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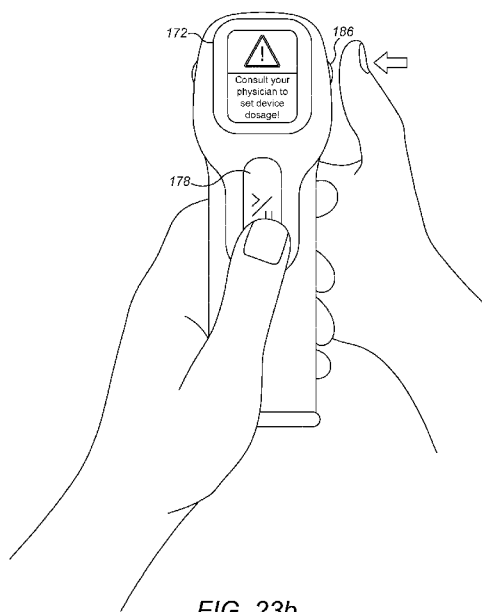
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FIG. 23b

(57) **Abstract:** Provided is a drive unit for an auto-injector. The drive unit comprises a cassette unit holder arranged for receipt of a cassette unit comprising a syringe. The cassette unit holder and cassette unit are movable from a rest position to a use position, in which the syringe is advanced. The drive unit comprises a drive arrangement for the cassette unit holder comprising an electrically powered source of axial drive; an electronic control unit; a display unit; arranged for display at said display unit, a first primary menu function for providing a menu of first control options to the electronic control unit; arranged for display at the display unit, a second hidden menu function for providing a menu of second control options to the electronic control unit; and a man machine interface for enabling the provision of one or more user input commands to the electronic control unit in response to one or more manual actions of a user. The first and second menu functions are arranged for alternate display at the display unit and wherein the second hidden menu function is accessible only in response to a particular series of input commands provided as a particular series of manual actions of a user to the man machine interface.

AUTO-INJECTOR AND DRIVE UNIT THEREFOR

Background

The present invention relates to an auto-injector device for receipt of a syringe that is suitable
5 for use in the injected delivery of a drug formulation to a patient.

It is well-known to use syringes for the delivery of injectable liquid drug formulation to a patient. Syringes rely on puncturing of the patient's skin by a hollow needle through which the injectable liquid drug (e.g. in solution or suspension form) is delivered to the muscle or
10 tissue of the patient. Typically, syringes comprise a barrel for containing a volume of the liquid drug; a hollow needle defining a needle tip for dispensing of the liquid; and a plunger that is axially movable within the barrel.

It is also well-known to provide auto-injectors for use with syringes. Such auto-injectors
15 typically comprise a body for housing the syringe and an actuating mechanism, which is triggered in use, to allow for automatic delivery of the liquid drug formulation from the syringe. Actuating mechanisms typically comprise a source of drive (e.g. a strong spring) for drivable movement of a drive transfer element (e.g. a plunger rod) that transfers drive to the plunger for axial movement thereof within the syringe barrel. Such movement of the plunger
20 results in the plunged driving of the liquid drug from the syringe barrel to the hollow needle for dispensing to the patient via the needle tip thereof.

For safety and hygiene reasons, it is desirable that the hollow needle does not protrude from the housing of the auto-injector other than when expelling the liquid drug formulation during
25 an injection procedure. Thus, auto-injectors have been developed in which, the housing is arranged such that a needle receiving part allows for the needle of the syringe to be axially moveable therein from a first (i.e. rest) position in which the hollow needle is shrouded by the needle receiving part to a second (i.e. use) position in which at least the tip of the needle protrudes from that needle receiving part of the housing for penetrating the skin of the patient
30 to an injection position. Only when the needle is at such injection position should it be possible for drug delivery to commence. Thus, auto-injectors have been developed which

provide a two stage actuating mechanism, which first acts to transfer drive force to move the syringe from the 'rest' to the 'use' position, and which only then secondly acts to transfer drive force to the plunger for expelling of liquid drug contents from the syringe barrel.

- 5 The majority of auto-injectors are configured as a single device that incorporates both syringe and actuating mechanism in the same device housing. It is common for such devices to be arranged to be disposable such that following injected delivery of the liquid drug formulation, and typically also following retraction of the syringe back into the housing, the whole device may be safely disposed of.

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Summary

It has been proposed to configure auto-injectors to include an electrically powered source of drive. Such configurations are particularly suitable for use by patients whose manual dexterity is so compromised (e.g. due to severe arthritis) that electrical powering is of real practical assistance. The use of electrically powered drive systems can also allow for more complex drive arrangements (e.g. two speed injection procedures) to be engineered. Furthermore, electrical powered devices can also be arranged to include electrical control systems and electronic data management systems including those that provide information and feedback to the patient by means of a suitable user interface.

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In some situations, it is undesirable for an electrically powered auto-injector to be fully disposable. Auto-injectors disclosed herein, in certain embodiments, include both a re-useable drive unit comprising an electrically powered source of axial drive and a cassette unit comprising a syringe, which releasably interfits with the drive unit and can be arranged to be disposable. The housing of the drive unit typically defines a docking cavity arranged for docking receipt of the cassette unit at a docking position. Such auto-injectors may be 'environmentally friendly,' where the majority of components are retained to be used for further injection procedures. It also allows for the drive unit to be fitted with additional features such as electronics, which may not be cost effective on a completely disposable device.

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Suitable cassette units typically comprise a cassette unit housing defining a cassette unit housing cavity and a needle projection aperture. The cassette unit housing cavity is arranged for receipt of a standard syringe. The cassette unit is also typically provided with a removable cap that fits over and thereby, acts such as to close off, the needle projection aperture.

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The drive unit suitably includes a drive arrangement comprising an electrically powered source of axial drive. In certain implementations, the drive unit includes a first drive transfer element for transferring the axial drive to the cassette unit for advancing the syringe to said use position, and a second drive transfer element for subsequently transferring the axial drive to the plunger of the syringe for moving the plunger into the barrel of the syringe to eject at least part of the volume of liquid drug formulation.

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The drive unit suitably comprises a drive unit housing defining a housing cavity and a needle delivery aperture and within said housing cavity, a cassette unit holder arranged for receipt of the cassette unit comprising a syringe and having a removable cap. The cassette unit holder and the cassette unit received thereby are movable from a rest position to a use position, in which the syringe is advanced towards the needle delivery aperture.

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The drive unit is generally provided with electronic control functions and means of providing user input thereto, which may be menu-driven. Thus, the drive unit suitably comprises an electronic control unit; a display unit arranged for display of a menu function for providing a menu of first control options to the electronic control unit; and a man machine interface (e.g. comprising one or more buttons, scroll wheels, or a touch screen) for enabling the provision of one or more user input commands to the electronic control unit in response to one or more manual actions of a user. In normal use of the drive unit, the user therefore accesses the menu function and provides user input commands manually via the elements of the man machine interface.

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Typically, the electronic control unit enables the drive unit to be set up to provide various dose regimen (e.g. for different drug types depending on the target therapy area, region of

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injection, severity of symptoms, amongst other factors) to match patient's needs depending on what their physician recommends or their condition.

Applicant has appreciated that such setting of dose regimen requires expert knowledge and is therefore typically carried out only by a healthcare provider (e.g. doctor). It is desirable for the drive unit to allow for a convenient means for the healthcare provider to provide such dose regimen setting input to the electronic control unit in a manner which is generally inaccessible to the patient and hence, cannot be altered (e.g. accidentally) by the patients.

Applicant has therefore devised a drive unit including a second hidden menu function accessible only using a particular series of manual inputs to the man machine interface (MMI) of the drive unit. The first primary menu and second hidden menu functions are arranged for alternate display at the display unit. The hidden menu is designed for access solely by a healthcare professional to whom only the particular series of manual inputs are provided. Once accessed, the hidden menu allows the healthcare professional to set or configure a specific dose regimen. The hidden menu is not intended to be accessible to patients or to lay users, so the particular series of manual inputs is suitably arranged to be relatively complex (e.g. comprising a series of three or more distinct manual input actions).

According to one aspect of the present invention there is provided a drive unit for an auto-injector comprising:

- a drive unit housing defining a housing cavity and a needle delivery aperture;

- within said housing cavity, a cassette unit holder arranged for receipt of a cassette unit comprising a syringe, wherein said cassette unit holder and said cassette unit receivable thereby are movable from a rest position to a use position, in which said syringe is advanced towards said needle delivery aperture;

- a drive arrangement for the cassette unit holder, said drive arrangement comprising one or more electrically powered sources of axial drive;

- an electronic control unit;

- a display unit;

arranged for display at said display unit, a first primary menu function for providing a menu of first control options to said electronic control unit;

arranged for display at the display unit, a second hidden menu function for providing a menu of second control options to the electronic control unit; and

5 a man machine interface for enabling the provision of one or more user input commands to the electronic control unit in response to one or more manual actions of a user,

wherein said first and second menu functions are arranged for alternate display at the display unit and wherein said second hidden menu function is accessible only in response to a particular series of input commands provided as a particular series of manual actions of a user
10 to the man machine interface.

In embodiments, the first menu function is for normal patient use of the drive unit.

15 In embodiments, the second hidden menu function is for configuration of a dose regimen.

In embodiments, the particular series of manual actions comprises a series of two (e.g. three) or more distinct (e.g. different) manual actions.

20 In embodiments, the man machine interface is selected from a keypad; a touch screen; a button; a toggle; a scroll wheel; and any combination thereof. In embodiments, the button is selected from go/pause button and power on/off button.

In embodiments, the first and second menu options are selected from drug dose options; drug dose scheduling options; drug target therapy area options; and any combinations thereof.

25 In embodiments, in normal patient use of the drive unit, the first menu function is the 'default' option. In embodiments, in normal patient use of the drive unit, the first menu function is accessible either automatically or in response to a single input command provided as a single manual action of a user to the man machine interface.

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In embodiments, on first use of the drive unit, a message is displayed at the display screen prompting configuration of a dose regimen via access to the second hidden menu function.

5 In embodiments, exiting from the second hidden menu function is in response to a particular series of input commands provided as a particular series of manual actions of a user to the man machine interface. In different embodiments, the series of input commands for exiting the second hidden menu function either correspond to or differ from those input commands employed to access the hidden menu function. In embodiments, exiting from the second hidden menu function is by switching off the power to the drive unit (e.g. by pressing a
10 'power off' button).

In embodiments, the second hidden menu function has a multi-layer (e.g. two or three layer) hidden menu structure. In embodiments, each layer of the hidden menu structure of the second hidden menu function is accessible only in response to a particular series of input
15 commands provided as a particular series of manual actions of a user to the man machine interface. In embodiments, each different layer of the hidden menu structure of the second hidden menu function is accessible only in response to a particular different series of input commands provided as a particular different series of manual actions of a user to the man machine interface. In embodiments, the multi-layer structure of the second hidden menu
20 function provides an additional security measure.

In embodiments, the drive unit will only allow injected use thereof using a cassette unit comprising a syringe following configuration of a dose regimen via access to the second hidden menu function. In embodiments, in these circumstances, the display unit displays a
25 prompt for a healthcare professional to configure a dose regimen.

In embodiments, in the absence of configuration of a dose regimen via access to the second hidden menu function, the drive unit will only allow training use thereof making use of a training cassette unit that comprises no syringe. In embodiments, the training cassette unit is
30 arranged to be of equivalent size and shape to that of a cassette unit comprising a syringe. Suitable training cassette units are described in Applicant's GB publication GB2,524,525 A1

and GB application no. GB1604065.1, the contents of all of which are incorporated by reference in their entirety and made part of this application.

5 In embodiments, the drive unit additionally comprises one or more cassette unit detection sensors for detecting the presence of the cassette unit within the drive unit, and capable of sending a cassette unit detection signal to said electronic control unit; and one or more cap detection sensors for detecting the presence of the removable cap on the cassette unit, and capable of sending a cap detection signal to the electronic control unit.

10 In embodiments, the electronic control unit is capable of collating the cassette unit detection and cap detection signals to determine an overall detected state of the cassette unit.

In embodiments, the electronic control unit is provided with a decision algorithm that decides upon and signals a control action dependent upon the overall detected state of the cassette
15 unit. Where no corrective action is necessary the control action may simply signal that 'all is fine'. Otherwise, corrective action of a suitable type may be signalled.

In embodiments, the decision algorithm references different decision making parameters or routines dependent upon whether an injection procedure has started or not.
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In embodiments, the decision algorithm references different decision making parameters or routines dependent upon whether a cassette unit ejection procedure has started or not.

In embodiments, the drive unit additionally comprises a display unit, wherein the electronic
25 control unit is capable of sending a command to the display unit to display a message when a particular overall cassette unit state is determined, said message being relevant to said particular determined overall cassette unit state. Where no corrective action is necessary the message may simply signal that 'all is fine'. Otherwise, where corrective action is necessary, a suitable advisory or warning message may be displayed.

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In embodiments, the electronic control unit is capable of sending an emergency stop or abort command to the drive arrangement when an unacceptable overall cassette unit state is determined.

- 5 In embodiments, the drive unit additionally comprises a USB data input port for connecting the drive unit to an electrical charger or to a personal computer.

10 In embodiments, the electronic control unit is capable of detecting electrical current flow at the USB data input port. In embodiments, the electronic control unit differentiates between whether the drive unit is connecting to an electrical charger or to a personal computer.

15 In embodiments, the electronic control unit is provided with a second decision algorithm that decides upon and signals a control action dependent upon both the overall detected state of the cassette unit and the detection or not of current flow at the USB data input port.

In embodiments, the cassette unit detection sensor detects whether the cassette unit is fully loaded into the cassette unit holder of the drive unit or not.

20 In embodiments, any or each cassette unit detection sensor or cap detection sensor has the form of a micro-switch.

In embodiments, the drive unit comprises one or more encoders to detect the position and movement characteristics of the movable parts of the drive unit.

- 25 In embodiments, the drive unit comprises a cassette unit holder motor encoder to detect the linear position and speed of the cassette unit holder.

In embodiments, the drive unit comprises a drive arrangement motor encoder to detect the linear position and speed of the drive arrangement.

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In embodiments, the electronic control unit is capable of combining (e.g. pairing) data from any of the sensors and/or encoders.

In embodiments, the electronic control unit is provided with a third decision algorithm that decides upon and signals a control action dependent upon the combined data from any of the sensors and/or encoders. In embodiments, the third decision algorithm decides upon and signals a control action dependent upon the combined data from any of the sensors and/or encoders; and the overall detected state of the cassette unit, or the detection or not of current flow at the USB data input port, or both of these.

In embodiments, the drive arrangement comprises

a first drive transfer element for transferring said axial drive to the cassette unit and/or to the syringe for advancing the syringe to said use position; and

a second drive transfer element for subsequently transferring the axial drive to the plunger of the syringe for moving the plunger into the barrel of the syringe to eject at least part of said volume of liquid drug formulation.

According to another aspect of the present invention there is provided a method of use of the drive unit described herein.

According to another aspect of the present invention there is provided an auto-injector comprising

- (a) a cassette unit; and
- (b) a drive unit.

These and other embodiments are set forth in the later description, which describes for illustrative purposes only various embodiments thereof.

In relation to aspects of the auto-injector device described herein the term 'forward' is used to mean that end of the device, which locates closest to the injection site in use (i.e. the needle tip end) and the term 'rear' or 'rearward' is used to mean that end of the device, which

locates furthest from the injection site in use. The term axial herein is used by reference to an axis, which runs from the forward end of the device to the rearward end of the device, and which typically corresponds to the axis of the syringe.

- 5 There is provided an auto-injector device that is arranged for use with a syringe that contains a liquid drug formulation. The syringe is arranged to be suitable for use in the injected delivery of the liquid drug formulation to a patient.

The auto-injector comprises both a drive unit and a cassette unit receivable by the drive unit.

- 10 The individual drive unit and cassette unit parts thereof comprise further separate aspects of the present invention. In embodiments the drive unit and cassette unit are provided as a kit of parts.

- 15 Auto-injectors comprising both a drive unit comprising an electrically powered source of axial drive and a cassette unit comprising a syringe, which releasably interfits with the drive unit already have been described in Applicant's PCT publications WO2012/164,390; WO2012/164,402; WO2012/164,404; WO2012/164,389; WO2012/164,397; WO2012/164,394; WO2013/001378; WO2012/164,406; WO2012/164,403; WO2014/019,997; WO2014/019,999; WO2014/020,000; WO2014/020,001; 20 WO2014/066,256; WO2015/110,533; WO2015/110,532 and WO2015/110,529, the contents of all of which are incorporated by reference in their entirety and made part of this application.

25 *Cassette unit*

The cassette unit comprises a cassette unit housing defining a cassette unit housing cavity.

The cassette unit housing cavity is arranged for receipt of a syringe and is therefore typically sized and shaped for this purpose. The cassette unit housing may be arranged as a single part or a multi-part (e.g. two part) cassette unit housing assembly.

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In embodiments, the syringe is held in generally fixed fashion within the cassette unit housing. In other embodiments, the syringe is movable within the cassette unit housing such as in a direction parallel with or along the drive axis.

In embodiments, wherein the syringe is held in generally fixed fashion within the cassette unit housing, at least the needle tip of the syringe normally protrudes out of the cassette unit housing cavity such as from a needle projection aperture thereof.

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In other embodiments, the syringe is movable within the cassette unit housing from a first position, in which the needle tip of the syringe is within the cassette unit housing to a second position, in which at least the needle tip protrudes from a needle projection aperture thereof.

- 10 The syringe that is receivable within the cassette unit housing cavity comprises a syringe barrel for holding a volume of the liquid drug formulation; a hollow needle at a front end of the barrel, the hollow needle defining a needle tip for dispensing of said liquid drug formulation; and a plunger (e.g. in the form of a rubber stopper) that is axially movable within the syringe barrel. The syringe plunger is movable axially within the barrel so as to
- 15 enable the liquid drug formulation to be expelled from the barrel and thence through the hollow needle via the dispensing tip for injection into the patient. The syringe barrel is typically comprised of glass but may also be comprised of a relatively hard plastic polymer such as hardened polyethylene, polycarbonate or cyclic olefin polymers.
- 20 In embodiments, the plunger is comprised of a natural or synthetic polymer friction material, which frictionally interacts with the side wall of the syringe barrel. Suitable plunger materials include natural or synthetic rubbers or elastomeric materials.

- In more detail, the syringe barrel is selected such as to define a barrel chamber for containing
- 25 a suitable volume of the liquid drug formulation. In embodiments, that suitable volume is selected to correspond to a single dose of the drug formulation to be delivered to the patient. In other words, delivery of that single dose involves expelling all of the liquid drug formulation contents of the barrel chamber through the hollow needle for injection into the patient.

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In embodiments, the rear end of the syringe barrel is provided with an end flange. In embodiments, the forward end of the syringe barrel is shaped to provide a shoulder. In embodiments, forward of that shoulder the syringe narrows further into a neck, which typically forms the needle-holding part thereof.

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In embodiments, the needle barrel is provided with a barrel sleeve that is arranged to fit over part or all of the length of the needle barrel. The barrel sleeve may also extend out beyond the syringe barrel to wholly or partly enclose a length of the forward shoulder of the syringe barrel and of the hollow needle that extends from (the forward shoulder) of the syringe barrel.

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In embodiments, the cassette unit is arranged to accommodate multiple syringe sizes. Common sizes of syringe include the 2.25 ml syringe and the 1ml 'long' syringe, which has a smaller syringe barrel diameter.

15 In embodiments, accommodation of multiple syringe sizes within the same cassette unit geometry is achievable by providing suitable adapters to the barrel of the syringe. In embodiments, sleeve form adapters are employed.

20 In embodiments, the sleeve form adapter is arranged for receipt by the syringe barrel and fits at least partly over the flange of the rear end of the syringe barrel. In embodiments, the sleeve adapter is arranged for snap fitting over the end flange of the syringe. In embodiments, the flange is effectively capped by the relevant 'end flange' part of the sleeve form adapter.

25 In embodiments, a major portion of the syringe barrel and end flange thereof is in use, sleeved by the sleeve form adapter. The overall effect of this sleeving of a major portion is firstly to increase the effective diameter of the syringe barrel; secondly to provide strengthening reinforcement to the end flange; and thirdly to increase the effective length of the syringe.

30 In embodiments, the forward shoulder of the syringe is provided with one or more shoulder support features. In embodiments, the one or more shoulder support features are integral (e.g. integrally formed) with the cassette unit housing. In other embodiments, the one or more

shoulder support features are defined by one or more separate shoulder support parts provided to the cassette unit.

5 In embodiments, the one or more shoulder support features locate (e.g. in snap-fit arrangement) between the needle cover (e.g. rigid needle shield) and the forward shoulder of the syringe. In embodiments, the sleeve adapter as described above, is provided with such one or more shoulder support features that in embodiments, snap-fit between the needle cover (e.g. rigid needle shield) and the forward shoulder of the syringe. This snap fitting is typically enabled after the syringe assembly has been pressed through the sleeve adapter during the
10 assembly operation.

In embodiments, a clearance space is defined between the bottom of the syringe flange and the closest surface of the sleeve adapter. In embodiments, the sleeve form adapter acts to space the end flange of the syringe from the inner walls of the cassette unit housing. In
15 embodiments, when the syringe is loaded within the cassette unit housing the flange of the syringe is spaced from the inner walls of the cassette unit housing and /or the sleeve adapter and in embodiments, is not in contact with anything.

The hollow needle defines a needle bore, which is most typically of circular cross-section and
20 of selected bore diameter. It may be appreciated that in embodiments, the bore diameter may affect the force required to expel the liquid drug formulation through the needle and also the velocity at which the liquid drug formulation is expelled.

Examples of typical needles that are suitable for use therein include 12.5mm (“half inch”)
25 long thin wall needles of grade 23G, 25G or 27G. These have a needle bore of from about 0.2 to 0.4mm such as from 0.25 to 0.35mm. Other examples include both regular and thin wall needles used in conventional syringes including those with bevels such as 3 and 5 bevels.

The cassette unit housing and any inner cassette unit housing sub assembly thereof is shaped
30 to define a cassette unit housing cavity within which the syringe is receivable, and in embodiments, a needle projection aperture. The cassette unit housing cavity is typically

cylindrical in form, thereby matching the typically cylindrical outer profile of a syringe. The cassette unit housing cavity may be further shaped with any manner of grooves, indentations or other shaping or surface details to define a 'lock and key' relationship between the cassette unit housing and any inner cassette unit housing sub assembly thereof and the syringe.

- 5 Colour guides, arrows and any other surface markings may also be employed.

Typically, the cassette unit housing and /or any inner cassette unit housing sub assembly thereof is provided with a barrel receiving part for receiving the barrel of the syringe; a plunger receiving part for receiving the plunger of the syringe; and in embodiments, a needle
10 receiving part for receiving the hollow needle of the syringe.

In embodiments, the plunger receiving part of the cassette unit housing and /or any inner cassette unit housing sub assembly thereof allows the plunger within the syringe barrel to be received thereby and for the plunger to be movable (e.g. axially) therein from a first position
15 to a second position, in which it is moved somewhat into the syringe barrel. During use the plunger is in embodiments, movable to a fully plunged position at which, in most embodiments all of the liquid drug formulation contents of the barrel have been expelled.

In embodiments, the needle receiving part of the cassette unit housing and /or any inner
20 cassette unit housing sub assembly thereof includes a needle projection aperture through which the hollow needle may protrude from the housing, for example during expelling of the liquid drug formulation through the hollow needle and its needle tip for delivery to the patient.

25 In embodiments, the cassette unit housing is provided with a removable cap that fits over and thereby, acts such as to close off, the needle projection aperture. It may therefore, be appreciated that when in the capped position, the removable cap acts such as to prevent ingress of contaminants into the needle receiving part of the housing.

30 In embodiments, the syringe further comprises a needle cover defining a needle sheath arranged in a sheathing configuration for sheathing (e.g. sealing) of the needle tip.

In embodiments, the needle sheath is comprised of a (e.g. resiliently) compressible material such as a natural or synthetic rubber material. In a storage configuration, the needle tip sticks into (e.g. is spiked or staked into) the needle sheath such that sealing of the needle tip is
5 achieved. Usually, at least the first 3 to 4mm of the needle tip end is so sheathed. It will be appreciated that for clinical reasons, the sealing of the needle tip acts in embodiments, such as to prevent passage of contaminant, bacterial or otherwise, through the needle tip and thus into the needle bore and syringe barrel chamber. Sterile sealing is preferred.

10 In embodiments, the needle cover is provided with a needle sheath cover for covering the needle sheath thereof. In embodiments, the needle sheath cover is comprised of a rigid material (e.g. polypropylene). In embodiments, the needle sheath cover is provided with one or more gripping elements (e.g. hooks) arranged for gripping of the needle sheath. In
15 embodiments, the needle sheath is provided with one or more features arranged for receipt of the one or more gripping elements such as one or more indents, grooves or cavities.

In embodiments, the needle cover is provided to (e.g. fixed to or integral with) a removable cap for the cassette unit housing. Thus, in embodiments, the needle cover projects within the cap such that when the removable cap is in the capped position the needle sheath and any
20 needle sheath cover therefor is arranged for receipt of the needle tip of the syringe. In such embodiments, when in the capped position, the needle tip is sheathed by the needle sheath, and when the cap is removed the needle sheath and any needle sheath cover therefor are also removed such as to thereby, unsheath the needle tip. In embodiments, the removable cap defines an essentially closed cylindrical cap chamber, optionally tapering, and the needle
25 sheath and any needle sheath cover are provided along the axis of that cylindrical chamber.

In embodiments, the interior of the removable cap is provided with a connector defining one or more needle cover gripping elements for gripping the needle cover (i.e. gripping the needle sheath and / or any needle sheath cover therefor). In embodiments, such gripping elements
30 are arranged for gripping of the needle cover when in the capping position. In embodiments such gripping elements are (e.g. additionally) arranged for gripping of the needle cover on

removal of the cap such that removal of the cap also results in removal of the needle cover and hence, unsheathing of the needle tip. In embodiments, the needle cover gripping elements are arranged to project away from the top inner surface (e.g. of the cylindrical cap chamber) of the removable cap and towards its open end.

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In embodiments, the connector comprises one or more needle cover gripping elements (e.g. gripping legs) attaching to a central hub. In embodiments, the connector is in the form of a cage-like needle cover gripper. In embodiments, each gripping element (e.g. leg) is provided (e.g. at the foot thereof) with one or more gripping protrusions such as one or more internally facing hooks or barbs. In embodiments, the internally facing hooks or barbs are disposed at an angle with respect to the gripping leg. In embodiments, the connector locates within the removable cap such that the central hub locates adjacent to or slightly spaced from the top inner cap wall or surface and the gripping legs project away from the top inner cap wall or surface and towards the open end of the cap. Other needle cover gripper arrangements are disclosed in Applicant's co-pending PCT publication no. WO2009/081103 the entire contents of which are incorporated herein by reference.

In embodiments, the removable cap is provided with a connector. The connector is shaped to fit within and engage the needle cover and to engage the inner part of the removable cap. In embodiments, the connector includes one or more needle gripper elements in the form of first legs attaching to a central hub and spaced symmetrically away from one another, each first leg having one or more internally facing barbs pointing toward a forward region of the connector and adapted to engage a proximal region of the needle cover. In embodiments, the one or more internally facing barbs are disposed at an angle with respect to the first leg. In embodiments, the connector also includes one or more second legs spaced symmetrically away from one another, each second leg having one or more externally facing barbs located in the forward region of the connector and adapted to engage a forward region of the inner part of the removable cap or cap insert, as described below. In embodiments, the one or more first legs are biased initially at about 60 to 80 degrees with respect to the horizontal. Arrangements of removable cap and connector of this type are disclosed in Applicant's co-

pending PCT publication no. WO2009/090499 the entire contents of which are incorporated herein by reference.

5 In embodiments, the geometry of the removable cap is selected to allow for the needle cover to be sufficiently aligned with the needle of the syringe so that on re-capping the needle does not undesirably catch on the needle sheath inside the needle cover.

10 In embodiments, particularly wherein the connector comprises one or more needle cover gripping elements (e.g. gripping legs) attaching to a central hub, Applicant has found that to assist re-sheathing of the needle cover it is desirable to position the connector within the removable cap such that the central hub is in spaced relationship to the top inner cap wall of the removable cap. When so-positioned, the gripping legs project away from the top inner cap wall and towards the open end of the cap.

15 In embodiments, to provide this spacing relationship, the removable cap is provided with a cap insert and at least part of the connector is provided to (e.g. locates within) the cap insert.

20 In embodiments, the cap insert is shaped to allow for limited axial travel of the connector there within. In embodiments, allowing this limited axial travel of the connector within the cap insert effectively allows for defining of a certain 'give' in the axial position of the connector and needle cover connecting thereto such that in the event of any snagging of needle cover by the needle tip during re-sheathing, the connector and /or needle cover is free to move into the 'give' space, thereby ensuring that the snagging event does not result in any bending, or in a worst case scenario snapping, of the needle. The occurrence of any needle
25 stick hazards during re-capping and re-sheathing is thus, minimized.

In other embodiments, wherein the cap is arranged for locking interaction with the cassette unit, allowing for this limited axial travel of the connector within the cap insert and for defining of a certain 'give' in the axial position of the connector and needle cover connecting
30 thereto, can improve the reliability of the cap locking interaction by preventing any

interference therewith as a result of snagging or other undesirable interaction of the needle cover by the needle tip during re-sheathing.

- 5 In particular embodiments, it has been found that the rubber needle sheath might potentially undesirably compress against the needle when the user replaces the cap. However, once the user lets go the cap might be pushed slightly away from the cassette unit housing as the needle sheath relaxes, and this potentially interferes with or prevents the cap from properly locking onto the cassette unit housing. In embodiments, where the auto-injector device is arranged to register locking interaction of the cap with the cassette unit housing, such a
- 10 scenario might potentially also undesirably result in a false reading of cap locking interaction. In embodiment, the aforementioned allowing for limited axial travel of the connector within the cap insert and for defining of a certain 'give' in the axial position of the connector and needle cover connecting thereto, can improve or prevent such undesirable situations.
- 15 In embodiments, the spaced relationship with the forward end wall of said cap interior allows for give in the axial position of the connector and needle cover within a give space. In embodiments, the limited axial travel of the connector within the cap insert allows for the give in the axial position of the connector and needle cover within the give space.
- 20 In embodiments, the cap insert defines a first axial channel arranged for receipt of at least part of the connector. In embodiments, the rearward extent of the first axial channel defines the rearward limit of axial travel of the connector within the cap insert. In embodiments, an inner forward end wall of the removable cap defines the forward limit of axial travel of the connector within the cap insert.
- 25 In embodiments, the connector includes one or more needle cover gripper elements in the form of first legs attaching to a central hub and spaced symmetrically (e.g. spaced in a rotationally symmetric sense) away from one another, each first leg having one or more internally facing barbs pointing toward a forward region of the connector and adapted to
- 30 engage a proximal region of the needle cover. In embodiments, the connector also includes one or more second legs spaced symmetrically (e.g. spaced in a rotationally symmetric sense)

away from one another and located in the forward region of the connector, each second leg having one or more externally facing barbs, which externally facing barbs are arranged for receipt within the first axial channel of the cap insert.

- 5 In embodiments, interaction of the externally facing barbs with an upper travel limiting element (e.g. a ledge or rim) provided at the upper extent of the first axial channel defines the upper limit of axial travel of the connector within the cap insert.

- 10 In embodiments, the cap insert further defines a second axial channel co-axial with the first axial channel and of smaller diameter relative thereto, which second axial channel is also arranged for receipt of at least part of the connector.

- 15 In embodiments, assembly of the connector into the cap insert involves inserting of the connector first into the second axial channel and then pushing through into the first axial channel.

- 20 In embodiments, wherein the connector includes one or more needle cover gripper elements in the form of first legs attaching to a central hub and spaced symmetrically away from one another, each first leg having one or more internally facing barbs pointing toward a forward region of the connector and adapted to engage a proximal region of the needle cover and also includes one or more second legs spaced symmetrically away from one another, each second leg having one or more externally facing barbs located in the forward region of the connector, which externally facing barbs are arranged for receipt within the first axial channel of the cap insert, such insertion step may involve inwards pushing in of some or all of said externally facing barbs within the narrower second axial channel, which externally facing barbs splay outwards on being received within said broader first axial channel.

- 30 In embodiments, a cap insert is provided to (e.g. locates within) the removable cap and the removable cap is shaped to allow for limited axial travel of the cap insert there within. In embodiments, the removable cap is shaped to allow for limited axial travel in the rearwards direction of the cap insert relative thereto.

Where in use, the cap insert is provided with the connector, which in turn connects with the needle cover for the syringe, allowing for limited axial travel of the cap insert within the removable cap can enable accommodation of the effects of shock (e.g. impact shock) when the cassette unit is dropped (e.g. onto a hard surface) or mishandled in such a way as to introduce shock thereat / thereto. In embodiments, such feature acts in tandem with the hereinafter described damping element defining a damping relationship between the cassette unit end-cap and the flange of the syringe, which thereby acts to damp movement (e.g. resulting from shock impact) of the syringe relative to the cassette unit end-cap.

In embodiments, the removable cap defines an axial guide arranged for receipt of at least part of the cap insert. In embodiments, the axial guide is defined by one or more axial track guide features provided to the inner surface of the removable cap. In embodiments, the cap insert is provided with one or more follower elements (e.g. protruding arms or legs) for receipt within the one or more axial track guide features.

In embodiments, upper and lower extents of at least a portion of the axial guide are bounded to define an axial guide channel for the cap insert. In embodiments, the upper and lower extents of the axial guide channel define the limit of axial travel of the cap insert within the axial guide channel.

In embodiments, the removable cap is provided with a finger-grip feature that is sized and shaped for gripping by the finger of a user and to provide a ready means for removing the cap and needle cover attached thereto. In embodiments, the finger-grip feature is shaped to provide a ring (e.g. a gripping ring or ring pull) for ready finger gripping by the user by placing a finger or thumb inside the ring.

In embodiments, the removable cap in a capping position, fits over and thereby, acts such as to close off, the needle projection aperture of the cassette unit housing.

In embodiments, the cassette unit housing is provided with one or more first engagement features arranged for reversibly engaging one or more second engagement features of the removable cap for reversible lock engagement of the removable cap to the cassette unit housing.

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In embodiments, the first engagement features of the removable cap and the second engagement features of the cassette unit housing are arranged to have a mutually engaging form selected from the group consisting of latching, peg and socket and snap-fit.

10 In embodiments, the cassette unit housing is provided at the forward end thereof with one or more axially protruding legs each having a first engagement feature arranged thereon, the one or more legs arranged to extend up into the removable cap when the cap is in the capping position and the one or more second engagement features are defined as sockets of the removable cap.

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In embodiments, the one or more legs are arranged in a circumferential arrangement about the forward end of the cassette unit housing and said sockets of the removable cap adopt a corresponding circumferential arrangement. In embodiments, each of the one or more first engagement features of the one or more legs is in the form of a protruding heel having a
20 shaped tip.

In embodiments, the geometry of the removable cap is selected to allow for the needle cover to be sufficiently aligned with the needle of the syringe so that on re-capping the needle does not undesirably catch on the needle sheath inside the needle cover. In embodiments, the
25 geometry of the first engagement features of the cassette unit housing and/or second engagement features of the removable cap is selected to allow for such ease of re-capping. In embodiments, once the first engagement features of the cassette unit housing begin to engage with the second engagement features of the removable cap it is held concentrically enough to prevent the needle from catching on the needle sheath. This is important to ensure that on re-
30 capping the needle cover is able to fully sheathe the used needle to minimize the occurrence of any needle stick hazards.

In embodiments, the cassette unit is provided with a cap lock (i.e. cap removal prevention) feature for selectively preventing removal of the removable cap. In embodiments, the cap lock feature is movable from a first cap locking position in which it prevents removal of the cap from the cassette unit to a second cap un-locking position in which it no longer prevents such cap removal.

In embodiments, the cassette unit is provided with a shuttle lock control defining one or more blocking elements for selectively blocking movement of said one or more first engagement features of the cassette unit housing relative to the one or more second engagement features of the removable cap.

In embodiments, the shuttle lock control is axially movable relative to the cassette unit housing between:

(i) a first 'cassette unused' position, in which said one or more blocking elements block movement of the one or more first engagement features relative to the one or more second engagement features, thereby keeping the removable cap in locked relationship to the cassette unit housing;

(ii) a second 'cassette unlocked' position, in which said one or more blocking elements no longer block movement of the one or more first engagement features relative to the one or more second engagement features, thereby allowing for unlocking of the removable cap from the cassette unit housing and for removal and replacement thereof; and

(iii) after replacement of the removable cap, a third 'cassette used' position, locating intermediate said first and second positions, in which the one or more blocking elements again block movement of the one or more first engagement features relative to the one or more second engagement features, thereby restoring the locked relationship between the removable cap and the cassette unit housing.

In embodiments, the shuttle lock is biased from the second position to the third position.

In embodiments, in use, on removal of the removable cap the shuttle lock control is in the second position; during use of the cassette for injection the shuttle lock control is biased into the third position; and during replacement of the removable cap the shuttle lock control is in the second position.

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In embodiments, the cap lock (i.e. cap removal prevention) feature selectively prevents removal of the removable cap until either the cassette unit locates at the docking position within the drive unit housing. In embodiments, the cap lock feature of the cassette unit is only movable from a cap locking position to a cap non-locking position when the cassette unit
10 locates at the docking position within the drive unit housing. In embodiments, the cap lock feature is in the first position during insertion of the cassette unit into the drive unit and moves to the second position when the cassette unit is in the docking position in the drive unit.

15 In embodiments, the drive unit includes a cap lock release feature arranged such that on moving of the cassette unit towards the docking position in the drive unit said cap lock release feature interacts with the cap lock feature of the cassette unit to move the cap lock feature to the second cap unlocking position when the cassette unit is at the docking position in the drive unit.

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In embodiments, the cassette unit includes a plunger slaving part, which is axially movable within the barrel of the syringe for forward movement into contact with the plunger. In embodiments, the plunger slaving part defines a circumferential wall arranged for frictional sliding relationship with the inner wall of the barrel, a rear drive-receiving face and a front
25 plunger-contacting face.

In injected use, the plunger slaving part is in embodiments, brought into contact with the plunger of the syringe and is axially movable within the barrel. In embodiments, the plunger slaving part arranged such that when a drive load is applied to the rear drive-receiving face to
30 bring the front plunger-contacting face into contact with the plunger the drive load is evenly transmitted to the plunger.

In embodiments, the front plunger-contacting face of plunger slaving part is arranged for engagement with the plunger. In embodiments, the diameter of the plunger slaving part corresponds to the diameter of the plunger.

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In embodiments, the plunger is made of a material that is resiliently compressible (e.g. rubber or an organic polymeric material) and the plunger slaving part is made of a less compressible material. In embodiments, the plunger slaving part is made of a rigid material (e.g. a hard plastic polymer material such as poly propylene).

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In embodiments, the rear drive-receiving face of the plunger slaving part has a central recess for receipt of a drive transfer element. In embodiments, the central recess is shaped such that the drive transfer element is rotatable therein. In embodiments, the central recess is of conical form. In embodiments, the central recess tapers to a square-cut end or to a neb end.

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In embodiments, the slaving part may be configured to perform a second purpose of providing an easy-to-identify visual indicator of the plunger's position within the syringe so that the patient can visually confirm the drug had been fully injected. In this embodiment, the slaving part may also be called a stopper position indicator.

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In embodiments, the circumferential wall of the plunger slaving part is provided with one or more slide restrictors that restrict frictional sliding movement thereof in relation to the inner wall of the barrel. In embodiments, the one or more slide restrictors are arranged to increase the resistance thereof to frictional sliding movement.

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In embodiments, each of the one or more slide restrictors comprises a flexible vane arranged to flex slightly in response to frictional sliding movement of the plunger slaving part. In embodiments, the one or more slide restrictors are arranged to increase the initial resistance to forward frictional sliding movement but to impart lesser resistance to said forward

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frictional sliding movement once movement is underway. In embodiments, the one or more slide restrictors are arranged to more greatly increase the resistance to a backward frictional

sliding movement than to the forward frictional sliding movement. In embodiments, the one or more slide restrictors are arranged at evenly spaced intervals around the circumferential wall.

- 5 In embodiments, the cassette unit housing defines a rearward entrance to the cassette unit housing cavity, additionally comprising in capping relationship with a rearward entrance of the cassette unit housing, a cassette unit end-cap. In embodiments, the cassette unit end-cap defines a drive rod-receiving opening for receipt of a drive rod for providing forward axial drive to said plunger slaving part.

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In embodiments, in a pre-use configuration, the plunger slaving part is shaped for releasable engagement with the cassette unit end-cap. In embodiments, the drive rod-receiving opening is defined by a periphery and the plunger slaving part is shaped for releasable engagement in the pre-use configuration with the periphery. In embodiments, the drive rod-receiving

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opening is defined by a peripheral rim and said plunger slaving part is shaped for releasable engagement in the pre-use configuration with the peripheral rim. In embodiments, the drive rod-receiving opening is defined by a periphery, the periphery is provided with a forward skirt and the plunger slaving part is shaped for releasable engagement in the pre-use configuration with the forward skirt. In embodiments, the forward skirt is provided with an

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inner-facing rim and the plunger slaving part is shaped for releasable engagement in the pre-use configuration with the inner-facing rim. In embodiments, the plunger slaving part defines a circumferential rim for releasable engagement in the pre-use configuration with the cassette unit end-cap. In embodiments, the plunger slaving part defines a circumferential trough for releasable engagement in the pre-use configuration with the cassette unit end-cap. In

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embodiments, the plunger slaving part is releasable from the cassette unit end-cap in response to forward axial drive provided to the rear drive-receiving face thereof. In embodiments, the end-cap is arranged for snap-fit relationship with the cassette unit housing.

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In embodiments, the cassette unit additionally comprises a biasing element defining a biasing relationship between the cassette unit end-cap and the flange of the syringe, thereby urging the syringe forwards in relation to the cassette unit end-cap.

In embodiments, the drive rod-receiving opening of the cassette unit end-cap is defined by a periphery, the periphery is provided with a forward skirt and the biasing element is arranged for receipt about the forward skirt.

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In embodiments, the cassette unit additionally comprises a damping element defining a damping relationship between the cassette unit end-cap and the flange of the syringe, thereby acting to damp rearward movement of the syringe relative to the cassette unit end-cap. In embodiments, the damping element thereby reduces any such relative movement of the syringe and cassette unit end-cap as may arise from the effects of shock (e.g. shock impact), and thus acts as a shock damping element.

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In embodiments, the biasing element and the damping element are comprised as a unitary (i.e. single) biasing and damping element.

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In embodiments, the biasing and damping element is provided as a separate component to the cassette unit end-cap. In other embodiments, the biasing and damping element is provided integrally with the cassette unit end-cap.

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In embodiments, the biasing and damping element may take any suitable form. In embodiments, the biasing and damping element comprises a ring form. In embodiments, the end-cap comprises a skirt that is arranged for receipt of the ring form biasing and damping element. In embodiments, the skirt of the end-cap projects forwards, and thus projects towards the flange of the syringe.

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In embodiments, it has been appreciated that careful geometric design and/or choice of material properties is required to modify the compression properties of the damping and biasing element to achieve the desired damping / compression force performance.

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In embodiments, biasing and damping element (e.g. the ring form) is provided with one or more damping projections that project forwards towards the flange of the syringe. In

embodiments, plural (e.g. from 2 to 8, such as 3 to 6) damping projections are spaced circumferentially (e.g. at regular intervals) about the ring form biasing and damping element. In embodiments, plural (e.g. from 2 to 8, such as 3 to 6) damping projections are spaced circumferentially (e.g. at regular intervals) about the ring form biasing and damping element
5 in a circle of diameter about equal to that of the syringe barrel.

In embodiments, each damping projection has a projecting tower form. In embodiments, the tower form is designed to yield in a controlled manner in response to compression by the syringe flange. In embodiments, each projecting tower has two sections, namely a forward
10 section, which is arranged to contact the syringe flange, and a rearward section that contacts the end-cap, wherein the rearward section is less readily deformable in the axial direction than the forward section. In embodiments, each projecting tower are has two sections, namely a forward section, which is arranged to contact the syringe flange, that is relatively slender and/or easily deformable; and a rearward section which increases (e.g. by a tapering
15 or sloping geometric form) in width from the base of the forward section to where it contacts the end-cap. In embodiments, this form of projecting tower is intended to provide a low biasing force by deforming mainly the forward section, and the high impact compression force mainly through compressing (e.g. partial compression of) the rearward section.

20 In embodiments, the cassette unit additionally comprises one or more shoulder support features for supporting the forward shoulder of the syringe.

In embodiments, the cassette unit further comprises a needle cover defining a needle sheath for sheathing of the needle tip, wherein the one or more shoulder support features locate
25 between the needle cover and the forward shoulder of the syringe.

In embodiments, the needle cover is provided with a needle sheath cover for covering the needle sheath thereof and the one or more shoulder support features locate between the needle sheath cover and the forward shoulder of the syringe. In embodiments, the needle
30 sheath cover is comprised of a rigid material.

In embodiments, the one or more shoulder support features are in snap-fit arrangement between the needle cover and the forward shoulder of the syringe.

5 In embodiments, the one or more shoulder support features are defined by one or more separate shoulder support parts provided to the syringe.

In embodiments, the one or more shoulder support features include a split-cylindrical form arranged for receipt by the barrel of the syringe.

10 *Drive unit*

The auto-injector herein is arranged to allow for actuation (i.e. firing) of the syringe and hence, to allow for injected delivery of drug to a patient. The auto-injector thus, also includes a drive unit for transferring axial drive to the syringe.

15 The drive unit comprises a drive unit housing defining a docking cavity and a needle delivery aperture. The docking cavity is arranged for docking receipt of the cassette unit at a docking position, whereupon said cassette unit and /or the syringe is movable from a rest position, in which the needle tip of the syringe is within the drive unit housing to a use position, in which the needle tip protrudes from said needle delivery aperture. The docking cavity and
20 receivable part of the cassette unit are correspondingly sized and shaped to facilitate the intended docking relationship. The drive unit housing may be arranged as a single part or a multi-part (e.g. two part) drive unit housing assembly.

25 The drive arrangement comprises at least one electrically powered source of axial drive. The electrical power may be provided by mains electrical supply or by a battery, which in embodiments may be rechargeable.

30 Electrical energy may be conserved by a variety of means to enable the auto-injector to operate for longer on a given source of energy, such as a battery. Energy conservation or saving methods have additional advantages in terms of reducing the size requirements of the power source (e.g. battery) and thus the weight and portability of the auto-injector.

Electrical energy saving methods may be employed to reduce power consumption of the drive unit. One such method is to use a clock or timer circuit to switch the power on and off at regular or predetermined intervals. In another method a power management system is employed to selectively switch on/off specific electronic functions, such as visual display units or sensors, in order to power these functions only when they are required to perform a particular sequence of events. Thus different electronic functions may be switched on and off at varying intervals and for varying periods under control of a power management system.

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- 10 In embodiments, the at least one electrically powered source of axial drive comprises an electrically powered motor. The motor may provide linear or rotary drive, but in general, rotary motors used in combination with suitable gearing arrangements are most suitable. The motor may for example, comprise a DC electric motor, a piezoelectric (PZ) motor, an ultrasonic motor, a solenoid motor or a linear motor. In embodiments, the electronic drive system comprises a DC
- 15 motor, a PZ motor, a stepper motor or an ultrasonic motor. Embodiments are envisaged in which, plural electrically powered sources of axial drive are employed such as a different drive source (e.g. motor) for each of the first and second drive transfer elements.

- The drive arrangement comprises a first drive transfer element for transferring axial drive to the cassette unit and /or the syringe for advancing the syringe to said use position; and a second drive transfer element for subsequently transferring axial drive to the plunger of the syringe for moving the plunger into the barrel of the syringe to eject at least part of the volume of liquid drug formulation.
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- 25 In embodiments, the first and second drive transfer elements are configured as separate parts. In other embodiments, the first and second drive transfer elements are in coupling relationship (e.g. via one or more coupling elements) or form an integral part of a single (i.e. composite) drive transfer element.

In embodiments, the source of axial drive is configured to selectively confer axial drive to the first and second drive transfer elements. Any manner of gearing and/or coupling arrangements may be employed to achieve this purpose.

- 5 In embodiments, the drive arrangement comprises one or more lead screw drive mechanism. In other embodiments, the drive arrangement comprises one or more rack and pinion drive mechanisms. In embodiments, any of such drive mechanisms directly comprise the first and / or second drive transfer elements. In other embodiments, any of such drive mechanisms may be arranged to communicate with the first and/or second drive transfer elements by suitable
10 gearing or coupling arrangements.

- In embodiments, the electrically powered source of drive is able to exert an axial drive force of up to 60N via the first and/or second drive transfer elements to the syringe. In
embodiments, the force exerted may be arranged to vary over the actuation profile such as
15 from a range of 60 to 40N at the start of actuation to from 40 to 20N at the end of the actuation profile.

- In embodiments, release of axial drive force (e.g. actuation of the electrically powered source of drive) is responsive to a trigger (e.g. a user-actuable trigger). In embodiments, the trigger
20 comprises a button, switch or lever arrangement. In other embodiments, a press actuation mechanism that is actuable in response to pressing of the drive unit housing against the skin of a patient is also envisaged.

- Axial drive force applied to the first drive transfer element results in drivable movement of
25 the syringe from the rest to the use position. In embodiments, the first drive transfer element communicates directly with (e.g. contacts or abuts) the syringe barrel for transferring drive thereto. In embodiments, the first drive transfer element communicates directly with (e.g. contacts or abuts) the cassette unit for transferring drive thereto, and thus results in drive being transferred to the syringe barrel. In embodiments, the first drive transfer element
30 communicates indirectly with (e.g. via a slaving or coupling element) the syringe barrel and /or the cassette unit for transferring drive thereto.

In embodiments, the first drive transfer element communicates directly or indirectly with a cassette unit holder that holds the cassette unit and syringe thereof within the drive unit such as to transfer drive to the cassette unit holder to thereby result in drivable movement of the syringe from the rest to the use position.

Axial drive force applied to the second drive transfer element (e.g. plunger rod) results in drivable movement of the plunger within the syringe barrel, ultimately to a fully plunged position when most, in embodiments all, of the liquid drug formulation contents of the syringe barrel have been drivably expelled therefrom.

In embodiments, the second drive transfer element communicates directly with (e.g. contacts or abuts) the plunger of the syringe for transferring drive thereto. In embodiments, an end portion of the second drive transfer element directly communicates with (e.g. contacts or abuts) the plunger. In other embodiments, the second drive transfer element communicates indirectly with (e.g. via a slaving or coupling element) the plunger of the syringe for transferring drive thereto. In certain other embodiments, an end portion of the second drive transfer element indirectly communicates with the plunger such as via a washer or other intermediate element.

In embodiments, the first and/or second drive transfer element takes the form of a screw drive element or rod drive element, but other suitable forms are also envisaged.

In embodiments, the drive arrangement includes a first coupling for coupling the first drive transfer element to the cassette unit and /or to syringe barrel of the syringe, wherein said first coupling is a reversible coupling arranged for decoupling when the syringe moves to the use position. Thus, in the initial rest position, application of axial drive force to the first drive transfer element results in movement of the syringe as a whole, but in embodiments, not of the plunger relative to the syringe barrel. It may be appreciated that this preferred initial absence of relative plunger movement is favoured if the frictional forces to be overcome in moving the syringe barrel within the housing are arranged to be much less than for moving

the plunger within the syringe barrel. This is typically so since the plunger is often a natural or synthetic rubber element, which frictionally interacts with the sidewall of the syringe barrel. In embodiments, the first coupling is a friction clutch coupling arranged for decoupling by declutching thereof when the syringe moves to the use position.

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In embodiments, once the syringe is in the use position (i.e. needle protruding) the first coupling decouples (e.g. demounts) such that no coupling then exists between the first drive transfer element and the syringe barrel. All further axial drive force applied to the second drive transfer element therefore results in plunging axial movement of the plunger within the syringe barrel, which acts to drive the liquid drug formulation contents of the syringe barrel into the hollow needle for injected delivery from the needle tip.

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In embodiments, the first and second drive transfer elements are comprised as a single drive shuttle element. In embodiments, the shuttle has an axially symmetric form such as cylindrical form. Guides (e.g. a central aperture of an end wall) may be provided to the shuttle to assist that axial receipt.

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In embodiments, a reset mechanism is provided for resetting the drive arrangement after actuation thereof. In embodiments, the reset mechanism is responsive to the electrically powered source of drive.

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It is noted that fundamentally any electrically powered source of drive herein must convert electrical energy (e.g. stored in batteries) into mechanical motion for movement of the syringe and/or cassette unit and/or the plunger. Electric motors typically use electrical energy to produce rotational motion in the form of a rotating shaft. Various methods are well known for conversion of rotational energy into linear displacement of the plunger.

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Conceivable methods are a lead screw and worm gear arrangement, cams, a rack and pinion system or a system of rigid linkages using the lever principle. The various methods have certain advantages and disadvantages in terms of complexity, efficiency, mechanical advantage, gearing, maximum displacement velocity, maximum force etc.

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Applicant has appreciated that generally for an injection, it is desirable to maintain a constant force over the full displacement stroke of the plunger. The performance in terms of maximum velocity and maximum force of cam and lever based mechanisms will typically vary with position along the injection stroke such that at extremes of the displacement range the maximum force or velocity of the plunger may be substantially different from that in the centre of the displacement range. The lead screw and worm gear or rack and pinion systems have the advantage that they can maintain constant forces over their full displacement range. The velocity of the plunger displacement determines the injection time, which is a key parameter in determining patient comfort. Finally, the maximum force that the electrically powered source of drive of the drive unit can produce will determine the limits of drug viscosity and/or needle bore that the device can use in injections. In general, the maximum plunger velocity and maximum force will be inversely related. That is, higher injection force will limit the velocity achievable.

15 *Interaction of cassette unit with drive unit*

In embodiments, the syringe is movable within the drive unit housing from a rest position, in which the needle tip of the syringe is within the drive unit housing to a use position, in which the needle tip protrudes from the needle delivery aperture of the drive unit housing.

20 In embodiments, the syringe is in fixed relationship to the cassette unit housing and the required movement of the syringe is by movement of the cassette unit housing and syringe fixed thereto within the drive unit housing.

In other embodiments, the syringe is in movable relationship to the cassette unit housing and the required movement of the syringe is by movement of the syringe within the cassette unit housing.

In other embodiments, composite arrangements are envisaged, in which the syringe movement is achieved by a combination of both movement of the syringe within the cassette unit housing and by movement of the cassette unit housing within the drive unit housing.

In embodiments, the drive unit housing and /or any inner drive unit housing sub assembly thereof includes a needle projection aperture through which the hollow needle may protrude, for example during expelling of the liquid drug formulation through the hollow needle and its needle tip for delivery to the patient.

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In embodiments, it is desirable for safety and hygiene reasons that the needle does not protrude from (i.e. out with) the drive unit housing other than when expelling the liquid drug formulation during an injection procedure. Thus, the drive unit housing and /or any inner drive unit housing sub assembly thereof and drive unit housing cavity defined thereby is generally arranged such that a needle receiving part thereof allows for the needle of the syringe to be axially moveable therein from the rest position in which the needle is wholly housed (or shrouded) by the needle receiving part to the use position in which at least the tip of the needle protrudes from that needle receiving part of the drive unit housing.

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15 In embodiments, the drive unit housing includes biasing means (e.g. a spring) arranged to act on the syringe and / or the cassette unit housing such that the needle of the syringe is normally biased towards the rest position, wherein such biasing means are overcome during the actuation of the syringe (e.g. by an actuating mechanism) to allow for movement of the needle to the use position.

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In embodiments, it is desirable for the drive unit housing to allow for the needle of the syringe to be retracted into the housing after use. Thus, it is desirable to be able to retract the needle back into the needle receiving part of the housing after the injection procedure, that is to say to retract the needle from the use position to a retracted position that may in

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embodiments, correspond to the rest position or in other embodiments, correspond to a third position, which in embodiments is further away from the needle delivery aperture. A needle retract mechanism may thus, be provided (e.g. responsive to a biasing means such as a light return spring or by reverse action of the drive mechanism) to retract the syringe needle back into the drive unit housing.

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In embodiments, it is desirable for the drive unit housing to allow for the needle of the syringe to be shrouded by a needle shroud element after use. Thus, in particular it is desirable to be able to provide a means of shrouding the needle of the syringe that is moved or otherwise brought into operation after completion of the injection procedure. Such means in
5 embodiments comprises a movable shroud element that is adapted to be movable to a shrouding configuration at the end of the injection procedure.

In embodiments, the drive unit includes a cassette unit holder for holding the cassette unit within the drive unit housing. In embodiments, the cassette unit holder defines one or more
10 inner walls against at least a part of which the cassette unit seats when held within the cassette unit holder.

In embodiments, the cassette unit holder is sized and shaped such as to allow for a relatively tight clearance between the cassette unit and the inner walls of the cassette unit holder. Such
15 tight tolerances allow for reliable positioning of the cassette unit within the cassette unit holder and drive unit.

In embodiments, the cassette unit holder is mounted within the drive unit for movement along the drive axis, which corresponds to the injection axis, thereby allowing for movement of the
20 cassette unit and syringe within the drive unit between its rest and in use (i.e. injected) positions. In embodiments, the cassette unit holder mounts to a linear slide that orients along a direction that is parallel with or corresponds to the drive axis.

In embodiments, the cassette unit holder is provided with one or more cassette unit locking
25 features for reversibly locking the cassette unit within the holder and hence, within the drive unit. In embodiments, the one or more cassette unit locking features are arranged to be in a locking position when the cassette unit is in the docking position. In embodiments, in the locking position the one or more locking features of the cassette unit housing align with corresponding features (e.g. apertures) of the cassette unit holder.

In embodiments, movement of the cassette unit from the intermediate pre-docking position to the docking position results in movement of the one or more locking features from the non-locking to the locking position.

- 5 In embodiments, each cassette unit locking feature comprises a latching feature, lock tab feature or snap-lock feature. In embodiments, engagement of the locking feature provides tactile or audible feedback to the user as an indication that the cassette unit has been correctly received within the cassette unit holder of the drive unit.
- 10 In embodiments, the cassette unit holder is provided with one or more cassette unit locking features protruding from the inner wall(s) thereof. In embodiments, the cassette unit locking features are biased towards (e.g. in response to biasing means) or naturally bias towards the cassette locking position.
- 15 In embodiments, the cassette unit holder has plural (e.g. two) cassette unit locking features (e.g. snap lock-tabs) integral with and protruding inwards from the walls thereof.

- In embodiments, each of the cassette unit locking features has one or more angled faces arranged such that the locking feature may be pushed outwards as a result of force applied to
- 20 the angled face.

- In embodiments, each cassette unit locking feature (e.g. lock tab) has angled faces at the top and bottom thereof arranged such that the locking feature (e.g. lock tab) flexes outwards when a force (e.g. from an edge of another mechanical part) is pushed into them from either
- 25 direction. In embodiments, the angled face at the bottom side of the locking feature allow for it to flex out of the way as the cassette unit is inserted into the cassette unit holder until the cassette unit is inserted to a holding and locking position, wherein the locking feature flexes back to its original position and lockingly engages the cassette unit housing. In this position the cassette unit is held in the cassette unit holder by the locking features (e.g. lock-tabs)
- 30 because the top faces of the locking features (e.g. lock-tabs) support the cassette unit. The angled faces on the top of the locking features (e.g. lock-tabs) also allow for the cassette unit

to be pulled out of the cassette unit holder by having the lock-tabs flex outwards in a similar fashion as when a cassette unit is inserted into the cassette unit holder of the drive unit of the auto-injector.

- 5 In embodiments, once the cassette unit has been inserted initially into the cassette unit holder, a reader of the drive unit reads an identifier on the cassette unit to verify details relating to it. Once positive verification has been established, the cassette unit is transported to the docking position such as by drawing it into the drive unit. In embodiments, this receipt of the cassette into the cassette unit holder corresponds to the pre-docking intermediate position referred to
10 hereinafter.

- In embodiments, as the cassette is transported to the docking position within the drive unit, the one or more locking features of the cassette unit holder are aligned with rigid features within the drive unit that maintain the locking features in the locking position such as by
15 preventing lock-tabs from flexing outwards. Thus, the cassette unit is effectively locked within the drive unit when the locking features are aligned with these rigid features of the drive unit.

- In embodiments, the length of the rigid features of the drive unit are arranged such that the
20 cassette unit cannot be locked in the drive unit with the needle protruding from the needle delivery aperture such as at any insertion depth of the needle. Typically during the injection process, high loads are transmitted from the plunger through the cassette unit and reacted on the top surfaces of the locking features (e.g. lock-tabs). In embodiments where the top surface is angled, there is a horizontal component to the reaction load that attempts to flex the
25 locking features (e.g. lock-tabs) outwards. However, where the locking features (e.g. lock-tabs) are aligned with (e.g. behind) the rigid features of the drive unit they cannot be flexed outwards and the cassette unit remains rigidly fixed in the drive unit.

- In embodiments, once the cassette unit has been received at the docking position the
30 removable cap and needle cover attached thereto is removed. Where in embodiments, there is a cap lock feature this must first be released. In embodiments, as the cassette is moved to the

docking position (e.g. by being drawn fully up into the drive unit) the cassette unit is also brought into contact with cap lock unlocking features, which in embodiments comprise one or more (e.g. two) rigid arms, which extend into the cassette unit to depress, and thereby to unlock, the cap lock feature. In embodiments, the rigid arms move into the cassette unit to depress, and thereby to unlock, the cap lock feature by passing through cut-outs in the top of the cassette unit holder.

In embodiments, the drive unit includes an electronic display and the time count is displayed on the electronic display.

In embodiments, to move the cassette unit within the drive unit, a first drive transfer element (e.g. a lead-screw) connects to (e.g. by threading through) a flange connecting to the cassette unit holder.

In embodiments, the cassette unit holder mounts to a linear slide such that it is slidably movable in a direction parallel to or corresponding to the drive axis. In embodiments, the first drive transfer element (e.g. lead-screw) couples to the output shaft of a motor / gear-head assembly such as via a universal joint. The universal joint allows for misalignment between the drive axis and the linear slide, which allows that the cassette unit holder and motor can be held rigidly in the drive unit without over-constraining the positioning of the cassette unit holder. Over-constraining the cassette unit holder could cause excessive friction or binding in the threads of the lead-screw and nut and so make high accelerations and velocities of the cassette unit holder difficult to achieve.

In embodiments, the lead-screw has four starts and a lead of 6.35mm. Such a high lead allows for rapid linear accelerations of the cassette unit holder so that the needle can reach a velocity of 100mm/sec before it pierces the patient's skin. In embodiments, this mechanism is arranged such as to be back-drivable.

In embodiments, the nut attached to the cassette unit holder has a specific linear travel for a given rotation of the screw. In consequence, the depth the needle is inserted into the patient is

set by the rotational position of the screw. The rotational position of the screw can be determined using several means including encoders and monitoring step-counts, in cases in which the motor being used is a stepper motor.

- 5 In embodiments, the drive unit can be configured to provide any suitable needle insertion depth with a typical needle insertion depth being between about 4 and 8mm. Once the needle has been inserted into the patient, the injection of drug may be initiated. To inject the drug, axial drive force is applied to the second drive transfer element (e.g. plunger rod) to drivably move the plunger within the syringe barrel.

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In embodiments, to apply the necessary driving load to the syringe plunger a second drive transfer element in the form of lead screw (e.g. a plunger screw) is rotated through a nut that is fixed relative to the syringe. Since the nut is fixed, the lead screw advances linearly as it is rotated. Having the nut fixed relative to the syringe allows for the plunger screw to stay fixed
15 relative to the syringe when the cassette unit holder is moved within the device for needle insertion or retraction in an emergency. Otherwise, in embodiments, the plunger screw would be required to travel the distance that the cassette unit holder moves during needle insertion prior to its being able to make contact with the syringe to apply drive load to the syringe plunger. In embodiments, in the case of emergency retraction when the cassette unit holder
20 needs to be moved into the drive unit in the middle of an injection, the plunger screw would have to be moved into the drive unit before the cassette unit could be rapidly retracted into the drive unit.

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In embodiments, during an injection, loads reaching near 60N are applied to the syringe plunger via the second drive transfer element (e.g. the plunger screw).

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In embodiments, the second drive transfer element (e.g. the rotating plunger screw) could direct undesirably high (e.g. torsion) drive loads on the system if the second drive transfer element makes direct contact with the syringe plunger. To minimize these torsion loads, the syringe barrel of the cassette unit may be provided with a plunger slaving part. Thus, the second drive transfer element acts to transfer axial drive to the plunger slaving part and

hence, to the plunger of the syringe for moving the plunger into the barrel of the syringe to eject at least part of said volume of liquid drug formulation.

In embodiments, the plunger slaving part is in contact with the plunger of the syringe and is axially movable within the barrel. In embodiments, the plunger slaving part is arranged such that when a drive load is applied to a rear (e.g. top) drive-receiving face thereof the drive load is evenly transmitted to the plunger. In embodiments, the plunger slaving part engages (e.g. is in threaded engagement) with the plunger. In embodiments, the diameter of the plunger slaving part corresponds to the diameter of the plunger.

In embodiments, the rear face of the plunger slaving part has a central recess for receipt of a drive transfer element. In embodiments, the central recess is of conical form. Thus in embodiments, the second drive transfer element defines a drive end arranged for receipt by the central recess of the rear drive-receiving face of the plunger slaving part. In embodiments, the drive end defines a conical tip and said central recess is of conical form to guide and centre said conical tip therein. In embodiments, the angle of the conical recess is greater than the angle of the conical tip.

In the above described plunger screw embodiment, the plunger screw is rotated through a fixed nut. In consequence, the combination of the high linear force with the rotating plunger screw could result in high torsion loads on the system if the plunger screw makes direct contact with the syringe plunger. To minimize these torsion loads, the plunger screw is in embodiments, provided with a pointed tip to give rise to a point load instead of a face load. The pointed tip of the plunger screw makes contact with a slaving part, which is made of a hard material, thus acting to reduce friction and torsion loads on the system. The slaving part contacts (e.g. engages) the plunger such that when a load is applied to its top face the load is evenly transmitted directly into the plunger. In embodiments, the top of the slaving part has a conical recess to guide and centre the pointed end of the plunger screw as it is lowered into contact. In embodiments, the angle of the conical recess is greater than the angle of the conical end of the plunger screw to achieve point contact between the tip of the plunger screw and the top surface, while also guiding the syringe plunger during its travel.

In embodiments, the plunger screw is rotated by a screw gear, which receives drive force from the source of axial drive. In embodiments, the plunger screw slide fits through the center of the gear and is keyed to gear via a flat. Since in this embodiment, the plunger screw
5 has a flat, there are sharp corners where the flat is cut across the threads. In consequence, reliefs are provided in the walls of pass-through hole in the screw gear to eliminate the possibility of the thread corners from catching on the screw gear as the plunger screw slides through it. In embodiments, the screw gear is fixed within the device via a press-fit with a ball bearing that is fixed within the drive unit.

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In embodiments, to control the position and angular velocity of the screw gear, and thus the position and velocity of the plunger screw, the screw gear is arranged to mesh with a gear mounting to the shaft of a motor/gearhead assembly. In embodiments, the rotation and angular velocity of the output of the motor/gearhead shaft directly correlates to the position
15 and velocity of the plunger screw. Thus, the position of the plunger screw is determined by the rotational position of the screw. This position of the plunger screw is in embodiments, monitored using encoders anywhere in the drive train that has rotating components or by monitoring step-counts if using a stepper motor.

20 In embodiments, the drive unit is arranged to initially receive the cassette unit housing at an intermediate pre-docking position for subsequent transport of the cassette unit to the docking position.

In embodiments, the drive unit is arranged to initially receive the cassette unit housing at the
25 intermediate pre-docking position for automated verification thereof. Such verification can for example, be for the purpose of checking of drug and dosage information, checking that the drug is not past its expiry date and / or checking that the cassette has not been used previously.

30 In embodiments, the cassette unit is receivable by a cassette unit holder of the drive unit and the position corresponding to (e.g. initial) receipt of the cassette into the cassette unit holder

corresponds to the intermediate position at which the automatic verification step is carried out.

5 In embodiments, the cassette unit further comprises an identifier. The identifier comprises data in a form that may be readily subject to interrogation. The drive unit comprises a reader for reading (interrogating) the identifier of the cassette unit and, in communication with the reader, a verifier for verifying the identifier.

10 In embodiments, the drive unit is arranged such that transport of the cassette unit to the docking position is permitted only following positive verification of the identifier. Thus, only appropriately identified cassette units are finally receivable into the device to enable injected drug delivery there from.

15 In embodiments, the identifier may include labelling selected from the group consisting of visual text, machine-readable text, bar codes, and dot codes. In embodiments, the identifier is in the form of a passive transceiver (e.g. an RFID tag) that is interrogable by means of an active transceiver (e.g. an RFID reader). In embodiments, the identifier is in the form of a bar code that is interrogable by means of a bar code reader.

20 In embodiments, the cassette unit comprises a first transceiver for transmitting and receiving data and the drive unit comprises a second transceiver for transmitting and receiving data, wherein data is transferable at least from the first transceiver to the second transceiver, and in embodiments in two-way fashion from the first transceiver to the second transceiver. The data is in embodiments in digital form and suitable for transfer by electronic, radio or optical
25 means.

An advantage of embodiments of this type is the ability to store many types of information in different parts of the memory structure of the transceivers. The information is furthermore stored in a form, which is readily and accurately transferable. The information could for
30 example, include manufacturing and distribution compliance information written to the memory at various points in the manufacturing or distribution process, thereby providing a

detailed and readily accessible product history of the cassette unit housing. Such product history information may, for example, be referred to in the event of a product recall. The compliance information could, for example, include date and time stamps. The information could also include a unique serial number stored in encrypted form or in a password

5 protectable part of the memory, which uniquely identifies the drug product and therefore may assist in the detection and prevention of counterfeiting. The information could also include basic product information such as the nature of the drug and dosing information, customer information such as the name of the intended customer, and distribution information such as the intended product destination.

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On loading the drive unit with the cassette unit housing the second transceiver may, for example, read the unique serial number, batch code and expiry date of the drug and any other information on the first transceiver. In this way the nature and concentration of the drug in the syringe of the cassette unit, may be determined. Other information, such as the date and

15 time of administration of the drug, or environmental exposure data such as the minimum / maximum temperatures or levels of humidity the cassette unit has been exposed to, may also be read and displayed to the user. In embodiments, this information is displayed to the patient on a visual display unit.

20 Data may also be transferred to and from any transceiver during the period of use of the auto-injector by the patient. For example, the auto-injector may include an electronic data system having various sensors associated therewith. Any data collected by the sensors or from any data collection system associated with the electronic data system including a clock or other date/time recorder is transferable. Data may be transferred each time the patient uses the

25 auto-injector. Or alternatively, data may be stored in a database memory of the electronic data system and periodically downloaded to any transceiver. In either case, a history of the usage of the auto-injector may be built up in the memory of any transceiver or within the device non-volatile memory.

30 In embodiments, the first and second transceiver each comprise an antenna or equivalent for transmitting or receiving data and connecting thereto a memory. The memory will typically

comprise an integrated circuit chip. Either transceiver may be configured to have a memory structure, which allows for large amounts of information to be stored thereon. The memory structure can be arranged such that parts of the memory are read-only, being programmed during/after manufacture, other parts are read/write and further parts are password

5 protectable. Initial transfer of information (e.g. at the time of manufacture or of dispensing) to or from any transceiver can be arranged to be readily achievable by the use of a reader which is remote from the auto-injector, thereby minimising the need for direct product handling.

10 In embodiments, data is transferable (e.g. in two-way fashion) between the first transceiver on the cassette unit and second transceiver on the drive unit without the need for direct physical contact therebetween. In embodiments, data is transferable wirelessly between the first and second transceiver.

15 In embodiments, the second transceiver on the drive unit is an active transceiver and the first transceiver on the cassette unit is a passive transceiver. The term active is used to mean directly powered and the term passive is used to mean indirectly powered.

In embodiments, the first transceiver on the cassette unit comprises an identifier or tag
20 comprising an antenna for transmitting or receiving interrogating energy; and an integrated circuit chip connecting with said antenna, and the second transceiver on the drive unit comprises a reader for said identifier or tag. In this case the identifier or tag is a passive transceiver and the reader is an active transceiver. In embodiments, the reader is not in direct contact with the tag or identifier that is to be read.

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In embodiments, the integrated circuit chip has a read only memory area, a write only memory area, a read/write memory area or combinations thereof. In embodiments, the integrated circuit chip has a one-time programmable memory area. In embodiments, the one-time programmable memory area contains a unique serial number. In embodiments, the
30 integrated circuit chip has a preset memory area containing a factory preset, non-changeable, unique data item. In embodiments, the preset memory item is in encrypted form. In

embodiments, the integrated circuit chip has plural memory areas thereon. In embodiments, any memory area is password protected. In embodiments, any memory area contains data in encrypted form. Electronic methods of checking identity, error detection and data transfer may also be employed. In embodiments, the integrated circuit has plural memory areas

5 thereon including a read only memory area containing a unique serial number, which may for example be embedded at the time of manufacture; a read/write memory area which can be made read only once information has been written thereto; and a password protected memory area containing data in encrypted form which data may be of anti-counterfeiting utility.

10 In embodiments, the tag is on a carrier and the carrier is mountable on the cassette unit. In embodiments, the carrier comprises an insulating material such as a glass material or, a paper material or an organic polymeric material such as polypropylene.

The interrogating energy may be in any suitable form including ultrasonic, infrared,
15 radiofrequency, magnetic, optical and laser form. Any suitable channels may be used to channel the energy including fibre optic channels.

In embodiments, the first transceiver on the cassette comprises a radiofrequency identifier (RFID) comprising an antenna for transmitting or receiving radiofrequency energy; and an
20 integrated circuit chip connecting with said antenna, and the second transceiver comprises a reader for said radiofrequency identifier. In this case the radiofrequency identifier is a passive transceiver and the reader is an active transceiver. An advantage of radiofrequency identifier technology is that the reader need not be in direct contact with the radiofrequency identifier tag or identifier to be read.

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The radiofrequency identifier can be any known radiofrequency identifier. Such identifiers are sometimes known as radiofrequency transponders or radiofrequency identification (RFID) tags or identifiers. Suitable radiofrequency identifiers include those sold by Phillips Semiconductors of the Netherlands under the trade marks Hitag and Icode, those sold by
30 Amtech Systems Corporation of the United States of America under the trade mark Intellitag,

and those sold by Texas Instruments of the United States of America under the trade mark Tagit.

5 In embodiments, the antenna of the RFID tag is capable of transmitting or receiving radiofrequency energy having a frequency of from 100 kHz to 2.5 GHz. Preferred operating frequencies are selected from 125 kHz, 13.56 MHz and 2.4 GHz.

10 In embodiments, the first transceiver on the cassette unit comprises a magnetic identifier or tag comprising an antenna for transmitting or receiving magnetic field energy; and an integrated circuit chip connecting with said antenna, and the second transceiver on the drive unit comprises a reader for said magnetic identifier or tag. In this case the magnetic identifier or tag is a passive transceiver and the reader is an active transceiver.

15 In embodiments, the first transceiver on the cassette unit comprises a microelectronic memory chip and the second transceiver on the drive unit comprises a reader for said microelectronic memory chip. The microelectronic memory chip may comprise an Electrically Erasable Programmable Read Only Memory (EEPROM) chip, a SIM card-type memory chip or a flash type memory chip. In this case the microelectronic memory chip is a passive transceiver and the reader is an active transceiver.

20

Once the reader has read (or interrogated) the identifier of the cassette unit, that identifier data is communicated to a verifier, which conducts a verification step.

25 In embodiments, the verifier carries out the verification by comparing one or more pieces of data read from the identifier with acceptable data values. In embodiments, the comparison makes reference to a look-up table of acceptable values, which may include data that is patient specific. In one embodiment, the acceptable values of look-up table are pre-loaded into an electronic data system of the drive unit. In another embodiment, the acceptable values of look-up table are downloadable to an electronic data system of the drive unit (e.g. by communicating with an online data source). In one embodiment, the acceptable values of look-up table are calculable by an electronic data system of the drive unit (e.g. based on data

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input by the user or feed-ins from sensors of the device). In one example, the data relates to type of drug with a comparison being made between the type of drug contained within the syringe and that required by the patient. In another example, the data relates to the 'use by' date of the drug with verification being made by reference to an electronic calendar of the electronic data system of the drive unit with positive verification being registered only if the 'use by' date of the drug has not been exceeded. In another example, the data relates to the 'lot number' of the cassette unit and a check is made against whether that 'lot number' has been subject to a recall or not.

10 In embodiments, the drive unit is arranged such that transport of the cassette unit from the intermediate position to the docking position is permitted only following positive verification of the identifier. Thus, only appropriately verified cassette units are finally receivable into the device for drug delivery there from.

15 In embodiments, that transport of the cassette unit to the docking position is by automatic control under the action of the electrically powered source of drive. Thus, in embodiments positive verification of the cassette unit gives rise to a 'transport to docking position' signal from the electronic data system to the source of drive, which results in the required transporting action.

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Inputs and sensors

In embodiments, the drive unit is provided with one or more inputs for receipt of data and/or commands relating to the operation thereof.

25 In embodiments, the inputs comprises one or more inputs from a man machine interface (MMI) for providing inputs in response to user actions. In embodiments, the MMI inputs are responsive to manual actions of a user, and are for example, selected from a keypad; touch screen; go/pause button (e.g. to start/pause the injection, or confirm a selection of a menu feature as shown on an electronic display); a power button (e.g. to turn on/off the device);
30 and a scroll wheel (e.g. to scroll up/down to select an injection speed, or for use in selection of a menu feature as shown on an electronic display). In embodiments, other suitable inputs

include a voice recognition interface; graphical user interface (GUI); or a biometrics interface. In embodiments, the drive unit is provided with visual input detectors (e.g. incorporating camera, light or laser input systems) that are, in embodiments arranged to detect gesture control and/or proximity of the hand or fingers of a user.

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In embodiments, the inputs comprise one or more data input ports such as a USB port (e.g. for charging the drive unit or for connecting the drive unit to a personal computer, for example, to view the injection log or for investigations of drive unit functioning).

10 In embodiments, the USB port is used to connect the device to a personal computer to view the user log, or connect to a wall electrical charger to recharge the internal battery. In embodiments, the drive unit can detect when there is a current connected thereto (different threshold to differentiate between connected to PC vs wall electrical charger).

15 In embodiments, the drive unit is provided with one or more sensors for sensing aspects of the operation thereof, in particular the drive operation thereof and/or the interaction of the cassette unit with the drive unit.

In embodiments, the drive unit is provided with an electronic control unit, wherein the one or
20 more inputs and/or the one or more sensors communicate with the electronic control unit.

In embodiments, one or more cassette unit detection sensors (e.g. cassette detection sensing means) are provided to detect the presence of the cassette unit within the drive unit. In embodiments, any or each cassette unit detection sensor has the form of a micro-switch.

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In embodiments, the cassette unit detection sensor detects when the cassette unit is fully loaded into the cassette unit holder (or 'slider') of the drive unit or not. In embodiments, the cassette unit detection sensor may be set up to give a reading of 'open' when no cassette unit is detected and 'closed' when a cassette unit is detected.

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In embodiments, one or more cap detection sensors (e.g. cap removal sensing means) are provided to detect the presence of the removable cap (and needle cover connected thereto) on the cassette unit. In embodiments, any or each cap detection sensor has the form of a micro-switch. In embodiments, the cap detection sensor may be set up to give a reading of 'open' when no removable cap is detected on the cassette unit and 'closed' when a removable cap is detected on the cassette unit.

In embodiments, the drive unit comprises an electronic control unit; one or more cassette unit detection sensors for detecting the presence of the cassette unit within the drive unit, and capable of sending a cassette unit detection signal to said electronic control unit; and one or more cap detection sensors for detecting the presence of the removable cap on the cassette unit, and capable of sending a cap detection signal to the electronic control unit. In embodiments, the electronic control unit is capable of collating said cassette unit detection and cap detection signals to determine an overall detected state of the cassette unit.

In embodiments, the cassette unit detection sensor detects whether the cassette unit is fully loaded into the cassette unit holder of the drive unit or not.

In embodiments, the electronic control unit is provided with a decision algorithm that decides upon and signals a control action (e.g. to the drive arrangement of the drive unit) dependent upon the overall detected state of the cassette unit. In embodiments, the decision algorithm references different decision making parameters or routines dependent upon whether an injection procedure has started or not, or dependent upon whether a cassette unit ejection procedure has started or not.

In embodiments, the drive unit comprises a display unit, and the electronic control unit is capable of sending a command to the display unit to display a message when a particular overall cassette unit state is determined, said message being relevant to said particular determined overall cassette unit state.

In embodiments, the electronic control unit is capable of sending an emergency stop or abort command to the drive arrangement when an unacceptable overall cassette unit state is determined.

- 5 In embodiments, the drive unit additionally comprises a USB data input port for connecting the drive unit to an electrical charger or to a personal computer. In embodiments, the electronic control unit is capable of detecting electrical current flow at the USB data input port. In embodiments, the electronic control unit differentiates between whether the drive unit is connecting to an electrical charger or to a personal computer. In embodiments, the
- 10 electronic control unit is provided with a second decision algorithm that decides upon and signals a control action dependent upon both the overall detected state of the cassette unit and the detection or not of current flow at the USB data input port.

- In embodiments, one or more encoders are provided to detect the position and movement characteristics of the movable parts of the drive unit. In embodiments, a slider motor encoder:
- 15 is provided to detect the linear position and speed of the cassette unit holder. In embodiments, a leadscrew motor encoder is provided to detect the linear position and speed of the leadscrew.

- 20 In embodiments, the drive unit is provided with a timer (e.g. timer function) that starts a time count on removal of the removable cap and needle cover from the cassette unit. In embodiments, the one or more cap detection sensors communicate with the timer (e.g. via an electronic data system or control unit). In embodiments, the timer function is initiated by the removal of the removable cap and needle cover from the cassette unit. In embodiments, the
- 25 timer counts upwards (i.e. from zero) on removal of the removable cap and needle cover). In other embodiments, the timer counts downwards (i.e. from a pre-determined time count) on removal of the removable cap and needle cover. Thus, for example an indication of time remaining to safely use the device may be calculated.

- 30 In embodiments, the timer is arranged such that on reaching a certain, pre-determined time count a stop command to stop the drive functioning of the drive unit is generated. Drive

action of the drive unit is thus, prevented. In embodiments, the stop command is to disable (e.g. switch off or de-power) said one or more electrically powered sources of axial drive. In embodiments, the stop command is to initiate a blocking function that acts to block the movement of said first and/or second drive transfer elements. In embodiments, the timer
5 therefore acts to ensure that drug is delivered to the patient within a set time limit following removal of the removable cap and needle cover from the syringe of the cassette unit.

In embodiments, a skin sensor mechanism is provided to the drive unit housing that is actuable in response to sensing of the skin of the patient. In embodiments, the skin sensor
10 mechanism comprises a skin sensor arrangement comprising an array of plural skin sensor electrodes (e.g. from 3 to 10, such as from 4 to 10 and from 6 to 8, individual skin sensor electrodes) located about that part of the housing of the drive unit of the auto-injector that defines the needle delivery aperture as described in Applicant's PCT publication no.

WO2014/066,256, the entire contents of which are incorporated herein by reference. In
15 embodiments, the array of plural skin sensor electrodes is evenly spaced about the needle delivery aperture. In embodiments, the needle delivery aperture of the drive unit housing is essentially circular in shape and the array of plural skin sensor electrodes is arranged circumferentially about the needle delivery aperture in an essentially circular arrangement. In embodiments, each skin sensor electrode takes the form of a capacitance skin sensor
20 electrode such as a proximity sensor arranged for detecting proximity of human skin thereto or contact of human skin therewith. One suitable capacitance skin sensor electrode is sold under the trade name AD7148 by Analog Devices Inc. of One Technology Way, PO Box 9106, Norwood, MA 02062-9106, USA. In embodiments, the drive unit additionally comprises an electronic control unit, wherein each of the plural skin sensor electrodes is
25 capable of sending an individual skin sensing signal to the electronic control unit. In embodiments, the electronic control unit is capable of collating (and in embodiments, analyzing) the individual skin sensing signals for each of the plural skin sensor electrodes to determine a skin sensing state for the array of plural skin sensor electrodes as a whole. In embodiments, the electronic control unit is provided with a decision algorithm that decides
30 upon and signals a control action dependent upon the determined skin sensing state. Suitable

decision algorithms are described in Applicant's PCT publication no. WO2014/066,256, the entire contents of which are incorporated herein by reference.

5 In embodiments, the drive unit is provided with a system for managing injection punctuality for a prescribed drug dosing regimen over a particular calendar period. In embodiments, the drive unit is capable of tracking injections made, and can set the next scheduled injection due date based on when the last injection was made. Where a complex injection regime consisting of one or more injections and/or at varying frequencies is envisaged, the drive unit may be configured to calculating punctual injection time frames and as appropriate, to raise alarms and/or provide advisory indications to the client. In embodiments, the drive unit provides a display of the injection calendar to allow a user to appropriately schedule injections, particularly the next injection.

15 In embodiments, user preparation to inject too early will give rise to appropriate audible and visual alarms and provide warning that the user is injecting ahead of schedule together with an advisory to follow physicians' instructions, but typically the drive unit will still allow the user to inject.

20 In embodiments, administering injections too late or a missed injection by the user will give rise to appropriate audible and visual alarms and provide warning of the scheduled dose date being missed together with an advisory to the user to contact their physician for correct dosing. Again, the drive unit will still allow a user to perform an injection should they wish.

25 In embodiments, for each drug dosing regimen, a specified injection interval, n , safety interval, S_i , depletion interval, P_i , and number of cassette units to inject per dose (both loading and/or maintenance) may be programmed into the drive unit. In embodiments, the next injection due date, early threshold dates and late threshold dates are calculated as a function of these parameters and also of the completion date of the user's last injected dose, and also of a function of whether the previous dose was fully or partially injected.

30

In embodiments, the drive comprises a geographic positioning system such as a global positioning system or a system, which relies on the use of multiple communications signals and a triangulation algorithm.

- 5 In embodiments, the drive unit comprises an orientation sensor for checking on the orientation thereof. In embodiments, the drive unit is arranged to operate only when in certain defined orientations (e.g. upright or nearly so).

Electronic data system

- 10 In embodiments, the auto-injector comprises an electronic data system, typically under the control of one or more microcomputers. In embodiments, the electronic data system has input/output capability and comprises a memory for storage of data; one or more microprocessors for performing operations on said data; and a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data. In embodiments, the
15 electronic data system may form of a part of or communicate with an electronic control unit of the drive unit.

- In embodiments, the electronic data system is integral with the drive unit. Alternatively, the electronic data system forms part of an electronic data system such as on a circuit board or
20 plug-in, which is reversibly associable with the drive unit.

- In embodiments, the electronic data system may receive inputs and/or commands from a man machine interface (MMI) for providing inputs in response to user actions. In embodiments, the electronic data system is arranged to be responsive to or activated by the voice of a user.
25 Thus, for example the electronic data system may be switched on or off in response to a voice command.

- In embodiments, the electronic data system comprises a visual display unit for display of data to the user. The display may for example, comprise a screen such as an LED or LCD screen,
30 which may also be a touch screen. In embodiments the visual display unit is associable with the drive unit.

In embodiments, the inputs comprises one or more inputs from a man machine interface (MMI) for providing inputs in response to user actions. In embodiments, the MMI inputs are responsive to manual actions of a user, and are for example, selected from a keypad; touch
5 screen; go/pause button (e.g. to start/pause the injection, or confirm a selection of a menu feature as shown on an electronic display); a power button (e.g. to turn on/off the device); and a scroll wheel (e.g. to scroll up/down to select an injection speed, or for use in selection of a menu feature as shown on an electronic display). In embodiments, other suitable inputs include a voice recognition interface; graphical user interface (GUI); or a biometrics
10 interface. In embodiments, the inputs comprise visual inputs and detectors (e.g. incorporating camera, light or laser input systems) are arranged to detect such visual inputs including gesture control and/or proximity of the hand or fingers of a user.

In embodiments, the electronic graphical user interface (GUI) provides the user with
15 guidance and/or feedback from the start to the end of an injection process. In embodiments, the graphical user interface includes features selected from the following: providing the user with warning messages, alarms or error codes when they encounter any issues; guiding the user on the correct injection process (from insertion of the medication, removing the needle cap, placing onto the skin, injecting, removing from the skin, replacing the needle cap,
20 removing the used medication, and powering off the injection device); providing information relating to battery charge status and advice for charging; providing injection calendar reminders for when the patient's next injection is, or providing an indication if they are injecting ahead or before their scheduled injection date; providing information on the status of the injection device for when it needs to be replaced; guiding users on how to proceed if
25 they encounter an interruption during their injection; and providing confirmation that the injection has successfully been completed, and advising how to proceed if not.

In embodiments, the auto-injector additionally comprises a data link for linking to a local data store to enable communication of data between the local data store and the electronic
30 data system. The data store may also comprise data management, data analysis and data communication capability. In embodiments, the data link comprises a USB data input port.

The data store may itself form part of a portable device (e.g. a handheld device) or it may be sized and shaped to be accommodated within the patient's home. The data store may also comprise a physical storage area for storage of replacement cassette units, accessories and/or spare parts. The data store may further comprise an electrical recharging system for recharging any electrical energy store of the drive unit, particularly a battery recharging system.

The data link may for example enable linking with a docking station, a personal computer, a network computer system or a set-top box by any suitable method including a hard-wired link, an infrared link or any other suitable wireless communications link.

Wireless connectivity

In embodiments, the drive unit comprises a communicator for wireless communication with a network computer system to enable transfer of data between the network computer system and the electronic data system of the drive unit. In embodiments, the communicator enables two-way transfer of data between the network computer system and the electronic data system. Wi-Fi enabled communicators are envisaged.

In embodiments, the communicator communicates via a gateway to the network computer system. In another aspect, the communicator includes a network server (e.g. a web server) such that it may directly communicate with the network.

In embodiments, the communicator communicates with the gateway via a second communications device. In embodiments, the second communications device is a telecommunications device, more in embodiments a cellular phone or pager. In embodiments, the communicator communicates with the second communications device using spread spectrum radiofrequency signals. A suitable spread spectrum protocol is the Bluetooth (trade mark) standard, which employs rapid (e.g. 1600 times a second) hopping between plural frequencies (e.g. 79 different frequencies). The protocol may further employ multiple sending of data bits (e.g. sending in triplicate) to reduce the effects of interference.

In embodiments, the communicator comprises a Bluetooth Low Energy (BTLE) chip.

In embodiments, the communicator comprises a 3G/4G enabled chip to allow communication directly over cellular technology to a cloud. In embodiments, the communicator comprises a
5 Wi-Fi chip to allow communication to a local or wider area network computer system.

In embodiments, communication between the network computer system and the drive unit is via a cradle or hub (e.g. communicating via Wi-Fi or BTLE); via a smartphone, communicating via BTLE, and then over the cellular or Wi-Fi network; or directly to the
10 network computer system via cellular technology

In embodiments, the network computer system comprises a public access network computer system. The Internet is one suitable example of a public access network computer system, wherein the point of access thereto can be any suitable entry point including an entry point
15 managed by an Internet service provider. The public access network computer system may also form part of a telecommunications system, which may itself be a traditional copper wire system, a cellular system or an optical network.

In another aspect, the network computer system comprises a private access network computer
20 system. The private access network system may for example, comprise an Intranet or Extranet, which may for example, be maintained by a health service provider or drug manufacturer. The network may for example include password protection; a firewall; and suitable encryption means.

25 In embodiments, the communicator enables communication with a user-specific network address in the network computer system. The user-specific network address may be selected from the group consisting of a web-site address; an e-mail address and a file transfer protocol address. In embodiments, the user-specific network address is accessible to a remote information source such that information from said remote information source might be made
30 available thereto.

In embodiments, information from the user-specific network address is made available to the remote information source. In embodiments, the remote information source is a source of drug prescriptions, for example a doctor's practice or a hospital; a pharmacy; an emergency assistance provider; a manufacturer of drugs; or a research establishment.

5

In embodiments, the data is communicable between the network computer system and the electronic data system in encrypted form. All suitable methods of encryption or partial encryption are envisaged. Password protection may also be employed. In embodiments, the communicator employs radiofrequency or optical signals.

10

Data transmission

In embodiments, the electronic data system of the drive unit communicates wirelessly with a cloud-based data system (i.e. one which is based separate from the drive unit and typically, on a network of computers forming a cloud system).

15

In embodiments, one-way communication of data from the electronic data system with the cloud-based data system is envisaged. In embodiments, one-way communication of data from the electronic data system to the cloud-based data system is envisaged, thus enabling 'pull' of data from the electronic data system onto a cloud-based data system. Once on the cloud-based data system, the data can then be analysed or sent to the health care provider or physician. In embodiments, data can include injection history for compliance; any faults or error codes for fault investigation; and number of injections (e.g. so that the device can prompt to the warehouse that the user will need a new device).

20

25 Examples of 'pull' data from the electronic data system of the drive unit to the cloud-based data system include:

- History of injections, which would be updated and sent to the cloud system after each injection to monitor compliance. Information such as the injection date/punctuality, number of cassette units, any use errors/alarms that were encountered, any pauses of injection, emergency stops, etc. can all be recorded and sent back to the cloud system.

30

This can then be sent to health care providers (e.g. physicians, nurses or payers) for patient visits, reimbursement, and other administrative purposes.

- Technical faults and error codes that the electronic data system of the drive unit can recognise, to be sent to the manufacturer or distribution centres. Complaints and replacement drive units can then be rectified much quicker and more precisely rather than having to get information from third party intermediaries/logistics.
- Logging use of cassette units by the drive unit to monitor supplies at the patient side, so new cassette units can be sent to the user in time for their next injection without the need for going to the pharmacy/physician.
- Monitoring the number of uses of a drive unit so a new drive unit can be sent at end of life
- Batch records and traceability of drive unit and cassette unit serial numbers in the field
- Other device technical information and data for monitoring usage, trends or patterns.

In other embodiments, two-way communication of data between the electronic data system with the cloud-based data system is envisaged, thus enabling both 'pull' of data from the electronic data system onto a cloud-based data system and 'push' of data from the cloud-based data system onto the electronic data system. Data to be transferred from the cloud-based data system may include device configurations; dose regimen set up; push software updates; and push injection reminders.

Examples of 'push' data from the cloud-based data system to the electronic data system of the drive unit include:

- Software updates and bug fixes.
- Configuration of the auto-injector dose regimen: injection frequency, dose strength, medication type, injection speeds, needle injection depths, time, language, and any other parameters in the algorithms.
- Resetting of any alarms, technical errors, injection dates/punctuality, and other resets

- Injection reminders or personalized messages in line with the patients' appointments with their physician or status.

5 In embodiments, data sent to the cloud-based data system can be under the control of the manufacturer or a third party vendor; and then managed via a web interface or a mobile application. In embodiments, this may be made accessible to physicians, patients, payers, manufacturers and other designated data users and can be linked to electronic health records, supply chain records, and other external data records.

10 In embodiments, two-way communication of control data between the electronic data system with the cloud-based data system is envisaged, thereby enabling remote control of an injection procedure.

Menu function

15 In embodiments, the drive unit comprises a first primary menu function for providing a menu of first control options to the electronic control unit; and a second hidden menu function for providing a menu of second control options to the electronic control unit.

20 In embodiments, the first and second menu functions are arranged for alternate display at a display unit. In embodiments, the second hidden menu function is accessible only in response to a particular series of input commands provided as a particular series of manual actions of a user to the man machine interface.

25 In embodiments, the first menu function is the 'default' option. In embodiments, the first menu function is accessible either automatically or in response to a single input command provided as a single manual input to the man machine interface. In embodiments, the first primary menu function is accessible only using a particular series of manual inputs to the man machine interface (MMI) of the drive unit.

In embodiments, the primary menu function includes control options selected from the following: starting and/or pausing the injection as required (e.g. by starting and/or pausing the action of the drive unit); and changing/varying the injection speed as required.

- 5 In embodiments, the second hidden menu function is accessible only using a particular series of manual inputs (e.g. two or more) to the man machine interface (MMI) of the drive unit. The hidden menu is designed for access solely by a healthcare professional to whom only the particular series of manual inputs are provided. Once accessed, the hidden menu allows the healthcare professional to set a specific dose regimen. The hidden menu is not intended to be
- 10 accessible to patients or to lay users, so the particular series of manual inputs is suitably arranged to be relatively complex.

- In embodiments, manual inputs to the MMI are selected from keypad inputs; touch screen inputs; button inputs; toggle inputs; scroll wheel inputs and any combinations of these. In
- 15 embodiments, the button inputs are selected from go/pause button inputs (e.g. to start/pause the injection, or confirm a selection of a menu feature as shown on an electronic display); and power button inputs (e.g. to turn on/off the device).

- In embodiments, the particular series of manual inputs is selected to be complex to therefore
- 20 minimize the risk of other users guessing or stumbling across the hidden menu by mistake, and then using the same combination of manual input to get to the next layer to access the hidden menu.

- In embodiments, exiting from the second hidden menu function is in response to a particular
- 25 series of input commands provided as a particular series of manual actions of a user to the man machine interface. In different embodiments, the series of input commands for exiting the second hidden menu function either correspond to or differ from those input commands employed to access the hidden menu function.

- 30 In embodiments, the electronic control unit can be set up to provide various dose regimen (e.g. for different drug types depending on the target therapy area, region of injection,

severity of symptoms, personalized dosing to meet individual patient needs, amongst other factors) to match patient's needs depending on what their physician recommends or their condition.

- 5 In embodiments, once the health care professional has accessed the second hidden menu function, using the particular series of manual inputs, then they can use hidden menu to define a particular dose regimen by providing various menu inputs to the hidden menu.

Prescription and supply

- 10 The cassette unit and drive unit may be arranged for use in different prescribing regimes to accommodate different patient therapeutic needs. In embodiments, prescribing data may be provided to a data store provided to the cassette unit (e.g. comprising an RFID tag); or to a data store provided to the drive unit (e.g. a memory of the electronic data system); or to any suitable combination of both of these. In embodiments, prescribing data may be provided to
15 any data store at any suitable point in the supply chain thereof, including at manufacture of the relevant unit or at the moment of prescribing thereof by an authorised healthcare professional or pharmacist.

- In one particular embodiment, a data store of the drive unit is provided with prescribing data
20 (e.g. comprising any of the patient's name; the medication type; the prescription regime, for example including injection interval and dose value; the local time; and the local language) at a defined point in the supply chain thereof, which may be defined to be the time of manufacture thereof. Thus, in essence, at a defined point in the supply chain, the drive unit is 'tailored' with data relating to a prescription regime and/or to a particular patient. This
25 'tailored' drive unit is then provided (e.g. by a healthcare professional) to the patient along with one or more cassette units, each of which has no particular prescribing data associated therewith. This type of approach is sometimes known as the "supply chain set-up" approach.

- In another particular embodiment, a data store of the drive unit is provided with a more
30 general, typically non-personalised, set of prescribing data (e.g. comprising any of the medication type; the local time; and the local language) at a defined point in the supply chain

thereof, which may be defined to be the time of manufacture thereof. Thus, the drive unit is not 'tailored' at any defined point in the supply chain with data relating to any particular patient prescribing regime. In addition, a data store of the cassette unit (e.g. RFID tag) is provided with prescribing data (e.g. comprising any of the patient's name; and the
5 prescription regime, for example including injection interval and dose value) at a defined point in the supply chain thereof, which may be defined as the time of manufacture thereof. Thus, in essence, at a defined point in the supply chain, the cassette unit is 'tailored' with data relating to a prescription regime and/or to a particular patient. One or more of these 'tailored' cassette units is then provided (e.g. by a healthcare professional) to the patient
10 along with a more general drive unit. This type of approach is sometimes known as the "RFID tag control" approach.

It will be appreciated that at the time of providing of the drive unit and cassette unit(s) to the patient (e.g. by the healthcare professional), the sum of prescribing data carried in
15 combination by the cassette unit(s) and drive unit can be arranged to be the same using either the "supply chain set-up" or "RFID tag control" approaches. It will also be appreciated that once the drive unit and any particular cassette unit are brought together (e.g. in assembled form to form the auto-injector herein) that prescribing data may be arranged for transfer from drive unit to cassette unit and vice-versa (e.g. by reading / writing to the RFID tag on the cassette
20 unit by means of a reader/writer on the drive unit).

On switching prescription regimes, where the "supply chain set-up" approach is employed, a change of prescription regime will typically require the drive unit to be sent back to the supply chain (e.g. to manufacturer, doctor or pharmacist) to 're-programme' the drive unit by
25 uploading the data store of the drive unit with new / replacement prescribing data relating to the new prescribing regime. The 're-programmed' drive unit is then provided again to the patient.

In particular embodiments, the healthcare provider is provided with a 'switching cassette'.

30 This 'switching cassette' does not contain any drug or syringe, but when inserted into a

patient's device information contained at the RFID tag is arranged to trigger a change in regimen settings within the device.

On switching prescription regimes, where the “RFID tag control” approach is employed, a
5 change of prescription regime will typically require the patient to be provided (e.g. by a
healthcare professional) with one or more cassette units ‘tailored’ with data relating to the
new prescribing regime. There is thus, with this approach, no need to send the drive unit back
for ‘re-programming’ on switching prescription regimes. In embodiments, on use of the new
cassette unit(s) with the original drive unit, that drive unit may be arranged to detect a change
10 of prescribing regime (e.g. vs. the previous regime) and will signal this change to the patient
(e.g. by displaying a message on a display unit) and/or may ask the patient to confirm the
change of prescribing regime before continuing.

Kit of parts

15 In embodiments, there is also provided a kit of parts comprising a cassette unit (absent
syringe) as described above; and a syringe containing a liquid drug formulation.

In embodiments, there is further provided a kit of parts comprising a cassette unit (which may
in embodiments, be in kit of parts form) as described above; and a drive unit as described
20 above.

In embodiments, there is further provided a kit of parts comprising an auto-injector (which
may in embodiments, be in kit of parts form) as described above; and packaging therefor.
Suitable packaging typically comprises a storage container for the drive unit and one or more
25 cassette units.

In certain implementations, an injection kit includes a cassette unit housing having an inner
surface and a plurality of syringe barrels having different physical dimensions. The kit may
also include a plurality of sleeve form adapters configured to receive at least one of the
30 syringe barrels, where the sleeve form adapter has an outer surface configured to interfit with
the inner surface of the cassette unit housing.

In certain embodiments, each syringe barrel has a unique circumference size or a unique contoured surface that mates with the sleeve form adapter.

5 *Method of assembling a medicament-injector*

In certain implementations, a method of assembly a medicament-injector includes selecting a syringe barrel among a plurality of syringe barrels, each of the plurality of syringe barrels having a different physical dimension than is found in the other of the plurality. The method may also include selecting a sleeve form adapter configured to mate with the selected syringe
10 barrel, interfitting the syringe barrel within the sleeve form adapter, and installing the sleeve form adapter within a cassette unit. In certain embodiments, each syringe barrel has a unique circumference size or a unique contoured surface that mates with the sleeve form adapter.

Brief Description of the Drawings

15 The disclosure is further described with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of a first cassette unit of an auto-injector herein and shown in the 'pre-use' configuration;

20 Figure 2 is a sectional view of the first cassette unit of Figure 1 arranged for use with a 1ml syringe also in the 'pre-use' configuration;

Figure 3 is an exploded view of the first cassette unit of Figure 1;

25 Figure 4 is a top plan view of the first cassette unit of Figure 1;

Figure 5a is a part-exploded view of a syringe with shoulder support assembly suitable for use with the cassette unit of Figures 1 to 4;

30 Figure 5b is a perspective view of the syringe with shoulder support assembly of Figure 5a;

Figure 5c is a sectional view of the syringe with shoulder support assembly of Figures 5a and 5b;

5 Figures 6a and 6b are perspective and cross sectional view of a first needle cover for use with the first cassette unit of Figures 1 to 4;

Figures 7a and 7b are perspective and cross sectional view of a rigid needle shield for use with the needle cover of Figures 6a and 6b;

10 Figures 8a and 8b are perspective side-on views of a cassette unit housing and shuttle lock control part-assembly of the first cassette unit of Figures 1 to 4 at respective, first 'cassette unused' and third 'cassette used' positions;

15 Figure 8c shows the separate cassette unit housing and shuttle lock control parts of the part-assembly of Figures 8a and 8b;

Figures 9a to 9c are close-up perspective side-on views of the cassette unit housing and shuttle lock control part-assembly of Figures 8a and 8b at respective, first 'cassette unused', second 'cassette unlocked' and third 'cassette used' positions;

20

Figures 10a to 10c are sectional views taken along the line A-A' of Figures 9a to 9c of the cassette unit housing and shuttle lock control part-assembly of Figures 8a and 8b at respective, first 'cassette unused', second 'cassette unlocked' and third 'cassette used' positions;

25

Figures 11a to 11c are sectional views taken along the plane bisecting locking arm 24 of Figures 9a to 9c of the cassette unit housing and shuttle lock control part-assembly of Figures 8a and 8b at respective, first 'cassette unused', second 'cassette unlocked' and third 'cassette used' positions;

30

Figure 12 is a perspective exploded view of an end-cap, end-cap biasing and damping element and plunger slaving part for use with the first cassette unit of Figures 1 to 4;

5 Figures 13 is a sectional view of the upper part of the first cassette unit of Figures 1 to 4 showing details of end-cap, end-cap biasing and damping element and plunger slaving part interaction with the rearward flange of the syringe within the cassette unit housing;

Figures 14a to 14d are side, rear plan, front plan and sectional views of a plunger slaving part for use with the first cassette unit of Figures 1 to 4;

10 Figures 15a to 15d are perspective, side, rear plan and front plan views of a first biasing and damping element for use with the first cassette unit of Figures 1 to 4;

Figure 16 is an exploded view of the connector, cap insert and removable cap of the first cassette unit of Figures 1 to 4;

Figure 17 is a perspective view of a first drive unit, particularly suitable for use with the first cassette unit of Figures 1 to 4;

20 Figure 18 is a perspective view of the first drive unit of Figure 17 with a first cassette unit received at the docking position;

Figure 19 is a perspective view of the first drive unit of Figure 17 with the outer cover removed to show the drive arrangement thereof;

25 Figure 20 is an exploded view of the first drive unit of Figure 17 with the outer cover removed to show the drive arrangement thereof;

Figures 21a and 21b are respectively perspective and side views of a second drive unit, which is a slight variant of the drive unit of Figure 17 showing the forward end thereof;

Figure 22 is a system drawing of a suitable electronic control system for use with the drive units of Figures 17 and 21; and

5 Figures 23a to 23h show sequential steps in setting up a dose regimen on the drive unit of Figure 21 via hidden menu access.

Detailed Description

To provide an overall understanding of the systems, devices and methods described herein, certain illustrative embodiments will now be described. For the purpose of clarity and
10 illustration these systems and methods will be described with respect to auto-injectors that employ electrically powered drive units and cassette units that receive medicament syringes. It will be understood by one of ordinary skill in the art that the systems, devices and methods described herein may be adapted and modified as is appropriate, and that these systems,
15 devices and methods may be employed in other suitable applications, such as for other types of drive units and cassette units, and that other such additions and modifications will not depart from the scope hereof.

Figures 1 to 4 show a first cassette unit 1 of an auto-injector herein arranged for use with a 1ml syringe 10 that contains a liquid drug formulation (not shown). The cassette unit 1
20 comprises an elongate form cassette unit housing 20 having an end-cap 40 that is arranged for receipt of the syringe 10 and is sized and shaped for this purpose. The cassette unit housing 20 and inner housing sleeve 30 contained thereby are made of clear plastic to allow for viewing of the syringe 10 to provide a visual indication of use. The inner housing sleeve 30 is further provided with security label 21, which may in aspects be an RFID tag label for use in
25 verification purposes. The cassette unit 1 is provided with a removable cap 50 that is arranged to engage the needle cover 19 via cap insert 90 of the syringe 10 and that is shown at Figures 1 and 2 in the capped position. The cap 50 is provided at the brim thereof with a peripheral arrangement of through-hole (i.e. socket like) first engagement features 52 (not visible on Figure 2). The cap 50 is shaped to define a ring pull 54 for receipt by the finger of
30 a user. The cap 50 is also provided with two axial guide channels 53 (spaced at 180°

intervals, only one visible on Figures 1 and 3), each for receipt of head 91a of a protruding leg 91 of cap insert 90.

5 The gripping ring 54 of the removable cap defines a finger aperture to receive a patient's thumb or other preferred finger for pulling the removable cap away from the cassette unit 1 to expose the needle 14. In certain embodiments, the finger aperture is adapted to receive a hook that some patients use to pull the removable cap 50 away from the cassette unit 1. The removable cap 50 with gripping ring 54 makes it easier for patients to engage and disengage the needle cover 17 and rigid needle shield 19 from the syringe barrel 12 as it does not
10 require the patient to contort their fingers by pressing on the sides of a narrow needle cover 17/19. As noted before, the present auto-injector is intended for use by patients having compromised manual dexterity who may therefore experience difficulty pulling a conventional needle cover 17 and/or rigid needle shield 19 off the syringe 10 before self-injection. The gripping ring 54 addresses this need by allowing the patient to simply put the
15 thumb or other preferred finger through the finger aperture 54 and pull on the removable cap to thereby remove the needle cover 17 and rigid needle shield 19.

The syringe 10 is of a standard 1ml type and comprises a barrel 12 with end flange 16 for holding a liquid drug formulation; a hollow needle 14 at one end of the barrel 12; and a
20 syringe plunger 18 in the form of a rubber stopper that is arranged for axial movement within the barrel 12 such as to enable the liquid drug formulation to be expelled through the hollow needle 14. As shown at Figure 2, the syringe plunger 18 is at the 'pre-use' position. The hollow needle 14 defines a needle bore, which is of circular cross-section (e.g. 23G, 25G or 27G diameter) and a needle tip 15. The needle tip 15 is sheathed by needle sheath 17, which
25 is also provided with rigid needle sheath shell 19. More detail of this relationship is now described by reference to Figures 6a to 7b, which illustrate an exemplary arrangement of needle sheath 17 and needle cover 19.

Figure 6a depicts a perspective view of an exemplary embodiment of a sheath-like needle
30 cover 17, which is cylindrical in shape and defines a shoulder 17a at the rear end. The needle sheath 17 may be made out of rubbery material that allows a portion of the connector 56 to

dig into the outer surface thereof, such as that defined by the shoulder 17a to permanently engage the needle sheath 17 to the connector 56. Figure 6b shows a cross sectional view of the same needle sheath 17. As depicted, the needle cover 17 includes a needle receiving portion 17b that is arranged in use, for piercing receipt of the tip 15 of the needle 14 as for example, shown at Figure 2. In embodiments, the needle receiving portion 17b is made from butadiene rubber. In certain embodiments, the needle sheath 17 is hollow, but other shaped arrangements of the interior of the needle sheath 17 are also possible.

Figures 7a and 7b show views of a rigid needle shield 19 for use with the needle sheath 17 of Figure 6a and 6b. Rectangular openings 19a are provided at the rear end of the needle shield for receipt of the shoulder 17a of the needle sheath 17 to enable the forming of a needle cover as may be seen at Figure 2.

The cassette unit housing 20 of the cassette unit 1 is arranged to define a cassette unit housing cavity that is sized and shaped for generally fixed receipt of the syringe 10. The cassette unit housing 20 defines at its forward end a needle delivery aperture 23 through which in use, the hollow needle 14 of the syringe 10 and a portion of the glass hub thereof protrudes on removal of the cap 50 there from. The cassette unit housing 20 is arranged to receive at its rearward end an end-cap 40 close to which the end flange 16 of the syringe 10 seats.

The cassette unit housing 20 is provided with a radial arrangement of first engagement features in the form of movable locking legs 24 defining angled tips 25 (not visible on Figure 2) thereon arranged for reversibly engaging the corresponding radial arrangement of second engagement features in the form of socket through holes 52 of the removable cap 50 for reversible lock engagement of the removable cap 50 to the cassette unit housing 20.

The cassette unit 1 is provided with an inner housing sleeve 30 for sleeved receipt of the syringe 10. The rear part of the inner housing sleeve 30 is provided with a spaced pair of rearward protruding arms 31. The inner housing sleeve 30 also forms a shuttle lock control feature 32 defining a radial arrangement of blocking elements 34 for selectively blocking movement of the movable locking legs 24 of the cassette unit housing 20 relative to the

socket holes 52 of the cap 50, thereby providing for selective control of cap locking / unlocking, more details of which are described hereinafter with reference to Figures 8a to 11c.

- 5 Applicant has found that to reduce the risk of the syringe 10 fracturing under the loads associated with injecting the drug, it is important for a majority of the load path to travel through the forward shoulder 11 of the syringe barrel 12 and lesser load to pass through the flange 16 at the rear end thereof. Thus, as further shown at Figures 5a to 5c but with syringe plunger 18 absent, the syringe 10 of the cassette unit 1 additionally comprises a shoulder
- 10 support feature 5 for supporting the forward shoulder 11 of the syringe. The shoulder support feature 5 may also be used to adapt a 1ml syringe for use in the cassette unit 1. It supports the 1ml syringe shoulder 11, and transmits the load through to the same surface that would support a 2.25ml syringe shoulder directly.
- 15 The shoulder support feature 5 may be seen to comprise a split-barrel 6 that is sized and shaped for receipt by the syringe barrel 12 and a forward lip 7 that is arranged to locate in snap-fit fashion between the rigid needle sheath shell 19 and the forward shoulder 11 of the syringe 10. In embodiments, the use of such a shoulder support feature 5 is to adapt the smaller diameter 1ml syringe to the diameter of the 2.25ml syringe shoulder 11. Provision
- 20 may also be made for poor dimensional control in the production of glass syringes.

Within the cassette unit 1, the shoulder support feature 5 for the syringe 10 interacts with the inner wall of the cassette unit housing 20, which thereby acts to constrain the position of the shoulder support feature 5 and syringe 10 within the cassette unit housing 20. The inner wall

25 of the cassette unit housing 20 also prevents the forward lip 7 of the shoulder support feature 5 from flexing outwards when injection loads are applied to the syringe 10. Thus, the forward shoulder 11 of the syringe 10 effectively captures the forward lip 7 of the shoulder support feature. Also, the rearward split-barrel part 6 of the shoulder support feature 5 acts to sleeve a portion of the syringe barrel 12.

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An additional consequence of this part-sleeved relationship between shoulder support feature 5 and syringe barrel 12 is to increase the effective diameter of the syringe barrel 12. By choice of different sizes, particularly inner diameters, of shoulder support feature 5 different syringe 10 sizes may be accommodated within the same cassette unit housing 20. Thus, the shoulder support 5 may also effectively be used as a syringe size adapter feature.

The syringe plunger 18 is provided with a plunger slaving part 60 that is axially movable within the syringe barrel 12 and for receipt by the rear end of the plunger 18. The syringe plunger 18 is made of a material that is resiliently compressible and the plunger slaving part 10 60 is made of a less compressible material, typically a rigid material.

Further structural details of the plunger slaving part 60 may be seen by reference to Figures 12, 13 and 14a to 14d. Thus, the plunger slaving part 60 defining a circumferential wall 62 arranged for frictional sliding relationship with the inner wall 12a of the syringe barrel 12, a rear face 63 and a front plunger-contacting face 64. As may be seen at Figures 13, 14b and 15 14d, the rear face 63 of the plunger slaving part 60 has a central recess 65 for receipt of a drive transfer element. The central recess 65 is shaped such that the drive transfer element is rotatably receivable therein and has a recess form 65 that tapers to a square-cut end 66. The slaving part 60 is arranged to function such that when a load is applied to the square cut end 20 66 the load is evenly transmitted directly into the plunger 18. The front plunger-contacting face 64 defines a protruding plug end 67 that is arranged for receipt by the rear end of the syringe plunger 18. In embodiments, the plug end 67 is designed to prevent collapse in use, of the plunger 18, which has a cavity in its centre into which a plunger rod may be screwed for manual syringe applications.

The circumferential wall 62 of the plunger slaving part is provided with an evenly spaced radial arrangement of slide restrictors 68 that function to restrict frictional sliding movement thereof in relation to the inner wall 12a of the syringe barrel 12. Each of the slide restrictors comprises a flexible vane 68 arranged to flex slightly in response to frictional sliding 25 movement of the plunger slaving part 60 and to thereby to increase the resistance of the plunger slaving part 60 to frictional sliding movement. In embodiments, the flexible vanes 68 30

are arranged to increase the initial resistance to forward frictional sliding movement but to impart lesser resistance to said forward frictional sliding movement once movement is underway. In embodiments, the flexible vanes 68 are arranged to more greatly increase the resistance to a backward frictional sliding movement than to the forward frictional sliding movement.

The slaving part 60 may be arranged to be coloured and to perform a second function of providing an easy-to-identify visual indicator of the position of the plunger 18 within the syringe 10 so that the patient can visually confirm the drug had been fully injected. The flexible vanes 68 act such as to maintain the plunger slaving part 60 in the 'after use' (i.e. post-injection) position such that this indicator can be relied upon to signal this 'after use' state. In embodiments, the plunger slaving part 60 has a third function; one of tamper evidence: If an attempt is made to access the syringe 10 via the end-cap 40, the plunger slaving part 60 will be pushed out of engagement with the end-cap 40, resulting in visible evidence of tamper.

The cassette unit 1 includes, in capping relationship with a rear opening of the cassette unit housing 20, a cassette unit end-cap 40. Further structural details of the cassette unit end-cap 40 may be seen by reference to Figures 4, 12 and 13. The cassette unit end-cap 40 defines a drive rod-receiving opening 41 for receipt of a drive rod (part of the drive unit, not shown) for providing forward axial drive to the plunger slaving part 60. Four fixing legs 39 with heels 39a locate at spaced intervals about the inner end wall of the end-cap 40 and protrude forwards for fixing receipt (not visible on Figure 13) with fixing sockets 29 of the cassette unit housing 20. In addition, fixing T-legs 38 with T-features 38a locate at 180° spacing about the inner end wall of the end-cap 40 and protrude forwards for fixing receipt (not visible on Figure 13) with fixing T-sockets 23 of the cassette unit housing 20.

The cassette unit end-cap 40 also defines a spaced pair of cut-away apertures 51 (see Figures 1 and 13) positioned such that when the cassette unit end-cap 40 is in capped relationship with the cassette unit housing 20 the cut-away apertures 51 are in registration with the protruding arms 31 of the inner housing sleeve 30. Each cut-away aperture 51 is designed

allow for insertion of a pushing member (e.g. a pin) such that forward pushing force may be applied to the top of the protruding arms 31 to push the inner housing sleeve 30 forward, thereby allowing for actuation of the shuttle lock control 32, as described in more detail hereinafter.

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In the pre-use configuration (e.g. as shown at Figures 2 and 13), the plunger slaving part 60 is in releasable engagement with the cassette unit end-cap 40. Structurally, the drive rod-receiving opening 41 is defined by a periphery, which is provided with a forward skirt 42 and the plunger slaving part 60 is shaped for releasable engagement in the pre-use configuration with the forward skirt 42. In more detail and with particular reference to Figure 13, the forward skirt 42 is provided with an inner-facing rim 43 and the plunger slaving part 60 defines a circumferential rim 61 and trough 69 shaped for releasable engagement in the pre-use configuration with the inner-facing rim 43 of the end-cap 40. In use, the plunger slaving part 60 is releasable from the cassette unit end-cap 40 in response to forward axial drive provided to the square cut end 66 thereof.

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The cassette unit 1 additionally comprises an end-cap biasing and damping element 45, which defines a biasing relationship between the cassette unit end-cap 40 and the flange 16 of the syringe 10, thereby urging the syringe 10 forwards in relation to the cassette unit end-cap 40. The effect of this sprung relationship is to better hold the syringe 10 within the cassette unit housing 20, and in particular to minimize any potential for the syringe to ‘rattle about’ within the cassette unit housing 20. It will also be appreciated, particularly when reference is made to Figure 2, that the effect of such urging forwards of the syringe 10 is also to bring the forward shoulder 11 of the syringe 10 into closer relationship with shoulder support feature 5, which sits between that forward shoulder 11 and the rigid needle sheath cover 19. Overall, thus the forward end of the syringe 10 thus, tends to be more supported. An additional effect of the biasing and damping element 45 is to prevent rearward movement of the syringe 10 during needle insertion, ensuring that full insertion depth is achieved.

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The biasing and damping element 45 of the cassette unit 1 also acts to define a damping relationship between the cassette unit end-cap 60 and the flange 16 of the syringe 10, and can

thereby act to damp rearward movement of the syringe 10 relative to the cassette unit end-cap 60. The biasing and damping element 45 can thereby damp any such relative movement of the syringe 10 and cassette unit end-cap 60 as may arise from the effects of shock (e.g. shock impact), which may arise e.g. if the cassette unit 1 is dropped onto a hard surface, and thus
5 act to damp the effects of shock impact.

Further structural details of the biasing and damping element 45, which is typically comprised of a polymeric material such as a thermoplastic elastomer, and may be formed by a moulding process, may be seen by reference to Figures 12, 13 and 15a to 15d. The biasing
10 and damping element 45 defines a central ring form 49. Within the cassette unit, this ring 49 is sized and shaped to fit about the forward skirt 42 of the end-cap 40 and when the plunger slaving part 60 is engaged with the end-cap 40 (e.g. as shown at Figures 2 and 13) about the outer circumferential wall 62 of the plunger slaving part 60. The rear face 46a of the forward part 46 of the biasing and damping element 45 defines an essentially flat profile, which
15 allows it to seat up against the inner end wall of the end-cap 40 where it is held in place by the through-molding via holes 44 on the inner wall of the end-cap 40 with integrally formed through-legs 44a, which may be seen to be radially arranged in spaced fashion between the ring-shaped rear part 48 of the biasing and damping element 45 and its main body. As shown at Figure 13, when the biasing and damping element 45 seats up against the end cap 40, the
20 ring-shaped rear part 48 of the biasing and damping element 45 lies within a circular grooved portion of the rear face of end cap 40. In the embodiment shown, four through-legs 44a are shown, but in other embodiments different numbers of through-legs (e.g. from two to six) may be employed. Four circumferentially spaced damping projections 47 extend forwards from the biasing and damping element 45 and connect with the rear end of the syringe flange
25 16, thereby biasing it forwards.

As shown at Figures 15a to 15d, each damping projection 47 has a projecting tower form, as shown schematically at Figure 18. The tower form is designed to yield in a controlled manner in response to compression by the syringe flange 16. Each projecting tower has two sections,
30 namely a forward section 47a, which is arranged to contact the syringe flange, that is relatively slender and easily deformed; and a rearward section 47b which increases (e.g. by a

tapering or sloping geometric form) in width from the base of the upper section to where it contacts the end-cap 40. In embodiments, this form of projecting tower is intended to provide a low biasing force by deforming mainly the forward section 47a, and the high impact compression force mainly through compressing (e.g. partial compression of) the rearward section 47b.

Details of the selective control of cap locking / unlocking of the first cassette unit 1 are now described by reference to Figures 8a to 11c. It will be noted that for illustrative purposes only, Figure 8c shows the separate cassette unit housing 20 and shuttle lock control 32 parts of the part-assembly of Figures 8a and 8b.

The cassette unit housing 20 is provided with a radial arrangement of first engagement features in the form of axially protruding locking legs 24 having heels defining angled tips 25 having a chamfered edge 25a and movable by flexing action and arranged for reversibly engaging a corresponding radial arrangement of second engagement features in the form of socket through holes 52 of the removable cap 50 (see Figures 1 and 3) for reversible lock engagement of the removable cap 50 to the cassette unit housing 20. In a secondary aspect, this arrangement also acts to prevent rotation of the cap 50 relative to the cassette unit housing 20.

The inner housing sleeve 30 defines a shuttle lock control feature 32 comprising a radial arrangement of blocking elements 34 for selectively blocking inwardly flexing movement of the movable locking legs 24 of the cassette unit housing 20 relative to the socket holes 52 of the cap 50, thereby providing for selective control of cap locking / unlocking.

The shuttle lock control 32 is axially movable relative to the cassette unit housing 20 in between three positions, namely:

(i) as shown at Figures 8a, 9a, 10a and 11a, a first 'cassette unused' position, in which the blocking elements 34 block movement of the locking legs 24 of the cassette unit housing 20 relative to the socket through holes 52 of the removable cap, thereby keeping the removable cap 50 in locked relationship to the cassette unit housing 20;

(ii) as shown at Figures 9b, 10b and 11b, a second 'cassette unlocked' position, in which the blocking elements 34 no longer block movement of the locking legs 24 of the cassette unit housing 20 relative to the socket through holes 52 of the removable cap 50, thereby allowing for unlocking of the removable cap 50 from the cassette unit

5 housing 20 and for removal and replacement thereof; and

(iii) as shown at Figures 8b, 9c, 10c and 11c, after replacement of the removable cap 50, a third 'cassette used' position, locating intermediate the first and second positions, in which the blocking elements 34 again block movement of the locking legs 24 of the cassette unit housing 20 relative to the socket through holes 52 of the removable cap, thereby

10 restoring the locked relationship between the removable cap 50 and the cassette unit housing 20.

Movement of the shuttle lock control 32 is typically achieved by application of forward pushing force to the top of the protruding arms 31 of inner housing sleeve 30 to push the

15 inner housing sleeve 30 and the shuttle lock control 32 forward. This is typically achieved by insertion of a pushing member (e.g. a pin) into each of the cut-away apertures 51 of the cassette unit end-cap 40 to push forward the protruding arms 31 of the inner housing sleeve 30. The shuttle lock 32 is biased by the action of shuttle lock spring 35.

20 The shuttle lock control 32 is further provided with a pair of diametrically oppositely located axial position locators 36, each of which is arranged to define three distinct axial positions of the shuttle lock control 32 relative to cassette unit housing 20 and corresponding to said first, second and third positions. Each axial position locator 36 comprises an axial protrusion having a follower 37 arranged thereon for receipt within a corresponding axial track 26 of the

25 inner cassette unit housing 20 such as to define an axial track-follower relationship between the shuttle lock control 32 / inner housing sleeve and the cassette unit housing 20. The previously defined first and second positions correspond to the opposite extremes of this axial track-follower relationship.

30 In use, the cassette unit 1 is initially in the first 'cassette unused' position, in which the angled tip 25 of each flexibly resilient locking leg 24 of the cassette unit housing 20

protrudes slightly into a socket through-hole first engagement feature 52 of the removable cap 50. It will be appreciated that this engaging interaction of the angled tip 25 of locking leg 24 with socket through-hole feature 52 effectively prevents movement (including rotation) of the cap 50 relative to the cassette unit housing 20. In this first position, the blocking elements 34 block movement of the locking legs 24 of the cassette unit housing 20 relative to the socket through holes 52 of the removable cap, thereby keeping the removable cap 50 in locked relationship to the cassette unit housing 20.

In the second ‘cassette unlocked’ position, this engaging interaction can be released by pushing each locking leg 24 inwards, thereby clearing the angled tip 25 from engaging relationship with each relevant socket through-hole 52. Such inward pushing action on the locking leg 24 can be achieved (in the cap unlocked position of Figures 9b, 10b and 11b) by pulling the cap 50 forwards and away from the cassette unit housing 20, which results in the angled tip 25 interacting with the wall edges of the through-hole 52 to push the locking leg 24 inwards.

After cap removal and during injected use, the action of shuttle lock spring 35 results in adoption of the third position until such time as the removable cap 50 is replaced when the second position is again adopted during cap 50 replacement. After cap replacement, the third position is again adopted. The shuttle lock control 32 is arranged to be brought into registration with the indicator opening of the cassette unit housing 20 at the third ‘cassette used’ position (see Figure 8b) as a visual indicator that the cassette has been used.

The cassette unit 1 further comprises flexible locking arms 99 for locking receipt within locking apertures 96 of a cassette unit holder 75 of a drive unit, as will be described hereinafter.

As is shown in more detail at Figure 16, cap insert 90 is arranged for receipt of connector in the form of needle cover gripper 56, which defines a cage-like (or ‘flower’) structure and defining plural gripping elements 58 arranged about a central hub 59. Such gripping elements 58 are arranged for gripping of the rigid needle shield 19 on removal of the removable cap 50

such that removal of the cap 50 also results in removal of the rigid needle shield 19 and needle sheath 17 enclosed thereby, and hence, unsheathing of the needle tip 15.

Cap insert 90 locates within the removable cap 50 and the removable cap is shaped to allow for limited axial travel of the cap insert there 90 within. Removable cap 50 defines first axial track guide features in the form of first track rails 97 provided to the inner surface of the removable cap 50 arranged for guided tracking receipt of protruding legs 91 of the cap insert 90. Removable cap 50 is also provided with second axial track guide features in the form of second track rails 98 provided to the inner surface of the removable cap 50 arranged for guided tracking receipt of track followers 92 of the cap insert 90. When the cap insert 90 is fully received within the removable cap 50, head 91a of each protruding leg 91 is received within axial guide channel 53, which thereby acts to limit the possible axial travel of the cap insert 90 there within, and hence also relative to the removable cap 50 (see also Figure 1). The first and second rack trails 97, 98 also act to assist with accurate registration of the cap 50 with the cassette unit housing 20, thereby assisting with secure fitting and reducing play.

Within the cassette unit 1, allowing limited axial travel of the cap insert 90 within the axial guide channel 53 of the removable cap 50 can enable accommodation of the effects of shock (e.g. impact shock) when the cassette unit 1 is dropped (e.g. onto a hard surface) or mishandled in such a way as to introduce shock thereat / thereto. Thus, in response to shock impact, limited rearwards movement of the syringe 10 with rigid needle shield 19 and needle sheath 17, connector 56 and cap insert 90 is allowed subject to the limits on axial travel determined by the interaction of head 91a of each protruding leg 91 of the cap insert 90 within the axial guide channel 53.

In embodiments, such feature of allowing 'limited rearwards movement' in response to shock impact can be arranged to act in tandem with the hereinafter described biasing and damping element 45, which defines a damping relationship between the cassette unit end-cap 60 and the flange 16 of the syringe 10, and which thereby acts to damp movement (e.g. resulting from shock impact) of the syringe 10 relative to the cassette unit end-cap 60. The rearwards movement of the syringe 10 with rigid needle shield 19 and needle sheath 17, connector 56

and cap insert 90 resulting from shock impact is thus, both damped and limited in terms of axial travel, but is otherwise within these constraints allowed for, which minimizes the effects of that shock impact on the syringe 10 and other potentially vulnerable parts of the cassette unit 1. In particular, the 'limited rearwards movement' allows the cap insert 90, connector 56, rigid needle shield 19 and needle sheath 17 to move with the syringe 10 in impact. If these parts were held rigid, there might be a potential risk that the syringe 10 will pull out of the rigid needle shield 19 / needle sheath 17 as it moves with damper compression. This in turn risks losing sterility.

The cap insert 90 is also provided with shaping at the upper part of its inner wall for defining a second axial channel 94 arranged for receipt of at least part of the connector 56; and with shaping at the lower part of its inner wall for defining a first axial channel 93 co-axial with the second axial channel 94, but of smaller diameter relative thereto, which first axial channel 93 is also arranged for receipt of at least part of the connector 56.

Figure 17 shows a drive unit 70 for use with the cassette unit 1 described herein. The drive unit 70 comprises a drive unit housing 71 for housing a drive arrangement 80, which drive unit housing 71 is sized and shaped at its forward end for receipt of a cassette unit 1. Figure 18 shows the drive unit 70 having received a representative cassette unit 1 at the docking position, wherein ring pull 54 of the removable cap 50 protrudes from the drive unit housing 71. The drive unit housing 71 is provided with a user-interface in the form of a screen 72, which may in embodiments be a touch-sensitive screen 72.

Figures 19 and 20 shows the inner workings of the drive unit 70 of Figures 17 and 18, which has been configured in particular for use with the first cassette unit 1 herein. User-interface 72 may be seen to communicate with circuit board 74, which comprises electronic system circuitry that provides electronic control for the drive arrangement 80 and data processing capability. Further details of a representative electronic control system herein are later described by reference to Figure 22. The circuit board 74 may also include inputs from various sensors and other electronic components including radiofrequency ID tag reader 73, which locates on cassette unit holder 75 and which is arranged for radiofrequency

interrogation of an RFID tag on the cassette unit 1. In other embodiments, the radiofrequency ID tag reader 73 locates at the drive unit at a position closer to where the cassette unit 1 is arranged for receipt.

5 The cassette unit 1 is received and held within the drive unit housing 71 by cassette unit holder 75, which is received within inner holder frame 77, which in turn seats at forward frame end 76, which defines a cassette-unit receiving aperture / needle delivery aperture 76a therein. Cassette unit holder 75 mounts within frame 77 and is axially (e.g. slidably) movable therein under the selective drive action of first motor 82. The first motor 82 (e.g. stepper
10 motor) selectively transfers drive via first gear 82a to a first drive transfer element in the form of worm 82b. That worm 82b interacts with a rack locating on the back of cassette unit holder 75 to axially move the cassette unit holder 75 and cassette unit 1 and syringe 10 held thereby within the frame 77 from a rest position, in which the needle 14 with tip 15 of the syringe 10 is within the drive unit housing 71 to a use position, in which the needle 14 with tip 15
15 protrudes from the needle delivery aperture 76a of the drive unit housing.

Second motor 85 (e.g. stepper motor) selectively communicates via second gears 83a, 83b to a second drive transfer element in the form of a threaded screw 83c having cover 79 for subsequently transferring axial drive to the plunger 18 of the syringe 10 for moving the
20 plunger 18 within the barrel 12 of the syringe 10 to eject at least part of the volume of liquid drug formulation contained therein.

In embodiments, the drive unit 70 is arranged for sequential receipt of a cassette unit 1 herein. Thus, in embodiments, the drive unit 70 is arranged for initial receipt of the cassette 1
25 at an intermediate pre-docking position and for subsequent transport of the cassette unit 1 to the docking position.

In embodiments, the drive unit 70 is arranged such that transport of the cassette unit 1 to the docking position is permitted only following positive verification of the identifier 21. Thus,
30 only appropriately identified cassette units 1 are finally receivable into the device to enable injected drug delivery there from.

In embodiments, the drive unit 70 is arranged such that transport of the cassette unit 1 from an intermediate position to a docking position is permitted only following positive verification of the identifier 21. Thus, only appropriately verified cassette units are finally
5 receivable into the device for drug delivery there from. In embodiments, that transport of the cassette unit 1 to the docking position is by automatic control under the action of the electrically powered source of drive 82. Thus, in embodiments positive verification of the cassette unit 1 gives rise to a 'transport to docking position' signal from the electronic control unit 74; 1001 to the source of drive, which results in the required transporting action.

10 Figures 21a and 21b shows a second drive unit 170, which may be appreciated to be a slight variant of the first drive unit 70 of Figure 17. This slight variant also has a drive unit housing 171 provided with a user-interface in the form of a screen 172, which may in embodiments be a touch-sensitive screen 172. The second drive unit also comprises user control features in
15 the form of a power button 186; a toggle button 178 and scroll wheel 179. Forward end cover 198 of the drive unit housing 171 defines a needle delivery aperture 198a therein. USB data input port 187 is provided at the top of the drive unit 170. In common with the first drive unit 70, the second drive unit 170 is arranged for receipt of a cassette unit 1 and houses a drive arrangement that is of generally corresponding structure, form and function to that drive
20 arrangement 80 described hereinbefore.

Figure 22 shows aspects of a typical electronic control system 1001 herein suitable for use with the drive unit as shown at Figure 17 or the second drive unit as shown at Figure 21. An electronic control unit in the form of main microprocessor control unit (MCU) 1010
25 communicates with the following:

- Non volatile memory 1020;
- Power regulating functions comprising serial bus connector 1030 in the form of a USB data input port 187, which is used for power recharge and data
30 communications; power connector 1032; battery charge controller 1034; rechargeable battery 1036; voltage regulator 1038 and power distribution 1039;

- Motor drive circuits for use in controlling the insertion motor 82, 1044 and injection motor 85, 1046; the motor drive circuits include one or more encoders for detecting the position and movement characteristics of the drivable parts of the drive unit 70; 170 and/or the linear position and speed of the cassette unit holder 75;
- RFID reader 1050 with RFID antenna 1052 for use in reading from and writing to an RFID tag 21 on the cassette unit 1;
- GUI microprocessor control unit (MCU) 1060 for user-interface functions comprising colour display 1070; and audio amplifier 1072 with speaker 1074;
- Power microprocessor control unit (MCU) 1075 and power button 1076; go/pause button 1078; and scroll wheel 1079;
- Sensing functions namely, cassette unit detection micro-switch 1080 for detecting the presence of the cassette unit 1 within the drive unit 70; Cap detection micro-switch 1082 for detecting the presence of the removable cap 50 on the cassette unit 1; and capacitive touch sense controller 1084 with electrodes 1085a, 1085b (many such electrodes may be present) for detecting the presence of a user's skin;
- Timer function 1090 (a sub-function of the MCU 1010), which in embodiments may comprise a real time clock
- Wireless communicator 1092, such as a low energy, Bluetooth-enabled chip.

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In embodiments, the timer function 1090 of the MCU 1010 is initiated by the removal of the removable cap 50 and needle cover 17, 19 from the cassette unit 1. In embodiments, cap detect switch 1080 detects removal of the removable cap 50 (e.g. together with needle cover 17 and rigid needle shield 19) from the cassette unit 1. The timer 1090 then starts counting.

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In embodiments, once the timer 1090 reaches a certain, pre-determined count a command to cancel the injection (e.g. by preventing the action of the drive / motor function of the drive unit 70; 170) is generated. Drive action of the drive unit 70; 170 is thus, prevented. In embodiments, the timer 1090 therefore acts to ensure that drug is delivered to the patient within a set time limit following removal of the removable cap 50 (e.g. together with needle cover 17 and rigid needle shield 19) from the cassette unit 1. Examples, of timers that may

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be used include time or actuation-based counters installed on an integrated circuit chip, such as an 'elapsed time counter' such as the DS1602 IC manufactured by Dallas Semiconductor.

5 During use, within the drive unit 70; 170, the cassette unit 1 is selectively locked into the cassette unit holder 75 by the interaction of engaging tips 95 of locking arms 99 with the locking apertures of the cassette unit holder 75.

10 There is now described sequential steps in a typical use operation of a first drive unit 70 essentially in accord with that already described by reference to Figures 17 to 20 as particularly used in conjunction with a first cassette unit 1 essentially in accord with that already described by reference to Figures 1 to 4. The first drive unit 70 includes an electronic control system (not shown) essentially of the type described by reference to Figure 22.

15 Initially, the auto-injector device is in the 'powered down' state, to which it returns after completion of a full use sequence, as described hereinbelow.

20 In a first stage of a typical use operation and to prepare for use of the device, the user hits the power on button 1076 and thereby turns the electronic control system 1001 on. A 'welcome message' is displayed on the screen 72; 1070 (see Figures 17 to 20), which instructs the user to insert the cassette unit 1.

25 After power on, the auto-injector device adopts a configuration, in which the drive unit 70 is initially in the 'cassette receipt' position. The cassette unit holder 75 has been withdrawn backwards slightly to the 'cassette receipt' position within frame 77. First drive transfer element in the form of worm drive 82b for movement of the cassette unit holder 75 sets it in the 'cassette receipt' position interacting with rack 75a provided along one side of the cassette holder. Second drive transfer element in the form of threaded screw 83c located within cover 79, the threaded screw 83c serving as a plunger rod 81 (for plunging movement of the plunger 18 of the syringe 10) is in its 'at rest' position.

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In a second stage of a typical use operation, the user inserts cassette unit 1 comprising syringe 10 and having removable cap 50 to the intermediate pre-docking position within the cassette unit holder 75 of the drive unit 70. Needle cover gripper 56 in the form of a cage-like (or 'flower') structure is provided to the removable cap 50 and its cap insert 90, which needle
5 cover gripper 56 grips the rigid needle sheath shield 19 and is configured such that removal of the cap 50 together with cap insert 90 also results in removal of the rigid needle sheath shield 19 and needle sheath 17 enclosed thereby, and hence, unsheathing of the needle tip 15. In this position, forward end of the plunger rod 81 with its tapering, round headed end-piece 84 is received within the drive rod-receiving opening 41 of the cassette unit end-cap 40. End-
10 cap biasing and damping element 45 defines a sprung biasing relationship between the cassette unit end-cap 40 and the flange 16 of the syringe 10, thereby urging the syringe 10 forwards in relation to the cassette unit end-cap 40. Plunger slaving part 60 is in releasable engagement with the cassette unit end-cap 40.

15 In the intermediate pre-docking position the cassette unit 1 is locked into the cassette unit holder 75. Thus, flexible locking arms 99 of the cassette unit housing 20 locate within locking apertures 96 of cassette unit holder 75.

In the intermediate pre-docking position, shuttle lock control 32 is in the first 'cassette
20 unused' position and thus, the removable cap 50 is in the cap locked position (see Figures 8a, 9a, 10a and 11a). The inner face of the locking arm 24 of the cassette unit housing 20 is blocked, thereby preventing any inwards movement thereof and so effectively also thereby, preventing any disengagement of the angled tip 25 of that locking arm 24 from socket through-hole 52 of the removable cap 50.

25 In the intermediate pre-docking position, pushing member in the form of pin 78 is spaced from the cassette 1, but locates immediately above protruding arms 31 of the inner housing sleeve 30, which are thus accessible to it via cut-away apertures 51 of the cassette unit end-cap 40. More typically, a spaced pair of pins 78 would be provided. It will be appreciated that
30 relative movement of the cassette 1 towards the pin 78 (e.g. to the position of third stage of a typical use operation) will result in receipt of pin 78 into cut-away aperture 51 of the cassette

unit end-cap 40 such as to bring pin 78 into pushing contact with protruding arm 31 of the inner housing sleeve 30 to thereby push the inner housing sleeve 30 and the shuttle lock control 32 forward.

- 5 Verification of the cassette unit 1 occurs at this intermediate pre-docking position. Thus, RFID reader 73; 1050 (see Figures 19, 20 and 22) of the drive unit interrogates RFID tag 21 (see Figure 3) of the cassette unit 1 and thereby, reads verification information from the RFID tag 21 of the cassette unit 1. Such verification can for example, be for the purpose of checking of drug and dosage information, checking that the drug is not past its expiry date
10 and / or checking that the cassette unit 1 has not been used previously.

- Upon positive verification of the cassette unit 1, the cassette unit holder 75 and cassette unit 1 held therein are drawn further up (i.e. transported) into the drive unit 70 to the docking position of third stage of a typical use operation. Such drawing up is achieved by the drive
15 action of worm drive 82b on rack 75a of the cassette unit holder. The worm drive 82b receives axial drive from first motor 82; 1042 via gear 82a in response to a command from motor drive circuits 1042 acting under the control of motor control MCU 1040, which in turn communicates with main MCU 1010.

- 20 In the docking position, the threaded screw 83c has been drawn deeper into its cover 79. It will also be noted that end-ring 54 of removable cap 50 still protrudes out-with the exit aperture 76a of drive 70, but otherwise the cassette unit 1 is fully within the drive unit 70.

- In the docking position, the shuttle lock control 32 is in the second 'cassette unlocked'
25 position (having been pushed relatively forward by the interaction of protruding arms 31 with pushing pin 78) and thus, the removable cap 50 is in the cap unlocked position (also see Figures 9b, 10b and 11b). The inner face of the locking arm 24 of the cassette unit housing 20 is no longer blocked. As a result, inwards movement of the locking arm 24 is no longer prevented and disengagement of the tip 25 of the locking arm 25 from socket through-hole 52
30 of the removable cap 50 is achievable by suitable inwards pushing action on the tip 25 / locking arm 24. Such inward pushing action on the locking arm 24 is achievable by pulling

the cap 50 away from the cassette unit 1, which results in the angled tip 25 interacting with the wall edges of the socket through-hole 52 to push the locking arm 24 inwards.

5 The screen 72; 1070 now displays an instruction to the user to remove the cap 50 of the cassette unit 1. The drive unit 70 is provided with a timer function 1090, which is initiated by the removal of the removable cap 50 from the cassette unit 1. Cap removal sensing means 1082 are provided to detect removal of the removable cap 50 from the cassette unit 1. The timer 1090 then starts counting. In embodiments, once the timer 1090 reaches a certain, pre-determined count a command to prevent the drive function 80 of the drive unit 70 is
10 generated. Drive action of the drive unit 70 is thus, prevented. The timer therefore acts as a safety measure to ensure that drug is delivered to the patient within a set time limit following removal of the removable cap 50 from the cassette unit 1.

In a fourth stage of a typical use operation, the user has removed the cap 50 together with cap
15 insert 90, needle sheath 17 and rigid needle shield 19. The needle 14 with tip 15 of the syringe 10 is now uncovered, but still shrouded by the drive unit 70 and does not protrude from the exit aperture 76a thereof. The screen 72; 1070 now displays an instruction to the user to place the device (i.e. the exit aperture 76a thereof) against the injection site. Once the exit aperture 76a has been placed against the injection site electrodes 1085a, 1085b of
20 capacitive touch sense controller (e.g. skin sensor) register the correct placing of the device at the injection site. The screen 72; 1070 now displays an instruction to the user to initiate the injection by pressing the 'inject' button. In other embodiments, such initiation of the injection may be configured to occur automatically on sensing of the correct placing of the device at the injection site.

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In a fifth stage of a typical use operation, the syringe 10 has now been advanced to the injection position, in which the tip 15 of the needle 14 protrudes out-with the exit aperture 76a. Such advancement of the syringe 10 has been achieved by forward movement of the cassette unit holder 75, which is responsive to the forward driving action of worm drive 82b
30 on rack 75a of the cassette unit holder 75. The worm drive 82b receives axial drive from first motor 82; 1042 via gear 82a in response to a command from motor drive circuits 1042 acting

under the control of motor control MCU 1040, which in turn communicates with main MCU 1010. It will also be noted that in the injection position, the threaded screw 83c has been drawn forwards within its cover 79.

- 5 Once the syringe 10 is at the injection position, ejection of drug from the syringe barrel 12 can commence. Such ejection in response to forward advancement of threaded screw 83c responsive to geared driving by gears 83a, 83b, which receive axial drive from second motor 85; 1046 in response to a command from motor drive circuits 1042 acting under the control of motor control MCU 1040, which in turn communicates with main MCU 1010. Threaded
- 10 screw 83c via end-piece 84 is brought into forward driving contact with rear drive-receiving end of slaving part 60. The resulting forward advancement thereof results in release of the plunger slaving part 60 from the end-cap 40 and then in forward sliding movement of that slaving part 60 within the syringe barrel 12, which in turn results in plunging movement of the plunger 18 within the barrel 12 of the syringe 10 to expel the drug formulation contents
- 15 through the tip 15 of the needle 14 and into the injection site (e.g. skin of the user). The slaving part 60 functions such that when a driving load is applied to its square cut end 66 by round headed end-piece 84 of threaded screw 83c the load is evenly transmitted directly into the syringe plunger 18.
- 20 To reduce the risk of the syringe 10 fracturing under the loads associated with injecting the drug, it is important for a majority of the load path to travel through the forward shoulder 11 of the syringe barrel 12 and lesser load to pass through the flange 16 at the rear end thereof. Thus, forward shoulder 11 of the syringe 10 is surrounded by shoulder support feature 5 (see Figures 5a to 5c). Information related to the progress of the injection may be displayed on the
- 25 screen 72; 1070 including for example, a signal that 'injection has been completed successfully'.

- In a sixth stage of a typical use operation, post-completion of the injection, the needle 14 with tip 15 of the syringe 10 has been withdrawn back into the drive unit 70. Such withdrawal of
- 30 the syringe 10 is achieved by rearwards movement of the cassette unit holder 75, which is responsive to the rearward driving action of worm drive 82b on rack 75a of the cassette unit

holder 75. The worm drive 82b receives axial drive from first motor 82; 1042 via gear 82a in response to a command from motor drive circuits 1042 acting under the control of motor control MCU 1040, which in turn communicates with main MCU 1010.

- 5 In the post-injection position threaded screw 83c with end-piece 84 has been advanced forward sufficiently to drive both slaving part 60 and the plunger 18 within the barrel 12 of the syringe 10 fully forwards. Thus, the leading end of the plunger 18 locates adjacent to the neck 11 of the syringe 10. The slaving part 60 is coloured and performs a secondary function of providing an easy-to-identify visual indicator of the position of the plunger 18 within the
10 syringe 10 so that the patient can visually confirm the drug had been fully injected. The screen 72; 1070 now displays a message instructing the user to replace the cap 50.

- In a seventh stage of a typical use operation, threaded screw 83c with end-piece 84 has been withdrawn into its cover 79 to the 'at rest' position. At this stage, the cassette unit 1 is still in
15 locked engagement with the cassette unit holder 75 and removal of the cassette unit 1 is therefore not possible.

- In an eighth stage of a typical use operation, the cassette unit holder 75 and cassette unit 1 carried thereby have been returned to a position slightly forward of the 'cassette receipt'
20 position. Such return is achieved by the drive action of worm drive 82b on rack 75a of the cassette unit holder. The worm drive 82b receives axial drive from first motor 82; 1042 via gear 82a in response to a return command from motor drive circuits 1042 acting under the control of motor control MCU 1040, which in turn communicates with main MCU 1010. Threaded screw 83c with end-piece 84 locates in the 'at rest' position.

25

The cap 50 with needle sheath 17 and rigid needle shield 19 is now been replaced on the cassette unit 1 following completion of the injection procedure.

- The shuttle lock control 32 is in the third 'cassette used' position, locating intermediate the
30 first and second shuttle lock control positions (see Figures 8b, 9c, 10c and 11c). The inner face of the locking arm 24 of the cassette unit housing 20 is again blocked, thereby

preventing any inwards movement thereof and so effectively also thereby, preventing any disengagement of the angled tip 25 of that locking arm 24 from socket through-hole 52 of the removable cap 50.

- 5 As the cassette unit holder 75 is returned forwards the leading edge thereof interacts with sprung-loaded cassette unit-unlock cams 88a, 88b to move them from their 'head upright' to 'head bowed' positions. When in the 'head bowed' position the rounded head 89a, 89b of each cam 88a, 88b presses on engaging tip 95 of locking arm 99 to move that locking arm 99 out of locking engagement with the locking aperture and thus, to allow the cassette unit 1 to
10 be released from the cassette unit holder 75.

- The screen 72; 1070 now displays a message instructing the user to remove the cassette unit 301 from the drive unit 70. The user accordingly removes the cassette unit 1. The screen 72; 1070 then displays a message confirming that the cassette removal operation is complete. A
15 battery check and / or data communication step may also be performed. The user then hits the power button to turn the drive unit off and the drive unit is stowed in the rest position until powered-up for a subsequent injection operation.

- The sequential steps in a typical use operation of the second drive unit 170 of Figure 21
20 correspond essentially to those described above in respect of the first drive unit 70.

The drive unit 70; 170 is provided with plural sensors 1080; 1082; for sensing aspects of the interaction of the cassette unit 1 with the drive unit 70; 170.

- 25 The cassette unit detection micro-switch 1080 detects whether the cassette unit 1 is fully loaded into the cassette unit holder 75 (or 'slider') of the drive unit 70; 170 or not, and is set up to give a reading of 'open' when no cassette unit 1 is detected and 'closed' when a cassette unit 1 is detected. The cassette unit detection 1080 readings are sent to the microprocessor control unit (MCU) 1010.

30

The cap detection micro-switch 1082 detects the presence of the removable cap 50 (and needle cover 17 with shield 19 connected thereto) on the cassette unit 1, and is set up to give a reading of 'open' when no removable cap 50 is detected on the cassette unit 1 and 'closed' when a removable cap 50 is detected on the cassette unit 1. The cap detection 1082 readings are sent to the microprocessor control unit (MCU) 1010.

The microprocessor control unit (MCU) 1010 is capable of collating the cassette unit detection 1080 and cap detection 1082 signals to determine an overall detected state of the cassette unit. The MCU 1010 is provided with a decision algorithm that decides upon and signals a control action (e.g. to the drive arrangement of the drive unit 70; 170) dependent upon the overall detected state of the cassette unit 1. In embodiments, the decision algorithm references different decision making parameters or routines dependent upon whether an injection procedure has started or not, or dependent upon whether a cassette unit ejection procedure has started or not. The MCU 1010 is also capable of sending a command to the display unit 1070 to display a message when a particular overall cassette unit state is determined, said message being relevant to the particular determined overall cassette unit state. The MCU 1010 is capable of sending an emergency stop or abort command to the drive arrangement when an unacceptable overall cassette unit state is determined.

The drive unit 70; 170 is arranged to perform different actions dependent on sensing input received from the cassette unit detector micro-switch 1080 and cap detector micro-switch 1082 during different phases of device operation, as set out at Tables 1 to 3 below. Within the drive unit 70; 170 the actions described may be stored in the form of look up tables in the electronic data system thereof.

Table 1 shows the action of the drive unit 70; 170 in response to sensing input received from the cassette unit detector micro-switch 1080; and cap detector micro-switch 1082 during the initial 'power on, self-test' phase of operation.

Table 1

Cassette unit detector status	Cap detector status	Control action of drive unit
Open	Open	Correct behaviour, so proceed.
Open	Closed	An object is inside the cassette unit holder 75, so drive unit 70; 170 goes to error mode to ensure the object is removed first. The drive unit 70; 170 needs to then be turned off/on again to re-zero the encoders.
Closed	Open	An un-capped cassette unit 1 is inside the drive unit 70; 170, either from a previous injection where the cassette unit 1 was not capped properly, or aborted. The drive unit 70; 170 will prompt the user to recap the cassette unit 1 immediately, whereupon if they do so the cassette unit 1 will be ejected to be discarded.
Closed	Closed	A capped cassette unit 1 is in the drive unit 70; 170, so the drive unit 70; 170 will prompt the user to remove the cassette unit 1 as it has been inserted too early.

Table 2 shows the action of the drive unit 70; 170 in response to sensing input received from the cassette unit detector micro-switch 1080; and cap detector micro-switch 1082 during an injection phase of operation.

Table 2

Cassette Detection Switch	Cap Detection Switch	Control action of drive unit
Open	Open	Signals a cassette unit 1 has been removed during an injection, therefore the drive unit 70; 170 will retract

		the cassette unit holder 75 and abort the injection.
Open	Closed	The drive unit 70; 170 will go into fault because means the cassette unit 1 is lost but there is an object (e.g. a cap 50 or cassette unit 1) midway in the cassette unit holder 75. The injection will be aborted.
Closed	Open	This is the correct behaviour as the cassette unit 1 is in the drive unit 70; 170 and no cap 50 is present.
Closed	Closed	The drive unit 70; 170 assumes the user has recapped the cassette unit 1 mid-way, so will prompt the user to remove the cap 50 and continue with their injection.

Table 3 shows the action of the drive unit 70; 170 in response to sensing input received from the cassette unit detector micro-switch 1080; and cap detector micro-switch 1082 during the ‘cassette ejection’ phase of operation.

5

Table 3

Cassette Detection Switch	Cap Detection Switch	Control action of drive unit
Open	Open	The drive unit 70; 170 will automatically retract the cassette unit holder 75 into the drive unit 70; 170 as it may mean an uncapped cassette unit 1 has come loose inside the drive unit 70; 170, so it goes into automatic retraction to maintain safety of the needle end.
Open	Closed	This is fine as there will be a moment when the cassette unit 1 is being removed from the cassette holder 75 where it will be pressing down on the cap detection switch 1082.
Closed	Open	This means that the cap 50 has been removed whilst the cassette unit 1 is being ejected at the end of the

		injection. The drive unit 70; 170 will then immediately retract the cassette unit 1 to prevent a contaminated sharp injury. If the cassette unit 1 is recapped, then the drive unit 70; 170 will eject the cassette unit 1.
Closed	Closed	This is correct behaviour: Drive unit 70; 170 has completed the injection so is ejecting the cassette unit 1.

The USB data input port 1030 is used to connect the drive unit 70; 170 to a personal computer to view the user log, or connect the drive unit 70; 170 to an electrical charger to recharge the internal battery. The MCU 1010 of the drive unit 70; 170 is capable of detecting electrical current flow at the USB data input port 1030. The MCU 1010 is capable of differentiating between whether the drive unit 70; 170 is connecting to an electrical charger or to a personal computer. The MCU 1010 is provided with a second decision algorithm that decides upon and signals a control action dependent upon both the overall detected state of the cassette unit and the detection or not of current flow at the USB data input port 1030.

The drive unit 70; 170 is arranged to perform different actions dependent on sensing input received from the cassette unit detector micro-switch 1080; cap detector micro-switch 1082 and USB data input port as set out at Table 4 below. Within the drive unit 70; 170 the actions described may be stored in the form of look up tables in the electronic data system thereof.

Table 4

USB port status	Cassette unit detector status	Cap detector status	Control action of drive unit
Connected to PC or electrical	No cassette unit	N/A	Charge battery or go to PC mode, depending on what it is connected to.

charger			
Connected to PC or electrical charger	Cassette unit in drive unit	Cap on cassette unit	Eject the cassette unit 1 so that the cap 50 cannot be removed (safe state), then go to charging or PC mode
Connected to PC or electrical charger	Cassette unit in drive unit	No cap on cassette unit	Retract the cassette unit 1 back into the drive unit 70; 170 so that the needle 14 does not protrude from the drive unit 70; 170. Prompt audible and visual alarms telling the user to remove the USB cable immediately. If the USB cable is removed, the user can proceed with their injection. If it is not removed within X minutes, then the device will eventually void the cassette as the injection will time out.

The above protocol is for the safety of users, in particular to ensure that users are not able inject whilst the drive unit 70; 170 is connected to any source of electrical power.

5

The electronic data system of the drive unit 70; 170 of the auto-injector device herein can be set up to provide various dose regimen for different drug types depending on the target therapy area, region of injection, severity of symptoms, amongst other factors. In one example, patients are recommended to start with a Loading Dose (2x injection every 2 weeks), followed by one of two Maintenance Doses (either 1x injection every 2 weeks, or 2 injections every 4 weeks). Therefore, each drug dose (related to the injection punctuality feature too) needs to be set for each patient's needs depending on what their physician recommends or their condition.

10

The electronic data system of the drive unit 70; 170 includes a hidden menu function, whereby a healthcare professional can access a hidden menu on the device using particular command inputs of the man machine interface (MMI) thereof. Once accessed, the hidden menu allows the healthcare professional to set a specific dose regimen. The hidden menu is not intended to be accessible to patients or to lay users, so instructions for accessing the hidden menu will be provided to healthcare professionals only.

Thus, arranged for display at the display unit 1070, is both a first primary menu function for providing a menu of first control options to the MCU 1010 and a second hidden menu function for providing a menu of second control options to the MCU 1010. The man machine interface in the form of power button 186; toggle button 178 and scroll wheel 179 enable the provision of one or more user input commands to the MCU 1010 response to one or more manual actions of a user. The first and second menu functions are arranged for alternate display at the display unit 1070. As a default, the first menu function is displayed. The second hidden menu function is accessible only in response to a particular series of input commands provided as a particular series of manual actions of a healthcare professional to the man machine interface 186, 178, 179. The second hidden menu function has a two-layer menu structure. A first set of user inputs is required to get to hidden menu level 1; then as an additional security measure the user is required to perform a different set of inputs to get to the hidden menu level 2. Once the user is past level 2, he or she can access the hidden menu freely to set the dose as required. Typically, the particular series of manual actions comprises a series of two (e.g. three) or more distinct (e.g. different) manual actions of the healthcare professional. The series of manual actions to access the second hidden menu function is arranged to be relatively complex to avoid accidental access (e.g. by a patient) thereto.

Figures 23a to 23h show sequential steps that a healthcare provider would undertake in setting up a dose regimen on the second drive unit 170 of Figure 21 via access to a hidden menu function thereof.

As shown at Figure 23a, a new drive unit 170 that has not previously been set up with any patient dose regimen is selected. The drive unit 170 is switched on by thumb or finger

actuation of the power button 186. A musical tone is played and a start-up icon is displayed on the screen 172.

As shown at Figure 23b, the display screen 172 now displays a message to “consult your physician to set device dosage”. This indicates that the drive unit 170 has not previously been set up. For the healthcare professional, this is the prompt to access the hidden menu function by a series of input commands, which will have been communicated separately.

In one example, the hidden menu function of the drive unit 170 is made accessible to the healthcare professional by performing the steps of:

1. Pressing the Go/Pause toggle button 178 three times, then the Power button 186 twice (as shown at Figure 23b). Completing these steps allows ‘level 1’ of the secure access procedure to be cleared.

2. Pressing and holding the Go/Pause toggle button 178 for five seconds (as shown at Figure 23c). Completing these further steps allows ‘level 2’ of the secure access procedure to be cleared.

The two-stage, multi-level (i.e. ‘level 1’ and ‘level 2’) nature of the secure access procedure minimizes the risk that an unauthorised user may ‘inadvertently’ enter the necessary input commands, and therefore contributes to the overall security of the procedure.

It will be appreciated that in embodiments, different variations of input commands may be employed. It will also be appreciated that the combination of steps is deliberately selected to be complex and therefore to minimize the risk of patient users guessing or stumbling across the second hidden menu function by mistake.

Once the health care professional has accessed the second hidden menu function, using the combination of steps described above, then they can define a particular dose regimen by providing various inputs to the second hidden menu function. Thus, in one example, as

shown at Figures 23d and 23e, the healthcare professional can then select if the patient requires a loading dose or not. As shown at Figure 23d, the scroll wheel 179 is used to select between 'yes' and 'no' options on the display screen; and as shown at Figure 23e, the go/pause toggle button 178 is used to confirm the selection. Typically, a confirmation screen (not shown) will then be displayed, which confirms the selection of loading dose. As shown at Figures 23f and 23g, the healthcare professional can then select a maintenance dose or not. As shown at Figure 23f, the scroll wheel 179 is used to select between maintenance dose options on the display screen 172; and as shown at Figure 23g, the go/pause toggle button 178 is used to confirm the selection. Typically, a confirmation screen (not shown) will then be displayed, which confirms the selection of maintenance dose. Once, the dose regimen has been fully set up, a 'dose setting complete' message is displayed on the screen 172, as shown at Figure 23h. The healthcare professional now exits the hidden menu function by turning off the drive unit 170 by pressing the power on/off button 186. Once the dose regimen has been set and the confirmation screen is prompted, the user cannot go back without turning off/on the drive unit again.

The next time that the drive unit 170 is switched on it will automatically display the 'default' Loading or Maintenance dose, which is for guidance of the patient in administering the defined dose regimen.

The healthcare provider may access the second hidden menu function at any time by inputting the particular series of input commands required to do this. Thus for example, if a patient needs to change dose (e.g. from one maintenance dose to another) the healthcare professional can access the hidden menu by carrying out the steps as described above in relation to Figures 23b and 23c; select 'no' for loading dose, using the steps described in relation to Figures 23d and 23e; and select the required maintenance dose, using the steps described in relation to Figures 23f and 23g.

Once a dose regimen has been set on the drive unit 170, the message displayed at the display screen 172 in Figure 23c will never be shown again: This message is shown only on a brand new drive unit 170 that has never been set up for injections. Therefore, if the healthcare

provider wants to change the dose regimen by accessing the second hidden menu function again, they will need to access it again (e.g. by accessing the first level, then the second level again).

- 5 In one example, by resetting the dose regimen, the calendar function is reset or put on hold. This allows the healthcare professional to set the dose whenever they can, and the calendar function then restarting as soon as the patient completes their first (new) dose. This allows flexibility without incorrectly prompting alarms for injecting too early or too late.
- 10 In another example, the drive unit 70; 170 will also automatically transition from the Loading to Maintenance dose at the end of the Loading Dose based on the dose regimen set by the healthcare professional.

- The drive unit 170 is further configured not to allow injected use thereof using a cassette unit 15 1 if a dose regimen has not been set. In this situation, on powering up the drive unit 170 by a patient user, the display screen 172 will display the message "Consult your physician to set device dosage" as shown at Figure 23b. In the absence of set up commands by a healthcare professional (as described above in relation to Figures 23b to 23h), the drive unit 170 will then only accept training cassettes (i.e. containing no syringe or drug formulation) for 20 training use of the drive unit 170. If a cassette unit 1 with syringe 10 / drug formulation is inserted, it will be automatically ejected by the drive unit 170. Such ejection of the cassette unit 1 will continue until it the drive unit 170 is configured by the healthcare professional to set a dose regimen via the second hidden menu function, as described above.

- 25 The auto-injector of the invention is suitable for the injected delivery of drug, particularly for the treatment and/or prophylaxis of a number of diseases, disorders or conditions, including infections (viral, e.g. HIV infection, bacterial, fungal and parasitic); endotoxic shock associated with infection; inflammatory diseases/autoimmunity such as osteoarthritis, rheumatoid arthritis, psoriatic arthritis, systemic lupus erythematosus (SLE), ankylosing 30 spondylitis, COPD, asthma, Alzheimer's Disease, Crohn's disease, ulcerative colitis, irritable bowel syndrome and psoriasis; immune mediated inflammatory disorders of the central and

peripheral nervous system such as multiple sclerosis and Guillain-Barr syndrome; graft-versus-host disease; organ transplant rejection; pain; cancer (including solid tumours such as melanomas, hepatoblastomas, sarcomas, squamous cell carcinomas, transitional cell cancers, ovarian cancers and hematologic malignancies, acute myelogenous leukaemia, chronic
5 myelogenous leukemia, gastric cancer and colon cancer); congenital disorders, e.g. cystic fibrosis and sickle cell anaemia; growth disorders; epilepsy; treatment of infertility; heart disease including ischaemic diseases such as myocardial infarction as well as atherosclerosis and intravascular coagulation; bone disorders such as osteopenia and osteoporosis; and metabolic/idiopathic disease, e.g. diabetes.

10

In embodiments, the syringe of the auto-injector herein contains a liquid drug formulation, which is designed for refrigerated rest (e.g. at from 2-8°C) and for injected delivery at room temperature (e.g. at or about 18-30°C). In embodiments, the viscosity of the liquid drug formulation is less than 120 mPa.s (120 centipoise), in embodiments less than 100 mPa.s
15 (100 centipoise) at a delivery temperature of 20°C.

20

Appropriate drugs may thus be selected from biologically active agents, including chemical entities, polysaccharides, steroids and, especially, naturally occurring and recombinant proteins, including glycoproteins, polypeptides and oligopeptides and polymeric derivatives thereof. Particular proteins, polypeptides and oligopeptides include hormones, such as insulin, epinephrine, norepinephrine, adrenocorticotrophin, somatotropin, erythropoietin and oxytocin; cytokines, such as lymphokines, chemokines and interleukins and receptors therefor, e.g. interleukin (IL)-1 α , IL-1 β , IL-1R, IL-2, IL-3, IL-4, IL-5, IL-6, IL-13, IL17, interferon (IFN)- α , IFN- β , IFN- γ , granulocyte monocyte colony stimulating factor, tumour
25 necrosis factor- α ; growth factors, such as nerve growth factor and platelet-derived growth factor; enzymes, such as tissue plasminogen activator; and, especially, immunoglobulins.

25

Immunoglobulins include whole antibodies and functionally active fragments and/or derivatives thereof, for example polyclonal, monoclonal, recombinant, multi-valent, mono- or multi-specific, humanised or chimeric antibodies, single chain antibodies, Fab fragments, Fab' and F(ab')₂ fragments. Polymeric derivatives of such proteins, polypeptides and
30 oligopeptides include derivatives formed between the protein, polypeptide or oligopeptide

and a naturally occurring or synthetic polymer, e.g. a polysaccharide or a polyalkylene polymer such as a poly(ethyleneglycol) [PEG] or derivative thereof, e.g.

methoxypoly(ethyleneglycol) [mPEG]. Particular agents include growth hormones and hormones for the treatment of infertility. Other particular agents are for the treatment of

5 epilepsy such as brivaracetam and levetiracetam.

The auto-injector device herein has been found to be of particular utility where the drug is an immunoglobulin or a fragment thereof, especially a PEGylated or mPEGylated antibody fragment.

10

The liquid drug formulations herein are typically aqueous formulations, which comprise the drug in solution and additionally other optional formulation components, which may include buffers (e.g. lactate, acetate), NaCl, and pH modifiers (e.g. NaOH).

15 The auto-injector device herein has been found to be of particular utility wherein the concentration of the drug (e.g. a therapeutic biologic type drug) in the liquid drug formulation is quite high. In particular, where the drug is a pegylated antibody the auto-injector device has been found to be of particular utility wherein the concentration of the drug is greater than 100mg/ml, particularly greater than 150mg/ml such as 200mg/ml.

20

It is to be understood that the foregoing description is merely illustrative and is not to be limited to the details given herein. While several embodiments have been provided in the present disclosure, it should be understood that the disclosed systems, devices, and methods, and their components, may be embodied in many other specific forms without departing from
25 the scope of the disclosure.

Variations and modifications will occur to those of skill in the art after reviewing this disclosure. The disclosed features may be implemented, in any combination and subcombinations (including multiple dependent combinations and subcombinations), with
30 one or more other features described herein. The various features described or illustrated above, including any components thereof, may be combined or integrated in other systems.

Moreover, certain features may be omitted or not implemented. Examples of changes, substitutions, and alterations are ascertainable by one skilled in the art and could be made without departing from the scope of the information disclosed herein. All references cited herein are incorporated by reference in their entirety and made part of this application.

5

The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described herein. They may take the form of product, method or use claims and may include, by way of example and without
10 limitation, one or more of the following claims.

Claims

1. A drive unit for an auto-injector comprising:
 - a drive unit housing defining a housing cavity and a needle delivery aperture;
 - within said housing cavity, a cassette unit holder arranged for receipt of a cassette unit comprising a syringe, wherein said cassette unit holder and said cassette unit receivable thereby are movable from a rest position to a use position, in which said syringe is advanced towards said needle delivery aperture;
 - a drive arrangement for the cassette unit holder, said drive arrangement comprising one or more electrically powered sources of axial drive;
 - an electronic control unit;
 - a display unit;
 - arranged for display at said display unit, a first primary menu function for providing a menu of first control options to said electronic control unit;
 - arranged for display at the display unit, a second hidden menu function for providing a menu of second control options to the electronic control unit; and
 - a man machine interface for enabling the provision of one or more user input commands to the electronic control unit in response to one or more manual actions of a user,
 - wherein said first and second menu functions are arranged for alternate display at the display unit and wherein said second hidden menu function is accessible only in response to a particular series of input commands provided as a particular series of manual actions of a user to the man machine interface.
2. A drive unit according to claim 1, wherein said particular series of manual actions comprises a series of two or more distinct manual actions.
3. A drive unit according to either of claims 1 or 2, wherein the man machine interface is selected from a keypad; a touch screen; a button; a toggle; a scroll wheel; and any combination thereof.

4. A drive unit according to claim 3, wherein the button is selected from go/pause button and power on/off button.
5. A drive unit according to any of claims 1 to 4, wherein in normal patient use of the drive unit, the first menu function is the default option for display at the display unit.
6. A drive unit according to claim 5, wherein in normal patient use of the drive unit, the first menu function is accessible either automatically or in response to a single input command provided as a single manual action of a user to the man machine interface.
7. A drive unit according to any of claims 1 to 6, wherein on first use of the drive unit, a message is displayed at the display unit prompting configuration of a dose regimen via access to the second hidden menu function.
8. A drive unit according to any of claim 1 to 7, wherein exiting from the second hidden menu function is in response to a particular series of input commands provided as a particular series of manual actions of a user to the man machine interface, wherein the series of input commands for exiting the second hidden menu function either correspond to or differ from the series of input commands employed to access the second hidden menu function.
9. A drive unit according to claim 8, wherein exiting from the second hidden menu function is by manually switching off the power to the drive unit.
10. A drive unit according to any of claims 1 to 9, wherein the second hidden menu function has a multi-layer hidden menu structure.
11. A drive unit according to claim 10, wherein each layer of the hidden menu structure of the second hidden menu function is accessible only in response to a particular series of input commands provided as a particular series of manual actions of a user to the man machine interface.

12. A drive unit according to claim 11, wherein each different layer of the hidden menu structure of the second hidden menu function is accessible only in response to a particular different series of input commands provided as a particular different series of manual actions of a user to the man machine interface.

13. A drive unit according to any of claims 1 to 12, wherein said first and second menu options are selected from drug dose options; drug dose scheduling options; drug target therapy area options; and any combinations thereof.

14. A drive unit according to any of claims 1 to 13, wherein the drive unit will only allow injected use thereof using a cassette unit comprising a syringe following configuration of a dose regimen via access to the second hidden menu function

15. A drive unit according to claim 14, wherein in the absence of configuration of a dose regimen via access to the second hidden menu function, the drive unit will only allow training use thereof using a training cassette unit that comprises no syringe.

16. A drive unit according to any of claims 1 to 15, additionally comprising
one or more cassette unit detection sensors for detecting the presence of the cassette unit within the drive unit, and capable of sending a cassette unit detection signal to said electronic control unit; and

one or more cap detection sensors for detecting the presence of the removable cap on the cassette unit, and capable of sending a cap detection signal to the electronic control unit,
wherein the electronic control unit is capable of collating said cassette unit detection and cap detection signals to determine an overall detected state of the cassette unit.

17. A drive unit according to claim 16, wherein the electronic control unit is provided with a decision algorithm that decides upon and signals a control action dependent upon the overall detected state of the cassette unit.

18. A drive unit according to claim 17, wherein said decision algorithm references different decision making parameters or routines dependent upon whether an injection procedure has started or not.
19. A drive unit according to claim 17, wherein said decision algorithm references different decision making parameters or routines dependent upon whether a cassette unit ejection procedure has started or not.
20. A drive unit according to any of claims 16 to 19, wherein the electronic control unit is capable of sending an emergency stop or abort command to the drive arrangement when an unacceptable overall cassette unit state is determined.
21. A drive unit according to any of claims 1 to 20, additionally comprising a USB data input port for connecting the drive unit to an electrical charger or to a personal computer.
22. A drive unit according to claim 21, wherein the electronic control unit is capable of detecting electrical current flow at the USB data input port.
23. A drive unit according to claim 22, wherein the electronic control unit differentiates between whether the drive unit is connecting to an electrical charger or to a personal computer.
24. A drive unit according to either of claims 22 or 23, wherein the electronic control unit is provided with a second decision algorithm that decides upon and signals a control action dependent upon both the overall detected state of the cassette unit and the detection or not of current flow at the USB data input port.
25. A drive unit according to any of claims 16 to 24, wherein the cassette unit detection sensor detects whether the cassette unit is fully loaded into the cassette unit holder of the drive unit or not.

26. A drive unit according to any of claims 16 to 25, wherein any or each cassette unit detection sensor or cap detection sensor has the form of a micro-switch.
27. A drive unit according to any of claims 1 to 26, wherein the drive unit comprises one or more encoders to detect the position and movement characteristics of the movable parts of the drive unit.
28. A drive unit according to claim 27, wherein the drive unit comprises a cassette unit holder motor encoder to detect the linear position and speed of the cassette unit holder.
29. A drive unit according to either of claims 27 or 28, wherein the drive unit comprises a drive arrangement motor encoder to detect the linear position and speed of the drive arrangement.
30. An auto-injector comprising:
- (a) a drive unit according to any of claims 1 to 29; and
 - (b) a cassette unit comprising a syringe, wherein the syringe contains a volume of a liquid drug formulation.

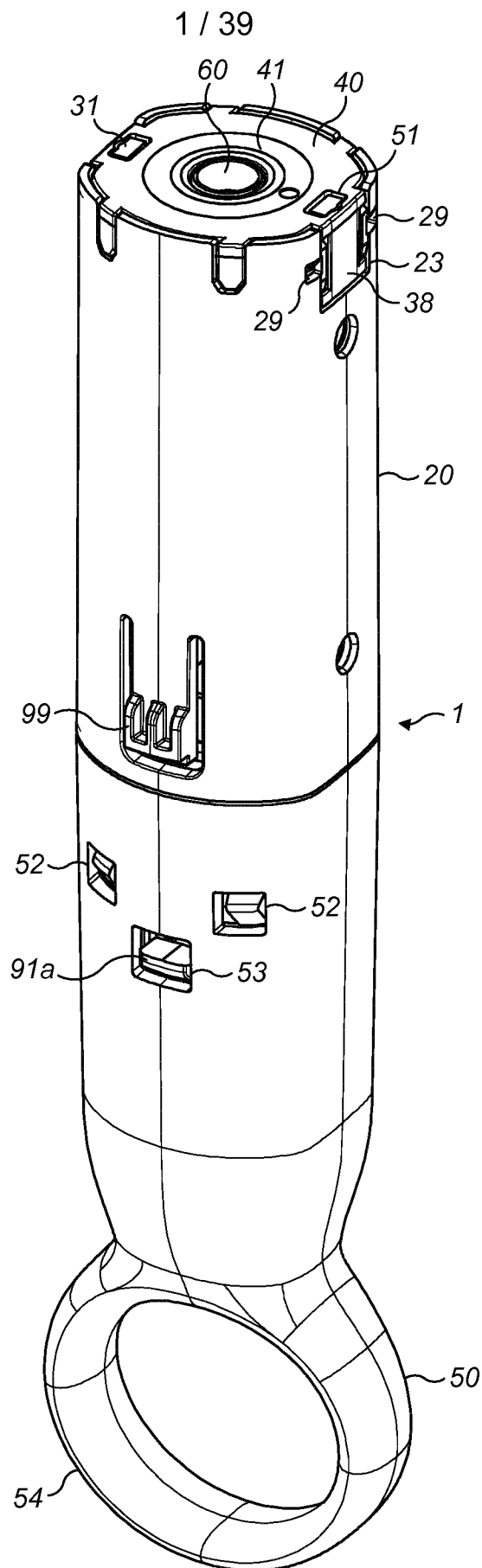
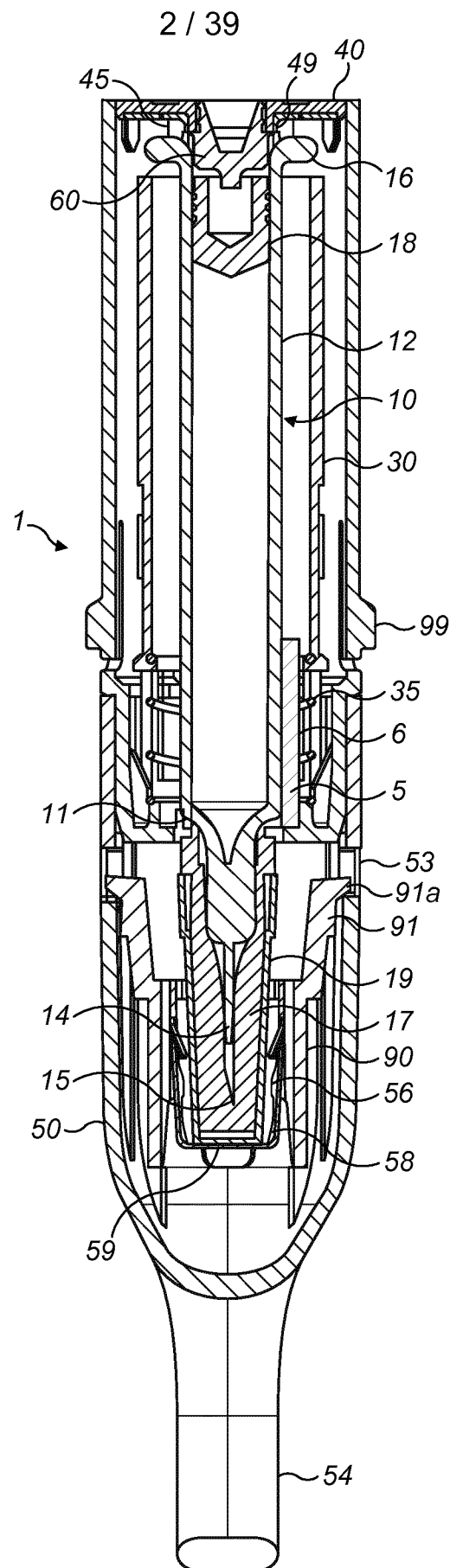


FIG. 1



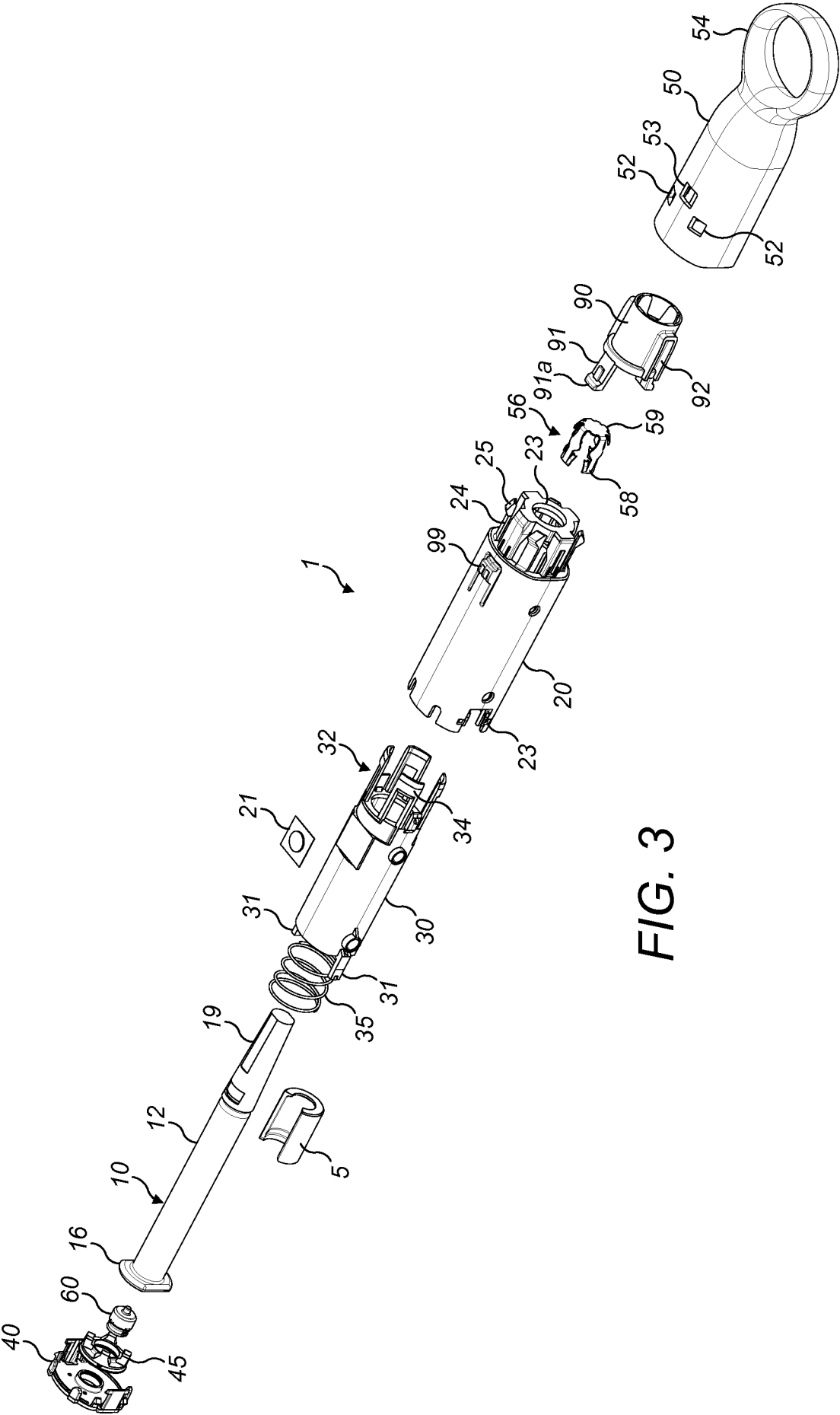


FIG. 3

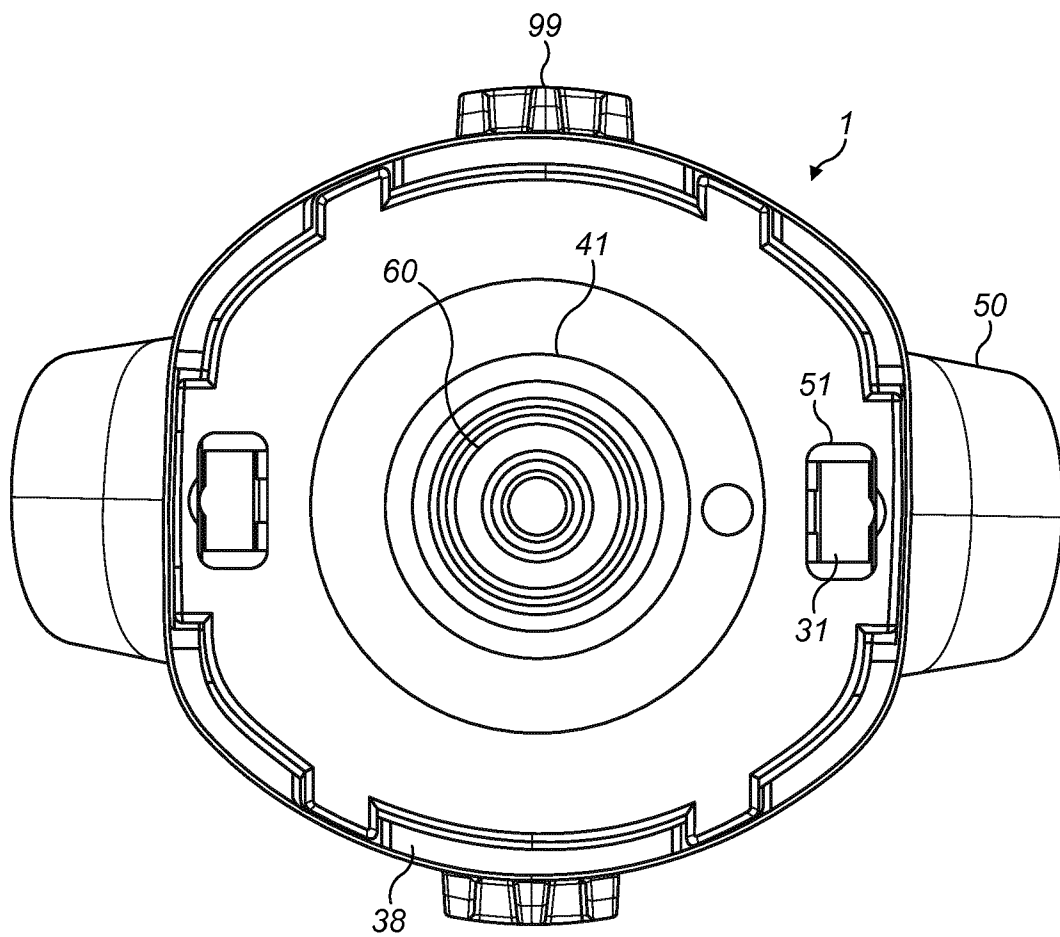
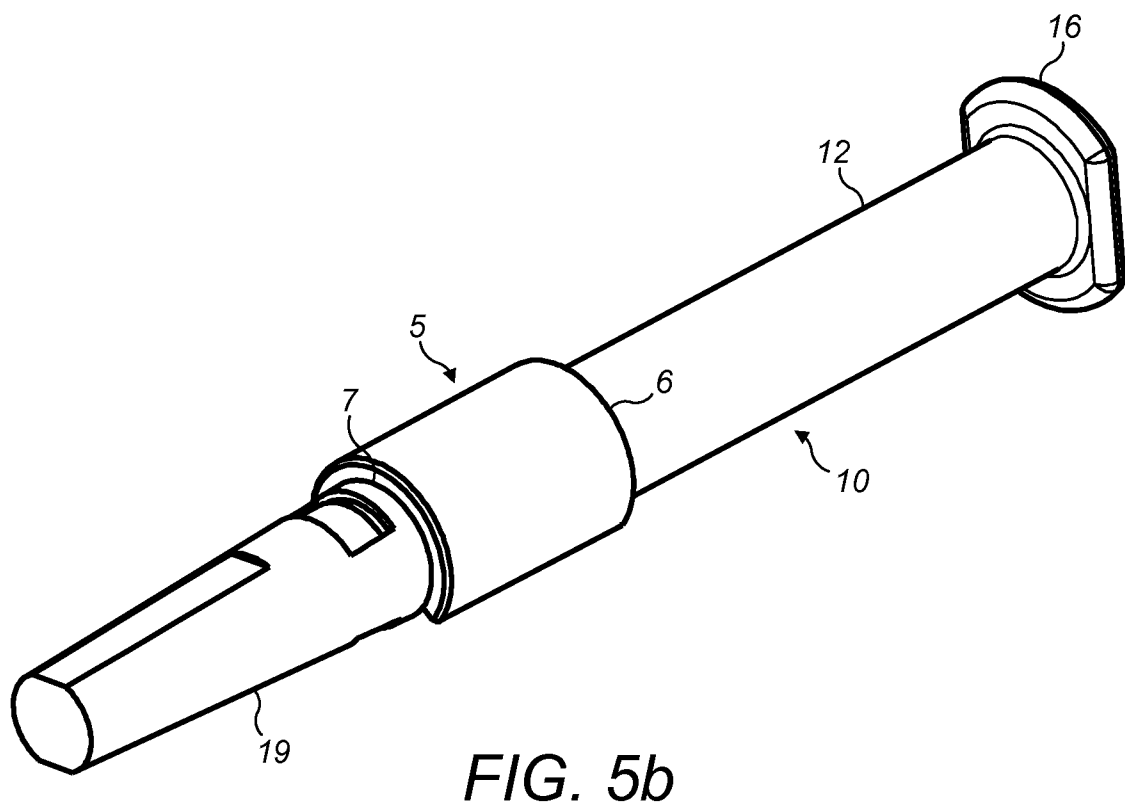
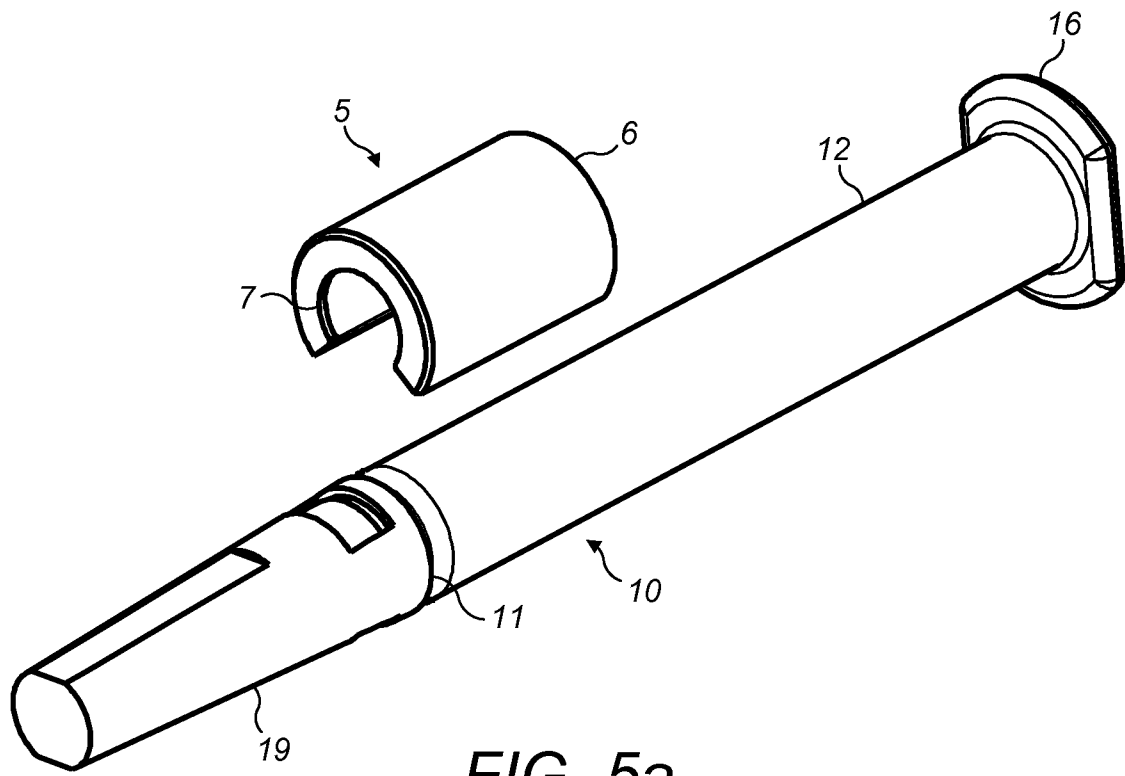


FIG. 4

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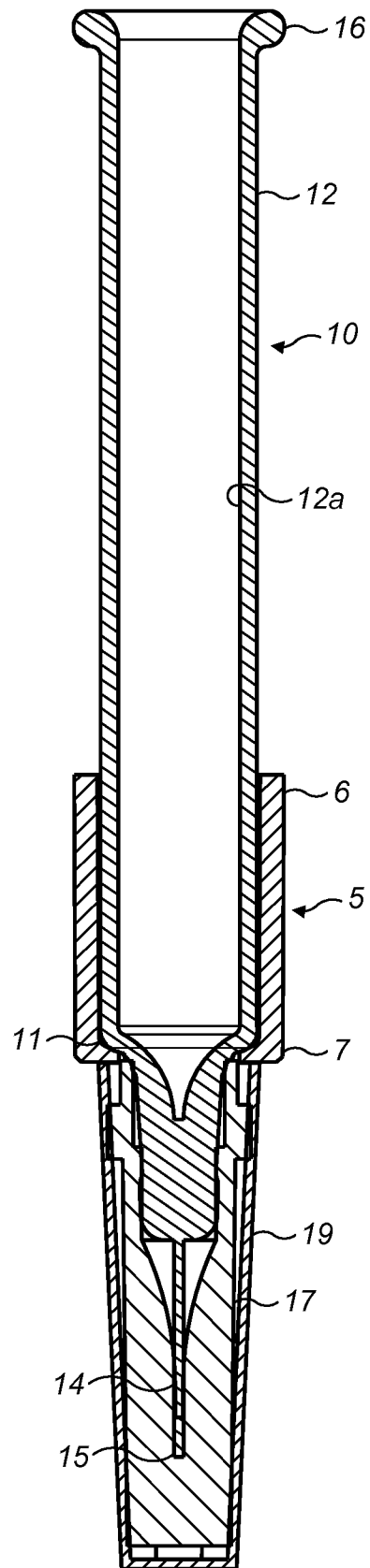


FIG. 5c

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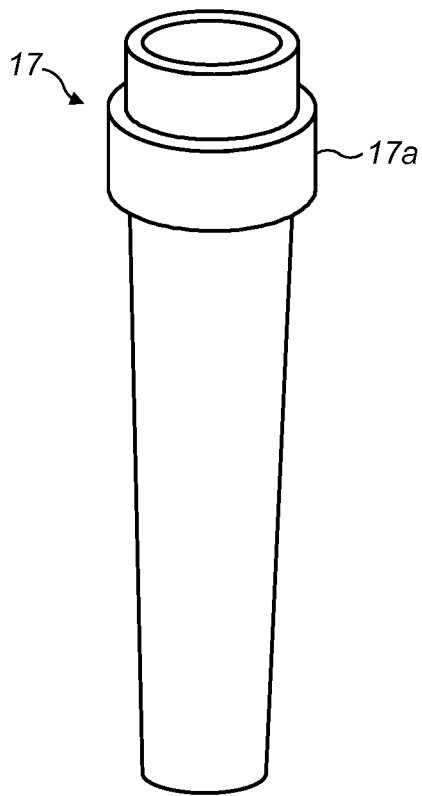


FIG. 6a

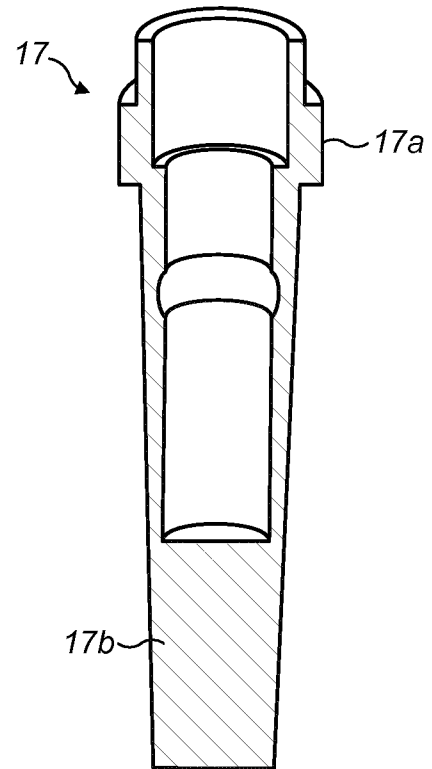


FIG. 6b

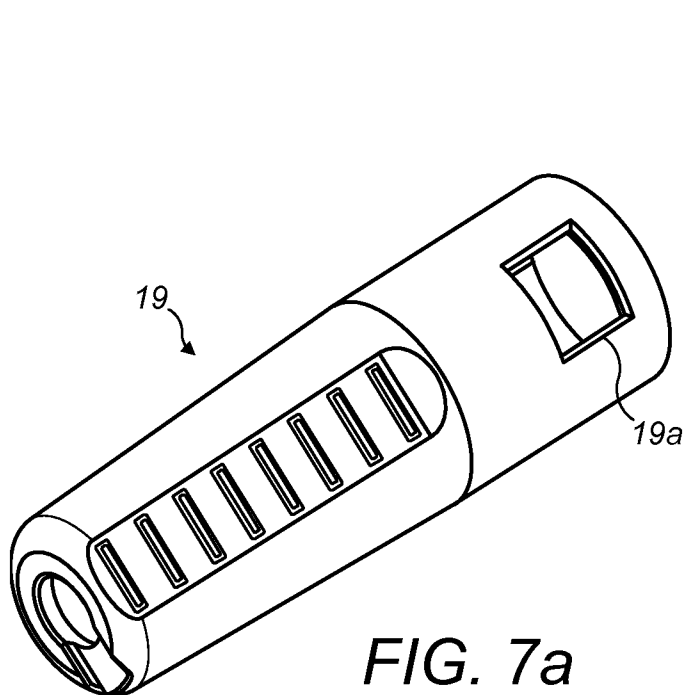


FIG. 7a

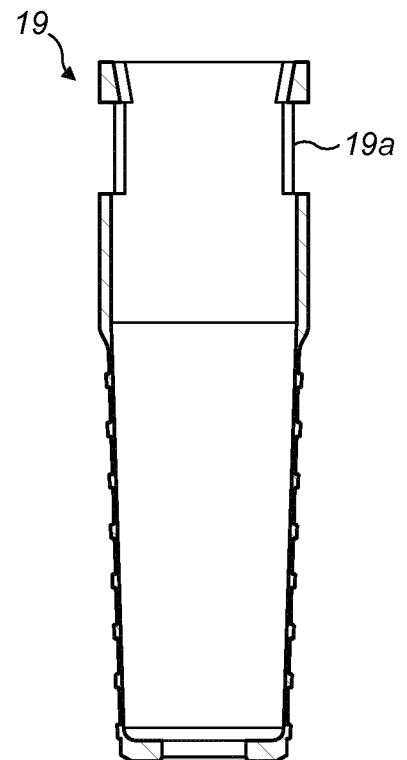
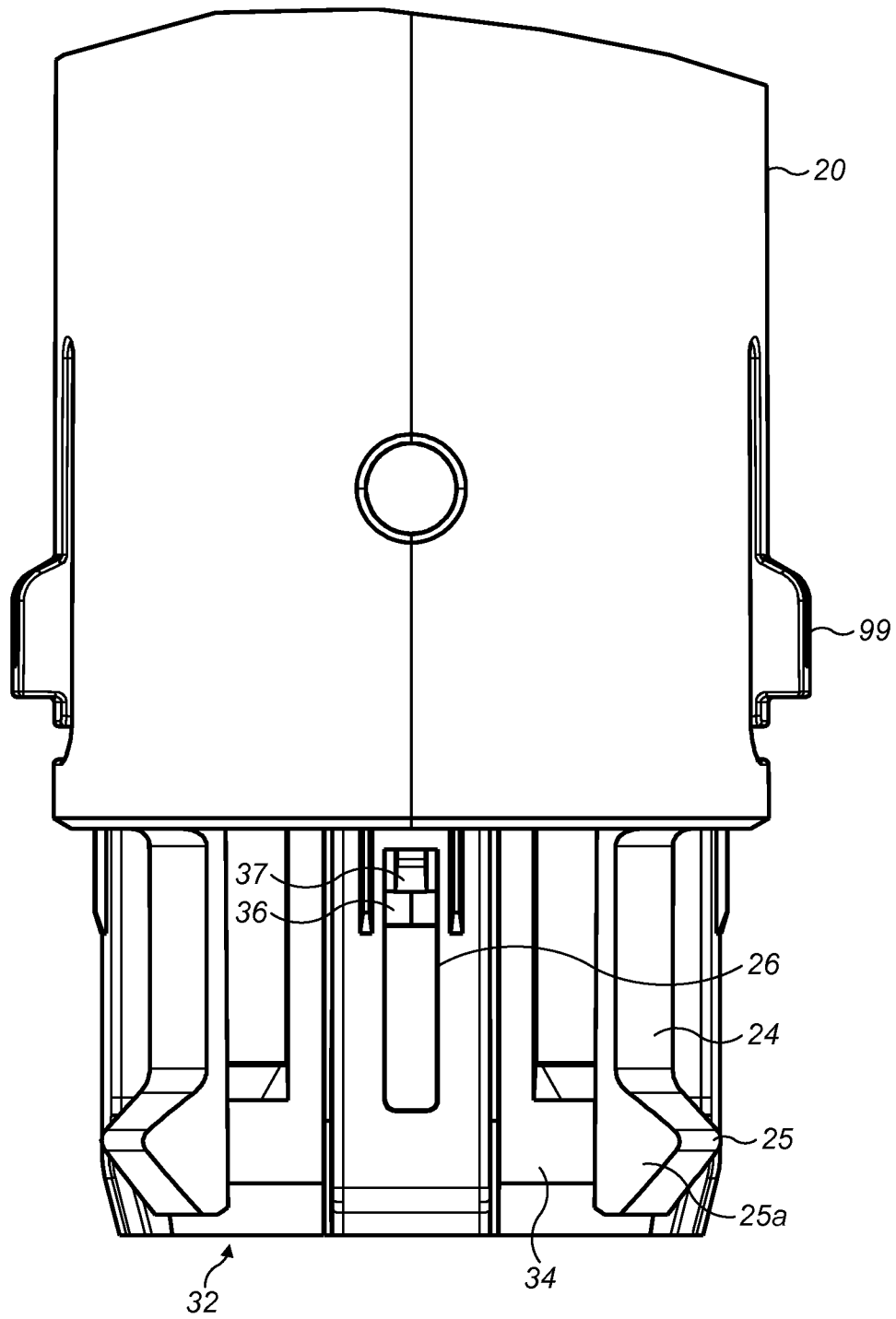


FIG. 7b



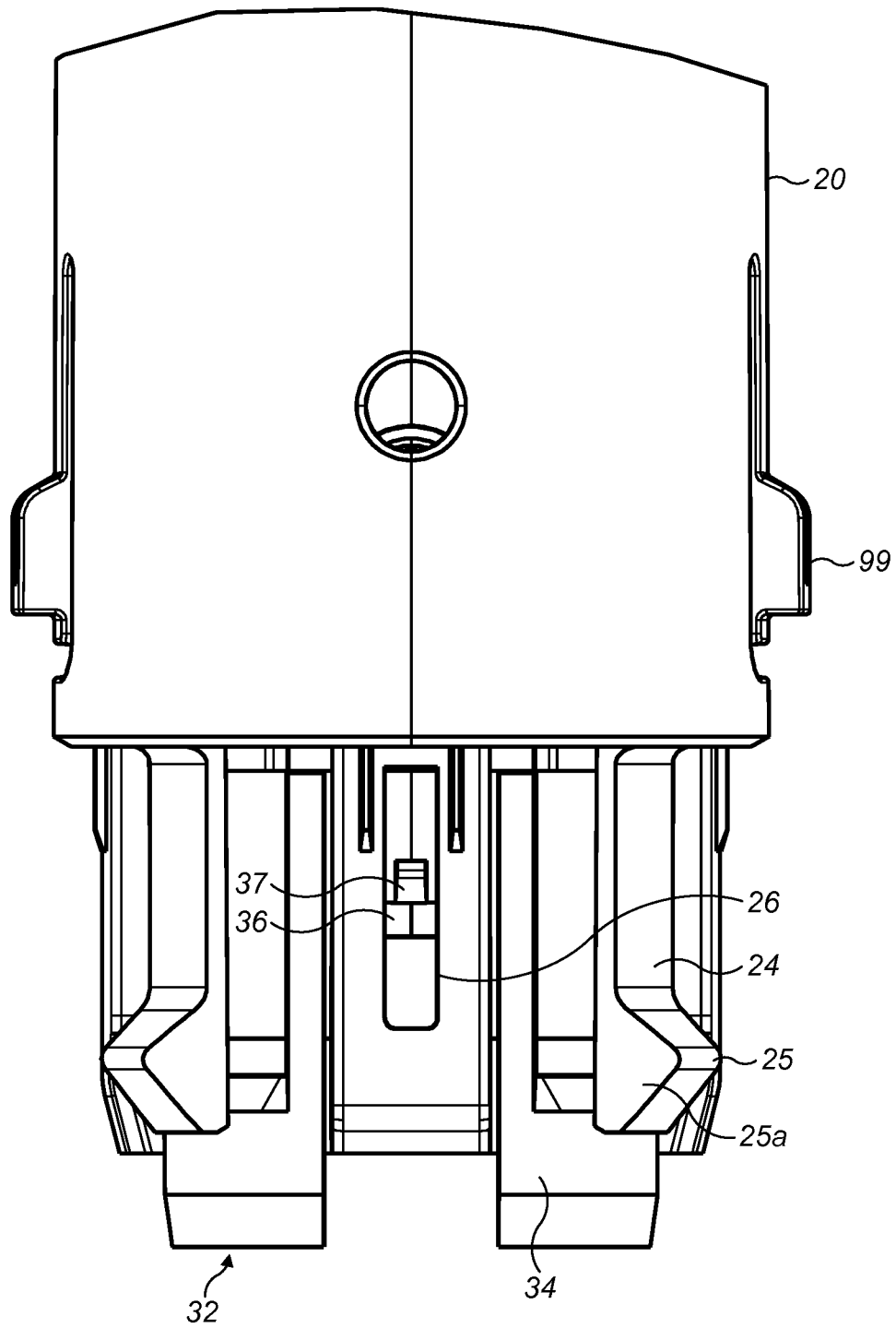


FIG. 8b

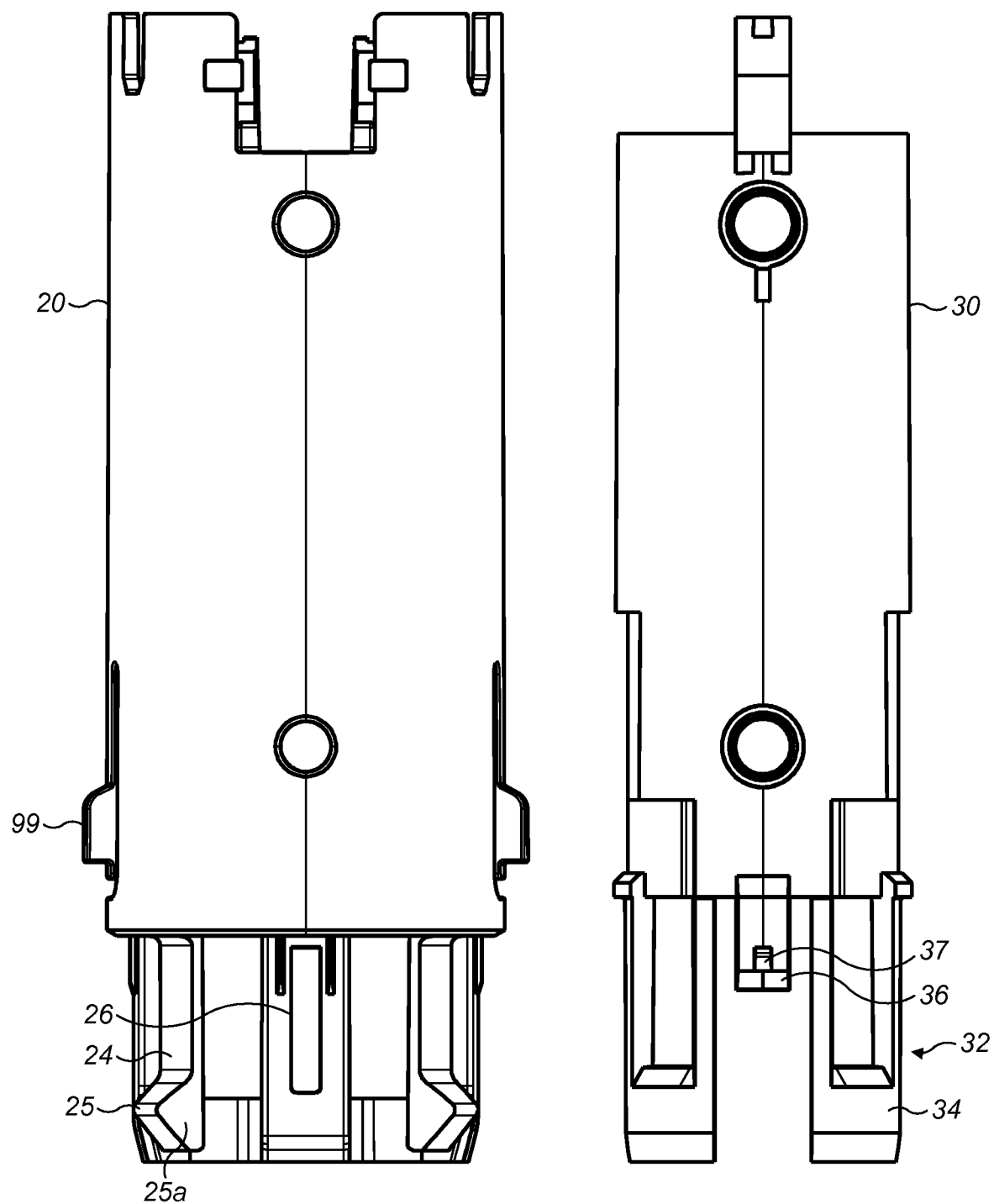


FIG. 8c

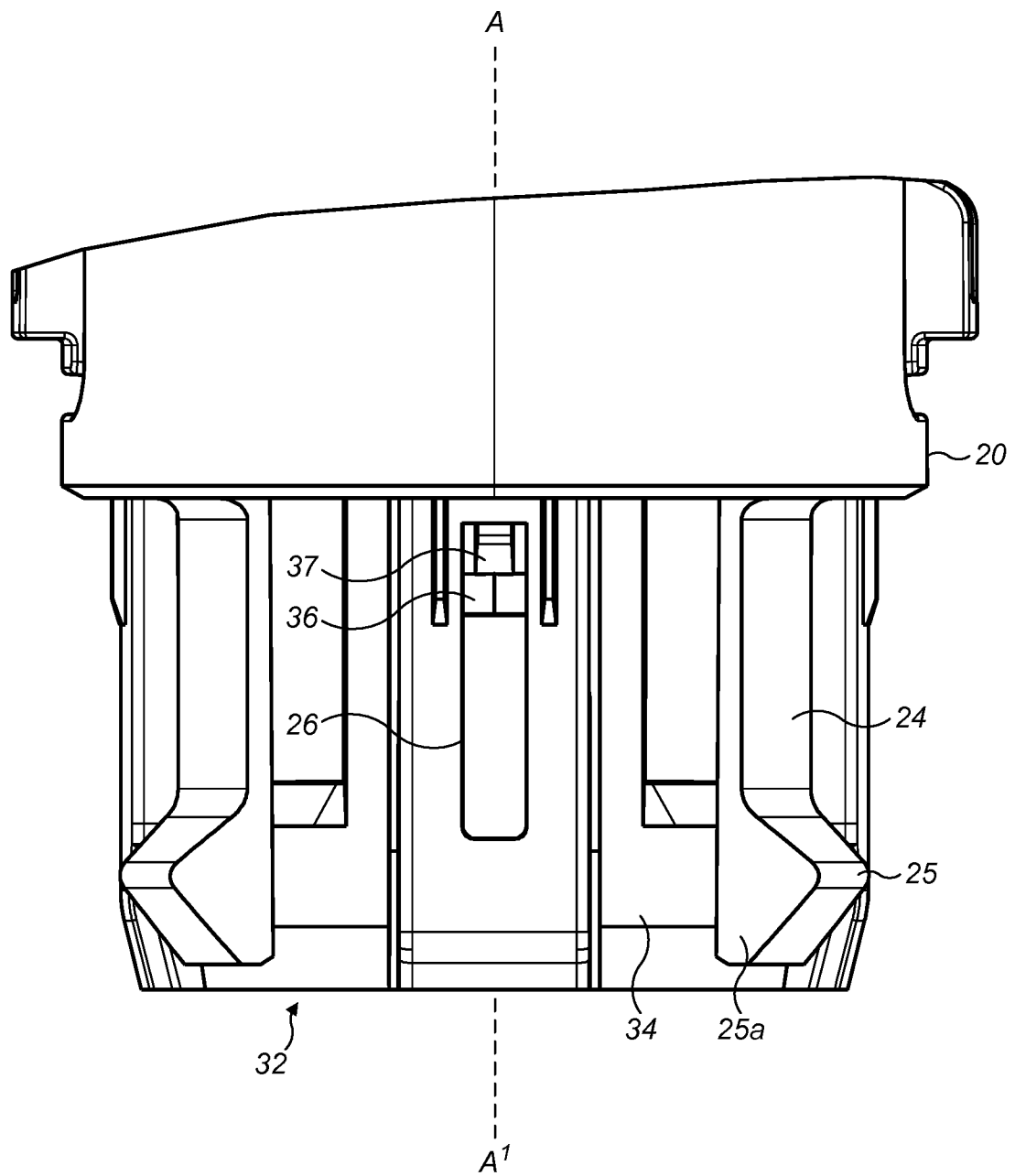
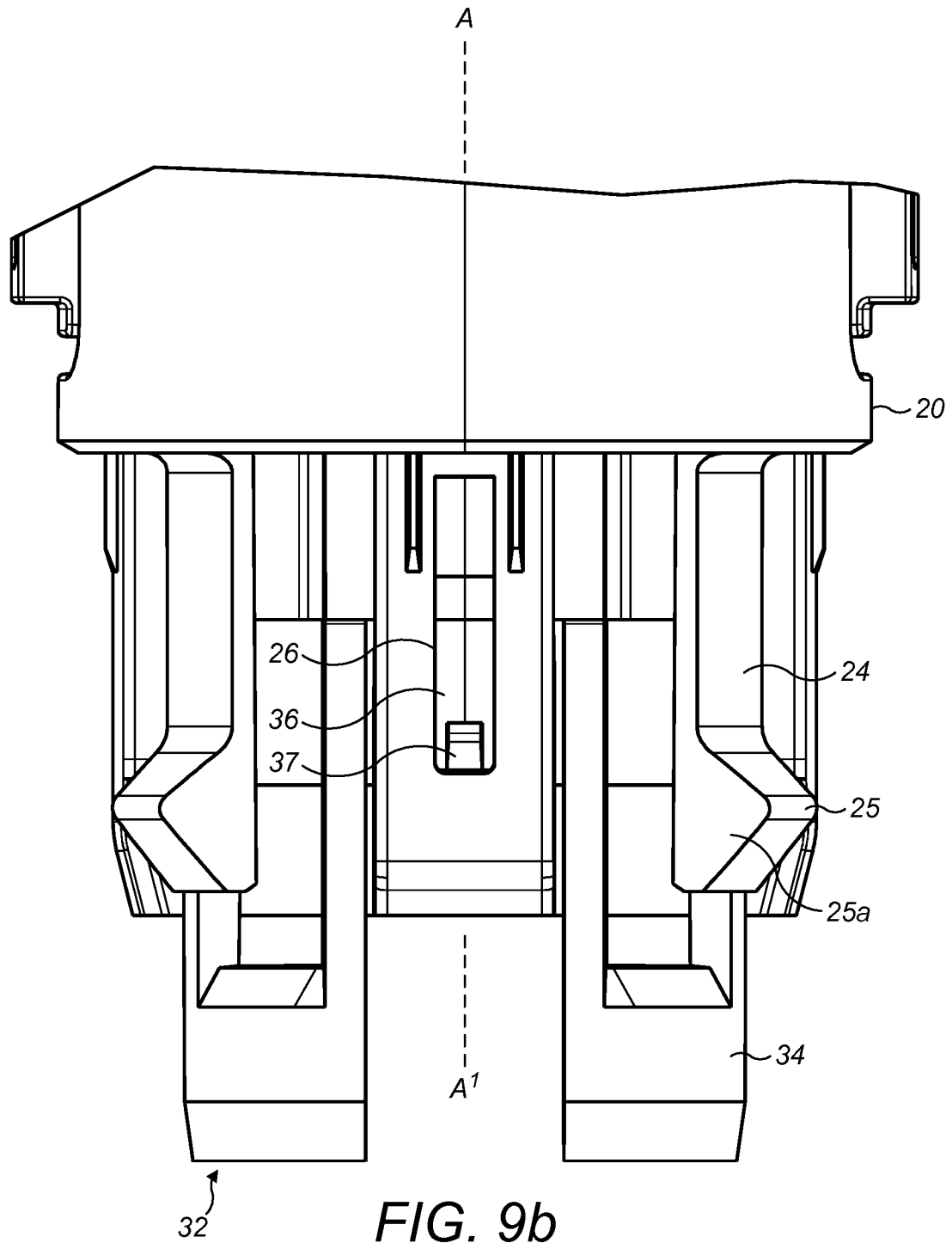


FIG. 9a

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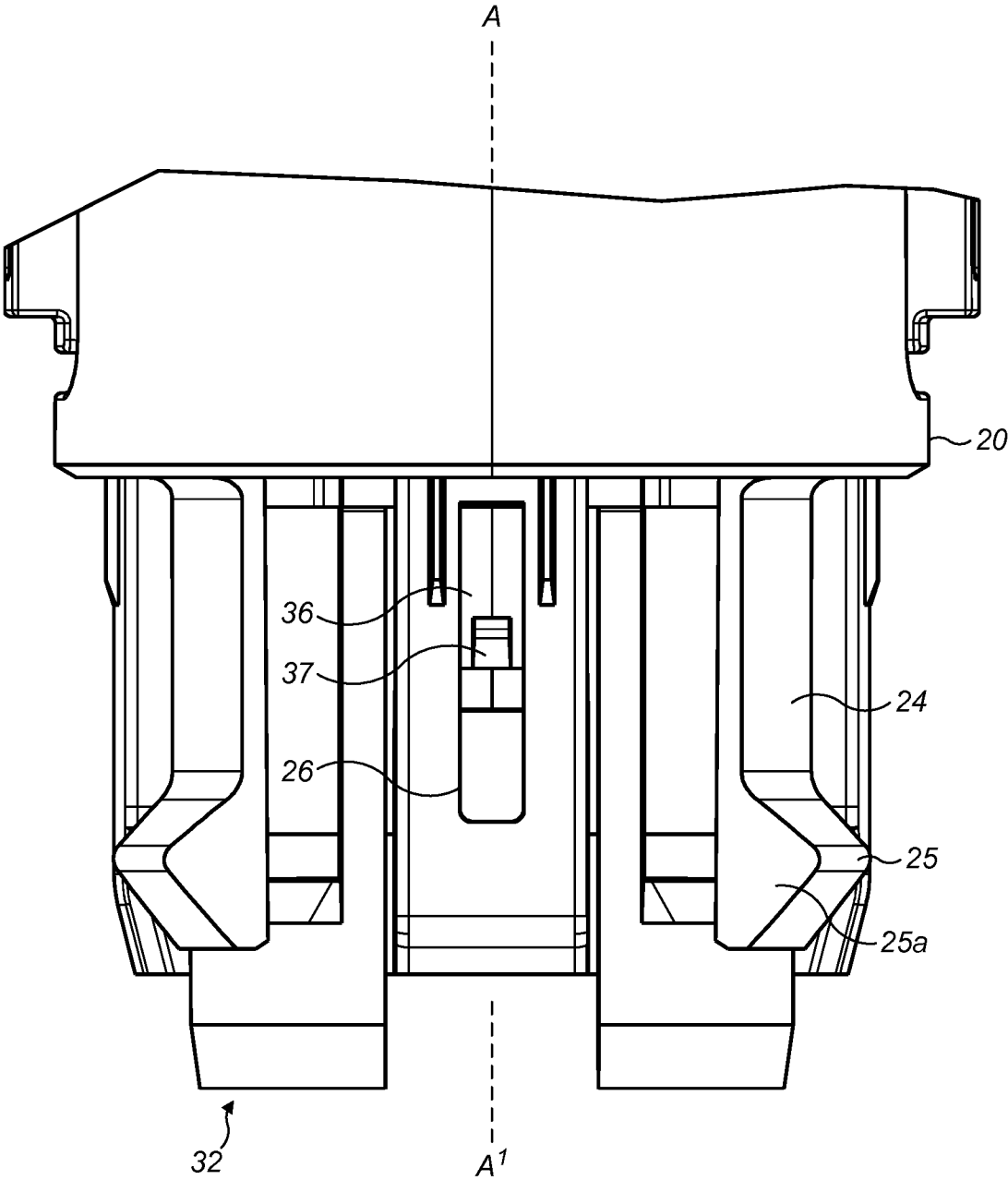


FIG. 9c

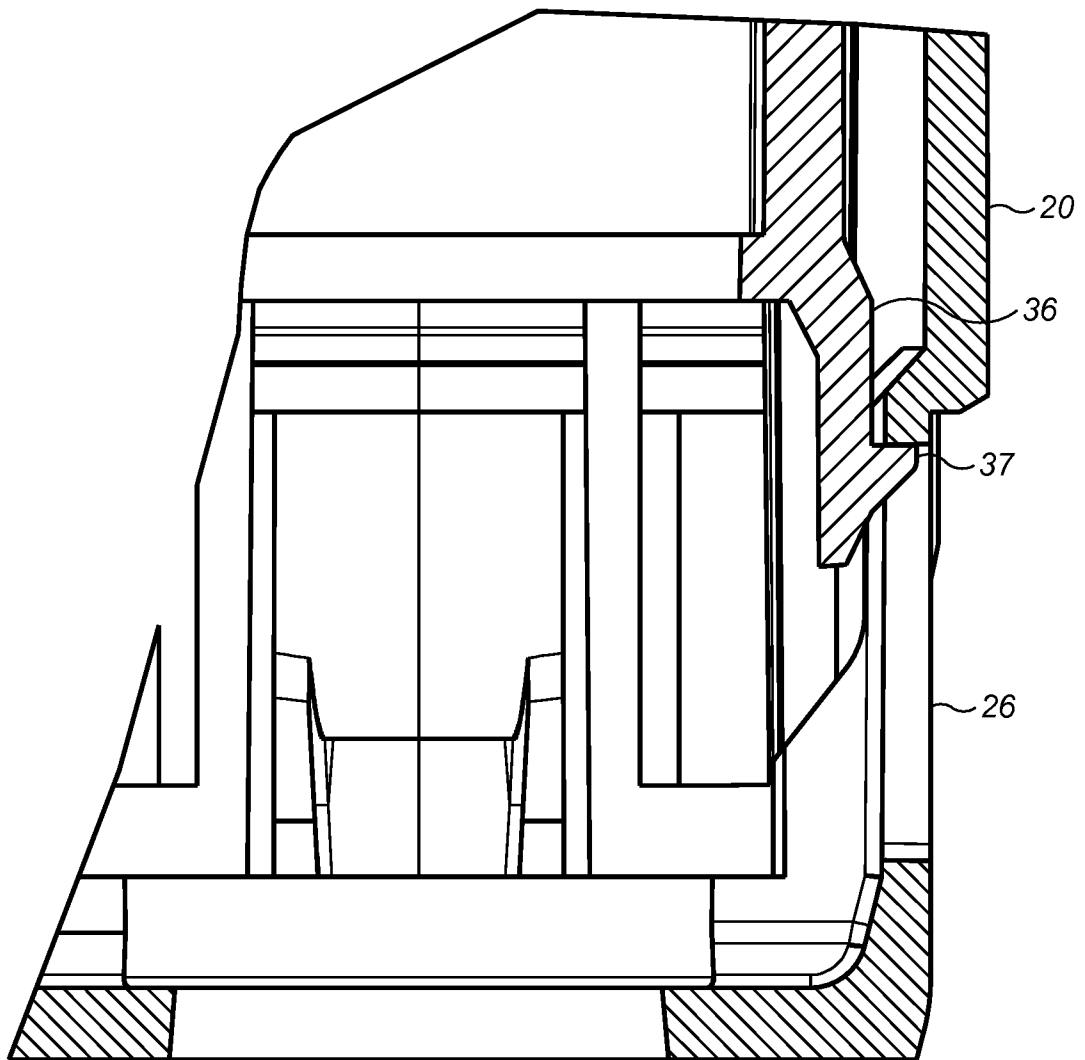


FIG. 10a

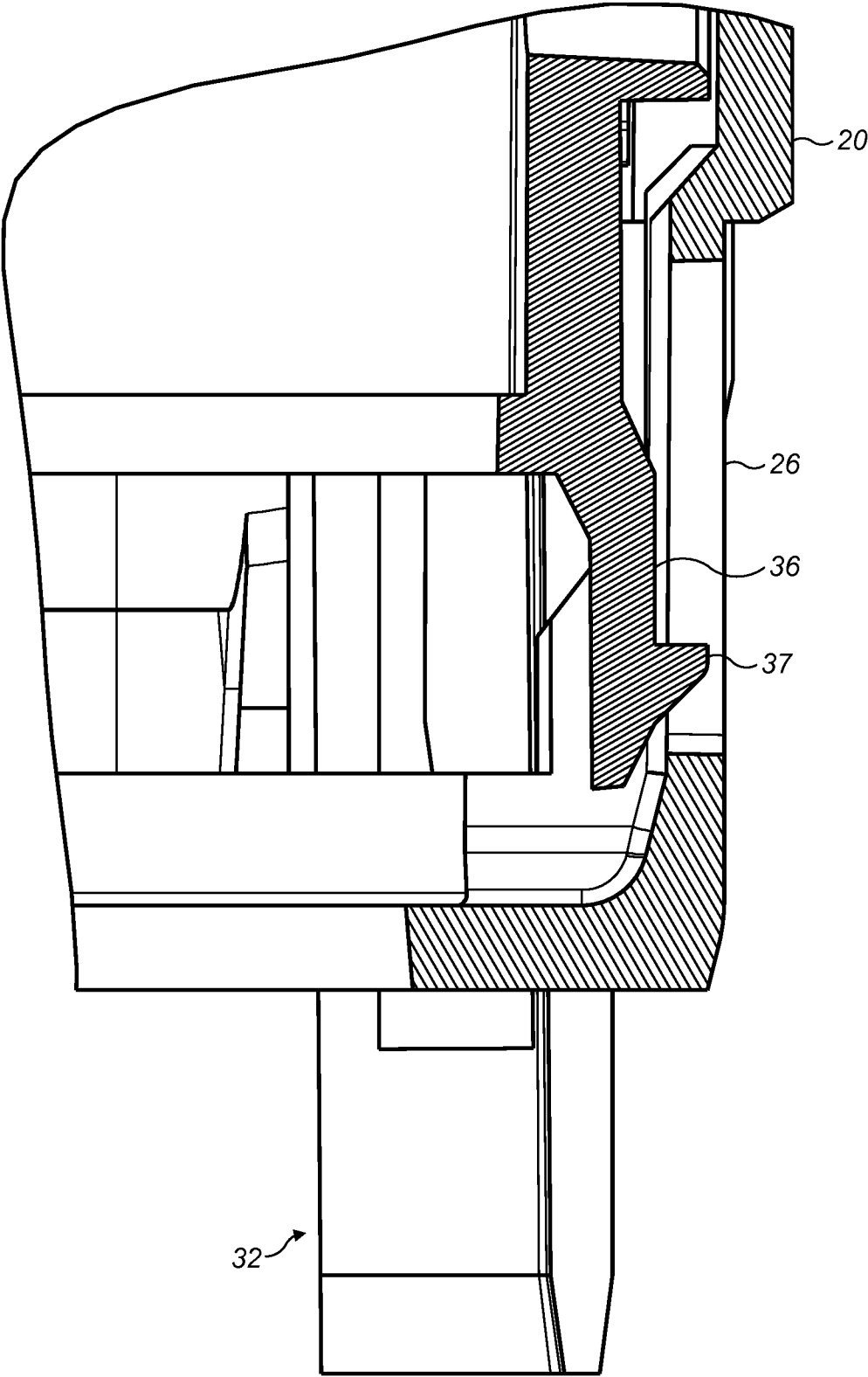


FIG. 10b

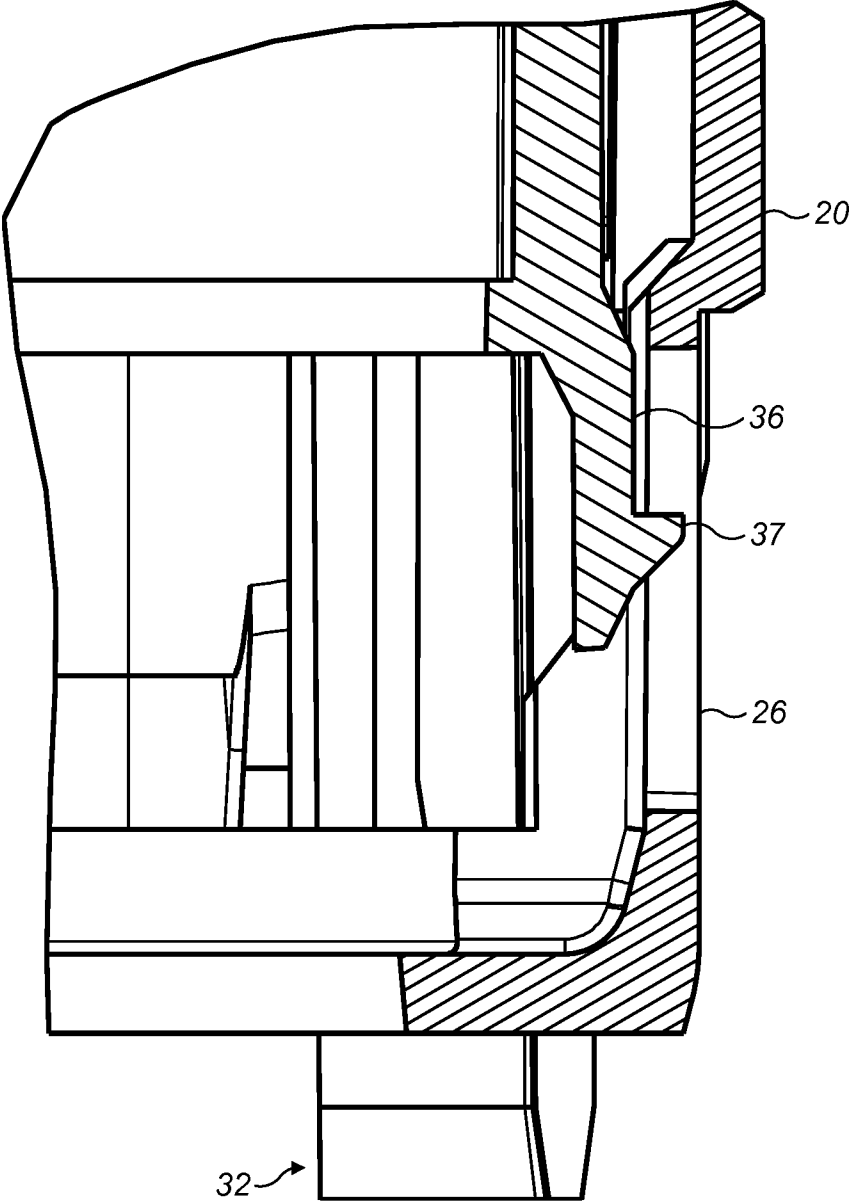


FIG. 10c

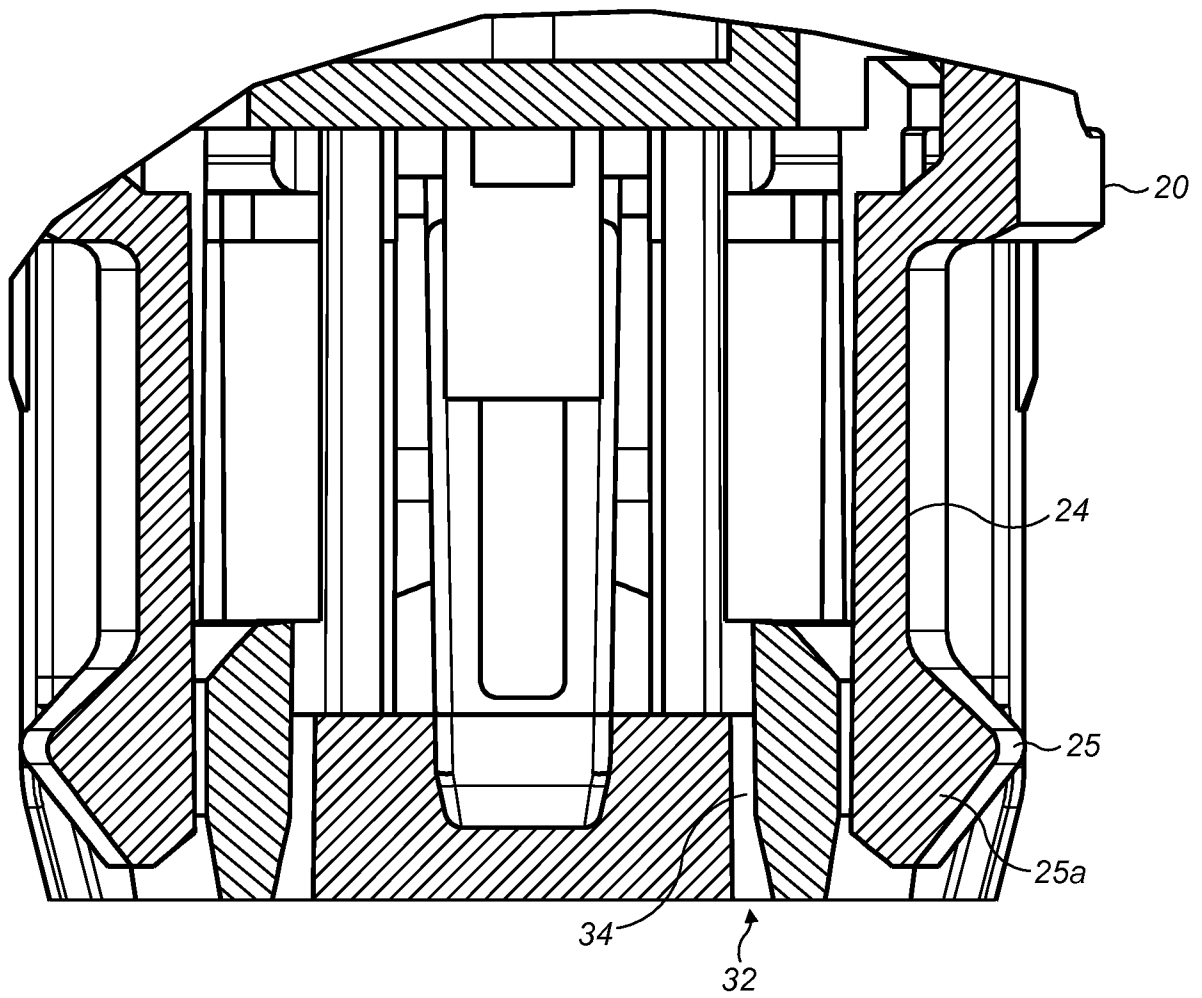
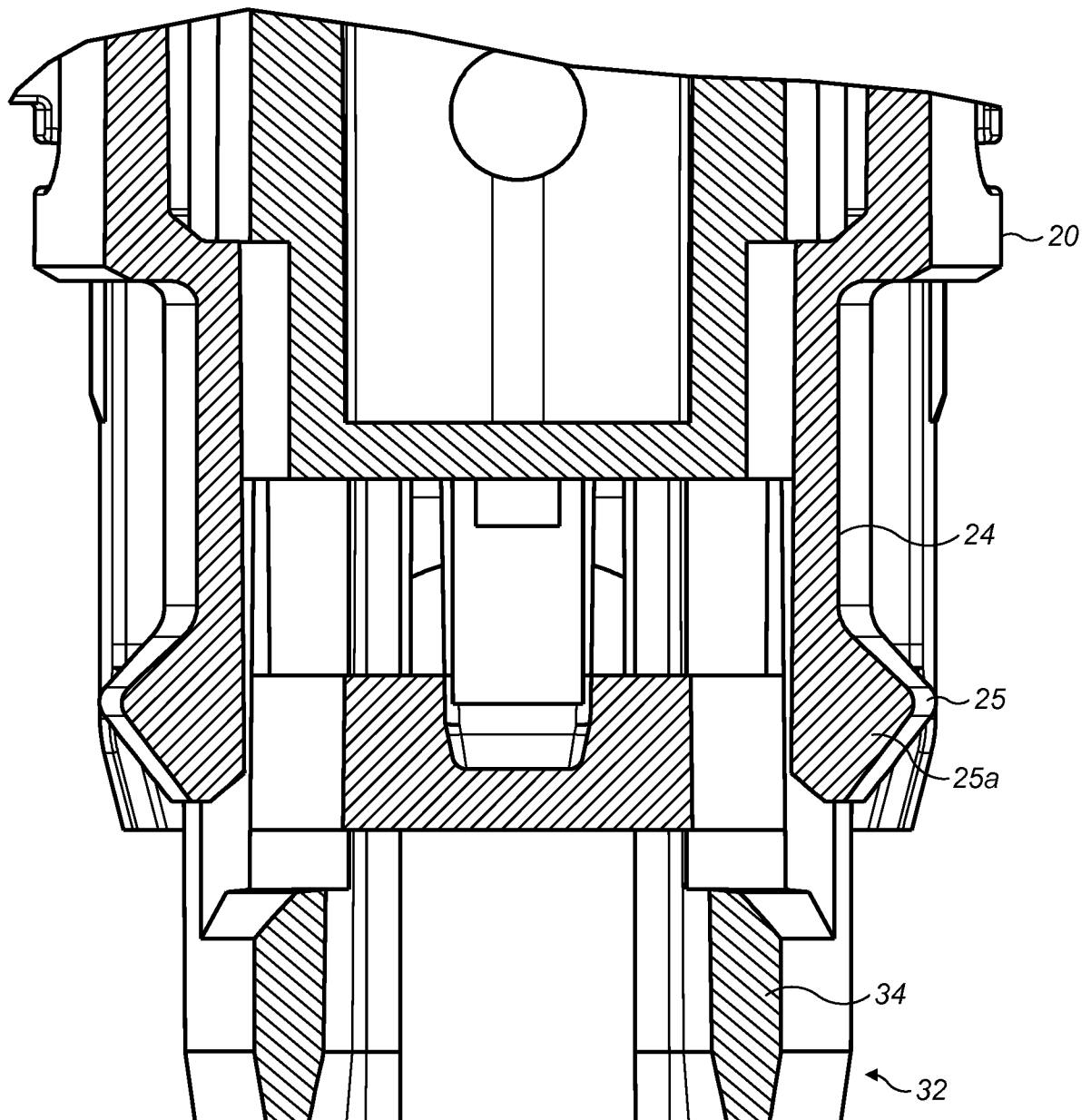


FIG. 11a



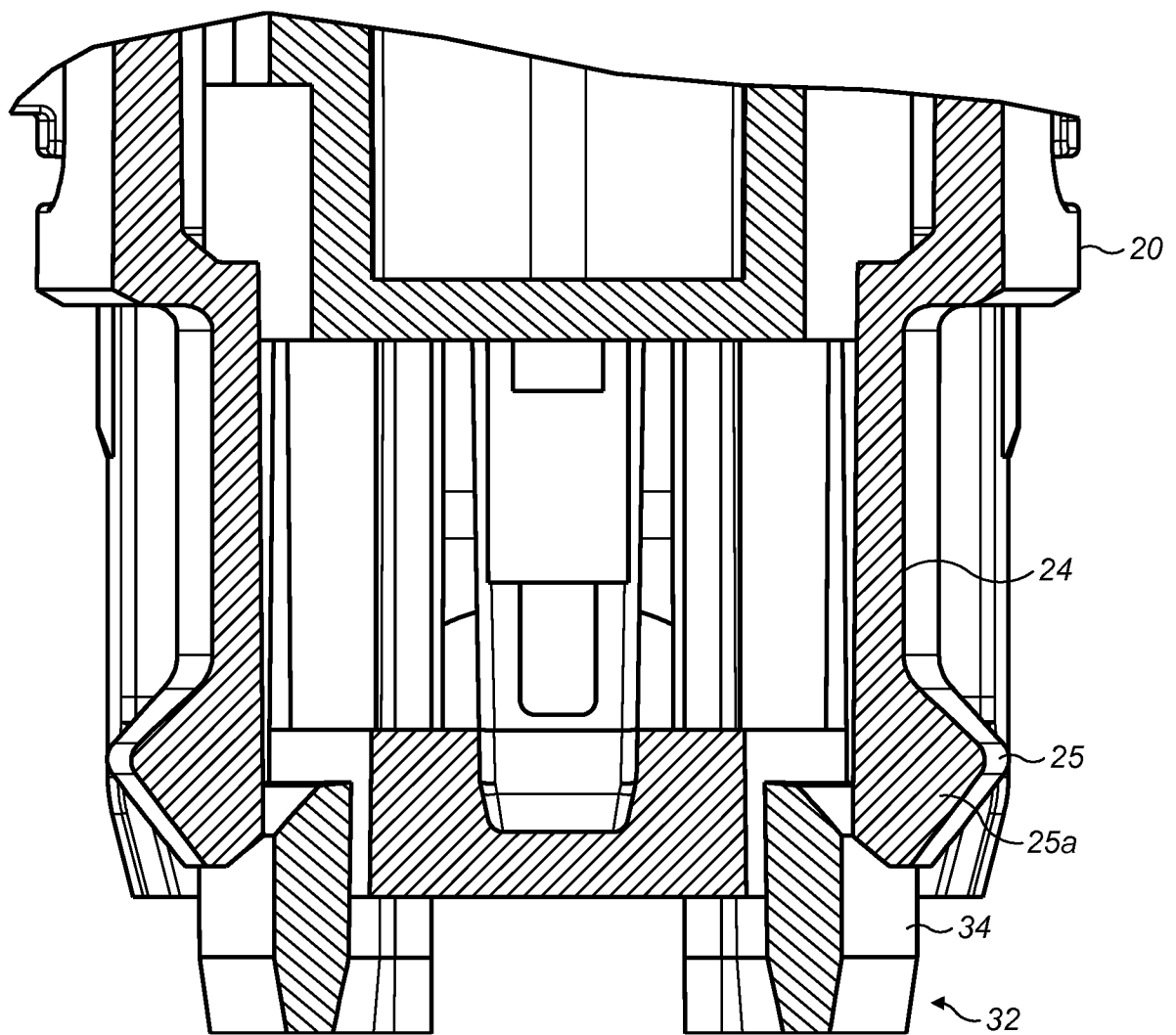
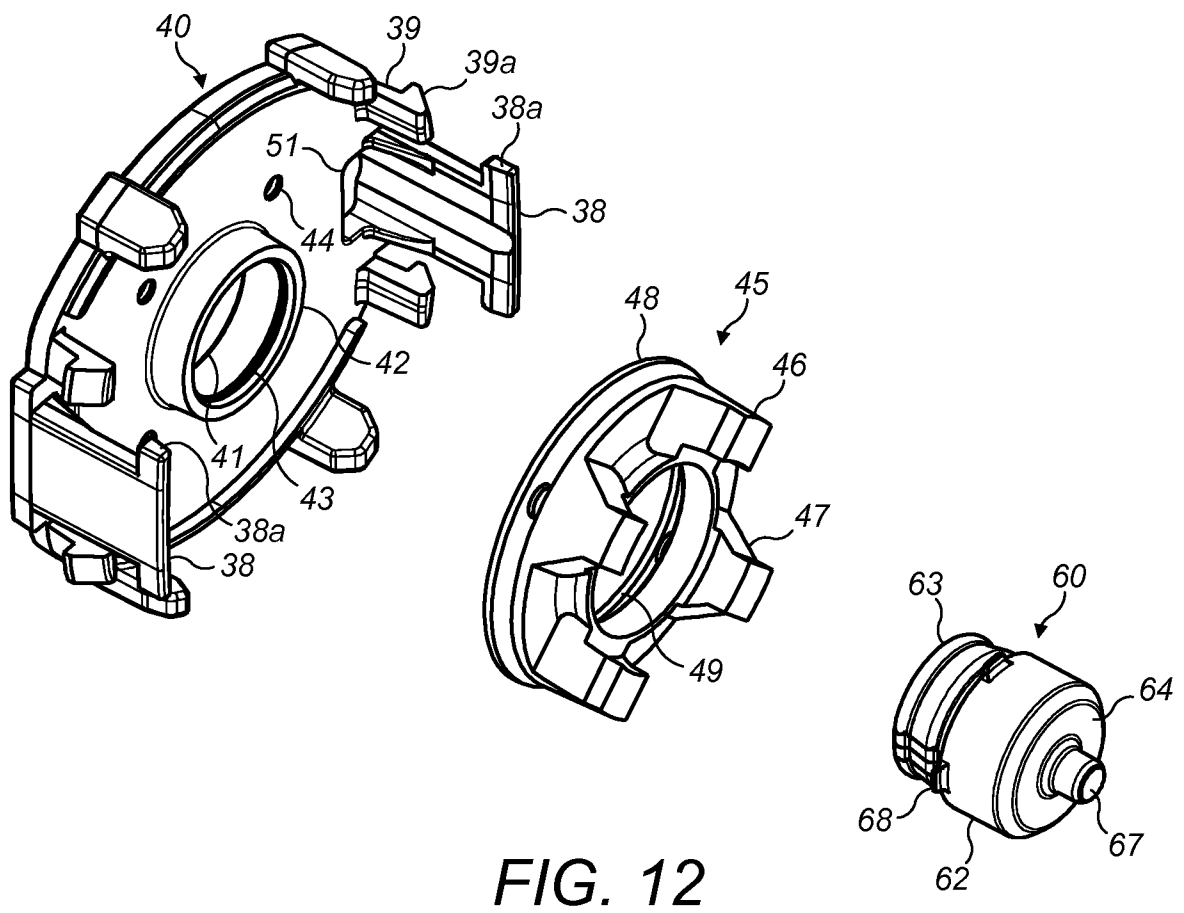


FIG. 11c



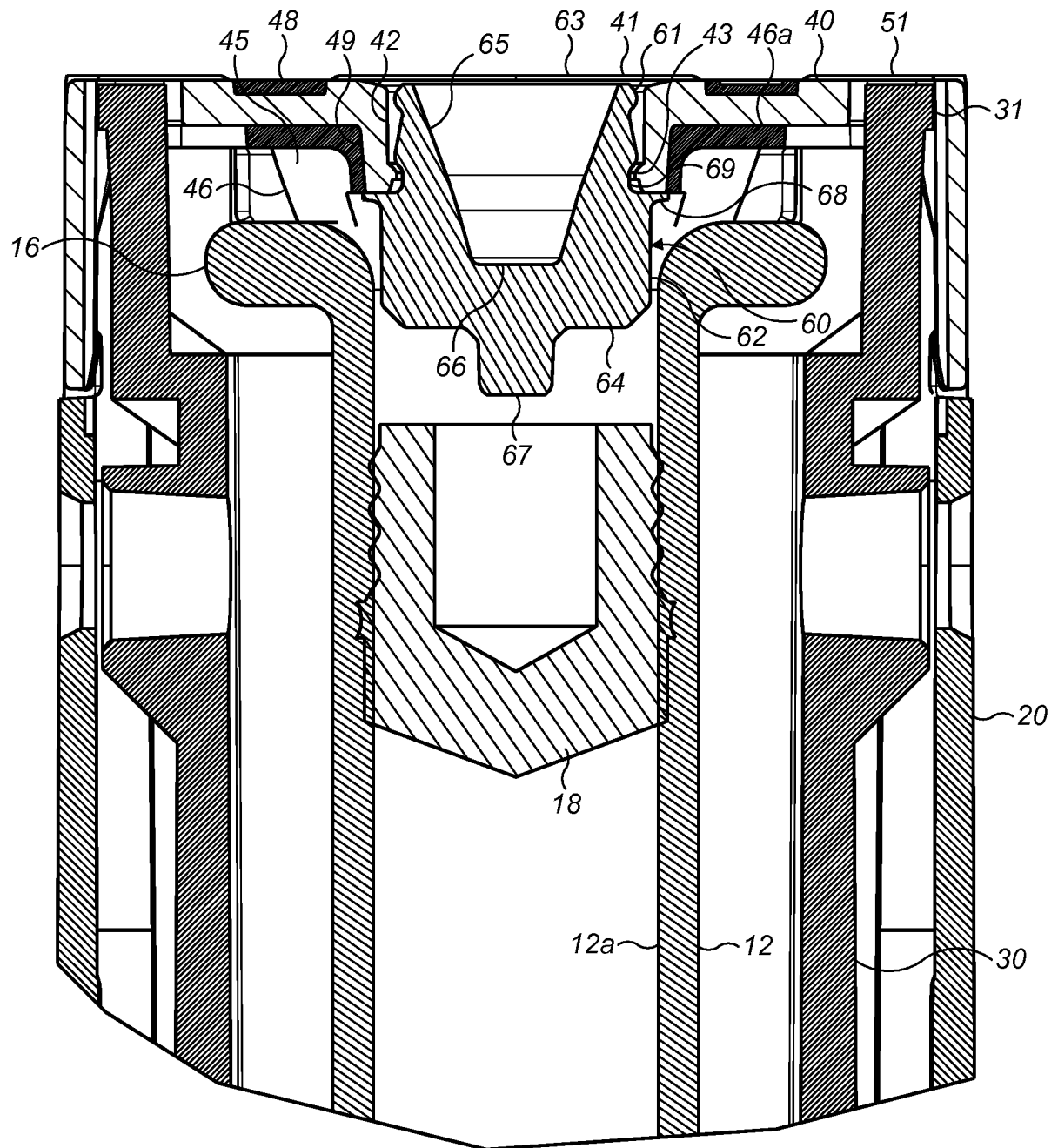


FIG. 13

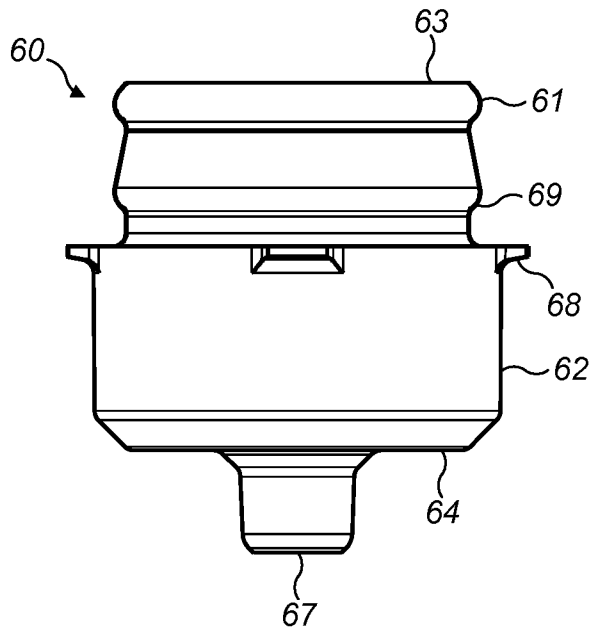


FIG. 14a

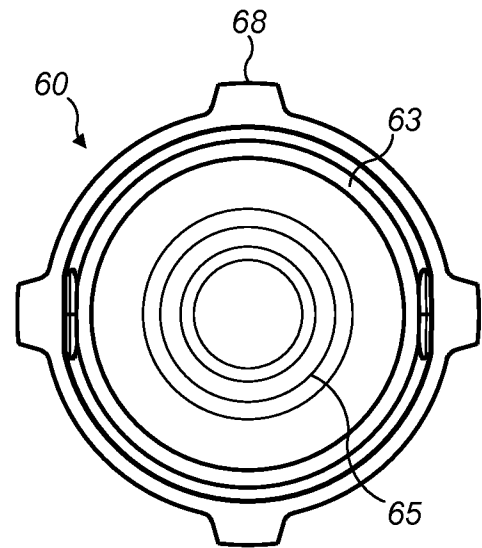


FIG. 14b

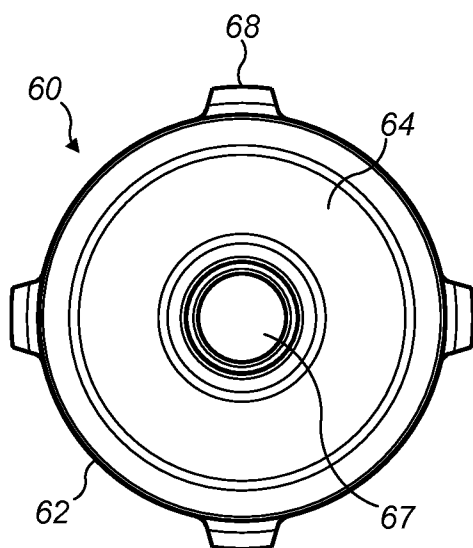


FIG. 14c

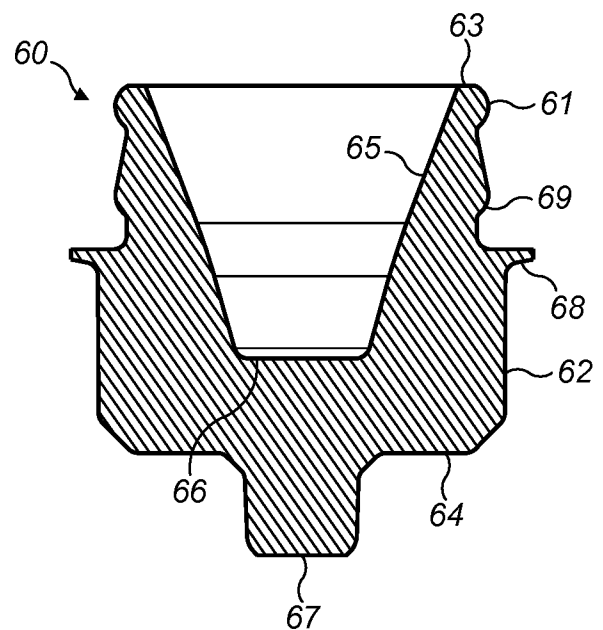


FIG. 14d

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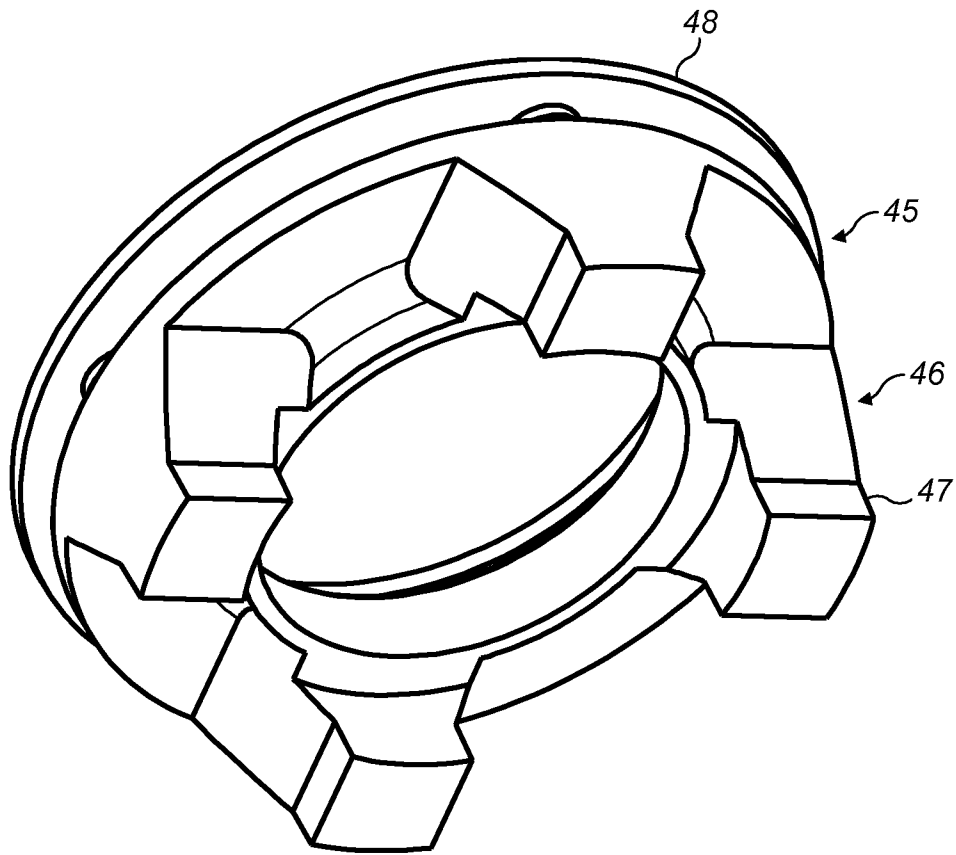


FIG. 15a

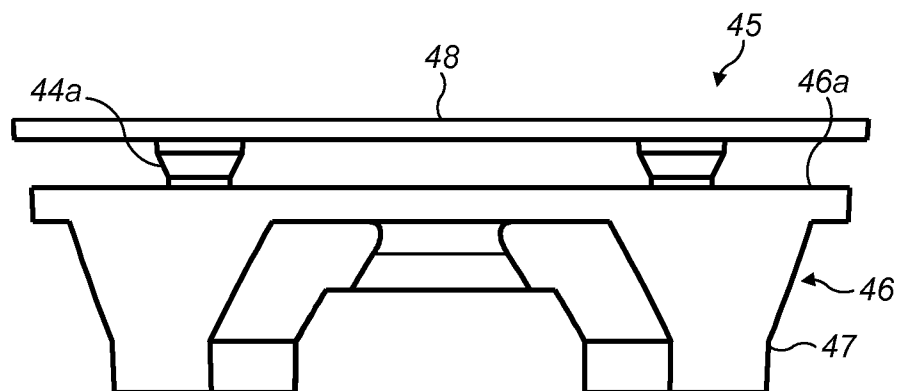


FIG. 15b

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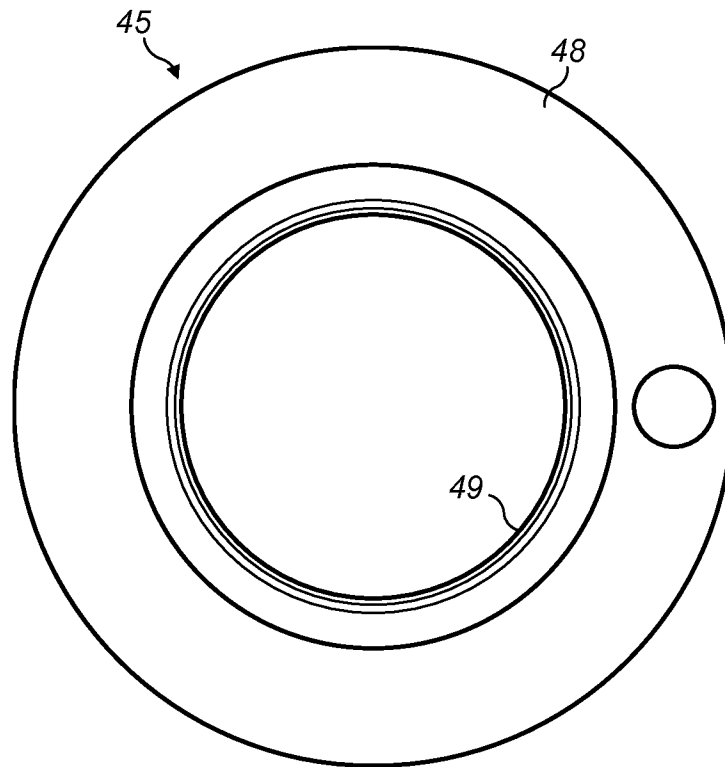


FIG. 15c

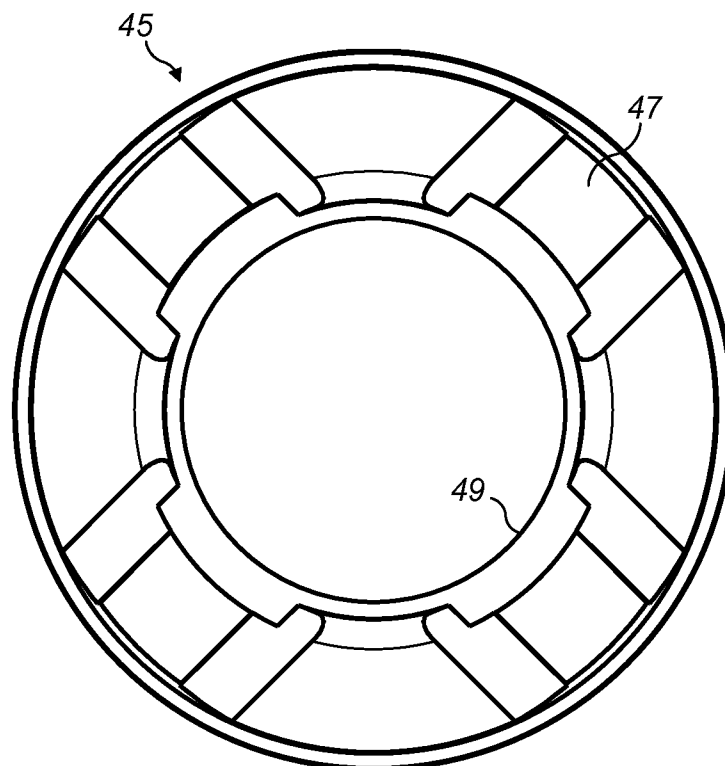


FIG. 15d

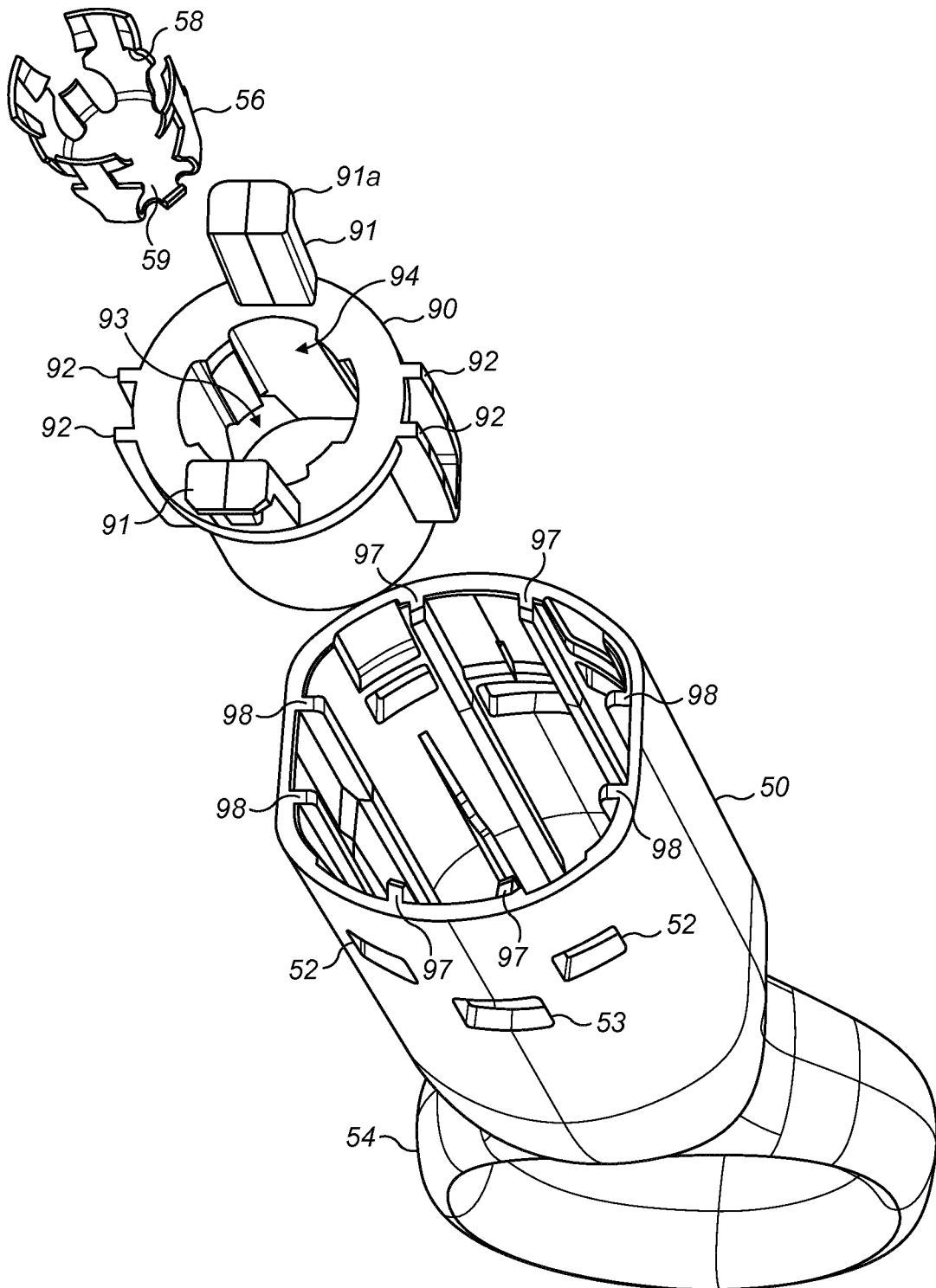


FIG. 16

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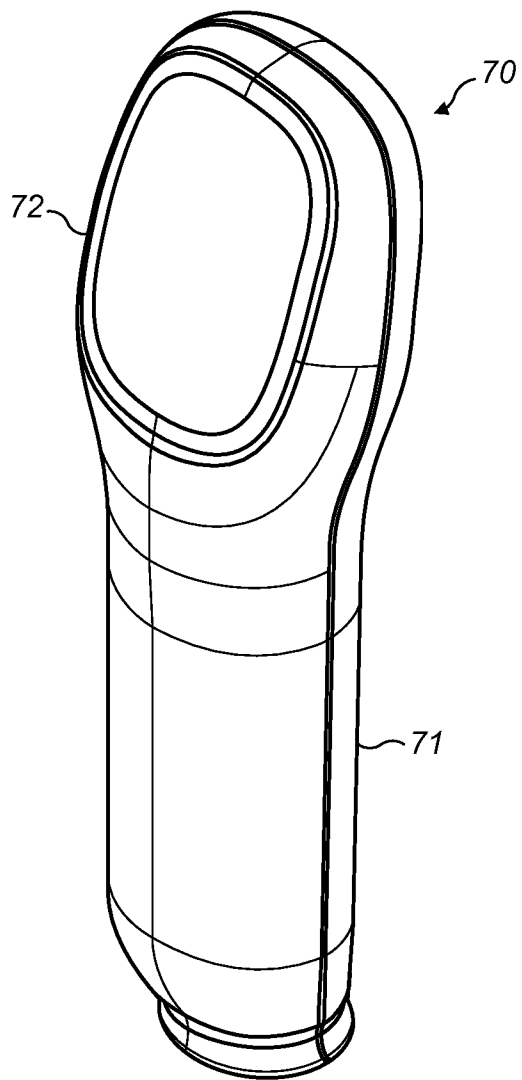


FIG. 17

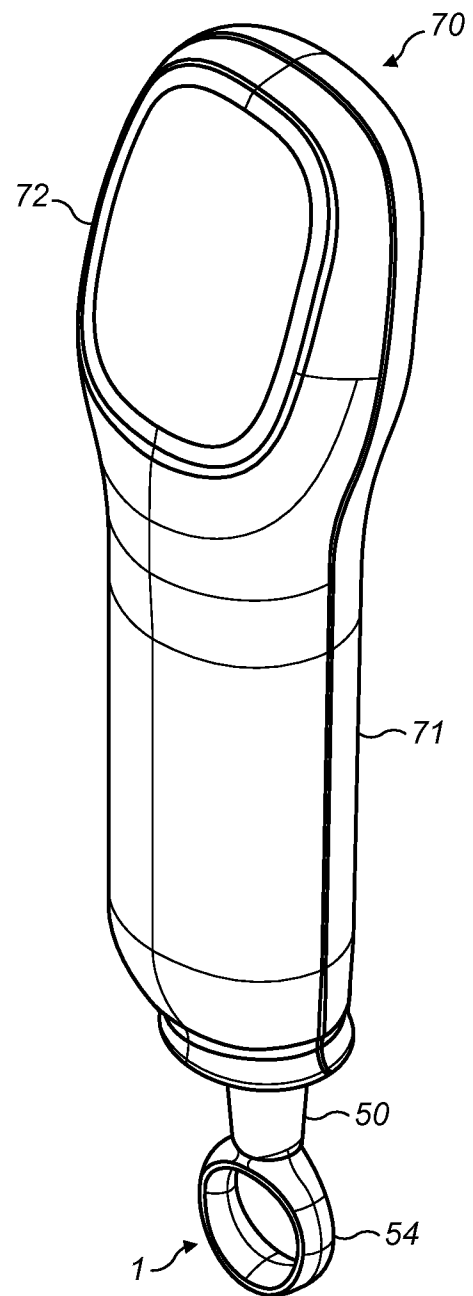


FIG. 18

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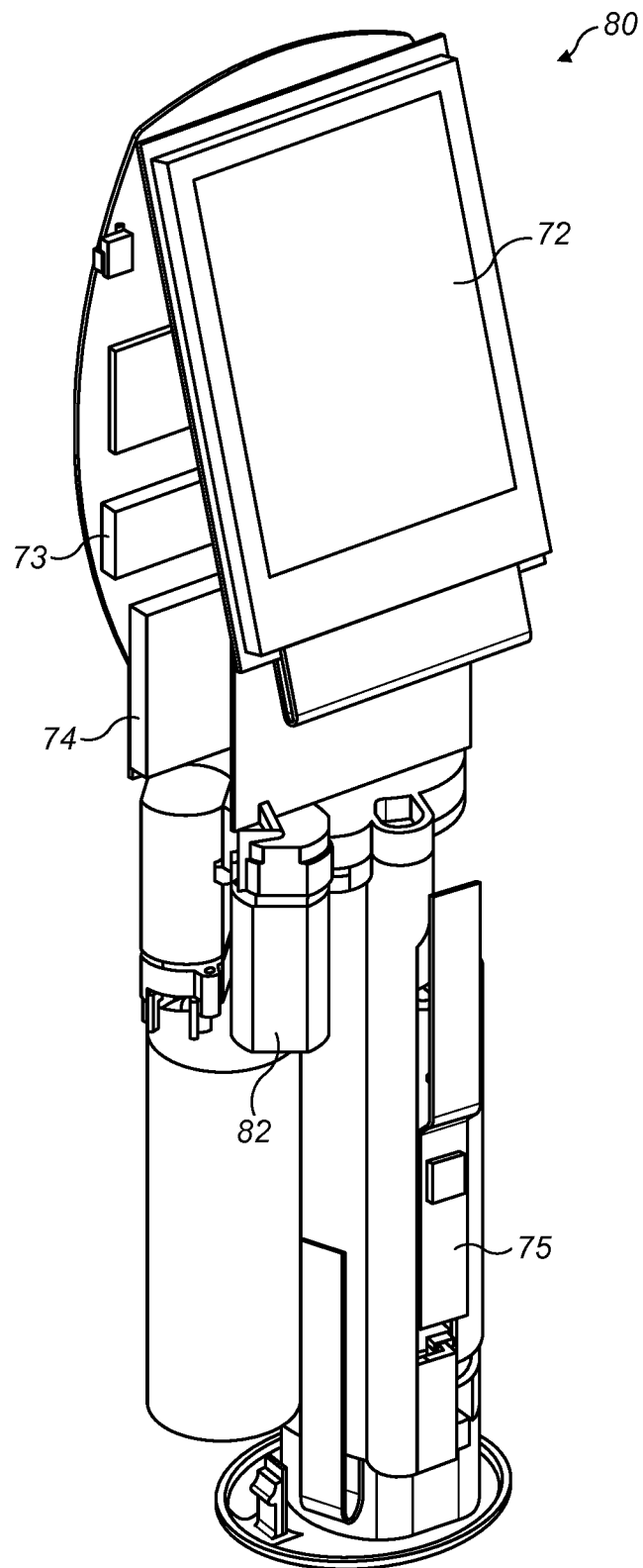


FIG. 19

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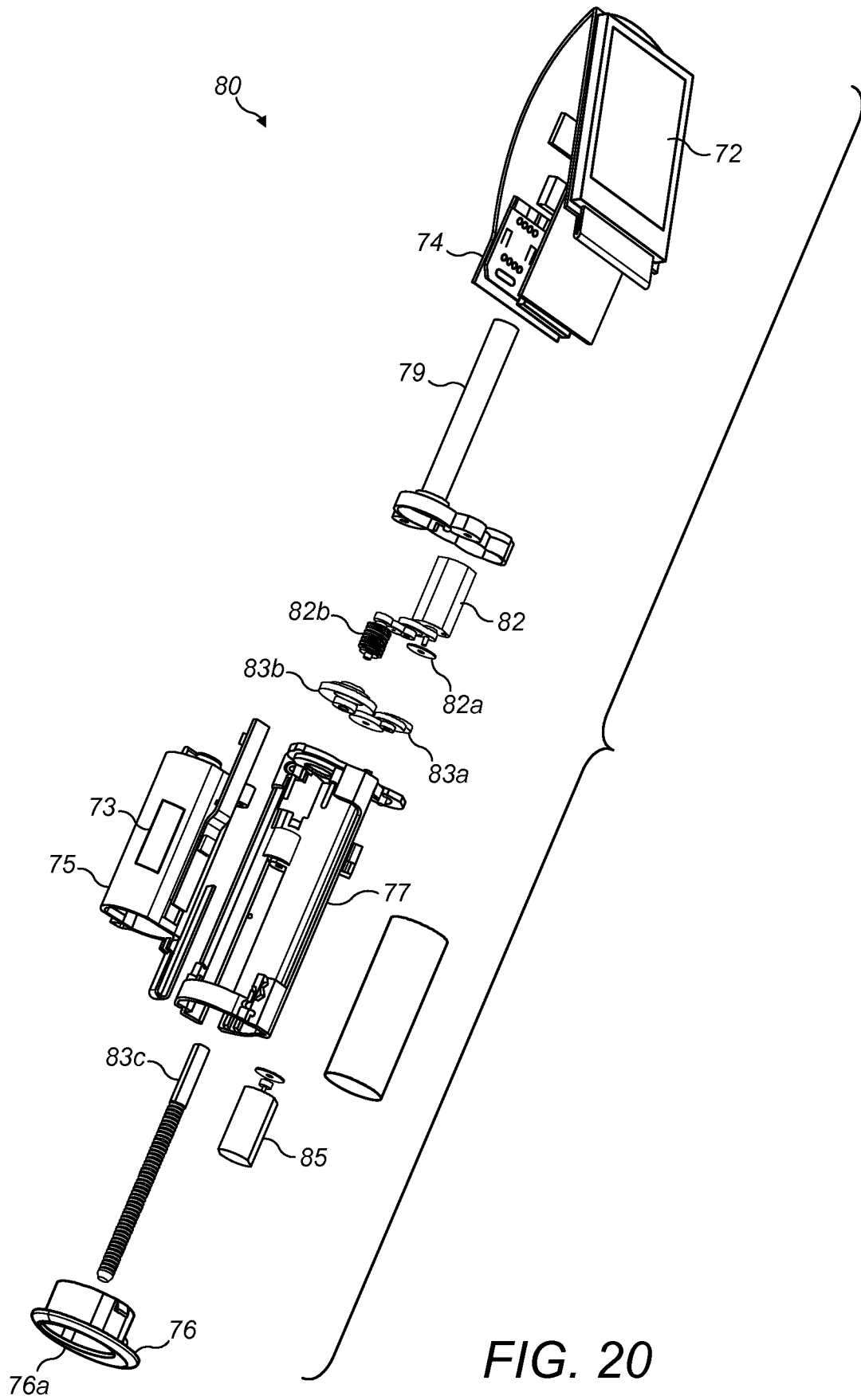
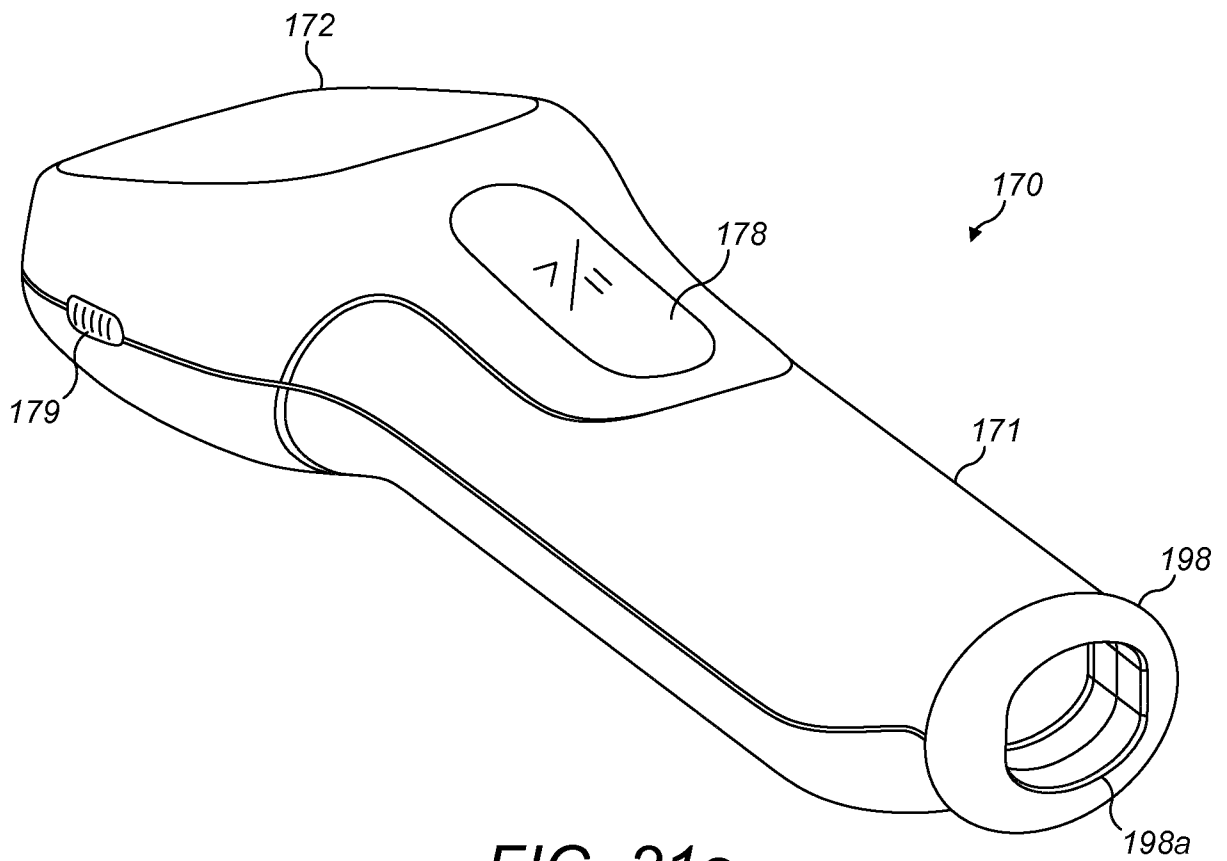


FIG. 20



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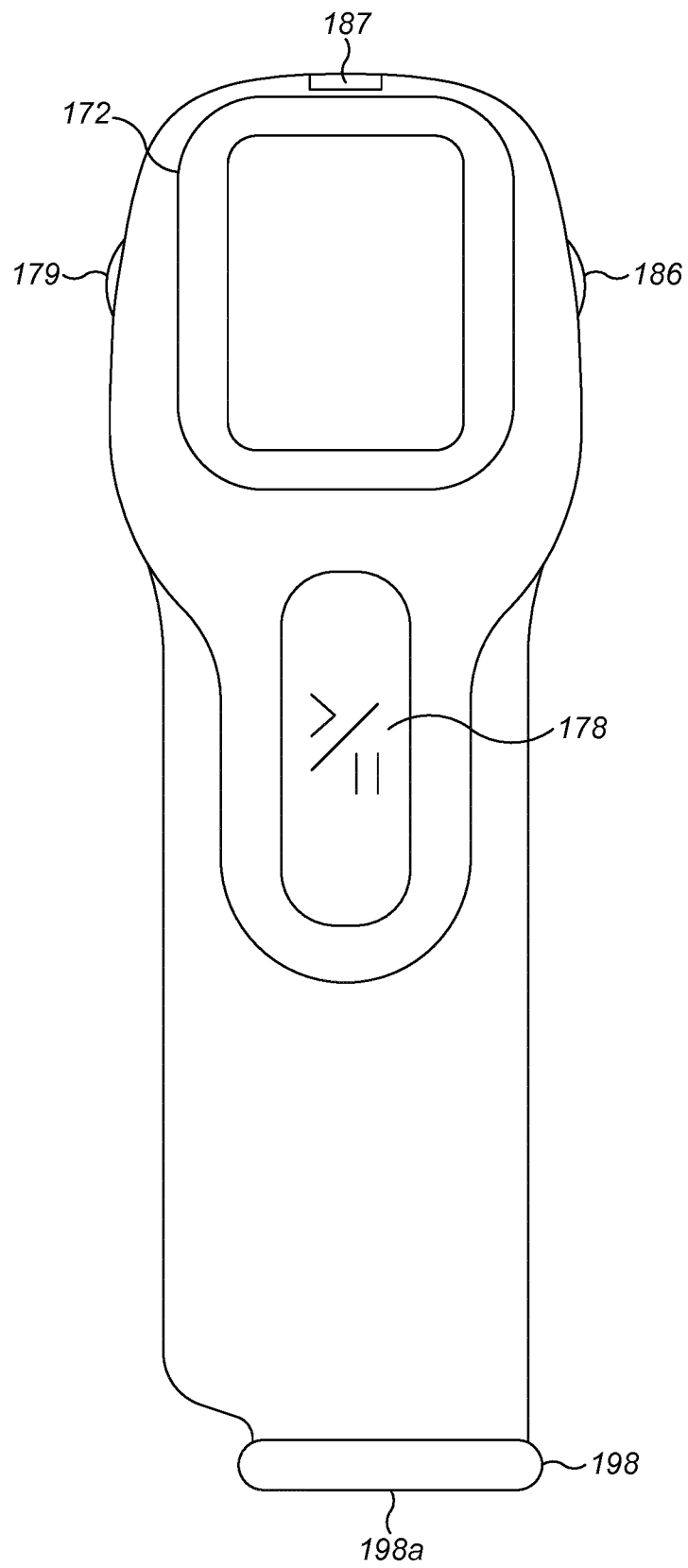


FIG. 21b

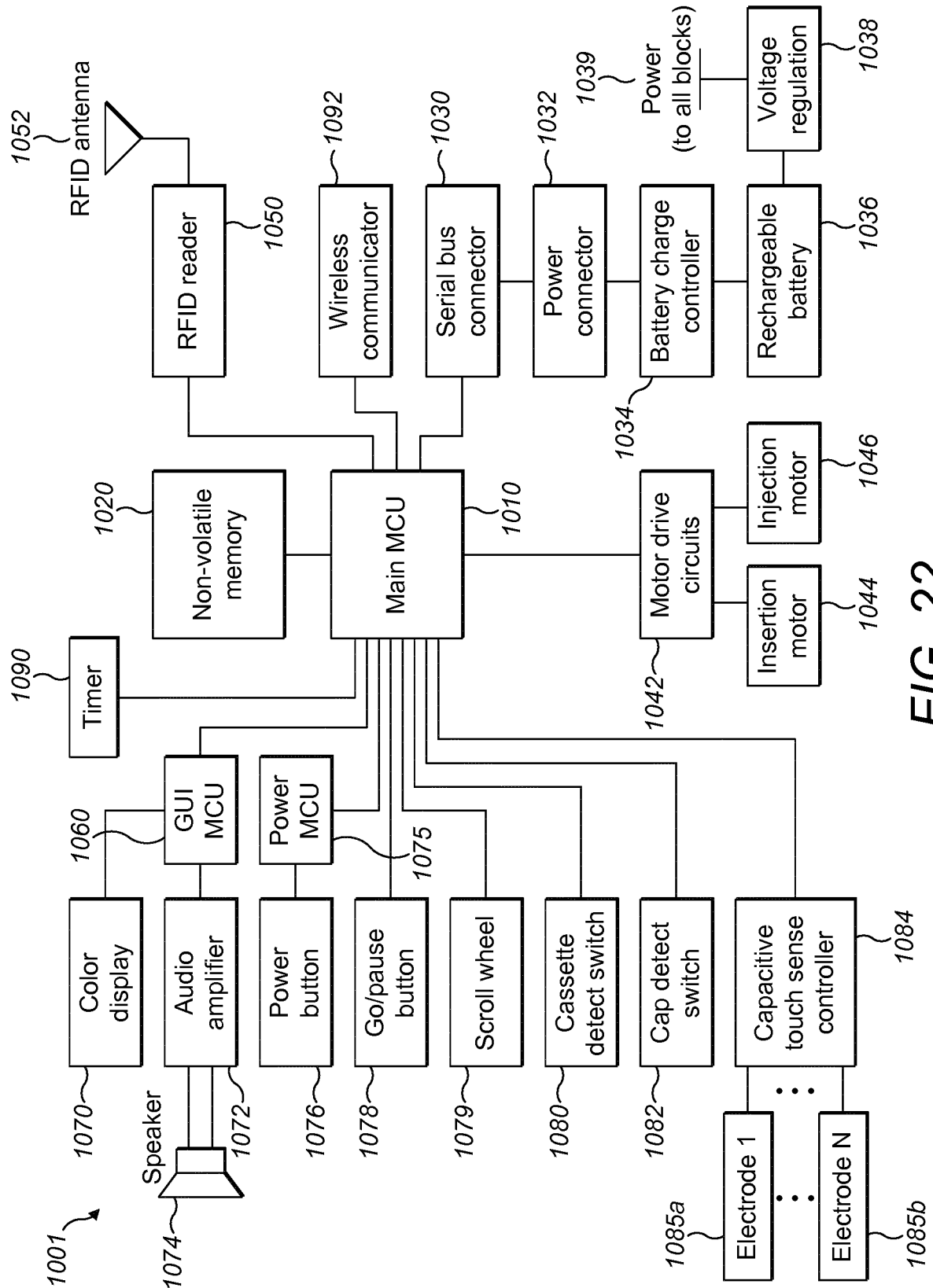


FIG. 22

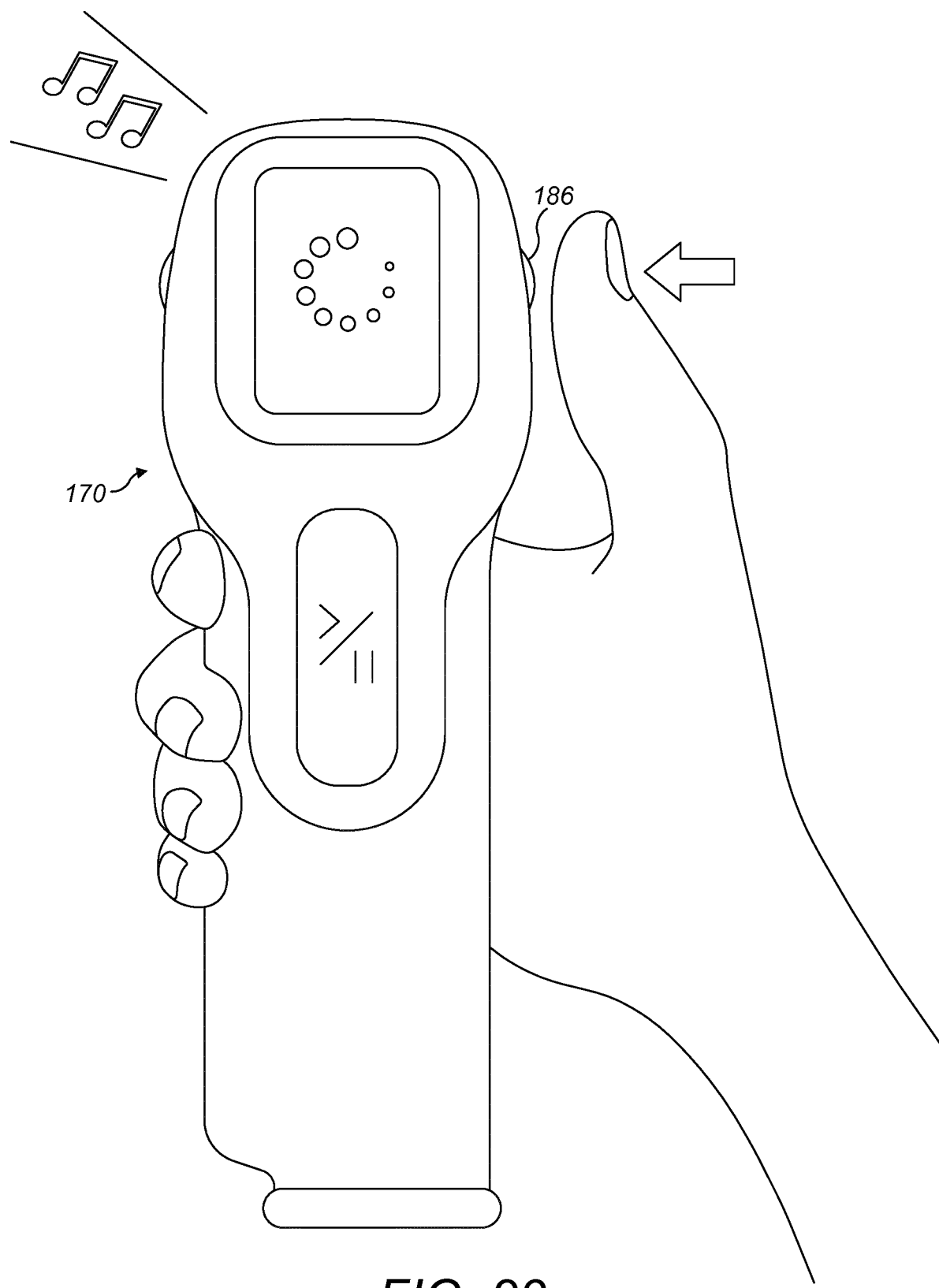


FIG. 23a

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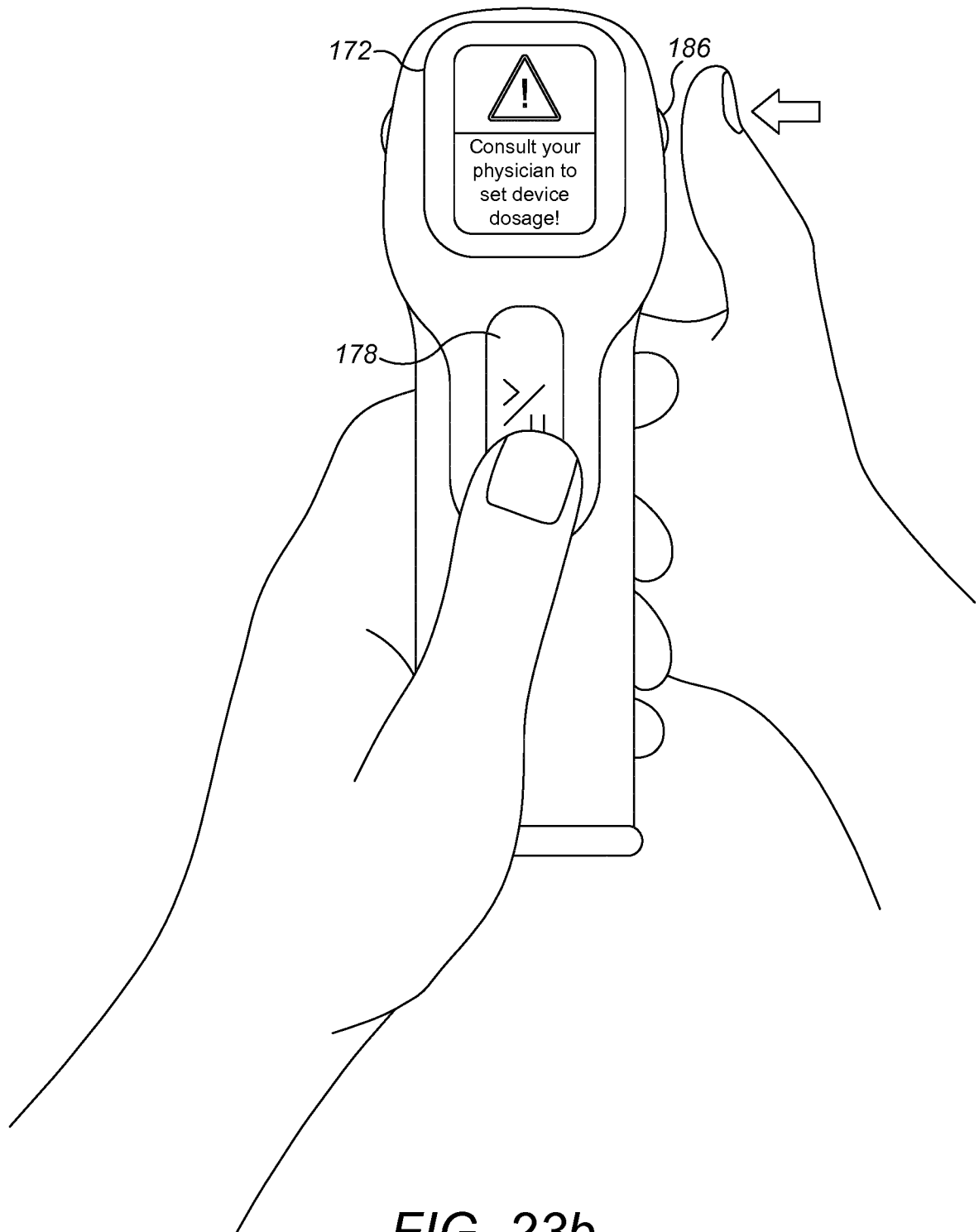


FIG. 23b

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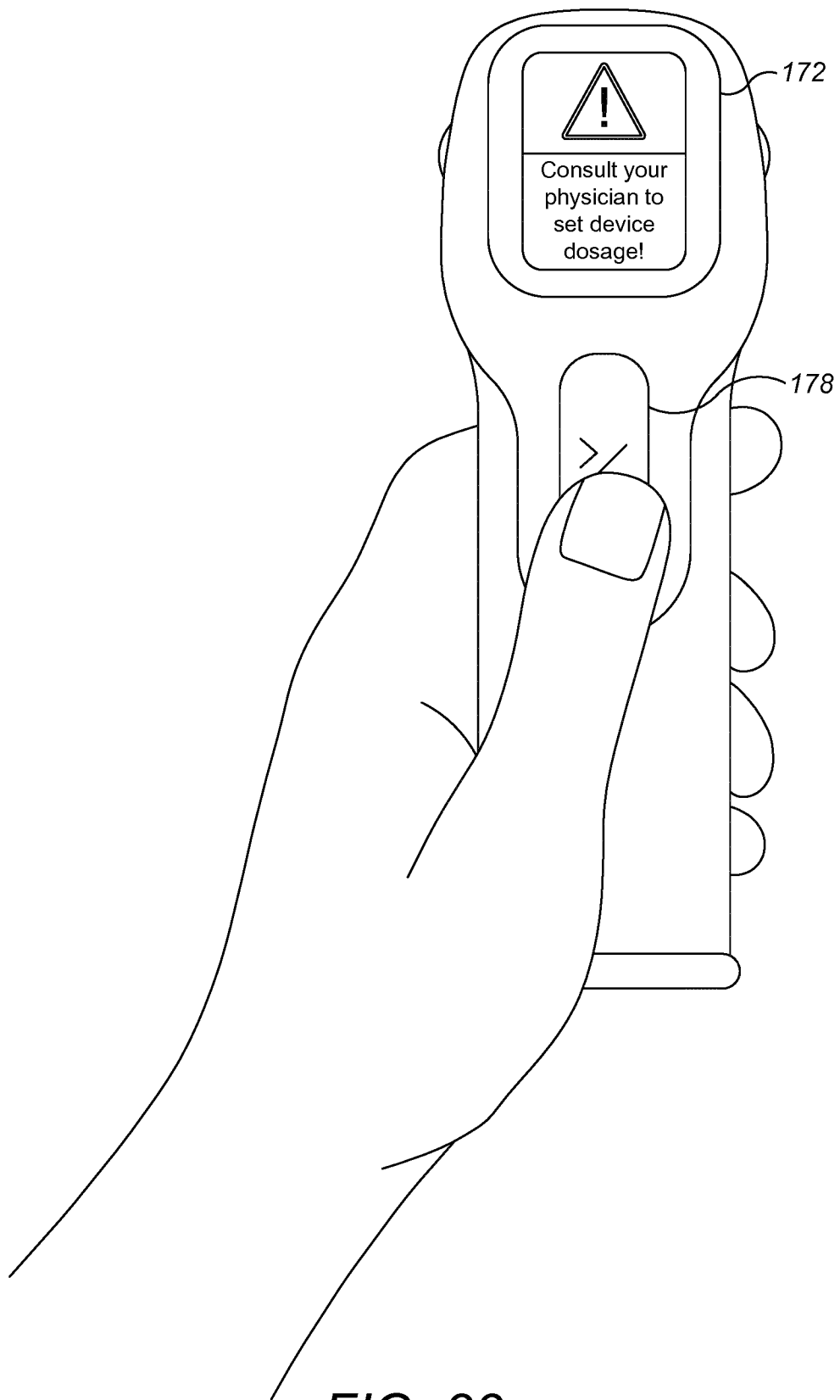


FIG. 23c

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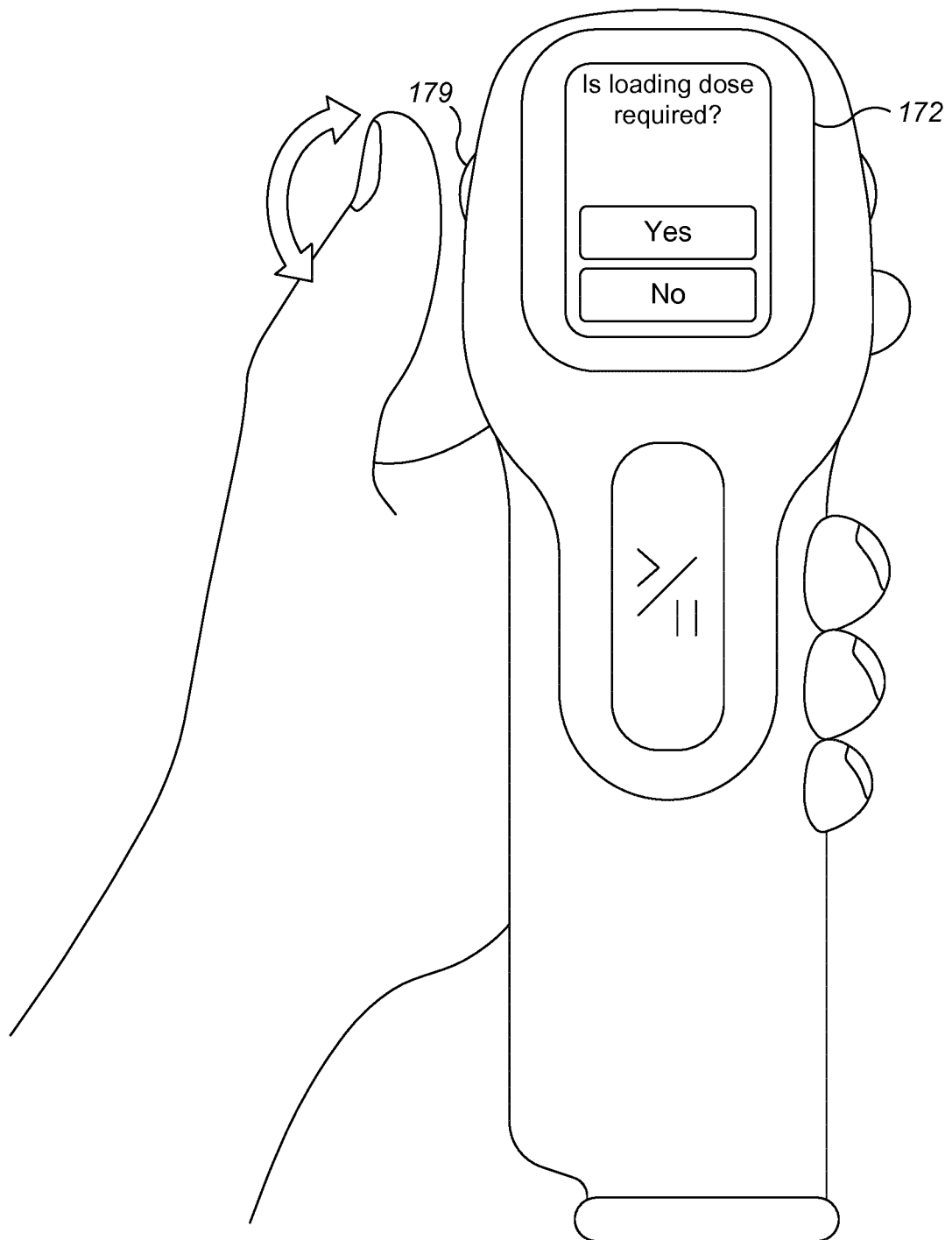


FIG. 23d

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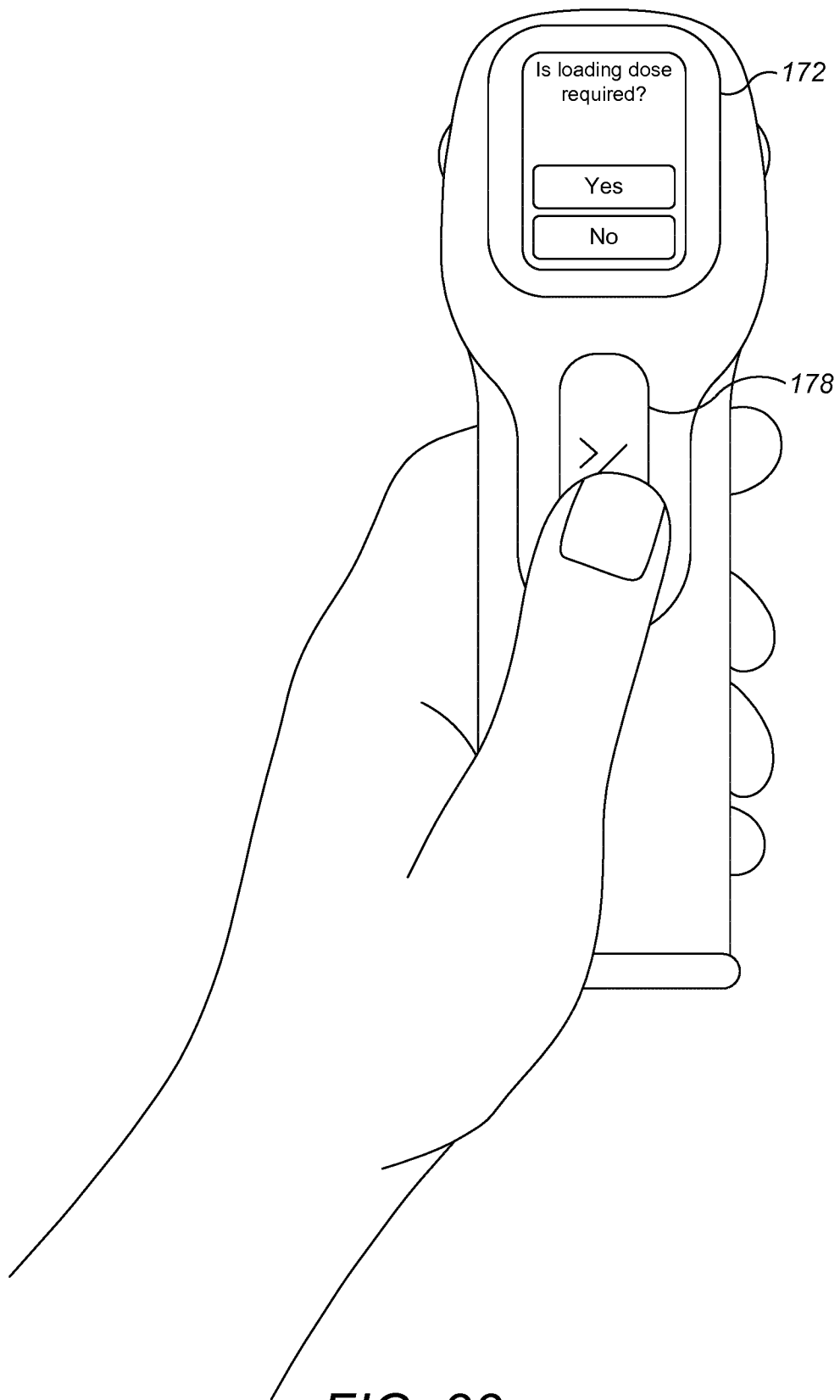


FIG. 23e

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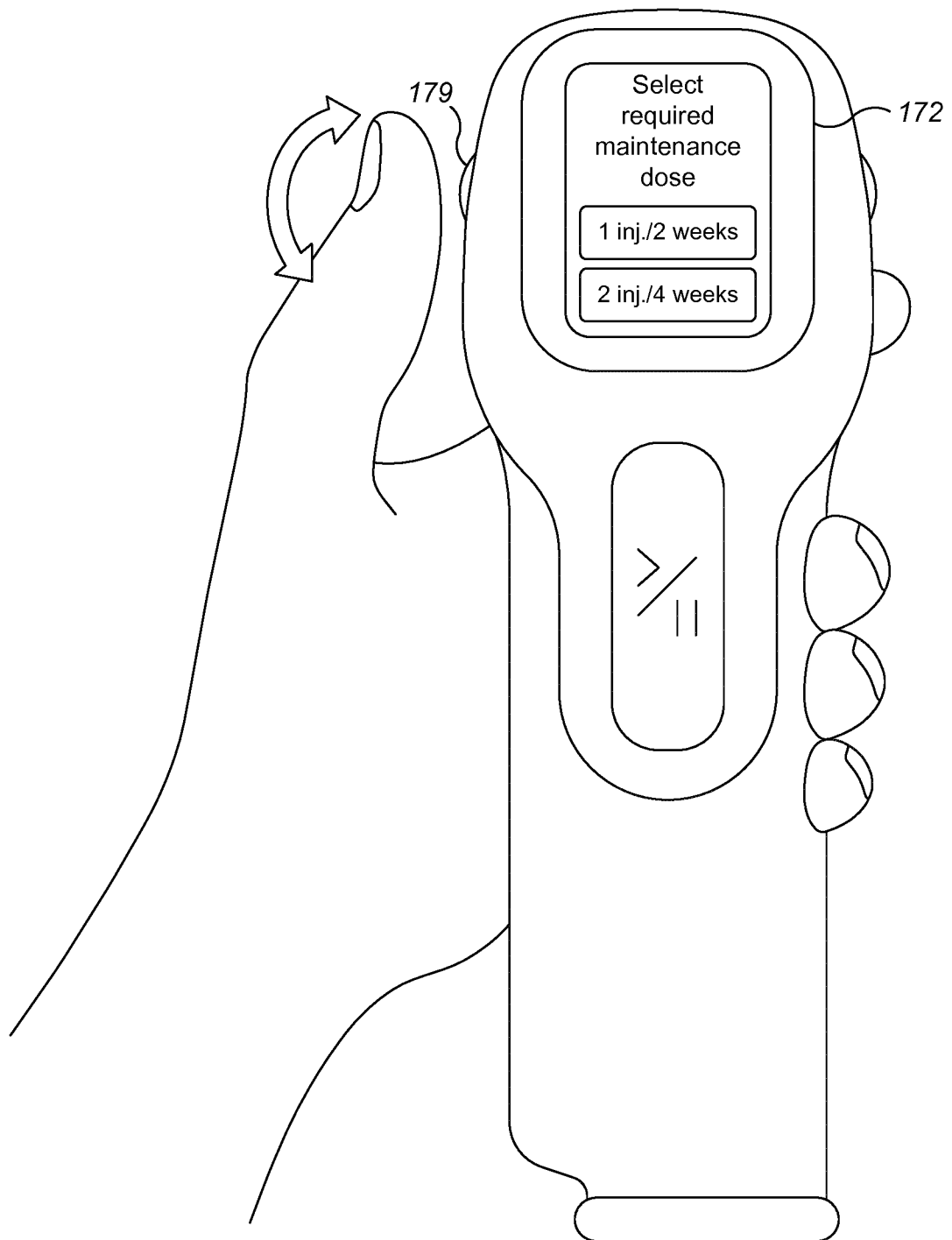


FIG. 23f

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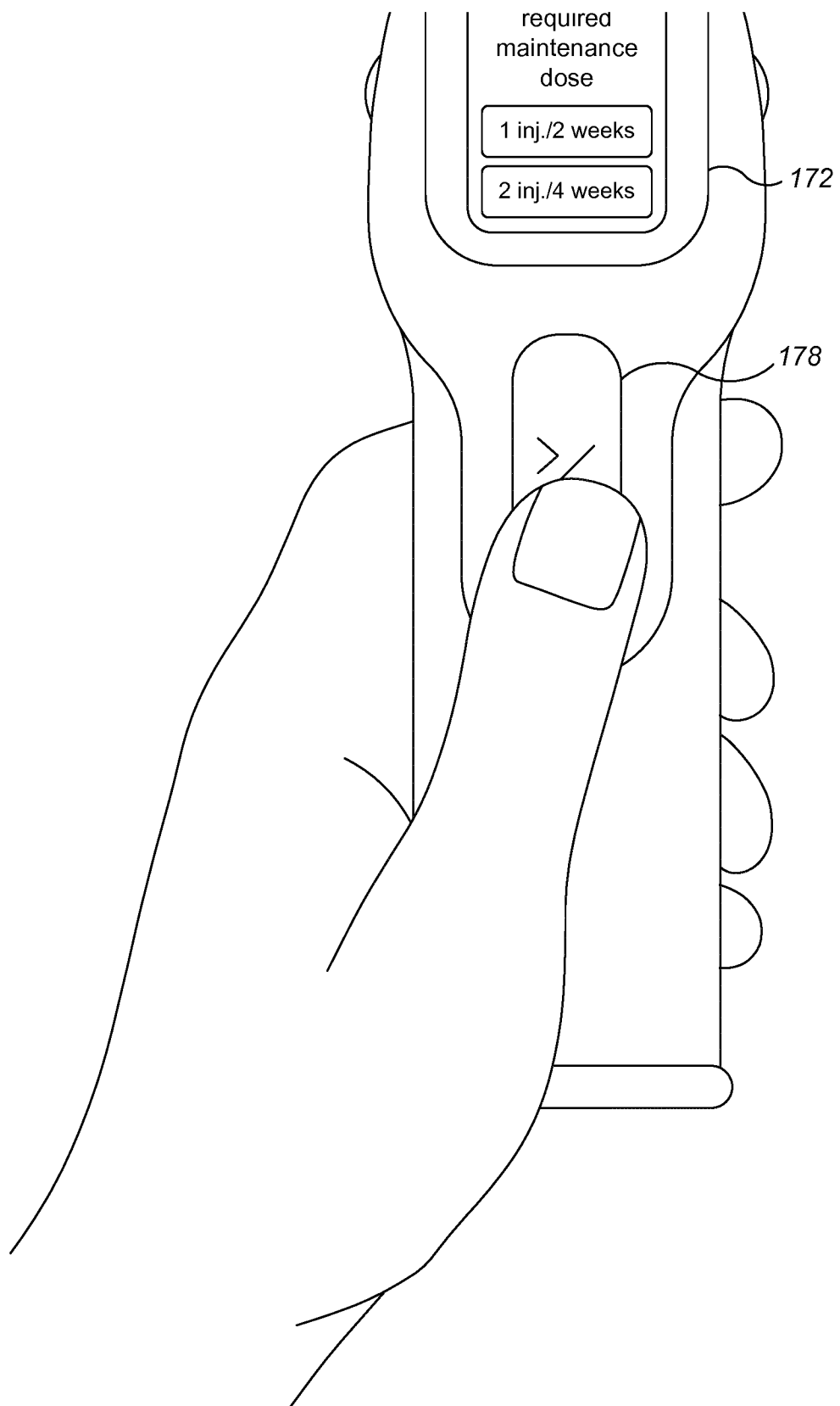


FIG. 23g

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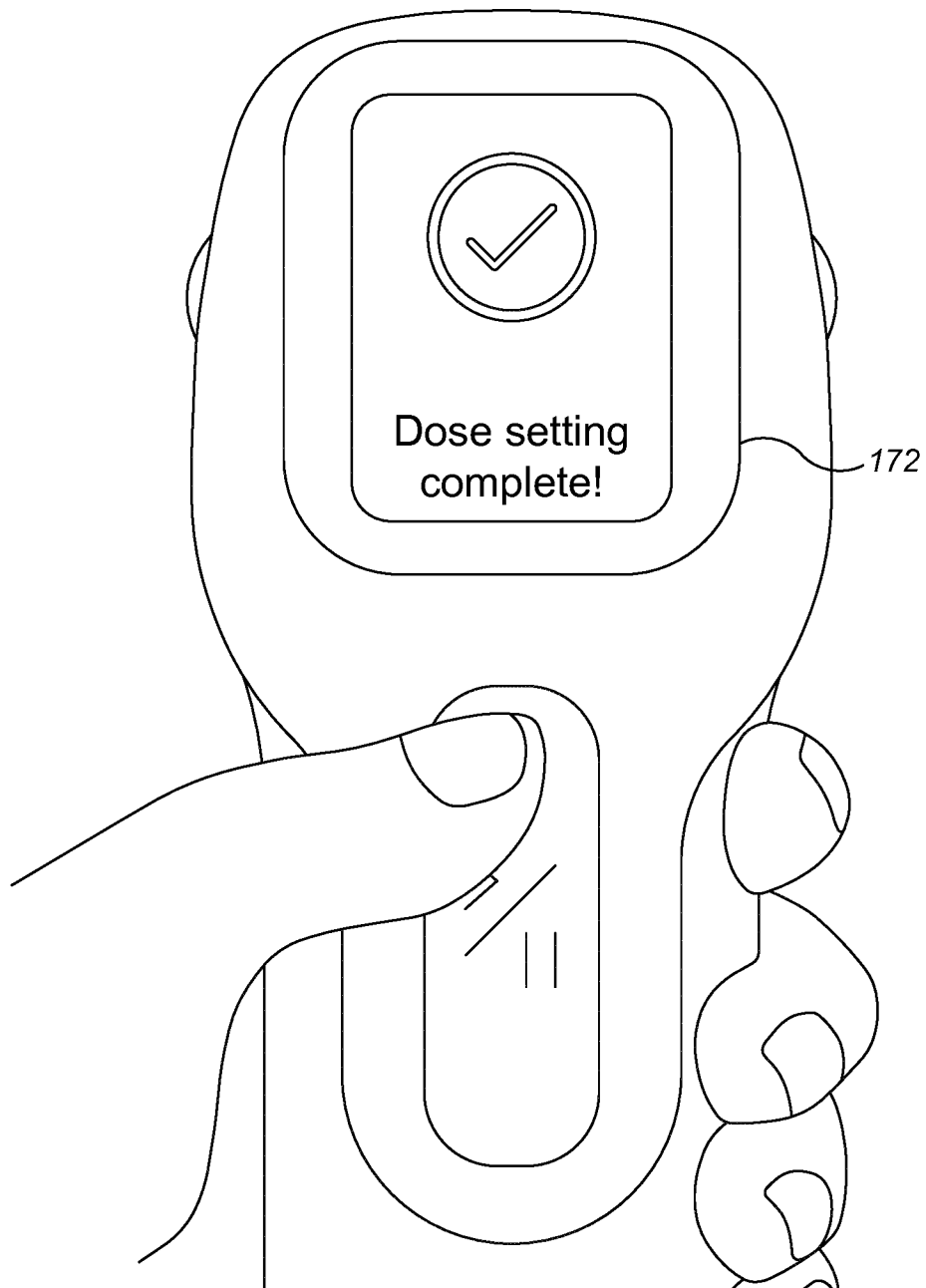


FIG. 23h

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2017/058141

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M5/20 A61M5/24
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	WO 2016/033507 A2 (UNITRACT SYRINGE PTY LTD [AU]; MARLIN ARTHUR [US]) 3 March 2016 (2016-03-03) paragraphs [0072] - [0076], [0116], [0222], [0223]; figures 1,6 -----	1-30
Y	US 2011/313395 A1 (KRULEVITCH PETER [US] ET AL) 22 December 2011 (2011-12-22) paragraph [0053] -----	1-30
Y	WO 2016/033496 A1 (UNITRACT SYRINGE PTY LTD [AU]; MARLIN ARTHUR [US]) 3 March 2016 (2016-03-03) paragraphs [0084], [0143] -----	1
Y	EP 2 756 857 A1 (ALLERGAN INC [US]) 23 July 2014 (2014-07-23) paragraph [0055] -----	1



Further documents are listed in the continuation of Box C.



See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search

30 June 2017

Date of mailing of the international search report

12/07/2017

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Fax: (+31-70) 340-3016

Authorized officer

Daintith, Nichola

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2017/058141

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