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The invention relates to an infusion pump for administering, in doses, a medical fluid to be injected and in particular for dispensing, in a controlled manner and over a long period of time, micro-doses of a fluid which contains a medical or therapeutic active agent, for example in order to dispense insulin or the like over
5 the longer term. The invention also relates to a method for controlling such administering in doses, a control program for this purpose and a semi-conductor device comprising such a control program for use in an infusion pump.

Infusion devices for administering, over a long period of time, a fluid which contains a medical or therapeutic active agent by injecting it into a body volume, for
10 example a venous volume or tissue, are known from the prior art, wherein one important parameter is the amount of fluid to be administered per unit of time, from which the active agent administered can be calculated. In hospitals, infusion bottles suspended above the injection point are usually employed, whence the
15 fluid is dispensed due to gravity via a variable tube clamp which serves as a delivery control device. Infusion bottles are not suitable as mobile infusion devices and in particular not for dispensing comparatively low doses over the longer term.

Infusion pumps in which the mode of operation is controlled such that the amount
20 of fluid administered corresponds to the desired dosage are also known from the prior art. Such infusion pumps comprise a drug container from which the fluid is delivered by advancing a piston stopper. The fluid is dosed by controlling the advance of the piston. In order to dispense comparatively low doses over the longer term, a reducing gear – for example, a toothed rod – can be provided for
25 advancing the piston stopper. Such infusion pumps have in common that the dosing precision is predetermined by production tolerances of the infusion pump itself. This requires strict production tolerances to be observed, which means that such infusion pumps are usually only suitable for one type of drug container, for example ampoules.

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US 6,348,043 B1 discloses an infusion device in which a medical fluid is delivered from an ampoule by advancing a piston stopper which serves as a fluid conveying means. Pressure is applied by a pressure spring to a membrane on the face of

the piston stopper, such that the fluid is delivered slowly, even directly after an advancing movement of the piston stopper. A stepped member which serves as an abutment serves to predetermine the dosage and has to be produced precisely in order to administer comparatively small doses. In this device, as in the
5 aforesaid infusion pumps, the functions of expelling the fluid by advancing the piston and of dosing are not decoupled from each other, which causes the aforesaid limitations with regard to dosing precision and flexibility.

US 4,077,405 describes an apparatus for injecting fluids into a tissue. The appa-
10 ratus comprises an internal reservoir for the drug with an integrated vessel which is filled with a substance which at body temperature exhibits a vapour pressure of up to three bars, in order to apply pressure to the drug and push it out of the reservoir and onto the input side of a valve. The valve can be set to dispense a predetermined dose of the drug to the patient at predetermined intervals. The
15 reservoir and/or the integrated vessel comprises a temperature or pressure sensor which measures changes in temperature, for example in the case of a fever, and varies the dispensing frequency or the opening times of a valve as a function of the measured state.

20 It is an object of the invention to provide an infusion pump using which the fluid to be injected can be precisely and flexibly dosed in a simple way. The intention is in particular to provide a mobile infusion pump for dispensing comparatively low doses of a fluid to be injected over the longer term. A control method, a control program and a semi-conductor device comprising such a control program for the
25 aforesaid purposes are also disclosed.

This object is solved by an infusion pump comprising the features according to claim 1. Advantageous developments are the subject of the dependent sub-claims.

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An infusion pump in accordance with the invention comprises: a fluid conveying means for conveying the fluid from a fluid container which contains the fluid to be

injected; and a delivery control device for dosing the delivery of the fluid. In accordance with the invention, the fluid conveying means applies a pressure to the fluid at an inlet of the delivery control device, at least immediately before and during delivery, and the fluid conveying means is decoupled from the delivery control device. The delivery control device is downstream of the fluid conveying means in the flow of the fluid. Both the fluid conveying means and the delivery control device act on the fluid, the latter downstream of the conveying means. There is advantageously no mechanical engagement, which controls or regulates the conveying action as a function of dosing, between the conveying means and the delivery control device; preferably, there is no mechanical engagement of any kind.

In accordance with the invention, the fluid conveying means thus exclusively serves to convey the fluid, for example by expelling it from an ampoule, and not to control and/or dose the delivery of the fluid. The fluid conveying means can advantageously be configured to be simple and cost-effective, since the dosing precision is not determined by the conveying means but rather by the delivery control device only. The use of mechanical precision components for the conveying means can advantageously be omitted. The fluid conveying means as a whole can also be configured more flexibly, for example for using various types of fluid containers, since a precise match between the conveying means, for example a threaded rod drive for a piston stopper, and the fluid container, for example an ampoule comprising such a stopper, is no longer necessary.

In accordance with the invention, the amount of delivered fluid which is conveyed from the fluid conveying means to the delivery control device by applying pressure is controlled by the delivery control device. Because the conveying means and the delivery control device are decoupled, the latter can advantageously be used with various types of conveying means and/or fluid containers, which increases the flexibility of the infusion pump even further.

Decoupling the functions of generating the conveying pressure and of dosing – i.e. by dosing by means of the delivery control device, downstream in the flow

direction in which the conveying pressure is generated – increases the certainty that only the desired amount of fluid is also actually delivered. In conventional infusion pumps, in which the fluid conveying means also simultaneously doses, incorrect delivery can occur due to thermal expansion in the fluid. In the infusion pump in accordance with the invention with the delivery control device downstream, by contrast, the pressure increases upstream of the inlet of the delivery control device in the event of thermal expansion. The conveying means may yield and so completely or partially compensate for the increase in pressure. Only thermal expansion in a volume of fluid downstream of the inlet of the delivery control device causes incorrect delivery, which however is correspondingly reduced as compared to conventional infusion pumps due to the reduced volume. The invention thus reduces incorrect delivery due to temperature fluctuations.

The fluid conveying means applies a pressure to the fluid at the inlet of the delivery control device at least immediately before and while the fluid is delivered by the delivery control device. In accordance with an advantageously simple embodiment, pressure is permanently applied to the fluid at the inlet of the delivery control device, such that additional control means for controlling the application of pressure do not have to be provided.

Preferably, the delivery control device temporarily opens an outlet which communicates with its inlet, such that pressurised fluid is delivered in a controlled manner for a predeterminable time interval. In order to control the delivery control device, an electronic control means is preferably provided in order to variably control the duration of the time interval in accordance with the dosage to be achieved.

A fluid container for storing the fluid is connected to the infusion pump or even integrated into it, such that a mobile infusion pump can be provided. In accordance with this embodiment, the fluid conveying means applies pressure – very particularly preferably, permanently – to the fluid stored in the fluid container, in order to convey the fluid from a delivery opening of the fluid container to the inlet of the delivery control device. Preferably, the fluid container is connected to the

delivery control device via a comparatively short and barely flexible or inflexible conduit, such that the pressure causes at most a negligible deformation of the conduit walls. The delivery control device can also be provided directly on or in the delivery opening of the fluid container and for example integrated into it.

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The fluid conveying means very particularly preferably applies pressure permanently to the fluid container, such that the fluid is conveyed to the delivery control device in an uncontrolled manner and delivery is controlled exclusively by the delivery control device which is decoupled from the fluid conveying means for this purpose.

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The fluid container can be a typical glass or plastic ampoule, for example exhibiting a substantially cylindrical cross-section, or a substantially rectangular body and comprises a piston stopper which delivers the fluid from the container when the piston stopper is advanced by the fluid conveying means. The fluid container can also be a pouch or the like, the wall of which is deformed by applying pressure, in order to deliver fluid. The delivery opening is preferably arranged at substantially the opposite end of the fluid container to the fluid conveying means, such that low forces can advantageously cause the fluid to be delivered.

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The fluid conveying means comprises a drive means which applies a drive force to the piston stopper towards the delivery opening. Preferably, the drive means is elastically biased and permanently applies a drive elasticity force to the piston stopper in order to advance it, for example by means of a biased pressure spring, a spiral spring mechanism, a torsion spring mechanism, an elastomer which is compressed in an initial position or a pressurised gas reservoir, for example a pneumatic system which can be pumped up. As long as the delivery control device assumes a closed position, i.e. a blocking position, in order to prevent the fluid from being delivered, the piston stopper cannot be advanced, since the fluid stored in the fluid container is substantially incompressible. If, by contrast, the delivery control device releases the fluid for delivery, then the throughflow rate is substantially predetermined by the elasticity force of the drive means, which can

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preferably be pre-set, and the resultant advance of the piston stopper in combination with the size of the flow cross-section and/or the opening time of the flow cross-section of the delivery control device, such that the dose actually administered can be calculated in a simple way by taking into account the concentration
5 of the medical or therapeutic active agent contained in the fluid. This calculation can be performed with the aid of a typical electronic control means, for example a microprocessor, which is advantageously part of the infusion pump.

The fluid conveying means can also be one which applies pressure to the fluid at
10 the inlet of the delivery control device only intermittently, i.e. at least before and while the delivery control device is operated, such that the energy consumption of the infusion pump can advantageously be reduced. Such an embodiment is advantageous in particular when a motorised fluid conveying means is used, for example a motorised piston stopper advancing mechanism.

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The pressure which is applied to the fluid at the inlet of the delivery control device can preferably be varied, which in a known way causes a change in the throughflow rate and therefore the dosage which is actually administered.

20 In all the above embodiments, the delivery control device preferably closes permanently and its outlet is only exposed temporarily in order to cause a dosed amount of fluid to be delivered. Preferably, the cross-section of the outlet of the delivery control device is variably predeterminable. A control means, for example a microprocessor or ASIC, is preferably provided for controlling the delivery control
25 device.

In a method which can be performed using the infusion pump for controlling the administering, in doses, of the fluid to be injected, preferably a fluid containing a medical or therapeutic active agent, pressure is applied to the fluid at the inlet of
30 the delivery control device. The delivery control device is operated in order to cause the pressurised fluid to be delivered, wherein applying pressure to the fluid is decoupled from operating the delivery control device. The control method can be used universally with various fluid and/or drug containers, fluid conveying

means and delivery control devices. Important control parameters – such as for example the period of time during which the delivery control device releases fluid for delivery, the cross-section of the outlet of the delivery control device during fluid delivery, the concentration of the medical or therapeutic active agent contained in the fluid, the pressure burden which prevails at the inlet of the delivery control device, etc. – can be inputted into the control means, for example from a fixed program or from sensors provided in the infusion pump, such that with the aid of the control method, precise dosing can be achieved in a simple and comparatively cost-effective infusion pump even over longer periods of time.

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The control method is preferably realised as a machine-readable or microprocessor-readable control program and is preferably stored on a semi-conductor device, for example an EPROM, an EEPROM or the like, which is also available as a separate component.

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Preferred embodiments of the invention are described below by referring to the enclosed figures, in which:

Figure 1 schematically shows the design of an infusion pump in accordance with the invention;

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Figure 2 schematically shows the design of an infusion pump in accordance with the invention, in which a peristaltic pump serves as a delivery control device; and

Figure 3 schematically shows a cycle of the peristaltic pump shown in Figure 2 for controlling and dosing the amount of fluid delivered.

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In the figures, identical reference signs denote identical or functionally identical components and functional groups. Other objects to be solved, advantages and features of the present invention will become evident to the person skilled in the art from the figures and the following description.

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Figure 1 schematically shows the design of a decoupled infusion pump in accordance with the present invention. The infusion pump comprises a drug container 1, a fluid conveying means 2 by means of which a conveying pressure is generated in the container 1, and a delivery control device 3 which is downstream of the drug container 1 for controlling the delivery of fluid from the drug container 1. The drug container 1 comprises a substantially cylindrical or polygonal – for example, rectangular – wall 7 which has a piston stopper 6 inserted at its proximal end, wherein when the piston stopper 6 is axially advanced, it conveys the fluid stored in the drug container 1, which contains a medical or therapeutic active agent, through a delivery opening 8 into the connecting conduit 9, in or to the delivery control device 3. The drug container 1 can also be a pouch comprising at least one flexible side wall, which is compressed in order to deliver the fluid stored in the pouch, for example by a motorised or electromagnetically advanced mechanism which can advance a side wall of the pouch inwards.

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The pressure generating means 2 comprises a drive means 5, for example: a pressure spring which is maximally biased in the initial state of the infusion pump, i.e. in the proximal end position of the piston stopper 6; a biased spiral spring mechanism which permanently applies pressure to the piston stopper 6; a biased torsion spring mechanism, comparable to that of a clock mechanism, which advances the piston stopper 6; an elastomer which is biased in the initial state; or a pneumatic system which is maximally pumped up in the initial state of the infusion pump. A drive force – in the example embodiment, an elasticity force – which acts axially in the direction of the delivery opening 8 is exerted on the piston stopper 6 by the drive means 5. The connecting conduit 9 and the side wall 7 of the drug container 1 are preferably inflexible. The incompressible fluid contained in the drug container 1 and connecting conduit 9 can only be delivered by the piston stopper 6 from an outlet 11 of the delivery control device 3 when the outlet 11 of the delivery control device 3 is open. In the embodiment shown in Figure 1, in which a pressure burden which is not necessarily constant permanently exists at the inlet of the delivery control device 3 connected to the container 1, the fluid conveying means 2 and the delivery control device 3 are decoupled from each

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other. The delivery control device 3 and the fluid conveying means 2 can be operated, manipulated or exchanged independently of each other, without this substantially affecting the mode of operation of the infusion pump.

- 5 The delivery control device 3 exclusively serves to dose the fluid delivery and in no way affects the fluid conveying and/or pressure generating means 2.

The infusion pump shown in Figure 1 is characterised by a modular design in which the most important individual components such as for example the delivery
10 control device 3, the drug container 1 and the fluid conveying means 2, can be exchanged and replaced with other components in a simple way, for example in accordance with specific applications. The drug container 1 can in particular be replaced with a drug container of a different size, shape, etc., as long as the fluid conveying means 2 can perform its proper function, for example that of applying
15 pressure to the piston stopper 6 permanently or at least immediately before and while the outlet 11 of the delivery control device 3 is open. A universal fastening point for connecting the piston stopper 6 to the drive means 5 can be provided on the rear side of the piston stopper 6 for this purpose, for example a universal thread for optionally connecting to different drive members 5, for example a pres-
20 sure spring, a torsion spring mechanism, a spiral spring mechanism, a biased elastomer, a pneumatic chamber or a threaded rod of a motorised conventional piston stopper advancing means.

Any device which only allows through a precisely defined amount of fluid at its
25 inlet, both when the pressure burden is permanent and when it is variable, is a possible delivery control device 3. One example is a throughflow pump which closes tight in its resting state, for example the peristaltic pump shown in Figures 2 and 3. Another example is a modified rotary-type or roller peristaltic pump which permanently and completely crimps a flexible tube, such that fluid cannot be de-
30 livered, and which crimps a flexible tube less severely in order to deliver the fluid, such that a predeterminable cross-section of the flexible tube releases the fluid for delivery.

The delivery control device 3 thus differs in principle with regard to a passive mode of operation, in which pressure is permanently or near-continuously applied to the inlet of the delivery control device 3 and a closing means – for example a valve, a nozzle or a cross-sectional constriction – is opened in synchrony with the delivery of fluid, and an active mode of operation in which the fluid conveying means merely ensures a sufficient supply of the fluid to be administered and the fluid is actively delivered by the delivery control device 3, for example by means of a peristaltic pump as described in Figures 2 and 3, a rotary-type pump or the like, which conveys a predeterminable amount of fluid through the outlet 11.

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In accordance with the invention, the dosing precision is not limited by the fluid conveying means 2 but is rather predetermined by the dosing precision of the delivery control device 3. It is therefore possible to use a simple and cost-effective fluid conveying means 2 which can exhibit broad production tolerances. The infusion pump in accordance with the invention can therefore in particular comprise an expelling mechanism which is embodied to be comparatively small and in which production tolerances are all the more relevant. In order to manufacture the expelling mechanism, it is in particular possible to omit the use of mechanical precision components, for example precise threaded rods and the like.

20

In order to control the delivery control device 3, a control program can be provided, for example integrated in a semi-conductor device, which can be provided with important parameters of the infusion pump shown or into which such parameters can be inputted and which controls the delivery control device 3 in a suitable way, in order to does the fluid in the desired manner. Important control parameters are in particular: the drive force which is applied, permanently or at least while the fluid is being dispensed, to the piston stopper 6 in order to advance it; the cross-section of the connecting conduit 9; the cross-section of the outlet 11 and any downstream components not shown, such as for example valves and the like; and the flow cross-section of the outlet 11 of the delivery control device 3. The pressure burden which prevails at the inlet of the delivery control device 3 can be calculated from the drive force which is applied to the piston 6. The

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throughflow rate which can be achieved can be back-calculated from said pressure burden in a known way if the flow cross-sections of the elements which determine the fluid flow are known. The active agent dosage which is actually administered can in turn be back-calculated from the throughflow rate if the concentration of the medical or therapeutic active agent contained in the fluid is known. Suitable calculating and controlling algorithms will be immediately evident to the person skilled in the art after studying the present description and therefore need not be explicated further.

Important parameters for the control program, for example the drive force which is applied to the piston stopper 6, the pressure burden which prevails at the inlet of the delivery control device 3, etc., can be determined using sensors which are known to the person skilled in the art and which can be arranged at suitable points in the infusion pump, and inputted into the control program in order to calculate a suitable time sequence control for the delivery control device 3 from them.

The infusion pump is in particular suitable for dispensing comparatively low doses over the longer term for the prolonged treatment of diseases, for example in order to adjust the blood sugar in diabetic patients. It is thus possible in accordance with the control program, into which measurement signals of a sensor for measuring blood sugar can also be inputted, to predetermine the times and dosages to be administered of insulin which is stored in the drug container 1.

In embodiments in which the piston stopper 6 is permanently mechanically biased in particular, it is possible to realise a particularly energy-saving infusion pump, since substantially the only energy consumer is the delivery control device 3 and its control program. The drive means 5, for example a restoring spring, can be mechanically biased, for example manually, before the infusion pump is put into operation. While the infusion pump is in operation, the drive means 5 completely or preferably only partially depletes its biasing force by generating the drive force due to advancing the piston stopper 6.

Figure 2 shows a variant of the embodiment shown in Figure 1, in which the delivery control device 3 is realised as a peristaltic pump 12. The peristaltic pump 12 comprises three fingers 13a, 13b and 13c which can for example be driven by cams (not shown) and a rotary shaft in order to perform a movement, substantially vertical with respect to the flow direction, between an upper position in which a cross-section of the connecting conduit 9 is exposed and a lower position in which the cross-section of the connecting conduit 9 is blocked, preferably completely, such that fluid cannot be relayed to the outlet 11 of the peristaltic pump 12.

10 The peristaltic pump 12 performs the cycle shown schematically in Figure 3, which begins with the initial state A in which all the fingers 13a–c block the cross-section of the connecting conduit 9, such that the upstream volume of fluid 14 is blocked upstream of the rear finger 13a. The rear finger 13a is then raised into its upper end position, such that the upstream volume of fluid 14 progresses as far as the middle finger 13b. Raising the middle finger 13b further conveys the upstream volume of fluid 14 as far as the downstream, front finger 13c. The rear finger 13a is then moved into its lower end position, such that a portion of the upstream volume of fluid 14 is trapped between the front finger 13c and the rear finger 13a. The dosage which is actually administered can be predetermined by selecting the raising height of the middle finger 13b, if the middle finger 13b can additionally also assume and hold intermediate positions between its two end positions. After the front finger 13c has been opened (Step E), the middle finger 13b transferred to its lower end position (Step F) and the rear finger 13a transferred to its lower end position, the initial state A has finally been reached again, wherein an amount of fluid which is predetermined by means of the delivery control device 3 has been dispensed to the downstream volume of fluid 15.

In this variant, the upstream volume of fluid 14 is further conveyed into the peristaltic pump 12 by the pressure burden which prevails at the inlet of the peristaltic pump 12, wherein the fluid is dispensed in a controlled manner from the peristaltic pump 12 under the control of the aforesaid control program.

By changing the control parameters of the aforesaid control program, the discharge of fluid can be configured variably and for a multitude of different components of the infusion pump, as will be immediately evident to the person skilled in the art when studying this patent description. The fluid can be dispensed according to a pre-programmed profile, inputted for example by the physician performing the treatment and/or in accordance with the patient's wishes. The infusion pump can be operated with an exchangeable drug container. The infusion pump described above can be particularly advantageously used as a modular infusion pump system in which an identically embodied delivery control device can be used with any drug modules, i.e. consisting of an expelling mechanism and a drug container.

Patentkrav

1. Infusionspumpe til doseret afgivelse af en medicinsk væske, som skal inji-
ceres, og som omfatter en væskebeholder (1), der indeholder den væske, der
5 skal injiceres;
et væsketransportmiddel (2) til transport af væsken fra væskebeholderen;
en udleverings-styreindretning (3) til dosering af den udleverede væske,
og hvor væsketransportmidlet kan (2) kan påvirke den i væskebeholderen (1)
opbevarede væske med et tryk, så at væsken føres fra en udleveringsåbning (8)
10 i væskebeholderen (1) til et indløb (9) i udleverings-styreindretningen (3), og hvor
væsketransportmidlet (2) kan påvirke væsken ved indløbet (9) til udleverings-sty-
reindretningen (3) med et tryk,
- kendetegnet ved,**
- at væsketransportmidlet (2) er koblet fra udleverings-styreindretningen (3),
15 at udleverings-styreindretningen (3), såvel ved permanent som ved variabelt
overtryk, ved sit indløb kun lader en nøjagtigt defineret væskemængde passere
igennem;
at udleverings-styreindretningen (3) omfatter en gennemstrømningspumpe eller
en karruselpumpe eller en rulleklempumpe;
- 20 at udleverings-styreindretningen (3) har et udløb (11), hvorigennem den trans-
porterer væsken;
at væskebeholderen (1) omfatter en stempelprop (6), som ved sin bevægelse
fremad kan medvirke til at udlevere væsken, og at væsketransportmidlet (2) kan
drive stempelproppen (6) fremad;
- 25 at væsketransportmidlet (2) omfatter et fremdrivningsmiddel (5) for med en driv-
kraft at kunne drive stempelproppen (6) hen til udleveringsåbningen (8);
at fremdrivningsmidlet er et med motor forsynet stempelprop-drev, fortrinsvis
med reguleret stødkraft til at drive stempelproppen (6) fremad,
eller en trykfjeder, en spiralfjedermekanisme, en drejefjedermekanisme eller en i
30 en udgangsstilling komprimeret elastomer.

2. Infusionspumpe ifølge krav 1, og hvor væsketransportmidlet (2) permanent kan påvirke væsken ved udleverings-styreindretningens (3) indløb (9) med et tryk.
- 5 3. Infusionspumpe ifølge et af de foregående krav, og hvor væsketransportmidlet (2) permanent kan påvirke væskebeholderen (1) med et tryk, så at væsken ukontrolleret føres til udleverings-styreindretningen (3).
4. Infusionspumpe ifølge et af de foregående krav, og hvor væsketransportmidlet (2) med et tryk kan påvirke væskebeholderen (1) ved dennes modsat væskebeholderens udleveringsåbning (8) beliggende ende.
- 10 5. Infusionspumpe ifølge et af de foregående krav, og hvor væsketransportmidlet (2) er således taktmæssigt afstemt, at det med et tryk kan påvirke indløbet (9) i udleverings-styreindretningen, i det mindste før og under en aktivering af udleverings-styreindretningen (3) med henblik på en udlevering.
- 15 6. Infusionspumpe ifølge et af de foregående krav, og hvor der ved indløbet (9) til udleverings-styreindretningen (3) kan tilføres et variabelt tryk til fluidet.
- 20 7. Infusionspumpe ifølge et af de foregående krav, og hvor udleverings-styreindretningen (3), når denne befinder sig i en hviletilstand, kan lukke, og at der findes et styreorgan, som kan bevirke udlevering af en doseret væskemængde.
- 25 8. Infusionspumpe ifølge et af kravene 1 til 7, og hvor udleverings-styreindretningen er en i hvile tætsluttende gennemstrømningspumpe.
9. Infusionspumpe ifølge krav 8, og hvor gennemstrømningspumpen er en peristaltikpumpe.

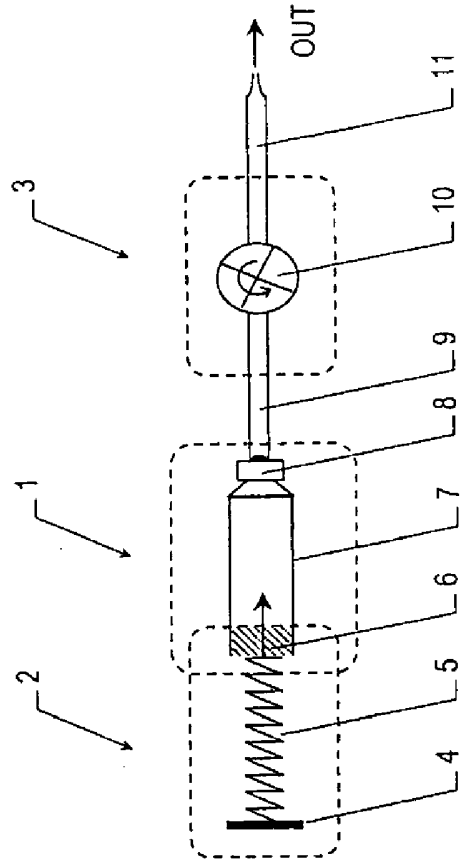


Fig. 1

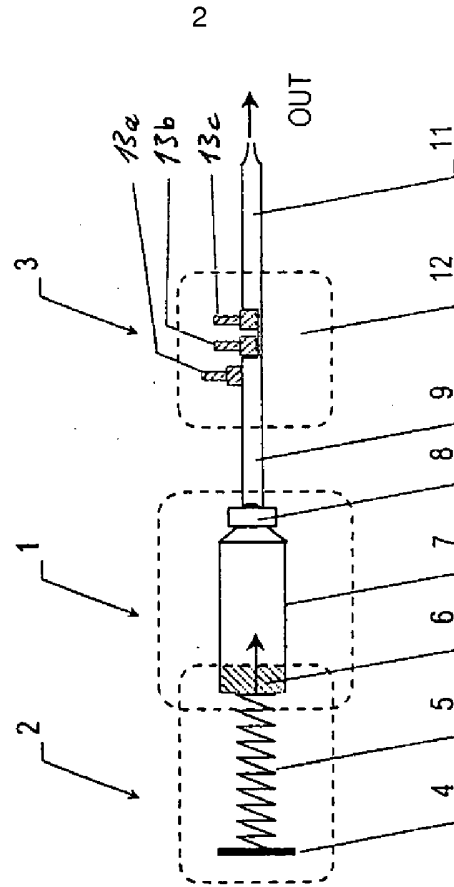


Fig. 2

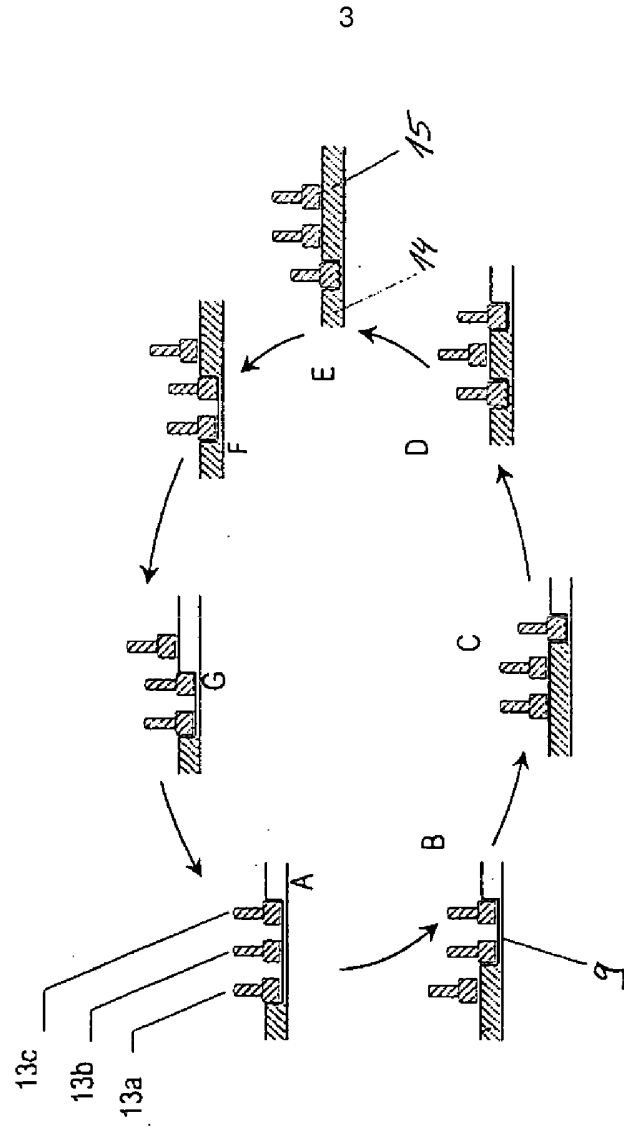


Fig. 3