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Priming system for infusion devices

Abstract

Priming systems and infusion assemblies are provided. For example, a priming system comprises a priming conduit having a priming portion and a pressure portion. The priming portion is in fluid communication with a first fluid source, with an inlet and an outlet for ingress and egress of a first fluid from the first fluid source. The pressure portion is in fluid communication with a second fluid source connected by a connector. Disposed within the priming conduit are a biasing member and a valve having an open position and a closed position. The biasing member is in operable communication with the valve to urge the valve into the closed position such that the valve defaults to the closed position. The open position allows the first fluid to flow from the inlet to the outlet and the closed position prevents the first fluid from flowing from the inlet to the outlet.

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Background/Summary

CROSS REFERENCE TO RELATED APPLICATIONS (1) This application is a continuation of U.S. application Ser. No. 16/627,828, filed Dec. 31, 2019 (now U.S. Pat. No. 11,389,584, issued Jul. 19, 2022), which is a national stage entry of PCT/US2017/040806, filed Jul. 6, 2017, the contents of which are incorporated herein by reference in its entirety.

FIELD
(1) The present invention relates to fluid dispensing apparatus and pertains particularly to features for priming components of infusion assemblies.
BACKGROUND
(2) In instances of severe pain, infection, and other medical ailments, it has been proven beneficial to administer a continuous flow of medicinal fluid to a patient through a catheter-based system. There are many types of medicinal fluids that can be administered in this manner including, but not limited to, insulin, analgesics, and antibiotics. Often, patients are intravenously supplied with the medicinal fluid, e.g., a pharmaceutically active liquid, at a controlled rate over a long period of time. The medicinal fluid also may be delivered to a patient's intramuscular space. Preferably, such infusion is accomplished while the patient is in an ambulatory state. Typically, an infusion

assembly includes an inflatable elastomeric pump forming a liquid container that is supported by a mandrel, as well as a flow control valve or device and tubing for supply of the liquid to the patient. The walls of the pump are forced to expand when filled with the liquid and provide pressure for expelling the liquid.

(3) Some infusion assemblies include components such as a flow rate selector and/or a device for providing a bolus of the medicinal fluid. Such components must be primed before use, e.g., to remove air from a reservoir in and/or the flow path through such components. Typically, a bolus device includes a prime key, which lifts up a clamp that acts as a flow restrictor on tubing to fill the device such that the prime key prevents flow restriction to the bolus device during priming of the device. However, such prime keys are prone to breakage and/or misuse that could allow a complete bypass of the bolus fill restrictor, which could result in an overdose of medication to the patient, e.g., by failing to limit the bolus dosage over a period of time and/or by allowing a larger bolus dose than is medically indicated. On the other hand, without bypassing such flow restrictors during priming, priming may be a slow, cumbersome process.

(4) Accordingly, priming systems that include one or more safety mechanisms for preventing over-administration of medication, as well as one or more features for facilitating faster or rapid priming of devices would be desirable. Infusion assemblies incorporating such priming systems also would be advantageous.

SUMMARY

(5) Aspects and advantages of the invention will be set forth in part in the following description, or may be obvious from the description, or may be learned through practice of the invention.

(6) In one aspect, the present subject matter is directed to a priming system. The priming system comprises a priming conduit having a priming portion and a pressure portion. The priming portion is in fluid communication with a first fluid source and has an inlet for ingress of a first fluid from the first fluid source and an outlet for egress of the first fluid. The pressure portion includes a connector for connecting a second fluid source such that the pressure portion is in fluid communication with the second fluid source. The priming system further comprises a valve disposed within the priming conduit. The valve has an open position and a closed position. The priming system also comprises a biasing member disposed within the priming conduit. The biasing member is in operable communication with the valve to urge the valve into the closed position such that the valve defaults to the closed position. The valve is disposed between the inlet and the outlet of the priming portion such that the open position of the valve is configured to allow the first fluid to flow from the inlet to the outlet and the closed position of the valve is configured to prevent the first fluid from flowing from the inlet to the outlet. It will be understood that the priming system may be further configured with any additional or alternative features described herein.

(7) In some embodiments, the priming conduit further comprises a stop, and the biasing member is in contact with the stop such that the biasing member works against the stop to control the position of the valve. Moreover, the pressure portion of the priming conduit may comprise a plug, e.g., to help build, generate, or create pressure within the pressure portion. Further, the connector may be a luer connector, and the second fluid source may be a syringe that supplies a positive pressure to the pressure portion. In other embodiments, the second fluid source is a vacuum source that creates a negative pressure within the pressure portion. The first fluid source may be an infusion pump.

(8) In still other embodiments, the priming system includes a seal disposed between the valve and the pressure portion of the priming conduit to prevent the second fluid from flowing into the priming portion. The valve may be a piston and the seal an O-ring that extends about the piston in contact with an inner surface of the pressure portion of the priming conduit. In some embodiments where the valve is a piston, the piston valve has a surface area, as well as a varying diameter to minimize the surface area in contact with the priming conduit.

(9) In another aspect, the present subject matter is directed to an infusion assembly. The infusion assembly comprises an elastomeric pump configured to provide a fluid under pressure, a flow path

in fluid communication with the pump for providing a continuous and substantially constant flow rate of fluid from the pump, a bolus flow path for the delivery of a bolus dose of the fluid, and a bolus delivery device positioned within the bolus flow path. The infusion assembly further comprises a priming system in fluid communication with the bolus flow path and configured to receive fluid from the pump to prime the bolus delivery device. The priming system includes a priming conduit having a priming portion and a pressure portion. The priming portion is in fluid communication with the pump and has an inlet for ingress of the fluid from the pump and an outlet for egress of the fluid. The pressure portion includes a connector for connecting a second fluid source such that the pressure portion is in fluid communication with the second fluid source. The priming system also includes a valve disposed within the priming conduit. The valve has an open position and a closed position. The priming system further includes a biasing member disposed within the priming conduit. The biasing member is in operable communication with the valve to urge the valve into the closed position such that the valve defaults to the closed position. The valve is disposed between the inlet and the outlet of the priming portion such that the open position of the valve is configured to allow the fluid to flow from the inlet to the outlet and the closed position of the valve is configured to prevent the fluid from flowing from the inlet to the outlet. It will be appreciated that the priming system may be further configured with any additional or alternative features described herein.

(10) In some embodiments, a flow restrictor is positioned within the bolus flow path, and the priming conduit bypasses the flow restrictor such that the inlet of the priming portion is in fluid communication with the bolus flow path upstream of the flow restrictor and the outlet of the priming portion is in fluid communication with the bolus flow path downstream of the flow restrictor. Further, the second fluid source may provide a second fluid to the pressure portion to move the valve from the closed position to the open position. In some embodiments, the priming conduit also comprises a stop, and the biasing member is in contact with the stop such that the biasing member works against the stop to control the position of the valve.

(11) In still other embodiments, the connector is a luer connector. The second fluid source may be a syringe that supplies a positive pressure to the pressure portion. In other embodiments, the second fluid source is a vacuum source that creates a negative pressure within the pressure portion.

(12) In further embodiments, a seal is disposed between the valve and the pressure portion of the priming conduit to prevent the second fluid from flowing into the priming portion. The valve may be a piston and the seal an O-ring that extends about the piston in contact with an inner surface of the pressure portion of the priming conduit. Moreover, in embodiments in which the valve is a piston, the piston valve may have a surface area, as well as a varying diameter to minimize the surface area in contact with the priming conduit.

(13) These and other features, aspects, and advantages of the present invention will become better understood with reference to the following description and appended claims. The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the invention and, together with the description, serve to explain the principles of the invention.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) A full and enabling disclosure of the present invention, including the best mode thereof, directed to one of ordinary skill in the art, is set forth in the specification, which makes reference to the appended figures, in which:

(2) FIG. **1** is a schematic view of an infusion assembly having a bolus delivery device according to an exemplary embodiment of the present subject matter.

(3) FIG. **2** is a schematic view of a priming system for priming the bolus delivery device of the infusion assembly of FIG. **1**, with the priming system in its default closed state, according to an exemplary embodiment of the present subject matter.
(4) FIG. **3** is the schematic view of the priming system of FIG. **2**, with the priming system in an open state.

DETAILED DESCRIPTION

(5) Reference now will be made in detail to embodiments of the invention, one or more examples of which are illustrated in the drawings. Each example is provided by way of explanation of the invention, not limitation of the invention. In fact, it will be apparent to those skilled in the art that various modifications and variations can be made in the present invention without departing from the scope or spirit of the invention. For instance, features illustrated or described as part of one embodiment can be used with another embodiment to yield a still further embodiment. Thus, it is intended that the present invention covers such modifications and variations as come within the scope of the appended claims and their equivalents.
(6) Moreover, the particular naming of the components, capitalization of terms, the attributes, data structures, or any other programming or structural aspect is not mandatory or significant, and the mechanisms that implement the invention or its features may have different names, formats, or protocols. Also, the particular division of functionality between the various components described herein is merely exemplary and not mandatory; functions performed by a single component may instead be performed by multiple components, and functions performed by multiple components may instead performed by a single component.
(7) Further, the detailed description uses numerical and letter designations to refer to features in the drawings. Like or similar designations in the drawings and description have been used to refer to like or similar parts of the invention. As used herein, the terms “first,” “second,” and “third” may be used interchangeably to distinguish one component from another and are not intended to signify location or importance of the individual components.
(8) Referring to the drawings, FIG. **1** provides a side view of an infusion assembly, e.g., for dispensing a fluid to a patient, according to an exemplary embodiment of the present subject matter. As shown, the exemplary infusion assembly **100** includes an elastomeric pump **102** having an upper support member **104** and a lower support member **106**. Infusion assembly **100** defines an axial direction A, and lower support member **106** is spaced apart from upper support member **104** along the axial direction A.
(9) More particularly, pump **102** defines a reservoir that serves as a pressurized fluid source, holding medicinal fluid, such as local anesthetics, and providing a source of fluid under pressure. Pump **102** forces the medicinal fluid through a tubing or conduit **108**. Conduit **108** forms a continuous flow path **110** for delivery of the medicinal fluid into a wound site nerve bundle or the blood stream of a patient P. In the depicted exemplary embodiment, conduit or tubing **108** defines an outlet **112** connecting the continuous flow path **110** to a catheter **114** that delivers the medicinal fluid to patient P. In such embodiments, conduit **108** and catheter **114** may together define continuous flow path **110** from pump **102** to patient P.
(10) Further, in some embodiments, infusion assembly **100** may be configured to provide for bolus delivery. In such configurations, conduit **108** may split into a continuous or primary flow path **110** and a controlled bolus flow path **140**. Thus, medicinal fluid may be delivered into a wound site nerve bundle or the blood stream of patient P from pump **102** via the continuous or primary flow path or from a bolus delivery device **150** via the controlled bolus flow path.
(11) Pump **102** preferably accommodates a volume from about 100 to 500 ml of fluid under a pressure of up to approximately 30 psi. In some embodiments, the pump may hold the fluid under a pressure of about 10 psi to about 30 psi and, in other embodiments, under a pressure of about 15 psi to about 25 psi. More particularly, pump **102** has an inner core **116** extending between upper support member **104** and lower support member **106** along axial direction A. Inner core **116** is

surrounded by an elastomeric bladder **118** within a housing **120**. Inner core **114** preferably has an inlet port **122**, e.g., to fill bladder **118** with fluid, and an outlet port **124** in fluid communication with conduit **108**, e.g., to dispense the fluid from bladder **118** to patient P through flow path **110**. Fluid is held under pressure within elastomeric bladder **118** and flows from elastomeric bladder **118** into conduit **108** through outlet port **124**, preferably flowing at a controlled and predictable rate. Alternatively, conduit **108** may be sized to serve as a flow restrictor. Further, elastomeric bladder **118** preferably is constructed from a resilient material that may comprise a variety of elastomeric compositions well known in the art, including vulcanized synthetic polyisoprenes, natural latex, natural rubber, synthetic rubber, silicone rubber, or the like.

(12) Exemplary pumps are described in U.S. Pat. Nos. 7,959,623 and 5,254,481, which are hereby incorporated by reference. A variety of other conventional pumps also may be used. For example, the pumps described in U.S. Pat. Nos. 5,080,652 and 5,105,983, which are hereby incorporated by reference, may be used. As will be understood by those of skill in the art, other suitable electronic or mechanical pumps offered by other manufacturers may be used as well.

(13) Continuing with FIG. **1**, an optional clamp **126** is positioned in flow path **110** downstream from pump **102**. Clamp **126** can compress conduit **108** such that fluid flow from pump **102** through flow path **110** is occluded. Such occlusion is advantageous, e.g., for the transportation and preparation of infusion assembly **100** as described herein. An exemplary clamp **126** is described in U.S. Pat. No. 6,350,253, which is hereby incorporated by reference. However, a variety of other conventional clamps known in the industry may be used to occlude the flow of fluid from pump **102** through flow path **110**, such as compression clamps, C clamps, roller clamps, and the like.

(14) An optional filter **128** downstream of clamp **126** separates the fluid from contaminates and other undesired particles that may be found within the fluid. Filter **128** also preferably eliminates air from fluid flow path **110**. One such filter **128** is described in U.S. Pat. No. 6,350,253, which is hereby incorporated by reference. Of course, other suitable filters recognized in the industry may be used to capture undesired particles and/or remove air from the system.

(15) As further shown in FIG. **1**, an optional flow regulator **130** is positioned in continuous flow path **110**. Flow regulator **130** sets the continuous and substantially constant flow rate of fluid from pump **102** to patient P via tubing **108**. In some embodiments, the flow rate may be adjusted to a rate within a range, e.g., within a range of about 0.5 to about 14 cubic centimeters of fluid per hour. Flow regulator **130** may be manually adjustable, if desired, and provided with a dial, switch, or lever with an adjustable flow rate control display corresponding to the range of flow rates. For example, the flow rate range may be from about 1 to about 7 or from about 2 to about 14 cubic centimeters of fluid per hour such that the flow rate control display includes a lowermost value of 1 and an uppermost value of 7 or a lowermost value of 2 and an uppermost value of 14. It will be appreciated that the foregoing flow rate values are only exemplary, and in other embodiments, infusion assembly **100** may have other flow rates and the flow rate may be adjustable within another range of flow rates. Alternatively, a constant flow regulator (i.e., a regulator that is not adjustable) can be employed. For example, an optional flow regulating orifice, such as a glass orifice tube **132**, may be employed in the primary or continuous flow path **110**. Moreover, in embodiments having a bolus flow path, an optional second flow regulating orifice **146** may be employed in the bolus flow path.

(16) The particular arrangement of clamp **126**, filter **128**, and flow regulator **130** (or glass tube **132**) described herein is merely exemplary. These elements, if present, may be arranged in any order, as will be easily understood by those skilled in the art. Desirably, however, glass orifice tube **132** is located downstream of filter **128** when orifice tube **132** and filter **128** are provided in infusion assembly **100**.

(17) In the exemplary embodiment illustrated in FIG. **1**, the conduit **108** splits into two flow paths, the continuous or primary flow path **110** and the bolus flow path **140**. As previously described, a bolus delivery device **150** is in fluid communication with the bolus flow path **140**. The bolus

delivery device **150** accumulates a quantity of fluid from the bolus flow path **140** leading from the pump **102** and holds the fluid under pressure until the bolus dose is triggered by an actuator (not shown) for release into the patient P. The actuator of the bolus delivery device **150** may be operable by any user, such as the patient P, a caregiver, a physician, etc., to dispense a bolus dose of the medicinal fluid to the patient P.

(18) Generally, the bolus delivery device **150** is configured to receive fluid, elastically expand to pressurize the fluid, store the pressurized fluid, and dispense the pressurized fluid while avoiding over-administration of a medicinal fluid to the patient. Downstream from the bolus delivery device **150**, the continuous flow path **110** and the bolus flow path **140** converge into a single flow path. Further, as illustrated in FIG. **1**, a clamp **142**, a filter **144**, and/or a flow restrictor **146**, such as a flow regulating orifice, may be positioned in the bolus flow path **140** upstream of the device **150**. The clamp **142** can compress the flow path **140** such that fluid flow from the pump **102** is occluded. Such occlusion is advantageous, e.g., for the transportation and preparation of the fluid delivery device. Moreover, the optional filter **144** downstream of clamp **142** separates the fluid from contaminates and other undesired particles that may be found within the fluid, as well as preferably eliminates air from the bolus flow path **140**. Exemplary clamps and filters that may be used for clamp **142** and filter **144** are described in greater detail above with respect to clamp **126** and filter **128**.

(19) The flow restrictor **146** restricts the flow of fluid to the bolus delivery device **150**, e.g., to help control the bolus refill rate. For example, fluid from the pump **102** refills a reservoir of the device **150** following the administration of a bolus dose to the patient P. By controlling the refill rate of the reservoir, the flow restrictor **146** may be one feature of the bolus system that helps prevent over-administration of medication to the patient, e.g., by limiting or restricting the delivery of additional medicinal fluid to the patient within a time period following the administration of a bolus dose of the medicinal fluid. As shown in FIG. **1**, a priming system **200** is included in parallel with the flow path **140**, providing a bypass circuit around the flow restrictor **146** for faster or rapid priming of the bolus delivery device **150**. The priming system **200** is in fluid communication with the bolus flow path **140** and is configured to receive fluid from the pump **102** to prime the bolus delivery device **150**.

(20) Although described herein with respect to the bolus system of the infusion assembly **100**, it should be appreciated that the priming system **200** described herein also may be used to prime infusion assembly tubing and/or other components of the infusion assembly **100**, such as flow selection devices or the like. Of course, the priming system **200** may be used with other appropriate assemblies, devices, or systems as well.

(21) Turning now to FIGS. **2** and **3**, the priming system **200** will be described in greater detail. As shown in FIG. **2**, the priming system **200** comprises a priming conduit **202** that has a priming portion **204** and a pressure portion **206**. The priming portion **204** is in fluid communication with a first fluid source **208** that provides a first fluid F.sub.1 to the priming system **200**. The priming portion **204** has an inlet **210** for ingress of the first fluid F.sub.1 from the first fluid source **208** and an outlet **212** for egress of the first fluid F.sub.1 from the priming system **200**. In the depicted embodiment, the first fluid source **208** is the pump **102**, which provides medicinal fluid to the bolus flow path **140** such that the medicinal fluid is the first fluid F.sub.1 in the exemplary embodiment. In other embodiments, the first fluid source **208** and first fluid F.sub.1 may be any suitable fluid source and fluid provided by such fluid source. The first fluid F.sub.1 flows into the bolus flow path **140** and, under certain conditions described in greater detail below, bypasses the flow restrictor **146** by flowing into the priming portion **204** of the priming system **200**. The first fluid F.sub.1 may then flow to the bolus delivery device **150**, e.g., to prime the device **150** and its associated tubing.

(22) The pressure portion **206** of priming system **200** is in fluid communication with a second fluid source **214** that provides a second fluid F.sub.2 to the priming system **200**. More particularly, the

pressure portion **206** includes a connector **216** for connecting the second fluid source **214** to the pressure portion. In the depicted embodiment, the connector **216** is a luer connector and the second fluid source **214** is a syringe that supplies a second fluid F.sub.2 such as saline or the like, but in other embodiments, other types of connectors **216**, fluid sources **214**, and second fluids F.sub.2 also may be used. For example, the second fluid source **214** may be a vacuum source that generates or supplies a vacuum within the pressure portion **206**. Thus, in various embodiments, the second fluid source **214** and second fluid F.sub.2 may generate either a positive pressure or a negative pressure within the pressure portion **206** of the priming conduit **202**.

(23) As shown in FIGS. **2** and **3**, a gate or valve **218** is disposed within the priming conduit **202**. In the illustrated embodiment, the valve **218** is a piston or plunger disposed in the pressure portion **206** of the priming conduit **202**, but the valve **218** may have any suitable configuration. Further, the valve **218** has a closed position, as shown in FIG. **2**, and an open position, as illustrated in FIG. **3**. In the depicted embodiment where valve **218** is a piston, the piston **218** has a varying diameter d; more particularly, the piston **218** has a first diameter d.sub.1 and a second diameter d.sub.2. The first diameter d.sub.1 is in contact with an inner surface **220** of the priming portion **206**, and the second diameter d.sub.2 is smaller than the first diameter d.sub.1. As such, the segments of the piston **218** having the second diameter d.sub.2 do not contact the inner surface **220** of the priming portion **206**.

(24) As illustrated in FIGS. **1-3**, the pressure portion **206** of the priming conduit **202** intersects the priming portion **204** at an intersection **222**. The valve **218** spans the intersection **222** between the priming and pressure portions **204**, **206** such that the closed and open positions of the valve **218** control whether the first fluid F.sub.1 may flow from the inlet **210** to the outlet **212** of the priming portion **204**. That is, the valve **218** is disposed between the inlet **210** and the outlet **212** of the priming portion **204** such that the open position of the valve **218** is configured to allow the first fluid F.sub.1 to flow from the inlet **210** to the outlet **212**, and thereby on to the bolus delivery device **150** via the bolus flow path **140**, and the closed position of the valve **218** is configured to prevent the first fluid F.sub.1 from flowing from the inlet **210** to the outlet **212**.

(25) More specifically, for the illustrated piston embodiment, the first diameter d.sub.1 of the valve **218** spans the intersection **222** when the valve **218** is in the closed position. Because the segments of the valve **218** having the first diameter d.sub.1 contact the inner surface **220** of the priming portion **206** of the priming conduit **202**, the valve **218** prevents the first fluid F.sub.1 from flowing across the intersection **222**, i.e., the valve **218** blocks the intersection **222** and thereby prevents the first fluid F.sub.1 from flowing from the inlet **210** of the priming portion **204** to the outlet **212** of the priming portion **204**. However, when the valve **218** is in the open position, a segment of the valve **218** having the second diameter d.sub.2 spans the intersection **222**. Because the second diameter d.sub.2 of the valve **218** is smaller than the first diameter d.sub.1, the second diameter d.sub.2 segment of the valve **218** does not block the intersection **222** of the priming and pressure portions **204**, **206**, and the first fluid F.sub.1 may flow from the priming portion inlet **210** around the valve **218** to the priming portion outlet **212**, where the first fluid F.sub.1 reenters the bolus flow path **140** to flow on to the bolus delivery device **150** and any other downstream components of the infusion assembly **100**.

(26) As illustrated in FIGS. **2** and **3**, the priming system **200** includes a biasing member **224**, such as a spring or the like, disposed within the priming conduit **202**. The biasing member **224** is in operable communication with the valve **218** to urge the valve into the closed position shown in FIG. **2**. Further, the priming conduit **202** comprises a stop **226**, and the biasing member **224** is in contact with the stop **226** such that the biasing member **224** works against the stop **226** to control the position of the valve **218**. As shown in FIG. **2**, the biasing member **224** pushes against the stop **226** to urge the valve **218** into the closed position. As depicted in FIG. **3**, when the second fluid F.sub.2 from the second fluid source **214** is introduced into the pressure portion **206** of the priming conduit **202**, the valve **218** pushes the biasing member **224** against the stop **226** as the valve **218**

moves to the open position. That is, the second fluid F.sub.2 applies sufficient pressure to the valve **218** to overcome the force of the biasing member **224** and move the valve until a valve segment having the second diameter d.sub.2 is positioned within the intersection **222** of the priming and pressure portions **204**, **206** of the priming conduit **202**. As previously described, the segment of the valve **218** having the second diameter d.sub.2 does not completely block the intersection **222**, such that the first fluid F.sub.1 may flow past the valve **218** and through the outlet **212** of the priming portion **204**. Thus, the valve **218** in the exemplary embodiment functions as a spring-loaded check valve that is opened with, e.g., water pressure supplied by the second fluid F.sub.2 and second fluid source **214**. However, as described above, the second fluid source **214** and second fluid F.sub.2 also may utilize a negative pressure, such as a vacuum, to manipulate the position of valve **218**. For instance, rather than pushing the valve **218** using a positive pressure from the second fluid source **214** and/or second fluid F.sub.2, the valve **218** may be pulled using a negative pressure from the second fluid source **214** and/or second fluid F.sub.2.

(27) The piston-style valve **218** of the embodiment illustrated in FIGS. **2** and **3** has a segment having the second diameter d.sub.2 between two segments that each have the first diameter d.sub.1. As such, when the valve **218** is in the open position as shown in FIG. **3**, the first fluid F.sub.1 flows past the valve **218** but only within the priming portion **204** of the priming conduit **202**. That is, the first fluid F.sub.1 does not flow into the pressure portion **206** of the conduit **202**. Similarly, the valve **218** and biasing member **224** are configured such that the valve **218** does not open to an extent to allow the second fluid F.sub.2 to flow into the priming portion **204**. In some embodiments, the priming system **200** comprises a seal **228** disposed between the valve **218** and the pressure portion **206** of the priming conduit **202** to prevent the second fluid F.sub.2 from flowing into the priming portion **204**, which also helps prevent the first fluid F.sub.1 from flowing into the pressure portion **206**. The seal **228** may be an O-ring that extends about the piston-style valve **218**, as shown in the exemplary embodiment, and that is in contact with the inner surface **220** of the pressure portion **206**. Of course, some embodiments may utilize more than one seal **228**, such as more than one O-ring or a variety of different types of seals.

(28) As described above, the valve **218** may have a varying diameter d; specifically, the exemplary valve **218** has a first diameter d.sub.1 and a second diameter d.sub.2 that is smaller than the first diameter d.sub.1. The position of the first and second diameters d.sub.1 and d.sub.2 with respect to the intersection **222** between the priming and pressure portions **204**, **206** of the priming conduit **202** determine whether the valve **218** is open, permitting the first fluid F.sub.1 to flow through the priming portion **204**, or closed, preventing the first fluid F.sub.1 from flowing through the priming portion **204**. However, the varying diameter d of the valve **218** also varies the surface area of the valve **218** in contact with the inner surface **220** of the pressure portion **206**. More particularly, the valve **218**, configured as a piston in the embodiment of FIGS. **2** and **3**, has a surface area A.sub.S. The length of each segment of the valve **218** having a diameter sufficient to contact the inner surface **220** of the pressure portion **206**, i.e., the first diameter d.sub.1 in the exemplary embodiment, determines the surface area A.sub.S of the valve **218** that is in contact with the inner surface **220**. The varying diameter of the valve **218**, e.g., the different diameters and the length of each segment of a given diameter, may be chosen to minimize the surface area A.sub.S in contact with the priming conduit **202**, specifically the pressure portion **206** of the priming conduit **202**. By minimizing the surface area A.sub.S in contact with the priming conduit **202**, friction between the valve **218** and the priming conduit **202** may be minimized, which may help the valve **218** move between the closed and open positions.

(29) As further illustrated in FIGS. **1-3**, the pressure portion **206** of the priming conduit **202** may be generally Y shaped, with a stem **230***a* and two arms **230***b*, **230***c*. The stem **230***a* intersects the priming portion **204**, and the stop **226**, biasing member **224**, and valve **218** are disposed within the stem **230***a*. The first arm **230***b* includes the connector **216**, to which the second fluid source **214** may be attached, and the second arm **230***c* includes a plug **232**. The plugged second arm **230***c*

provides additional area within the pressure portion **206** to build sufficient pressure with second fluid F.sub.2 to open the valve **218**, i.e., when second fluid F.sub.2 supplies a positive pressure within the pressure portion **206**. In some embodiments, the second arm **230***c* and plug **232** may be omitted. For example, the pressure portion **206** of the priming conduit **202** may have a shape and/or size such that sufficient pressure is built up with the pressure portion **206** when the second fluid F.sub.2 is inserted into the pressure portion **206** without the need for the second arm **230***c*.
(30) With the valve **218** opened by the positive or negative pressure of the second fluid F.sub.2 supplied by the second fluid source **214** as shown in FIG. **3**, fluid (i.e., first fluid F.sub.1) from the pump **102** (i.e., first fluid source **208**) flows through the priming portion **204** of the priming conduit **202** and on through the bolus delivery device **150**, which preferably includes a reservoir for receipt of a volume of fluid from the pump **102**. As such, the fluid F.sub.1 displaces air within the device **150**, as well as any other devices downstream of the priming system **200**. Once the fluid has flowed through the device **150**, the second fluid source **214** may be removed, such that the valve **218** moves to the closed position illustrated in FIG. **2**, and the fluid F.sub.1 flows through the flow restrictor **146**, rather than the priming system **200**, to fill the reservoir of the device **150**. At this point, the bolus delivery device **150**, and any other devices downstream of the priming system **200**, is primed, and the connector **216** may be removed from the priming portion **206** to prevent bypassing of the flow restrictor **146** as a second fluid source **214** cannot be positioned in fluid communication with the priming conduit **202** to supply a second fluid F.sub.2 to pressurize and open the valve **218**. That is, the priming system **200** permits priming of, e.g., the bolus delivery device **150** in a faster manner or reduced amount of time by bypassing the flow restrictor **146**, which controls the flow rate of the medicinal fluid from pump **102** to the bolus delivery device **150**. As such, the medicinal fluid reaches the bolus delivery device **150** faster when the fluid travels through the priming system **200** rather than the flow restrictor **146**. If the medicinal fluid is permitted to flow through the priming system **200** to completely fill and/or refill the bolus delivery device **150**, an excess or overdose of medicinal fluid could be provided to the patient P by not allowing a clinically sufficient time between bolus doses. Thus, in exemplary embodiments, the priming system **200** includes features such as a removable connector **216** to help prevent bypassing of the flow restrictor **146** outside of priming the bolus delivery device **150**.
(31) The priming system **200** also may include other safety features that, in particular, prevent bypassing the flow control provided by the flow restrictor **146** to help prevent over-administration of medication to the patient. For instance, the pressure required to move the valve **218** to the open position of FIG. **3**, i.e., the cracking pressure, may be selected to ensure the valve **218** stays closed until and/or only when the second fluid source **214** applies at least the cracking pressure to the valve **218**. As an example, the cracking pressure may be about 10 psi, such that the valve **218** opens when the pressure portion **206** of the priming conduit **202** is pressurized by the second fluid source **214** over 10 psi. It will be appreciated that the cracking pressure may be adjusted by, e.g., changing the spring rate where the biasing member **224** is a spring and/or changing the dimensions of the valve **218** or other components of the priming system **200**. As another safety feature, the priming conduit **202**, particularly the pressure portion **206**, may a micro flow path to discourage and/or prevent users from sticking objects into the pressure portion **206** to try to manually open the valve **218**. That is, in some embodiments of the priming system **200**, at least the pressure portion **206** may have a sufficiently small diameter such that objects cannot be inserted into the pressure portion **206** to bypass the flow restrictor **146** by moving the valve **218** from the closed position of FIG. **2** to the open position of FIG. **3**. The priming system **200** may incorporate other safety features as well.
(32) Accordingly, as described herein, a system is provided for faster priming of various components of an infusion assembly. In exemplary embodiments, the priming system described herein allows faster priming of certain components of the infusion assembly by bypassing a flow restrictor that otherwise controls the flow rate of fluid to the components. However, the priming

system also includes features for discouraging or preventing continuous and/or non-priming related bypassing of the flow restrictor, such that the flow rate may be controlled per the design of the infusion system. For instance, the priming system defaults to a closed position, such that the fluid of the infusion assembly is permitted to flow through the priming system, bypassing the flow restrictor, upon a positive action by a user. In particular embodiments, the positive action may be the connection of a second fluid source that applies pressure to a check valve controlling flow through the priming system, and the ability to connect the second fluid source may be disabled after priming, e.g., by removing or breaking off a connector, such that the priming system returns to its default closed position and cannot be re-opened. Other benefits and advantages of the subject matter described herein also may be realized by those of ordinary skill in the art.
(33) This written description uses examples to disclose the invention, including the best mode, and also to enable any person skilled in the art to practice the invention, including making and using any devices or systems and performing any incorporated methods. The patentable scope of the invention is defined by the claims and may include other examples that occur to those skilled in the art. Such other examples are intended to be within the scope of the claims if they include structural elements that do not differ from the literal language of the claims or if they include equivalent structural elements with insubstantial differences from the literal language of the claims.

Claims

1. A priming system, comprising: a priming conduit having: a priming portion in fluid communication with a first fluid source, the priming portion having an inlet for ingress of a first fluid from the first fluid source and an outlet for egress of the first fluid, wherein the inlet and the outlet are aligned, and a pressure portion in fluid communication with a second fluid source and intersecting the priming portion, wherein the second fluid source generates either a positive pressure or a negative pressure; a valve movable between an open position and a closed position, the valve comprising a linear actuator, wherein the linear actuator comprises a first segment a first diameter and a second segment having a smaller second diameter; and a biasing member disposed within the pressure portion, the biasing member in operable communication with the valve to urge the valve toward the closed position, wherein in the closed position, the first segment is aligned with the inlet and the outlet to obstruct a flow of the first fluid, and wherein in the open position, at least a portion of the second segment is aligned with the inlet and the outlet to allow the flow of the first fluid around the second segment.
2. The priming system of claim 1, wherein when the valve is in the open position, the first fluid flows from the inlet, around the second segment, to the outlet.
3. The priming system of claim 1, wherein the positive pressure moves the valve linearly along an axis of the pressure portion away from the second fluid source supplying the positive pressure to the pressure portion positioning the second segment of the linear actuator -at the intersection of the priming portion and the pressure portion.
4. The priming system of claim 1, wherein the negative pressure shifts the valve linearly along an axis of the pressure portion in a direction towards the second fluid source supplying the negative pressure to the pressure portion into the open position such that the second segment of the linear actuator is at the intersection of the priming portion and the pressure portion.
5. The priming system of claim 1, wherein the first fluid does not flow into the pressure portion of the priming conduit.
6. The priming system of claim 1, wherein the valve and the biasing member are configured to stop prior to allowing the second fluid into the priming portion.
7. The priming system of claim 1, wherein the priming conduit further comprises a stop, and wherein the linear actuator further comprises an extension configured to engage the stop, wherein the biasing member is in contact with the stop such that the biasing member biases against the stop

to control the position of the valve, and wherein the extension of the linear actuator extends into a central channel of the biasing member.

8. The priming system of claim 7, wherein a stem of the pressure portion intersects the priming portion, and the stop, the biasing member, and the valve are disposed within the stem.

9. The priming system of claim 1, wherein the pressure portion is Y-shaped with a stem and at least one arm.

10. The priming system of claim 9, wherein the at least one arm of the pressure portion comprises a first arm, wherein the first arm includes a connector connecting the second fluid source.

11. The priming system of claim 9, wherein the at least one arm of the pressure portion comprises a second arm, wherein the second arm of the pressure portion provides an additional area within the pressure portion to build sufficient pressure with the second fluid to open the valve.

12. The priming system of claim 11, wherein the second arm of the pressure portion further comprises a plug.

13. The priming system of claim 1, further comprising a seal disposed between the valve and the pressure portion of the priming conduit.

14. The priming system of claim 13, wherein the seal is an O-ring extending about the valve and in contact with an inner surface of the pressure portion of the priming conduit.

15. The priming system of claim 1, wherein the valve includes a piston having a surface area and wherein the piston has a varying diameter to minimize the surface area in contact with the priming conduit.

16. The priming system of claim 1, wherein axial alignment of the inlet and the outlet of the priming portion minimizes resistance and enables efficient flow of the first fluid through the priming conduit.
