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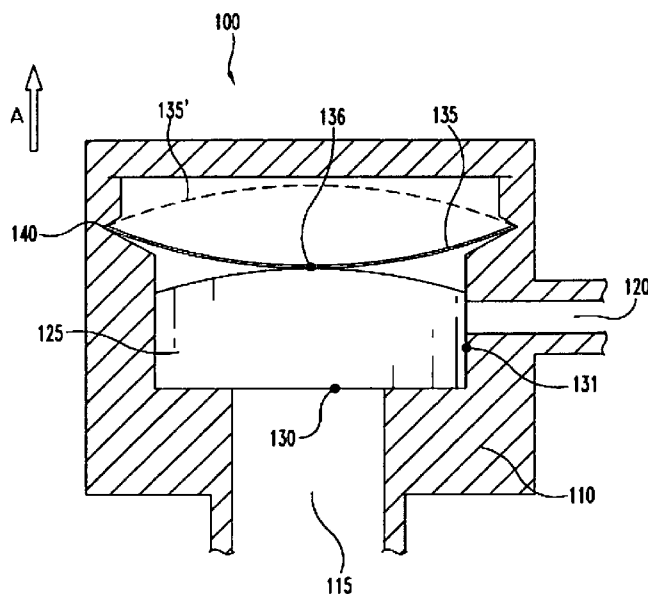
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(54) Title: VALVE FOR AN AMBULATORY INFUSION SYSTEM AND AMBULATORY INFUSION SYSTEM INCLUDING A VALVE

**Fig. 1**

(57) Abstract: Valve (100, 300) for an ambulatory infusion system, the valve (100, 300) having a resting state and an activated state, the valve (100, 300) including (a) an inlet (115, 315) and an outlet (120, 320), (b) a valve body (125, 325), wherein a liquid transfer from the inlet (115, 315) to the outlet (120, 320) is controlled by movement of the valve body (125, 325), the valve body (125, 325) being movable by a fluidic driving force and a restoring force, the restoring force opposing the fluidic driving force, (c) a snap spring (135), the snap spring (135) being operatively coupled to the valve body (125, 325), thus exerting the restoring force onto the valve body (125, 325) upon being elongated by the valve body (125, 325), the snap spring being designed to snap from a resting configuration into an activated configuration upon a force that is exerted onto snap spring (135) exceeding a switching force, such that the valve (100, 300) switches from the resting state to the activated state in a substantially binary way. The disclosure is further directed toward ambulatory infusion systems including such valves.



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Valve for an ambulatory infusion system and ambulatory infusion system including a valve

Technical Field

The present disclosure is related to valves for use in an ambulatory infusion system
5 and to corresponding infusion systems.

Background

Ambulatory infusion systems are known in the art for a variety of applications. In particular, systems adapted for insulin administration form a basis for the state-of-the-art therapy of diabetes mellitus by CSII (Continuous Subcutaneous Insulin
10 Infusion). The systems are typically based on computer-controlled micro-dosing pumps that are adapted to be worn continuously and concealed from view, e.g., in a clothes pocket, with a belt clip, or as patch that is adhesively attached to the skin. The insulin is infused via a subcutaneous cannula that is replaced by a user, e.g. a PwD (Person with Diabetes) or a relative of such a person, every few days. Such
15 insulin pumps are commercially available from a number of suppliers.

Insulin pumps are typically designed to infuse a liquid insulin formulation drug substantially continuously according to a basal administration profile that is variable over the time of day. In addition, they are often designed to infuse larger drug boli in a comparatively short time interval on demand. In CSII, insulin boli are typically
20 administered to compensate food intake and to lower an undesirably raised blood glucose level. The total daily amount of infused insulin may vary in dependence on personal factors and habits of a PwD in a considerable range (between, e.g., 10IU to 80IU, with 100IU (International Units) corresponding to 1ml of a liquid insulin formulation for the currently most common concentration U100).

In the following, the present invention is mainly explained and discussed in the context of CSII therapy. Phrases like "infusion system" or "infusion device" may therefore refer to systems and devices which are suitable for CSII. Besides CSII, those systems and devices may also be used in similar applications, such as various hormone therapies, pain therapy or cancer treatment without requiring substantive
25 modification, if any.
30

Those infusion systems often include a positive-displacement pump of the syringe-

driver type that is, during application, coupled to a cylindrical drug cartridge out of which a liquid drug formulation is forced into an infusion line by displacing a cartridge plunger in a controlled manner. Reference is made to the disclosures of the WO 2003053498 A2 and the WO2000025844A1 for exemplary typical designs and
5 typical features of a state-of-the-art infusion pump. The present disclosure, however, is not limited to a specific therapy or system design.

During application, the infusion cannula and the drug container are often not on exactly the same altitude over sea level. This is the case, for example, if a user carries the pump with the drug cartridge in a necklace-like way, while the infusion
10 cannula is placed in a thigh. The maximum possible altitude difference that may occur is given by the length of the tubing that is typically present between pump and cannula and may be in the range of, e.g., up to 1.5m. An altitude difference close to the maximum may occur in practice, for example, when the user is having a shower with the infusion pump being placed at an elevated position for water protection
15 reasons.

While the pressure inside the tissue in which the cannula is placed may show some variability, it is typically close to the ambient air pressure. In dependence of the design of the infusion system, the altitude difference may cause an unintended drug flow from the elevated drug container to the cannula according to the laws of
20 hydrostatics, resulting in an unintended infusion with potentially severe medical consequences. A similar effect may occur, for example, if the drug inside the drug container expands in an unintended way, in particular due to a temperature change. The unintended and uncontrolled infusion is typically referred to as "free flow" or "siphoning".

25 Check valve systems have therefore been designed which may be fluidically arranged between drug container and cannula and which open only for flow that is directed from a valve inlet to a valve outlet at a pressure difference that is greater than the maximum pressure that may occur because of an elevated drug container. Such a valve is disclosed, for example, in the EP0882466A2 to which reference is
30 made in particular with respect to the physical effect of free-flow or siphoning.

Such valves have to fulfill a number of application-specific requirements. In particular, they should be small and simple to use, have a small fluidic dead volume and allow sterilization. Since they are typically disposables with a useful lifetime of some days,

they should further be as inexpensive as reasonably possible.

The US 6312409 B1 discloses a switch valve with a blocking member or valve member that is driven by a snap spring. The snap spring is coupled to and moved by an elastic diaphragm that moves under the influence of a fluidic pressure inside an internal valve chamber. For such a valve, the switching characteristics is dependent on the diaphragm properties which typically show considerable variation, drift, and the like.

It is an objective of the present disclosure to provide improved valves for use in an ambulatory infusion system as described above.

10

Summary of the disclosure

The objective is achieved based on the insight that it is generally favorable to provide a valve that changes between discrete states, namely a resting state and an activated state, in a substantially binary way at a given pressure. This kind of state change is in the following referred to as "switching". In contrast, currently available valves change between the states continuously over a considerable pressure range.

15

A valve in accordance with the present disclosure may include:

- (a) an inlet and an outlet,
- (b) a valve body, wherein a liquid transfer from the inlet to the outlet is controlled by movement of the valve body, the valve body being movable by a fluidic driving force and a restoring force, the restoring force opposing the fluidic driving force,
- (c) a snap spring, the snap spring being operatively coupled to the valve body, thus exerting the restoring force onto the valve body upon being elongated by the valve body, the snap spring being designed to snap from a resting configuration into an activated configuration upon a force that is exerted onto the snap spring exceeding a switching force.

25

Since the snap spring is coupled to the valve body, the latter is also displaced in a substantially binary and "switching" way as the snap spring changes its configuration. The valve therefore switches from the resting state to the activated state.

The term "valve body" refers to a liquid-contacting body that is movable within a casing or housing and controls the liquid flow from the inlet to the outlet via this displacement by selective opening and blocking of fluid passages.

30

In the context of the present disclosure, the term "switching" is generally used for a state change of the valve, while the term "snapping" is used for a configuration state of the snap spring. A switching of the valve is associated with a snapping of the snap spring and a corresponding movement of the valve body. The term "driving force" refers to a force that is acting on the valve body in its motion direction.

A position of the valve body that is assumed if the valve is in its resting state is referred to as "resting position" of the valve body. A position of the valve body that is assumed if the valve is in its activated state is referred to as "activated position". As will be discussed below in more detail, the resting state and the activated state are the only states of the valve during operation.

In the following, it is generally assumed that the valve body is linearly displaceable and is directly coupled to the snap spring such that an increasing or decreasing elongation of the snap spring is associated with a displacement of the valve body about the same amount and in the same direction. This is, however, not necessarily the case. The snap spring and the valve body may, for example also be coupled via a lever. If, for example, a lever or a similar element is present, the displacement of the valve body and the elongation of the snap spring are in a design-given ratio. The same holds true, in an inverted way, for the fluidic driving force and the force that is exerted onto the snap spring.

For achieving the desired snapping characteristics, the spring characteristics of the snap spring may deviate from the typical linear spring characteristics as it is given by Hook's law. In the following, reference is made to Figure 5 which schematically shows an exemplary curve 200 of the spring characteristics of a suited snap spring.

For illustrative purposes, Figure 5 also shows the spring characteristic of an ordinary linear spring in accordance with Hook's law as dashed line 290.

The total elongation range of the snap spring may be in the range of typically 0.1mm to 5mm, for example in a range of 0.5mm to 1.5mm, depending on the overall design. Small elongations are generally preferred.

The spring characteristics, that is, the restoring force F that is exerted by the spring in dependence of its elongation s has a first section 205 in which the restoring force increases with increasing elongation in accordance with Hook's law. In a second section 210, the restoring force decreases with increasing elongation, thus deviating

from Hook's law with a local force maximum 220 separating the sections 205, 210. As will be explained below, the maximum 220 defines the switching elongation s_{switch} and the switching force F_{switch} at which snapping of the snap spring occurs.

With the spring elongation passing and increasing beyond the switching elongation
5 s_{switch} the useful elongation range of the snap spring is fully utilized, with further elongation resulting in a steep force increase, as indicated by curve section 215.

While the spring characteristics 200 is shown as comprising straight lines 205, 210, 215 for clarity reasons in Figure 5, the single sections may be somewhat curved in practice and further be smooth, that is, continuously differentiable.

10 An "isolated" valve that is not connected to a liquid supply is referred to as being in an "initial" state. In this initial state, no driving force is exerted onto the valve body and the valve body is in a design-given initial position. In this state of the valve, the snap spring may be fully non-elongated, such that no restoring force is exerted by the snap spring onto the valve body and some amount of play may be present at the
15 coupling between valve body and snap spring. This corresponds to the origin 201 of curve 200. Alternatively, the snap spring may be somewhat elongated in this configuration, thus exerting a biasing force as restoring force, corresponding to a point on curve section 205. For this purpose, mechanical stops may be present to counter-act the biasing force, resulting in the valve body being clamped between the
20 snap spring and one or multiple stops in its initial position.

The snap spring may be elongated, via the valve body, by a fluidic driving force resulting from a fluidic pressure which is exerted onto an interface surface of the valve body. The valve body accordingly serves as transmitter which transmits the fluidic driving force to the snap spring.

25 When a pump unit upstream of the valve is operated for the first time after connecting the valve, thus replacing the initially present air with liquid (so called "priming"), a fluidic driving force is exerted onto the valve body, resulting in the valve body being displaced out of its initial position resulting in the spring elongation increasing. Here and in the following, it is generally assumed that operation of the
30 pump unit generates a fluidic driving force that is larger than the switching force.

Passing the switching elongation results in a sudden decrease or substantial removal of the restoring force that opposes the fluidic driving force. Therefore, the

further applied fluidic driving force causes the snap spring to snap into the activated configuration and the valve body to move into the activated position, such that the valve switches to the activated state. This activated state is maintained as long as the fluidic driving force exceeds the switching force.

5 As the pump unit upstream of the valve terminates operation, the fluidic pressure and, thus, the fluidic driving force are reduced. Therefore, the restoring force that is exerted by the snap spring onto the valve body displaces the valve body in the opposite direction and the snap spring elongation decreases. When passing the maximum 220 in the opposite direction, snapping of the snap spring occurs and the
10 valve switches back.

However, if the pump unit is based on a positive-displacement pump of the syringe-driver type, or the like, the fluidic pressure and, thus, the fluidic driving force are not completely released since the fluidic components upstream of the valve have limited elasticity. As a consequence, the snap spring assumes a "floating" working point 207
15 on section 205 of curve 200 with some residual pressure acting on the valve member. The corresponding residual fluidic driving force equals the restoring force and the valve body assumes a corresponding working point position. For a given valve design, the working point 207 depends on the fluidic elasticity of the components, such as cartridge and plunger, upstream of the valve as well as the residual pressure.
20 When the pump unit is subsequently operated again, elongation of the snap spring starts from working point 207. The floating working point according sets the resting state of the valve during normal operation. Consequently, the valve switches forth and back between its floating resting state and its activated state, in dependence of the fluidic driving force.

25 It is generally preferable to choose a working point 207 and a corresponding resting state close to the snapping point at maximum 220. In this way, the valve changes its configuration substantially immediately when the pump unit is operated. In such a design, most of curve section 205 is run through, starting from an initial state, only during priming, while only the snapping or switching characteristics of the snap
30 spring is exploited during subsequent operation.

In the following, it is generally assumed that the pressure-free initial state of the valve is different from the resting state with the spring elongation in the resting state being between the spring elongation in the initial state and the activated state,

respectively. The floating resting position of the valve body is accordingly between its initial position and its activated position. For the restoring force being large and the elasticity of the fluidic components upstream of the valve being high, however, the resting state may be identical with the initial state.

5 From the above, it follows that the resting state of the valve with the snap spring being in the resting configuration and the valve body being in the resting position is a stable position of the valve during application that is assumed if the fluidic driving force is below the snapping force. Typically, the snap spring is somewhat elongated in the resting state by residual fluidic pressure acting on the valve member as
10 discussed above.

The activated state of the valve with the snap spring being in the activated configuration and the valve member being in the activated position is assumed and maintained stable only if and as long as a fluidic driving force is applied to the valve body that exceeds the snapping force. When, starting from the activated state, the
15 fluidic driving force decreases, the valve switches back into the resting state.

For this type of valve, the switching characteristics is largely determined by the snap spring characteristics and does not rely on further elastic components, such as a rubber-like diaphragm or membrane.

The switching characteristics is the more distinct the harder the snap spring is, that is,
20 the greater the absolute value of the slope of the force-elongation curve both before and beyond the switching elongation is.

In some embodiments, the snap spring is made from spring steel sheet. A snap spring made from spring steel sheet is particularly favorable with respect to its low hysteresis. Other materials, such as bronze, copper or high-performance plastics
25 may be used as well.

In contrast, state-of-the-art valves that are used in ambulatory infusion systems typically comprise spring elements that are made from a comparatively soft and rubber-like-material, such as silicone which typically shows a considerable hysteresis. In the present context, "hysteresis" means that the elongation-force-curve (see Fig.
30 5) is different for increasing and decreasing elongation. The technical effect of the hysteresis is that the fluidic pressure for switching into the activated state of the valve is different, in particular higher, as compared to the fluidic pressure for

switching back to the resting state, which is generally undesired.

For typical embodiments of a valve in accordance with the present disclosure, the hysteresis is substantially reduced as compared to currently available valves. This is caused by the fact that a typical snap spring has a low hysteresis as compared to
5 silicone and/or rubber-like spring elements that are currently used and further critical components, in particular the valve body, may be made of hard and substantially hysteresis-free materials. Some small inherent hysteresis, however, is typically present even if the snap spring is made from a low-hysteresis material, such as spring steel. A small amount of hysteresis is not critical and is even favorable for a
10 valve having switch-like or binary characteristics because it prevents the valve from uncontrolled switching and/or fluttering between the resting state and the activated state.

In some embodiments, the snap spring is further designed to snap back from the activated configuration into the resting configuration upon the force exerted onto the
15 snap spring falling below a back-switching force which may especially also equal the switching force. For such embodiments, the resting state is the only stable state of the valve. If hysteresis is present, the back-switching force is somewhat smaller as compared to the switching force, as described above. Alternatively, a locking device, such as a latch, may be provided to lock the valve in the activated state permanently
20 or until the locking is released. Such a design may be favored, for example, for overpressure safety valves.

In some embodiments, the snap spring has the form of a substantially dome-shaped disk, for example a circular disk. If such a disk is supported along its circumference while the crown of its dome is elongated towards the concave side of the dome, it
25 undergoes a so-called mode change, that is, a substantially sudden change of its geometrical configuration, resulting in the disk bending into the opposite direction. Besides a dome-shaped disk, other spring elements may be used that undergo a mode-change in the described way, such as a bent leaf spring that is supported at its ends.

30 The overall shape of the snap spring may, for example, be similar to the shape of snap springs that are known in the art for use as contact elements in membrane or plastic foil keyboards.

In some embodiments, the valve is a check valve which is open, that is, enables

direct liquid flow from the valve inlet to the valve outlet, the activated state and that is closed in the resting state. A check valve generally prevents a flow from the outlet to the inlet.

In some of those embodiments, the inlet is continuously fluidically coupled to the valve body, such that the fluidic driving force is constantly exerted as described above.

In some embodiments, the valve is a metering valve, the valve transferring a pre-defined liquid amount from the inlet to a transfer chamber of the valve upon the valve changing from the resting state to the activated state and transferring the pre-defined liquid amount from the transfer chamber to the outlet upon the valve changing from the activated state back into the resting state.

A change of the valve from the resting state into the activated state and back into the resting state is referred to as "valve cycle". Therefore, a valve of this type transfers the pre-defined amount of liquid from the inlet to the outlet in each valve cycle.

In some embodiments of a metering valve, the inlet is fluidically coupled to the transfer chamber if the valve is the resting state while the outlet is fluidically coupled to the transfer chamber if the valve is in the activated state, with the other of the inlet and the outlet, respectively, being blocked.

As will become apparent below in the context of exemplary embodiments, the transfer chamber may have a volume that may vary during in each valve cycle. The pre-defined liquid amount is given by the difference between the volume of the transfer chamber in the resting state and the activated state, respectively.

In some embodiments of a metering valve, the valve body includes a transfer passage, the transfer passage alternatively fluidically coupling the inlet or the outlet to the transfer chamber in dependence of the valve state.

Further aspects of the valve design as check valve or metering valve are discussed below in the context of exemplary embodiments.

In some embodiments, the valve body includes a plunger. The plunger is typically linearly displaceable between a resting position and an activating position, The plunger may be of generally cylindrical geometry with a top surface, a bottom surface and a circumferential surface and may be sliding arranged in a casing of the valve. In such a configuration, the circumferential surface of the plunger and an inner surface

of the casing, in combination, form a liquid-tight sealing. Either of the top-surface or the bottom surface may serve as liquid-contacting interface surface while the other of the two surfaces couples to the snap spring. Instead of a circular top view, the top view of the plunger may be oval, hexagonal, rectangular, or the like.

- 5 In some embodiments, the switching force corresponds to a fluidic pressure difference between the inlet and the outlet or to a fluidic pressure at the inlet in the range from 50mbar to 1bar. This switching threshold pressure should generally be selected such that the valve may not incidentally during under any operational conditions and in particular because of the drug container and the infusion cannula
10 being at different altitudes over sea level, but can be generated only by a pump upstream of the valve.

The switching force should additionally be selected such that it is overcome by the pressure generated by a pump upstream of the valve. In the following, the term “pump” is generally used for a pressure pump. Typically, the pump is a volumetric or
15 positive-displacement pump, such as a plunger pump, e.g. of the syringe-driver-type, a membrane pump or a peristaltic pump.

In some embodiments, the valve includes a sensor, the sensor being designed to detect the occurrence of a switching of the valve, or an interface structure for operatively coupling to such a sensor. Further aspects will be discussed below.

- 20 In some embodiments, the valve includes either of a liquid drug container, the liquid drug container being fluidically coupled to the inlet, or a container coupler for fluidically coupling the inlet to a liquid drug container distinct from the valve.

In some embodiments, the valve includes either of an infusion tubing, the infusion tubing being fluidically coupled to the outlet, or a tubing coupler for fluidically
25 coupling the outlet to an infusion tubing distinct from the valve.

In some embodiments, the valve is designed for a liquid flow of 0.5ml/min or less, in particular for a maximum liquid flow in the range of 0.05ml/min to 0.4ml/min.

- A liquid flow in this range is a typical maximum liquid flow that is generated by insulin pumps. For those pumps, the maximum flow typically occurs during priming, that is,
30 when filling a fresh tubing prior to the application, and may also occur during the infusion of drug boli.

It is a further objective of the present disclosure to provide ambulatory infusion

systems that include a valve in accordance with the present disclosure. Embodiments of such a system may include:

- a) a liquid drug container,
- b) an infusion tubing and/or an infusion cannula,
- 5 c) a valve according to the present disclosure, the inlet coupling, during application, to the drug container and the outlet coupling, during application to the infusion tubing or infusion cannula,
- d) a pump unit, the pump unit being, during application, operatively coupled to the drug container,
- 10 e) an electronic control unit, the control unit being designed to control the pump unit for infusion with a controlled infusion rate.

The control unit is typically designed to control the pump unit with a time-varying infusion rate, such as the infusion rates for basal and bolus insulin infusion in CSII therapy. Further aspects and variants of such an ambulatory infusion system will be
15 discussed below in more detail in the context of exemplary embodiments.

Exemplary embodiments

In the following, exemplary embodiments of valves and ambulatory infusion systems in accordance with the present disclosure are described in more detail.

Figure 1 schematically shows an exemplary valve 100 in accordance with the
20 present disclosure, valve 100 being a check valve.

Figure 2 schematically shows valve 100 in an initial state, a resting state and an activated state, respectively.

Figure 3 schematically shows a further exemplary valve 300 in accordance with the present disclosure, valve 300 being a metering valve.

25 Figure 4 schematically shows valve 300 in an initial state, a resting state and an activated state, respectively.

Figure 5 schematically shows a curve of the spring characteristics of a snap spring that may be used in valves 100, 300 (discussed above).

Figure 6 schematically shows a curve of the reaction force exerted by the snap
30 spring as a function of its elongation or a valve cycle of valve 100 or 300, respectively and the percentaged opening of valve 100 as a function of the spring

elongation.

Figure 7 schematically shows a functional view of an ambulatory infusion system 500 in accordance with the present disclosure.

Figure 1 shows an exemplary embodiment of a valve 100 in accordance with the present disclosure. Valve 100 operates as check valve that may be alternatively be open or closed and may change between those states in a substantially binary way if the fluidic pressure at the inlet 115 exceeds a switching pressure. The "closed" state corresponds to valve 100 being in the resting state and the "open" state corresponds to valve 100 being in the activated state. When no fluidic pressure and, thus, no fluidic driving force are present at its inlet 115, valve 100 is in a further initial state as described above. Depending on the dimensioning of valve 100 and depending on the further components of the fluidic system, however, the initial state may also be identical with the resting state. In Fig. 1, valve 100 is shown in the initial state.

Valve 100 includes a casing 110 that is typically made of injection molded plastics, but may also be made of stainless steel, ceramics, or the like. Even though the casing 110 is shown as a single part, it may also be made from two or more components which are bonded in a liquid and gas-tight way by means such as adhesive bonding, ultrasonic bonding, or laser welding.

Casing 110 includes an inlet 115 and an outlet 120. Inlet 115 is designed to couple, directly or via intermediate components, to a drug container with a liquid drug to be infused. Outlet 120 is designed to couple, directly or via intermediate components, to infusion tubing and/or an infusion cannula. Further aspects of the coupling and of intermediate components which may be present in some embodiments will be discussed below in more detail.

A typically cylindrical plunger 125 serves as valve body and is arranged inside casing 110. Plunger 125 is sliding displaceable inside the casing 110 in and against direction "A" as indicated by a corresponding arrow. A circumferential surface of plunger 125 and an inner surface of casing 110 (not referenced) contact each other to form a liquid sealing 131. Plunger 125 is displaceable with negligible or low friction. Plunger 125 may be made of hard rubber, injection molded plastics, metal, ceramics or other suited materials which fulfill, in combination with casing 110, the sealing and frictional requirements. Plunger 125 is sufficiently stiff not to substantially deform under the forces acting during operation.

While not visible in Figure 1, plunger 125 may include dedicated sealing components such as circumferential sealing lips, O-rings, or the like. Plunger 125 may, for example, be realized as two-component injection molded part with a hard plastics body and with soft material sealing lips. In case of sealing lips, O-rings or the like
5 being provided, plunger 125 and casing 110 contact each other only along the circumference of those elements to for the liquid sealing 131 rather than liquid sealing 131 extending over the whole circumferential surface of plunger 125 as shown in Figure 1.

Valve 100 further includes a snap spring 135. Snap spring 135 has the form of a
10 dome-shaped disk and is typically made from spring steel sheet. At its circumference (not referenced), snap spring 135 is hold in and supported by a recess 140 of casing 110. A crown 136 of snap spring 135 is in contact with a convex top surface (not referenced) of plunger 125, thus operatively coupling snap spring 135 and plunger 125. The circumference of snap spring 135 is supported such that its position is
15 maintained independent of the bending of snap spring 135, while the amount and direction of the bending may change, thus allowing snapping.

In the initial state of valve 100 that is shown in Figure 1, plunger 135 is in a stable position where a bottom surface 130 of plunger 125 contacts an inner surface of casing 110. For this position of plunger 125, snap spring 135 is either unloaded or
20 preloaded, thus exerting a biasing force onto plunger 125. By a biasing force, plunger 125 is clamped between snap spring 135 and casing 110.

The arrangement of plunger 125 and outlet 120 is such that outlet 120 is blocked by plunger 125 in a sealing way, thus preventing a liquid flow from inlet 115 to outlet 120.

25 As will be discussed in more detail below, snap spring 135 may change to a activated configuration in which snap spring 135 is bent into the opposite direction, as indicated by dashed line 135'.

While not shown in Figure 1, valve 100 may additional include a flexible and liquid-tight diaphragm between the liquid filled regions of the valve and plunger 125. Such
30 a diaphragm might extend below bottom surface 130 of plunger 125 over the whole cross sectional area of plunger 125 and may be fixed along it circumference to valve housing 110. In such a configuration, the liquid driving force acts on the bottom surface 130 via the diaphragm. Such a diaphragm may be used for sealing the liquid

drug contacting sections of the valve 100 against plunger 125. In such a configuration, sealing is performed by the diaphragm rather than the circumferential surface of plunger 125.

At least the liquid-contacting portions of valve 100 are favorably designed for sterilization. Valve 100 is typically provided in a sterile one-way package. The same
5 holds true for further embodiments as described below.

A venting aperture (not shown) may be present in a portion of casing 110 above snap spring 130 thus equalizing the pressure in valve region above snap spring 135 with the ambient pressure.

10 The displacement of plunger 125 in dependence on the fluidic inlet pressure is defined according to Figure 5 as discussed above.

For best understanding the operation of valve 100, reference is additionally made to Figure 6a. Figure 6a shows the curve 200' of the restoring force F that is exerted by snap spring onto plunger 125 for a valve cycle as a function of elongation s . In
15 addition, reference is made to Figure 2. Figure 2a shows valve 100 in the initial state, Figure 2b in the resting state and Figure 2c in the activated state.

When valve 100 is operated for the first time during priming, plunger 125 is first displaced from the initial position shown in Figure 2a in direction "A". If no biasing force is present, plunger 125 starts moving as soon as a fluidic pressure is present at
20 inlet 115 and a fluidic driving force acts accordingly onto interface surface 130, resulting from operation of the pump upstream of inlet 115. If a biasing force is present, plunger 125 will start moving only when the fluidic driving force exceeds the biasing force. The corresponding elongation-force-relation of snap spring 135 is indicated by section 205' of curve 200'.

25 For the configuration shown in Figure 2b, the fluidic driving force is slightly below the switching force. While plunger 125 is displaced out of its initial position, it still blocks outlet 120. In Figure 2b, snap spring 135 is shown in a flat configuration. In practice, however, the shape may be non-flat and more complex, depending on the general design and shape of snap-spring 135.

30 As plunger 125 is further displaced in direction "A" under the influence of the fluidic driving force and snap spring 135 is accordingly further elongated according to curve section 205', force maximum 220' is passed and snap spring 135 snaps into the

activated configuration and bends into the opposite direction, as indicated by dashed line 135' in Figure 1. Accordingly, plunger 125 moves quickly and in a substantially binary way into its activated position.

Motion of plunger 125 into the activated position results in the blockage of outlet 120 being released, thus enabling liquid to flow from inlet 115 to outlet 120 and opening valve 100, as shown in Figure 2c. Valve 100 accordingly switches into the activated state.

As operation of the pump continues, the fluidic driving force acting on interface surface 130 and the counter-acting restoring force maintain plunger 125 in its activated position while snap spring 135 is maintained in its activated configuration. Here, the restoring force assumes a local minimum 225'. This configuration is maintained as long as the pump upstream of inlet 110 is operated. Plunger 125 maintains its activated position because of a force equilibrium of fluidic driving force and restoring force, in which case the activated position is "floating". Alternatively, plunger 125 may be mechanically stopped by casing 110.

When the pump terminates operation, the restoring force will exceed the liquid driving force, resulting in snap spring 135 snapping back into its resting configuration and in plunger 125 moving quickly against direction "A", in accordance with curve sections 210", 205". By this displacement of plunger 125, valve 100 is closed. When outlet 120 is closed, no further liquid can exit valve 100. Accordingly, the pressure upstream of inlet 115 is not completely released. At point 207", the fluidic driving force equilibrates the restoring force, such that plunger 125 is not further displaced. Valve 100 accordingly remains in the configuration of Figure 2b until the pump upstream of the valve is operated again. Figure 2b accordingly shows the resting state during operation.

When the pump is operated the next time, the valve cycle starts from operating point 207' which substantially corresponds to point 207".

The dome-shaped or generally non-flat shape of snap spring 135 in the stress-free state ensures a mono-stable behavior of snap spring 135. That is, snap spring 135 snaps back to its initial resting configuration as shown in Figure 1 and can not statically assume a configuration with an opposite directed curvature as indicated by line 135' in Figure 1.

According to the description given above, the motion of plunger 125 is in direction "A" for opening valve 100 and against direction "A" for closing valve 100. For clarity reasons, the restoring force is shown as a function of the spring elongation in an "unfolded" way in Figure 6a, with the closing being represented by curve sections 210'', 205'' and appearing as continuation of the opening motion in the same direction. In Figure 6a, the maxima 220' and 220'' indicate the snapping of snap spring 135, and, thus, the state change of valve 100. The actual restoring force as a function of the elongation is obtained from Fig. 6a by folding the section of the curve right of minimum 221 back to the left side of the diagram. Section 205'' of curve 200' is identical to section 205' but is run through in the opposite direction. The same holds true for curve sections 210' and 210'', respectively. The maxima 220', 220'' both correspond to maximum 220 in Figure 5, with maximum 220' being passed with increasing and maximum 220'' being passed with decreasing spring elongation. It should further be noted that Figure 6a does, for clarity reasons, not reflect the hysteresis as discussed above. In practice, the hysteresis results in the restoring force at maximum 220'' being somewhat smaller as compared to maximum 220' and the restoring force at point 207'' being somewhat smaller as compared to operating point 207'.

Figure 6b schematically reflects the relative, i.e., percentaged, opening of valve 100 as a function of the elongation s for a valve cycle by curve 250. 0% corresponds to valve 100 being fully closed, 100% corresponding to valve 100 being fully opened. It can be seen that, resulting from the characteristics of snap spring 135, valve 100 opens and closes in a substantially binary and switching way, as opposed to valves having a conventional spring. For illustrative purposes, the diagram of Figure 6b additionally shows a corresponding dashed curve 290 for a valve including a linear spring rather than a snap spring.

Figure 3 shows a further exemplary valve 300 in accordance with the present disclosure. While many of the structural and functional features of valve 300 correspond to the above-described embodiments, the following description largely focuses on the differences. Valve 300 is a metering valve that transfers a pre-defined liquid amount from inlet 315 to outlet 320 with each valve cycle.

This embodiment includes a plunger 325 with two concentric cylindrical section 326 and 327 of equal diameter, section 326 being in the following referred to as "top

section" and section 327 being referred to as "bottom section". The convex top surface (not referenced) of top section 326 contacts snap spring 135, while bottom surface 330 of bottom section 327 serves as liquid-contacting interface surface. A spacer section 328 is arranged between top section 326 and bottom section 327, with spacer section 328 being concentrically with top section 326 and bottom section 327, respectively, but having a smaller diameter. The resulting overall configuration of plunger 325 is accordingly cylindrical with a circumferential cut-in 340 in the area of spacer section 328. At least one aperture or bore 345 is provided in bottom section 327, thus fluidically connecting cut-in 340 with a transfer chamber 312 that is limited by inner bottom surface 313 of casing 310 and interface surface 330. In combination, cut-in 340 and the aperture or apertures 345 serve as transfer passage. Aperture 345 may be a single aperture or a number of apertures or bores around the circumference of bottom section 327. The resulting total aperture area should be as large as possible while ensuring sufficient mechanical stability.

Inlet 315 and outlet 320 are radially arranged at casing 310 with an axial distance. In Figure 3, valve 300 is shown in its initial state. In this position of plunger 325, the relative position of inlet 315 and cut-in 340 is such that inlet 315 is fluidically coupled with cut-in 340, and via apertures 345, with transfer chamber 312. In this state, outlet 320 is blocked and sealed by the circumferential surface (not referenced) of top section 326.

Operation of valve 300 is best understood with additional reference to Figure 4. Figure 4a shows valve 300 in the initial state with plunger 325 accordingly being in its initial position. Figure 4a corresponds to Figure 3.

If a pump upstream of inlet 315 is operated, liquid will flow through inlet 315 into cut-in 340 and, via aperture 345, into the transfer chamber 312, thus generating a fluidic pressure and exerting a fluidic driving force in direction "A" onto interface surface 330, the fluidic driving force acting against a biasing force that may be exerted by snap spring 135. As operation of the pump continues, plunger 325 is displaced in direction "A", thus increasing the volume of transfer chamber 312. As the displacement of plunger 325 continues, valve 300 changes into the activated state in the same way as discussed above for the previously described embodiment.

Figure 4c shows valve 300 in the activated state. In this state, snap spring 135 is in the activated configuration and plunger 325 is in the activated position.

Here, the liquid-filled transfer chamber 312 is, via apertures 345 and cut-in 340, fluidically coupled to outlet 320 while inlet 315 is blocked by plunger 325. Accordingly, liquid will flow from transfer chamber 312 through apertures 345 and cut-in 340 to outlet 320 and out of valve 300, while no liquid can enter valve 300.

5 As liquid leaves transfer chamber 312, the pressure inside transfer chamber 312 is reduced and plunger 325 is displaced against direction "A" under the spring force exerted by snap spring 135, thus forcing the liquid out of transfer chamber 312 to outlet 125. Plunger 325, however, does not return into the initial position (Fig. 4a) but only into a resting position in which the fluidic driving force equilibrates the restoring
10 force as in the previously described embodiment. Figure 4b shows valve 300 in the resting state.

Like in the initial state, liquid may enter valve 300 in the resting state, while no liquid may exit valve 300. The resting state of valve 300 is accordingly an inlet state. Liquid may exit valve 300 if valve 300 is in the activated state while no liquid may enter
15 valve 300. The activated state of valve 300 is accordingly an outlet state.

Valve 300 provides special favorable safety features. If a pump upstream of inlet 315 is continuously operated, valve 300 may repeatedly switch between the inlet state and the outlet state as described above, thus transferring a defined liquid volume from inlet 315 to outlet 320 with each cycle, largely independent of the exact
20 operation of the pump. The defined liquid amount is given by the volume difference of transfer chamber 312 between resting state and activated state. Such an embodiment is especially favorable with respect to controlling the pump since the pump may be operated continuously during delivery, for example via a DC motor. The actually delivered liquid amount can be determined by detecting and counting
25 the valve cycles via a sensor as will be discussed below. Alternatively or additionally, the liquid pressure variation upstream and/or downstream of the valve that is associated with each valve cycle may be detected and evaluated for that purpose.

Alternatively, the system may be designed and operated such that the pump upstream of valve 300 is activated for a short time period for each cycle. In such an
30 embodiment, further operation of the pump after the valve has switched into the activated state results in a typically steep pressure increase in the fluidic system upstream of valve 100, resulting from inlet 315 being blocked. This pressure increase may be detected by a fluidic pressure sensor or a force sensor in the pump

and be used as trigger signal for stopping the pump unit. Additionally or alternatively, the valve cycles may be detected via a sensor as will be discussed below. Such an embodiment is especially favorable with respect to safety since it prevents an unintended and continuously delivery even for the case of the pump being operated continuously due to a device malfunction.

Since one of the inlet 315 and the outlet 320 is always blocked by plunger 315, no continuous flow may occur from inlet 315 to outlet 320 even in case of a valve defect such as plunger 325 being blocked in any position or in the case of extensive suction pressure at outlet 320.

For both exemplary valves 100, 300, displacement of the plunger from the activated position into the resting position is associated with a displacement of fluid out of the valve. This liquid volume is stored by the further fluidic components of the system due to their inherent elasticity.

While not shown in the figures, a typically electrical sensor, e.g. an optical, capacitive or magnetic displacement sensor, may be provided which monitors the valve operation and/or enables counting the number of valve strokes. In this way, a defined liquid drug amount can be infused. Alternatively or additionally to the above-mentioned sensors, a vibration transducer may be provided that senses the characteristic air and/or impact sound that is associated with each configuration change of the snap spring.

Both the exemplary valves 100 and 300 include a valve housing in which the snap spring as well as a plunger as valve body is arranged. Other designs, however, may be used as well. For example, the EP2008681A1 discloses valve arrangements which include a liquid-filled conduit, such as an infusion line, which is, in a valve section, collapsible and loaded by a radial force that is, e.g., exerted by a spring via a clamp. The valve section is collapsed for a liquid pressure below a threshold pressure. In such a design a snap spring may be used instead of a linear spring. In such an embodiment, the valve body is integral with the moving walls of the valve section of the conduit while the inlet and the outlet of the valve are integral with the beginning and the end of the collapsible valve section of the conduit.

Figure 7 exemplarily shows an ambulatory infusion system 500 in accordance with the present disclosure in a schematically and structural view.

The ambulatory infusion system 500 includes an ambulatory infusion pump 505, a valve 525, tubing 530 and an subcutaneous infusion cannula 535. Valve 525 may be of any design in accordance with the present disclosure and may especially be designed as either of a check-valve or a metering valve.

5 The ambulatory infusion pump 505 includes an electronic control unit 510, a pump unit 515 that is powered and controlled by control unit 510, and a liquid drug container 520. In a typical embodiment, drug container 520 is a cartridge with a cylindrical elongated body and a plunger that is displaceable within in the cartridge body to force liquid out of the cartridge body for the infusion. For this type of drug
10 container 520, pump unit 515 typically includes a spindle drive which is operatively coupled to the plunger of the drug container 520 in order to displace it in a controlled way. Several designs for such pump units are known in the art, an exemplary design of a pump unit with a telescopic spindle drive is disclosed in the EP0991440A1.

Control unit 510 includes typically microcontroller-based control circuitry with one or
15 more controllers, power circuitry for driving an actuator of pump unit 515, memory, safety circuitry, user interfaces, and the like. Typically, pump unit 515 includes one or multiple sensors, such as a rotary encoder that is coupled to a motor, e.g., a stepper motor, DC motor, or brushless DC motor of pump unit 515. It may further include a force sensor that measures the force that is exerted by the drive onto a cartridge
20 plunger of drug container 520. During operation, control unit 510 controls pump unit 515 such that infusion pump 505 infuses drug in a substantially continuous way according to a typically time-variable infusion profile. In the case of infusion system 500 being used in the context of diabetes therapy, drug container 520 holds a liquid insulin formulation and the infusion profile reflects the diabetic's basal insulin
25 demand. In addition, infusion pump 505 can further infuse additional drug boli on demand.

Control unit 510, pump unit 515 and drug container 520 are enclosed by a compact housing (not referenced) that is designed to be carried by a person substantially continuously and concealed from view. For the overall design of such devices,
30 reference is made to WO2003053498A2 and WO2000025844A1 for typical state-of-the-art designs. Drug cartridge 520 is user-replaceable and is received in a cartridge compartment of the housing.

Valve 525 is coupled to infusion pump 505 such that pump 505 and valve 525,

during operation, form a single compact unit. Valve 525 may, for example, be coupled to the housing of infusion pump 505 by a screwed connector, a bayonet or a snapping connector. The inlet of valve 525 is fluidically coupled to an outlet of drug container 520 by a fluidic coupler, such as a Luer connector, or the like. In some
5 embodiments, drug container 520 includes a piercable septum and the inlet of valve 525 includes a corresponding hollow piercing cannula, or vice versa. The design may especially be such that valve 525 simultaneously serves as closure for a cartridge compartment of infusion pump 505. Releasably coupling valve 525 to infusion pump 505 simultaneously establishes a fluidic coupling as disclosed in
10 EP0882466A2 or WO2001024854A1. While the internal structure and operation of valve 525 are given by the present disclosure, the casing design and the fluidic couplers at its inlet and outlet may, for example, be similar to the disclosure of WO2001024854A1.

The ambulatory infusion system 500 may further include an optional sensor 527 that
15 detects switching of the state of valve 525. Control unit 510 may include corresponding processing circuitry and/or firmware. Sensor 527 may be of any type as discussed above. Sensor 527 is shown as integral part of pump 505. This is favorable, for example if sensor 527 is an air or impact sound transducer. However, sensor 527 may, fully or partly, be integral with valve 525, for example in form of an
20 electrical contact that is comprised by or coupled with the valve body. In a similar way, the valve body may include a small permanent magnet and pump 505 may include a corresponding electrical reed contact.

The outlet of valve 525 is coupled to an infusion tubing 530 having a length L, either permanently or via a releasable or non-releasable coupling that is established prior
25 to use. The length L of tubing 530 is typically in a range of 0.3m to 1.5m and is selected to allow comfortable motion with cannula 535 being placed in the user's subcutaneous tissue. In particular, length L is selected to allow placement of cannula 535 at a variety of infusion sites and infusion pump 505 to be carried at a variety of locations, including somewhat remote from the user. This situation occurs, for
30 example, when the user places the pump on a bedside cabinet at night while the infusion continues.

Infusion cannula 535 is coupled to an outlet of tubing 530 and is typically made from stainless medical grade steel or a soft material, such as Teflon. Cannula 535 may be

integral with tubing 530 or may separate and coupled with a releasable or non-releasable coupler.

Tubing 530 and cannula 535 are typically designed for an application time of some days. Drug container 520 and valve 525 may be used for the same time interval or
5 may have a somewhat longer lifetime of, e.g., one to two weeks. In the context of insulin therapy, the volume of drug container 520 may typically be in a range of 0.5 to 5ml, for example 1.5 or 3ml.

Pump unit 515 is designed to generate a fluidic pressure at the inlet of valve 525 that exceeds the fluidic inlet pressure that is required for the valve to change its state.

10 The presence of valve 525 is particularly favorable in embodiments of infusion system 500 where pump unit 515 is coupled with drug container 520 only in a pushing engagement and the pump unit 515 can not retain a plunger of drug container 520 in case of a negative pressure at the drug container outlet as described above. This is the case, for example, for the system disclosed in
15 WO2001024854A1.

As compared to alternative valve designs, valve 525 in accordance with the present disclosure has the advantage changing between its states in a substantially binary way as discussed above.

A valve in accordance with the present disclosure has further particular advantages.

20 Once a fluidic pressure is built up in the system by the pump, the inlet of valve 525 will generally be constantly exposed to over pressure, even if the pump is not operated. This results from the fact that, after the pump stops operation, an over pressure is still present at the valve inlet that can not be fully released as described above. The liquid in drug container 520, and, thus, the inlet of valve 525, is
25 accordingly permanently pressurized, resulting in the snap spring being constantly exerted to some fluidic driving force. In addition, the snap spring may be exerted to a constant biasing force as discussed above. In state-of-the-art valve designs which employ a rubber-like spring element, the spring element tends to creep over time under the permanent load. In combination with the continuous rather than binary
30 valve characteristics as discussed above, this results in a tendency to leak, with the tendency increasing over time. In some situations, this results in a substantially continuous and uncontrolled drug infusion. Under certain circumstances and for small infusion rates, such as the basal insulin infusion rate of some kids, this

unintended infusion can be therapeutically significant, including medical complications, such as hypoglycemia. According to the present disclosure, this effect is largely reduced or completely avoided due to the binary valve characteristics. Even if the snap spring shows some creep over time, this does not result in a valve leakage.

The exemplary embodiments have a further desirable characteristic. Because the (positive or negative) pressure at outlet 120, 320 acts perpendicular to the linear displacement direction A, switching of the valve from the resting state to the activated state it does not substantially effect the switching from the resting state into the activated state. With other words, valves 100, 300 switch from the resting state to the activating state upon the inlet pressure exceeding a switching vale. Any pressure at outlet 120, 320, in particular a suction pressure that may result form different altitudes of drug container and infusion site, can not cause the valve to switch its state.

The ambulatory infusion system 500 as shown in Figure 7 may be modified or varied in a number of ways. For example, drug container 520 and valve 525 may be formed in an integral and pre-assembled disposable unit. The fluidic connection between drug container 520 and valve 525 is favorably established only directly at the beginning of the usage. One or both of tubing 530 and cannula 535 may optionally be included in such a unit.

Pump unit 515 and drug container 520 may be designed in a number of alternative ways. In particular, pump unit 515 may be, at least in part, disposable and include a disposable spindle. Such a spindle may be integral with drug container 520 or a container-valve-unit as described above.

Instead of arranging valve 525 upstream of infusion tubing 530, it may also be arranged downstream of infusion tubing 530, directly at cannula 535.

It has to be considered, however, that an altitude difference between drug container and infusion site results in an additional driving force, according to the hydrostatic head. The fluidic inlet pressure for switching the valve state should accordingly be higher than the maximum hydrostatic pressure that may occur in dependence of the tubing length L.

The typically present plunger of drug container 520 may further not be displaced via

a spindle drive. Instead, a force generating means, such as a spring may be present that constantly exerts a driving force onto the plunger. In further variants, the drug container 520 is not a cartridge, but is a fully flexible or partly-flexible bag or pouch.

In such embodiments, pump unit 515 includes a pumping mechanism that is
5 arranged downstream of drug container 520, that is, between an outlet of drug container 520 and the valve inlet. The pump mechanism may, for example, be a micro membrane pump, a peristaltic pump or dosing unit, as disclosed in the EP 2163273A1 or the EP 1970677A1. At least the fluid-contacting components of the pumping unit may be integral with drug container 520 and/or a disposable unit as
10 described above.

In addition to the components that are shown in Figure 7, further fluidic components may be present, such as an air bubble remover, a bubble detector, a fluidic pressure sensor and/or a flow sensor. Those sensors are favorably coupled to the controller unit 510.

15 Especially if valve 525 is of the metering-type, one or multiple sensors may further be present for counting the valve strokes and/or supervising the valve operation as described above.

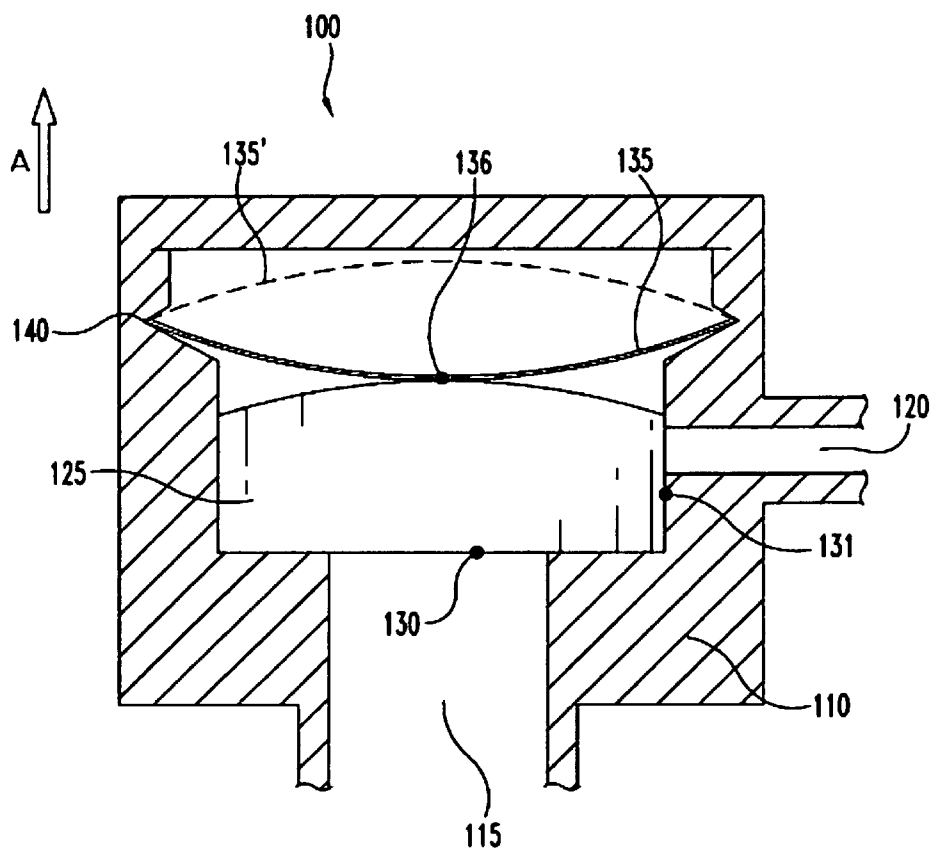
Claims

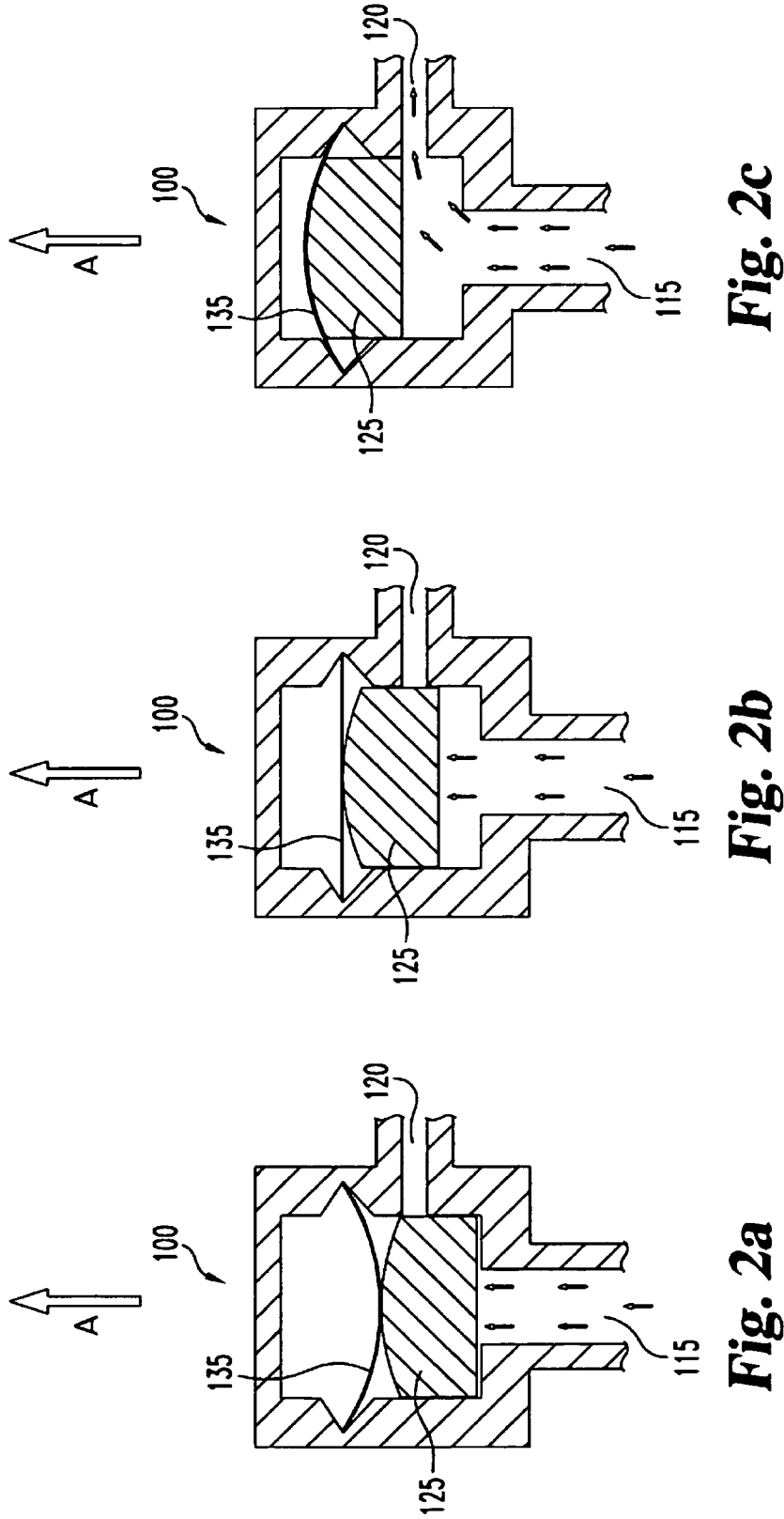
1. Valve (100, 300) for an ambulatory infusion system, the valve (100, 300) having a resting state and an activated state, the valve (100, 300) including
 - (a) an inlet (115, 315) and an outlet (120, 320),
 - 5 (b) a valve body (125, 325), wherein a liquid transfer from the inlet (115, 315) to the outlet (120, 320) is controlled by movement of the valve body (125, 325), the valve body (125, 325) being movable by a fluidic driving force and a restoring force, the restoring force opposing the fluidic driving force,
 - 10 (c) a snap spring (135), the snap spring (135) being operatively coupled to the valve body (125, 325), thus exerting the restoring force onto the valve body (125, 325) upon being elongated by the valve body (125, 325), the snap spring being designed to snap from a resting configuration into an activated configuration upon a force that is exerted onto snap spring (135) exceeding a switching force,
 - 15 such that the valve (100, 300) switches from the resting state to the activated state in a substantially binary way.
2. Valve (100, 300) according to Claim 1, wherein the valve is designed such that it switches from the activated state to the resting state in a substantially binary way upon the fluidic driving force falling below a back-switching force.
- 20 3. Valve (100, 300) according to any of the preceding claims, wherein the snap spring (135) has the form of a substantially dome-shaped disk.
4. Valve (100, 300) according to any of the preceding claims, wherein the snap spring (135) is made from spring steel sheet.
5. Valve (100, 300) according to any of the preceding claims, wherein the valve
25 (100) is a check valve, the valve being opened in the activated state and being closed in the resting state.
6. Valve (100) according to Claim 5, wherein the inlet (115) is continuously fluidically coupled to the valve body (125) such that the fluidic driving force is continuously exerted.
- 30 7. Valve (300) according to any of Claim 1 to Claim 4, wherein the valve (300) is a metering valve, the valve (300) transferring a pre-defined liquid amount from the

inlet (315) to a transfer chamber (312) upon the valve changing from the resting state to the activated state and transferring the pre-defined liquid amount from the transfer chamber (312) to the outlet (320) upon the valve changing from the activated state to the resting state.

- 5 8. Valve (300) according to Claim 7, wherein the inlet (315) is fluidically coupled to the transfer chamber (312) if the valve (300) is the resting state and the outlet (320) is fluidically coupled to the transfer chamber (312) if the valve (300) is in the activated state.
9. Valve (300) according to Claim 7 or Claim 8, wherein the valve body (325)
10 includes a transfer passage (340, 345), the transfer passage (340, 345) alternatively fluidically coupling the inlet (315) or the outlet (320) to the transfer chamber (312) in dependence of the valve state.
10. Valve (100, 300) according to any of the preceding claims, wherein the valve body (125, 325) includes a plunger.
- 15 11. Valve (100, 300) according to any of the preceding claims, including a sensor (527), the sensor being designed to detect the occurrence of a switching of the valve (100, 300), or an interface structure for operatively coupling to such a sensor (527).
12. Valve (100, 300, 525) according to any of the preceding claims, including either
20 of a liquid drug container (520), the liquid drug container (520) being fluidically coupled to the inlet (115, 315), or a container coupler for fluidically coupling the inlet to a liquid drug container (520) distinct from the valve (100, 300, 525).
13. Valve (100, 300, 525) according to any of the preceding claims, including either of
25 an infusion tubing (530), the infusion tubing (530) being fluidically coupled to the outlet (120, 320), or a tubing coupler for fluidically coupling the outlet (120, 320) to an infusion tubing (530) distinct from the valve (100, 300, 525).
14. Valve (100, 300) according to any of the preceding claims, the valve (100) being designed for a liquid flow of 0.5ml/min or less, in particular for a maximum liquid flow in the range of 0.05ml/min to 0.4ml/min.
- 30 15. Ambulatory infusion system (500), including:
 - a) a liquid drug container (520),
 - b) an infusion tubing (530) and/or an infusion cannula (535),

- c) a valve (100, 300, 525) according to any of the preceding claims, the inlet (115, 315) coupling, during application, to the drug container (520) and the outlet (120, 320) coupling, during application to the infusion tubing (530) or infusion cannula (535),
- 5 d) a pump unit (515), the pump unit (515) being, during application, operatively coupled to the drug container (520),
- e) an electronic control unit (510), the control unit (510) being designed to control the pump unit (515) for infusion with a controlled infusion rate.

**Fig. 1**



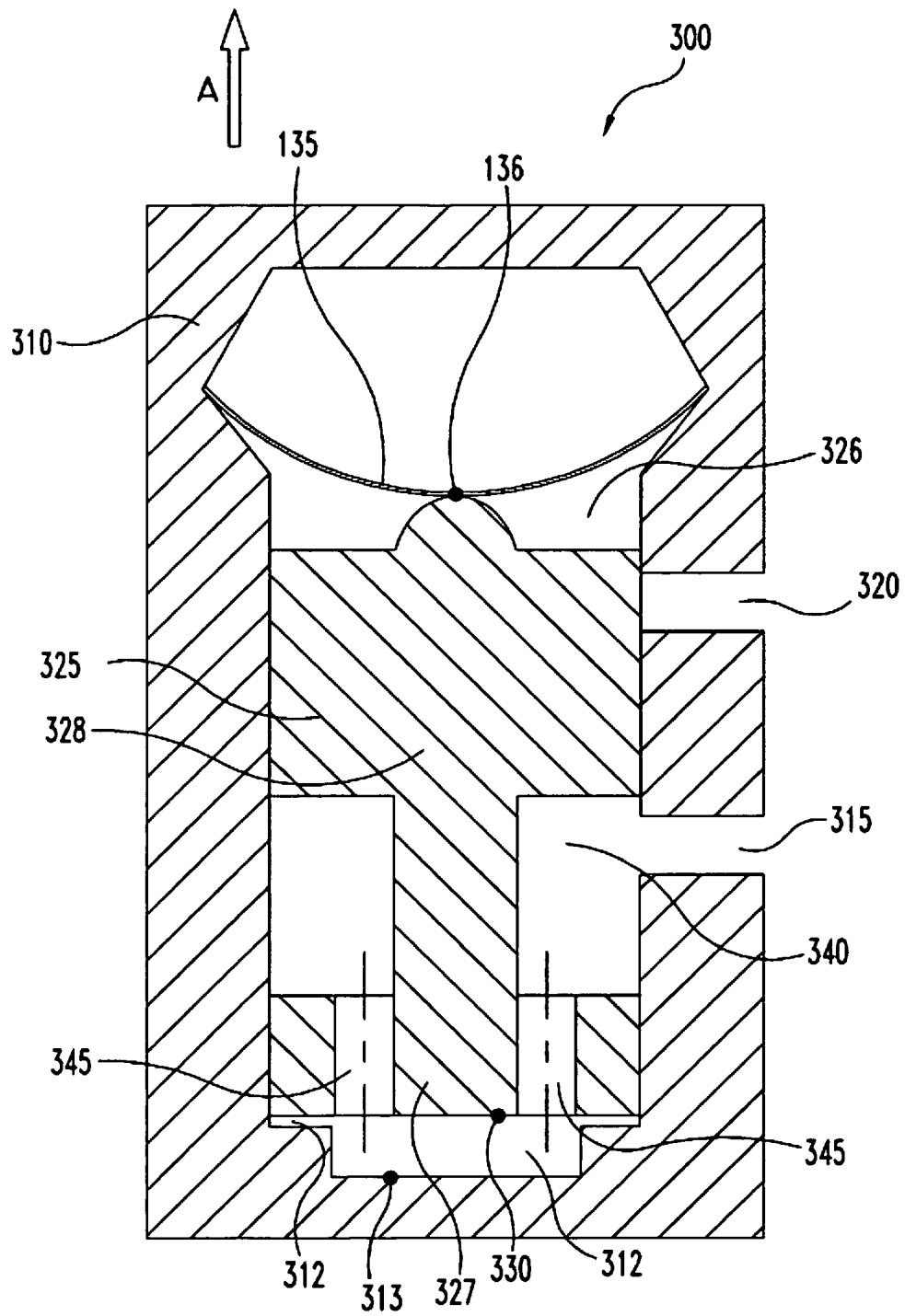


Fig. 3

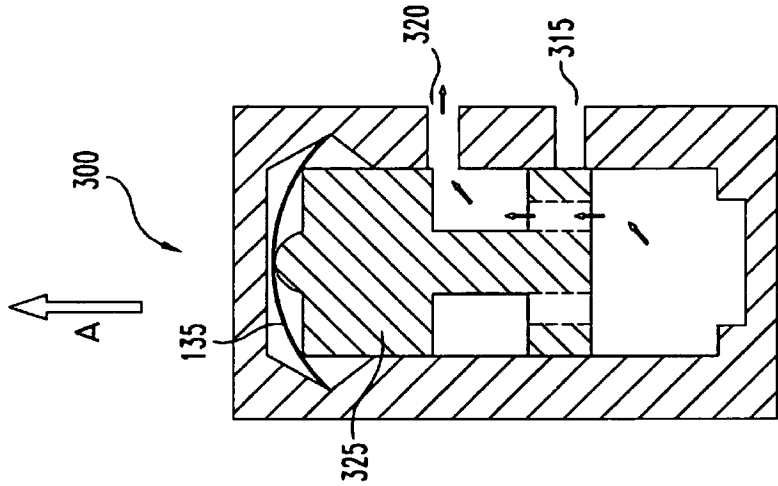


Fig. 4c

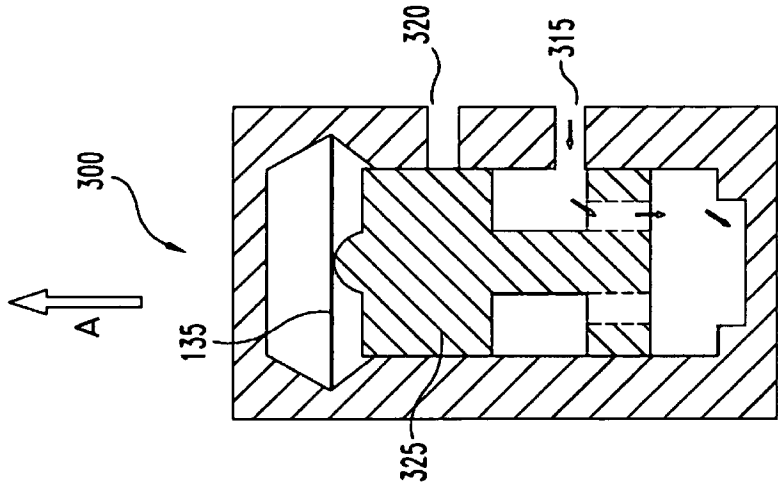


Fig. 4b

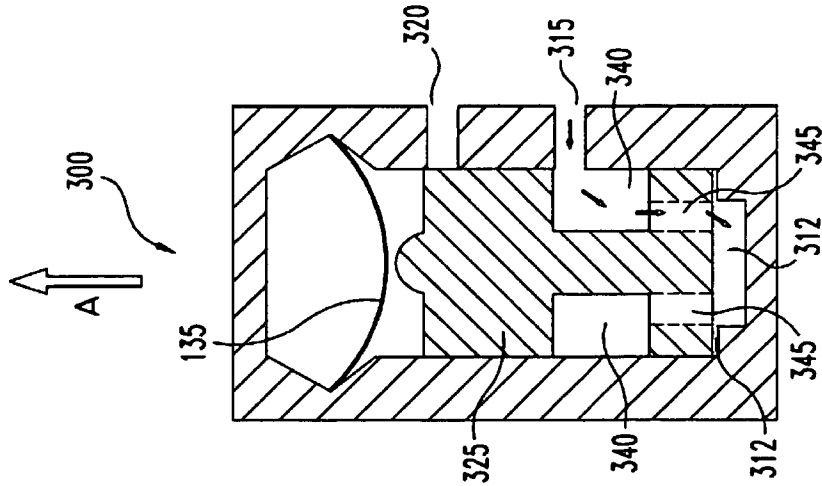


Fig. 4a

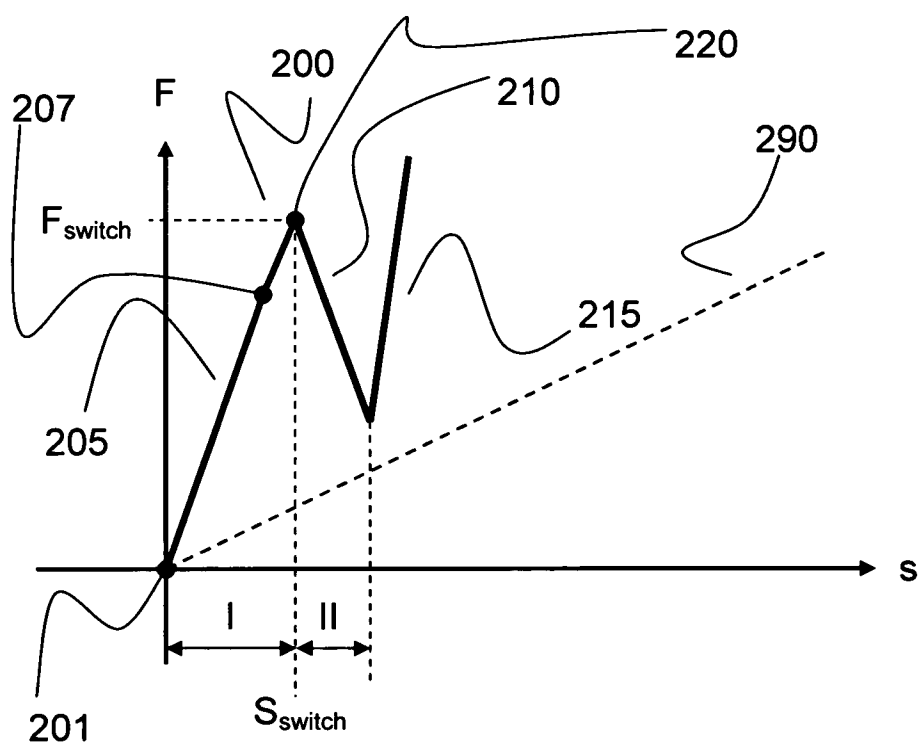


Figure 5

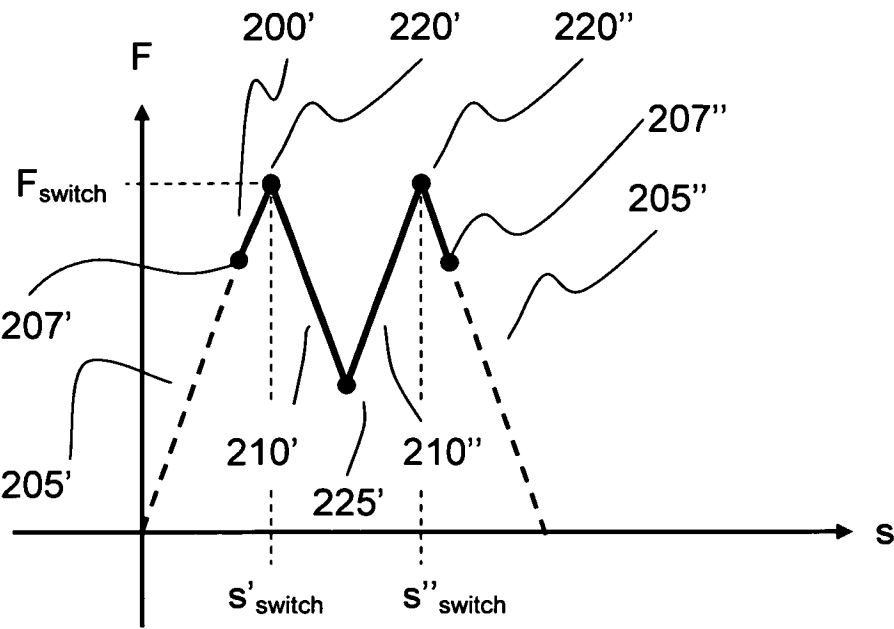


Figure 6a

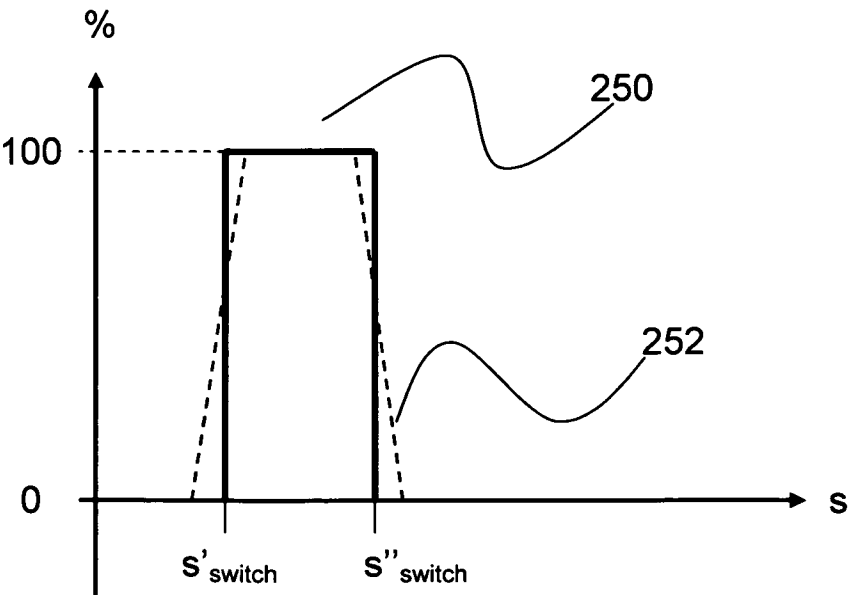


Figure 6b

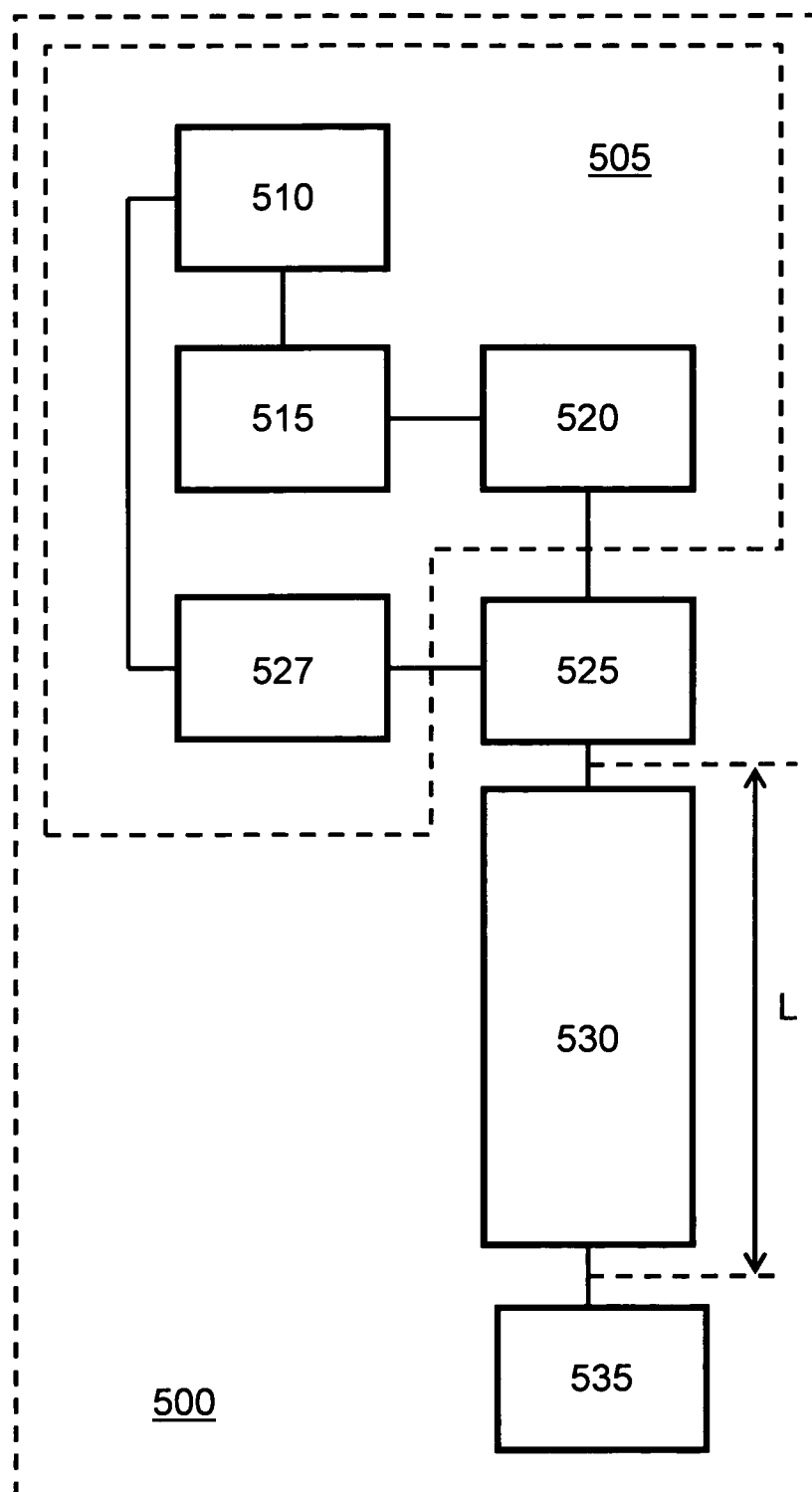


Figure 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/003845

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/168 A61M39/24
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 312 409 B1 (GROSS JOSEPH [IL]) 6 November 2001 (2001-11-06) column 5, line 39 - column 9, line 38 -----	1-6, 12-15
A	US 4 350 477 A (MAZAL CHARLES N) 21 September 1982 (1982-09-21) column 4, line 68 - column 6, line 66 -----	1-15
A	EP 1 897 585 A1 (BARAK SWI [IL]) 12 March 2008 (2008-03-12) the whole document -----	1-15
A	US 2003/014011 A1 (ROBERT RENEE JOY [US]) 16 January 2003 (2003-01-16) the whole document -----	1-15



Further documents are listed in the continuation of Box C.



See patent family annex.

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

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Date of the actual completion of the international search

10 October 2011

Date of mailing of the international search report

18/10/2011

Name and mailing address of the ISA/

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Authorized officer

Manschot, Jan

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2011/003845

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6312409	B1	06-11-2001 IE 960927 A1	01-07-1998
US 4350477	A	21-09-1982 NONE	
EP 1897585	A1	12-03-2008 US 2008066810 A1	20-03-2008
US 2003014011	A1	16-01-2003 NONE	