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(71) Applicant (for all designated States except US):
TECPHARMA LICENSING AG [CH/CH]; Brunnmatt-
strasse 6, CH-3401 Burgdorf (CH).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **BAUMERT, Jan**
[DE/CH]; Unter Fürten 848, CH-3455 Grünen (CH).
GENTZ, Michael [DE/CH]; Lindenfeldweg 3a, CH-3400
Burgdorf (CH). **GURTNER, Thomas** [CH/CH]; Willadin-
genstrasse 12, CH-3425 Koppigen (CH). **GRUBERT,**
Peter [CH/CH]; Balmweid 26, CH-4525 Balm bei Güns-
berg (CH). **BAMBERG, Klaus** [DE/CH]; Platanenweg 11,
CH-4528 Zuchwil (CH). **SIDLER, Rudolf** [CH/CH];
Ringstrasse 16, CH-4542 Luterbach (CH). **BURI, Thomas**
[CH/CH]; Simon-Gfellerstrasse 2B, CH-3400 Burgdorf
(CH). **MARGGI, Rolf** [CH/CH]; Alpenstrasse 33, CH-
3073 Gümligen (CH). **MATHYS, René** [CH/CH]; Hagen-
holzstrasse 70, CH-8050 Zürich (CH). **RUFER, Michael**
[CH/CH]; Höhenweg 2, CH-4500 Solothurn (CH).
STECK, Jürg [CH/CH]; Tschiffeliweg 15, CH-3422

Kirchberg (CH). **FRAUCHIGER, Vinzenz** [CH/CH];
Hans Roth-Strasse 7B, CH-4500 Solothurn (CH).
MOSER, Ulrich [CH/CH]; Sigristenhaus, CH-3412 Heim-
iswil (CH). **KIRCHHOFFER, Fritz** [CH/CH]; Wassermatt,
CH-3454 Sumiswald (CH). **SEIBOLD, Alexander**
[DE/DE]; Gerhard-Jung-Strasse 12, 79539 Lörrach (DE).
SCHELLER, Benedikt [CH/CH]; Schützenweg 4, CH-
4542 Luterbach (CH). **MICHEL, Peter** [CH/CH]; Kreuz-
graben 6, CH-3400 Burgdorf (CH).

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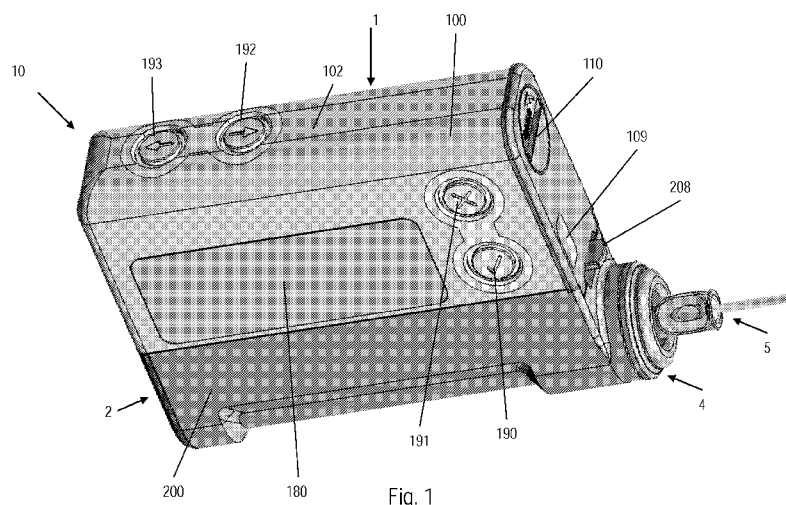


Fig. 1

(57) Abstract: A device (10) for administering a fluid product, in particular a drug in liquid form, with a modular design, compris-
ing a re-usable base unit (1) comprising a drive device (127); an exchangeable cartridge unit (2) comprising a conveying device (6),
wherein the conveying device comprises a piston pump comprising a rotating piston (231); and a transmission device (125) which
can transmit mechanical movement from the drive device onto the conveying device.

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Device for Administering a Fluid Product

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Technical Field

The present invention relates to a device for administering a fluid product, in particular a drug in liquid form. Such a device is referred to in the following as an administering device for short.

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Prior art

In the case of various diseases, it can be necessary to administer a patient over a longer period of time with a drug which is provided in liquid form, for example an insulin preparation or a haemodiluting drug such as heparin. Compact portable infusion apparatus are known for this purpose which are continuously carried around close to the body by the patient. In most cases, a carpoule is provided as the drug container in such infusion apparatus, i.e. a glass container comprising a stopper which can be moved within it. The carpoule (often also referred to as an ampoule) is connected to an infusion set, the cannula of which feeds into the body tissue of the patient. The stopper is advanced in the carpoule by a suitable drive, for example a spring drive or an electric motor, and the drug is thus expelled from the carpoule. As soon as the carpoule is empty, it is removed from the infusion apparatus and replaced with a new carpoule.

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In many portable infusion apparatus, the stopper is advanced in the carpoule via a threaded rod which acts as a piston rod for the stopper. A nut which is mounted such that it is rotatable runs on the threaded rod and is driven by an electric motor. Rotating the nut advances the threaded rod, wherein the electric motor is in general arranged next to the carpoule in order to limit the length of the infusion apparatus and to simplify exchanging the carpoule.

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US 6,248,093 discloses an infusion apparatus in which the drive motor and the gear system are arranged coaxially with the drug reservoir. The stopper of the drug reservoir is advanced by a sleeve-like advancing element which is connected via an inner thread to a drive screw, which is driven by the motor, and thus linearly advanced. In its initial position, the advancing element at least partially surrounds the gear system of the motor, wherein the advancing

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element is a part of the base unit, while the stopper is part of the exchangeable drug reservoir. The advancing element and the stopper are therefore configured such that they can be separated from each other. In order to ensure that the drug is not unintentionally expelled by fluctuations in the ambient pressure, the advancing element and the stopper are connected
5 such that the connection can also absorb tensile forces while the infusion apparatus is in operation. In this way, the stopper necessarily follows the movement of the advancing element and cannot be advanced, by pressure fluctuations or differences, further than is predetermined by the position of the advancing element. When the drug reservoir is exchanged, the stopper and the advancing element are separated from each other by a
10 rotational movement. The advancing element is then moved back into its initial position by the motor. On the one hand, this arrangement requires a relatively complicated connection between the stopper and the advancing element; on the other, the advancing element necessarily has to be moved back after administering is finished. Particular steps also have to be taken in case a drug reservoir which is not completely filled is used.

15 Systems are also known from the prior art which omit a threaded rod as the advancing element. WO 05/039674, for example, discloses an infusion apparatus in which the drive motor and a pump element are arranged coaxially with the drug reservoir, wherein the pump element is arranged between the drug reservoir and the infusion set in the drug path. The
20 pump element suctions the drug from the reservoir and conveys it into the infusion set, wherein the pump element is formed as a valveless piston/cylinder element comprising a rotating piston. The piston comprises axially orientated grooves which are etched in the region of the cylinder inlet and in the region of the outlet and connect the inlet or outlet, respectively, to the pump chamber in particular rotational positions, wherein the grooves are
25 arranged such that the inlet and the outlet are at no time directly connected to each other. It is thus possible to effectively prevent the drug from flowing out undesirably, for example due to fluctuations in the ambient pressure. The rotating piston also has the advantage that the pump element can be configured with no actual valves. When using carpoules as the drug reservoir, this arrangement requires exact knowledge and limiting of the frictional forces which arise
30 during the movement of the stopper in the carpoule, and of the air which is situated between the pump piston and the carpoule stopper in the drug path. Since the pump system exhibits a limited capacity, gas – which is either present as a bubble or is dissolved and can escape under a partial vacuum – can act on its inherent elasticity as a gas spring and completely prevent the transport of liquid if the friction on the stopper is high. In addition, if a pump

element is arranged directly in the drug path, care must be taken that the drug is not altered – i.e. in the case of insulin, for example, denatured – by either the material or the pump process.

WO 2008/106806 discloses a modular infusion apparatus which comprises: a re-usable base unit comprising a drive means; and an exchangeable cartridge which can be releasably connected to the base unit and comprises a product container for the fluid product, i.e. the device is modularly designed. A rotational movement can be transmitted between the base unit and the cartridge. To this end, the base unit comprises a slaving means which can be rotationally set in motion about a rotational axis by the drive means. The cartridge comprises a complementary rotatable transmission element which is formed such that rotating the transmission element causes the fluid product to be expelled from the product container. The slaving means and the transmission element can be releasably connected to each other in order to transmit the rotational movement. In order to simplify the connection between the cartridge and the base unit, the slaving means and the transmission element are configured such that they can be shifted relative to each other along the rotational axis. The slaving means and the transmission element can thus be connected to each other by sliding them into each other. The slaving means of the base unit thus only transmits a rotational movement and not a translational movement. It is thus not necessary to reset the slaving means when changing the cartridge unit. The transmission element is guided in the cartridge along the rotational axis by means of a self-locking threaded connection and converts the transmitted rotation into a helical movement. The axial advance of the transmission element acts on the stopper of the hydraulics provided in the system. The movement is thus indirectly transmitted onto the drug reservoir. The hydraulics of the system consist of: the stopper which can be shifted and is fixedly connected to the transmission element; a hydraulic reservoir which is attached to the stopper; a hydraulic connection; and a shift reservoir which is partially formed by the drug stopper of the drug reservoir. The volume of the hydraulic reservoir can be reduced by shifting the stopper; hydraulic fluid is expelled from the hydraulic reservoir and transferred through the hydraulic fluid connection into the shift reservoir. The increase in the hydraulic fluid volume in the shift reservoir causes the drug stopper to be shifted and the drug to thus be conveyed out of the drug reservoir. The hydraulic fluid – water or oil – directly abuts the drug stopper, which together with the described self-locking threaded connection of the transmission element prevents any undesirable flow of the drug due to fluctuations in the ambient pressure and enables standard drug reservoirs such as carpoules to be used without any problems. The described arrangement of the hydraulic drive requires the residual gas

present in the hydraulic system to be minimised, since this can influence the elasticity in the drive and the dosing accuracy.

5 **Description of the Invention**

It is an object of the present invention to specify an improved administering apparatus which comprises a hydraulic drive and modularly consists of a base unit and a cartridge unit, wherein the administering apparatus exhibits a dosing accuracy which is stable in the long term.

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It is another object of the present invention to specify an improved administering apparatus which modularly consists of a base unit and a cartridge unit and has a reliable cartridge module and drive monitor.

15 It is another object of the present invention to specify an improved administering apparatus which comprises a reciprocating rotary piston pump and modularly consists of a base unit and a cartridge unit and which comprises a simplified mechanical drive interface between the base unit and the cartridge unit.

20 The objects are solved by devices for administering a fluid product, such as are specified in the independent claims. Preferred embodiments are specified in the dependent claims.

General description

Such a device comprises: a re-usable base unit comprising a drive means; and an
25 exchangeable cartridge unit which is releasably connected to the base unit and comprises a product container for the fluid product, i.e. the device is modularly designed.

A rotational movement can be transmitted between the base unit and the cartridge unit. To this end, the base unit comprises a slaving means which can be rotationally set in motion
30 about a rotational axis by the drive means. To this end, the cartridge unit comprises a complementary rotatable transmission element which transmits the rotational movement to a conveying pump. The conveying pump translates the rotational movement into a conveying movement, wherein the conveying movement causes fluid product to be expelled from the product container. The slaving means and the transmission element are releasably connected

to each other in order to transmit the rotational movement, wherein the base unit and the cartridge unit can be connected in a very simple way, since a torque is to be transmitted but tensile or pressure forces are not. Thus, when changing the cartridge unit, the cartridge unit can simply be removed from the base unit and a new cartridge unit can be inserted, without
5 having to reset the drive unit in the base unit.

In order to keep the connection between the cartridge unit and the base unit simple, the slaving means and the transmission element are configured such that they can be shifted relative to each other along the rotational axis. In this way, the slaving means and the
10 transmission element can be engaged with each other by sliding them into each other. This type of connection as a coupling allows a relative axial movement of the transmission element while the administering device is in operation. The slaving means and the transmission element are interlocked with each other in a plane perpendicular to the rotational axis. In more general terms, regions of the slaving means and transmission element preferably encompass
15 each other in such a plane, i.e. regions of the slaving means and transmission element alternate with each other along a suitable circle in the circumferential direction.

The drive device contained in the base unit preferably comprises an electric motor and a gear system which is connected to the electric motor and transmits the drive movement of the
20 motor into a rotational movement of the slaving means, wherein the motor, the gear system and the slaving means are preferably arranged coaxially and successively, and the slaving means is arranged in the base unit such that it breaches a housing which surrounds the base unit, in order to be able to be engaged with the transmission element. In the assembled state, the cartridge unit completely surrounds the slaving means protruding out of the housing of the
25 base unit.

The base unit can contain other components in addition to the drive device, in particular one or more energy sources, control electronics, sensor technology for identifying the cartridge unit and operational states and also operating elements and display elements.

30 The base unit and the cartridge unit are formed such that they can be slid into each other along a direction which runs parallel to the rotational axis of the slaving means. To this end, guiding elements are provided on both units. An accommodating region is in particular provided on the base unit and is embodied to be planar and runs parallel to the rotational axis of the

slaving means. An area which is complementary to the accommodating region is formed on the cartridge unit and lies on the accommodating region when the base unit and the cartridge unit are slid together. In addition, various guiding grooves and springs are also arranged on the cartridge unit and the base unit and run parallel to the accommodating region and guide the base unit and the cartridge unit as they are slid together, such that incorrect manipulations can be avoided and even visually impaired persons can correctly slide the units together without any problems.

In the assembled state, the base unit and the cartridge unit are fastened to each other via a latch. The latch is intended to prevent the cartridge from unintentionally detaching from the base unit. The latch is advantageously secured via a latching mechanism, preferably a snapping mechanism. During latching and unlatching, the latching mechanism moves in a direction which is perpendicular to the rotational direction of the slaving means. The latching mechanism thus acts parallel to the rotational direction of the slaving means and thus also parallel to the sliding-together direction. In one advantageous embodiment, the latching mechanism consists of a moving tongue which runs parallel to the sliding-together direction. The tongue is fastened to the cartridge unit at one end and arranged on an outer wall of the cartridge unit which comes into contact with a wall of the base unit when the base unit and the cartridge unit are slid together. At its free end, the tongue can be moved perpendicular to the sliding-together direction, like a bending beam which is clamped at one end. A tooth is arranged on the tongue, perpendicular to the longitudinal direction.

Complementary to the tooth, the base unit comprises a recess in a housing wall, with which the tooth engages as soon as the base unit and the cartridge unit have been slid together. The tooth comprises two flanks. The first flank exhibits a pitch angle of less than 90° relative to the tongue, while the second flank is approximately perpendicular to the tongue. When the base unit and the cartridge unit are slid together, the tooth slides along an outer wall of the base unit, wherein the tongue is deflected perpendicular to the sliding-together direction, wherein the tooth slides, with its first flank to the fore, over the housing wall. If the tooth reaches the complementary recess, then it snaps into the recess by the tongue moving out of its deflection back into its resting position. If an attempt is then made to pull the base unit and the cartridge unit apart, the steep second flank of the tooth prevents this movement, since it engages with a complementarily aligned flank of the recess and so prevents the retracting movement. When the base unit and the cartridge unit are assembled, the free end of the

tongue protrudes beyond the housing of the cartridge unit and the base unit. In order to release the latch, the tongue can thus be manually deflected such that the tooth arranged on the tongue is no longer in engagement with the recess on the housing wall of the base unit. As soon as the engagement has been released, the base unit and the cartridge unit can be shifted
5 relative to each other and separated. This solution is advantageous, since the moving part of the latch is arranged on the cartridge unit and not on the base unit as in the prior art in for example WO 2008/106806. The tongue and the tooth are parts which fatigue and wear, such that it can be necessary to regularly exchange them. Since the cartridge unit is only used for a limited length of time anyway, exchanging these parts becomes obsolete, and the risk of a
10 malfunction while the administering device is being used is thus minimised.

The base unit advantageously comprises a drive device which transmits a rotational movement onto the transmission element, wherein the drive device comprises an electric motor. In one advantageous embodiment, the electric motor is a direct-current (DC) motor. In
15 other advantageous embodiments, the electric motor can be embodied as a step motor, a brushless direct-current motor, an alternating-current motor or a piezo-actuated motor, wherein the electric motor comprises a centrally arranged drive shaft which is rotationally set in motion by the motor. A so-called encoder is arranged on this shaft. The encoder enables the control electronics, such as may be provided, to monitor the motor movement. In one
20 advantageous embodiment, the encoder comprises a wheel which is fixedly connected to the drive shaft, i.e. which rotates along with the drive shaft, wherein the wheel is formed as a planar disc and comprises various drilled holes or windows in the disc. In this embodiment, the encoder comprises at least one optical light barrier which can be interrupted by the disc or, respectively, is closed when the light is channelled through one of the windows. If the disc
25 then rotates with the drive shaft, the light barrier is alternately opened and closed. If the disc is stationary, then the light barrier is either open or closed. On the basis of the changing cycles and their speed, the controller electronics can deduce whether the disc and therefore also the drive shaft is moving, and also how fast and in which direction the disc is moving. The optical encoder described here represents one possible embodiment. Alternatively, the encoder can
30 also function via magnetic fields, wherein one or more magnets can be arranged on the drive shaft. The rotation of the drive shaft can then be detected via Hall sensors, electromagnetic coils or Reed contacts. In another advantageous embodiment, the encoder can be mechanically and/or electromechanically embodied, wherein an element which is arranged on the drive shaft periodically shorts electrical conduits as the drive shafts are rotated.

In one embodiment, the drive device of the administering apparatus in accordance with the invention comprises a gear system which can be connected to the drive shaft and gears up or gears down the rotation of the drive shaft, wherein a combination of a DC motor and a gearing-down gear system proves advantageous. This enables a relatively weak and therefore economically priced electric motor to be used, since the transmitted torque follows from the gearing ratio and the effectiveness of the gear system. Thus, if a gearing-down gear system which has a gearing-down ratio of 300:1 and an effectiveness of 50% is used, the torque of the drive shaft can be roughly increased by a factor of 150, i.e. if the cartridge unit requires a torque of 20 mNm at the transmission element of the cartridge unit in order to administer the drug, then a moment of only about 0.13 mNm is applied at the motor. Consequently, a motor such as is advantageously used only then requires about 40 mA of current. In the embodiment described, the gear system output is provided with a shaft which relays the rotational movement to the slaving means.

The slaving means is likewise encompassed by the drive device. The slaving means in turn transmits the rotation onto the transmission element of the cartridge unit. The connection between the two elements is configured to be releasable, as has been described. The slaving means can thus be shifted relative to the transmission element along the rotational axis, in order to establish or release the engagement. In one advantageous configuration, the transmission element and the slaving means interlock via a toothing, wherein the teeth are directed radially with respect to the rotational axis. The connection can thus be referred to as a radially positive-fit connection. In an alternative embodiment, the connection between the transmission element and the slaving means can also be configured as a force-fit connection. The slaving means can in particular be conically tapered along the rotational axis. The transmission element can comprise a complementary negative mould. If, in this embodiment, the slaving means is slid into the negative mould of the transmission element, the surface area of the slaving means at least partially comes into planar contact with the negative mould, wherein the rotation is transmitted via the static frictional force between the slaving means and the transmission element, wherein a movement compensator for a possible axially oscillating conveying movement can be provided on the slaving means if for example a piston pump is used as the conveying pump. This can for example be achieved via an axial spring bearing of the slaving means or transmission element. In other advantageous configurations, the force-fit connection between the transmission element and the slaving means can also be

established via magnetic or electrostatic forces. Either the transmission element or the slaving means can then comprise a permanent magnet or electromagnet, and the counterpart to the slaving means or transmission element can comprise a ferromagnetic material such as a ferritic stainless steel. In this configuration, too, the slaving means can be fitted with a movement compensator.

The base unit advantageously also comprises an electronic control unit. Said control unit controls and monitors the administering apparatus. In addition, the control unit also advantageously comprises user interfaces such as a display, keys or service interfaces. In one advantageous configuration, the control unit comprises at least two micro-controllers. This enables security-related functions of the administering apparatus to be redundantly designed. In one advantageous embodiment, the two micro-controllers also monitor each other reciprocally. The micro-controllers of an administering apparatus in accordance with the invention are for example micro-controllers from the PIC24 family manufactured by Microchip. These are 16-bit micro-controllers comprising a volatile and non-volatile memory. Likewise, the protocols and interfaces such as RS-232 or IrDA are also integrated in this family. Check digit generators are also integrated. Alternatively, the electronic control unit can be formed by one or more micro-processors in combination external control circuits, such as customised ASICs.

In another advantageous embodiment, the redundant design of the electronic controller can be complete. This means that all the applications can be run on both micro-controllers, each micro-controller comprises all the interfaces provided, and the micro-controllers can monitor each other reciprocally.

In one embodiment in accordance with the invention, the two micro-controllers of the control unit contain a series of software applications. These applications serve to specifically control and monitor the functions of the administering apparatus. In one advantageous embodiment, these applications are contained in the micro-controllers in such a way that they can be altered, exchanged or deleted from via interfaces. In one advantageous configuration, it is thus possible to add functions to the base unit, which for example secure an administering apparatus, during the service life of the administering apparatus. Moreover, the applications may be patient-specific. The micro-controllers advantageously contain a time application or a

clock, wherein in one advantageous embodiment, the time application or clock can evaluate a clock pulse which is generated by a quartz crystal component.

The applications in accordance with the invention comprise applications which control and monitor the administering of the drug. This in particular means controlling and monitoring the drive device. The electronic controller contains a memory in which the parameters which are necessary in order to administer particular amounts of the drug are stored. The controller can read these parameters and, on the basis of them, activate the drive device via a drive regulator, wherein in one advantageous configuration, a drive monitor of the controller monitors the current and the movement of the drive device. The current is measured by measuring the drop in voltage at an ohmic resistor or using inductive measurement means, wherein the drive monitor receives the movement alert from the encoder assembly described. On the basis of the encoder signal, the drive monitor ascertains for example the direction and speed of the drive. The drive regulator uses the ascertained value of the speed in order to supply the drive with more or less energy as required, wherein in one advantageous embodiment, so-called pulse width modulation is used as a method for supplying energy which also allows for ramping of the drive speed.

In another advantageous embodiment, the signals evaluated by the drive monitor are used to detect problems in delivery, in particular occlusions, wherein "occlusion" is understood to mean an obstruction of the flow of the drug, wherein the obstruction is localised between the output of the injection needle and the output of the conveying pump and causes an increase in pressure in the drive region of the cartridge unit. In one advantageous configuration, the occlusion can be identified by the electronic controller by detecting an increase in the required amount of energy which has to be employed in order to achieve a particular movement in the drive unit, wherein advantageously only the electrical output, i.e. the product of the voltage, current and time, has to be monitored. This way of identifying occlusions is sufficiently known to the person skilled in the art, and reference is therefore made to US 2007/0191770, including all the members of its family which draw priority from US provisional application No. 60/106,237, and to WO 2011/044706, all of which are hereby incorporated in their entirety into the present document by reference. In an alternative configuration, an occlusion can also be detected via the encoder signal. This is advantageously employed when the drive monitor cannot detect any movement at the encoder despite the drive unit being activated by the drive regulator.

In one advantageous embodiment, the electronic controller contains another application for detecting occlusions. To this end, the controller evaluates pressure measurements. A device is provided in the cartridge unit which can experience a mechanical deformation which is dependent on a liquid pressure in the cartridge unit and can transmit the change in pressure to the base unit, preferably mechanically, via said deformation. Accordingly, a pressure absorbing device is complementarily provided in the base unit and comprises for example at least one strain gauge which converts the mechanically transmitted pressure signal into a measurement signal. This measurement signal can be recorded and evaluated by the control unit, specifically by the occlusion identifying application. The mechanical deformation can also be measured optically, magnetically or inductively. In advantageous configurations, the pressure measurement signal is either compared to absolute reference values, or the change in pressure over a period of time is determined and compared to reference increases, in order for an occlusion to be identified. The method for identifying occlusions described here is in particular described in US 4,950,244, FR 2 684 556 and WO 2011/009224. All three documents are hereby incorporated in their entirety into the present document by reference. Additionally, similar ways of detection occlusion have been used in commercially available infusion systems, such as Disetronic Multifuse or Disetronic Dahedi.

In another advantageous configuration, the electronic controller of the base unit contains an energy supply controller and a feed monitor. In one advantageous embodiment, the base unit comprises a fail-safe power supply which is monitored and controlled by the energy supply controller application. The fail-safe power supply such as can be used in embodiments in accordance with the invention is described in WO 2011/022850, for which reason WO 2011/022850 is hereby incorporated in its entirety into the present document by reference. The fail-safe power supply comprises at least a primary energy source, in particular a battery or a cell, and a secondary energy source, in particular a power pack which can for example be a lithium-polymer power pack. The primary energy source can for example be an AAA alkali-manganese cell. Other batteries, such as zinc-carbon or zinc-air or also lithium batteries, can however also be used. The design shape is also varied in alternative configurations. It is thus also possible to provide an AA battery or cell. Moreover, the primary energy source may alternatively be constituted by a rechargeable battery. In one advantageous embodiment, the base unit can be predominantly supplied with power by the secondary energy source, wherein the secondary energy source is charged by the primary energy source. In this embodiment, the

primary energy source can assume the function of supplying power if required and guarantee the uninterrupted functioning of the administering apparatus.

For operating and programming purposes, the electronic controller can comprise interface applications which control physical interfaces. In advantageous embodiments, the base unit comprises keys and a display which enable the user or other competent operators to retrieve information from the administering apparatus and to input data and commands. In one advantageous configuration, the display is for example embodied as a liquid crystal display and the keys are for example embodied as simple push buttons or also as membrane keys. In order to read or write larger amounts of data, an interface can be provided on the base unit which can connect the electronic controller to an external computer, in particular an infrared interface, a Bluetooth interface, a network interface, for example a wireless network interface, a serial interface or a USB interface. The memories of the micro-controllers can for example be read or written on via said interface between the administering apparatus and the computer, or applications can be altered, deleted or added. In one advantageous embodiment, the data communication between the electronic controller and the external computer is encrypted.

In advantageous configurations, the base unit also comprises a buzzer or loudspeaker via which alarm tones or confirmation tones can be outputted, wherein buzzers or loudspeakers are connected to the electronic controller and activated by corresponding applications of the controller. In advantageous configurations, the base unit also comprises a vibration alarm which in particular vibrates the housing parts of the administering apparatus for the purpose of alerting the user or for the purpose of outputting confirmation pulses. Buzzers, loudspeakers and/or a vibration alarm can also be used to output information, in order to simplify imparting information to visually impaired or hearing-impaired patients, respectively. Thus, the level of the dosage or the period of time until the final individual dosage is dispensed can for example be outputted. For example, the loudspeaker may be used for synthesised voice output of information.

In advantageous configurations, the base unit comprises a device for identifying the cartridge unit, wherein the cartridge unit identifying device can detect whether a cartridge unit is correctly connected to the base unit. In one advantageous configuration of the embodiment, the cartridge unit is identified on the basis of optical methods. A transmitter, in particular a light-emitting diode, can for example emit light through a window arranged on the housing of

the base unit, towards the cartridge module. If a cartridge unit is correctly installed, then a reflector or light conductor arranged on the cartridge unit can channel the light back towards the base module, wherein the light channelled back is measured by a receiver. Alternatively, the transmitter can be configured as an acoustic transmitter and the receiver can be configured
5 as an acoustic receiver, wherein acoustic waves in the ultrasound range can in particular be used. In other alternatives, magnetic electro-static or inductive fields can assume the transmitter function, and deflecting or reflecting devices which are suitable for the fields can be provided on the cartridge unit, wherein the receiver can then be embodied as a sensor which can detect changes in or disruptions to the fields, wherein the transmitter and the
10 receiver are monitored in all the described configurations by the electronic controller, such that the measurement values can be evaluated in the micro-controllers. It is then in particular possible to output a warning alert via the display or one of the other interfaces mentioned when the base unit and the cartridge unit are not assembled properly.

15 In advantageous configurations of the invention, the base unit comprises a device for monitoring the conveying pump conveying movements. This device allows pump movements of the conveying pump in the cartridge unit to be detected. This can be important to the extent that the drive monitor, as described further above, monitors the drive activity within the base module. The functioning of the administering apparatus can be monitored across the different
20 modules by the conveying pump conveying movement monitoring device. The conveying pump conveying movement monitoring device functions using optical methods. A transmitter, in particular a light-emitting diode, can for example emit light through a window or a part transparent for the used light arranged on the housing of the base unit, towards the cartridge unit. If a cartridge unit is correctly installed, then a reflector or light conductor arranged on
25 the cartridge unit can channel the light back towards the base module, wherein the light channelled back is measured by a receiver. The light conductor in the cartridge unit which is responsible for monitoring the conveying pump conveying movement comprises a cavity through which the light from the light conductor is channelled. If an object which is impermeable to light is moved into said cavity, the light path in the light conductor can thus
30 be interrupted. Consequently, this interruption can also be measured in the receiver. An element is arranged on the conveying pump which indicates a conveying movement by moving when the conveying pump mechanism of the conveying pump is moved. In one preferred embodiment, the conveying pump is formed as a piston pump comprising a rotating piston, and in particular as a reciprocating rotary piston pump. In one embodiment, an

element – in particular, a coding ring – can be arranged on the piston and projects radially from the piston skirt and partially encircles the piston skirt. “Partially” can mean that the element encircles the piston skirt as a coding ring but comprises at least one interruption in its annular structure, wherein the coding ring is arranged in the cartridge unit such that it runs in the cavity of the light conductor. Rotating the piston also rotates the coding ring arranged on it, such that the coding ring interrupts the light path. Since the coding ring comprises at least one interruption, the light path is temporarily unobstructed, dependent on the rotational position, and light can pass through the entire light conductor and be fed to the receiver, wherein the transmitter and the receiver are monitored by the electronic controller, such that the measurement values can be evaluated in the micro-controllers. It is then in particular possible to output a warning alert via the display or one of the other interfaces mentioned when the light path is interrupted or, respectively, unobstructed for a sustained period and the drive is simultaneously active, since this could indicate a malfunction of the administering apparatus. It is in particular also possible to use acoustic waves or, respectively, magnetic electro-static or inductive fields in place of light, in combination with corresponding conductors, deflecting devices or reflectors, as described further above in the case of identifying cartridge units. By analogy with the described embodiment in which light is used to monitor the conveying pump conveying movement, the coding ring which has likewise been described can also be used to influence magnetic or inductive fields, wherein the receiver measures a field change which arises when a conveying movement occurs. Alternatively, the conveying movement can also influence the deflecting or reflecting devices, such that the signal measured at the receiver is influenced by a change in the deflecting or reflecting behaviour.

In one advantageous configuration of the cartridge unit identifying device and the conveying pump conveying movement monitoring device, the two devices are combined in a single device of the base module. The combined device can then advantageously comprise an individual transmitter, wherein the signal emitted by it is divided between at least two partial paths arranged in the cartridge unit, wherein one partial path is assigned to the cartridge unit identifier and one to the conveying pump conveying movement monitoring device. The combined device respectively comprises a receiver which is respectively assigned to one of the two functions of the device. By way of the combined device, it is advantageously possible to save on components and design volume, such that the administering apparatus as a whole

can be designed more compactly, while maintaining the same level of security. It is then also possible to realise simplified control and monitoring applications in the electronic controller.

5 In one embodiment in accordance with the invention, the cartridge unit comprises a hydraulic system which acts on the product container and causes fluid product to be delivered. In preferred embodiments, the hydraulic system is arranged as follows: a conveying pump is arranged between a hydraulic reservoir and a shift reservoir, such that the conveying pump can suction hydraulic fluid from the hydraulic reservoir and convey it to the shift reservoir, wherein the path of the hydraulic fluid between the hydraulic reservoir and the shift reservoir
10 forms a hydraulic path. The shift reservoir directly abuts the product container, which in the present embodiment is formed as a drug reservoir and in particular as a so-called carpoule, wherein the movably mounted stopper of the drug reservoir also forms a moving wall of the shift reservoir. If hydraulic fluid is then conveyed from the conveying pump into the shift reservoir, then a pressure is applied to the moving stopper of the drug reservoir. The stopper is
15 thus shifted, and product is consequently delivered from the drug reservoir. In one preferred configuration, the drug reservoir can be inserted into the cartridge unit directly before the base unit and the cartridge unit are assembled. Since the shift reservoir is at least partially formed by the drug reservoir, it is advantageous if the hydraulic path between the conveying pump and the shift reservoir is closed as long as the drug reservoir has not been inserted into the
20 cartridge unit.

Various incompressible liquids can be used as the hydraulic fluid, many of which are known from US 5,041,094. One possible hydraulic fluid is sterilised pure deionised water. This does not present any safety hazard to the patient. However, metal parts which may be provided and
25 are in contact with the fluid may begin to corrode over a long storage life. It is therefore an advantageous embodiment of the invention, when water is used as the hydraulic fluid, to buffer the fluid, in particular with a phosphate buffer and in particular at an alkali pH value of the fluid. This can in particular passivate steels and therefore protect them against corrosion.

30 Another problem over a long storage life and when using water as the hydraulic fluid can be the escape of hydraulic fluid from the hydraulic reservoir or, respectively, from the hydraulic path. This can be caused by minimal cracks or openings in the system or also by the diffusion of water molecules through the surrounding walls of the reservoir or path. It is therefore an advantageous embodiment of the invention, when water is used as the hydraulic fluid, to

provide the water with a hygroscopic additive in order to be able to arrest the net decrease in the amount of water present in the hydraulic system and ideally prevent it entirely, wherein advantageous additives include polymers or oligomers based on ethylene glycol or propylene glycol or, respectively, pure glycerin.

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Alternatively, one advantageous embodiment of the invention is to use oligomers of ethylene glycol, which are liquid at the temperatures at which the administering apparatus is used, as the main constituent of the hydraulic fluid, wherein in order to stabilise the net mass of the hydraulic fluid, which is itself hygroscopic, a certain amount of water is mixed in with the fluid.

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In another embodiment, liquid perfluoropolyethers or silicone oil are used as the hydraulic fluid.

15 The hydraulic fluid is primarily stored in the hydraulic reservoir; a smaller proportion is situated in the remaining hydraulic system during storage. In accordance with the invention, the hydraulic reservoir is capable of adapting the interior volume to the amount of hydraulic fluid present.

20 The reservoir is advantageously formed as a collapsible and in particular pliable pouch. In accordance with the invention, the pouch prevents hydraulic fluid from escaping from the reservoir for a sustained period of several years. In one advantageous embodiment, the pouch is made of plastic. In order to close the pouch tight, the peripheral regions to be closed are fused. In order to prevent hydraulic fluid from diffusing out of the reservoir, the pouch material is designed to be multi-layered in another advantageous embodiment and comprises at least one diffusion blocking layer. In particular, this at least one blocking layer consists for example of aluminium foil or a layer which is vapour-coated onto a substrate layer and is made for example of silicon or aluminium. This multi-layered embodiment comprises at least an inner layer made of plastic, for example polyethylene, a blocking layer and an outer layer made of plastic, for example polyethylene. The inner and outer layers provide the pouch with the necessary mechanical stability and protect the blocking layer from damage. Alternatively, the pouch can also consist entirely of metal, in particular aluminium foil.

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In another advantageous embodiment, the reservoir is formed as a flexible reservoir which can be elastically deformed. In another advantageous embodiment, the hydraulic reservoir is formed as a carpoule or in a similar way to a syringe and comprises a stopper which can be shifted. The hydraulic reservoir is connected to the hydraulic path of the administering
5 apparatus via a fluid connection. In one advantageous embodiment, this connection can be closed. To this end, a spout made of plastic, for example polyethylene, is arranged at the open end of the reservoir. At the end directed towards the reservoir, the spout comprises a nozzle which protrudes into the reservoir. The open end of the reservoir encloses the nozzle and is for example fused or adhered to it, such that the pouch can only then be emptied through the
10 nozzle. The nozzle is in a fluid connection with the other end of the spout via a fluid conduit, wherein the fluid conduit is closed at the second end by means of an elastomer septum. By arranging the spout on the reservoir, it is possible to fill and empty the reservoir via the septum, without damaging the reservoir itself.

15 In another advantageous embodiment, the reservoir is connected directly to a flexible fluid conduit, wherein the flexible fluid connection is advantageously formed as a flexible plastic tube, in particular one made of polyethylene, which protrudes into the interior of the reservoir and is fused or adhered to the reservoir wall in a tight seal. The hydraulic reservoir which is connected to the flexible tube can be filled via the flexible tube and then attached directly to
20 the conveying pump.

The conveying pump is embodied in accordance with the invention as a valveless reciprocating rotary piston pump. A pump in accordance with this principle is already described in CH 679172. The conveying pump preferably does not have any actual valves nor
25 an electronic controller. The valve function is instead assumed by the pump piston. This enables the number of moving parts to be restricted to a minimum. In order to operate the pump, the piston is rotated by merely applying a torque. The piston is axially advanced and retracted via a guide of the piston on a control cam. The piston is connected at one end to the transmission element which is in turn driven by the slaving means of the base unit. Depending
30 on the pump phase, i.e. on whether fluid is being suctioned or expelled, either the inlet or the outlet of the pump cylinder is connected to the pump volume in the interior of the cylinder via a valve area arranged on the piston, i.e. when fluid is being suctioned, the inlet is in fluid connection with the pump volume, which is increased by the axial movement of the piston and so suctioned fluid into the pump, and when fluid is being expelled, the piston is rotated

until the valve area connects the pump volume to the outlet. The reciprocal movement, which reduces the pump volume, thus expels fluid from the pump through the pump outlet. The tightness of seal at the boundary area between the surface area of the piston and the inner area of the cylinder is important to the dosing precision of the conveying pump. A loss of fluid via this boundary area means that the patient is ultimately administered with less of the drug. The connection between the piston and the cylinder should be tight, but the friction between the two areas simultaneously also has to be at a minimum in order to keep the required drive torque and the energy consumption of the pump to a minimum. At least three factors play an important part in the design of the conveying pump: on the one hand, the geometric diameters of the piston and the inner diameter of the cylinder; and on the other hand, the choice of material. The frictional forces between the piston and the cylinder play a major part as the third factor. Although the frictional forces are fundamentally influenced by the dimensioning of the parts and the choice of material, they can however also be influenced by changes in the surface structure, surface chemistry or lubrication.

The boundary area between the piston and the cylinder is in principle sealed by a press fit between the outer diameter of the piston and the inner diameter of the cylinder, wherein it is important that neither the cylinder material nor piston material, when exposed to the mechanical tensions generated by the press fit, relaxes to the extent that the press fit is released. An embodiment consisting of a relatively rigid material such as steel for the piston and a relatively soft material such as plastic for the cylinder is advantageous. In the case of the combination of steel and plastic, there is the danger of mechanical relaxation, i.e. of a depletion in mechanical tension due to plastic deformation, in particular in the case of plastic. In one advantageous embodiment, the cylinder therefore consists of an elastomer, in particular a thermoplastically mouldable elastomer. In another advantageous embodiment, the piston is manufactured from a composite material such as for example glass fibre reinforced polyester. In another advantageous embodiment, the piston consists of ceramics, in particular aluminium oxide. In a further advantageous embodiment, the piston consists of a stiff bulk materials, such as metal, and a soft shell material, such as a soft elastomer like silicone.

Given known materials for the piston and cylinder of the conveying pump, the tribological properties of the tribological pairing of the piston and the cylinder are further optimised in accordance with the invention, dependent on the fluid to be pumped. In one advantageous embodiment, the frictional forces between the piston and the cylinder are reduced by coating

the piston and/or the cylinder with silicone, in particular with a partially cross-linked form of silicone containing a 20 to 80% proportion of liquid non-cross-linked silicone. In another advantageous embodiment, the piston and/or the inner area of the cylinder is/are at least partially coated with a solid inorganic lubricant, in particular molybdenum disulphide or graphite, wherein the lubricants can be applied with the aid of a fatty or oily matrix. In another advantageous embodiment, mineral or vegetable oil or fat is used as the lubricant, in particular together with other additives such as zinc dialkyldithiophosphate or the like. In another advantageous embodiment, the piston and/or the inner area of the cylinder are coated with a perfluorinated polymer, in particular polytetrafluoroethylene (PTFE) or perfluoropolyether (PFPE), wherein the layer at least partially contains liquid phases.

In one advantageous embodiment, the perfluoropolyether coating is partially cross-linked and contains a particular proportion of non-cross-linked molecules which are in a liquid aggregate state under conditions of use, wherein the cross-linked proportion is covalently bonded to the surface to be coated and absorbs the non-cross-linked proportion in its network. The advantage of this type of lubrication is that the network formed during cross-linking holds the liquid phase on the surface. When exposed to mechanical stress, the network can excrete the liquid phase, such that a liquid lubricating film is created on the frictional area, which exhibits a very low shearing strength and consequently minimises the frictional force.

In one advantageous alternative embodiment, the hydraulic fluid which is to be pumped is used to lubricate the sliding areas. Silicone oils, liquid perfluoropolyethers or vegetable oils such as rapeseed oil are in particular suitable for the combined application in accordance with the invention as a hydraulic fluid and a lubricant.

In another advantageous embodiment, lubricating materials are mixed in with the cylinder material and/or piston material, in particular silicone, graphite or molybdenum disulphide.

The conveying pump suctions hydraulic fluid from the hydraulic reservoir into the interior volume of the cylinder and conveys it via the outlet and the subsequent hydraulic path to the shift reservoir. A pressure measuring device is arranged between the conveying pump and the shift reservoir at a blind channel of the hydraulic path, i.e. a branch of the hydraulic path which is closed at one end. This pressure measuring device comprises an element which can be deformed and which changes its shape when there is a change in pressure in the hydraulic

path between the conveying pump and the shift reservoir. This change in shape can be detected by means of a sensor assembly in the base unit.

5 In one advantageous embodiment, the element which can be deformed can be configured as a round, elastic membrane on which a cylindrical plunger is centrally arranged which is perpendicular to the membrane. If the membrane is deformed via a change in pressure, the plunger moves and can thus transmit the change in pressure, wherein the plunger and the membrane are arranged on a wall of the housing of the cartridge unit which is orientated with respect to the base unit such that the plunger – already described further above – can transmit
10 the change in pressure from the cartridge unit onto a sensor unit of the base unit which is provided for this purpose.

In another advantageous configuration, the membrane is configured such that only a small change in pressure is necessary in order to deform the membrane. Consequently, the plunger
15 is geometrically moved even by small changes in pressure, such that it can equalise geometric production tolerances on the base unit and cartridge unit. When the administering apparatus is actuated, i.e. when the conveying pump is started, after the base unit and cartridge unit have been slid together, the pressure between the conveying pump and the shift reservoir increases as expected. Consequently, the membrane is deformed and the plunger arranged on the
20 membrane moves towards the sensor unit. If the membrane then exhibits a very low deformation resistance, the plunger moves even when the increase in pressure is weak, until it comes into contact with and is stopped by the sensor assembly.

In one advantageous embodiment, the membrane and the plunger are two separate elements,
25 wherein the membrane can transmit pressure to the plunger element by being able to locally shift the plunger due to its pressure-induced deformation.

The hydraulic path leads from the outlet of the conveying pump to the shift reservoir. The shift reservoir is at least partially formed by the drug reservoir. The drug reservoir is
30 advantageously formed as a carpoule. In this case, the outwardly pointing wall of the stopper, which is movably mounted in the carpoule, forms a moving wall of the shift reservoir. Another wall of the shift reservoir is formed by the carpoule wall situated between the stopper and the open end of the carpoule. On the side of the shift reservoir opposite the stopper, the shift reservoir is limited by a carpoule seal arranged in the cartridge unit. It exhibits a similar

shape to the carpoule stopper and seals off the open end of the carpoule. The carpoule seal comprises an opening through which a fluid connection to the hydraulic path can be established.

5 In one advantageous configuration, the connection between the hydraulic path and the shift reservoir is interrupted until a drug reservoir, such as for example a carpoule, is inserted into the cartridge unit. In this advantageous embodiment, the carpoule seal is movably mounted in the cartridge unit. Inserting the carpoule shifts the carpoule seal and thus opens the fluid connection between the hydraulic path and the shift reservoir. A hollow pointed element is
10 thus arranged on the carpoule seal in this embodiment, which is driven into a sealing element of the hydraulic path during the insertion movement of the carpoule and thus establishes a fluid connection. Alternatively, the pointed element is formed such that it slits or punctures a sealing film. In another advantageous variant, the movement of the carpoule seal opens a valve, in particular a non-return valve, a ball non-return valve, a Schrader valve or a quick-
15 release valve.

In one advantageous embodiment, the carpoule is inserted into an interior space of the cartridge unit via an opening in the housing of the cartridge unit. The carpoule seal is arranged on a side of the cartridge unit opposite the opening, coaxially with respect to the
20 opening, wherein the carpoule seal is movably mounted on a receptacle which is fastened to the housing of the cartridge unit.

When inserting the drug reservoir into the cartridge unit, in particular when inserting a carpoule onto the carpoule seal, i.e. when establishing the shift reservoir, it is advantageous to
25 vent the initial space which the shift reservoir encompasses before the connection between the hydraulic path and the shift reservoir is established. In one configuration in accordance with the invention, the carpoule seal comprises elements which enable venting when the carpoule is inserted. In one advantageous embodiment, the venting elements are arranged on the surface area and orientated parallel to the carpoule axis. The venting elements comprise ribs
30 and channels. As the carpoule is inserted into the cartridge unit, the open end of the carpoule is slid onto the carpoule seal, wherein the longitudinally orientated rib elements ensure that the carpoule wall is guided, and the channels arranged between the ribs enable air which is still present in the shift reservoir being established to escape. In an alternative configuration, the shift reservoir is not vented via peripheral channels but rather via the central opening in

the carpoule seal. Venting is then possible as long as the hydraulic connection has not yet been opened.

A sealing element is arranged immediately following the venting elements and closes the shift reservoir, once vented, in a tight seal. The sealing element encircles the carpoule seal along the circumference and seals the shift reservoir between the carpoule wall and the carpoule seal, wherein the carpoule seal is advantageously formed in one part, such that the venting elements and sealing element are integral constituents of the carpoule seal.

10 In an alternative advantageous embodiment, the carpoule seal is composed of several parts, wherein the sealing element can for example be embodied as an O-ring and arranged on the surface area of the carpoule.

In another advantageous configuration of the carpoule venting function and the carpoule sealing function, the sealing element can also be arranged offset from the carpoule sealing part, wherein the carpoule seal is reduced to its venting and guiding function. In this embodiment, the actual sealing element is arranged coaxially with respect to the carpoule seal, such that once venting is complete, the open end of the carpoule is positioned axially on the sealing element and sealed off, wherein the sealing element can be configured as an O-ring or
20 in another geometric shape which allows the open end of the carpoule to be sealed.

In order to fix the drug reservoir, in particular a drug reservoir which is formed as a carpoule, in the housing of the cartridge unit after the shift reservoir has been vented and established, the opening through which the drug reservoir has been inserted is closed. An infusion set adaptor, which can also connect the interior of the drug reservoir to a lumen of an infusion set
25 to be used, serves as the shutter.

Before the drug reservoir can be inserted into the cartridge unit, the hydraulic path is advantageously pre-filled with hydraulic fluid in order to hold as little air as possible enclosed
30 in the hydraulic path and thus minimise the elasticity of the hydraulic system.

In one advantageous embodiment, this is achieved even as the cartridge unit is assembled in production, wherein as the cartridge unit is assembled, the sealing element which can be opened by the carpoule seal is not yet closed, wherein the hydraulic reservoir is inserted into

the cartridge unit filled. Hydraulic fluid can thus be conveyed out of the hydraulic reservoir into the hydraulic path by the conveying pump immediately before the hydraulic path is closed. As soon as the hydraulic path is completely filled, the sealing element can be closed.

- 5 In an alternative configuration to the aforesaid embodiment, a hydraulic fluid is used which has a vapour pressure at room temperature which is low enough that the hydraulic path does not have to be closed after being filled in order to prevent the hydraulic fluid from excessively vaporising, i.e. escaping from the hydraulic path. Ethylene glycol oligomers, perfluorinated polyethers or the like can be used as the hydraulic fluid in this case, wherein the hydraulic
10 fluid used preferably exhibits thixotropic or structurally viscous flow properties, for example by adding appropriate additives such as hyaluronic acid to a hydraulic fluid.

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20 **Description of the figures**

Figures 1 to 13b show embodiments of the administering apparatus in accordance with the invention. The administering apparatus 10 shown in Figures 1 and 2 consists of a re-usable base unit 1 and a complementarily formed and exchangeable cartridge unit 2. The drug reservoir 3 (shown, by way of example, as a carpoule 500 in Figure 5a) can be inserted into
 25 the cartridge unit 2. As shown in Figures 2 and 5a, the drug reservoir 3 can be fixed in the housing 200 of the cartridge unit by means of an infusion set adaptor 4 which is fitted onto the cartridge unit 2, wherein the infusion set adaptor 4 connects the drug reservoir 3 to the infusion set 5 which is attached to the infusion set adaptor 4. The infusion set 5 thus establishes a liquid connection between the administering apparatus 10 and the injection point,
 30 wherein an injection needle of the infusion set 5 is injected through the skin into the user's tissue at the injection point. Figures 1, 2 and 7 show one possible embodiment of an overall system of the administering apparatus in accordance with the invention. The embodiments shown in the figures are intended to show, by way of example, configurations in accordance with the invention. Other embodiments have already been described further above, and

additional possible embodiments will be evident to the person skilled in the art on the basis of the description of the invention, such that the embodiments described below are not to be regarded as limiting.

5 In order to specify the directions within the administering apparatus, directional designations are defined as follows. The distal direction is respectively understood to mean the direction in which the liquid and the drug stopper move when the drug is administered. As described below in more detail, liquid in the liquid path is deflected in the interior of the administering apparatus and changes its flow direction. The distal direction therefore corresponds to
10 different absolute spatial directions for different parts of the administering device. The proximal direction is correspondingly defined as the opposite direction to the distal direction. A lateral direction is a direction perpendicular to this.

As shown in Figures 3, 3a, 3b, 3c, 4a and 4b, the base unit comprises a housing 100 which
15 comprises an elongated holding region 102 which is substantially shaped as a rounded cuboid or prism. As shown in Figure 3, the bearing region 103 for the cartridge unit 2 is arranged attached to the holding region and comprises elements for mechanically guiding 104, 105, 105' and 107 and latching 106 the cartridge unit. A coupling toothed wheel 125 is arranged as a slaving means in the bearing region 103 and is driven by a motor 120 – which lies behind it
20 and is completely encompassed by the housing 100 – via a gear system 121 and transmits the drive movement into the cartridge unit.

The exchangeable cartridge unit 2, which is shown in Figure 5, can be connected to the base unit 1 and comprises a housing 200 which is divided into three regions, wherein the regions
25 are separated from each other by the intermediate walls 204 and 205. The first region is defined by a carpoule accommodating region 203 into which the drug reservoir 3 is inserted, as shown in Figure 5a, wherein the reservoir 3 is embodied here, by way of example, as a carpoule 500 and is inserted with its proximal end to the fore into the opening 206 of the cartridge unit 200 and positioned onto a carpoule seal 260 which is shown in detail in Figure
30 5b. The second region, between the intermediate walls 204 and 205, contains a hydraulic reservoir 270 together with a spout 275. The hydraulic reservoir is limited by the hydraulic reservoir wall 272, is formed as a pouch-like collapsible structure, and contains a hydraulic fluid 271, wherein the spout 275 enables the hydraulic fluid 271 to be transferred into the hydraulic conduit 291.

The third region contains the conveying pump 6 which suctions hydraulic fluid 271 from the hydraulic reservoir via the hydraulic conduit 291 and conveys it to the carroule accommodating region 203 via the hydraulic conduit 292. The blind channel 293 is connected to the hydraulic conduit 292, wherein the blind end is formed by the membrane for the occlusion identifier 250. The third region of the housing 200 comprises an opening 207 through which the coupling toothed wheel 125 of the base unit 1 can be engaged with a complementarily formed transmission element via an inner toothing of a pump piston module 230 (shown in detail in Figure 9) of the conveying pump 6.

The infusion set adaptor 4, which is shown in detail in Figures 5a and 10, comprises a housing 300 and is inserted into the opening 206 once the drug reservoir 3 has been inserted into the cartridge unit 2, wherein the adaptor spring portion 310 snaps fixedly and in particular non-releasably onto the housing 200 of the cartridge unit 2, wherein the cannula 330 establishes a liquid connection with the drug present in the drug reservoir.

An infusion set 5 can be attached to the infusion set adaptor 4 at the Luer lock connector provided for this purpose, as shown in Figure 5a.

In the advantageous embodiment shown in Figures 6 and 6a, the drive of the base unit is formed from the DC motor 120, a drive shaft 127, the gear system 121, the coupling toothed wheel 125, the encoder wheel 122 arranged on the drive shaft 127, and the rotation detector 123. The drive is controlled and supplied with energy via an electronic controller. Since the coupling toothed wheel 125 protrudes out of the housing 100 through the opening 128, a seal 126 (as shown in Figure 3) ensures that neither dirt nor moisture can penetrate into the housing. The gear system 121 gears down the rotational movement of the drive shaft at a ratio of 300:1.

The encoder wheel 122 is fixedly arranged directly on the drive shaft 127, such that a revolution of the drive shaft is directly converted into a revolution of the encoder wheel. The encoder wheel comprises peripherally arranged openings 129. During a rotation, the movement of these elements can be detected by the rotation detector 123, wherein the signals detected by the rotation detector are relayed to the electronic controller 150.

The base part 1 comprises a means for identifying the cartridge unit. The arrangement is shown in an overview in Figure 7, and a detailed view is shown in Figure 7a. The cartridge unit identifier is designed to determine whether a cartridge unit is connected to the base module. The means comprises a transmitter 165, in particular a light-emitting diode, which transmits light through a window 108 in the housing 100. The means also contains a receiver 166 which receives the emitted light, which is deflected by a partial light conductor 281 of a light conductor 280 on the housing 200 of the cartridge unit, when the cartridge unit is correctly arranged on the base unit. The base unit 1 comprises a means for detecting the rotation of the pump piston 231 during operation, as shown in Figures 7 and 7a. The means comprises the transmitter 165 which transmits light through a window 108 in the housing 100. The means also contains a receiver 167 which receives the emitted light, which is deflected by a partial light conductor 282 of the light conductor 280 on the housing 200 of the cartridge unit, when the cartridge unit is correctly arranged on the base unit and the light path in the partial light conductor 282 is not interrupted by a coding ring 241 of the rotating piston.

The embodiment outlined here, in which the function of identifying the cartridge unit and detecting the rotation of the pump piston are combined, is characterised by the integration of the two functions, i.e. by the fact that only one transmitter is required. The light emitted by the transmitter 165 is divided in the light conductor module 280 and fed to the two functions mentioned via the partial light conductors 281 and 282. This high level of integration not only has the advantage that it is possible to save on components, in particular transmitters, but also enables the functions of detecting the cartridge unit or detecting the rotation of the pump piston to be used as a plausibility check on the other function in each case or, respectively, in order to verify the transmitter function. If, for example, no light can be measured at the receivers 166 and 167 for either of the partial light conductors 281 and 282, although a cartridge module is correctly installed, then the functioning of the transmitter 165 may be in question.

The base unit 1 comprises an occlusion identifying device 130 via which the liquid pressure in the cartridge unit 2 can be measured. In the embodiment shown in Figures 7 and 7b, the device 130 comprises a transmission element 131 onto which a plunger 252 of the cartridge unit 2 mechanically transmits a force. The transmission element 131 consists of a circular membrane 133 and a plunger 134 which is perpendicular to the membrane. The membrane 133 is fastened to the housing 100 or guided by the housing 100 along the circular

circumference. The plunger 134 is guided through the opening 135 of a sealing element 132. At its end which projects from the membrane 133, the plunger 134 comes into contact with the force measuring sensor device 140. The plunger 134 is in principle held in position by the membrane 133. If an increase in pressure is then transmitted to the base unit 1 from the cartridge unit 2, the transmission element 131 relays this change to the force measuring sensor device 140 via the plunger 134, wherein the sealing element 132 guides the transmission deflection of the plunger 134. In the embodiment shown in Figure 7b, the force measuring sensor device 140 is a strain gauge device 141 which is integrated into the circuit board of the control electronics and comprises a resistance bridge, wherein details of this embodiment can be seen in Figure 13b. In alternative configurations, the strain gauge device can be a device which is arranged separately from the circuit board, or other sensors – in particular, piezoelectric sensors – could be used instead of the strain gauge device.

The base unit 1 shown in Figure 3 comprises a battery compartment 115 into which a battery 7 of the commercially available AAA type can be inserted. The battery compartment 115 can be closed by means of a battery compartment cover 110. The battery compartment cover also comprises a seal 112 which prevents moisture from penetrating into the battery compartment, wherein the thread which is arranged on the battery compartment cover 110 for closing the compartment engages with a counterpart thread of a threaded insert 111 of the battery compartment 115. A spring 117 is arranged at the closed end of the battery compartment 115 and contacts the negative terminal of the battery 7 on the one hand and stabilises the position of the battery in the compartment on the other. The positive terminal of the battery 7 is contacted via the at least partially electrically conductive battery compartment cover 110 which, as soon as it is screwed into the threaded insert 111, is electrically connected to it. The battery 7 supplies the base unit 1 with power, wherein during operation, it also charges a power pack 118 which serves to ensure an uninterrupted power supply. The power supply design is described in WO 2011/022850, for which reason reference is made to this document for the details of the power supply. In the example embodiment shown, the power pack 118 is a rechargeable lithium-polymer power pack; other power packs could however also be used. The power pack 118, like the battery 7, is capable of supplying the entire base unit with power.

In the embodiment of the administering apparatus 10 shown in Figure 8, a lateral area of the housing 100 of the base unit 1 comprises a display 180, in particular a liquid crystal display,

which is divided into seven regions 181 to 187. The regions are shown in detail in Figure 8a. The region 181 serves to display date information, the region 182 serves to display the time, and the region 183 serves to display the state of the energy store 7, 118. The display regions 184 and 185 serve to display administering data. The graphic display elements 186 and 187 enable symbols to be graphically displayed, depending on context. Other or additional information can be assigned to the regions, depending on the application.

The housing 100 of the embodiment of the base unit 1 shown in Figure 1 comprises a total of four push buttons 190 to 193 for operating the administering apparatus 10. The push buttons 190 and 191 are arranged on the right next to the display 180. The push buttons 192 and 193 are arranged above the display in the holding region 102.

The base part 1 comprises a central controller unit 150. This controller unit comprises two micro-controllers 151 and 152. As explained more precisely further below, this redundant design allows important functions to be duplicated and the micro-controllers to monitor each other and software applications which may be provided. The controller unit 150 comprises a series of software applications which are necessary for controlling the administering apparatus. The controller unit is schematically shown in Figure 12, and a possible embodiment is shown in Figures 13a and 13b, wherein Figures 13a and 13b differ merely in terms of their view. The arrangement of the electronic circuit board shown in Figure 13a is referred to as a so-called flex-rigid combination, i.e. rigid circuit board elements are combined with flexible elements in order to be able to achieve an advantageous space-saving three-dimensional arrangement. The necessary parameters for administering the drug, in particular administering profiles, basal rates or bolus values, are stored in a memory for delivery parameters 603 in the controller unit 150. The effective administering data or also measurement values are complementarily stored in a log memory 604 and evaluated by the controller 150. Energy is fed to the controller unit 150 from the battery 7 or the power pack 118 via a voltage converter 154. Conversely, the energy supply is monitored by a feed monitor 609 and is actively controlled via an energy supply controller 610. Over a longer storage life, the energy supply controller 610 can in particular actively separate the power pack 118 from the consumers, such as for example the controller 150, by means of a load-shedding switch 119, in order to protect the power pack. The controller 150 also comprises elements which control and monitor administering. Thus, a delivery regulator 605 can read administering data from the memory for delivery parameters and activate a drive regulator

606 in accordance with the desired administering amount. The drive regulator 606 and the delivery regulator 605 both interact with a drive monitor 607 which reads the encoder signal from the rotation detector 123 and controls and monitors the motor 120. In order for the controller 150 to perform administering at the right time, it can be fitted with a clock 601
5 which evaluates a clock pulse signal from a quartz crystal 153. The controller 150 also comprises an occlusion identifying unit 608 which reads measurement data from the occlusion identifier 130 via the force measuring device 140 and evaluates them. An application 602 of the controller 150 monitors and controls the cartridge unit identifier and the piston rotation detector via the transmitters 165 and the receivers 166 or, respectively, 167.
10 The controller 150 also comprises various input and output functions which control the interfaces between the administering apparatus and external points such as for example users or service means. In the embodiment shown in Figure 8, the administering apparatus 10 comprises four push buttons 190, 191, 192 and 193, for example for inputting delivery parameters or selecting functions. The keys are connected to a key monitor 611 of the
15 controller 150 which evaluates the signals of the keys and relays them to the next entity. In order to output and display information, the administering apparatus 10 also comprises the display 180 which is connected to the controller 150 via a display controller 613. Bidirectional communication between the administering apparatus 10 and the outside can also occur via the infrared interface 160 which is linked to the controller via a controller
20 application 612. In order to emit signals, the administering apparatus 10 comprises a buzzer 155 together with a corresponding buzzer controller and a vibration alarm unit 156 which is linked to the controller 150 via a vibration alarm controller application 615.

The controller 150 is redundantly designed, wherein not all the functions need be
25 implemented twice. In the embodiment shown in Figure 12, the redundancy is focused on functions which are crucial to the user of the administering apparatus, such as the delivery regulator 605 or the controller of the occlusion identifier 608. The controller 612 of the infrared interface 160, for example, is not crucial and is therefore not redundantly provided. What is also important about the embodiment of the controller 150 shown in Figure 12 is the
30 fact that the two micro-controllers 151 and 152 monitor each other reciprocally.

The electronic controller 150 of the administering apparatus 10 can be operated by the user with the aid of the push buttons 190, 191, 192, 193 and the display 180. To this end, the controller 150 comprises a programmed user interface which exhibits a menu structure and is

stored in the micro-controllers 151 and 152 and can be shown on the display 180 in a way which is comprehensible to the user, wherein the user can in particular navigate through the menu structure shown on the display 180, confirm alerts and also input delivery parameters with the aid of the push buttons 190, 191, 192, 193.

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A lateral area of the housing 100 comprises an infrared window 109, as shown in Figures 1, 3b and 3c. Through this window 109, the control electronics 150 communicate in particular with service or support apparatus via the infrared interface 160, preferably in accordance with the Infrared Data Association (IrDA) specification. The infrared interface 160 comprises a
10 transmitter 161 and a receiver 162.

The embodiment of the cartridge unit 2 shown in Figures 5, 5a, 5b, 5c, 5d and 5e comprises a hydraulic path 290 which extends from the hydraulic reservoir 270 via the spout 275 and the hydraulic conduit 291 to the conveying pump 6 and from there onwards via the hydraulic
15 conduit 292 to a carpoule seal receptacle 216, from which the path leads through a carpoule seal 260 into a shift reservoir 295.

In the embodiment shown in Figure 7, the hydraulic fluid used is preferably a mixture of polyethylene glycol (PEG) and water, in which water is present in a proportion of about 10%.
20 Oligomers with an average of less than 10 oxyethylene units are used as the polyethylene glycol.

The hydraulic reservoir stores the hydraulic fluid, wherein the hydraulic reservoir 270 contains a particular amount of hydraulic fluid 271 before use, which at least slightly exceeds
25 the amount of drug present in the drug reservoir 3, wherein the example embodiment shown in Figures 5 and 7 comprises a hydraulic reservoir which can accommodate a volume of about 4 ml of hydraulic fluid, wherein the drug reservoir 3 shown, which exhibits the shape of a carpoule 500, has a maximum drug volume of about 3 ml. The hydraulic reservoir 270 is formed as a pouch which adapts its interior volume to the volume of liquid. The wall 272 is
30 preferably formed in multiple layers. In particular, a thin layer of aluminium is inserted as a diffusion block between two layers of polyethylene.

The distal end of the hydraulic reservoir comprises an opening to which a spout 275 is attached. The spout establishes a fluid connection between the reservoir 270 and the hydraulic

conduit 291. The spout 275 is connected to the reservoir 270 and can ensure that the hydraulic reservoir 270 is fixed within the cartridge unit 2 due to its connection to the base plate 210.

The distal end of the spout 275 comprises an elastomer septum 276 which closes the fluid connection at one end. The septum is pierced by the proximal end of the hydraulic conduit 291 in order to establish the fluid connection between the hydraulic reservoir 270 and the conveying pump 6, wherein the hydraulic conduit 291 is formed as a cannula and is connected at its distal end to the inlet nozzle 214 of the conveying pump 6, in particular pressed into it and adhered in a tight seal, as shown in Figures 5 and 7.

Figure 5 shows the cartridge unit 2 before a carpoule 500 is inserted. Figure 5a shows the cartridge unit 2 after a carpoule 500 has been inserted and fixed in the cartridge unit 2 by means of the infusion set adaptor 4. Figure 5e shows the cartridge unit after a partial amount of the drug has been administered from the carpoule 500. The shift reservoir 295 in particular can be clearly seen in Figure 5e.

In an alternative embodiment which is shown in Figures 11 and 11a, a flexible plastic tube 1275 is connected, in particular fused, directly to the hydraulic reservoir 270 in place of the spout and channels the hydraulic fluid directly from the reservoir into the conveying pump 6. The distal end of the flexible tube 1275 is connected to the inlet nozzle 214 of the conveying pump 6 in an analogous way to the hydraulic conduit 291, in particular pressed in and adhered in a tight seal.

The conveying pump operates in accordance with the principles of a valveless reciprocating rotary piston pump such as is shown on the basis of an example embodiment in an exploded drawing in Figure 9. The pump is also shown in Figures 5 and 7. The conveying pump 6 comprises a cylinder 211 which is fixedly connected to or, respectively, formed integrally with the base plate 210. In the embodiment shown in Figure 5, the cylinder and the base plate are embodied integrally in plastic as a bi-component injection-moulding, in order to achieve optimum properties for the cylinder and the base plate. The cylinder is closed towards the base plate and comprises a circular opening 212 on the opposite side. The surface area 213 of the cylinder comprises an inlet nozzle 214 and an outlet nozzle 215, wherein the inlet nozzle 214 is connected to the hydraulic conduit 291, such that hydraulic fluid 271 can be introduced into the interior space of the cylinder from the hydraulic conduit 291. The outlet nozzle 215 is

connected to the hydraulic conduit 292, such that hydraulic fluid 271 can pass from the interior space of the cylinder, via the outlet nozzle 215 and the hydraulic conduit 292, to the carroule accommodating region 203. The conveying pump 6 also comprises a pump piston module 230 which contains the piston 231. On the opposite side to the piston, the pump piston module 230 comprises an accommodating region 232 for the coupling toothed wheel 125 for establishing a rotationally secure connection between the coupling toothed wheel 125 and the pump piston module 230, wherein in the coupled state, the coupling toothed wheel and the pump piston module 230 are mounted such that they can be axially slid relative to each other. In order to control the pump stroke, the pump piston module comprises a control cam counterpart area 234 which encircles the module. This control cam counterpart area 234 is axially guided by control cams 221 which are arranged on the control cam module 220, i.e. if the piston module 230 is rotationally set in motion via the coupling toothed wheel 125, then the piston module is axially slid, due to the engagement between the control cams 221 and the control cam counterpart area 234, back and forth between two positions which are predetermined by the control cams 221 and the counterpart area 234. If the piston 231 moves out of the cylinder, a pump volume 235 which is limited by the facing area 236 of the piston and the inner area of the cylinder is increased. If the piston moves in the opposite direction, the pump volume 235 is reduced.

Figure 9 shows an embodiment of a conveying pump in accordance with the invention. The end of the piston which protrudes into the cylinder comprises a valve area 233 which alternately exposes the inlet 214 and the outlet 215 of the conveying pump and thus establishes a fluid connection between the inlet or outlet and the pump volume in the pump. Thus, when fluid is suctioned from the hydraulic fluid reservoir 270 into the conveying pump 6, the valve area 233 is orientated towards the inlet nozzle 214. If fluid 271 is conveyed from the conveying pump 6 into the shift reservoir 295, then the valve area is directed towards the outlet nozzle 215.

Superimposing the active rotation driven by the coupling toothed wheel 125 and the passive axial movement of the piston 231 guided by the cam disc 221, in combination with the valve area 233 arranged on the piston, thus allows fluid 271 to be conveyed by means of the conveying pump 6 without actual inlet and outlet valves being necessary and without electronically controlling the inlet and outlet.

The outer diameter of the piston 231 and the inner diameter of the pump cylinder 211 are exactly adjusted to each other, as are the materials used. In the embodiment in accordance with the invention shown in Figure 9, stainless steel such as for example DIN 1.4301 or AISI 304 is used as the piston material. A thermoplastic elastomer, such as an appropriate polyester, with a Shore hardness of 55D at a nominal diameter of the piston of about 3 mm is used as the material for the cylinder. The piston exhibits a slightly larger outer diameter as compared to the inner diameter of the cylinder. In order to ensure the tightness of seal at the boundary area between the cylinder 211 and the piston 231, the outer diameter of the piston has an excess of about 0.02 to 0.2 mm as compared to the inner diameter of the cylinder in advantageous embodiments. In the embodiment of the invention shown in Figure 9, the excess is in the region of 0.1 mm. In an alternative to the embodiment shown, the Shore hardness of the cylinder material can be in the region of 45D to 65D. The capacity of the conveying pump is about 15 μ l. In order to keep the frictional forces between the surface area of the piston and the inner area of the cylinder as low as possible during operation, the tribological pairing is lubricated in the embodiment shown, wherein a partially cross-linked coating which consists of a perfluoropolyether and comprises about a 50% proportion of liquid phase and has a thickness of about 2 to 10 μ m when not mechanically stressed is used as the lubricant.

The hydraulic conduit 292 is fixedly connected to the outlet nozzle 215 of the conveying pump 6, wherein the hydraulic fluid 271 is channelled through said hydraulic conduit 292 to the shift reservoir 295.

The hydraulic channel 292 comprises a blind channel 293 which runs in an extension of the outlet nozzle 215, as shown in Figures 7 and 7b. At its distal end, the blind channel 293 is limited by the space 251 and closed off by the membrane 250. The membrane 250 shown in Figure 5 and also in Figure 7b exhibits a circular base area. A plunger 252 is arranged in the centre of the base area and is perpendicular to the base area. The end of the plunger which projects from the base area can protrude out of the cartridge unit through an opening 283 in the light conductor 280. The circumference of the circular base area is reinforced, such that an annular boundary of the membrane is created. The membrane is manufactured from a material which can be deformed – in the embodiment shown, a thermoplastic elastomer, in particular a polyester which exhibits elastomeric properties. The membrane 250 can be deformed in accordance with the pressure in the hydraulic system. If the pressure increases, the membrane 250 is dilated and the plunger 252 moves along its axis away from the blind channel 293,

wherein the extent of protrusion beyond the opening 283 increases. This movement of the plunger 252 can be recorded by the occlusion identifying unit 130 of the base unit in the form of a measurement of force.

- 5 The cartridge unit 200, which is shown in one possible embodiment in Figure 5, comprises an accommodating region 203 for a drug reservoir 3, in particular a carpoule 500 comprising a cylindrical glass body 501.

10 The carpoule, shown in Figures 5a or 5c, comprises an end which is closed by means of a shutter 504 and a septum 503 and slightly tapered as compared to the cylindrical base body 501 of the carpoule. The septum 503 can be pierced by the cannula 330 of the infusion set adaptor 4. The opposite end 505 of the carpoule 500 is open. A stopper 502 is mounted in the glass body such that it can be slid and forms a movable wall of the drug reservoir. The volume of the carpoule 500 can be reduced by shifting the stopper 502 in the distal direction,
15 and the patient can be administered with the drug via the infusion set adaptor 4 and the infusion set 5.

The carpoule seal 260 is arranged at the proximal end of the accommodating region 203, as shown by way of example in Figures 5b and 5d. The carpoule seal 260 exhibits an
20 approximately cylindrical base form and is positioned onto a cylindrical receptacle 216 of the base plate 210, wherein the carpoule seal 260 can be shifted axially on the receptacle 216 between a distal and a proximal position. The circumference of the carpoule seal 260 shown in Figure 5c comprises a sealing rib 262 which serves to seal off the shift reservoir 295, which is limited by the stopper 502, the base body wall 501 and the carpoule seal 260, in the
25 proximal direction once the carpoule 500 has been positioned onto the seal 260. In order to be able to completely vent the space between the carpoule stopper 502 and the carpoule seal 260 when inserting the carpoule 500, axially orientated ribs 265 are arranged upstream of the sealing rib 262 in the configuration shown in Figure 5c. The ribs 265 are arranged around the circumference of the carpoule seal 260; channel-like recesses 266 are formed between the ribs
30 265. The axial ribs ensure that venting through the channels 266 remains possible up until the moment the proximal end of the carpoule body 501 is positioned on the sealing rib 262.

A liquid through-let 263 is arranged at the distal end of the carpoule seal 260 and connects the space 295 to the hydraulic path 290. A tooth 264, which is tapered axially in the proximal

direction, is arranged on the inner side of the carpoule seal in the region of the through-let 263. The carpoule seal 260 is mounted such that it can be shifted relative to the receptacle 216.

The receptacle 216 comprises a passage 294 for the hydraulic conduit 292. This passage is closed by means of circular seals 217. By sliding the carpoule seal 260 and the receptacle 216 into each other, the movement of the carpoule seal 260 relative to the receptacle 216 enables the tooth 264 to puncture the circular seals 217 and thus connect the space 295 to the hydraulic conduit 292. The final state, i.e. after the carpoule 500 has been completely inserted and the hydraulic conduit 292 of the carpoule seal 260 is open, is shown in Figure 5d.

In an alternative embodiment (not shown) venting takes place through at least one closed channel, such as the carpoule seal through-let, which leads in an axial direction through the carpoule seal. In this case, the interface between the carpoule seal receptacle and the carpoule seal allows venting until the carpoule seal has been completely inserted.

The housing 200 of the embodiment of the cartridge unit 2 shown in Figure 5 comprises various guiding elements which are intended to simplify and secure assembling the base unit 1 and the cartridge unit 2, wherein these are linear guides in the manner of grooves and springs 218 which are arranged at various locations on the housing, in the contact region with the base unit 1, in the embodiment shown in Figure 2. These guiding elements are all formed parallel to the sliding-together direction and find complementary elements on the housing 100 of the base unit 1.

As shown for example in Figure 5, the housing 200 of the cartridge unit 2 comprises a latching snapper 202 which is fixedly connected to the housing 200 at one end and is free at the other end. The latching snapper 202 prevents any unintentional relative shift between the base unit 1 and the cartridge unit 2 while the administering apparatus is being used. In the embodiment shown in Figure 5, the snapper 202 is formed as part of the housing 200, wherein an optically transparent copolyester is used as the material for the housing 200 and the latching snapper 202. The latching snapper comprises a tongue 208 and a tooth 209. When the administering apparatus 10 is assembled, the tooth 209 engages with a recess 106 (see Figures 3 and 7) arranged in the housing wall of the housing 100 and thus prevents the cartridge unit 2 from being unintentionally detached from the base unit 1.

The infusion set adaptor 4 can be inserted into the opening 206 of the housing 200 of the cartridge unit. The opening 206 has an approximately circular cross-section. The embodiment of the opening 206 shown in Figures 5 and 5a comprises two locking teeth 350 and two
5 guiding grooves 355, in order to ensure that the adaptor 4 is correctly inserted. The two locking teeth 350 oppose each other in the opening and have an identical geometry. The two guiding grooves oppose each other in the opening and are orientated along the length of the carpoule accommodating region, i.e. they run parallel to a carpoule such as may be inserted. The locking teeth 350 and the guiding grooves 355 are arranged in the opening 206 such that
10 the infusion set adaptor can be inserted in two orientations which correspond to a rotation by 180°.

The infusion set adaptor 4 comprises the adaptor portion 300, a Luer lock connector 305, the spring portion 310, the spring 320 and the cannula 330. The infusion set adaptor 4 shown by
15 way of example in Figures 10, 10a and 10b has an approximately cylindrical shape and fits into the opening 206 of the housing 200 of the embodiment of the cartridge unit 2 shown in Figures 5 and 5a. The Luer lock connector is arranged on the distal side of the adaptor 4. The adaptor portion 300 accommodates the spring 320 and the spring portion 310 in its interior. The spring 320 is held in the interior of the adaptor portion at its distal end by an annular
20 channel 309. The spring portion 310 is attached to the proximal end of the spring and is formed in the embodiment shown in Figure 10b as a circular disc comprising two mutually opposing spring portion arms 311 which are arranged perpendicular to the area. The spring portion arms 311 point in the distal direction. The spring portion arms 311 are guided such that they can be axially shifted in the windows 304 of the adaptor portion. A tooth 312 is
25 respectively arranged on the distal ends of the spring portion arms 311. The teeth 312 project in a lateral direction. The spring 320 is compressed between the annular channel 309 and the spring portion 310, wherein the teeth 312 limit the axial movement of the spring portion arms and spring portion in the proximal direction, since they enter into engagement with the proximal end of the window opening 304 in a predetermined position and thus prevent the
30 spring 320 from expanding further. Pressure on the spring portion in the distal direction enables the spring portion 310 to be shifted in the distal direction, against the resistance of the spring 320, relative to the adaptor 300.

The cannula 330 is arranged coaxially with respect to the adaptor 300 and runs along its central rotational axis through the Luer cone 306. The cannula 330 is fixedly fastened in the Luer cone 306, in particular pressed in and adhered or welded. The cannula 330 establishes a fluid connection between the infusion set, which is connected to the cartridge unit 2 via the Luer lock connector 305, and the drug reservoir. The arrangement of the cannula is shown in Figures 10a and 10b in two longitudinal sections of the adaptor 4 which are orthogonal with respect to each other. As soon as the adaptor 4 is positioned onto the housing 200, the cannula 330 pierces the septum 503 on the carpoule, as shown in Figure 5a, wherein the spring portion 310 is pressed in the distal direction, against the spring resistance of the spring 320, by the distal end of the carpoule 3. The carpoule 3 is locally fixed by the accumulating spring force.

The surface area of the adaptor portion 300 comprises two mutually opposing locking recesses 301, as shown in Figure 10. These locking recesses are formed complementarily with respect to the locking teeth 350 arranged in the opening 206 of the cartridge unit 2. Linear guides 302 are formed on the surface area of the adaptor 300, complementarily with respect to the guiding grooves 355 which are likewise arranged in the opening 206.

The Luer lock connector is compatible in principle with infusion set connector portions which are standardised in accordance with DIN EN 1707:1996. In a deviation from DIN EN 1707:1996, however, the outer diameter of the Luer thread 307 is larger than the 8 mm specified in DIN EN 1707:1996, such that proprietary infusion set connector portions such as the Luer lock connector portion 410 in Figure 2, which exhibit an increased outer diameter of the thread, can also be connected to the Luer lock connector 305.

How the user of the administering apparatus 10 assembles, actuates and uses it is described in the following on the basis of an example embodiment. What happens in the event of errors in the apparatus or, respectively, the administering path is likewise additionally explained on the basis of an example embodiment. The following embodiments merely represent possible examples; the person skilled in the art will be aware that embodiments which deviate from this outline may be developed in an obvious way. These deviating embodiments are hereby expressly inferred and form part of the content of this application, wherein the references used in the following outline relate to the embodiments already discussed.

In order to actuate the administering apparatus 10 a first time, the user firstly inserts a battery 7 into the battery compartment 115 of the base unit 1 provided for this purpose. Once the battery 7 has been inserted, the battery compartment 115 is closed in a tight seal with the aid of the cover 110. Due to the seal 112 provided in the cover, this also closes the battery compartment 115 in a waterproof seal. The administering apparatus 10 is activated by the supply voltage from the battery 7 which is then applied. This switches the load-shedding switch 119, and the power pack 118 is supplied with voltage and charged by means of the energy supply controller 610. The controller 150 simultaneously checks whether a cartridge unit 2 is coupled to the base unit 1. This is achieved via the cartridge unit identifier 602 which controls transmitters 165 and receivers 166. This check is advantageously made every second; in other advantageous configurations, however, polling can also be faster or slower. In one advantageous embodiment, the check rate at which the cartridge unit identifier checks for the presence of a cartridge unit is dependent on the user activity, such that the check rate increases as soon as the user presses one of the push buttons 190, 191, 192 or 193, the apparatus is controlled via another interface, an interrupt of one of the micro-controllers is triggered or the drug is administered or, respectively, drops when no user activity is determined over a particular period and/or administering is not performed.

Once the base unit has been activated, a drug reservoir 3 – in particular, a carpoule 500 – can be inserted into the cartridge unit 2. If a carpoule 500 is used, then it is inserted with its open end to the fore through the opening 206 into the carpoule accommodating region 203 and then loosely positioned onto the carpoule seal 260. The Luer lock connector portion 410 is then screwed into the thread 307 of the infusion set adaptor 4. This establishes a liquid connection between the cannula lumen of the cannula 330 and the lumen of the infusion set 5. The infusion set adaptor 4 is then fitted into the opening 206 of the cartridge unit 2. The adaptor 300 can only be inserted into the opening 206 in two positions, since the guides 302 have to be aligned with the guiding grooves 335 of the cartridge unit. As soon as the adaptor 300 has been inserted deep enough into the opening 206, the locking teeth 350 of the cartridge unit 200 snap into the locking recesses 301 of the adaptor. The adaptor 300 is thus fixed in the opening 206 and can no longer be removed. When inserting the adaptor 300, other steps are performed in a staggered sequence which are exactly co-ordinated in order to ensure that the administering apparatus 10 functions without any problems. By way of explanation, the sequence of these steps is reiterated here: the adaptor 300 is rotatively aligned with respect to the guiding grooves 355, wherein the infusion set adaptor 4 presses the ampoule 500 via the

carpoule seal 260 until it abuts the carpoule stopper 502, and the intermediate space 295 is vented. The carpoule seal 260 then seals off the shift reservoir 295 via the sealing rib 262. The spring 320 is then compressed, since the distal end of the carpoule presses onto the spring portion 310. The cannula 330 then pierces the septum 503 and establishes a fluid connection
5 between the carpoule lumen and the lumen of the infusion set 5. In a final step, the carpoule 500 is slid further in the proximal direction together with the carpoule seal 260, thus opening the hydraulic path, in particular the hydraulic conduit 292. Finally, the carpoule 500 is slid relative to the carpoule seal 260 even further in the proximal direction as far as an axial abutment 267. This shifts the carpoule stopper 502 in the distal direction and moves it into a
10 defined initial position. This shift also causes the drug to be shifted out of the carpoule 500 into the infusion set 5.

As mentioned, the infusion set adaptor ultimately snaps fixedly onto the cartridge unit and can no longer be removed. The cartridge unit 2 is then ready to be coupled to the base unit 1,
15 wherein the two housings 100 and 200 are slid into each other. In order to facilitate coupling, the coupling toothed wheel 125 and the accommodating region 232 are aligned coaxially with respect to each other, such that the coupling toothed wheel 125 points towards the open accommodating region 232 of the pump piston module 230. The accommodating region 104 of the base unit 1 and the guiding elements provided on the two housings facilitate sliding the
20 base unit and the cartridge unit into each other. Once the two units have been completely slid into each other, the latching snapper 202 of the cartridge unit 2 snaps into the latching recess 106 of the base unit 1. As soon as this has occurred, the base unit 1 and the cartridge unit 2 are connected to each other via various interfaces, in particular the drive, the cartridge unit identifier, the piston revolution monitor and the occlusion identifier, wherein one advantage
25 of the design in accordance with the invention is that there are no electrical contacts between the base unit and the cartridge unit, which reduces its susceptibility to malfunctions.

Once the cartridge unit has been correctly coupled to the base unit, the cartridge unit identifying device identifies that a cartridge unit 2 is present. The user can subsequently prime
30 the administering device via the user menu of the administering apparatus 10, wherein priming means completely venting or, respectively, filling the drug path from the drug reservoir 3 up to the distal output of the injection needle on the infusion set 5. After priming, the user will inject the injection needle of the infusion set into the designated tissue of the body and fasten it. It is then possible to begin administering basal profiles or individual

dosages/boli. If a drug is being administered, the drive unit of the base module 1 drives the conveying pump 6 which in turn conveys hydraulic fluid 271 from the hydraulic fluid reservoir 270 into the shift reservoir 295. This increases the volume of the shift reservoir 295 and consequently reduces the drug volume within the carpoule 500. The drug flows via the infusion set adaptor and the infusion set into the tissue of the user. The user can programme administering profiles or also individual dosages via the menu control of the administering apparatus 10.

As already mentioned, the pump piston 231 rotates while conveying hydraulic fluid 271. The coding ring 241 also rotates with the pump piston 231 and thus periodically interrupts the light path of the partial light conductor 282 of the revolution monitor. Thus, this periodic interruption and the respectively subsequent opening of the light path is then a confirmation of the actual rotation of the piston and therefore of the functioning of the conveying pump. The revolution monitor simultaneously produces a measurement variable which serves as a measure of the amount of drug delivered from a particular drug reservoir. In advantageous embodiments, the carpoule 500 contains a defined amount of drug, wherein the drug can in particular be insulin, in which case the carpoule advantageously contains a nominal amount of 300 IU (advantageously at a volume of 3 ml), wherein alternative sizes such as 600, 200 or 150 IU are also conceivable. The measurement variable read from the revolution monitor 602 is correlated with the measurement signals read from the drive monitor 607 and converted in the controller 150 into an amount of drug administered. If the controller 150 identifies that the nominal amount has been reached, the controller stops delivery and prompts the user to change the cartridge unit. In one advantageous configuration, the controller 150 warns the user of the imminent depletion of the drug reservoir via the display 180, buzzer 155 and/or vibration alarm 156 at least 12 hours before the nominal amount is reached, dependent on the administering parameters. These warning alerts are repeated at ever shorter intervals. This alarm mechanism prepares the user in good time for exchanging the cartridge unit 2. In order to change the cartridge unit, the latching snapper 202 is released from its engagement with the latching recess 106, such that the base unit 1 and the cartridge unit 2 can be slid apart. A new cartridge unit 2 can then be coupled to the base unit 1, wherein the same procedure is used as has already been described above. Once the new cartridge unit 2 has been correctly coupled to the base unit 1 and the cartridge unit 2 has been successfully identified by the cartridge unit identifying device 602, the base unit prompts the user in one advantageous embodiment to specify whether the inserted cartridge unit 2 is a unit with a new drug reservoir 3 or whether

the drug reservoir 3 has already been partially emptied. If the drug reservoir is a partially emptied reservoir, then in one advantageous configuration of the embodiment, the user can programme the residual amount of the drug present into the administering apparatus. In the next step, priming can again be performed in order to fill the infusion set 5 with the drug. The user can in fact trigger priming at any time, advantageously when the infusion set has to be changed. In order to change the infusion set, administering can be temporarily interrupted by the user via the controller. The user can then unscrew the Luer lock connector portion 410 from the infusion set adaptor 4 and then screw a new infusion set back in. The user can then trigger priming and, after priming, restart administering.

In one advantageous embodiment of the administering apparatus, the first priming also activates the occlusion monitor which monitors the pressure in the hydraulic system. If the pressure exceeds a particular limit value or if the pressure increases excessively quickly, the controller can output a warning to the display 180 or, respectively, output warning signals via the buzzer 155 or vibration alarm 156. In one advantageous configuration of the embodiment, the controller 150 correlates the pressure signals with the revolution monitor 602 the drive monitor 607 and/or the means for identifying the cartridge 165, 166, 167 and verifies the pressure signals against the revolution monitor 602 and the drive monitor 607. The measurement results can thus be verified as to their plausibility before a warning alert is triggered, and differentiated warning alerts can be generated.

The administering apparatus 10 can only draw a finite amount of energy from the battery 7, for which reason the battery has to be changed from time to time. The energy supply controller 610 monitors the energy level of the battery, such that in preferred embodiments, the controller can firstly output warning alerts when the energy level is low and then trigger an alarm when the energy level is very low and stop the administering of the drug. The warning alerts and the alarm can be outputted via the display 180, the buzzer 155 and/or the vibration alarm 156. The user can exchange the battery 7 at any time, independently of warning alerts or an alarm. To this end, the user opens the battery compartment cover 110 in one preferred configuration. This interrupts the voltage supply from the battery 7, and the power pack 118 assumes the function of supplying power to the administering device. The controller 150 can accordingly interrupt administering and output an alarm alert, in an analogous way to the alarm alert described when the energy level of the battery 7 is low. In one preferred embodiment, the user can then insert a new battery 7, close the battery

compartment cover 110 and confirm the alarm alert by pressing a key, in order for the administering device 10 to continue administering the drug.

In another embodiment, inserting the battery 7 and confirming the alarm alert which follows the opening of the battery compartment can be followed by a self-test of the administering apparatus 10, wherein in particular the display, the buzzer and the vibration alarm are checked as to whether they are functioning, wherein in one preferred configuration, the user confirms each partial function. Alternatively, the self-test can be concluded by a single confirmation or can be automatically concluded without any user activity. In preferred embodiments, the self-test described can be enforced not only by a battery change, but in another advantageous configuration also at regular time intervals. In another configuration, the self-test can also be performed after the cartridge unit is changed.

6 List of reference signs

15	10	administering apparatus
	1	base unit
	2	cartridge unit
	3	drug reservoir
	4	infusion set adaptor
20	5	infusion set
	6	conveying pump
	7	battery
	100	housing of the base unit
	101	housing cover
25	102	holding region
	103	bearing region
	104	accommodating region
	105	guiding region
	105'	guiding region
30	106	latching recess
	107	guide
	108	window for the cartridge unit identifier
	109	IrDA window
	110	battery compartment cover

	111	battery compartment cover threaded insert / opening
	112	seal
	115	battery compartment
	116	battery compartment threaded insert
5	117	negative terminal connector in the battery compartment / spring
	118	power pack
	119	load-shedding switch
	120	motor
	121	gear system
10	122	encoder wheel
	123	rotation detector
	125	coupling toothed wheel
	126	seal
	127	drive shaft
15	128	opening
	129	rotational elements / openings
	130	occlusion identifier
	131	transmission element for the occlusion identifier
	132	seal for the occlusion identifier
20	133	membrane
	134	plunger
	135	opening
	140	force measuring sensor device
	150	redundant control electronics
25	151	micro-controller 1
	152	micro-controller 2
	153	quartz crystal
	154	voltage converter
	155	buzzer
30	156	vibration alarm
	157	rigid circuit board element
	158	flexible circuit board element
	160	IrDA interface
	161	infrared transmitter

	162	infrared receiver
	165	transmitter
	166	receiver
	167	receiver
5	180	display
	181	date
	182	time
	183	battery status
	184	line 1
10	185	line 2
	186	graphic display segment
	187	graphic display segment
	190	push button
	191	push button
15	192	push button
	193	push button
	200	housing of the cartridge unit
	201	bottom plate
	202	latching snapper
20	203	carpoule accommodating region
	204	intermediate wall
	205	intermediate wall
	206	opening
	207	opening
25	208	tongue
	209	tooth
	210	base plate comprising cylinder
	211	pump cylinder
	212	opening
30	213	surface area
	214	inlet nozzle
	215	outlet nozzle
	216	receptacle for the carpoule seal
	217	circular seals

	218	guiding elements
	220	control cam module
	221	control cam
	230	pump piston module
5	231	pump piston
	232	accommodating region
	233	valve area
	234	control cam counterpart area
	235	pump volume
10	240	coding ring module
	241	coding ring
	250	membrane for the occlusion identifier
	251	space
	252	plunger
15	260	carpoule seal
	261	sealing element
	262	sealing rib
	263	liquid through-let
	264	tooth
20	265	axial ribs
	266	axial channels
	267	axial abutment
	270	hydraulic reservoir
	271	hydraulic fluid
25	272	hydraulic reservoir wall
	275	spout
	276	septum
	280	light conductor module
	281	partial light conductor for cartridge unit identifier
30	282	partial light conductor for piston revolution identifier
	283	opening
	290	hydraulic path
	291	hydraulic conduit
	292	hydraulic conduit

	293	blind channel
	294	hydraulic passage
	295	shift reservoir
	300	adaptor
5	301	locking recess
	302	guide
	303	abutment
	304	window
	305	Luer lock connector
10	306	Luer cone
	307	Luer thread
	308	collar
	309	annular channel
	310	spring portion
15	311	spring portion arm
	312	tooth
	320	spring
	330	cannula
	350	locking tooth
20	355	guiding groove
	410	Luer lock connector portion
	420	flexible tube
	500	carpoule
	501	glass body
25	502	stopper
	503	septum
	504	shutter sleeve
	505	opening
30	600	software
	601	clock
	602	cartridge unit identifier and revolution monitor
	603	memory for delivery parameters
	604	log memory

- 605 delivery regulator
- 606 drive regulator
- 607 drive monitor
- 608 occlusion identifier
- 5 609 feed monitor
- 610 energy supply controller
- 611 key monitor
- 612 controller for the infrared interfaces
- 613 display controller
- 10 614 buzzer controller
- 615 vibration alarm controller

- 1275 flexible tube

5 Claims

1. A device for administering a fluid product, in particular a drug in liquid form, with a hydraulic drive, comprising:

- 10 - a hydraulic path;
- hydraulic fluid which can be transported via the hydraulic path;
- a drug reservoir comprising a moving stopper which can be moved by the hydraulic drive in order to administer the drug, wherein the stopper divides the drug reservoir into two volume regions,
- 15 - the first of which comprises the drug, and
- the second of which comprises a shift reservoir into which hydraulic fluid can be introduced through an opening;
- a housing comprising a receptacle for the drug reservoir;
- a conveying pump which can convey the hydraulic fluid to the shift reservoir via the
- 20 hydraulic path;
- a sealing device via which the hydraulic path can be connected to the shift reservoir,

wherein the drug reservoir can be inserted into the receptacle and is formed such that it can be fitted onto the sealing device, and the sealing device seals off the opening in the shift

25 reservoir after the drug reservoir has been fitted on,

characterised in that

the sealing device comprises guiding elements, at least one venting element and at least one

30 sealing element,

wherein the shape and size of the at least one sealing element are adapted to the opening, the guiding elements are aligned such that they guide the drug reservoir during the fitting-on movement, and the venting elements vent the shift reservoir during the fitting-on movement, and

wherein the at least one sealing element is arranged downstream of the guiding elements in the direction of the fitting-on movement, such that the sealing element seals off the shift reservoir at the end of the fitting-on movement.

5 2. The device according to claim 1, characterised in that the guiding elements are formed as ribs and are arranged on an outer area of the sealing device.

3. The device according to claim 1, characterised in that the at least one venting element exhibits the shape of an open channel and runs on an outer area of the sealing device.

10

4. The device according to claim 1, characterised in that the at least one venting element exhibits the shape of a closed channel and leads in an axial direction through the sealing device.

15 5. A device for administering a fluid product, in particular a drug in liquid form, with a modular design, comprising:

- a re-usable base unit comprising a drive device;
- an exchangeable cartridge unit comprising a conveying device;
- 20 - a transmission device which can transmit mechanical movement from the drive device onto the conveying device; and
- a checking device for verifying the connection between the base unit and the cartridge unit,

wherein the checking device contains a transmitter which is arranged in the base unit and
25 emits a field or waves,

wherein the checking device contains a first deflecting device which is arranged in the cartridge unit and deflects some of the field or waves emitted by the transmitter, and

wherein the checking device contains a first receiver which is arranged in the base unit and measures the field deflected by the first deflecting device or receives the waves deflected by

30 the first deflecting device when the cartridge unit is correctly connected to the base unit,

characterised in that

- the checking device contains a second deflecting device which is arranged in the cartridge unit and deflects some of the field or waves emitted by the transmitter, wherein the field or the path of the waves in the second deflecting device is influenced by the conveying device when the conveying device is moved by the drive device, and **in that**

- 5 - the checking device contains a second receiver which is arranged in the base unit and measures the field deflected by the second deflecting device or receives the waves deflected by the second deflecting device.

10 6. The device according to claim 5, characterised in that the waves are electromagnetic waves.

7. The device according to claim 6, characterised in that the electromagnetic waves are light.

15 8. The device according to claim 7, characterised in that the deflecting devices contain at least one light conductor.

20 9. The device according to any one of claims 6 to 8, characterised in that the second receiver receives deflected waves when the cartridge unit is correctly connected to the base unit and the path of the waves in the second deflecting device is not influenced by the conveying device.

10. The device according to claim 5, characterised in that the waves are acoustic waves.

25 11. The device according to claim 10, characterised in that the acoustic waves are ultrasound.

12. The device according to any one of claims 5 to 11, characterised in that the deflecting device contains at least one reflector.

30

13. A device for administering a fluid product, in particular a drug in liquid form, with a modular design, comprising:

- a re-usable base unit comprising a drive device;

- an exchangeable cartridge unit comprising a conveying device, wherein the conveying device comprises a piston pump comprising a rotating piston; and
- a transmission device which can transmit mechanical movement from the drive device onto the conveying device,

5 wherein the transmission device comprises a slaving means which is arranged on the base unit and is rotationally set in motion about an axis by the drive device,
wherein the transmission device comprises a transmission element which is arranged on the piston of the piston pump and can be rotationally set in motion by the slaving means, and
wherein the transmission element and the slaving means can be releasably connected to each
10 other,

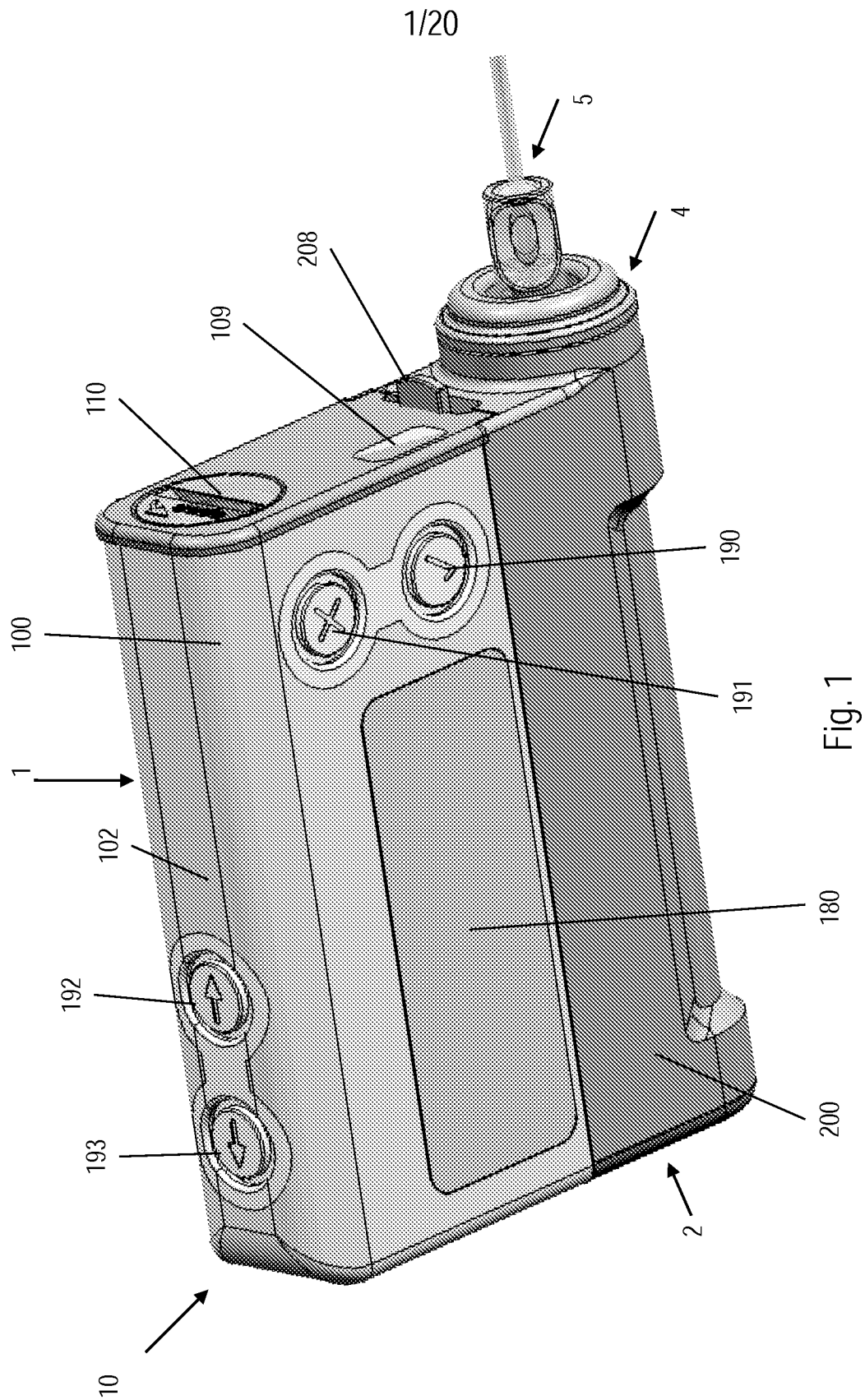
characterised in that

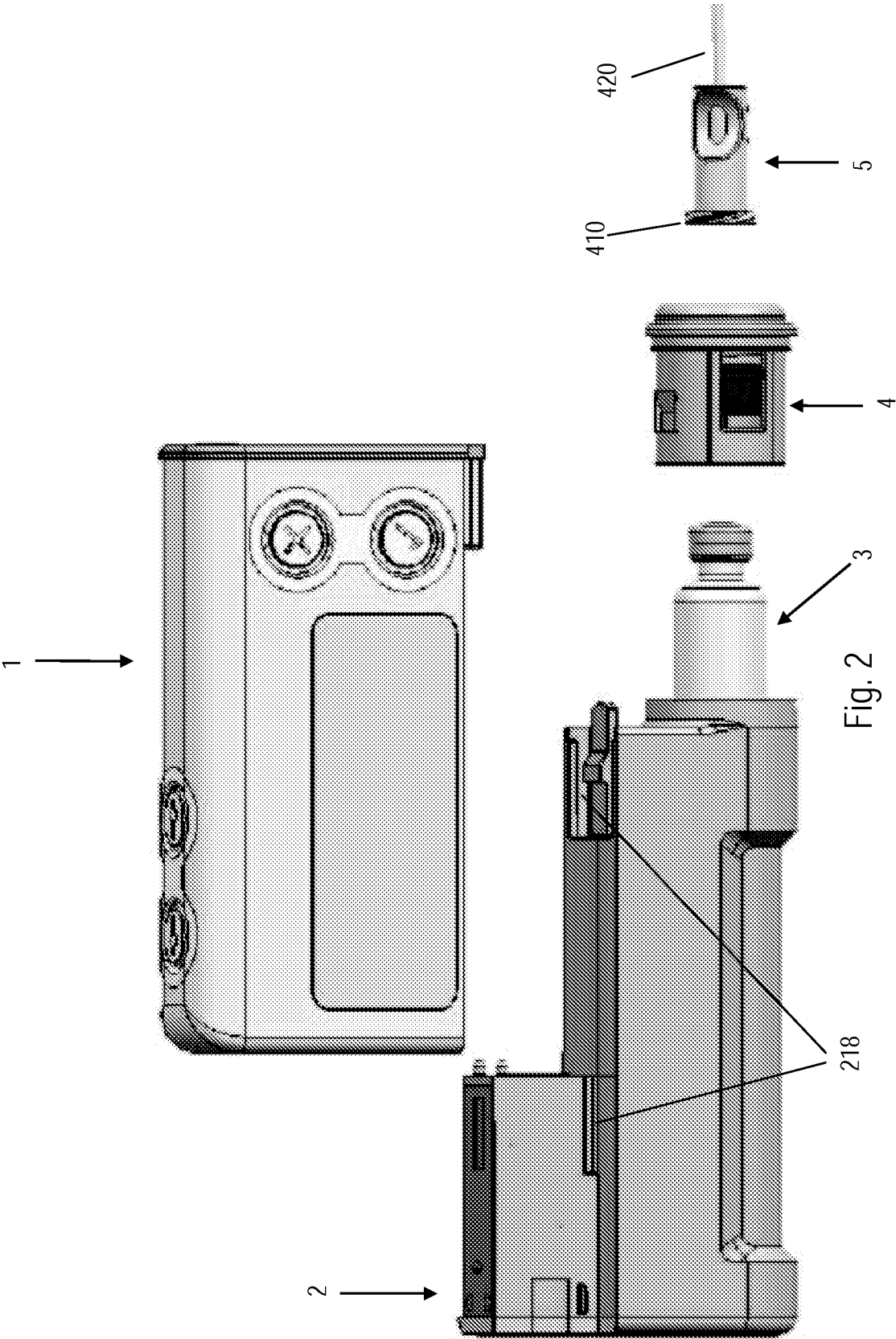
the drive device can drive the piston pump by transmitting a rotational movement, wherein
15 the rotational movement is transmitted from the slaving means onto the transmission element, and the transmission element is mounted such that it can be slid relative to the slaving means but is secured against rotation during the rotation, such that the drive movement is transmitted independently of the stroke position of the piston.

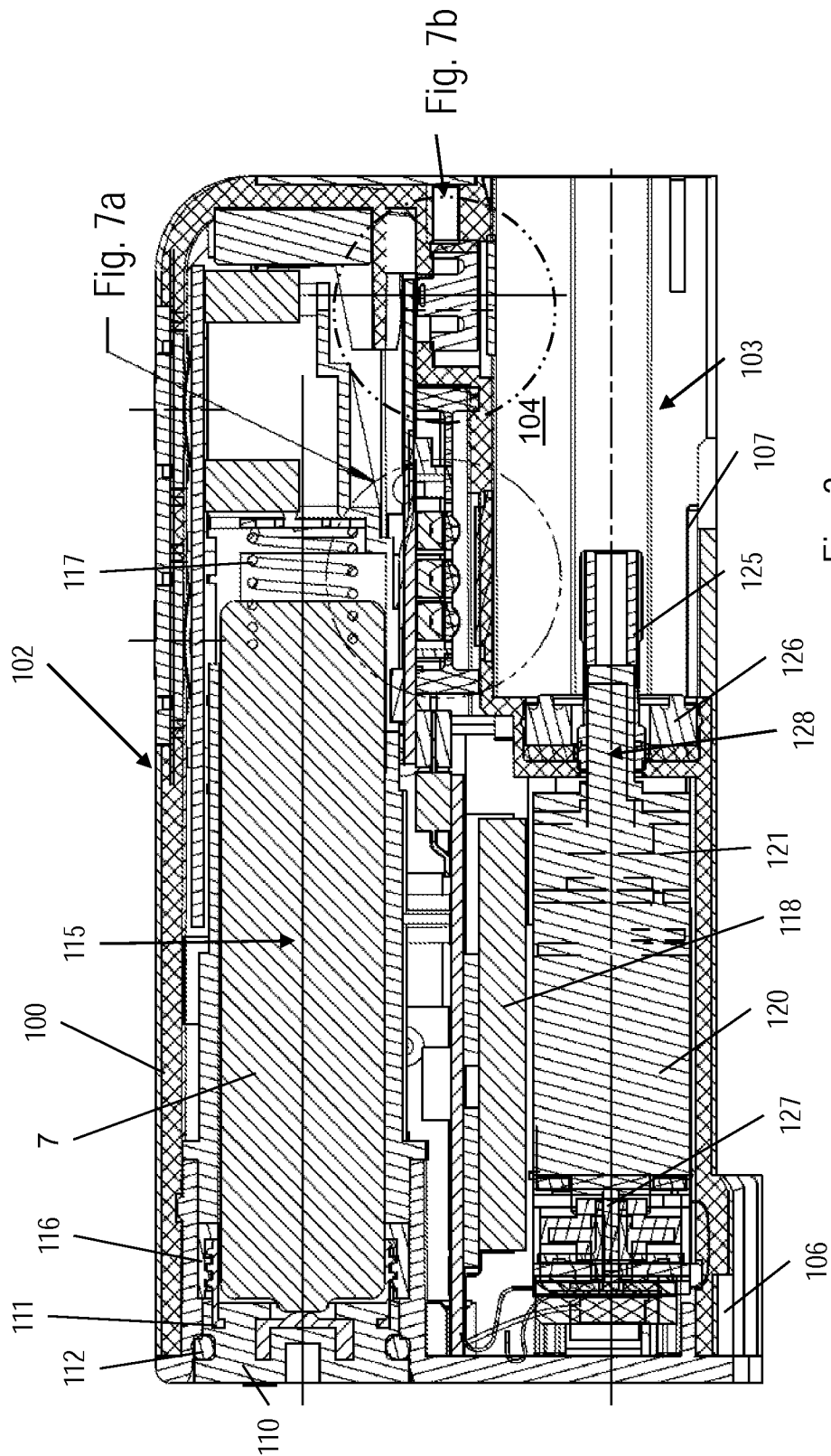
20 14. The device according to claim 13, characterised in that the slaving means and the transmission element can be engaged with each other via a toothing.

15. The device according to claim 14, characterised in that the toothing is generated by teeth on the slaving means and transmission element which are perpendicular to the axis of
25 the rotation.

16. The device according to claim 14, characterised in that the toothing is generated by teeth on the slaving means and transmission element which run parallel to the axis of the
30 rotation.







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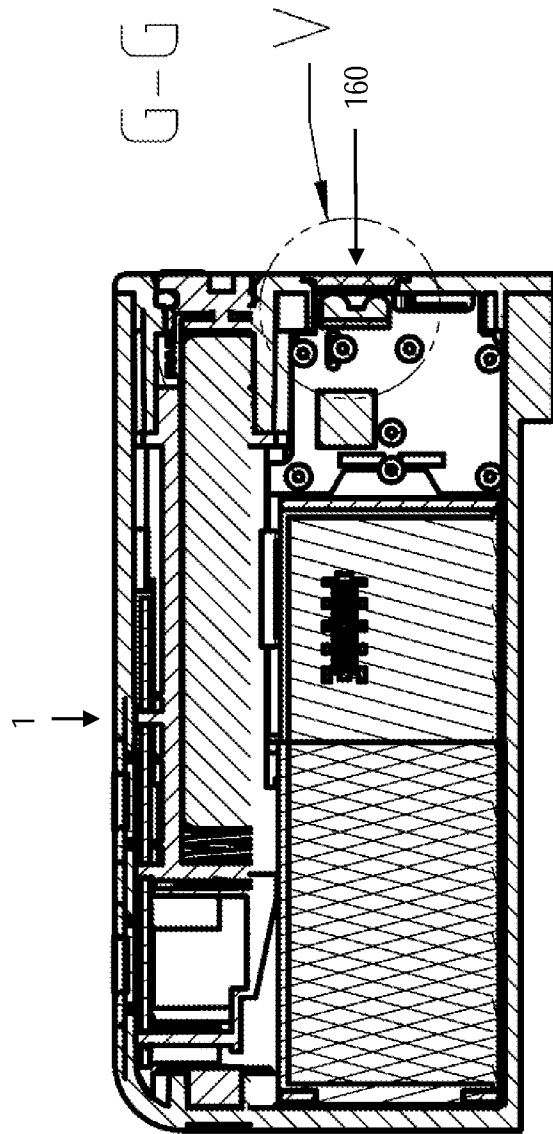


Fig. 3b

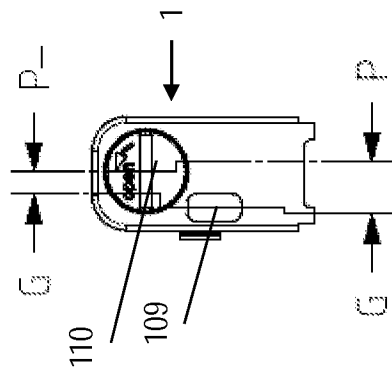


Fig. 3a

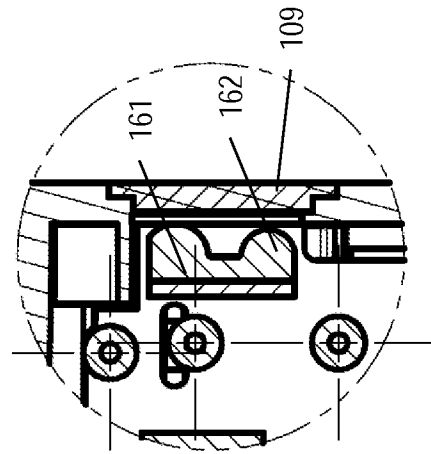


Fig. 3c

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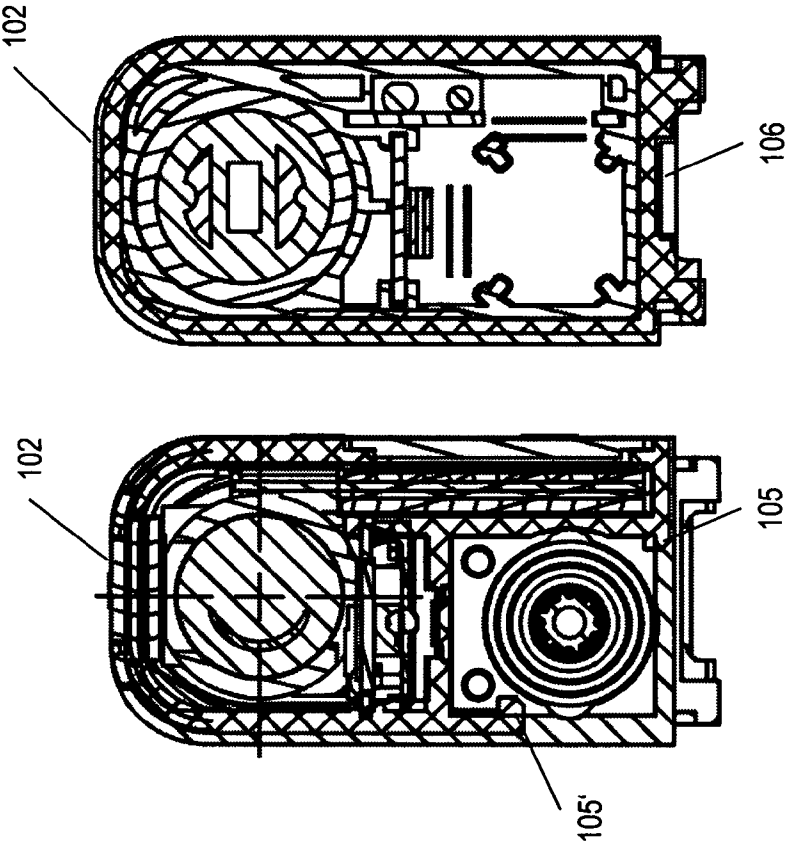


Fig. 4b

Fig. 4a

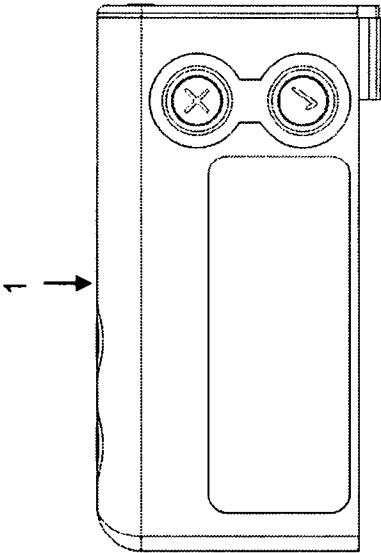
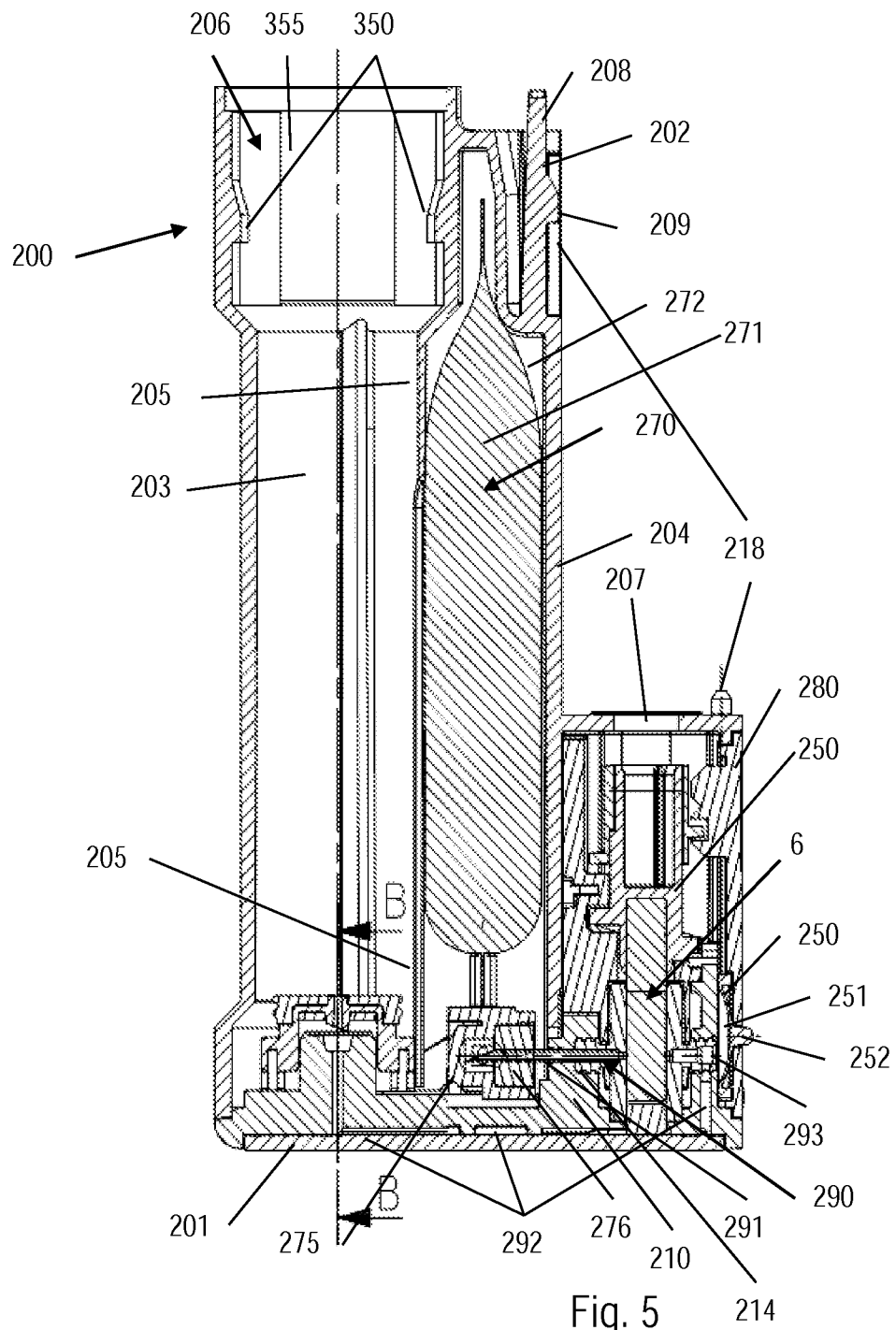


Fig. 4

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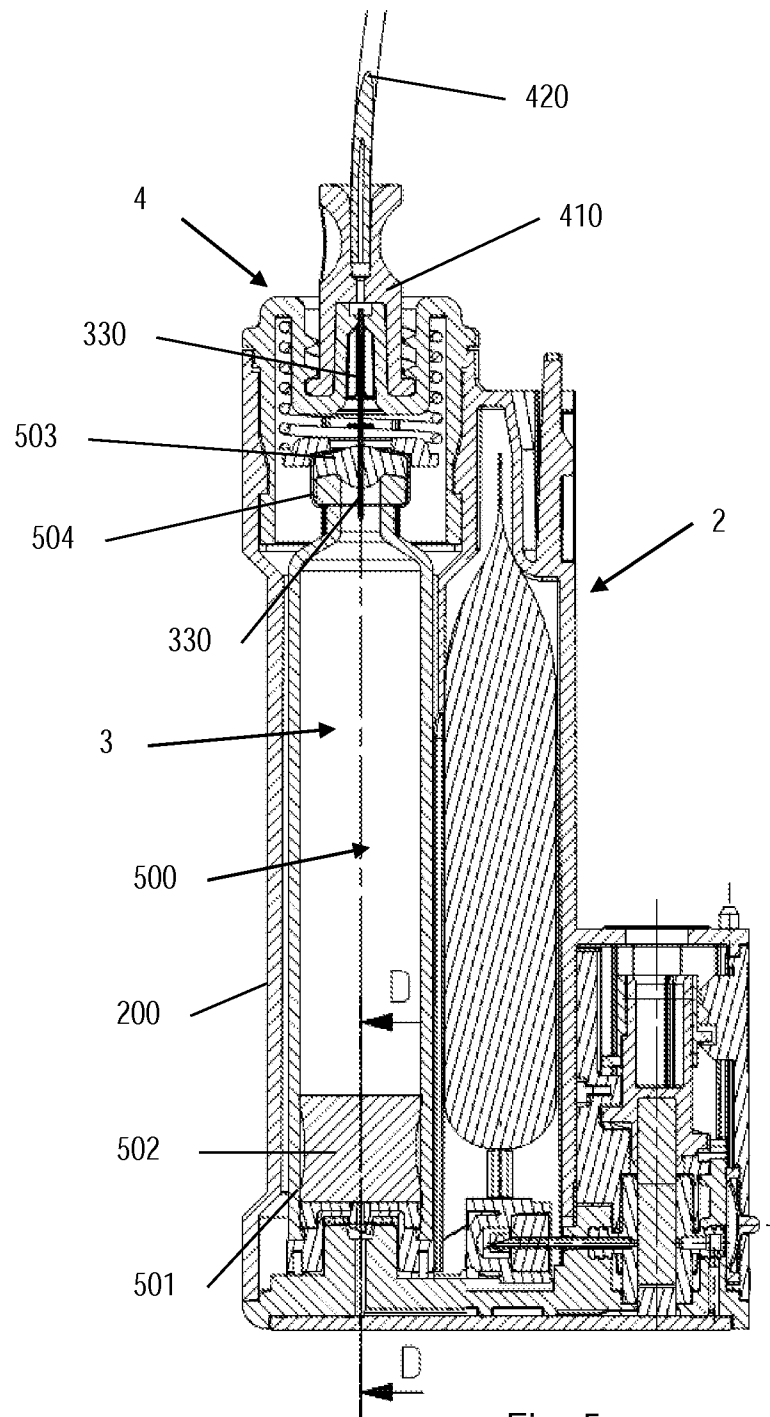


Fig. 5a

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D-D

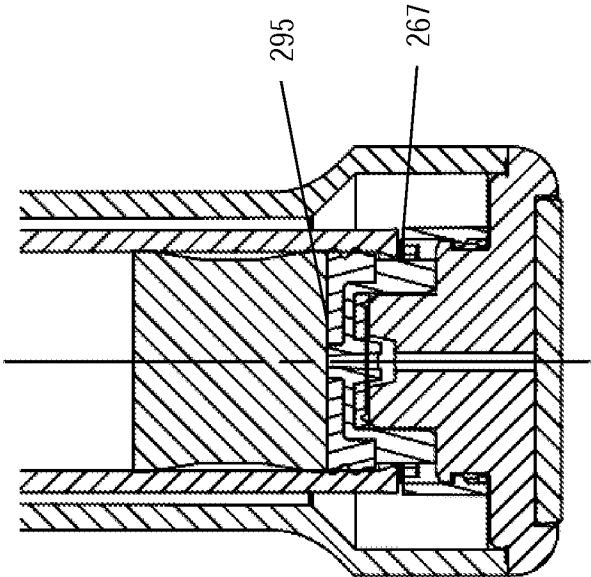


Fig. 5d

B-B

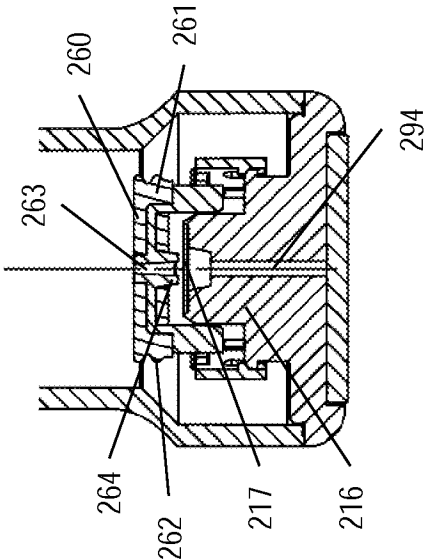


Fig. 5b

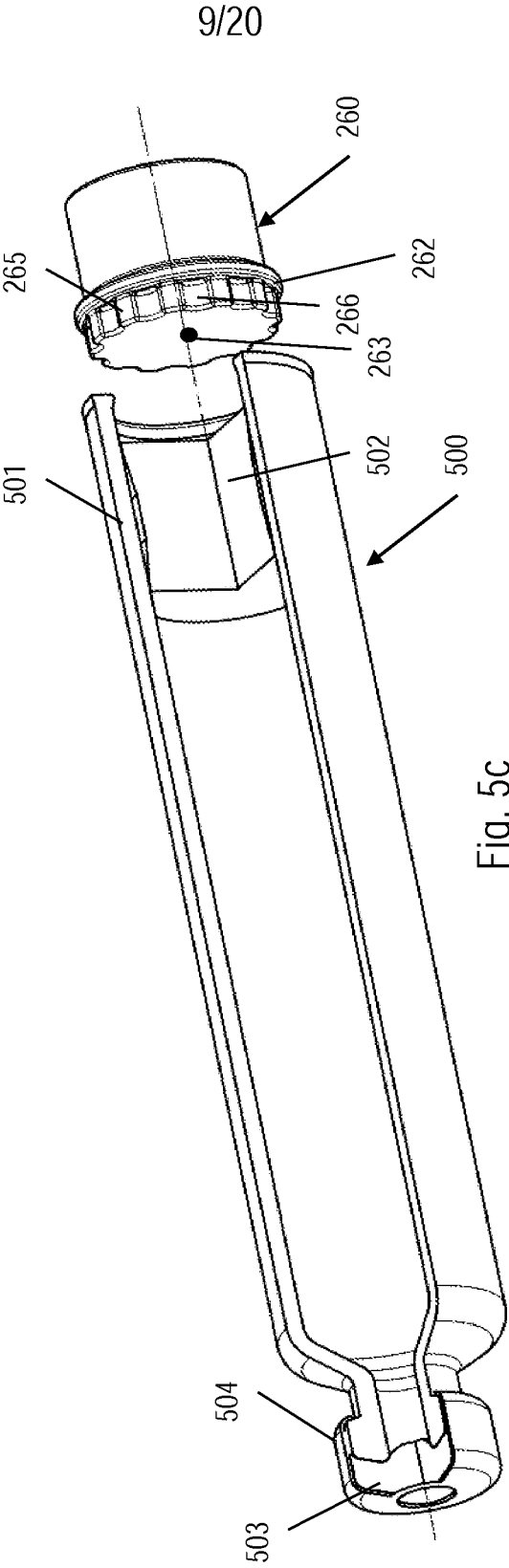


Fig. 5c

10/20

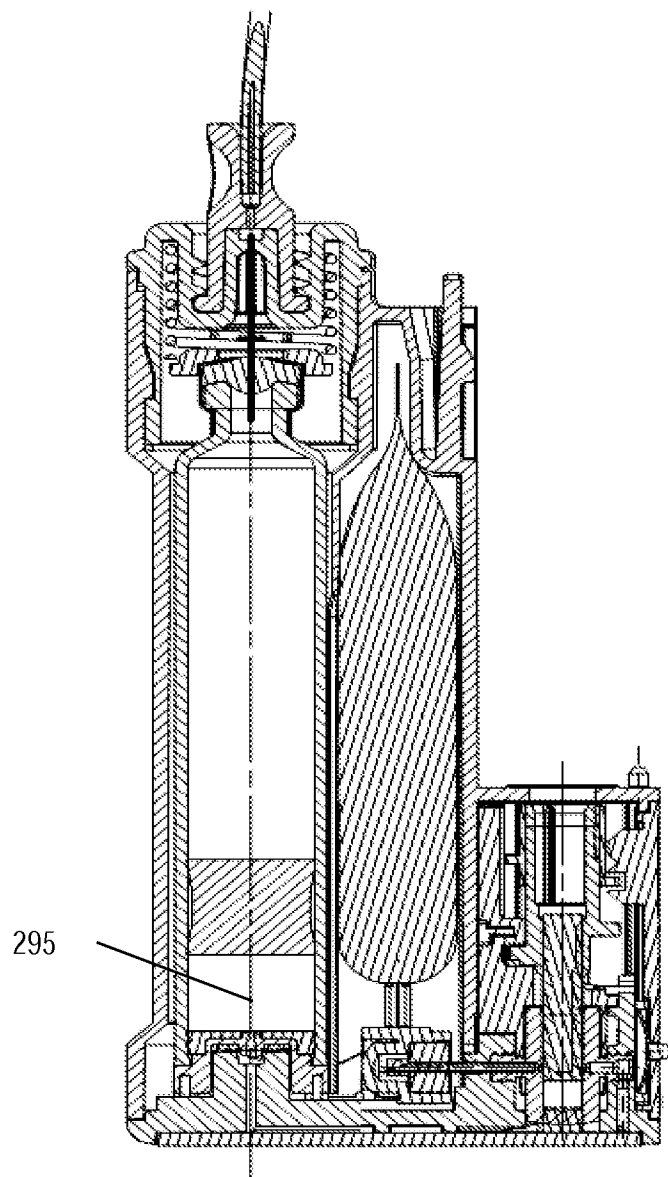


Fig. 5e

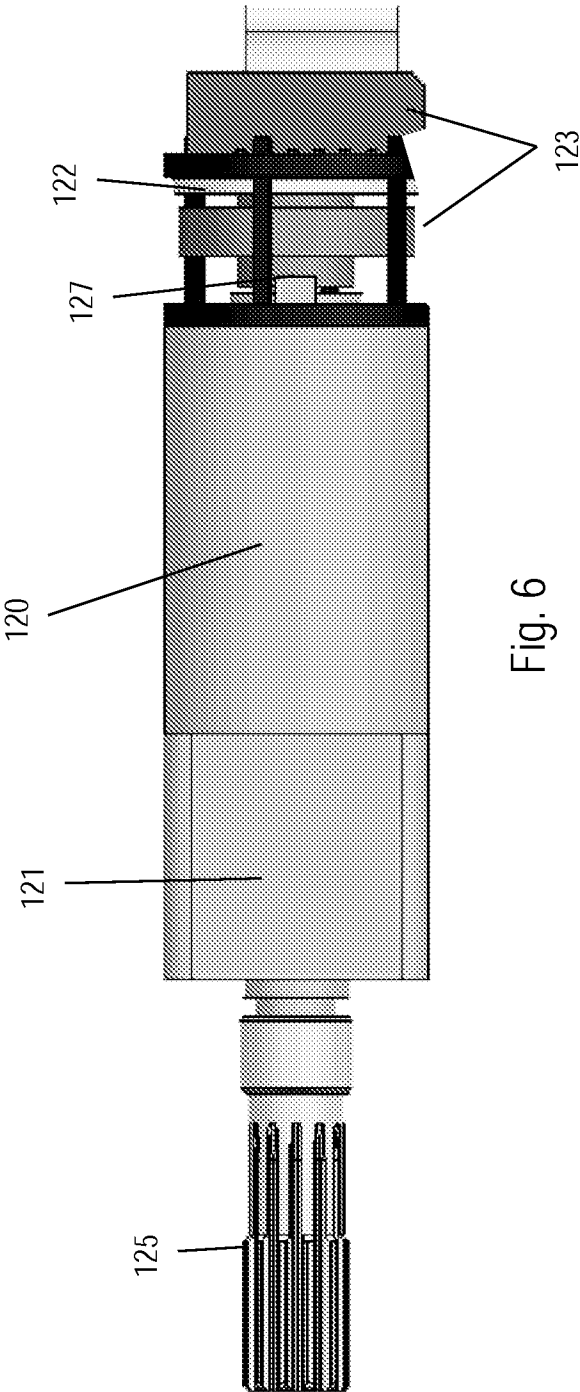


Fig. 6

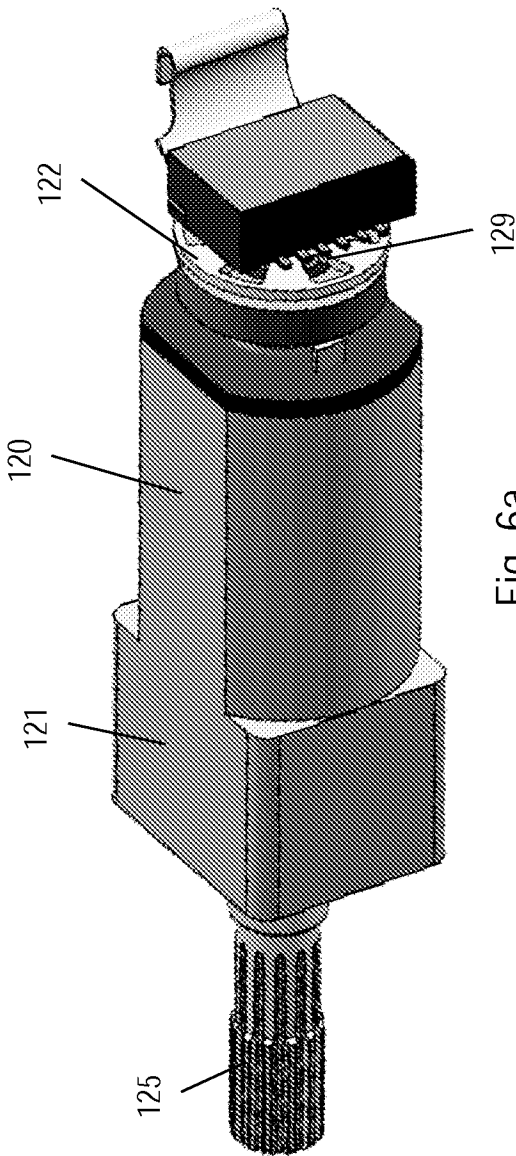
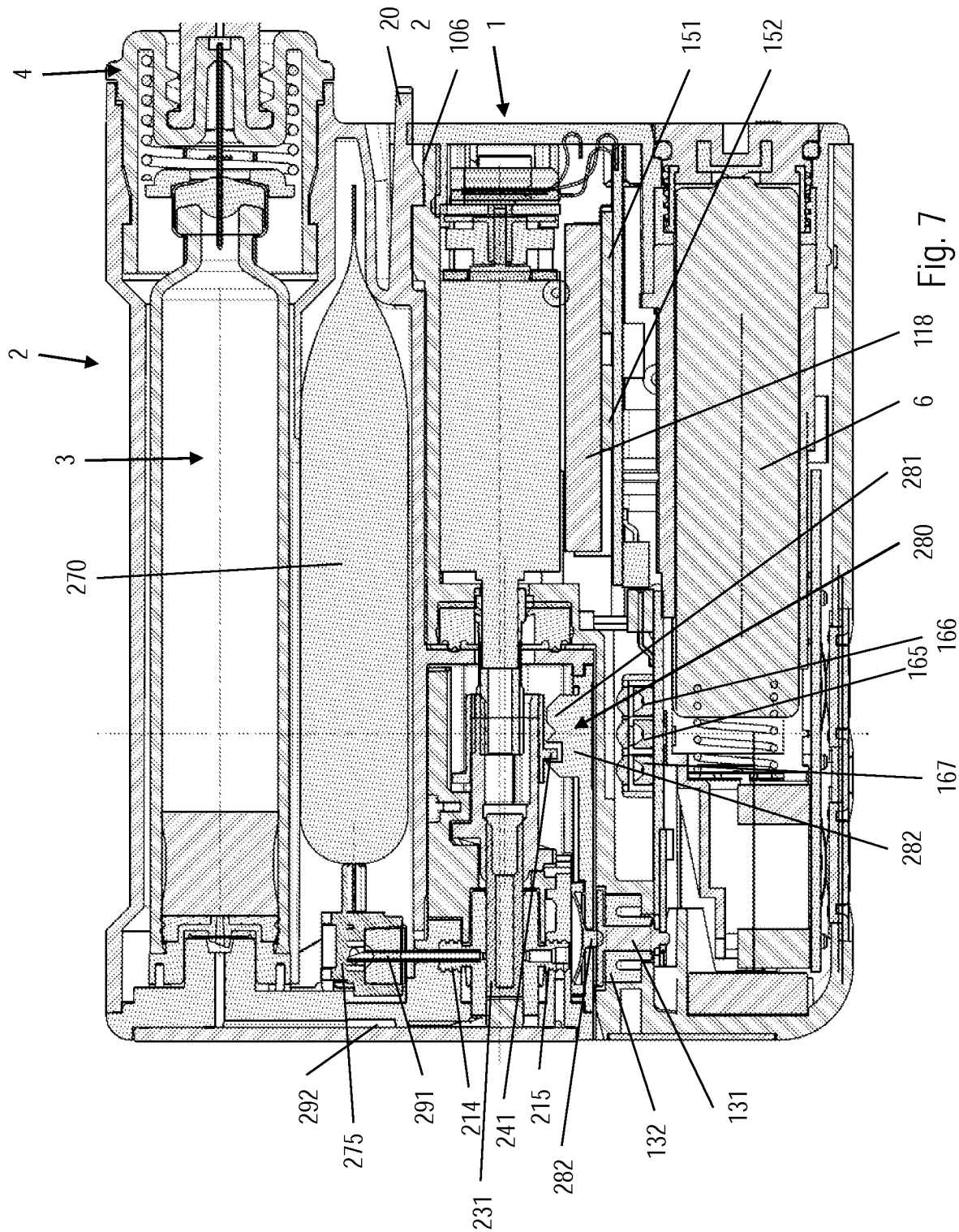


Fig. 6a

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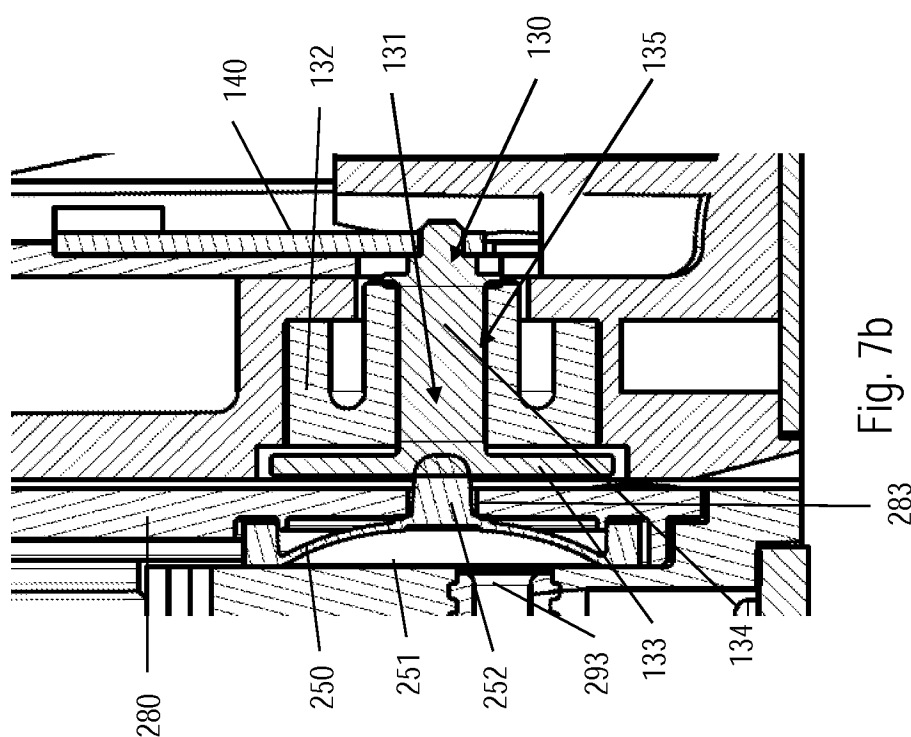


Fig. 7b

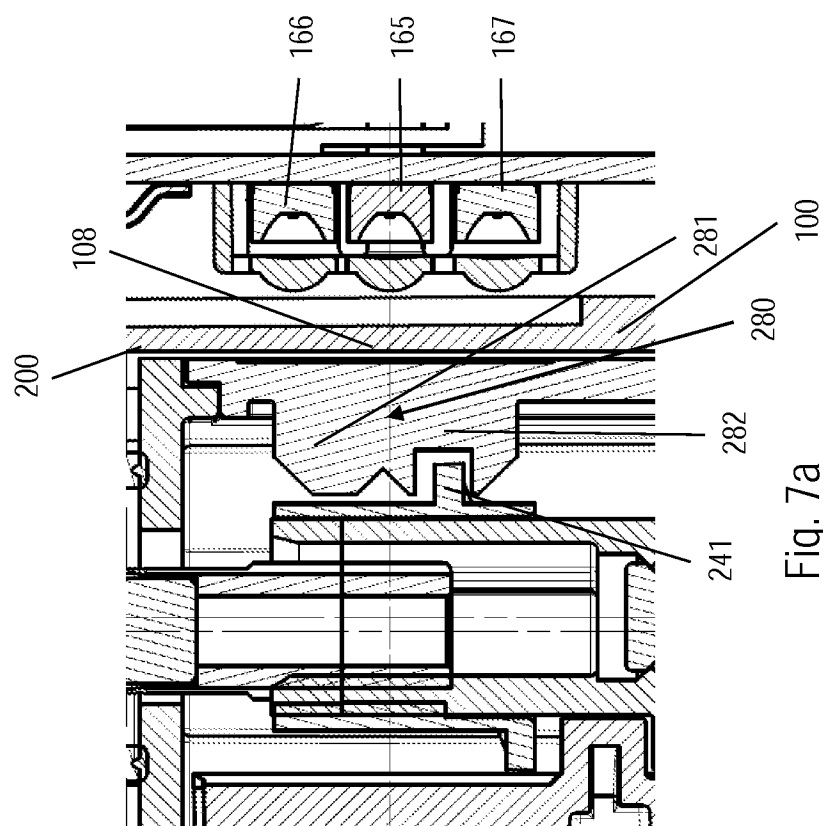


Fig. 7a

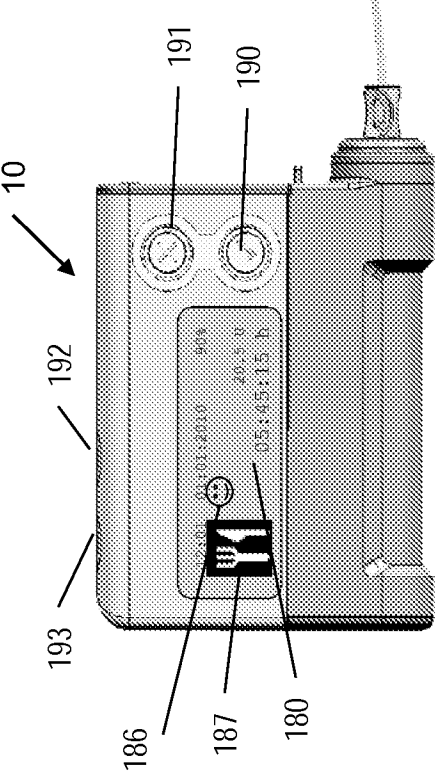


Fig. 8

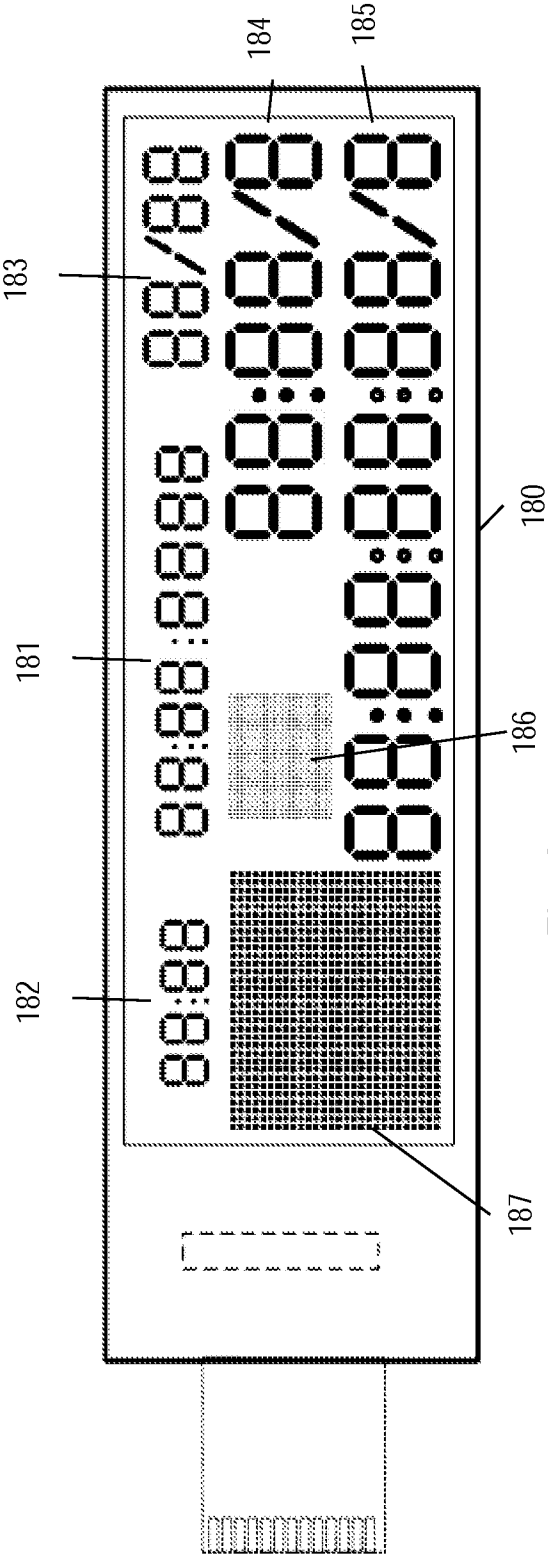


Fig. 8a

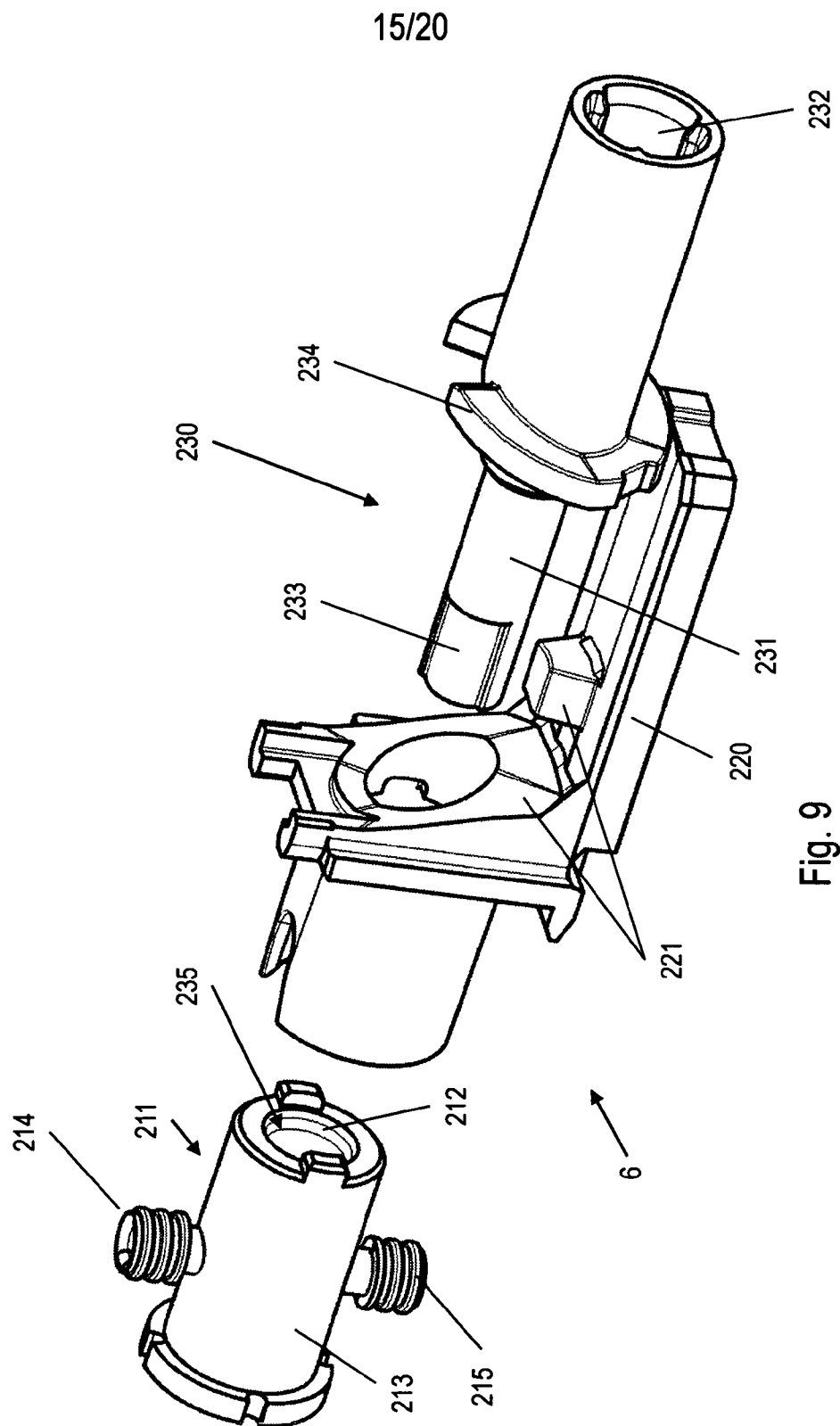


Fig. 9

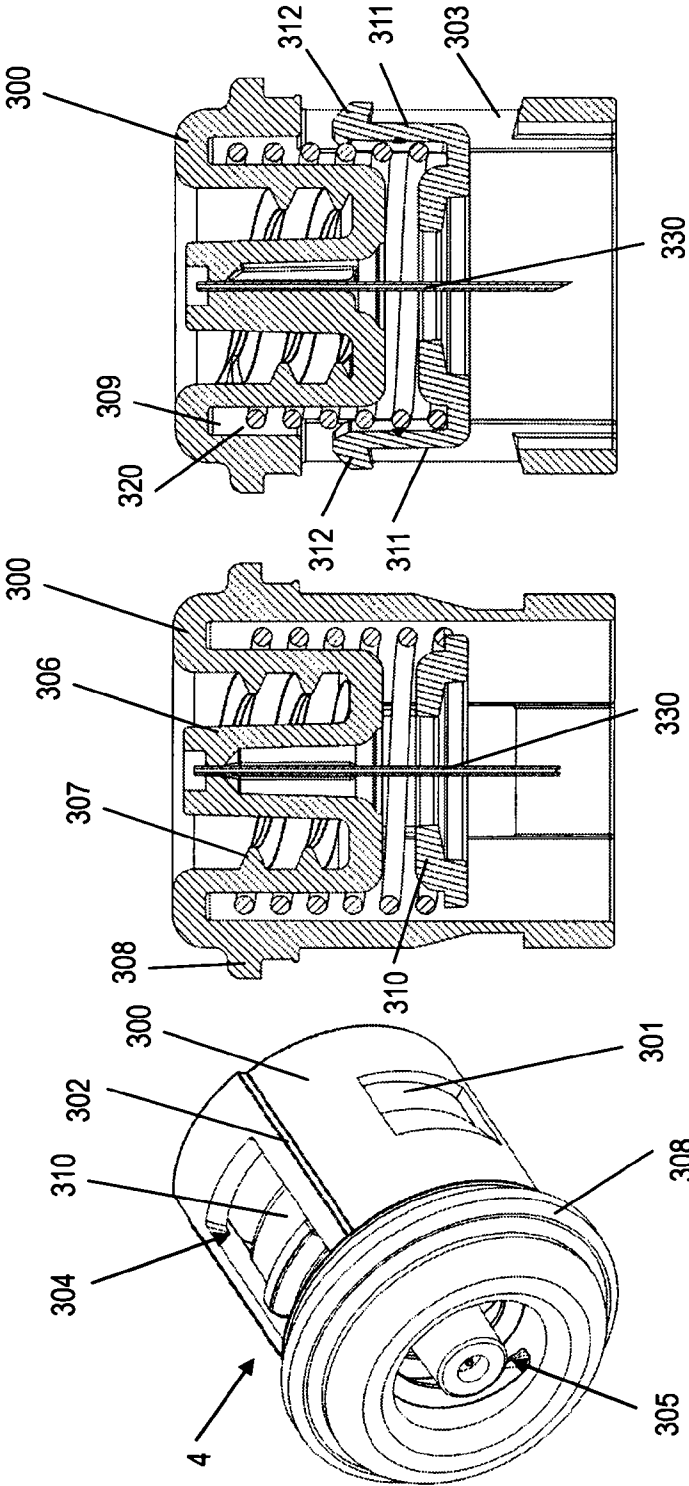


Fig. 10b

Fig. 10a

Fig. 10

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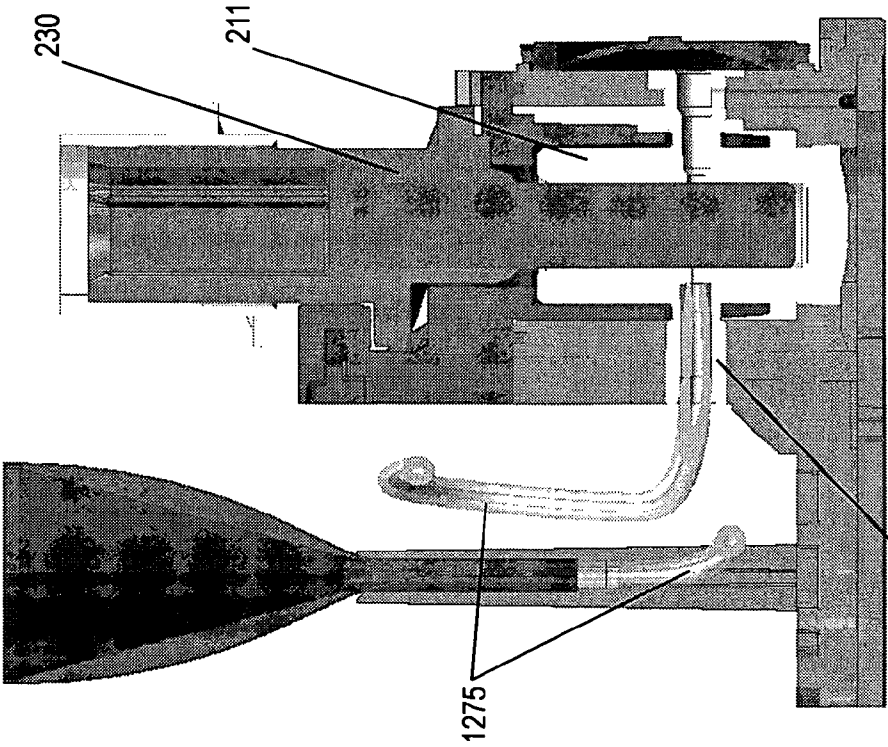


Fig. 11a

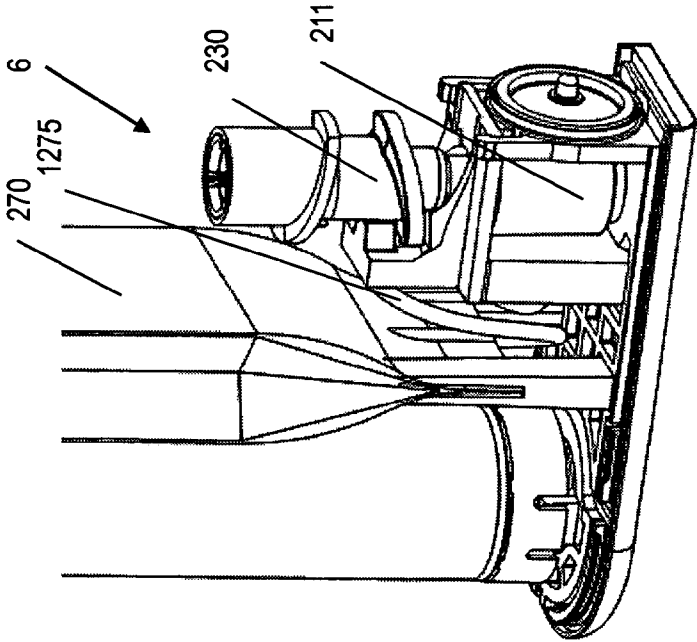
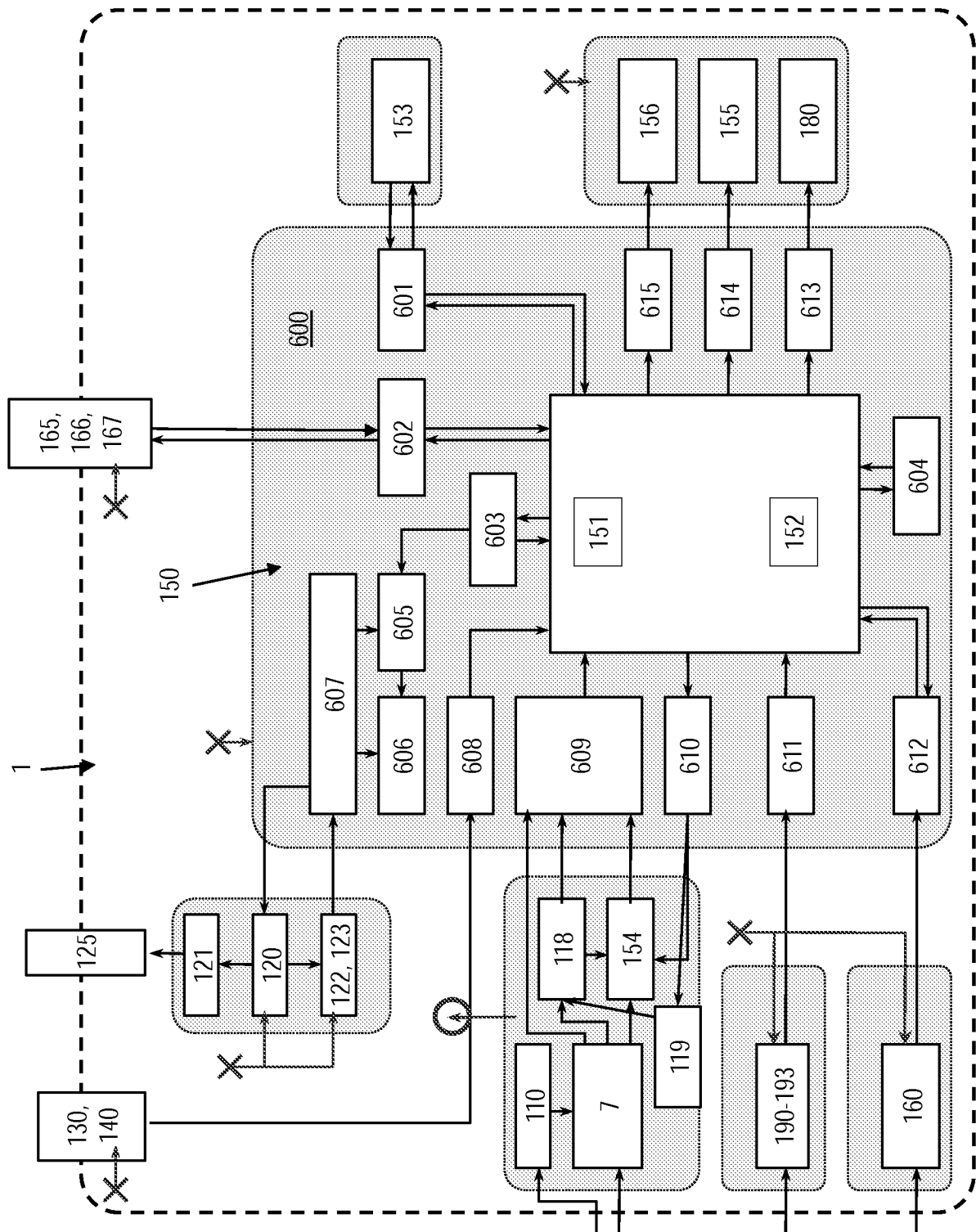


Fig. 11



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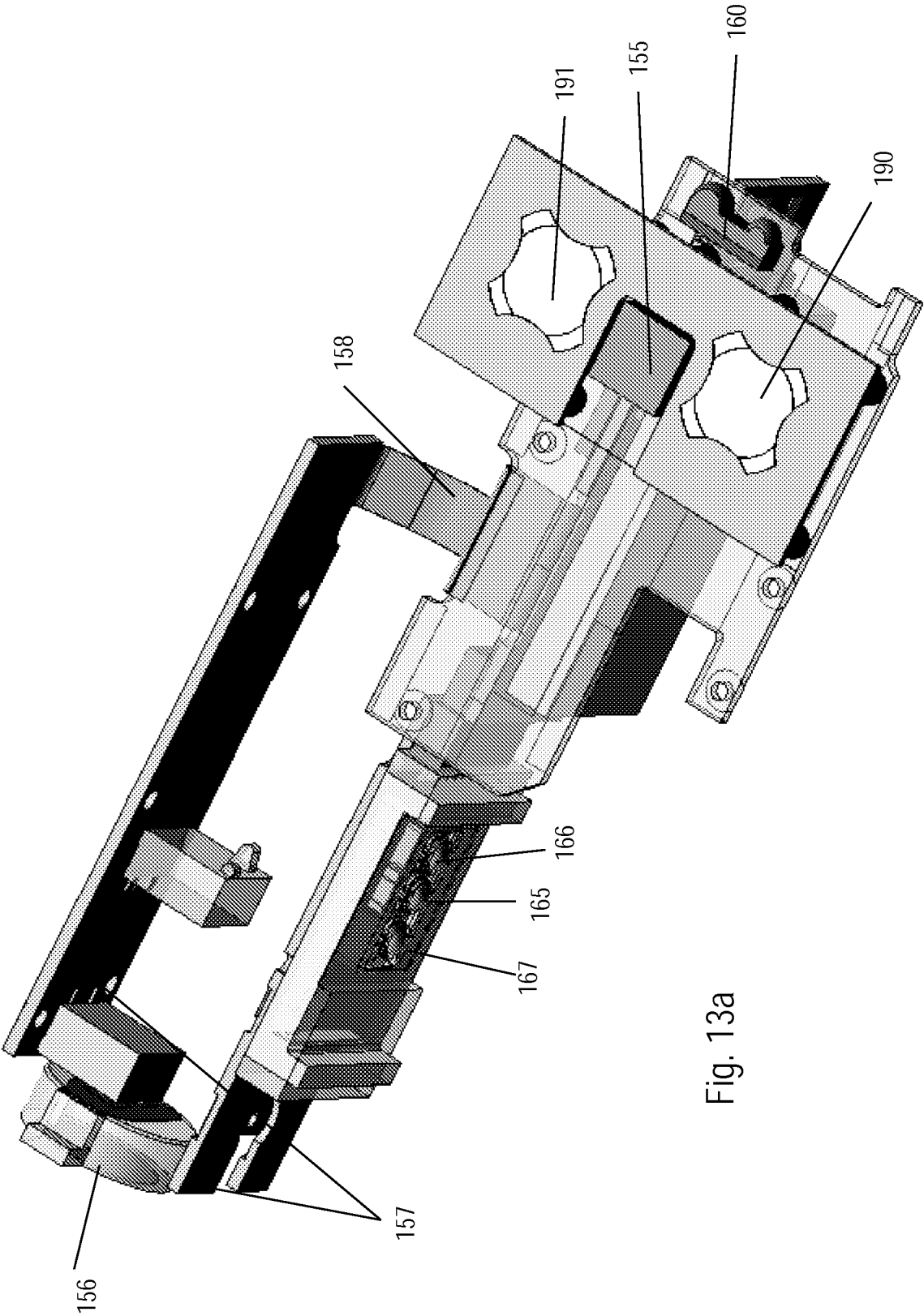


Fig. 13a

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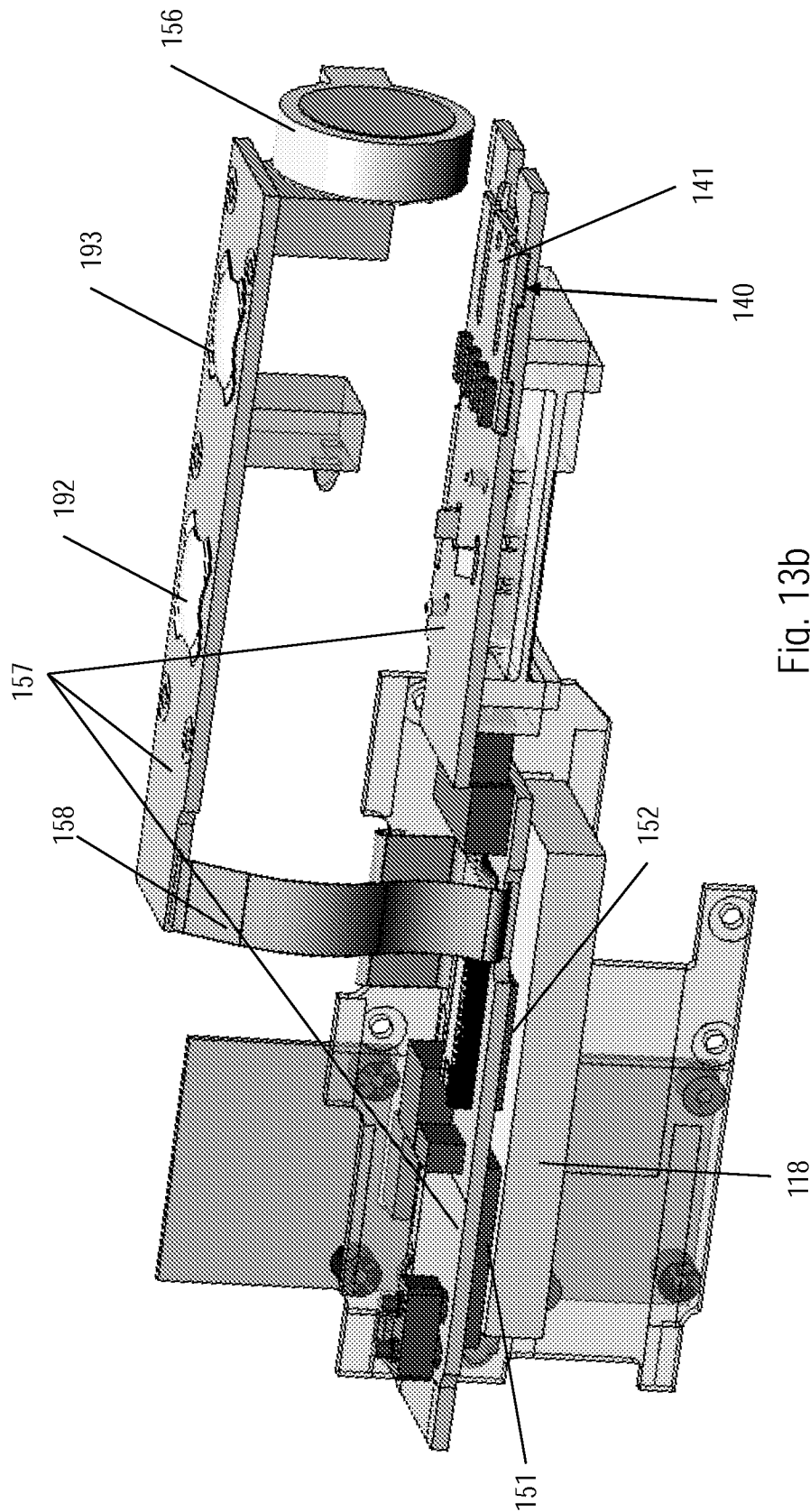


Fig. 13b

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/060065

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/14 A61M5/142 A61M5/145
ADD. A61M5/168

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)

EP0-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2011/009224 A2 (TECPHARMA LICENSING AG [CH]; HOMMANN EDGAR [CH]; HATTLER ERIC [CH]; MA) 27 January 2011 (2011-01-27) the whole document -----	1-4
X	WO 2006/114012 A1 (TECPHARMA LICENSING AG [CH]; KIRCHHOFFER FRITZ [CH]) 2 November 2006 (2006-11-02) the whole document -----	1-4
X	WO 2007/131367 A1 (TECPHARMA LICENSING AG [CH]; KIRCHHOFFER FRITZ [CH]; CLAVADETSCHER JUER) 22 November 2007 (2007-11-22) the whole document -----	1-4

☐

Further documents are listed in the continuation of Box C.

☒

See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

19 April 2012

Date of mailing of the international search report

27/07/2012

Name and mailing address of the ISA/

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

Authorized officer

Ceccarelli, David

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2011/060065

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-4

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-4

A device for administering a fluid product with a hydraulic drive with a hydraulic path, a drug reservoir comprising a moving stopper which can be moved by the hydraulic drive in order to administer the drug, a housing comprising a receptacle for the drug reservoir, a conveying pump and a sealing device via which the hydraulic path can be connected to the drug reservoir, wherein the drug reservoir can be inserted into the receptacle and is formed such that it can be fitted onto the sealing device, the sealing device comprises guiding elements, at least one venting element and at least one sealing element.

2. claims: 5-12

A device for administering a fluid product comprising a re-usable base unit comprising a drive device, an exchangeable cartridge unit comprising a conveying device, a transmission device which can transmit mechanical movement from the drive device onto the conveying device and a checking device for verifying the connection between the base unit and the cartridge unit, wherein the checking device contains a transmitter which is arranged in the base unit and emits a field or waves, a first and second deflecting device which are arranged in the cartridge unit and deflect some of the field or waves emitted by the transmitter, and a first and second receiver which are arranged in the base.

3. claims: 13-16

A device for administering a fluid product comprising a re-usable base unit comprising a drive device, an exchangeable cartridge unit comprising a conveying device, wherein the conveying device comprises a piston pump comprising a rotating piston and a transmission device which can transmit mechanical movement from the drive device onto the conveying device, wherein the transmission device comprises a slaving means which is arranged on the base unit and is rotationally set in motion about an axis by the drive device, wherein the transmission device comprises a transmission element which is arranged on the piston of the piston pump and can be rotationally set in motion by the slaving means, wherein the transmission element and the slaving means can be releasably connected to each other, and wherein the drive device can drive the piston pump by transmitting a rotational movement, wherein the rotational movement is transmitted from the slaving means onto the transmission element, and the transmission element is

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

mounted such that it can be slid relative to the slaving means but is secured against rotation during the rotation, such that the drive movement is transmitted independently of the stroke position of the piston.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2011/060065

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2011009224 A2	27-01-2011	CH 701492 A1 WO 2011009224 A2	31-01-2011 27-01-2011
WO 2006114012 A1	02-11-2006	AU 2006239707 A1 CH 699723 B1 CN 101287510 A EP 1890744 A1 JP 4660589 B2 JP 2008536588 A US 2008132840 A1 US 2011087186 A1 WO 2006114012 A1	02-11-2006 30-04-2010 15-10-2008 27-02-2008 30-03-2011 11-09-2008 05-06-2008 14-04-2011 02-11-2006
WO 2007131367 A1	22-11-2007	AU 2006343564 A1 BR PI0621686 A2 CN 101495165 A EP 2023976 A1 JP 2009537184 A US 2009099524 A1 WO 2007131367 A1	22-11-2007 20-12-2011 29-07-2009 18-02-2009 29-10-2009 16-04-2009 22-11-2007