A to 18D illustrate another embodiment in which the carpoule is inserted from above by a rotating movement. The displaceable carpoule adapter 12 has guide grooves 12d, in which the cams 51 control the movement of the carpoule adapter. As a result, the carpoule 18 can be inserted in the carpoule adapter at an angle from above and the carpoule 18 together with the carpoule adapter can be folded into the injection device. The injection device can then be closed by the cover 1k. The blocking slide 3, unlocked once and/or after the carpoule 18 has been folded in or the injection device has been closed by the cover 1k, is moved in translation and the release button 4 lying underneath the blocking slide 3 is exposed as a result, thereby enabling the injection to be triggered.

In addition or as an alternative to this triggering or actuation sequence, the injection device may be designed so that it is necessary to apply the injection device to a surface or the injection device has to be adhered to enable the injection device to be triggered. This applying or adhering lock may be used as the sole locking system or as an additional lock or blocking system. In this case, one exemplary possible sequence for triggering the injection device might involve the following steps: close carpoule holder 2, adhere injection device, optionally operate release mechanism or push blocking slide 3 and depress trigger or release button 4.

Another possible embodiment of a trigger lock is illustrated in Figures 19A to 19D. In the case of this embodiment, the release button 4 is locked before the plaster or adhesive of the device is applied to the skin. This is done by a lock element 23, which is fixedly connected to the plaster film 22b through an orifice 22a in the plaster 22. The lock element prevents two catch arms 4g on the release button 4 from being inwardly deflected. As a result, the snappers 4h disposed on the catch arms 4g sit against a chamfer 5m of the base plate 5 and the button cannot be pushed in. When the plaster film 22b is

removed from the plaster, the lock element is pulled off as well and the snappers 4h can be deflected outwardly when pressure is applied to the release button 4. Figure 19B illustrates a detail in this respect, prior to pulling off the plaster film 22b, while Figure 19B shows the same detail immediately after removing the plaster film 22b and lock element 23. Figure 19D shows the same detail once and/or after the release button 4 has been depressed.

With regard to the design of such a "stick-on" lock, reference may also be made to the disclosure and teaching of WO 2008/139464 A (English equivalent US 7,951,122), which may be used in conjunction with the injection device described here and which is incorporated entirely herein by reference. In particular, a sensor element disposed in the stick-on region or on the bottom face of the injection device may detect whether the injection device has been applied to a surface or adhered to it. The sensor element may be an electronic and/or a mechanical sensor element. For example, the sensor element may be provided in the form of a displaceable element projecting or protruding out from the bottom face of the injection device which is pushed or folded into the injection device when the injection device is placed on a surface.

One possible embodiment of a mechanical sensor mounted on the bottom face of the injection device is illustrated in Figures 19E to 19K. As illustrated in Figure 19E, the unlocking bolt 24 extends beyond the base plate 5 in the initial position. To activate the injection device, the protective film 22c is removed from the base plate. The cam 5n in the base plate 5 prevents the unlocking bolt 24 from being prematurely pushed in. Accordingly, to effect a release directly before the injection device is adhered to the patient's skin, the unlocking bolt 24 is rotated by approximately 90° until one of the recesses 24b of the unlocking bolt lies above the cam 5n, as illustrated in Figures 19F and 19G. The injection device can now be adhered. Figure 19H is a view in cross-section illustrating the injection device in the initial state once and/or after the film 22c has been removed. The unlocking bolt 24 has a conical end 24d. This end lies against the chamfer 10e of the lock element 10. When the bolt 24 is pushed into the device as it is being adhered, the movement of the bolt 24pushes the lock element 10. The blocking slide 3 is

released as a result. In another variant of this embodiment, illustrated in Figure 19K, snapper elements 24a may be provided on the unlocking bolt 24. When the bolt is pushed in, the snapper elements 24a are pushed beyond the lock snappers 5o provided and latch irreversibly, thereby preventing the injection device from being inadvertently locked again once and/or after it has been stuck down, for example by a movement of the patient.

The insertion or fold-in operation can then unlock or release the injection device, making it ready for subsequent operation. In some preferred embodiments, the injection device may not be operated or triggered unless the lock element has been released, in other words, for example, if a folding or sliding element is still protruding out from the bottom face of the injection device. The lock element may be pre-tensioned by a spring, for example, and is moved or folded against the force of this spring when the injection device is placed on a surface. By the lock element, it is also possible to detect whether the injection device is still in contact with the surface. For example, when the injection device is removed from a surface or a user's skin, the lock element can be pushed back out of the injection device by an elastic or spring force and thus interrupts any continuing injection. In this respect, the injection device may be designed so that the injection is ultimately interrupted and can no longer be resumed if the injection device is removed after and/or during the injection. Alternatively, it is also possible to configure the interruption function so that the injection starts again as soon as it is detected on the basis of the pushed-in or folded-in lock element that contact has been reestablished with the surface again.

Based on another alternative embodiment, the slide described above may be replaced by or provided in conjunction with a pin which locks the injection device and the injection is not triggered until the pin has been pulled and/or is triggered by a release button.

As opposed to the arrangement described above, the release or trigger button, together with or separately from the blocking slide, may naturally be disposed in a

different position on the injection device. In some preferred embodiments, the direction in which the trigger button is operated is perpendicular or approximately perpendicular to the surface on which the injection device is placed to prevent the injection device from sliding sideways or grip being lost due to operation of the release button.

Alternatively, the release button based on the push button design may also be replaced by a lever, a rotating element or a sliding element, in which case the lever can or must be operated or pressed or a rotating element or rotating knob rotated or a slide element slid to start dispensing from the injection device.

As an alternative or in addition to the pre-tensioned injection spring 13 or compression spring described above, a different mechanism or energy source may be provided. For example, the compression spring 13 may be provided in the injection device in a relaxed or only partially tensioned state and tensed by the user to provide the energy needed to perform the injection. For example, the compression spring 13 may be tensioned during assembly, e.g. when closing the carpoule holder 2, in other words folding in the rotating part-carpoule holder or pushing in the drawer-carpoule holder for example, or when inserting a carpoule 18. The compression spring 13 may also be tensioned before or during triggering, for example by operating a trigger button 4 or trigger lever, in which case operating the trigger element or a release element causes the compression spring 13 to be tensioned. In addition or as an alternative, the compression spring 13 may also be tensioned by a separate additional step, such as priming the injection device for example, by rotating or sliding a priming element. The priming element may also be integrated in another element, for example in the carpoule holder 2, a lock, or a trigger element 4.

In addition or as an alternative to a compression spring 13, it would also be possible to provide other types of driving systems, for example a torsion spring, coil spring or tension spring. All of the functions described above in terms of tensioning and securing the spring may be used similarly in conjunction with the types of spring mentioned above.

Another option is to provide a gas generator or a gas cartridge as a drive system. This being the case, the gas generated by the gas generator or gas cartridge may be directed onto the stopper or introduced into a closed volume on the rear face of the carpoule so that the stopper is pushed into the carpoule by the gas pressure generated.

It would also be possible to use a pyrotechnic element as an energy storage, which would cause the stopper to be pushed into the carpoule when ignited.

A shape memory alloy or a memory metal may also be used as the energy storage, in which case the change of shape may be brought about thermally or induced by tension, for example triggered by depressing a release button.

It would also be possible to initiate dispensing by using an electric motor as described in WO 2009/044401 A2 (and English equivalents US 2009/093793 and US 2009/093792), for example, the entire disclosure and teaching of which is incorporated herein by reference. A battery-operated electric motor drives a plunger rod or threaded rod, for example, which pushes the stopper 21 of the carpoule 18 and moves it into the carpoule 18 to dispense the substance.

The mechanism(s) described above may be provided as a means of storing the injection energy and triggering the injection, whereby a lock element, such as a clamping element 7, locks the plunger. On triggering, the lock element 7 moves in the housing 1 in the opposite direction from that in which the plunger 6 is pushed for dispensing purposes.

Alternatively, the lock element 7 or catch element may also be disposed in the injection device in such a way that when triggered, it moves in the same direction as the plunger 6 during dispensing. In this case, retaining arms of the clamping element 7 may sit against a trigger or control sleeve 8, and the arms 7b holding the plunger 6 are moved by a movement of the clamping element 7 caused by a release button 4, thereby enabling

the plunger 6 to be released, as illustrated in the embodiment shown in Figures 20A and 20B.

Alternatively, the retaining arms of the clamping element holding the plunger 6 prior to the injection may be disposed on a control sleeve 8. This control sleeve 8 may be rotated about its own longitudinal axis for triggering purposes, as illustrated in Figures 21A and 21B, to enable the retaining arms of the clamping element 7 to be pushed radially outwardly, thereby releasing the plunger 6. In this respect, Figure 21A illustrates the injection device in the initial state and Figure 21B illustrates the injection device once and/or after the control sleeve 8 has been rotated so that the snapper element release orifices 8e lie opposite the control sleeve retaining cams 7f.

Alternatively or in addition, the plunger 6 and/or the clamping element 7 may be hooked in the injection device by catch elements, for example in the proximal part of the injection device. Triggering takes place by unhooking the hooked retaining elements, for example by depressing the release button 4.

Alternatively or in addition, an extractable pin may be provided in the injection device, which extends partially or fully through the plunger 6 from an orifice, thereby preventing the plunger 6 from being moved before the pin is extracted. The plunger 6 cannot be released and moved to perform an injection until the pin has been pulled out.

As an alternative to the variant in which a control sleeve 8 is pre-tensioned by a sleeve spring as described above, the movement of the control sleeve 8 may also be achieved without spring force, in that a triggering movement of the release button 4 is transmitted to the control sleeve 8. This being the case, the direction in which the control sleeve 8 moves is parallel with or at an angle to or perpendicular to the direction in which the release button 4 is moved or triggered. To this end, a deflector element may be provided or oblique surfaces 4a, 8b of the trigger element 4 and control sleeve 8 lie one against the other.

The carpoule holder 2 can be locked to prevent it from being introduced or inserted into the housing 1 before a carpoule 18 has been inserted and released for the movement for pushing or folding it into the injection device, and then locked once and/or after the carpoule 18 has been inserted, by the closure lock lever 11 described above.

In addition or as an alternative, inserting the carpoule 18 in the carpoule holder 2 may cause an element to be linearly displaced, thereby moving it out of a carpoule holder locked position. The displaceable element may be a carpoule adapter 12 for example, in which a carpoule 18 is inserted. When the carpoule holder 2 is in the closed state, the carpoule holder 2 and/or the displaceable element is latched by a snapper, a catch connection, a bolt or other suitable lock element.

The described closure lock lever 11 may also be disposed and designed so that it does not move or rotate parallel with the base but at an angle or perpendicular to it. This being the case, the closure lock lever 11 should also be designed so that when the injection device is in the closed state, i.e. when the carpoule18 is inserted and the carpoule holder 2 is closed, it locks, latches or snaps to prevent the carpoule holder 2 from opening.

Alternatively or in addition to the mechanism described above, the carpoule or ampoule holder 2 may also be designed so that it can be closed at any time, even if no carpoule 18 has been inserted. However, it can be opened again at any time or pushed open again by a spring or an elastic element if no carpoule 18 has been inserted. If a carpoule 18 has been inserted in the carpoule holder 2 and the carpoule holder 2 has been closed, however, the carpoule holder 2 latches in the closed position and can no longer be opened.

The carpoule holder 2 may optionally be fixedly locked in the closed state and unlocked again by using a manually operable additional element or additional bolt.

The release button 4 may be held in an upper position by a chamfer 4a of the control sleeve 8 to which a force is applied by the sleeve spring 14. In addition or as an alternative, a separate spring element may also be provided, such as a button spring for example, as a means of holding the release button 4 in the upper, non-triggered position.

Apart from using the mechanism described above based on a linear movement of the lock element 10 while or after inserting the carpoule holder 2, the blocking slide 3 and release button 4 may also be locked by other means. For example, a lock element 10 or lock snapper which blocks the movement of the blocking slide 3 and/or the release button 4 may be released by a closing movement of the carpoule holder 2 or a carpoule drawer or by a movement when inserting the carpoule 18 in the injection device. This may happen in such a way that the lock element 10 or a lock snapper is pushed away or pressed away, e.g. upward, downward or to one side. A lock element 10 can likewise be pushed away due to a closing movement of the carpoule holder 2 or a carpoule holder drawer or by a movement when inserting the carpoule 18 to release operation of the blocking slide 3 and/or release button 4. Optionally, a pin may be provided, which can be pulled out to unlock the blocking slide 3 and/or release button 4. Also, the release button 4 need not necessarily be disposed underneath the blocking slide 3 and may be locked directly by the blocking slide 3, for example on the basis of an engagement of the blocking slide 3 in a groove 4f on the button 4, as illustrated in Figures 22A and 22B. In this respect, the blocking slide 3 must firstly be operated or moved as described above before the release button 4 can be operated or depressed if no element of the blocking slide 3 in disposed in a lock groove on the release button 4 any longer.

As illustrated in Figures 23A and 23B, the release button 4 may be designed so that the release button 4 itself or an outer ring on the release button 4 has to be rotated to release the button before the release button 4 can be operated and depressed, for example. To this end, an orifice 1c is provided in the housing 1, through which a rotating cam 4e of the release button 4 can be pushed. If the release button 4 is rotated so that the cam 4e does not lie above the orifice 1c, the button 4 cannot be depressed. The blocking slide 3 and/or release button 4 may be unlocked directly or indirectly by the pushing-in

movement of the carpoule 18 into the carpoule holder 2 and/or directly or indirectly by the movement of inserting or pushing or folding the carpoule holder 2 into the injection device.

The septum 18a of the carpoule 18 may be pierced manually when the carpoule 18 is inserted, as described above, for example.

As an alternative to the above, a system would also be possible whereby the septum 18a is not pierced until pressure is applied to the stopper 21 of the carpoule 18, for example by an injection spring 13 prior to dispensing. The carpoule 18 will be unharmed and the carpoule interior protected until immediately before the start of the injection using such a force-controlled sequence control.

Alternatively, the septum 18a can be pierced when the carpoule holder 2 effects a closing movement. In this respect, if the carpoule 18 may be pushed forward or in the distal direction relative to the carpoule holder 2 and/or relative to the injection device or a housing 1 thereof. The carpoule 18 may be pushed or forced forward in the direction toward a connector needle 17 using an oblique surface once and/or after the carpoule 18 and/or the carpoule holder 2 have been introduced or pushed into the injection device. For example, an oblique surface may be provided on the injection device in such a way that the carpoule 18 moves into contact with the oblique surface at the rear or proximal region of the carpoule 18 during the insertion movement so that the carpoule 18 is forcibly guided toward a piercing or connector needle 17 by the oblique surface during a continuing insertion movement, and once and/or after the carpoule 18 has been fully inserted in the injection device, the septum 18a has been fully pierced by the needle 17.

As an alternative to the above, the carpoule 18 may be pushed by an unlocking or triggering movement in the direction towards a connector needle 17. For example, the carpoule 18 may be pushed by operating a blocking slide 3 and/or by operating a release button 4 so that the septum 18a is pierced by a needle 17 disposed inside the injection device or in the carpoule holder 2.

In the case of another alternative, the septum 18a might already be pierced before the carpoule 18 is placed in the carpoule holder 2 or in the injection device. In this case, at least one needle 17 with an internal opening and also an adapter 12 to which the needle 17 can be attached and optionally also a hose or connector hose 12c is connected to the carpoule 18. Once and/or after the carpoule 18 has been connected, which may take place outside of the injection device and outside of the carpoule holder 2, the carpoule 18 with the needle 17 and optionally the fitted adapter 12 and hose 12c can be inserted in or pushed into the injection device. The connection between the needle 17 or hose element 12c and a fluid path of the injection device is then established, for example by an inserter 15, to provide a fluid connection between the interior of the carpoule 18 and the dispensing cannula. Alternatively, the hose 12c may be of such a length that the connection to the inserter is already established when the septum 18a is pierced.

Alternatively, the needle used to pierce the skin may pierce the septum 18a from the oppositely lying end during the piercing process so that the injection device can be manufactured with only a single needle.

Alternatively, a needle can be moved in the direction of the septum 18a to pierce it during the movement of closing the carpoule holder 2. During the closing movement, the needle is moved toward the carpoule 18 or the carpoule 18 toward the needle or the two elements are moved toward one another.

As described above, the carpoule 18 may be held by an adapter element 12 which is inserted or snapped into the carpoule holder 2. Alternatively, the carpoule 18 may also lie against a shoulder, for example of the carpoule holder 2, to set or fix the position of the carpoule 18 relative to the carpoule holder 2. The adapter element 12 may be spring-biased to enable any impact force which occurs to be absorbed, thereby reducing or preventing any mechanical stress on the carpoule 18 or carpoule neck.

In some embodiments, the adapter element 12 may be designed as an integral part of the carpoule holder 2.

As an alternative to the embodiment described above in which the blocking slide 3 is pushed to the side away from the release button 4, the slide 3 may also be designed so that it is rotated away from or folded up from the button 4 to release the release button 4 for subsequent operation.

The indication or feedback to the user to provide information about the operating status may be visual, acoustic and/or tactile, as described above. On the one hand, an element such as the control sleeve 8 mentioned above may have a colored marking 8f on the external face and the individual colored portions 8f are axially offset from one another. The display element 8f and the control sleeve 8 are moved past a viewing orifice, e.g. a display orifice 1a of the housing 1, by a transparent element or orifice to show a different color at the display orifice 1a depending on the operating status. A noise to indicate the end of the injection may be produced by the described movement of the control sleeve 8 against a stop element of the housing 1 or housing base 5, for example, driven by a sleeve spring 14. In this respect, the thickness of the stop is such that a user is able to perceive a slight movement or vibration of the injection device through it. To ensure that the injection has actually ended, the user can look at the above-mentioned display element 1a, 8f.

In addition or as an alternative to the feedback options described above, a snapper element or sleeve may be provided, for example the control sleeve 8, so that the snapper or sleeve 8 latches in an orifice or opening of the housing 1 and optionally even protrudes out from the housing 1, thereby enabling a visual, acoustic and tactile feedback to be provided because the user will feel the protrusion as illustrated in Figures 24A and 24B. Figure 24A illustrates the injection device before the injection has been triggered. The orifice 1j is then empty. Once and/or after the injection has ended, the snapper element 8g is pushed into the orifice 1j as illustrated in Figure 24B so that the snapper element provides perceptible feedback of the fact that the injection has ended.

This protrusion or pushing-out of an element at the end of the injection may take place in a region of the injection device, in other words through an opening of the housing, for example. It would also be possible for an element to be pushed out through the base or a base plate 5 of the injection device so as to impact in the direction of a patient's skin and thus provide feedback.

The trigger or release button 4 may be designed so that it moves back (or upward) into its initial position or beyond at the end of the injection. A user will then be able to tell from the protruding release button 4, which may be locked in the protruding position, that the injection has been completed.

It is also possible to provide a visual display on the basis of a relative movement of an element such as a control sleeve 8, for example, relative to the injection device or a housing 1 thereof which provides a display due to the fact that a pointer or a display element is pushed with it externally on the housing 1. A user would therefore be able to tell with the additional aid of an optionally provided marking, for example, in which operating state the injection device currently is.

Alternatively or in addition to generating an end click by the force of the sleeve spring 14, the end click may be generated by the injection spring 13. For example, the injection spring 13 may release an element held by a predefined minimum force from its holder when the plunger 6, 19 has been pushed completely into the carpoule 18.

If a motor or electric motor is used to move the stopper 21 and thus dispense a substance, a vibration alarm may also be provided by activating the electric motor accordingly by an appropriate control at the end of dispensing.

If a carpoule 18 which is only partially filled is used, a system with a plunger rod of a telescopic design (e.g. comprising elements 6, 19) may be used as described above, in which case a front flange element is released once and/or after the carpoule holder 2

has been closed, for example by moving a clamping element, and establishes contact with the stopper 21 of the carpoule 18.

Alternatively, the plunger 6 or a plunger rod 19 may be adapted to the filling quantity in terms of its initial length and made longer accordingly as the filling quantity of the carpoule 18 becomes less. In this case, the carpoule 18 would be inserted in the injection device so that the plunger 6 or plunger rod 19 already moves into contact with the stopper 21 of the carpoule 18 during the insertion process already or the plunger 6 or plunger rod 19 at least extend into the carpoule 18 at the proximal end.

It would also be possible to provide a separate lock element which locks the flange element or the telescopic rod 19 in front of the plunger 6 or plunger rod. This separate element may either be operated separately by a operating action of a user or in connection with another operating function, such as for example unlocking the injection device.

The element of the injection device incorporating the energy storage, in other words a tensioned spring for example, may also be described as a power pack. Accordingly, the injection device may be designed so that the power pack and the carpoule 18 move toward one another once and/or after the carpoule 18 has been inserted or the injection device has been closed by folding in or pushing in the carpoule holder 2. This mutual movement may be achieved manually, for example by a user, or automatically, for example by one or more biasing elements. The carpoule 18 may be pushed in the direction toward the power pack or the power pack may be pushed in the direction toward the carpoule 18 or the two elements may be pushed toward one another. It would also be possible to design the housing 1 so that it becomes smaller, e.g. telescopically smaller, in other words automatically contracts in its axial extension, to set as short a distance as possible or even establish a contact between the stopper 21 and plunger rod 6, 19.

The plunger rod 6 or plunger rod movement may be damped during the idle stroke by which the plunger rod 6 is moved in the direction toward the stopper 21 of the carpoule 18 and, in some preferred embodiments, this takes place relatively slowly so as to cause as little impact as possible or none at all. This may be advantageous in the case of only partially filled carpoules. Two possible embodiments are illustrated in Figures 25A to 26C.

In the embodiment with partially filled carpoules illustrated in Figures 25A to 25C, an additional element 19b is mounted on the plunger 6, which snaps into the plunger by cams 19c. When triggered, the end face of the plunger 6 presses the additional element 19b forward, driven by the injection spring 13. The additional element has a thread 19d on its external face, which adjoins cams 7i on the internal face of the sleeve-shaped internal guide 7h. The two cams 7i on the sleeve element 7 are disposed so that the thread 19d adjoins one side at any one time. The additional element 19b is pushed by the oblique abutment surface so far to one side so that the threaded piece moves past the cam 7i and the thread rests or sits against the cam on the other side. The thread pitch of the thread 19d is selected so as to be small to the degree that the additional element 19b does not rotate. Accordingly, the additional element moves constantly backward and forward during the forward movement of the plunger 6, which decelerates the movement due to the friction between the parts and the constant acceleration and deceleration of the additional element 19b. The damping action ideally continues until shortly before the additional element hits the stopper. From this point, dispensing takes place in the manner described above. Figure 25A illustrates the initial state of the additional element 19b, Figure 25B illustrates the injection device during the idle stroke movement and Figure 25C illustrates the injection device after the additional element 19b has hit the stopper 21.

In the case of the embodiment with partially filled carpoules illustrated in Figures 26A to 26C, the plunger 6 has an additional element 19b which is snapped into the plunger by cams 19c. When triggered, the end face of the plunger 6 pushes the additional element forward, driven by the injection spring 13. The additional element has a thread 19d on its external face, which adjoins an internal thread 7k of the internal face of the

sleeve-shaped internal guide 7j. This causes the additional part 19b to rotate during the forward movement of the plunger 6. The forward movement is therefore damped due to the friction between the parts. The damping may continue until shortly before the additional part hits the stopper. From this point, dispensing takes place in the manner described above. Figures 26A to 26C illustrate the same states of the injection device as Figures 25A to 25C.

If a system with a plunger rod based on a telescopic design is used, the part which telescopes out, e.g. flange element 19, may be locked directly by the carpoule holder 2, for example a carpoule holder 2 based on a drawer design. The flange element 19, which is biased by a telescope spring 20 relative to the rest of the plunger element 6, is released when the carpoule 18 is inserted and/or the carpoule holder 2 is introduced into the housing 1.

With a system using a plunger rod based on a telescopic design, a sequence control may be adopted whereby an element such as the clamping element described above locks the flange element 19 and the latter locks the plunger 6. It is not until the lock element or clamping element has been released, for example by a user depressing a release button for example, that the flange element 19 can be pushed out of the plunger 6 and the plunger 6 released for a subsequent movement.

Embodiments, including preferred embodiments, have been presented in this application for the purpose of illustration and description. They are not intended to be exhaustive or to limit the invention to the precise forms and steps disclosed. The embodiments were chosen and described to illustrate the principles of the invention and the practical application thereof, and to enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the invention as determined by the appended claims when interpreted in accordance with the breadth they are fairly, legally, and equitably entitled.

Claims

1. An injection device securable to the body of a user for automatic administration of a fluid substance comprising:

a housing,

a fluid reservoir comprising a piston slideable along a longitudinal axis to expel fluid substance from the reservoir,

a holder to accommodate the fluid reservoir, the holder movably coupled to the housing,

a cannula or hollow needle extending from the injection device,

a drive mechanism to force fluid substance from the reservoir into the cannula or hollow needle to administer the fluid substance,

a triggering mechanism comprising a release element, and

a control device functionally coupled to the triggering mechanism and the drive mechanism, wherein the control device is movable along said longitudinal axis relative to the housing, wherein

by the activation of the triggering mechanism by moving the release element the control device is moved from a first position to a second position thereby releasing the drive mechanism, and

upon completion of the administration of fluid substance the control device is moved from the second to a third position producing an acoustic noise upon reaching the third position, and

the movements of the control device are opposite the direction of the movement of the piston during administration.

2. The injection device of claim 1 wherein the injection device is adherable to skin.

3. The injection device of claim 1, wherein the control device is a control sleeve.

4. The injection device of claim 3, wherein the movement of the control sleeve is assisted by a spring.

5. The injection device of claim 1, wherein the movement of the control device from said second to said third position is a movement relative to the reservoir.

6. An injection device securable to the body of a user for automatic administration of fluid substances comprising

a housing,

a fluid reservoir comprising a piston slideable along a longitudinal axis to expel fluid substance from the reservoir,

a holder to accommodate the fluid reservoir, the holder movably coupled to the housing,

a cannula or hollow needle extending from the injection device,

a drive mechanism comprising a plunger and a spring acting on the plunger to force fluid from the reservoir into the cannula or hollow needle to administer fluid substance,

a triggering mechanism comprising a release element and

a control device operably coupled to the triggering mechanism and the drive mechanism, wherein the control device is movable along said longitudinal axis relative to the housing, wherein by the activating of the triggering mechanism by moving the release element the control device is moved from a first position to a second position thereby releasing the drive mechanism, and wherein the drive mechanism further comprises a brake capable of decelerating the drive mechanism.

7. The injection device of claim 6, wherein the brake comprises:

a sleeve shaped guide in an axially secured position relative to the injection device, and

an additional element carried by the plunger for cooperating with the sleeve shaped guide, wherein

the additional element cooperates with the sleeve shaped guide during said administration of fluid substance to create a braking effect.

8. The injection device of claim 7, wherein the sleeve shaped guide and the additional element are disposed coaxially and wherein the sleeve shaped guide surrounds the additional element at least partially before said administration is started.

9. The injection device of claim 8, wherein the sleeve shaped guide comprises an at least partially threaded inner surface and wherein the additional element comprises an at least partially threaded outer surface which is in threaded engagement with said threaded inner surface, said threaded engagement creating said braking effect.

10. The injection device of claim 8, wherein

the sleeve shaped guide comprises at least two cams disposed on an inner surface of said sleeve shaped guide, wherein the cams are disposed roughly at the same axial position on the sleeve shaped guide and opposite each other on the inner circumference of the sleeve shaped guide, and

the additional element comprises an at least partially threaded outer surface,

whereby the threads of the additional element engage alternatingly the two cams during said administration thereby forming said brake.

11. The injection device of claim 6, wherein the brake is a frictional brake.

12. An injection device for automatic administration of fluid substances, comprising:

a housing comprising a base plate securable to the user's skin by an adhesive patch,

a fluid reservoir comprising a piston slideable along a longitudinal axis to expel fluid substance from the reservoir,

a holder for accommodating the fluid reservoir, the holder movably coupled to the housing,

a cannula or hollow needle extending from the injection device,

a drive mechanism for sliding the piston to force the fluid substance from the reservoir into the cannula or hollow needle to administer the fluid substance or a portion thereof,

a triggering mechanism comprising a release element, wherein the administration of fluid substance is started by moving the release element, and

an unlocking element movably mounted on the base plate and extending therefrom in an initial position, said unlocking element functionally coupled to the triggering mechanism, wherein

in the initial position the unlocking element blocks movement of the release element therefore preventing administration of fluid substance,

upon securing the injection device to the user's skin the unlocking element is moved by the user's skin in a direction substantially perpendicular to the base plate into the housing into a second position, and

in the second position the unlocking element allows movement of the release element.

13. The injection device of claim 12, wherein the triggering mechanism further comprises a slideable locking slide disposed on housing, thereby covering the release element in an initial position to prevent unintended start of said administration.

14. The injection device of claim 13, wherein the unlocking element is an unlocking bolt, and the triggering mechanism further comprises a lock element functionally coupled to said locking slide, wherein upon moving of said unlocking bolt from said first position to said second position the lock element is moved out of engagement with the said locking slide thereby enabling a start of said administration of fluid substance.

15. The injection device of claim 12, wherein the unlocking element has to be rotated about an axis perpendicular to the base plate prior to be moved from said first position to said second position.

16. An injection device for automatic administration of fluid substances, comprising:

a housing comprising a base plate, wherein the base plate is securable to the user's skin by an adhesive patch,

a fluid reservoir comprising a piston slideable along a longitudinal axis to expel fluid substance from the reservoir,

a holder for accommodating the fluid reservoir, the holder movably coupled to the housing by a pivoting mechanism,

a cannula or hollow needle extending from the injection device,

a drive mechanism for forcing fluid from the reservoir (18) into the cannula or hollow needle to administer fluid substance, and

a triggering mechanism comprising a release element and a lock element, wherein said administration of fluid substance is started by moving the release element,

the holder is pivotable from a first position relative the housing in which the fluid reservoir can be inserted into the holder to a second position in which the fluid reservoir is aligned with the drive mechanism to enable administration of fluid substance,

the holder further comprises a closure lock lever which prevents movement of the holder from said first position to said second position before the reservoir is accommodated in the holder,

as the holder is pivoted from said first position to said second position the lock element is moved out of a blocking engagement with the triggering mechanism by the holder, and

administration of substance may only be started after the holder is moved from the first to the second position.

17. A control device for a device for administering a substance, the device having a longitudinal axis, a drive mechanism, and a triggering mechanism comprising a release element, wherein actuating the triggering mechanism by moving the release element causes control device to move along said longitudinal axis from a first position to a second position thereby releasing the drive mechanism and to move from the second to a third position producing an acoustic signal upon reaching the third position.

18. The control device of claim 17, wherein the device for administering further comprises a reservoir and a piston movably in the reservoir, and wherein the movements

of the control device are opposite the direction of movements of the piston during an administration.

19. The control device of claim 17, wherein the control device comprises a sleeve.

20. The control device of claim 19, wherein the movement of the sleeve is assisted by a spring.

21. The control device of claim 20, wherein the device for administering further comprises a brake.

22. The control device of claim 21, wherein the brake comprises a guide in an axially secured position relative to the device for administering and an element associated with the drive mechanism and cooperable with the guide, the cooperation of the guide and element creating a braking effect during an administration.

Figure 1

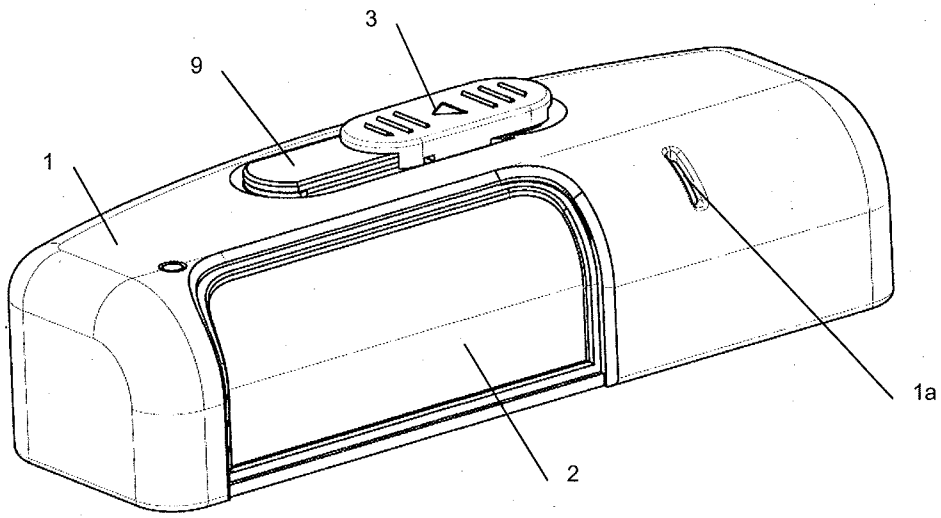


Figure 2

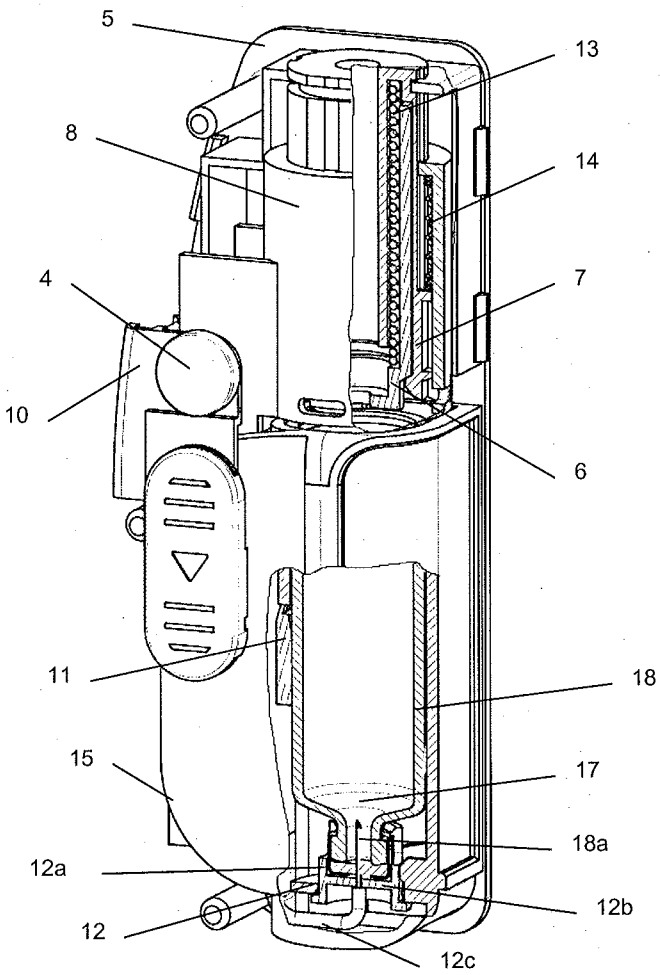
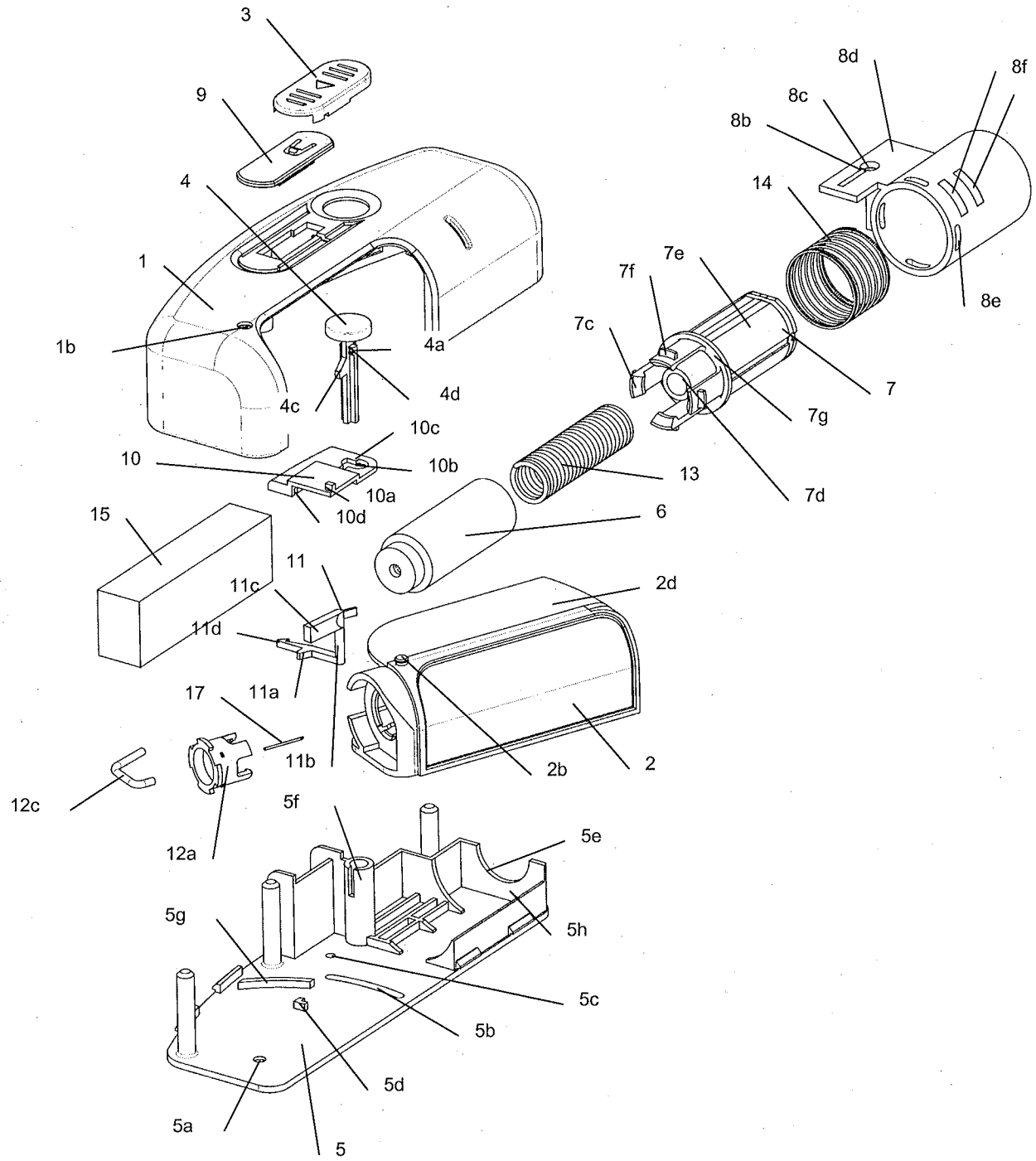


Figure 3


3
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1b
4a
4c
4d
10c
10
10b
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11a
11b
12c
12a
5f
5e
5g
5h
5c
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5d
5a
5
8d
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7g
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13
6
2d
2b
2

Figure 4

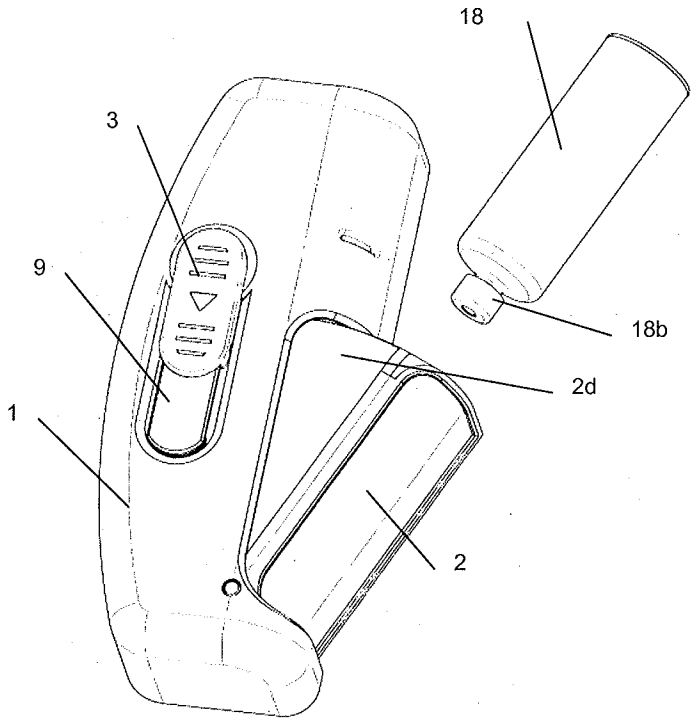

Figure 5

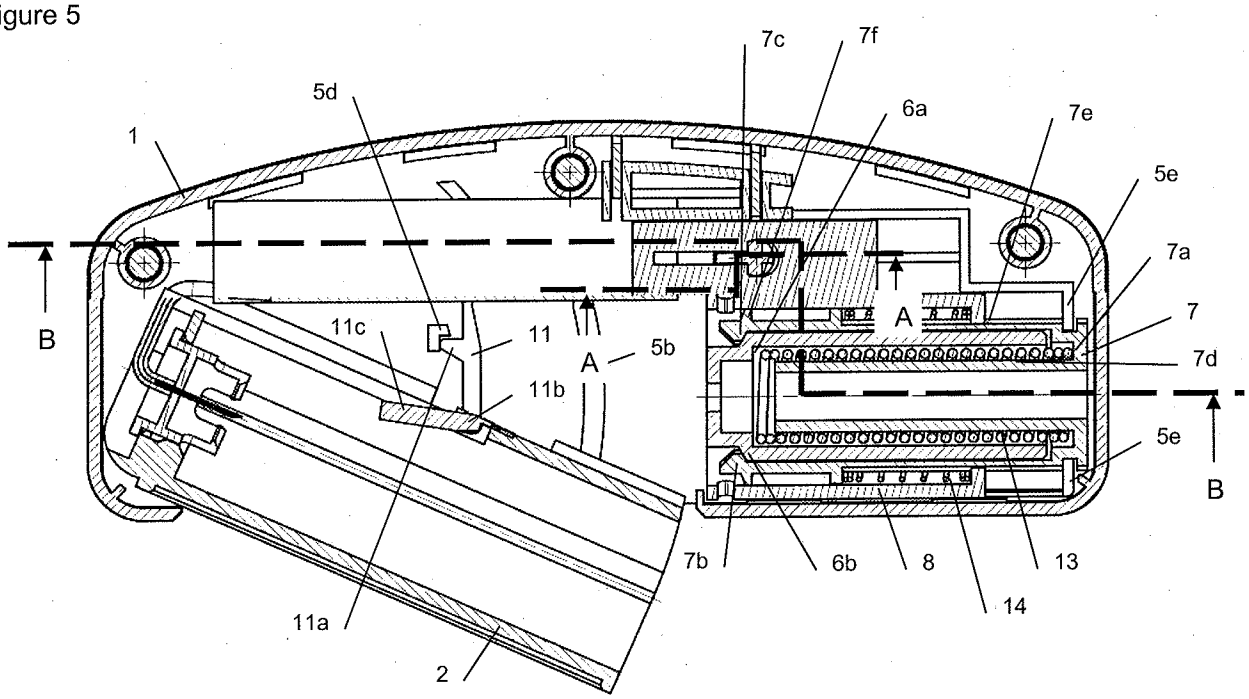

Figure 5A

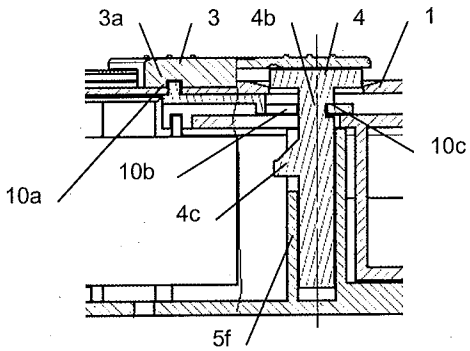

Figure 5B

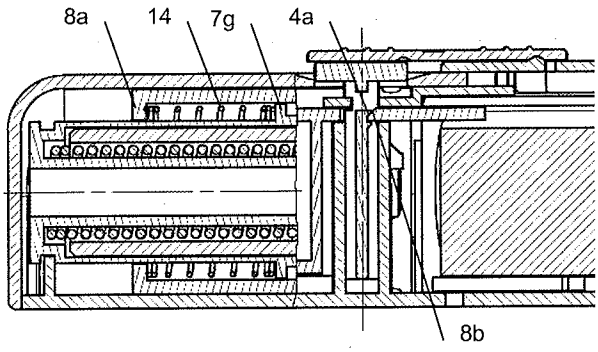

Figure 6

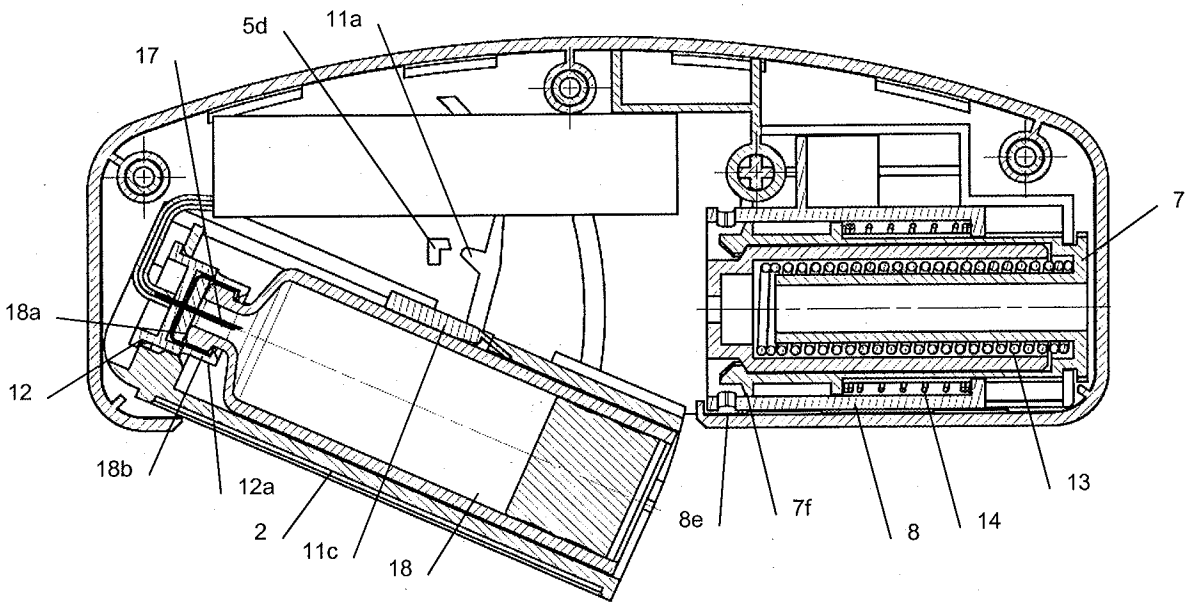

Figure 7

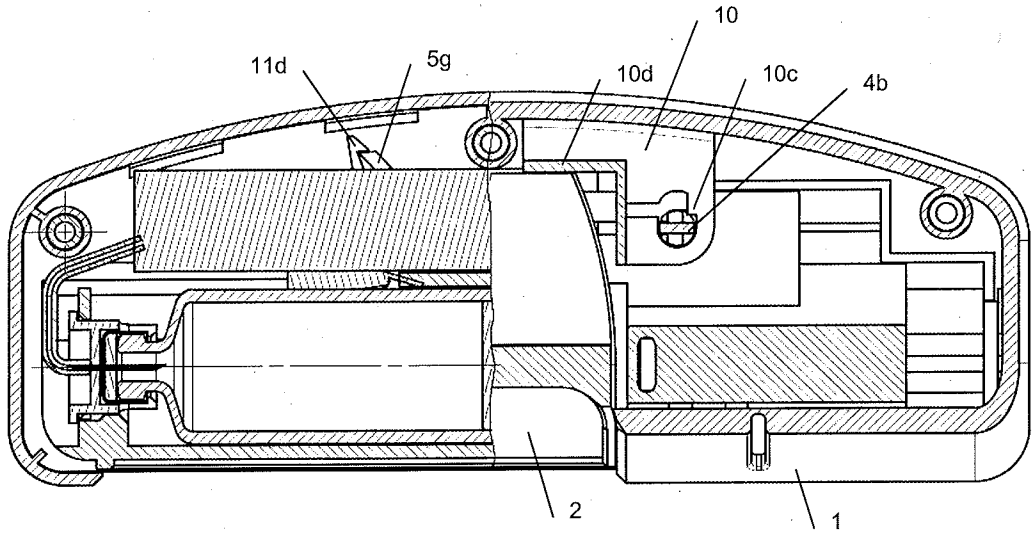

Figure 7A

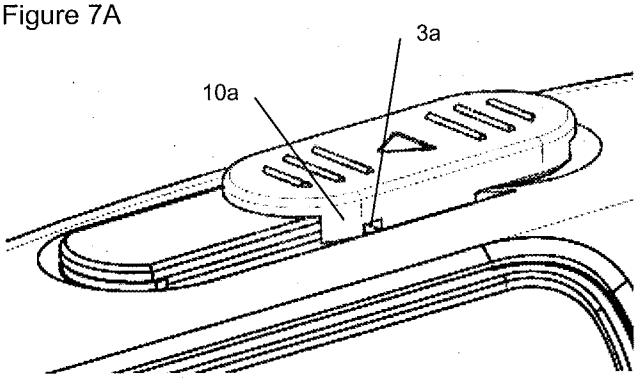

Figure 8

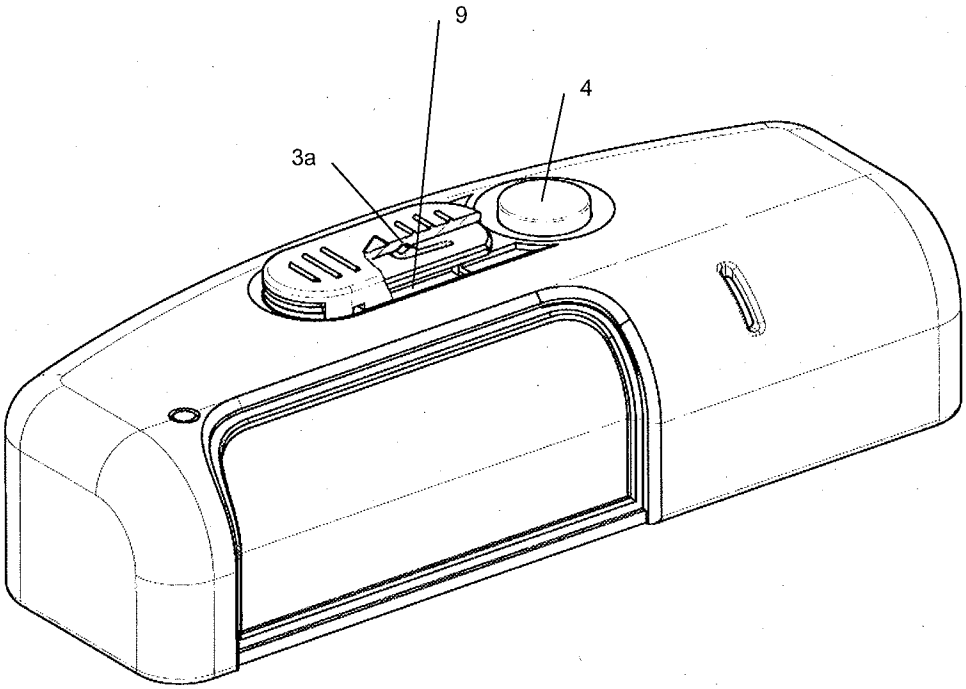

Figure 9A

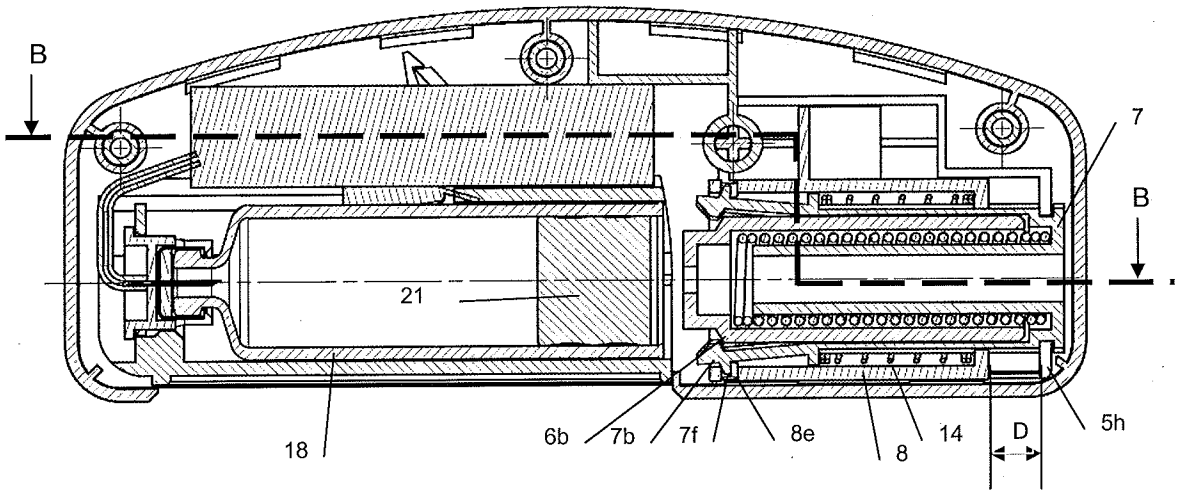

Figure 9B

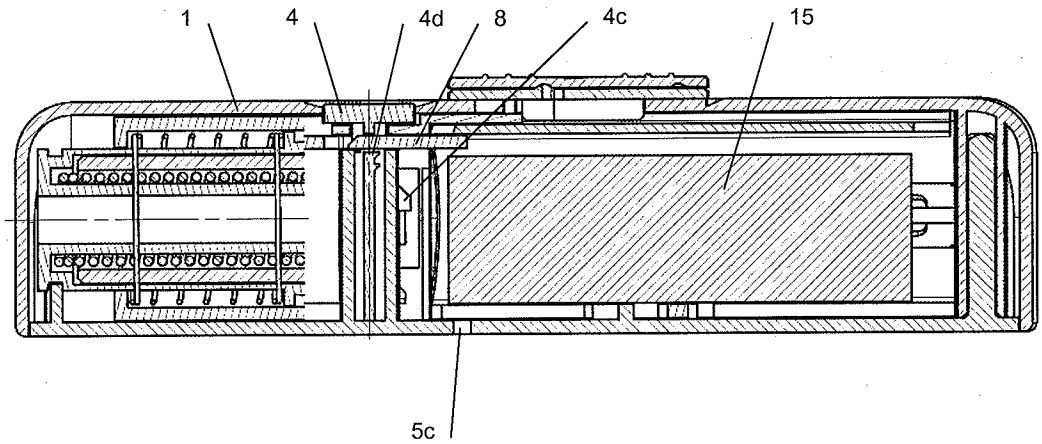

Figure 10A

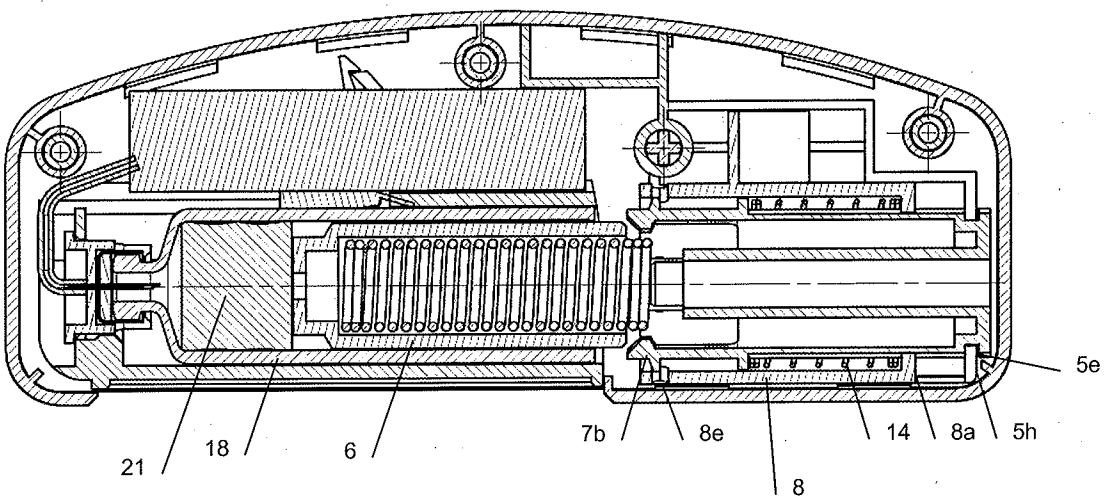

Figure 10B

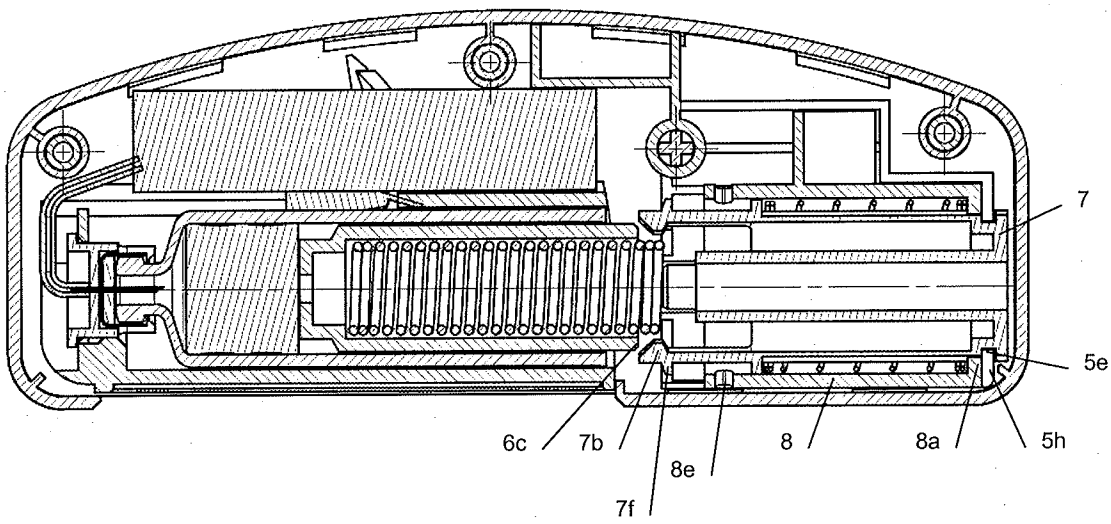

Figure 11A

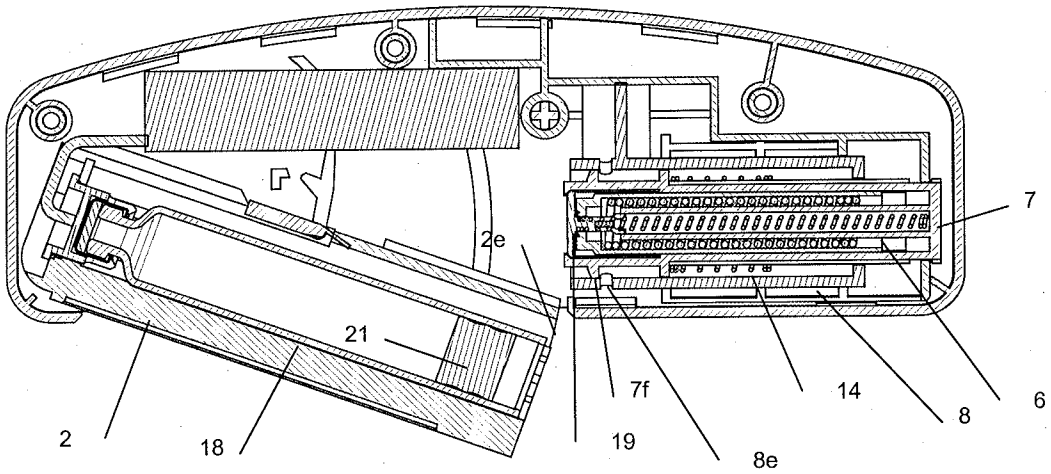

Figure 11B

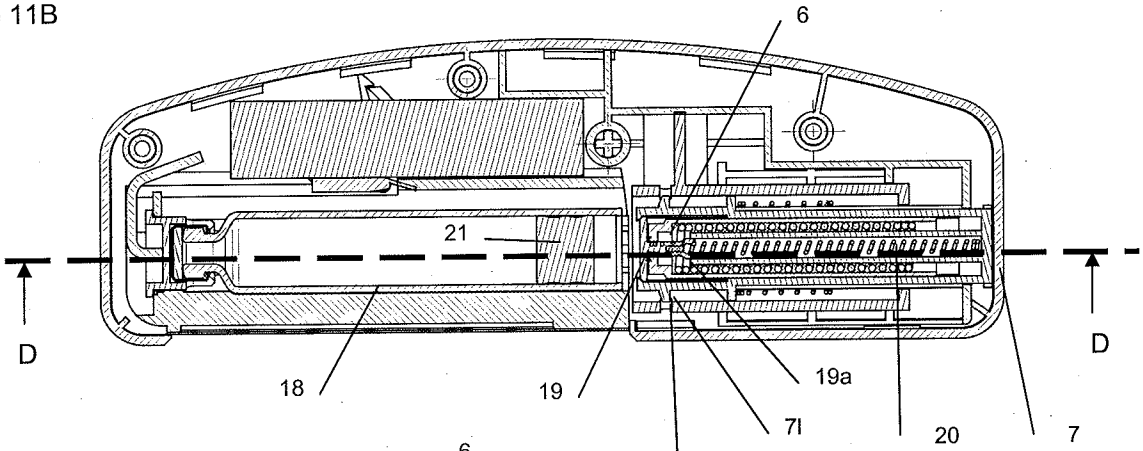

Figure 11C

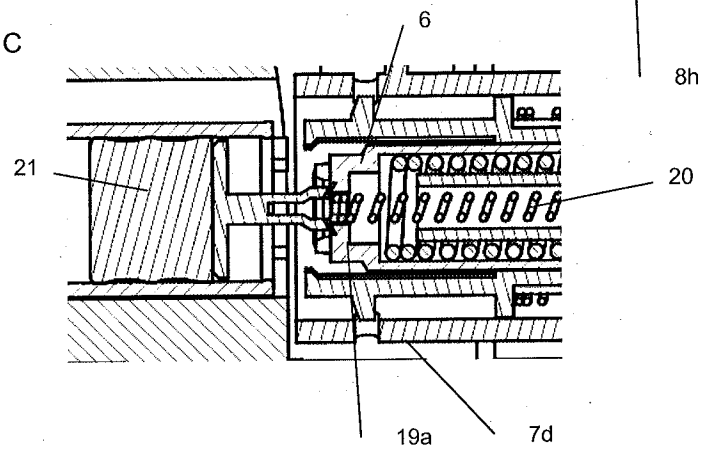

Figure 11D

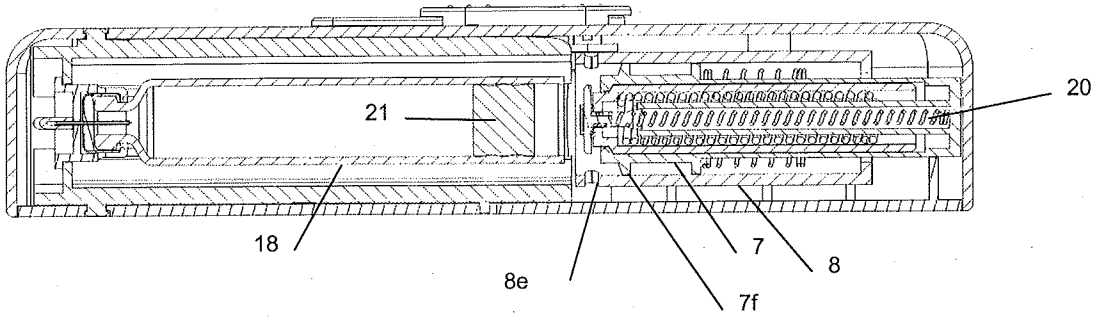

Figure 12

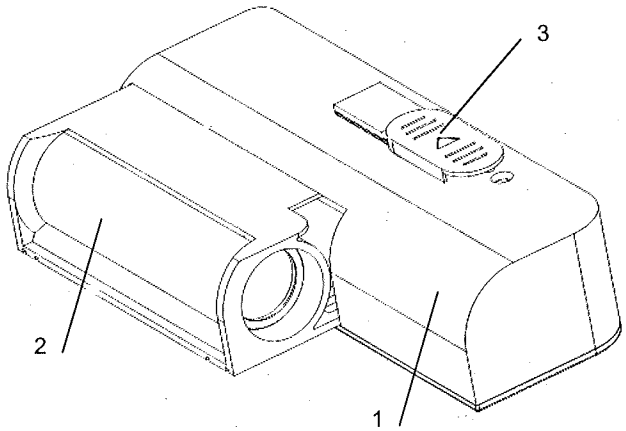

Figure 13A

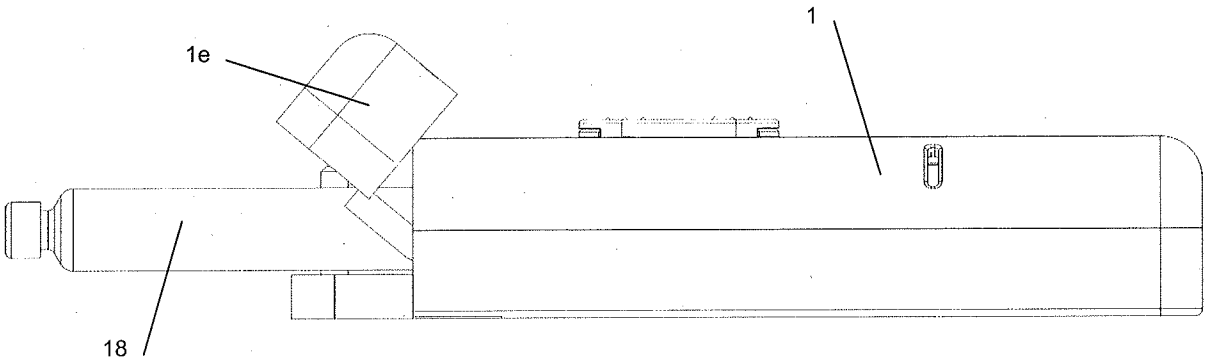

Figure 13B

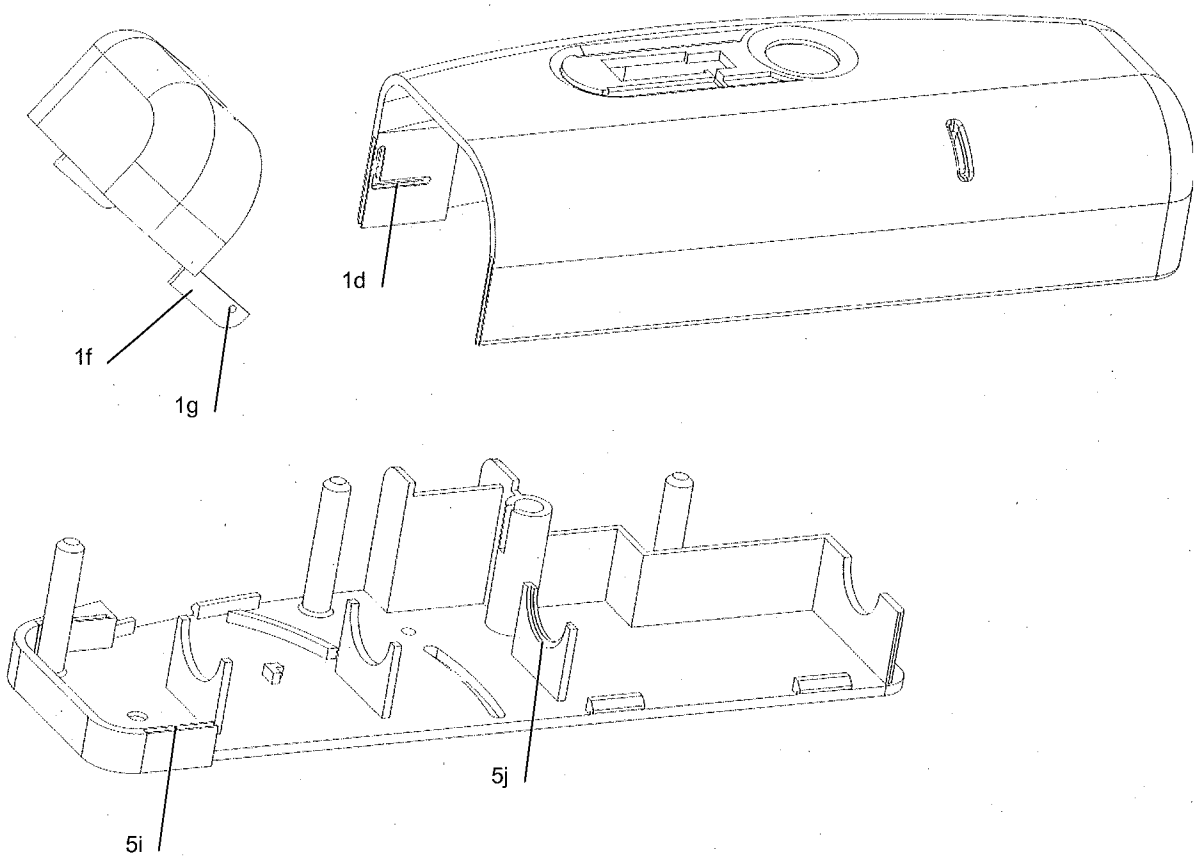

Figure 14A

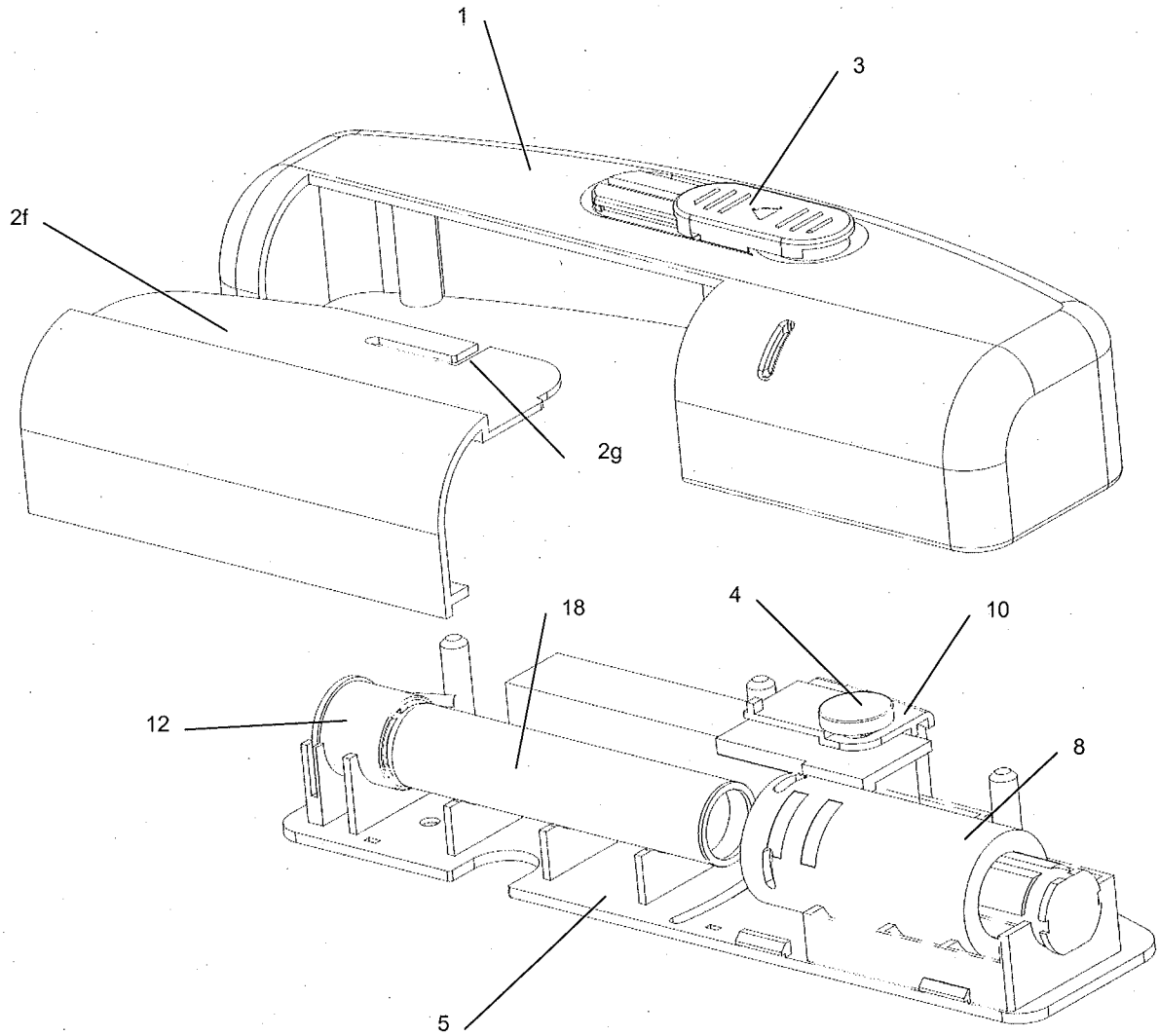

Figure 14B

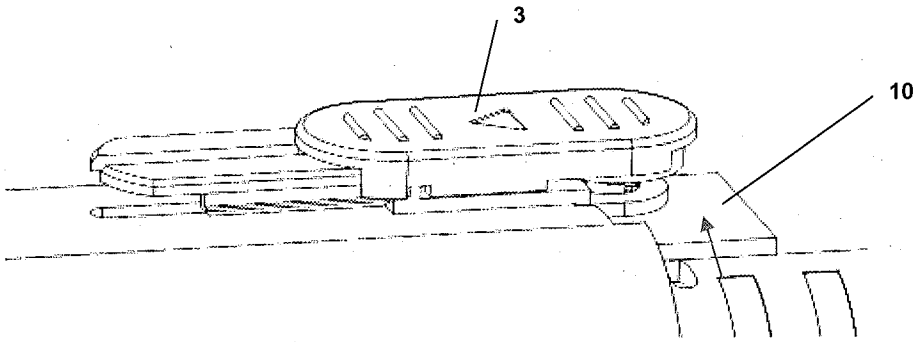

Figure 14C

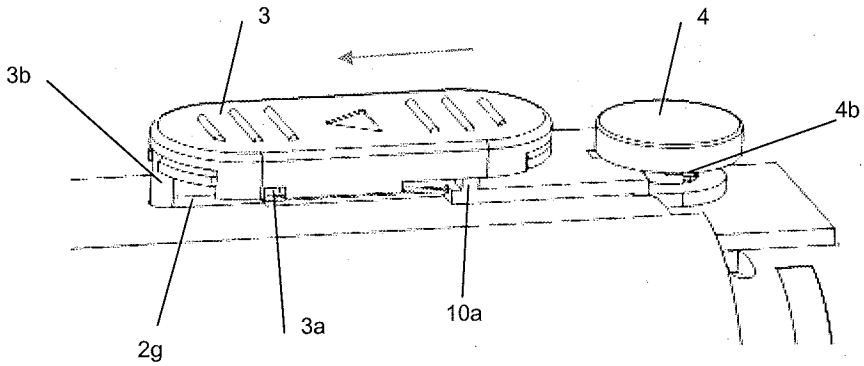

Figure 15A

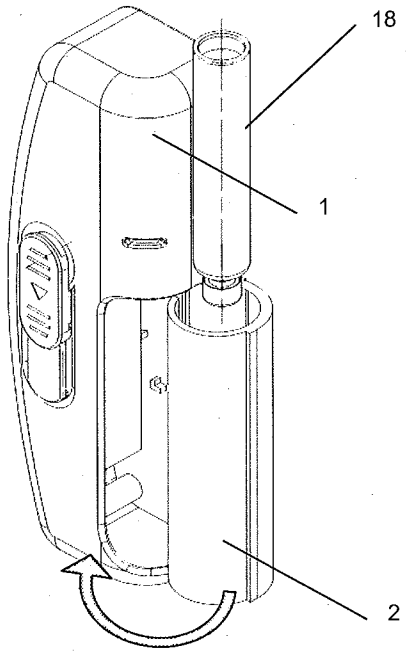

Figure 15B

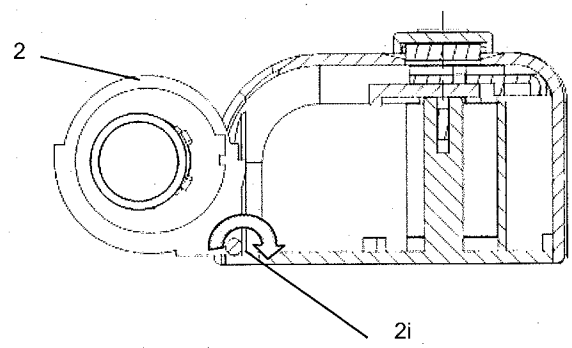

Figure 16A

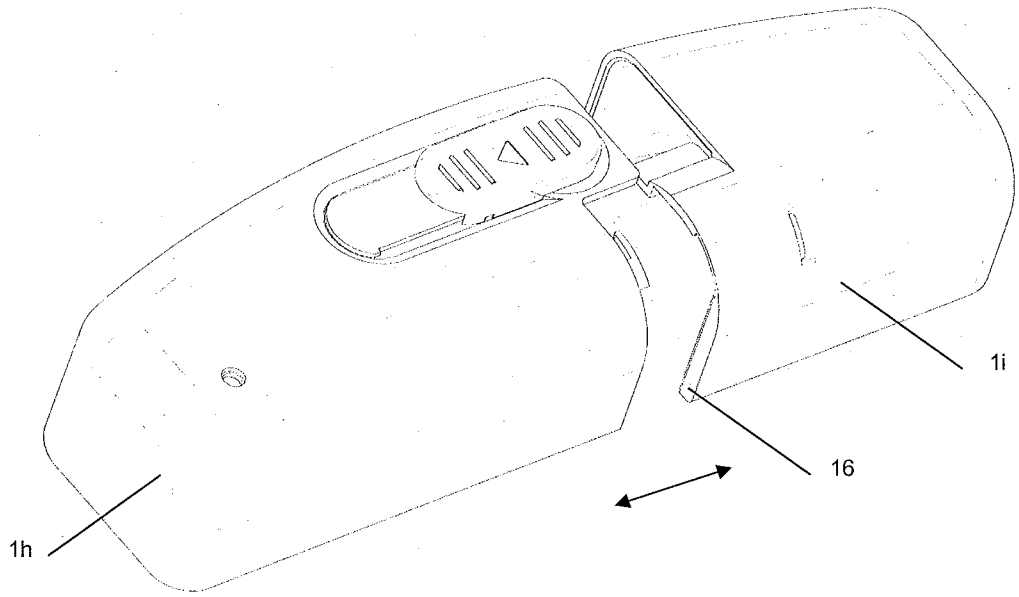

Figure 16B

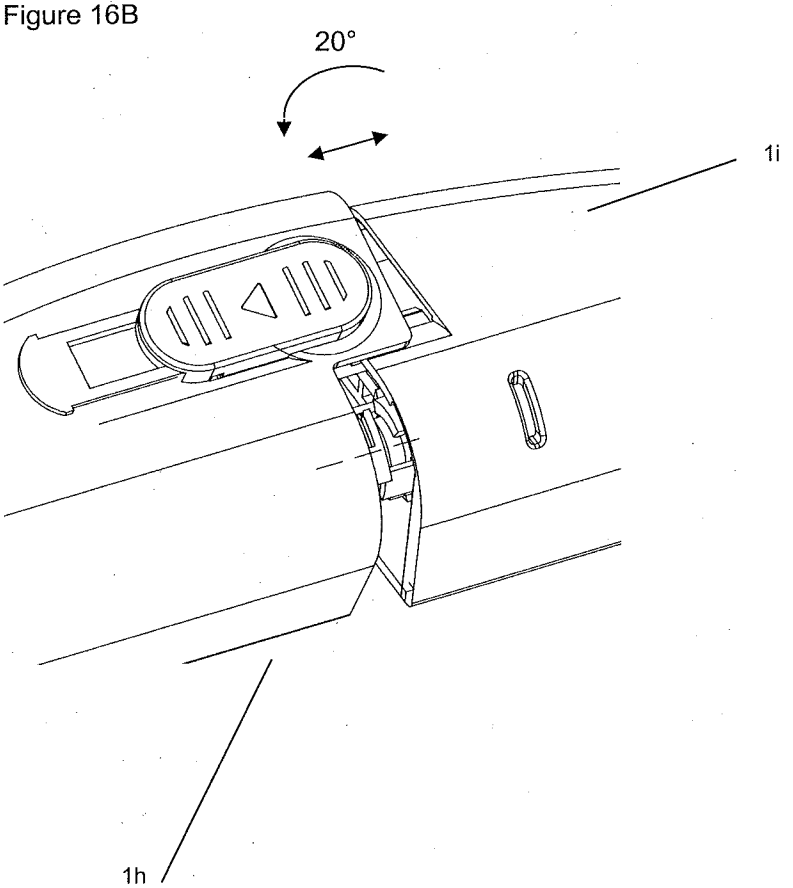

Figure 17A

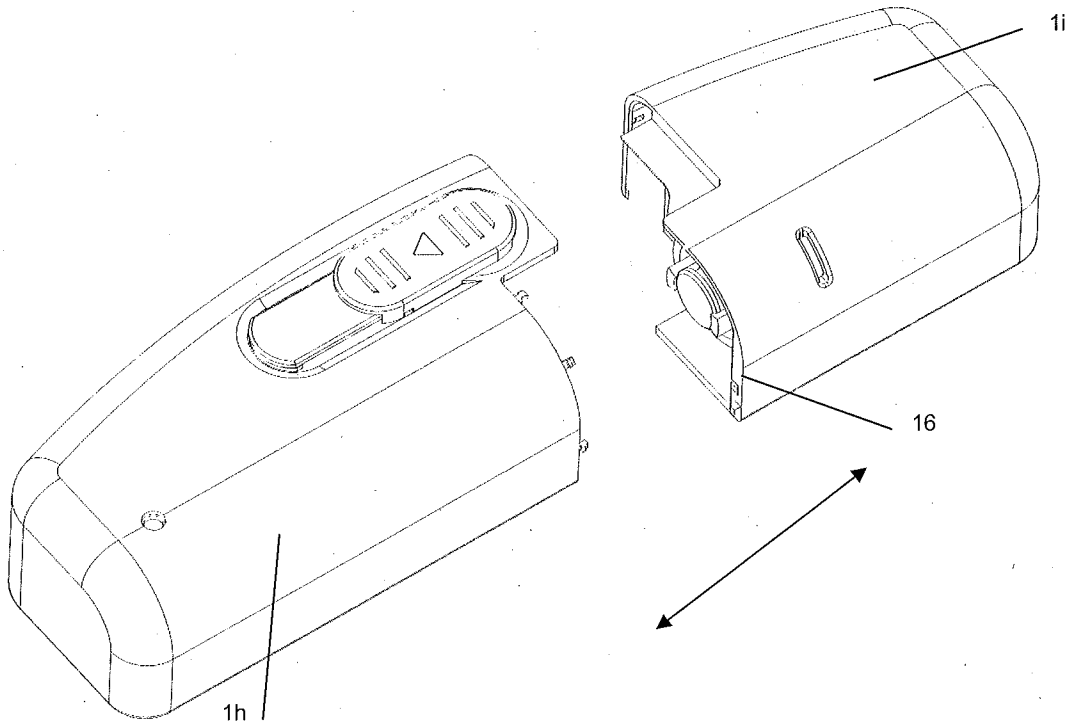

Figure 17B

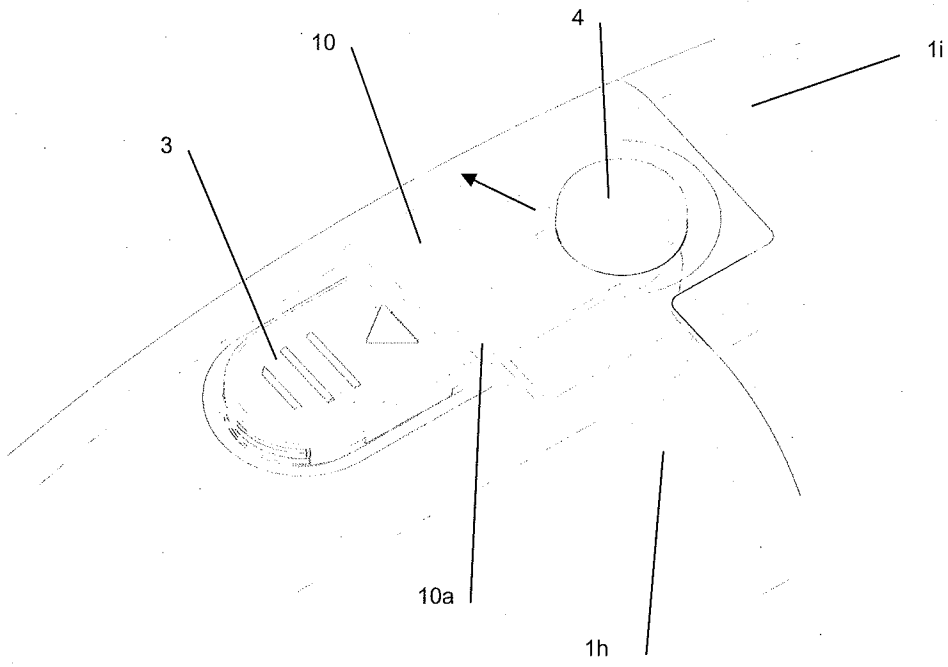

Figure 18A

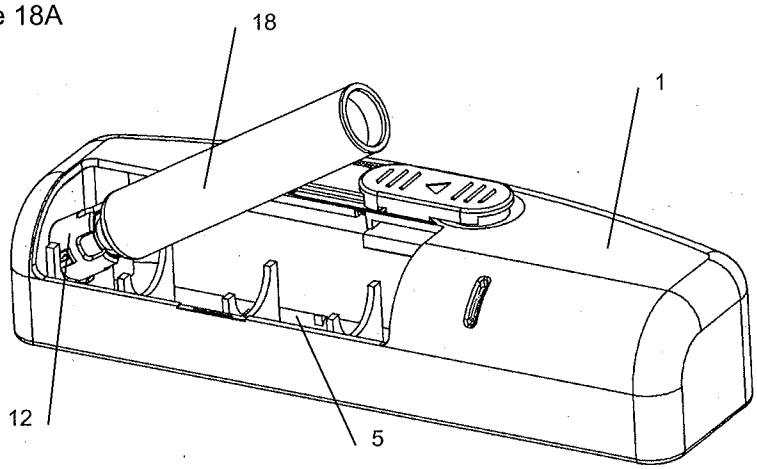

Figure 18B

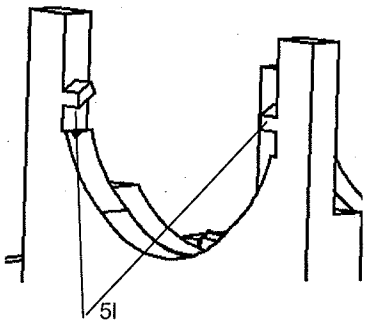

Figure 18C

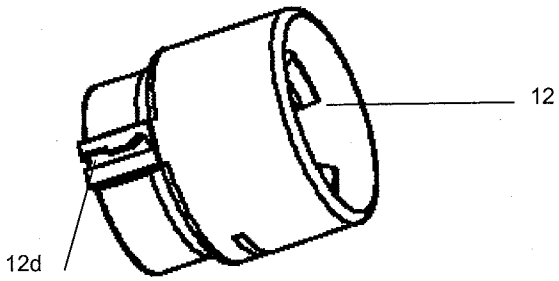

Figure 18D

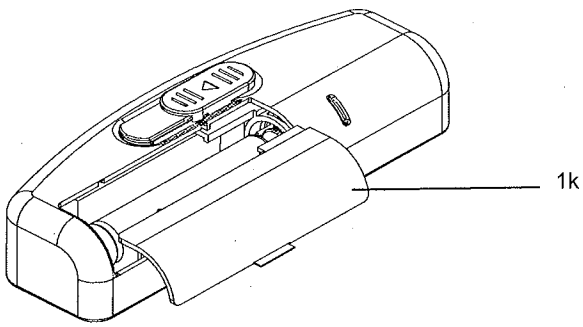

Figure 19A

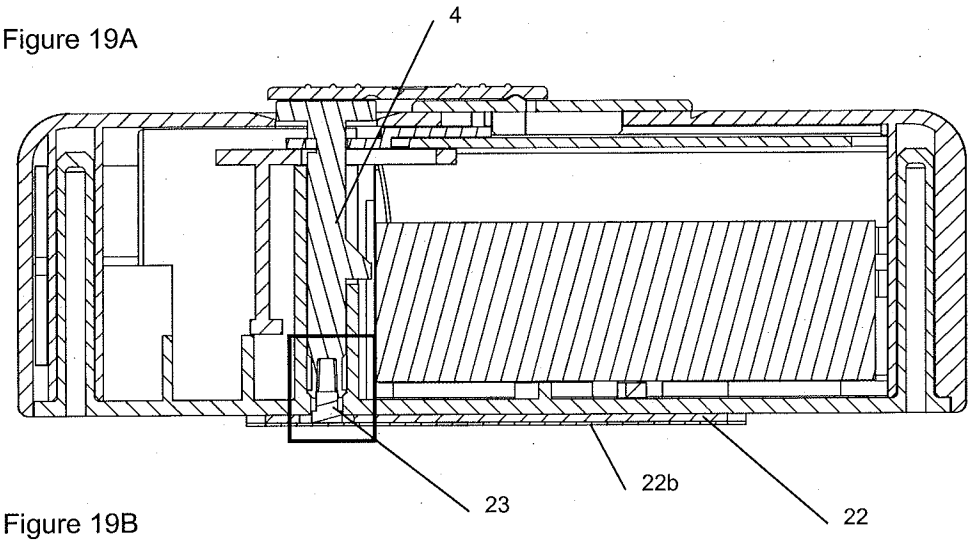

Figure 19B

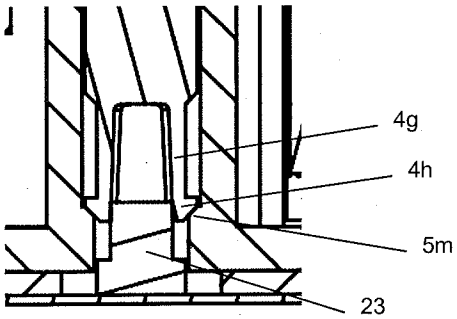

Figure 19C

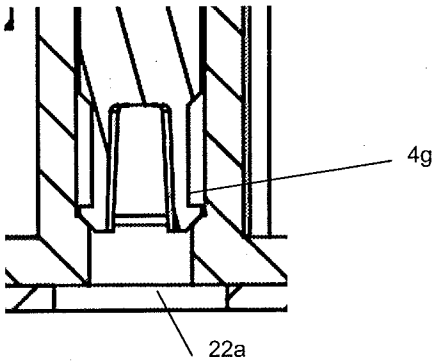

Figure 19D

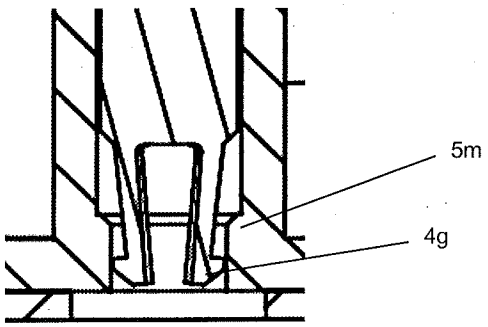

Figure 19E

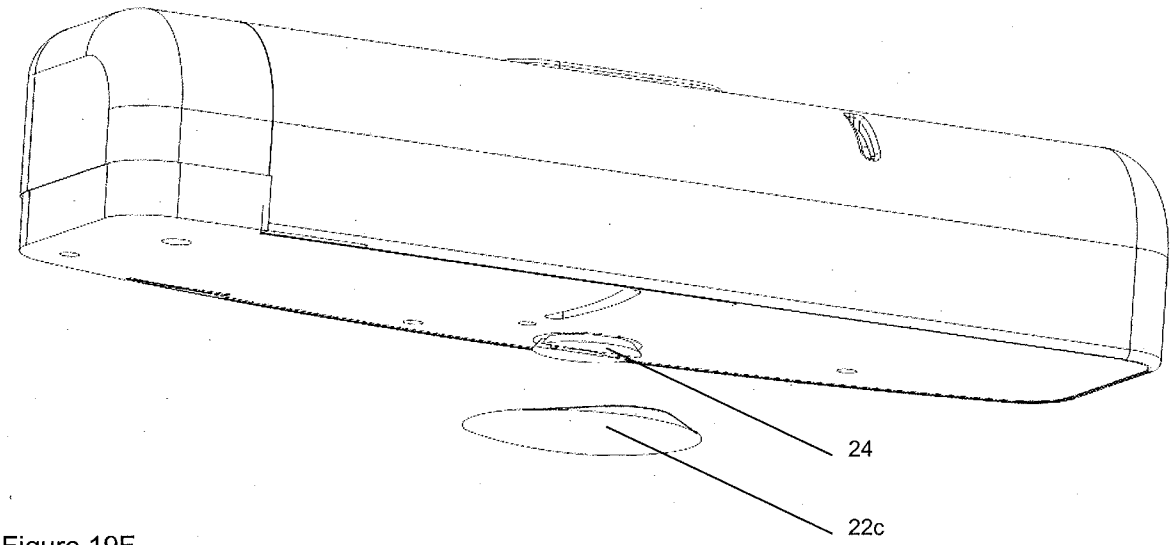

Figure 19F

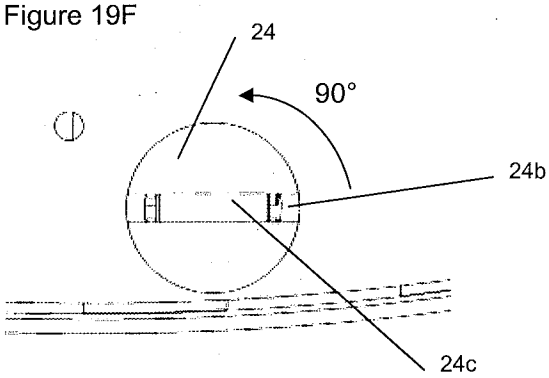

Figure 19G

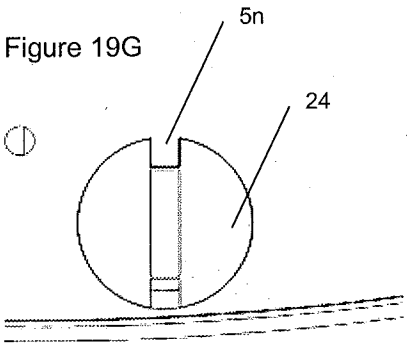

Figure 19H

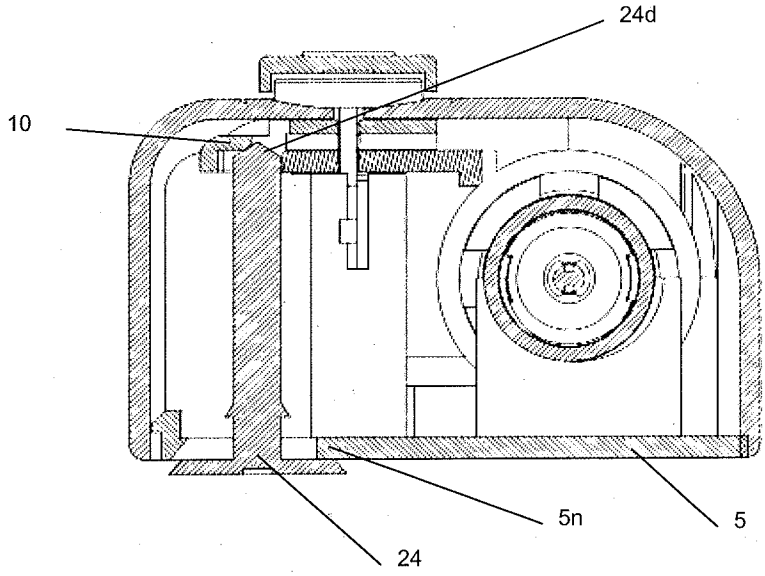

Figure 19I

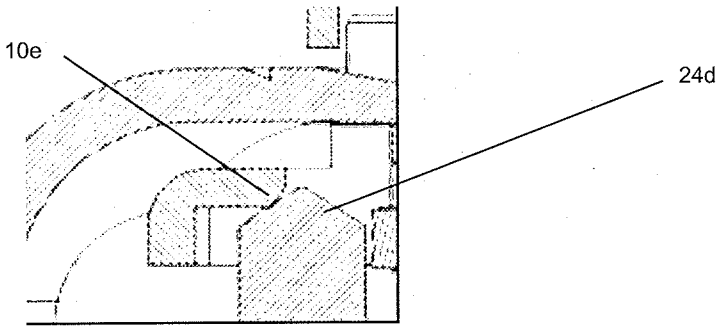

Figure 19J

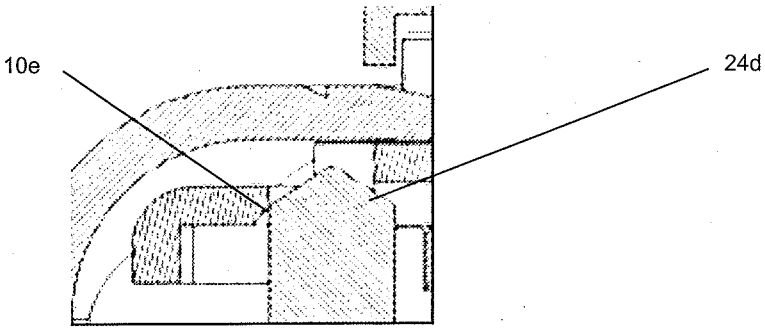

Figure 19K

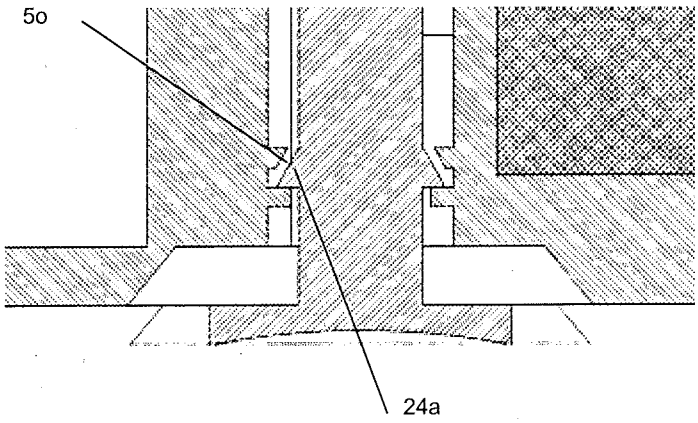

Figure 20A

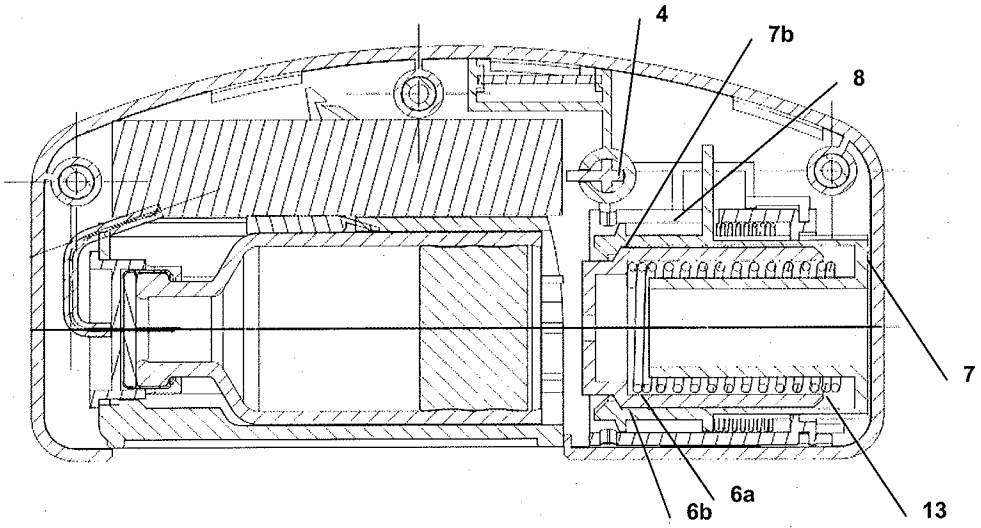

Figure 20B

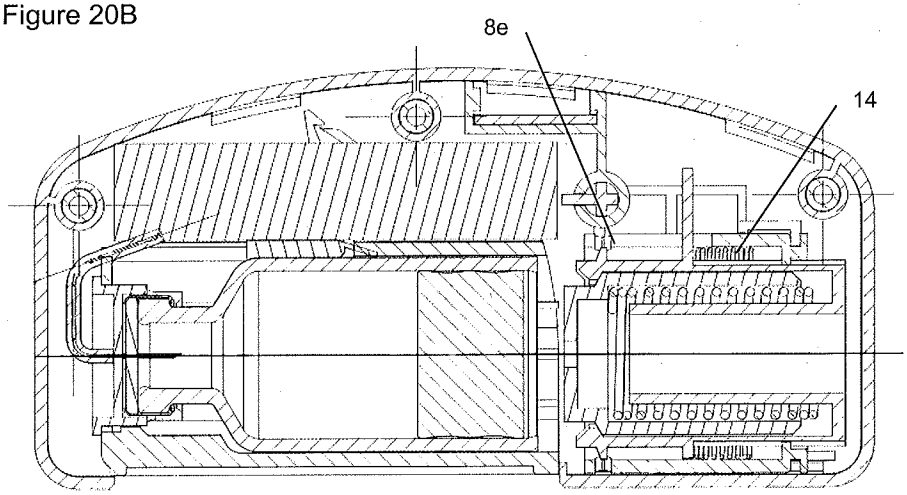

Figure 21A

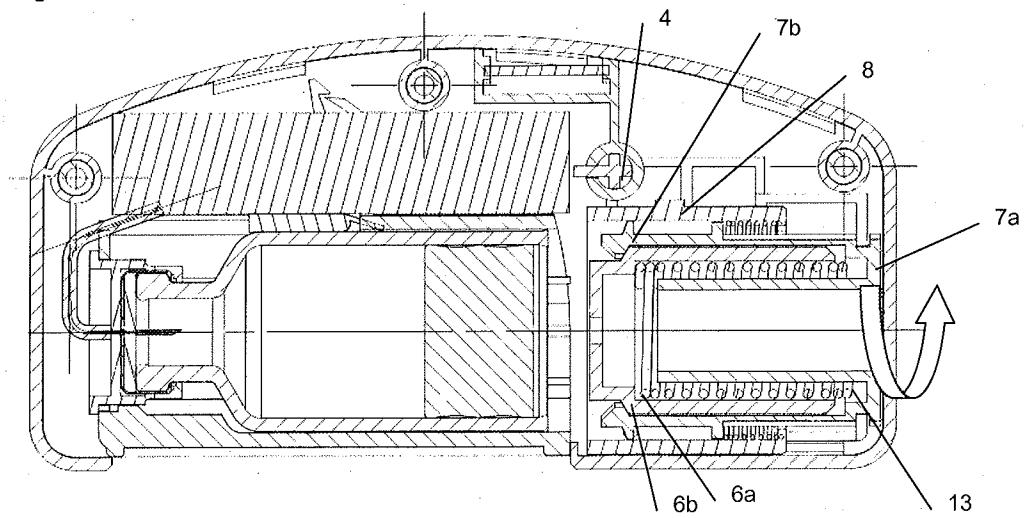

Figure 21B

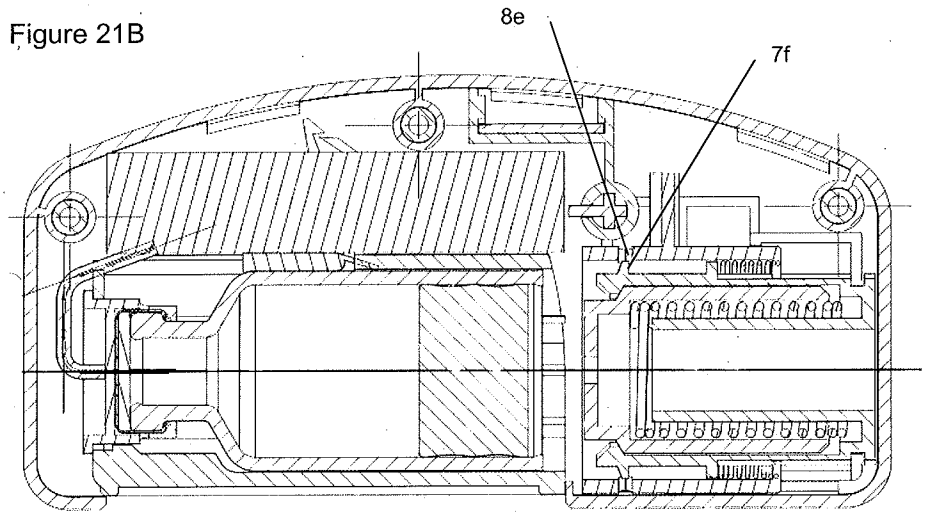

Figure 22A

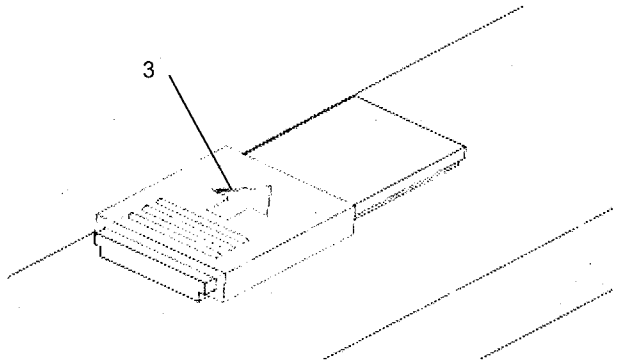

Figure 22B

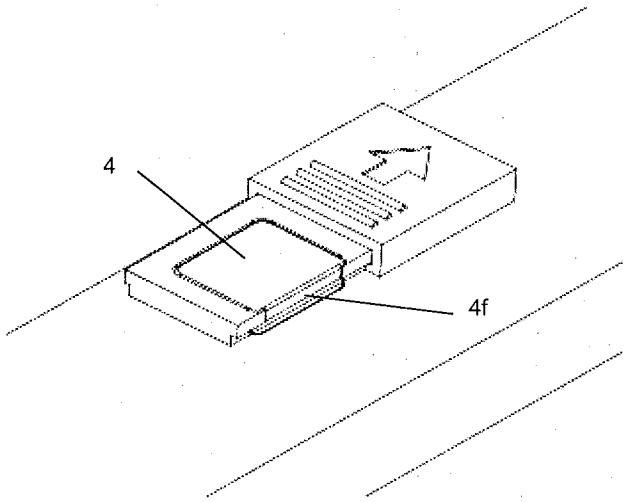

Figure 23A

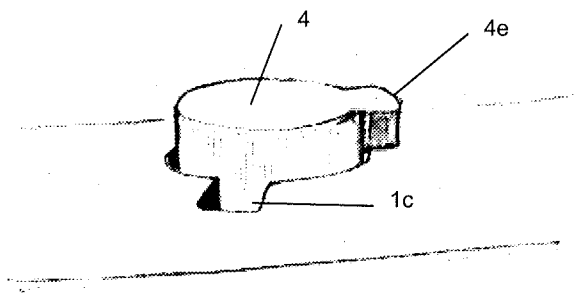

Figure 23B

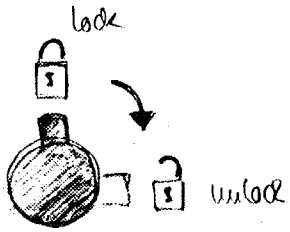

Figure 24A

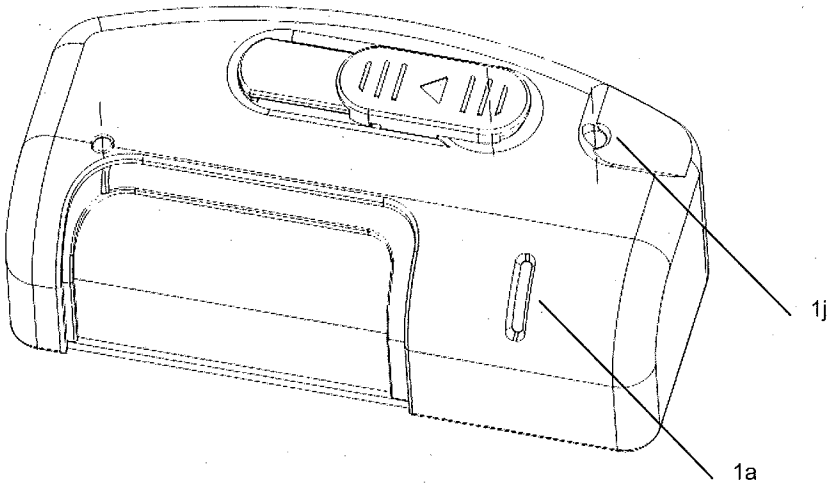

Figure 24B

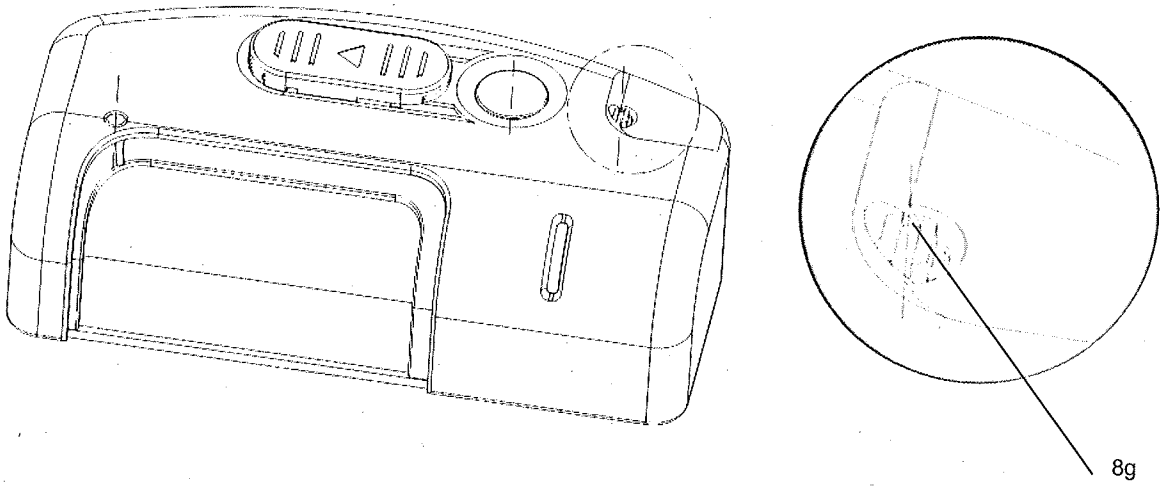

Figure 25A

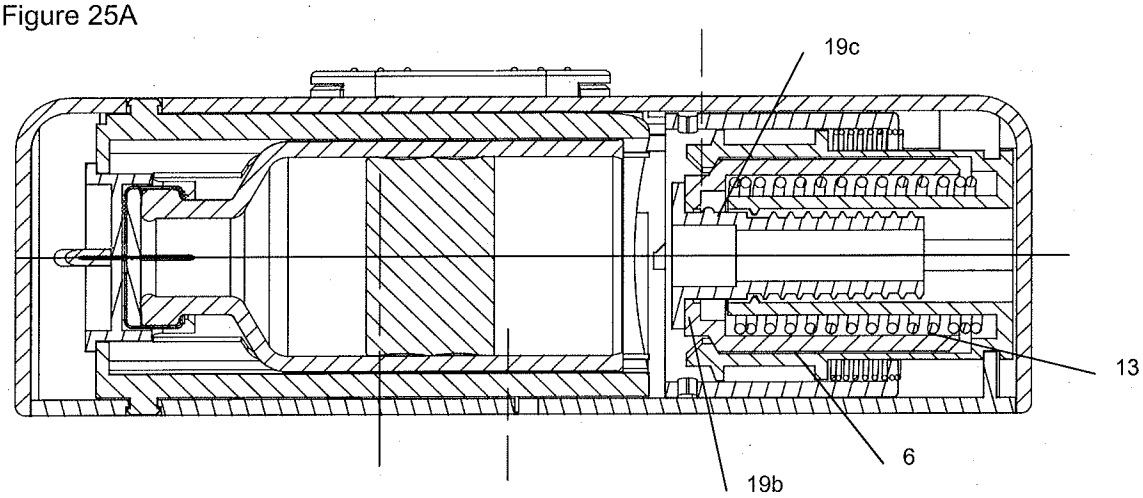

Figure 25B

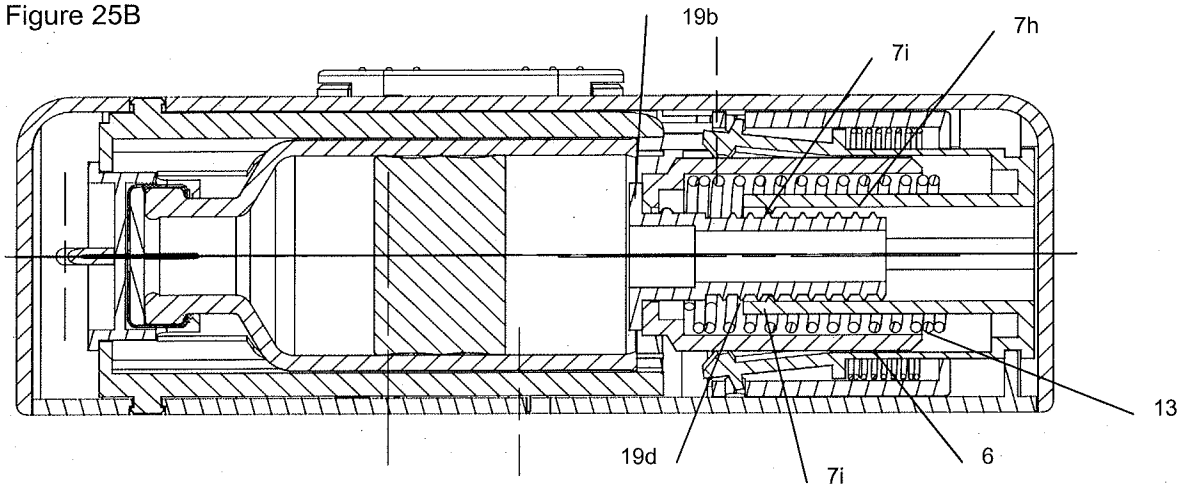

Figure 25C

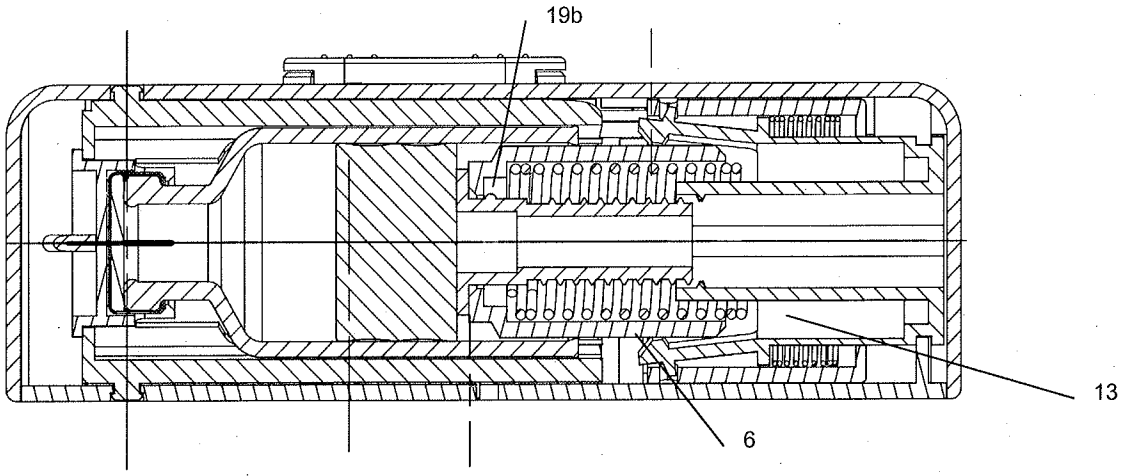

Figure 26A

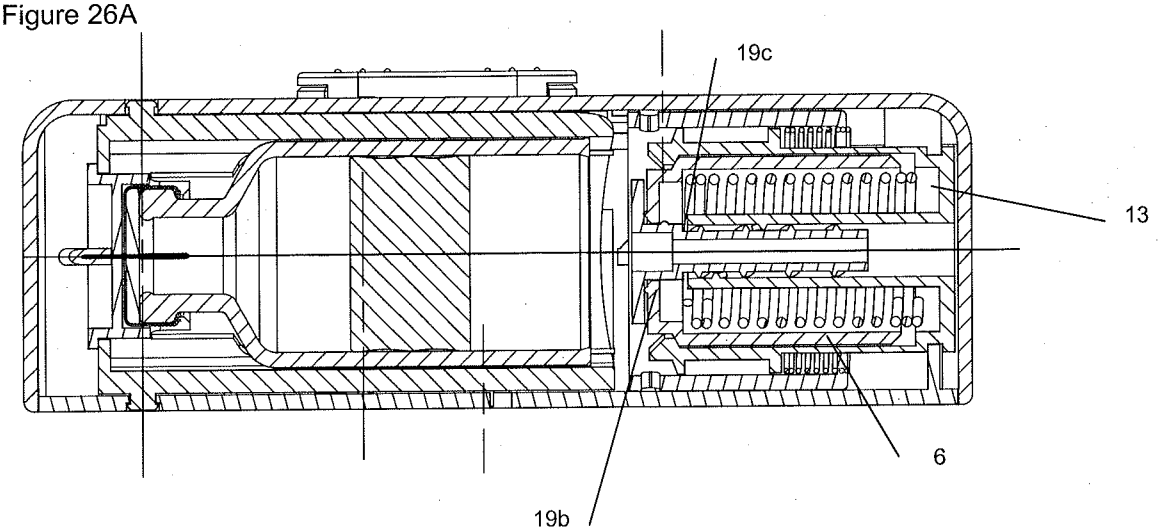

Figure 26B

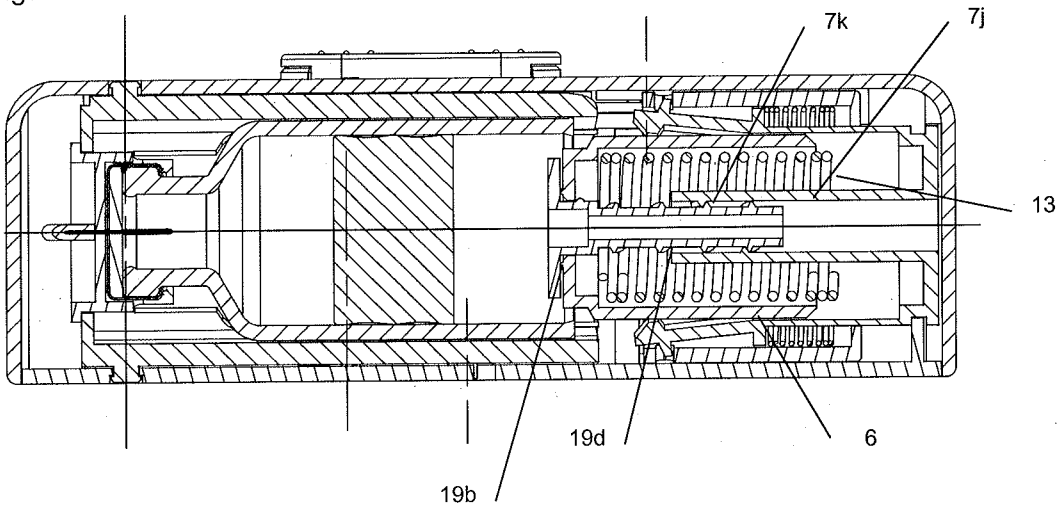

Figure 26C