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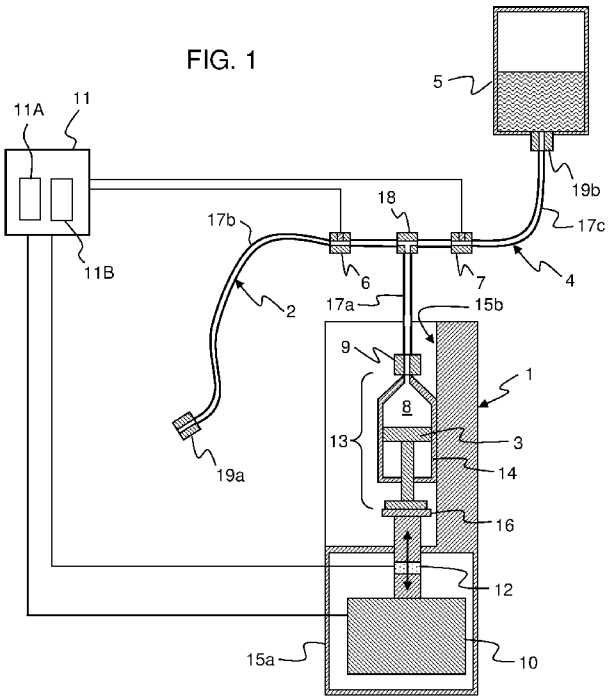
(54) Title: METHODS AND DEVICES FOR OPERATING AN INFUSION SYSTEM

FIG. 1



(57) Abstract: An infusion system defines a fill path (4) for an infusion liquid from a source (5) to a displacement volume in a fluid chamber (8) of an infusion pump (1), and an infusion path (2) from the displacement volume to a connector (19a). The infusion pump (1) is operated to repeatedly draw infusion liquid from the source (5) into the displacement volume via the fill path (4) and push infusion liquid from the displacement volume through the connector (19a) via the infusion path (2). A controller (11) selectively effects a priming operation, by operating the infusion pump (1) to generate a priming fill stroke, in which a priming volume of the infusion liquid is drawn from the source (5) to the displacement volume, and a priming pump stroke, in which at least part of the priming volume is pushed from the displacement volume back to the source (5). The infusion system is thereby operable to be primed automatically, and proper priming may be verified by evaluating a measurement signal representative of fluid pressure in the displacement volume during either of the priming fill stroke and the priming pump stroke.

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METHODS AND DEVICES FOR OPERATING AN INFUSION SYSTEM

Technical Field

The present invention generally relates to infusion systems such as those used for controlled delivery of fluid to a human or animal subject. More specifically, the invention relates to priming of an infusion system.

Background art

Infusion pumps and systems are well-known in the art, for use in delivering or dispensing an infusion liquid or a prescribed medication to a patient through parenteral or intravenous administration.

A typical infusion pump includes a housing, which encloses a pump drive system, a fluid containment assembly, an electronics system and a power supply. The pump drive system typically includes a small electrical motor and drive train components such as gears, screws and levers that convert rotational motor motion to a translational movement of a plunger in a reservoir. The fluid containment assembly typically includes the reservoir with the plunger, tubing, and a catheter or infusion set to create an output fluid path for carrying infusion liquid from the reservoir to the body of the patient. The electronics system regulates power from the power supply to the motor. The electronics system may include programmable controls that operate the motor continuously or at periodic intervals to obtain a closely controlled and accurate delivery of infusion liquid over an extended period of time.

CA1067781 and US4137913 disclose an infusion system in which the electronics system controls the motor to reciprocate the plunger back and forth in the reservoir in alternate fill and pump strokes. The reservoir is connected to the body of the patient via a line set that defines an output fluid path. The reservoir is also connected to a source of infusion liquid, via a line set that defines an input fluid path. A pair of valves are arranged to open and close the input fluid path and the output fluid path, respectively, in synchronization with the reciprocating movement of the plunger. Thereby, infusion liquid is sucked into the reservoir via the input fluid path on a fill stroke, and infusion liquid is dispensed to the patient through the output fluid path on a pump stroke.

Generally, medical infusion systems need to be primed whenever the source of infusion liquid is exchanged or replenished, or any other fluid-containing part of the infusion system is replaced, in order to expel gases from the infusion system. This is typically done by a nurse, who activates the infusion system, while it is disconnected from the patient, to pump a quantity of infusion liquid from the source through the reservoir and out of the disconnected output fluid path. The infusion system is kept operative until the

nurse by experience judges that a sufficient quantity of liquid has been pumped out through the output fluid path and that the system thereby has been purged from air. Such a manual priming process is time-consuming and labour-intensive. Further, the priming process may lead to spillage and a general waste of infusion liquid. Still further, such a priming process leaves room for human error and may result in inadequate priming of the infusion system.

The prior art also comprises WO93/12825, which discloses an automated priming system for an infusion system which includes a reciprocating plunger mechanism and a pumping cassette through which a drug is pumped to a manifold for distributing the drug to a patient. The cassette includes air sensors for detecting air in the drug path inside the cassette, as well as pressure detectors. The automated priming includes a back-priming sequence, in which the drug is first drawn from a drug vial into the a pumping chamber in the cassette and then dispelled back toward the drug vial, with the result that air entrapped in the drug is released into the drug vial. The back-priming sequence is followed by normal priming, in which drug is pumped from the cassette into a distal tubing that extends between the cassette and the manifold. During the automated priming, the quantity of air is monitored by the air detectors. After priming the distal tubing, a cassette pressure test is performed to verify that no significant quantity of air remains in the cassette. During this test, the inlet and outlet of the cassette are closed, the pumping chamber is pressurized and the quantity of pressure increase is evaluated to assess the amount of air remaining in the cassette. The infusion system operates with a highly specialized cassette provided with different types of sensors, and is designed to identify presence of air inside the cassette. Testing for remaining air in the proximal tubing that extends between the cassette and the drug vial may require the automated priming to be repeated. The infusion system is not suited to verify proper priming of the distal tubing.

US6368314 discloses a portable infusion pump with a housing for receiving an ampulla filled with insulin. A piston in the housing is advanced to dispense the insulin through a catheter connected to an outlet of the ampulla. The reaction force exerted on a the piston during pumping is acquired and used as a measure of the fluid pressure inside the ampulla. It is stated that the reaction force may be monitored for determination of completed priming, identification of possible occlusion and leakages, and determination of the fill condition of the ampulla.

The prior art also comprises US5935105, which discloses an infusion system for pumping an infusion liquid through an IV line from a source via an outlet valve to a patient. The infusion system includes a return line which is fixedly arranged to extend from a position on or near the outlet valve back to the source. When an air detector signals presence of air bubbles in the IV line upstream of the outlet valve, the outlet valve is closed, the return line is opened and the pump is operated to push infusion liquid and air bubbles back to the source. A similar infusion system is disclosed in WO01/91829.

Summary

It is an object of the invention to at least partly overcome one or more limitations of the prior art.

This and other objects, which may appear from the description below, are at least partly achieved by means of methods, computer program products, control devices, infusion systems, and a fluid transportation kit according to the independent claims, embodiments thereof being defined by the dependent claims.

A first aspect of the invention is a method of operating an infusion system. The infusion system defines a fill path for an infusion liquid from a source to a displacement volume in a fluid chamber of an infusion pump, and an infusion path for the infusion liquid from the displacement volume to a system connector. The method comprises the steps of: operating the infusion pump to repeatedly draw infusion liquid from the source into the displacement volume via the fill path and push infusion liquid from the displacement volume through the system connector via the infusion path; selectively effecting a priming operation, in which the infusion pump is operated to generate a priming fill stroke, in which a priming volume of the infusion liquid is drawn from the source to the displacement volume, and a source-directed priming pump stroke, in which at least part of the priming volume is pushed from the displacement volume back to the source. The method further comprises: obtaining a measurement signal representative of fluid pressure in the displacement volume during at least one of the priming fill stroke and the source-directed priming pump stroke, and verifying proper priming based on the thus-obtained measurement signal.

The method of the first aspect thus performs a priming of the fill path and the displacement volume and executes a priming test during the priming fill stroke and/or the source-directed priming pump stroke. During these strokes the displacement volume is open towards the fill path, and the fluid pressure in the displacement volume is affected by presence of gases not only in the displacement volume but also in the fill path. By evaluating the measurement signal, it is thus possible to verify that both the fill path and the displacement volume are properly filled with infusion liquid and/or purged from gases. The first aspect also enables the priming test to be completed before the infusion liquid is pumped into the infusion path. This may enable a partial priming of the infusion system, e.g. when an empty source has been exchanged for a filled source. After such an exchange, the infusion path may be presumed (or otherwise verified) to be filled with infusion liquid, whereas the fill path may contain gases. In this situation, it may be advantageous to perform and verify a partial priming of only the displacement volume and the fill path. The first aspect also provides an ability to detect, as part of the priming, presence of leakages of air into the infusion system upstream of the infusion pump, e.g. in the fill path and at its connection to the source.

In one embodiment, the duration of at least one of the priming fill stroke and the source-directed priming pump stroke is controlled based on said measurement signal.

In one embodiment, the step of verifying proper priming comprises verifying that the fill path and at least part of the displacement volume are filled with infusion liquid after completion of the priming fill stroke.

In one embodiment, the step of verifying proper priming comprises verifying that gases are absent in the fill path after completion of the source-directed priming pump stroke.

In one embodiment, the step of verifying proper priming comprises verifying presence of a certain temporal change in the magnitude of the measurement signal.

In one embodiment, the fluid chamber comprises at least one fluid port which is connected to the infusion and fill paths, and the infusion pump is arranged such that gases in the fluid chamber are accumulated intermediate the infusion liquid and said one or more fluid ports, by action of gravity. In such an embodiment, the method of the first aspect may further comprise a step of operating the infusion pump to generate a series of pressure pulses in the displacement volume to promote the gases to accumulate in the fluid chamber.

In one embodiment, the infusion pump comprises a valve arrangement for selectively opening and closing the infusion and fill paths, and the priming operation comprises: operating the infusion pump to generate the priming fill stroke, while causing the valve arrangement to open the fill path and close the infusion path; and operating the infusion pump to generate the source-directed priming pump stroke, while causing the valve arrangement to open the fill path and close the infusion path. The valve arrangement may be caused to open and close the infusion and fill paths by active control.

In one embodiment, the method of the first aspect further comprises a step of causing the valve arrangement to close both the infusion path and the fill path, and operating the infusion pump to generate a sub-atmospheric pressure in the displacement volume, so as to promote release of gases from the liquid in the fluid chamber.

A second aspect of the invention is a computer program product comprising instructions for causing a computer to perform the method according to the first aspect.

A third aspect of the invention is a control device for operating the above-mentioned infusion system. The control device comprises: means for operating the infusion pump to repeatedly draw infusion liquid from the source into the displacement volume via the fill path and push infusion liquid from the displacement volume through the connector via the infusion path; and priming means for effecting a priming operation, in which the infusion pump is operated to generate a priming fill stroke, in which a priming volume of the infusion liquid is drawn from the source to the displacement volume, and a source-directed priming pump stroke, in which at least part of the priming volume is pushed from the displacement volume back to the source. The control device further comprises: means for

obtaining the measurement signal representative of fluid pressure in the displacement volume during at least one of the priming fill stroke and the source-directed priming pump stroke, and means for verifying proper priming based on the thus-obtained measurement signal.

A fourth aspect of the invention is an infusion system comprising: an infusion pump comprising a fluid chamber and an actuator for driving a fluid displacing element in the fluid chamber in alternate first and second directions to define a varying displacement volume, a fill path for an infusion liquid between a source of infusion liquid and the displacement volume, an infusion path for the infusion liquid between the displacement volume and a system connector, a valve arrangement for selectively opening and closing the infusion and fill paths, and a control device according to the third aspect.

Any one of the embodiments of the first aspect may be combined with the second to fourth aspects to attain corresponding technical advantages.

A fifth aspect is an infusion system comprising: an infusion pump comprising a fluid chamber and an actuator for driving a fluid displacing element in the fluid chamber in alternate first and second directions to define a varying displacement volume; a fill path for an infusion liquid between a source of infusion liquid and the displacement volume; an infusion path for the infusion liquid between the displacement volume and a system connector; a valve arrangement for selectively opening and closing the infusion and fill paths; a recirculation enabler in fluid communication with the source and configured for coupling to the system connector so as to establish a fluid recirculation path from the displacement volume to the source, via the infusion path and through the system connector and the recirculation enabler. A control device is configured to perform a priming operation with the system connector coupled to the recirculation enabler. The priming operation comprises: operating the infusion pump to generate at least one priming fill stroke, in which a priming volume of the infusion liquid is drawn from the source to the displacement volume; and operating the infusion pump to generate at least one source-directed priming pump stroke, in which at least part of the priming volume is pushed from the displacement volume back to the source, wherein said at least one priming fill stroke and said at least one source-directed priming pump stroke circulate infusion fluid from the source to the displacement volume and back to the source via the fill path and the fluid recirculation path.

The infusion system of the fifth aspect enables priming of all fluid-containing parts of the infusion system, i.e. not only the displacement volume and fill path, but also the infusion path that extends to the system connector. The priming of the infusion system requires a minimum of manual labor, and may be automated subsequent to an initial coupling of the system connector to the recirculation enabler. In this context, it is understood that the system connector may be directly or indirectly coupled to the recirculation enabler so as to establish the fluid recirculation path. The fifth aspect provides

an infusion system that is practical and easy to use for nurses as well as other users, which may but need not be medically trained. The infusion system allows the priming to be performed on a closed system, such that any gases in the infusion system are collected in the source. By way of the closed system, spillage and waste of infusion liquid during priming may be limited, or even eliminated.

In one embodiment, the infusion system further comprises a sensor for generating a measurement signal representative of fluid pressure in the displacement volume, and the control device is configured to obtain the measurement signal during at least one of said at least one priming fill stroke and said at least one source-directed priming pump stroke, and verify proper priming based on the thus-obtained measurement signal.

In one embodiment, the control device is configured to control the duration of at least one of said at least one priming fill stroke and said at least one source-directed priming pump stroke based on said measurement signal.

In one embodiment, the control device is configured to verify proper priming by verifying that at least part of the displacement volume and at least one of the fill path and the fluid recirculation path are filled with infusion liquid after completion of said at least one priming fill stroke.

In one embodiment, the control device is configured to verify proper priming by verifying that gases are absent in the fill path and the fluid recirculation path during or after completion of said at least one source-directed priming pump stroke.

In one embodiment, the control device is configured to verify proper priming by verifying presence of a certain temporal change in the magnitude of the measurement signal.

In one embodiment, the fluid chamber comprises at least one fluid port which is connected to the infusion and fill paths, wherein the infusion pump is arranged such that gases in the fluid chamber are accumulated intermediate the infusion liquid and said one or more fluid ports, by action of gravity. In one embodiment, the control device is configured to operate the infusion pump to generate a series of pressure pulses in the displacement volume to promote the gases to accumulate in the fluid chamber. In one embodiment, the control device is configured to cause the valve arrangement to close both the infusion path and the fill path, and operate the infusion pump to generate a sub-atmospheric pressure in the displacement volume, so as to promote release of gases from the liquid in the fluid chamber.

In one embodiment, the control device is configured to perform a first sequence of a first priming fill stroke and a first source-directed priming pump stroke while one of the fill path and the fluid recirculation path is open and the other is closed, and a second sequence of a second priming fill stroke and a second source-directed priming pump stroke while said one of the fill path and the fluid recirculation path is closed and the other is open.

In one embodiment, the control device is configured to perform a sequence of a first priming fill stroke while at least one of the fill path and the fluid recirculation path is open, and a first source-directed priming pump stroke while one of the fill path and the fluid recirculation path is open and the other is closed.

In one embodiment, the control device is configured to actively control the recirculation enabler to selectively open and close the fluid recirculation path.

In one embodiment, the recirculation enabler is connected in fluid communication with the fill path between the source and the displacement volume.

In one embodiment, the recirculation enabler is connected to the source on a fluid path separate from the fill path.

In one embodiment, the recirculation enabler is configured as one of a connector with integrated valve function, and a combination of a connector for coupling to the system connector and a physically separate valve device.

In one embodiment, the control device is configured to, subsequent to the priming operation, control the infusion pump to repeatedly draw infusion liquid from the source into the displacement volume via the fill path and push infusion liquid from the displacement volume through the system connector via the infusion path. The control device may be configured to actively control the valve arrangement to open and close the infusion path and the fill path. Alternatively, the valve arrangement may comprise a first one-way valve in the infusion path, and a second one-way valve in the fill path.

A sixth aspect is a control device for operating the infusion system of the fifth aspect. The control device is operable to control the infusion pump to perform a priming operation when the system connector is coupled to the recirculation enabler. The priming operation comprises: operating the infusion pump to generate at least one priming fill stroke, in which a priming volume of the infusion liquid is drawn from the source to the displacement volume: and operating the infusion pump to generate at least one source-directed priming pump stroke, in which at least part of the priming volume is pushed from the displacement volume back to the source, wherein said at least one priming fill stroke and said at least one source-directed priming pump stroke circulates infusion fluid from the source to the displacement volume and back to the source via the fill path and the fluid recirculation path.

A seventh aspect is a method of operating the infusion system of the fifth aspect. The method comprises controlling the infusion pump to perform a priming operation when the system connector is coupled to the recirculation enabler. The priming operation comprises: operating the infusion pump to generate at least one priming fill stroke, in which a priming volume of the infusion liquid is drawn from the source to the displacement volume; and operating the infusion pump to generate at least one source-directed priming pump stroke, in which at least part of the priming volume is pushed from the displacement volume back to the source, wherein said at least one priming fill stroke and said at least one source-

directed priming pump stroke circulates infusion fluid from the source to the displacement volume and back to the source via the fill path and the fluid recirculation path.

An eighth aspect is a computer program product comprising computer code which, when executed on a data-processing system, is adapted to carry out the method of the seventh aspect.

A ninth aspect is a fluid transportation kit, which comprises tubing with connectors for connection to a source of infusion liquid and to a fluid chamber of an infusion pump, and which is configured to define a fill path for the infusion liquid from the source to the fluid chamber and an infusion path for the infusion liquid from the fluid chamber to a system connector attached to an end of the tubing, further comprising a recirculation enabler, which is attached to the tubing so as to provide fluid communication with the source and which is configured for coupling to the system connector so as to establish a fluid recirculation path from the fluid chamber to the source, via the infusion path and through the system connector and the recirculation enabler. In one embodiment, the recirculation enabler is coupled to the system connector. In one embodiment, the fluid transportation kit is sterilized. In a further embodiment, the source of infusion liquid is included in the fluid transportation kit and is connected to the fill path. In a further embodiment, the fluid transportation kit comprises a cartridge, which is connected to the fill and infusion path to define the fluid chamber and which is configured to be mounted in the infusion pump.

Any one of the embodiments of the fifth aspect may be combined with the sixth to ninth aspects to attain corresponding technical advantages.

Still other objectives, features, aspects and advantages of the present invention will appear from the following detailed description, from the attached claims as well as from the drawings.

Brief Description of the Drawings

Embodiments of the invention will now be described in more detail with reference to the accompanying schematic drawings.

Fig. 1 is an elevated section view of an exemplary infusion system.

Fig. 2 is a flow chart of an integrated priming sequence and priming test in the infusion system of Fig. 1 according to an embodiment.

Fig. 3 is a section view of an alternative embodiment of a connector in the system of Fig. 1.

Fig. 4A illustrates a variant of the infusion system in Fig. 1 which allows automatic priming of the infusion line, Fig. 4B is a section view of an alternative installation of a recirculation enabler in the system of Fig. 4A, and Fig. 4C is a section view of an alternative recirculation enabler for installation in the system of Fig. 4A.

Figs 5A-5B are flow charts of priming tests in the infusion system of Fig. 4A according to first and second embodiments.

Figs 6A-6B are block diagrams of control devices for operating the infusion systems in Fig. 1 and Fig. 4A, respectively.

Detailed Description of Example Embodiments

In the following, an exemplary infusion system is described for the purpose of illustrating different embodiments, including processes for priming the infusion system, and for verifying proper priming. Throughout the following description, like elements are designated by the same reference signs.

EXEMPLARY INFUSION SYSTEM

The following sections describe techniques for priming of an infusion system, and system tests that are undertaken in conjunction with such priming. The system tests may be carried out by selectively operating a fluid displacing element and a valve arrangement in the infusion system, and by measuring and analysing a signal indicative of fluid pressure within the infusion system. These tests will be explained in relation to an exemplifying infusion system shown in Fig. 1.

The infusion system in Fig. 1 includes a positive displacement pump 1 which operates to pump a fluid through an infusion line 2, typically to a patient (not shown). The pump contains a fluid displacing element 3 that defines an internal displacement volume. The internal displacement volume is connected via a filling line 4 to a source container 5. Control valves 6, 7 are arranged in the infusion and filling lines 2, 4 such that the displacement volume may be repeatedly filled from the source container 5 and infused into the patient while the pump operates to move the fluid displacing element 3 back and forth in a fluid chamber 8 inside the pump. The source container 5 may contain any liquid that may be dispensed to a patient, such as medications, drugs, vitamins, vaccines, hormones, water, nutrition, etc, or combinations thereof. In the following, any such liquid is referred to as an “infusion liquid”. As used herein, a liquid used for the sole purpose of priming the infusion system is also referred to as an infusion liquid. The source container 5 may generally be part of a "source" which may include further elements normally associated with source containers of infusion liquid, such as a drip chamber, a metering chamber, etc.

In the example shown in Fig.1, the infusion pump is a so-called syringe pump which defines a cylindrical fluid chamber 8. The fluid displacing element 3 is implemented as a plunger or piston, which is slidably received and adapted to be reciprocated back and forth along the axis of the chamber 8. The front end of the chamber 8 has a port for connection to the infusion and filling lines 2, 4, via an appropriate connector 9. The plunger 3 is coupled to and driven by an actuator 10 of any suitable type. The actuator 10 may, e.g., include a DC or stepper motor, which is adapted to drive the plunger 3, via appropriate

gearing (not shown). A control unit 11 is electrically connected to the actuator 10 to supply a control signal for controlling the movement of the plunger 3 in the chamber 8. The control unit 11 is also connected to obtain a measurement signal from a sensor 12 which is arranged to measure the axial force on the plunger 3. This measurement signal is representative of the fluid pressure in the displacement volume, which is the varying front-end space between the plunger 3 and the chamber 8. As will be further explained below, this measurement signal may be used by the control unit 11 to carry out system tests during operation of the infusion system.

In one embodiment, the fluid-containing part of the infusion pump 1 is designed as a disposable part or cartridge 13, e.g. of plastic material. The cartridge 13, typically formed as a syringe, includes a cylinder or barrel 14 that defines the chamber 8 in which the plunger 3 is mounted. The actuator 10 and gearing (not shown) is arranged in a pump housing 15a, which defines a mounting compartment 15b for the cartridge 13. When mounted in the mounting compartment 15b, the plunger 3 is engaged with a fixture/holder 16 which is driven by the actuator 10, such that the plunger 3 may be driven to reciprocate along the cylinder 14. The use of a disposable cartridge 13 may facilitate the task of keeping the infusion system clean and substantially sterile (such that the number of micro-organisms is reduced to such a low population that the likelihood of infection or contamination is substantially reduced or eliminated). Whenever the infusion system needs to be cleaned, the infusion and filling lines 2, 4 may be disconnected from the patient and the source 5, respectively, and the pump 1 may be operated to drain any remaining liquid in the infusion system through the disconnected infusion line 2 and/or filling line 4. Then the cartridge 13 and filling and infusion lines 2, 4 may be detached and replaced by a new, suitably sterilized, set.

The sensor 12 may be placed anywhere in the drive train from the actuator 10 to the plunger 3 to measure variations in the force applied to one or more components within the drive train. If the fluid-containing part of the pump 1 is provided as a disposable cartridge 13, the sensor 12 is suitably arranged in the drive train within the pump housing 15a. In one embodiment, the sensor 12 is a force sensitive resistor, whose resistance changes as the force applied to the sensor changes. In alternative embodiments, the sensor is a capacitive sensor, piezoresistive sensor, piezoelectric sensor, vibrating wire sensor, magnetic sensor, optical sensor, potentiometer, micromachined sensor, linear transducer, encoder, strain gauge and the like.

In the example of Fig. 1, the infusion line 2 is formed by a first line section 17a that extends from the cartridge connector 9 attached to the port on the front end of the cartridge 13 to a first port of a 3-way connector 18, and by a second line section 17b that extends from a second port of the 3-way connector 18 to a system connector 19a (which is a distal or front connector of the infusion system). The filling line 4 is formed by the first line section 17a and a third line section 17c that extends from a third port of the 3-way

connector 18 to a source connector 19b. The connectors 9, 18, 19a, 19b may be of any suitable type, e.g. Luer lock or slip connectors, threaded connectors, snap-fit connectors, etc. Suitably, at least the system connector 19a and the source connector 19b are releasable connectors, which may be attached and detached from the downstream system (e.g. a patient catheter or a downstream line set) and the source container 5, respectively. Depending on implementation, the infusion and filling lines 2, 4 may be made up of flexible tubing (e.g. plastic), rigid tubes, or pathways/channels of a solid block (e.g. a plastic cassette), or any combination thereof.

In the example of Fig. 1, the filling valve 7 is arranged to control the flow of fluid in the filling line 4, and the infusion valve 6 is arranged to control the flow of fluid in the infusion line 2. The valves 6, 7 are opened and closed in synchronization with the movement of the plunger 3 in the chamber 8. Specifically, the filling valve 7 is opened and the infusion valve 6 is closed during a fill stroke, in which the plunger is retracted within the fluid chamber 8, so as to generate a suction force that draws fluid into the fluid chamber 8 from the source container 5 via the filling line 4. Conversely, the infusion valve 6 is opened and the filling valve 7 is closed during a pump stroke, in which the plunger 3 is pushed into the fluid chamber 8, so as to generate a driving force that pushes fluid through the infusion line 2 and out of the system connector 19a.

It should be understood that the infusion system may be operated at low flow rates and that a pump stroke may last for several minutes, hours, or even days. When the plunger 3 reaches the end of the pump stroke, which may be indicated by a dedicated sensor (not shown) in the pump, the control unit 11 initiates the fill stroke, which generally should be completed as fast as possible, whereupon the control unit 11 again initiates a pump stroke. In certain embodiments the displacement volume of the pump may be about 10-200 cm^3, and the infusion rate may be about 1-500 ml/h. These numbers are just examples and should not be interpreted in a limiting sense.

It should be realized that the above operation of repeatedly filling and emptying the fluid chamber 8 may be achieved without any active valve control, e.g. by using check valves, also known as non-return valves or one-way valves, as infusion and filling valves 6, 7. These check valves automatically open when subjected to a sufficient pressure differential in one direction, while otherwise being closed, also when subjected to a pressure differential in the opposite direction. However, for the purpose of enabling one or more of the different system tests that are described in the following, at least one of the infusion and filling valves 6, 7 may be a control valve, which is actively controlled to open and close by a control signal from the control unit 11. The other valve may also be actively controlled, as shown in Fig. 1, or be implemented as a check valve, depending on the system tests that are to be enabled. The control valve/valves may, e.g., be implemented as a pinch valve, a clamp, a revolution valve, a sliding valve, an integrated valve function of a cassette, etc, wherein the opening and closing of the valve may be controlled by an electro-

magnet subject to the control signal from the control unit 11. Each control valve may be either normally closed or normally open.

The source 5 may be of any conventional type, e.g. a flexible container, such as a sealed plastic bag, a rigid container, such as a glass bottle, or a source that is capable of producing fluid on-line.

Certain system tests may involve causing a certain combination of open/closed states among the valves 6, 7 in the infusion system, and activating the pump 1 to displace a test volume V_t. The test volume V_t is typically displaced by controlling the pump to displace the plunger 3 a certain distance to decrease (pump direction) or increase (fill direction) the displacement volume in the fluid chamber 8. Typically, the displacement is only a small part of a complete stroke, allowing for the system test to be carried during a short time period. For example, the displacement may be less than about 10%, and preferably less than about 1%, of a complete stroke. The system tests may further involve measuring and evaluating the force response in the hydraulic system, i.e. the fluid displaced by the plunger 3, it is possible to determine the status of the hydraulic system. The force response may be measured by the aforesaid force sensor 12, either during and/or after the displacement of the test volume, or at a certain time point after initiation or completion of the displacement of the test volume. The evaluation may involve comparing the force response with a reference value, e.g. measured before the displacement of the test volume, or a reference response, e.g. obtained by theoretical modelling or from preceding calibration measurements. Generally, the system tests aim at determining the integrity of the infusion system based on a measurement signal from the sensor 12, typically by identifying presence/absence of a temporal change in the signal values of the measurement signal caused by the displacement of the test volume V_t. The temporal change may, e.g., occur in the signal values (signal profile) during and/or after the displacement, or in a difference between the signal values before and after the displacement.

AUTOMATIC PRIMING AND TESTING FOR PROPER PRIMING

It may be desirable to be able to intermittently and preferably without manual intervention carry out a priming sequence, in which the infusion system is to be purged from gas, typically air.

It may also be desirable to be able to carry out the priming sequence while the infusion system is connected to a patient, e.g. if an empty source container 5 needs to be replaced or refilled during a treatment. Furthermore, it may be desirable to carry out a priming sequence while minimizing or even avoiding spillage and waste of infusion liquid.

It may also be desirable to verify that the infusion system has been properly primed, denoted "priming test" in the following. The priming test may, e.g., be performed repetitively at well-defined time intervals, and/or each time the source 5 has been replaced or refilled, and/or each time the pump 1 has been manipulated manually, e.g. if a new

cartridge 13 has been installed in the pump 1. It may be desirable to carry out the priming test without requiring a plurality of specialized sensors, such an air detector, a drop detector, etc.

A first embodiment of a combined priming sequence and priming test will now be described for the infusion system in Fig. 1, with reference to the flowchart in Fig. 2. In this embodiment, the priming test is designed to test the hydraulic system extending from the cartridge 13 to the source container 5, while effecting a priming sequence of this hydraulic system. This embodiment, like other priming embodiments, requires the cartridge 13 to be arranged vertically with the internal displacement volume above the plunger 3, such that gas bubbles may rise to the top of the fluid chamber 8 and be expelled through the front-end port into the infusion/filling lines 2, 4.

First, the actuator 10 is controlled to arrange the plunger 3 at a desired start position (step 20). The start position need not be a specific predefined position but may be selected to at least allow the plunger 3 to be displaced a given first distance in the filling direction, so as to suck a preset priming volume V_p into the fluid chamber 8 (also denoted "priming fill stroke"). Then, the infusion valve 6 is closed and the filling valve 7 is opened (step 21). The initial force F_0 in the hydraulic system is then measured, using the sensor 12 (step 22). All subsequent force measurements may then be related to F_0, e.g. by subtracting F_0 from the actual reading. Thereafter, the actuator 10 is operated to suck the priming volume V_p via the filling line 4 into the fluid chamber 8 (step 23). The priming volume V_p is selected such that the filling line 4 and at least part of the displacement volume is filled with fluid. During the displacement of the plunger 3, the force F(t) applied to the hydraulic system is monitored, e.g. by continuously sampling a measurement signal from the sensor 12 (step 23). In step 24, the measured force is evaluated to verify proper filling. This evaluation may involve verifying if the force reaches a sufficient and/or constant level at the end of the displacement or that the force follows a certain profile during the displacement. If certain deviations are detected, the priming test proceeds to step 25 in which an alarm is issued and the priming sequence is aborted. Although not indicated in Fig. 2, step 24 may involve evaluating the measured force to verify that the source container 5 is not empty (or conversely, to verify if the source container 5 is empty), and/or verify that there are no leakage of air into the filling line 4, by operating the valves 6, 7 to close the infusion line 2 and open the filling line 4, driving the plunger 3 a given distance in the fill direction, and evaluating the force response in the hydraulic system based on the measurement signal of the sensor 12. Techniques for such evaluation are further disclosed in Applicant's U.S. provisional patent application No. 61/453,987, entitled "METHODS AND DEVICES FOR OPERATING AN INFUSION SYSTEM", which was filed on March 18, 2011 and which is incorporated herein by reference.

If step 24 indicates proper filling of the infusion system, the plunger 3 is maintained in position during a predetermined settling time, in order to allow any gas bubbles in the

displacement volume to rise to the port at the top of the fluid chamber 8 (step 26). Step 26 may also involve controlling the pump 1 to generate pressure pulses in the hydraulic system so as to detach any gas bubbles from the walls of fluid chamber 8 and the tube sections 17a-17c. The pressure pulses may be generated by vibrating the plunger 3 back and forth in the fill and pump directions. Step 26 may additionally or alternatively include a step of generating a negative (sub-atmospheric) pressure in the fluid chamber 8 to promote release of gases from the liquid, e.g. by temporarily closing the valves 6, 7 and displacing the plunger 3 a certain distance in the fill direction. Then, in step 27, the actuator 10 is operated to displace the plunger 3 a second distance in the pump direction (also denoted "priming pump stroke"), thereby driving liquid and any gas back to the source container 5. The second distance is typically less than the first distance and selected such that a certain amount of liquid remains in the displacement volume. During this displacement of the plunger 3, the force F(t) applied to the hydraulic system is monitored via the sensor 12.

Then, the measured force is evaluated to verify that the hydraulic system from the fluid chamber 8 to the source container 5 has been properly primed, i.e. that there are no significant gas residues (step 28). This evaluation may involve verifying that that the force reaches a sufficient and/or constant level at the end of the displacement or that the force follows a certain profile during the displacement. If certain deviations are detected, the priming test proceeds to step 25 in which an alarm is issued and the priming sequence is aborted, otherwise the priming sequence is successfully completed. Following completed priming, the plunger 3 may be displaced in the fill direction until the cartridge 13 is filled with liquid from the source 5. In a variation, if step 28 indicates improper priming, steps 20-28 may be repeated. Here, the process may be configured to proceed to step 25 if proper priming is not indicated by step 28 after a given number of repetitions/iterations.

In a variation, step 27 involves effecting the priming pump stroke, whereupon the filling valve 7 is closed (and the infusion valve 6 in maintained in closed position). Then, in step 28, the plunger 3 is displaced a second distance in the pump or fill direction, so as to displace the above-mentioned test volume V_t, and the force F(t) applied to the hydraulic system from the fluid chamber 8 to the valves 6, 7 is monitored via the sensor 12. Any gas residues are then identified by comparing the measured force after the displacement to a predetermined limit, or by comparing the profile of the force measured during the displacement to a reference profile.

In further variations, the length of the priming fill stroke (steps 23-24) and/or the priming pump stroke (steps 27-28) is not preset, but is controlled based on the measurement signal, i.e. the priming fill stroke/priming pump stroke is continued until the control unit 11 is able to verify, by analysing the measurement signal, that the hydraulic system is properly filled with infusion liquid/purged from gas. An alarm may be issued e.g. if the length of the priming fill stroke and/or the priming pump stroke exceeds a

predetermined limit, or if the plunger 3 comes to a fully extracted/inserted position (end-of-stroke), which may be indicated by a dedicated sensor, as is well-known in the art.

It should be realized that the priming sequence in steps 20-28 may be followed by a subsequent priming sequence for priming the hydraulic system from cartridge 13 to connector 19a. The subsequent priming sequence effects a priming fill stroke and then a priming pump stroke that pushes liquid from the fluid chamber 8, via line sections 17a and 17b, out through the connector 19a. The subsequent priming sequence may be manually terminated when liquid is seen to flow out of the connector 19a.

Fig. 3 illustrates a modification to the system of Fig. 1 that enables automatic priming of all fluid-containing parts of the infusion system. Specifically, the connector 19a is modified to incorporate a so-called hydrophobic filter 40, which is a component that allows free passage of gas while preventing passage of liquids and aerosols. The hydrophobic filter is known *per se*, and is typically used for venting gas from liquid streams, e.g. as disclosed in US4278084 and US6328789. A multitude of hydrophobic filters are commercially available. The priming sequence may involve the sequence of steps 20-28 described above, for priming and testing the hydraulic system from cartridge 13 to container 5, followed by a second execution of steps 20-28 to effect a priming fill stroke and then a priming pump stroke that pushes liquid and any gas from the fluid chamber 8, via line sections 17a and 17b, towards the connector 19a. It is realized that step 27 in the second execution is modified such that the filling valve 7 is closed and the infusion valve 6 is opened. The gases will be pushed through the filter 40 by the action of the liquid, whereas the liquid will be blocked by the filter 40. Here, the expulsion of gases may be facilitated by a vertical arrangement of line section 17b. In this fashion, the entire hydraulic system of the infusion system is primed with minimum spillage of liquid. Generally, the filter 40 may be installed anywhere along the infusion line 2, although it may be preferable to arrange the filter 40 near the connector 19a to ensure priming of the entire infusion system.

In a variant, the priming sequence involves the sequence of steps 20-24 described above, for executing a priming fill stroke, which is followed by a priming pump stroke that pushes liquid and any gas from the fluid chamber 8, via line sections 17a and 17b, towards the connector 19a. The priming pump stroke may be effected according to steps 26-28, with step 27 being modified to close the filling valve 7 and open the infusion valve 6.

The length of each priming pump stroke may be preset. In such embodiments, the priming test (step 28) may be effected by displacing the plunger 3 a second distance in the pump direction, so as to displace the above-mentioned test volume V_t. Any gas residues are then identified by comparing the force measured after the displacement to a predetermined limit, or by comparing the profile of the force measured during the displacement to a reference profile. Alternatively, the control unit 11 may control the length of the priming pump stroke based on the measurement signal from the sensor 12.

For example, the measurement signal will increase abruptly when the liquid from the source 5 reaches the filter 40 and all gases have been purged through the connector 19a. The control unit 11 may terminate the priming sequence upon detection of this signal increase, possibly after a certain time delay. Thereby, the priming test (step 28) is an integral part of the priming pump stroke (step 27).

After the priming sequence, the filter 40 may be manually removed from the connector 19a to enable connection of the connector 19a to a patient catheter or a line set. In an alternative embodiment, the filter 40 is arranged to be automatically opened or ruptured when the connector 19a is connected to another connector, e.g. in the patient catheter/line set, such that liquid is allowed to flow from the infusion line 2 through the connector 19a.

It is conceivable to verify the integrity of the hydrophobic filter 40 before or as part of the priming sequence (e.g. to check that the filter 40 has not been unintentionally ruptured). This may be done by evaluating, based on the measurement signal of the sensor 12, the force response to a displacement of the plunger 3 in the pump or fill direction, where a small force response may be taken to indicate a ruptured filter 40.

In one embodiment, the hydrophobic filter 40 is integrated with the connector 19a, which is made commercially available as a unitary disposable. It is also conceivable to provide a fluid transportation unit which includes an infusion line that extends between the connector 19a with the hydrophobic filter 40 and a proximal connector for connection to an infusion system. The fluid transportation unit may be a disposable. The proximal connector may be adapted to be connected to the outlet of the infusion pump 1, either directly (e.g. as connector 9) or indirectly (via one or more line segments connected to the infusion pump). In the example of Fig. 1, the fluid transportation unit may include connector 19a, line segment 17b, 3-way connector 18, line segment 17a, connector 9, and line segment 17c, as well as valves 6, 7. The unit may exclude valves 6, 7, which instead may be configured for re-use in the infusion system by being separately attached to the unit before use. Such valves may be configured as pinches/clamps.

Fig. 4A illustrates a further variation of the infusion system in Fig. 1 to enable automatic or semi-automatic priming of all fluid-containing parts of the infusion system. The illustrated system is identical to the system in Fig. 1, except for a recirculation enabler 19c, which is attached to a diverted tubing portion 30 of the line section 17c. It is realized that the tubing portion 30 may instead be a separate tube segment which is coupled to the line section 17c by a 3-way connector. The recirculation enabler 19c is thus arranged in fluid communication with the source 5 via the filling line 4. In the illustrated example, the recirculation enabler 19c is a connector with an integrated valve function and is configured to be coupled, directly or indirectly, to the system connector 19a. The integrated valve function is operable to selectively close and open the fluid path through the recirculation enabler 19c. In the illustrated example, the opening and closing of the fluid path through

the recirculation enabler 19c is selectively controlled by the control unit 11. During normal infusion operation of the system, the fluid path through the recirculation enabler 19c is closed and the system connector 19a is connected, directly or indirectly, to the patient. During priming, as shown in Fig. 4A, the system connector 19a is instead connected to the recirculation enabler 19c, such that fluid communication may be established between the infusion and filling lines 2, 4 by opening the valve function of the recirculation enabler 19c. It may also be desirable to check that the system connector 19a is properly connected to recirculation enabler 19c, e.g. by closing valve 7 and recirculation enabler 19c and opening valve 6, and by displacing the plunger 3 a certain distance in the pump or fill direction. A proper connection may be verified based on the force response as measured by sensor 12.

As shown in Fig. 4B, the recirculation enabler 19c may instead be in fluid communication with the source 5 by the tubing portion 30 forming a separate fluid line that extends to a source connector 31 coupled to a dedicated port on the source 5. Depending on implementation, this port may be arranged to be above (as shown) or beneath the infusion liquid in the source 5. Many conventional sources only offer a single fluid connection (port), and it may thus be advantageous for the recirculation enabler 19c to be coupled to the filling line 4, between the filling valve 7 and the connector 19b, e.g. as shown in Fig. 4A.

As indicated above, the recirculation enabler 19c may be implemented as a unitary device with a connector portion, which is configured to be coupled to the system connector 19a, and a valve portion, which is configured to selectively open and close fluid communication through the recirculation enabler 19c. In an alternative configuration, exemplified in Fig. 4C, the recirculation enabler 19c is implemented as a combination of a connector 19c' for engagement with the system connector 19a and a separate valve device 19c", which implements the valve function and which may be arranged anywhere between the connector 19c' and the filling line 4 (or in the embodiment of Fig. 4B, anywhere between the connector 19c' and the source 5). The valve device 19c" may be arranged either in the fluid path, i.e. in contact with the infusion fluid, or on the outside of the fluid path, i.e. on the tubing portion 30. The valve device 19c" may be a pinch valve, a clamp, a revolution valve, a sliding valve, etc. Since the recirculation enabler 19c, irrespective of configuration, comprises a valve function it may alternatively be denoted a "recirculation valve" or a "recirculation valve means".

There are many different ways to implement priming processes and priming tests in the system of Fig. 4A. Below, two different embodiments are briefly described with reference to a flowchart in Fig. 5A and 5B, respectively.

In the embodiment in Fig. 5A, first and second hydraulic systems are primed separately and in sequence by selective activation of the valves 6, 7 and the recirculation enabler 19c. In the illustrated example, the first hydraulic system is defined by opening the

filling valve 7, and by closing at least one of the recirculation enabler 19c and the infusion valve 6 (step 50), whereupon steps 22-28 of the priming sequence in Fig. 2 are executed. If the evaluation step 28 indicates proper priming, the second hydraulic system is defined by closing the filling valve 7 and by opening the recirculation enabler 19c and the infusion valve 6 (step 52). Then, steps corresponding to steps 22-28 of the priming sequence in Fig. 2 are executed for the second hydraulic system. It is to be understood that the order of defining and testing the first and second hydraulic systems may be reversed.

In the embodiment in Fig. 5B, first and second hydraulic systems are primed in one and the same operation. In the illustrated example, the first hydraulic system is defined by opening the filling valve 7, and by closing at least one of the recirculation enabler 19c and the infusion valve 6 (step 54), whereupon steps 22-24 of the priming sequence in Fig. 2 are executed. Thus, fluid is drawn from the source container 5 into the fluid chamber 8 via the first and third line segments 17a, 17c. Then, if step 24 indicates proper filling, the second hydraulic system is defined by closing the filling valve 7 and by opening the recirculation enabler 19c and the infusion valve 6 (step 56). Thereafter, steps corresponding to steps 26-28 of the priming sequence in Fig. 2 are executed for the second hydraulic system. Thus, liquid and any gas residuals are pumped from the fluid chamber 8 into the source 5 via the first and second line segments 17a, 17b (and part of the third line segment 17c). It is to be understood that the order of defining the first and second hydraulic systems may be reversed.

In both embodiments in Figs 5A-5B, proper priming of the second hydraulic system may be tested by closing the recirculation enabler 19c before or during the pumping of liquid from the fluid chamber 8 to the source 5 via the first and second line segments 17a, 17b, and by evaluating the force response measured by sensor 12.

In a variation of the embodiments in Figs 5A-5B, the first and second hydraulic systems are filled concurrently, by the valves 6, 7, 19c being opened and the plunger 3 being operated to draw liquid from source 5 into the fluid chamber 8. After verifying proper filling, one of the first and second hydraulic systems may be primed by closing the appropriate valves and operating the plunger to push liquid from the fluid chamber 8 to the source 5. After verifying proper priming, the plunger may be stopped, the states of the valves changed and the plunger operated to push liquid from the fluid chamber 8 to the source 5 through the not yet primed hydraulic system. Alternatively, the sequence may be repeated to fill both hydraulic systems (or only the one not yet primed), whereupon the liquid is pushed back to the source 5 through the not yet primed hydraulic system. In yet another alternative, the first and second hydraulic systems may be primed in parallel by closing the appropriate valves and operating the plunger to push liquid from the fluid chamber 8 back to the source 5.It should be noted that the infusion system in Fig. 4A may be primed according to any of the above-described priming processes without verifying proper priming based on the measurement signal from the sensor 12. Instead, proper

priming may be verified by conventional means, such as an air detector, a drop detector, etc. Alternatively, the priming test may be omitted entirely.

It is to be noted that the recirculation enabler 19c may instead be manually opened and closed, by an operator, as needed before and after the priming operation, as well as during the priming operation (if needed). For example, after having coupled the system connector 19a to the recirculation enabler 19c, the operator may manually open the recirculation enabler 19c (if not already open) and then cause the control unit 11 to operate the pump 1 to perform the priming operation. In such an implementation, the recirculation enabler 19c may remain open during the priming operation, in which the infusion and filling valves 6, 7 control the circulation of infusion liquid from the source 5 to the cartridge 13 and back to the source via the infusion line 2 and the filling line 4. After the priming operation is completed, the operator may manually close the recirculation enabler 19c and disconnect the system connector 19a from the recirculation enabler 19c.

In a further example, part of the infusion system is provided as a disposable, which defines a fluid transportation kit, e.g. in the form of a line set. The line set may comprise the filling and infusion lines 2, 4 as well as suitable connectors. In the example of Fig. 4A, the line set may include recirculation enabler 19c, connector 19a, line segment 17b, 3-way connector 18, line segment 17a, connector 9, line segment 17c and connector 19b. The line set may also include valves 6, 7, although it may be desirable to operatively connect the line set to permanent valves 6, 7 of the infusion system before use. Similarly, the recirculation enabler 19c may (but need not) consist of the connector 19c' (Fig. 4C), whereas the valve device 19c" may be formed by a permanent valve of the infusion system. The line set may be delivered with the system connector 19a coupled to the recirculation enabler 19c, e.g. in a sterilized bag. The operator may prepare the infusion system for operation by coupling the connectors 9, 19b to the pump 1 and the source 5, respectively, by attaching the line set to the valves 6, 7, by manually opening the recirculation enabler 19c (if not already open), and by causing the control unit 11 to operate the pump 1 and perform the priming operation. After completion of the priming operation, the operator may manually close the recirculation enabler 19c and disconnect the system connector 19a from the recirculation enabler 19c. In a variant, the line set also includes at least one of the source 5 and the cartridge 13.

In yet another example, the recirculation enabler 19c is configured as a connector with an integrated valve function which is normally closed and forced to open by the engagement with the system connector 19a. Thereby, the recirculation enabler 19c is selectively opened only when it is coupled to the system connector 19a.

The invention has mainly been described above with reference to a few embodiments. However, as is readily appreciated by a person skilled in the art, other embodiments than the ones disclosed above are equally possible within the scope and spirit of the invention, which is defined and limited only by the appended patent claims.

For example, the priming process and the priming tests are applicable for any conceivable type of positive displacement pump, in which a fluid displacing element defines a displacement volume which is connected to an infusion line and a filling line. Such positive displacement pumps include diaphragm and membrane pumps, in which the fluid displacing element is a membrane which may be driven to flex in alternate directions, as well as peristaltic and roller pumps, in which the fluid displacing element is one or more rollers that repeatedly engage a flexible tube to move a fluid inside the tube.

Furthermore, even though the foregoing description refers to operations of "opening" and "closing" of valves, it is evident that such an operation will be redundant if the valve already is in an appropriately closed or opened state at the relevant time point. Still further, certain valves need not be actively controlled by the control unit, but may be implemented as appropriately arranged check valves. For example, to enable the priming test in Fig. 2, both the filling valve 7 and the infusion valve 6 may be actively controlled by the control unit 11. To enable the sequential priming of the first and second hydraulic systems according to Fig. 5A, the filling and infusion valves 7, 6 may be actively controlled, and the recirculation enabler 19c may comprise a check valve. To enable the simultaneous priming of the first and second hydraulic systems according to Fig. 5B, the valves 6, 7 may be implemented as check valves, and possibly also the valve function of recirculation enabler 19c. However, any such check valve may be replaced by an actively controlled valve, e.g. to increase precision, obtain lower response times for opening/closing valves, to achieve a certain timing for the opening/closing of a valve in relation to the movement of the fluid displacing element 3, etc. As noted in the foregoing, the recirculation enabler 19c may alternatively be manually switched between an open and a closed state.

In the illustrated embodiments, the infusion and filling lines 2, 4 share a common fluid path in the first line segment 17a. In an alternative, the infusion and filling lines are fully separated, by extending from different ports on the pump.

Furthermore, the force sensor 12 may be replaced or supplemented by a sensor that is arranged to directly measure the fluid pressure in the displacement volume, or in the infusion and filling lines 2, 4 between the fluid chamber 8 and the infusion and filling valves 6, 7. Thus, there is at least one sensor that, irrespective of its type and placement, generates a measurement signal representing fluid pressure in the displacement volume.

Still further, the skilled person realizes that the priming process and priming tests may be adapted to an infusion system in which the pump is arranged to draw liquid from more than one source, via a respective combination of filling line and filling valve, and/or in which the pump is arranged to infuse the liquid to more than one patient, via a respective combination of infusion line and infusion valve.

Furthermore, in all of the above embodiments, it may be convenient to implement an overall security check, which compares the measurement signal of the force sensor 12 to maximum and minimum safety limits F_{safety_max} and F_{safety_min}. If one force reading, or a

predetermined number of consecutive force readings, fall outside the range F_{safety_max}-F_{safety_min}, the actuator 10 is suitably controlled to stop the plunger 3 and an alarm signal is issued.

The control unit 11 may be configured to collect sensor data at specific time points before and/or during and/or after a plunger displacement, as required by the respective test, and to carry out the test(s) based on the thus-collected measurement values. Alternatively, the control unit 11 may collect sensor data on a continuous basis at a particular sampling rate, and carry out the system test(s) by evaluating the resulting sequence of measurement values.

In all of the above embodiments, the control unit 11 may be implemented by one or more separate devices containing analog or digital circuitry for generating control signals for the actuator 10 and the valve(s), for obtaining the measurement signal from the sensor 12, and for executing any one of the above-described tests. The control unit 11 may be implemented by special-purpose software (or firmware) run on one or more general-purpose or special-purpose computing devices. In this context, it is to be understood that each "element" or "means" of such a computing device refers to a conceptual equivalent of a method step; there is not always a one-to-one correspondence between elements/means and particular pieces of hardware or software routines. One piece of hardware sometimes comprises different means/elements. For example, a processing unit serves as one element/means when executing one instruction, but serves as another element/means when executing another instruction. In addition, one element/means may be implemented by one instruction in some cases, but by a plurality of instructions in some other cases. Such a software-controlled computing device may include one or more processing units (indicated by reference numeral 11A in Fig. 1 and Fig. 4A), e.g. a CPU ("Central Processing Unit"), a DSP ("Digital Signal Processor"), an ASIC ("Application-Specific Integrated Circuit"), discrete analog and/or digital components, or some other programmable logical device, such as an FPGA ("Field Programmable Gate Array"). The computing device may further include a system memory (indicated by reference numeral 11B in Fig. 1 and Fig. 4A) and a system bus that couples various system components including the system memory to the processing unit. The system bus may be any of several types of bus structures including a memory bus or memory controller, a peripheral bus, and a local bus using any of a variety of bus architectures. The system memory may include computer storage media in the form of volatile and/or non-volatile memory such as read only memory (ROM), random access memory (RAM) and flash memory. The special-purpose software may be stored in the system memory, or on other removable/non-removable volatile/non-volatile computer storage media which is included in or accessible to the computing device, such as magnetic media, optical media, flash memory cards, digital tape, solid state RAM, solid state ROM, etc. The computing device may include one or more communication interfaces, such as a serial interface, a parallel interface, a USB interface, a wireless interface, a network

adapter, etc. One or more I/O devices may be connected to the computing device, via a communication interface, including e.g. a keyboard, a mouse, a touch screen, a display, a printer, a disk drive, etc. The special-purpose software may be provided to the computing device on any suitable computer-readable medium, including a record medium and a read-only memory.

Fig. 6A is an exemplifying block diagram of a control unit 11 for operating the infusion system in Fig. 1. The control unit 11 comprises outputs for providing the respective control signal to the actuator 10, the infusion valve 6 and the filling valve 7, and an input for receiving the measurement signal from the sensor 12. The control unit further comprises means 61 for operating the pump, by control of the actuator 12 and the valves 6, 7, in its regular reciprocating mode to dispel infusion liquid through the system connector 19a. The control unit 11 further comprises means 62 for priming the hydraulic system from the fluid chamber to the source container, e.g. as described above with reference to Figs 1-2, means 63 for obtaining the measurement signal during one or more of the priming fill and pump strokes, and means 64 for verifying proper priming based on the measurement signal.

Fig. 6B is an exemplifying block diagram of a control unit 11 for operating the infusion system in Fig. 4A. The control unit 11 comprises outputs for providing the respective control signal to the actuator 10, the infusion valve 6, the filling valve 7 and the recirculation enabler 19c, an input for receiving the measurement signal from the sensor 12, as well as means 65 for operating the infusion pump in its regular reciprocating mode to dispel infusion liquid through the system connector 19a. The control unit 11 further comprises means 66 for priming the first and second hydraulic systems when the system connector 19a is coupled to the recirculation enabler 19c, e.g. by controlling the actuator 10 and selectively opening and closing the valves 6, 7 and the recirculation enabler 19c as described above with reference to Figs 4-5. In the illustrated example, the priming means 66 comprises means 66A for operating the pump to generate at least one priming fill stroke, in which a priming volume of the infusion liquid is drawn from the source container into the fluid chamber, and means 66B for operating the pump to generate at least one priming pump stroke, in which at least part of the priming volume is pushed from the fluid chamber back to the source container. The means 66A and 66B thereby operates the pump to circulate infusion fluid from the source container through the first and second hydraulic systems of the infusion system. The control unit 11 further comprises means 67 for obtaining the measurement signal from the sensor 12 during the priming operation, and means 68 for verifying proper priming based on the measurement signal.

CLAIMS

1. A method of operating an infusion system, said infusion system defining a fill path (4) for an infusion liquid from a source (5) to a displacement volume in a fluid chamber (8) of an infusion pump (1), and an infusion path (2) for the infusion liquid from the displacement volume to a system connector (19a), said method comprising the steps of:

operating the infusion pump (1) to repeatedly draw infusion liquid from the source (5) into the displacement volume via the fill path (4) and push infusion liquid from the displacement volume through the system connector (19a) via the infusion path (2);

selectively effecting a priming operation, in which the infusion pump (1) is operated to generate a priming fill stroke, in which a priming volume of the infusion liquid is drawn from the source (5) to the displacement volume, and a source-directed priming pump stroke, in which at least part of the priming volume is pushed from the displacement volume back to the source (5); wherein said method further comprises:

obtaining a measurement signal representative of fluid pressure in the displacement volume during at least one of the priming fill stroke and the source-directed priming pump stroke, and verifying proper priming based on the thus-obtained measurement signal.

2. The method of claim 1, wherein the duration of at least one of the priming fill stroke and the source-directed priming pump stroke is controlled based on said measurement signal.

3. The method of claim 1 or 2, wherein the step of verifying proper priming comprises verifying that the fill path (4) and at least part of the displacement volume are filled with infusion liquid after completion of the priming fill stroke.

4. The method of any one of claims 1-3, wherein the step of verifying proper priming comprises verifying that gases are absent in the fill path (4) after completion of the source-directed priming pump stroke.

5. The method of any one of claims 1-4, wherein the step of verifying proper priming comprises verifying presence of a certain temporal change in the magnitude of the measurement signal.

6. The method of any preceding claim, wherein the fluid chamber (8) comprises at least one fluid port which is connected to the infusion and fill paths (2, 4), wherein the infusion pump (1) is arranged such that gases in the fluid chamber (8) are accumulated intermediate the infusion liquid and said one or more fluid ports, by action of gravity.

7. The method of claim 6, further comprising a step of operating the infusion pump (1) to generate a series of pressure pulses in the displacement volume to promote the gases to accumulate in the fluid chamber (8).

8. The method of any preceding claim, wherein the infusion pump (1) comprises a valve arrangement (6, 7) for selectively opening and closing the infusion and fill paths (2, 4), wherein said priming operation comprises: operating the infusion pump (1) to generate

the priming fill stroke, while causing the valve arrangement (6, 7) to open the fill path (4) and close the infusion path (2); and operating the infusion pump (1) to generate the source-directed priming pump stroke, while causing the valve arrangement (6, 7) to open the fill path (4) and close the infusion path (2).

9. The method of claim 8, wherein the valve arrangement (6, 7) is caused to open and close the infusion and fill paths (2, 4) by active control.

10. The method of claim 8 or 9, further comprising a step of causing the valve arrangement (6, 7) to close both the infusion path (2) and the fill path (4), and operating the infusion pump (1) to generate a sub-atmospheric pressure in the displacement volume, so as to promote release of gases from the liquid in the fluid chamber (8).

11. A computer program product comprising computer code which, when executed on a data-processing system, is adapted to carry out the method of any one of claims 1-10.

12. A control device for operating an infusion system, said infusion system defining a fill path (4) for an infusion liquid from a source (5) to a displacement volume in a fluid chamber (8) of an infusion pump (1), and an infusion path (2) for the infusion liquid from the displacement volume to a system connector (19a), said control device comprising:

means (61) for operating the infusion pump (1) to repeatedly draw infusion liquid from the source (5) into the displacement volume via the fill path (4) and push infusion liquid from the displacement volume through the connector (19a) via the infusion path (2); and

priming (62) means for effecting a priming operation, in which the infusion pump (1) is operated to generate a priming fill stroke, in which a priming volume of the infusion liquid is drawn from the source (5) to the displacement volume, and a source-directed priming pump stroke, in which at least part of the priming volume is pushed from the displacement volume back to the source (5); wherein said control device further comprises:

means (63) for obtaining the measurement signal representative of fluid pressure in the displacement volume during at least one of the priming fill stroke and the source-directed priming pump stroke, and means (64) for verifying proper priming based on the thus-obtained measurement signal.

13. An infusion system comprising: an infusion pump (1) comprising a fluid chamber (8) and an actuator (10) for driving a fluid displacing element (3) in the fluid chamber (8) in alternate first and second directions to define a varying displacement volume, a fill path (4) for an infusion liquid between a source (5) of infusion liquid and the displacement volume, an infusion path (2) for the infusion liquid between the displacement volume and a system connector (19a), a valve arrangement (6, 7) for selectively opening and closing the infusion and fill paths (2, 4), and the control device according to claim 12.

14. An infusion system comprising:

an infusion pump (1) comprising a fluid chamber (8) and an actuator (10) for driving a fluid displacing element (3) in the fluid chamber (8) in alternate first and second directions to define a varying displacement volume;

a fill path (4) for an infusion liquid between a source (5) of infusion liquid and the displacement volume;

an infusion path (2) for the infusion liquid between the displacement volume and a system connector (19a);

a valve arrangement (6, 7) for selectively opening and closing the infusion and fill paths (2, 4);

a recirculation enabler (19c) in fluid communication with the source (5) and configured for coupling to the system connector (19a) so as to establish a fluid recirculation path from the displacement volume to the source (5), via the infusion path (2) and through the system connector (19a) and the recirculation enabler (19c); and

a control device (11) configured to perform a priming operation with the system connector (19a) coupled to the recirculation enabler (19c), wherein the priming operation comprises: operating the infusion pump (1) to generate at least one priming fill stroke, in which a priming volume of the infusion liquid is drawn from the source (5) to the displacement volume; and operating the infusion pump (1) to generate at least one source-directed priming pump stroke, in which at least part of the priming volume is pushed from the displacement volume back to the source (5), wherein said at least one priming fill stroke and said at least one source-directed priming pump stroke circulate infusion fluid from the source (5) to the displacement volume and back to the source (5) via the fill path (4) and the fluid recirculation path.

15. The infusion system of claim 14, further comprising a sensor (12) for generating a measurement signal representative of fluid pressure in the displacement volume, wherein the control device (11) is configured to obtain the measurement signal during at least one of said at least one priming fill stroke and said at least one source-directed priming pump stroke, and verify proper priming based on the thus-obtained measurement signal.

16. The infusion system of claim 15, wherein the control device (11) is configured to control the duration of at least one of said at least one priming fill stroke and said at least one source-directed priming pump stroke based on said measurement signal.

17. The infusion system of claim 15 or 16, wherein the control device (11) is configured to verify proper priming by verifying that at least part of the displacement volume and at least one of the fill path (4) and the fluid recirculation path are filled with infusion liquid after completion of said at least one priming fill stroke.

18. The infusion system of any one of claims 15-17, wherein the control device (11) is configured to verify proper priming by verifying that gases are absent in the fill path (4) and the fluid recirculation path during or after completion of said at least one source-directed priming pump stroke.

19. The infusion system of any one of claims 15-18, wherein the control device (11) is configured to verify proper priming by verifying presence of a certain temporal change in the magnitude of the measurement signal.

20. The infusion system of any one of claims 14-19, wherein the fluid chamber (8) comprises at least one fluid port which is connected to the infusion and fill paths (2, 4), wherein the infusion pump (1) is arranged such that gases in the fluid chamber (8) are accumulated intermediate the infusion liquid and said one or more fluid ports, by action of gravity.

21. The infusion system of claim 20, wherein the control device (11) is configured to operate the infusion pump (1) to generate a series of pressure pulses in the displacement volume to promote the gases to accumulate in the fluid chamber (8).

22. The infusion system of claim 20 or 21, wherein the control device (11) is configured to cause the valve arrangement (6, 7) to close both the infusion path (2) and the fill path (4), and operate the infusion pump (1) to generate a sub-atmospheric pressure in the displacement volume, so as to promote release of gases from the liquid in the fluid chamber (8).

23. The infusion system of any one of claims 14-22, wherein the control device (11) is configured to perform a first sequence of a first priming fill stroke and a first source-directed priming pump stroke while one of the fill path (4) and the fluid recirculation path is open and the other is closed, and a second sequence of a second priming fill stroke and a second source-directed priming pump stroke while said one of the fill path (4) and the fluid recirculation path is closed and the other is open.

24. The infusion system of any one of claims 14-22, wherein the control device (11) is configured to perform a sequence of a first priming fill stroke while at least one of the fill path (4) and the fluid recirculation path is open, and a first source-directed priming pump stroke while one of the fill path (4) and the fluid recirculation path is open and the other is closed.

25. The infusion system of any one of claims 14-24, wherein the control device (11) is configured to actively control the recirculation enabler (19c) to selectively open and close the fluid recirculation path.

26. The infusion system of any one of claims 14-25, wherein the recirculation enabler (19c) is connected in fluid communication with the fill path (4) between the source (5) and the displacement volume.

27. The infusion system of any one of claims 14-25, wherein the recirculation enabler (19c) is connected to the source (5) on a fluid path (30) separate from the fill path (4).

28. The infusion system of any one of claims 14-27, wherein the recirculation enabler (19c) is configured as one of a connector with integrated valve function, and a combination of a connector (19c') for coupling to the system connector (19a) and a

physically separate valve device (19c").29. The infusion system of any one of claims 14-28, wherein the control device (11) is configured to, subsequent to the priming operation, control the infusion pump (1) to repeatedly draw infusion liquid from the source (5) into the displacement volume via the fill path (4) and push infusion liquid from the displacement volume through the system connector (19a) via the infusion path (2).

30. The infusion system of claim 29, wherein the control device (11) is configured to actively control the valve arrangement (6, 7) to open and close the infusion path (2) and the fill path (4).

31. The infusion system of claim 29, wherein the valve arrangement (6, 7) comprises a first one-way valve (6) in the infusion path (2), and a second one-way valve (7) in the fill path (4).

32. A control device for operating an infusion system, said infusion system comprising an infusion pump (1) comprising a fluid chamber (8) and an actuator (10) for driving a fluid displacing element (3) in the fluid chamber (8) in alternate first and second directions to define a varying displacement volume, a fill path (4) for an infusion liquid between a source (5) of infusion liquid and the displacement volume, an infusion path (2) for the infusion liquid between the displacement volume and a system connector (19a), a valve arrangement (6, 7) for selectively opening and closing the infusion and fill paths (2, 4), and a recirculation enabler (19c) in fluid communication with the source (5) and configured for coupling to the system connector (19a) so as to establish a fluid recirculation path from the displacement volume to the source (5), via the infusion path (2) and through the system connector (19a) and the recirculation enabler (19c), wherein said control device (11) is operable to control the infusion pump (1) to perform a priming operation when the system connector (19a) is coupled to the recirculation enabler (19c), wherein the priming operation comprises:

operating the infusion pump (1) to generate at least one priming fill stroke, in which a priming volume of the infusion liquid is drawn from the source (5) to the displacement volume: and

operating the infusion pump (1) to generate at least one source-directed priming pump stroke, in which at least part of the priming volume is pushed from the displacement volume back to the source (5),

wherein said at least one priming fill stroke and said at least one source-directed priming pump stroke circulates infusion fluid from the source (5) to the displacement volume and back to the source (5) via the fill path (4) and the fluid recirculation path.

33. A method of operating an infusion system, said infusion system comprising an infusion pump (1) comprising a fluid chamber (8) and an actuator (10) for driving a fluid displacing element (3) in the fluid chamber (8) in alternate first and second directions to define a varying displacement volume, a fill path (4) for an infusion liquid between a source (5) of infusion liquid and the displacement volume, an infusion path (2) for the

infusion liquid between the displacement volume and a system connector (19a), a valve arrangement (6, 7) for selectively opening and closing the infusion and fill paths (2, 4), and a recirculation enabler (19c) in fluid communication with the source (5) and configured for coupling to the system connector (19a) so as to establish a fluid recirculation path from the displacement volume to the source (5), via the infusion path (2) and through the system connector (19a) and the recirculation enabler (19c), wherein said method comprises controlling the infusion pump (1) to perform a priming operation when the system connector (19a) is coupled to the recirculation enabler (19c), wherein the priming operation comprises:

operating the infusion pump (1) to generate at least one priming fill stroke, in which a priming volume of the infusion liquid is drawn from the source (5) to the displacement volume; and

operating the infusion pump (1) to generate at least one source-directed priming pump stroke, in which at least part of the priming volume is pushed from the displacement volume back to the source (5),

wherein said at least one priming fill stroke and said at least one source-directed priming pump stroke circulates infusion fluid from the source (5) to the displacement volume and back to the source (5) via the fill path (4) and the fluid recirculation path.

34. A computer program product comprising computer code which, when executed on a data-processing system, is adapted to carry out the method of claim 33.

35. A fluid transportation kit, which comprises tubing (17a, 17b, 17c) with connectors (9, 19b, 31) for connection to a source (5) of infusion liquid and to a fluid chamber (8) of an infusion pump (1), and which is configured to define a fill path (4) for the infusion liquid from the source (5) to the fluid chamber (8) and an infusion path (2) for the infusion liquid from the fluid chamber (8) to a system connector (19a) attached to an end of the tubing (17a, 17b, 17c), further comprising a recirculation enabler (19c), which is attached to the tubing (17a, 17b, 17c) so as to provide fluid communication with the source (5) and which is configured for coupling to the system connector (19a) so as to establish a fluid recirculation path from the fluid chamber (8) to the source (5), via the infusion path (2) and through the system connector (19a) and the recirculation enabler (19c).

36. The fluid transportation kit of claim 35, wherein the recirculation enabler (19c) is coupled to the system connector (19a).

37. The fluid transportation kit of claim 35 or 36, wherein the fluid transportation kit is sterilized.

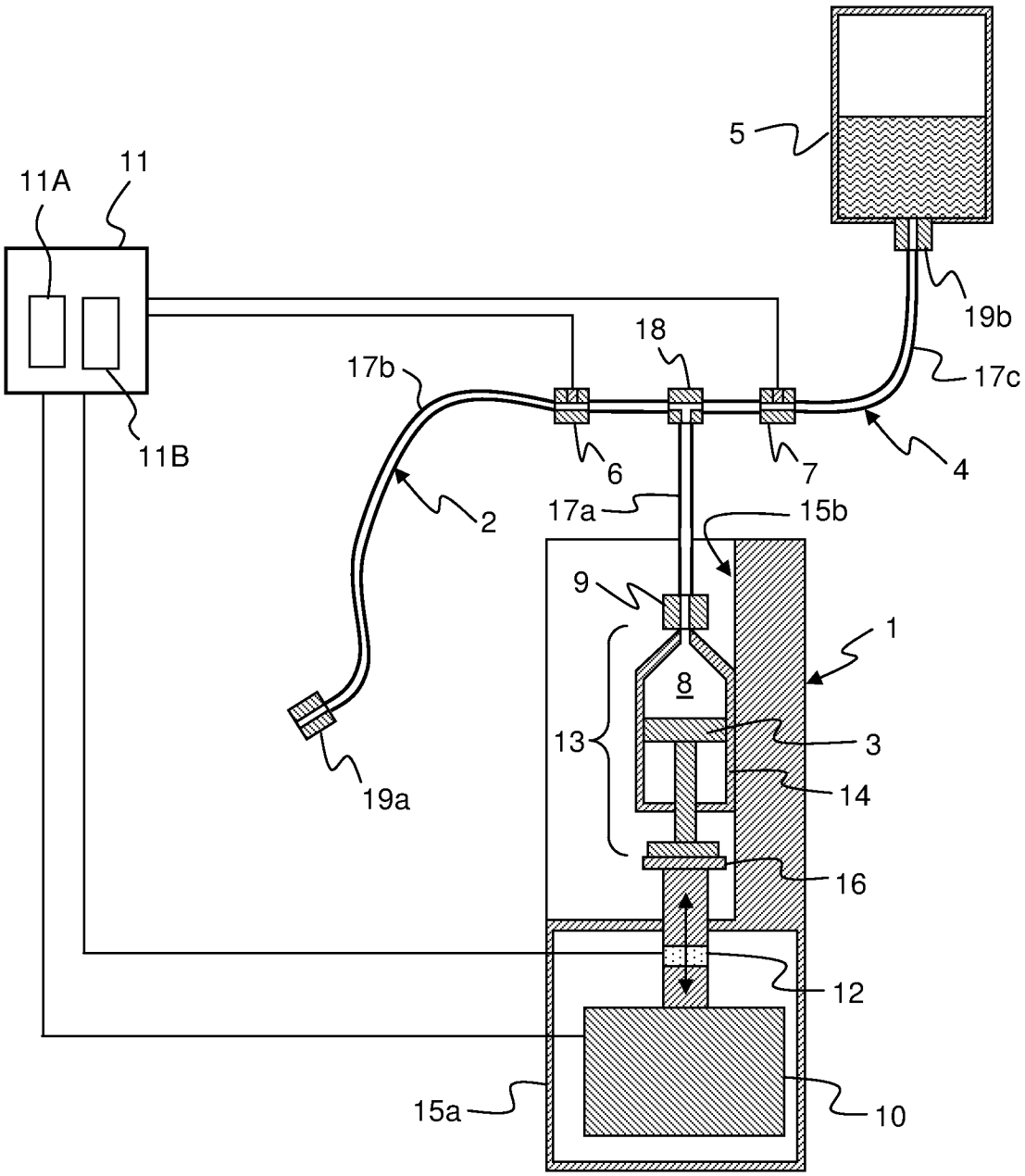
5
11A
11
19b
18
17b
17c
11B
6
7
4
2
17a
15b
9
1
8
13
3
14
19a
16
12
15a
10

FIG. 1

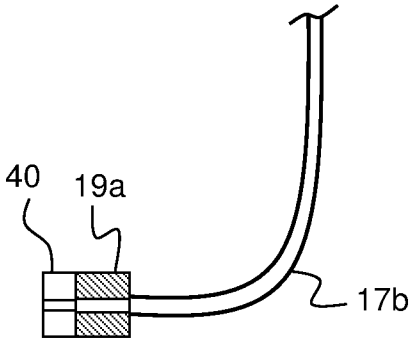
40
19a
17b

FIG. 3

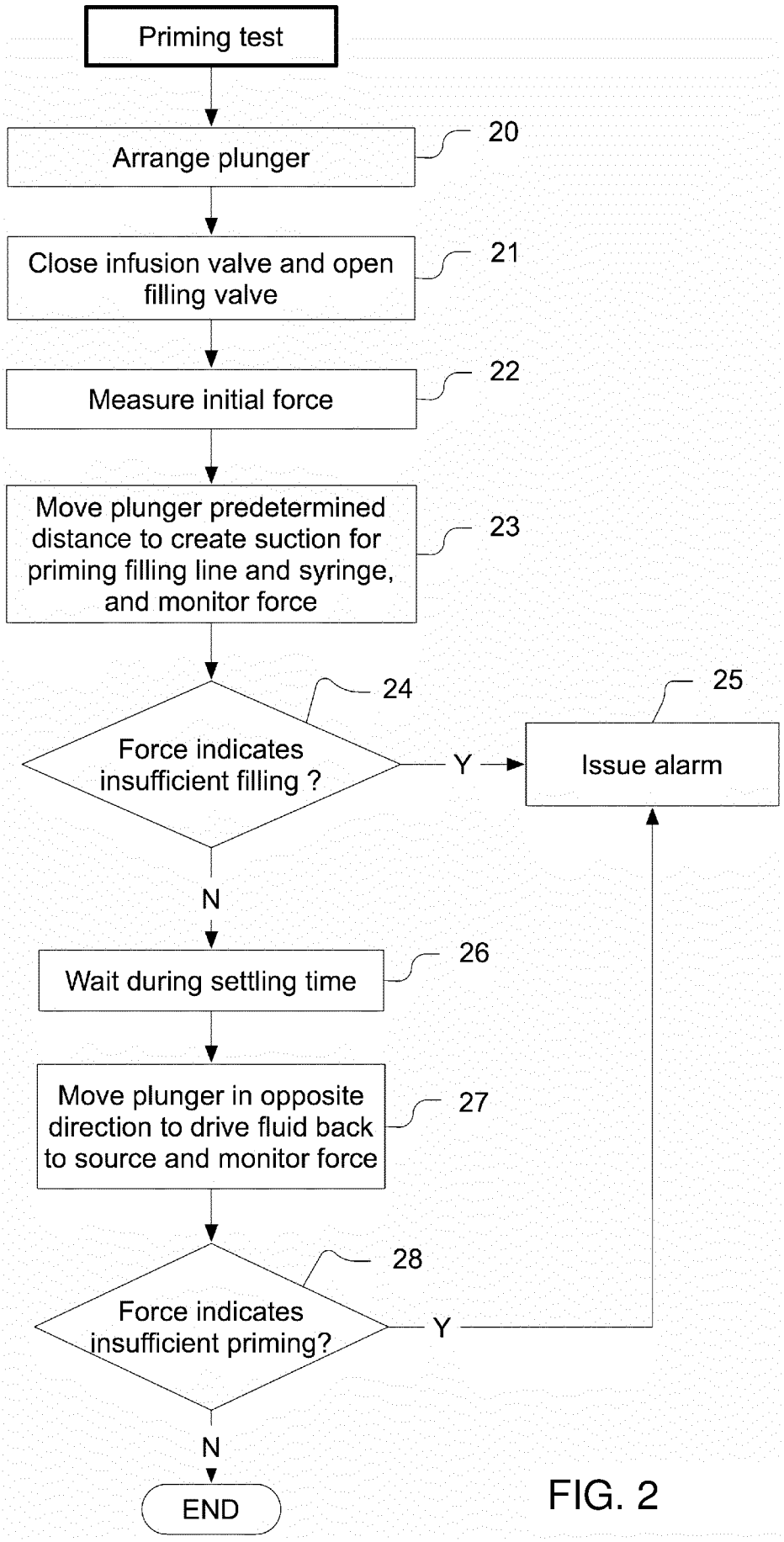
Priming test
Arrange plunger
20
Close infusion valve and open filling valve
21
Measure initial force
22
Move plunger predetermined distance to create suction for priming filling line and syringe, and monitor force
23
Force indicates insufficient filling ?
24
Y
Issue alarm
25
N
Wait during settling time
26
Move plunger in opposite direction to drive fluid back to source and monitor force
27
Force indicates insufficient priming?
28
Y
N
END

FIG. 2

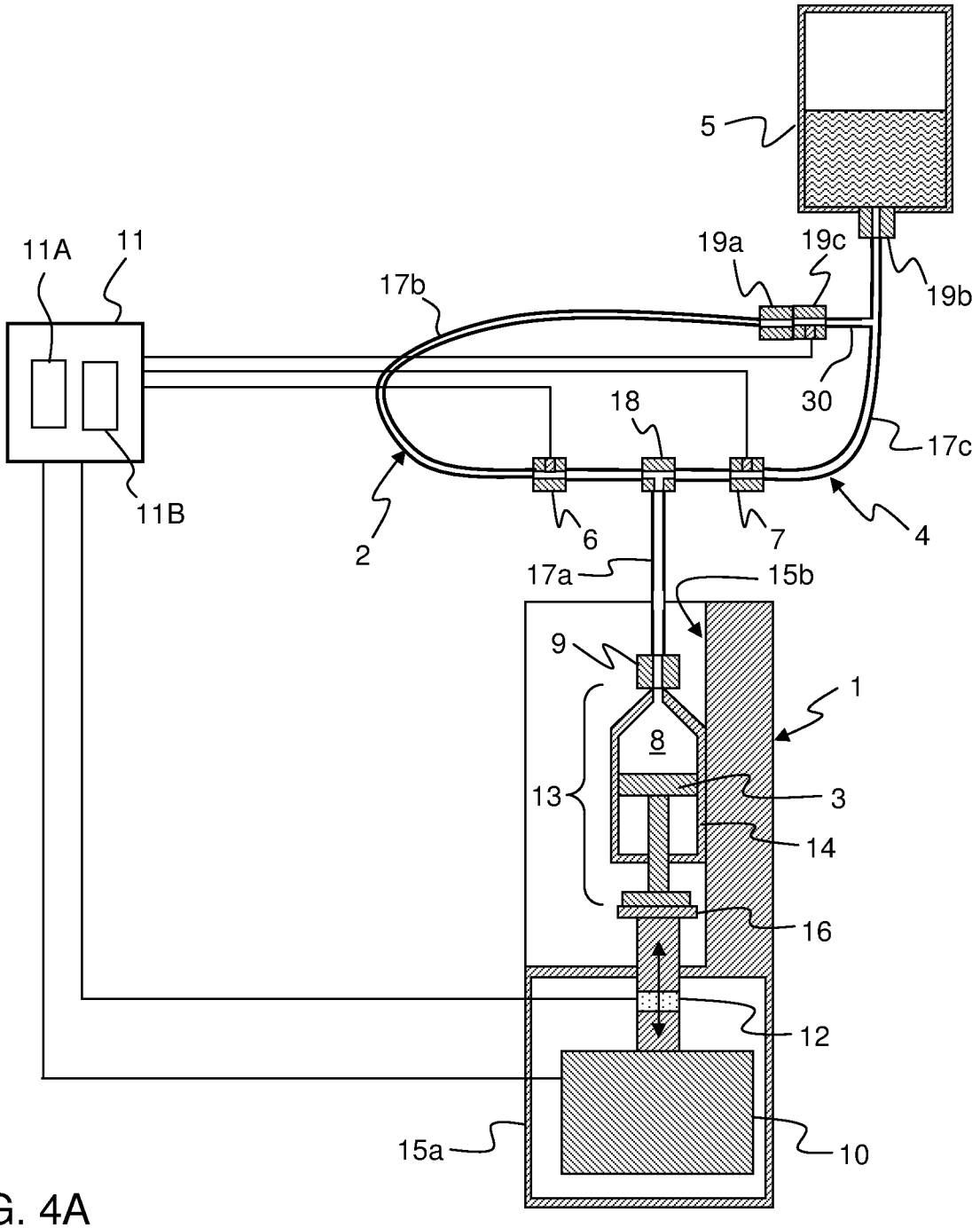

FIG. 4A

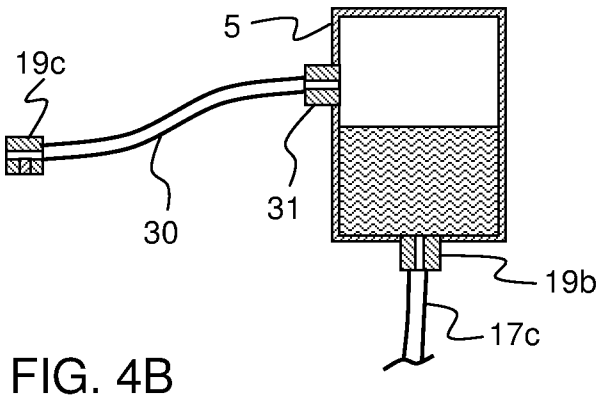

FIG. 4B

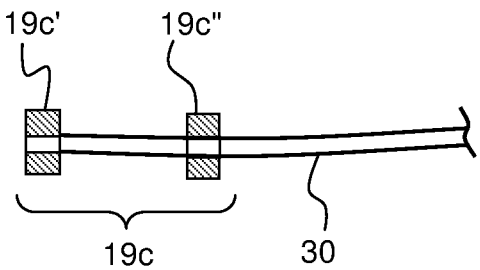

FIG. 4C

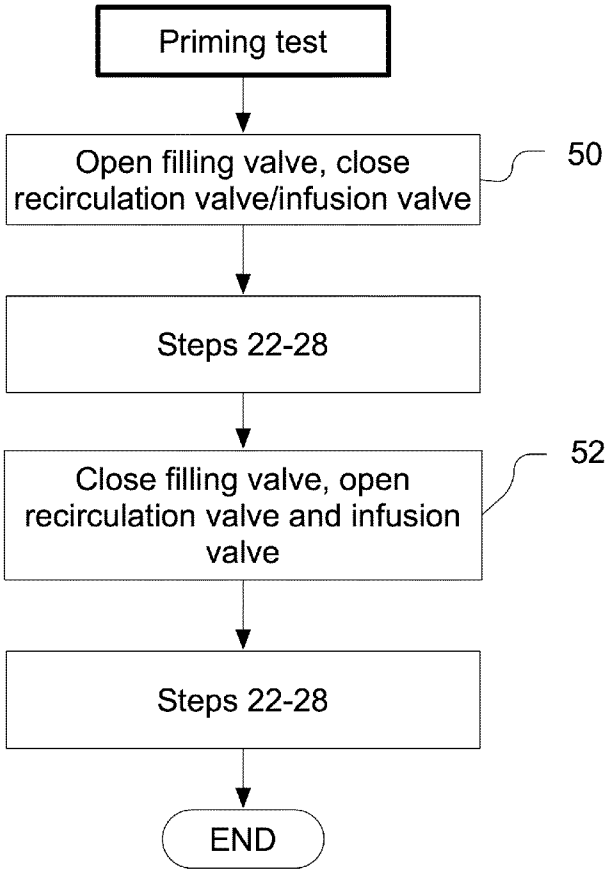
Priming test
Open filling valve, close recirculation valve/infusion valve
50
Steps 22-28
Close filling valve, open recirculation valve and infusion valve
52
Steps 22-28
END

FIG. 5A

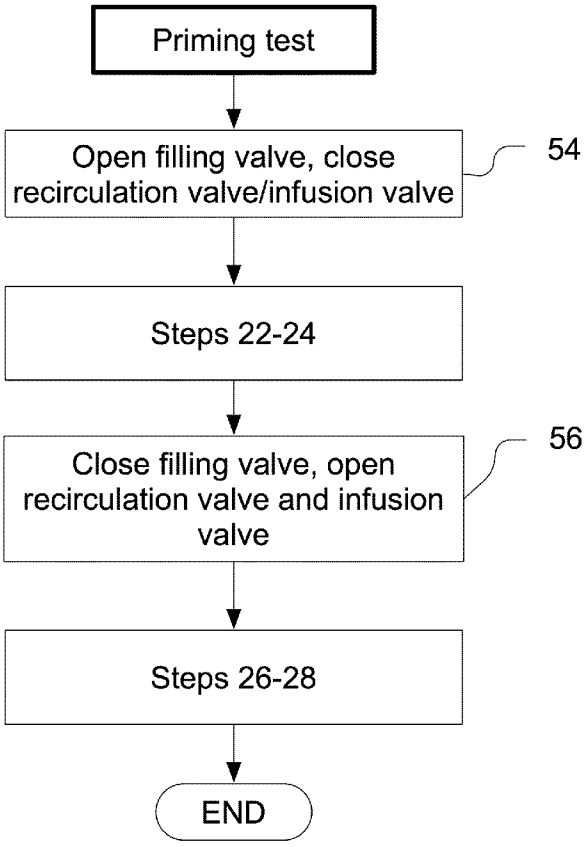
Priming test
Open filling valve, close recirculation valve/infusion valve
54
Steps 22-24
Close filling valve, open recirculation valve and infusion valve
56
Steps 26-28
END

FIG. 5B

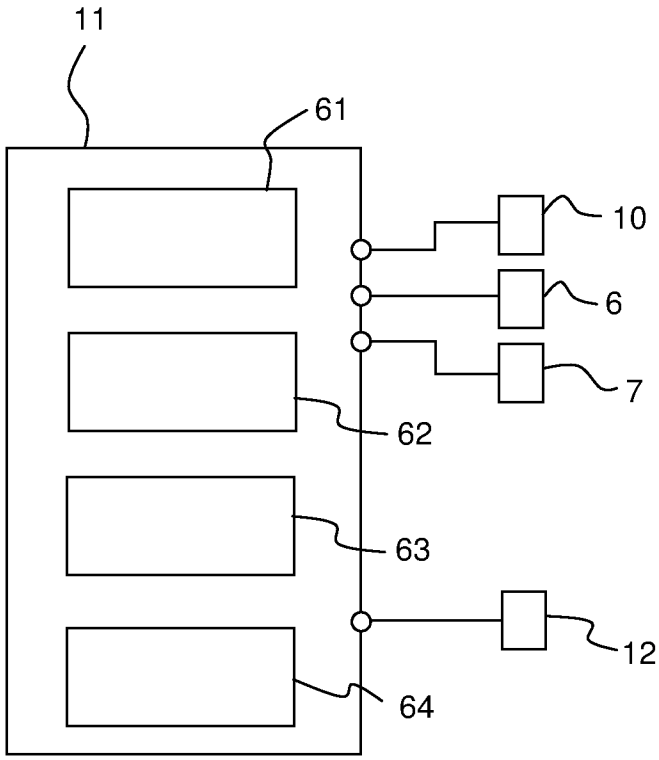

FIG. 6A

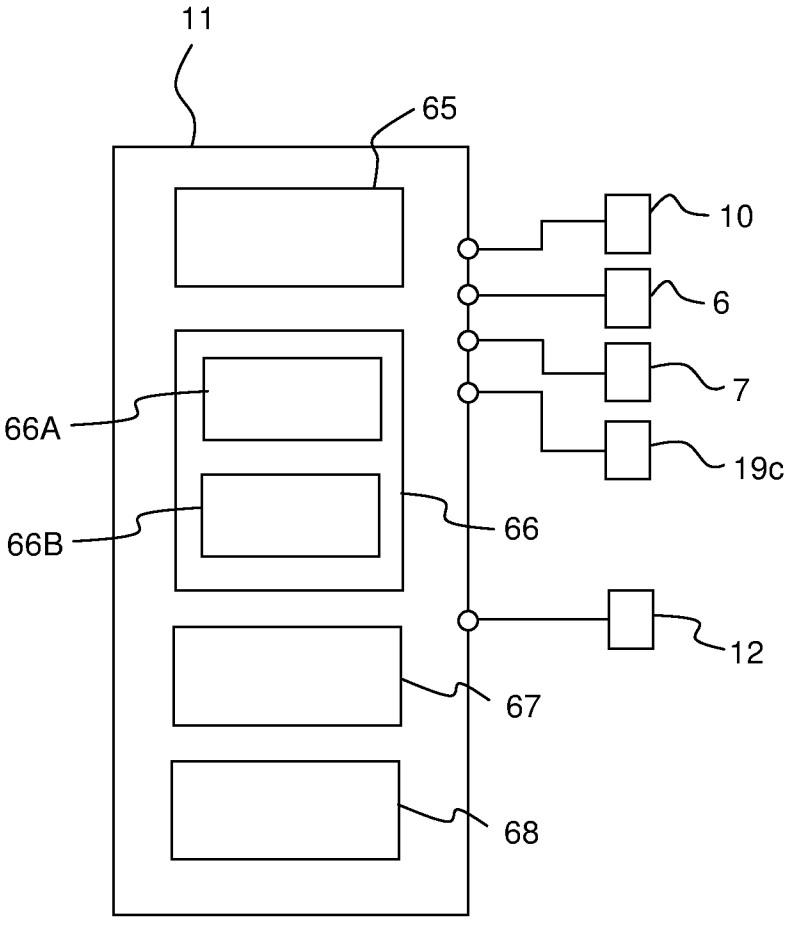

FIG. 6B